Effects of Innovative WALKBOT Robotic-Assisted Locomotor Training on Balance and Gait Recovery in Hemiparetic Stroke: A Prospective, Randomized, Experimenter Blinded Case Control Study With a Four-Week Follow-Up

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***Abstract*—The present clinical investigation was to ascertain whether the effects of WALKBOT-assisted locomotor training (WLT) on balance, gait, and motor recovery were superior or similar to the conventional locomotor training (CLT) in patients with hemiparetic stroke. Thirty individuals with hemiparetic stroke were randomly assigned to either WLT or CLT. WLT emphasized on a progressive, conventional locomotor retraining practice (40 min) combined with the WALKBOT-assisted, haptic guidance and random variable locomotor training (40 min) whereas CLT involved conventional physical therapy alone (80 min). Both intervention dosages were standardized and provided for 80 min, five days/week for four weeks. Clinical outcomes included function ambulation category (FAC), Berg balance scale (BBS), Korean modified Barthel index (K-MBI), modified Ashworth scale (MAS), and EuroQol-5 dimension (EQ-5D) before and after the four-week program as well as at follow-up four weeks after the intervention. Two-way repeated measure ANOVA showed significant interaction effect (time $\times$ group) for FAC ($p = 0.02$), BBS ($p = 0.03$), and K-MBI ($p = 0.00$) across the pre-training, post-training, and follow-up tests, indicating that WLT was more beneficial for balance, gait and daily activity function than CLT alone. However, no significant difference in other variables was observed. This is the first clinical trial that highlights the superior, augmented effects of the WALKBOT-assisted locomotor training on balance, gait and motor recovery when compared to the conventional locomotor training alone in patients with hemiparetic stroke.**

***Index Terms*—Balance, gait, neurorehabilitation, robotic-assisted locomotor training, stroke.**

I. Introduction

STROKE is a common, leading cause of balance and locomotor disorders that may lead to chronic physical disabilities; patients with stroke are burdened with high medical costs [1], [2]. They are vulnerable to balance and locomotor dysfunctions due to the hemiparetic lower extremity after a sudden loss of the brain functions. In addition, they are more inclined to use nonaffected lower extremity while standing and walking. Thus, they are vulnerable to arrhythmic, asymmetric weight bearing and reduced gait cycle [3], [4]. Animal experimental studies have shown that neuroplasticity leading to motor recovery in ischemic lesions occurs after the balance and gait training was repeated 400–600 times [5], [6]. However, according to the report of Lang *et al.*, the typical numbers of repetitions for balance and gait (steps) training accounted for 6.0 and 291.5 repetitions per each session, respectively, in a neurorehabilitation program [7]. It can therefore be inferred that the effects of the conventional locomotor training would be enhanced if combined with the robot-assisted one providing an accurate sensorimotor feedback *via* haptic guidance and various built-in software programs in the early stage of stroke rehabilitation [8].

Neurorehabilitation programs have been used to improve balance and locomotor functions; these include neurodevelopmental technique, repetitive task training, biofeedback, body weight-supported treadmill training, robot-assisted training, and high-intensity physical therapy. Still, however, controversial opinions exist regarding their effects in improving the balance and locomotor functions [9], [10]. Of these, the task-specific locomotor training with a body weight-supported treadmill has been commonly used in a clinical setting [11]–[14]. But it is disadvantageous in that it is often labor-intensive, thus posing challenging problems for clinicians who aim to raise

