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RESEARCH ARTICLE

Design, Realization, and Assessment of a High-Fidelity Physical Simulator for the Investigation of Childbirth-Induced Pelvic Floor Damage

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ABSTRACT Vaginal delivery is one of the main causes of pelvic floor damage, which can lead to short- and long-term clinical consequences called pelvic floor dysfunctions. The number of women affected by this pathology is continuously rising, representing both a medical issue and an important financial burden. Prevention represents the best strategy of care, but it requires a deep understanding of the injury mechanisms, which is currently lacking. Simulation can help to identify the main factors affecting a clinical event, reducing the need for in vivo investigations. However, current simulators poorly mimic the pelvic structures and do not provide any feedback. These limitations led to the development of an innovative high-fidelity physical simulator to study the mechanisms behind pelvic floor damage caused by vaginal delivery. Anatomically correct gynecological structures were realized using soft materials able to resemble human tissue behavior. Ad hoc stretch sensors were realized with conductive fabric and integrated into the simulator to evaluate tissue elongation caused by the passage of the fetal head. Evaluation of the simulator was carried out both in laboratory conditions and by involving expert clinicians. Gynecologists determined that the simulator is a valid teaching and training tool that is able to provide feedback on instantaneous pelvic floor elongation, thus potentially preventing induced tissue damage.

INDEX TERMS Pelvic floor, pelvic floor damage, delivery-induced damage, gynecology, high-fidelity simulators, training.

I. INTRODUCTION

Vaginal childbirth is the entire process through which a fetus makes its way from the womb to the outside world through the birth canal. It includes both labor, i.e., the body preparation process, and delivery, i.e., the birth itself. It is a crucial process that could compromise the health of the mother and child, both at the moment of the event or through long-term effects. Currently, the knowledge about the process of childbirth is good enough to deal with life-threatening complications, but gynecologists are still far from having a deep comprehension of the physiological mechanisms behind the overall process. This uncertainty is related not only to the self-evolving peculiarity of childbirth but also to the

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lack of appropriate tools for objective measurements and investigations [1]. Moreover, for ethical and safety reasons, unnecessary exams and analyses are not applied to women undergoing physiological childbirth [2].

An important yet under investigated issue regarding childbirth is pelvic floor (PF) damage caused by the passage of the fetus through the birth canal. PF is a muscle-fascial system that inferiorly closes the pelvis and its functioning is important for women because it guarantees the correct positioning of the pelvic organs, promotes urinary and fecal continence and evacuation, and allows for sexual activity and childbirth [3], [4]. PF dysfunctions have important physical and psychological consequences in women's daily lives and involve significant expenses for treatment [5]. At the age of 80 years, 11% of women need a surgical procedure to treat urinary incontinence or pelvic organ prolapse, which are two of the most common PF dysfunctions [6].

Vaginal delivery represents one of the main risk factors for the onset of PF disorders [7]. The PF is able to readapt itself during pregnancy and childbirth. In fact, in pregnant women, the pelvic muscles show increased laxity and elasticity when compared with those in nonpregnant women [8], [9], [10]. Moreover, the PF undergoes considerable stretching during the passage of the fetus through the birth canal, which often results in medium- and/or long-term tissue injury [7], [11]. Even during delivery, several risk factors, considered to be preventable, can influence PF damage, e.g., traumatic birth or the use of forceps [5]. Prevention and timely recognition of both PF damage and injury grade during childbirth are generally recognized as the best form of treatment [1]. Thus, dedicated studies are essential for a complete and accurate understanding of the mechanisms of PF injuries to improve clinical techniques and thus to provide the best care for mothers.

In this framework, physical simulators deepen the study of the medical factors behind a clinical event and allow clinicians to have physical support, which is essential for technique refinement and knowledge transfer in clinical practice [12]. In particular, high-fidelity simulators are suggested as valid teaching and retraining tools promoting repetitive practice, real-time feedback, difficulty-level calibration, multiple clinical scenarios ranging from common to rare, and a safe learning environment [13], [14]. In gynecological and obstetrical simulation, the main goal is the improvement of the quality and safety of the assistance provided to mothers and newborns, thus reducing clinical practice difficulties [15]. A high-fidelity simulator is a device intended to faithfully replicate the anatomy with its biomechanical properties and that somewhat replicates a physiological behavior relevant for clinical application [16]. Currently, the birth simulators available on the market include low-fidelity PF simulation in terms of anatomical and physiological features [17], [18], [19]. In addition, commercial simulators equipped with PFs are limited in number and are entirely passive; hence, they do not provide any feedback to clinicians.

