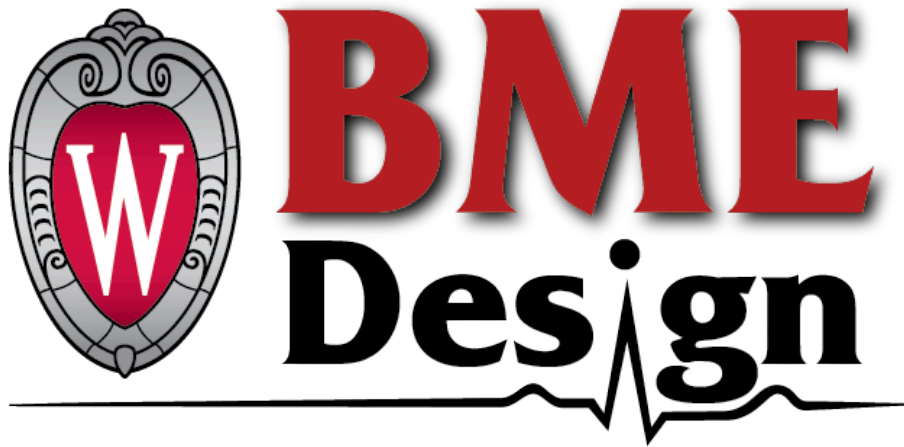




Intracranial EEG Phantom

Preliminary Report

Lab: 308

Date: 10/7/2026

Client: Dr. Raheel Ahmed

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Abstract

A growing method of treating epilepsy, a condition especially common in children, is Transcranial Magnetic Stimulation (TMS), which changes excitability of neurons. The effects of TMS are not entirely understood and testing with intracranial electroencephalography (iEEG) is necessary to view these effects. Theoretical issues with the use of the two prevent use in humans, and a pediatric brain phantom must be created to model the use of the two together and ensure safety. Current models only focus on adult brains, which fails to address a majority of individuals with epilepsy. The phantom will be split into three distinct sections of the brain: the skull, the gray matter, and the white matter. The skull will be made out of PMMA which will be 3D printed into the shape of a scan provided by the client. The gray and white matter will be made of saline gelatin, with a gelatin concentration of 0.6%. The gray matter will have a NaCl concentration of 62.25 mg/ml, and white matter 25.26 mg/ml to give the gel a conductance that matches the values found in literature. The brain will be created from a mold in the shape of a scan of a brain also provided by the client, with the gray matter having a thickness of 2.5 mm. TMS and iEEG can then be performed to view its effects on the brain. Electrode heating past 40 degrees celsius and any measurable displacement will be considered dangerous.

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Introduction and Background

Motivation

Seizures are the symptoms caused by excessive or synchronous firing of neurons in the brain [1]. While 5-10% of the human population will experience a seizure during their life, epilepsy, the condition wherein seizures consistently occur, only affects 0.3-0.5% of the human population [1]. Additionally, a majority of an individual's seizures occur during childhood [1]. While a variety of methods already exist to treat epilepsy, one novel method is transcranial magnetic stimulation (TMS) which functions by producing a small magnetic field to change the excitability of neurons [2]. Despite its growing prevalence, the exact functional impact it has on the brain is relatively unknown and is subject to extensive research. One method used to see exact changes in excitability of neurons, especially for epilepsy research, is intracranial electroencephalography (iEEG) [3]. iEEG, similar to normal electroencephalography, reads the voltage difference between two electrodes implanted on separate parts of brain tissue, with the main difference being that the electrodes are directly implanted onto the brain instead of across the scalp in order to reduce resistance from the skin and skull [2]. While iEEG would be an acceptable measurement with most other treatments, a variety of problems are suspected to take place if used in tandem with TMS, primarily the dissipation of power from induced currents as heat onto the brain and the displacement of electrodes from magnetic forces [2]. Heat in particular could be an issue since brain cells can only withstand an increase of 3° Celsius before irreversible damage occurs [4].

While some promising research has been done into simultaneous iEEG and TMS, enough data hasn't been gathered to approve the use of the two in humans [2]. Typically, testing to confirm the validity of the two would be performed in a brain phantom, a model designed to mimic the physical properties of the human brain [5]. Since the brain has a multitude of complex properties such as anisotropy, an accurate model is very difficult and no current models are entirely accurate to the brain [5]. Furthermore, because seizures and epilepsy are so prominent in children, a pediatric focused model needs to be developed to verify safety in the population that would be the most heavily affected. This need for a pediatric brain phantom is even more difficult to fulfill, as the brain must be scaled to an appropriate size without any air bubbles or other impurities appearing in the material when it is constructed [6].

