A Pilot Study of Randomized Clinical Controlled Trial of Gait Training in Subacute Stroke Patients With Partial Body-Weight Support Electromechanical Gait Trainer and Functional Electrical Stimulation
Six-Month Follow-Up

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Background and Purpose—This study aimed to assess the effectiveness of gait training using an electromechanical gait trainer with or without functional electrical stimulation for people with subacute stroke.

Methods—This was a nonblinded randomized controlled trial with a 6-month follow-up. Fifty-four subjects were recruited within 6 weeks after stroke onset and were randomly assigned to 1 of 3 gait intervention groups: conventional overground gait training treatment (CT, n = 21), electromechanical gait trainer (GT, n = 17) and electromechanical gait trainer with functional electrical stimulation (GT-FES, n = 16). All subjects were to undergo an assigned intervention program comprising a 20-minute session every weekday for 4 weeks. The outcome measures were Functional Independence Measure, Barthel Index, Motricity Index leg subscale, Elderly Mobility Scale (EMS), Berg Balance Scale, Functional Ambulatory Category (FAC), and 5-meter walking speed test. Assessments were made at baseline, at the end of the 4-week intervention program, and 6 months after the program ended.

Results—By intention-to-treat and multivariate analysis, statistically significant differences showed up in EMS (Wilks’ λ = 0.743, P = 0.005), FAC (Wilks’ λ = 0.744, P = 0.005) and gait speed (Wilks’ λ = 0.658, P < 0.0001). Post hoc analysis (univariate 2-way ANCOVA) revealed that the GT and GT-FES groups showed significantly better improvement in comparison with the CT group at the end of the 4 weeks of training and in the 6-month follow-up.

Conclusions—For the early stage after stroke, this study indicated a higher effectiveness in poststroke gait training that used an electromechanical gait trainer compared with conventional overground gait training. The training effect was sustained through to the 6-month follow-up after the intervention.

Key Words: electrical stimulation ■ exercise therapy ■ gait ■ randomized clinical trial ■ rehabilitation
An approach that combines functional electrical stimulation (FES) with simultaneous use of the electromechanical gait trainer is now gaining much attention. FES has major therapeutic benefits in the early phase of gait rehabilitation, facilitating people with brain injury to achieve a better functional result in terms of strength and motor recovery in a shorter period of time.\textsuperscript{14,15} Graded sensory stimuli with meaningful muscle active participation (ie, sensorimotor coupling) may cause plasticity in cortical sensorimotor representation areas.\textsuperscript{16,17}

The purpose of this study was to compare the effectiveness of 3 gait-training interventions in the subacute stroke stage to determine the extent of carryover from machine training to overground locomotion, and perhaps to suggest the extent of the recovery process after stroke in the long-term. Our hypothesis was that early intensive gait-oriented training on a gait trainer with FES could be an effective intervention for stroke survivors.

### Methods

#### Participants

All people with a first stroke who were admitted to the inpatient unit of a rehabilitation hospital in Hong Kong were screened as potential subjects. Patients had to satisfy the 5 inclusion criteria for this study: (1) diagnosis of ischemic brain injury or intracerebral hemorrhage by MRI or computed tomography <6 weeks after the onset of stroke; (2) sufficient cognition to follow simple instructions as well as understand the content and purpose of the study (Mini-Mental State Examination score >21);\textsuperscript{18} (3) ability to stand upright, supported or unsupported, for 1 minute; (4) significant gait deficit (Functional Ambulatory Category [FAC], scale <3);\textsuperscript{19} and (5) no skin allergy, eg, redness or itchiness to the FES stimulation pads after electrical stimulation.

Patients were excluded if they had any one of the following criteria: (1) a recurrent stroke or other neurological deficit that would affect ambulation ability; (2) any additional medical or psychological condition that would affect their ability to comply with the study protocol, eg, a significant orthopedic or chronic pain condition, demand cardiac pacemaker placement; (3) aphasia with inability to follow 2 consecutive step commands, or a cognitive deficit; or (4) severe hip, knee or ankle contracture or orthopedic problem affecting ambulation that would preclude passive range of motion of the paretic leg.

