Medical Xpress

# Q&A: Challenges and advances in brain-computer interfaces

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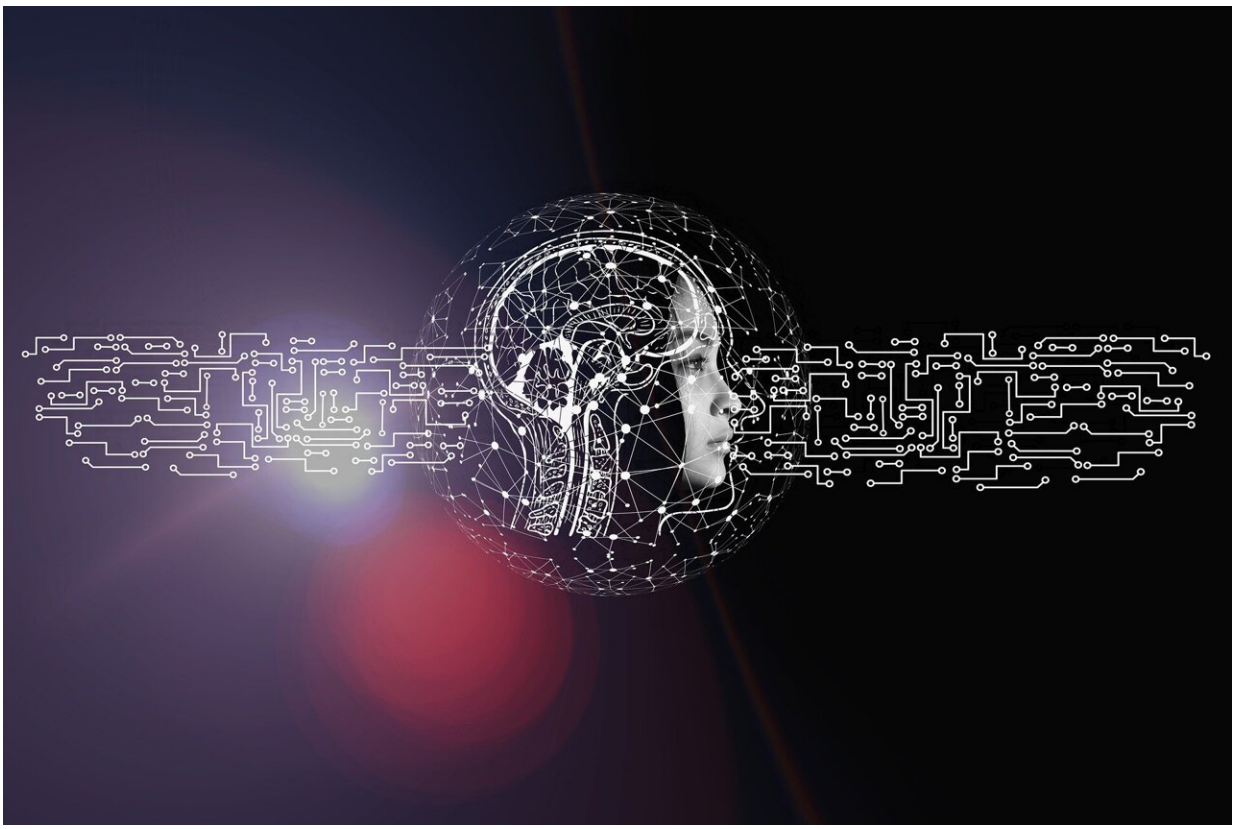

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In a significant step forward in neurotechnology, companies that make implantable brain-computer interfacing (BCI) devices, such as Neuralink , have received approval from the U.S. Food and Drug Administration

(FDA) to conduct human clinical studies.

BCIs have been around for a few decades; however, many companies and institutes have found navigating the stringent FDA approval process for a commercial medical BCI device challenging. These medical devices are typically surgically implanted deep within or onto the surface of the brain.

Penn Today met with Anna Wexler, an assistant professor in the Department of Medical Ethics and Health Policy in the Perelman School of Medicine, to discuss the promising possibilities and potential pitfalls of advancements in neurotechnology.

## What exactly is a BCI, what does it do, and why does it need to be surgically implanted into the brain?

A BCI is a piece of technology that allows for direct communication between a brain and an external device. They primarily do this by recording electrical activity generated by neurons.

Not all BCIs are surgically implanted. For example, there are non-invasive BCIs that utilize technology like EEG or fNIRS to record brain activity from the scalp. These typically have lower resolution than BCIs that are implanted in the brain, where the electrodes make direct contact with neural tissue.

Consumer noninvasive BCIs have been around for the last 15 years or so and are marketed for the control of objects or for wellness purposes, but it's not clear whether there is sufficient evidence to support companies' claims.

