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DESIGN AND DEVELOPMENT OF PERINEOMETRIC SIGNALS ACQUISITION SYSTEM, VIA WIRELESS (BLUETOOTH)

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Abstract. *The increasing advancement of technological devices has been bringing more and more efficient and accurate methods of evaluation, testing and exercises. In the area of evaluation of the pelvic floor muscle contraction, the use of perineometry has been more preferred by physiotherapists because they are effective and simple applicability methods. In this context, it was identified the absence in the clinical practices of the use of biofeedback applied in perineometry. Thus, this study has as main objective to present the design and development of a Perineometric Signals Acquisition System (PSAS) via wireless aided by a graphical user interface (GUI) that allows audio and visual biofeedbacks, allowing to facilitate the progress of the physical evaluation of the individual.*

Keywords: *perineometry, biofeedback, wireless, perineometer, graphical user interface.*

1. INTRODUCTION

The evaluation of muscular strength and endurance is of great importance, since it allows to identify the degree of muscular weakness and thus to carry out the planning of a specific treatment program for each subject (Baracho, 2012). The pelvic floor muscle (PFM) correspond to a set of muscles located between the pubis and the coccyx and responsible for the inferior closure of the pelvis. In general, PFM are composed of 70% slow contraction muscle fibers (type I), responsible for the maintenance of muscular tonus, and 30% of fast twitch fibers (type II) responsible for the strength (Greer, *et. al.*, 2008; Sand and Dmochowski, 2002). This muscle group has some functions: support the pelvic organs, sexual function, act on the stabilization of the trunk and maintain the pressure responsible for the closure of the urethra and anus during the different activities (World Health Organization, 2000; World Health Organization, 2015). The functional evaluation of the musculature is considered a relevant prognostic factor in the treatment of pelvic diseases like urinary/ fecal incontinence, prolapses pelvic and sexual dysfunctions (Botlero, *et. al.*,2009).

In view of the growing number of elderly people and the consequent increase in the number of cases of these problems, it is expected that the demand for health services specialized in pelvic floor muscle dysfunctions will grow significantly in the coming decades (Walters, 2004).

The first training of the PFM was done by Arnold Kegel (1948). As the pathogenesis of dysfunctions begins with loss of support of the pelvic floor muscles, training of these muscles has proven to be an effective method of prevention (Slieker-ten-Hove, *et al.*, 2010). Individual targeting and verification that the patient is adequately contracting the musculature are essential prior to initiating treatment, as approximately 30% of women are unable to contract the PFM in the first evaluation (Bø, 2012).

Among the physiotherapeutic methods of evaluation of the pelvic floor muscle strength, we can highlight: visual functional evaluation, vaginal cones, surface electromyography (SEM), biofeedback, perineometry, ultrasound and magnetic resonance imaging (Do Nascimento, 2008). Among pelvic floor muscle evaluation methods, perineometry is performed using a perineometer, a simple, minimally invasive and inexpensive instrument (Rahmani and Mohseni-Bandpei, 2011) that measures the pressure exerted by the contraction perineal, indirectly measuring the strength of PFM (Baracho, 2012).

Perineometry, also known as manometry, is one of the techniques recommended by the International Continence Society (ICS) for the functional evaluation of PFM (Sultan, *et. al.*, 2016). It is already established that this resource has high intra-rater reliability (ICC 0.95) (Herrera, *et. al.*, 2008).

The operation of a perineometer is based on the variation of intravaginal pressure that is caused by the contraction of the pelvic floor muscles measured through a compressible vaginal catheter (Frawley, *et al.*, 2006). The contraction of the PFM provides a variation of the pressure of the probe that is captured by a pressure sensor, processed by data acquisition system and shown on some display, set of LED's or sent to another electronic device in order to be better visualized and automatically. Currently, several equipment with different specificities are available such as Peritron^{TM} (Cardio-Design, Australia) and Perina^{TM} (Quark, Brazil) which are the most commonly used perineometers Other equipment known in the literature are Neurodyn Evolution^{TM} (Ibramed, Brazil) and SensuPower^{TM} (Kroman, Brazil) (Barbosa, et al., 2009). However, the current equipment do not provide some data or resources of great importance for the evaluation like mean pressure, maximal voluntary pressure and fatigue.

