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IMPLANTED BRAIN-COMPUTER INTERFACE SIGNAL STABILITY OVER TIME

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ABSTRACT: In recent years, implanted BCIs gained increasing interest. Relying on subdural or intracortical electrodes, these systems carry the advantage of brain signals gathered at the source. Successes in this field have been reported in controlling robotic arms, intended for severe paralysis or arm amputation, and recently also for replacing communication. A prerequisite for long-term use of implantable BCIs is that there is no decrease in signal quality over time. In this paper we examined the signal stability of a fully implanted BCI system for communication over a period of 12 months. Three different tasks were used to investigate signal stability since implantation, all of which show a stable and decodable signal, indicating that the implanted electrodes are durable and information transfer is preserved for at least 12 months. These findings suggest that ECoG-based BCI systems are robust and can be used at home for long-term in patients that need them.

INTRODUCTION

For people with severe paralysis and communication problems, assistive technologies are an important part of their lives, particularly for people suffering from locked-in syndrome (LIS). LIS is characterized by the loss of all voluntary movement, resulting in quadriplegia and the loss of speech. LIS can be divided into three categories, *classic* LIS, where only vertical eye movement and eye blinks remain, *incomplete* LIS, which is the same as *classic* LIS, but with additional voluntary movement other than vertical eye movements, and *complete* LIS, which is LIS without any voluntary movement. In all variants cognition is intact and people are aware of their surroundings [1]. The causes of LIS are very diverse and include brainstem stroke, trauma and motor neuron diseases like amyotrophic lateral sclerosis (ALS). The latter affects about 5 in 100.000 people and especially late-stage ALS patients on invasive ventilation may progress into LIS. The ability to communicate is correlated with quality of life in people with LIS [2], [3]. Current methods for communication mainly rely on residual motor control such as eye-movements or minimal movement of a finger [4]. When also that last motor function fails, communication becomes almost impossible and a BCI becomes one of the last remaining options.

Since the beginning of BCI-research, non-invasive, mostly EEG-based, BCIs have promised to be a replacement for communication in patients [5], [6]. However, the clinical application is only slowly realized and for LIS-patients, EEG-BCI performance is lower than for less severely paralyzed people [7]. Recently, functional near-infrared spectroscopy (fNIRS) was used to enable complete locked-in patients to communicate [8]. However, the application of such a device at the patients' home is currently not an option as experts need to setup the system.

Implantable *BCIs*, utilizing the brain signal recorded with electrodes on or in the brain, have the potential to become a useful solution to the daily obstacles of people suffering from LIS, due to their high signal quality and potential 24/7 availability. The promises of implantable BCIs have been investigated and demonstrated in a laboratory setting [9]–[11] but recently, the first successful independent home-use of an implantable BCI by an ALS-patient was described by our group [12]. We showed high spelling performance and user-satisfaction, bridging the gap between research and the application of implantable BCIs at home. The system was implanted in November 2015 and is still used at home by the patient. In order to allow the current patient, as well as future users, to use the system with high accuracy for an even longer period of time, the long-term stability of the measured ECoG signal is important. Long-term use of an ECoG-based BCI has not been tested before and signal recordings have mainly been done in epilepsy patients or patients receiving, experimental, closed-loop Deep Brain Stimulation (DBS). Sillay and colleagues showed long-term stability of impedance in both subdural and depth electrodes, indicating a stable tissue-electrode contact a prerequisite for good signal recordings [13].

Here we report on the signal stability of a fully implanted BCI system, the Utrecht NeuroProsthesis (UNP) during a period of 12 months, and conclude that implanted BCIs can be a long-term solution for LIS-patients.

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MATERIALS AND METHODS

The implanted system: The UNP consists of two four-electrode ECoG-strips connected to an implanted amplifier/transmitter device (the device; Activa® PC+S Medtronic) by subcutaneous leads. The strips are placed subdurally over the left sensorimotor hand area and on top of the left prefrontal cortex. Both locations were preoperatively determined by functional MRI. Here we only report on data collected by the strip placed on the left sensorimotor hand area. The device was implanted in the left thorax and filters and amplifies the signal before it sends it wirelessly to a computer outside the body. Outside the body, the signal is received by a receiver module connected to a Windows tablet running custom software based on the BCI2000 platform [14] for signal processing and translation. For a complete lay-out of the implant see figure 1.

