Electrode and Headgear Design for Accurate TDCS

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THESIS

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ABSTRACT

Stimulating the brain with a low current that is focused on specific regions of the brain has been shown to modify brain function and treat various neurological diseases. Transcranial direct current stimulation (TDCS) has been an effective and life changing alternative treatment for a vast range of neurological conditions including depression, epilepsy, stroke rehabilitation, addiction and chronic pain but only if it is administered correctly.

During TDCS, a weak constant current is applied to precise locations on the scalp to modulate brain activity. Those locations can be determined by the cumbersome 10-20 EEG measurement system, transcranial magnetic stimulation or neuronavigation. These various methods require highly trained technicians, are extremely expensive, and magnetic stimulation and neuronavigation are not mobile enough to be done outside a clinical setting. After the time consuming routine of finding the locations for the electrodes, technicians then must perform a complicated multistep setup in order to setup the device, secure the electrodes to a patient’s head and start the treatment. Making TDCS simple and easy enough for a patient with M.S. to setup and administer treatment without the help of a caregiver can immeasurably increase the number of patients that are able to be treated with TDCS, researchers studying its effects and increase its efficiency.
Improving the design of the sponge electrodes and making a TDCS headgear that ensures the precise placement of the electrodes all while making the process and equipment simpler is one way to increase the use of TDCS. This paper discusses the background on TDCS and other brain stimulation methods and will explain how improving the equipment used for TDCS will make it easier, safer, cheaper and more efficient.

A novel TDCS headgear was designed that has snap sponge electrodes that can be setup by a patient at home or their caregiver. The accuracy of the headgear was validated by testing repeated placements of the headgear and measuring the displacement of the electrodes from their predetermined positions. The data obtained from this study was then analyzed by computational modeling and it was determined that the headgear would be an ideal option for at home TDCS. The headgear has been adopted by many successful studies and may very likely be more accurate than the most widely used previous method of utilizing the 10-20 EEG System.

This new method saves time, money, and increases the accessibility of treatment. It is also more accurate and replicable than a trained technician using previous methods. These updates to inadequate headgear permit the headgear to be used by disabled patients at home which will enable studies to include many more patients because of saved time and funding which will expand the number of patients treated by breakthrough technology and immensely improve the efficacy and reproducibility of treatment.
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CHAPTER I

Introduction to Brain Stimulation

Humans have always been curious about the powers and capabilities of their brains, and scientists have been seeking ways to control its amazing feats. A new field of research has been born that focuses on a growing technology called brain stimulation where healthcare professionals can modify the brain to treat diseases. Some recent organizations have published astonishing results that can lead to the future of medicine and completely change the approach physicians take with the treatment of diseases.

The idea of brain stimulation was first introduced by Scribonious Largus, a physician for the court of Roman emperor Claudius over two thousand years ago. In his book “Compositiones Medicamentorum”, he describes in detail the different drug compounds or recipes that were used by the physicians of the time. One of those treatments involved the use of electrical currents to ease headaches and gout by applying electric torpedo fish to the affected regions or by placing the extremities that were in pain into a pool of water containing torpedo fish. The treatment reportedly caused a numbness in that part of the body and was a form of relieving the unbearable pain caused by the disease. (1), (2)

In the late 1700’s Luigi Galvani discovered that when touching a frog leg with his scalpel while also touching an electrified brass hook connected to it, would cause the
frog’s leg to twitch. (Figure 1) He called this phenomenon “animal electricity” which he described as the life force within the muscles of an animal. His colleague Alessandro Volta later discovered that it was the electricity in the metals that caused the leg to twitch. This amazing discovery lead to the unearthing that our body is controlled by electrical impulses. (3)

Galvani’s nephew, Giovanni Aldini, authored a book "Essai Theorique et Experimental sur le Galvanisms" in (1804). In his book, he described using electric therapy to treat psychoses and melancholia (later named depression). Aldini demonstrated that by shocking a dead body, he could get it to move and this lead to the start of cardiac shock therapy. (4)

One method of brain stimulation transcranial direct current stimulation (TDCS), has many advantages compared to the other methods of stimulation like electroconvulsive therapy, transcranial magnetic stimulation and deep brain stimulation. TDCS has been used in many forms as an alternative for medication and many researchers have found
astonishing results. It is safe, it can be easy for a patient to administer at home, convenient, portable and a fraction of the cost of other stimulation methods.