In addition to the peak of pressure generated by the muscular contraction, information such as the time of support and the fatigue threshold must be evaluated and are necessary items to be analyzed before and after a rehabilitation protocol. Furthermore, among the equipment available on the market, such as Peritron^{TM} (Cardio-Design, Australia), Perina^{TM} (Quark, Brazil), Neurodyn Evolution^{TM} (Ibramed, Brazil), none of them have wireless transmission of perineometric signals. It is known that the presence of wire makes it difficult to evaluate this area and greater care is needed to avoid contamination. Another deficient point of the perineometric evaluation of the PFM is the absence of the results in the form of qualitative and quantitative graphs of muscle activity, due to the lack of a computer-equipment interface. Although these features are already possible to be acquired through surface electromyography, the SEM technique presents some limitations like cross talk and high cost.

In this sense, this study aims to develop a perineometric signals acquisition system (PSAS) that is able to provide data remotely of peak pressure, mean pressure, base pressure and that allows the temporal graphical analysis of these variables and the muscle activity and fatigue assessment to generate different types of interactive biofeedbacks transmitted wirelessly to the screen of a computer, smartphone or tablet, facilitating the effectiveness of the examination and the understanding of the verbal commands that are used by the professional to direct the patient's actions during the evaluation.

2. EXPERIMENTAL PROCEDURE

The development of PSAS occurred in three stages: 1- Project; 2- Manufacture; 3 - System tests.

Initially, essential requirements were established for the construction of the prototype, they were: compact, lightweight, low-cost, energy-independent and wireless transmission hardware; intuitive, simple graphical user interface with option of recording the exam to make the patient's history and focusing on the possibility of obtaining different types of interactive audio-visual biofeedbacks transmitted wirelessly.

To meet the requirement of being a wireless transmitting instrument, it was decided to use a transmitting module with Bluetooth technology. This decision is due to the fact that Bluetooth is a low-cost, low-power technology, ISM frequency band operation available worldwide, has methods to reduce interference and has a well-defined protocol structure, avoiding the interoperability of devices from different manufacturers (Martincoski, 2003). These characteristics, coupled with the wide availability of Bluetooth transmission on computers and mobile devices, make this technology an advantageous alternative for the acquisition of perineometric signals. The flowchart that exposes the flow of data read from the pressure sensor to its transformation into biofeedback in the software is shown in Fig. 1.

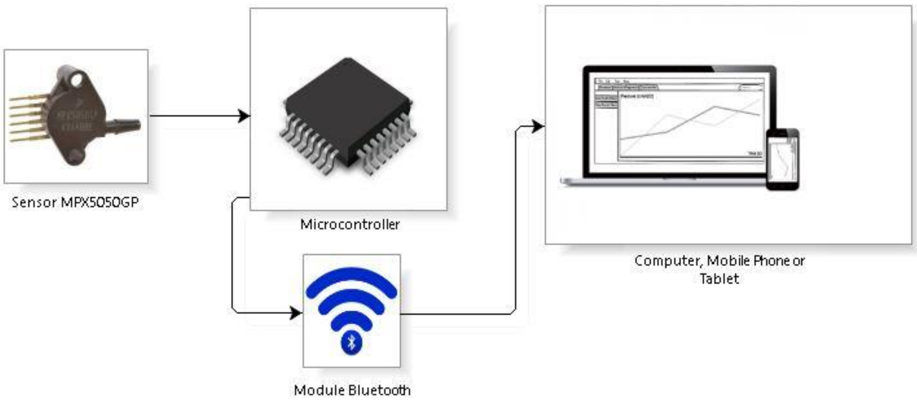

Figure 1. Schematic layout between PSAS and a Computer, Mobile Phone or Tablet.

In order to allow a greater mobility of the equipment during the perineometry, increasing the comfort of the patient and the professional during the evaluation of the PFM, it was decided to use a feed with four AA (R6) batteries in the PSAS. In addition to generating significant device positioning autonomy during the evaluation, the use of batteries further reduces the cost of the equipment, as there would be no need to include an external voltage source to the device.

