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Effect of Robot-Assisted Wearable Exoskeleton on Gait Speed of Post-Stroke Patients: A Systematic Review and Meta-Analysis of a Randomized Controlled Trials

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Objective: The greatest motor impairment after stroke is a decreased ability to walk. Most stroke patients achieve independent gait, but approximately 70% do not reach normal speed, making it difficult to reach a standard of daily living. Therefore, a wearable exoskeleton is recommended for optimal independent gait because different residual disorders hinder motor function after stroke. This review synthesized the effect on gait speed in randomized controlled trials (RCTs) in which gait training using a wearable exoskeleton was performed on post-stroke patients for qualitative and quantitative analysis.

Design: A systematic review and meta-analysis of a randomized controlled trials

Methods: RCTs using wearable exoskeletons in robotic rehabilitation of post-stroke patients were extracted from an international electronic database. For quality assessment and quantitative analysis, RevMan 5.4 was used. Quantitative analysis was calculated as the standardized mean difference (SMD) and presented as a random effect model.

Results: Five studies involving 197 post-stroke patients were included in this review. As a result of the analysis using a random effect model, gait training using a wearable exoskeleton in post-stroke patients showed a significant improvement in gait speed compared to the non-wearing exoskeleton (SMD = 1.15, 95% confidence interval: 0.52 to 1.78).

Conclusions: This study concluded that a wearable exoskeleton was more effective than conventional gait training in improving the gait speed in post-stroke patients.

Key Words: Robotic exoskeleton, Wearable Technologies, Stroke, Gait speed

Introduction

After a stroke, survivors experience various neurological defects and disorders, such as hemiplegia and impairment of cognition, communication, and spatiotemporal cognition [1, 2]. Even after standard rehabilitation is provided to post-stroke patients, 50 to 60% remain impaired. As a result of the movement disorder, the patient will always be partially dependent in daily life, which significantly impacts the patient's life and comes at a substantial financial cost [3].

The greatest motor impairment after stroke is a decreased ability to walk. Most stroke patients achieve independent gait, but approximately 70% do not reach normal speed, making it difficult to reach a standard of daily living [4, 5]. Compared to conventional gait training performed in hospitals, treadmill-based robotic-assisted gait training (t-RAGT) has a better or similar effect on gait speed [6-8]. t-RAGT enables repetitive and intensive training without the physical burden on the therapist and can provide objective and quantitative evaluations [9, 10]. However, wearable exoskeletons are recommended for optimal active gait because different residual disorders could hinder

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exercise ability after stroke [11].

It may differ depending on the remaining movement disorders in rehabilitation for improving walking ability, but a graded approach is suggested. In the initial stage, a passive mode is needed to recover walking ability to some extent with a fixed trajectory, such as t-RAGT. In the middle stage, robot support is applied as an auxiliary means owing to the active movement of the user. In the later stage, gait training, such as a wearable exoskeleton that is operated according to the active movement of the user, is proposed [12, 13]. This intuitively improves walking ability, which is determined based on the functional ambulation category (FAC) that judges and grades it [14, 15]. For an FAC of 0-2, a passive mode such as t-RAGT is recommended in the initial rehabilitation stage. In the middle to late stages, gait training can be performed using a wearable exoskeleton suitable for stages 2-5.

Research on wearable exoskeletons is rapidly increasing, and they are attracting attention as innovative devices. Therefore, this review synthesized the effect on gait speed in randomized controlled trials (RCTs), in which gait training through a wearable exoskeleton was performed on post-stroke patients for qualitative and quantitative analysis.

Methods

Study design

This review is a systematic review and meta-analysis to synthesize gait training studies using a wearable exoskeleton for post-stroke patients. It was prepared according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines and the protocol was registered in the Prospective Register of Systematic Reviews (PROSPERO) (CRD42022309155).

Search strategy and selection of studies

Inclusion criteria

Inclusion criteria were classified using PICOSD (participants, intervention, comparisons, outcomes, and study design), which are key questions of systematic review.

