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Effectiveness of Powered Hand Exoskeleton on Upper Extremity Function in People with Chronic Stroke

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Abstract: Impairment of upper limb function is common after a stroke and is closely linked to decreased functional independence in activities of daily living. Robot-assisted training has been used in clinical settings to improve hand function in stroke patients; however, many existing devices are costly and require specialized training to operate. This study aimed to propose a novel powered hand exoskeleton (EO) and verify its effectiveness on upper extremity function in people with chronic stroke. Thirty participants were randomly assigned to either the experimental group or the control group. Each participant underwent 30 min interventions twice a week for 8 weeks. The experimental group received 15 min of conventional therapy followed by 15 min of training with the powered hand EO, while the control group received 30 min of conventional therapy. The primary outcome measures included the Fugl-Meyer Assessment for upper extremity function (FMA-UE), the Box and Block Test (BBT), and handgrip dynamometer. Assessments were conducted at baseline and then at 4-week intervals throughout the 8-week period. Results showed that, after the 8-week intervention, the average changes in FMA-UE scores for the experimental group were significantly greater than those for the control group ($p < 0.01$). A clear upward trend in both FMA-UE and BBT scores was observed in the EO group. Statistical analysis revealed significant improvements in the overall, proximal, and distal components of the FMA-UE scores (all $p < 0.01$) and in BBT scores (both $p < 0.05$) in the EO group compared to the control group at 4 and 8 weeks, respectively. However, no significant differences in grip strength were observed between the groups at either time point. Our findings suggest that the proposed powered hand EO is both feasible and safe for training the impaired hand in stroke survivors. Given the characteristics of the device, it has potential for use in hand rehabilitation aimed at regaining upper extremity function.

Keywords: rehabilitation engineering; assistive robotics; exoskeletons

Academic Editors: Mahdy Eslamy, Geetika Aggarwal and Jinoop Arackal Narayanan

Received: 20 November 2024
Revised: 15 January 2025
Accepted: 21 January 2025
Published: 2 February 2025

Citation: Yeh, S.-J.; Wang, Y.-C.; Fang, W.-C.; Huang, S.-C.; Yang, Y.-S. Effectiveness of Powered Hand Exoskeleton on Upper Extremity Function in People with Chronic Stroke. *Actuators* **2025**, *14*, 67. https://doi.org/10.3390/act14020067

1. Introduction

About 30% to 66% of stroke survivors have upper limb motor impairment [1], and of those with reduced arm function early after a stroke, 50% still have problems after 4 years [2]. In order to maximize functional motor recovery and independence after a stroke, early intervention can significantly improve rehabilitation outcome. It has been proven that early and intensive rehabilitation predicts good functional outcomes [3–5].

Previous systematic reviews have shown that repetitive, goal-directed functional activities for the paretic upper limb suggested that stroke survivors benefit from these exercise programs in which functional tasks were directly trained [6–8]. Repetitive task training is a cornerstone of stroke rehabilitation, leveraging neuroplasticity to facilitate motor re-learning [9–11]. Neuroplasticity, the brain's remarkable ability to adapt and reorganize, is driven by the strengthening of neural connections through repeated activation [12,13]. While repetitive task training holds immense promise, its effectiveness hinges on key factors: intense practice, active patient engagement, and consistent performance feedback [14]. These demands necessitate significant time investment and extensive therapist interaction, making repetitive task training costly and potentially inaccessible for many stroke survivors. To address these limitations, technological interventions offer a valuable adjunct and alternative to traditional repetitive task training. By providing accessible and affordable rehabilitation options, technology can overcome barriers related to time, cost, physical limitations, and even patient motivation. These interventions empower individuals to engage in personalized and engaging rehabilitation exercises, ultimately enhancing their recovery journey.

In an effort to create an alternative form of treatment, a number of robotic devices have been developed. The adoption of robot-based technologies in the clinical practice of stroke rehabilitation has been shown to be as effective as high-intensity training [15–18]. It has been extensively demonstrated that robot-assisted therapy may enhance motor recovery and neuroplasticity, due to their ability to supply highly intensive, repeatable, accurate, and patient-tailored movement therapy, while guaranteeing patient safety and unloading therapist workload with respect to traditional methods.

