

The use of AI-powered thermography to detect early plantar thermal abnormalities in diabetic patients: a cross-sectional observational study

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Abstract

Background: Diabetic foot problems are among the most debilitating complications of diabetes mellitus. The prevalence of diabetes mellitus and its complications, notably diabetic foot ulcers (DFUs), continues to rise, challenging healthcare despite advancements in medicine. Traditional detection methods for DFUs face scalability issues due to inefficiencies in time and practical application, leading to high recurrence and amputation rates alongside substantial healthcare costs. Human Medical Thermography presents a viable solution, offering an inexpensive, portable method without ionizing radiation, which could significantly enhance disease monitoring and detection, including DFUs.

Objective: The purpose of this study is to evaluate the efficacy of AI-powered thermography in detecting plantar thermal patterns that differentiate between adult diabetic patients without visible foot ulcers and healthy individuals without diabetes.

Methods: This prospective cohort validation study recruited a random sample of 200 patients; 100 patients were healthy, and the other 100 were diagnosed with diabetes but without a visible foot ulcer. Participants completed a baseline study questionnaire to gather initial data. Following this, a Research Assistant prepared participants for thermal imaging, which was conducted to capture plantar thermal patterns. All collected data, including thermal images and questionnaire responses, were stored on a password-protected computer to ensure confidentiality and data integrity.

Results: Participants were categorized into two groups: a healthy control group (n = 98) with no prior diabetes or PAD diagnosis and normal circulatory findings, and a diabetic group (n = 98) comprising patients with diabetes, regardless of peripheral circulatory status. Analysis of both feet revealed significantly greater differences between feet in the diabetic group compared to controls (control $0.47^{\circ}\text{C} \pm 0.43^{\circ}\text{C}$ vs diabetic $1.78^{\circ}\text{C} \pm 1.58^{\circ}\text{C}$, $p < 0.001$, CI 0.99, 1.63). These results identified clinically relevant abnormalities in 10% of the diabetic cohort, whereas no such findings were observed in the control group. We used a linear regression model to indicate that being diagnosed with diabetes is a significant predictor of abnormal temperature, while age and gender were not found to be significant predictors in this model.

Conclusions: DFUs pose a significant health risk for diabetes patients, making early detection crucial. This study highlights the potential of an AI-powered computer vision system in identifying early signs of diabetic foot complications by differentiating thermal patterns between diabetic patients without visible ulcers and healthy individuals. The findings suggest that the technology could improve early diagnosis and outcomes in diabetic foot care. Further research with larger and more diverse populations is essential to validate its effectiveness and applicability.

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Original Manuscript

The use of AI-powered thermography to detect early plantar thermal abnormalities in diabetic patients: a cross-sectional observational study

1/3/2025

CONFIDENTIAL

Abstract

Background

Diabetic foot problems are among the most debilitating complications of diabetes mellitus. The prevalence of diabetes mellitus and its complications, notably diabetic foot ulcers (DFUs), continues to rise, challenging healthcare despite advancements in medicine. Traditional detection methods for DFUs face scalability issues due to inefficiencies in time and practical application, leading to high recurrence and amputation rates alongside substantial healthcare costs. Human Medical Thermography presents a viable solution, offering an inexpensive, portable method without ionizing radiation, which could significantly enhance disease monitoring and detection, including DFUs.

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The purpose of this study is to evaluate the efficacy of AI- powered thermography in detecting plantar thermal patterns that differentiate between adult diabetic patients without visible foot ulcers and healthy individuals without diabetes.

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This cross-sectional observational study recruited a sample of 200 patients, 100 patients were healthy and the other 100 were diagnosed with diabetes but without a visible foot ulcer. Participants completed a study questionnaire to gather initial data. Following this, a Research Assistant prepared participants for thermal imaging, which was conducted to capture plantar thermal patterns. All collected data, including thermal images and questionnaire responses, were stored on a password-protected computer to ensure confidentiality and data integrity.

Results:

In this study, participants were categorized into two groups: a healthy control group ($n = 98$) with no prior diabetes or Peripheral Artery Disease (PAD) diagnosis and normal circulatory findings, and a diabetic group ($n = 98$) comprising patients with diabetes, regardless of peripheral circulatory status. Temperature analysis indicated a wider range in the diabetic group (18.1°C to 35.6°C) than in the healthy controls (21.1°C to 35.7°C), with the diabetic group showing significantly higher mean temperatures ($29.0^{\circ}\text{C} \pm 3.0^{\circ}\text{C}$) compared to controls ($28.9^{\circ}\text{C} \pm 2.8^{\circ}\text{C}$, $P < .001$). Analysis of both feet revealed significantly greater differences between feet in the diabetic group compared to controls (control $0.47^{\circ}\text{C} \pm 0.43^{\circ}\text{C}$ vs diabetic $1.78^{\circ}\text{C} \pm 1.58^{\circ}\text{C}$, $p < 0.001$, CI 0.99, 1.63). These results identified clinically relevant abnormalities in 10% of the diabetic cohort, whereas no such findings were observed in the control group. We used a linear regression model to indicate that being diagnosed with diabetes is a significant predictor of abnormal temperature, while age and sex were not found to be significant predictors in this model.

