Transcervical Chorionic Villus Sampling

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Table of Contents

Transcervical Chorionic Villus Sampling Model........ 1

Table of Contents........ 2

Abstract........ 3

Background........ 3

Problem Statement........ 4

Motivation........ 5

Client Requirements & Ergonomics........ 6

Materials Testing........ 7

Existing Devices........ 9

Design Option 1 – Plastic Sheet Uterus........ 10

Design Option 2 – Plastic Sheet Uterus With Elbow........ 12

Design Option 3 – Rigid Uterus With Elbow and Elongation........ 13

Final Design........ 15

Design Matrix........ 17

Testing........ 18

Future Work........ 19

Acknowledgments........ 20

References........ 22

Appendix A (PDS)........ 23

Abstract

Transcervical Chorionic Villus Sampling (CVS), a very difficult procedure with a steep learning curve, allows doctors to obtain placental tissue from the uterus of a pregnant woman. In addition to its difficulty, the procedure poses significant risks to the developing fetus. Consequently, instruction of, and training for the techniques involved cannot be practically carried out on actual patients. However, an adequate model for such training exercises does not yet exist. In response to the demand for such a model, our team has engineered a working prototype to simulate, in ultrasound image and in feel, the anatomy of a candidate for CVS such that doctors may practice the procedure in a controlled environment.

Background

Chorionic villus sampling (CVS) is a procedure performed in early pregnancy (typically 10-13 weeks) to obtain a genetic sample of the placenta [1]. The genetic material obtained from this procedure is primarily used to diagnose fetal genetic disorders (Down syndrome, Tay-Sachs disease, Sickle-cell disease, etc.), and possibly to determine the baby's gender or blood type [3]. Knowledge of gender and blood type are helpful if other complications arise later in pregnancy. CVS provides an earlier diagnosis than amniocentesis, which is performed later (typically 16-20 weeks) in the pregnancy [3].

There are two methods of CVS, a transabdominal and a transcervical approach. Depending on the location of the placenta relative to the amniotic sac in the uterus, a pregnant woman may choose one procedure over the other. Some risks associated with CVS are birth defects, miscarriage, infection and bleeding. Infection and bleeding are extremely rare, and the rate of birth defects is significantly reduced if the procedure is performed later in pregnancy [4].

Transabdominal CVS is very similar to amniocentesis. To obtain a chorionic villus (placental) sample, the doctor guides a needle to the placenta using ultrasound images of the abdominal cavity. Once the placental sample is obtained, the needle is gently removed. This procedure is relatively simple to perform and very few complications result. However, doctors will only take this approach if the placenta is located on the anterior wall of the uterus.

Transcervical CVS is more complex and requires skill and creativity on the doctor's part but may be used to obtain a sample of placenta on the posterior and side walls of the uterus. To obtain the placental sample, a thin catheter is guided through the vagina and cervix to the precise location of the placenta. The cervical canal is very thin (~2mm) and rigid and does not allow for simple control of the catheter upon entering the uterus. Sometimes elaborate techniques must be used to correctly guide the catheter to the placenta without compromising the amniotic sac. Miscarriage could result if the amniotic sac is compromised.

Problem Statement

Chorionic villus sampling is a prenatal diagnosis procedure that involves extracting placental tissue from the uterus of a pregnant woman in her first trimester of pregnancy. This tissue contains the same genetic information as the unborn fetus. Testing thus allows chromosomal abnormalities and genetic defects to be diagnosed early on in the gestation period. The current, and most difficult, method for chorionic villus sampling requires a catheter to be inserted through the woman's vagina and into the cervix (also known as the transcervical approach). However, doctors and residents currently do not have a model to simulate female anatomical structures and practice the transcervical method. The goal of this project is to develop a realistic and affordable model that precisely replicates the anatomy of a pregnant woman, is constructed out of ultrasound permeable materials, and can be repeatedly used to practice the transcervical approach.

Motivation

Since the advent of the field of human genetics, the question has been asked, "If you could run a test to determine if your unborn child has a genetic disorder, would you do it?" Today the question is no longer, "would you if you could?" but rather, "will you since you can?" Considering the frequency with which prenatal genetic testing occurs, the overwhelming response appears to be that yes, expecting mothers chose to know whether their fetus is genetically sound. CVS serves as a powerful tool for obtaining the genetic information of a fetus as early as ten weeks into pregnancy. With data in hand this rapidly, both doctors and expecting parents may begin to make decisions concerning the fetus. If a genetic defect does appear, in some cases prenatal measures may be taken, and in other cases, plans may be made for postnatal management. In more severe cases, the results of CVS return while abortion is still an option.

