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Neuralink and Brain–Computer Interface—Exciting Times for Artificial Intelligence

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Abstract

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Brain–computer interfaces are becoming a tangible reality, capable of significantly aiding patients in real-world scenarios. The recent approval by the U.S. Food and Drug Administration for clinical human trials of Neuralink marks a monumental stride, comparable to Mr. Armstrong's moonwalk. Numerous other companies are also pioneering innovative solutions in this domain. Presently, over 150,000 patients in the United States possess brain implants. As technology advances, it holds the potential to alleviate various conditions, notably motor paralysis, cerebral palsy, and involuntary movements.

Keywords

- BCI
- human trials
- implant
- motor paralysis
- optical coherence tomography

Introduction

Artificial intelligence has become a buzzword after the release of Chat Generative Pre-Trained Transformer (ChatGPT) to the public. Developments are moving forward at rocket speed in several specific directions. One is in the field of implantable devices for neurological conditions. We bring to you the recent advances in this field with reference to Neuralink 1 and its recent approval by U.S. Food and Drug Administration (US FDA) for human clinical trials.

Viewpoint

A brain–computer interface (BCI), also called brain–machine interface, is a system that can acquire and analyze brain signals and translate them into commands that are relayed to an output device to carry out a desired action. While several such devices are in development, Neuralink has finally received approval from US FDA (May 2023) to initiate their trials that will implant these chips into humans.[1] The approval took 3 years, while the company gathered more data to address concerns that the regulatory authority had raised.[2] While Neuralink was established as a company in 2016, the recent trial approval resulted in a jump of its valuation from 2 to 5 billion USD—making the world's richest man (Elon Musk) richer.[3]

What Neuralink is developing is a unique BCI, which if successful, will revolutionize the value of artificial intelligence.[4] It aims to allow a person with impaired neurological function (e.g., paralysis) to use brain activity to directly

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operate a computer or a phone.[5] While Stephen Hawking used eye/cheek muscle movements to use a computer and communication with the outside world, Neuralink proposes to take it to an entirely new level.[6,7]

Neuralink 1 is a device that is made of multiple chips, a wireless battery, and supporting other electronics inside an implant. Ultrathin wires (64 of them having 1,024 electrodes) coming out of this implant are akin to tentacles that will be spread out to different parts of the brain.[8] Signals emitting out of the implant are carried via Bluetooth to the computer that decodes them so as to move a robotic arm or onscreen cursor.[9] In 2021, Elon Musk said, "it's like a Fitbit in your skull with tiny wires that go to your brain."[10] The device is inserted using a robotic surgery instrument that uses a needle thinner than human hair. It also has five built-in camera systems for brain imaging using optical coherence tomography.[11] Preclinical data have documented efficacy in Neuralink implanted pigs and monkeys. In fact, the video showing the monkey playing Pong on the computer did go viral on social media in early 2021.[12] Implantation of BCI in monkeys enabling their brain to control a cursor has been done previously in 2014 by Dr Miguel Necolelis at Duke University.[13] The unique selling point of Neuralink is the significantly higher bandwidth and number of electrodes, such that the speed and accuracy of the motor movements are finely tuned.

We do not know when the trial will commence enrolling volunteers. And it could be decades before Neuralink brain implants become available commercially, perhaps its "n"th version.

In 2022, US FDA had rejected Neuralink's application citing concerns regarding how it will be implanted, migration of the wires to other parts of the brain and regarding how the device will be removed.[2] Other concerns raised by authorities and scientists included animal ethics, safety, and logistic issues.[14–16] Neuralinks research so far has involved rats, mice, sheep, pigs, and monkeys.[17] Chips from their brains were removed under questionable circumstances and were also shipped, without documenting precautions against contamination/infectious organisms.[18]

Neuralink is not alone in this endeavor to have a bionic chip–brain–computer person. The competitors are discussed in the following text:

Blackrock Neurotech was probably the first organization to start testing brain implants approximately 20 years ago.[19] Their focus was on patients with paralysis and/or prosthetic limbs. They are yet to receive US FDA approval for commercial use.

Synchron is ahead and has commenced human trials for BCI (ClinicalTrials.gov Identifier: NCT03834857).[20]

Stentrode With Thought-Controlled Digital Switch (SWITCH) is a prospective single-center study at Royal Melbourne Hospital in Australia.[21] A total of five patients with severe bilateral upper-limb paralysis were implanted with the device and followed up for 12 months (between May 2019, and January 2022). The recording devices were connected to subcutaneous electronic units that then communicated to another external device (wirelessly) for computer control. All the patients were able to control the external computer via the BCI (this included hands-free texting, emailing, online banking, shopping, and expressing their needs via their thoughts). No serious adverse events (including venous occlusion or device migration) occurred.

Paradromics is also in the race to initial human trials with their implantable device.[22] Their approach is similar to that of Neuralink.

Precision Neurosciences (established by a cofounder of Neuralink) has developed a layer 7 cortical interface, in which an electrode array is akin to a flexible scotch tape and can be "implanted' on the brain surface without damage to any brain tissue.[23] This has been used in three patients who were undergoing surgery for brain tumors.

In United States, as many as 150,000 patients have brain implants, mainly as deep brain stimulators, for the treatment of severe tremors and movement disorders (e.g., Parkinsonism).[24] While helping the patients, it also led them to forget how to swim, a potentially life-threatening adverse effect. When a novel path breaking method is envisaged (especially those that are likely to be disruptive), there is a tendency to raise concerns, especially potential ethical conflicts.[13–15,23] Fear of serious safety risk is always on the list of protesters. When preclinical and laboratory data are "sloppy," the naysayers cause get strengthened.[17,18] In the BCI and Internet-of-things era, data privacy is paramount.[25] Who will have access to what the chip transmits wirelessly? What will it be used for? Can it be hacked? Could this open a novel way of remote control of people? Such questions need to be addressed taking into confidence all relevant stakeholders.[26]

Conclusions

We are living in exciting times. There is real hope for patients with compromised neurological function in the immediate future. This has the potential for wide ramifications across specialities. Imagine the power of brain signals in moving paralyzed limbs, silencing involuntary movements and beyond. Several ethical issues need to be resolved, especially to prevent misuse of the device (brain chip) and the information obtained from BCI.

Conflict of Interest
None declared.

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