Transcranial Direct Current Stimulation: Are we ready to go home?

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Soterix Medical Inc. produces tDCS and High-Definition tDCS. Marom Bikson is founder and has shares in Soterix Medical Inc. Some of the clinical data presented may be supported by Soterix Medical Inc.

Marom Bikson is on the scientific advisory board of Boston Scientific Inc.

Soterix Medical Inc., Neuroconn Inc., and Thync Inc. are developing home-use tDCS.
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 tDCCS 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
Current home use

USA FDA cleared

Tyler et al. OTC tES
Naturalistic Extended Use transcranial Electrical Stimulation (NEU-tES) trials

n=100 healthy subjects: tDCS, tPCS, Sham
Up to 6 weeks, 5 session per week
High capacity adhesive electrodes

Paneri et al. NEU-tES
Naturalistic Extended Use transcranial Electrical Stimulation (NEU-tES) trials

n=100 healthy subjects: tDCS, tPCS, Sham
Up to 6 weeks, 5 session per week
High capacity adhesive electrodes
1905 sessions (tDCS: 623, tPCS: 646, Sham: 636)
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Expertise of operator

Home-use
Self application or Supervised

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?
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, limited repetition number and interval

- Ongoing compliance monitoring
  - Defined corrective measures/ abort criterion
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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?

HIGH

PAIN LEVEL?

MILD

Completion code #724

Great! Thanks
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Risk Management
tDCS electrode technology has not changed in 15+ years
“Sponge pocket” held by rubber band head-gear

✧ Adhesive electrodes
   Off hairline, High charge capacity

✧ Pre-saturated sponges with embedded electrodes
   Single position “snap on” head-gear
Is more risk acceptable?

Risk?

Home  Clinic  Medical Center

Remote Supervised
Study specific tDCS technology + protocols = flat risk (to be tested and validated)
Things to address...

- For medical: Who should prescribe
  By indication
- For neuro-enhancement....
- Adaptive dose
  Neuro-feedback, telemedicine
- Level of evidence for off-label
  Professional standards, protocols, guidelines
  Liability
- Clinical trials for home-use
  Home-use vs. self-use
  Dealing with related/unrelated adverse events
- Adjunct therapy
  Cognitive / physical training
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