FEASIBILITY AND POTENTIAL EFFECTS OF ROBOT-ASSISTED PASSIVE RANGE OF MOTION TRAINING IN COMBINATION WITH CONVENTIONAL REHABILITATION ON HAND FUNCTION IN PATIENTS WITH CHRONIC STROKE

Chia-Yu HSU^{1,2}, MD, PhD, Chu-Ming WU¹, MD, Chieh-Cheng HUANG³, MD, Hung-Hai SHIE¹, MSc and Yuh-Show TSAI², PhD

From the ¹Department of Rehabilitation Medicine, Ten-Chan General Hospital, ²Department of Biomedical Engineering, Chung Yuan Christian University and ³Department of Neurology, Ten-Chan General Hospital, Taoyuan City, Taiwan

Objective: To assess the effects of exoskeleton robot-assisted passive range of motion for induction training in combination with conventional hand rehabilitation in patients with chronic stroke.

Design: Single-cohort feasibility study.

Subjects: Chronic stroke with severe upper extremity hemiparesis.

Methods: Thirty sessions of therapy over a period of 10 weeks. Each session started with 30 min robotassisted passive range of motion for the hand, followed by 30 min conventional hand rehabilitation. The Fugl-Meyer Assessment for upper extremity, arm subscore of Motricity Index, Functional Independence Measure and Fugl-Meyer assessment for sensation (Fugl-Meyer assessment-sensory) were conducted at pre-intervention (pre) and after the 16th (16-post) and 30th (30-post) sessions of interventions.

Results: Twelve patients with chronic stroke were recruited. The Fugl-Meyer assessment for upper extremity (16-post vs 30-post, p = 0.011), arm subscore of Motricity Index (pre vs 30-post, p = 0.012) and Functional Independence Measure (pre vs 30-post, p = 0.007; 16-post vs 30-post, p = 0.016) improved significantly after the therapy. However, FMA-sensory did not change significantly.

Conclusion: Exoskeleton robot-assisted passive range of motion of the hand using an exoskeleton can be considered as an induction therapy before starting conventional therapy for hand rehabilitation in patients with chronic stroke. Further randomized control trials are needed to verify the therapeutic benefits.

Key words: robot; rehabilitation; hand; stroke; wearable exoskeleton.

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Correspondence address: Yuh-Show Tsai, Department of Biomedical Engineering, Chung Yuan Christian University, No. 200, Zhongbei Road, Zhongli District, Taoyuan City 320, Taiwan (R.O.C.). E-mail: yuhshow@cycu.edu.tw

LAY ABSTRACT

Motor recovery of hand dexterity is challenging during the chronic phase of stroke. Patients achieve different levels of hand function during the acute or subacute phase of stroke. Those receiving conventional physical therapy during the chronic phase of stroke usually experience difficulty in hand dexterity improvement after achieving motor recovery plateau. This pilot study investigated the effects of robot-assisted passive range of motion training in combination with conventional rehabilitation on hand function in a cohort of patients with chronic stroke who underwent follow-up at an outpatient rehabilitation clinic. The affected upper extremity function, strength and general function improved significantly after the therapy for the 12 patients recruited to this study. Using robot-assisted passive range of motion training as an induction therapy in combination with conventional rehabilitation may be beneficial for patients with chronic stoke who have impairment of hand function.

The numbers of incident strokes, prevalent stroke survivors and disability-adjusted life-years lost due to stroke are large and have increased since 1990 (by 68%, 84% and 12%, respectively) (1). In Netherlands, patients at 6 months after ischemic stroke, 67% of patients are left with impairments of upper extremity (UE) movement and only 11.6% reach complete functional recovery in hand dexterity (2); these impairments typically present as hand weakness and abnormal contractions of the UE. Studies in Netherlands and UK have reported hemiparetic patients who have not regained hand function 6 months after a stroke (2–5). Motor recovery of hand dexterity is slow and challenging, leading to limited hand activities and occupational disability. Therefore, facilitating post-stroke motor recovery of hand dexterity is crucial for stroke rehabilitation.

