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Development of a Smart Insole for Baropodometric and Gait Analysis

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Abstract. With recent technological advances, in-soles or smart insoles have been designed, with a different arrangement of sensors. The objective of this project is to develop a new model of smart, wearable insole composed of hardware with twelve resistive force sensors, $FSR^@$ 402 short, coupled to an ESP-WROOM-32 embedded microprocessor module for wireless data acquisition, processing, storage and transmission, integrated with Android application software for data reading, sensor fusion and creation of dashboards to be displayed on an interface. The results of the concept validation tests in the laboratory have demonstrated that this new device can be used in future clinical studies as a tool for real-time baropodometric and motion analysis in various daily life, work and sport activities, with respect to injury prevention, disease assessment and diagnosis, and rehabilitation support.

Keywords: Smart Insole, Wearable Devices, Baropodometry.

1 Introduction

According to Shumway-Cook and Woollacott [25] for postural control, constant neuromuscular adjustments are required, through the processing of information from the visual, vestibular and somatosensory systems (proprioceptive, joint and cutaneous receptors). The plantar region of the feet also plays a fundamental role in stabilizing the body, as they contribute to the distribution of weight in the orthostatic position and influence postural control and gait parameters [30].

In the standing position, balance is controlled by muscular action, which moves the distribution of plantar pressure, changing the rotation of the foot around the ankle (anterior-posterior) and the distribution of total body weight on both sides. feet (side). [6]. The heads of the 1st and 5th metatarsals and the calcaneal tuberosity support greater pressure [11]. These stability limits change constantly depending on the task, the biomechanics of the person and the support surface, which can be stable or unstable, depending on the type of footwear.

In this way, the foot is considered a link between an imbalance of high origin and the ground, which will always adapt to neutralize the support, and can be considered the terminal cap of the postural system, in descending postural alterations, or the initial one, in the ascending postural alterations [5]. Foot and ankle disorders are prevalent in the general population and one of the main motivations for primary care consultations, usually these disorders are associated with the type of plantar pressure distribution [14].

The measurement of plantar pressure is generally confined to a laboratory environment, primarily through pressure platform systems, also known as baropodometers. However, in recent years, with recent advances in sensor technology and mobile devices, in-shoes or smart insoles have been designed, each with a different arrangement of sensors [20]. Despite this variety of models, it was found that the main benefit observed in smart insoles is the continuous monitoring of functional, occupational and sports activities in real time.

Several studies with populations at risk have already been carried out using smart insoles, with the aim of evaluating the plantar pressure of hemiplegics [8, 10, 22]; in the postural control of children with Cerebral Palsy [17]; to detect when excessive pronation occurs in patients with hallux valgus [3]; in the treatment of Parkinson's Disease [28]; alcohol-induced gait disorders [19]; as well as in the prevention and healing of pressure ulcers in individuals with diabetic neuropathy [1, 16, 23, 26].

Some studies [15, 27, 32] used smart insoles to analyze the gait pattern, whose main parameters are: stride duration, cadence, stride length and gait speed. Substantial evidence on cognitive neuroscience and motor control suggests that gait parameters can reveal important factors that determine general health and well-being [2], with gait speed being considered a sixth vital sign because it has been validated as a marker of frailty and mortality in the elderly [04].

Smart insoles are flexible, portable and comfortable for gait analysis and can monitor plantar pressure in real time by means of built-in sensors that convert the applied pressure into an electrical signal that can be displayed and analyzed later. Several research teams are still working to improve the insole features, such as size, sensitivity of the insoles' sensors, durability, and the use of artificial intelligence to monitor and control the gait of subjects, providing recommendations to improve gait performance.

Therefore, the objective of this research is the development of a new model of smart insole, composed by force sensors, coupled to an embedded system for acquisition, processing, storage and wireless transmission of data, integrated to a software for reading the data, fusion of sensors and creation of dashboards that will be displayed in an interface.

This new device could become an objective and low-cost tool for real-time baropodometric and movement analysis in various daily, work and sports activities, regarding injury prevention, evaluation and diagnosis of diseases and support for rehabilitation of osteomyoarticular pathologies related to stepping and gait pattern.

