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Original Article

Effects of Robot-assisted Gait Training Combined with Functional Electrical Stimulation on Recovery of Locomotor Mobility in Chronic Stroke Patients: A Randomized Controlled Trial

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Abstract. [Purpose] The purpose of the present study was to investigate the effects of robot-assisted gait training combined with functional electrical stimulation on locomotor recovery in patients with chronic stroke. [Subjects] The 20 subjects were randomly assigned into either an experimental group (n = 10) that received a combination of robot-assisted gait training and functional electrical stimulation on the ankle dorsiflexor of the affected side or a control group (n = 10) that received robot-assisted gait training only. [Methods] Both groups received the respective therapies for 30 min/day, 3 days/week for 5 weeks. The outcome was measured using the Modified Motor Assessment Scale (MMAS), Timed Up-and-Go Test (TUG), Berg Balance Scale (BBS), and gait parameters through gait analysis (Vicon 370 motion analysis system, Oxford Metrics Ltd., Oxford, UK). All the variables were measured before and after training. [Results] Step length and maximal knee extension were significantly greater than those before training in the experimental group only. Maximal Knee flexion showed a significant difference between the experimental and control groups. The MMAS, BBS, and TUG scores improved significantly after training compared with before training in both groups. [Conclusion] We suggest that the combination of robot-assisted gait training and functional electrical stimulation encourages patients to actively participate in training because it facilitates locomotor recovery without the risk of adverse effects.
Key words: Robot-assisted gait training, Functional electrical stimulation, Chronic stroke

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INTRODUCTION

To recover locomotor ability after a stroke, various therapies are traditionally used, such as single-joint motor training with proprioceptive stimulation and conventional overground gait training with walking devices. However, self-gait training without therapeutic intervention in stroke patients can lead to an asymmetrical gait pattern[1)]. In addition, in stroke patients, inappropriate weight bearing on the affected side with symptom-like foot drop may cause severe problems in postural control and body alignment, as well as asymmetry and alteration of muscle activation[2)]. As a result, walking in patients with stroke even after rehabilitation therapy may be associated with increased energy expenditure and less efficiency[3)].

Body weight-support treadmill training (BWSTT) is used in stroke rehabilitation to improve gait function by training of a normal gait pattern and for training in a safe environment[4–6)]. However, BWSTT is too labor intensive. To perform BWSTT, which entails a high workload even at a very slow speed, patients require the assistance of 2 or more therapists[4)].

Robot-assisted gait training (RAGT) provides a more supportive environment and normalized physiological gait training with benefits of temporal aspects and ideal kinematics[7)]. Therefore, patients with severely affected hemi-

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plegia can be treated more effectively with RAGT than with treadmill training[8]. RAGT is a form of training of a normal gait pattern programmed automatically, and it can be performed regularly over a longer period compared with treadmill training[9]. This automated process can also relieve therapists of the manual labor required during manual treadmill training[10].

The Lokomat system is the most widely used system for RAGT that is effective for locomotor recovery in patients with stroke. It can retrain a patient's hip and knee movement patterns while the patient walks[8, 9]. The system is able to fix the ankle motion of stroke patients but confers a foot-drop symptom[7]. This limitation may lead to an inappropriate walking pattern[8].

Functional electrical stimulation (FES) applied to the lower extremity is well known as an effective intervention for improving functional walking in chronic stroke patients[11]. FES has been used in therapeutic methods for ankle motion and muscle strengthening in stroke and spinal cord injury patients during walking training[11]. FES applied to the dorsiflexors during the pre-swing and swing phases of the gait cycle can be a more effective therapy than use of an ankle-foot orthosis, which decreases walking function on uneven surfaces and limits ankle flexibility[12, 13]. This repetitive and active movement training, which is similar to a normal walking pattern, can affect motor learning and motor recovery[12].

Although FES can be used to supplement RAGT, no study has been conducted on the effects of the combination of RAGT and FES. The purpose of this study was to investigate the effects of RAGT combined with FES on locomotor recovery in patients with chronic stroke.

SUBJECTS AND METHODS

All hemiplegic patients (20 subjects, 13 men and 7 women; age 46–72 years) who were admitted to the Department of Physical Medicine and Rehabilitation, Samsung Medical Center (SMC) had difficulties in walking but were able to walk 10 m with or without an assistive device. The inclusion criteria for this study were[14] (1) a diagnosis of stroke (ischemic or hemorrhagic stroke) >6 months after stroke onset; (2) sufficient cognition to follow simple instructions and understand the content and purpose of the study (mini-mental state examination − Korean version score >21); and (3) the ability to perform the examinations in the Modified Motor Assessment Scale (MMAS), Berg Balance Scale (BBS), Timed Up-and-Go Test (TUG), and gait analysis.