Although transcervical CVS has many benefits, it is not without its drawbacks. A single mistake in executing the CVS procedure can lead to puncture of the amniotic sac and unwanted termination of the pregnancy. What’s more, the high degree of difficulty associated with the procedure makes mistakes all the more likely. Therefore, one might assume that only highly skilled doctors with a great deal of experience with the procedure may perform it. However, no adequate models currently exist to simulate the transcervical CVS procedure. Thus, new doctors must receive instruction and hone their skills while operating on actual patients. As one can see, this situation is not ideal for either patient or doctor.

The creation of a model which accurately mimics the conditions and environment of a transcervical CVS procedure will allow doctors to gain experience with the procedure without putting patients in harm's way. This in turn should result in a higher rate of success, more information for doctors and parents, and fewer mistakes at the expense of patients.

Client Requirements & Ergonomics

After extensive meetings with our client detailed literature searches, we have outlined a set of requirements that this model must meet (see Appendix A).

Our client desired one prototype to be used repeatedly by doctors in a clinical setting and stored with other medical equipment in a clean environment. Therefore, little emphasis was placed on measures to prevent wear due to negligent use or unclean conditions.

The design of the model is highly limited by the anatomy of a pregnant woman in her first trimester as the main goal of the model is to mimic this anatomy. The uterus must be about 400 milliliters in volume, the cervical canal about five to six centimeters in length and two millimeters in diameter. The posterior wall of the uterus must be readily accessible to allow for easy placement of the placental tissue, which our client will provide. The angle between the cervical canal and the lower uterine wall should be between 30 degrees and 45 degrees to provide the user with a challenging but possible practice procedure and to maintain anatomical accuracy.

Our client put an emphasis on the "feel" of the model, as the goal is to simulate all aspects of an actual transcervical CVS procedure. All materials used to simulate the cervix, uterus and amniotic fluid must be penetrable to ultrasound waves, as the doctor must be able to navigate from the end of the cervix to the placental sample, guided only by ultrasound imaging.

The material of the cervix and uterus must be fairly firm to retain its shape, and to inhibit the user's maneuvering of the catheter once it is inserted. In addition, the cervix must provide some resistance to catheter insertion.

After deliberation and testing, our client arrived at the conclusion that a simulated amniotic sac is of less importance than a clear ultrasound image. Therefore, the model must incorporate a means of containing liquid to fill the uterine cavity both to simulate the amniotic fluid and to provide a clean, airless interface between the upper uterine wall and the cavity itself. With the sacrifice of the amniotic sac comes the added requirements that the ultrasound image produced by the model show very clearly the placenta, the angle and trajectory of the catheter and the end of the cervical canal and that the model must withstand contact with liquid for extended periods of time.

Our client did not put an emphasis on the aesthetic appeal of the design of this model. The only concern was the accuracy of its appearance under ultrasound.

The design should accurately model the difficulty of an actual CVS procedure and thus confine the physician's movements to an accurate extent. Therefore, the ergonomics of the model are predetermined. However, ease of cleaning and replacing the components of the model is a concern. It should require little effort to place the placental tissue in the desired location, and fill the model with liquid. After taking into consideration these limitations, along with each specification set forth by our client, four potential design options have been devised.

Materials Testing

After research of the speed of sound in various materials we concluded that a silicone based material would best simulate the qualities of human body tissue as viewed under ultrasound. Therefore, a critical step in our formulation of design options and ultimately our selection of which option with which to move forward was the testing of various silicone rubber materials, including Smooth-On EcoFlex shore 10, Smooth-On Dragonskin and Polytek materials of various shore strength, for penetrability to ultrasound. In order to gauge which silicone material created the least interference under ultrasound we scanned each one while holding the catheter directly beneath it. The Dragonskin produced the most interference, rendering the catheter invisible, while the Polytek materials produced a visible but foggy image. However, the EcoFlex allowed for a fairly clear picture of the catheter to be seen. Consequently, we selected EcoFlex, a two part, platinum cure silicone rubber, which costs $28.67 per two pounds, for use in our design.