In this line of work, there are multiple assistive robotic platforms for reducing the burden of therapy. Robotic rehabilitation devices are mainly of two types: end-effector (EE) and exoskeleton (EO) according to their mechanical structures [19–22]. The EE devices are connected to patients at one distal point and the patient is required to place the affected hand onto the device to receive the treatment. Because their joints do not match with human joints, the EE devices make isolated movement of a single joint difficult. On the other hand, EO devices resemble human limbs as they are connected to patients at multiple points and their joint axes match with human joint axes. Therefore, EO devices enable assisted movement of distal joints in the hand and wrist. These two robotic rehabilitation devices typically incorporate multiple sensors in their design, allowing for more precise monitoring of movement execution compared to traditional intervention methods. With these advanced technologies, the range of movements can be programmed with greater accuracy, leading to improved therapeutic outcomes. Additionally, they integrate various feedback mechanisms, including biosignal-based feedback, to enhance user performance.

The last decade has seen exponential growth in both the types and numbers of robotic rehabilitation devices as well as clinical trials. For rehabilitation of hand motor function, both EE and EO devices showed similar or superior effects relative to traditional therapy in patients with chronic stroke [15,21,23,24]. Recently, this distinction has become less clear. In fact, the rise of wearable and portable EO devices allows robot-assisted therapy to take place in various settings, such as at home, thereby reducing the burden on therapists and inpatient facilities [25]. Furthermore, portable EO devices designed for assistance or at-home rehabilitation are always available to patients, who may find it stimulating and motivating to engage in these training programs while carrying out their daily activities at home. Therefore, hand EO rehabilitation devices have gradually been adopted widely.

Hand EO devices offer patients both active and passive rehabilitation through various actuation sources and mechanisms. These devices utilize different methods to generate and transfer power from actuators to facilitate finger movements. Actuation can be classified as

elector motor, hydraulic, and pneumatic [26]. The actuation mechanism's main function is to transform the motion of the actuator to the fingers to achieve the hand exercises. They depend on the nature of the actuator and can be categorized into main classifications: pneumatic actuation, linkage-based actuation, cable-driven systems, and gear-motor actuation [27,28]. Linkage and gear-motor actuation are commonly employed in hand rehabilitation devices. However, these systems often incorporate numerous rigid linkages, pulleys, gears, and mechanisms to control finger movements and joints. Consequently, the resulting exoskeleton hand devices tend to be bulky and complex, making them costly and heavy, leading to uncomfortable experiences for users.

It is widely recognized that user requirements—such as weight, comfort, aesthetics, and cost—are directly linked to the success or failure of hand rehabilitation devices [29]. Moreover, cost is a significant issue for patients, often representing the out-of-pocket expenses they must cover for healthcare services. High prices may lead patients to opt solely for conventional treatments. Furthermore, the acquisition of such devices may be unfeasible for intensive training within patients' homes. To address these issues, we developed a low-cost hand EO for post-stroke patient training utilizing 3D printing technology. The powered hand EO was designed to assist fingers flexion and extension motions in a natural manner. The proposed multi-degree of freedom system consists of a direct-driven, optimized, and underactuated serial linkage mechanism with the capability to exert extremely high force levels perpendicularly on the finger phalanges. Furthermore, we conducted this study to determine the effectiveness of the proposed powered hand EO in assessing upper extremity motor function in patients with chronic stroke. The quantitative data from this study not only could support evidence-based therapies with the proposed EO device, but also establish protocols for large-scale implementation in the future.

2. Materials and Methods

2.1. Clinical Trial Participants

A total of 32 stroke participants were recruited from outpatients at Kaohsiung Medical University Hospital and Kaohsiung Municipal United Hospital. Inclusion criteria were as follows: (1) participants were over 18 years of age, and (2) they had experienced their first stroke resulting in upper-limb hemiplegia at least six months before the study began. Exclusion criteria included: (1) language or cognitive impairments that could hinder cooperation in the study, (2) severe upper-limb spasticity, defined as modified Ashworth scale (MAS) scores greater than 2 for the wrist and/or finger flexors, and (3) having received botulinum toxin injections less than six months prior to study enrollment. Participants taking oral anti-spastic drugs were only included in the study if the dosage had not been changed during the month before joining. All participants provided informed written consent. The study was conducted in accordance with the Declaration of Helsinki Ethical Principles and Good Clinical Practices and was approved by the Institutional Review Board of Kaohsiung Medical University Chung-Ho Memorial Hospital (KMHIRB-F(I)-20230090).