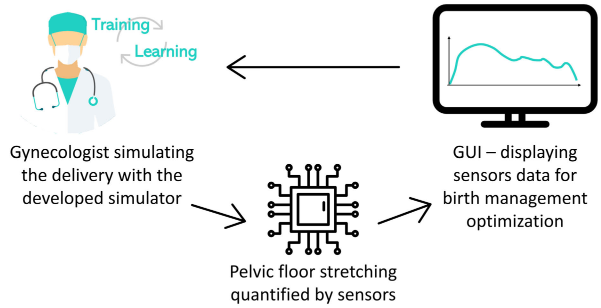

FIGURE 1. Schematic of the functioning of the system. The user simulates the delivery with the simulator. The stretching of the PF is assessed using sensors and displayed in the graphic user interface (GUI). Then, the user employs the provided information to learn how to better manage the birth process.

TABLE 1. Design parameters.

Design parameters	Value	Metric	Ref.
Young's modulus of the PF muscles	0.06	MPa	29, 38
Maximum force between the PF and FH	30	N	25
PF main geometrical dimensions:			
-Lower section (a x b)	45X75	mm	26
-Upper section (c x d)	135X105	mm	3
-Height (h)	60	mm	36
-Thickness	10	mm	29
FH diameter	100	mm	25
PF maximum deformation	73	%	30

Main parameters used to design the PF simulator.

Finally, only two active prototypes equipped with pneumatic actuators for fetal descent simulation were identified in the literature [2], [20]. In these systems, the mother's PF is replicated as a simple polymeric film, while the pelvic bones and fetal head (FH) are realized through rapid prototyping techniques. However, as these simulators are dedicated to birth simulation, they poorly replicate the features of the PF.

In this framework, the aim of this paper was to realize a sensorized high-fidelity physical simulator of the PF that can be used not only as a teaching and/or a training system for gynecologists and obstetricians but also as a physical model for deepening the knowledge about PF damage during delivery. The innovative features of the proposed simulator are as follows:

- High-fidelity reconstructed PF structures.
- Use of soft and biomimetic materials able to replicate the biomechanical properties of human tissues.
- Active evaluation of the muscle deformation induced by the passage of the FH through the birth canal.

In Figure 1, a schematic of the functioning of the system is depicted.

II. MATERIALS AND METHODS

A. DESIGN REQUIREMENTS

Delivery is a complex event that is not well understood at an engineering level. Limited information about the forces acting between the PF and the fetus is available in the literature, and the biomechanical parameters of gynecological human tissues are rarely discussed. In fact, appropriate and safe clinical tools to measure these parameters in vivo are not currently available. In contrast, the behavior of the PF during fetal descent has been deeply investigated in the literature through multiple finite element simulations [21], [22], [23], [24], [25], [26], [27], [28], [29], [30], [31], [32], [33]. In these simulations, the PF muscles, bones and either the FH or the entire fetal body are replicated, changing the constitutive parameters values to investigate different clinical scenarios. Different geometries of the PF are simulated, and a deformable or nondeformable FH is used [34].

In this work, biomechanical tissue parameters for physical simulator realization were collected from the literature. In particular, Young's modulus of the PF muscles, the geometrical dimensions of the anatomical structures and the maximum value of the force between the PF and the FH were identified, as reported in Table 1 and Fig. 2.

