Effect of Stride Management Assist Gait Training for Poststroke Hemiplegia: A Single Center, Open-Label, Randomized Controlled Trial

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Background: Poststroke gait disorders negatively impact activities of daily living. Rehabilitation for stroke patients is aimed at improving their walking ability, balance, and quality of life. Robot-assisted gait training (RAGT) is associated with an increased number of task-specific exercises, which may benefit poststroke motor learning. We investigated the effects of RAGT using Stride Management Assist (SMA, which increases walk ratio by inducing hip-joint flexion and extension) in subacute stroke patients with hemiplegia. *Methods:* We conducted a single center, open-label randomized controlled trial in hemiplegia patients who experienced a first ever stroke and were admitted to the convalescent rehabilitation ward. A total of 41 were divided into the control (20 patients) and experimental group (21 patients). A 10-day, conventional gait training program was carried out for the control group; and RAGT with SMA was used for the experimental group. The maximum walking speed and other gait parameters were compared preintervention and postintervention. The intergroup differences in the improvement ratio were compared using an intention-to-treat analysis. *Results:* Ten-day intervention was completed by 36 patients. There was no difference between the 2 groups regarding gait parameters at intervention initiation. The improvement ratio of the maximum walking speed was significantly higher for the experimental group. Significant improvements were observed postintervention for maximum walking speed, paralysis-side step length, symmetry, and cadence in the experimental group. No adverse events attributable to the SMA were observed. *Conclusions:* Ten days of RAGT with the SMA was effective for improving gait disorders of subacute stroke patients.

Key Words: Gait—hemiplegia—robotics—Rehabilitation

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Introduction

Stroke is the second most prevalent cause of death and the third most prevalent cause of physical disability worldwide.[1] In Japan, where the aging population is large, stroke is the fourth most common cause of death[2] and the most common reason for long-term care.[3] Population aging is prevalent throughout the world.[3,4] And poststroke sequelae are expected to increase accordingly; therefore, reducing the incidence of sequelae is becoming a worldwide task. Among poststroke sequelae, gait disorders have a particularly strong effect on the activities of daily living and are one of the main targets of rehabilitation.[5] Rehabilitation for stroke patients is aimed at allowing the patient to gain higher levels of walking ability, balance, and activeness, to contribute to a better quality of life.[6,7] Hemiplegic gait due to stroke is characterized by decreased walking speed and step length and the emergence of left-right asymmetry involving step length.[8,9] To improve the walking ability of stroke patients, intensive and repetitive mobility task training is recommended[10]; therefore, asking stroke patients to walk faster during training can be considered a key training strategy.[11] Although walking faster may also lead to the achievement of community ambulation,[12] this effect involves the integration of walking with other tasks in a complex environment. Gait speed, therefore, may not consistently reflect the level of community ambulation[12] but remains an effective marker with which to predict community walking after stroke.[13] Thus, an increased gait speed may improve community ambulation.

Progress in technology has led to growing interest in robot-assisted gait training (RAGT). Robots can generally perform an increased number of task-specific exercises at increased intensity, and these advantages may be useful for poststroke motor learning.[14] Physiotherapeutic assistance by 1 or more individuals working in combination with a robot rather than the existing protocol of assistance by individuals alone may result in increased improvements in gait, as well as increasing the intensity of walking exercise for motor learning, which could heighten the learning effects and further improve walking ability. The 2017 Cochrane Systematic Review[15] reported that independent walking improves with electromechanical-assisted training for walking in combination with physiotherapy. However, there was no significant increase in walking speed, thus providing insufficient evidence for its use in gait training. Honda R&D developed the Stride Management Assist (SMA) with the objective of obtaining improvements in walking patterns such as decrease in step lengths of elderly individuals and increasing community mobility and social interaction[16,17] (Fig 1). Unlike existing robots with added relief and lower limb overall movement assist functions, the SMA is a highly convenient, wearable robot that is worn from the waist to thigh. The reported effects of its use to date include immediate improvement in walking efficiency for healthy persons[18] and improved walking speed for elderly individuals after long-term use.[16] Buesing et al[19] reported that the use of the RAGT with the SMA for chronic stroke patients led to better step lengths and improvements in other parameters compared to the results of usual physiotherapy. However, because the SMA is relatively new, its effects on the walking speed of stroke patients during the subacute phases have not yet been investigated in a randomized controlled trial. Therefore, we performed a randomized controlled trial to investigate whether RAGT with the SMA resulted in greater improvements in maximum walking speed for subacute stroke patients than usual physiotherapy.

