Reaching and grasping training based on robotic hybrid assistance for neurological patients

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Abstract: *The aim of the RETRAINER project is to tune and validate advanced, robot-based technologies to facilitate recovery of arm and hand function in stroke survivors and to verify extensively the use of the system by end-users. RETRAINER allows the users to use their own arm and hand as much and as soon as possible after the trauma so to achieve the best outcomes in rehabilitation. RETRAINER makes available two systems that could be used either combined or stand-alone. RETRAINER S1 provides the end-user with a robot that does not completely take over the user's tasks and substitute the functionality of the body, but specifically supports the user only whenever he/she really needs support. Residual functionality is trained and improved on rather than replaced by the robotic device. Arm movements is supported by the combined action of a passive exoskeleton for weight relief and Neuromuscular Electrical stimulation (NMES)delivered to several arm muscles in a controlled manner. RETRAINER S2 exploits a wearable NMES system with multiple arrays of electrodes for hand rehabilitation facilitating the grasping function. Both systems benefit from use of interactive objects, i.e. daily-life objects able to supply information about themselves to drive usage.*
The systems will undergo a thorough randomized control clinical trial with end users to assess their efficacy in rehabilitation.

Keywords: *Hybrid robotic rehabilitation system, stroke survivors, upper limb rehab, exoskeleton, wearable functional electrical stimulation, myocontrol neuroprosthesis, randomized control clinical trial*

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]. Stroke is the second most common cause of death in Europe, in 2008, there were approximately 1.3 million deaths from stroke in Europe, accounting for almost 14% of all deaths [2]. There are currently approximately 8 million stroke survivors in the European Union (EU). Stroke costs the EU over 62 billion euros a year including the cost of health care services, medications to treat stroke, and missed days of work. Stroke is a leading cause of serious long-term disability.

At present there is no routinely available curative treatment for stroke patients and therefore rehabilitation interventions are relied upon to maximize patient outcomes. Upper limb (arm) hemiparesis is widely reported in the literature as one of the primary impairments following stroke. While many patients recover ambulatory function after dense hemiplegia, restoration of arm motor skills is often incomplete.

Rehabilitation's outcomes often conclude in incomplete motor recovery and over 60% of patients cannot use their paretic hands in functional activities [3]. Nevertheless, the recovery of voluntary arm movements is one of the most important goals during stroke rehabilitation in order to avoid long- term disability in activities of daily living (ADL), social and occupational activities, and depression. The aim of rehabilitation is to reduce impairment and minimize disability and a number of interventions to achieve these aims and improve arm function after stroke have been suggested.

The aim of RETRAINER Project is to tune and validate advanced robot-based technologies to facilitate the recovery of the arm and hand functions in post-stroke patients, and to extensively verify the use of the system by end-users under three perspectives: 1) the usability of the system in clinical and in home settings; 2) the perceived benefits by the end-users and the informal and formal caregivers; 3) the impact of the use of the system on the rehabilitative outcomes.

RETRAINER system overview

RETRAINER makes available two systems which could be either combined or used stand-alone according to users' needs.

RETRAINER S1 - Training of arm movements: S1 provides the end-user with a robot that does not completely take over the user's tasks and substitute the body's functionality, but specifically supports the user only wherever he/she really needs support. Residual functionality is trained and improved rather than replaced by the robotic device. Arm movements are supported by a combined action of a passive exoskeleton for weight relief and Neuromuscular Electrical stimulation (NMES) delivered to arm muscles in a controlled manner (Fig.1). The lightweight exoskeleton provides the user with an adjustable amount of weight support to reduce necessary muscular effort for movements and at the same time NMES increases muscle activation and strengthen the muscles. Stimulation amplitudes is controlled based on the residual EMG activities of the same stimulated muscles since the combination of NMES with the voluntary effort of the patients seems to maximize the therapeutic effects of NMES, thus having the highest potential to increase the rehabilitative outcomes.

From a rehabilitative point of view, RETRAINER S1 has the major advantage of being intrinsically controlled by the subject himself/herself and stimulating the use of the arm in a context of real life activities, it indeed ensures the active participation of the users while keeping a good level of assistance to the user, depending on the condition.

