

# A novel Robotic Gait Training System (RGTS) may facilitate functional recovery after stroke: A feasibility and safety study

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## Abstract.

**BACKGROUND:** Robot-assisted gait training has been introduced as a practical treatment adjunctive to traditional stroke rehabilitation to provide high-intensity repetitive training. The design of robots is usually based on either the end-effector and exoskeleton method. The novel Robot Gait Training System (RGTS), a hybrid mixed type of end-effector and exoskeleton, tries to combine advantages from both methods.

**OBJECTIVE:** This preliminary study was conducted to report whether this novel system is feasible and safe when applied to non-ambulatory subacute patients with stroke.

**METHODS:** Six patients with stroke participated in this study and received 15 daily RGTS sessions. The outcome measures included the lower extremity subscale of the Fugl-Meyer Assessment (FMA-LE), Postural Assessment Scale for Stroke (PASS), Berg Balance Scale (BBS), and Barthel Index (BI). These measurements were performed at the pretest and posttest.

**RESULTS:** The RGTS demonstrated significant after-before changes in the FMA-LE, PASS, BBS and BI ( $p < 0.05$ ), which indicated improvements substantially across the neurological status, balance, and activities of daily living after intervention.

**CONCLUSIONS:** This study demonstrated that the novel RGTS designed was practical, safe, and suitable to use in substantial leg dysfunction with stroke.

Keywords: Robot gait training, stroke, neuroplasticity, balance

## 1. Introduction

Stroke continues to be a leading cause of mortality and morbidity globally (Strong, et al., 2007). Survivors usually sustain various impairments which cause difficulties in their daily lives. Disabilities caused by motor impairment are the most common problem after a stroke. About 60% of patients lose

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their walking ability immediately at stroke onset (Jørgensen, et al., 1995), and 20% of patients were still unable to walk independently 1 year later (Skilbeck, et al., 1983). Loss of walking ability impacts the quality of life, and restoring the walking ability is the paramount goal of rehabilitation settings.

For several decades, traditional physical and occupational therapy programs have been used to facilitate neurological and functional recoveries after a stroke. Because these recoveries are usually unpredictable and suboptimal, researchers keep searching for new strategies to enhance post-stroke recovery. Robotic-assisted gait training (RAGT) was introduced as a new treatment to improve walking recovery (Mehrholz, et al., 2013). Robot-assisted gait training uses either an end-effector (e.g., Gait trainer G1 I (Schmidt, et al., 2007) or the G-EO system (Hesse, et al., 2010)) or exoskeleton (e.g., Lokomat (Mayr, et al., 2007)) to provide programmable gait training. The development of robot-assisted gait training was based on the hypothesis of modern rehabilitation that a task-specific repetitive approach may help motor learning and facilitate functional recovery (Daly & Ruff, 2007; Dietz, et al., 1994; Krakauer, 2006; Plautz, et al., 2000). The robot is designed to provide high-intensity repetitive work and can save manpower. With the robot-assisted gait training, a patient can practice 1000 steps within 30 min, which cannot be offered by a physiotherapist (Schmidt, et al., 2007). Although there has been debate as to the beneficial effects of robot-assisted gait training on post-stroke ambulation, a Cochrane review indicated that patients who received robot-assisted gait training in combination with physiotherapy after a stroke were more likely to achieve independent walking than those without robot-assisted gait training (Mehrholz, et al., 2013). The robotic Hybrid Assistive Limb (HAL) improved maximum walking speed in  $11.6 \pm 10.6$  m/min (HAL group) and  $2.2 \pm 4.1$  m/min (control group) in subacute stroke patients. (Yoshikawa, et al., 2017) Accordingly, robot-assisted gait training is ideal for use as an adjunctive treatment to traditional rehabilitation programs. RAGT using Lokomat may be more effective than treadmill gait training (TGT) in improving waking ability, balance, and balance confidence and restored symmetrical gait pattern with gait discrepancies in patients with chronic stroke (Bang and Shin, 2016).

