Long-term outcomes after trapeziometacarpal joint arthroplasty: a radiostereometric study with 10 years of follow-up

No registrations found.

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

Summary

ID

NL-OMON21597

Source
NTR

Health condition

RSA; TMC joint; trapeziometacarpal joint arthroplasty; carpometacarpaal; radiostereometrische analyse

Sponsors and support

Primary sponsor: -
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

To evaluate implant stability of the SR-TMC prosthesis 10 years after surgery

Secondary outcome

To monitor improvement of function, pain scores and long-term survival 10 years after implantation of the SR-TMC prosthesis.

Study description

Background summary

Osteoarthritis of the trapeziometacarpal joint (TMC or 1st carpometacarpal joint; CMC-1) is a disabling disease. Restoration of thumb function with a pain-free, stable, and mobile joint with preserved strength is the main goal of surgical treatment. For degenerated joints as the hip and the knee, total joint arthroplasty has been developed to a successful, reliable and durable treatment strategy with high patient satisfaction. This is not the case with total joint arthroplasty of the TMC joint where most designs are a constrained ball-and-socket joint with a fixed centre of rotation of the prosthesis in the axis of the first metacarpal. This does not reproduce the anatomy of the trapeziometacarpal joint and is prone to early failure due to aseptic loosening. The SR-TMC prosthesis is a resurfacing joint replacement that closely duplicates the anatomy of the articular surfaces of the first metacarpal and trapezium. This prosthesis is supposed to perform better in terms of survival, which is among dependent on implant stability. Implant stability can be assessed with high accuracy using Roentgen Stereophotogrammatric Analysis (RSA). The SR-TMC prosthesis is used in a clinical study (NL22370.098.08) in 10 patients and analysed using RSA. In 2018, these patients will have 10 year follow up.

Primary Objective is to evaluate implant stability of the TMC prosthesis, 10 years after surgery. Secondary Objectives are to monitor improvement of function, pain scores and long term survival after 10 years of TMC prosthesis implantation.

Study objective

The SR-TMC prosthesis is stable after 10 years after implantation.

Study design

1 follow-up moment at 10-year follow-up (between July and October 2018)

Intervention

Follow-up after implantation of the SR-TMC prosthesis(SRTMTMC, Avanta®, San Diego, CA)

Contacts

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Eligibility criteria

Inclusion criteria

- Received an SR-TMC joint prosthesis between June and October 2008

-Participated in the study assessing the mid-term results of the SR-TMC joint prosthesis (Ten Brinke et al, 2016)

- Sign informed consent of the proposed study

Exclusion criteria

Subjects who underwent revision of the CMC-1 prosthesis

Study design

Design

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

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-07-2018
Enrollment:	8
Type:	Actual

Ethics review

Positive opinion

Date:	04-09-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45754
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7126
NTR-old	NTR7472
CCMO	NL65616.098.18
OMON	NL-OMON45754

Study results

Summary results

Ten Brinke B, Mathijssen NMC, Blom I, Deijkers RLM, Ooms EM, Kraan GA. Model-based roentgen stereophotogrammetric analysis of the surface replacement traziometacarpal total joint arthroplasty. J Hand Surg Eur Vol 2016;41(9):925-929

Ooms EM, Ten Brinke B, Mathijsen NMS, Blom IF, Deijkers RL, Kraan GA. Feasibility of model-based Roentgen Stereophotogrammetric Analysis to evaluate early migration of the trapeziometacarpal joint prosthesis. BMC Muskuloskelet Disord 2015;16:295