Brain-Computer Interface based Neuro-prosthetics

Augments physical and cognitive human abilities by linking brain activity to external devices.

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WHAT IT DOES

A Brain–Computer Interface (BCI or Brain-Machine Interface; BMI) is a hardware and software communication system that can read a certain set of patterns in brain signals, using them to control computers or external devices.

BCI acquires electrical activities from the brain and nerves. The complexity and volume of brain signals are difficult and complicated to read and interpret, so BCI relies on Artificial Intelligence (AI, the concept of machines being able to carry out complex tasks with applications of machine learning, deep learning, neuronal network models, and big data).

BCI devices are "Neuroprostheses that interface with the central or peripheral nervous system to restore lost motor or sensory capabilities" (an FDA working definition of BCI). Restoration is accomplished by:

1. Delivering electrical stimulation that excites or inhibits neural tissue; or
2. Reading electrical activities generated by the brain or nerves and then, uses BCI to control external devices.

Neuronal signals from the brain or nerves are measured by:

- Non-invasive BCI: No surgery is needed. Instead, topical electric sensors are placed over the head or nerves (e.g., via a hat, belt, or patch) to measure Electroencephalography (EEG), which reads the rhythm of brain activities or electromyography (EMG) to read muscle activities.
- Partial-invasive BCI: Electrocorticography (ECoG, or intracranial electroencephalography; iEEG) is a process in which electrodes are placed inside of the skull, above the brain’s surface.
- Invasive BCI: Intracortical recording occurs when electrodes penetrate brain tissue. In comparison to non-invasive BCI, this method typically fosters better signal quality, spatial resolution, and a higher range of frequency. This technique records neural activity from an assembly of single brain cells.

BCI - based neuro-prosthetics can enhance hearing, vision, mood, mobility, cognition, and communication. Specific examples include:

- Cochlear implants: Medical devices for people who have lost hearing capacity because of a damaged inner ear (cochlea). This device detects sound through an external sound processor and then converts this sound into electrical signals. An electrode array that is implanted in a damaged inner ear is activated by these electrical signals, which is then sent to the brain where it is interpreted as sound. Cochlear implants became FDA-approved in 1995.

- Visual prostheses: Medical devices for individuals with vision loss. This device converts visual information read by a camera into electrical signals, which stimulate the visual cortex where an electrode array has been placed. Argus II is one type of retinal implantation that was approved by FDA in 2013.

- Brain stimulation, of which there are several variations, including:
  ○ Deep Brain Stimulation (DBS): An implantation of electrodes into specific target areas of the brain, which are connected to a neurostimulator. Through this device, brain activities are monitored and excited. DBS is an FDA approved treatment for Parkinson’s disease and essential tremor symptoms (originally approved in 1997), dystonia (approved in 2003), and
obsessive-compulsive disorder (OCD) (approved in 2009).

- **Transcranial Direct Current Stimulation (tDCS)** - A non-invasive brain stimulation where very low levels of constant current are delivered to specifically targeted areas of the brain. This technique has been developed as a product to modulate stress levels or enhance cognition.

- **Transcranial Alternating Current Stimulation (tACS)** - A non-invasive form of brain stimulation sending current (sine-waves) at a specific rhythmic frequency in order to alter the brain’s activity pattern. It has been studied as a new treatment for epilepsy, schizophrenia, or cognitive impairment.

- **Repetitive Transcranial Magnetic Stimulation (rTMS)** - A non-invasive form of brain stimulation using a magnet to target and stimulate certain areas of the brain. It has been used as an investigational treatment for auditory hallucinations and depression.

- **BCI limb prostheses**: Artificial arms or legs that are controlled by brain or nerve activities for individuals with a paralyzed or missing body part. Currently, researchers are actively pursuing 1) closed-loop neuro-prosthetic systems in which the brain or nerves receive sensory information feedback from the prosthetics, allowing users to experience the “feel” of sensory information conveyed through the prosthetic limb, and 2) wireless neuro-prosthetics that can be remotely controlled by brain signals.

- **Brain-to-Brain Interfaces**: Allows real-time transfer of brain activity by linking the brains of two individuals. Published studies have demonstrated direct transmission of brain activity between two humans, between two animals, and even between human and rat.

