ORIGINAL ARTICLE

Effectiveness of Gait Training Using an Electromechanical Gait Trainer, With and Without Functional Electric Stimulation, in Subacute Stroke: A Randomized Controlled Trial

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ABSTRACT. Tong RK, Ng MF, Li LS. Effectiveness of gait training using an electromechanical gait trainer, with and without functional electric stimulation, in subacute stroke: a randomized controlled trial. Arch Phys Med Rehabil 2006;87: 1298-304.

Objective: To compare the therapeutic effects of conventional gait training (CGT), gait training using an electromechanical gait trainer (EGT), and gait training using an electromechanical gait trainer with functional electric stimulation (EGT-FES) in people with subacute stroke.

Design: Nonblinded randomized controlled trial.

Setting: Rehabilitation hospital for adults.

Participants: Fifty patients were recruited within 6 weeks after stroke onset; 46 of these completed the 4-week training period.

Intervention: Participants were randomly assigned to 1 of 3 gait intervention groups: CGT, EGT, or EGT-FES. The experimental intervention was a 20-minute session per day, 5 days a week (weekdays) for 4 weeks. In addition, all participants received their 40-minute sessions of regular physical therapy every weekday as part of their treatment by the hospital.

Main Outcome Measures: Five-meter walking speed test, Elderly Mobility Scale (EMS), Berg Balance Scale, Functional Ambulatory Category (FAC), Motricity Index leg subscale, FIM instrument score, and Barthel Index.

Results: The EGT and EGT-FES groups had statistically significantly more improvement than the CGT group in the 5-m walking speed test (CGT vs EGT, $P=.011$; CGT vs EGT-FES, $P=.001$), Motricity Index (CGT vs EGT-FES, $P=.011$), EMS (CGT vs EGT, $P=.006$; CGT vs EGT-FES, $P=.009$), and FAC (CGT vs EGT, $P=.005$; CGT vs EGT-FES, $P=.002$) after the 4 weeks of training. No statistically significant differences were found between the EGT and EGT-FES groups in all outcome measures.

Conclusions: In this sample with subacute stroke, participants who trained on the electromechanical gait trainer with body-weight support, with or without FES, had a faster gait, better mobility, and improvement in functional ambulation than participants who underwent conventional gait training. Future studies with assessor blinding and larger sample sizes are warranted.

Key Words: Electric stimulation; Exercise; Gait; Rehabilitation; Stroke.

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ACCORDING TO THE WORLD Health Organization, stroke is the third most common cause of mortality in developed countries; each year, 15 million people suffer a stroke.[1] Stroke is also a leading cause of serious, long-term disabilities, including loss of motor, sensory, or cognitive functions.[2] Gait in people with hemiplegic stroke can be greatly disrupted. More than half of people with stroke in the acute phase are not able to walk, and walking impairments are still present 3 months later.[3,4] Effective gait training is among the goals of neurologic rehabilitation after stroke. Early physical therapy (PT) intervention in gait training has been generally recognized as beneficial. Friedman[5] showed that the sooner a stroke survivor attained the ability to ambulate, the more likely independent walking would be re-established.

In several studies,[6-8] intensive gait-focused training in the early stage after stroke has been shown to be effective. These studies indicated that repetitive task–oriented exercise programs improved functional capabilities in people with neurologic deficits. However, conventional gait training required manual support and guidance from physical therapists in patients with severely impaired motor control and postural control. Therefore, body-weight–supported (BWS) treadmill training was developed to support a percentage of body weight to allow safe weight shifting and stepping. In subjects with subacute stoke (<6wk poststroke), the studies of da Cunha-Filho et al[9] and Visintin and Barbeau[10] showed that BWS treadmill ambulation training was a feasible and safe technique and had a promising role in gait training. A Cochrane systematic review[11] surveyed 15 trials (622 participants) and found there were no statistically significant differences between treadmill training with or without body-weight support and other types of interventions for walking speed or dependence. The review also noted that some studies suggested that treadmill training with body-weight support may be more effective than treadmill training without body-weight support, whereas others found that treadmill training plus task-oriented exercises may be more effective than sham exercises. Treadmill training may also have several disadvantages. Kosak and Reding[12] stated that therapists preferred conventional overground gait training with aggressive bracing rather than treadmill walking. This is because treadmill walking can require manual guidance by 2 or more therapists to advance the paretic limb and control trunk movements.

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To enable wheelchair-bound people with stroke to practice gait with minimal assistance, an electromechanical gait trainer (GT II)[a] was designed by Hesse et al.[13] In case reports[13,14] and a randomized crossover study,[15] the designers showed that the electromechanical gait trainer was an effective alternative to treadmill therapy with partial body-weight support in intense gait rehabilitation after stroke for gait ability and walking velocity. Although they found no difference in effectiveness between BWS treadmill training and using the BWS gait trainer, they stated that the gait trainer helped to reduce manual guidance from the therapist and provided a highly symmetric, more independent gait practice for the nonambulatory participants.

