Generation of subject-specific, dynamic, multi-segment ankle and foot models to improve the design of foot and ankle foot orthoses

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To generate the information required to produce accurate and dynamic computational models of the human foot and ankle for the purposes of orthotic development.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON38031

Source
ToetsingOnline

Brief title
A-FOOTPRINT

Condition

- Other condition
- Diabetic complications
- Tendon, ligament and cartilage disorders

Synonym
general foot problems

Health condition

CVA

Research involving
Human

Sponsors and support

Primary sponsor: orthopaedie
Source(s) of monetary or material Support: Europese Unie: 7th framework;projectnummer: NMP2-SE-2009-228893

Intervention

Keyword: foot orthoses, modelling, personalisation

Outcome measures

Primary outcome

This study is a feasibility/pilot study. The primary aim of the study is to collect the imaging and motion analysis data that is required to develop and validate accurate computational models of the foot and ankle, and incorporate these into high fidelity dynamic simulations. As such, the outcome measure could be defined as how close to "real life" these simulations are shown to be. This will be achieved by validating the model against plantar pressure data and surface EMG data taken during the gait analysis.

Secondary outcome

nvt

Study description

Background summary

It has been estimated that up to 196 million Europeans have disabling foot and ankle pain and that its prevalence is set to rise in an aging society with increasing chronic long term conditions. Foot pain causes loss of function, discomfort, and a general lowering of the patient's quality of life. Ankle and foot orthoses are used to treat many of the conditions causing foot pain,

however, 70% of these medical devices are made using traditional techniques relying on impressions casts, templates and hand fabrication. Patient supply typically takes 28 days, the functional form of orthoses is difficult to verify, and repeat prescriptions can be inaccurate. These traditional approaches also limit design choice and personalised function to simple parameters such as cushioning and range of motion.

Computer-based modelling of the human body - ranging from the force interactions of joints to the way cells communicate with one and other - has advanced significantly in the past few decades to a level where it is now an important and useful tool for researchers working in the life sciences. These models provide a method of simulating and assessing interventions that are being developed; reducing the time and risk involved with trialling in humans. The musculoskeletal field in particular is an area where extensive modelling work has been successfully carried out, supporting the development and assessment of a range of treatments and interventions.

In the field of foot biomechanics there is a growing body of research incorporating computer modelling based on CT and MRI images, pressure distribution measurements and gait analysis. This includes work on inflammation of the plantar fascia, pressure assessment of the diabetic foot and therapeutic footwear. This approach is particularly popular in this field because of the difficulties relating to investigating the internal loading and movement of the complex collection of bones and soft tissues within the foot.
It is therefore suggested that there is a great deal of potential for cutting edge computer base musculoskeletal modelling technologies to be incorporated into the process of developing orthotic interventions for the foot and ankle. This could lead to changes in terms of reduced pain, improved function, more comfort and higher quality of life for the patient; as well as reducing the overall cost of the intervention to the health provider. This study aims to begin exploiting this potential. The data generated in this study and through the other aspects of the A-Footprint project of which it is part will be used to advance the technology of foot orthotics.

Study objective

To generate the information required to produce accurate and dynamic computational models of the human foot and ankle for the purposes of orthotic development.

Study design

This study is a feasibility/pilot study. It is a multicentre-study, between Glasgow Caledonian University and University Hospital Maastricht. The data acquisition will be independent, after acquisition the data will be pooled. This datapool will be used to develop a biomechanical model of the foot. The

next step will be a larger trial for clinical evidence for the use of the model for the development of (ankle-) foot ortheses, which will lead to cost effectiveness.

Study burden and risks

One of the main ethical issues associated with this study are that detailed examination of the participants' feet and gait will be undertaken, both a physical examination by a qualified podiatrist and 3D medical imaging of the foot using CT. These examinations will not be part of their standard care regime. It is possible that in some cases pathologies will be detected as a result of these examinations. Should this occur the consultant/GP responsible for the participant's medical care will be notified so that the appropriate management/treatments can be initiated.
Exposure to ionising radiation is another important ethical issue with this study. Every effort has been made to keep exposure to a minimum, with the fewest number of scans needed to generate the required data. During this study only the foot and lower leg will be scanned. Participants will have the risks of exposure to ionising radiation at the doses to be used in the study described to them and it will be explained why the scan is an essential part of the methodology. If potential participants have been exposed to ionising radiation in the previous year, an assessment will be made by the radiological team to determine if participation in this study would put them at unnecessary risk. Particular attention has been paid to pregnant women and new mothers and it has been emphasised in the Participant Information Sheet and Consent form that these individuals must not take part in this study.
During the assessments of foot function, participants will be required to walk barefoot which may result in some transient discomfort. The amount of barefoot walking will be kept to a minimum and patients will be encouraged to rest when necessary and will be able to stop testing at any time. There may also be some slight irritation as a result of light abrasion and cleansing of the skin where EMG electrodes will be attached (this is necessary to insure a high quality signal). The MUMC+ have extensive experience of undertaking these types of assessments and measurements in the populations being targeted by this study.
During imaging of the foot, the participant will be asked to push with their foot against a fixed plate (this is so we can identify internal changes in the foot that occur under loading). This force needs to be applied for around 30 seconds, and prior to the scan beginning the level of force the participant is comfortable applying will be tested. (up to a level equivalent to 50% of body weight).
The only other ethical issue which may arise relates to the extra time involved in conducting these examinations. This will involve the participants giving up their own time to attend MUMC+ for their appointments. This whole process is estimated to take 4 hours.

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

Group healthy feet:
• Physically able to perform testing (able to walk at least 20 meters barefoot and unaided)
• 38 < Shoe size < 44 (EUR), 5.5 < Shoe size < 9.5 (UK)
• 18 < age < 50 year
• Fully competent and able to give informed consent
Group pathological feet:
• Three groups, one group who would be prescribed pressure relieveing orthotics (e.g. diabetic patients), one group who would be prescribed orthotics to improve alignment (e.g. flexible flat foot deformities), and a final group of stroke patients who would be prescribed an ankle foot orthosis for motion control. The included CVA patients will be fully competent and able to give informed consent.
• Physically able to perform testing (able to walk at least 20 meters barefoot and unaided)

• 38 < Shoe size < 44 (EUR), 5.5 < Shoe size < 9.5 (UK)
• 18 < age < 50
• In need of an (ankle-)foot orthosis
• Fully competent and able to give informed consent

Exclusion criteria

Group healthy feet
• Footproblems, requiring medical treatment
• Lower extremity problems
• Diabetes Mellitus
• Rheumatoid Arthritis
• Pregnant and lactating women
Group pathological feet
• Lower extremity problems, causing gait variation
• Pregnant and lactating women

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2011
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	15-12-2010

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-06-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL31656.068.10