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Effects of robot-(Morning Walk®) assisted gait training for patients after stroke: a randomized controlled trial

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Abstract

Objective: To investigate the effects of Morning Walk®–assisted gait training for patients with stroke.
Design: Prospective randomized controlled trial.
Setting: Three hospital rehabilitation departments (two tertiary and one secondary).
Patients: We enrolled 58 patients with hemiparesis following a first-time stroke within the preceding year and with Functional Ambulation Category scores ⩾2.
Intervention: The patients were randomly assigned to one of two treatment groups: 30 minutes of training with Morning Walk®, a lower limb rehabilitation robot, plus 1 hour of conventional physiotherapy (Morning Walk® group; $n = 28$); or 1.5 hour of conventional physiotherapy (control group; $n = 30$). All received treatment five times per week for three weeks.
Main outcome measurements: The primary outcomes were walking ability, assessed using the Functional Ambulation Category scale, and lower limb function, assessed using the Motricity Index-Lower. Secondary outcomes included the 10 Meter Walk Test, Modified Barthel Index, Rivermead Mobility Index, and Berg Balance Scale scores.
Results: A total of 10 patients were lost to follow-up, leaving a cohort of 48 for the final analyses. After training, all outcome measures significantly improved in both groups. In Motricity Index-Lower of the affected limb, the Morning Walk® group (Δmean ± SD; 19.68 ± 14.06) showed greater improvement ($p = .034$) than the control group (Δmean ± SD; 11.70 ± 10.65). And Berg Balance Scale scores improved more ($p = .047$) in the Morning Walk® group (Δmean ± SD; 14.36 ± 9.01) than the control group (Δmean ± SD; 9.65 ± 8.14).
Conclusion: Compared with conventional physiotherapy alone, our results suggest that voluntary strength and balance of stroke patients with hemiparesis might be improved with Morning Walk®–assisted gait training combined with conventional physiotherapy.

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Introduction

Many patients experience gait disturbance following stroke due to reduced mobility of their lower extremities, and restoration of walking ability is often a major rehabilitative goal. The recommended approaches for lower extremity rehabilitation include task-oriented physical training for walking, high-intensity therapy for gait recovery, and repetitive task training for gait speed and transfers.[1–3]

Physical therapists typically conduct gait training through manual assistance of the legs and pelvis. This places a heavy burden on the therapists, and the limited availability of physical therapists and treatment facilities can make it difficult to meet the needs of patients, potentially impeding their effective rehabilitation. One approach that may help address these challenges is to use rehabilitation robots, which can assist with repetitive, interactive, high-intensity, task-specific limb treatment.[4] Furthermore, robot-assisted gait training may help improve post-stroke walking ability by accelerating neuroplastic processes.[5]

Several studies have shown that patients with subacute stroke who were treated with an end effector–type robotic device (the Gait Trainer®) in combination with conventional physiotherapy exhibited greater improvement in functional gait than those treated with conventional gait training alone.[6–9] However, other studies have found no difference in outcomes between robotic and conventional therapy,[10] and the issue remains controversial.

Morning Walk® is a new end effector–type lower limb rehabilitation robot developed in 2015 in Korea for patients with gait disturbance. Unlike other end effector–type rehabilitation robots, it has a saddle that provides a seat-like support for the patient's body weight. It offers various training modes, including ground walking and ascending and descending stairs. However, the effectiveness of the device has not been investigated through clinical trials. The aim of this study was to investigate the effects of Morning Walk®–assisted gait training on patients with stroke.

Methods

This study was a non-blinded, prospective, randomized controlled trial that compared the effects of Morning Walk®–assisted gait training with those of conventional physiotherapy (KCT0003090). Three hospitals participated in this study: the Asan Medical Center and Ulsan University Hospital, which are tertiary hospitals, and the National Health Insurance Service Ilsan Hospital, which is a secondary hospital. The study was approved by (1) the Asan Medical Center Institutional Review Board (IRB), No. 2016-1337; (2) the National Health Insurance Service Ilsan Hospital IRB, (NHIMC 2016-11-008); and (3) Ulsan university hospital IRB (No. 2016-11-028), and all participants were informed of the study purpose and procedures before they signed an informed consent form.

