

Enhanced Wearable Prototype for Continuous Monitoring of Diabetic Foot Ulcers: A Pilot Study

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ABSTRACT

Background: Diabetes, characterized by high blood glucose levels, can lead to complications like diabetic foot ulceration (DFU), primarily caused by Neuropathy, ischemia, and Charcot foot. These conditions damage foot nerves, leading to loss of sensation. DFUs result from abnormal foot pressure and temperature variations. Early detection and treatment are crucial to prevent complications, and daily foot examinations can improve efficiency, enabling earlier detection of DFUs.

Methods: This crisscross section focuses on designing and developing an innovative monitoring shoe to detect foot pressure and temperature in real-time and prevent early-stage ulceration. The shoe has an ESP-32 microcontroller, piezoelectric sensors embedded in the insole, DHT11 temperature sensors, and wireless communication capabilities. These components monitor dynamic foot pressure and temperature, transmitting data to a mobile application provides continuous monitoring.

Results: The innovative shoe prototype, tested on 30 participants (diabetic with and without Neuropathy and non-diabetic), revealed significant differences in plantar pressure and foot temperature. Normal foot pressure ranged from 160–470 kPa, while diabetic patients showed 470–550 kPa, neuropathic patients 550–850 kPa, and ulcer patients >850 kPa. Foot temperature ranged from 28–29°C in healthy individuals to 32–33°C in ulcer patients. The prototype effectively detected these variations, highlighting its potential for early detection of diabetic foot ulcers.

Conclusion: The prototype enhances diabetic foot care by enabling real time monitoring of pressure and temperature variations. It promotes early detection and prevention, improving foot health management and timely intervention.

Keywords: Diabetes, Diabetic Foot Ulcer, Neuropathy, Plantar Pressure, Temperature, Monitoring.

Received: September 26, 2024; **Revised:** December 5, 2024; **Accepted:** January 16, 2025

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DOI: <https://doi.org/10.59564/amrj/03.01/021>

INTRODUCTION

Diabetes is a severe, chronic health condition that is caused by increased glucose levels in the blood. Over the years, the number of people with diabetes has been increasing around the world, and the statistics are going up in recent years¹. The World Health Organization (WHO) states that 422 million individuals were on the planet in 2014, or around 425 million people in 2017, who had diabetes worldwide, compared to 108 million in 1980². To articulate, one out of ten adults had diabetes in 2021, around 10.5% of the entire adult

population, or almost 537 million adults aged 20–79. This number is projected to increase to 643 million in 2030 and 783 million in 2045³.

It is predicted that about half of all diabetic patients (49.7 %) remain undiagnosed according to WHO⁴. Undiagnosed diabetes can lead to poor blood sugar control, causing nerve damage and poor circulation, making foot injuries harder to heal. This can result in severe infections and amputations. Early detection and management,



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including regular foot inspections, reasonable blood glucose control, and proper footwear, are crucial to prevent DFUs. If the diabetes is not diagnosed correctly, then it can cause many complications.

One of the significant complications of diabetes is diabetic foot ulceration (foot pathology). The term "Diabetic Foot" refers to any pathology of the lower limb caused by diabetes, including ulcers, ischemia, infections, and other complications. Diabetes can impair lower-limb function in a variety of ways (often at the same time). Infection, ulceration, and/or degeneration of deep tissues in the lower leg caused by neurological abnormalities and peripheral vascular disease are all symptoms of diabetic foot⁴.

Diabetes causes two primary foot conditions: Neuropathy and vasculopathy⁵. In various combinations, these result in the diverse appearance of Peripheral Neuropathy in the foot. In diabetic patients, diabetic foot ulcer (DFU) is caused by a combination of co-occurring risk factors⁶. Peripheral Neuropathy, Peripheral edema, Peripheral Vascular Disease, Deformities of the foot, vascular insufficiency, trauma, deformity, high plantar pressures, Retinopathy, poor glucose control, advanced age, and long-term diabetes are all risk factors. The main complication of tissue damage to the foot can become sufficiently severe to cause amputation and is classified as a medical emergency.

