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Robotic Assist-As-Needed as an Alternative to Therapist-Assisted Gait Rehabilitation

Shraddha Srivastava[1*], Pei Chun Kao[2], Darcy S Reisman[3], John P Scholz[3], Sunil K Agrawal[4] and Jill S Higginson[5]

[1]*Department of Health Sciences and Research, Medical University of South Carolina, Charleston, SC 29425, USA*

[2]*Department of Physical Therapy, University of Massachusetts Lowell, Lowell, MA 01854, USA*

[3]*Department of Physical Therapy, University of Delaware, Newark, DE 19713, USA*

[4]*Department of Mechanical Engineering, Columbia University, USA*

[5]*Department of Mechanical Engineering, University of Delaware, USA*

***Corresponding author:** Shraddha Srivastava, Department of Health Sciences and Research, College of Health Professions, Medical University of South Carolina, 77 President Street, Charleston, SC 29425, USA, Tel: 8437926165; Fax: 8437922829; E-mail: srivasts@musc.edu

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Abstract

Objective: Body Weight Supported Treadmill Training (BWSTT) with therapists' assistance is often used for gait rehabilitation post-stroke. However, this training method is labor-intensive, requiring at least one or as many as three therapists at once for manual assistance. Previously, we demonstrated that providing movement guidance using a performance-based robot-aided gait training (RAGT) that applies a compliant, assist-as-needed force-field improves gait pattern and functional walking ability in people post-stroke. In the current study, we compared the effects of assist-as-needed RAGT combined with functional electrical stimulation and visual feedback with BWSTT to determine if RAGT could serve as an alternative for locomotor training.

Methods: Twelve stroke survivors were randomly assigned to one of the two groups, either receiving BWSTT with manual assistance or RAGT with functional electrical stimulation and visual feedback. All subjects received fifteen 40-minutes training sessions.

Results: Clinical measures, kinematic data, and EMG data were collected before and immediately after the training for fifteen sessions. Subjects receiving RAGT demonstrated significant improvements in their self-selected over-ground walking speed, Functional Gait Assessment, Timed Up and Go scores, swing-phase peak knee flexion angle, and muscle coordination pattern. Subjects receiving BWSTT demonstrated significant improvements in the Six-minute walk test. However, there was an overall trend toward improvement in most measures with both interventions, thus there were no significant between-group differences in the improvements following training.

Conclusion: The current findings suggest that RAGT worked at least as well as BWSTT and thus may be used as an alternative rehabilitation method to improve gait pattern post-stroke as it requires less physical effort from the therapists compared to BWSTT.

Keywords: Robotic exoskeleton; Assist-as-needed; Stroke; Gait rehabilitation; Body weight supported treadmill training; Force-field; Locomotion

Introduction

Stroke is a leading cause of serious long-term disability in the United States. Each year approximately 3795,000 people experience stroke, out of which about 610,000 are first and 185,000 are recurrent stroke events [1,2]. Approximately 45% of the individuals discharged from hospital after stroke return directly home [2]. However, a large percentage of home-dwelling stroke survivors are unable to achieve unsupervised community ambulation immediately following discharge [3]. Additionally, at 6 months post-stroke, about thirty percent of the survivors still need some assistance to walk [1,4]. Walking ability in chronic stroke survivors is an important determinant of social participation and independence in activities of daily living [5,6]. Therefore, gait disability leading to reduced functional independence and social participation can result in a decline in the quality of life post-stroke.

Gait rehabilitation following stroke has the potential to improve walking economy and functional independence during activities of daily living [7]. Previous studies suggest that gait training provides better improvements than training focused on other isolated components such as strength, balance, and coordination [8,9]. One such gait rehabilitation strategy often used for stroke survivors is the Body Weight Supported Treadmill Training (BWSTT) [10,11]. During BWSTT, an overhead suspension system and a harness are used to support an individual's body weight partially and symmetrically while practicing walking. In addition, one or more therapists may provide manual assistance to the individual to help with the stepping movements of their paretic lower extremity and weight shifting during walking [12]. The BWSTT allows the individual to learn weight bearing and walking at faster speeds at an early stage post-stroke [13], thus resulting in greater improvements in functional walking capacity compared to gait training methods without body weight support [9,12-15]. However, this gait training strategy is labor intensive, requiring manual assistance from the therapists [16].

