Original Article

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Effects of robot-assisted gait training on the balance and gait of chronic stroke patients: focus on dependent ambulators

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Abstract. [Purpose] The purpose of this study was to confirm the effect of robot-assisted gait training on the balance and gait ability of stroke patients who were dependent ambulators. [Subjects and Methods] Twenty stroke patients participated in this study. The participants were allocated to either group 1, which received robot-assisted gait training for 4 weeks followed by conventional physical therapy for 4 weeks, or group 2, which received the same treatments in the reverse order. Robot-assisted gait training was conducted for 30 min, 3 times a week for 4 weeks. The Berg Balance Scale, Modified Functional Reach Test, Functional Ambulation Category, Modified Ashworth Scale, Fugl-Meyer Assessment, Motricity Index, and Modified Barthel Index were assessed before and after treatment. To confirm the characteristics of patients who showed a significant increase in Berg Balance Scale after robot-assisted gait training as compared with physical therapy, subgroup analysis was conducted. [Results] Only lateral reaching and the Functional Ambulation Category were significantly increased following robot-assisted gait training. Subscale analyses identified 3 patient subgroups that responded well to robot-assisted gait training: a subgroup with hemiplegia, a subgroup in which the guidance force needed to be decreased to needed to be decreased to ≤45%, and a subgroup in which weight bearing was decreased to ≤21%. [Conclusion] The present study showed that robot-assisted gait training is not only effective in improving balance and gait performance but also improves trunk balance and motor skills required by high-severity stroke patients to perform activities daily living. Moreover, subscale analyses identified subgroups that responded well to robot-assisted gait training.

Key words: Stroke, Robotics, Gait

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INTRODUCTION

Patients with stroke have gait and balance problems related to joint mobility and stability, muscle tone, muscle weakness and endurance, and loss of proprioception[1)]. While most patients regain independent ambulatory function within 6 months, problems with balance continue even after 6 months[2)]. Impairment of balance ability makes the daily life of a stroke patient difficult, and the fear of falls and other secondary disabilities is likely to aggravate the state of disability[3)]. In particular, poor sitting balance in the acute stages after stroke indicates a poor prognosis for motor recovery in performing routine activities such as wheelchair transfer and eating[4, 5)]. For these reasons, balance ability is most important component in rehabilitation[6)].

Robust balance can be achieved through either direct balance training for enhancing balance performance or gait training[2)]. Of these two intervention methods, gait training is predominantly a direct approach requiring the involvement of a therapist, such as body weight-supported treadmill training and overground walking training. However, such overground walking therapies are not likely to provide hemiplegic stroke patients with continuous and consistent training, and they impose substantial physical burdens on even skilled therapists[7)]. Moreover, high-severity stroke patients incapable of walking owing to weakness and poor coordination cannot benefit from overground walking therapies[8)]. To address these limitations, robot-assisted gait train-

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ing (RAGT) was introduced, and it is attracting interest[7]. RAGT has the advantages of enabling gait training in otherwise non-trainable patients by assisting their ambulatory functions with exoskeletal assistive devices to enable a task-focused training and providing the patient with regular feedback. Furthermore, it provides continuous and symmetrical training without time and duration constraints[9, 10]. A 2013 review, which examined 23 randomized controlled studies with a total of 999 subjects, showed that the likelihood of attaining independent ambulation is greater in a stroke patient group receiving a combination of RAGT and conventional gait training than in a stroke patient group receiving conventional gait training only, thus supporting a previous review's finding[11]. Numerous other randomized controlled studies also reported improved independent ambulation and enhanced lower extremity functionality in combination groups compared with single therapy groups[12–14]. According to the results of a study with chronic stroke patients, contrary to the generally known poor prognosis for improvement of ambulatory function of patients with high-severity lower extremity paresis more than 11 weeks post stroke, the subjects demonstrated improved ambulatory functions after body weight-supported treadmill training, and the results of some domestic studies supported this finding[15, 16]. In light of these findings, numerous studies presented the possibility of using RAGT as a therapy device for non-ambulatory chronic stroke patient groups[17, 18].

Against this background, this study aimed to determine the effectivenss of RAGT as a therapy. To this end, we provided RAGT to individuals who were dependent ambulators to confirm its effects on balance and gait function as well as to identify the patient group that responded well to RAGT.

