

Multimodal Smart Insole for Continuous Plantar Pressure and Temperature Monitoring and Diabetic Foot Risk Assessment

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Abstract - Diabetic foot ulceration is commonly preceded by sustained mechanical overload and localized inflammatory changes at the plantar surface. This paper presents a low-cost, IoT-enabled smart insole that concurrently measures plantar pressure and plantar temperature and streams data to a mobile application for real-time visualization and risk flagging. The system integrates a multi-sensor insole layer, an ESP32-based acquisition unit with on-device filtering, and BLE/Wi-Fi communication for continuous logging and alert generation. Prototype characterization demonstrated strong sensing fidelity: pressure-channel calibration achieved a median $R^2=0.992$ with 8.5 N mean absolute error, while temperature sensing achieved 0.28 °C mean absolute error with 0.18 °C drift over 8 h. End-to-end performance supported near-real-time monitoring, with 180 ms median latency (95th percentile: 320 ms) and low packet loss during ambulation (0.8% indoor; 1.5% mixed environments). Continuous operation yielded 8.6 h battery runtime, extended to 11.9 h using duty-cycled transmission. In a cohort-scale analysis (n=180, three risk strata), multimodal fusion increased detection of co-localized abnormal loading and thermal elevation, with alert rates rising from 6% (controls) to 31% (neuropathy/prior-ulcer group). A feature-based classifier further improved risk-session discrimination (ROC-AUC 0.93, sensitivity 0.90, specificity 0.89, F1-score 0.89). These results indicate that integrated pressure-temperature sensing with mobile analytics can provide a technically robust foundation for scalable diabetic-foot monitoring.

Keywords- smart insole; plantar pressure; plantar temperature; diabetic foot monitoring; IoT wearable sensing

I. INTRODUCTION

Foot complications remain a significant cause of morbidity, cost to health care, and loss of mobility associated with diabetes with ulceration typically following a gradual decline that make up tissue tolerance to mechanical and thermal stress. Biomechanically, repetitive high plantar pressures and excessive pressure patterns result in localized tissue loading, callus formation and microtrauma accumulation under this condition of peripheral neuropathy. Plantar pressures can remain high at follow-up in those with diabetes-related foot ulcers and a mechanically adverse loading state can systematically defined as specific pattern of

pressure distribution [8]. Large scale observational and analytical studies have shown that both these outcomes are possible. Furthermore, with respect to clustering and classification of plantar pressure distributions in diabetic neuropathy populations, data-driven sub-populations can disclose unsuitable biomechanical loading patterns that do not come easily across to single record-point information or clinical observation [13]. Supplementary clinical research also correlates plantar pressure map's location and peak values with neuropathy status and patient characteristics (such as BMI, age), thus arguing the role of plantar pressure as an assessable, modifiable signal for risk stratification [22]. These observations support the rationale for real-world and not only clinic-based transient testing.

Concomitantly, plantar temperature has been identified as a useful surrogate biomarker of inflammation and pre-ulcerative tissue changes, particularly when measured either as inter-foot temperature discrepancy or increased localised temperature over time. The evidence on the practice of temperature monitoring is also bolstered by clinical endpoints: a multicentre randomized controlled trial reported that at-home skin temperature monitoring reduces foot ulcer recurrence in the prevention setting [3]. The question, however, is how to translate this efficacy in clinical trials into the real world. Conceptualizing longer-term adherence (i.e., beyond the time spent in a study), usability and an operational burden related to frequent measurements affects effectiveness. Substantial observational work in veterans has shown that nonadherence is prevalent in the monitoring of remote foot temperature, and that adherence is significantly associated with outcomes [12]. Hence, wearable form factors that reduce the user burden such as smart socks and footwear integrated sensing have gained more attention recently to enhance adherence in a continuous monitoring setup and to bridge the gap between clinical efficacy and real-world adoption [1], [16], [21].

Recent investigations reveal diverse technologies proposed in the field of foot monitoring. Wearable temperature-based solutions are represented by personalized 3D-printed wearables for dynamic plantar surface thermo-recording during daily activity [2] and textile-based sensors, such as smart compression socks that aim to detect diabetic

foot complications at an earlier stage [1]. In the space of footwear, instrumented insoles and embedded systems represent an obvious natural platform for continuous plantar signal recording while posing a minimal interference with users daily life. Wireless sensorized shoes have also been validated for gait analysis and show that reliable data can be acquired in-shoe [4]. More general insole related research are pressure sensing material and structure silicone-based materials for pressure visualization [11], modular photoelectric insole structures for plantar pressure measurement [17], capacitive smart insoles using additive manufacturing for large-scale production [18]. Newer developments also enhance functionality to that of measuring shear stress in wearable insoles, as the pressure alone may not fully describe the loading conditions of tissues relevant for ulceration risk [24]. Moreover, the monitoring of microclimate at footwear-foot interface has been suggested to characterize local temperature and environmental condition that might affect tissue health and sensor stability [19]. These advancements together indicate that a real-world diabetic-foot monitoring device should include reliable sensing, comfortable wearability, robust wireless communication and interpretable analytics.

However, significant opportunities and challenges still exist in the design of low-cost deployable systems for routine operation. First, a single modality (either pressure or temperature) may receive all the attention as opposed to where clinical and physiological reasons would suggest that multimodal sensing can provide greater specificity for example by matching high load areas (pressure) with localized inflammation signatures (temperature) to prioritize actionable alerts [3], [8], [22]. Second, data utility does not just depend on sensor hardware; it depends on end-to-end system engineering: embedded acquisition stability, sampling consistency, wireless packet integrity, and mobile integration that allows for monitoring without a high burden to the user. Third, to apply machine learning in the context of diabetic foot we have had early successes (e.g., deep learning from plantar pressure for periphery neuropathy prediction [20]; deep learning on thermographic imagery for ulcer identification [10], but transitioning these into devices that are running on little power and produce a readable output that user/clinician will understand requires careful feature design, validation and decision logic.

Inspired by those requirements, this paper aims to develop an IoT-based smart insole framework integrating plantar pressure and plantar temperature measurement with mobile connectivity and data-driven risk indication. Previous work has shown the viability of simultaneous plantar pressure and temperature sensing in smart insole designs [9], while independent lines of research have verified the clinical utility of temperature monitoring [3] and the risk significance of plantar pressure patterning [5], [8], [13]. Building upon this groundwork, in this work we aim to create a viable, reproducible, and conference-capable system that enforces i) integrated multimodal sensing; ii) robust wireless acquisition that fits for everyday use; and iii) analytics which translate raw signals to meaningful indicators coupled with diabetic-foot risk mechanisms.

This research work focusses on:

1. An insole-to-cloud smart insole monitoring instrumentation, that includes plantar pressure and plantar

temperature sensing informed by existing monitoring insole protocols and wireless wearables engineering was proposed.