Material	Testing	Rank
Smooth-on ECOFLEX	Saw the catheter under the material very well, the catheter was clearly seen and the material provided very little interference	1
Smooth-on Dragonskin	Catheter was more foggy due to the air bubbles in the material, the catheter was seem but if the material was thicker, visibility would decrease	4
Polytek shore 10	Catheter was fairly clear, but more foggy than the ECOFLEX, seemed to be a good material for a second choice if ECOFLEX will not work	2
Polytek shore 40	Hard to get a good test, sample was small in size, able to see catheter, more foggy than shore 10 hardness	3

Table 1-Materials testing comparison. Smooth-On EcoFlex silicone material decided to be best option

Existing Devices

Preliminary research has revealed existing devices that are used to teach doctors the proper techniques of ultrasound-guided procedures. A team of doctors from Paris Ouest University in Poissy, France developed a gravid uterus model composed of various foams and rubbers in the shape of a sphere to simulate the abdomen of a pregnant woman. This model was to teach the transabdominal approach to chorionic villus sampling, and contained a water filled uterine cavity with two artificial placentas inside; one inserted posterior and one inserted anterior [2]. While this model successfully improved the learning curves of doctors being trained on it, it would not suffice for teaching the transcervical approach to chorionic villus sampling. This is because the model does not contain a cervix or a vagina for the extraction catheter to be inserted through. However, those two structures were to be implemented on this model, it would pose as a significant competitor to ours.

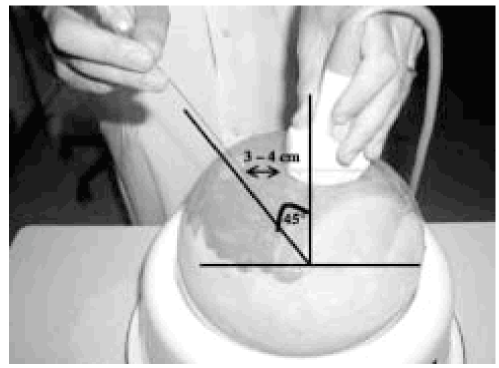

Figure 1- Gravid uterus model used to teach ultrasound guided transabdominal chorionic villus sampling.

A second existing model is manufactured by CIRS Incorporated is a fetal ultrasound biometrics phantom (model 068). This model is used to teach and demonstrate proper ultrasound techniques used during gestational age estimation examinations and birth defect screenings. The advantages provided by this model include incorporating two fields of view, non-echoic amniotic fluid, and a simulated abdominal wall and cavity composed of proprietary gels [5]. Similar to the gravid uterus model mentioned above, the CIRS Inc. model does not contain a cervix or vagina. This limits the model to being used only for transabdominal procedures, but could be easily modified to contain a cervix and vagina, and thus be used to practice transcervical procedures.

Figure 2- Fetal biometrics phantom manufactured by CIRS Inc.

Design Option 1

Since the anatomy of the human structure constrains the construction of the model, only certain parts of the model can be manipulated and changed. The model itself consists of three basic parts; the vagina, the cervix/cervical canal, and the uterus. The parts of the anatomy will rest on a platform so the model can sit flat on a table. The vagina will be constructed out of silicone rubber material that is pliable and can be easily molded. This will simulate both the feel and look of a natural vagina. The 10 cm vagina will rest on the platform with a foam layer in between, giving the structure support and also allowing the vagina to be manipulated into a proper position as would a human's. The cervix and cervical canal is made of a harder silicone material that will not puncture due to the insert of the catheter. The cervical canal is 2 mm in diameter and extends for 6 cm. The vagina will be directly attached to both the top and bottom of the cervix. The uterus is attached to the other side of the cervix and is approximately 20 cm long. The uterus will be constructed of two different materials. The bottom half is made of the same material as the cervix and is directly attached to the cervix. The top half is constructed out of a thin plastic material that is attached to the end of the cervix and a rigid form at the opposite end of the uterus. The uterus will be open at one end in order to insert a water filled plastic bag to resemble an amniotic sac. The cervix is able to rotate due to a metal rod inserted at the front end of the cervix and an adjustable shaft holding up the uterus.

