Design of Medical Simulators in Obstetrics

M.T. Pham, R. Moreau, A. Jardin, T. Redarce
Laboratoire Ampère, UMR CNRS 5005,
INSA-Lyon, Université de Lyon, F-69621, France

P. Boulanger
Advanced Man-Machine Interfaces Laboratory
University of Alberta, T6G2E8, Canada

O. Dupuis
Centre Universitaire Hospitalier Lyon Sud, 69495 Pierre-Bénite, France

1 Introduction

Obstetric procedures can lead to irreversible maternal and neonatal sequelae. During the 19th century, such accidents were cataloged but had no impact on obstetric practices. In the 21st century, these kinds of incidents have medical as well as legal repercussions, which lead to an especially damaging and vicious circle: increase in practitioners faced with charges -including damages and interest- increase in physician insurance premiums and stress, decrease in the number of services offered as well as a scarcity of obstetricians, continuous increase in in utero transfers, increase in caesarian sections, reduction in obstetric procedures (breech births, forceps deliveries, and shoulder dystocia treatment), and a lowering of the capacity to treat complications. This scarcity in dystocia treatment could bring about an increase in accidents. Breaking this vicious circle is a major challenge for the specialty.

For preventive purposes and to minimize risks, the leaders in high-risk industries -such as nuclear and aeronautics- have invested significant funding in simulation technology. With significant progress in new technologies and modern techniques in mini-invasive surgery, the introduction of medical simulators is gaining an increasing appeal in the clinical environment [1]. In [2], authors described the surgical simulation for medical education as a valuable addition to traditional teaching methods. Satava *et al.* show the role of simulators as another tool for education [3]. These tools allow the visualization of the position of organs, the planning of surgical interventions, and the carrying out of more comprehensive postoperative monitoring. The flexibility of such tools also permits to reset some parameters in order to adapt the medical intervention to each patient's data and to adapt the difficulty of the procedure. In fact medical simulators take into account the needs of physicians but also the ethical problems and risks that patients may be exposed to during the learning period of a new technique. The main interest of these tools is to train inexperienced physicians without putting the patients' well-being in danger. For instance, currently available obstetric simulators make it possible to train obstetrics residents in numerous procedures, including episiotomy suturing, total perineal repair, instrument-assisted delivery, and breech delivery. Several teams have demonstrated the superior skills of residents trained with simulators. Simulators also give experienced practitioners exposure to rare and serious complications that occur in obstetrics practice, such as amniotic embolism and severe bleeding during delivery. Training using simulation also makes it possible to avoid exposing pregnant women to the hazards of traditional training and offers obstetrician gynecologists an ethical alternative with respect to training [4]. Simulation not only allows the training of practitioners, but, in the future, could also allow them to demonstrate their skills. In the near future, the falling prices of computer materials should favor the wider distribution of these learning methods.

This paper describes the approach which has led to the design of a childbirth simulator developed in collaboration with physicians of CHU Lyon Sud (South University Hospital Centre of Lyon) [5, 6, 7]. This anthropomorphic and dynamic simulator is equipped with 6D position sensors that make it possible to record numerical data in real-time, which is then used into a display interface. This system offers real-time visualization of the position of both the obstetric instruments and the patient's body from several viewpoints [8]. This kind of simulators offers operators the possibility of viewing inside the patient's body, thereby making a manipulation inside the body visible. This helps the trainees to understand the correct gesture and for the instructors to check their knowledge. This paper is divided into three parts. Section 2 presents a classification system for obstetric simulators and describes their various uses. Then a short discussion is made about this state of art. The specifications of the BirthSIM simulator have been analyzed and translated in terms of mechanical, hardware, and software specifications in the third section. We then conclude by discussing some experimental results and our future experimental works.

2 A classification system for obstetric simulators

There are currently several types of childbirth simulators, each characterized by their functionalities:

- **Mechanical simulators** generally make use of anthropomorphic manikins, often used in midwifery and medical schools.
- **Virtual simulators** make it possible to observe the path of the fetus through the pelvis. Some of these simulators offer haptic feedback systems.
- **Combined Mechanical and Virtual Simulators** are much more attractive because they integrate the functionalities of both of the above types.

2.1 Mechanical Anthropomorphic Simulators

2.1.1 First-Generation: *Static* Simulators

These simulators are anthropomorphic, reproducing a part of the human body. The first versions of these simulators were static and had no moving components. To model a delivery, it was necessary to use an aid to push the fetal dummy through the pelvic canal.

One of the first simulators of this type was constructed in 1759 by Madame du Coudray [9]. It consisted of a female pelvis and the body of a fetus and was used to teach anatomy and the principles of childbirth (Figure 1). The dummy was formed of tissue and a real pelvis. After 24 years of use, 5000 midwives and 500 physicians received their training using this system.

Figure 1: The first childbirth simulator

Nowadays, plastic simulators, created using rapid prototyping of anatomical elements, are currently on the market, including a pelvis with a full-term fetus (Simulaids, Inc.) and perineum with anal sphincter (Limbs & Things, Inc.). They cost between 500 and 1000 euros (Figure 2).

Figure 2: The commercialized childbirth simulator

These simulators make it possible to teach the anatomy of the pelvis and fetal head, as well as provide an overall view of the delivery process. The perineum simulator allows to train medical teams in episiotomy suturing and total perineal repair. Two US teams compared randomized, traditionally trained internal cohorts with those using simulators. For both episiotomy suturing and total perineal repair, they demonstrated that the groups trained using simulators had significantly stronger skills [10, 11].

2.1.2 Second-Generation: *Dynamic* Simulators

These simulators are anthropomorphic as well as dynamic, meaning they can reproduce the movement of the fetus through the pelvic canal without external assistance. With these simulators, the fetus is attached to a rail or cylinder system that allows its descent through the pelvic canal (Figure 3). These simulators are available on the market for between 1700 and 2800 euros (Noelle S551 and S552 childbirth simulators). Using this type of simulator, it was shown that students trained with simulators felt significantly better prepared to carry out deliveries, compared to those who only received theoretical training [12].

2.1.3 Third-Generation *Dynamic* and *Instrumented* Simulators

These are anthropomorphic and dynamic simulators. They are equipped with systems that make it possible to record numerical data. Using these systems, you can

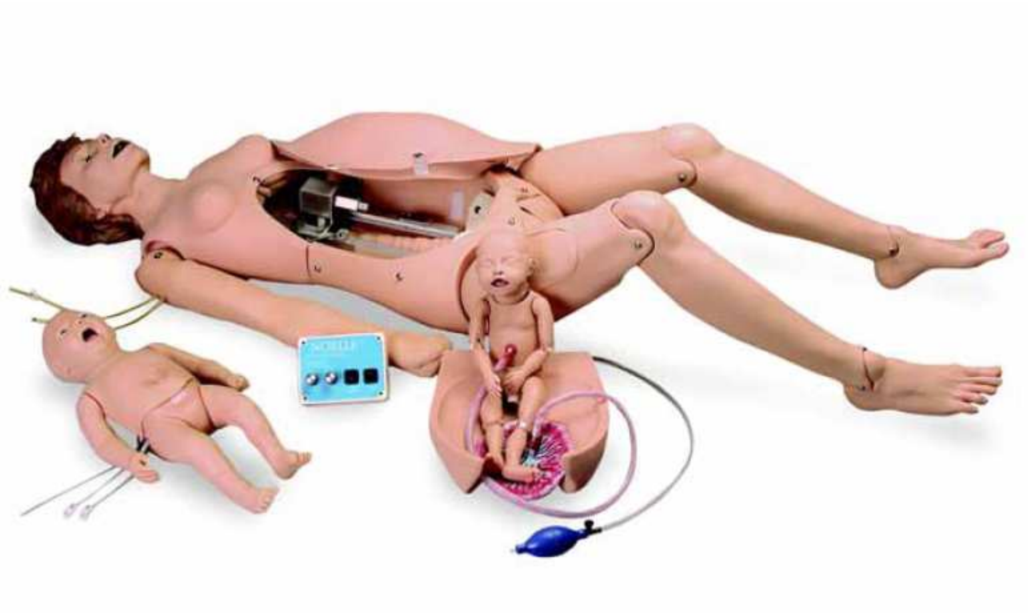


Figure 3: The Noelle S551 childbirth simulator

quantify the procedures performed and offer more detailed instruction. They all continue to increase in complexity and cost.

Diagnosis Related to Cervical Dilation and Fetal Descent: The latest version of the Noelle simulator (S565 about 20,000 euros) makes it possible to follow cervical dilation and fetal descent. This simulator includes a mechanical birthing system and a complete fetal heart rate simulation system. There are also programs that allow students to practice normal and forceps deliveries and learn episiotomy-suturing technique. This type of simulator also allows educators to evaluate students [13, 14].

Carrying Out Breech Deliveries: Deering developed a modified version of the Noelle simulator to simulate breech births. His research team demonstrated that training with this simulator significantly increased the performance of students in performing breech deliveries [15].

Treating Shoulder Dystocia: Using birthing simulation, experimental and clinical studies of shoulder dystocia have been carried out.

