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Effects of robot-assisted gait training on spatiotemporal gait parameters and balance in patients with chronic stroke: A randomized controlled pilot trial

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Abstract.
BACKGROUND: Body weight-supported treadmill training assisted by a robotic gait orthosis is a helpful tool for restoring a symmetrical gait pattern in people with gait discrepancies.
OBJECTIVE: This study's aim was to compare the effects of robot-assisted gait training (RAGT) versus treadmill gait training (TGT) on spatiotemporal gait parameters, balance, and activities-specific balance confidence with stroke patients.
METHODS: Eighteen participants with stroke were randomly assigned to RAGT or TGT. Each group underwent twenty sessions (1 h/d, 5 d/wk for 4 weeks). Patients were assessed with gait parameters (gait speed, cadence, step length, and double limb support period) using the GAITRite, the Berg Balance Scale (BBS) score, and the activities-specific balance confidence (ABC) score before and after the intervention.
RESULTS: Gait speed ($P = 0.003$), cadence ($P = 0.002$), step length ($P = 0.004$), the BBS score ($P = 0.048$), and the ABC score ($P = 0.017$) were significantly higher in the RAGT group than in the TGT group, while the double limb support period was significantly lower in the RAGT group ($P = 0.043$).
CONCLUSION: RAGT using Lokomat may be more effective than TGT in improving waking ability, balance, and balance confidence in patients with chronic stroke.

Keywords: Rehabilitation, robot-assisted gait training, stroke

1. Introduction

Gait disruption not only limits independent living for stroke patients, but also puts them at risk for fall-related injuries and for generating secondary impairments (e.g., depression, pain) (Lord & Rochester, 2005). Thus, one of primary goals in stroke rehabilitation is to improve walking ability (Michael, Allen, & Macko, 2005). As a result, there is a critical need for more effective interventions for increasing walking ability after a stroke, which could also improve self-confidence. Numerous studies examining methods improve walking ability in individuals with impaired central nervous systems have suggested that repeatedly practicing walking on a treadmill is an effective, task-oriented intervention to improve walking ability (Ada, Dean, Hall, Bampton, & Crompton, 2003; Grealy, Johnson, & Rushton, 1999; Pohl, Mehrholz, Ritschel, & Rückriem, 2002; Shumway-Cook et al., 2007).

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Robot-assisted gait training (RAGT) is an effective method for improving walking ability in patients early after stroke (Tefertiller, Pharo, Evans, & Winchester, 2011). The RAGT exoskeleton device can control the lower limb to improve symmetry and coordination (Swinnen, Duerinck, Baeyens, Meeusen, & Kerckhofs, 2010). It can also offer the sensory feedback needed for increasing walking ability by correcting the gait pattern during gait training (Rossignol, 1996).

The merits of RAGT compared to conventional rehabilitation strategies (e.g., reducing the physical burden on the therapist, providing a psychological sense of safety during gait training, and controlling the participant's performance) contribute to its effectiveness in gait training (Banala, Kim, Agrawal, & Scholz, 2009).

However, little is known about the effectiveness of RAGT for chronic stroke patients in the Republic of Korea, including whether it improves walking performance to contribute to independent living for stroke patients. Considering that decreased walking ability is the most important determinant in quality of life (Shumway-Cook et al., 2007), more evidence is necessary to determine which is the more effective strategy for increasing walking ability in chronic stroke patients.

The aim of present study was therefore to investigate whether robot-assisted gait training is an effective method for increasing the walking ability more than treadmill gait training in chronic stroke patients.

2. Methods

2.1. Experimental design

This study was a double-blinded randomized controlled trial, clinical pilot study, and is reported according to the CONSORT statement (Moher, Schulz, Altman, & Group, 2005). Both the assessor was blinded. The assessor, who not participated in the study, was experienced, and well qualified in the use of the tests. The participants performed the tests after gaining sufficient familiarity with the test protocols.

