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ORIGINAL REPORT

FURTHER EFFECTS OF ELECTROMECHANICALLY ASSISTED GAIT TRAINER (EXOWALK®) IN PATIENTS WITH CHRONIC STROKE: A RANDOMIZED CONTROLLED TRIAL

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Objective: **To assess the effect on walking ability of electromechanically assisted gait training with a gait trainer (Exowalk®) for patients with chronic stroke.**
Design: **Randomized controlled trial.**
Subjects: **Forty patients with hemiplegia after stroke.**
Methods: **Patients were randomly assigned to control and experimental groups. The control group underwent physical therapist-assisted gait training and the experimental group underwent electromechanically assisted gait training. Interventions were provided for 60 min, 5 days a week, for a period of 2 weeks. Primary outcome was change in Functional Ambulatory Category. Secondary outcomes were walking speed, walking capacity, leg muscle strength and balance. All outcomes were measured before and after the intervention.**
Results: **Although the Functional Ambulatory Category improved significantly after gait training in both groups, the change in Functional Ambulatory Category did not differ between groups. In both groups most secondary outcomes also improved after gait training, but the changes in secondary outcomes did not differ between groups.**
Conclusion: **In patients with chronic stroke, walking improved after gait training with or without electromechanical assistance. Electromechanically assisted gait training was not superior to conventional physiotherapy.**

Key words: gait; exoskeleton device; rehabilitation; stroke; chronic.

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LAY ABSTRACT

Electromechanically assisted gait training is effective in patients with acute and sub-acute stroke and there is a continued possibility of further functional improvement even in patients with chronic stroke. The aim of this study was to evaluate the further effect of electromechanically assisted gait training with Exowalk® for patients with chronic stroke. Forty patients with hemiplegia after stroke randomly assigned to control and experimental groups. The control group underwent physical therapist-assisted gait training and the experimental group underwent electromechanically assisted gait training. As results, the change in ambulatory function did not differ between two groups. In patients with chronic stroke, walking improved after gait training with or without electromechanical assistance. However, electromechanically assisted gait training was not superior to conventional physiotherapy.

After a stroke approximately 80% of individuals regain some ambulatory function, although many present with significant gait deficits, including reduced gait speed and spatiotemporal abnormalities (1, 2). For gait rehabilitation of patients with stroke, highly repetitive practice is recognized as an intervention to restore gait function, and electromechanically assisted or robotic gait training may be effective (1). Many studies have demonstrated the effectiveness of robotic-assisted rehabilitation. Mehrholz et al (3) reported that patients who receive electromechanically assisted gait training in combination with physiotherapy after a stroke are more likely to achieve independent walking than those who receive gait training without these devices.

Electromechanically assisted gait training has been shown to be effective in patients with acute and sub-acute stroke, but not in those with chronic stroke, according to subgroup analysis of 461 participants in the chronic phase, defined as more than 3 months after stroke (3). However, several studies have reported that electromechanically assisted gait training can improve gait function in patients with chronic stroke (4–7). Hornby et al. (4) showed improvements in speed and single-limb stance time on the impaired leg after robotic-assisted locomotor training in chronic stroke patients with hemiparesis of more than 6 months. Nam et al. (8) suggested that patients with stroke duration of less than one year should benefit from electromechanically assisted gait training, although those benefits declined with increased duration of stroke (8). Since electromechanically assisted gait training can provide repetitive and accurate motion, it should be considered for use in treating patients with chronic stroke.

Exowalk® (HR-02, HMH Co. Ltd, Republic of Korea) is a electromechanically assisted gait training device (Fig.

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Fig. 1. Front and side view of electromechanically assistive gait trainer of Exowalk® (HR-02, HMH Co. Ltd, Republic of Korea).

1). A previous study of this device showed that the use of electromechanically assisted gait training for 30 min per day for 5 days a week for a period of 4 weeks was as effective as gait training with a physical therapist. In addition, questionnaires regarding patient satisfaction with the electromechanically assisted gait training revealed that the patients had confidence in their gait and a desire to continue gait training (8). The optimal training intensity is based on the number of repetitions of walking movements and high-intensity gait training that benefits the chronic stroke patients (9). Therefore, the current study planned to provide gait training of higher intensity than in the previous study in patients with chronic stroke.

