Abstract:

There currently exists no long term, portable, brain imaging technology that can detect brain activity. While other real time imaging methods exist, such as functional Magnetic Resonance Imaging (fMRI), none of them are able to be portable or utilized continuously. It has been shown in previous work that ultrasound (US) is a capable technology for detecting perfusion in several key areas of the brain. It has also been shown that changes in perfusion correlate with neural activity in these areas of the brain. Therefore, one could envision using US for real-time brain imaging. However, the probes must be held static for long periods of time. In this work, we propose an ultrasound brain helmet. This helmet would hold the probes static and allow their signals to be registered, creating a 3 dimensional map of brain perfusion. The helmet holds three probes. One is on the occipital bun and two are on either temple. These areas were chosen since they provide the maximum resolution. The helmet is adjustable for head sizes from the 5th percentile of women to the 95th percentile of men. The helmet has optically tracked fiducials attached, allowing the US signals to be registered in 3D space. The ventricles will be a shared anatomical feature between the two probes on the temples, ensuring the accuracy of the registration.

Problem Description:

Current medical technologies involved in real-time functional imaging of the brain (e.g. functional magnetic resonance imaging) are massive, resource-intensive, and simply inconvenient. Thus, there is significant interest in developing alternative methods for monitoring brain activity. Ultrasound, a potential candidate as an existing alternative method, is an imaging technique known for its robustness, versatility, and convenience. However, a major limitation to ultrasound imaging, particularly when applied to the cranium, is the high amount of attenuation of sound waves in the skull, which limits its ability to resolve anatomical structures in the brain. Additionally, transcranial ultrasound imaging is able to detect blood perfusion in the brain, which correlates with relative neuronal activity. However, ultrasound alone cannot provide accurate real-time data on brain activity, due to its inability to detect stimulated areas.

Project Objective Statement:

One proposed solution to the above problem is to integrate transcranial ultrasound, a relatively limited technique, with a more established technique that is better able to resolve brain activity in real time, such as electroencephalography (EEG). Thus, the ultimate goal of this project is to develop a noninvasive brain monitoring device that incorporates two modern technologies: ultrasound and EEG. The union of these two technologies will allow for the capture of more accurate and better resolved functional brain information, particularly real-time blood perfusion and electrical patterns, than the devices alone can capture. Optimistically speaking, the complete development of such a device is at best a 5-year endeavor, and currently we are only in its first year. As the inaugural step of this long-term project, we developed a prototype of the helmet that houses ultrasound probes to be used in transcranial imaging. This helmet functions primarily in stabilizing ultrasound probes that are placed at both temporal lobes and the occipital bun. Other features of this model include: adjustability to different head shapes and sizes; mobility of ultrasound probes for localization onto specific regions of the skull; and secure fitting around the subject's head. Additionally, because integration with EEG is a future goal in this project, the helmet is compatible with EEG netting that is placed over the head.

Documentation of the Design:

In order to take the helmet from the ideation state to an actual product, we established that the two most important features of our helmet will be: customizable and secure. The innovative features that accomplish customizability are adjustable sliders in the base of the helmet. The sliders follow a sleeve and insert model that are secured by two screws on either side of the band

. Once the technician adjusts the length, they would just need to fasten the two small screws on each side to lock the slider in place. This locking mechanism allows us to attach straps at the bottom of each box, which in turn allows us to keep the entire helmet in place on the patients head. This is significant as we expect the ideal helmet will allow the patient to move and participate in daily activities, while the clinician is able to observe his/her brain physiology and function.

Another innovative aspect behind our helmet design, is the addition of the foam that is placed in between the plastic base of the helmet and the head of the patient. This foam not only adds structural support to the helmet, but it also allows the helmet to be adjustable between patients. The foam will be molded to fit a patient's head type and thus each patient will have a helmet this is completely customized to him or her. The foam is easily removable from the plastic backing of the helmet, and can be replaced within seconds with the foam molded to another patient's head. This separation of the plastic backing and the customized foam allows us to create a product that fits each patient who have completely different head sizes and shapes, without needing to create an entire new helmet.

Prototype of the Final Design:

One of the major challenges with the ultrasound imaging helmet was to maintain its rigidity while providing adjustable positions for the probe(s). To address this need, we distributed our design into three different parts: the probe location, the helmet, and the moving mechanism.

