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An Optical-Fiber-Based Smart Textile (Smart Socks) to Manage Biomechanical Risk Factors Associated With Diabetic Foot Amputation

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Abstract

Objective: This study aimed to validate a smart-textile based on fiber-optics for simultaneous measurement of plantar temperature, pressure, and joint angles in patients with diabetic peripheral neuropathy (DPN).

Methods: After in-vitro validation in the laboratory, 33 eligible subjects with DPN were recruited (age: 58 ± 8 years, BMI: 31.5 ± 8 kg/m^2) for assessing plantar pressure and temperature during habitual gait-speed in a clinical-setting. All participants were asked to walk at their habitual speed while wearing a pair of sensorized socks made from highly flexible fiber optics (SmartSox). An algorithm was designed to estimate temperature, pressure, and toe range of motion from optical wavelength generated from SmartSox. To validate the device, results from thermal stress response (TSR) using thermography and peak pressure measured by computerized pressure insoles (F-Scan) were used as gold standards.

Results: In laboratory and under controlled conditions, the agreements for parameters of interest were excellent ($r > .98$, $P = .000$), and no noticeable cross-talks between measurements of temperature, angle, and pressure were observed. During clinical data acquisition, a significant correlation was found for pressure profile under different anatomical regions of interest between SmartSox and F-Scan ($r = .67$, $P < .050$) as well as between thermography and SmartSox ($r = .55$, $P < .050$).

Conclusion: This study demonstrates the validity of an innovative smart textile for assessing simultaneously the key parameters associated with risk of foot ulcers in patients with DPN. It may empower clinicians to objectively stratify foot risk and provide timely care. Another study is warranted to validate its clinical application in preventing limb threating problems in patients with DPN.

Keywords

diabetic foot ulcer, SmartSox, wearable, fiber optics, plantar pressure, plantar temperature

Diabetic foot ulceration (DFU) is a common comorbidity affecting 25% of patients with diabetes and loss of protective sensation.[1-4] Contributing factors that increase risk of developing DFU include nerve damage disorders associated with diabetes, an altered gait, and increased localized plantar pressure.[5] Many health care quality improvement experts recommend improving the process of high risk foot care through use of stratified foot risk exams.[6] These exams have been shown to be useful in identifying diabetic foot at risk and assisting in prevention of DFU up to 70%.[4] However, currently available technologies remain insufficient to be used on a routine basis because of impracticality, time-consuming, or difficulty to be used by nonexpert caregivers or by patients.

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The barriers to high risk foot care are even more critical in Qatar, where the average physician time spent in direct patient consultation is half of that in the United States,[7] and presents a large health care delivery challenge with competing comorbidities for consultant time. Because of the threefold higher prevalence of diabetes in Qatar and, relative to US benchmarks, 40% hospital capacity, and 50% physician consultant time spent with Qatari patients, there is a desperate need for better identification of risk factors of DFU[8] and subsequent nonhealing[9] to better inform Qatari podiatry referral guidelines. Many quality improvement experts recommend improving the process of high risk foot care through use of stratified foot risk exams. Hence, there is an unmet need to design a simple and practical technology that allows for measuring key biomechanical markers of DFU in clinic. Such technology may enable foot care specialists to implement timely strategies to minimize risk as well as empower patients to take of their feet at home.

In addition to clinically based risk classification systems, sophisticated gait lab measures (eg, plantar foot pressure and thermometry) have also been identified as high-leverage tools for DFU prevention.[10-14] At first glance, the practicality of routine use of these measures under the current constraints of the Qatari health care delivery system appears ambitious at best.

Current objective modalities to identify diabetic foot risk often suffer from poor specificity, thus limiting its application in routine care applications. For example, high plantar pressures increase the risk of developing foot ulcers and managing peak pressure is an important strategy in reducing ulceration risk. However, there is no optimal cut-point for plantar pressure to predict DFUs with minimum false detection.[5,15] Thus, systems that operate uniquely based on measuring peak plantar pressure, independent of thermal stress response, which is a marker of inflammation in response to stress, may not be sufficient to predict and manage DFUs. False alarms in particular could drastically reduce adherence on usage of such technologies during activities of daily living.

Recent progress in developing fiber-optic sensors has opened new avenues for designing innovative wearable technology with stealth measurement features. An optical fiber is a glass or plastic thread that carries light along its length. One of the key advantages of using fiber optics is that they could be easily integrated unobtrusively in any textile. Fiber optic sensors can also measure pressure and skin temperature, which are of key importance for assessing and preventing the risk of foot ulcer in patients with diabetes patients.

