

Advances in BCI: A Neural Bypass Technology to Reconnect the Brain to the Body

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1 Introduction

Millions of people worldwide suffer from diseases that lead to paralysis through disruption of signal pathways between the brain and the muscles. Neuroprosthetic devices aim to restore or substitute for a lost function such as motion, hearing, vision, cognition, or memory in patients suffering from neurological disorders. Current neuroprosthetics systems have successfully linked intracortical signals from electrodes in the brain to external devices including a computer cursor, wheelchair and robotic arm [1–11]. In non-human primates, these types of signals have also been used to drive activation of chemically paralyzed arm muscles [12, 13]. However, technologies to link intracortical signals in real time to a neuroprosthetic device to re-animate a paralyzed limb to perform complex, functional tasks had not yet been demonstrated.

We recently showed, for the first time, that intracortically-recorded signals can be linked in real-time to muscle activation to restore functional and rhythmic movements in a paralyzed human [14, 15]. We utilized a chronically-implanted intra-cortical microelectrode array to record multiunit activity from the motor cortex in a study participant with quadriplegia from cervical spinal cord injury. Then, using an innovative system of our design, signals from the cortical implant were decoded and re-encoded continuously, in real-time, to drive a custom neuromuscular electrical stimulation (NMES) cuff that enabled the patient to regain lost function. In essence, we have demonstrated an electronic ‘neural bypass technology (NBT)’ that has the ability to circumvent disconnected neurological pathways.

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Figure 1 shows the NBT system used by the participant. The system translates the patient's intentions to move his wrist and fingers into evoked movements that smoothly combine stimulated wrist and finger movements with voluntary shoulder and elbow movements and enables him to complete functional tasks relevant to daily living. Clinical assessment showed that when using the system, the patient's motor impairment level improved from C5-C6 to a C7-T1 level unilaterally, conferring on him the critical abilities to grasp, manipulate and release objects. This is the first demonstration of successful control of muscle activation utilizing intracortically-recorded signals in a paralyzed human. These results have significant implications in advancing neuroprosthetic technology for people worldwide living with the effects of paralysis.

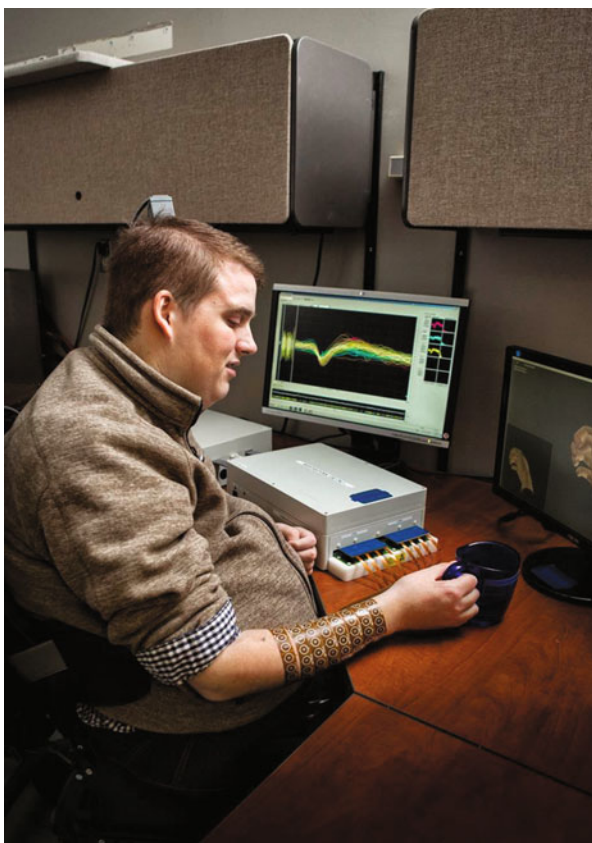


Fig. 1 Experimental neural bypass technology (NBT) system in use with the participant (seated in a wheelchair) in front of a table with a computer monitor

2 Methods

2.1 Study Design and Surgery

The neural bypass technology has been successfully demonstrated during a Food and Drug Administration (FDA) and Institutional Review Board (IRB)-approved study [14, 15]. The study participant is a 25-year-old male who sustained a C5/C6 level spinal cord injury (SCI) from a diving accident. At baseline (without the BCI), he retains the ability to voluntarily control shoulder and some elbow movements, but has lost finger, hand and wrist function. A 96-channel microelectrode array (Utah array, Blackrock Microsystems, Salt Lake City, UT) was implanted in the left primary motor cortex of the participant. As shown in Fig. 2a, the hand area of the primary motor cortex was identified preoperatively by performing functional magnetic resonance imaging (fMRI) while the participant attempted to mirror videos of hand movements. The NeuroportTM system was used to acquire neural data.

