The influence of gait training combined with portable functional electrical stimulation on motor function, balance and gait ability in stroke patients

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Abstract.

BACKGROUND: Problems with motor functions, balance and gait ability commonly occur in stroke patients and cause asymmetric posture imbalance and gait patterns.

OBJECTIVE: We examined the effects of gait training (GT) combined with portable functional electrical stimulation (FES) on motor functions, balance and gait ability of stroke patients.

METHODS: A single blind, randomized control trial was conducted with 34 post stroke patients who were randomly allocated to two groups: 1) FES + GT group (n=17) and the placebo FES + GT (PLBO + GT) group (n=17). All interventions were given for 30 minutes, 5 days a week for 4 weeks. Fugl-Meyer assessment (FMA) was used to measure motor function of lower extremity. Performance oriented mobility assessment (POMA) was used to balance and gait ability. OptoGait was used to analyze gait ability. **RESULTS:** Both groups showed significant improvements in motor function, balance and gait ability. The FES + GT group showed significantly greater improvement in motor function, balance and gait abilities after four weeks compared to the PLBO + GT group.

CONCLUSION: It was found that the gait training applied with FES is effective in improving the motor function, balance and gait abilities of stroke patients.

Keywords: Functional electrical stimulation, stroke, gait, balance

1. Introduction

Stroke patients commonly experience various complications such as hemiplegia, sensory impairment, damages to motor functions and muscle strength problems in accordance with the section and degree of the damage [1]. Muscle strength imbalance occurs when there are problems in balance ability while in the standing position to describe asymmetric gait patterns [2].

Several studies relating to gait training (GT) have demonstrated the results of improved lower extremity function in post-stroke patients [3]. Gait is considered the most important factor determining functional independence in daily life activities [4]. Treadmill training, which is widely used as part of a gait training, can help with loading by controlling the patient's weight, and the following effects are expected: improvement of muscle strength, re-awareness of balance, and gait improvement [5].

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Functional electrical stimulation (FES) is used in various rehabilitation fields and applied to GT, reduction of edema [6], improvement and maintenance of the range of motion [5], prevention of muscular atrophy [7], and improvement of ankle dorsiflexor strength [8]. However, a disadvantage of FES is that it does not involve the active will of the patient, and it is simply repetitive and considered less effective in relearning motor functions, which is a crucial factor for recovery in stroke patients. Therapists conducted GT in stroke patients by artificially inducing FES [9].

Foot drop is so frequent that it affects nearly 20% of stroke patients [10]. Foot drop makes it difficult for the heel to touch the ground when walking and causes the foot to be dragged, leading to abnormal gait patterns such as swinging pattern gait and hip flexion gait [11]. Such abnormal gait not only decreases the quality of life by reducing the gait/walking speed but also causes several other problems, such as exposure to the risk of falling [12].

"Walkami," a FES treatment equipment, is a gait assisting device that supports dorsal flexion while walking by inducing electrical stimulation for ankle movement. The FES generally has less contact area with the skin; it does not restrict ankle movement and hence does not hamper the gait of a person, facilitating effective contraction of the muscles [13]. According to a previous study, when FES is applied to the dorsiflexor and hamstring, it can be more effective in controlling the lower extremities than when applied to only the dorsiflexor [14].

Recent study have found the treadmill exercise as an effective intervention method to improve balance and gait in various cases. Reportedly, after conducting treadmill exercise for six weeks, significant effects could be seen on gait and balance [15,16]. In et al. reported that treadmill GT with thera-band effectively improves on motor functions of lower limb, balance and gait in poststoke patients [17]. Bao et al. reported that body weight supported treadmill plus FES could significantly improve lower extremity function, balance, spasticity and gait in post-stroke [18]. Hakakzadeh et al. argued that bilateral multi joint FES and treadmill exercise showed statistically significant difference in spasticity and gait in poststroke [19]. Furthermore, Ray et al. indicated that combined treadmill control with FES showed a statistically significant increase in gait speed in poststroke patients [20]. As noted above, it is important to find a treatment method combining treadmill GT and FES to improve motor functions, balance and gait of stroke patients. Therefore, this study aimed to examine the effect of GT + FES treatment on motor functions, balance and gait ability of stroke patients to determine if the treatment method combining FES and treadmill trainings is effective. This can immensely help improve the functional ability of stroke patients who turn to FES along with the GT method for a successful recovery.

