Robotics and Other Devices in the Treatment of Patients Recovering from Stroke

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Stroke is the leading cause of permanent disability in the United States despite advances in prevention and novel interventional treatments. Randomized controlled studies have demonstrated the effectiveness of specialized post-stroke rehabilitation units, but administrative orders have severely limited the length of stay, so novel approaches to the treatment of recovery need to be tested in outpatients. Although the mechanisms of stroke recovery depend on multiple factors, a number of techniques that concentrate on enhanced exercise of the paralyzed limb have demonstrated effectiveness in reducing the motor impairment. For example, interactive robotic devices are new tools for therapists to deliver enhanced sensorimotor training for the paralyzed upper limb, which can potentially improve patient outcome and increase their productivity. New data support the idea that for some post-stroke patients and for some aspects of training-induced recovery, timing of the training may be less important than the quality and intensity of the training. The positive outcome that resulted in the interactive robotic trials contrasts with the failure to find a beneficial result in trials that used a noninteractive device that delivered continuous passive motion only. New pilot data from novel devices to move the wrist demonstrate benefit and suggest that successive improvement of the function of the arm progressing to the distal muscles may eventually lead to significant disability reduction. These data from robotic trials continue to contribute to the emerging scientific basis of neuro-rehabilitation.

Introduction

In a recent issue of this journal, we discussed the rehabilitation of the patient with stroke in terms of enhancing the natural recovery of function by focusing on impairment reduction of the paralyzed upper limb with evidence-based treatment strategies [1]. The multidisciplinary approach to impairment reduction combined novel advances in biomechanical engineering and robotics with the basic and clinical neurology of central nervous system recovery from injury [2••,3,4•]. This new information suggested strongly that therapists who used robotic tools, which intensified the "dose" of a therapy session with logarithmic-scale increase in repetition, systematically measured the amount of therapy, and delivered adaptive guidance for each movement, produced beneficial therapeutic effects that both registered statistically significant improvements compared with a control group and, most importantly, produced real-world effects that the patients articulated [5,6•,7•]. Administrative efficiencies have decreased the length of stay and have challenged the clinical investigator to focus on testing alternate devices and testing whether positive outcomes can result from outpatient treatment. In this brief review, we report pilot data that test whether simpler devices (*ie*, continuous passive motion machines) affect motor outcome, whether the positive response to robotics is limited to a time period soon after stroke, and whether the new device that trains the wrist can also produce better motor outcome.

Can Continuous Passive Motion Devices Improve Motor Outcome?

In the clinic, passive range of motion is a standard part of the therapists' treatment session, and it is considered effective at preventing contractures [8]. Whether passive motion could alter the motor outcome has not been established, but new experiments support a rationale for a test. These recent clinical experiments demonstrated that passive movement altered the inhibitory state of the central nervous system and subsequently affected the behavioral response. Subjects who had passive rhythmic flexion (*ie*, extension movements of the wrist systematically delivered by a passive movement apparatus) were found to have disinhibited local cortical environ-

Table 1. Impairment assessment*

Group	Patients, *n*	Time	Score, *adjusted mean ± SEM*		
			MP†	MSS/S,E‡	F-M/S,E§
CPM trained	17	Admission	3.71 ± 1.94	4.27 ± 1.46	7.53 ± 1.69
		Discharge	9.70 ± 1.3	9.20 ± 1.3	10.90 ± 1.1
Control	15	Admission	1.33 ± 1.00	1.22 ± 0.49	5.20 ± 0.49
		Discharge	7.0 ± 1.4	8.3 ± 1.4	8.9 ± 1.2

*Discharge means were adjusted for admission score, age, gender, and lesion side in an analysis of covariance model, and there were no significant differences.
†Scores of the individual muscle power, on a 6-point scale, of the 14 muscles that move the arm about the shoulder and the elbow (maximum score = 70).
‡Measures components of functional movements of the shoulder and elbow on a 6-point scale (maximum score = 42).
§Measures upper limb functional movements (maximum score = 42).
CPM—continuous passive motion; F-M/S,E—Fugl-Meyer for shoulder/elbow and coordination; MP—motor power; MSS/S,E—motor status scale of shoulder and elbow; SEM—standard error of mean.

ments that were independent of spinal cord activity [9,10•]. These results may be important to limb motor recovery after stroke, because others have demonstrated that cortical disinhibition facilitated practice-dependent plasticity that produced improved motor performance [11].

Because devices have the advantage of reproducibility in delivering repetitive activity [4•,6•], we tested whether the addition of a formal daily treatment session with a device that moves the upper limb passively in patients with stroke and a paralyzed upper limb would alter motor outcome, spasticity, and shoulder joint integrity. Pain and disability outcome were also measured.

