A Wearable Pad for Detecting and Monitoring Heel Pressure Ulcer: Preliminary Study

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***Abstract*— This paper addresses a critical gap in wearable sensors for monitoring pressure ulcers, focusing on heel pressure ulcers, a high-risk area. In This study, a wearable pad for monitoring pressure ulcers in bedridden patients was developed. The pad integrates pressure and temperature sensors into a comfortable fabric bandage, allowing for data collection and analysis. Machine algorithms classify sensor readings as healthy or risky, with a user-friendly display communicating the risk level. The wearable pad is tested on three individuals, recording the difference between a heel without a pressure ulcer and one with an existing one. This wearable sensor pad's successful development and validation could revolutionize early detection and prevention strategies for bedridden patients, improving health outcomes and reducing healthcare costs.**

***Index Terms*— Pressure ulcer, wearable pad, monitoring sensors, heel pressure injuries.**

I. Introduction

Decubitus ulcers, also known as pressure ulcers (PUs), are a significant complication for bedridden patients, causing immense discomfort and serious health problems. Current preventative measures have limitations, particularly in monitoring heel PUs, which are anatomically complex and cannot be effectively offloaded by immobilization in a patient's bed. Shear force cannot be detected by current methods of PU measurement, leading to wound deterioration [1]. Heel PUs can last for months or years, prolonging hospital stays and increasing healthcare costs [2]. The lack of early detection between high and low risk ulcers causes them to progress into worse stages, characterized by tissue necrosis extending to the muscle and bone, causing severe pain and direct patient morbidity [3, 4].

These challenges highlight the need for heel-specific PU monitoring technology, specifically designed for early detection in the heel, a high-risk area for bedridden patients. This study aims to address the limitations of current prevention measures and improve early detection and prevention strategies for PUs in the heel region.

A. Overview of the Formation of Heel PUs

Heel pressure injuries (HPIs) occur when mechanical forces compress and deform tissues between the bony prominence of the calcaneus and the external surface [5, 6].

The posterior portion of the heel, which contains the inflexible Achilles tendon, has a low subcutaneous fat volume, making it vulnerable to pressure and tissue disintegration [7-9]. The heel is made up of skin covering the reticular dermis and avascular fat contained in fibrous septa compartments supplied by blood vessels [8]. The sole muscle in the heel is the thin layer of panniculus carnosus muscle, which is likely responsible for forming HPIs [7, 8]. Heel PU may appear as dark, dry eschar areas or rankles packed with fluids or blood that eventually re-epithelialize behind the eschar [10]. The degree of tension applied is not often reflected in the severity of a HPIs [7]. Early detection of tissue damage using skin staining may lead to more potent anticipation training and less severe skin damage. Subepidermal moisture (SEM) is a biophysical measurement used to represent oedema in tissues below the layer corneum to distinguish it from moisture on the outer layer of the epidermis [11]. HPIs are most common in bedridden people, as persistent pressure from lying flat for prolonged periods compresses blood vessels, limiting blood flow to the tissue, leading to ulcer development and cell death. Preventive measures can improve early detection and prevention strategies [5].

Fig. 1 shows a real-life image of heel PU for one of the subjects participated in this study. Evidently, the person's heel has soreness and is on the initial stage of PU.

Fig. 1. Heels of bedridden patient participated in this study with initial stage of PU.

B. Pressure Injuries

Pressure on the skin can cause physical and psychological responses, such as sensations like touch, pressure, and pain, and impact temperature regulation. However, excessive pressure can impede blood circulation, leading to conditions like PUs. PUs are characterized by localized skin and tissue damage due to factors such as pressure, friction, and internal health issues like malnutrition or anemia [12, 13].

The severity of PUs is assessed using systems like the national PU advisory panel (NPUAP) staging, which categorizes injuries into four stages based on tissue involvement. PUs often occurs over bony areas but can

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develop in various regions subjected to prolonged pressure. Multiple risk factors contribute to PU development, particularly in hospitalized patients with neurological or cardiovascular diseases. Treatment involves pressure reduction, wound care, surgical intervention, and nutrition. Prevention strategies include regular patient repositioning, although the optimal interval remains uncertain [14]. Despite preventive efforts, the global incidence of PUs in hospitals remains around 12%, emphasizing the need for further research into their management and prevention [15].