For the creation of the graphical interface for presentation of biofeedback, it was thought to divide the software into four categories distributed in tabs, they are: exercises, analysis, diagnosis and questionnaire. In the exercise chart, we thought of plotting the perineal pressure graph (cmH_2O) for the time (s) as the standard chart, but other chart types with colors and formats will also be available. In this screen, it would be possible to plot guide functions so that the patient can exercise the PFM, replicating the graphical functions from the professionals orientation. In the second tab, in analyzes, the physiotherapist would have access to the summary of the exercises done by the patient. Then, in the diagnostic tab, it would be possible to obtain the data of peak pressure, mean pressure, baseline pressure, muscle activity of tonic fibers and evaluation of muscle fatigue. Finally, in a questionnaire, the patient would answer some questions to register and better understand which exercises with greater difficulties and record their evolution. In the development of the graphical interface, we tried to develop user-friendly software, composed only of the essential elements in the clinical practice of perineometry. The software prototype can be seen in Fig. 2.

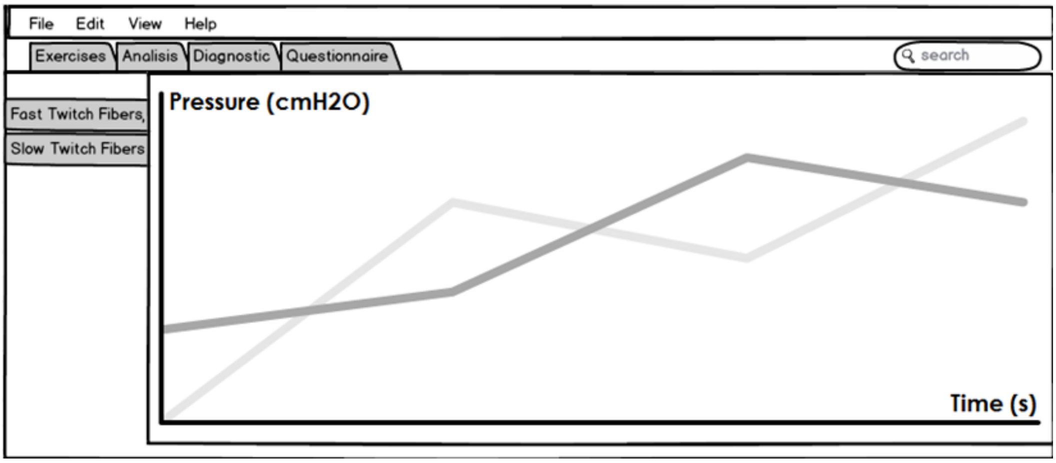

Figure 2. Prototype of the graphical user interface with use case example with visual biofeedback.

At the manufacturing stage, a prototype was developed that met the usability requirements quoted using a compatible microcontroller and Bluetooth module. For this, two printed circuit boards were designed using CAD software where all electrical and electronic components were allocated with satisfactory space between them, maintaining the system's compactability.

After the completion of the design of the printed circuit boards, it was necessary to make the boards. Due to the need for practicality and the agility to produce them, we opted for the prototype method of prototyping printed circuit boards made in this study.

For the acquisition of pressure signals obtained through an inflatable probe, the MPX5050GP pressure sensor was chosen because it satisfactorily fulfilled the operating range commonly used in perineometry considering the maximum mean contraction of 40.8 cmH_2O for nulliparas (Kim, *et al.*, 2012), from 0 to 300 cmH_2O, enabling mathematical manipulations to avoid the most uncertain operating range, the range less than 25% of the maximum operating value and greater than 75% of the maximum operating value of the sensor.

The calibration process of the MPX-5050GP pressure sensor was performed at the Metrology Laboratory at the Nucleus of Industrial Technology of the Federal University of Rio Grande do Norte. Initially a system was set up to put under the same pressure both the sensor to be calibrated and the calibrator. For this, a three-way valve was used where the inlet was connected to a 60 mL capacity syringe, the first outlet was connected to the sensor and the second to the calibrator. Before and after the instruments were connected, PTFE tape (Teflon tape) was used in order to avoid any leakage in the system.

