

The Fantastical Claims of Consumer Brain Stimulation Wearable Devices. Really?



The business of wearable brain measurement and stimulus devices promising benefits that range from improved mood to the betterment of age-related decline, is booming. The digital brain health market, which includes wearable brain devices, is likely to grow to \$6 billion by 2020. Technology companies already are marketing brain recording and stimulating devices directly to consumers. Are these companies adequately—and ethically—educating consumers about both their benefits and the risks involved? Given this technology's intimate relationship with the brain, a number of ethical questions must be addressed so that the technology can achieve the goal of contributing to human performance. Topics that must be considered before using one of these devices include; *safety, privacy, authenticity, and oversight.*

A recent paper published in the scientific journal *Neuron* counted 41 direct to consumer wearable neurodevices on the market of which 22 are EEG recording devices and 19 are direct stimulation devices claiming to do various different things from relieving stress, enhancing mood and improving sleep to increasing concentration, improving productivity, enhancing memory and enhancing physical performance. ***Really?***

Most of the claims were based on references to general scientific papers not specific to the device and in some cases, even entirely irrelevant to the claims being made.

Where's the evidence?

The authors attempted to find the research referenced by these companies that supported their claims. Out of the 41 devices they found links to research for 33 of these devices but only 8 referenced studies specific to the device. The rest had references to general scientific papers not specific to the device and in some cases, even entirely irrelevant to the claims being made. So what is the evidence for these broad claims? Are they supported in the scientific literature? Here are some major issues that have not yet been answered:

Quality of the signal

The first concern is whether they can actually record sufficiently good quality data to make any sense of it at all. Consumer devices such as Muse, Neurosky and pretty much all the others, use dry electrodes which have notoriously bad contact quality, and therefore impedance values, which influence the quality of the signal, fluctuate wildly. With no real studies demonstrating the quality of their signals by comparison to gel based systems, it is pretty safe to assume they are poor quality EEG signals. These receptors are simply not good enough to make accurate estimates of EEG features in real time for any individual.

Individual Variability

Another challenge is individual variability. People have their own unique profiles that differ from one another and also fluctuate over time. This is one of the reasons population level data is so difficult to translate into predictions at the individual level. It is also one of the reasons there are so many inconsistencies in the literature and contradictory studies and why only experienced clinicians should determine treatment protocols for the application of these modalities.

Consumer brain recording and stimulant technologies make all sorts of claims that are simply not substantiated in the literature at the level of individual effects.

So, taking into account poor signal quality, added to weak correlations between individual EEG features and any particular state, what you get out of it as a user is essentially “junk”. The really big concern with these devices is that the “junk” may not be harmless.

“We know that these technologies have the power to affect our brain, in some cases very profound changes can occur. We just don't know to what degree and in what areas they are affecting our brains, or what degree of damage might they bring about in the short or long term?” stated Dr Randy Beck, Director of the Institute of Functional Neuroscience, an expert in the application and clinical effects of the stimulus modalities that many of these devices claim use to change your brain.

Dr Beck expressed caution when using these devices until a deeper understanding of their effects are understood. “In the clinic, we have protocols that control how many sessions, the duration, and the intensity of these methods and we monitor the effects of the stimulation very closely. But when you leave it to consumers that usually have no training or understanding of neuroscience to make those decisions, it's really difficult to know, or even anticipate, what harms they could be doing to themselves.”

Who's minding the space?

There are few regulations or oversight when it comes to wearable brain devices. Most devices don't have, and are not required to have, U.S. Food and Drug Administration (FDA) approval to go to market. In fact, in 2016 the FDA issued a guidance that it would not enforce regulations for low risk devices marketed for general cognitive enhancement or wellness purposes. So consumers must trust the very companies who develop and market these products to explain both the potential benefits and risks of their use.

References

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