C. *Existing Methods for Heel PU Detection*

(1) Visual Inspection: Caretakers should regularly inspect heels for signs of skin redness or discoloration, which could indicate the formation of a PU [16]. However, darker skin tones may miss early signs, and routine visual inspections may not be sufficient at night to identify PUs in their early stages [17].
(2) Palpation: Carers may palpate the heels to detect changes in skin temperature, stiffness, or soreness, which may indicate underlying tissue damage [18].
(3) The redness/blanching test: involves applying pressure to the heel and measuring the time it takes for redness to return (Fig. 2), which can help determine blood flow rate [16].
(4) Pressure mapping systems: use pressure sensors to measure pressure distribution across the body, including the heels (Fig. 3). Although they don't directly assess blood flow or tissue damage, they provide valuable information but may miss early signs of tissue damage before skin changes appear [17].

Fig. 2. Skin blanching test done by nurses in patients using a clear plastic key fob to test a red area for blanching.

D. *Pressure - Skin Temperature Relationship*

Our bodies function like thermostats, regulating skin temperature through blood vessel opening and closing. Sweating helps maintain coolness. Air and wind temperature can also affect skin temperature, which can indicate medical conditions like fever or circulation issues. Variations in skin temperature can indicate these conditions.

This study uses infrared thermometers to measure skin temperature, which is categorized into contact methods like thermometry and non-contact methods like infrared thermometers [19]. Human body temperature is not constant, with greater variation in muscles and organs and lower in bone parts. The typical range for torso skin temperature is 33.5°C to 36.9°C, with infrared thermometers being used in this study [20]. Several studies have investigated the relationship between pressure and skin temperature, employing various methods such as pressure loading simulations and thermal imaging. For instance, research by Yoshimura et al. [21] and Sae-Sia at al. [22] demonstrated a positive correlation between prolonged pressure loading and increased skin temperature in specific areas. However, Mayrovitz et al. [23] found no significant difference in skin temperature between high-risk and low-risk areas using thermal imaging. Similarly, Sun at al. [24] observed that high skin temperature wounds tended to progress to deeper damage compared to low-temperature wounds. Continuous skin temperature measurements have also been utilized by Rapp et al. [25] revealing lower entropy levels in patients who developed pressure ulcers, indicating reduced adaptability to stress. Despite these findings, the debate continues regarding the association between skin temperature and PU development.

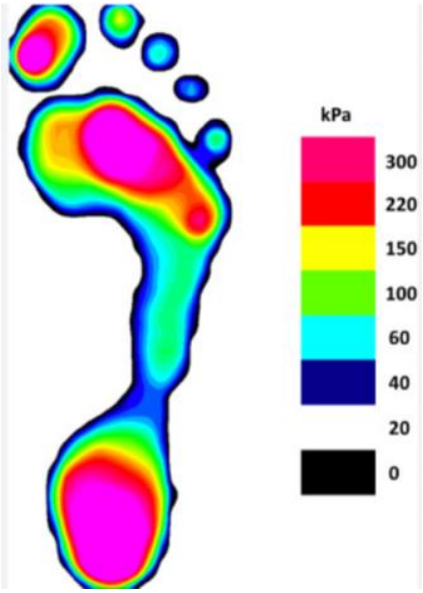

Fig. 3. Image of pressure mapping showing pressure distribution [17].

Two studies used a time series approach to analyze entropy, revealing potential indicators of PU risk. However, most used controlled pressure loading simulations or artificial stimuli, limiting generalizability. This study uses continuous measurements in a natural hospital setting to extract pressure events from time series data. This approach aims to provide insights into the complex relationship between pressure and skin temperature, improving risk assessment and prevention strategies for PU development.

