Novel flexible cap for application of transcranial electric stimulation: a usability study

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ABSTRACT

Background
Advances in transcranial electric stimulation (TES) were hampered by the conventional rubber electrodes manually attached to the head with rubber bands. This procedure limited montages to a few electrodes, was error prone with respect to electrode configurations and was burdensome for participants and operators.
A newly developed flexible cap with integrated textile stimulation electrodes was compared to the conventional setup of rubber electrodes fixated by rubber bands, with respect to usability and reliability.
Two operators applied both setups to twenty healthy volunteers participating in the study. Electrode position and impedance measures as well as subjective evaluations from participants and operators were obtained throughout the stimulation sessions.

Results
Our results demonstrated the superiority of the flexible cap by means of significantly higher electrode configuration reproducibility and a more efficient application. Both, operators and volunteers evaluated the flexible cap as easier to use and more comfortable to wear when compared to the conventional setup.

Conclusion
In conclusion, the new cap improves existing and opens new applications scenarios for TES.

KEYWORDS
Transcranial direct current stimulation, patient comfort, reproducibility, electrodes, electric impedance
BACKGROUND

Non-invasive techniques to modulate neuronal activity include the transcranial electric (current) stimulation (TES) [1]. TES can be classified based on the current form to transcranial alternating current stimulation (tACS), transcranial direct current stimulation (tDCS), and transcranial random noise stimulation (tRNS). The technique has applications to different neurological and psychiatric disorders such as stroke [2,3], depression [4,5], epilepsy [6,7] and chronic pain [8,9].

TES applies weak currents in the range of 1–2 mA via at least two electrodes to change the brain activity level. In early applications of tDCS, the anode was positioned above the motor cortex and cathode at a contralateral prefrontal position by rubber bands surrounding the head [10]. In order to establish a safe low impedance of the electrode-skin interface, the rubber electrodes were embedded in sponge pockets soaked with saline solution [11] or spread with conductive gel to contact the scalp.

These procedures were complex and required professionally trained personnel to perform them. The cumbersome positioning of single electrodes generated errors in the electrodes’ placement and, in their effective areas, and it limited their applications to target different neuronal areas. In longitudinal studies, reproducibility in TES applications is relevant [12] and depends to a large extent on consistent positioning and placement. Generally, clinical studies are carried out by different operators, with different patients and in different places, thus the manual and unstable electrode placement has a negative effect on the reproducibility of the tests [13].

Moreover, the electrodes used in the conventional applications had a rectangular shape, which limited the ability to follow the curved surface of the scalp, resulting in partial displacement. Further, in new applications, the number of electrodes and their positions increase montage complexity, which is currently limited by the rubber bands [14].

To overcome limitations in the electrodes configurations for TES applications, we propose a flexible cap with integrated textile stimulation electrodes. Here, we compare the novel flexible cap (setup C) to the conventional rubber electrodes in sponge pockets fixed with rubber bands (setup R), with respect to usability and reliability.

MATERIAL AND METHODS

Subjects

Twenty healthy volunteers (age: 24.0 ± 1.6 a; 7 female) participated in the study, and two operators, without considerable prior experience in TES studies, carried out the experiment. All volunteers were asked about potential contraindications and provided written informed consent.
**Stimulation setup**

The TES configuration incorporated two stimulation channels with two electrodes each. The electrodes for channel one were positioned at Fp1 and F3 and for channel two at Fp2 and F4 [15,16].

The conventional application system, setup R, incorporated 4 cm x 4 cm rubber electrodes that were placed in saline-soaked sponges and fixed by rubber bands (Figure 1a).

The novel flexible cap, setup C, was manufactured with a highly flexible thread of cotton and elastane. The cap was produced by flat knitting (warmX GmbH, Apolda, Germany). TES electrodes were produced with a second knitting magazine, holding conductive, silver-coated, poly-amide threads, implementing reproducible TES electrodes with respect to their size and positioning in the caps.

Pockets of the flexible fabric on top of the electrodes held sponges, sockets, and studs of snap fasteners. The latter contacted the conductive thread, which fed into the pocket's outer side to provide an electric contact for medical-grade, press-stud cable. The saline solution used to realize the electric contact from the textile electrode to the scalp was buffered in the sponges, which provided an electrolyte reservoir. The flexible fabric surrounding the electrode with the electrolyte reservoir pocket was coated with medical grade, low viscosity silicone (Silpuran 2400, Wacker Chemie AG, Munich, Germany) in order to avoid a diffusion of the saline solution throughout the flexible textile. Figure 1b depicts the cap on a head model.