Conclusions:

DFUs pose a significant health risk for diabetes patients, making early detection crucial. This study highlights the potential of an AI-powered computer vision system in identifying early signs of diabetic foot complications by differentiating thermal patterns between diabetic patients without visible ulcers and healthy individuals. The findings suggest that the technology could improve early diagnosis and outcomes in diabetic foot care, although further research is needed to fully validate its effectiveness. The ability of the technology to detect compromised blood supply indicates its value in preventative clinical strategies.

Introduction

Diabetic Foot Ulcers

Diabetes affects 1 in 10 adults worldwide (537 million) [1]. This number is predicted to rise to 643 million by 2030 and 783 million by 2045. In the Middle East and North Africa (MENA) region, the prevalence is higher as it affects 1 in 6 adults (73 million) [1]. Despite advances in medical therapies, the prevalence of diabetes mellitus and diabetes-related complications continues to rise [2].

Diabetic foot problems are among the most debilitating complications of diabetes mellitus. It is commonly referred to as diabetic foot ulcer (DFU). The International Working Group on the Diabetic Foot defines a DFU as a break of the skin of the foot that includes minimally the epidermis and part of the dermis among patients with diabetes mellitus [3]. It is estimated that one-third of people with diabetes will develop a DFU during their lifetime [4]. Edmonds, Manu, and Vas emphasized the alarming statistic that every 20 seconds, a lower limb is amputated due to complications of diabetes, with 85% of these amputations preceded by a foot ulcer [5]. The mortality risk at 5 years for individuals with DFUs is 2.5 times higher than for those without ulcers [4]. Furthermore, Armstrong et al. revealed that DFUs and lower extremity amputations (LEAs) are not only markers of poor health but also independent risk factors associated with premature death [6].

Unfortunately, even after a DFU has been resolved, recurrence is common and is estimated to be 40% within one year, 60% within three years, and 65% within five years [4].

Economic Burden

Diabetes foot care costs are the single largest category of diabetes-related medical costs. Driver et al. found that the cost of care for patients with a foot ulcer is 5.4 times higher than that for diabetic patients without ulcers, accentuating the heightened financial burden linked to DFUs [7]. Armstrong's study further contributes to this understanding, stating that on the order of one-third of the direct costs of diabetes are attributable to care for diabetic foot disease [6]. Leveraging thermography as a screening modality for DFUs has already demonstrated a noteworthy cost-saving potential, as evidenced by the findings of Kurkela et al. [8]. Despite the requirement for human thermographers in their methodology, their study projected substantial savings through the integration of thermography as a standard procedure.

Current Challenges in Early Detection of Diabetic foot Ulcers

Unfortunately, DFUs can be difficult to detect, especially in the early stages when it is not visible to the human eye. This is due to a number of factors, including inconsistent screening guidelines, limited awareness among patients and providers, and the frequent occurrence of silent or non-standard symptoms [4, 9, 10]. To improve the early detection of DFUs, it is important to develop and implement universal screening guidelines, increase awareness among patients and providers, and develop and implement better screening tools and methods.

The Role of Thermography in Diabetic Foot Ulcer Detection

Medical Thermography results from decades of research and development in the performance of infrared imaging equipment, standardization of technique, and clinical protocols for thermal imaging [11-12]. It could visualize diseases not readily detected or monitored by other methods. It is a fast, passive, non-contact and non-invasive imaging method that has been used by numerous peer-reviewed studies [13]. There is an increase in publications and high-impact studies, emphasizing thermography's importance as a crucial tool for the early detection, prevention, and management of diabetic foot issues [14]. The American Academy of Thermology (AAT) established guidelines for the use of thermography in the evaluation of diabetic patients. These guidelines provide recommendations for the use of thermal imaging in the detection and monitoring of diabetic neuropathy, including protocols for image acquisition and interpretation [15]. Figure 1 shows the thermal images of the lower extremities of diabetic patients.

A major limitation of the current state of medical thermography is that even the most skilled human thermographer can only observe, analyze, and successfully interpret a limited number of thermograms. Computers, however, can process an image efficiently and extract useful information. Leveraging Artificial Intelligence (AI) algorithms, specifically, computer vision, can objectively observe the findings and minimize inter-observer variability.

