 doi:10.20944/preprints202203.0311.v1

Article

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

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Abstract: Robot-assisted gait training (RAGT) is a promising treatment for stroke rehabilitation. Although the coordination between the upper and lower limbs is important for locomotor training, commercially available robotics for gait training mainly focus on the restoration of lower limb function. We aimed to evaluate the feasibility and usability of complex upper and lower limb RAGT in stroke patients using the GTR-A®, end effector-type robotic device. Patients with subacute stroke (N=9) received 30-minute RAGT thrice a week for two weeks (six sessions). Functionally, the hand grip strength (HGS), Functional Ambulatory Categories, modified Barthel Index, muscle strength test sum score, Berg Balance Scale, Timed Up and Go test, and Short Physical Performance Battery were used. The heart rate and a structured questionnaire were used to evaluate cardiorespiratory fitness and the usability of RAGT. Among the nine patients, all functional parameters between the baseline and post-training were significantly improved after RAGT, except for HGS and the muscle strength test. The questionnaire's mean scores for each domain were as follows: safety 4.40±0.35, effects 4.23±0.31, efficiency 4.22±0.77, and satisfaction 4.41±0.25. The GTR-A® is a feasible and safe robotic device for patients with gait impairment after stroke. It showed functional improvement with endurance training effects.

Keywords: robot-assisted gait training; rehabilitation; stroke; cardiorespiratory fitness; robotics; disability; locomotion

1. Introduction

Restoration of walking ability is one of the primary therapeutic goals of stroke rehabilitation [1]. Gait disturbance in patients with hemiparetic stroke reduces social participation and quality of life and increases socioeconomic burden and mortality [2, 3]. Regarding the importance of task-specific training similar to actual gait in the early stages of recovery, robot-assisted gait training (RAGT) has been highlighted as an efficient intervention after stroke [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 the 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]. 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 [10, 11]. These complications generate a vicious cycle in which patients' decreased cardiorespiratory endurance further limits their physical activity. Recently, robotic devices have been considered 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 voluntary engagement of the patient, and the exercise intensity is much lower than in independent self-gait. The G-EO (Reha Technology AG, Olten, Switzerland) and RT600 (Restorative Therapies, Baltimore, Maryland, USA) have partial assist modes and hybrid rehabilitation systems that can provide additional functional electrical stimulation along with the gait cycle. However, these methods are expensive and have limited use [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 the actual gait. We aimed to evaluate the feasibility and usability of the newly developed GTR-A® robotic device. We hypothesized that gait training with GTR-A® would be safe and have an endurance training effect with the functional gain.

2. Materials and Methods

2.1 Study population

Patients with gait impairment after suffering a stroke between June 2021 and November 2021 were included in this study. Considering that this is a feasibility test for a newly developed robotic device, the required sample size was calculated to be 10 [15]. The inclusion criteria were as follows: (1) patients with 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 as follows: (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 six months before the study, (5) functional limitation in the upper extremities due to weakness or contracture, and (6) severe physiological, cardiopulmonary diseases, hemodynamic instability, and inability to participate. All participants provided written informed consent. The study was approved by the local Institutional Review Board (DSMC 2021-05-028) and registered with the Clinical Research Information Service (http://cris.nih.go.kr, KCT0007104).

2.2 End effector-type gait assistive robotic device

The GTR-A® (HUCA system, Daegu, Korea) is a newly developed gait assistive robot with a complex upper and lower limb rehabilitation system commercially available in Korea (Figure 1A). It is a footplate-based end effector-type robotic device with four 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 [16]. This mechanism ensures that the pelvis, knee, and ankle movements are similar to the actual gait pattern (Figure 1B). In addition, the driving force of the lower crank is transmitted to the upper crank through the timing belt. It forms the trajectory of the distal upper extremities simultaneously, which enables reciprocal movement of the upper and lower extremities (Figure 1C). The stride length was adjusted according to the length of the crank link.

