Professor Nicholas D. Fila

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An Ethical Evaluation of Current Invasive BCI Technology in Motor Neuroprosthetics

Introduction

By enabling cognition, the human brain supports arguably the most important function in the human body. One could venture that sustaining this cognition and enabling the mind to interact and experience the outside world is the primary purpose of the rest of the body. While a quadriplegic's ability to process their environment is not impaired, their ability to interact with and control their environment is. Since this ability to interact and directly control a person's environment is a basic human desire and is intrinsically linked to a person's mental well-being (Leotti et al.), enabling a quadriplegic to directly control their environment could offer people living with quadriplegia a significant improvement to both their quality of life and life satisfaction more generally. Enabling quadriplegics to control their environment via enabling the control of wheelchairs, computer cursors, and robotic arms is the primary problem that current invasive brain-computer interfaces (BCIs) are trying to solve. Recent clinical trials of invasive BCIs by companies like BlackRock Neurotech and Neurolink have demonstrated the amount of progress that has been made in BCI technology in the past two decades; their success increases the likelihood that these neuroprosthetic devices could enter the market within the next ten years (Gilbert and Siddiqui, Rubin and Hochberg). With this technology comes the possibility of transforming the lives of hundreds of thousands of people living with quadriplegia, however, considering that the BCI devices with the greatest potential to offer the best performance and, thus, the most significant quality-of-life improvements feature electrodes that must be implanted

in the patient's brain in a non-trivial, not fully reversible surgical procedure and feature ethical and long-term safety concerns, the question of whether the benefits of this invasive BCI technology outweighs its risks must be carefully evaluated before these devices are allowed to enter into widespread use. I aim to evaluate the ethical concerns related to current invasive BCI technology with particular emphasis on questions regarding these devices' long-term safety, efficacy, upgradability/repairability, and relevance. I intend to analyze these issues as if I were in the position of a professional engineer working for a regulatory agency with the authority to decide how or whether this device should be allowed to enter widespread clinical use.

Background

Before a judgment can be made on whether invasive BCI technology should be adopted for widespread use, a basic understanding of invasive BCI technology and an awareness of the perspectives of the various stakeholders involved must be established.

What is a BCI?

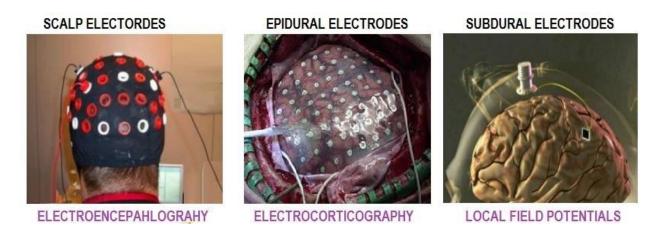


Figure 1. The three types of BCI electrode technologies: EEG, ECoG, and Implantable Electrode (Popović).

A brain-computer interface is a device that facilitates a direct communication link between electrical activity inside the brain and a computer. The computer may be used to either

write signals to the brain or read signals from the brain by measuring and/or sending varying electric potential patterns. In the case of reading signals from the brain, the BCI sends the measured electrical potentials from the brain through various amplifiers and noise filters to a computer, where the signals are decoded and interpreted as commands that can then be used to control various outputs that correspond to its user's desired task. Although advancements in BCI technology have enabled a limited amount of two-way communication, the read-type BCI is currently the more mature technology; because of this, read-only BCIs are the primary focus of this paper. Besides the distinction between BCIs, which are able to read from and write to the brain, there are an additional three categories of BCIs currently being developed: invasive, semi-invasive, and noninvasive. I will attempt to give a brief overview of each in order to give some context on why invasive BCIs, as opposed to their less invasive counterparts, are currently seen as the most practical technology for use in motor neuroprosthetics.

Invasive BCIs

Invasive BCIs feature hard (generally metal) electrode arrays. This electrode array is surgically implanted by removing part of the skull and inserting electrodes designed to penetrate the neural tissue into the motor cortex (the region of the brain responsible for planning and executing muscle movements). Invasive BCIs are capable of measuring electrical impulses of individual neurons (Rubin and Hochberg) and offer the best signal-to-noise ratios when compared to other BCI designs, thus allowing the best response times relative to noninvasive and semi-invasive BCIs (Dunlap et al.). However, despite invasive BCIs' superior signal-to-noise ratios, there exist concerns regarding whether these devices' signal quality can be sustained over a person's lifetime, as studies have shown that scar tissue may continue to build up around an invasive BCI's electrodes years after it has been implanted. This gradual increase in scar tissue

contributes to the deterioration of an invasive BCI's signal-to-noise ratio over time (Sharafkhani et al.).

