DEVELOPMENT OF A DEVICE TO MEASURE MULTIDIRECTIONAL ISOMETRIC PELVIC FLOOR STRENGTH

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Abstract. *Pelvic floor muscles exercises are recommended as an initial conservative management of Stress Urinary Incontinence because it contributes to continence mechanism. Measuring pelvic floor muscle strength is one of physical therapy goals in the rehabilitation of pelvic floor dysfunctions. Many different techniques have been developed, but none of them measured pelvic floor in a multidirectional way. The aim of the present work is to report the development and the calibration of a device designed to measure pelvic floor strength in a multidirectional form in the vaginal canal. The device was elaborated to follow the morphology and anatomy of the vaginal canal described in the literature. Its geometry consists of a main cylindrical probe with the medium portion composed by four pairs of sensors (force sensitive resistor type) shifted by ninety degrees around the main axis. With this configuration, it is possible to measure eight different force points, being able to measure isometric pelvic floor strength. In order to guarantee the reproducibility of the measurement results, it was developed a dedicated system to calibrate the proposed device.*

Keywords*: pelvic floor, device, calibration, strength.*

1. INTRODUCTION

Urinary incontinence and pelvic organ prolapse are urogynecology dysfunctions that have great impact in sexual function and in women's quality of life. Surgical intervention, pharmacological treatment and physiotherapy are the currently available therapeutic options for these affections.

Physical therapy has been postulated as first line treatment of stress urinary incontinence; by promoting strengthen of pelvic floor muscles (Dumoulin, 2003). Pelvic floor strengthen and the increase of the muscular stiffness, help the improvement of the pelvis support through a superior displacement of these muscles promoting a higher stability of the pelvic complex (Bo, 2004; Bo and Sherburn, 2005).

The voluntary function of the pelvic floor is the massive contraction that results in the rise and closing of the urethral, vaginal and anal openings (Bump, 1991). The inward movement of these muscles and the resulting action in the pelvic region reflect the power, the resistance and the functional status of the pelvic floor muscles. For that reason, reliable direct measurement of this musculature strength is essential for assessing the effects of such treatment (Schull, 2002).

Vaginal digital palpation, pressure measurements, dynamometers are clinical approaches to measure pelvic floor muscle strength (Dumoulin, 2003; Verelst, 2004; Morkved, 2004). Vaginal digital palpation is the most common method for evaluating strength. It is simple, low cost but it is a subjective assessment (Shull, 2002). Pressure measurement instrument reads any pressure modification in the vaginal canal, regardless if it comes from the abdominal or vaginal cavity (Bo, 1990). In order to overcome this limitation, the dynamometer is designed to measure the static force of pelvic floor muscles. It is composed of a dynamometric speculum and a computerized central unit, which allows pelvic floor muscles be measured at different muscles lengths (Dumoulin, 2004; Verelst, 2004).

Vaginal digital palpation and pressure assessments are methods that measure pelvic floor muscles in an indirect way (Verelst, 2004). The dynamometer measures force in a direct form, but in one direction at a time. Diagnostic or

evaluation procedures based on these measurements do not take in account the actual pelvic floor dynamics, once it is known that the movement occurs both in the transverse plane and in the mid-sagital plane.

In the present work, in order to meet the requirements of plane measures, it was developed a new prototype device that measures pelvic floor isometric force in both mid-sagital and transverse plane at the same time. In this context, the objective of this article is to present the new prototype and its calibration protocol and results.

2. METHODOLOGY

2.1. Measurement system

The measurement system is composed of three parts: the vaginal probe with FSR (force sensitive resistors) sensors, the data acquisition system and the operational software. The vaginal probe may be constructed in different diameters, which it is suitable for different morphologies of vaginal canal. It is divided in three parts: the tip, the sensitive cylinder and the grasp cylinder, as shown in "Fig. 1". The tip has rounded shape format in order to allow the device insertion into the patient vaginal canal with a minimum level of discomfort. The sensitive cylinder consists of the part where the four pairs of sensors are mounted. The grasp cylinder is responsible to adjust the best handling to the operator. The device can be obtained in different diameters, ranging in the interval of 30-40 mm. Following the literature recommendation, Verelst *et al* (2004), it was chosen a diameter of 35 mm.