The calibration method chosen was the multipoint method whereby the pressure value applied by the syringe is measured in the pressure calibrator Presys PC-507, used as standard, and read in the pressure sensor of the PSAS, thus creating by means of linear regression calibration curve. Six series of eleven pressure measurements were performed with a measurement range of 0 to 400 cmH_2O generated by the application of a force on the syringe plunger in ascending order of values, alternating with the decreasing one, where the electric voltage readings were obtained in millivolts , in the PSAS sensor and the corresponding pressure value, in cmH_2O in the pressure gauge. The system assembled for calibration can be seen in Fig. 3.

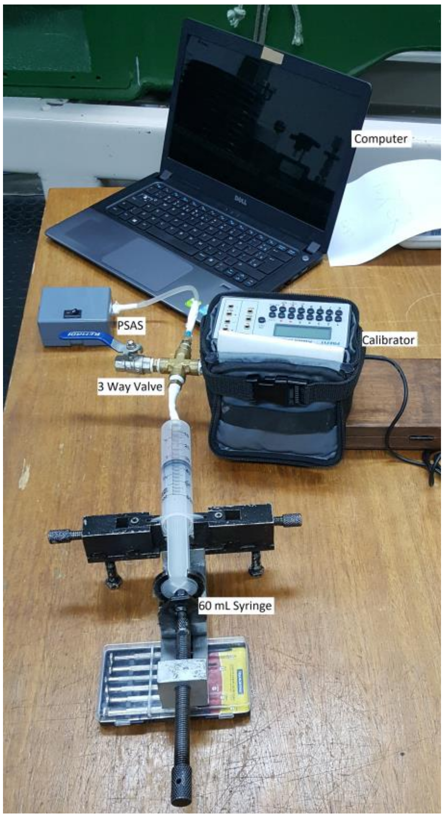

Figure 3. Assembly of the circuit made for the MPX-5050GP sensor calibration process, using a Presys PC-507 Pressure Calibrator next to the assembled data acquisition system.

In the development of the graphical interface, we tried to develop user-friendly software, composed by essential elements in clinical practice of perineometry.

3. RESULTS AND DISCUSSION

After the manufacturing process of the printed circuit boards, assembly of components, connection tests, the obtained data were grouped into six series of eleven measurements and were plotted on a graph that relates the values measured by the sensor with the values read by the calibrator. Subsequently, the mean value of the measurements at each point was calculated and also plotted on the graph. Finally, using simple linear regression, it was possible to define an equation of the curve that passes through all the points corresponding to the mean of each of the eleven measurements. The graph generated at the end of the calibration process is shown in Fig. 4.

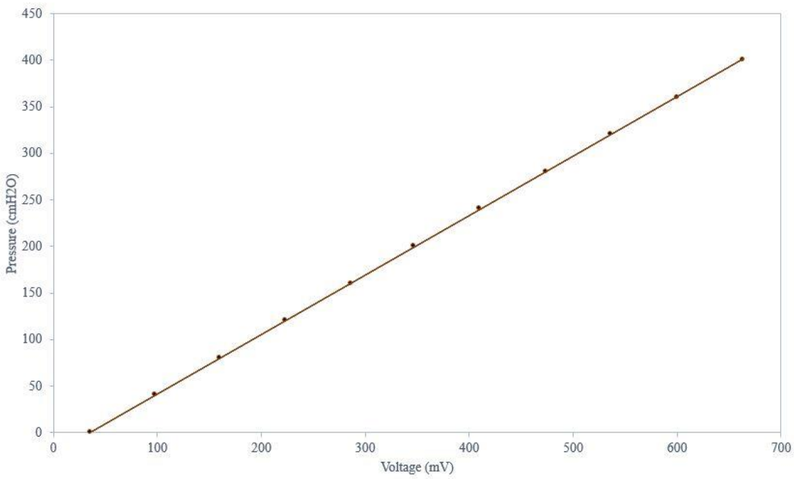

Figure 4. Calibration curve of measurements of MPX-5050GP sensor.