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the frequency of the repetition of the locomotor training for neuroplasticity in the neurorehabilitation of patients with stroke. To address these issues, we have recently developed a robot-assisted locomotor training system, WALKBOT (P&S Mechanics, Seoul, Korea), for the purpose of providing an accurate haptic guidance *via* a proprioceptive, kinematic and kinetic biofeedback, variable practice, high-intensity, repetitive, task-specific and interactive exercises for patients with paretic lower limbs [15]. It is useful to perform a quantitative analysis of the kinematic and kinetic parameters and spastic stiffness during the weight-supported treadmill walking and then to provide a sensorimotor feedback for the patients [15]. Recent clinical studies have shown that the robot-assisted gait training system is highly effective in improving the locomotor functions as compared with the conventional one; it shows a new paradigm for the guidance practice [16]–[20]. According to a review of the literature, however, the guidance practice and the variable one are predominantly involved in the early and the intermeditate-to-late stage of the gait training, respectively [15]. Thus, both practices are involved in the long-term potentiation and neuroplasticity [21]. Recently, a randomized, controlled study was conducted to assess the effects of a 12-week robot-assisted gait training program using the LOKOMAT (Hocoma AG, Volketswil, Switzerland) in improving the gait velocity in patients with incomplete, chronic spinal cord injury, thus demonstrating its minimal efficacy [22]. Thus, it showed that the LOKOMAT was effective only in a minimal manner presumably because it is only efficient in adapting to the degree of the need for the gait training or responding to that of the complexity [23]. It can therefore be inferred that the robot-assisted gait training system might also be effective in improving the gait velocity if combined with conventional one that provides a contextual interference in the gait training based on the variable practice or if installed with the variable practice. To date, however, no studies have been conducted to raise the gait velocity in patients with stroke.

Therefore, the specific aim of the present investigation was to evaluate whether the effects of WALKBOT-assisted locomotor training (WLT) on balance, gait and motor recovery were superior or similar to the conventional locomotor training (CLT) in individuals with hemiparetic stroke. We hypothesized that WLT would produce greater enhancements on balance, gait, and motor recovery than CLT alone in patients with hemiparetic stroke.

II. Subjects and Methods

A. Subjects and Study Procedure

In the current prospective, randomized, single-blind study, we enrolled a total of 30 patients (22 men, mean age $= 51.9 \pm 13.8$ years) with stroke. Inclusion criteria for the current study are as follows: 1) the patients with first stroke whose onset not exceeded one year; 2) the patients who reached a almost plateau in recovery of the locomotor functions after a 30-day conventional neurorehabilitation [24]. Exclusion criteria for the current study are as follows: 1) the patients with severe spasticity based on the modified Ashworth's scale >2; 2) the patients with tremor; 3) the patients with severe visual and cognitive impairments; 4) the patients with musculoskeletal diseases (e.g., arthritic pain); 5) the patients with cardiopulmonary diseases (e.g., unstable angina or hypertension); 6) the obese patients with a body weight of >135 kg); 7) The patients with a short height of <150 cm. Patients were assigned randomly to either the WLT group or the CLT group.

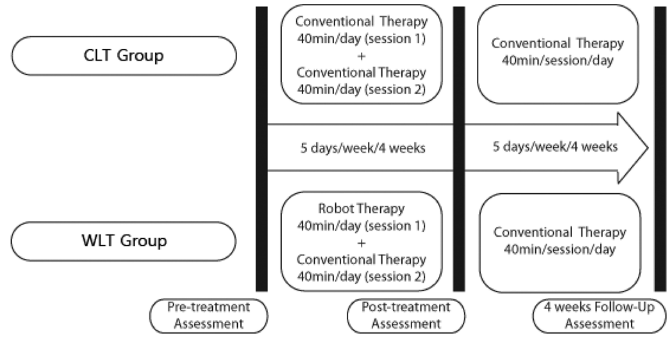

Fig. 1. Study flowchart.

Fig. 2. Side view of the Walkbot.

All the patients submitted a written informed consent. The current study was approved by the Institutional Review Board (IRB) of Pusan National University Yangsan Hospital (IRB approval number: # 03-2013-011). Moreover, the current study was registered with ClinicalTrials.gov (Identifier: NCT02053233).