B. SENSOR DESIGN AND EVALUATION

To evaluate the muscle deformation during the delivery simulation, sensors capable of following the entire elongation of the PF are needed [30]. Commercial elongation sensors made with soft and flexible materials (e.g., rubber-like materials, thin plastic sheets) were not used because they are still too rigid for our application and do not meet the requirements for integration into the PF. As an alternative, elastic conductive fabrics were used to fabricate a custom homemade resistive strain sensor. Conductive fabric has already been demonstrated as a valid solution for motion detection of human joints, soft robotics and exoskeletons [35]. Textile resistive strain sensors are made of elastic conductive fabric that is simply cut into the needed shape. Elastomeric deformations result in resistive stain sensors leading to changes in their resistance values. Signal acquisition is ensured by firm electrical connections made of conductive wires (conductive bobbin thread, Less EMF, NY, USA) that are properly hand-stitched onto the fabric mesh. The conductive wires are then constrained to the pelvic bones to optimize connection stability. Then, copper tape wrapped around the conductive wires is used to weld traditional cables, thus guaranteeing connection to the electronics.

The simple manufacturing process enables the production of sensors with arbitrary shapes and dimensions, but compliant and robust electrical connections, as well as electronic components for signal conditioning and acquisition, are needed for reliable functionality.

First, the sensor calibration process was conducted. To evaluate the sensor resistance-elongation curve, tensile tests were performed by using an Instron 5965 machine (Instron, MA, USA). Rectangular-shaped textile samples were stretched from 0% to 100%—a cautionary value to cover at least the entire human tissue stretch range, which is approximately 73%, as in [30] —for 5 cycles at a speed of 150 mm/min. To guarantee testing consistency and assess data replicability, the test was repeated 3 times for each sample with a rest time between tests of 5 minutes. The working speed is an indicative value to allow the understanding of a sensor's electrical behavior under controlled stretching. In fact, it is impossible to use a unique biomechanical parameter as a reference since there is no standard velocity of fetal descent through the birth canal; nevertheless, a speed of 150 mm/min is compatible with many average speed values found in childbirth. A cyclical testing modality was chosen to demonstrate the robustness of the proposed technology, thus guaranteeing its repeated usage during a training course.

C. SIMULATOR DESIGN, EVALUATION AND VALIDATION

By combining anatomical data with literature information [24], [29], [36], a 3D model of the PF was reconstructed as a funnel-like structure with a 1-cm thickness by using Fusion 360 software (Autodesk, CA, USA). In contrast to the anatomical geometries used in the finite element simulations reported above, the perineal body was added in correspondence with the bi-ischial line. This was done because it is an essential element for the integrity of the PF and represents one of the most stressed areas during childbirth, therefore at higher risk of injuries [21], [28]. In this way, as in the human body, both the urogenital triangle and anal openings are reproduced. The model was utilized for muscle fabrication through a molding technique (Fig. 2).

The PF tendon structures were then replicated to guarantee the correct positioning of the muscle component and provide an inextensible and flexible interface between the muscles and bones (details are reported in Section III-B). Finally, an adult female pelvis model derived from medical images was downloaded from [37] for anatomically accurate bone replication and to provide a support structure to the PF muscles.

Then, when the different system components were integrated, the final device was validated both at the bench and with clinicians. To calibrate the entire simulator and to collect data that could be compared with the literature, a controlled descent of the FH through the PF was simulated by using the Instron machine. A vertical descent of 100 mm at a speed of 150 mm/min was repeated 3 times; applied forces and sensor elongation were acquired from the Instron and simulator electronics, respectively. As in the literature, an approximately 10-cm rigid FH made of PETG (RS PRO, RS COMPONENTS, UK) was realized by means of the FDM technique used as a reference [25].

Finally, to complete the system validation phase, a preliminary testing protocol was carried out by involving three expert gynecologists at the Azienda Ospedaliero Universitaria Pisana (AOUP). Tests were performed by combining our simulator with a commonly used FH simulator. The descent of the FH through the birth canal was reproduced