Participants were selected as post-stroke patients with FAC 2 or higher that can be worn with a wearable exoskeleton. Intervention was selected as a wearable exoskeleton capable of overground walking, not t-RAGT. Comparisons included robot-free gait training to compare the effects of wearable exoskeletons. Outcomes were limited to gait speed that could represent gait ability. For the study design, only RCTs were extracted.

Exclusion criteria

Studies in which the control group used robots or no gait training, studies without gait speed variables, and studies that were not RCTs were excluded.

Literature-search strategy

Data were collected in May 2022. Since the wearable exoskeleton is a walking training robot developed after t-RAGT, studies since 2015 were searched. Researchers have experience in meta-analysis, and each performed data collection. The search was conducted by combining the following terms according to PICOSD; robotic-assisted gait training, wearable exoskeleton, gait training, post-stroke, stroke, and randomized controlled trial.

The international electronic databases searched for are Medical literature analysis and retrieval system online (Medline)/ Excerpta Medica Database (Embase)/ Cochrane central register of controlled trials (Central), and Web of Science. Further searches were performed on Google Scholar.

Study selection and data extraction

For studies extracted through the database, duplicate data were removed by reference management software (EndNote 20, Thomson Reuters, USA). First, the researchers reviewed the title and abstract. The full text of the selected studies was reviewed according to inclusion criteria. The contents reviewed were finally decided after consultation among the researchers.

Quality assessment

The quality assessment of RCTs used risk of bias (RoB) [16]. RoB was also rated as low (+), uncertain (?), and high (−) by the researchers. Items (random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, other bias) inconsistent in the results were re-evaluated after consensus among researchers.

Results

Literature search and characteristics of the included studies

A total of 22 studies were extracted through the electronic database, and a total of 25 studies were extracted, including three studies through additional searches. Five duplicate studies were excluded using EndNote 20. Of the 20 studies, 15 studies were excluded after reviewing the titles and abstracts by the researchers. Among the excluded studies, one study that was not written in English, 13 studies that did not meet the inclusion criteria, and one study that did not provide data were excluded [17-21]. The five selected studies were analyzed through systematic review and meta-analysis (Figure 1).

Methodological quality assessment of the wearable exoskeleton applied to post–stroke patients

After each quality assessment, the researchers agreed the results through a consensus process. In the quality assessment of five studies, random sequence generation (low: 4; high: 1), allocation concealment (uncertain: 5), blinding of participants and personnel (low: 1; uncertain: 2; high: 2), blinding outcome assessment (low: 3; high: 2), incomplete outcome data (low: 3; high: 2), selective reporting (low: 3; uncertain: 2), and other

