A wearable hand neuroprosthesis for hand rehabilitation after stroke: preliminary results of the RETRAINER S2 randomized controlled trial

Franco Molteni, Mauro Rossini, Giulio Gasperini, Proserpio Davide, Karsten Krakow, Immick Nancy, Andreas Augsten, Johannes Zajc, Andrea Crema, and Silvestro Micera

***Abstract*— Stroke is the main cause of permanent and complex long-term disability in adults. RETRAINER S2 is a system able to recover and support person's ability to perform Activities of Daily Living (ADL) in early stage after stroke. The system is based on exercises for hand and wrist performed using Neuro Muscular Electrical Stimulation (NMES). This work describes the preliminary results of a multi-center Randomized Controlled Trial (RCT) aimed at evaluating effectiveness of the system. The preliminary results were calculated on 18 patients who completed the protocol. Data is promising, the RETRANER S2 system seems to be a good tool for stroke rehabilitation. Data confirms also a general good usability of the system.**

I. Introduction

STROKE is the main cause of permanent and complex long-term disability in adults and has implications for patients, caregivers, health professionals and society in general [1]. There is common agreement in the literature that functional recovery after stroke is positively influenced by goal-specific sensorimotor input through training or everyday use of the arm and hand [2]. Neuro Muscular Electrical Stimulation (NMES) is one of the treatments used to recover the use of paretic limb after a stroke and improve grasp capability. NMES systems have been tested extensively with chronic patients, but rarely in a coherent way on acute or sub-acute patients [3] for inherent limits of epidemiology.

TABLE I
PATIENT' CHARACTERISTICS

	Control Group	RETRAINER Group	p‡ value
Age*	64(12)	63(15)	0.915
Time since Event* (days)	100(74)	81(61)	0.412
Gender* (Male/Female)	9/9	9/9	
Aetiology* (Ischemic/hemorrhagic/Mixed)	14/4/0	11/5/2	
Affected Side (left/right)	10/8	9/9	

*Mean (standard deviation) - ‡ t-test for independent sample.

*Research supported by European Union's Horizon 2020 research and innovation program under grant agreement No 644721.

F.M., M.R., G.G. and D.P. are with Villa Beretta Rehabilitation Center of Valduce Hospital, Costamasnaga, Italy. (F.M. is the corresponding author; phone: +39-031-8544217; e-mail: fmolteni@ valduce.it).

K.K., I.M. and A.A. are with Asklepios Neurologische Klinik Falkenstein, Königstein, Germany.

J.Z. is with Ottobock Health Products GmbH, Wien, Austria.

A.C. and S.M. are with Ecole Polytechnique Federale de Lausanne, Switzerland.

RETRAINER S2 is a system able to recover and support person's ability to perform Activities of Daily Living (ADL) in subjects with upper limb impairment due to a stroke at the sub-acute or early chronic stage. This work describes the preliminary results of a multi-center Randomized Controlled Trial (RCT) aimed at evaluating effectiveness of the system in the recovery of hand functions. The RCT was registered on ClinicalTrials.gov registration number NCT03199833.

II. Material and Methods

A. Participants and sample

Subjects were selected within a cohort of stroke patients meeting the following inclusion criteria. A subject was considered eligible if his/her brain hemispheric lesion was unilateral, if s/he had no history or evidence of previous neurological and/or psychiatric disorders, if s/he was vigilant, collaborative and without global cognitive impairment. Other inclusion criteria were: age between 18 and 85 years, a distance from the acute event between 2 weeks and 9 months, Motricity Index (MI) lower than 80%, Medical Research Council (MRC) at least 1 for the target muscles, no limitation for using the system due to impairment of Passive Range of Motion PROM and/or Pain due to Spasticity evaluated using Modified Ashworth Scale, muscle response to NEMS and comfort (VAS <= 3) with the possibility to perform the required actions.

Sample size of 68 subjects was defined on the basis of ability to detect a Minimally Clinically Important Difference for primary outcome measure Action Research Arm Test (ARAT). The clinical trial was performed in two clinical centers: Valduce in Italy and Asklepios in Germany. The clinical trial compared one group of post-acute stroke survivors using the RETRAINER S2 system in addition to conventional therapy, and a second one treated only with conventional therapy. The subjects were randomly assigned to either the conventional or the RETRAINER S2 therapy group. Block randomization was applied to maintain the two groups balanced.

In Table I is shown the patients' characteristics.

B. System description

The system is a wearable hand neuroprothesis composed by a splint used for constrain wrist and finger motion plus electrode arrays able to stimulate the target muscles. In companion paper [4] the system is fully described.

C. *Exercises description*

RETRAINER S2 system proposes two different groups of exercises. The first group is performed with the wrist and the thumb fixed by an orthosis whilst the second one is setting with free wrist and thumb.