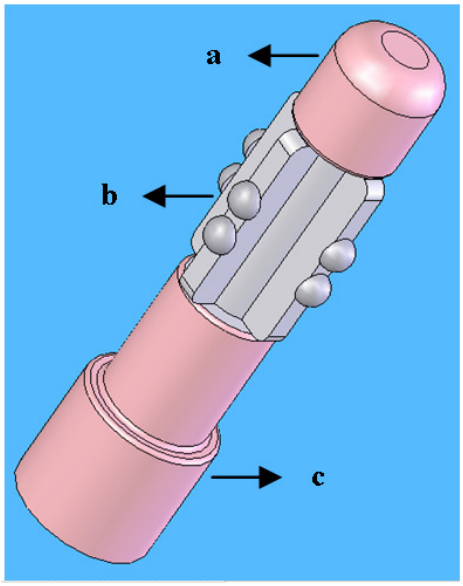

Figure 1. Schematic view of the vaginal probe: (a) tip, (b) sensitive cylinder and (c) grasp cylinder.

2.2. Data acquisition and processing software

The acquisition system is responsible to acquire the signal coming from the force sensors. The electrical resistance (measured in ohms) is variable according to the applied force at the sensor surface. To measure the sensor resistance variation it is usual to apply a voltage divider. This voltage divider is an electrical circuit composed by the sensor (variable resistance) connected in series to a chosen resistance. Both resistances are under an also chosen voltage. Using this voltage divider it is possible to evaluate the voltage value variation, V_s, generated by the sensor. In this study, the chosen values were of 470 kΩ for the resistance and 1,225 V for the voltage. The voltage signal, V_s, passes through an operational amplifier with a gain of 10. The signal then is sent to a lowpass filter with a cut frequency of 5 Hz, in order to remove the noises of high frequency (filter anti-aliasing). The filter output is connected to an analogical/digital converter (A/D) with 12 bits resolution. The digital signal is collected with a 200 Hz frequency. This signal passes through a digital filter to remove noises of low frequency components. The final filtered signal is sent to the computer and then analysed by the processing software. The data sample frequency is of 10 Hz. The processing software (BIOS LTDA., Belo Horizonte, Brazil) reads the voltage data proceeding from the acquisition system and, firstly, convert it on resistance data. Secondly, according to the sensor calibration curve, it can be measured the force applied on each sensor. The software is able to plot he force values versus time and also to generate files for posterior analysis.

2.3. Calibration methodology

The measurement system was calibrated at a traceable laboratory (CETEC-MG). It was employed a test force machine (INSTRON Universal Machine of Assays - UMA, model 5869). It is an electromechanical device that is computer controlled by the analysis Software (BlueHill, USA). The machine consists of a force transducer of nominal band of 200 N (model DMP 40). The calibration unit consisted of the force transducer associated to the of 6 ½ digits signal indicator.

A special mechanism was built in order to accommodate and fix the probe on a guide placed at the inferior portion of the UMA. This guide was able to translate the probe in the two directions, *x, y* as can be seen on "Fig. 2". By performing this way, the transducer force could be on an adequate contact with the sensor to be calibrated.

According to NBR 6674-1999 standard it was planned the calibration protocol. Loads varying from 2 to 45 N were applied at the sensor. It was applied six loading cycles on each sensor, with rising or decreasing loading, as can be seen on "Tab. 1". Also, at the end of each cycle actions were done before starting the next cycle.

Table 1 – Calibration cycles

Cycle Number	Loading Type	Action After Cycles
1	Rising	Load removing plus 20 s pause
2	Rising	Load removing plus probe translation in *x* and *y* directions
3	Rising	No load removing plus 20 s pause
4	Decreasing	Load removing plus probe translation in *x* and *y* directions
5	Rising	No load removing plus 20 s pause
6	Decreasing	Load removing

At the end of the sixth cycle the calibration curve of each sensor could be established. Then, these curves were used to adjust digitally by the processing software the measurement signals and display the force values when the probe is used during a pelvic floor muscle contraction.