This article introduces a novel Robotic Gait Training System (RGTS), which is a hybrid of end-effector and exoskeleton systems. With an end-effector design, the gait cycle is programmable and driven by

footplates in a closed-chain pattern. The exoskeletons secure the leg movements within a desired trajectory. Different from other commercial robot-assisted gait training products, this system uses a 3-point-support design (i.e., the abdomen, hips, and knees) to help the patient maintain an upright position during training. This system is designed to use in patients who have sustained severe leg dysfunction when active control of the paretic leg is insufficient to allow traditional standing or ambulation training. Accordingly, this preliminary study was conducted to report on whether this novel system is feasible and safe when applied to non-ambulatory patients who have sustained significant leg dysfunction after a stroke.

## 2. Methods

### 2.1. Participants

Patients were recruited if they had had a first-ever supratentorial stroke in the past 10~60 days, displayed substantial leg disabilities (e.g., a Brunnstrom stage (BS) of I~III in the paretic leg) (Brunnstrom, 1966; Naghdi, et al., 2010), and were unable to stand or walk independently even with orthosis included (e.g., a Functional Ambulation Classification (FAC) of 0~1) (Mehrholz, et al., 2007). Patients were excluded if they had substantial spasticity over the affected leg, severe osteoarthritis, or had walking disabilities before the stroke. Accordingly, six stroke patients were recruited from the Neurological, Neurosurgical and Rehabilitation Departments of Shuang-Ho Hospital. The study protocol was approved by the Joint Institutional Review Board of Taipei Medical University (TMU-JIRB, No: N201509027) and was explained to all participants before their participation. All participants gave their informed consent.

### 2.2. Stroke characteristics

Basic participant characteristics including stroke information and comorbidities were obtained from a chart review. Information about the lesion location and stroke type was obtained from brain computed tomography (CT) or magnetic resonance imaging (MRI). The National Institutes of Health Stroke Scale (Goldstein & Samsa, 1997) (NIHSS, 0~42), modified Ashworth scale (MAS, 0~5), modified Rankin Scale (Quinn, et al., 2009) (mRS, 1~6), Brunnstrom stage (BS, 1~6), and the manual muscle test (MMT,

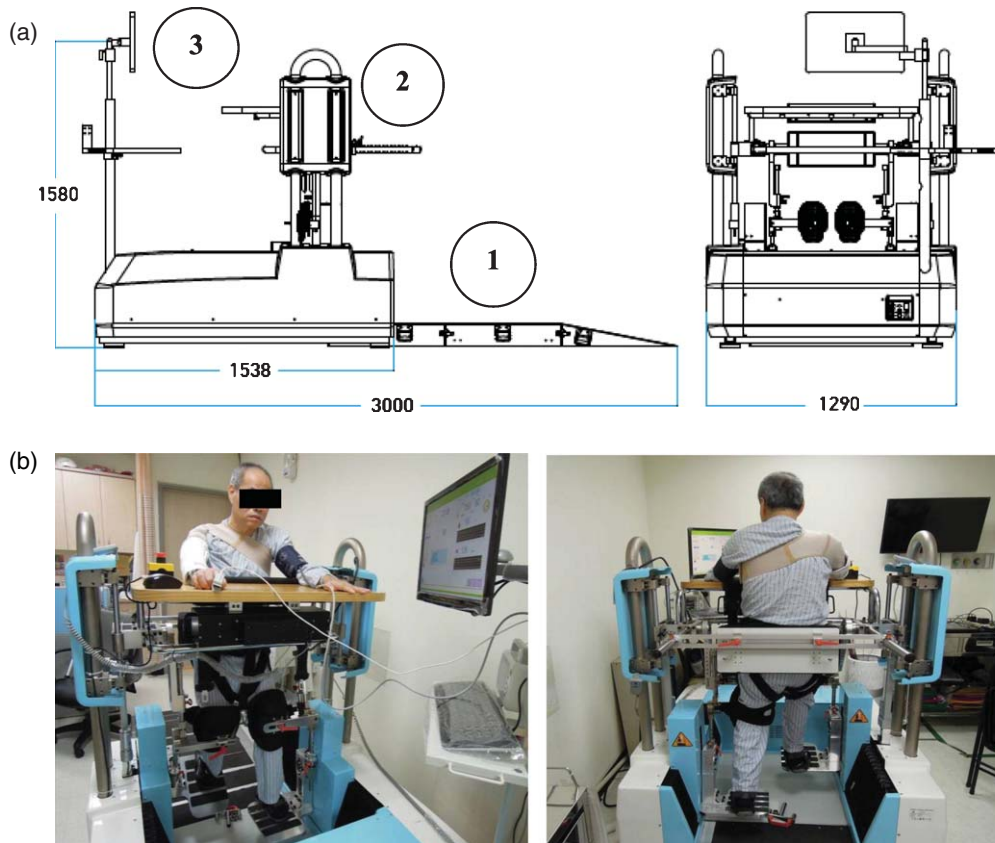


Fig. 1. The Robotic Gait Training System (RGTS). (a) Dimensional cross-sectional view of the motion mechanism of the RGTS. (b) Photographs of frontal and back views of actual use of the Robotic Gait Training System (RGTS).

