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Development and Validation of a Fully Implantable Brain-Computer Interface System

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Introduction: Brain-computer interface (BCI) systems hold significant promise for restoring motor, sensory, and communication functions in individuals with neurological disorders. However, challenges such as miniaturization, biocompatibility, and high-channel-count neural signal acquisition remain critical barriers to clinical translation. Here, we present a fully implantable BCI system featuring advanced integration of high-density flexible electrodes, signal acquisition, and wireless communication technologies, designed to meet safety and performance standards for long-term implantation.

Material, Methods and Results: The system incorporates 256-channel or 1024-channel flexible electrodes with a custom-designed 256-channel signal acquisition integrated circuit (IC), a low-power Bluetooth chip, and a wireless power supply module. This configuration enables the acquisition, processing, and wireless transmission of up to 256/1024 channels of neural data. The system is miniaturized and highly integrated, utilizing biocompatible materials and advanced packaging techniques to meet implantable safety standards. Animal studies have been conducted to evaluate the safety and efficacy of the implantable BCI system. Results indicate successful neural signal acquisition and transmission with minimal tissue inflammation and no adverse effects observed during the study period. The system has demonstrated the capability to perform real-time neural signal processing and BCI control by the animals, which is a critical step towards its application in clinical settings.

Conclusion: We have developed a fully implantable BCI system that showcases high performance, miniaturization, and integration, suitable for long-term use in clinical environments. Preliminary validation in animal models has confirmed the system's safety and effectiveness. With the system's design meeting implantable device safety standards, we are poised to initiate clinical trials this year. The outcomes of these trials will be instrumental in determining the clinical utility of this BCI system for a variety of neurological applications.

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