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ORIGINAL REPORT

ROBOT-MEDIATED THERAPY FOR PARETIC UPPER LIMB OF CHRONIC PATIENTS FOLLOWING NEUROLOGICAL INJURY

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Objective: **To evaluate the effectiveness of robot-mediated therapy targeted at the motor recovery of the upper limb in chronic patients following neurological injury.**
Design: **Pre-post treatment study.**
Subjects: **Twenty patients were enrolled in the study.**
Methods: **Robot-mediated therapy was provided to chronic hemiparetic patients (acute event had occurred at least one year prior to the study), 3 times a week, for 6 weeks. The therapy consisted of goal-directed, planar reaching tasks that exercised the hemiparetic shoulder and elbow. The items for the shoulder and elbow of Motor Status Score, Modified Ashworth Scale and range of motion were used as outcome measures.**
Results: **Statistically significant improvements before and after treatment were found in each outcome measure. A 3-month follow-up evaluation indicated that patients maintained the improvements.**
Conclusion: **The results confirm that robot-mediated therapy, through short-term, but intensive, repetitive and goal-directed trials, contributes to a decrease in the upper limb's motor disability in people with a chronic neurological injury by reducing motor impairment and shoulder pain. The treatment was well accepted and tolerated by patients. No adverse events occurred.**

Key words: motor recovery, paresis, upper extremity, robotics, rehabilitation.

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INTRODUCTION

The World Health Organization (WHO) estimates that approximately 5 million people worldwide remain permanently disabled after a stroke (1). Recently, the American Heart Association has estimated that each year approximately 700,000 people in the USA experience a new or recurrent stroke. Of these, approximately 500,000 are first attacks and 200,000 occur in people who have had a stroke previously. Men's stroke incidence rates are greater than women's at younger ages, but not at older ages (2).

Epidemiological studies have shown that the incidence of stroke differs widely throughout Europe, with marked differences between eastern and western European countries. In 1997 crude incidence rates of acute stroke were higher for most eastern (range 3.0/1000 to 5.0/1000) than western countries (range 2.0/1000 to 2.5/1000) (3).

The most recent Italian guideline for stroke "Stroke Prevention and Educational Awareness Diffusion" (SPREAD), indicates that 196,000 cases of stroke occur in Italy every year, 80% of those are first occurrence of stroke and 20% are relapses. A total of 39,000 persons die in the first month after stroke, 58,800 persons survive with severe disability and remaining persons show a good recovery (4).

Functional limitations of the upper limbs, which are normally more frequent than walking deficit, are responsible for the reduction in the survivor's quality of life (5). A year after the acute event, patients are usually considered as chronic, and rehabilitative treatments are stopped. As confirmed for traumatic brain injuries, recent studies have demonstrated that improvements in motor abilities induced by therapy may occur even in chronically impaired paretic upper limbs more than 6–12 months post-stroke (6, 7).

Approaches involving repetitive training of paretic upper limb activities, for example, task-oriented therapy or constraint-induced movement therapy (CIMT) (8, 9), have provided evidence of further improvements in hemiparetic patients more than one year after stroke onset (10, 11).

Task-oriented functional training customizes therapy for repetitive practice of tasks that are relevant to a patient's daily life, performed in random order to optimize learning. CIMT, conceptually based on the idea that learned non-use is common after the completion of formal rehabilitation, requires intensive functionally oriented task practice of the paretic upper limb obtained by restraint of the not-impaired upper extremity. The rationale for the use of this kind of treatment is related to the evidence that stroke and other neurological injuries cause partial destruction of the cortical tissue and result in a disturbed generation of motor programmes through the involvement of

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sensorimotor areas. Robotic devices for rehabilitation can provide a safe and intensive motor therapy to patients with mild, moderate and severe upper limb motor impairment. Furthermore, robot-mediated training can be highly accurate, intensive and prolonged.