Functional electric stimulation (FES) could be combined with the gait trainer in a treatment protocol to generate active movement from paralyzed muscles. FES has major therapeutic benefits in the early phase of gait rehabilitation, facilitating people with brain injury to achieve a better functional result in a shorter period of time.[16,17] Repetitive active or passive practice of movements identical or similar to those in normal gait may enhance motor learning and recovery.[18,19] Separately, the use of an electromechanical gait trainer and FES have been shown to have positive therapeutic effects during poststroke rehabilitation. In a study by Peurala et al,[20] the 2 techniques were applied simultaneously on participants with chronic stroke to compare the use of the gait trainer, gait trainer with FES, and training consisting of overground walking. The results showed a faster gait after 3 weeks of training for all 3 groups, and no difference was found between the groups.

The therapeutic effect of FES coupled with gait-trainer intervention has not been investigated in people with subacute stroke (<6wk poststroke). The purpose of this study was to compare the effectiveness of 3 gait-training interventions in subacute stroke: an electromechanical gait trainer (EGT), an electromechanical gait trainer with FES (EGT-FES), and conventional gait training (CGT). Outcomes were to be assessed at baseline, midtraining (after 2wk), and at the end of training (after 4wk). The outcome measures included 5-m walking speed, Elderly Mobility Scale (EMS), Berg Balance Scale (BBS), Functional Ambulatory Category (FAC), Motricity Index leg subscale, FIM instrument, and Barthel Index.

METHODS

Participants

All people with a first stroke who were admitted to the inpatient unit of a rehabilitation hospital in Hong Kong were screened from October 2003 to December 2004 as possible participants. Inclusion criteria for this study were (1) a diagnosis of ischemic brain injury or intracerebral hemorrhage shown by magnetic resonance imaging or computed tomography less than 6 weeks after the onset of stroke; (2) sufficient cognition to follow simple instructions and understand the content and purpose of the study (Mini-Mental State Examination score >21)[21]; (3) the ability to stand upright, supported or unsupported, for 1 minute; (4) significant gait deficit (FAC score <3)[22]; and (5) no skin allergy to electric stimulation.

Patients were excluded if they had (1) a recurrent stroke or other neurologic deficit that would affect ambulation ability; (2) any additional medical or psychologic condition that would affect their ability to comply with the study protocol—for example, a significant orthopedic or chronic pain condition, major poststroke depression, history of potentially fatal cardiac arrhythmias, implanted cardiac pacemaker, Parkinson's disease, or clinical signs of newly developed thrombosis of the thigh; (3) aphasia with an inability to follow 2 consecutive step commands or a cognitive deficit; or (4) severe hip, knee, or ankle contracture that would preclude passive range of motion of the leg.

All participants gave informed consent through methods approved by the university and the hospital's institutional review board. The study protocol and procedures were also approved by the university's and the hospital's ethics committees. The study design was a randomized controlled trial of 4 weeks. Randomization was done by computer-generated random numbers. Each participant was assigned to a group according to the list of generated random numbers after the baseline assessment.

Measurements

Stroke patients who met all of the selection criteria during screening were allowed to participate in the study. All assessments during the study period, including the screening of patients, were performed by a single research physical therapist. Participants were assessed at the PT department of the hospital. Neither participants nor the research physical therapist were blinded to the treatment because it was impractical to do so. The 3 groups were compared in terms of general mobility, gait ability, overground walking speed, and motor impairment.

The EMS has proven to be a valid scale with good interrater reliability (Spearman correlation coefficient ρ=.88) that can be readily applied during daily clinical work[23] and hence was used in this study to detect improvement in mobility. This is a 20-point scale assessing 7 elements of mobility, incorporating gait speed and functional reach.

Balance was assessed by the BBS. This has excellent interrater and intrarater reliability for elderly subjects[24] and for subjects with acute stroke (interrater intraclass correlation coefficient model 2,1 [$ICC_{2,1}$]=.98; intrarater $ICC_{2,1}$=.97).[25] It can detect change in balance of people with acute stroke.[26] Ambulatory ability was rated by using the FAC scale.[22,27] Participants were rated according to the personnel support needed for gait, regardless of use of an assistive device, according to a 6-point scale. The interrater reliability of the FAC scale has been assessed as .85.[27]

The leg subscale of the Motricity Index evaluates 3 joint movements (hip flexion, knee extension, ankle dorsiflexion) and was used to analyze motor loss of the affected lower limb after stroke.[28] It is sensitive to motor recovery after stroke. This measure has good reliability, with a Cronbach α of .77.[29] The Pearson correlations between the Motricity Index and the isometric strength from a dynamometer are good to excellent (r range, .78–.91).[29]

Overground walking speed was measured by timing a 5-m walk with a stopwatch. The speed was calculated in meters per second. The test-retest variability in the 5-m walk for subjects after stroke (2–6y) was measured by calculating the maximum difference between any 2 readings as a percentage of the lowest time. The results showed that it was reliable on test-retest, with 95% of subjects' speed within 25% of the lowest time.[22] The Pearson correlations between the 5-m and the 10-m walk and between the walks done in the first and second trials were good (r range, .95–.99).[22] Each participant was asked to walk as fast as possible on a walkway for 5m using a walking aid if necessary. No other assistance was given, and no orthoses were allowed for the walk. If a walking aid was used for the first timed walk, it was also used for each subsequent timed walk. The walking speed was regarded as 0.0m/s if a participant required manual assistance from a therapist to walk or was unable to finish the whole 5m. Walking speed was measured from 2 trials, with the average of the 2 speeds recorded as the final gait speed of each participant. The 5-m walking test was designed for acute stroke survivors by da Cunha-Filho et al.[9] The short distance enables people with relatively poor

aerobic fitness, balance, and lower-limb strength to complete the test more readily.