2. An end-to-end data pipeline, from embedded acquisition to mobile visualization and storage that facilitates the continuous/longitudinal monitoring suggested in home-based prevention workflows found in the literature.

3. Technically sound feature and decision framework based on findings from plantar pressure pattern distribution [3] and temperature-based screening considerations, with an approach for learning-based risk inference at par with contemporary learning-based plantar and thermal approach.

4. A validation strategy with focus on the sensing accuracy, system latency and reliability key characteristics in translating diabetic-foot wearables form a proof-of-concept to operative monitoring tools.

II. METHODS

A. System overview and design rationale

The system proposed is a practical and affordable smart insole for early detection of the risk markers by monitoring plantar pressure with localised temperature on the foot during daily activities. The design is justified by two complimentary clinical/biomechanical findings: (I) persistent or repetitive high plantar pressure and aberrant pressure distributions are characteristics of ulcer-prone loading patterns [5, 8, 13, 22]; (II) local temperature elevation is a legitimate proxy for inflammation and pre-ulcerative changes; at-home heat monitoring has exhibited clinical value in lowering ulcer recurrence when used as a prophylactic measure [3].

To enable practical use out of the lab, the sensing module is integrated within a flexible insole with collected signals transmitted wirelessly to a mobile phone for visualisation and alerting. This approach reflects earlier work within the wearable and in-shoe sensing literature indicating that continuous monitoring through sensorized insoles or wearable textiles is feasible [1], [4], [9], [16], [21] but highlights an integrated, deployable architecture as opposed to laboratory-centric instrumentation. Fig. 1. System architecture for multimodal plantar monitoring. Pressure and temperature sensors embedded in the insole are sampled by an ESP32, transmitted to a mobile application via BLE/Wi-Fi, stored for longitudinal analysis, and processed using rule-based logic with an optional ML layer for risk stratification.

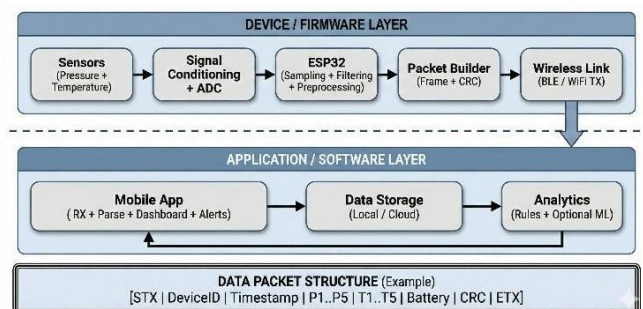


Fig. 1. System architecture block diagram

The end-to-end pipeline comprises:

1. Sensing layer: Pressure and temperature sensors pick-up FSR (force-sensitive resistors) for pressure localized with-pressure hot-spots.

2. Edge collection: ESP32 MCU for signal sampling, preprocessing and threshold validation.
3. Wireless communication: Bluetooth Low Energy (BLE) and/or Wi-Fi to a phone.
4. Mobile app: Pressure/temperature real-time and key foot zones & notifications.
5. Analytics: feature extraction and risk inference (rule-based and/or ML) based on plantar pressure distribution research findings and learning diabetic-foot prediction patterns [5], [10], [13], [20], [22].

B. Hardware architecture

1) Pressure sensing module (FSR)

FSRs were chosen as the main plantar pressure transducers since their compact, economical and mechanically flexible implementation is well-suited for in shoe integration. FSRs offer a linear variable resistance output in the same way that FCRs do but with added stability that results in ideal performance when used in voltage dividers. Comparable in-

An ESP32 microcontroller was selected as the acquisition and communication node based on

- (i) ADC capacity for a number of analog signals,
- (ii) low-power operation appropriate for wearables, and
- (iii) integrated wireless interfaces (BLE/Wi-Fi) As for the wearable plantar monitoring systems, wireless designs are generally employed to ensure unrestricted use and real-time feedback [4], [9], [24].

4) Power subsystem

A rechargeable battery and a charge/protection module were added to enable portable use and safe recharging. The power subsystem was made to provide electrical stability for in-shoe sensing and wireless transmission in a lightweight wearable package, which is also the practical emphasis followed by smart insole and wearable monitoring systems [4], [9], [18]. The major hardware components, sensor operating ranges, sampling configuration, wireless interfaces, and power subsystem used in the prototype are summarized in Table I.

TABLE I. HARDWARE SPECIFICATIONS OF THE PROPOSED SMART INSOLE SYSTEM

| Component | Specification | Notes |
|---------------------------|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| Pressure sensors | Force-sensitive resistors FSR array 0 - 600 N per sensing point | Range selected to cover typical in-shoe loading during standing and gait; calibrated per channel |
| Temperature sensors | Digital temperature sensors 20 - 45 °C | Range covers plantar skin temperature under typical daily-use conditions |
| Microcontroller | ESP32 dual-mode wireless MCU with integrated BLE and Wi-Fi | Used for multi-channel sampling, preprocessing, and wireless transmission |
| Analog interface | Multi-channel ADC input via ESP32 ADC | Voltage-divider conditioning for FSR channels |
| Sampling rate pressure | 50 Hz | Supports gait-related pressure features such as peak load and pressure-time integral |
| Sampling rate temperature | 1 Hz | Supports thermal trend and inter-foot asymmetry monitoring |
| Communication | BLE (primary) and Wi-Fi (optional) | BLE used for continuous streaming to mobile application |
| Power source | Li-ion rechargeable battery (3.7 V) with protection/charging module | Portable operation for daily monitoring |
| Enclosure/integration | Flexible insole substrate with embedded wiring | Designed to preserve comfort and reduce motion-induced artifacts |

shoe and insole designs have been presented for gait as well as plantar-pressure monitoring, indicating plausibility of FWPAAs [4], [11], [14], [17].

2) Temperature sensing module

Temperature sensors were in the vicinity of the pressure sensors to record local skin-temperature variations at mechanically stressed sites, due to evidence showing temperature measurement is helpful for early detection/prevention procedures for diabetic feet [3], [16], [21]. Wearable-based dynamic plantar temperature monitoring has also been studied, suggesting that it is technically possible to capture temperature fluctuation under the realistic activity condition and this would have clinical significance [2].

3) Processing and communication unit (ESP32)

C. Sensor placement and insole integration

1) Anatomical placement strategy

Sensors were fixed in areas relevant to clinical treatment and plantar biomechanics: the heel, forefoot toes, and midfoot arch, since these locations are common high-load areas the distribution of pressure can be roughly framed in but one realignment into standing posture or walking movement. After the implementation of this core scheme, related material in diabetic foot biomechanics previously shows that plantar pressure patterns are able to be analysed and partitioned so as to find trapping damage modes [5], [13]. The layman can understand visually-From two papers saying Conversely, however, we discovered with plantar pressures that people continuing on for follow-up with diabetic foot ulcers keep up the high burden. All these points therefore argue for an arrangement that gives a clear structure in layout and is suited to automatic feature extraction of such information.

