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

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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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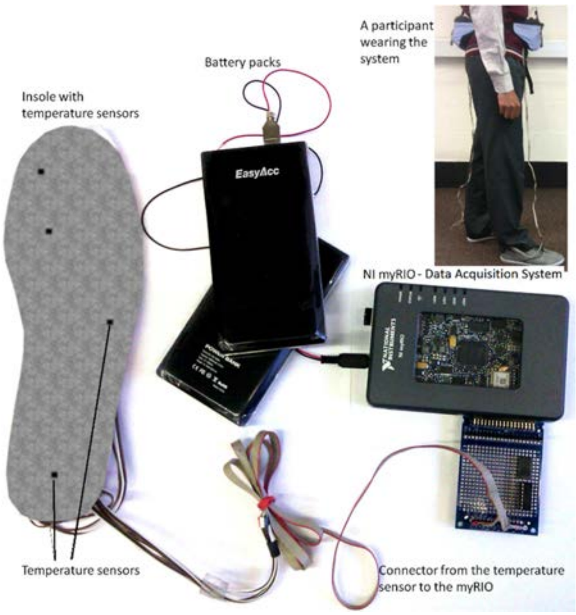

Fig. 1 Components of the foot temperature measurement device. The insole with the temperature sensors is connected to the myRIO which records the temperature and stores it on the USB drive. The battery packs (5V) power the myRIO. The inset shows a participant wearing the entire system.

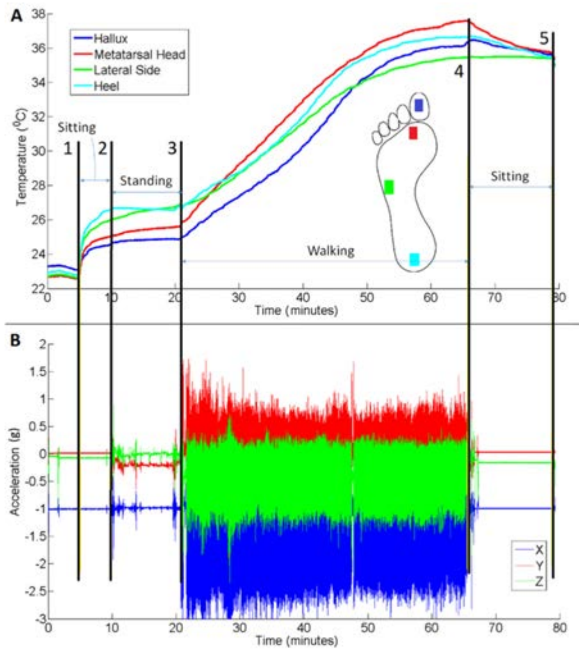

Fig. 2 A typical trace of temperature and acceleration measured in one experiment. Notice how the data is divided into different regions using the black lines. Line 1 is the place where the foot is placed on the temperature sensor - the participant is sitting in the time between line 1 and line 2. Line 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 is given in Table 1. Fig. 3 shows the mean (over all participants) temperature rise profiles of the right foot with walking. The temperature rise is shown for the four different locations on the foot while the participants walked at three different speeds.

We performed a factorial 3x4x2 ANOVA with speed, location of the foot and the two feet - right and left as variables. The temperature rise with walking mainly depends on speed of walking, $F(2,190)=3.75$, $p=0.025$. The effect of the foot location is very mild, $F(3,1279)=1.69, p=0.169$ and there is no difference between the two feet, $F(1,1279)=0.937, p=0.749$ (as we would expect for healthy test subjects). The interaction between location and speed was not significant, $F(6,1279)=0.35, p=0.912$.

The temperature of the foot was minimum for the medium speed and maximum for the highest speed (Min-Med: p=0.04,CI–[0.04,1.38]; Min-Max: p=0.02,CI–[-2.16,0.15]; Max-Med: p=0.002,CI–[0.8,3.17]). The temperature of the metatarsal head was significantly higher than the other locations (Met head-Hallux: p=0.0002,CI–[0.61, 1.0]; Met Head-Lateral Side: p<0.0001,CI–[0.66, 1.4]; Met Head-Heel: p=0.0016,CI–[0.38, 1.52]).