- Shoulder Dystocia Simulators: Gonik *et al.* developed an original simulator specifically designed to analyze shoulder dystocia [16]. This non-commercial, scientific simulator includes several innovations: a pelvis with changeable direction that simulates the pelvic inlet, a head covered with a silicon film and fitted with epoxy plates to simulate the rigidity of the jawbone, fetal shoulders with variable diameters, a brachial plexus simulator attached to the base of the neck and including a potentiometer allowing determination of plexus elongation, a fetal neck, and instrumented gloves with strain sensors. Using this system, the authors objectively demonstrated the effectiveness of the McRobert maneuver. Up to biacromial diameters of 12 cm, this maneuver reduces the necessary tractive force, stretching of the brachial plexus, and the rate of clavicle fractures. Recent improvements in this simulator have made it possible to demonstrate the superiority of the Rubin maneuver over the McRobert maneuver in limiting as much as possible the tractive forces and stretching of the plexus when shoulder dystocia occurs [17].

- The Modified Noelle Simulator: Deering's research team modified the Noelle simulator by installing a harness around the fetus to simulate shoulder dystocia [18]. They showed that interns trained using this simulator achieved better results than those who received traditional training, especially with regard to the time between the delivery of the fetal head and the delivery of the fetal body; the time was half (61 seconds versus 146 seconds) in the simulation group [19].

2.2 Virtual Simulators

These simulators offer an entirely virtual environment: the delivery does not actually take place but is represented by 3D computer simulation. These simulators are often prototypes and, to the best of our knowledge, none of them have entered the birthing simulator market. Currently, virtual simulators are for research purposes.

In France, Boissonnat developed a 3D model of the pelvis and fetal head from MRI images. The objective of this simulator is to perform a prognosis of the delivery based on different pelvic parameters (size and shape of the pelvis) and various sizes of the fetal head (Figure 4). This program makes it possible to simulate uterine contractions and different positions of the fetal head. It also allows simulation of the fetal rotation within the pelvic canal [20]. The Complex Systems Laboratory in Evry, France, also developed a simulator consisting of a 3D model of a fetus, pelvis, muscles, a force feedback system covering the three translational axes, and a virtual hand. Contractions move the fetus forward. The operator uses the virtual

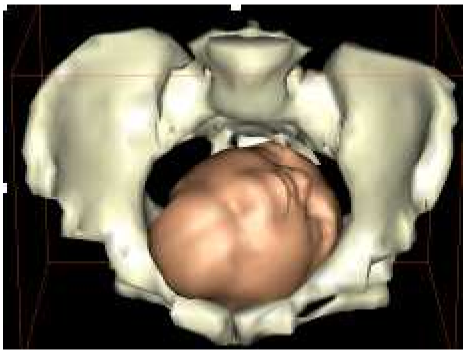


Figure 4: A virtual simulator developed by Boissonnat *et al.*

hand to control the delivery (Figure 5). This simulator makes it possible to measure the forces between the fetus and the muscles [21].

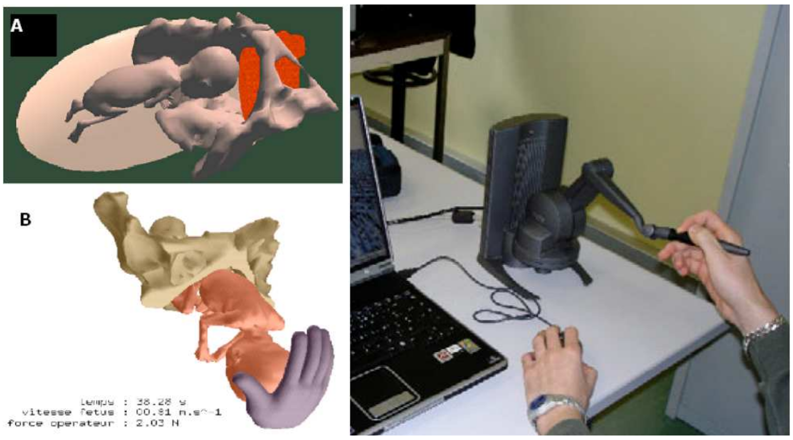


Figure 5: A virtual simulator developed by the Complex Systems Laboratory, Evry, France

One can associate this type of simulator with mathematical programs that allow the simulation of all or part of a delivery. Currently, two teams in the United States have developed such simulators. The team of Gonik recently developed a model based on the MADYMO (MAthematical DYnamic Model) model, which is normally used to simulate crushing and the forces at play during traffic accidents. After the modification, this model was able to analyze the endogenous forces (uterine contractions and expulsive forces) and tractive forces that the brachial plexus of the fetus is subjected to, depending on the type of maneuver performed [22]. In 2000, the same team developed a basic mathematical model to analyze the tractive forces when shoulder dystocia occurs [23]. In the same manner, Lien [24] carried out a simulation of soft-tissue deformation, focusing on the levator muscles during delivery and [25] proposed a method, based on a biomechanical modeling of concerned organs, to recover the different forces generated during delivery. The modeling process should eventually permit to develop a new training device to take into account different anatomies and different types of delivery. To obtain interactive time performance, a simplification of organs anatomy is proceed.

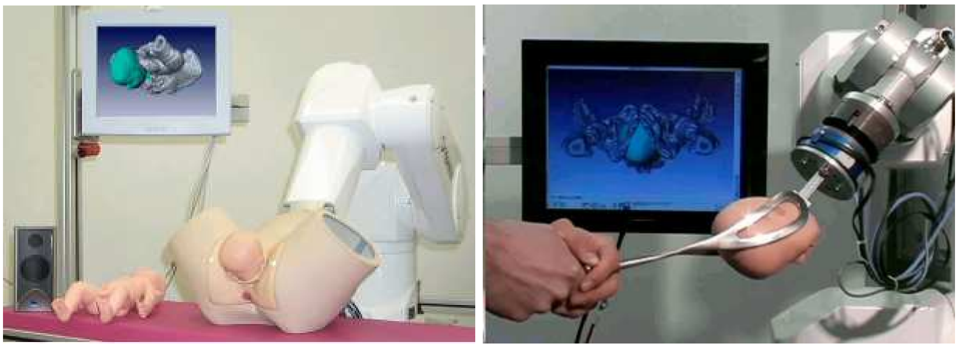
Finally, the simulator developed by Lapeer is a refined virtual simulator, which allows to manipulate a virtual fetus using real forceps within a pelvis skeleton. Thanks to real-time optical tracking of the procedure by a NDI Polaris system, this simulator makes it possible to analyze deformations of the fetal skull based on the movements performed [26].

2.3 Combined Mechanical and Virtual Simulators

These simulators consist of a combined mechanical system, which simulates an actual delivery, a control board, which reproduces the efforts during a delivery in real time, and a computer system, which allows to treat and visualize the data.

Simulator based on a 6-Axis Robot: In Switzerland, the Automatic Control Laboratory developed an interactive birthing simulator. With this system, it is possible to position the fetus in a variety of ways using a 6-axis robot [27, 28]. This simulator consists of a pelvis dummy, a model of a fetal head, actuators, and a programmable control unit (Figure 6).

Operators can train using obstetric instruments. The programs can be modified to simulate the different phases of delivery. The computer system connected to the simulator is complex and performs two types of measurements: direct measurements taken from different sensors, and force and moment calculations. Sensors are placed on the neck to record trajectory, body shifting, and head movements. Force sensors are placed on the top of the head to provide tactile feedback to the operator. Display of the parameters takes place in real time. The display system alerts the operator to dangerous situations using several color-coded levels and displays advice. Loudspeakers simulate sounds and immerse the operator in the delivery room environment. This simulator includes a force feedback system on the abdomen of the dummy. Any manipulation of the abdomen triggers a reaction in the virtual model. The simulation programs work with mathematical models of the uterus, pelvis, muscles, skin, and ligaments. These programs create dynamic



(a) General view (b) Simulator with forceps but without the pelvis

Figure 6: The patented simulator by Riener *et al.*, 2003

relationships between the forces and moments exerted by the operator on biomechanical models. Changes in the parameters of the biomechanical model allow the simulation of rare or pathological situations. The dynamic models produce reactions in the virtual model and move the fetus forward. Because of its cost, this simulator is not available on the market.

Simulator based on electropneumatic actuator: A childbirth simulator has been developed in collaboration with physicians of CHU Lyon Sud (South University Hospital Centre of Lyon) for the training and evaluation of obstetric gestures with forceps [5, 6]. This anthropomorphic and dynamic simulator is equipped with 6D position sensors that make it possible to record numerical data in real-time, which is then used by a dynamic display interface. This tool gives a visualization of the position of both the obstetric instruments and the patient's body from several viewpoints. An electropneumatic component allows to reproduce the dynamic process of a delivery and to perform extraction manipulations.

2.4 Discussion

Thanks to simulation, educators can evaluate students through a third party or self-assessment (film and audio recordings). Simulation also allows the training and evaluation of teams by exposing them to rare and dangerous situations [29]. In addition, simulation makes it possible to avoid the use of animal experimentation.

Simulation offers a teaching method that applies to a large number of fields, including role-playing involving actors and simulators [30]. It can include the complete immersion of a team of two midwives and one physician in a scenario, such as the care of a woman with serious bleeding during delivery [29], or a simpler case involving the simulation of a codified procedure (for example, episiotomy suturing) by a single operator [10].

