

A Hybrid Robotic System for Arm Training of Stroke Survivors: Concept and First Evaluation

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Abstract—Objective: To develop and evaluate a hybrid robotic system for arm recovery after stroke, combining ElectroMyoGraphic (EMG)-triggered functional electrical stimulation (FES) with a passive exoskeleton for upper limb suspension. **Methods:** The system was used in a structured exercise program resembling activities of daily life. Exercises execution was continuously controlled using angle sensor data and radio-frequency identification technology. The training program consisted of 27 sessions lasting 30 min each. Seven post-acute stroke patients were recruited from two clinical sites. The efficacy of the system was evaluated in terms of action research arm test, motricity index, motor activity log, and box & blocks tests. Furthermore, kinematics-based and EMG-based outcome measures were derived directly from data collected during training sessions. **Results:** All patients showed an improvement of motor functions at the end of the training program. After training, the exercises were in most cases executed faster, smoother, and with an increased range of motion. Subjects were able to trigger FES, but in some cases, they did not maintain the voluntary effort during task execution. All subjects but one considered the system usable. **Conclusion:** The preliminary results showed that the system can be used in a clinical environment with positive effects on arm functional recovery. However, only the final results of the

currently ongoing clinical trial will unveil the system's full potential. **Significance:** The presented hybrid robotic system is highly customizable, allows to monitor the daily performance, requires low supervision of the therapist, and might have the potential to enhance arm recovery after stroke.

Index Terms—Exoskeleton, functional electrical stimulation, hybrid technology, upper limb, rehabilitation, stroke, assessment.

I. INTRODUCTION

STROKE is one of the leading causes of death and acquired adult disability and handicap [1]. The most common impairment after stroke is upper limb paresis, which is found in 77% of stroke survivors [2].

When the stroke leads to a flaccid hemiplegic arm, more than 60% of patients fail to achieve some arm dexterity six months after the event and only 12% show a complete arm functional recovery [3]. Thus, most stroke patients are severely affected in their ability to perform activities of daily life (ADL) [4]. A reduced arm dexterity has a huge impact on independent living and quality of life of stroke survivors and their families [5], [6], making very urgent the need for effective interventions to improve arm recovery after stroke.

It has been shown, that strength training [7] and repetitive task training [8] positively influence the recovery of motor functions after stroke. Rehabilitation robots can support human therapists to conduct these types of training as they allow a therapy paradigm which is intensive, frequent, repetitive and task-oriented in agreement with the motor learning principles [9]. Stroke patients involved in robot-assisted arm training are more likely to improve their capability to perform ADLs [10] and show small but significant improvements in motor control and muscle strength of the paretic arm in comparison to patients receiving non-robotic treatments [11]. Various robots have been designed for post-stroke arm rehabilitation [12]. Among them, interactive robots, which allow the active involvement of the residual neuromuscular pathways, showed better therapeutic effects than devices which provide only passive limb motions [13].

There is a common agreement that Functional Electrical Stimulation (FES) can be used as a motor relearning tool by enabling hemiparetic patients to participate in goal-oriented repetitive

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movement therapy [14]–[16]. A review article by Howlett *et al.* [17] concluded that FES "appears to moderately improve activity compared with both no intervention and training alone", therefore recommending the use of FES in stroke rehabilitation. Effects seem to be particularly beneficial when FES is applied within 2 months after stroke [18]. A systematic review showed that ElectroMyoGraphic (EMG)-triggered FES is more effective than non-triggered FES in facilitating arm motor recovery after stroke [19]. Conversely, a recent randomized controlled trial (RCT) did not observe any difference between cyclic, EMG-triggered and sensory FES on motor impairment and functional limitations, with all three FES modalities showing significant improvements [20]. The use of FES concomitant with the voluntary drive has been shown to enhance cortical plasticity so as to potentially improve the therapeutic effects of FES [21]–[23]. However, EMG-triggered FES might not be enough to guarantee a close association between the voluntary drive and the stimulated motor response throughout the task execution. To overcome this limitation, FES control strategies, which promote the subject's active involvement during the whole task and not just trigger it [24], [25], have been developed but an extensive clinical validation of their efficacy is still missing.

In agreement with the theory that interventions can be merged in order to enhance functional recovery [26], the combined use of FES and robotic technologies, referred to as Hybrid Robotic Rehabilitation Systems, has gained increased interest for arm stroke rehabilitation [27]. A recent RCT involving chronic stroke survivors showed that the combined action of robot-assisted therapy and FES for wrist movements in case of bimanual tasks has a positive effect on hand movement quality and spasticity [28]. More recently, a pilot RCT on 24 subacute stroke patients compared the training effects of an EMG-triggered FES-robotic system supporting elbow, wrist and finger movements with traditional physical therapy, showing that the novel system was more effective [29]. Positive effects on muscle coordination at elbow, wrist and fingers were achieved when the same system was used with 11 chronic stroke patients [30]. All these studies targeted on distal joints and did not include shoulder movements.

FES was combined also with passive anti-gravity exoskeletons, e.g., the Hocoma ArmeoSpring [31] and a custom-built passive suspension exoskeleton developed during the European project MUNDUS [32], [33]. In the former study [31], FES was mediated by iterative learning control in virtual reality tracking trajectories; elbow extension and shoulder flexion and abduction were trained achieving promising results on 5 chronic stroke patients. In the latter study [32], FES was applied to the deltoids and the biceps muscles and a feedback control system sequentially controlling each joint angle was developed. However, the final aim of this system was assistive and non-rehabilitative.

So far, few hybrid robotic systems have focused on shoulder movements and have exploited EMG-controlled FES; additionally, none of them have monitored the subject's involvement during training. This work proposes a hybrid robotic system, called RETRAINER-ARM system, for arm stroke rehabilitation [34]. This system was designed within the European project RETRAINER, which in parallel was focused on the development of a wearable multi-site FES system for hand function restoration [35].

