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Insole with Pressure Control and Tissue Neoformation Induction Systems for Diabetic Foot

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Abstract— **This article presents the development of a prototype insole derived from natural rubber from *Hevea brasiliensis*, equipped with pressure control and capable of neoformation of tissue for people who have diabetic foot. The active element of this insole is the electronic circuit that monitors the plantar pressure. In addition, on the present stage of the research, a signal irradiating cell is used based on the principle of tissue regeneration using laser. This project proposes a "smart" insole prototype with a pressure monitoring system and an electronic system for tissue regeneration, which will open a new approach in an attempt to solve the problem of diabetic foot.**

I. Introduction

Diabetes mellitus (DM) is one of the most important health problems today. It is a disease with high morbidity and mortality. It is a chronic disease characterized by a variety of complications. One of these complications is the diabetic foot, which is considered a serious disease and often presents devastating consequences due to ulcerations, which can result in amputation of toes, feet or legs [1] [2].

Diabetes causes neurovascular complications which changes the biomechanics of the normal foot, producing high pressure areas in the regions of the metatarsal heads, heel and toes [3]. For this reason, it is vitally important to identify these areas by using pressure gauges in order to prevent injuries on the feet. One way of treating the diabetic foot is by reducing the foot's tissue pressure. According to several studies [5] [6], the value of plantar pressure correlates with the risk of developing foot ulceration. Several studies have been conducted, using data from records of plantar pressure in order to determine the main risk factors for foot ulcerations. Cavanagh et. al used a system inside the footwear to measure and record the plantar pressure and locate the areas of major risk in patients with diabetic foot [5]. Their study with patients with no sensitivity in their feet indicated that the repetitive application of high pressure associated with neurovascular changes may lead to ulceration on the plantar surface. Zequera et. al used a wydrocell pressure sensor to study the plantar pressure distribution on the sole of the foot of normal and diabetic subjects in the early stages [4].

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Zequera et al. also developed a new method for making and producing therapeutic insoles, which integrates various technologies such as computer-aided design manufacturing for registration of foot sole pressure, podoscopy, and an knowledge-based expert system [7]. Chang et al. proposed a methodology for molding and making a custom insole and adaptive multi-airbag for redistribution of plantar pressure using a rapid system for measuring pressure based on images [8]. Viswanathan et al. developed three different types of insoles, with polyurethane, ethylene vinyl acetate, microcellular rubber and cork, for diabetics with neuropathy [9]. Bernard et al. used pressure and temperature sensors in high-risk areas on insoles, which are used to detect the early formation of ulcers on the feet [10]. Frade et al. handled diabetic skin ulcers with the use of a natural latex biomembrane, as an alternative with curative ability to accelerate healing [11]. However, optimal techniques for the treatment and prevention of diabetic foot with a satisfactory rate of success have yet to be found.

This paper presents a novel insole derived from natural latex rubber (*Hevea brasiliensis*) with pressure monitoring system and electronic system for tissue regeneration, which will open a new approach in an attempt to solve the problem of diabetic foot.

II. Methodology

This work used a simultaneous engineering project methodology to ensure that the project specifications are not conflicting within macro-steps and can not produce a result different from the originally specified. We use a combination of techniques and project methodologies based on engineering and design. Figure 1 presents a block diagram of the electronic systems for pressure monitoring and tissue regeneration.

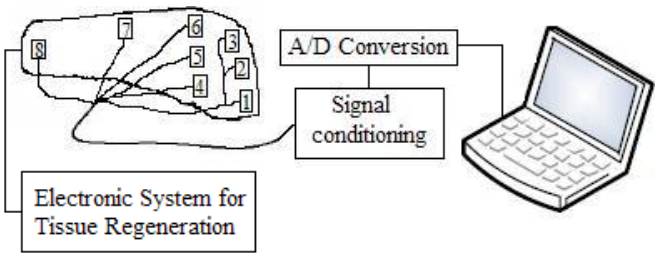

Fig. 1. Block diagram of the electronic systems for pressure monitoring and tissue regeneration.

In the idealization of the development of the insole, we considered materials which already exist in the market, which are mostly made of silicone, polyurethane, ethylene vinyl acetate and viscoelastic. The physical and chemical

biocompatibility characteristics, antigenicity, flexibility, elasticity, softness, strength, impermeability and hypoallergenicity of the materials were also taken into consideration. Based on these considerations, natural latex extracted from rubber tree *Hevea brasiliensis* was chosen. This material is also used in making esophageal prosthesis, biomembranes and esophageal flow controller module [12] - [15].

