Original Article

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Feasibility and Usability of a Robot-Assisted Complex Upper and Lower Limb Rehabilitation System in Patients with Stroke: A Pilot Study

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Objective To evaluate the feasibility and usability of cost-effective complex upper and lower limb robot-assisted gait training in patients with stroke using the GTR-A, a foot-plate based end-effector type robotic device.

Methods Patients with subacute stroke (n=9) were included in this study. The enrolled patients received 30-minute robot-assisted gait training thrice a week for 2 weeks (6 sessions). The hand grip strength, functional ambulation categories, modified Barthel index, muscle strength test sum score, Berg Balance Scale, Timed Up and Go Test, and Short Physical Performance Battery were used as functional assessments. The heart rate was measured to evaluate cardiorespiratory fitness. A structured questionnaire was used to evaluate the usability of robot-assisted gait training. All the parameters were evaluated before and after the robot-assisted gait training program.

Results Eight patients completed robot-assisted gait training, and all parameters of functional assessment significantly improved between baseline and posttraining, except for hand grip strength and muscle strength test score. The mean scores for each domain of the questionnaire were as follows: safety, 4.40±0.35; effects, 4.23±0.31; efficiency, 4.22±0.77; and satisfaction, 4.41±0.25.

Conclusion Thus, the GTR-A is a feasible and safe robotic device for patients with gait impairment after stroke, resulting in improvement of ambulatory function and performance of activities of daily living with endurance training. Further research including various diseases and larger sample groups is necessary to verify the utility of this device.

Keywords Gait, Locomotion, Rehabilitation, Robotics, Stroke

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INTRODUCTION

Restoration of walking ability is one of the primary therapeutic goals of stroke rehabilitation [1,2]. Gait disturbance in patients with hemiparetic stroke reduces social participation and quality of life and increases socioeconomic burden and mortality [3]. Robot-assisted gait training (RAGT) has been highlighted as an efficient intervention after stroke that provides task-specific training similar to actual gait in the early stages of recovery [4,5]. RAGT can provide abundant repetitive tasks that facilitate the integration of the remaining sensory and motor functions and help reorganize the motor engram [6]. Bilateral, reciprocal upper and lower limb locomotor training enhances cortical reorganization [7], and self-paced treadmill walking simulating actual gait improves brain activity with higher cognitive engagement in stroke survivors [8]. However, commercially available gait training robotic devices mainly focus on the recovery of lower extremity function [9,10]. Even if a handrail is used for balance and body weight support, it cannot provide reciprocal movements of the upper and lower limbs during gait training.

Although recovery of balance, motor strength, and control are crucial for gait function in patients with stroke, facilitating cardiorespiratory fitness (CRF) is also an important goal in gait rehabilitation. Gait impairment can reduce physical tolerance, which leads to a sedentary lifestyle and can result in further sarcopenia and osteoporosis [6,11]. These complications generate a vicious cycle in which patients' decreased cardiorespiratory endurance further limits their physical activity. Recently, robotic devices have been considered as an alternative tool for endurance training in physically disabled patients [12]. However, most gait training robotic devices only provide entirely passive gait training, regardless of the voluntary engagement of the patient, and exercise intensity is much lower than that of independent self-gait. The G-EO (Reha Technology AG, Olten, Switzerland) and RT600 (Restorative Therapies, Nottingham, MD, USA) have a partial assist mode and hybrid rehabilitation systems that can provide additional functional electrical stimulation along with the gait cycle. However, these methods are expensive, and their use is limited [13,14].

The purpose of this study was to develop a robot-assisted complex upper and lower limb rehabilitation system that can implement reciprocal movements similar to actual gait. We aimed to evaluate the feasibility and usability of the newly developed GTR-A (HUCASYSTEM, Sejong, Korea) robotic device. We hypothesized that gait training using the GTR-A is safe and has an endurance training effect with functional gain.