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**Figure 1.** Electrode configurations of setup R (a) and setup C (b) on a head model. The inset in (b) depicts the inside of the cap with the textile electrodes exposed.
**Experimental procedure**
Each volunteer participated in three sessions; in each, the stimulation was applied with the cap (setup C) and the conventional rubber bands (setup R) in a randomized order. The three sessions were conducted with at least a one-day break in between. The two operators performed 30 sessions, each with 10 volunteers.

Participants received sham stimulation from two channels of a DC-Stimulator MC (neuroConn GmbH, Ilmenau, Germany) for 30 minutes. A sinusoidal current was provided with 50 μA peak to peak and a frequency of 85 Hz [13]. The stimulator recorded the applied current and the adjusted voltage with 8 ksps.

At the beginning and throughout the stimulation sessions (10 minutes, 20 minutes and 30 minutes) subjective evaluations were obtained. Participants reported their status by completing a questionnaire (Appendix A.1). For each application, the time to position the electrodes was obtained, and the operators evaluated the application process for each setup by completing a questionnaire (Appendix A.1). The four corners of each electrode were digitized with a Polaris Spectra system (Northern Digital Inc., Waterloo, Canada) immediately after application and at the end of the stimulation.

**Data processing**
A FIR band-pass filter between 80 Hz and 90 Hz, designed using a Hamming window, was applied to the recorded sinusoidal signals for the applied current and the adjusted voltage. The impedance was calculated, after an initial settling time of 10 minutes, using the effective current and voltage values. These effective values were obtained with signal windows of 10 sinus cycles and 50 % overlap. Finally, the mean impedance was calculated for each channel.

Position recordings were used for stability (sD) and reproducibility (rD) analyses. Stability was evaluated with Euclidean distances between positions within a session. Reproducibility was calculated with Euclidean distances among the three sessions of each volunteer, after aligning the positions from the second and third session to the positions from the first session, using an iterative closest-point search (Per Bergström, Matlab, The Mathworks Inc., Natick, USA).

**RESULTS**
On average, the placement took 3.9 minutes ± 3.4 minutes (mean ± std) with a confidence interval of the mean value of [2.6; 5.2] minutes for setup C; it took 6.8 minutes ± 2.6 minutes with a confidence interval of the mean value of [5.8; 7.8] minutes for setup R.

Figure 2 shows the operators’ evaluations of the effort involved in application and the material flexibility in 60 tests. For ease of application (Figure 2a), 87 % (n = 52) of the
responses described setup C as “very easy” or “easy,” and only 3 % (n = 2) described it as “difficult” to fit the cap to the participant’s head, while setup R was considered “very easy” or “easy” in 66 % (n = 40), “difficult” in 13.3 % (n = 8), and “very difficult” in 8.3 % (n = 5) of the responses. With respect to the material assessment, setup C was described as “very flexible” or “flexible” in 98 % (n = 59) of the applications, and setup R was evaluated as “flexible” in 43.3 % (n = 26) of the applications and as “very rigid” or “rigid” in 50 % (n = 30) of the tests.

Figure 2. Histograms of operators’ responses on the evaluation for ease of application (a) and material flexibility (b). The total number of responses (n = 60) refers to the two operators conducting 30 sessions each (10 volunteers, each in three sessions).

The participants evaluated the comfort of the two setups for each session, the pressure level in four positions (underneath the electrodes, at the temples, underneath the straps, other locations) and their perceptions of itching and sweating throughout the stimulation periods of 30 minutes. Figure 3a shows that 90 % (n = 54) of the participants found setup C to be “very comfortable” or “comfortable” and only 2 participants (10 %, n = 6) considered the comfort as “normal.” In contrast, 8 participants (40 %, n = 24) reported the setup R to be “uncomfortable” or “very uncomfortable,” 6 (30 %, n = 18) found it “normal,” and 8 (30 %, n = 18) evaluated it as “very comfortable” or “comfortable”.
Figure 3. Histograms of participant’s responses on the evaluation of comfort (n = 60) (a), pressure sensation at four considered locations (n = 240 from 60 recordings of 4 positions) (b), sweat (n = 60) (c), and itch (n = 60) (d) sensations.

The results for pressure sensation at 4 positions (n = 240 from 60 responses for 4 positions) are reported in Figure 3b. During the session, the pressure sensation increased over time; for setup C, the highest value was “light” pressure and it increased 3 % (initial n = 25; after
30 minutes, n = 32) over time, while in setup R, “strong” pressure was the highest value, and the increase over time was of 9 % (initial n = 3; after 30 minutes, n = 24).

