Results of a 3 Year Study of a BCI-Based Communicator for Patients with Severe Disabilities

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***Abstract*— The Brain-Computer Interface (BCI) technology can convert brain electrical signals into commands able to control external devices without the need of any voluntary movement. This can be an innovative solution that allows interaction, especially for patients with pathologies such as Amyotrophic Lateral Sclerosis, Multiple Sclerosis, Muscular Dystrophy or ischemic/traumatic injuries, unable to use standard Augmentative Alternative Communication (AAC) devices because of the loss of limbs movements, gaze control or ophthalmological disorders. Among different approaches of signal analysis, a recent BCI device, Braincontrol Basic Communicator, based on event related desynchronization (ERD) produced by motor imagery (MI), has been recently developed by Liquidweb s.r.l. and used in the current study to overcome physical issues of these patients. The aim of this study was to verify the efficacy of the Braincontrol as an AAC device and to validate the training methodology with regards to patients in locked-in state (LIS). The study was conducted, from 2012 to 2015, on two groups: 42 patients with communication and motility disorder (of these 13 were in LIS and 10 in condition similar to the complete locked-in state, with no feedback and unknown cognitive status) and 63 healthy users. The results of this observation confirm that the device, after the first phase training, is efficient and robust for patients. Trainings have been completed successfully for all the healthy users and patients in initial and severe stage of the disease, only 2 out 42 patients failed the training. In particular, the 2 patients were in the condition similar to the complete locked-in state (CLIS). After this study, 17 locked-in patients have continued to use the system as a unique tool for communication.**

Keyword-Brain-Computer Interface (BCI); Augmentative and Alternative Communication (AAC); Assistive Technologies; Amyotrophic Lateral Sclerosis (ALS).

I. INTRODUCTION

Motor neuron diseases and degenerative neuromuscular disorders are characterized by a gradual loss of muscular function while usually retaining complete cognitive functions.

The progressive neurodegeneration induces progressive loss of upper and lower motor neurons, causing a progressive complete destruction of the peripheral and central motor system. The resulting condition is called Completely Locked-in State (CLIS).

If rudimentary control of at least one muscle is present, we speak of Locked-in State (LIS). The principal assistive technologies for LIS patients include residual movement controlled systems [16]-[17], voice-controlled systems, eye-tracking and brain computer interface (BCI). Brain-computer interface technology interprets electrical signals corresponding to a specific brain activity and allows the control of a computer or other external devices [1]-[13][18] (See Figure 1).

The interaction methods of BCI are classified on the identification and collection of the signal: there are Invasive, Partially Invasive and Noninvasive BCI.

The invasive category needs a neurosurgical implant of the sensors on the cerebral cortex, the partially invasive one requires the application of the sensors on the epidural or subdural space to record Electrocorticographic (ECoG) signal, while the noninvasive category uses external surface sensors in contact with the scalp permitting to record different kinds of signals, like Electroencephalography (EEG), Magnetoencephalography (MEG) and functional Magnetic Resonance Imaging (fMRI).

A different signal analysis, approaching to the EEG-BCI, includes Event-Related (P300) Potentials, Slow Cortical Potentials, Steady State Visual Evoked Potentials (SSVEP), Sensorimotor Rhythms (SMRs), and the Event Related Desynchronization or Synchronization (ERD/ERS) produced by Motor Imagery (MI).

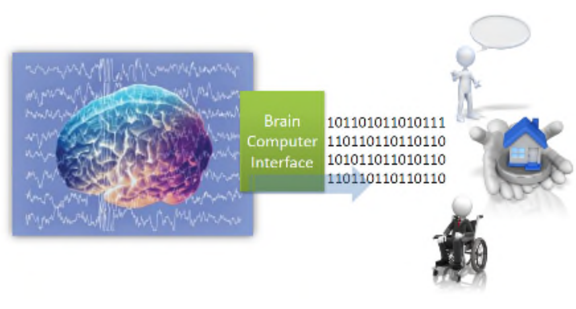

Figure 1. BCI Technology

Most of projects detects P300 Potentials or Visual Evoked Potentials but due to the need of sight in order to concentrate on the desired object, there are many patients who cannot use this technology. Furthermore, the weak electrical signal created by P300 requires gel-based EEG sensors, which means more time and hassle to prepare before use and clean after use.