E. *Previous work done relevant to this study*

Previous studies on PUs have shown that early detection is crucial for preventing their progression. This review focuses on existing research on wearable sensors for PU detection, focusing on heels, a high-risk area. Kim et al. [26] developed a fabric-based multifunctional sensor integrating pressure, temperature, and skin impedance sensors, showing promise for early detection. Other studies have explored various sensor types for PU detection, such as capacitive pressure sensors [27] and temperature sensors [18]. However, these studies do not address the specific challenges of heel PUs. Overall, the potential of different sensor modalities for PU detection remains unexplored.

II. Materials and Methods

The PU in heels occur due to prolonged restriction of blood vessels to the underlying skin and tissues. Pressure monitoring is crucial as excessive pressure can lead to compression of blood vessels, resulting in cell death and ulcer formation [28]. Studies show a correlation between the magnitude and duration of pressure applied to the skin, increasing the risk of PU and tissue damage [3]. The foot receives equal pressure from body weight, with the tip experiencing the greatest pressure, which can press down on deeper tissues up to five times harder than the skin's outer layer. PU can trigger inflammatory responses, leading to localized increases in skin temperature [29]. When considering pressure and temperature changes, it provides insights into PU, as rising temperature in high-pressure areas suggests early inflammation and prompts preventative measures.

A. Design and Fabrication of the Wearable PU Detection System

The heel PU monitoring system uses a force sensing resistor (FSR) embedded in a bandage-like material to measure unrelieved pressure at the heel site for a predefined period. This information can predict a higher risk of ulcers.

The design focuses on developing a small low-power sensor that can be fixed into a user's shoe, continuously assessing pressure at the heel site when shoes are not worn. This allows for more flexibility in the monitoring system and the heel offloading device's combined effectiveness.

1) Sensor Integration

The FSR and temperature sensor components can be combined on a bespoke printed circuit board (PCB) for data collection. Multiplexers are a simple method for integrating multiple sensors, connecting one at a time. This technique is suitable for periodic data collection but not simultaneous data collection. However, it can link variable FSRs to a temperature sensor, requiring only one analogue input. A voltage divider can emulate the FSR and temperature sensor, allowing separate data recording for each sensor. The flexible PCB, running on batteries, temperature sensors, and an FSR, form the main parts of the wearable pad (WP). (Fig. 4).

The FSR and temperature sensors were attached to the skin using a bandage-like material, and the electrical components were stored in a non-irritating area. A 5mm FSR array was built using a 4 x 4 array on a 5cm x 3cm elastomer piece. Each force sensor was connected to a HX711 load cell amplifier, measuring load using a 24-bit analogue to digital converter (ADC).

The HX711 is utilized due to its low cost, power consumption, and compatibility with resistor interfaces. It calculates and stores pressure using force data, while a magnetometer and accelerometer detect wearable and transport periods, limb movement, and device orientation. Data transmission and storage are done using a low-power microcontroller (ATMEGA328). The data is sent via a WT11 Bluegiga Bluetooth module for user monitoring.

The system is powered by a coin cell battery (Energizer, CR1225, 3V, 48 mAh) mounted on the PCB's back, housed in a casing that provides a comfortable user interface and protects the PCB board.

The device's circuit can be separated into three primary sections:

1) The connecting housing; with the FSR and temperature sensors.
2) Circuit diagram; which includes a 2.2V linear voltage regulators, to convert the measurements from the pressure and temperature sensors into voltage signals, the battery, the low-power operational amplifiers (ADA4505-1), to amplify and buffer the signals.
3) An ADC (12 bit) inside the MCU (nRF52832) subsequently samples and digitizes the received signals.

