Hemorrhage Team

BME 400

October 18th, 2021

Client: Dr. Wally Block

Advisor: Dr. Paul Campagnola

Team Members:

Rushabh Tolia (Team Leader), Siva Ramalingam (Communicator & BPAG),

Logan Hoffman (BSAC)

Abstract

Intracerebral hemorrhaging can affect any individual at any age, but is most prevalent for individuals who are at high risk of strokes and seizures. This condition is very dangerous as it causes blood clotting and does not allow adequate blood into and out of the brain and, if not treated, can lead to death. For this reason, the client, Dr. Block has tasked the team to come up with a phantom head model that can be scanned into an MRI, so a neurologist can practice different surgical techniques. These include stereotactic clot aspiration and craniotomy. Stereotactic clot aspiration is a minimally invasive surgery for large clots located deep inside the brain.This method is also known as irrigation [1]. Another commonly used method is craniotomy which involves cutting a hole in the skull with a drill to expose the brain and remove the clot. For this reason, the team has decided to come up with a phantom model that contains polyacrylamide gel with varying consistencies that will be processed via photopolymerization. The diffusion-controlled termination reactions associated with acrylamide are expected to be postponed or suppressed leading to the different elastic and shear modulus that will be used to match the different components of the brian [2]. The team decided that the most optimal skull design would be a half pressurized skull model and have a pressurized system developed in the future. The team will use statistical studies to determine how accurate the neurosurgeon can determine the clot's location and how well they can remove it.

Table of Contents

I. Introduction

Our project works with intracerebral hemorrhaging (ICH). ICH affects between 40,000 and 67,000 Americans each year with an expected 10 year survival rate of 24.1% [3]. Clots can form because of ICH. Clots form when a blood vessel bursts, releasing blood into the brain [4]. The arteries near the clot lack oxygen-rich blood, causing the patient to experience strokes [5]. Immediate actions need to be taken for ICH patients since blood shears white matter, resulting in brain damage. Over time, the RBCs from the blood released in the bursting of the vessel coagulate and separate from the plasma. This separation makes individual clots very heterogeneous which complicates the decision of which method of evacuation to utilize since the best method is dependent on the stiffness of the clot [6]. Currently, it is difficult for surgeons to assess the stiffness of clots prior to surgery. When a patient displays symptoms of ICH, it is standard for that patient to undergo diagnostic tests such as an MRI and a CT scan. These tests allow doctors to determine the location of the clot, but do not provide information about the stiffness of the clot [4]. Without knowing the characteristics of clots, it is difficult for neurosurgeons to decide on a surgical approach prior to surgery.

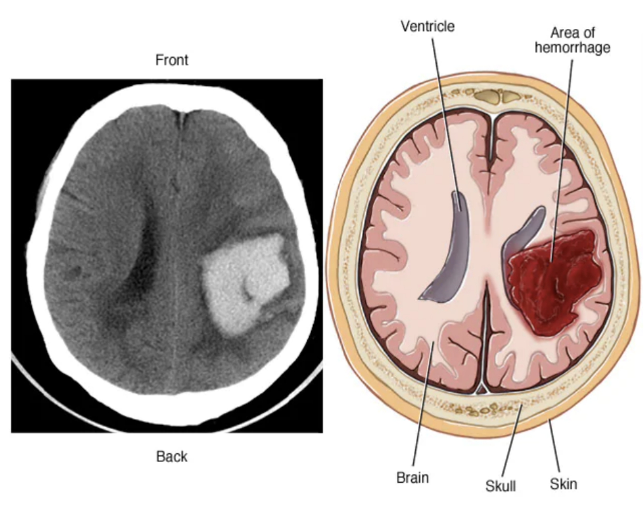

Figure 1. Intracerebral Brain Hemorrhage[7]

Hypertension and old age both increase a person's risk of experiencing ICH. Until recently, doctors were only able to stabilize patients with ICH. Now, multiple surgical methods have been developed that allow doctors to evacuate clots before brain damage occurs. Removal of the clot is critical as clots can cause cells in the brain to damage and act as harmful biological cues in the brain[5].

