Model for Pre-Surgical Intracerebral Hemorrhage Planning Product Design Specifications

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Function/Abstract:

Intracerebral hemorrhaging (ICH) is an extremely dangerous condition that without intervention can ultimately lead to death. Recently, new methods have been developed for evacuating clots formed as a result of ICH. However, the stiffness of the brain clots can be very different from patient to patient, which complicates the decision of what method of evacuation to utilize. Professor Walter Block presented the team with the challenge of designing a brain phantom that will be used to generate a database that allows neurosurgeons to compare MRE phantom images to MRE images of ICH patients. By comparing the patient's scan to the database of phantom images, a surgeon will be able to determine the stiffness of the clot prior to surgery, and decide on the best method of evacuation. Other brain phantoms have been created, but none target ICH specifically or include a gel-gel interface. Last semester, the team created an alginate phantom with "clots" inside base gels to prove materials of different stiffness can be differentiated in MRE images. This semester, further investigation will be performed to obtain more information on the capabilities of the alginate gel/imaging combination with varying stiffnesses. After that, the resolution quality of decreasing size clots will be researched.

Client Requirements:

- Have a variety of stiffness of gels to create a database of known MR
- Have multiple clots within the phantom that can model varying stiffnesses of clots representing the differences in patients' clots
- Provide mechanical testing of gels to enhance image meaning
- 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

Design Requirements:

1. Physical and Operational Characteristics:

a. Performance Requirements:

The device must imitate the structure and rigidity of brain tissues to understand the rigidity of blood clots. We need a model that can be imaged in MR so that surgeons are more informed before choosing a treatment. The phantom design will allow for imaging of a large array of stiffnesses, with varying resolutions to create a database of known stiffnesses at known resolutions.

b. Safety:

The device will have an outer casing that must be safe to handle. The materials that mimic the native tissue should also be safe to handle with reasonable personal equipment such as latex gloves. All the materials within the device must be safe to use with MRI.

c. Accuracy and Reliability:

Our phantom is meant to mimic the size and consistency of the human brain. Mechanical testing will be done to compare Young's Moduli of different stiffnesses.

d. Life in Service:

The phantom is meant to last for 3 months and able to withstand multiple scans. It will be stored in a refrigerator when not in use. Part of the issue with phantom work today is that the old models erode which produces unreliable results. Each scan should take 30-45 minutes, so the device must be able to be outside of a refrigerator for that amount of time.

e. Shelf Life:

This phantom must not deteriorate significantly over time. Alginate deterioration is characterized by cloudiness in the gel and an increased liquid character. 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 while being stored in the refrigerator.

f. Operating Environment:

This phantom will be exposed to extremely powerful magnetic fields and therefore cannot contain any metal as this will ruin the image that the MRI produces. The outer casing of the phantom must be compatible with Ultrasound as well.

g. Ergonomics:

The phantom has to be transported to various imaging machines so ideally it shouldn't weigh more than an average person can carry. A simple case such as a metal box is enough to provide sufficient protection while the phantom is not in use. The case 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 that goes into the MRI machine.

i. Weight:

The average brain weighs about 3 pounds or 1300-1400 grams. The weight of this phantom can be heavier than this, as there is no cause for concern on placing the phantom on an MRI table. An average person should be able to carry the phantom easily so it should not exceed 10 pounds.

j. Material:

We need to imitate four different materials found in the brain. This can be achieved by varying the properties of alginate gel. The outer casing of the phantom will be 3D printed using PLA plastic. Both materials are safe for human contact.

k. Aesthetics:

For the scope of the project that we will be focusing on, the sample holder can be very simple, as we are just looking for a way to image different stiffnesses of gels at one time. This way we can create a database of known stiffness values and how they are perceived in MR.

2. Production Characteristics:

a. Quantity:

Our client wants to model different types of clots. Our current design does this in a single phantom.

b. Target Product Cost:

Our client notified us that money was not an issue. Additionally, the device will use simple plastic and basic chemicals, so the cost will likely be less than \$100.

3. Miscellaneous:

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.

Works Cited

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