Optical fibers are widely used in information communication system, as they permit transmission over longer distances and at higher bandwidths (data rates) than any other forms of communication lines. Optical fibers are also preferred over metal wires because signals can be transmitted with less loss, and optical fibers are immune to electromagnetic interference, can handle extremely large pressures (approaching gigapascal [GPa] pressure), can survive at temperatures exceeding 700°C, and can carry an extremely large amount of data. Recently, because of these unique properties, optical fibers have found many applications in traditionally challenging and complex settings. For example, fiber-optic sensor arrays are used in bridges[16] and buildings[17] to measure wind forces, vibrations, and so on. Fibers can be used for illumination, and bundles of fiber can be used to extract visual image from tight spaces, where the traditional camera-based system cannot be penetrated.[18]

Fibers have many uses in remote and wearable sensing, where specially designed fibers can become sensors or lasers. An optical fiber can be used to connect another optical sensor to a measurement system, or even become a sensor itself. Fiber sensors offer extremely small size and zero electrical power consumption. Furthermore, many sensors can be multiplexed along the length of a fiber either by using different wavelengths of light for each sensor, or by sensing the time delay as light passes along the fiber through each sensor using devices such as an optical time-domain reflectometer. Optical fibers can also be used as sensors to measure strain, temperature, pressure, and other parameters by modifying the fiber so that the parameter to be measured modulates the intensity, phase, polarization, wavelength, or transit time of the light in the fiber. Sensors that vary the intensity of light are the simplest, since only a simple source and detector are required. In addition to intensity-based sensors, pressure sensors based on monitoring the phase of the light propagating through the fiber have been demonstrated.[19]

This study proposed an innovative technology named SmartSox, which is based on highly flexible fiber optics embedded in a comfortable standard sock. Using an optical amplifier and signal processing, SmartSox allowed simultaneous measurement of temperature, plantar pressure, and toes range of motion, which makes it suitable for objectively assessing lower extremity regions at risk. This study provides the method of measurements and the validity of SmartSox against conventional measurements.

Method

SmartSox Design

For the purpose of this study, we used a SmartSox prototype designed and made by Novinoor LLC (Wilmette, IL, USA). The prototype uses embedded highly flexible and thin (<0.3 mm) fiber optic sensors based on fiber Bragg gratings (FBGs).[20] FBGs are lightweight durable sensors made from silica core wrapped in a plastic jacket. They are engineered to reflect back specific wavelengths, and their responses can be tuned to the strain caused by external effects such as angular deformation. The sensor works by sending broadband infrared light through multiple FBG sensors. Each FBG sensor reflects back a certain wavelength and analyzes the reflected-back light spectrum using an optical filter and infrared detector. The data are processed to yield angular