Repeated exercises of the affected hand have proven beneficial for hand function recovery in patients with stroke (6). Continuous passive motion (CPM) exercise, Journal of Rehabilitation Medicine

which is a repetitive movement, has been applied for patients with contractures (7). It is commonly implemented for patients with stroke with spasticity before occupational hand therapy. Studies have also demonstrated that passive movement alters the inhibitory state of the central nervous system and further affects motor responses (8,9), which may facilitate activity-dependent plasticity (10). However, clinical evidence favouring the use of passive motion for motor recovery in patients after stroke is not sufficient.

The high intensity of sensorimotor end-effector robot-aided training targeting the affected shoulder and elbow has resulted in improved UE function in patients with chronic stroke (11-16). Most of these groups studying robot-aided training showed larger improvements in the proximal UE, which was compatible with the principle of training specificity (17). However, there have been few studies of the use of a wearable exoskeleton robotic hand device for dexterity training of the affected hand (18). Studies using robot-assisted CPM report it as beneficial for arm- and hand-function improvement in patients after stroke (19, 20); the provision of a training programme for the distal part of UE warrants investigation.

The aim of this study is to evaluate the feasibility and efficacy of robot-assisted hand rehabilitation for improving functional abilities of the affected hand in patients with chronic hemiplegic stroke. A powered exoskeleton hand was used to provide automatic passive range of motion (PRoM) exercise in patients who were more than 6 months since stroke onset. The study hypothesis is that adding robot-assisted hand exercise as an induction therapy to conventional rehabilitation therapy could improve the function of the paretic hand.

METHODS

Patients

A total of 12 patients with stroke were recruited at the Ten-Chan General Hospital, Taoyuan City, Taiwan, from September 2017 to June 2019. Inclusion criteria were: age >20 years; diagnosis of haemorrhagic or ischaemic stroke with severe UE hemiparesis (Brunnstrom recovery stage I-III). Exclusion criteria were: severe pain and instability in the wrist of the affected arm; severe cognitive impairment, aphasia, hemispatial neglect and apraxia; and joint contractures $>20^{\circ}$ in the affected hand. The experimental protocol was approved by the institutional review board of the hospital. Written informed consent was obtained from all patients.

Robotic hand device

The wearable exoskeleton robotic hand device (HS 001, Rehabotics Medical Technology Corporation, Hsinchu County, Taiwan) was used for this study. The device provides 3 finger movement models, which are single-finger, 5-fingers and mirror-guided models. Through the exoskeletal hand, the patient's affected hand finger could be moved by the device to perform flexion/extension movements. The single- and 5-finger modes (the movement speeds of finger extension and flexion are approximately 3 s, respectively) were used to conduct PRoM exercises for patients (Fig. 1); each mode could achieve a maximum of 15 repetitions per min.

Training programme

The patients were provided with 30 sessions of therapy by a well-trained occupational therapist over a period of 10 weeks, with each session starting with 30 min of passive robotic hand therapy followed by 30 min of conventional hand rehabilitation. In the robotic hand therapy, each finger would receive 3 min single-finger mode and 15 min 5-finger mode with a maximum of 270 repetitions in total. In the conventional hand training, the therapist conducted one-on-one individualized programmes focused on arm and hand function. Treatment included functionoriented specific tasks, such as reach, grasp, transport and release of various objects between different targets. All patients underwent basic rehabilitation following the guidelines according to the Bobath concept (21).

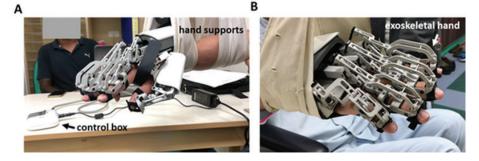


Fig. 1. Wearable exoskeleton robotic hand device. (A) Left-side view, (B) right-side view.

