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A Pilot Study of Robotic-assisted exercise for hand weakness after stroke

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***Abstract*—Upper limb paresis is a major source of disability in stroke survivors, and robotic aided exercise therapy is a promising approach to enhance motor abilities. Few devices have been available to provide robotic therapy to the fingers and hand. We report an open-label pilot study of 12 individuals with chronic moderate hemiparesis after stroke who underwent a six-week training program using a hand robotic device. Participants received a total of 18 hours of robotic therapy. Improvements were found in multiple measures of motor performance, including the Upper Extremity Fugl-Meyer, the Motor Activity Log, the Manual Ability Measure-36, and the Jebsen Hand Function Test. All subjects tolerated the treatment well and no complications were observed. We conclude that robotic therapy for hand paresis after stroke is safe and feasible, and that further studies of efficacy are justified by these preliminary results.**

Keywords-stroke, hemiparesis, robotics

I. INTRODUCTION

There are approximately 6.4 million stroke survivors in the United States, many of whom live with residual disability [1]. Hemiparesis is a substantial contributor to post-stroke disability, and extensive resources are devoted to motor rehabilitation. Despite these efforts, outcomes for upper extremity function are frequently inadequate, leaving stroke survivors with very limited or no functional use of the upper limb.

Exercise therapy remains the mainstay of rehabilitation for hemiparesis after stroke. Repeated exercise has been found useful in restoring some degree of motor performance post-stroke, even in individuals with persistent hemiparesis [2]. Accompanying changes in the brain indicative of cortical plasticity have been demonstrated [3]. The use of robotic devices is appealing as a means of delivering well-defined repetitive exercises in a consistent fashion. Robotic devices also are suitable for use by individuals with more severe weakness, who may not be able to complete conventional exercises without assistance. Robots also have the potential to provide a more labor-efficient exercise program that does not require as direct supervision by highly trained therapists. Ultimately, robotic therapy should allow patients to achieve larger overall doses of exercise treatment through the use of home-based or unsupervised robotic training.

The use of visual displays can incorporate gaming or virtual reality as a means of making performance of the exercises more engaging for the patient. A variety of upper limb robotic devices have been developed to provide robotic exercises for stroke survivors, and several of these are now available commercially. Results of training with these devices have been promising, although no conclusive evidence exists that they offer benefits exceeding that of human-delivered exercise [4].

Few of these devices have specifically targeted the hand, and very limited data on the feasibility or efficacy of robotic hand rehabilitation exists. A pilot study of a prototype hand robot that does not permit individuated finger movements has been published [5]. A hand robot designed for grasping exercises is available commercially, but as of yet, there are no published reports on its efficacy [6]. The Amadeo hand robotic system (Tyromotion GmbH, Graz, Austria)[1] provides robot-assisted exercise for the finger flexors and extensors. This system provides a position-controlled active assisted exercise mode, as well as isometric modes with visual feedback provided during computerized games emphasizing flexion and extension. There are no prior published reports of the use of this device for hand retraining after stroke.

We undertook this open-label pilot study to test the feasibility of treating hemiparetic stroke survivors with this device and to obtain preliminary evidence of efficacy in restoring motor performance.

II. METHODS

Subjects were recruited through the use of a voluntary registry of stroke survivors maintained for clinical trials of stroke rehabilitation, as well as patients cared for at Columbia University Medical Center. Inclusion criteria included a single stroke (hemorrhagic or ischemic) at least 6 months prior to study entry, with confirmation by appropriate imaging studies.

[1] The robotic equipment used was loaned by Tyromotion, GmbH, which was not otherwise involved in study design or interpretation.