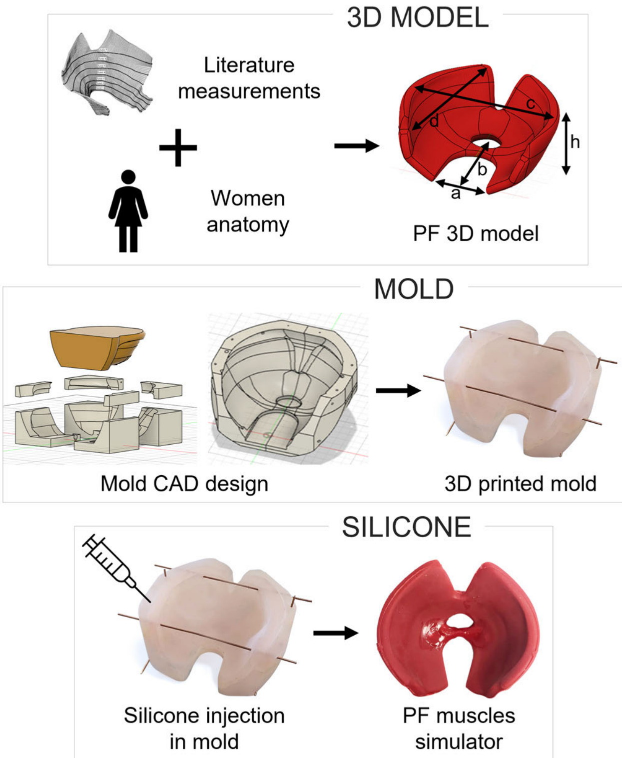

FIGURE 2. PF muscle manufacturing process. From top to bottom: 3D model design, mold realization, silicone injection process and PF prototype.

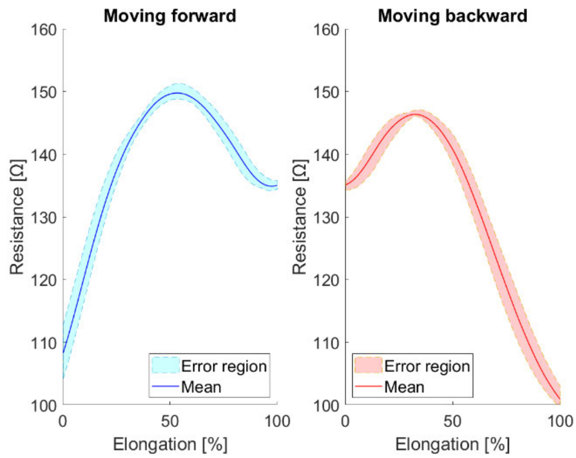

FIGURE 3. Resistance vs. elongation for the sensor calibration curve obtained moving forward (on the left) and moving backward (on the right). Bold lines represent the mean values obtained in 5 consecutive cycles, whereas the error region is shown as the shaded area.

by simulating the five different positions that the FH might assume during delivery:

- Occiput anterior (OA): the fetus enters and exits facing toward the mother's spine;
- Occiput posterior (OP): the fetus enters and exits facing toward the mother's belly;
- Left occiput anterior (LOA): the fetus enters and exits facing toward the mother's belly and rotates toward the right iliac bone;
- Left occiput posterior-occiput anterior (LOP-OA): the fetus enters facing toward the mother's belly, rotates toward the right iliac bone and exits facing toward the mother's spine;
- Left occiput posterior-occiput posterior (LOP-OP): the fetus enters facing toward the mother's belly, rotates toward the right iliac bone and exits facing toward the mother's belly.

It is worth mentioning that the right occiput anterior/posterior (ROA/P) FH positions are simply the opposite of the LOA and LOP positions; thus, we can assume the same behavior. For simplicity, we used the left positions only for the entire study. Tests were repeated 3 times for each position to guarantee testing and data consistency, and they were manually interrupted by the operators immediately after the exit of the head from the simulator. The test setup was previously prepared with the gynecologists, and dedicated informed consent forms were signed by all the participants.

III. RESULTS

A. SENSOR DESIGN AND EVALUATION

The conductive fabric chosen to realize the custom-made resistive strain sensors was Med-tex P130 (Shieldex, Germany) due to its high conductivity and good elongation properties. Three different sensors were made to cover the muscular areas stressed the most during childbirth: 2 rectangles 51 mm x 6.5 mm in size were positioned between the pubic symphysis and the perineal body and 1 smaller rectangle 44 mm x 6.5 mm in size was integrated close to the perineal body (Fig. 5, bottom view). A piece of conductive fabric was fully covered with paper tape and subsequently cut into the desired shapes by a CO_2 laser cutter (VLS3.60, Universal Laser System, Austria).

