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Proposal of a Non-Invasive Measurement of Physical Properties of Tissues in Patients with Diabetic Foot: Measurement Experiences in Diagnosed Patients

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Abstract: Diabetic foot is one of the most serious complications in patients with diabetes mellitus. It is distinguished by the development of ulcerations on the sole of the foot. Before the appearance of these, patients with diabetes suffer changes in the tissues of the foot and nearby tissues. This work proposes systems that measure and identify the changes in the physical characteristics of the foot tissues in two study groups, diabetic patients and healthy subjects, with the purpose of proposing tools to physicians to follow up each patient and identify with certainty the evolution in symptoms. The results of the temperature systems show that there is an average temperature difference of ~2 °C between diabetic patients and healthy subjects. Using an electrical impedance system, a frequency window was found between 5 kHz and 22 kHz, where the impedance is significantly different ($p > 0.001$) between diabetic and healthy patients. The system oriented to macules on the skin is able to identify the type of macules developed by the diabetic patient. In temperature measurement with images from a smartphone, plantar temperature monitoring was achieved in at-risk areas in uncontrolled environments. The results presented in this work were obtained in a time period from 2014 to 2022. Considering the standardization of this equipment when making a diagnosis regarding the study of tissues in the diabetic foot, it will be possible to detect it early. Through differences between the measurements, we have an indicator of the patient's evolution, and we must highlight that these systems are easy to install, easy to interpret and low cost. Currently, there are no systems with these characteristics, which is why the early detection of diabetic foot is being widely studied.

Keywords: diabetes mellitus diabetic foot; neurovascular complications; early detection; foot status

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1. Introduction

Diabetes mellitus affects a large number of people worldwide: about 537 million adults currently suffer from this condition, and it is estimated that this number will increase to 106 million by 2030 [1]. It is estimated that there are 6.7 million deaths per year worldwide due to complications of this disease. If the disease is not treated by a medical specialist, glucose levels will increase, and over time, damage can occur in different areas of the patient's body, causing health complications. In the case of diabetic foot, untreated disease can cause the progressive amputation of parts of the foot and in extreme cases the entirety of the lower limb [1]. The most evident symptoms in patients with diabetic foot are the affectation of the nerves (structure and function) and of the arteries that carry blood to the feet, so that the blood flow does not reach the foot in a normal way [1]. Diabetic foot syndrome is generally diagnosed when there are one or more foot ulcers associated with

neuropathy, peripheral arterial disease and infection [2]. However, early identification and treatment of patients with diabetes and feet at risk for ulcers and amputation can delay adverse outcomes [3]. It is necessary to have methods for the routine detection of diabetes to give the physician the opportunity to confirm the onset of diabetes, and then to start the treatment for diabetes control. Moreover, it is important to monitor the diabetic patient's feet to identify the appearance of risk factors: skin macules, onset of ulcers, temperature differences, blood pressure differences, bone deformities, and neurological and vascular evaluation [3].

Currently, to the best of our knowledge, there are no systems for measuring the effects of diabetes on the physical properties of tissues. In medical practice, the standard diagnostic method is the medical examination of the patient accompanied with blood tests. The proposal we present in this article is the noninvasive measurement of different physical properties of foot tissues.

Temperature Measuring System. Foot temperature in diabetic patients has been studied for many years and it has been shown that there is a relationship between increased skin temperature and irregularities between the same regions of both feet [4]. This is why there is currently research that seeks to be more accurate and effective in measuring the temperature of patients' feet. Pooria Mostafalu et al. developed a smart band for the monitoring and treatment of chronic wounds based on temperature sensors and PH measurement in diabetic patients [5]. Another of the current advances is a proposal for an intelligent system consisting of a sock capable of measuring temperature and humidity and indicating if there is a risk of ulceration, proposed by Torreblanca Gonzalez et al. [6]. In the search for early detection of diabetic foot ulcers, V. G. Sangam et al. presented a device based on strategically placed sensors to evaluate temperature, plantar pressure and PPG (peak plantar gradient). They recorded pressure increases (ulceration) and decreases (necrosis), thus alerting ulceration risk zones [7].

Electrical impedance spectroscopy system. The application of electrical impedance has been favorable due to its safety, low cost, efficacy and applicability, as in the case of cancer diagnosis and characterization of biomaterials. Nowadays, it is being applied to the diabetic foot. Such is the case of Gonzalez Correa et al. who performed electrical impedance measurements in a range of 0 to 50 kHz in six patients with diabetic foot ulcers and a control group of eight healthy subjects. Differences were found between ulcerated and non-ulcerated legs, in which the electrical impedance values were much lower in the healthy feet [8]. Rodriguez Timani et al. developed an electrical impedance analyzer for the analysis of diabetes. Their results showed that people with diabetes have a curve relating their bioimpedance over a frequency range from 10 kHz to 80 kHz [9].

Skin macule characterization system. Diabetes mellitus is associated with different dermatologic conditions. Dermatologic manifestations can be the first indicator of diabetes in some patients, and certain conditions may indicate poor control of the diabetic patient [10].

Infrared emission thermography system (IRT). Currently, studies with IRT have reported efficiency in preventing diabetic foot ulcers, conducting a thermal evaluation of the plantar surface of the foot. Torreblanca Gonzalez et al. used infrared thermography to develop and evaluate a portable sock to monitor foot temperature in diabetic subjects. It was observed that there is a relationship between the areas with greater temperature changes and the risk of ulceration in diabetic patients [4]. Doremalen et al. involves the validation of a smartphone-based IR camera against a high-end IR camera for diabetic foot assessment. Contralateral temperature differences of the entire plantar foot and nine pre-specified regions were compared for validation. Near-perfect agreement was found for temperature measurements on both the sole of the foot and the combined prespecified regions, with diagnostic accuracy of 94% and 93% sensitivity, and 86% and 91% specificity [11].

Virtual platform for the diabetic foot ulcer. Currently, there are different electronic advances to help diabetic patients and medical professionals to monitor the state of their feet for the prevention and follow-up of ulcers, such is the case of Luay Fraiwan et al.

They work with a mobile application for the detection of ulcers and analyze the thermal distributions, looking for a temperature difference greater than 2.2 °C and identifying the regions with possible ulcers [12]. To promote foot care in diabetic people, Barbosa Marques et al. present their virtual platform PEDCARE; its content and appearance were validated, registering a 0.95 content validity index [13]. Rafael Colodetti et al. are working with a mobile application that seeks to help nurses to choose an appropriate topical treatment for diabetic foot ulcers [14].

In this article, we present different systems that claim to be future supports in the diagnosis of diabetic foot using tissue analysis with non-invasive methods. Today the diagnosis of this disease is made when it has advanced enough to show ulcers or advanced tissue damage. Currently, there are no systems that are used for the early detection of diabetic foot, which means that these systems will have a great impact in the future since, at this time, they are easy to use for doctors and patients; that is, they are user-friendly in terms of their understanding of results, in addition to being easy to access, easy to install and low cost.