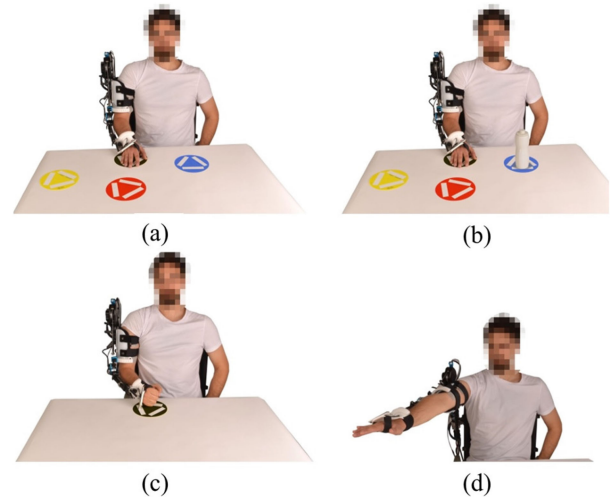


Fig. 1. RETRAINER-ARM training exercises.

The most innovative features of the RETRAINER-ARM system are: 1) the subject interacts with a real environment during ADL-inspired exercises; 2) the exercises involve shoulder and elbow movements; 3) FES is triggered by the EMG signal with an automatic threshold setting on single user and session; 4) activation of FES is modulated on task goals; 5) voluntary participation is monitored and fed back to the user; 6) FES can be delivered to two muscles, selected from a panel of five, tailored on the specific subject condition; 7) a Graphical User Interface (GUI) and an embedded controlled system assure a smooth execution of all procedures (from donning the system to the setting and execution of the training session) with a low supervision of the therapist.

II. METHODS

A. Participants

Participants were adults (age range 18-85 years) who have suffered a first stroke between two weeks and nine months (subacute stage) before study enrollment. A subject was considered eligible if his/her brain lesion was unilateral, if she/he had no history or evidence of previous neurological and/or psychiatric disorders, if she/he was vigilant, collaborative and without major cognitive impairment (Mini-Mental State Examination >20). Participants were inpatients and outpatients of the Asklepios Neurologische Klinik Falkenstein (ANKF) in Germany and of the Villa Beretta Rehabilitation Center (VB) in Italy, recruited within a wider multi-center randomized controlled trial (ClinicalTrials.gov Identifier: NCT03171649). The study was approved by the Ethical Committees of the two clinical centers, and participants were asked to sign a written informed consent.

B. Exercise Description

The RETRAINER-ARM system offers the therapists the possibility to choose among several exercises (Fig. 1).

Each exercise resembles activities of daily life and is composed of multiple tasks, each consisting of a single target movement. All exercises, but *Lateral Elevation*, started from

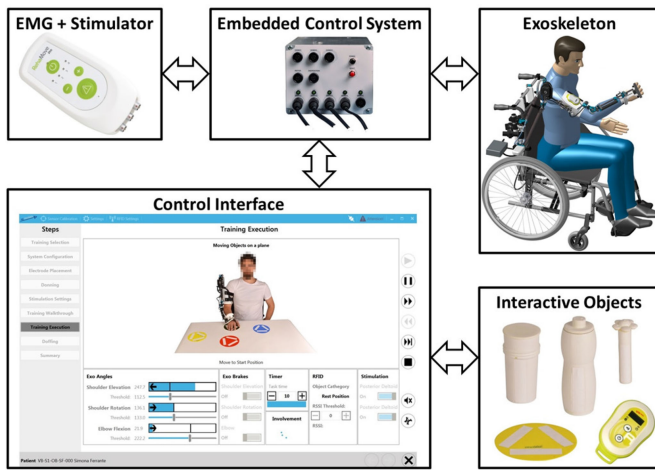


Fig. 2. RETRAINER-ARM system: apparatus overview.

the *Rest Position*: the subject is seated in front of a table with a low friction surface, with the hand on the table and the elbow at about 90° of flexion (Fig. 1-A).

The available exercises are the following ones:

1) Anterior Reaching (on a Plane or in the Space): The subject, from *Rest Position*, has to either reach or elevate his/her hand over three target positions. Position targets are placed on the table at central, lateral internal and lateral external positions, according to the subject's working volume. Once a position target is reached, the subject has to return to the *Rest Position*.

2) Moving Objects (on a Plane or in the Space): Three position targets are either placed on a higher plane (i.e., a carpentered desktop shelf with a similar surface as the table), roughly at the subject's shoulder level, or on the surface of the table as the *Rest Position* (Fig. 1-B). The subject has to grasp the object in the central position, then - with the maximum feasible elbow extension - push/pull or lift it to first reach the lateral internal and thereafter the lateral external position. Once a target position is reached, the subject has to release the object and return to the *Rest Position*. Lastly, the object is to be returned to the central position.

3) Hand to Mouth (With or Without Object): The subject's hand is in the *Rest Position*, grasping or not an object (Fig. 1-C). The subject has to reach his/her mouth with the hand and move it back to the *Rest Position*.

4) Lateral Elevation: The subject starts with the arm along the side (Fig. 1-D). The arm has to be elevated in the frontal plane to reach the horizontal position, e.g., the shoulder level, and move back to the initial position.

C. Apparatus

The RETRAINER-ARM system (Fig. 2) consists of a passive arm exoskeleton, a current-controlled neuro-muscular stimulator capable of recording EMG signals, a set of interactive objects, a real-time capable Embedded Control System, and a tablet computer running a Control Interface.

TABLE I
ADJUSTABLE PARAMETERS OF THE EXOSKELETON

Height adjustment	0mm...150mm ^a
Upper arm diameter	S-M: max. 80mm M-L: max. 96mm
Upper arm length	245mm...295mm ^b
Humeral Rotation	$0^\circ \dots 90^\circ$ ^c
Forearm length	215mm...305mm ^b
Wrist Pro-/Supination	$-50^\circ \dots 50^\circ$ ^c
Wrist diameter	40mm...70mm
Hand Extension	25°
Elbow flexion/extension (α)	ROM 120°
Shoulder elevation (β)	ROM 120°
Shoulder rotation (γ)	ROM 130°
Trunk Inclination (δ)	ROM 25°

^aZero position depending on mounting. ^bManually settable in 10 mm steps; ^cmanually settable in 10° steps. ROM, Range of Motion.