Outcome assessments

Hand motor function was assessed before (pre), after the 16th training session (16-post) and after the 30th training session (30-post). The primary outcome was the change in the Fugl-Meyer assessment (FMA), which was used to evaluate sensorimotor recovery in patients with particular attention to the hand and wrist section (maximum score 66 in motor function and 24 in sensory function) to assess the functional capacity of the affected hand (22).

For other assessments, the arm subscore of Motricity Index (MI) scale was used to measure strength in UE after stroke. The weighted score based on the ordinal 6-point scale of the Medical Research Council was used to measure the maximum isometric muscle strength and the motor recovery rate of the patients (100%=maximum MI) (23). Functional Independence Measure scale (FIM) was used to assess the degree of independence and need-of-assistance in basic activities of daily living at the time of enrolment and at the end of the study. FIM is an 18-item ordinal scale, rated from 1 (total dependence) to 7 (total independence) per item; furthermore, 13 items of this scale and the subscale motor-FIM were used to evaluate motor disability (24). All the assessments were performed by an independent occupational therapist.

Finally, the visual analogue scale (VAS) was used to access the level of operator difficulty for the occupational therapist in managing the device (0 (extremely simple)–10 (extremely difficult)) (25). The therapist was required to report any adverse events occurring during the study with respect to the use of the robotic hand.

Statistical analysis

Friedman's test and multiple Wilcoxon signedranks tests (IBM, SPSS Inc. Version 12.0. Chicago, Illinois, USA) were performed to investigate hand

Table I.	Participant	demographics

functional changes in pre, 16-post and 30-post interventions. All data are represented as median (interquartile range). The significance levels in Wilcoxon signed rank tests were set to 0.0167 with Bonferroni's adjustment.

RESULTS

The demographic and clinical characteristics of the patients before intervention are shown in Table I. Twelve patients with chronic stroke were recruited for the study; 6 with cerebral haemorrhage, 4 cerebral infarction, 1 atherothrombotic cerebral embolism, and 1 cardiogenic cerebral embolism stroke. The median age of patients was 55.5 years (15.5 years), and median time from stroke onset was 12.0 months (15.0 months).

All patients completed the training programme. Data for FMA-UE, MI, FIM and FMA-sensory at pre, 16-post and 30-post assessments are shown in Table II, and the mean of clinical assessment scores are shown in Table III. Motor function of the UE in all patients was severely impaired (FMA-UE=13.5 (12.0)) at pre-assessment. At 30-post with robot-assisted PRoM exercises for the hand and finger followed by conventional occupational hand function training, the FMA-UE had improved significantly (16-post: 13.5 (17.0), 30-post: 16.5 (15.0), n=12, p=0.011).

UE strength measured using arm subscore of MI at pre, 16-post and 30-post interventions improved significantly after the training programme (pre: 26.5 (29.0), 30-post: 37.0 (22.5), n=12, p=0.012). Functional independence was evaluated using FIM assessment; function significantly improved during the training (pre: 82.5 (57.5), 16-post: 85.5 (36.5), 30-post: 85.5 (35.5); pre vs 30-post, p=0.007; 16-post vs 30-post, p=0.016). However, sensory function did not change significantly (FMA-sensory scores at pre: 22.0 (10.5), 30-post: 23.5 (12.0), n=12, p=0.017).

Participant number	Age (years)	Sex	Stroke type	Stroke onset (months)	Affected hand	Comorbidity
1	54	F	Cerebral haemorrhage	6	R	Hypertension
2	53	М	Cerebral infarction	6	R	Hypertension and diabetes mellitus
3	70	М	Cerebral infarction	6	R	Hypertension, diabetes mellitus, and dyslipidaemia
4	55	Μ	Cerebral haemorrhage	6	L	Hypertension, diabetes mellitus, dyslipidaemia, and coronary artery disease
5	78	F	Cerebral haemorrhage	9	R	Renal stone
6	58	М	Cerebral haemorrhage	12	R	Seizure
7	52	F	Atherothrombotic cerebral embolism	12	L	Hypertension, dyslipidaemia, and aortic dissection
8	31	F	Cerebral infarction	18	L	Dyslipidaemia
9	56	F	Cerebral haemorrhage	18	L	Hypertension and diabetes mellitus
10	66	Μ	Cerebral haemorrhage	24	L	Hypertension, diabetes mellitus, hepatitis B, and righ ventriculoperitoneal shunt placement
11	74	F	Cerebral infarction	36	L	Hypertension
12	43	М	Cardiogenic cerebral embolism	36	L	Arrhythmia

