THE DEVELOPMENT OF A LOW-COST OBSTETRIC SIMULATOR TO TRAIN MIDWIFERY STUDENTS AND TEST OBJECTIVE EXAMINATIONS' SKILLS

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ABSTRACT

The study presents the design a low cost simulator that allows precise identification of the fetal position, enabling doctors and students to train and improve their skills by inspecting visually and manually what happens inside a simulated birth canal. The system consists on a female pelvis, a custom-made fetal mannequin, and a visual display to show in real time the birth canal and the position of the fetus. Students are often unable not only to identify correctly the fetal head position, but also to discriminate between the two fontanels. This system can help them to train this ability and could be an important instrument for the instructors to objectively assess the clinical skill of each student.

Keywords: obstetric, simulations, fetopelvic relationships, OSCE

1. INTRODUCTION

The knowledge of the correct position and orientation of the fetal head is important for obstetricians and midwives during spontaneous deliveries and especially before operative vaginal deliveries. Nevertheless, these parameters are estimated in a subjective way. This fact leads to discordant evaluations, errors and failures in ventouse extraction and forceps application, worse outcomes for mother and newborn, increased use of urgency cesarean section.

The problem is longstanding. In 1952 E. Parry Jones, in his famous book about Kielland's forceps, stated: *"Kielland did much for obstetrics, but perhaps his most important contribution was his emphasis on the need for determining the exact position of the fetal head.."* (Parry Jones 1952).

Nowadays, students can practice deliveries only in cases where there is no danger for both the mother and the fetus. However, when they start their career, they could come across emergency situations in which they have to act quickly (Macedonia et al. 2003). Thus the birth simulation is very important to improve the skill of midwifery students and residents and to test their progresses during Objective Structured Clinical Examination (OSCE).

In 1988-1989 R. H. Allen, J. Sorab and G. Gonik from the Huston University, measured the forces applied by clinicians during birth, using tactile sensing technology. In particular they used sensors applied on a clinician's hand in order to investigate the relation between applied forces and the risk of birth injury (Allen et al. 1988, Sorab et al. 1988).

In 2002 C. M. Pugh and P. Youngblood, from the Stanford University, implemented the simulator "E-Pelvis" to simulate pelvic examinations; it consists of a partial mannequin instrumented internally with electronic sensors that are interfaced with a data acquisition card and a graphic software to visualize the examinations (Pugh and Youngblood 2002).

In 2003 the "Laboratoire Ampère" of Lyon (France) developed the Birth simulator: it includes a fetal mannequin; the maternal anatomically correct pelvic model; an interface pressure system mimicking the pelvic muscles; a software to visualize in real time the head location (Dupuis et al. 2005, Moreau et al. 2008).

One of the main problems of the commercially available simulators is the high price. Moreover, most of them do not allow detecting the fetal position and its orientation with respect to the female ischial spines (Dupuis et al. 2005). The birth simulator presented in this article is a low cost model that overcomes this problem allowing an identification of the fetal position.

2. THE DELIVERY: FETAL HEAD AND MATERNAL PELVIS

According to the "Williams Obstetrics" textbook (Cunningham et al. 2010) the pelvis is composed of four bones: the sacrum, coccyx, and two innominate bones, formed by the fusion of the ilium, ischium, and pubis. The pelvic cavity can be divided into the false and the true pelvis. The false pelvis is bounded posteriorly by the lumbar vertebra and laterally by the iliac fossa, whereas the true pelvis is bounded above by the sacrum, the linea terminalis, and the upper margins of the pubic bones, and below by the pelvic outlet.

Extending from the middle of the posterior margin of each ischium are the ischial spines. These are of great obstetrical importance because the distance between them usually represents the shortest diameter of the pelvic cavity. They also serve as valuable landmarks in assessing the level to which the presenting part of the fetus has descended into the true pelvis.