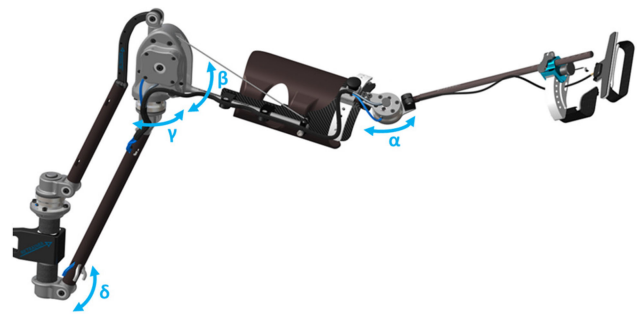


Fig. 3. Degrees of freedom of the exoskeleton.

1) Exoskeleton: The exoskeleton is highly adaptable to the subject's anthropometric measures (Table I). Indeed, it can fit and support subjects within 5th and 95th female/male percentile. It can be mounted on the user's wheelchair or on a normal chair.

The exoskeleton is characterized by four degrees of freedom (DOFs), as shown in Fig. 3. An inclination mechanism enables the subject to move the trunk without restriction (δ). The mechanism is realized by a four-bar linkage which integrates the shoulder module thereby guaranteeing that it remains in a vertical position independent of the inclination angle.

The remaining three DOFs (shoulder rotation γ , shoulder elevation β , and elbow flexion/extension α) are each equipped with a goniometric angle sensor (Vert-X 13 E, ConTelec AG) to track the patient's movements and with an electromagnetic brake (MBG0S2AA and MBG0S4AA, Chaintail Co. Ltd). The brakes can be used to selectively block DOFs.

The exoskeleton provides a suspension against gravity of the forearm and of the upper arm by using spring mechanisms.

These mechanisms consist of a carbon-fiber tube with springs inside and a cable pull [36]. The level of suspension can be adjusted to the subject's needs by changing the pre-tension of the springs. The adjustment of the forearm suspension is done manually by changing the position of the carbon-fiber tube. The suspension torque does not only depend on the pretension of the spring, but also on the flexion/extension angle (Fig. 4-A). The arm gravity suspension consists of two springs, one of which

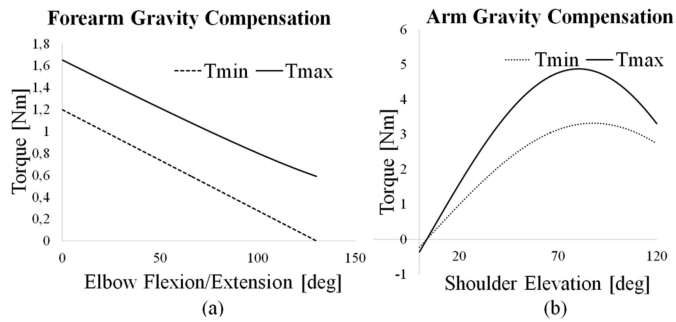


Fig. 4. Suspension torques as function of the corresponding angles, with T_{min} and T_{max} being the minimal and maximal providable torque.

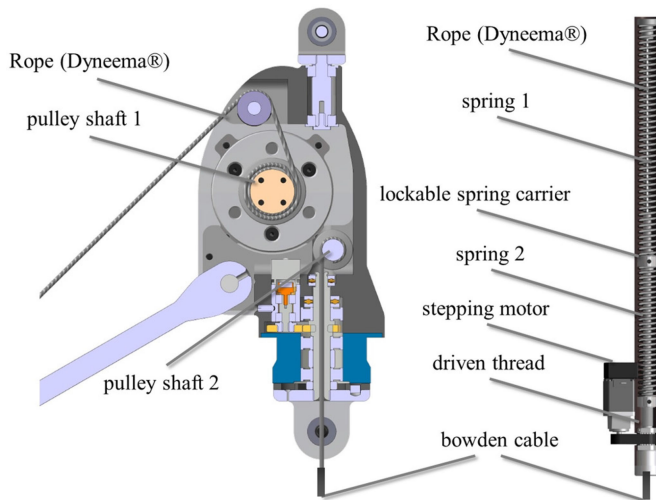


Fig. 5. Arm suspension against gravity consists of a cable pull integrated in the exoskeleton's shoulder module (left) and a carbon fiber tube with two springs inside (right), connected by a bowden cable.

can be locked manually to achieve higher torques (Fig. 5). The arm gravity suspension can be adjusted electronically via a stepper motor (ST2818, Nanotec Electronic GmbH und Co. KG). Analogous to the forearm suspension, the shoulder suspension depends on the shoulder elevation angle (Fig. 4-B).

2) Stimulator and FES Controller: The system includes a current-controlled battery-powered stimulator providing up to ± 150 mA stimulation current and a supply voltage between 30 V and 150 V settable in 30 V steps (Rehamove Pro, Hasomed GmbH).

The stimulator has four channels, two of which can be used to acquire EMG signals with a sampling frequency of 4 kHz [37]. An adaptive linear filter is used to estimate the volitional EMG contribution during hybrid muscle contractions [25]. FES is triggered by the volitional EMG signal using a patient-specific threshold, set at each session with an automatic procedure. A timer triggers FES in case the threshold is not reached within a predefined time-out. The stimulation frequency and the pulse width are fixed at 25 Hz and 300 μ s, respectively, while the stimulation intensity is set at the beginning of the training session for each muscle individually to a value tolerated by the

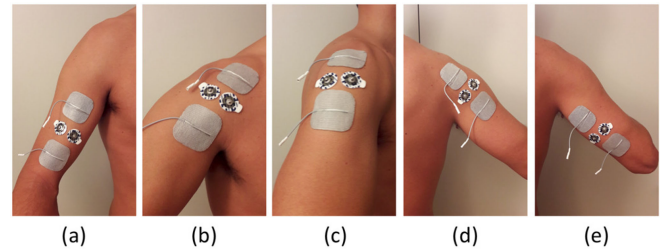


Fig. 6. Placement of the electrode on biceps, (a) anterior deltoid, (b) medial deltoid, (c) posterior deltoid, (d) and triceps (e) muscle.

subject and able to induce a functional movement. EMG signals are recorded using Ag/AgCl pre-gelled electrodes (Convien Kendall, 24 mm contact size), while surface 50 \times 50 mm electrodes (Pals electrodes, Axelgaard Manufacturing Co. Ltd.) are used for stimulation. EMG electrodes are placed between the stimulation electrodes perpendicular to the muscle fibers direction (Fig. 6).

