Placenta Extraction Model

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Abstract

The placenta is an important organ that is used to transfer nutrients between mother and fetus during pregnancy. Once the baby is delivered, the placenta is no longer needed. If the placenta does not detach from the uterus (in 3% of cases), the physician must use his or her hand to break the placenta-uterine connection and manually deliver the placenta. There are many different birthing models and simulators currently on the market that can be used to train medical professionals. However, their high costs are disadvantageous for developing countries, where the highest maternal death rates from postpartum hemorrhage occur. In addition to the high cost, these simulators do not accurately represent the uterus and placenta for the manual extraction procedure, such as using Velcro for attachment and hard plastic parts for the placenta. Therefore, our client has proposed that we create an inexpensive add-in placenta extraction simulation that can be integrated into the model currently being used in his training program.

In order to create a realistic placenta and uterus model, the team came to the conclusion that silicone was the only material that could accurately represent the necessary physical characteristics. With client feedback, the team has chosen silicone materials for each part of the design. In addition, a preliminary design was determined utilizing magnetic field sensors and embedded magnets. This will allow the user to have little interference with the attachment mechanism, providing the most realistic experience, as well as provide quantitative data that can be used as a feedback mechanism for the user and observers. Future work includes fabrication the uterus and placenta, integrating the magnet field sensors, and developing a user-interface to display the information gathered by the magnetic field sensors.

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Introduction

Client Description

Dr. Lee Dresang is a Professor of Family Medicine at UW-Madison school of Medicine and Public Health and practices at St. Mary's Hospital. He is a former board chair and current member of Advanced Life Support in Obstetrics (ALSO). This program was developed by The American Academy of Family Physicians (AAFP) and provides physicians, midwives, and other healthcare providers with courses in perinatal care in over 47 countries around the world [1]. These courses use models in order to simulate emergencies during fetal delivery. However, the models that are readily available and affordable do not incorporate the manual extraction of a retained placenta—one of the leading causes of postpartum hemorrhage and maternal death. Our client has proposed that we develop an inexpensive add-in to supplement this portion of the training course.

Placenta

The placenta is a flat pancake-shaped organ that connects to the fetus by the umbilical cord and attaches to the inner surface of the uterus (usually the top or the sides) during pregnancy (Figure 1) [2]. It serves as an exchange site, allowing nutrients, oxygen, and waste to transfer between mother and baby without the two blood supplies mixing [4]. Once the baby is delivered, the placenta no longer serves any purpose and it too must be expelled from the uterus. The mother will continue to feel small contractions throughout the third stage of labor, which slowly shear the placenta from the endometrium of the uterine wall. As the surface area of the uterus shrinks with each contraction, the placenta attachment weakens. These contractions will continue

Figure 1: The placenta attaches to the inner layer of the uterus and allows the exchange of nutrients and waste between mother and fetus [3].

until the placenta completely detaches and falls into the lower uterine segment, and finally is expelled from the body. This normally occurs within 30-60 minutes after the delivery of the baby [5].

Retained Placenta

Although the third stage of labor is usually uneventful, there are some hazards that can lead to maternal mortality. If the placenta is not expelled naturally within one hour of delivery, the patient is said to have a retained placenta and high risk. The biggest risk to a patient's safety is postpartum hemorrhage (PPH) due to a retained placenta, which occurs in about 3% of vaginal deliveries and has up to a 10% fatality rate. There are three main types of retained placentas: placenta adherens (failed contraction of the myometrium behind the uterus), trapped placenta (the placenta detaches but it trapped due to a closed cervix), and placenta accreta (the placenta grows into the myometrium during pregnancy and cannot detach). In all these cases, it is best to remove the placenta in order to minimize the risk of postpartum hemorrhage, which often leads to a hysterectomy [6]. Depending on the severity, a caesarian section may be needed, but most commonly, the placenta can be removed manually.

In order to manually remove the placenta, the doctor follows the umbilical cord through the vagina and into the uterus. Once inside, the doctor uses their hand to find the placenta-uterine interface and, using a side-to-side motion with their fingers, detaches the placenta from the uterus. This slowly separates the placenta away from the uterus and allows the doctor to grab the organ and remove it from the uterine cavity through the vagina [6].

