Development of Shape and Pressure Models for a Comprehensive Analysis of the Healthy Foot

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

Summary

ID

NL-OMON57386

Source
ToetsingOnline

Brief title
Pressure and Shape Models of the foot

Condition

- Other condition

Synonym
Foot malformations, malformed feet

Health condition

Voetdeformiteiten, maar niet in deze studie met gezonde proefpersonen

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Finite Element Model, MRI, Pressure Plate, Statistical Shape Model

Outcome measures

Primary outcome

Main study parameters are (1) a workflow that creates a database of WB and non-WB MRI scans from the feet of 20 healthy subjects; (2) the difference in foot morphology between WB and non-WB conditions; (3) validation of the FEM by using the input of the healthy feet to match and compare the PP with empirical data of a pressure plate.

Secondary outcome

Secondary study parameters are (1) a relatively simple initial SSM of the foot that is developed by using the foot data of the 20 healthy subjects; (2) the plantar pressure of the healthy foot.

Study description

Background summary

Foot deformities occur in multiple planes and cause pain and mobility issues in patients. Surgeons currently freehandedly reconstruct such feet using 2D X-rays. However, the patients optimal foot shape and the postoperative pressure distribution of the foot are unknown preoperatively. Predicting this optimal foot shape and pressure distribution could enhance surgical precision, efficiency, and reduce complications like recurrence of ulcers and amputation. A statistical shape model (SSM) of the healthy foot offers a potential solution to predict the patients optimal foot shape, by capturing the mean foot shape and its variations. An explorative and simplified SSM will be developed using

MRI data from 20 healthy participants in weight-bearing (WB) and non-weight-bearing (non-WB) conditions. This database is yet to be created by including 20 healthy subjects and scanning their feet in a WB and non-WB MRI scanner. Current SSMs are based on supine MRI or CT scans and therefore do not reflect real-life conditions influenced by gravity. WB MRI allows the assessment of biomechanical and anatomical adaptations of the foot under gravitational forces, addressing this gap. Although this study involves a limited sample size, it lays the groundwork for future SSM development, estimating the data needed for a proper functioning SSM. Additionally, the study explores finite element modeling (FEM) based on WB MRI data and pressure plate measurements of the subjects* feet to preoperatively simulate the plantar pressure (PP) distribution of the foot.A validated FEM could predict pressure points preoperatively, reducing the risk of ulcers and reoperations. The FEMs accuracy is validated by comparing its PP predictions with actual pressure plate measurements in healthy subjects. In the future, this simulation may help in the preoperative prediction of the postoperative pressure distribution of the foot.

Study objective

The primary objectives of this study are to: 1) create a database of WB and non-WB MRI scans from the feet of 20 healthy subjects, 2) evaluate the morphological differences in the human foot under WB and non-WB conditions to assess the impact of gravitational loading on bone configuration, and 3) match and validate a FEM by comparing the predicted plantar pressure (PP) distribution with empirical data from a pressure plate. The secondary objectives include: 1) developing an initial, relatively simple SSM of the foot based on the data from the 20 healthy subjects, modelling the foot shape as two segments: the soft tissue envelope and all bones as a single segment, and 2) identifying the plantar pressure distribution of the healthy foot using the mean shape that is obtained from the initial SSM.

Study design

Observational cross-sectional study with an explorative nature.

Study burden and risks

This study is classified as non-therapeutic research involving capacitated adults. The primary risk to subjects is exposure to MRI scanning in both standing and lying positions, which is considered a minimal risk procedure with no known significant adverse effects. The standing MRI has a magnetic field strength of 0.25T and the lying MRI has a field strength of 1.5T, both of which are considered safe for routine imaging. There is no risk involving the pressure plate measurements. There are no direct benefits to the participants in this study. However, the research contributes valuable knowledge in the

field of foot morphology, which in the far future may aid in more accurate foot surgeries and better post-operative outcomes for patients. The burden to participants, including the time commitment for MRI scans and the potential discomfort of standing in the scanner, is minimal and proportional to the potential scientific value of this research.

Contacts

Public
Ziekenhuisgroep Twente

Zilvermeeuw 1
Almelo 7609PP
NL
Scientific
Ziekenhuisgroep Twente

Zilvermeeuw 1
Almelo 7609PP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

This study includes healthy participants. A healthy participant is defined as a person who:

Does not have a foot deformities like hallux valgus, Charcot foot, severe pes planus or pes cavus or a clubfoot.

Does not have a medical history of foot surgeries

Has no current foot pain or functional limitations at rest, or when walking or standing on bare foot

Has no neurological or systemic conditions affecting foot structure or sensory and motor functions of the foot (e.g. diabetes mellitus, rheumatoid arthritis, neuropathies)

Has a normal mobility and does not use walking aids.

Does not have vascular conditions affecting circulation in the foot.

The investigators expect to have a normal pressure plate profile. A normal pressure plate profile is characterized by:

A plantar pressure distribution consistent with a physiological gait pattern, with the highest pressure peaks located under the heel, the first and fifth metatarsals, and the hallux.

A smooth roll-off of the foot, without extreme lateralization or medialization of the pressure distribution.

Other inclusion criteria to be eligible to participate in this study are:

Age: Between 18 and 65 years

Sex: Both biological female and male participants will be included.

Informed Consent: the participant must be able to understand and provide informed consent regarding the nature and goals of the study.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

Participants who do not wish to be informed about unexpected medical findings

Foot Deformities: Presence of significant foot deformities.

Neuropathy: Any history of neuropathy or conditions affecting foot sensation.

Foot Surgery: History of foot surgery that may alter anatomical or biomechanical characteristics.

Amputation: Any amputation of (part of) the lower extremities.

Skin Conditions: Any abnormal skin conditions, including ulcers or open wounds on the foot.

Medical Implants: Presence of any medical implants or devices that may interfere with MRI imaging.

Inability to stand for a period of 5 minutes.

Pregnancy: The exclusion of pregnant women is not only due to the safety concerns of contrast agents, as no contrast is used in the MRI scans for this study. Hormonal changes that can affect foot structure, potentially influencing result interpretation, were also considered.

MRI Safety: Any other condition that would make MRI unsafe or unreliable.

Height > 200 cm

Weight > 150 kg

Can people with flat feet or orthotics participate?

People with mild flat feet (pes planus) or high arches (pes cavus) can participate if they do not have functional complaints or pain at rest or when walking or standing on bare foot. In such cases, their pressure profile is considered part of the natural variation within a healthy population. If abnormal pressure distributions are measured, these can be analysed as a subgroup within the healthy participants.

People who wear orthotics can only participate if they exhibit a physiological gait pattern and pressure distribution without orthotics during the measurement and if they have no functional complaints or pain at rest or when walking or standing on bare foot.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-03-2025
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-04-2025
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL88645.091.24