To promote the involvement of the subject during training, a feedback about the volitional effort is displayed in the GUI through a happy/sad emoji.

Up to two muscles, from a panel of five (biceps, triceps, anterior, medial, posterior deltoid) can be stimulated simultaneously.

More details on the FES controller can be found in [34].

3) Interactive Objects: The system exploits Radio-Frequency Identification (RFID) technology and includes a RFID reader, so-called interactive objects, and a backend to manage the operations and elaborate the reader's signal (Fig. 2). The reader is a compact commercial device (qIDmini R1170I) operating at UHF (840-960 MHz) and compliant with the Class 1 Gen2 standard. The reader was modified to substitute the built-in antenna with an external one, mounted on the exoskeleton at the hand level. The term "interactive object" refers to either 3D-printed cylindrical objects of daily life (e.g., a bottle) or target positions. Interactive objects with different weight and diameter are available for training. Each interactive object is equipped with 3 passive tags associated to the same unique identifier (UID). The RFID reader retrieves the UID and the Received Signal Strength Indicator (RSSI) of the interactive objects in the proximity of the antenna. Since the RSSI is inversely proportional to the distance of the tag to the antenna, the RSSI can be interpreted as a measurement for the relative distance between an interactive object and the subject's hand. Thus, the RSSI is used during the training to determine if the subject has reached a target position or an object.

The backend is a C# library, communicating with the reader via Bluetooth, retrieving the UID and estimating the RSSI.

4) Embedded Control System: The Embedded Control System (ECS) acts as hardware interface between the Control Interface and the hardware components. The ECS directly controls the modules requiring real-time constraints, which are the stimulator and the exoskeleton. The ECS is composed of a BeagleBoneBlack, a signal board, a power module and a USB-hub. The USB-hub enables the communication with the stimulator, while the power module provides the different voltage levels for

the signal board, the stepper motor and the relay drivers connected to the exoskeleton brakes. The signal board provides the circuits to set the brakes, to get the sensor values from the goniometric sensors and to set the stepper motor of the arm gravity suspension module. The BeagleBoneBlack runs an executable implemented using Matlab/Simulink and compiled to a C/C++ executable following the ISO/IEC 9899:1990 Norm. This executable contains the before mentioned adaptive filter and the FES controller.

5) Control Interface: The Control Interface (CI) is an application implemented using C# and Windows Presentation Foundation and optimized to be used on a Windows-based tablet (Surface 3 running Windows 7 or higher). It comprises of a GUI, a database, a finite state machine, and a communication interface to the ECS. The communication follows a strict master-slave concept using a User Datagram Protocol (UDP) to keep the ECS and the CI synchronized: the CI sends commands, the ECS executes the corresponding algorithms and responds with an acknowledgment upon reception. For safety and usability reasons, the GUI is implemented as a wizard: each step has to be finished before the next is started. Textual explanations, images, and audio messages guide the therapist and the user throughout the entire training session.

A training session is composed of four main phases: configuration, donning, parameterization and training.

The configuration phase contains the connection to the RFID-reader via Bluetooth, the selection (or creation) of a patient profile, the selection of a sequence of exercises, of the interactive objects, and of the muscles to stimulate. Additionally, the exoskeleton and the gravity suspension are configured according to the subject's anthropometric measures and needs, following instructions displayed on the GUI.

The donning phase consists of the placement of EMG and stimulation electrodes and the donning of the exoskeleton.

In the parameterization phase, the stimulation parameters (i.e., stimulation currents and EMG thresholds) are set automatically, and the exercise state machine is initialized by setting subject-specific parameters for each exercise (position of targets and time-out periods). To guarantee the reward of task completion, while keeping the exercises challenging, the weight suspension, the weight and size of the interactive objects, and the support provided through FES are adaptable to the patient's needs and throughout the training.

Finally, in the training phase, the exercise is executed automatically by the finite state machine. Intervention by the therapist is only required if the execution is halted (e.g., when the target of a task can't be reached by the subject). Each task performed by the subject during an exercise is represented by a specific state in the state machine. Transitions between tasks and thus states are triggered whenever either angle sensor data or RFID data assess for task completion, i.e., current data meet the subject-specific thresholds set during the parameterization phase. Each state is associated with actions, performed by the system whenever the state is entered, and a new task begins:

- 1) The GUI is updated and provides audio-visual instructions;
- 2) Depending on the task, brakes are activated to lock DOFs;

TABLE II
DESCRIPTION OF THE EXERCISES

Exercise/ Task ^a	Brakes ^b			Muscles ^c					Trigger	
	γ	β	α	B	T	AD	MD	PD	Exo	RFID
ARP										
Center										
Rest										
Internal										
Rest										
External										
Rest										
ARS										
Center										
Rest										
Internal										
Rest										
External										
Rest										
MOP										
Center										
Internal										
Rest										
Internal										
External										
Rest										
External										
Center										
Rest										
MOS										
Center										
Lift Object										
Internal										
Rest										
Internal										
Lift Object										
External										
Rest										
External										
Lift Object										
Central										
Rest										
LE										
Up										
Down										
HM										
Mouth										
Rest										

^aARP, Anterior Reaching on a Plane; ARS, Anterior Reaching in the Space; MOP, Moving Objects on a Plane; MOS, Moving Objects in the Space; LE, Lateral Elevation; HM, Hand to Mouth.

^b γ , shoulder rotation; β , shoulder elevation; α , elbow flex-extension.

^cB, Biceps; T, Triceps; AD, Anterior Deltoid; MD, Medial Deltoid; PD, Posterior Deltoid.

- 3) If the muscles selected by the therapist are used in the current task, the corresponding FES controller is activated.

Throughout the task execution, the volitional involvement of the user is monitored. A visual feedback on the voluntary activity concurrent to FES is provided at the end of each task to motivate the user to be actively involved in the training. Each task is followed by a pause (relax phase) of few seconds during which all brakes are active.

Table II provides an overview of the tasks of each exercise. The chart provides information for each task about which brakes are active, which muscles can be stimulated (if previously

selected in the configuration phase), and which inputs can trigger a transition to move to the next task.