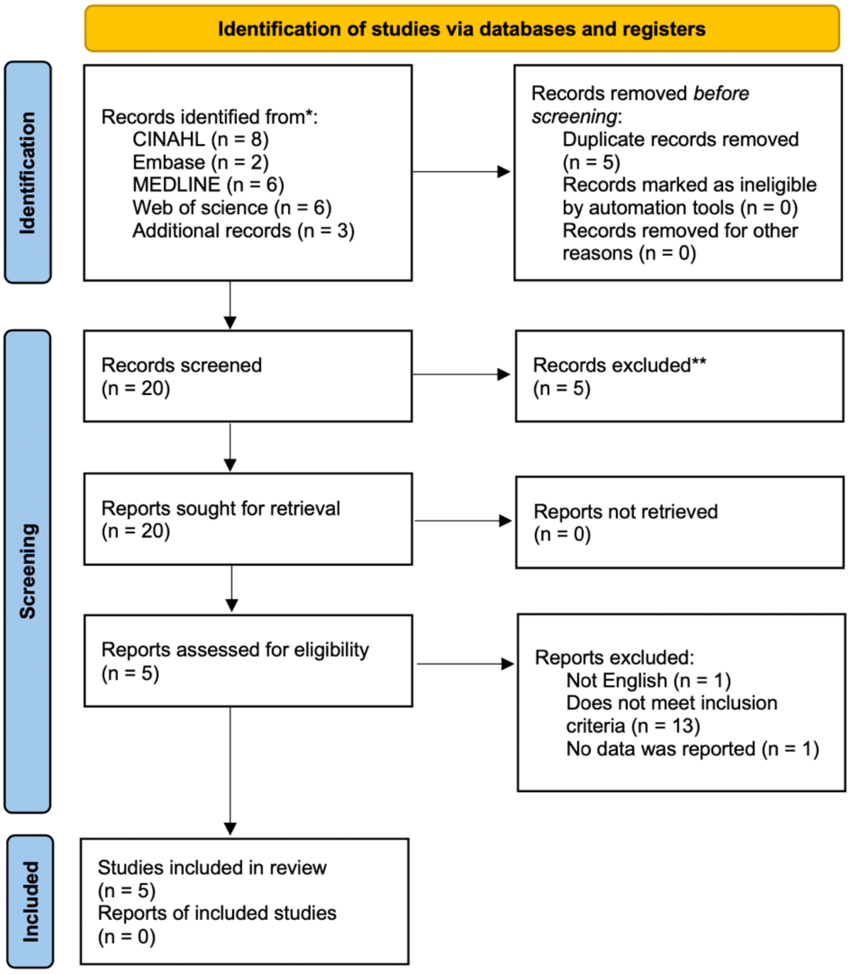
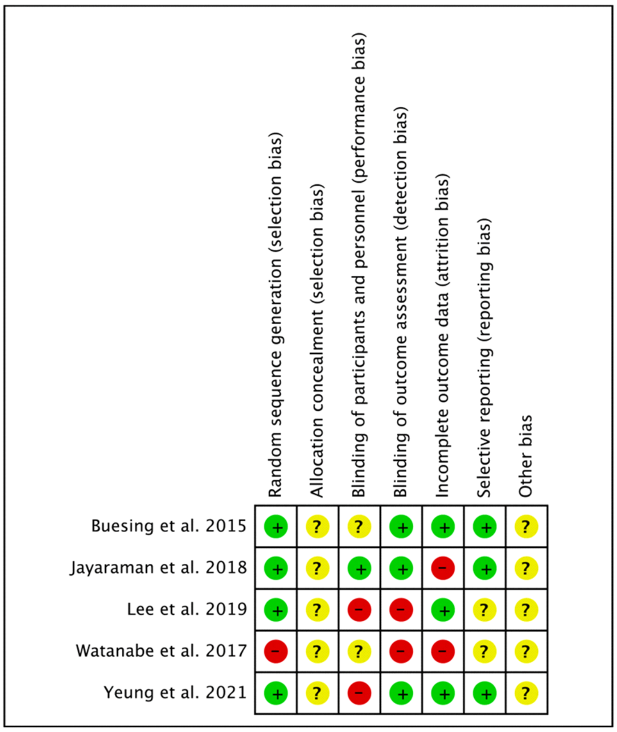


Figure 1. Preferred reporting items for systematic reviews and meta-analysis flow diagram.



	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Buesing et al. 2015	+	?	?	+	+	+	?
Jayaraman et al. 2018	+	?	+	+	−	+	?
Lee et al. 2019	+	?	−	−	+	?	?
Watanabe et al. 2017	−	?	?	−	−	?	?
Yeung et al. 2021	+	?	−	+	+	+	?

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included trial.

biases (uncertain: 5) (Figure 2). The assessment of other bias was judged by referring to the systematic survey [22].

Effectiveness of wearable exoskeleton on gait speed

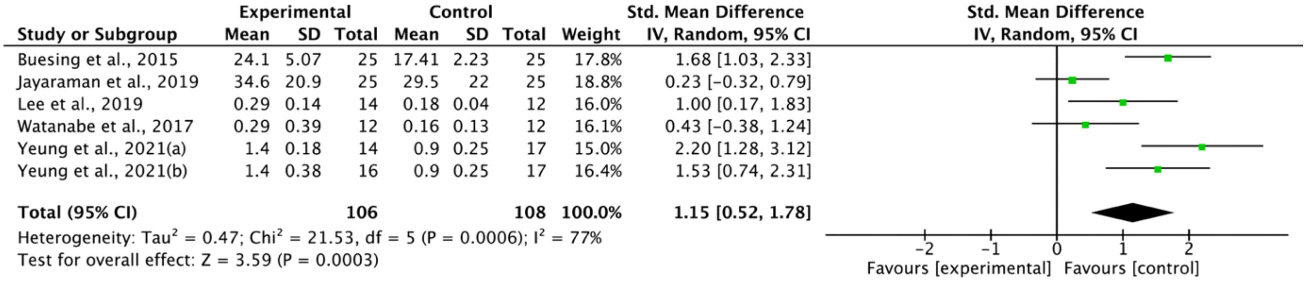
Five studies involving 197 post-stroke patients were included in the review. We analyzed the effects of wearable exoskeletons excluding t-RAGT on gait speed in post-stroke patients. Gait speed was measured by an assessor or by an instrument analyzing spatiotemporal gait parameters (Table 1).