B. Evaluation Scales

In the current study, we evaluated the locomotor functions based on such scales as the Functional Ambulation Category (FAC) [25], Berg Balance Scale (BBS) [26], Korean version

TABLE I
DEMOGRAPHIC AND BASELINE CLINICAL CHARACTERISTICS OF THE PATIENTS

	WLT group (n=13)	CLT group (n=13)	*P*-value
Age (years)	54.1±12.6	50 ± 16.2	0.68
Male-to-female ratio	9:4	10:3	0.66
The time from the onset of stroke (days)	80.1±60.2	119.5±84.3	0.52
The ratio of the left-to-right side	5:8	3:10	0.40
The ratio of ischemic-to-hemorrhagic stroke	8:5	5:8	0.24
FAC scores	1.46±1.55	1.62±0.92	0.08
BBS scores	19.23±14.62	19.77±9.00	0.58
K-MBI scores	43.85±19.89	44.15±16.9	0.46
EQ-5D scores	0.40±0.30	0.37±0.31	0.49
MAS scores			
- Knee	0.08±0.27	0.00±0.00	0.31
- Ankle	0.19±0.46	0.08±0.27	0.59

Abbreviations: WLT, WALKBOT-assisted locomotor training; CLT, conventional locomotor training; FAC, Functional Ambulation Category; BBS, Berg Balance Scale; K-MBI, Korean version of Modified Barthel Index; EQ-5D, EuroQol-5 dimension; and MAS, Modified Ashworth Scale.
Data are expressed as mean±SD (SD: standard deviation).
P-values at the independent t-test.

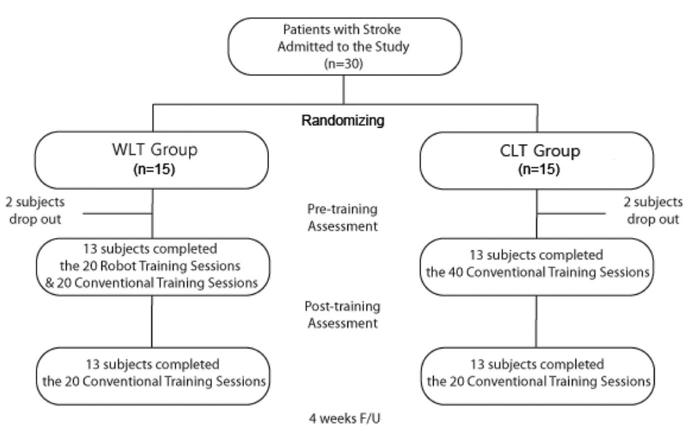

Fig. 3. Enrollment and flow of subjects of the study.

of Modified Barthel Index (K-MBI), Modified Ashworth Scale (MAS), and EuroQol-5 dimension (EQ-5D). To do this, we measured scores of each scale at baseline, endpoint and follow-up. Thus, we evaluated the balance using the BBS, locomotor functions using the FAC, daily activity function using the K-MBI, the spasticity using the MAS and the quality of health using the EQ-5D. The validity and reliability and validity of each scale have been well documented [27], [28].

C. Intervention

WLT emphasized on a progressive, conventional locomotor retraining practice (40 min) combined with the WALKBOT-assisted, haptic guidance and random variable locomotor training (40 min) whereas CLT involved conventional physical therapy alone (40 min $\times$ 2 $=$ 80 min) (Fig. 1). Both intervention dosages were standardized and provided for 40 min $\times$ 2 times/day (total of 80 min), five days/week for four weeks. Specifically, CLT was comprised of bed mobility exercises (rolling, bridging, quadruped) and stretching (5 min); training of balance (i.e., maintaining, reactive, and anticipatory postural control exercise) during sitting (5 min); training the transfer from sit-to-stand and vice versa while maintaining static and dynamic balance and strengthening exercise for tibialis anterior, quadriceps and gluteus maximus and medius with or without functional electrical stimulation (FES) (10 min); standing balance training with force, center of pressure, sway,

