Non-Invasive Electrical Brain Stimulation - Transcranial direct current stimulation (tDCS)

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BACKGROUND

Transcranial Direct Current Stimulation (tDCS) is a non-invasive and painless treatment that uses direct low intensity, generally 1–2 mA, electrical currents through electrodes wrapped in an electrode gel or saline-soaked pockets to stimulate different parts of the brain. This helps modulate the neuronal activity [1]. There are two types of stimulation for tDCS: Anodal and cathodal stimulation which excites the neuronal activity and inhibits or reduces neuronal activity, respectively [2]. The basic design of tDCS has existed for over 100 years. Before the 19th century, Luigi Galvani and Alessandro Volta were using direct current (DC) to test the animal and human electricity. In 1801, Galvani's nephew started using direct current stimulation in the clinical scene to improve the mood of melancholy patients which was a successful experiment [3].

The orientation of anodes and cathodes localization can lead to different treatments and purposes such as cognitive improvement, neuropsychiatric condition improvement, and other has various advantages[4].There are studies that show tDCS is a promising treatment for major depressive disorders (MMD). tDCS is not fully approved for treatment of depression - it is not FDA-approved [5,6]. There is another study that talks about how tDCS can be introduced as an alternative treatment for Obsessive-Compulsive Disorders (OCD). tDCS can be helpful for regulating the brain and behavioural system [7]. Also, there is a study that shows tDCS with visual illusion can improve the intensity of overall naturopathic pain after spinal cord injury with minimal side effects and such a good tolerability [8]. There is also evidence that shows cathodal tDCS is the most promising treatment to improve the activities of daily living (ADL) for patients after stroke [9]. This non-invasive tDCS method can be introduced as a rehabilitation technique and treatment of post-stroke aphasia patients. It can improve language performance by enhancing the activation in lesional cortical speech areas [10]. tDCS is a non-invasive neuromodulation technique that is one of promising neurorehabilitation techniques available today. It induces prolonged brain excitability changes and augmented cerebral plasticity. Deep Brain Stimulation (DBS) is an invasive surgical procedure for treating and improving some diseases such as Parkinson's disease, dementia, depression, traumatic brain injury, and etc. [11]. It can be seen in Appendix A, DBS is a different form of tDCS in terms of the target, current intensity and duration, associated risks. The main difference between these two techniques is tDCS is the non-invasive one and DBS is the invasive technique [12-14].

RESEARCH

As time progressed, tDCS devices have become a more reliable form of treatment to aid in stimulating specific parts of the brain with small amounts of direct electrical currents. Due to the non-invasiveness feature of tDCS, no surgery or operations need to be conducted, it is favorable amongst users/patients. It functions by wrapping an electrode, with electrode gel or saline-soaked sponge pockets, and supplying a constant direct current, typically of low intensity of 1-2 mA, to stimulate the brain. The intensity level of the current is changed based on how much stimulation one's brain requires, ranging from 0.5 – 2 mA, to meet those needs while still establishing a safe current threshold for users to not suffer brain damage. To ensure that the correct sections of the brain are being stimulated, it is advised that the user receives an initial magnetic resonance imaging (MRI) scan to identify the location that needs stimulation and where the electrode should be placed [15].

Treating Major Depressive Disorder with tDCS (MDD)

tDCS is known for treating different types of disorders and problems, and one of them is major depressive disorder or clinical depression. This disorder causes an individual to experience persistent sadness and loss of interest/motivation and has a huge impact on one's behaviour, attitude, emotions, and outlook on life. Depression is often confused as weakness where many assume that one can simply avoid. However, depression is cured through long-term treatment of medication and/or psychotherapy [16].

