

Individual finger synchronized robot-assisted hand rehabilitation in subacute to chronic stroke: a prospective randomized clinical trial of efficacy

Clinical Rehabilitation 0(0) 1–9 © The Author(s) 2012 Reprints and permission: sagepub.co.uk/journalsPermissions.nav DOI: 10.1177/0269215511431473 cre.sagepub.com



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Abstract

Objective: To evaluate individual finger synchronized robot-assisted hand rehabilitation in stroke patients. **Design:** Prospective parallel group randomized controlled clinical trial.

Subjects: The study recruited patients who were ≥18 years old, more than three months post stroke, showed limited index finger movement and had weakened and impaired hand function. Patients with severe sensory loss, spasticity, apraxia, aphasia, disabling hand disease, impaired consciousness or depression were excluded. Interventions: Patients received either four weeks (20 sessions) of active robot-assisted intervention (the FTI (full-term intervention) group, 9 patients) or two weeks (10 sessions) of early passive therapy followed by two weeks (10 sessions) of active robot-assisted intervention (the HTI (half-term intervention) group, 8 patients). Patients underwent arm function assessments prior to therapy (baseline), and at 2, 4 and 8 weeks after starting therapy.

Results: Compared to baseline, both the FTI and HTI groups showed improved results for the Jebsen Taylor test, the wrist and hand subportion of the Fugl-Meyer arm motor scale, active movement of the 2nd metacarpophalangeal joint, grasping, and pinching power (P < 0.05 for all) at each time point (2, 4 and 8 weeks), with a greater degree of improvement for the FTI compared to the HTI group (P < 0.05); for example, in Jebsen Taylor test (65.9 ± 36.5 vs. 46.4 ± 37.4) and wrist and hand subportion of the Fugl-Meyer arm motor scale (4.3 ± 1.9 vs. 3.4 ± 2.5) after eight weeks.

Conclusions: A four-week rehabilitation using a novel robot that provides individual finger synchronization resulted in a dose-dependent improvement in hand function in subacute to chronic stroke patients.

Keywords

Rehabilitation, stroke, hand, robot

Received: 9 March 2011; accepted: 6 November 2011

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Introduction

Impairments of hand function are found in 60% of stroke survivors¹ and 30–66% of hemiparetic patients have not regained hand function six months after a stroke.² Hand rehabilitation cannot be executed well without spontaneous motor actions, in contrast to lower leg rehabilitation which can be performed with the help of a brace, spasticity and the contralateral leg in patients with low strength on the hemiplegic side.

Robot-assisted rehabilitation of the upper arms has been found to improve function in stroke patients.^{3–8} However, improvements due to targeted upper arm therapy did not appear to spread to the distal arm. Recently, Takahashi et al. reported that hand function was ameliorated using a robot that assisted hand motions.⁹ Their exo-skeleton machine acted on the whole hand rather than individual fingers, and therefore could not be used to specifically train individual finger motion. That study reported on improvements in whole arm function. While the development of robot-assisted techniques has great potential in the field of hand function rehabilitation, many studies are still required in order to characterize the various techniques and their outcomes.

The present study examined the use of a novel type of robotic device to assist in hand rehabilitation in stroke patients. The robot was an end-effecter design rather than an exo-skeleton, and engaged synchronized individual finger movements. The study assessed proximal and distal arm function, and the effect of robot-assisted rehabilitation time on outcomes. To our knowledge, this is the first prospective randomized controlled trial examining an individual finger synchronized robot-assisted hand rehabilitation intervention.

Materials and methods

The study was a prospective, single-blinded (i.e. assessor-blinded), parallel group, randomized (allocation ratio 1:1) clinical trial performed from June to September 2010. It was approved by the institutional review board, and patients provided formal consent.

The patient inclusion criteria were ≥ 18 years old, more than three months after stroke, >10° voluntary range of motion of the 2nd metacarpophalangeal joint, a Fugl-Meyer arm motor scale of 2-20 for the wrist and hand subportion¹⁰ and requiring a >25% longer time to finish the nine-hole pegboard test¹¹ with the affected arm compared to the contralateral arm. The wrist and hand subportion of the Fugl-Meyer scale was a measure of wrist and hand reflex and activity. Flexion and extension of the wrist with the elbow flexed or extended was scored using a scale of 0-10 points, and gross flexion and extension of the fingers and five different kinds of grasping were scored using 0-14 points. The pegboard test required the placing of pegs in board with nine holes arranged in a tetragonal pattern.

