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Clinical efficacy of overground powered exoskeleton for gait training in patients with subacute stroke

A randomized controlled pilot trial

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Abstract

Background: To investigate the efficacy and usefulness of 12 sessions of overground robot-assisted gait training (RAGT) in subacute stroke patients.

Methods: In this pilot study, 17 subacute stroke survivors were randomly assigned to the intervention (n = 9) and control (n = 8) groups. In addition to the conventional stroke neurorehabilitation program, the intervention group received 30 minutes of overground exoskeletal RAGT, while the control group received 30 minutes of conventional gait training by a physiotherapist. All interventions were performed in 12 sessions (3 times/week for 4 weeks). The primary aim was to assess ambulation ability using the functional ambulation category (FAC). The 10-m walk test, Berg Balance Scale, timed-up-and-go Timed-up-and-go, Fugl–Meyer assessment of lower extremity, pulmonary function test, the Korean version of the modified Barthel index, and Euro quality of life-5 dimensions (EQ-5D) were assessed. All outcomes were evaluated both before and after the intervention.

Results: The Berg Balance Scale, Korean version of the modified Barthel index, and EQ-5D scores ($P < .05$) improved significantly in both groups. Only those in the RAGT group improved significantly in the FAC, timed-up-and-go, and 10-m walk test ($P < .05$). In the FAC and EQ-5D, the intervention group showed greater improvement than the control group ($P < .05$).

Conclusion: We found that 4 weeks of overground RAGT combined with conventional training may improve walking independence and quality of life in patients with subacute stroke.

Abbreviations: 10 MWT = 10-m walk test, BBS = Berg Balance Scale, EQ-5D = Euro quality of life 5-dimensions, FAC = functional ambulation category, FMA-LE = Fugl–Meyer assessment of lower extremity, K-MBI = Korean version of the modified Barthel index, K-QUEST 2.0 = Korean version of the Quebec user evaluation of satisfaction assistive technology 2.0, RAGT = robot-assisted gait training, TUG = timed-up-and-go.

Keywords: cerebrovascular disorders, neurological rehabilitation, rehabilitation, stroke

1. Introduction

Stroke is a fatal condition characterized by sudden neurological deficits caused by cerebral infarction, intracerebral hemorrhage, or subarachnoid hemorrhage. It is the leading cause of disability in developed countries, and its treatment is extremely expensive.[1] More than half of the stroke survivors suffer from physical, cognitive, and psychosocial impairments, that limit their activities of daily living (ADL) and social participation, reducing their quality of life (QoL). Gait dysfunction is a significant disability following a stroke and is associated with independence and autonomy in daily living. Therefore, the primary aim of stroke rehabilitation is to restore gait function. Consequently, gait training is the primary focus of

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stroke rehabilitation programs, particularly in the subacute phase. After a stroke, repetitive experience and goal-directed training induce physiological and morphological plasticity.[2] The principles of task-specific and context-specific rehabilitation with high-intensity progressive training are key to motor learning, including gait training.[3] The two main approaches for task-specific gait training in stroke are treadmill training with or without body weight support and intensive practice of various functional mobility tasks, including walking, stair climbing up and down, and sit-to-stand from chairs. Gait training is combined with endurance, functional strength, and balance training. Other rehabilitation strategies include neurodevelopmental techniques, such as Bobath, proprioceptive neuromuscular facilitation, and muscle strengthening training.[4] Currently, these rehabilitation strategies rely heavily on physical therapy. However, conventional gait rehabilitation is inherently labor-intensive and heavily reliant on individualized therapy programs delivered by trained therapists.