A study was conducted in 2013, where 120 unipolar depressed patients were studied to identify which intervention yielded to have more impact on the user's brain – tDCS only, tDCS and sertraline, sertraline only, and placebo effect [17]. Sertraline is an antidepressant drug that manipulates different chemicals in the brain to help users cope with depression, anxiety, panic attacks, etc. [18]. After this experiment was performed, the efficacy of these interventions were measured by a group of people which resulted in some contradicting results [19]. Kalu et al., Berlim et al., Shiozawa et al. concluded that the efficacy of tDCS was greater than the placebo effect, no significant correlation between tDCS and placebo, and tDCS more superior than placebo, respectively [20-22]. After more calculations and observations, it was concluded that tDCS is most effective when paired with other medications and interventions and the results are more permanent. There is a review paper that explored through all related papers up to 2018. Despite all differences in design and stimulating parameters in different studies, they found beneficial effects of tDCS for MDD [15]. In 2020, tDCS is not fully approved to be used as a treatment for MDD in the USA, but FDA grants the investigational device exception (IDE) to launch a trial for home-based tDCS [23]. It is not approved by Health Canada for clinical use in psychiatric illness yet but it is in experimental trial [24]. There is a European expert group that has proposed the level B recommendation (probable efficacy) for patients with depression who are treated or not treated with antidepressant and are not treatment resistant. This level B includes a minimum of 10 sessions (2mA, 20-30 minutes), using anode over the left d1PFC and a cathode over the right supra-orbital region [25]. There is one other study that they found tDCS has higher effectiveness on reducing depression symptoms compared to antidepressants [26].

Usage of tDCS for Chronic Pain

Chronic pain is very common in today's world with the constant repetition of movement, long periods of sitting, bad ergonomics, and illnesses. According to HealthLinkBC, chronic pain is essentially any pain that lasts longer than 3 months [27]. Like pain, chronic pain is also a way the body communicates with the brain indicating that something is wrong. From a review paper, it was found that 40-60% of patients who experience chronic pain have had success mitigating that pain with the use of medications such as antidepressants, opioids, and topical anesthetics [28]. However, although these medications work for 40-60% of patients, it was discovered that the effects of using medications to treat chronic pain was not a long term solution. Furthermore, medications are used for treating immediate pain and illnesses, but is not ideal to frequently use pharmacological treatments to treat chronic pain. This can cause irreversible damage to one's body. Studies also display that central sensitization is the main neural mechanisms associated with chronic pain and is a factor for the development and advancement of chronic pain [28]. Thus, various other therapies like acupuncture and thermotherapy have been developed and performed to reduce pain levels, but the effectiveness of these therapies lacks for dealing with chronic pain [28]. Over the years, tDCS has been improving its techniques for treating chronic pain and has shown to be more effective than the traditional methods.

In addition, another study was conducted where an anode is placed on the Ipsilesional (C3) or the Contralesional (C4) location and a cathode is placed on the opposite prefrontal cortex (FP2 or FP1) which can be seen in Appendix B. From this study, there were clinical studies that focused on pain caused by spinal cord injuries, lower back pain, chronic stroke, and chronic post-stroke pain where it was found that as the stimulation and durability in intensity rises, the level of chronic pain experienced by the user was reduced [30]. Theoretically, the advantage tDCS has over other methods is that it directly affects the central neural targets.

Using of tDCS for Post-Stroke Patients

The most common impairment after stroke is motor deficit which can cause physical complications. Stroke can lead to dynamic changes in motor cortical excitability, typically decreases cortical excitability of the lesion hemisphere and increases cortical excitability of contra-lesion hemisphere. tDCS can modulate the cortical excitability which can be used on stroke patients to increase the lesion cortical excitability by using an anodal electrode and decreasing the contra-lesion cortical excitability by using a cathodal electrode. This would help the post-stroke patient for motor recovery and rehabilitation [31]. There are studies that show tDCS can improve the activity daily living after stroke and it can be used as a rehabilitation technique and treatment of post-stroke aphasia patients [15,32]. According to studies, tDCS can improve motor recovery, motor skills, and motor learning in post-stroke patients [33,34].

