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Thermal analysis of the diabetic foot using mobile infrared thermography: A pilot study in primary

Análisis térmico del pie diabético mediante termografía infrarroja móvil: Estudio piloto en atención primaria

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Abstract

Introduction: Infrared thermography is a non-invasive tool for early detection of complications associated with the diabetic foot.

Objective: To evaluate the usefulness of mobile infrared thermography as a complementary screening technique for diabetic patients in primary care settings.

Methods: A cross-sectional observational study with 20 diabetic patients was conducted at a primary care center in Málaga, Spain. Thermal images were captured following the TISEM consensus using a FLIR One Edge Pro® device. Thermographic variables including the Thermal Risk Index and thermal asymmetry were analyzed with ThermoHuman® software and correlated with clinical variables such as neuropathy, ankle-brachial index, and self-care knowledge.

Results: Forty-five percent of participants showed moderate to high risk of ulceration according to the International Working Group on the Diabetic Foot. No significant differences in thermal asymmetry were found over time ($p > 0.05$). Mixed-effects modelling did not reveal significant associations between ankle-brachial index, neuropathy, and thermal asymmetry.

Conclusions: Mobile infrared thermography can detect plantar thermal changes related to ulceration risk. However, further studies are needed to support its systematic implementation in diabetic foot screening.

Keywords: Diabetic Foot; Diabetic Neuropathies; Early Diagnosis; Infrared Thermography; Peripheral Arterial Disease; Primary Health Care.

Resumen

Introducción: La termografía infrarroja (TI) se postula como una herramienta no invasiva y objetiva para la detección precoz de complicaciones en el pie diabético.

Objetivo: Evaluar la utilidad de la TI móvil como técnica de cribado complementaria en personas con diabetes mellitus en un entorno de atención primaria.

Metodología: Estudio observacional, descriptivo y transversal realizado con 20 pacientes diabéticos en un centro de salud de Málaga. Se aplicó un protocolo basado en el consenso TISEM para la captura de imágenes con cámara FLIR One Edge Pro®. Se analizaron variables termográficas como el índice de riesgo térmico (TRI) y la asimetría térmica mediante software ThermoHuman®. Se correlacionaron con variables clínicas como neuropatía, ITB, y conocimientos de autocuidados.

Resultados: El 45% de los sujetos presentó riesgo moderado-alto de ulceración según IWGDF. No se observaron cambios significativos en la asimetría térmica a lo largo del tiempo ($p > 0.05$). El modelo de efectos mixtos no encontró asociaciones significativas entre ITB, neuropatía y asimetría.

Conclusiones: La termografía infrarroja móvil permite detectar alteraciones térmicas plantares relacionadas con factores de riesgo para ulceración, aunque son necesarias más investigaciones para establecer su aplicabilidad sistemática en el cribado.

Palabras clave: Diagnóstico Precoz; Enfermedad Arterial Periférica; Neuropatías Diabéticas; Pie Diabético; Prevención Primaria; Termografía Infrarroja.

Introduction

Diabetes mellitus is one of the most prevalent chronic diseases of the 21st century, and its impact on public health continues to grow. The 11th edition of the IDF Diabetes Atlas estimates that, in 2024, approximately 643 million adults (aged 20–79 years) are living with diabetes, with projections exceeding 850 million by 2050, driven by rising obesity rates, physical inactivity, and unhealthy dietary patterns.^{1,2} The global prevalence among adults is currently 10.9% and is expected to increase to 11.8% over the next 25 years, with the greatest increases anticipated in low- and middle-income countries.²

One of the most severe and costly complications of diabetes is diabetic foot, characterized by ulceration, infection, or destruction of foot tissues associated with neuropathy and/or peripheral arterial disease.³ These lesions are associated with high rates of morbidity, hospitalization, amputations, and mortality. It is estimated that up to 85% of diabetes-related amputations are preceded by a foot ulcer⁴, with an average hospital cost per episode exceeding €7,000 in Spain.⁵

In Andalusia, lower-limb amputation rates remain high. In 2019, 2.7 amputations per 1,000 individuals with diabetes were reported, a figure that temporarily decreased in 2020, likely due to the confinement measures during the COVID-19 pandemic.⁶

The International Working Group on the Diabetic Foot (IWGDF) defines diabetic foot as infection, ulceration, or destruction of foot tissues associated with neuropathy and/or peripheral arterial disease in individuals with diabetes mellitus.^{3,7}