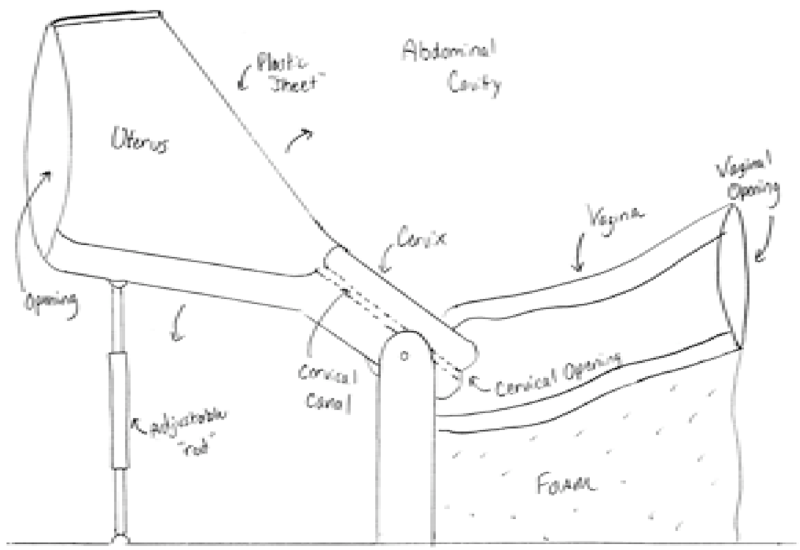

Figure 3- Proposed apparatus for design option #1

This model is created to ensure ultrasound function because the thin plastic separating the abdominal cavity from the uterus is known to be an effective material. The open format of the uterus allows easy access for insertion and removal of the amniotic sac and placenta. Some disadvantages of this model are the rotational effect and loss of rigidity. When the cervix/uterus rotates the open end may allow the placenta and amniotic sac to slip out, or may cause an air bubble in the bag, affecting the ultrasound. The plastic sheet separating the abdominal cavity from the uterus is not rigid and therefore not as strong and easy to work with. A more rigid material would be easier to use. Overall, this design proves to be fairly effective and will provide a good practice model.

Design Option 2

The second design incorporates much of the first design because of the anatomical similarity but also provides a few changes in model structure. Again, the model will contain the vagina, cervix/cervical canal, and the uterus. The vagina is constructed out of silicone rubber material that will create a natural look and feel. The vagina is approximately 10 cm long and will rest on a layer of foam to provide rigidity and support. The cervix is constructed of a harder silicone material that prevents the catheter from puncturing the material during insertion through the 2mm diameter x 6 cm cervical canal. The vagina will be attached to the anterior side of the cervical canal. The uterus will be attached to the posterior side of the cervical canal and the bottom half will be constructed out a rigid silicone material. The top half will be constructed out of a thin plastic sheet material and will be supported by a rigid frame on the opposite side of the uterus. The back of the uterus will be in the shape of an elbow to prevent movement during rotation. The uterus will be open on top of the elbow to allow insertion of the placenta and the amniotic sac. The cervix and uterus can rotate because of the rod attached to the cervix and the adjustable shaft attached to the back end of the uterus.

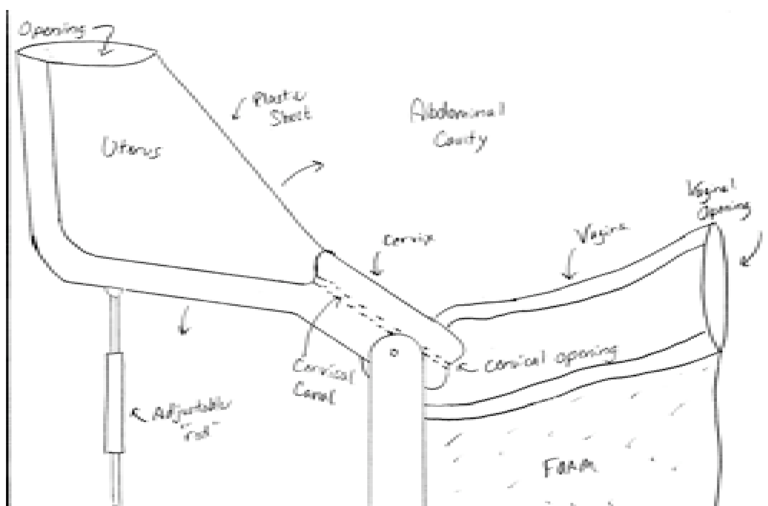

Figure 4- Proposed apparatus for design option #2

The open format of this model still allows for insertion of the placenta and amniotic sac and account for the rotation. When the model is rotated, the elbow will prevent the amniotic sac and placenta from slipping out of the uterus, and also allow the amniotic sac to be larger, therefore eliminating the air bubble interference effect. The plastic sheet is known for its efficiency in ultrasound images, and will provide little interference. This design proves to be very effective, but it still lacks the rigidity between the abdominal cavity and the uterus that is present in actual patients.

