Fixation and Migration of the BIOPRO Metallic MTP-1 hemiprosthesis analysed with roentgen stereophotogrammetry analysis: A pilot study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29606

Source
NTR

Brief title
BIOPRO-RSA

Health condition

- roentgen stereophotogrammetry analysis
- MTP-1 hemiarthroplasty
- hallux rigidus
- migration

Sponsors and support

Primary sponsor: Medical Center Haaglanden, The Hague, The Netherlands
Source(s) of monetary or material Support: MCH wetenschapsfonds

Intervention

Outcome measures

Primary outcome

- RSA analysis in terms of micromotion, loosening and subsidence.

Secondary outcome

- clinical outcome

- subjective outcome

- complications

Study description

Background summary

Hallux rigidus is one of the most common foot problems encountered in orthopaedic practice, leading to pain and restricted foot and hallux motion. Depending on the stage of the disease the treatment is conservative or surgical. For advanced stages of hallux rigidus both arthrodesis and arthroplasty have been advised. Reports in literature up to 33 years of clinical follow up, about the outcome of arthroplasty with a metallic hemiprosthesis, e.g. BIOPRO MTP-1, have shown mixed results. Persisting pain in the first metatarsophalangeal joint due to loosening of the implant has been reported to be the main reason of disappointing outcome.

In Medisch Centrum Haaglanden both arthrodesis and arthroplasty are performed for advanced and end-stage hallux rigidus. For arthroplasty the BIOPRO MTP-1 metallic hemiprosthesis is used. We are planning a pilot study to determine the subsidence and loosening of the prosthesis with RSA analysis and to correlate the radiological with the clinical follow up.

Study objective

The aim of this pilot study is to demonstrate the biomechanical behavior of the BIOPRO MTP-1 prosthesis and to obtain the clinical precision of the RSA technique and model used.

Study design

preoperative

6 weeks

3 months

6 months

1 year

2 years

Intervention

- RSA analysis, implantation of tantalum beads

Contacts

Public
Haaglanden Medical Center
PO Box 432

B.J.W. Thomassen
Den Haag 2501 CK
The Netherlands
+31 (0)70 3303109
Scientific
Haaglanden Medical Center
PO Box 432

B.J.W. Thomassen
Den Haag 2501 CK
The Netherlands
+31 (0)70 3303109

Eligibility criteria

Inclusion criteria

1. All patients with advanced or end stage hallux rigidus with an indication for a MTP1-hemiarthoplasty

2. Patients who signed the Ethics Committee approved specific Informed Consent Form

Exclusion criteria

1. Earlier surgery to the first ray

2. Cerebral palsy

3. Not motivated for inclusion

4. Pregnant patients

5. Prior inclusion in this study

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:	Recruiting
Start date (anticipated):	25-03-2014
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-02-2015
Application type:	First submission

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
NTR-new	NL4963
NTR-old	NTR5067
Other	NL44485.098.13 : METC no. 13-052, MCH no. 2013-066

Study results