

# **Mechanical Model for Neuro-Endoscopic Surgery Simulation**

BME 300  
University of Wisconsin-Madison  
Department of Biomedical Engineering  
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## Abstract

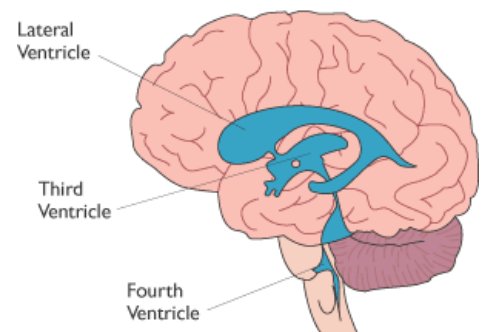
A surgical procedure known as endoscopic third ventriculostomy is performed on patients with hydrocephalus. This surgery takes place within the brain's ventricular system, most commonly in the cerebral aqueduct, the channel connecting the third and fourth ventricles. The endoscopic surgery removes cerebral aqueduct blockages that occur due to hemorrhage, malformation of tissue, tumors, or cysts. Medical students need to practice this endoscopic procedure so they do not perform their first procedures on live patients. At present, no such teaching mechanism exists. An anatomically correct, mechanical model needs to be designed in order to properly train students on endoscopic third ventriculostomy. The focus of the model will be in allowing the medical students to rehearse the insertion of the endoscope into the ventricles with the correct entry angle and practice controlled navigation of the endoscope throughout the ventricular system.

## Problem Statement

The client, Dr. Bermans Iskandar, of the Department of Neurological Surgery at the UW Hospital, performs pediatric neurosurgeries. Currently, his medical students do not have a surgical simulator to practice endoscopic third ventriculostomy to remove blockages in the cerebral aqueduct. A model of the ventricular system to teach and practice surgeries is necessary so that patients are not subject to initial trial surgeries by medical students. The model needs to be anatomically correct and allow the surgeon to practice control of their fine motor skills. The model should include insertion of the endoscope into the ventricles and be durable enough to train multiple students on the surgical techniques.

## Background

The ventricular system consists of four ventricles: two lateral ventricles (1<sup>st</sup> and 2<sup>nd</sup>) along with the third and fourth ventricles which lie in the medial plane. The ventricles are cavities in the brain that produce cerebrospinal fluid to nourish the brain. The cerebrospinal fluid (CSF) bathes the brain and

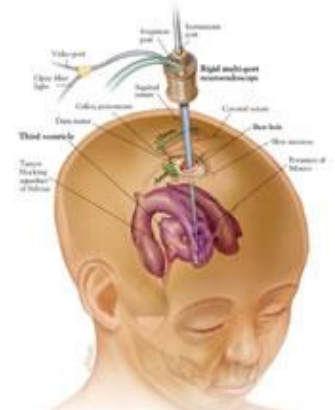


**Figure 1.** Ventricular system within the brain.

spinal cord and is important for nutrient delivery to the brain, waste removal from the brain, and mechanical protection of the brain. The ventricles are interconnected by aqueducts that allow the CSF to flow from the lateral ventricles, through the 3<sup>rd</sup> ventricle, drain out of the 4<sup>th</sup> ventricle into the membranous area surrounding the brain, and finally flow into the spinal cord. The foramina of Monro are the set of aqueducts that connect the two lateral ventricles to the 3<sup>rd</sup> ventricle and the cerebral aqueduct connects the 3<sup>rd</sup> and 4<sup>th</sup> ventricles. See Figure 1 for a side view of the ventricular system (Ventricular System, 2010).

A medical condition known as hydrocephalus is a buildup of cerebrospinal fluid within the brain that causes increased pressure on the brain. Hydrocephalus affects approximately 1 in 500 children shortly after birth (NINDS, 2010). A common cause of hydrocephalus is a blockage between two of the ventricles, limiting the flow of CSF out of the ventricles. The most common obstruction occurs within the cerebral aqueduct. This blockage can be caused by granular material in the channel, tumors, cysts, or malformation of the duct tissues. The excess fluid buildup puts pressure on important brain structures and may lead to memory loss and cognitive changes. In order to correct the problem, the blockage must be surgically removed.

A surgical procedure to remove an obstacle in the cerebral aqueduct using an endoscope is called endoscopic third ventriculostomy. Endoscopic aqueductoplasty is another surgery performed to remove the blockage; however, endoscopic third ventriculostomy is the most common and will therefore be the focus of our model. The endoscopic third ventriculostomy procedure begins with the insertion of the endoscope into the first or second ventricle (Figure 2). The endoscope (Figure 3) is a hollow tube with a size range from 1 to 6.2 mm in diameter. A camera and other tools are inserted down the endoscope tube and maneuvered through the lateral ventricle, then the foramina of Monro, and finally into the third ventricle. Once inside of the third ventricle, the surgeon used the mammillary bodies as a guide to find the location to make an incision in the wall of the third ventricle. Once the incision is made, the surgeon uses a balloon to dilate the hole to a diameter of 4-5 millimeters. Any larger than 5 millimeters and the surgeon runs the



**Figure 2.** Diagram of how endoscope is inserted into lateral ventricles (Pope, 2010).



**Figure 3.** MINOP neuro-surgery Endoscope manufactured by Aesculap. This model is used by our client.

risk of damaging the surrounding brain structures and potentially killing the patient. This is why anatomical accuracy is so important to our model. The surgeon continues moving the camera into the cerebral aqueduct and removes the blockage with other tools, using the camera to view the surgical area. Maneuverability and coordination are imperative in these surgeries and these skills can only develop from experience and training (Aesculap, 2010).

## **Motivation**

Training medical students in procedures using endoscopic technology has some challenges. There are surgery simulators for the body, even ones specific for laparoscopic procedures, but there are no good models for medical students to practice endoscopic procedures involving the brain ventricles. There is a need for a model to practice endoscopic third ventriculostomy, the surgical procedure commonly used to relieve hydrocephalus. Currently, practice endoscopic third ventriculostomy surgeries are done on cadavers, but this is not an accurate model for live brains. After death, the fluid in the ventricles drains into the rest of the body, causing the ventricles to shrink from their natural size, and the texture of the brain tissue is also stiffer in cadavers. This causes the medical students to have an unrealistic practice situation, and therefore does not properly equip them with the necessary skills to perform the procedure in an actual surgery.

Designing a complete computer software program is possible, but would be extremely expensive. This is because this specific surgical procedure has not been implemented into a software program to date. A mechanical model would allow medical students to practice the endoscopic third ventriculostomy without the textural, size, and cost issues. This will benefit medical students by giving them experience using the endoscope and tools within a ventricular system. Patients will benefit because their surgeon is not performing this surgery for the first time. A patient should not be the first learning tool for any student, and our model will address anatomy and provide a beneficial learning experience.

## **Client Requirements**

The model must simulate the endoscopic third ventriculostomy surgical procedure. It will help train neurosurgeon's fine motor skills that are used during the surgery, and it will simulate the removal of the most common blockage of the ventricular system within the cerebral

aqueduct. The model must have an anatomically correct ventricular system. Structures immediately surrounding the ventricular system including, but not limited to: blood vessels, arteries, and choroid plexus should also be present if applicable in the design. The model must work for the endoscope with a minimum diameter of 1mm and a maximum diameter of 6.2 mm. The model must be one unit and weigh less than 5 kg. Model dimensions should not exceed 25 cm x 25 cm x 25 cm. The model needs to withstand daily use for two years in a classroom environment, storage and use at room temperature, and have a shelf life of 5 years. The material that the model is constructed from should simulate the texture and properties of the ventricular system tissues, exhibit compatibility with fluid, and not damage the surgical equipment used during the procedure.

### Existing Devices

Although there are many versions of the surgical simulation devices, we have included the three devices that are most applicable to our client's problem. The first of these devices is the Robotic Surgical Simulator (RoSS) manufactured by Simulated Surgical Systems (see Figure 4). This virtual reality surgical simulator is specifically geared to enabling surgeons to become proficient at using the Da Vinci surgical robot. This device allows surgeons to practice a wide variety of surgeries; however, endoscopic third ventriculostomy is not currently one of the available choices. The cost is also in the tens of thousands of dollars range, depending on the features that are desired.

Sensimmer manufactured by Immersive Touch is another virtual surgical simulation device (see Figure 5). This product consists of a stereoscopic display with head and hand tracking devices to allow the surgeon to see and feel exactly what they would during actual surgery. As with the previous device, multiple practice surgeries are available, but endoscopic third ventriculostomy is not an option. This system costs between \$200,000 and \$ 250,000. Our client is looking for a cheaper option.

The final type of surgical simulator is a mechanical model manufactured by SimuLab Corporation called TraumaMan (see Figure 6).



**Figure 4.** RoSS virtual surgical simulator (Simulated Surgical Systems).



**Figure 5.** Sensimmer virtual surgery simulator (Immersive Touch).



**Figure 6.** TraumaMan physical model surgical simulator (SimuLab Corp).

This surgical simulation dummy gives surgeons a life size mannequin to practice surgeries. However, this physical model does not include any surgeries related to the head or brain.

### **Ethics**

The ethical concerns involved with creating a model with which surgeons will practice brain endoscopy are related indirectly to patient care. The model needs to be a precise, accurate, and anatomically correct model of a real patient's brain ventricles because any errors in constructing the model could cause a surgeon to practice surgical techniques that are harmful or fatal when applied to a live patient. Any surgeon practicing surgeries using the model should be aware that the model does not simulate surgical complications that may arise during an actual procedure, and should be properly trained to handle any situations that may arise. When using MRI scans of a real patient to construct and present the model, patient privacy must be respected.

### **Ergonomics**

The brain model needs to be able to facilitate all of the surgical tools required during an endoscopy. It should not damage surgical tools, such as the endoscope, used during the stimulated procedure. The fluid used inside the model should not degrade the materials used to construct the model. The exterior housing and mounting base for the brain model should be free of sharp edges so the user is not harmed. In order to make the simulation more realistic, the exterior housing needs to resemble as human head or skull. The forces applied by the user to the model should not be excessive, since the materials will be somewhat prone to puncturing in order to mimic the brain tissue's elasticity.

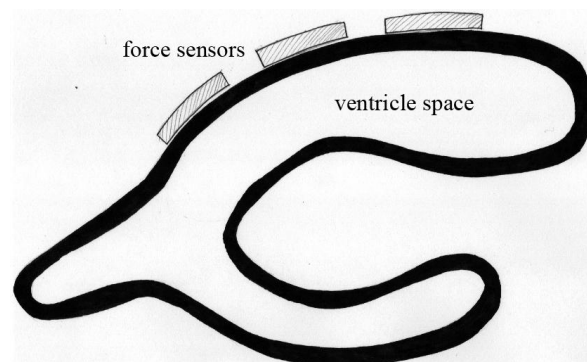
### **Design Proposal Overview**

The model functions as a training simulation for neurosurgeons performing endoscopic third ventriculostomy on patients. Proper anatomic representation of the ventricular system must be preserved in the model. The surgical procedure targets the third ventricle because it is connected the cerebral aqueduct, the most commonly block area of the ventricular system. The surgical procedure needs to be mimicked as precisely as possible, without erroneous distraction to the procedure itself. Textures and properties of the tissue surrounding the ventricles should be taken into account when choosing materials for the model. All three designs feature a skull-

shaped exterior, which provides a realistic map for the surgeons to practice inserting the endoscope with a sense of where the entry point is relative to the rest of the skull. Every design has different features that distinguishes itself and provides a unique solution to the problem.

### Design 1: Force Sensor Design

The force sensor design is based on the ability of the surgical simulation to give auditory feedback to the user if they apply too much force to a fragile brain structure. As a training tool, this is incredibly useful to let a student know if they perform the procedure incorrectly. The design of the ventricle structures would have to have thin walls outlining the cavity of the ventricular structure. On the outside of these thin walls, we would put force



**Figure 7.** Force Sensor Design.

sensors (see Figure 7). A deformation in the ventricular walls would transfer to the outside wall of the structure and trigger the force sensor to send a signal to a buzzer. The force sensors will be supported on the outside by a gel substance to provide support and resistance to pressure. The buzzer would be set to give feedback only in the case of a threshold pressure being applied. Different structures that surround the ventricles would be assigned different threshold values. Some structures are more likely to be punctured, tear easily, or are fatal if struck during surgery. These structures would have a lower threshold pressure than the rest of the ventricular cavity programmed into the sensors for providing the buzzer feedback.

The ventricles would be created by using MRI scans of a person's head to assemble a 3-dimensional computerized image of the ventricles. This image would be sent out to a company for rapid prototyping and would be made into a 3-dimensional structure. This rapid prototype would be made of a polymer that is pliable even after being fully cured. This recreation of the ventricles would be fitted with a system of force sensors providing information to a buzzer. The ventricles with the force sensors attached would be placed inside a skull shaped holding container. An issue with this design would be the lack of structural support for the ventricles. Not all surfaces would require sensors and these solid areas would be utilized in providing some structural support. Maintenance of the model would be problematic if the electrical sensors



malfunctioned, since there is no way to access the ventricle walls once the model has been assembled.

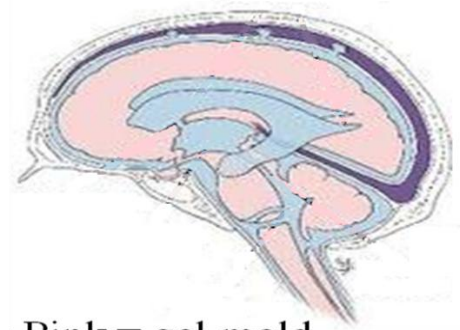
### Design 2: Injection Mold Ventricle System

The injection mold design will use a cast of the brain ventricles to make a mold representing the ventricles in the actual brain (See Figure 8). Like the force sensor model, the cast of the ventricles would be constructed using MRI scans and rapid prototyping. Once the cast is made, the negative of the cast can be made from a gel by means of liquid injection. The rapid prototype material will be firmer than the actual tissue, whereas the injection mold gel will better approximate the consistency of the tissues and organs surrounding the brain

One of the main features of this design is that the models will be mass-producible and relatively cheap after the initial model has been made. This is due to the high cost of creating the molds when producing a single model; however, the same mold can be used multiple times. The mass production of this design makes it so practicing surgeons do not need to worry about damaging an expensive model. Mass production will also allow multiple surgeons to practice at the same time, such as in a classroom setting where each student would have their own model to follow along on. A drawback of this design is the loss in accuracy due to the use of a non-dissolving cast will be used (the rapid prototype is the cast) and therefore a seam from where the cast was removed will be present on the model.

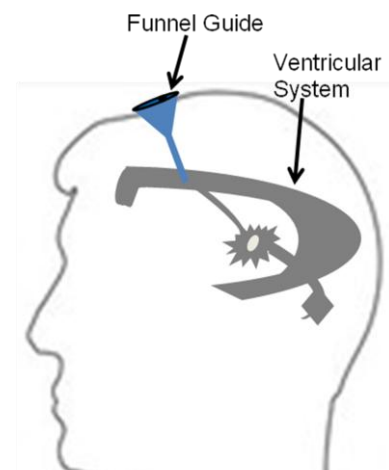
### Design 3: Fluid Filled Ventricles

The final design is a fluid filled ventricular system model (see Figure 9). The ventricular cavities will be produced by rapid prototyping as described in the first force sensor design. The rapid prototype would be printed using an elastic polymer that maintains pliability even after curing. This prototype will be also be secured



Pink = gel mold  
Blue = ventricle spaces

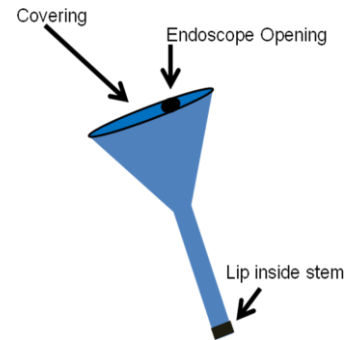
**Figure 8.** Injection Mold Ventricle schematic. (LifeART, 2006).



**Figure 9.** Schematic of Fluid Filled Ventricle Design

inside a head shaped container. Surrounding the ventricular rapid prototype inside the head shaped container, a gel will add stability to the thin prototype. To simulate blockage of the cerebral aqueduct, material will be inserted into the cast within the cerebral aqueduct.

Two key features of this design are the funnel entry guide and the fluid filling the ventricular cavities. The funnel entry guide will allow surgeons to practice the correct angle of entry (see Figure 10). This is an important skill to have the model enable a surgeon to practice. Use of an incorrect entry angle during surgery could lead to temporary or permanent damage of the ventricles and surrounding tissues. The funnel will be covered on the outside of the model by a piece of cloth-like material with a single, small, circular opening for inserting the endoscope through. The material allows the placement of the endoscope relative to the head to be known, but prevents the surgeon from seeing the funnel guide underneath. This will cause the endoscope to be freely controlled by the surgeon, but as the endoscope is inserted deeper into the head, the walls of the funnel will provide a smaller region where the surgeon must keep the endoscope. The walls of the funnel will be tough to prevent breaking and the surgeon will be able to know that if the endoscope hits the hard wall that their angle needs to be corrected. At the very stem of the funnel, a lip will be in place to secure the endoscope at the proper angle so that the rest of the procedure may be performed. The stem will have an inside diameter of 6.2mm and the lip will be 1-1.25 mm wide. This will hold the 6.2mm diameter endoscope in place without letting it slip further into the model. This is similar to the surgical procedure where the endoscope is secured to free up the surgeon's hands and prevent the endoscope from penetrating further into the patient.



**Figure 10.** Funnel Guide for Endoscope Entry.

The second important feature is the inclusion of a fluid inside the model. This design allows students to practice siphoning the fluid properly out of the ventricles and replacing it. We are currently considering mineral oil to simulate the cerebral spinal fluid. We discarded water as the fluid source due to the prevalence of air bubbles found in most tap water sources. Any air bubbles in the model would disrupt the optics of the endoscopic camera during use. Mineral oil is clear, like the cerebral spinal fluid, and its density allows air bubbles to rise to the top of the fluid and be dispersed within the volume of the liquid and not interfere with the endoscope; however more information and testing is needed to finalize this decision.

## Design Evaluation

Table 1 lists evaluation criteria of the model which include anatomical accuracy, effectiveness in teaching, durability, feasibility, and cost. The final design was chosen based on these criteria. The designs were assigned a score between 1 and 5 for every criterion, with 5 being the highest possible score meaning that it is the most desirable in that category. First, the model has to be anatomically accurate because it serves as a practice simulation for neurosurgeons, and accuracy is of utmost importance. Due to the necessity of creating a seam in the injection mold model to remove the cast, we awarded it a 3. The force sensor design and the fluid filled model were both given a 4 because they are based on rapid prototyping and the ventricles will be one continuous piece of material. Next, the effectiveness of teaching the surgical procedure was evaluated for each of the designs. The injection mold ventricular system design was given a 3 because the anatomical defect of the seam in the middle of the model will take away from the realness of the surgery. The force sensor design will give the user direct feedback on their performance and so we awarded it a 4. The fluid filled model that was given a 4 will best simulate the use of an endoscope inside the brain due to the presence of fluid in the model, but this design will not give the user feedback. The next criterion is that the model has to be durable to withstand regular use. The injection mold design scored a 1. It is the least durable and is designed to be discarded after one use. The force sensor model was given a 3 due to the inability to repair the circuitry of the force sensors, without ruining the model, if something went awry. The fluid filled model will likely be the most durable in terms of maintenance and material durability combined. This design earned a 4 and not a 5 because the rapid prototype polymer will be elastic and may tear if excessive force is used. The feasibility of constructing the model within the timeframe of a semester was also taken in account in choosing the design. The force sensor design received a 1 because the circuitry involved in determining and programming the force sensors, would most likely take longer than a semester along with building the model itself. The injection mold design earned a 4 and the fluid filled design a 5. Even though most of the steps to create the model are the same in the beginning construction of each design, time wise, the extra step of having another company make the injection mold of the rapid prototype will take longer to complete, whereas the fluid filled model stops with the rapid prototype cast. Finally, the model cost has to be reasonable. The injection mold design would be the most expensive and received a 2. The force sensor design was given a 3 because it would involve the

major cost of rapid prototyping and the cost of the force sensors. The fluid filled model was awarded a 5 in cost effectiveness because the only major cost of the design would be the rapid prototyping. Based on the scores awarded in each category (see Table 1), our highest scoring design and our chosen final design is the fluid filled ventricle design.

**Table 1:** Matrix for design evaluations

Design	Anatomical accuracy	Teaching Effectiveness	Durability	Feasibility	Cost	Total score
Force Sensor Design	4	4	3	1	3	15
Injection Mold Ventricle System	3	3	1	4	2	13
Fluid Filled Ventricles	4	4	4	5	5	22

### Materials Evaluation

The criteria for material choice are: durability, similarity to brain tissue texture, and compatibility of the material with fluid. The materials that are evaluated in Table 2 are all rapid prototype polymers. We are evaluating these polymers since the rapid prototype cast is a major construction component of the model. The durability of the material overtime was evaluated first. Both, the Fullcure 720 and Tango Black polymer are stiffer and would be most resistant to tearing. The score of a 4 was given to the DuraForm Flex Plastic and Tango Plus Fullcure 930. They are flexible and elastic and may tear easier if too much force is applied. The resemblance of each material to the properties of the ventricular tissues was also considered in determining the material for rapid prototyping. Fullcure 720 is hard like polyvinyl chloride (PVC) and therefore does not mimic the brain at all, earning a 1. Tango Black is more elastic, but only comes in the color black. The brain has multiple colors that would be seen by the endoscope so we gave it a 3. Both the DuraForm Flex Plastic and the Tango Plus Fullcure 930 are the most pliable and come in a variety of colors, earning them both a 5 on their ability to imitate brain tissue. Finally, the fluid compatibility of the material was assessed. The hard Fullcure 720 was specifically designed to hold fluid and earned a 5 in the category. Tango Black and Tango Plus Fullcure 930 earned a 4

because they are elastic even though they are not specifically designed to hold fluid. They are not porous meaning that they would not soak up the fluid. The DuraForm Flex Plastic earned a 5, because it was flexible, yet the material was listed as being able to withstand fluid. Based on the final scores, the material we selected for the rapid prototype is the DuraForm Flex Plastic.

**Table 2:** Matrix for material evaluations

Material	Durability	Representative of Brain Tissue Properties	Fluid Compatibility	Total
Fullcure 720	5	1	5	11
Tango Black	5	3	4	12
DuraForm Flex Plastic	4	5	5	14
Tango Plus Fullcure 930	4	5	4	13

### Prototype Construction

The prototype construction began with creating a 3D image of the brain ventricle cavities that was anatomically accurate. The ventricles were created using MRI scans of a patient's brain to assemble a 3-D computerized image of the ventricles. We obtained Nifti formatted MRI scans of a patient's brain from the UW-Hospital. We converted the .nii files into JPEG files and loaded the images into Autodesk Inventor Professional 2010. Using Inventor, we reconstructed the images into 3-D model of the ventricles, making the .stl file to be used in the rapid prototyping. Due to the accuracy of the MRI scans, we will be able to mimic the slight nuances in the surface of the tissues surrounding the ventricular cavities. Since any freehand machining of the ventricular system without the use of digital images would not be anatomically accurate, the use of rapid prototyping to create the ventricles was imperative to achieve maximum anatomical accuracy. The image was created with a 6.25mm opening for the endoscope to access the ventricular cavities. The 3D image was printed using a 3D printer to give a rapid prototype made of ABS plastic. See Figure 11 for a picture of the inside of the 3D image.

The rapid prototype was secured to the inside of the Life-Size skull sold by YGM Medical Supply Group LLC. Lightweight foam-like modeling clay was used to secure the rapid prototype of the ventricles inside the skull. By using the modeling clay, the ventricle prototype was able to be situated at the correct height



Figure 11. Inside view of the 3D image of the brain ventricles.

from the base of the skull. A small funnel with a wide opening of 5.5cm and a stem opening of 1cm was used to make the funnel guide. The stem of the funnel was completely removed and the wide opening of the funnel was cut down approximately 2.5 cm around the whole circumference. The funnel was secured over the opening for the endoscope of the rapid prototype. A 5.08 cm circular opening was drilled into the removable top half of the skull using a bi metal hole saw drill bit. This hole was cut directly above the opening for the endoscope and the funnel on the rapid prototype. A piece of black felt was cut and fixed to the underside of the top of the skull and a slit was cut in the middle to allow the endoscope to access the funnel and therefore the ventricular cavities. The top half of the skull is placed into the proper position to attach to the bottom half during model use. See Figure 12 for a picture of the inside of the prototype.

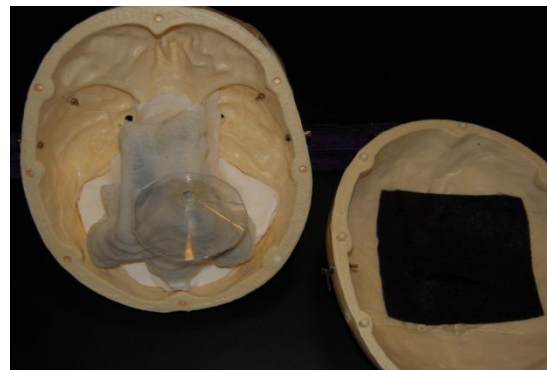


Figure 12. Inside view of model prototype. The top of the skull is removable and is secured to the bottom half of the skull during model use.

The assembled prototype needed to be stabilized to prevent side-to-side motion of the skull, while maintaining the approximate  $45^{\circ}$  angle that was required by the client during the surgery. A piece of cedar with dimensions 2.22 cm x 2.22 cm x 26.35 cm was painted with a blue acrylic paint and placed behind the mandible on the skull. Fishing line was wound through both eye sockets of the skull and then pulled down at an angle and tied to upholstery tacks. The tacks were hammered into the wood so that the string was pulled taut. The wood piece secured to the skull allowed the skull to have more stability and prevented side-to-side movement of the skull so that the medical students do not have to secure the skull before practicing with it.

## Testing

To test the prototype, the client inspected the prototype and was showed how the medical students would use the model. To navigate the ventricular cavities, the material needs to be flexible and soft, like the DuraForm Flex material that the final product would be made of. The client inserted the endoscope into the ventricle prototype; however, the prototype made of ABS plastic, a hard plastic, prevented him from navigating far into the ventricle cavities. The client was able to insert the endoscope into the opening and he did say that the funnel and design concepts were good to provide medical students with experience. The change that he would like

to see with the design is the use of hydrocephalic brain ventricles in the rapid prototype rather than healthy brain ventricles.

### **Future Work**

In the future, we will adapt the design to model a hydrocephalic brain, which will be useful for the medical students to practice the procedure in a common situation: blockage in the ventricles causing hydrocephalus. The surrounding structures like the optic nerve and basilar artery will be included in the model and equipped with force sensors to alert the students if these structures are disturbed, which could be fatal in an actual surgery. One possible way to achieve inclusion of these structures is to use a program that is designed for reconstructing a 3D image from MRIs, such as a program called 3D-Doctor. Because these structures are so fragile, the inclusion of these structures in the model is crucial to equip the medical students with the skills and dexterity required to perform neuro-endoscopic procedures, specifically an endoscopic third ventriculostomy.

## Works Cited

- Academic Encyclopedias and Dictionaries. (2010). Ventricular System. Retrieved on October 8, 2010 from: <http://en.academic.ru/dic.nsf/>
- Aesculap. (2010). "Aesculap Neurosurgery MINOP Neuroendoscopy Systems." Retrieved on October 8, 2010 from: <http://www.aesculapusa.com/default.aspx?pageid=218>
- Fine Line Prototyping Inc. (2010). Materials. Retrieved on September 26, 2010 from: [www.finelineprototyping.com](http://www.finelineprototyping.com)
- Immersive Touch. (2010). Sensimmer. Retrieved on September 12, 2010 from: <http://www.immersivetouch.com>
- Iskandar, B. J. (2010). University of Wisconsin-Madison Department of Neurological Surgery.
- LifeART image (2006). Lippincott, Williams , Wilkins. Retrieved on October 8<sup>th</sup>, 2010 from: <http://www.obfocus.com/questions/qanda10.htm>
- National Institute of Neurological Disorders and Stroke (NINDS). (2010). Hydrocephalus Fact Sheet. *National Institutes of Health*. Retrieved on October 8, 2010 from: [http://www.ninds.nih.gov/disorders/hydrocephalus/detail\\_hydrocephalus.htm#toc](http://www.ninds.nih.gov/disorders/hydrocephalus/detail_hydrocephalus.htm#toc)
- Objet Geometries Inc. (2010). Materials. Retrieved on September 26, 2010 from: [www.objet.com](http://www.objet.com)
- Pope, R. E. (2010). Neuroendoscopy. Retrieved on October 8, 2010 from: <http://www.spinesurgeon.com.au/index.htm>
- ProtoCam. (2010). Materials and Polymers. Retrieved on September 26, 2010 from: [www.protocam.com](http://www.protocam.com)
- SimuLab Corporation. (2010). TraumaMan. Retrieved on September 12, 2010 from: <http://www.simulab.com/home-traumafamily>
- Simulated Surgical Systems. (2010). RoSS: Robotic Surgical Simulator. Retrieved on September 12, 2010 from: <http://www.simulatedsurgicals.com/index.html>



**Appendix A: Product Design Specification Report**  
**Product Design Specification Report**  
**Brain Model for Neuro-Endoscopic Teaching and Practice**

**Date:** 18 October 2010

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**Problem Statement**

Our client, Dr. Bermans Iskandar, of the Department of Neurological Surgery at the UW Hospital, performs pediatric neurosurgeries. Currently, his medical students do not have a surgical simulator to practice endoscopic third ventriculostomy to remove blockages in the cerebral aqueduct. A model of the ventricular system to teach and practice surgeries is necessary so that patients are not subject to initial trial surgeries by medical students. The model needs to be anatomically correct and allow the surgeon to practice control of their fine motor skills. The model should include insertion of the endoscope into the ventricles and be durable enough to train multiple students on the surgical techniques.

**Client requirements**

- Practice Endoscopic Third Ventriculostomy
- Simulate blockages within cerebral aqueduct between 3<sup>rd</sup> and 4<sup>th</sup> ventricles
  - Cause of blockage: duct malformation, hemorrhage, tumor, or cysts
- Surgical entrance, if present should be located on coronal suture, 2-3mm away from the midline
- Includes anatomically correct ventricular system and immediate surroundings including
  - Memory Structures
  - Choroid Plexus
  - Blood vessels
- No air bubbles present if fluid is used inside model
  - Would allow practice siphoning and replacing CSF
- Train surgeon's fine motor skills in controlling endoscope
- Model is 1 unit
- Weigh less than 5 kg
- Dimensions less than 25cm x 25cm x 25cm
- Must allow 1-6.2 mm diameter endoscope to be used in procedure
- Material is similar in texture of brain structures
  - elastic
  - Non-abrasive
- Material must not degrade with constant use
  - Lifetime is 2 years
  - Use daily

- 90 minute procedure
- Material must withstand room storage conditions
  - 25°C
  - 50% humidity

## **Design requirements:**

### **1. Physical and Operational Characteristics**

- a. *Performance requirements:* The model will be used daily to simulate the 90 minute neuro-endoscopy procedure. The practice model material must not degrade with multiple uses or with storage periods from 1 week to 1 year.
- b. *Safety:* This model must not endanger the user. There must not be toxic materials or sharp edges within the model. There should not be any pathological concerns due to fluids or gels used in model. Though dangerous tools may be used during operation of model, the model itself should not pose a safety risk to the user.
- c. *Accuracy and Reliability:* This model should accurately replicate a neuro-endoscopic procedure. 730 practice surgeries to be performed on the model without significant degradation of model features.
- d. *Life in Service:* The model should not degrade performing practice procedures daily for 2 years. The materials should uphold their anatomical features to allow for multiple repetitions of neuro-endoscopy procedures.
- e. *Shelf Life:* The materials of the model should not degrade over time in storage for 5 years. The model will not be in storage for more than a week at a time under normal conditions of use.
- f. *Operating Environment:* The model will be used by one surgeon at a time. The practice neuro-endoscopy will be performed at 25°C and 50% humidity.
- g. *Ergonomics:* Model should only be used with proper neuro-endoscopic tools such as the endoscope.
- h. *Size:* The model should not exceed a size of 25cm x 25 cm x 25 cm. There should be a minimum of 1 m of space surrounding the model to allow proper use by a surgeon.
- i. *Weight:* The model should be portable with the use of a cart or other transportation device. The model should not exceed 5 kg.
- j. *Materials:* Materials used must be safe for use around humans. Any material used should not pose a health risk or be abrasive when the model is handled. Non-radioactive, non-flammable, and non-corrosive materials should be used. Material must not degrade when introduced to fluid (to be determined) inside the model.

k. *Aesthetics, Appearance, and Finish*: The model should be pleasing to the eye and follow basic anatomical shapes. The colors do not have to be realistic, but realistic colors are preferable. The finish should be smooth and clean looking.

## 2. Production Characteristics

a. *Quantity*: One model is required at this time. However, if the product is to be produced on a large scale in the future, additional models will have to be manufactured.

b. *Target Product Cost*: The target manufacturing cost for the product is \$500, which is significantly cheaper compared to existing products. One of the cheaper models currently on the market costs around \$5000 and other models are even more expensive.

## 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 basic requirements: anatomically accurate and targeted toward training medical students in neuro-endoscopy. The client's requirements will be addressed in producing the model.

c. *Patient-related concerns*: The product will not be in contact with any patients, nor will the patients' data be utilized in any way; therefore patient-related concerns will not be applicable. The model should not endanger surgeon practicing with 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.