Robot-assisted gait training (RAGT) reduces the burden on therapists and incorporates key components of rehabilitation, such as repetitive, intensive, and task-oriented training.[5] Therefore, together with recent advances in technology, RAGT has received considerable attention as a novel approach in post-stroke rehabilitation. Robotic exoskeletons are highlighted in particular because they can direct the lower extremities through a predetermined gait pattern by directly controlling individual joints and minimizing abnormal posture or movement.[6] According to Calabr et al,[7] RAGT can be classified as treadmill-based or overground gait training. The most widely studied RAGT in stroke is treadmill-based RAGT, which allows cyclic movement of the lower extremities with stationary robotic devices and bodyweight support. Robotic devices are further classified mechanically into exoskeleton and end-effector systems.[8] The end-effector type applies mechanical forces to the distal segments of the lower extremities, making it simple to set up. However, it has limited control over the lower limbs' proximal joints leading to abnormal gait patterns. Meanwhile, the exoskeleton allows direct control of individual joints and allows preprogrammed gait patterns.[5,9] However, both types of the treadmill-based gait training are performed passively on a fixed treadmill with constant velocity, which is different from normal walking.

However, overground RAGT, uses wearable powered exoskeletons and provides a more ecological setting, allowing the patient to walk overground and explore the environment. It differs from treadmill-based RAGT because it involves the patient's participation and provides near-normal multisensory and proprioceptive input during gait.[10] Therefore, overground RAGT may open up new possibilities for rehabilitation for gait recovery and other clinical benefits. However, because it is a cutting-edge technology in the robotic rehabilitation, only a few studies on patients with stroke have been conducted. Previous studies have suggested that overground RAGT modulates neuroplastic changes, including brain connectivity[11] and corticomotor excitability during the chronic stroke phase.[12] Furthermore, locomotor function,[12,13] balancing, and cardiopulmonary metabolic efficiency during walking[14] are improved in patients with chronic stroke. Furthermore, while overground RAGT has promising effects on spatiotemporal gait parameters, such as cadence and step length, the improvements are not statistically significant when compared to conventional gait training.[9] The RAGT improved knee flexion during the swing phase and reduced knee hyperextension by improving walking performance, such as walking distance and speed.[15] Furthermore, a recent study examined stroke survivors perceptions and the usefulness of RAGT and found that it appears to be an acceptable intervention even in acute hospital settings.[16] However, due to the small number of studies, a recent meta-analysis concluded that there is still insufficient scientific evidence to support its efficacy on gait function and ADL and that additional studies including subgroup analyses are needed.[17]

Subacute stroke phase is the optimal period for an active multidisciplinary rehabilitation program. Therefore, because it is closely related to prognosis, promotes neuroplasticity, and facilitates functional recovery, intensive subacute stroke rehabilitation has been emphasized.[2] Furthermore, patients with subacute stroke are expected to benefit more from RAGT than those with chronic stroke.[18] Nevertheless, the effects of overground RAGT in the subacute stroke phase have received little attention. Only a few randomized controlled trials have been conducted, with results indicating that RAGT has similar or superior effects of RAGT on gait function compared with conventional gait training.[19,20] Therefore, further research is required to fully understand the effects of an overground powered exoskeleton in the subacute stroke phase.

This study aimed to investigate the efficacy and usefulness of overground RAGT in patients with subacute stroke. We compared the clinical effects of powered exoskeletons on functional ambulation outcomes, QoL, and ADL to those of conventional gait training. We evaluated user satisfaction with a powered exoskeleton to examine whether the new technology can be incorporated into new stroke rehabilitation.

2. Methods

2.1. Participants

In this pilot randomized controlled trial (KCT0006679), we prospectively enrolled patients admitted to the Department of Rehabilitation Medicine of Korea University Anam Hospital between January, 2020 and June, 2021. The inclusion criteria included: age > 18 years; first-ever stroke, confirmed by computed tomography or magnetic resonance imaging; within the subacute stage (≤6 months) at the time of the study; inability to walk independently due to post-stroke lower extremity paresis or sensory impairment (functional ambulation category [FAC] ≤ 3); ability to maintain a sitting position independently or under supervision for at least 5 minutes; ability to understand training instructions; and body size compatible with a robotic exoskeleton (height between 155 and 185 cm and weight <100 kg). The exclusion criteria included: lower extremity contracture or severe spasticity (modified Ashworth scale score ≥3) restricting gait movements; and cardiovascular or other medical conditions incompatible with intensive gait training.