Four diameters of the pelvic inlet are usually described (fig. 1):

- anteroposterior is the shortest distance between the promontory of the sacrum and the symphysis pubis and it normally measures 10 cm or more;
- transverse measures 13 cm and represents the greatest distance between the linea terminalis on either side;
- oblique extends from one of the sacroiliac synchondroses to the iliopectineal eminence on the opposite side. They average less than 13 cm.

The fetal head is composed of two frontal, two parietal, and two temporal bones, connected by a thin layer of fibrous tissue. These bones are separated by membranous spaces that are termed sutures. The most important sutures are:

- the frontal, located between the two frontal bones;
- the sagittal, placed between the two parietal bones;
- the two coronal, situated between the frontal and parietal bones;
- the two lambdoid, located between the posterior margins of the parietal bones and upper margin of the occipital bone.

Where several sutures meet, an irregular space forms, which is enclosed by amembrane and designated as a fontanel. The greater, or anterior, fontanel is a lozenge-shaped space that is situated at the junction of the sagittal and the coronal sutures. The lesser, or posterior, fontanel is represented by a small triangular area at the intersection of the sagittal and lambdoid sutures.

The fetal diameters include (fig. 2):

- The occipitofrontal (11.5 cm), which follows a line extending from a point just above the root of the nose to the most prominent portion of the occipital bone;
- The biparietal (9.5 cm), the greatest transverse diameter of the head, which extends from one parietal boss to the other;
- The bitemporal (8.0 cm), which is the greatest distance between the two temporal sutures.
- The occipitomental (12.5 cm), which extends from the chin to the most prominent portion of the occiput;
- The suboccipitobregmatic (9.5 cm), which follows a line drawn from the middle of the large fontanel to the undersurface of the occipital bone just where it joins the neck.

At the onset of labor, the position of the fetus with respect to the birth canal is critical to the route of delivery. Fetal orientation relative to the maternal pelvis is described in terms of:

- Fetal lie that is the relation of the fetal long axis to that of the mother;
- Presenting part which is the portion of the fetal body that is either foremost within the birth canal or in closest proximity to it;
- Attitude is the characteristic posture assumed by the fetus in the later months of pregnancy;
- Position refers to the relationship of an arbitrarily chosen portion of the fetal presenting part to the right or left side of the birth canal.

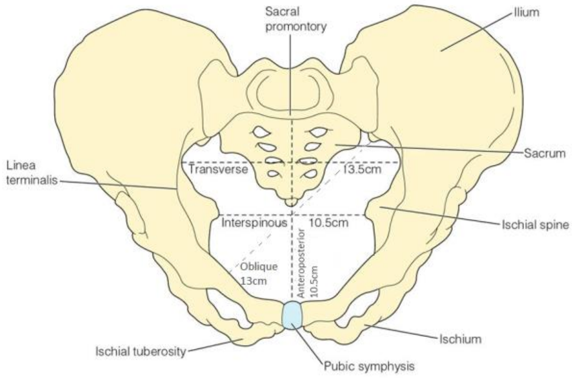

Figure 1 Main pelvic diameters and bones (Floresta 2011)

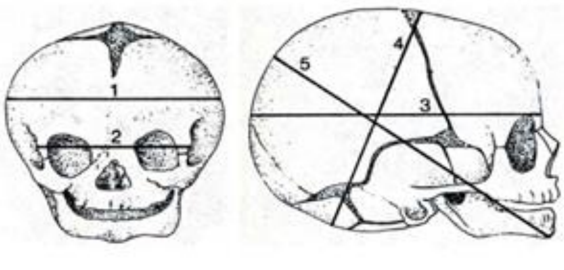

Figure 2 Fetal head diameters 1. Biparietal, 2. Bitemporal, 3. Occipitofrontal, 4. Subooccipitobregmatic, 5. Occipitomental (Barbone et al. 2012).