- **Hippocampal (or cognition) prostheses**: Implantable microelectrode arrays in the hippocampus of the human brain to enhance cognition. The hippocampus is a part of the brain that plays a critical role for learning and memory. This device may be used as a treatment for individuals who have cognitive impairments as a result of neurodegenerative diseases like Alzheimer’s Disease and also for individuals who desire to enhance cognitive ability.

**RELEVANT SCIENCE**

A brain contains approximately 100 billion neurons. Neurons communicate with each other via electrical impulses (called spikes or action potentials). To understand how the brain’s activity is measured and what activity is recorded, we can imagine that neurons are singers in a choir and electrodes are microphones. With microphones located at a distance from a choir, we can listen to the harmony of the different voices in the choir (e.g. soprano, alto, tenor, bass). Using an electroencephalogram (EEG) is like listening to the harmony of neurons’ electrical signals. EEG electrodes, shaped like small metal discs, are non-invasively positioned on the scalp to detect voltage fluctuations generated from the electrical impulses of a group of neurons appearing as oscillations (rhythms) of different frequencies. These are often called brain waves. An EEG is often used to diagnose epilepsy, sleep disorders, coma, and brain death.

Muscles also produce an electrical current when they are active. An Electromyography (EMG) is a test that records the electrical activity of muscles through electric sensors that are placed on muscles. An EMG is analyzed to detect medical abnormalities in order to identify neuromuscular diseases. Just as we can install microphones close to some members of the choir in order to listen to and record their specific voices, Electromyography (ECoG) or intracranial electroencephalography (iEEG) are methods to measure more localized electrical activity in the brain by placing electrodes in direct contact with the surface of the brain. Just as we can listen more clearly to the beats and rhythms of a specific voice type, ECoG provides higher temporal and spatial resolution measurements of brain activity in the area close to the electrodes. However, ECoG is a partially invasive recording modality which requires a craniotomy to implant an electrode grid, which entails significant health hazards. This method is used to monitor and control seizures in patients with epilepsy.

To record an individual singer’s voice in the choir, the individual should have a targeted microphone. Similarly, to listen to an individual neuron’s “voice,” electrodes have to be close to just that single neuron. This is a recording technique called **intracortical single neuron recording** that measures electrical activity of single neurons inside the brain. It is an invasive recording modality that requires implanting microelectrode arrays inside a brain region where targeted neurons are located to capture single neuron signals.
This technique provides much higher spatial and temporal resolution than EEG or ECoG recording, which gives more information about where in the brain the activity is generated and at what frequency the activity occurs. Using these same electrode arrays, it is also possible to record local field potentials (LFP): like EEG and ECoG, this technique is composed of the summed electrical signals from multiple nearby neurons, but the signals are much more specific to the targeted area.

WHY IT MATTERS

BMI technologies are currently used in limited circumstances, but in the near future, neuroscience breakthroughs in this area may translate into commercially available products that will increasingly be used for both disabled and healthy people to improve quality of life.

Rapidly evolving areas of science often require a parallel exploration of the related ethical, legal, and social implications (ELSI). In turn, ELSI often forms the foundation for policies that will guide stakeholders, including policy-makers, researchers, engineers, manufacturers, and users. Concerns raised related to this technology have considered identity, liability, privacy, security, justice, normality / transhumanism, autonomy (freewill), and informed consent.

BCI-based treatments and products acquire a high volume of brain data, which contains sensitive information related to memory, thought, and emotion, for example. Such information could be manipulated by authorities or criminals, in the event a BCI device is hacked. Studies have showcased a few examples:

- **Criminal Forensic Lie Detection**: The electrical signals of the brain electroencephalography (EEG) can be used in forensic investigation as a tool for lie detection.
- **Computer User Authentication**: The brain waves of the person, recorded in real time, can be used as a password to unlock the screen.
- **Retrieving Passwords from a Human’s Brain**: Researchers figured out a way to pluck sensitive information from a person’s head, such as PIN numbers and bank information.
- **Tracking Brain Signals Reveals Individuals’ Thoughts**: By measuring the brain signals at the precise time the images were displayed, researchers could glean clues about the player's thoughts and feelings about the images. This suggests that the same setup could be used to extract much more sensitive information, including a person's religious beliefs, political leanings, medical conditions, and prejudices.