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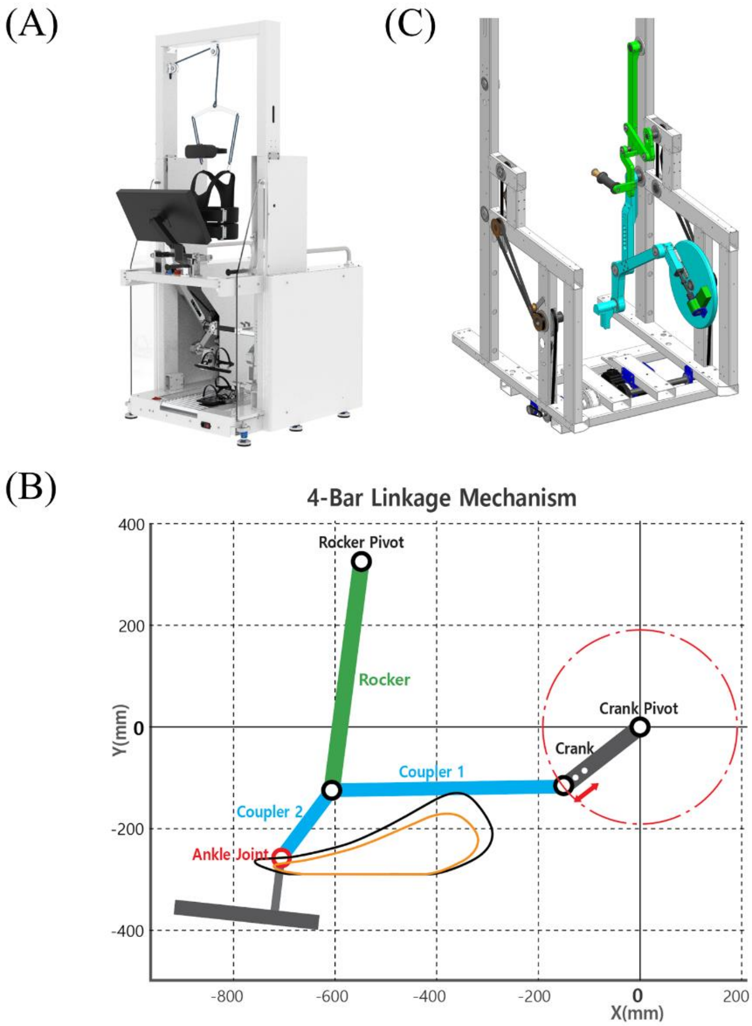

Figure 1. GTR-A®, a complex upper and lower limb rehabilitation system. (A) Gross image of the robotic device, (B) four-bar linkage mechanism with implemented gait trajectory, and (C) interconnection of upper and lower extremities drive system using a timing belt.

The GTR-A® has three types of gait training modes: (1) automatic gait mode (*passive mode*) driven by a 100% electric motor, (2) *active-assisted mode* that detects patient's 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 patient's own physical ability and strength. Depending on the severity of the impairment, a patient-tailored training mode can be selected and applied for gait rehabilitation.

2.3 Intervention

RAGT with GTR-A® was carried out for 30 min each session, thrice a week, for a total of six sessions. Before starting the main treatment session, a single training session was held in *passive mode* (walking speed, 0.5 km/h) to allow the patients to acclimatize to the robotic device. Two treatment sessions for 11 min followed by four sessions for 15 min in *the active-assist mode* were conducted. The walking speed varied from 0.5 to 1.5 km/h, according to the patient's intention to walk. The harness was selectively used 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.

2.4 Outcome measures

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Baseline evaluations were performed after study enrollment and post-training evaluations were performed immediately after the last treatment session.

2.5 Functional assessments

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

2.6 Cardiorespiratory measurement and analysis

To investigate the cardiorespiratory response to RAGT, the heart rate (HR) was measured in real time during each treatment session and maximal HR (HRmax) was recorded. Exercise intensity was determined as %HRmax, calculated as the proportion of HRmax during exercise to the age-predicted HRmax [17]. The temporal trend was analyzed as the sessions progressed.

2.7 Usability evaluation

A usability evaluation was conducted using a structured questionnaire [18]. It consisted of four subdomains (safety, effects, efficiency, and satisfaction), with a total of 23 questions evaluated with a 5-point Likert scale.