Semi-invasive BCIs

Similar to invasive BCIs, most semi-invasive BCIs require the removal of part of the skull during installation. However, in contrast to the neural-tissue penetrating microelectrodes of invasive BCI designs, the electrodes used in semi-invasive devices are designed to lie atop the brain tissue. This electrode design relies on an EEG-based technology called electrocorticography (ECoG), the difference in the name signifying these electrodes' placement below the skull. Thus, while this electrode design carries similar risks to invasive BCIs due to the fact that an intrusive surgical procedure is required, semi-invasive designs have the benefits of better signal-to-noise ratios relative to noninvasive designs and better long-term signal stability compared to invasive BCIs. This is because, in contrast to invasive BCI electrodes, semi-invasive BCIs' non-penetrating electrode design is not as susceptible to scar tissue buildup around the device's electrodes.

Noninvasive BCIs

The second type, noninvasive BCIs, are electroencephalogram (EEG) based devices that feature electrodes designed to measure the changing electric potentials in the brain from the scalp. The primary benefit of this technology is that it is relatively inexpensive and safe; however, the drawbacks of EEG-based BCIs include that they require long and tedious training sessions, and the neural signals measured using this method are highly susceptible to pollution by environmental noise and changes in the skin's conductance due to sweat. These factors contribute to EEG-based noninvasive BCI design's low signal-to-noise ratios (Caiado and Ukolov). As a consequence of these EEG-based systems' susceptibility to noise, complex signal

processing must be employed to extract useful signals from EEG-based BCIs. This additional signal processing contributes to substantial delays in reaction time and increases the chances of erroneous BCI output. These aspects of current noninvasive, EEG-based BCIs render these devices impractical for everyday use (Baranauskas). However, despite the technology's current shortcomings, Edelman et al. have suggested that recent developments in the performance of AI pattern recognition and GPU processing may show the potential to increase the performance of noninvasive EEG-based devices significantly enough that the use of these noninvasive devices may become more practical and widespread in the future (Edelman et al.).

In summary, despite the risks and uncertainties associated with invasive BCIs, invasive BCIs are currently seen as the most viable solution for practical use. This is largely due to their ability to capture higher-quality neural signals, which leads to improved accuracy and faster response times for users compared to less invasive alternatives (Dunlap et al.).

Major Stakeholders and Their Perspectives

A decision regarding whether the BCI devices in clinical trials should be allowed to enter clinical use should center around the various stakeholders affected by this decision. In considering this ethical issue, I have identified seven relevant stakeholders and aim to briefly outline their perspectives.

Quadriplegic Patients

Firstly, and most importantly, of primary consideration are the people that this device is designed to help. Life as a quadriplegic is a significant challenge. Quadriplegics may suffer from a variety of physical health concerns due to their disability, like pressure sores, ulcers, and infections, due to their inability to change their position and less frequent skin hygiene (Kotler, Ingersoll). Additionally, quadriplegics may suffer from depression and a lower sense of self-

esteem (Blanes et al., Khazaeipour et al.). They may also feel that they are a burden due to their heavy dependence on others for care (Wright 46). Similar to people without quadriplegia, quadriplegics strive to lead a meaningful life by forming deep bonds with friends and family and engaging in various hobbies (Manns).

Caretakers

The mood of the quadriplegic patient affects the mood of their caretakers and vice versa. The quadriplegic caretakers desire that the person they are caring for is content and stays positive. They may have a stressful life due to juggling their other day-to-day tasks along with caring for their quadriplegic patient/loved one. Since they desire the best for their patient, they will likely encourage their patient to choose whatever path their patient believes will best improve their quality of life.

Engineers & Scientists

The engineers and scientists creating this invasive BCI device want to see their hard work put to good use for the benefit of others. They have put much effort into developing what they believe to be a safe and efficacious product. They desire to strike a balance between feasibility and innovation while holding uncompromisingly to the relevant ethical standards.

