Intracranial EEG Phantom for Brain Stimulation Studies

Product Design Specifications (PDS)

BME 400

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Function

Intracranial electroencephalography (iEEG) is routinely used in surgical planning for individuals with uncontrolled seizures, such as those with epilepsy. Utilizing electrode systems either connected across the surface of or implanted into the brain, this method provides high spatiotemporal resolution [1]. Transcranial magnetic stimulation (TMS) assesses brain circuit excitability through electromagnetic induction, inducing currents to produce action potentials and painlessly activate brain networks [2]. While this neuromodulation technique may provide complementary information for mapping out critical brain regions that should be avoided during surgery, there are several safety concerns around the use of TMS in patients with iEEG: that of secondary electrical currents, heating of the implanted electrodes, and electrode array displacement, all of which would have severe consequences for the affected individuals [1]. Additionally, the impact of these techniques has not been previously studied on children with epilepsy, but instead on adult patients; dissimilar physiology and comparative higher resting motor thresholds might require higher levels of stimulation, both of which indicate the need for adjusted treatment [3]. The goal of this project, therefore, is to develop a pediatric brain phantom model that can be used to simulate the main effects of TMS on iEEG electrodes: currents, temperatures, and changes in position.

Client requirements

1. The phantom should represent the physiology of the pediatric brain in terms of overall matter volume, between 50 and 100 mm^3, and circumference of the surrounding skull, between 50 to 54 cm [4], [5].
2. The material should have efficient conductivity to allow for proper current testing; to represent brain tissue conductivity, this value should lie between 0.2 and 0.5 S/m [6].
3. The device must be able to withstand a minimum of 50 magnetic pulses, as is common in TMS sessions for human participants [1].
4. The phantom must not physically interfere with TMS coil application to allow for adequate testing. To allow for optimal orientation, the TMS operator should be able to hold the coil within 5.5 ± 1.6 mm of the scalp [7].
5. The budget must not exceed $500.

Design requirements

1. Physical and Operational Characteristics

a. Performance requirements

i. The phantom must withstand magnetic pulses up to a frequency of 0.5 Hz, as performed in a previous TMS study on patients with implanted electrodes [1].

ii. To reflect the higher motor threshold present in a pediatric nervous system, as the corticospinal tract continues to develop, the phantom should tolerate pulses up to 2T in magnitude [8], [9].
iii. Similar physiological properties to the young child brain are ideal, including an overall brain matter volume between 50 and 100 mm^3 and appropriate conductivity levels in the range of 0.2 to 0.5 S/m [4], [5].
iv. The shape and structure of the model must be maintained despite implantation of electrode arrays – up to 90 mm [1].
v. The construction of the phantom and any necessary container must allow for measurements of displacement, temperature change, and induced current; as such, the device should be accessible from several points, such as from each of the embedded electrodes.

b. Accuracy and Reliability

i. After treatment with TMS, the implanted electrodes should experience <1°C of heating [10].
ii. The iEEG electrodes should experience displacement of less than 20 mm, as some deformations of the brain can naturally occur [11]. Ideally, there will be no significant displacement.
iii. Charge density must be less than 30 $\mu C/cm^2$ when TMS is being administered at full power [1].

c. Life in Service

i. The phantom will be used to ensure the safety of TMS being used with iEEG technology.
ii. The phantom must be constructed from material that will not degrade over the entire testing period, such as a 3D printed acrylic polymer. The client will define the length of time in vitro testing with the phantom will occur.
iii. Each round of TMS testing will last approximately 350 seconds [12].

d. Shelf Life

i. The shelf life necessary for this phantom will extend for the duration of client testing. After in vitro testing is complete, the client will begin clinical trials with pediatric patients.
ii. To ensure minimal material degradation, the phantom will be stored at room temperature and humidity, 22-24 °C and 40-60%, respectively [13].
iii. Depth electrodes will be used. They will not be permanently implanted but should be used within approximately 3 years [14].

e. Operating Environment

i. The phantom will be used in conjunction with TMS and iEEG technology. Materials must be compatible with this technology.

ii. The phantom will be used in a sterile environment and handled by neurosurgeons during testing.
iii. The phantom will be used at average room temperature, 22-24 ℃, and humidity, 40-60% [13].