2. Materials and Methods

2.1. Sample Inclusion Criteria

All the measurements in this work were performed in two study groups: diabetic patients, diagnosed with type 2 diabetes mellitus, and healthy subjects. Measurements were taken following a protocol approved by the Ethics Committee of the hospital where the measurements were taken, and each participant signed an informed consent form.

Electrical impedance and punctual temperature: a group of 25 diabetic patients from the National Institute of Rehabilitation and 8 healthy subjects were selected for performing these studies, in an age range of 25 to 85 years, the sample of diabetic patients is composed by 60% female and 40% male, 40.9% were overweight, 36.36% were obese and 100% of the sample suffered from different types of macules on the legs and feet. The study of the maculae was performed in 19 diabetic patients without diabetic foot and with a variety of macules, which were namely vascular macules, petechiae, macules due to trophic changes and macules due to trauma; this classification was carried out by clinical observation. Temperature, impedance and macule measurements were performed in the period from January to August 2016. A group of 90 patients from a private clinic in the State of Mexico were selected to carry out this infrared thermography study, in an age range of 30 to 75 years; 32% were diabetic patients, 26% were patients diagnosed with diabetic foot and 26% were healthy subjects. A total of 16% of the patients who attended the study had arterial problems. The measurements with this system were repeated at different times with the supervision of medical personnel, recording the results obtained. Environmental parameters were also established, such as a humidity of 34.7% and temperature of 20.3 °C, with 15 min of acclimatization, before starting to take the images. Infrared measurements were performed in the period from August to September 2022. To visibly show temperature variations in healthy subjects and diabetic patients, a comparison was made between 6 healthy subjects and 6 diabetic patients from our sample.

2.2. Statistical Analysis

For the analysis of the data obtained, statistical processes were carried out. In the case of the punctual temperature system, averages of the temperatures were obtained for each zone for each of the groups, the absolute averages of the differences between both feet were obtained for each zone, and the 2-way ANOVA, post-test Bonferroni study was carried out. The standard deviation of the results was obtained.

The data obtained from the electrical impedance equipment were statistically processed by two-way ANOVA study for the two study groups, normalization of the data was performed and the behavior of the impedance for different frequencies was shown. The other procedure performed with the impedance data was to divide the measured voltage

by the injected voltage. The data from the infrared temperature measurement system are shown as a comparison of temperatures by zones of the sole of the foot.

2.3. Temperature Measuring System

In this work, it was decided to apply punctual temperature measurements on the soles of the feet of patients with diabetes mellitus and to study their behavior when compared with measurements in healthy subjects.

This system measures the temperature in four zones of the sole of the foot (Zone 1: hallux toe, Zone 2: first metatarsal, Zone 3: arch and Zone 4: heel), selected because they are some of the most prone to ulceration in patients with diabetes mellitus [15]. These areas have a relationship with the increase in temperature caused by inflammation and tissue degradation [16]. We can divide this system into the templates with four LM35 sensors (accuracy $\pm$ 0.2 °C) in the special areas of the foot and the electronic equipment shown in Figure 1a, which is a box with dimensions of 10 $\times$ 5 $\times$ 3 cm with an electronic board that measures and stores the temperatures obtained from a measurement in an EEPROM memory and erases the stored measurements and/or sends them via USB communication to a computer. In the user interface, one can see the result of different processes, such as data acquisition, processing, and data storage, among others, performed by the electronic circuit of this system. The duration of the measurements is fifteen minutes and the sensors capture data every two seconds to have an average of each minute, so at the end there are fifteen temperatures of each zone per measurement [17]. A thermostatic bath (RCTB 3000, OMEGA Engineering, Inc., Norwalk, CT, USA) and a fractional degree precision mercury thermometer with an accuracy of $\pm$0.1 °C (ThermcoProducts, Lafayette, NJ, USA) were used to characterize this system in terms of temperature [17].

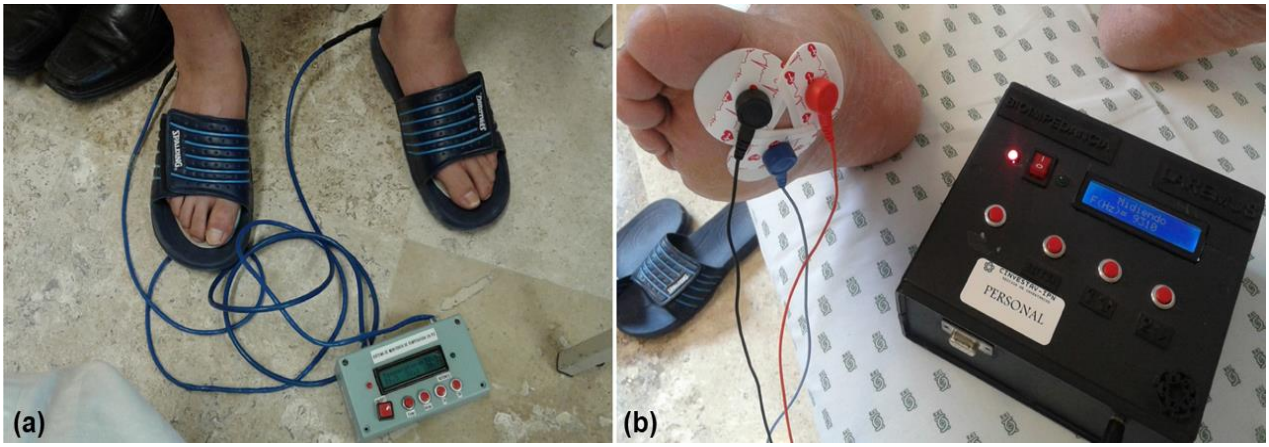


Figure 1. (**a**) Electronic system and templates with integrated sensors for temperature measurement [17]. (**b**) Electrical impedance measurement system with three electrodes performing an impedance measurement [18].

2.4. Electrical Impedance Spectroscopy System

In Figure 1b, we can see the electrical impedance measurement system performing a measurement of the first metatarsal; the system is portable and user-friendly. It is used to control and store the measurements, and internally it is made up of an OPA2277 operational amplifier that measures and injects the current, an AVR ATMEGA 328P microcontroller and an Analog Devices AD9850 signal. The three-electrode method was used for the measurement [19] using commercial electrodes placed on the first metatarsal of the sole of the diabetic patient's foot; the communication for data management is via a USB to a computer. For the characterization of this system, nine measurements were performed at three different resistances in a range of operating frequencies (10 Hz–22.2 kHz) in a precision impedance analyzer (Agilent 4294A, Farmingdale, NJ, USA) with an average

deviation from the true value considered of 4.2% (maximum relative error of 10.5% at a specific point) [18].