0~5) of the quadriceps muscle were evaluated at the pretreatment assessment.

### 2.3. Device

The RGTS (MRG-P100, HIWIN) is a hybrid of end-effector and exoskeleton systems, which is presented in Fig. 1. Figure 1a illustrates a dimensional cross-sectional view of the motion mechanism of the RGTS. 1. The transfer system includes a retractable ramp plate and electric body lifting device. 2. The three-point support system (non-suspension system) includes abdominal support, supportive knee caps, and a rear buttock block. 3. The intelligent monitor system (Celeron B810 1.60 GHz 1.88 GB, 32 GB hardware, Microsoft NET Framework 4) includes setting individual user's basic data, thigh (upper leg) and calf (lower leg) lengths, and training parameters, and monitoring vital signs. Figure 1b. Photographs of frontal and back views of actual use of the Robotic Gait Training System (RGTS). It consists of a three-point (i.e., knees, pelvis, and abdomen)

support system, exoskeleton modules and footplates, an electrical-driven transfer system, and a computerized monitor. When standing on the machine, the patient's abdomen contacts the abdominal support from the front. The hip block from the rear prevents the patient from falling backward. The knee pad/support from the front avoids knee buckling. Without a suspension harness which is frequently used in commercial robot-assisted gait training systems, the 3-point support (abdomen, hips, and knees) enables the patient to receive weight-bearing training in a more-comfortable environment. The peddling cycle is driven by two coordinating footplates and is secured by the exoskeletal modules. Development of the desired peddling trajectory was based on the pedal trajectory of an elliptical trainer and elliptical-shaped trajectory was shown to have similar joint kinematics as that of a normal walking pattern (Burnfield, et al., 2010). The RGTS program predetermines the trajectories according to different leg lengths. With a certain leg length, the trajectory can be adjusted automatically using a different desired

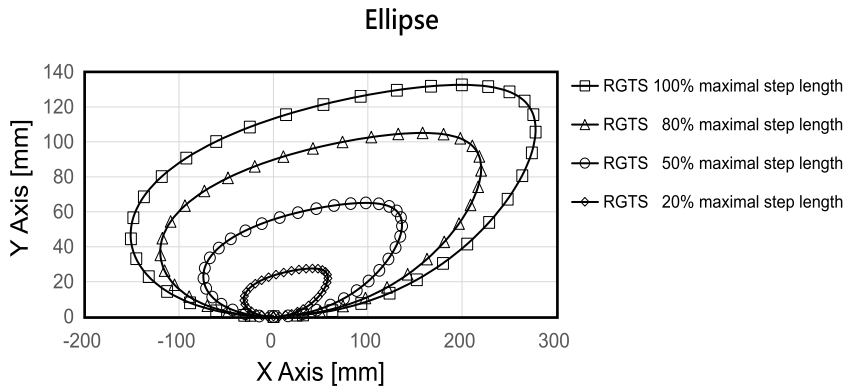


Fig. 2. Trajectory of the ankle center during the peddling cycle of the Robotic Gait Training System (RGTS).

step length which is presented as the percentage of the maximal step length that is preset by the RGTS program. The trajectory is shown in Fig. 2. The trajectory of the ankle center during the peddling cycle with a specific leg length (thigh: 50 cm, calf: 52 cm) with four different step lengths. The x- and y-axes represent the anterior-posterior and vertical postural change of ankle center during the cycle, respectively. The Robotic Gait Training System (RGTS) program presets the maximal step length. In the case of the

elliptical trajectory, the maximal step length equals the maximal anterior-posterior postural change of the foot during the peddling cycle. With a given leg length, the trajectory can be adjusted to different step lengths. In the case of the RGTS, the step length represents the maximal anterior-posterior displacement of the foot during a peddling cycle. Changed in the trajectory and joint angle with different given step lengths were illustrated in Fig. 3. The exoskeleton fits the leg length that ranges 38~50 cm in the thigh