SUBJECTS AND METHODS

Subjects

As the subjects of this study, stroke patients with hemiplegia or quadriplegia admitted to the National Rehabilitation Center were evaluated. The inclusion criteria were onset period of >6 months, functional ambulation category <2, independent ambulation before stroke, capability of understanding and executing RAGT, and an absence of other orthopedic or neurosurgical problems in the lower extremities. The exclusion criteria were weight >120 kg; femoral length <35 cm or femoral length >47 cm; history of low extremity fracture after stroke, instability or subluxation of the hip joint, or pressure ulcers on the hips or lower extremities; and any underlying disease preventing execution of RAGT.

Methods

This study was an 8-week prospective, crossover research study with parallel groups (AB, BA) and designed as a randomized controlled trial. Group 1 underwent RAGT in the first 4 weeks, and group 2 commenced RAGT after 4 weeks. Conventional physical therapy (PT) was performed throughout the 8 weeks in both groups; only the application of RAGT was different. Balance and walking ability were evaluated before the commencement of RAGT and 4 and 8 weeks thereafter.

A Lokomat® (Hocoma AG, Zurich, Switzerland) system was used for RAGT. Initially, the guidance force was set at 100% for both the hip and knee joints. Depending on the patient's functional characteristics, the guidance force was decreased in increments of 10%. In cases of quadriplegia, settings appropriate to the symptoms of the most severely affected side were used. Patients selected the walking speed, in the range of 1.0–1.8 km/h that they felt was most comfortable. Initially, the level of weight bearing support was set at 40% of the patient's weight, and this was decreased by 2 kg each session. Subjects used the Lokomat system for 30 min, 3 times a week for 4 weeks. The PT consisted of the Bobath training approach, neurophysiological exercise training and theory, inhibition of spasticity and synergy pattern movement, and standing or sitting exercises for 30 min, 5 times a week.

The Berg Balance Scale (BBS) and Modified Functional Reach Tests (MFRTs; forward and lateral) were used for evaluating the primary outcome of balance. The BBS is designed to assess static and dynamic balancing in the elderly and disabled adults with 14 different criteria[16]. Since the MFRT is a balancing ability evaluation that requires stretching the arm in the sitting position, patients who are unable to walk may also be evaluated[19]. The patient's maximum forward and lateral reach are measured for evaluation.

The secondary outcomes measured in the study were walking ability, motor function, and independence in activities of daily living (ADL). Gait ability was measured using the Functional Ambulation Category (FAC); patients were scored from 0–5 depending on the amount of help needed when walking. Muscle tone and muscle recovery degree of the extremities were used to evaluate movement function. The Modified Ashworth Scale (MAS), which defines 6 different categories, was used to evaluate muscle tone, and the Fugl-Meyer Assessment of Lower Extremity (LeFMA) and Motricity Index (MI) were used to evaluate the degree of muscle recovery of the extremities. The Modified Barthel Index (MBI) was used to assess the patient's independent mobility for ADL, and the scores for lower classifications such as transfer and ambulation were recorded separately.

To confirm the characteristics of patients who showed a significant increase in BBS score after RAGT when compared with after PT, subgroup analysis was performed according to the patient's paralyzed side, guidance force, and body weight support rate. The guidance force (GF) subgroup was divided into GF subgroup 1, which had a median guidance force below 45%, and GF subgroup 2, which had a guidance force greater that 50%. The weight bearing support (WBS) subgroup was divided into WBS subgroup 1, which had a median weight bearing support below 21%, and WBS subgroup 2, which had a median weight bearing support of more than 21%.

This research received IRB approval (09-01) from the Korea National Rehabilitation Center IRB Committee, and all participants gave informed consent to the research.

Statistical analysis was performed to compare the 2 treatments. The possibility of a period effect was tested using a 2-sample t test to compare differences in period between the 2 groups of patients. We also investigated the possibility of a treatment period interaction by assuming that in the absence of an interaction, a patient's average response to the

Table 1. General characteristics

Group	Age (years)	Onset (months)	MMSE	Diagnosis	Affected side
1 (n=13)	55.3±11.9	15.1±8.7	19.3±7.8	Infraction (4) Hemorrhage (7) Both (2)	Right (5) Left (4) Double (4)
2 (n=7)	55.4±15.3	13.4±6.7	14.6±10.2	Hemorrhage (7)	Right (3) Left (1) Double (3)

MMSE: Mini Mental State Evaluation

Table 2. Assessment of primary outcome measures before and after intervention

		Lokomat phase		PT phase	
		Before	After	Before	After
BBS		10.5±12.1	14.9±16.2*	11.0±14.1	13.2±15.3*
MFRT	Forward reach (cm)	24.3±15.3	29.9±16.1*	26.4±15.6	31.0±16.5*
	Lateral reach (cm)	16.1±12.2	21.7±12.2*	18.4±13.4	20.5±12.8

