Placenta Extraction Model

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Team

Clara Chow – Communicator

Katherine Lake – BWIG

Ashley Mulchrone – BSAC

Henry Hu – Leader

Client

Dr. Lee Dresang

Family Medicine, St. Mary's Hospital

Advisor

Dr. Thomas Yen

Associate Instrumentation Innovator-Instructor

Biomedical Engineering

Abstract

The placenta is an organ 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, they have high costs and do not realistically represent the physiology of the body. Thus, our team has designed a silicone uterus and placenta model that is compatible with the current simulator model used in our client's training program. The final design will consist of: the placenta and uterus embedded with neodymium magnets for attachment at various locations, A1302 hall effect sensors embedded in the uterus in a grid-like manner for detection of the placenta, and visual feedback showing a color map of the placenta to indicate its attachment to the uterus.

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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
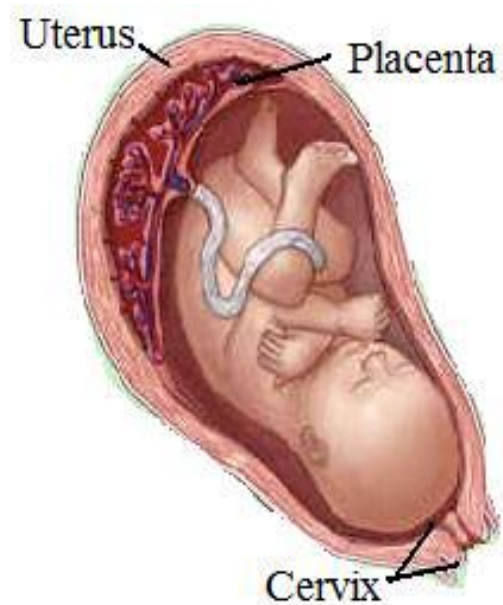

Figure 1: The placenta attaches to the inner layer of the uterus and allows the exchange of nutrients and waste between mother and fetus [3].

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 is at 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 of 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,

Figure 2: Noelle Neonatal Simulation System [7].

fetal force/torque/positioning graphed in real time, 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 on manual extractions.

Design Overview

Design Criteria

In order to design a model that satisfies the requirements of the client, several design criteria were 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 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 the 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,

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

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.

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 the 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 thus, 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 that 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.

Silicone Molding

Once it was decided that silicone would be used to make the placenta and uterus, the team sought out the expertise of silicone molding expert Greg Gion. We discussed the characteristics we wished for our model—elastic materials that are easily deformed and compressed. He provided us with a handful of samples that we offered to our client and his colleagues to test. Since the uterus wall is stiffer than the placenta, the doctors decided that multiple silicones would be needed in order to portray the different characteristics of the uterine wall and placenta. Our team concluded that Ecoflex-0030 and DragonSkin F/X PRO best represented these properties. Along with these silicones, additional materials were required. A third silicone (A-564) to cover the magnets, Platinum Silicone Additive "Slacker" to lower the Young's Modulus of the silicones, and TinThix thixotropic agent to remove the self-leveling property.

Embedding Magnets

As discussed previously, magnets were determined to be the best attachment mechanism because they can be embedded into the silicone and provide a seamless transition between the placenta and the uterus. It was determined that they would be placed in a 1 inch x 1 inch arrangement along both the uterine wall and the placenta with the sensor being oriented in the middle of each set of

Figure 3: Four magnets (in the 1 inch x 1 inch arrangement) adhered to power mesh using silicone A-564.

four magnets. In order to provide accuracy in magnet placement, the magnets were adhered to squares of power mesh using the A-564 silicone, which also provided extra security to insure the magnets do not rip through the silicone (Figure 3). These sheets could then be placed in/on the model instead of applying every magnet individually, which proved to be extremely valuable during molding. When working with the stronger magnets (above 1 lb. pull force), it was discovered that the 1 inch x 1 inch configuration was almost impossible. As soon as they were brought close together, the magnets instantly attracted. The team was able to overcome this by placing a strong metal strip under the power mesh to keep the magnets in place during curing. Once the silicone completely cured, the metal could be removed and the magnets were fixed in place.

