Clinical Study

Hand Robotics Rehabilitation: Feasibility and Preliminary Results of a Robotic Treatment in Patients with Hemiparesis

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Background. No strongly clinical evidence about the use of hand robot-assisted therapy in stroke patients was demonstrated. This preliminary observer study was aimed at evaluating the efficacy of intensive robot-assisted therapy in hand function recovery, in the early phase after a stroke onset. *Methods.* Seven acute ischemic stroke patients at their first-ever stroke were enrolled. Treatment was performed using Amadeo robotic system (Tyromotion GmbH Graz, Austria). Each participant received, in addition to inpatients standard rehabilitative treatment, 20 sessions of robotic treatment for 4 consecutive weeks (5 days/week). Each session lasted for 40 minutes. The exercises were carried out as follows: passive modality (5 minutes), passive/plus modality (5 minutes), assisted therapy (10 minutes), and balloon (10 minutes). The following impairment and functional evaluations, Fugl-Meyer Scale (FM), Medical Research Council Scale for Muscle Strength (hand flexor and extensor muscles) (MRC), Motricity Index (MI), and modified Ashworth Scale for wrist and hand muscles (AS), were performed at the beginning (T0), after 10 sessions (T1), and at the end of the treatment (T2). The strength hand flexion and extension performed by Robot were assessed at T0 and T2. The Barthel Index and COMP (performance and satisfaction subscale) were assessed at T0 and T2. *Results.* Clinical improvements were found in all patients. No dropouts were recorded during the treatment and all subjects fulfilled the protocol. Evidence of a significant improvement was demonstrated by the Friedman test for the MRC ($P < 0.0123$). Evidence of an improvement was demonstrated for AS, FM, and MI. *Conclusions.* This original rehabilitation treatment could contribute to increase the hand motor recovery in acute stroke patients. The simplicity of the treatment, the lack of side effects, and the first positive results in acute stroke patients support the recommendations to extend the clinical trial of this treatment, in association with physiotherapy and/or occupational therapy.

1. Introduction

Hand plays a critical role in upper limb function [1], with various cortical and subcortical structures which are devoted to its sensorimotor control and a wide representation of hand in homunculus. Loss of hand dexterity is a common consequence of a cortical lesion due to cerebrovascular disease [2]. The most important motor deficit, after stroke, is the paresis of the affected side, contralateral to vascular lesion in the brain. The recovery of upper limb, after stroke injuries, is complex and requires multidisciplinary and multifactorial approaches [3, 4]. Currently, functional recovery of the affected arm can be predicted by means of clinical evaluation at the bedside; in particular, active finger extension has been demonstrated to be a strong early predictor of short-, medium- and long-term poststroke upper limb recovery

[5]. The robotics rehabilitation devices are tools specifically developed to assist and to perform exercises for recovering lost functions [6–8]. Various systems have been carried out, in the last 15 years, to treat the upper limb. A high number of devices have been made to administer the therapy for the proximal section of the upper extremity, in particular the shoulder and the elbow segments. Besides, there has been a steady increase in the number of devices that assist and train distal upper extremity movements, such as wrist and/or finger movement, during the last five years. Since 1997, more than 60 clinical trials reported the use of two dozens of different robots for neurorehabilitation of shoulder and elbow segment, with a large number of pilot studies that did not materialize into deeper studies [9]. In particular, from the kinematics point of view, each human finger has three joints and four degrees of freedom (DOFs), which

give 20 DOFs in total. Each finger joint position determines the position of a centre point of rotation (CPoR) for each joint, hence with a great impact on the rehabilitation system architecture, and the consequent difficulty to made a robot. The Amadeo robotic system (Tyromotion GmbH Graz, Austria) can be considered as an external manipulator with end-effector workspace suitable to cover the human hand fingers workspace. The robot performs an intensive training, with a high frequency of gripping movements combined with visual feedback. The exercises may therefore be accompanied by a goal-oriented rehabilitation games, whose difficulty is based upon the progress of rehabilitation and level of success rate in games. Only one preliminary study investigated the effect of a treatment with Amadeo robot on motor and functional recovery in patients with stroke [1]; therefore, there are no studies that considered the effect of this robotic training on ADL and quality of life (QoL). Stein and colleagues tested an Amadeo robotic device for hand rehabilitation in chronic stroke survivors. A total of 12 individuals, with chronic moderate hemiparesis after stroke, were enrolled in this study and all participants underwent a 6-week training programme using a hand robotic device. The results showed an improvement in multiple measures of motor performance, and all subjects tolerated the treatment well, with no complications. The aims of our preliminary study are to evaluate, in acute stroke patients, the efficacy of high-intensity robot-assisted training treatment, to improve hand function and/or sensorimotor hand recovery, and to assess whether the achieved improvements can reduce disability in ADLs and ameliorate patients QoL.

