SMF Helmet

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***Abstract* — This paper will focus on the development of a static magnetic field (SMF) home-based device prototype and the initial clinical trial conditions for the fine-tuning and feasibility of such a device. The SMF helmet will utilize static magnetic fields and will achieve a frequency component by reversing the fields regularly via mechanically flipping the magnets. Optimal field intensity, positioning, and duration of stimulation will be assessed in voluntary, healthy-person clinical trials before being applied to larger-scale, blind trials to measure effectiveness towards stroke rehabilitation.**

I. Introduction

TRANSCARANIAL magnetic stimulation (TMS) is a noninvasive tool used in neuroscience and medicine to disrupt neural activity in conscious individuals. TMS uses electrical currents and coils to induce magnetic fields of varying frequencies, which are then placed in key points around the head to polarize target areas of the brain. In recent years, TMS has been used to treat depression[1] and several neurodegenerative diseases including Parkinson's and Alzheimer's [2]–[4], with varying degrees of success.

Investigation into the range of application regarding TMS expanded as the first FDA-approved TMS therapy device for depression, the NeuroStar[5], became available on the public market in 2008. Similarly, SMF therapy engages magnetic fields towards the purpose of neural therapy without the use of electrical current. Studies into the application of SMF are fewer and more recent thought the use of static magnetism as a type of holistic medicine has been practiced by people world-wide[6]. This paper will focus on the development of an SMF home-based device prototype and the initial clinical trial conditions.

The design concept for the SMF Helmet includes even numbers of strong, permanent magnets. Rare-earth magnets are up to ten times stronger than ferrite magnets and are the strongest type of fixed-magnets available on the public market[7]. The placement of the magnets in the helmet must be flexible to meet the needs of individual users. Key locations in relation to the brain include the frontal lobe, the temporal lobe, parietal lobe, and occipital lobe. In order to build the feasibility of individualized positioning into the helmet, pairs of magnets have been designed into pods whose locations can be maneuvered and secured above the desired area of the brain. The pods offer the functionality for flipping the poles, creating a frequency pulse of magnetic fields into the brain. Ultimately, the design will be motorized, but preliminary mechanical designs are offered in this paper.

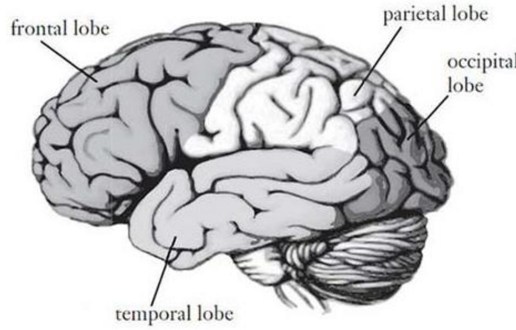


Figure 1: Target lobes of the brain. The front of the head is towards the left, the back is towards the right.

II. Project Management

A. Project Manager/Design Engineer: Riley Davis

Primary ongoing responsibility for team management. Focus on meeting project commitments, including communications with sponsors and between team members. Facilitate definition of project goals, tasks, and resource requirements. Assist in the resolution of conflicts, monitor project progress, and manage project budget and resource allocation where necessary. Write all necessary reports and paperwork for project and monitor adherence to engineering standards.

Assume overall responsibility for the preparation of protocols and report forms, Ethics committee approval, development of recruitment strategies, the provision of clinical trial materials, and management of the trial.

Responsible for researching and developing new ideas and processes. Create concepts, performance, and production criteria. Produce final hand drawings and specifications.

B. Software/Electronics Engineer: Zachery Jacobson

Primary programmer of PIC processor and motor wiring. Systematically improve the detailed design of the electronic component of the project. Determine operational feasibility by evaluating requirements, test results, problem definition, and proposed solutions. Prepare and implement solutions by determining and designing new system specifications, standards, and programming. Ensure the project is designed and built to conform to the latest relevant specifications and standards. Ensure the process is well documented to allow future maintenance and modification.

C. Mechanical Engineer: Shante Dezrick

Create robust designs by analyzing functionality of device, impact resilience, and comfort of wear. Develop and improve mechanical design procedures and practices. Create parts lists and make samples of working models for demonstration.

Improve usability of the design. Use computer-aided design (CAD) to design concepts. Utilize SolidWorks and other software to print all necessary parts and components for the construction of the design. Ensure the process is well documented to allow future maintenance and modification.

D. Project Timeline

For the timeline outlines the concept, design and build phases of the SMF Helmet project, please see Appendix A.