Regardless of the procedure simulated -episiotomy suturing [10], total perineal repair [11], instrument-assisted delivery (personal results), breech delivery [15], or shoulder dystocia treatment [18]- residents trained with simulators have significantly greater skills than residents who receive only traditional training. These simulators make it possible to reduce the learning curve. There are three types of learners: those who learn theoretical concepts quickly, but have difficulty making accurate movements, those who learn slowly but succeed in performing complex movements, and rare individuals who have exceptional mental and technical capabilities, allowing them to learn both concepts and complex movements quickly. The potential of each learner cannot be changed, but learning through simulation can avoid having inadequately trained students come in contact with pregnant women and newborns. Simulators also make it possible to carry out pre- and post-testing before and after training. This is the case for the simulator we developed, which automatically calculates the score of a resident by comparing the trajectory of the positioning performed with the reference trajectory.

The third generation anthropomorphic simulators -those equipped with sensors, virtual simulators, and combined simulators- also allow the detailed study of obstetric mechanics. In the United States, it was simulation that made it possible to document the effectiveness of obstetric procedures in treating shoulder dystocia; the effectiveness of the McRobert maneuver [16] and, more recently, that of the Rubin maneuver [17] has been demonstrated. Virtual simulators also allow more basic research to be performed. Gonik's team used virtual simulators and complex computer programs to demonstrate the extent of harmful endogenous mechanical forces (uterine contractions and expulsive forces) in the pathophysiology of the brachial plexus [23, 22]. To the best of our knowledge, there is however none anatomical instrumented simulators offering a complete training program. To fill this gap the Laboratoire Ampère has designed and developed a new simulator, called BirthSIM [7]. In the long term, we hope that this tool will enable junior physicians and midwives to train risk free and to acquire a first experience before proceeding to the classical training in the delivery ward.

3 Design of the childbirth simulator BirthSIM

The BirthSIM simulator integrates the following three distinct components (Figure 7):

- a mechanical component and its forceps,

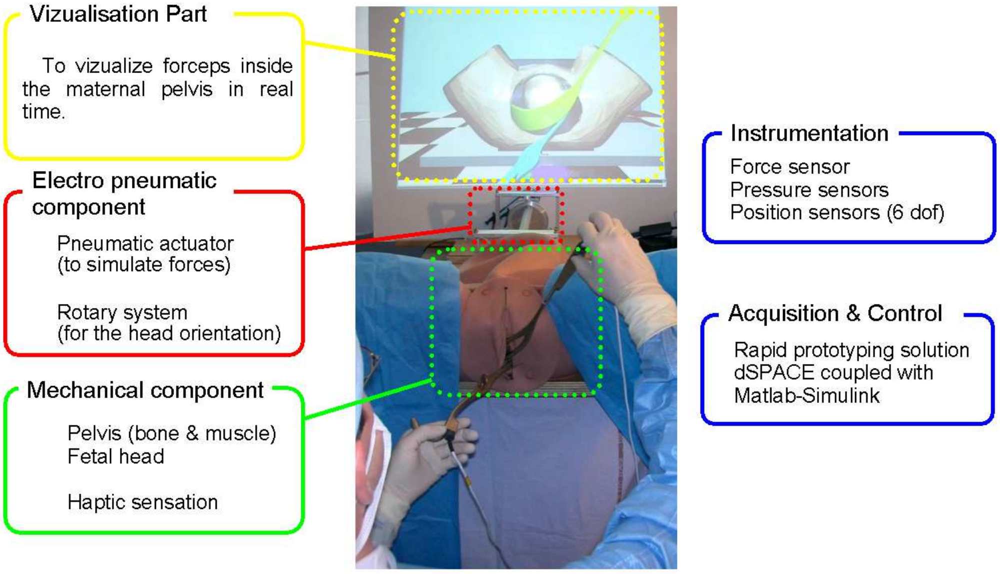


Figure 7: The BirthSIM simulator

- an electropneumatic component,
- a visualisation component.

3.1 Mechanical component

3.1.1 Pelvis and fetal head

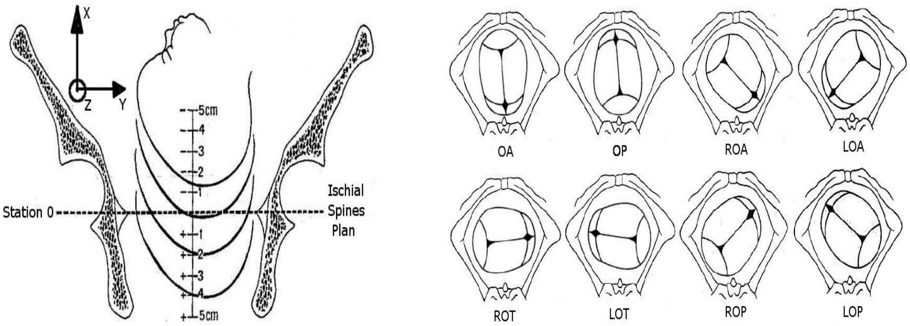
The mechanical component of the BirthSIM simulator consists of an anthropomorphic dummy of the pelvis (Fig. 8(a)) with the main anatomical markers (ischial spines, coccyx, sacrum, and pubis) manufactured by Simulaids Corporation [31]. Only the head of the fetus is used as the model for the fetus. We assume the fetus is in a cephalic presentation and that, once the head has been extracted, the rest of the body is usually expelled without any complication. A 3-D model of the cranium of a fetus was obtained from medical scans provided by the hospital. Then, through rapid prototyping, we constructed a cranium and molded a silicone head [32]. The head bears the main anatomical landmarks (fontanels, sutures, ears), allowing realistic examination of the fetal head (Fig. 8(b)).

With the BirthSIM simulator, a medical professional can palpate the expected landmarks and make transvaginal assessment diagnosis [33]. This determines the

(a) Station (b) Location

Figure 8: The anthropomorphic models of the maternal pelvis and the fetal head

fetal presentation inside the pelvis. The fetal head presentation is given by two parameters: fetal head station and location. The station is the distance of the head from the ischial spines, from -5cm to +5cm (Figure 9(a)), as defined by the American College of Obstetricians and Gynecologists [34]. A station of +5cm corresponds to the moment when the fetal head is at the level of the vaginal introitus. Obstetrical instruments in deliveries are only used if the fetal head is in front of the ischial spines (from 0 to +5cm). The location concerns the orientation of the fetal head around the axis of the pelvic canal. Traditionally, eight different positions (every 45°) are used to describe fetal head orientation (Figure 9(b)).



(a) Station (b) Location

Figure 9: The different presentations of the fetal head according to the ACOG

3.1.2 Instrumented Forceps

Forceps have been used for more than 400 years, but only during the last 70 years has there been several research studies to measure the forces linked with their use. Several studies have been undertaken to quantify the tractive effort to apply during instrumental deliveries. For example, forceps have been equipped with a dynamometer [35], strain gauges [36, 37] and analyzed through theoretical calculations based on the maximum pressure of the amniotic liquid in the second phase of labor [38]. The results were quite varied and inconclusive; the maximum tractive force ranged from 150 to 300 N. In addition, some researchers have attempted to quantify the compressive forces applied to each side of the fetal head by instrumenting a forceps with optical fiber sensors [39]. Along the same lines, Moolgaoker used water-inflatable sensors to study the compressive forces applied by various types of forceps and vacuum extractors [40, 41]. He showed that the total compressive and tractive forces were weaker for forceps compared to vacuum extractors. Finally, a recent study focused its analysis on the area of the fetal head acted on by the forceps. Dupuis developed the concept of quality forceps blade placement [42], which is based on this principle: a significant force applied symmetrically is safer than a weaker force applied asymmetrically. Thus, we developed an instrumented forceps in order to measure forceps displacements. To analyze forceps blade placement, the forceps were instrumented with position sensors (Figure 10).

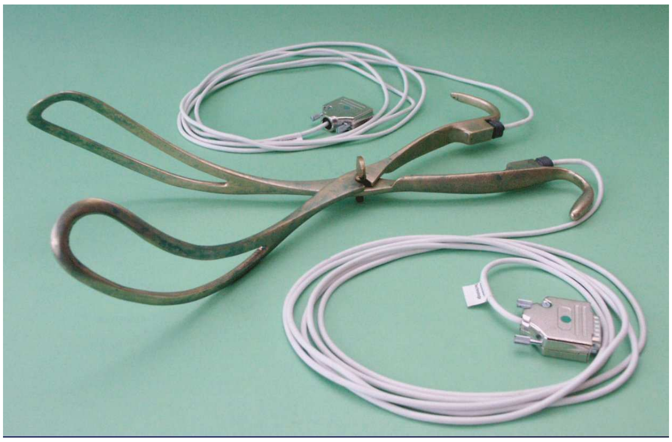


Figure 10: Instrumented forceps with position sensors

3.1.3 Miniaturized Position Sensors

The originality of the instrumented forceps is that it makes it possible to study forceps paths inside the pelvis. To monitor the simulator's various components, several challenges had to be overcome: the restricted workspace and obscuring of some objects means they cannot be monitored inside the pelvis. We chose a system using electromagnetic sensors that can follow masked objects. These sensors have six degrees of freedom (dof) (position and orientation). We chose the MiniBird [43] system of measurement, developed by Ascension company. It measures, in real time, the position and orientation of one or several miniaturized sensors. These sensors measure the impulse of the magnetic field emitted by a box called a transmitter.

