

TECHNOLOGY AND ETHICS

Help, hope, and hype: Ethical dimensions of neuroprosthetics

Accountability, responsibility, privacy, and security are key

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rain-controlled prosthetic robots that restore independent activities of daily living to paralyzed people are about to enter everyday life environments (1). The regained ability to grasp a cup of coffee, hand over a credit card, or sign a document with a pen (1) enhances the independence and self-determination of severely paralyzed individuals. However, introducing devices controlled via brain-machine interfaces (BMIs) into everyday environments, possibly enhancing the capabilities of ablebodied people to interact with digital devices, raises a number of ethical and social challenges in the areas of (i) autonomy, responsibility, and accountability; (ii) data security and privacy; and (iii) managing end-user expectations about a promising field of medical advances. We here take a closer look at these issues and suggest some possible answers to addressing them.

The use of BMIs shares some ethical issues with other modern tools, such as sophisticated smartphones and semiautonomous systems (e.g., self-driving cars). But there are unique concerns about BMI technology: Although effortless interactions between mind and machine seem intuitively appealing, creating direct links between a digital machine and our brain may dangerously limit or suspend our capacity to control the interaction between the "inner" personal and outer worlds. For many, such a scenario raises fundamental, even existential, fears—including the fear of losing privacy and autonomy and of self-dissolution.

These fears may seem exaggerated in light of the current state of the art of BMIs, but given the exponential growth of the field over the last decades (I-7), we should anticipate that technological feasibilities might change rapidly. Rather than neglecting such possibilities as being too far-fetched, current decisions and technical developments should be informed by such eventual scenarios.

For example, the highest information readout of currently available BMIs is a tiny fraction of the information transfer rate via normal sensorimotor channels and the information processed in the brain (8). However, development of advanced sensors [e.g., (9)], allowing brain activity to be recorded at higher spatial resolution, coupled with advances in machine learning and artificial intelligence, could substantially enhance BMI capabilities in the near future and overcome the input-output constraint. This could enable more in-depth "mind-reading," i.e., classification of brain states related to perceptions, thoughts, emotions, or intentions.

RESPONSIBILITY AND ACCOUNTABILITY

In some sense, BMI-controlled devices might be seen as just another tool (*10*, *11*). However, inclusion of more and more autonomous components into the tools (*12*) transforms their operation into an endeavor of shared control. Where do we draw the line between the responsibility and accountability of the user and the manufacturer in such systems?

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Will brain and/or neural control of a prosthetic hand soon be a commonplace?

brain processes occur unconsciously, and the highly complex computations in the brain are difficult to resolve. Human accountability for injuries caused in the use of such a symbiotic robot might occur in several ways. First, where there is a form of "veto" built into the system [e.g., override through voluntary ocular movements (*I*)], a person could be held liable for failing to exercise the veto, just as a driver may be responsible for failing to apply brakes.

Second, using an unpredictable or poorly controllable semiautonomous robot in circumstances posing a risk of injury may be viewed as negligent (e.g., using it to pick up a baby, versus using it for other, less-risky activities). Holding people responsible for injuries they inflict despite their lacking capacity or control at the time of the injury is consistent with theories of moral and legal responsibility (13), e.g., holding a driver responsible for injuries caused during an epileptic seizure if the driver knowingly failed to take antiseizure medication properly (14). Accordingly, the user's responsibility may transfer from the earlier to the later time if harm from the inappropriate use of the device in the circumstances was reasonably foreseeable, and the user had cognitive control over the risky choices that resulted in an injury.

Third, manufacturers of potentially risky tools bear moral and legal responsibilities related to design, manufacture, and marketing (including risk disclosure). Legal systems usually tolerate a certain level of risk in many products, although reasonable steps to minimize risks, including education of users, are often expected.

We propose that any semiautonomous system should include a form of veto control. This could be a useful adjunct to address some current weaknesses of direct brain-machine interaction. The circumstances under which it will be safe, ethical, and legal to use the systems depend on the reliability of the veto signal and the conditions under which it can effectively mitigate possible risks. A device that continuously records all relevant system parameters could help to distinguish malfunctions from misuse in possible legal cases. Such continuous surveillance, however, can be privacy-invasive and is arguably discrimi-

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natory, given that such information is not collected or available from the many non-BMI users.

