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Investigation of therapeutic effects of wearable robotic gloves on improving hand function in stroke patients: A systematic review

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Abstract

Background: Over the past decades, wearable robotic gloves due to their positive features are used by clinicians to improve motor function in the upper extremity. This systematic review aims to evaluate the studies that investigated the therapeutic effects of wearable robotic gloves to improve hand function in stroke patients.

Methods: The most related databases including MEDLINE (PubMed), ISI Web of Knowledge, Scopus, IEEE, and Google Scholar were systematically searched and studies were collected up to September 2021. The methodological quality assessment was done using an adapted version of the Downs and Black checklist.

Results: Of the 2674 articles searched, 5 studies were recognized as being relevant in this systematic review. The methodological quality of all included studies was between 7 to 10 points of adapted 12-point score of Downs and Black checklist. All studies concluded that the introduced robotic device had a good therapeutic effect on investigated patients' hand function. The studies had limitations in terms of the level of evidence, sample size, stroke patient groups, and therapeutic process.

Conclusion: There is no standard approach with definite intervention timing to evaluate the effect of such devices. Therefore, more comprehensive studies are needed to confirm the therapeutic effects of wearable robotic gloves on improving hand function after a stroke.

Introduction

Stroke is one of the leading causes of disability and handicap worldwide[1] and in most countries, it is the second most common reason of death.

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Stroke can also result in a variety of motor, sensory, and cognitive deficits. The majority of patients with stroke experience limitation on motor activities that reduces their social participation.[2,3]

Loss of motor function in the upper extremity, particularly that of the hand, is most often seen after stroke.[4,5] Hand dysfunction occurs in 75% of stroke survivors. Since the function of hand is essential to independent performance of activities of daily living (ADLs), improving hand function has been a major aim of rehabilitation.[1,2]

Hand rehabilitation is a complex process that requires intensive approaches.[6] Researches have shown that therapy based on repetitive, interactive, high-intensity, and task-specific treatment can be effective in regaining hand function after stroke.[7,8] Over the past decades, modern developments have been made in the field of robotic systems. Investigation of these systems has indicated that they can provide such desirable approaches with aim of rehabilitation and physical assistance.[9,10]

Robotic devices can provide more prolonged rehabilitation than conventional rehabilitation with lower therapeutic costs and less burden on the therapists.[11] Until now, various robotic devices have been developed for assisting hand functional recovery and their positive effects on motor impairments have been shown.[12]

Present hand robotic devices can be differentiated into two groups: robotic machines and wearable robotic devices. Robotic machines are devices that often are employed in specialized medical centers and need the supervision of specialists due to having complex mechanism. Although the effectiveness of these devices has been determined for assistance and recovery of motor and sensory deficits, they are bulky and heavy which makes them unportable and limited to desktop use.[13]

Unlike robotic machines, wearable robotic devices are compact devices that can be used at every environment especially home. Rehabilitation at home could provide functional and psychological efficiency for the patients and helps them to reach independence.[14] Because the wearable robotic devices can control body segment motions independently, they are attended strongly in clinical and research fields.[15] Wearable robotic devices can be categorized structurally into two groups: exoskeleton devices and robotic gloves. Exoskeletons are devices that fit on impaired limbs and attach to the human body only through external joints and linkages. These devices have rigid exoskeletons that require precise adjustment with the patient's limbs and segments.[13,16] Examples of exoskeleton devices include: hand mentor,[17] Wave flex,[18] HandSOME2,[19] and BRAVO.[20]

Robotic gloves are more compact forms than exoskeleton devices. The structure of robotic devices is similar to a glove and envelops the paretic hand. The glove-like nature of these devices gives them intuitive functionality and can reduce stresses on the hand joints.[13,16] Examples of wearable robotic glove include: the HandinMind (HiM),[21] PneuGlove,[22] Gloreha,[23] and electromyography (EMG)-controlled power hand orthosis (EPHO).[24]

Generally, robotic gloves demonstrate positive features including precision control, sufficient feedback, close cognitive and physical interaction, being compact and lightweight, and portability. Despite these positive features, this question remains: how effective are these devices in improving hand motor function in patients with stroke?

