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Monitoring Diabetic Foot by Designing a New Smart Sole

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Abstract

Early diagnosis of a foot ulcer can prevent amputation for diabetic patients. In the present study, we designed a smart foot insole for diabetic patients to monitor temperature, pressure, and humidity to record and display their smartphone's measured values. By using our device, diabetic patients can do self-monitoring of their feet and ensure any complications. A significant difference of increase was recorded for almost all the parameters (temperature, humidity, and pressure) by using our device. Our study displays a significant difference in values measured at room temperature, sitting, and walking for a healthy individual using our smart insole device. The occurrence of foot ulcers can be reduced significantly if such soles are incorporated inside traditional foot uniforms for diabetic patients prone to foot ulceration.

***Keywords** - Foot amputation, diabetic foot, temperature, humidity, pressure.*

I. INTRODUCTION

Since the last century, the number of diabetic patients was increased drastically in all parts of the world. The increase in diabetes patients and chronic diabetes can lead to severe cardiovascular disease, neuropathy, kidney failure, foot ulcer, and many more [1-4]. The epidemiology of diabetes directly affects the standard and quality of living, consistent medical care requirements, and direct financial impact. International variation and burden due to diabetes-related complications still need to be studied further as current literature is insufficient [5]. Currently available data from few high-income countries display myocardial infarction, stroke, and mortality decline among diabetic patients [5]. However, amputations are still growing for diabetic patients [6]. The presence of an unregulated amount of blood glucose in the human body is known as diabetes.

To regulate the blood glucose amount in the bloodstream, and insulin is produced by the organ pancreas whenever the blood glucose amount exceeds the desired amount [7]. The purpose of injecting this insulin is to store the excess quantity of the glucose into energy to be used by the body or store the energy in the body tissues, such as body fat and muscles [8]. If the metabolic process falls apart and the pancreas generates little or no insulin, it results in excess blood glucose in the bloodstream for a healthy body [9]. This illness and malfunction of the pancreas to regulate the blood sugar level is called diabetes. There are three different types of diabetes. Type 1 diabetes is when the pancreas produces little or no insulin, which means the patient requires a daily insulin injection to control the blood glucose levels. Type 1 diabetes can found at any age, mostly occurs in children and teens. At the same time, type 2 diabetes is more common in adults. When suffering from type 2 diabetes, the human body does not benefit from the insulin it generates, thus requiring oral drugs and/or insulin injection to keep their blood glucose level under control. Type 3 diabetes is called gestational diabetes that happens during pregnancy and is linked to mother and child complications. Gestational diabetes usually disappears after child delivery but exposes women and children to the increased danger of developing kind 2 diabetes later in life [10].

Uncontrolled and unmonitored diabetes can cause the development of neuropathy by intricacy to metabolic pathways. Diabetic patients suffer from many problems in the feet. Simple problems may develop and can cause serious complications. The diabetic foot problem often occurs when the nerves of the feet are damaged (diabetic neuropathy). Diabetic neuropathy often begins in the feet and legs, followed by hands and arms. Problems may start with a loss of sensation in the feet and reach amputation at worst. Diabetes causes the lower limbs to be amputated every 30 seconds around the world. When high blood sugar in people with diabetes, blood vessels and nerves are affected over time, and the nerves affected lead to a loss of sensation in the feet, that is, the feeling of wounds and sores that affect the foot, which leads to inflammation, while the blood vessels may lead to a lack of delivery of a quantity sufficient blood oxygenated to the feet, as well as difficult to heal wounds or change the shape of the foot.

Commonly lack of sensation caused by peripheral neuropathy may bring foot ulcers. Foot ulcers are one of the most common symptoms related to diabetes amputations [9]. Currently, 347 million people have diabetes worldwide. China ranked first with 116.4 million, India ranked 77 million, and the United States ranked third with 31 million [11]. In 2017, 4 million people alone died from diabetes [12]. By 2030, the number of diabetic patients is expected to be 522 million across the globe. Saudi Arabia has a higher percentage of diabetic patients compared to its total population. The figure is 32.8%, which is expected to reach 45.36% by 2030 [13].