Safety Factors of tDCS

When using tDCS devices alone or with a therapist, it is always important that the user/patient is safe and away from harm. For this reason, The FDA (Food and Drug Administration), along with Health Canada have confirmed that tDCS for therapeutic needs poses no significant risk. In other words, “it is a technique without reasonable expectation of any Serious Adverse Effects” [35]. It is known that too much of one thing can be harmful. However, studies have shown that 1000 subjects who used repetitive conventional tDCS protocols across more than 32,000 sessions did not experience any serious adverse effects. This ensures that patients can responsibly and consistently do this type of therapy without putting themselves and others at risk [35]. Although, one may experience some side effects such as mild tingling, itching, and headaches the overall safety protocols are being followed and many research centers have stated that the mild adverse effects that are experienced slowly disappear once the tDCS session ends [35,36]. It is worth mentioning that studies in the past have shown that using high current levels can cause permanent damage in animals because the simulation heats up the brain tissues [37]. In addition, it was proven that using tDCS along with pharmacological and behavioral therapies increases the success rate of the therapy and shows promising results [35]. A study was conducted on depressive patients which showed that stimulation of the brain using non-invasive methods, like tDCS, combined with medication yields the best results for curing the patient. Moreover, since electrodes will be sending small amounts of current to the brain through the scalp, people that experience epilepsies and seizures should not use tDCS treatments for their own safety [38].

FIELD WORK

For the field work of this project, the group interviewed a family relative, who will remain unnamed. The interviewee was a 65 year old male, family man, and experienced a stroke in 2014. The interview was conducted through a Zoom meeting. He is currently still recovering and had a lazy eye resulting in problems regarding depth perception. Back in 2014, after the stroke, he mentioned that he was debating between using the Deep Brain Stimulation (DBS) method and the transcranial Direct Current Simulation (tDCS) method. He later mentioned that because of tDCS' invasiveness and inexpensive feature, it would be more beneficial to try using it first before going through surgery to utilise DBS.

A series of questions were asked as follows:

1. What were your initial thoughts on tDCS?
2. First time using the tDCS device?
3. Can you give us a brief overview of the few devices you have used?
4. Did you experience any discomfort or pain when using the device?
5. How long did the device or devices last?
6. Noticed any significant improvement after using tDCS for a long time?

From these sets of questions we were able to get a better understanding of advantages/ disadvantages of tDCS devices, concerns that could be corrected, which will be discussed in the "Discussion" Section, and improvements to cognitive features. When we asked the interviewee about his first thoughts on tDCS, he thought tDCS was a placebo effect where people only thought they were seeing improvements because it was in their mind as opposed to actually getting better. The reason for his belief came from his research where he saw very low amounts of current being passed through the electrodes thinking that it was not enough to penetrate through the skull and stimulate the brain. He did later mention that he decided to give tDCS a try before going through surgery as it was non-invasive and he could completely avoid the surgical operation and recovery.

It was later asked how he felt when he used the tDCS device for the first time. He stated that the device gave off a tingling sensation which he found relaxing ultimately giving him an indication that the device was working. However, based on only the first time using the device, he was not able to see any slight or significant improvements to his cognitive abilities. During his time from 2014 to 2020, he has purchased 3 tDCS devices which we wanted to learn more about. He told us that the first tDCS device he bought was in 2015, approximately half a year after his stroke incident, which was called the Brain Stimulator - Travel Mode. The other two devices he purchased were both in the year 2020, in January and September to be specific, and were named Brain Driver Model v2.1 and ActivaDose II, respectively. Based on these 3 devices, he made it known that his favorite was the Brain Stimulator, bought in 2015, as it still produced tingling sensations whereas the two recent devices did not after a few sessions of use. For this reason, he decided to use a voltmeter to measure the output current produced by the 2 devices and came to a realization that no measurable output current was detected - despite the device indicating that it was functioning correctly. From here, he proceeded to show Nona and Arsalan the areas of his head that experienced acute burning symptoms, which slowly faded as days passed. He got these burns due to the initial sponges that he received with the device which were thin and non-existant. He later replaced these sponges with a new pair he got from Amazon, and he has not experienced any burning symptoms since. Lastly, we asked if he noticed any significant improvement after using tDCS devices for over 3 years to which he stated that he notices improvements in he depth perception and his lazy eye. He stated that he noticed significant motor ability improvements to his lazy eye just after a few sessions with tDCS. A revised version of this interview can be seen in Appendix D.