Competing Devices

There are currently many different birthing simulators on the market. They range in complexity from simple anatomical models to full computer-operated simulation systems. The most well-known and advanced system is the NOELLE®S575, which has a dilating cervix, blood pressure, multiple heart sounds, convulsions and tremors, drug recognition system, ECG monitor, virtual oxygen saturation, fetal force/torque/positioning graphed in real time,

Figure 2: Noelle Neonatal Simulation System [7].

intubatable airway and IV arm, postpartum hemorrhage/fundal massage, programmable scenarios, and much more (Figure 2) [7]. These simulators can cost upwards of $4,000, an expense most training program budgets cannot afford, especially in developing countries where material mortality is the highest. In addition, these simulators lack in realism when concerning a retained placenta procedure. They use Velcro strips in order to attach the placenta onto the inside of a hard silicone interior. For a procedure that is performed completely on feel, this is an unacceptable learning method. Our team sets to design an inexpensive, realistic model that can be used to train doctors in developing countries on manual extractions.

Design Overview

Design Criteria

In order to design a model that satisfies the requirements of the client, several design criteria is used to guide the team. First, the model should be low in cost to prevent unnecessarily increasing the cost of the birthing simulator. Second, the model should incorporate a uterus and a placenta that simulates to a retained placenta. Since this model will be used for practicing manual extraction of retained placenta, the physical sensation of extracting the placenta model should be as realistic as possible in order to give the students the best hands-on experience. Third, the model should be compatible with the current birthing simulator that is widely used in physician training programs around the globe. Although there are many versions of birthing simulators available, the basic body cavity of most simulators is similar. Therefore, the design of the retained placenta model should be flexible so it can be integrated into many different simulators. The model should not only imitate the anatomical properties of uterus and placenta, but it should also be appropriate to be used for manual extraction training programs.

Design Considerations

The major considerations regarding this design can be divided into three categories: the materials used for the uterus and the placenta, the mechanism that affixes the placenta to the simulated uterine wall, and the feedback mechanism integrated into the design.

Materials

Preliminary research into other types of birthing simulations was performed to identify materials used in other simulators. Most birthing simulators are latex-free and are typically made of hard plastics. However, hard plastic does not adequately simulate the pliable and vascularized nature of the placenta or the muscular uterine wall. Several silicone samples with varying degrees of hardness and texture were obtained and our client, along with several of his colleagues, determined which silicone was the most appropriate for the uterine wall and the placenta.

Attachment Mechanism

As the placenta extraction procedure is performed entirely by feel, the mechanism that attaches the placenta to the uterine wall is of great importance for this simulation. Additionally, the placenta does not always attach in the same position during pregnancy; it can be attached to the uterine wall at any point inside the uterus. Therefore, the attachment mechanism used must be realistic feeling and must be fabricated so that the instructor can place the placenta in any configuration within the uterus. Four preliminary attachment mechanisms were discussed: Velcro, magnets, snaps, and suction cups. In the case of Velcro, magnets, or snaps, attachment pieces would be affixed to both the uterus and the placenta. Suction cups would have attachment pieces that would only be affixed to the placenta or only to the uterus.

Each attachment mechanism was evaluated (Table 1). The mechanisms were evaluated based on durability, how accurately it represented the actual attachment between the uterus and the placenta, how costly the mechanism was, how easy the mechanism was for instructors to use, and how easy it would be to manufacture. Each mechanism was given a score out of 10 in each category and then weighted in order to give a score out of 100 points.

Table 1: Design Matrix for the attachment mechanism.

Criteria	Weight	Velcro	Snaps	Magnets	Suction Cups
Durability	**3.5**	6	9	7	5
Accuracy	**2.5**	6	3	10	3
Cost	**2**	9	5	3	7
Ease of use	**1.5**	7	5	8	4
Ease of manufacturing	**0.5**	6	3	8	3
Total (out of 100)	**10**	**67.5**	**58**	**71.5**	**46.5**

Snaps received the highest score in the Durability category because they are made of metal and once embedded will be difficult to remove from the silicone placenta and uterus. Magnets received the second highest score because misaligned magnets may cause the silicone to wear faster than expected or cause the magnets to come out of the silicone. Magnets were the only attachment mechanism that could be completely embedded within the silicone, and therefore, received a perfect 10 in the Accuracy category. Every other attachment mechanism received a relatively low score in that category because the student would be able to feel the attachment mechanism throughout the uterus and on the placenta. Velcro and suction cups were the least costly option, and Velcro and magnets were the easiest designs to use. Magnets received the highest score for Ease of manufacturing because they can be embedded directly in the silicone; all other design options would be partially embedded in the silicone or affixed after.

As magnets scored the highest of all the designs, we determined magnets would be used as an attachment mechanism. Further investigation revealed that neodymium magnets are frequently embedded into silicone prostheses, as neodymium magnets are very strong—even at small sizes. Magnets embedded in a grid like fashion one inch apart throughout the uterus and on one side of the placenta would allow for the easy positioning of the placenta at any point in the uterus.