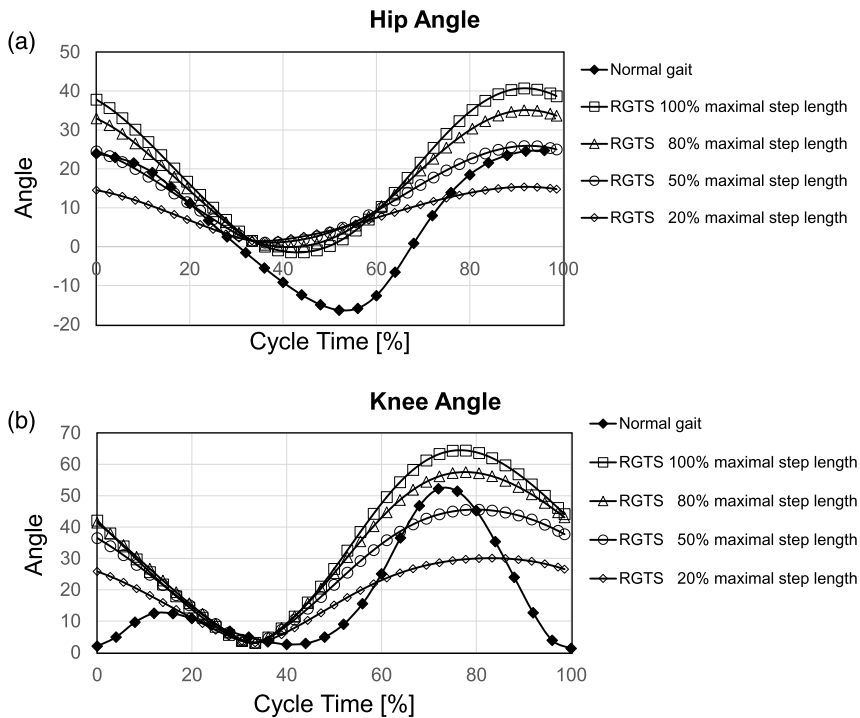


Fig. 3. Angle change during the peddling cycle of the Robotic Gait Training System (RGTS) in a subject with 50 cm in thigh (upper leg) length and 52 cm in calf (lower leg) length with different given step lengths. (a) Hip angle changes in the sagittal plane during the peddling cycle. (b) Knee angle changes in the sagittal plane during the peddling cycle.

and 40~52 cm in the calf. With different combinations of leg length, step length, and peddling rate, the walking speed can be set from 1 to 10, corresponding to 0.066~0.917 km/h. The weight of the user is limited to 135 kg.

#### 2.4. Intervention

Interventions included 15 daily sessions of 30 min of RGTS training. A physical therapist (PT) pushed the wheelchair toward the platform through the ramp plate and helped the patient settle down on the machine (e.g., from sitting in the wheelchair to standing on the footplate of the RGTS). In cases with severe leg dysfunction that caused marked difficulties in transferring, the electric body lifting device of the RGTS can be used to help the settling process. Then, the PT helped place the patient's bilateral feet on the footplate, well fit the patient's knees in the anterior knee pads of the exoskeleton, and tightly contacted the chest/abdomen against the anterior trunk pad. After standing on the platform in a proper posture, the rear hip block, which is a horizontal rod placed tightly against the buttocks, was put in place and locked. Accordingly, the 3-point support provided by the abdomen pad, knee pads, and hip block kept the patient in an upright posture.

Through the intelligent monitoring system, the PT typed in the anthropometric data after measuring the length of the thigh and calf and then set up the training parameters including the training duration, step length, and speed. The 30 min of training duration included 5 min of warm-up, followed by 20 min of workout, and 5 min of cool-down. The intensity of the warm-up and cool-down was set to 30% of the maximal step length and a speed of 3 for all sessions. The training intensity progressed by increasing the step length by 10% and speed by 1 unit for every subsequent session if no discomfort was reported, until the maximal intensity (i.e., a ratio of 100% and speed of 10) was achieved.