Diabetic polyneuropathy mostly initiates in the legs. It causes loss of sensitivity to the foot, such as humidity changes, temperature, pressure, or injury. Thus neuropathic diabetic foot wounds cause mild to severe infections on foot. Therefore, it is significantly important to measure these infections and their inflammation. Inflammation can be detected by measuring the difference in temperature, pressure, and humidity in the foot's different spots. Suppose foot inflammation is detected at early stage for a diabetic patient. In that case, it can save the patient from getting ulcer and amputations and reduce the financial expenses that might require medical care. Early diagnosis of foot ulcer can prevent amputation for diabetic patients.

Many smart shoes are available for diabetic patients but have room for improvement for the patient's self-monitoring. Using smartphone technology, we designed a smart foot insole for diabetic patients that can monitor temperature, pressure, and humidity to record and display the patient's smartphone's measured values. Hence it can lower the chance of getting foot ulcers and amputation among diabetic patients. Using our device, diabetic patients can monitor their feet and ensure any complications [14-16].

II. MATERIAL AND METHODS

Designing our smart diabetic insole was parted into two segments. The first segment was to design the circuit and link it with the software using a WiFi module. The second segment was to arrange the inflexible hardware material to be used as a sole.

A. Electrical and Software Design

Keeping track of humidity, pressure, and temperature can help lessen the risk of foot ulceration. Spots are the first indicators of inflammation, and they are the warning signs of danger. Thus 3 spots were chosen carefully to monitor the well-being of the foot. Two spots were selected across the ball of the foot, and 1 spot at the heel of the foot was selected, as seen in figure 1. These three spots are the center for bearing the body's maximum load and are considered the most vulnerable spots to initiate the ulcers and their infections [17].

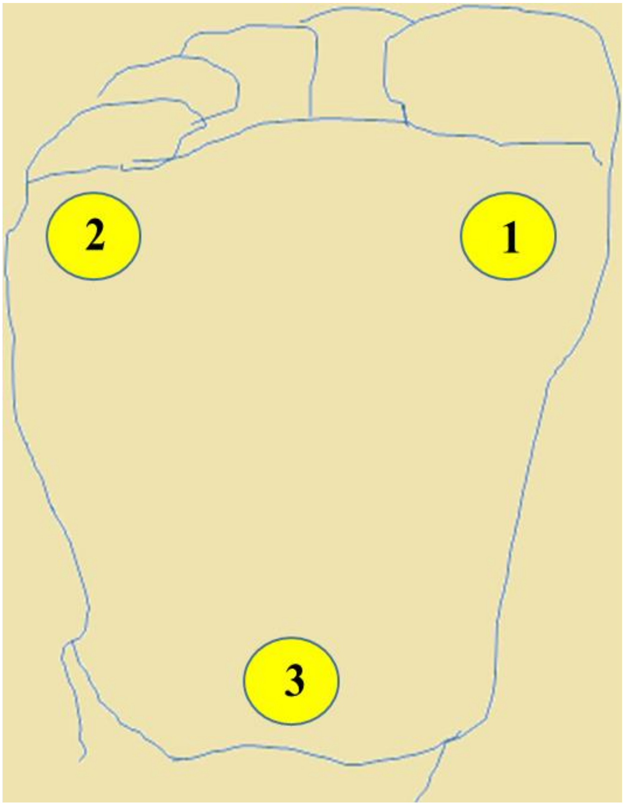

Figure 1: Shows the distribution of the three spots.

We have used sensor DHT22 to measure the humidity and temperature readings, while pressure was measured using the strain gauge. The DHT22 is a basic, low-cost digital temperature and humidity sensor. It uses a capacitive humidity sensor and a thermistor to measure the surrounding air and sends out a digital signal on the data pin [9], and the strain gauge is a sensor whose resistance varies with applied force. It converts pressure into a change in electrical resistance, which can then be measured [9] are the two sensors that have been placed at each spot. Since we have two sensors per spot, the total number of sensors required for the 3 spots is 6. Microcontroller (MCU), model ESP8266 was used to connected the circuit with a Wi-Fi module. The charging unit was based on the piezoelectric principle to re-charge the circuit as the patients walk. The piezoelectric effect is the ability of certain materials to generate an electric charge in response to applied mechanical stress [18]. The existing library of Arduino was modified to obtain readings from the sensors. All readings were measured every 2 seconds.