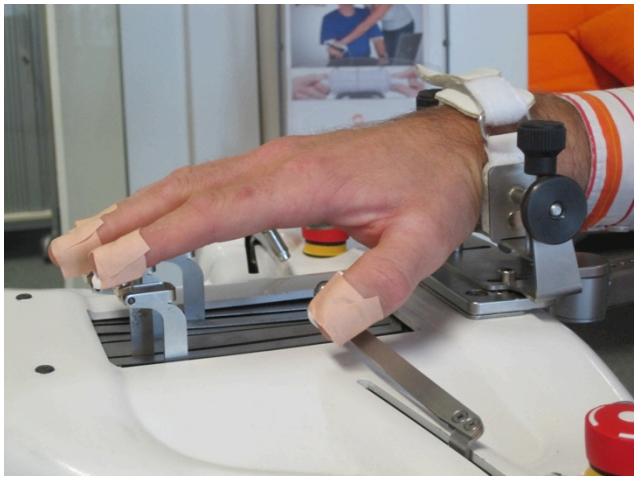

Figure 1. Amadeo Robot showing attachment of fingers to device

(CT or MRI). Subjects were required to have at least trace finger flexion (1/5 on manual muscle testing using the MRC scale) of at least 3 digits of the affected hand, as well as be experiencing difficulty with activities of daily living using the affected hand and upper limb. Subjects were not receiving any physical or occupational therapy to the affected upper limb during the course of the study. Potential subjects with recent botulinum toxin injections within the prior 12 weeks were excluded, and subjects were asked not to undergo these injections during their participation in this study.

Exclusions include other neurologic disorders, such as Parkinson Disease, a history of more than one stroke clinically, excessive spasticity (defined as a Modified Ashworth Scale of greater than 3 (out of 4) at the wrist or finger flexors, uncontrolled hypertension, unstable coronary artery disease, contractures of the affected upper limb interfering with positioning in the device (e.g. shoulder or elbow), and contractures of any of the fingers of the affected hand greater than 10 degrees of flexion at any joint (MP, PIP, DIP), impaired cognition defined by a Folstein Mini-mental status

Figure 2. Amadeo robotic device with fingers in flexion

exam (MMSE) score below 24, or other medical conditions that might interfere with the subject's ability to complete the study. Subjects with severely impaired sensation in the affected hand (graded as 2 on the sensory item on the NIH Stroke Scale) were excluded.

After undergoing baseline assessment, subjects received 1 hour of therapy with the device daily, 3 days/week for six consecutive weeks (a total of 18 sessions). Therapy sessions were conducted an experienced physical therapist trained in the use of the device. Subjects were seated in a comfortable position, and the arm strapped into an adjustable stabilizing splint attached to the robotic device with the wrist in approximately neutral position, and with the forearm pronated to 180 degrees. The height of the device and the chair was adjusted to achieve an angle of approximately 30 degrees of flexion at the elbow. Sessions included 20 minutes of 'CPM Plus' mode, which is an active-assisted training mode wherein subjects were asked to assist the device complete movements in both finger flexion and extension. This included both collective and sequential flexion and extension of the digits as well as flexion and extension of each digit individually. Visual feedback was provided using two games – one in which the flexion or extension force exerted resulted in a proportional movement of a figure down or up in an obstacle avoidance task (see figure 3), and the other in which a flexion or extension force resulted in leftward or rightward movement of a virtual figure in an attempt to reach a targeted position. This was followed by 20 minutes of an isometric mode in which isometric digit contractions were sustained using a variety of games selected by patient and therapist. Following completion of the isometric mode, each subject underwent an additional 20 of training with the 'CPM Plus' mode. Subjects were offered a five-minute rest period at the midpoint of each session if desired. Subject performance was monitored by the supervising physical therapist, and task difficulty was gradually increased throughout the course of the training, with manual incremental increases in task difficulty on the 'CPM Plus' mode every 2 weeks, and automated increases in difficulty on isometric modes based on the successful completion of each difficulty level.

All subjects reported stable motor function prior to study enrollment, consistent with a population of stroke survivors more than six months post-stroke and without ongoing physical or occupational therapy. Subjects underwent a reassessment of motor abilities at the midpoint of the training period, and then again at the conclusion. All scales were measured by an experienced Occupational Therapist familiar with administration and scoring of these instruments, and who was not involved in the administration of the robotic therapy.