Uterus Model

In order to test the properties of the Ecoflex and DragonSkin, a small uterus model was constructed of clay. This model represents the open space in the uterus, allowing silicone to be applied on its outer surface. Once dried, the silicone can be peeled away leaving the uterus lining. Because Ecoflex and DragonSkin are liquid rubbers composed of two parts (they do not cure until part A and part B are mixed in equal proportions), a few drops of the thixotropic agent TinThix was added to each mix. This thickened the silicone and allowed us to be able to "paint" the silicone on the surface of the clay. Without it, the silicone would simply drip off the sides.

Three different samples were made using TinThix, different proportions of the purchased silicones, and Slacker. These models comprised of a single layer of silicone. For future models, additional layers will be added to each dry layer until the desired thickness is reached.
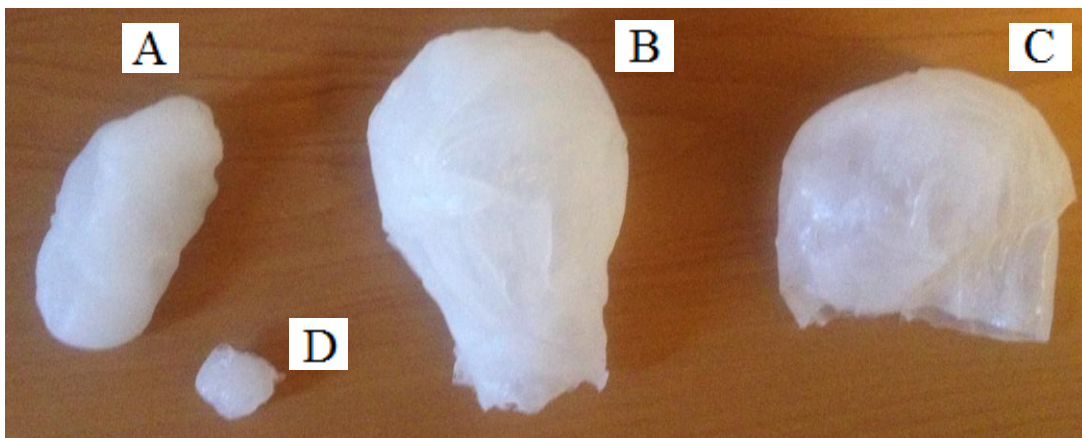

Figure 4: Three small-scale uterus models composed of different silicone mixtures. A) Dragon Skin and Slacker in 1:1 ratio with two drops of TinThix. B) Dragon Skin with two drops of TinThix. C) Ecoflex with two drops of TinThix. D) A section of part A with a thin coating of A-564.

The first small-scaled uterus was made using DragonSkin and Slacker in a 1:1 ratio, the second using DragonSkin but no Slacker, and the last using Ecoflex (Figure 4). From these models, we could easily see the different characteristics each silicone offered. The DragonSkin resulted in a thick, sturdy membrane that retained the original shape of the clay mold. It exhibited some elastic flexibility, but still provided excellent structural support (part B). On the other hand, the Ecoflex resulted in a thinner, more flexible membrane. This model was much more pliable and did not retain its shape as well as the DragonSkin; it was also much easier to break through (part C). Lastly, the added Slacker resulted in a uterus that did not retain its shape at all (part A). Instead, it was so tacky that it stuck to itself and turned into a clump. This closely modeled the properties of the placenta; however, it was much too sticky and would need to be incased in another type of silicone (part D). In this case, a small piece was covered in a thin layer of A-564, which successfully removed the sticky surface while maintaining its malleability.

These models showed that the DragonSkin would be the best choice for the uterus because of its structural stability. However, due to its stiffness, a few layers of Slacker will be applied in the middle to provide additional flexibility to the overall structure. After determining the desired silicone recipe, the team then constructed a life-sized uterus model similar to the small-scaled one used previously. Since this needed to be significantly larger than before, a combination of other materials was used in addition to the clay. First, two floral foam pieces were adhered using toothpicks and carved to create the uterus shape. These foam pieces were then covered in tin foil to avoid flaking and provide a surface that the final clay layer could stick to (Figure 5).

Figure 5: Life-sized uterus mold from floral foam covered in tin foil and clay.