D. Experimental Protocol

The training program included 27 sessions, 3 sessions per week for a total of 9 weeks. Each session consisted of a 30-minute training with the RETRAINER-ARM system, while a maximum of 30 minutes was reserved for donning, doffing and parameterizing the system. The therapist assessed the strength of the arm muscles using the Medical Research Council Scale (MRC). Based on the muscles scores, the two weakest muscles and thereby best candidates for FES were identified. Table II was used as a guideline to determine which exercises were best suited to train the target muscles. The exercise sequence and the duration per exercise were chosen in order to build a feasible but always challenging training session. Each exercise was executed in a repetitive loop for a settable time. Three therapists, one at VB and two at ANKF, participated in the study, after been properly instructed. The final decision of the target stimulated muscles and the sequence of exercises was determined on the basis of clinical considerations specific for each single patient, possibly evolving across sessions. No strict rules were a priori imposed to permit the proper personalization of the therapy.

E. Clinical Outcome Measures

Before and after the training program, the following clinical outcome measures were collected:

- 1) *Action Research Arm Test (ARAT)*: A 19-item outcome measure divided into 4 sub-tests (grasp, grip, pinch, and gross arm movement), which ranges between 0 (maximal impairment) and 57 (no impairment);
- 2) *Motricity index (MI) – arm*: A clinical scale to evaluate motor impairment of the upper limb after stroke, which ranges between 0 (maximal impairment) and 100 (no impairment);
- 3) *Motor Activity Log (MAL)*: A semi-structured interview to assess arm function. Individuals are asked to rate quality and amount of movement during 30 daily functional tasks; it consists of two sub-scales (MAL quality and MAL quantity), each ranging between 0 (not used) and 5 (fully used).
- 4) *Box & Blocks Test (BBT)*: A test to assess unilateral gross manual dexterity. Individuals are seated at a table, facing a rectangular box that is divided into two square compartments of equal dimension. 150, 2.5 cm, wooden blocks are placed in one compartment. The test is scored by counting the blocks moved over the partition from one compartment to the other during the one-minute trial period.

At the end of the training program, subjects were also asked to complete the System Usability Scale (SUS) which consists of ten 5-point Likert scale questions ranging between 0 (no satisfaction) to 100 (extreme satisfaction) [38], [39]. A SUS score >68 is considered above average.

TABLE III
CLINICAL AND DEMOGRAPHIC CHARACTERISTICS OF THE PARTICIPANTS

Subject	Sex	Age	Time since stroke [days]	Affected side	Type of stroke
VB-01	M	75y	96	Left	Ischemic
VB-02	M	54y	19	Left	Hemorrhagic
VB-03	F	24y	41	Right	Ischemic
VB-04	M	68y	50	Left	Ischemic
ANKF-01	M	68y	35	Left	Ischemic
ANKF-02	M	83y	20	Right	Ischemic
ANKF-03	F	65y	80	Right	Ischemic

Due to the small number of participants, a Wilcoxon test was used to compare clinical measures collected before and after training.

F. Kinematics-Based Outcome Measures

To quantitatively assess the day-by-day performance of the patients in the completion of the exercises, the following outcome measures were calculated starting from the kinematics data acquired by the system. In this context, a repetition means the completion of all sequential tasks to return to the starting position (e.g., moving the hand to the mouth and returning to the *Rest Position*).

- 1) *Exercise Duration [s]*: The duration of a single repetition of an exercise was computed as the sum of the duration of its tasks. Relax phases were discarded since their duration was set a priori by the therapist and was not representative of the motor capability of the subject.
- 2) *Smoothness*: The movement smoothness of each task was calculated as the mean angular speed divided by the peak angular speed [40]. Values were computed separately for the shoulder elevation, shoulder rotation and elbow angle but only if relevant movements for the specific angle (ROM > 5°) were performed. A global value for a single repetition of an exercise was computed by averaging first across tasks and then across angles. The final value ranges from 0 to 1, with higher values reflecting smoother movements.
- 3) *ROM [°]*: The ROM of each task was computed separately for the three measured angles (shoulder elevation, shoulder rotation, and elbow). Only the most relevant angles for each exercise were considered (e.g., for Anterior Reaching and Moving Object: all the three angles; for Hand to Mouth: shoulder elevation and elbow; for Lateral Elevation: shoulder elevation). Then, separately for each regarded angle, the maximal ROM for a single repetition of an exercise was computed considering all tasks.

The effect of training was evaluated by comparing, through a Student's t-test, kinematics-based outcome measures collected during the first three and the last three training sessions. The statistical analysis was performed separately for each patient and exercise.

TABLE IV
CLINICAL OUTCOME MEASURES BEFORE (T0) AND AFTER (T1) THE INTERVENTION

	ARAT [0-57]		ARAT gross arm movement [0-9]		MI [0-100]		MI elbow & shoulder [0-66]		MAL Quality [0-5]		MAL Quantity [0-5]		BBT		Exercises (# sessions) ^a					Usability	
	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	ARP	ARS	MOP	MOS	LE	HM	SUS
VB-01	8	57	3	9	56	77	33	50	0.57	3.17	0.33	3.27	2	32	23				24	24	95%
VB-02	3	55	3	9	19	71	18	44	0	0.9	0	0.63	0	17				22	22	88%	
VB-03	5	52	5	7	56	73	44	50	0.1	1.93	0.03	2.3	0	25	19			5	5	85%	
VB-04	3	46	3	8	40	70	28	50	0.1	1.04	0.1	0.86	0	23				23	24	75%	
ANKF-01	0	14	0	4	30	56	18	33	0.07	0.9	0.07	0.9	0	10	19				5	75%	
ANKF-02	3	38	3	9	56	77	33	50	0.52	1.7	0.24	1.63	0	11	18	1			9	43%	
ANKF-03	0	47	0	7	56	60	33	33	0.67	3.17	0.6	3.17	11	36	6	4	2	7	4	70%	
Median (IQR)	3 (5)	47 (17)	3 (3)	8 (2)	56 (26)	71 (17)	33 (15)	50 (17)	0.10 (0.50)	1.70 (2.27)	0.10 (0.30)	1.63 (2.31)	0 (2)	23 (21)							
Z score (p-value)^b	-2.371 (0.018)		-2.384 (0.017)		-2.371 (0.018)		-2.207 (0.028)		-2.366 (0.018)		-2.366 (0.018)		-2.371 (0.018)								

^aARP, Anterior Reaching on a Plane; ARS, Anterior Reaching in the Space; MOP, Moving Objects on a Plane; MOS, Moving Objects in the Space; LE, Lateral Elevation; HM, Hand to Mouth.