Three factors must be taken into account when using such a system: the presence of ferromagnetic materials in the measurement field can disrupt measurements; the measurement field is limited in size; and the 120 Hz sampling rate is divided by the number of sensors used. The first constraint is solved using nonmagnetic materials for the simulator (wood, aluminium, plastic). Because traditional forceps used in delivery rooms are composed of magnetic, stainless steel material, it was necessary to manufacture forceps using nonmagnetic material. To construct a realistic simulator, we had to choose material that weighs approximately the same as that used in today's hospital forceps, meaning 661 g for Levret's forceps. Bronze, in addition to being nonmagnetic, has a density similar to stainless steel. We, therefore, molded bronze forceps, whose mass is 774 g. The second constraint can be solved using appropriate sensors for the task. Here the workspace dimension of the sensors (a 80-cm diameter half-sphere) is more than sufficient because data acquisition takes place inside or beside the maternal pelvis. Since we are using three sensors (one in the fetal head and one in each forceps blade), the sampling rate is 40 Hz. This frequency is compatible with classic childbirth.

We calibrated the sensors in order to check their accuracy and the influence of the simulator's ferromagnetic materials on the measurements. The fetal head was then moved inside the pelvis to reproduce the different head stations and locations. For each station, the head was moved through the different locations, thus delineating a circle. This experiment was repeated throughout the twenty centimeters, which corresponds to the maximum displacement of the fetal head in the maternal pelvis. The fetal head's workspace is shown in Figure 11 where the $\mathbf{x}$-axis rests along the pelvic canal (Figure 9).

Concerning the analysis of data, the Controldesk software provided with a D-Space data acquisition board allowed us to collect the flow of data stemming from the sensors [44]. Figure 12(a) shows the static errors revealed along the $\mathbf{x}$-axis. The $\mathbf{y}$-axis corresponds to the transversal axis, while the $\mathbf{z}$-axis corresponds to the

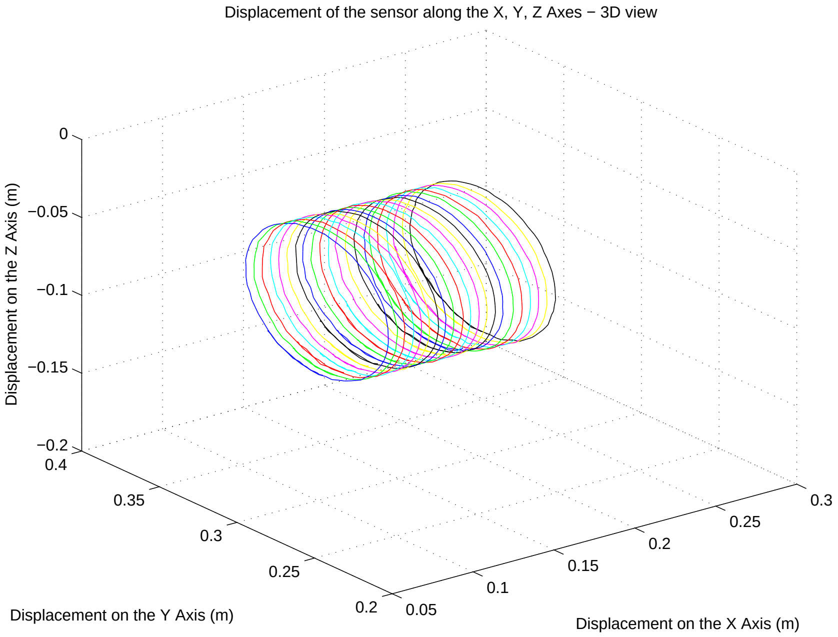
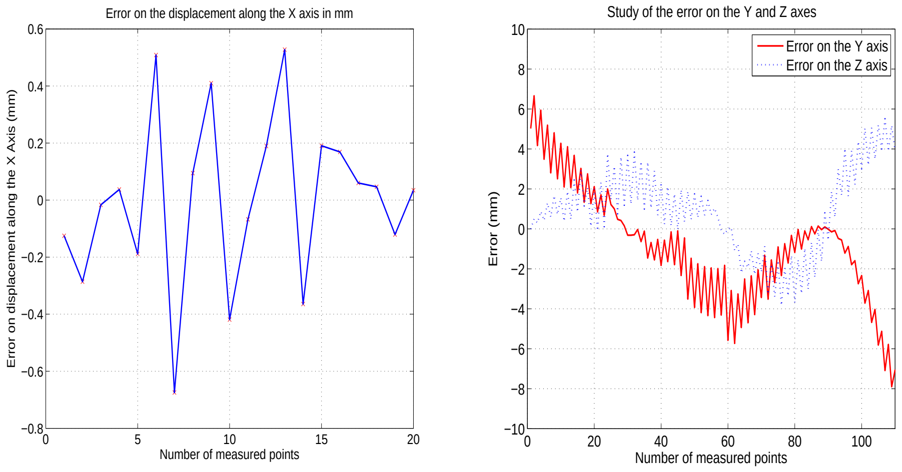


Figure 11: Measurements of the sensor displacement on separated circles of 0.5 cm along the $\mathbf{x}$-axis

vertical axis. To control the errors along the $\mathbf{y}$- and $\mathbf{z}$-axes, the circular paths are compared with perfect circles. This experiment was carried out while the fetal head was in motion. The worst dynamic errors are shown graphically in Figure 12(b). From a medical point of view, the BirthSIM simulator should guarantee accurate positions to within one centimeter; in our case, the maximum error obtained was less than one centimeter, allowing us to conclude that the error is insignificant.



(a) Sensor static errors along the $\mathbf{x}$-axis

(b) Sensor dynamic errors along the $\mathbf{y}$- and $\mathbf{z}$-axes

Figure 12: Sensor errors along the three axes

3.2 Electropneumatic component

The BirthSIM simulator integrates an electropneumatic system, which allows to simulate the dynamics of the childbirth process. This system consists of a servo-valve and a pneumatic cylinder. Pressure sensors are mounted near each chamber of the pneumatic actuator. Different control laws of this system make it possible not only to position the head of the fetus but also to reproduce the different childbirth-related forces. A force sensor is mounted between the fetal head and the extremity of the pneumatic actuator rod to measure the force exerted on the head of the fetus by the operator (Figure 13).

The electro-pneumatic component of the BirthSIM simulator replicates the different forces involved during a childbirth. Ten procedures required by the medical team are proposed and implemented (Figure 14) [45]. They are based on a position feedback control, but also velocity and force tracking controls. The originality of this study comes from the use of simple control laws to simulate different deliveries which allow the operator to learn and to train gradually. The objective is to improve his attitude and his reflexes for the transvaginal diagnosis, when the parturient exerts her abdominal thrust, and when he applies an additional force to expel the fetus with the forceps. During a delivery the involved forces are:

- the resistive force due to the pelvic muscles which tend to prevent the fetus

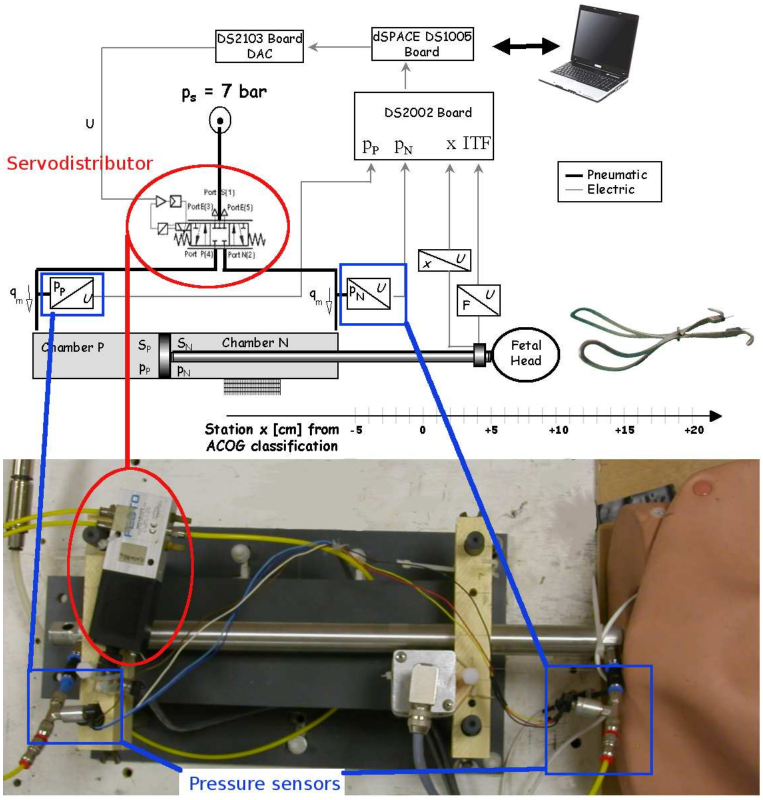
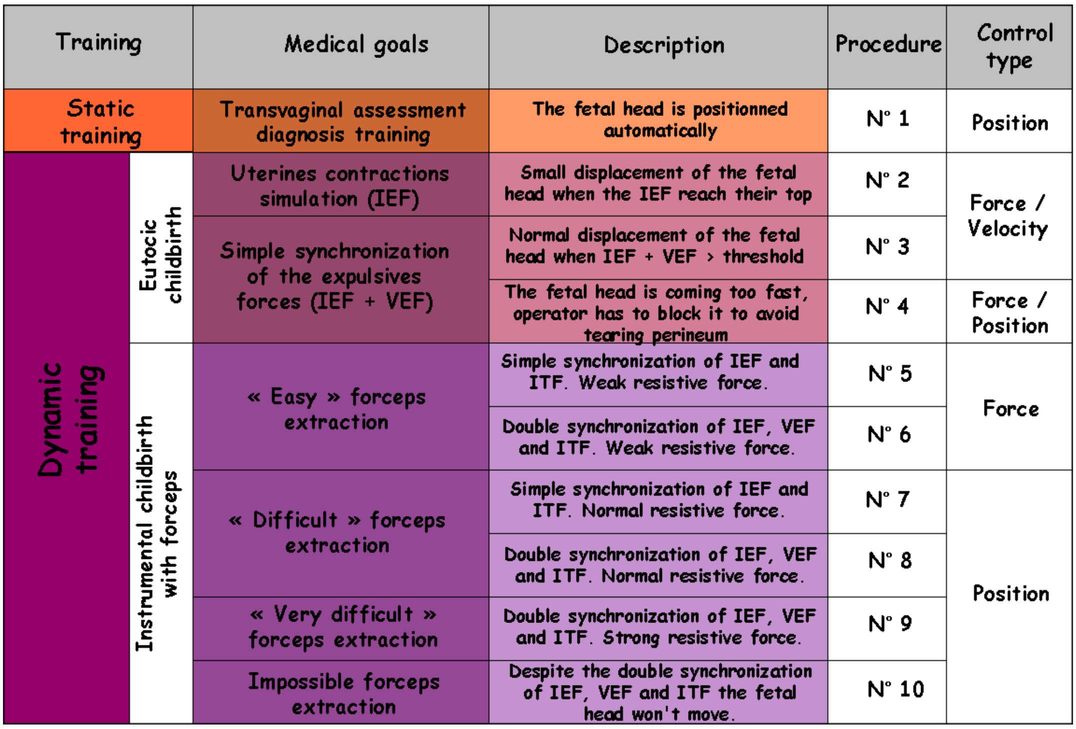