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The inclusion criteria were as follows: the diagnosis of a first-time stroke (either ischemic or hemorrhagic, confirmed by brain computed tomography or magnetic resonance imaging (MRI)) within the preceding year; age >18 years; previously an independent walker; hemiparesis with gait disturbance after the stroke; Functional Ambulatory Category score $\geqslant 2$; and the ability to participate in Morning Walk®–assisted gait training. Patients were excluded if they met any of the following criteria: severe cognitive disorder; aphasia that impeded communication; severe lower extremity musculoskeletal disease; psychological instability; body weight >135 kg; height >195 cm; severe limb contracture or deformity; an open wound, fracture, or pressure

ulcer; the risk of compression fracture due to severe osteoporosis; or contact infection.

In total, 58 patients with hemiparesis due to stroke, who were hospitalized in the rehabilitation departments of the three hospitals between December 2016 and April 2017, were enrolled. A random number table was used to assign the participants randomly to either the experimental group or the control group. All participants received their assigned treatment five times per week for three weeks (i.e. 15 sessions in total). The parameters of interest were measured before and after the whole treatment. All evaluations were made by a licensed physiotherapist. During the study, we monitored if the adverse events or safety problems related to training happens.

The experimental group received robot-assisted gait training with Morning Walk® for 30 minutes per session plus 1 hour of conventional physiotherapy. The control group received 1.5 hour of conventional physiotherapy. The conventional physiotherapy was based on traditional neurodevelopmental treatment techniques, per session. Patients with sensorimotor impairments practiced sitting and standing balance, active transfer, sit-to-stand, and strengthening exercises. As their physical function improved, they progressed to dynamic standing balance training and, eventually, to functional gait training, while continuing to perform strengthening exercises.[11]

Morning Walk® (Supplemental Figure 1) is a rehabilitation robot developed by Hyundai Heavy Industries and Taeha Mechatronics in Korea. The Food and Drug Administration approved the device in December 2014. It is an end effector–type robot for lower limb rehabilitation that enables ankle, knee, and pelvic movements in the patient, according to the footplate trajectory. It has a saddle to support the patient's weight, so that patients who need assistance can be safely boarded. Getting on and off the Morning Walk® usually took approximately 5–10 minutes. The participants started with ground-level gait at a cadence of 30–35 steps/minute and a step length of 30–35 cm; these parameters were adjusted according to the individual's performance. Subsequently, the participants progressed to up and down stair gaits.

Morning Walk® is different from well-known end effector–type robot, Gait Trainer® (Reha-stim, Germany) in several aspects. First, therapists can adjust various parameters of ground walking such as cadence, step length, step height, initial contact angle, and toe-off angle according to the specific status of the patient. Especially therapists can precisely control the patient's ankle motions. The Gait Trainer® can change the parameters only for the step length and velocity. Morning Walk® also provides several different walking experiences for patients, such as the ground walking, stair ascending, and stair descending.

In addition, it provides the graphical information on the monitor of the "ground reaction force" on each foot and the amount of "body weight support" of the saddle in real-time while walking. This is a visual biofeedback to the patient for forming good center of pressure pattern. Morning Walk® also provides monitor-based virtual reality software that shows patient's avatar on a parkway. And it shows gait guidance; when the patient steps on the ground with a left/right foot, a foot icon of a left/right turns light on.

The primary outcome measures were walking ability, assessed using the Functional Ambulatory Category score, and lower limb function, assessed using the Motricity Index for the lower extremities (Motricity Index-Lower). Functional Ambulatory Category scale is reliable for measuring functional gait.[12] The test categorizes the patient according to the six levels (from 1 to 6) of physical assistance required to maintain gait.[13] The Motricity Index-Lower is a valid tool for evaluating muscular coordination and strength.[14] Motricity Index-Lower comprises the items from Motricity Index that evaluate the lower extremity muscles, including those of the ankle, knee, and hip. Because all the participants had hemiparesis, we completed Motricity Index-Lower measurements for the right and left sides individually. Motricity Index scores range from 0 to 100, with higher scores indicating better function of the tested lower limb.

The secondary outcome measures included scores for the 10 Meter Walk Test,[15] the Modified Barthel Index,[16] the Rivermead Mobility Index,[17] and the Berg Balance Scale.[18] The 10 Meter Walk Test is a commonly used measure of gait velocity

Table 1. Participants characteristics by group.

