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ORIGINAL REPORT

ROBOT THERAPY FOR FUNCTIONAL RECOVERY OF THE UPPER LIMBS: A PILOT STUDY ON PATIENTS AFTER STROKE

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Objective: **To verify the possibility of administering robot-aided therapy for the upper limbs in patients after stroke; to evaluate patients' degree of acceptance and compliance with the treatment; to establish if the treatment has an effect on motor impairment and functional outcome.**
Design: **Quasi-experimental, uncontrolled study.**
Subjects: **Fourteen patients with chronic hemiparesis after stroke.**
Methods: **Patients were treated with a robotic system for the upper limbs (ReoGo™; Motorika Medical Ltd, Israel). Subjects performed the following assessment, at the start (T0), at the end of treatment (T1), and at the follow-up performed one month after the end of treatment (T2): Fugl-Meyer test (FM) for upper limbs; strength evaluation; Ashworth scale; visual analogue scale (VAS) for pain; Frenchay Arm test (FAT); Box and Block test (B&B); Functional Independence Measure (FIM™); ABILHAND Questionnaire; Timed Up and Go test (TUG); Euro-Quality of Life questionnaire and; a VAS for treatment satisfaction were administered to the subjects.**
Results: **Total scores of FM, B&B, FAT and FIM™ showed a statistically significant improvement from T0 and T1 (FM $p < 0.002$, B&B $p < 0.012$, FAT $p < 0.023$, FIM™ $p < 0.007$) and from T0 and T2 (FM $p < 0.003$, B&B $p < 0.011$, FAT $p < 0.024$, FIM $p < 0.027$). No statistically significant differences were found between evaluations at T1 and T2 (FM $p < 0.595$, B&B $p < 0.491$, FAT $p < 0.317$, FIM $p < 0.180$).**
Conclusion: **The sample was capable of completing the treatment and demonstrated good participant satisfaction. This pilot study led to the finding of a clinical improvement and excellent patient compliance. It can be hypothesized that the results are robot-dependent and that they were learned and then maintained. However, the study is limited in that a control group was not used. As such, it is desirable to continue this study with a control group, as well as by designing a prospective longitudinal randomized controlled trial study.**

Key words: stroke, upper limbs, robotics.

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INTRODUCTION

Stroke is the main cause of disability in industrialized countries, with a significant impact on individual, family, and societal healthcare. As such, any form of treatment that increases the functional recovery of patients after stroke could significantly reduce the physical, emotional, and financial load that this condition carries for the sufferers, their families and society in general (1–3).

Therefore, as far as functional recovery is concerned, various longitudinal studies have shown that the upper limbs are involved at the onset of disease in 85% of cases, and that they remain non-functional 6 months after the acute event in 30–66% of cases, while only 5–20% of cases present complete functional recovery (4). Consequently, over the last few years, rehabilitative medicine has encouraged research in an attempt to identify the modalities, time-frames and proper motivations of the rehabilitative intervention: attempting to identify predictive indicators of outcomes in the acute phases (4, 5); and seeking to understand the neurophysiological mechanisms underlying functional recovery (6, 7), in order to plan the most incisive therapeutic interventions.

Within the scope of this research, it has emerged that the proposed exercise must be intensive and specific in order for treatment to be effective (3); in addition, treatment must be repetitive, functional and motivating (8, 9), so as to bring about an increase in performance, as well as learning, acquisition and generalization (10).

These requirements seem to be satisfied by robotic devices for rehabilitation (11), both in terms of clinical results as well as in terms of positive effects on healthcare costs and increased efficiency. The use of robotic devices for rehabilitation of the upper limbs shows various advantages, including: a large number of patients that can benefit from robotic therapy, due to the flexibility of robotic systems; excellent acceptance of the therapy among patients; and, finally, that the therapy can be performed by the patient under the supervision of a physiotherapist. Recent technological advances have made it possible to develop robotic instruments capable of performing a safe and intensive rehabilitative intervention. Robotic therapy can be developed in different directions in order to reduce motor impairment and increase functional recovery, even in patients affected by moderate/severe impairments, following injuries

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to the central nervous system, as in the case of stroke. Numerous robotic systems have been developed for sensory-motor rehabilitation of the upper limbs of hemiplegic patients, such as, for example, MIT-MANUS and its commercial version, the InMotion Shoulder-Elbow Robot (12), ARM-Guide (13), MIME (14), BiManu-Track (15), NeReBot (16), and the REO Therapy System (17).