Patients were excluded if they had (1) problems with weight bearing due to unstable fractures or severe osteoporosis; (2) a body weight >130 kg; (3) skin problems with a severity beyond the scope of application of the Lokomat harness; (4) orthostatic circulatory problems; (5) severely fixed contracture; (6) severe cognitive deficits; (7) mechanical ventilation; (8) severe vascular disorders of the lower limbs; and (9) hip, knee, and ankle arthrodesis[14].

No significant differences in the participants' characteristics were found between the experimental and control groups (Table 1).

Table 1. General and disease-related characteristics of the participants

Variables	Experimental (n = 10)	Control (n = 10)
	Mean ± SD or N	Mean ± SD or N
Age (years)	45.4 ± 19.7	52.0 ± 16.1
Height (cm)	165.7 ± 5.5	166.0 ± 6.1
Weight (kg)	63.7 ± 10.2	61.5 ± 11.4
Postoperative period (months)	9.8 ± 6.0	11.5 ± 5.1
Sex		
Male	6	7
Female	4	3
Affected side		
Right	5	8
Left	5	2
Assist device		
Quad cane	6	6
Standard cane	4	4

No significant difference between the experimental and control groups

All the participants gave informed consent through methods approved by the SMC's institutional review board. The study protocol and procedures were also approved by the SMC's ethics committee.

All the participants were assigned to either the experimental or control group by using a random permuted block design with sealed envelopes. The experimental group received RAGT combined with FES applied on the affected dorsiflexor, and the control group underwent the RAGT only. Both groups received the respective therapies for 30 min/day, 3 days/week for 5 weeks. In addition, all the participants received a regular 30-min conservative physical therapy session based on neurodevelopmental therapy. Before and after the 15 sessions for 5 weeks, motor function, gait ability and balance were evaluated in all participants by a blinded examiner. There were a total of two physical therapists for the pre- and post-intervation assessments and two physical therapists conducted the intervations.

Lokomat (Hocoma AG, Zurich, Switzerland) was designed for RAGT in individuals. It consists of a treadmill, dynamic body weight support system, and motor-driven robotic orthosis, which enables patients to walk in a physiological gait pattern. The patients wore a harness to keep themselves safely standing on the treadmill and started the gait training using the body weight support system and motor-driven gait orthosis. The motor-driven gait orthosis was designed to allow joint movement depending on a variable walking speed, and it is controlled by a computer system. According to the programmed gait pattern, RAGT started after lowering the patients with the body weight support system.

During training, therapists were able to control the gait speed, angle of the hip and knee joints, and amount of support provided by the body weight support system. According to the patient's tolerance, the guidance force was set from 100 to 0%. As the guidance force was reduced, more active participation of the patient was required. Therapists increased the gait speed from 1.2 km/h up to the maximum speed to which patients could adapt. The amount of body weight support was reduced from 40 to 0% according to the patient's gait pattern. The sessions were kept at a demanding level; the velocity of the treadmill was set to the maximum speed tolerated by the patients, the force of the drives was regulated, and body weight support was reduced as soon as the patients could tolerate it. Therapists motivated patients to actively move their legs[14].

WalkAide (Innovative Neurotronics, Austin, TX, USA) was used for the RAGT with FES to stimulate the peroneal nerve in the affected side, and the intensity of the device was painlessly controlled by allowing sufficient dorsiflexion and eversion during the swing phase of the robot-assisted gait cycle. It stimulated the peroneal nerve through an activated tilt sensor when the affected leg was tilted from heel off to toe off in the stance phase. It stopped just after foot strike when the leg was tilted forward. It was attached below the knee, and it contained a cuff with soft electrodes[15].