The FIM instrument[30] and Barthel Index[31] were used to provide a comprehensive view of overall function. The FIM measures not only self-care activities and mobility but also communication and cognitive functions. It is well validated, the interrater reliability is high, and the Cronbach α was .88 to .91 in people with stroke.[32,33] The Barthel Index is a validated and widely used instrument to measure dependency in activities of daily living, and the Cronbach α for reliability has been shown to be .84 to .85 in people with stroke.[32,33] The FIM and Barthel Index were performed before and after the 4 weeks of intervention by nurses who were blinded in this study.

Interventions

All participants received their regular weekday 40-minute PT sessions and 1.5-hour multidisciplinary treatments, which consisted of occupational therapy, speech therapy, and psychology throughout the study period. All participants participated in the 4 weeks of training during the study period in the same hospital. The study consisted of 1 training session per weekday during the 4 weeks. To prevent contamination FES was not allowed to be used during the regular PT sessions. Each participant of the experimental groups (EGT, EGT-FES) underwent gait training with BWS by the electromechanical gait trainer, and each participant of the EGT-FES group also received FES to the paretic lower limb during the gait training. Participants in the CGT group underwent overground walking for their gait training. Figure 1 shows the training program details for each group.

The CGT group received conventional PT gait training based on the principles of proprioceptive neuromuscular facilitation and Bobath concepts.[34,35] It was conducted by each subject's own hospital physical therapist, who administered his/her regular rehabilitation. The aim of the Bobath treatment is to improve a person's posture and movement.[34] Through specialized handling techniques, muscle stiffness may be reduced, muscle control against gravity may be increased, and fluctuating muscle activity may be stabilized. Participants could undergo the overground walking gait training with or without a walking aid or orthoses and with or without manual assistance depending on their abilities. The conventional rehabilitation provided by the hospital was tailored to each patient's needs, focusing on his/her particular impairments and disabilities, and therefore each patient received varying degrees of specific therapies. Each session of conventional treatment was documented, with each type of activity and its duration recorded.

The EGT group used the electromechanical gait trainer. Each gait-training session was to last 20 minutes with an optional rest break (of 1–3min) after the first 10 minutes. The electromechanical gait trainer simulated a normal gait cycle in a symmetric manner with a ratio of 60% to 40% between the stance and swing phases. The gait trainer also supported part or all of each person's body weight via a harness attached by ropes to a gear system, according to the participant's ability to lift his/her foot during the swing phase.[13] If partial or full body weight needed to be supported, the participant's physical therapist manually tugged on the system's pulley. Each harnessed participant was positioned over the gait trainer's footplates, to which his/her feet were secured. The propulsion of the footplates helped with the movement of the feet and legs during both the stance and swing phases. Step length and walking speed could be adjusted from 34 to 48cm and from 0 to .70m/s, respectively. Other training variables included the percentage of body-weight support provided and each participant's use of the gait trainer's front horizontal bar for hand

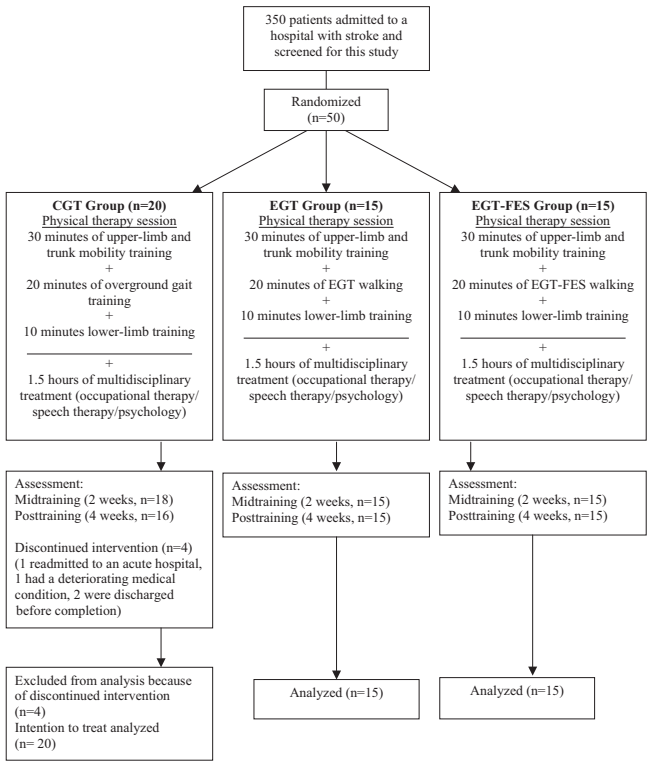

Fig 1. CONSORT flowchart of the training programs.

support to increase stability. The target training velocity was relatively slow (.20–.60m/s) to avoid overexertion of participants.[15] Body weight was partially supported to compensate for the paresis of the affected lower limb, and this support was reduced as soon as a participant could take his/her full body weight. The physical therapist would give assistance during gait training to help with each participant's knee extension and would give verbal cueing to facilitate each participant's head and trunk extension and midline awareness when the participant leaned to the paretic side or increased trunk kyphosis. Participants who achieved adequate balance on the gait trainer were encouraged not to use the horizontal bar for hand support to further train their balance and postural control of the lower limbs.