RELEVANT EXPERTS

**Warren M Grill, PhD**, is a professor of Biomedical Engineering at Duke university. His research employs engineering approaches to understand and control neural function. His research group works on fundamental questions and applied development in electrical stimulation of the nervous system to restore function to individuals with neurological impairment or injury.


**Jonathan Viventi, PhD**, is an assistant professor in the Department of Biomedical Engineering at Duke university. His research uses
flexible electronics to create new technology for interfacing with the brain at high resolution over large areas. These new tools can help diagnose and treat neurological disorders such as epilepsy, and help improve the performance of brain machine interfaces.


BACKGROUND

The neurostimulation devices market is expected to reach $13 billion by 2023 and includes stimulation products targeting the spinal cord, deep brain, sacral nerve, vagus nerve, and gastric region. The neuroprosthetics market is expected to garner just slightly less: $14 billion by 2020.

BCI based products currently available on the market include:

- **Thync Relax** - A combination of targeted electrode placement and proprietary transdermal (through the skin) electrical neuromodulation waveforms to modulate stress levels, mood, and sleep cycles.
- **Halo Neuroscience** - A motor cortex stimulator marketed to enhance muscle memory for coordination, technique, endurance, strength, and explosiveness.
- **Cricket** - A wearable sensor monitoring EMG of muscles for health and fitness purposes.
- **Emotive, MUSE, NeuroSky** - Brain signal monitoring headbands for meditation, tracking sleep cycles, and measuring stress levels.
- **Neuroon** - A wearable sleep mask measuring EEG, EOG, motion, and temperature to track biorhythm and sleep cycles.
- **4DForce** - A headset detecting EEG, EOG, EMG signals and converts into electric signals for users to control games.
- **SmartCap** - A hat with fatigue monitoring system designed for industrial purposes using EEG sensors that analyzed to determine the drowsiness level for keeping truck drivers safe.
- **Medtronic** - Neurostimulators for DBS have been approved by FDA to treat some movement symptoms of Parkinson’s disease and essential tremor.

BCI based startups include:

- **Kernel Co.** - A human intelligence company for hippocampal prosthetic development in applications for patients with cognitive disorders. The company has received funding in the amount of $100 million.
- **MindMaze** - A Swiss company, founded in 2012, building a user interface integrated into a wearable Head Mount Display (HMD) and 3D motion-capture cameras to create a VR and Augmented Reality (AR) environment that provides multi-sensory feedback to patients with brain injuries to stimulate motor functions during rehabilitation. The company has received funding totaling $108.5 million.
- **NeuroPace** - Founded in 1997, this company has received $67 million to develop a medical device that monitors specific brain activity to stop epileptic seizures.
- **Ebb Therapeutics (formerly Cerève)** - A Pittsburgh based startup was founded in 2008 to produce a device that helps people with sleep disorders or insomnia; it took in $38 million.
- **BrainRobotics** - Founded in 2015, the company has taken in $5 million to provide a low-cost basis robotic prosthesis that is customized and controlled by EMG for arm amputees; expected price-point is under $3,000.
- **NeuroLutions** - Founded in 2007 with a total of $2.15 million, the company is developing a BCI platform to restore functions to paralyzed limbs through use of a robotic exoskeleton called IpsiHand.

- **Neurable** - Founded in 2015, the Cambridge, Massachusetts startup took in $2 million to develop BCI using EEG to operate devices like toys, games or cars.

- **Neuralink**, Tesla Inc. - The company is developing electrode implantations or cognition prostheses.

- **Cognescent** - Founded in 2015, this company is building technology that computers capture and decode subtle body movements from muscles and motor neurons to create personalized transformative BCI spans.

**BCI history:**

- 1976: UCLA's Brain Computer Interface Laboratory provides evidence that single trial visual evoked potentials could be used as a communication channel effective enough to control a cursor through a two-dimensional maze. Professor Jacques J. Vidal coins the term BCI.

- 1998: First (invasive, non-EEG) implant in the human brain that produces high quality signals.

- 1999: BCI is used to aid a quadriplegic for limited hand movement.

- 2002: Monkeys are trained to control a computer cursor.

- 2003: First BCI game is demonstrated to the public ([BrainGate](https://braingate.org): A collaborative, diverse research team focusing on developing BCI technologies).

- 2005: Monkey brain controls a robotic arm.