Figure 2 displays the block diagram of the circuit. The piezoelectric material used is made of ceramic lead zirconate titanate that transforms the positive and negative charge centers in the material, resulting in an external electric field if it is placed under mechanical stress. The rectifier converts alternating current, which reverses from piezoelectric, to direct current. The voltage regulator generates a fixed output voltage of 3V to charge the battery. MCU linked with sensors to obtain the readings for each of the three parameters. The data is then sent from MCU through an attached WiFi to the smartphone that displays the data on an app for self-monitoring. The app then sounds an alarm as soon as a considerably large difference is received for any parameter parameters.

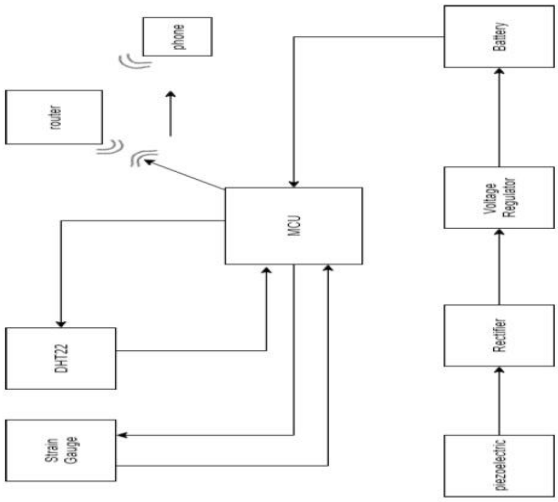

Figure 2: Shows the block diagram of the circuit.

In the current study, we have paired the smart insole with an iOS-based smartphone through Wi-Fi. An existing iOS app connects through Wi-Fi to an Arduino and displays sensor readings of the three parameters at one spot. The smartphone display is transformed into 3 columns with each sensor readings to monitor all three parameters. The first column displays the temperature reading from all three sensors. The second column displays the humidity reading from all three sensors. The third column displays the pressure readings from all three sensors. Alerts are also sent to the smartphone if the readings pass the set threshold values for each parameter. The threshold values for temperature, humidity, and pressure were set at 32° C, 60%, and 700KPa, respectively [19]. The application was coded and designed using Arduino and Simulator programs.

B. Sole Architecture

The sole was initially designed and extruded using SolidWorks, and later it was printed using a 3D printer. The materials used for 3D printing are thermoplastic polyurethane. The electrical circuit was brought in line to fit the printed sole just for the checking phase. After a thorough inspection of the printed sole, a custom hand-made silicone sole was made with a shoe size of 43 to enclose all the electrical circuits and flexible enough to fit inside the shoe. The sole and electrical circuit was wrapped and switched using an electrostatic material, as shown in figure 3.

Figure 3 Diabetic Insole for monitoring temperature, humidity, and pressure.

C. Statistical Analysis

The statistical analysis was performed with SPSS version 21.0 software for Windows (IBM Corporation, Armonk, NY). All data are presented as mean ± standard deviation. One-way analysis of variance was performed using the Tukey honestly significant difference test to determine the level of significance among the 3 groups at $P < .05$.

III. RESULTS

The graphic user interface (GUI) on the mobile application can be seen in figure 4, with all the readings showing zero values.

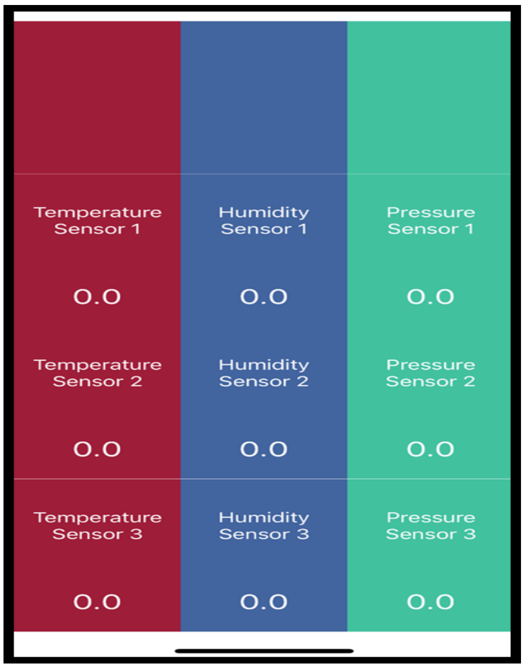

Figure 4: GUI of the smartphone app.

Figure 5 shows the smart device's readings at different positions (room temperature, sitting position, and while walking).