2.5. Skin Macule Characterization System

This system was designed to keep track of the changes that occur in the skin of the extremities of diabetic patients. The image is captured by a device called WIAS (Wireless Image System) composed of an 18 MP digital camera (Sony DCS-QX100, New York, NY, USA) and a metal-based positioning frame (see Figure 2a). Then, the maculae are characterized by image processing techniques that find the areas of interest by using a segmentation and characterization algorithm. The system is composed of a graphical user interface (GUI) developed in MATLAB. The images of the maculae are introduced into an artificial neural network classifier, which differentiates them with an accuracy of 97.5%. In Figure 2b, we can see the delimited region for image processing, removing the information that is not necessary, and in Figure 2c, we can see the regions selected by the system and the classification of the macules. These images show the first steps for the study of this system, but we can say that with the correct monitoring of the cutaneous manifestations, it is possible to provide insights into the progression of tissue damage at the feet and provide early treatment and support in the prevention of amputations due to diabetic foot [20].

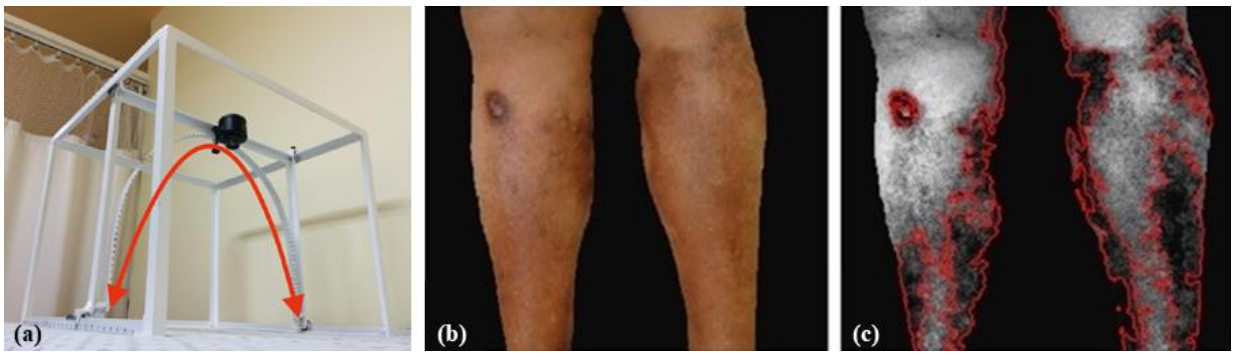


Figure 2. (**a**) The patient takes their place with both feet inside the box and the camera will cover X and Y axis; this improves the panorama of all macules that patient has; (**b**) Region selected for the study (skin); (**c**) Selection of atrophic, traumatic and vascular macules.

2.6. Infrared Emission Thermography System

This system was developed as a low-cost portable device, which meets the needs of the clinical field to function as one of the first pieces of front-end equipment for diabetes mellitus complications. The device was developed with a Raspberry Pi card as an embedded system, a touch screen and a Lepton Flir sensor as an IR (Infrared) sensor. The codes were established in SPI and I^2C communications between the computer and the sensor [21]. The system was programmed in C++ with Qt, designing also a database to store the collected information. The system provides as a result three files per patient: the thermographic image, the data matrix obtained from the sensor and a color map, which gives us the information about the temperature in degrees Celsius. The IR sensor was characterized to measure the surface of the sole of the feet radiometrically; the characteristic equation allows non-ionizing imaging studies related to temperature changes characteristic of diabetic foot complications. These data obtained allow the user to visually analyze and perform image processing in order to determine the condition of each patient as we obtain qualitative information, in order to support the physician's information and diagnosis.

The system has a thermographic image acquisition protocol, with accessories that facilitate repeatability in image acquisition, as we can see in Figure 3a, in which the user is lying supine on the examination table with a system that limits the visual noise for the thermography sensor, as well as the base of the device with height, distance and angulation adjustments for the acquisition of thermographic images. To comply with the creation of

a useful database, quantitative data were chosen to support the thermographic images obtained. Each patient has information of vital signs, glycated hemoglobin, glucose, weight and height, as well as the writing of a medical note in which the responsible physician describes the observations at the time of the study to obtain a comparative record of the patient's evolution [21].

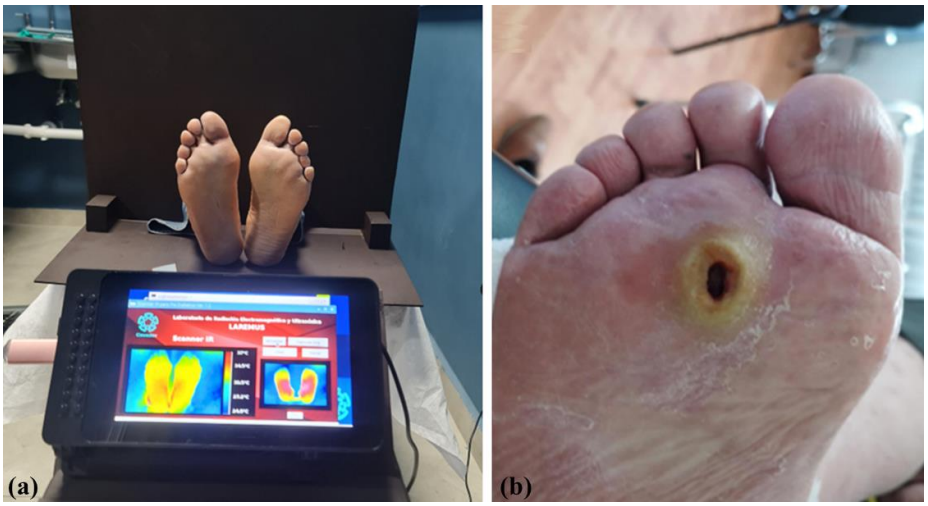


Figure 3. (**a**) IR Scanner device in a study with a diabetic patient. (**b**) Photograph of a characteristic diabetic patient's lesion.

In Figure 3b, we can see a photograph captured with this system of a patient in follow-up of a diabetic foot injury. In each zone, the temperature was taken and an average of each of the zones (1, 2 and 3) was made. Once the average temperature of each of the zones of both feet was obtained, a temperature comparison of each evaluated zone was made to know the degrees of difference between each of the zones of the diabetic foot.

2.7. Automatic Detection of Risk Zones by a Smartphone

This system seeks non-invasive monitoring of the sole of the diabetic foot by processing images taken with different smartphones, in an uncontrolled environment (non-homogeneous environment and at room temperature), to detect increases and decreases in temperature in the plantar areas and classify the temperature differences in areas with different degrees of ulceration. A Fluke TI32 dual IRT camera was used to capture thermographic images; it has a visible spectrum (VS) and TI camera (infrared thermography), and the storage format is IS2. A protocol was established for image capture: the patient remained seated with the legs extended on a support. Three samples were taken per patient: sample 1 was acquired when removing the footwear (initial temperature), sample 2, after five minutes (intermediate temperature) and sample 3, after 10 min (ambient temperature). The distance between the feet and the camera was 92 cm, creating a capture frame of 28 cm and 37 cm. The emissivity established was 0.98 [22]. Two databases were created: database 1, consisting of 108 images with 4 different backgrounds of 17 non-diabetic subjects, taken with and IRT camera with a resolution of 240 × 320 pixels; and database 2, with 141 images of 47 diabetic patients, with different background images taken with different smartphones; the resolutions of the images vary between 394 × 1280 and 2304 × 4096 pixels. All participants of this study were informed of the procedures and signed a consent document, all of them agreeing that their data can be used for research purposes.

