ABSTRACT

Purpose—Patients with diabetes are often prescribed foot orthoses to help prevent foot ulcer formation. Orthotics are used to redistribute normal and shear stress. Shear stresses are not easily measurable and considered to be responsible for skin breakdown. Local elevation of skin temperature has been implicated as an early sign of impending ulceration especially in regions of high shear stress. The purpose of this study was to measure the effects of commonly prescribed insole materials on local changes in plantar foot temperature during normal gait.

Methods—Six commonly used foot orthosis materials were tested using the Thermo Trace™ infrared thermometer to measure foot temperature. Ten healthy adult volunteers without any history of diabetes or abnormal sensation participated in the study. During each trial the subject walked on a treadmill with the test material in the dominant foot’s shoe, for six minutes at a speed of four miles per hour and rested for six minutes between trials. Four locations on the foot (hallux, first and fifth metatarsal heads, and heel) and the contralateral bicep temperatures were measured at 0, 1, 3, 5 minutes during the rest period. The order of material and skin location testing was randomized.

Results—Significant differences were found between baseline temperatures and foot temperatures for all materials. However, no differences were found between materials for any location on the foot.

Conclusion—Previous studies have attempted to characterize materials based on laboratory and clinical testing, while other studies have attempted to characterize the effect of pressure on skin temperature. However, no study has previously attempted to characterize foot orthosis materials based on foot temperatures. This study compared foot temperatures of healthy adults based on the material tested. Although this study was unable to distinguish between materials based on foot temperatures, it was able to show a rise in foot temperature with any material used. This study demonstrates a need to a larger study on a population with diabetes.

INTRODUCTION

Diabetes is the leading cause of lower-limb amputations in the United States, totaling 82,000 per year between 1997 and 1999. Although patients diagnosed with diabetes only account for 6.2% of the U.S. population, 19% of the personal healthcare expenditures in 2002 were for this population. Patients with diabetes are often prescribed foot orthoses to help prevent or treat plantar foot ulcers. The purpose of the orthotic is generally to reduce pressure and shear. Brand has suggested that the main problem causing ulceration is shear induced “tenderizing” of the plantar soft tissue with resultant elevated temperature that results in cellular injury. In a case series he has shown that repeated injury increases focal plantar temperatures and has correlated repeated shear stresses to tissue breakdown and ultimate ulceration.

Although several investigators have examined the effects of pressure, diabetes, leprosy, and diabetic neuropathy on skin temperature, none have evaluated the potential interaction of orthotic material and plantar soft tissue temperature. The purpose of the present study is to evaluate the thermal response of the sole of the foot to standard insert material with substantially different structural and material properties.

METHODS

Subjects

Thirteen healthy young adult volunteers were recruited from the University of Iowa for participation in this IRB approved study. All subjects denied any his-
tory of diabetes, lower extremity deformity, abnormal sensation in the lower limbs, traumatic injury to the lower extremities within the last 12 months, or previous use of lower limb orthoses. Subjects were able to walk unassisted. The subject group consisted of 7 men and 6 women with mean: age 21.9 years (range 19-27 years), height 164.2cm (range 83.5-184cm), weight 77.1 kg (range 57.6-117.2 kg). Each subject’s dominant foot, determined by which foot he or she would kick a ball, was tested. Subjects were issued the same style and brand of shoe and socks.

**Surface Temperature Measurement**

The ThermoTrace infrared thermometer (Delta TRAK Scientific, model 15007) was used to test skin temperature over the contralateral biceps and four locations on the plantar aspect of the foot: hallux, first (1st M et) and fifth (5th M et) metatarsal heads, and heel. One cotton swab was attached to each of the four corners of the thermometer to guarantee that the same orientation and distance from the skin surface was used for each subject. The tip of the swab was set 1” from the end of the device ensuring that an area with 0.1” diameter was measured. All subjects used the same heart rate monitor (Polar Electro Inc., New York, Model 1901201) for all tests, to monitor each subject’s exertion.