f. Ergonomics

i. Neurosurgeons handling the phantom must be able to safely use and replace components of the phantom, such as the gel and electrodes, between testing.
ii. The phantom will be placed on a table for the duration of testing, approximately 1 meter (m) off the ground.

g. Size

i. The phantom should mimic the size of an average pediatric brain and skull.
ii. The approximate volume of the phantom will be 50-100 mm^3 [4].
iii. The approximate circumference of the skull of the phantom will be 50-54 cm [5].

h. Weight

i. The phantom will ideally be less than 2 kg to ensure the phantom is easy to transport and lift without causing strain to the user.

i. Materials

i. The base of the phantom will be constructed from a 3D printed acrylic polymer. Acrylic based filament or resin for 3D printing has good optical clarity for viewing access into the phantom and good durability. 3D printed polymethyl methacrylate (PMMA) parts showed minimal degradation over 5 years [15].
ii. 6-12 contact EEG electrodes will be embedded in silicone for precise positioning of the implanted electrodes [1]. Depth arrays (platinum macro contacts) are implanted while grid arrays (platinum-iridium) are placed on the cortical surface [12].
iii. A hydrogel will be used to approximate brain tissue. Similar phantoms have used a polyacrylic acid saline gel [1], agar, gelatin, or agarose. The addition of NaCl is necessary to achieve physiologically accurate electrical conductivity [16].
iv. Fiberoptic fluorescent temperature sensors can be connected perpendicular to the electrodes to measure changes in temperature [12].
v. Ferromagnetic materials will be avoided so as to not interfere with the TMS induced magnetic field [17].

j. Aesthetics, Appearance, and Finish

i. The base of the phantom should be 3D printed from a clear filament/resin so that the implanted electrodes and internal components can be easily viewed.

ii. A replaceable hydrogel brain mimics the texture and conductive properties of the brain. However, a gel with greater optical clarity is desired for positioning and viewing the electrodes.
iii. A gel-based phantom housed in a rectangular box is better for calibration testing and can be used to evaluate temperature changes and basic electromagnetic effects of TMS [18].
iv. A skull-based phantom would provide greater anatomical accuracy and more complex geometry is important to evaluate TMS induced fields more realistically [19]. Therefore a combination approach will be taken, where a simpler gel-box phantom will be created for initial testing, before moving onto a more complex skull-based phantom.

2. Production Characteristics

a. Quantity

i. The client desires one gel based phantom housed in a 3D printed rectangular box to first be created for preliminary testing before progressing to a skull-based phantom for improved accuracy.

b. Target Product Cost

i. The total production cost must not exceed the budget of $500.

3. Miscellaneous

a. Standards and Specifications

i. MTR Standards 2.4 and 3.3 require pediatric patients with implanted electrodes to have an inter-electrode impedance of up 10 kOhms maximum, and that electroencephelograms be run with a reduced sensitivity of 7 microvolts (uV), respectively [20].
ii. CFR Standard 882.5802 defines the use of TMS coils for treatment of neurological and psychiatric disorders as Class II medical devices with specific controls. Therefore, the testing procedure defined must consider magnetic pulse output, magnetic and electrical field, built in device safety features, and patient exposure to sound during device use [21].
iii. The testing of the phantom must follow ASTM standard F2182, which details a test procedure for measuring temperature change due to induced current during magnetic resonance applied to implanted devices [22].

b. Customer

i. The customers for this project are pediatric patients with intracranial implanted electrodes who will need to undergo neurosurgery.

c. Patient-related concerns

i. Patient-related concerns during simultaneous iEEG and TMS include heating of electrodes, induced electrical current, and displacement of electrodes. This phantom will investigate the likelihood and severity of each of these concerns on a pediatric patient.

d. Competition

i. A similar phantom used to test the safety of combined iEEG and TMS was recently made at the University of Iowa [1]. This phantom used a polyacrylic acid (PAA) gel base with a polymethyl methacrylate (PMMA) wall, representing the brain and skull tissue, respectively. This phantom was successfully used to verify safety of concurrent iEEG and TMS use in adult patients undergoing treatment for neuropsychiatric disorders. While this phantom addresses many of the current project's concerns, it fails to account for more stringent safety standards and physiological differences required when considering pediatric patients.

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