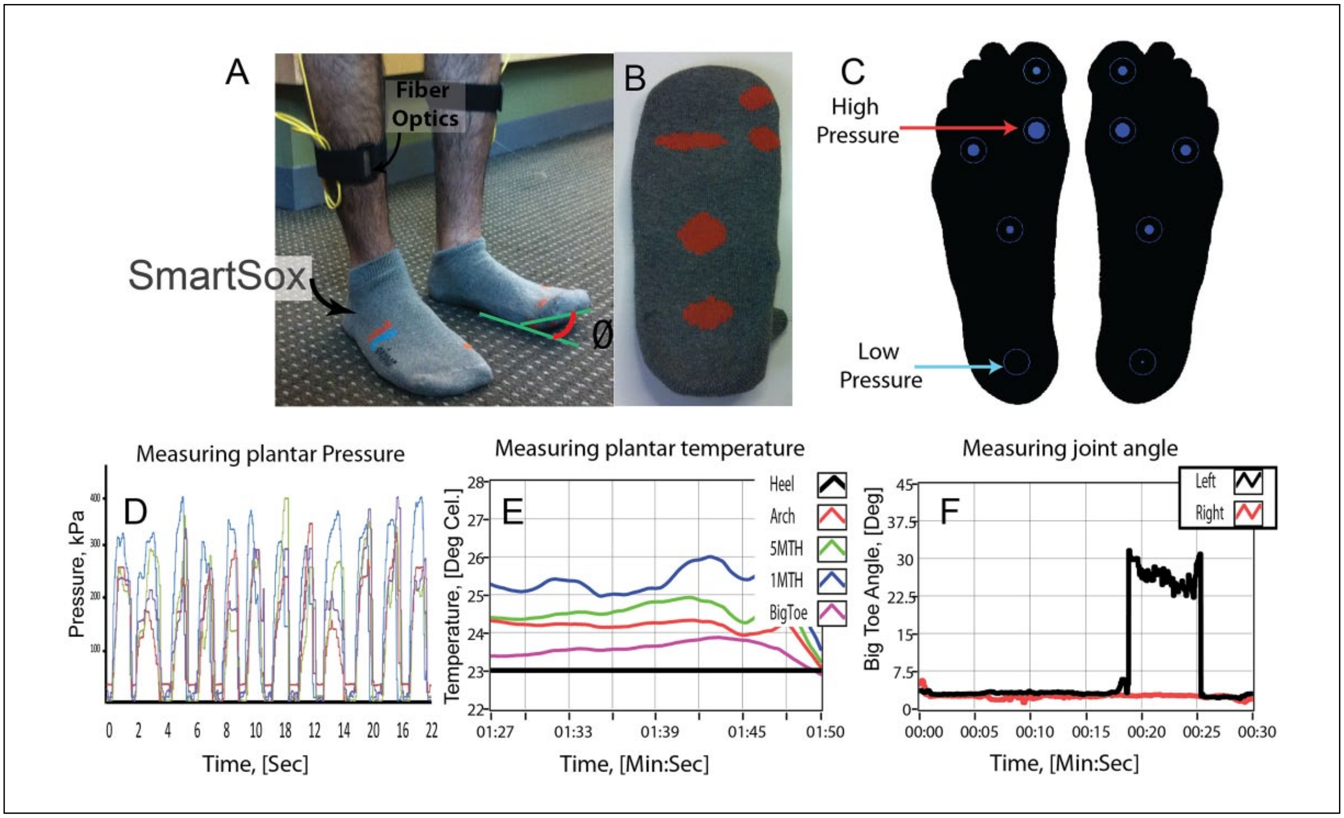

Figure 1. (A) SmartSox prototype. (B) Multiple sensors were juxtaposed on the length of an optical fiber integrated in a comfortable sock. (C) A visual interface was designed to visualize in real-time magnitude of pressure (circles with size proportional with pressure magnitude) and temperature (pseudocolor coding of temperature). (D) A typical example of plantar pressure measurements under region of interest by SmartSox. (E) A typical example of changes in plantar temperature under regions of interest as a function of time. (F) A typical example of changes in big toe range of motion (flexion-extension) representation of big toe motion illustrated in (A).

motion, temperature, and/or pressure changes at each FBG sensor set and then sent to a micro-processor for monitoring and storage.

For the purpose of this study, the fiber with 5 embedded FBG sensors were woven into a comfortable sock to measure plantar temperature and pressure under respectively, big toe, first metatarsal head (MTH), fifth MTH, midfoot, and hind foot as illustrated in Figure 1. In addition, another FBG sensor was placed on top of the big toe, as illustrated by a red-color circle in Figure 1A, to measure big toe range of motion in reference to the sensors located under big toe and first MTH (red-color circles in Figure 1B). The setup and dedicated algorithm allow measuring in real-time (sample frequency of 500 Hz) temperature and pressure under regions of interest as well as big toe range of motion. An interface using LABVIEW (National Instruments, Austin, Texas, USA) was designed for facilitating data acquisition from SmartSox, recording, visualization, and data storage.

Study 1: In Vitro Laboratory Testing

Before testing the SmartSox in human subjects, its accuracy, reliability, cross-talk, and durability were assessed in a laboratory condition against reliable and accurate reference systems including a goniometer (reference system for angle measurement) and a controllable heater wires (reference system for temperature measurement) .

Figure 2A illustrates the setup used for assessing plantar temperature. Using controllable heater wires (reference system), various temperatures were induced to regions of interest in SmartSox. Then output of SmartSox in response to changes in temperature was extracted. To examine cross-talk between SmartSox's outputs for temperature and pressure, the measurement was repeated under different scenarios including no load on SmartSox's sensors and two different loading conditions. To apply load, first, the foot model mold, which is worn by SmartSox as illustrated in Figure 2A, was vertically placed on a table; thus the weight of the model was applied to the sensor (small loading condition). Next, the foot model mold was pressed against the table surface with steady force to generate a high pressure load on the sensitive areas of SmartSox, while changing temperature via the controllable heater (high loading condition). This protocol not only allowed measuring the accuracy of temperature measurement against an accurate reference system (highly accurate controllable heater) but

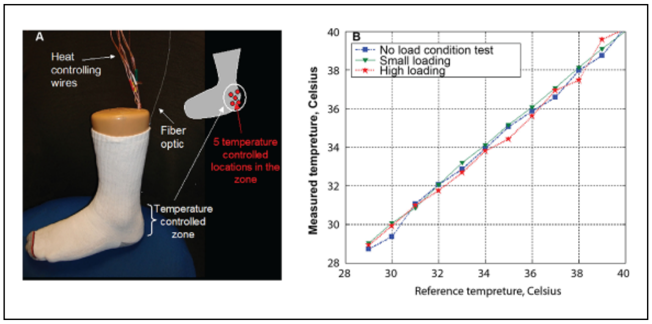

Figure 2. Laboratory testing of SmartSox to assess its accuracy to measure and track changes in temperature. (A) Laboratory setup to assess temperature accuracy. Using heat-controlling wires (reference system), various temperatures induced to regions of interest in SmartSox and output of SmartSox in response to changes in temperature were measured. (B) An excellent agreement was observed with reference (r = .98, P = .000).

also allowed assessing the cross-talk effect of pressure on measurement of temperature.

To examine the accuracy of SmartSox to measure joint angle, the fiber sensor was bent in 2 perpendicular directions representing anterior-posterior and medial-lateral angles. The measured angles were compared to an accurate goniometer (reference system). The range of motion varied between –10 and +10 degrees. This test also allowed assessing strength of fiber against breaking down during bending.

To measure potential cross-talk between temperature measurement and angle measurement, the temperature was varied from 0 to 60°C using the heater described above.

Study 2: In Vivo Human Subject Testing

To assess the accuracy of SmartSox to measure parameters of interest in a clinical setting, we designed a cross sectional study that compared measurements of SmartSox with two reference systems.