Prior informed consent was given by all subjects via methods approved by the university and the hospital’s institutional review board. The study design was a randomized controlled trial of a 4-week intervention with a follow-up after 6 months. Randomization was done by computer-generated random numbers in which a list of random numbers was generated. The numbers were assigned according to the order of the subjects’ admission to the hospital. The randomization was done before baseline measurements were carried out on the subjects. The subjects were then assigned to 1 of 3 groups: conventional overground gait training (CT), gait training on an electromechanical gait trainer (GT), or gait training on an electromechanical gait trainer with FES (GT-FES; Figure 1).

#### Interventions

All subjects in all groups underwent one gait training session of 20 minutes duration per weekday for the 4 weeks under supervision of a physical therapist. In addition to the assigned group treatment, each subject also received his or her own regular hospital-prescribed 40 minutes of physical therapy and a 1.5-hour multidisciplinary treatment session every weekday throughout the 4-week intervention period. The multidisciplinary treatment consisted of a scheduled occupational therapy, speech therapy and psychology multidisciplinary program. To minimize interference from FES by external electrical stimulation on the study’s results, no electrical stimulation was applied during the subjects’ regular hospital rehabilitation. Figure 2 shows details of the intervention and regular hospital treatment sessions for the 3 groups. Total time of different kinds of exercise and gait intervention was standardized in each session. If a subject missed >3 of his or her gait-training sessions because of medical reasons or an inability to participate, the subject was considered as dropped from the current study. Intention-to-treat analysis was used for all of the subjects and data were replaced by the first assessed scores.

The CT group received conventional physical-therapy gait training begun with individual assessment in order to plan specific physiotherapy treatment to maximize potential recovery for each patient after stroke. A physiotherapy session usually begins with stretching exercises to restore flexibility to tight muscles in the affected side of trunk, arms and legs based on the principles of proprioceptive neuromuscular facilitation and Bobath concepts.\textsuperscript{20,21} The principle of the Bobath treatment is to train up the key proximal segments then distal segments in order to improve the subject’s posture and movement.\textsuperscript{20} Cardiovascular exercises for both arms and legs are used to build endurance and improve circulation. Specific strengthening exercises are also planned for weakened arm, leg and trunk muscles. Activities for daily living such as changing positions from sitting to standing, getting out of bed are also parts of the routine rehabilitation training. The CT subjects were to undergo the overground walking gait training with or without a walking aid or
The duration of the overground walking gait training for each CT subject was the same as that for each GT and GT-FES subject on the electromechanical gait trainer for their respective gait-training interventions. Each gait-training session was conducted by the subject's own hospital physical therapist who was blinded to the group assignments.

Subjects in the GT group trained on the electromechanical gait trainer with their body weight partially supported by a harness attached by ropes to a gear system, according to the subject's ability and trunk mobility training (physical therapy) + 20 minutes of conventional overground gait training (intervention) + 10 minutes of lower limb training (physical therapy) + 1.5 hours of multidisciplinary treatment (occupational therapy/speech therapy/psychology)

CT Group (n=21)

GT Group (n=17)

GT-FES Group (n=16)

Assessment:
Post-training (4 weeks, n=17); 4 patients discontinued (1 re-admitted to an acute care hospital, 1 had a deteriorating medical condition, and 2 were discharged prior to completion)

Intention-to-treat analyzed (n=21)

Analysis:
(n=17)

Analyzed (n=16)

14 patients evaluated for 6-month follow-up
Intention-to-treat analyzed (n=11)

15 patients evaluated for 6-month follow-up
Intention-to-treat analyzed (n=17)

16 patients evaluated for 6-month follow-up
Intention-to-treat analyzed (n=16)

Figure 2. CONSORT flowchart of the training programs.
nerve in the paretic side was stimulated during the swing phase to elicit ankle dorsiflexion and knee flexion. This training procedure had been used previously in a case study.22

Measurements
The characteristics of all subjects were recorded before treatment. For outcome measurements, all subjects were evaluated before gait training and at the completion of the 4-week intervention period and at follow-up 6 months later. All assessments during the study period, including the screening of patients, were made by a single research physical therapist at the physical therapy department of the hospital. Neither the patients nor the research physical therapist were blinded to the treatment because it was impractical to do so due to practical resource problems.