Robot-aided gait training (RAGT) that provides automated training has been developed as a potential gait rehabilitation method for individuals with neurological impairments [17-19], as it is less fatiguing for physical therapists than the therapist-assisted BWSTT. RAGT was initially developed to provide continuous movement guidance so subjects would walk in a prescribed gait pattern. However, previous studies have shown that RAGT results in similar or poorer improvements in the functional walking ability compared to BWSTT or conventional gait training post-stroke [17,20]. Metabolic costs and muscle activations during RAGT are significantly reduced with continuous guidance in comparison to therapist-assisted BWSTT [21], as a result of reduced subject effort [22]. In addition, step-to-step variability which is considered to be important for motor learning [23,24] is absent when subjects are forced to walk in a predefined fixed gait pattern during RAGT with continuous assistance. These limitations could lead to insignificant improvements in functional walking ability following RAGT.

An assist-as-needed RAGT that provides assistance to the participants based on their performance was developed recently [22,25-28]. This method encourages subjects' active participation and preserves movement variability while walking. A pilot study has demonstrated greater improvements in functional walking ability following an assist-as-needed RAGT paradigm compared to the RAGT with continuous assistance [22]. In addition, another pilot study on a single stroke survivor has shown considerable improvements in muscle coordination, propulsive ground reaction forces, and ankle malleolus path during walking following the assist-as-needed RAGT [28]. Our recent publication demonstrated improvements in functional walking ability following an assist-as-needed RAGT in post-stroke individuals [27]. However, it is not known if the compliant assist-as-needed RAGT can serve as an alternative to conventional physical therapy or therapists' assisted gait training for post-stroke individuals.

In the current study, we extended our previous findings to compare the effects of an assist-as-needed RAGT with BWSTT on functional walking ability post-stroke. Although Duncan et al. suggested that BWSTT is not superior to a home-exercise program for restoring functional gait in stroke survivors [29], a more intensive BWSTT may render greater therapeutic effects [30,31]. RAGT is less fatiguing for therapists compared to the therapist-assisted BWSTT and has the potential to provide more intensive training sessions as needed. The purpose of this study was to understand whether or not RAGT with an assist-as-needed training paradigm results in less, greater, or equal improvements in functional walking ability post-stroke in comparison to the BWSTT.

Methods

Subject information

Twelve stroke survivors (9 males, 3 females) were recruited (Table 1). Inclusion and exclusion criteria were the same as the previous study from our lab [27] which is as follows: subjects were included if they had sustained stroke more than three months prior to their participation and had a single stroke. Subjects were excluded if they had evidence of chronic white matter disease on magnetic resonance imaging, congestive heart failure, peripheral artery disease with intermittent claudication, cancer, pulmonary or renal failure, unstable angina, uncontrolled hypertension (>190/110 mmHg), dementia (Mini-Mental State Exam<22) [32], severe aphasia, orthopedic conditions affecting the legs or the back, or cerebellar signs (e.g., ataxia). Subjects were screened by a physical therapist for their eligibility to participate in the study based on the set criteria.

Subject ID	AGE(yrs)	Duration Post-stroke(months)	Side of affected Limb	Gender
RAGT 1	56	95	Left	M
RAGT 2	80	53	Left	M
RAGT 3	60	3	Right	F
RAGT 4	43	3	Right	M
RAGT 5	67	20	Left	M
RAGT 6	70	149	Left	F
BWSTT 1	58	17	Left	M
BWSTT 2	48	11	Right	F
BWSTT 3	75	14	Right	M
BWSTT 4	54	12	Left	M
BWSTT 5	59	35	Left	M
BWSTT 6	59	3	Right	M

Table 1: Demographic detail of the stroke survivors.

All subjects gave written informed consent to participate in the study, approved by the University's Review Board. Subjects received a total of 15 training sessions by having 5 daily sessions per week, every other week.