Government Regulators

Similar to the engineers, government regulators also desire to strike a balance between encouraging innovation and ensuring high safety standards are maintained in the process of invasive BCI development.

Medical Professionals

The medical professionals involved in implanting this device desire that these devices are safe, effective, relatively straightforward to service and install, and are capable of providing long and reliable service to their patients.

Company Leadership and Investors

The leadership and investors in the companies developing invasive BCI technology have funneled millions of dollars into this product's research and development. They have strong motivation to bring this product to market so they can finally reap the financial benefits of their investment. However, they also realize that the product they are funding must prove safe and effective to establish their company's reputation, thus ensuring its ability to provide long-term financial benefits.

The Department of Veterans Affairs

The Department of Veterans Affairs has historically sponsored the research and development of BCI technology due to its potential to help restore independence to wounded veterans (BrainGate). This suggests that the Department of Veterans Affairs is also motivated to ensure BCI technology is safe, reliable, and effective, and will likely continue to fund research efforts whose goal is to advance BCI technology in these areas.

Method

The primary ethical framework I have chosen for this analysis is reflexive principlism.

The reason why I have chosen reflexive principlism is that it offers a patient-centered approach that balances structured ethical principles based on the ethical theories of deontology, consequentialism, and virtue ethics while still allowing sufficient contextual flexibility to promote a nuanced analysis of complex ethical issues such as the question of whether BCIs should be allowed to be commercially available.

Analysis

Now that an ethical framework with which to analyze the question of whether or how invasive BCI technologies should be allowed to enter widespread clinical use has been established, three additional aspects must be considered before the final recommendation is made. Firstly, the ethical considerations relevant to current invasive BCI technology will be presented and discussed. Secondly, a specialization for how the four principles – respect for autonomy, nonmaleficence, beneficence, and justice – relate to invasive BCIs will be established. Thirdly, some of the ethical concerns related to invasive BCI devices will be compared to devices with similar ethical considerations in widespread use. Finally, the options that will be considered for the final recommendation will be presented.

Ethical Considerations of Invasive BCIs

There are six main ethical considerations of invasive BCI technology that must be considered when assessing whether invasive BCI devices should be released to the public. These considerations center around invasive BCIs' safety, efficacy, cybersecurity, continued relevance, upgradability/repairability, and cost.

Safety

The first issue of major concern is the safety of the invasive BCI electrode implantation procedure and the long-term effects of the device. A major issue related to the safety of microelectrodes is the brain's foreign body response, which is triggered by the initial trauma of the electrode insertion. This reaction works to encapsulate the implant with scar tissue (Collinger et al.; Dunlap et al.). The insertion of the microelectrode array also damages the blood-brain barrier, an essential protection mechanism for the brain that protects the brain from exposure to pathogens such as viruses and bacteria. Damaging this barrier not only heightens the risk of

irreversible brain damage caused by an infection entering the brain but may also increase the risk of future brain hemorrhage. Furthermore, damaging the brain's blood vessels exacerbates the brain's foreign body response, potentially leading to chronic inflammation that may further damage brain tissue and degenerate the signal quality recorded by the microelectrodes (Ferguson et al.).

Another factor that contributes to inflammation is that current invasive BCI designs use microelectrodes that are tethered to the skull via their wired connections. This design has been demonstrated to cause additional mechanical strain on the brain tissue and stimulate a sustained foreign-body response around the implantation site, causing further damage to the surrounding brain tissue. Ferguson et al suggest that this design choice is significant enough that such tethered designs should not be approved for clinical use.

Despite these risks, the microelectrode implantation procedure has demonstrated a clean safety track record thus far. As of April 2025, about 100 people worldwide have received implanted BCIs (Regalado). While comprehensive long-term outcomes are not available for all these patients, a study of 14 adults implanted with Blackrock Neurotech's Utah array – BlackRock's proprietary implantable microelectrode array design – between 2004 to 2021 reports a very low rate of adverse medical events. According to a press release published by the Massachusetts General Hospital, none of the reported medical events were serious enough to warrant removal of the microelectrode array, and the most commonly reported issue related to the device was skin irritation around the implant site. This report concludes by suggesting that these results may indicate that this implantable electrode array technology may have a level of safety comparable to other chronically implanted devices currently in clinical use, such as deep-brain stimulators (Chase, Rubin and Hochberg).