A total of 33 patients (age: 58 ± 8 years; BMI: 31.5 ± 8 kg/m^2; HbA1C: 8.55 ± 1.45%; duration of diabetes: 20 ± 11 years) with type 2 diabetes and confirmed diabetic peripheral neuropathy (DPN) and moderate-to-high risk of DFU were enrolled and consented by Hamad Medical Co, Doha, Qatar. Inclusion criteria were men or women (non-pregnant) 18 years old or older, diagnosed with diabetes and peripheral neuropathy, with foot deformity and/or history of DFU (moderate to high risk based on the American Diabetes Association's Comprehensive Diabetic Foot Exam[21] and Peters et al[22]) and able to independently walk for a distance of minimum 30 m. Peripheral neuropathy (PN) was confirmed as insensitivity of a 10 gram monofilament at 1-3 sites in any following locations in either foot: hallux, first, third, and fifth MTHs and lack of perception of vibratory sensation (VPT, vibratory perception threshold) of 25 volts or higher. Subjects with a major amputation (above ankle) or plantar active ulcers were excluded. Other exclusion criteria included cognitive deficits (Mini–Mental State Examination [MMSE] score of 24 or lower), alcohol or substance abuse within 6 months, refusing or lacking medical decisional capacity to provide informed consent, and major psychiatric disorder. Informed consent was obtained by the study coordinators or key investigators prior to any screening measures.

Eligible subjects underwent walking trials wearing SmartSox. To examine the accuracy of SmartSox to measure plantar temperature, we used the protocol described in our previous studies in which thermal stress response was used to identify Charcot foot[23] and quantify shear force.[24] Briefly, the change in plantar temperature values measured by SmartSox before and after walking was compared with changes in thermography images taken before and after walking using an infrared thermal camera (Fluke Ti25, Fluke Corporation, WA, USA). Subjects were instructed to walk while wearing SmartSox and a standard sandal (Figure 3) for a predetermined standardized route of 50-60 steps (approximately 30 m). A plantar thermal image was taken as baseline temperature, before starting to walk and after foot acclimatization for a duration of at least 5 minutes with shoes and socks off. Then subjects were asked to quickly put on the SmartSox and sandal with assistance of the study coordinator. Another thermal image was acquired immediately post-walking to capture changes in temperature as a result of induced stress.

To examine the accuracy of SmartSox to measure plantar pressure, subjects' sandals were fitted with computerized pressure insoles (F-Scan®, Tekscan, Inc, Boston, MA, USA) as illustrated in Figure 3.

Data Analysis

F-Scan and thermal image data were acquired and exported to Matlab (v. R2012b Mathworks, Natick, MA, USA) for post-processing. During post-processing, data were extracted from 5 anatomical regions in plantar foot corresponding to locations at SmartSox. These regions included big toe, first and fifth MTHs, midfoot (under arch), and heel. For assessing between systems agreement for plantar pressure measurement, the peak pressure at each stride was estimated and then the estimated values for all strides were averaged to represent a single value per subject. Pearson's correlation of coefficient (r-value) was calculated for quantifying the inter-subject agreement between two systems.

For assessing the agreement between SmartSox and thermal camera, the thermal stress response (changes in temperature in response to walking) was estimated for each subject and from each system. Specifically, for extracting parameters of interest from the thermal camera, we used a toolbox that was designed and validated in our previous study.[23] This toolbox allows measuring the median and 95 percentile of temperature (as indicator of hot spot) under regions of

Figure 3. To access the accuracy of SmartSox in measuring parameters of interest, participants were asked to walk a distance of 30 m as comfortable speed while wearing SmartSox. Computerized plantar pressure insoles (F-Scan®, Tekscan, Inc, Boston, MA, USA) were used as a reference to validate the accuracy of SmartSox to measure plantar pressure. Thermal stress response was measured using a thermography. To control number of taken steps, a validated gait analyzer based on wearable sensors (LEGSys™, Biosensics LLC, Boston, MA, USA) was used.

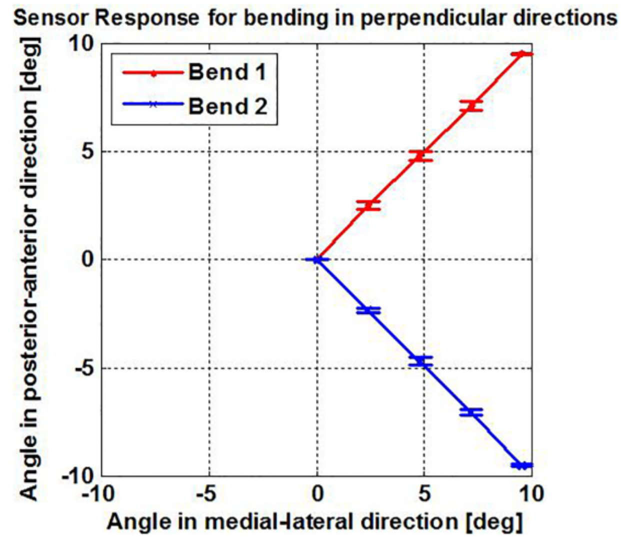

Figure 4. Experimental results showing angular deformation. The fiber sensor is bent in two perpendicular directions, and the sensor data are analyzed to yield the angular deformation direction and strength.

interest using thermal image data. For the purpose of this study, only the median values of thermal image data under regions of interested were assumed as reference values. SmartSox provided continuous temperature measurement for the period of walking trial at each region of interest. To estimate the thermal stress response from both systems, the value at the end of walking was subtracted from the measured value at the baseline. To assess the agreement between two systems, for each subject and both systems, the maximum value of thermal stress responses from all anatomical regions of interest was compared. Then the degree of agreement between two systems was quantified by Pearson's correlation of coefficient (r-value).