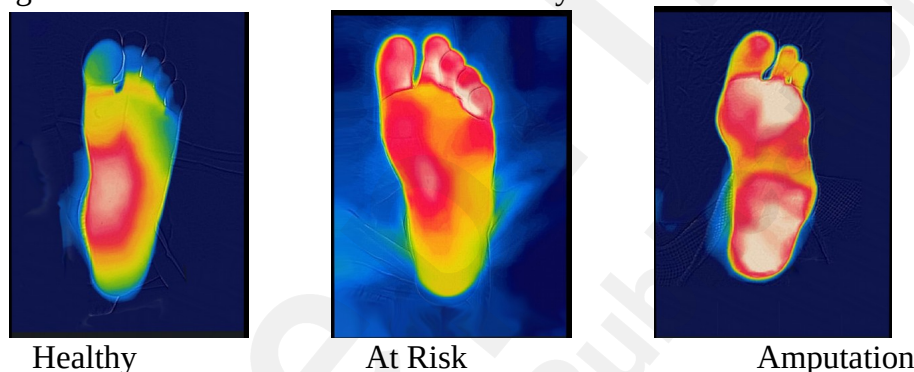


Figure 1: Typical thermal images of plantar region for healthy, at risk, and amputated patients.

Thermography is helpful for the early detection of abnormalities of the foot by analyzing asymmetries and local temperature changes over time. Assessing temperature differences can enable the early detection of ulcers [16-17]. The application of thermal imaging for the detection of diabetic foot complications is based on the premise that variations in plantar temperature are associated with these types of complications [17-24]. Several articles highlighted that high temperature gradients between feet may predict the onset of foot ulcers [25- 28]. Furthermore, the international working group of diabetic foot recommends a person with diabetes who is at moderate or high risk of foot ulceration to self-monitor foot skin temperatures once per day to identify any early signs of foot inflammation and help prevent a foot ulcer [29].

The rapid development of handheld smartphone-based thermal infrared imagers presents a creative solution for detecting and monitoring DFUs [30]. To address the lack of thermographers, practical AI algorithms are needed to automate the process of image acquisition and analysis. These rapidly expanding, low-cost, and widely available resources can help predict one's risk of developing foot ulcers, potentially saving limbs and lives. In this study, we will leverage AI technologies that are deployed on a smartphone-based thermal imager and application.

Rationale for the study

The purpose of this study is to evaluate the efficacy of AI- powered thermography in detecting plantar thermal patterns that differentiate between adult diabetic patients without visible foot ulcers

and healthy individuals without diabetes.

Methods

Study design

This is a cross-sectional observational study

Study timing

The data collection phase spanned from June 2023 to February 2024. This timeframe was sufficient to recruit people into both the healthy and individuals without diabetes groups.

Study location

Participants were recruited from King Khalid University Hospital, part of the King Saud University Medical City, a multi-disciplinary facility offering general and subspecialty medical services, including primary, secondary, and tertiary care. Patients with diabetes were consecutively recruited from the diabetes clinics during the study period, reflecting real-world clinical practice. Healthy participants, on the other hand, were recruited from those visiting the hospital for routine check-ups or preventive care during the same period. All eligible individuals meeting the inclusion criteria were invited to participate, ensuring representativeness of the control group. A research assistant (RA) was present to facilitate recruitment and collect the necessary data. This consecutive sampling approach ensured that all eligible patients attending the clinic were considered for participation.

Inclusion criteria

The study included participants who:

- Over 18 years old.
- Healthy individuals, with no history of diabetes or cardiovascular disease (n=100).
- Have been diagnosed with diabetes (n=100).

The inclusion of healthy participants as controls allowed for clear differentiation between diabetic and non-diabetic thermal patterns, emphasizing the distinct thermal asymmetry observed in diabetic patients.

Exclusion criteria

Eligibility for participation was assessed through self-report during recruitment. The study excluded participants who:

- Have a visible foot pathology, such as visible ulcers, infections, or amputations.
- Are unable to stand without assistance due to the higher risk of falling or injuring themselves during the study.

Participants who meet the inclusion criteria and are willing to participate were asked to provide their informed consent.

Withdrawal of participants from the assessment

Participants were free to withdraw from the study at any time without giving a reason. Patients were advised that if they requested to withdraw from the study, at any time during the trial, then this would have no negative consequences.

Description of the technology

We have created a non-invasive system to identify diabetic foot complications at an early stage. We leverage off-the-shelf thermal cameras, compatible with smartphones or tablets, to capture detailed thermal images of Participants' feet (see figure 2). We also used AI based algorithms to perform semantic segmentation and reduce sensor noise in the captured thermograms. The AI models were trained to extract the plantar region as the region of interest and suppress any background or sensor noise. In addition, the AI was able to detect asymmetric thermal emission of 2.2°C or greater which can be indicative of pathology in a properly cooled participant [3, 15, 26, 28, 31, 32].

The system utilized AI to process images efficiently and extract useful information. It made the findings more objective and minimized inter-observer variability. This could result in faster throughput and through a centralized cloud-based processing where samples were anonymized by removing identifiable information from the data., increasing thermographic accuracy and reliability. The technology analyzes thermal images captured from specific thermal camera models, the FLIR ONE Edge Pro. We selected the FLIR One Edge for its practicality and ease of use in clinical settings. While its resolution is lower than the AAT recommendation of 320×240 pixels, several studies have successfully used the FLIR One, which has an even lower resolution of 80×60 pixels, and concluded that it can effectively capture thermal signals indicative of diabetic foot ulcers [31, 33, 34]. The software identifies temperature variations consistent with inflammation and ulcerative patterns, signaling potential DFUs. The system records, stores, and transmits usage events from thermal cameras to a remote storage system.