Foot ulcers represent one of the most serious complications of diabetes, with a significant impact on quality of life, healthcare burden, and economic costs. They are also associated with an increased risk of cardiovascular events and mortality.^{8,9} Up to 70% of patients with diabetic foot may eventually undergo amputation, and 85% of cases are preceded by an ulcer that progresses to gangrene or severe infection.^{3,10}

Risk factors for amputation include clinical variables such as neuropathy and vascular disease, as well as social and demographic determinants³. The five-year survival rate after the onset of a diabetic foot ulcer is approximately 50–60% and decreases further when major amputation is required.^{3,4,11}

Early diagnosis is therefore essential to prevent severe complications. Prevention programs should focus on the early identification of warning signs and the implementation of effective screening strategies.¹²

In this context, infrared thermography has emerged as a promising technique enabling the detection of cutaneous thermal alterations associated with inflammation,

ischemia, or neuropathy. Its application through mobile devices may facilitate its use in primary care settings and in environments with high clinical workload.^{8,13} This non-invasive and objective tool allows for the quantification of temperature differences associated with early tissue damage, prior to the appearance of visible lesions.⁸ Consequently, infrared thermography represents a technology with potential to be integrated into diabetic foot screening protocols. However, its clinical applicability, diagnostic reliability, and relationship with established risk factors require further validation in prospective studies.

Accordingly, the aim of the present study was to evaluate the effectiveness of infrared thermography as a complementary tool to identify patients with diabetes mellitus at risk of developing foot complications, such as neuropathic ulcers and peripheral arterial disease (Figure 1).



Figure 1. Bilateral plantar thermographic image showing temperature distribution patterns. Areas of increased temperature (red) and decreased temperature (blue/green) reflect variations in plantar thermal response, potentially associated with underlying inflammatory, vascular, or biomechanical factors.

Methodology

A descriptive, observational, and cross-sectional study was conducted in a primary care setting within the Andalusian Public Health System (Huelin Health Center, Málaga, Spain).

The selection of thermographic variables and their analysis were based on the available scientific evidence on infrared thermography in diabetic foot, gathered through a narrative review of the literature. The search was performed in PubMed/MEDLINE, Scopus, Web of Science, Cochrane Library, and CINAHL databases, prioritizing publications from 2014 to 2024 in English

and Spanish. Controlled vocabulary (DeCS/MeSH) terms such as Infrared Thermography, Diabetic Foot, Peripheral Arterial Disease, Diabetic Neuropathies, Primary Health Care, and Screening were used to guide the theoretical and technical framework of the study.

The study was approved by the Research Ethics Committee of the Andalusian Regional Government (CEIm Provincial de Málaga), as stated in the favorable report issued during session no. 12 on December 19, 2024 (approval code: SICEIA-2024-001888). The project, entitled Applicability of Mobile Infrared Thermography in the Evaluation of the Diabetic Foot (TERMOPIE), was conducted in accordance with current regulations on biomedical research, medicinal products, and personal data protection (Law 14/2007, Royal Legislative Decree 1/2015, and Organic Law 3/2018).

Participants

The sample consisted of 20 patients with type 1 and type 2 diabetes mellitus, selected through consecutive sampling from individuals enrolled in a diabetic foot screening program.

Inclusion criteria:

- Individuals with type 1 diabetes mellitus aged ≥ 30 years or with a duration of diabetes ≥ 10 years, or type 2 diabetes regardless of disease duration.
- Absence of active foot pathology or conditions that could affect body temperature.
- Provision of written informed consent.
- Compliance with pre-assessment preparation measures (avoidance of direct sun exposure, stimulant intake, use of lotions or cosmetics on the feet, physical exercise, or the use of vasoactive medications).

Exclusion criteria:

- Plantar skin disorders, fever, or active infections.
- Inability to walk 100 meters.
- Cognitive impairment or body weight > 150 kg.
- Active or previous foot ulcers.
- Thermographic images of insufficient quality.

Collected Variables

Sociodemographic and clinical variables were recorded, including age, body mass index, glycated hemoglobin (HbA1c), duration of diabetes, level of physical activity, smoking status, and the presence of hypertension, retinopathy, foot deformities, and joint limitations.

Functional variables were also assessed, including pedal and posterior tibial pulses, ankle-brachial index (ABI), and peripheral neuropathy evaluated using the 10 g monofilament (Figure 2) and 128 Hz tuning fork (Figure 3). Ankle-brachial index (ABI) was measured using a

handheld Doppler device and sphygmomanometer (Figure 4).