2

2 Methodology

When a new technology is created or conceptualized, it must go through delimited, described and standardized maturity levels, until it is ready for use and commercialization. The Technological Maturity Level (TML) is a systematic metric, with nine levels, developed in 1974 by Stan Sadin, a senior scientist at the National Aeronautics and Space Administration (NASA), which allows the assessment, at a given moment, of the maturity level of a particular technology or the comparison of maturity levels between different types of technologies, as well as the entire context of a specific system, its application and its operating environment [29].

Based on the TML scale, a strategic plan was organized focusing on the feasibility of the concept and product development. This project reached level 4 of technological maturity, including the validation of the prototype in the Laboratory of Biomedical Instrumentation and Electronic Tests of the Nucleus of Strategic Technology in Health (NUTES) of the State University of Paraíba (UEPB).

The dimensions of the smart insole correspond to number 40 according to the Brazilian standard of measurements, with approximately 265 mm in length, 90 mm in width and 3 mm in thickness. The structure of the insole has three layers: two layers of armor composed of Ethylene Vinyl Acetate (EVA) and Corotex; and a conductive layer for connecting the sensors, consisting of a double-faced copper plated phenolite. The printed circuit manufacturing process was carried out by machining in a CNC milling machine, through copper grinding.

Shielding layers are important to increase the durability of the insole, once they protect the sensors from mechanical damage and from the influence of environmental factors such as temperature and humidity. The material indicated by the FSR datasheet [12] to be used in the shielding layers is a thin elastomer (3 mm), as it allows a better sensor repeatability.

For plantar pressure sensing, FSR® 402 short resistive force sensors manufactured by Interlink Electronics (Canada) were used. The FSR® exhibits a decrease in resistance with increasing pressure applied to the sensor's active area (12.70 mm). The sensitivity range of the FSR® 402 short ranges from 0.1 Kgf/cm2 to 10 Kgf/cm2, with an accuracy of \pm 5 to \pm 25% depending on measurement system consistency, repeatability tolerance and device calibration [13].

Regarding the choice of types of pressure sensors, according to Razak and collaborators it appears that force-sensitive resistance sensors, especially the FSR 402, are the most used in smart insoles projects, especially because of the following characteristics: low cost, low hysteresis, low temperature sensitivity, linear response and a pressure sensitivity range from 0.1 Kgf/cm2 to 10 Kgf/cm2 [20].

This sensor also meets the recommended size in systematic reviews which is 5mm×5mm, as a larger sensor may underestimate peak pressure, and with a smaller sensor it is difficult to control the displacement of pressure points of interest during gait, therefore, smaller sensors are recommended for use in an array system, such as pressure platforms [20, 21].

Twelve sensors were used in this smart insole, which are positioned in specific areas of the plantar region: four sensors in the rearfoot (1-4), region of the calcaneal bone; two sensors in the midfoot (5-6), medial and lateral longitudinal arch region; and six sensors in the forefoot (7-12), region of the metatarsal bones and phalanges (Fig.1).

In the literature, there is no consensus between the quantity and positioning of sensors in the smart insole to obtain a better measurement of plantar pressure. According to Razak and collaborators [20] this determination depends on which clinical and functional analyzes will be performed by the smart insole and is limited to different sizes of feet, since the position of the pressure points changes. However, the literature indicates that the minimum number of sensors per insole is between three and four, due to the main pressure areas in the plantar region, which includes the heel, the head of the first and fifth metatarsals and the hallux, such as observed in the studies [10,11].

Shu and collaborators [24] mentioned that the plantar region of the foot can be divided into 15 areas: heel (area 1-3), midfoot (area 4-5), forefoot, on the metatarsal heads (area 6-10) and phalanges (area 11). -15). These areas support most of the body weight and are adjusted by the body's balance. Therefore, ideally fifteen pressure sensors are needed to cover most body weight changes based on foot anatomy.

Fig. 1. - Positioning of the FSR[®] 402 short sensors on the smart insole. (Source: Author's own data)

In this project the sensors are connected in an "n+1" line structure to build a sensor array. The use of matrices has the advantage of not having to make any a priori decisions about the areas to be monitored, since a larger area of the plantar surface can be accessed at once. [20]. Line "1" connects the set of sensors to the ground (GND) and line "n" represents the output of each sensor. By combining several force sensors, it is possible to measure force at a single point, as well as distributions by region. To connect the sensors to the conditioning circuit, a flat cable was used due to its flexibility, malleability and viable thickness for application [18].