The patient's foot resists temperature fluctuations, serious injuries, and pressure due to lack of sensation. A foot ulcer can develop due to little friction or wearing uncomfortable shoes, and the patient may be unaware of it⁷. Motor neuropathy affects the patient's foot and leg muscles, as well as foot biomechanics. Autonomic Neuropathy is also involved in the development of diabetic foot ulcers⁸. Neuropathy-related loss of protective sensation, physical trauma, changes in temperature and extreme pressure may cause damage to the feet, making patients more vulnerable to complications, including tissue breakdown and ulceration, resulting in surgical criteria for amputation, which are a significant risk factor for diabetic foot ulcers⁹.

Higher-than-normal pressures on the sole and temperature variations usually cause DFU.

Preventive studies have shown that effective treatment can reduce foot ulcers and amputations¹⁰. Regular foot tests, temperature regulation and orthotic shoes are the precautions for preventing diabetic foot ulcers¹¹. This initiative allows early identification and offers treatment and prevention of severe medical conditions. The treatment is complicated, costly and requires long-term therapy when ulcers appear¹². The equipment used to calculate the distribution of foot pressure is either too costly to own or too heavy to be portable.

The primary goal is to determine the pressure and temperature of the foot at early stages and prevent foot ulcers leading to amputation. Therefore, the smart shoe is designed to monitor the foot condition, providing information about temperature and pressures reported around the feet. Temperature and pressure are the two key characteristics that can predict foot ulcer conditions. This system would affect diabetic patients by enabling them to maintain foot care and minimize the incidence of diabetic foot problems. It helps to reduce and regulate the rising number of DFUs among diabetes patients. Monitoring these conditions is crucial for reducing or eliminating foot ulcers. Daily foot testing aims to improve patient outcomes by making the process easier, quicker, and more effective, leading to earlier detection of DFU. The benefit of the system is the reduction in such incidences and the associated healthcare costs. This wearable prototype helps to provide physicians with remote monitoring tools, allowing them to closely monitor patients and detect diabetic foot ulcers at an early stage, potentially even before they become noticeable.

METHODOLOGY

Study Design and Setting

This pilot study was conducted at Liaquat University of Medical Health and Sciences Civil Hospital, Hyderabad, Sindh.

Study Size

This study was designed to compare the health parameters of diabetic and non-diabetic patients aged 30 to 70. A total of 30 patients were included in the study, with 15 patients diagnosed with diabetes and 15 non-diabetic patients. The study

assessed various health metrics such as blood glucose levels, blood pressure, and lifestyle factors.

Sample Technique

To sample diabetic and non-diabetic patients, stratified random sampling will be done. The diabetes status of patients will be considered to divide patients into two strata, where 15 patients with diabetes will be randomly chosen from each category, and 15 non-diabetic patients will also be randomly chosen to ensure each group is fairly represented. Diabetic patients are categorized based on the presence of neuropathy and foot ulcers. Out of 15 diabetic patients, six patients have neither neuropathy nor foot ulcers, five patients have neuropathy but no foot ulcers, while four patients have who do not have severe cases of foot ulcers but show symptoms or are at risk of developing foot ulcers. It will ensure a proportional representation of both groups in the study. By dividing diabetic patients into these categories, healthcare providers can better understand the prevalence of neuropathy and foot ulcers, identify risk factors, and develop targeted interventions to prevent and manage these complications.

Development of Prototype

A smart wearable shoe monitors diabetic foot ulcers by detecting real-time pressure and temperature. The innovative shoe prototype comprises an ESP-32 microcontroller, six Piezoelectric sensors, and three DHT11 temperature sensor^{13,14,15}. ESP-32 microcontroller unit (MCU) is used to control all of the peripheral components. The microcontroller controls the device's work process. A Blynk app software application is used to receive data from an MCU and display the results of foot condition (Figure-1).

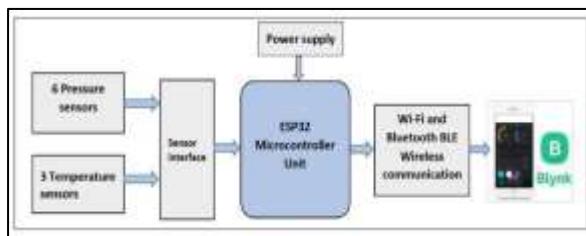


Fig.01 Hardware Architecture of the Shoe System for Monitoring Diabetic Foot Ulcers

The ESPRESSIF (ESP32) microcontroller is a low-cost, ultra-low-power device with a dual-core

processor, Wi-Fi, and Bluetooth capabilities. It offers advanced features like faster processing, higher memory capacity, and the ability to handle multiple tasks concurrently. It acts as a central unit, collecting sensor data, processing it, and sending the results to output devices. Designed for durability and adaptability, the ESP32 provides high performance in various power conditions, making it ideal for Internet of Things (IoT), wearable devices, and mobile applications¹⁶. Piezoelectric sensors are used to measure the changes in pressure. This sensor utilizes the piezoelectric effect to convert the strain, force, and pressure changes into an electrical charge. It generates an output signal without using an external voltage or current source; instead, the strain applied is employed to generate the signal¹⁷.