Feedback Mechanism

Feedback is important during this simulation for several reasons. Feedback that monitored the placenta position during the procedure would allow students to gain more detailed knowledge about how the procedure is performed. Additionally, in the cases that multiple students are being trained on one model, a visual feedback system keeps all of the students engaged during the procedure. Four general feedback mechanisms were initially discussed: magnetic field sensors, force sensors, a camera, and a transparent uterus.

Magnetic field sensors would be placed in a grid like fashion between the magnets embedded in the uterus; one sensor would correspond to four separate magnets. If embedded into the silicone, the magnetic field sensors would not be felt during the simulation. The sensors would monitor the changing magnetic fields due to the motion of the placenta and an algorithm could be designed to monitor where the placenta is at all times. Force sensors would be also be embedded in the uterus, but each force sensor would be placed over a magnet. When the placenta is attached to the uterus, the force sensors can provide feedback about the location of the placenta. The sensors would monitor the drop in force that occurs between each pair of magnets when the placenta is removed from the uterine wall. In both sensor cases, the sensing input would be used to design a graphical output to monitor the placenta location at all times.

A camera could be positioned such that it could see inside the uterus. Several lights embedded into the silicone uterine wall would light the inside of the uterus for the camera. The camera's display could be shown on any screen. The transparent uterus model is the least technical model. In this design alternative, the uterus would be fabricated of a transparent silicone instead of an opaque silicone so students and instructors could look inside of the simulator as the procedure is performed

Each of the four design alternatives was evaluated (Table 2). Each was evaluated on the basis of how quantitative of feedback the alternative could provide, the total cost, how easy the feedback was to use, how much power the feedback mechanism consumed, and how easy the feedback system was to implement. Each alternative received a score out of 10 in each category. Those scores were then weighted by a factor to give a total score out of 100.

Table 2: Design matrix for the feedback mechanism.

Criteria	Weight	Magnetic Field Sensor	Force Sensor	Camera	Transparent Uterus
Quantitative Feedback	**4**	8	6	2	0
Cost	**2.5**	3	1	5	10
Ease of use	**2**	4	4	7	10
Power Consumption	**1**	5	2	6	10
Ease of implementation	**0.5**	4	4	6	8
Total (out of 100)	**10**	**52.5**	**38.5**	**43.5**	**59**

Magnetic field sensors and force sensors were determined to provide more quantitative feedback than both the camera and transparent uterus design options. However, as magnetic field sensors and force sensors require many sensors, both received low scores in the cost section. The transparent uterus, followed by the camera, is the easiest to use and repair. The transparent uterus uses no power, and so received a perfect score of 10, while the number of force sensors required for the simulation led to the force sensor receiving a very low score in the power consumption category. It was determined the transparent uterus, followed by the camera, would be the easiest design to implement.

The transparent uterus design was the overall winner, but it is lacking in one significant factor: the transparent uterus design provides no quantitative feedback to the user. Therefore, it was decided that both the highest and second highest scoring options would be implemented into the simulation design. Magnetic field sensors will provide the quantitative feedback required and a transparent uterus will allow students and instructors to easily visualize and give feedback on the procedure.

Preliminary Design

The preliminary design is composed of a silicone placenta and uterus. The silicone materials were chosen by the client and several of his colleagues based on which silicone sample was most realistic feeling. For the attachment mechanism, magnets would be embedded into one side of the placenta and uterus in a complementary pattern, of approximately 1 square inch per magnet. The magnetic field sensors would be positioned between every four magnets. Images of the placenta and uterus with the magnets and sensors are shown in Figures 3 and 4.

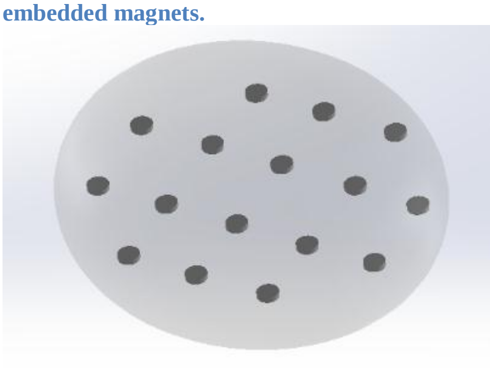

Figure 3: SolidWorks of the placenta with embedded magnets.