2. Material and Methods

Seven eligible voluntaries, who met the inclusion criteria and signed a consent form, were assigned to an experimental group according to tailored schedules. The study included acute stroke patients at their first-ever stroke exclusively, enrolled after the event onset, with ischemic lesions forms only. The diagnoses were confirmed by means of CT scan and/or MRI exam. The inclusion criteria were first ischemic stroke, at least 26 ± 10 days from the event, unilateral paresis, Mini Mental State Examination higher than 20, muscle strength in finger flexion, and extension higher than 2 (movement without gravity) evaluated with Medical Research Council (MRC), absence of sensory impairment evaluated by neurological test.

The exclusion criteria were as follows: patients aged less than 18 or more than 75, previous cerebrovascular disease or TBI, botulinum toxin injection within the previous 15 days from enrolment, cognitive disorders such as neglect (more than 2 errors after Albert Test score), upper limb apraxia (evaluated by De Renzi Test), and bilateral upper limb impairment.

2.1. Evaluation Procedures and Materials. The patients were evaluated before (T0), after 10 robotic treatments (T1), and at the end of the treatment (T2). Evaluation protocols involved two trained professionals physicians and occupational therapy (OT) not involved in the research treatment,

who were responsible for clinical scales and robotic test administration, respectively. They were blind to the type of rehabilitative protocol administered to the participants. Clinical outcomes were assessed using valid and reliable tools for stroke, that included all levels of the International Classification of Functioning, Disability, and Health. The evaluation scales were as follows: Fugl-Meyer Scale (FM) [10], Medical Research Council Scale for Muscle Strength (hand flexor and extensor muscles) (MRC) [11], Motricity Index (MI) [12], modified Ashworth Scale for wrist and hand muscles (AS) [13], Barthel Index, Functional Independence Measure scales FIM, and Canadian Occupational Performance Measure (COPM) (performance and satisfaction subscales). All the previous scales are validated. The strength flexion and extension were assessed by Robot.

2.2. Robot Device. The Amadeo Robot has got 5 DOFs and provides the motion of one or all five fingers, thanks to a passive rotational joint placed between fingertip and an entity moving laterally; (the thumb has got two passive rotational joints). All five translational DOFs are independent and provide large coverage of the fingers workspace (but not all of it is covered). The interface between human hand and the machine is realized thanks to elastic bands or plasters, and the wrist is restrained from the movements by a velcro strap.

2.3. Treatment Procedures. All subjects underwent an inpatient rehabilitation treatment, consisting in at least a daily 3-hour physiotherapy session, including both dexterity and gait training, according to individually tailored exercise scheduling. In addition to standard rehabilitation, eligible patients also received one daily session of at least 40 minutes of robot experimental treatment (EG).

2.4. Robot Experimental Treatment (EG). Treatments involved two OT. Each participant received 20 treatment sessions for 4 consecutive weeks (5 days/week). Each session lasted for 40 minutes (30 minutes of hand training and 10 minutes of passive upper limbs mobilization). Treatments were performed using Amadeo. According to our previous experience, the exercises were carried out as follows: (1) CPM therapy (the hand is stimulated in continuous passive motion therapy modality for 5 minutes); (2) assisted therapy (the hand motion is assisted by robot and adjusted to the individual limit of function and performance of each patients for 10 minutes); and (3) balloon (active training in a virtual environment by carrying out various target-oriented tasks, 10 minutes). Passive movement speeds were selected according to patient's skill. The difficulty of each exercise was increased day by day, according to the hand motor improvements of the single patient. In particular, the therapist may select from a number of different modules, according to the progress made during the therapy and may also choose between completely passive, assisted, or active variations. Resting time (1 minute) within intersession exercise was allowed according to the individual needs. The strength hand flexion and extension were performed by