2.4. Clinical protocol

After the calibration step, it was possible to evaluate the probe performance for pelvic floor muscle strength measurement. A clinical protocol was developed and had the authorization to be conducted with human beings (COEP-UFMG n. 289/06). For the pelvic floor muscle assessment, the patient adopts a supine position, hips and knees flexed and supported by a pillow. The probe is prepared for insertion by covering it with a latex condom and lubricating it with a hypo-allergen gel. The probe is inserted into the vaginal canal, contractions are asked to visualize where maximal force points are located. The probe is stabilized by the therapist to prevent it to move into the vaginal canal. In this position, it is possible to measure the passive and active force of pelvic floor muscle. A preliminary study was conducted with one patient. A set of three contractions were required to the user. Each contraction was hold during ten seconds and a resting period of one minute and a half was required between each contraction. All trials are recorded on a portable computer. At the end of the measurement session, the condoms are discarded.

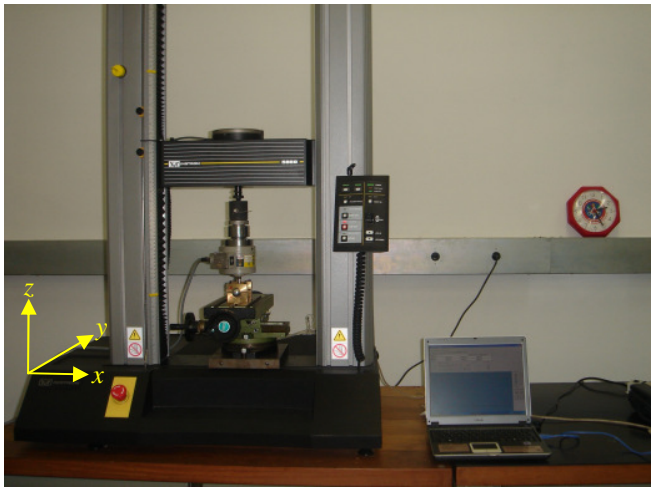

Figure 2. Calibration unit photo.

3. RESULTS AND DISCUSSION

The data (applied load and respective resistance value) response of one sensor reached during the calibration procedure, which followed the NBR 6674-1999 standard, can be visualized at "Tab. 2".

Table 2: Calibration Cycle of one sensor

Cycle 1		Cycle 2		Cycle 3		Cycle 4		Cycle 5		Cycle 6	
Load [N]	**Resistance x 10^3[Ω]**	**Load (N)**	**Resistance x 10^3[Ω]**	**Load (N)**	**Resistance x 10^3[Ω]**	**Load (N)**	**Resistance x 10^3[Ω]**	**Load (N)**	**Resistance x 10^3[Ω]**	**Load (N)**	**Resistance x 10^3[Ω]**
1,91	33,22	2,35	25,25	2,13	27,34	2,01	24,00	2,38	25,20	2,00	24,04
5,10	14,67	5,08	14,03	5,04	13,93	5,01	11,55	5,20	14,24	4,95	12,30
8,09	10,72	8,13	10,39	8,11	10,36	8,00	9,13	8,13	10,39	8,05	9,26
10,93	9,33	11,08	8,96	11,07	8,98	10,88	7,94	10,96	9,06	10,87	8,09
15,00	8,14	15,05	7,99	15,06	7,89	14,83	7,19	15,05	7,89	14,96	7,17
19,93	7,19	19,90	7,24	20,01	7,14	19,80	6,60	20,05	7,09	19,83	6,60
29,95	6,32	29,94	6,40	29,89	6,35	29,70	6,03	29,90	6,30	29,79	5,98
44,87	5,53	44,90	5,63	44,75	5,61	44,75	5,61	45,00	5,61	45,00	5,61

Data analysis of each sensor response during the calibration showed that a second order exponential decay function could be fitted to the rising and decreasing loads applied. This regression analysis demonstrates a Pearson of R^2 around 0,99 to the rising and to the decreasing cycle as can be seen on the following "Fig. 3" and "Fig. 4". "Figure 3" shows the calibration curve of a sensor denoted as *sensor 8*. "Figure 3a" illustrates its response for a rising load cycle. On the other hand, "Fig. 3b" presents this sensor response for a decreasing load cycle.

