Mini-Symposia Title:

Implantable BCI and clinical applications: functional compensation and rehabilitation for motor impairment

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Theme:

- ( ) 01. Biomedical Signal Processing
- ( ) 02. Biomedical Imaging and Image Processing
- ( ) 03. Micro/ Nano-bioengineering; Cellular/ Tissue Engineering &
- ( ) 04. Computational Systems & Synthetic Biology; Multiscale modeling
- ( ) 05. Cardiovascular and Respiratory Systems Engineering
- (•) 06. Neural and Rehabilitation Engineering
- ( ) 07. Biomedical Sensors and Wearable Systems
- ( ) 08. Biorobotics and Biomechanics
- ( ) 09. Therapeutic & Diagnostic Systems and Technologies
- ( ) 10. Biomedical & Health Informatics
- ( ) 11. Biomedical Engineering Education and Society
- ( ) 12. Translational Engineering for Healthcare Innovation and Commercialization

Mini-Symposia Synopsis— Max 2000 Characters

- The development of Brain machine interface is one of the greatest medical and technical challenge of this century. Indeed, brain is one of the most complex systems ever approached by the scientific community and is only accessible partially either by electrodes or imaging techniques recording the temporal activity of groups of neurons.
- From the technical point of view, one need to catch the brain activity from the most relevant areas of the cortex and send digitalized brain signals to an external (portable) computer. The latter embeds complex algorithms for on-line decoding and interface with a communication tool or a motor compensation or rehabilitation system.
- Invasive BCI allows real time and complex multiaxial commands. However, the neurosurgeon must tackle invasiveness and safety. Signal quality and stability shall also be maximized. To this aim, there is a growing interest for fully implantable active devices using intracortical multielectrode arrays or cortical recordings either intracranial EEG, also called subdural or epidural ECoG. Depending on the electrode size and distance to the group of interest, one contact may integrate the activity of a few neurons for intracortical and up to 500 000 neurons for ECoG recordings. Therefore, decoding algorithm strategies and technical constraints such as sampling frequency or effective bandwidth are dramatically different.
- We propose in this symposium a series of recent clinical achievements exploring the promise of brain computer interfaces using chronic implantable devices in the field of motor impairment. In each of these talks, the speaker will present proof of concept results based on clinical data using different recording strategies, decoding approaches and compensation systems for motor or communication deficit. The challenges of the translation of these

Targeted epidural spinal cord stimulation to restore walking in humans with spinal cord injury

Grégoire Courtine, Henri Lorach, Center for Neuroprosthetics and Brain Mind Institute, School of Life Sciences, Swiss Federal Institute of Technology (EPFL), Lausanne, Switzerland.

Abstract— **Spinal cord injury leads to severe locomotor deficits or even complete leg paralysis. Here we introduce targeted spinal cord stimulation neurotechnologies that enabled voluntary control of walking in individuals who had sustained a spinal cord injury and presented with permanent motor deficits or complete paralysis despite extensive rehabilitation. Using an implanted pulse generator with real-time triggering capabilities, we delivered trains of spatially selective stimulation to the lumbosacral spinal cord with timing that coincided with the intended movement. Within one week, this spatiotemporal stimulation had re-established adaptive control of paralyzed muscles during overground walking. Locomotor performance improved during rehabilitation. After a few months, participants regained voluntary control over previously paralyzed muscles without stimulation and could walk or cycle in ecological settings during spatiotemporal stimulation. These results establish a technological framework for improving neurological recovery and supporting the activities of daily living after spinal cord injury.**

I. INTRODUCTION

Recent evidence suggests that epidural electrical stimulation of the lumbar spinal cord combined with intensive locomotor training can restore locomotion in individuals with chronic spinal cord injury [1-2]. We developed epidural electrical stimulation programs that are participant- and activity- specific, and can be spatially and temporally modulated in real-time to adapt to the individual's needs. Here, we report our recent advances in the development of these neurotechnologies to facilitate supraspinal control of the legs in individuals with chronic spinal cord injury.