The 3 groups were compared in terms of general mobility, gait ability, overground walking speed, and motor impairment. General mobility independence was assessed by the Elderly Mobility Scale (EMS).23 Balance was assessed by the Berg Balance Scale (BBS), which has been shown to have excellent inter-rater and intra-rater reliability for elderly subjects24 and subjects with acute stroke25; and lower-limb strength to complete the walking test more readily.9 The EMS, BBS, FIM, and FAC were compared using the Kruskal-Wallis analysis of variance (ANOVA), whereas gender, diagnosis (ischemic or hemorrhagic), side of the hemiplegia, ordinal variables (Motricity Index, EMS, BBS, FAC) were compared using the Kruskal-Wallis analysis of covariance (ANCOVA) to indicate the overall effect of the assigned interventions and to reduce the probability of type I error owing to multiple comparisons.32 This is a technique for assessing group differences across multiple metric-dependent variables simultaneously, based on a set of categorical variables acting as independent variables. The within-subject factor was set as time and the between-subject factor was set as group. The baseline measurement of each respective outcome was entered as the covariate. If the MANCOVA revealed a significant effect, post hoc analysis using univariate 2-way ANCOVA was used to indicate which particular measurement time showed significant difference between particular groups.

To explore the practical significance of group differences, the effect size (ES) was calculated: \( ES = \frac{\text{Mean}_{\text{Group 1}} - \text{Mean}_{\text{Group 2}}}{SD_{\text{pooled}}} \). The established criteria of the ES, which reflects the effect of a treatment within a population of interest, are small (<0.41), medium (0.41 to 0.70), or large (>0.70).33 An \( \alpha \) level of \( P<0.05 \) was assumed to be significant, and the Tukey significant difference test was then used for post hoc comparison.

Results
A total of 380 hemiplegic patients from a first stroke who were admitted to the hospital for rehabilitation were screened for this study, of whom 54 fulfilled the inclusion criteria and agreed to join the study as subjects. They were randomly assigned to 1 of 3 gait-training groups (CT: \( n=21 \), GT: \( n=17 \), GT-FES: \( n=16 \)). Table 1 shows the characteristics and the pretraining scores of all the subjects. There may have been a difference in the mean ages of the groups with the control group being older. There were no clinically relevant differences between the 3 groups for demographic variables or outcome measures at baseline. Four subjects (all from the CT group) of the 54 subjects admitted to the study did not attend all their gait-training sessions (1 subject was admitted to an acute-care hospital, 1 had a deteriorating medical condition, and 2 were discharged from the hospital before completion of the 4-week intervention period). Five more subjects (3 from the CT group and 2 from the GT group) did not come back for the 6-month follow-up (1 subject had died, 3 had recurrent stroke, and 1 had lost contact).

| Table 1. Baseline Demographic Characteristics of the CT, GT and GT-FES Groups |
|-------------------|-------------------|-------------------|-------------------|
|                   | CT Group          | GT Group          | GT-FES Group      |
|                   | \( n=21 \)         | \( n=17 \)         | \( n=16 \)         |
| **Age (years)**   | 73.4 (11.5)        | 66.6 (11.3)        | 62.0 (10.0)        |
| **Gender (male/female)** | 13/8              | 11/6              | 10/5              |
| **Etiology**      | 18/3              | 13/4              | 11/4              |
| (ischemic/hemorrhagic) |                 |                  |                  |
| **Side of hemiplegia** | 8/13             | 8/9               | 6/9               |
| (right/left)      |                  |                  |                  |
| **Time poststroke before recruitment** (weeks) | 2.5 (1.2) | 2.7 (1.2) | 2.3 (1.1) |

*Values: mean (SD).

