Transcranial Direct Current Stimulation: Transition to home-based therapy for pain treatment and other disorders

Marom Bikson
The City College of New York

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American Pain Society

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Disclosure:

Soterix Medical Inc. produces tDCS and High-Definition tDCS. Marom Bikson is founder and has shares in Soterix Medical. Marom Bikson serves on the scientific advisory board of Boston Scientific Inc.

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Questions: Twitter #APStDCS
Why go home?
Why go home?

Because we can
- tDCS is deployable, simple and safe

Because patient demand
- Burden of travel for repeated sessions

Because we should
- Lack of good options leads to unfortunate substitutions ("DIY-tDCS")

To advance science
- High volume and naturalistic testing
Why worry?

Is current tDCS technology suitable for home use?

Reliability of electrode
  - Poor design / preparation can lead to skin burns, pain

Electrode position
  - Position of electrodes important for outcomes

Dose limitations
  - Safety data based on tested protocols

Compliance
  - Outcomes rely on prescription
tDCS is not “everything goes”

Poor electrode preparation and head-gear = irreproducible tDCS results
Things that are NOT debated

✓ tDCS is regulated by federal / state laws
   Both for medical treatment or neuro-enhancement
   Fregni et al. Regulatory Considerations 2015

✓ Even low intensity stimulation can cause harm when applied using bad technology
   Not all devices are equal

✓ More clinical trials are needed to establish efficacy
   Clinicians prescribe therapies off-label

✓ tDCS can change the brain
   Decades of animal and clinical neurophysiology

✓ People will seek relief from suffering + self-improvement
   Special consideration required in medical care
When is the right time?

40,000+ sessions
No documented serious adverse event in controlled clinical trials
Bikson et al. Safety consensus.

tDCS is investigated for a wide range of indications
Off-label use is inevitable for majority of patient candidates (who are suffering now)

Considered safe enough to test on healthy subjects
USA FDA cleared

Current home use
Why worry?

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Expertise of operator

Home-use
Self application
or Superseded

Clinic
Trained operator

Medical center
or University
Increased automation

**Home**: Fully automatic, No flexibility

**Clinic**: Semi-automatic, Some flexibility

**Medical Center**: Customization, flexibility, integration with other equipment
Is more risk acceptable in any case?
Risk Management

Remotely-supervised transcranial direct current stimulation (tDCS) for clinical trials: guidelines for technology and protocols

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Remote supervision involves clinical trial specific technology and protocols
Risk Management

- **Training of staff and supervision**
  - Formal certification

- **Assessment of users capability for remote tDCS**
  - Clinic based evaluation, tolerability
  - User may be subject or care-giver

- **Training procedures and material for user**
  - Manuals, video... customized to user

- **Simple and fail safe electrode preparation**
  - Given user’s capability

- **Strict dose control for each session**
  - Pre-set timing + intensity, electrode placement

- **Ongoing compliance monitoring**
  - Defined corrective measures/ abort criterion
Training of staff and supervision
  Formal certification

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A. Prescription – Dose limited
B. Dose stored on physical module (battery)
C. Single use electrodes
D. Single position head-gear
E. Simple activation (one button)
F. Storage of compliance (time of use, resistance)
G. Clinical supervision
Current home use

Contact Us

Hi, doctor! I have electrode #32.

Great! Your code is #22.

CODE?

PAIN LEVEL?

PAIN LEVEL?

MILD

Completion code #724

Great! Thanks
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tDCS electrode positioning (M1-SO montage)

10-20 based measurement and placement

Head-gear based positioning and placement

1x Measure to select cap size – provided to subject

Electrodes snap to head-gear, positioned at once

Electrodes “held” in place while rubber bands positioned
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- Formal certification

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tDfCS electrode technology was unchanged in 15+ years

“Sponge pocket” held by rubber band head-gear
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“Sponge pocket” held by rubber band head-gear

✧ Dry electrodes
Off hairline, Non adhesive
tDCS electrode technology was unchanged in 15+ years
“Sponge pocket” held by rubber band head-gear

✧ **Dry electrodes**
  Off hairline, Non adhesive

✧ **Adhesive electrodes**
  Off hairline, Self-Adhesive
tDCS electrode technology was unchanged in 15+ years
“Sponge pocket” held by rubber band head-gear

- **Dry electrodes**
  Off hairline, Non-adhesive

- **Adhesive electrodes**
  Off hairline, Self-Adhesive

- **Pre-saturated sponges with embedded electrodes**
  Single position “snap on” head-gear
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Remote Supervised

Home  Clinic  Medical Center
Application specific tDCS technology + protocols = flat risk (to be tested and validated)
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Extra Slides
What is the “dose” of tDCS?

- Size, position, and current applied to electrodes
- Example: 5x5 cm$^2$ electrodes, C3 Anode, SO Cathode, 2 mA for 20 minutes

Peterchev, Bikson et. al.  
*Brain Stimulation* 2012
What is the High-Definition tDCS?

• Use of small “HD” gel-electrodes, instead of sponges
• Categorical increase in control on brain targeting
• Useful with EEG

Dmochowski, Bikson et al
*J. Neural Engr.* 2011
What is the 4x1 HD-tDCS?

- Five HD electrodes (one center, four surround)
- Used for focal unidirectional cortical modulation

Datta, Bikson et al

*Brain Stimulation* 2009
Montovani Montage (tested for OCD)
“Active” electrode over the pre-Supplementary Motor Area
“Return” on the right shoulder
Current flows in and out of brain

Physics
- Current goes from anode to cathode
- All current that enters the cortex must exit

**tDCS design implications**
- Must consider both electrodes
- No such thing “anodal” or “cathodal” tDCS

Bikson et al. *Clinical Neurophys. 2010*
Current does not stop at cortex

Physics

- Current is conserved when passing through grey matter
- Electric fields can increase based on anatomy

TDCS design implications

- Deep brain structures cannot be ignored
- Spine sometimes cannot be ignored

Dasilva et al. *Headache*. 2012
Current does not stop at cortex

Physics

- Hot-spots around deep structures
- Cellular morphology is varied

**tDCS design implications**

- Difficult to predict "increase" or "decrease" in deep structures
- Details idiosyncratic