DIY and Regulatory Aspects of Transcranial Stimulation

Transcranial Stimulation in Neuropsychiatric Research Course

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Perelman School of Medicine, University of Pennsylvania
Talk Outline

Do-it-yourself and direct-to-consumer tDCS

*Who are home users, what devices do they use, how and why do they stimulate, and do they find tDCS effective?*

Regulation of tCS devices in the US

*FDA medical device law & tDCS devices*
Number of academic journal publications about tDCS by year (2000-2016)
Rise of DIY tDCS

Brain-O-Matic
Can a jolt from a nine-volt battery make you smarter? Happier? Medical researchers revive a discarded technology and set the stage for the ‘brain pod’

By PAGAN KENNEDY | February 7, 2007
Do-it-yourself device

- Cathode
- Anode

R5 - 4kΩ
(Required to give LED proper current)

LED
(High efficiency)

LM334Z
Current Reg.
(Stabilizes and sets current at a fixed level)

C1 - 470μF
Capacitor
(Creates a soft start and stop for the device)

4 Position Switch
(Switches between current settings)

R1 - 33Ω ~ 2.0mA
R2 - 50Ω ~ 1.5mA
R3 - 66Ω ~ 1.0mA
R4 - 80Ω ~ 0.5mA

5mA
Safety
Fuse

DIY How to make a tDCS Transcranial Direct Current Stimulation Device Tutorial

How to Build a Simple tDCS Device of Your Own (that you can use)
Repurpose an Iontophoresis Device

Chattanooga Ionto™

ActivaDose II
Current source/tDCS device

Super Specific Devices

Caputron Medical
tDCS Devices and “Device Kits”

Brain Stimulator

tDCS-Kit

PriorMind

Apex Type A

Cognitive Kit
Other tDCS Devices

TCT Research Limited (Hong Kong)
Wearable Devices
Blurred boundaries between do-it-yourself and direct-to-consumer

Do-it-yourself (DIY)  Direct-to-consumer (DTC)

Thync

halo neuroscience

headphones
Studying home users of tDCS

**Ethnography** of home users (*Wexler 2015*)

- Analysis of DIY tDCS websites, forums and blogs
- Semi-structured interviews with home users

**Survey** of consumers of tDCS devices (*Wexler, in preparation*)

- 7 companies agreed to participate on the condition of anonymity; emails sent to companies’ customer lists with link to online survey
- Quantitative and open-ended qualitative questions about tDCS device(s), use practices, beliefs, attitudes, and demographics
Who are home users?

339 respondents

327 (96.5%) for self-use and 12 (3.5%) on others

Participants' Ages (in years; mean 45.3)

Country of residence (n=339)

- North America (73.5%)
- Australia & New Zealand (5.3%)
- Europe (15.9%)
- Asia (2.7%)
- Central and South America (2.4%)
- Prefer not to answer (1.2%)

Male (83.5%) Female (15.3%)
Who are home users?

- Wealthy

- Highly educated (77.9% have a college degree or higher; 36.5% Master’s or higher)

- Politically liberal (70.5%)

- Early adopters of technology (63.7%)

- Read articles about science frequently or very frequently (82.3%)

- Never or rarely attend religious services (77.9%)

- Nearly half have used dietary supplements or non-prescription drugs to improve cognition

Wexler (in preparation)
A. Treatment, enhancement and restoration: total numbers

- Enhancement (76.9%)
- Treatment (42.5%)
- Restoration (26.3%)

B. Treatment, enhancement and restoration: user combinations (n=308)

- Only enhancement (41.2%)
- Treatment & enhancement (15.9%)
- Restoration & Enhancement (10.7%)
- Treatment, restoration & enhancement (9.3%)
- Treatment & restoration (4.2%)
- None of the three (0.2%)
- Only treatment (13.3%)
- Only restoration (2.3%)

Wexler (in preparation)
## Table 4. Detailed usage indications for treaters, enhancers, and restorers*

<table>
<thead>
<tr>
<th>Treatment</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>97</td>
<td>74.0%</td>
</tr>
<tr>
<td>Anxiety</td>
<td>55</td>
<td>42.0%</td>
</tr>
<tr>
<td>ADD/ADHD</td>
<td>35</td>
<td>26.7%</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>12</td>
<td>9.2%</td>
</tr>
<tr>
<td>Bipolar disorder</td>
<td>7</td>
<td>5.3%</td>
</tr>
<tr>
<td>Migraine</td>
<td>7</td>
<td>5.3%</td>
</tr>
<tr>
<td>Tinnitus</td>
<td>6</td>
<td>4.6%</td>
</tr>
<tr>
<td>Addiction</td>
<td>5</td>
<td>3.8%</td>
</tr>
</tbody>
</table>