The objectives of this study are: (*i*) to verify the actual possibility of administering the robotic system for the upper limbs; (*ii*) to evaluate patients' degree of acceptance and compliance with the treatment; (*iii*) to establish if the treatment has an effect on motor impairment and on functional outcome in these patients.

MATERIALS AND METHODS

Patients

This was a quasi-experimental, uncontrolled study. Patients with chronic hemiparesis were recruited for the study. Persons meeting the following criteria were included: (*i*) patients with motor impairment and consequent disabilities related to the first acute cerebrovascular event; (*ii*) outpatients at least one month after suspension of specific treatment for the upper limbs, insofar as they had already reached the objectives of the programme designed by the team, without further signs of changes in the motor picture. Patients were excluded who presented: (*i*) a lesion located in the posterior circulation; (*ii*) serious cognitive (Mini-Mental State Examination < 24), linguistic, or perceptual deficits; (*iii*) an absence of control of the trunk in a seated position; (*iv*) lack of consent to participate in the study; (*v*) people who stopped treatment for more than 5 consecutive days were considered drop-outs; under this threshold, any lost sessions were recovered.

Treatment

Each patient underwent a cycle of treatment with a robotic system for the upper limbs (ReoGo™; Motorika Medical Ltd, Israel, Fig. 1) (17). This instrument makes it possible to perform a specific treatment for the upper limbs, in particular through the mobilization of the shoulder and elbow joints. The robot makes it possible to execute movements in 3 dimensions and on all spatial planes. The exercises can be performed in various ways: with forearm support, wrist support only, or through a handgrip. Thus, the system makes it possible to perform numerous kinds of exercises, the purpose of which is to reach the objectives on the computer screen connected to it, with visual and audio feedback.

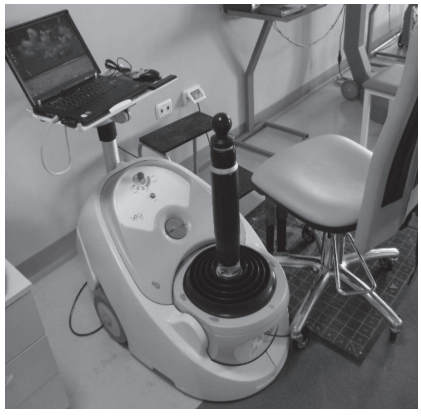

Fig. 1. Robotic system for the upper limbs: ReoGo™ (Motorika Medical Ltd, Israel).

The movement mode can vary from completely passive to completely active, through varying degrees of intervention that the patient can exert on the robot's arm. Even the width of the movement itself can be modulated on the basis of each subject's unique characteristics. The treatment consisted of a total of 20 sessions lasting 45 min each, 5 days a week, for a total period of 4 weeks; a protocol we designed was used, with exercises that presented a progression for both movement type (i.e. the joints involved, with a proximal-distal progression) and mode of execution of the movement itself, with a progression from passive movement, to assisted movement, to free movement. Forearm support was used during treatment. Patients did not undergo any kind of specific treatment for the upper limbs during treatment or in the preceding and subsequent month.

Evaluations

Subjects performed the following assessment: Fugl-Meyer test for upper limbs as modified by Lindmark & Hamrin (18, 19); muscle evaluation of 10 muscles, according to Medical Research Council (MRC) criteria (20); Ashworth scale for spasticity (21); visual analogue scale (VAS) for upper limb pain; Frenchay Arm test (22); Box and Block test (23); FIM motor (24, 25); and the ABILHAND questionnaire (26). In addition, subjects underwent a comprehensive evaluation using the Timed Up and Go test (27). Finally, the Euro-Quality of Life (QoL) questionnaire (28) and a VAS for treatment satisfaction were administered.

Evaluations were administered at the start of treatment (T0), at the end of treatment (T1), and at the follow-up performed one month after the end of treatment (T2), during which the patient did not undergo any kind of specific rehabilitation for the upper limb.

Statistical analysis

A descriptive analysis of the distribution of patients was used to process the data; the following tests were used to verify the existence of a possible relationship between the variables examined: Student's *t*-test, verified with the Wilcoxon signed-rank test and the exact tests.