Figure 13: Principle diagram of the electropneumatic component of the BirthSIM simulator

progression inside the pelvic canal;

- the expulsive forces, which come either from :
  - the Uterine Contractions (UC) which are involuntary produced by the parturient at a regular frequency. These UC can be easily identified using a tocography which provides the intra-abdominal pressure variation as a function of time. The UC are the source of an **Involuntary Expulsive Force (IEF)** [46];
  - The abdominal pressure the parturient exerts on her uterus which leads to produce a **Voluntary Expulsive Force (VEF)**. This force is voluntarily produced by the parturient and its aim is to complete the IEF in order to overcome the natural resistive force due to the pelvic muscles.

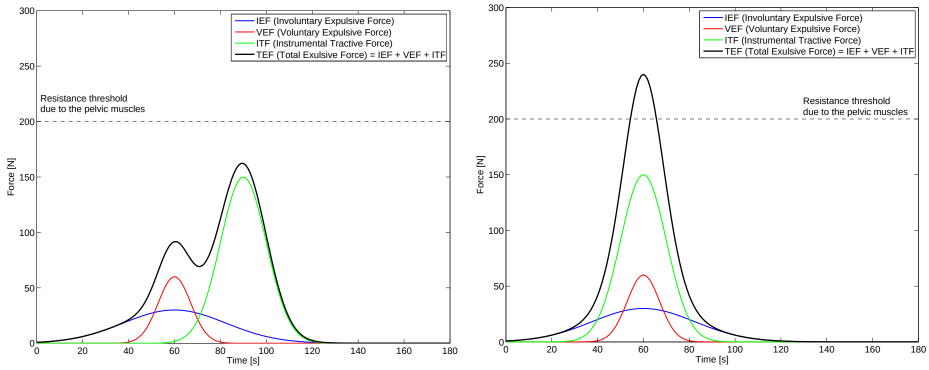


Training		Medical goals	Description	Procedure	Control type
Static training		Transvaginal assessment diagnosis training	The fetal head is positionned automatically	N° 1	Position
Dynamic training	Eutocic childbirth	Uterines contractions simulation (IEF)	Small displacement of the fetal head when the IEF reach their top	N° 2	Force / Velocity
		Simple synchronization of the expulsives forces (IEF + VEF)	Normal displacement of the fetal head when IEF + VEF > threshold	N° 3	
			The fetal head is coming too fast, operator has to block it to avoid tearing perineum	N° 4	Force / Position
	Instrumental childbirth with forceps	« Easy » forceps extraction	Simple synchronization of IEF and ITF. Weak resistive force.	N° 5	Force
			Double synchronization of IEF, VEF and ITF. Weak resistive force.	N° 6	
		« Difficult » forceps extraction	Simple synchronization of IEF and ITF. Normal resistive force.	N° 7	Position
			Double synchronization of IEF, VEF and ITF. Normal resistive force.	N° 8	
		« Very difficult » forceps extraction	Double synchronization of IEF, VEF and ITF. Strong resistive force.	N° 9	
		Impossible forceps extraction	Despite the double synchronization of IEF, VEF and ITF the fetal head won't move.	N° 10	

Figure 14: Available procedures of the simulator

During a childbirth without any complication, the parturient forces (IEF and VEF) are sufficient to expel the fetus. When obstetric instruments are required to extract the fetus, the sum of the expulsive forces, denoted **Total Expulsive Force (TEF)**, has to be superior to the resistive force. This principle leads to the concepts of simple and double synchronization. Its aim is to optimize the TEF to ensure the fetus progression with a minimum ITF in order to obtain an instrumental delivery as close as an eutocic delivery (when obstetric instruments are not necessary). When only two expulsive forces are involved (IEF and VEF or IEF and ITF), we talk about simple synchronization concept. The double synchronization concept appears when the three expulsive forces are involved as it is often the case during instrumental deliveries. Figure 15 shows an example of a simple and an excellent double synchronization. On these figures, the basic tone is considered as null and the resistive force due to pelvic muscles is arbitrary fixed around 200 N. This value can change according to the delivery difficulty.

Because this notion of resistance threshold is very difficult to quantify, only



(a) Simple synchronization of the IEF and the VEF but ITF is applied too late

(b) Excellent synchronization: all expulsive forces are synchronized

Figure 15: Simple and double synchronization concepts

a close collaboration with experienced obstetricians allows obtaining an estimate. Indeed, it depends on the mechanical properties of the uterus and the vagina which define the resistance force exerted by the organs on the fetus. For ethic and practical reasons, the *in vivo* measurements of this force during a childbirth is not possible. Therefore the tuning of the control laws has been thus carried out according to the experience of senior obstetricians so that they best perceive the sensations they are accustomed to feel in delivery ward.

3.3 Visualisation component

Nowadays simulators provided with a 3D visualization system are more and more used in the medical field. Indeed such simulators allow the reproduction of various types of operations in order to train, to teach, to check the knowledge and the know-how, and to try new techniques to validate them. These simulations offer several advantages (training without any risks for the patients, economy of time and money, greater availability of the operating room…). Thus, in order to allow the medical team a greater interactivity with the simulator, two interfaces were developed:

- An interface developed with ControlDesk dSPACE [44] allowing the instructor to choose the procedure to simulate, to set and to visualize the different forces involved during an delivery (Figure 16);
- An interface developed with MotionDesk dSPACE [47] where it is possible to visualize in real time the position of the obstetrical instruments and the

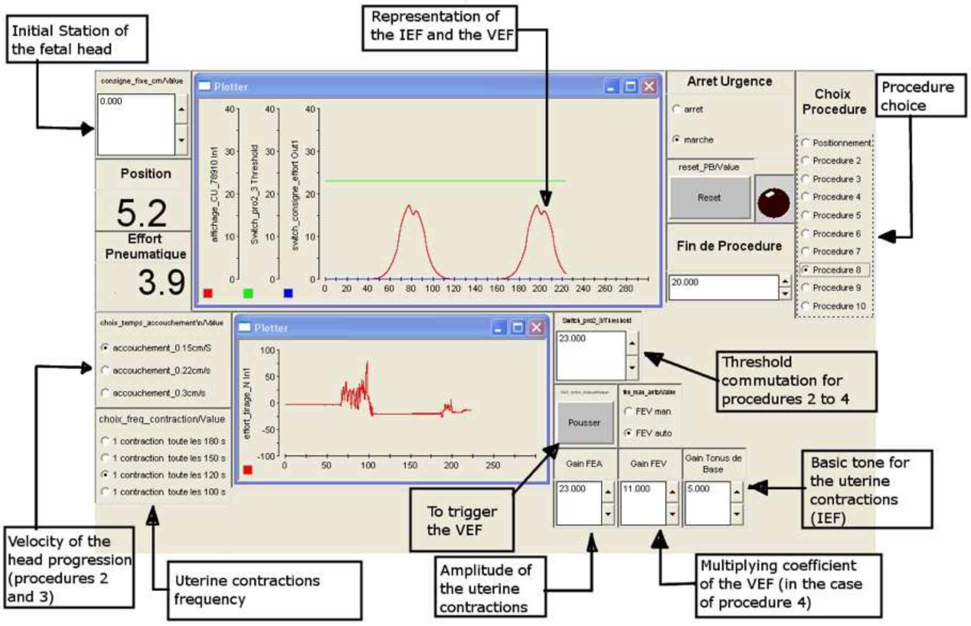


Figure 16: Instructor Interface to choose and set up a simulation

fetal head with respect to the maternal pelvis from several points of view (Figure 17). The BirthSIM simulator provides to operators the possibility to watch inside the maternal pelvis and thus to make visible a ”blind” manipulation. To make this possible, it was necessary to digitize the mechanical component and the forceps blades.