When considering the removal of a clot, its mechanical characteristics must first be considered. Two different types of clots are commonly identified in ICH patients. One type is a fluid or gel-like, for which the best removal method is irrigation or suction, performed by a vacuum catheter. The second type of clot is much stiffer and requires a drug-based approach. The drugs break down the clot before it is evacuated, and once the clot is less viscous, surgeons can remove it with the vacuum catheter.

A medical phantom is a device that is used to calibrate imaging devices and to develop methods to better analyze the images. Phantoms often seek to mimic the material characteristics of human tissue. Researchers are able to manipulate and analyze phantoms with greater ease than they are able to manipulate human tissue due to ethical reasons and some secondary characteristics. This allows imaging machinery's resolution and accuracy to be tested and calibrated [7]. Our phantom has a gel-gel interface which when imaged using MRE, will show how different stiffnesses will appear on MRI.

a. Existing device

1. Switzerland Research team

When the interface is imaged using MR elastography (MRE), it will show how different stiffnesses appear on MRI. The gel to gel interface is meant to mimic the interface between clots and native brain tissue. Currently, there are no phantoms that mimic clot-tissue interactions in a gel to gel interface like the team’s design, however other phantoms have been designed that analyze the appearances of different stiffnesses on various diagnostic images. For example, researchers from Switzerland designed an anatomically correct phantom that modeled white matter and gray matter[8]. They were able to mimic the material properties of these tissues using agar gel.

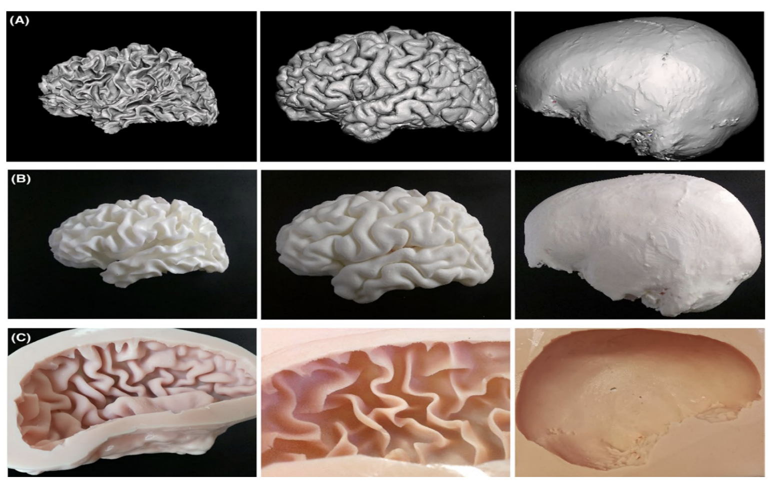

Figure 2. Switzerland Agar Gel Model[8].

2. Wax Barrier - Hydrophobic Model

Other phantoms have explored the idea of gel interfaces, involving hydrophobic sprays and wax barriers [9]. These come with their own downsides, such as stability issues or a lack of anatomical detail. This phantom uniquely provides a long-lasting, anatomically relevant model of gels, which differ in their mechanical properties and can be verified via rheology

3. Previous UW-Madison Team

The previous UW- Madison Team that came up with the polyacrylamide (PA) gel model for the phantom. Results obtained from rheometric analysis were quite promising, as the team was able to develop PA gels that closely mimic brain tissue and its mechanical properties. Results from the MRI scan of the newly designed sample holder are also promising. By fabricating the holder in the shape of a human skull, the team fit snugly in the MRI head pillow, thus removing space between the pillow and holder, and ultimately minimizing phase issues found in the previous design. The current team is planning on improving this model the team came up with.