2.2. Intervention

We conducted a randomized, single-blind, controlled trial to evaluate the effects of powered hand EO over eight weeks in patients with chronic stroke. The study flowchart is shown in Figure 1. We began with a baseline assessment (T0) of the participants, followed by evaluations at 4-week intervals (T4, and T8) throughout the 8-week period. Participants were randomly assigned to either an experimental group (EO group) or a control group using a computerized random number generator. Both groups received conventional rehabilitation therapy from experienced therapists, which included positioning the limbs in a normal posture, applying stretching techniques for the wrist and finger flexor muscles,

utilizing proprioceptive neuromuscular facilitation (PNF), employing neurodevelopmental techniques (NDT), and conducting task-oriented trainings. This comprehensive approach aimed to enhance motor and sensory functions of the wrist and hand, as well as to support activities of daily living for the upper limb. Participants in the control group received conventional rehabilitation therapy three times per week, with each session for 30 min over the 8-week intervention. In contrast, participants in the EO group received a similar intervention dosage but engaged in 15 min of conventional rehabilitation followed by 15 min of powered hand EO training during each session. During the powered hand EO training sessions, participants were instructed to sit in an ergonomic chair with their arm flexed at a 90° angle, resting their forearm on a semi-soft wedge on a table. This setup allowed both hands to be free for movements performed with the powered hand EO. The training included repetitive hand opening and closing actions, squeezing a soft ball, and grasping and releasing an object with the impaired hand, using remote control operated by either a therapist or the participant's unaffected hand.

