

Effects of robot (SUBAR)-assisted gait training in patients with chronic stroke

Randomized controlled trial

Cheon Ji Kang, MD^a, Min Ho Chun, MD, PhD^{a,b,*}, Junekyung Lee, MD, PhD^a, Ji Yeon Lee, PT, MSc^o

Abstract

Background: SUBAR is a new ground walking exoskeletal robot. The objective of this study is to investigate SUBAR-assisted gait training's effects in patients with chronic stroke.

Methods: This preliminary study is a prospective randomized controlled trial. Thirty adults were enrolled 6 months after the onset of stroke with functional ambulation category scores \geq 3. Patients were randomly assigned to receive robot-assisted gait training (SUBAR group, n = 15) or conventional physiotherapy (control group, n = 15). All patients received a total of 10 treatment sessions of 30 minutes each for 3 weeks. Before and after the 10-treatment sessions, patients were evaluated. The primary outcome is the 10 meter walk test and the secondary outcomes were the functional ambulation category scale, the Motricity Index-Lower, Modified Ashworth Scale (MAS), timed up and go, Rivermead Mobility Index, Berg Balance Scale (BBS), and gait analysis.

Results: In the SUBAR group, MAS and step length were significantly improved between pre- and posttreatment measurements ($\Delta mean \pm SD$: -1.1 ± 1.6 and 5.5 ± 7.6 , P = .019 and .016, respectively). The SUBAR group improved the stride length and step length of the affected limb but not significantly. The control group had significant improvements in the BBS, MAS, and stride length between pre- and posttreatment measurements ($\Delta mean \pm SD$: 3.5 ± 4.6 , -0.8 ± 1.5 , and 6.5 ± 9.5 ; P = .004, .031, and .035, respectively). The BBS improved more in the control group than in the SUBAR group. There were no other differences between the SUBAR group and the control group.

Conclusion: Our results suggest that SUBAR-assisted gait training improved gait parameters in patients with chronic stroke. However, there was no significant difference in most outcome measures compared to conventional physiotherapy. Further research is warranted to measure the effects of SUBAR-assisted gait training.

Abbreviations: 10MWT = 10 meter walk test, BBS = Berg Balance Scale, BWSTT = body-weight supported treadmill training, FAC = functional ambulation category, GEMS = gait enhancing and motivating system, MAS = Modified Ashworth Scale, MI = Motricity Index.

Keywords: gait, neurological rehabilitation, robotics, stroke

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^a Department of Rehabilitation Medicine, Asan Medical Center, 88 Olympic-ro 43gil, Songpa-gu, Seoul, Korea, ^b University of Ulsan College of Medicine, 88 Olympic-ro 43-gil, Songpa-gu, Seoul, Korea, ^c Asan Laboratory for Rehabilitation Robot Biomedical Engineering Institute, Asan Institute for Life Sciences, 88 Olympic-ro 43-gil, Songpa-gu, Seoul, Korea.

^{*} Correspondence: Min Ho Chun, Department of Rehabilitation Medicine, Asan Medical Center, Seoul, Korea (e-mail: mhchun@amc.seoul.kr).

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1. Introduction

Annually, 15 million people worldwide have a stroke. Of these, 5 million people become permanently disabled.^[1] Patients with a stroke experience many disabilities that cause serious health problems and much burden to their families. Half of the patients are unable to walk immediately after a stroke, and one third of the patients are unable to walk at 3 months after a stroke.^[2,3] Reduction in gait function severely limits activities of daily living and social activity. Therefore, the recovery of walking ability is the primary goal in stroke patients.^[4,5]

Physical therapy aims to improve balance, gait, and movement through manual therapy conducted by physical therapists.^[6] Such treatment is burdensome for therapists who are small in stature or weak in strength. Sometimes, therapists do not meet the patient's needs and impede recovery potential.^[7] The use of rehabilitation robots can provide repetitive, interactive, high-intensity, and task-specific limb treatment.^[6]