Therefore, the calibration curve obtained at the end of this study is presented in Eq. (1):

$$f(x) = 0.6376 \cdot x - 21.7580 \tag{1}$$

In Eq. (1), $f(x)$ represents the pressure value measured in cmH_2O and x is the value read by the output of the sensor in electric voltage in millivolts.

At the end of software development where the perineometric probe signal will be transformed into audio-visual biofeedback, the pressure graph option (cmH_2O) x time (s) was implemented in the exercise screen, the other screens of the software were not implemented. The resulting final screen of this implementation can be seen in Fig. 5.

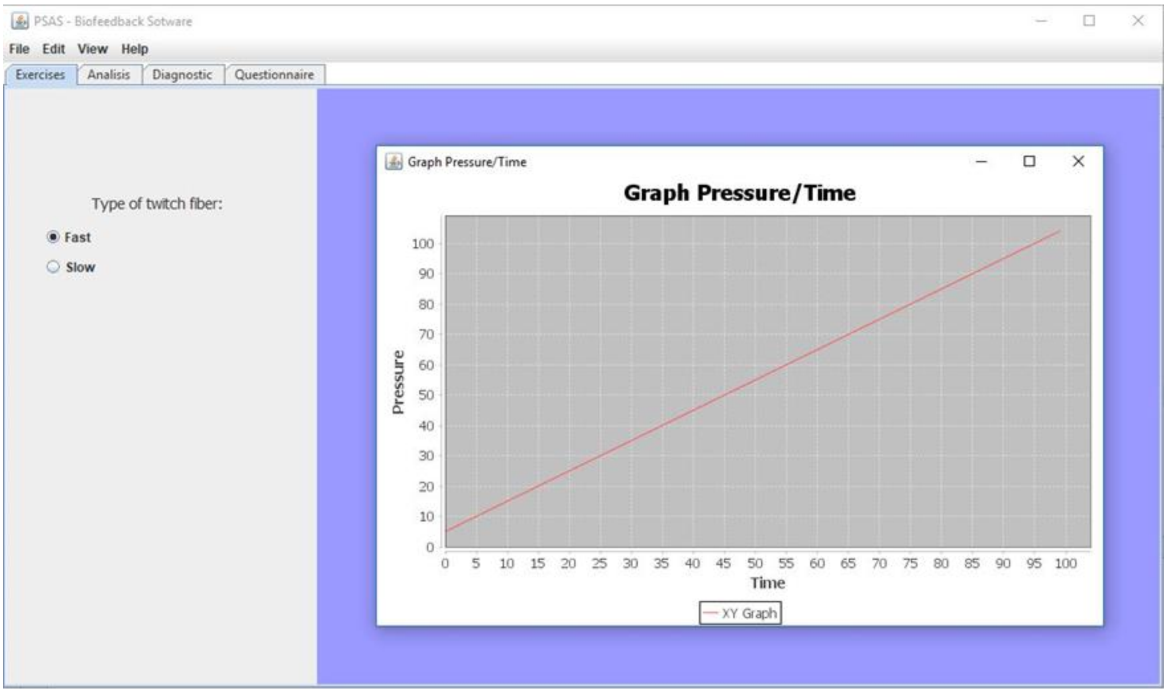

Figure 5. Final software showing the graphical user interface with use case example with visual biofeedback.

Tests using real PFM assessments were not performed in this study.

4. CONCLUSION

It is important to note that the ratio obtained between the values measured in cmH_2O in the calibrator and those measured by the pressure sensor in millivolts, resulted in a linear relationship within the measurement range used in the experiment from 0 to 400 cmH_2O. The largest relative error present in measurements within the measurement range 0 to 40 cmH_2O was found, which was due to the fact that below 25% and above 75% of the measurement range there is of course a lower reliability of the values read by any sensor.

Based on the data obtained from the prototype at the end of the calibration processes and creation of the graphical interface, it can be stated that in order to make the communication, as regards the understanding of the verbal commands between the professional and the individual, more effective, generating greater comfort and tranquility for the individual, it was possible to develop a low cost data acquisition system that allows to use software and hardware, in order to generate a deeper interaction during the perineometry, previously seen only for surface electromyography.

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6. RESPONSIBILITY NOTICE

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