Studies using continuous passive motion (CPM) devices have demonstrated effectiveness in the postoperative maintenance of joint motion and muscle length [12]. We programmed a CPM device (Shoulder 600; Orthologic, Tempe, AZ), chosen for safety and sound design, to mobilize the gleno-humeral joint repetitively and reproducibly. The movements avoided extremes of shoulder joint excursion. There are no reported studies to our knowledge of the use of this apparatus to treat a paralyzed upper limb after stroke, although there are reports of its use in the treatment of shoulder-hand syndrome [13].

Treatment plan and results

Consecutively admitted patients to a post-stroke rehabilitation unit were screened for inclusion, which required a single first stroke (verified by imaging techniques) within 3 weeks and significant motor impairment of the arm (no greater than a score of 3 on a scale from 0 to 5 on the Motor Power assessment of any muscle group in the upper limb, and an upper limb Fugl-Meyer score for the shoulder and elbow of less than 20). Thirty-two subjects met the criteria, were informed of the study, and gave consent to an approved protocol that randomly assigned them to receive an extra daily treatment of CPM or occupational group therapy in addition to the standard post-stroke therapy that all patients experienced. All patients received the standard post-stroke interdisciplinary therapy that included at least 3.5 hours a day of physical, occupational, and speech therapy. Standard protocols for impairment reduction were coupled with teaching compensation strategies to perform daily functional activities.

For the CPM treatment, the patient sat upright in the chair to which the device was attached so that the axis of the shoulder motor was aligned with the patient's shoulder. The patient's arm was supported by a rigid padded brace that was adjusted for each patient. The daily treatment period (5 days a week) lasted 25 minutes, so that during the first 15 minutes the patient's shoulder was elevated in the scapular plane to 90° (2° per second), with a 3-second pause at the beginning and end of each movement. The next 10-minute period consisted of shoulder elevation in the scapular plane to 30°, 45° of abduction, and 80° of external rotation in a sequential synchronous manner. Control subjects received daily (5 days a week) an extra 25-minute occupational group therapy session that included a standard regimen of stretching and mobility exercises.

Both groups began with severe flaccid hemiparesis, yet we controlled for group imbalances by using an analysis of covariance model and then compared the interval outcome measures between the two groups. Table 1 compares the discharge motor impairment measures for the CPM-treated and control groups. All the discharge values displayed in Table 1 were adjusted for admission impairment level, age, gender, and lesion side. Although the CPM-treated group had higher interval changes, the differences were not significant. Table 2 compares the discharge joint stability, spasticity, pain, and disability measures for the CPM and control groups. As before, all the displayed discharge values were adjusted for admission impairment level, age, gender, and lesion side. The two groups had comparable scores except on the joint stability score, in which the CPM group approached significant improvement (on this scale lower scores mark greater stability).

Table 2. Assessment of pain, joint stability, spasticity, and disability*

Group	Patients, *n*	Time	Score, *adjusted mean ± SEM*			
			Joint stability†	Ashworth score‡	F-M pain (S,E,Fa,W,Fi)§	FIM (self-care)¶
CPM trained	17	Admission	3.00 ± 0.45	1.88 ± 0.52	22.18 ± 0.78	19.88 ± 2.13
		Discharge	2.4 ± 0.4	1.3 ± 0.5	22.6 ± 0.5	27.7 ± 1.2
Control	15	Admission	3.53 ± 1.94	1.13 ± 0.47	22.27 ± 0.88	16.60 ± 1.75
		Discharge	3.6 ± 0.4	2.1 ± 0.5	21.8 ± 0.5	26.4 ± 1.3

*Discharge means have been adjusted for admission score, age, gender, and lesion side in an analysis of covariance model. There were no significant differences except for joint stability, where the difference demonstrated that $P = 0.06$.
†Dependent on the relationship of the humeral head and the glenoid rim and has been demonstrated to correlate with degree of translation [23–25].
‡Measured spasticity.
§Measured index pain at the shoulder, elbow, forearm, wrist, and fingers. Higher score indicates less pain; a total score of 24 indicates no pain.
¶FIM, self-care, and mobility subscales total score of 56.
CPM—continuous passive motion; E—elbow; Fa—forearm; Fi—fingers; FIM—functional independence measure; F-M—Fugl-Meyer; S—shoulder; SEM—standard error of mean; W—wrist.