	Morning Walk® group ($n=25$)	Control group ($n=23$)	p-value
Age (years)	57.7 ± 12.9	60.4 ± 13.2	.450
Gender (n)			
Male	20	13	.080†
Female	5	10	
Height (cm)	168.9 ± 8.2	163.8 ± 8.2	.032*
Weight (kg)	68.9 ± 10.4	60.4 ± 11.7	.010*
BMI (kg/m^2)	24.4 ± 2.5	22.7 ± 3.6	.066
Time post-stroke (months)	2.0 ± 2.4	2.6 ± 3.1	.327
Stroke etiology (n)			
Infarction	14	18	.102†
Hemorrhage	11	5	
Side of hemiparesis (n)			
Left	14	14	.735†
Right	11	9	

Values are presented as mean ± SD or number/percentage.
BMI, body mass index.
*$p < .05$.
†Chi-square test; Mann–Whitney U test for time post-stroke, otherwise independent t-test.

(m/s) in stroke patients. Patients who were unable to walk were considered to have a walking velocity of 0 m/s.[19] The Modified Barthel Index (scored from 0 to 100) is a reliable index for measuring activities of daily living, with higher scores indicating greater independence. Rivermead Mobility Index (scored from 0 to 15) tests functional abilities, and the Berg Balance Scale (scored from 0 to 56) assesses static and dynamic balance.

The data were analyzed using SPSS Statistics version 18.0 (SPSS Inc, Chicago, IL, USA). The Kolmogorov–Smirnov test was used to assess the normality assumption. Participant characteristics in each group were examined using independent t-tests for normally distributed variables and Mann–Whitney U tests for variables that were not normally distributed. The changes before and after the treatment were compared between the two groups using the Wilcoxon signed-rank test. Statistical significance was indicated by p-values $<.05$.

Results

In total, 182 stroke patients were screened for eligibility between December 2016 and April 2017, of which 124 were excluded according to the exclusion criteria. We recruited the remaining 58 patients (Asan Medical Center: $n=33$, National Health Insurance Service Ilsan Hospital: $n=12$, Ulsan university hostipal: $n=13$) and randomized them to either the Morning Walk® group ($n=28$), which received Morning Walk®–assisted gait training with conventional physiotherapy or the control group ($n=30$), which received only conventional physiotherapy (Figure 1). Among the dropped participants, one participant in Morning Walk® group got unexpected septic shock, and this was not considered to be related to the Morning Walk® treatment. And there were no adverse events or safety problems related to training with Morning Walk® during the study.

Thus, the final analyses included 48 patients: 25 in the Morning Walk® group and 23 in the control group. Height ($p=.032$) and weight ($p=.010$) were significantly greater in the Morning Walk® group than in the control group, but age, sex ratio, body mass index, time post-stroke, stroke etiology, and the side of hemiparesis did not differ significantly between the two groups (Table 1).

We measured improvement by calculating differences in the scores at baseline and at three weeks for each group. As the data were not normally distributed, Mann–Whitney U tests were used to compare

