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Improving the design of insoles for diabetic foot disease

Submission date
19/08/2015

Recruitment status
No longer recruiting

Registration date
21/08/2015

Overall study status
Completed

Last Edited
10/07/2017

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
People living with diabetes often have to live with long-term complications of the disease. One of these complications is diabetic peripheral neuropathy, where nerve damage is caused in the arms, hands, legs and feet. People suffering from diabetic peripheral neuropathy are at much greater risk of developing problems with their feet, such as foot ulcers, because the damage to the nerves reduces sensation in the foot. It is thought that high pressure on the heel and bottom of the foot (plantar pressure) increases the risk of diabetic foot ulcers. For this reason, people with diabetic neuropathy are often prescribed custom-made insoles in order to reduce the pressure on the parts of the foot that usually develop ulcers. The aim of this study is to compare insoles that have been designed using a computer simulation to those designed using traditional methods, in order to find the best design for helping relieve the pressure foot pressure for diabetic patients.

Who can participate?
Diabetic adults with diabetic peripheral neuropathy in the foot and elevated planar pressures

What does the study involve?
Each participant is provided with three sets of insoles to use. The first is a standard insole which is made using traditional methods and is the standard insole currently prescribed. The second insole is designed using a computer simulation and is made using a mold. The third insole is also designed using a computer simulation and is made using 3D printing. The two insoles made using a computer simulation are tailor-made for each participants' feet so that the best support possible is given. The participants are asked to wear each of the insoles for approximately 5 minutes, and are asked to walk at least 20 steps. A number of sensors are placed between the foot and the insole within their shoes, which measures the plantar pressure to find how each insole is relieving this pressure.

What are the possible benefits and risks of participating?
A benefit of participating in this study is that an experienced podiatrist will carry out a foot exam. If any problems are found, then a doctor will be notified so that treatment can be arranged. Also, participants can keep the three sets of personalised insoles made for them in the study. There are no potential risks of participating.

Where is the study run from?
University Hospital Ayr (UK)

When is the study starting and how long is it expected to run for?
March 2015 to October 2015

Who is funding the study?
Seventh Framework Programme (Belgium)

Who is the main contact?
Dr Scott Telfer
scott.telfer@gcu.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Scott Telfer

ORCID ID
https://orcid.org/0000-0002-0104-4027

Contact details
Institute of Applied Health Research
Glasgow Caledonian University
Cowcaddens Road
Glasgow
United Kingdom
G4 0BA
+44 (0)141 331 8475
scott.telfer@gcu.ac.uk

Additional identifiers

Study information

Scientific Title
Optimisation of custom insoles for pressure relief in patients with diabetes via finite element modelling

Study objectives
Custom insoles optimised using computer simulations of forefoot loading will provide significantly better forefoot offloading at sites of elevated pressure than those designed using standard techniques.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Committee 4, 27/01/2015, ref: 14/WS/1150

Primary study design
Interventional

Study design
Single-centre randomised repeated measures crossover design

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Diabetes with peripheral neurpathy

Interventions
Three interventions are administered to each participant in a randomised, crossover fashion:
1. Standard, total contact insole with modifications for forefoot offloading (control). This is a traditionally designed insole that is currently the standard device prescribed for at risk diabetic feet.
2. Virtually optimised pressure offloading insole manufactured through direct milling. This is an insole design that has been optimised for pressure offloading using a numerical model simulation and is manufactured via direct milling.
3. Virtually optimised pressure offloading insole manufactured through 3D printing. This is an insole design that has been optimised for pressure offloading using a numerical model simulation and is manufactured via 3D printing.
The study tests the acute effects of the insoles. Each participant will have approximately 5 minutes to acclimatise to each pair of insoles before being data collection. The in-shoe measurement system is a flexible array of sensors that is placed between the foot and the insole and records interface forces. We will collect at least 20 steps of data for each foot.

Intervention Type
Device

Primary outcome(s)
Forefoot peak plantar pressure, measured using an in-shoe plantar pressure measurement system (Pedar, Novel GmbH, Munich) at a single timepoint immediately after the insoles are provided to the patient

Key secondary outcome(s)
Validation of computational models in this patient population comparing the predicted plantar pressures to those measured experimentally

Completion date
05/10/2015

Eligibility

Key inclusion criteria

1. 18-75 years of age
2. Shoe size 5-11 (UK)
3. Able to walk 300m (including ~20m barefoot) safely
4. Diabetes mellitus Type 1 or 2 with duration ≥10 years
5. Diabetic peripheral neuropathy defined as loss of sensation to 10g monofilament test at one or more forefoot sites
6. Elevated barefoot plantar pressure (>700kPa) measured at the forefoot during walking

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Key exclusion criteria
1. Lower limb, foot or digital amputation (at a level proximal to the distal IPJ, or involving the hallux)
2. Severe callus (callus will not result in exclusion if it has been reduced to a level that does not affect sensation of underlying skin)
3. History of medical conditions, injuries or surgical procedures that significantly influence gait, or which cause pain on walking (including Charcot)
4. Severe foot deformity or reduction in ROM that result in abnormal gait or preclude good fit of study shoe (including Charcot)
5. Severe concurrent medical condition that would prevent participation in study procedures (e. g. severe cardiac/pulmonary condition that precludes activity) or with life expectancy ≤ 3 months.
6. Pregnancy

Date of first enrolment
01/03/2015

Date of final enrolment
16/07/2015

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University Hospital Ayr
Dalmellington Road
Ayr
United Kingdom
KA6 6DX

Sponsor information

Organisation
Glasgow Caledonian University

ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/07/2017		Yes	No
HRA research summary			28/06/2023	No	No