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Monitoring plantar pressure forces - Instrumentation proposal for foot damage reduction related to Diabetic Neuropathy

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***Abstract* - The Diabetic Neuropathy is a problem associated with Diabetes Mellitus which generates complications that directly affect some body nerves. One of the symptoms is numbness, specially in the legs, feet and hands, thus, in many cases people affected can be hurting their peripheral limbs without even realizing it. Furthermore, one of the most known syndromes observed in people with the illness is the diabetic foot, a term associated with some problems like ulcers that usually happen. In view of the lack of a cure for this disease, there are only attempts to improve the patient's life quality. So, in this work, it is proposed an instrumented insole with sensors made of resistive fabrics to measure the plantar pressure in important points of the foot to warn the wearer in case of any overload. Moreover, a matricial strategy to collect data from the insole and control it is proposed. In this starting phase, the tests were made with a smaller sensor with the same technology, and its response curve was traced to understand its operation, limitations and pros. Promising results were observed.**

***Keywords* – Diabetes, Foot, Insole, Neuropathy, Pressure, Sensor.**

I. INTRODUCTION

Diabetic Neuropathy (DN) is a pathology associated with Diabetes Mellitus (DM) that causes metabolic disorders and nerve complications [1]. The main form of manifestation is affecting patient's peripheral limbs and DM is the most common cause of Distal Symmetric Polyneuropathy (DSP), which is present in approximately 50% of people with diabetes. If neglected or in case of late diagnosis, it may lead to losses of sensibility and amputations. There is no well-known cure for it and the right use of insulin and glycemic control are the observed attempts to recover and to prevent worse scenarios [1-3]. Even in developed countries, DM is the cause for the most part of peripheral neuropathy cases [3]. However, people in social vulnerability are still the most affected ones, because of the difficulty in getting access to the right treatment process, taking as an example some parts of brazilian northeast region [4].

Diabetic Foot is a term related to a group of pathologies that affect the feet of diabetic patients and it is one of the principal complications of the disease [5]. Ulcerations are connected to DSP and are a common consequence that appears which is the main cause of limb amputation in those who have diabetes [5,6]. Researchers demonstrate that the majority of diabetes patients will first have both vascular insufficiency and peripheral neuropathy while presenting any ulcer on their feet, which indicates that those are very important risk factors [5-8]. Furthermore, there is a considerable probability of ulceration recurrences that occur in the initial healing stage [9]. Thus, ulcers, infections and amputations are common issues that reduce the quality of life of diabetic patients and can lead to death in some cases.

Besides the expanding mortality and morbidity related to diabetes foot disease, there is an economic issue caused by hospital admissions as well, which indicates the importance of this health problem in both spheres [9,10]. This scenario is not recent, it was estimated to be £252 million the cost of diabetic foot complications in the United Kingdom in 2001 [10]. Recently in Brazil, more than 10,000 lower limbs amputations were made in 2020, costing R$12 million for its national healthcare system [11]. Although, most scientific findings highlight the possibility of treating the diabetic foot willing to avoid and prevent complications, especially the worst end stage, amputations.

Thus, there are many ways to avoid bigger trouble on diabetic patient's life. In Khanolkar[6], it can be possible to find some of them. One specific way approached is the Offloading, which basically is to put the pressure on healthy regions willing to reduce where the wounds are [6]. It is important to understand that neuropathy affects the way the plantar pressure is distributed in diabetic patient's feet [12]. So, the study of plantar pressure using sensors has shown to be an opportunity to minimize the risks and all the complications related to diabetic foot. There are attempts to build technologies following this direction, willing to help diabetic patients by monitoring and/or relieving their feet pressure.

Technological products focused on plantar pressure measuring are not recent. Baropodometry is one way to study it, being a platform system that people stand in and analysis is made to understand forces behavior on their feet and patterns besides their steps [13]. However, this instrument is a statical one, which can't follow a moving user, but there already are in-shoe items capable of measuring pressure using distinct sensors and techniques, such as instrumented insoles [14].