For data acquisition, processing, storage and transmission, an ESP-WROOM-32 microcontroller manufactured by Espressif Systems (China) was chosen, with the following characteristics: low cost; small size, measuring just 18mm x 25.5mm and pin spacings at 1.27mm pitch; Tensilica Xtensa 32-bit LX6 dual core microprocessor; adjustable clock from 80MHz to 240MHz; has 512KB SRAM and 32Mb external flash memory; 36 general purpose GPIO ports; SPI interface; 18 ADC pins; WiFi and Bluetooth communication [9].

In order to physically protect the embedded system, a protective case was designed, manufactured by additive manufacturing in the LT3D Laboratory (NUTES/UEPB), so the embedded system can be protected, isolating the possibility of any physical contact between the user and the board and the electrical supply system (battery). For the device's power system, a 3.7v, 1500 mAh, 2-Wire Lithium Battery was used. Charging time for this battery varies from 3 hours in fast mode and from 2 to 6 hours in standard mode.

Voltage signals in the FSR® 402 short sensors are extracted from voltage dividers (R = 10kΩ) and then sent to the 12-bit analog-to-digital (A/D) channels (0 to 4095) of the ESP-WROOM microcontroller -32 via a flat cable and then transmitted to a mobile device such as a smartphone or tablet via Bluetooth transmission (Fig. 2). The software is an Android application, capable of processing and reading the collected data, merging the force sensors and plotting all the data in images.

Fig. 2. - Smart insole integrated circuit prototype. (Source: Author's own data)

For software development, Flutter was used, which is an Open Source SDK (Software Development Kit) or user interface (framework) toolkit developed by Google, to build natively compiled applications on iOS and Android, for mobile devices, web and desktop from a single codebase.

3 Results and Discussion

The results of the proof-of-concept tests with the electronic components and the smart insole system were carried out in the following stages: 1st) test of the FSR® 402 short sensors; 2nd) sensor integration test to the ESP-WROOM-32; 3rd) test of data transmission via Bluetooth; and the 4th) application functionality tests.

To analyze the responses of the FSR® 402 short sensors and their operating range, tests were performed by applying pressure directly to the active area of the sensor. Each sensor was subjected to increasing loads from 1 to 10 kg, using metal washers as they are standardized and easy to handle. In order to verify the responses to the applied loads, the output voltage was measured on the FSR, using a Minipa Digital Multimeter, model ET-1100A, and using the Arduino analog reading (Fig. 3).

Fig. 3. Bump test of FSR® 402 short sensors. (Source: Author's own data)

Seeking to ensure that the correct weight was added only in the active area of the sensor, an instrument with two metal plates and a fixed rod with two magnet tips of different dimensions was designed and manufactured by the Machining Center of NUTES/UPEB, adapt to different types of sensors (Fig. 4)

Fig. 4. Instrument developed for testing the response of the FSR® 402 short. (Source: Author's own data)

To measure the pressure through an FSR, the values read in the range of 0V to the voltage of 3.3V were mapped. The regression curve relating the force/pressure and tension of each FSR can be obtained from the information contained in its datasheet [11] and represented in Equation 1:

$$
F(kgf) = 511,6 \times V_{fsr}^{-1,683} - 22,75 \tag{1}
$$

In Figure 5 it is possible to observe the comparative graph between the points obtained from the datasheet and the regression curve of Equation 1, with a correlation coefficient (R2) of 0.9991.

Fig. 5. Comparative graph between the datasheet points and the force/pressure regression curve in relation to the FSR voltage.

In the tests of hardware integration with the embedded system, it was evidenced that the ESP-WROOM-32's 12-bit ADC has an output signal that can vary from 0 to 4026 as the sensor is pressed. This range represents the voltage variation on the analog port, which can also be interpreted as a variation range from 0 to 3.3 volts, according to the sensor resistance variation.

The sampling period is shaped by the processing time and data acquisition, where the 12 sensors are read in a time of 10 ms, so the device can operate with a sampling frequency of 100 Hz. The data transmission time is determined by the ESP-WROOM-32 Bluetooth version 4.2 bit rate per second which is approximately 1 Mbps with a sampling rate of 2.45 GHz, 1,200 data per second are generated depending on of the sampling time of 10 ms. The sensors were read continuously during the tests, allowing the evaluator to visualize in real time the pressure distribution in the plantar region.