Methods

Study Design

We performed a single center, open-label, parallel-group, comparative study randomized by even and odd patient identification (ID) numbers. Patient ID numbers were assigned in the order of hospital admission and were unrelated to sex, disease, days from onset, severity, or other attributes. Ten-day interventions consisting of gait training either with the usual physiotherapy alone or with the usual physiotherapy carried out wearing the SMA were compared. Data were gathered from the convalescence rehabilitation ward[20] of Nishi-Hiroshima Rehabilitation Hospital. The study plan was approved in advance by the Ethics Committee of Nishi-Hiroshima Rehabilitation Hospital and was explained by the attending physician; only those patients who provided written consent were enrolled in the study.

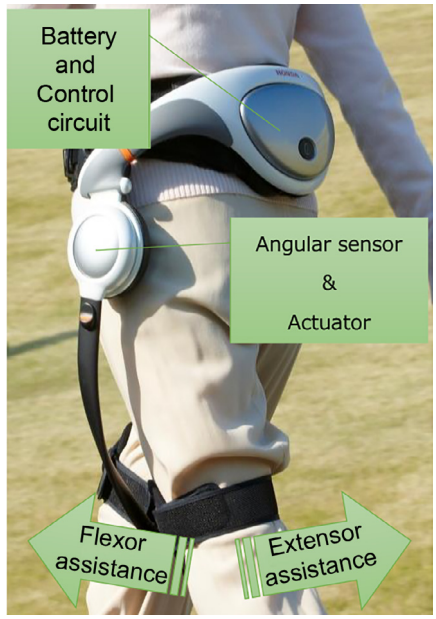

Figure 1. *Electrical actuators were equipped with angular sensors to monitor cadence, angular velocity, and the degrees of extension and flexion of the hip joints. The system weighed 2.4 kg and was positioned so that both actuators were located above the greater trochanters. Battery power was sufficient for approximately 2 hours of independent activity. Abbreviation: SMA, Stride Management Assist.*

Participants

Subjects were hospitalized between April 1, 2012 and July 30, 2016, and this period included a study suspension of 1.5 years. Stroke patients were recruited within 60 days of their first stroke. The study suspension was from December 1, 2014 to April 30, 2016, because of changes in the study personnel, maintenance, and changes in the SMA; as well as malfunctions and changes in the assessment instrument. However, the basic performance of SMA, the assessment instrument, and the overall research protocol remained unchanged. We therefore conclude that the changes did not affect the results. Patient inclusion criteria were: medical stability enabling positive rehabilitation, diagnosis of a first stroke, hemiplegia, ability to walk independently or with minimal assistance, and ability to complete gait training sessions lasting 10 minutes or more. Exclusion criteria were: severe aphasia or worse brain dysfunction, severe complications, sensory loss or locomotor pain, receipt of rehabilitation that was not usual (e.g., body weight-supported treadmill training, repetitive transcranial magnetic stimulation), insufficient study implementation period due to discharge from the hospital, absence of an SMA of an appropriate size, cerebellar lesion, or consent not provided.

Sample Size

The minimum clinically important difference in walking speed of hospitalized rehabilitation stroke patients is considered 13 cm/s.[21] Using a pilot study,[22] we found a mean maximum walking speed of 68.5 cm/s (standard deviation [SD], ±14.3 cm/s). We used OpenEpi[23] to calculate the sample size and assumed a minimum clinically important difference of 13 cm/s for speed between the control group and the SMA group. We assumed a 95% confidence interval, test power of 80%, and standard deviation of 14 for each group. We obtained 19 patients for each group and assumed a 10% dropout; therefore, 41 patients had to be enrolled.