The aim of the present study was to further assess the effect of an electromechanically assisted gait trainer (Exowalk®) by comparing gait training of 60 min with or without electromechanical assistance for chronic stroke patients with an onset of more than 3 months.

METHODS

Subjects

From 3 March 2017 to 31 December 2017, 40 patients after stroke, age over 19 years, were recruited according to the following inclusion and exclusion criteria. Inclusion criteria: hemiplegia or hemiparesis after stroke; stroke onset more than 3 months previously; patients had recovered sufficiently to ambulate with or without the assistance of another person. Exclusion criteria were: poor cognition, with inability to control the Exowalk®; severe trunk ataxia, with inability to stand; severe spasticity, Modified Ashworth Scale (MAS) grades 3 and 4; severe leg osteoarthritis, with inability to walk; and any aetiology of ambulation with or without physical assistance, resulting in inability to participate in gait training.

The current study was conducted in 2 university hospitals; Dongguk University Hospital, Gyeonggi-do, Korea and Wangjing Hospital of Medical Science Academy, Beijing, China.

Trial registration

The study was approved by Institutional Review Board (IRB) of the 2 university hospitals; Dongguk University Hospital in Korea (number IRB 2017-18) and Wangjing Hospital of Medical Science Academy in China (number 2017-012-P002) and registered at Clinical Research Information Service (CRIS) (registration number KCT0002552).

This randomized controlled trial (RCT) was designed following the principles of the Declaration of Helsinki. Written consent to participate in the study was obtained from all subjects recruited.

Randomization and blinding

This is a prospective multi-centre, control group design, single-blind, randomized controlled trial. Subjects were randomly assigned into 2 groups by the inclusion sequence: an experimental group with electromechanically assisted gait trainer and a control group with a physiotherapist. The central code manager allocated subjects to the experimental group or the control group according to a random number table each time a patient was registered in each hospital. The single-blind methodology was that the outcome assessors were blind. Intervention and evaluation were performed by different physiotherapists with 5 years or more of experience, in order to increase reliability by minimizing the measurement error. At enrollment, patients were instructed not to reveal their allocation arm to the outcome assessor. The researcher who performed the randomization and data analyses was not involved in any assessment and training.

Gait training

The experimental group underwent a therapeutic intervention with electromechanically assisted gait training for 60 min using Exowalk®. The control group underwent therapeutic intervention comprising physical therapist assisted gait training for 60 min with the conventional method. Both groups continued to have other physical and occupational therapy in addition to gait training. The therapeutic intervention was initially provided for 5 days a week for 2 weeks. At the end of the intervention, an additional intervention for 2 weeks (a total of 4 weeks) was provided in both groups with the patient's consent.

Satisfaction with electromechanical exoskeleton-assisted gait training

A brief questionnaire was included in the study to survey patients' satisfaction with 10 items after a 2-week initial intervention in the experimental group. These items were: appropriateness of gait training time; increased confidence in gait; increased motivation; increased energy in daily life; decreased stress in daily life; improvement in depression; improvement in nervousness; increased rehabilitation concentration; increased desire to continue gait training; likelihood of recommending the training to other patients. The patient answered the questionnaire based on a 5-level Likert scale of 1–5, with scores indicating the patients' response (strongly disagree, disagree, neither agree nor disagree, agree, strongly agree).