Along with the piezoelectric sensor, the piezoelectric vibration sensor module is also used to generate a predictable output voltage in response to applied force¹⁸. In this study, six piezoelectric sensors are used on the soles of the shoes and placed in different spots, with their modules around the shoes. Two pressure sensors were placed on the anterior part of the sole (first toe and third toe), three pressure sensors were placed on the medial part at the first, second and fifth metatarsal, and one sensor was placed on the heel as shown in Figure-2. Pressure sensors placed on the third toe indicate the P0 pressure point and placed on the first toe indicate a P1 pressure point, P2 pressure sensor on the fifth metatarsal, P3 on the second metatarsal, P4 on the first metatarsal, and P5 indicates the pressure point on heel.

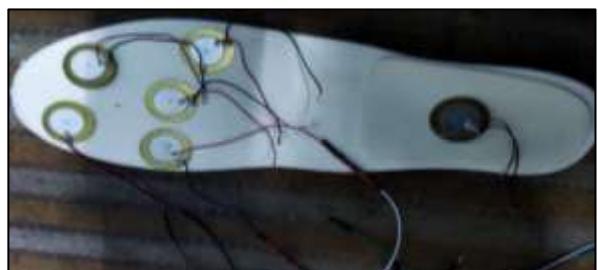


Fig.02 Piezoelectric Sensor Placement on Sole and Modules around the Shoe

Pressure is applied to the piezoelectric sensor, which is turned into an electrical charge and sent to the modules connected to the piezoelectric

sensor. Then, the converted electrical charge travels into the ESP32 to produce the pressure value that can be measured. Three temperature sensors are used in the shoe's anterior, middle and posterior parts. At the start of the system, DHT11 gets the temperature values and sends them to the ESP32, and the ESP32 uploads them onto the cloud of the Blynk app. Both the pressure and temperature sensors' data travel to the ESP32. It will upload to the Blynk app cloud to show values on the screen.

When a person walks or performs any activity while wearing the proposed model, the sensors are positioned so that the pressure from each part of the foot is recognized. ESP32 microcontroller is connected to the Blynk app through a Wi-Fi network, and the system starts when pressure on the shoe is applied. The data of the pressure and temperature sensors travel to the ESP32 microcontroller; then, the microcontroller will upload the pressure and temperature sensors data to the Blynk app cloud and display the data on the screen.

The display data obtained from the temperature and pressure sensor will be detected, as shown in Figure-4. If the range of pressure and temperature data increases compared to the normal range, there is a possibility that there may be a diabetic foot ulcer. Therefore, early prevention is also necessary for a problem to be identified. The complete process for monitoring diabetic foot ulcers is shown in Figure-3.

Ethical Considerations

Ethical guidelines were performed in this study, and approval was by the Institute of Biomedical Engineering and Technology, Liaquat University of Medical Health and Sciences, Jamshoro and written informed consent was obtained from all participants prior to inclusion. Participant confidentiality and data privacy have been strictly adhered to while conducting the research.