The study excluded patients showing apraxia (≤2 on the Alexander Scale¹²), impaired consciousness (≥1 for the NIH Stroke Scale question Ia–c¹³), sensory impairment (<75% of the contralateral score on the Nottingham Sensory Scale¹⁴), increased spasticity (4 on the Ashworth Scale¹⁵), aphasia (≥2 for the NIH Stroke Scale question IX¹³) or depression (≥8 on the Geriatric Depression Scale¹⁶), with a combined disabling disease on the hemiparetic hand, or who refused to participate.⁹

Random allocation of patients to two groups was performed using a random assignments generator (Wichmann–Hill random number generator).

The robot allowed for individual finger synchronization (Amadeo, Tyromotion, Austria). This robot is an end-effecter design.¹⁷ The device was attached to the tips of fingers and measured aligned multiple joints movement of the fingers. The robot was free from the anatomical limitations of joint alignment with degrees of freedom (DOF). The set-up involved securing a small magnetic disc to the pulp of each finger with cohesive tape for connection with the end-effecter, which would move back and forth in accordance with lanes aligned with the finger movement direction. The wrist was immobilized using a Velcro strap so that the elbow and shoulder would be inhibited from moving. Sensors transmitted realtime movement information to the main computer and projected it to the screen, on which the synchronous finger motions were represented as five columns and the remaining range of motion was



Figure 1. Robot of individual finger synchronized assisted mode.

shown. The robot could calibrate the full passive range of motion for each finger before the start of a session, and supply the assistive force to patients to complete the remaining range of motion during an exercise (Figure 1).

Patients were divided into two therapeutic groups. The FTI (full-term intervention) group underwent intervention session five times a week for four weeks, resulting in a total of 20 sessions. A maximum of one intervention session was performed per day. A session involved simulated grasping and releasing training for 20 minutes, a 5-minute rest break, and then a virtual reality-based recreational activity (e.g. firefighting or balloon escaping obstacles) for 20 minutes, for which the level of difficulty was adjusted for the individual disability state of the hand.

The HTI (half-term intervention) group underwent passive range of motion training for two weeks (10 sessions), and then the same intervention as the FTI group for two weeks (10 sessions), resulting in a total number of 20 sessions. No patient participated in any other conventional occupational therapy during the study period.

One week prior to the intervention, patients underwent a series of tests to determine baseline arm function. Assays comprised the Jebsen Taylor test¹⁸ (determines the time completely perform seven different hand activities), the Fugl-Meyer Scale¹⁰ (subdivided into an assessment of wrist and hand motor function, and proximal arm motor function: scored on a 0–36 point scale), the Ashworth

Scale¹⁵ (for wrist and elbow tone), the nine-hole pegboard test,¹¹ a hand motor subscale of the Stroke Impact Scale¹⁹ (involving 12 questions regarding hand function while activities of daily living, with a minimum score of 12 and maximum score of 60), a grasping force test, a pinching force test, and a 2nd metacarpophalangeal joint active range of motion. Those same assessments were performed at 2, 4 and 8 weeks after the commencement of intervention.

The assessor and the principal investigator were blinded as to the group to which a patient was assigned.

Statistics

Statistical analysis was performed using SPSS 17.0KO for Windows (SPSS Inc, Chicago, IL, USA). Two-tailed and parametric statistical methods were used. An α level ≤0.05 was considered to indicate significance, and a power value of 80% was introduced. Based on a previous report9 on the Stroke Impact Scale on the hand motor subscale, a significant mean difference minimum value of 0.6, a standard deviation of 0.4 and a standardized difference of 1.5 were calculated. Using Lehr's formula, we calculated that the study required 14 patients. Presuming a drop-out rate of 20%, we determined that 17 patients needed to be enrolled. Demographic data (age, sex ratio, time from stroke and interval or categorical variables) were compared using Fisher's exact or Wilcoxon Mann-Whitney *U*-tests. The effects of variables on 4- and 8-week outcomes for individual patients were determined using a two-sample paired t-test. Variables for each group at three end points (2, 4 and 8 weeks) were using Wilcoxon Mann–Whitney *U*-tests. Time × group interactions and variable × time interactions for within-group and between-group were examined using repeated-measures ANOVA.

