Transcervical Chorionic Villus Sampling Model

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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, a team of four undergraduate Biomedical Engineering students present three potential models to simulate, in ultrasound image and in feel, the anatomy of a candidate for CVS such that doctors may practice the procedure without risk.

Background

Chorionic villus sampling 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 [2]. 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 [1].

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 [3].

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.

Transcervical CVS is more complex and requires skill and creativity on the doctor's part. 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. And in an age of breakthroughs, the time has never been better to gain this knowledge early. 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 meeting with our client and performing a brief literature search, we have outlined a set of requirements that this model must meet (see Appendix A). Our client only requires one prototype that will be used repeatedly and will be constructed for a maximum of around $500. The model will be used by doctors in a clinical setting and stored with other medical equipment in a clean environment. The model will be used in a setting similar to that which the CVS procedure is usually performed. The ultimate goal of this model is to help doctors practice the transcervical approach of CVS.

The design of the model is highly limited by the anatomy of a pregnant woman in her first trimester. The uterus will be about the size of a large grapefruit, the cervix will be 5-6 cm in length and 2-3 cm in diameter. The cervical canal will be 2 mm in diameter. The amniotic sac will be slightly smaller than the uterus and fill in the space around the placental sample, which will be provided by our client. This sample should be able to be placed at any location on the posterior side of the uterus. The angle between the cervix and the vaginal canal will be adjustable, as this angle is varied amongst patients.

Our client put an emphasis on the “feel” of the model, as our goal is to simulate the actual transcervical CVS procedure. All materials used to simulate the cervix, uterus, and amniotic sac will be penetrable to ultrasound waves, as the doctor needs to see clearly, on the ultrasound image, from the end of the cervix to the placental sample. The material of the cervix and uterus needs to be firm and hold its shape, yet flexible and penetrable to ultrasound waves. The amniotic sac will be filled with fluid contained in a delicate bag, as to provide a negative feedback to the doctor if the procedure is performed incorrectly and the amniotic sac is broken. While using the model, it should not slide. 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 we are attempting to confine the physician’s movements to that 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 sample in the desired location, along with the filling and placement of the amniotic sac. Also, in the event that the amniotic sac is broken, it should be easily repaired or replaced. Breaking of the amniotic sac should not compromise any other components of the model. After taking into consideration these limitations, along with each specification set forth by our client, three potential design options have been devised.

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.

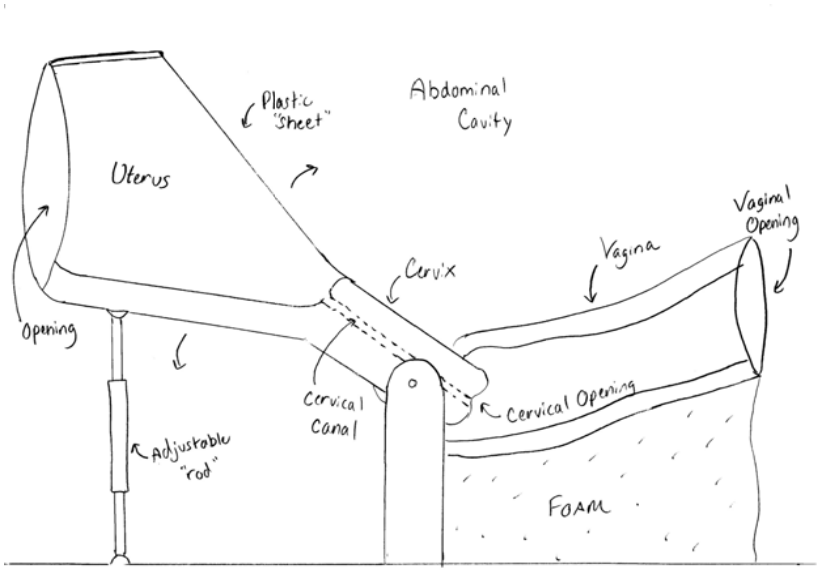

Figure 1- Proposed apparatus for design option #1

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.