Figure 3 is a forest plot showing the wearable exoskeleton compared with conventional or functional task-specific gait training for gait speed. From the results analyzed through the random effect model, gait training using a wearable exoskeleton in post-stroke patients showed a significant improvement in gait speed compared to the non-wearing exoskeleton (SMD = 1.15, 95% confidence interval [10]: 0.52 to 1.78; heterogeneity ($\chi^2=21.53$, df = 5, I2 = 77%); and overall effect (Z = 3.59, $p<0.001$).

Table 1. Characteristics of included studies.

Study	Sample size	Duration	Therapeutic intensity	Gait speed	Author's conclusion
Buesing et al., 2015 [17]	SMA = 25 FTST = 25	6-8 weeks	FAC ≧2 3 times per week for 6–8 weeks for a maximum of 18 training sessions	GAITRite electronic walkway platinum	The SMA device could be a useful therapeutic tool to improve spatiotemporal parameters and contribute to improved functional mobility in stroke survivors
Jayaraman et al., 2019 [18]	SMA = 25 FTST = 25	6–8 weeks	FAC ≧2 18 sessions over 6–8 weeks	10MWT-SSV	Gait training with the SMA improved walking speed in persons with chronic stroke, and may promote greater walking endurance, balance, and CME than functional gait training
Lee et al., 2019 [19]	GEMS = 14 CGT = 12	4 weeks	FAC ≧3 4 weeks with 3 sessions of training per week	3D motion capture system	Gait training with Gait Enhancing and Motivating System was effective for improving locomotor function and cardiopulmonary metabolic energy efficiency during walking in patients with stroke.
Watanabe et al., 2017 [20]	HAL = 12 CGT = 12	4 weeks	FAC ≧2 3 times a week with a total of 12 sessions	Maximal walking speed	The results suggested that a gait training program based on HAL may improve independent walking more efficiently than CGT at 1 and 2 months after intervention.
Yeung et al., 2021 [21]	PAAR = 14 SACR = 16 CGT = 17	10 weeks	FAC ≧1 20 session robot-assisted gait training (2 sessions per week)	10MWT	The active powered ankle assistance might facilitate users to walk more and faster with their paretic leg during stair and over-ground walking.

10MWT, 10-meter walk test; CGT, conventional gait training; CT, conventional training; FAC, functional ambulation categories; FTST, functional task specific training; GEMS, gait enhancing and motivating system; HAL, hybrid assistive limb; PAAR, power-assisted ankle robot; SCAR, swing-controlled ankle robot; SMA, Stride Management Assist; SSV, self-selected walking velocity.



Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Buesing et al., 2015	24.1	5.07	25	17.41	2.23	25	17.8%	1.68 [1.03, 2.33]
Jayaraman et al., 2019	34.6	20.9	25	29.5	22	25	18.8%	0.23 [−0.32, 0.79]
Lee et al., 2019	0.29	0.14	14	0.18	0.04	12	16.0%	1.00 [0.17, 1.83]
Watanabe et al., 2017	0.29	0.39	12	0.16	0.13	12	16.1%	0.43 [−0.38, 1.24]
Yeung et al., 2021(a)	1.4	0.18	14	0.9	0.25	17	15.0%	2.20 [1.28, 3.12]
Yeung et al., 2021(b)	1.4	0.38	16	0.9	0.25	17	16.4%	1.53 [0.74, 2.31]
Total (95% CI)			**106**			**108**	**100.0%**	**1.15 [0.52, 1.78]**

Heterogeneity: $Tau^2 = 0.47$; $Chi^2 = 21.53$, df = 5 (P = 0.0006); $I^2 = 77\%$
Test for overall effect: Z = 3.59 (P = 0.0003)

Figure 3. Forest plot of gait speed according to wearable exoskeleton. Yeung et al., 2021(a), power-assisted ankle robot; Yeung et al., 2021(b), swing-controlled ankle robot.