However, the length of these devices' implantation must also be considered. In many of the clinical trials involving Blackrock Neurotech's Utah array, participants' electrode arrays were removed after only a few years due to safety concerns. Currently, the longest record for wearing an implantable electrode is held by Nathan Copeland, who has worn a NeuroPort BCI device for ten years (Mullin, Copeland). While this is a noteworthy milestone, it falls short of demonstrating the long-term safety of a device that should be designed to last a lifetime.

Efficacy

The expense and risks of invasive BCI implantation warrant that the implanted device provides its users with a lifetime of service. Whether current invasive BCI systems are able to fulfill this expectation must be weighed when considering whether these devices should be adopted for widespread clinical use. One issue that may hinder this device's long-term effectiveness is that small motions of the brain called micromotion, caused by small continuous movements such as breathing, pulsing blood vessels, and the user's head and body motion, may result in small amounts of shifting between the electrodes and their surrounding brain tissue. If present, this micromotion between the hard electrodes and the brain tissue may contribute to continued scar tissue growth around the electrodes. As this scar tissue increases over time, it increases the resistance between the electrodes and the neurons, causing a reduction in the BCI's neural signal-to-noise ratio (Sharafkhani et al.).

Researchers hope to mitigate this problem by using materials that more closely match the softness of the brain tissue, such as the flexible polymer-coated threads used by Neurolink's BCI (Musk et al.). However, the success of the materials the scientists and engineers at Neurolink have chosen in maintaining long-term signal stability and reducing scarring is still unknown.

Finally, an additional issue that may affect invasive BCIs is that a person's ability to use the BCI may vary due to variations in an individual's brain structure and function (Becker et al.). The inability to control a BCI is dubbed BCI illiteracy by researchers. The existence of the phenomenon of BCI illiteracy suggests that certain people may have a more frustrating experience, or may be unable to use this device at all. This raises further concerns regarding this device's wide applicability.

Cybersecurity

Since invasive BCI devices directly interface the human brain with a computer, and because of the sensitivity of the information stored in and processed by the mind, it is natural to worry about the type and amount of information that might be extracted from it by malicious third parties. With current read-only BCI devices, the amount of information that can be extracted mostly has to do with patterns in a quadriplegic's desired muscle commands (finger or tongue movements, for example), so, while there does exist a concern that the data collected and processed by the BCI could be compromised and/or the device being controlled could be hijacked by a malicious person, the amount of useful information a hacker could extract from this device is limited by the fact that the device reads signals only from a specific region of the brain: the motor cortex. This means that a hacker using the information extracted might be capable of predicting at most the user's cursor movements ("Brain-Computer Interface: No Open Brain Surgery Required"). So, while a cybersecurity concern exists, the security risks of current BCIs have been compared to other implantable medical devices currently in clinical use, like pacemakers, deep-brain stimulators, and insulin pumps (Schroder et al.).

Continued Relevance

In my prior discussion of noninvasive BCI technologies, I alluded to the fact that some sources have suggested that advances in machine learning and machine learning hardware could render current, invasive BCIs obsolete in the future. While it is difficult to gauge exactly how likely it is for such advancements to come to fruition, this unknown does highlight a valid concern: that is, whether technological advancements in the next ten years could close the performance gap between invasive and less invasive BCIs. Currently, invasive BCIs are still viewed as the most feasible option for real-time control due to their substantially higher signal-to-noise ratios relative to noninvasive BCIs (Liu et al.). However, the consensus seems to be that there are substantial performance gains that will be achieved in the future as better materials are employed for the electrodes and greater knowledge is developed regarding the function and structure of the brain (Jiao et al., Baranauskas, Lim et al.).