Additionally, self-care level was assessed using the DSFQ-UMA questionnaire. Environmental conditions (room temperature and humidity) were recorded, and patients were stratified according to risk using the IWGDF and SAS classification systems.



Figure 2. Assessment of superficial sensation using a 10 g monofilament.

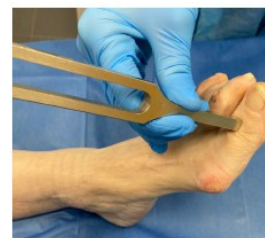


Figure 3. Evaluation of vibratory sensation using a 128 Hz tuning fork.

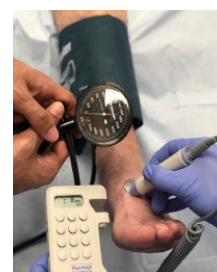


Figure 4. Measurement of the ankle-brachial index using a handheld Doppler device and sphygmomanometer.

Instrumentation and Procedure

Thermal images were acquired using a FLIR ONE Edge Pro® thermal camera (Figure 5) connected via Bluetooth to a smartphone, with a thermal resolution of 160×120 pixels and a thermal sensitivity of 70 mK.



Figure 5. FLIR ONE Edge Pro® thermal camera.

The procedure was standardized according to the TISEM (Thermographic Imaging in Sports and Exercise Medicine) consensus (Figure 6), which establishes the following conditions:

- A resting acclimatization period of at least 15 minutes.
- Ambient temperature between 20–22 °C and relative humidity of 40–70%.
- Absence of heat sources or air currents.
- Horizontal and perpendicular positioning of the camera relative to the plantar surface of the foot.
- Use of a homogeneous black background with a lower temperature than the foot.



Figure 6. Standardized positioning with a cold black background and the camera placed perpendicular to the plantar surface of the foot, according to the TISEM protocol.



Figure 7. Plantar thermographic image acquired using a FLIR ONE Edge Pro® camera.

During the examination, patients remained in a supine position, without socks or footwear. A total of five thermographic images were obtained for each participant. A representative example is shown in Figure 7.

1. After 15 minutes of rest in the supine position.

Following the initial clinical assessment and data collection, patients were instructed to walk a distance of 100 meters on a flat surface to induce a physiological thermal stimulus (mechanical thermal stress). After walking, patients were repositioned on the examination table in the supine position for post-exercise thermographic image acquisition. Footwear and socks were removed only once the patient was lying down, thereby avoiding direct contact of the foot with the floor and preventing external temperature influences. This procedure ensured the thermal validity of the protocol and minimized potential imaging artifacts.

2. Immediately after walking 100 meters.

3. At 5, 10, and 15 minutes of post-exercise rest.

A black cardboard support with plantar openings was used to standardize thermal contrast, and the camera emissivity was set at 0.98, corresponding to the emissivity value of human skin.

Image Analysis

The thermographic images were processed using ThermoHuman® software (Figure 8), which automatically segments the plantar regions of the foot and allows extraction of the following variables:

- **TRI (Thermal Risk Index):** a scale ranging from 0 to 100 that integrates both the number and magnitude of detected thermal asymmetries.
- **ASYMMETRY RL-AVG:** the mean temperature difference between the right and left foot.

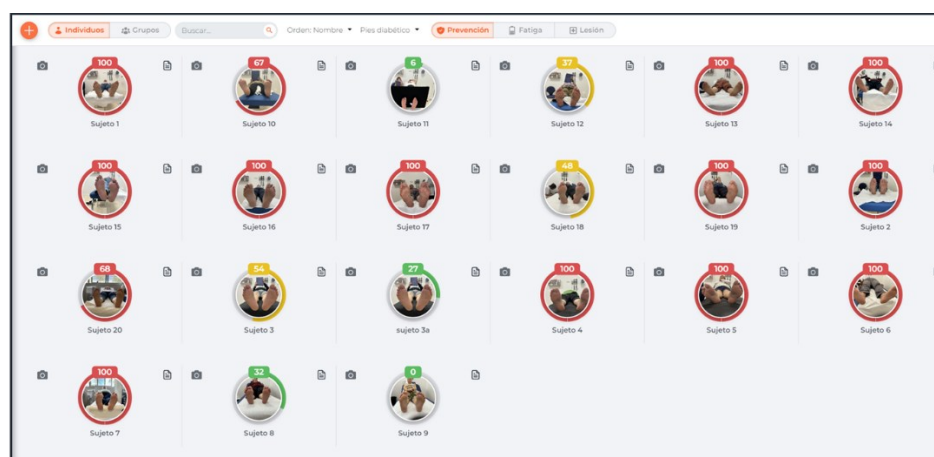


Figure 8: Thermal Risk Index (TRI) of the study participants obtained using ThermoHuman® software.