TABLE II
FUNCTIONAL SCORES OF EACH EVALUATION SCALE AT BASELINE, FOUR WEEKS, AND EIGHT WEEKS

	WLT group (n=13)			CLT group (n=13)			
	Pre-training (Baseline)	Post-training (At 4 weeks)	Follow-up (At 8 weeks)	Pre-training (Baseline)	Post-training (At 4 weeks)	Follow-up (At 8 weeks)	*P*-value
FAC	1.46±1.55	2.54±1.50	2.69±1.49	1.62±0.92	1.69±0.91	1.85±0.86	0.02*
BBS	19.23±14.62	33.85±12.92	39.15±11.49	19.77±9.00	27.00±7.88	31.23±7.33	0.03*
K-MBI	43.85±19.89	57.08±19.39	65.77±15.87	44.15±16.9	49.46±16.35	53.46±15.33	0.00*
EQ5D	0.40±0.30	0.55±0.25	0.64±0.25	0.37±0.31	0.4±0.32	0.43±0.30	0.10
MAS							
- Knee	0.08±0.27	0.08±0.27	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.57
- Ankle	0.19±0.46	0.12±0.40	0.19±0.46	0.08±0.27	0.08±0.27	0.08±0.27	0.57

Abbreviations: WLT, WALKBOT-assisted locomotor training; CLT, conventional locomotor training; FAC, Functional Ambulation Category; BBS, Berg Balance Scale; K-MBI, Korean version of Modified Barthel Index; EQ-5D, EuroQol-5 dimension; and MAS, Modified Ashworth Scale. Data are expressed as mean±SD (SD: standard deviation).
*Statistical significance at repeated measures of analysis of variance (ANOVA).

symmetry of weight bearing, and position biofeedback using a force platform with force sensors (10 min); treadmill locomotor training with the patient's body-weight partially supported by a harness and progressing to overground gait training with or without assistive devices, orthotics, or FES (10 min) [29].

For the WLT, in addition to the conventional physical therapy described previously, the Walkbot-assisted gait training was augmented for another 40 min. All individuals wore a suspension vest and harness connected to a counterweight system to provide lumbopelvic stability and body weight support. The patient's hip, knee and ankle joint axes were consistently aligned with the exsoskeletal system's actuators and elastic straps were used to secure the legs (Fig. 2). Unlike LOKOMAT-assisted training system, the WALKBOT assisted system has an independent ankle actuator to control excessive ankle plantar flexion and toe clearance. Depending on the neuromuscular skeletal conditions (e.g., pain, muscle weakness, spasticity, tolerance, fatigue, or endurance) of each patient, approximately 40%–60% (adjustable range, 0%–100%) of the total body weight was initially supported at the first session, and then gradually decreased in 5%–10% increments per session as tolerated without substantial knee buckling or toe drag. Based on each individual's height, stride length, and walking velocity were concurrently adjusted at 1.0–1.6 m/cycle and at 1.00–1.20 km/h during the initial session, respectively. The walking speed was increased by 0.1 km/h every 5 min as tolerated to 2.40–2.60 km/h (maximally adjustable to 3.00 km/h), and remained thereafter for subsequent visits. The guidance force or torque of the knee and hip actuators can be adjusted from 100% to 10% (with a 10% increment) for one leg at a time. Initially, continuous visual and proprioceptive feedback about sagittal kinematics and force trajectories of the hip, knee, and ankle joints, approximating symmetrical, rhythmic, reciprocal locomotor pattern were provided to stimulate corresponding central pattern generators (CPG) network, which play important roles in creating the rhythm and shaping the pattern of the motor neuron firings in the spinal cord [30]. However, as the locomotor skill becomes mostly rhythmic and automatic, more variable practice using different walking velocities and guidance forces were provided to maximize locomotor learning. Furthermore, the subject could increase or decrease walking velocity automatically during the gait training session as he or she improved walking performance. Because the locomotion is primarily mediated by spinal locomotor reflex or the CPGs with a cortical or subcortical modulation, a subcortical motor learning paradigm was used where the subjects were instructed to kick a ball automatically in front of the treadmill frame rather than consciously attempting to make an accurate step [31]. Blood pressure and heart rate were assessed and monitored to maintain below 80% of age-appropriate level during the training sessions and inter-training rest was provided as needed.