**Materials**

Seven materials and the shoe sock liner were tested. The tested materials were: Bocklite (BOC), Pe-Lite (PEL), Plastazote (PLA), Poron (POR), Nylon-covered Poron (NPOR), Ortholite EVA (EVA), and a tri-laminate of Ortholite/Poron/Ortholite (TRI). All materials were 1/4”, except the tri-laminate which was made out of 1/16” Ortholite, 1/16” Poron, and 1/8” Ortholite.

**Testing Protocol**

Each subject was tested three times, approximately one week apart. No more than three materials were tested during any session. The order of testing was randomized for each subject. During the first test day each test site was marked with a semi-permanent pencil. These marks were then transferred to a piece of paper and the foot traced, to be used for marking the foot during the next two test days. The protocol for every test day was the same. Once the foot and biceps were marked with the semi-permanent pencil, the subject sat without shoe or sock for 10 minutes to allow the foot to acclimate to room temperature. Baseline temperatures were taken prior to the start of any trials each day to account for individual daily variability.

The subjects then completed a warm-up walk on a treadmill for 6 minutes at 4mph. After that, subjects sat for 6 minutes without shoe or sock; no measurements were taken at that point. Each trial was then performed by the subject walking with a test material in the shoe for 6 minutes at 4mph, followed by a 6-minute measurement and rest period without shoe or sock. A new sock was issued for each trial to avoid potentially confounding effects of foot perspiration. The following measurements were recorded for each trial: start and end treadmill heart rate, and heart rate and temperature measurements at the five sites during the rest period. The temperature and heart rate measurements were taken in a random order and within the first 25 seconds after shoe and sock were removed (0 min) to avoid a cooling effect and at 1, 3, and 5 minutes afterwards. The 0 minute data was collected to determine surface plantar foot temperature after use of a material, while the 1, 3, and 5 minute data were collected to examine the cooling effect of the foot. All measurements are expressed in degrees Fahrenheit.

Repeatability and reliability measurements were gathered on three subjects, not in the study. The same five locations’ temperatures were measured three times each; subject, site, and order were randomized; all testing occurred on the same day. All subjects sat for 10 minutes without shoe or sock prior to testing and only baseline measurements were gathered.

**Data Analysis**

Each subject was considered his or her own control, eliminating covariates of height, weight, age, and gender. Each material was compared for each test location. A paired t-test was used to compare each subject’s baseline temperature to the temperature for each test material and location. Bonferroni’s method was used to adjust the p-values to account for the number of tests performed; p-value <0.05 was considered statistically significant. Temperatures for all test materials were compared for each location and for all subjects using the linear mixed model for repeated measures. To ad-
just for differences in the baseline temperature, room temperature, and heart rate, these variables were included as covariates in the model. Tukey’s test was used as the post-hoc test for pair-wise comparison of the means between materials and the overall significance level was controlled at 0.05.

RESULTS

The mean and standard deviations for the repeatability testing is recorded in Table 1. The hallux had the greatest variability for all subjects, while the biceps site had the least.

With walking, the mean temperature on the sole of the foot was increased at 0 minutes and 5 minutes. Immediately after walking, the temperature increase averaged 9.1˚ (range, 7.3˚-11.4˚) under the hallux, 7.7˚ (range, 5.6˚-9.2˚) under the first metatarsal head, 6.8˚ (range, 4.9˚-9.0˚) under the fifth metatarsal and 8.6˚ (range, 6.6˚-11.1˚) under the heel (Table 2). Five minutes after walking, the temperature increase averaged 8.8˚ (range, 6.1˚-11.7˚) under the hallux, 7.3˚ (range, 5.1˚-9.0˚) under the first metatarsal head, 7.5˚ (range, 4.7˚-8.7˚) under the fifth metatarsal and 6.8˚ (range, 4.6˚-7.9˚) under the heel (Table 2). No significant differences were found between any materials for any location. Baseline had a positive effect on temperature for all locations and room temperature had a positive affect on the biceps site reading, while heart rate had no affect on temperature at any location.

DISCUSSION

The repeatability testing indicated that the device and method used to test skin temperatures was adequate for determining differences in temperatures. The changes at the hallux were likely due to localization difficulties on this relatively small target. Similarly, the low standard deviations at the heel and biceps sites were likely related to the relative ease of reproducing a site specific reading in these anatomically less discrete areas.

