Clinical and Thermographic Database of Patients with Diabetes Mellitus with Perspective for Quantitative Studies.

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***Abstract*— Diabetes mellitus is a chronic degenerative disease suffered by 9.3% per year worldwide. In Mexico, 9.17% are currently diagnosed with diabetes, in which 30% have experienced complications such as diabetic foot. In this sense, early diagnosis could decrease the morbidity statistics arising from a diabetic foot that is not properly managed. However, some techniques employed for early diagnosis are based on medical imaging, e.g., medical IR thermography. Therefore, this paper presents a prelude for a clinical application based on medical IR thermography in which physiological data was retrieved from patients among thermographs in order to correlate variables as a perspective study. The database structure contains the obtained thermal images, which data processing is performed to filter and segment them to clearly observe the risk areas, in addition to some physiological parameters such as vital signs and the percentage of glycated hemoglobin in order to have knowledge of the patient's physical condition. The study was carried out in 55 patients, 58% of which belonged to diabetic patients, in which patients with a diagnosis of diabetic foot with classifications 1, 2 and 4 on the Wagner scale. The information gathered in this study has the perspective of finding applications in quantitative studies (e.g., classification) that correlate physiological variables and thermograms in patients with a history of diabetes mellitus.**

Keywords—Diabetes Mellitus, Diabetic foot, infrared thermography, database, Segmentation, Physiological parameters.

I. INTRODUCCIÓN

Diabetes mellitus (DM) is a chronic degenerative disease characterized by an increase in normal glucose levels [1]. There are two kinds of diabetes: type 1 DM, in which there is a lack of insulin production in the pancreas, and type 2 Diabetes in which the insulin does not metabolize glucose [2]. In both cases, complications may be triggered such as retinopathies, arteriopathies, diabetic foot (DF), among others [3]. However, a main complication is peripheral arterial disease which is a vascular problem which generates arterial calcification, stenosis and occlusion of the arterial system which will lead to ischemic problems which cause tissue damage such as infection, ulceration and tissue destruction [4]. The latter complications may drive to diabetic foot, causing a total or partial loss of the lower extremities [5,6].

Diabetic foot is a challenging condition to assess in advance before the patient refers symptoms. Certain methods to evaluate the diabetic foot condition are based on medical imaging, among them, medical infrared (IR) thermography. Medical IR thermography is a technique to measure the superficial skin temperature of the patient, whose fundamental principle is quantitative studies based on the temperature gradient difference. Particularly in the study of the diabetic foot, the study focuses on the search for asymmetries between pairs of feet, assuming that non-homogeneity of temperature is an indicator of ischemia [7].

Quantitative IR thermography studies require a database that supports the diabetic foot exclusion criteria. Commonly, the database is composed of thermograms of patients with no history of diabetic foot and those previously diagnosed. However, because DM is a multifactorial disease, studies should be complemented by a clinical history that correlates the involved variables. Therefore, this study presents the design and implementation of a database system for the collection of the clinical history of diabetic patients (with or

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without diabetic foot). The perspective of this work is to provide clinical data in search of the correlation between the thermal distribution in the foot and the physiology of a patient diagnosed with DM before developing diabetic foot.

On the other hand, the importance of the development of multiple applications for the diagnosis of risk areas and complications of diabetic foot are very useful to solve this problem, the Bioelectronics Laboratory of Cinvestav has worked over the years, Table 1 shows a summary of the state of the art on diagnostic techniques developed in this laboratory focused on a common goal.

Table 1: Summary of the state of the Art

Author	Research line	Year
Bayareh-Mancilla R.	Infrared Thermography studies of the diabetic foot. Creation of the IR Scanner Prototype [8].	2018
Toledo-Peral C. L.	Application for the characterization of cutaneous macules based on a 3-stage image processing algorithm. [9]	2018
Anahi -Torres I.	Measurement of biological tissue thickness using a multilayer acoustic pressure model [10].	2019
Maldonado-Loyo H.	Proposal of a pre-diagnosis system identifying risk areas in the sole of the foot using thermal images taken in an uncontrolled environment.	2020
Anahi -Torres I.	Electrical impedance measurements in diabetic foot. [11]	2020
Bayareh-Mancilla R.	Image processing and IR thermography to analyze temperature differences between the sole of the foot and regions with abnormal temperature patterns. [12]	2021

II. METHODS

A. *Patient criteria for selection*

For the selection of patients, the criteria of age and sex were omitted.