In summary, this system can be divided into the following algorithms: image segmentation and application of the resulting mask on IRT (infrared thermography) matrices using deep learning techniques by means of a re-trained mask R-CNN model, the detection of regions by temperature difference using normalized thresholds and the filtering and classification of temperatures [23].

2.8. Virtual Platform for the Clinical Diagnosis of the Diabetic Foot Ulcer

The purpose of the virtual platform is to keep a record and follow up on the foot health status of each diabetic patient. With an Internet connection, this allows the physician to interact directly with the patient's recorded data and to have the possibility of proposing an adequate treatment for the patient. The virtual platform was designed together with diabetic foot medical specialists. It is divided into several sections, and some of them include the creation of the patient's file with personal data, clinical diagnosis by the physician in charge, medical treatment, and description of the state of the patient's feet. In case there are ulcers, the location and classification of these can be registered as foot deformities, along with an additional section to add special notes. The virtual platform is designed and built with the following free tools: WampServer, HTML, PHP and SQL. It is an easy-to-use and user-friendly system. We consider that it is a first approach to describe the patient's clinical status and follow their evolution in each medical visit.

Figure 4 shows the diagram of the virtual platform for diabetic foot, with the incorporation of this platform to the health sector intended to help the physician to keep track of the feet of the patient with diabetes, as well as the treatment applied in each medical consultation. The virtual platform works like a general platform for all the information that each one the systems gives; with this a single record is created to find the patient's foot health status [24].

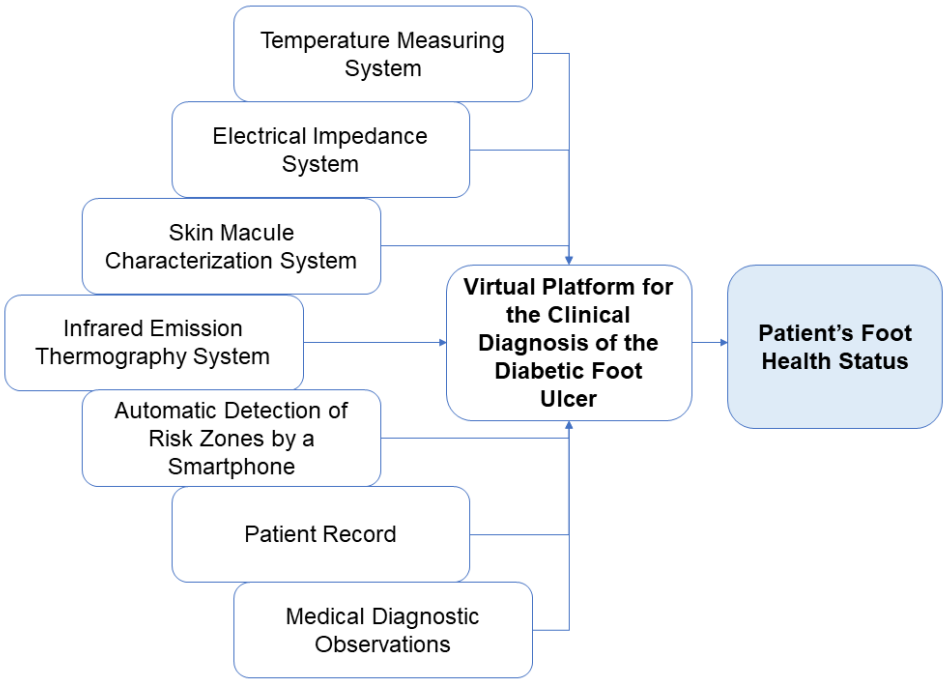


Figure 4. Diagram of the virtual platform for the national diabetic foot ulcer data. The virtual platform show a dashboard where all the information is centralized for each one of the systems gives; after that, all the information generated a single register into the database with the purpose of defining the patient's foot health status.

2.9. Hub of Information of Diabetic Patients

The concentrator and registry of patient information is a tool that has the objective of acquiring and saving the information of each of the patients with diabetes mellitus who participate in the study. The information comes from the systems for measuring the physical characteristics of the feet and the evaluation made for each patient by the treating physician. The system consists of a low-cost small-board computer Raspberry Pi (Raspberry Pi Foundation, Cambridge, UK) with a display. The connection to other devices can be made via USB, which operates at a maximum speed of 480 Mbps and RS232 to read, sort and post-process the data. Users can perform the tasks with a touch screen that has

a user-friendly user interface. The system has the ability to store patient data and show the results for physicians' consultation. The data sequence design of the central system is shown in Figure 5. This system is a proposal for easy access to updated diabetic patient information for correct follow-up and treatment of the disease [25].

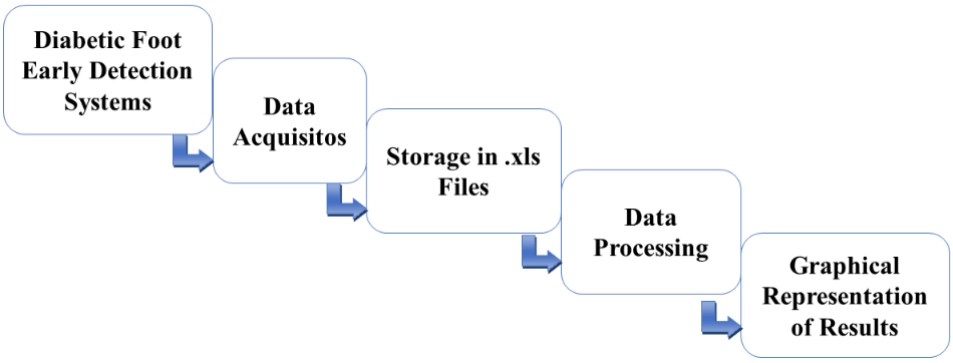


Figure 5. Diagram of the hub of information on diabetic foot. This shows the synchronous process that the systems follow to achieve the results. First, the data acquisition through USB, which operates at a maximum speed of 480 Mbps to each of the systems, then saves the information in .xls format to use it later on. The device reads through the file using Python language; then, the system finds the graphical results [26].

3. Results

3.1. Temperature Measuring System

Figure 6a shows the averages of the temperatures by zones for the groups with the standard deviation (SD). The results of the temperature averages in diabetic patients are higher, although they are not significant between the same zone for diabetics and healthy subjects, since the SDs are very large.