II. METHODS

In a first-in-human feasibility study, seven individuals with chronic spinal cord injury (> 4 years post injury) were surgically implanted with electrode arrays placed over the lumbosacral spinal cord and connected to a pulse generator implanted in the abdomen. After surgery, we used a control system capable of real-time communication to deliver personalized task-specific stimulation programs to facilitate various motor tasks such as walking. We adjusted the electrical stimulation parameters (location, timing, etc.) in order to modulate the spinal cord segments containing the motor neuron pools associated with the intended movement. After one month of stimulation optimization, participants completed an intensive 5-month training program mainly focused on walking, and also including cycling and single-joint movements.

III. RESULTS

Seven participants with chronic spinal cord injury recovered standing and stepping abilities within the first 5 training sessions using spatiotemporally-patterned spinal cord stimulation, body-weight support and physiotherapist assistance. In the less severe patients, voluntary contribution over the stimulation allowed them to modulate the motor output to a functional extent. In the most severe patients however, this modulation ability was limited and correlated with weaker neurological recovery.

IV. DISCUSSION & CONCLUSION

These results demonstrate the potential of epidural spinal cord stimulation to restore locomotor function even in motor complete patients, after a few calibration sessions only. Voluntary contribution to the stimulation was correlated to higher functional recovery suggesting the importance of brain-controlled stimulation paradigms for the most severely affected patients. This Brain to Spine Interfacing concept could be implemented in humans using EEG or ECoG recording modalities to drive the epidural stimulation, thus restoring natural control to the patient.

ACKNOWLEDGMENT

We thank Medtronic for donated devices and support.

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Electrocorticogram-Based BCIs for Walking and Leg Sensation

Progress, next steps and obstacles in the development of a fully implantable electrocorticogram (ECoG)-based bi-directional brain-computer interface (BCI) system for the restoration of walking and leg sensation are discussed.

Zoran Nenadic, UC Irvine

***Abstract*— The development of a fully implantable ECoG-based bi-directional BCI for restoration of walking and leg sensation requires addressing significant engineering and scientific challenges. If successfully developed, such a system could improve independence and quality of life of those affected.**

I. Introduction

Subdurally recorded ECoG signals may have a sufficient resolution for the accurate decoding of gait parameters. Also, clinical trials demonstrated that implanted ECoG electrodes remain stable over time, which makes them suitable for long-term BCI use. Finally, ECoG grids are used clinically to deliver cortical electrostimulation, and can, therefore be re-purposed to elicit artificial leg sensation. These properties suggest that it may be possible to engineer a fully implantable ECoG-based BCI for the restoration of walking and leg sensation in those with spinal cord injury (SCI). To realize such a bi-directional (BD) BCI, significant technological challenges must be overcome.

II. Methods

Figure 1 shows the envisioned fully implantable BD-BCI. ECoG signals underlying walking intentions will be sensed by motor electrodes, amplified and serialized into a single path by a skull unit (SU), and routed out of the head and neck using a subcutaneous tunneling cable. The signals will be decoded using BCI algorithms executed on an embedded system housed within a chest wall unit (CWU). The CWU will also wirelessly transmit commands to a leg prosthesis to actuate walking. Sensors within the prosthesis will measure leg movements and send signals wirelessly back to the CWU, where they will be converted into electrical stimulation patterns. These will be delivered to the brain via the tunneling cable and sensory ECoG electrodes, thereby eliciting artificial leg sensation. This design is free of any external electronics and skull-protruding components. It also avoids sending high-bandwidth data through the skull, which may pose safety risks. Realizing such a system requires: (1) designing application-specific integrated circuits for ECoG acquisition; (2) the development of algorithms for motor decoding and artificial sensation that are amenable to low-power digital signal processor (DSP) execution; (3) the development of artifact suppression methods to enable bi-directional BCI operation; (4) the testing of the system in individuals with paraplegia due to SCI; (5) the execution of all functions in a power regime that conforms to the safety requirements of active implantable medical devices.

