The use of AI-powered thermography to detect diabetic foot ulcers: a validation study

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Submitted to: Journal of Medical Internet Research
on: August 10, 2024

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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 °C ± 0.43°C vs diabetic 1.78 °C ± 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. 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.

(JMIR Preprints 10/08/2024:65209)
DOI: https://doi.org/10.2196/preprints.65209

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9/07/2024

CONFIDENTIAL

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Introduction

Diabetes Mellitus

Diabetes affects 1 in 10 adults worldwide (537 million) (Sun et al., 2022). 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) (Sun et al., 2022). Despite advances in medical therapies, the prevalence of diabetes mellitus and diabetes-related complications continues to rise (Namazi et al., 2024).

Diabetic Foot Ulcers

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 (van Netten et al., 2020). It is estimated that one-third of people with diabetes will develop a DFU during their lifetime (Armstrong et al., 2017). Edmonds, Manu, and Vas (2021) 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. The mortality risk at five years for individuals with DFUs is 2.5 times higher than for those without ulcers (Armstrong et al., 2017). Furthermore, Armstrong et al. (2020) revealed that DFUs and lower extremity amputations (LEAs) are not only markers of poor health but also independent risk factors associated with premature death.

Unfortunately, even after a DFU has been resolved, recurrence is common, estimated to be 40% within one year, 60% within three years, and 65% within five years (Armstrong et al., 2017). Lower limb amputation is the most severe and costly outcome if DFU complications persist (Sen et al., 2019). Many researchers stated that early detection of DFU can reduce the economic burden (Swaminathan et al., 2024; Søndergaard et al., 2015 & Habib et al., 2010).

Economic Burden

DFUs constitute a significant and multifaceted economic burden within healthcare systems worldwide. Diabetes foot care costs are the single largest category of diabetes-related medical costs. Driver et al. (2010) 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. Armstrong's study further contributes to this understanding, stating that one-third of the direct costs of diabetes are attributable to care for diabetic foot disease (Armstrong et al., 2020). 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. in 2023. Despite the requirement for human thermographers in their methodology, their study projected substantial savings by integrating thermography as a standard procedure.

Preventing these lower limb complications could significantly improve health outcomes and reduce costs. Unfortunately, current tools for detecting DFU have limited scalability in terms of time efficiency and practicality (Ilo et al., 2020). These findings collectively emphasize the urgent need for comprehensive prevention, specialized care teams, and limb salvage strategies to mitigate the economic and health-related consequences of DFUs.

Current Challenges in Early Detection of Diabetic Foot Ulcers

Unfortunately, DFUs can be challenging to detect, especially in the early stages when they are not visible to the human eye. This is due to several factors, including inconsistent screening guidelines, limited awareness among patients and providers, and frequent silent or non-standard symptoms (Armstrong et al., 2017; Everett & Mathioudakis, 2018; Miranda et al., 2021). Inconsistent screening guidelines can lead to confusion and variation in practice among healthcare providers. Many people with diabetes are not aware of the risk factors for DFUs or the signs and symptoms to look for. Healthcare providers may also not be aware of the latest screening guidelines or best practices for DFU prevention and management.

In the diagnosis of DFUs, clinicians have long depended on traditional methods, each bearing distinct advantages and limitations. The following section critically examines these diagnostic tools:

Monofilament test

The monofilament test is a simple, cheap, and quick assessment tool. It is not always reliable for early detection of DFUs because it primarily identifies loss of protective sensation, missing other risk factors like arterial insufficiency and structural deformities (Droos et al., 2009; Wang et al., 2017). The technique of the administrator can also influence the test's accuracy, patient factors like swelling and temperature, and may not pick up early or intermittent neuropathy symptoms (Wang et al., 2017). For a more comprehensive assessment, clinicians often use the monofilament test in conjunction with other evaluations and tests (Droos et al., 2009).