2.8 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 [19]. HGS results were classified as the affected versus the unaffected hand, considering the hemiplegic component of patients with stroke. All numerical data are presented as mean ± standard deviation. Detailed interventional 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 non-parametric data before and after the treatment sessions. Statistical analyses were conducted using Statistical Package for the Social Sciences version 21.0 (SPSS Inc., Chicago, IL, USA). Statistical significance was set at a P-value of < 0.05.

3. Results

3.1 Participant demographics

Of the 75 patients screened for stroke, 9 (seven men and two women; mean age, 67.4 ± 14.7 years) were enrolled in the study. One patient withdrew after the first treatment session because of right calf pain. 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.

Table 1. Baseline demographics.

Patient Characteristics	Total (n = 8)
Sex	
Male	6
Female	2
Age	67.6 ± 15.7
Height (cm)	152.3 ± 37.6
Weight (kg)	71.3 ± 14.9
Etiology	
Stroke (ischemic)	8
Right-side weakness	5
Left-side weakness	3
HGS (kg)	
Affected side	23.8 ± 10.5

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Unaffected side	27.3 ± 9.4
MRC sum score	56.6 ± 2.9
FAC	2.63 ± 0.7
BBS	43.5 ± 5.0
MBI	63.0 ± 9.9
SPPB	7.1 ± 2.3
TUG	18.0 ± 9.4

Values are presented as mean ± SD or number.
Abbreviations: HGS, hand grip strength; MRC, Modified Research Council; FAC, functional ambulatory category; BBS, Berg Balance Scale; MBI, modified Barthel Index; SPPB, Short Physical Performance Battery; TUG, Timed Up and Go

3.2 Walking distance and gait speed

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

Table 2. Intervention parameters of the study subjects.

Subject	Distance (m)	Speed (km/h)	Steps/Round
001	110.33 ± 20.51	0.5	357.17 ± 66.72
002	255.25 ± 95.30	1.2 ± 0.22	825.50 ± 307.37
003	90.50 ± 10.48	0.43 ± 0.10	332.83 ± 78.30
004	361 ± 49.48	1.55 ± 0.08	1167.33 ± 160.06
005	219.67 ± 46.51	1.02 ± 0.08	709.67 ± 150.22
006	116.67 ± 20.12	0.53 ± 0.81	379 ± 65.20
007	192.17 ± 46	0.87 ± 0.14	620.33 ± 148.18
008	176.50 ± 15.18	0.83 ± 0.15	570.33 ± 75.21

Values are presented as mean ± SD.

3.3 Changes in functional outcome measures

Table 3 shows differences in muscle strength and functional ambulatory measures between baseline and after RAGT. Except HGS and MRC sum score, FAC, BBS, MBI, SPPB, and TUG showed statistically significant improvements after treatment.

Table 3. Changes in functional outcome measures between baseline and post-training.

	Baseline	Post-training	Difference	P-value
HGS (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
MRC sum score	56.6 ± 3.0	57.4 ± 2.6	0.8 ± 1.2	0.109
FAC	2.6 ± 0.7	3.9 ± 0.9	1.3 ± 1.0	0.026*
BBS	43.5 ± 5.0	51.3 ± 4.5	7.8 ± 3.6	0.011*
MBI	63.0 ± 9.9	89.4 ± 7.1	26.4 ± 7.1	0.012*
SPPB	7.1 ± 2.3	9.5 ± 2.4	2.4 ± 1.3	0.011*
TUG	18.0 ± 9.4	11.52 ± 5.8	- 6.5 ± 6.3	0.012*

*$p < 0.05$
Values are presented as mean ± SD.
Abbreviations: HGS, hand grip strength; MRC, Modified Research Council; FAC, functional ambulatory category; BBS, Berg Balance Scale; MBI, modified Barthel Index; SPPB, Short Physical Performance Battery; TUG, Timed Up and Go.

3.4 Exercise intensity

The cardiorespiratory burden of RAGT was calculated according to HR. The approximate classification of exercise intensity is indicated by gray shading in Figure 2. %HRR showed that most participants underwent moderate to vigorous exercise intensity training during treatment sessions. There were no temporal trends in the changes in %HRR.