TDCS became popular in the 1960’s by researchers like D.J. Albert. He reported that low levels of currents when applied to exposed parts of animal brains can cause a lasting response in cortical excitability for hours after only minutes of stimulation. (5) Later, scientists discovered that they could get a similar effect by stimulating the brain non-invasively and pass the current through the scalp.

Electrical stimulation of the brain was first used as a method of determining which functions different parts of the brain are responsible for. (6) Researchers would stimulate different parts of animal brains with varying levels of electric current and would record the responses. This knowledge was used to map out the functions of animal and eventually human brains. Currently, scientists have created brain atlases that are extremely accurate and give precise locations of select brain areas which are responsible for certain functions. Examples of this are the motor cortex and Broca's and Wernicke's areas. (Figure 2 and 3)

2. Map of the different areas and lobes of the brain and what they are responsible for.

3. Map of the motor cortex and which segments of it correspond to which body part.
The focus of TDCS research has recently shifted from using it as a learning tool to explore the brain to determining ways that TDCS can be effective as a medical treatment, to enhance our brain function and how the cellular responses to TDCS cause the results of the stimulation. There are ongoing clinical trials and past studies that have found remarkable findings. One example is a study that was run by the United States Air Force in which they reported accelerated learning because of brain stimulation. (7) There also has been a tremendous amount of research in the field of pharmacology in investigating if brain stimulation can be used to treat patients with brain disorders such as anxiety, depression, insomnia, and epilepsy. Brain stimulation is believed to be a possible safe and effective alternative to drugs.
CHAPTER II

Brain Stimulation Methods

There are many different methods of brain stimulation used today, some of the most popular (excluding TDCS) are electroconvulsive therapy (ECT) (Figure 4), transcranial magnetic stimulation (TMS) (Figure 5), and deep brain stimulation (DBS) (Figure 6). Each method revolves around a different type of stimulation and they have very different outcomes and side effects.

4. A patient receives electroconvulsive therapy (ECT) to treat his major depression.

5. Repetitive transcranial magnetic stimulation (rTMS) therapy is administered by a skilled technician.
Electroconvulsive therapy (ECT) has been the most used method of brain stimulation in history and has many clinical uses that are still regarded by some as the most effective treatments for severe depression today. (8) During ECT, an electric current is used to induce controlled seizures in the patient. The patient is put under general anesthesia and the entire procedure generally lasts 5-10 minutes. The reason that ECT is usually a last resort after a patient has had a few failed attempts of treatment with medication and could be a danger to themselves and society is because it has many adverse effects. Many patients have reported experiencing some type of memory loss because of the treatment. (9) It can range from forgetting conversations or events around the time of the treatment to forgetting memories from months or years earlier. Compared to TDCS, ECT uses a much larger current which induces an action potential and therefore is not as safe as TDCS and has more adverse effects.
**TMS**

Transcranial magnetic stimulation (TMS) is done by placing a magnetic coil directly over the area of the brain that you want to stimulate. The magnetic coil produces low levels of current in the cells by a process called electromagnetic induction which can trigger action potentials. TMS is similar to TDCS because they both use small amounts of electrical current to targeted areas of the brain non-invasively.

TMS is used commonly in patients with severe depression and has very few side effects with only very rarely causing seizures. TMS is regarded as safe and non-invasive and for that reason it has been used in similar applications to TDCS. Many researchers prefer to use TDCS over TMS because TDCS requires less equipment and is a fraction of the cost. Someone interested in exploring the field of brain stimulation can purchase a complete TDCS setup with all the components necessary for brain stimulation from anywhere between fifty to one thousand dollars while an equivalent TMS setup starts around fifty thousand dollars and more elite models can cost over three hundred thousand dollars. (10)

Another reason why TDCS is more popular for hobbyists or personal users is that a TDCS device is usually small enough to be portable and handheld while a TMS stimulator is a much larger machine similar in size to an x-ray machine that cannot be easily brought to patient’s homes to use for treatment. Also, the average consumer can now set up and perform TDCS on themselves while for TMS you need a highly trained technician to setup and operate the device.
**DBS**

