Mechanical 3-D Model for Neuro-Endoscopic Surgery Simulation

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Abstract

Endoscopic third ventriculostomy is a surgery commonly performed on patients with hydrocephalus to release the pressure in the brain ventricles caused by blockages. These blockages could be due to tumors, brain tissue malformation, hemorrhages or cysts. The surgery occurs within the ventricular system of the brain and usually involves making an incision on the third ventricle floor. A model is required to properly train medical students and allow practice of this surgery to ensure that patients are not subjected to inexperienced surgeons performing their first procedure. The model has to be anatomically accurate and realistically simulate an actual surgery, including insertion of the endoscope, navigation through the ventricular system and finally the puncturing of the ventricle floor.

Problem Statement

Our client, Dr. Bermans Iskandar[6], Director of Pediatric Neurosurgery in the Department of Neurological Surgery at the University of Wisconsin Medical School, trains medical students to perform pediatric neurosurgeries. Presently, there is no viable model to train the students to perform endoscopic third ventriculostomy to relieve pressure in the ventricles due to build-up of Cerebrospinal Fluid (CSF). An anatomically accurate and realistic model is required to sufficiently train the medical students in technique so that patients are not subject to inexperienced surgeons performing their first surgery. The model should be disposable and similar to a hydrocephalic brain. It has to include the insertion of the endoscope and allow maneuverability in the ventricular system.

Background

There are approximately 100 billion nerve cells in the brain.[1] They form the main component of the brain and transmit and receive electrochemical signals; they control everything we do. Many structures are necessary to maintain this control, one of which is called the ventricular system (See Figure 1).[2]

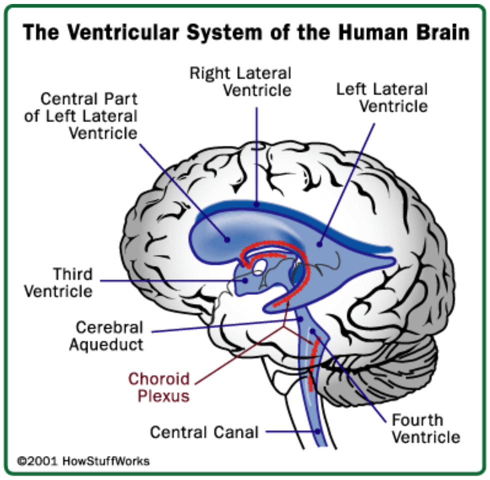

Figure 1: A representation of the human ventricular system[3].

The ventricular system is composed of four ventricles. These protect and nourish the brain by secreting cerebrospinal fluid (CSF). CSF surrounds the brain and spinal cord and seeps into the meninges, eventually getting absorbed by the body. The brain maintains around 120 mL of CSF and has to constantly produce more at a rate of 400-500 mL/day.[2] Normally, CSF starts out in the 1st and 2nd Lateral Ventricles and drains out via the intraventricular foramen into the smaller 3rd ventricle. From there, CSF flows through the cerebral aqueduct (located in the back of the 3rd ventricle) and down into the 4th ventricle or the subarachnoid space of the brain via the foramen of Magendie and the two foramen of Luschka.[4]

However, a condition called hydrocephalus can occur if there is a blockage in the ventricular system.[5] Hydrocephalus is most common in the very young and the very old and costs the U.S. about $1 billion in healthcare expenses every year.[12] It affects around three babies for every thousand births and is the leading cause of brain surgery in American children. The rate of death associated with hydrocephalus has decreased from 54% to 5% since 1980 and the rate of intellectual disability in children is about 30%. The most common blockage that obstructs the flow of CSF occurs in the cerebral aqueduct between the 3rd and 4th ventricles. Hydrocephalus is the buildup of CSF in the brain, causing excess pressure on important structures within the brain and possibly resulting in memory loss and cognitive damage. The blockage can be the result of a tumor, cyst, tissue malformation, or granular material. The problem can sometimes be rectified by removing the source of the blockage, allowing CSF to flow freely within the ventricular system.[6]

Our client performs a procedure called endoscopic third ventriculostomy, a common surgery used to remove the CSF buildup and reduce pressure in the ventricles.[6] To start the surgery, a hollow tool called an endoscope is inserted into one of the lateral ventricles. The surgeon then inserts a camera and other tools into the endoscope, maneuvering them through the ventricular system's foramens to get to the 3rd ventricle. From there, the surgeon can make an incision on the third ventricle floor to allow CSF to escape the ventricles.

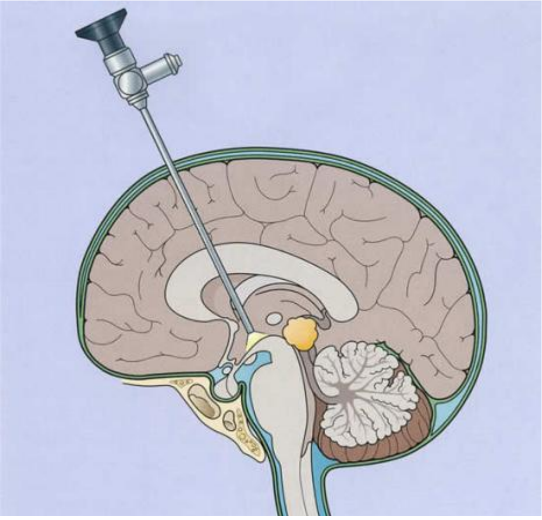

Figure 2: Endoscopic third ventriculostomy.[13]

Coordinating the movements of all the tools, the endoscope and the camera takes patience, experience and lots of practice; this is why our model needs to be as realistic as possible in simulating all aspects of the surgery. Thus, our model will focus on this procedure and be designed to allow the teaching and practice of performing this specific surgery.

Motivation

Training medical students in endoscopic neurosurgery is a difficult and delicate process and there are currently few products on the market for practicing endoscopic third ventriculostomy.[6] There are both mechanical and computer simulators on the market for surgeries, even ones for brain surgeries, but nothing specifically for endoscopic third ventriculostomy. Our client currently uses cadavers in order to train his medical students in endoscopic third ventriculostomy. This is not ideal because CSF drains from the ventricles after death, causing brain tissue to stiffen and the ventricle cavities to shrink. These problems make it difficult for medical students to maneuver the endoscope in the ventricular system and reach the 3rd ventricle floor. It also gives them a distorted perspective as they perform the procedure.

Surgeons should not be performing their first surgeries on actual patients because a neurosurgeon that lacks of practice, experience, or skill could endanger his or her patient's health. Our model will allow these students to practice their motor skills in practicing this procedure realistically, hopefully saving many children's lives in the process.

Client Requirements

The model should accurately simulate a hydrocephalic ventricular system and tissues to allow medical students to practice endoscopic third ventriculostomy, including insertion of the endoscope through the lateral ventricles and puncturing of the third ventricle floor. The model should resemble a hydrocephalic brain in anatomy and texture and be flexible enough to allow a rigid endoscope to maneuver in the ventricular system. The model should be disposable and easily reproduced so that multiple medical students can train using it. Structures surrounding and within the ventricular system include, but are not limited to: fornix, foramen, mammillary bodies, optic chiasm, basilar artery, pituitary glands and the third ventricle floor. These structures should be incorporated in the design of the model to ensure medical students are properly equipped to perform the surgery. We'll be incorporating them where it is appropriate. The model should allow endoscopes of diameters between 1-6 mm to be inserted in the ventricles. The model material should resemble the brain's texture in its shape, viscosity, elasticity, density, and strength. In addition it should allow a fluid resembling CSF to be added into the ventricular cavities, and cannot damage any surgical equipment. The model is a single unit and should not exceed the dimensions of 50 cm x 50 cm x 50 cm and weight of 10 kg. The model should withstand storage and usage under normal conditions of 25° C and 50% humidity.

Existing Devices

There are many versions of surgical simulation devices currently on the market; however we included the four devices most relevant to our client's requirements. The first is the Robotic Surgical Simulator (RoSS)[8] manufactured by Simulated Surgical Systems (see Figure 3). This virtual reality surgical simulator is specifically designed to enable surgeons to become adept at using the Da Vinci surgical robot. This device allows surgeons to practice a wide variety of surgeries; however, endoscopic third ventriculostomy is not one of the available choices.

Figure 3. RoSS virtual surgical simulator (Simulated Surgical Systems).8

Sensimmer[9] manufactured by Immersive Touch is another virtual surgical simulation device (see Figure 4). This product consists of a stereoscopic display with head and hand tracking devices to allow the surgeon to experience exactly what they would during an actual surgery. As with the previous simulator, multiple practice surgeries are available, but endoscopic third ventriculostomy is not a choice. This system is also very expensive-selling for around $200,000-$250,000-and our client is looking for a less expensive alternative.[14]

Figure 4. Sensimmer virtual surgery simulator[9]

Another surgical simulator is a mechanical model manufactured by SimuLab Corporation called TraumaMan (see Figure 5).[10] This surgical simulation dummy gives surgeons a life-size model to practice surgeries on. However, this physical model does not include any surgeries related to the head or brain.

Figure 5. TraumaMan physical model surgical simulator (SimulLab Corp).[10]


Figure 6. Simont model (ProDelphus)[11]

The final surgical simulator we found is the S.I.M.O.N.T. (Sinus Model Oto-Rhino Neuro Trainer), which is a surgical simulator capable of replicating various surgeries, including endoscopic third ventriculostomy (see figure 6).[11] Every model is custom-made to suit the client's preferences and demands. However, because of this, the model is very expensive, costing about $3,000 per model. The model also does not include fluid in the ventricles because it is made to be relatively durable. Therefore, it is not specific to endoscopic third ventriculostomy and cannot simulate the entire procedure.

Ethics

The ethical issues related to the model are indirectly, but closely related to patient well-being. The model has to imitate an actual hydrocephalic brain as far as possible because any mistakes in the design could cause the surgeon to practice improper surgical techniques that could seriously injure a patient in an actual procedure. Any medical student training with the model should understand that the model is a basic instrument for teaching, and cannot extensively simulate all possible surgical complications. The model will be constructed based on patient MRI scans. Hence, patient privacy is of utmost importance and should be respected.

Ergonomics

The model should be easy to prepare for use and should not be hazardous to set up. The model itself should not pose a threat to the user's health and should not contain any hazardous materials. It should be compatible for use with the tools and devices required to do an endoscopic third ventriculostomy; this is a design requirement of the client. In order to make the surgery look more realistic, the outside of the model should resemble an actual human head or skull.

During its use, the model should be easy to work with as though in an actual surgery. It should behave exactly like a real human head during an actual surgery. The non-disposable model head that will hold our model should be free of sharp edges to prevent accidental injuries. It should also lie at approximately a 45-degree angle to simulate a human head resting during an actual surgery. At the end of the procedure, the model should be easily maintained for further use. Any non-disposable parts of the model should not degrade too fast with repeated use or cleaning prior to an expected usage period. There is expected wear and tear on the model, but this outer model skull should last for at least one hundred practice surgeries.

Design Proposal Overview

The three design outlines below have been proposed as possible surgical practice models. Each design will contain disposable components, be fluid-filled, have a skull shaped exterior and an entry system to provide a realistic map for surgeons to practice endoscopic third ventriculostomy. All the designs have different distinguishing features that provide unique solutions to the problem.

Design 1: Enclosed Ventricular System Model

This design is a model of the ventricular system made from two halves of silicone molds that can be combined into one entire disposable insert to be used in a durable skull exterior. Low density silicone is a very good representation of the actual brain and would allow our client to use a rigid endoscope to perform the surgery in the model. It is pliable and can withstand a lot of torsion before tearing relative to some other materials we considered.

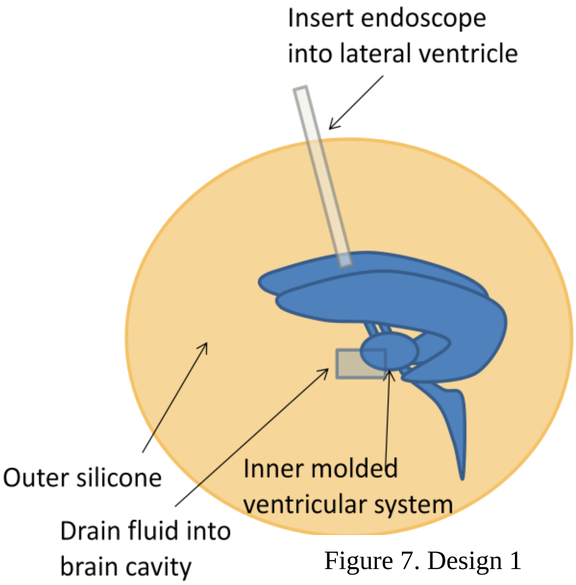

Figure 7. Design 1

The design and materials allow the ventricle floor to be punctured, just like in an actual endoscopic third ventriculostomy procedure. The model would be pre-filled with mineral oil before the halves were assembled so that the ventricular system would contain a fluid resembling CSF inside it also adding to the realism of the model. The mineral oil would be filled by the same company that will assemble the model before shipping it to us. The entry to the first ventricle will be puncturable so that the user could begin using the model as if starting the actual surgery.

The model will be constructed using MRI scans of a hydrocephalic brain to create master cast that will be made using injection molding technology. This master cast of the ventricles will be used to cast the ventricular system as a negative, which will have silicone molded around it, giving us a silicone model with a realistic hollow ventricular system inside it. Due to the puncturing of the model and the possible wear on silicone throughout the process, the models are designed to be disposable. However, once the master cast has been made, mass production of silicone models is relatively easy and cost-effective. This allows multiple models to be produced. Therefore, our client can teach multiple students at once and students can practice the procedure multiple times.

Because the model is pre-filled and pre-assembled by a silicone molding company, one of the biggest strengths of this model is that it is very convenient for our client to begin using the model. After the top of one of the lateral ventricles is punctured, the model will be ready for use. However, the model may burst or leak during shipping and handling. Once the fluid is drained out of the model, it is essentially useless because there is no mechanism to refill the model with fluid. This is the biggest weakness of the design.

Design 2: Capped Ventricles Model

The capped ventricles model will allow medical students to puncture and stretch the third ventricle floor during the procedure without worrying about fluid leakage in the model. A cap attached to the outside of the third ventricle floor will catch the fluid as it escapes through the incision and prevent any fluid leaking in the model. The medical students can stretch the ventricle floor and continue the remainder of the surgery without having to worry about fluid escaping the model and interfering with the equipment.

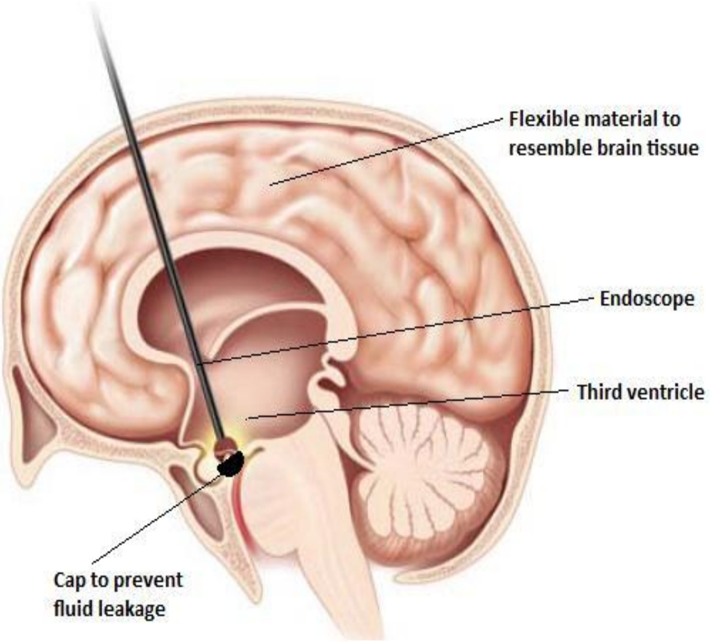

Figure 8: Design 2.[6]

The model will feature a block of material resembling brain tissue at the top of the head where the endoscope enters. This will allow medical students to practice inserting the endoscope into the brain as though it were an actual surgery. Because the model is designed to be flexible, disposable and easily reproducible, the medical students can afford to err in their endoscope entry angle until they arrive at the correct position.

A fluid resembling CSF will be introduced into the ventricular model via a valve system, which allows medical students to inject the fluid into the model using a syringe. The valve prevents any leakage of the fluid and ensures that the system is completely filled with fluid. Medical students can tilt the model slightly to ensure that air bubbles can escape and are not present during the surgery. Air bubbles in the ventricular system can interfere with endoscope optics and significantly affect the performance of the surgeon.

The model will feature the disposable ventricular system insert made of a material chosen to represent brain tissue, as well as the durable human skull, which will have a solid interior that allows the disposable insert to be fitted and removed easily. The model will be created based on MRI scans of a patient affected by hydrocephalus. After creating the computer program of the ventricular system, the entry section and ventricle floor cap will be added in the program and sent to a rapid prototyping company to be created using an S.L.A. (Stereolithography) technique. The model will be created using urethane casting technology, which is a cheaper alternative given the number of models required to be printed. An elastomeric and fluid-resistant material will be used to construct the model, since it has to resemble brain tissue in its flexibility, yet withstand the pressure of the fluid in the model.

The model is relatively simple and inexpensive to produce because it is composed entirely of the same material and does not include any additional components. The medical students can practice on the model, discard it, place a new disposable ventricular system insert in its place, and simulate the surgery again. The interior of the model will be a cheap and non-toxic material similar to Styrofoam and will hold the inserts in place as the surgery is practiced. This allows the medical students to practice the entire surgery numerous times, including the insertion of the endoscope, making of the incision on the ventricle floor, and stretching of the incision. However, the valve system may not always function properly if the medical students are unfamiliar with it, and this could result in air bubbles present in the ventricles, distorting the endoscope optics and reducing the realism of the simulation.

Design 3: Ballistics Gel Model

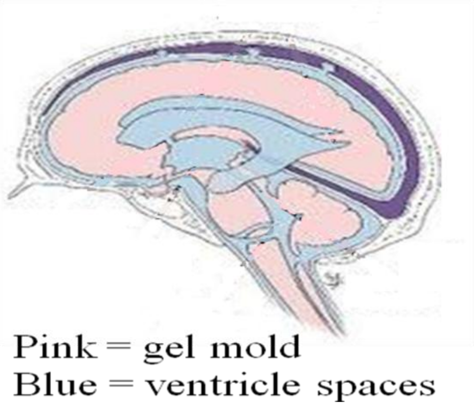

Figure 9. Injection Mold Ventricle schematic. Blue represents the ventricle system and Pink represents the final model. (LifeART).[3]

The Ballistics Gel Model will be a full-size brain made of ballistics gelatin cast around a previously made model of the ventricles and surrounding structures. Because the entire model is made of the gel, it allows the client to discard each one after the procedures. The gel is very cheap and can only last a few days after it is made, so the models would be produced right before usage. Another advantage of using the gelatin is that it allows control of the consistency of the model by varying the recipe. Because of this, an accurate and realistic model can be created, with a material comparable to the realistic consistency of the brain.

Figure 10. Ballistics Gel Material www.RottenEggs.com

This outline will be made by first having a rapid prototype company create a hard cast of the ventricles (see figure 9). This cast will then be placed into a skull-shaped mold and gelatin poured over it to create a model with hollow cavities in it. After the molding process is complete, the model will be split into multiple components to be separated from the cast because it is too intricate to be removed as a single piece. We'll be cutting it with a room temperature, sharp knife; minimizing any tearing and deformations that may occur. After the removal of the ventricles, the pieces will be re-assembled by 'welding' them back together. This is done by heating up the respective cut areas with a heat source, such as a hot pan, for a few seconds and then holding them together. Initial experiments with the gel showed that this makes an adequate, watertight seal and is barely noticeable afterward. The gel model will then be filled with a mineral oil to imitate CSF in the ventricles with a needle and a syringe.

Design Evaluation

In order to evaluate the designs, a list of criteria for the model was developed that includes: anatomical accuracy, teaching effectiveness, cost, duplicability and feasibility. Table 1 evaluates the designs based on these criteria and allows a final design to be chosen. Each criterion was given a certain weight based on the importance it has on developing an accurate surgical simulation. The maximum total score a design can receive is 100.

The first and most important category is anatomical accuracy; therefore, it is given the highest weight of 30. The enclosed ventricular system will be made by injection molding and MRI scans and will come pre-filled with fluid, leading to a more accurate representation of the ventricular system. Urethane casting can produce an accurate representation of the brain tissue and ventricular system for the capped ventricle model, but will not be as detailed as 3D printing. The ballistics gel design requires the model to be removed from the cast in separate sections and put back together. This causes its accuracy to be diminished, giving it a lower score (See Table 1).

The effectiveness of the model as an endoscopic third ventriculostomy teaching tool is a critical aspect to the design. This gives the criterion a weight of 30 as well. The enclosed ventricular system will also be effective in teaching due to the model's high accuracy and pre-filled ventricular system, which gives the simulation added realism. The capped ventricle design may face the problem of air bubbles developing in the ventricles while it's being filled despite the valve system. These air pockets may interfere with the optics of the endoscope and decrease the realism of the simulation. The ballistic gel model will be a realistic representation of the brain and ventricular system. Its entry system and material are similar to that of a real surgery, allowing surgeons to fully practice the entire procedure. The ballistic gel model will be effective as a practice and teaching tool (See Table 1).

The next criterion is the cost to develop the models. This cost includes the start up cost along with the long term cost of reproducing more models since these designs are disposable. This category receives a weight of 20. For the enclosed ventricular system, the cost of having a rapid prototyping company print and pre-fill the model with a fluid will be high. The capped ventricles model will also be costly because of the valve system that has to be printed with the model. Ballistics gel molding will be the cheapest to reproduce but the initial cast is expensive and it will be labor intensive (See Table 1).

Duplicability is the ease with which the model can be reproduced so that neurosurgeons can continue practicing with it. This category includes the time it will take and the ease with which the models can be produced. It has a weight of 10. The enclosed ventricular system is complicated to produce because of the pre-filling of the model with fluid. Also, any accidents during transport or storage could cause the model to leak, rendering it useless. The capped ventricles system is simpler in comparison, but still moderately difficult to reproduce because it involves coordinating with a rapid prototyping company and involves shipping and handling. Ballistics gel molding is achievable in a relatively short amount of time and only takes a small amount of effort in cutting the ventricular system out and rebuilding the model (See Table 1).

The last criterion is the feasibility of producing these designs, which is the plausibility of it being completed within our time frame of a single semester. Since these designs are formulated with that in mind, this criterion only receives a weight of 10. The enclosed ventricular system requires a high degree of complexity in the model because of its pre-filled design. The capped ventricles model requires that a working valve system be designed in the model. The ballistic gel model involves only the printing of the ventricle system and the design of a system of producing the model from the cast (See Table 1).

By adding up the scores of all the criteria, a final design can be chosen. Ballistics gel molding has the highest score and is hence our final design choice.

Design	Weight	Enclosed Ventricular System	Capped Ventricles Model	Ballistics Gel Molding
Accuracy	30	28	27	25
Teaching Effectiveness	30	28	24	28
Cost	20	13	14	18
Duplicable	10	7	7	9
Feasibility	10	8	8	9
Total	100	84	80	89

Table 1: Design matrix evaluations

Material Evaluation

The materials being used in the designs need to accurately represent the brain tissue in almost every way. In order to ensure this accuracy, we judged the materials in the categories of strength, flexibility, small detail capability and fluid compatibility. Each category has a max score of 5. Because some of the materials are closely related to the technology with which they are printed, some natural pairings of material and technology choice result and are discussed below. The materials being evaluated are silicone, urethane, PolyJet Gray, Tango Plus and ballistics gel. Silicone is a polymer that is thermally stable, fluid-resistant, and air-tight. It has a low chemical reactivity, is flexible and has a high tear-resistance. Urethane is a widely used molding material with high tear-strength and elasticity. The properties of urethane can be varied by combining it in different proportions with other materials. PolyJet Gray is commonly used for prototypes and parts that require fine detail. Tango Plus is a flexible rubber-like material used in high-accuracy parts. Ballistics gel is a solution of gelatin and water, so its density and viscosity can be varied to represent different materials by simply changing the proportions of gelatin and water. Table 2 compares the materials and evaluates them as suitable materials to produce the model out of.

Some of these materials require specific printing technologies to match them. These printing technologies include injection molding, urethane casting and sterolithography. Injection molding is a thermoplastic manufacturing process that takes 3D CAD files and turns them into fully functional parts. A cast is produced from the CAD files, essentially a negative of the final product, and is used to subsequently cast the model. It involves a high initial cost to produce the cast, but subsequent models made of silicone can be created at a lower cost. Urethane casting is a faster and cheaper method that is similar to injection molding. This technology can produce low cost silicone and urethane models, but we will primarily use it with urethane. Stereolithography is an additive process using a UV-sensitive resin. A laser traces out the shape on a particular layer of the design. The resin cures upon exposure to UV, hardening it and adhering it to the previous layers.

As shown in Table 2, all the materials evaluated received a similar total score. Therefore, the material choice was not a major factor in our consideration of the final design.

Material	Silicone	Urethane	PolyJet Gray	Tango Plus Fullcure 930	Ballistics Gel (Ballistics Gel Model)

Durability	5	5	5	4	5
Flexibility	4	4	3	5	4
Small Detail Capability	4	4	5	4	4
Fluid Compatibility	5	4	4	4	4
Total	18	17	17	17	17

Table 2: Evaluation of materials matrix

Prototype Construction

We initially planned to create a CAD version of the brain ventricles using MRI scans and use that for rapid prototyping to obtain the solid ventricle system. However, the first program we tried, 3D doctor, was unable to save any of the files because it was a trial version. A licensed version costs $750, which was beyond our budget, so we decided to change to another program.

We met with Alan Meyer, one of the team members from last year, to learn the AutoCAD program and use it to create the ventricles instead. However, despite our efforts, the program version we had was unable to handle the intricate details in the brain ventricles and constantly crashed because of it. Because of these difficulties, we decided to modify our design to meet the impending deadline.

We constructed a model of the ventricular system with modeling clay using our general knowledge of the system and the MRI images (see figure 11). The model was then baked to solidify and harden. Meanwhile, we had been testing the properties of ballistics gel to formulate the most realistic recipe to cast the model with. Once we had a solid ventricular system, we cast our model out of the ballistics gel by pouring the premixed ballistics gel into a watertight skull. This was left to cool in a fridge, above 0° C, for about 36 hours to set. We then removed the entire system of gelatin and ventricles from the skull. Next, we made a circular cut into the ballistics gelatin with a sharp knife at room temperature, and removed the solid ventricles in one piece. We minimized the number of cuts needed with practice and found that we could put the ballistics gel back together using a method similar to cauterizing.

Figure 11. Solid ventricular system model

We placed the cut halves of the model cut side down on a hot pan over the stove to melt the cut surfaces. Once they were sufficiently melted, we fitted them back together and allowed them to cool and set again. This made a watertight seal and our model was able to keep its shape. After the model was reconstructed, we could then fill the hollow ventricles of the model with mineral oil using a needle and a syringe.

Material testing

Figure 12. BB embedded in ballistic gel

The consistency of ballistics gel varies with its proportions and temperature. Therefore, there is the need to test the ballistics gel to determine the optimal consistency that will most accurately represent the properties of human brain tissue. We decided to test the ballistics gel by using BB gun calibration test, which is the standard test used by professionals to ensure that the ballistic gel accurately represents human tissue before it is used in gun ranges. It is performed by shooting a BB gun into the gel and then measuring the distances traveled by the BBs (see figure 12). This then gives a quantitative representation of the tensile strength of the ballistic gel. We decided to test three different consistencies that we believed could accurately represent human brain tissue. The formulas we used to create these consistencies were: 1 oz (28.3g) gelatin to 1 cup (237mL) of water, 1.5 oz (42.5g) gelatin to 1 cup of water, and 2 oz (56.7g) gelatin to 1 cup of water. We also tested these consistencies at three different temperatures: 40° F (4.4°C), 55° F (13°C), and room temperature of 70° F (21.1°C). To keep the results consistent, we first ensured the BBs would fire at the same velocity by pumping the gun twice and firing it into a control batch of ballistic gel. We then measured how far the BBs traveled. The BBs traveled approximately the same distance, indicating that the gun was firing at approximately the same velocity each time.

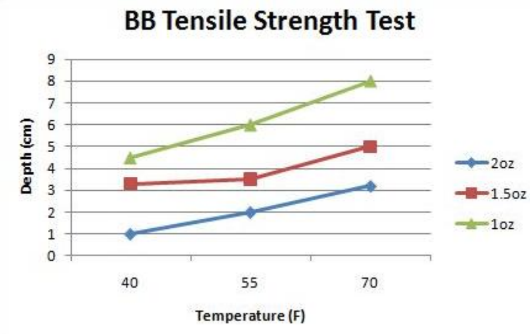

Figure 13. BB gun testing results

Through the testing, we discovered that initially at 40°F the 1 oz: 1 cup mixture produced the gel with the lowest tensile strength, indicated by the longest distance traveled by the BB (see figure 13). Similarly, the 1.5 oz: 1 cup mixture was more tensile and the 2 oz: 1 cup mixture had the highest tensile strength. As temperature rose, all the ballistic gel consistencies lost tensile strength as expected.

In order to determine which consistency would represent human brain tissue, we relayed on the expertise of our client. We had our client feel a 1 oz: 1 cup mixture of ballistics gel at approximately 55° F. The client like the overall texture of the ballistic gel but believed it was slightly too stiff. However, he also said that the current tensile strength could work to create practice model if necessary. Since we had discovered through our testing that ballistic gel loses tensile strength as temperature rises to room temperature, we predicted that the 1 oz: 1 cup mixture would accurately represent human brain tissue at room temperature. Therefore, we used this mixture to produce our final design. This choice is also optimal because practice surgeries with this model will be performed at room temperature, so a model at room temperature would be the most convenient to produce and maintain. However, the temperature would need to be taken before the practice surgery is performed to ensure the model is ready to be used with the correct tensile strength.

Future Work

For the future of this project, we will work on getting a program able to handle the MRI images and produce a working CAD file of the hydrocephalic ventricular system. The file will then be sent to a rapid prototyping company to be printed. The result will be a reusable and durable ventricular system that will be used as a negative to produce the final ventricular system model. Incorporated into this model will be the system to give an obstruction between the third and fourth ventricle. We will then produce the models using a head-shaped container as the outside mold. The final product will resemble a head shape and have hollow cavities as the ventricular system.

Further down the road we could implement a series of gel models to complement the training of the medical students. We could produce basic models similar to our current model, but also include more advanced models that are higher in difficulty. One possible way of doing this could simply be with the changing of the color of the ballistics gelatin. Because the angle of entry of the endoscope is so critical to the success of the surgery, the easier it is to see the ventricles, the easier this vision of the entry point will be. A way to make this surgery more realistic and challenging would be to create opaque models to ensure that medical students are able to guide the endoscope to enter with the proper angle of entry without any help.

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Appendix A: Product Design Specification Report

Product Design Specification Report

Mechanical 3-D Model for Neuro-Endoscopic Surgery Simulation

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Date:	4th February 2011

Problem statement:

Our client, Dr. Bermans Iskandar, Director of Pediatric Neurosurgery in the Department of Neurological Surgery at the University of Wisconsin Medical School, trains medical students to perform pediatric neurosurgeries. Presently, there is no viable model to train the students to perform Endoscopic Third Ventriculostomy to relieve pressure in the ventricles due to build-up of Cerebrospinal Fluid (CSF). An anatomically accurate and realistic model is required to sufficiently train the medical students in technique so that patients are not subject to inexperienced surgeons performing their first surgery. The model should be disposable and similar to a hydrocephalic brain. It has to include the insertion of the endoscope and allow maneuverability in the ventricular system.

Client requirements

- Allow practice of Endoscopic Third Ventriculostomy
- Anatomically accurate and similar to brain texture
  - Allow maneuver of rigid endoscope
- Similar to a hydrocephalic brain
- Disposable and mass-producible
- Include surgical entrance through lateral ventricles
- Include structures in the lateral ventricles and 3rd ventricle
  - Fornix
  - Foramen
  - Ventricle floor (3rd ventricle)
  - Mammillary bodies
  - Optic chiasm
  - Basilar artery
- Allow endoscopes of diameter 4mm-6mm in procedure
  - Tract and foramen at least 7mm in diameter
- Puncturable 3rd ventricle floor
- Allow CSF in model
- Storable under normal conditions
  - 25°C
  - 50% humidity

- Dimensions smaller than 50cm x 50cm x 50cm
- Weight below 10kg
- Under $500 budget

Design Requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The model should be able to withstand the simulation of a 90-minute neuro-endoscopy procedure, including the addition and removal of mineral oil and the movement of the rigid endoscope within the model.

b. *Safety*: The model should not pose any safety risk to the user or contain any toxic materials or sharp edges. There should be no fluids or materials in the model that can pose pathological concerns. Though dangerous instruments may be used during the usage of the model, the model itself should pose no danger to the user.

c. *Accuracy and Reliability*: The model should accurately reflect the described neuro-endoscopic procedure and include all the necessary structures for teaching this procedure. Specifically, it should be 292mm x 172mm x 195mm, which are the dimensions of the model based on the MRI scans. The material should be flexible and resemble brain tissue. It should be easily re-producible for multiple procedures.

d. *Life in Service*: The model should not degrade during the 90-minute procedure. It may be destroyed or modified during the procedure, but it should not otherwise change. The model should be identical to all other models produced to ensure anatomical accuracy.

e. *Shelf Life*: The model and all its components should not degrade in storage under normal storage conditions for at least 5 years. It should withstand storage for a week under usage conditions without any changes to its structural or material qualities.

f. *Operating Environment*: The neuro-endoscopy procedure will be performed at approximately 25°C and 50% humidity.

g. *Ergonomics*: The model will be used by one surgeon at a time but other surgeons will be present to observe the procedure. The model should only be used with proper neuro-endoscopic tools such as the endoscope, specifically a high quality rigid endoscope. The surgeon will insert the endoscope in the ventricular system through the lateral ventricles, navigate through the system using the rigid endoscope, arrive at the third ventricle, make an incision on the third ventricle floor, and finally stretch the incision to a maximum of 7mm in diameter.

h. *Size*: The model should not exceed 50cm x 50cm x 50cm and should allow a minimum of 1m space around the model to allow the surgeon to access the model easily.

i. *Weight*: The model can be portable or stationary, depending on its sophistication. No limitation on weight since it can depend on the quality of the model.

j. *Materials*: All materials used must not pose health risks or be abrasive to humans under normal use. Materials should be non-radioactive, non-flammable, and non-corrosive. Material should be able to with hold fluid (to be determined) inside the model.

k. *Aesthetics, Appearance, and Finish*: The model should be visually appealing and represent the anatomy of the brain. The color should preferably be gray or another color similar to brain tissue. The overall model should have a smooth, polished appearance.

2. Production Characteristics

a. *Quantity*: One model is required at present. However, the model should be easily replicated and multiple models should be easily manufactured in the future.

b. *Target Product Cost*: The target manufacturing cost for the product is $500, which is approximately one tenth the price of the cheapest comparable products on the market.

3. Miscellaneous

a. *Standards and Specifications*: This model will not require any approval by the FDA because this product is not a medical device used in or with human subjects.

b. *Customer*: The product should adhere strictly to the customer’s requirements of being anatomically accurate and effective in the training of medical students in Endoscopic Third Ventriculostomy.

c. *Patient-related concerns*: The product will not be in contact with any patients. However, patient information may be required to produce the hydrocephalic brain model and therefore patient privacy has to be protected. The model should not endanger the surgeons using the model.

d. *Competition*: There are 3 virtual programs and 1 physical model currently on the market that are similar to our client’s requirements. The software programs are manufactured by Vivendi Software, Simulated Surgical Systems, and Immersive Touch. The physical model is made by Simulab Corporation. These products are very expensive, limited in practice procedures, or both.