In addition to the magnets, magnetic field sensors were also incorporated into the uterus. The team decided that in order to make the model as reusable as possible, the sensors must be located on the outside of the uterus and not embedded into the actual surface. Then, if one of the sensors happened to malfunction, the whole model would not become useless. However, magnetic field sensors are extremely sensitive to changes in distance and must be placed as close to the placenta as possible. After the first couple layers of silicone are added when the uterus is being molded, small rectangular pieces of clay will be added to the center of each magnet quartet

(this can be done by placing a thin needle through both the clay piece and the uterus model). Silicone will then be added as normal, surrounding the clay pieces, until the desired thickness is reached. From here, the clay piece can be removed leaving a small cavity that reaches all the way to the inside layers of the uterus.

The sensor can then be placed within the uterine wall and secured by placing a small piece of silicone on top. This way, the sensor can be placed within the uterine wall without being molded into the final product allowing for easy access and part replacement if necessary. A small 1-inch thick sample was made to illustrate this mechanism (Figure 6).
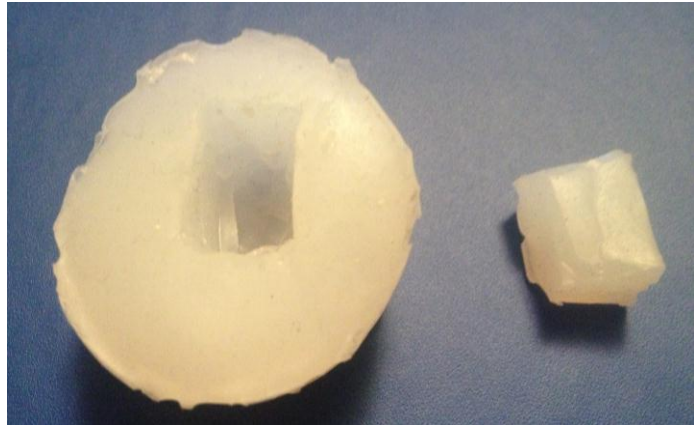

Figure 6: The mechanism that will be used to place the sensors within the uterine wall.

The team then used the previously mentioned methods to make the upper $1/4^{th}$ of the life-sized uterus model. Two layers of the DragonSkin were applied before adding the three different magnet squares with the magnet side facing up and the power mesh side facing the model. This orientation was decided for multiple reasons. First, the magnets are accessible to the placenta magnets without the extra silicone on the other side being in the way. This will create larger attraction forces and result in a better attachment. Secondly, it will keep the magnets in place and make sure they cannot tear through the silicone. For future testing purposes, three different magnet strengths were used: 0.56 lb., 1.19 lb., and 2.05 lbs. This was later used in order to determine the best placenta/uterus magnet combination to provide the most realistic feel as well as insure the placenta can hold itself up on the uterus wall.

A couple additional layers were added before the rectangular pieces were added in the centers of the magnet sheets. In order to conserve some of the silicone, the model was not made to its full thickness. Instead, only a handful of additional layers were added focusing around the clay pieces. This created the cavities that we desired for the sensors without wasting extra silicone. In summary, the final repetitive model was composed with

Figure 7: The upper ¼ of the uterus with embedded magnets and open slots to house the sensors.

three separate square inch sections with varying magnet strengths, each with a centered cavity that can house a magnetic field sensor (Figure 7).

Placenta Model

As described earlier, adding the Slacker causes the silicone to have a lower Young's Modulus, and become tackier. There were no major differences seen when the Slacker was added to the DragonSkin or Ecoflex. Both resulted in a tacky, easily deformable piece of silicone that gradually regained its original shape once the pressure was removed—a property consistent with the characteristics of the placenta. The Ecoflex had slightly less spring to it, so its use was decided for the placenta model.

Similar to the uterus model, the placenta needs to contain the square inch orientation of magnets, keeping polarity in mind, so that they line up correctly with the uterus magnets. They also must contain a fifth magnet in the center. This magnet will align with each of the sensors in the uterus. To insure that the placenta assumes the correct orientation, this magnet was placed with the opposite polarity of the placement magnets facing the uterus. This magnet will then repel all the magnets lining the uterine wall, and make sure it aligns correctly with the sensor instead.