2. Method

2.1. Research design

The present study was conducted with the randomized clinical trial pretest-posttest design. By using the single-blind test, a therapist with over 5 years of clinical experience and no knowledge of the groups, conducted the evaluation, analysis and each training. The basis of calculation for the number of subjects was calculated by conducting the statistical evaluation with G*power Version 3.1.9.4. The effect size was calculated based on pilot study of 6 stroke patients. Effects size was 1.01, α error probability was 0.05 and the power was 0.8 for the overall number of samples to select 34 study subjects.

2.2. Participants

The present study conducted experiments on both female and male stroke patients hospitalized at B hospital in Gyeonggi-do and the details regarding the selection of patients are as follows. The inclusion criteria as follows: (1) first episode of unilateral stroke with hemiplegia caused by brain damage, (2) above 21 points from the Mini Mental State Korea (MMSE-K), (3) enabled to communicate, (4) had no allergic reactions to FES and had no gait problems with ankle joint contracture. The exclusion criteria as follows: (1) cerebellum-related diseases, (2) sight and hearing impairments, (3) cardiovascular system problems. This study was approved by the judging committee at Gimcheon University (GU-201805-HRa-03-02-P) and each subject signed the informed consent form.

2.3. Experimental procedure

The motor function balance and gait abilities of patients before the experiment and four weeks afterward were evaluated. The selected individuals participated in the study after receiving detailed explanations of the study procedure. Using a lottery method, those who picked odd numbers were set as the FES + GT group (n = 19), whereas those who chose even numbers were

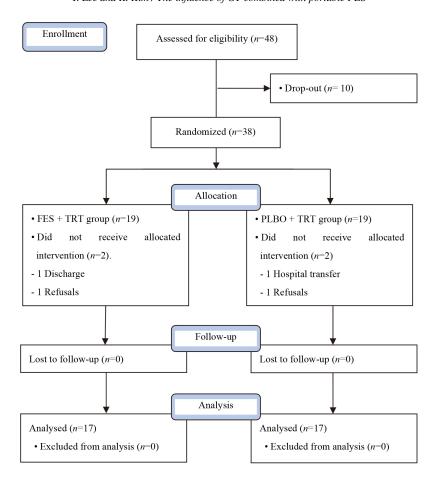


Fig. 1. Flow diagram of this study.

set as the PLBO + GT group (n=19). All participants took part in 20 treatments for 30 minutes a day, five times a week. In accordance with the rehabilitation program for inpatients, both groups participated in general treatments that lasted 30 minutes a day, one a day, five times a week. Among the FES + GT group participants, one patient was discharge, and another refused to participate. One patient was excluded from the PLBO + GT group due to hospital transfer, and another refused to participate. Thus, 34 patients finally participated in the study (Fig. 1).

2.4. Intervention

In this study, GT refers to treadmill GT. The GT + FES group received 30 minutes of GT (rehabilitation treadmill, 2010-2Si, Korea) training while wearing portable FES (Walkami foot drop system XFT-2001D, XFT Electronics CO., Ltd., China) (Fig. 2). Electric stimulators were attached to the tibialis anterior muscle and the common peroneal nerve in a manner that the

yellow indicator was in a straight line with the fibular head. As for the GT speed, the average speed of gait analysis evaluated prior to the training was set as the starting speed. The speed was then increased by 0.1 m/s every week during the experiment. The speed was maintained when the patient displayed a stable walk for 20 seconds [21,22]. Portable FES was set to gait mode at a frequency of 33 Hz, a pulse width of 200 μ s, and a foot sensor of 90 mA. The degree of stimulation was set at the maximum within the ranges that the patient could endure. The gyroscope speed sensor was installed inside the device to analyze electrical stimulation for the first five steps taken by the patient. From the sixth step, the electrical stimulation was applied to dorsal flexion during the swing phase [23] (Fig. 3).