Competing Devices

The unique difficulties creating a pediatric brain phantom combined with the fact that brain phantoms are not typically produced commercially means that there are very few currently existing brain phantoms for pediatric brains. The closest existing model for the problem presented is a phantom designed to be used to test the safety of TMS and iEEG used together,

though this model differs from the given requirements by modelling an adult's brain [2]. Furthermore, previous teams that have worked with the client who requested this project have made a model to address this same problem, though no testing has been done with it.

Problem Statement

Intracranial electroencephalography (iEEG) is used in patients with epileptic seizures that are prominent in pediatric patients to help locate brain regions responsible for their seizures and help surgical planning. Transcranial magnetic stimulation (TMS) may provide additional information about critical regions to avoid. However the TMS can raise safety concerns because the interaction of the magnetic fields with the electrodes can cause heating or possibly displace the electrodes. To address this, a pediatric brain phantom that enables safe TMS and iEEG testing on implanted cortical electrodes must be created.

Client Information

The client commissioning this project is Dr. Raheel Ahmed, a pediatric neurosurgery specialist who works at the American Family Children's Hospital with UW Health and is an associate professor in the Department of Neurological Surgery. He is interested in pediatric cases of epilepsy and is looking for more possible treatment options.

Background Research

To create a sufficiently accurate brain phantom, a few design choices are necessary. TMS only reaches roughly 4 centimeters into the brain tissue, so for the sake of simplicity, the model will be split into 3 distinct material parts: the skull, the gray matter, and the white matter of the brain [2]. This removes the need to model the more complex internal parts of the brain such as the nuclei and cerebrospinal fluid ventricles. The conductances of the brain are possibly the most crucial points to model, as they are what ensures that the voltage readings on the iEEG are correct according to Ohm's law. The reported conductances of the skull, gray matter, and white matter is 0.016, 0.3787, and 0.1462 S/m respectively [7]. Another important property to address is the physical strength of the brain in order to ensure that any physical damage caused by electrode displacement will be shown in the phantom. Since most forces applied to the brain will be a shear force from the electrodes pulling parallel to the walls of the brain where they are implanted when under possible magnetic forces from TMS, the shear strength of 1 kPa seen in virtually all brain tissue including white and gray matter should be used as a reference strength to match [8]. Less concerning since it is easy to achieve, but still important to model, is the materials ability to withstand the TMS conditions used to treat epilepsy which are less than 1 Hz in frequency magnetic field single pulse testing that lasts for 20-30 minutes [9]. Since this device will strictly be used as a research tool, no codes or standards apply to it. The only standard that could possibly be required is if it is used in magnetic resonance imaging (MRI) testing, in which

case the ASTM-F2812 standard for brain phantoms in MRI would apply. The final requirement to fulfill is the client's request that the total cost of the phantom be under \$1000.

Design Research

Many methods exist to actually fabricate a brain phantom, and it largely depends on the material chosen for the different parts. Skull materials are very often 3D printed using MRI scans, since many materials that mimic the properties of bone can be 3D printed [10]. Other, more uncommon methods, include direct sculpting and then firing of certain clays into the shape of a skull [11]. Physical brain matter materials for brain phantoms are much more straightforward, as most simply create either a hydrogen or a gelatinous brain from a mold of MRI scans of a brain [5]. Once the molded brain has cooled, it can be inserted into the skull in a variety of ways. One common method is to have the hot, liquified gelatinous material injected into compartments in the skull where the part of the brain it represents is located [12]. Another method is to split the skull into an upper and lower half when fabricating it, allowing the skull to open and have the brain placed inside.

Preliminary Designs and Evaluation

Hydrogel Materials

Gelatin

Hydrogels are crosslinked polymeric networks that are able to contain large amounts of water, and can be prepared using various natural or synthetic polymers. Gelatin is a protein obtained from the hydrolysis of collagen and has been popularly used in hydrogels because of its large number of functional groups allowing it to be easily crosslinked and because of its abundance and low cost. At around 35°C the hydrogels crosslinking bonds disrupt causing the gelatin to convert back to liquid. Increasing gelatin concentrations or adding a crosslinking agent can strengthen the structural integrity, delay degradation, and increase temperature stability of the hydrogel [14]. One possible additive to increase temperature stability is Transglutaminase which is an enzymatic cross-linking agent between glutamine and lysine residues in gelatin molecules [16].

Agar

Agar is a polysaccharide extracted from different types of red algae. Agar is composed of two polymers, agarose and agaropectin – agarose is what allows the agar to form a hydrogel. One of the significant properties of agar is its stability at high temperatures and melts around 80°C. Depending on what species of red algae the agar is sourced from can alter the concentrations of the two polymers and therefore properties of the hydrogel. Agar-like gelatin can also be strengthened by increasing concentrations of the agar or addition of a crosslinking agent [15].