Studies were carried out on uncomplicated diabetic patients, diabetic patients with diabetic foot and healthy patients in order to have a complete database to be able to look for differentiating elements of each type of patient.

Patient age varied from 30 to 70 years, in which 32% did not have diabetic foot complications, and 26% patients were referred with DM and DF. Also, 57% where female and 43% were male.

B. *Data base design*

In order to store each of the patient's results, a digital book was designed for data storage so the user type the data for each patient, this with additional documents such as a medical note, may serves as a backup in case of more data is required in the near future.

Fig. 1. Data template for the patient's medical note

Fig.1 shows the different sections in which the patient's physician or guardian can enter data. A medical note is made by the responsible physician, this in order to have a diagnosis of each thermographic study and storage of thermographic images separated by folder with the name of the patient.

To fill out the form it is necessary to keep an order in the completion of questions as presented in Fig. 2, in the section of physiological parameters a medical equipment will be used to acquire the necessary parameters may provide information to understand the physiological behavior with the thermal images.

The medical database was saved inside the thermography device reported in [13], so that the storage of data and images is done automatically.

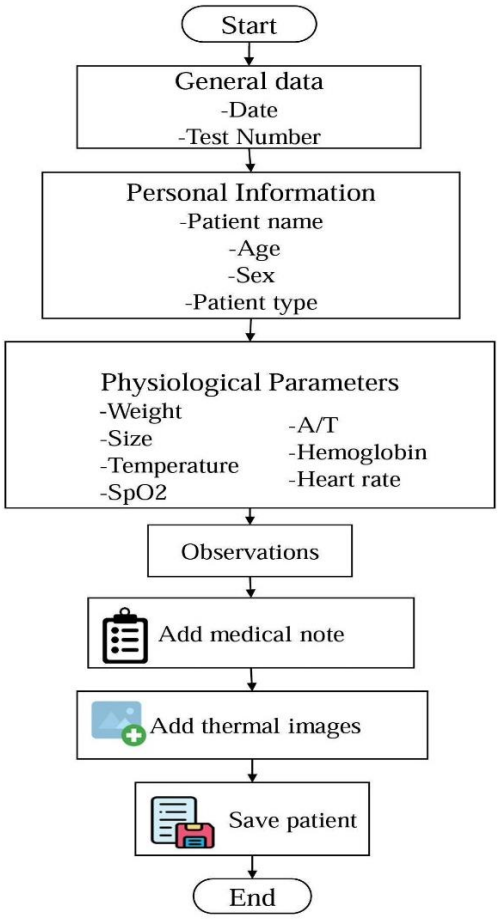
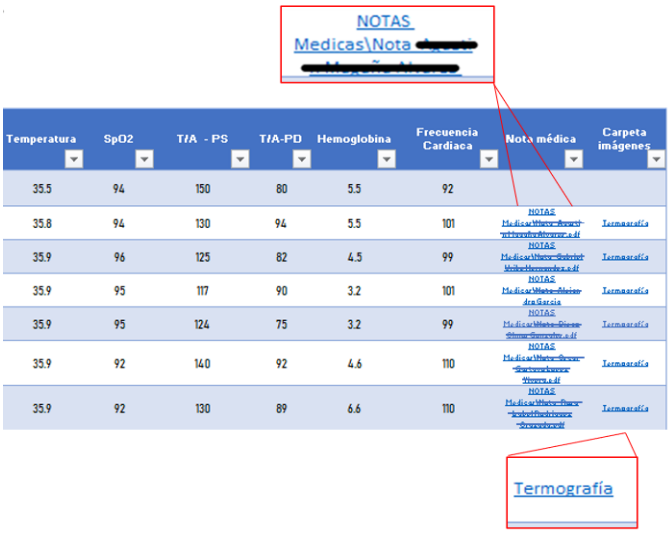


Fig. 2. Form filling process

For future searches the data is managed in an orderly way showing the links to each generated document, as shown in Fig.3. Image displayed in low quality to protect patient names.