Ankle-brachial index (ABI)

Foot ulcers can be exacerbated by underlying peripheral arterial disease (PAD). The ankle-brachial index (ABI) is a widely used, non-invasive method for diagnosing PAD (Xu et al., 2010). However, its accuracy is debated, especially in patients with exertional leg pain (Crawford et al., 2016). Furthermore, it is not helpful to detect PAD among patients with diabetes because calcified vessels can distort results (Bhasin & Scott, 2007; Casey et al., 2020). This raises concerns about the potential for an unreliable ABI to overlook those at heightened risk for foot ulcers, emphasizing the importance of a comprehensive assessment in diagnosing PAD and determining ulcer risk.

Duplex ultrasonography (DUS)

It is a standard imaging test used to diagnose and monitor PAD. It can accurately identify the location and severity of narrowing or blockage in arteries. However, some artery segments are difficult to visualize with DUS, especially in the lower limb, and the results may not be fully reliable (Eiberg et al., 2010). Additionally, DUS is not well-suited for people with diabetes because their calcified vessels are less flexible and more difficult to visualize with ultrasound (Collins et al., 2007). For this reason, other testing methods are often more reliable for diagnosing PAD in people with diabetes.

Angiography

The most accurate way to diagnose DFUs is by using a particular type of X-ray called an angiogram; however, this test has some drawbacks (Amin & Doupis 2016). First, repeated exposure to X-rays can be harmful to patients' health. Second, the test is expensive. Third, it is time-consuming, and sometimes patients must be hospitalized overnight for the procedure.

To improve the early detection of DFUs, universal screening guidelines, increased awareness among patients and providers, and better screening tools and methods must be developed and implemented.

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, technique standardization, and clinical thermal imaging protocols (Campbell et al., 2022; Serbu, 2009). It could visualize diseases that are not readily detected or monitored by other methods. It is a fast, passive, non-contact and non-invasive imaging method used by numerous peer-reviewed studies(Lahiri et al., 2012). It is currently used globally to screen, detect, and monitor diseases. Research on diabetic foot complications and thermography highlights a field experiencing substantial growth in research activity, technological advancements, and clinical focus. 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 (Zakaria et al., 2024). The American Academy of Thermology (AAT) established guidelines for using thermography to evaluate diabetic patients. These guidelines provide recommendations for using thermal imaging in detecting and monitoring diabetic neuropathy, including protocols for image acquisition and interpretation (Schwartz et al., 2021). Figure 1 shows the thermal images of the lower extremities of diabetic patients.

Medical Thermography has many advantages that could encourage widespread adoption. Thermal imaging is relatively inexpensive, compact, portable, involves no ionizing radiation, and requires little electric power. Recent technological breakthroughs have transformed large and expensive stationary cameras into portable and inexpensive solutions while maintaining quality imaging (Van Doremalen et al., 2019). One study emphasized that thermography is a valuable, cost-effective strategy for detecting Peripheral Artery Disease (PAD) below the knees, conditions closely associated with the risk of DFUs, showcasing high precision (97.62% sensitivity, 91.67% specificity) compared to Doppler ultrasound (Passos et al., 2022). By overcoming ultrasound's limitations, thermography non-invasively identifies temperature changes signaling arterial blockages, which is crucial for early PAD detection and preventing DFUs. Its quick, safe, and non-radiative nature makes it ideal for DFU screening.

A significant 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, precisely computer vision, can objectively observe the findings and minimize inter-observer variability. Ongoing progress in software image analysis and reduced reliance on human labor results in faster throughput and centralized processing. This can lead to increased thermographic accuracy and reliability. Nevertheless, computer-aided thermography will require high-level training and experience to ensure quality outcomes.