All the statistical analyses were performed using SPSS (IBM, version 22, Chicago, IL, USA), with a significance level of $P < .05$.

Results

Figure 2 illustrates the laboratory test of SmartSox in response to changes in temperature via a controllable heater (reference system) and under three different loading conditions. Results suggest that irrespective of the loading condition, there is a high agreement between measured values by SmartSox and by the reference system ($r > .98$, $P = .000$). The results indicated not only that the accuracy of SmartSox to track changes in temperature was high, but also that the cross-talk with pressure was minimal and did not impact the thermal measurement.

Figure 4 illustrates the output of SmartSox for measuring the changes of angles in 2 perpendicular directions. A high agreement ($r > .98$, $P = .000$) was observed for measuring both angles compared to reference system (goniometer) while no cross-talk was observed between two angles outputs (ie, cross-talk between measurement of anterior-posterior and medial-lateral measurements). This indicates that the fiber optic is able to simultaneously measure two dimensional angles. Figure 5 illustrates the output of angles, when

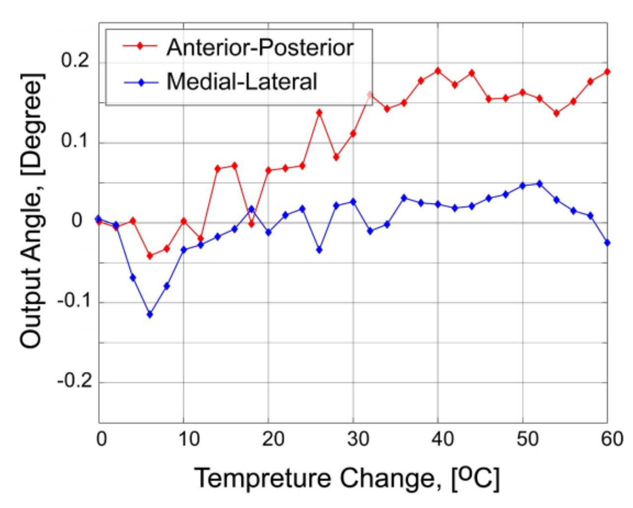

Figure 5. When the temperature changes from 0 to 60°C without bending the fiber, the changes in the SmartSox outputs associated with angles were <0.2°. Thus it can be concluded that the cross-talk between temperature and angle outputs for human motion applications is negligible.

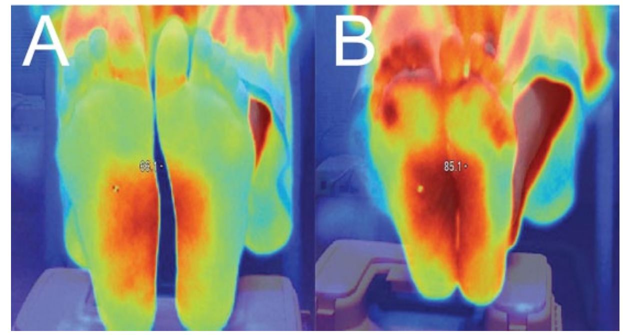

Figure 6. Thermal stress response. (A) Baseline thermography of feet after acclimatization. (B) Thermography of feet immediately after 30 m walking. Changes in 95th percentiles of temperatures values measured in each SmartSox sensor location were estimated to assess thermal stress response.

the temperature changes from 0 to 60°C without bending the fiber (ie, no changes in inputs of angles). While a small trend in increase in angle output was observed in particular in anterior-posterior direction by changing temperature from 0 to 60°, the change in angle output was <0.2°, which is considered as a negligible change in particular for human motion applications. Thus it can be concluded that the cross-talk between temperature and angle outputs for human motion applications was negligible (Figure 5).

After successful assessments of SmartSox in the laboratory condition, we initiated clinical studies in the target population, who were all patients with type 2 diabetes and moderate to high risk of DFU. In our initial attempts, we failed to use SmartSox platform for the purpose of human testing mainly due to fragility of the fiber optic cable and specifically the fragility of the interface between external fiber optic cable and the sock. This was particularly the case for those with major foot deformities (eg, hammer toes), obese participants, and those with minor amputation (eg, toes amputation) in whom high plantar pressure (above 1.2 MPa/cm^2) was observed and/or often the sock was not well fitted, thus causing the fiber to twist leading to its breakdown. Another reason for fiber breakdown was associated with twisting the fiber connector during walking because of poor design of connection interface between sock and cable transferring the data from the socks to a computer for the purpose of real-time visualization and data recording. The initial version was not wireless and required a fiber optic cable to transfer data from the socks to the measurement system. Poor design of the cable connection and sometimes unintentional pulling on the cable (eg, stepping on the cable during walking) led to cable disconnection and breaking the fiber during walking tests. Finally, after multiple attempts, we achieved a prototype that was robust while being comfortable and easily applicable to any type of footwear including offloading boot. To protect the fiber from twisting inside of the sock (the main reason for fiber breakdown), a thin soft padding was added on the plantar surface of sock. This also improved the level of comfort during walking. To prevent the breakdown between sock and the cable transferring data to a computer, a thread latch lock was added instead of the traditional screw-based connector. Figure 1 illustrates the final prototype. From the outward appearance SmartSox looks like a normal sock, while gray fabric and red polka dots on the sole of the feet indicate the sensor location points. The sock detects excessive pressure, hot spots (ie, elevated plantar temperature), or limited joint angle of the big toe and subtalar joint (indictor of stiffness or rigidity)—all occurrences that with repetition can cause foot ulcers. Using this information, a simple graphical interface (Figure 1C) was developed, highlighting the plantar region at risk, which required attention. The final prototype was successfully tested on 33 participants without major operational problems or adverse events. During feasibility observations, we found that clinical implementation of SmartSox was much easier that initial prototype and acceptable for patients because of ease of wearing and short measurement protocol (50-60 steps walking test).