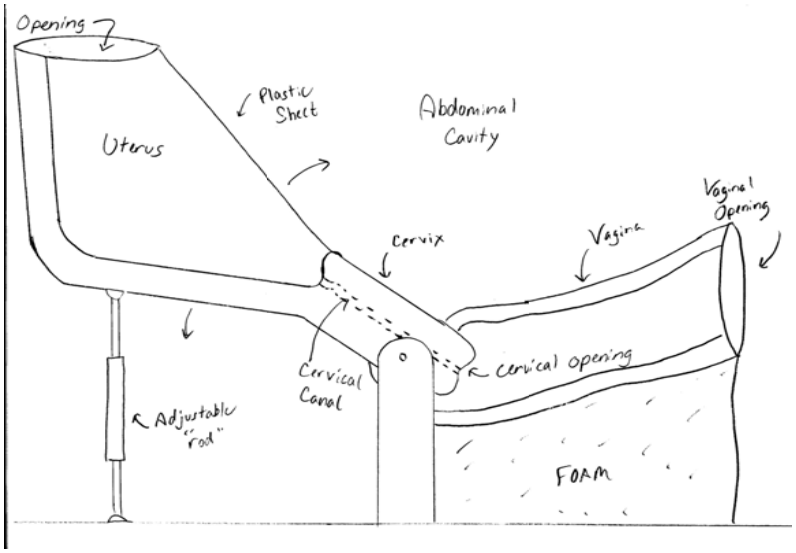

Figure 2- Proposed apparatus for design option #2

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.

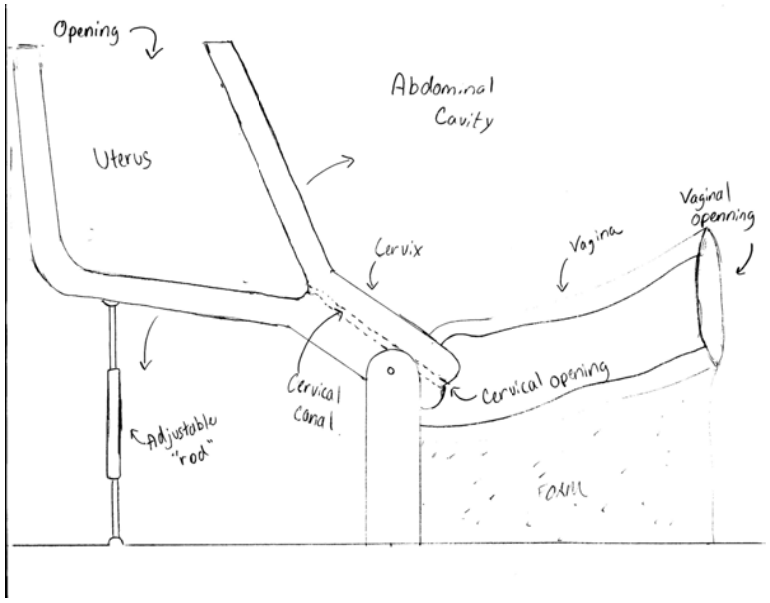

Figure 3- Proposed apparatus for design option #3

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.

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 three scored the highest in these two categories because it was the only option that incorporated an entirely enclosed uterus. Furthermore, design option three scored highest in the ease of use category because the Smooth-On EcoFlex® material provides the clearest ultrasound image, and the posterior uterine extension prevents any air bubbles in the amniotic sac from interfering with the ultrasound waves. Design option three received the lowest ratings under the ease of manufacturing and cost categories simply because it will require the most materials. However, this had a very minor effect on the overall rating of design option three.

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

Table 1- Design Matrix containing weighted point values

Future Work

Future work to be conducted over the course of the second half of this semester will be focused on manufacturing the model, then designing a support system for our device, and implementing this system into the final product for our client. After purchasing all the required materials, it will be necessary to construct a mold of the cervix and uterus, into which the Smooth-On EcoFlex® material will be poured. The molded cervix and uterus can then be engineered to incorporate the plastic vagina that is connected to the cervix by a hinge. Currently, we are exploring a few options for the support scheme for the model. These include, but are not limited to: the strategic placement of adjustable metal rods underneath and adjacent to the uterus and vagina, or encapsulating the model in a polyurethane rubber that could function for support as well as functioning as an abdominal cavity and abdominal wall. From there, the last task of the semester will be to conduct preliminary testing with our client to determine any flaws in the model. Testing will serve as the model's first exposure to a medical setting, and will be our last chance to make any necessary adjustments before our client puts the model to use.

References

[1] "Chorionic Villus Sampling (CVS)." Health and Baby. 13 May 2008. WebMD. 11 Feb. 2009. <http://www.webmd.com/baby/chorionic-villus-sampling-cvs>

[2] "Chorionic Villus Sampling." Medical Encyclopedia. 2 May 2008. Medicine Plus. 11 Feb. 2009. <http://www.nlm.nih.gov/medlineplus/ency/article/003406.htm>

[3] "Chorionic Villus Sampling." Pregnancy. 15 May 2008. Mayo Clinic. 11 Feb. 2009. <http://www.mayoclinic.com/health/chorionic-villus-sampling/MY00154>

Appendix A- Product Design Specifications (PDS)

Transcervical Model
2/10/09
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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.