Design, realization and preliminary validation of an active physical simulator for the study of pelvic floor damages during childbirth

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INTRODUCTION

Pelvic floor (PF) is a muscle-fascial system that inferiorly closes the pelvis. It is really important in woman's life because it guarantees the correct positioning of the pelvic organs, the urines and feces continence and evacuation, and it allows sexual activity and childbirth [1]. Dysfunctions of PF involve important physical and psychological consequences in the daily life of a woman and significant expenses for their treatment. Vaginal delivery represents one of the main risk factor for the onset of PF disorders.

Pelvic muscles in pregnant women show very different elastic characteristics if compared with non-pregnant women's muscles. Moreover, they undergo considerable stretching during the passage of the foetus, that often results in a medium and/or long-term tissues injury. Thus, dedicated studies could both pave the way to a better comprehension of this phenomena, and improve the use of prevention clinical techniques, i.e., c-section.

High-fidelity and active physical simulators deepen the study of the factors characterizing a clinical event and allow the doctor to have a physical support and real time feedback, which are essential for technique refinement and knowledge transfer in the clinical practice. Currently, there are only birth simulators available on the market, in which the PF is merely an additional element recreated at a low-fidelity level in terms of anatomical and physiological features. In addition, commercial simulators equipped with PF are limited in number and entirely passive, hence they don't provide any feedback to the clinician.

In this framework, the aim of this paper is to realize a sensorized physical simulator of maternal PF that can be used both as a teaching and/or a training system for gynaecologists and obstetrics. The innovative features of the proposed simulator are the following: i) high-fidelity reconstruction of the maternal PF anatomy; ii) use of soft materials able to replicate the biomechanical properties of human tissues; iii) active evaluation of the muscle deformation induced by the foetal head (FH) passage through the PF structure.

MATERIALS AND METHODS

By combining anatomical data with literature information, a 3D model of the maternal PF was reconstructed and utilized for muscle fabrication through molding technique (Figure 2). Ecoflex 0030 silicone (Smooth-On, PA, USA) was used for reproducing the biomechanical behavior of the PF muscles. Its elastic modulus of E=0.068 MPa is close to the pregnant woman muscles modulus, i.e., E=0.06 MPa [2]. The tendons structures of the PF are then replicated for guaranteeing the right positioning of the muscle component (Figure 2 for details). Finally, a female pelvis model with standard dimensions was found for bones replication [3].

In order to record the muscle deformation during the delivery simulation, elastic sensors capable to follow the elongation of the PF are required. Commercial sensors were discarded because commonly they are rigid and thus they do not meet the silicone elasticity and integration requirements. As an alternative, a specific elastic conductive fabric (Med-tex P130, Shieldex, Germany) was investigated for fabricating a custom home-made resistive sensor. Conductive fabric has been already demonstrated as a valid solution for soft applications [4], allowing to evaluate the elongation by changing its resistance. Finally, signal acquisition is ensured by firm electrical connections made of conductive wires properly hand-stitched on the fabric mesh. Electronic components for signal conditioning and acquisition are required.

To evaluate the sensors resistance-elongation relation, several tensile tests were performed by using the Instron 5965 machine (Instron, USA). Rectangular shaped textile samples were stretched from 0% to 100% - in order to cover the entire human tissue stretch range - for 5 cycles at 400 mm/min speed. Test was repeated 3 times. The components were integrated and the final device was validated both on the bench and with clinicians. In order to calibrate the simulator and to collect data that can be used for comparing the obtained system with literature, a descent of the FH through the PF was simulated by using the Instron machine. A vertical descent of 100 mm at 150 mm/min speed was repeated 3 times; applied forces and sensor elongation were acquired from the Instron and simulator electronics, respectively. As in the literature, it was used a rigid FH approximating a 10 cm sphere made of PETG realized by means of the FDM technique.

Ultimately, to complete the preliminary system validation phase, a pre-clinical testing protocol was realized by involving expert gynecologists at Azienda Ospedaliero Universitaria Pisana. The tests were performed by combining our simulator with a commonly used FH simulator. The descent of the FH through the PF was reproduced. Five different positions that the FH might assume during the delivery were simulated by the clinicians. Tests were repeated 3 times.

RESULTS

Three different sensors were made in order to cover the muscular areas mostly stressed during childbirth: 2 rectangles of 51mmx6.5mm in size were positioned between the pubic symphysis and the perineal body; 1 smaller rectangle of 44mmx6.5mm was integrated near the perineal body. Sensors signal was acquired using a Wheatstone bridge. The electronic circuit was powered and managed through the Arduino Mega 2560 board (Arduino, Italy). By combining the elongation applied by the Instron machine on the sensors samples with their resistance values, the sensor calibration curve was obtained (Figure 1). As shown in the figure, the resistance increases linearly up to 60% of the elongation and decreases linearly from 60% to 100%. An equal and opposite behaviour was observed during the shortening phase of the sensor. The acquired signal proved to be accurate, showing an identical behaviour over time and during multiples tests.