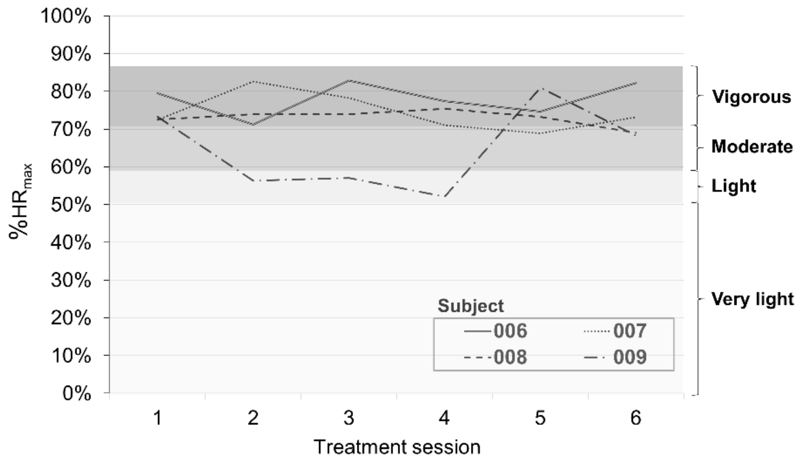

Figure 2. Mean %HRmax for each robot assist gait training session for four participants. The gray scale revealed the range of exercise intensity.

$$\%\text{HRmax} = \frac{\text{HR}_{\text{max}}\ (\text{during exercise})}{\text{age predicted HR}_{\text{max}}}$$

3.5 Usability evaluation

A usability evaluation survey was conducted after 2 weeks of RAGT. The mean scores of the safety, effects, efficiency, and satisfaction domains were 4.40 ± 0.35, 4.23 ± 0.31, 4.22 ± 0.77, and 4.41 ± 0.25, respectively (Figure 3). When comparing each questionnaire, the questions of "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 revealed relatively low scores, with a mean of 3.75 ± 0.89 and 3.13 ± 1.13, respectively.

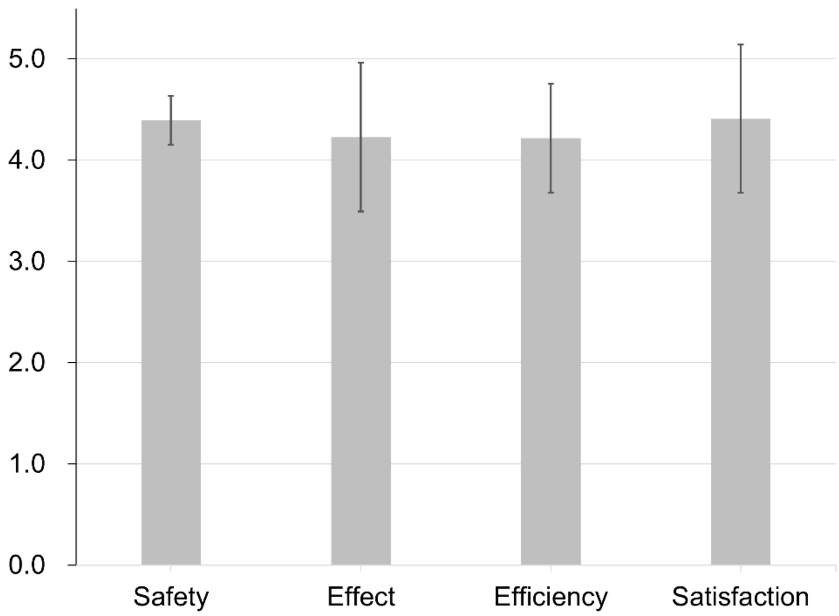

Figure 3. Mean value of the usability questionnaire in four subdomains (safety, effect, efficiency, and satisfaction) evaluated using a 5-point Likert scale.

3.6 Adverse events (AEs)

One patient reported an AE with 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 symptoms and radiological findings showed improvement. There were no other serious AEs, such as falls, fractures, neurologic deterioration, or dizziness during or after RAGT.