Deep brain stimulation (DBS) is an invasive form of brain stimulation. A surgeon will implant electrodes into the brain that are connected to a stimulator which is usually implanted under the skin in a patient's chest. DBS works by interrupting and sometimes reversing abnormal brain signal pathways in the brain which are the results of neurological disorders like Parkinson’s disease. Since DBS is an invasive procedure, it comes with the many risks of surgery and a high price range of thirty to fifty thousand dollars per patient. Also, because the stimulation device runs on a battery, a patient must go back every three to five years for a small outpatient procedure to replace the battery. DBS has been used successfully in many Parkinson’s disease patients to relieve the symptoms of the disease like tremors and the slowness that is attributed to abnormal brain signals. (11)

**TDCS**

TDCS or transcranial direct current stimulation delivers low levels of constant current to the scalp via electrodes. That current is lower than the amount needed to produce an action potential but is large enough to produce a measurable effect on brain function. Some of the major reasons why TDCS research is so popular is because it is non-invasive, more cost effective, and readily accessible method compared to other techniques.

To perform TDCS all that is needed is a compact device which is powered by a simple 9-volt battery. Two electrodes, an anode and a cathode, are placed on the scalp. There are professional devices that are packed with features and options that come with
kits containing everything you need made for research or you can find directions online
to make your own for under $50. (Figures 7 and 8). The electrodes are commonly different
types of sponges soaked in salt water or conductive gels. The position of the electrodes
governs the distribution of the underlying brain current flow and which areas of the brain
are stimulated.

7. Example of the Soterix 1X1 TDCS stimulator meant for a clinical
or research setting.

8. Basic instructions how to make a simple DIY 1ma stimulator.

Some researchers have reported that TDCS can treat depression, migraines, post-
traumatic stress disorder, pain, schizophrenia, epilepsy, tinnitus and obsessive-
compulsive disorder. (12) (13) (14) (15) (16) (17) TDCS is evolving at an extremely fast
pace and we are discovering more uses for it every day. There has been an exponential
increase in the number of published medical journal articles investigating TDCS and its
effects and the field is expected to grow. (18)

In recent years, new companies have emerged that market TDCS stimulators to
healthy consumers. Some allege amazing or almost too good to be true claims for their
products from help with meditation, relaxation, insomnia, mood boosting, increased energy levels, decreased appetite and even a competitive edge in video games and professional sports.

One such company, Halo Neuroscience, makes a TDCS stimulator embedded into stylish Bluetooth headphones for professional athletes. They advise wearing their device during practice and warm-ups to increase their peak performance and make their training more effective. Figure 9) The New York Times published in an article a large and growing list of world renowned athletes are now using this new technology and it’s expected to grow exponentially. (19)

![Figure 9](image)


Even Red Bull has jumped into the scene by running a major trial in conjunction with Weil Cornell Medical College. The researchers spent 5 days running every imaginable physical and emotional test with Olympic cyclists and triathletes. (Figure 10) After 4 days of “training” the athletes were brought to specially designed track in which they raced against a lighted track which they thought displayed their best time but was actually slightly faster. Although their findings were statistically inconclusive, their work did not go to waste because they were able to study many new responses exhibited by individuals that were in top physical shape and many believed that they did in fact observe
slight improvements in the body’s physical ability. The athletes also reported that they were less fatigued than they normally would have been after such a race. (20)

Do It Yourself TDCS

The field of TDCS goes further than just research and clinical trials. There are many hobbyists that are very excited about TDCS. Some are excited because of the overwhelming issues they face with prescription drugs and medical treatments and some who are looking for a competitive edge so they have turned to TDCS or other forms of brain stimulation. There are plenty of “do it yourself” instructions on how to make your own stimulator and how to apply the treatment. (Figure 8) One popular blogger on TDCS lost his father and grandfather to suicide and was diagnosed with severe depression at a young age. After years trying all the major antidepressant medications, suicide attempts and forced hospitalization after depressive episodes, he turned to TDCS to try and control his depression. He was in danger of once again being hospitalized when he started stimulating himself. He says he is now feeling great, his depression is under control just by stimulating himself 3-4 times weekly, and he no longer takes any medication. He
stimulates while doing household chores like laundry or while reading and says he doesn’t even notice the sensation after the first minute or two. (Figure 11) (21)

Figure 11

11. Joel, a popular TDCS blogger being stimulated by his homemade TDCS equipment that he made with $50 worth of supplies from a local electronics shop.

