In vivo RSA analysis of total joint arthroplasty of the trapezio metacarpal joint of the thumb;
10 yrs follow up.

Published: 28-06-2018
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Implant stability of the SR-TMC prosthesis, function and pain 10 years after surgery?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON45754

Source
ToetsingOnline

Brief title
RSA in TMC joint replacement, 10 yr FU.

Condition

- Other condition

Synonym
prosthesis, stability

Health condition

stabiliteit van gewrichtsprothese

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: de Stichting Research Orthopedie Delft vergoedt de kosten voor het polibezoek. Een subsidie zal aangevraagd worden bij de wetenschappelijke activiteitencommissie (WAC) van het RdGG voor de kosten van de rontgenfoto's.

Intervention

Keyword: 10 yr FU, RSA, TMC, Total joint arthroplasty

Outcome measures

Primary outcome

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

Secondary outcome

To monitor improvement of function, pain scores and long term survivalship 10

years after TMC prosthesis implantation

Study description

Background summary

Arthrosis of the TMC is a common problem, it can give pain and discomfort. One of the options is placing a joint replacement prosthesis of the TMC. In comparison to hip and knee joint replacement prostheses there are few long term results of the TMC prosthesis.

Study objective

Implant stability of the SR-TMC prosthesis, function and pain 10 years after surgery?

Study design

Cohort study

Study burden and risks

There are no benefits for patients who take part in this study. all patients included in our previous study, will be invited for a single visit to our outpatient clinic of the RdGG Hospital. During this visit clinical assessment will be done measuring the active and passive range of motion and strength of the thumb. a RSA radiographs will be made. Patients will be asked to complete validated questionnaires: VAS score for grading pain, the Dutch version of the DASH questionnaire and the Nelson Hospital score.

Contacts

Public
Reinier de Graaf Groep

Reinier de Graafweg 5
Delft 2625 AD
NL
Scientific
Reinier de Graaf Groep

Reinier de Graafweg 5
Delft 2625 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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
- Sign informed consent of the proposed study

Exclusion criteria

Subjects who underwent a revision of the TMC prosthesis.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

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

Ethics review

Approved WMO

Date:	28-06-2018
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

No registrations found.

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

ID: 21597
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65616.098.18
OMON	NL-OMON21597