Safety & Guidelines for tDCS

Felipe Fregni, MD, PhD
Spaulding Neuromodulation Center
Spaulding Rehabilitation Hospital & Massachusetts General Hospital
Harvard Medical School
The FDA has not approved tDCS as a therapy or approved ANY device for tDCS.
Risks to Subjects
Theoretical Risks (1): skin

• Potential Effects
  – Electrolysis, Permeability Changes, Increased Metabolic Activity, Seizure?

• Burn

• Stimulating subjects with:
  – Reduced Sensation
  – Broken Skin
  – Conductive Implants
  – Tumor
  – Concurrent Pharmacological Treatments
Tissue heating

• Animal study –

Liebetanz et al, 2009
Skin lesion:
“The anodal electrode was fixed by an EEG cap. Two mA stimulation current was applied for 26 min, including 30 s ramp in and 30 s ramp out.”

Healthy subject – single session (Wang, 2015)
Skin lesion (2)

Patient – several sessions (4/5) – 1mA over 20 minutes.

(Palm, 2008)
Contact dermatitis

Healthy subject:
Single session, symptoms appeared after 24 hs of stimulation and got worse. (Kaubish, 2012)
How about if a subject has a skull defect?
Current Distribution in tDCS

- Datta et. al., 2009
- Wagner et al., 2007
Transcranial direct current stimulation in patients with skull defects and skull plates: High-resolution computational FEM study of factors altering cortical current flow

Abhishek Datta\textsuperscript{a,\*}, Marom Bikson\textsuperscript{a}, Felipe Fregni\textsuperscript{b,\*}

\textsuperscript{a} Neural Engineering Laboratory, Department of Biomedical Engineering, The City College of New York of CUNY, New York, NY 10031, USA
\textsuperscript{b} Laboratory of Neuroimaging, Spaulding Rehabilitation Hospital, Harvard Medical School, Boston, MA 02114, USA

\textsuperscript{c} Bronson-Allen Center for Noninvasive Brain Stimulation, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA, 02215, USA
A. 7 x 5 cm² pads
Other Adverse Effects
Adverse Effect Reports

• Brunoni et al., 2011 – Systematically reviewed reports of AE’s in human studies of patients and healthy subjects.
  – 172 articles (209 studies) included
  – 117 studies assessed AE’s
  – 74 studies reported at least 1 AE
• Findings for Active Stimulation:
  – Most commonly reported effects are mild
  – Itching (39.3%)
  – Tingling (22.2%)
  – Headache (14.8%)
  – Burning sensation (8.7%)
  – Discomfort (10.4%)
Device Safety Features

- Automatic Current Ramping
- Impedance Check
- Display of Actual Current
- Soterix Medical Device
  - SMARTscan
  - “Relax” Slider
  - “Tickle” Button
  - Low Battery Light
Cables

Copper Anode (A) → Copper Cathode (C)

Graphene layer

Copper deposited

CuSO₄ solution + GO (electrolyte)
Practical Safety Considerations

- Hair
- Excess Water Run-off
- Old/Dried out sponges
- Broken Electrodes
- Rusting of Equipment
- Battery Charge
- Current Fluctuation During Stimulation
- Current Spiking During Device On/Off
Safety Recommendations

• Screening for exclusion criteria
• Keep informed of new safety guidelines
• Consider specific device
• Obtain IRB approval
• Consider environment for stimulation (ex. Hospital/University)
• Have emergency procedures prepared
Thank You