III. Results

We designed an ultra-low power amplifier array/serializer system (0.69 μW/channel) and tested its performance in EEG and ECoG data acquisition [3]. We also designed and tested a low-power transceiver for wireless communication [4]. On the artifact suppression front, we devised both front-end [5] and back-end [6] solutions. Together, these can achieve as much as 60 dB of artifact suppression. Additionally, we recently designed and tested a benchtop analogue of the whole system using off-the-shelf components [7]. Finally, we also investigated how ECoG signals from the leg motor cortex encode human gait [8] and found that gait parameters could be decoded from these signals with unprecedented accuracy.

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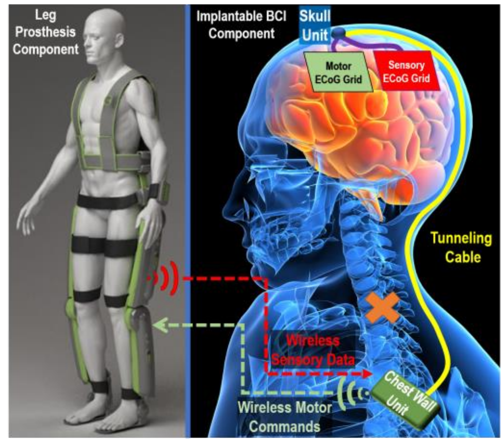

Figure 1: Fully implantable ECoG-based BD-BCI system.

IV. Discussion & Conclusion

If successfully developed, a fully implantable BD-BCI could improve the quality of life and reduce the disability of the affected population. Before such a system can be deployed in humans, its safety must be tested in animal studies.

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Interference of overt movements during intracortical BCI control

Kristin M. Quick, University of Pittsburgh, Jennifer L. Collinger, University of Pittsburgh, VA Pittsburgh Healthcare System

Abstract— **Brain computer interfaces (BCI) bypass spinal cord injuries (SCIs) by translating motor cortical signals into command signals for computer cursors. After cervical SCI, overt movement is retained above the level of injury. Ideally, people could simultaneously control their overt and BCI movements. Towards this goal, we investigated whether overt arms movements interfere with BCI movements. We found that arm movements both ipsilateral and contralateral to the array interfered with BCI performance, with contralateral arm movements interfering more than ipsilateral arm movements.**

I. Introduction

Intracortical brain computer interfaces (BCIs) can enable high degree-of-freedom movements of a robotic arm in a laboratory environment [9]. As a step towards translation, we recently demonstrated a portable intracortical BCI system for computer cursor control [10] that can be used at home. To ensure high-fidelity, safe BCI control at home, it is necessary to understand the influence of any variables that may interfere with this goal. One such variable is the possible interference of overt arm movements on BCI cursor control.

After cervical spinal cord injury (SCI), natural overt movements are retained above the level of injury. Ideally, people could continue making natural arm movements without them interfering with their BCI control. Concurrent overt and BCI movements have been shown to be possible for ECoG-based BCI in humans [11]. With this in mind, we wished to see whether concurrent overt movements interfered with intracortical-based BCI movements.

II. Methods

This study was conducted as part of an ongoing intracortical BCI clinical trial (NCT01894802) under an Investigational Device Exemption (IDE) granted by the US Food and Drug Administration. The study participant was a 31-year-old male with C5/C6 ASIA B SCI that resulted in complete paralysis of his hands with some residual function of the proximal arms and wrists. At age 28, 10-years post-SCI, the participant had two 88-electrode-microarrays (4 mm x4 mm, 1.5mm shank length, Blackrock Microsystems, Salt Lake City, UT, USA) implanted in his left motor cortex.

We recorded neural activity while the participant made movements with the arm either contralateral or ipsilateral to the microelectrode arrays. While at rest, we trained a one-dimensional optimal linear estimator (OLE) decoder to translate neural activity into horizontal cursor velocity. We then tested his BCI cursor performance (1) with his arms at rest or (2) with concurrent ipsilateral or contralateral arm movements towards the right or left side of his body.

III. Results

With arms at rest, the BCI cursor moved towards the target on 95% of trials. With the ipsilateral arm moving concurrently with the BCI cursor, the BCI cursor moved towards the target on 80% of trials. With the contralateral arm moving concurrently, the BCI cursor moved towards the target on 47% of trials. As such, both concurrent ipsilateral and contralateral arm movements interfered with BCI control.