Results

The study initially recruited 31 patients. Fourteen of those patients were excluded based on the study criteria, leaving a total of 17 enrolled patients for testing. Nine patients were assigned to the FTI and eight

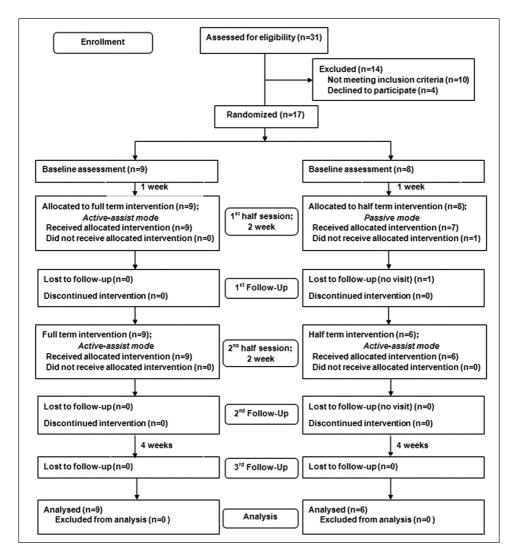


Figure 2. Flow diagram.

patients to the HTI group. Two HTI patients were lost to follow-up; one due to lack of intervention, and the other due to lack of follow-up visits. Therefore, the study analysed the data of nine FTI patients and six HTI patients. Although there were initially 17 patients, because two patients were considered protocol violators, a per-protocol analysis was used to analyse the data from the final data of 15 patients (Figure 2). Intervention proceeded for four weeks, and participants underwent outpatient clinic assessments at baseline (prior to

intervention), and at 2, 4 and 8 weeks post initiation of intervention.

The two patient groups were found to be similar in terms of demographic data and pre-interventional characteristics (P=0.56–1.0) (Table 1).

Compared to baseline scores, each patient showed improvement at both 4 (P<0.05) and 8 (P<0.05) weeks on the following tests: Jebsen Taylor, wrist and hand Fugl-Meyer, 2nd metacarpophalangeal joint active range of motion, grasping power and pinching power. The mean scores for

Table 1. Demographic data and pre-intervention patient characteristics

	All patients $(n = 15)$	FTI (n=9)	HTI (n=6)
Age (years)	50.6 ± 10.0	50.2 ± 3.7	51.3 ± 3.0
Male/female	9/6	5/4	4/2
Months after stroke	6.5 ± 5.3	7.3 ± 6.3	5.3 ± 5.9
Jebsen Taylor test (seconds)	188.4 ± 154.6	209.9 ± 51.3	152.7 ± 60.4
FM, wrist & hand	18.3 ± 5.5	18.7 ± 1.6	17.5 ± 2.7
FM, proximal arm	21.7±7.2	21.8 ± 2.3	21.5 ± 3.2
AS, wrist	0.8 ± 0.8	0.9 ± 0.3	0.5 ± 0.2
AS, elbow	1.3 ± 0.7	1.2 ± 0.1	1.3 ± 0.4
Nine-hole pegboard (seconds)	134.4 ± 215.7	113.1 ± 48.2	170.0 ± 126.0
SIS, activities	42.5 ± 15.7	38.8 ± 6.0	48.7 ± 1.7
Grasping power (kg)	13.1 ± 9.0	14.5 ± 4.5	12.2 ± 2.6
Pinching power (kg)	2.0 ± 1.5	2.1 ± 0.5	1.9 ± 0.5
Active range of motion, 2nd MCP joint (°)	55.5 ± 30.2	57.4 ± 9.5	52.3 ± 13.5

Values are means ± SD.

FM, arm motor Fugl-Meyer scale; AS, Ashworth Scale; SIS, Stroke Impact Scale; MCP, Metacarpopharangeal joint.

those tests were similar for both the FTI and HTI groups at 2, 4 and 8 weeks.

Other tested variables showed no significant improvements for either the individual patient or between the groups.

We performed a further analysis of the five tests that showed a significant difference in scores at eight weeks. We found that none of those variables showed time \times intervention group interactions (Table 2). For the FTI group, the mean scores for those five tests at 2, 4 and 8 weeks differed from the baseline scores (P<0.05). The same held for the HTI group. At 2, 4 and 8 weeks, the mean scores for those five tests for the FTI group were better than the mean scores for the HTI group (P<0.05).

No serious side-effects were observed, other than miscellaneous reports of minor headache and mental fatigue.

Discussions

The present study examined the efficacy of a novel individual finger synchronization robot for hand rehabilitation in subacute-to-chronic stroke patients with affected arms. The study found that the four-week robot-assisted intervention resulted in improved hand function that could be maintained

for one month after the cessation of therapy. In addition, the study findings suggested that the effect of the intervention was dose-dependent.