- 2008: Voiceless phone calls are demonstrated ([The Audeo – TI developers conference](https://www.ti.com/education/programs/audesources/))

**ENDORSEMENTS & OPPOSITION**

**Transcranial Direct Current Stimulation**

Citizens are trying brain stimulation independent of medical oversight; they call the practice “brain zapping” and are sharing experiences and technical reviews online. [SpeakWisdom](https://www.spiewisdom.com), a blog by Breast Williams, has nearly 4,000 subscribers who are interested in attempting brain stimulation to generate positive health benefits (Reddit also offers a thriving community, committed to self-administration of tDCS).

Scientists and psychologists have raised questions about the safety and proper regulations for brain stimulation:

- Dr. Cohen Kadosh addressed ethical issues raised by at-home use of tDCS by healthy people in a [2012 paper](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5908486/): “TDCS has the potential not only to treat congenital or acquired neural disease or dysfunction but also to enhance the psychological skills of subjects already performing within the normal range. The issue of cognitive enhancement using TDCS raises special ethical issues that differ in important ways from those raised by pharmacological interventions.”

- Dr. Davis, a psychologist in Swansea University, warned against the safety and efficacy of noninvasive brain stimulations in a [2013 paper](https://www.journals.uchicago.edu/doi/10.1086/668155): “These techniques [tMS and tCS] have collectively become known as ‘non-invasive brain stimulation.’ We argue that this term is inappropriate and perhaps oxymoronic, as it obscures both the possibility of side-effects from the stimulation, and the longer-term effects (both adverse and desirable) that may result from brain stimulation.”

- In a [2014 paper](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4221584/), Dr. Cabrera stated: “Although brain stimulation techniques offer considerable benefits to society, they also raise a number of ethical concerns, various dilemmas related to brain stimulation in the context of clinical practice and biomedical research.”

- Dr. Matsumoto published [a review](https://www.frontiersin.org/articles/10.3389/fnagi.2017.00132/full) about adverse events of tDCS and tACS in 2017: “We need to scan the literature continuously for information on the adverse events of both stimulation techniques. Further safety investigations are also required.”

- Dr. Fregni claimed in a [2015 paper](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4556369/) that it is critical for a global or local effort to be organized to pursue definite evidence to
either approve and regulate or restrict the use of tDCS in clinical practice on the basis of adequate randomized controlled treatment trials.

- Recent review articles (Bikson et al., 2013, Horvath et al., 2015a, and Horvath et al., 2015b) claimed that tDCS was found not to have a significant cognitive impact, including no effect on any working memory outcome or language production task.

- Previous studies (Benwell et al., 2015, Hsu et al., 2016) also pointed that tDCS outcomes are strongly influenced by individual differences and variations in experimental parameters, some of which are likely explained by the brain’s state at the time of tDCS-delivery, but for which explanatory, mechanistic models are lacking.

Policy

In a 2012 Vanderbilt Law Review article, Stephanie Kostiuk proposed creation of a Neuro Information Nondiscrimination Act (NINA), to protect against discrimination and adverse social consequences of neuroscientific test results, including EEG, brain-imaging (fMRI), and others. This idea originated from concepts within the Genetic Information Nondiscrimination Act (GINA), which became effective in 2008 and prohibits health insurance companies and employers from discriminating against (potential) employees/customers based on pre-existing genetic conditions. Kostiuk states “federal legislation entitled the Neuro Information Nondiscrimination Act (“NINA”) should be considered to prohibit employers from (1) requesting, acquiring, or disclosing neuro information and from discriminating on the basis of neuro information, and (2) requesting or requiring that applicants or employees engage in neuroenhancement and from directly or indirectly discriminating on the basis of the use or nonuse of neuroenhancement techniques.”

RELATED POLICIES

The FDA’s Center for Devices and Radiological Health (CDRH) oversees regulation of brain implantation devices:

“The regulatory pathway for a specific device depends on the classification of the device, which is based on risk as well as the level of control necessary to mitigate such risks to health. Medical devices are categorized into one of three classes based on their degree of risk. There are relatively few class I (lowest risk) neurological devices. Most neurological devices are classified as class II (moderate risk) or class III (high risk) devices.”

The agency has also released numerous guidance documents for the safety assessment of neurological devices as well as an outline of the nonclinical review considerations.

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