It's a particularly exciting time for implantable BCI research. Many start-

ups have entered the space and have raised significant amounts of venture capital.

## Could you speak about some of the specific benefits BCIs provide and some of the ways they could help people?

Today, implanted neurotechnology devices are widely used in the clinic. For example, neurostimulation devices have an extensive track record for treating conditions such as epilepsy and Parkinson's disease.

BCIs have been used experimentally to help people suffering from serious physical disabilities or diseases to restore some degree of communication or motion. For instance, Blackrock Neurotech has been working with researchers to help patients with conditions like paralysis since 2004 by providing them the ability to interact with computers or control robotic limbs using their thoughts. But none of these devices has received FDA approval; they are all still experimental.

The coming trials for the next generation of implantable neurotech devices will likely be a major step forward in producing better patient outcomes. Not only will they give us important insights into the safety and efficacy of the next-generation devices, but they'll also help to pave the way for future developments in the field. It's just important to emphasize that these trials be conducted ethically, with proper oversight and safeguards in place.

## Considering the potential impact of this technology, what are some of the ethical considerations?

There are a number of ethical considerations that come into play when talking about BCIs. The first and perhaps most immediate concern is

informed consent. These are experimental procedures involving invasive brain surgery, and it is crucial that patients fully understand the risks involved, the potential benefits, and the experimental nature of the technology.

Second, privacy and data security are significant concerns. BCIs read neural signals which may contain health data and may someday contain sensitive information about a person's thoughts, intentions, or emotional states. It's crucial that the data gathered from these devices is used ethically.

At the moment, our personal information is not well-protected. For example, if you were to investigate my browser search history, then my email and integrate that with the location or motion data from my smartwatch, you could infer a lot about me. It's quite possible that one day, neural data will be yet another layer to this data profile, but we're not there yet.

Third, there are questions about what happens after a trial with an implanted neurotechnology device concludes. Clinical trials typically last no more than a few years, but in some cases, research participants who experience benefits choose to keep the device implanted for decades. So, there are really complicated and tricky considerations surrounding who is responsible for maintaining the implant in the long term and for supporting participants, especially as they may not be able to get standard MRIs with their implants. Should it be the responsibility of the participants? Investigators? Insurance companies? Research institutions? Funders? Medical device manufacturers? There are no straightforward answers.

Finally, there are larger societal issues to consider. What happens when such technology becomes widely available? How might it change our perception of normal human function or exacerbate existing

inequalities? These are complex questions without clear answers, and they merit ongoing discussion as the technology develops.

## With companies like Neuralink making headlines over ambitious goals of creating a medical device that will cure neurological disease and a consumer product that merges artificial and human intelligence to improve human cognitive abilities, how do you think that will affect other firms operating in this space?

Well, Neuralink is an interesting player in this industry because their co-founder is often in the media and has a track record of making optimistic proclamations about what his technologies can do, not just for Neuralink but his other companies.

You don't typically see this sort of willingness to generate hype around devices in the medical sector.

At Neuralink, there's a dissonance between the CEO's claims and what the company is actually working on. So, it seems that the company is mostly focused on the medical applications of the device, whereas Elon Musk will speak to some of the applications of BCI that may be coming down the pike, the ones that tend to capture imaginations.

On the one hand, this is a good thing because you have the general public becoming increasingly interested in BCI, which will spur more investment in the technology, which will accelerate innovation. On the other hand, there's still so little known about the brain that getting people's hopes up about what's possible in the near term may be misleading and may lead to skepticism around neurotech.

We also need to ask, what value will implantable devices have for the average consumer? Personally, if a device allowed me to type 5% to 10% faster, I likely wouldn't go through with neurosurgery to have it implanted. Others might. But overall, the practical value of potential consumer applications has not been fully fleshed out.

## How do you think oversight will be provided if more and more companies operating in the medical space opt to create a consumer version of their implantable BCIs?

First, it's unclear how implanted consumer BCIs would be regulated. We haven't really seen anything like this before. From a practical perspective, what's happening now is that the companies operating in this space are aiming to establish safe and effective protocols, and, if they're able to achieve a level of success, then the next question will be if and how they move their products to a consumer space. There may be parallels to look at in the realm of cosmetic surgery.

A physician would likely need to be involved in prescribing, approving, and/or administering this sort of elective surgery. The level of risk associated with the implant procedure would also be an issue, and I anticipate many neurosurgeons would be reluctant to take part in the implantation procedure.

In the context of medical devices, entities in this space need to abide by HIPAA laws and work with insurance companies who are also federally regulated, so there are structures in play to ensure that patient information is secured. So, if these companies move to marketing consumer products, there will need to be a planned, well-thought-out data protection system.