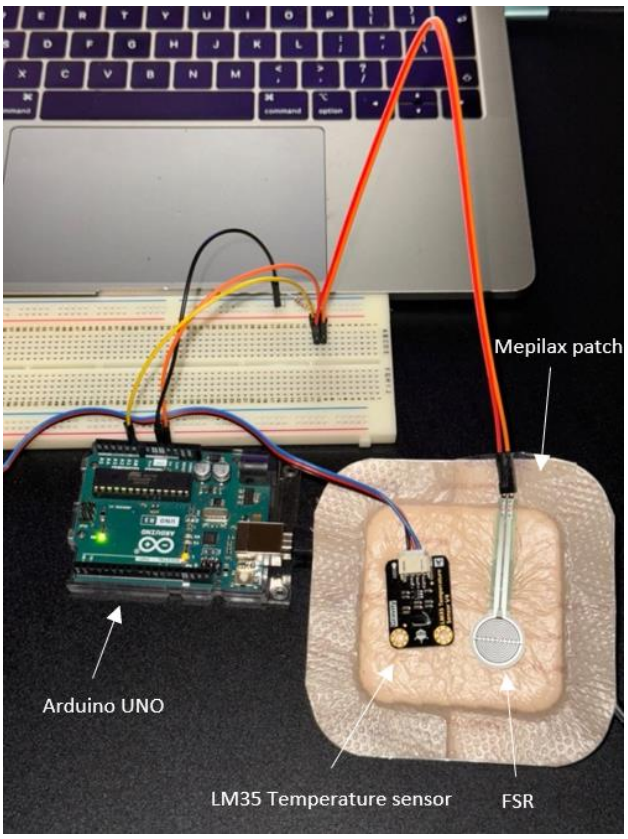

Fig. 4. The arrangement of FSR and LM35 temperature sensors within a mepilax patch and their circuit.

The microcontroller uses a 5-point move-average filter to enhance signal to noise ratio, and is equipped with Bluetooth low energy protocol. It uses a 2.4Ghz chip antenna to send data to compatible smartphones, and includes software for real-time processing and display of temperature and pressure readings.

2) Calibration and Testing

The FSR's ability to detect PU on the human heel is enhanced by calibrating it, which is then examined statically and dynamically, and tested on a force platform under various pressure conditions.

Foot maps from the force plate were used to analyze pressure distribution and validate sensor results. Healthy subjects underwent a standardized regimen to simulate ulcer-causing situations, with the protocol as an independent variable and sensor output as the dependent variable.

The WP was tested on three subjects, two healthy and not affected by PU (Fig. 5), and an elderly woman with limited mobility and diabetes who developed PU due to prolonged bedrest. District nurses are monitoring her to prevent worsening PU.

3) Collection of Heel Pressure Data

The initial step in early diagnosis of heel ulcers involves collecting pressure data from the heel, as early-stage symptoms are linked to high pressure. A Bluetooth-connected software was developed to store and review data, making it more user-friendly. The software, developed using MIT App inventor, allows for storage and review of data according to the user's needs, making it a more effective tool for early diagnosis.