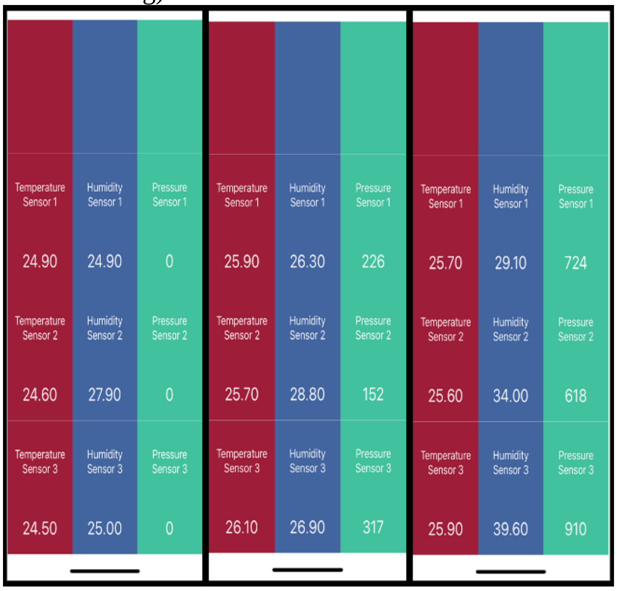

Figure 5: GUI of the smartphone app; (a) At room temperature, (b) At sitting position, and (c) While walking.

The mean temperature at each position tends to show a significant difference for all the events, as shown in figure 6. *P* values with a significant difference *(all P < .05)* were recorded between room temperature and sitting position, sitting position and while walking, and room temperature and walking.

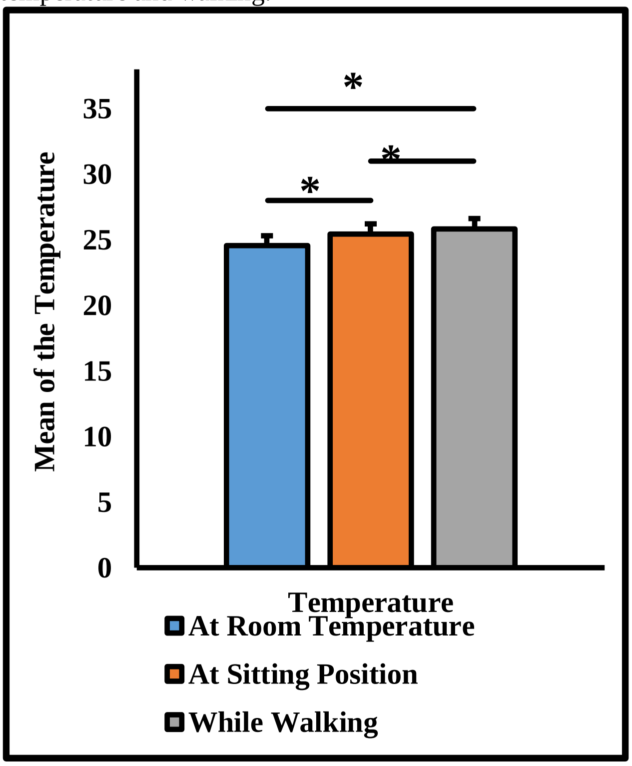

Figure 6: Temperature readings at different events.
*** Significant difference between the events.**

The humidity displayed an increase from room temperature to sitting position and from sitting position to while walking. The humidity did not show a significant difference for all the events, as seen in the figure. 7. Humidity at room temperature compared with a sitting position tended to have no significant difference (all P > .05). A significant difference (all P < .05) were observed in room temperature compared with while walking, and room temperature compared with while walking position.