Temperatura	SpO2	TIA - PS	TIA-PD	Hemoglobina	Frecuencia Cardiaca	Nota médica	Carpeta imágenes
35.5	94	150	80	5.5	92		
35.8	94	130	94	5.5	101	NOTAS	Termografía
35.9	96	125	82	4.5	99	NOTAS	Termografía
35.9	95	117	90	3.2	101	NOTAS	Termografía
35.9	95	124	75	3.2	99	NOTAS	Termografía
35.9	92	140	92	4.6	110	NOTAS	Termografía
35.9	92	130	89	6.6	110	NOTAS	Termografía

Fig. 3. Database with links to stored documents

C. Data acquisition protocol

An informed agreement submitted to volunteer patients based on the provisions of NOM 004-SSA3-2012 of the Clinical File, numeral 10.1 [14, 15].

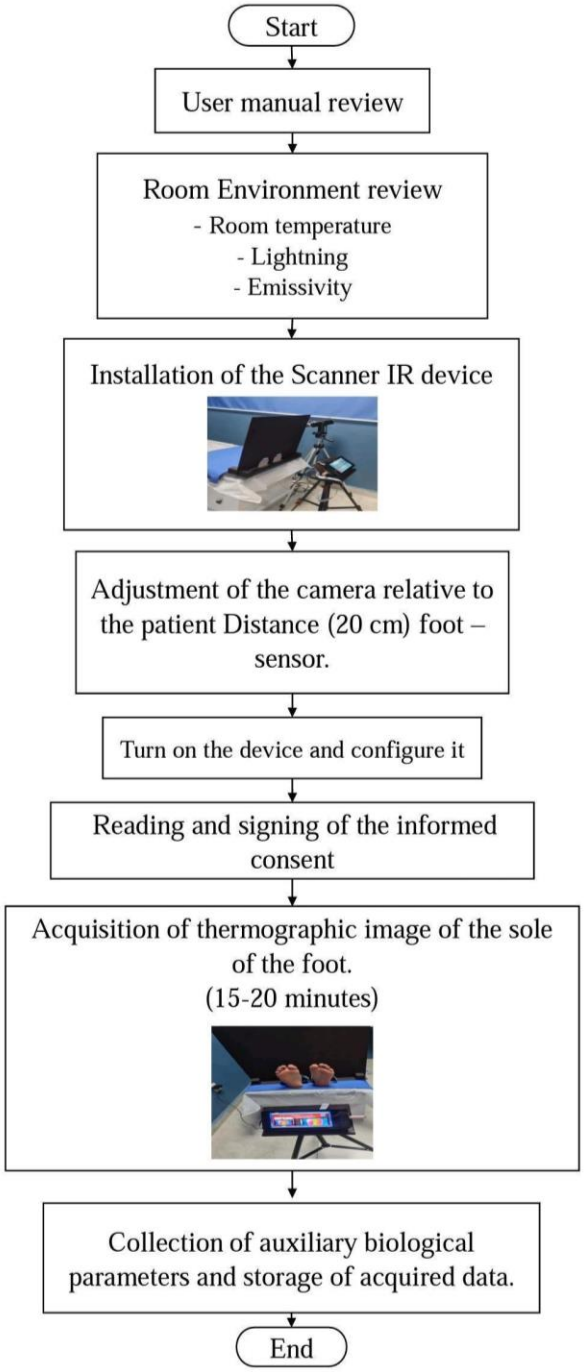


Fig. 4. Steps to follow for the study of thermography

The informed agreement must explain clearly the procedure within a maximum answer time about 30 minutes, then, the document should be signed being mandatory to resolve any doubts presented.