Different reviews show that robot-mediated therapy can improve muscle strength and movement co-ordination in patients with neurological impairment (12–14), although a limited number of clinical studies have examined the effect of post-stroke rehabilitation with robotic devices on the hemiparetic upper limb. Of these, only 3 studies have involved more than 30 subjects and only 2 were experimental trials with pre- and post-treatment measurements of both an experimental and a control group. Only one study provided robot-mediated therapy to subacute patients (15).

The rehabilitative treatment of chronic neurologically impaired patients is delivered for different periods of time and by different protocols according to the local healthcare system e.g. in Italy.

Every year chronic hemiparetic patients receive at least 2 cycles of physiotherapy treatment, consisting of 45 min per day for 3–4 weeks paid by the National Public Health System. The objectives of the above-mentioned intervention are: (*i*) to maintain the functional level achieved by the treatment in the acute and subacute phase; (*ii*) to avoid the possible expected progression of motor impairment. If one considers the epidemiological data and, in particular, the high and continuously increasing prevalence, rehabilitative interventions for chronic neurologically impaired subject can be very expensive.

The aim of this study is to present the effectiveness of robot-mediated therapy on the paretic upper limb of an experimental group of 20 chronic hemiparetic outpatients, both for the reduction of motor impairment and the preservation of functional levels obtained during early stages of rehabilitation.

METHODS

Subjects

A group of 20 subjects, age range 33–69 (mean age 53.3, standard deviation (SD) 11.2) years, 14 men and 6 women, was recruited for the clinical trial (Table I). Seven of 20 were resulted in right hemiparesis, and 13 in left hemiparesis. Eleven subjects had an ischaemic stroke, 6 had a haemorrhagic stroke, and 3 had brain injury.

They had experienced the acute event at least one year prior to the study (mean time from onset of neurological damage 24 months). Inclusion criteria were: (*i*) unilateral paresis; (*ii*) ability to understand and follow simple instructions; (*iii*) minimum ability to perform active movements, even through trunk compensation, using the shoulder and/or the elbow joints. Exclusion criteria were: (*i*) bilateral impairment; (*ii*) severe sensory deficits in the paretic upper limb; (*iii*) cognitive impairment or behavioural dysfunction that would influence the ability to comprehend or perform the experiment; (*iv*) inability to provide informed consent; and (*v*) other current severe medical problems. All subjects were right-handed.

The experimental protocol was approved by the local ethics committee and each subject signed a consent form.

Apparatus

Robot-mediated therapy was delivered using the MIT-MANUS, a robot designed for clinical neurological application (16), developed at the Massachusetts Institute of Technology, Boston, USA. The MIT-MANUS (Fig. 1) allows subjects to execute reaching movements in the horizontal plane. During the movements the device can assist or resist the subject's movements. The machine was designed to have a low intrinsic end-point impedance (i.e. be back-driveable), with a low and nearly-isotropic inertia (1 kg ± 0.33, maximum anisotropy 2:1) and friction (0.84 N ± 0.28, maximum anisotropy 2:1), and be capable of producing a predetermined range of forces (0–45 N) and impedances (0–2 N/mm). It is a modular system, consisting of a planar module, a wrist module and a linear module.

The planar module was used during the present study; it provides 2 translational degrees-of-freedom (DOFs) for shoulder and elbow joint movements. A monitor in front of the subject displays the exercises to be performed. A second monitor is dedicated to the operator. The workstation is mounted on a custom-made adjustable chair, which allows the chair to be rotated 360° and translated 0.5 m toward a table-top, specially designed to facilitate transfer of wheelchair-bound patients.