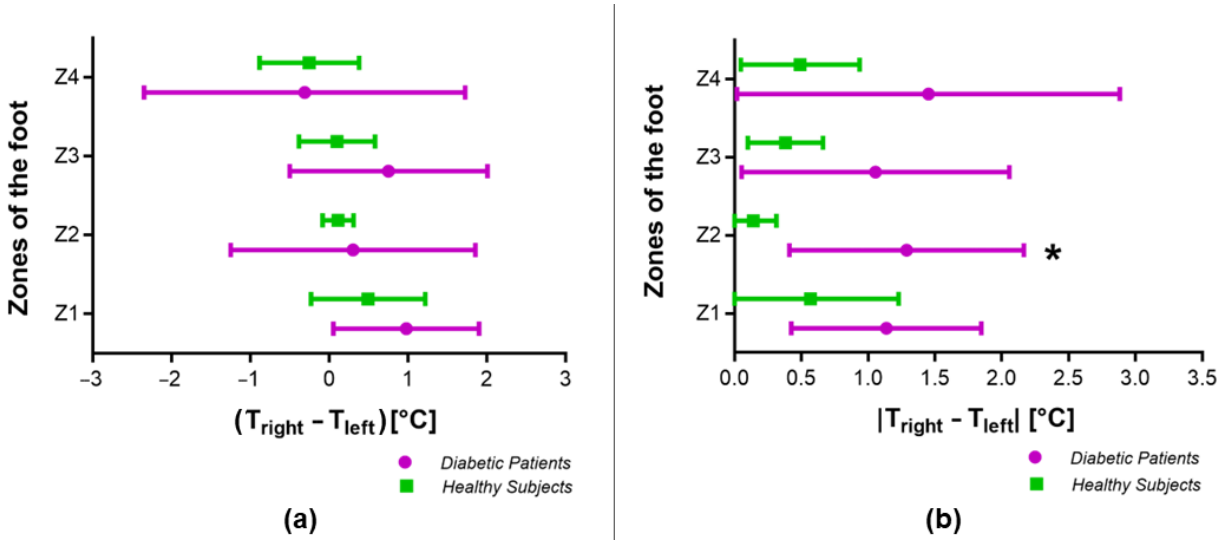


Figure 6. (**a**) Average by zone of the temperature difference of the right foot with respect to the left foot (subtraction of the temperature of the right and left feet), bars = SD. (**b**) Average by zone of the absolute difference in temperature of the right foot with respect to the left foot (absolute value of the subtraction of the temperature of the right and left feet), bars = SD, significant differences (*).

Figure 6b shows the results obtained from calculating the mean absolute difference of each region for all patients. In this case, zone 2 was significantly different, its $p < 0.05$ (2-way ANOVA, post-test: Bonferroni); these results can be expected because it

is the zone with the highest incidence of diabetic foot ulcers. However, all regions have significantly different means between the two groups. The fact that the other regions do not reach statistically significant differences may be due to the small sample size. From the results of the point temperature analysis, we can say that this physical property of plantar tissues can be used as a predictor of diabetic foot. We found that the averages of zone 2 temperature are significantly different in diabetic patients. Our results allow us to find significant differences between the data measured in different zones of the foot of patients with diabetes and healthy subjects. However, due to the size of the sample and not having a diagnosed diabetic foot, it is not possible at this time to know the medical reasons for these differences.

3.2. Electrical Impedance Spectroscopy System

The results of the measurements were analyzed; Figure 7a shows the result of the comparison between the normalized electrical impedances of diabetic patients versus healthy subjects. Significant differences were found for frequencies above 20 kHz ($p < 0.05$). The graph shows the behavior of the normalized impedance in both study groups: in healthy subjects, it is less than 0.05 for frequencies higher than 20 kHz, while the normalized impedance in diabetic patients is almost double (0.09) compared to healthy subjects.

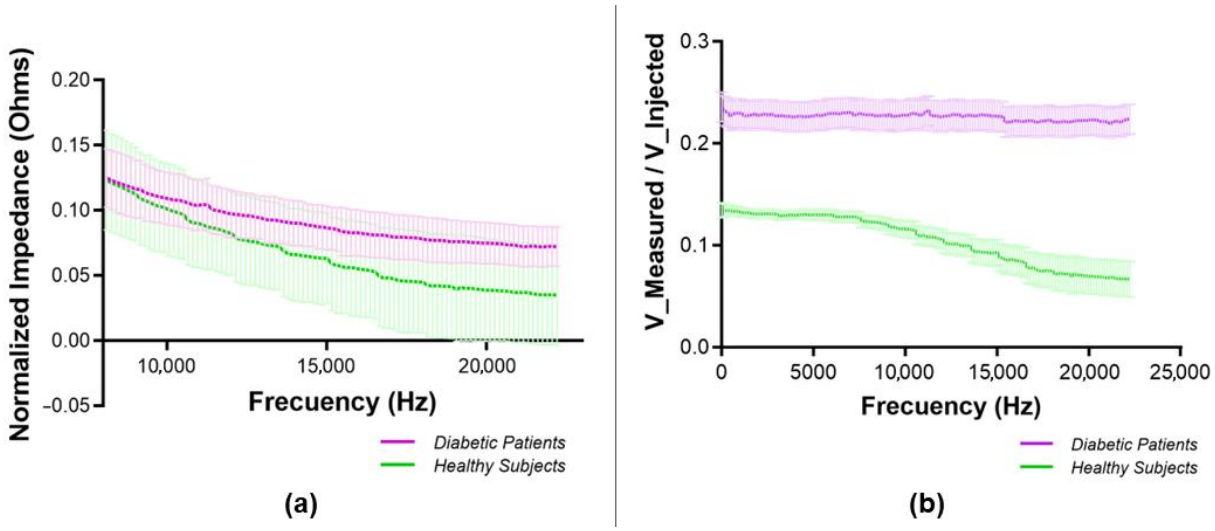


Figure 7. (**a**) Comparison of normalized impedance in diabetic patients and healthy subjects. Dotted lines indicate the standard error of the mean (SEM). (**b**) Comparison of the ratio of measured voltage over injected voltage in diabetic patients and healthy subjects. Behavior of the ratio of the measured voltage to the injected voltage in the two study groups: diabetic patients and healthy subjects. The dotted lines are the standard deviation (SD). SEM is not shown as it appears very close to the mean values.

Figure 7b shows that another analysis method that was performed to find greater differences is to use the result of dividing the voltage measured at the electrode by the injected voltage. That is, using the data one step before the impedance determination:

$$Z = \frac{V_{meas}}{I_{inj}} = \frac{V_{meas}}{\frac{(V_{ref} - V_{inj})}{R_{out}}} = \frac{V_{meas}}{V_{ref} - V_{inj}} R_{out} \quad (1)$$

For the measurement of the injected current, the impedance equipment of Garcia 2015 [18] uses the assumption of a known and previously characterized floating reference voltage upstream of the output resistor, whose trend is exponentially decreasing but invariant (200 mA to 10 mA). By using this voltage to determine the current, the output values are small and hide variations in the measurements that could be important. For this reason and given that V_{ref} and R_{out} are constant, it was decided to study the result of

dividing directly the V_{meas} by the V_{inj} of the previous equation. The results, dimensionless but electrical impedance-related data, are shown in Figure 7b, with a statistical significance level of $p < 0.0001$ for most frequencies (some frequencies of $p < 0.001$), using two-way ANOVA. The behavior of the measured voltage/injected voltage is stable in diabetic patients for all applied frequencies and above 0.2, contrary to healthy subjects where this value drops after 10 kHz for values lower than 0.15.