Polyvinyl Alcohol Cryogel (PVA)

The term cryogel refers to a class of hydrogel that is formed using sub zero temperatures. Cryogels are formed using multiple freeze thawing cycles (typically -20°C and back to room tem) in this way the cross-linking of polymer chains is facilitated by the phase transformation of water. PVA is a popular cryogel because of its proven to form robust hydrogels. There are varying grades of PVA characterized by varying molecular weights and degrees of hydrolysis that can be used for a brain phantom. PVAs main drawback is its many freeze thaw cycles [15].

Skull Materials

Polymethyl Methacrylate (PMMA)

Polymethyl methacrylate (PMMA) is a polyester that is synthesized from acrylic acid polymerization and is commonly used as a 3D printing filament in the medical field because of its low cost, durability, and similarities to human bone strength. Its ease of use is very desirable for the skull phantom because it can be 3D printed from a 3D scan of a pediatric skull provided by the client. This ease of use also allows for easy repetition and duplication of similar pediatric skull phantoms. PMMA also has a thermal conductance of 0.3-0.5 W/mK, which is extremely similar to the thermal conductance of the human skull [10].

Gypsum

Gypsum is a sulfate mineral made of calcium sulfate dihydrate, and is popularly used in skull and bone phantoms because of its similarity to cortical bone density and electrical conductivity. Gypsum's solid crystal structure allows it to have similar properties to the skull. It is fabricated by mixing with water to form a plaster that can be poured into a negative skull mold to make the skull phantom [11].

Plastic Clay

Plastic Clay is a type of moldable ceramic clay and is normally used in early prototyping because of its low cost and accessibility. Although it matches the electrical conductivity of the skull it has major drawbacks in fabrication. To obtain proper anatomical geometry of the skull using clay would take a lot of meticulous time and effort to precisely mold the clay. Some specific clay samples have conductivity values ranging from 0.02 S/m to 0.2 S/m, which is directly in the range of the human skull. Plastic clay can also be reused after deep cleaning to remove any accumulated NaCl; however, a potential drawback with this is that the repeated soaking and cleaning cycles may cause gradual material deterioration, as parts of the clay can dissolve over time [11].

Design Matrices and Summary

		Polyvinyl Alcohol Cryogel		Agar		Gelatin	
Criteria	Weight	Score (5 max)	Weighted Score	Score (5 max)	Weighted Score	Score (5 max)	Weighted Score
Electrical Conductance	25	5	25	5	25	5	25
Thermal Conductance	25	5	25	5	25	5	25
Shelf Life	20	4	16	2	8	2	8
Ease of Fabrication	20	2	8	4	16	4	16
Cost	10	4	8	2	6	5	10
Total	100	Total	82	Total	80	Total	84

Table 1: Preliminary Design Matrix for Potential Hydrogels Used for the Brain Design.

Three materials, consisting of polyvinyl alcohol (PVA) cryogel, agar, and gelatin, were evaluated as potential materials for the brain portion of the phantom design. The considered criteria was electrical conductance, thermal conductance, shelf life, ease of fabrication, and cost. Electrical and thermal conductance were given the largest weights because the material to be used must replicate the relevant electrical and thermal properties of brain tissue to insure accuracy during iEEG testing. Shelf life and ease of fabrication were also heavily weighted because the phantom is intended for repetitive testing, so it must be practical to maintain and fabricate.

Gelatin received the highest overall score of 84, followed by PVA cryogel with 82, and agar with 80. All three materials received maximum scores for electrical and thermal conductance because their water-based compositions are similar to the thermal properties of brain tissue, and their electrical conductivity can be adjusted through the addition of sodium chloride (NaCl). The primary differences in the materials were ease of fabrication, shelf life, and cost. PVA cryogel received the highest shelf life score because of its structural stability; however, it received a lower fabrication score because producing the cryogel requires multiple freeze-thaw cycles. Agar and gelatin are much simpler to fabricate to reflect the human brain, therefore receiving higher scores. Gelatin would also be the most economical material, giving it the

highest score for cost. Based on the weighted criteria, gelatin provided the best overall balance of electrical and thermal properties that are similar to the brain, is simple to fabricate, and has a low cost and acceptable shelf life.

Skull Materials:

		Polymethyl Methacrylate (PMMA)		Gypsum		Plastic Clay	
Criteria	Weight	Score (5 max)	Weighted Score	Score (5 max)	Weighted Score	Score (5 max)	Weighted Score
Electrical Conductance	25	5	25	5	25	5	25
Thermal Conductance	25	4	20	5	25	4	20
Ease of Fabrication	20	4	16	3	12	1	4
Shelf life	20	5	20	5	20	3	12
Cost	10	5	10	3	6	4	8
Total	100	Total	91	Total	88	Total	69

Table 2: Preliminary Design Matrix for Potential Materials used for the External Skull.