The Institutional Review Board of Korea University Anam Hospital approved the study (2019AN0483). All participants provided written informed consent prior to participation.

2.2. Study design

Eligible patients were randomly assigned to either the intervention or control group. A computer-generated random list of allocations was used. All participants underwent conventional daily stroke neurorehabilitation program (90 minutes/day, 5 days/week, for 4 weeks) that included physical and occupational therapy. The conventional program consisted of individualized exercises to improve muscle strength, limb motor function, balance, ability to perform ADL tasks, and gait function. In addition, the patients underwent 12 sessions of gait training (30 minutes/day, 3 days per week, for 4 weeks) according to the group assignment. The intervention group underwent overground RAGT, whereas the control group underwent conventional manual gait training performed by a physiotherapist.

2.2.1. Overground RAGT. The intervention group underwent overground gait training using a robotic exoskeleton (ExoAtlet Medy; ExoAtlet Asia Co., Ltd., Seoul, Korea). ExoAtlet Medy delivers power to the hip and knee joints, assisting and guiding the execution of predefined movements, such as sit-to-stand, step-in-place, and overground walking. Walking speed and stride length could be adjusted individually. Because exoskeleton

robots provide all of the power required for the legs during walking, patients with complete loss of voluntary activation of gait muscles can use this robot for overground gait graining.

A trained physiotherapist (HJ) ensured the exoskeleton was fitted properly and safely before starting training. Each training session lasted for 30 minutes (net walking time) and consisted of exercises to improve proprioception, endurance, balance, and weight shifting while standing and walking. The structure and intensity of the program were individualized according to each participant's abilities. The training intensity was gradually increased in each session by modifying the walking speed and distance. The patients were harnessed in a mobile suspension system during training for safety without any bodyweight support.

2.2.2. Conventional gait training. The training program focused on gait and was performed by a physiotherapist. Each session consisted of exercises to enhance lower limb endurance, static and dynamic standing balance, trunk control, and gait function. Weight-shifting and stepping-in-place training were performed to promote proprioception and motor function of the affected side. Overground gait training was conducted with manual assistance from a physiotherapist. Assistive devices, such as walkers and canes, were also used as needed. The structure and intensity of the program were customized according to each participant's functional level. As the session progressed, the walking distance and speed gradually increased, and the amount of assistance gradually reduced.

2.3. Outcome measures

Clinical assessments were performed at 2 time-points: before and after the intervention. The primary outcome measure was FAC. The FAC categorizes a patient's ambulation ability into 6 levels based on the amount of manual support required during walking: from nonfunctional ambulators (level 0) to independent ambulators (level 5).[21] The secondary outcomes were mobility and motor function, balance, pulmonary function, ADL, QoL, 10-m walk test (10 MWT) for walking speed, Berg Balance Scale (BBS) and timed-up-and-go (TUG) test for static and dynamic balance, Fugl–Meyer assessment of lower extremity (FMA-LE) for motor function of the lower extremity, pulmonary function test, Korean version of the modified Barthel index (K-MBI) for independence in ADL, and Euro quality of life 5-dimensions (EQ-5D)[22] for health-related QoL. Furthermore, the usefulness of the robotic exoskeleton was assessed in the intervention group using the Korean version of the Quebec user evaluation of satisfaction assistive technology 2.0 (K-QUEST 2.0) questionnaire after the end of the overground RAGT.[23] The participants in the intervention group evaluated the robot across 8 items: "dimensions," "weight," "adjustments," "safety," "durability," "simplicity of use," "comfort," and "effectiveness." They were asked to rate each item on a scale ranging from 1 (not satisfied at all) to 5 (very satisfied).

