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Personalized foot orthoses with embedded temperature sensing: Proof of concept and relationship with activity

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ABSTRACT

Plantar foot surface temperature has been identified as a clinically relevant physiological variable. Embedding sensors in foot orthoses (FOs) may allow long term monitoring of these temperatures, with compliance via the detection of periods of activity being a potential clinical utilization. This study aimed to test novel designs for FOs with embedded sensing that were produced via additive manufacturing and determine if foot temperature measurements could be used to detect periods of increased activity. FOs with embedded temperature sensors were developed and tested in 10 healthy participants over four day wear periods. Activity monitoring was used to estimate energy expenditure during testing. A threshold-based algorithm was developed to identify time periods of high activity from foot temperature data. Group differences in estimated energy expenditure between time periods below and above the threshold were significant in both the training and validation sets ($p < 0.001$). Significant differences were also seen at individual participant level ($p < 0.001$ in all cases). These results demonstrate the feasibility of using FOs with embedded sensing to monitor plantar surface foot temperatures during normal daily activities and for extended periods and show that periods of increased activity can be identified using foot temperature data.

1. Introduction

The ability to measure physiological and mechanical variables relating to the foot over extended periods of time is of potential interest for a number of clinical conditions. For example, monitoring temperatures at the plantar surface of the foot has been demonstrated as an efficacious method for detecting the early signs of inflammation associated with ulceration risk, [1,2] and to monitor the resolution of acute Charcot's arthropathy [3]. The in-shoe environment, however is challenging for long term measurements due to a combination of cyclic high loading patterns, varying temperature and humidity levels, and difficulties in accessing data from the sensors [4,5].

Previous studies have used sensors attached to the dorsum of the foot [4,6] and at the lateral side of the foot below the malleolus [7] to monitor the variations in temperature seen in healthy and diabetic subjects. The plantar surface of the foot may, however be a more clinically relevant area to monitor as it is here that the high and repeated loads associated with gait are concentrated [1,2]. To measure these temperatures, a suitable sensor must be positioned at the required location under the foot, preferably without the need for modifications to the subject's footwear.

Foot orthotics (FOs) or insoles are a widely prescribed and recommended intervention for a number of conditions with a biomechanical component [8,9]. Embedding sensors in an FO is an appealing option as these devices can be used in multiple sets of footwear and can provide a structure that can house the sensors and associated hardware.

Increasingly, computer aided design (CAD) is being utilized to produce personalized FOs from 3D surface models of the foot. Two main CAD approaches are commonly used to define the form of the device. In the first approach, the shape of the FO is extruded directly from the foot scan itself, producing an anatomically accurate device. This is known clinically as a "custom" FO but for the remainder of this paper is referred to as an anatomical-FO. In the second approach, the CAD package uses a standard template model which is morphed to suit the individual based on a set of design parameters, for example heel width, which are defined by identifying landmarks on the foot scan. The resulting FO is generally