Randomization

Randomization was performed in accordance with the even or odd value of the final digit of the ID number assigned to patient at the time of admission to the hospital. In other words, the patient was assigned to the control group if the final digit was odd or to the SMA group if the final digit was even.

Devices

The SMA is an external skeletal-system robot developed by Honda R&D (Fig 1) that comprises 3 components: a hip frame, 2 thin motors, and 2 thigh frames. The system, including its batteries, weighs 2.4 kg. One thin motor is placed on either side of the hip frame and aligned outside the left or right hip joint when worn. The maximum output of each motor is approximately 4 Nm of torque, which is applied via the thigh frame to assist the wearer with hip flexion and extension. An angle sensor works in conjunction with each motor, and the SMA calculates the walk ratio (step length/cadence) in real time using the wearer's hip-joint movement, and assists with the hip-joint movement to slightly increase the walk ratio and make the right and left step lengths symmetric. Each thigh frame is free to move in directions other than hip-joint flexion and extension. With appropriate placement in the belt secured at the thigh, there was no hindrance of hip-joint abduction or adduction or thigh rotation. The SMA force for flexion and extension of either hip joint can be separately adjusted with the included tablet and dedicated software. The SMA can be placed within 1 or 2 minutes by a healthy individual, and it is used on indoor or outdoor slopes, stairs, or level differences. In the present study, the SMA was turned off for safety when descending stairs. SMA operation was performed by a physiotherapist who had completed the appropriate training provided by Honda R&D or one who had been well instructed by another physiotherapist who had completed the training.

Interventions

Physiotherapy was performed on a one-to-one basis by qualified physiotherapists for 1-2 hours per day for 10 consecutive days for patients in both groups. The exercise load and other aspects were adjusted depending on the patient's symptoms and condition. The physiotherapists performing the training for the SMA group were asked to include at least 1 gait training session each day with the patient wearing the SMA for 10 minutes or more and, if possible, 1 lasting approximately 20 minutes. In each group a cane, orthoses, or other assistive device was used during the gait training as necessary in accordance with the patient's symptoms. In addition, when using the SMA, the patient always wore a hip belt to prevent falling, and the physiotherapist held the belt to ensure safety. No particular instructions regarding walking speed, step length, or other such guidance were provided during gait training for the groups; and the training depended on the judgment of the physiotherapist performing it. The physiotherapist implementing the training each day had to complete a checklist composed by the investigators regarding the gait training during the intervention period, the specified assessments, and general management of implementation or nonimplementation.

Outcome Measurements

Primary outcome parameter

The primary outcome parameter was the maximum walking speed (cm/s), as this reflects the improvements in stride length and symmetry of the wearer that may result from the use of SMA. It was assessed before intervention and after the 10-day intervention using a WalkWay MW-1000 (Anima Corporation, Tokyo, Japan). With its 2.4 m thin-sheet configuration, the WalkWay (Anima Corporation) can measure footprints and pressure distribution of walking in real time.

We set up a 3 m runway on both sides of this device. For the measurement of maximum walking speed, the physiotherapist walked next to the patient and asked the patient to walk as fast as possible. The walking measurements were performed while the patients used their usual cane or other device. The left and right stride lengths were measured 2 or more times using the WalkWay (Anima Corporation), and the mean of the measured values was used for the analysis.

Secondary outcome parameters

The secondary outcome parameters of paralyzed-side and nonparalyzed-side step lengths, symmetry (nonparalyzed-side step length/paralyzed-side step length), and cadence using the WalkWay (Anima Corporation) were measured at the same time as the maximum walking speed under the same conditions used when the maximum walking speed alone was measured, before the intervention, and after the 10-day intervention. Safety and adverse events were noted throughout the trial.

