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Dry tDCS: Tolerability of a novel multilayer hydrogel composite non-adhesive electrode for transcranial direct current stimulation

Niranjan Khadka [a], Helen Borges [a], Adantchede L. Zannou [a], Jongmin Jang [b], Byunggik Kim [b], Kiwon Lee [b], Marom Bikson [a, *]

[a] Department of Biomedical Engineering, The City College of New York, CUNY, New York, NY, 10031, USA
[b] Ybrain Inc, Seongnam-si, Republic of Korea

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ABSTRACT

Background: The adoption of transcranial Direct Current Stimulation (tDCS) is encouraged by portability and ease-of-use. However, the preparation of tDCS electrodes remains the most cumbersome and error-prone step. Here, we validate the performance of the first "dry" electrodes for tDCS. A "dry electrode" excludes 1) any saline or other electrolytes, that are prone to spread and leaving a residue; 2) any adhesive at the skin interface; or 3) any electrode preparation steps except the connection to the stimulator. The Multilayer Hydrogel Composite (MHC) dry-electrode design satisfied these criteria.

Objective/Hypothesis: Over an exposed scalp (supraorbital (SO) regions of forehead), we validated the performance of the first "dry" electrode for tDCS against the state-of-the-art conventional wet sponge-electrode to test the hypothesis that whether tDCS can be applied with a dry electrode with comparable tolerability as conventional "wet" techniques?

Methods: MHC dry-electrode performance was verified using a skin-phantom, including mapping voltage at the phantom surface and mapping current inside the electrode using a novel biocompatible flexible printed circuit board current sensor matrix (fPCB-CSM). MHC dry-electrode performance was validated in a human trial including tolerability (VAS and adverse events), skin redness (erythema), and electrode current mapping with the fPCB-CSM. Experimental data from skin-phantom stimulation were compared against a finite element method (FEM) model.

Results: Under the tested conditions (1.5 mA and 2 mA tDCS for 20 min using MHC-dry and sponge-electrode), the tolerability was improved, and the erythema and adverse-events were comparable between the MHC dry-electrode and the state-of-the-art sponge electrodes.

Conclusion: Dry (residue-free, non-spreading, non-adhesive, and no-preparation-needed) electrodes can be tolerated under the tested tDCS conditions, and possibly more broadly used in non-invasive electrical stimulation.

1. Introduction

Transcranial direct current stimulation (tDCS) is a non-invasive brain stimulation tool used in healthy and patient populations where a weak direct current (1–2 mA) is applied through two or more electrodes placed on the scalp [1], [2]. A major contributor to the rapid and broad adoption of tDCS is portability and ease-of-use. tDCS is well tolerated with common mild side-effects such as transient cutaneous sensations (for e.g. as warmth, itching, and tingling) and erythema [3–7]. However, when (and only when) established standard protocols are not followed [8], tDCS can produce significant skin irritation [9–12]. Given that cutaneous sensation and irritation are the primary risks of tDCS [3] [7] [13], [14], proper electrode preparation and monitoring are vital for tolerability and reproducibility [4] [6], [15]. Yet, the preparation and placement of tDCS electrodes remain the most cumbersome and prone-to-error steps [7]. For example, both the level of sponge fluid saturation and head-gear tightness need to be titrated to balance good skin contact while avoiding of saline spread, and sponges can dehydrate or move [16] over an extended time. Thus, despite success with current research/clinical grade equipment and

* Corresponding author. Department of Biomedical Engineering, The City College of New York, CUNY, 160 Convent Avenue, New York, NY, 10031, USA.
E-mail address: bikson@ccny.cuny.edu (M. Bikson).

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accessories, even for remote-supervised home use [17], there is an interest to continue to enhance technology to deploy tDCS.

The sponge-pocket style electrode (25–35 cm^2) with conductive rubber insert, pin connectors, and saline application by the operator is the most traditional tDCS electrode used [16] [18], but most prone to preparation error, notably when poor materials are used by insufficiently trained users [19]. Circular sponges do not appear to provide an advantage [14], [20]. The introduction of pre-saline-saturated snap-connector sponge electrodes [21] automates most of the sponge electrode preparation process. Electrolyte gel or paste is used in specialized tDCS application (e.g. in MRI [22]). Specialized adhesive hydrogels electrodes can support tDCS [4]. High-Definition electrodes with a distinct small form factor (~1 cm diameter [23]) use specialized hydrogels [24]. What all these electrodes design share, is a "wet" electrode-skin-interface, where a fluid or viscous electrolyte is assumed to saturate the skin [25], which in turn result in some residue on the skin.

Here, we validate the performance of the first "dry" electrodes for tDCS. Dry electrodes exclude: 1) any saline or other conductive hydrogel-based gel or paste, that are prone to leak or spread, and that leave a residue; 2) any adhesive at the skin, either around the electrode or part of the hydrogel; or 3) any electrode preparation steps by the operator except connection to the stimulator. A novel Multilayer Hydrogel Composite (MHC) electrode design fulfills these criteria. FEM models and a skin-phantom were used to verify electrode performance followed by tolerability validation in healthy subjects. Adverse events, erythema, and VAS pain were scored using established protocols [4] [7] [10], [13], [26]. In addition, we developed a biocompatible flexible printed circuit board current sensor matrix (fPCB-CSM) to map current distribution inside the electrode during phantom or subject stimulation. In all experiments, MHC dry-electrode performance was compared against a state-of-the-art sponge electrode to address the hypothesis: can tDCS be applied with a dry electrode with comparable tolerability as conventional "wet" techniques.