SECURITY AND PRIVACY

As soon as a biological signal is electronically amplified, the resulting signal can be intercepted and manipulated. There is, to our knowledge, no established technological solution for this problem. Amplified biological signals are often transmitted wirelessly (e.g., Bluetooth or Wi-Fi) without secure communication protocols. Permanent use of a BMI in everyday life environments could be a considerable source of potentially sensitive data related to neural activity. These data could be valuable for research but also raise questions regarding data security and privacy. How and where can data be encrypted and stored? Which standard of encryption would be acceptable and necessary? Who should have access to these sensitive data?

Fortunately, we can begin applying solutions from other fields, e.g., digital communication, that face similar challenges. These include rigorous implementation of the highest data encryption standards and information-hiding methodologies, as well as network security measures, e.g., firewalls or intrusion prevention systems.

The availability of sensitive neuronal data becomes particularly problematic in the use of BMIs for the completely paralyzed (6). Here, successful system calibration might depend on brain responses related to personal, closed-ended questions provided by the patient's family (e.g., "your daughter's name is Emily"). In such a paradigm, a strict data protection code has to be established for all involved persons comparable to codes for sensitive medical information.

Regardless of the eventual data security, BMI users should know the kind of data that are recorded and stored and understand the range of personal information that can be inferred. Companies providing BMI hardware should protect the amplified signals and ensure that the data are safe from unauthorized access. Alternatively, they should clearly state that data recorded with their devices are not protected from misuse.

There have also been concerns about malicious hacking of neural devices and calls for secure computer design principles in neural engineering ("neurosecurity") (15). Besides data security, the possibility of "brainjacking," i.e. malicious manipulation of brain implants (16), represents a serious threat.

Although BMI systems intended to restore movements or communication to people with paralysis seem a less appealing target for hackers, this may change with increased availability and scope of BMI technology and the status of the users (e.g., paralyzed politicians). The potential for hacking biomedical devices with possibly fatal consequences has been demonstrated for insulin pumps and implantable cardiac defibrillators (17). Some hackers could attack BMIs simply for gratification, to demonstrate the skills, or as a technophobe statement.

MANAGING EXPECTATIONS

Impressive demonstrations of BMI technology (4-7) have so far involved relatively few participants. Many of these people did not require a BMI to restore such functions because they could control the prosthetic devices with other biosignals, such as muscle activity or eye movements (7). There are reliable reports of only four persons worldwide with complete locked-in syndrome (CLIS; i.e., complete paralysis including eye movements) who could answer simple "yesno" questions (5, 6) on the basis of signals recorded with near-infrared spectroscopy monitoring of cerebral oxygen saturation. In contrast to common beliefs, severely para-

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lyzed BMI users with locked-in syndrome reported a surprisingly high quality of life and a positive attitude toward living (6, 11). The fact that about 95% of all patients suffering from amvotrophic lateral sclerosis decide for end of life before entering CLIS suggests that making BMI available to such patients could drastically change their attitudes, from wanting to die to wanting to live. It was estimated that around 30% of people considered apallic or in a vegetative state are not correctly diagnosed but may in fact be locked-in and cognitively intact (18). This substantially increases the number of patients requiring BMIs and suggests that these issues (including fairness to access) are urgent. The majority of end users for medical neurotechnology belong to this lobbyless segment of the population. A German court sent an important legal signal by requiring a health insurer to reimburse for a BMI that restored communication in a CLIS patient (19).

The extent to which results from these limited studies can be generalized to larger and more diverse patient populations remains unclear, but the issues need to be addressed. Evidence that repeated use of BMIs could trigger neurological recovery and improve brain functions awaits larger confirmatory clinical studies (20). Accordingly, it is necessary to manage expectations of potential end users, caregivers, clinicians, scientists, and investors. This involves widespread responsibility, but particularly among the media, health care providers, and companies that promote and profit from neuroprosthetic technology.

We encourage improved health literacy and neuro-literacy in the broader society. Every citizen should be provided the basic understanding necessary for an informed choice. This includes public information, teaching in school, and teacher education. BMIs have restored autonomy and quality of life for many individuals, but the full capability and long-term effects on the human brain and mind remain unclear. The promise that noninvasive BMIs could improve brain functions like focus, attention, or concentration and could decrease distractibility in normal users requires sound and clear scientific evidence. Should society accept unlimited marketing of such BMI devices under possibly exaggerated promises, as long as they are safe and do no physical harm? Or must we take steps to protect end users from being exploited or exposed to possible side effects? The time is now to set the course and take actions to ensure beneficial and safe use for brain-machine interaction.

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