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Universal Transcranial Direct Current Stimulation (tDCS) Headset for targeting the bilateral Dorsolateral Prefrontal Cortex: Towards facilitating broader adoption

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Abstract— **Electrode position affects the brain current flow intensity and distribution induced by transcranial direct current stimulation (tDCS). The dorsolateral pre-frontal cortex (DLPFC) is a common target in neuropsychology and neuropsychiatry applications. A positioning scheme and subsequently a headgear has previously been developed to target the DLPFC automatically - devoid of any scalp ruler or neuronavigation method. This approach minimizes the time cost for pre-treatment measurements without compromising targeting accuracy and induced electric field focality. The goal of this study was to further develop this headgear to facilitate broader adoption while maintaining its core design elements intact. Briefly, we developed the headset to accommodate all adult head sizes (52-62 cm) rather than having multiple sizes, to have increased robustness, enhanced visual aesthetics, and have improved usability.**

We recruited 8 subjects and tested the accuracy of electrode placement on various head sizes. We also tested usability with the System Usability Scale (SUS) and asked the subjects to rate visual appeal. Our study demonstrated that the newly developed headset had greater usability and was more visually appealing than its predecessor without compromising targeting accuracy.

Clinical Relevance— **This study introduces a headset for routine tDCS administration targeting bilateral DLPFC. The headset is highly usable, robust, and is expected to facilitate home and high-volume use.**

I. INTRODUCTION

Transcranial Direct Current Stimulation (tDCS) involves the non-invasive delivery of a weak, direct current through electrodes to the brain that creates plastic changes in neural activity [1-3] and modulates brain function [4]. Various brain regions can be targeted with tDCS through different electrode arrangements. The dorsolateral prefrontal cortex (DLPFC) is critically involved in higher order processes, namely conscious decision making, working memory, inhibition, reasoning, etc. [5-6] Numerous studies have therefore targeted the DLPFC not only for cognitive control but also as a treatment option (major depression disorder, anxiety, and craving) [7]. There are several mapping techniques typically used to determine the correct electrode placement for targeting the left DLPFC with tDCS. The "EEG 10-10" method involves placing the electrode on the "F3" location guided by an EEG map [8,9].

Alternatively, the "Beam F3-System" [10] uses anatomical landmarks such as the nasion and inion in conjunction with the "Beam F3 Shortcut Software" (clinicalresearcher.org/software.htm) to determine the proper electrode positions. A third method, the "5-cm Rule" simply places the electrodes 5 cm anterior to the motor cortex [11].

Seibt and colleagues simulated the electric field (EF) created by these aforementioned different electrode montages on 6 different sized heads. They found significant discrepancies in the EF between heads and between positioning systems, and often, the left DLPFC was not successfully targeted [12]. They also developed a Omni-Lateral-Electrode (OLE) headset to target the bilateral DLPFC without the need for functional imaging, mapping, or neuro-navigation techniques. Forward modeling verified optimized targeting, making it more efficient in terms of cost and accuracy than the EEG 10-10 System, Beam F3 System, and 5-5-cm rule.

While tDCS for therapeutic use has shown Class B evidence thus far [7], several on-going large multi-center trials increase its likelihood for demonstrating better therapeutic evidence. Nonetheless, tDCS has already been approved for clinical use by medical regulatory agencies in the European Union, Canada, Australia and other nations. Further, it is likely that it will become a home medical treatment in the future given favorable risk/benefit profile, relatively simple technology, and established success in delivering remote stimulation [13, 14]. This motivates development of a robust headset suitable for high volume use across different head sizes that patients can reliably self-apply without technical guidance.

The OLE headset design essentially comprises of an occipital strap, a frontal electrode strap, and a chin strap. The occipital strap is centered at the inion and is connected to the chin strap and electrode strap by a hinge above the dorsal part of the ears. 5x5 cm^2 conventional sponge-based electrodes are held 10 cm apart on the electrode strap which is kept in place by the chin strap. There is a 165 degree angle between the electrode strap and occipital strap. The OLE headset is provided in 3 sizes for different head circumferences (in cm): Small: 52-55, Medium: 55-58, and Large: 58-62. The headset use has been successfully validated across several applications in both laboratory [15] and supervised home settings [14].

While the OLE headset remains viable for use in laboratory settings, broader adoption motivates further design updates.