Data acquisition and analysis

The primary outcome measure was Functional Ambulation Category (FAC) (10). Secondary outcome measures were: 10-m walk test (10MWT) (11), 6-min walk test (6MWT) (12), Motricity Index (MI) (13), and Berg Balance Scale (BBS) (14). FAC represented general walking ability on a 6-point scale. Walking ability was assessed by the need for walking assistance. The 10MWT was used to measure walking velocity based on a mean speed (in m/s) after 3 sessions of 10-m walking. The 6MWT was used to measure walking capacity, which was recorded as the distance calculated as the number of repetitions in a 30-m cycle for 6 min. MI was calculated only for the lower legs, to represent muscle strength. Ankle dorsiflexion, knee extension, and hip flexion score were each assigned 0–33 points. The total score of MI was recorded on a range of 0–100 points, with 100 points consisting of the sum of leg points +1 point, with a higher number representing good muscle strength (13). BBS was conducted with a regular protocol, with a higher number representing adequate function. All assessments were conducted within one week before gait training (pre 0 week), after initial intervention (after 2 weeks), and after additional intervention (after 4 weeks). For the 10MWT and 6MWT, the patients used the same walking assistive device and orthosis during both pre- and post-intervention. Investigators in the 2 hospitals synchronized all outcome measures by consensus meetings.

The baseline data and characteristics are presented as mean and standard deviation (SD) for continuous variables, and as numbers and percentages for categorical variables. Continuous data compared using the *t*-test, and binary data using a χ^2 test. The significance of changes between pre- and post-intervention in each group was assessed using a paired Wilcoxon signed-rank test, and the change in outcome between groups was analysed using an independent-samples *t*-test. Repeated analysis of variance (ANOVA) was used to analyse the change in outcomes pre- and post-intervention (at 0, 2 and 4 weeks). All statistical analyses were performed using SPSS Ver.22 (IBM Corporation, USA). Statistical significance level was set at $p<0.05$. Statistical significance level for the changes in outcome measure at 0, 2, and 4 weeks with the Bonferroni correction was set at $p<0.025$.

Sample size estimation

Based on the results of a previous study (15), the mean change in FAC for the primary outcomes was 0.54 (95% confidence interval (95% CI) 0.19–0.89) in the control group and 1 (95% CI 0.69–1.30) in the experimental group of HAL (Tsukuba University/Cyberdyne, Japan). While gait training of 12 sessions and 20 min per day (total 240 min) was performed in the previous study (15), the current study was 10 sessions of 60 min (total 600 min). The intervention time in the current study was therefore approximately 2.5 times that of the earlier study, and the intervention was expected to be 2 times as effective as the experimental group of HAL, and the mean change was set to 2. It was therefore assumed that the difference in the mean change between the control and experimental groups was 1.46, and the SD was set to 1.4, which was the largest SD in the previous published article using a conservative approach. This would be achieved by enrolling 17 evaluable participants in each group. To allow for a possible 20% dropout rate, 20 participants per group (total 40 participants) were randomized to each group. The selected sample size could achieve a power of 80% at the 5% level of significance.

RESULTS

A total of 40 subjects were included in the study, 38 of whom completed the gait training and outcome measures at 2 weeks after the initial intervention. Two patients in the experimental group withdrew because they did not complete their evaluation schedules. There were no significant differences in baseline characteristics between the control and experimental groups. All subjects could control their gait direction and speed, and their mean score on the Mini-Mental Status Examination (MMSE) was 26.16 (SD 5.12). All subjects could ambulate with or without the assistance of another person, and their FACs were 2 and above (Table I).

The mean FAC in the control group was 3.85 (SD 1.30) before intervention (pre 0 week) and 4.20 (SD 1.19) after initial intervention (post 2 weeks). Mean FAC in the experimental group was 4.00 (SD 1.45)

Table I. Baseline characteristics of the control and experimental groups and the Functional Ambulation Category (FAC) at pre- and post-intervention (0–2 weeks)