Three materials were evaluated to be used as the skull material in the final phantom, consisting of polymethyl methacrylate (PMMA), gypsum, and plastic clay. The five important criteria to be considered were the same as for the brain; however, some aspects were weighted differently. Electrical and thermal conductance were given the highest weight since the material used for the skull must be anatomically accurate to the human skull in terms of these properties to provide the most accurate testing results. Ease of fabrication was also heavily weighted because it needed to be relatively fast to fabricate so that more time could be spent refining the brain design to provide the most accurate testing results.

PMMA received the highest overall score of 91, followed by gypsum with a score of 88, and finally, plastic clay with 69. All three materials received the same score for electrical conductance because their electrical properties were in the same conductance range of the human skull. PMMA also scored well in ease of fabrication because it can be 3D printed directly from the brain and skull scans provided by the client. This would also reduce fabrication time and allow for more consistency with the human skull. Gypsum received a lower fabrication score because it would require additional molding and casting steps. Finally, plastic clay received the lowest fabrication score because achieving the anatomical accuracy would require repeated shaping by hand and firing. Shelf life and cost further distinguished the materials, with plastic

clay scoring the lowest due to its maintenance and cleaning requirements between uses. Gypsum also received a lower cost score than PMMA because it would be the most costly material.

Proposed Final Design

Based on the design matrices, the proposed final design will feature a 3D-printed PMMA skull surrounding a gelatin-based interior. The PMMA skull will be fabricated using the available pediatric brain scans to achieve an anatomically accurate skull geometry, while still maintaining durability during repeated testing. The interior will use gelatin because of its low cost, ease of fabrication, and ability to achieve different electrical conductivity values through sodium chloride concentration.

The brain interior will distinguish between gray and white matter by using different sodium chloride concentrations. Approximately 65.25 mg/mL of NaCl will be used for the gray matter to reach an electrical conductivity of approximately 0.3787 S/m. Then, approximately 25.26 mg/mL of NaCl will be used for the white matter portion to reach a conductivity of around 0.1462 S/m. This allows for the proposed phantom to represent the electrical differences between gray and white matter, while still maintaining a relatively simple fabrication process. Together, the PMMA skull and gelatin-based interior will provide an anatomically representative pediatric brain phantom for iEEG testing, while prioritizing conductive properties.

Fabrication

Materials and Methods:

Previous Team's Skull Model

PMMA has the closest material properties to the skull necessary for this project. Furthermore, the previous team designed a skull of the same material using a model of a pediatric skull provided by the client. This skull was determined to be a satisfactory fit for the phantom, as it would allow for more resources to be spent developing a more intricate model of the brain and more time to conduct tests.

3D Printed Brain Mold

The mold of the brain was designed in Autodesk Fusion 360 to be a simplified interpretation of the brain. A model of a pediatric brain from an anonymized 5-7 year old patient was supplied by the client and was used to create this mold. For this work, it is not necessary to recreate the surface texture of the brain. This is because the effects that the iEEG electrodes will have on the composition of the brain are the main focus of the phantom. A rough outline of the brain will be sufficient to recreate the desired conditions.

The average grey matter thickness of the brain was found to be 2.5mm thick [13]. To replicate this in the phantom, a mold was designed with a scaled-down brain that inserts into the mold. This allows for an initial layer of the grey matter gelatin to form on the exterior of the mold before the final addition of the white matter gelatin can be made. The mold and its insert will be printed on a Bambu Labs X1 Carbon available in the Grainger Engineering Design Innovation Lab on the UW-Madison campus. To create the mold, PETG will be used because it provides a smooth surface after printing. These properties are important to ensure the gelatin settles correctly and is easily removed from the mold afterwards.

Grey and White Matter

The conductivity(σ)(S/M) of gelatin gels at a temperature of 21 +/- 1°C was found to have a linear relationship with the concentration of NaCl (c)(mg/ml)

$$\sigma(S/M) = (172 \pm 5) * c + (0.116 \pm .002) \quad [5]$$

The concentration of NaCl mixed with Deionized water used will be 65.25 mg/ml for the grey matter, and 25.26 mg/ml for the white matter to match an in vitro pediatric brain. These values were calculated by using the above equation and the previously stated conductivities. This, in

conjunction with ultrafiltered water, will be added to the gelatin mix till the gelatin is 0.6% by weight of the mixture. The grey matter mixture will be stirred with a stir bar at 60-65°C, then poured into the mold with the insert in place [14]. It will be allowed to cool overnight, and the next day the process can be repeated for the white matter concentration, except the insert will be removed.

Testing

Verify NaCl and Gelatin ratios

To determine the proper concentrations of gelatin and NaCl that the phantom needs to properly mimic the physiological properties of the brain, a variety of tests must be performed. Different NaCl concentrations can change the electrical conductivity of the hydrogel, and different gelatin concentrations can affect the structure of the hydrogel. To verify that concentrations of gelatin and NaCl closely match the properties of the brain, a current will be run through the phantom and use an EEG electrode to measure the voltage. Using Ohm's law, the voltage should match the expected value of the current applied and the concentrations would therefore accurately model the brain.