The sensor signal was acquired using a Wheatstone bridge that allowed for accurate measurement of the sensor output values and detection of small resistance variations. The electronic circuit was powered and managed through the Arduino Mega 2560 board (Arduino, Italy), with its computational power being appropriate for this application and showing ease of implementation.

The conductivity of the sensors was maintained when they were wetted with water and paraffinum oil, confirming their use with lubricants and in wet environments, as occurs in high-fidelity child delivery simulation.

By combining the elongation applied on the sensor samples by the Instron machine with their resistance values recorded by the Arduino board, the sensor calibration curve was obtained (Fig. 3). As shown in the figure, the resistance increased linearly up to 60% of the elongation and decreased linearly from 60% to 100%. An equal and opposite behavior was observed during the shortening phase of the sensor.

The acquired signal proved to be accurate, showing a similar behavior over time and during multiple tests. As shown in Fig. 4, the sensor revealed a response to stretching with hysteresis in the first cycle and an additional increasing relaxation phenomenon during the five consecutive cycles. The

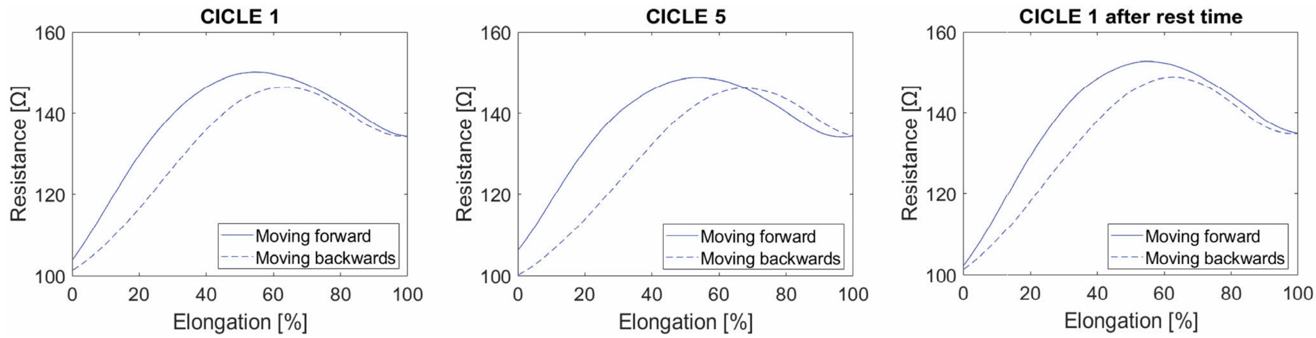

FIGURE 4. Sensor behavior during cyclic tests. First cycle (on the left): hysteresis between the forward and backward movements is visible. Fifth cycle (in the middle): combination of hysteresis (as for the cycle 1) and relaxation phenomena, resulting in a delayed sensor response. First cycle after 5 minutes rest time (on the right): the sensor returned to its initial behavior.

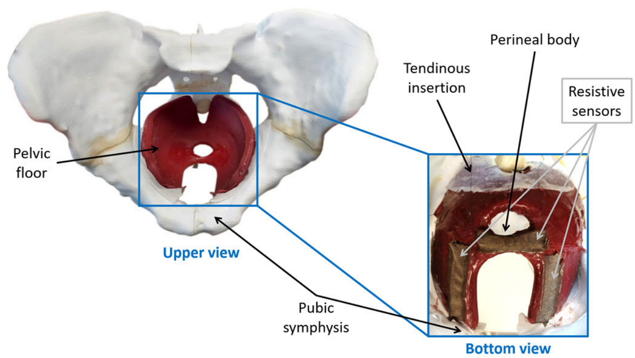

FIGURE 5. Complete simulator. On the left upper view and on the right bottom view. The main simulator features are highlighted.