Characteristics	Control group ($n=20$)	Experimental group ($n=18$)	*p*-value
Sex, *n* (%)			
Male	14 (70.0)	8 (44.5)	0.188
Female	6 (30.0)	10 (55.0)	
Age, years, mean (SD)	57.30 (8.71)	60.00 (11.48)	0.417
Duration, days, mean (SD)	600.45 (505.62)	545.67 (295.94)	0.690
MMSE, mean (SD)	24.25 (6.28)	28.28 (2.02)	0.590
Type, *n* (%)			
Ischaemic	12 (60.0)	13 (72.2)	0.506
Haemorrhagic	8 (40.0)	5 (27.8)	
FAC at pre-intervention (0 weeks), *n* (%)			
1	0 (0.0)	0 (0.0)	0.112
2	3 (15.0)	4 (22.2)	
3	7 (35.0)	2 (11.1)	
4	2 (10.0)	6 (33.3)	
5	6 (30.0)	2 (11.1)	
6	2 (10.0)	4 (22.2)	
FAC at post-intervention (2 weeks), *n* (%)			
1	0 (0.0)	0 (0.0)	0.584
2	1 (5.0)	2 (11.1)	
3	6 (30.0)	3 (16.7)	
4	4 (20.0)	5 (27.8)	
5	6 (30.0)	3 (16.7)	
6	3 (15.0)	5 (27.8)	

MMSE: Mini-Mental State Examination.

Table II. Changes in outcome measures and the difference between pre- and post-intervention (0–2 weeks)

Measures	Control group ($n=20$)				Experimental group ($n=18$)				*p*-value between groups
	Pre 0 week Mean (SD)	Post 2 week Mean (SD)	Difference Mean (SD)	*p*-value	Pre 0 week Mean (SD)	Post 2 week Mean (SD)	Differences Mean (SD)	*p*-value	
Primary outcome									
FAC	3.85 (1.30)	4.20 (1.19)	0.35 (0.489)	0.008*	4.00 (1.45)	4.33 (1.37)	0.33 (0.485)	0.014*	0.917
Secondary outcomes									
10MWT	0.36 (0.27)	0.40 (0.33)	0.04 (0.12)	0.019*	0.45 (0.27)	0.51 (0.30)	0.05 (0.06)	0.003*	0.664
6MWT	111.82 (88.13)	132.73 (92.66)	20.91 (29.78)	0.003*	130.33 (94.19)	152.44 (100.23)	22.11 (20.31)	0.001*	0.887
MI	54.50 (14.87)	56.90 (17.08)	2.40 (5.67)	0.068	59.56 (19.59)	60.78 (17.63)	1.22 (5.15)	0.345	0.509
BBS	35.50 (12.75)	37.60 (12.50)	2.10 (2.19)	<0.001*	36.39 (18.72)	39.28 (17.79)	2.89 (3.04)	0.001*	0.363

*p-value <0.05 FAC: Functional Ambulation Category; 10MWT: 10-Meter Walk Test; 6MWT: 6-Minute Walk Test; MI: Motricity Index; BBS: Berg Balance Scale.

before intervention and 4.33 (SD 1.37) after initial intervention. Between pre- and post-intervention (0–2 weeks), the FAC underwent significant improvement in both groups (Table II). However, the change in FAC did not differ between groups. Most secondary outcomes showed significant improvement after the initial intervention: 10MWT, 6MWT, and BBS in the control group and 10MWT, 6MWT, and BBS in the experimental group (Table II). However, the changes in the secondary outcomes did not differ between groups (Table II).

Of the 40 total patients, 23 agreed to have an additional 2-week intervention, all of whom completed gait training and outcome measures after the additional intervention (post 4 weeks). Baseline and characteristics of this sub-group had no significant differences between the control ($n=10$) and experimental groups ($n=13$) (Table III). 6MWT and BBS in the control group showed significant improvement after the initial intervention (0–2 weeks), but no further improvement after the additional intervention (2–4 weeks). Berg Balance Scale (BBS) in the experimental group showed significant improvement over the 4 weeks (Fig. 2). No adverse events were found during gait training in either group.

Table III. Data of characteristics in the sub-groups and the Functional Ambulation Category (FAC) at pre- and post-intervention (0–4 weeks)*