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Specifically, we identified the following needs:1) an universal headset design accommodating typical range of adult head sizes, 2) increase robustness both by design and by choice of appropriate materials, 3) enhance visual aesthetics to provide a more finished appearance and thereby augment end user experience, and 4) improve overall usability. We note that the OLE headset introduced previously [12] currently incorporates a "snap" connection mechanism to enable simple attachment to the tDCS electrodes (male end on electrode side and female end on the lead wire). It was therefore required to ensure that the new headset option maintained the same attachment mechanism to the tDCS electrodes.

In this study, we developed a Universal tDCS headset for targeting the bilateral DLPFC (called the "OLE-2") that positions the electrodes in the same anatomical location as the OLE headset [12]. We retained core design elements of having a 165 degree angle between the frontal and occipital sections and a 10 cm separation between electrodes. The final engineered OLE-2 headset was characterized by a rotary gear in the occipital section to enable simple adjustment to 10 different size fittings. Additionally, electrical lead wires running from the tDCS device are hidden within the headset facilitating a more robust and visually appealing set-up.

We recruited 8 participants encompassing a range of head sizes (Small. Medium, Large) and compared accuracy of electrode positioning by having them self-load the OLE headset followed by the OLE-2 headset. We then used the System Usability Scale (SUS) to perform an usability analysis and posed an additional question regarding visual appeal. We plotted both individual and average metrics to compare across the headset options.

II. METHODS

1) Headset Development As with any typical industrial design workflow, we started with sketch ideation meeting the required design inputs of the final envisioned headset. This was followed by the iterative steps of 3D CAD modeling and 3D printing and machining to verify ideas. All prototypes were fabricated using Formlabs Form 2 printer with a setting of 100 microns per layer. All resins were washed with isopropyl alcohol for 20 minutes and then cured in UV light for 6 min.

Over the course of the entire product development cycle, 4 distinct headset designs were developed (**Figure 1**). Briefly, Version A focused on hiding lead wires, testing materials, and associated look, feel, and function. Version B adopted a rotational positioning mechanism that allowed rotation of the section holding the tDCS electrode with one degree of freedom. However, internal testing confirmed that an approach that fully covers the electrodes served better to ensure uniform scalp contact. This was realized in Version C after screening across several material choices that allowed needed flexibility (bending) without hampering durability. Finally, for Version D, we dropped the forehead band and replaced the occipital elastic strap with a rotary gear and

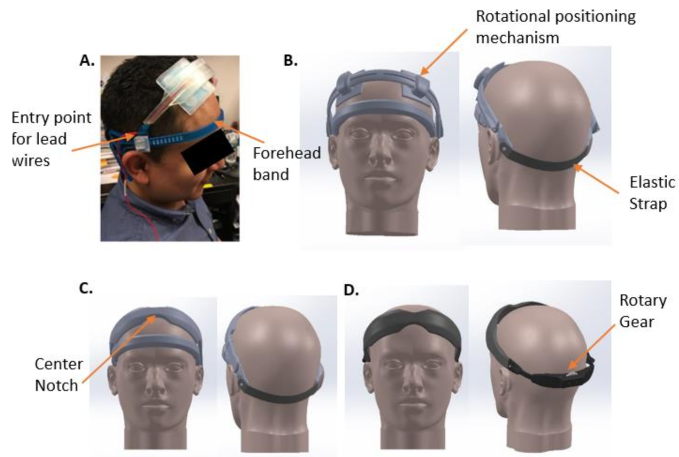

Figure 1: Distinct headset designs developed over the course of the study. Version A focused on lead wire concealment. Version B explored a rotational positioning mechanism. Version C included a center notch for alignment with nose. Version D incorporated the rotary gear mechanism for universal fit.

slider mechanism. This rotary design choice enabled the occipital section to be self-adjusted to different head sizes, without compromising final electrode position. Specifically, 10 different positions accommodating different head sizes could be set by the following scheme: Position 8 corresponded to the circumference of the Large OLE headset and Position 6 and Position 4 were equivalent to the Medium and the Small OLE headset respectively. Once the initial design constrains were met, we again tested different materials to increase durability, finish, and related tactile properties. The final materials chosen are listed in Table I.