Figure 6 illustrates changes in thermal images in response to walking for a typical subject. As it showed, 50-60 steps were sufficient to observe noticeable thermal changes under regions of interest among patients with DPN and moderate to high risk of foot ulcers. Figure 7 illustrates the output of SmartSox for a typical subject in response to walking for different anatomical regions of interest. As illustrated the plantar temperature in particular for the big toe and first MTH were increased in response to walking. When the maximum

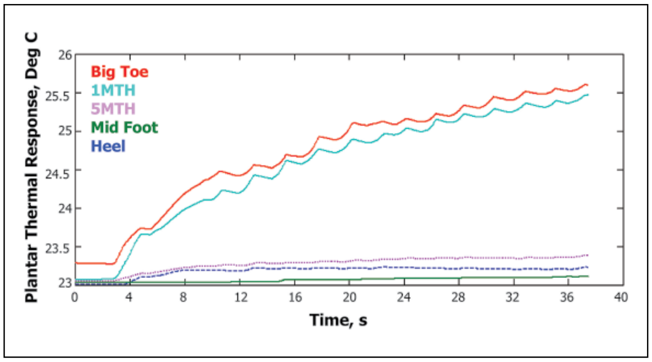

Figure 7. Thermal stress response measured using SmartSox in a typical patient with DPN. The temperature is increasing during walking and as a function of repetitive stresses due to walking steps

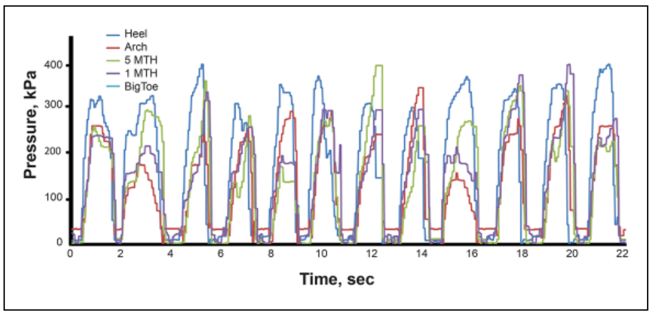

Figure 8. A profile of pressure changes obtained from SmartSox during gait trial in one of the recruited participants.

value of thermal stress response was estimated from SmartSox and from the thermal camera, a significant moderate agreement was observed between two systems ($r = .55$, $P < .050$).

Figure 8 illustrates plantar pressure measured using SmartSox during walking and for different regions of interest. Similar to thermal stress response, a significant moderate agreement was observed between peak pressure measured using SmartSox and F-Scan (Figure 9; $r = .67$, $P < .050$).

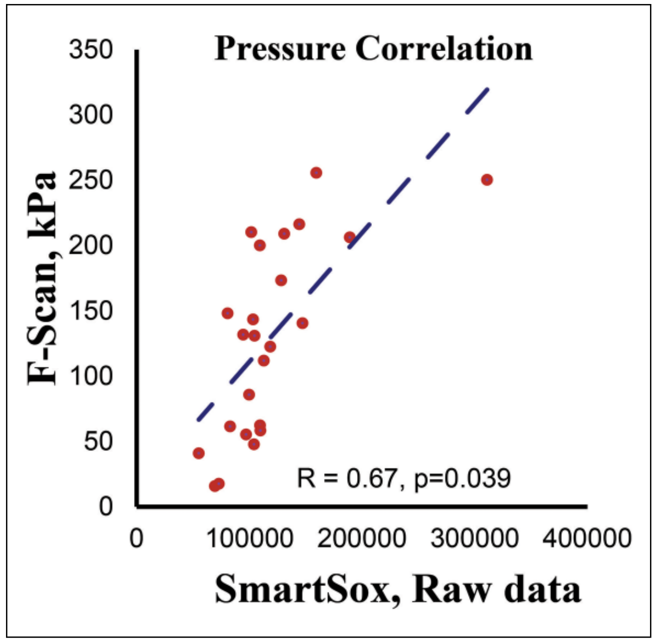

Figure 9. Agreement between peak pressures measured using computerized pressure insoles (F-Scan) and SmartSox.