All the assessments were performed by a single research physical therapist in a quiet, isolated place, without any interruption. The two groups were compared in terms of gait function and motor and balance performances. Motor performance was assessed using the MMAS (intraclass correlation coefficients, ICC=0.95)[16]. Balance performance was assessed using the TUG (ICC=0.97) and BBS (ICC=0.98)[17, 18]. These tests have excellent interrater and intrarater reliabilities for subjects with stroke. Gait ability was assessed through gait analysis[19]. A three-dimensional video-base motions analysis system with 6 cameras with infrared light sources (Vicon 370, USA) was used to assess the angles of the joints during walking. The Vicon system was considered to have an accuracy of 1° and 1.5° (root mean square) in static and dynamic angular measurements, respectively. The measured variables were the temporal-spatial gait parameters (gait speed, cadence, step length, stride length, double support) and kinematics gait parameters (pelvic, hip, knee, ankle joint angle).

Data analysis was performed using SPSS version 19.0 (IBM Corp., Armonk, NY, USA). The Kolmogorov-Smirnov verification was used to prove the normality of the data, which were found to be normally distributed. For demographic data of both groups, independent t tests were used for continuous variables, while χ^2 tests were used categorical variables. A paired t test was used to compare the pre- and post-therapy data, whereas the independent t test was used to compare the changes between the groups. To prove statistical significance, the significance level was set at $p < 0.05$.

RESULTS

After completion of the 5-week intervention, gait speed ($p = 0.035$), step length ($p = 0.010$), stride length ($p = 0.041$), maximal knee flexion ($p = 0.009$), and maximal knee extension ($p = 0.018$) were significantly greater than those before the intervention in the experimental group, and gait speed ($p = 0.014$), stride length ($p = 0.047$), and maximal knee flexion ($p = 0.002$) were significantly greater than before the intervention in the control group. Only maximal knee flexion ($p = 0.019$) showed a significant difference between the experimental and control groups (Table 2).

A comparison of motor and balance functions before and after treatment showed that MMAS and BBS significantly increased and TUG significantly decreased in both groups. These results show that the improvement in the experimental group was greater than that in the control group, but the difference between the two groups was not significant (Table 3).

DISSCUSSIONS

The data shows that RAGT with FES was more beneficial than RAGT only for ambulatory patients with hemiparesis after stroke. After completion of the 5-week intervention, step length and maximal knee extension were significantly greater than those before intervention in the experimental group only. There was a significant difference in maximal knee flexion between the experimental and control groups. Motor and balance functions improved significantly after intervention compared with those before the intervention in both groups. The experimental group tended to improve better than the control group, but the difference between both groups was not significant. These results suggest that RAGT with FES has an advantage in terms of regaining gait ability and motor and balance functions. Husemann et al.[14] and Mayr et al.[20] reported a significant improvement in gait ability and motor and balance functions after RAGT in stroke patients. Husemann et al.[12] found that the period of weight bearing on the affected side was increased after RAGT in stroke patients. Because of the weakness and sensory impairment of the paretic leg, the hemiparetic gait is characterized by a shortened single-support phase on the paretic leg and a prolonged single-support phase on the healthy leg[1]. After the RAGT, the patients were assumed to be able to support their body weight on the paretic leg for a longer period. Thus, their gait patterns became more symmetrical[21]. Positive effects of higher speed on gait quality have been reported in RAGT[22]. We think that there was a significant improvement in gait ability and motor and balance functions in both groups because of the strong advantageous of RAGT compare with FES.

Tong et al.[23] reported the effectiveness of the combination therapy of BWSTT and FES on walking speed and motor function. Hesse et al.[24] also reported that a combined therapy of treadmill gait training and FES produced positive training effects on gait ability and motor and balance functions compared with either treadmill training or FES alone. However, they did not measure the kinematic gait parameters through gait analysis with a three-dimensional video-based motion analysis. In our study, we measured the kinematic gait parameters. FES was applied to stimulate ankle dorsiflexor in the experimental group. In addition, stroke patients received cues from the tingling sensation of FES to stimulate ankle dorsiflexor during the swing phase of the robot-assisted gait cycle, which encouraged them to