Figure 1: Typical thermal images of the 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 (Ilo, 2020; Nagase et al., 2011). Peripheral vascular disease (PVD) is a common complication of diabetes, which can result in alterations in blood flow that induce changes in skin temperature. These changes in skin temperature may also indicate tissue damage or inflammation resulting from trauma or excessive pressure. The etiology of these traumas is frequently related to moderate repetitive stress that goes unnoticed due to diabetic neuropathy (DPN). 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 (de

Deus Passos et al., 2022; Zhou et al., 2021; Ilo et al., 2020; Hernandez-Contreras et al., 2019; Sudha et al., 2018; Nagase et al., 2011; Bagavathiappan et al., 2010; Papanas et al., 2010). Furthermore, there appears to be a positive correlation between Body Mass Index and the risk of diabetic foot complications in patients with type 2 diabetes (Renero, 2017; Neves et al., 2015).

Several articles highlighted that high-temperature gradients between feet might predict the onset of foot ulcers (Araújo et al., 2022; Ena et al., 2021; Houghton et al., 2013 & Armstrong et al., 2007). Furthermore, the International Working Group of Diabetic Feet recommends a person with diabetes who is at moderate or high risk of foot ulceration self-monitor foot skin temperatures once per day to identify any early signs of foot inflammation and help prevent a foot ulcer (Schapet et al., 2024).

The rapid development of handheld smartphone-based thermal infrared imagers presents a creative solution for detecting and monitoring DFUs (Basatneh et al., 2015). To address the need for 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.

The Role of Thermography-based AI in Diabetic Foot Ulcer Detection

AI and its applications are increasingly promising in detecting and managing DFUs (Chemello et al., 2022; Kaselimi et al., 2022). Diabetes foot syndrome, with its lack of early symptoms and significant impact on patients' quality of life, necessitates the use of AI in timely screening and detection of risk for foot ulcers and possible amputations (Chemello et al., 2022; Kaselimi et al., 2022).

Studies such as Peregrina-Barreto et al. (2015) showed the potential of infrared thermography for detecting foot complications in diabetic patients. Several researchers demonstrated promising results in detecting DFUs using machine-learning techniques to analyze foot images (Cruz-Vega et al., 2020; Goyal et al., 2020; Khandakar et al., 2021). These findings suggest that AI's application to data derived from thermal plantar images yields promising results. AI has a significant potential to revolutionize the detection and management of DFUs. This study will leverage AI technologies deployed on a smartphone-based thermal imager and application.

The Importance of Early Intervention

Early active intervention significantly reduces foot ulcer incidence and amputations in people with diabetes (Chatwin et al., 2020). Therefore, early diagnosis and treatment of DFUs are crucial, as highlighted by the International Working Group on the Diabetic Foot (Schaper et al., 2024). An annual foot exam is recommended to identify high-risk conditions, with more frequent assessments depending on individual findings. Patients with one or more high-risk foot conditions should receive professional diabetic foot care (Lung et al., 2020).

Rationale for the study

This study aims 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 prospective cohort validation 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 multidisciplinary facility with general and subspecialty medical services that provides primary, secondary, and tertiary care to its patients. Patients with diabetes were recruited from the diabetes clinics; healthy participants who came to the hospital for routine check-ups or preventive care were recruited. A research assistant (RA) was present to recruit patients and collect the necessary data using convenience sampling.

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).

Exclusion criteria

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 met the inclusion criteria and were willing to participate were asked to provide 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, 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, including convolutional neural networks (CNNs), for the captured thermograms' semantic segmentation and noise reduction. The AI models were trained on a dataset of labeled thermograms and validated using cross-validation techniques to ensure robustness and accuracy. 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 an adequately cooled participant (Ena et al., 2021; Schwartz et al., 2021’ Fraiwan et al., 2017; Vilcahuaman et al., 2015; van Netten et al., 2013 & Armstrong et al., 2007).

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 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. 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.