Statistical Analysis
SPSS (version 14.0) was used in statistical analyses in this study. Descriptive statistics and pretraining outcome variables of age, time since onset of stroke, and gait speed were compared using 1-way analysis of variance (ANOVA), whereas gender, diagnosis (ischemic or hemorrhagic), side of the hemiplegia, ordinal variables (Motricity Index, EMS, BBS, FAC) were compared using the Kruskal-Wallis test. Intention-to-treat was used in this study, and all patients were included into the analysis regardless of which intervention actually received. Overestimation of the clinical effectiveness could be avoided by using intention-to-treat. Data that were missing owing to subjects being dropped from the study were replaced by the last scores obtained.

We used multivariate analysis of covariance (MANCOVA) incorporating all outcome measures recorded in all time intervals to test the overall effect of the assigned interventions and to reduce the probability of type I error owing to multiple comparisons.32 This is

Training Variables
The mean gait trainer initial training speed for the GT group was 0.11 ± 0.06 m/s, whereas for the GT-FES group it was 0.17 ± 0.04 m/s. The mean speeds gradually increased to 0.39 ± 0.11 m/s for both groups by the end of the 4-week intervention period. Body-weight support for the GT group was initially at 25 ± 7.2% and gradually decreased to 0.5 ± 0.9% by the end of the 4 weeks. For the GT-FES group, body-weight support began at 20 ± 6.3%; most of the GT-FES
subjects (70%) could walk without any body-weight support after the 16th gait-training session. Most of the subjects in the GT and GT-FES groups completed all their gait training sessions; from those 2 groups, a total of 6 subjects required 1 or 2 rest breaks during the sessions. Adverse side effects during the training and overexertion of the subjects did not occur.

**Post-4-Week Intervention Effect**

Subjects in all of the groups showed significant improvement in mobility, ambulation ability, walking speed and lower-limb strength after the 4 weeks of gait training. The results for all outcomes are presented in Table 2. MANCOVA with baseline values of individual outcomes as covariates showed significant time by group interaction in 3 of the 7 outcome measures.
measures: EMS (Wilks’ $\lambda=0.743$, $P=0.005$), FAC (Wilks’ $\lambda=0.744$, $P=0.005$), and gait speed (Wilks’ $\lambda=0.658$, $P<0.0001$). Post hoc analysis (univariate 2-way ANCOVA) revealed significantly better improvement in the 2 gait-trainer groups than the CT group immediately after the 4 weeks of training (Table 2). Only the GT-FES group showed significantly more improvement in ambulation independence (FAC) than the CT group. Seven of the 16 subjects (43.8%) in the GT-FES group could walk independently with at least verbal supervision, with FAC=4 at the end of the 4 weeks of training. Only 5 of the 17 subjects (29.4%) in the GT group and 6 of the 17 subjects (35.3%) in the CT group who finished the 4 weeks of intervention reached this level. Further comparison between the groups was done in effect size calculations (Table 2).

**Follow-Up After 6 Months**

To assess any long-term effect, all outcomes of the study were reassessed 6 months after the 4-week intervention period ended. A total of 45 subjects (CT: n=14; GT: n=15; GT-FES: n=16) came back 6 months after their gait training for a follow-up assessment. All the 45 subjects had received non–study-related outpatient rehabilitation at the same hospital for 3 to 4 weeks (3 sessions a week, with each session lasting 3 hours) after their discharge from the hospital. Five of them (1 from CT, 2 from GT and 2 from GT-FES) had also received private acupuncture treatment (mean: 8 weeks, SD: 3.5 weeks), whereas 7 of them (3 from CT, 3 from GT and 1 from GT-FES) received private physical therapy treatment (mean: 4 weeks, SD: 2.8 weeks) after the outpatient rehabilitation. Outpatient rehabilitation therapy was prescribed to each patient with stroke aimed at continuing improvement of movement, sensation, balance and coordination for activities of daily living after discharged.