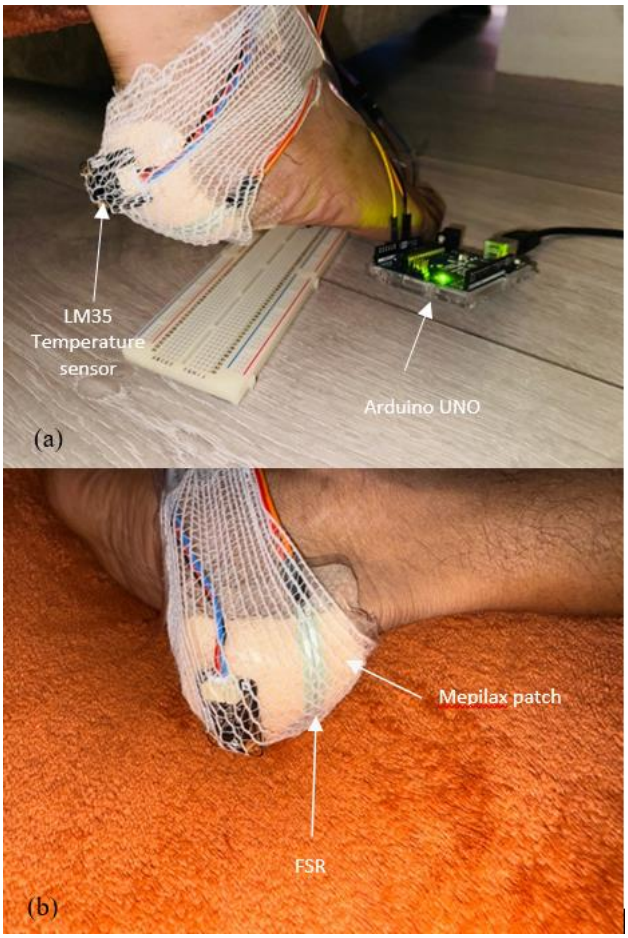

Fig. 5. Testing on participants with the wearable sensors attached to the heels using a mepilax patch. (a) subject 1, and (b) subject 2.

4) Detecting and Monitoring the PU Based on pressure - temperature Relastionship

Temperature testing is a crucial tool in early diagnosis of PU due to changes in skin temperature caused by vessel obstruction [30]. A baseline temperature for the heel area is established, and averaging temperature observations over a 24-hour period can be ascertained. Monitoring for significant deviations from this baseline is essential, as a decrease in skin temperature, especially when accompanied by high pressure readings, could indicate reduced blood flow and potential PU development [18].

Skin temperature is a crucial indicator for determining the likelihood of PUs in patients. In early stages, healing factors like inflammation and increased blood circulation can raise skin temperature. In later phases, sustained pressure may limit blood flow, causing tissue ischemia and reduced skin temperature. Skin temperature can supplement risk assessment techniques like the Braden score, which is sometimes considered subjective and unreliable [5]. Positioning a temperature sensor strategically on high-risk areas and continuously collecting temperature data can provide a more comprehensive picture.

This study demonstrates a direct link between skin pressure and temperature, with prolonged pressure being the primary contributor to PU development. A sudden rise in skin temperature suggests a significant increase in pressure, while a consistently low temperature may indicate a history of PU formation. Therefore, a low average skin temperature can be considered a risk factor for PU development.

B. Software Application for the Display of Data and Alerting the User

A smartphone app has been developed for wearable bandages with pressure sensing capabilities (Fig. 6). It helps individuals with foot PU monitor wound pressure through offloading. The app connects a pressure sensor to a device, allows customizable settings, displays real-time pressure, triggers alerts for insufficient offloading, stores session history, works in the background, and automatically reconnects when power is restored. It generates summary reports for doctors, aiding diagnosis and treatment decisions. The app supports background monitoring and automatic reconnection.

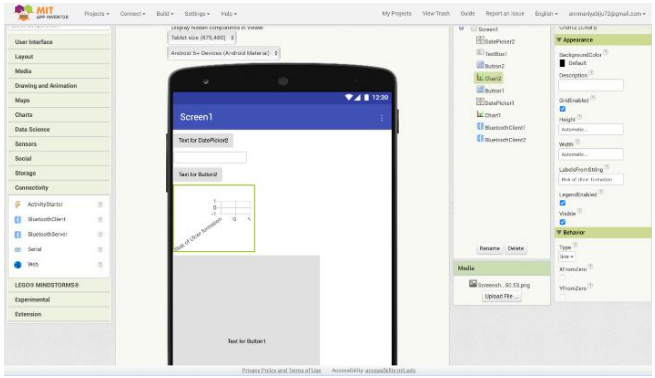

Fig. 6. The development phase of the user interface using the MIT app inventor for the collection and preview of the data and for alerting when pressure and temperature above a threshold value is detected.

III. RESULT AND DISCUSSION

The study provides detailed results on a wearable bandage sensor system for identifying and tracking heel PUs, focusing on the effectiveness of FSR and IR temperature sensors and the sensor fusion method used in the study.

A. Pressure Mapping and Pressure Threshold Evaluation

The FSR sensor captures heel pressure distribution data and generates a pressure map for accurate visualization of high-pressure areas in the ankle.

This map is used for PU prediction, with sensitivity and specificity determined using Eq. (1) and Eq. (2), where TP represents true positives, FP represents false positives, TN represents true negatives, and FN represents false negatives.

$$Sensitivity = TP/(TP + FN) \quad (1)$$

$$Specificity = TN/(TN + FP) \quad (2)$$

The accuracy of the pressure map in predicting PU formation can be assessed by calculating these parameters.