From this field work, it was concluded that tDCS really helped the interviewee with his depth perception and motor ability improvement. In addition, he said that it would be better if the tDCS devices were more durable and the overall quality of the electrodes that come with the device can be better to prevent others from experiencing burn-like symptoms.

DISCUSSION

As you can see in Appendix E, the four top tDCS devices are compared in terms of their advantages and disadvantages. These disadvantages can be improved to better suit the user's needs. The Brain Stimulator v3.0 has a perfect combination of functionality and simplicity and impressive circuitry design but its travel model only uses two current levels. TransCranial Technology Stimulator has a defined session length timer, automatic pause, and notification for electrode repositioning but lacks in portability. The device is very bulky and not customer friendly. Super Specific Devices has selectable voltage features and retro analog metering, but it has poorly designed electrodes. Focus v2/v3 Stimulator is packed with great safety features but it is overpriced. It is evident that all these devices have the disadvantages that can be improved [39,40]. There are few tDCS essential features such as build quality, accurate current delivery, automatic current ramp up or down, built-in timer, battery, and types of electrodes. You can read more details on its feature quality in Appendix E as well.

From this project, it was learned that not all of the universal design features are being implemented to the tDCS devices. To be specific, tolerance for error, low physical effort, and size and space for approach and use are being neglected. Due to this, the proposed solution will address these principles and ultimately allow tDCS devices to follow all principles in universal design. For tolerance in error, an automatic voltage adjustment and automatic current ramp up/down can be implemented. It was found that increasing the current or voltage too fast causes lightheadedness and dizziness which causes discomfort to the user and can potentially injure them if standing or moving. Furthermore, encasing sponge electrodes in a protective shell and adding timer features can ensure the prevention of accidental burns and safety, respectively. For low physical effort, pre-set options and extended battery life can be added for regular users who use tDCS often. Finally, for size and space for approach and use, the device can be made to be compact and portable allowing the user to easily move the device to different locations in their house with ease and exert less energy. A complete breakdown of all optimized feature qualities that can be used to improve current tDCS devices can be found in Appendix F since this section heavily discussed the 3 out of the 7 principles of universal design that were not followed.

CONCLUSION

In conclusion, it was seen that tDCS is greater than a lot of stimulation methods solely because of its non-invasiveness, a physician's prescription is not required for this type of therapy, and people can use it in the comfort of their homes. In addition, tDCS is used to solve various problems and illnesses such as depression and post-stroke patients while also improving day-to-day issues like chronic pain relief and cognitive improvements. However, if improvements are not being seen when using tDCS, other methods of therapy should be used. Lastly, tDCS devices currently are not following universal design standards and can be improved such that they are to make users more comfortable and safe as discussed in this report.

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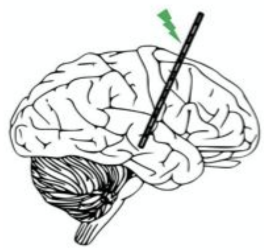
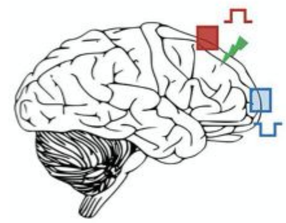
APPENDIX

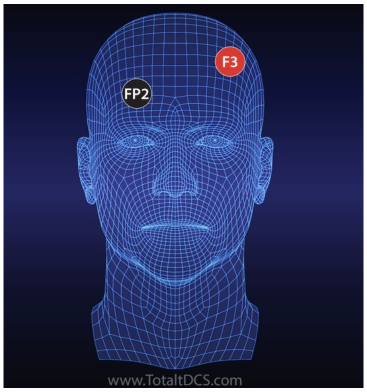
Appendix A

Difference between tDCS and Deep Brain Stimulation (DBS)