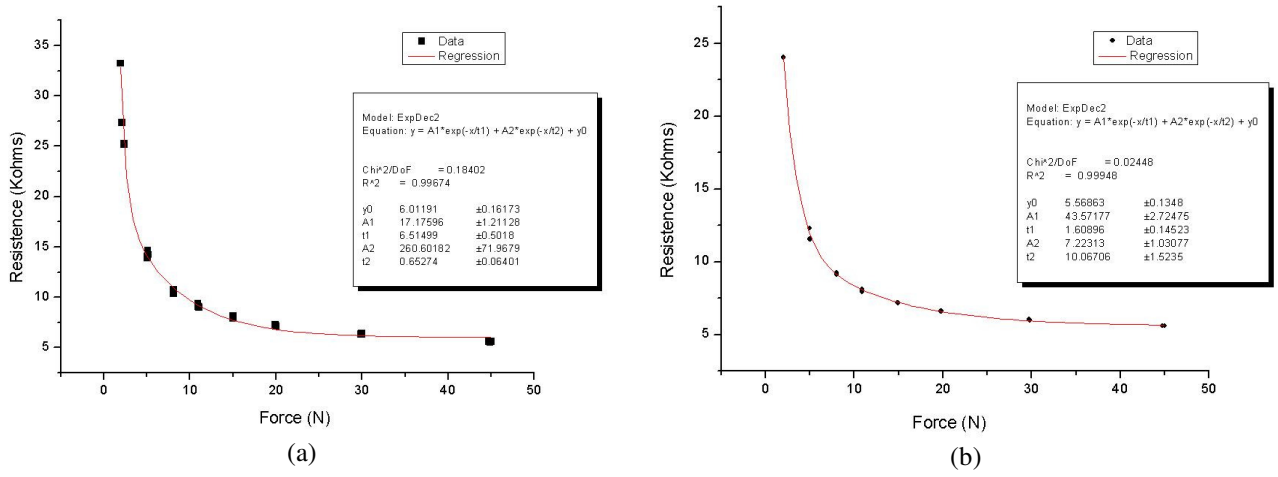

Figure 3. Calibration fit result for *sensor 8* responses: (a) rising load application and (b) decreasing load application.

"Figure 4" presents the calibration curve of another sensor called as *sensor 3*. "Figure 4a" illustrates its response for a rising load cycle. Likewise, "Fig. 4b" shows this sensor response for a decreasing load cycle. Those curves shows that both sensors behaved in the same way during the calibration protocol and this behaviour can be extrapolated to the other sensors. This is true mainly if it is analyzed all obtained curves, nevertheless this curves will not presented in this work. Furthermore, these curves are in accordance to the curve presented in the sensor technical specifications.

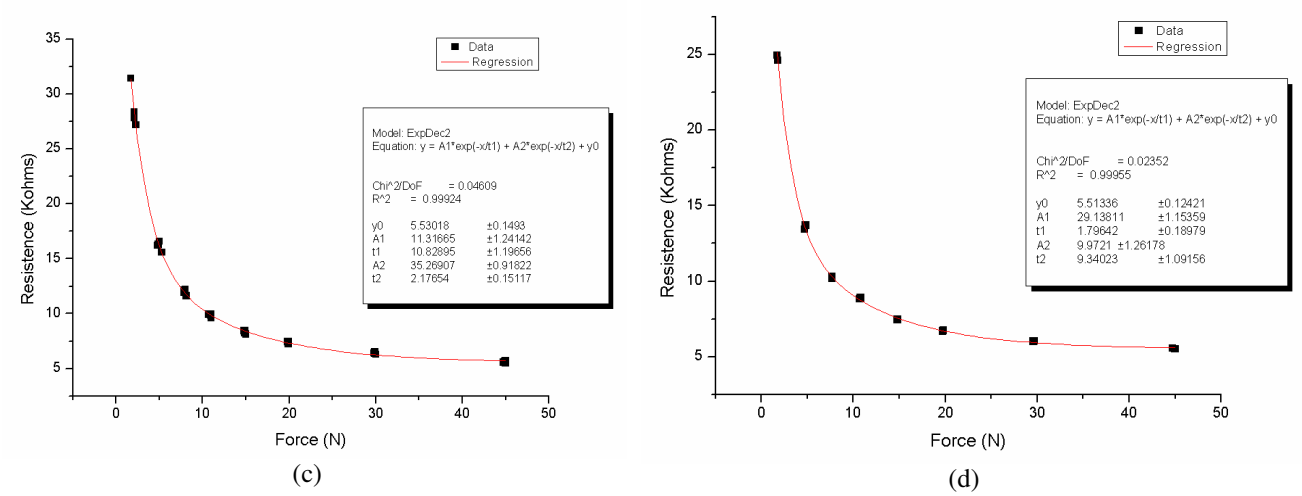

Figure 4. Calibration fit result for *sensor 3* responses: (a) rising load application and (b) decreasing load application.