In order to conserve silicone, two small-scaled placenta models were made using two different magnet strengths, 0.56 lb., and 1.19 lb., along with a thicker sensor magnet in the middle. Each square was then placed magnet side up in a clay mold in roughly the shape of an oval (Figure 8). The molds were then filled using the Ecoflex/Slacker combination and allowed to dry for an hour (no ThinThix was necessary, which allowed the silicone to self-level). The clay was then peeled away. Since the Slacker results in a tacky product, a thin layer of just Ecoflex was added along each surface. The result was a placenta with the desired deformable properties, but without the tacky outer surface (Figure 9).

Figure 8: Clay mold used to make the small-scaled placenta model.

Figure 9: One of the small-scaled placenta models with the four placement magnets surrounding the sensor magnet.

Sensor Implementation

Circuitry

Each magnetic field analog sensor was attached to an analog input pin of the Arduino Uno board, which reads the sensor's voltage output and transmits it to a Java program. The Arduino Uno board was chosen over other microcontroller boards for its overall ease of use and programmability, as well as its low cost. The Arduino code is included in Appendix B.

When the Arduino is used to collect data, only the float values, from 2.49 to 5.00, are printed to the serial port. The float value is followed by an ASCII newline character and carriage return character. The Arduino serial port is set at 9600 baud, or 9600 bits per second. As each voltage measurement is six characters long, the Arduino is capable of reading 9600/6 characters/ 8 bits per character = 200 voltage measurements per second. This reading capacity is more than sufficient for the number of analog sensors expected for this model.

Programming

Java was chosen as the program to read the Arduino serial output data because of its ease of use and our prior experience programming in Java. The program reads the Arduino serial output line-by-line and converts that ASCII value into a float, then normalizes it to a value from 0 to 0.67. The values from 0 to 0.67, when multiplied by 360°, correspond to 0 to 241, or to the colors red to dark blue on the HSB color scale. This normalized value is passed in to a function that converts a specific HSB color into a Java color object. That Java color object is then used to set the background color of a window to provide visual feedback. The Java code is included in Appendix C.

Visual Feedback

The Java program converts the output voltage from the sensors to a color value and displays the color on a computer screen. The color red represents a configuration where the sensor magnet is directly on top of the sensor and the color blue represents a configuration where the magnet is too far away from the sensor to be detected. Distances in between correspond to the HSB color spectrum between red and blue.
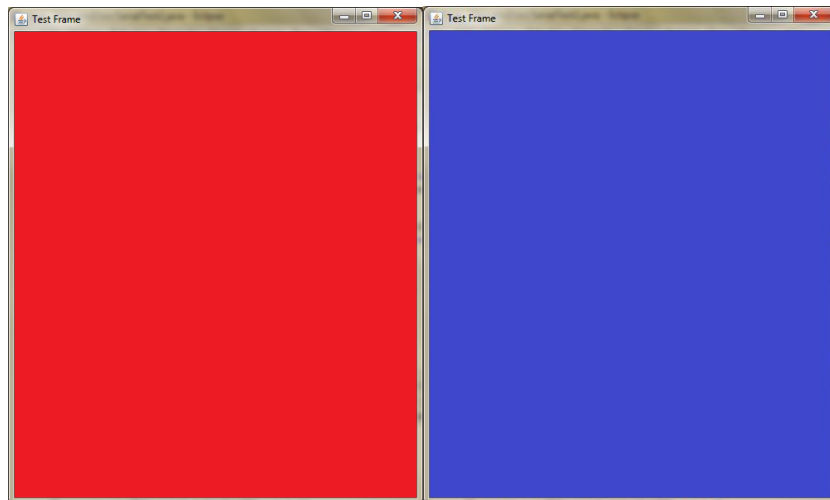
Figure 10: Red and blue example of color output from Java program.

Testing

Testing Protocol

Testing was conducted to choose the most appropriate sensor and magnet to use for the best performance of the design. Prior to testing, a test plan was prepared and is attached in Appendix D. Testing is summarized here as follows.

Magnets were attached to steel calipers and placed 3, 2.5, 2, 1.5, 1, 0.5 and 0 cm away from the sensor (Figure 11). The corresponding voltage signal was measured and recorded. Since the caliper is made of steel, the caliper caused a change in the voltage prior to the attachment of the magnet. Thus, two baseline values were measured: one with the sensor only, and one with the caliper. The voltage measurements shown were normalized with the difference between the caliper and sensor baseline values values.