4 Experimental Results

4.1 Forceps Blade Placement Training

Before proceeding to the forceps extraction, operators have to know how to correctly place the forceps. The study presented in this section concerns the measurements recorded with the position sensors during the forceps blade placement. In this section, only the positions and orientations of the forceps blades are studied. The extraction manipulation will be taken into account in the section 4.2.

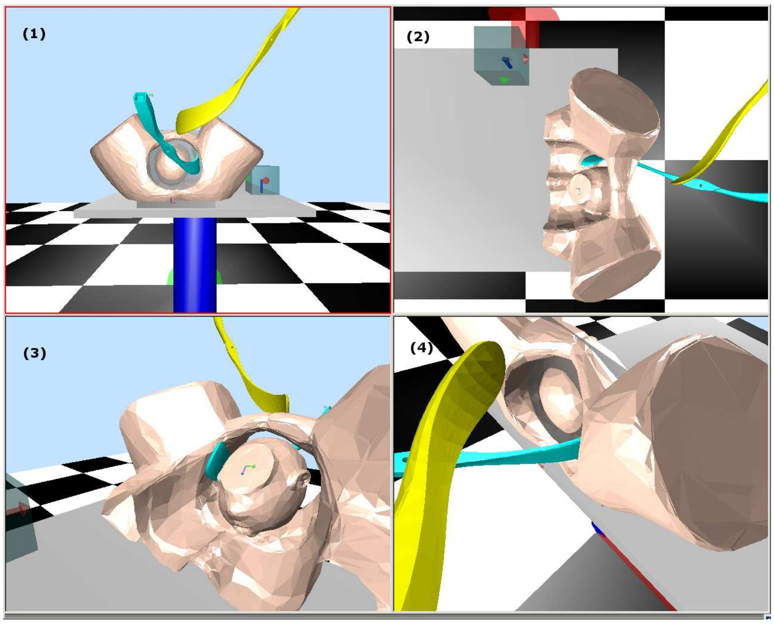


Figure 17: The visual component of the BirthSIM simulator

4.1.1 Experimental Protocol

In collaboration with the Hospices Civils de Lyon (HCL), three junior obstetricians were trained on the BirthSIM simulator. A junior obstetrician is a young obstetrician with less than twelve months of experience in obstetrics. The training on the BirthSIM simulator is supervised by a senior obstetrician who has the role of instructor. A senior obstetrician is defined here as an obstetrician with more than ten years of experience and uses forceps in more than 80% of its instrumented interventions. The presentation is OA+2 according to the ACOG classification [34]. OA means Occipito-Anterior location, forceps have to be placed in a symmetrical way. +2 means that the fetal head is at station +2 (two centimeters from the ischial spines plan), forceps have to be placed deep inside the maternal pelvis. The training lasted three days at the rate of one hour per day. At the beginning of the training junior physicians placed the forceps as they will do in the delivery ward without any advice from the senior physician. Then, during the training, the senior physician explained to them how to correctly place the forceps using the mechanical and the visualization components of the BirthSIM simulator. The manipulations of junior physicians are progressively recorded throughout their training. Finally three forceps recorded placements are carried out at the end of the training day because an operator will have acquired a more secure manipulation at the end of a training day that at the beginning of the following one. Nine placements (three per day) were thus recorded at the end of training. In order to reproduce the reference manipulation, junior physicians can use a visualization interface (Figure 17), where concentric spheres, called ”guide spheres” (Figure 18), with various radii (one, two, and three centimeters) are represented [48]. The centers of these spheres correspond to the coordinates of five particular points regularly laid out along the reference path defined by the senior physician. The training consists in passing through these spheres with the numerical model of the forceps blades. Junior physicians have to place their forceps the closest to the centers of these guided spheres in order to reproduce the reference manipulation. The smaller the crossed sphere is, the closer to the reference the manipulation is. During a learning session, junior physicians can visualize their manipulations off line and have a critical analysis *a posteriori*. They also have the possibility to compare on the visual interface their paths with another trainee or with the reference manipulation.

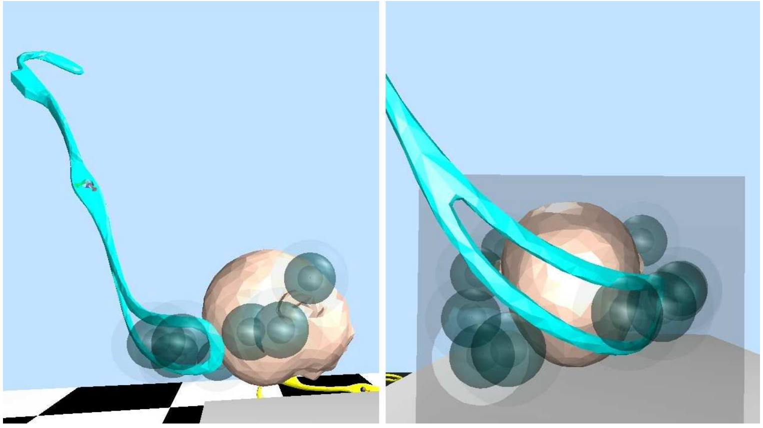


Figure 18: The ”guide spheres” (profile and face view) for the forceps placement training

4.1.2 Analysis Criteria of the Forceps Blade Paths

From an obstetrical point of view, manipulations have to be analyzed according to criteria established by the medical team. These criteria are:

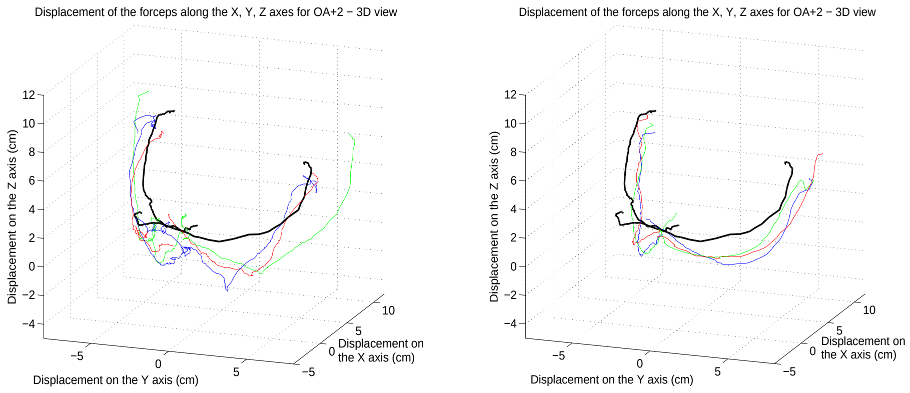
- An independent analysis from the duration of the manipulation. In fact, given the dynamics of the manipulation, the time required to place the forceps blades is not a critical parameter. In an emergency situation, it is necessary to remove as soon as possible the fetus. But a recent study has shown that extraction by forceps is twice faster than a Caesarean section [49]. Furthermore the action to place the forceps is about several tens of seconds, which makes it a relatively short maneuver compared to a surgery act such as a Caesarean section. The duration of the manipulation should not be taken into account in its analysis, the manipulation simply has to be studied in space.

- The manipulation has to be entirely analyzed and not just only according to particular points. Indeed forceps are almost always in contact with the pelvic muscles and the fetal head inside the maternal pelvis. So there is a continuous risk to injure either the woman or the fetus, or both.

Three methods have been developed to analyze the forceps blade placement. The first presented in [5] is used to study the operator repeatability by calculating the distance between specific points from different paths. This analysis provides a time independent study, however, it takes into account only a few specific points. The second method developed takes into account the global manipulation by calculating the error integral compared to a reference manipulation defined by a senior physician [6]. That calculation requires however a normalization of data. This can lead to a modification in data especially when the duration difference is large, which is the case for junior physicians. To completely answer the obstetrician requests, a third method is proposed in [8, 50, 51]. This method evaluates the manipulations by comparing the correlation of their curvatures. To ensure time independence, data are first expressed as a function of the cumulative arc length before proceeding to the curvature calculation. This method can also be applied to the manipulation orientations [52, 53]. In this case, they are first expressed in the quaternion unit space to ensure the time independence [54, 55]. Once position and orientation data are expressed according to their respective cumulative arc length and after being filtered in order to reduce the noise sensor, the manipulation curvature is calculated by a numerical derivation. The curvatures of each manipulation are calculated, then compared to the curvature of the reference manipulation by calculating the Pearson correlation coefficient [56]. The curvature gives also information about how smooth is the manipulation carried out by an operator.