Repetitive, functional and specific task-oriented rehabilitation should be applied to ensure arm function improvement in stroke patients.^{20,21} Similarly, hand rehabilitation should involve sufficient repetition.²² The advantages of robot-assisted hand rehabilitation include that a robot can administer stereotyped and intensive repetitive exercises for longer and with greater precision than a human therapist.²³ Arm recovery demands enriched sensory environments with multimodal stimulation such as vision and attention, ^{24,25} and contextual performance with a real object can enhance motor recovery.²⁶ By exploiting the ability of virtual reality to introduce a real object in a contextual manner, which augments the visual and attentive feedback, a robot can have a synergistic effect on hemiparetic improvement.²⁷ In addition, robot therapy is associated with good compliance via providing incentives for patients.²³

The advantageous rehabilitation environment created through the use of robots can result in stronger afferent sensory signals being sent to the sensory cortex.²⁸ There are abundant anatomical and functional interconnections between the sensory and motor cortex,²⁹ and through sensorimotor integration,³⁰ afferent sensory stimuli can influence the

Table 2. Changes in variables over eight weeks

	Pre-intervention	2 weeks	4 weeks	8 weeks
Jebsen Taylor test (seconds)			
FTI (n = 9)	209.9 ± 51.3	160.1 ± 41.7§	142.8 ± 37.1§	142.9 ± 32.3
HTI (n=6)	152.7 ± 60.4	143.5 ± 57.8	105.2 ± 38.1	108.1 ± 29.8
FM, wrist & hand				
FTI	18.7 ± 1.6	20.2 ± 6.9§	22.6 ± 2.0§	22.6 ± 3.1§
HTI	17.5 ± 2.7	18.8 ± 6.3	21.3 ± 2.7	21.0 ± 2.9
FM, proximal arm				
FTI	21.8 ± 2.3	23.8 ± 6.3	23.1 ± 1.9	23.9 ± 3.1
HTI	21.5 ± 3.2	21.5 ± 8.1	21.7±3.1	21.5 ± 4.7
AS, wrist				
FTI	0.9 ± 0.3	0.8 ± 0.9	0.7 ± 0.3	0.7 ± 0.6
HTI	0.5 ± 0.2	0.5 ± 0.5	0.5 ± 0.2	0.5 ± 0.3
AS, elbow				
FTI	1.2 ± 0.1	1.2 ± 0.4	1.2 ± 0.2	1.2 ± 0.2
HTI	1.3 ± 0.4	1.3 ± 1.0	1.3 ± 0.4	1.3 ± 0.4
Nine-hole pegboard (secon	nds)			
FTI	/ 113.1 ± 48.2	76.0 ± 87.0	68.4 ± 24.7	69.3 ± 60.3
HTI	170.0 ± 126.0	98.5 ± 159.6	40.8 ± 17.1	50.0 ± 39.7
SIS, activities				
FTI	38.8 ± 6.0	47.6 ± 7.5	50.3 ± 2.5	49.5 ± 4.1
HTI	48.7 ± 1.7	47.0 ± 6.2	48.7 ± 2.7	48.1 ± 3.5
Grasping power (kg)				
FTI	14.5 ± 4.5	16.2 ± 10.1§	17.2 ± 4.3§	17.1 ± 4.5§
HTI	12.2 ± 2.6	13.5 ± 8.2	14.1 ± 2.5	14.0 ± 3.9
Pinching power (kg)				
FTI	2.1 ± 0.5	2.6 ± 1.6§	2.8 ± 0.6§	2.7 ± 0.9§
HTI	1.9±0.5	2.2 ± 1.5	2.2 ± 0.5	2.1 ± 0.7
Active range of motion, 2nd				
FTI	57.4±9.5	69.4 ± 22.7§	76.5 ± 4.7§	78.2 ± 11.3§
HTI	52.3 ± 13.5	62.7±31.6	62.3 ± 11.3	64.0 ± 15.7

Values are means ± SD.

FM, arm motor Fugl-Meyer scale; AS, Ashworth Scale; SIS, Stroke Impact Scale; MCP, metacarpophalangeal. $\S P < 0.05$ in repeated-measures ANOVA.

excitability of the motor cortex.³¹ These improved motor performances are not caused by an increased number of recruited peripheral motor units but by greater volumes of recruited sensorimotor cortices neighbouring the lesion.⁹

In addition to the abovementioned brain plasticity, other proposed mechanisms of arm function improvement include decreased spasticity, increased strengths and compensatory strategies of the proximal arm or trunk.²³ However, the present study did not detect that decreased spasticity was associated with the

intervention and provided the immobilization of arm, indicating that the present improvements did not involve changes to spasticity or compensatory strategies.