	Control group ($n=10$)	Experimental group ($n=13$)	*p*-value
Sex, *n* (%)			
Male	6 (60.0)	6 (46.2)	0.680
Female	4 (40.0)	7 (53.8)	
Age, years, mean (SD)	57.80 (8.244)	59.15 (13.12)	0.778
Duration, days, mean (SD)	878.60 (507.59)	582.92 (255.14)	0.082
MMSE, mean (SD)	23.90 (6.15)	27.69 (2.09)	0.090
Type, *n* (%)			
Ischaemic	5 (50.0)	8 (61.5)	0.685
Haemorrhagic	5 (50.0)	5 (38.5)	
FAC at pre-intervention (0 week), *n* (%)			
1	0 (0.0)	0 (0.0)	0.252
2	2 (20.0)	4 (30.8)	
3	3 (30.0)	1 (7.7)	
4	1 (10.0)	5 (38.5)	
5	3 (30.0)	1 (7.7)	
6	1 (10.0)	2 (15.4)	
FAC at post-intervention (4 week), *n* (%)			
1	0 (0.0)	0 (0.0)	0.934
2	1 (10.0)	2 (15.4)	
3	3 (30.0)	2 (15.4)	
4	2 (20.0)	3 (23.1)	
5	3 (30.0)	4 (30.8)	
6	1 (10.0)	2 (15.4)	

MMSE: Mini-Mental State Examination.

The questionnaire on patient satisfaction with the electromechanically assisted gait training found that mean overall satisfaction rate was 4.16 (SD 0.37). The mean satisfaction rates were 4.82 (SD 0.60) for "increased desire to continue gait training", 4.64 (SD 0.67) for "want to recommend this training to other patients", 4.45 (SD 1.00) for "improvement in depression", 4.18 (SD 0.87) for "increased motivation", 4.09 (SD 0.83) for "increased confidence in gait", 4.00 (SD 0.77) for "appropriateness of gait training time", 4.00 (SD 0.89) for "increased energy in daily life", 4.00 (SD 1.00) for "decreased stress in daily life", 3.91 (SD 1.04) for "increased rehabilitation concentration" and 3.55 (SD 1.04) for "improvement in nervousness".

DISCUSSION

This study aimed to assess the effect of electromechanically assisted gait training, using high-intensity gait training of 60 min for chronic stroke patients with an onset of more than 3 months. Although the results revealed that gait training with or without electromechanically assistance improved walking, the effect of electromechanical assistance was not superior to that of physiotherapy assistance. Furthermore, the improvement in walking ability was not large enough to support the use of the electromechanically assisted gait trainer instead of physiotherapy in chronic stroke patients, when considering its benefit in acute stroke patient (3). However, the patients included in this study had recovered from stroke sufficiently to ambulate with or without the assistance of another person, and they were thus candidates for use of this device compared with general chronic stroke. The change in walking ability in this study might benefit these patients both clinically and emotionally, since they had good mental functioning with a high level of desire for gait training.