#### 2.5. Outcome measurements

The neurological status of the paretic leg was assessed by the lower extremity subscale of the Fugl-Meyer Assessment (FMA-LE; 0~34 points) (Gladstone, et al., 2002). The functional performance of postural control and balance was assessed by the Postural Assessment Scale for Stroke (PASS, 0~36 points) (Benaim, et al., 1999) and the Berg Balance Scale (Blum & Korner-Bitensky, 2008). The Barthel

Index (BI; 0~100 points) assesses the independence of activity of daily living (ADL) (Sulter, et al., 1999). The outcome measurements were performed at the pretest and posttest. In addition, vital signs (e.g., heart rate, blood pressure, and blood O<sub>2</sub> saturation) of patients were monitored during each session. Any discomfort perceived during or after the interventions was recorded.

#### 2.6. Statistical analysis

The within-group difference in functional improvements was assessed by the Wilcoxon signed-rank test that was used for a paired non-parametric sample. A two-tailed  $p < 0.05$  represented the level of significance. All analyses were performed using the Statistical Product and Service Solutions (SPSS, statistical package version 17.0, Chicago, IL, USA).

### 3. Results

The demographic and disease-specific information of the six participants are shown in Table 1. Five of the six participants were recruited from an acute stroke care setting on about the 10th post-stroke day. The mean  $\pm$  SD for body-mass index (BMI) was  $27.0 \pm 6.8$  kg/m<sup>2</sup> which indicated a relatively overweight sample. All had a level 0 in FAC at recruitment. Three of the participants had a Brunnstrom stage of 1 in the paretic leg. The median (IQR) of MMT was 0 (1.5), the Brunnstrom stage was 1.5 (2.0), and mRS was 5 (1.0). These findings indicated a group of patients who had substantial leg paralysis along with marked disabilities. Functional changes are shown in Table 2. There were significant after-before changes in the FMA, MMT, PASS, BBS, and BI, (all  $p < 0.05$ ) indicating significant improvements across the neurological status, muscle power, postural control, balance, and ADL after 15 sessions of interventions.

It took less than 2 min to complete settling on the machine (e.g., including standing up from the wheelchair, stepping onto the platform, placing the trunk and lower extremities in the proper positions, and locking the rear hip block). Getting off the machine was even quicker. All participants were able to tolerate the training with the RGTS. Heart rate changes through the intervention sessions in one patient were showed in Fig. 4. The mean of heart rate was 89.8 beats/min at rest and that increased to 108.7 beats/min at 30 min of the intervention. One

Table 1  
Participant characteristics

	Age (years)	Onset duration (days)	BH (cm)/ BW (kg)/ BMI (kg/m <sup>2</sup> )	Gender (M/F)	Side of lesion (R/L)	Stroke type (I/H)	NIHSS	MAS	mRS	Brunnstrom stage (LE)	MMT
Case 1	44	9	165.0/98.0/36.0	M	R	H	10	0	5	3	1
Case 2	43	45	160.0/60.0/23.4	F	L	I+H	12	3	4	2	0
Case 3	55	12	178.0/95.5/30.1	M	L	H	15	0	5	1	0
Case 4	64	10	158.0/81.0/32.5	F	R	H	10	0	5	1	0
Case 5	64	10	163.0/56.0/21.1	M	L	I	14	1	5	1	0
Case 6	56	7	156.0/46.0/18.9	F	L	H	9	0	4	3	3
Mean ± SD	54.3 ± 9.2	15.5 ± 14.5	163.3 ± 7.9/72.8 ± 21.8 /27.0 ± 6.8				11.7 ± 2.4	0.7 ± 1.2	4.7 ± 0.5	1.8 ± 1.0	0.7 ± 1.2
Median (IQR)							11.0 (4.5)	0 (0)	5.0 (1.0)	1.5 (2.0)	0 (1.5)

Abbreviations: cm, centimeter; BH, body height; BW, body weight; BMI, body-mass index; kg, kilogramme; m, meter; M, male; F, female; R, right; L, left; I, ischemic; H, hematological; NIHSS, National Institutes of Health Stroke Scale; mRS, modified Rankin scale; LE, lower extremity of the paretic leg; MMT, manual muscle power test for paretic knee extensor; MAS, modified Ashworth scale for paretic knee joint. Values are expressed as the mean ± SD, Median (IQR), or as frequencies.