As a result of the tremendous changes in technology and how easily accessible new information is, the population of people interested in brain stimulation has exploded. This shows our inherent drive to know more but does not come without consequences. Researchers that are leading the way in TDCS research are worried that until we know more about what brain stimulation can and can’t do people should proceed with extreme caution. There have been several attempts to warn the DIY community to ensure public safety and prevent tragedies while still allowing innovation. (22)
**Safety**

In recent years, there has been a large need for safety standards to be put in place for TDCS and other brain stimulation techniques. There are still many studies going on that are attempting to find the optimal length of stimulation with the optimum current level. Since TDCS is a non-invasive therapy, the patient will only have transient mild adverse side effects like skin irritation, fatigue headaches and nausea. (23) Those side effects are dependent on the maximum electric current levels, the placement of the electrodes and the length of time of stimulation. The most used level of current in TDCS is a two-milliamp current but studies have been known to use levels between one and four milliamps. (24)

If TDCS is administered incorrectly the patient is at risk of electrical burns and irritation. Some ways to prevent electrical burns are to ensure the electrodes are flush with the skin, to use certain electrodes and gels that have been proven to help the transfer of current from the electrode to the skin and method of starting stimulation slowly and then ramping up the electrical current.

When administering stimulation, it is important to start with a very small amount of current and very gradually raise it to the desired level. This is called a ramp up phase and usually lasts between thirty seconds and one minute. Ramping up primes the skin for stimulation and has been found to drastically reduce burns and irritation. By gradually changing the current levels, a person can habituate to the stimulation and usually after the first couple minutes of stimulation, people report no pain or sensation from the stimulation. (25)

TDCS is a very safe treatment and there are no known major risks in administering it if the guidelines are carefully followed and it is setup by medical professionals. The only
exclusion criteria is usually someone that has epilepsy or are prone to seizures because they are more sensitive to changing current levels which could cause them to have a seizure and someone with metal implants in their head. (26) Most health professionals agree that there are no serious short-term side effects while long term effects of TDCS treatment have not been fully explored yet.

**TDCS Cellular Models**

The necessity of discovering the different cellular mechanisms of TDCS has grown tremendously with the increased human usage of the technology. The studies of direct current electric fields (DCEFs) on various cell types has proven to be extremely useful in understanding what’s occurring at the cellular level. (27)

Early in vivo studies of DCEFs in rodents found that low intensity stimulation modulated the spontaneous firing rate of cortical neurons. (28) In vitro studies showed that DCEFs change neuronal excitability, and that this effect is likely driven by changes in membrane potential at principal neuron somas. (29) The neurons were polarized when placed in an electric field, and experience a change in membrane potential that is graded along the direction of the electric field vector. The DCEFs hyperpolarize one end of a neuron and depolarize the other end, with a gradient of polarization in between. (30) This change in membrane potential was particularly important at principal neuron somas, where the probability of a neuron firing depends critically on the membrane potential.

Many have thought that the predominant mechanism of TDCS was with cell excitability. (31) However, this simplistic explanation often fails to predict the outcome of human experiments. (32) Therefore, other cellular mechanisms must play roles and the excitability hypothesis falls short of being correct. Another possibility is that TDCS can
change the strength of synaptic connections or synaptic plasticity and by doing so can influence learning and memory. (33) Fritsch, et al. 2010 were able to demonstrate that direct current stimulation (DCS) in cortical brain slices induces synaptic plasticity that is dependent on the canonical NMDA receptor and the neurotrophin BDNF. (34) The exact mechanism of these findings still has not been determined.

Various drugs have been used to research the mechanism of TDCS, to either enhance or block the activities of neurosignaling pathways. (35) Studies revealed that in anodal TDCS, blocking voltage-gated sodium (Na+) and calcium (Ca2+) channels decreases the excitability which are in synchronization with the assumption that TDCS shifts the membrane resting potential of cortical neurons. The inhibitory and facilitatory plasticity induced by TDCS is controlled by NMDA-glutamatergic receptors. Blocking NMDA receptors eliminates the after effects of TDCS, whereas enhancement of NMDA receptor efficacy (using d-cycloserine) increases selectively facilitatory plasticity. (36) Although such effects of current delivery are suggested, it still needs to be addressed whether administration of current in one area of the brain is influencing other neighboring regions of brain or not.

