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End-effector lower limb robot-assisted gait training effects in subacute stroke patients

A randomized controlled pilot trial

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Abstract

Background: This pilot study investigated end-effector lower limb rehabilitation robot training effects in subacute stroke patients.

Methods: Forty-nine stroke patients were randomly assigned to 2 treatment groups: a 30-minute end-effector lower limb rehabilitation robot training plus 1.5-hour conventional physiotherapy (robot group; n = 26), or a 2-hour conventional physiotherapy (control group; n = 23). All patients received 5 treatments weekly for 4 weeks. The functional ambulatory category was the primary outcome and the motricity index, Fugl Meyer assessment-lower extremity, rivermead mobility index, 10 meter walk test, Berg balance scale, and modified Barthel index were secondary outcomes.

Results: All outcome measures significantly improved in both groups after training ($P > .05$). The robot group improved more in FAC than the control group ($P = .005$).

Conclusions: Compared with conventional physiotherapy alone, end-effector lower limb robot-assisted gait training with conventional physiotherapy improved subacute stroke patients walking ability.

Abbreviations: 10MWT = 10 meter walk test, BBS = Berg balance scale, FAC = functional ambulatory category, FMA-LE = Fugl Meyer assessment-lower extremity, MBI = modified barthel index, MI = motricity index, RAGT = robot-assisted gait training, RMI = rivermead mobility index.

Keywords: gait, neurological rehabilitation, robotics, stroke

1. Introduction

Stroke is a leading cause of adult disability,[1] causing mobility, balance, and coordination deficits that considerably limit daily living and social interaction.[2] Many patients experience gait impairments post-stroke; thus, gait recovery is a primary rehabilitation goal for stroke patients.[1,2]

Robot-assisted gait training (RAGT) provides highly intensive and task-specific gait training for stroke patients and reduces therapists physical burden.[3,4] It is a widely used rehabilitation strategy for stroke survivors, as ambulation tasks are possible even if the patient cannot walk.[5] RAGT effects are well-established to lead to significant improvements in clinical outcomes.[5,6] Lower limb rehabilitation robotic devices are classified into end-effector and exoskeleton systems based on their mechatronics design and human-machine interaction.[7] Although RAGT superior effect of using end-effector and exoskeleton devices in stroke patients was controversial,[5,8,9] systematic reviews of the literature demonstrated that end-effector systems increased independent walking and walking function rates compared to an exoskeleton system.[4,6,8]

RAGT provides the most benefit for patients unable to walk within the first 3 months post-stroke.[4,6] A previous study showed that end-effector RAGT combined with conventional physiotherapy improved voluntary strength and balance compared to conventional physiotherapy alone, but did not improve walking ability.[10] This study included patients within 1 year after stroke, not just patients with subacute stroke. In addition, because this previous study included patients with functional ambulatory category (FAC) scores of 2 or higher, the study was conducted mainly on patients who were able to walk, confirming more benefits for patients with a FAC score of 2 than for patients with scores of 3 or higher. We hypothesized that end-effector

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Clinical Trial Registration: This study was registered on the Clinical Research Information Service database (KCT0005373).

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lower limb RAGT would be effective in patients with reduced walking function within 3 months after onset, when it is most effective. Therefore, this study investigated end-effector lower limb RAGT effects in subacute stroke patients.

2. Materials and Methods

2.1. Study design

This prospective, single-blind, multi-center, randomized controlled pilot trial was conducted between November 2020 and November 2022 at 3 university hospitals in the Republic of Korea. The trial was registered on the Clinical Research Information Service database (KCT0005373) and was approved by each hospital Institutional Review Board. All patients provided written informed consent before study enrollment. Although this is a sponsored study, the researchers designed and conducted the study, including data analysis, manuscript drafting, revision, and submission, with no involvement by the funding source.

2.2. Participants

The patient inclusion criteria were: age ≥19 years; within 3 months of stroke onset; hemiparesis; FAC score ≤3; Trunk Control Test ≥49; the ability to participate in gait training using the Morning Walk; and pre-stroke was an independent walker.

The exclusion criteria were: severe cognitive disorders (Mini-Mental State Exam < 10) or aphasia that impeded communication; severe lower extremity musculoskeletal disease; severe lower extremity contracture that limited the range of motion; fractures, open wounds, or unhealed ulcers; body weight >135 kg or height >195 cm; difficulty participating in robot-assisted gait treatment due to severe medical conditions such as cardiovascular or lung disease; compression fracture risk due to severe osteoporosis; or other neurological disorders affecting the lower extremities.