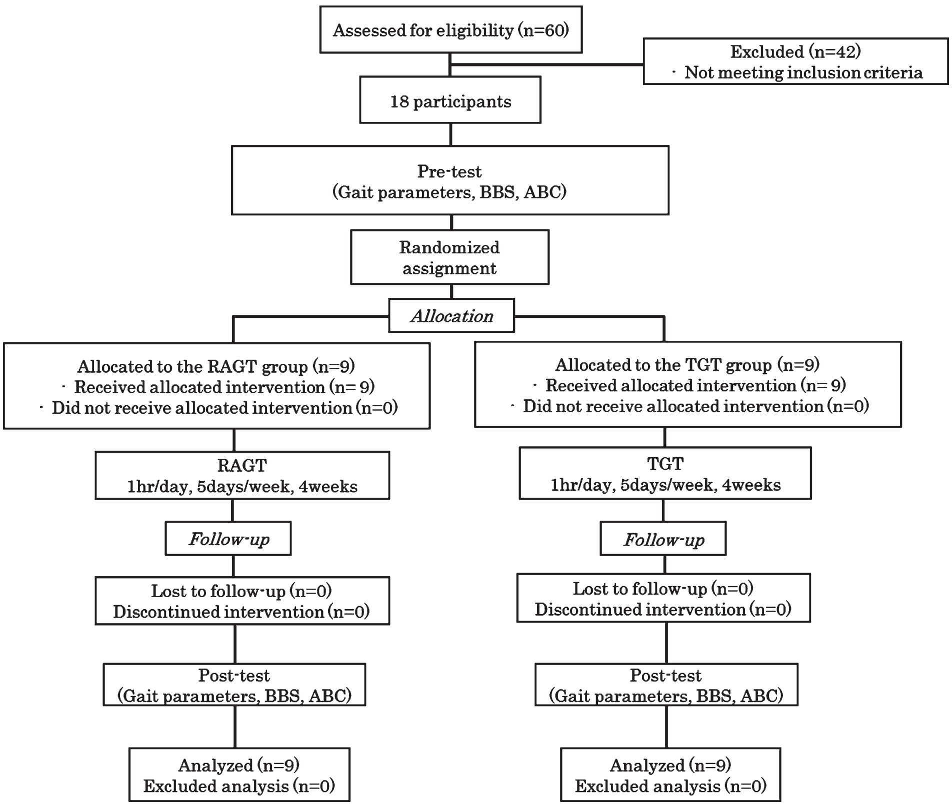

Fig. 1. Flow diagram of the study. Gait parameters conclude the gait speed, cadence, step length, and double support period. Abbreviations: BBS, Berg balance scale; ABC, activities-specific balance confidence; RAGT, robot-assisted gait training; TGT, treadmill gait training.

A four-week training study was designed to evaluate the influence of RAGT on walking ability. Gait parameters (gait speed, cadence, step length, and double limb support period) using the GAITRite, the Berg Balance Scale (BBS) score, and the activities-specific balance confidence (ABC) score were assessed before and after the intervention. All procedure showed in the flow diagram (Fig. 1).

2.2. Participants

Eighteen stroke patients who had been admitted to a Rehabilitation clinic in the Republic of Korea were randomized into either the RAGT ($n = 9$) or TGT ($n = 9$) groups (directly after obtaining baseline measures) by a physical therapist not otherwise associated with the study. The randomization was performed by selection of an opaque closed envelope from envelopes in which the group assignment was written, and sealed envelope was given to the physical therapist. The inclusion criteria were (1) history and clinical presentation (hemiparesis) of stroke (first hemorrhage or infarction); (2) event occurring >6 months previously; (3) a gait speed over 0.4 m/s, sufficient for using the treadmill (Pohl et al., 2002); (4) no previous gait-related training interventions; (5) possible independent gait over 10 m; and (6) sufficient cognition to participate in the training, which was defined as a Mini-Mental State Exam (MMSE) (Folstein, Folstein, & McHugh, 1975) score of 24 or higher. The exclusion criteria were: (1) the presence of any comorbidity or disability other than stroke that would preclude gait training; and (2) any uncontrolled health condition for which exercise is contraindicated. Participation in the study was voluntary and patients fully understood the purpose of the study. All participants were informed about the tests and the use of the results and were asked to sign a written informed consent statement. The study was approved by our-institutional review board (IRB) and follows the principles outlined in the Declaration of Helsinki.

2.3. Training interventions

The experiment began on the day after randomization. For both groups, the intervention progressed during the regularly scheduled therapy session and all other routine interdisciplinary stroke rehabilitation proceeded as usual. Each participant underwent a training program consist of 20 sessions that were 1 h per day, 5–days a week for four weeks.