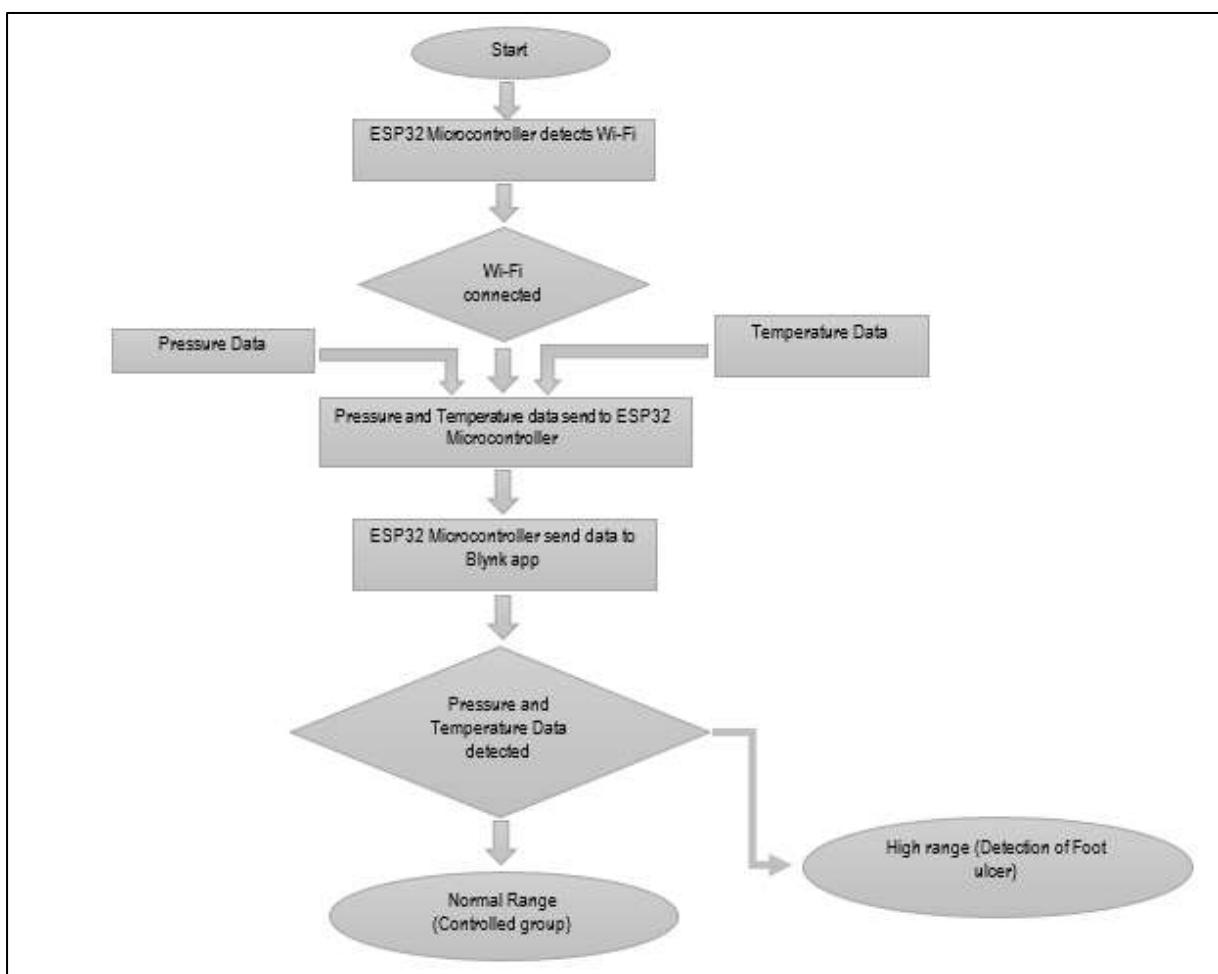


Fig.3 Workflow of the Process

RESULTS

The results obtained from different groups of people who are non-diabetic and diabetic patients for identifying the pressure and temperature values are shown in Table-1.

The typical values of the foot pressure of a regular patient are 160 to 470 kPa, and the values of the diabetic patient are 470 to 550 kPa; the values of the diabetic patient with Neuropathy range from 550 to 850 kPa, and the values of foot ulcer patients are 850 kPa and above.

Table-1 Readings of the temperate and dynamic foot pressure.

Study groups	Temperature (C°)			Dynamic foot pressure (kPa)					
	T1	T2	T3	P0	P1	P2	P3	P4	P5
Normal	28	29	28	160	210	107.5	200	431.2	470
Diabetes Mellitus	30	29	30	479.25	224	210.75	276.25	492	526.25
Diabetes Mellitus with Neuropathy	31	30	31	615	597.5	527.5	363	527.5	850
Foot Ulcer	32	33	33	875	675	566	401.5s	967	995

Whereas the expected value of foot temperature ranges from 28 C° to 29 C°, for diabetes mellitus, the temperature ranges from 29 C° to 30 C°, the values obtained for diabetic patients with Neuropathy range from 30 C° to 31 C° and the values of temperature of foot ulcer ranges from 32 C° to 33 C°.