There have been several research studies on robot-assisted gait training in stroke patients. Westlake et al^[8] found that body-weight supported treadmill training (BWSTT) with Lokomat, an exoskeleton-type robot, is associated with similar improvement in walking speed compared with manually assisted BWSTT. Also, Kelley et al^[9] showed that Lokomat and overground gait training groups had no differences at postintervention and 3-month follow-up except in the Fugl–Meyer Lower Extremity Motor

score and Barthel Index, which were more improved with Lokomat-assisted gait training than overground gait training. According to the Cochrane Review, robot-assisted gait training with physiotherapy in acute stroke patients is more beneficial for independent walking than physiotherapy alone, but not for walking velocity or walking capacity.^[10]

Previous treadmill-based robots provide gait training in a static environment, such as a fixed and confined area, and take up a lot of space. Overground robots, on the other hand, provide a community environment and experience near-normal proprioception.^[3,11] Unlike end-effector robots where movement occurs due to distal segments such as footplates, exoskeleton-type robots are controlled by the compatibility of robots with multiple joints.^[11]

Molteni et al^[12] showed that an exoskeleton robot (Ekso) for overground gait training improved ambulatory functions in patients with chronic stroke. Lee et al^[13] found that a wearable hip-assist robot [gait enhancing and motivating system (GEMS)] had improved parameters of gait analysis. And Wright et al^[14] also found that a wearable overgound robot (Alter-G Bionic Leg orthosis) showed improvement in the 6-minute walk test. However, the wearable exoskeleton robot is a new technology not often used in rehabilitation centers, so the study of overground robot-assisted rehabilitation is limited.^[3]

SUBAR is a new ground walking exoskeletal robot for assisting lower limb movement. It was developed in 2018 for patients with gait disturbance. SUBAR provides walking assistance like a BWSTT robot. But unlike other exoskeleton-type rehabilitation robots, SUBAR is not fixed, not bigger, and can be used while moving indoors. It offers forward walking, backward walking, and walking in a sitting position. However, there are few studies on the effects of exoskeleton- and ground walking-type robots.

The aim of this preliminary study is to investigate the effects of a new ground walking exoskeletal robot (SUBAR)-assisted gait training in patients with chronic stroke.

2. Methods

2.1. Design

This study was a nonblinded, prospective, randomized controlled trial that compared the effects of SUBAR-assisted gait training with those of conventional physiotherapy.

The study was approved by the Asan Medical Center Institutional Review Board (No. 2018-0525), and registered on the Clinical Research Information Service (PRE20200128-003). All participants were given written informed consent and were informed of the study purpose and procedures before they signed the consent form.

2.2. Patients

We enrolled 30 patients from November 2018 to May 2019 at the Asan Medical Center, a tertiary hospital. Inclusion criteria were: age \geq 18 years old, stroke diagnosis (either ischemic or hemorrhagic, confirmed by brain computed tomography or magnetic resonance imaging), stroke onset 6 months prior, a previously independent walker, functional ambulation category (FAC) score \geq 3, and the ability to participate in SUBAR–assisted gait training. This study enrolled patients with FAC 3 or higher for patient safety as a preliminary test of a new ground walking exoskeletal robot. Patients were excluded if they met any of the following criteria: severe cognitive disorder or aphasia that impeded communication, body weight ≥ 100 kg, height < 150 cm, severe medical disease affecting gait, severe neurologic and musculoskeletal disease affecting gait, or other disabilities affecting gait training.

2.3. Intervention

Using block randomization with a block size of 4, the patients were randomly assigned to 1 of 2 groups: the exoskeleton-type robot SUBAR (SUBAR group, n=15) or the conventional physiotherapy (control group, n=15). After randomized assignment, the participants were not blinded to the intervention. All received 10 treatment sessions for 3 weeks. Each treatment is 30 minutes. A licensed physiotherapist evaluated the parameters before the first treatment and after the final treatment. We monitored for adverse events and safety issues related to training.

The conventional physiotherapy was based on traditional neurodevelopmental treatment techniques. Patients practiced passive and active range of motion exercises, strengthening exercises, sitting and standing balance, sit-to-stand movement, and functional gait training.