All the 3 groups showed continued improvement after the completion of the 4-week intervention. In between-group comparisons, both the GT and GT-FES groups showed a higher level of mobility, gait independence and velocity than the CT group in the follow-up assessment (Table 2). Post hoc analysis (univariate 2-way ANCOVA) revealed that both the GT and GT-FES groups had significantly more improvements in EMS (GT versus CT: $P=0.024$; GT-FES versus CT: $P=0.006$), FAC (GT versus CT: $P=0.018$; GT-FES versus CT: $P=0.003$) and gait speed (GT versus CT: $P=0.006$; GT-FES versus CT: $P=0.004$) than the CT group. Thirteen of the 16 subjects (81.3%) in the GT-FES group could walk independently with FAC=4 at the 6-month follow-up. Only 9 of the original 21 subjects (42.9%) in the CT group and 11 of the original 17 (64.7%) in the GT group reached this level.

**Discussion**

Subjects in all 3 groups showed improvement in terms of lower-limb strength, mobility, ambulation ability, walking speed, and activities in daily living during the study period. The improvement may combine the spontaneous recovery and the training effects. The improvement was significantly greater in the GT and GT-FES groups than in the CT group after the interventions. Subjects in the GT and GT-FES groups improved significantly in mobility score (EMS), walking speed and FAC than subjects in the CT group except for FAC (GT versus CT) post–4-week intervention. This immediate positive effect after the training period in subjects who underwent gait training on the electromechanical gait trainer with or without FES was also found in one of our previous studies. However, the previous study’s design did not feature a follow-up 6 months after the intervention period ended. This current study continues the work of the previous study by including a follow-up of subjects in the 3 types of groups, providing more information on the long-term effects of finishing the 4-week intervention programs. In the current study, all 3 groups of subjects showed continued improvement in all outcome measures at the 6-month follow-up after the end of the 4-week training period. This finding suggests the subjects were able to build on their interventions, regardless of the kind of gait training they underwent in the 4 weeks, to make continual gains in gross motor and gait improvement even after the gait training had ended.

Effect sizes were calculated for the 3 significant outcome measures (EMS, walking speed and FAC) to see the potential of having a statistically significant effect for the insignificant ones. For the FAC (4 weeks), effect size calculations revealed a medium value in the GT versus CT groups. However, although most of the effect size differences between the CT and GT-FES groups were small, the gait speeds in the 4-week intervention period showed a medium effect size difference, with the GT-FES group more superior for a treatment effect. This suggested that a larger sample size would have possibly produced a more statistically significant effect.

The findings of the current study were compared with the study of Peurala et al., who studied people with chronic stroke (poststroke >2 years) undergoing a 20-minute training session every weekday for 3 weeks. Their results did not show any difference in performance between subjects who were assigned to conventional overground gait training and those who used an electromechanical trainer with or without FES. At the 6-month follow-up in their study, they found that all of the gait characteristics remained unchanged. Our study design was on subjects with subacute stroke. Our current study, in contrast, indicated that subjects in the GT and GT-FES groups not only walked significantly faster than those in the CT group during the 4-week intervention period, the 6-month follow-up also showed continued improvements in all 3 groups. The difference between the findings in the Peurala et al study and the current study might owe to the fact that the subjects in Peurala et al’s study were in a chronic phase of stroke and therefore many of them might not have been severely impaired in walking. Faster recovery and more significant improvement would be expected in acute or subacute phase of stroke than in chronic phase.

The results of the current study provide evidence that the body weight support electromechanical gait trainer, which could be used for early rehabilitation after stroke onset, could significantly shorten the ambulation-dependence time when compared with conventional overground gait training. Supportive results from a study by Pohl et al also indicated that patients with subacute stroke who underwent gait training on an electromechanical gait trainer gained superior ambulatory
Our findings showed clinical significance for an intensive 4-week intervention that used an electromechanical gait trainer for accelerating locomotor recovery in patients after stroke in the subacute phase and maintaining an improved ambulatory ability up to at least 6 months after the completion of the intervention. Our current study involved gait training of patients before they could even stand independently owing to weak trunk and proximal limb control. This approach is different from the conventional Bobath therapeutic approach, which advocates the training of proximal stability before distal mobility. The limitation on this study was the possible bias in the nonblinded trial design, and a larger scale blinded randomized controlled trial is warranted in future studies based on this pilot. It is essential that clinicians, given the resource limitations of current healthcare systems, explore alternative forms of training that may be effective for more than one of disablance for stroke patients.

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Disclosures
None.

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