MATERIALS AND METHODS

Study population

Patients with gait impairment after stroke identified between June 2021 and November 2021 were included in this study. U.S. Food and Drug Administration guidelines indicate that a sample size of 10 participants is sufficient to detect an average of 95% of all problems in feasibility and usability tests of a new medical device [15,16]. Because we intended to use a newly developed robot device in our study, the required sample size was 10 patients. The inclusion criteria were (1) gait impairment within 30 days of stroke onset; (2) age between 18 and 85 years; (3) functional ambulatory category (FAC) >2; and (4) ability to provide informed consent. The exclusion criteria were (1) severe cognitive impairment (Korean version of Mini-Mental Status Examination ≤18); (2) severe dizziness with orthostatic hypotension and other neurologic compromises; (3) limb contracture or deformity, open wound, fracture, or pressure sore; (4) lower extremity or other orthopedic surgery within 6 months before the study; (5) functional limitation in the upper extremities due to weakness or contracture; and (6) severe physiological condition, cardiopulmonary diseases, hemodynamic instability, and inability to participate. All the participants provided written informed consent. The study was approved by the Institutional Review Board of Keimyung University Dongsan Medical Center (DSMC 2021-05-028) and registered with the Clinical Research Information Service (http://cris.nih.go.kr, KCT0007104).

End-effector type gait assistive robotic device

The GTR-A is a newly developed gait assistive robot with a complex upper and lower limb rehabilitation system commercially available in Korea (Fig. 1A). It is a footplate based end-effector-type robotic device with 4-bar linkage structures. Based on the rocker and crank, rotation of the crank link causes the coupler link movement to implement an ankle joint trajectory [17]. This mecha-

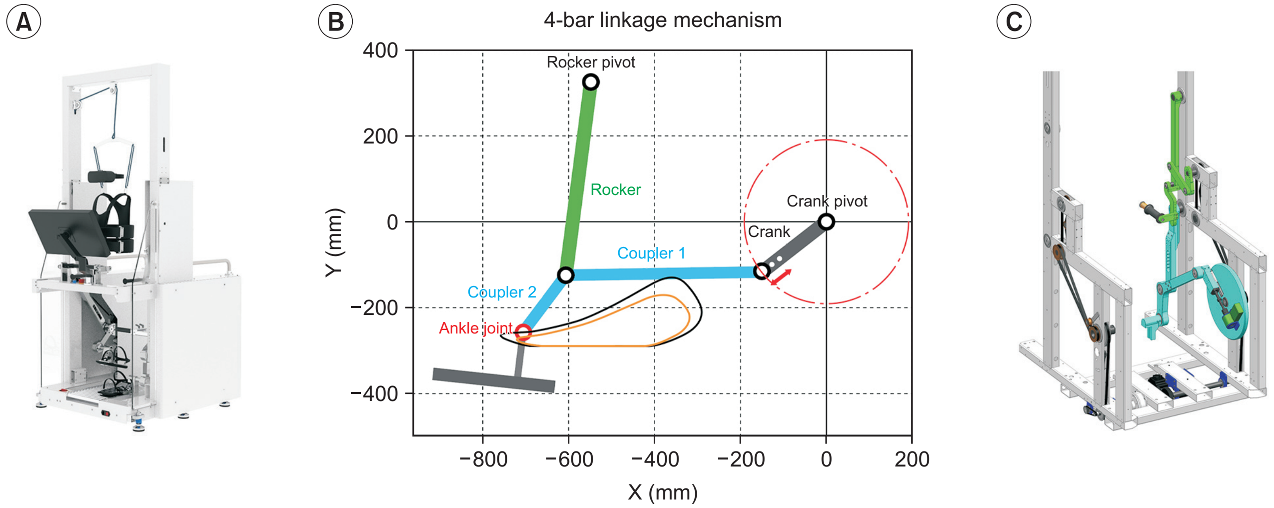

Fig. 1. GTR-A (HUCASYSTEM, Sejong, Korea), a complex upper and lower limb rehabilitation system. (A) Gross image of the robotic device. (B) Four-bar linkage mechanism with implemented gait trajectory. (C) Interconnection of the upper and lower extremity drive system using a timing belt.

nism ensures that the pelvic, knee, and ankle movements correspond to the actual gait pattern (Fig. 1B). In addition, the driving force of the lower crank is transmitted to the upper crank through the timing belt. This forms the trajectory of the distal upper extremities simultaneously, which enables reciprocal movement of the upper and lower extremities (Fig. 1C). The stride length is adjusted according to the length of the crank link.

The GTR-A has 3 types of gait training modes: (1) automatic gait mode (*passive mode*) driven by a 100% electric motor; (2) *active-assisted mode,* which detects patients' intention to walk and supports the driving force of the electric motor according to the degree; and (3) *active mode*, which enables walking only with the patients' own physical ability and strength.

The *active mode* uses only a selected stride length and applies an algorithm to increase or decrease the stride length using an electric motor according to the walking speed. Depending on the severity of movement dysfunction, a patient-tailored training mode can be selected and applied to gait rehabilitation.