The RAGT group was trained with the Lokomat device (Hocoma AG, Zurich, Switzerland). Participants were fitted with a harness so that a portion of their body weight could be supported in the device when walking. The participant's lower-limbs were aligned by the Lokomat. The Lokomat allows users to be trained in gait speed, step length, and a typical gait pattern. With the device properly adjusted, the Lokomat initiated stepping patterns that participants were instructed to follow. Specifically, their goal was to move legs like the device to minimize the amount of assistance the Lokomat provided. For this first session, up to 40% body-weight support was provided to allow participants to focus on timing their gait patterns under moderate intensity level. Initial walking speeds were normally around 0.45 m/s. In subsequent sessions, training intensity (Hidler et al., 2009) was increased progressively in terms of walking speed, level of body-weight support, and duration of continuous walking. In our study, all participants used the same treadmill protocol, with the addition of the Lokomat device in the RAGT group.

The TGT (Pohl et al., 2002) group performed gait training without body-weight support on the treadmill. The treadmill was equipped with hand railings and a sensor that would stop the treadmill if there were a problem with balance or safety. The TGT was conducted using the treadmill in a flat position. The maximum overground walking speed was determined before the first training session. This speed was halved for a 5-min warm-up. After the warm-up, the first speed-dependent training phase began. During a period of 1–2 min, with communication with the participant, the speed was increased to higher speed at which the participant could walk safely. The maximum-achieved speed was held for 10 s, followed by a recovery period during which the participant's pulse was allowed to return to its resting level. If the participant maintained the maximum-achieved speed and felt safe during those 10 s, the speed was increased by 10% during the next session. During any phase, if the participant was unable to maintain the speed or, felt unsafe, the speed was reduced by 10% in the next session. After each session, the participants finished the training with deep breathing and simple stretching.

2.4. Outcome measures

2.4.1. Gait parameter

The GAITRite (CIR Systems Inc, Clifton, NJ, USA) system measures a spatial and temporal gait parameters (Chien et al., 2006). And has high intra-rater and retest reliability and validity (van Uden & Besser, 2004). The GAITRite system forms an electronic walkway with pressure sensors embedded in a horizontal grid, 4.6 m long and 0.89 m wide, that connects to a computer's serial port. The sensors close under the pressure of the participant walking over the walkway, enabling collection of spatial and temporal gait parameters. Data were sampled from the walkway at a frequency of 80 Hz, allowing a temporal resolution of 11 ms. A rail on the wall beside the walkway was available for the participants to grasp if they felt unstable or unbalanced.

2.4.2. Balance

The BBS was used as a balance test (Blum & Korner-Bitensky, 2008). This scale consisted of 14 balance activities, ranging from sit-to-stand and to standing on one leg. A participant's performance on each task was graded using a 5-point ordinal scale ranging from 0 to 4, with higher scores awarded on the basis of speed, stability, and degree of assistance required for task completion. The task scores were summed for a total BBS score out of a possible 56 points, with higher scores representing better balance.

2.4.3. Balance confidence

The ABC scale consist of 16 items and used to assess participants' balance confidence (Salbach, Mayo, Hanley, Richards, & Wood-Dauphinee, 2006). Participants rated their level of confidence on a scale of 0% (no confidence) to 100% (complete confidence) when performing activities such as climbing stairs, reaching above the head, and walking on different surfaces. Responses were summed and divided by 16 to provide an overall mean balance confidence score. If the participant did not currently do the activity in questions, the participant was asked to imagine how confident they would be doing the activity. Over 80% represents a the high level of physical functioning, 50–80% is a moderate level of physical functioning, and below the 50% is a low level (Miller, Speechley, & Deathe, 2002).

2.5. Data and statistical analysis

Descriptive and analytical statistics were performed (Table 2). Independent *t*-tests compared differences between group means and change scores. A two-way (group × time) repeated measures ANOVA was performed. Data were presented as mean and SD. Effect size were calculated as the difference between the means of the experimental and control groups divided by the mean SD at baseline (Cohen, 1988). Significance was set at $P < 0.05$.

3. Results

Participants in the RAGT group performed the robot-assisted gait training with Lokomat and those in the TGT group performed treadmill gait training during intervention. All participants completed the entire study. There were no significant group differences in the sex, side and type of stroke, time after stoke, age, MMSE (Table 1) or gait parameters (gait speed, cadence, step length, and double support period), the BBS score, or the ABC score at baseline.