The PLBO + GT group received placebo portable FES simultaneously with the other group. The placebo FES had the same pads and equipment. The analysis was conducted for the first five steps without electrical stimulation and with electrical stimulation from the sixth to the tenth step; however, the electrical stimu-



Fig. 2. FES equipment.



Fig. 3. Task-related training combined with portable functional electrical stimulation.

lation was reduced to 0 using a remote control. It was explained to the physical therapist that patients might experience difficulty sensing the stimulation because the placebo FES flows at a low frequency. If the patients felt exhaustion, pain, difficulties in breathing, or showed changes in complexion after starting the GT, five minutes of rest was allowed [24].

2.5. Outcome measures

Fugl-Meyer assessment (FMA) was performed to evaluate the motor functions of the lower extremities. It is composed of 17 items and the score range is 0–34. The intra-rater reliability for stroke patients was r=0.96, and concurrent validity was r=0.99, making it

a highly accurate evaluation tool [25]. Performance-Orientated mobility assessment (POMA), a measurement evaluation tool for balance and mobility of braindamaged patients, was used in this study. The POMA can be divided into two items: balance control and gait ability. Balance control evaluation consists of 16 points and the gait ability test consists of 12 points, accounting for a total of 28 points [26]. For the gait test, a gait analyzer (OptoGait, Microgate S.r.l, Italy) was used, which collected data of quantitative gait analysis for the gait types of patients. The gait analyzer was composed of two 4 m transmission and reception bars and a webcam (Logitech Webcam Pro 9000). Furthermore, the width of each bar that was to be installed on the ground was 1 m. Inside each bar, light-emitting diodes were installed at every 1 cm, which communicated using infrared rays immediately sent from the transmission bar. Patients were requested to walk 10 m at a comfortable speed between the two bars. With the exclusion of the first 3 m and last 3 m, the participant's feet were detected for the 4 m to collect information on the gait variables. Video information was saved with the webcam to accurately initialize the measured gait. The optical sensor could transmit and receive data at 1000 Hz and collect information on temporal and spatial gait variables and gait while the experimenter walked between two parallel bars. For accurate data collection, calibration was performed prior to the experiment. Information on collected gait variables was processed using Opto-Gait, version 1.5.0.0 (Microgate S.r.l, Italy) software. As the temporal and spatial characteristics of gait, stride length, gait cycle, total double support, affected step length, affected single support, affected speed, affected step time, and average speed. analyzed. All measurements were taken by an experience physical therapist to remove variables between testers. Test-retest reliability was r = 0.98–0.99, and inter-rater reliability was r =0.99 [27].

2.6. Statistical analysis

The overall statistical analysis of this study was conducted by using the SPSS 21.0. The test of normality for variables was conducted through the Shapiro-Wilk test. For the comparison of general characteristics of subjects and the pre-homogeneity of two groups, independent t-test and Chi-square test (for categorical variables) were conducted. For the before and after comparison of dependent variables in accordance with the rehabilitation training within the group, paired sample t-test was conducted. All statistically significant levels (α) were set below 0.05.