3. BACKGROUND

The simulator consists of a female pelvis, a custom-made fetal head and a visual display, connected to custom electronics, able to show in real time the birth canal and the position of the fetus. More specifically the system has four parts:

- A physical model of the fetus and the pelvis;
- A correspondent graphic model;
- A client side web application which allows the users' authentication and the registration of the subjects' performance during the OSCE;
- A server-side subsystem to manage communications among the physical model, the graphic model and the web application;

3.1. The birth simulator project: main goals

Our goal is to develop a system

- to train the ability in internal examination during labor;
- to discriminate between the two fetal fontanels;
- to estimate correctly the position and the orientation of the fetal head with respect to the female ischial spines;
- to measure the force applied on the fetal head.

An analysis of commercially available birth simulators revealed that most of them are not able to detect and display the position of the fetus in the birth canal. They focus on the delivery as a situation in which the mother and the newborn need help; moreover, commercially available simulators are very expensive.

We decided to implement a birth simulator able to detect physically and visually the position of the fetus with respect to maternal ischial spines and the forces applied on the fetal fontanels. The system will have also the following features:

- Low-cost
- Wireless
- Plug and play
- Space-saving

3.2. Communication and data visualization

The communication sub-system is based on a Raspberry Pi 2 model B, which acts as a bridge connecting physical and virtual simulator. Raspberry Pi 2 model B is a low cost single-board computer that plugs into a computer monitor. It has various functionalities including the ability to interact with the outside world. All data, coming from the fetal head, are received and transmitted to Raspberry via Bluetooth and from Raspberry to the client via Wi-Fi (fig. 3).

This system doesn't have cables coming out from the pelvis. All sensors, which send data to the Raspberry, are connected to the open-source electronics platform Arduino, powered by a rechargeable battery and positioned inside the fetal head.

The software is implemented with Node.js, that is a platform used to build applications based on JavaScript V8 runtime. It uses sockets (software abstraction) such as Socket.IO or UDP to communicate in real time: the first socket is used to communicate in release mode, whereas the second one is used to send information in development mode. Socket.IO enables real-time bidirectional event-based communication; UDP is used to connect Node.js and the graphic editor Unity.

Unity is a graphical shell for a desktop environment; it is a cross-platform game engine known for its ability to target projects to multiple platforms.

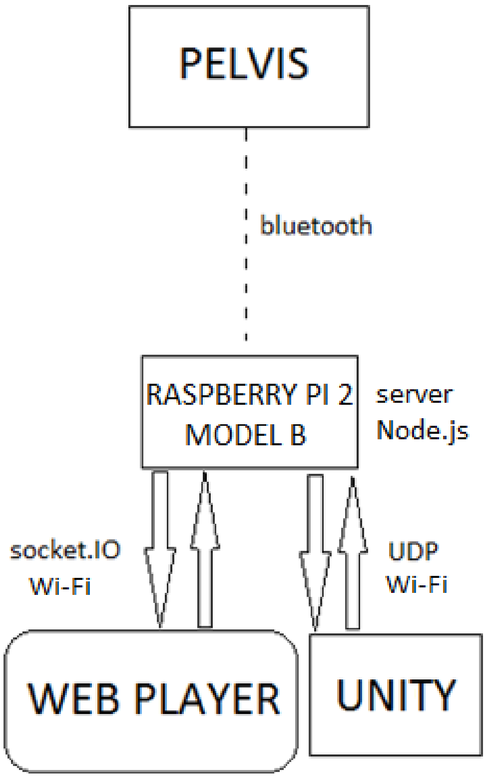

Figure 3 The communication system of the birth simulator

3.3. The physical model

We bought a model of a female pelvis, the female pelvis skeleton A61, distributed by 3b Scientific (Hamburg, Germany) and we printed a 3D fetal head with the main anatomical landmarks.

3.3.1. The fetal head

The free fetus model available online (http://www.3dxtras.com/3dxtras-free-3d-models-details.asp?prodid=38) is used as a base to made the printable fetal head (fig. 4); starting from this model we edited the head using Blender and Geomagic; Blender is an open-source 3D computer graphics software product used for creating animated films, visual effect, 3D applications, video games and 3D printed models, whereas Geomagic Studio is a mechanical Computer-Aided Design software, used for the design of mechanical systems and assemblies.