2.4. Statistical analysis

Nonparametric statistics were used as the sample size was small, and the data did not show a normal distribution in the Shapiro–Wilk test ($P < .05$). The Mann–Whitney U test was used to compare baseline characteristics and Fisher exact test for continuous and categorical variables. Furthermore, the Wilcoxon signed-rank test was used for within-group analysis, and the Mann–Whitney U test was used for between-group analysis after the completion of the training. For all tests, statistical significance was set at $P < .05$. SPSS software (SPSS version 20.0; SPSS Inc., Armonk, NY) was used to conduct all statistical analysis.

3. Results

3.1. Characteristics of the participants

We admitted 90 patients with stroke to the Department of Rehabilitation Medicine during the study period. All patients were screened for eligibility, and 25 were included in the study and randomized to the exoskeleton (n = 16) or control group (n = 9) using a computer-generated random sequence. Of the 90 patients, 17 (9 in the exoskeleton group and 8 in the control group) completed all evaluations and study protocols. Seven participants in the exoskeleton group dropped out for the following reasons: transfer to another specialized stroke rehabilitation facility during the study period (n = 3), general weakness due to infectious diseases, such as urinary tract infection (n = 2), and dissatisfaction with gait training with the exoskeleton (n = 2). One patient in the control group dropped out because of an early transfer to another rehabilitation facility. A CONSORT diagram is shown in Figure 1. Tables 1 and 2 show the demographic and clinical characteristics of the patients, including gait function, at baseline. The 2 groups were homogeneous in all features except the time from stroke onset to the start of the study (19 days in the exoskeleton group and 43 days in the control group, $P = .036$). One patient in the control group participated in the study 119 days after stroke onset, resulting in different data.

Furthermore, we compared the baseline characteristics of the participants in the exoskeleton group between those who completed the study and those who dropped out during the study. No significant differences in baseline characteristics were observed between the 2 groups (Table S1, Supplemental Digital Content, http://links.lww.com/MD/I370).

3.2. Clinical outcomes

We compared the clinical scales of both groups at the end of the study (Table 2). The median value in the analyses of the primary outcome and FAC were relatively higher in the exoskeleton group than in the conventional group; however, the difference was insignificant. In the secondary outcome analyses, the median values of FMA-LE, BBS, 10 MWT, and K-MBI were relatively higher in the exoskeleton group, and TUG was shorter in the exoskeleton group. However, the differences were not statistically significant. Only the EQ-5D score was significantly higher in the exoskeleton group after gait training (0.767 in the exoskeleton group, 0.434 in the control group, $P = .028$).

We further analyzed the change (Δ; follow-up value – initial value) in improvements in each clinical measure after the completion of gait training, and the results are summarized in Table 2. In the within-group analysis, both groups showed significant improvements in the BBS, K-MBI, and EQ-5D scores after 12 gait training sessions ($P < .05$). In addition, the participants in the exoskeleton group showed significant improvements in the FAC, TUG, and 10 MWT, whereas those in the control group showed no significant improvements. Interestingly, the control group showed a significant improvement in the FMA-LE score (median value 2.5, ranging from −1 to 5, $P = .027$). In the between-group analysis, the improvements in the FAC and EQ-5D were statistically higher in the exoskeleton group than in the control group ($P < .05$). No significant improvement was observed in pulmonary function in either group.