Robot-aided gait training

Second version of the Active Leg Exoskeleton (ALEX II) developed at the University of Delaware was used in the current study to deliver RAGT [33,34]. During training, the subjects walked on a treadmill, and an assist-as-needed compliant guidance force was applied on the stroke subject's paretic leg. No body weight support was provided to the subjects in the RAGT group. Details of the RAGT paradigm are provided in Figure 1. Briefly, the leg exoskeleton applied an assist-as-needed compliant guidance force on the paretic leg when subject's walking patterns deviated from a prescribed target template based on the ankle path during walking [25,27]. The assist-as-needed force-field tends to guide the subject's ankle towards the target template (Figure 1). To increase subjects' independent control of the leg motion within a session, we gradually reduced the robotic assistance across the eight training bouts in a single session. The target template for the training was based on the walking pattern of ten healthy individuals and the stroke survivor's baseline walking pattern at a given speed and leg length. The malleolus path of healthy individuals was considered to be 100%, and the stroke survivors' baseline pattern was considered as 0%. The stroke survivors' malleolus path was scaled at each data point to a certain percentage of the healthy data to generate the target template [25,27]. Based on the subject's performance on the previous training

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session, the training speed was increased gradually and scaling of the stroke survivor's path was increased towards that of the healthy template with the progression of the training across 15 sessions [27].

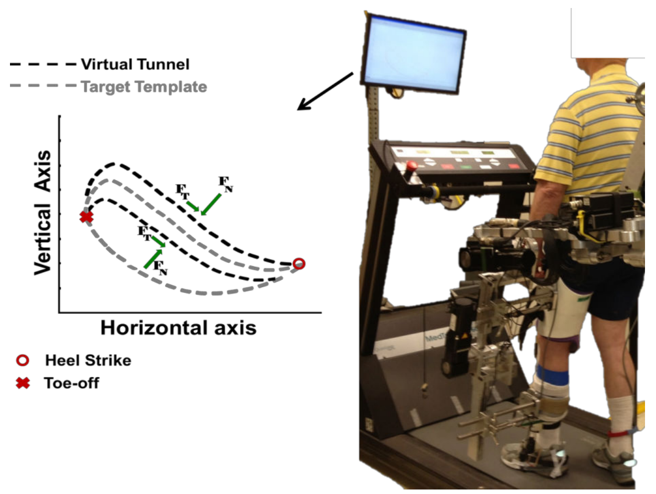

Figure 1: Second version of Active Leg Exoskeleton (ALEX II) worn on the subject's paretic extremity. The assist-as-needed force-field provides guidance in the form of a virtual (elastic) tunnel around a target ankle malleolus path that works similarly to an elastic band, tending to bring the subject's ankle towards the target template. The target template for the training was based on the walking pattern of ten healthy individuals, and the stroke survivor's baseline walking pattern at a given speed and leg length. Healthy individuals' malleolus path was considered as 100% of the template and stroke survivors' baseline pattern was considered as 0%. A normal force (F_N) would be applied to the ankle malleolus towards the virtual tunnel; if the subject's instantaneous ankle malleolus position went beyond the tunnel. The amount of F_N required increased with the increase in subjects' error to match the target ankle malleolus path. A minimal tangential force F_T helped the subjects to move along the target malleolus path. The force-field was decreased gradually within a single session by varying the force stiffness and tunnel width, providing less constraint on the subject's swing phase movement. The target path was made more challenging by scaling it to different percentages of the healthy pattern with the progression of the training.

Each training session included eight 5-minute training bouts with rest breaks after every bout, the rest breaks were at least 2 minutes long. Subjects received the force-field assistance throughout each five-minute training bout. They also received visual feedback on their instantaneous lateral ankle malleolus position and the target path, and functional electrical stimulation (FES) on their ankle plantar flexors and dorsi flexors during alternating minutes of each training bout (Figure 2) [27]. The stimulation intensity for both muscle groups was set using 300-ms long, 30-Hz train with 150-Volt amplitude. Pulse duration for dorsiflexors was set with subjects seated. For plantar flexors, the subjects stood in a position similar to terminal double support of the paretic leg. Pulse duration was set to achieve lifting of the paretic heel off the ground or until the subject's maximal tolerance was reached, whichever occurred first. The FES stimulation pattern comprised a high-frequency (200-Hz) 3-pulse burst followed by a lower frequency (30-Hz) constant frequency train [27,35,36].