2.3. Randomization

Patients were randomly assigned in a 1:1 ratio to the robot or control group using a computer-generated random-number table. Both investigators and patients could access the assigned treatment group information. However, the randomization information was not disclosed to the evaluators who assessed the outcome measures to prevent bias.

2.4. Intervention

Patients were randomly assigned into 2 treatment groups: 30-minute training with an end-effector lower limb rehabilitation robot plus 1.5-hour conventional physiotherapy (robot group); or 2-hour conventional physiotherapy (control group).

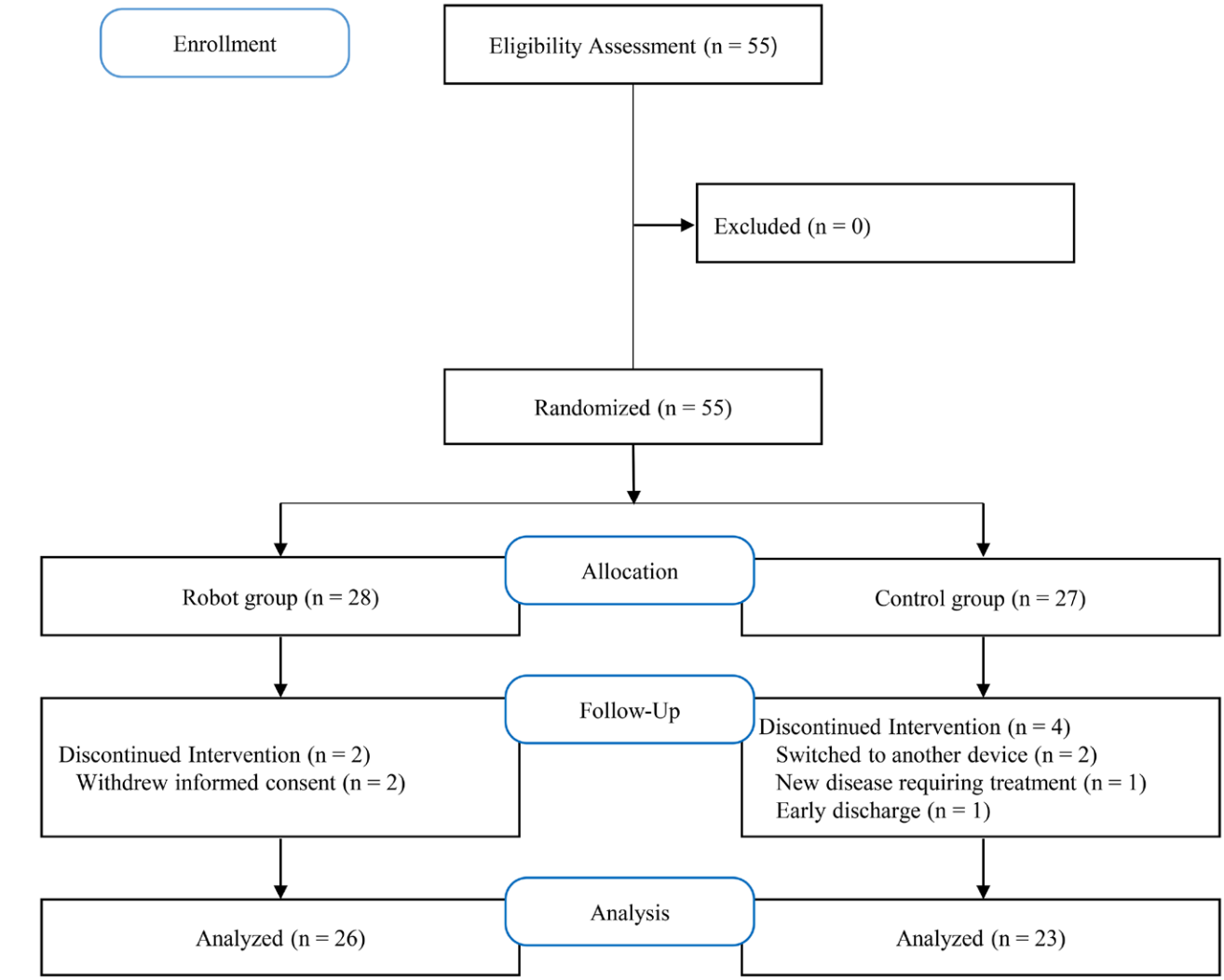

Figure 1. Study flowchart.