3.3. User experience from the subjects

Table 3 shows that after completing the 12-session gait training, we performed a usability test using K-QUEST 2.0. Overall, most participants perceived themselves positively and were satisfied with RAGT. In particular, the participants were satisfied with the "safety," "comfort," and "effectiveness" domains (median value 4.5, ranging from 3 to 5). On the other hand, some

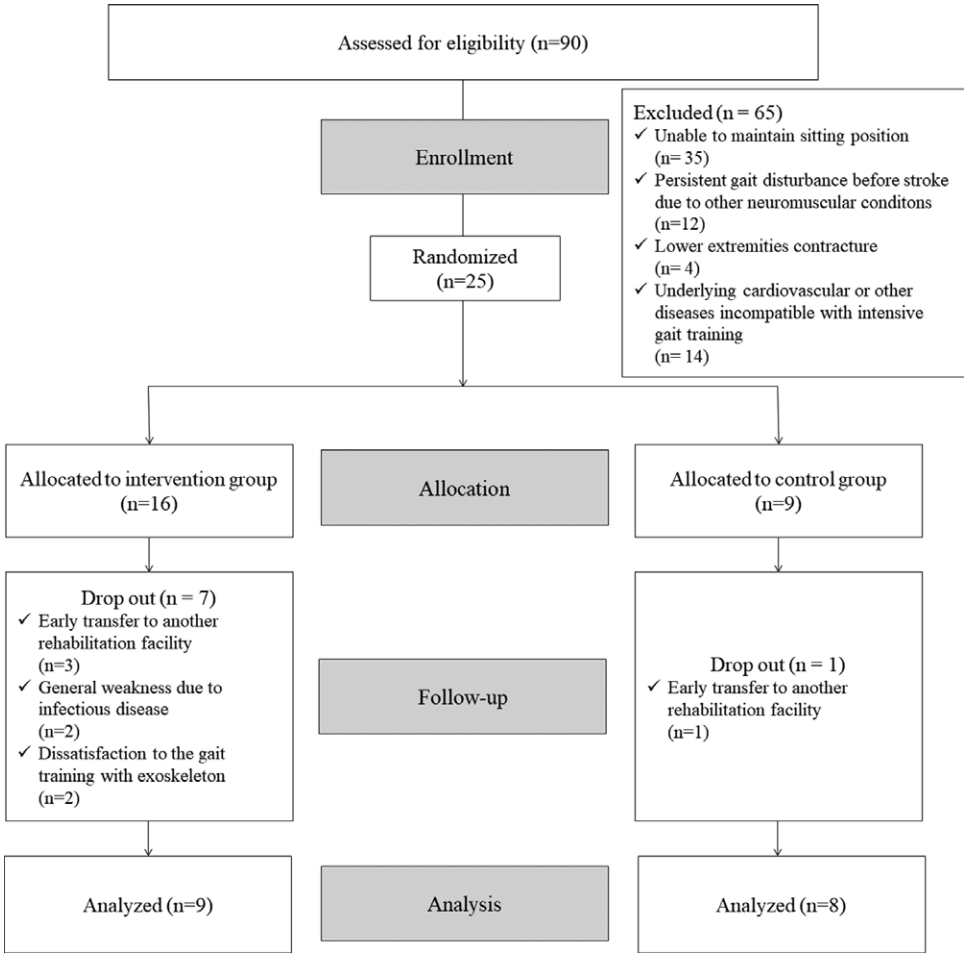

Figure 1. Flowchart of the study.

Table 1

Baseline characteristics of the study participants (N = 17).

	Exoskeleton group (n = 9)	Control group (n = 8)	*P* value
Sex (male: female)	4:5	5:3	.541
Age (yr)	61 (42–85)	65 (43–87)	.541
Lesion type (ischemic:hemorrhagic)	7:2	5:3	.606
Lesion side (right:left)	6:3	3:5	.321
Days from onset (d)	19 (10–30)	43 (11–119)	.036*
BMI (kg/cm^2)	24.2 (20.5–27.5)	26.0 (20.1–30.6)	.423
NIHSS	6.5 (4–12)	11 (4–13)	.281
K-MMSE	27 (7–30)	26 (17–29)	.423
BDI	7 (4–18)	9 (1–41)	.867

Data are expressed as median (range) or n, unless otherwise indicated.