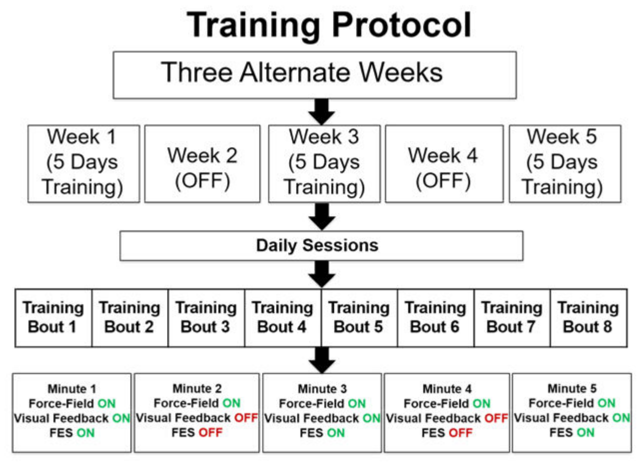

Figure 2: Training protocol. Stroke subjects in both groups participated in 5 daily training sessions per week, for three alternating weeks, each subject received 15 training sessions in total. Each training session included eight 5-minute training bouts with rest breaks after every bout.

Body weight supported treadmill training

Subjects receiving BWSTT walked on the treadmill with partial body-weight support and manual assistance. Starting with 40% of the body weight support and preferred walking speed, the amount of body weight support was gradually decreased to 0% and the training speed was gradually increased by increments of 0.1 miles per hour. Two therapists provided manual assistance for assisting stepping motion of the affected leg and step-to-step weight shifting. The amount of therapists' assistance was gradually reduced from bout one to bout eight in a single session to increase subject's control over the leg movement and weight shift during walking.

Data acquisition and analysis

Stroke subjects received a battery of clinical evaluations and biomechanical gait analysis before the training (baseline) and immediately after the training (post-training). The clinical evaluation sessions included lower-extremity Fugl-Meyer Assessment (FMA) [37], Functional gait assessment (FGA) [38], Six-Minute Walk Test (6MWT) [39], and Timed Up and Go test (TUG) [40]. Detail of the clinical assessment scores at baseline for all the stroke survivors are provided in Table 2. Each subject's gait was evaluated during over-ground walking at the self-selected speed. Kinematic data were collected from the paretic leg by using an eight-camera motion capture system (Qualisys, Gothenburg, Sweden) and sampled at 120 Hz. Data were low-pass filtered at 6-Hz, using a bi-directional second order Butterworth filter. The gait events were identified based on the toe and heel markers on the foot segment. Visual 3D (C-Motion Inc., Rockville, MD) was used to estimate over-ground walking speed, and to compute hip, knee and ankle joint angles. Peak flexion angles during swing phase of the gait cycle were computed for further analysis.

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	Timed Up and Go (s)	Six-Minute Walk Distance (m)	Functional gait assessment	Fugl-Meyer Assessment
RAGT 1	7.6	476	19	24
RAGT 2	15.6	268	14	25
RAGT 3	29.2	72	10	11
RAGT 4	16.2	232	12	21
RAGT 5	29.3	150	8	12
RAGT 6	13.2	332	18	28
BWSTT 1	14.3	169	7	24
BWSTT 2	12.2	234	14	27
BWSTT 3	24.3	107	10	17
BWSTT 4	19.4	250	11	17
BWSTT 5	9.53	295	13	24
BWSTT 6	17.1	265	13	17

Table 2: Detail of clinical measures for stroke survivors.

EMG data from biceps femoris longus, vastus lateralis, vastus medialis, rectus femoris, gluteus medius, soleus, medial and lateral heads of gastrocnemius, medial hamstrings, and tibialis anterior muscles were recorded using a 16-channel EMG system (MA-416-003 Motion Lab System, Baton Rouge, LA) at a sampling frequency of 1200 Hz with a 16-bit resolution. All data were collected from the paretic leg. EMG signals were high-pass filtered with a cutoff frequency of 20-Hz, rectified and then low-pass filtered with a cutoff frequency of 6-Hz using a second order Butterworth filter. EMG from each muscle was normalized to its peak amplitude across all gait cycles. EMG data of twelve gender-and age-matched (± 5 years) healthy individuals were collected at their self-selected speeds for comparisons with the stroke subjects.

A dimensionality reduction method, non-negative matrix factorization, was used to compute the muscle modes to understand the effects of gait training on muscle coordination [41]. Non-negative matrix factorization (NMF) factorizes the concatenated original EMG data (EMG_O) into two matrices. One matrix corresponds to the mode structure that specifies the relative contribution of each muscle to a muscle mode and another matrix is the activation timing of each muscle mode across a gait cycle. The two matrices were computed such that their product is the reconstructed EMG data (EMG_R). The number of adequate modes required for reconstructing the original EMG (EMG_O) after data reduction was based on the variability accounted for (VAF). VAF was defined as the ratio between sums of squared errors between the original and reconstructed EMG data $(EMG_O - EMG_R)^2$ and the sum of squared original EMG data $(EMG_O)^2$.