Passive Movement Maintained Joint Flexibility (Tone) and Stability for Future Aggressive Therapy but did not Affect Motor Outcome

These results add to the clinical evidence that CPM is useful for the treatment of shoulder joint stability after stroke [8]. Soon after stroke, the use of device-delivered CPM appears to maintain and improve shoulder joint integrity and potentially prepares the patient with upper limb paralysis for additional task-specific training protocols. Improved shoulder stability probably resulted from the repetitive stretching activity delivered by the CPM that counteracted the preferred internally rotated and adducted shoulder posture. That there were no significant effects on motor outcome suggests that a more effective approach might be (like those used with robotic devices) to demand the best possible motor activity.

Interactive Robotic Treatment is Effective in Patients with Chronic Stroke

In general, outcome results in patients with stroke concentrate on the gains that occur within the first 3 months [14]. The protocols in these treatment plans were based on best practice guidelines for medical and neurologic care and not on detailed post-stroke treatment principles, which more often rely on some rigorous task-specific concentration on impairment reduction [4•,15,16•,17•]. Because there is little precedent that impairment might be altered in patients with chronic stroke and moderate to severe hemiparesis, we embarked on an uncontrolled pilot trial to test the effect of task-specific treatment delivered by robotic training protocols on proximal arm motor outcome.

Treatment plan and results

Thirty-six stroke survivors responded to a local newspaper advertisement to participate in a study to test whether robotic training improved motor function in the affected upper limb. The patients were between the ages of 39 and 81 years (average, 64.8 ± 2.3 years) and had hemiparesis or hemiplegia of the upper and lower extremity after a single stroke identified by neuroimaging that had occurred at least 8 months prior to the initial assessment (the group had stroke injury on average for 3.7 years). Sensory or visual field impairment, aphasia, or cognitive impairment was not an exclusion criterion, but the patient needed to be able to follow simple instructions. Patients also needed to have reasonable passive motion around the shoulder, so a fixed contracture was an exclusion criteria. We used historical records to derive scalar estimates of stroke severity and assigned a patient to a moderate or severe category based on these criteria [7•]. The interactive robotic therapy required that patients perform over 1000 flexion extension movements of the paralyzed arm with gravity eliminated to move the end of the robotic arm in the direction represented by eight points of a compass. The training program lasted 1 hour a day, 3 days a week, for 6 weeks.

The robotic training is interactive because patients move the robot arm easily, and, if a patient could not move the robot arm, it guided the limb to provide an adaptive sensorimotor experience. A key feature of this device is the low, near isotropic, inertia and reduced friction in the robot arm so that, when appropriate, it can "get out of the way." The interactive robot features have been discussed at length elsewhere [2••,3,18]. Measuring therapists were different from treating therapists, as is the standard in our studies. All patients had five evaluations; three baseline evaluations 2 months prior to the start of training, a midpoint evaluation, and a discharge evaluation. The measuring therapist assessed the motor impairment with standardized and reliable scales as described previously.

We used a repeated measure of analysis of variance, with age and mean admission impairment level as covariates. Both the moderate and severe group demonstrated

Table 3. Motor impairment measured on admission after robotic training in patients with moderate and severe stroke

			Score, *mean ± SEM*		
Severity	**Patients, *n***	**Time**	**MP***	**MSS/S,E†**	**F-M/S,E‡**
Moderate	14	Admission	36.64 ± 2.51	23.25 ± 1.64	15.92 ± 1.20
		Discharge	45.00 ± 1.57	27.27 ± 1.33	22.24 ± 1.21
Severe	22	Admission	18.81 ± 2.13	11.44 ± 1.11	8.22 ± 0.82
		Discharge	24.72 ± 1.97	14.70 ± 1.24	11.45 ± 0.98

*$P < 0.001$.
†$P < 0.01$.
‡$P = 0.11$.
F-M/S,E—Fugl-Meyer for shoulder and elbow; MP—motor power; MSS/S,E—motor status scale of shoulder and elbow; SEM—standard error of mean.

improved motor function and power in the trained shoulder and elbow as reflected in significant change on the Fugl-Meyer for shoulder/elbow and coordination (F-M/S,E,C) score ($F = 3.7$; $P < 0.01$) and the motor power (MP) score ($F = 8.3$; $P < 0.0001$) (Table 3). There were additional significant interactions, indicating that the moderate group had greater improvements. For the moderate and severe group, the pair-wise comparisons between admission and discharge for the two impairment measures, F-M/S,E,C and MP, were significant ($P < 0.0001$). Importantly, there were no significant changes during the first three evaluations on any of the impairment scales, suggesting all the patients were in a stable phase of their illness. The 3-month follow-up evaluations in 33 patients have been completed and suggest that the improvement is stable.