Nowadays, various studies have been done about the robotic gloves which evaluated them according to their mechanical structure, control system, and clinical applications. With respect to importance of improving hand function in patients with stroke, there is a need to gain more comprehensive information regarding capability of robotic gloves toward restoring hand function of stroke patients. To the authors' knowledge, there has not been a comprehensive review on effectiveness of robotic gloves in recovery of hand function in patients with stroke.

Therefore, in the present research, the studies which show clinical applications of robotic gloves were reviewed with the aim of improving motor recovery and functional abilities of the paretic hand in patients with stroke. The hope is that this systematic survey can be used as a reliable guidance for clinicians to select suitable device for the patients and for scientists to reveal the research gaps and future directions.

Materials and Methods

Search strategy: The scientific databases of MEDLINE (PubMed), ISI Web of Science, Scopus, IEEE, and Google Scholar were systematically searched and studies were collected up to September 2021. In this search, only articles that were published in peer-reviewed journals and conference papers written in English were considered. The search strategy was provided by considering appropriate keywords and their corresponding Mesh terms in mentioned databases.

Study selection: After exclusion of duplicates, titles and abstracts of all identified articles were assessed by two reviewers independently based on the following inclusion criteria:

- Human participants with stroke
- Wearable robotic glove used in the experimental protocol
- Robot therapy used for motor recovery, function, or control of the paretic hand
- Relevant outcomes measuring functional or motor recovery of the upper limb used.

The full texts of related articles and the reference lists of these articles were independently evaluated by the same reviewers. In regular meetings, disagreements between the two reviewers were resolved by consulting.

Data extraction: The selected studies were reviewed by two reviewers and the required information was extracted based on the prepared checklist. The checklist included the following information: authors/year of included studies, participants' demographics, sample size, stroke type, device, intervention methodology, intervention time, outcome measurements, functional variables, and study results.

Methodological quality assessment: The methodological quality assessment was done using an adapted version of Downs and Black checklist.[25] This 27-point checklist was used to evaluate the methodological quality of both randomized controlled trials (RCTs) and non-randomized trials and it addressed the following methodological components: quality of reporting, external validity, internal validity, and power. The psychometric properties of this quality index were reported as follows: internal consistency of 0.89, test-retest reliability of 0.88, and inter-rater reliability of 0.75.25

Twelve items from the original checklist (items 1-4, 6-7, 10, 11, 18, 20, 23, and 27) which were more relevant to our study were used to rate all included studies. Two reviewers rated the quality of each study independently and disagreements between them were resolved by consulting.

The Cohen's kappa and absolute agreement percentages were used to assess inter-reviewer agreements. Due to the small numbers of studies and variation in outcome measurements, data were analyzed descriptively.

Results

The selection process of the included studies is summarized in figure 1. From the systematic literature search which was accomplished from three scientific databases [MEDLINE (PubMed), ISI Web of Knowledge, Scopus, IEEE, and Google Scholar], 2674 records were retaken. After removing duplicates, the records reached 2239. After screening the titles, the number of relevant studies was reduced into 326 and by screening abstracts of these records, the number of eligible studies was 28.