All healthy individuals' EMG data required four modes to explain 90% or more of VAF. NMF was performed using 4 modes for all stroke survivors for comparisons with healthy individuals. Mode one primarily consisted activity from soleus (SO), medial head of gastrocnemius (MG), and lateral head of gastrocnemius (LG) and was active during late stance. Mode two consisted activity from tibialis anterior (TA) and rectus femoris (RF) and was active during early and late swing. Mode three consisted activity from gluteus medius (GM), vastus lateralis (VL), vastus medialis (VM), and rectus femoris RF and was active during early stance. Mode four consisted activity from biceps femoris longus (BF) and medial hamstrings (MH) and was active during late swing and early stance [41]. Pearson's correlation was performed to determine the level of similarity in the mode structure and timing between stroke survivors and matched controls at baseline and post-training [28,41,42].

Statistical analysis

Due to the small sample size, we used Wilcoxon signed rank test to test for within-group differences in the gait parameters, clinical outcome measures, mode structure, and mode timing before and after the training. Between-group differences were tested using the Mann Whitney U test with Monte Carlo estimation of p-values. The significance level for all statistical analyses was set at $p<0.05$. All statistical analyses were performed in SPSS version 21 (IBM Co., Somers, NY).

Results

In the current study, there were no significant differences between the two groups at baseline for any outcome measures. No significant differences were seen between the groups post-training based on Monte Carlo simulation for 10,000 random samples. For within-group differences, kinematic measures were not improved following BWSTT whereas swing-phase peak knee flexion angles changed significantly following RAGT (p=0.02; baseline=43.9° ± 18.7°; post-training=48.1° ± 17.4°) (Figure 3). The current study showed that stroke survivors receiving assist-as-needed RAGT significantly improved their self-selected over-ground walking speed (p=0.02; baseline=0.58 ± 0.3 m/s; post-training=0.70 ± 0.3 m/s). The improvements following BWSTT were not statistically significant (p=0.07; baseline=0.57 ± 0.2m/s; post-training=0.75 ± 0.3 m/s).

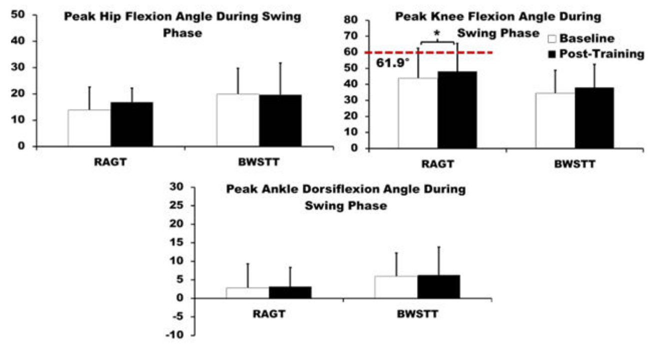

Figure 3: Over-ground kinematic data before and immediately after RAGT and BWSTT. Peak hip and knee flexion angles and peak ankle dorsiflexion angle (°) during the swing phase of gait cycle averaged across subjects for the paretic leg following RAGT (right) and BWSTT (left), at baseline and after training (post-training). Error bars represent the standard deviation across subjects. *p<0.05. Red dashed line on the right panel indicates the normal peak knee flexion angle of ~61.9°.

