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THE PROMOTŒR: A SUCCESSFUL STORY OF TRANSLATIONAL RESEARCH IN BCI FOR MOTOR REHABILITATION

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ABSTRACT: Several groups have recently demonstrated in the context of randomized controlled trials (RCTs) how sensorimotor Brain-Computer Interface (BCI) systems can be beneficial for post-stroke motor recovery. Following a successful RCT, at Fondazione Santa Lucia (FSL) a further translational effort was made with the implementation of the Promotœr, an all-in-one BCI-supported MI training station. Up to now, 25 patients underwent training with the Promotœr during their admission for rehabilitation purposes (in add-on to standard therapy). Two illustrative cases are presented. Though currently limited to FSL, the Promotœr represents a successful story of translational research in BCI for stroke rehabilitation. Results are promising both in terms of feasibility of a BCI training in the context of a real rehabilitation program and in terms of clinical and neurophysiological benefits observed in the patients.

INTRODUCTION

Several groups have recently demonstrated in the context of randomized controlled trials (RCTs) how sensorimotor Brain-Computer Interface (BCI) systems can be beneficial for post-stroke motor recovery [1]–[3]. At Fondazione Santa Lucia (FSL) we demonstrated in a RCT that an EEG-based BCI-supported Motor Imagery (MI) training can improve motor rehabilitation of the upper limb in subacute stroke patients with clinically relevant benefits as well as neurophysiological signs of increased activation of the affected hemisphere [4]. A further translational effort was made at FSL with the implementation of an all-in-one BCI-supported MI training station, namely the Promotœr, which is currently employed in add-on to standard therapy in patients admitted for rehabilitation. In this paper we will briefly retrace the path of BCIs for stroke rehabilitation at FSL, from prototype design, through clinical validation, to actual use in everyday practice as a possible successful example of translationality in BCI research. Furthermore, 2 case reports of training with the Promotœr will be presented.

MATERALS AND METHODS

The prototype in [4] was developed with continuous involvement of rehabilitation experts and endowed with strong rehabilitation principles such as: an ecological feedback for correct hand MI performance, selective reinforcement of correct brain activation (i.e. enhancement of affected hemisphere activation), continuous assistance of an expert therapist during the BCI training (the therapist is indeed part of the training setting receiving feedback of the patient's brain activity on a dedicated screen). Inputs on acceptability from professionals and patients were collected first in the form of a proof-of-principle study [5] and continuously throughout the experimentation.
Subsequently we conducted a RCT in 28 subacute patients [4]. Fourteen patients received the BCI supported hand MI training across four weeks, while 14 performed the MI training without the BCI support. At completion of training, the BCI group had a significantly greater improvement in Fugl-Meyer Assessment (FMA) scores that was clinically relevant. This improvement was accompanied by a significant increase of EEG motor-related oscillatory activity over the lesioned hemisphere only in the target group.
The continuous interaction with the clinical counterpart and the experience gathered in the RCT prompted us to implement an all-in-one BCI-supported MI training station, which we called Promotœr, for its main aim to *promote motor* recovery after stroke. The Promotœr comprises a computer, a commercial wireless EEG/EMG system, a screen for the therapist feedback (EEG and EMG activity monitoring) and a screen for the ecological feedback to the patient (a virtual hand performing the imagined movement in successful trials). Two Promotœr are currently installed in a rehabilitation ward at Fondazione Santa Lucia (Fig. 1).
During training with the Promotœr, the patient is seated on a chair (or wheelchair) with arms resting on a pillow. A visual representation of the forearms and hands is given on a dedicated screen, adjusted in size, shape and position as to resemble the patient's own hands. The patient is asked to perform MI of affected hand (timing

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of exercise is provided via a spotlight on the screen enlightening the target hand and reinforced verbally by the therapist). During MI, the therapist is provided with continuous feedback of the patient's brain activity on a dedicated screen; in brief, desynchronization occurring on electrodes placed above the affected sensorimotor area at sensorimotor relevant frequencies (BCI control features) is represented by a cursor moving towards a target (with speed proportional to the desynchronization). In successful trials (i.e. when the cursor reaches the target) the patient receives a positive reward represented by the visual representation of the affected hand moving accordingly with the imagined movement; otherwise, no visual feedback is represented on the patient's screen. Along the whole session, the therapist is allowed to monitor the patient's EEG and EMG activity (recorded from forearm muscles) in order to ensure complete relaxation and to guide/encourage him/her during the exercise.