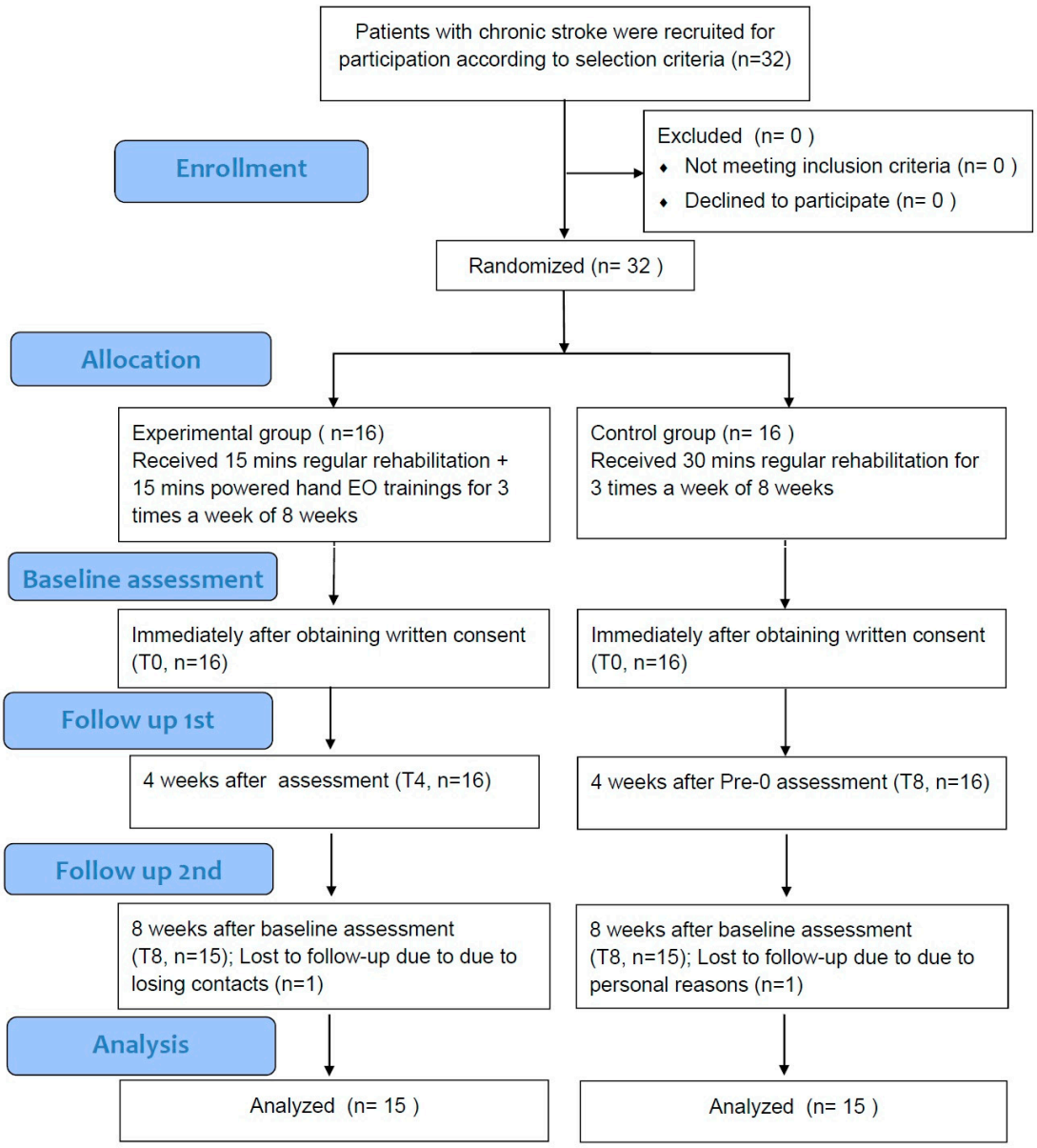

Figure 1. Flowchart of the experimental design.

2.3. Powered Hand EO Design

The powered hand EO design was based on linkage rods connected to two 12 Volt DC linear actuators, each capable of generating 96 Newtons of force, to enable the user to open their hand (Figure 2). The dimensions of this powered hand EO are 21 × 8 × 7 cm, but it can be customized to fit the user's affected hand anthropometry. The total weight, including the lithium-ion battery, is approximately 0.5 kg. The actuators were designed to be used in exercises that focus on opening and closing the thumb, index, and middle fingers, facilitating a tripod grasp, which is the most common and efficient grasp pattern [30]. A small infrared receiver was connected to two linear actuators, enabling simultaneous operation of both actuators using a simple infrared remote with a forward-reverse switch. Stroke users could open and close the gap between their thumb, index, and middle fingers on their affected hand by using their unaffected hand or with the assistance of therapists operating infrared remote controls. Compared to existing powered hand exoskeletons with five finger actuators, this novel design not only reduced mechanical complexity but was also easier to wear. Three rigid finger sleeves designed to secure the fingers and thumb were illustrated in Figure 2. These hard finger sleeves were manufactured using fused deposition modeling (FDM) technology, accommodating a wide range of finger sizes and ensuring ease of application on the hand. The estimated manufacturing cost for this powered hand EO is approximately $900 USD.

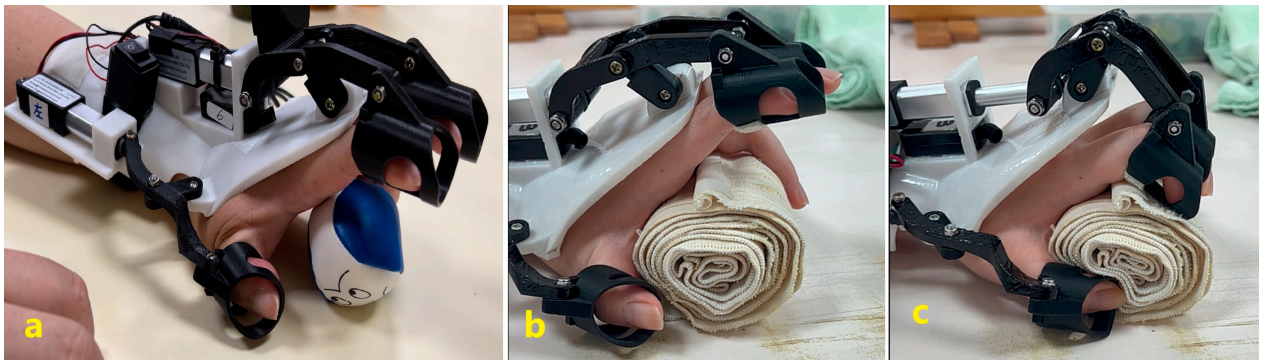

Figure 2. (**a**) Design overview of the powered hand exoskeleton (**b**) releasing an object and (**c**) grasping an object with the exoskeleton.

2.4. Assessments

The primary outcome measure was the Fugl-Meyer Assessment for Upper Extremity (FMA-UE), recognized as the "gold standard" for evaluating motor recovery in post-stroke hemiparesis during clinical trials [31,32]. The FMA-UE comprises 30 items that assess motor function and 3 items that evaluate reflex function, with total scores ranging from 0 to 66. Higher scores indicate better motor function. The inter-rater and intra-rater reliability for the FMA-UE were 0.95 and 0.98, respectively [33–35].