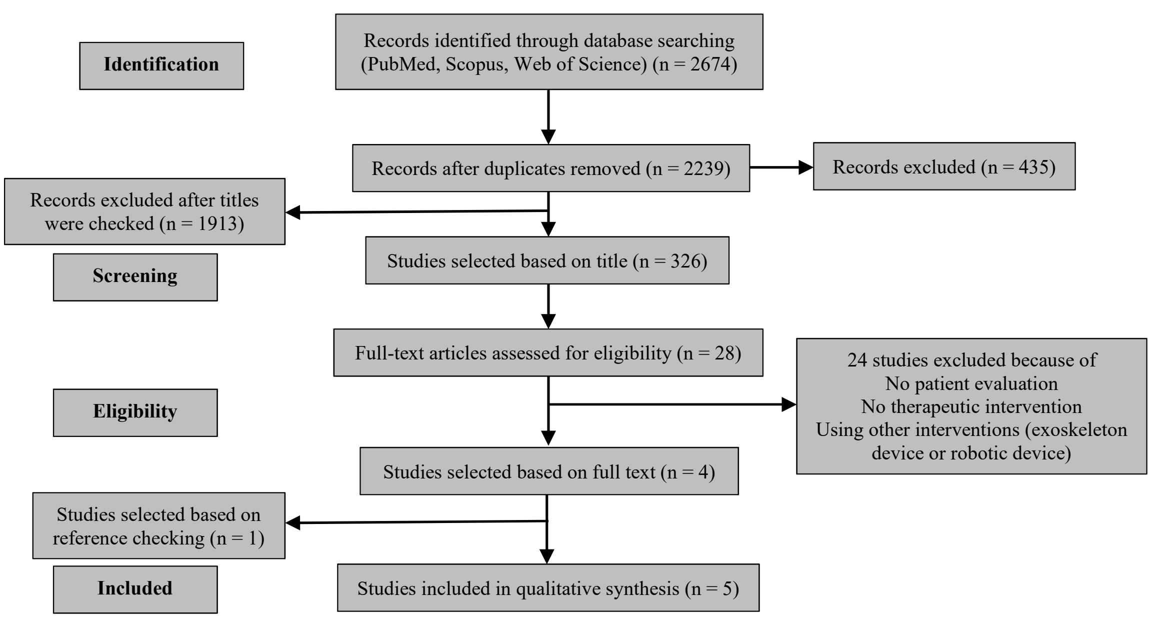

Figure 1. The flow diagram of study selection process based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline

In the next step - full text checking - 24 studies were excluded because of not meeting inclusion criteria. Finally, 5 studies were recognized as being relevant: 4 records were selected based on full text and 1 study was selected based on reference checking.

A summary of the 5 included studies is displayed in table 1 with the studies information such as authors, year of publication, sample size, participants' demographics, intervention characteristics, functional variables, and study results. All studies concluded that the introduced robotic device had good therapeutic effects on hand function of their investigated patients.

The participants who were investigated in included studies were the patients with subacute or chronic stroke. The number of participants in these studies, which included both men and women, ranged from 3 to 13. In addition, the patients' age ranged from 21 to 84 years. The patients of three studies had mild-moderate spasticity (classified as stage 3 to 5 on the Hand Stage of Recovery of the Chedoke-McMaster Stroke Assessment).[24,26,27] One study considered the patients who were free of severe spasticity,[21] and the other one did not specify spasticity condition of the patients.[28]

Five wearable robotic gloves were used in these studies: EPHO,[24] PneuGlove,[26] eXtension Glove (X-Glove),[27] HiM system,[21] and IronHand system.[28] Among them, three devices focused on recovery of finger extension,[24,26,27] and two other ones concentrated on grip strength and task performance.[21,28] Most of the studies were purposed on designing an effective device that provided both assistive and therapeutic approaches.

The EPHO is a portable EMG-controlled power hand orthosis that was introduced by Fardipour et al., in 2018.[24] This device was designed to provide two distinct purposes of restoring and training of finger extension in patients with stroke. This wearable glove is composed of two mechanical and electrical sections and allows patients to manipulate real objects.

Connelly et al., in 2009, offered a pneumatic glove (the PneuGlove) which could be effective in training finger movement after stroke.[26] This glove uses air pressure for assisting each finger extension and after removing air pressure, finger is free to flex. Moreover, the device allows the patient to train in virtual environments and interact with real objects.

The X-Glove was developed by Fischer et al.[27] This portable glove has the linear servoactuators for moving each finger independently and allows the patient to interact with real objects. The actuated glove has two distinct modes: the stretching mode and the active training mode, that provide constant finger extension. This device might be effective for patient with severe hand impairment after stroke.

The HiM system was developed by Prange-Lasonder et al.[21] This soft-robotic glove could support hand function of patient with stroke. The device purposes are categorized into two parts: assistive and therapeutic functions. An embedded control unit controlled the device when used in assistive mode. Besides, the therapeutic software with motivating game-like exercises was used for training when the system was used in therapeutic mode.

The IronHand system was introduced by Van Ommeren et al.[28] The device consists of a three-fingered glove which has a control unit for supporting grip strength that is joined to the glove by a cord. This wearable soft-robotic glove could be used as an assistive device during ADLs in the home environment and might have therapeutic effects after stroke.

