Model for Pre-Surgical Intracerebral Hemorrhage Planning

Preliminary Product Design Specifications

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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. Alginate 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 alginate 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*.

References

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