### Enhancement

<table>
<thead>
<tr>
<th>Enhancement</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus/concentration</td>
<td>100</td>
<td>42.2%</td>
</tr>
<tr>
<td>Memory</td>
<td>61</td>
<td>25.7%</td>
</tr>
<tr>
<td>Learning</td>
<td>57</td>
<td>24.1%</td>
</tr>
<tr>
<td>General Enhancement</td>
<td>56</td>
<td>23.6%</td>
</tr>
<tr>
<td>Mood/emotion</td>
<td>26</td>
<td>11.0%</td>
</tr>
<tr>
<td>Physical abilities</td>
<td>25</td>
<td>10.5%</td>
</tr>
<tr>
<td>Speed/reaction time</td>
<td>23</td>
<td>9.7%</td>
</tr>
<tr>
<td>Creativity</td>
<td>14</td>
<td>5.9%</td>
</tr>
</tbody>
</table>

### Restoration

<table>
<thead>
<tr>
<th>Restoration</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Memory</td>
<td>31</td>
<td>38.3%</td>
</tr>
<tr>
<td>Focus/concentration</td>
<td>21</td>
<td>25.9%</td>
</tr>
<tr>
<td>General enhancement</td>
<td>19</td>
<td>23.5%</td>
</tr>
<tr>
<td>Problem solving</td>
<td>12</td>
<td>14.8%</td>
</tr>
<tr>
<td>Mood/emotion</td>
<td>9</td>
<td>11.1%</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
<td>9.9%</td>
</tr>
<tr>
<td>Learning</td>
<td>7</td>
<td>8.6%</td>
</tr>
<tr>
<td>Speed/reaction time</td>
<td>4</td>
<td>4.9%</td>
</tr>
<tr>
<td>Physical abilities</td>
<td>4</td>
<td>4.9%</td>
</tr>
</tbody>
</table>

*Participants who answered affirmatively to having used tDCS for either treatment, enhancement, or restoration were asked to provide follow-up information, by selecting from a list of diseases/conditions (for treatment) or elaborating via free-form text (for restoration/enhancement); the latter responses were coded thematically.
Treaters vs. Non-treaters, by gender

<table>
<thead>
<tr>
<th></th>
<th>Treaters</th>
<th>Non-treaters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (n=251)</td>
<td>61.8%</td>
<td>34.6%</td>
</tr>
<tr>
<td>Female (n=45)</td>
<td>73.3%</td>
<td>26.7%</td>
</tr>
</tbody>
</table>

\[ \chi^2(1, N=296)=19.11, p<.001; \text{Cramer's V} = .254 \]

Treaters vs. Non-treaters, by ratings of success of tDCS

<table>
<thead>
<tr>
<th></th>
<th>Treaters</th>
<th>Non-treaters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Found tDCS unsuccessful (n=81)</td>
<td>65.4%</td>
<td>34.6%</td>
</tr>
<tr>
<td>Found tDCS successful (n=130)</td>
<td>56.2%</td>
<td>43.8%</td>
</tr>
</tbody>
</table>

\[ \chi^2(1, N=211)=9.32, p=.002; \text{Cramer's V} = .210 \]
How did you learn which stimulation parameters to use?

- Internet: 52.9%
- From the company: 20.8%
- Trial and error: 14.6%
- Science journal: 14.6%
- Device was preset: 9.1%
- Placement website: 8.1%
- Mention of Reddit: 7.5%

n=308
Home users transform existing scientific literature into user-friendly indexes and guides geared towards their needs.

(Wexler 2015)
How do home users learn about stimulation parameters?

- link to scientific articles (when behind firewall, post unrestricted copies)
- use video tutorials on electrode positioning

(Wexler 2015)
Home users mostly adhere to established scientific protocols (e.g., current level & session duration) but depart regarding number of stimulation sessions

Wexler (in preparation)
To what extent did you feel that your use of tDCS was successful?

- Totally unsuccessful (16.2%)
- Somewhat unsuccessful (11.4%)
- Not Sure (29.9%)
- Somewhat successful (32.1%)
- Totally successful (10.4%)

n=308
Did you experience unwanted side effects from tDCS? If yes, please describe.