D. Statistical Analysis

All data was expressed as mean±SD (SD: standard deviation). We used two-way repeated measures analysis of variance (ANOVA) to compare scores of each scale between baseline and endpoint in each group. Then, we also used the independent t-test to compare differences in scores of each scale between the two groups. Finally, we performed a post-hoc analysis to identify pairwise differences. Statistical analysis was done using the

TABLE III
KOREAN-MODIFIED BARTHEL INDEX SCORES OF EACH EVALUATION SUBSCALES AT BASELINE, FOUR WEEKS, AND EIGHT WEEKS

	WLT group (n=13)			CLT group (n=13)			P-value
	Pre-training (Baseline)	Post-training (At 4 weeks)	Follow-up (At 8 weeks)	Pre-training (Baseline)	Post-training (At 4 weeks)	Follow-up (At 8 weeks)	
Grooming	2.23±1.59	3.00±1.00	3.23±1.17	2.23±1.09	2.62±0.87	3.38±0.51	0.09
Bathing	0.62±0.51	1.69±1.32	1.92±1.44	1.77±1.24	2.38±1.04	2.54±1.13	0.55
Feeding	4.15±3.36	5.15±3.18	6.46±2.40	5.00±2.44	5.38±2.53	5.85±2.41	0.13
Toilet Use	4.00±3.57	5.54±3.34	7.08±2.47	4.77±2.80	5.85±2.70	6.08±2.47	0.07
Stairs	0.77±1.89	1.69±2.93	2.38±3.50	1.00±1.53	1.62±2.43	2.62±2.69	0.73
Dressing	3.31±2.56	5.15±3.21	6.38±2.82	4.77±2.59	5.46±2.40	5.92±1.89	0.03*
Bowels	8.69±2.50	9.54±0.88	9.85±0.56	7.46±2.50	7.46±2.50	7.77±2.68	0.09
Bladder	8.31±2.93	8.92±2.78	9.69±0.75	7.31±2.39	7.31±2.39	7.46±2.50	0.36
Ambulation	4.38±4.81	7.85±3.85	8.92±4.01	4.23±3.24	5.69±3.15	6.08±2.66	0.04*
Transfers	7.38±4.46	8.54±4.10	9.85±3.91	5.85±4.08	6.46±3.71	6.46±3.71	0.05
Total	43.85±19.89	57.08±19.39	65.77±15.87	44.15±16.9	49.46±16.35	53.46±15.33	0.00*

Abbreviations: WLT, WALKBOT-assisted locomotor training; CLT, conventional locomotor training.
Data are expressed as mean±SD (SD: standard deviation).
*Statistical significance at repeated measures of analysis of variance (ANOVA).

SPSS for windows version 12.0 (SPSS, Chicago, IL, USA). A P-value of <0.05 was considered statistically significant.

III. RESULTS

A. Demographic and Baseline Clinical Characteristics of the Subjects

The 26 subjects have successfully completed the pretest, intervention, posttest, and follow up test, and attrition rate was 13.33% at follow-up (Fig. 3). One subject dropped out because of rib fracture which was not related to the study and the other three subjects dropped out because of the decline in general health condition. Baseline and clinical characteristics of the patients are represented in Table I. There were no significant differences in the age, the male-to-female ratio, the time from the onset of stroke, the ratio of the left-to-right side and the ratio of ischemic-to-hemorrhagic stroke between the two groups ($P > 0.05$).

B. Outcome Measures

As shown in Table II, two-way repeated measure ANOVA revealed significant interaction effect (time × group) for FAC ($p = 0.02$), BBS ($p = 0.03$), and K-MBI ($p = 0.00$) across the pretest, posttest, and follow-up tests. In the subscales analysis of K-MBI, subscales of dressing ($p = 0.03$) and ambulation ($p = 0.04$) showed significant interaction effect and subscale of transfer ($p = 0.05$) revealed moderately significant interaction effect (time × group) across the pretest, posttest, and follow-up tests (Table III). There were no significant differences in mean scores of the EQ-5D and MAS between the two groups ($P > 0.05$).