The second outcome measure was the Box and Blocks Test (BBT). BBT is a widely used outcome measure to quantify upper limb motor function, especially gross manual dexterity. The BBT comprises a wooden box divided into two compartments, as well as 150 blocks. Participants had to move the blocks one by one from 1 compartment of a box to another in 60 s. A greater number of blocks indicate better motor performance. The inter-rater and intra-rater reliability for the BBT were 0.98, and 0.95, respectively [36,37].

The third outcome measure was grasp strength assessment by Jamar Plus Dynamometer. It is a clinical tool designed to measure grip strength in individuals. It is widely used in various rehabilitation settings. It can measure grip strength across a range of 0 to 90 kg, making it suitable for a wide variety of patients.

2.5. Statistical Analysis

The demographic characteristics of the participants were analyzed using the Mann–Whitney U test to compare ages between the two groups, and the chi-square test to evaluate the distributions of sex, type of stroke, and affected side. A paired *t*-test was utilized to assess the scores of FMA, BBT, and grip strength within each group before and after the intervention. An independent *t*-test was used to compare the changes in differences in FMA, BBT, and grip strength between the two groups before and after the intervention. All statistical analyses were conducted using SPSS software (version 20 for Windows, IBM, Armonk, NY, USA), with a significance level set at 0.05.

3. Results

3.1. Baseline Characteristics of Participants

A total of 32 participants were recruited for this study. Two participants dropped out due to personal reasons or unavailability throughout the study period. Consequently, 30 participants successfully completed the entire study, and no adverse events were reported. The baseline characteristics of participants between the two groups were described in Table 1. No significant bias was found between the two groups with respect to age, gender, affected side, stroke type, and mean months from the onset. Furthermore, the FMA-UE, BBT, and grip strength were also not significantly different between the experimental group and the control group at baseline.

Table 1. The baseline characteristics of participants between the two groups.

Demographic Characteristics	EO Group (n = 15)	Control Group (n = 15)	p-Value
Mean age (SD)	50.8 (12.2)	58.9 (9.5)	0.06
Sex, male (%)	53.3%	40.0%	0.72
Affected side, right (%)	38.5%	36.4%	1.00
Stroke type, hemorrhagic (%)	38.5%	36.4%	1.00
Mean months from onset (SD)	34.8 (21.8)	47.1 (32.9)	0.39
FMA-UE score (SD)	26.8 (12.9)	26.9 (17.5)	0.98
BBT-pcs (SD)	1.5 (5.7)	3.5 (7.2)	0.41
Grip strength—kg (SD)	4.2 (2.8)	2.5 (2.4)	0.07

3.2. Primary Outcome Measures

A summary of the statistical analysis for intra-group comparisons of assessment scores is presented in Table 2. After the 4-week intervention, the experimental group showed significant improvements on the proximal part (FMA-UE prox), distal part (FMA-UE dist), overall FMA-UE (FMA-UE total), BBT scores, and grip strength, with these enhancements remaining significant compared to the baseline at 8 weeks (both $p < 0.01$). In contrast, the control group did not exhibit significant improvements on the FMA-UE, and BBT exhibited grip strength after the 4-week intervention. However, after 8 weeks, the control group showed improvements on the overall ($p = 0.02$), proximal part FMA-UE ($p = 0.02$), and grip strength ($p < 0.01$) compared to the baseline, not BBT ($p = 0.31$), after the 8-week intervention.

Table 2. Intra-group comparison of primary outcomes before and after intervention.

	EO Group (n = 15)			Control Group (n = 15)		
	T0	**T4**	**T8**	**T0**	**T4**	**T8**
	Mean (SD)	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
FMA-UE total	26.8 (12.9)	32.6 (13.4) **	35.3 (14.6) **	26.9 (17.5)	27.9 (17.2)	28.1 (17.6) *
FMA-UE prox	19.7 (8.2)	22.9 (7.6) **	24.5 (7.9) **	20.1 (10.0)	20.8 (10.2)	21.2 (10.4) *
FMA-UE dist	7.1 (5.1)	9.7 (6.2) **	10.8 (7.1) **	6.8 (8.3)	7.1 (7.8)	6.9 (7.9)
BBT	1.5 (5.7)	2.7 (5.8) **	4.3 (8.5) **	3.5 (7.2)	3.5 (7.6)	3.7 (7.8)
Grip strength	4.2 (2.8)	5.4 (2.8) **	5.3 (3.3) **	2.5 (2.4)	3.3 (2.7) *	3.4 (2.9) **

* $p < 0.05$, when the score was greater than the baseline score. ** $p < 0.01$, when the score was greater than the baseline score.

