

Robot-Assisted Gait Training for Patients with Hemiparesis Due to Stroke

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Robot-assisted devices are becoming a popular alternative to manual facilitation in stroke rehabilitation. These devices have the potential to reduce therapist burden and treatment costs; however, their effectiveness in terms of functional recovery remains in question. This pilot study compared the outcomes of a stroke rehabilitation program that incorporates robot-assisted gait training (RAGT) with a more traditional therapy program that does not. Twenty hemiparetic stroke patients were recruited at a rehabilitation hospital in Houston, Texas, and were randomly assigned to 2 groups. The control group (n = 10) received 24 1-hour sessions of conventional physical therapy, whereas the RAGT group (n = 10) received 24 1-hour sessions of conventional physical therapy combined with RAGT on a treadmill. Gait function was assessed before and after treatment by an 8-m walk test, a 3-minute walk test, and the Tinetti balance assessment. Both groups showed significant improvement in all 3 outcome measures following treatment ($P < .05$), but there was no difference between groups. It is concluded that RAGT may provide improvements in balance and gait comparable with conventional physical therapy. A larger multicenter trial is required to investigate the effectiveness of RAGT in hemiparetic stroke. **Key words:** gait, hemiparesis, robot-assisted training, stroke, treadmill training

A large proportion of strokes result in hemiparesis and gait impairments. Recovery of balance and walking function are key goals for many stroke patients, and significant improvements are possible through rehabilitation. The current evidence indicates that intensive, task-specific therapy produces the highest level of recovery of motor function, even in cases of severe impairment.¹ Locomotor training is the process of retraining gait through the repetitive execution of assisted walking movements. The traditional approach to locomotor training involves manual assistance from therapists as patients walk on a treadmill or overground.² When applied at a high enough intensity and for a sufficient duration, locomotor training has the potential to produce significant, long-lasting improvements in gait function.³ In recent years, there has been a lot of attention focused on the development of advanced therapeutic interventions involving technologies such as functional electrical stimulation⁴ (FES) and robotics.⁵ These interventions are designed to facilitate walking and enable patients to engage in gait retraining at the earliest point in their rehabilitation program.

Currently, there are many treatment options available for gait rehabilitation after stroke.⁶ Many

of these have proved to be effective in clinical studies; however, it is not clear that any particular approach is superior for improving gait speed or quality.³ The use of partial body weight support to facilitate locomotor training became popular in the mid-1990s. Many severely impaired stroke patients have difficulty bearing their total body weight on the affected leg during the swing phase of gait. This problem can be addressed by partially relieving the patient's body weight using an overhead harness, thus compensating for weakness of the weight-bearing muscles and allowing the patient to focus on motor control during walking. In stroke rehabilitation, body weight-supported treadmill training (BWSTT) typically involves 1 or 2 therapists who provide manual assistance to facilitate correct movement. Compared with traditional locomotor training approaches, BWSTT enables patients to walk longer and to take more steps, thus significantly increasing the number of repetitions and functional gains.⁷ BWSTT has been shown to be effective in improving gait function in

both mild and severe hemiparesis due to stroke, even in nonambulatory patients.^{1,8}

BWSTT has also been shown to be effective in the recovery of gait function. However, BWSTT can require a large amount of effort from therapists; in certain situations, 2 therapists are required per patient to perform the BWSTT intervention.^{9,10} Rehabilitation robots are electromechanical devices that provide external forces to the limbs of patients to create normal kinematics during the performance of tasks such as reaching¹¹ and walking.^{12,13} Robot-assisted gait training (RAGT) is an alternative to therapist-assisted BWSTT that is becoming increasingly popular. In RAGT, the assistance provided by the robot is intended to serve as an analog to manual assistance provided by therapists. However, most of the robotic-assisted devices discussed in the literature are designed to provide constant guiding forces resulting in near-normal kinematics and do not mimic the variable assistance that a human therapist applies. Whether the clinical benefits of RAGT are comparable with therapist-assisted BWSTT is a vibrant topic of debate among rehabilitation practitioners and researchers.