The mean change in gait speed in the RAGT group was significantly greater than in the TGT group (0.16 ± 0.03 m/s vs. 0.09 ± 0.05 m/s, $P = 0.003$), as

Table 1
Demographic data of the participants

	Robot-assisted gait training group ($n = 9$)	Treadmill gait training group ($n = 9$)	*P*-value
Sex(n)			
Men	5	4	0.64
Women	4	5	
Side of stroke(n)			
Right	5	5	1.00
Left	4	4	
Type of stroke(n)			
Infarction	7	6	.0.60
Hemorrhage	2	3	
Time after stroke(month)	11.56 (2.60)	12.56 (2.65)	0.43
Age(years), mean(SD)	53.56 (3.94)	53.67 (2.83)	0.95
MMSE(scores), mean(SD)	26.27 (1.12)	26.00 (1.73)	0.35

NOTE. Baseline demographic data for participants include in the two different groups and significance level at $p < 0.05$ for difference between the groups. Abbreviations: MMSE, mini-mental state examination.

Table 2
Descriptive measurements

Variables	RAGT group ($n = 9$)		TGT group ($n = 9$)		Between groups P-values (95% CI) – 2 tailed	Effect sizes
	Pre-test	Post-test	Pre-test	Post-test		
Gait parameters						
Gait speed (m/s)	0.48 (0.05)	0.64 (0.04)*†	0.46 (0.04)	0.55 (0.04)*	0.002 (0.038∼0.135)	1.64
Cadence (steps/min)	63.91 (1.05)	69.30 (1.92)*†	63.78 (1.61)	66.24 (2.02)*	0.003 (1.437∼4.682)	1.78
Step length (cm)	30.19 (0.95)	34.62 (1.11)*†	29.54 (0.86)	32.27 (0.73)*	0.028 (1.432∼3.278)	2.37
Double support period (%)	34.81 (2.08)	31.29 (0.98)*†	35.12 (2.63)	32.75 (0.88)*	0.005 (–2.382∼–0.520)	0.70
BBS (scores)	43.22 (2.54)[a]	48.89 (2.37)*†	42.11 (2.42)	46.33 (1.87)*	0.022 (0.413∼4.697)	0.61
ABC Scale (scores)	46.67 (9.09)	69.33 (4.85)*†	47.86 (7.85)	60.00 (3.93)*	0.013 (4.905∼13.761)	1.63

[a]Means (SD); *Significant difference within groups; †Significant difference between groups. Pre-test was performed before the intervention, and post-test was performed after 4 weeks. In the pre-test between groups, there was no significant difference ($P > 0.05$). The significance level were set at $p < 0.05$ for differences between the groups. Abbreviations: RAGT, robot-assisted gait training; TGT, treadmill gait training; BBS, Berg balance scale; ABC, activities-specific balance confidence. Effect sizes of Cohen: 0.15 = small; 0.4 = medium; 0.75 = large; 1.1 = very large; 1.45 = huge effect size.

was the mean change of cadence (5.38 ± 1.23 steps/min vs. 2.45 ± 1.92 steps/min, $P = 0.002$). Similarly, the mean change in step length in the RAGT group was significantly greater than that in the TGT group (4.46 ± 1.09 *cm* vs. 2.73 ± 0.93 *cm*, $P = 0.004$), as was the mean change in the double limb support (–3.51 ± 1.79% vs. –2.37 ± 2.05%, $P = 0.043$). The mean change in BBS score in the RAGT group was significantly greater than in the TGT group (5.67 ± 1.12 vs. 3.87 ± 1.92, $P = 0.048$). The mean ABC score change in the RAGT group was significantly higher than that in the TGT group (23.38 ± 8.77 vs. 13.33 ± 1.80, $P = 0.017$). The RAGT group showed improvements in gait speed, cadence, step length, double limb support period, the BBS score, and the ABC score which were significantly different from those in the TGT group (Table 2).

4. Discussion

This study was designed to evaluate the effects of RAGT on walking ability in chronic stroke patients, who usually use compensatory strategies for gait (Hidler, Carroll, & Federovich, 2007). Such compensatory strategies may be decrease movement efficiency act as barriers to functional improvement (Hidler et al., 2007), revealed by factors such as poor balance, weakness, misalignment, joint instability, hypertonia, etc (Mayr et al., 2007). RAGT with the Lokomat may aid patients in overcoming some of these problems by allowing them to practice the typical gait patterns, decreasing the participant's body weight for normal alignment and aiding foot clearance, and executing an automated, intensive walking training program (Swinnen et al., 2010).