Intervention

RAGT with the GTR-A was carried out for 30 minutes for each session, 3 days per week for 2 weeks (total, 6 sessions) by the same physical therapist. Before starting the main treatment session, a single training session was held in the *passive mode* (walking speed, 0.5 km/h) to allow the patients to acclimatize to the robotic device. The actual GTR-A training was conducted in the *active-assist mode*. The first two sessions, which served as an adaptation period, lasted 11 minutes, and the next four sessions lasted 15 minutes. Unlike the training session, the walking speed varied from 0.5 km/h to 1.5 km/h according to the patients' intention to walk. We used the harness selectively for partial body weight support only for participants with balance impairment who were at risk of falling. All participants received conventional rehabilitation treatment, including physical therapy, during the intervention period.

Outcome measures

Baseline evaluations were performed after study enrollment, and posttraining evaluations were performed immediately after the last treatment session. A trained researcher not involved in the treatment session conducted all functional assessments and cardiorespiratory measurements.

Functional assessments

To assess motor function, the FAC and modified Barthel index (MBI) were evaluated, and hand grip strength, muscle strength test (Medical Research Council [MRC] sum score), Berg Balance Scale (BBS), Timed Up and Go Test (TUG), and Short Physical Performance Battery (SPPB) were performed.

Cardiorespiratory measurement and analysis

To investigate the cardiorespiratory response to RAGT, heart rate (HR) was measured in real-time during each treatment session, and the maximal HR (HRmax) was recorded. Exercise intensity was determined as %HRmax, calculated as the proportion of HRmax during exercise with respect to the age-predicted HRmax [18]. The temporal trend was analyzed as the sessions progressed.

Usability evaluation

We conducted a usability evaluation on participants using a structured questionnaire developed to evaluate gait assistive robotic devices [19]. It consisted of four subdomains (safety, effects, efficiency, and satisfaction), with a total of 23 questions on a 5-point Likert scale.

Statistical analysis

The MRC sum score was calculated as the sum of the MRC scores at shoulder abduction, elbow flexion, wrist extension, hip flexion, knee extension, and ankle dorsiflexion in both the upper and lower extremities [20]. Handgrip strength results were classified as affected versus unaffected hand rather than dominant versus nondominant hand, considering the hemiplegic component of patients with stroke. Normally distributed data are presented as mean±standard deviation, and nonnormally distributed data are presented as median (interquartile range). Detailed intervention parameters obtained from the robotic device for each participant were analyzed using descriptive statistics. We performed the Wilcoxon signed-rank test to evaluate differences in nonparametric data before and after the treatment sessions. Statistical analysis were conducted using IBM SPSS version 21.0 (IBM Corp., Armonk, NY, USA). Statistical significance was set at $p<0.05$.

RESULTS

Participant demographics

Of the 75 patients screened for stroke, 10 consented to participate in the study. After informed consent was obtained, one patient suddenly refused to participate in the study. Thus, 9 patients (7 male, 2 female; mean age, 67.4±14.7 years) were included in the study. One participant withdrew after the first treatment session because of right calf pain, and eight patients completed the intervention. Patients with relatively good functional capacity (determined by baseline functional assessment) participated in the study. The demographic characteristics and clinical information of the nine participants are presented in Table 1.

Walking distance and gait speed

The detailed intervention parameters obtained from the GTR-A are shown in Table 2. Because the *active-assist mode* additionally supports the gait speed according to the degree of gait intention, there was a difference in gait speed, steps/round, and the total distance between patients.

Changes in functional outcome measures

Table 3 shows differences in muscle strength and functional ambulatory measures between baseline and post-RAGT. Except for the handgrip strength and MRC sum

Table 1. Baseline demographics

Patient characteristic	Value (n=9)
Sex	
Male	7
Female	2
Age (yr)	67.4±14.7
Height (cm)	165 (62–178)
Weight (kg)	71.3±14.9
Ischemic stroke	8
Right side weakness	5
Left side weakness	3
Hand grip strength (kg)	
Affected side	23.8±10.5
Unaffected side	27.3±9.4
Medical Research Council scale for muscle strength	
Sum for both upper extremities	28.6±1.5
Sum for both lower extremities	28.0±2.0
Total sum score	56.6±2.9
Functional ambulatory category	2.6±0.7
Berg Balance Scale	43.5±5.0
Modified Barthel Index	63.0±9.9
Short Physical Performance Battery	7.1±2.3
Timed Up and Go Test (s)	18.0±9.4

Values are presented as number only, mean±standard deviation, or median (interquartile range).

score, the FAC, BBS, MBI, SPPB, and TUG showed statistically significant improvement after treatment.