Regarding the baropodometric variable analyzed in the Application, it concerns the distribution of plantar pressure, expressed by the Engineering Unit kilogram-force per square centimeter ($kgf/cm²$), which will be displayed in the interface in the form of images with chromatic spectrum, to demonstrate the variations in pressure levels in each sensor and by plantar area, taking as an example the commercial software of baropodometers (Fig. 6).

Fig. 6. Smart Insole Application. (Source: Author's own data).

The color spectrum is divided into six colors that represent the pressure ranges of each sensor:

- a) Dark blue: $0 1,6$ kgf/cm²
- b) Light blue: $1,6 3,3$ kgf/cm²
- c) Green: $3,3 4,5$ kgf/cm²
- d) Yellow: $4,5 5,9$ kgf/cm²
- e) Orange: $5.9 6.8$ kgf/cm²
- f) Red: $6.8 10$ kgf/cm²

With the values obtained it is also possible to manually calculate the maximum pressure (1), average pressure (2) and center of pressure (3) using the following equations [33]:

$$
Peak = Max(p_1, ..., p_i, ..., p_n)
$$
 (1)

$$
Mean = \frac{1}{n} \sum_{i=1}^{n} p_i
$$
 (2)

$$
\begin{cases}\nX_{cop} = \frac{\sum_{i=1}^{n} X_i P_i}{\sum_{i=1}^{n} P_i} \\
Y_{cop} = \frac{\sum_{i=1}^{n} Y_i P_i}{\sum_{i=1}^{n} P_i}\n\end{cases}
$$

where *p* is the plantar pressure, *n* indicates the total number of sensors, *i* denotes the i-th sensor, and *X* and *Y* are the coordinates of the entire area of the foot.

4 Conclusion

This project had as main objective the development of a new model of smart insole, whose system is divided into hardware and software. The hardware collects, stores and transmits the plantar pressure data on the feet to the software, which saves and displays the data in an interface.

In the conceptualization phases of the insole, the resistive force sensors of the FSR® 402 short type were chosen to be used in the measurement of plantar pressure, as they meet the main requirements of this system, among which its linear response, low hysteresis stand out, operating range from 0.1 Kgf/cm2 to 10 Kgf/cm2 and an active area diameter of 0.5 inches. It should also be noted that the number of twelve sensors and their respective locations in the smart insole proved to be effective for the features of this device, given that these specifications were determined based on the areas of greatest plantar pressure through a review in studies with baropodometric analysis.

The collection, storage and transmission of output signals from the sensors by the embedded system containing an ESP-WROOM-32, showed correct functioning in the hardware feasibility tests. The data transmission rate of this smart insole is 100Hz, which allows its application in various clinical gait analysis tests at different speeds.

The power system with a 3.3 V battery allowed energy autonomy to isolate the individual from the electrical network, as well as not limiting its use in relation to the structure in the environment (socket, cables, etc.), and still responded efficiently to the energy consumption of the smart insole, as it did not interrupt data collection for at least three hours of system use with the battery at full charge.

As this project is still in the prototype phase, the hardware design and the types of materials used in the manufacture can be modified after technical evaluation, to make this device even more comfortable, light and flexible. In addition, it is intended to develop several sizes of insoles, in order to adjust their use by individuals of different age groups and sex, adapted to foot sizes and types of shoes.

For this system, a graphical interface of the Android application type compatible with smartphone was developed, allowing a better display and reading of the data of

(3)

each sensor, which were represented numerically and by figures with chromatic spectrum.

As the results of this project only showed the feasibility of the concept with laboratory tests, it is necessary in future works to validate this prototype through clinical studies in various environments, considering changes in temperature and humidity, with the performance of several functional tasks (work, sports and daily activities), both for healthy individuals of different ages, and for the evaluation and diagnosis of diseases.

A suggestion for future work is to add to the hardware a 9-axis MPU 9250 type IMU (InvenSense Inc., USA) with inertial sensors accelerometer, gyroscope and magnetometer, enabling the evaluation of all spatio-temporal parameters of gait, as well as tracking the angular and rotational movement of the ankle joint during locomotion.

Furthermore, we will try to implement more functions in the software such as: analysis of maximum and average pressure by region; stabilometry; step count; gait speed; ankle angulation; warning signs to prevent injury hazards, detect a pre-fall condition or pathological gaits. One can also think about the use of appropriate and efficient algorithms to relate the pathologies to the sensor signals. Therefore, the objectives of this work were achieved, regarding the characterization and development of a new smart insole and its demonstration in the laboratory through concept validation tests.

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