Upgradability/Repairability

Because BCI technology is expected to advance significantly in the next few years, and due to the invasive nature of the implant procedure – as well as the expectation that these devices should last a lifetime – it is important that these devices are designed in a way that they can be repaired and/or upgraded if necessary. Currently, the electrode array design used in Blackrock Neurotech's BCI cannot be reimplanted in the same region in the brain from which it was removed, as this would risk further mangling the area damaged by the initial implant procedure (Dunlap et al.). While it is unknown, it is unlikely that Neurolink BCIs' flexible electrodes allow reinsertion for the same reasons. This suggests that current BCI electrode designs generally lack upgradeability and repairability post-implantation. While this issue may not be as critical for optimal electrode designs, as the current gaps in neuroscientists' understanding of the brain's

function and structure are filled, future electrode designs will likely be developed that are better optimized for the brain's structure and efficient signal extraction (Baranauskas).

Cost

When making an assessment regarding whether invasive BCIs should be released to market, it is important that an assessment is made on whether this device's cost is attainable for anyone whose quality of life might benefit from this device, so as to ensure equitable access for all people with quadriplegia to this technology. Since these BCIs are still at the beginning of their clinical trials, it is difficult to estimate how expensive these devices would be if they were made commercially available. However, using implantable neurotherapeutic devices such as deepbrain stimulators as a reference allows a rough estimate regarding the cost of BCI installation surgery. Based on the cost of deep-brain stimulator implantation, the BCI installation surgery could cost at least \$25000, not including the cost of the device (Canadian Agency for Drugs and Technologies in Health). The cost of the BCI is difficult to estimate. Currently, Blackrock Neurotech sells its NeuroPort electrode array system to hospitals for research at around half a million dollars (Rao). A company executive at Neurolink suggested in an interview that their BCI device would be expensive on release but over time could decrease to "a few thousand dollars" ("Elon Musk talks Neurolink price (interview)"). While the final cost of a BCI device remains difficult to estimate at this early stage in these devices' vetting process, the consensus seems to be that if the device passes its clinical trials and is released, the initial cost would be substantial. Specification of the Four Principles in Relation to BCIs

To facilitate the clear application of the four principles of reflexive principlism to the ethics of allowing invasive BCIs to enter into widespread clinical use, the four principles –

respect for autonomy, nonmaleficence, beneficence, and justice – must first be specified in relation to the problems that arise with invasive BCIs.

Respect for Autonomy

An invasive BCI design that is designed to respect its user's autonomy should maximize its benefits by enabling its user greater control over their environment while minimizing infringements on its user's autonomy by enabling secure storage and handling of usage data and supporting standardized electrode interfaces so that the user is not restricted to having a particular brand of BCI imbedded in their body and can freely choose which BCI device interfaces with their mind. To further avoid infringements of a user's autonomy, the invasive BCI design should ideally also be removable in the event that the user no longer wants the device.

Nonmaleficence

Although it would be ideal if implanting invasive BCIs carried no risk, this would likely be an unreasonable specification, as the nature of an invasive BCI's design requires that electrodes be implanted into the brain tissue, so, rather than suggesting that the risks associated with invasive BCIs be removed altogether, I would define a non-maleficent invasive BCI design as a design that minimizes the amount of damage to the brain tissue and decreases the long term risks associated with the implanted electrodes by employing a design which minimizes the micromotion between the electrode and the brain tissue. This minimization of harm could be done by designing the electrodes with materials that have a similar elasticity to the brain tissue and redesigning the electrode array so that it uses a floating design rather than a design where the wires are tethered to the skull.

Beneficence

With respect to beneficence, the goal of a BCI is relatively straightforward: this device should provide its users with a reliable method of interfacing and controlling various external devices. Current invasive BCI designs in clinical trials by Blackrock Neurotech and Neurolink have already demonstrated the ability of invasive BCI designs to control wheelchairs, computer cursors, and robotic arms (Vilela and Hochberg).

Justice

Ideally, this device would be relatively affordable and covered by insurance so that it is attainable for anyone who might benefit from this device. However, while this device does aim to provide a significant quality of life improvement to people living with quadriplegia, it is not a life-saving technology. Therefore, other factors besides the device's initial cost should be prioritized, such as the device's long-term stability, relevance, and responsiveness. Additionally, it is common for medical devices to be expensive when first released and then become more affordable over time as economies of scale and competitive pressures help to drive their costs down. This is likely what would happen if the invasive BCI devices being developed are made commercially available, as several companies already exist actively developing these devices. Because of these factors, it would be reasonable to expect that this device could become widely accessible a few years after its initial release, enabling equitable access to this technology. *Options*

There are three options that I will consider regarding whether the benefits of this invasive BCI technology outweigh its risks and should be allowed to be commercially available.