Table I. *Subject characteristics*

Subject ID	Age, years	DH	Pathology	AS	CM	MSS-SE Admission	MSS-SE Discharge	MSS-SE Follow-up
M01	61	R	Haemorrhagic stroke	R	3	9.6	14.2	13.4
M02	45	R	Haemorrhagic stroke	R	3	10.4	12.0	12.0
M03	62	R	Ischemic stroke	L	3	12.2	13.6	13.6
M04	53	R	Haemorrhagic stroke	R	3	14.4	17.8	17.8
F01	63	R	Haemorrhagic stroke	L	4	15.4	16.2	16.0
M05	64	R	Haemorrhagic stroke	R	3	10.6	12.2	11.4
M06	57	R	Haemorrhagic stroke	L	3	8.8	11.4	11.4
F02	47	R	Ischaemic stroke	L	1	1.6	1.6	1.6
M07	57	R	Ischaemic stroke	R	4	10.4	11.6	11.6
M08	62	R	Ischaemic stroke	L	3	12.8	16.2	14.4
M09	69	R	Ischaemic stroke	L	1	13.6	13.6	13.6
F03	36	R	Brain injury	L	3	14.6	15.0	18.8
M10	50	R	Brain injury	L	4	28.2	31.0	30.8
F04	63	R	Ischaemic stroke	L	3	13.8	16.2	18.2
M11	34	R	Ischaemic stroke	R	3	9.2	11.2	11.0
M12	41	R	Ischaemic stroke	L	3	17.6	20.2	18.0
F05	68	R	Ischaemic stroke	L	1	7.2	10.4	7.2
M13	52	R	Ischaemic stroke	R	3	13.2	13.6	13.4
F06	50	R	Brain injury	L	3	10.2	11.8	11.8
M14	33	R	Ischaemic stroke	L	5	35.2	37.4	37.4

AS: affected side; CM: Chedoke–McMaster Stroke Assessment; DH: dominant hand; L: left; MSS-SE: Motor Status Score – Shoulder-Elbow; R: right.

The chair includes 3 seat-belts to limit torso movements and an adjustable footrest. Custom-made hand holders (for each arm), connect the subject's impaired limb to the robot end-effector.

Subjects held the end-effector of the robot through a handle; they were seated so that the centre of the range of targets, lying approximately at the centre of their reachable workspace, was aligned with the shoulder in the proximal-distal direction (y-axis).

All subjects were asked to perform goal-directed, planar reaching tasks that emphasized shoulder and elbow movements. As they attempted to move the robot's handle toward designated targets, the robot was able to recognize the active component of movement: in this case it allows the patient to perform the movements without any support.

When the patient is unable to reach to the target, the robot supports the patient by driving the end-effector to the target. Subjects received a physiological proprioceptive feedback while performing a voluntary movement, which appears to be useful for motor re-learning. The computer screen in front of the patient provided visual feedback of the target location and the movement of the robot end-effector.

Intervention

Each subject was asked to perform goal-directed, planar reaching tasks, which emphasized shoulder and elbow movements, moving from the centre target to each of 8 peripheral targets In each session subjects received 45 min of robot-mediated therapy, 3 sessions per week for 6 weeks. The robotic therapy was composed of 2 different kinds of exercises, unassisted (*Record*) and assisted movements (*Adaptive*), based on 8 targets placed around a circumference and a centre target. In detail:

- *Record:* a series of 16 unassisted clockwise repetitions to each robot target. The goal is to reach toward each of the red targets shown on the monitor in front the patient and placed around a circumference. If the patient is able to reach the respective targets, the robot prompts him or her to move toward the next one. The patient is invited to complete one set around the circle in a clockwise fashion. In the event that the patient is unable to reach the target, the therapist pauses the device and moves the patient's arm passively to the next start position.
- *Adaptive:* a series of 320 assisted clockwise repetitions to each robot target. The robot pre-positions the patient's arm at the centre target when the programme is activated. A visual performance display appears following 5 series of clockwise repetitions. This is an exercise programme that is adaptive in nature. Based on the patient's performance, the programme either increases or decreases the assistance provided to reach the targets.

Each session comprised: (*i*) a series of assisted clockwise repetitions to each robot target (training test); (*ii*) a series of unassisted clockwise repetitions to each robot target (*Record*); (*iii*) 3 series of assisted clockwise repetitions (*Adaptive*). At the end of each *Adaptive* series, the patient is asked to perform a series of 16 unassisted clockwise movements (*Record*).