Table 2  
Functional assessments

	Pretest	Posttest	Change	<i>p</i> value
FMA-LE (0~34)	7.7 ± 2.9 7 (5)	14.2 ± 4.1 13 (7.3)	6.5 ± 2.30 5.5 (3)	0.026
MMT (0~5)	0.7 ± 1.2 0 (1.5)	2.0 ± 1.3 1.5 (2.3)	0.8 ± 0.8 1 (1.3)	0.023
PASS (0~36)	11.2 ± 5.2 11.5 (7.5)	20.3 ± 8.3 19.5 (15.3)	9.2 ± 6.2 7 (10.3)	0.027
Berg Balance Scale (0~56)	2.2 ± 2.0 2.0 (2.3)	15.7 ± 14.2 11.5 (24.3)	13.5 ± 13.9 8.5 (25)	0.027
BI (0~100)	18.3 ± 15.7 15 (22.5)	37.5 ± 28.2 30 (48.8)	19.2 ± 27.8 10 (26.3)	0.042

Values are expressed as the mean ± SD and *median* (IQR). Abbreviations: FMA-LE, lower extremity subscale of the Fugl-Meyer Assessment; PASS, Postural Assessment Scale for Stroke Patients; BI, Barthel Index; MMT, manual muscle power test for paretic knee extensor.

patient reported knee discomfort after the first couple of sessions. Erythematous change in the knee surface with tenderness was noted. We suggested that he wear short pants rather than the hospital uniform of long pants so that the knee skin would tightly contact the soft knee pad. This action avoided friction between the skin and the clothes, and the discomfort became tolerable and subsided thereafter. Additionally, a particular notice was given to a case who had an MAS of 3 for the paretic knee indicating a marked increase in muscle tone through the total range of motion. Still, the patient was able to complete the intervention smoothly without reported discomfort.

#### 4. Discussion

The RGTS features a hybrid of end-effector and exoskeleton systems. The gait trajectory is driven

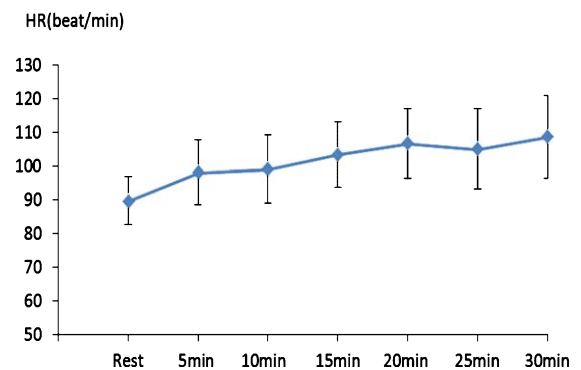


Fig. 4. Average heart rate (mean ± SD) with 15 sessions Robotic Gait Training System training of a participant.

by the end-effector and secured by the exoskeleton. Instead of body suspension, the 3-point support design of the RGTS keeps the patient undergoing training in a weight-bearing condition. Without the suspensive harness, the system has an advantage of

easy mounting and dismounting, avoiding the discomfort caused by the harness suspension and hence providing intensive training in a relatively comfortable condition. This study demonstrated that this novel RGTS is practical and safe for use with stroke patients who have sustained marked disabilities in mobility with heavy leg paralysis. The training process was smooth without adverse effects. The results supported the RGTS being a practical adjunctive treatment to traditional physical therapy in stroke care settings. It is particularly suitable for use when there is limited active leg control, which is needed to initiate standing or ambulation training. These findings should be useful for future clinical trials that explore the beneficial effects of this system in facilitating leg motor recovery.

The end-effector and exoskeleton methods are the most common principles for driving rehabilitation robots (Mehrholtz, et al., 2013). However, each method has its own advantages and disadvantages. Current end-effector products with the body suspended allow a high degree of spatial freedom of movement of the legs, which makes the trajectory unsecured. For a stroke patient with poor control of the paretic leg (e.g., poor activation of the knee extensor or unintentional hip rotation caused by spasticity), physical assistance provided by a PT is usually required to help control the knee or adjust the leg and trunk position to secure the gait trajectory (Hesse, et al., 2010; Schmidt, et al., 2007). Because one of the goal for building a robot is to save the manpower, the PT-dependent procedure which is manpower consuming is not in line with human's expectations toward a robot. On the contrary, the exoskeleton of the RGTS secures the desired gait trajectory. The automation brings about high-intensity repetitive training in safe conditions and saves manpower. However, the complex design of exoskeletons of current commercial products may make it inconvenient to set up. The RGTS combines advantages of both systems. It was shown that the system is easy to set up. All patients were able to tolerate the high intensity (e.g., 100% of maximal step length and a speed of 10) through the progression of training.