III. Engineering Standards

The SMF Helmet would likely be classified under the FDA PART 882 – Neurological Devices section as a Category I or II device. Because it is noninvasive, the SMF Helmet may be viewed as a Class I, however, since the long term effects of magnetic fields have not been fully researched, it has potential to be classified as a Class II. Based on a search of the FDA database and comparison to a "Permanent Magnet" reviewed by the Ophthalmic Panel with a 510(K) Exempt status, the SMF Helmet will likely be a Class I Exempt device.

A. Restriction of Hazardous Substances Directive (RoHS)

The final design will have electrical components, moving and metal parts, and batteries, so the electronics and mechanical engineers will ensure that all aspects of their design are RoHS compliant.

B. IEC: 60601-1 International Standard

Engineers will minimize hazards of electrical shock, radiation, fire, and excessive energy output as per the IEC 60601-1 international standards

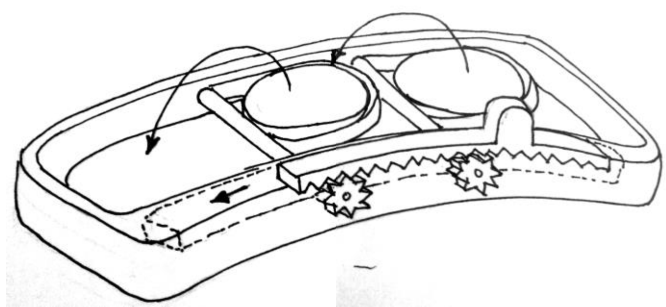
IV. Methods

A. Design Process

The SMF Helmet design will involve a motor moving wires in a parallel fashion around the perimeter of the skull. The wires will be supported away from the head by several eyebolts in strategic locations around the support webbing from the inside of the helmet. The support webbing is similar to the inside structure of a construction helmet. It involves a strip of plastic completely encircling the head with cloth webbing connecting the left frontal lobe to the right occipital and vice versa. The eyebolts will be attached to the plastic, holding the wires off the frame. The wires will pull the magnets in a fashion that flips them and reverses the active polarity of the field facing the head. A priority in the construction of the SMF Helmet is to maintain minimal proximity between the magnets in their resting position and the wearer's head. An ideal fit would have the magnets directly against the skin or hair of the wearer over the target area of the brain. The overall design of the Helmet will afford the flexability to position the magnets over any part of the four target lobes, individualized for each patient, resulting in a functional and stable design that can withstand constant wear.

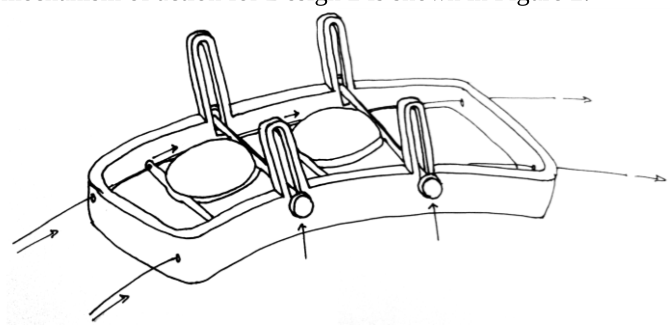
The motorized design (Design 2) will include a PIC processor and a 555-timer as well as the necessary programming to create the desired frequency of inverted fields. The tiny motor will be powered by a small battery, preferably a button cell or a AAA battery.

There are two design proposals for the pods containing the magnet-flipping mechanism. Design 1 shows a mechanical option for flipping the magnetic poles. The pod can be secured by velcro to the inside of the helmet shell or to the outside of the cap covering the head directly. The overall design of the helmet must hide the magnets to afford the possibility of a blind study.



Design 1: Mechanical flip, independent magnet pod.

Design 2 offers less flexibility but more easily translates into a motor-driven mechanism for flipping the magnets. The pod can be connected to the mechanical flip or motors by two wires, which are then pushed or pulled to rotate the magnets. This limits the locational flexibility of the design and removes the parietal lobe from the current scope of possibility. The mechanism of action for Design 2 is shown in Figure 2.



Design 2: Wire-rotated magnets, linear movement flexibility

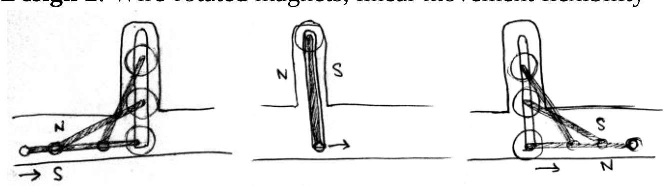


Figure 2: Mechanism of action for Design 2

B. Clinical Studies

A preliminary, small-scale clinical trial, supported by an IRB, has been built into the construction of the SMF Helmet prototype in order to evaluate optimal magnetic-field intensity, pod positioning, and effective duration of stimulation. The study will be comprised of a small, 15-30 person group of healthy volunteers who will wear the helmet with the magnets in varying positions for varying amounts of time. Short-term memory, hand-eye coordination, and speed will be tested through a randomized, timed, dot-connecting game.