4.2. Measurement Issues

As we looked at the data, we found that there were some recordings that had problems with the measurement. We think that the two problems with measurement were due to the foot lifting off the sensors and the sensors being misplaced. We describe the kind of data that we recorded when such errors happened in this section (see Fig. 4).

4.2.1. Foot lifting off the sensors

For a good temperature recording, we want the foot to be in contact with the sensors all the time. Once the person stops walking and sits down, we expect that the temperature of the foot will slowly decrease. However, in some cases we found that the temperature of the foot increased as soon as the person sat down (see Fig. 4b). This was most commonly observed with the heel and the hallux sensors and may be explained by the sensors now making contact with the plantar tissue. Another possible explanation for this might be the thermal lag due to the heat flux travelling through the tissue.

Table 1 Temperature rise (in ^{0}C) of feet with walking (mean ± standard deviation; N=18)

Speed	Hallux	Met. Head	Lat. Side	Heel
0.8 m/s	2.01 ± 1.51	3.55 ± 1.36	3.16 ± 0.99	3.01 ± 0.89
1.2 m/s	2.80 ± 2.02	3.74 ± 1.43	3.14 ± 0.97	2.69 ± 1.29
1.6 m/s	3.12 ± 2.16	4.55 ± 1.39	3.70 ± 1.19	4.23 ± 2.50 (N=16)

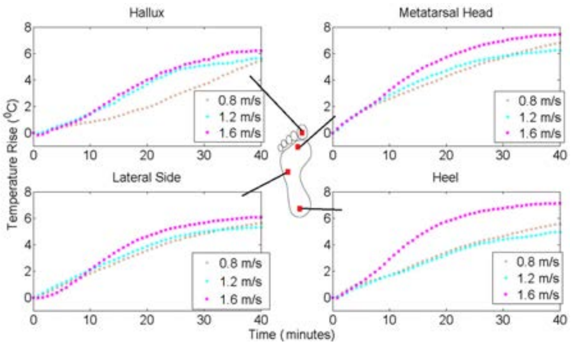

Fig. 3 Mean temperature rise curves during 40 minutes of walking for all participants for different speeds (0.8 m/s, 1.2 m/s and 1.6 m/s) and different locations of the foot (hallux, metatarsal heads, lateral side of foot, heel) (Adapted from [3])

4.2.2. Misplaced sensors

During some recordings (see Fig. 4a), instead of getting a rising curve at the onset of walking, some sensors record temperature that does not increase at all during walking. This kind of error happens most with the sensor under the hallux and could be explained by sensor being misplaced and not contacting the plantar tissue (over even any part of the foot).

5. Discussion

5.1. Foot temperatures

In this paper, we have presented a measurement system that can be used to measure temperature of the foot during dynamic activities. We have collected temperature data of 14 healthy participants as they walked on the treadmill at different speeds (0.8 m/s, 1.2 m/s and 1.6 m/s). We have found that the temperature of the foot increases as participants walked on the treadmill. The rate of change of temperature reduces with the duration of the walking - approaching a stable temperature.

We have found no difference between the temperatures of the same locations in the two feet. The relationship of the temperature of the foot to the speed of walking is not apparent. We will need to account for confounding factors like differing pressure-time integrals, change of gait pattern etc. to elucidate the relationship of the speed of walking to the temperature of the foot. We are currently undertaking research to achieve this goal.

The temperature rise also changes with the location of the foot. We found that the temperature of the metatarsal head was higher than all the other locations. This, probably, is a function of the varying load at different locations of the foot. We are conducting studies that are investigating the relationship between the load and the temperature rise of the foot or a location of the foot.