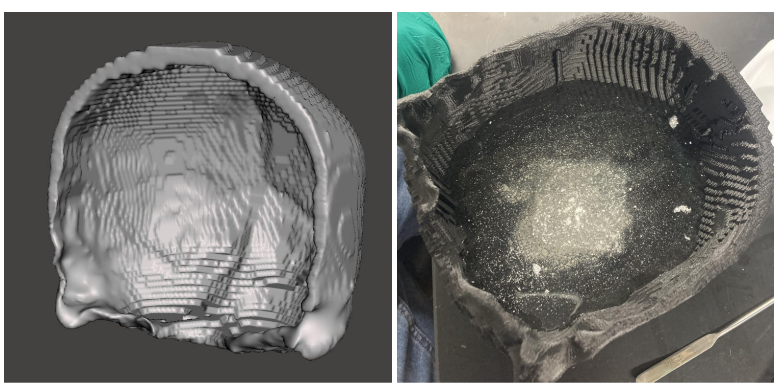

Figure 3. UW- Madison team model

b. Problem Statement

Currently, it is difficult for surgeons to assess the stiffness of clots prior to surgery. When a patient displays symptoms of ICH, it is standard for that patient to undergo diagnostic tests such as magnetic resonance imaging (MRI) or computed tomography (CT) scans, which allow doctors to determine the location of the clot, but do not provide enough information about the stiffness[4]. A phantom brain is needed to acquire a range of stiffness measurements to be used in a database. Surgeons will be able to compare the images of their patients to those of the phantom and deduce the best method of clot extraction. The Goal for the first semester is to improve upon the phantom model created by the previous UW-Madison team to simulate the interior of the brain with various clots to image and validate the effectiveness of mapping techniques and represent anatomical correctness. The team would also focus on improving the phantom skull model to cooperate better with scanner shape that would minimize wave interference.

II. Background

a. Research

A brain phantom is used by neurosurgeons to compare the MR scans of the phantom with a scan of their patients' brains. The phantom's purpose is to illustrate the stiffness of the patient's brain [10]. Characteristics of the patient's brain that are compared to the phantom include the rigidity, structure, clots, and fluids. It is essential for the phantom to have a precise replication of the brain's components since its design helps doctors decide how they will treat the patient. For instance, when doctors begin to remove a blood clot from a patient they must decide between using a catheter or creating an incision [11]. They make a decision based on the relationship between the stiffness of the clot in the MRI with the stiffness of the clot in the phantom. Thus, it’s very important for brain phantoms to represent the human brain closely.

The composition of the phantom is therefore the most important part of our design and fabrication. Our focus thus leads to the research of different biomaterials to make up our phantom. Since the previous team was able to get promising results with the PA (polyacrylamide) gel model, We decided to go ahead with that as the final biomaterial for the phantom. The next priority for the phantom will be the integration of the PA gels into the skull shape. This will allow for comparison between the rheology data and MRE analysis of the shear modulus, which would ideally be identical; however, it has been shown that lower values are typically seen in rheometry compared to MR analysis. The other main focus regarding improvements to the model is adding more features to the phantom to increase its anatomical accuracy. This includes the incorporation of air and fluid pockets to mimic sinuses and CSF, respectively. Progress has been started in this respect; the team was able to create a 3D replication of a Child’s skull from a sample CT scan via 3DSlicer and Mesh mixer 3D print the result using PLA

