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An in-shoe temperature measurement system for studying diabetic foot ulceration etiology: preliminary results with healthy participants

Prabhav Nadipi Reddy[a,]*, Glen Cooper[b], Andrew Weightman[b], Emma Hodson-Tole[a], Neil Reeves[a]

[a]*Manchester Metropolitan University, Manchester, United Kingdom*
[b]*University of Manchester, Manchester, United Kingdom*

* Corresponding author. Tel.: +44-746-749-2128. *E-mail address:* p.nadipi-reddy@mmu.ac.uk

Abstract

Diabetes is a major public health challenge on a global scale but our scientific understanding of diabetic foot ulceration is limited. A recent systematic review concluded that an increase in skin temperature is predictive of foot ulceration. In-shoe temperature measurement could be a useful tool for studying the etiology of diabetic foot ulceration, we present such a device and preliminary results of its use with 14 healthy participants. Our results show that temperature rise with walking mainly depends on the speed, $F(2,190)=3.75$, $p=0.025$, the effect of foot location is mild $F(3,1279)=1.69$, $p=0.169$, and there is no difference between the two feet $F(1,1279)=0.937$, $p=0.749$. We conclude that such systems are feasible but there are measurement issues to be addressed before they can be utilized further.

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Keywords: Diabetic Foot Ulceration; Temperature; Measurement; In-shoe

1. Introduction

Diabetic foot ulceration is a major complication which reduces the quality of life of patients and in many cases leads to amputations. Diabetic foot ulcer related treatments cost the NHS around £650 million every year [1]. The key to preventing complications due to ulceration is early detection and clinical intervention. An early detection system for diabetic foot ulceration would prevent these complications improving the health of people and reducing treatment costs.

It has been shown that a difference in temperature of 2^0C or more in the same location of the contra-lateral feet indicates a risk of ulceration in the feet with the higher temperature [2]. This leads us to make the hypothesis that temperature may be a marker for early detection or even prediction of ulceration. To test this hypothesis we need to build a device that would measure the temperature of the foot continuously, even during dynamic activities like walking, running etc.

In this paper, we present a device to measure temperature during dynamic activities. We have presented the pilot data we have collected in a conference [3]. In this paper, we focus on the measurement system and the problems associated with it.

2. System Design

To record temperatures of the feet during dynamic activities we have built an insole that can be put into a shoe (Fig. 1).

The insole is made of hard foam and has a thickness of 5 mm. Temperature sensors are embedded at four foot locations in the insole - the hallux, between the first and second metatarsal head, the lateral side of the foot and the heel. Insoles with temperature sensors were made for different foot sizes. The location of the sensors were based on average data. We used TMP35 (Analog Devices) for sensing the temperature. Wires from the sensors in the insole go under the insole and exit out of the shoe from the lateral side of the shoe opening.

The data from the temperature sensors is digitized and stored using the NI myRIO, a reconfigurable input-output device from National Instruments. The data is stored in a USB drive connected to the myRIO. A pair of battery packs power the myRIO for up to 10 hours of continuous recording.

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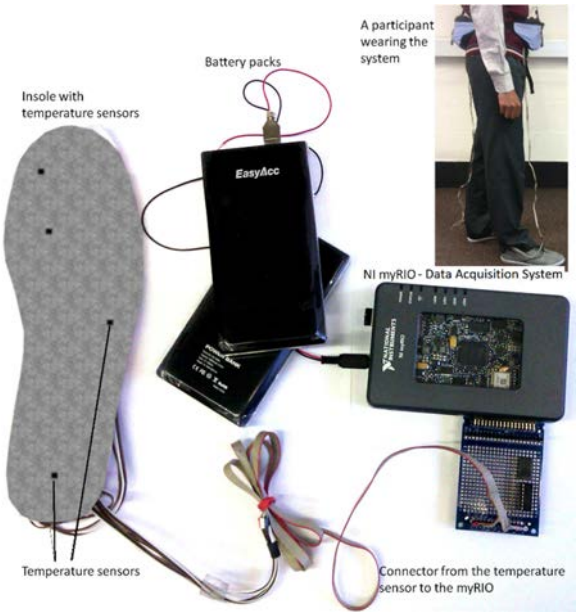

Fig. 1 Components of the foot temperature measurement device. The insole with the temperature sensors is connected to the myRIO which records the temperature and stores it on the USB drive. The battery packs (5V) power the myRIO. The inset shows a participant wearing the entire system.