Exercise intensity

We calculated the cardiorespiratory burden of RAGT according to HR. The approximate classification of exercise intensity is indicated by gray shading (Fig. 2) [18]. The %HRmax showed that most participants underwent moderate-to-vigorous exercise intensity training during the treatment sessions. There were no temporal trends in the changes in %HR.

Usability evaluation

A usability evaluation survey was conducted after 2 weeks of RAGT. The mean scores of the safety, effect, efficiency, and satisfaction domains were 4.40±0.35, 4.23±0.31, 4.22±0.77, and 4.41±0.25, respectively (Fig. 3). When comparing each questionnaire, the questions “Have you had positive changes with pain?” in the effects domain and “Do you think that walking with the device is similar to actual walking?” in the efficiency domain had relatively low scores, with a mean of 3.75±0.89 and 3.13±1.13, respectively.

Table 2. Intervention parameters for the study participants who completed gait training

Participant	Distance (m)	Speed (km/h)	Steps/round
001	110.3±20.5	0.5±0.0	357.2±66.7
002	255.3±95.3	1.2±0.2	825.5±307.4
003	90.5±10.5	0.4±0.1	332.8±78.3
004	361.3±49.5	1.6±0.1	1,167.3±160.1
005	219.7±46.5	1.0±0.1	709.7±150.2
006	116.7±20.1	0.5±0.8	379.2±65.2
007	192.2±46.0	0.9±0.1	620.3±148.2
008	176.5±15.2	0.8±0.2	570.3±75.2

Values are presented as mean±standard deviation.

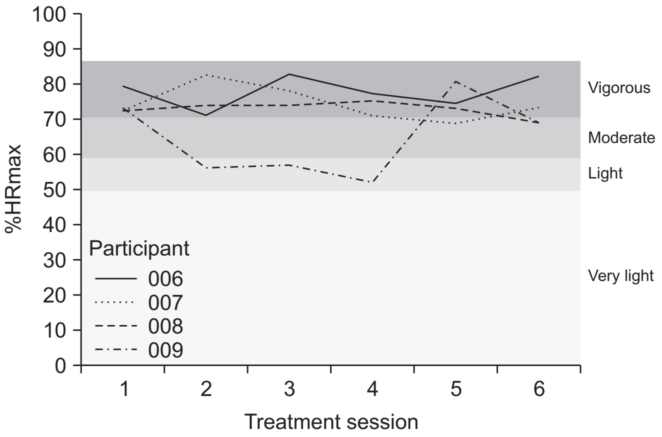

Fig. 2. The mean percent of maximal heart rate (%HRmax) for each robot-assisted gait training session in 4 participants. The gray scale reveals the range of exercise intensity. %HRmax=HRmax (during exercise)/age predicted HRmax.

Table 3. Changes in functional outcome measures between baseline and posttraining

	Baseline	Posttraining	Difference	p-value
Hand grip strength (kg)				
Affected side	23.9±10.5	25.6±9.3	1.8±3.3	0.123
Unaffected side	27.3±9.4	28.6±8.2	1.4±2.6	0.161
Modified Research Council scale for muscle strength				
Sum of both upper extremities	28.8±1.5	28.8±1.5	0	-
Sum of both lower extremities	27.9±2.1	28.6±1.7	0.8±1.2	0.010*
Total sum score	56.6±2.9	57.4±2.6	0.8±1.2	0.001*
Functional ambulatory category	2.6±0.7	3.9±0.9	1.3±1.0	0.026*
Berg Balance Scale	43.5±5.0	51.3±4.5	7.8±3.6	0.011*
Modified Barthel Index	63.0±9.9	89.4±7.1	26.4±7.1	0.012*
Short Physical Performance Battery	7.1±2.3	9.5±2.4	2.4±1.3	0.011*
Timed Up and Go Test	18.0±9.4	11.5±5.8	-6.5±6.3	0.012*

Values are presented as mean±standard deviation.
*$p<0.05$.