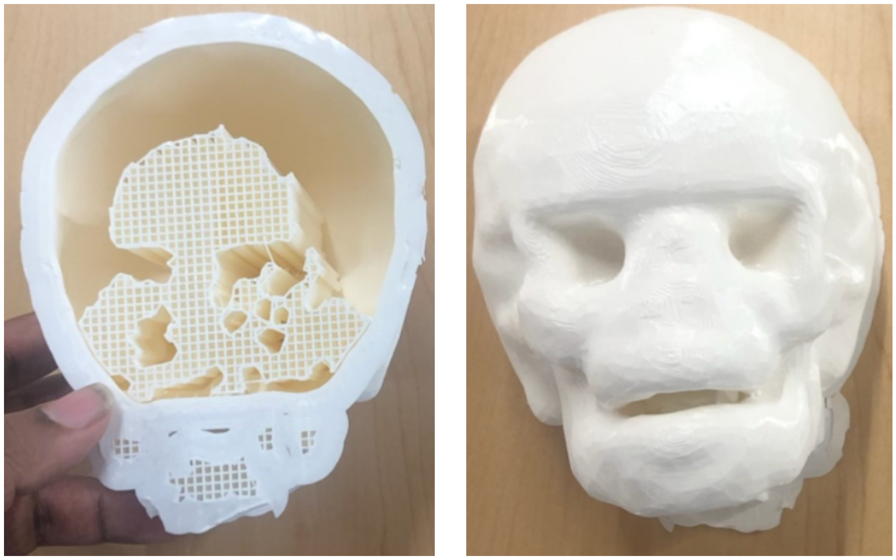

Figure 4. 3D printed skull model

b. Client Information

The client, Dr. Walter Block, is a professor of MRI department in UW Madison. He had been the client for the previous UW-Madison team.

c. Design Specification

In order to ensure that the final product meets the requirements of Dr. Block, the team generated a document of design specifications, which contains all of the properties that the final design must adhere to. The document describes the Physical and Operational Characteristics of the skull model, the characteristics that will be required to produce the model, as well as documentation of previous designs of how the teams used these designs as inspiration and models for this product. Overall, the skull model will be 3D printed and made of PLA to allow for the most durable material that can be scanned within an MRI. Additionally, the anatomical features of the skull will accurately represent a head and will contain air and fluid components that will be cut from the polyacrylamide gel. There will also be a variety of stiffness of polyacrylamide gels, from photopolymerization or when UV light/natural light initiate a polymerization reaction to form a polymer, that will be used to create a database of known MR images to compare to. Also, there will be an in depth fabrication process, so the following procedures can be replicated for affordable commercial purposes. Lastly, if time is allocated the model should be enclosed in a way that there should exist a way for the neurosurgeon to change the internal skull pressures to match the conditions of a specific hemorrhage or blood vessel pathway. For more clarifications and specifications, see **Appendix A**.

III. Preliminary Designs

1.Full Skull Pressurized:

This skull model will be entirely pressurized by using internal gas chambers that will act as the blood vessels and hold oxygen/hydrogen gas. Depending on the conditions the neurosurgeon wants to work on with the brain, the skull will act in accordance with those specified pressure conditions. The pressure will increase by having the volume of the gas fill the chamber of the skull, while a reduction of pressure will occur by having pressurized gas leave the chamber. Due to this pressurized system, this skull model will be able to most accurately act as an actual brain model. However, this model will require complex hardware to set up the pressurized chamber and will need to be placed in a location where it will not have any interaction with the polyacrylamide gel so as to not cause any combustible reaction. Additionally, due to this complexity the idea of having this skull model be available commercially reproducible will no longer be applicable.

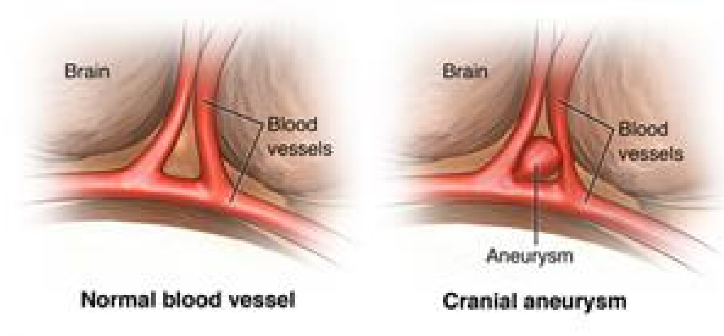

Figure 5. Pressurized System [12]

2.Full Skull Non-Pressurized:

Similar to the last design this skull model will be a full model as it will not be cut laterally across the brainstem, but will illustrate the entire brain including all the accessory lobes. However, the model will not be pressurized and will not be able to accurately change the corresponding blood vessel pressures to compare to an actual skull model. Due to this hardware change, the complexity of the model will be simpler, but will still require more time in Slicer3D for the processing of the skull. In the future, this model will allow a pressurized system to be added more easily than the half, so that it can be converted into a different design. One drawback with this model is that it will be more difficult for the neurosurgeon to practice certain surgical practices as it will require more robust methods to reach certain difficult regions in the brain as compared to the half model.