Data Analysis

The maximum walking speed, paralyzed-side and nonparalyzed-side step lengths, and cadence measurements were adjusted for body height, and the resulting values were used in the analysis[24]:

$$\text{Adjusted speed} = \text{speed}/\sqrt{(\text{height}/\text{mean height})}$$

$$\text{Adjusted step length} = \text{step length}/(\text{height}/\text{mean height})$$

$$\text{Adjusted cadence} = \text{cadence} \times \sqrt{(\text{height}/\text{mean height})}$$

We performed an intention-to-treat analysis and included the initially assigned patients who dropped out of the study. When comparing the control group patients and SMA group patients before the intervention, we used the chi-square test and Fisher's exact test for categorical values. For ordinal scale and continuous variables, we used the Mann-Whitney *U* test and the unpaired *t* test, respectively. We used the paired *t* test for intragroup comparisons before and after the intervention. We compared the 2 groups using the unpaired *t* test; the change ratio for each group was calculated with a preintervention value of 1. Statistical calculations were performed using SPSS statistics (version 24; IBM Japan, Ltd., Tokyo, Japan); 5% was considered the level of significance.

Results

Patient Population

Of 227 patients screened during the relevant period, 186 patients were excluded; of the 41 patients who met the eligibility criteria, 20 patients were assigned to the control group and 21 patients were assigned to the SMA group based on the patient ID number (Fig 2). Two patients withdrew from the control group for nonmedical reasons. In the SMA group, 1 patient withdrew due to a problem with a lower limb orthosis and 2 patients withdrew for nonmedical reasons. The scheduled 10-day training by the physiotherapist and the assessment were performed for all patients except these dropouts. The interventions caused no serious adverse effects or injuries. Table 1 shows the baseline attributes of the 2 groups. The proportion of cerebral hemorrhage patients that were treated with SMA was lower than that of the control group. Therefore, we compared the gait parameter at baseline between infarction and hemorrhage (Table 2). There were no significant differences in any of the measured parameters.

Primary Outcome

Regarding the intragroup comparisons before and after intervention in terms of the primary outcome parameter of maximum walking speed, the control group value went from 103.04 ± 55.89 cm/s to 106.6 ± 61.31 cm/s, thus indicating no significant difference. However, the value of the SMA group increased from 98.98 ± 42.80 cm/s to 108.49 ± 61.31 cm/s, thus indicating a significant improvement ($P < .001$; Table 3). The change ratio of the maximum walking speed between before and after the intervention was 1.01 ± .13 for the control group and 1.11 ± .11 for the SMA group (significantly larger for the SMA group: $P = .013$).

Since there was a significant difference in stroke types in the 2 groups, we compared the maximum walking speeds of the patients who suffered each type of stroke both within and between the control and SMA groups. The results showed that SMA resulted in improvements in infarction patients which were significant. No significant difference was found when comparing the improvement ratio between the groups (Table 4).

Secondary Outcomes

Only the SMA group had significant improvements when intragroup comparisons were performed before and after intervention in terms of the secondary outcome parameters: from 50.02 ± 14.45 cm to 53.34 ± 14.81 cm for paralyzed-side step length ($P = .004$), from 1.16 ± .31 to 1.09 ± .29 for symmetry ($P = .036$), and from 112.42 ± 25.28 to 116.56 ± 24.66 for cadence ($P = .040$). No significant difference was found when comparing the improvement ratio between groups. However, in the SMA group, the improvement ratios for paralyzed-side step length and cadence were higher; therefore, the effect size was moderate.

