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Mechanical simulator for the *Levator ani*

Simulador mecânico para o levantador do ânus

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Abstract
The pelvic floor is a complex muscular structure and the urogynaecological dysfunctions of this muscular structure are innumerable. The diagnosis of these urogynaecological dysfunctions can be performed by anamnesis, clinical evaluation (digital palpation, perineometry and observation), urodynamics and by ultrasound or magnetic resonance imaging. Physiotherapist relies on vaginal digital palpation to obtain relevant data about pelvic floor strength. The aim of the present application was to develop an electromechanical device able to simulate *in vitro* the *levator ani* muscle in order to train the sensitivity of future examiners during a vaginal digital palpation. Five springs were fixed on a resin anatomical model of the human pelvis in a configuration that could represent the *levator ani* muscle. A traction unit composed by a load cell and a step motor was used to produce the traction of the springs being able to measure the traction force. One well trained physiotherapist executed all the fourteen series of digital palpation procedures between the five springs. It was possible to establish force values that were correlated to the six scores of the modified Oxford scale. The mean forces obtained for the complete digital assessment were compared using one-way ANOVA. According to the results, score 0 of the modified Oxford scale represented no elongation of the springs. Scores 1 to 5 showed the following mean force values: 1 (55.69 N), 2 (56.17 N), 3 (56.94 N), 4 (59.61 N), 5 (65.36 N). The proposed device presented itself as a useful tool which is able to establish a relation between the forces of the springs and the modified Oxford scale.

Keywords: Pelvic floor, Digital vaginal palpation, *Levator ani*, Modified Oxford scale.

Resumo
O assoalho pélvico é uma estrutura muscular complexa e as disfunções uroginecológicas desta musculatura são inúmeras. O diagnóstico das disfunções uroginecológicas podem ser realizadas por anamnese, avaliação clínica (palpação digital, perineometria e observação), urodinâmica, ultrassom e ressonância magnética. Os fisioterapeutas utilizam a palpação digital vaginal para obter informações de força da musculatura do assoalho pélvico. O objetivo do presente trabalho foi desenvolver um dispositivo eletromecânico, capaz de simular in vitro o músculo levantador do ânus, a fim de treinar futuros examinadores na sensibilidade do toque digital vaginal. Cinco molas foram fixadas em um modelo anatômico de resina da pelve em uma configuração que poderia representar o músculo elevador do ânus. Uma unidade de tração composta por motor de passo interligado a uma célula de carga foi utilizada para a caracterização da força de tração do sistema mecânico. Uma fisioterapeuta bem treinada realizou quatorze séries de palpação bidigital entre as cinco molas. Neste sentido, foi possível estabelecer valores de força que se correlacionavam com os seis graus da escala modificada de Oxford. As forças médias para todas as palpações bidigitais foram comparadas usando-se o teste de ANOVA de um fator controlável. De acordo com os resultados, o grau zero representou o alongamento nulo das molas. Os graus de 1 a 5 mostraram os seguintes valores médios de força: 1 (55,69 N), 2 (56,17 N), 3 (56,94 N), 4 (59,61 N), 5 (65,36 N). O dispositivo proposto apresentou-se como uma útil ferramenta para estabelecer a relação entre a força das molas e a escala modificada de Oxford.

Palavras-chave: *Assoalho pélvico, Palpação digital vaginal, Elevador do ânus, Escala modificada de Oxford.*

Introduction

Urinary incontinence and pelvic organ prolapse are common pathologies that affect the pelvic floor muscles. Both are social embarrassing conditions, causing withdraw from social situations and decreasing quality of life. The diagnosis of these urogynaecological problems can be performed by anamnesis, by clinical evaluation (digital palpation, perineometry and observation), by urodynamics, ultrasound or magnetic resonance image (Bø and Sherburn, 2005). Surgery, medications and conservative management such as physiotherapy are the commonly prescribed treatments to those pathologies.