Participants in the EGT-FES group underwent the same interventions as the EGT group, except for the additional feature of FES during their gait-trainer sessions. Each participant received electric stimulation modalities, including waveform and pulse width with fixed values. The stimulation intensity was adjusted by the supervising physical therapist according to how successful the correct limb movement was elicited and to each participant's comfort threshold (table 1). A pair of self-adhesive electrodes (Platinum Blue 901220; size, 5×5cm square electrode)[b] was attached to each participant's quadriceps on the paretic side and stimulated in the stance phase to facilitate weight acceptance. Another pair of electrodes (Ultraflex 881150; size, 3.8mm round electrode)[b] was attached to each participant's common peroneal nerve on the paretic side and stimulated during the swing phase to generate ankle dorsiflexion. The stimulation sites were determined beforehand, with each participant in a seated position, and when a correct functional response was obtained—that is, the knee extended when the quadriceps were stimulated and the ankle dorsiflexed when the peroneal nerve was stimulated. Stimulation intensity was then raised until the functional movement over the desired

Table 1: FES Parameters Set During EGT-FES Training Sessions

Parameters	Quadriceps Muscle	Common Peroneal Nerve
Stimulation phase	Stance phase	Swing phase
Pulse width (μs)	400	400
Rising edge ramp (s)	0.3	0.3
Falling edge ramp (s)	0.3	0.3
Waveform	Rectangular pulse	Rectangular pulse
Extension (s)	0.1	0.1
Current (mA)	50–85	50–70

range of motion (knee angle $<20°$ from full extension, ankle angle in neutral position or dorsiflexed position) was achieved with comfort for each participant; then the sites were marked on the skin with nonconductive, semipermanent ink. Electrodes were then attached to the same marked sites throughout the 4-week intervention period. Before each participant's first training session, intermittent stimulation was tested continuously on the participant for at least 10 minutes to rule out skin allergy. Two connection wires linked the gait-trainer control box and the 2 single-channel FES stimulators[c] that were developed to synchronize the gait phase and the stimulation timing for the quadriceps and the common peroneal nerve.

Blood pressure was monitored continuously during each gait-training session to safeguard participants' health. Set criteria for cessation of intervention included if a participant reported having a headache, confusion, or onset of angina and if an excessive change in blood pressure was detected. A rest break was given if a participant requested a rest because of fatigue. A daily log sheet was kept to record gait speed generated by the gait trainer, percentage of body-weight support from the harness, total walking distance, and number of rest breaks during training. If a participant missed more than 3 scheduled sessions because of medical reasons or an inability to participate, he/she was withdrawn from the study.

These interventions have not been investigated in the subacute stroke population; therefore, parameters for sample size calculation were not available. We chose a sample size of 50, because this number of participants could be reasonably recruited with the available resources.

Statistical Analysis

Difference scores of all outcome measures were calculated from posttreatment scores minus pretreatment scores to evaluate the effect of gait training. Intention-to-treat analysis was used for all of the recruited participants. Data that were missing because participants had withdrawn from the study were replaced by the last scores obtained. SPSS[d] was used to compare the differences in outcome measurements. For nonparametric variables, the Friedman test for repeated measurements was used to compare the 3 assessments within a group, and the Wilcoxon signed-rank test was used to perform pairwise multiple comparisons. The Kruskal-Wallis test was used for comparison between the 3 groups (CGT, EGT, EGT-FES). If a significant difference was found between any of the 3 groups, the Mann-Whitney *U* test was used to perform multiple comparisons between the 2 groups. For continuous variables, 1-way analysis of variance was used to determine differences in the clinical outcome measures across the 3 groups. An α level of *P* less than .05 was assumed to be significant, and the Bonferroni adjustment was then used for post hoc comparison. No correction for multiple statistical testing was performed.

RESULTS

Fifty hemiplegic patients with subacute stroke met the inclusion criteria and participated. The flow diagram of the study is given in figure 1. Four of the 50 participants who were admitted to the study did not complete the protocol (1 participant was readmitted to an acute care hospital, 1 had a deteriorating medical condition, 2 were discharged from the hospital before completion of the 4-wk intervention period), and they were from the CGT group. As a result, 46 participants completed the entire study protocol: 16 in the CGT group, 15 in the EGT group, and 15 in the EGT-FES group.

Table 2 shows the clinical characteristics of the groups, and table 3 shows the pretraining, midtraining, and posttraining results. There may have been an important difference in the mean ages of the groups, with the control group being older. There were no clinically relevant differences between the 3 groups on the outcome measures at baseline. All groups showed statistically significant improvements from baseline to posttraining.

