Long-term results of the Scarf and Chevron Osteotomy for the correction of Hallux Valgus.
A PROSPECTIVE, RANDOMISED TRIAL WITH MORE THAN 12 YEAR FOLLOW-UP.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON42711

Source
ToetsingOnline

Brief title
>12 years survival of the Hallux valgus osteotomy: a RCT

Condition

- Joint disorders

Synonym
hallux valgus osteotomy

Research involving
Human

Sponsors and support

Primary sponsor: Orbis Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chevron Osteotomy, Hallux Valgus, Long term follow up, Scarf osteotomy

Outcome measures

Primary outcome

The primary outcome of this follow-up study will be the recurrence rate of

hallux valgus and reoperation rate of the same toe for HV. Recurrence of HV is

defined as a HVA > 15 degrees with a symptomatic bunion at physical examination

[5,16]

Secondary outcome

The secondary outcome includes patients satisfactory and the results from the

SF-36, AOFAS rating system, MOXFQ and radiographic measurements IMA and HVA.

Patients satisfactory will be defined as less than 9 points in total on the

three five-points satisfactory questions in the general questionnaire.

Study description

Background summary

One of the most common foot deformities. Its prevalence is higher in females and increasing with age. The etiology is believed to be multifactorial in which both extrinsic factors like high heel shoes as intrinsic factors such as genetics contribute to the pathophysiology. Numerous non-operative and more than 100 operative techniques have been described in literature with operative treatments varying from distal soft tissue release to proximal and distal osteotomies. Two widely used and accepted treatments in HV corrections are the chevron and the scarf osteotomy.

Study objective

The present study is designed 1) to compare the long-term survival using the recurrence rate of hallux valgus in the scarf and chevron osteotomy group; 2) to compare the long-term results with the results at 27 months; and 3) to asses patients* view on their treatment and current situation including patient reported outcome measures.

Study design

The present study is a follow-up of a RCT carried out at the Atrium-Orbis Medical Center location Sittard in the Netherlands (previously known as Maaslandziekenhuis Sittard) published by Deenik et al. in 2007. One hundred and eight feet in 96 patients were included in the primary study and randomized into the scarf (n=49) or chevron (n=47) osteotomy group. Follow-up moments were pre-operative and at 3, 6, 12 and 27 months.
The inclusion criteria for present study will be patients who had participated in the previous study. Patients who did not want to contribute were excluded from follow-up.
The primary outcome of this follow-up study will be the recurrence rate of hallux valgus and reoperation rate of the same toe for hallux valgus.
Recurrence of hallux valgus is defined as a HVA > 15 degrees with a symptomatic bunion at physical examination.
The secondary outcome include patients satisfactory and the results from the SF-36, AOFAS rating system, MOXFQ and radiographic measurements IMA and HVA.
Patients satisfactory was defined as less than 9 points in total on the three five-points satisfactory questions in the general questionnaire.

Study burden and risks

Patients will be asked to visit the hospital once for filling in 4 quesionnaires and at the same visit physical examination will take place (in which one of the authors inpects the foot and passively moves the MTP joint). There will also be one conventional x-ray of the foot.
Our hospital will take care of the costs of the outpatient contact and x-ray.

Radiation produced by conventional x-ray used in present study is negligible. Everybody in a normal environment receives röntgen radiation on a daily basis. This is called background radiation and it is expressed in millisievert (mSv). An average person in the Netherlands receives 2 mSv by radiation from the soil, from space an surrounding materials like concrete. People living on higher altitudes can even receive 10 mSv per year. The radiation that somebody receives when a conventional x-ray is made is similar to a flight to Japan. This is about 0.1 mSv and considered safe.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Participated in the original RCT by Deenik et al. (2007)

Exclusion criteria

Not willing or able to contribute to the 12 year follow-up.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-04-2015
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO

Date:	04-05-2015
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL52911.096.15