All patients received 5 treatments weekly for 4 weeks. RAGT utilizes the Morning Walk (CUREXO, Seoul, Republic of Korea), an end-effector gait rehabilitation robot system that provides knee, ankle, and pelvic movements by footplate trajectories.[10,11] It has a seating-type body weight reinforcement system that supports the patient weight with a saddle, allowing safe boarding and various training modes, including ground walking, ascending, and descending stairs. Training started in ground walking mode with a 30 to 35 steps/minute cadence and a 30 to 35 cm step length; parameters were adjusted relative to patient performance. Afterward, the training proceeded to ascending and descending stairs modes. Approximately 5 to 10 minutes were needed to get on and off the Morning Walk. The conventional physiotherapy was performed based on traditional neurodevelopmental treatment techniques.[10] Patients with sensorimotor disorders were trained in sitting and standing balance, active locomotion, sit-to-stand, and muscle strengthening exercises. As physical function improved, the patients progressed to dynamic standing balance training and eventually functional gait training, while they continued to perform muscle strengthening exercises.[10]

2.5. Outcome measures

The primary outcome measure was FAC. FAC is a reliable and valid walking ability assessment scale, distinguishing 6 levels (from 0–5) based on the physical support required to maintain walking.[12,13] The motricity index (MI), Fugl Meyer assessment-lower extremity (FMA-LE), rivermead mobility index (RMI), 10 meter walk test (10MWT), Berg balance scale (BBS), and the modified Barthel index (MBI) were secondary outcome measures. MI is an instrument that accurately measures post-stroke muscular coordination and strength. It primarily assesses the lower extremity through measures of hip flexion, knee extension, and ankle dorsiflexion.[14] We evaluated the MI of the lower extremity paretic side with a 0 to 100 score, where higher scores indicate improved function. The RMI utilizes mobility items to measure functional ability with a score from 0 to 15, with higher scores indicating improved functional mobility.[15] We used the 10MWT to assess gait velocity by recording patients average walking speed (m/second) over 2 trials.[16,17] The BBS is a 14-item scale for measuring static and dynamic balance; with scores ranging from 0 to 56, where higher scores indicate improved balance ability.[18] The MBI scale measures daily living performance with scores ranging from 0 to 100, with a higher score indicating greater daily living independence.[19] Lastly, the FMA-LE assesses motor impairment degree post-stroke,[20,21] using 17 items to measure the paretic lower extremity motor function and coordination. Its scores range from 0 to 34, with higher scores indicating less impairment. Outcome measures were evaluated before initial training (baseline) and after final training (week 4). Experienced physical therapists blinded to patient group assignment collected the measurements. Each gait training session was monitored for potential adverse events for safety.

2.6. Statistical analysis

A formal sample size calculation was not conducted as this was a pilot study. This study data will benefit future power analyses guiding the design of new studies. Statistical analysis was performed using SPSS Statistics version 18.0 (SPSS Inc., Chicago, IL). The normality assumption was assessed with the Shapiro–Wilk test. Independent *t* tests or Mann–Whitney *U* and Chi-square tests were used to analyze patient demographic and baseline characteristics for continuous or categorical between-group comparisons. The Wilcoxon signed-rank test was used to analyze baseline and after-treatment changes. The Mann–Whitney test was used to compare baseline to post-intervention changes for all outcome measures from the robot and control groups. Statistical significance was set to a P value < .05.

3. Results

3.1. Demographic and baseline characteristics

Figure 1 presents the study flowchart. Fifty-five patients were recruited and randomized into the robot or control groups. However, 6 patients were excluded at follow-up, resulting in 49 patients for the final analysis (robot group: 26; control group: 23). No significant demographic or clinical characteristic differences were found between the groups (Table 1). There was no significant difference in the baseline scores of the FAC, MI, FMA-LE, RMI, 10MWT, BBS, or MBI between the 2 groups ($P > .05$). No adverse intervention events or safety issues occurred during the study.

3.2. Outcome measures

Table 2 presents each group baseline and after-treatment outcome measures. All outcome measures indicated substantial improvement post-training in both groups ($P < .05$). Table 3 portrays baseline to after-treatment outcome measure changes. The robot group showed greater baseline to post-intervention FAC score improvement than the control ($P = .005$).

Compared to the control group, the robot group showed greater changes after treatment compared to the baseline for MI, FMA-LE, RMI, 10MWT, BBS, and MBI. However, the inter-group difference in changes in the MI, FMA-LE, RMI, 10MWT, BBS, and MBI after treatment compared to baseline were not statistically significant ($P > .05$).