- Skin irritation (38.0%)
- "Skin burn" or "burning" sensation (35.4%)
- Headache (10.1%)
- Flash of light (phosphene) (8.4%)
- Dizziness (1.9%)
- Metallic Taste (1.5%)

10 reports of serious skin burn
Current Users, Formers Users, and Never Used

- **[Category Name]** (n=114)
- **[Category Name]** (n=19)
- **[Category Name]** (n=46)
- **[Category Name]** (n=66)
- **[Category Name]** (n=82)

*Wexler (in preparation)
Practices of DIY Brain Stimulation

- **Recognize** that home users are utilizing tDCS both for treatment and enhancement.
- **Be aware** that an unintended “second audience” is utilizing published scientific research.
- **Be prepared** for individuals to approach you for guidance.
- Warning home users/DIYers of risks (Wurzman et al. 2016)

An Open Letter Concerning Do-It-Yourself Users of Transcranial Direct Current Stimulation
Are consumer non-invasive brain stimulation devices considered medical devices under US law?

Do-it-yourself (DIY)

Direct-to-consumer (DTC)
BREWSTER'S MEDICATED ELECTRICITY!

AN INFALLIBLE REMEDY FOR

Headache, Neuralgia, Hay Fever,
Catarh and Cold in the Head.

NOT A SNUFF, PASTE, SALVE OR LIQUID, BUT A PERFECT

ELECTRIC BATTERY,
Combined with Vegetable Compounds,
That generate a vapor which is a safe, convenient, and speedy method of obtaining relief from Nervous Headache, Catarrh, Hay Fever, Neuralgia; also, Failing Eyesight and Deafness caused by Catarrh.

NO MAN can weigh, measure, estimate or comprehend the power of Electricity. We do know that it has already accomplished the day from one part of the world to another, and the day is not far distant when the propelling power of the railways, factories and commerce of the world will be Electricity. Thus it is when this Great Power is used to propel the healing properties of the best remedies known for the above ailments and diseases, it is no wonder that the cure is truly musical. By inhaling the Medicated Vapor from the Battery, it will cure Headache in one to three minutes, and will break up the most severe Cold in the Head, Throat or Lungs in a few hours.

THE ELECTRIC PATENT SOCKS.
FOR CREATING A CONSTANT ELECTRIC CURRENT AND PRODUCING A HIGH DEGREE OF WARMTH.

Testimonials.

From Miss Elam, Thorne Hall, Sedbergh, Yorks, Oct. 21, 1894.

Never before having worn any kind of socks, Miss Elam has been wearing these socks for a month, and finds them most comfortable. She has previously suffered much from cold feet.

From T. J. Black, 402 Royal Hotel, Reno, Nevada, Sept. 17th, 1894.

These socks are the best I have ever worn, and I shall continue to wear them. They are very comfortable.

From Rev. B. Taylor, 730 Vine St., Missouri, March 18, 1894.

These socks are the best I have ever worn, and I shall continue to wear them. They are very comfortable.


These socks are the best I have ever worn, and I shall continue to wear them. They are very comfortable.


929 Walnut St., Kansas City, Mo.
Food & Drugs Act (1906)
- Prohibited misbranded & adulterated food and drugs

Federal Food Drug & Cosmetic Act (1938)
- Granted FDA limited jurisdiction over medical devices

Medical Device Amendments (1976)
- Device manufacturers required to notify FDA of medical device prior to marketing
<table>
<thead>
<tr>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low risk</td>
<td>Moderate risk</td>
<td>High risk</td>
</tr>
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**Most products exempt from pre-market notification**

**Pre-market notification (PMN) required via 510(k). Devices are "cleared."**

**Pre-market approval (PMA)—must demonstrate safety & efficacy**
<table>
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<tbody>
<tr>
<td>Low risk</td>
<td>Moderate risk</td>
<td>High risk</td>
</tr>
<tr>
<td></td>
<td>TENS (pain/headache)</td>
<td>DBS (Parkinson’s related)</td>
</tr>
<tr>
<td></td>
<td>rTMS (treatment-resistant MDD)</td>
<td>ECT (severe depression)*</td>
</tr>
<tr>
<td></td>
<td>TMS (headache)</td>
<td>VNS (epilepsy-related)</td>
</tr>
<tr>
<td></td>
<td>tVNS (cluster headache)</td>
<td>CES (depression, insomnia* &amp; anxiety*)</td>
</tr>
</tbody>
</table>

*Subject of recent proposed order to reclassify
According to Section 201(h) of the Food, Drug & Cosmetic (FD&C) Act, a medical device is:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.
Definition of a Medical Device

How does the FDA establish intended use?