In included studies, two studies used combination of game exercise in virtual reality and ADLs for intervention,[21,26] and three studies used a task-oriented approach.[24,27,28] The duration of intervention in three studies was designated three times per week[21,24,26] and in the other two studies, it was 180 and 270 minutes per week, respectively.[27,28] Length of intervention in included studies was considered from 4 to 6 weeks.

Summary of the results of the methodological quality assessment using an adapted version of Downs and Black checklist is presented in table 2. Assessing the quality of included studies showed that the total score of all included articles was between 7 to 10 points of 12. Inter-rater agreement for all items of adapted version of Downs and Black was 100% except items 7 and 8 which was 80%. Inter-rater reliability for all items was 1.00 except items 7 and 8 which was 0.61.

Discussion

The aim of this review was to investigate the therapeutic effect of wearable robotic gloves on hand function in patients with stroke. Until now, various wearable robotic gloves have been developed to assist hand rehabilitation after stroke, such as Gloreha,[23] soft robotic glove developed by Polygerinos et al.,[29] the rehabilitative robotic glove designed by Delph et al.,[13] soft robotic glove introduced by Ullah et al.,[30] and Hand Extension Robot Orthosis (HERO).[31]

Table 1. The key characteristics of included papers

Authors	Device	Participants	Sex (men/women)	Mean age (year)	Intervention time (week)	Outcome measure	Baseline (mean ± SD)	Post-intervention (mean ± SD)	P
Connelly et al.[26]	PneuGlove	7 chronic stroke	NR	57	6	Upper Extremity Fugl-Meyer score	37.0 ± 0.8	43.1 ± 0.7	< 0.010
Fischer et al.[27]	X-Glove	13 subacute stroke	10/3	63	5	Action Research Arm Test score Chedoke Arm and Hand Activity Inventory score Graded Wolf Motor Function Test-Time score Graded Wolf Motor Function Test-FAS score Motor Activity Log score	10.5 ± 6.2 1.8 ± 0.8 2.7 ± 1.1 68.3 ± 29.4 0.6 ± 0.5	12.4 ± 7.9 2.4 ± 1.0 3.1 ± 1.3 56.2 ± 30.7 1.2 ± 0.9	0.020 < 0.001 0.029 0.001 0.001
Prange-Lasonder et al.[21]	HiM system	5 chronic stroke	3/2	64*	6	Jebsen-Taylor Hand Function Test score	NR	NR	NR
Van Ommeren et al.[28]	IronHand system	5 chronic stroke	2/3	65*	4	Jebsen-Taylor Hand Function Test score	175.99	134.43	0.040
Fardipour et al.[24]	EPHO	3 chronic stroke	1/1	52	6	Wolf Motor Function Test-Time score Wolf Motor Function Test-FAS score Box and Block Test score	49.4 ± 3.5 2.8 ± 0.1 4.0 ± 1.0	46.3 ± 3.9 2.9 ± 0.1 9.5 ± 1.5	NR

*The values are median

FAS: Functional Ability Score; EPHO: Electromyography-controlled power hand orthosis; NR: Not reported; SD: Standard deviation

Table 2. Modified Downs and Black Quality Index results

Quality items	Reporting							External validity	Internal validity			Power	Total
	1	2	3	4	5	6	7	8	9	10	11	12	
Connelly et al.[26]	1	1	1	1	1	1	0	1	1	1	0	0	9
Fischer et al.[27]	1	1	1	1	1	1	1	1	1	1	0	0	10
Prange-Lasonder et al.[21]	1	1	1	1	1	1	0	1	1	1	0	0	9
Van Ommeren et al.[28]	1	1	1	1	1	1	1	1	1	1	0	0	10
Fardipour et al.[24]	1	1	1	1	1	0	0	0	1	1	0	0	7

1 = Yes; 0 = No; 0 = Unable to determine

This review shows that despite the rapid advances in development of wearable robotic gloves in recent years, few studies have been conducted on the therapeutic effects of these devices in patients with stroke. Most studies focused on development and introduction of new devices and no investigation was conducted by them.[29,30,32] Other researches investigated the devices in combination with other interventions or their immediate effects.[31,33,34]

With respect to current systematic search, only 5 studies investigated the effects of these devices in a therapeutic approach on stroke patients. By reviewing these 5 studies, it was found that no RCT studies have been performed to evaluate the effect of wearable robotic gloves on the hand function of stroke patients. In addition, there was no level I evidence in the literature based on current evaluation. Although these studies were experimental, none of them had control group. Besides, in these studies, no comparison between the wearable robotic gloves and other therapeutic approaches or devices was made.