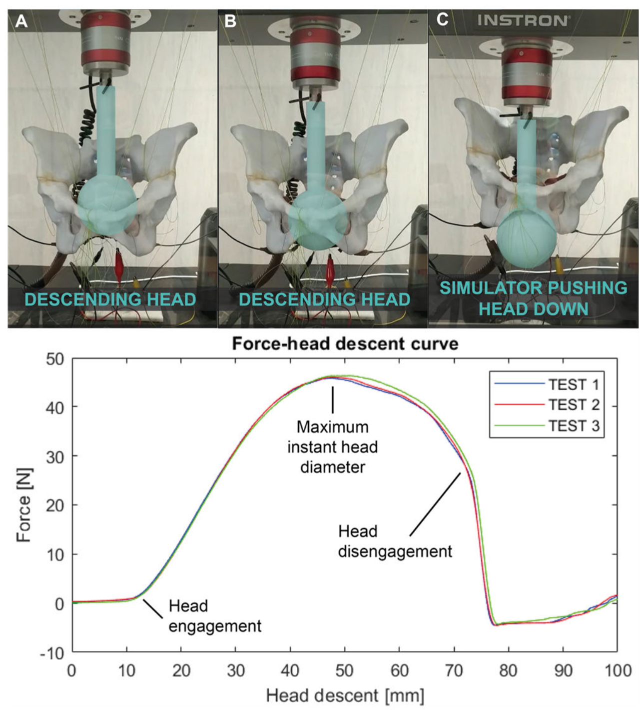

FIGURE 6. Top: fetal head descent simulation using an Instron machine. (A) Start of test. (B) Continued testing with Instron pushing the head at a speed of 150 mm/min. (C) End of test: the head exits from the pelvic floor, and the simulator is weighed down on it. Down: forces applied by the FH on the active PF simulator during the fetal descent simulation produced by the Instron.

latter resulted in a delayed sensor response at the fifth cycle and increased losses, emphasizing the hysteresis. After the five-minute rest time, the sensor returned to its initial behavior. What is described is typical of viscoelastic materials, and as the conductive fabric was made of 22% elastomer, the obtained results are in line with what was expected based on previous literature knowledge.

B. SIMULATOR DESIGN, EVALUATION AND VALIDATION

Pelvis bones were made of PETG by using a fused deposition modeling printer (i3 MK3S+, Prusa Research, Czech Republic) to obtain a rigid structure unable to be flexed during the passage of the FH, exactly like in the maternal body. The PF muscle mold was 3D printed in UV-curable resin (VisiJet M3 Crystal, 3D SYSTEM, SC, USA) through solid ground curing technology. Ecoflex 0030 silicone (Smooth-On, PA, USA) was poured into the mold and allowed to cure, and the PF muscles were realized. Ecoflex 0030 was used to reproduce the biomechanical behavior of the PF muscles. The elastic modulus (i.e., $E = 0.068$ MPa [38]) was very similar to that of the muscles in pregnant women, i.e., $E = 0.06$ MPa [29], [39]. The silicone was colored with "blood" Silc-Pig pigments (Smooth-On, PA, USA) to visually reproduce the structure of the human PF muscles.

The resistive sensors, made with Med-tex P130 fabric, were sealed to the soft PF structure using Ecoflex 0010 silicone to allow optimal integration without adding extra rigidity, as a classic silicone glue would have entailed. The muscles and bones were glued together using a thin inextensible fabric (common cotton fabric) replicating the PF tendons. The integrated system is shown in Fig. 5.

The forces measured during the simulated descent of the FH within the birth canal showed a 45 N peak force corresponding to the maximum diameter of the FH (Figure 6).

This value was comparable with the literature data, i.e., a peak force of 30 N with a rigid FH [25]. In detail, the force values linearly increased due to pelvic muscle resistance to the elastic deformation induced by the FH. Once

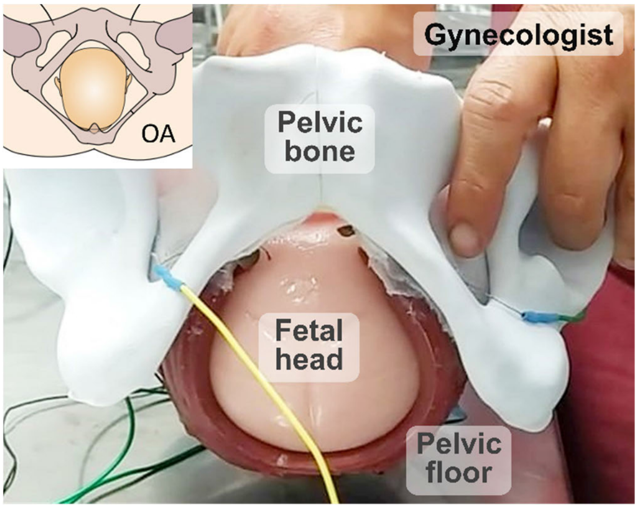

FIGURE 7. Example of a test conducted with expert gynecologists. Testing setup in the specific case of OA presentation.