Reis, for example, built an insole focused on diabetic foot with strain gauges to monitor plantar pressure [15].

II. FORCE AND PRESSURE SENSORS

There are a lot of sensors capable of measuring the pressure exercised in a region, which is a metric directly related to pressure. The objective of this work is to build an insole efficient in identifying peaks of pressure in the foot of patients with diabetes viewing to warn the wearer in case of overload. Thus, there are some sensors more appropriate to build an in-shoe product. Ramirez-Bautista[15] evaluated the most used ones in products, academic or commercial, with similar purposes (plantar pressure measuring inside a shoe): resistive, capacitive, and piezoelectric sensors. Therefore, in this paper they will be shortly described using literature [16,17] to understand their operation.

A. Force Resistive Sensor

Also known as just FSR or sometimes 'piezoresistive sensors', this type of sensor is built using a semi-conductive polymer material or fabric, which changes its resistance when a force is exercised. It is enveloped by two thin layers of conductive electrodes separated by the composite material and can be made focused on measuring a single point or using space distribution. The way that this sensor is constructed and its physical characteristics give it a good flexibility. It also has a good linearity and a small hysteresis.

B. Capacitive Sensor

This kind of sensor is made of two metallic plates with an elastic dielectric material between them, building a capacitor. As the dielectric layer can change its length, the capacitance is changed when some force is applied, because the two conductive parts will move closer to each other proportionally to this force. This relation is described by the equation 1, that gives the capacitance value (C) in a capacitor made of two parallel plates, where d is the distance between the plates, A is the area of the plates and ε is the electric permittivity of the dielectric material. Capacitive force sensors can be not linear and their accuracy is usually less than FSR and Piezoelectric ones.

$$C = \frac{\varepsilon.A}{d} \qquad (1)$$

C. Piezoelectric Sensor

The piezoelectric effect is basically a phenomenon related to the capacity of some materials, usually crystals, of generating electric power when some mechanical force is applied to them. The reverse path can be observed as well, in other words the piezoelectric material can also vibrate while stimulated by an electrical signal. So, sensors were made using those materials and the read signal is proportional to the pressure exercised following a relation that depends on the constructive aspects of each sensor, as the used crystal. The main trouble related to piezoelectric sensors is that they can hardly measure static or slow varying pressures.

D. Strain Gauges

Strain Gauges are resistive sensors capable of measuring deformations using an ohmmeter because they are made of conductors and their conductive properties are changed when a strain occurs, respecting Ohm's second law (equation 2, where R is the resistance of a conductor with a ℓ length, an A transversal area and a ρ resistivity). Considering some limits, the stretching of a material follows a proportionality relation with the applied force. So, the operation principle is that the resistance varies with the exercised pressure. sensors can be not linear and their accuracy is usually less than FSR and Piezoelectric ones.

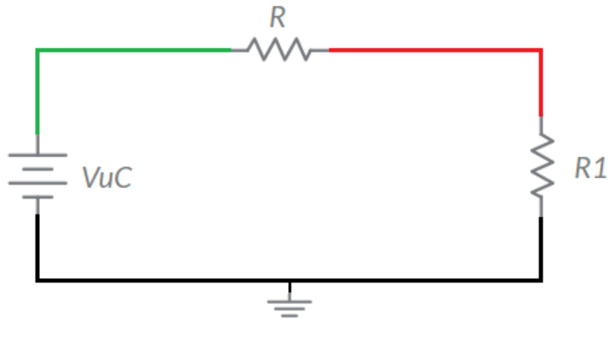
$$R = \frac{\rho.l}{A} \qquad (2)$$

III. MATRIX RESISTIVE TEXTILE INSOLE

There are some points that must be observed to build an instrumented system for measuring plantar pressure [15, 17]. Between them, in this project the focus is on flexible sensors well distributed to not disturb the way the user puts the shoes, giving a good monitoring process with a low cost. Due to the characteristics of those available sensors, FSR showed to be the best option, but the price for buying the right number of them to promote a good cover of the foot areas would be elevated. So, a similar operating principle was chosen and the purpose is to build an insole with conductive layers separated by a resistive fabric. When this kind of cloth is forced, stretched or any mechanical disturbance occurs, their conductive properties are changed. So, the resistance between the two conductive layers is directly influenced by the force exercised in the point. This principle was already explored and published by researchers from Hong Kong Polytechnic University, that reached a conclusion those textile sensors can measure trustable values, besides the good softness and sensitivity [18].