Robot at the end of the treatment and during assessment session. The limit of the movement can be set for each individual finger; single fingers can be excluded altogether or limited. In this way, the therapist can react optimally to each and every restriction a patient has. The patient's therapist designs a therapy process for each individual. Every missed session was retrieved. Subjects who did not retrieve sessions and interrupted treatment for more than 3 consecutive days were excluded from the study.

2.5. Data Analysis. A preliminary descriptive analysis was performed to check the normal distribution of patients' clinical and instrumental data using Shapiro-Wilk test. Unless collected variables showed a normal distribution, we used parametric statistic tests. A repeated measure analysis of variance model (ANOVA) was carried out by using time as a within-group factor in order to evaluate within-group changes over time. The Friedman test was used to analyze ordinal data in the different evaluation sessions within each patient group. In the presence of significant main effects, the Wilcoxon signed-ranks test was performed to determine the location of any significant differences between time points. The alpha level for significance was set at $P < 0.05$ for first level of analysis.

3. Result

From March to August 2012, we screened 50 voluntary patients, 7 of whom satisfied the inclusion criteria and were assigned to the robot-assisted therapy (EG). No dropouts were recorded during the treatment and all subjects fulfilled the protocol (compliant subjects: $N = 7$). Table 1 summarizes the observed mean ± standard deviation and other statistical results for all tests, as they were measured on the compliant subjects at T0 ($N = 7$), T1 ($n = 7$), and T2 ($N = 7$) (Table 1). Clinical improvements were found in all patients that fulfilled the protocol. The Fugl-Meyer scores were as follows: T0 47.4 ± 22.77, T1 51.4 ± 32.67, and T2 52.6 ± 32.22. The MRC flexion values of 1.2 ± 1.64 at T0, of 2.2 ± 1.79 at T1 and 2.4 ± 1.67 at T2 were found. The MRC extension values of 1.2 ± 1.64 at T0, of 2.00 ± 2.00 at T1, and 2.0 ± 1.74 at T2 were found. The HAND AS scores were T0 2 ± 1, T1 1.4 ± 1.14, and T2 1.6 ± 0.9. The WRIST AS scores were T0 1 ± 0.7 T1 1 ± 0.7, and T2 1 ± 0.7. The MI value of 19.8 ± 23.27 at T0, of 32 ± 41.24 at T1, and 32 ± 41.24 at T2 were found. The Barthel Index of 30.6 ± 10.99 at T0 and 55.6 ± 23.9 at T2, and the FIM of 57.4 ± 18.6 at T0 and 83 ± 21.35 were found. The statistical analysis using the Friedman test showed statistically significant improvements for the MRC wrist ($P = 0.0085$) and MRC hand ($P = 0.0239$). No statistically significant improvements on Fugl-Meyer Scale (FM), Medical Research Council Scale for Muscle Strength (MRC), Motricity Index (MI), and modified Ashworth Scale for Hand (AS) were found (Table 2).

4. Discussion

Paralysis following neurological disorders can disconnect the brain from the body, eliminating the ability to perform

TABLE 1: Distribution of the study participants by age, gender, etiology, lesion side, and other clinical characteristics.

	Experimental group (EG) ($n = 7$)
	n (%)
Dropouts	0 (0%)
Complains	7 (100%)
Gender	
Female	4 (57%)
Male	3 (43%)
Etiology	
Hemorrhagic	0 (0%)
Ischemic	7 (100%)
Lesion side	
Right	0 (0%)
Left	7 (100%)
	Mean ± SD
Age (years)	67.0 ± 12.4
Time since stroke (days)	28.8 ± 8.10