A final compound was prepared with natural latex, which gave the insole indispensable features such as elasticity, softness, opacity and hypoallergenicity. This compound was achieved through addition of chemicals [12]. The insole has been developed through four macro-steps: i) making the mold, ii) treatment of the biomaterial, iii) making the product, and iv) circuit instrumentation.

A. Making the Mold

The first step of the development was to make the insole mold using nylon tecnil. The mold was designed in CATIA V5, taking into consideration the anatomical shape of the average size human foot (6-6.5) for the prototype, as shown in Fig. 2.

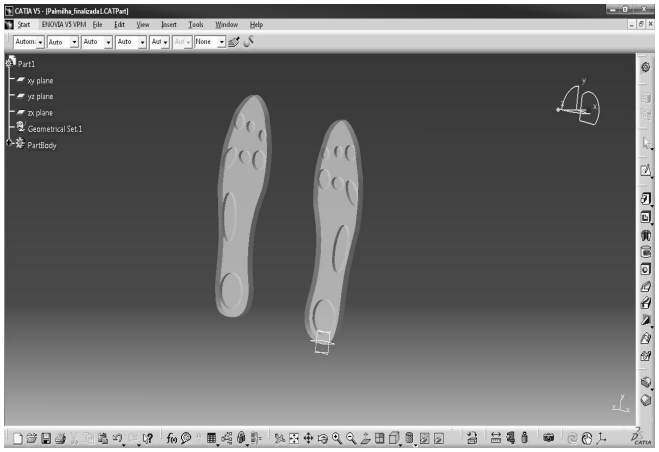

Fig. 2. Outline of the insole instrumented with sensors positioned. The software used was CATIA V5.

B. Biomaterial Treatment and Manufacturing of the Product

The second step was biomaterial treatment, i.e., the process of making the material biocompatible and suitable for the proposed application. The fabrication protocol was divided in two micro-steps: preparation and characterization of the product. Characteristics which are vital to the product — e.g., softness, comfort, hygiene and shock absorption — were taken into consideration.

The latex was submitted to a centrifugation process to reduce the amount of protein naturally contained in it. Many of these proteins are responsible for allergic reactions. Sulfur and resin were added to give the final compound the necessary elasticity and resistance [12] - [13].

This confection process transforms the latex into a compound which is vulcanized and become sticky when in contact with the skin. Water is sufficient for its removal. In tecnil nylon surfaces, removal is facilitated due to the low friction that this material provides.

The technique of successive immersion baths was used in the process of making the insole [12]. The molds were immersed slowly in a perpendicular position into the final latex compound, followed by heating in an oven with a thermostat.

The molds were previously washed with soap and water, dried with hot air, sterilized by autoclaving (heated in an oven at 50 ° C), withdrawn and immersed in latex, and kept immerse in this compound for 1 minute. This step represents the beginning of polymerization phase, which determines the final product manufacture. After this stage, the molds were removed slowly and gradually, and placed inside the stove (subjected to heat for vulcanization in a temperature of 100° C) at intervals of five minutes. The stove was then turned off, and the molds were kept inside for another 20 minutes.

The steps of bath and heating were repeated to obtain a 7-mm insole thickness. After the period of vulcanization, the insole was kept in room temperature for 24 hours to complete the process of confection. At the end of the process, the insole was removed from its mold using running water.

C. Instrumentation Circuit

The active element of the insoles is an electronic circuit to monitor the pressure applied by the feet in each step cycle (gait). The force sensors are designed to be inserted into the insoles. The strength sensor system was designed to allow the monitoring of the force distribution in the plantar region and consists of strain gauges, signal conditioning circuits, A/D converter and the software acquisition system.

The signal from the sensors is first amplified and filtered, then digitized, processed and then sent to the PC through a serial port. There are several types of digital pressure sensors for different applications and with different dimensions, according to the application needs. This research project uses the extensometer, which is a transducer capable of measuring object deformation. The transducers designed to monitor the force distribution exerted on the plantar region of patients were resistance strain gages (strain gages model KFG-1-120-C1-16, Kyowa Electronic Instruments Company Ltd., Japan) which present array dimensions = 4.8 mm x 2.4 mm, width = 1.1 mm grid and tolerance resistance: 120 ohm.