Design Option 3

Design option three is very similar to design option two, with the exception of a posterior elongation of the uterus, and the material it will be constructed from. The uterus and cervix will be molded out of Smooth-On EcoFlex® material, which provides the clearest ultrasound image according to preliminary ultrasound testing. The amniotic sac will be simulated by a water-filled plastic bag, and the 10 cm long vagina will be simulated by a lightweight plastic tube (roughly the diameter of a male condom) that is supported underneath by piece of foam. At the connection point of the cervix and vagina, a hinge joint consisting of two thin aluminum rods will be implemented. By constructing a hinge at this connection point, the doctors will have the freedom to adjust the angle between the vagina and cervix, thus allowing the anatomies of a wide-range of patients to be simulated. Adjustment of this angle is accomplished by raising or lowering the uterus, and allowing the hinged cervical-vaginal joint to vary until the desired angle is achieved. In addition to implementing an elbow shaped contour on the underside of the uterus as described in design option two, the posterior section of the uterus will be elongated. This extension will serve the purpose of allowing the amniotic sac to be filled with a volume of water greater than the actual volume of the uterus. Consequently, as the uterus is tilted downward due to an adjustment of the cervical-vaginal angle, the air bubble present in the top of the amniotic sac will form in this posterior extension (as opposed to forming underneath the top face of the uterus), and out of the way of any permeating ultrasound waves. This feature of the design is extremely vital because any pockets of air that form inside the uterus or amniotic sac will cause significant disturbance on an ultrasound image, resulting in a non-realistic picture for the doctor practicing on the model.

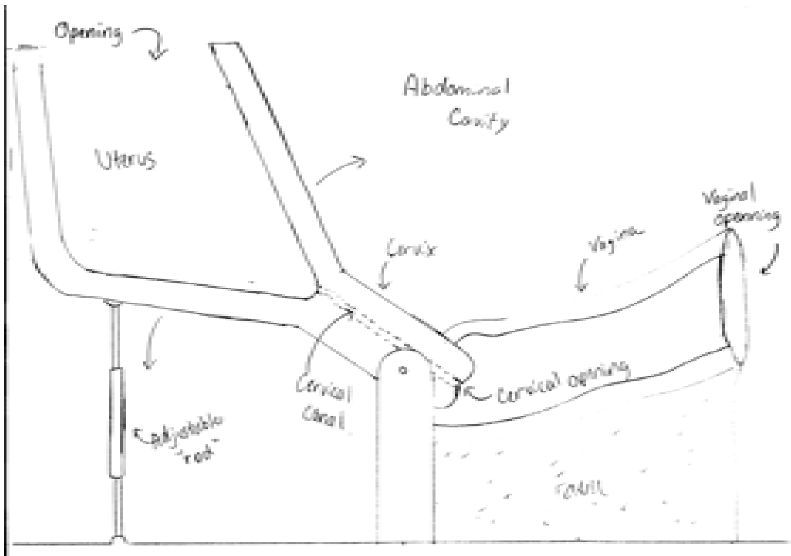

Figure 5- Proposed apparatus for design option #3

There are a few disadvantages associated with design option three. The simulated amniotic sac has to be removed from the uterus, filled with water and then tied off prior to use. This may prove to be a lot of work for the doctors; however, a removable amniotic sac of this nature is the most reasonable option to allow for sample placental tissue to be placed inside the uterus prior to every use. The most troublesome disadvantage stems from the nature of the Smooth-On EcoFlex® material. Unfortunately what makes this material so well-suited for ultrasound imaging is its low density characteristic. As a result, the material will not be able to support significant amounts of weight, and it is undetermined whether or not the model will even be able to support its own weight once molded. The weight of the liquid-filled amniotic sac, the weight of the simulated abdominal cavity (our client has specified that a bag of saline solution or bag of ultrasound gel will suffice as a simulated abdominal cavity), along with any additional pressure placed on the model by the doctor during practice, must all be taken into consideration when designing a mechanism of support for design option three.

Final Design

The dimensions and basic structure of the design have been constricted by female anatomy all along. As such, we incorporated the three basic parts of female anatomy into the final design, which are relevant to the CVS procedure: (1) vaginal obstruction, (2) cervical canal, and (3) uterine cavity. Some aspects of the final design are very similar to those of the previously discussed design options, while others have dramatically changed for the better. The uterus and cervical canal are supported by a case made of ABS plastic with an open, angled top to allow for easy and clear ultrasound.

An elbow design, like Design Options 2 and 3, was also incorporated into the final design. In this way it is possible to fill the uterine cavity completely with water and prevent air bubbles from interfering with the ultrasound on the top of the uterine cavity.