Patient: For this study a locked-in patient (58-year-old female) who suffers from late-stage ALS was implanted with the UNP.

Tasks and data acquisition: Shortly after implantation, the best performing bipolar electrode pair within the strip was selected based on the correlation of the high frequency band (HFB) power (65-95Hz) with a screening task (expressed as R^2) measured at a sampling rate of 200Hz. The screening task consisted of alternated blocks of attempted movement of the right hand (finger tapping) and rest. At home, weekly repetitions of the screening task enabled us to track the R^2 values over time, as an indication of signal stability.

Additionally, we did regular baseline/rest measurements in order to follow the raw signal over time. For this we used a baseline task, in which the patient had to look at a screen with a blue circle for 3 minutes and think of nothing in particular. Data were recorded with a sampling frequency of 200Hz and HFB-power was calculated for each run using multitaper time-frequency transformation based on multiplication in the frequency domain (average power over 65-95Hz, 1Hz bin, Hanning window) [15].

Finally, in order for the patient to learn to control her brain signal we used a one-dimensional continuous cursor control task (cursor task). For this task the patient controlled the vertical speed of a cursor travelling from the left side of the screen to the right (horizontal speed was fixed), using attempted movement to steer the cursor up and rest to lower the cursor in order to hit a target on the right side. The cursor task was performed regularly after implantation, allowing us to follow the usability of the control signal over time. Data for the cursor task were recorded in the energy-saving mode of the device, this means that bandwidth filtering on HFB was done on the device with 5Hz sampling frequency. For each repetition of this task, following an initial calibration run to acquire offset and gain values for that day, a 5 minute run was done. The amount of trials varied during the year as feedback time was reduced from 6 to 2 seconds. Therefore, the amount of total trials in a 5 minute run was between 26 and 47 during the year. The score was calculated as the percentage of correct target hits. Besides the score, we report here the average power during the baseline (down) trials, as transmitted by the implanted device. For all tasks, data acquisition and stimulus presentation were done on the BCI2000 software running on a separate research laptop.

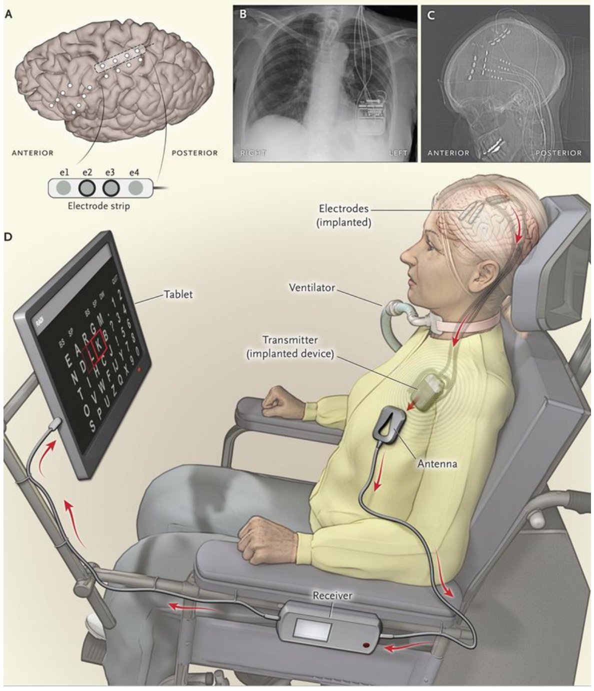

Figure 1: Electrode Placement and System Setup in the Brain–Computer Interface System. Panel A shows the contact points of the electrode strips, which are indicated by white dots, over the sensorimotor and dorsolateral prefrontal cortex; the positions of electrodes were based on postoperative computed tomographic (CT) scans merged with the pre-surgical MRI. Electrodes e2 and e3 on the electrode strip were chosen for brain–computer interface feedback. Panel B shows a postoperative chest radiograph displaying the transmitter device (Activa® PC+S, Medtronic), which was placed subcutaneously in the chest, and wires leading to the electrodes. Two of four wires were connected to the device. Panel C shows the postoperative CT scan with the locations of four electrode strips. The dots on the four wires are connectors. Panel D shows the components of the brain–computer interface system, including the transmitter, receiving antenna, receiver, and tablet. (Copyright © 2016, Massachusetts Medical Society)