Measurements were performed with two types of magnets: D51-N42 magnet from K&J magnets and NSN0601/N40 magnet from
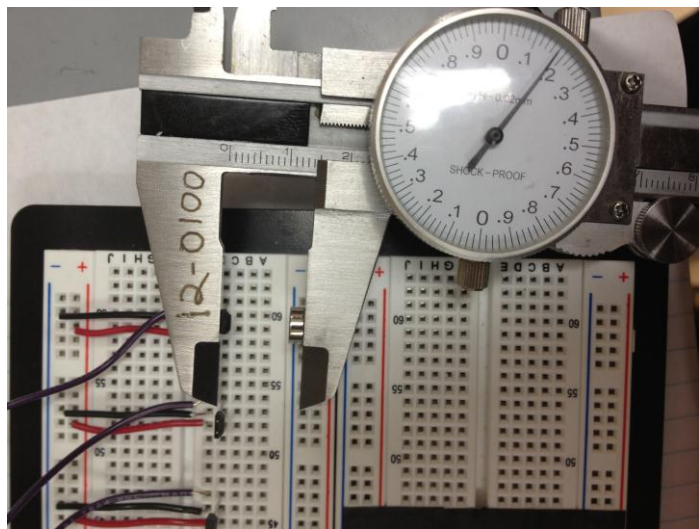

Figure 31: The distance between the magnet and sensor measured by calipers.

MAGCRAFT. The tests were performed with the bare magnets and with the magnets covered with 0.45 cm DragonSkin silicone and power mesh. For measurements of magnets with silicone, the closest distance used was 0.5cm.

To ensure consistency of the testing, the same team member performed the test during measurements. Thus, user error was consistent and eliminated differences between tests. Each bare magnet was tested two times per sensor, and measurements at each distance were averaged from five voltage values. The magnets with silicone and power weave were tested once per sensor.

Data analysis

First, it was determined that voltage values measured by using the D51-N42 magnet were smaller than the values measured by using NSN0601/N40 in the range of 2-3 cm. This correlates to a smaller magnetic field strength from the D51-N42 magnet. Therefore, data was only analyzed for the sensor magnet and the three subsequent sensors.

Graphs of voltage output vs. magnet distance from sensor were generated for each sensor and summarized in Figure A. Standard deviations were also plotted but too small to be visible on the graph.
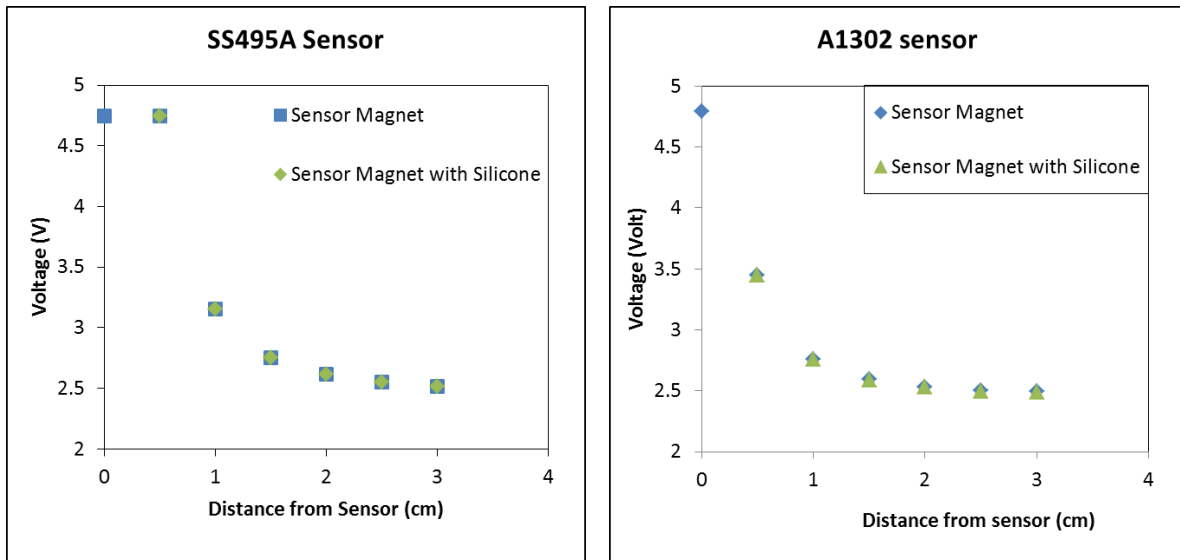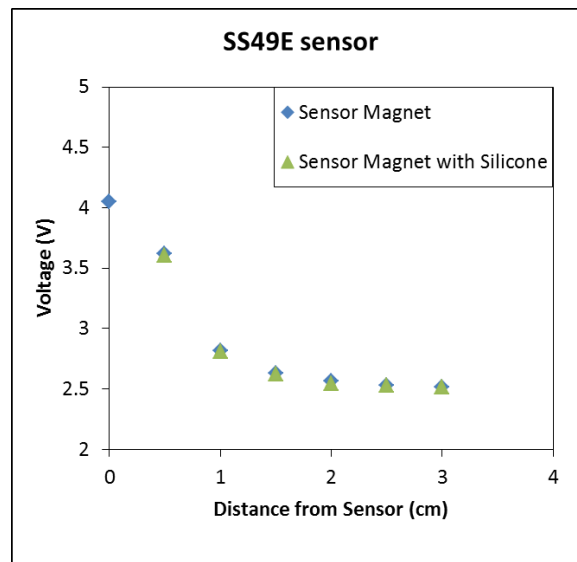
Figure 12: Sensor output voltage vs. magnet distance from center for the SS495A sensor, A1302 sensor, and SS49E sensor.