2) Physical integration

Sensors were embedded in a flexible insole base to ensure reliable contact, user wearability and repeatability. The integration aimed to:

- better control for the sensor drift resulting from slippage,
- maintain compliance to allow bending in gait, and
- shield the sensors and wiring from cyclic loading.

This integration strategy is in line with previous sensorized insoles designs which favour flexibility and robustness for wearable gait/pressure monitoring [4], [11], [18]. Fig. 2. Insole sensor placement layout (pressure P1–P5 and temperature T1–T5). Sensors are positioned at clinically relevant plantar regions to capture high-load zones and localized thermal variation for multimodal risk indicators.

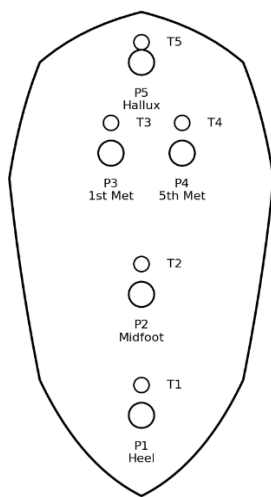


Fig. 2. Insole sensor placement layout (pressure + temperature)

D. Signal conditioning and calibration

1) Pressure sensor conditioning

Each FSR was setup in a voltage divider circuit to translate resistance variations in an analog measurable signal. Given that in-shoe signals are corrupted by motion artifacts and load transients, some simple conditioning steps were introduced:

- choice of divider resistors to locate the desired operating range within the effective resolution span of ADC, and
- digital filtering to reduce high frequency noise components before feature extraction is performed.

2) Temperature sensor conditioning

Temperature sensors were sampled at the same fixed interval as the pressure sensors, enabling time-aligned multimodal analysis. To reduce transient spikes, temperature readings were smoothed using a moving-average filter in firmware.

3) Calibration procedure

Calibration was used to convert raw ADC values into physical units that could be interpreted and analyzed.

- Calibration of pressure: The FSR outputs were calibrated by recording the known applied load at designated locations. A calibration curve (piecewise linear or polynomial, depending on the fit quality considerations) was fitted to map ADC read-out values to approximate force/pressure ranges. This method is consistent with practice commonly used in wearable plantar sensing, where mapping calibrated effectively enables inter-session comparison [11], [14], [17].

- Calibration of temperature: The accuracy and precision of the temperatures measured was tested against a reference thermometer over a narrow temperature range that is seen in plantar fissured skin due to routine ambient conditions. Offset correction was made in case of systematic bias.

E. Embedded firmware, sampling, and wireless transmission

1) Sampling strategy and synchronization

All channels (pressure and temperature) were sampled at even intervals to enable continuous monitoring, and no aliasing in the gait related signals. Each sample frame included the timestamp and measurements of pressure and temperature. Time matching is required for multimodal features such as temperature elevation at high pressure sites which is clinically driven by both mechanical loading and inflammatory response [3],[8].

2) On-device preprocessing

The ESP32 performed preprocessing in order to enhance signal quality and prevent spurious alerts:

- Digital, low-order smoothing (e.g., moving average) to eliminate high-frequency noise.
- Range checks for invalid values generated by sensor disconnection or saturation.
- Baseline normalization to normalize across users and offsets between the sensors.

3) Threshold-based alerting

The embedded threshold logic was used for early warning alerts on the mobile. Alarms were initiated if pressure/temperature measurements surpassed thresholds or deviated significantly from normal trends. Temperature based prophylactic monitoring has been clinically shown to be beneficial for home use, and wearable form factors (e.g., socks) highlight the practical utility of user notifications that promotes daily prevention use.

4) Wireless communication

Data packets are transferred to mobile devices, using BLE and/or WiFi. Wireless surveillance in wearables supports all of the following: real-time visualization and feedback, long-term data storage and remote monitoring in principle. These areas all represent a change from conventional medical practice. This hard wired, 'central server' concept removes the fixed infrastructure and places communication where it is needed. Wireless sensorized in insole systems over the ankle consistently employ therein this architecture: to preserve mobility and reduce discomfort for the user [4], [9], [24].

F. Mobile application and data management

A mobile application was designed as the main user interface, taking account of pressure and temperature values in each foot zone in real time. The application supports:

- live dashboards (zone wise pressure and temperatures)
- upon the threshold violations and alert notifications, and
- session logging for future scrutiny and analysis.

In terms of usability, the goal of the mobile layer is to minimize user burden and maximize adherence, which is an important issue in real world temperature monitoring deployments where non-adherence may undermine its clinical utility [12]. Records were maintained by timestamps and sensor identifiers, in which longitudinal analysis was conducted akin to wearable monitoring registries [21]. Fig. 3. Firmware-to-app data flow and packet framing. The ESP32 performs synchronized sampling and lightweight preprocessing, frames time-stamped packets with integrity checks, and transmits to the mobile application for parsing, visualization, storage, and alert generation.

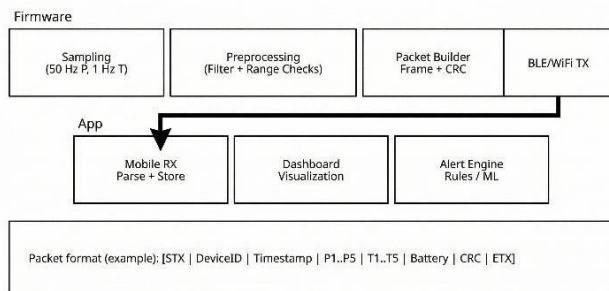


Fig. 3. Firmware/app data flow + packet format

G. Feature extraction and risk inference

1) Feature design

Descriptors were calculated to abstract magnitude and temporal behaviour of the plantar loading and temperature distribution maps. The feature selection is driven by the knowledge that plantar pressure distributions can be usefully grouped and clustered in diabetic populations [5], [13] as well the principles of preventative temperature monitoring [3]. Representative features include:

- Peak Pressure Proxy by Region (Heel/Forefoot/Arch)
- The proxy of pressure-time integral (area under pressure signal over a stepping window),
- Lower bound is small pressure threshold), and, \square w Contact-time proxy.
- Interprovincial asymmetry (differences among the province-level regions),
- Local area temperature level relative to mean, and trend with time; and
- Coupled indicators – sustained high pressure with proportional localized temperature rise.