The Graph of the pressure points (P1, P2, P3, P4, P5) of different participant groups, Normal individuals, Diabetic patients, Diabetes Mellitus with Neuropathy, and Foot ulcers are shown below in Figure-4. This bar graph shows the distribution of foot pressure (kPa), as measured at different regions of the foot (P0 to P5) for four different groups: Normal individuals (green), Diabetes Mellitus patients (blue), Diabetes Mellitus patients with Neuropathy (orange), and Foot ulcer patient (dark green). The observations provide the following descriptions:

P0 (Heel Region):

Normal persons show low pressure (~160 kPa). Diabetics and neuropathics show moderate pressure on P0 (~479.25 to 615 kPa). Foot ulcer patients, on the other hand, show the highest pressure (~875 kPa).

P1 (Metatarsal Region 1):

Normal: ~210 kPa
Diabetes: Higher by about ~224 kPa
Neuropathy: Increased (~597.5 kPa)
Foot ulcer: Very high (~675 kPa)

P2 (Metatarsal Region 2):

Normal: ~107.5 kPa, the lowest of all
Diabetes: Moderate (~210.75 kPa)
Neuropathy: Increased (~527.5 kPa)
Foot ulcer: ~565 kPa

P3 (Midfoot Region):

Normal: ~200 kPa
Diabetic: ~276.25 kPa
Neuropathy: ~401.5 kPa
Foot ulcer: ~527.5

P4 (Toe Region 1):

Normal: ~431.2 kPa
Diabetes: ~527.5 kPa
Neuropathy: very high (~967 kPa)
Foot ulcer: Extreme (~higher than 967 kPa)

P5 (Toe Region 2):

Normal: ~470 kPa
Diabetes: ~526.25 kPa
Neuropathy: ~850 kPa

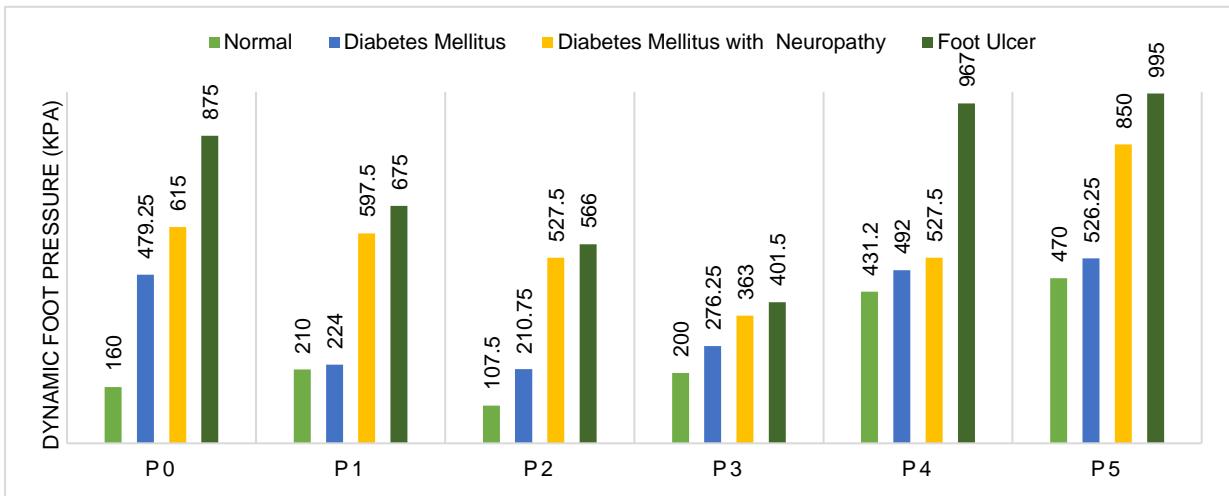


Fig.4 Pressure Points in Normal, Diabetic, Neuropathic, and Foot Ulcer Groups

Foot ulcer: 995 kPa, which is the highest in the dataset. Foot ulcer patients start experiencing the highest foot pressure across all regions, particularly the toe and heel regions. Neuropathy patients are showing a significant increase in plantar pressure, which establishes a strong association between Neuropathy and DFU (risk). Even diabetic patients with no neuropathy record higher plantar pressures than normal individuals,

hence the need for early intervention. Moderate pressure increments were observed in the midfoot regions- a fair share of ulcer formation danger sits on the metatarsals (P1, P2) and toes (P4, P5). The Graph of the three temperature sensor values (T1, T2, T3) of different participant groups is shown in Figure-5.