^bWilcoxon test. ARAT, Action Research Arm Test; MI, Motricity Index; MAL, Motor Activity Log; BBT, Box & Block test; SUS, System Usability Scale; IQR, interquartile range.

G. EMG-Based Outcome Measures

The following outcome measures were computed for each exercise and averaged across all training sessions:

- 1) *% of EMG-triggered FES tasks*: It indicates the overall percentage of tasks in which the FES was triggered by the residual muscular activity rather than by the time-out.
- 2) *% of tasks with active involvement*: It was calculated as the ratio between the number of tasks in which the volitional EMG reflected an involvement of the patient over the total number of tasks in which FES was activated. In particular, active involvement occurred when the volitional EMG overcame a threshold set during the parameterization phase.

III. RESULTS

In this Section the outcome measures collected from the first seven patients to finish the clinical trial are presented: three of them participated at ANKF and four at VB. The two clinical centers had two different roles in the project: while VB was actively involved in designing and testing the system, ANKF was trained in the use of the system only after its completion.

Table III reports the clinical and demographic characteristics of the patients, while Table IV presents the clinical outcome measures before (T0) and after (T1) the training program, including the sub-tests of interest of the ARAT and MI scales, the performed exercises, and the SUS scores. The subjects showed a statistically significant improvement after training for all outcome measures; however, this result has to be considered with caution due to the small sample size and the absence of a control group. Statistically-powered conclusions about the efficacy of the system in comparison to conventional therapy performed by a control group will be provided at the end of the RCT.

Interestingly, the two centers adopted different strategies, when selecting the exercises. While VB therapists used to train

TABLE V
EMG-BASED PERFORMANCE PARAMETERS

Subject	Exercise ^a	Stimulated muscles (# sessions) ^b					EMG-triggered task (%) ^c	Tasks with active involvement (%) ^c
		B	T	AD	MD	PD		
VB-01	ARP	23	0	0	0	0	100.0 (0.0)	45.1 (90.0)
	LE	0	0	0	24	0	100.0 (0.0)	100.0 (4.1)
	HM	24	0	0	0	0	100.0 (0.0)	90.3 (30.4)
VB-02	LE	0	0	0	22	0	100.0 (0.0)	100.0 (0.0)
	HM	22	0	0	0	0	100.0 (0.0)	96.0 (14.9)
VB-03	ARP	0	0	19	0	19	100.0 (0.0)	95.5 (6.1)
VB-04	LE	0	0	0	23	0	92.7 (8.4)	54.3 (85.4)
	HM	24	0	0	0	0	100.0 (0.0)	100.0 (0.0)
ANKF-01	ARP	1	11	17	0	7	98.0 (2.8)	38.6 (87.0)
ANKF-02	ARP	5	5	13	0	13	95.2 (7.2)	8.7 (47.3)
	HM	9	9	0	0	0	97.5 (5.6)	0.0 (5.9)
ANKF-03	ARP	0	4	4	0	2	95.7 (0.3)	40.0 (59.7)
	MOS	0	7	7	0	0	98.1 (2.1)	27.2 (37.9)

^aARP, Anterior reaching on a Plane; MOS, Moving objects in the Space; LE, Lateral Elevation; HM, Hand to Mouth;

^bB, biceps; T, triceps; AD, anterior deltoid; MD, medial deltoid; PD, posterior deltoid;

^c Median (interquartile range) over sessions.

two exercises per session, ANKF patients did mostly one exercise per day but changed the exercises across sessions.

Also, the selection of the muscles to stimulate was different across users, as reported in Table V. Even in case of the same exercise, the muscles selected were different, addressing the specific weaknesses of each patient. Exercises with objects could only be performed if the subject had sufficient hand functionality, since grasping and releasing of objects were not supported. ANKF-03 experienced a rapid improvement of motor functions (Table IV) and consequently performed more challenging exercises over the course of the training program (from *Hand to*

TABLE VI
KINEMATICS-BASED PERFORMANCE PARAMETERS

Subject	Exercise ^a	# sessions	Exercise duration [s]			Smoothness (0-1)			ROM γ [°]			ROM β [°]			ROM α [°]		
			First ^b	Last ^b	P-value ^c	First ^b	Last ^b	P-value ^c	First ^b	Last ^b	P-value ^c	First ^b	Last ^b	P-value ^c	First ^b	Last ^b	P-value ^c
VB-01	ARP	23	14.9 (3.2)	8.0 (1.6)	<0.001	0.22 (0.07)	0.27 (0.07)	<0.001	39.9 (9.2)	31.7 (7.1)	<0.001	26.2 (7.6)	43.0 (4.8)	<0.001	38.6 (10.8)	74.0 (5.6)	<0.001
	LE	24	1.9 (0.5)	1.2 (0.3)	<0.001	0.67 (0.13)	0.71 (0.13)	0.007				62.0 (3.1)	75.1 (5.0)	<0.001			
	HM	24	3.0 (0.6)	1.2 (0.1)	<0.001	0.53 (0.10)	0.63 (0.09)	<0.001				36.3 (8.2)	29.7 (9.7)	<0.001	66.5 (15.8)	68.1 (7.9)	0.361
VB-02	LE	22	2.3 (0.6)	3.5 (0.6)	<0.001	0.71 (0.22)	0.56 (0.12)	<0.001				56.4 (6.5)	67.6 (2.5)	<0.001			
	HM	22	2.8 (1.4)	3.4 (0.5)	<0.001	0.27 (0.15)	0.37 (0.08)	<0.001				23.4 (15.0)	38.1 (4.0)	<0.001	47.2 (11.3)	67.3 (6.4)	<0.001
VB-03	ARP	19	13.5 (1.2)	8.4 (1.1)	<0.001	0.28 (0.05)	0.42 (0.09)	<0.001	38.2 (5.0)	30.8 (4.7)	<0.001	14.1 (2.4)	30.3 (2.6)	<0.001	36.3 (6.4)	48.6 (4.6)	<0.001
VB-04	LE	23	3.4 (0.9)	2.6 (0.3)	<0.001	0.56 (0.17)	0.68 (0.11)	<0.001				27.8 (6.6)	58.2 (2.7)	<0.001			
	HM	24	4.2 (1.3)	2.3 (0.3)	<0.001	0.50 (0.14)	0.63 (0.14)	<0.001				9.8 (5.3)	9.1 (3.6)	0.150	56.4 (4.1)	54.5 (5.9)	<0.001
ANKF-01	ARP	19	22.4 (10.4)	9.2 (2.0)	<0.001	0.13 (0.08)	0.23 (0.08)	<0.001	45.2 (28.2)	62.7 (17.1)	<0.001	5.1 (3.1)	7.2 (2.3)	<0.001	19.7 (8.6)	11.5 (3.8)	<0.001
ANKF-02	ARP	18	28.4 (13.0)	25.1 (7.5)	0.103	0.15 (0.06)	0.20 (0.11)	0.002	26.6 (10.0)	28.2 (22.4)	0.602	9.9 (5.0)	7.5 (7.6)	0.032	38.1 (11.8)	24.8 (21.2)	<0.001
	HM	9	10.7 (6.4)	8.1 (5.7)	<0.001	0.13 (0.07)	0.15 (0.14)	0.05				9.0 (7.2)	1.5 (1.6)	<0.001	35.5 (22.0)	38.9 (10.1)	0.031
ANKF-03	ARP	6	13.2 (5.1)	9.0 (5.0)	<0.001	0.28 (0.12)	0.33 (0.10)	<0.001	31.7 (6.2)	31.9 (7.2)	0.835	16.9 (6.8)	13.2 (3.4)	<0.001	39.9 (5.2)	39.2 (15.1)	0.615
	MOS	7	23.4 (7.3)	23.0 (7.6)	0.915	0.27 (0.13)	0.31 (0.14)	0.182	47.9 (7.1)	64.6 (13.3)	<0.001	22.0 (4.7)	13.7 (4.6)	<0.001	27.4 (11.2)	17.4 (4.6)	<0.001