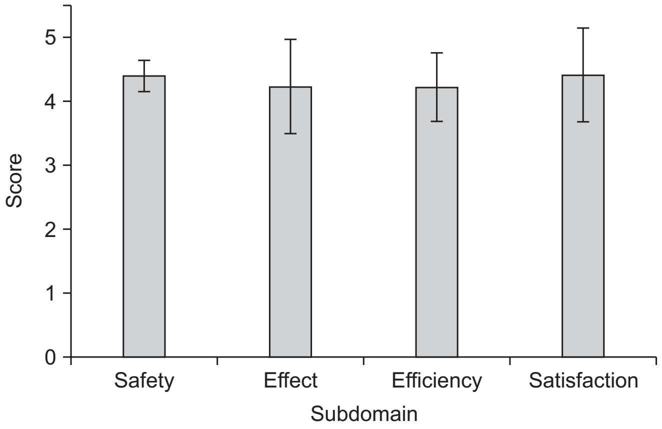

Fig. 3. The mean scores of the usability questionnaire in 4 subdomains (safety, effect, efficiency, satisfaction) on a 5-point Likert scale.

Adverse events

Among the participants, only one reported an adverse event (pain in the right calf) after the first treatment session. Ultrasonography confirmed a small hematoma in the right soleus muscle. After resting for 1 week, both the symptoms and radiological findings showed improvement. There were no other serious adverse events, such as falls, fractures, neurologic deterioration, or dizziness, during or after RAGT.

DISCUSSION

The present study showed that gait rehabilitation with the GTR-A is feasible and safe for patients with gait impairment in the acute stage after stroke. Balance, ambulatory function, and physical performance improved after six sessions of RAGT, and moderate-to-vigorous physical intensity was provided during training.

In human locomotion, movements of the upper and lower limbs are closely interconnected. Temporospatial coordination of the interlimb segments is essential for balance, energy conservation, and gait speed maintenance. This coordination is mediated by the supraspinal inter-neuronal circuit to regulate the out-of-phase movement of the upper limb synchronized with stride frequency [21]. Although gait without upper limb movement is possible in healthy adults, it requires greater muscle activation, indicating that arm swing plays a crucial role in gait safety and postural body control [22]. There is debate on whether stroke affects the interlimb coordination pattern. Some authors have demonstrated that synchronized arm-leg coordination is maintained after stroke [23,24]. However, in patients with hemiplegia, walking slowly with reduced arm movement could affect the phase and frequency coordination during the gait cycle [25]. Interlimb coordination may be disturbed by excessive movement of the unaffected limb, compensating for the passive movement of the affected limb [26]. Based on this evidence, recovery of both lower and upper limb function is an important factor in gait rehabilitation after stroke. Bovonsunthonchai et al. [25] emphasized that rehabilitation should focus on the affected upper limb, which plays a major role in enhancing walking efficiency and gait performance.

Most commercially available gait-assisted robotic devices mainly focus on rehabilitation of lower limb function. There are handles or handrails, but they exist for body weight support or safety and do not provide reciprocal upper- and lower-limb movements [27]. The GTR-A is an end-effector-type complex upper and lower limb rehabilitation system that most closely simulates the actual gait pattern among the existing gait-assisted robots.

Several studies have evaluated functional improvements using end-effector-type robots after a stroke. Patients with subacute stroke who underwent RAGT combined with conventional physical gait rehabilitation showed greater functional improvement than patients who underwent physical therapy alone [28-30].

In studies that considered interlimb coordination, Kim and Lim [22] proposed coordinative locomotor training mimicking the skater and sprinter patterns. There was significantly greater gait speed and stride length improvement in the treatment group than in the conventional treatment group in hemiplegic gait after stroke [22]. Stephenson et al. [23] reported that treadmill training with horizontal handrail sliding enables reciprocal upper and lower limb movements to improve gait speed and coordination in stroke patients. Consistent with a recent meta-analysis, the patients in this study showed statistically significant improvements in functional assessments, including in the BBS, MBI, SPPB, and TUG [31]. Hornby et al. [32] proposed that substantial gait training can improve nonwalking functional tasks according to the *"reverse transfer"* theory, explaining how repetitive gait training using the GTR-A also improved static balance and postural stability evaluated by the BBS, SPPB, and

TUG. Reciprocal upper and lower limb action requires much more physiological movement than isolated lower limb walking. It may transfer abundant proprioceptive information to the central nervous system and enhance motor re-education [33]. The *active-assist mode* of the GTR-A also motivates patient, thereby promoting neuroplastic changes, which may improve the performance of activities of daily living [34]. All results showed a minimal clinically important difference. However, most patients were in the subacute stage within 2 weeks of stroke onset, and functional improvement may have been affected by spontaneous recovery. Since patients with relatively mild motor weakness were enrolled, it was inferred that handgrip strength and MRC scores did not significantly differ before and after the intervention.