2.2 Novel Hardware and Software Development

The study required the development of novel hardware and software components. A custom neuromuscular electrical stimulator system was developed, including a high-definition, flexible, circumferential NMES cuff that adheres to the user's forearm. The cuff is comprised of up to 160 electrodes, allowing precise control of individual forearm muscles (Fig. 2b). The high number of electrodes not only allowed stimulation of isolated superficial forearm muscles but also enabled electric field steering to activate individual deep muscles. This combination proved essential for generating isolated finger movements as well as multiple forms of

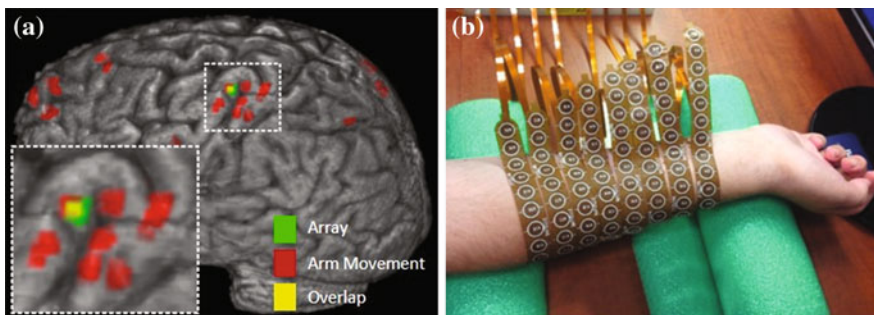


Fig. 2 Implant locations and NMES cuffs **a** Red regions are brain areas active during attempts to mimic hand movements, where the t-values for the move-rest T1-weighted fMRI contrast are greater than 7; The implanted microelectrode array location from post-op CT is shown in green; The overlap of the red and green regions is shown in yellow. **b** Neuromuscular electrical stimulation cuffs

functional grips. Electrical stimulation was provided intermittently in the form of current-controlled, monophasic, rectangular pulses of a 50 Hz pulse rate and 500 μ s pulse width. Pulse amplitudes ranged from 0 to 20 mA and were updated every 100 ms.

Software development included novel machine learning-based decoding algorithms that are robust to context changes (such as arm position), which allowed the participant to perform complex tasks using a combination of both non-paralyzed and paralyzed muscles simultaneously. Algorithms also included methods to remove stimulation artifacts from the neural data due to electrical stimulation being applied to the arm, giving the participant the ability to start and stop stimulation at will. Our approach to intra-cortically recorded neural data was also innovative: Instead of using single unit activity, which is known to decline over months, we used a wavelet decomposition method to approximate multi-unit neural activity. Wavelet decomposition has shown to be an effective tool in neural decoding applications and provides information encompassing single unit, multiunit, and LFP, without requiring spike sorting [16]. In this study, four wavelet scales (3–6) were used, corresponding to the multiunit frequency band spanning approximately 235–3750 Hz to estimate a feature termed mean wavelet power (MWP). This allowed for recording and analysis of signal features that were detectable and robust over time, providing the potential for a system that could be used for long term applications.

2.3 Participant Sessions and Neural Decoder Training

The study sessions with the participant were typically conducted three times per week, lasting approximately 3–4 h. Stimulation patterns were first calibrated for the desired movements. Decoders were trained for a given movement by asking the participant to imagine mimicking hand movements cued to him by an animated virtual hand on a computer monitor. The neural decoders were trained in training blocks, each consisting of multiple repetitions of each desired motion. This full set of data was used as input for training a nonlinear Support Vector Machine (SVM) algorithm to generate a robust set of decoders. A decoder for each motion (against all other motions and rest) was built using a nonlinear Gaussian radial basis function kernel [17] to process this full set of data and a non-smooth SVM algorithm that uses sparsity optimization to improve performance [18]. During the test period, all decoders ran simultaneously and the decoder with the highest output score above zero was used to drive the NMES.