Figure 2: Thermal Imaging Device.

Data Collection

Before enrolling participants, the RA was trained to follow the study protocol, including participant recruitment, questionnaire administration, and thermal image capture. The RA completed a questionnaire via an application that included questions about the participant's age, sex, type of

diabetes, duration of diabetes (years), HbA1c, BMI, physical activity habits, smoking habits, and history of hypertension. In addition, they completed Inlow's 60-second Diabetic Foot Screen to assess the foot [35]. After completing the questionnaire, the RA prepared the participant and completed the thermal imaging.

Experimental equipment and procedure

The results of infrared thermography can be influenced by various environmental, individual, and technical factors that affect human skin. To obtain accurate results, the thermal images of the participants in the study were carried out in compliance with the protocols and guidelines set by the American Academy of Thermology [15].

To maintain a stable blood flow to the feet, we asked participants to remove their shoes and socks and sit with their legs hanging freely for at least 10 minutes before the measurements were made. We maintained the humidity in the room to ensure that there is no moisture build-up on the skin, perspiration, or vapor levels that can interact with radiant infrared energy. Relative Humidity below 70% is generally acceptable. The temperature was kept between 19–25 °C. The camera was set about one meter from the foot (the region of interest will fill ~75% of the image), and thermal masking was employed to ensure a homogeneous background. Images of the plantar aspect of the feet were recorded for analysis.

Ethical Considerations

Ethical approval for this study was obtained from King Saud University Institutional Review Board (E-23-7866). Before agreeing to participate, all participants were informed about the nature of the research project, possible risks and benefits, and their rights as research participants. All participants completed a written consent form. They were also given a copy of the consent form. No compensation provided to participants. This decision was communicated to participants during the consent process, ensuring complete transparency.

Participants were coded with a specific clinical investigation identification number. All participants were registered in a participant identification list (participant enrolment and identification list) that connects the participant's name and personal number with a clinical investigation identification number. All data was registered, managed, and stored in a manner that enables correct reporting, interpretation, and verification.

Statistical Analysis

A database of the questionnaire results was created using unique non identifying numbers. The information is password-protected. Before conducting the analysis, data was cleaned and coded using Python Pandas Numpy and Scipy packages. Each item was discussed, and a decision concerning its eligibility and entry was made. The characteristics of participants are summarized with percentages for categorical variables and mean (Standard Deviation) values for continuous variables. To compare the mean ages and BMI values between the healthy and diabetic groups, independent two-sample t-tests were conducted. For categorical variables, such as sex and health conditions, we used two-proportion z-tests to compare both groups.

For the correlation analysis, the foot skin temperature obtained is the average for the entire plantar region. We used the independent t-test and the effect size (Cohen's d) to compare foot skin temperature in healthy participants versus diabetic participants. The level of significance is set at $p < 0.05$.

In addition, we conducted an Ordinary Least Squares (OLS) regression to examine the relationship

between the temperature delta (difference in plantar temperatures between feet) and several predictor variables. The primary predictor of interest was diabetes status (healthy vs diabetic). To control for potential confounders, the model also included age, sex, BMI, physical activity level, diabetes duration, diabetes type, HbA1c, and the presence of retinopathy.. The OLS regression analysis was conducted to determine the significance and strength of the predictors in explaining the variance in the temperature delta. Statistical significance was set at $p < 0.05$.

While we did not perform a formal sample size calculation prior to the study, our sample size of 200 participants (100 individuals with diabetes and 100 healthy controls) was determined based on practical considerations, including the availability of eligible participants during the study period and the resources at our disposal. We aimed to ensure that the sample was sufficiently large to capture variability in thermal patterns between the two groups and to allow for meaningful statistical analyses. To support the adequacy of our sample size, we reviewed several related studies [17, 19, 21, 24], many of which employed smaller sample sizes while investigating similar research questions.

Results

Participant Characteristics

Participants were divided into two groups. Individuals with normal circulatory findings and with no earlier diagnosis of diabetes or Peripheral Artery Disease (PAD) were assigned to the healthy control group ($n = 98$). All patients with diabetes, with or without peripheral circulatory disturbance, were assigned to the diabetic group ($n = 98$). It is important to note that the diabetic group did not have a visible foot ulcer. Approximately 61% (119/196) of participants were female, with a mean age of 39.2 ± 15.5 years. The average BMI was 26.4 ± 5.6 kg/m². There was a significant difference between both groups and the diabetic group was slightly older and had a higher BMI. Diabetic patients exhibited various comorbidities: cardiovascular disease (16.9%, 33), retinopathy (15.4%, 30), neuropathy (11.8%, 23), and peripheral vascular disease (12.8%, 25). Furthermore, 15.9% of diabetic patients reported poor glycemic control. The diabetic group included 57.14% with Type 1 diabetes ($n=56$) and 41.84% with Type 2 diabetes ($n=41$), with a mean diabetes duration of 15.38 years (SD 8.99). The mean HbA1c level was 7.37% with a standard deviation (SD) of 1.56%. Table 1 illustrates the participant characteristics.