With these results of the electrical impedance measurement in this number of subjects, we can conclude that the electrical impedance measurements between patients with diabetes and healthy subjects are different, and this variable will allow us to deduce some change in the structure of the tissues once we have more samples and more specific clinical analysis.

3.3. Skin Macule Characterization System

In this section, we present some of the results of the system for the detection and monitoring of macules in diabetic patients. With the processing of the images using the WAIS (Wireless Image System), the segmentation of the patients' maculae into vascular, atrophic and traumatic was obtained, as well as the percentage of damage in the patient. A specialized software for skin macules called Skin Macules Characterization Software (SMaC©) was designed in MATLAB GUI; by analyzing the macules of this study (vascular, petechiae, atrophic and traumatic), it has been possible to identify the properties of each one of them, such as shade indices and morphological properties. It can be said that, with this system, it is possible to differentiate the types of macules since significant differences of $p < 0.05$ were found.

In Figure 8, we can see a screen of the SMaC© software for the segmentation and characterization of macules; it shows some images of the processing, data of the morphological properties and shadow indices of a macule by trauma, and it seeks to keep track of the changes of the macules in diabetic patients and thus help the treating physician to provide correct treatment for the patient.

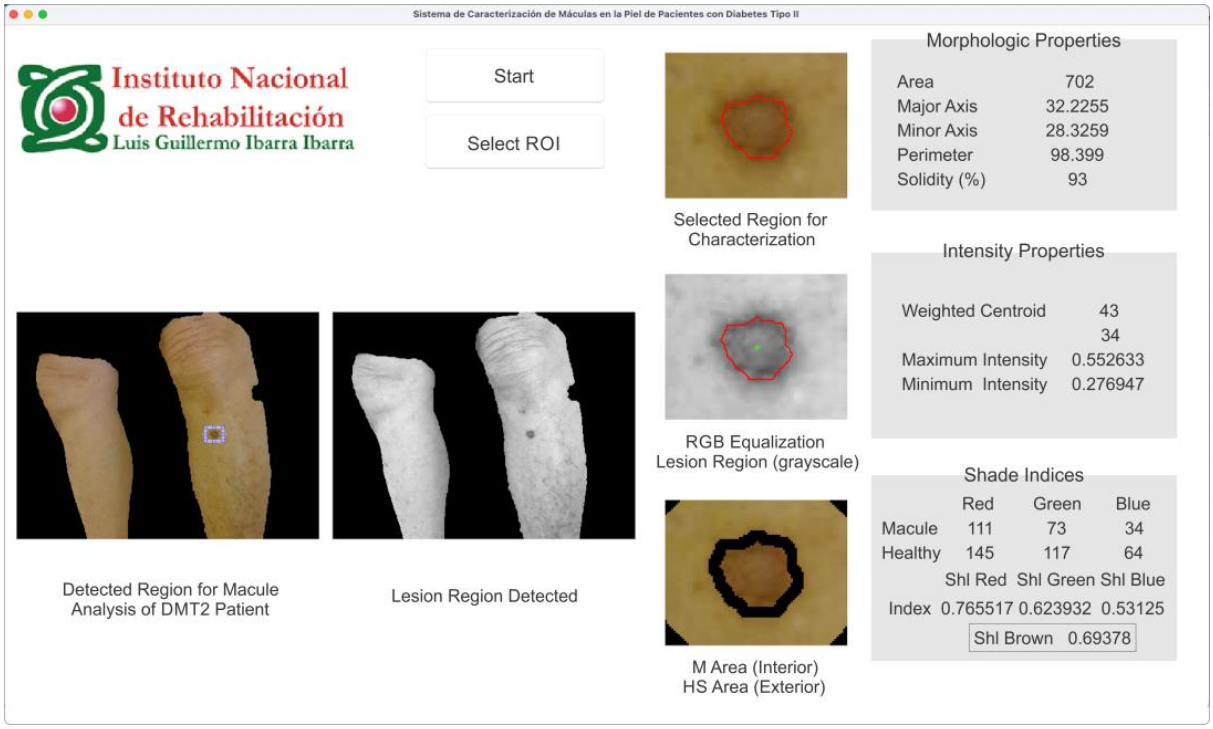


Figure 8. SMaC© software for segmentation and characterization of macules in diabetic patients. The macule shown is due to trauma.

3.4. Infrared Emission Thermography System

We present some of the results of the system infrared thermography system in diabetic patients. Figure 9a shows the temperature variation in healthy subjects and diabetic patients in which the hottest spots on the soles of the feet can be observed. On the other hand, it can be noted that in diabetic patients, the area with the highest percentage of change is zone 2, giving us an indication that it is an area to which we should pay more attention in subsequent consultations. This figure shows the results of the infrared temperature, and variations in the temperature of the areas of greatest risk are shown; on average the difference in temperature between both soles of the feet of diabetic patients is 1.06 °C, but on the other hand, performing the analysis between healthy subjects and diabetic patients, it was found that there is a variation of 1.33 °C. The average temperature of patients in zone 1 was 0.83 °C. The average temperature variation in patients in zone 2 was 0.6~1.5 °C. The average temperature variation in patients in zone 3 is 0.54 °C. In healthy subjects, the variation is 0–0.5 °C, which corresponds to conditions other than diabetic foot, such as flat feet, rheumatoid arthritis and/or vascular problems. These results were obtained from the analysis of the entire set of patients. Figure 9b shows the risk zones of the sole of the patient foot, and three out of the five zones with the highest risk of ulceration were chosen.

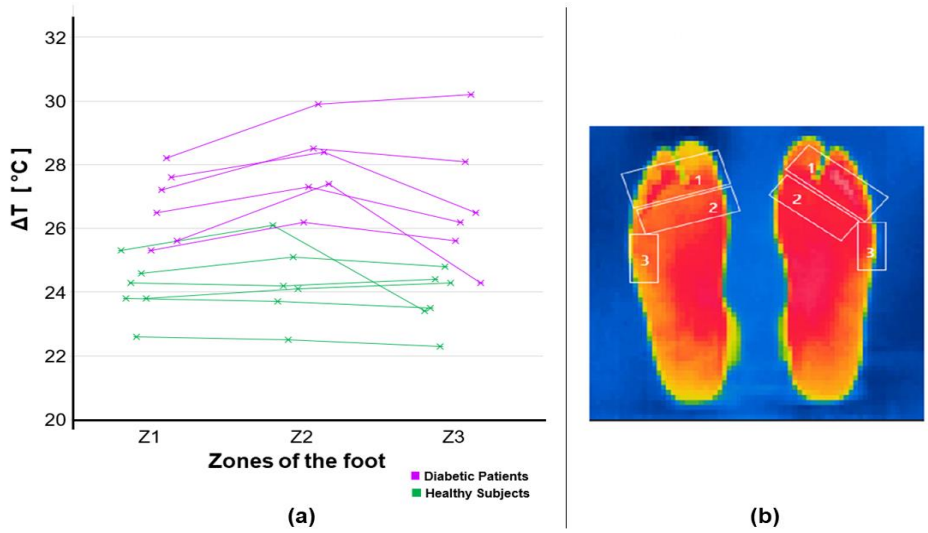


Figure 9. (**a**) Comparison of temperatures by zone of the sole of the foot; the purple line corresponds to the temperatures of diabetic feet and the green line to healthy subjects. (**b**) Areas selected for the temperature study.

