PM R 10 (2018) S244-S248

www.pmrjournal.org

Innovations Influencing Physical Medicine and Rehabilitation

Ethical Issues Surrounding a New Generation of Neuroprostheses for Patients With Spinal Cord Injuries

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Traumatic spinal cord injury (SCI) is a significant life event, one that often defines a fixed time point: life before SCI and life after it. However, the rise of new neuroprostheses may introduce a new point to this timeline, one that could be as precise as the injury itself: the restoration of volitional movement and perhaps even sensation. Neuroprostheses offer possibilities that may forever change physical and psychological experiences after SCI. Yet it is important to balance excitement about these possibilities with consideration of the ethical dimensions of the study and use of these technologies.

Previous work on the ethical dimensions of neuroprostheses has focused largely on the broader implications of these and similar technologies once they become more widely available [1,2]. In this article, we focus on the local issues of neuroprosthetic research in its current stage of development and their effects on research participants and cli006Eic patients after SCI. We highlight 4 ethical issues with novel neuroprostheses: co-investigatorship, explantation, off-target effects, and societal responsibilities. Through introducing these issues in the context of current research, our hope is to begin a conversation regarding these new technologies and to propose methods for ongoing consideration of ethical issues as this research progresses.

When the Research Participant Becomes a Co-Investigator

Acute, traumatic SCI traditionally is associated with loss. Loss of volitional movement, loss of sensation, loss of bowel/bladder control, and loss of independence may all accompany this condition [3]. However, in-depth research may introduce a gain to balance this loss: the role of co-investigator. Implanted neuroprostheses, especially the many new technologies involving brain—computer interfaces (BCIs), introduce the possibility of bypassing focal impairments in the nervous or musculoskeletal systems [4]. These BCIs can be used invasively [5] or non-invasively [6].

In their exploratory current state, significant training is required to tune interfacing neurons to specific patterns that can then be interpreted by computer algorithms and translated into functional end effector commands. Recently, this has been accomplished in patients with SCI by using the participant's brain to control peripheral functional electrical stimulation in their own muscles [7] and also in a bidirectional manner, in experiments in which a brain-controlled robotic arm directly conveyed sensory feedback from the robot back to the somatosensory cortex [8]. These applications, and the many that are still in early planning phases, require a significant investment in time and energy from the participant with the implanted device. This is needed not only to fine-tune the neuron firing patterns within the participant that are then read by the BCI but also to optimize the computer algorithms needed to decode these signals.

Given this intense training and time commitment from both participant and researchers, the participant gradually may become more of a co-investigator than a passive volunteer, exploring new scientific frontiers along with the research team and making scientific contributions by providing technical insights not otherwise freely available. Many participants, and the researchers pushing the knowledge boundaries alongside them, discuss their experiences in terms of this pioneering partnership. Ian Burkhart, who was one of the first participants in an experiment to connect a BCI to the limb of a person with paralysis, says, "I really can't complain about the way my life is right now. If nothing else, I can say I was the first person ever to do something, which is an opportunity I never expected to have" [9].

This novel role for the participant may provide a notable sense of self-worth and meaning but also can blur ethical boundaries. For instance, in a recent article reporting on the use of a BCI to control a robotic arm, the research participants, Tim Hemmes and Jan Scheuermann, are included in the publication as co-authors of the study, and the article includes descriptions by Hemmes and Scheuermann of their experiences participating in

1934-1482/$ - see front matter
https://doi.org/10.1016/j.pmrj.2018.05.020

the research [10]. It is likely that there are other studies in which participants played similar roles as Hemmes and Scheuermann but were not credited. The question remains at what threshold research participants become co-investigators proper, requiring due credit in publication. A retrospective review may be helpful to determine how common co-investigatorship has been and whether cases are increasing. Furthermore, ethical analysis is needed to determine in which cases co-authorship is an appropriate reflection of the working relationship and when it could be used to influence participant decisions within the study itself.

