Optimization of Portal Placement for Endoscopic Calcaneoplasty in Valgus, Cavus and Normal Feet

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Ethical review	Approved WMO
Status	Pending
Health condition type	Synovial and bursal disorders
Study type	Observational invasive

Summary

ID

NL-OMON33190

Source
ToetsingOnline

Brief title
FOPP

Condition

- Synovial and bursal disorders

Synonym
retrocalcaneal bursitis; inflammation of the bursa in front of the heel

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: amphoraest fonds (Stichting Steun Orthopedie AMC)

Intervention

Keyword: calcaneus, distance, fibula tip, foot deformity

Outcome measures

Primary outcome

the distance between the fibulatip and the posterosuperior part of the

calcaneus for validation of the FOPP-device.

correlation of the difference of this distance to the amount of foot deformity.

the measurements of 2 angles (the calcaneal pitch angle and the talometatarsal

angle) to determine the exact foot deformity of the volunteers.

Secondary outcome

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Study description

Background summary

In the AMC, patients with a chronic retrocalcaneal bursitis are treated through a technique called 'endoscopic calcaneoplasty'. In this procedure the posterosuperior calcaneal prominence and the bursa will be removed. For this endoscopic procedure the surgeon uses two entrance points called 'portals'. These portals are right above the posterosuperior part of the calcaneus, lateral and medial from the Achilles tendon. For the experienced orthopaedic surgeon it may be easier to palpate this superior part of the calcaneus, but it happens that a less experienced surgeon places the portal too far proximal. Especially when the bursitis changes the outside appearance of the soft tissue around the Achilles tendon, it is harder to identify the posterosuperior part of the calcaneus. Standardizing portal placement in endoscopic calcaneoplasty therefore would be useful. In posterior ankle arthroscopy, the distal tip op the fibula is an important landmark for portal placement. The portals in posterior ankle arthoscopy differ from the portals in endoscopic

calcaneoplasty. We feel that the fibula tip is a useful landmark for endoscopic calcaneoplasty, and that maybe the distance between this tip and the posterosuperior calcaneus could be a useful tool for portal placement. The three different foottypes (cavus, valgus, normal), however, should be taken into account since tilting the calcaneus causes differences in this distance. We would use a conventional lateral radiograph of the foot to accurately measure the distance between fibula tip and posterosuperior calcaneus. A fibula is not visible on conventional x-rays; herefore we developed a device, which we named the FOPP- device (For Optimization of Portal Placement). This device needs to be validated.

Study objective

The objective of the study is to standardize portal placement in endoscopic calcaneoplasty, thereby taken into account the three different foot shapes, cavus, valgus and normal feet. Primarily the FOPP- device needs to be validated. If found valid, the measurements can be used.

Study design

This study is designed as a validation study of the FOPP- device for standardizing portal placement in volunteers. 30 volunteers will receive 3 X-rays.
In two X-rays, the FOPP-device is used, which means that a metal bar will be put against the lateral malleolus. This way the fibulatip is visible on the X-ray, so we can measure the distance between the fibulatip and the posterosuperior part of the calcaneus. When the device is valid, we can use the measurements for further analysis.
We will look for difference in distance between the three different foot types.
If the radiological measurements of the distance between top of the bar and calcaneus in the first 5 volunteers show low association within each volunteer (difference between measurements within one subject > 3 mm), measurements are not reproducible and the device needs revision before continuing the study.
One X-ray is to determine the exact foot deformity.

Study burden and risks

Manufacturing 3 X-rays has a trivial radiation risk. An additional visit to the hospital is will not be necessary. It will take 30 minutes time for the volunteers to co-operate.

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

Adult subjects with no other foot problems than a flatfoot or cavus deformity.

Exclusion criteria

Inability of standing, inability of placing the foot in a 90 degree position, a history of fracture of or surgery on the ankle, (possible) pregnancy.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2009
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

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	NL27349.018.09