RESULTS

Fourteen patients participated in the study (9 men and 5 women, mean age 60.57 years (standard deviation (SD) 8.18, range 35–71 years)) (Table I). There were 9 cases of ischaemic stroke and 5 of haemorrhagic stroke; 6 of right-side hemiparesis and 8 of left-side hemiparesis; distance from the acute event ranged from 4 months to 25 years; and distance from the last treatment period ranged from a minimum of 30 days to a maximum of 6 months. Only one patient left the study, due to an inability to maintain a seated position for a long time owing to the flare-up of a degenerative disease in a vertebral lumbar disc. One other patient did not attend the follow-up.

The Fugl-Meyer test ranged from a total score of 76 (T0) to a score of 85.2 at T1; the improvement was statistically significant ($p < 0.002$). At T2 the value increased by an additional 2.2 points and was significant ($p < 0.003$) compared with the value at T0. The Box and Block showed a change from T0, where the mean value was 13.1, to T1, e.g. an increase of 3.9 points, and from T0 to T2, an increase of 6.6 points. The mean value of the evaluations at T1 and T2 was statistically significant ($p < 0.012$ at T1; $p < 0.011$ at T2) compared with T0. The Frenchay Arm test, which recorded an average value at T0 of 2.6, obtained an improvement at T1, reaching 3.2 points, and a further increase at T2, reaching a mean

Table I. *Description of the sample*

	n (%)	Mean (SD)	Min–max
Age, years	14	60.57 (8.18)	45–71
Gender	14		
Male	9 (64.3)	–	–
Female	5 (35.7)	–	–
Affected side	14		
Left	6 (42.9)	–	–
Right	8 (57.1)	–	–
Time since stroke (months)	13	49.76 (89.49)	3–291
Disease severity (FMUL)	13		
Low	7 (53.8)	–	–
Moderate	4 (30.7)	–	–
Severe	2 (15.5)	–	–

n: sample evaluated; SD: standard deviation; FMUL: disease severity based on the score of the Fugl-Meyer for Upper Limb (modified by Lindmark & Hamrin (19)) at T0: Low FM, 0–35; Moderate FM, 36–75; Severe FM, 76–115.

score of 3.6. A comparison of the average values from T0 to T1 was significant ($p < 0.023$), as was a comparison of mean values between T0 and T2 ($p < 0.024$). The data recorded by the FIM™ showed a value of 80.1 at T0, which increased at T1 to a statistically significant ($p < 0.003$) score of 82.6, with an additional increase at T2, where the value corresponded to 84. The same average value at T2 was significant compared with the T0 value ($p < 0.027$) (Fig. 2).

The Ashworth elbow scale had an average value at T0 of 1.7 and showed a decrease of 0.3 at T1 compared with T0, and a decrease of 0.2 at T2. There was a statistically significant difference in the mean value at T1 compared with T0 ($p < 0.025$), and in the mean value of the evaluations at T2 compared with the initial ones ($p < 0.046$). The VAS of pain at T0 had a total mean value of 29.8, which decreased notably at T1, to 14.0, and again at T2, where it reached a value of 3.8. The decrease from T0 to T2 was statistically significant ($p < 0.010$). The Timed Up and Go Test showed a decrease from T0 to T1, with the mean value changing from 18.9 to 18.7. This value decreased further from T1 to T2, reaching 17.3. The decrease from T0 to T2 was statistically significant ($p < 0.040$). The ABILHAND questionnaire showed an increase from T0 to T1, with the average value changing from 22.4 to 23.6, but there was not a statistically significant difference ($p = 0.136$). The Euro-QoL had a mean value at T0 of 0.6 and showed an increase at 0.7 at T2, there was not a statistically significant difference ($p = 0.229$). The VAS for treatment satisfaction had a mean value at T1 of 98.2 (SD 4.01) mm (range 85–100) (Table II).