We changed the head's dimensions so that they were compatible with our pelvis; then we cut the head at the beginning of the neck, so that it can join an existing body and we divided the head in two parts, both to make the printing process easier and to locate sensors correctly (fig. 5).

Before printing the fetal head, we choose the right material which form the final model; that material must have features similar to the skin: it can be elastic but, at the same time, stiff enough so that the measurement are not affected by error caused by surface deformation.

Our first model, was very realistic and too much complex to be printed. As a matter of fact, we decided to simplify it using Geomagic, i.e. we reduced the number of vertices in order to have a lighter model usable to print the head and to visualize the scene. In figure 6 there are shown the phases of our work, while the result of printing is observable in figure 7.

The 3D printed head has the main anatomical landmarks, i.e. the anterior and posterior fontanels connected by the sagittal suture. The diameters of the printed head are:

- bitemporal: 7.5 cm;
- biparietal: 9 cm.
- occipital-frontal: 11.3 cm;
- suboccipitobregmatic: 9.2 cm.
- occipitomental: 13 cm.

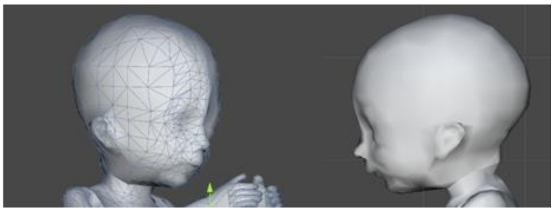

Figure 4 The free fetus model

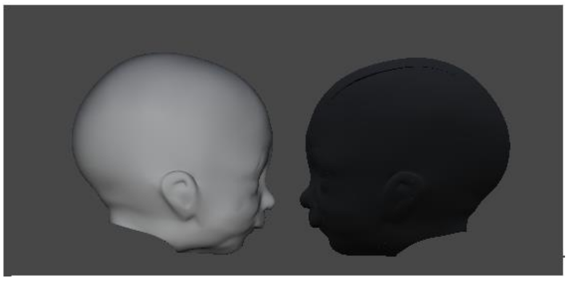

Figure 5 The model's editing

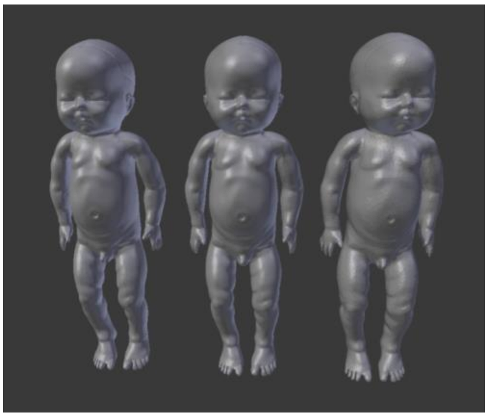

Figure 6 The starting model, the model used, a simpler model not usable for printing because of its defects on the head caused by an excessive reduction of the vertices.

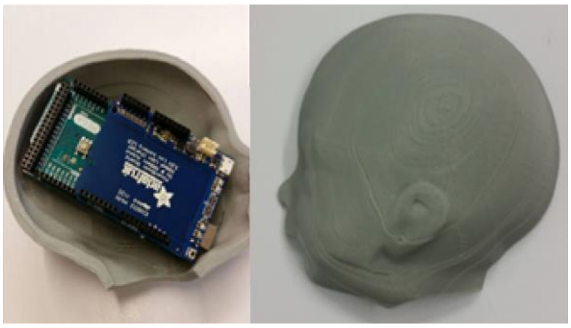

Figure 7 The two parts of the printed head. On the left it is possible to see some electronic component: the Arduino Mega and the Adafruit powerBoost. Furthermore the fetal head contains two IMUs and two pressure sensors.

3.3.2. Sensor used in the model

The head position and the orientation of the fetal head with respect to maternal ischial spinesare detected by two Inertial Measurement Units (IMUs).

The contact force of the user's hand on the mannequin's fontanels is measured by two pressure sensors.

