## Participant Information Sheet

**Characterisation of Plantar Loading for Foot Health**

Please also see the [Privacy Notice for Research](https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2019/02/Research-Privacy-Notice.pdf) supplied with this information sheet.

You are being invited to take part in a research project. Before you decide whether to take part it is important for you to understand the goal of the research and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Feel free to ask the lead researcher if anything is not clear or you would like more information. Take time to decide whether or not you wish to take part.

**What is the purpose of the project?**

This research project aims to demonstrate the implementation of 3D DIC methods to measure plantar loads within in a shoe and highlight any additional information that 3D methods provide in contrast to 2D. By doing so, it is hoped to improve the prevention and management of diabetic foot ulcers.

Background

Diabetes is a chronic condition with growing global prevalence. Numbers are expected to reach 537 million and 783 million by 2030 and 2045 respectively. Of those with diabetes, up to 25% will go on to develop a diabetic foot ulcer (DFU) with a 40% recurrence rate at 1 year. Additionally, DFUs can lead to infection, amputation, and even death if timely interventions are not performed, with an approximate 40% mortality at 5 years in patients with diabetes who underwent amputation. Consequently, diabetic foot care has been estimated to cost nearly £1 billion annually based on NHS spending from 2014/15.

Studies have shown that pressure and shear stress at the plantar surface of the foot (the sole of the foot) are influential in DFU development. Technology to measure these could improve the clinical assessments used to determine a patient’s risk of developing DFUs. However, commercially available sensing technologies are limited to measuring plantar pressures, lacking the capability to measure shear stresses and therefore reducing clinical applicability.

To address this, the STrain Analysis and Mapping of the Plantar Surface (STAMPS) system was developed to measure strain on the plantar surface of the foot. This utilises digital image correlation (DIC) to track the deformation of a plastically deformable insole after a period of gait. A speckled pseudorandom pattern is adhered to the surface of the insole, images are taken before and after a period of gait. The images are compared, and the strain of the insole is measured, corresponding to that of which the foot has been placed under.

The STAMPS system used with a single participant is proposed to evaluate the performance of 3D DIC methods as an alternative to the 2D methods implemented previously. This will guide the use of 3D DIC in future research and clinical trials.

Description of the STAMPS insole method

The STAMPS system uses ‘Digital Image Correlation’, which is a technique used to map strain patterns on the surface of the foot. A pseudo-random pattern is adhered to the surface of an insole, images are taken before and after being worn for 10 steps. Strain patterns are tracked according to the difference in the images. This technique will be adapted by tracking the strain patterns on a plastically deformable insole to measure the strain on the plantar surface of the foot. The strain patterns are processed using two programs to generate the strain patterns for each anatomical region of the plantar foot surface.



Plantar strain in local anatomical regions across the foot

DIC analysis (Ncorr/DuoDIC) of STAMPS insole – strain heat map

Anatomical segmentation of the plantar strain data (MATLAB)

**Figure 1:** *STAMPS data collection, DIC analysis and post-processing.*

The motivation for this study

This study is designed to evaluate the performance of 3D DIC methods together with the STAMP system. Using the systems with healthy participants will provide information on what additional information can be captured using 3D methods in contrast to previously implemented 2D methods. It is hoped that measurements captured using 3D DIC will better represent the surface of a foot, since 2D methods are unable to capture the ‘curved’ nature of the foot.

This information will enable the research team to plan further development before proceeding to clinical trials in people at risk of developing DFUs.

**Why have I been chosen?**

You have been chosen because you meet all the requirements to take part in this study.

**Do I have to take part?**

Taking part in this research is entirely voluntary and you as the participant may withdraw from the study at any time without penalty and do not have to give a reason for doing so. If you decide to take part you will be given this information sheet to keep, a copy of the experimental procedure to look over and will be asked to sign a consent form.

**What do I have to do?/ What will happen to me if I take part?**

You will be asked to wear a pair of shoes containing the a) STAMPS insole alone, and b) custom orthotic insole with STAMPS insole overlaid. For the final assessment, participants will be asked to wear a pair of shoes containing the Pedar insoles and instructed to walk 20 steps along a flat walkway. Three repeats of each test will be performed but should not take longer than 60 minutes for completion. During the tests, photographs may be taken to document the research. For more details, please see the provided experimental procedure sheet and the full risk assessment is available on request.

**What are the possible disadvantages and risks of taking part?**

No disadvantages associated with taking part.

Minimal short-term risk overall in the activities required. Trials involve each participant walking or standing in an unforced, low-speed and normal manner. Participants included must be fit to walk at a self-selected walking speed and have no medical conditions that impact their ability to walk or maintain balance during activities. The footwear the participants are asked to wear is provided to the NHS and is equivalent to commercially available footwear. The instrumented insole placed inside the right-hand shoe is mechanically soft and has no features (e.g. sharp elements) which may cause injury to the participant’s foot. The custom orthotic insoles will be made by trained professionals at Steeper, ensuring correct moulding and fit to the participants feet. All materials in contact with the human skin have been selected from medical grade elastomers which are biocompatible and non-allergenic. Disposable socks will be given to participants to avoid direct contact between the skin and insoles and everything will be disinfected with disinfectant wipes between trials to avoid cross-contamination. No travel expenses are available.

**What are the possible benefits of taking part?**

While there is no immediate benefit for participants, they will have the knowledge they are helping develop technology with the potential of greatly improving people lives. The only participants that may see a direct benefit are those working within the specific field of interest who may be interested in the results of the study.

**Use, dissemination and storage of research data**

Following the collection of data, it will be processed and stored securely on the University of Leeds OneDrive. There is the potential for data from this study to be published in journal articles. All data will be anonymised at source during collection so it cannot be traced back to any individual participant. During publication anonymised data will be made available to third parties.

**What will happen to my personal information?**

All data for publication will be anonymised with no trace of personal information published. In any photos captured participants faces will be digitally masked to maintain anonymity. If you decide to withdraw from this study your contact information will be destroyed however any anonymised data could be retained for the study.

**What will happen to the results of the research project?**

Steps will be taken at the point of collection to anonymise the research data so that you will not be identified in any reports or publications.

The results from this study will be published within a year of testing and participants can receive a copy of results upon request and will be linked to the article once published, participants will not be named within any publications. Data collected during this study may be used in future studies, this data will be only available in a fully anonymised state.

Photos of your activities made during this research will be used only for analysis and for illustration in conference presentations and lectures. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.

**What type of information will be sought from me and why is the collection of this information relevant for achieving the research project’s objectives?**

The personal information collected will relate to your height, weight, age and shoe size to ensure that the STAMPS insole and corresponding shoe is correctly sized for each participant. Individual measurements will be anonymised.

**Who is organising/ funding the research?**

The research has been organised by the University of Leeds and was funded by the Engineering and Physical Sciences Research Council (EPSRC).

**Contact for further information**

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**Documents provided to participants**

* Signed consent form
* This participant information sheet
* Experimental procedure
* Research privacy notice
* Risk assessment

**Thank you for taking the time to read through this information sheet.**

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