4. Discussion

This single-blind, multi-center, randomized controlled study compared the effects of end-effector lower limb RAGT with conventional physiotherapy to conventional physiotherapy only

Table 1

Patient demographics and baseline characteristics.

	Robot group (n = 26)	Control group (n = 23)	*P* value
Age (yr)	63.04 ± 15.69	64.78 ± 12.81	.478*
Sex (%)			
Male	15 (57.69)	11 (47.83)	.490†
Female	11 (42.31)	12 (52.17)	
Height (cm)	163.50 ± 12.34	163.68 ± 8.25	.953*
Weight (kg)	62.29 ± 13.77	61.86 ± 10.26	.903*
BMI	23.64 ± 3.27	23.40 ± 2.79	.777*
Stroke etiology (%)			
Ischemia	20 (76.92)	20 (86.96)	.365†
Hemorrhage	6 (23.08)	3 (13.04)	
Hemiparesis side (%)			
Right	15 (57.69)	11 (47.83)	.490†
Left	11 (42.31)	12 (52.17)	
Post-stroke (mo)	0.93 ± 0.69	0.91 ± 0.71	.960‡
MMSE	21.50 ± 6.49	23.61 ± 5.22	.220*
TCT	78.27 ± 15.57	74.96 ± 17.73	.555‡
FAC	0.96 ± 0.87	1.04 ± 0.93	.763‡
MI	53.19 ± 15.57	43.48 ± 18.11	.100‡
FMA-LE	19.85 ± 8.92	16.13 ± 8.83	.154‡
RMI	4.35 ± 2.64	3.91 ± 2.17	.618‡
10MWT (m/s)	0.30 ± 0.26	0.22 ± 0.13	.358‡
BBS	25.08 ± 22.67	19.65 ± 21.25	.316‡
MBI	34.50 ± 16.82	34.48 ± 16.60	.888‡

10MWT = 10 meter walk test, BBS = Berg balance scale, FAC = functional ambulatory category, FMA-LE = Fugl Meyer assessment-lower extremity, MBI = modified Barthel index, MI = motricity index-lower extremity, MMSE = mini-mental state examination, RMI = rivermead mobility index, TCT = trunk control test.

*Independent *t* test.

†Chi-square test.

‡Mann–Whitney test.

Table 2

Baseline and after-treatment outcome measures.

	Robot group (n = 26)			Control group (n = 23)		
	Pre	Post	*P* value*	Pre	Post	*P* value*
FAC	0.96 ± 0.87	3.35 ± 1.23	<.001	1.04 ± 0.93	2.48 ± 1.12	<.001
MI	53.19 ± 15.57	67.54 ± 14.28	<.01	43.48 ± 18.11	56.09 ± 13.47	<.01
FMA-LE	19.85 ± 8.92	27.42 ± 4.87	<.01	16.13 ± 8.83	21.65 ± 7.86	<.01
RMI	4.35 ± 2.64	9.15 ± 2.95	<.01	3.91 ± 2.17	8.30 ± 2.74	<.01
10MWT (m/s)	0.30 ± 0.26	0.60 ± 0.36	<.01	0.22 ± 0.13	0.43 ± 0.29	<.01
BBS	25.08 ± 22.67	47.58 ± 21.33	<.01	19.65 ± 21.25	38.87 ± 22.56	<.01
MBI	34.50 ± 16.82	63.85 ± 19.52	<.01	34.48 ± 16.60	60.87 ± 21.45	<.01

10MWT = 10 meter walk test, BBS = Berg balance scale, FAC = functional ambulatory category, FMA-LE = Fugl Meyer assessment-lower extremity, MBI = modified Barthel index, MI = motricity index-lower extremity, RMI = rivermead mobility index.
*Wilcoxon signed rank test.

Table 3

Baseline to after-treatment outcome measure changes.

	Robot group (n = 26)	Control group (n = 23)	*P* value*
FAC	2.39 ± 0.94	1.44 ± 1.27	.005
MI	14.04 ± 12.01	12.65 ± 7.95	.641
FMA-LE	7.58 ± 6.60	5.57 ± 4.51	.225
RMI	4.81 ± 2.51	4.39 ± 2.33	.552
10MWT (m/s)	0.38 ± 0.34	0.31 ± 0.28	.771
BBS	22.50 ± 13.13	19.22 ± 10.94	.350
MBI	29.35 ± 17.09	27.09 ± 21.67	.685

10MWT = 10 meter walk test, BBS = Berg balance scale, FAC = functional ambulatory category, FMA-LE = Fugl Meyer assessment-lower extremity, MBI = modified Barthel index, MI = motricity index-lower extremity, RMI = rivermead mobility index.
*Mann–Whitney test.

for subacute stroke patients. The results of this study showed that subacute stroke patients who received combination therapy exhibited greater walking ability improvement than conventional physical therapy alone.

