The regulation of consumer tDCS: engaging a community of creative self-experimenters

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Peer commentary on 'A pragmatic analysis of the regulation of consumer transcranial direct current (TDCS) devices in the United States' by Anna Wexler.

ELECTRICAL BRAIN STIMULATION AS A TOOL

Brain stimulation with electric currents is an important tool in the neuroscience lab and the neurology clinic. We can learn about the function of the brain with observational techniques such as studying stroke victims, or with correlational techniques such as fMRI where the brain's physiology is monitored. However, to have a truly complete understanding of the relationship between function and behavior, it is necessary to use an intervention such as brain stimulation to perturb the brain and to observe the effects of that perturbation.

In contrast to the more established technique of transcranial magnetic stimulation (TMS), transcranial electric stimulation (tES), of which tDCS is one variant, has a number of advantages. tES is a fairly gentle experience for the recipient, with a faint tingling sensation often the only giveaway that the current has been turned on. This gentleness has a scientific advantage that sham ('placebo') conditions and double blind experiments are possible.[1] It is thought to be relatively safe, although I will discuss some possible safety concerns below. tDCS also has two features that have generated excitement within neuroscience and beyond. First, the equipment is cheap and portable, meaning that tDCS has spread rapidly through labs and clinics. Second, reversing the electrode montage may in some instances reverse the effect of stimulation. So while TMS typically only disrupts brain function and diminishes task performance, tDCS may sometimes improve function and thereby enhance performance.[2] Clearly this is of potential benefit to people with neurological disorders, but intriguingly some studies have also shown enhanced cognitive performance in people with otherwise normal abilities.

These latter features of tDCS have meant that excitement about brain stimulation has spread into the public domain. The rise of at-home tDCS, either through commercial or home-made devices, has created interest in the ethical and regulatory rules that govern its use. In a recent article, Anna Wexler surveyed the complex layers of regulation that pertain to consumer brain stimulation devices in the USA.[3] Wexler's conclusion is that at-home users of commercial tDCS are protected by a number of restrictions on the manufacture, marketing, and sale of brain stimulation devices.

PERCEIVED SAFETY OF tDCS

Like many in the field, Wexler refers to tDCS as 'non-invasive'. I find this term rather misleading, believing that however the stimulation is delivered, directly influencing brain physiology is an invasion of some sort.[4] This is hardly an academic quibble: the term implies a degree of safety and harmlessness which is not currently supported.

So what are the harms in using tDCS? Manipulating brain excitability may affect the risk of a seizure, which is an episode of abnormal synchronized activity either in a small region of the brain or across the whole organ. This synchronized firing is normally suppressed through interconnections within or across brain areas, so altering these interconnections raises the risk of adverse events. To date, only one seizure has been reported following tDCS,[5] in a highly vulnerable paediatric neurological case; however, this probably reflects caution in recruitment of people into tDCS procedures. Other risks are poorly mapped out, but some clues come from the legitimate and desirable use of tDCS to change the state of the unhealthy brain. Prolonged, repeated sessions of tDCS are known to change brain function in several pathological conditions such as chronic pain, tinnitus, and depression.[6] These longer-lasting changes are likely to be due to similar processes to those that underlie long-term potentiation and long-term depression, which are key mechanisms of learning in the brain.[7] Even in healthy people we have shown that daily sessions of tDCS can lead to long-lasting changes in mood and resilience.[8]

Is it desirable to induce lasting changes in brain function? If the goal is to cure the recipient of severe tinnitus or clinical depression, then clearly there is a huge benefit in reorganizing brain function with tDCS. However, the commercial tDCS devices that Wexler discusses are not marketed as clinical devices, but as leisure or lifestyle devices to help play computer games or to relax after a hard day at the office. No area of the brain is associated with a single, unique function. For example, the dorsolateral prefrontal cortex (DLPFC), which is a common target for stimulation because of its role in cognitive processing, is a major hub of the brain, supporting a vast number of operations in a wide range of contexts.[9] While a dose of stimulation to the DLPFC (or elsewhere) may positively affect the function of interest, users (and, admittedly, scientists) rarely look for unintended consequences in apparently unrelated functions. It has been suggested that enhancement due to brain stimulation is 'zero-sum', implying that the enhancement comes at a cost to an unrelated function.[10]

A further complication, and one which is highly relevant given the demographics of at-home users, is that stimulation applied to the head of a young person may have vastly different effects compared to stimulation applied to an older person. I have expanded on this elsewhere,[11] but the essential argument is that the skull of a younger person is thinner, the scalp-to-brain distance is smaller, and the brain is still developing, meaning that the same stimulation protocol delivered to a child will most likely have a greater net effect than the same protocol given to a fully developed adult. The point at which a child becomes an adult (neurologically speaking) is somewhat hard to define, although there is an argument for drawing the line at the legal age of majority.[12]

There are several different types of unknowns in tDCS, from its mode of action to the precise consequences of a dose or overdose of stimulation. Although lab-based and clinical studies are helping to clarify some of these unknowns, there remains ambiguity around some safety-relevant parameters of the technique, and commercial devices are therefore being sold with some important questions outstanding.