3.5. Automatic Detection of Risk Zones by Smartphone

Some of the results found with this procedure are shown below. With the training Mask R-CNN (foot with background) with BD2 (database 2) of high-resolution images, a classification between foot and background was established with 99.25% accuracy, 98.83% in the creation of the detection box and 94.95% in the generation of the region mask. On the other hand, validation using 24 DB1 EV images (database 1) with lower resolution resulted in 99.32% accuracy in classification, 93.48% in detection box creation and 90.09% in region mask generation for each object. In Figure 10c, the masks generated after the adjustment made to Mask R-CNN can be seen; the images are taken in order to observe the difference in the system, and in Figure 10 you can see an example of how the system recognizes and generates the individual masks of the plantar zones. Figure 10a,b show two images of the soles of the feet of two test subjects, captured with the IR camera with different backgrounds and their respective thermographic images (Figure 10d,f). The images show that there is less interference if the areas to be studied are isolated, as well as the distribution of temperatures in the plantar area of the foot [27].

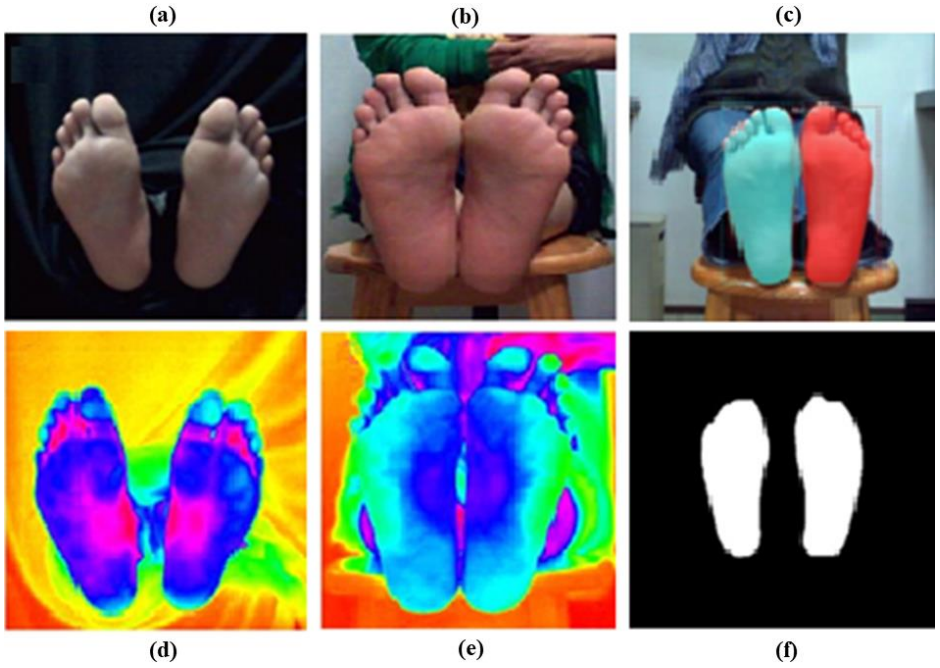


Figure 10. Images captured by the IRT FLUKE TI32 camera with two different backgrounds for the creation of the databases. (**a**) Image of feet with homogeneous black background, (**b**) image of feet with non-homogeneous background, (**c**) adjustment of Mask R-CNN to binary classification system (foot-bottom), (**d**) thermographic image corresponding to the capture of item a, (**e**) Thermographic image corresponding to the capture of item b and (**f**) segmentation of plantar zones in an uncontrolled background environment.

The results illustrated a detection accuracy of 90% for ulcers and 88% for necrosis, while labeled areas had an error of 7.05% and 10%, respectively. These results demonstrated that the system is capable of detecting and visualizing sample-specific temperature differences in an uncontrolled environment.

3.6. Virtual Platform for the Diabetic Foot

A virtual platform was designed to monitor the health status of the feet of diabetic patients. This platform contains a database with the patient file, where we can find the diagnostic and follow-up evaluations, physician notes, pictures and the results of the measurements of the equipment mentioned earlier in this work for the detection of changes in the tissues of diabetic patients and for their routine follow-up. In addition, this platform has controlled access and user roles through registers and user validation, ensuring their privacy.

The virtual platform is composed of different screens, but it can be divided into three parts: new user registration and login (see Figure 11), patient file registration (personal data, vital signs, general data), and diagnostic evaluation of the diabetic patient's legs and feet. In the first part of the platform, the user can register by self-management; however, the access has to go through a validation process by the administrator, since it is important to control the information registered. In the second part of the platform, we can create and update the patient record by adding personal data and vital signs upon entering the medical office. Finally, in the next screen, we can carry out the registration of the health status of the legs and feet of patients through evaluation and monitoring studies in this stage. We can save images of ulcers and compare them with their images at different times and add the results of measurements and tests. All the information introduced in this platform is stored in a specialized database designed for the diabetic foot, thus helping to give access to other variables of the disease.

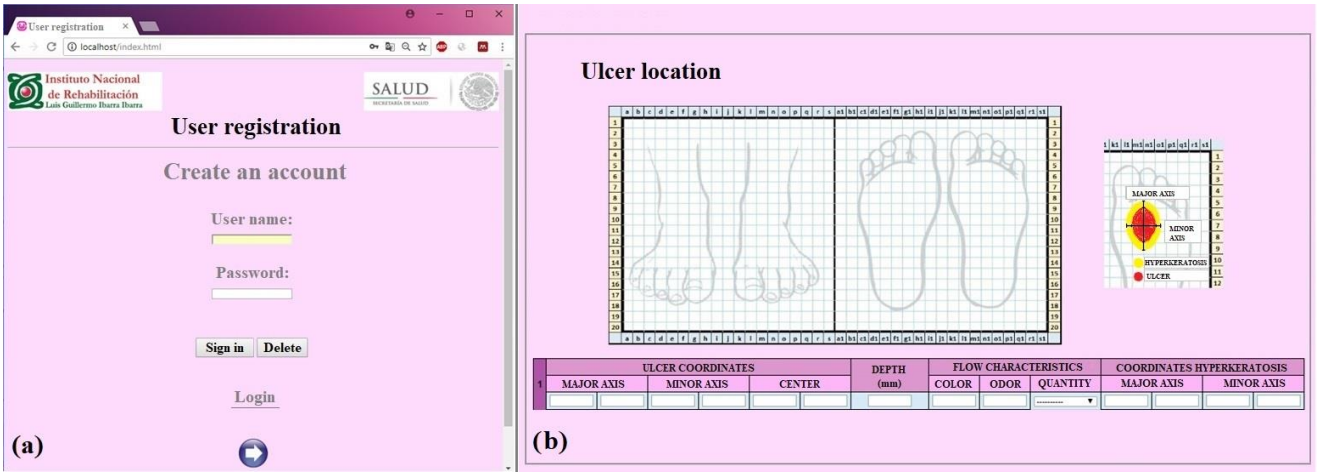


Figure 11. (**a**) Screen of the virtual platform to create a new account and log in; (**b**) screen for locating patients' ulcers by recording their coordinates and their characteristics.