2. Materials and methods

This study involves experimental measures in phantom (voltage) and participants (via VAS and adverse events reporting questionnaire), computational FEM simulation in phantom, current mapping in the electrode, and an algorithm based image processing of erythema distribution.

2.1. Participants

The study was conducted in accordance with the protocols and procedures approved by the Institutional Review Board of the City College of New York, CUNY. Twenty healthy participants (13 males and 7 females; age 19–34 years; mean age 24.7 ± 4.9) completed this study. Volunteers with any sign of skin disorder/sensitive skin (ex. eczema, severe rashes), blisters, open wounds, burn including sunburns, cuts or irritation (e.g. due to shaving), or other skin defects which compromise the integrity of the skin at or near stimulation locations were excluded from this study. However, participants on mild acne medication with non-irritating skin disorders were not excluded. Similarly, prospective volunteers with any neuropsychiatric disorders or receiving medication for such disorders were excluded from this study. Participants volunteered in four different tDCS sessions using 1.5 mA and 2 mA current intensities plus an additional two sessions at 2 mA with the fPCB-CSM for both MHC dry and sponge-electrodes in a randomized order. All participants provided written informed consent to participate in the study. Participants were seated in an upright relaxed position and performed a lexical decision task throughout the duration of the stimulation.

2.2. Novel sensor array

The current sensor made up of a novel biocompatible flexible printed circuit board current sensor matrix (fPCB-CSM) comprises two units: 1) measuring unit (top view) and 2) sensor unit (bottom view) (Fig. 1, Fig. 2A and B). The measuring unit (rubber electrode positioning side) of the novel sensor array has an exposed gold (Au) plated uniform copper (Cu) metal surface, whereas on its distal side, there are twenty-five 50 Ω soldered resistors (5 rows and 5 columns of resistors) and five common grounds for each row. The sensor unit underneath the measuring unit (sponge/MHC-dry electrode side) has a high heat resistance polyimide insulating substrate that divides the conductive metal into twenty-five small sensor electrode arrays. Each of these twenty-five sensor arrays is connected independently to the twenty-five test resistors located at the measuring unit. Each end of the sensor array has a dimension of 5 cm × 5 cm x 0.03 cm (Fig. 1). The entire sensor array is assembled into one compound unit using a biocompatible polyimide substrate.

2.3. Voltage sensor array for phantom study

Twenty-Five Ag/Agcl pellet shaped electrodes (diameter = 1 mm) were embedded inside an agar phantom (based on [27] [28]) such that the planar assembly mimics the shape of an overlaid 5 × 5 cm^2 tDCS electrode, and the position of each electrode corresponds to the center of the 25-small fPCB-CSM sensor arrays. An embedded reference electrode placed 5 cm away from the twenty-five electrode array was used as a ground for voltage measurement across the recording electrodes.

2.4. MHC dry-electrode

The dual layer structure of the MHC dry-electrode includes independently optimized mechanical, electrical, and chemical properties of the hydrogel. The top layer (thickness, 0.6 mm) of the MHC dry-electrode was composed of an adhesive polymer hydrogel, whereas the bottom layer (thickness, 1 mm) had a non-adhesive bio-compatible polymer hydrogel containing Poly-Vinyl Alcohol (PVA) (Fig. 1). Both layers were optimized in a way that the top layer becomes less resistive to redistribute the injected current across the electrode plane, whereas the bottom layer becomes highly resistive layer and minimizes current clustering at the skin [18]. Furthermore, any electrochemical produced (e.g. pH changes) at the electrode (non-ionic/ionic conduction) interface within the electrodes were optimized using the top layer as a diffusion barrier [25]. The electrode components weight by percentage) were: *cross-linked acrylic resin* (top layer: 15–25; bottom layer: 15–25); *polyhydric alcohol* (top layer: 40–60; bottom layer: 30–60); NaCl as an *electrolytic salt* (top layer: < 10; bottom layer: < 8); *additives/stabilizers* (top layer: < 0.5; bottom layer: < 0.5); *deionized water* (top layer: 20–40; bottom layer: 20–40); *polyvinyl alcohol resin* (top layer: none; bottom layer: 1–5).

The effectiveness of the MHC dry-electrode was successfully evaluated not only as a current re-distribution layer but also as a diffusion barrier layer [29]. In the diffusion barrier test, pH changes were measured at the entire conductive silicone rubber/top hydrogel layer, top/bottom hydrogel layer, and bottom hydrogel layer/skin interface after 2 mA 30min stimulation. There was no pH change at the bottom/skin hydrogel interface. Only less than 0.3% of the total electrode area showed pH change at the top/bottom hydrogel layer interface (n = 30).

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