The lack of standardized studies and methods makes it harder to analyze data from such varying populations and sample sizes. TDCS is currently studied primarily in academic settings. Because it only recently starting to be used in the treatment of patients with neurological disorders, there have not been as many clinical trials with TDCS compared to similar technologies. To date there is no researcher that can define the specific outcome from TDCS. Meaning, even if someone reports positive findings using TDCS to enhance their language skills, what really might be happening is that they are
speeding up the computing power of their brain and that is why they can see an effect on language skills.

There are different approaches to quantify the effects of TDCS in humans using functional magnetic resonance imaging (FMRI), positron emission tomography (PET), electroencephalography (EEG) near infrared spectroscopic imaging (NIRSI), and TMS either together or alone in conjunction with other scientific methods like questionnaires or post-training tests. (37)

When a constant electric field is applied to the brain, multiple cellular pathways will be activated that are extremely hard to isolate. (38) It is very difficult to predict the focal membrane potential due to the diffuse nature of electricity in the brain and the highly folded varying human cortex. (39) It is also hard to use results from animal studies because of the many differences between animal and human anatomy. (40)

One of the most accepted effects of TDCS is that it lowers the resting membrane potential and therefore can make it more polarized which can inhibit a neuronal response or make it less polarized which causes it to fire more easily. Most believe that anodal TDCS of a neuron will cause it to depolarize. Whereas cathodal stimulation will cause it to hyperpolarize. Some have published inconclusive or even opposing ideas. TDCS has also been found to cause or enhance cell migration and neuronal growth due to the change in the orientation and speed of cell migration caused by localized shifts of intracellular Ca2+. (41) (42)

The main technique to measure the cellular effects of TDCS was to measure motor evoked potentials and fMRI imaging in humans during trials. Another interesting mechanism that has only recently been tested is the modulation of blood-brain-barrier
Synaptic plasticity has been associated with both memory and learning and in forming and selecting connections in the developing nervous system. We know that Ca2+ plays a crucial role in synaptic plasticity, but little work has been done on the study of the different possibilities of how that happens. (27) It is unclear if the stimulation (anodal or cathodal) causes depolarization or hyperpolarization of the site directly under the stimulation and if the surrounding cells are also affected. (27) Bikson, et al. showed that in an electric field, a cell is differentially affected. Contrary to the conventional rationalization, they demonstrated that structural components of like neurite, nucleus at the cathode are depolarized while those facing the anode were subject to hyperpolarization. (44)

During TDCS, a series of multiple cellular pathways and processes (inflammation, activation of one neurotransmitter while inhibition of another neurotransmitter) are occurring simultaneously. Hence, these specific cellular mechanisms that ensue during TDCS remain unsolved. Due to the higher Na+ channel density in the soma than at the dendrite, it was previously hypothesized that cortical excitability that occurs due to changes in the cell-firing rate is derived from somatic membrane polarization rather than axonal polarization. (13) However, a study conducted by Kabakov, et al. on rat hippocampal slices proved that the excitatory or inhibitory effects of DCS are based on the orientation of the axon under the electric field. Furthermore, another study showed the complexity of transitioning from animal study into human study. (40)

Nitsche, et al. demonstrated that a blockade of serotonin reuptake enhanced long-term potentiation (LTP) due to anodal TDCS in the human motor cortex. (45) Surprisingly,
Tanaka, et al. carried out the same stimulation on rat frontal cortex and found that cathodal TDCS enhances extracellular serotonin. (46) Another mystery regarding cellular mechanisms is how TDCS influences learning, which is based on synaptic plasticity. Modulation of synaptic plasticity depends upon neurotransmitter release and the increase of Ca2+ influx inside the neuron. (47) TDCS can activate both processes via the electro-diffusivity phenomenon and the opening of voltage-gated Ca2+ channels. (48)

**TDCS Finite Element Models**

Besides conventional animal models of TDCS and other brain stimulation methods, scientists use computational models to predict specific outcomes of variable stimulation. These models incorporate many of the characteristics of the subject being studied and use computerized algorithms to simulate experiments. This method has become increasingly popular because it easily allows scientists to examine certain phenomena that normally would be impossible in living human subjects. For example, if a researcher was considering the effect of TDCS in the human brain they would put all the necessary variables into the computer based algorithm like electrode type, stimulation parameters, tissue types and the computer would then run a simulated experiment and will display the expected results. (Figure 12)