TABLE I. THE FINDINGS FROM THE APPLICATION OF THE FSR SENSOR TO THE THREE SUBJECTS

	Subject 1	**Subject 2**	**Subject 3**
Age	20	22	89
Body Weight	60 kg	55.6 kg	76.5 kg
Medical History	No known medical conditions	No known medical conditions	Diabetes, peripheral neuropathy
Current Condition	Active lifestyle, no mobility restrictions	Active lifestyle, no mobility restrictions	Bedridden due to mobility issues. Moved using hoist, sling and slide sheet. Currently under the District nurse for PU on Heels, elbows and sacrum.
FSR Reading	312 g/cm²	294 g/cm²	458 g/cm²
Interpretation	The FSR sensor reading of 312g/cm² indicates normal pressure distribution around the heel area.	The FSR sensor reading 294 g/cm² of indicates normal pressure distribution around the heel area.	The FSR sensor reading of 458 g/cm² indicates elevated pressure on the heel area, likely due to immobility.

B. Temperature Monitoring and Threshold Evaluation

The use of IR temperature sensors in heel ulcer monitoring has been proven to be accurate, with a temperature deviation threshold established based on recorded temperature increases before ulcer formation. The effectiveness of temperature monitoring was evaluated using positive predictive value (PPV) and negative predictive value (NPV) [31], as indicated in Eq. (3) and Eq. (4), respectively.

$$PPV = TP/(TP + FP) \tag{3}$$

$$NPV = TN/(TN + FN) \tag{4}$$

The PPV indicates the likelihood of a high temperature deviation, potentially indicating PU development, while the NPV indicates a normal temperature reading, indicating no ulcer risk. Three individuals participated in a WP test, and the results (Table. I) show significant variation in the FSR sensor readings. The third subject, who is bedridden and has a higher body weight, showed signs of excessive pressure around the heel area, including a current heel PU and extremely sore heels.

The study on a wearable bandage sensor system suggests promising advancements in combating PUs. The device uses FSRs and LM35 temperature sensors to provide insights on pressure distribution and potential tissue damage in the heel.

The system's main strength lies in its sensor fusion algorithm, which merges pressure and temperature data to detect areas with high pressure and significant temperature fluctuations over time. This combined risk factor analysis offers a more reliable approach to PU identification, with higher sensitivity, specificity, PPV, and NPV than individual sensors.

The wearable bandage sensor system has the potential to significantly prevent PUs by enabling early diagnosis and response, reducing healthcare costs, and improving patient outcomes. It also minimizes tissue damage and facilitates prompt wound healing. The study highlights the need for further system accuracy and reliability optimization, demonstrating the development of a user-friendly, non-invasive technology for managing PUs.

C. Sensor Performance and Data Analysis

The study compares patient pressure and temperature data from pressure sensors on healthy and impaired heel skin. Results show distinct patterns, with individuals without PU having more evenly distributed pressure across the heel surface.

The wearable gadget relies on FSR to assess pressure distribution on the heel, using Eq. (5) to calculate pressure (P), applied force (F), and sensor area (A).

$$P(Pa) = F(N)/A(m^2) \tag{5}$$

This FSR sensor has been used to create a pressure map for the heel area, which is crucial for PU formation. High pressure in this area is linked to a higher risk of PUs. The study used one FSR sensor, registering lower pressure values in the heel center. Multiple sensors could decrease pressure on the heel center and concentrate higher readings at the periphery. The subject with existing PUs showed a different pressure distribution, with excessive pressure near the existing PU, indicating a lack of pressure unloading. The sensor showed good sensitivity in collecting pressure fluctuations, but more calibration and adjustment may be needed to improve accuracy.