According to 21 C.F.R. § 801.4:

The words intended uses... refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.
Regulated by the Food and Drug Administration (FDA)

Regulated by the Consumer Product Safety Commission (CPSC)
Importance of intended use

**Drug vs. Cosmetic**

**Drug**
- “reduces wrinkles”
- Sunscreen lotion

**Cosmetic**
- “reduces the appearances of wrinkles”
- Suntan lotion
Direct-to-consumer tDCS Devices

Power Your Mind!

**tDCS Provides a Learning Boost**
Increase your attention span and stimulate your neurons to improve math skills, language abilities, creativity, and visual association.

**RECHARGE YOUR BRAIN**
tDCS allows you to unlock your brain’s true potential!

**tDCS for Medical Use**
tDCS had been widely applied to treat Depression, also in Chronic Pain, Amblyopia, Alzheimer’s disease, Migraine, Parkinsonism, Tinnitus, Stroke and etc.

tDCS has also been documented as having impressive potential to treat depression, anxiety, PTSD, as well as chronic pain.

Finally, there is drug free (DIY) method to increase Concentration as well as relief for Depression, Anxiety and Migraines!
intended to affect the structure or any function of the body of man or other animals…

Three wrinkle-remover cream cases:

United States v. An Article … Sudden Change, 409 F. 2d 734 (2d Cir. 1969)
United States v. An Article … Line Away, 415 F.2d 369 (3d Cir. 1969)

“intended to affect the structure or function of the body” [in some medical or drug-type fashion]
FDA and public health risk

Various cases have shown that the courts are often willing to allow the FDA significant leeway.

21 USC § 393: “promote the public health... protect the public health”
A **general wellness product** is one that makes claims related to “maintaining or encouraging a general state of health” without references to diseases or conditions.

Examples of acceptable wellness claims are those relating to:

- “mental acuity”
- “concentration”
- “problem-solving”
- “relaxation and stress management”

**General Wellness: Policy for Low Risk Devices**

Draft Guidance for Industry and Food and Drug Administration Staff

*Draft Guidance*

This guidance document is being distributed for comment purposes only.
A product is *not* a low-risk device if “it involves an intervention or technology that may pose a risk to a user’s safety if device controls are not applied.”

**Are consumer non-invasive brain stimulation device** low-risk **devices?**
General Wellness: Policy for Low Risk Devices
Guidance for Industry and Food and Drug Administration Staff


The following are examples of products that would not be considered “low risk” as described in this guidance:

- A neurostimulation product that claims to improve memory, due to the risks to a user’s safety from electrical stimulation.
(1) to protect the public against unreasonable risks of injury associated with consumer products;
(2) to assist consumers in evaluating the comparative safety of consumer products;
(3) to develop uniform safety standards for consumer products and to minimize conflicting State and local regulations; and
(4) to promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.

What is a consumer product?

any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise;
Section 5 of the FTC Act prohibits “unfair or deceptive acts or practices” in commerce.
CDPH Warns Consumers Not to Use TDCS Home Device Kit

Date: 6/28/2013
Number: 13-029
Contact: Anita Gore, Heather Bourbeau (916) 440-7259

SACRAMENTO

The California Department of Public Health (CDPH) today warned consumers not to use the unapproved medical device sold on the Internet as a TDCS (Transcranial Direct Current Stimulation) Home Device Kit.

TDCS Device Kit, Inc. of Petaluma, Calif., is voluntarily recalling the TDCS Home Device Kits because the product has not been federally approved to market in the United States, and has not been determined to be safe and effective for their intended use. During a recent inspection, CDPH determined that the devices had not been manufactured in compliance with good manufacturing practices for medical devices. Also, the devices were found to be labeled without adequate directions for use and without adequate warnings against uses that may be dangerous to health.

Use of the device could pose a health risk including, but not limited to: epileptic seizures, cardiac arrhythmias, cardiac arrest, optic and otic nerve injuries, skin irritation, headaches, blurred vision, and dizziness. No illnesses or injuries have been reported at this time.

Recalled TDCS Device Kits were manufactured and distributed worldwide from November 2012 through April 2013. The devices have no identifying control numbers (e.g.: lot codes, serial numbers, or production dates) printed either on the packaging, or the units themselves, but would have been received by mail from TDCS Device Kit, Inc.
Enforcement clarity is needed
Take-away points

- FDA and MDD definition of a medical device is based on “intended use” not mechanism of action

- Most recent actions demonstrate that FDA is monitoring the sphere and does not view tDCS as completely low-risk

- Unclear whether cognitive enhancement devices marketed for “wellness” fit the structure/function clause of FDA definition of a medical device

- Even absent FDA regulations, other regulatory agencies might play a role
Thank you!


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