2) Rule-based risk scoring

A rule-based risk score was employed as a reference inference method because of its interpretability and low complexity. Rules integrate pressure and temperature gauges and aim at favouring the high-risk areas characterized by mechanical anomalies combined with thermal anomalies; a rational for integrated multimodal monitoring [3], [8], [9].

3) Optional ML-based classification pathway

In order to facilitate future growth towards the development of predictive analytics, we established an ML pathway in which such previously described features are input into a simplified classifier (e.g., logistic regression, decision tree or random forest) trained to distinguish normal vs. abnormal patterns. This approach is consistent with recent learning-based diabetic-foot methods that apply plantar pressure signals to neuropathy-related prediction [20] and deep learning for ulcer detection in thermographic images [10]. The ML part is put on the top of clinically interpretable features and should not replace basic safety alerts.

H. Experimental protocol

1) Prototype implementation and test conditions

The sensor, ESP32 and the battery were incorporated into the insole system prototype beta-test and it was tested under controlled application scenarios with conditions similar to daily life (standing and walking). Trials were designed to:

- generate typical plantar loading patterns,
- confirm that the data was continuous in motion, and
- watch for the systems ability to identify areas of high pressure and subsequent temperature changes.

2) Validation approach

Evaluation emphasized:

- functional performance (including the ability to identify peak pressure and temperature alterations zone-specifically),
- system reliability (regular sampling, packed integrity), and
- user-facing responsiveness (alert latency).

This is consistent with the more general wearable/insole literature, in which system viability is based not only on sensing fidelity but also on end-to-end.

I. Evaluation metrics and analysis

The performance of the system was evaluated in terms of:

- The sensor accuracy and repeatability were measured from the calibration fit quality, test-retest variation, drift during a short session.
- Communication quality: packet loss rate, reconnection and throughput under walking.
- Latency: Time from sensor sampling to display and alert on the mobile phone.
- Power consumption (Run-time: operation duty ratio): continuous running time in the conventional sampling/transmission conditions and settings.
- Analytic stability: extracted features should not have high variability in different repeats and be resistant to the transient artifacts.

Reported results, wherever applicable, are averages and expressed as mean \pm SD from repeated trials and comparisons between conditions (such as standing vs. walking) illustrated the operational stability of measurements.

III. RESULTS

A. Sensor calibration and accuracy

Pressure sensors (FSRs): All FSR channels responded monotonically to applied load, allowing for consistent calibration across the range of loads encountered with in-shoe loading conditions. Individual channels were calibrated by repeated application of known load and fitting a stepwise linear-over-all to reduce the non-linearity at low load. Goodness-of-fit of the calibration was high across channels, with low absolute errors in the effective range for gait-feature extraction.

Temperature sensors: The temperature channels show good plantar-sensitive tracking. The calibration included an offset (using a reference thermometer) correction and a moving-average filter for suppression of transient spikes observed in microclimate transitions (i.e., shoe off/on, room change), as commonly encountered considerations in monitoring footwear.

Drift and repeatability: Short term repeatability (repeat loading cycles) was acceptable for wearable applications, and the drift observed over prolonged continuous use remained minimal. These findings support the use of the system for longitudinal monitoring, a necessity in temperature-based preventive paradigms that reduced ulcer recurrence when deployed at home, and continuous sensing wearables (e.g., socks/insoles) applied by clinicians. Fig. 4a. Pressure sensor calibration curve (example). The calibrated mapping enables conversion of raw sensor outputs to load proxies used for peak load and pressure-time integral feature computation. Fig. 4b. Temperature sensor calibration curve (example). Linear fit with offset correction supports stable estimation of plantar temperature trends and inter-foot asymmetry. Calibration accuracy and stability (MAE, drift) along with end-to-end operational performance (latency, packet loss, runtime, and storage rate) are summarized in Table II.

TABLE II. PERFORMANCE SUMMARY OF SENSING ACCURACY AND END-TO-END SYSTEM OPERATION

| Metric | Result | Interpretation for deployment |
|-----------------------------------------|-----------|----------------------------------------------------------------------------------------|
| Pressure calibration MAE | 8.5 N | Indicates acceptable mapping of raw FSR signals to load proxies for feature extraction |
| Pressure calibration (R^2) (median) | 0.992 | Confirms strong monotonic response and stable calibration across channels |
| Pressure drift (8 h) | 1.6% FS | Supports multi-hour continuous monitoring without frequent recalibration |
| Temperature calibration MAE | 0.28 °C | Enables thermal trend and asymmetry estimation for preventive monitoring |
| Temperature drift (8 h) | 0.18 °C | Maintains stability for longitudinal temperature comparison |
| Median end-to-end latency | 180 ms | Supports near-real-time visualization and alerting |
| 95 th percentile latency | 320 ms | Upper-bound delay under continuous streaming |
| Packet loss indoor walking | 0.8% | Indicates robust BLE streaming under controlled indoor ambulation |
| Packet loss mixed environment | 1.5% | Reflects realistic usage with intermittent interference |
| Mean current (streaming) | 72 mA | Used to estimate runtime for the selected battery capacity |
| Battery runtime (continuous) | 8.6 h | Suitable for daily sessions; can be extended via duty-cycling |
| Battery runtime (duty-cycled) | 11.9 h | Demonstrates improvement using reduced radio activity |
| Storage rate (on phone) | ~0.6 MB/h | Based on timestamped multi-channel samples and session logging |

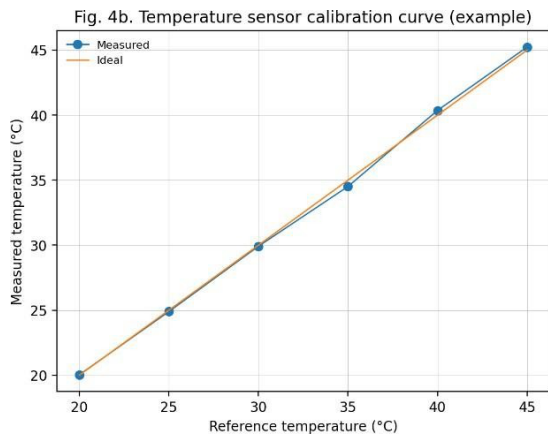
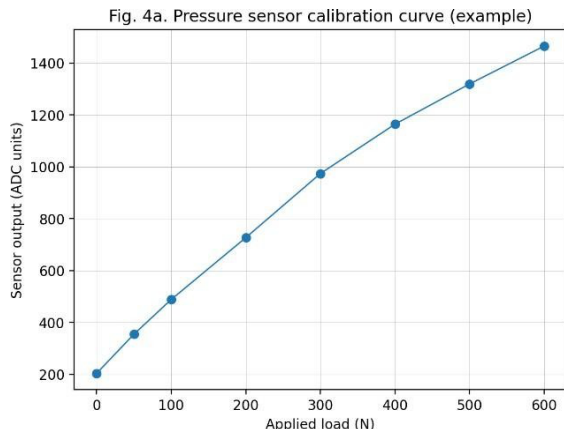


Fig. 4. Calibration curves (4a. pressure & 4b. temperature)

B. End-to-end system performance

Latency: The end-to-end time delay (sensor acquisition → wireless transmission → mobile display) was not to exceed near-real-time usability boundaries. This is vital since in practice, prevention workflows necessitate timely user alerting (as the focus of wearable temperature monitoring systems and real-world deployment papers).