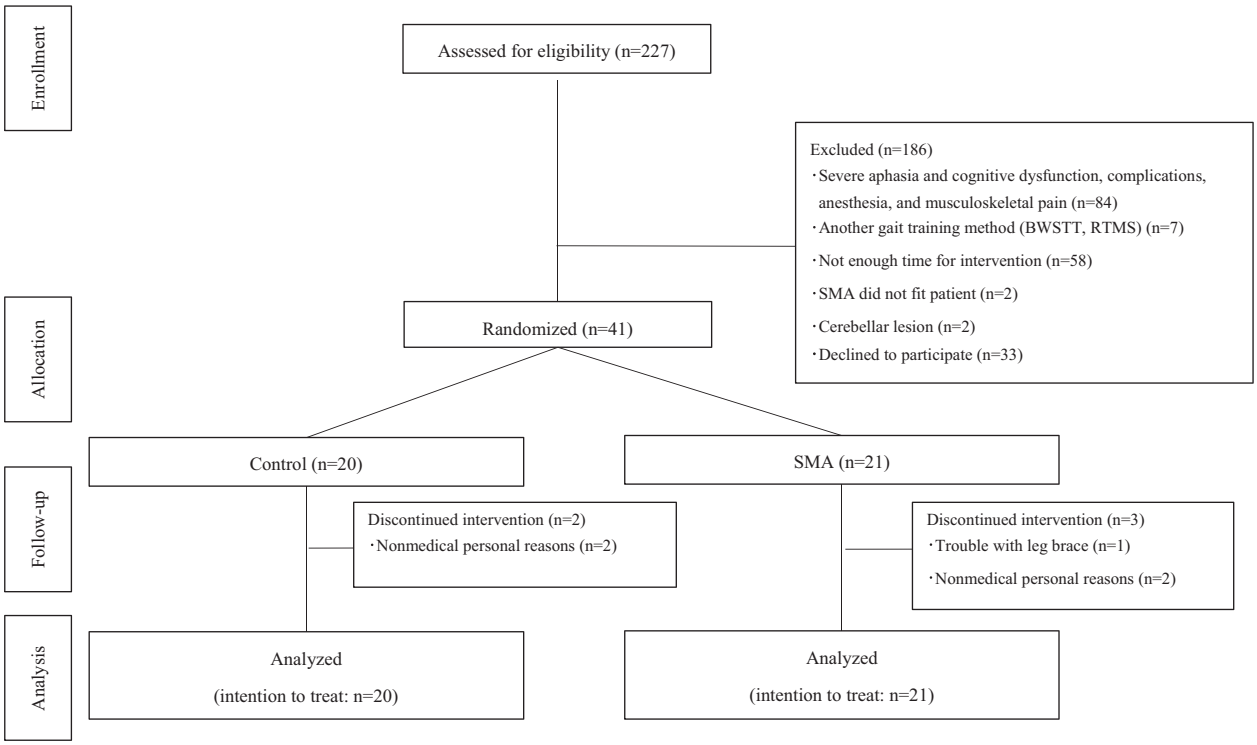

Figure 2. *Flowchart of study participants according to CONSORT. Abbreviations: BWSTT, body weight-supported treadmill training; RTMS, repetitive transcranial magnetic stimulation; SMA, Stride Management Assist.*

Table 1. *Demographic and baseline characteristics of subjects*

	Control n = 20	SMA n = 21	*P*
Demographics			
Age (years), mean (SD)	62.3 ± 9.3	64.9 ± 12.2	.448*
Sex, male/female, n	14/6	13/8	.585†
Affected side, left/right	10/10	8/13	.443†
Discoordination +/−, n	3/17	2/19	.663‡
Types of stroke, infarction/hemorrhage, n	11/9	18/3	.043‡,§
Distribution of stroke lesion, supratentorial/infratentorial, n	17/3	18/3	1.000‡
Duration, onset to intervention (Day), mean (SD)	92.9 ± 35.9	103.9 ± 28.1	.280*
Ankle foot orthosis (AFO), n	10	8	.443†
Assistive device (cane), n	9	12	.437†
Baseline impairments			
BRS, I/II/III/IV/V/VI	0/4/1/7/4/4	0/2/4/5/8/2	.946‖
SIAS-L/E position, 0/1/2/3	0/2/7/11	0/4/1/16	.328‖
Gait parameter, mean (SD)			
Maximum walking speed (cm/sec)	103.0 ± 55.9	99.0 ± 42.8	.795*
Step length (nonparalyzed, cm)	55.8 ± 14.4	53.3 ± 12.6	.557*
Step length (paralyzed, cm)	51.9 ± 17.2	50.0 ± 14.4	.705*
Step-length symmetry (nonparalyzed/paralyzed)	1.17 ± .22	1.16 ± .31	.859*
Cadence (steps/min)	108.5 ± 33.2	112.4 ± 25.3	.670*

Abbreviations: BRS, Brunnstrom recovery stage; SD, standard deviation; SIAS-L/E position, stroke impairment assessment set-lower extremity position sense; SMA, Stride Management Assist.

*Unpaired *t* test.