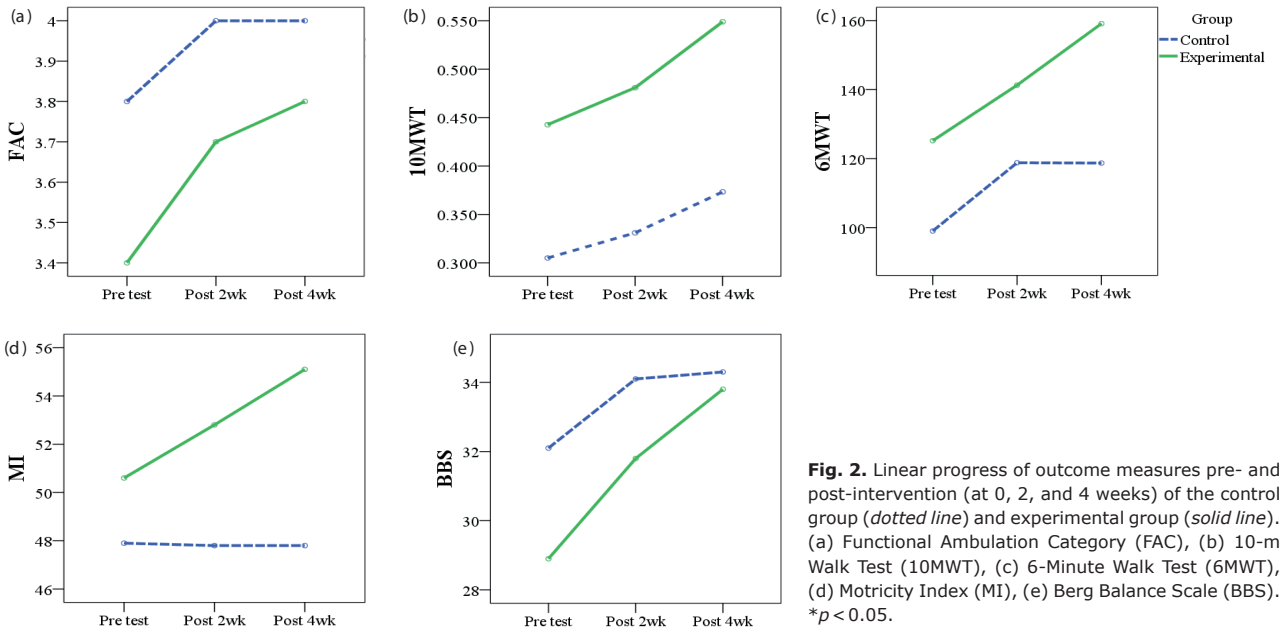

Fig. 2. Linear progress of outcome measures pre- and post-intervention (at 0, 2, and 4 weeks) of the control group (*dotted line*) and experimental group (*solid line*). (a) Functional Ambulation Category (FAC), (b) 10-m Walk Test (10MWT), (c) 6-Minute Walk Test (6MWT), (d) Motricity Index (MI), (e) Berg Balance Scale (BBS). $*p < 0.05$.

An improvement in walking ability was expected after the initial 2-week intervention, since this study provided a total of 600 min of gait training (60 min a day, 5 days a week, for 2 weeks) which was the same total duration as in the previous study (30 min a day, 5 days a week, for 4 weeks). Most outcomes showed significant improvement after the initial intervention in the control and experimental groups, but the results of gait training on walking were not superior to those of conventional physiotherapy. The mean stroke duration in this study was 600.45 days (SD 505.62) in the control group and 545 days (SD 295.94) in the experimental group. It was necessary to include the chronic patients with relatively short stroke duration, because the previous study found that the effect of electromechanically assisted gait training declined with increase in stroke duration (8).

Both groups showed statistically significant differences in 10MWT, 6MWT and BBS, after the intervention, but the differences were small and would not have clinical meaning for stroke patients. The mean difference in 10MWT after the intervention was 0.04 (SD 0.12) in the control group and 0.05 (SD 0.06) in the experimental group. However, the minimally clinically important difference (MCID) in 10MWT for stroke patients is considered to be 0.16 m/s (16). The mean difference in 6MWT was 20.91 (SD 29.78) in the control group and 22.11 (SD 20.31) in the experimental group, but the MCID in the 6MWT is 44 m (17). The mean difference in BBS was 2.10 (SD 2.19) in the control group and 2.89 (SD 3.04) in the experimental group, but MCID in BBS is 13.5 (18). Although those MCIDs were for acute stroke patients, the differences in 10MWT, 6MWT and BBS in this study were not clinically significant. Furthermore, the mean range of improvement in FAC in previous studies of various interventions was 0.3–1.0 (19–21). The mean difference in FAC in this study was 0.35 (SD 0.49) in the control group and 0.33 (SD 0.49) in the experimental group, and these differences in FAC were also considered not to be clinically significant, even though the study was performed with chronic stroke patients.

Continual improvement in gait ability after the additional intervention of 2 weeks was hypothesized, because high-intensity gait training may benefit, and electromechanically assisted gait training could provide unlimited repetition (9). However, neither primary nor secondary outcomes, except for BBS, improved further in either group. A recent study reported a change in gait ability and walking ability with electromechanically assisted gait training (Morning Walk®, Curexo, Seoul, Republic of Korea), and showed a greater improvement in lower leg muscle strength and balance in the experimental group than in the control group (22). The current study also found a continual improvement in BBS in the experimental group over time (Fig 2). Electromechanically assisted gait training, which requires repetitive tasks, can improve neuro-plasticity with a motor learning focus on reorganization of brain tissue, resulting in better balance (23). The lack of a pelvic strap on the Exowalk® allows the patient to sway the pelvis naturally with the movements of the lower limb. This symmetry and repetitive movement of the lower leg may interfere with balance, and the patient should actively maintain an upright position during gait training. This effort may

activate the patient's trunk and pelvic muscle so as to prevent falling, which might improve balance function.