Clinical measures

Each subject underwent an upper limb evaluation by an experienced physiatrist using the following scales:

- Stage of Arm section of the Chedoke-McMaster (CM) Stroke Assessment Scale – an evaluation tool that has high inter- and intra-rater repeatability, as well as strong correlation with the Fugl-Meyer (FM) score (17, 18).
- Motor Status Scale (MSS) – which measures shoulder, elbow (maximum score = 40), wrist, hand, and finger movements (maximum score = 42). The MSS expands the measurement of upper extremity impairment and disability provided by the FM score and affords a reliable and valid assessment of upper limb impairment and disability following stroke (19). The Motor Status Assessment for shoulder and elbow (MSS-SE) was administered to the subjects.
- Passive range of motion (ROM) in 11 different muscle groups (7 for the shoulder and 4 for the elbow).
- Modified Ashworth Scale (MAS) (20) – to assess muscle spasticity by rating resistance to passive stretch.

A common condition in neurologically impaired patients is pain in the shoulder joint (21). The level of pain in the affected arm was assessed using a 4-point verbal rating scale (0–3, where 0 represents no pain, and 3 represents maximum pain) (22).

The level of feedback is critical to the success of patients. During the initial robot experiences (first 3 training sessions), it was important to review procedures and assess the level of understanding of each patient. A description of each performance measure was provided with the score. Upon demonstration of competency and understanding by the patient, minimal feedback was provided. Verbal encouragement and environmental distraction was kept to a minimum.

A follow-up was carried out after 3 months. The same evaluation tools were used for each subject before and after the robotic therapy and in the follow-up phase.

For statistical analysis a Wilcoxon signed-rank test was used.

RESULTS

The results show a significant decrease in motor impairment in the paretic upper limb after the treatment. As shown in Table II, statistically significant improvements were found on the MSS-SE measured before and after the robotic treatment ($W = 153.00$, $T+ = 153.00$, $T- = 0.00$; $p < 0.001$). As shown by MSS-SE follow-up evaluation (Table I), motor improvements remained after 3 months. No statistically significant changes were observed between MMS-SE at the end of the treatment and at 3 months follow-up ($W = -19.00$, $T+ = 18.00$, $T- = -37.00$; not significant $p > 0.05$).

In the MAS, the sum of muscles trained in the shoulder (7 muscles) was considered. The shoulder MAS score decreased significantly after the training ($W = -112.00$, $T+ = 4.00$, $T- = -116.00$; $p < 0.001$). No modifications in the shoulder MAS score were found at follow-up ($W = -34.00$, $T+ = 16.00$, $T- = -50.00$; not significant $p > 0.05$). The change in the elbow MAS score after the training was not statistically significant ($W = -43.00$, $T+ = 17.50$, $T- = -60.50$; not significant $p > 0.05$).

Table II. *Outcome measures comparison at admission and discharge*

	Admission		Discharge		
Evaluation	Median	IQR	Median	IQR	*p*
MSS-SE	12,800	10,350–14,800	14,200	11,950–16,600	<0.001
MAS shoulder	8,000	4,750–11,250	4,000	2,750–6,625	<0.001
MAS elbow	1,500	750–2,000	1,000	0–1,500	ns
ROM shoulder	440,000	408,750–566,250	550,000	477,500–647,500	<0.001
ROM elbow	440,000	417,500–460,000	460,000	450,000–460,000	<0.005

IQR: interquartile range; MAS: Modified Ashworth scale; MSS-SE: Motor Status Score – Shoulder-Elbow; ns: not significant; ROM: range of motion.

Passive ROM in the shoulder also increased in both groups. The results show that, for the shoulder, a statistically significant improvement was found (W = 134.00, T+ = 135.00, T– = –1.00; $p < 0.001$). At follow-up the passive ROM values of the shoulder showed a further statistically significant reduction in impairment (W = 91.00, T+ = 98.50, T– = –7.00; $p < 0.05$).