As shown in Fig. 4, a post-hoc analysis showed that WLT was more beneficial for balance, gait, and daily activity function than CLT alone ($P < 0.05$).

IV. DISCUSSION

For the current study, we have hypothesized that WLT might achieve a recovery of balance, gait, and motor functions to a greater extent as compared with CLT alone in subjects with hemiparetic stroke. Thus, we found that there were significant differences in mean scores of the FAC, BBS, and K-MBI between the two groups. We therefore reached a conclusion that the robot-assisted gait training is more effective in improving the balance, gait, and motor functions when combined

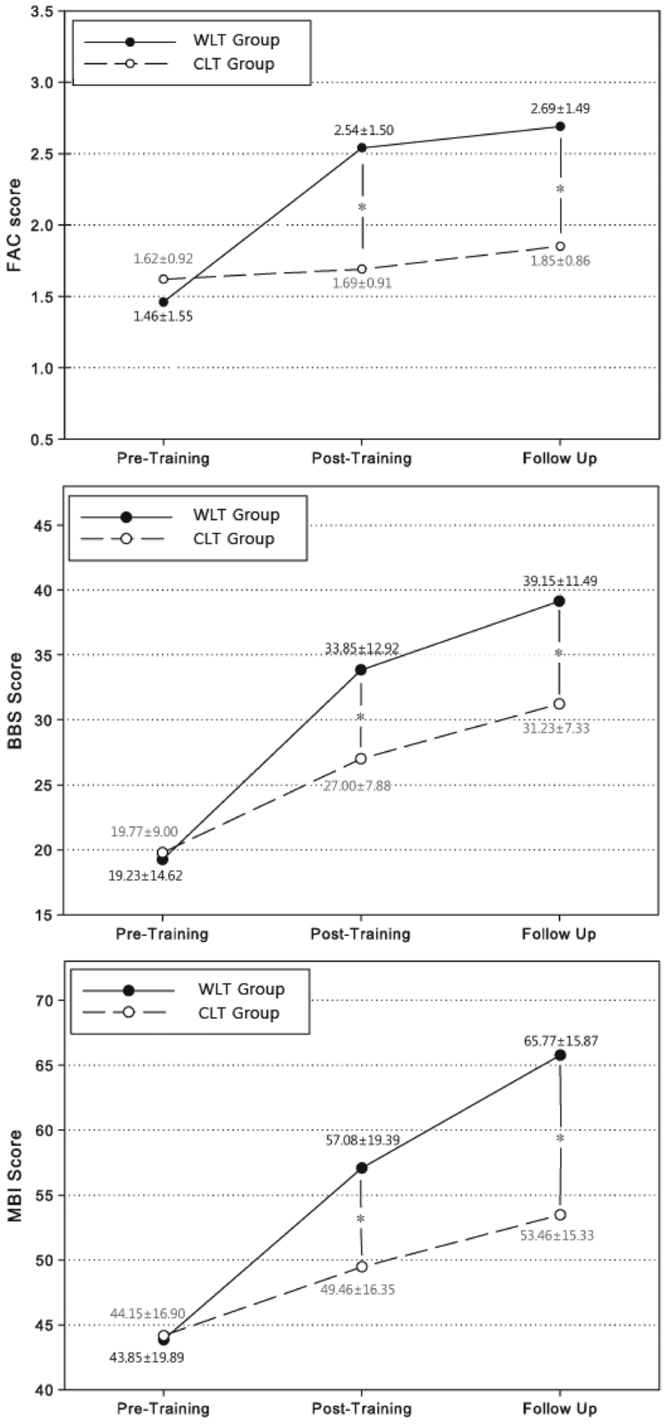

Fig. 4. Scores of each evaluation scale at baseline, four weeks, and eight weeks/

There were significant differences in the FAC, BBS and K-MBI between the two groups ($P < 0.05$). But, there were no significant differences in mean scores of the EQ-5D and MAS between the two groups ($P > 0.05$). Moreover, a post-hoc analysis showed that there were also significant differences in the FAC, BBS and K-MBI between the two groups ($P < 0.05$).

with the conventional one as compared with the conventional one only. Most importantly, this is the first clinical evidence demonstrating superior therapeutic effects of the combination of a conventional physical therapy and WALKBOT-assisted gait training on balance, gait, and daily activity function.