Training sessions are carried out with the assistance of the same therapist in charge of the standard treatment for each patient, thus encouraging a further integration of our approach within the specific rehabilitation program of each patient. Before and after training, patients undergo a neurophysiological assessment in a similar way as described in [4] but with reduced number of EEG electrodes (31 positions vs 61). The aim of the screening is twofold: a) to extract EEG features for BCI training b) to evaluate the expected reinforcement of MI induced brain activation in the affected hemisphere (pre – post training). During the neurophysiological assessment, 30 trials of MI of affected hand are performed, randomized with 30 trials of rest of equal duration. BCI training is conducted with 8 electrode positions (vs 31), personalized according to the initial screening session: control features are selected among electrodes placed above the affected sensorimotor area (4 electrodes) and the montage is completed with the 4 homologous electrodes on the contralateral hemiscalp.

Figure 1: Training session with the Promotœr. The patient is seated on a wheelchair with arms resting on a pillow. A visual representation of the forearms and hands is given on a dedicated screen, resembling the patient's own hands. The patient is asked to perform MI of affected hand and the therapist is provided with continuous feedback of the patient's EEG and EMG activity (recorded from forearm muscles).

RESULTS

Up to now, 25 patients completed training with the Promotœr during their admission for rehabilitation purposes (in add-on to standard therapy). Of these, 21 suffered from ischemic or haemorrhagic unilateral stroke, while the remaining four had other type of acquired brain injury resulting in motor impairment of the upper limb. Twelve patients were in the subacute phase (< 6 months from the event) while 13 where chronic. In total, approximately 300 BCI training sessions were carried out. No drop-outs in the scheduled training program were observed, while two patients did not perform the post- training neurophysiological assessment (for being discharged beforehand or moved to another hospital).

We will present the cases of two patients (A and B). Patient A is a 77 years-old woman; she suffered from an ischemic stroke in the territory of the right middle cerebral artery and was admitted to FSL for rehabilitation with severe left hemiparesis. She started training with the Promotœr approximately one month from the event, performing 11 training session across one month of admission. Control features were selected according to the pre- neurophysiological screening (Fig. 2, left panel) on the right hemisphere, on the central line (C2) at frequency of 13-14 Hz. At the end of the training, the neurophysiological assessment was repeated showing an increased activation on the right hemisphere at EEG frequencies employed for BCI control (Fig. 2 right panel). A significant increase in upper limb FMA score was observed after training (from 31 to 46, i.e. above the threshold of Minimal Clinically Important Difference of 7 points).

Patient B is a 20 years-old man who had a traumatic haemorrhage in the left hemisphere with severe right hemiparesis and motor aphasia (initial upper limb FMA of 9). He was attending FSL outpatient service for rehabilitation and started training with the Promotœr approximately one year from the event, performing 22 training session across two months of admission. Control features were selected according to the pre-neurophysiological screening (Fig. 3, left panel) on the left hemisphere, on the central line (C1) at frequency of 9-10 Hz. At the end of the training, the neurophysiological assessment was repeated showing an increased activation on the left hemisphere at EEG frequencies employed for BCI control (Fig. 3 right panel). Clinical assessment of upper limb function did not show a relevant improvement, however a reduction in upper limb pain was reported.

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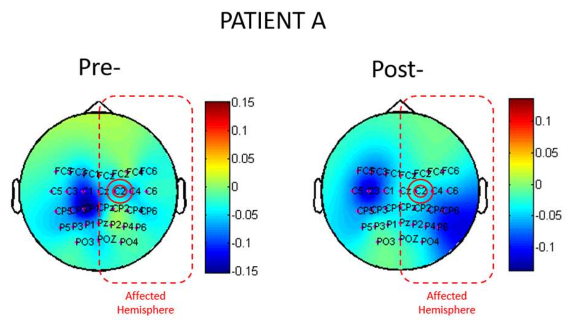

Figure 2: Pre- and Post- training neurophysiological assessment in representative patient A. Statistical maps of Rsquare values of Rest vs- left hand motor imagery at 13-14 Hz (frequency employed for BCI control; electrodes used for BCI training are circled in red).