Table 1
General characteristics of subjects

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Variable	FES + TRT group $(n = 17)$	PLBO + TRT group $(n = 17)$	p-value			
Gender						
Male	7	8	0.730^{b}			
Female	10	9				
Height (cm)	166.07 (4.07) ^a	163.18 (5.79)	0.276^{c}			
Weight (kg)	67.38 (6.51)	64.46 (8.67)	0.831 ^c			
Age (year)	52.24 (11.39)	53.24 (7.04)	0.761 ^c			
Stroke type						
Infarction	7	10	0.303^{b}			
Hemorrhage	10	7				
Affected side						
Left	6	9	0.300^{b}			
Right	11	8				
MMSE-K (score)	27.00 (0.87)	27.35 (0.86)	0.242^{c}			
Post-stroke duration (month)	9.24 (2.02)	9.00 (1.54)	0.705^{c}			

 $^{^{\}rm a}$ Mean \pm SD. $^{\rm b}$ Chi-square test. $^{\rm c}$ Independent t-test. MMSE, mini-mental state examination.

Table 2 Chances of the FMA

Parameter	FES + TRT group $(n = 17)$			PLBO + TRT group (n = 17)			Between groups P
	Pre-test	Post-test	Change	Pre-test	Post-test	Change	-
FMA (score)	21.12 (2.12) ^a	25.53 (1.62)	4.41 (1.33) ^b	21.53 (2.15)	22.76 (1.99)	1.24 (0.75) ^b	< 0.001*

^aMean (\pm SD). *p < 0.05. ^bSignificantly difference between pre and post-test (p < 0.05). FMA; fugl meyer assessment.

Table 3 Chances of the POMA

Parameter (score)	FES + TRT group (n = 17)			PLBO + TRT group (n = 17)			Between groups P
	Pre-test	Post-test	Change	Pre-test	Post-test	Change	•
Balance	14.06 (0.83) ^a	14.42 (0.71)	1.35 (0.49) ^b	14.06 (0.90)	14.82 (0.73)	0.76 (0.46) ^b	0.003*
Gait	8.06 (0.75)	9.35 (0.61)	1.29 (0.45) ^b	8.12 (0.60)	9.00 (0.79)	$0.88 (0.60)^{b}$	0.033*
Total	22.12 (1.17)	24.76 (0.97)	2.65 (0.61) ^b	22.17 (1.13)	23.82 (0.73)	1.65 (0.70) ^b	< 0.001*

^aMean (\pm SD). *p < 0.05. ^bSignificantly difference between pre and post-test (p < 0.05). POMA, performance-oriented mobility assessment.

3. Results

The general characteristics of the 34 stroke patients are show in Table 1. In the FMA score test was more significantly increased in the FES + GT group than in the PLBO + GT group. The changeable amount before and after training was 4.41 ± 1.33 and 1.24 ± 0.75 , respectively (Table 2). Balance POMA was more significantly increased in the FES + GT group than in the PLBO + GT group. The changeable amount before and after training was 1.35 ± 0.49 and 0.76 ± 0.46 , respectively. The Gait POMA and total POMA significantly increased in the FES + GT group (1.29 ± 0.45 , 2.65 ± 0.61 , respectively) than in the PLBO + GT group (0.88 ± 0.60 , 1.65 ± 0.70 , respectively) (Table 3).

During the OptoGait assessment, stride length (SL) and gait cycle (GC) significantly increased in the FES + GT group (4.08 \pm 3.17, -0.47 ± 0.26 respectively)

compared to the PLBO + GT group (1.87 \pm 1.72, 0.18 \pm 0.21 respectively) after intervention. Cadence and total double support (TDS) significantly increased in the FES + GT group $(0.07 \pm 0.08, -2.69 \pm 1.06 \text{ re})$ spectively) compared to the PLBO + GT group (0.02 \pm 0.03, -1.68 ± 1.09 respectively) after intervention. Affected step length (ASL) and affected single support (ASS) significantly increased in the FES + GT group $(4.46 \pm 3.02, 1.09 \pm 1.64)$ compared to the PLBO + GT group (2.09 \pm 1.11, 0.89 \pm 1.14) after intervention. Also, affected speed (Asp) and affected step time (AST) significantly increased in the FES + GT group $(0.11\pm0.07,\,-0.30\pm0.22)$ compared to the PLBO + GT group (0.05 \pm 0.04, 0.16 \pm 0.15 respectively) after intervention. Finally, average speed (AS) significantly increased in the FES + GT group compared to the PLBO + GT group. The changeable amount before and after training was 0.13 ± 0.10 and 0.04 ± 0.06 , respectively (Table 4).