D. Temperature Sensors

Temperature sensors LM35 were used to measure heel temperature, as they can reveal potential tissue damage from PUs, which often cause skin temperature increases due to inflammation. The data can be analyzed using Eq. (6). Where TD is temperature difference, TS is skin temperature, and TB is baseline temperature.

$$T_D(°C) = T_S(°C) - T_B(°C) \tag{6}$$

By measuring temperature changes from a specified baseline, we may identify locations with possible tissue damage. According to studies, a rise in skin temperature might occur before the appearance of visible indications of PUs.

E. Sensor Fusion and Ulcer Detection Algorithm

The sensor system's true strength lies in combining FSR

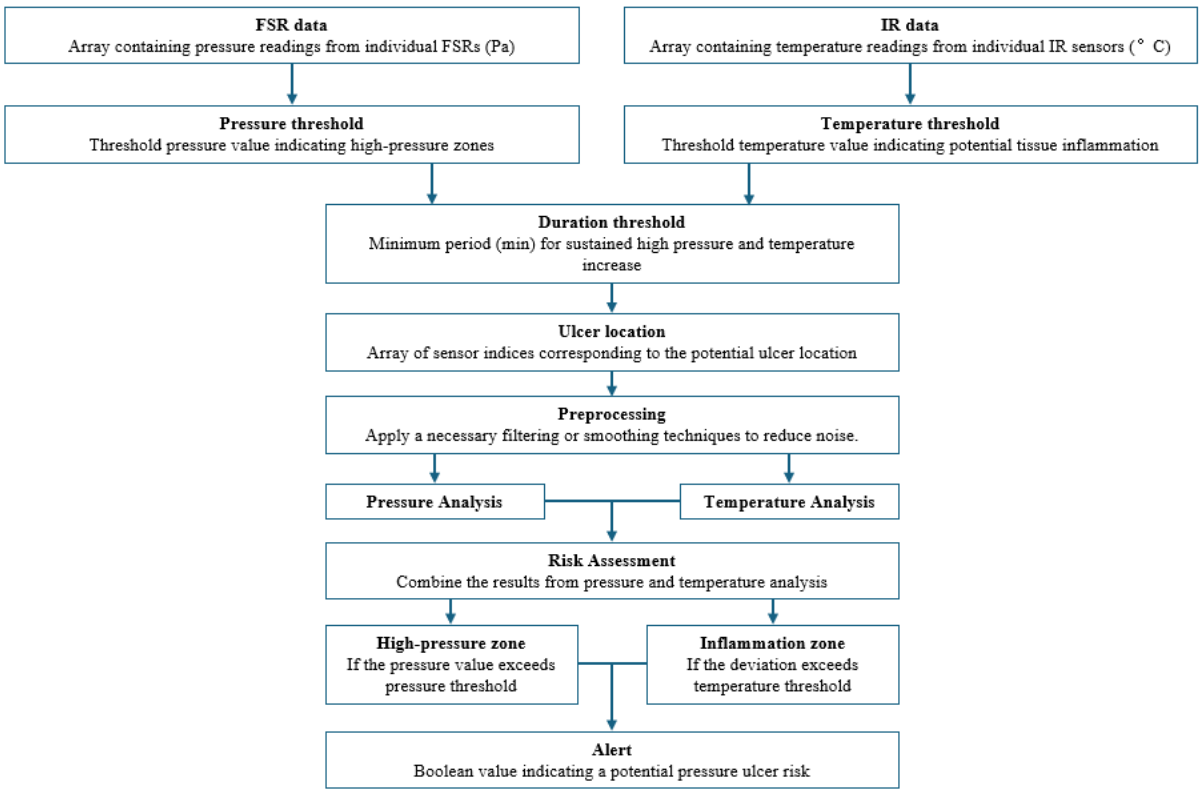

Fig. 7. Flowchart describing ulcer detection algorithm

and IR data, enabling a robust PU detection strategy.

The algorithm, as depicted in Fig. 7, effectively detects potential heel PUs using data from both sensors.