Next, we used a Naïve Bayes classifier to determine if both BCI target and overt movement direction information were encoded in the neural activity. For each arm, we grouped trials according to (1) BCI target and (2) overt movement direction and trained independent classifiers for each group. We then predicted each trial's BCI target and overt movement direction. The classification results were similar to the performance results. The neural activity during ipsilateral movements encoded both the ipsilateral movement (98.7% classification accuracy) and the BCI target (92.9%). The neural activity during contralateral movements encoded only the contralateral movement (100%) and was near chance level for the BCI target (57.8%).

IV. Discussion & Conclusion

We found that contralateral arm movements interfered with BCI control more than ipsilateral movements. To realize high-fidelity, safe BCIs for use at home, future work will focus on minimizing the interference from overt movements.

Acknowledgment

Thank you to those who collaborated on this work: Michael Boninger, Brandon Burger, Angelica Herrera, Jeffrey Weiss, Robert Gaunt, and Elizabeth Tyler-Kabara.

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Brain implant for daily communication in people with Locked-in Syndrome

Nick F Ramsey, Erik Aarnoutse and Mariskva Vansteensel, University Medical Center Utrecht, Netherlands

***Abstract*— People with severe loss of motor control, such as complete paralysis, suffer from an inability to communicate and are excluded from social interaction. Until recently, there was no solution to offer to these patients. In November 2016, we presented the first case of a implanted Brain-Computer Interface system that enabled a late-stage ALS patient with Locked-In Syndrome to control spelling software at home, without help. Key to this system is the principle that the brain generates motor signals even when they do not reach the muscles, which can be detected and interpreted in real-time. I will present this case, and explain how it works. Research leading up to the implantation is moving forward to provide technology for the next generation of BCI implants that will enable better communication capabilities. The ultimate goal is to realize synthetic speech by directly linking electrical brain signals to a speech computer. The mechanisms underlying this concept will be explained, as well as the status of the research.**

I. Introduction

People with severe loss of motor control, such as complete paralysis, suffer from an inability to communicate and are excluded from social interaction. Until recently, there was no solution to offer to these patients. In November 2016, we presented the first case of an implanted Brain-Computer Interface (BCI) system that enabled a late-stage ALS patient with Locked-In Syndrome to control spelling software at home, without help [12]. Key to this system is the principle that the brain generates motor signals even when they do not reach the muscles, which can be detected and interpreted in real-time. High reliability performance was the key for home use, which constrained control to a simple but robust switch ('brain click'). This work incentivizes development of more capable implant technology that is required to accomplish synthetic speech by directly linking electrical brain signals to a speech computer.

II. Methods

Two people with Locked-in Syndrome (LIS, one due to ALS, one due to Brainstem Stroke) were implanted with a 4-channel sensing device (Medtronic Activa PC+S, off-label use)[12]. This device contains four amplifiers and is capable of non-stop wireless transmission. Signals from the sensorimotor cortex were recorded with 4mm diameter cortical surface electrodes. Signals were processed and converted to a control signal in custom and commercial communication software, on a standard tablet. Tests were conducted at the home of participants. One participant used the system at home.

* Research supported by the European Union (ERC-Adv 320708) and the Dutch Technology Foundation STW (grant 14906)

III. Results

One participant has used the system at home for over 3 years [13]. Due to progression of the illness, she currently relies on the system for daily communication with caregivers. Parameter setting for the filters converting raw brain signals to a control signals remained stable from the day the system worked at her home (6 months after implantation).

The brain signals proved to be most informative in two bandwidths, ~6-30 Hz and ~60-100 Hz, as was expected based on literature for movement. Signals remained stable for the periods investigated, albeit with a light decline in one participant (possibly due to ALS). In one participant, power in the lower bandwidth proved to be unstable, possibly due to brainstem damage, causing slower BCI performance (i.e. longer window to determine and generate a click).