4.1.3 Clinical Results

Figure 19 represents the paths of both forceps blade during their placement. The senior physician paths which are used as a reference are plotted in bold. The paths correspond to the forceps blade placements carried out during the first training day and during the third training day. On these figures, we notice that the paths after the training are more similar to the senior physician ones than before the training, the study of the curvature correlation allows to quantify this similarity. Table 1 presents



(a) Before

(b) After

Figure 19: Junior manipulations before and after the training compared to a reference manipulation (in bold)

the results according to the training day (from 1 to 3). These results are the correlation coefficient of the path curvature compared to the reference manipulation curvature. It corresponds to an average of the three recorded manipulations at the end of the training day (except for the first training day when the first placement allows to know the junior physician skills before training, the recorded manipulations were thus performed at the beginning of the training day). In this table LFB means Left Forceps Blade and RFB Right Forceps Blade.

For the position data, all the correlation coefficients increase to overcome 43% (except for the right forceps blade of junior physician 3 and the left forceps blade for junior physician 4 where their coefficient reached 35%). By comparing the average of junior physician results between their first and their last forceps placements, we can notice that the correlation coefficients increase by 48% for the left forceps blade and 178% for the right forceps blade. Concerning orientations, all the correlation coefficients are higher than their initial values except for the right forceps blade of junior physician 1. The average correlation coefficients of junior physicians have increased about 136% and 41% respectively for the right and left forceps blade between the initial and the final placements.

4.2 Training of the extraction with simulation of the involved forces

Once the forceps placement is correctly acquired by junior physicians, they can proceed to the extraction.

Presentation OA+2		Correlation coefficient %						
		Position				Orientation		
		Training Day 1	Training Day 2	Training Day 3		Training Day 1	Training Day 2	Training Day 3
Junior 1	LFB	33.16	48.93	45.89		22.93	21.18	30.79
	RFB	19.05	51.42	70.49		46.59	26.76	25.87
Junior 2	LFB	33.54	11.29	44.51		4.92	7.88	30.96
	RFB	27.88	25.45	52.95		22.57	46.44	40.43
Junior 3	LFB	17.92	38.23	43.81		22.89	35.58	46.48
	RFB	4.22	48.13	35.98		27.25	33.22	61.04
Junior 4	LFB	29.49	16.66	35.15		8.69	2.66	31.99
	RFB	28.19	26.2	61.37		41.23	10.44	66.35
Junior Average	LFB	**28.53**	28.78	**42.34**		**14.86**	16.83	**35.06**
	RFB	**19.84**	37.80	**55.20**		**34.41**	29.22	**48.42**

Table 1: Evolution of the correlation coefficient during the training

4.2.1 Experimental Protocol for the Extraction Training

Five new junior physicians are trained on the BirthSIM simulator. During these experiments, the forceps blade placement is not evaluated, the instructor can help to place the forceps if necessary. The fetal head presentation is also OA+2 and is considered as extracted from the maternal pelvis when it reached the station +15 which triggers the end of the experiments. During these experiments, the parturient is supposed to be too tired so that her expulsive forces are not sufficient to ensure the fetus progression. An ITF is then necessary to complete the parturient efforts. The ITF has to be applied with a minimal intensity to limit the risks of complications but with a sufficient intensity to allow the fetus progression. To minimize the ITF, the synchronization concept has to be respected (see section 3.2). Operators have the opportunity to watch on a screen the IEF and the VEF of the parturient and they can therefore synchronize their ITF with the parturient forces. The electro-pneumatic system of the BirthSIM simulator is set up to carry out the procedure 8 (”difficult” forceps extraction in Figure 14). The objective of these experiments is to enable junior physicians to be aware of the forces involved and to offer them a risk free training to master the ITF they develop. The training session lasts about an hour during which they proceed to ten extractions. It is thus possible to observe the evolution of their ITF during the training and to determine for each of them if they are able to master their ITF before proceeding to the traditional training in the delivery ward.

4.2.2 Analysis of the Extraction Based on an Evaluation Function

The parameters studied to evaluate the extraction are the ITF provided by the operator (work, maximum intensity, average intensity denoted respectively ITF_{work}, ITF_{max} and ITF_{ave}), the duration required to extract the fetal head denoted D, the total displacement of the head during the extraction denoted $Disp$, and finally the synchronization percentage between the ITF and the maternal expulsive forces (IEF and VEF) denoted P_r. The extraction ensuring the safest delivery is obtained when the values of D, ITF_{max}, ITF_{work}, ITF_{ave} and $Disp$ are minimal and the value of P_r maximal. These evaluation parameters are then normalized between 1 and 10 for the first five parameters (the highest value obtained by junior physicians is assigned to 10 and the lowest value obtained by the senior physicians is assigned to 1). Concerning the parameter P_r, it varies between 0.1 and 1 (0.1 is the lowest synchronization percentage value obtained by the junior physicians and 1 corresponds to the highest synchronization percentage value obtained by the senior physician). Once all the parameters are normalized, an evaluation function E is then defined by [51, 57]:

$$E = \frac{\omega_1}{D} + \frac{\omega_2}{ITF_{\text{max}}} + \frac{\omega_3}{ITF_{\text{work}}} + \frac{\omega_4}{ITF_{\text{ave}}} + \frac{\omega_5}{Disp} + \omega_6 P_r \tag{1}$$

Where the terms ω_i (i from 1 to 6) are the weight coefficients for each parameter. To assign their values, the evaluation parameters were sorted according to their consequences. So, with the medical team, we assign the highest coefficient for the maximum ITF intensity and for the work it applies on the fetal head. Indeed the developed ITF caused major problems for the fetus or the parturient whether in terms of its maximum intensity or its work. The average ITF causes less important consequences, the value assigned to its weight coefficient is thus lower. Then, in decreasing the importance of the consequences, come the total displacement of the head, the synchronization percentage and the manipulation duration. Indeed for these parameters, the operator can watch on a screen the IEF, so it can easily synchronize both forces. Concerning the duration, the time required to extract the fetus is not a determining factor in the context of this experiment. The values assigned to these weight coefficients are:

$$\begin{cases} \omega_1 = \omega_6 = 5 \\ \omega_2 = \omega_3 = 30 \\ \omega_4 = 20 \\ \omega_5 = 10 \end{cases} \tag{2}$$

The sum of these coefficients is equal to 100 which allows to obtain scores between 10 and 100. So, if an operator gets a value close to 100, he carried out an ideal manipulation *i.e.* all the parameter values are close to the minimum values of the senior physician results (except for the synchronization percentage which is a maximum). Note that these values can be modified according to the desired experiment. For example if an emergency procedure has to be simulated, the duration will have a higher coefficient. In our case, the aim is to extract the fetus with a minimal ITF intensity in order to limit the risk for the fetus and the parturient.

4.2.3 Clinical Results

By comparing the first results obtained with those issued from the literature, the ITF intensity is in the range. It is noteworthy that the results from the literature are disperse: the ITF intensity varies from 180 N to 300 N. This dispersion comes from the difficulty to achieve in vivo measurements and the variations of each childbirth. The literature results are issued from [35, 58] where the ITF is measured in vivo by instrumenting forceps with a dynamometer. Fleming [36] and then Kelly [37] confirmed the range of these results by instrumenting forceps with constraint gauges. The results obtained on the simulator are in the range of the in vivo results while offering the opportunity to carry out measurements without risk. These results confirm the realism of the BirthSIM simulator concerning the simulation of the forceps extraction. In the literature, only the ITF intensity has been taken into account, we propose here a more complete study by taking into account several parameters.

Concerning the force involved, it can be studied considering its mean intensity, its maximal intensity and its work (ITF_{ave}, ITF_{max} and ITF_{work}). The following figures show the average results of all novices compared to an expert. On theses figures the extremal values and their average are plotted in a histogram forms. Concerning the expert values, they are represented by the horizontal lines. Figure 20 represents the ITF average values applied by operators while proceeding to the extraction of the fetal head on the BirthSIM simulator. Figure 21 represents the maximal ITF applied and Figure 22 represents the ITF work exerted on the fetal head.