volitional movements [14]. A majority of studies examine repetitive task practice, facilitated by robots, for the treatment of upper extremity paresis, with particular attention to the elbow, the shoulder and the wrist segment, using standardized protocols applied to large groups. The use of robotic systems in stroke rehabilitation has witnessed 25 years of development. However, no clinical trials were conducted with a robotic device made for the hand rehabilitation. The robotics systems have already been demonstrated in upper limb motor rehabilitation training, providing safe and intensive treatment to subjects with motor impairments due to a neurological injury. Several studies showed the advantages of robotic therapy on chronic poststroke patients, even if no consistent influence on functional abilities was found, together with evidence of better results after intensive treatments, both robotic and conventional rehabilitative techniques. Furthermore, it has been demonstrated that it is difficult to ascertain the effectiveness of rehabilitative interventions on conditions leading to long-term disability, such as stroke, because the outcome depends on many interacting factors. Many studies, though, underline the importance of brain plasticity and its therapeutic potential in neurological disorders. Accredited theories of cortical reorganization after brain lesion endorse the use of early, intensive, repetitive, and context-related exercise as optimal strategies to promote motor relearning and minimize motor deficit. Currently, in order to improve the motor function, the paradigm of stroke rehabilitation strategies is focused on high-intensity, repetitive finalized, and task-specific training [15], even if there is no widely accepted protocol for hand rehabilitation after stroke, and the treatment varies in duration, intensity, and frequency. The evaluation of outcomes is also a key factor in the robotic rehabilitation treatment, having direct consequences on the patient's amount and time of recovery. A large number of instruments are available, but they are

TABLE 2: Results of observed means ± standard deviation of all tests and significant P value.

	T0 Mean ± SD	T1 Mean ± SD	T2 Mean ± SD	Statistical significance
MMSE	25.1 ± 2.138			
FM	47.4 ± 22.77	51.4 ± 32.67	52.6 ± 32.22	
MRC flexion	1.2 ± 1.64	2.2 ± 1.79	2.4 ± 1.67	*($P = 0.0085$)
MRC extension	1.2 ± 1.64	2 ± 2	2 ± 1.73	*($P = 0.0239$)
AS HAND	2 ± 1	1.4 ± 1.14	1.6 ± 0.9	
AS WRIST	1 ± 0.7	1 ± 0.7	1 ± 0.7	
MI	19.8 ± 23.27	32 ± 41.24	32 ± 41.24	
Barthel Index	30.6 ± 10.99		55.6 ± 23.9	
FIM	57.4 ± 18.6		83 ± 21.35	
COPM performance	3.17 ± 1.563		3.97 ± 1.321	
COPM satisfaction	2.79 ± 1.329		4.51 ± 2.294	
Strength hand flexion	6.06 ± 6.882		9.5 ± 10.4	
Strength hand extension	1.4 ± 3.13		2.56 ± 5.391	

FM: Fugl-Meyer Scale, MRC: Medical Research Council Scale for Muscle Strength (hand flexor and extensor muscles), MI: Motricity Index, AS: modified Ashworth Scale for wrist and hand muscles, FIM: Functional Independence Measure scales, COPM: Canadian Occupational Performance Measure performance and satisfaction subscales.

poorly validated [16]. Till now, a shared consensus on specific clinical outcome examinations that should be used to assess the effects of robot-assisted therapy is lacking [17]. Mehrholz and colleagues assessed the effectiveness of robot-assisted arm training in improving ADL independence and arm function in stroke patients [18]. They identified 11 trials and the result showed that, in general, a robotic device for the upper limb resulted safe with no side effects, with improvements in arm function and motor strength, but without improvements in ADL independence. These results were confirmed by Kwakkel and collaborators [19]. A recent meta-analysis, for patients after stroke, conducted by Mehrholz and colleagues, focused on electromechanical and robot-assisted arm training for recovery of arm function, with other rehabilitation or placebo interventions—or no treatment at all—, showed that patients who received electromechanical and robot-assisted arm training after stroke are more likely to improve their generic activities of daily living, with an improvement of the paretic arm function, but not the arm muscle strength. In the 19 trials, involving a total of 666 participants, that have been examined, the most important issue was the total absence of the robotic device for the hand. The authors suggested that the results must be interpreted with caution because there were variations between the trials in the duration and amount of training, type of treatment, and in the patient characteristics [20]. Our result shows that an intensive robot-assisted treatment in stroke patient may achieve a significant decrease of motor impairment in the paretic hand [17]. The present study represents the first one carried out, so far, to test the effects of a robot-assisted hand treatment systematically, using the robotic technology as neurorehabilitation therapy in acute patients who experienced a first stroke. The protocol is easy and reproducible and allows the treatment of patients