IV. Discussion & Conclusion

With the proof provided by this research that home use of BCI as an alternative means of communication is feasible [14], societal expectations for implantable solutions for severe disabilities are materializing, increasing the incentive for labs to focus on translating BCI neuroscience to real-life applications. This in turn hopefully encourages industry top develop more capable BCI systems in terms of number of channels and signal quality.

Acknowledgment

The UNP research team, Clinical teams of the Medical Center and participants and their caregivers.

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Signal quality assessment of chronic epidural recording using WIMAGINE® implant

Sauter-Starace Fabien, Univ. Grenoble Alpes, CEA, LETI, CLINATEC, MINATEC Campus

Abstract— **The CLINATEC team, which developed the WIMAGINE system, presents here a series of quantitative results upon signal quality acquired in epidural conditions. These results are computed upon 20 months of cortical recording in the framework of the BCI and tetraplegia clinical trial.**

V. INTRODUCTION

For long-term use of an implantable brain recorder, safe and stable interface with the brain is highly recommended. To prepare the “BCI and tetraplegia” clinical trial (NCT0255052), we designed, manufactured and qualified WIMAGINE®, a wireless brain signal recorder. The implants were first successfully implanted in two sheep[15] to assess the operability and the signal quality on a 10-month time frame. Signal quality is of paramount importance for brain signal decoding, which ends up into command for different effectors from a mouse on a screen to a motorized wheelchair or a 4-limb exoskeleton.

In this mini-symposium, we highlight some aspects of the signal quality of Epidural cortical recording with the WIMAGINE implant, which turns out to be very stable on the long-term.

VI. METHODS

The patient is a stabilized quadriplegic. Chronic spinal cord injury lesion is at the C4-C5 level. A neuro-navigation software was used to locate the center of the craniotomies on each hemisphere. Resulting from anatomical and functional imaging using MEG and a CT-scanner, the target points are expected in the Sensory Motor Cortex (SMC). Surgery was performed under general anesthesia. A semi-invasive surgical procedure was used (craniotomy 5cm in diameter, epidural placement to avoid intracranial propagation of infections).

After training, the patient was able to command 8 degrees of freedom[16]. Putting aside the performance of decoding algorithm, the stability assessment of the ElectroCorticoGraphic (ECoG) signal encompasses analysis of power spectrum, signal to noise ratio, effective bandwidth and electrode inter-correlation over time. The electronic boards of WIMAGINE embed two integrated circuit called CINESIC able to magnify, digitalized 32 brain signals each on a [0.5; 300]Hz bandwidth with a 12 bit resolution. The cut-off frequency of the low pass filter being 300Hz we defined [250; 260]Hz as the noise band.

The Effective BW is computed as explained in [15]. Whereas the power bands are normalized by the frequency bandwidths.

VII. RESULTS

Based on our data and according to Figure 2, the band power for the two high frequency bands ([40-100]Hz and [100-200]Hz) is remarkably stable over a 20 months period and so the effective bandwidth around 230Hz. This assessment of the epidural ECoG signal quality is still under process as the first patient is still implanted with the devices and new data will be gathered meanwhile.

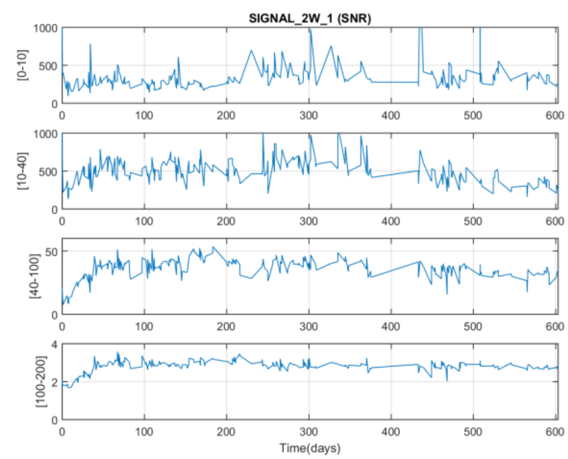

Figure 2: Bandpowers of the 64 contacts pulled together in [0-10], [10-40], [40-100] and [100-200] Hz

VIII. DISCUSSION & CONCLUSION

These preliminary results support the feasibility of a long-term brain computer interface based on a wireless epidural ECoG recorder. While major results were published [16], the question remains on the very long-term use in particular out of the lab.