Discussion

This study, for the first time to our knowledge, introduced and demonstrated the validity of using a wearable technology based on highly flexible sensors to simultaneously measure key biomechanical markers of plantar ulcers including thermal stress response, plantar pressure, and plantar joints stiffness. No noticeable cross-talks were observed between parameters of interest including pressure, temperature, and joint angles. This suggests that SmartSox could be used for simultaneous measurement of plantar pressure, temperatures, and phalanges joint angles, which are of key important to assess risk level for DFU.

In this study, we used fiber optics based on fiber Bragg gratings (FBG) as a sensing element. A key advantage of the proposed fiber based on FBG technology is that they are made of extremely thin glass, very flexible and are chemically and mechanically very resistant, in contrast to conventional plastic optical fibers (POF), which are commonly used for sensing pressure or temperature.[20] POF is not mechanically tough, as a pressure of only 0.3 MPa/cm^2 can make the sensor irreversibly deformed. Thus POF is impractical for patients with diabetes and in particular in the case of foot deformity in where the peak pressure could exceed 1.2 MPa/cm^2.[15] Furthermore, POF also has low durability, large transmission loss, and a diameter that is not compatible with current optical devices such as optical sources and detectors, leading to an excessive cost. FBG fibers—in contrast to POF—have less cross-talk effect. Such a property translates to a sensing platform where measuring each of the individual variables is not sensitive to the other variables. This property has been confirmed in the current study in which changing temperature up to 60°C does lead to an extremely small change in measuring angles: <0.2° (Figure 5). A similar small cross-talk effect was observed for measuring other parameters including the pressure and angles (Figures 2 and 4).

SmartSox could fill the current gaps for objective assessment of biomechanics of lower extremities for the purpose of routine diabetic foot inspection. Unfortunately, the currently available technologies for objective assessment of diabetic foot risk are unreliable or unsuitable for the usage in busy clinics. These technologies often requiring dedicated gait laboratory equipment and space usually remote from clinical sites are highly expensive and impractical for patient care. While modalities like thermometry and infrared camera could provide a snapshot of plantar temperature, they are unable to provide any information about dynamic fluctuation of temperature in response of repetitive stresses. Our previous study[23] revealed plantar temperature increased sharply as a function of number steps for the high DFU risk foot while the change of temperature in the low risk group was significantly lower and even was decreased in the first 50 steps. In addition, we found that walking prior to thermal evaluation may mask temperature differences between the at risk foot and contralateral foot.[23] This may reduce the reliability of assessing foot temperature in a busy clinic where baseline non-weight-bearing temperature acclimation is impractical. Therefore, it stands to reason that simultaneously assessing plantar loading and plantar temperature could enhance the reliability of assessing risk factors for DFU.

In this study, we have tested the ease of use, feasibility, and accuracy of SmartSox in assessing plantar pressure and thermal stress response among patients with diabetes and moderate to high risk of foot ulcers (those with loss of plantar sensation and history of DFUs) and in a busy outpatient podiatry clinic (Diabetic Foot and Wound Clinic in Doha, Qatar with a daily average visits of 80 patients with diabetic foot issues). Results suggest that parameters of interest including thermal stress response and peak plantar pressure could be extracted using a simple short walking test (less than 1-minute walking test over a distance of approximately 30 m) and in a real-world condition (outpatient podiatry clinic). This supports the potential of using SmartSox as an objective tool to assess biomechanics of foot during routine case assessments and in busy outpatient clinics. Routine assessment of risk of ulceration in a diabetic foot involves measurement of plantar pressure and determination of the extent of sensory neuropathy. However, it should be emphasized that these procedures alone cannot be used to predict mechanisms that lead to tissue damage and initiate ulceration.[25] SmartSox may assist in filling the gap by providing a simple and practical form factor facilitating measuring biomechanical markers of foot at risk during routine assessment of risk of ulceration in patients with diabetes and foot risks.

When SmartSox driven parameters of interest were compared with the reference systems (ie, F-Scan for plantar pressure and infrared thermal camera for thermal response to stress), we observed a moderate and significant agreement, suggesting that SmartSox despite its simplified form factor (unlike sophisticated high resolution plantar sensors) is enough sensitive to track harmful peak pressure during walking irrespective of footwear condition as well as tracking thermal stress response, which is known to be a surrogate of shear-force[24] and could identify foot at risk.[23]

One of the major advantages of SmartSox is its ability to simultaneously measure plantar pressure and plantar temperature from the same anatomical plantar regions. This could enhance sensitivity and specificity of identifying plantar spots at risk of ulceration. While plantar pressure assessment can help with identifying risk of DFU, these procedures alone cannot be used to predict mechanisms that lead to tissue damage and initiate ulceration.[25] Limited lack of consensus on appropriate threshold values leading to DFU further complicates the problem, suggesting the need for supplementary screening techniques and evidence-based diagnosis. Bharara et al[26] and Roback et al[27] have reviewed various thermological techniques relevant to the diabetic foot disease and emphasize the importance of using thermometry for lower extremities as a tool for supplementary assessment of diabetic foot at risk. Thermal changes at the plantar surface in response to stress (measurable by SmartSox) may better reflect the risk factors increasing risk of skin breakdown in response to activity[28] in dynamic (eg, walking) or static (eg, standing posture).[15] Unhealthy plantar temperature response to stress (eg, sharp increase in plantar temperature after few walking steps) could be because of a host of changes in the tissues of the foot such as in the skin, fat, peripheral vascular system, tendons, and joints.[5] In clinical trials using infrared thermometry, the effect size ranged from a 4- to 10-fold reduction in reulceration are on top of patients already having pressure reduction addressed through total contact insoles, rocker sole shoes, and callus debridement.[11,29-31] Therefore, simultaneous measurement of both plantar temperature and plantar pressure and in particular thermal stress response could not only be very valuable to identify foot at risk but also assist in preventing DFU.