SUBAR (Fig. 1) is a rehabilitation robot developed by Cretem in Korea and approved by the Medical Device Information & Technology Assistance Center in March 2018. The device is an exoskeleton-type robot for lower limb rehabilitation that assists the patient's ankle, knee, and hip movements. It also supports the patient's weight by buttock and anterior side upper trunk pedestals, all of which were adjusted according to the leg length of each patient. The participants started at a gait speed of 0.5 km/h and a step length of 20 to 50 cm. According to the individual's performance, gait speed was adjusted up to 2.5 km/h, and step length was adjusted in 1-cm increments. A joystick is used to change the direction of left and right movement.

SUBAR differs from the well-known exoskeleton-type robot Lokomat. SUBAR has a length, width, and height of about 140 cm, 140 cm, and 130 cm, respectively. It does not need to be fixed, nor does it require a large space for installation, so it is applicable in hospital corridors.

2.4. Outcome measurements

The primary outcomes were walking speed and walking endurance, assessed using the 10 meter walk test (10MWT). This test requires maximal effort, so it correlates with lower extremity muscles.^[15] We evaluated self-selected velocity and fast velocity for the 10MWT. Participants were asked to walk at their usual walking speed for self-selected velocity measurements and to walk as fast as possible for self-selected velocity measurements. Subjects walked an additional 2 m from both ends of the sidewalk to allow for acceleration and deceleration in each 10MWT. We tested 3 times and used the average.

The secondary outcomes were walking ability, assessed using the FAC scale, and lower limb function, assessed using the Motricity Index (MI)-lower, Modified Ashworth Scale (MAS), timed up and go, Rivermead Mobility Index, Berg Balance Scale (BBS),^[16] and OptoGait for gait analysis.

The FAC divides patients into 6 levels (from 1–6) depending on assistance for gait.^[17] The MI-lower uses items from the MI to evaluate the muscle strength of upper and lower limbs.^[18] The tool is highly reliable for assessing the maximal isometric strength of the hip, knee, and ankle in poststroke patients.^[19] Scores range



Figure 1. SUBAR exoskeleton- and ground walking-type robot.

from 0 to 100, with high scores indicating better function of the lower extremity. Since the patients were all hemiparetic, they were evaluated on the affected side. The MAS assessed spasticity in the flexor and extensor of the hip, knee, and ankle. Scores range from 0 to 4; grade 1+ equates to a score of 1.5. We used the sum of the scores. Timed up and go is a valid and easy-to-use clinical test for stroke patients.^[20] The patient stands up from the chair, turns around a cone 3 m away, and returns to the chair. We used the average of 2 measurements. Rivermead Mobility Index is a useful scale for assessing mobility in stroke patients.^[21] It consists of 15 questions (14 self-reported items and 1 direct observation item). The total score, which ranges from 0 to 15, is determined by summing up the scores of all items. The BBS evaluates static and dynamic balance, and scores vary from 0 to 56.

A gait analysis included step length, stride length, single support, double support, cadence, and gait speed. OptoGait is a floor-based photocell system detecting interruptions in communication between the bars, which are caused by the patient's movement (Microgate, Bolzano, Italy). It has high validity and reliability for the assessment of spatiotemporal parameters.^[22,23]

After 10 treatment sessions, we surveyed satisfaction via a 10-question self-questionnaire in the SUBAR group. Responses to each question ranged from 0 to 4, with higher values indicating higher satisfaction.

2.5. Statistical analysis

The data were analyzed using SPSS Statistics version 18.0 (SPSS Inc., Chicago, IL). The normal distribution was assessed using Kolmogorov–Smirnov and Shapiro–Wilk test. Baseline patient characteristics were compared between groups via independent t test and Mann–Whitney test, except for gender, stroke type and affected side, for which the chi-square test was used. The Wilcoxon signed-rank test was employed to compare measures before and after treatment in each group. The Mann–Whitney

test was used to compare changes before and after treatment between the SUBAR and control groups. Statistical significance was indicated by P-values <.05.