Braincontrol system, instead, based on Motor Imagery, was developed by Liquidweb s.r.l. around the needs of CLIS and can also be used by blind people.

The first prototype, able to recognize 6 imagined movements, pull/push, top/bottom, left/right, was released in the fall of 2010 [14]. It has been continuously implemented between 2010 and 2012 and tested in the same period with more than 30 healthy volunteers providing excellent results and encouraging the development. The first version, Braincontrol "Basic Communicator", was completed in the middle of 2013. It fills a technological void for CLIS patients who cannot use eye-tracking systems or other assistive technologies.

Future versions of BrainControl, which are currently under development, will include advanced communication and entertainment (virtual keyboard, text-to-speech, social networks, email,), home automation (lights, temperature, etc.), control of a wheelchair and robotics (See Figure 2).

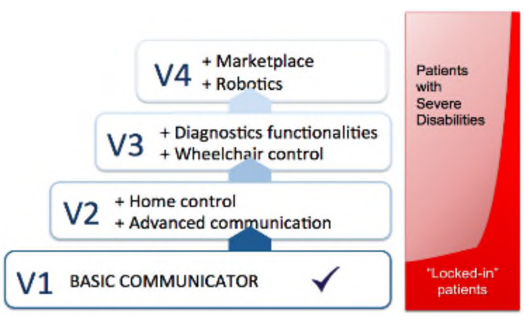

Figure 2. Roadmap

Working prototypes of all these functionalities have been developed and one of these, in robotic field, is BrainHuRo, a research project that applies BCI to humanoid robots [15].

The rest of the paper is structured as follows. Section II explains the aims of this study and the research protocol with Braincontrol. Section III reports the results of the study, concerning the percentage of success, while Section IV draws conclusions about the results.

II. AIM AND METHOD

The first aim of this study was to verify the efficacy of Braincontrol as an effective AAC communicator in patients with communicative and motility disorder. This aim will be evaluated on performing specific tasks described below. The secondary aim was to validate the trainings methodology in terms of targets roadmap, sessions timing and number of sessions, with regards to patients in locked-in state, in particular using feedbacks and advices from the healthy control group. The interaction system used is a sensorimotor rhythm (SMR) based BCI on top of a neurological process known as Event-Related Desynchronization (ERD). The ERD is detectable as a decrease in power in the β-frequency band on corresponding motor cortices. It has to be adapted to person-specific by the use of machine learning techniques. The heart of Braincontrol is a proprietary classifier of EEG patterns based on neural network technology and combined with an adaptive Bayesian algorithm for customizing different needs in different patients. The EEG headset, by Emotiv Inc. [19], detects and transfers the signals to the computer through wireless technology. The electrodes simply need to be dampened using a saline solution, instead of a special gel required from other headsets. It works like a mental joystick, detecting 6 types of imagined movements (IM), allowing a computer or other external devices to be controlled (See Figure 3).

Figure 3. BraincontrolArchitecture

The device used for the study includes a "Yes/No/Don't know" Selector (See Figure 4) and a "Sentence Finder" (See Figure 5). The user interface uses a scanning mode to move between available options and utilizes just one movement-related thought to select the desired choice.

