EDITORIAL

Challenges for translating implantable brain-computer interface to medical device

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Implantable brain-computer interface (iBCI) is currently a fast-growing field of active implantable medical devices.[1] To achieve direct communication between the brain and computers/machines, the iBCI collects neural signals by implanting electrodes (including electrocorticography (ECoG) electrodes) into the brain, enabling direct signal readings at the neuronal level. Due to the ability to collect high throughput and high spatiotemporal resolution neural signals, iBCI holds greater potential than non-invasive BCI in achieving real-time and precise brain-computer interaction and in clinical applications including deficit restoration/replacement and mental disorder diagnosis/treatment.

Figure 1. Translating implantable brain-computer interface to medical device faces multiple challenges.

A complete iBCI system consists of a neural information acquisition device (sensor), a neural information parsing device (processor), a functional execution device (effector), and a feedback training device (feedback). Specifically, the "sensor" is a critical component of a BCI system that utilizes neural interface technology to sense brain nerve signals, including the use of microelectrodes to record subtle electrical signals generated by neuronal activity. The "processor" filters and amplifies the analog electrical signals recorded by the "sensor", converts them into digital signals for preprocessing, extracts neural feature information through digital processing algorithms, and uses near real-time decoding algorithms to convert the extracted information features into understandable signals, completing neural information decoding. The "effector" receives decoded brain information from the signal processor and achieves the user's intention. Commonly used interactive devices include cochlear implants, intelligent wheelchairs, robotic arms, digital terminals, etc. Lastly, the iBCI system establishes an information communication channel between the brain and external devices, but "feedback" training is still needed to enable the brain to proficiently gain direct control of external devices. The principle is to use the built-in device to electrically stimulate the brain through closed-loop feedback training, reshape relevant neural networks, and establish new brain control functions.

These features together make translating iBCI technology to a feasible medical device challenging, which requires efficient integration of complex

components and improvement of algorithm and computing power. In the spirit of encouraging innovation and the urgent need for clinical devices to be launched as soon as possible, the Food and Drug Administration (FDA) of the United States released "Implanted Brain-Computer Interface Devices for Patients with Paralysis or Amputation-Non-Clinical Testing and Clinical Considerations" in May 2021.[2] This guidance provides an experimental device exemption (IDE) for iBCIs used in paralyzed or amputated patients, including devices connected to the central or peripheral nervous system to restore or replace motor function in paralyzed or amputated patients. In addition to previous medical device specifications, this guideline also adds new emphases on the collection of neural data, data security during transmission and analysis, as well as the need to train users (such as patients, surgeons, rehabilitation therapists, and nursing staff).

Following the guidelines, to promote the smooth development of iBCI, we list the major challenges and our perspective below (Figure 1).

(1) Data privacy and communication security: iBCIs collect a large amount of neural signal data, thus software for decoding and encoding signals is required during signal processing. It is important to ensure secure data access during the usage of the software and avoid any data leakage. Perform rigid tests to validate the functionality of the software. For auxiliary components controlled by software (such as electric wheelchairs, robotic arms, and other effectors), it is recommended to ensure secure communication and defend against any illegal control through networks.

(2) System modularization: A set of iBCI systems is composed of multiple complex components. It is challenging for any manufacturer to make all components parallelly with high quality on their own. Therefore, it is recommended to design the entire iBCI system on a modular basis, which gives advantages in design, manufacturing, and maintenance. For example, an iBCI system can be divided into multiple modules including sensor, processor, communicator, and effector, and different manufacturers can focus on refining one or more modules. All modules and configured devices must comply with mandatory regulatory requirements such as biocompatibility, sterility, pyrogen, electrical safety, electromagnetic compatibility, wireless technology, magnetic resonance compatibility, etc., to fulfill the requirement of medical device registration.