The IMUs are inside the head whereas the pressure sensors are on the surface, in correspondence with the anterior and posterior fontanels. Thus, we chose small sensors so as they could be placed easily in the head, which contains:

- One Arduino Mega;
- Two IMUs;
- Two pressure sensors;
- One Bluetooth component;
- One rechargeable battery.

The two IMUs MPU6050 have an embedded 3-axis MEMS gyroscope, a 3-axis MEMS accelerometer and a Digital Motion Processor hardware accelerator engine with an auxiliary I2C port. The MPU-6050 features three 16-bit analog-to-digital converters (ADCs) for digitizing the gyroscope outputs and three 16-bit ADCs for digitizing the accelerometer outputs. For precision tracking of both fast and slow motions, the parts feature a user-programmable gyroscope full-scale range of ±250, ±500, ±1000, and ±2000°/s(dps) and a user-programmable accelerometer full-scale range of ±2*g*, ±4*g*, ±8*g*, and ±16*g*. The MPU-6050 operates from VDD power supply voltage range of 2.375V-3.46V.

Each force sensing resistors is composed by a polymer thick film device, which exhibits a decrease in resistance with an increase in the force applied to the active surface. Its force sensitivity is optimized for use in human touch control of electronic devices and it is able to measure forces up to 10 kg; the pressure sensitivity range from 0.1 kg/cm^3 to 10 kg/cm^3. It has a 18.3 mm diameter with an active area of 12.7 mm. It is composed by three substrates: a flexible substrate with printed semiconductor; a spacer adhesive; a flexible substrate with printed interdigitating electrodes, the overall thickness is of 0.47 mm.

Bluetooth nRF8001 Bluefruit Low Energy Breakout allows establishing a wireless link between Arduino and any compatible iOS or Android (4.3+) device. It works by simulating a UART device beneath the surface. It sends and receives data up to 10 meters away, from your Arduino to a device.

Adafruit powerBoost shield goes onto Arduino and provides a slim rechargeable power pack, with a built in battery charger as well as DC/DC booster. The powerBoost shield can run off of any Lithium Ion Battery. We chose a Lion Rechargeable Battery able to power the mannequin for six/eight hours. Its model is 103456A-1S-3M, its nominal voltage is 3.7V and its capacity is 2050 mAh.

3.3.3. The physical model's features

Starting from these sensors' measures, a calibration procedure allows to precisely define in real time the head position with respect to the pelvis.

The head position is defined according to the eleven stations postulated by the American College of Obstetrician and Gynecologists (ACOG), i.e. eleven positions where the head can be placed in the birth canal with respect to the maternal ischial spines (fig. 8). The position '0' corresponds to the vertices at the ischial spines and then there are five stations over and five under it. Each fifth station is located a centimeter above or below the spines. Thus, as the presenting fetal part descends from the inlet toward the ischial spines, the designation is –5, –4, –3, –2, –1, then 0 station. Below the spines, as the presenting fetal part descends, it passes +1, +2, +3, +4 and +5 stations to delivery. (Cunningham et al. 2010, Hagadorn-Freathy et al. 1991, Robertson et al. 1990).

The manual evaluation of these stations is not easy, as Dupuis demonstrated in his prospective study: *"transvaginal assessment of fetal head station is poorly reliable, meaning clinical training should be promoted"* (Dupuis et al. 2005).

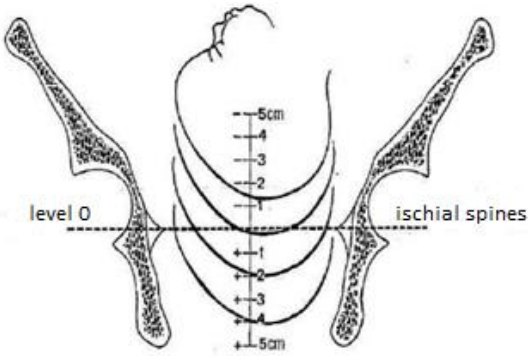

Figure 8 Head levels with respect to maternal ischial spines according to ACOG classification (Moreau 2007).