3 Results

The applicability of NBT was demonstrated in three different contexts, highlighting different facets of the technology. In the first experiment, the participant was asked to mimic a virtual hand on a computer screen in front of him. The virtual hand cued him to perform six different movements with his right hand: thumb extension, wrist flexion, wrist extension, middle finger flexion, thumb flexion, and hand open. Each movement was cued five times and the presentation order was randomized so the participant could not anticipate the next movement. The participant was able to successfully achieve the movement on 29 of the 30 cues, although he was not always able to maintain the movement for the duration of the cue. Overall, he was able to match the cue $70.4\% \pm 1.0\%$ (mean \pm S.D., $P < 0.01$ by permutation test) of the time. Examples of neural modulation, decoder output, and physical movement for each of the six cues are shown in Fig. 3. This was the first demonstration of a tetraplegic human regaining volitional control of six distinct hand and wrist movements with an intracortical BCI system.

The second demonstration used the Graded and Redefined Assessment of Strength, Sensibility, and Prehension (GRASSP) test [19] to quantify the participant's sensorimotor impairment level both with and without the neural bypass system. Five domains were evaluated; strength, dorsal sensation, ventral sensation, gross grasping ability (qualitative prehension), and prehensile skills (quantitative prehension). Since the NBT was only expected to improve motor function and not sensory outcomes, we focused on the strength, quantitative prehension and qualitative prehension measures.

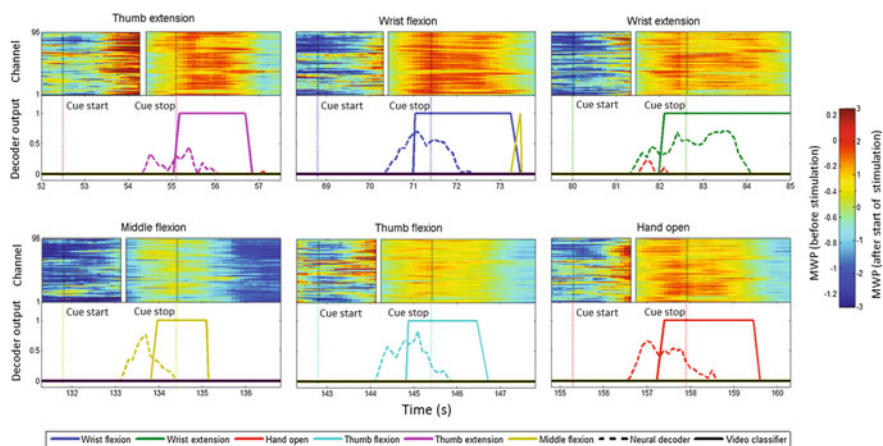


Fig. 3 Mean wavelet power and system performance for individual hand movements For each movement, (*top*) heat maps of MWP and (*bottom*) neural decoder (*dashed line*) with physical hand movements (*solid line*). The vertical *dashed lines* indicate the start and end of the movement cue, while the break in the heat map indicates when the stimulation turns on. When the stimulation is on, we introduce stimulation artifacts into the data, hence the modified color scale. These artifacts can be partially removed as detailed in Bouton et al. [14]