The positioning of the sensors was chosen based on the literature [6], and considering the opinion of health professionals. In each insole, eight transducers were installed, and positioned in areas where there is a greater discharge of patient weight. The eight areas selected for analysis and evaluation of plantar pressure were: hallux, 3rd toe, 5th toe, 1st metatarsal head, 3rd metatarsal head, 5th metatarsal head, mid foot and heel. Fig. 2 shows the outline of the insoles and the sensor locations.

The signal conditioning circuit produced by the strain gauges is comprised of: power circuit, amplifier, filter and a PIC18F452 microcontroller. This signal conditioning circuit captures the signal coming from the transducers, amplifies and filters it. The microcontroller receives the signals from

the analog signal conditioning circuit and performs the A/D conversion. LM324N operational amplifiers are used to amplify the signals to an operating range more suitable to the converter. Given that the converter operates between 0V and 5V, and that the analog input is on the order of millivolts, we used a signal amplification gain of 2000. A 2nd order Butterworth low-pass filter, built on the integrated circuit, was used. The power supply is a 3V 1216 CR battery with 12 mm of length. This battery is responsible for supplying energy to power all devices, circuits and sensors with adequate voltage levels, and is essential for maintaining proper circuit functioning. The transducers were statically calibrated with increasing and/or decreasing application of forces. A communication interface for the transmission of data from the microcontroller to the PC was designed using Matlab tools.

D. Electronic System for Tissue Regeneration

The electronic circuit also includes a signal irradiating cell based on the principle of tissue regeneration using laser. Low power laser radiation with electromagnetic wave spectra possess angiogenic action, which may cause an increasing rate of tissue formation. Low intensity laser therapy has been used in specific disorders, since its application reduces the duration of the inflammatory process by stimulating tissue repair, thus producing a mechanism of action that creates mainly anti-inflammatory effects [16]. Laser radiation has been frequently used to accelerate the healing process, both in experimental models and in clinical setting. The effects of low power laser radiation in bone and tissue regeneration have been studied with encouraging results [16] - [18].

The tissue regeneration electronic system inside the insole emits laser radiation in eight points (heel, mid foot, metatarsal head 5, metatarsal head 3, metatarsal head 1, toe 5, toe 3 and hallux). These are the same points used for the introduction of the plantar pressure monitoring sensors, shown in Fig. 1. We used a green laser device of He-Ne (helium neon) type, whose power is 0.95 mW with a length of 632.8 nm (visible color).

III. RESULTS AND DISCUSSION

The technique of successive immersion baths was used in the process of preparation [12], followed by heating and subsequent room-temperature cooling. This resulted in a new type of insole derived from a cheap material that, once treated properly, becomes a biomaterial that has its own characteristics for the proposed application.

The tissue regeneration electronic system was initially evaluated with "in vitro" experiments. This system is still in early development stage, and will be presented in more detail in future works.

During the design stages, the main difficulties occurred during the mold design stage, and during the design of the pressure monitoring system. For this system, we planned to use a module with embedded software, but this was not possible because of size limitations.

The product's differential is the instrumentation circuitry, which may provide important data for preventive physical therapy. With the data from the pressure sensor, it is possible to analyze the patient's gait and train him to step in a more appropriate manner. An inadequate gait may cause injuries, which is dangerous for diabetes patients.

Human studies are planned, and the authors are currently waiting for protocol approval from the research ethics committee of the University of Brasília. One of the possible applications of the proposed insole is to collect data regarding the mobility of diabetic subjects in daily situations. This could provide more useful data than the current tests, which typically measure plantar pressure in a hospital environment. The proposed circuit may be modified with respect to the power supply for recording data during these "in vivo" studies.

The need for specific treatment in this field of study is clear, and the high degree of amputation due to disease is alarming. Thus, an alternative product to prevent ulcerations and amputations will guarantee quality of life for diabetes patients. The proposed insole is very accessible, and may be produced at a low cost price.

For future work we propose an evaluation of the product in diabetes patients. Such study would be important to evaluate factors such as the behavior of the diabetic foot in relation to gait and pressure distribution — thus providing data that can be applied in a preventive protocol through physical therapy — and the analysis of the laser cell — which can aid in regeneration tissue, which eventually could be applied in other types of wounds.

IV. CONCLUSION

A prototype of a "smart", high quality and low cost insole was designed to act as a preventive mechanism for diabetic foot, opening a new approach in attempting to solve the problem of diabetic foot. According to the results, we conclude that the insole has admissible applicability. The material and the proposed model demonstrated a prospect of obtaining a multidisciplinary approach with potential for treatment and prevention of diabetic foot.

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