TABLE 1: Material properties of OLE-2 headset

Design Element	Material	Tensile Strength	Tensile Modulus	Elongation at Break
Frontal Section	Photopolymer resin (Tough 2000)	46 MPa	2.2 GPa	48%
Rotary Gear	Rigid 10k	65 MPa	10 GPa	1%

2) Accuracy, System Usability Scale, and Visual Appeal Testing. Each subject was given a tape measure and mirror to measure their own head circumference. Based on their head circumference, the subject chose one of the three OLE headsets and placed the headset on their own head using the mirror. The subject was instructed to follow typical OLE headset positioning instructions – i.e. align the center of the occipital strap on the inion and position the electrodes as shown in **Figure 2A**. The electrode location was marked on the subject's head using a marker. Subsequently, the subject removed the OLE headset and donned the OLE-2 headset using the mirror. The subject was similarly instructed to align the middle of the occipital section at the inion and center the electrodes on the head. The subject then tightened the gear until the headset sat firmly on their head. The subject was not instructed as to what gear position the headset should be adjusted at, rather they just tightened it until the headset felt firmly in place. We measured the distance between the location of the OLE headset electrodes and the OLE-2 headset electrodes using a tape measure to determine replication accuracy. Then the subject removed the OLE-2 headset and was informed as to the correct size it should have been set to. Then the subject re-donned the OLE-2 headset for a second time and the corresponding distance between the new electrode position and the position of the OLE headset were re-measured. To verify adequate scalp contact across the tests, the electrodes were connected to a tDCS device and appropriate contact quality was confirmed.

Each subject was asked the 10 questions of the System Usability Scale (SUS) for both the OLE headset and the OLE-2 headset (**Table II**). The final SUS scores were calculated from their responses using standard approaches [17]. Additionally, each subject was asked to respond to the statement "How visually appealing is the headset" for both options. To help facilitate an accurate response, the experimenter asked the subjects to consider proportion, symmetry amongst functional parts, form, and texture [18].

TABLE II. System Usability Scale (SUS) used and additional question posed to the subjects.

SUS survey for the subjects (1-strongly disagree, 5- strongly agree)	
I think that I would like to use the product frequently.	I thought there was too much inconsistency in this product.
I found the product unnecessarily complex.	I would imagine that most people would learn to use this product very quickly.
I thought the product was easy to use.	I found the product cumbersome.
I think that I would need the support of a technical person to be able to use the product.	I felt very confident using the product.
I found the various functions in the product were well integrated.	I needed to learn a lot of things before I could get going with this product.
Additional question (1-strongly disagree, 5- strongly agree)	
How visually appealing is the headset or aesthetically pleasing to the eye?	

III. Results

As dictated by design constraints, the OLE-2 headset replicated the core design principles of the OLE headset – namely the angle between the occipital and frontal sections (165 degree) and the inter-electrode distance (10 cm) (**Figure 2A**). The 8 recruited healthy subjects spanned the typical adult head size range (Small: 1; Medium: 5; Large: 2). With regards to electrode positioning accuracy, OLE-2 was found to replicate positioning of the OLE headset to within 0.4-0.95 cm on average (**Figure 2B**). This validated the universal size design characteristic of the headset as electrode shifts to the tune of ~1 cm on scalp would not affect induced cortical EF pattern [19]. We in fact, noted accuracy of up to 0.4 cm can be attained, if the subject is apprised apriori of the exact number of turns to set the rotary gear to. Since this information can be simply relayed to the subject and is straightforward for a layperson to follow, the OLE-2 headset can be expected to closely mimic the OLE headset over repeated runs. With respect to the degree to which a subject felt a headset was "aesthetically pleasing to the eye", OLE-2 design was deemed substantially superior (**Figure 2C**). The average visual appeal score for the OLE-2 headset was ~60% higher than the OLE-1 headset. This was an expected result given the design upgrades related to concealing lead wires and using materials to engineer a more finished and firm look.

The average SUS scores indicated a score of 72 for the OLE headset increasing to 82.5 for the OLE-2 headset (**Figure 2D**). Moreover, for both visual appeal and SUS survey, each and every participant scored the OLE-2 headset higher than the predecessor.