RETRAINER S2 - Training of hand functions: Electric stimulation as restorative or assistive technology is among the best available practices, though not necessarily widespread in clinical environment. In the framework of RETRAINER, a novel wearable NMES system with multiple arrays, which could be a modular tool usable as a platform for grasp rehabilitation potentially improving the clinical applicability of NMES is being developed. The device is designed for providing electrical stimulation on extrinsic and intrinsic grasp muscles. It is composed of independent electrode arrays, customizable to user needs and anthropometric characteristics, which can be donned on the user forearm and hand, and can deliver NMES provided by an external stimulator with demultiplexers (Fig.2). The actual implementation offers a scalable anthropometric based design, which takes advantage of a priori knowledge of human anatomy. The aim is to have a device, with modular components that can be adapted to single patient needs. The stimulation patterns can be manually tuned to elicit functional grasp, to obtain whole muscle conditioning, and to produce open-loop or closed-loop grasp control.

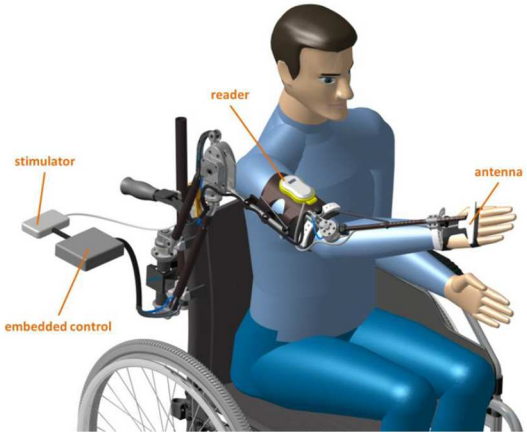

Figure 1: Digital mock-up of the complete RETRAINER S1 system

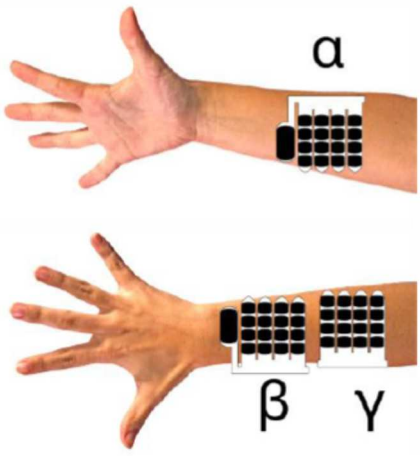

Figure 2: RETRAINR S2 system: electrode array placement.

RETRAINER interactive objects: Both systems will benefit from the use of interactive objects. Interactive

objects are daily life objects able to supply the robotic system with some information on themselves (e.g. physical characteristics, expected sequence of use) to drive their usage. The objects are equipped with RFID (Radio Frequency IDentification) tags and a suitable reader embedded in the robotic system. A devoted processing of Received Signal Strength Indication (RSSI) from the RFID tags and environmental constraints allow the recognition of the selected objects among several ones. The system identifies the proximity of an object to start grasping, the size and weight of an object to modulate grasp, the proximity of the table to return an object and to relax the hand [4]. The developed algorithms allow repeated selections of "target objects" aimed at driving a sequence of tasks in a known environment while the user is interacting with them. As soon as the sequence of tasks develops the system plans next task to be performed.

RETRAINER clinical trial

Potential end users will be selected among stroke patients. A subject will be considered eligible if his/her brain hemispheric lesion is unilateral, if s/he has no history or evidence of previous neurological and/or psychiatric disorders, if s/he is vigilant, collaborative and without global cognitive impairment. This last feature will assure the possibility for the potential participant subject to accept and sign by him/herself the informed consent.

The primary endpoint is the pre- and post-treatment difference in the ARAT Test, as well as in the other clinical scales that measure the effectiveness of the treatment. Sample size will be defined on the basis of ability to detect a Minimally Clinically Important Difference for primary outcome measure. It is calculated that a sample size of 68 patients would be capable of detecting a between-group difference of 5.67 points in the primary endpoint, this is the value indicated like Minimally Clinically Important Difference in Chronic Stroke population with a standard deviation of 12.5, a type I error of 5%, and a power of 80%78. Since ARAT is the reference scale for the upper limb functions, we consider it as the primary outcome measure of either the clinical trial with S1 and the one with S2. 68 end users will then be recruited for each clinical center.