3. Results

Of the 31 stroke patients screened from November 2018 to May 2019 at the Asan Medical Center, 1 person was excluded because of height below 150 cm, leaving the 30 enrolled patients. There was no loss to follow-up. We randomized the participants to the SUBAR group (n=15), which received SUBAR-assisted gait training, or the control group (n=15), which received only conventional physiotherapy (Fig. 2). In the SUBAR group, 2 patients only completed 9 treatments. One person, who was on medication for diabetes mellitus and had recurrent skin problems, experienced a skin abrasion at the left tibial area. After 3 weeks, the abrasion was cured, and there were no serious side effects or safety issues. The other person hadn't completed treatments until the trial was over. In the control group, all patients received 10 treatments.

We finally analyzed 30 patients, 15 patients in each group. Age, height, weight, gender, stroke etiology, duration from onset, and affected side did not differ significantly between the 2 groups (Table 1).

We measured improvement by calculating differences in the scores at pretreatment and after 10 treatments for each group. In the SUBAR group, MAS and step length were significantly improved after treatments. The SUBAR group also showed greater improvement in stride length, but not significantly. In the control group, there were significant improvements after treatments in the BBS, the MAS, and stride length (Table 2).

For step length of the affected limb, the SUBAR group showed greater improvement than the control group, but these results did not differ significantly. The BBS improved more in the control group than in the SUBAR group. There were no differences in other measurements between the 2 groups (Table 3).



Overall treatment satisfaction in the SUBAR group, as indicated by the self-questionnaire, was 3.6 out of 4 points. Scores for the training time and number of sessions were 3.20 and 3.00, respectively. Some patients gave 2 points because of the short time and number of sessions.

Table 1							
Baseline characteristics.							
	SUBAR (<i>n</i> =15)	Control (n=15)	P-value				
Age (yr)	64.3 ± 4.6	62.9 ± 6.0	.480				
Height (cm)	161.2±7.5	159.8±8.0	.625				
Weight (kg)	68.5 <u>+</u> 10.9	64.9 <u>+</u> 9.9	.344				
Gender (n)							
Male	10	8	456*				
Female	5	7					
Etiology (n)							
Infarction	7	9	.464*				
Hemorrhage	8	6					
Duration from onset (mo)	168.3 ± 67.3	142.6±59.2	.276				
Affected side (n)							
Right	10	6	.143 [*]				
Left	5	9					

Values are presented as mean \pm SD or number.

^{*} Chi-square test; otherwise independent *t* test and Mann–Whitney test.

4. Discussion

The study suggests that SUBAR-assisted gait training improved gait parameters for patients with chronic stroke. Compared with the control group, patients who had robot-assisted gait training showed a significant improvement in step length. In terms of the MAS and stride length, the robot-assisted gait training group had a positive effect after 10 treatment sessions.

In a Cochrane systematic review, robotic-assisted gait training in combination with physiotherapy have an increased walking independence in people with walking ability due to acute stroke.^[10] Our preliminary study showed different results because we enrolled independently walkable patients with a FAC score of 3 or higher for patient safety. There was a therapeutic effect when physiotherapy was combined with robotic treatment, but this study seems to have shown different results because of the use of robot training alone. However, in the subgroup analysis of the Cochrane review, robot-assisted gait training did not significantly change patients' walking ability after 3 months of onset,^[10] which is consistent with this study.

Our study showed that the BBS improved more in the conventional physiotherapy group than in the robot group, which is consistent with previous studies. Morone et al^[24] found that the improvement in walking ability was higher with therapist-assisted physiotherapy than robotic therapy in patients