For between-group differences, there were statistically significant differences between the non–gait-trainer CGT group and the 2 gait-trainer groups (EGT, EGT-FES). The effect of using the electromechanical gait trainer showed up after 2 weeks of training based on FAC (CGT vs EGT, $P=.001$; CGT vs EGT-FES, $P=.004$) and walking speed (CGT vs EGT-FES, $P=.023$). At the end of the fourth week, further improvements were observed in the FAC (CGT vs EGT, $P=.005$; CGT vs EGT-FES, $P=.002$), walking speed (CGT vs EGT, $P=.011$; CGT vs EGT-FES, $P=.001$), EMS (CGT vs EGT, $P=.006$; CGT vs EGT-FES, $P=.009$), and Motricity Index (CGT vs EGT-FES, $P=.011$). These differences were clinically important for the EMS, FAC, and walking speed. For the Motricity Index, only the difference between the CGT and the FES groups was clinically important. No statistically significant differences were found in BBS, Barthel Index, or FIM. Of these, the difference between the CGT and the gait-trainer groups may have been clinically important for the BBS.

Although no significant differences were discovered in all outcome measures between the 2 gait-trainer groups (EGT, EGT-FES), effect size calculations showed a medium strength difference in overground walking speed (effect size, .55) and FAC (effect size, .55) in favor of the EGT-FES group.

Table 2: Baseline Demographic Characteristics of the CGT, EGT, and EGT-FES Groups

Variables	CGT Group (n=20)	EGT Group (n=15)	EGT-FES Group (n=15)
Age (y)*	71.4±14.0, 73.5 (34–86), 4	66.1±9.9, 68.0 (45–80), 4	61.8±10.8, 65.0 (42–75), 7
Sex (male/female)	12/8	9/6	10/5
Etiology (ischemic/hemorrhage)	17/3	11/4	11/4
Side of hemiplegia (right/left)	7/13	7/8	6/9
Time poststroke before recruitment (wk)†	2.7±1.2	2.7±1.3	2.3±1.0

*Values are mean ± standard deviation (SD), median (range), and number of participants with age <65y.
†Values are mean ± SD.

Table 3: Comparison of Pretraining and Posttraining Outcome Measures Within Groups and Between Groups

Measures	CGT (n=20)			EGT (n=15)			EGT-FES (n=15)			P*	
	Pretraining	Midtraining (Week 2)	Posttraining (Week 4)	Pretraining	Midtraining (Week 2)	Posttraining (Week 4)	Pretraining	Midtraining (Week 2)	Posttraining (Week 4)	Midtraining – Pretraining	Posttraining – Pretraining
Motricity Index leg score†	53.0 (21)	67.5 (39)	73.0 (36)	48.0 (21)	59.0 (28)	76.0 (22)	43.0 (26)	64.0 (30)	84.0 (33)	.516	.046‡
EMS†	4.5 (5)	8.0 (8)	12.5 (10)	6.0 (5)	10.0 (4)	17.0 (3)	6.0 (5)	10.0 (10)	19.0 (4)	.864	.007‡
BBS†	9.5 (11)	16.0 (21)	30.0 (27)	12.0 (12)	28.0 (17)	40.0 (12)	12.0 (23)	18.0 (28)	42.0 (17)	.865	.194
FAC†	1.0 (1)	2.0 (1)	2.0 (2)	1.0 (0)	3.0 (1)	3.0 (1)	1.0 (0)	2.0 (1)	4.0 (1)	.001‡	.001‡
5-m walking speed (m/s)	.00±.00	.07±.13	.24±.30	.00±.00	.16±.17	.47±.21	.00±.00	.17±.26	.63±.37	.035‡	.001‡
Barthel Index†	42.5 (28)	NA	73.0 (32.5)	54.0 (18)	NA	84.0 (19)	56.0 (20)	NA	91.0 (17)	NA	.084
FIM instrument†	66.5 (18)	NA	89.5 (26.5)	56.0 (20)	NA	91.0 (17)	78.0 (16)	NA	107.0 (16)	NA	.191

NOTE. Values are mean ± SD unless otherwise indicated.
Abbreviation: NA, not applicable.
*Significance level of change scores between 3 groups.
†Median (interquartile range); nonparametric test was used.
‡Significant differences were shown.