with moderate to severe upper limb paresis. The intensive training, with a high frequency of gripping movements, especially encourages this rethinking process. During the task-oriented training, the demands on the motor functions could be increased continually. The device supports the intensity, which is needed for the patient to exercise at their individual limit of performance, exactly. This characteristic could be the neurophysiological basis of our result. In particular, the results of statistical analysis of MRC, which demonstrate a positive effect of the robot-assisted approach in early phase on recovery the muscle strength, and the scores of AS suggested that the management of the spasticity is more effective if the rehabilitative treatment starts during the acute phase. The spasticity can develop days to weeks after an acute stroke and, although it may improve or resolve in some individuals, eventually, it may be a permanent sequel in others [21]. Moreover, the management of the spasticity in the first phase of recovery must interfere with the ability and it can be painful or predispose to the development of ulcers and contractures [22]. Furthermore, a gain of FM score, that is related to a reduction of sensorimotor impairment, and a gain of MI scale score, that measures the muscle force with a good recovery on quality of life detected by Barthel Index scale, were also found. The use of robotic platforms to administer the rehabilitation therapy must be crucial, for this reason, because the physical therapies based on robotic platforms assure that each patient, in the same testing group, is treated in the same repeatable way, eliminating the intrinsic subject-dependent variability that affects traditional therapies. Moreover, the robotic platforms, in conjunction with EEG and EMG recordings, could be used to assess the effects of the rehabilitative treatments in a quantitative, measurable way, providing reliable and objective methods for measuring functional recovery after stroke.

5. Study Limitations

The very small sample size, the absence of control group, and the absence of power calculation did not allow to have a high significance in the clinical scales score. Moreover, the lack of control group did not give the possibility to verify if this treatment is valid in terms of effectiveness, but the improvement of all scales could encourage to design a large RCT.

6. Conclusions

The focus on the very early phase of stroke recovery represents a further innovative characteristic of this study, which makes this research useful to clinical practice. The lack of side effect and the good participation, with an absence of the dropout, may suggest a large clinical use. Future positive results of the robotic treatment could be relevant for the advancement of knowledge in hand rehabilitation field and for the development of new clinical guidelines about hand rehabilitation in subjects with stroke.

References

[1] J. Stein, L. Bishop, G. Gillen, and R. Helbok, "Robot-assisted exercise for hand weakness after stroke: a pilot study," *American Journal of Physical Medicine & Rehabilitation*. In press.

[2] S. Balasubramanian, J. Klein, and E. Burdet, "Robot-assisted rehabilitation of hand function," *Current Opinion in Neurology*, vol. 23, no. 6, pp. 661–670, 2010.

[3] M. Franceschini, M. G. Ceravolo, M. Agosti et al., "Clinical relevance of action observation in upper-limb stroke rehabilitation: a possible role in recovery of functional dexterity. A randomized clinical trial," *Neurorehabilitation and Neural Repair*, vol. 26, no. 5, pp. 456–462, 2012.

[4] P. Sale and M. Franceschini, "Action observation and mirror neuron network: a tool for motor stroke rehabilitation," *European Journal of Physical and Rehabilitation Medicine*, vol. 48, no. 2, pp. 313–318, 2012.

[5] N. Smania, S. Paolucci, M. Tinazzi et al., "Active finger extension: a simple movement predicting recovery of arm function in patients with acute stroke," *Stroke*, vol. 38, no. 3, pp. 1088–1090, 2007.

[6] F. Bovolenta, P. Sale, V. Dall'Armi, P. Clerici, and M. Franceschini, "Robot-aided therapy for upper limbs in patients with stroke-related lesions. Brief report of a clinical experience," *Journal of NeuroEngineering and Rehabilitation*, vol. 8, no. 1, article 18, 2011.