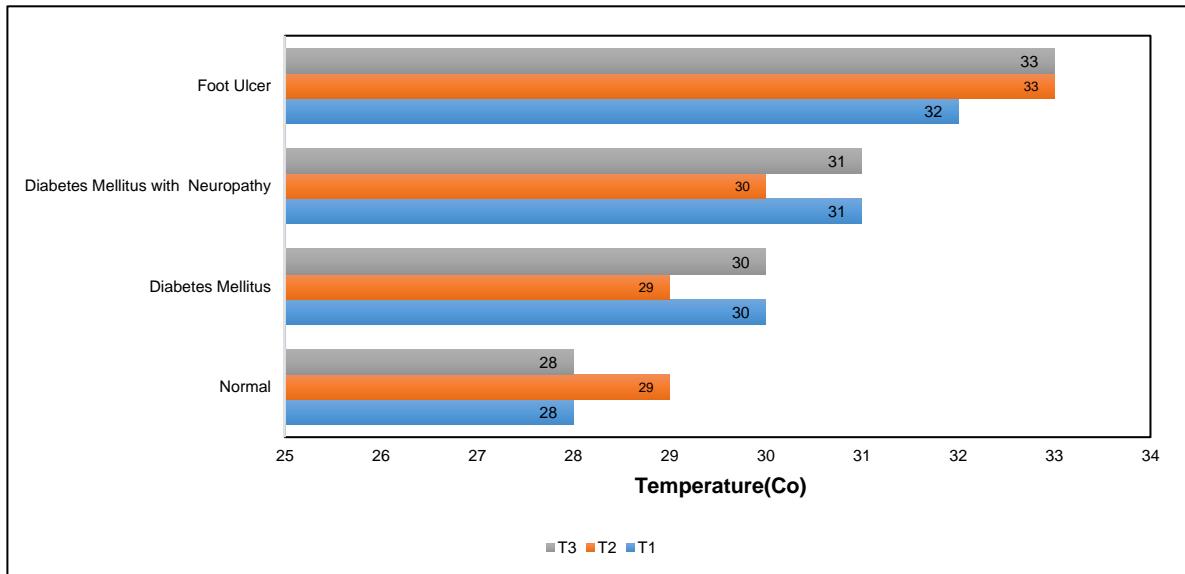


Fig.5 Graph of Temperature Sensor Values across Different Participant Groups

The bar graph depicts variations in foot temperature (°C) measured at three sites (T1, T2, T3) in four groups: normals, Diabetes Mellitus patients, Diabetes Mellitus with Neuropathy patients, and Foot Ulcer patients. Each pole expresses temperature measurements at three-

foot regions: (T1) anterior-foot region (Blue), (T2) midfoot region (orange), and (T3) posterior or heel region (grey). The observations provide the following descriptions:

1. Normal Individuals:

It ranged from 28 to 29°C in all three regions.

This might constitute an essential foot temperature for a healthy individual.

2. Diabetics (without Neuropathy):

Above typical values (29 to 30°C) would indicate slightly higher temperatures.

This is due to lesser microvascular circulation and mild inflammation in diabetic feet.

3. Diabetes with Neuropathy:

Temperature further increases up to 30°C - 31°C. Neuropathy results in defective sweating and thermoregulation, leading to an increase in temperature.

An increase in inflammatory processes may also support this increase in temperature profile.

4. Foot Ulcerous Patients:

Recorded the highest temperature (32°C - 33°C) in all regions.

Ulceration brings local inflammation, increased blood flow, and infection, resulting in significantly elevated temperature.

The temperature differences between normal persons (~28-29°C) and foot ulcer patients (~32-33°C) reflect the direct correlation between temperature elevation and ulcer formation. These results suggested that diabetic patients with high values of plantar pressure have a risk of foot ulcers. This project would affect diabetic patients by enabling them to maintain foot care and minimize the incidence of diabetic foot problems.