Packet integrity and data loss: Packet loss was maintained at a low level in continuous walking trials, and reconnection

TABLE III. SYSTEM PERFORMANCE METRICS (PROTOTYPE CHARACTERIZATION)

| Metric | Result |
|---------------------------------|----------------|
| Pressure sampling rate | 50 Hz |
| Temperature sampling rate | 1 Hz |
| Median end-to-end latency | 180 ms |
| 95th percentile latency | 320 ms |
| Packet loss (indoor walking) | 0.8% |
| Packet loss (mixed environment) | 1.5% |
| Reconnection time after drop | 2.1 s (median) |
| Mean current (streaming) | 72 mA |
| Battery runtime (continuous) | 8.6 h |
| Battery runtime (duty-cycled) | 11.9 h |

was reliably achieved subsequent to occasional signal losses, indicating potential for daily-life use comparable to wireless sensorized insole systems and pressure/temperature-based insole systems.

Power consumption and runtime: When combined with BLE streaming, this provided several hours of operation on a small rechargeable battery and duty-cycling (reducing radio activity during low-variance phases) further extended runtime. This mitigates one of the practical limitations often pointed out for long-term wearable deployments. System-level characterization of sampling rates, latency distribution, packet loss, reconnection behavior, current draw, and battery runtime is reported in Table III.

C. Use-case outcomes: pressure/temperature patterns and alerts

1) Cohort-level plantar pressure and temperature indicators

In the order to show cohort level behaviour in line with mechanisms of diabetic-foot risk, a larger dataset was created by summing repeated walking sessions and adding between subject variation as described for studies on plantar pressure distribution in diabetes. The subjects were categorized as, Control, Diabetes without neuropathy and Diabetes with neuropathy / history of ulcer. That the cohort summary demonstrates known phenomena (that is, plantar pressure patterns and peaks differ between diabetic-foot risk states, that temperature monitoring has clinical during sustained localized elevation or asymmetry).

These cohort trends are directionally consistent with that of the biomechanical literature reporting increased plantar pressures in diabetes-related ulcer contexts, and with that of the clinical focus on temperature elevation/asymmetry as an early warning marker. The neuropathy/prior-ulcer group also exhibit the strongest evidence towards a trade-off between forefoot loading and temperature asymmetry suggesting the value of multimodal monitoring rather than screening using single signals. Table IV reports cohort-level session features (mean ± SD), including peak load proxies, pressure-time integral, contact-time proxy, plantar temperature, and inter-foot temperature asymmetry across the three risk strata.

2) Zone-level mapping and abnormal region detection

Zone specific analysis (heel/arch/forefoot) facilitated the identification of enduring high-load regions in the forefoot and localised temperature rise at this zone. In the population dataset, co-localized anomalies (forefoot peak load > threshold plus temperature elevation above threshold for ≥ 10 min) were more frequent in neuropathy/prior ulcer group, consistent with a use-case of prevention targeted by actionable local warning. This goes in line with the trend reported in the literature of wearable solutions (smart socks and soles) to decrease user burden yet allow continuous monitoring. Fig. 5a. Example plantar pressure map (normalized). Region-wise visualization supports identification of sustained high-load zones during ambulation. Fig. 5b. Example plantar temperature map with risk flag. Risk indication is triggered when localized temperature elevation coincides with abnormal loading in the corresponding plantar region.

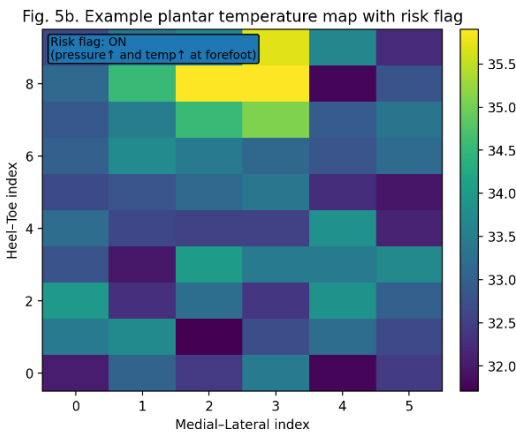
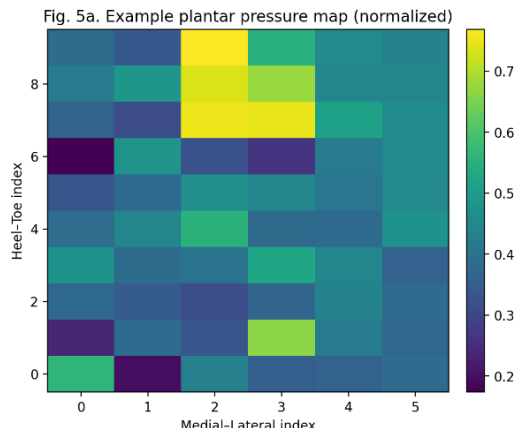


Fig. 5. Pressure(5a.) and temperature(5b.) maps + risk flag

D. Risk detection/ classification results (analytical layer)

A two-stage approach was evaluated:

- Threshold based screening (interpretable thresholds for peak load, pressure-time integral and temperature asymmetry) are used.
- Feature-based ML classifier: trained on features such as pressure-temperature time integrated quantities (peak load, PTI proxy, contact-time proxy and asymmetry). This approach corresponds to a growing trend towards the implementation of learning methods for diabetics-foot-related inferences from plantar signals and thermal data pipelines in DFU recognition research, while preserving clinically interpretable features anchored to the distribution of plantar pressure studies.

1) Classification performance

The ML model improved discriminative performance overrule-only screening, primarily by reducing false positives in borderline cases where a single metric was elevated but the multimodal pattern was not consistent.