The probe location part of the design addresses the issue with the cranium. Since ultrasound waves have difficulty transmitting through the cranium, the placement of the probes must be organized to target the ultrasound waves towards the thinner parts of the bone. According to the previous studies, the temple and lower back of the head are areas ultrasound waves can penetrate. Thus, we decided to design our device to place the probes in all three locations. This would not only allow collection of quality ultrasound images, but also will provide data in multiple dimensions.

The second part of the design involved the general construction of the helmet. The skeleton of the helmet involves a sturdy plastic design distributed in three directions to account for the specified placements. This skeleton of the helmet would also contain punched holes in areas where the moving mechanism will intercept the helmet.

The third part of the design involves the moving mechanism. The moving mechanism is designed to give the probe adjustable features in the horizontal and vertical direction. As depicted in the Figure 1, we used sleeve-insert mechanism to produce movement in Y and Z directions. These movement accounts for the adjustment to different sizes of the head, and accounts for the vertical localization of the temple. The movement in the X direction, however, has a slightly different mechanism. There are two reasons why the sleeve-insert mechanism used for the other dimensions is not optimal for the X direction. The first of which is that the X-direction mechanism is required to have the ability to firmly hold a probe. Another reason why the sleeve-insert mechanism is dysfunctional in the X-direction is its location in a small space within the box where a sleeve-insert mechanism is difficult to implement. Thus, a new mechanism must be devised for the movement in the X-direction. This mechanism involves a 3D printed shell attached to the side of the box by a bolt and nut mechanism. This mechanism, as depicted in the figure, serves both essential purposes: providing movement in X-direction and acting as an ultrasound probe carrier.

Combining these elements addresses the problems described earlier and meets the expectations from the device. Furthermore, these three parts could easily be connected to each other to form the overall architecture of the design as depicted in the figure.

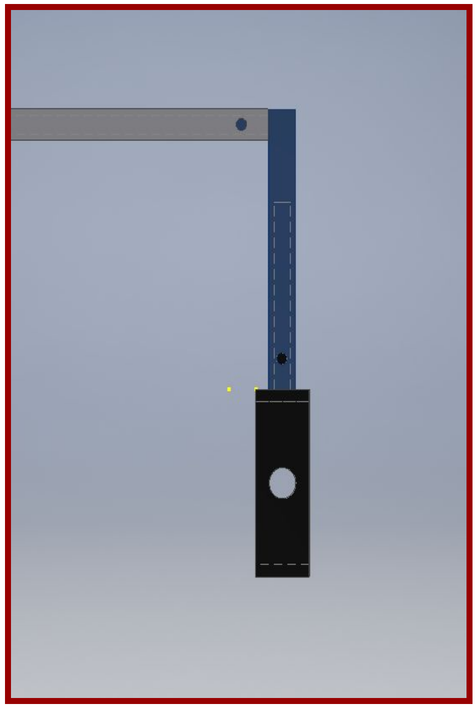

Figure 1: Movement Mechanism in Z direction

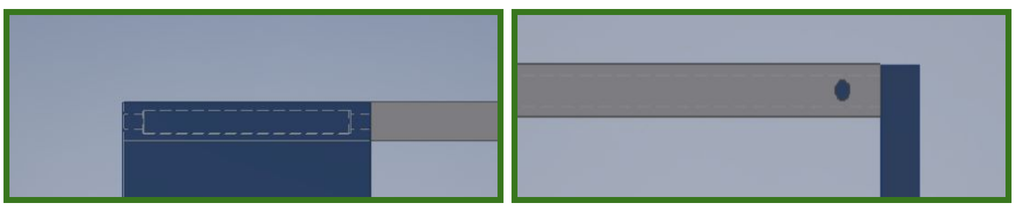

Figure 2: Movement mechanism in Y direction

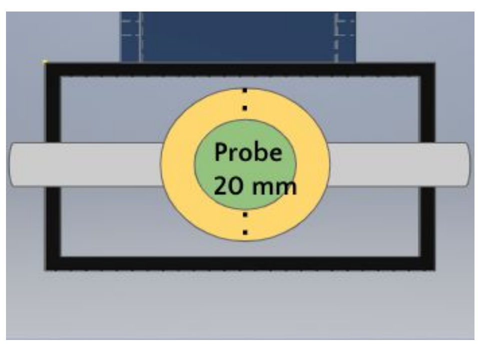

Figure 3: Movement mechanism in X direction.