3.4. Graphic model

The graphic model allows users to visualize what happens inside the birth canal in real time. It consists of a female pelvic 3D model and a fetus 3D model (fig. 9). The first one is a free model available online (http://www.3dxtras.com/3dxtras-free-3d-models-details.asp?prodid=10508), edited so that its dimensions are the same as the physical pelvic model; the second one is the model used to build the fetal head (fig. 4).

The graphic representation can be used both in training and in examination mode. During a training session the student makes a pelvic examination and he checks his skills by a feedback provided on a screen. In particular, he has to detect the correct position and orientation of the fetus with respect to the female ischial spines. Moreover, the graphic model shows in real time the correct identification of the fontanels thanks to pressure sensors: when a user touches a fontanel, i.e. a pressure sensor, the graphic model highlights that fontanels.

In examination mode the student cannot take advantage of the virtual representation, which is visualized only by the doctor so that he can evaluate the student's performance.

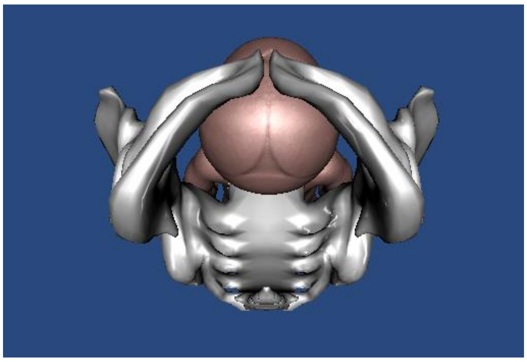

Figure 9 Graphic representation of the delivery allowing users to visualize what happens inside the birth canal

3.4.1. Calibration system

An important point for the correct representation of the graphic model is the calibration process that is necessary to identify the starting fetus position in the birth canal. Calibration allows a unique correlation between the pivot of physical fetus head and the system of reference inside the pelvis. Without calibration the computer is not able to detect properly the physical position and orientation of the mannequin, as a matter of fact the two IMUs cannot return an absolute position of the fetal head in the world coordinates.

At the beginning we decided to implement an internal calibration, i.e. to define a starting position of the fetus inside the birth canal; before each session the user should have placed the fetus in the same position. However, this procedure could generate errors if the user positioned the mannequin in a wrong way. For this reason we opted for an external calibration where the starting position is outside the birth canal and it is a bound positionin which the fetus must be located before starting a session (fig. 10).

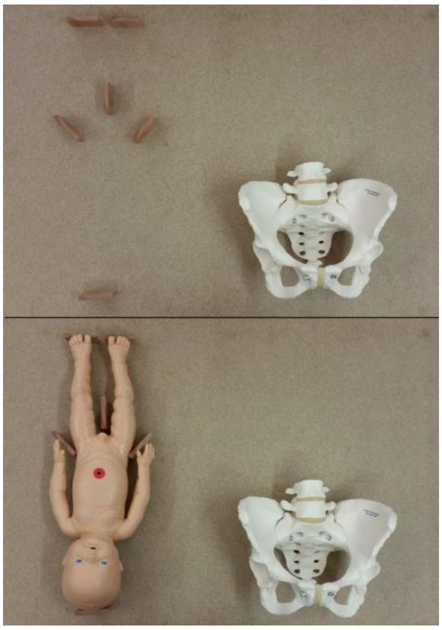

Figure 10 On the top there is the pelvis and the shape which defines the starting position; below it is shown an example of external calibration: the fetus must be positioned according to the shape before each session.

3.5. User interface

The birth simulator is a didactic instrument made to improve students' skills and knowledge concerning the delivery. For this reason, we implemented a web player application, which is a platform with all the data. After authentication each user accesses to his personal page: the student's page gives information about previous sessions and it allows students to start a training session. Users can also check their improvement and difficulties (fig. 11); the doctor's page has information about the whole class; the teacher can visualize the list of students and their past evaluation, moreover he can start an exam session. When an evaluation has started, he must validate the calibration and gives performance scores (fig. 12).