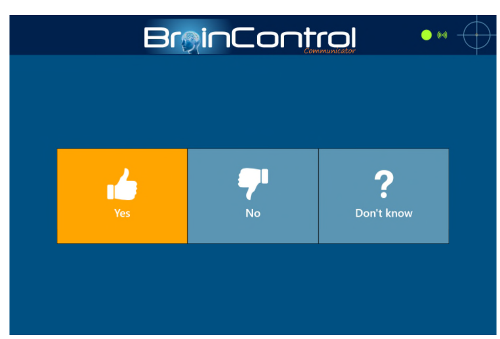

Figure 4. Yes/No/Don't Know Selector

Figure 5. Sentence Finder

The trainings have been carried out in four remote sessions (video conference with remote desktop control) of one hour each, planned in one month period for each user, from August 2012 to June 2015, with two groups of users:

I. 63 healthy volunteers
II. 42 patients with communicative and motility impairment.

The sample of healthy users was considered as a control group, to improve the quality of trainings through advices and to verify eventual differences on the roadmap.

During the first training, the trainer explains to the patient how the system works, its functionalities and the training purpose, then he starts with multiple iterative sessions of calibration and testing. During the calibration phase (See Figure 6), the software records the EEG data from the user which was asked to stay focused for a few seconds on the movement-related thought that will be used for controlling the system.

The test phases consist of asking the patients to select predefined sequences of choices.

This iterative session is conducted for 30-40 minutes and is replicated in the followings 3 sessions during the first month. If the user selects at least 4 predefined choices without errors during the test phase, the training is considered successful.

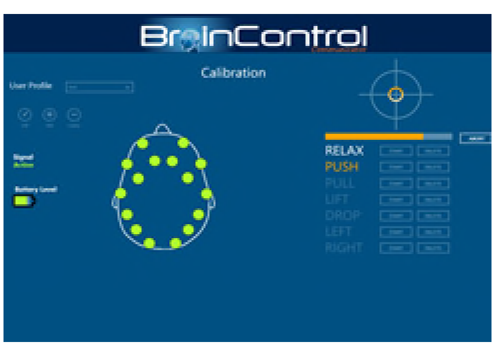

Figure 6. Calibration

After this first training phase the work is focused on the improvement of performances, by increasing the scanning speed and reducing the time of selection, in order to have a fast and efficient interaction.

III. RESULTS

In the period of August 2012 – June 2015 we carried out sessions of training with two groups of users:

I. 63 healthy volunteers
II. 42 patients with communicative and motility impairment
   A. 19 in initial or severe stage of the disease
   B. 23 locked-in (10 of these are in a condition similar to the complete locked-in state, with no possibility to give feedback).

The group of healthy volunteers, as the group IIA (19 initial and severe patients), completed successfully the training phase representing the 100% of the efficacy of the device.

Also in the LIS group (IIB) 21 out of 23 patients overcame the training phase (with a percent of 91% of success). The two, in particular, were in similar CLIS, in which cognitive abilities were unknown, and no kind of feedbacks was possible.

These results were stable over time, after the first phase of training. In patients who achieved the objectives it was possible to continue with the training and make them keen and able to use the device independently as a communicator.

IV. CONCLUSION

The aim of this study was to verify the efficacy and the effectiveness of Braincontrol as an AAC, improving training methodology with regards to patients in locked-in state. The study was conducted from 2012 to 2015, on a group of 63 healthy users and on 42 patients with communication or mobility impairment, planning four trainings in a one month period. The results of this observation confirm that the device, after the first phase training, is efficient and robust. Trainings have been completed successfully for all the healthy users and for patients in initial and severe stage of the disease. Only 2 out of 42 patients located in the locked-in group failed the training. In particular, these patients were in similar CLIS, in which cognitive status information where unknown. Seventeen locked-in patients, who really need this technology, are presently using the system as a communicator.

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DECLARATION OF INTEREST STATEMENT

The authors disclose they have the following financial or other interests in objects or entities mentioned in this paper:

- Pasquale Fedele is founder and CEO of Liquidweb s.r.l., the company producer of the BrainControl;
- Myriam Gioia is a speech therapist, employee in Liquidweb s.r.l. with trainer role.

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