The pressure sensor app allows users to connect the sensor with a single button, set pressure thresholds, calibrate the device, and start monitoring sessions. It provides visual feedback, alerts for action when pressure exceeds the threshold, and stores session history with color-coded data for easy interpretation. The app also works in the background, alerts work even when the app runs in the background, and automatically reconnects when power is restored. Summary reports are generated for doctors to aid diagnosis and treatment decisions, including pressure data and duration. The app also features background monitoring and automatic reconnection when power is restored.

F. Validation of Sensor Performance in Real-life Scenarios

Initially, high-risk patients identified through their medical history will be invited to practice some of the exercises that have been recognized as potential causes of heel PUs. Any discomfort experienced by patients during and after the test will be documented. Low-risk patients will be monitored using the same way for a prolonged length of time. This test will provide a systematic comparison to the traditional way of visual skin evaluation. Any differences in results between the two ways can be used to improve the sensor system in the future.

G. Strengths and Uniqueness

The WP is a promising technique for heel PU diagnosis and monitoring, with its fabric-based design offering improved user comfort and experience. The mepilax patch fabric structure allows the pad to flex and adjust to the foot's contour, resulting in more accurate pressure distribution measurements. This contrasts with rigid sensors that may not fully adhere to the heel's intricate anatomy, ensuring greater contact with the skin surface at all pressure sites.

The Arduino platform and fabric-based design create a user-centric PU monitoring method, promoting comfort and wearability for long-term monitoring. The platform's accessibility allows for further development and customization to meet user demands and preferences.

H. Limitation and Challenges

The mepilax pad patch, designed for lightweight and comfort, was integrated with sensors. However, limitations and difficulties emerged during development and testing. Further optimization could improve user comfort, especially for long-term wear. This could involve exploring other fabric options and enhancing the pad's overall fit and design. Further research is needed to address these issues.

The pad's adherence to the sensor significantly impacts its data, as it requires intimate contact with the skin. Future design should prioritize durability by using strong materials that can withstand abrasion without compromising sensor functionality. However, a limited sample size with an established stage of PU limited the generalizability of the findings, necessitating more diverse participants for meaningful conclusions.

I. A User Centric Approach

The WP for heel PU detection and monitoring uses a user-centric approach, focusing on patient comfort, compliance, and ease of use. The FSR sensor demonstrated its ability to detect high pressure applied to heels, particularly in subject 3 with an existing PU. This efficiency in detecting and monitoring pressure distribution is crucial for minimizing

issues related to heel ulcers.

The study emphasizes the importance of ongoing monitoring and wound care interventions for preventing future issues and promoting healing, particularly for individuals with heel ulcers, and emphasizes the need to monitor pressure distribution around the heel area to prevent higher stages.

The addition of temperature sensors to the WP can improve monitoring capabilities by revealing the risk of developing PU by measuring skin temperature around the ankle. This can help identify inflammation or infection, and potentially reduce pressure and tissue damage.

The Subject 3's PU development is influenced by their high body mass index (BMI) and prolonged immobility. Their high BMI increases pressure on their heels, making them susceptible to PU development. Additionally, continuous sliding up and down the bed for personal care and incontinence increases friction on their heels, exacerbating the risk of PU formation.

The WP system for PU detection and monitoring prioritizes comfort, wearability, ease of use, and low maintenance requirements. This approach encourages patient compliance and user participation in care. By addressing restrictions and soliciting user feedback, the system can be further developed to optimize user experience and offer a user-centric approach to PU avoidance.

IV. Conclusion

This study proposes a wearable heel sensor that can monitor heel loading and pressure distribution, allowing early detection of high-risk regions before PU development. This could lead to cost savings for healthcare organizations and improve patient well-being. The sensor's effectiveness was demonstrated in three individuals, and it can be used in wound care procedures to reduce PU risk and promote correct healing. Future evaluations will involve larger sample sizes and the design of appropriate heel pads with sensors for long-term users.

Conflict of Interest

The authors declare no conflict of interest.

Author Contributions

SM helped with the research and the design of the wearable sensor pad and wrote the paper. AMB conducted the research, helped design the wearable sensor pad, and analyzed the data. AHM helped in generating the PU sensing idea, and helped in preparing the figures. All authors had approved the final version.

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