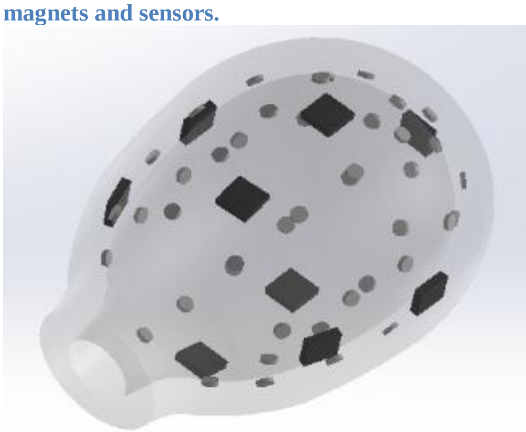

Figure 4: SolidWorks of the uterus with embedded magnets and sensors.

Ergonomics

The International Ergonomics Association has defined ergonomics as "the understanding of interactions among humans and other elements of the system in order to optimize human well-being and overall system performance" [8]. Since there is direct human interaction with this model, ergonomics may seem to be a concern that needs to be addressed. However, the purpose of this model is to replicate the human body and thus, the primary concern is not to design the model for optimized use, but to be as realistic as possible. The feedback program, on the other hand, would need to have an easy to use graphical user interface.

Ethical Considerations

The main ethical consideration for this project is that no harm comes to the users during the duration of the manual extraction. All testing and data collection would be performed with prior IRB approval.

Future Work

First, molds for the placenta and uterus would be constructed to create the silicone models. Before integration of the magnets and sensors into the model, testing would occur to determine if the number of magnets and sensors would be sufficient for successful attachment and feedback mechanisms. Next, a program would be created to provide feedback of the placenta location and manual extraction for use during teaching. Once the entire model is complete, the device would be tested with physicians and students, and data would be obtained of students performing the manual extraction with the device. The data would be compared to students performing the extraction without prior practice with the device to determine success of the model. If the device is successful, the team may pursue a patent since no other device of its kind exists in the current market.

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Appendix: Project Design Specifications

Placenta Extraction Model
Project Design Specifications
10/23/2012

Group Members: Henry Hu, Katherine Lake, Clara Chow, Ashley Mulchrone
Advisor: Professor Thomas Yen
Clients: Dr. Lee Dresang, UW Department of Family Medicine

Problem Statement: Our team has been tasked by Dr. Lee Dresang of St. Mary's Hospital to create a teaching model for the manual removal of the placenta. During a normal birth, the placenta is delivered within 15 minutes after the baby is delivered. If the placenta is not delivered, it must be removed manually. Since this occurs rarely, many general practitioners and doctors in rural areas are not experienced in manual placenta removal, which puts patients at risk during the procedure. Dr. Dresang currently has simulation aids used to teach birthing procedures, but none of the models incorporate a placenta that must be manually extracted. We propose to create a molded silicone model of the placenta and then develop a method to attach the placenta model to the current birthing simulation.

Client Requirements:
- A prototype shall be designed and manufactured.
- The system shall be reusable.
- This system shall be a better teaching tool than current methods.
- The model shall incorporate multiple scenarios for placenta delivery.

1. Physical and Operational Characteristics

A. **Performance requirements**: The model shall simulate a manual extraction of a retained placenta and educate the user about the procedure. It shall simulate scenarios of varying placenta locations and conditions.
B. **Safety**: The prototype must not be harmful to the user or model.
C. **Accuracy and Reliability**: TBD
D. **Life in Service**: The model must last for the duration of the current model, approximately 50 uses.
E. **Operating Environment**: The model shall be versatile and used in a hospital, conference setting, or outdoors.
F. **Ergonomics**: There are no ergonomic concerns relating to the prototype.
G. **Size**: The placenta model shall be the average size and shape to a real placenta and must be compatible with the current pelvic model.
H. **Weight**: The placenta model shall be of similar weight to a real placenta. The overall prototype shall be as lightweight as possible to ensure easy transport.
I. **Materials**: The material used must not harm the existing pelvic model or the user and be of similar texture to reality.
J. **Aesthetics, Appearance, and Finish**: The model shall have realistic coloring and texture to reality.

2. Production Characteristics

A. **Quantity**: One prototype shall be produced.
B. **Target Product Cost**: The budget for this semester is $150.

3. Miscellaneous

A. **Standards and Specifications**: The final product will require the approval of the Food and Drug Administration and clinical trials. The prototype is a proof of concept, and therefore will not require government approval.
B. **Customer**: The intended user is a medical professional or researcher who will utilize Digital Beam Attenuation to improve CT image quality during a medical procedure or for diagnostic purposes.
C. **Patient-related Concerns**: As our design may eventually be commercially available for medical professional use, it should follow all restrictions enforced by the Food and Drug Administration. It must not cause any harm to its user.
D. **Competition**: Most pelvic models include a placenta, but does not incorporate its manual extraction.