Although, our sock prototype is currently designed for the clinic environment, the results of our proposed research could inform device design for home and community application. SmartSox uses optical light wavelengths, which are emitted using a laser diode along a fiber optic weaved in a standard sock. This may have significant advantages compared to traditional sensors which are dependent on electrical signals circulated via a conductive electrical wire. For example, using optical signals could reduce the risk of electroshock, electrostatic accumulation, overheating, and risk with walking on a wet surface/sweating unlike to sensors based on electrical signals such as piezoresistive sensors.[32]In particular management of electrostatic shock is highly challenging for sock-based sensors in which because of constant friction, the likelihood of accumulation of electrostatic signals could be high. Furthermore, fiber optic is more durable than piezoresistive and doesn't need frequent calibration unlike traditional pressure sensing materials. In addition, optical fiber is washable and could be cleaned in a high temperature condition for the purpose of reuse and sanitization unlike alternative electronic sensors. An additional advantage of SmartSox is its use irrespective of footwear type (eg, offloading boot, sandals, etc) unlike pressure sensing devices based on computerized pressure insoles, which are often hard to wear with some types of footwear such as sandals. This allows monitoring feet irrespective of footwear type and in any environment condition including in house, where patients often prefer to remove outdoor shoes and thus insole-based sensors may not be practical. The design has particular advantages for patients with diabetes in Qatar, where majorities of patients prefer to wear sandals, and thus traditional monitoring systems (eg, F-Scan, Pedar, etc) may not be practical to screen diabetic foot risk inside and outside of clinic. Further development is however required to make the prototype fully wireless and suitable for remote monitoring applications.

Although the results of this study are promising, the current study has several weaknesses. The reference systems, in particular for study 2 may not be optimal. SmartSox does not have sufficient spatial resolution to cover the entire anatomical regions of interest. Thus the measured values by SmartSox are not guaranteed to match to the same anatomical regions measured by each of the reference systems (ie, F-Scan and thermal camera). Furthermore, the measured values by SmartSox are not guaranteed to exactly reflect the skin temperature. This may explain significant decline in agreement between two systems despite a high agreement observed in the laboratory condition (in vitro study) against well controlled reference systems. In addition, no synchronization was done between F-Scan and SmartSox. Instead, the average of all measured peak pressure during each step and under all regions of interest was estimated for evaluating the degree of agreement between two systems. Despite these limitations, a relatively good agreement was observed for parameters of interest measured by SmartSox and reference systems. However, more prospective studies are warranted to examine whether SmartSox is sensitive enough to capture clinically meaningful information such as prediction of DFUs and/or identifying foot at risk (eg, acute Charcot foot),[23] foot type classification, and effect of footwear or surgical intervention to enhance foot biomechanics.[15,33-35]

Conclusion

This proof of concept study examined and revealed feasibility of an intelligent textile, SmartSox, based on thin (<0.3 mm) and highly flexible fiber optics able to simultaneously measure plantar temperature, pressure, and big toe stiffness. Skin temperature measurement and plantar pressure assessments offer objective and reproducible measurement to identify pathologic processes before they result in ulcers. However, a critical issue in implementing these objective assessments is competing comorbidities for consultant time. SmartSox addresses the above challenge via simultaneous measurement of three major parameters including plantar temperature, pressure and joint angles using a quick walking test. This may improve the feasibility of measuring these biomechanical markers of risk factors for DFUs in busy clinics and for the purpose of routine foot screening. A major benefit of this innovative sensor is its ability to reach places which are otherwise inaccessible using traditional methods, such as measurement inside the hostile environment of the unaltered shoe. If it is validated in a large sample and in a prospective study, it could provide podiatrists and diabetic foot specialists a unique objective and practical tool to provide a personalized preventive care to manage and prevent diabetic foot at risk of foot ulcers. In additional this innovative sensor could assist specialists to quickly examine effectiveness of offloading or shoe design to relieve harmful plantar pressure of shear forces, which are often difficult to capture using traditional measuring modalities and cannot be easily placed to some offloading modalities like offloading sandals.

Abbreviations

BMI, body mass index; DFU, diabetic foot ulceration/ulcer; DPN, diabetic peripheral neuropathy; FBGs, fiber Bragg gratings; IRB, institutional review board; MEMS microelectromechanical systems; MMSE, Mini–Mental State Examination; MTH, metatarsal head; PFO, plastic optical fibers; PHI, projected health information; PN, peripheral neuropathy; VPT, vibratory perception threshold.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: HM is a cofounder of Novinoor LLC, the maker of SmartSox. He was not involved in the clinical study design, patient recruitment, or analyzing data. He did contribute to laboratory testing and critical review of this article.

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