The uterus and cervical canal were made entirely of Smooth-On EcoFlex, similar to Design Option 3; however, this was taken even further in the final prototype. Instead of molding the uterine wall and cervix on their own, the final design incorporates a mold in which the space occupied by the uterine cavity and the cervical canal was left after molding. In the final prototype, the uterus and cervical canal are simply the absence of EcoFlex material in the ABS casing. This dramatically simplified the molding process and enhanced the stability and usability of the model. While the thicker EcoFlex material was a point of concern at first, it was determined that a thicker layer of silicone material transmits ultrasound waves better and make the image clearer, to a certain extent. Also, molding of the cervical canal out of EcoFlex rather than a harder rubber enhances the feel of the model, as the cervix is not an entirely rigid structure and is able to be manipulated by a few millimeters in each direction. EcoFlex is a flexible enough material to allow for this manipulation. However, making the model one solid mold did affect its adjustability. While each of our three design options allow for adjustment of the angle of the cervix and uterus with respect to the horizontal plane, this angle is fixed in our final design.

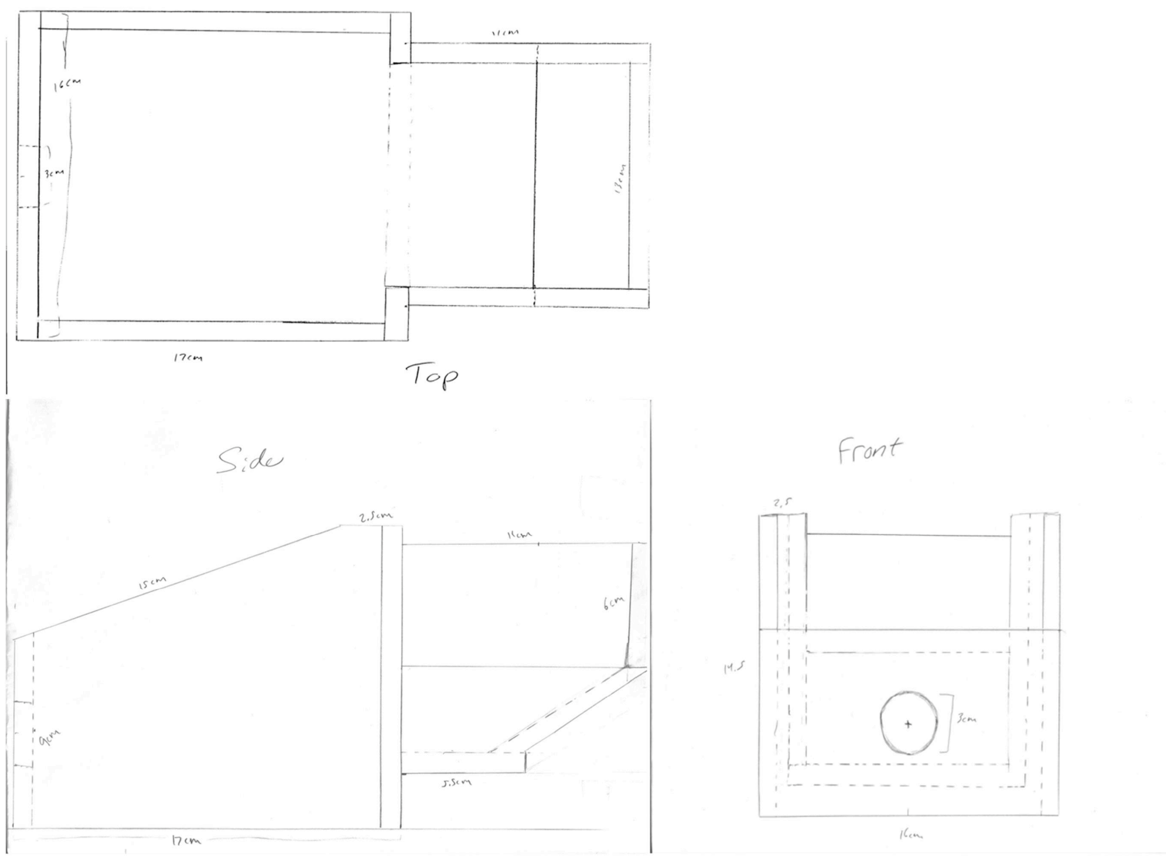

Figure 6-Final design drawings

The vaginal canal is simply an obstruction for doctors when they are performing the CVS procedure. For this reason, the realistic appearance of the vagina was not a huge concern. To model the vaginal obstruction, a cylinder of heavy-duty rubber 3 cm in diameter and 10 cm in length was glued with epoxy to the case at the cervical opening. This material was firm enough to support itself, yet flexible enough to allow for slight adjustments from the outside, as would occur in the actual procedure.

In the original design options, a plastic bag (amniotic sac) was required to hold the water or amniotic fluid in the uterus. However, with this new design, this was not needed. Because the mold of EcoFlex took up the entire box volume, water could now be poured simply into the elbow extension to fill the uterine cavity completely. This elbow extension extends 8.5 cm out from the main body of the box to allow for easy placement and removal of placental tissue between uses.

