DOI: 10.3217/978-3-99161-050-2-172

A Novel Fully Implantable High Data Rate BCI for Speech Restoration.

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Introduction: Brain-computer interfaces (BCIs) have demonstrated their ability to provide functional control of computing devices and to restore lost communication abilities for individuals with profound motor and speech deficits due to neural injury or progressive neuromuscular disease. Recently, these systems have achieved a level of performance high enough to enable restoration of interactive, conversational communication [1]. BCIs operating at these highest levels of performance are enabled by intracortical electrode arrays implanted in motor areas. Although BCIs are poised to address unmet clinical needs, current speech BCI studies utilize research devices with percutaneous components. We present a fully implantable, intracortical BCI system designed for clinical adoption while simultaneously supporting higher electrode counts that could facilitate increased BCI performance.

Figure 1: (Left) Rendering of the fully implanted intracranial BCI. (Right) Photographs of the Cortical Module (top) and Internal Transceiver (bottom).

Materials, Methods, and Results: The system is composed of a cortical module, lead, and an internal transceiver. A single cortical module has 421 intracortical microelectrodes (each 1.5mm in length, 40 µm in diameter) that are amplified and digitized on the module to allow for neural signal transmission over a subcutaneous lead. The internal transceiver form factor and implant procedure follow an approach similar to that of an implantable pulse generator of a deep brain stimulator. The internal transceiver receives power for the system with a wireless inductive link from an external, wearable transceiver. Broadband data are telemetered via a wireless optical communications link and support extraction of spiking, spikeband, and local field potential (LFP) based features. Power delivery and optical communications bandwidth are designed to support up to four cortical modules, or 1684 intracortical microelectrodes. Preclinical testing of the system is underway for safety, biocompatibility, and functionality. In 31 research ovine model procedures, zero serious device or procedure-related events were observed, and signal stability has been observed out to 2 years. Twenty-six week biocompatibility is currently supported in accordance with ISO10993. Chronic implantation of the cortical module in ovine auditory cortex yields both neuronal spiking and LFP features, and demonstrates a high bit rate readout of brain state. Neural features were validated based upon their signal characteristics and their dynamics with respect to auditory stimuli.

Conclusion: This system will be tested in a First-In-Human clinical study, under IDE, to investigate the feasibility of speech restoration in a population suffering from impaired communication due to a progressive neuromuscular disease or a neural injury.

Disclosures: Paradromics, Inc. authors hold company equity. VG holds equity in Neuralink Corp. DMB is an inventor on IP owned by UC Davis, and is an ad-hoc surgical consultant for Paradromics Inc.

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Published by Verlag der Technischen Universität Graz