Inter-group comparisons of FMA-UE assessment scores at both 4 weeks ($p = 0.56$) and 8 weeks ($p = 0.66$) did not reveal significant differences between the EO group and the control group. However, the EO group exhibited a clear trend of improvement in both FMA-UE and BBT scores (Figures 3 and 4). As shown in Table 3, the changes in the overall, proximal, and distal parts of the FMA-UE scores (all $p < 0.01$) and in the BBT scores (both $p < 0.05$) were significantly greater in the EO group compared to the control group at both 4 and 8 weeks. However, there were no significant change of differences between the two groups in grip strength at either 4 weeks or 8 weeks after training.

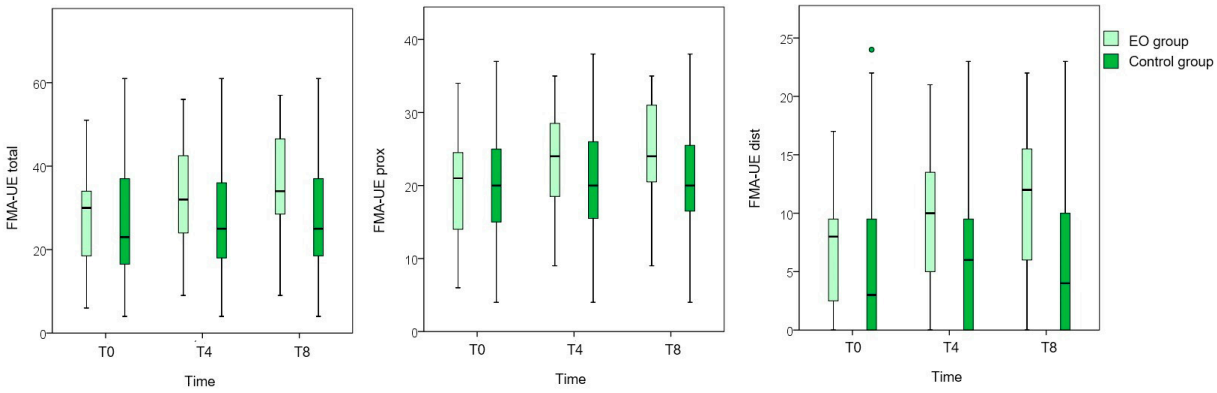

Figure 3. FMA-UE scores for experimental and control groups at baseline (T0), 4 weeks (T4) and 8 weeks (T8). Circles represent outliers; the median is shown by the thick black line.

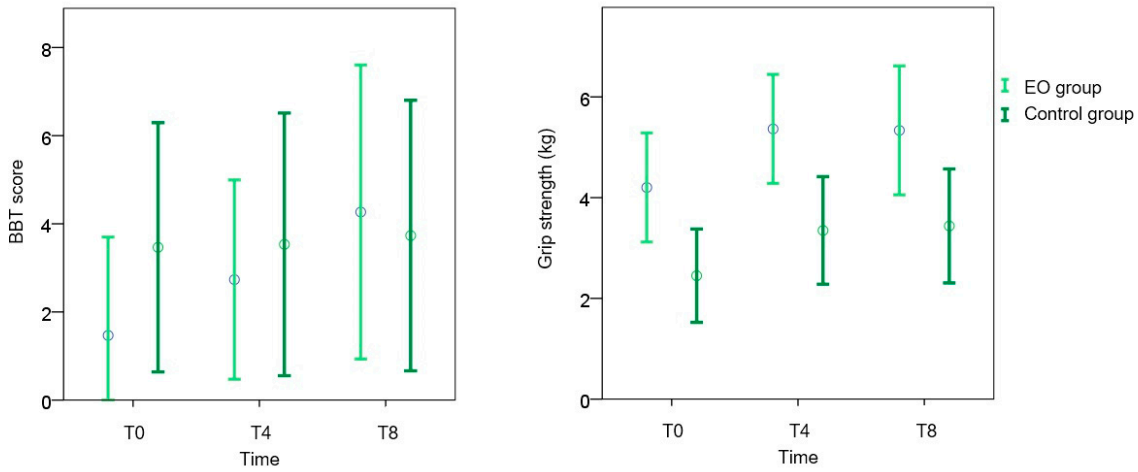

Figure 4. BBT and grip strength assessment for experimental and control groups at baseline (T0), 4 weeks (T4) and 8 weeks (T8). Circles represented the mean.