Proof that Design Works:

The design is still in its infancy, so neither clinical nor pre-clinical trials have been conducted. Despite this, several tests have been performed to prove that the design is both functional and practical. One key facet of the design is that it makes use of the temples. These portions of the skull provide a window to the ultrasound probes, allowing them to view the brain. In order to verify that the helmet can properly hold the probes and will in effect provide the necessary data, tests have been performed using clinically available and widespread ultrasound probes. These tests have shown that the positioning of the probes over the temples is an accurate and effective way to obtain images of the brain using ultrasound imaging.

Another factor that must be taken into account is the variability in each human skull. There are slight differences in both size and shape. To account for these changes, the helmet employs technology to allow for translation and rotation of the probes. To prove that the translation and rotation technology will be effective and applicable, a prototype of the helmet was created and mock ultrasound probes were placed in the holders. It was found that the helmet design could support 30 degrees of rotation, in both the sagittal and transverse planes. In addition, it was found that the design can support four millimeters of movement in these same planes. However, to successfully adapt the design to many different patients, it must also contain movement in that direction to accommodate different head sizes. The ranges for these movements were determined using an anthropomorphic table. The 5th percentile of a female head sizes and 95th percentile of male head sizes were used as the end points of this range. This allowed the prototype to be adjustable to practically any head size. Anthropomorphic values were used in a similar way for localization of the temple and movement in other directions. Therefore, it is believed that this product can be universal for all patients.

In order for ultrasound to function, there must be a gel between the probe and the part of the body that is being imaged for acoustic coupling. In the proposed design, a gel interface would be needed between the probes of the helmet and the head. There are two design considerations to take into account. The first is if the gel will continue to function with increased hair. The second is if the gel will last long enough for continuous monitoring. The first consideration was proven in the initial experiments with ultrasound probes on the head. Although heads with more hair obstructing the ultrasound probe will require more gel, they will still image properly. The second was also proven with the initial ultrasound probe experiments. The gel was able to last more than 30 minutes, which is a long enough period for the initial prototype.

Although the design has not been tested on specific subjects, all the tests of the individual components and experiments have yielded passing results.

Patent Search:

A patent for a previously developed ultrasound stimulation helmet was found in our patent search, which provided the platform for much of our initial design ideas. The ultrasound stimulation helmet has a main body with both a forehead and a back head adjustment knob. Furthermore, there is an overall support frame, and multiple ultrasound probes that are detachably mounted on the main body. The fastening support frame can be used to adjust the length of the main body according to the size of a head of a patient, and the ultrasound probes are connected to the position adjustment knobs to enable the ultrasound probes to move upward, downward, or toward the left or right with respect to the head of the patient (*Figure 4*).

Many of the features in this previously developed ultrasound helmet were taken into account when designing our prototype. Some major changes from the previously developed model that were incorporated into our model include: ability to place a third ultrasound onto the back of the head; less overall material used, which contributes to easier assembly, lighter weight, and less bulk; secure straps that wrap around the head to keep the helmet from moving; and more intuitive adjustment of the helmet size/probe positioning.

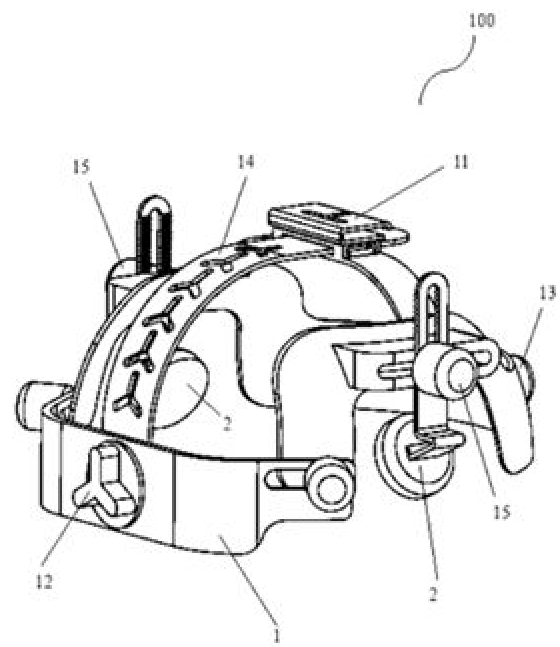

Figure 4: Image of previously designed ultrasound helmet

Anticipated FDA Regulatory Pathway:

The Food and Drug Administration (FDA) regulatory pathway that we anticipate to be the most reasonable approach for this medical device is the 510(k) exemption. After searching in the FDA's database for previously accepted helmet devices, we discovered a product classification report laying out the pathway and details regarding the 510(k) process for previous helmets. According to the report, the device was exempt due to its classification as a Class 1 device (little to no risk for user of device) based on its similar features as other helmet devices. This part of the 510(k) exemption will exempt the device from premarket notification requirement. The FDA clearance is also not required before marketing the product. The report also listed certain features the device possessed that eased the device's clearance. For example, the report highlighted that the device was neither implantable, life supporting, nor third party review eligible. These features match our design and thus could ease the regulatory pathway. We then anticipate that our regulatory pathway will be very similar to the one in the example.

Reimbursement:

Currently, our device is constructed as a proof of concept. The entire product has a 5-year plan, where reimbursement will be discussed at a much later stage, continuing even after the 5 years' time. Our involvement with the project lasts only for the initial first year, on the manufacturing aspect, and so we fortunately are not currently aware of future decisions. From our current knowledge of the project and its intended long-term usage, it will function primarily under the care of an academic institution, research lab, or physician. Thus, we do not expect our model to be reimbursable by Medicare or Medicaid as it will not be sold directly to the public. One future application of this device is to become a commercialized product, which would also not be covered under either healthcare programs.

Estimated Costs:

The costs for manufacturing this device can be broken down into several key categories: the physical helmet, the EEG net, and the ultrasound probes. It will be impossible to buy any precursor to the helmet for the physical manifestation, so it will have to be manufactured completely. Therefore, the startup cost (beyond the first prototype) will be quite high, with volume playing a key role in bringing down the cost per unit. While no manufactures have been contacted yet, research performed shows this to be around a 30% reduction in cost per unit. In addition, the cost will also depend heavily on the material used. Currently, it is expected that we will use a polymer, but this depends on what manufacturer are able and willing to produce. Despite all of the above uncertainties, the current research shows that the initial cost to manufacture per unit should be around $1000, but can vary depending on the type of material used, assembly costs, etc. For this project specifically, 3D printing was utilized for fabrication of the initial prototype of the helmet, which costs around $25-$50 per kg of filament for a high-quality material such as ABS. 3D printers were available for us to use free of charge; however, this may not be the case for everywhere that this device is fabricated/used, so costs of 3D printer availability should also be considered. Additionally, both the ultrasound and EEG systems will contribute to a significant portion of the cost. The price of an ultrasound system depends on its quality and amount of functionality: low-end systems with limited amounts of functionality run about $5000, whereas high-end systems can run up to tens (or even hundreds) of thousands of dollars. US systems that are capable of performing Doppler ultrasound are mostly in the high-end spectrum of systems, and therefore will cost more. Similarly, the price of EEG systems depends on factors such as the number of electrodes, sensitivity of the electrodes, spatial and temporal resolution, etc. EEG systems that are research-grade can range from a few thousand dollars to up to $25,000.

Intended Market:

The intended market will include, but is not limited to, physicians, patients with neurological disorders, academic institutions and research institutions, and other third-party entities, for example non-profit organizations. Both physicians and patients with neurological or mental disorders will have a relatively inexpensive device to aid in the patient's overall medical care. One of the expected uses for the device is to serve as a diagnostic tool for physicians to probe and identify areas of the brain that are dysfunctional due to disorder. This product achieves the intended goal of imaging the brain, searching for expected localized functionality. Academic institutions and research laboratories interested in investigating neurological activity in the brain may heavily benefit from such a device that combines the ultrasound and EEG modalities, where neurological activity can ideally be better resolved compared to ultrasound and/or EEG alone. Lastly, the device may be able to serve as an alternative to high-end, more expensive medical technologies in lesser developed areas, and thus may be of interest to non-profit organizations focusing on medical outreach in these areas.