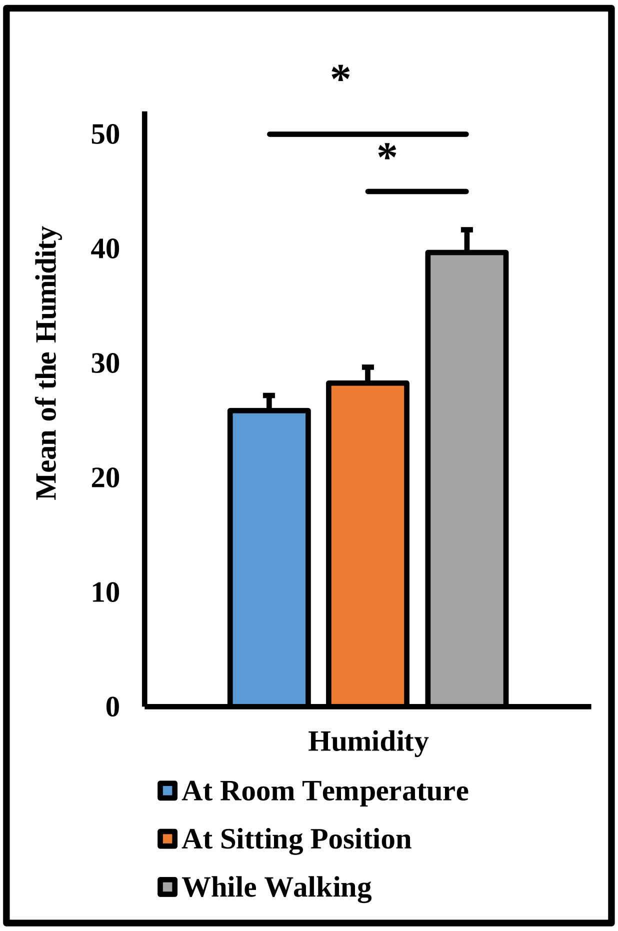

Figure 7: Humidity readings at different events.
*** Significant difference between the events.**

The pressure displayed a prominent increase among all the events. The pressure value showed a significant difference (all P < .05) for all the events (see figure 8.

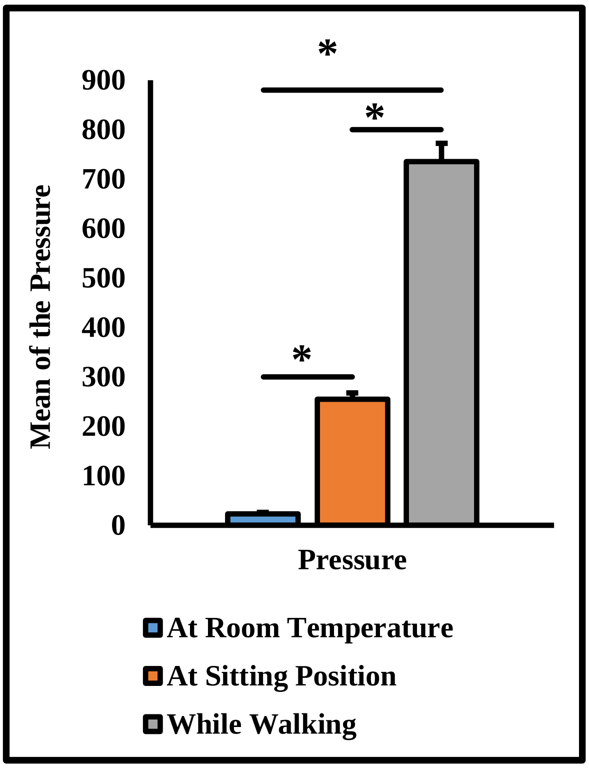

Figure 8 Pressure readings at different events.
*** Significant difference between the events.**

IV. DISCUSSION

The present study was carried on to monitor diabetic foot by using diabetic insole, which can considerably alert the patient that need arises and lessen the chance of getting foot ulcers for diabetic patients. Our device can provide real-time monitoring for temperature, humidity, and pressure at three hotspots on foot. The temperature was significantly increased for all the events, which corroborates earlier findings [16, 20, 21]. In addition, humidity significantly increases for sitting to walking positions, which also validates our readings [22, 23]. The parameter that increased tremendously was the pressure parameter, and it also plays an important role in initiating the foot ulcer for diabetic patients [24, 25]. The pressure values at the three hotspots varied significantly for all the activities. Such variation was recorded in earlier studies as well [26, 27].

Our product design is practical and easy to use inside any shoe. However, we tested our device on a healthy individual. Future studies are required to prove the design's accuracy and efficiency in all age groups, including diabetic patients. In conclusion, while using our smart insole device, our study displays a significant difference in values measured at room temperature, sitting, and walking for a healthy individual. The occurrence of foot ulcers can be reduced significantly if such soles are incorporated inside traditional foot uniforms for diabetic patients prone to foot ulceration.

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