Data Analysis

Statistical analysis was performed using R software (version 4.4.0, April 24, 2024) and RStudio (version 2024.04.1 +748). Three different datasets were used:

- **Subject-level data (cross-sectional):** one observation per participant ($n=20$), including clinical, demographic, and environmental variables.
- **Thermographic data (time series):** five observations per participant (corresponding to each measurement time point), including TRI and ASYMMETRY values.
- **Longitudinal data:** dataset obtained by merging the previous two, resulting in a total of 100 observations.

Descriptive analyses and longitudinal analyses using mixed-effects models were conducted to assess the temporal evolution of thermographic variables and their association with clinical variables such as ABI, presence of neuropathy, HbA1c, and level of self-care.

Ethical Considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki, and written informed consent was obtained from all participants prior to participation. Data were anonymized and handled in compliance with current data protection regulations, including Regulation (EU) 2016/679.

Results

Data from 20 patients with diabetes mellitus were analyzed, describing their clinical and demographic characteristics, as well as thermographic variables obtained at five measurement time points. The mean age of participants was approximately 65 years, and the mean body mass index was within the obesity range (32.37 kg/m^2). The average glycated hemoglobin

(HbA1c) was 7.50%, indicating moderate glycemic control. The mean duration of diabetes was 13 years, reflecting a population with long-standing disease.

Regarding lifestyle habits, 80% of participants were non-smokers, and 60% reported engaging in some form of physical activity, although only 25% performed moderate-intensity exercise. Hypertension was present in 70% of participants, and a similar proportion exhibited foot deformities. Ankle joint limitation was highly prevalent. Retinopathy was observed in 45% of participants, while chronic kidney disease was present in only 5%. Most participants retained adequate sensory perception according to monofilament and tuning fork testing, although signs of neuropathy were identified in approximately one-third of the sample.

According to IWGDF risk stratification, 45% of patients were classified as moderate risk, 30% as very low risk, 15% as low risk, and 10% as high risk. In contrast, application of the Andalusian Diabetic Foot Screening Protocol resulted in a markedly different distribution: 75% of participants were classified as high risk and 25% as moderate risk, with no individuals identified in the low or very low risk categories.

Regarding thermographic variables, five measurements per participant were obtained, resulting in a total of 100 observations. Bilateral plantar thermographic image showing temperature distribution patterns is presented in Figure 1. The variables analyzed were TRI and mean thermal asymmetry (ASYMMETRY). TRI showed a high concentration of maximum values, limiting its discriminative capacity. The distribution of the Thermal Risk Index (TRI) across participants is shown in Figure 8. In contrast, ASYMMETRY presented a more balanced distribution closer to normality and was therefore selected as the dependent variable for longitudinal analyses.

The analysis of ASYMMETRY over time, across five measurement points (pre-exercise, immediately post-exercise, and at 5, 10, and 15 minutes post-exercise), did

not show statistically significant differences according to repeated-measures ANOVA ($p = 0.336$). This result remained unchanged after sphericity correction (Greenhouse–Geisser), thus no post hoc analyses were required.

To further explore potential associations between ASYMMETRY and relevant clinical variables, a mixed-effects model was constructed including time, presence of neuropathy, and right and left ABI as fixed effects. This model also did not yield statistically significant associations, indicating that neuropathy, time points, and ABI values did not significantly influence plantar thermal asymmetry. However, residual inter-individual variance was high (0.811), suggesting considerable variability between participants.

Discussion

Early detection of underlying conditions that compromise the integrity of foot skin and tissues prior to the appearance of visible lesions, currently represents a priority in diabetic foot research. Timely diagnosis is essential to prevent adverse outcomes such as ulcers and amputations. In this context, infrared thermography has shown potential as a non-invasive technique capable of identifying subtle thermal changes associated with inflammatory, neuropathic, or ischemic processes on the plantar surface.¹²

One of the most widely studied indicators is localized temperature increase, which may precede ulcer development. In routine clinical practice, thermal assessment is typically performed by manual palpation, a subjective method with limited sensitivity and poor reproducibility for detecting small temperature differences. In contrast, thermography enables objective, real-time, and contactless measurement of skin temperature distribution, potentially improving diagnostic capacity, particularly in primary care settings.^{15,16}