Table 1. Participant characteristics (N=196)

Variables	Total (196)	Healthy group (98)	Diabetic group (98)	P value	95% CI
Age, mean (SD)	39.3(15.5)	33.2 (11.2)	45.7(16.8)	<0.05	8.4, 16.5
< 25 years	21.7(1.7)	22.05(1.3)	21.1(2.1)	>0.05	-2.1, 0.3
25- 40 years	31.2(4.8)	30.7(4.7)	32.6(4.6)	>0.05	-0.3, 4.3
> 40 years	55.4(10.3)	51.1(7.6)	57(10.7)	<0.05	0.8, 11.1
Body Mass Index,	26.4 (5.6)	24.31 (4.1)	28.75 (6.2)	<0.05	2.9, 5.9
Males, n(%)	76(38.7)	38 (38.7)	38 (38.7)	>0.05	-13.7, 13.7
Females, n(%)	120(61.2)	60 (61.2)	60 (61.2)	>0.05	-13.7, 13.7

Cardiovascular disease, n(%)	33 (16.8)	0	33 (33.6)	<0.05	-44.2, -23.1
Retinopathy, n(%)	30 (15.3)	0	30 (30.6)	<0.05	-40.7, -20.4
Neuropathy, n(%)	23 (11.7)	0	23 (23.4)	<0.05	-32.5, -14.4
Peripheral vascular disease, n(%)	25 (12.7)	0	25 (25.5)	<0.05	-34.9, -16.1
Diabetes Type		N/A	N/A	N/A	N/A
Type 1, n(%)	56 (57.14)				
Type 2, n(%)	41 (41.84)				
Other, n(%)	1 (1.02)				
Duration of Diabetes, mean (SD)	15.38 (8.99)	N/A	N/A	N/A	N/A
H1bAC	7.37 (1.56)	N/A	N/A	N/A	N/A
Physical activity					
Never n(%)	63 (32.14)	39 (19.9)	24 (12.24)	<0.05	0.02, 0.28
Several times a week n(%)	21 (10.71)	7 (3.57)	14 (7.14)	>0.05	-0.15, 0.01
Rarely n(%)	58 (29.59)	30 (15.31)	28 (14.29)	>0.05	-0.10, 0.14
Once a week n(%)	14 (7.14)	9 (4.59)	5 (2.55)	>0.05	-0.03, 0.11
Daily n(%)	40 (20.41)	13 (6.63)	27 (13.78)	<0.05	-0.25, -0.03

Thermographic Analysis

The temperatures spanned a wider range in the diabetic group than in the healthy control group, with a range of 18.1°C to 35.6°C in the diabetic group and of 21.1°C to 35.7°C in the control group. The mean temperatures were significantly higher in the diabetic group than in the control group ($P < .001$). Considering both feet as one bloc, the mean temperatures were 28.9°C $\pm$ 2.8°C among controls, and 29.0°C $\pm$ 3.0°C ($P < .001$) in the diabetic group.

Side-to-side comparisons of temperatures revealed significant differences between feet ($P < 0.05$) at all measurement sites (Table 2). Analysis of both feet revealed significantly greater differences between feet in the diabetic group compared to controls (control 0.47 °C $\pm$ 0.43°C vs diabetic 1.78 °C $\pm$ 1.58 °C, $p < 0.001$, CI 0.99, 1.63). These results identified clinically relevant abnormalities in 10% of the diabetic cohort, whereas no such findings were observed in the control group.

Table 2. Absolute Values of the Between-Foot Temperature Differences in Healthy Control Participants and Participants With Diabetes.

Region mean (SD)	Total (196)	Healthy group (98)	Diabetic group (98)	P value	95% CI
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Lateral calcaneal artery	1.182 (1.37)	0.496(0.44)	1.87(1.62)	<0.05	1.04, 1.71
medial calcaneal artery	1.197(1.29)	0.57(0.47)	1.81(1.53)	<0.05	0.92, 1.56
lateral plantar artery	1.169(1.30)	0.54(0.49)	1.79(1.54)	<0.05	0.92, 1.57
medial plantar artery	1.128(1.29)	0.49 (0.45)	1.76 (1.52)	<0.05	0.96, 1.60
Entire plantar region	1.13(1.33)	0.47(0.43)	1.78(1.58)	<.005	0.99, 1.63

Regression Analysis of Thermographic Predictors

This analysis examines the relationship between the temperature delta (dependent variable) and the predictor variables (age, sex, BMI, diabetes duration, diabetes type, HbA1c, and physical activity, and whether the participant was healthy or diagnosed with diabetes). The results of the OLS regression analysis are summarized in Table 3.

The overall model was not statistically significant (F-statistic = 1.010, $p = 0.457$), indicating that the predictors collectively explained only a small proportion of the variance in the temperature delta. The R-squared (uncentered) value was 0.224, and the adjusted R-squared (uncentered) was 0.002, suggesting a weak fit of the model to the data.