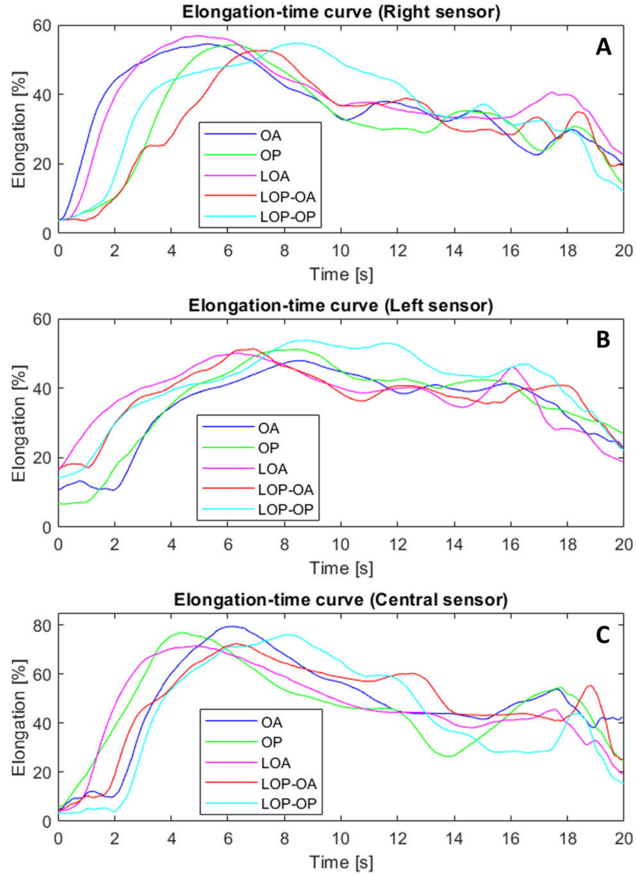

FIGURE 8. Percentage of stretch caused by the passage of the FH through the birth canal in the five simulated fetal presentations. Unfiltered data from a single test. A)-B) Data collected from the sensors positioned between the pubic symphysis and the perineal body—right side and left side, respectively. C) Data collected from the sensor positioned near the perineal body. This sensor showed the highest stretch values (i.e., 80% vs. 55%). In the figure, the sensor outcomes at the end of the procedure did not return to the initial value because the acquisition was stopped in concomitance with the end of the task without waiting for sensor relaxation.

the maximum value was exceeded, the forces fell: due to the gradual decrease in the instant head diameter and the friction caused by the silicone elastic recoil, the recorded force slowly decreased until the head disengaged from the structure, when the recorded forces rapidly returned to zero. It is worth mentioning that the final force value registered here was negative due to the test setup.

At the end of the test, the simulator weighted and pushed the head down, causing negative values. Thus, these data should not be taken into account (see Fig. 6).

From the validation process with the three expert gynecologists (Fig. 7), it was possible to identify and reproduce the fetal positions that caused greater muscle distension, resulting in an increased possibility of PF injuries and/or the onset of PF dysfunctions in the postpartum period.

Furthermore, thanks to the chosen multiple sensor configuration described above, observing the behavior of each sensor during the simulation allowed us to identify the PF area that was most stressed in each simulated FH descent (Fig. 8). In each head presentation position, the perineal body, i.e., the central sensor, was the one that primarily yielded to the passage of the FH: a stretching rate up to 80% was observed. This result was in line with the literature [1], [28], and we can reasonably assume that this behavior is caused by the smaller dimensions of the perineal body compared to the lateral regions of the PF structure. Being the whole muscle structure made with the same material, i.e., Ecoflex 0030 silicone, and subjected to approximately homogeneous pressure, it is understood that the perineal body is the weakest area of the all pelvic muscles. Confirming this, a maximum elongation of approximately 55% was reached on the lateral areas of the PF, as indicated by the right and left sensors.