Table 2

Differences pretreatment and posttreatment in SUBAR and control groups.								
		SUBAR (n=15)			Control (n=15)			
		Pre	Post	P-value	Pre	Post	<i>P</i> -value	
10MWT (SSV) (m	/s)	9.4±4.9	9.2±5.7	.609	9.1 ± 2.5	8.3±2.8	.173	
10MWT (FV) (m/s)	7.8 ± 4.0	7.6 ± 4.9	.256	7.0 ± 2.2	6.7 ± 2.6	.609	
FAC		4.4 ± 0.5	4.4 ± 0.5	>.99	4.7 ± 0.7	4.7 ± 0.7	>.99	
TUG (s)		17.1±6.9	17.3 ± 9.7	.532	17.3±4.9	15.1 ± 4.3	.065	
BBS		48.3 ± 2.7	48.5±2.8	.599	47.3±4.9	50.8 ± 2.5	.004 [*]	
MAS		3.1 ± 2.1	2.0 ± 1.1	.019 [*]	2.2 ± 2.0	1.4 ± 1.4	.031 [*]	
MI		49.0±7.5	48.8±7.4	.859	50.1 ± 9.5	54.7 <u>+</u> 6.6	.114	
RMI		11.2 ± 0.4	11.3 ± 0.4	.317	11.1 ± 0.5	11.2 ± 0.6	.317	
Gait analysis	Step Length (cm)	42.0±7.7	47.4 ± 10.6	.016 [*]	43.6±9.8	44.9 <u>+</u> 12.1	.379	
	Stride length (cm)	82.6±15.0	87.7 <u>+</u> 15.1	.088	80.8 ± 16.2	87.2 ± 19.6	.035 [*]	
	Single support (%)	31.5 ± 10.0	31.4±9.2	.900	28.1 ± 6.1	31.2 ± 6.5	.140	
	Double support (%)	33.4±8.7	32.5±6.1	.363	38.3 ± 9.9	33.5±6.4	.065	
	Cadence (step/min)	103.0±18.4	107.1 ± 27.9	.363	97.6±19.8	101.1 ± 15.8	.256	
	Speed (m/s)	0.7 ± 0.2	0.8 ± 0.2	.396	0.7 ± 0.3	0.8 ± 0.3	.061	

Values are presented as mean + SD.

10MWT = 10 meter walk test, BBS = Berg Balance Scale, FAC = functional ambulation category, FV = fast velocity, MAS = Modified Ashworth Scale, MI = Motricity Index, RMI = Rivermead Mobility Index, SSV = self-selected velocity. TLIG = timed up and go

Statistically significant by Wilcoxon signed rank test for pretreatment versus posttreatment.

with ambulatory chronic stroke.^[25] In another study, manualassisted treadmill training in chronic stroke patients did not differ significantly from robot-assisted training.^[8] These results appear to be because robotic treatment restricts the pelvis and trunk, impeding spontaneous movements and changes in motor memory reinforcement.^[25] Our ground walking exoskeletal robot supports active movement in the lower extremities with fastening to thighs, calves, and feet.

Although results vary slightly from study to study, walking speed, single limb stance time, and Fugl-Meyer lower extremity motor score have shown improvements in robotic treatment groups. However, there have been no significant differences between robot-assisted and manual training.^[9,24-26] Showing similar results as previous studies, our study demonstrated better MAS, step length, and stride length with robot-assisted training.

Table 3

Differences between SLIBAD and central groups

		SUBAR	Control	<i>P</i> -value
ΔFAC		0	0	>.99
Δ 10MWT (SSV)		-0.2 ± 1.4	-0.9 ± 2.1	.486
Δ 10MWT (FV)		-0.1 ± 1.2	-0.3 ± 1.5	.775
Δ TUG		0.2 ± 3.2	-2.1 ± 3.9	.250
ΔBBS		0.1 ± 1.3	3.5±4.6	.004 [*]
Δ MAS		-1.1 ± 1.6	-0.8 ± 1.5	.436
ΔMI		-0.1 ± 6.5	4.6±9.4	.187
ΔRMI		0.1 ± 0.3	0.1 ± 0.3	>.99
Gait analysis	Δ Step Length	5.5 ± 7.6	1.3 ± 8.0	.098
	Δ Stride Length	5.1 ± 10.7	6.5 <u>+</u> 9.5	.595
	Δ Single support	-0.1 ± 7.6	3.1 ± 7.1	.285
	Δ Double Support	-0.9 ± 7.7	-4.8 ± 9.4	.412
	Δ Cadence	4.1 ± 17.2	3.5±13.1	.653
	Δ Speed	0.04 ± 0.2	0.07 ± 0.1	>.99

Values are presented as mean + SD

10MWT=10 meter walk test, BBS=Berg Balance Scale, FAC=functional ambulation category, FV=fast velocity, MAS=Modified Ashworth Scale, MI=Motricity Index, RMI=Rivermead Mobility Index, SSV = self-selected velocity, TUG = timed up and go.