Concerning the ITF maximal values, we notice that novices obtained values slightly beyond the expert values. Novices 1 and 5 managed to master the force they applied *i.e.* they reduce the risks. The other novices may continue to train in order to master more appropriately the force they exerted. For the ITF work, results are also disperse. Most of the novices (except novice 3) have average and minimal values close to the expert ones. However, their lack of experience is translated by a maximal ITF work beyond the expert ones. The same remark is also available for the average ITF. Their average and their maximal values are beyond expert ones. These remarks confirm the fact that novices do not need the same training time and suggest a personalized training. A training adapted to each novice can not be car-

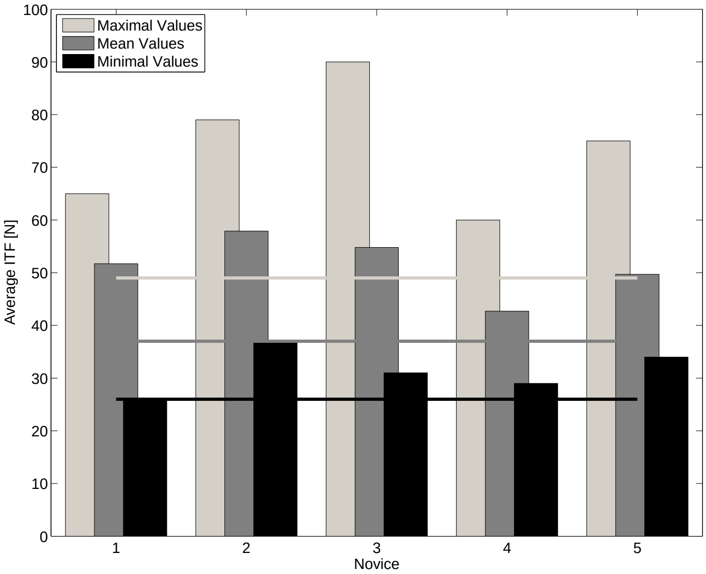


Figure 20: Comparison between expert *vs.* novices concerning the ITF average values. Expert values are represented by the horizontal lines

ried out during classical training, a childbirth simulator has to be used. To take into account all the parameters previously identified, the evaluation function is used. The results stemming from the evaluation function are gathered in Figure 23. The curves represent the evolution of the evaluation function results for the different junior physicians. The two rectangles correspond to the valid zone for the upper one and the non valid zone for the lower one. The frontier between both corresponds to the average of the evaluation function obtained by a senior physician. This figure highlights the dispersion between the junior physicians. Indeed, the junior physicians 1 and 5 manage to obtain results in the valid zone whereas the other junior physicians have all their results in the non valid zone (except the first attempt of the junior physician 4 which result is on the frontier between the two zones). This dispersion means that the junior physicians do not need to spend the same training time to begin to master their ITF and to become aware of the involved forces. This leads to the following conclusion: the training has to be customized according to the trainees. A simulator training allows to easily adapt the training to the trainee whereas the classical training does not offer this opportunity. The evaluation function used here enables to check if the trainee managed to obtain results in the valid zone on several attempts.

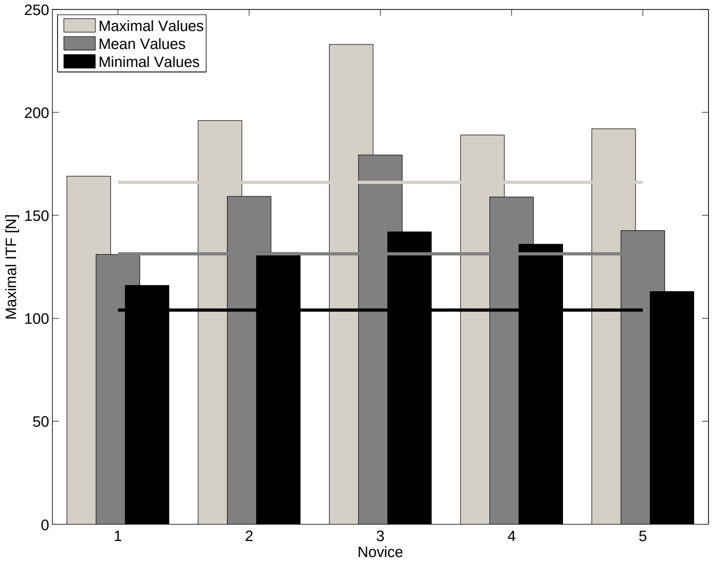


Figure 21: Comparison between expert *vs.* novices concerning the ITF maximal values. Expert values are represented by the horizontal lines

5 Conclusion

Simulation is successfully used in a number of fields, such as aeronautics (flight simulators), meteorology (avalanche simulators), and sports (horse racing and rugby simulators). These simulators are used for training, certification, and continuing education as well as understanding phenomenology. In medicine, simulation has appeared in heart surgery, laparoscopic surgery, and anesthesia and critical care. Recent studies have demonstrated the value of simulation in obstetrics [5, 6, 33, 59, 60], in gynecology [4, 61], in laparoscopic surgery [62, 63], in endoscopic surgery [64, 65], in orthopedic surgery [66] or in otologic surgery [67]. Studies are currently underway to evaluate the value of these new teaching techniques [68, 69, 70, 71]. There are numerous benefits in training by simulation. Simulation benefits:

- The patients: because it reduces the compulsory training time on the patients and reduces complications associated with the learning curve of the junior physicians.
- The junior physicians: because it allows to repeat different situations, to customize the training and confront themselves to exceptional circumstances

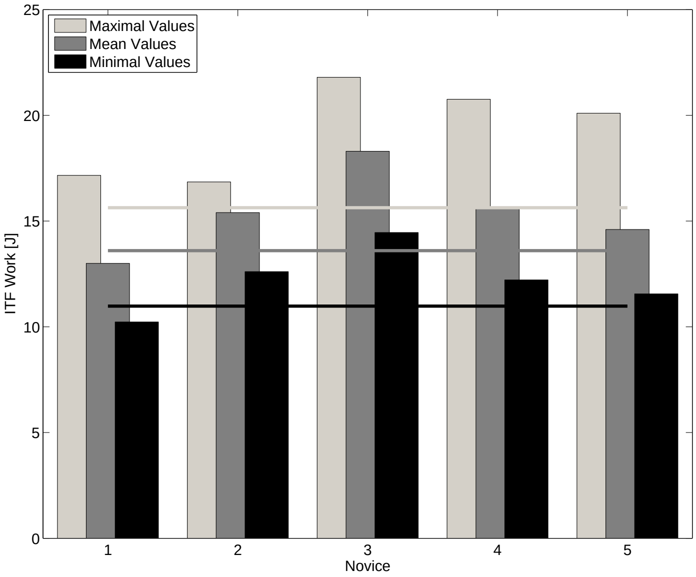


Figure 22: Comparison between expert *vs.* novices concerning the ITF work values. Expert values are represented by the horizontal lines

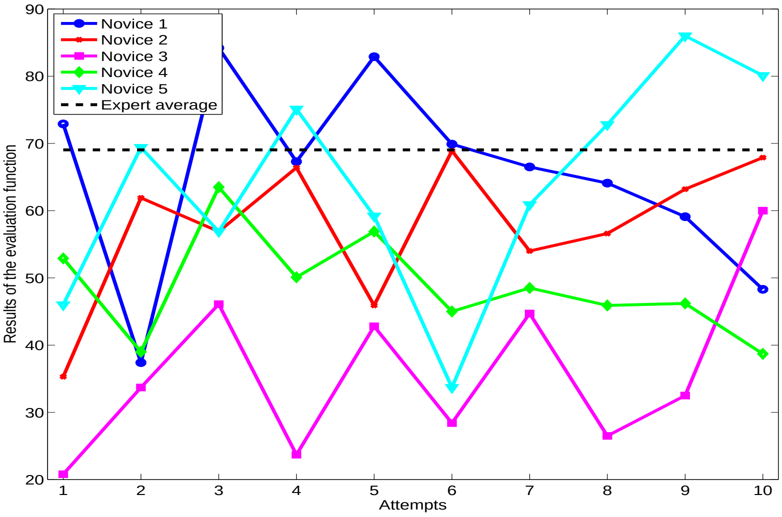


Figure 23: Junior extraction results during their five attempts according to the evaluation function

which can nevertheless lead to tragic consequences when they occur.

- The teacher physicians: because it offers the opportunity to assess students in their abilities and to standardize the training.
- The researchers: because it allows them to experiment and compare new tools and techniques before validating them *in vivo*.
- Finally the society: because it leads to a financial gain by reducing the training time of physicians.

We have shown in this paper that currently available obstetric simulators make it possible to train obstetrics residents in numerous procedures, including episiotomy suturing, total perineal repair, instrument-assisted delivery, and breech delivery. Several teams have demonstrated the superior skills of residents trained with simulators. Simulators also give experienced practitioners exposure to rare and serious complications that occur in obstetrics practice, such as amniotic embolism and severe bleeding during delivery. Training using simulation also makes it possible to avoid exposing pregnant women to the hazards of traditional training and offers obstetrician gynecologists an ethical alternative with respect to training. Simulation not only allows the training of practitioners, but, in the future, could also allow them to demonstrate their skills, when appropriate. In the near future, the falling prices of computer materials should favor the wider distribution of these learning methods and increase biomechanical research possible, bringing significant benefits to pregnant women and their newborns.

Finally, this paper presents an overview of the different features available on the childbirth simulator, BirthSIM, as well as clinical results during the training of junior physicians. The training is divided into two steps. The first step is to allow junior physicians to train in placing correctly the forceps. Experimental results have clearly shown that junior physicians are able to improve their manipulations by becoming increasingly similar to those of a senior physician. The second step of the training focuses on the extraction manipulation. By instrumenting the head with a force sensor it has been possible to record the force exerted by the junior physician. In order to take into account the different criteria to analyze the extraction manipulation, an evaluation function is used. It allows to calculate a performance score to evaluate the performed manipulations and therefore to quantify the junior physician skills and ability. With a simulator training, junior physicians become aware of the force intensity involved during an instrumental delivery and can try to master their ITF without any risk. The BirthSIM simulator is a tool to train junior obstetricians by offering them the opportunity to overcome the constraints related to the traditional training. The proposed training allows junior obstetricians to carry out obstetric manipulations with no time limit and no risk to acquire a first experience. These first results are encouraging but have to be completed with more junior physicians to obtain more representative results. A prototype of the simulator has been installed at a hospital (Centre Hospitalier Universitaire Lyon Sud) since July 2007.

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