The figure 1 shows the electric circuit that will provide the pressure measurement. The monitoring system will work using a voltage divider technique, where the input voltage from the microcontroller (VμC) and the second resistor (R1) are known and the other resistance is related to the resistive fabric (R). So, the greater the force exercised, the lower the resistance of the fabric, so it can be said that the first resistor value is controlled by the current pressure over it and the voltage value observed is correlated. The equation 3 is the electric expression that is directly related to Kirchhoff laws and describes the voltage at R. It can be observed that the equation is not linear, so the circuit may have a response different from an affine function.

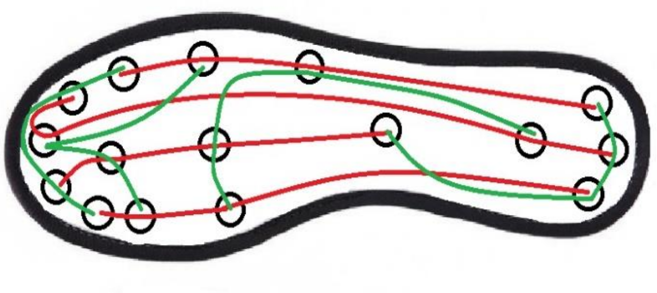
Figure 1: Insole Electric Circuit Abstraction.



$$V = \frac{VuC.R}{R1+R} \qquad (3)$$

The chosen strategy to collect pressure data from different points of the feet consist in a matrix of conductors. On one side of the insole, it will have horizontal conductive thin layers and on the other side vertical conductive thin layers, as shown in figure 2. Each point of intersection will have a resistance value related to R, in function of the fabric between the bottom and top layer of the insole, monitoring some specific area of the foot. Thus, in the following image, it can be seen three principal elements: a red wire, a green wire and the gray part inside the insole. The green lines are the voltage input of the electronics circuit, where each one will be connected to a distinct digital output of the microcontroller. The red lines are wires that go to R1 and to an analog input to measure the tension. The colors are like those used on figure 1 to make it easy to understand. Between these two layers there will be a resistive fabric, so one conductor will be on top of the conductive material and the other underneath it. The black circles are the points where the resistance will change in function of the force exercised. Therefore, there are 16 sensors in this initial proposal distributed in important regions of the feet [12,13].

Figure 2: Insole Conductive Matrix.



So, a high digital signal will be sent in each green wire and all the analog voltages in the red lines will be read, one by one in different microcontroller pins. In this way, with this scanning method, it will be possible to collect the pressure magnitude in all regions delimited by the black circles, that is directly related to the resistance of the fabric electrical contact with the two conductors. This resistance, as already said, decreases when some force compresses those areas. With this initial distribution proposal, it is required a microcontroller with 4 digital outputs and 4 analog input pins. The programming code must have a cycle where the four analog inputs values are read four times, each one with a different output pin in high level.