Present review shows that these wearable robotic gloves were tested in a small sample of patients with stroke. The number of included participants in 5 studies ranged between 2 to 13 people. There was no sample size and power calculation in these studies. Due to these issues, the results of these studies could not be generalized. Therefore, further research should be needed with larger sample size in patients with stroke to support the results of the studies.

Most studies used a chronic stroke population to evaluate the therapeutic effect of the device. Generally, after flaccid stage following a stroke, spasticity in finger flexors occurs.[35] This spasticity is a motor disorder which causes involuntary muscle contraction. It is the main reason of severe reduction in hand function, particularly that of the finger extension.[36-38] Spastic level assessment of patients in included studies shows that these wearable robotic gloves were used for patients with low spasticity and the effects of these devices are unknown for patients with higher than moderate spasticity level.

The focus of three studies of five included studies was on improving finger extension,[24,26,27] but two other ones did not specify this.[21,28] As finger and hand flexion have an important role in hand function and they may be affected in stroke patients, consideration of these functions should be noted. Recently, various robotic devices have been designed to assist and rehabilitate the finger and hand flexion,[39,40] but no therapeutic intervention was conducted to determine the effect of these devices on hand function after stroke.

In included studies, both virtual environment and task-oriented approach in conjunction with real objects were used. As the role of therapeutic environment on recovery of hand function after stroke with robotic devices is not clear, further researches are needed to compare the effect of such devices in various therapeutic environments. As regards time of intervention in included studies, definite expression about the best duration of intervention which may provide the best result could not be provided due to lack of standard intervention duration time for use of wearable robotic devices.

With respect to considered outcome measures in these studies, appreciated outcome measures with optimal conceptual relationship were used to evaluate functional and performance ability in patients with stroke. These outcome measures have a good reliability and validity in the field of patients with stroke. According to international consensus recommendations for outcome measurement in post-stroke arm rehabilitation which were introduced in 2020, the outcome measures used in these studies had good compatibility with domains of the International Classification of Functioning, Disability and Health (ICF).[41] Based on this consensus, the Box and Block Test (BBT) and Motor Activity Log (MAL) were related to activity/participation domains, and the Wolf Motor Function Test (WMFT), Upper Extremity Fugl-

Meyer (UE-FM), and Action Research Arm Test (ARAT) were related to body functions and activity/participation domains of ICF.

In summary, despite major advance in design and development of wearable robotic device up to now, few studies have been conducted to evaluate the therapeutic effects of such devices on improving hand function in patients with stroke. These studies did not include studies with high level of methodological quality and further researches with high level of evidence are needed.

In these few published researches, the effect of wearable robotic devices has been investigated on small samples. More studies with appropriate sample size and power are needed to provide certain discussions about the efficacy of such devices. Besides, defining standard and appropriate criteria for selecting the patients in future studies could facilitate comparison of the effects of different devices. This especially is important with reference to severity of spasticity. In order to provide a more reasonable generalization of the results, patients with different severities of spasticity should be investigated. In these studies, there were limitations in terms of evaluated subgroups of stroke patients and the patients' characteristics which need to be considered in future studies. Evaluation of acute stroke patients and comparison of efficacy of wearable robotic device in different subgroups of stroke patients were not considered in studies.

Conclusion

Although the wearable robotic devices could provide a variety of motor functions such as wrist and finger flexion, extension, or both, evaluation of therapeutic effects of devices which could restore flexion or both flexion and extension movements was less done. Furthermore, the therapeutic function of these devices is not clear in comparison with conventional interventions such as physical and occupational therapies and comparison of these therapeutic approaches in future studies is suggested.

According to the new approaches to the use of wearable robotic devices in the rehabilitation of stroke patients, more comprehensive studies are needed to confirm the therapeutic effects of these devices. Current researches due to the limitations in terms of the level of evidence, sample size, the studied subgroups, and therapeutic process are incapable to address efficacy of wearable robotic devices and it is necessary to address these deficiencies in future studies.

Conflict of Interests

The authors declare no conflict of interest in this study.

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