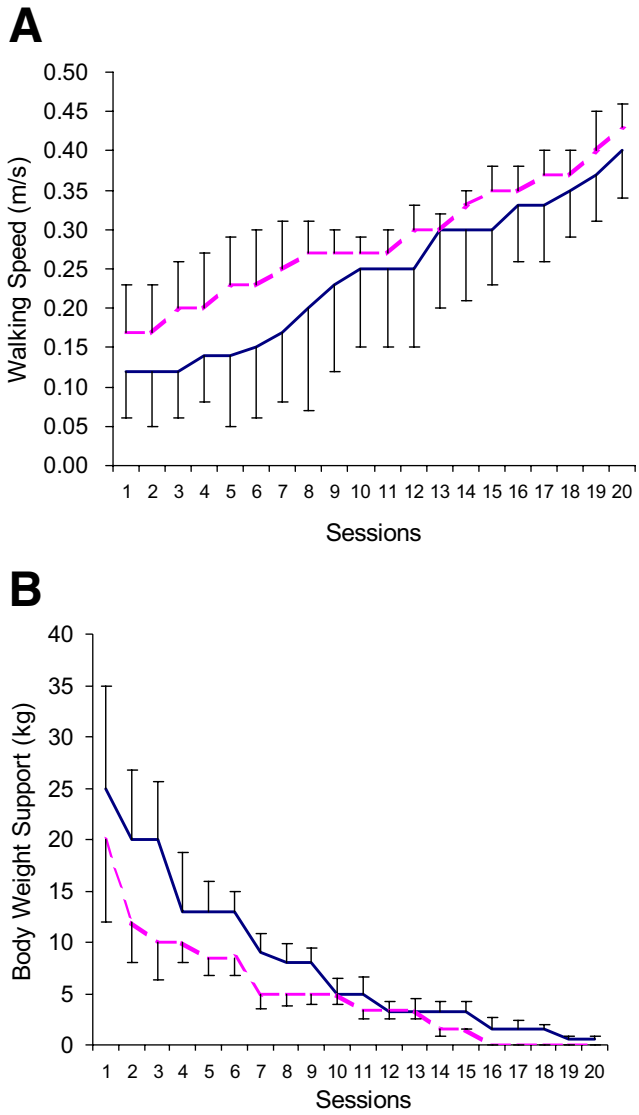

Fig 2. (A) Mean walking speed in the gait trainer and (B) mean body-weight support from sessions 1 to 20 for the EGT group (solid line) and the EGT-FES group (dotted line). The vertical bars represent the standard deviation.

On the first day of the gait-trainer intervention, the mean walking speed in the gait trainer of the EGT group was .11±.06m/s, and for the EGT-FES group it was .17±.04m/s. The mean speeds in the gait trainer gradually increased to .39±.11m/s for both groups by the end of the 4 weeks of training (see fig 2). Body-weight support commenced in the EGT group at 25%±7.2%, whereas for the EGT-FES group it was 20%±6.3%. Body-weight support gradually decreased in the EGT group to 0.5%±0.9% by the end of the 4 weeks of training, whereas most participants in the EGT-FES group could walk without any body-weight support by the gait trainer after session 16 (see fig 2). Most participants in the EGT and EGT-FES groups completed all of the 20-minute sessions of gait training; from the 2 groups, a total of 6 participants required 1 or 2 rest breaks during the sessions. Adverse side effects from the training and overexertion of participants did not occur.

DISCUSSION

All participants in all 3 groups showed improvement in terms of lower-limb strength, mobility, ambulation ability, walking speed, and activities of daily living during the 4-week intervention period. The results of this randomized clinical trial indicated that gait training using the electromechanical gait trainer with and without FES was more effective than conventional overground gait training. In our study, participants in the EGT and EGT-FES groups improved significantly in EMS, walking speed, muscle strength, and FAC versus participants in the CGT group.

Gait rehabilitation for people with stroke should be goal-directed. The BWS electromechanical gait trainer provided active stimulation of the stance and swing phases in a physiologic manner. The body weight of participants was partially supported to compensate for the paresis of the affected lower limb. This was considered among the major advantages of using a BWS system for early rehabilitation, in that a participant's body weight could be supported as needed to help the participant establish an upright position for taking steps while also providing task-specific, repetitive walking training.[13] The gait trainer enabled our participants to walk for 500 to 1000 repetitions each session compared with conventional gait training for only 50 to 100 steps with each PT session. Nevertheless, it should be noted that there are differences in the activation patterns of some muscles during mechanically assisted walking compared with a natural gait. The study of a robotic device (Lokomat)[36] stated that reducing the degrees of freedom through which the person is allowed to move caused a decrease in muscle activation (electromyographic) patterns from what is commonly observed in ranges of normal walking.

Peurala et al[20] studied people with chronic stroke who underwent a 20-minute training session every weekday for 3 weeks. The results did not show any difference in performance between participants who were assigned conventional overground walking training and those who used the gait trainer with or without FES. This might be due to the fact that participants were in a chronic phase of stroke, and most participants might not have been severely impaired in walking. Peurala reported that although the motor recovery of participants in the 3 groups was similar, the gait trainer allowed more repetitions of steps and a longer walking distance per session than conventional overground gait training. It seems that during the subacute phase of stroke, intensive rehabilitation on a gait trainer is more effective than during the chronic state of stroke.

In our study, FES was used to stimulate the quadriceps and the common peroneal nerve in participants in the EGT-FES group. The EGT-FES group had statistically significantly more improvement than the CGT group, but there was no statistically significant difference between the CGT and the EGT groups in the Motricity Index at the end of the 4 weeks or in the walking speed after 2 weeks. This indicated that FES combined with EGT could hasten improvement in muscle strength and walking speed more effectively than EGT alone or conventional gait training. Reports from Waters[37] and Burridge[38] and colleagues stated that there was a short-lasting or long-lasting carry-over effect after using FES. It was proposed that FES potentially provides an artificial way of ensuring synchronized presynaptic and postsynaptic activity in the affected population of anterior horn cells, as long as FES is coupled with simultaneous voluntary effort by the participant, so that the combination would activate the residual pyramidal tract.[18] In other words, FES might improve the fitness and strength of the paralyzed motor units of people with stroke who still have voluntary control. Hesse et al[39] found that a combined therapy of treadmill gait training and FES produced a positive training effect compared with either treadmill training or FES alone. The improvement in outcome measures in the EGT and EGT-FES groups in our study did not show statistically significant differences between these 2 groups. Although a gait trainer helps with the movement of the feet and legs during the stance and swing phases and with assisting in weight shifting by increasing the stability of the center of mass, a gait trainer is unable to provide knee control during weight bearing or provide ankle dorsiflexion and knee flexion during the swing phase of the paretic limb.[14] The stance-phase motor tasks could therefore be more effectively assisted by FES-induced muscle activations, which also reduce the need for continuous manual guidance by a physical therapist during the gait-trainer exercise. EGT-FES participants also reported that they were willing to put weight on the paretic limb, because they believed that the induced contraction by the FES brought extra strength to the leg during the single-leg stance phase. The EGT-FES group had less mean body-weight support and a faster mean walking speed than the EGT group during gait-trainer training sessions (see fig 2). Moreover, they also received cues from the tingling sensation of FES to straighten the knee and flex the knee during the gait cycle, which encouraged them to actively participate in the training process. By doing so, they could gain a more meaningful and functional therapeutic effect from electric stimulation instead of passively letting their paralyzed muscles be stimulated electrically during conventional treatment in a seated position.

