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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21597

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: -
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Subjects who underwent revision of the CMC-1 prosthesis

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	13-07-2018
Aantal proefpersonen:	8
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	04-09-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45754
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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