The first group includes four different exercises: i) Flexion and extension of fingers - the subject has to open and close the fingers alternatively; ii) Grasp and release objects - the subject has to grasp and release cylindrical objects with different size (Small, Medium and Large) and weight; iii) Grasp, move and release objects on a plane - the subject is seated in front of a desk, the height of the desk is adjusted in order to have the elbow at 90° of flexion and no compensation of shoulder in frontal plane. The subject must move an object on the desk in three different positions reaching, grasping and releasing it each time; iv) Grasp, move and release objects in space – activities mimic the previous exercise but the subject, in order to move the object to the new position, has to lift it at the shoulder level.

The second group includes just one exercise of flexion and extension of the wrist and fingers. The subject has to flex and extend the wrist and the fingers alternatively, and the anti-slacking stimulation is activated only in case of insufficient voluntary response.

The grasping exercises require from the subjects to be able to reach the objects, this means that patients must have good functional ability at both shoulder and elbow joints.

D. *Description of training program*

The treatment included three sessions a week for nine weeks for each patient. Each treatment session consisted of 30 minutes of RETRAINER S2 treatment or conventional treatment as a supplement to the standard allocation of 60 minutes of treatment. The patients were evaluated before the treatment (T0), at the end of treatment (T1) and four weeks after the end of treatment. Additionally to the main outcome measure, usability was measured by System Usability Scale (SUS).

The rationale behind the selection of each single exercise, for each patient, is clinically driven. In fact, the clinician selects the set of exercises from the available according to two factors: the residual functional ability of each subject and the rehabilitation goals.

III. Results

The preliminary results were calculated on 18 patients who completed the protocol. In Table II is shown the data (mean about the primary outcome ARAT for the complete test and for the gross Movement Items (gMT).

Usability data, evaluated using the System Usability Scale (SUS), is shown in Fig. 1 and indicates a quite good usability perception.

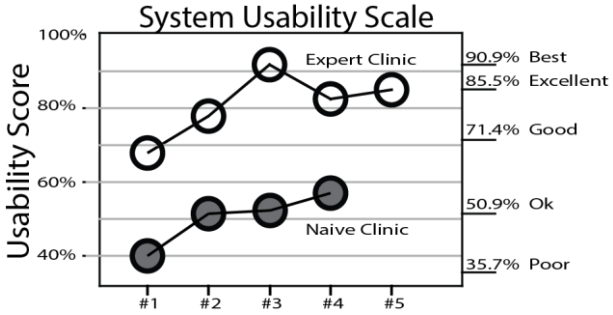

Fig. 1. RETRAINER Usability. Different levels of usability are perceived by operators of different clinics, both showing different initial levels of confidence with the used technology. In both cases is visible positive trend in the SUS rating, suggesting that a learning phase is required to use the device with effectiveness.

IV. Discussion

The preliminary results show that RETRAINER group patients have improved more than Control group patients. Data confirm a general good usability of the system by all patients, with a difference between the two center maybe due to the fact that one of them was more skilled at the beginning of the trial. The sample size at this stage is not enough to generalize the results to the target population. The study is ongoing and the complete sample should provide more robust information on the effects of the treatment.

V. Conclusion

The preliminary results are promising and RETRANER S2 system seems to be a good tool for stroke rehabilitation in early stage.

References

[1] Coupar F et al. Simultaneous bilateral training for improving arm function afterstroke. Cochrane Database of Systematic Reviews 2010, Issue 4. Art. No.: CD006432

[2] S. M. Hatem et al. "Rehabilitation of Motor Function after Stroke: A Multiple Systematic Review Focused on Techniques to Stimulate Upper Extremity Recovery," Front Hum Neurosci, vol. 13, 2016.

[3] S. Mangold et al. "Motor Training of Upper Extremity With Functional Electrical Stimulation in Early Stroke Rehabilitation," Neurorehabil. Neural Repair, vol. 23, no. 2, pp. 184–190, Feb. 2009.

[4] Crema A et. Al Development of a hand neuroprosthesis for grasp rehabilitation after stroke: state of art and perspectives. IEEE International Conference on Neurorehabilitation,Pisa, October 2018

TABLE II
TRIAL RESULTS

	Group	T0	T1	T2	p‡ group effect	p‡ time effect	p‡ group* time effect
ARAT (0-57)*	Control	30.6(21.3)	36.6(22.2)	40.7(20.8)	0.675	0.075	0.044
	RETRAINER	26.4(20.8)	42.3(18.8)	42.0(18.2)			
ARAT gMT* (0-9)	Control	6.4(2.3)	6.7(3.1)	7.2(2.5)	0.282	0.623	0.02
	RETRAINER	5.0(3.6)	7.6(1.9)	7.6(1.5)			

*Mean (standard deviation) - ‡ Linear mixed model analysis for repeated measures.