After the calibration the software was adjusted following the each sensor calibration curve. In this way, it can be seen at "Fig. 5" the measurement results for each sensor. As can be seen the sensors behaviour are similar although response varies around 15 to 20% between each other. The nominal band during the contractions ranges from a minimal 0 N to a maximal over 50 N.

Analysing the behaviour curve from one patient it can be identified four distinctive regions: (1) represents the baseline recorded; (2) represents the first ten seconds contraction; (3) denotes the second ten seconds contraction and (4) the last ten seconds contraction. It is important to mention that after baseline recording, the software was set up and the contractions were required.

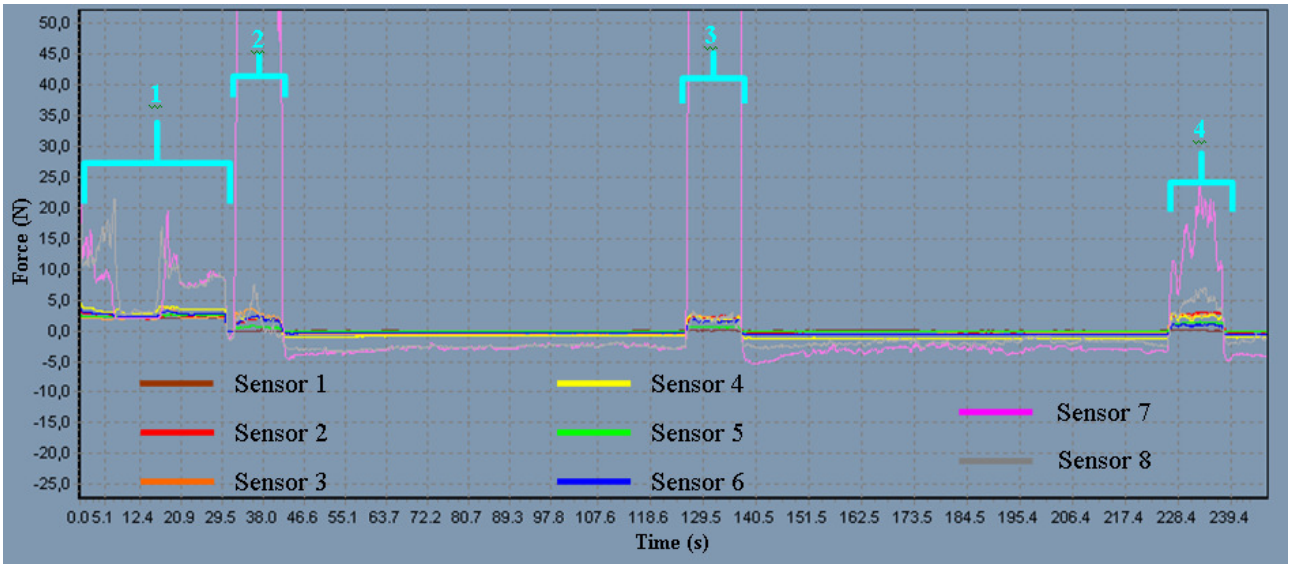

Figure 5. Curves of the measured forces obtained from isometric pelvic floor contraction.

The reading forces only can be performed over the sensors, confirming that the measurement is depended of the site of application of the force. The relation between the sensor number and its respective position into the vaginal canal was chosen in following criteria: sensors 1 and 2 represented the muscles at the left vaginal canal; sensors 3 and 4 were connected to the levator ani muscle; sensors 4 and 5 represented the muscles of the right vaginal canal and sensors 7 and 8 measured the abdominal muscles influence.

"Figure 6" shows the third ten seconds contraction in detail. It can be seen that, sensors 7 and 8 presented higher force values, but this fact is attributed to abdominal muscles influence. This is of extreme importance, because in other measurement devices, this muscle actuation interferes in the measurement result as it can not be isolated from the real pelvic floor response. This drawback was eliminated in the proposed device, since it is a multidirectional measurement system.