†Chi-square test.

‡Fisher exact test.

§$P < .05$.

‖Mann-Whitney *U* test.

Table 2. *Comparison of gait parameters at baseline between infarction and hemorrhage*

	Infarction n = 29	Hemorrhage n = 12	*P*
Gait parameter, mean (SD)			
Maximum walking speed (cm/sec)	103.9 ± 47.6	93.9 ± 53.5	.560
Step length (nonparalyzed, cm)	55.6 ± 12.9	49.6 ± 13.8	.133
Step length (paralyzed, cm)	52.6 ± 15.5	48.0 ± 16.4	.449
Step-length symmetry (nonparalyzed/paralyzed)	1.19 ± .29	1.11 ± .19	.406
Cadence (steps/min)	110.7 ± 26.5	110.0 ± 36.0	.954

Abbreviation: SD, standard deviation.
P: unpaired *t* test.

Discussion

We investigated whether using the SMA during RAGT improves the maximum walking speed when compared with the results of the usual physiotherapy alone. The maximum walking speed, which was the primary outcome parameter, increased significantly with 10-day intervention only for the SMA group, and the improvement ratio was significant. Regarding the secondary outcome parameters, only the SMA group showed significant improvements in paralyzed-side step length and cadence; both of which affect the maximum walking speed and symmetry, before and after intervention.

The SMA, which is a robot worn on the hip and thigh region, assists with hip-joint flexion and extension movements as the wearer walks. It causes the wearer to increase the hip-joint flexion to an extension angle while walking, and automatically adjusts to increase the walk ratio.[16] Reports to date regarding the effects of using the SMA have described improvements in the walking efficiency of healthy individuals,[18] comfortable walking speeds and muscle activity efficiency for healthy elderly individuals,[16] and improvements in gait parameters of chronic stroke patients.[19] Watanabe et al[25] also reported significant improvements in comfortable walking speeds for subacute stroke patients after 4 weeks of training with the SMA compared with the historical data of a control group. These findings are limited, but each report has shown improvements in gait parameters with the SMA and apparently supports the results of the present study. Other authors who reported the use of SMA for walk training of stroke patients[19,22,25] did not study different types of stroke. In recent years, it has been reported that the improvement of activities of daily living and walking speed following cerebral hemorrhage is greater than that observed following cerebral infarction.[26,27] In the present study, the primary outcome for each disease type was compared between the groups (Table 4), but the number of cases was insufficient to draw firm conclusions. Differences in outcomes due to disease type require further study.

Using 10 days of gait training, the SMA group showed significant improvements in maximum walking speed, paralyzed-side step length, symmetry, and cadence; however, no significant improvement was found in the control group. Walking speed is generally determined by step length and cadence. In the SMA group, improvements in paralyzed-side step length and cadence presumably contributed to the improvements in maximum walking speed. Furthermore, poststroke walking speed is related to paralyzed-side hip-joint extension muscle strength,[28] and hip-joint work production is considered important for increasing this speed.[29,30] The SMA assists the wearer with hip-joint flexion and extension; therefore, its assistance force may be expected to generate immediate improvements in step length and walking speed, and to have long-term effects. The maximum SMA assistance force is only approximately 4 Nm, which represents just 5%−10% of the hip-joint moment required for human walking.[31] Therefore, the SMA assistance force itself could be considered insufficient to increase the walking speed. In this regard, it is very interesting that hearing an auditory cue during gait training may increase walking speed and stride and improve symmetry.[32,33] In an analogous manner, the SMA, rather than providing power assist to the hip joint of the wearer, may lead to a small increase in the walk ratio and left-right symmetry in response to the hip-joint rhythm input measured by its angle sensor.[17] In the present study, the improvements in paralyzed-side step length, symmetry, and cadence in the SMA group were largely in accordance with the type of action created by the SMA. Therefore, the SMA may have functioned as a sensory cue with the effect of improving the wearer's walking pattern and rhythm. In this study, the immediate effect of wearing the SMA was not measured. Therefore, an investigation of this possibility should be performed in the future.