RISK AND ADVENTURE

The previous section highlighted some of the uncharted waters in stimulating the brain with electric current. At-home users of tDCS are therefore assuming some degree of risk when using the technique in unmonitored environments and in untested protocols. Risk in itself is not a bad thing, and when a person takes pleasure in the presence of risk we call this *adventure*. There seems nothing particularly wrong with adventures that are not harmful to others, such as long-distance hiking, rock-climbing,[13] or underground exploration. However, some risky pursuits do engender some risks to others: smoking, drink-driving, and high-stakes gambling are notable examples. Adventures and play are crucial to the development of a child's notion of self.[14] As we grow, we channel that creativity into activities of self-experimentation that develop knowledge about our minds and our bodies, and our relations with others. I suggest that at-home tDCS users are adventurers, in that they are accepting some risk in return for the potential leisure or health benefits of tDCS.[15]

Self-experimentation also has a long and noble history in science and medicine. The 2005 Nobel Prize in Physiology or Medicine was awarded to Barry Marshall and Robin Warren for demonstrating the link between the bacterium *Helicobacter pylori* and common gastric complaints; this link was demonstrated partly through Marshall's self-administration of a drink containing *H. pylori*. Of current interest, the mode of transmission of the Zika virus was deduced in the 1950s when William Bearcroft injected Zika-infected tissue into himself.

Self-experimentation is one means of advancing a field of study when there are clear doubts about the acceptability of subjecting others to risky procedures. Point five of the Nuremberg code states: ‘No experiment should be conducted, where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects’. This point is often taken to justify self-experimentation, even in cases where the experimenters are the only subjects. It is certainly the case that many ethical worries, such as informed consent, are eliminated when the experimenter experiments on herself.

INVOLVING AT-HOME USERS

Are at-home users self-experimenters? In an ideal world the consumer would know exactly what his new product was for, what it would do, and what the risks and benefits might be. But as we have seen, tDCS does not afford this sort of certainty at present. Manufacturers, regulators, and scientists must therefore ensure that at-home users have access to the most accurate and up-to-date information on the harms and benefits of tDCS. It would be unreasonable to expect that any device that changes the state of the brain be completely without risk, but that risk should be communicated clearly to give users at least a partially informed choice.

But that communication need not be unidirectional. I would argue that the fine tradition of self-experimentation can be harnessed, if structures are created that allow at-home users to contribute their experiences to a common store of knowledge. At present online sharing of tDCS experiences is haphazard, and is restricted to the more anarchic fringes of the internet.[16] However, those communities are generating potentially valuable information, which could be of great interest to researchers and to manufacturers. At-home and DIY users frequently stretch the limits of protocols, delivering higher current for greater amounts of time.[17] Bringing at-home users into the fold will provide useful information about safe and unsafe protocols, and will generate important information about the milder side-effects of tDCS that are thought to be under-reported by researchers.[18] In this way, at-home users will be following in the tradition of the scientific self-experimenters, by contributing their knowledge willingly and openly to the community. It has been proposed that the regulation of tDCS and related devices in Europe be brought under the remit of the Medical Devices Directive (MDD).[19] This Directive encourages reporting mechanisms for faulty or non-compliant devices. Although the MDD may turn out not to be an appropriate instrument for tDCS devices, the notion of a government- or industry-monitored database of protocols in current use, by people in labs or clinics or at home, points towards an instantaneous snapshot of safe and unsafe regions of the tDCS protocol landscape. At-home users must be given the best available knowledge by scientists and manufacturers. However, regulation should allow for a degree of liberty around at-home tDCS use, with the potential benefit of creating a pool of creative and engaged self-experimenters who will shape and inform the future uses of tDCS. Anna Wexler's survey of the current regulatory geography in the USA reveals a series of frameworks that may, if tested, be stretched to fit tDCS devices. I suggest that the scientific, legal, and philosophical communities positively and proactively engage with the commercial actors, and with the end users of tDCS devices, to develop practical and sustainable practices for the future of brain stimulation.

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