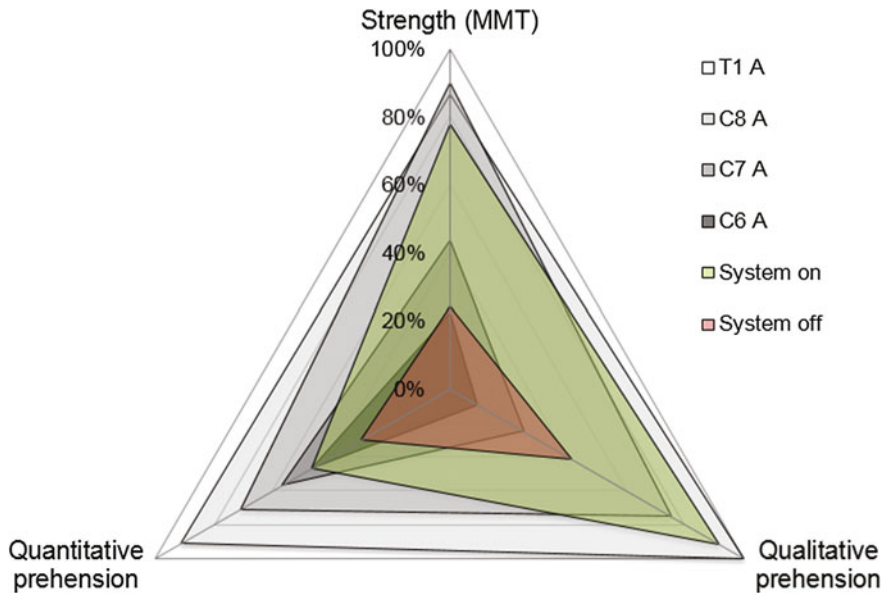


Fig. 4 GRASSP performance on the three motor function domains The *brown* triangle shows the participant’s baseline score without the use of the system, and the *green* triangle shows his scores while using the system. The *grayscale* triangles show the International Standards for Neurological Classification of Spinal Cord Injury and the American Spinal Injury Association Impairment Scale for comparison

Figure 4 shows that when the participant used the NBT, his Manual Muscle Test (MMT) strength improved from C6 to C7–C8 level, his gross grasping ability improved from C7–C8 to C8–T1 level, and his prehensile skills improved from C5 to C6 level. Taken together, these results quantify the improvement the participant gained while using the system, and suggest that a system that users could take home would significantly improve their ability to live independently.

Finally, the participant demonstrated that he could use the system to complete complex functional tasks that are relevant to tasks of daily living. The functional task required him to pick up a bottle, pour the contents of the bottle into a jar, replace the bottle, then pick up a stir stick and stir the contents of the jar (Fig. 5). This task required the participant to combine his residual shoulder and elbow movement with three hand movements using the NBT (hand open, cylindrical grip, pinch grip). We observed differences in neural patterns when the participant was performing shoulder and elbow movements, which necessitated including those movements in the training process to assist in building robust decoders.

In this study, for the first time, a human with quadriplegia regained volitional, functional movement using intracortically-recorded signals linked to neuromuscular stimulation in real-time. Using our investigational system, our C5/C6 participant gained wrist and hand function consistent with a C7/T1 level of injury.

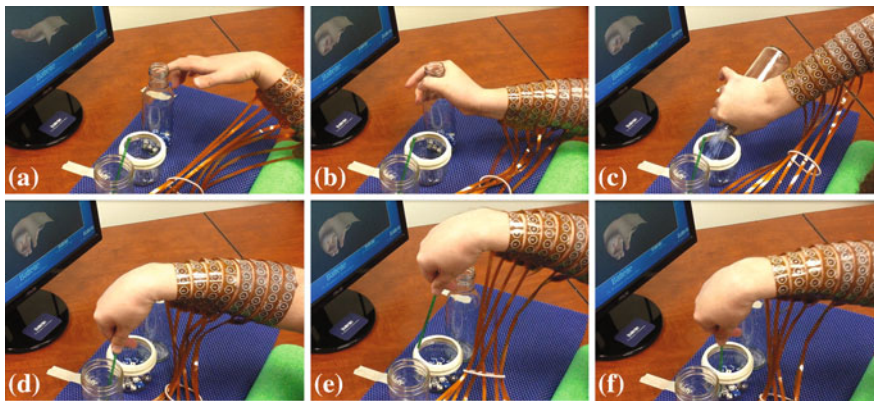


Fig. 5 Grasp-pour-and-stir functional movement task Sequential snapshots (a–f) from the functional movement task showing the participant opening his hand (a), grasping the glass bottle (b), pouring its contents (dice) into a jar (c), grasping a stir stick from another jar (d), transferring the stir stick without dropping it (e), and using it to stir the dice in the jar (f)

This improvement in function is meaningful for reducing the burden of care in patients with SCI, as most C5/C6 patients require assistance for activities of daily living, while C7/T1 level patients can live independently. The technology also has potential applications in the field of BCI-controlled neuroprosthetics, which could improve patient independence through improved motor function.

4 Current Work and Outlook Towards Future

Our current efforts are focused on adapting the NBT for home use. To make this technology ready for home use, the system must be made smaller and easier to use, with fewer adjustments needed from the user over long-term use. Making these improvements to this system will require several technological hurdles to be overcome as detailed below.