Participants will be evaluated based on timing and accuracy. The order in which the location and duration is tested will be randomized among the participants to negate any acquired skill with the game. Sham helmets will also be used to test against placebo effects. The interface for the evaluation tool is shown in Figure 3.

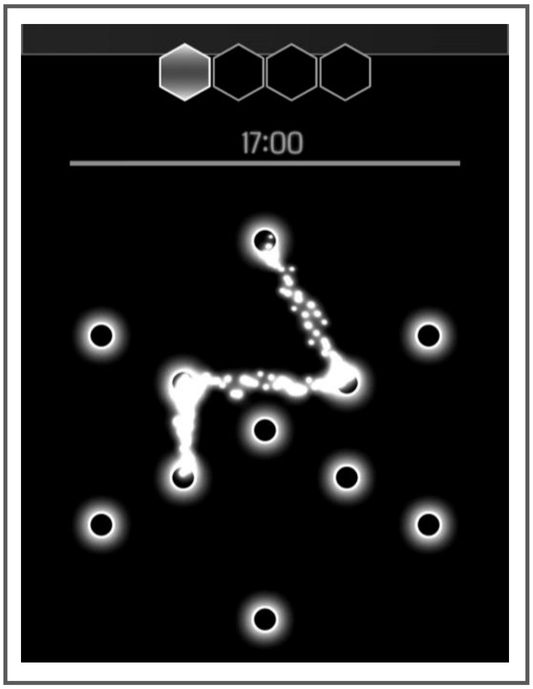


Figure 3: GUI for dot-connecting game to be used in clinical trial. It includes 4 sets of figures shown over 4 seconds. The user than has 17 seconds to correctly reproduce the 4 figures in order.

V. Discussion

A successful SMF Helmet prototype will include flexibility in magnet positioning, a hands-free mechanism for reversing the magnetic field polarity, and a programmed timer for creating a frequency out of the reversal of the fields. At the conclusion of the SMF Helmet development, the prototype will be manufactured and a large-scale clinical study will be performed based out of Rhode Island Hospital to test its effectiveness on stroke-rehabilitation. It is hypothesized, based on the effectiveness of TMF rehabilitation techniques [1]–[4], [8]–[10], that an SMF Helmet could replace or augment the very expensive and time-consuming TMF procedures. The SMF Helmet is designed to be a long term, hassle-free, home-use device for a fraction of the cost of currently available hospital-based treatments.

VI. References

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Appendix A

SMF Helmet **Timeline**	09/05/14	09/12/14	09/19/14	09/26/14	10/03/14	10/10/14	10/17/14	10/24/14	10/31/14	11/07/14	11/14/14	11/21/14	11/28/14	12/05/14	12/12/14	12/19/14	12/26/14	01/02/15	01/09/15	01/16/15	01/23/15	01/30/15	02/06/15	02/13/15	02/20/15	02/27/15	03/06/15	03/13/15	03/20/15	03/27/15	04/03/15	04/10/15	04/17/15	04/24/15	05/01/15
AT conference (11/20/14)											■	■																							
Mid-year progress report													■	■																					
Grant proposal (TBA)													■	■													■	■							
NEBEC Conference paper														■	■	■	■	■	■	■	■	■													
NEBEC Conference (TBA)																												■	■	■	■				
Final Report																																			
CITI training for team		■																																	
Design prototype		■	■	■																															
Materials list			■	■																															
Design clinical trial		■	■																																
IRB application (if applicable)				■	■	■	■	■	■	■																									
Clinical trial prototype: complete					■	■	■																												
Clinical trials (depends on IRB)								■	■	■	■																								
Data analysis											■	■	■																						
Write Code			■	■	■																														
Fabricate Circuit					■	■	■																												
Fabricate Device				■	■	■	■																												
Test system as a whole							■	■																											
Overall: Project prototype				■	■	■	■	■	■	■	■	■	■	■																					
Overall: Testing & improvement													■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■							

Appendix A: SMH Helmet design project timeline. Table includes important paperwork and funding deadlines as well as conferences and paper proposals. Important project goal markers are also included in the table to keep the design on track.