12. Examples of FEM models of TDCS and the resulting electrical current densities caused by different electrode types.
CHAPTER III

Design

Previous TCDS Setup

Before the redesign of the sponge electrodes and the headgear, the process of setting up TDCS was complicated and cumbersome. It would start off with the trained technician measuring the patient’s head with the 10-20 EEG system. The 10-20 EEG system is a grid of 20 locations that are separated by set percentages based on standard measurements of the head. (Figure 13) A typical highly trained individual will take at least 3-4 minutes to map out the locations. Once the locations have been marked they must insert a rectangle carbon rubber electrode inside a sponge pocket and connect a wire to it. The other end of the wire is then connected to the stimulation device. Once the electrodes are connected to the device they are fastened to the patient’s head with rubber bands or medical tape. Saline is then added to help transition the current from the electrode to the skin and the contact quality between the electrodes is measured.

**Figure 13**

13. A. Diagrams of the 10-20 EEG system and the locations of the electrodes/ the percentages between them.

B. How to align headgear based on measurements.
New Electrode Design

The electrode design was based off one major obstacle with other electrodes used currently for TDCS, they needed a highly trained technician to assemble and correctly place on the head. Patients, in particular those with M.S., and other neurodegenerative diseases, have a very hard time coming to a clinic multiple times a week because the technology was not capable of being used at home. Multiple iterations were considered including an electrode that was magnetic but the simplest design was a stainless-steel snap that was in the center of a carbon rubber electrode inside a preassembled sponge. The pair of electrodes now come presaturated with saline and already sealed in an easy to open zip lock bag. (Figure 14) After the design of the snap electrodes were finished the headgear had to be redesigned to accommodate the new electrodes.

Figure 14

14. Bags of pre-saturated pairs of snap electrodes ready to be given to patients

New Headgear Design

The new EASYSTRAP headgear was designed to easily incorporate the snap electrodes into a band in a way that is easy for a disabled patient to do without the help of a caregiver. It must be accurate enough to replace the need for a highly trained technician to measure the head by the 10-20 EEG method. For the new headgear, the patient’s head circumference is first measured from the nasion to the inion along the
forehead above the eye brows. This determines the size Easystrap that the patient will use. The headgear was designed in four sizes; S, M, L and XL, to accommodate for head sizes with circumferences ranging from 52 cm (S) to 65 cm (XL), using elastic elements to accommodate appropriate fit within the different sizes.

Two sponge electrodes are then snapped onto the wires labeled “BLACK” and “RED” and the Easystrap is ready to be placed on the head. The strap is clearly marked front and back to guide its placement by the patient. The user must align the arrow in front in between the eyes with the lower part of the strap laying across the forehead above the eyebrows. (Figure 15) By using a fixed angle between the two straps that varies depending on the head size and intended electrode location and easy to use reference points the strap is able to reliably target the intended locations within 3mm. This enables a patient to setup and apply TDCS at home without the need for the traditional method of measuring the head.

Figure 15

15. A. Easystrap ready to be place on patient’s head.
B. Easystrap properly placed with blue arrow lining up directly between the eyes.
C. Snap electrode snapping onto wire imbedded into band
D. Attaching the previous design of electrode to the band.
Fabrication Methods

To make the original working prototype of the sponge electrode a highly conductive 2mm carbon rubber sheet was cut into 42mm circles by a laser cutter to ensure exact fit. Then the male end of a stainless-steel snap was fastened by a riveting machine to the center of the circle. (Figure 16) Then a hole is punched out of the top sponge with a hole puncher. (Figure 17) The carbon electrode is placed in between the two sponges with the snap lined up in the circle cutout of the top sponge. Then the four small plastic rivets in the corners are fastened making sure the flat end is on the bottom. (Figure 18) The sponges are then saturated with 5mL of saline each and a pair of sponges is packed into a small zip lock bag. (Figure 14)

16. Carbon rubber electrode with stainless steel snap.
17. Punching hole out of top sponge.
18. Finished snap sponge electrode.