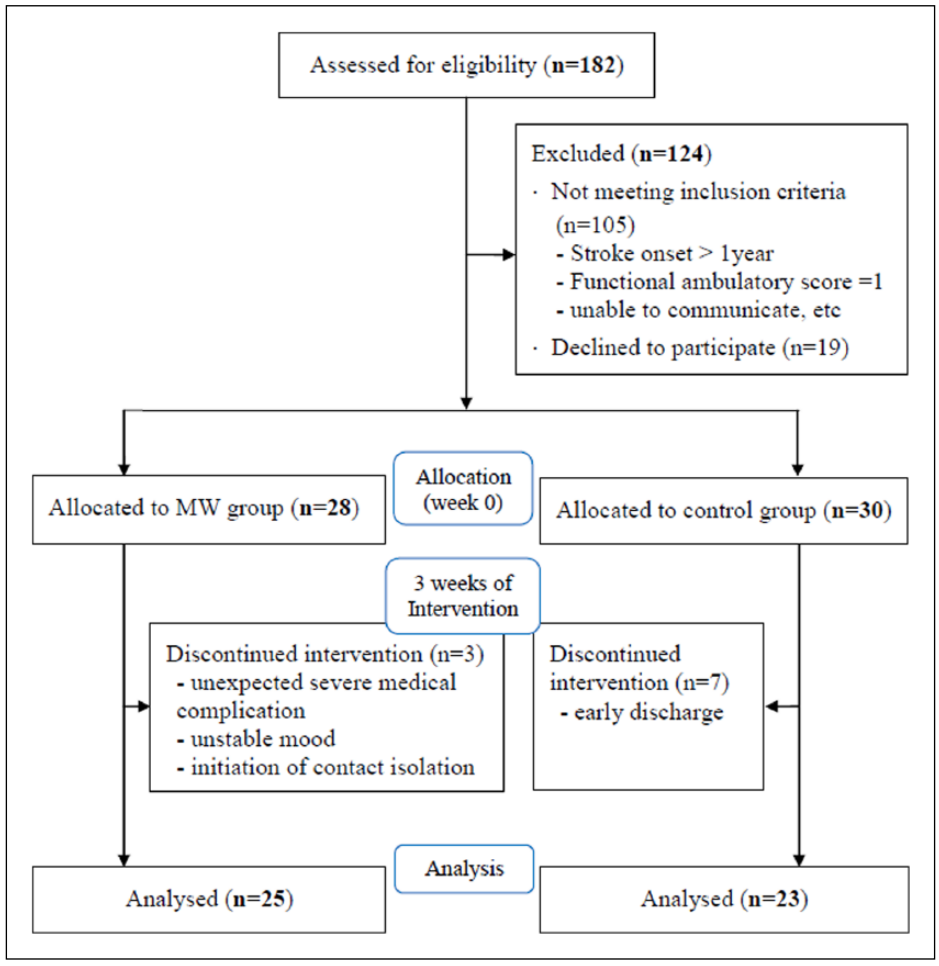

Figure 1. CONSORT flow diagram.

the baseline and post-training measurements between the two groups. There were no significant between-group differences in any outcome measure before treatment. After 15 training sessions, both groups showed significant improvements in every outcome measure (Table 2). The Morning Walk® group showed significantly greater improvement than the control group in the Motricity Index-Lower score for the affected limb ($p = .034$) and in the Berg Balance Scale score ($p = .047$). We performed subanalysis according to severity of stroke using initial Functional Ambulatory Category score (Table 3). The Morning Walk® group of initial Functional Ambulatory Category score 2 showed largest change in the Berg Balance Scale score ($p = .047$).

Discussion

This study demonstrated that, compared with conventional physiotherapy alone, Morning Walk®–assisted gait training together with conventional physiotherapy was also beneficial for patients with stroke and hemiparesis. Compared with the control group patients, the patients who received the Morning Walk®–assisted training showed greater improvements in the motor power of their affected limb and in their balance. To the best of our knowledge, this is the first preliminary pilot study to investigate the effects of Morning Walk®–assisted gait training for patients with stroke and hemiparesis.

Table 2. Outcome measures at baseline and at three weeks.

	MW group ($n=25$)		Control group ($n=23$)		p-value
	Baseline	Three weeks	Baseline	Three weeks	
FAC	2.9 ± 1.2	3.9 ± 1.4*	2.9 ± 1.2	3.7 ± 1.4*	.342
MI-Lower, affected limb	55.0 ± 16.2	74.7 ± 19.2*	59.4 ± 14.4	71.0 ± 13.3*	.034**
10mWT (m/s)	0.5 ± 0.5	2.5 ± 5.4*	0.5 ± 0.5	0.9 ± 0.7*	.391
MBI	56.6 ± 21.5	74.9 ± 19.7*	54.0 ± 4.05	69.6 ± 21.2*	.861
RMI	6.0 ± 2.6	8.6 ± 2.8*	6.7 ± 2.3	8.5 ± 2.6*	.146
BBS	25.5 ± 16.3	39.8 ± 15.6*	26.9 ± 14.8	36.5 ± 14.8*	.047**

Values are presented as mean ± SD.
MW, Morning walk® group; FAC, Functional Ambulation Category; MI, Motricity Index; 10mWT, 10 Meter Walk Test; MBI, Modified Barthel Index; RMI, Rivermead Mobility Index; BBS, Berg Balance Scale.
*$p < .05$, by the Wilcoxon signed-rank test, for baseline versus three weeks.
**$p < .05$, by the Mann–Whitney U test, for the difference (three weeks–baseline) of the MW group versus control group.

Table 3. Difference after treatment according to initial Functional Ambulatory Category score.