Although the RGTS provides passive gait training, active participation by the patient can be improved with the help of a PT who can encourage the patient to actively contract the leg muscles (e.g., quadriceps, iliopsoas, and gluteal muscles) during the peddling cycles. The increasing heart rate of a participant through the session is shown in Fig. 4. The trend

of heart rate changes through the 15 intervention sessions in one patient. The mean of heart rate was 89.8 beats/min at rest and that increased to 108.7 beats/min at 30 min of the intervention. It indicates increased energy consumption and supports the possibility of active participation. On the other hand, the passive leg motion provided by the RGTS can also be beneficial. During passive gait training, the proprioceptive receptors at the joints (including tendons or ligaments) produce sensory input to the cerebral sensory cortex through complex neural connections. Figure 3b shows knee angle changes through the peddling cycle. The RGTS intensity at 80% of the maximal step length provides similar knee angle changes (e.g.,  $3^{\circ}\sim 57^{\circ}$  of flexion) with that in a normal gait (e.g.,  $2^{\circ}\sim 52^{\circ}$  of flexion). In other words, a training intensity of >80% of the maximal step length produces larger proprioceptive input regarding knee joint changes than the normal gait does. Moreover, weight bearing of the joint can further enhance the proprioception input. It was found that the proprioception sense in the weight-bearing position was significantly higher than that in the non-weight-bearing position (Bang, et al., 2015). Thus, the RGTS can be seen as a sensory stimulation intervention which can possibly affect neural plasticity after a stroke (Hamdy, et al., 1998; Kaelin-Lang, et al., 2002; Magnusson, et al., 1994).

Interventions that use sensory stimulation to intentionally enhance motor recovery after a stroke have been tried (Bolognini, et al., 2016; Hamdy, et al., 1998; Johansson, et al., 1993; Lewis & Byblow, 2004; Magnusson, et al., 1994; Marconi, et al., 2011). Although the sensory and motor systems function differently, there is accumulating evidence which indicates that these two components are tightly connected in many circumstances. For example, sensory feedback is needed to properly control body movements, especially during tasks for which proficiency and dexterity are required (Pavlidis, et al., 1993). In stroke patients, it was also found that somatosensory deficits can influence motor learning, with worse motor recovery occurring in those who had more-severe sensory loss (Nudo, et al., 2000). Therefore, it was speculated that the sensory input may connect to brain plasticity in terms of motor recovery (Bolognini, et al., 2016). Animal and human studies showed that sensory input can affect the corticomotor excitability of the target area (Cuypers, et al., 2010; Floel, et al., 2008; Hamdy, et al., 1998; Meesen, et al., 2011; Ridding, et al., 2000).

Transcranial magnetic stimulation (TMS) studies showed that the excitability of the motor cortex increased by applying sensory electrical stimulation to the corresponding body region on the contralateral side (Hamdy, et al., 1998; Kaelin-Lang, et al., 2002; Tinazzi, et al., 2005). On the contrary, the excitability of the motor cortex can be reduced by deprival of sensory inputs from the contralateral extremity (Floel, et al., 2008). With respect to proprioceptive modalities, both functional MRI and TMS studies showed that sessions of continuous passive motion of a joint affected the cortical excitability (Lewis & Byblow, 2004; Vér, et al., 2016). These neurophysiological-based findings encourages further clinical trials to explore the clinical effects of the RGTS as a proprioceptive intervention on functional performance.

This small-sample pilot study was conducted to evaluate the feasibility and safety of the novel device for stroke patients. Without the control group for comparison, it is impossible to assess the beneficial effects of the RGTS on improving the poststroke recovery. However, after proven as a practical treatment with RGTS, our results may encourage further randomized control trials in the future to explore the effectiveness of the RGTS.

## 5. Conclusions

The RGTS features a standing posture while performing passive leg motions that mimic the gait cycle. Whether this system helps to facilitate motor recovery of the paretic leg deserves further evaluation. This study demonstrated that the RGTS is practical, safe, and suitable to use in patients with substantial leg dysfunction.

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## Conflict of interest

The authors declare that they have no competing interests.

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