Systematic reviews have reported that stroke patients who participated in electromechanical-assisted gait training with physiotherapy were likelier to achieve independent walking than patients who only received physiotherapy, and this study supports these previous findings.[4,6] Contrarily, in a previous study, although end-effector RAGT was beneficial for stroke patients, walking ability measured by FAC did not differ when comparing end-effector RAGT with physiotherapy to physiotherapy alone.[10] However, because their study included stroke patients with a FAC score of 2 or more, they had better ambulatory function results than ours. Moreover, whereas the current study only included subacute stroke patients, the previous study selected patients within 1 year post-stroke. Mehrholz et al speculated that as non-ambulatory patients benefit from RAGT and ambulatory patients do not, subacute stroke patients should exhibit better results (independent walking) than chronic stroke patients.[6] This is consistent with the reported walking ability differences between the current study and the previous study on end-effector RAGT.[10]

Both the robot and control groups in this study had improved MI, FMA-LE, RMI, 10MWT, BBS, and MBI outcome measures. The various clinical outcome effects were reported in RAGT studies using end-effector lower extremity rehabilitation robots for non-ambulatory subacute stroke patients.[22–26] With RAGT using the G-EO System, robot training with physiotherapy and physiotherapy alone groups significantly improved regarding FAC, RMI, gait velocity, and MI.[22] These results are also consistent with our study. Furthermore, greater FAC, RMI, and velocity improvements were observed in patients who received robot training and physiotherapy compared to physiotherapy alone. Chua et al concluded that electromechanical gait training with conventional physiotherapy improved gait speed and FAC, consistent with the current study results.[23] However, the efficacy of RAGT with conventional physiotherapy did not differ from conventional physiotherapy alone. The FAC and Barthel Index improved after intensive locomotor training (Gait Trainer GT I; Reha-Stim, Berlin, Germany) with physiotherapy, which improved considerably in intensive locomotor training with physiotherapy relative to physiotherapy alone.[19] Ng et al reported that electromechanical gait training improved lower-limb strength, ambulation ability, walking speed, and daily living, indicating more impressive walking speed and FAC improvements from electromechanical gait training than conventional training.[25] We theorize that these mixed clinical results in the studies applying RAGT to non-ambulatory subacute stroke patients are due to using different robotic devices, intervention periods, and protocol differences. However, further research is needed for confirmation.

A recent meta-analysis found that electromechanical and RAGT devices could improve gait in patients with stroke.[6] Stroke patients who receive electromechanical-assisted gait training combined with physiotherapy were more likely to achieve higher levels of independent walking than those receiving physiotherapy alone. Our results, which showed that walking ability measured by FAC was more improved with RAGT combined with conventional physiotherapy than with conventional physiotherapy alone, are consistent with this. The secondary outcomes, including MI, FMA-LE, RMI, 10MWT, BBS, and MBI, improved after RAGT combined with conventional physiotherapy. These outcome measures also showed greater changes from baseline to post-treatment after RAGT combined with conventional physiotherapy relative to physiotherapy alone. However, no statistically significant differences were observed between RAGT combined with conventional physical therapy and physical therapy alone. In this study, the mechanism for the effect of RAGT was not identified. However, the lack of statistical significance is presumed to be because this study was a pilot study and the sample size was small. Therefore, further large-scale studies are needed to expand upon our findings.

This study has some limitations. First, this study sample size was relatively small, potentially lowering the results statistical power. As this is a pilot study, a minimal sample size to achieve sufficient statistical power was established. Thus, a future study with a larger sample size is needed. Second, the study period was relatively short, and the outcome measures were only evaluated at baseline and after training. Therefore, it is necessary to assess the long-term effects through long-term follow-up in future research.

In conclusion, our results suggest that walking ability is more improved with end-effector type lower limb RAGT combined with conventional physiotherapy compared with conventional physiotherapy alone in patients with subacute stroke. Additional studies are required for confirmation.

Author contributions

Conceptualization: Junekyung Lee, Dae Yul Kim, Seung Hak Lee, Deog Young Kim, Kil-Byung Lim, Jeehyun Yoo.
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Visualization: Junekyung Lee, Ji Hye Kim.
Writing – original draft: Junekyung Lee.
Writing – review & editing: Junekyung Lee, Dae Yul Kim.

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