Design Matrix

The design matrix used to determine which of the three design options most accurately meets our client's design specifications consists of five categories. Each category is weighted with a designated amount of points out of 100. The categories are: Realistic feel (50), anatomical accuracy (20), ease of use (10), ease of manufacturing (10), and cost (10). Realistic feel and anatomical accuracy were assigned the largest fraction of points simply because the design specifications set forth by our client call for a model that creates a realistic replication of the anatomy of a pregnant woman. Design option four scored the highest in these two categories because it was the only option that incorporated an entirely enclosed uterus and an abdominal wall. Furthermore, design option four scored highest in the ease of use category because the

Smooth-On EcoFlex® material combined with the water interface provides the clearest ultrasound image, and the posterior uterine extension and compact design allow for easy accessibility and refilling. Design option four received the highest score in terms of manufacturing due to the ease of pouring the EcoFlex into a box rather that attempting to mold it around a uterus form in open space. Design option four received the lowest rating under the cost category simply because it will require the most materials. However, this had a very minor effect on the overall rating of design option four.

Design Number	*Realistic "Feel" (50)*	*Anatomical Accuracy (20)*	*Ease of Use & Setup (10)*	*Manufacturing (10)*	*Cost (10)*	*Total (100)*
1	20	15	6	10	10	61
2	20	20	7	8	8	63
3	45	20	9	7	8	89
4	47	20	10	10	8	95

Table 2- Design Matrix containing weighted point values

Testing

The most important requirement of final prototype was that it appeared realistic under ultrasound. The final prototype was tested for this appearance first without water in the uterus, then with water in order to see a comparison of the clarity of the image. The effectiveness of this test is difficult to measure, but our client said that the model worked well and the image of the catheter and placental sample was extremely clear and similar to a real ultrasound of a patient. Here are the two images that were compared:

Figure 7-Ultrasound of model without water

Figure 8-Ultrasound of model filled with water. See placental sample, catheter, and uterine wall clearly

When the catheter was not inserted into the cervical canal, water leaked very slowly out of the cervical opening. The time it took for enough water to leak out of the opening to the point that the ultrasound could no longer be seen was 5 minutes and 20 seconds. However, this is not a large concern because during the majority of the procedure, the catheter will be inserted into the model, and water will not leak out.

Even with multiple tests, there was no observable detrimental effect of insertion of the catheter on the cervical canal. Smooth-On EcoFlex 00-30 has a very high tensile strength of 200 psi, and can stretch to 900% of its original length before breaking. Because the only part of the model undergoing any real stress is the EcoFlex material, and this material is highly durable, the lifetime of this model is estimated to be about 10 years.

Future Work

Although the outcome of this semester should be considered a successful one, should this project continue through upcoming semesters several issues must be addressed. First of all, while not of critical importance, our client mentioned a desire for a model with variable angles between the cervical canal and the lower uterine wall. Such a model could be accomplished by creating several new molds, each with a unique angle. Since the EcoFlex slides in and out of our ABS housing fairly easily, these EcoFlex pieces could act as interchangeable inserts for quick and easy variation of the cervix to uterus angle. Second of all, our client would like to see the addition of more anterior obstructions near the vaginal canal such as simulated pelvis and limb structures. Such structures would more accurately depict the conditions under which a doctor must operate when performing transcervical CVS. Finally, our current model leaks liquid at a slow but noticeable rate from the cervical opening and lacks a simulated amniotic sac. Both of these issues may be resolved with some type of method for incorporating an amniotic sac without causing significant ultrasound interference. These final issues will presumably pose the greatest challenge for teams who work on this project in the future, as good ultrasound visibility requires an almost complete exclusion of air from the material under scrutiny and containing the liquid in a sack almost always introduces air into the uterine cavity, particularly in the critical areas surrounding the catheter. Despite these few and, for the most part, minor issues our client seemed pleased with our prototype and thus the need for future work does not seem especially vital.

Acknowledgements

This design project would not have been possible without a significant amount of time and effort put forth by several professionals. Gregory Gion of Medical Art Prosthetics LLC helped a great deal with this project. Gion is an expert in silicone molding and material and we used his skills to help us find the proper material to use for this project. He was also helpful in creating a mold for the uterus shape and in his willingness to lend us his materials and equipment. The entire project would not have run as smoothly if he weren't there to guide us with his expertise. We would also like to thank Barb Trampe and Tim Heiser of Meriter Hospital for their expertise in ultrasound imaging. They conducted the tests on our model as well as gave us some ideas on material choice. Furthermore we would like to thank our client Dr. Jesus Iruretegoyena for letting us help with this project. He was very cooperative, supportive, and appreciative of our ideas and overall prototype. Most of all we would like to thank our advisor, Dr. Pamela Kreeger for guiding us along the design process and offering constructive insight for our project. Without the help of these individuals, this project would not have been as successful.