Publication Bias

Since there were less than 10 selected studies, publication bias was not analyzed [23].

Discussion

We are the first to qualitatively and quantitatively synthesize the effect of a wearable exoskeleton on gait speed, representing the gait ability of post-stroke patients. In this review, 25 studies were extracted using international electronic databases and five were included. As a result of the analysis, wearable exoskeletons were classified into three types. In the five included RCTs [17-21], gait training using a wearable exoskeleton showed significant improvement in gait speed compared to conventional gait training (SMD = 1.15, 95% CI:0.52 to 1.78).

This study reviewed the effects of wearable exoskeletons in post-stroke patients with FAC ≥ 2. The benefits of robots concerning independent gait and gait speed have been reported in a Cochrane systematic review [24]. In addition, a meta-analysis of robotic gait rehabilitation reported that positive changes in independent gait were remarkable in subacute stroke patients compared to conventional physical therapy [10]. However, it was difficult to find evidence that robotic gait training using the end-effector type or t-RAGT provided better effects in patients with chronic stroke [25]. Similarly, controversial results have been reported in the acute and subacute phases of exoskeletons [25].

In this systematic review, considering the stroke onset as the period after a subacute stroke, we reviewed the effect of a wearable exoskeleton that can be applied to patients who need intermittent assistance for independent walking. We found a faster gait speed in post-stroke patients than in conventional gait training. An increase in gait speed is a representative index indicating that speed-related body and limb kinematics and muscle activation patterns are improved [26]. However, an asymmetrical gait is a prominent feature of the gait pattern of patients with stroke [27]. Although gait symmetry was not synthesized in this review, gait speed and symmetry were reported as moderate correlations in a study reporting the relationship between spatiotemporal gait parameters in chronic stroke patients [28]. Therefore, improvement in gait speed can partially explain the improvement in gait symmetry. In addition, in a study that analyzed the effects of wearable exoskeletons in stroke patients using functional near-infrared spectroscopy [29], symmetrical sensorimotor cortex activation was induced. Interestingly, it was confirmed that the oxyhemoglobin concentration decreased in the ipsilesional sensorimotor cortex and bilateral supplemental motor areas at the end of the training, resulting in a rhythmic efficient gait pattern with minimal cortical participation.

In clinical practice, it has been reported that stationary robots such as t-RAGTs and end-effectors for improving the walking ability of stroke patients are effective in the acute and subacute phases. However, the chronic phase is controversial. If independent walking is partially possible, gait training suitable for various environments should be provided, as the wearable exoskeleton is capable of overground walking.

In this review, various potential benefits were suggested by quantifying the improvement in gait speed using wearable exoskeletons in post-stroke patients. However, our study has some limitations. First, wearable exoskeletons in robotic rehabilitation are the latest technology, and there are few studies on post-stroke patients, so it is difficult to generalize it. Second, the protocol and intensity of the gait training were not the same (assisted force, operating algorithm, etc.). Third, stroke was not classified according to its onset period. Fourth, out of five studies, three studies were classified as hip type [17-19] in wearable exoskeletons, and other studies were classified as suit type [20] and ankle type [21]. Subgroup analysis according to the diversity of types is required; however, quantitative analysis is impossible with meta-analysis. Finally, although it is difficult to say that only gait speed is effective in improving gait ability among the various gait training programs, the potential benefits of the wearable exoskeleton could be confirmed.

Conclusion

This study concluded that a wearable exoskeleton was more effective than conventional gait training in improving the gait speed in post-stroke patients. If independent walking is possible with minimal assistance, then the effect of a wearable exoskeleton is expected. However, further studies are needed to generalize these effects and to provide an optimal training protocol.

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Conflicts of interest

The authors declare no conflict of interest.

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