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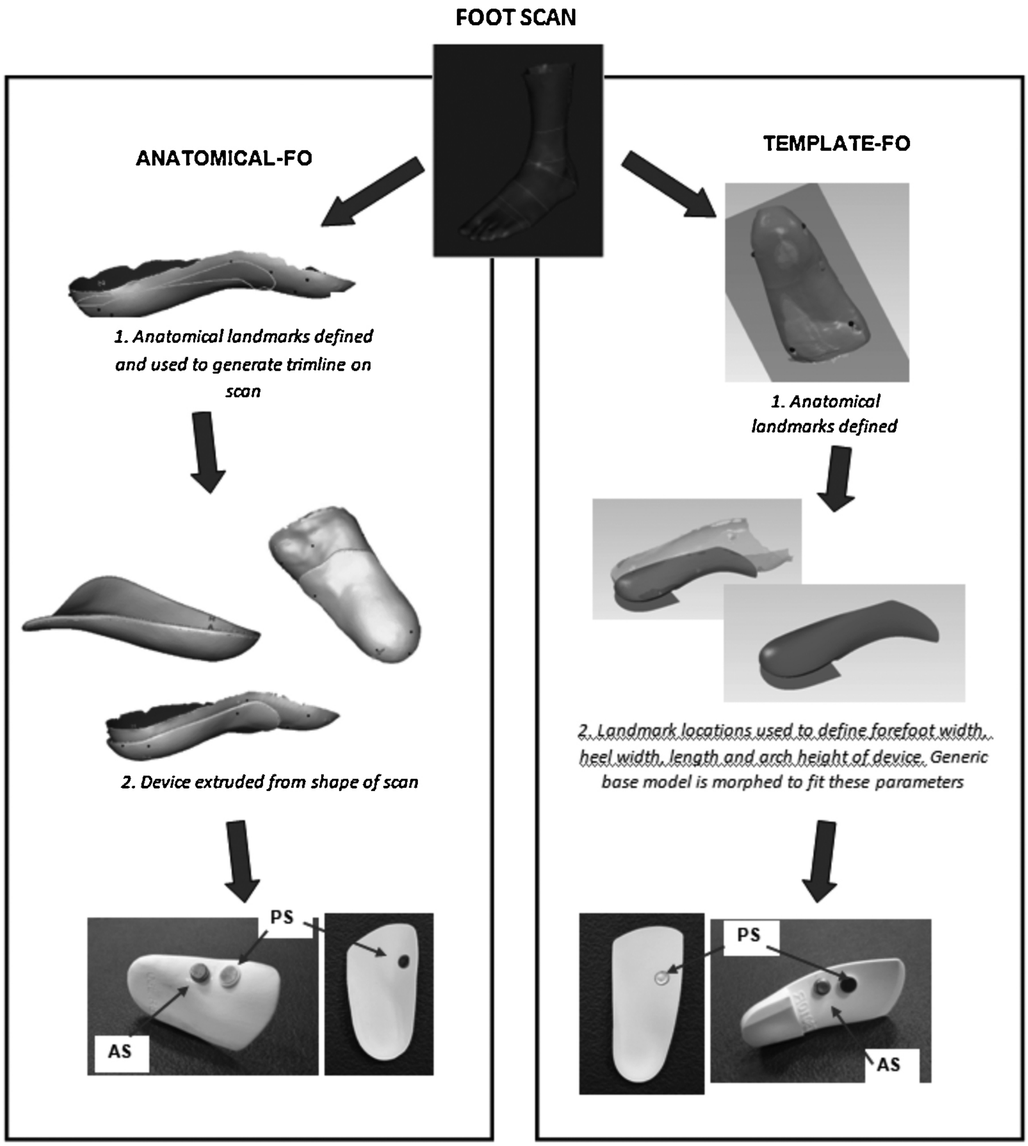

Fig. 1. Design process for S-FOs and L-FOs with embedded temperature sensors. PS: plantar sensor; AS: ambient shoe sensor.

described as a template device, and is henceforth referred to as a template-FO.

FOs have previously been shown to have suboptimal compliance rates [10]. Bus et al. [7] have previously demonstrated that temperature sensors attached to prescribed footwear can be used to monitor when the shoe is donned and doffed, giving a potential measure of compliance. Embedding temperature sensors directly in an FO may also provide further information regarding temperature changes at the plantar surface and detection of periods of ambulatory activity. Compliance with the device during periods of ambulatory activity, when loads on the foot and therefore potential for injury to occur are increased, may also be detected via this method.

The aim of this study was to test the feasibility of FOs with embedded temperature sensors for monitoring foot temperatures and to determine if the recorded temperature measurements could be used to detect periods of ambulatory activity. In addition, it was hypothesized that anatomical-FOs and template-FOs may produce differing results due to the proximity of the sensor position to the skin. Therefore these devices were compared to determine if the type of device used affected the ability to identify periods of activity.

2. Materials and methods

2.1. Participants

Ten healthy participants (5♀), mean weight 68.9 kg (range 56.6–91.6), height 1.72 m (range 1.57–1.9), age 32 years (range 22–46) volunteered to take part in this study. Participants were excluded if they had a history of musculoskeletal foot conditions, diabetes, vascular disease, peripheral neuropathy, abnormal or assisted gait pattern or other organic disease likely to affect foot and lower limb structure and function. Ethical approval for this study was provided by the institutional review board (reference number A11/012) and informed written consent was obtained prior to enrolment.

2.2. Embedded sensing foot orthosis design

Participants had their feet assessed by a Health Professions Council UK registered podiatrist who performed sensory and biomechanical tests to ensure suitability for the study. Weight bearing surface scans of both feet were obtained using a 3D laser