Figure A indicates that the SS495A sensor cannot differentiate between 0 and 0.5 cm. There is also a large discrepancy between 0.5 and 1 cm. Therefore, the SS495A sensor is not sensitive enough to accurately model the change between 0 and 1 cm. Due to this insensitivity, the SS495A sensor was disregarded as a possible sensor in our final model.

The A1302 sensor, on the other hand, shows a fairly smooth distribution of voltage values over the measuring range. This provides a better model to fit the data and leads to a large range of voltages for generating a visual color map. Furthermore, the voltage difference between 0 and 0.5 cm is more than sufficient to determine the position of the placenta in relation to the uterus. In comparing the bare magnet measurement and the magnet with silicone measurement, the magnet with silicone had slightly smaller voltage values regardless of the distance. However, the voltage difference between bare magnet and magnet with silicone was no more than 0.1 V, which demonstrates that the silicone layer does not significantly interfere with the performance of the sensor.

The SS49E sensor showed similar sensitivity properties as the A1302 sensor. The major difference between the two sensors was the discrepency in voltages between 0 and 0.5 cm. Since A1302 had a larger range between 0 and 0.5 cm, the sensor had higher sensitivity and can detect more precisely between that range. A1302 was also cheaper, at $1.33 per sensor in comparison to $1.98 for the SS49E sensor. Therefore, the A1302 sensor was chosen for the final design.

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.

Budget

Table 3: Current expenses

Item	Quantity	Cost
Clay and molding materials	3	$48.13
Magnets	90	$34.85
Silicone materials	6	$240.77
Sensors	5	$43.46
Power mesh	2 yards	$20
Arduino board & USB cable	1	$54.84
Total		**$442.05**

Table 4: Projected future expenses

Item	Quantity	Cost
Magnets	100	$40

Sensors	40	$60
Arduino Analog Multiplexer	1	$30
Silicone	3	$100
Miscellaneous items	N/A	$20
Total		**$250**

Final cost of project approximately $750.
Final cost of model with sensors approximately $250 (excluding labor).
Final cost of model without sensors approximately $150 (excluding labor).

Future Work

In order to finish our device, we must first determine the ideal sensor and magnet configuration to optimize the number of placenta orientations, keeping in mind a method to implement placenta accreta. Once determined, the uterus and placenta will be cast using a negative mold of each piece. The uterus will then be embedded with the sensors and the corresponding circuitry. An external power source, such as a battery, will be designed to power the device.