RESULTS

The results of the screening task showed a stable R^2 for the bipolar pair used from 0.88 just after implantation to 0.86 one year after implantation (Figure 2).

After an initial 21% decrease of HFB power 8 weeks post-surgery, mean baseline/rest HFB power was stable and remained so for the following year. The cause for the fluctuation of 8.8% (relative Std) in mean HFB power during that year, which was also apparent in the rest periods of the cursor task (down trials; 5.7%), is uncertain but possibilities include biological factors such

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as, temperature, level of fatigue and circadian rhythm. The average performance on the cursor task over 12 months with sensorimotor control was 91 ± 6%, which is significantly above chance (50%, p<0.001).

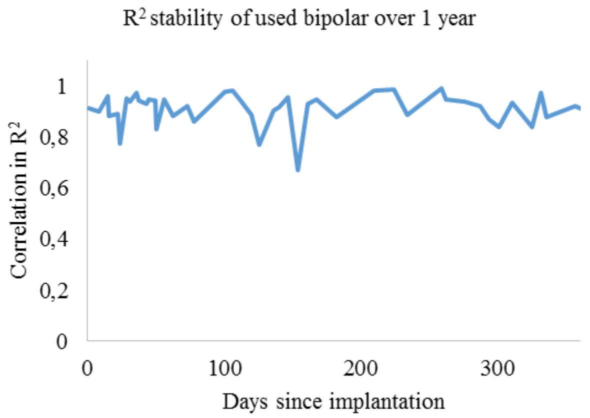

Figure 2: R^2 values of the bipolar pair used for brain-computer interface control (HFB power), measured frequently with the screening task for one year.

DISCUSSION

Here we show that a fully implantable, ECoG-based BCI system can be used by a late-stage ALS-patient at home for over a year. Twice weekly visits during a year and regular visits after that year show that the signal measured is stable and can be used for BCI-control.
This is the first study to show long-term ECoG-BCI control-signal stability. Earlier ECoG-BCI studies have mainly been performed with epilepsy patients, who were temporarily implanted with ECoG electrodes. In these patients, the time constraints of the clinical procedure generally does not allow for long-term BCI measurements. Available data did indicate, however, that ECoG-based BCI performance is good for multiple days when calibrating or using adaptive algorithms [16], [17]. In 2009, Blakely and colleagues showed robust BCI control over the course of 5 days without the need of retraining or adaptive algorithms [18].
Long-term ECoG measurements have been performed before for other purposes than BCI. Earlier studies with implanted electrodes in non-human primates show that most signal changes occur in the first months and that relevant motor system frequencies (beta and gamma bands) are detectable over the course of 24 months [19]. Additionally, in humans, long-term ECoG recordings have been done in patients receiving experimental closed-loop DBS as a treatment for epilepsy or Tourette's syndrome [13], [20], concurrent with our results that signal transfer is maintained for long-term.
A stable and robust BCI control signal for long-term use is important as it ensures availability of a BCI for patients who are likely to need the device for years. Additionally, it is also needed for reducing, or even to circumvent, the need for (re)calibration, making the system faster to start up and easier to use. Importantly, the current results suggest that there is no indication that in the future signal quality will decrease.

CONCLUSION

In conclusion these data indicate that implanted ECoG electrodes provide a durable signal quality and information transfer is preserved over the course of at least 12 months. These results demonstrate that long-term ECoG signal quality suffices for meeting the needs of late-stage ALS patients for a reliable communication device for home use.

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