Task-oriented training has become the most favored approach for increasing motor function after stroke (Yang, Wang, Lin, Chu, & Chan, 2006). Both RAGT and TGT are forms of task-oriented training for increasing walking ability after stroke (Shumway-Cook et al., 2007). However, RAGT was more effective than TGT at improving walking ability, possibly because participants could practice a many steps in the Lokomat without fear of falling and also because the Lokomat promotes a symmetrical gait pattern (Banala et al., 2009).

In previous studies, RAGT was a method for rehabilitating subjects with decreased walking ability, and its usefulness in the recovery of weight-bearing ability, walking speed, and endurance has been studied (Banala et al., 2009; Michael et al., 2005; Miller et al., 2002). Several studies focused on the evaluation and optimization of leg kinematic trajectories, muscle activation, and gait pattern while walking using the Lokomat (Banala et al., 2009; J. M. Hidler & Wall, 2005; Regnaux, Saremi, Marehbian, Bussel, & Dobkin, 2008). Recent, studies suggest that automatized gait training may be an effective method for improving walking ability, whereby patients may walk more symmetrically, with less spasticity, and with better joint/ankle displacements (Uhlenbrock, Sarkodie-Gyan, Reiter, Konrad, & Hesse, 1996; Werner, Von Frankenberg, Treig, Konrad, & Hesse, 2002). Krishnan (2013) reported that cooperative control robotic training is superior to conventional robotic training and was more effective in improving gait ability after stroke. In our study, RAGT showed a more significant improvement compared with the TGT group in gait speed, cadence, step length, double limb support period, and BBS and ABC scores. RAGT has also been shown in previous studies to improve cardiovascular fitness, which is necessary for improving motor function (Banala et al., 2009; Mayr et al., 2007; Picelli et al., 2013). Mayr et al. (2007) suggested that improving walking ability requires (1) reduction of body weight support; (2) increase in walking duration; (3) increase in velocity of walking; and (4) reduction of guidance force on the more affected leg. In our study, RAGT provided these factors for improving walking ability.

Stroke patients manifest reduced walking ability, which occurs due to the loss of balance and excessive energy consumption from compensatory gait patterns (Bang, Shin, Kim, & Choi, 2013). Therefore, it is important to improve balance and minimize the compensatory gait pattern in patients with decreased walking ability. In a previous study, RAGT was reported as an effective method for increasing balance and improving normal gait patterns (Banala et al., 2009). In our study, RAGT improved balance and balance confidence significantly better than TGT. Those improvements may have been due to the RAGT device, which included a harness and bar felt safe and comfortable to participants in walking training, allowing them to practice more intensive and efficient training.

Our results differ from those reported by Hindler et al. (2005) in which participants who received conventional gait training experienced significantly greater improvements in walking speed and distance than those trained on the Lokomat. We hypothesize that this is because participants in the Hindler et al. (2005) study were stroke patients in the subacute phase, when patients show rapid recovery naturally. Thus, the natural recovery of stroke patients less than 6 months from stroke onset might be a confounder for the interpretation of improvements in walking ability (Kwakkel, Kollen, & Wagenaar, 2002).

4.1. Study limitations

This study has several limitations that may be overcome by future studies. First, a major limited factor in generating our results to the entire population with stroke patients is probably the small sample size. Our results must be validated by further studies with larger sample sizes. Second, absence of long-term follow-up after the end of intervention did not allow for determination of the durability of effects. Therefore, conduct of further studies, including long-term follow-up assessment is required in order to evaluate the long-term effects of RAGT. Therefore, the results must be interpreted with caution.

5. Conclusion

The results of our study indicate that RAGT improved walking ability and suggest the applicability of RAGT for clinical rehabilitation. Stroke patients present with loss of motor function and may show fear of independent due to decreased walking ability caused by muscle weakness, spasticity, poor balance, malalignment, and joint instability (Mayr et al., 2007). Thus, improvement in the walking ability of stroke patients increases the opportunities for independent and social living.

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Conflict of interest

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