The EASYstrap was computer designed with Corel draw and then cutout of biocompatible plastic sheets with a laser cutter. (Figure 19) After cutting the plastic and washing off the residue, band is ready to have the elastic attached. The elastic is attached
by metal rivets in the front of the band and the back. (Figure 20) After the elastic, the wires are fastened to the band with wire clamps and rivets and then coiled together with plastic wire coil to prevent tangling. (Figure 21)

19. M1SO Easystap designed on Corel Draw to be cut by laser cutter.

20. Fastening front elastic with rivet.

21. Wires attached with wire clamps and fastened with wire coil.

During the design process, it took numerous iterations to ensure the accuracy and the proper fit of the headgear. The first few iterations did not even consider where the electrodes were placed but more importantly the fit on the subject’s head, how many sizes are needed and the ranges they should have.

Once a proper fitting band was made, it was cut out in incremental sizes and placed on many test subjects. The test placements followed the same procedure as explained in below in Chapter IV. (49) The average displacement of all the placements was calculated and was used to guide the moving of the electrodes to make a new iteration. (Figure 22)
This process was repeated until the average displacement from the predetermined positions was close to 3mm which was known to be well within the maximum displacement range that can still produce equivalent current distribution. (49) Once the electrode placement was accurate, extra elastic and diamond shaped cutouts were added to help expand the head size ranges it can accommodate. This process was used to make custom headgear that can be used at home by patients.

22. Bands that were made to measure locations F3 and F4

**Different Montages**

To prevent a patient or even an insufficiently trained researcher or medical professional from accidentally placing the electrodes in the wrong location and ruining the treatment or the results of a study, there were a few different versions of the headgear designed that target different brain regions. Each version can be used for only one set of electrode locations or montages.

A very popular setup or montage used for TDCS is called the M1SO montage. In the M1SO, TDCS is applied on the areas above the motor cortex (C3/C4 in the 10-20 EEG system) and the contralateral supraorbital region (above the opposite side eyebrow). (Figure 23) This montage was used to test the accuracy of the headgear by Dr. Helena Knotkova of MJHS. (49)
The second most popular montage used for TDCS is called bi-frontal. This montage is used to target the frontal lobe of a patient more specifically the dorsolateral prefrontal cortex (DLPFC) which many believe to be the center of depression in our brains. (50) There are two different bi-frontal band versions, one that the electrodes are on the locations F3 and F4 and the other is called the OLE. The OLE has a set location for the electrodes for every size head and has been shown that in all head sizes the current density is concentrated over DLPFC. (51) (Figure 24)

24. Bi-frontal OLE strap being placed on the head. From instructional video for proper headgear placements. (52)

Other montages that are used are F3 and the right bicep, F7 and F8 which some believe is more efficient than the bi-frontal montage. Other montages were custom made for a researcher's study.
CHAPTER IV

Results

Accuracy and Replicability of the Easystrap

Dr. Knotkova from MJHS has been studying the effects of TDCS on patients with chronic pain or end of life care and has administered TDCS on many patients. She was looking for a way to increase the number of subjects she could treat for her experiments. The main problems she faced were that her patients had a very hard time coming into the clinic and that she did not have nearly enough staff to send to the patient’s homes or care centers. With the help of the Easystrap she was able to greatly increase the number of patients she could treat. She set up a system that a trained technician would be present during the first session and by training the patients on the setup of the Easystrap they would be able to continue by themselves while video calling a researcher in the clinic. For this plan to be successful she had to validate the accuracy of the M1SO Easystrap.

The headgear prototype was evaluated by first measuring the subject’s head and determining the locations by the conventional method (10-20 EEG System) and then placing the headgear under two conditions and manually recording the displacement from the previously marked location. The first condition was the subject placing the headgear on themselves in the mirror after only brief instruction and the second condition was placed by a proxy. There was no significant difference between the two conditions and in two hundred placements (100 for each condition) the mean and median were calculated to be 3.61mm and 3mm respectively.

There was one outlier with a 13mm deviation from the marked location that was
not excluded from computations and used the value of maximal error of placement. The data was then analyzed by a computational model and it was determined that not only the mean but also the outlying 13mm deviation would not cause a significant change in the underlying current distribution in the brain.