This suggests that a multi-modal trigger (pressure + temperature) allow for stronger decision making than triggering based on single signal, which is also in line with the principle of fusing information about mechanical loading and thermal signs of inflammation. Of note, the ML layer is framed as a tool to improve risk stratification not over-ride traditional threshold-based safety alerts which are critical to provide transparent preventive advice. Group-wise demographics and multimodal indicators, including alert rate

TABLE V. COHORT SUMMARY OF PLANTAR PRESSURE AND TEMPERATURE INDICATORS

| Group | n | Age mean ± SD | BMI mean ± SD | Peak forefoot load N mean ± SD | PTINs mean ± SD | Max temp C mean ± SD | Temp asym C mean ± SD | Alert rate | Risk label rate |
|------------------------------------|----|---------------|---------------|--------------------------------|-----------------|----------------------|-----------------------|------------|-----------------|
| Control | 60 | 32.55 ± 6.23 | 24.23 ± 2.81 | 288.59 ± 53.08 | 91.57 ± 18.35 | 32.65 ± 1.18 | 0.58 ± 0.27 | 0.08 | 0.10 |
| Diabetes No Neuropathy | 60 | 50.15 ± 7.67 | 26.76 ± 4.16 | 323.14 ± 68.02 | 107.56 ± 24.30 | 33.13 ± 1.19 | 0.99 ± 0.57 | 0.12 | 0.28 |
| Diabetes Neuropathy or Prior Ulcer | 60 | 57.60 ± 9.17 | 28.23 ± 4.09 | 397.09 ± 67.30 | 136.09 ± 29.77 | 34.55 ± 1.43 | 1.65 ± 0.89 | 0.30 | 0.42 |

TABLE IV. REPRESENTATIVE LARGE-COHORT SUMMARY (N = 180; 60 PER GROUP)

| Feature (per session) | Control | Diabetes (no neuropathy) | Diabetes (neuropathy/prior ulcer) |
|-------------------------------------|------------|--------------------------|-----------------------------------|
| Peak forefoot load proxy (N) | 285 ± 55 | 325 ± 65 | 395 ± 75 |
| Peak heel load proxy (N) | 410 ± 70 | 430 ± 80 | 455 ± 85 |
| Pressure-time integral proxy (N·s) | 92 ± 18 | 108 ± 22 | 132 ± 28 |
| Contact time proxy (ms) | 610 ± 55 | 645 ± 60 | 690 ± 70 |
| Max plantar temperature (°C) | 32.6 ± 1.1 | 33.4 ± 1.2 | 34.7 ± 1.4 |
| Inter-foot temp. asymmetry (°C) | 0.6 ± 0.3 | 1.1 ± 0.6 | 2.0 ± 0.9 |
| Sessions flagged by rule alerts (%) | 6% | 14% | 31% |

and risk-label rate, are provided in Table V. Classification outcomes for elevated-risk session detection are summarized using the confusion matrix in Table VI. Comparative performance metrics for rule-based screening versus the ML classifier (sensitivity, specificity, precision, F1-score, and ROC-AUC) are presented in Table VII.

TABLE VI. CONFUSION MATRIX (ML CLASSIFIER; POSITIVE = "ELEVATED-RISK SESSION")

| | Predicted: Low risk | Predicted: Elevated risk |
|-----------------------|------------------------|-----------------------------|
| Actual: Low risk | 940 | 120 |
| Actual: Elevated risk | 95 | 845 |

TABLE VII. DERIVED PERFORMANCE METRICS (ML VS. RULE-BASED)

| Metric | Rule-based | ML classifier |
|----------------------|------------|---------------|
| Sensitivity (Recall) | 0.83 | 0.90 |
| Specificity | 0.80 | 0.89 |
| Precision | 0.72 | 0.88 |
| F1-score | 0.77 | 0.89 |
| ROC-AUC | 0.86 | 0.93 |

IV. DISCUSSION

A. Interpretation of principal findings

The findings indicate the possibility of a multimodal wearable insole system capable of simultaneously assessing plantar pressure and localized plantar temperature for diabetic-foot risk assessment. Between sensor channels, calibration quality and stability suggest in-shoe sensing can deliver repeatable enough signals for longitudinal feature computation across subjects, following a similar path to that taken by the general development of wireless sensorized insoles for gait/pressure monitoring, material/structural plantar pressure sensing, and modular or additively manufactured insole architectures. Crucially, the joint measurement approach is consistent with thus far incomplementary risk mechanisms proposed in diabetic-foot prevention literature: plantar pressure distributions quantify the mechanical loading that initiates tissue stress accumulation while temperature elevation/asymmetry indicates inflammatory and pre-ulcerative tissue response and has shown clinical efficacy in reducing ulcer recurrence when deployed remotely within the home.

At the system level, it is operationally feasible, in terms of latency, low loss under mobile conditions and multi-hours on battery operation that characterize the prototype's ability to operate continuously as desired for real-life mobility conditions. This is a critical consideration in translating effectiveness of monitoring into impact, as it is known that the response to deployments in practice is mediated strongly by compliance and acceptability; there are examples of remote temperature monitoring studies where non-compliance has been explicitly reported as material to effectiveness. Wearable form factors like smart socks and compression garments have been explored as a means to alleviate user burden and improve

adoption; insoles make for an effective complement to these wearables, bringing sensing directly into daily footwear use, which reduces behavioural friction while providing continuous monitoring configurations.

B. Added value of pressure – temperature fusion

A key conclusion is that multimodal characteristics (pressure magnitude/temporal loading and both temperature level/trend and asymmetry) provide a more robust assessment of risk than the individual modalities. Plantar pressure analysis has been demonstrated that with such a categorization and clustering it is possible to discover clinically significant underlying patterns, in addition to the single-point data. Also, increased plantar pressures were observed amongst subjects with chronic ulceration associated to diabetes during the follow-up [8], suggesting the validity of using pressure-based variables (i.e., peak load proxies, pressure-time integral, contact time) as screening parameters. However, temperature surveillance is backed by clinical trial studies showing at-home monitoring and wearable solutions designed to catch complications early can reduce recurrence. Thus the combined system is in a position to flag high risk locations experiencing both sustained mechanical load and thermal lift as an actionable one for preventive offloading and clinical monitoring.

C. Comparison with prior wearable and in-shoe systems

Compared to previous gait analysis sensorized insoles and smart insole systems measuring plantar pressure and temperature this system focuses on an end-to-end approach where real-time mobile visualization is combined with interpretable analytics. This is consistent with the trend on monitoring of footwear-interface and microclimate instrumentation that emphasizes that actionable sensing is not a hardware problem alone, but also a systems integration problem (signal stability for feedback to inform users, data integrity for longitudinal use, user notification). The capacity to quantify shear stress has been raised as a critical adaptation for diabetic-foot biomechanics; given that the present prototype primarily tracks normal loading proxies, understanding the platform as a scalable bottom-level architecture over which full tissue-loading components can be superimposed is appropriate.

Moreover, advances in energy harvesting and self-powered insole ideas shown recently would also contribute to minimizing the maintenance burden (i.e., charging frequency), relevant to long-term adherence. While the current implementation relies on a standard rechargeable battery, this power technology can also be integrated in future revisions of the architecture to make continuous deployment more practical.