However, no significant difference was found between the 2 treatment groups. The effect size calculations showed that a medium strength difference was found in the overground walking speed and FAC. The effect size differences suggest that a larger sample size would have possibly produced a statistically significant effect. Another reason may be an insufficient number of stimulation sites on each participant in the EGT-FES group. A study by Daly et al[40] showed that the more muscles stimulated by intramuscular electrodes, the better the improvement in gait. More paretic muscle groups (eg, plantarflexors, knee flexors, hip extensors) could be stimulated using intramuscular electrodes in EGT-FES groups in future studies.

There were several limitations to our study. Nonblinding of the outcome assessors may have resulted in bias, and we did not adjust for multiple statistical testing. Even with a Bonferroni adjustment for tests on 7 outcomes, the EMS, FAC, and 5-m walking speed would still be statistically significant. The age of the control group participants was slightly higher than that of the gait-trainer groups. In future studies, larger sample sizes are needed to improve the success of randomization for balancing groups and to detect clinically important differences between the gait-trainer groups with and without FES. In addition, future research should include a follow-up evaluation with blinded outcome assessors.

CONCLUSIONS

Participants who underwent 4 weeks of gait training using an electromechanical gait trainer alone or combined with FES had significantly greater improvement in mobility, functional ambulation, and walking speed compared with participants who underwent conventional overground gait training. A BWS system could enable nonambulatory people with subacute stroke to receive more effective, early intensive gait training. There could be a benefit from shifting the rehabilitation paradigm from neurodevelopmental therapy to task-specific training, with the electromechanical gait trainer being one of a number of strategies that could be used. Our research supports the development of further studies using larger samples and rigorous methodology to reach a more confident conclusion about this method of rehabilitation.