Type	**DBS**	**tDCS**
		
Target	Midbrain, Thalamus, Pallidum, Striatum	Left dorsolateral prefrontal cortex or posterior parietal cortex
Current	Low (8-30 Hz) or High frequencies (50-250 Hz), 1-20 V voltages	20 minutes sessions (single or repeated) 1-2 mA intensities
Treatment	Treating severe neurological conditions such as essential tremor, Parkinson's disease, Tourette's Syndrome, Dystonia	Numerous disease and conditions such as depression, chronic pain, addiction, epilepsy, schizophrenia
Requires physician?	Yes	No
Invasive	Yes	No
Other	Risky but still effective	Affordable and Safe

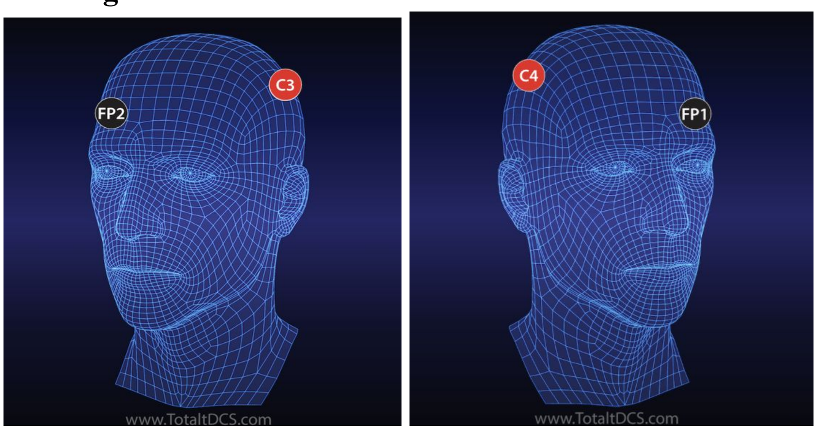
Appendix B

Treating Major Depressive Disorder



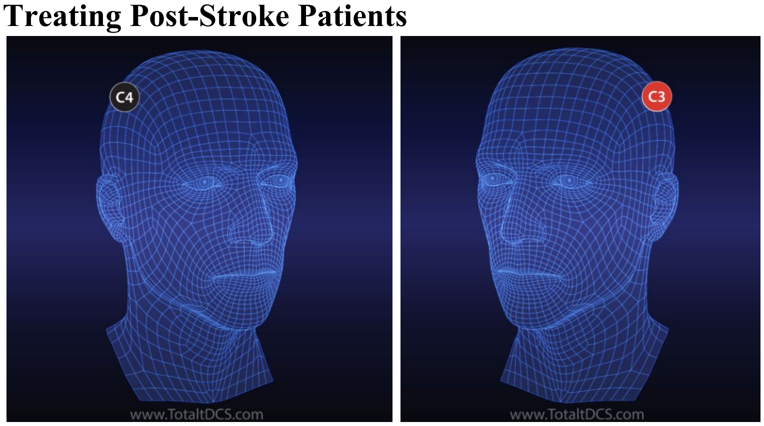
- **Anode: Left DLPFC (F3)**
- **Cathode: Right Supraorbital (FP2)**

Treating Chronic Pain



- **Anode: Ipsilesional (C3) or Contralesional (C4)**
- **Cathode: Opposite Prefrontal Cortex (FP2 OR FP1)**