Figure 6. Full Skull [13]

3. Half Skull:

Unlike the previous designs, this model will no longer have a full scale figure and will now be cut laterally across the brainstem to allow for only the most apparent lobes that a neurosurgeon to work with. Though this model is the least accurate to an actual human model, this model would work the best for the neurosurgeon practicing to perform a surgical procedure as it will allow the easiest and best access to all the parts that are necessary to be worked on. However, this skull will not be able to be made into a pressurized system, as the blood vessels transporting the blood will be taken away from the skull and will not adhere to the actual biomimicry of an actual adult skull. Lastly, this model will be the easiest to be made in 3DSlicer as it requires the least amount of time to process.

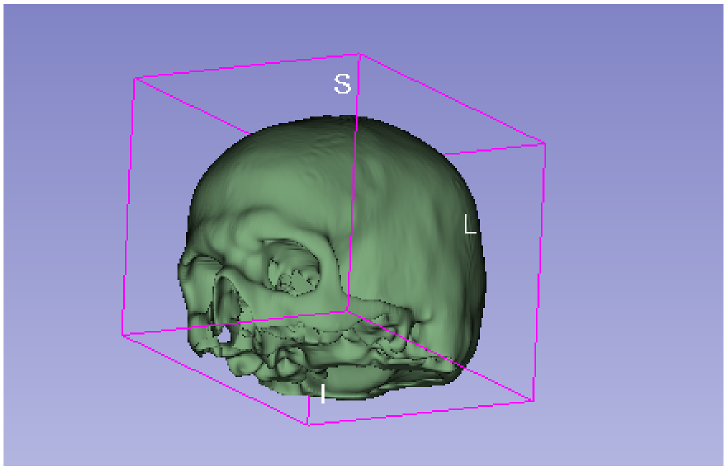

Figure 7. Half Skull

IV. Preliminary Design Evaluation

a. Design Matrix

Table 1: The Pre-Surgical Hemorrhage Model design matrix.

Critera	**Weight**	Full Skull Pressurized		Full Skull Non-Pressurized		Half Skull	
Ease of Fabrication	30	1/5	6	3/5	18	4/5	24
Bio-mimicry	25	5/5	25	4/5	20	2/5	10
Durability	20	2/5	8	3/5	12	3/5	12
Replicability	15	1/5	3	3/5	9	4/5	12
Cost	5	1/5	1	3/5	3	4/5	4
Saftey	5	5/5	5	5/5	5	5/5	5
Total	100	**48**		**67**		**67**	

b. Justification of Criteria

Ease of Fabrication: This criteria would include how feasible it would be for our team to create the phantom model and set it up for simulation. Our team weighted this category the highest due to it being overall the most important factor in the project to be successful. We factored in the ease of creating the skull model and adding the non homogenous aspects of the model such as the model hemorrhage and air pockets. The Half-Skull model won in this category since the model is open. The openness of the Half-Skull allows our team to create the non homogenous aspects of the phantom with higher simplicity.

Biomimicry: Biomimicry was the next highest weighted category of the design matrix. The scores in this category are based on how well the proposed phantom model can mimic a human brain. This is primarily based on the similarity of the design's MRI scans to in-field MRI scans of intracerebral hemorrhage. The Full-Skull Pressurize model won in this category based on its ability to alter the internal pressure inside of the skull, similar to what a real brain would experience due to hemorrhaging.