For visual feedback, the color map will be further developed to display relative distances between the placenta and uterine wall throughout the procedure. We envision our final display to combine the color map with the placenta's orientation within the uterus. This will allow us to collect data during the procedure, and serve as a way for instructors to monitor students' performance in practice. If the device is successful, we hope to patent and introduce our device into the market.

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Appendix A: 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.

Appendix B: Arduino Code

```
void setup()
{
  Serial.begin(9600);
  // Set the data rate at 9600 bits per second for serial transmission
}

void DoMeasurement()
{
  // Turn on pullup resistors for digital sensors
  pinMode(9, INPUT_PULLUP);

  // Read values from input pins. Digital Pin 9, Analog pins 0-2
  // Value from 0.0 to 1023.0
  int d9 = digitalRead(9);
  int a0 = analogRead(0);
  int a1 = analogRead(1);
  int a2 = analogRead(2);

  // Convert the input value to a voltage value, based on 5V as highest voltage value possible
  float a0v = a0 * (5.0 / 1023.0);
  float a1v = a1 * (5.0 / 1023.0);
  float a2v = a2 * (5.0 / 1023.0);

//Print values to serial port as ASCII human-readable text
```

```
  Serial.print("Digital 9: ");

void loop()
{
//Run measurement code every 100 ms
  delay(100);
  DoMeasurement();
}
```

Appendix C: Color Code

```java
import gnu.io.CommPortIdentifier;
import gnu.io.NoSuchPortException;
import gnu.io.PortInUseException;
import gnu.io.SerialPort;
import gnu.io.UnsupportedCommOperationException;

import java.awt.Color;
import java.io.BufferedReader;
import java.io.IOException;
import java.io.InputStream;
import java.io.InputStreamReader;
import java.io.OutputStream;

/**
 * @author Katherine Lake
 * Project: BME Design Placenta Extraction Model
 *
 */
public class ArduinoSerialComm
{
    SerialPort serialPort;
    private static final String PORT_NAME = "COM6";
    private InputStream inputStream;
    private OutputStream outputStream;
    private static final int TIME_OUT = 5000;
    private BufferedReader bufferedReader;
    private static final float MIN_VOLTAGE = .09f;
    private static final float MAX_VOLTAGE = 5f;
    private static final float REST_VOLTAGE = 2.5f;

    public ArduinoSerialComm(int baudrate) throws IOException{
        CommPortIdentifier commPortIdentifier;
        //Find requested comm port
        try {
            commPortIdentifier = CommPortIdentifier.getPortIdentifier(PORT_NAME);
        } catch (NoSuchPortException e) {
            throw new IOException("No such port " + PORT_NAME + ": " +
    e.getMessage());
        }

        //Open the comm port
        try {
```

```java
            serialPort = (SerialPort)commPortIdentifier.open("Arduino", TIME_OUT);
            System.out.println("Serial port opened");
        } catch (PortInUseException e) {
            throw new IOException("Port in use " + PORT_NAME + ": " +
    e.getMessage());
        }

        //Set the flow control to none
        try {
            serialPort.setFlowControlMode(SerialPort.FLOWCONTROL_NONE);
            System.out.println("Flow control set");
        } catch (UnsupportedCommOperationException e) {
            throw new IOException("Failed to set flow control: " + e.getMessage());
        }

        //Configure the comm port with supplied baudrate, 8 data bits, 1 stop
        // bits, and no parity (8N1)
        try {
            serialPort.setSerialPortParams(baudrate, SerialPort.DATABITS_8,
                SerialPort.STOPBITS_1, SerialPort.PARITY_NONE);
            serialPort.enableReceiveThreshold(0);
            serialPort.enableReceiveTimeout(Integer.MAX_VALUE);
            System.out.println("Parameters set");
          } catch (UnsupportedCommOperationException e) {
            throw new IOException("Failed to configure the serial port " + PORT_NAME
                + ": " + e.getMessage());
          }

        //OutputStream and InputStream
        inputStream = serialPort.getInputStream();
        System.out.println("Input stream opened");
        bufferedReader = new BufferedReader(new InputStreamReader(inputStream));
        System.out.println("Buffered reader opened");
    }

    public void close() throws IOException {
        inputStream.close();
        serialPort.close();
        System.out.println("Serial port closed");
    }

    public float readSensor() throws Throwable {
        try {
            String line;
            float meas;
            if ((line = bufferedReader.readLine()) != null) {
                meas = Float.parseFloat(line);
                System.out.println(meas);
                return meas;
            } else
                return 0;
        } catch (Exception e){
            inputStream.close();
            bufferedReader.close();
            serialPort.close();
            System.err.println("Error in sensor read: " + e.toString());
```

```java
            return 0;
        }
    }

    public Color colorConverter(float voltage) {
        float norm;
        Color c;
        norm = (float) (Math.abs(MAX_VOLTAGE - voltage)) / (MAX_VOLTAGE -
    REST_VOLTAGE);
        System.out.println(norm*360);
        if (norm > .67) {
            norm = .67f;
        }
        c = Color.getHSBColor(norm, 1, 1);
        System.out.println(c);
        return c;
    }

}


import java.awt.Color;
import java.awt.Container;
import javax.swing.JFrame;
public class ArduinoTest
{
    public static void main(String[] args) throws Throwable{
        Color c;
        float voltage;

        JFrame frame = new JFrame("Test Frame");
        Container content = frame.getContentPane();
        frame.setSize(500, 600);

        SerialTest2 test = new SerialTest2(9600);
        System.out.println("Serial port successfully opened");
        frame.setVisible(true);
        for (int i = 0; i < 500; i++) {
        voltage = test.readSensor();
        c = test.colorConverter(voltage);
        content.setBackground(c);
        }
        test.close();
    }


}
```