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References

1. Mackay J, Mensah G. The atlas of heart disease and stroke. Part three: the burden. World Health Organization. Available at: http://www.who.int/cardiovascular_diseases/resources/atlas/en/. Accessed June 30, 2006.
2. Hajek VE, Gagnon S, Ruderman JE. Cognitive and functional assessment of stroke patients: an analysis of their relation. Arch Phys Med Rehabil 1997;78:1331-7.
3. Clifford J. Managing disability from stroke. Can Fam Physician 1986;32:605-14.
4. Wade DT, Wood VA, Heller A. Walking after stroke: measurement and recovery over the first three months. Scand J Rehabil Med 1987;19:25-30.
5. Friedman PJ. Gait recovery after hemiplegic stroke. Int Disabil Stud 1990;12:119-22.
6. Hesse S, Bertelt C, Jahnke MT, et al. Treadmill training with partial body weight support compared with physiotherapy in nonambulatory hemiparetic patients. Stroke 1995;26:976-81.
7. Richards CL, Malouin F, Wood-Dauphinee S, Williams JI, Bouchard JP, Brunet D. Task-specific PT for optimization of gait recovery in acute stroke patients. Arch Phys Med Rehabil 1993;74:612-20.
8. Visintin M, Barbeau H, Korner-Bitensky N, Mayo NE. A new approach to retrain gait in stroke patients through body weight support and treadmill stimulation. Stroke 1998;29:1122-8.
9. da Cunha-Filho TI, Lim PA, Qureshy H, Henson H, Monga T, Protas EJ. Gait outcomes after acute stroke rehabilitation with supported treadmill ambulation training: a randomized controlled pilot study. Arch Phys Med Rehabil 2002;83:1258-65.
10. Visintin M, Barbeau H. The effects of parallel bars, body weight support and speed on the modulation of the locomotor pattern of spastic paretic gait. A preliminary communication. Paraplegia 1994;32:540-53.
11. Moseley AM, Stark A, Cameron ID, Pollock A. Treadmill training and body weight support for walking after stroke. Cochrane Database Syst Rev 2005;(4):CD002840.
12. Kosak MC, Reding MJ. Comparison of partial body weight-supported treadmill gait training versus aggressive bracing assisted walking post stroke. Neurorehabil Neural Repair 2000;14:13-9.
13. Hesse S, Uhlenbrock D, Werner C, Bardeleben A. A mechanized gait trainer for restoring gait in nonambulatory subjects. Arch Phys Med Rehabil 2000;81:1158-61.
14. Hesse S, Uhlenbrock D. A mechanized gait trainer for restoration of gait. J Rehabil Res Dev 2000;37:701-8.
15. Werner C, Von Frankenberg S, Treig T, Konrad M, Hesse S. Treadmill training with partial body weight support and an electromechanical gait trainer for restoration of gait in subacute stroke patients: a randomized crossover study. Stroke 2002;33:2895-901.
16. Malezic M, Kljajic M, Acimovic-Janezic R, Gros N, Krajnik J, Stanic U. Therapeutic effects of multisite electric stimulation of gait in motor-disabled patients. Arch Phys Med Rehabil 1987;68:553-60.
17. Kralj A, Acimovic R, Stanic U. Enhancement of hemiplegic patient rehabilitation by means of functional electrical stimulation. Prosthet Orthot Int 1993;17:107-14.
18. Rushton DN. Functional electrical simulation and rehabilitation—an hypothesis. Med Eng Phys 2003;25:75-8.
19. Hayashi S, Shimura K, Kasai T. Rapid plastic changes of human primary motor cortex with repetitive motor practice and transcranial magnetic stimulation. Percept Motor Skills 2005;101:575-86.
20. Peurala SH, Tarkka IM, Pitkanen K, Sivenius J. The effectiveness of body weight-supported gait training and floor walking in patients with chronic stroke. Arch Phys Med Rehabil 2005;86:1557-64.
21. Tombaugh TN, McIntyre NJ. The Mini-Mental State Examination: a comprehensive review. J Am Geriatr Soc 1992;40:922-35.
22. Collen FM, Wade DT, Gradshaw CM. Mobility after stroke: reliability of measures of impairment and disability. Int Disabil Stud 1990;12:6-9.
23. Prosser L, Canby A. Further validation of the Elderly Mobility Scale for measurement of mobility of hospitalized elderly people. Clin Rehabil 1997;11:338-43.
24. Thorbahn L, Newton R. Use of the Berg Balance Test to predict falls in elderly persons. Phys Ther 1996;76:567-83.
25. Berg K, Wood-Dauphinee S, Williams JI, Maki B. Measuring balance in the elderly: preliminary development of an instrument. Physiother Can 1989;41:304-11.
26. Wood-Dauphinee S, Berg K, Bravo G, Williams JI. The balance scale: responsiveness to clinically meaningful changes. Can J Rehabil 1997;10:35-50.
27. Stevenson TJ. Using impairment inventory scores to determine ambulation status in individuals with stroke. Physiother Can 1999;51:168-74.
28. Demeurisse G, Demol O, Robaye E. Motor evaluation in vascular hemiplegia. Eur Neurol 1980;19:382-9.
29. Cameron D, Bohannon RW. Criterion validity of lower extremity Motricity Index scores. Clin Rehabil 2000;14:208-11.
30. Keith RA, Granger CV, Hamilton BB, Sherwin FS. The Functional Independence Measure: a new tool for rehabilitation. Adv Clin Rehabil 1987;1:6-18.
31. Viosca E, Lafuente R, Martinez JL, Almagro PL, Gracia A, Gonzalez C. Walking recovery after an acute stroke: assessment with a new functional classification and the Barthel Index. Arch Phys Med Rehabil 2005;86:1239-44.
32. Hsueh IP, Lin JH, Jeng JS, Hsieh CL. Comparison of the psychometric characteristics of the Functional Independence Measure, 5 Item Barthel Index, and 10 Item Barthel Index in patients with stroke. J Neurol Neurosurg Psychiatry 2002;73:188-90.
33. Hamilton BB, Laughlin JA, Fiedler RC, Granger CV. Interrater reliability of the 7-level Functional Independence Measure (FIM). Scand J Rehabil Med 1994;26:115-9.
34. Lennon S. Gait re-education based on the Bobath concept in two patients with hemiplegia following stroke. Phys Ther 2001;81:924-35.
35. Wang RY. Effect of proprioceptive neuromuscular facilitation on the gait of patients with hemiplegia of long and short duration. Phys Ther 1994;74:1108-15.
36. Hidler JM, Wall AE. Alterations in muscle activation patterns during robotic-assisted walking. Clin Biomech (Bristol, Avon) 2005;20:184-93.
37. Waters RL, McNeal DR, Faloon W, Clifford B. Functional electrical stimulation of the peroneal nerve for hemiplegia. J Bone Joint Surg Am 1985;67:792-3.
38. Burridge J, Taylor P, Wood D, Swain I. The effects of common peroneal stimulation on the effort and speed of walking: a randomized controlled trial with chronic hemiplegic patients. Clin Rehabil 1997;11:201-10.
39. Hesse S, Malezic M, Schaffrin A, Mauritz KH. Restoration of gait by combined treadmill training and multichannel electrical stimulation in non-ambulatory hemiparetic patients. Scand J Rehabil Med 1995;27:199-204.
40. Daly JJ, Marsolais EB, Mendell LM, et al. Therapeutic neural effects of electrical stimulation. IEEE Trans Rehabil Eng 1996;4:218-30.

Suppliers

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b. Pals; Nidd Valley Medical Ltd, Knaresborough, North Yorkshire, HG5 9AY, UK.
c. Model R01-0093; Department of Health Technology and Informatics, Hong Kong Polytechnic University, Hong Kong.
d. Version 13.0; SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.