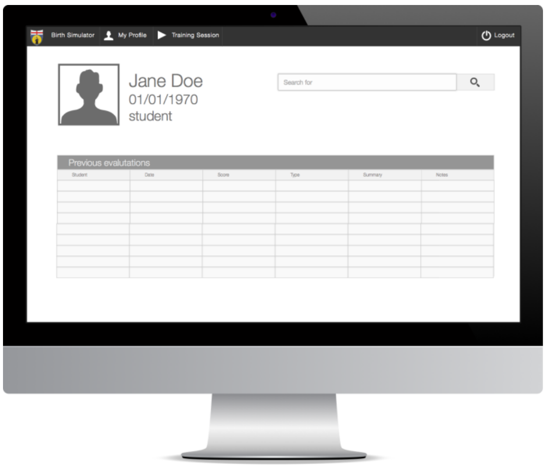

Figure 11 Student's page in which each student can visualize his own profile, examine his past training, write notes and start a new training session.

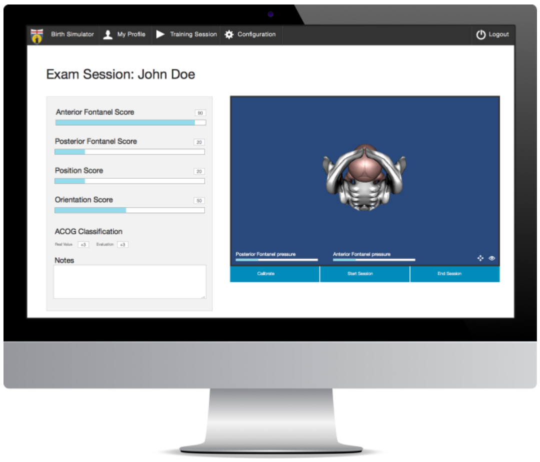

Figure 12 In the exam mode, the teacher has the possibility to give scoresto the students and record his impression.

4. CONCLUSION

The aims of the project are:

- to implement a birth-simulator able to detect properly the position and orientation of a fetus with respect to maternal ischial spines.
- to develop a portable low-cost device.
- to create an instrument that can train and evaluate students' OSCE skills to improve their obstetric abilities.

The communication had to be wireless, in order to have no cables coming out from the pelvis, that's why we chose a Bluetooth low-energy device. However, this device only allows a point-to-point communication and presents difficulties in software management. For these reasons we use a Raspberry Pi 2 model B in order to expand communication possibilities. This system facilitates the development of new functionalities linked to multiple simultaneous connections. Moreover it will allow the development of mobile applications, which will make the simulator even more portable.

Each electronic component of the simulator had to be low-cost and with dimension that were adequate to the head dimension. This made the research hard, but we succeeded in sensorizing the simulator, buying the pelvis and implementing the software using free tools by spending less than 400 euros. To prevent errors caused by the undesirable movement of the IMUs, we modeled the head so that the inner part had grooves in which locate the IMUs. We did not have any problem with the pressure sensors because they are located on the head's surface and they cannot move improperly.

5. FUTURE DEVELOPMENT

It will be useful to know the whole force applied on the fetal head during the delivery and the corresponding strain. These measurements can be obtained covering the fetal with a Roboskin layer. Roboskin is based on conformable mesh of sensors having triangular shape and interconnected in order to form a networked structure. Each sensor is supported on a flexible substrate allowing the sensor to conform to smooth curved surfaces, implementing 12 taxels based on capacitive transducers (Cannata et al. 2008).

To parallel it is useful to display the head's strain in the graphic visualization so that users can get a visual feedback about the forces they applied; this leads to the modification of the virtual head: currently it behaves as a rigid body, butin the future the head's behavior might be turned into a deformable body. This development can be realized using the *cloth* component in the Unity Editor, which will allow a more realistic graphic representation.

Another important step will be to test and validate the prototype of the simulator in the Centre of Advanced Simulation of Genoa University. In that occasion a selected group of doctors and students will be asked to use and become familiar with the prototype, in order to give us some feedback and suggestions to improve the simulator.

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