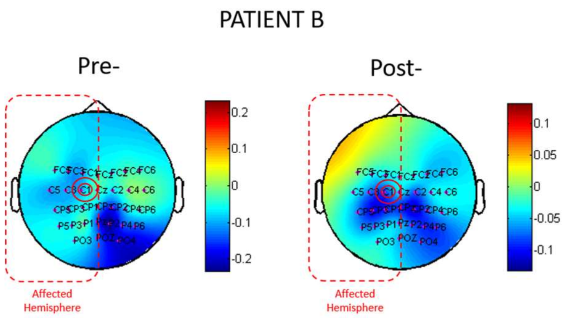

Figure 3: Pre- and Post- training neurophysiological assessment in representative patient B. Statistical maps of Rsquare values of Rest vs- right hand motor imagery at 9-10 Hz (frequency employed for BCI control; electrodes used for BCI training are circled in red).

DISCUSSION

The story of BCIs for post-stroke motor rehabilitation of the upper limb at FSL started within the TOBI project in 2008 (www.tobi-project.org). During the development and testing of our system, we fostered continuous involvement of rehabilitation experts, which resulted in a RCT on subacute patients supporting the efficacy of our approach [4]. A further translational effort led us to implement the Promotœr, a dedicated all-in-one station for BCI supported MI-training of the upper limb, which is currently used in the clinic outside any specific research program.
In this preliminary report, we are able to confirm some of the main results of the RCT [4].
First, a large number of patients/sessions with virtually no drop-out: it is indeed possible to integrate BCI technology in the real rehabilitation program of (mainly stroke) patients. Though anecdotal, general impressions from patients are enthusiastic, as they are extremely motivated to carry on the training sessions with the Promotoer.
Similarly, the close interaction with the clinical rehabilitation team is running smoothly, confirming a high acceptance of the approach among rehabilitation professionals [5].
The representative Patient A was a subacute stroke patient (thus comparable with the RCT population) showing a clinically relevant improvement of upper limb function accompanied by a reinforcement of sensorimotor related activity on the affected hemisphere (specific for the EEG feature employed in the training).
These confirmative results have some important implications. Since in the Promotœr we were able to simplify the setting (e.g. reducing the number of EEG electrodes for both training and Pre- Post- assessment) and maintain the main principles of the original system [4], we are now optimistic about the feasibility of a larger, multi-centric RCT to extend our results beyond our own institution. In this perspective, the challenges to prove the efficacy of our approach on a large scale are partially shared with other post-stroke rehabilitation strategies: a solid clinical trial design with proper randomization and proper sham/control conditions; a reliable follow-up evaluation to establish the duration of the effects. Other important aspects to take into consideration in view of a multi-centric RCT are strictly related to the BCI approach: the reliability of the system; the reproducibility of some operator dependent procedures such as features selection.
Furthermore, the possibility to extend our approach to chronic patients and patients with central nervous system lesions from different etiology (as for Patient B) paves the way for possible novel applications.
Patient B was in the chronic phase, with a severe, stabilized motor impairment. We were able to show an increase in sensorimotor related activity on the affected hemisphere throughout the training (specific for the EEG feature employed in the training). The subjective report of upper limb pain reduction along the training sessions is promising in terms of possible new applications.

CONCLUSION

The Promotœr represents a successful story of translational research in BCIs for stroke rehabilitation [6]. Though restricted to our institution, this experience allowed us as a BCI laboratory to be fully integrated in the clinic and receive daily inputs from rehabilitation experts. On one hand, the positive experience with the Promotœr prompts us to pursue a further clinical validation in a large, multi-centric RCT. On the other hand, everyday interaction with the clinical team extends our views beyond the specific intended application (e.g. spasticity or pain) which might apply not only to our approach, but to the use of BCIs in rehabilitation in general [7], [8].

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