DISCUSSION

This study showed that the patient sample was capable of completing the treatment and demonstrated good participant satisfaction. Furthermore, the response of the therapists involved was positive, both from an organizational point of view and with regard to the clinical-rehabilitative responses obtained. Finally, the pilot study showed a clinical improvement for the subjects who took part in it. First of all, an improvement from T0 to T2 was observed on the evaluation scales administered, both in terms of impairment and functionality. At the end of treatment (T1) with robotic therapy, statistically significant changes were observed compared with the initial evaluations

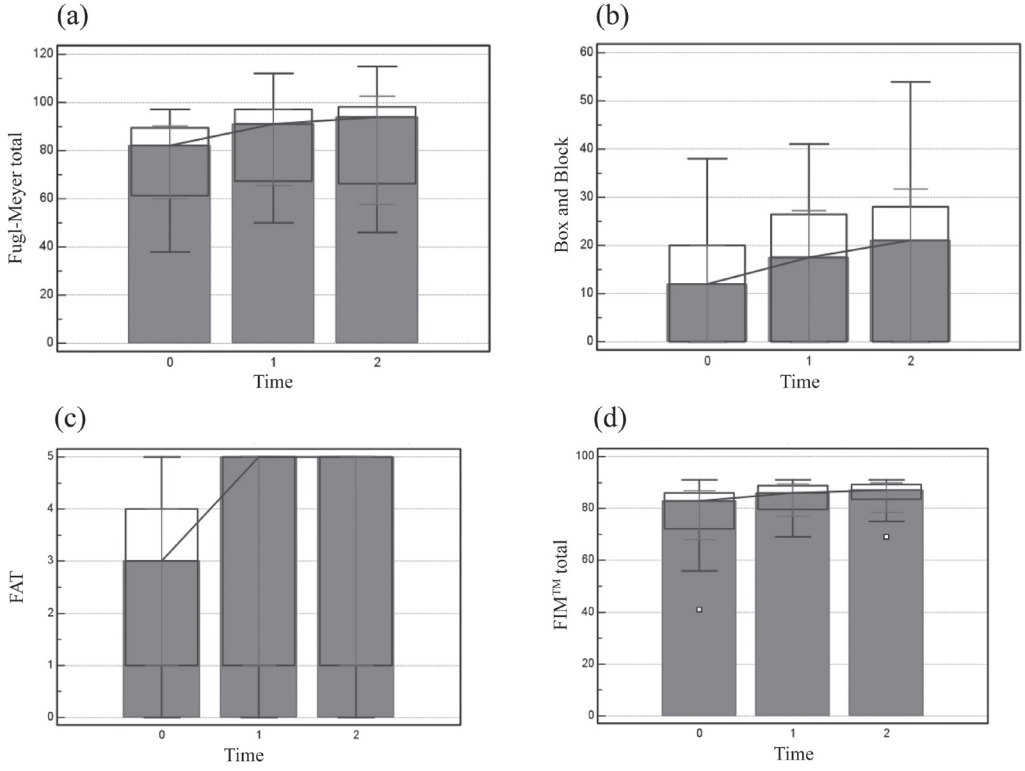

Fig. 2. Data at T0, T1 and T2 of total scores of: (a) Fugl-Meyer, (b) Box and Block, (c) Frenchay Arm test, and (d) FIM™. All showed a statistically significant improvement from T0 and T1 and from T0 and T2. There was no statistically significant improvement between evaluations at T1 and T2. Box-and-whisker Medians (error bars: 95% confidence interval for median).

