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The Development of High-Performance Communication Neural Prostheses

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<u>Introduction</u>
Neural prostheses, or brain-machine interfaces, are an emerging class of medical systems designed to restore lost function to those suffering from paralysis, be it from injury or degenerative disease. Systems can range from communication prostheses that control computer cursors and keyboards to motor prostheses that manipulate robotic arms and wheelchairs. Over the last several years, gains in performance and reliability of these systems have been largely through algorithmic and system-level innovation of intracortical electrode array based systems.

<u>Methods</u>
We implanted two rhesus macaques with 96 channel Utah electrode arrays in motor regions of cortex (M1 and PMd) and trained them to make point-to-point reaches to navigate a cursor in a virtual world. We implemented a neural prosthesis using an algorithm we developed (ReFIT-KF) to control the cursor, resulting in more accurate and reliable cursor control versus conventional algorithms. Additionally, a hidden Markov model (HMM) was later run in parallel to the cursor control algorithm, enabling a "click" selection signal to be detected. System performance was measured via real-world metrics of achieved bitrate and typing speed (words per minute). System reliability was measured both by sustained performance within a day's session and across days, both with and without prosthesis recalibration.

<u>Results</u>
This system achieved bitrates of 4 bits per second (bps) and a typing rate of 10 words per minute (wpm) using a cursor driven solely by neural activity. When paired with the HMM, it achieved up to 6 bps and 15 wpm. Performance was reliable for hours across daily sessions. Furthermore, in one monkey, the prosthesis was stable for nearly two years without recalibration.

<u>Conclusions</u>
By improving communication neural prostheses from an algorithmic and systems perspective, we have significantly increased the performance and reliability of such systems, bringing them closer to clinically relevant translation.

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High Performance Communication Using Neuronal Ensemble Recordings from the Motor Cortex of a Person with ALS

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<u>Introduction</u>
Brain-Machine Interface (BMI) systems have the potential to restore communication, mobility, and independence for persons with paralysis, by translating neural activity into control signals for assistive devices. Recent demonstrations with non-human primates (NHPs) showed that BMIs using chronically implanted intracortical electrodes can achieve high-performance control of computer cursors; thus these systems could provide a rapid method of communication for persons with paralysis. Here we demonstrate the successful translation of one such system to a human research participant, yielding a high-performance communication interface used by a person with Amyotrophic Lateral Sclerosis (ALS).

<u>Methods</u>
A 50-year-old woman with ALS underwent implantation of an array of 100 silicon microelectrodes into the “hand knob” area of the precentral gyrus, as part of a multi-site pilot clinical trial (Braingate2, IDE). During weekly experimental sessions (2-3 days/week), the participant guided a computer cursor under neural control to acquire targets on a computer screen. Using a blinded study design, we compared the performance of the previous state-of-the-art algorithm (Velocity Kalman Filter, VKF) against a novel control algorithm developed through NHP research, “ReFIT”. After each experimental block, the participant subjectively rated its ease-of-use on a Visual Analog Scale (VAS). Finally, she used the BMI to communicate by controlling a standard assistive typing program.

<u>Results</u>
BMI control using the novel algorithm (ReFIT) showed a 20% increase in performance over the previous state-of-the-art algorithm in an 8-target acquisition task (1 sec/target vs. 1.2 sec/target, $p<0.01$). Further, the participant’s self-report described a near doubling in ease of use (2.3 vs. 4.2 on the VAS, $p<0.01$). Finally, using the novel algorithm, the participant was able to comfortably communicate at ~6 words-per-minute in a free-paced typing task.

<u>Conclusions</u>
BMIs based on recent algorithmic advances, such as ReFIT, can provide high-performance communication options, which would substantially improve quality of life for persons with paralysis.