(3) Human factors engineering considerations: As a medical device, iBCIs should not only include hardware and software, but also medical service including providing usage instruction and feedback training plans. However, even if the devices are operated according to the instructions, risks may still exist during the operation by end-users (such as patients, surgeons, rehabilitation therapists, and caregivers). To overcome such operational safety risks, it is necessary to have a comprehensive understanding of user behavior, usage environment, and the potential environmental influence on device usage. Therefore, repeated usability evaluations must be conducted during the equipment design process. In addition, in a clinical application scenario, patients who implant with BCI devices need a caregiver who is willing and capable of performing basic assistance such as managing device startup and maintenance during home use, connecting the electrodes and starting the system, monitoring patients, and contacting a doctor if needed. Therefore, the safety awareness of caregivers and their ability to assist users should be evaluated. To popularize the usage of iBCI devices in home environments, users and caregivers must undergo sufficient and effective training before leaving hospitals.

(4) Sufficient observation cycles in clinical trials: When designing clinical trials, the research objectives and assumptions should be clearly defined. Select appropriate inclusion and exclusion criteria based on the target population and disease type, and determine the key endpoints, including primary safety endpoints, primary efficacy endpoints, and secondary efficacy endpoints. It is also important to perform a long-term follow-up to validate the safety and effectiveness of iBCI devices as durability and reliability are important factors for evaluating the therapeutic efficacy. For example, a clinical trial should reveal the long-term durability and reliability of the sensor module to detect neural signals over time after implantation.

(5) Affordability: Lastly, affordability must be considered before bringing a medical device to the market. The cost of an iBCI device, which may include direct and indirect costs, significantly determines users' choices, the market scope, and eventually the achievement of the product. For example, if only a tiny minority can afford the device and the affiliated service, there is zero chance that the device can succeed in becoming a regular medical device. Therefore, to provide commonly affordable devices and services, an enterprise should draw up a clear marketing strategy during the design and manufacturing process.

Overall, as a cutting-edge system in the field of active implantable medical devices, iBCI will inevitably face various performance and safety challenges, especially when the gap between our knowledge regarding the brain and the goal we are pursuing is still large. Nevertheless, iBCI technology is transitioning from scientific research to clinical applications, and multiple companies in the United States have obtained FDA's breakthrough equipment certification or entered the clinical trial. On the one hand, with the rapid progress of technologies such as micro/nano processing, microelectronics, power supply, and wireless communication, iBCI devices will continue to iterate and upgrade. On the other hand, with the development of artificial intelligence,[3] the application of iBCI technology improves the efficiency of data collection from the human brain, which in turn benefits the optimization of the decoding algorithm and deepens the understanding of the working principles of the brain.[4] These two wings together will bring a spiral rise to the development of iBCI devices. In the foreseeable future, by cooperating with patients, neurosurgeons, rehabilitation therapists, and nursing staff, the successful application of iBCI devices will no doubt achieve therapeutic effects. To further accelerate the translation of iBCI technology to medical devices, close communication must be maintained among device development and manufacturing enterprises, representatives of doctors and patients, academic professionals, and governmental agencies.[5] Through the joint efforts of all parties, the prospect of promoting the iBCI as an innovative medical device is promising.

REFERENCES

1. Nurmikko, A. (2020). Challenges for Large-Scale Cortical Interfaces. Neuron **108**: 259–269. DOI: 10.1016/j.neuron.2020.10.015.
2. Food and Drug Administration. https://www.federalregister.gov/d/2021-10622.
3. Huang, T., Xu, H., Wang, H., et al. (2023). Artificial intelligence for medicine: Progress, challenges, and perspectives. The Innovation Medicine **1**: 100030. DOI: 10.59717/j.xinn-med.2023.100030.
4. Shan, L., Huang, H., Zhang, Z., et al. (2022). Mapping the emergence of visual consciousness in the human brain via brain-wide intracranial electrophysiology. The Innovation **3**: 100243. DOI: 10.1016/j.xinn.2022.100243.
5. Qiao, J. (2023). Win-win cooperation for advancing medical innovation. The Innovation Medicine **1**: 100002. DOI: 10.59717/j.xinn-med.2023.100002.

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DECLARATION OF INTERESTS

The authors declare no competing interests.