Figure 11 shows a screenshot of a part of the virtual platform; this screen is for registering a new user by entering their name and a personally chosen password, then when accepted by the administrator, the new physician user will be able to log in and enter the patient file to start the consultation or perform a follow-up.

3.7. Hub of Information of Diabetic Patients

The diabetic foot information hub shown in Figure 12a was designed as a portable system, with a unique and friendly interface for the medical user; it could receive and store the information in a database, in which the measurements from external equipment for the monitoring and diagnosis of diabetic foot can be included. The initial screen of the hub has six buttons to control the acquisition from external equipment, which are saved in .xls files. Another six buttons are used to view the results of the previously stored data, and the rest of the buttons are for the general control of the application: create patient file, view the database and exit (see Figure 12b).

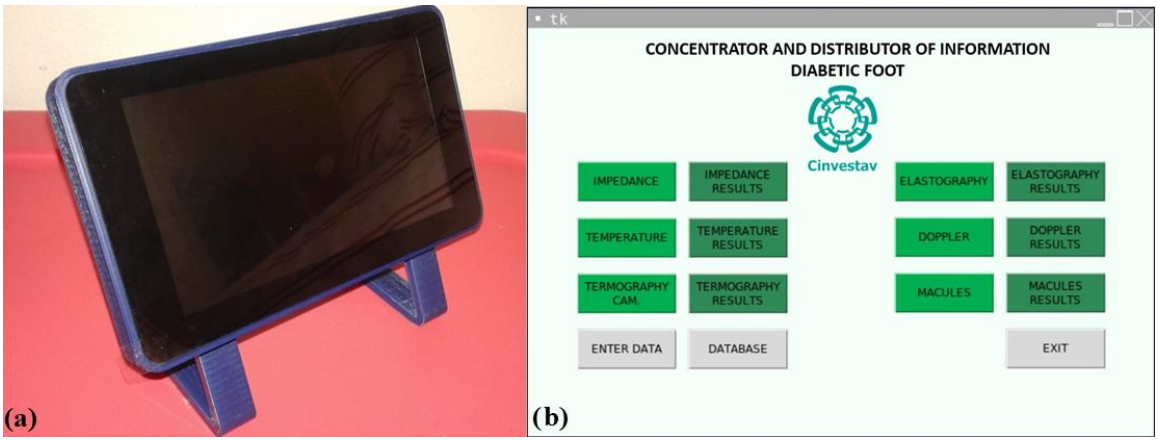


Figure 12. (**a**) Image of the portable diabetic foot information hub system; (**b**) screenshot of the interface for system control, acquisition of measurements, creation of the file, access to database, etc.

4. Discussion

A set of systems was presented that is intended to help in the follow-up and study of the diabetic foot. Comparisons were made of the measurement differences for each physical principle between the results of healthy people and people diagnosed with diabetic foot.

Differences were found in the measurements of punctual temperature, electrical impedance and infrared thermography.

From the results of the punctual temperature presented in this work, we can say that there are differences between the temperatures of diabetic patients and healthy subjects: the temperature in diabetic patients is higher, coinciding with what the authors of these works say [4,16,28]; in addition, they state that this temperature increase is an indicator of foot lesions. The punctual temperature system was tested with a very small sample; a larger sample is required to increase the reliability of our results.

With impedance results, we cannot conclude that any structural damage is present in the feet of patients with diabetes, but we can say that the electrical impedances of diabetics and healthy subjects are significantly different for frequencies from 5 kHz to 22 kHz and the impedances in diabetic patients are higher than in healthy subjects. The study of this work agrees with our results by finding the frequency range from 10 kHz to 80 kHz where the impedance is different in diabetic patients [9]. The author agrees that impedances in healthy subjects are lower than those in diabetic patients [8]. The results shown in Figure 7b are new to the research; since the behavior of the measured voltage between the injected voltage in diabetic foot has not been studied, we found that there are significant results of $p < 0.0001$ for most frequencies.

An algorithm for image processing of skin macules is proposed with a classification network, resulting in an accuracy of 97.5% for the four types of macules studied in this work. Vascular, petechiae, trophic changes and traumacutaneous manifestations are not taken into account in diabetic patients; however, Lasschuit et al., says that they can be some of the first indicators of diabetes and diabetic foot in patients [10], and other authors says that 60% of diabetic patients suffer from this affectation [29].

The infrared temperature measurement system provides images that identify the characteristics of diabetic foot complications; the results of this work indicate that there is an average difference of 1 to 2 °C in the temperature of healthy tissue with respect to the diabetic foot, and given the study of Torreblanca Gonzalez et al., we could say that there is a relationship between the areas with greater temperature changes and the risk of ulceration in diabetic patients [3].

The smartphone-based diabetic foot sole risk zone identifier system in uncontrolled environments can detect risk zones for ulcers and necrosis by analyzing temperature increases and decreases in uncontrolled environments, with an accuracy of 90.09%. A system for remote monitoring of diabetic patients' feet has been developed with the purpose of being implemented as an assistance and follow-up tool for them.

Evidence of the use of a smartphone to follow the evolution of temperature changes in the plantar region was presented, and results of the use of an IR thermometry system in the medical consultation of diabetic patients are shown. A platform for diabetic patients capable of recording the patient's history with graphic material is presented and, finally, the concept of an information concentrator system capable of distributing the information to specialized medical personnel is described.

The results presented in this work are the first indicators that show the possibility of using the characteristics of the physical changes in the tissues of the foot produced by diabetes in medical services, in addition to being unique in its class up to now, at an accessible cost that facilitates the reading of results for both patients and doctors and can have an easy implementation since they are portable.

5. Conclusions

The present work shows the first technological approaches specialized in diabetic foot in order to provide more information on the state of the diabetic patient's plantar tissues and thus help the specialist physician to provide a correct follow-up of the patients, studying the characteristics and changes of the tissues and registering them in specialized databases on diabetic foot. We can conclude from the results shown that it is possible to differentiate the changes in the plantar tissues between the study groups (healthy subjects

and diabetic patients), this being an opening to the study of the behavior of the tissues of the feet in patients with diabetes mellitus. It is intended that in the future the group of these technologies will help the physician for the early detection of diabetic foot and to give an adequate treatment and follow-up to each patient with this condition.

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