F: female; M: male; R: right; L: left.

Participant — Pre.	I	FMA-UE-mot	or	MI-UE			FIM			FMA-UE-sensation		
	Pre.	16-Post.	30-Post.	Pre.	16-Post.	30-Post.	Pre.	16-Post.	30-Post.	Pre.	16-Post.	30-Post.
1	20	25	25	19	58	58	81	89	91	27	29	29
2	2	1	1	1	21	30	65	71	71	23	26	26
3	2	2	3	19	19	19	20	20	21	7	7	8
4	15	20	20	10	32	32	84	84	84	14	14	14
5	11	12	14	19	19	24	30	37	41	17	17	17
6	3	2	2	10	10	10	21	21	21	0	0	0
7	23	26	26	49	49	49	87	87	87	18	18	18
8	16	16	16	48	48	48	104	104	105	29	30	30
9	12	12	18	39	39	50	93	93	93	21	21	21
10	27	27	27	58	58	58	87	87	87	26	26	26
11	15	15	17	39	39	39	34	74	74	26	26	26
12	9	9	12	34	34	35	92	92	92	26	29	30

Table II. The raw data of outcome measurements at pre, 16-post and 30-post interventions

FMA: Fugl-Meyer assessment; MI: arm subscore of Motricity Index; FIM: Functional Independence Measure scale; UE: upper extremity.

Table III. Outcome measurements at pre, 16-post, and 30-post interventions

Assessment	Pre.	16-post	30-post	Friedman's test, p	Wilcoxon signed-rank test, p
		•			
FMA-UE-motor	13.5 (12.0)	13.5 (17.0)	16.5 (15.0)	0.004	0.048ª
					0.04 ^b
					0.011°
MI-UE	26.5 (29.0)	36.5 (28.5)	37.0 (22.5)	0.001	0.068
					0.012
					0.027
FIM	82.5 (57.5)	85.5 (36.5)	85.5 (35.5)	< 0.001	0.028
					0.007
					0.016
FMA-UE sensation	22.0 (10.5)	23.5 (12.0)	23.5 (12.0)	0.002	0.027
					0.017
					0.157

Friedman's test with a=0.05; a: pre vs. 16-post; b: pre vs 30-post; c: 16-post vs 30-post.

Data are presented as median (interquartile range), FMA: Fugl-Meyer Assessment; MI: Motricity Index; FIM: Functional Independence Measure scale, UE: upper extremity.

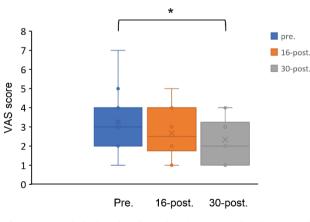


Fig. 2. Box and whisker plot of visual analogue scale (VAS) was rated by the occupational therapist who assessed the difficulty in managing the robot device for the participants (0 (extremely simple)-10 (extremely difficult)). *p<0.016, Wilcoxon signed-rank test, VAS: visual analogue scale, pre: pre-intervention, 16-post: after the 16th session of intervention, 30-post: after the 30th session of intervention.

Finally, the study evaluated the feasibility of the use of the robot device in patients. VAS results indicated that the occupational therapist could use and understand the robotic device easily (evaluated at pre: 3.0 (2.0), 16-post: 2.5 (2.75), 30-post: 2.0 (2.75); pre vs 30-post, p=0.016) (Fig. 2). No adverse events were reported.