Parameter	FES + TRT group (n = 17)			PLBO + TRT group (n = 17)			Between groups P
	Pre-test	Post-test	Change	Pre-test	Post-test	Change	-
SL (cm)	64.91 (7.35) ^a	68.99 (6.61)	4.08 (3.17)b	65.34 (8.23)	67.21 (7.64)	1.87 (1.72) ^b	0.017*
GC (step/sec)	2.38 (0.45)	1.91 (0.35)	$-0.47 (0.26)^{b}$	2.32 (0.36)	2.14 (0.35)	0.18 (0.21)b	0.001*
Cadence (step/sec)	0.53 (0.10)	0.60 (0.08)	$0.07 (0.08)^{b}$	0.54 (0.07)	0.56 (0.07)	$0.02 (0.03)^{b}$	0.038*
TDS (%)	34.55 (3.51)	31.86 (3.09)	2.69 (1.06) ^b	33.44 (2.42)	31.75 (2.66)	1.68 (1.09) ^b	0.011*
ASL (cm)	37.38 (6.30)	41.84 (5337)	4.46 (3.02) ^b	37.90 (6.26)	39.99 (6.07)	2.09 (1.11) ^b	0.007*
ASS (%)	33.91 (2.76)	35.81 (2.81)	1.90 (1.64) ^b	35.36 (1.71)	36.25 (2.14)	0.89 (1.14) ^b	0.046*
ASp (m/s)	0.59 (0.18)	0.71 (0.18)	$0.11 (0.07)^{b}$	0.61 (0.16)	0.66 (0.15)	$0.05 (0.04)^{b}$	0.008*
AST (m/s)	1.27 (0.31)	0.97 (0.18)	$-0.30(0.22)^{b}$	1.26 (0.29)	1.10 (0.26)	0.16 (0.15)b	0.034*
AS (m/s)	0.60 (0.23)	0.74 (0.21)	$0.13 (0.10)^{b}$	0.65 (0.22)	0.70 (0.23)	$0.04 (0.06)^{b}$	0.004*

Table 4
Chances of the gait ability

 a Mean (\pm SD). $^{*}p$ < 0.05. b Significantly difference between pre and post-test (p < 0.05). SL, stride length, GC, gait cycle, TDS, total double support, ASL, affected step length, ASS, affected single support, ASP, affected speed, AST, affected step time, AS, average speed.

4. Discussion

In generally, the ultimate rehabilitation goal for stroke patients is enable them to execute daily activities independently. This study looked at the influence of a four-week therapy session with portable FES combined with GT on motor functions, balance and gait in stroke patients. The study was conducted every day for 30 minutes, five times a week, for four weeks. The purpose was to confirm the usefulness of treadmill GT with Walkami.

The FES treatment is used as an accessory for GT and improving conditions for gait disabilities, strengthening affected muscles in patients recovering from a stroke, and treating injuries to the central nerves such as spinal cord injuries [28]. The effects of FES application to the tibialis anterior muscle show considerable improvements in Fugl-Meyer score, gait speed, stride length, security, reduction of physiological energy consumption efficiency, and stiffness in plantar flexion [8,24]. Lindquist et al. state that FES revitalizes the tibialis anterior muscles on the affected side, leading to increased muscular contraction, accelerated dorsal flexion, and movement relearning [23].

Thus, this study helped provide GT to participants through treadmill GT for electrical stimulation of the tibialis anterior muscle that causes dorsal flexion of the ankle, which is important in improving motor functions, balance, and gait in recovering stroke patients based on prior research.