Table 3. Comparison of the change in differences between EO and control group.

	EO Group (n = 15)		Control Group (n = 15)		Inter-Group p-Value	
	ΔT4-T0 Mean (SD)	ΔT8-T0 Mean (SD)	ΔT4-T0 Mean (SD)	ΔT8-T0 Mean (SD)	ΔT4-T0	ΔT8-T0
FMA-UE total	5.8 (5.0)	8.5 (7.1)	1.0 (2.0)	1.1 (1.7)	<0.01 **	<0.01 **
FMA-UE prox	3.2 (3.1)	4.8 (4.1)	0.7 (1.2)	1.0 (1.3)	<0.01 **	<0.01 **
FMA-UE dist	2.6 (2.7)	3.7 (4.2)	0.3 (1.5)	0.1 (1.0)	<0.01 **	<0.01 **
BBT	1.3 (1.3)	2.8 (3.7)	0.1 (1.5)	0.3 (1.0)	0.03 *	0.02 *
Grip strength	1.2 (1.2)	1.1 (1.0)	0.9 (1.4)	1.0 (1.2)	0.57	0.72

* $p < 0.05$, when the change in differences was greater than the control group. ** $p < 0.01$, when the change in differences was greater than the control group.

4. Discussion

Intra-group comparisons of FMA-UE and hand grip strength revealed significant improvements in upper limb function after the 8-week intervention in both the experimental and control groups. Notably, the EO group, which utilized the powered hand EO device, demonstrated substantial gains in FMA-UE, BBT, and grip strength as early as 4 weeks, with sustained improvements observed after 8 weeks. Additionally, inter-group comparisons showed that the EO group experienced greater increases in FMA-UE and BBT scores compared to the control group. These findings suggest that the powered hand EO is more effective than conventional therapy alone in enhancing upper limb recovery. Consistent with prior reviews [38–41], combining wearable hand EO training with conventional rehabilitation therapy significantly improved key measures of upper limb motor function, namely FMA-UE and BBT.

The positive results of this study with powered hand EO training were in agreement with those of previous studies using a Gloreha device [42], Amadeo device [43], and EMG-driven exoskeleton hand robotic hand device [44] for patients with chronic stroke. Unlike these previous wearable hand exoskeletons designed with support for all five fingers, our proposed powered hand EO adopts an innovative three-finger design specifically optimized for facilitating the tripod grasp. This streamlined approach offers comparable effectiveness in upper limb function recovery while reducing mechanical complexity and costs. The tripod grasp is one of the most commonly used prehensile patterns for both static and dynamic tasks [30]. It serves as a foundation for developing other grip patterns, such as the lateral grasp and cylindrical grip, which are essential for a wide range of functional activities. Strengthening and retraining the tripod grasp helps stroke patients restore dexterity and regain control over hand movements.

Although the Fugl-Meyer Assessment for Upper Extremity (FMA-UE) is a widely used tool for evaluating motor function recovery after a stroke, assessing movement, coordination, and dexterity, not all tasks in the FMA-UE require the use of a tripod grasp. However, as our findings have shown, the EO group focusing on regaining the tripod grasp may not fully capture the ability to perform tasks requiring other grip types but still demonstrates substantial improvement in FMA-UE scores. Using the powered hand EO to practice the tripod grasp encourages repetitive motion, stimulating the brain to form new neural connections and promoting neuroplasticity [45]. While training the tripod grasp does not encompass all types of hand grips, it lays the groundwork for developing the motor functions necessary for fine motor control and dexterity. This targeted rehabilitation approach might play a crucial role in enhancing the recovery of upper limb function.

In line with previous studies [46–49], our findings revealed that motor improvements were observed across the entire upper limb, including both proximal and distal joints, following EO training, even though this device primarily targeted the hand and fingers.