The current NBT system was designed for the research setting where space and mobility is not a constraint. However, for home use, the technology will need to be miniaturized. On the recording side, Blackrock Microsystems has made progress in developing a wireless headstage that can handle the high bandwidth data, but it does not yet have FDA approval for human use. It also uses a large receiver to interface with the PC, which must be shrunk down. The PC used to control the system would ideally be replaced with a small device such as a tablet or a custom designed, small form factor device with an embedded processor. This can be challenging due to the complexity of the algorithm and the amount of data that needs to be processed, and it will require the algorithms to be streamlined. The NMES will also need to be simplified and made more user friendly. The high voltage and high

channel count as well as the size of the battery that is needed makes it challenging to shrink the NMES. Shrinking the entire system will increase portability, but even more improvements must be made to the electrode cuff before the system can be easily used in home settings. These stimulation electrodes will need to be embedded in a sleeve form that can be donned as a piece of garment that can keep the electrodes in good contact with the skin.

The decoding algorithms need to be adapted to make them more robust to any variability in neural modulation. Currently, the user needs to go through a retraining process every few hours to build new decoders. The decoders need to be rebuilt because neural activity in the brain changes, even over the course of just a few hours. Many environmental conditions, mental states of the user (e.g. emotions, focus level, etc.), sensory feedback, and other movements the user is making, among other things, will all factor into how the neural activity changes. Decoders must be developed that can account for these changes so that the user does not constantly have to go through time-consuming retraining. Use of deep neural networks can be one possible way to improve decoder performance.

5 Neurorehabilitation Outcomes and Need for Standardized Tests for Evaluating SCI Neuroprosthetics

As the options for BCI-neuroprosthetics expand to include a range of more or less invasive control options (from brain implants to surface EEG to myoelectric control) and more or less cybernetic effector mechanisms (from surface electrical stimulation, surgical implants and tendon transfers, to robotic arms), it is increasingly important to be able to counsel consumers on both costs and risks—whether financial, technological, surgical, or self-image related—and comparative device performance. However, there is no consensus for how to evaluate device performance. Multiple upper limb standardized tasks have been evaluated by expert reviews [20–22] and consensus panels (SCI EDGE task force [23, 24], and the SCI RE project [25, 26]), with general agreement that the ideal evaluation tasks have the following established psychometric properties:

- *Ecological and construct validity*, such that arm and hand functional tasks be relevant to Activities of Daily Living (ADLs) but do not confound hand function with other impairments, like balance;
- *Sensitivity* to detect small clinically significant changes important for evaluating treatment effects and comparing interventions;
- *Performance range* sufficient to avoid ceiling and floor effects;
- *Reliability* associated with repeatable, standardized, unambiguous scoring that (1) does not confound performance speed with degree of ability to complete the task or level of assistance needed, (2) provides some estimate of trial-to-trial

performance variability, (3) is based on observed measurements and not on subjective reports, and (4) is not subject to practice effects;

- *Clinical relevance*, such that the *measurement domain* falls within the arm and hand activity domain of the International Classification of Functioning, Disability and Health [27]; and
- *Prognostic implications* for functional independence, established by presence of normative performance data for patients with SCI by ASIA Impairment Scale level.

A recent review from the tendon-transfer literature [21] identifies 8 measures that fall within the ICF Arm and Hand Activity domain: The Grasp and Release Test (GRT [28]), the Capabilities of Upper Extremity Questionnaire (CUE-Q [29, 30]), the Van Lieshout Test (VLT, [31, 32]), the Action Research Arm Test (ARAT, [33]), the Tetraplegia Hand Activity Questionnaire (THAQ [34]), the AuSpinal Test [35], the Sollerman Hand Function Test (SHFT [36]) and the Graded and Redefined Assessment of Strength, Sensibility, and Prehension (GRASSP [19, 22, 37, 38]). Of these, only 6 are based on rater observations of performance (GRT, VLT, ARAT, AuSpinal, SHFT, GRASSP), only 4 of which (GRT, VLT, SHFT, GRASSP) have been endorsed for research in spinal cord injury either by the SCI EDGE task force of the Neurology Section of the APTA [23, 24] or the Canadian SCI Research Evidence (SCIRE) Project [25, 26]. To date, BCI-neuroprosthetic studies have alternatively used the GRT (Freehand and/or tendon transfers [39–43] [44]), ARAT (Robotic Applied Physics Laboratory arm [45, 46]), Box and Block Test (BBT [47])—which is also endorsed by SCIRE; Robotic Applied Physics Laboratory arm [45]), or GRASSP (NBT system [14]).

