

tCS: risks, benefits and the need for control

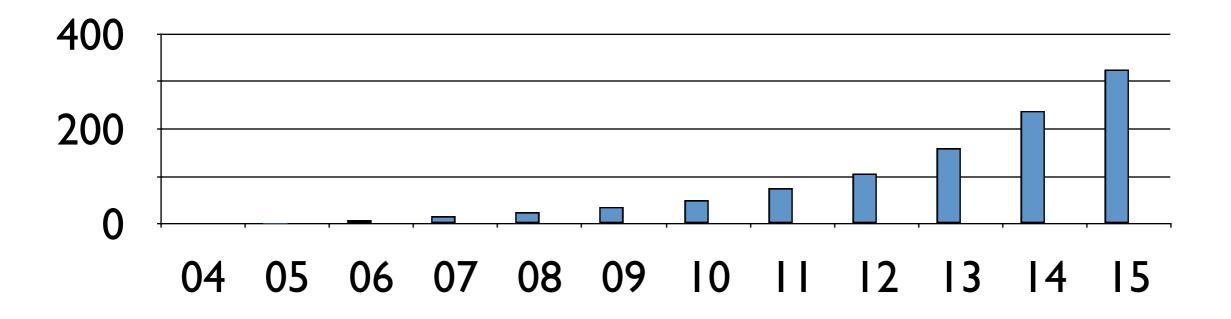
Giulio Ruffini - Neuroelectrics Corporation / Starlab



Neuromodec, NY, Jan 10 2010

NEUROELECTRICS

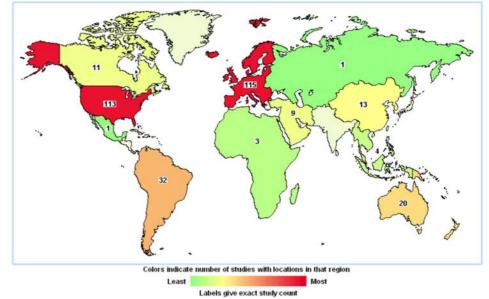
Benefits ...Clinical studies from 2003 @ <u>clinicaltrials.gov</u>





326 studies found, shown on map. A similar map is available for all studies in ClinicalTrials.gov

Click on the map below to show a more detailed map (when available) or search for studies (when map not available)



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ClinicalTrials.gov tdcs OR "transcranial current stimulation" OR "transcranial direct current stimulation" | hreceived on or before 01/01/2015

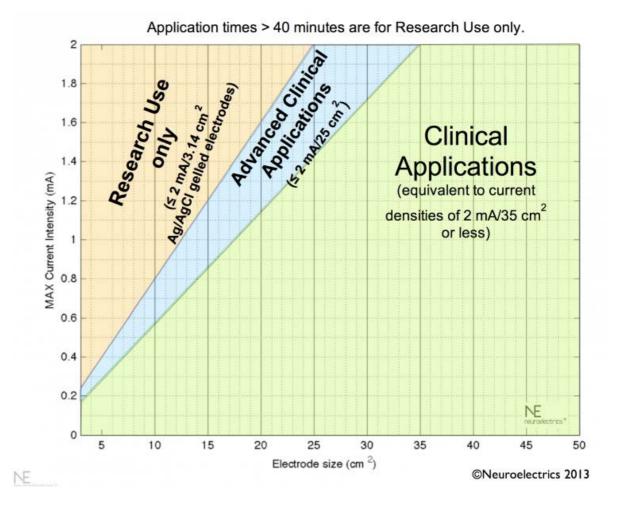


- <u>Short term tDCS</u> safety is well established using good practices both with sponges or Ag/AgCI electrodes +gel.
- Ill effects limited to skin irritation or small burns in rare cases (probably due to wrong placement of sponges)
- Safety verified in adults with intact skulls, no implants, etc. Other groups much less studied.
- Research studies carefully specify and limit duration, intensity, repetition of sessions.
- Other forms of tCS (such as tACS, tRNS) less studied

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Safety aspects

- After thousands of hours of stimulation, short term ill effects associated to tCS in <u>controlled</u> settings remain scarce and minor
- Devices need to implement safety measures
- Starstim designed for safety:
 - -Current at electrode < 2 mA
 - -Max injected current < 4 mA
 - -Programmend duration < 1 h
 - -Impedance check before
 - -Impedance check during
 - -For use with our electrodes
- -Our safety record is excellent