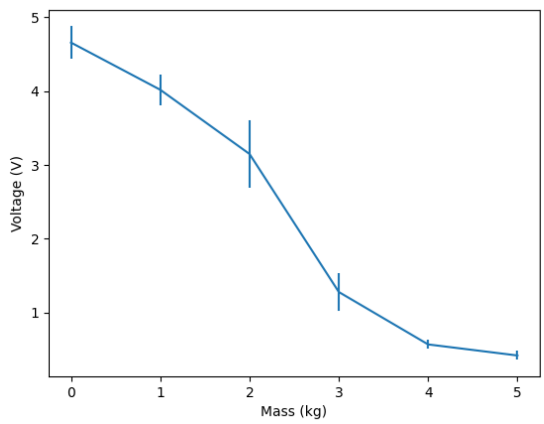
IV. RESULTS

To start to verify the utility of this kind of instrumentation, a smaller sensor made using the same strategy, conductors separated by a resistive fabric, was tested. The sensor, with a central area of 1,5 cm x 1,5 cm, is shown in figure 3, where it can be seen one side of the perpendicular conductors, the darker lines into the brown film. The main objective was to see how the cloth resistance changes under variable pressure, to verify the possibility to apply this technology in the insole, with a view on the needed requirements, specially to provide a good and trustworthy measure system to be used in neuropathy patients.

Figure 3: Small Fabric sensor.

So, to start the experiments, a microcontroller was programmed with simple code of analog read and digital write functions. Thus, in this first experiment made to see how the sensor operates, it did not require huge processing and memory storage capacities. Basically, a high voltage signal of 5 V was sent to the circuit with two resistors, similar as shown in figure 1, where a 10 kΩ resistor was used in series with the fabric sensor. The higher the voltage value over the sensor, the lower the pressure exerted, and this variable was read and displayed using a communication by serial port. It did not need many analog readings in a second, so the sampling rate was chosen aiming to understand the time spent to stabilize the analog measure of the microcontroller.

Figure 4: Response curve.



With the system in running mode, different weights were put over the sensor to see how the voltage changes. All the mass was positioned in a way that all the pressure forces stand over all the sensor area, so the results are reliable. For each weight, ten measures were made. To plot the response curve the average of those ten values was used, and to provide a metric of the error the standard deviation was included (figure 4). Using linear regression techniques, it was possible to find the expression that approaches the most to the sensor behavior (equation 4). It is observable that the expression is a quadratic function that provides an estimate of the voltage value on the sensor when some mass *m* is placed on top of it. So, knowing the voltage V it is possible to find that mass with mathematical calculation, which will indicate the roots of the equation. The data collected experimentally and used to build the graphic is shown in table 1.

$$V = 4{,}92 - 1{,}23 * m + 0{,}055 * m^2 \qquad (1)$$

Table 1: Voltage value per mass

Mass (kg)	Voltage (V)	Error (V)
0	4.66	0.23
1	4.02	0.21
2	3.15	0.46
3	1.28	0.26
4	0.57	0.06
5	0.42	0.06

The figure 1 shows the electric circuit that will provide the pressure measurement. The monitoring system will work using a voltage

V. CONCLUSIONS

The diabetic neuropathy is one of the main consequences related to Diabetes Mellitus, affecting a large part of the population suffering from this disease. If neglected it can lead to ulcerations and, in the worst scenario, to amputations, mainly in the lower limbs, especially in the feet. It is a public health issue in all parts of the globe that negatively impacts the economy and, most important, is responsible for human losses. Academic trials showed that one of the ways to avoid bigger troubles is to lead the load over healthy areas to reduce the exerted pressure on the bruised and fragile ones. So, an instrumented insole made with resistive fabric was proposed to monitor the applied force in, initially, 16 points of the feet, that can be easily made in the laboratory and it is not expensive. The data will be collected with a scanning system that will be able to read the voltage in all those places at high speed. The voltage between the two sides of the fabric can be converted into information about pressure by knowing how the response curve of the material is. So, in order to understand better how this tissue works, a small sensor was tested and its similar quadratic behavior identified. The appropriate microcontroller capabilities to be applied in the insole, such as the required clock, memory and number of digital and analog pins might be specified later, because in this starting phase the goal was only to test the sensor operation. But the primary projection is that the system will not require a lot of computational power. Therefore, despite some deviations, the sensor showed a good proportionality relation between pressure and resistance, especially considering the incipient aspect of the tests, so it can be used to build the insole. The next steps consist in building the insole, parameterizing and testing to validate it.

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