 $\Delta =$ Difference of "posttreatment – pretreatment.".

Statistically significant by Mann-Whitney test for the difference in the SUBAR group versus control aroup

There have been a few studies on exoskeletal and overground walking robots. Walking velocity and the 6-minute walk test improved significantly using Ekso in 12 treatment sessions of 60 minutes each, according to Molteni et al^[12] study. However, there were no significant differences in MI or 10MWT. These results, in turn, are no different from those of our study and existing studies using Lokomat. In research by Lee et al,^[13] gait speed, cadence, and stride length had significant improvement in gait training with GEMS versus gait training without GEMS. However, this study used 45-minute sessions, and 5 treadmill and 5 overground gait trainings. Importantly, both studies evaluated patients with chronic stroke, but patients in our study had longer than 3 times the duration from stroke onset than those in Lee et al study.

Wright study^[14] found the 6-minute walk test improved in the robot-assisted gait training group. However, this study had more training sessions and a shorter postmorbidity period than our study. The intervention group was offered the robot-assisted gait training with conventional physiotherapy and training sessions 5 to 6 days per week for 10 weeks. And patients in Wright study had an average of 31 months after stroke onset. Above all, Wright et al also showed no difference in the 6-minute walk test between the robot-assisted gait training with conventional physiotherapy and conventional physiotherapy only. These results are also similar to those of our study.

In the self-questionnaire conducted in the robot-assisted training group, overall satisfaction was observed to be as high as 3.67. Satisfaction with the training time and the number of trainings was as low as 3.20 and 3.00, respectively, but subjects with 1 or 2 points wanted longer rehabilitation time and more training sessions. Therefore, it seems that the satisfaction with robot-assisted training is very high. Given that the patient's motivation and active participation lead to better rehabilitation results,^[6] the high subjective satisfaction with robot-assisted rehabilitation is an advantage.

In summary, our study is the first of a new ground walking exoskeletal robot-assisted gait training for patients with chronic stroke. SUBAR-assisted gait training was effective and safe. Therefore, robot-assisted gait training can be used for rehabilitation.

This study has some limitations. First, our study was conducted at a single center with a small sample size. Sample size was determined based on previous studies, but larger numbers yield better results. Second, there was no long-term follow-up; we just measured before and after treatments. Third, we offered 10 treatment sessions, which is a short period for larger effectiveness. Fourth, the participants did not blind themselves to the treatment they received. We did not consider a double-blind study, which reduces experimenter bias. Finally, people in the first 3 months after stroke did not participate. If patients with acute stroke had been enrolled, the results would more likely have shown an improvement in walking ability. For a better study, future studies should consider these points. With long-term assessment, it is preferable to consider robot-assisted gait training in acute stroke patients. Double-blinded, multicenter studies with larger sample sizes are needed.

Author contributions

CJK wrote the original draft and formal analysis of data. JL and MHC helped review and edit the paper. JYL and CJK had data collection. All authors started the study, designed it, and monitored the progress together.

Conceptualization: Cheon Ji Kang, Ji Yeon Lee.

Data curation: Cheon Ji Kang, Ji Yeon Lee.

Formal analysis: Cheon Ji Kang.

Investigation: Cheon Ji Kang, Ji Yeon Lee.

Methodology: Cheon Ji Kang.

Project administration: Cheon Ji Kang, Min Ho Chun.

Software: Cheon Ji Kang.

Supervision: Cheon Ji Kang, Min Ho Chun, Junekyung Lee, Ji Yeon Lee.

Writing – original draft: Cheon Ji Kang.

Writing – review & editing: Cheon Ji Kang.

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