Elbow passive ROM showed a statistically significant improvement (W = 64.00, T+ = 65.00, T– = –1.00; $p < 0.005$).

At admission to the clinical trial, 5 subjects had shoulder pain. At the end of the robotic therapy they showed a reduction in the pain score. The scores of two subjects decreased from 1 to 0, and three from 2 to 1. No patients showed an increased score on the pain scale.

The robot-mediated therapy was well accepted and tolerated by the patients. No adverse events occurred during the study and no patient withdrew from therapy. At the end of treatment patients informally reported improved use of the impaired upper limb and some of them also reported an improvement in locomotion.

DISCUSSION

These results confirm the effectiveness of robot-mediated rehabilitation therapy for chronic patients and support the hypothesis that improvements in motor abilities after a neurological injury can continue for more than one year after the acute event.

In the group of patients treated with the robotic system, MSS-SE score and ROM increased in the shoulder and elbow, and MAS scores decreased and did not increase. These results do not support the hypothesis that active motor action in spastic patients may be responsible for increasing muscle tone, and do not imply any worsening in motor performance. In fact, most traditional rehabilitative methodologies, based on reflex inhibition (e.g. Bobath) (23), aim to reduce and limit spasticity and, in some cases (24), to delay execution of active movements, since they could be responsible for an increase in muscular tone and a worsening of spasticity.

According to these methodologies, active movements involving flexor muscles, such as shoulder adduction, shoulder intra-rotation and, in particular, elbow flexion, can induce an increase in muscle spasticity, thus resulting in a worsening of upper limb motor impairment.

A reduction in shoulder pain, the prevalence of which is very high in chronic hemiparetic subjects (21), is an additional advantage of robot-mediated therapy.

Patients with severe spasticity (CM = 3) also improved, and thus it is advised that this group of patients are recruited to robotic training.

Patients with flaccid hemiparesis (CM = 1) appear to display a rather lower improvement in the MMS-SE score after the training. This might imply that it is less effective to perform a specific intervention in the chronic phase compared with the addition of sensorimotor stimulation during the acute phase after a stroke (25).

The mechanisms involved in the improvement in motor performance after repetitive training are not known; the induced modifications in impairment in chronic patients after neurological injury could be related to motor recovery and motor relearning.

It is well known that for motor learning and motor planning, humans have to perform voluntary movements. Proprioceptive, visual and tactile feedback is also important for motor learning: the first-mentioned being the most important.

The patients, including severely spastic subjects, have to perform voluntary movements as far as possible. If the subject is unable to complete the movement the robot helps him or her to reach the desired target, thus providing an adequate proprioceptive feedback.

Robotic systems can provide some advantages in motor rehabilitation for people with chronic neurological injury involving the upper limb, by delivering an intensive and repetitive treatment. In each session the patient can perform almost 1000 goal-directed movements in approximately 45 min. Such treatments can be physically exhausting for a physiotherapist. A robotic system can contribute to the treatment being performed in a repetitive way and to supporting the trajectories with a high precision. Therefore, robotic therapy may be a substitute for traditional therapy, at least in chronic patients, for the preservation of functional recovery obtained during the initial period after an acute event. The large and increasing number of surviving neurologically impaired chronic patients requiring treatment suggests that robot-mediated therapy could also be useful in reducing costs to the healthcare system.

Furthermore, kinematic and kinetic data can be recorded and used to search for useful markers that can quantify the motor recovery process of each patient. Anyway, the search for such markers is not the objective of the present work, which is mainly focused on the clinical assessment.

It is noteworthy that such systems (using reprogrammable software code) are helpful in investigating the pathophysiological mechanisms underlying motor recovery following neurological damage.

As set out in the International Classification of Functioning, Disability and Health (ICF) terminology (26), future efforts should aim to maximize the improvement in the activity level and not only in the structure and body functioning.

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