^aARP, Anterior Reaching on a Plane; MOS, Moving Objects in the Space; LE, Lateral Elevation; HM, Hand to Mouth.

^b Mean (standard deviation) over the first / last three sessions.

^c t-test for independent samples. ROM, Range of Motion; γ , shoulder rotation; β , shoulder elevation; α , elbow flex-extension. Green: statistically significant improvement (N = 32); Yellow: no statistically significant changes (N = 9); Red: statistically significant worsening (N = 14).

Mouth and Anterior Reaching on a Plane to exercises in the space and involving the use of objects).

The average SUS score was 75.9 (± 15.6 SD), with six out of seven participants presenting a positive score (>68%) (Table IV).

Table V and Table VI report the quantitative analysis only for the exercises which were performed in more than six training sessions.

Table VI shows the results of the kinematics-based outcome measures collected during training. All subjects improved the performance in terms of faster and smoother movements, most of them significantly (green cells; p-value < 0.05). Please note that the number of sessions each exercise was trained was different among subjects; for example, ANKF-03 only performed 6 sessions of Anterior Reaching on Plane and 7 sessions of Moving Objects in the Space and this can explain the reduced training effect.

Fig. 7 presents the trends of the kinematic-based outcome measures for three exemplary patients and exercises. For the sake of visualization, VB patients were chosen since they performed the same exercises for a higher number of sessions. For all parameters but exercise duration of VB-02, a trend of improvement is visible. VB-02, who showed a significant increase of the exercise duration, was quite fast already at the beginning and the higher execution time went with a wider movement (significant increase of ROMs). About ROMs, results were less univocally interpretable; reductions could be associated to different joint solutions to complete the task. For example, VB-01

showed in the ARP exercise a significantly reduction of the shoulder rotation ROM accompanied to larger ROMs for both elbow and shoulder elevation, indicating a change of the inter-segmental strategy which overall produced a faster and smoother execution of the task.

Finally, the EMG-based outcome measures are presented in Table V. Most of the tasks were successfully triggered by the EMG (median value for all subjects and exercises >92%). On the contrary, the volitional involvement during stimulation after trigger was not that high for all subjects, indicating the importance of monitoring this data and also to feed it back to the subject and the therapist in order to improve it.

IV. DISCUSSION

The herein presented data of the first seven patients completing the clinical trial with the RETRAINER-ARM system provides some promising results.

A. Personalization

The system proved to be highly personalizable; each of the seven patients used the system in a different initial configuration, which was changed over time in order to fulfill the personal rehabilitative target. The therapists were trained on how to use the system, but they were not provided with strict step-by-step instructions on how to select the “best” training session (which and how many exercises, which muscles to stimulate, etc.). Conversely, the therapists tailored the system on the specific needs