Table II. *Results for assessment at T0, T1 and T2*

	T0			T1			T2		
	n	Mean (SD)	Min–max	*n*	Mean (SD)	Min–max	*n*	Mean (SD)	Min–max
VAS for pain	14	29.79 (26.54)	0–80	13	15.77 (23.17)	0–75	12	3.75 (0.62)**	3–5
Timed Up and Go test	14	18.93 (8.53)	10–40	13	18.69 (8.73)	10–38	12	17.33 (7.66)**	9–34
Ashworth shoulder	14	0.36 (0.50)	0–1	13	0.15 (0.38)	0–1	12	0.80 (0.29)	0–1
Ashworth elbow	14	1.71 (1.07)	0–3	13	1.46 (0.97)*	0–3	12	1.50 (1.00)**	0–3
Ashworth wrist	14	0.50 (0.52)	0–1	13	0.54 (0.52)	0–1	12	0.50 (0.52)	0–1
MRC trapezius	14	3.43 (0.51)	3–4	13	3.62 (0.65)	3–5	12	3.75 (0.62)**	3–5
MRC deltoid	14	3.79 (0.58)	2–4	13	4.46 (0.66)*	3–5	12	4.67 (0.65)**	3–5
MRC pectoral	14	3.71 (1.33)	0–5	13	4.54 (0.88)*	2–5	12	4.83 (0.39)**	4–5
MRC internal rotators	14	3.50 (1.16)	0–5	13	3.92 (1.32)	0–5	12	4.08 (1.44)	0–5
MRC external rotators	14	3.29 (1.14)	0–4	13	3.15 (1.63)	0–5	12	3.50 (1.38)	0–5
MRC biceps	14	3.93 (1.07)	2–5	13	4.54 (0.66)*	3–5	12	4.75 (0.45)**	4–5
MRC triceps	14	3.71 (1.38)	0–5	13	4.08 (1.19)	1–5	12	4.25 (1.22)**	1–5
MRC wrist flexors	14	2.93 (1.54)	0–5	13	3.00 (1.87)	0–5	12	3.33 (1.72)	0–5
MRC wrist extensors	14	2.86 (1.46)	0–4	13	3.00 (1.68)	0–5	12	3.33 (1.50)**	0–5
MRC latissimus dorsi	14	2.64 (1.22)	0–4	13	3.15 (1.21)	1–5	12	3.67 (1.07)**	1–5
VAS for satisfaction				13	98.84 (4.00)	85–100			
ABILHAND	13	22.38 (9.58)	5–40	13	23.62 (10.15)	7–41			

*Statistically significant improvement from T0 and T1; **statistically significant improvement from T0 and T2.
VAS: visual analogue scale; MRC: strength evaluation measured with the criteria of Medical Research Council; T0: start of treatment; T1: end of treatment; T2: follow-up (one month after the end of treatment); *n*: sample evaluated; SD: standard deviation.

(T0) on all scales except for the pain evaluation (VAS), the Timed Up and Go Test, the shoulder and wrist Ashworth scale, and the MRC scale of the trapezius muscle, external and internal rotators, triceps, pectoralis major, wrist flexors and wrist extensors.

These data indicate an effective improvement in motor performance after administering robotic treatment, even in those patients classified as "chronic", i.e. stabilized from a rehabilitation point of view; moreover, these results had been found previously by other studies in the literature (11, 29), thus supporting our own.

However, this statistically significant finding was not observed in the analysis of the results between T1 and T2. This fact is interesting, because neither additional spontaneous recoveries nor worsening were found in the time interval during which the patient did not undergo exercise with the robot system; thus, it can be hypothesized that the results are robot-dependent and that they were learned and then maintained. Another very important consideration emerges from the comparison between the evaluations of T0 and T2, where other significances emerge in addition to those found at T1, such as the VAS for pain, certain muscular components (trapezius and wrist extensors) in the MRC and the Timed Up and Go test, which leads one to hypothesize that the maintenance of motor performances of the upper limbs could also improve ambulatory function. This could indicate that statistical significance is also maintained after one month, a period in which the patient does not perform any kind of treatment specific to the upper limbs. The fact that results are maintained is confirmed by other authors at 6 months and at 3 months (12, 30, 31).

The fact that the motor performances acquired are maintained leads one to think that the therapeutic training was translated into "motor learning". This factor is in line with and Gordon (32); indeed, the robotic instrument makes it possible to administer, in accordance with the theories of Constraint Induced Therapy (33, 34), an intensive, diversified and stimulating exercise that results in changes at the motor and cerebral neuroimaging level (3, 9, 10).

This pilot study led to the finding of a clinical increase and excellent patient compliance. However, the study is limited, in that a control group was not used. Despite this, nearly all the patients were known by our centre and had been suspended from treatment, since they did not show changes in the scales that were used in part by our study.

In addition, the fact that there were no statistically significant changes between T1 and T2 in either an improving or worsening direction encourages us to undertake further research. Indeed, the former indicates that no spontaneous improvement of the motor and functional picture occurred, and the latter indicates that the improvement recorded was not strictly robot-dependent, but rather a sign of motor learning.

As such, it is in any case desirable to continue this study with a control group, as well as by designing a prospective longitudinal randomized controlled trial, perhaps focussing on the early stages of inpatient rehabilitation.

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