ACKNOWLEDGMENT

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Implantable Epidural Brain Machine Interface for movement compensation of tetraplegic patients

Charvet Guillaume, Univ. Grenoble Alpes, CEA, LETI, CLINATEC, MINATEC Campus

***Abstract*— A Brain Computer Interface (BCI) system for clinic chronic application with a high number of degrees of freedom is one of the major challenges in the field of neuroprosthetics. An Epidural ElectroCorticoGram (ECoG)-based BCI platform was developed and evaluated in a context of a clinical trial with a tetraplegic patient. The outcome of this on-going clinical trial is to bring the proof of concept that it is feasible for a tetraplegic subject to control complex effectors (such as a 4-limb exoskeleton) after training, thanks to his cortical brain electrical activity decoding.**

IX. Introduction

Among neuroprosthesis, motor controlled-BCIs system aim at providing users with control over upper or lower limb orthoses or prostheses. The major challenge for BCI systems with home use for motor disabled subjects is the ability of recording long-term stable neuronal signals and decoding in real-time complex multi-limb effectors with robustness and precision. Here, we present the development and clinical feasibility of an ECoG based BCI platform for motor compensation.

X. Methods

An approach based on chronic recording of Epidural ECoG recording using an innovative wireless implantable device (WIMAGINE®[17]) is proposed. The device was designed for semi-invasive implantation for long-term recording of electrocorticograms (ECoG) using a 64 electrode array in contact with the dura mater. The implantation took place in Clinatec in June 2017. The electrocorticograms recorded are then decoded in real-time to predict the deliberate movement imagined by the patient. Depending on the paradigm, the patient can interact and train in a virtual environment at home and once a month drive an exoskeleton in Clinatec. Decoding ECoGs required the development of algorithms based Machine Learning methods [18] and dedicated software to control the exoskeleton movements in real-time. The decoding software allows an asynchronous decoding (Cue free) in real time (high decision rate: 10Hz). An adaptive learning software was developed to create the decoding model in real-time.

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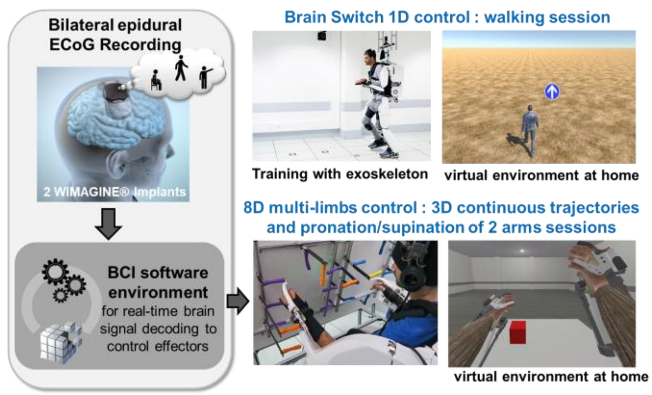

XI. Results

During the clinical trial (NCT255052), the patient was trained progressively to control the exoskeleton [16]. We performed the demonstration of a high dimensional control of 2 exoskeletic arms in 3 dimensions and pronation-supination (i.e. 8 degrees of freedom), using neural population recording system (safe and compatible with chronic clinical use). We demonstrated the decoder stability over several weeks.

XII. Discussion & Conclusion

This proof of concept for a neuroprosthesis providing these degrees of freedom is a milestone toward new applications to drive effectors adapted for daily needs at home by people with severe mobility handicap in their everyday lives. The Clinatec team is working at integrating new effectors, such as a motorized wheelchair, and developing even more robust and more precise algorithms; manipulating daily life objects being on our roadmap.

Acknowledgment

This work was supported by French Atomic Energy Commission, French Ministry of Health, Edmond J Safra Philanthropic Foundation, Institut Carnot, Fonds de Dotation Clinatec.

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