These results in patients with chronic stroke and stable motor impairment of the proximal upper limb who are treated with interactive robotic therapy in the outpatient department demonstrate significant improvement of motor power, regardless of whether the stroke was moderate or severe. These results are consistent with our past results in patients with acute stroke [19,20] and with other recent reports of the success of task-specific training for impairment reduction in patients with chronic stroke [7•,16•,17•]. The general impression of the patients with moderate damage is that the training improved the strength of the affected limb in a variety of functional tasks, such as dressing and grooming. Three patients were able to manage table utensils. Those with severe damage remarked that they had become more "aware" of their affected limb. Notably, only two patients displayed signs of neglect, which was apparent on examination by extinction to double simultaneous visual stimulation. From the point of view of a standard of care, these results suggest that an aggressive approach to impairment reduction will generate further disability reduction. Because the training focused on shoulder and elbow mobility, the lack of improvement in wrist and hand function was expected. Reduction of impairment in the wrist and hand would likely increase dramatically the functional use of a paretic arm. Whether additional impairment reduction will occur after task-specific training of anti-gravity or distal motor behavior and whether it will continue to contribute to disability reduction needs to be investigated.

An Interactive Robotic Device to Manipulate the Wrist

Our collaborators at the Massachusetts Institute of Technology have designed a new interactive robotic device that performs in a similar fashion as the planar device for the arm, except that it moves the hand through wrist flexion and extension, wrist and forearm supination and pronation, and abduction (radial deviation) and adduction (ulnar deviation). The first three patients with chronic stroke have participated in a pilot trial. The interval measurements are encouraging (Table 4). Improved gripping power was especially noticeable and due in part to the improved ability to extend the hand at the wrist. Trials now include patients who have registered improvement in the planar robot and patients who are naive to robot training.

Conclusions

Studies show significant benefits for the improvement of motor function in paralyzed arms of patients with acute or chronic stroke who are trained with interactive robotic techniques. These data are consistent with a growing focus on impairment training that may occur a long time after the acute event. We are currently running a randomized trial that matches robot-training sessions with physical therapy sessions to test whether one or the other or both are effective at improving motor outcome. Clearly, many patients continue to be receptive to training programs, and these data on the effect of robotic training contribute to the general consensus to add rigor to outpatient programs. These tools for therapists will allow them to focus on compensation strategies for disability reduction and so meet the patients' needs under the circumstances of decreased length of stay in acute facilities and decreased treatment sessions in outpatient clinics. These techniques will also relieve some of the burden of treating the impairment.

Table 4. Motor impairment measured on admission and after robotic training patients with chronic stroke

		Score, *mean ± SEM*				
Time	**Patients, *n***	**MP, wrist/hand**	**MSS, wrist/hand**	**F-M, wrist/hand**	**Grip strength, lb**	**Pinch strength, lb**
Admission	3	1.8 ± 0.7	7.8 ± 3.6	6.2 ± 4.5	14.7 ± 7.4	2.7 ± 3.1
Discharge	3	2.6 ± 0.5	14.4 ± 3.2	13.3 ± 4.3	20.7 ± 10.3	5.1 ± 3.6

F-M—Fugl-Meyer; MP—motor power; MSS—motor status scale; SEM—standard error of mean.

Patient acceptance and staff enthusiasm for robot training is consistently high. Robot training data are consistent with other controlled studies that more activity in the form of task-specific activity leads to more motor improvement.

Simpler machines that only move the arm passively demonstrate benefits for shoulder joint stability, but treatment with passive motion in our experiment had no effect on motor behavior. Currently, the passive motion device is used to reduce tone and, at times, for pain management. It may be that early training with passive motion devices maintains the shoulder joint so that additional, more aggressive interactive therapy can proceed.

Ultimately, for the robot to be an effective tool, reductions in impairment must translate into reduced disability. As some patients treated with the robot have progressed to near functional reaching and sweeping movements, and others, especially those with chronic stroke, to raising their arms with shoulder abduction and external rotation of the humerus, we need now to move on to functional pointing, better hand positioning, and eventually finder dexterity. For in order to make a paralyzed arm more functional, improved wrist, hand, and finger function will be required. New robotic devices are now in the process of testing whether training the wrist can alter impairment and ultimately disability. Multicenter collaborative efforts will test efficacy.

Although the degree of impairment depends on the type, size, and location of the brain injury, it may be that interactive robotic training techniques coupled with pharmacologic intervention will influence the physiology of the undamaged brain to generate optimal recovery. One long-term goal is to use interactive robotic training to develop strategies to identify subsets of patients who, based on the nature of their injury and their genetic background, will experience proven benefit.

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