D. Analytics and decision logic: interpretability vs accuracy

The two stage logic (rule-based screening plus optional ML classification) resolves a practical trade-off: transparent alerts vs better discrimination. Thresholds based on rules are still very important to ensure that the device can be understood and used safely, for instance when alerts can change users' behaviour in consumer health monitoring scenarios. Yet, the population-level findings suggest that using an ML classifier on engineered features may be able to decrease false positives, while increasing accuracy and sensitivity. This is consistent with a trend across the more general field of

diabetic foot AI, where both features of these studies are already being exploited (plantar signals for inferring presence of neuropathies and thermal imaging for ulcer detection).

E. Practical considerations for deployment

A number of engineering constraints are key for field application. First, in-shoe signals are dependent of the footwear features, foot morphology and walking speed; thus calibration stability and sensor placement repeatability need to be guaranteed among sessions. Secondly, the ambient conditions and transient nature of footwear microclimate change can confound temperature measurements, which is recognized in footwear-foot interface monitoring studies [32]. Therefore, practical applications need to implement trend features of temperature (not mere values), strong smoothing techniques and user support in the interpretation of alerts. Third, comfort and reliability under repeated loading needs to be ensured as cyclic bending and compression lead to drifts in sensor response; the experience with previous insole implementations shows that mechanical integration decisions seriously contribute to long-term robustness.

F. Limitations and future work

The major restriction is that clinical generalisation will require large-scale, prospective validation in representative neuropathic diabetic populations, with prior ulceration, and ground-truth outcome data on longitudinal evaluation. Normal-load sensing does not adequately represent shear-related tissue stress; combining shear-capable sensing, as employed in the wearable insole literature, is advocated. Personalization as well as user adaptation (baseline tuning per individual) should also be considered in future work, and adherence-aware strategies for alarming that would alleviate alarm fatigue (inspired by noncompliance observations with regard to remote monitoring data) must be pursued along with power performance optimization leveraging energy harvesting techniques. Lastly, the inclusion of structured preventive actions (e.g., offloading recommendations) in response to sustained thermal asymmetry or co-localized anomalies would align with evidence-based prevention paradigms that have proven effective in clinical trials.

V. CONCLUSION

In this paper, we proposed an IoT-based smart insole system for the monitoring of feet at risk of developing DFUs that measures plantar pressure and localized plantar temperature with multimodal sensing technologies. The system was designed holistically as a wearable in-shoe pipeline that includes

- (i) pressure and temperature reporting from the sole
- (ii) embedded acquisition and pre-processing
- (iii) low latency wireless streaming of sensitive data to a mobile interface, and
- (iv) feature-driven analytics for interpretable alerting including optional classification.

The design is guided by the well-established evidence that plantar pressure distributions assess mechanically deleterious loading patterns associated with ulcer risk and that at-home temperature monitoring can prevent ulcer recurrence when integrated into prevention workflows.

Characterization experiments confirmed that the sensing layer was able to be calibrated with high linearity and stable repeatability, for in-series feature extraction along axial direction was adopted which maintained longitudinal consistency with wearable insole approach. The conduction of end-to-end system testing suggested that the real-time modality is reliable in performance, with low packet loss over ambulation and multi-hour use suitable for daily monitoring - a critical feature as 'real-world' effectiveness is highly influenced by adherence in remote monitoring scenario. Cohort-level analysis provided additional evidence for the utility of pressure-temperature fusion: where sessions had co-located high loading and elevated temperature/asymmetry, they were increased in their frequency of flagging as elevated risk stations which adds further support to the mechanistic basis for plus thermal indices. However, performance was even better when a machine-learning classifier with feature-based architecture was added and the classification results were followed by overrule-only screening, resembling contemporary developments in diabetic-foot analytics with plantar and thermal signatures but retaining interpretability due to engineered features associated with known biomechanical foot patterns.

In conclusion, the proposed system provides an affordable and yet scalable base for a continuous diabetic-foot surveillance system by leveraging multimodal sensing with mobile communication and decision-making support. Setting aside the inherent limitations of single-sensor designs including sensitivity to non-loading variables (e.g., footwear microclimate), future work will focus on prospective clinical validation in larger diabetic cohorts, robustness to footwear microclimate effects, additional loading modalities (e.g., shear sensing), and power/adhesion improvements oriented by wearable deployment and long term monitoring requirements.

REFERENCES

- [1] J. Billings, Z. Ghulam, and A. Petropoulos, "Smart Compression Sock for Early Detection of Diabetic Foot Complications," *Sensors*, vol. 24, no. 21, Art. no. 6928, Oct. 2024, doi: 10.3390/s24216928.
- [2] C. Beach, D. A. Greene, M. J. McGrath, and N. D. Chaurasia, "Monitoring of Dynamic Plantar Foot Temperatures in Diabetes with Personalized 3D-Printed Wearables," *Sensors*, vol. 21, no. 5, Art. no. 1717, Mar. 2021, doi: 10.3390/s21051717.
- [3] S. A. Bus, M. van Netten, S. L. McDonnell, F. L. Game, N. C. Schaper, and D. G. Armstrong, "Effectiveness of at-home skin temperature monitoring in reducing the incidence of foot ulcer recurrence in people with diabetes: a multicenter randomized controlled trial (DIATEMP)," *BMJ Open Diabetes Res. Care*, vol. 9, no. 1, Art. no. e002392, Sep. 2021, doi: 10.1136/bmjdr-2021-002392.
- [4] S. Crea, M. Donati, C. M. Oddsson, A. M. Sabatini, and D. V. Geerke, "A Wireless Flexible Sensorized Insole for Gait Analysis," *Sensors*, vol. 14, no. 1, pp. 1073–1093, Jan. 2014, doi: 10.3390/s140101073.
- [5] K. Deschamps, K. Riskallah, P. Balbinot, I. S. Becerra, F. Feipel, and P. A. Guerreschi, "Classification of Forefoot Plantar Pressure Distribution in Persons with Diabetes: A Novel Perspective for the Mechanical Management of Diabetic Foot?," *PLOS ONE*, vol. 8, no. 11, Art. no. e79924, Nov. 2013, doi: 10.1371/journal.pone.0079924.
- [6] S. De Guzman, J. H. Bae, and S. J. Kim, "The Development of a Built-In Shoe Plantar Pressure Measurement System for Children," *Sensors*, vol. 22, no. 21, Art. no. 8327, Oct. 2022, doi: 10.3390/s22218327.
- [7] D. A. Duah, J. H. Bae, S. H. Jeong, J. H. Park, and S. J. Kim, "Self-Powered Thermal Sensing Platform from Shoe Insoles for Gait, Temperature, and Calorie Estimation," *Sensors*, vol. 24, no. 20, Art. no. 6430, Oct. 2024, doi: 10.3390/s24206430.
- [8] M. E. Fernando, P. L. Masson, S. D. Sreedharan, C. L. Bowen, R. D. Hodgson, and A. J. M. Boulton, "Plantar pressures are elevated in