Lack of differentiation between materials can be due to several effects. First, there may be no true difference in the response of plantar skin to the varying material properties of these insert materials, and selection of materials should be made purely each individual’s need to redistribute foot loads. The potential other causes for lack of differentiation between the effects of orthotic materials on plantar skin temperature relate to the testing protocol. The type of shoewear, duration and type of testing were selected to facilitate the performance of the tests. We realized the limitations and difficulties with insuring that subjects returned multiple times for the same tests, and that to some extent fatigue and loss of interest may undermine our ability to collect sufficient data to perform the comparison. The choice of walking speed and the duration of all aspects of the testing were based on these considerations. The choice of shoe and sock were based on the typical footwear of a diabetic patient with neuropathic-related foot disease.

The use of young healthy adults may be responsible for the lack of differentiation between material effects on plantar thermal response. These subjects all were presumed to have intact neurovascular responses and may have been able to modify their gait or plantar loading to prevent any regions from excessive stress.
Whether these findings are generalizable to neuropathic patients is unknown. The effects of peripheral neuropathy in diabetes can be protean—inducing a change or elimination of a sweating response, eliminating protective sensation, and causing pressure problems from intrinsic muscle wasting, toe clawing and arch elevation. Because of these clear differences, further study in the diabetic neuropathic population is needed to delineate if these orthotic materials differentially increase skin temperature.

**REFERENCES**


**TABLE 3**

Mean Difference from Baseline for Each Material, Each Location, All Subjects at 5 min

<table>
<thead>
<tr>
<th>Material</th>
<th>Bicep</th>
<th>Hallux</th>
<th>1st Met</th>
<th>5th Met</th>
<th>Heel</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRI</td>
<td>-0.85 (1.27)</td>
<td>8.59 (8.00)</td>
<td>6.74 (5.65)</td>
<td>7.22 (6.16)</td>
<td>6.00 (5.94)</td>
</tr>
<tr>
<td>BOC</td>
<td>-1.18 (1.48)</td>
<td>6.09 (7.33)</td>
<td>5.08 (4.45)</td>
<td>4.65 (5.09)</td>
<td>4.55 (5.17)</td>
</tr>
<tr>
<td>NPOR</td>
<td>-1.36 (1.46)</td>
<td>7.63 (6.26)</td>
<td>7.50 (4.74)</td>
<td>7.50 (4.46)</td>
<td>7.86 (4.96)</td>
</tr>
<tr>
<td>POR</td>
<td>0.41 (5.44)</td>
<td>11.02 (6.63)</td>
<td>8.50 (4.05)</td>
<td>8.72 (4.40)</td>
<td>7.82 (6.16)</td>
</tr>
<tr>
<td>PEL</td>
<td>-1.38 (1.14)</td>
<td>7.75 (9.64)</td>
<td>5.99 (7.20)</td>
<td>6.48 (8.14)</td>
<td>5.88 (6.90)</td>
</tr>
<tr>
<td>PLA</td>
<td>-1.08 (1.17)</td>
<td>7.53 (8.47)</td>
<td>7.40 (6.20)</td>
<td>8.62 (7.67)</td>
<td>7.52 (5.92)</td>
</tr>
<tr>
<td>EVA</td>
<td>0.22 (5.14)</td>
<td>10.04 (7.13)</td>
<td>9.02 (5.19)</td>
<td>8.55 (5.48)</td>
<td>7.52 (5.72)</td>
</tr>
<tr>
<td>SHOE</td>
<td>-0.42 (1.06)</td>
<td>11.74 (7.64)</td>
<td>7.83 (6.56)</td>
<td>7.86 (7.42)</td>
<td>6.85 (6.47)</td>
</tr>
</tbody>
</table>

The mean differences and standard deviations of plantar surface temperature 5 minutes after walking for each material and location. Positive values indicate increased temperatures in degrees Fahrenheit. Materials tested included Bocklite (BOC), Peltite (PEL), Plastazote (PLA), Poron (POR), Nylon-covered Poron (NPROR), Ortholite EVA (EVA), and a tri-laminate of Ortholite/Poron/Ortholite (TRI).