Evaluation of a new stress CT base-plate for 3D measurements of hindfoot kinematics and its pre-operative use in patients with primary osteochondral defects of the talus

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First part of the study: evaluation of the new CT base-plateCompare the results obtained with the original base-plate to the results obtained with the newly developed prototype platform and validate its use for future clinical applications.Second...

Ethical review	Approved WMO
Status	Pending
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational invasive

Summary

ID

NL-OMON32141

Source
ToetsingOnline

Brief title
Validation of stress CT base-plate and clinical application

Condition

- Tendon, ligament and cartilage disorders

Synonym
bone-cartilage damage, osteochondral defects

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ankle, base-plate, CT, osteochondral defect

Outcome measures

Primary outcome

Deviation in position and orientation of the segmented bones in the extreme

positions when the old and new base plate are used.

Angle of maximum plantarflexion as defined from the neutral position in the

sagittal plane.

Secondary outcome

Arthroscopic approach of patients with an OCD

Study description

Background summary

The hindfoot complex, existing of the ankle and the subtalar joint, is prone to a variety of disorders. There are a number of hindfoot joint affections, such as degenerative joint disease after calcaneal fractures, foot deformities, subtalar dislocation or instability, that cause severe pain and limit the patient*s foot function. The wide range of values for injured and uninjured ankles makes differentiation between normal and abnormal outcome difficult, and differentiation at joint level is even more difficult. The high incidence of chronic ankle instability after ankle ligament injury necessitates the existence of effective diagnostic and treatment methods. In order to asses the range of motion of the subtalar and talocrural joints independently, a diagnostic tool was developed to perform a 3-dimensional stress CT (MEC 04/132). This CT-base-plate study proved to be a reliable method for analysing joint mobility in extreme foot positions with little variation between the testing subjects. Despite these positive results this device cannot be applied in a clinical setting. Thereto, a new base-plate as designed that is smaller

and more ergonomic, has increased user friendliness, and does not require assembling. Once validated, the new base-plate is used to measure the angle of the maximum plantar flexion in patients with primary osteochondral defects of the talus (OCD). This measure, combined with the position of the osteochondral defect may be useful to decide the arthroscopic approach to be used in the subsequent surgical procedure.

Study objective

First part of the study: evaluation of the new CT base-plate
Compare the results obtained with the original base-plate to the results obtained with the newly developed prototype platform and validate its use for future clinical applications.
Second part of the study: clinical use of the new CT base-plate
Investigate whether the operative procedure can be planned more accurately with the clinically measured maximal plantarflexion angle and the CT both in healthy volunteers as in patients with an OCD that need surgical intervention.

Study design

First part of the study: evaluation of the new CT base-plate
We will analyse CT data of the ankles and hindfeet of a group of twenty healthy individuals following a protocol similar to MEC 04/132, but with the addition that their maximum plantarflexion angle in their right ankle is first measured clinically by the surgeon. The subjects included in this project will be volunteers of equally distributed to both sexes. Besides a CT scna in de neutralposition, tn each subject four extreme foot positions will be measured with both platforms: maximum dorsiflexion (DF), maximum plantarflexion (PF), maximum anterolateral (AL) and maximum posteromedial (PM) position.

Second part of the study: clinical use of the new CT base-plate
In a subsequent period, twenty patients with an osteochondral defect who are scheduled for a CT-scan of the ankle for preoperative planning of arthroscopic treatment will be included. Their ankles are first measured clinically by the surgeon. When routine CT-scans of the ankles for preoperative planning are obtained, an additional low-dose CT-scan in the extreme plantarflexed positions is also obtained, using the validated CT base-plate.

Study burden and risks

The research has no direct advantages for the twenty healthy individuals. As opposed to the previous protocol the time required for the acquisition of CT-scans will be reduced due to the use of the new base-plate. Disadvantage for the volunteers is the radiation dose of the CT-scans, which is kept as low as possible. Each subject will undergo one CT scan with a standard dosage (120 kV; 150 mAs) and 8 CT scans with a low dosage (120 kV; 26 mAs). Total exposure per

subject is 358 mAs, equal to ~ 0.3 mSv.
The research could potentially give a direct advantage for the twenty patients participating. The results of the scans may provide the surgeon very detailed information to decide which surgical approach would be the best for a patient. Disadvantage for the patients is the extra (low) radiation dose of the additional CT-scan.
The patients will undergo one CT scan with a standard dosage (120 kV; 150 mAs) and one additional CT-scan with a low dosage (120 kV; 26mAs). Total exposure per patient is 176 mAs, equal to ~ 0.15 mSv.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

healthy volunteers:

1. No known history of injuries or disease of the lower extremities
2. 18 years or older;patients:
1. Patients should be scheduled for a CT-scan of the ankle for preoperative planning of arthroscopic treatment of an OCD by the orthopaedic surgeon.
2. 18 years or older

Exclusion criteria

No abnormalities of the lower limbs at a physical examination

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2008
Enrollment:	40
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	NL21444.018.08