Heating around electrodes

To determine the relationship between TMS and heating of iEEG electrodes, multiple test runs of TMS stimulation with iEEG will be performed on the brain phantom. To perform these test runs, multiple stereo-EEG electrodes spaced 2mm apart will be inserted. Subdural electrodes will also be placed on top of the brain. The temperatures at the electrodes will then be obtained after running the TMS at multiple positions on the skull to test how the position affects the relationship of the TMS and electrode temperature. Finally, the temperature difference will be measured at the electrodes after every trial. After TMS application, if electrodes heat past 40°C, brain damage can occur and would render TMS unsafe to use in conjunction with iEEG.

Electrode displacement

The electrode displacement is very important in analyzing the relationship between TMS and iEEG because any displacement of the electrodes can damage brain tissue or misidentify location of brain activity. To test this, a similar setup for the electrode heating test will be implemented, but instead, during TMS stimulation, visual displacement of the electrode will be recorded. Any amount of displacement in the electrodes during testing will render the use of TMS with iEEG unsafe.

Discussion

The proposed pediatric brain phantom provides a controlled method for evaluating the interaction between transcranial magnetic stimulation (TMS) and intracranial electroencephalography (iEEG) electrodes before use in pediatric research. Extensive research into hydrogels indicates that gelatin and sodium chloride (NaCl) concentrations can be tuned to match the target electrical conductivities of pediatric brain tissues: 0.3787 S/m for gray matter and 0.1462 S/m for white matter [5]. Furthermore, increasing the gelatin concentration strengthens the material and delays degradation, allowing the gel's mechanical response to approximate the physiological shear strength benchmark of 1 kPa [8].

Under clinical single-pulse TMS exposure parameters (< 1 Hz for 20–30 min), thermal monitoring across stereo-EEG electrodes and subdural electrode sites evaluates whether localized heating remains safely below the 40° C critical threshold for irreversible cellular damage [4]. Visual and spatial displacement assessments evaluate whether magnetic field gradients impart sufficient torque or shear forces to shift cortical electrodes within the gelatin.

When compared to existing literature, this design expands upon adult brain phantom models [5]. While prior adult phantoms validated basic electromagnetic interactions [2], they failed to account for pediatric skull dimensions, tissue density variations, and smaller anatomical scale factors [6].

Developing medical devices for pediatric populations carries substantial ethical constraints. Conducting preliminary safety evaluations regarding electromagnetic force generation and localized heating directly on pediatric human subjects is ethically unfeasible due to patient vulnerability and the risk of irreversible neurological injury [4]. By establishing a non-biological, anatomically accurate pediatric brain phantom, this project provides a risk-free benchtop platform for neurosurgeons and clinical researchers to evaluate safety parameters before pursuing human clinical trials. Testing on a physical phantom avoids exposing pediatric patients to potential clinical risks during early-stage investigation.

Many sources of experimental error and physical limitations were identified during design analysis and fabrication planning.

1. Thermal Stability Limits: Pure gelatin hydrogels melt near 35 °C as hydrogen bonds disrupt, restricting long-term testing at elevated temperatures without thermal stabilization.
2. Dehydration and Environmental Degradation: Gelatin hydrogels are prone to water evaporation over time. Evaporation increases localized NaCl concentration, altering electrical conductivity and shrinking phantom dimensions.

3. Thermal Measurement Interference: Standard metallic thermistors or thermocouples placed near iEEG electrodes can perturb local magnetic fields during TMS pulses or act as heat sinks, potentially distorting temperature readings.
4. Internal Bubble Trapping: Manual mixing and pouring of gelatin can trap bubbles, introducing non-uniformities within the hydrogel.

Based on preliminary matrix evaluations and literature reviews, several key design choices were established:

1. Gelatin Weight Optimization: Increasing the concentration of gelatin by weight was incorporated to optimize structural integrity and delay degradation of the uncrosslinked gel matrix.
2. Dual-Layer Conductive Matrix: Rather than utilizing a single homogeneous gel, a two-step casting procedure was adopted to isolate white matter (0.1462 S/m) and gray matter (0.3787 S/m) conductivities.
3. 3D-Printed PMMA Skull Interface: Transitioning from clay or gypsum molds to direct 3D printing of polymethyl methacrylate (PMMA) derived from pediatric CT scans improved structural consistency, anatomical accuracy, and skull conductivity matching (0.016 S/m) [5].

Conclusion

In this project, a pediatric brain phantom was designed to evaluate safety concerns regarding electrode displacement and heating during simultaneous TMS and iEEG procedures. The proposed design incorporates a 3D-printed PMMA skull (0.016 S/m) surrounding a dual-layer gelatin hydrogel configured to mimic the distinct conductivities (0.3787 S/m gray matter, 0.1462 S/m white matter) and shear strength of pediatric brain tissues [5], [8].