NMES treatments literature suggests that effective treatments have prolonged duration and frequent sessions [5]. In this study, we will have not less than 30 minutes of effective NMES per session. Each session will last one hour considering the don on and off time, setup and calibration. The treatment will include three sessions a week for nine weeks for each end-user. The clinicians will choose a subset of exercises according to patient's condition and needs and will define the set of exercises to be performed at the beginning of the training session. The composition of each training session could be changed by the clinicians before starting according to the clinical situation of the patient. The RETRAINER software running on the tablet provides an interface for the therapist to setup the system for the patient, including configuration and calibration of all attached modules as well as teaching of reference positions if needed. The exercise subset includes arm and hand dedicated exercises. See in the tale below some examples.

ARM exercises	HAND exercises
Anterior Reaching Exercise on plane	Flexion and extension of fingers
Anterior Reaching Exercise in the space	Grasp and release objects
Moving Object on a plane	Grasp, move and release object on a plane
Moving Object on a plane in the space	Grasp, move and release object in the space
Moving Object in space	Flex Extension of wrist and fingers
Lateral elevation on frontal plane	
Hand to Mouth	
Hand to Mouth with an object in the hand	

Additionally to the main outcome measure, other specific outcomes will be measured to best evaluate the effects of the trials. Some of these clinical and quality of life outcome measurements are: Mini-Mental State Examination (MMSE), motricity index, Motor Activity Log (MAL), Box & Blocks Test (BB), System Usability Scale (SUS), Stroke Specific Quality Of Life scale (SS-QOL). During the training session some information on the treatment are shown on the GUI to let the therapist understand how the training is going on. The therapist for instance has a simple feedback on the actual involvement of the patient during training that can be used to give the patient proper instructions in order to stimulate his attention to the training. To evaluate the effectiveness of RETRAINER S1 and S2 will be used the Modified Ashworth Scale (MAS). The muscular assessment will be performed on different target muscles for each subsystem: on pectoralis major, deltoids, biceps and triceps for S1; wrist flexor and extensor, fingers and thumb flexor and extensor for S2.In both subsystem, kinematic data will be used to have an evaluation of the functional range of motion during the trial movements. The timeline for the application of the three evaluations is shown in Fig.3.

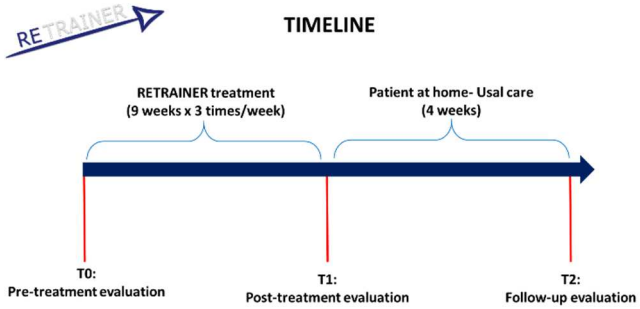

Figure 3: RETRAINR clinical trial design

Conclusions

The wide on the field validation of the RETRAINER system aims at objective assessment of robotic

neurorehabilitation on stroke survivors. From a robotics point of view, the RETRAINER arm module is an innovative and original system where the actuation exploits as much as possible the residual muscle functionality of the user himself/herself. This approach goes beyond the current classical rehabilitation robotics paradigms. Furthermore, the exoskeleton in S1 assures the gravity compensation and the control of the target motion using the contraction of the subjects own muscles. NMES controls the muscular activation until the user has achieved the desired task. The repetition of functional tasks with the participation of the user volition are key ingredients for re-learning and the additional proprioceptive feedback provided by the NMES has been recently proved in the literature as an additional elements in favour of recovery and brain remapping [6] [7]. An effective clinical validation of this system is a key issues in supporting technological innovation in current rehabilitation practices. The concept and design of this clinical trial validation is another interesting output of this project. The personalized set of exercises selected by the clinician according to patient's functional conditions is a real benefit for the patient: thanks to this unique solution, the upper limb movement could be rehabilitated according the therapist clinical evaluation, using his/her expertise integrated with the technology facilities to get the feasible best rehabilitation outcome.

RETRAINER is a clear example of multidisciplinary cooperation aimed at the design and setup of a rehabilitation system including technology development as well as exercises design and clinical assessment.

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