Physical therapy treatment involves pelvic floor muscles (PFM) exercises. The inner surface of the pelvis basin is cover by the PFM that maintains continence by actively supporting the pelvic organs and closing the pelvic openings when contracting (Retzky and Rogers, 1995). A voluntary contraction is a simultaneous contraction of all PFM and can be described as an inward movement and closure around the urethral, vaginal and anal meatus (Bump *et al*., 1991). The inward movement is a consequence of those muscles capability to generate tension, power, resistance and functional status (Shull *et al*., 2002). Pelvic floor muscles training aims to change all these muscle performance components (impairments) so that the patient can function adequately and enhance quality of life (Bø, 2004).

PFM function and strength evaluations are necessary to teach and to give feedback regarding woman ability to contract PFM and to document changes throughout interventions (Shull *et al*., 2002). Vaginal palpation is the standard procedure when assessing the ability to contract the PFM. It is a simple, but subjective evaluation method. However, there is a great difficulty in teaching a new physical therapist the capability to differentiate the grades from any scale utilized for vaginal palpation.

In the present study, a pilot device able to perform the simulation of the *levator ani* muscle *in vitro* was developed at the Bioengineering Laboratory (UFMG). In this device, the *levator ani* muscle was modeled using an arrangement of five springs fixed in a resin anatomic model of a female pelvis. The aim of this application was to aid physiotherapist students to learn the modified Oxford scale while they feel in their fingers different levels of the vaginal model closure force produced by the device.

In vitro training has an additional advantage: since there is a fixed correlation between the force introduced by the springs and the different modified Oxford scale degrees, it is possible to give the students a quantified reference of the vaginal closure force, eliminating subjective interpretation. This is important for the uniformity of the information transmitted to the students.

Materials and Methods

The device consisted of an electromechanical configuration of five springs fixed in a pelvis anatomical model. The springs were displayed in order to reproduce the movement and the force produced by the *Pubococcygeus*, *Illicoccygeus*, *Ischiococcygeus* (the *levator ani* muscles), Figure 1, as following described:

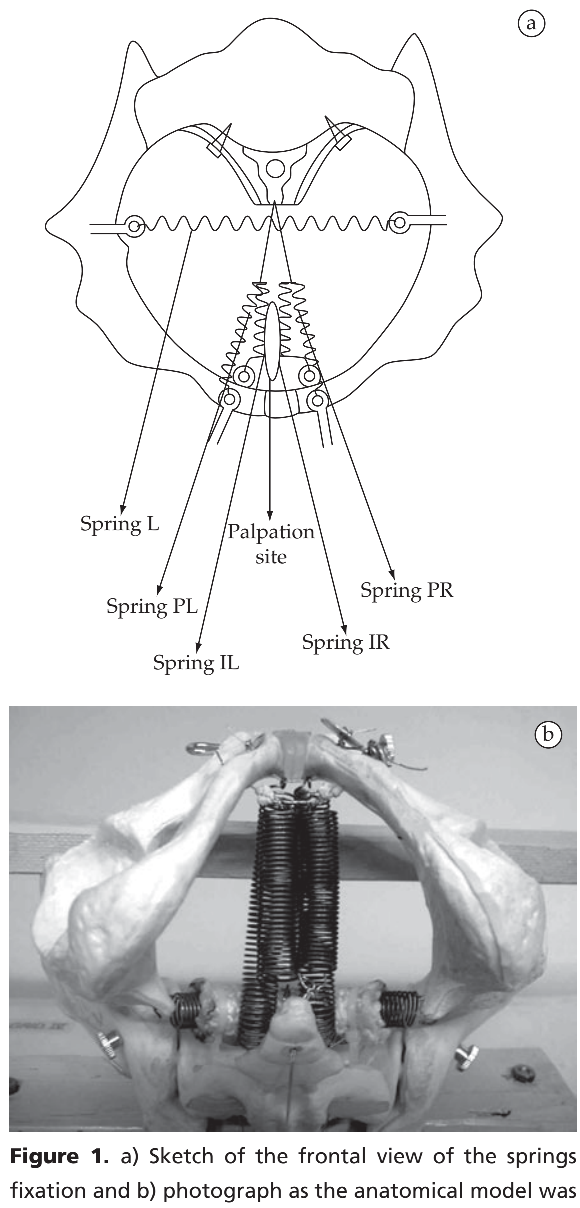

Figure 1. a) Sketch of the frontal view of the springs fixation and b) photograph as the anatomical model was displaced.

Pubococcygeus muscle model

One of the ends of the springs (PL and PR) was attached to a bandage fixed in the pelvis at the height of the pubic symphysis. The other spring connection was fixed to a steel cable, one for each spring, in the coccyx portion, passing through a steel handle, simulating the *pubococcygeus* muscle behaviour under vaginal contraction.

Iliococcygeus muscle model

One extremity of the springs (IL and IR) was attached to a lower bandage fixed in the pelvis at the height of the ileum. As described above, the opposite extremities were connected to a steel cable in the coccyx portion, passing through the same steel handle. In this way, it was tried to simulate the *iliococcygeus* muscle behaviour under vaginal contraction.

Ischiococcygeus and _levator ani_ muscles model

The spring (L) was fixed to both ischyatic extremities, simulating tension in the *ischiococcygeus* muscle and the upward movement of the *levator ani* muscle during a maximum contraction.

The configuration established by the disposition of the springs generated a meatus (a hall) between springs IL and IR where the digital palpation was performed. The diameter of the springs was determined according to the plastic pelvis model used in the study, once the springs had to enclose and cover all the base of resin pelvis. Helicoid springs with outer diameter of 10 mm and 1 mm of wire diameter were chosen because of their mechanical properties. The equivalent elastic constant for the spring association was estimated as 1.36 N/mm. The spring free length was selected in function of the inferior opening of the pelvis, considering the anatomy described by Netter (2001). As a result, the spring *L* presented a length of 60 mm and the other four springs had 35 mm in length.

The steel cables of the four springs had been fixed to the load cell. To confer a correct alignment of the contraction and movement of those springs, it was used a sheave system between the steel handles and the load cell. A piezoresistive load cell (nominal load: 200 N and uncertainty: ± 0.1 N) was used to quantify the equivalent spring forces input by the step motor action. The step motor characteristics were: nominal voltage: 3 V_{DC}, current: 2.2 A/phase, holding torque: 6.5 kgf·cm and 1.8° step angle. A control unit was designed in order to activate the step motor, capable of adding or subtracting angle steps of the angular position of the motor, Figure 2.

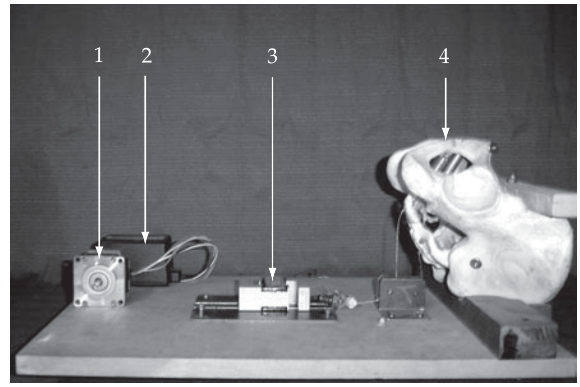

Figure 2. Lateral view of the device with its main components: step motor (1), control unit (2), load cell (3) and anatomical pelvis model (4).

The control unit was an open loop circuit that acquires the load cell data. It was composed by an analogic circuit able to perform the load cell signal preprocessing and a microcontroller, which received this analogic signal in one of its analogical input and activated the step motor through its digital outputs (Figure 3).