However, diabetes status remained a statistically significant predictor of temperature delta ($\beta = 5.544$, $p = 0.017$), with a 95% confidence interval of [1.064, 10.024]. This confirms that diabetic participants had significantly greater foot temperature asymmetry compared to healthy participants, even after adjusting for potential confounders. Retinopathy also emerged as a statistically significant predictor ($\beta = 1.3676$, $p = 0.039$), with a 95% confidence interval of [0.075, 2.660], indicating that participants with retinopathy exhibited greater temperature asymmetry than those without. This finding highlights a potential link between microvascular complications and thermal abnormalities, consistent with the established connection between diabetic retinopathy and peripheral microvascular dysfunction.

In contrast, age ($\beta = -0.0165$, $p = 0.454$), sex ($\beta = -0.5768$, $p = 0.285$), BMI ($\beta = 0.0366$, $p = 0.375$), physical activity ($\beta = -0.1464$, $p = 0.367$), diabetes duration ($\beta = -0.0440$, $p = 0.217$), diabetes type ($\beta = -0.0264$, $p = 0.966$), and HbA1c ($\beta = -0.1430$, $p = 0.382$) were not statistically significant predictors of temperature delta in this model.

These results suggest that diabetes status itself is the strongest predictor of thermal asymmetry, while retinopathy provides an additional clinically meaningful signal. These findings suggest that plantar thermography may capture microvascular abnormalities relevant to broader diabetic complications.

Table 3. Regression Analysis of Predictors for Between-Foot Temperature Differences

Predictor	β	SE	t value	P value	95% CI
Intercept	-	-	-	-	-
Age	-0.0165	0.022	-0.756	0.454	[-0.060, 0.028]
Diagnosed with diabetes	5.544	2.220	2.498	0.017	[1.064, 10.024]
Gender	-0.5768	0.532	-1.084	0.285	[-1.651, 0.497]
BMI	0.0366	0.041	0.897	0.375	[-0.119, 0.046]

Physical activity	-0.1464	0.161	-0.911	0.367	[-0.471, 0.178]
Diabetes duration	-0.0440	0.035	-1.253	0.217	[-0.115, 0.027]
Diabetes type	-0.0264	0.611	-0.043	0.966	[-1.259, 1.206]
HbA1c	-0.1430	0.162	-0.884	0.382	[-0.470, 0.184]
Retinopathy	1.3676	0.641	2.135	0.039	[0.075, 2.660]

β: Coefficient; **SE:** Standard Error; **CI:** Confidence Interval

Discussion

Principal Findings

This study has indicated that the technology can objectively detect an abnormal thermal pattern in adult patients with diabetes without visible foot ulcers when compared to healthy individuals without diabetes. This abnormal heat signature could indicate the presence of a DFU. The skin temperature was significantly different between participants with diabetes and the healthy control group, and the blood skin surface temperature of patients with diabetes was higher than that of the healthy control group. In addition, the technology was able to reveal differences between angiosome areas, as outlined in table 2. None of the healthy individuals exhibited a temperature delta of 2.2°C or greater, whereas a subset of diabetic patients did, highlighting the distinct thermal patterns associated with diabetes.

In addition to diabetes status, our analysis revealed that retinopathy was significantly associated with greater foot temperature asymmetry. This finding is clinically meaningful, as retinopathy reflects underlying microvascular dysfunction, which may also contribute to impaired circulation and thermal regulation in the feet. This reinforces the concept that diabetic complications are interconnected, and thermography could serve as a non-invasive window into broader microvascular health.

The technology offers a promising approach to identifying early signs of DFUs before these ulcers become visible without specialized tools. This capability implies that it could serve as an effective early warning system, potentially allowing for preventive measures to be taken before the condition worsens and becomes more challenging to treat.

Comparison With Previous Work

Using technology to predict foot ulcers could play a vital role in the management of diabetes. Several studies have assessed the effectiveness of thermology in detecting

abnormal temperature patterns among patients with mild diabetes [19, 20, 28]. It has been shown that the peripheral vessels and nerves are damaged producing an irregular thermoregulation of both feet [23, 36]. However, there is a lack of prospective studies that used AI powered thermography technology to detect these abnormal patterns.

Some of our findings confirm those previously reported in the context of using a human thermographer to detect DFUs. Our findings are in agreement with those of Ilo et al., [20], Zhou et al. [19], and Armstrong et al. [28], who concluded that thermography revealed local temperature differences in high-risk diabetic feet. However, these studies relied on a human thermographer to do the analysis while we leveraged an automated AI-powered software. It is the novel part of the current study.

Strengths and Limitations

The RA who was collecting the data was blinded to the results of the technology. An independent analyst compared the data between the diabetic and healthy groups. The use of AI and portable thermal cameras could enhance access to thermology and diabetic foot screening. It could also improve access throughout sparsely populated rural areas as they can access information remotely.