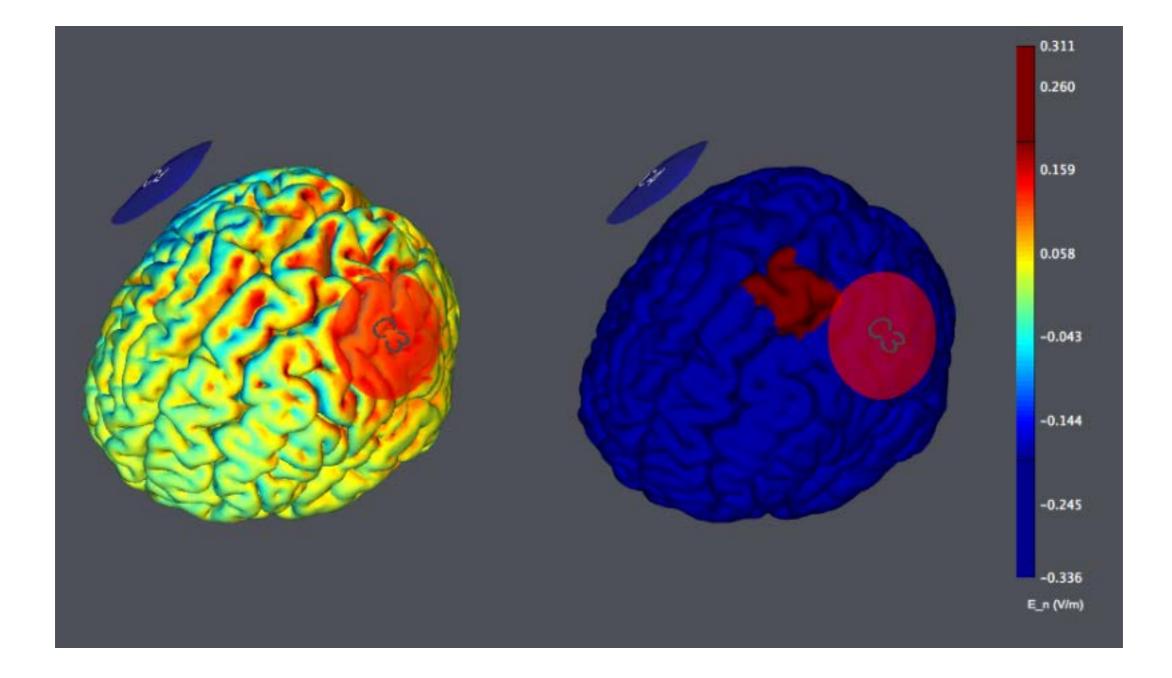


- Long term safety not so clear
- tCS has demonstrated physiological effects
- Stimulation affects brain connectivity and brain function
- Effects depend on many factors: montange, intensity, duration, repetition framework, brain state. Age probably important.
- Response function of brain not 100% understood. E.g., intensity: more is less? Enhacement at a price (loculano & Kadosh 2013)?
- Classical paradigms employing large stimulation areas probably affect large areas of the brain
- Need to understand these phenomena well in a <u>controlled</u> fashion (i.e., medical, research settings) bofore unleashing tCS to the public.