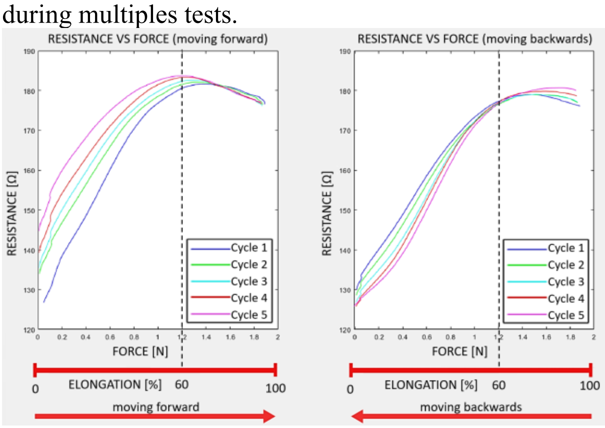

Fig. 1 Resistance VS Force calibration curves of a single sensor: moving forward (left) and moving backward (right).

The integrated system is reported in figure 2. Pelvis bones were made of PETG through a FDM printer (i3 MK3S+, Prusa Research, Czech Republic). The resistive sensors, made with Med-tex P130 fabric, were integrated on the PF structure using Ecoflex 0010 silicone. Muscles and bones were glued together through a thin inextensible fabric replicating PF tendons in the corresponding anatomical position.

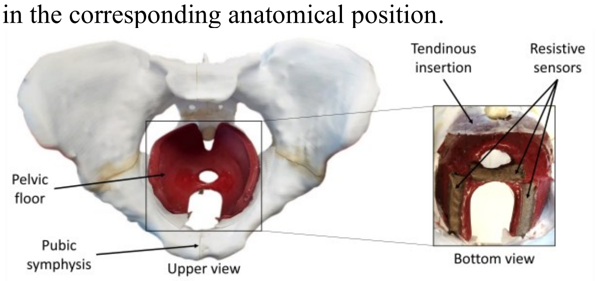

Fig. 2 Complete simulator. On the left upper view and on the right bottom view.

The forces acquired during the test simulating FH descent with the Instron machine (i.e., 45N as peak force) are similar to those found in literature (i.e., 30 N as peak force) [5]. Moreover, the sensor resistance-elongation curve acquired with the final system, show the same behaviour obtained for the single sensor, demonstrating the system robustness and the analysis repeatability.

From the tests with three expert gynaecologists (Figure 3), it was possible to replicate the literature findings in terms of which one of the reproduced foetal positions (e.g., occiput anterior (OA) position - baby facing towards mamma's spine) causes greater muscle distension, resulting in an increased possibility of PF injury and/or the onset of PF dysfunction in the postpartum period. The obtained results (Figure 3A) confirmed that all the integrated sensors worked correctly during the tests. In addition, sensors provided different output signals, showing different peak values (point of instantaneous main contact between FH and PF) at different descent instants.

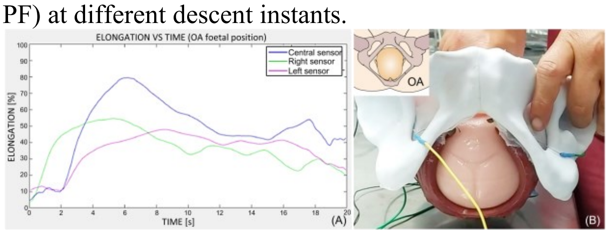

Fig. 3 Test conducted with expert gynaecologist. A) Elongation VS Time curves extracted from the integrated sensors; (B) Testing set-up.

DISCUSSION

The described active high-fidelity simulator showed good potentialities and it could be considered a valid system for PF damages evaluation. Clinicians confirmed the simulator is anatomically and physiologically faithful to human anatomy. Resistive textile sensors allowed to monitor the elongation of the PF tissues during the FH descent. The device, therefore, represents a promising tool that can be included both in training courses for experienced and non-experienced clinicians, and in gynecological education lessons.

Future efforts will be dedicated to a structured test protocol with at least 40 trainees (expert and residents). Additionally, a simple solution for fixing the system to the gynecological table during the test protocol will be identified for avoiding to affect the experimental data with drawbacks due to a not-stable manual held.

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