Despite these advantages, several challenges remain for the systematic implementation of infrared thermography in clinical practice. These include **limited robust clinical evidence, the lack of consensus on the interpretation of thermal patterns, and the absence of standardized thresholds or priority anatomical regions**. For instance, segmentation based on angiosomes—such as those defined by Taylor and Palmer (medial plantar artery, lateral plantar artery, medial calcaneal artery, and lateral calcaneal artery)—has been proposed as an anatomically coherent approach, although its application is not yet standardized.^{8,13,17}

Furthermore, not all thermal asymmetries indicate tissue damage, and not all lesions present with evident thermal imbalance. Therefore, thermography should be

considered a **complementary tool** that provides useful physiological information but requires integration with other clinical and diagnostic methods.¹⁸

Regarding equipment, devices with a standard resolution of 320×240 pixels and thermal sensitivity ≤ 0.1 °C are most commonly used in clinical research. However, advances in portable technologies have promoted the use of smartphone-based thermal cameras, such as the FLIR ONE Edge Pro® (160×120 pixels). Although these devices have lower resolution, they have demonstrated acceptable validity for preliminary screening, particularly in high-demand clinical settings (19,20). Kanazawa et al. reported that these devices allow rapid and efficient image acquisition, supporting their use in diabetic foot monitoring.²¹

With respect to thermogram analysis, visual interpretation may be subject to bias, particularly in the absence of specific training. In this regard, computer-aided diagnosis (CAD) systems represent a promising advancement. These systems enable automated segmentation, quantification of variables such as mean thermal asymmetry, and objective classification of ulceration risk, thereby reducing inter-observer variability and improving reproducibility.²²

Recent studies have also highlighted the potential clinical and economic benefits of the systematic use of TRI as a screening tool. Models applied to the Finnish healthcare system estimate that routine TRI use could prevent severe complications and generate annual savings of up to €1.7 million.¹⁴

In our study, risk stratification according to IWGDF criteria revealed a substantial proportion of patients at moderate and high risk, reinforcing the importance of identifying complementary tools for early assessment. Notably, discrepancies were observed between the stratification systems used. While the IWGDF classified 45% of patients as moderate risk, 30% as very low risk, 15% as low risk, and 10% as high risk, the Andalusian protocol classified 75% as high risk and 25% as moderate risk, with no patients in lower-risk categories. These differences may be explained by the distinct criteria considered: the IWGDF prioritizes loss of protective sensation, deformities, and ulcer history, whereas the Andalusian protocol incorporates additional clinical variables such as hypertension, retinopathy, and self-care practices (e.g., smoking or inappropriate nail care). This methodological divergence highlights the need to harmonize criteria and adapt risk stratification systems to the clinical context in which they are applied.

The high residual variance (0.811) observed in the mixed-effects model indicates substantial inter-individual variability, possibly related to factors not captured in the analyzed variables, such as microcirculatory status or treatment adherence. This finding underscores the complexity of diabetic foot

assessment when approached from a single diagnostic perspective.

Strengths and Limitations

This pilot study presents several strengths including the standardized application of the TISEM protocol, the use of portable thermographic technology in a primary care setting, the integration of clinical and thermographic variables, and the use of automated analysis software. Nevertheless, several limitations should be acknowledged, including the small sample size ($n = 20$), limiting generalizability, the absence of a control group (patients without diabetes or without clinical risk), the use of a single geographic setting, reducing population representativeness, and the limited resolution of the thermal device, which may affect measurement accuracy.

Despite these limitations, this study demonstrates the feasibility of implementing a rigorous thermographic assessment protocol for diabetic foot in a real-world primary care setting. The reproducibility of the measurements, the high level of patient acceptability, and the integration with clinical variables provide a solid foundation for future research.

Conclusion

Infrared thermography represents a promising tool in the assessment of the diabetic foot, though its widespread implementation requires overcoming methodological, technological, and training-related challenges. In this pilot study, the use of mobile infrared thermography allowed the characterization of plantar thermal profiles in patients with diabetes mellitus, demonstrating its feasibility as a complementary tool in primary care settings.

However, no statistically significant associations were observed between thermal asymmetry and clinical variables such as neuropathy or the ABI. This finding may be attributed to the small sample size and the high inter-individual variability not explained by the variables collected.

Future research involving standardized protocols, multicenter clinical validation, and larger longitudinal studies is needed to establish more robust and clinically meaningful relationships between thermographic findings and diabetic foot risk factors. This evidence will be essential to support integration of infrared thermography into comprehensive strategies for the prevention and monitoring of diabetic foot complications.

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