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Effectiveness of custom 3D-printed foot orthoses in improving foot symptoms: a pre-and post-intervention study

Submission date
23/02/2025

Recruitment status
No longer recruiting

Registration date
13/03/2025

Overall study status
Completed

Last Edited
07/03/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to evaluate the effectiveness of custom 3D-printed foot orthoses in improving foot symptoms and functional status by comparing baseline and post-intervention outcomes. Custom 3D-printed foot orthoses are expected to effectively improve functional status and alleviate foot symptoms, supporting their use as a personalized treatment option in clinical practice. Future research should investigate their long-term efficacy and adaptability across diverse populations.

Who can participate?
Participants aged from 18 to 75 years old with and without foot pain

What does the study involve?
Baseline data included demographic and clinical characteristics (e.g., age, sex), physical function questionnaire scores, and pain intensity assessed using the numeric rating scale (NRS), and 3D-scanned foot morphology data. After three months of using custom 3D-printed foot orthoses, follow-up questionnaire scores were collected for comparison.

What are the possible benefits and risks of participating?
Possible Benefits: The custom insoles are designed based on the user's foot morphology, providing active support to redistribute foot pressure, alleviate fatigue, and reduce pain. They offer excellent support and cushioning, protecting the feet, ankles, and knees from sports-related injuries. The insoles can also correct biomechanical misalignment caused by conditions such as high arches, flat feet, or foot deformities, helping to distribute foot pressure, enhance balance, improve athletic performance, and prevent injuries. They are particularly beneficial for older adults, as they support the arch of the foot, alleviate joint degeneration and fatigue, and improve overall quality of life. Additionally, the insoles can slow down or prevent the progression of hallux valgus and related foot conditions, promoting foot health.

Possible Risks: There is a possibility that foot pain symptoms may not improve, and foot function may not be enhanced.

Where is the study run from?
Affiliated Kunshan Hospital of Jiangsu University, China

When is the study starting and how long is it expected to run for?
November 2023 to May 2024

Who is funding the study?
Medical Innovation (Suzhou) Clinical Research Co., Ltd

Who is the main contact?
Dr Chong Li, lichong1705@163.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effectiveness of custom 3D-printed foot orthoses in improving FAAM scores among general populations: a pre-and post-intervention study

Study objectives

Custom 3D-printed foot orthoses have a positive effect on foot pain and foot function

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/07/2024, The First People’s Hospital of Kunshan (No. 566 East of Qianjin Road, Suzhou, Jiangsu, 215300, China; +86-0512-57029736; sgu8434@sina.com), ref: 2024-03-029-H01-K00

Study design
Single-group pre-and post-intervention study

Primary study design
Interventional

Study type(s)
Quality of life, Efficacy

Health condition(s) or problem(s) studied
The improvement effect of custom 3D printed foot orthoses on foot pain and foot function

Interventions
A pre- and post-control study using Custom 3D printed foot orthoses
The study involves the use of custom 3D-printed foot orthoses tailored through 3D scanning technology, with participants from the general population using the orthoses for at least 24 days per month and 8 hours per day over a 3-month follow-up period. The intervention is location-independent, and data collection includes participant demographics, baseline and follow-up FAAM scores, baseline NRS scores, and 3D foot scan data.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Custom 3D printed foot orthoses

Primary outcome(s)
Physical function measured Foot and Ankle Ability Measure (FAAM) at baseline and three months after using Custom 3D printed foot orthoses

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
07/05/2024

Eligibility

Key inclusion criteria
1. Age under 75 years, able to cooperate with the use of orthotic insoles independently
2. No medication treatment within the past three months
3. No other foot issues, such as skin ulcerations or diabetic foot
4. Participants agree to have no plans for pregnancy from the time of signing the informed consent until the end of the trial
5. Participants fully understand the purpose, nature, methods, and potential adverse reactions of the study, voluntarily consent to participate and sign the informed consent form before the initiation of any research procedures

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Total final enrolment
76

Key exclusion criteria
1. Individuals who use any medications or medical devices outside of the study-required trial products during the study period
2. Those with cognitive impairments who are unable to comply with treatment
3. Participants who have received topical treatments, physical therapy, or rehabilitation for foot conditions within one month prior to screening, or who are undergoing other treatments that may affect efficacy
4. Individuals with a history of foot surgery within the past 12 months or those planning surgery on the affected area during the trial
5. Participants who used anesthetics, opioid analgesics, antispasmodics, long-acting non-steroidal anti-inflammatory drugs (e.g., piroxicam, meloxicam, naproxen, etoricoxib) or other medications that could influence efficacy assessment within the last 7 days prior to screening; those who use analgesics during the 3-month trial period will be considered to have withdrawn voluntarily
6. Foot and ankle pain due to neurological disorders, autoimmune diseases, foot trauma, or referred pain unrelated to structural abnormalities
7. Individuals with severe organic primary diseases affecting the cardiovascular, hepatic, renal, or hematological systems, as well as those with mental illnesses
8. Other reasons deemed inappropriate for enrollment by the researchers or participants who

withdraw from the trial for personal reasons
9. During the follow-up period, the worker was unable to complete the follow-up due to various reasons

Date of first enrolment
03/11/2023

Date of final enrolment
07/05/2024

Locations

Countries of recruitment
China

Study participating centre
The First People’s Hospital of Kunshan
No. 566 East of Qianjin Road
Suzhou, Jiangsu
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Sponsor information

Organisation
First People's Hospital of Kunshan

ROR
https://ror.org/01kzsq416

Funder(s)

Funder type
Industry

Funder Name
Medical Innovation (Suzhou) Clinical Research Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes