Mechanical 3-D Model for Neuro-Endoscopic Surgery Simulation

BME 201

University of Wisconsin-Madison

Department of Biomedical Engineering

4th March 2011

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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 result 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.

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, right).[2]

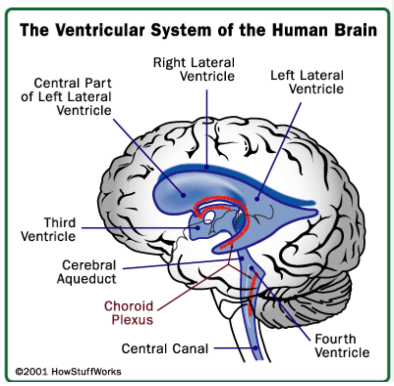

Figure 1: A representation of the human ventricular system, http://static.howstuffworks.com/gif/brain-ventricles.gif

The ventricular system is composed of four ventricles that secrete cerebrospinal fluid (CSF), which is used to protect and nourish the brain. CSF surrounds the brain and spinal cord and seeps into the meninges, eventually getting absorbed by the body. The brain maintains around 120mL 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.[3]

However, a condition called hydrocephalus can occur if there is a blockage in the ventricular system.[4] 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.[5]

Our client performs a procedure called endoscopic third ventriculostomy, a common surgery used to remove the CSF buildup and reduce pressure in the ventricles.[5] Thus, our model will focus on this procedure and be designed to allow the teaching and practice of performing this specific surgery. 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.

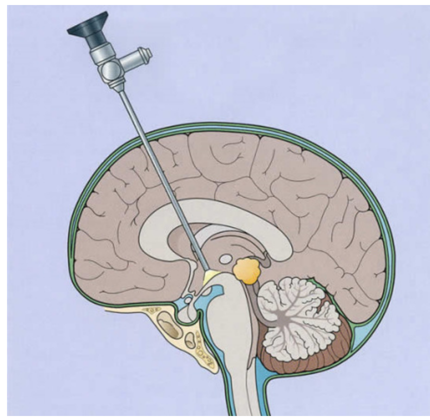

Figure 2. Endoscopic third ventriculostomy.
http://www.seattlechildrens.org/uploadedimages/Seattle_Childrens/cmsassets/Images/endoscope_large.jpg

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.

Motivation

Training medical students in endoscopic neurosurgery is a difficult process and there are currently no products on the market for 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 make it difficult for medical students to maneuver the endoscope in the ventricular system and reach the 3rd ventricle floor.

Surgeons should not be performing their first surgeries on actual patients because their lack of practice could endanger the patients. 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.

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.

Client Requirements

The model should accurately simulate endoscopic third ventriculostomy and allow medical students to practice the entire surgery, 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. The model should allow endoscopes of diameters between 1mm-6mm to be inserted in the ventricles. The model material should resemble brain texture, allow a fluid resembling CSF to be added in the model, and cannot damage any surgical equipment. The model is a single unit and should not exceed the dimensions of 50cm x 50cm x 50cm and weight 10kg. 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 include the three devices most relevant to our client's requirements. The first is the Robotic Surgical Simulator (RoSS) manufactured by Simulated Surgical Systems (see Figure 3).[7] 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).

Sensimmer manufactured by Immersive Touch is another virtual surgical simulation device (see Figure 4).[8] 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 and our client is looking for a cheaper alternative.

Figure 4. Sensimmer virtual surgery simulator (Immersive Touch).

The final type of surgical simulator is a mechanical model manufactured by SimuLab Corporation called TraumaMan (see Figure 5).[9] 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).

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, which 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, therefore 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 container 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 not move any more freely than a head during an actual surgery and should behave exactly like an actual human head. This non-disposable outer shell should be free of sharp edges to prevent accidental injuries. 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 with repeated use or cleaning prior to the expected usage period.

Design Proposal Overview

The model will function as a training simulation for neurosurgeons performing endoscopic third ventriculostomy on patients. Therefore, the anatomical structure of the ventricular system needs to be properly represented in the model. As previously stated, this surgical procedure is used to release CSF buildup in the ventricular system. The overall model and simulation needs to imitate the surgical procedure as precisely as possible with minimal misrepresentation. Materials used in the model will be evaluated based on how closely they mimic the texture and properties of the tissues surrounding the ventricular system. The three designs 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 allows 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.

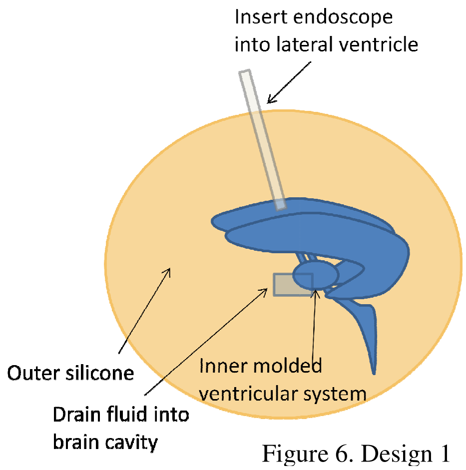

Figure 6. Design 1

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. The design and materials allow the ventricle floor to be punctured, just like in an actual endoscopic third ventriculostomy procedure. The entry to the first ventricle will also be puncturable so that the user could begin using the model.