The phantom provides a standardized testing platform to confirm that single-pulse TMS regimens do not induce electrode displacement or elevate localized temperatures above the critical biological threshold of 40 °C [4]. The fabrication plan meets all primary performance and safety criteria outlined in the Product Development Specification while staying well within the \$1000 budget.

For subsequent iterations of the prototype, several alternative fabrication and testing methodologies should be adopted. Specifically, integrating vacuum chamber degassing during gelatin preparation will eliminate bubbles trapped during casting, ensuring uniform electrical and mechanical properties throughout the matrix.

Future work will focus on key improvements to prepare the pediatric brain phantom for clinical use. Material refinements will focus on testing cross-linking additives, such as transglutaminase, to keep the gel from melting at temperatures above 35 °C. Combining these with storing the phantom in airtight containers will prevent drying out and mold growth, significantly extending its shelf life.

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B. Brain Mold Design Images

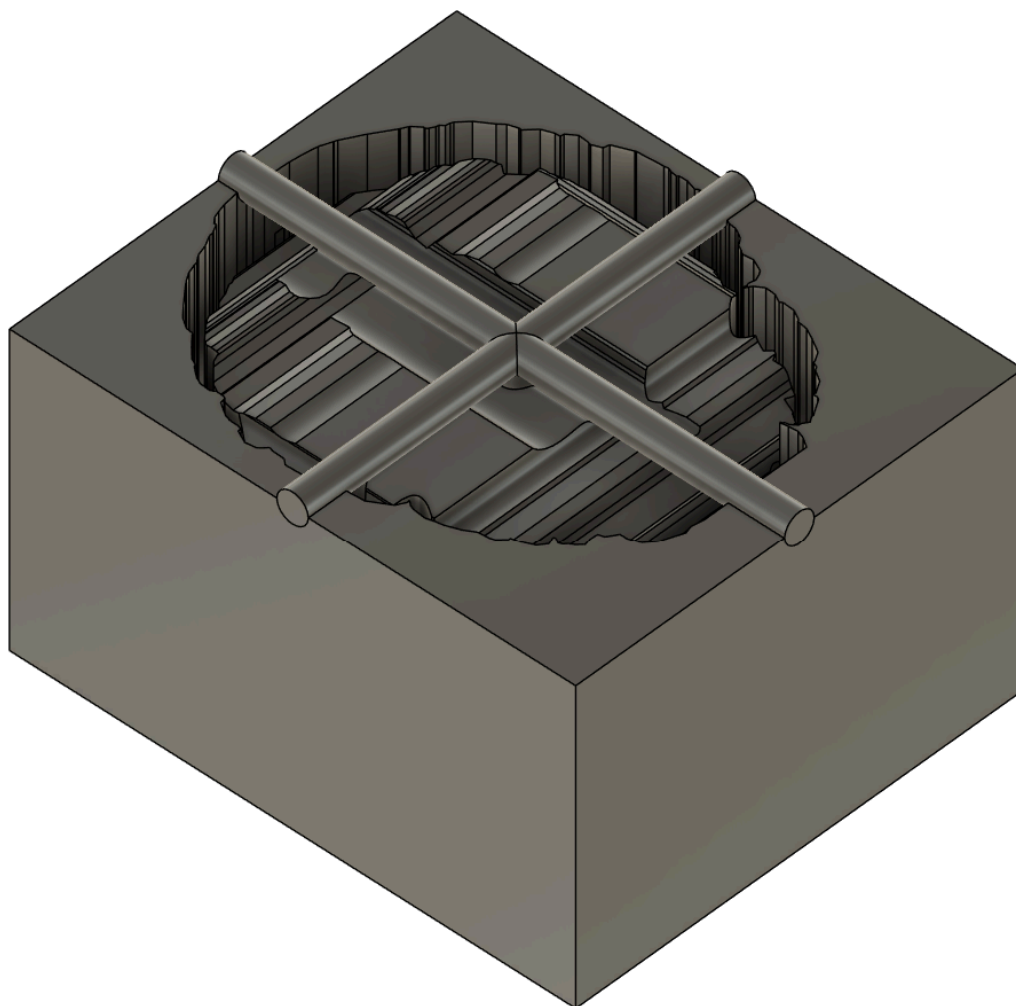


Figure B1. Isometric view of the in-progress Brain Phantom Mold and Insert in Fusion 360.