Our results are consistent with the results of a randomized, clinical study showing that a three-week course of robotic-assisted gait training was more effective in improving the gait velocity, endurability, muscle strength and muscle tone as compared with the conventional one in 16 patients with hemiparetic stroke [19]. Presumably, this might be because the WALKBOT-assisted locomotor training system provides a haptic guidance or a proprioceptive and somatosensory feedback by controlling an exoskeletal orthotic devices involved in the coordinated, rhythmic, kinematic, and kinetic movement of the hip, knee, and ankle. In association with this, it has been suggested that afferent proprioceptive signals generated from the haptic guidance stimulate the central pattern generator (CPG) in the network of motor neurons in the spinal cord and thereby are involved in the rhythmic, coordinated intersegemental locomotion of the limb [32]. Moreover, the efficacy of the robot-assisted gait training system is based on the body weight-supported treadmill walking. To put this in another way, it is useful to provide a body weight bearing for patients with early stoke without fear of falls [33]. These benefits of robot-assisted gait training system were made to improve the balance-related functions, such as BBS score and transfer and ambulation subscales of K-MBI. In particular, it plays an important role that the patients overcome the fear of falling and obtain the confidence about the walk in the subacute period of stroke. Moreover, it is advantageous in that it simulates the human locomotion. At a walking cadence of 100 steps/min and the robot-assisted gait training system provides a 20-min session of training, it allows patients to repeat the gait training for the postural and locomotor control up to 2000 times. As compared with the conventional gait training, the frequency of the repetition of up to 2000 times is sufficient to provoke plasticity of motor neurons and to achieve a recovery of locomotor functions [34]. In addition, the robot-assisted gait training system is also useful to control the posture and locomotor functions only in a limited scope and to provide a contextual interference by making minimal changes in them in response to the intensity of the gait training and the coordination between the two limbs.

It has been previously shown that controversial opinions exist regarding the effects of the LOCOMAT-assisted gait training in significantly improving the velocity and distance of the gait as compared with the conventional one [16], [35]. Presumably, this might be due to a lack of the motor recovery because of the haptic guidance and biosensory feedback. According to a recent experimental study, the robot-assisted gait training was more effective in achieving a recovery of motor functions as compared with the conventional one during the flexion and extension of the knee and ankle in normal healthy individuals [23]. Taken together, our results suggest that the robot-assisted locomotor training system might be effective in maximizing the degree of the recovery when combined with the conventional one in patients with hemiparetic stroke.

There are several limitations of the current study as shown below: 1) we enrolled a small number of patients in the current study. It is therefore difficult to generalize our results; 2) we enrolled the patients with sub-acute hemiparetic stroke. This suggests that clinicians should consider the effects of the robot-assisted training in making a spontaneous recovery of the functions when interpreting the results; 3) despite a lack of statistical significance, there was a difference in the ratio of ischemic-to-hemorrhagic stroke between the two groups. Further large-scale studies are therefore warranted to generalize our results.

V. Conclusion

In conclusion, our results indicate that the WALKBOT might be a potentially more effective robotic-assisted gait training system as compared with the conventional one in patients with hemiparetic stroke. Advanced research and development in the robot-assisted locomotor training system will open up new possibilities and more opportunities for maximal restoration of the locomotor recovery and independent ambulation in neurological populations with posture and gait impairment in the near future. But further large-scale studies are warranted to establish our results.

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Authors' photographs and biographies not available at the time of publication.