BDI = Beck Depression Inventory, BMI = body mass index, K-MMSE = Korean version of Mini-Mental State Exam, NIHSS = National Institute of Health Stroke Scale.

* $P < .05$.

patients reported discomfort in the "weight," "adjustments," and "durability" domains, scoring 2, which indicates that they were not satisfied. None of the participants reported difficulty or discomfort related to the study protocol, nor did any severe adverse events occur during the study period.

We surveyed the K-QUEST 2.0 scores of the exoskeleton groups dropped-out participants after their last training session. The results suggest that no specific factors closely relate to compliance with overground RAGT. No significant differences were found between the completed and dropout groups (Table S1, Supplemental Digital Content, http://links.lww.com/MD/I370).

4. Discussion

This study investigated the effect of overground RAGT using an exoskeleton in patients with subacute stroke compared with conventional gait training. These results suggest that overground gait training using a robotic exoskeleton could benefit walking independence and QoL when added to conventional training. According to recent reviews, RAGT using robotic exoskeletons may have a potential role in gait recovery and increase the chance of independent walking in patients with subacute stroke when combined with conventional physiotherapy.[5,18,24] However, most of the studies performed to date have been

Table 2

Changes in clinical scales and comparisons within and between groups.

		Exoskeleton group (n = 9)			Control group (n = 8)		
			P (within group)			*P* (within group)	*P* (between group)
FAC	Pre	1 (0 to 3)		Pre	0 (0 to 3)		0.370
	Post	3 (0 to 4)		Post	0 (0 to 3)		.074
	Δ	1 (0 to 4)	.017*	Δ	0 (0 to 2)	.180	.046*
FMA-LE	Pre	20 (12 to 29)		Pre	17.5 (4 to 29)		.423
	Post	27 (13 to 32)		Post	22 (4 to 31)		.236
	Δ	2 (–3 to 11)	.154	Δ	2.5 (–1 to 5)	.027*	1.000
BBS	Pre	23 (4 to 37)		Pre	4.5 (4 to 36)		.139
	Post	39 (7 to 55)		Post	8.5 (3 to 52)		.093
	Δ	21 (–4 to 26)	.021*	Δ	5.5 (0 to 17)	.028*	.200
TUG (s)	Pre	131.73 (30.93 to 131.73)		Pre	131.73 (52.37 to 131.73)		.423
	Post	28.43 (10.86 to 131.73)		Post	131.73 (22.78 to 131.73)		.093
	Δ	–34.57 (–105.39 to 0.00)	.018*	Δ	0.00 (–108.95 to 0.00)	.180	.114
10 MWT (m/s)	Pre	0 (0 to 0.36)		Pre	0 (0 to 0.35)		.541
	Post	0.42 (0.00 to 1.09)		Post	0.00 (0.00 to 0.56)		.167
	Δ	0.28 (0.00 to 0.82)	.018*	Δ	0.00 (0.00 to 0.49)	.109	.114
K-MBI	Pre	33 (22 to 77)		Pre	32.5 (8 to 63)		.370
	Post	70 (37 to 98)		Post	40.5 (23 to 91)		.200
	Δ	21 (–2 to 44)	.011*	Δ	19.5 (0 to 38)	.028*	.423
EQ-5D	Pre	0.370 (0.160 to 0.724)		Pre	0.277 (0.052 to 0.552)		.382
	Post	0.767 (0.492 to 0.842)		Post	0.434 (0.112 to 0.856)		.028*
	Δ	0.342 (0.070 to 0.605)	.012*	Δ	0.224 (0.000 to 0.304)	.028*	.015*
FVC	Pre	2.51 (2.19 to 3.73)		Pre	2.66 (2.13 to 4.05)		.933
	Post	2.82 (1.80 to 3.49)		Post	2.74 (1.56 to 4.27)		.724
	Δ	0.095 (–0.39 to 0.75)	.575	Δ	0.32 (–0.38 to 0.69)	.273	.683
FEV1	Pre	2.24 (1.65 to 2.84)		Pre	2.18 (1.79 to 3.18)		1.000
	Post	2.25 (1.28 to 2.81)		Post	2.07 (1.53 to 3.38)		.833
	Δ	–0.03 (–0.37 to 0.30)	.833	Δ	0.24 (–0.28 to 0.35)	.357	.368
FEV1/FVC	Pre	82.79 (74.96 to 99.87)		Pre	81.33 (74.34 to 99.87)		.933
	Post	80.27 (66.83 to 96.57)		Post	81.07 (74.30 to 98.17)		.724
	Δ	–2.47 (–0.18.88 to 7.87)	.293	Δ	–1.47 (–10.04 to 0.40)	.273	1.000