The mean time between stroke and intervention was 6.5 ± 5.3 months in the current study. There is generally very little hand function recovery in the chronic period. Therefore, we conclude that the observed improvements were due to the robot-assisted intervention rather than natural recovery.

The present study found that subacute to chronic stroke patients can improve arm function via robot-assisted rehabilitation. Although these findings are consistent with other reports,^{3–8,17} most previous studies have used the proximal arm as the target, and improvements were restricted to the proximal arm.^{6,23} Recently, Takahashi et al. reported that using a robot to actively assist in hand movements, especially mass grasping and releasing, could enhance hand function in chronic stroke patients.⁹ Those findings broadly agree with ours.

The Takahashi et al. study involved interventions totalling 22 hours duration, with a similar design to the present study. The present study used a different type of robot, and involved only 13 total hours of intervention. Therefore, it appears that the present method was superior to that used in the previous study if standardization of total numbers of finger training could be excluded. Hence, we believe that the novel individual finger synchronization robot-assisted method described here results in better outcomes compared to the mass grasping and releasing robot-assisted method. However, further the kinematic analyses are required before firmer conclusions can be made.

A total rehabilitation duration time of 10 hours is traditionally considered necessary for classic rehabilitation.²⁷ Functional retraining for 9 hours made no differences to moderate arm weakness 1 year after a stroke,³² and hand rehabilitation for 57 hours was effective at improving moderate weakness in the chronic stage.²² The present intervention model involved a total duration of 13 hours, and the subsequent improvements appear to be as good as those achieved using conventional therapies in terms of duration of therapy.

Robot-assisted hand rehabilitation was shown to be as effective as other methods when performing repetitive task practice in subacute stroke patients.³³ Standardizing the methodology is required in order to compare conventional occupational therapy with robot-assisted therapy. In experiments in which the intensity of repetitive motions was equalized, both therapies were found to be of equal efficacy.³⁴ However, robot-assisted

repetitions were found to be simpler and easier to execute, and were found to be of greater intensity, compared to other therapies.²³

The current study had some limitations. The single-blinded designs may result in internal validity bias. The study spanned two months, and therefore the long-term effects of the intervention are yet to be determined. In addition, it was a single-centre study. Finally, two patients were classified as protocol violators, and therefore a per-protocol analysis was used instead of an intention-to-treatment analysis. However, per-protocol analyses can be flawed such that outcomes might be overestimated.³⁵

Most studies have found that proximal improvements do not migrate to the distal arm^{6,23} or the reverse,9 and that arm improvements do not manifest as improved ADL performance, 6,23 indicating a lack of generalizability. The present study did not use ADL measures such as the Functional Independence Measurement or the Barthel Index. However, the study included patients aged from 30 to 70 years, showing Fugl-Meyer hand and wrist subportion scores of 2–20 and proximal arm subportion scores of 7-36. Those characteristics should encompass most arm weaknesses in stroke patients. In contrast to most reports showing the positive results of combined robot-assisted and conventional occupational therapy,²³ conventional occupational therapy was excluded from our study so that the results reflected solely the effect of the robot-assisted intervention. No multiplicity of analyses was found in our study. Based on the above comments, the significant time shortening of the Jebsen Taylor test representing functional performances of essential motions of ADL might imply that functional ends improvements as well as surrogate ends were induced, suggesting the generalizability of the study findings.

The present findings indicate that new and meticulous robot-assisted hand rehabilitation procedure should be considered a valuable tool for physicians. This is despite the opinions of others who argue a simple intervention design would be more effective than a complex one.¹⁷

Clinical messages

- Individual finger-synchronized robotassisted hand rehabilitation over four weeks can provide hand improvements in functional and surrogate ends in subacute to chronic hemiparetic patients.
- These improvements were induced in a dose-dependent manner, and were maintained for a month after the cessation of treatment.

Acknowledgements

Authors give great thanks to Geum Mi Lee, nurse practitioner, for her excellent coordination of scheduling and communications with patients.

Conflict of interest

No commercial group being interested with the results of our study gave or is going to give an economic or other benefit to the authors or to organizations to which the authors belong.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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