Clinical evaluations that assess dynamic postural stability [43, 44] such as TUG (p=0.02; baseline=18.5 ± 8.8 s; post-training=15.9 ± 7.5 s) and FGA (p=0.02; baseline=12.0 ± 3.1 s; post-training=13.8 ± 3.1 s) improved significantly following RAGT (Figure. 4). However, only one subject following RAGT and none following BWSTT group achieved a change greater than the reported Minimal detectable change (MDC) in TUG (i.e., 7.84 seconds) [45]. Furthermore, none of the subjects in either group demonstrated changes greater than MDC in FGA (i.e., 4.2) [46]. In the current study, the distance walked during the 6MWT improved significantly (p=0.04; baseline=211.7 ± 66.1 m; post-training=257.9 ± 71.6 m) following BWSTT but not following RAGT. However, one out of the six subjects demonstrated changes in the 6MWT greater than the MDC (i.e., 54.1 m) [47] following BWSTT. No significant changes were observed in FMA scores for either of the two groups. Two subjects following RAGT and three following BWSTT showed changes in FMA greater than the MDC (i.e., 3.57) [45]. We found that post-stroke individuals receiving RAGT demonstrated improvements in the structure of one muscle mode by showing greater similarity to the healthy controls (p=0.04; baseline=0.69 ± 0.1; post-training=0.74 ± 0.1) (Figure 5). This mode primarily consists of activation of tibialis anterior and rectus femoris. No changes were found in the activation timing of any mode following RAGT, or mode structure and mode activation timing following BWSTT.

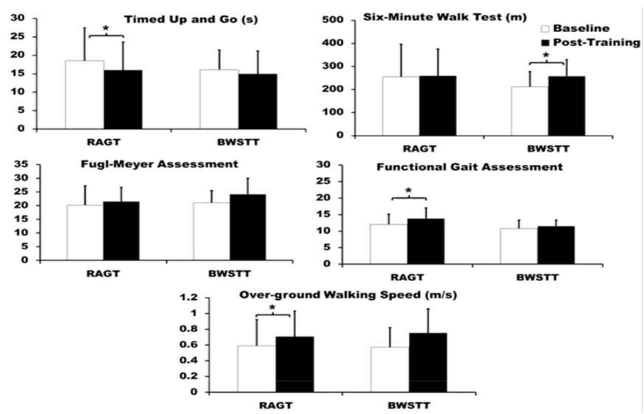

Figure 4: Changes in the clinical outcome measures and over-ground walking speed after the two training paradigms. Clinical measures and self-selected gait speed averaged across subjects for RAGT (right) and BWSTT (left) groups, at baseline and after training (post-training). Error bars represent the standard deviation across subjects. *p<0.05.

Discussion

The current study is the first to compare the effects of therapist-assisted BWSTT with RAGT using an assist-as-needed paradigm combined with visual feedback of real-time performance and FES on the ankle plantar flexors and dorsi flexors. Previous gait training studies that assessed the effectiveness of post-stroke gait rehabilitation were primarily based on clinical measures [17,18,29]. The current study also evaluated stroke survivors' over-ground walking pattern along with the clinical measures, providing additional information regarding the effects of RAGT on the over-ground gait pattern compared to BWSTT.

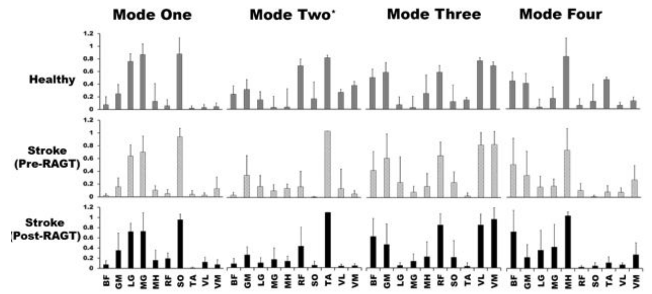

Figure 5: Mode structure of healthy controls and stroke survivors before and after RAGT. Stroke survivors' mode two was similar in structure to healthy controls following RAGT. *p<0.05.

In the current study over-ground gait assessments demonstrated an increase in subjects' peak knee flexion angle towards normal i.e. towards ~61.9º [48]. Compared to the neurologically intact individuals, stroke survivors usually have reduced swing peak knee flexion [48,49]. Therefore, improvement in the peak knee flexion angle in the current study suggests that an assist-as-needed RAGT may improve the gait pattern post-stroke. However, further research is needed to determine whether the increase in the peak knee flexion angle is an effect of the FES or assist-as-needed force-field alone or a combined effect from both modalities. Additionally, over-ground walking speed improved significantly following RAGT which is similar to findings from previous literature on RAGT with continuous assistance [17]. All subjects in the current experiment demonstrated improvements in gait speeds following RAGT and two out of six subjects who trained with RAGT improved greater than the minimum clinically important difference (MCID) (i.e., 0.16 m/s) [50]. Although there was an increase in walking speed following BWSTT, however the changes were not significant. Four subjects improved greater than the MCID, but one subject did not change at all, and another subject demonstrated slight decrease in the self-selected over-ground walking speed. Current results do not agree with previous studies that have demonstrated improvements in over-ground self-selected walking speed in people post-stroke following BWSTT [12,16]. The discrepancy in the results from the current study could be due to the larger standard deviation in the change of speed following BWSTT.