References

[1] **Jenkins, T. M. and R. J. Wapner.** 1999. First trimester prenatal diagnosis: Chorionic villus sampling. Semin. Perinatol. **23:**403-413.

[2] **Nizard, J., Duyme, M., & Ville, Y.** (2002) Teaching ultrasound-guided invasive procedures in fetal medicine: Learning curves with and without an electronic guidance system. *J Ultrasound Obstet. Gynec.* 19: 274-277

[3] **Papp, C., A. Beke, G. Mezei, E. Toth-Pal, and Z. Papp.** 2002. Chorionic villus sampling: A 15-year experience. Fetal. Diagn. Ther. **17:**218-227.

[4] **Wilson, D.** 2000. Amniocentesis and chorionic villus sampling. Curr. Opin. Obstet. Gynecol. 12**:**81-86.

[5] http://www.cirsinc.com/068_ultra.html

Appendix A- Product Design Specifications (PDS)

Transcervical Model
2/10/09
Group Members: Andy LaCroix, Derek Klavas, Jon Mantes, Mason Jellings
Advisor: Professor Kreeger

Function:

During transcervical chorionic villus sampling, doctors must navigate through the cervical canal of a pregnant woman, and retrieve a sample of placental tissue from the wall of the uterus. Due to the risk and difficulty associated with this procedure, doctors require a great deal of practice in order to perfect their technique. Our client has requested a model to accurately mimic the anatomical structures of a pregnant woman (i.e. vagina, cervix, uterus, amniotic sac). The entire process of chorionic villus sampling is monitored via ultrasound, so the model must appear on an ultrasound image as would an actual patient's abdomen. Repeated use of this model as a training device should prepare doctors to safely complete a transcervical chorionic villus sampling procedure.

Client Requirements:

- Rigid and restrictive cervical canal with accurate dimensions and feel
- General vaginal opening with adjustable vagina-cervix angle
- Accessible uterine cavity to place placental sample
- Liquid-filled sack to simulate amniotic sac
- Cervix and uterus must be penetrable to ultrasound waves

Physical and Operational Guidelines:

Performance Requirements- Accurately depict the anatomy of a pregnant woman in her first trimester. The model will be used daily by doctors, and should be able to accommodate all medical instrumentation associated with transcervical chorionic villus sampling. This instrumentation includes but is not limited to ultrasound equipment and a 1mm diameter catheter. The model must be reloaded with placental tissue prior to each use.

Safety Requirements- The use of this model will be limited to doctors and residents in training, and will not directly interact with any patients, so there are minimal safety requirements to be considered. Sharp edges should be avoided to prevent lacerations.

Accuracy and Reliability- Since the anatomical dimensions can vary from patient to patient, the size of the model should be in the range associated with the average pregnant woman in her first trimester. However, all relative locations of anatomical structures should be closely followed.

Life in Service- Service should be conducted as deemed necessary by the doctors using the model. The model should be able to withstand daily use, for up to 2 years before requiring service.

Shelf Life- Long periods of storage time should not affect the performance of the model.

Operating Environment- The model will be subject to ultrasound waves and ultrasound gel during use. The model must also exhibit durability during frequent handling in between uses. Usage in a hospital will pose a clean environment, with normal pressure and temperature ranges.

Ergonomics- The model should interface with a doctor as would the pelvic region of an actual patient.

Size- The cervical canal should be 2mm in diameter and 50-60mm in length. The size of the uterus is much more flexible, but should be no larger than 150mm.

Weight- Transportation will be conducted by hand, so the design should minimize bulk and weight. Our client has specified that weight is of minimal concern.

Materials- All materials must be permeable to ultrasound waves in order that their image appears on an ultrasound image. Therefore, the model cannot be made of thick materials and air cannot be involved in the system. All materials should also accurately correspond to the texture and level of rigidity of the tissue they represent.

Aesthetics- The appearance is of minimal concern to our client.

Production Characteristics:

Quantity- Only one unit will be constructed at this time.

Target Cost- A maximum amount of $500 should be spent in designing this product.

Miscellaneous:

Competition- To the best of our knowledge, there are no other models being marketed as a potential competitor to our design.