The primary outcome measure for this study was the Upper Extremity component of the Fugl-Meyer (UEFM) [7]. Secondary outcome measures included the Motor Activity Log (MAL) [8], including both the amount of use and the quality of use scales, the nine-hole peg test [9], the Manual Ability Measure-36 (MAM-36) [10], the Jebsen Hand Function Test [11], and the Stroke Impact Scale-16 (SIS-16) [12].

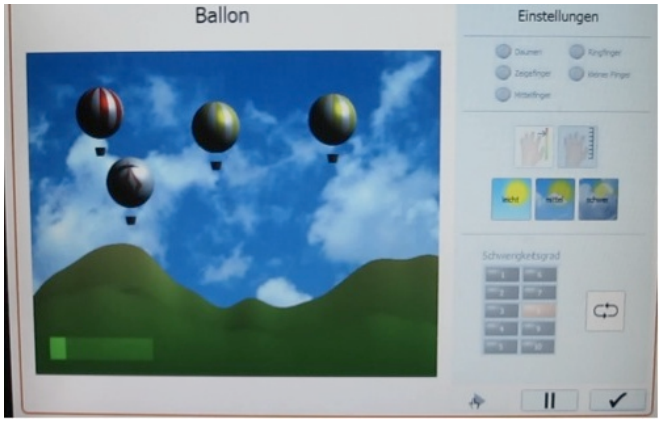

Figure 3. Target avoidance task. Flexion causes the target balloon (2nd from the left in this figure) to move inferiorally, and extension superiorally.Users are instructed to avoid making contact with the ground or other balloons.

Primary and secondary outcome measures were analyzed using a paired t-test of baseline values compared with values at the completion of treatment. Results were considered significant at a p-value of <0.05.

Twelve subjects were enrolled in this study; all completed the training program, and no complications of robotic therapy were observed. Subject characteristics are provided in table 1.

All subjects had some degree of spasticity in the wrist or hand, with a Modified Ashworth Scale (MAS) of at least 1. Six of the subjects had a MAS of 2 at either the wrist or finger flexors, but no subjects were enrolled with scores of 3 or higher.

	Subjects (n=12)
Male/Female	9/3
Mean Age (SD)	53 (14)
Mean Duration Post-Stroke (SD)	66 (100)
Right/Left Handed	12/0
Side of Hemiparesis: Right/Left	8/4
Baseline UEFM Mean (Range)	37.9 (23 – 52)

Table 1..Subject Characteristics

This study was approved by the Institutional Review Board of Columbia University Medical Center.

III. Results

The UEFM scores improved from a mean of 37.9 (SD 11.1) to 43 (SD 10.8) from baseline to the conclusion of therapy (P=.0004). Individual subject UEFM scores are shown in Figure 4.

Improvements were seen in the Motor Activity Log (both the amount of use and the quality of use), the Manual Ability Measure-36 (MAM-36), and the Jebsen Hand Function Test (see Table 1). No change was seen in the Stroke Impact Scale-16 (SIS-16) (see Table 1).

The nine-hole peg test proved difficult for most subjects to perform, with 7/12 subjects unable to place any of the pegs at baseline. None of these 7 subjects showed any improvement on this measure at the conclusion of training. Three subjects placed 4 to 5 pegs at baseline; all improved to 8 or 9 pegs by study end. The two subjects capable of placing all 9 pegs at baseline were able to perform the 9-peg placement faster at the conclusion of treatment, with a reduction in time required of 36 seconds and 49 seconds, respectively, compared with baseline.