Data are expressed as median (range).

10 MWT = 10-m walk test, BBS = Berg Balance Scale, EQ-5D = Euro quality of life 5-dimensions, FAC = functional ambulation category, FEV1 = forced expiratory volume in 1 s, FMA-LE = Fugl–Meyer assessment of lower extremity, FVC = forced vital capacity, K-MBI = Korean version of the modified Barthel index, TUG = timed, up-and-go, Δ = changes between pre- and post-intervention.

* $P < .05$.

Table 3

Usability survey using K-QUEST 2.0: device domain.

	Items	Satisfaction score
Assistive device domain	Dimensions	4 (3–5)
	Weight	4 (2–5)
	Adjustments	3.5 (2–5)
	Safety	4.5 (3–5)
	Durability	4 (2–5)
	Simplicity of use	3.5 (3–5)
	Comfort	4.5 (3–5)
	Effectiveness	4.5 (3–5)
	Sum	30.5 (28–39)

Data are expressed as median (range).

K-QUEST 2.0 = Korean version of the Quebec user evaluation of satisfaction assistive technology 2.0.

conducted using treadmill-based exoskeletons, and evidence supporting the benefits of overground RAGT using robotic exoskeletons is still limited. In this pilot study, we conducted a prospective randomized controlled trial to provide evidence of the efficacy and usefulness of gait training using an overground robotic exoskeleton in subacute stroke survivors.

For the primary outcome measure, we assessed FAC, which is known to correlate with walking speed and balance.[21] The FAC categorizes patients' walking ability based on their degree of physical assistance during ambulation. Compared with the control group, a significantly greater improvement in FAC was observed after the 4-week overground RAGT. At baseline, 14 of the 17 participants (7 in each group) required continuous body weight support (FAC 0 or 1). At the end of the study, 7 out of 9 participants in the intervention group progressed to FAC 2 to 4, indicating that the participant required intermittent or no manual support during ambulation. However, most participants (6 out of 8) in the control group remained in the FAC 0 or 1. In addition, the FAC score following in-patient rehabilitation can be dichotomized into FAC < 4 (dependent walking) and FAC ≥ 4 (independent walking), which can be used to predict the community ambulation level 6 months after stroke.[21] Three out of 9 participants in the intervention group reached FAC level 4, whereas none were in the control group.

No significant between-group difference was found in the improvement in the 10 MWT and TUG test results. However, the within-group analysis showed a significant longitudinal improvement in the intervention group. Walking velocity, measured using 10 MWT, is a commonly used index to assess functional mobility and predict the potential ability for community ambulation in post-stroke patients.[25] At baseline, the walking velocity of all participants in both groups was below 0.4 m/s, classified as household ambulators. At follow-up, 5 out of 9 participants in the intervention group recovered to a level of limited community ambulation, walking speed between 0.4 and 0.8 m/s. However, only 2 out of 8 participants in the control group reached the level. Furthermore, an improvement in gait speed of more than 0.10 m/s is a meaningful change in patients with subacute stroke.[26] Six out of 9 participants in the intervention group showed more than 0.10 m/s increase in gait speed, whereas only 2 out of 8 participants in the control group showed meaningful changes.