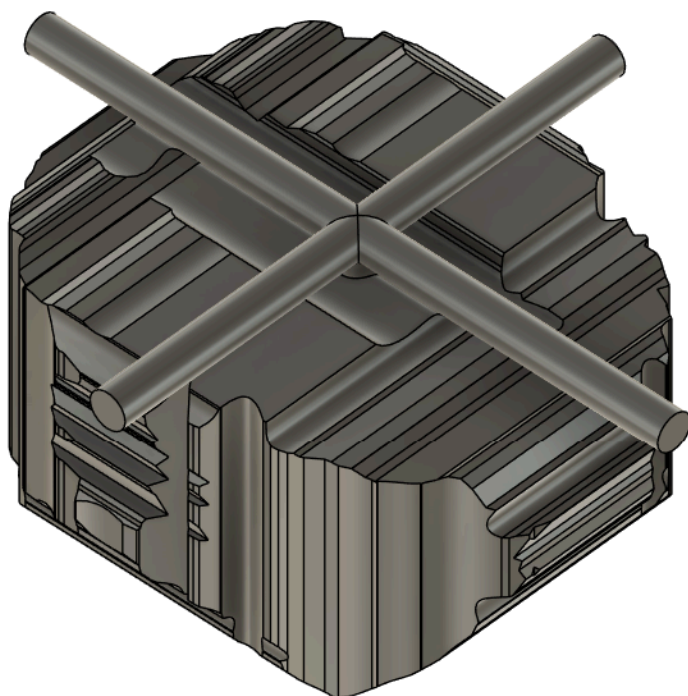
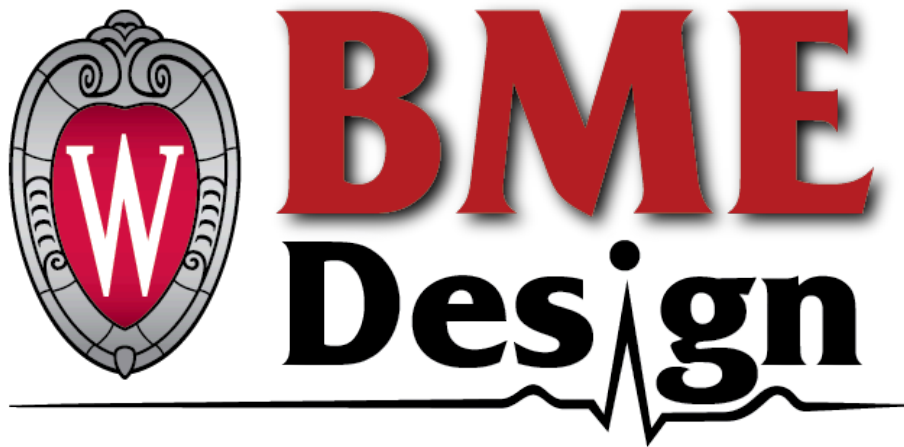


Figure B2. Isometric view of the in-progress Brain Phantom Insert in Fusion 360.

C. Product Design Specification



Intracranial EEG Phantom

Product Design Specifications

Lab: 308

Date: 9/17/2026

Client: Dr. Raheel Ahmed

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Function

A brain phantom is a model of a human brain designed to mimic the physical properties of the brain for the sake of testing. This brain phantom will be used to test the simultaneous use of transcranial magnetic stimulation (TMS) and intracranial electroencephalography (iEEG) in pediatric subjects for the study of TMS's effect on epilepsy. This means the phantom must exhibit expected responses from a normal, pediatric brain and skull when subjected to TMS and iEEG experiments individually. TMS works by sending a magnetic field into the brain, changing excitability of certain regions, while iEEG directly reads the electrical potential of the brain [1].

Client requirements

- The phantom must be separated into 3 unique materials: the skull, the white matter, and the gray matter
- The budget for this phantom is \$1000
- The phantom must be an accurate anatomical representation of any pediatric brain
- The phantom must be able to withstand iEEG and TMS separate of each other

Design requirements

1. Physical and Operational Characteristics

a. Performance requirements

The brain phantom will undergo transcranial magnetic stimulation (TMS) and intracranial electroencephalography (iEEG) in order to simulate the use of these two simultaneously in pediatric patients with epilepsy. The phantom must withstand a magnetic field with a frequency of 1 Hz or less, for 20-30 minutes, with an intensity set at or slightly above the resting motor threshold (RMT) to show it is strong enough to withstand TMS operations commonly used to treat epilepsy [2]. The brain phantom must be able to have electrodes inserted into it and should not sustain any significant damage when doing so.

b. Safety

The brain phantom must not be made out of an easily flammable material, as TMS testing with iEEG always runs the risk of creating a very large current [1]. This large current dissipates a lot of power as thermal energy, meaning the brain phantom could catch fire if made of a flammable material.