Individually, these 4 measures address different aspects of the performance profile of BCI-neuroprosthetics (see Fig. 6), so they may be best utilized as a battery. Of these 4 measures, only the ARAT assesses fine pincer grip, which is important for manipulating small objects. However, the ARAT incorporates only the power grip into dynamic object manipulation (pouring a cup), and not fine fingertip grasps. The GRASSP evaluates power and fine grips in dynamic tasks, but has potential floor and ceiling effects. The GRASSP can provide prognostic implications for functional independence, as its scoring is normed to AIS Impairment Scale levels, which are widely recognized by patients and clinicians alike. For example, the participant using our NBT system was scored on the GRASSP as improving from C5/6 to C7/T1 level function using the device, which would correlate to a significant improvement in functional independence if used in the home setting. The BBT does not specify grip type, and some patients can do the object transfer task without the neuroprosthetic, with only their baseline adaptive grip. This task may help identify speed and efficiency limitations of BCI systems, and when patients should *not* use the BCI-neuroprosthetic over their adaptive grip. Lastly, the GRT was developed to assess hand and wrist function in isolation from trunk and arm control for a range of light to heavy objects. It has also been widely used to assess recovery of function after tendon transfer surgery, which is

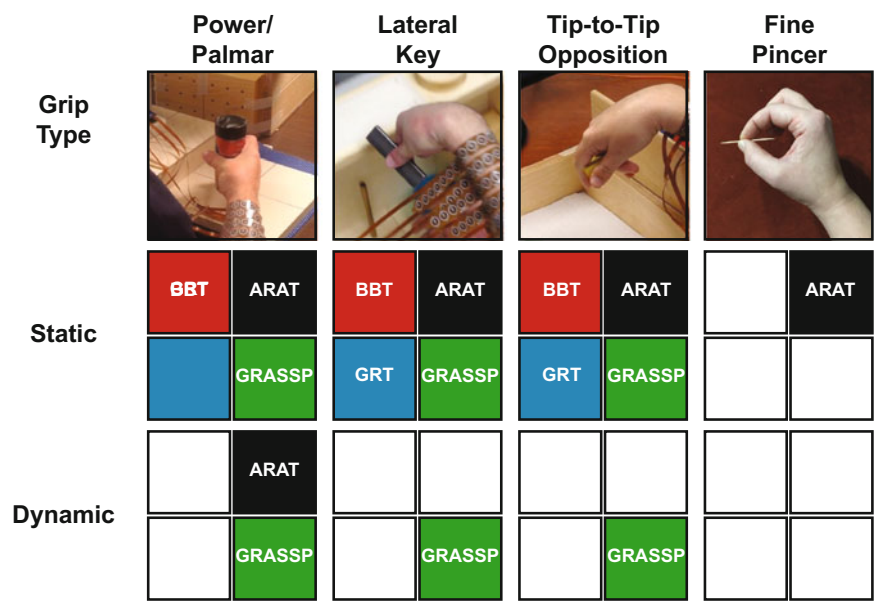


Fig. 6 Grip types featured in standardized tests of *upper* limb motor function for BCI-neuroprosthetic research and between-device comparisons No single outcome measure adequately assesses performance across static and dynamic performance across the four essential grip types (power/palmar, lateral key, tip-to-tip opposition, and fine pincer). Static tasks isolate hand and wrist function from other *upper* limb movements, while dynamic tasks require stable grip through forearm pronation/supination for successful completion

the only neuroprosthetic-like intervention that has been widely translated into clinical practice.

In summary, research and development, clinical translation and future prescriptions for upper limb BCI-neuroprosthetics depend on the rational development of a battery of upper limb functional measures to compare devices in meaningful ways. Together, the ARAT, BBT, GRT, and GRASSP provide complementary measures to assess device strengths and limitations across 4 essential grip types (power/palmar, lateral key, tip-to-tip opposition, and fine pincer) in static and dynamic hand and wrist tasks.

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Brain-Computer Interface Research

A State-of-the-Art Summary 6

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