Nolan et al conducted a randomized controlled trial to prove that robotic exoskeletons provide a higher dose of gait training, positively affecting functional recovery in subacute stroke survivors.[27] The study reported that participants in the RAGT group walked twice the distance during the same duration of the training and showed significant changes in motor function compared with those in the conventional gait training group. In particular, limitations exist in providing a sufficient dose and task-specific repetition for individuals who require maximum support to maintain an upright standing position, such as our study participants. However, training with a robotic exoskeleton can provide intensive overground reciprocal gait training with more physiological patterns of lower-limb coordination and loading,[13] even in the early stage of recovery after stroke. Moreover, improved walking ability and functional status through intensive training are associated with improved QoL.[28] Such inherited characteristics of overground RAGT are speculated to contribute to the improvement of participants' walking ability and QoL.

To date, only a few studies have examined the effects of overground RAGT in patients with subacute stroke. Most single-arm studies have reported the beneficial effects of overground RAGT. They demonstrated improvements in the FAC,[29–31] walking speed[29–31] and endurance,[30,31] gait symmetry,[29] lower limb strength,[30] trunk control, and balance.[31] In contrast, the results of randomized controlled trials are conflicting and inconclusive, especially when comparing the therapeutic effects with conventional rehabilitation.[19,20,27,32,33] Study conducted by Molteni et al[19] showed significant improvements in functional walking ability after overground RAGT; however, the effects were similar to those of conventional gait training. However, other studies have reported significant differences in the improvement in FAC, walking speed, and walking endurance after overground RAGT compared with conventional gait training.[20,32,33] Overground RAGT is expected to have a potential role in gait recovery considering previous studies, However, further well-designed studies are warranted to validate the additional effects compared with conventional gait training in the subacute stroke phase. We believe this study adds value to the evidence of overground RAGT, emphasizing its additional effect on gait function.

The survey on usability is an important aspect of patient-centered research. In this study, we evaluated user satisfaction with the robotic exoskeleton using K-QUEST 2.0, which was developed in Canada to evaluate user satisfaction with a various assistive technologies. Various versions of QUEST are available in different languages.[23] Given the survey results most the participants positively perceived the exoskeleton. They were satisfied with gait training with the exoskeleton, particularly on the items of "safety," "comfort," and "effectiveness." Although some participants reported discomfort with "weight," "adjustments," and "durability," they scored higher on most of the items than those in other previous studies.[34,35]

4.1. Study limitations

The main limitations of this pilot study were the small sample size and the different dropout rates between the groups. Further controlled studies with larger sample sizes are needed to increase the robustness of this study. In particular, previous research found that the intensity of robotic rehabilitation varied from 2 to 8 weeks with different durations ranging from 4 to 30 hours.[5] Therefore, the optimal intensity of overground RAGT, including the time and number of sessions, needs to be investigated further. Second, the number of days from stroke onset to the start of the study differed between the 2 groups because 1 participant participated in the study as the control group, 119 days after stroke onset. There was no statistical difference in the days from onset' between the 2 groups when this patient's data was excluded. Even after excluding the patients' data, there was no difference in the statistical analysis results within and between groups. Finally, most patients were nonambulatory at baseline; therefore, the beneficial effects of overground RAGT in ambulatory patients could not be investigated. A long-term follow-up study is warranted to confirm the long-term effects of overground RAGT. Nevertheless, this randomized controlled pilot study is important because it provides new findings about patients with subacute stroke, which have been very few in the past.

5. Conclusions

The results of this study suggest that ground RAGT is effective and useful for patients with subacute stroke. Compared to conventional gait training, 4 weeks of overground gait training with a robotic exoskeleton resulted in significant improvements in independent walking ability and QoL. To validate the findings of this study, larger randomized controlled trials are required.

Author contributions

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