In this way, the preprocessing of the load cell signal consisted of a low-pass filtering (cut frequency of 20 Hz) and then amplification (gain of 100 times). The step motor driver was composed by a microcontroller (PIC16F) commanded by a dedicated software.

The resin anatomical pelvis model had 95 mm of anterior-posterior dimension (imaginary line from the superior point of the pubic symphysis to the superior point of the promontory) and 115 mm transverse dimension (imaginary line that superiorly cuts the pelvis cavity).

In order to perform the exam simulation, the digital assessment was performed with the pelvis fixed in anatomical position. One well trained physiotherapist executed all the palpation procedures between the five springs simulating the *levator ani*.

It was decided to use a modified Oxford scale (Table 1) because in this study there was no intention to simulate neither resistance nor fatigue of the *levator*

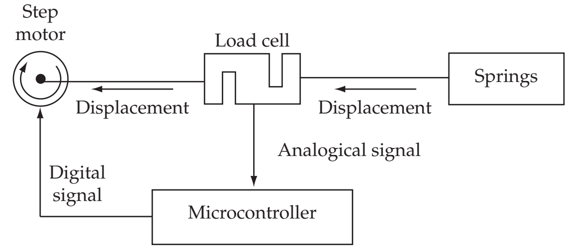

Figure 3. Sketch of the electronic components communication.

Table 1. Modified Oxford scale employed for digital evaluation of the *levator ani* muscle contraction.

Score	Findings
0	Null
1	Flicker of Muscles
2	Weak Contraction
3	Medium: Slight lift of examiners fingers
4	Strong: Elevation of examiners fingers
5	Very Strong: Elevation of examiners fingers

ani muscle, just the force produced by the springs that simulated the *levator ani* muscle. According to Morin *et al*. (2004) dynamometric results, forces range from 0.1 N to 32 N, depending on vaginal opening.

The control unit was able to set different angular positions in the motor and, as consequence, to impose different muscular forces in the simulated vagina. By doing this, it was possible to establish a relation between a quantified value of force with the six scores of the modified Oxford scale in a way that the physiotherapist could identify their level differences.

Fourteen series of digital palpation procedures were performed by the same physical therapist. There was a break of fifteen minutes between each assessment in order to provide a recovering time to the sensitivity of the physiotherapist fingers. Once it was identified by the physical therapist a score of the modified Oxford scale, the force measured by the load cell was saved. After fourteen assessment series, a relation between the scores conferred for the modified Oxford scale and the force measured by the load cell was established. The mean of the measured forces was computed for each category of the modified Oxford grading system and compared using a one-way ANOVA to identify the existence of statistically significant differences between assessment categories results. A significance level of 0.05 was chosen.

One-way ANOVA determines whether the measured force is differentially expressed in any of the scores tested. However, it does not indicate which specific score pair are the ones where statistical differences occur. Post Hoc Test can be used in conjunction with ANOVA to determine which specific score pair are statistically different from each other. So, it was performed Post Hoc comparisons among pairs of means with the Scheffé test.

In analysis of variance, if F is significant, the Scheffé test can be used to see which specific force mean differs from the others making a pairwise comparison of the scores. The F_s ratio for the difference between the means of two scores was calculated and then it was tested the significance of this F_s value.

Results and Discussion

The use of a scale based on the sensitivity of the fingers introduced in the patient's vagina during the contraction of the pelvic muscles (digital palpation) is a very common procedure to search for urogynaecological dysfunctions. Despite of its subjective nature, the modified Oxford scale is a useful diagnostic tool, at the same time it is cheap and very simple to be performed. However, it is strongly dependent on training and experience. The methodology described in the present paper was addressed to improve the quality of the evaluations developed by the examiner's fingers.

The use of the device made possible to establish a relation between the elastic force of the springs and the Oxford scale. The measurement of the force was realized by a load cell with an uncertainty of 0.1% of the measured value. The results achieved for the fourteen series of vaginal digital palpation are presented in Figure 4.

