ABSTRACT: We report a case study where a user provided with a fully implantable Brain-Computer Interface (BCI) has been using the BCI at home for almost three years for communication. At the start of participation ECoG electrodes were placed subdurally over motor cortex and signals are amplified and transmitted to a tablet with BCI software. This software processes and translates the brain signal to control AAC software. To select letters on the tablet, the user generates clicks by attempting hand movement. Since the start of home use, the participant used the BCI on average during 11 sessions per month with an average duration of 21.2 hours per month. Use of the BCI correlates with situations in which other means of communication are more difficult.

An auditory spelling paradigm was investigated for future use. Auditory spelling was reliable, but speed was lower than vision-based spelling. This report emphasizes that a BCI has an added value to a user.

MATERIALS AND METHODS

Participant: The user is a woman with late stage ALS, who was diagnosed with the disease in 2008 and required positive-pressure mechanical ventilation through a tracheostomy. At the start of the study she had a score of 2 on a scale of 40 on the Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS). She gave informed consent in September 2015, when she was 58 years old. The study was approved by the MREC Utrecht and was conducted in accordance with the Declaration of Helsinki (2013). The study protocol allows for yearly extension of participation, which the participant did for three consecutive years.

Her methods of communication in September 2015 were rudimentary speech, an AAC device controlled by eye-movements with spelling software (Tobii, Communicator-5, Tobii Dynavox) and eye-blinks for answering yes/no to closed questions. Since then her ability to use these means of communication declined. Her methods of communication in September 2015 were rudimentary speech, an AAC device controlled by eye-movements with spelling software (Tobii, Communicator-5, Tobii Dynavox) and eye-blinks for answering yes/no to closed questions. Since then her ability to use these means of communication declined.

Implanted BCI: In October 2015 the participant was implanted with a BCI system as the first participant in the Utrecht Neuroprosthesis study.

The Utrecht Neuroprosthesis records ECoG signal from two subdural electrodes strips (Resume II®, Medtronic, 4 electrodes each, 4mm diameter, 1cm distance, off label use) which were implanted through burr holes (1cm diameter) over the hand area of the left motor cortex.
cortex and over the left dorsolateral prefrontal cortex. The target areas were determined by an fMRI session several weeks prior to implant, where the participant performed motor and counting backwards localizer tasks. The strips were connected subcutaneously to an amplifier/transmitter device (Activa® PC+S, Medtronic, off label use), that was placed subcutaneously under the clavicle. ECoG data is streamed through an antenna to a receiver which is connected to a Microsoft Surface 3 tablet computer running BCI software derived from the BCi2000 software platform.

**BCI Control:** The participant attempts to move her hand to generate a click. Bandpass filtered data with center frequencies of 20Hz and 80Hz are streamed 5 times per second to the tablet where the BCI software filters the data and translates the data into a click. The BCI software converts this click to a keypress signal in Communicator-5 AAC software (Tobii Dynavox). A matrix of letters (and a few icons for e.g. backspace and pronunciation of a written word or sentence) is presented and a moving rectangle highlights the letters one by one. Several schemes are used to speed up spelling, e.g. selecting letters in two steps (rows, columns) or three steps and predicted words are presented as an option to select. The rectangle moves at a fixed scan rate of once per 2.4 s. Recently, the speed is increased, the scan rate is now once per 2.0 s. The user decides to pronounce by selecting the pronounce icon. In the auditory version the letters are announced one by one, by a different voice than when the spelling result is pronounced. Similar to the visual interface, letters can be selected by making a click. The scan rate is reduced to allow for announcing letters to once every 3 or 4 s.

**BCI data:** Frequency and duration of home use is logged, but no EC0G data is analysed to preserve privacy. Therefore, we rely on user feedback for what the BCI is used for. Data from auditory BCI was recorded during research visits and is available to the researchers. The communication software does not allow for precise logging. The task was to copy-spell words of 3-5 letters. Accuracy is defined by (TP+TN)/(TP+TN+FP+FN). No home use of the auditory paradigm was performed yet.

**RESULTS**

The participant used the eye-tracker as the main means of communication for free spelling, but she reported before implant that the performance of eye-tracking was unsatisfactory outside her home due to different light conditions. Prior to eye-tracker use she preferred her voice, but unfortunately, she lost the ability to use her voice within months after giving informed consent. In autumn 2018 progression of the disease reached her orbicularis oculi muscle, causing difficulties to close her eyelid, and drying out of the cornea. With this, the use of the eye-tracker became painful.

Since May 2016, home use, outside of research visits, was on average 1270 minutes per month, which equals 21.2 hours (Fig. 1). Frequency of BCI use however was closely correlated with seasonal frequency of outdoor activities and progression of the disease. The user reports that the BCI is used mostly for spelling, and secondly to alert the caregiver.

![Figure 1. Summary of home use of the BCI. The number of sessions per month since the start of home use in May 2016 until January 2019 is shown in the upper panel. The total number of minutes where the BCI was used is depicted in the lower panel. The duration of home use in the periods May-June 2016 and February-October 2017 are estimated, because logging turned out to be unreliable. Note that in winter periods use was lower than during summer, correlated with outside use of the BCI. In the first month of home use (May 2016) many short sessions were performed as home practice. The increase of BCI use since August 2018 corresponds to decline of control over the orbicularis oculi muscle.](image-url)
Spelling with an auditory paradigm was performed in 12 runs. In 9 runs the word was spelled correctly, 1 run was aborted for technical reasons. In all runs, corrections were allowed. Total accuracy over 12 runs was 90.2%. On average 1.3 correct characters were spelled per minute.

DISCUSSION

In this report the user has continued use of the BCI until present, almost three years after she gained reliable control of the BCI and the system was left at her home. Commitment to use an implanted BCI is arguably larger than with a non-invasive BCI, given the required surgery. However, BCI use was mainly associated with failure to use other available methods for communication. The user preferred spelling with the eye-tracker over spelling with the BCI, because of speed of communication. In situations where the eye-tracker was less reliable (outside her home or when problems with her eyelid caused dryness of her eyes), BCI was her primary (and increasingly only) method of communication.

In this study feedback proved to be of quintessential importance to improve on the design of this BCI and BCIs in general. The user requested a function to alert the caregiver, which gave her an improved feeling of safety [4]. She also requested an auditory feedback mode, anticipating loss of control over her eyelids. Continued participation in the study is voluntary and not required for home use. Provisions for post-trial access to intervention, as required in the declaration of Helsinki, are made in this study. The BCI software in this study is developed compliant to the requirements of medical software.

Use of the BCI using an auditory paradigm showed that this compromised speed. The speed of auditory EEG based BCI is reported to be approximately 1 character per min [2]. It has to be noted that the user had ample experience with the BCI with a visual paradigm. It is unknown whether the same speed and accuracy would have been reached without prior visual feedback. These results emphasize a clear need to improve on auditory paradigms.

CONCLUSION

The implanted BCI system proves to be valuable to the user. It functions as a fail-safe method for communication when other AAC technologies are not (or no longer) accessible or available. Auditory BCI was successful, although at a reduced but encouraging speed, and may give the user reassurance that communication remains possible when control over eyelids fails.

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