The model will be constructed using MRI scans of a hydrocephalic brain using injection molding technology. A master cast of the ventricles will be made and used to cast the ventricular system as a negative. 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 an external vendor, one of the biggest strengths of this model is that it is very convenient for our client to begin using the model. The top of the lateral ventricles has to be punctured, and the model is ready for usage. 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.

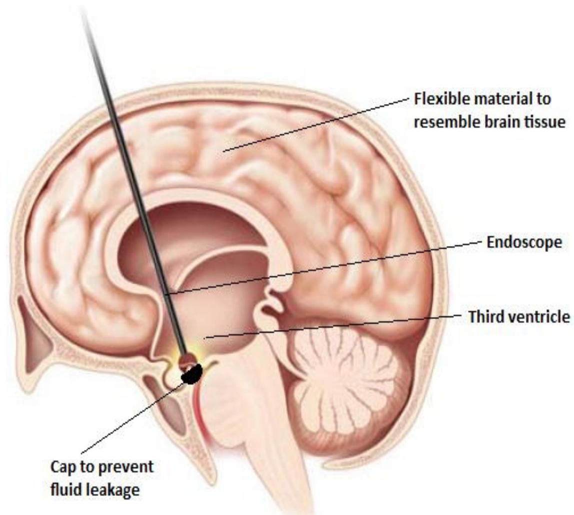

Figure 7. Design 2

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, 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 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.

As mentioned previously, 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. 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. It 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

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 extremely comparable to the realistic consistency of the brain.

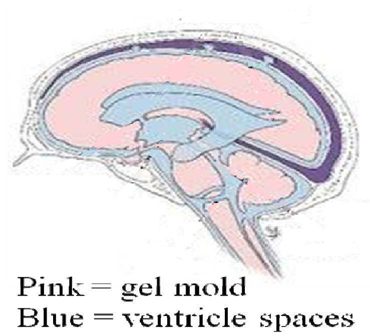

Figure 8. Injection Mold Ventricle schematic. Blue represents the ventricle system and Pink represents the final model. (LifeART).

This outline will be made by first having a rapid prototype company create a hard cast of the ventricles (see figure 1). 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. After the removal of the ventricles, the pieces will be assembled and filled with a mineral oil to imitate CSF in the ventricles.

Figure 9. Ballistics Gel Material
www.RottenEggs.com

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 have a company print the ventricular system and pre-fill it with fluid, which will represent the ventricular system better; therefore, this design receives a 28. 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. This gives it a score of 27. 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 score of 25.

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 enclosed ventricular system design therefore receives a score of 28. 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; therefore, the capped ventricles model receives a 24. The ballistic gel model will be a realistic representation of the brain and ventricular system. Its entry system and material are extremely 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, giving it a score of 28.

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, so it receives a score of 13. The capped ventricles model will also be costly because of the valve system that has to be printed with the model, so it receives a score of 14. Ballistics gel molding will be the cheapest to reproduce but the initial cast is expensive; therefore it receives an 18.

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. Therefore, this design receives a 7. 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. Therefore it receives a 7. Ballistics gel molding is achievable in a relatively short amount of time and with minimal effort, which gives it a score of 9.

The last criterion is the feasibility of producing these designs, which is the plausibility of it being completed within our time frame of 1 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, so it receives a score of 8. The capped ventricles model requires that a working valve system be designed in the model, so it also receives a score of 8. 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, therefore it receives a score of 9.

By adding up the scores of all the criteria, a final design can be chosen. According to table 1, 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. This causes the need for the materials to be analyzed. Because the materials are closely related to the technology with which they are printed, some natural pairings of material and technology choice result. The printing technologies are discussed below. The materials are judged in the categories of strength, flexibility, small detail capability and fluid compatibility. Each category has a max score of 5. 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 can be created at a lower cost. It will be used with silicone. 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

Future Work

For the remainder of the semester, we will pursue the development and construction of the ballistic gel model. We will develop a CAD file of the 3D ventricular system model from MRI scans of the brain using the program 3D doctor. 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 also test ballistics gel properties and decide on a formula that gives the texture most similar to brain tissue. 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. In order to produce the final hollow cavities we will have to design a way to put the separated brain pieces back together. We will do this by either melting the pieces back, which will give the tightest fit, or by gluing them back together, which will be the simplest and easiest approach. Once the model is completed, we will have our client and medical students practice endoscopic third ventriculostomy to test our model. We will obtain feedback and work on improving the design.

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Appendix A: Product Design Specification Report

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Product Design Specification Report

Mechanical 3-D Model for Neuro-Endoscopic Surgery Simulation

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Group: Anyi Wang – Group Leader
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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.

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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.

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