Durability: The durability category is based on how long the phantom model can be effectively used in MRI scans without failure. This category is important for possible mass production. If the model needs high amounts of attention for it to work, it is a bad product. We scored the Half-Skull and the Full-Skull Non-Pressurized as the winners because the team predicted the pressurizing system would be less durable than having a model without it. And that the Full-Skull Non-Pressurized and Half-Skull models' durability would be equal.

Replicability: In this category our team gave each proposed model a score based on its replicability. A model's replicability is how easy it would be to replicate the design in a production setting and transport it to a buyer. Our team gave the Half-Skull the highest score in this category because transportation would be similar for all models, but replicating the internals of the Half-Skull model would be the easiest.

Cost: The cost category is scored on the affordability of buying the biomaterials required for fabrication. Our team has decided the cost of each individual model should cost between 150 to 200 US dollars. The main costs for the project will be the 3D printed materials associated with the phantom, the different clotting materials, the fluid that will act as the blood inside the head, the polyacrylamide gel, and a pressurized system to mimic the conditions of a human brain. Based on the materials listed the Half-Skull model received the highest score.

Safety: The safety category is based on the safety of handling the fabricated model, and the safety of the design while performing MRI scans. The Full-Skull Non-Pressurized and Half-Skull model received the same score in this category, whereas the Full-Skull Pressurized received the lowest score because our team predicted the pressurizing system hardware could be unsafe with the magnetic resonance imaging.

c. Proposed Final Design

Based on the scoring of the design matrix, the Half-Skull and Full-Skull Non-Pressurized received the same high score. After the scoring of the design matrix and the preliminary design presentations, our team had a large team meeting and decided to move ahead with the Half-Skull model. The team considered going ahead with the Full-Skull Non-Pressurized model but ultimately decided against it. This is because since this is a year long progress our team predicts there to be challenges along the way, and with the Half-Skull model, it’s easier to modify the design without major difficulties. In the future, when our team has ironed out the kinks we can replicate our production process with the other models in the design matrix to achieve a higher level of biomimicry.

V. Fabrication/Development Process

a. Materials

The model chosen based on the design matrix will require PLA to form the 3D print of the skull model and polyacrylamide gel that will be subjected to photopolymerization, while requiring the gel, cell plate, and UV light source to actually achieve the desired polymer. The team will try to obtain the polyacrylamide gel from the leftovers the previous teams have and will actually make new gel from the photopolymerization step as opposed to purchasing gels of different consistencies. Approximately, the total cost of this material will be roughly $340-$400, which is below the budget allocated to the team, so monetary wise the team should be within range. To create the skull model itself, the team will be using 3DSlicer for the rendering and processing of the skull model and will do further processing in MeshMixer.

b. Methods

The team plans to execute these tasks in the following order:

1. First they will design the skull model in 3DSlicer and finish the processing components needed to complete the full design
2. The team will show the model to the client and get it verified
    a. Once verified the team will go to the MakerSpace and print the actual model using PLA

3. Once the model gets printed the team will obtain the polyacrylamide gel
4. The team will subject the polyacrylamide gel to photopolymerization
    a. Depending on the conditions outlined by the previous group for the different modulus of the components in the brain, the team will match the gel to those conditions
    b. The team will design compartments, so the skull will contain all the different parts of the gel
5. The team will test the gel in the printed prototype child skull to find how well it works in a MRI
6. The team will test and improve the design based on the previous step
7. If time allows, make finalizations to the model to allow for pressurized chambers to be built within the model

c. Final Prototype

To be completed later in the semester.

d. Testing

To be completed later in the semester.

VI. Results

To be completed later in the semester.

VII. Discussion

a. Sources of Error

To be completed later in the semester.