This study found that Exowalk® has the same effect as traditional physical therapy for chronic stroke. Exowalk® provides a normal gait pattern for a healthy adult during walking. It provides walking simulation, and the design generates a feeling of independent walking, because most of the device components are located dorsally to the patient, who can control the speed and direction by turning a knob. This platform may motivate the patient to actively perform walking simulation during gait training for subjects with chronic stroke who can ambulate with cane or the assistance of another person. The patient satisfaction with electromechanically assisted gait training was high. The mean overall satisfaction rate was almost the same as in the previous study (4.07 (SD 0.23)) (8). However, electromechanically assisted gait training requires a high level of technical and human resources. Thus, the current study could not provide electromechanically assisted gait training at the same efficacy as traditional gait training for chronic stroke patients, and costs and time efficiency need to be taken into account.

These findings showed a linear increase in balance and a high level of satisfaction for patients after 60-min electromechanically assisted gait training. Further research is needed into the dose dependency of electromechanically assisted gait training, including a larger number of patients, since most chronic stroke patients could endure gait training of 60 min and favoured an intervention period of 4 weeks. In addition, the patients' trunk and pelvic muscle strength should be evaluated, and the mechanism of balance improvement investigated, since both muscle strength and balance underwent a linear improvement in the experimental group.

Study limitations

The patients in this study were recruited according to the inclusion criteria for use of the Exowalk® device, and hence the results are not representative of chronic stroke patients. Further research into the full effects of gait training is necessary in order to determine the clinical importance of electromechanically assisted gait training for chronic stroke patients. The sample size should have been estimated by setting the change in FAC more conservatively, since this study was designed for chronic stroke patients who had recovered sufficiently to ambulate with or without the assistance of another person. The initial intervention of 2 weeks may be too short to fully determine the effect of electromechanically assisted gait training, even though the total intervention time used in previous research was met.

Conclusion

For patients with chronic stroke who could ambulate with or without the assistance of another person, both physical therapist-assisted and electromechanically assisted gait training resulted in improved walking ability, walking speed, walking capacity, and balance after 2 weeks of gait training. Electromechanically assisted gait training with the Exowalk® was not superior to conventional physiotherapy for chronic stroke patients.

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REFERENCES

1. Bauman WA, Spungen AM, Raza M, Rothstein J, Zhang RL, Zhong YG, et al. Coronary artery disease: metabolic risk factors and latent disease in individuals with paraplegia. Mt Sinai J Med 1992; 59: 163–168.
2. Roth EJ, Merbitz C, Mroczek K, Dugan SA, Suh WW. Hemiplegic gait. Relationships between walking speed and other temporal parameters. Am J Phys Med Rehabil 1997; 76: 128–133.
3. Mehrholz J, Thomas S, Werner C, Kugler J, Pohl M, Elsner B. Electromechanical-assisted training for walking after stroke. Cochrane Database Syst Rev 2017; 5: CD006185.
4. Hornby TG, Campbell DD, Kahn JH, Demott T, Moore JL, Roth HR. Enhanced gait-related improvements after therapist- versus robotic-assisted locomotor training in subjects with chronic stroke: a randomized controlled study. Stroke 2008; 39: 1786–1792.
5. Kelley CP, Childress J, Boake C, Noser EA. Over-ground and robotic-assisted locomotor training in adults with chronic stroke: a blinded randomized clinical trial. Disabil Rehabil Assist Technol 2013; 8: 161–168.
6. Macko RF, Ivey FM, Forrester LW, Hanley D, Sorkin JD, Katzel LI, et al. Treadmill exercise rehabilitation improves ambulatory function and cardiovascular fitness in patients with chronic stroke: a randomized, controlled trial. Stroke 2005; 36: 2206–2211.
7. Bonnyaud C, Pradon D, Boudarham J, Robertson J, Vuillerme N, Roche N. Effects of gait training using a robotic constraint (Lokomat (R)) on gait kinematics and kinetics in chronic stroke patients. J Rehabil Med 2014; 46: 132–138.
8. Nam YG, Lee JW, Park JW, Lee HJ, Nam KY, Park JH, et al. Effects of electromechanical exoskeleton-assisted gait training on walking ability of stroke patients: a randomized controlled trial. Arch Phys Med Rehabil 2019; 100: 26–31.
9. Globas C, Becker C, Cerny J, Lam JM, Lindemann U, Forrester LW, et al. Chronic stroke survivors benefit from high-intensity aerobic treadmill exercise: a randomized control trial. Neurorehabil Neural Repair 2012; 26: 85–95.
10. Holden MK, Gill KM, Magliozzi MR, Nathan J, Piehl-Baker L. Clinical gait assessment in the neurologically impaired. Reliability and meaningfulness. Phys Ther 1984; 64: 35–40.