	FAC = 2 ($n=27$)		FAC > 2 ($n=21$)	
	MW ($n=15$)	Control ($n=12$)	MW ($n=10$)	Control ($n=11$)
ΔFAC	1.3 ± 1.2	0.6 ± 1.0	0.7 ± 0.7	0.9 ± 0.7
ΔMI-Lower, affected limb	24.2 ± 16.6	17.6 ± 17.9	9.6 ± 12.8	13.4 ± 6.5
Δ10mWT (m/s)	.44 ± .58	.25 ± .32	.33 ± .48	.38 ± .52
ΔMBI	22.5 ± 14.1	10.3 ± 11.0	15.4 ± 13.5	13.2 ± 10.6
ΔRMI	2.9 ± 1.6	1.8 ± 1.3	2.0 ± 1.6	1.8 ± 1.3
ΔBBS	16.7 ± 8.7*	10.8 ± 10.5	10.8 ± 8.7	8.4 ± 4.5

Values are presented as mean ± SD.
MW, Morning walk® group; FAC, Functional Ambulation Category; MI, Motricity Index; 10mWT, 10 Meter Walk Test; MBI, Modified Barthel Index; RMI, Rivermead Mobility Index; BBS, Berg Balance Scale.
Δ = Difference of "after treatment–before treatment."
*$p < .05$, by the Mann–Whitney U test, for the difference of the MW group versus control group.

In a Cochrane review, Mehrholz et al.[2] found moderately strong evidence that automated electromechanical and robot-assisted gait training devices could improve gait after stroke. Patients with stroke who receive electromechanical-assisted gait training in combination with physiotherapy achieved higher levels of independent walking than patients who received physiotherapy alone. Our findings are consistent with this, and we can suggest the possibility of application of the Morning Walk®–assisted gait training to stroke patients.

The Morning Walk® group showed greater improvements than the control group in Motricity Index-Lower scores of the affected limb and in Berg Balance Scale scores. These data were similar to the results of a recent study that showed that gait training with an end effector–type robotic rehabilitation device was effective for improving strength, balance, and endurance.[20] Gait velocity, measured by the 10 Meter Walk Test, showed greater improvement in the Morning Walk® group than in the control group, but difference was not statistically significant. Lower limb muscle strength correlates with gait speed.[21,22] Suzuki et al.[22] have reported that muscle strength on the affected and unaffected sides is a determinant of patients' maximum walking speed. As the Motricity Index-Lower scores for the affected limb showed greater improvement in the Morning Walk® group than in the control group, gait velocity appeared to be a potential outcome measure. Future studies should examine this using a larger patient cohort.

As with other end effector–type rehabilitation robots, Morning Walk® allows the therapist to easily getting on and off the patient the device within 10 minutes. In contrast, the Lokomat® (Hocoma, Switzerland) exoskeleton-type robot requires more time for the patient to board. Less burden for preparation would increase the intensity of treatment. Morning Walk® provides partial body weight support through the use of a saddle, chest support, and body weight support link. The saddle moves up and down actively and rotates horizontally during patient's walk. It can therefore be used for both non-ambulatory and ambulatory patients who require continuous manual contact for body weight support, and the support reduces the effort needed by the therapists. Partial body weight support is effective for gait rehabilitation in patients with stroke.[23]

This study had several limitations. Our study cohort was smaller than that of other multicenter studies, which may have reduced the statistical power for some measures. The participants were not blinded to the treatment they received, so it is possible that those in the Morning Walk® group felt as if they were receiving double therapy, even though the net treatment time was identical for both groups. In addition, the researchers who made the measurements were not blinded to the treatment group, which may have limited the study's internal validity. Finally, this study assessed outcomes only at the beginning and at the end of the treatment. Future research should examine the persistence of treatment effects over time with larger sample size. Though we cannot draw firm conclusion, this study showed a potential that Morning Walk®–assisted training might be effective. A large-scale study with double-blind method is needed.

Clinical messages

- This pilot study suggest that Morning Walk®–assisted gait training combined with conventional physiotherapy has potential to improve the motor power of the affected limb and balance in stroke patients with hemiparesis.
- Morning Walk®–assisted gait training seems to contribute to the balance of stroke patients who need continuous support during walking.

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Declaration of conflicting interests

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Supplemental material

Supplemental material for this article is available online.

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