With respect to sweating (Figure 3c), there were small rises in the sensations over time. For setup C, sweating did not change between 10 minutes and the end of the test (after 30 minutes), 100% (n = 180, 60 responses at three time points) of the participants stated there was no sweating or it was “light.” In setup R, small changes were shown; 98.3 % (n = 59, out of 60) described the sensation as “no” or “light,” and 1.7% (n = 1, out of 60) described it as “moderate” when the test finished.

In the itching evaluation (Figure 3d), for setup C, 100% (n = 180, 60 responses at three time points) of the participants reported “no” or “light,” and it was stable across time. In contrast, setup R showed small rises: after 30 minutes of stimulation, 93.3 % (n = 56, out of 60) of the participants reported they did not feel itching or it was “light,” and 6.7 % (n = 4, out of 60) evaluated it as “moderate” or “strong.”

The applications of setup C and setup R were evaluated quantitatively through the use of impedance values and electrode positions. Figure 4 summarizes the results for the n = 120 (2 stimulation channels measured from 20 volunteers, in each three sessions) impedance values derived from the sham stimulation signals, reflecting the electric contact, but not intended for treatment or intervention. In setup C, the impedance averaged 10.0 kΩ ± 4.4 kΩ (mean ± std), with a confidence interval of the mean value of [8.8; 11.4] kΩ. The impedance in setup R was, on average, 5.3 kΩ ± 3.1 kΩ with a confidence interval of the mean of [4.8; 5.9] kΩ.

![Figure 4](image)

**Figure 4.** Violin plots of the impedance values derived from setup C (median 8.1 [white dot], interquartile range 7.1 [black box]) and setup R (median 4.5 [white dot], interquartile range 3.2 [black box]). Central black line indicates 1.5 times the inter quartile range (IQR). Distributions of each n = 120 impedance values from 2 stimulation channels measured from 20 volunteers, in each three sessions.

The measurements taken of the positions of the electrodes enabled the evaluation of the stability and reproducibility of the two setups. For the stability analysis (sD), the Euclidian distance between electrode positions at the start of the test and after 30 minutes showed a mean and standard deviation of 2.1 mm ± 1.4 mm, with a confidence interval of the mean
value of [2.0; 2.2] mm for setup C. Comparable values were obtained for setup R: a mean and standard deviation of 2.4 mm ± 1.6 mm and a confidence interval of [2.3; 2.6] mm. Figure 5a depicts the distributions of sD with n = 960 Euclidean distances of 4 corners from 4 stimulation electrodes on 20 volunteers, each in three sessions.

![Figure 5a](image)

**Figure 5.** (a) Stability evaluation calculated as the Euclidean distance between electrode corner digitizations at initial position and after 30 minutes – Setup C (median 1.8 mm [white dot], inter quartile range 1.5 mm [black box]), Setup R (median 2.1 mm [white dot], inter quartile range 1.8 mm [black box]). Distribution of n = 960 Euclidean distances from 4 corners of 4 stimulation electrodes measured on 20 volunteers, each in three sessions. (b) Reproducibility evaluation calculated as the Euclidean distance between the initial electrode corner digitizations aligned across sessions – Setup C (median 2.8 mm [white dot], inter quartile range 1.8 mm [black box]) Setup R (median 9.0 mm [white dot], inter quartile range 6.6 mm [black box]). Central black lines indicate 1.5 times the inter quartile range (IQR). Distribution of n = 640 Euclidean distances from 4 corners of 4 stimulation electrodes measured on 20 volunteers for two placement repetitions (session 1–session 2, session 1–session 3).

Reproducibility (rD) was evaluated, taking into account the Euclidian distance among the initial position measurements taken in each session. Figure 5b summarizes the result for n = 640 Euclidean distances between positions measured in two application repetitions (session 1–session 2, session 1–session 3) from 4 corners of 4 stimulation electrodes on 20 volunteers. In setup C, the mean distance was 3.0 mm ± 1.5 mm (mean ± std), with a confidence interval of the mean value of [2.9; 3.1] mm. In direct comparison, the setup R
showed a significant increase, with a mean and standard deviation of 9.8 mm ± 4.7 mm and a confidence interval of the mean of [9.5; 10.2] mm.

**DISCUSSION**

The newly developed flexible cap with integrated textile electrodes as an application system for TES was compared qualitatively and quantitatively to the conventional setup of rubber electrodes in sponge pockets, with respect to their usability.

The flexible knitted cap incorporated multi-compartment electrodes consisting of a contact surface of silver-coated threads, a pocket behind the fabric containing sponges soaked in saline solution, and a diffusion barrier of silicone surrounding the electrode.