To examine the influence that FES and treadmill training have on motor functions, the FMA changes were studied. In our study, the FES + GT group showed significantly improved results in the FMA score. Sabut et al. reported a significant increase post 12 weeks of regular physical therapy and FES application on the tibialis anterior muscle for 30 patients recovering from

a stroke. It helped significantly recover the movement range of ankle joints, alleviated the stiffness of calf muscles, and increased the FMA scores [29]. Sabut et al. found that as a result of applying the FES to the tibialis anterior muscle of recovering stroke patients, significant improvements were seen in the FMA scores and gait dynamic index compared to other conventional electrical muscle stimulations, which is in line with the current study [30]. The fact that the tibialis anterior muscle, which helps recognize muscular activities of knees and ankles was vitalized suggests that participants' motor functions improved. The vitalization was achieved through neurological retribution, which improved the motor functions of the lower extremities. Moreover, it helped strengthen the muscle required for GT while in the combined treadmill GT.

The present study examined the changes in balance and gait ability to examine the influence of FES + GT training. In our study, the FES + GT group showed significantly improved results for variances of balance and gait. Tong et al. reported that the Berg balance scale increased from 12 points to 42 points after four weeks of motor-operated GT combined with FES. The motoroperated GT group showed an increase from 12 to 40 points [31]. Sheffler et al. reported a significant improvement in muscle performance in peak hip and ankle joints power in pre-swing and push-off while walking after applying peroneal nerve stimulation. Improvements in stride length, cadence, and gait speed were also noted in the patients [32]. The results agree with the research conducted by In et al., where improved motor functions, balance, and gait were noted in 30 stroke patients after four weeks of treadmill GT with TheraBand [17].

In this study, In this study, 4 weeks of intervention were conducted. In a previous study, mirror therapy training combined with functional electrical stimulation was performed 5 times a week for 4 weeks. This study identified an effective intervention method for motor function, balance, and gait. Combined training of gait and FES stimulation led to significant improvements in balance and gait [33]. Such improvement could be attributed to the induction of nerve and muscle reorganization by providing additional afferent stimulation and repetitive gait training [34]. Therefore, this study also found that the electrical stimulation of tibialis anterior muscle is considered to have influenced the posture control of stroke patients as the muscle recovery of tibialis anterior muscle moved the weight to the affected side to act as the stabilizer of the ankle joint and induced appropriate alignment of the affected lower extremities. As for the improvement of gait, the occurrence of toe drag was reduced due to the FES of Walkami, which shortened the offering period of the affected lower limbs [35]. The gait speed is considered to have increased as the movements of the lower extremities accelerated through the muscle recovery of the tibialis anterior muscle [29].

Furthermore, Walkami improved the weight-bearing ability by allowing users to efferently control the affected ankle during the stance phase in the affected leg by assisting dorsal flexion and reducing the time of stance phase by moving to one-foot support from two feet support [36]. Furthermore, it helped by lengthening the swing phase time to create a more relaxed forward stepping and considerably improving the gait. The FES led to the contraction of the tibialis anterior muscle from the terminal stance of the affected side, thereby improving insufficient dorsal flexion and preventing toe drag. Moreover, the application of FES during the dorsal flexion of the affected side increased the joint movement range of the knee and hip joints during the swing phase, thereby improving gait [37].

There are a few limitations to this study. The number of participants was insufficient, and a tracer study was not conducted to confirm whether the effects were lasting. Tracer studies can help identify the long-term effects of the training and biomechanical elements such as energy consumption efficiency, joint angle, muscle activity, and muscle exhaustion.

5. Conclusion

The present study exhibited that treadmill GT combined with portable FES showed significantly improved results in the motor functions, balance and gait ability of the lower extremities when compared to the treadmill gait training combined with placebo FES. Moreover, it was found that the treadmill training applied with FES on the tibialis anterior muscle and the common peroneal nerve was effective in improving the motor functions, balance and gait abilities of stroke patients. Therefore, it can be considered as an element that can increase the recovery abilities when planning programs for enhancing functions of stroke patients.

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Conflict of interest

The authors declare that there were no conflicts of interest.

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