The first option would be to allow current BCI technologies to enter the market once they have proven their safety and efficacy in clinical trials. This option would have the potential benefit of fueling further developments in BCI technology by providing a source of profit for the

companies developing BCI technology. Additionally, this approach could contribute to making invasive BCIs more accessible and affordable by fostering increased production and demand, leading to economies of scale that drive down costs. The drawbacks of this approach would be that patients who receive this implant would be implanted with a device whose ability to maintain a high signal to noise ratio over a lifetime is questionable and whose level of performance will likely be eclipsed when future discoveries about the brain's structure will enable BCI designs that are better optimized for the human brain.

The second option would be to make stipulations regarding invasive BCIs' safety and performance that must be fulfilled by the invasive BCI's design before it is allowed to be made commercially available. The benefit of this approach would be that, if these performance goals are achieved, the resulting product would be more mature and could provide the device's users with a safer, more intuitive, and reliable implant. The possible cons of this approach could be that the stipulations put forward are not achievable and the device's development would be smothered, halting the development and adoption of a technology that has significant potential to improve the lives of people living with quadriplegia. Even if the development is not smothered, this approach could possibly significantly delay the release of this device. An additional risk is that even if the stated design improvement goals are met and the invasive BCI is made commercially available, the changes made would likely raise the initial price of this BCI, which could harm the chances of this device's price becoming widely attainable in the future.

The third option would be to determine that the benefits associated with invasive BCI designs are not worth the risks of this design, and therefore, the resources used in the development of invasive BCI designs should be directed towards improving safer, less invasive BCI designs. The benefit of this approach is that this would eliminate the risks associated with

invasive BCIs; however, the drawbacks with this approach would be that it would substantially shrink the possibility of practical and performant BCIs entering the market in the near future.

Recommendation

The approach I believe yields the best outcomes for all stakeholders is the second option: regulatory bodies establishing performance goals for invasive BCI designs. When thoughtfully defined, these goals can set a baseline standard for BCI performance, ensuring that devices are not only safe but also capable of delivering reliable, long-term functionality for users.

Two key standards should be implemented and enforced. First, invasive BCI designs should incorporate a floating electrode design instead of a tethered electrode array, as the latter presents a risk of ongoing brain tissue damage and neuron loss due to the relative movement between the brain and skull that causes motion between the electrodes and the brain tissue (Wang et al.). Second, a standardized assessment method for BCI microelectrode materials should be developed such that a minimum threshold for the acceptable level of scar tissue formation over a person's lifetime can be clearly established. This would help ensure long-term stability between the electrode material and brain tissue and preserve consistent performance.

While further performance goals could be added, I believe that any additional requirements would risk stifling this technology's development. On the other hand, I believe that imposing too few requirements would risk allowing a device whose short-term benefits do not displace the long-term issues that current devices offer. Thus, I view the standards I present here as the minimum standards that an invasive BCI device should meet.

From the perspective of the four principles in reflexive principlism, my recommendation places the most emphasis on beneficence and nonmaleficence towards the device's users. The standards I propose are designed to ensure an invasive BCI's performance over the user's

lifetime, enabling its users to benefit from reliable and consistent functionality while minimizing long-term brain tissue damage caused by the implanted electrodes.

Since invasive BCIs are intended to restore a certain amount of control to individuals with quadriplegia, I believe these recommendations also best respect the autonomy of the user. Although my recommendation does not contain explicit stipulations mentioning removability/upgradability standards, I argue that, while these standards may be ideal, adding such restrictions would likely be unrealistic given that many currently available implantable medical devices are not designed with removability in mind and this goal may also come in conflict with the stipulation that the material used by the device should create a minimal amount of scarring.

With respect to justice, I believe that my recommendation supports equitable outcomes by not placing too many restrictions on the required functionality. I believe this approach will strike a balance between affordability, reliability, and performance, and should not prevent the device from becoming attainable.

In summary, while I do not believe that current invasive BCI designs are ready for widespread clinical use due to concerns about their long-term reliability, I believe that setting clear performance-based standards for invasive BCI designs will ensure the best outcomes for the patients and promote safe and reliable BCI technology without smothering innovation.

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