Score 0 represented the null elongation of all springs and scores 1 to 5 presented the following mean values and standard deviation: 1 (55.69 ± 0.28 N), 2 (56.17 ± 0.35 N), 3 (56.94 ± 0.37 N), 4 (59.61 ± 1.88 N), 5 (65.36 ± 2.63 N).

The one-way ANOVA showed that the force means were statistically different ($F = 103.29$ and $p = 0$). The F_s ratio results obtained by Scheffé test were: $F_{s12} = 0.19$; $F_{s13} = 1.28$; $F_{s14} = 12.46$; $F_{s15} = 75.84$; $F_{s23} = 0.48$; $F_{s24} = 9.57$; $F_{s25} = 68.42$; $F_{s34} = 5.75$; $F_{s35} = 57.41$ and $F_{s45} = 26.81$. Comparing these values with the critical value for $F_{.05}(4.65) = 2.51$, it was noted that there were significant difference between score one and scores four and

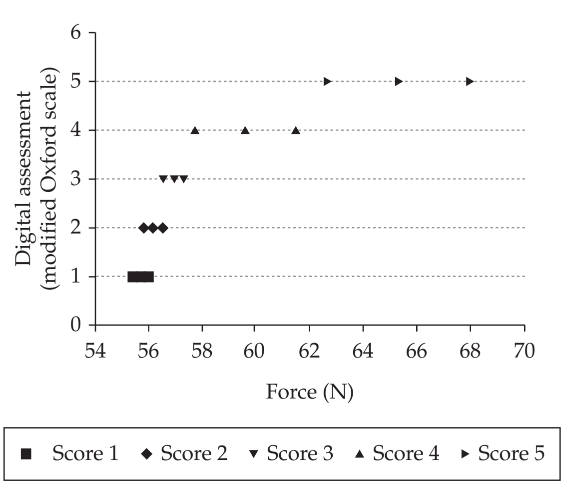

Figure 4. The mean, minimum and maximum forces obtained by the load cell in correlation with the digital assessment using the modified Oxford scale.

five; score two and scores four and five; score three and scores four and five and score four and score five, because the F_s values for those scores were greater than 2.51.

Vaginal palpation is extremely important when teaching a patient how to perform a correct pelvic floor muscle contraction. It is well used by all clinicians to give the patient feedback about the quality of the contraction.

Different materials and devices have been searched to simulate the *levator ani* muscles. The use of springs presented two important characteristics: develops similar forces and exhibits physiological volumes at the examiners fingers. However, when performing the evaluation of grade 4 and grade 5 the physiotherapist examiner had difficulties to identify those points in the scale. According to Bø and Finckenhagen (2001), palpation-categorizing scale does not have sufficient sensitivity (responsiveness) to differentiate between these scores.

Morin *et al*. (2004) compared vaginal digital assessment with dynamometric measurements to determine the maximal strength of the pelvic floor muscles. They found that the dynamometric mean forces of PFM increased across subsequent categories of digital assessment, but the force values between grade 1 was divergent from grades 3, 4 and 5, and grade 2 could be distinguished from grades 4 and 5 using ANOVA Post-Hoc-Scheffé statistical criterion. Even in a different range of values, the data obtained in the present application agree with Morin's findings, and also found statically difference between some others categories, which could be attributed to the larger number of assessments made for each category.

Conclusions

Pelvic floor muscle is a complex structure that has a difficult strength evaluation. The device developed in the present study, able to simulate *in vitro* the *levator ani* muscle, showed itself as a complementary tool to the modified Oxford scale to teach future physiotherapy students how to distinguish each grade during vaginal digital palpation.

However, future applications must be done concerning the calibration of the whole system, a complete analysis of best geometric and mechanical characteristics of the springs and also the use of different professionals to procedure the palpation in order to confer validity and reliability of the measurement results. Finally, a complete uncertainty analysis of the device and a statistical evaluation of the results must be done.

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