**Studies Using Headgear**

Dr. Leigh Charvet in the NYU Langone Medical Center used the bands for her study researching the effects of TDCS on patients with Multiple Sclerosis. (52) In their study they were looking to see if TDCS can reduce fatigue in individuals with MS. After one session of training the patients were able run the rest of the sessions over video call from the comfort of their own homes. They used the bi-frontal OLE strap to administer left anodal TDCS paired with 20 minutes of cognitive training. (Figure 25) Study 1 delivered 10 open-label TDCS treatments (1.5 mA; \( n = 15 \)) compared to a cognitive training only condition (\( n = 20 \)). Study 2 was a randomized trial of active (2.0 mA, \( n = 15 \)) or sham (\( n = 12 \)) delivered for 20 sessions. The fatigue of the patients was assessed and the patients were given a post-treatment questionnaire.

*Figure 25*

25. An example of a patient using the Bi-frontal OLE strap while being monitored by researchers over video call. (52)
CHAPTER V

Conclusion

When compared to previous versions of the headgear or other available models, this new version was far superior in many aspects. It saves time, money, and increases the accessibility of treatment. The first two clinics that fully switched to at-home trials with the help of this technology and have had nothing but success. They have tripled the average amount of patients they can use in their studies and have even called back patients who were ineligible for previous trials because they were unable to setup the treatment on their own to now participate. The headgear has been used by patients with M.S., chronic pain, stroke, addiction, and depression. Now a researcher can administer treatment over video call to many more patients from their desk which reduces travel time and inestimably increased the number of patients they can treat. Many labs have even switched to using the headgear in a lab setting instead of training their technicians in using the 10-20 EEG system and it has even shown to be more accurate and replicable than an inexperienced technician.

A few TDCS pioneers have described the precision of the headgear as incredibly accurate. During the trial and after 600 recorded placements on the M1-SO strap alone, many placements had no displacement at all and only twelve tests that had displacements of over 5mm, with only two of them over 7mm.

There were two subjects excluded from the study because of the improper fit of the headgear. Both subjects were assigned a headgear that did not sit uniformly on their heads due to their abnormally shaped heads or large amount of hair. This may suggest
that the headgear can only be reliable on subjects with standard sized and shaped heads and must be examined before each stimulation to ensure the headgear and the electrodes are placed correctly on the head with properly saturated electrodes flush against the scalp.

The headgear has helped patients that were unable to be treated beforehand because of their inability to travel multiple times a week to a clinic. In a post-treatment questionnaire conducted by Dr. Charvet, one patient wrote an astonishingly moving answer to how they have benefitted:

“I 'found' my words again. I found my voice and my ability to recall words and I the 'grunting, pointing and stammering I'd been reduced to was replaced my 'the old me' and brilliant genius who can write a well-composed sentence. Equally as thrilled, possibly more so, is speaking, not just my words but I speak quickly again, no need to ask anyone to slow down because I can't comprehend what they're saying. Either I couldn't follow their story or I couldn't keep up. Things shock me all the time more and more benefits, improvements and more reasons to want MORE…. You gave me back my life, how does one ever say thank you or repay that?”
References

1. **S., Largus.** *De Compositionibus Medicamentorum.* Paris: s.n., 1529.


7. *Acceleration of image analyst training with transcranial direct current stimulation Correction to McKinley et al. (2013).** al., **McKinley et.** 2015, Behavioral Neuroscience, Vol. 129.

8. **Unilateral and Bilateral Electroconvulsive Therapy Effects on Depression, Memory, and the Electroencephalogram.** **Richard Abrams, Max Fink, Rhea L. Dornbush, Stanley Feldstein, Jan Volavka, Jiri Roubicek.** 1, 1972, Arch Gen Psychiatry, Vol. 27, pp. 88-91.


10. **Rapposelli, Dee.** Is TMS Cost Effective? Major Depressive Disorder.


43. Transcranial Direct Current Stimulation Transiently Increases the Blood-Brain Barrier Solute Permeability in Vivo Medical Imaging. Shin, Da Wi, Niranjan Khadka, Jie Fan, Marom Bikson, and Bingmei M. Fu. 2016, Biomedical Applications in Molecular, Structural, and Functional Imaging.

44. Role of cortical cell type and morphology in subthreshold and suprathreshold uniform electric field stimulation in vitro. C. Brumberg, Marom Bikson. 4, 2009, Brain


51. The Pursuit of DLPFC: Non-neuronavigated methods to target the left dorsolateral pre-frontal cortex with symmetric bicephalic transcranial direct current stimulation (tDCS). **Seibt O, Brunoni AR, Huang Y, Bikson M.** 3, 2015, Brain