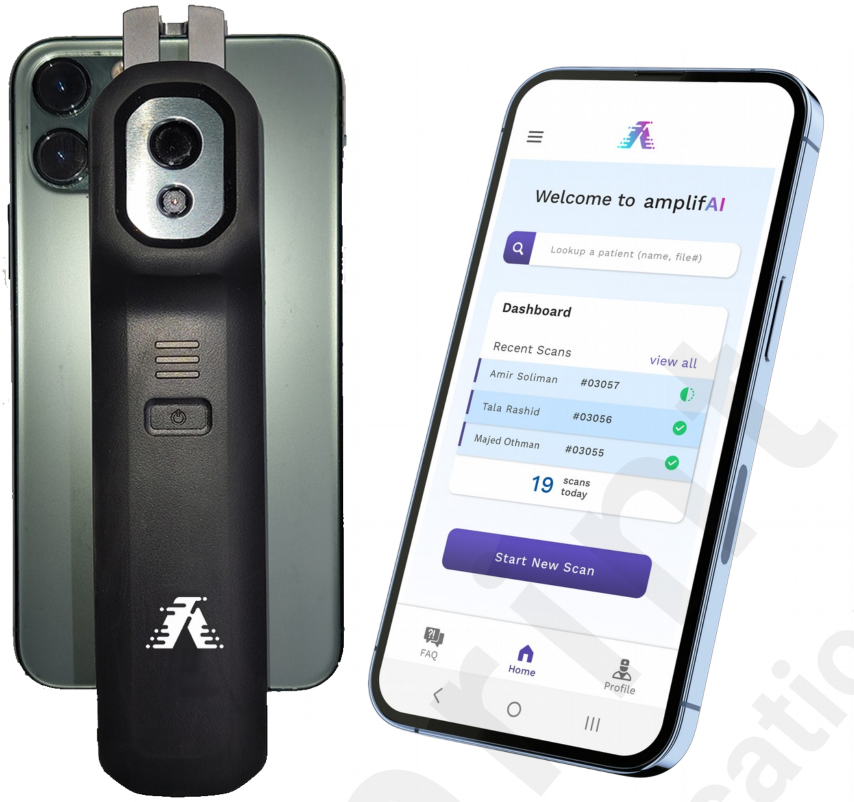

Figure 2: Thermal Imaging Device.

Data Collection

Before enrolling participants, the RA was trained to follow the study protocol, including participant recruitment, baseline questionnaire administration, and thermal image capture. Participants completed a baseline study questionnaire. It asked about their 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 (Murphy et al. 2012). 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 study participants were taken in compliance with the protocols and guidelines set by the American Academy of Thermology (Schwartz et al., 2021).

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 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.

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 baseline characteristics of participants are summarized with percentages for categorical variables and mean (SD) values for continuous variables. Independent two-sample t-tests were conducted to compare the mean ages and BMI values between the healthy and diabetic groups. For categorical variables, such as gender 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 (dependent variable) and the predictor variables (age, gender, and where the participant was healthy or diagnosed with diabetes). The OLS regression analysis was conducted to determine the predictors' significance and strength in explaining the temperature delta variance. Statistical significance was set at $p<0.05$.

Results

Participant Characteristics

Participants were divided into two groups. Individuals with normal circulatory findings and no earlier diagnosis of diabetes or 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; 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. 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	33 (16.8)	0	33 (33.6)	<0.05	-44.2, -23.1
Retinopathy	30 (15.3)	0	30 (30.6)	<0.05	-40.7, -20.4
Neuropathy	23 (11.7)	0	23 (23.4)	<0.05	-32.5, -14.4
Peripheral vascular disease	25 (12.7)	0	25 (25.5)	<0.05	-34.9, -16.1

