The 10-year follow-up of the Delta-TT trial:
Stability of the Delta-TT cup with Polyethylene insert compared to the Delta-TT cup with Ceramic insert.

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This 10-year follow-up study aims to further investigate long-term migration patterns of the uncemented Delta-TT cup and H-MAX S stem, comparing outcomes between ceramic and polyethylene liners. Given the predictive value of early RSA migration...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56982

Source
ToetsingOnline

Brief title
RSA-10

Condition

- Joint disorders

Synonym
Hip implants

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: Limacorporate spa. Via Nazionale 52. 33038 Villanova di San Daniele (Udine). Italië.

Intervention

Keyword: Delta-TT, Migration, RSA, Stability

Outcome measures

Primary outcome

The primary outcome in this study is long-term (10-year) stability of the

Delta-TT cup combined with the H-MAX S stem and compared between a ceramic and

polyethylene liner, measured in 3D translations and rotations of the Delta TT

cup by means of RSA X-rays.

Secondary outcome

Secondary endpoints at 10-years postoperatively are:

- Long-term stability of the H-MAX S stem, expressed in 3D translations and

rotations (Method: RSA X-rays).

- Implant survival of the Delta TT cup and H-MAX S stem (Method: Revision yes /

no; reason for revision).

- Radiographic signs of osteolysis around the cup and the stem (Method:

Radiolucent lines at X-ray).

Study description

Background summary

Aseptic loosening of the acetabular component of hip implants in total hip arthroplasty (THA) remains one of the main causes of implant failure and

revision surgery. To address this issue, Trabecular Titanium (TT) has been integrated into the Delta-TT cup, a cementless press-fit hemispheric implant, aiming to optimize initial stability and osseointegration while reducing the risk of long-term aseptic loosening. Studies have demonstrated that titanium cups with a polyethylene liner facilitate a more natural load transfer to the surrounding bone, attributing both cup and liner stiffness to the construct's stability.

Stiffness of ceramic bearings thus might affect primary stability and migration of implants in press-fit THA. In our initial Delta-TT Radiostereometric Analysis (RSA) study, it was therefore hypothesized that Delta-TT cups with a ceramic liner would exhibit more migration due to their higher stiffness compared to Delta-TT cups with a polyethylene liner. However, the 2- and 5-year results showed stabilization of Delta-TT cups within six months, regardless of liner type. Although a trend towards increased migration was observed in cups with ceramic liners, the between-group effects were small and lacked statistical significance.

Study objective

This 10-year follow-up study aims to further investigate long-term migration patterns of the uncemented Delta-TT cup and H-MAX S stem, comparing outcomes between ceramic and polyethylene liners. Given the predictive value of early RSA migration patterns at the 2-year mark for identifying implants at risk of aseptic loosening, we hypothesize that the Delta-TT cup will demonstrate good stability at the 10-year postoperative mark. Besides, it is hypothesized that migration of Delta TT-cups is comparable between ceramic and polyethylene liners.

The primary objective of this study is to measure the long-term stability of the Delta TT cup, combined with either a ceramic or cross-linked polyethylene liner, by means of RSA at 10-years postoperatively.

Secondary objectives are to measure long-term stability of the H-MAX S stem, by means of RSA at 10-year postoperatively. Furthermore the study aims to measure implant survival rates and patient-reported outcomes for both the Delta-TT cup and H-MAX S stem, comparing outcomes between the ceramic and polyethylene group.

Study design

This study is a long-term follow-up of the Delta-TT trial, in which 52 patients who underwent unilateral primary hip arthroplasty were randomized between a polyethylene liner (n = 25) and a ceramic liner (n = 27). The initial study included RSA imaging at baseline (within 3 days postoperative before weightbearing) and at 6 weeks, 3 months, 6 months, 1 year, 2 years and 5 years

postoperatively. At these same marks PROMs were documented, including EuroQol 5D-3L (EQ5D-3L), Hip disability and Osteoarthritis Outcome Score-Physical function Short form (HOOS-PS), Numeric (Pain) Rating Scale (NRS) and Oxford Hip Score. In this 10-year follow-up, for the 51 patients still included in the study at the 5-year follow-up, RSA imaging is repeated and PROMs will again be documented. Instead of EQ5D-3 the more recent EQ5D-5L will be used, because it shows a reduced ceiling effect compared to the EQ5D-3L version (Feng, Devlin, & Herdman, 2015; Herdman et al., 2011). To compare these EQ5D-5L scores to the values of the initial study they will be translated to the EQ5D-3L scores (van Hout et al., 2012). In addition, patients will be questioned about potential (Serious) Adverse Device Events, including re-operation related to the hip included in the study, hip luxation, THA revision, and hip squeaking.

Study burden and risks

Patients have already been randomized in the initial study and are being re-evaluated by means of Patient Reported Outcome Measures (PROMs) and RSA imaging. There are, in our view, no risks associated with participation in this study. The effective radiation dose per RSA-radiograph is 0.27 mSv. This is negligible when compared to the natural annual exposure of 2.9 mSv. There is no guarantee that patients will personally benefit from inclusion in this study. Patients undergo a more thorough screening than non-study patients and may benefit from this increased surveillance. Information gathered in this study may benefit others undergoing THA with Delta-TT cups.

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

Enrolled in the initial Delta-TT trial

Exclusion criteria

Patient is unable or unwilling to sign the Informed Consent specific to this study.
Patient is unsuitable for participation in the study based on the investigator*s judgement.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-11-2024

Enrollment:	51
Type:	Actual

Medical products/devices used

Generic name:	Hip implant;Delta TT cup with H MAX S femoral stem;32 mm ceramic head and either a ceramic or polyet
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-08-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL86542.100.24