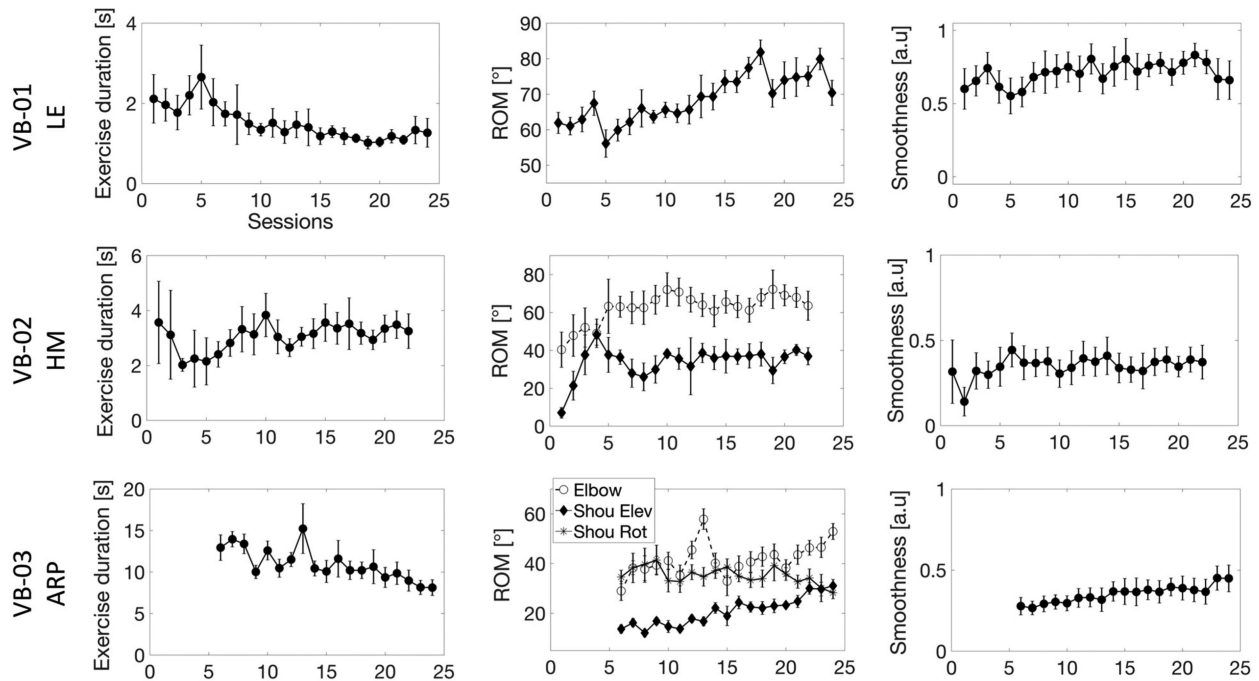


Fig. 7. Trends of kinematic-based parameters over sessions for three exemplary subjects and exercises. ARP, Anterior Reaching on a Plane; LE, Lateral Elevation; HM, Hand to Mouth.

of each patient based on their own experience and their clinical evaluation, which includes the MRC scale for testing muscle strength. Personalization was exploited across treatment for what concerns exercise choice, selection of muscles to stimulate, duration of exercises, targets positions, and size and weight of interactive objects. Besides these parameters, the automatic procedure for setting stimulation and EMG thresholds was successfully used allowing a reliable EMG trigger of the stimulation and checking for patients' volitional involvements.

B. Usability

The overall mean time for preparation (donning and parameterization of the system) was 13.4 minutes with a standard deviation of 7.7, which were judged as feasible for a clinical environment during a clinical trial using a prototype system. The manual interventions to let the training continue when the target could not be autonomously reached by the subject were very few, with a median failure rate (number of tasks requiring a manual intervention over the total number of tasks) of zero for all subjects and exercises but the ARP exercise of two subjects, who achieved a median (interquartile range) failure rate of 1.4 (4.1) and 2.7 (11.6).

Positive results were obtained in terms of usability, expect for one subject (SUS score <68) [38]. Interestingly, the same subject had also the lowest percentage of active involvement (Table V). Although the overall positive results, there was a different level of perceived usability between the two clinical sites (Table IV), with VB participants achieving higher SUS values. This might be explained by the different roles of the two centers, likely resulting in a lack of experience of ANKF therapists during the first training sessions. Overall, the RETRAINER-ARM

system demonstrated to be suitable for a clinical environment and reliable during 27 sessions, but requires the therapists a familiarization phase to become comfortable using the system.

C. Functional Recovery

Despite the small number of patients, the results suggested that recovery of volitional movements is possible using the described system. However, statistically based efficacy in comparison to conventional therapy must await the conclusion of the multicenter RCT currently ongoing.

All desired functions, such as EMG-triggered FES and automatic execution of the exercises, were well integrated and operational. A high percentage of FES tasks were triggered by the patients' volition (mean value of $98.2\% \pm 2.2\%$, in Table V). The overall data shows a high active involvement ($64.0\% \pm 35.5\%$, in Table V), indicating a good participation of the subjects in the training. Participants showed a general improvement, with faster and smoother movements execution over time. Also, the system was not preventing the user to exploit new joints coordination schemes.

D. Automatic Session Execution and Monitoring

The subjects received an online knowledge of result about task completion, being guided through the execution of tasks by means of RFID data and/or angle sensor data, as well as the emoji feedback about the active involvement. Besides, the automatic logging of kinematic data allowed the quantitative monitoring of the performance over time with no additional effort. Currently, data of each session are included in a report available to clinicians for checking the therapy and adjusting

the system personalization. This allows the training set-up to be further optimized to each patient's needs and abilities.

E. Limitations and Further Developments

The interpretation of the kinematic data requires experience with the system. The development of exercise-specific metrics to interpret the kinematic data – especially for the more complex exercises – could be a desirable follow-up.

The absence of strict step-by-step instructions for decision-making how to configure the system for each patient is on one hand a limitation, since the training efficacy might depend on the therapists' experience. It might be interesting to analyze this relationship in the evaluation of the results of the RCT. On the other hand, the absence of strict instructions is also a point of strength since it makes the results of the training more generalizable. Furthermore, this choice might potentially increase the acceptability of the therapists, who remain responsible for tailoring the therapy. The RETRAINER-ARM system was conceived to be used by expert therapists in clinical environment, so there was no need of an automatic setting. Automatic calibration of the exercise parameters based on individual scores could be in future developed in order to exploit the system in external ambulatory or home settings.

Manual interventions of the therapist to complete the task were quite rare, but still it was the most annoying aspect of the system operability. Different solutions could be envisaged to improve this issue. More powerful RFID sensors, currently under development, could be employed. Angles check for task completion is much less natural than RFID, limiting the possibility to use multiple strategies. Kinematics models could be eventually used to estimate end-effector position and check for target reach, as soon as an additional sensor for the trunk inclination monitoring is available.

Usability of the GUI could be improved by separating the feedback given to the patient and to the therapist. The latter could keep an online feedback of angles, RFID data and training parameters, while the patient's feedback could be reduced to only task indications and volitional involvement.

Finally, the RETRAINER-ARM system only supports arm rehabilitation, while many stroke survivors also need to recover wrist and hand functions. To overcome this limitation, the RETRAINER-HAND system has been developed within the context of the same European project [35]. The two systems have been designed in a way that they could be easily integrated, making therefore available a complete platform for the recovery of arm and hand functions after stroke.

V. CONCLUSION

The herein described hybrid robotic system was successfully tested on seven stroke survivors. The first datasets are very promising, indicate the suitability of the system for arm rehabilitation, and demonstrate a very good usability of the system. However, a bigger sample size will be necessary to provide conclusive results about the efficacy of the system and only the outcome of the currently performed clinical trial will unveil its full potential.

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