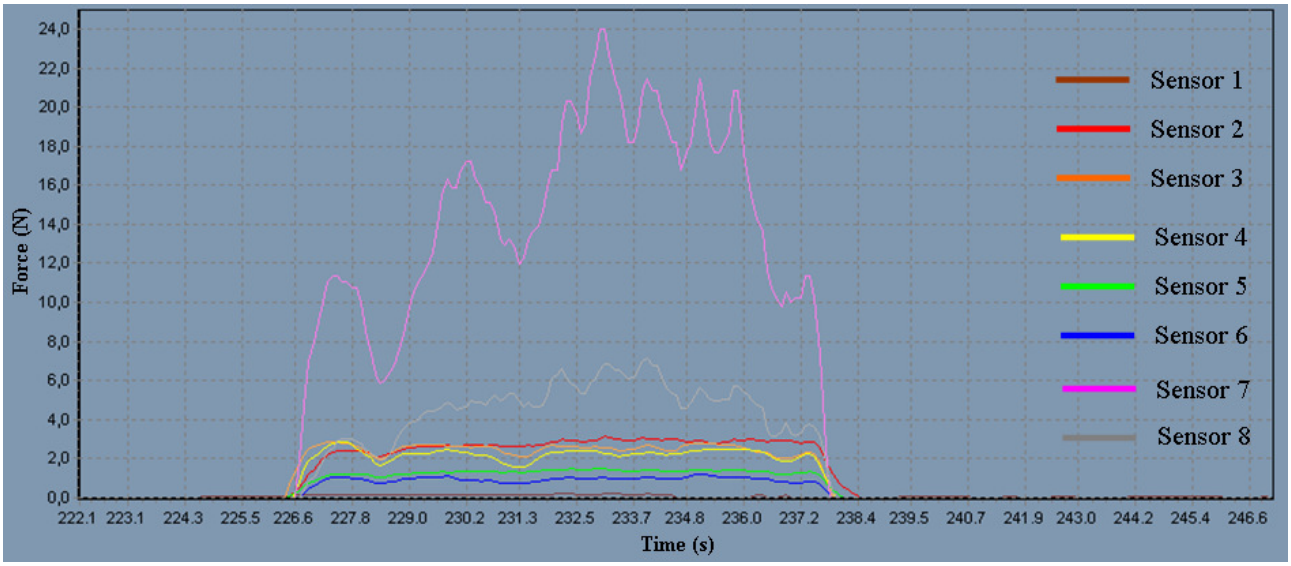

Figure 6. Zoom of the third ten seconds contraction.

Once the force only can be read if it is applied over the sensor these leads to sources of errors, which are related to: (a) the correct disposable of the sensors along the vaginal probe, (b) the adequate insertion of the probe into the vaginal canal and (c) the discomfort generated by the probe insertion (Dumoulin, 2003; Vereslt, 2004) giving lower pelvic floor muscle force response.

According to Bo (1992) the pelvic floor muscular mass is located some 3,5 cm from vaginal opening and has a 2,4 cm length inside the vaginal canal. These anatomical considerations were of great help when inserting the probe into the vaginal canal and to dispose the four pairs of sensors along the cylindrical probe. The feedback conferred by the software made sure to the therapist that the force applied to the sensors was the highest that could be recorded.

Considering that measurements must be taken without patient discomfort, it can be assumed that any device that will be inserted into the vaginal canal to evaluation exam or treatment program will raise discomfort to the patient. This can be considerable as a systematic source of error that can not be eliminated and will be present at all assessments.

This was a pilot study conducted at only one patient, so a better behaviour analysis of the measurement system must be done mainly considering psychometric properties as validation and reliability.

The new prototype is a useful tool to measure isometric pelvic floor strength. It has the advantage over manual muscle test and pressure devices because it provides an objective and direct measurement of pelvic floor strength. Over the dynamometer, which provides force measurements in one direction (mid-sagital plane), the proposed measurement device takes into consideration the actual dynamic of the pelvic floor, measuring forces not only at the mid-sagital plane but also at the transverse plane.

5. CONCLUSION

In the present study, the developed new prototype device showed itself as a promising tool for pelvic floor isometric force measurement in both mid-sagital and transverse plane meeting the requirements of plane measures. The UMA machine and the calibration protocol utilized and the data acquisition system were adequate to the new instrument proposal and conferred good Pearson response.

However, it is necessary to analyse the system performance, the mechanical and electronical behaviour, under different tests conditions and clinical research. Moreover it is important to better understand the measurement results with the chosen sensors. In addition, these analyses could be developed during the collection of its psychometric properties, which is the next step of this work.

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