4. Discussion

Our 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. It is mediated by the supraspinal interneuronal circuit to regulate the out-of-phase movement of the upper limb synchronized with stride frequency [20]. 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 [21]. Whether stroke affects the interlimb coordination pattern is a controversial topic. Previous studies demonstrate that synchronized arm-leg coordination is maintained after stroke [22, 23]. However, in patients with hemiplegia, walking slowly with reduced arm movement could affect the phase and frequency coordination during the gait cycle [24]. Interlimb coordination may be disturbed by excessive movement of the unaffected limb, compensating for the passive movement of the affected limb [25]. Thus, the recovery of both lower and upper limb function is an important factor in gait rehabilitation after stroke. Rehabilitation should focus on the affected upper limb, which plays a major role in enhancing walking efficiency and gait performance [24].

Most commercially available gait-assisted robotic devices mainly focus on rehabilitation of lower limb function. Handles or handrails are for body weight support or safety and do not provide reciprocal upper and lower limb movements. 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. RAGT combined with conventional physical gait rehabilitation in patients with subacute stroke showed greater functional improvement than patients who underwent physical therapy alone [26, 27].

Considering interlimb coordination, a coordinative locomotor training mimicking the skater and sprinter patterns was proposed; it showed a more significant improvement in gait speed and stride length than the conventional treatment group in hemiplegic gait after stroke [21]. Treadmill training with horizontal handrail sliding enables reciprocal upper and lower limb movements to improve gait speed and coordination in stroke subjects.[22] Consistent with previous studies, the patients in this study showed statistically significant improvements in functional assessment, including the BBS, MBI, SPPB, and TUG. 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 HGS and MRC sum scores did not show a significant difference before and after intervention.

The endurance training effect of the GTR-A® was also examined. 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 [28]. Another study reported that gait training in the Lokomat group showed a 12.8% improvement in peak oxygen uptake after training compared with that in the conventional physical therapy group [27]. HR during RAGT was evaluated, and %HRmax was calculated. Moderate to vigorous exercise intensity was observed in three of four patients. An exercise tolerance test was not performed with gas analysis before and after training, but it was assumed that repeated moderate- or high-intensity exercise may positively affect CRF [29].

In the usability evaluation, a mean of four or more points were obtained for all domains. However, 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, it was found that the mechanism of the robotic device for simulating the gait pattern itself was similar to the actual gait. However, multiple responses revealed that the movement of the joint was not sufficiently smooth while 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, the occurrence of AEs due to the robotic device was unclear. The most common AEs in stationary gait robots are soft tissue-related and musculoskeletal problems [30]. In all studies wherein body weight support of the harness was above 50%, skin irritation in the armpit or groin occurred. Soft-tissue injuries related to the cuff or strap occurred more in the exoskeleton type because of the numerous contact interfaces between the skin and robot than in the end-effector type due to the multi-joint structure.

None of the participants reported any soft tissue-related AEs. Patients who could sufficiently control their body weight participated in this study.

Musculoskeletal AEs such as muscle soreness, joint pain, and bone fractures have been reported. Lack of movement guidance in the end-effector type and misalignment in the exoskeleton type can cause musculoskeletal complications. In patients with hemiplegic stroke with significant balance impairment and misalignment, the therapist should consider and monitor possible AEs. 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 complications.

4.1 Study limitations

This study has several limitations. The sample size was small, and the results were statistically underpowered and difficult to generalize. The number of treatment sessions was less, and the majority of participants were in the acute stage after stroke; therefore, it was challenging to confirm the therapeutic effect of RAGT. Furthermore, an exercise tolerance test with gas analysis was not conducted to measure maximal peak oxygen uptake, which is the most reliable parameter for evaluating CRF.

5. Conclusions

In conclusion, gait rehabilitation using a complex upper and lower limb gait rehabilitation system (GTR-A®) with conventional physiotherapy is safe and eligible for patients with stroke. Physical performance and gait ability improved after six sessions of RAGT with a moderate endurance training effect. Further research involving various disease groups and a larger sample size is warranted.

Author Contributions: Conceptualization, Resources: Y.M.C., S.Y.L., and K.T.K.; Data curation: K.T.K.; Formal analysis: J.H.C.; Supervision: S.Y.L.; Methodology: S.Y.L.; Writing-original draft: K.T.K.; Writing-review & editing: S.Y.L.

Funding: This study was funded by KMEDIhub (DGMIF-HW-2021-001).

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of Keimyung University Dongsan Hospital (IRB No: 2020-12-039).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

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