

# Treatment of osteoarthritis of the carpometacarpal joint of the thumb: Evaluation of the Swanson prosthesis

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The aim of this study is to: - Analyse the survival of the Swanson implant- Analyse the functional outcome of the CMC-I joint after placing a Swanson implant- Analyse subluxation of the CMC-I joint after placing a Swanson implant- Analyse cyst...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Joint disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON35869

### Source

ToetsingOnline

### Brief title

Evaluation of the Swanson prosthesis

### Condition

- Joint disorders
- Bone and joint therapeutic procedures

### Synonym

degeneration, Osteoarthritis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Carpometacarpal joint, Osteoarthritis, Swanson prosthesis

## Outcome measures

### Primary outcome

The primary outcome is the survival of the Swanson prosthesis.

### Secondary outcome

- Functional Limitation of the upper extremity (DASH score)
- Pinch strength
- Opposition was measured using the Kapandij scale
- Subluxation
- Proximalization of the thumb
- Pain (VAS scores, during rest and activity)

## Study description

### Background summary

Osteoarthritis of the CMC-1 joint is a noninfectious degeneration of the cartilage of the carpometacarpal joint of the thumb. There are a number of conservative options such as immobilization splint therapy and intra-articular injections with corticosteroids. Furthermore a surgical treatment is possible, including arthrodesis, excision of the trapezium with ligament reconstruction, excision of the trapezium with a prosthesis or with interposition-arthroplasty. Another possibility is a combination of ligament reconstruction and interposition arthroplasty, LRTI. The present study was conducted to establish the long-term results and to highlight the problems associated with the implant of an Swanson prosthesis. Instability of the prosthesis and silicone-induced synovitis have led most surgeons to abandon use of the Swanson trapezium implant for the treatment of primary osteoarthritis. However, the literature contains little information on the results of long-term follow-up.

### Study objective

The aim of this study is to:

- Analyse the survival of the Swanson implant
- Analyse the functional outcome of the CMC-I joint after placing a Swanson implant
- Analyse subluxation of the CMC-I joint after placing a Swanson implant
- Analyse cyst formation after placing a Swanson implant

Research hypotheses:

- The five-years survival of a Swanson implant is 90%
- After a Swanson prosthesis is implanted a grip strength of 85% standard for age and sex is expected (Appendix 1)
- After a Swanson prosthesis is implanted a good DASH score is expected (<50 points)
- No subluxation is expected after implanting a Swanson prothese
- After a Swanson prosthesis is implanted there is cyst formation in surrounding structure expected

## **Study design**

Descriptive retrospective cross-sectional cohort study

## **Study burden and risks**

This study contains no additional risks for the included patients. The patients fill out two questionnaires which takes about an hour to complete. In addition, the patients are invited for a clinical visit for a half hour. During this clinic visit some functional tests will be performed of the hand and a X-ray of both hands is taken.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Swanson implant for the basal joint of the thumb

Treatment in VUmc

Signed informed consent

### Exclusion criteria

Other pathology of the same hand

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Will not start

Start date (anticipated): 01-02-2012

Enrollment: 29  
Type: Anticipated

## Ethics review

Approved WMO  
Date: 24-01-2012  
Application type: First submission  
Review commission: METC Amsterdam UMC

## 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	NL35877.029.11