Every patient was placed in supine position and the feet were left to cool between 12 to 20 minutes. Then, the thermographic equipment [16] was set up at 20 cm regard to the sole of the foot. Fig. 4 shows the steps in order to retrieve feet thermograms.

The IR sensor employed was the LWIR Lepton 3.5. Table 2 presents the technical characteristics.

Table 2: Lepton 3.5 LWIR thermal imager

Characteristics	Range	Units
Infrared sensor resolution	160 x 120	Pixel
Pixel size	12	µm
Thermal Sensitivity	≤ 50	mK
Infrared Spectral Band	8 – 14	µm
Voltage	2.8	V
Refresh rate	8.8	FPS

D. Segmentation

The thermograms collected in the previous section were segmented in order to remove thermal interferences, delimit the region of interest and contrast the thermal distribution over the sole of the foot.

The method employed in this section was presented in [17,18]. The fundamental idea is to use the radiometric signals from the sensor, which are data arrays, to delimit the values that are related to the sole of the foot. This principle is based on taking advantage of the acquisition protocol. Commonly, in the acquisition of thermograms of the lower or upper limbs, the extremities have a higher temperature than the scene. In this way, values below a certain threshold can filter out those values that belong only to the feet. Fig. 5 shows the thermal images of the patients for this study.

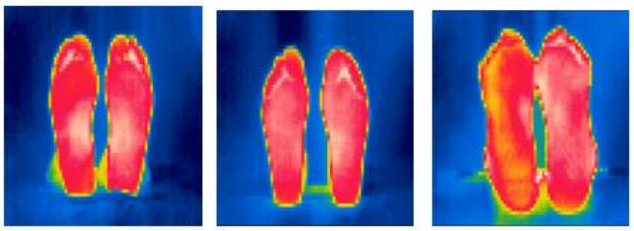


Fig. 5 Thermal images taken with Lepton 3.5

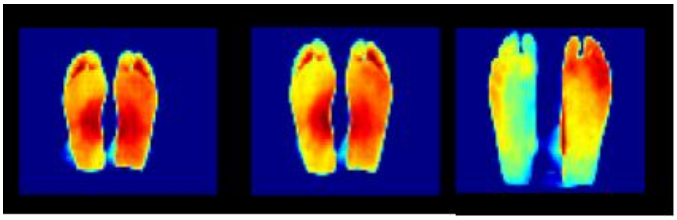


Fig. 6 Depicts the segmentation process presented in [17,18].

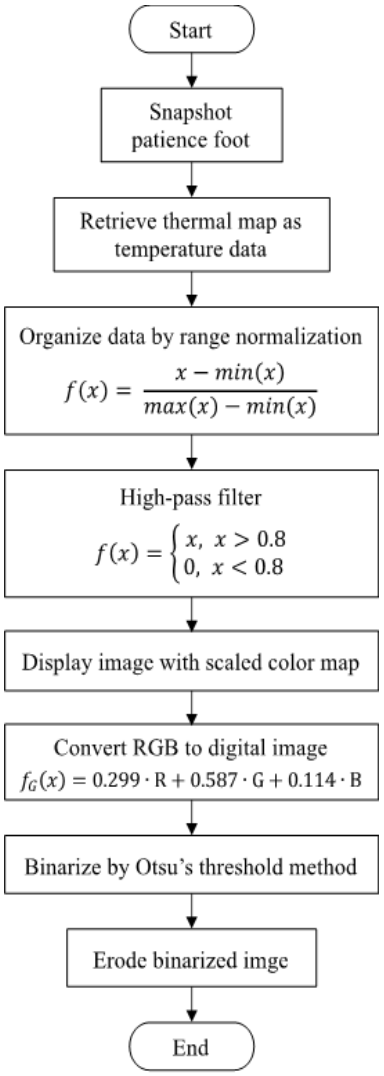


Fig. 7: Flow chart for detect high-risk zones to develop ulcers in the sole of the foot by temperature differences [17,18]

III. RESULTS

The results presented in this paper are based on the acquisition of medical information from patients and thermograms that were segmented to appreciate risk areas.