Finally, from the finite element analysis [30], the OP position was recognized as the presentation placing the most stress on the PF. That result was not obtained in our simulator; in fact, significant differences between the simulated FH descents were not observed. This may be due to the use of a single FH simulator instead of a whole fetal body simulator as in the finite element simulations. However, as reported in Fig. 8, the OA, OP and LOP-OP presentations caused the most stretching. Thus, these results can be considered encouraging and aligned with previous theoretical studies, as two of the three identified dangerous positions include the OP presentation.

Fig. 8 shows that all the integrated sensors worked properly during the tests. In addition, the sensors provided different output signals, showing different peak values (point of instantaneous main contact between the FH and PF) at different times of descent.

IV. CONCLUSION

Multiple lines of evidence suggest that a vaginal delivery can compromise the functionality of the maternal PF musculature, leading, in the short and/or long term, to the onset of several dysfunctions. This issue has become increasingly important in recent years due to the growing percentage of women experiencing one or more of these disorders. The main reason behind this growth is the increase in the average age of women at the time of delivery [1], [40].

The ability to adopt prevention strategies requires a deep understanding of PF tissues and the FH, as well as their structural and functional interactions. The bipedal nature has made the human pelvis unique in terms of the anatomy and forces imposed on it [41]. In parallel, it is difficult to extrapolate human geometric data, which is usually derived from cadaver studies, and even more difficult to understand the mechanical properties of these structures since, for obvious ethical reasons, in vivo studies cannot be conducted. Investigations performed on cadavers or nonpregnant women are not efficient.

There are no simulators able to dynamically reproduce the effects induced by the passage of the FH on the maternal pelvic muscles at the research level or on the market. An aid to understanding PF damage is provided by finite element simulations, but they still suffer from the intrinsic limitations of the virtual environment and theoretical assumptions.

In this context, clinicians expressed the need for a physical simulator to provide both a training tool for gynecologists and a research device to deepen the current knowledge about PF dysfunctions. The active high-fidelity simulator described here showed good potential and could be considered a valid physical system for the investigation of PF damage. Anatomical features of the PF have been replicated by using clinical images and literature models as references. A soft material was utilized for simulating human tissue behavior both in terms of structural fidelity and behavior during the passage of the FH. Conductive textile sensors allowed proper monitoring of the elongation of the PF muscles during the descent of the FH without any soft tissue elasticity modification or encumbrance limitation. Dedicated bench tests proved that the adopted solutions had good performance in terms of elongation evaluation. System robustness in repetitive tasks demonstrates the adequacy of the proposed simulator both for clinical training courses and teaching purposes. By exploiting the clinical experience of the medical team of this study, we also proved the reliability of the acquired data: sensor outputs changed consistently with the movement of the FH through the birth canal. Moreover, the obtained forces and stretch percentages were comparable with the literature findings, supporting the integrity of the simulator design.

Clinicians confirmed that the simulator is anatomically and physiologically accurate to human anatomy. However, they recognized that the presence of the constituent elements of the mother's vulva could additionally improve the fidelity of the simulator and the simulation quality. This could also provide additional useful reference points for medical staff during training sessions. Thus, according to their advice, the addition of external anatomical structures simulating the vulva is foreseen.

Difficulties encountered in finding detailed anatomical and biomechanical parameters led to an inevitable simplification of the real anatomical complexity. However, despite its limitations, the realized simulator represents a promising tool that can be included both in training courses for experienced and nonexperienced clinicians and in gynecological education.

Future efforts will be dedicated to further technical improvements, such as the design of a solution for fixing the system to the gynecological table during the test to avoid affecting the experimental data due to a nonstable manual hold and the realization of a more accurate and deformable head to better characterize simulator compliance.

In conclusion, to further improve the high-fidelity simulator and thus to add the possibility to teach more skills and foster new applications, other anatomical parts, such as the skin, legs and belly, will be added, and a technological solution to simulate muscular tissue lesions during childbirth will be investigated to teach how to repair PF damage.

APPENDIX

No appendix is attached to the manuscript.

ACKNOWLEDGMENT

The authors declare no conflicts of interest.

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