c. Accuracy and Reliability

The phantom must accurately display the electromagnetic and some physical properties of real, pediatric white matter, gray matter, and skull tissue to ensure accurate testing. Conductance in particular can be modeled after adult samples due to it being a property that does not change with age [3]. Conductance for white matter should be roughly 0.22 S/m for white matter, 0.47 S/m for gray matter, and 0.02 S/m for the skull [4]. The shear modulus must also be taken into account to ensure any movement of the electrodes during testing is accurate to what would happen in human samples. The shear modulus of pediatric patients, who have had some brain development and stiffening, is roughly the same shear modulus as adults [5]. Adult samples are roughly around 1 kPa, meaning the model should have a shear modulus of around 1 kPa [5].

d. Life in Service

The lifetime of the phantom must last the entire duration of testing to validate simultaneous TMS and iEEG safety protocols. The phantom must be able to withstand repeated stimulation of TMS application without degradation of the phantom materials.

e. Shelf Life

The shelf life for the phantom must last the entire duration of testing. Gelatin based phantoms should be stored in a dark humid refrigerated environment to prevent degradation of bacterial growth and drying out and extend shelf life to around 50+ days. The addition of many different additives like 4% chlorhexidine gluconate can also extend shelf life of gelatin phantom. The shelf lives of the iEEG and skull material is negligible and should outlast testing.

f. Operating Environment

The phantom will be used in a sterile environment and room temperature and humidity at around 22-24 C and 40-60%. The phantom will be used in conjunction with TMS and iEEG technology which requires non metallic sensors as to not affect signals and reactions.

g. Size & Weight

The Brain Phantom will be a 1:1 replica of a pediatric brain, including the skull, white matter, and gray matter. The volume and weight of each replicated material must be comparable to what is found in a pediatric brain. The volume of a pediatric brain is dependent heavily on the age of the subject in question. For example, the volume of the brain was found to grow by 25% between early childhood (19-33 months) and mean adolescence (12-15 years) [6]. For this project, brain specifications for 6-8-year-olds will be used to develop a comparable brain phantom to an adolescent brain before it reaches its developmental maximum.

h. Materials

The Brain Phantom must use three distinct materials to represent the skull, gray matter, and white matter. The gray and white matter should be made from nonmetallic tissue-mimicking materials whose electrical conductivity can be adjusted by changing the concentration of additives. The materials should target conductivities of ~0.47 S/m for gray matter and ~0.22 S/m for white matter. The skull should be made from a rigid, nonmetallic material with a conductivity of ~0.02 S/m. Previous head phantom research has shown that synthetic materials can be modified to reach

a threshold that simulates the electrical properties of a skull [9]. All materials must withstand repeated TMS and iEEG testing while remaining under the \$1000 budget.

i. **Aesthetics, Appearance, and Finish**

The phantom should accurately represent the general anatomy of a pediatric brain and skull so that TMS coils and iEEG electrodes can be positioned realistically. The skull, gray matter, and white matter should be distinguishable by some metric. The exterior should be smooth with no noticeable defects, and contain identifiable anatomical features to allow consistent placement of equipment between tests.

2. **Production Characteristics**

a. **Quantity**

One pediatric brain phantom with a pediatric-representative skull and brain that can accommodate implanted iEEG electrodes for TMS testing and allow measurement of TMS-induced electrical current, temperature changes, and electrode displacement.

b. **Target Product Cost**

Total cost should remain within the project budget of \$1,000, using existing department equipment and available iEEG electrodes when possible. The team is targeting a cost-optimized approach to keep the prototype within budget.

3. **Miscellaneous**

a. **Standards and Specifications**

The phantom is designed for research use only and is not intended for clinical or diagnostic use.

The phantom will follow applicable requirements under 21 CFR Part 882 for neurological devices related to intracranial EEG and TMS.

Electrical components and measurement equipment will follow applicable IEC 60601-1 for laboratory equipment safety requirements.

b. **Customer**

The primary customer will be the physician or researcher conducting iEEG studies. There is a need for a reliable phantom that functions as a controlled alternative to the patient, replicating the different sections of the brain for the most accurate results.

c. **Patient-related concerns**

Patient-related concerns during TMS and iEEG treatments include electrode displacement, electrode heating, and induced current from the electrodes. The phantom must mimic conditions where iEEG electrodes are located in the brain with a TMS coil positioned above it, so the treatment can be safely conducted on pediatric patients.

d. **Competition**

A similar phantom was recently designed at the University of Iowa to replicate the conditions of the brain during TMS and iEEG studies. This design was developed using polyacrylic acid (PAA) saline gel inside a 3/16 in. polymethyl methacrylate (PMMA) container. The gel was designed to simulate the brain tissue, while the PMMA container represented the skull. The phantom also used platinum electrodes embedded in a silicone-based material to replicate the electrode setup for iEEG testing [8]. This design provides a useful starting point for iEEG phantom development; however, the existing phantom was designed for general use and does not account for the anatomical and safety considerations associated with pediatric patients.

4. Citations

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