Fastening conventional electrode setups by rubber bands limits the number of electrodes in use as well as the positions that can be addressed [14]. The flexible cap allows for the integration of multiple electrodes as indicated in Figure 1. Multi-channel TES applications essential for addressing target areas [17] or administering currents from multiple sources [18] are applicable through the utilization of the flexible cap with integrated multiple electrodes. The production of the textile cap is possible in lot size 1, which would also allow for personalization.

The flexibility of the knitted fabrics allowed a very good fit to individual head shapes with an elongation of about 320 % [19]. This, and the diffusion barrier infiltrated into the textile surrounding the electrode defined the desired effective electrode area, which contributes to stimulation. The textile stimulation electrodes prevented partial displacements due to bending or protrusion often perceived with conventional TES electrodes [20]. The textile electrodes integrated in the flexible cap adapted to the individual head curvatures. Thus, the electrode shape was not rigid and deformation due to uneven stretching could not be ruled out.

A simulation study [21] demonstrated the importance of electrode position and orientation for a precise TES application. The evaluation of the electrode positions showed an increase in the electrode configuration stability and reproducibility when facilitating the novel flexible cap in comparison to the conventional system [22].

The aspects discussed above could improve the ease of use for patients and volunteers and potentially allow the application of the cap without trained medical personnel. The most relevant difference between the setups were in comfort and pressure grading. A fraction (14 %) of the responses indicated a "modest" or "strong" pressure sensation for the conventional setup. In contrast, only one of 240 reactions indicated a "modest" feeling of pressure when the cap was applied. The participants reported that the locations for the pressure sensation were mostly associated with the rubber straps in setup R. Due to the specifics of this setup, one rubber strap crossed the forehead and the temples, which have
the lowest pressure threshold on the head [23]. In setup C, the discomfort was mainly caused by the chinstrap which tightens the cap on the person’s head.

The comfort rating favored the cap, as it received 18 marks as "comfortable" or "very comfortable" and only six participants gave the same for the conventional setup. According to the participants’ responses, setup C was overall more comfortable for TES application. Further, the ratings for setup C were stable, which can help to keep the focus on potential experiments and reduce changes in the test conditions [11].

The flexible cap also allows for the integration of recording electrodes, as introduced by Wunder et al. [19]. In this study, the low preparation effort and high reproducibility were highlighted by the operators, and the participants reported a good and comfortable fit of the cap. Such advances and the achieved ease of use broadens application scenarios of the new cap to combined TES–EEG studies and home-use scenarios.

The operators’ evaluations valued the flexibility in setup C, allowing an electrode to be placed more easily that in setup R. This indicated advantages introduced by setup C, which can help to reduce training time and ease the use of TES for different operators.

In the present study, the time for fitting the electrodes onto a participant’s head showed a difference of mean values of 2.9 minutes in favor of setup C. In practice, setup C cut the temporal effort for trained personnel almost by a factor of two. This also decreased the time burden for participants, which is important in a clinical environment.

The stimulation signal in the present study was used to evaluate the electric contact, only. Here no treatment or intervention was intended. Therefore, we applied the sham stimulation signal, since a stimulation at 80 Hz remained without an effect [24]. However, the influence of sham stimulation requires further investigation [25]. The impedance analysis evaluated here showed that there is a mean difference of 4.7 kΩ between both setups. The mean for setup C was 10 kΩ and for setup R was 5.3 kΩ. However, even the value of 10 kΩ is fully acceptable for a typical electric stimulation (with 2 mA), translating to a voltage of 20 V, which is within the safety limit [26]. True impedance measurements during active stimulation with the textile stimulation electrodes were introduced by Wunder et al., [19].

**CONCLUSION**

The flexible cap with integrated textile stimulation electrodes overcomes some of the fundamental limitations of the conventional TES application systems.
DECLARATIONS

Ethics approval and consent to participate
This study protocol was approved by the Ethics commission at the medical faculty of the Friedrich-Schiller-University Jena, Germany. All volunteers provided written informed consent to participate in the study.

Consent for publication
All volunteers provided consent for pseudonymous data publication.

Availability of data and materials
All data generated or analyzed during this study are included in this published article.

Competing interests
The authors, AH, DO and JH, declare that they have no competing interests.
KS is a shareholder and works for neuroCare Group GmbH.

Funding
This project received funding from the Free State of Thuringia (2017 VF 0035), co-financed by the European Union under the European Regional Development Fund (ERDF).

Authors’ contributions
AH essentially contributed to the conception of the study, the data acquisition, processing and analysis, and the manuscript drafting and revision.
DO essentially contributed to the data acquisition, processing and analysis, and the manuscript drafting and revision.
KS and JH essentially contributed to the conception of the study, the interpretation of data, and the manuscript revision.

Acknowledgement
The authors thank Anna Kongo and Michael Werthmann for support during data acquisition.

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