Treating Post-Stroke Patients



- **Anode: Ipsilesional (C3)**
- **Cathode: Contralesional (C4)**

Appendix D

1. **What were your initial thoughts on tDCS?**
    - Placebo effect
    - Good if it works because non-invasive
2. **First time using the tDCS device?**
    - Experienced tingling sensation
    - Couldn't tell if it worked but felt good
3. **Can you give us a brief overview of the few devices you have used?**
    - Used 3 different tDCS devices in total at 2mA
        - The Brain Stimulator, Travel Mode - purchased in 2015
        - Brain Driver Model v2.1 - purchased Jan. 2020
        - ActivaDose II - purchased in Sept. 2020
    - Enjoyed all 3 but the Brain Simulator was the only one still giving tingling sensations
4. **Did you experience any discomfort or pain when using the device?**
    - Initial sponge that he received seemed to be thin and non-existant once placed on the head
        - Due to this he experienced acute burn symptoms
    - Replaced the sponges with another pair from Amazon and it worked perfectly

5. **How long did the device or devices last?**
    - The Brain Stimulator still seems to work
    - The newly purchased devices do not output any measurable currents
6. **Noticed any significant improvement after using tDCS for a long time?**
    - Felt like his depth perception improved
    - Motor ability in his lazy eye has improved a lot over the years
        - But noticed changes in only a few sessions.

Appendix E

Top tDCS Devices Comparison

Devices	The Brain Stimulator v3.0	TransCranial Technology Stimulator	Super Specific Devices 12-24v Device	Focus v2/v3 Stimulator
Advantages	-Perfect combination of simplicity and functionality -Impressive circuitry design including a low battery indicator and session timer - 'Introduced" the concept of boost voltage (constant power availability despite battery health)	- User defined session length timer - Session can be set current increments of 0.1 mA - Automatic pause if external resistance is too high (electrodes become disconnected) - Notification to reposition sponges if external resistance is too variable	- Feature selectable voltage (hardware based) - A nice "retro" analog metered tDCS device which is significantly smaller than the Apex device - Cool retro styles (quite small for a device with an analog meter) - Analog meter has a max reading of 3mA (much better than 5mA meter)	- Very featured packed device → practically robous as TCT device but packed into a size of a BIc lighter - Great safety features - Super compact device that you can take it anywhere
Disadvantages	- Older products don't include ramping - Their "travel model" (no longer sold) only include two current levels - Community concern with 1st gen travel model overcoming high resistance	- Pretty bulky device (stuck at your desk while using) - Not customer friendly - LED screen is too small - Not possible to change output current during a session (must first end the session and set up a new session)	- Self-adhesive electrodes (poorly designed electrodes) - Device enclosure appear to be 3D printed, and actually uses the same back over the brain stimulator v3.0 device - Analog can break → incorrect current readings	- Overpriced, terrible customer service -Focus' "Go Flow" product - very confusing and hard to use -Go Flow v4 can reach up to 4mA (Very unsafe)

Feature Quality

tDCS Essentials	Comment
1. Build quality	Testing for safety & accuracy
2. Accurate Current Delivery	Accurate and stable direct current waveform, ensuring having enough power (voltage) (despite different skin resistances - impedance), min of 20 volts for 2mA current (Ohm's Law), automatic voltage adjustment
3. Automatic Current Ramp up/down	Required to accomodate the sensation of stimulation and to prevent the patient from becoming light-headed at the onset of a session (Analog devices will allow you to do this manually)
4. Built-in Timer	Automatic Timer - Selecting the desired length of stimulation (pre-set times of either 20 or 30 minutes)
5. Battery	Needs a clear visual indicator for informing the user if the devices is in low battery and it should be replaced
6. Types of Electrodes	Should come up with sponge electrodes encased in a protective shell to reduce the risk of accidental burns during stimulation

Appendix F

Proposed Solution - Optimized Feature Quality

1. Equitable Use	Use for different problem and disabilities
2. Flexibility in Use	Anyone can use it
3. Simple and Intuitive Use	Text, buttons, and displays
4. Perceptible Information	- Clear visual indicator for battery notification - Automatic time for desired length of stimulation
5. Tolerance for Error	- Automatic Voltage Adjustment & Automatic Current Ramp Up/Down - Encasing sponge electrodes in a protective shell → preventing accidental burn - Setting timer features
6. Low Physical Effort	Pre-setting options for repetitive use and longer battery life
7. Size and Space for Approach and Use	Compactable and portable