Table 2. Comparison of gait function between the 2 groups

Variables	Group	Before Mean ± SD	After Mean ± SD
Gait speed (meters/sec)	Experimental (n = 10)	0.347 ± 0.204	0.425 ± 0.241*
	Control (n = 10)	0.370 ± 0.193	0.431 ± 0.236*
Cadence (steps/min)	Experimental (n = 10)	67.522 ± 22.582	70.044 ± 25.047
	Control (n = 10)	67.833 ± 20.170	71.644 ± 19.779
Step length (m)	Experimental (n = 10)	0.278 ± 0.130	0.331 ± 0.119*
	Control (n = 10)	0.330 ± 0.100	0.348 ± 0.129
Stride length (m)	Experimental (n = 10)	0.562 ± 0.212	0.635 ± 0.226*
	Control (n = 10)	0.634 ± 0.199	0.692 ± 0.238*
Double support (%/cycle)	Experimental (n = 10)	41.333 ± 15.554	40.100 ± 11.209
	Control (n = 10)	35.478 ± 10.344	31.800 ± 9.851
Pelvic motion (°)	Experimental (n = 10)	12.865 ± 3.720	10.009 ± 5.113
	Control (n = 10)	10.638 ± 6.314	10.016 ± 3.131
Hip maximal (°)	Experimental (n = 10)	−5.341 ± 27.521	−4.626 ± 28.882
	Control (n = 10)	−12.223 ± 10.687	−10.529 ± 10.579
Maximal Knee flexion (°)	Experimental (n = 10)	24.443 ± 17.431	43.190 ± 17.607*, **
	Control (n = 10)	19.113 ± 14.277	34.220 ± 14.544*
Maximal Knee extension (°)	Experimental (n = 10)	−0.161 ± 12.802	6.743 ± 11.102*
	Control (n = 10)	−0.353 ± 10.935	−0.557 ± 6.510
Ankle plantar flexion (°)	Experimental (n = 10)	24.740 ± 14.673	16.507 ± 7.188
	Control (n = 10)	16.453 ± 8.154	14.224 ± 7.163
Ankle dorsiflexion (°)	Experimental (n = 10)	−1.396 ± 15.474	4.090 ± 11.921
	Control (n = 10)	8.337 ± 4.354	8.755 ± 4.629

*p < 0.05, between the pretreatment and posttreatment parameters in each group
**p < 0.05, between the experimental and control groups

Table 3. Comparison of motor and balance performances between the 2 groups

Variables	Group	Pretreatment Mean ± SD	Posttreatment Mean ± SD
MMAS	Experimental (n = 10)	35.30 ± 7.67	37.22 ± 6.81*
	Control (n = 10)	37.81 ± 7.02	39.77 ± 6.06*
TUG	Experimental (n = 10)	33.28 ± 17.43	27.65 ± 11.34*
	Control (n = 10)	30.14 ± 18.35	25.02 ± 14.94*
BBS	Experimental (n = 10)	44.20 ± 8.70	47.63 ± 6.94*
	Control (n = 10)	47.36 ± 6.81	49.62 ± 4.67*

MMAS, Modified Motor Assessment Scale; TUG, Timed Up-and-Go Test;
BBS, Berg Balance Scale
*p < 0.05, between the pre- and post-intervaion data

actively participate in the training process. FES could stimulate skin and proprioceptive receptors, which could provide appropriate alternate movement training by concentric and eccentric stimulation[11]. FES might improve the fitness and strength of the paralyzed motor units of stroke patients who still have voluntary control[15]. In the abovementioned previous studies, the combination of walking training with FES was significantly more effective than conventional walking training for reduction of spasticity, improvement of strength in the affected leg, and prevention of muscular atrophy in stroke patients. These effects have also been shown in chronic stroke patients[12]. We thought that compared with RAGT alone, RAGT with FES led to increases in maximal knee flexion and step length and a greater decrease in knee hyperextension. Therefore, hyperextension of the knee might be corrected and step length could be increased by the FES effects of increased ankle dorsiflexion angle. However, it is thought that we could not observe the strong advantage of peroneal stimulation with FES because the Lokomat system involves ankle fixation.

We expected that the combination of RAGT and FES would be more beneficial than RAGT alone because FES applied to the ankle dorsiflexor could positively affect the mobility of the knee, which would improve gait ability and motor and balance functions. By receiving the combination therapy, patients could gain a more meaningful and functional therapeutic effect from FES instead of passively letting their paralyzed muscles be stimulated electrically during RAGT.

We found that the 5-week combination therapy of RAGT and FES had advantages with respect to improvement of gait ability and motor and balance functions in the chronic stroke patients compared with RAGT alone, although the motor and balance performances were not significantly statistically different. Therefore, we suggest that the combination of RAGT and FES encourages patients to actively participate in training because it improves gait ability and motor and balance functions without adverse effects. Thus, this combination therapy may be useful for treatment of chronic stroke patients.

The only limitation of this study is that the gait analysis was not explained in detail using a variety of methods. Future research with a larger number of subjects is recommended.

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