During EO training, the assistance provided by the powered hand EO was integrated into coordinated tasks involving arm reaching/withdrawing and hand opening/closing. As a result, proximal joints were actively engaged automatically, despite not receiving direct mechanical assistance from the device. Another possible explanation could involve the intrahemispheric competitive interaction between the distal and proximal arm regions within the motor cortex during whole upper limb tasks [50]. Localized hand movements may promote motor recovery by facilitating neural plasticity while minimizing competitive interactions between the hand and proximal arm. Such localized hand movements can lead to a more balanced excitability distribution between the hand and proximal arm regions within the ipsilesional primary motor cortex, supporting coordinated recovery.

By the end of the intervention, both groups exhibited slight improvements in grip strength; however, the difference between the two groups was not statistically significant. After a stroke, grip strength is often dramatically reduced, affecting the ability to sustain sufficient force overtime and limiting the use of the paretic upper limb for daily activities. Spontaneous recovery of hand function post-stroke is typically imbalanced. Wrist and digit flexors tend to regain hypertonic activity, while extensors remain weak, significantly contributing to disability. The powered hand EO device assists by using its actuators to counteract high finger tone and aid in opening the fingers, allowing stroke survivors with severe hand impairments to open and grasp everyday objects. However, once the device is removed, stroke survivors with toned hands often struggle to produce strong grip force. As a result, the improvement in grip strength achieved through EO training was relatively limited.

Although the results demonstrated some significant changes in outcomes, this study has several limitations. First, while robot-assisted therapy is feasible for individuals with varying levels of impairment, we recruited stroke survivors across a broad spectrum of impairments, resulting in a high degree of variability in our findings. Commonly used FMA-UE cutoff scores defined each category: 0 to 28 severe, 21 to 50 moderate, and 51 to 66 mild [51]. In this study, 47%, 47%, and 6% of the experimental group participants, and 60%, 27%, and 13% of the control group participants had severe, moderate, and mild motor impairments, respectively. The high proportion of participants with severe impairments may have affected outcomes related to distal dexterity recovery, such as BBT performance and grip strength. Second, the heterogeneity of our participant population may have influenced the results. Although the baseline FMA scores suggested that the two groups were relatively homogeneous, the BBT, which requires greater speed and precision, directly challenging manual dexterity and fine motor skills, revealed a clear disparity between the groups. A skewed distribution of severe cases within the control group may have contributed to their unchanged scores. In contrast, the EO group began with significantly lower baseline BBT scores and improved only enough to match the control group's level. Consequently, while the EO group demonstrated progress, it could be argued that their improvement merely brought them on par with the control group, rather than providing a clear and significant advantage. Future research should consider larger sample sizes or employing cluster analyses to group participants based on impairment levels for more precise evaluations.

5. Conclusions

This study demonstrated that the proposed powered hand EO device is both a safe and effective tool for training the impaired hand in stroke survivors. Results indicated that integrating EO training with conventional rehabilitation therapy can lead to significant improvements in paralyzed upper limb function. What sets this device apart from existing alternatives is not only its affordability, portability, and accessibility but also its ability to

promote recovery of upper extremity function in a comprehensive manner. The powered hand EO is designed for use not only in hospitals and clinical settings but also in patients' homes, enabling the delivery of intensive rehabilitation and promoting enhanced motor recovery. By supporting greater engagement in meaningful activities, this device has the potential to significantly improve the quality of life for stroke survivors. Future research could explore the potential advantages of combining EO training with a smartphone app to enhance telerehabilitation services for stroke patients at home.

Author Contributions: Conceptualization, S.-J.Y., S.-C.H. and Y.-S.Y.; methodology, Y.-S.Y. and Y.-C.W.; validation, S.-J.Y., Y.-C.W. and W.-C.F.; formal analysis, Y.-S.Y. and S.-C.H.; investigation, S.-J.Y., Y.-C.W. and W.-C.F.; data curation, S.-J.Y. and Y.-C.W.; writing—original draft preparation, S.-J.Y. and Y.-S.Y.; writing—review and editing, Y.-S.Y.; project administration, Y.-S.Y.; funding acquisition, Y.-S.Y. All authors have read and agreed to the published version of the manuscript.

Funding: This research was funded by Kaohsiung Medical University, Taiwan, (PT111004).

Data Availability Statement: Data available on request due to privacy/ethical restrictions. The data presented in this study are available on request from the corresponding author.

Conflicts of Interest: The authors declare no conflicts of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

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