The effect of soft tissue artifacts on the kinematics as calculated by multi-segment foot models

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The aim of this study is to quantify the 3D movement of skin-mounted markers on the foot relative to the bone locations they represent and their effect on the calculated foot kinematics.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON46288

Source
ToetsingOnline

Brief title
Soft Tissue Artifacts on the Foot (STAF)

Condition

- Bone disorders (excl congenital and fractures)

Synonym
but the results of this study can be applied to all conditions with foot deformities that can lead to gait problems (e.g. cerebral palsy), No specific condition is studied

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Computed Tomography, Foot, Gait analysis, Kinematics

Outcome measures

Primary outcome

The main study parameters are the 3D movement of the skin-mounted markers with respect to their corresponding bones and the effect of these soft tissue artifacts on the foot kinematics as calculated by several multi-segment foot models.

Secondary outcome

Other study parameters included are age, length, weight, foot posture index, foot length and width, range of motion in the ankle, soft tissue between the bone and skin of the foot.

Study description

Background summary

Knowledge about foot kinematics during gait can assist in treatment planning of patients with foot problems (e.g. cerebral palsy). These kinematics are determined with skin-mounted markers that represent bony landmarks. However, relative motion is shown between skin-mounted markers and corresponding bones of the lower leg and foot (i.e. soft tissue artifacts). These soft-tissue artifacts (STA) result in altered axes of the local coordinate systems of the joints and therewith possibly incorrect kinematics. Therefore, STA should be quantified to determine their influence on the calculated foot kinematics. Research has been conducted on STA with intra-cortical percutaneous pins and 2D imaging. However, pins are very invasive and have other negative effects on the outcome measure and STA measured with 2D imaging do not provide the complete picture and are therefore not really applicable to 3D gait analysis. Hence, we developed a CT-scan protocol to be able to overcome these issues and quantify STA. With that knowledge, models can be improved, which eventually improves treatment decisions. This study will be the first that quantifies STA in 3D of all the markers of the two most frequently used multi-segment foot models and

their effect on the estimated kinematics.

Study objective

The aim of this study is to quantify the 3D movement of skin-mounted markers on the foot relative to the bone locations they represent and their effect on the calculated foot kinematics.

Study design

Observational study

Study burden and risks

The radiation exposure of the series of CT scans was optimised by performing a pilot study in a cadaveric specimen, in which the minimal acceptable dose was determined. The total exposure for the participants for all the scans combined is estimated to be 0.09 mSv. The exposure is within the category I (<0.1 mSv) of the International Commission on Radiological Protection (ICRP), which qualifies as: trivial risk.

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

Subject must be over the age of 18 years and be willing and able to give informed consent

Exclusion criteria

Exclusion criteria are:
- Wearing insoles or something similar
- A right ankle or foot injury in the last 3 months
- A history of trauma or surgeries on the right ankle or foot
- A hindfoot to lower leg range of motion which is less than:
- 40° plantar flexion
- 20° dorsal flexion
- 10° varus/inversion
- 10° valgus/eversion
- Pregnancy
- Not being able to understand the written informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-11-2018

Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	26-10-2018
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	NL66940.018.18