All values are shown as the mean±SD. BBS: Berg Balance Scale; MFRT: Modified Functional Reach Test
*Statistically significant (p<0.05) in comparison with pre-test data

Table 3. Assessment of secondary outcome measures before and after intervention

	Lokomat phase		PT phase	
	Before	After	Before	After
FAC	0.8±0.8	1.2±1.0*	0.9±0.8	1.1±1.0
MAS	2.7±2.3	2.1±1.7	2.2±1.8	2.6±2.0
Lefma	15.5±6.9	18.3±7.0*	16.2±7.0	18.4±7.3*
MI	28.7±20.9	32.7±20.8*	29.9±19.9	31.8±19.9*
MBI				
Total	35.2±17.1	43.9±19.8*	37.6±18.4	42.4±20.2*
Transfer	4.8±4.4	8.0±4.7*	6.1±4.7	7.0±4.9†
Ambulation	2.0±3.4	3.5±4.7*	2.4±3.3	3.6±4.5*

All values are shown as the mean±SD. FAC: Functional Ambulatory Category; MAS: Modified Ashworth Scale; LeFMA: Fugl-Meyer Assessment scale of Lower Extremity; MI: Motoricity Index; MBI: Modified Barthel Index
*Statistically significant (p<0.05) in comparison with pre-test data
†Statistically significant (p<0.05) in comparison between Lokomat training and PT phase

2 treatments would be the same regardless of the order in which they were received. The treatment effect was tested by performing a 1-sample t test on all 20 subjects regardless of differences between the 2 treatments because there was no period effect and no treatment period interaction. Because the 2 crossover groups were not the same size, we considered the average effect in the 2 periods, which was the equivalent of performing a 2-sample t test. The data were analyzed using the SPSS 14.0 software for Windows (SPSS Inc., Chicago, IL, USA). A p value less than 0.05 was regarded as statistically significant.

RESULTS

Patients were randomly assigned into 2 groups; group 1 contained 13 patients and group 2 contained 7 patients. The general characteristics of the study participants are shown in Table 1.

The patients' BBS scores were significantly improved after RAGT and PT, and there was no significant difference between the 2 groups. The results of the forward reaching MFRT were similar to those of the BBS ($p<0.05$). There were no significant differences between the 2 groups (Table 2).

The FAC score, which evaluates a patient's walking ability, significantly improved in the RAGT group ($p<0.05$). However, there were no significant differences between the 2 groups. The MAS score evaluates a patient's motor function; no significant improvements in motor function were observed after treatment sessions. After each training session, the LeFMA and MI scores showed significant improvements ($p<0.05$); however, there were no inter-session score improvements. Independence in ADL was evaluated

Table 4 . Improvement in balance measured by the BBS score in the subgroups after Lokomat and PT

		Subgroup 1		Subgroup 2	
		Lokomat	PT	Lokomat	PT
BBS	Hemi (12/8)	6.5±6.7*	2.6±2.7*†	1.1±0.9*	1.5±2.3*
	GF (9/11)	6.5±5.6*	2.4±2.7†	2.5±5.5*	2.0±2.6*
	WBS (10/10)	5.9±5.7*	2.0±2.7*†	2.8±5.7*	2.4±2.5*

All values are shown as the mean±SD. BBS: Berg Balance Scale; GF: Guidance Force on the affected side; WBS: Weight Bearing Support

using the MBI. The subitem “transfer” significantly improved with treatment within and between groups ($p<0.05$). Another subitem, “ambulation,” only showed significant improvements within treatment groups ($p<0.05$) (Table 3).

In hemiplegic patients, the change in BBS score was significantly different both within and between sessions ($p<0.05$). In quadriplegic patients, the BBS score was significantly different within sessions ($p<0.05$) but not between sessions. The change in BBS score was significantly different after RAGT ($p<0.05$), but the change was not significant after PT. The difference between RAGT and PT was significant in GF subgroup 1 ($p<0.05$). In GF subgroup 2, the BBS score increased after RAGT and PT; these differences were significant ($p<0.05$); however, the difference in the BBS score between RAGT and PT was not significant. Changes in the BBS score between after RAGT and PT were significantly higher in WBS subgroup 1 ($p<0.05$). Significant differences were also observed between the 2 sessions ($p<0.05$). The WBS subgroup 2 showed significant changes after RAGT and PT ($p<0.05$), but the differences between the sessions were not significant (Table 4).