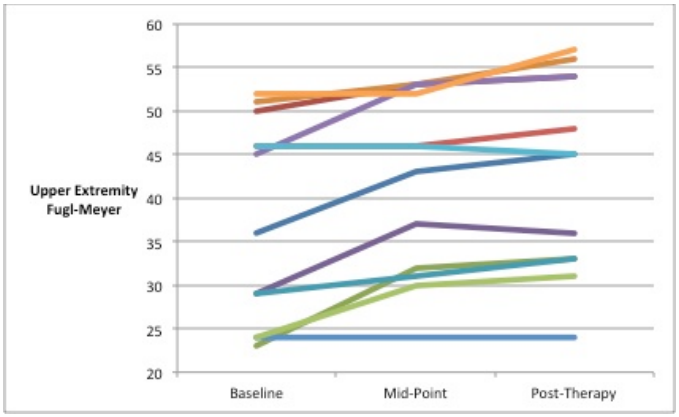

Figure 4. Individual subject Upper Extremity Fugl-Meyer scores

	Mean Baseline (SD)	Conclusion (SD)	Change (SD)	p-value
Upper Extremity Fugl-Meyer	37.9 (11.1)	43 (10.8)	5.08 (3.38)	0.0004
Motor Activity Log – Amount of Use	37.8 (27.1)	55.7 (34.7)	17.96 (14.06)	0.001
Motor Activity Log – Quality of User	40.2 (25.9)	54.2 (29.6)	14.04 (13.06)	0.004
MAM-36	103 (20)	112 (15)	8.7 (10.7)	0.02
Jebsen Hand Function	701.5 (371.1)	649 (397)	52.4 (52.4)	0.007
Stroke Impact Scale-16	67.6 (7.3)	69.4 (6.0)	1.8(5.8)	0.31

Table 2..Outcome Measures before and after therapy

IV. DISCUSSION

This pilot study found that individuals with chronic hemiparesis after stroke were able to successfully train with the Amadeo robotic device, and demonstrated improvements in multiple measures of motor performance over the course of a six-week program consisting of 18 total hours of robot-assisted therapy.

We selected individuals with residual finger flexion of at least trace movements in three or more digits in an effort to identify a population likely to tolerate and benefit from the intervention. The range of UEFM scores is indicative of moderate levels of motor impairment, and the most severely impaired individuals with hemiplegia were not included in this study. It remains unknown, therefore, whether this type of therapy would be beneficial for individuals without volitional finger flexion post-stroke. Nonetheless, the population targeted encompasses a broad range of motor impairment, and suggests that this therapy may be useful for a substantial portion of hemiparetic stroke survivors.

The open label, uncontrolled nature of this pilot study limits the ability to make any definitive statements regarding efficacy, or to compare this therapy to other promising upper limb exercise training programs. Nonetheless, the results of this pilot study are encouraging, and justify further study of the efficacy of this device in larger controlled trials.

The magnitude of the improvements in motor function seen in this study are similar to those found in other studies of chronic hemiparetic individuals receiving comparable doses of robot-assisted motor retraining using devices that target more proximal muscles [13].

The hand serves a unique and critical role in upper limb function. Therapies focusing solely on the more proximal segments of the upper limb are unlikely to result in substantial improvements in actual upper limb functional use. The development of robotic devices capable of providing exercise therapy for the hand is therefore an important milestone on the path to upper limb functional restoration after stroke.

Combining robotic training at multiple sites in the upper limb using a set of modules targeting different limb segments (e.g. the shoulder, elbow flexors and extensors, wrist, and hand) is conceptually appealing as a means of improving the effect size on motor impairment. Despite the intuitive appeal of this approach, a prior study failed to demonstrate larger gains in UEFM with a combination of multiple upper-limb robotic modules [4]. The reasons for this failure remains unclear. One possibility is that there are fundamental limits on the amount of motor performance/plasticity that is achievable using exercise therapy post-stroke, whereby adding more extensive training fails to provide incremental benefit. Another possibility is that the design of the individual robotic modules may not yet be optimally effective, and that improvements in robotic technology may expand the range of achievable motor improvements. Lastly, the modular approach to training may be inferior to an integrated approach incorporating multiple limb segments, although prior studies have not demonstrated superiority of this approach [14]

Further clinical tests of novel robotic modules such as this one in controlled studies, both as individual therapies and in combination with modules directed at other limb segments are needed to answer these questions. Moreover, combining robotic therapy with other techniques to enhance brain plasticity, such as non-invasive brain stimulation, is an appealing strategy that requires empiric testing. Other strategies to enhance the magnitude of the clinical effect might include providing robotic therapy earlier post-stroke, when plasticity may be more robust, or providing training programs of greater duration or intensity.

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