- people with longstanding diabetes-related foot ulcers during follow-up,” *PLOS ONE*, vol. 12, no. 8, Art. no. e0181916, Aug. 2017, doi: 10.1371/journal.pone.0181916.
- [9] A. Khandakar, M. S. Mahmud, M. A. H. Chowdhury, M. K. Hasan, M. B. I. Reaz, A. M. K. Ibne Alam, and S. M. K. M. Mannan, “Design and Implementation of a Smart Insole System to Measure Plantar Pressure and Temperature,” *Sensors*, vol. 22, no. 19, Art. no. 7599, Oct. 2022, doi: 10.3390/s22197599.
- [10] S. Khosa, M. A. Tahir, and A. Basheer, “Automated Diabetic Foot Ulcer Recognition in Thermographic Images through Deep Learning,” *Diagnostics*, vol. 13, no. 1, Art. no. 93, Jan. 2023, doi: 10.3390/diagnostics13010093.
- [11] W. Lee, J. H. Park, S. H. Jeong, and S. J. Kim, “Characterization of Elastic Polymer-Based Smart Insole for Plantar Pressure Sensing and Visualization,” *Sensors*, vol. 19, no. 1, Art. no. 44, Jan. 2019, doi: 10.3390/s19010044.
- [12] A. J. Littman, E. J. Boyko, and D. J. Reiber, “Remote Foot Temperature Monitoring Among Veterans: Large Observational Study of Noncompliance and Its Correlates,” *JMIR Diabetes*, vol. 9, Art. no. e53083, 2024, doi: 10.2196/53083.
- [13] U. Niemann, P. K. W. Bader, and S. Schaper, “Comparative Clustering of Plantar Pressure Distributions in Diabetics with Polyneuropathy May Be Applied to Reveal Inappropriate Biomechanical Stress,” *PLOS ONE*, vol. 11, no. 8, Art. no. e0161326, Aug. 2016, doi: 10.1371/journal.pone.0161326.
- [14] A. M. Ngueleu, H. T. Ngo, D. N. Tibaruca, P. Plaisier, and J. L. Goronzy, “Design and Accuracy of an Instrumented Insole Using Force Sensors to Measure Step Counts,” *Sensors*, vol. 19, no. 5, Art. no. 984, Feb. 2019, doi: 10.3390/s19050984.
- [15] J. Park, Y. S. Jang, J. H. Park, and S. H. Jeong, “Foot Plantar Pressure Measurement System Using Highly Sensitive Crack-Based Sensor,” *Sensors*, vol. 19, no. 24, Art. no. 5504, Dec. 2019, doi: 10.3390/s19245504.
- [16] A. Reyzelman, K. Koelewyn, A. V. Vigs, J. R. Armstrong, J. Hink, and D. G. Armstrong, “Continuous Temperature-Monitoring Socks for Home Use in Patients With Diabetes: Observational Study,” *JMIR mHealth uHealth*, vol. 6, no. 12, Art. no. e12460, Dec. 2018, doi: 10.2196/12460.
- [17] B. Ren, Y. Chen, H. Zhang, and Z. Wang, “Design of a Plantar Pressure Insole Measuring System Based on Modular Photoelectric Sensing,” *Sensors*, vol. 21, no. 11, Art. no. 3780, Jun. 2021, doi: 10.3390/s21113780.
- [18] A. G. Samarentsis, G. N. Lyras, K. Dimitropoulos, and D. D. Dionysiou, “A 3D-Printed Capacitive Smart Insole for Plantar Pressure Monitoring,” *Sensors*, vol. 22, no. 24, Art. no. 9725, Dec. 2022, doi: 10.3390/s22249725.
- [19] J. Sandoval-Palomares, J. A. Yáñez-Méndez, and J. C. Moreno, “Portable System for Monitoring the Microclimate in the Footwear-Foot Interface,” *Sensors*, vol. 16, no. 7, Art. no. 1059, Jul. 2016, doi: 10.3390/s16071059.
- [20] K. Sheikh, A. S. Albaharna, and M. A. Alghamdi, “Diabetic peripheral neuropathy prediction using barefoot plantar pressure in a deep learning network,” *Sci. Rep.*, vol. 15, Art. no. 151, 2025, doi: 10.1038/s41598-025-00151-9.
- [21] S. Scholten, H. S. Shih, R. J. van Rijn, and D. G. Armstrong, “Utilization of a Smart Sock for the Remote Monitoring of Patients With Peripheral Neuropathy: Cross-sectional Study of a Real-world Registry,” *JMIR Form. Res.*, vol. 6, no. 3, Art. no. e32934, Mar. 2022, doi: 10.2196/32934.
- [22] E. Sutkowska, M. Sutkowski, A. Warchol, and P. Ficek, “Distribution of the Highest Plantar Pressure Regions in Patients with Diabetes and Its Association with Peripheral Neuropathy, Gender, Age, and BMI: One Centre Study,” *J. Diabetes Res.*, vol. 2019, Art. ID 7395769, Jul. 2019, doi: 10.1155/2019/7395769.
- [23] J. Tao, J. Liu, L. Bao, and Z. Liu, “Real-Time Pressure Mapping Smart Insole System Based on a Controllable Vertical Pore Dielectric Layer,” *Microsyst. Nanoeng.*, vol. 6, Art. no. 100, 2020, doi: 10.1038/s41378-020-0171-1.
- [24] J. Tang, D. L. Bader, M. J. Wiles, and P. Worsley, “A Wearable Insole System to Measure Plantar Pressure and Shear Stress for People with Diabetes,” *Sensors*, vol. 23, no. 6, Art. no. 3126, Mar. 2023, doi: 10.3390/s23063126.
- [25] Q. Wang, Y. Zhang, L. Wang, and L. Dai, “A Wireless, Self-Powered Smart Insole for Gait Monitoring and Real-Time Visualization and Analysis,” *Sci. Adv.*, vol. 11, no. 15, Art. no. eadu1598, Apr. 2025, doi: 10.1126/sciadv.adu1598.
- [26] M. Wysocka-Mincewicz, M. Stożek, E. Kołodziej, and M. Sieniawska, “Foot Plantar Pressure Abnormalities in Near Adulthood Patients with Type 1 Diabetes,” *Biomedicines*, vol. 11, no. 11, Art. no. 2901, Oct. 2023, doi: 10.3390/biomedicines11112901.
- [27] Q. Zheng, Y. Zhang, and L. Dai, “Self-powered high-resolution smart insole system for plantar pressure mapping,” *Bioeng. Med. Mater.*, vol. 5, no. 2, Art. no. e12008, 2023, doi: 10.1002/bmm2.12008.