A limitation of this study is that the diabetic population was not specifically stratified based on the duration of diabetes or presence or absence of PAD. However, we did include self-reported data on PAD to mitigate its potential impact. While this approach might not be as robust as clinical verification, it helps to ensure that any effect on the thermal imaging results is minimal. Although attempts were made to diversify recruitment, the findings should be interpreted with caution regarding their applicability to other racial or ethnic populations. Thus, studies with different ethnic populations should be performed. Another limitation of this study is that it was clinic-based and hence there could have been some referral bias in the selection of the participants. Finally, the sample size was relatively small and we lack a formal sample size calculation. In future research, we plan to perform formal sample size estimations based on preliminary data or expected effect sizes to enhance the statistical power and reliability of our studies. Nevertheless, despite these constraints, the outcomes imply that thermal imaging could serve as a beneficial supplementary resource within primary healthcare clinics.

Implications for Practice and Future Research

The study aims to provide evidence of differences in plantar thermal patterns detected by computer vision between adult patients with diabetes without visible foot ulcers and healthy individuals without diabetes. The use of thermography is increasingly gaining importance in the early detection of DFUs [18- 20]. Ilo et al. (2020) highlighted how thermography can adequately pinpoint local hotspots in diabetic patients, aiding in uncovering subclinical infections and discovering areas of high plantar pressure,

where early identification is key to effective management [20]. Furthermore, Armstrong et al. found that thermography could provide early clinical insights before visible signs of foot ulcers [28]. We have included a temperature analysis image (Figure 3) to illustrate how the system identifies areas of concern, including the angiosome divisions. This detailed representation allows individuals with diabetes and their healthcare providers to focus on specific regions of the foot for targeted care and monitoring. Several researchers recommend regular thermogram assessments for diabetic patients, even in those with controlled diabetes, since high glucose levels can damage blood vessels and nerves at any time [23, 28, 36].

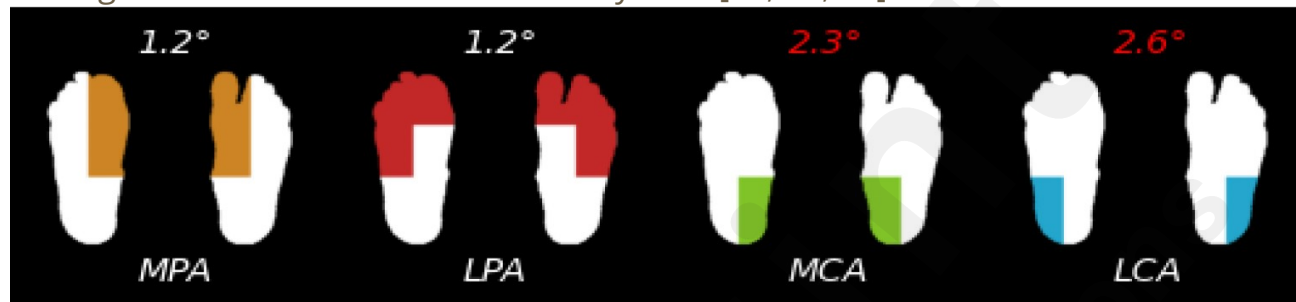


Figure 3: Asymmetry Divided by Angiosomes.

Early active intervention can significantly lower the incidence of foot ulcers and amputations in people with diabetes [37]. Therefore, it is essential to diagnose and treat DFUs early. An annual foot exam for people with diabetes is recommended to find high-risk conditions. Depending upon findings, more frequent assessments may be required, as recommended by the International Working Group on the Diabetic Foot [29]. Patients should receive professional diabetic foot care if they have one or more high-risk foot conditions [38]. Many pharmacological and non-pharmacological interventions are available to promote blood circulation in diabetic feet.

This study provides insights into the effectiveness of the technology in identifying early signs of DFUs. The key advantage of the technology is that it leverages core thermography principles while eliminating the need for a specialized thermographer. This attribute significantly enhances its utility, enabling a broader range of healthcare practitioners to employ this technology. The system could automatically generate a report of the findings and share it with the healthcare providers or the patient. If thermography shows a compromised blood supply to a specific angiosome in patients with diabetes, we can focus more on preventing the development of diabetic ulcers in that area. Health care providers can view the data to determine if additional testing or procedures are necessary to avoid foot complications or amputations. If an intervention is carried out at an early stage, it is expected that serious foot complications can be prevented and treated [17, 19, 20]. The integration of the technology into clinical practice has the potential to offer a more accessible, efficient, and effective approach to managing the risks associated with DFUs.

We are conducting additional studies to compare AI-based thermography with the assessment of a healthcare professional. In addition, future studies should examine skin temperature maps, and how they correspond with patient symptoms, conditions,

and disease stages. A larger and more heterogeneous sample with a longer follow-up period could confirm the study findings and expand the knowledge around the effectiveness of the technology in predicting DFUs. In addition, future studies should evaluate the feasibility of the technology as a complementary diagnostic tool or screening test for DFUs. It's important to conduct further studies to better understand the relationship between the unusual heat signatures that were detected and the actual development of DFUs. Understanding this connection could significantly enhance our ability to predict and prevent these ulcers, improving patient outcomes and reducing the need for more invasive treatments.