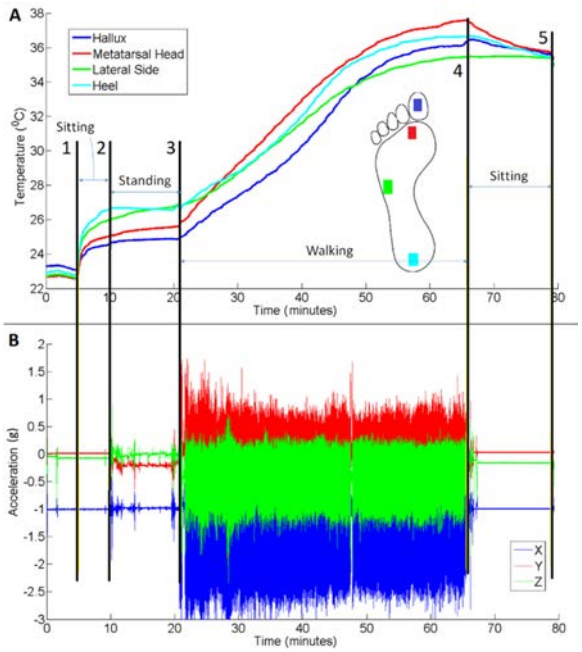

Fig. 2 A typical trace of temperature and acceleration measured in one experiment. Notice how the data is divided into different regions using the black lines. Line 1 is the place where the foot is placed on the temperature sensor - the participant is sitting in the time between line 1 and line 2. Line 2 is where the participant stands. Line 3 and 4 denote the start and end of walking, respectively while Line 5 denotes the place where the foot is lifted off the sensors after the experiment. The illustration of the foot in the figure shows the location on the foot at which the temperatures were taken.

3. Methods

3.1. Experimental Protocol

To test our temperature recording device, we recorded foot temperatures of healthy participants as they walked on the treadmill at three different speeds. We recruited 14 people (13 male and 1 female) between the ages of 21 and 40. The participants did not have any foot problems including deformities. We tested the participants using the 10 gm filament test to make sure none of them had loss of sensation in their feet.

The insoles were placed in standard 'Darco' shoes. The participants wore these shoes and were asked to walk on the treadmill at three different speeds - 0.8 m/s, 1.2 m/s and 1.6 m/s. The three speeds corresponds to slow, medium and fast walking.

The temperature and acceleration (from an accelerometer on board the myRIO) data was recorded at 12-bit resolution with a sampling rate of 100 Hz.

During an experiment, the participants started by sitting with their legs stretched out for 10 minutes. This was so that the temperatures of the feet would return to resting state temperatures. They put on the shoes with the insoles and sat for 5 minutes and then stood for 10 minutes. After this waiting period, the participants walked on the treadmill for 45 minutes. The walking period was followed by a period where the participants sat with the shoes on for 15 minutes.

The order in which participants walked at different speeds were randomized. Ideally all the participants would have walked on the treadmill 3 times, but for logistical reasons this was not possible (participants did not come all the three times for different reasons). 5 participants walked in all the 3 speeds. Temperatures were recorded in 27 separate trials.

3.2. Marking Activity Periods on the Data

A plot of the temperatures of the foot and the acceleration data for one foot for the duration of the experiment is shown in Fig. 2A and B, respectively. The acceleration data can be used to mark the temperature data into parts with different activities. The initial rise of the temperature data is the time when the foot comes into contact with the foot. The change in the accelerometer data shows the place where the person has stood up. The regular pattern of change in the accelerometer data is the time when the participant is walking.

4. Experimental Results

4.1. Foot Temperatures

Fig. 2A is a typical trace of the temperature as a function of time as the person walks on the treadmill. We can see that the temperature rises very quickly as the person starts to walk and plateaus. The mean temperature rise as the participants walked