Thermographic Analysis

The temperatures spanned a broader 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 21.1°C to 35.7°C in the control 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 ± 0.43°C vs diabetic 1.78 °C ± 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**
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, gender, and where the participant was healthy or diagnosed with diabetes). The results of the OLS regression analysis are summarized in Table 3. The overall model was statistically significant (F-statistic = 21.22, p<0.001), indicating that the predictors collectively explained a substantial portion of the variance in the temperature delta. The R-squared (uncentered) value was 0.254, and the adjusted R-squared (uncentered) was 0.242, suggesting a moderate fit of the model to the data. Diabetic subjects had a significantly higher temperature delta compared to healthy subjects (β = 1.4044, p<0.001), with a 95% confidence interval of [1.041, 1.767]. Age was not significantly associated with the temperature delta (β = -0.0057, p=0.340), with a 95% confidence interval of [-0.017, 0.006]. Similarly, gender was not a significant predictor of the temperature delta (β = 0.0525, p=0.763), with a 95% confidence interval of [-0.290, 0.395]. These results indicate that being diagnosed with diabetes is a significant predictor of the temperature delta between the right and left feet, while age and gender were not found to be significant predictors in this model.

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

Predictor	β	SE	t value	P value	95% Confidence Interval
Intercept	0.637	0.241	2.694	0.009	[0.163, 1.112]
Diagnosed with diabetes	1.4044	0.184	7.633	0.000	[1.041, 1.767]
age	-0.0057	0.006	-0.957	0.340	[-0.017, 0.006]
gender	0.0525	0.174	0.302	0.763	[-0.290, 0.395]

β: Coefficient; **SE**: Standard Error

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.

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 (Ilo et al., 2020; Zhou et al., 2020 & Armstrong et al., 2007). It has been shown that the peripheral vessels and nerves are damaged, producing irregular thermoregulation of both feet (Renero (2017) & Bagavathiappan et al., 2010). However, there is a lack of prospective studies that have 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. (2020), Zhou et al.(2020), and Armstrong et al.(2007), 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 automated AI-powered software. This is the novel part of the current study.

Strengths and Limitations

The RA collecting the data was blinded to the technology's results, enhancing the objectivity of the data collection process. 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 users can access information remotely.

Although attempts were made to diversify recruitment, the findings should be interpreted cautiously 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; hence, there could have been some referral bias in the selection of the participants.

Finally, the sample size was relatively small. Nevertheless, despite these constraints, the outcomes imply that thermal imaging could be 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. Thermography is increasingly gaining importance in the early detection of DFUs (Passos et al., 2022; Ilo et al., 2020; Zhou et al., 2020). Ilo et al. (2020) highlighted how thermography can adequately pinpoint local hotspots in diabetic patients, uncovering subclinical infections and discovering areas of high plantar pressure, where early identification is key to effective management. Furthermore, Armstrong et al. (2007) found that thermography could provide early clinical insights before visible signs of foot ulcers. 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. (Renero, 2017; Bagavathiappan et al., 2010 & Armstrong et al., 2007).

Early active intervention can significantly lower the incidence of foot ulcers and amputations in people with diabetes (Chatwin et al., 2020). 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 (Schaper et al., 2024). Patients should receive professional diabetic foot care if they have one or more high-risk foot conditions (Lung et al., 2020). 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 healthcare providers or patients. 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. Healthcare 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 (Nagase et al., 2011; Zhou et al., 2021 & Ilo et al., 2022). The integration of 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 more extended 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 understand better the relationship between the unusual heat signatures detected and the 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 AI as a potential tool for early detection. It validated a system that detects plantar thermal patterns, distinguishing between healthy individuals and diabetic patients without visible ulcers. Our findings indicate that the technology can distinguish between the thermal patterns of diabetic patients and healthy individuals. Future studies will focus on validating these findings in larger and more diverse populations to assess the broader impact of AI-powered thermography on detecting preclinical diabetic ulcers and its preventative strategies in clinical practice. This research aims to establish AI-powered thermography as a complementary diagnostic tool or screening test for DFUs.

Acknowledgment

We would like to express our sincere gratitude to the staff and patients at the Diabetes Center, Medical City King Saud University, for their invaluable assistance in completing our recruitment process. Their support and cooperation were instrumental in the success of this study.

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