We investigated the endurance training effect of the GTR-A. In a previous study, patients who underwent 4 weeks of feedback-controlled robot-assisted treadmill exercise during gait impairment early after stroke showed significantly increased cardiovascular fitness with peak oxygen uptake and %HR reserve [35]. Chang et al. [30] reported that gait training in the Lokomat group showed a 12.8% improvement in peak oxygen uptake after training compared to conventional physical therapy. We evaluated the HR during RAGT and calculated the %HRmax. Moderate-to-vigorous exercise intensity was noted in three of four patients. We did not perform an exercise tolerance test with gas analysis before and after training, but we assumed that repeated moderate- or high-intensity exercise may positively affect CRF [36].

In the usability evaluation, a mean of four or more points was obtained for all domains. However, contrary to expectations, it showed the lowest score in the individual question about the similarity of the robot device to actual walking. In the narrative interview with each patient, they said that the mechanism of the robotic device for simulating the gait pattern itself was similar to actual gait. However, there were many responses that stated that the movement of the joint was not sufficiently smooth for walking, resulting in intrusiveness. This was thought to have occurred because of the reduction in the number of driving motors and the simplification of the structure in developing a cost-effective device.

One patient withdrew from the study after the first treatment session because of pain in the right calf. However, the pain existed before the treatment session; therefore, it was unclear if the adverse event occurred due to the robot device. The most common adverse events associated with using stationary gait robots are soft tissue-related and musculoskeletal problems [37]. In all studies where body weight support of the harness was >50%, skin irritation in the armpit or groin occurred [35,38]. More soft tissue injuries related to the cuff or strap occurred in the exoskeleton type because of the numerous contact interfaces between the skin and the robot compared to the end-effector type in terms of multi-joint structure [39,40].

None of the participants reported any soft tissue-related adverse events. Patients who could sufficiently control their body weight participated in this study. Musculoskeletal adverse events, such as muscle soreness, joint pain, and bone fractures, have been reported [37]. Lack of movement guidance in the end-effector type and misalignment in the exoskeleton type can cause musculoskeletal problems [40]. In patients with hemiplegic stroke with significant balance impairment and misalignment, the therapist should consider and monitor possible adverse events. We also believe that if the robotic device is operated exclusively in the *passive mode*, the intention of the patient and the movement of the robot may not be aligned, which may lead to muscle fatigue or overload. In the *active-assist mode* used in this study, the gait intention of the patient was automatically detected, and the gait speed was flexibly adjusted, which reduced potential musculoskeletal problems.

This study has some limitations. First, with only nine participants completing treatment, it was difficult to adequately evaluate the feasibility of the robotic device. The results were statistically underpowered and are difficult to generalize with the small sample size. Second, the number of treatment sessions for each participant was also small, and most participants were in the acute stage after stroke; therefore, it was challenging to confirm the therapeutic effect of RAGT. Furthermore, although an RAGT system using the principle of reciprocal movement of the upper and lower extremities is novel, the GTR-A system cannot control the movement of each joint in detail and can only be applied in patients with relatively low motor impairment and high functional levels. It requires more than moderate exercise intensity, suggesting that it can be applied in patients with severe neurologic deficits such as stroke and in patients with chronic diseases who need aerobic exercise. Finally, an exercise tolerance test with gas analysis was not conducted to measure maximal oxygen uptake, which is the most reliable parameter for evaluating CRF.

In conclusion, gait rehabilitation using a complex upper and lower limb gait rehabilitation system (GTR-A) with conventional physiotherapy is safe and appropriate for patients with stroke. Further research involving a larger sample is needed to determine the feasibility and efficacy of the GTR-A system. Additionally, it will be necessary to validate the use of the system in various disease groups and disease severities to verify its safety.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTION

Conceptualization: Lee S, Kim KT. Methodology: Lee S, Kim KT, Cho JH, Choi Y. Formal analysis: Kim KT, Cho JH, Choi Y. Funding acquisition: Lee S. Project administration: Lee S. Visualization: Kim KT, Cho JH, Choi Y. Writing – original draft: Kim KT. Writing – review and editing: Lee S, Kim KT. Approval of final manuscript: all authors.

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