DISCUSSION

This study combined robot-assisted PRoM exercises and conventional hand training for patients with stroke onset longer than 6 months prior to an outpatient rehabilitation setting. The findings demonstrate that the combinational therapy significantly improved affected hand function and strength, as well as overall function, as indicated by FMA-UE, MI and FIM. The results also showed high feasibility of use of the robotic device for patients, as indicated by the VAS. A benefit of the robot-assisted PRoM exercise is that, once the therapist has set up the robotic device, the patient can be left alone with the device, and this reduces the need for one-on-one attention while performing repetitive motions of a single PRoM exercise of the hand. Finally, no adverse effects were reported in this study.

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reproducible and interactive forms of hand training. The advantages of using robots in neurorehabilitation includes favouring attention, boosting motivation and adherence to treatment (26); they are beneficial for multi-sensory and sensorimotor integration (27). Studies showed that robot-assisted therapy is safe and well tolerated and has a positive impact on muscle strength and function of the paretic arm (28–30). Furthermore, robot-assisted exercises can optimize labour efficiency by allowing for unsupervised practise of highly repetitive exercises that would otherwise require direct supervision; for example, flexion/extension exercise of warm-up before functional training. The positive results of the current study with the use of the exoskeleton robotic hand training were in agreement with those of previous studies using a soft robotic hand (31), Gloreha device (32) and Amadeo device (33) for patients with chronic stroke. The current study found that adding robotic hand training before conventional rehabilitation could significantly improve UE function and muscle strength, which were in accordance with other studies using electromyography-driven exoskeleton hand robot devices (34, 35). For FMA-UE motor scale, although the median improvement from baseline to follow-up was 3 points on the group level, which is below what is considered of minimal clinical importance, patients 1, 4, and 9 had better improvement, up to 6 points. This suggests that the robotic-assisted hand training may have potential therapeutic effects is this subgroup of stroke patients who were relatively younger (<60 years old), onset less than 2 years and intracerebral haemorrhage. A simple training programme using repetitive passive motions was provided as an induction therapy before conventional occupational hand therapy according to the Bobath concept (36). First, it helps the paretic hand complete a hand movement and stretches hand muscles and soft tissue to reduce spasticity (37) and prevent contracture (38). Secondly, the patient could achieve the training task more easily in the following rehabilitation exercise while potentially increasing the number of repetitions, and hence the intensity of practice post-stroke (39). The enhanced somatosensory input may help motor planning and result in better hand movement with faster motor recovery and expedited motor learning, which are considered related to neuroplasticity in the lesioned brain areas (6). Purely passive movement could activate some cortical areas similarly to voluntary movements (40). Thirdly, neurophysiological studies demonstrated that PRoM exercises may decrease the inhibition effect in the affected brain areas (9), facilitating the neural functional compensation to the damaged brain areas. The use of an exoskeleton robotic hand with structure design of individual finger

Robotic systems can provide standardized, repetitive,

modules and metacarpophalangeal, proximal and distal interphalangeal joints can provide individual finger movements. The video-guided passive motion hand exercise has also demonstrated motor improvement in patients with stroke (17). The mechanism using passive motion as an introduction to the following convention hand training warrants further investigation.

Although the results showed significant changes in outcomes, this study has some limitations. First, there was no control group. The single-cohort study design did not allow any distinction between the relative contribution of robotic and conventional training. Validation for examining the treatment effect is required. Secondly, the sample size was small; a larger sample size is needed to confirm the results and longterm benefits. Thirdly, it was difficult to control the attention of the patient. Further larger, high-quality, randomized controlled studies are needed to verify the therapeutic benefits of this technique.

CONCLUSION

Exoskeleton robot-assisted PRoM hand training may be a good induction therapy before conventional therapy for hand rehabilitation of patients with chronic stroke. Further randomized control trials are needed to verify the therapeutic benefits of this technique.

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The authors have no conflicts of interest to declare.

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