In the current study, subjects demonstrated a significant improvement in TUG and FGA following RAGT. Although only one subject demonstrated an improvement greater than the reported MDC in the measures for dynamic postural stability, all subjects demonstrated a trend towards improvement following RAGT. Unlike the commercially available Lokomat that restricts trunk movements [17], ALEX II is designed with four degrees of freedom (DOF) at trunk [33]. Therefore, additional DOFs in ALEX II may possibly provide beneficial effects on trunk control and postural stability during walking resulting in improved performance on clinical assessment measures of postural stability during walking. In the current study, the BWSTT group improved their endurance whereas the RAGT group did not. However, it has been shown previously that individuals receiving BWSTT or RAGT with continuous assistance demonstrated improvements in 6MWT [17,18]. As evidenced by the improvement in kinematic measures, it can be inferred that stroke survivors improved their over-ground gait pattern following an assist-as-needed RAGT. However, walking in an ideal gait pattern can be challenging post-stroke and may consequently have resulted in smaller improvements in endurance after RAGT compared to the subjects receiving BWSTT. Additionally, no improvements were observed in the FMA scores following RAGT or BWSTT. Duncan et al. [29] have demonstrated improvements in FMA following BWSTT. However, subjects in the aforementioned study received 36 sessions of gait training. Some previous studies also showed improvements in FMA and 6MWT following assist-as-needed RAGT paradigm. However, those pilot studies included data from a single stroke subject [22,28]. Therefore, further investigation is needed to understand the effects of assist-as-needed RAGT on sensorimotor function and endurance post-stroke.

Following RAGT, stroke survivors also demonstrated improvements in the structure of one out of the four muscle modes required during walking. The mode structure that changed towards healthy pattern primarily includes contribution from tibialis anterior and rectus femoris muscles and is important for controlling leg motion during early and late swing [51]. This mode contributes towards accelerating the leg into swing and also decelerates the leg in early and late swing in preparation for foot contact. The improvement of this mode may suggest better control of the paretic leg during swing. We did not see any changes in the mode structure or activation time following BWSTT. However, Routson et al. [52] showed improvements in mode structure as well as activation timing following 36 sessions of BWSTT. It is possible that stroke survivors may require more training sessions to normalize their muscle mode structure and activation timing. Therefore, a more intensive gait training program may be required to modify muscle coordination following stroke.

One limitation of the current experiment is that it is difficult to determine which component of our robotic gait training paradigm had stronger therapeutic effects than others. A previous study from our laboratory reported that healthy individuals receiving robotic gait training with a combination of visual feedback and assist-as-needed force field demonstrated larger modification in their gait pattern compared to those individuals receiving gait training with visual feedback or force field alone [53]. Therefore, purpose of the current study was to evaluate the potential of a comprehensive, robotic training paradigm that includes visual feedback, force guidance, and functional electrical stimulation as a training alternative for gait rehabilitation. In addition, another limitation of the current study is the small sample size that includes subjects with mild to moderate impairments. Thus, investigating the effects of assist-as-needed RAGT in comparison to BWSTT on stroke survivors with a larger sample size and more diverse motor impairment level may help us identify the population cohort that may benefit the most from RAGT in combination with FES and visual feedback or stroke survivors who may better respond to BWSTT.

Conclusion

There were no significant differences in the changes of clinical and biomechanical measures between the two training groups. However, subjects in both groups demonstrated a trend towards improvement, suggesting that assist-as-needed RAGT has similar effects as BWSTT on improvements of gait pattern in stroke survivors. In addition, RAGT is less fatiguing for therapists compared to the therapist-assisted BWSTT and thus, has the potential to provide more intensive training sessions as needed. Our findings suggest that the combined approach of assist-as-needed RAGT with FES and visual feedback may be used as an alternative for locomotor training to restore functional walking ability post-stroke. Future studies are needed to identify the appropriate dosage for rendering significant long-term effects of RAGT with assist-as-needed training paradigm on improvement of functional walking ability post-stroke.

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