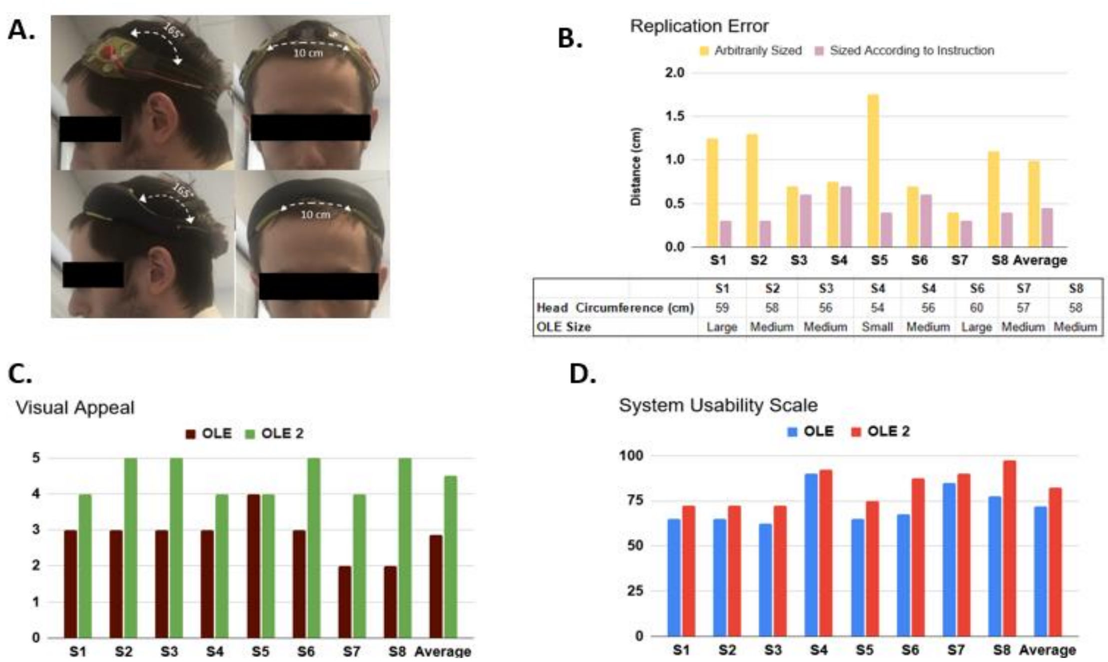

Figure 2. A. Newly developed OLE-2 design replicated essential design principles of OLE headset. **B.** Replication accuracy of the OLE-2 headset and the head circumferences of the recruited subjects **C.** Visual Appeal **D.** SUS scores.

IV. Discussion

This central aim of this study was to extend an existing reproducible electrode positioning scheme for DLPFC targeting by incorporating features needed for wider clinical adoption. The final engineered headset (OLE-2) was found to meet our initial universal fit requirement Further, OLE-2 was shown to have both substantially higher aesthetically pleasing effect and usability score.

Bangor and colleagues reviewed thousands of publications that tested usability of products and found the mean score among those products to be 70.5 [16]. They further note that a SUS score of 77.8 and higher reflected the top 25% of the results. Accordingly, the OLE headset scored a SUS score slightly above average (72) while the OLE-2 headset scored in the top 25% percentile (82.5).

While the SUS survey is by design focused on usability, visual aesthetics are known to influence scores in a positive fashion. For instance, exposed lead wires are expected to add a sense of complication and decreased confidence using the OLE headset in comparison to the OLE-2. It was noted by the experimenter that some subjects often felt the need to cross check that the wires were properly connected and appropriately positioned. Furthermore, the firm composition of the OLE-2 headset ensured that the subject did not mistakenly twist or bend it incorrectly. These aforementioned differences contributed to better responses for SUS questions pertaining to OLE-2- namely, “I felt very confident using the headset” and “I thought the headset was easy to use”. Additionally, OLE-2 headset generally scored higher across all participants for “I found the various functions in the headset were well integrated”. This is likely due to the well-integrated gear and sliding mechanism present in OLE-2.

In summary, the proposed new OLE-2 headset incorporates all appealing features of its predecessor (i.e. rapid set-up, low cost, no measurement approach) while adding needed updates for broader adoption. It is a step towards enabling the possibility of true home-tDCS treatment for many debilitating illnesses and high-volume applications. We note that while the proposed headset solution addresses a fixed tDCS electrode placement, essential design concepts presented here (universal size, gear mechanism, lead wire concealment) may be extended for other placements.

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