Indeed, numerous studies have shown that researchers and participants have divergent expectations and risk tolerance with regard to SCI research outcomes [11,12] and diverse functional priorities for BCI use [13]. Given these differences between participants, clinicians, and researchers regarding the purpose of such research, special protocols may be needed to ensure that expectations are discussed and disagreement is fairly adjudicated. Investigators especially will need to be on guard against novel biases and misconceptions emerging from this new form of researcher—participant relationship. In addition to preempting potential issues early on through recruitment procedures and informed consent language, additional outside review may be needed to address unexpected conflicts as they emerge throughout the research process.

The situation could become further ethically ensnarled when the experimental time period is over and the participant must transition away from their role as a pivotal team member on cutting-edge science to that of an outside observer. To date, there has not been any focused research on participants' potential feelings of loss from no longer being a part of an investigative team, or, comparably, beneficial feelings of pride from this experience. As BCI neuroprostheses become more popular, further research is needed to better quantify these psychosocial reactions, not just the raw neural signals reduced to device commands.

When Invasive Research Ends

Planned explantation of implanted neuroprostheses presents additional ethical issues. When experimental neuroprostheses are implanted, there are usually clear expectations that the device will be removed at a given time point due to increased risks of infection for the participant [14]. Current devices with implanted recording components also experience signal degradation from the innate foreign-body reaction over time around implanted electrodes [15,16]. Yet it is difficult to ensure that the participant (or the researchers themselves, for that matter) is truly informed as to what this explantation will mean at some future time point. At the very least, explantation often involves a potentially dangerous surgery, one that the participant could very reasonably refuse for health concerns alone.

However, an additional consideration is that of integration of these devices into a participant's self-image. Research has demonstrated that individuals with SCI often assimilate their wheelchairs as an extension of their physical bodies, a requisite extension of themselves to achieve needed mobility [17,18]. A similar phenomenon may occur with this next generation of even more closely integrated assistive devices (BCI), further complicating how we provide information for informed consent to these potential participants. Although participants may cognitively understand and be able to consent to research that will restore or replace their abilities to stand, walk, reach, etc, both researchers and participants may not understand the true psychological implications of abruptly taking those capabilities away. Rehabilitation medicine providers are intimately aware of the benefits to quality of life that seemingly incremental improvements in a realm such as hand function can have for patients. The ability to grasp a pen or text a loved one can provide an immense source of pride and independence. Being subsequently stripped of these abilities through explantation may prove a significant blow, reopening the wounds of the initial loss from traumatic SCI.

An eerily similar situation is that of removing ventilatory assistance from a dependent patient with acute SCI. In this setting, many ethicists, psychologists, and rehabilitation medicine providers have suggested that patients should undergo a "time-limited trial" to see what living with an SCI is truly like before such withdrawal of care [18]. These professionals argue that a patient in an acutely traumatic situation, often with little actual knowledge of what living with paralysis would be like, is poorly equipped to make an informed and life-ending decision to withdraw the ventilator. To some fractional degree, a participant agreeing to explantation of a neuroprosthesis before experiencing restoration of lost abilities—an experience that may be identity-altering in itself—may not be able to truly be "informed" as to what this will mean. Although proposing a time-limited trial of a neuroprostheses may not be an equivalent solution for this issue, acknowledgment during the initial consent process by researchers of the potential future internal conflict volunteers may experience may be helpful.

A further issue with explantation, which we also raise herein, is responsibility for device maintenance if explantation is not chosen. If explantation is refused by the research participant, do the researchers or sponsoring corporation have an obligation to make hardware or software available for use? A real-world example of this in the SCI medicine realm is the Freehand device. This implanted functional electrical stimulation device was marketed by NeuroControl Corp from 1993 to 2001 and stimulated individual muscles to improve tenodesis grasp for patients with cervical SCI. After NeuroControl