The effect of the SMA on step length in the present study was larger on the paralyzed side than on the nonparalyzed side, which was similar to the findings of Buesing et al.[19] Although there was no significant difference between the 2 groups regarding the improvement ratio, a large effect on step length on the paralyzed side was observed. It has been noted that in hemiplegia patients, the step length on the paralyzed side is more susceptible to impairment,[34] and step-length asymmetry may be disadvantageous in terms of balance and energy cost. Furthermore, it has been noted that gait asymmetry of stroke

Table 3. *Comparison of primary and secondary outcome, intention to treat (ITT)*

		n	Pretraining Mean (SD)	Post-training Mean (SD)	Intragroup* *P*	Mean (95% CI)	% change from baseline Mean (SD)	Effect size	Intergroup† *P*	Mean (95% CI)
Primary outcome measures										
Maximum walking speed	Control	20	103.04 (55.89)	106.60 (61.31)	.199	3.56 (−2.04 to 9.16)	1.01 (.13)	.86	.013‡	.09 (.02-.17)
(cm/sec)	SMA	21	98.98 (42.80)	108.49 (43.75)	<.001§	9.51 (5.66-13.35)	1.11 (.11)			
Secondary outcome measures										
Nonparalyzed-side step length	Control	20	55.81 (14.36)	57.06 (18.38)	.490	1.26 (−2.45 to 4.99)	1.01 (.13)	.27	.404	.03 (−.11 to .04)
(cm)	SMA	21	53.31 (12.56)	55.58 (13.28)	.054	2.27 (−.05 to 4.58)	1.05 (.11)			
Paralyzed-side step length	Control	20	51.91 (17.20)	52.74 (19.24)	.495	.83 (−1.67 to 3.33)	1.01 (.10)	.57	.074	.62 (−.13 to .01)
(cm)	SMA	21	50.02 (14.45)	53.34 (14.81)	.004§	3.32 (1.21-5.43)	1.07 (.11)			
Step-length symmetry	Control	20	1.17 (.22)	1.13 (.21)	.117	−.05 (−.10 to .01)	NA	NA	.695	NA
(nonparalyzed/paralyzed)	SMA	21	1.16 (.31)	1.09 (.29)	.036‡	−.06 (−1.12 to .00)				
Cadence	Control	20	108.48 (33.23)	108.80 (32.78)	.850	.33 (−3.22 to 3.87)	1.00 (.08)	.51	.120	.04 (−.09 to .01)
(steps/min)	SMA	21	112.42 (25.28)	116.56 (24.66)	.040‡	4.14 (2.14-8.07)	1.04 (.08)			

Abbreviations: CI, confidence interval; NA, not available; SD, standard deviation; SMA, Stride Management Assist.
*Paired *t* test.
†Unpaired *t* test.
‡$P < .05$.
§$P < .01$.

Table 4. *Comparison of maximum walking speed for each stroke type*

			n	Pretraining Mean (SD)	Post-training Mean (SD)	Intragroup* *P*	Mean (95% CI)	% change from baseline Mean (SD)	Effect size	Intergroup† *P*	Mean (95% CI)
Infarction	Maximum walking speed (cm/sec)	Control	11	108.20 (58.77)	114.41 (62.95)	.190	5.86 (−3.42 to 15.14)	1.04 (.13)	.77	.065	−.05 (−.21 to .12)
		SMA	18	101.20 (41.30)	115.93 (115.93)	<.001‡	14.69 (8.74-20.65)	1.16 (.17)			
Hemorrhage	Maximum walking speed (cm/sec)	Control	9	96.75 (54.99)	106.55 (61.93)	.078	9.80 (−1.40 to 21.01)	1.10 (.12)	.46	.550	−.05 (−.16 to .07)
		SMA	3	85.42 (59.10)	99.75 (73.67)	.234	14.33 (−22.27 to 50.93)	1.15 (.05)			

Abbreviations: CI, confidence interval; SD, standard deviation; SMA, Stride Management Assist.
*Paired *t* test.
†Unpaired *t* test.
‡$P < .01$.

patients progresses over the long term.[35] Significant improvements in paralyzed-side step length and symmetry found with the SMA in the present study indicate that wearing the SMA during gait training would be beneficial for hemiplegia patients with walking disabilities. It should also be noted that the SMA can be worn easily and can be used outdoors, indoors, and in the hospital. Therefore, it can be used for gait training at home or in the hospital by chronic stroke patients. It should be considered a useful training tool for improving walking disabilities that may progress.