Appendix D: Test Plan

1. Introduction

This test approach document describes the appropriate strategies and processes used to plan, organize, and execute testing of the placenta extraction model sensors and magnets.

1.1 Quality Objective

1.1.1 Primary Objective

The primary objective of testing this system is to ensure it meets the full requirements, including the quality requirements, provided by the client. The system shall employ the most effective and accurate sensor and magnet system for best performance of the device. At the end of the design project, the client should find that the project has met or exceeded all of their expectations as detailed in the requirements.

1.2.1 Secondary Objective

The secondary objective of testing the sensor and magnet system is to identify and expose all issues and potential fallbacks to this system, communicate discovered issues to the design team, and ensure that all issues are addressed prior to the completion of the design project. All areas of the system must be examined and all issues found must be documented and dealt with appropriately.

2. Test Methodology

2.1 Purpose

The purpose of the Test Plan is to achieve the following:

- Define strategies to test all the functional and quality requirements.
- Identify required resources and related information.

2.2 Test Strategies

2.2.1 Sensor Sensitivity Test Based on Bare Magnet Distance Using Calipers

The purpose of this test is to determine the voltage output generated by the sensor in response to the magnet positioned at various distances from the sensor.

The test shall be conducted as follows:

1. Connect the Arduino, sensors, and corresponding circuit to power and to the computer.
2. Run the Arduino program to measure the voltage output from the sensors.
3. Measure the baseline voltage of the sensor and determine any possible changes from the calipers to the sensor.
4. Determine the thicknesses of the sensor and magnets and calculate the actual distance of the magnet from the sensor.
5. Determine the maximum distance between the magnet and the sensor before the sensor can no longer detect the magnet.
6. Continue voltage measurements in set distances.
7. Record the voltage output at each distance.
8. Use $n = 5$ measurements per distance and $n = 2$ sets for each magnet per sensor.

Analysis of the data shall be conducted as follows:

1. Normalize the voltage values to the baseline if necessary.
2. Calculate the standard deviation for each distance.
3. Plot the voltage vs. magnet distance from the sensor.
4. Determine the best sensor and best magnet based on data.
5. Find the best model that fits the data. Based on previous research, the sensors should display an exponential relationship with the strength of the magnetic field.

All values shall be recorded in a Microsoft Excel spreadsheet.

2.2.2 Sensor Sensitivity Test Based on Silicone-Magnet Distance Using Calipers

The purpose of this test is to determine whether silicone positioned between the sensor and the magnet interrupts the measurement or decreases the voltage reading.

The test shall be conducted as follows:

- Model the magnet attachment mechanism by attaching power weave and silicone with uniform thickness to the magnet.
- Measure the thickness of the silicone and power weave layer.
- Repeat steps 1-8 of Test 2.2.1 and steps 1-5 of the analysis.