DISCUSSION

This study was conducted on chronic stroke patients who were dependent ambulators in order to determine the therapeutic effects of RAGT on balance and gait functions and to identify the patient group suitable for RAGT.

Balance is a key element contributing to the optimal gait function in stroke patients. In particular, sitting balance is an important prerequisite for conducting independent daily activities in the stages prior to recovery of ambulatory function[20, 21]. One of the approaches used for the recovery of balance ability in stroke patients is gait training. A study that investigated the relationship between gait training and balance in stroke patients reported that its Lokomat training group showed significantly greater improvement in terms of the BBS score than its control group[2]. Studies evaluating the balancing ability of chronic stroke patients (≥6 months post stroke) also reported significant positive effects of RAGT that were comparable with those of regular physiotherapies[17, 22]. According to a study conducted on severe stroke patients, RAGT was more efficient than a regular ambulation therapy in improving the functions necessary for ambulation, such as proprioceptive balance control, lower-extremity mobility, and endurance[23]. A large number of studies have presented their findings of investigations of the effects of RAGT, and a systematic review showed that the efficacy of RAGT in improving the balance ability of stroke patients is comparable to but not superior to that obtained with other ambulation training methods[2]. In this study, too, the BBS evaluation results revealed that both RAGT and PT contributed to enhancing balance ability, although there were no significant duration-dependent differences. The Texas Woman’s University provided MFRT-related standards of forward reaching ≥ 32 cm and lateral reaching ≥ 18 cm[4]. In the present study, while the number of patients that showed improvements in forward reaching ≥ 32 cm increased by 25% after PT, no patient showed post-training improvement in lateral reaching ≥ 18 cm compared with his/her baseline performance. In contrast, while the extent of RAGT-mediated improvements in forward reaching ≥ 32 cm was similar to the 25% achieved after PT, the number of patients who demonstrated improvements in lateral reaching ≥ 18 cm increased by 35% relative to the baseline level. From these results, it can be inferred that RAGT is superior to PT as a treatment method for improving lateral reaching. Furthermore, these findings are similar to those of previous studies in which improvement in the weight-supporting function of the paretic lower extremities was directly associated with improvement in forward and lateral reaching and findings in previous studies indicating that successful coordination between the trunk and upper extremities improves extension performances in the sitting position[24].

Both groups showed significant improvements in the ability to perform ADL. This was induced by the improvement of balance ability, as judged on the basis of the findings of previous studies that confirmed the positive relationship between ADL and sitting balance[25, 26]. In previous studies conducted on acute- and subacute-stage patients who were dependent ambulators and chronic ambulatory patients, the post-intervention MIs were significantly improved compared with baseline levels in their RAGT and PT groups[27, 28]. The results of the current study showed similar pre-post differences in both groups, thus supporting the results of previous studies. The post-intervention MAS score tended to decrease in the RAGT group but tended to increase in the PT group.

The subgroup analyses revealed that the hemiplegia subgroup showed statistically greater improvements in BBS than the quadriplegia subgroup and that the RAGT group managed to reduce the GF to ≤45% and successfully decreased the WBS to ≤21%, showing significant improvements compared with the PT group.

This study included chronic stroke patients who were dependent ambulators to determine the effects of RAGT. We verified that RAGT is efficacious in regaining balance and gait functions in stroke patients who are dependent ambulators. Additionally, patient groups suitable for obtaining optimal RAGT effects could be identified using subgroup analyses. These results are expected to serve as basic data for discussions about rehabilitation training methods that can maximize the advantages of robot-assisted devices as well as for the development of treatment protocols tailored according to patient characteristics. They will also serve as important basic data for development of future treatment devices for stroke patients who are dependent ambulators.

The following may be mentioned as limitations of this study: difficulties related to finding stroke inpatients who were dependent ambulators with a symptom duration ≥6 months and a high dropout rate during the study owing to health status aggravation anticipated in high-severity patients, refusal of study participation, and adverse dermatological effects. Moreover, the session and program durations were insufficient to induce physical changes. Thus, future research must focus on verifying the advantage of RAGT over PT in inducing significant balance ability improvements. Additionally, studies with larger sample sizes and longer time frames are needed to provide regular guidelines on training protocol progression and manifest physical functions.

In conclusion, RAGT is a treatment method with obvious therapeutic effects that is safely applicable to chronic stroke patients who are dependent ambulators. Not only was it efficacious in improving balance and gait performance to an extent equivalent to PT, but it was also verified to be conductive to improving the trunk balance and motor skills necessary for high-severity stroke patients to perform daily routine activities. Moreover, subscale analyses identified three patient subgroups that responded well to RAGT.

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