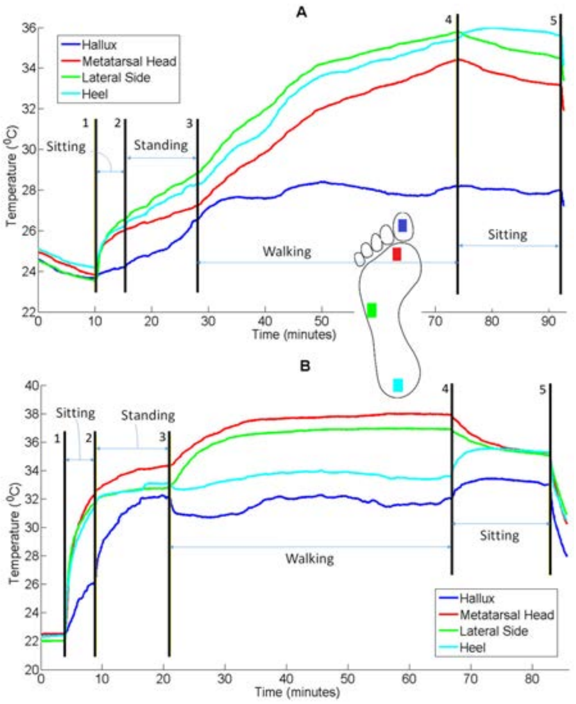

Fig. 4 Measurement system issues. **A**. Notice that the temperature of the hallux doesn't increase at all during walking. This is most likely due to misalignment of the hallux and the sensor in the insole. **B**. Notice how the temperature of the heel and hallux increase once the participant stops walking. This temperature rise is due to the heel and hallux sensors not being in contact with the foot during walking. The foot in the figure shows the location on the foot at which the temperature curves were measured.

5.2. Measurement issues

There were some problems with the measurement of the temperature using the setup we have described. In some cases, we found that the temperature of the sensors (at the hallux) did not increase while walking (Fig. 4a). We hypothesize that the reason for the error is that our sensor locations are not in the same anatomical locations for all individuals. It is possible, that in some cases the foot and sensor are displaced and so the sensor is not measuring the temperature of the foot as we want it to. This error would be most apparent for the hallux sensor as even a small displacement could result in mismatch between the foot and sensor. For other sensors, even if there is displacement some other area of the foot would be in contact with the sensor and we may not notice a huge error.

In other cases, we found that the temperatures recorded by the sensors increased after the participant sat down after walking (see the temperatures recorded by the heel and the hallux sensors in Fig. 4b). We would expect the temperatures to reduce at this time. This implies that in some cases, when the participants started walking, the foot was not in contact with one of the sensors. This could be because of the fitting of the shoes, unnatural gait due to the fact that people were not used to walking on the treadmill. While walking the sensor was measuring the temperature of the air between the foot and the sensor. When the participants sat down the foot touched the sensors and recorded the actual foot temperature, which is higher than the temperature recorded without contact.

This issue could also be due to the fact that the foot is in proper contact with the sensor (exerting significant pressure against the sensor) only for a part of the entire gait cycle. Some studies have shown that the temperatures recorded by the sensors is a function of the pressure with which the foot is touching the sensor [4]. This effect could be an additional confounding factor in the measurement.

We have modified the measurement setup by making insoles that are tailored individually for each participant, by taking measurements of the locations of interest. The problem of lift off is being addressed by using a way for the insoles to be attached to the foot (possibly using a sock).

6. Conclusion

We have presented a device to measure foot temperature during dynamic activity. We have shown results of foot temperatures measured using the device and discussed measurement issues that need to solved before such a system can be used to measure the temperature of the foot.

We believe a measurement system like this would prove valuable in measuring continuous temperatures of the foot in normal and diabetic people. It would help us to understand the mechanism of the ulceration and also provide a way for early detection or even prediction of diabetic foot ulcers.

References

[1] Footcare for people with diabetes, Factsheet, Available online at https://www.diabetes.org.uk/upload/News/Factsheet%20Footcare%20for %20people%20with%20diabetes.pdf, Accessed on 26 June 2015

[2] Houghton VJ, Bower VM, Chant DC. Is an increase in skin temperature predictive of neuropathic foot ulceration in people with diabetes? A systematic review and meta-analysis. J Foot Ankle Res 2013;6(1):31.

[2] Rou HS, Sim SY, Kim HB, Han JM, Park KS. Preliminary study for developed foot plantar surface temperature monitoring system by reducing pressure effect. IFMBE Proceedings 2014; 43:884-7.

[3] Reddy PN, Cooper G, Weightman A, Hodson-Tole E, Reeves N. Changes in temperature of the plantar tissue of the feet as a function of walking speed. Accepted for presentation at the International Society of Biomechanics Conference 2015, Glasgow