11. van Loo MA, Moseley AM, Bosman JM, de Bie RA, Hassett L. Inter-rater reliability and concurrent validity of walking speed measurement after traumatic brain injury. Clin Rehabil 2003; 17: 775–779.
12. Guyatt GH, Sullivan MJ, Thompson PJ, Fallen EL, Pugsley SO, Taylor DW, et al. The 6-minute walk: a new measure of exercise capacity in patients with chronic heart failure. Can Med Assoc J 1985; 132: 919–923.
13. Cameron D, Bohannon RW. Criterion validity of lower extremity Motricity Index scores. Clin Rehabil 2000; 14: 208–211.
14. Berg KO, Wood-Dauphinee SL, Williams JI, Maki B. Measuring balance in the elderly: validation of an instrument. Can J Public Health 1992; 83: S7–S11.
15. Watanabe H, Tanaka N, Inuta T, Saitou H, Yanagi H. Locomotion improvement using a hybrid assistive limb in recovery phase stroke patients: a randomized controlled pilot study. Arch Phys Med Rehabil 2014; 95: 2006–2012.
16. Tilson JK, Sullivan KJ, Cen SY, Rose DK, Koradia CH, Azen SP, et al. Meaningful gait speed improvement during the first 60 days poststroke: minimal clinically important difference. Phys Ther 2010; 90: 196–208.
17. Fulk GD, He Y. Minimal clinically important difference of the 6-minute walk test in people with stroke. J Neurol Phys Ther 2018; 42: 235–240.
18. MJ Song,, JH Lee, WS Shina, Minimal clinically important difference of Berg Balance Scale scores in people with acute stroke. Phys Ther Rehabil Sci 2018; 7: 102–108.
19. Pohl M, Werner C, Holzgraefe M, Kroczek G, Mehrholz J, Wingendorf I, et al. Repetitive locomotor training and physiotherapy improve walking and basic activities of daily living after stroke: a single-blind, randomized multicentre trial. Clin Rehabil 2007; 21: 17–27.
20. Hidler J, Nichols D, Pelliccio M, Brady K, Campbell D, Jennifer H, et al. Multicenter randomized clinical trial evaluating the effectiveness of the Lokomat in subacute stroke. Neurorehabil Neural Repair 2009; 23: 5–13.
21. Yoshikawa K, Mizukami M, Kawamoto H, Sano A, Koseki K, Sano K, et al. Gait training with Hybrid Assistive Limb enhances the gait functions in subacute stroke patients: a pilot study. NeuroRehabilitation 2017; 40: 87–97.
22. Kim J, Kim DY, Chun MH, Kim SW, Jeon HR, Hwang CH, et al. Effects of robot- (Morning Walk) assisted gait training for patients after stroke: a randomized controlled trial. Clin Rehabil 2019; 33: 516–523.
23. Kwakkel G, Kollen B, Lindeman E. Understanding the pattern of functional recovery after stroke: facts and theories. Restor Neurol Neurosci 2004; 22: 281–299.