[7] P. Sale, M. Franceschini, A. Waldner, and S. Hesse, "Use of the robot assisted gait therapy in rehabilitation of patients with stroke and spinal cord injury," *European Journal of Physical and Rehabilitation Medicine*, vol. 48, no. 1, pp. 111–121, 2012.

[8] M. Franceschini, M. Agosti, A. Cantagallo, P. Sale, M. Mancuso, and G. Buccino, "Mirror neurons: action observation treatment as a tool in stroke rehabilitation," *European Journal of Physical and Rehabilitation Medicine*, vol. 46, no. 4, pp. 517–523, 2010.

[9] A. C. Lo, "Clinical designs of recent robot rehabilitation trials," *American Journal of Physical Medicine & Rehabilitation*, vol. 91, no. 11, supplement 3, pp. S204–S216, 2012.

[10] S. J. Page, P. Levine, and E. Hade, "Psychometric properties and administration of the wrist/hand subscales of the fugl-meyer assessment in minimally-impaired upper extremity hemiparesis in stroke," *Archives of Physical Medicine and Rehabilitation*, vol. 93, no. 12, pp. 2373.e5–2376.e5, 2012.

[11] T. Paternostro-Sluga, M. Grim-Stieger, M. Posch et al., "Reliability and validity of the Medical Research Council (MRC) scale and a modified scale for testing muscle strength in patients with radial palsy," *Journal of Rehabilitation Medicine*, vol. 40, no. 8, pp. 665–671, 2008.

[12] D. T. Wade, "Measuring arm impairment and disability after stroke," *International Disability Studies*, vol. 11, no. 2, pp. 89–l92, 1989.

[13] D. K. Sommerfeld, U. Gripenstedt, and A. K. Welmer, "Spasticity after stroke: an overview of prevalence, test instruments, and treatments," *American Journal of Physical Medicine & Rehabilitation*, vol. 91, no. 9, pp. 814–820, 2012.

[14] L. R. Hochberg, D. Bacher, B. Jarosiewicz et al., "Reach and grasp by people with tetraplegia using a neurally controlled robotic arm," *Nature*, vol. 485, no. 7398, pp. 372–375, 2012.

[15] J. Bernhardt, M. N. T. Thuy, J. M. Collier, and L. A. Legg, "Very early versus delayed mobilisation after stroke," *Cochrane Database of Systematic Reviews*, no. 1, Article ID CD006187, 2009.

[16] K. Salter, J. W. Jutai, R. Teasell, N. C. Foley, and J. Bitensky, "Issues for selection of outcome measures in stroke rehabilitation: ICF body functions," *Disability and Rehabilitation*, vol. 27, no. 4, pp. 191–207, 2005.

[17] M. Sivan, R. J. O'Connor, S. Makower, M. Levesley, and B. Bhakta, "Systematic review of outcome measures used in the evaluation of robot-assisted upper limb exercise in stroke," *Journal of Rehabilitation Medicine*, vol. 43, pp. 181–189, 2011.

[18] J. Mehrholz, T. Platz, J. Kugler, and M. Pohl, "Electromechanical and robot-assisted arm training for improving arm function and activities of daily living after stroke," *Cochrane Database of Systematic Reviews*, no. 4, Article ID CD006876, 2008.

[19] G. Kwakkel, C. G. M. Meskers, E. E. van Wegen et al., "Impact of early applied upper limb stimulation: the EXPLICIT-stroke programme design," *BMC Neurology*, vol. 8, article 49, 2008.

[20] J. Mehrholz, T. Platz, J. Kugler, and M. Pohl, "Electromechanical and robot-assisted arm training for improving arm function and activities of daily living after stroke," *Cochrane Database of Systematic Reviews*, no. 4, Article ID CD006876, 2008.

[21] D. A. Gelber and P. B. Jozefczyk, "Therapeutics in the management of spasticity," *Neurorehabilitation and Neural Repair*, vol. 13, no. 1, pp. 5–14, 1999.

[22] D. K. Sommerfeld, E. U. B. Eek, A. K. Svensson, L. W. Holmqvist, and M. H. Von Arbin, "Spasticity after stroke: its occurrence and association with motor impairments and activity limitations," *Stroke*, vol. 35, no. 1, pp. 134–139, 2004.