In contrast to the improvements found in the present study regarding walking speed and other parameters during RAGT with the SMA, Hornby et al[36] and Hidler et al[37] reported that the usual physiotherapy was more effective than RAGT. Hornby et al[36] indicated that a possible reason could be that the presence of the robot may cause the patient to reduce the voluntary effort expended for motor training. Robots used in those studies were end-effector or exoskeleton devices. It has also been noted that the fixed trajectory control strategy used with these robot types may cause a loss of variability in lower limb exercise necessary for movement adaptability, thus curtailing the natural walking pattern.[38] Cai et al[39] proposed an assist-as-needed concept; they noted that during motor training for walking, it may be more useful to assist only when necessary and provide control with bilateral lower limb coordination rather than forcing lower limb assistance in a fixed trajectory with a robot. The concept of the SMA is similar to that of the assist-as-needed concept[31]: it cannot be used without voluntary effort by the wearer, the degree of freedom in movement is high, and it assists in a coordinated manner by using walk ratio control in both hip joints. Regarding coordination of the limbs, Zehr et al[40] reported locomotor-like movements of the upper and lower limbs controlled by common rhythm and pattern generators and a control system that coordinates reflexive output, thus advancing the common core hypothesis. It is known that the human cutaneous reflexes and H-reflex are subject to task-dependent and phase-dependent modifications during locomotor-like movements with this kind of rhythm-generation system.[40,41] For patients with central nervous system disorders and rhythmic walking disabilities, the SMA can induce more highly coordinated rhythmic movements and more symmetrical walking movements, thereby stimulating the rhythm-generation system and promoting recovery of muscular activity while walking.[40] In the present study, it was not possible to investigate muscular activity, the H-reflex, or other neural mechanisms of walking. However, the SMA characteristics of promoting coordinated movement of both lower limbs and the capability for setting motor tasks with a high degree of freedom, in close conformity with the assist-as-needed concept, were among the factors that yielded improvements in gait parameters.

Regaining walking ability is a major objective of rehabilitation[42]; and the maximum walking speed, which was the primary outcome parameter in this study, represents the level of impairment in walking ability[43] and affects quality of life.[44,45] In this study, the mean change in walking speed created by the SMA was 9.51 cm/s (95% confidence interval, 5.66-13.35 cm/s); therefore, it was smaller than the generally regarded minimum clinically important difference of 13 cm/s for the comfortable walking speed of stroke patients.[21] It has been noted that the effectiveness of RAGT may increase with longer periods and higher movement intensities. The 10-day period of RAGT used in the present study was shorter than the frequently used period of 3-4 weeks[46]; therefore, its movement intensity may have been insufficient. Because no significant differences were found for gait parameters of the control group, a more effective intervention period and movement intensity should be investigated.

This study had several limitations. First, it was a comparative study performed at a single facility using an open-label trial and a randomization with patient ID numbers, thus allowing the possibility of bias due to non-blinding and the potential confounder due to incomplete randomization. Second, an immediate effect of RAGT with the SMA was not verified. Only longer-term effects of the SMA were investigated, and there was no follow-up period, thus precluding a discussion of the sustained duration of the effects.

Conclusions

In this single center, open-label randomized controlled trial, usual gait training and RAGT with the SMA were performed for 10 days with subacute stroke patients. No significant improvement in gait parameters was found for the usual gait training before and after the 10-day intervention. In the SMA group, significant improvements were found in maximum walking speed, paralyzed-side step length, symmetry, and cadence. Furthermore, the improvement ratio of maximum walking speed in the SMA group was significantly higher than that in the usual gait training group. Additionally, no adverse events attributable to the SMA were observed during the intervention period. Therefore, it may prove to be a safe and effective RAGT for ambulatory patients with walking disabilities due to stroke.

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