VIII. Conclusions

a. Overview (paragraphs)

The team has been tasked by the client to create a phantom model for intracerebral hemorrhage planning. The model would be used for neurosurgeons to compare MRI scans of patient's brains to determine the appropriate surgical method. Because of this, it is important for the team's phantom to illustrate the different possibilities for different patients' clots. To achieve accurate biomimicry, the model should contain polyacrylamide gel of varying stiffness from photopolymerization to give an accurate MRI database neurosurgeons can reference. Based on this knowledge the team has decided to go forward with the Half-Skull model and then if time allows create corresponding Full-Skull and Full-Skull Pressurized models because of their higher biomimicry. Our team has 3D printed a smaller version of the skull model for show and tell. From this our team has learned that PLA will work well with the larger model and based on inspection, the preset requirements for wall thickness from the makerspace allow the skull to be mechanically stable enough to hold polyacrylamide gel without failure. From our design matrix and preliminary presentation, our team has decided to move forward with the Half-Skull model

This section will be expanded upon as the design process and semester progresses.

b. Future Work

In the future, the team plans to print a larger, life size skull model for the Half-Skull model. The team also plans on obtaining polyacrylamide gel to test UV polymerization by creating different consistencies from different light exposure times. Then, the team will next add the polyacrylamide gel into the skull model with the different consistencies. How the team will get the gel to have the different consistencies inside of the skull to accurately depict the qualities of the non-homogeneous human brain has yet to be determined. Afterwards the team will create replica hemorrhage with swine blood combined with clotting agents. The swine blood will then be injected with a needle into the phantom model at a desired location. The team will also create air pockets in the phantom by injecting air into the polyacrylamide with a needle into desired locations, if this method is not successful, the team will 3D print PLA pieces to mimic air pockets since they should not show up on the magnetic resonance imaging. Once the phantom model with the Half-Skull is complete, the team will hand it off to Professor Block to obtain MRI images. Based on the MRI results, the team will either modify the Half-Skull or move onto one of the other two designs following the steps used for the Half-Skull.

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Appendix

A: Product Design Specifications

Model for Pre-Surgical Intracerebral Hemorrhage Planning

Preliminary Product Design Specifications

Team: Logan Hoffman, Siva Ramalingham, Rushabh Tolia

Client: Dr. Walter Block

Advisor: Paul Campagnola

BME 400 - Section 307

September 23rd, 2021

Problem Statement/Abstract:

Intracerebral hemorrhaging is a dangerous condition that occurs when blood vessels burst in the brain and cause blood clots and eventually, if not treated, death. However, the treatment for the specific clot removal can be very difficult as there are many different material properties for the clot and can vary between different patients. The team has been tasked with coming up with a phantom for neurosurgeons to compare MRI scans with scans of patient's brains to determine the appropriate surgical method. For this reason, the purpose behind the phantom is to illustrate the different stiffness and conditions of different patient's clots. From previous years it has been found that the model should contain different polyacrylamide gels with varying stiffness' to develop an overall database that neurosurgeons can look into as a reference.

Client Requirements:

- Have a variety of stiffness of gels to create a database of known MR
- Refine material stiffness and further comparison analysis with MRE data
- Add more anatomical features to accurately represent a head, such as air and fluid pockets
- Have multiple clots within the phantom that can model varying stiffnesses of clots representing the differences in patients' clots
- Find smallest clot size that still provides functional image
- Have an in depth fabrication process so that it can be replicated and improved upon for future work
- The phantom should be able to be scanned by MRI
- Enclose model to represent skull pressure

1. Physical and Operational Characteristics:

a. Performance Requirements:

- The phantom must be as close as possible to the structure and rigidity of brain tissues since we would imbue blood clots in the phantom brain complex. The primary need for the phantom is to be observed under an Magnetic Resonance Imaging (MRI) by surgeons who would make decisions of surgical method or treatments for the patient. The phantom model needs to be analysed at varying ranges of stiffness and which must be recorded. It also needs to be anatomically accurate to brain design

b. Safety:

- The outer casting of the gel model and the brain odel cast needs to be safe and applicable for mechanical testing . The materials chosen for the brain model needs to be safe to handle with minimal equipment such as gloves. All the materials within the device must be safe to use with MRI, therefore should not contain anything metallic to avoid negative results.

c. Accuracy and Reliability:

- The phantom should mimic the size and consistency of the human brain. Mechanical testing will be done to compare Young's Moduli of different stiffnesses among the different materials selected for the phantom, in order to determine the best one for the scope of this project.

d. Life in Service:

- The phantom is ideally meant to be able to withstand multiple scans. The client expects the phantom to be well intact for 3 months, there the material chosen for it would be done so accordingly. It will be stored in a refrigerator when not in use. Phantoms currently in the market erode with time providing unreliable results. Each MRI scan should take 30-45 minutes, so the gel must remain intact for that amount of time , outside of the refrigerator.

e. Shelf Life:

- In an ideal scenario the phantom would not deteriorate in time. Polyacrylamide gel deterioration is characterized by cloudiness in the gel and an increased liquid character, which the team believes might occur. We are looking into methods to avert this situation. The client wants to be able to run many tests on the phantom and it must maintain its material properties within the +/- 10% margin of error.

f. Operating Environment:

- Since the phantom would be used in MRI scans, the gel material or ould should not contain any kinds of metal. The outer casing of the phantom must be compatible with Ultrasound as well.

g. Ergonomics:

- Since the phantom model is going to be gel based, the weight of the model shouldn't be a concern. However, the phantom would be taken to different imaging instruments therefore must not exceed 15 pounds for ease. The phantom would be refrigerated while not in use, hence an aluminium or tin alloy box should be ample enough to store it. The storage box must open to allow users to easily take the phantom out to scan it.

h. Size:

- The average brain is 14 cm wide and 16.7 cm long. This phantom must adhere to these dimensions in order to fit inside the head coil on the table of the MRI machine.

i. Weight:

- The average brain weighs about 1243 g. The weight of this phantom can be heavier than this, since it is going to be kept on the scan table which can endure higher loads. We would keep the phantom under 15 pounds since we are dealing with gel material

k. Materials:

- There are four different materials found in the brain. The phantom would have materials that mimic all 4 of these materials. A suitable solution to this issue is to vary the properties of polyacrylamide gel, a complex polysaccharide. The outer casing or mold of the phantom will be 3D printed using plastic.

2. Product Characteristics

a. Quantity:

- The client expects to have different phantoms depending on varying ages and have different materials that can substitute as the clotting material for an actual hemorrhage for a patient with a set specific demographic condition.

b. Target Product Cost:

- The main costs for the project will be the 3D printed materials associated with the phantom and the different clotting materials, as well as the fluid that will act as the blood inside the head. Additionally, another cost that will be factored in is the actual pressurized system that will mimic the conditions of an actual human brain. For this reason, the costs should be roughly between $150 to $200 and the client has notified the team that money should not be a deterrent in the project.

3. Miscellaneous

a. Standards and Specifications:

- The FDA's Center for Devices and Radiological Health is responsible for regulating all medical devices sold, imported, repackaged, etc. in the United States. The FDA will need to certify all possible devices as a medical instrument. [5]
- a. *Standards and Specifications:*
  - The phantom needs to have clots with different stiffnesses, with proportional differences that are clinically relevant. The accuracy of the phantom in terms of imitating the material properties of the native tissues is more important than the design. Compression testing via MTS will provide numerical data to enhance the imaging later in the semester.
- b. *Customer:*
  - According to Professor Block, this device is the first of its kind and is meant to be used in a research setting.The primary focus is to cater to Professor Block and the team's preferences. It is important that they understand our entire fabrication

process and the inner workings of the phantom so they are able to use it as effectively as possible and continue to improve upon the device once the semester is over.

- c. *Patient-related concerns:*
  - Since our device will not be used clinically, there aren't many patient related concerns. Each patient's clot has different material properties, so we need to mimic varying clot stiffness.*vivo*.

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