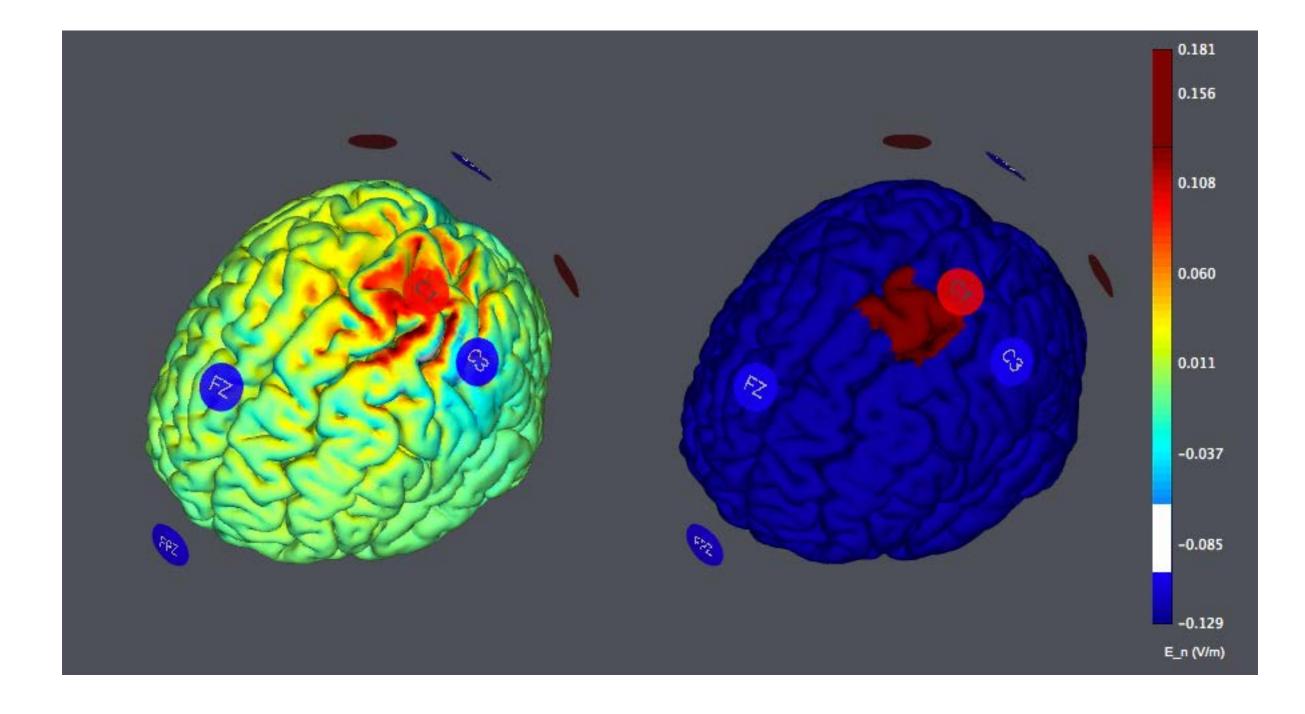
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Typical montage: very large action area





Quasi-monopolar stimulation using multi-electrode techniques



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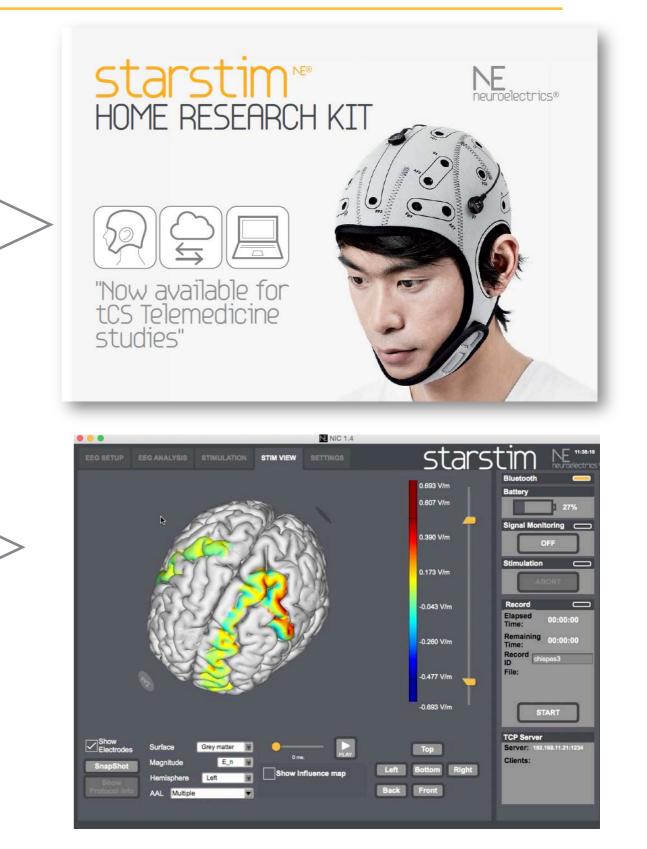
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- Today: lab, clinical settings
- Transition to tele-monitored home use to better understand impact of repeated use in natural settings (NE has already begun doing this with partners)
- Use of repeatable montages; protocols aiming for specificity of stimulation effects (e.g., targeted rather than "shotgun").

[Protocol = specification of electrode type, positions, current type and intesity, duration, session sequencing.]

- Modeling of electric fields
- Coregistration to study physiological effects such as EEG, fMRI, etc.
- Safety documentation to continue checking for short term effects





Thank you for your attention!

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