Conclusion

Diabetic foot ulceration significantly impacts the morbidity and mortality of patients with diabetes, with early detection being crucial in limiting its progression and the potential for amputation. This study introduces the use of AI as an effective tool for early detection. It validated a system that detects plantar thermal patterns, distinguishing between healthy individuals and diabetic patients without visible ulcers, to demonstrate its potential in identifying early diabetic foot complications. Our findings indicate that the technology can distinguish between the thermal patterns of diabetic patients and healthy individuals, highlighting its capability to enhance early diagnosis and outcomes in diabetic foot care. It can identify compromised blood supply in diabetic patients which suggests that it could play a crucial role in targeted prevention strategies in clinical practice.

Data Availability

The data sets generated during this study are not publicly available due to the confidential nature of the information but are available from the corresponding author on reasonable request.

Author Contributions

MFA, MA, ASA, IA, MT, & AJ: ideation, design, conceptualization, methodology, analysis, and interpretation. AA & AAA: recruitment of participants. All authors met the ICMJE criteria for authorship, contributed equally to the subsequent preparation of the manuscript, wrote the initial draft, critically reviewed the manuscript, and reviewed and accepted the final version of the manuscript.

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Conflict Disclosure

The Seha Virtual Hospital, which is part of the Saudi Ministry of Health, and Amplifai Health sponsored this study. MFA and MA are full-time employees and shareholders of Amplifai Health. All authors have reviewed and approved the final version of this manuscript."

Acronyms

AAT: American Academy of Thermology

AI: Artificial Intelligence

DFU: diabetic foot ulcer

LEA: lower extremity amputation

MENA: Middle East and North Africa

OLS: Ordinary Least Squares

PAD: Peripheral Artery Disease

RA: research assistant



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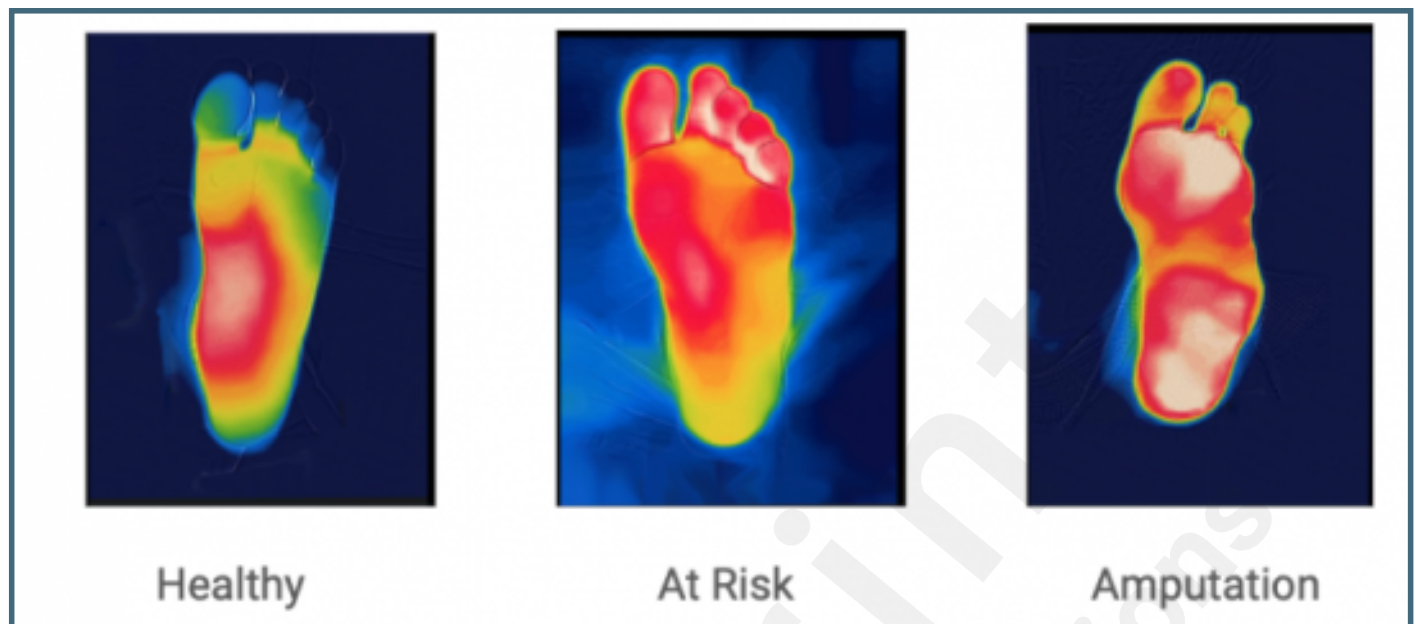
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Supplementary Files

Figures

Typical thermal images of plantar region for healthy, at risk, and amputated patients.



Thermal Imaging Device.



Asymmetry Divided by Angiosomes.