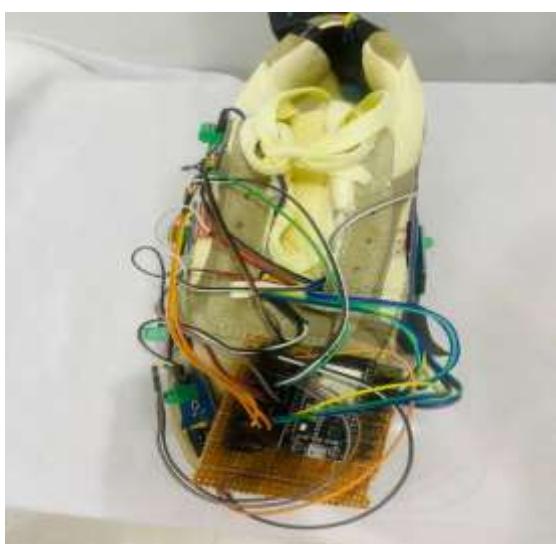


Fig.6. Prototype that monitors the pressure and temperature of diabetic foot

DISCUSSION

A wearable prototype for DFU monitoring and care has the potential to improve diabetic foot health substantially. The present study proposed a smart shoe that can identify early signs of DFU by analyzing the pressure and temperature change on the sole. The analysis revealed that diabetic patients have significantly higher plantar pressure and foot temperature than non-diabetic patients, which are critical factors in the development of ulcerations^{19,20}.

The results are consistent with earlier research documenting that, in combination with sensory loss from Neuropathy, excessive and prolonged pressure on the foot leads to ulceration. Neuropathy causes a decreased sensation of injury, while vascular issues hamper healing²¹. In this study, piezoelectric pressure sensors and DHT11 temperature sensors provided real-time data transmission to a mobile application, allowing timely intervention through continuous monitoring. A significant advantage of this setup is that it allows for real-time, wireless metrics on the ESP32 microcontroller and theBlynk app²². The feature allows for proactive management of diabetic foot conditions by alerting patients or healthcare providers when critical pressure or temperature thresholds are exceeded²³. Compared with existing approaches based on punctual clinical access, this prototype offers the potential to assess the health of the feet quickly and affordably, making it relevant in our society today²³.

However, they have some limitations that should be addressed. It was tested in a small cohort, and further studies with more significant and more diverse sample sizes are needed to ensure their clinical applicability. It was also likely that differences in stride, alterations in shoe size, and differences in sensor calibration would affect the measurements. Further advancements can target the optimization of sensor placement, refinement of data processing algorithms, and inclusion of more parameters, including humidity and gait analysis, for better ulcer prediction performance²⁴.

These limitations notwithstanding, this study shows the potential for the use of wearable technology in DFU prevention. The prototype could be incorporated into daily activities because

it is non-invasive and easy to use. It would thereby reduce the risk of foot ulceration and lower-extremity amputation in people with diabetes. AI-powered predictive models and cloud-based data analytics may be some of the advancements seen in the future that further improve early detection^{25,26}.

CONCLUSION

This study focuses on developing an innovative shoe prototype for monitoring and preventing diabetic foot ulcers by detecting foot temperature and pressure early. The prototype incorporates pressure and temperature sensors and configurable wireless setup modes, making it suitable for clinics, outdoor testing, and activity monitoring. The system identifies normal and abnormal foot pressures and temperature variations, indicating that diabetic patients exhibit higher pressure and temperature ranges than non-diabetic individuals, increasing their susceptibility to foot ulcers. Early detection of these parameters is crucial for timely diagnosis and management, and the prototype aims to enhance patient care through effective daily foot monitoring.

Future Recommendations

There are a few suggestions for changes and enhancements to the present shoe design.

- Currently, the Android app only monitors data from one foot. Using Bluetooth mesh in Bluetooth 5.0, a single application might be used to monitor data from both legs at the same time.
- A neural network may be taught to analyze sensor data from the end-point device for real-time foot evaluation.
- Future improvements can be achieved by reducing the size of the components used within the shoe to make it appear more comfortable to the user.
- It is a prototype and desires further enhancement.

Acknowledgments

None.

Author Contributions

Saba Abro conceptualized and designed the study. **Kainat Jamali** contributed to data collection and methodology development. **Bisma Maqsood** performed data analysis and interpretation. **Murk Rehman** assisted in the literature review

and manuscript drafting. **Murk Saleem** contributed to manuscript editing and final approval. All authors reviewed and approved the final version of the manuscript.

Ethical Approval

This study received approval from the Institutional Ethical Review Committee of Department of Biomedical Engineering and Technology, Liaquat University of Medical Health and Sciences, Jamshoro, Sindh.

Grant Support and Funding Disclosure

None.

Conflict of Interests

None.

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