The image acquisition protocol was carried out leaving the patient lying supine on the scanning table with the body adjustment equipment for about 15 minutes to normalize the temperature with the working environment [19], after this time the images were taken with the Scanner IR device, at the end of which the forms with personal data and physiological parameters were filled out as shown in Figure 8.

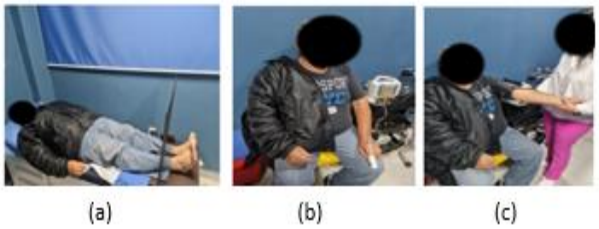


Fig. 8: (a) Patient in supine position for thermographic imaging. (b) Patient in SPO2 acquisition. (c) Patient in T/A acquisition.

The study was carried out in 55 patients, of whom 26 were male and 29 females, which are divided into three different groups as seen in Table 3.

Table 3: Study patient group

Type of patient	Quantity
Healthy patients	23
Uncomplicated diabetics patients	17
Diabetic patients with diabetic foot	15

Of the 15 diabetic patients with diabetic foot who underwent the study, 3 of them had a diabetic foot with Wagner classification grade 4, the others had grade 0 and 1 which we could observe that differences were noted between healthy patients, as we can see in Fig. 9.

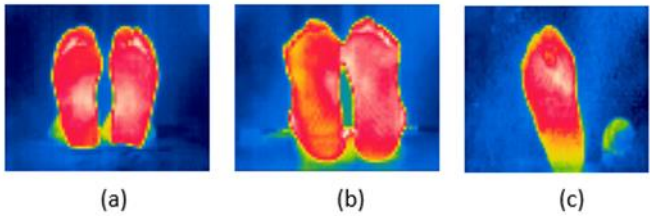


Fig. 9. (a) Healthy patient, (b) Diabetic patient with notable areas at risk of ulceration and (c) Diabetic patient with diabetic foot Wagner classification grade 4, with left lower limb amputation.

During the process of acquiring thermographic images and thanks to the segmentation, we were able to observe areas of injury in which the change in temperature is shown, for which correlations were made between physiological parameters, percentages of glycated hemoglobin and what was diagnosed with the doctor to determine the degree of injury of the patient.

Fig. 10 shows a thermal image and the segmentation process where the risk zone can be observed.

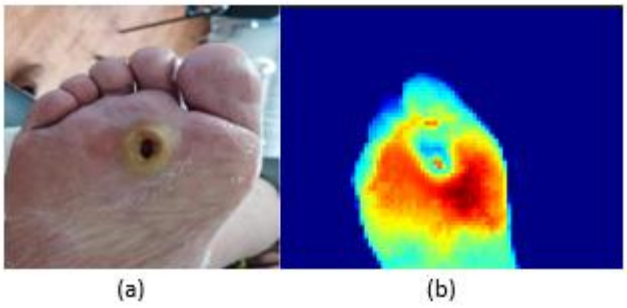


Fig. 10: (a) Original image (b) Segmented thermographic image with ulceration and notable risk areas.

IV. CONCLUSIONS

IR medical thermography has proven to be a reliable auxiliary tool reported in different clinical works, however, it is relevant to understand that DM and its complications are multifactorial. In this sense, to understand the abnormal distributions of surface temperature in the feet, physiological variables that can be obtained from studies or clinical notes should be contemplated.

Processed thermal images in this study showed variations that provided us with information on each patient. The correlation of this information along with the patient's history can support the physician's decision to choose an appropriate treatment. The inclusion of physiological parameters with segmented thermal images and the medical note my provide useful information to support qualitative analysis.

The information retrieved for the creation of the database presented in this paper, future research can be carried out for the development of new techniques for the detection of risk areas in diabetic foot.

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