RAGT devices currently come in 2 distinct forms. First, there are the powered exoskeletons, such as the Lokomat (Hocoma SA, Switzerland),¹⁴ the AutoAmbulator (HealthSouth, Houston, Texas, USA),¹⁵ and the LOPES exoskeleton robot,¹⁶ which attach in parallel to the lower limb segments and move in unison with the patient. These devices are typically mounted over treadmills and include some form of body weight support. An alternative to powered exoskeletons are RAGT devices that use movable footplates to which the patient's feet are attached. Two examples are the Gait Trainer I^{5,17} and the HapticWalker.

Despite the number of RAGT devices that have been developed in the past 10 years, there have been only 3 randomized controlled studies comparing RAGT with neurofacilitative physical therapy or BSWTT. No significant differences were found in terms of walking function when RAGT was compared with conventional physical therapy.¹⁸ When RAGT was compared with manually assisted BWSTT, 1 study involving 48 participants found that BWSTT resulted in greater improvements in gait function,¹⁹ whereas another

study involving only 16 participants found no significant differences.¹⁰ In all 3 cases, the Lokomat was the RAGT device in question.

In the present study, our goal was to compare the outcomes of conventional physical therapy with the outcomes of RAGT using the AutoAmbulator. The personnel needs of a conventional physical therapy program are significantly higher than for RAGT; however, it is still not clear to what extent RAGT can improve functional recovery. The purpose of this study was to determine the feasibility of using the AutoAmbulator as a form of RAGT and compare the functional outcome measures with conventional physical therapy. We hypothesized that patients who received RAGT as part of their rehabilitation program would recover more gait and balance function than patients who received an equal dosage of conventional physical therapy.

Methods

Participants

Participants were recruited from the inpatient program at the HealthSouth Rehabilitation Hospital in Humble, Texas. All new patients who were admitted with hemiparesis due to a stroke less than 12 months prior were considered eligible and were referred to the investigators. Eligible patients were then screened according to the following criteria.

Inclusion criteria:

1. Age between 18 and 80 years

Exclusion criteria:

1. Orthopedic problems or muscle diseases that impair mobility
2. Severe congestive heart failure with ejection fraction of less than 30%
3. Unstable angina requiring medications
4. Intrathecal baclofen pump implantation within 6 weeks
5. Evidence of active infection
6. Severe dementia or other cognitive impairment preventing meaningful communication (as determined by Mini-Mental State Examination [MMSE])
7. Body weight more than 300 pounds (135 kg)
8. Pregnancy

Patients who satisfied all of the screening criteria were invited to join the study and were required to sign informed consent documents. All procedures followed in this study were approved by the Institutional Review Board of the HealthSouth Rehabilitation Hospital.

Protocol

After consenting to enter the study, each participant underwent a walking assessment consisting of 3 components. First, participants performed an 8-m walk test by walking for a distance of 8 m in a wide, empty hallway. Participants were allowed to use canes or walkers as necessary. The time to complete this task was recorded. If a participant could not complete the task in 4 minutes, the test was terminated and a score of 240 seconds was recorded. Next, in a 3-minute walk test, participants were instructed to walk as far as they could for 3 minutes, and the distance traveled was recorded. Later in the day, participants completed the Tinetti balance assessment²⁰; their total score (out of 28) was recorded.

After the baseline walking assessment, each participant was randomly assigned to 1 of 2 groups. A sequence of 20 one-digit numbers was selected from a random number table by the research coordinator, and participants were assigned in the order of their enrollment. If the digit corresponding to their enrollment was between 0 and 4, they were assigned to the first group, referred to as the control group, and received 24 one-hour sessions of goal-oriented physical therapy administered by a highly trained neurorehabilitation team consisting of a physical therapist and 2 physical therapy assistants. These sessions consisted of stretching and strengthening exercises of the affected lower extremity, as well as overground walking exercises using durable medical equipment such as canes and walkers. During these exercises, therapists used neurofacilitation techniques by applying appropriate manual assistance when needed.

The second group, referred to as the RAGT group, also received 24 one-hour sessions of therapy. These sessions consisted of 30 minutes of goal-oriented physical therapy (as per the control group) followed by 30 minutes of RAGT using the HealthSouth Autoambulator. Illustrated in

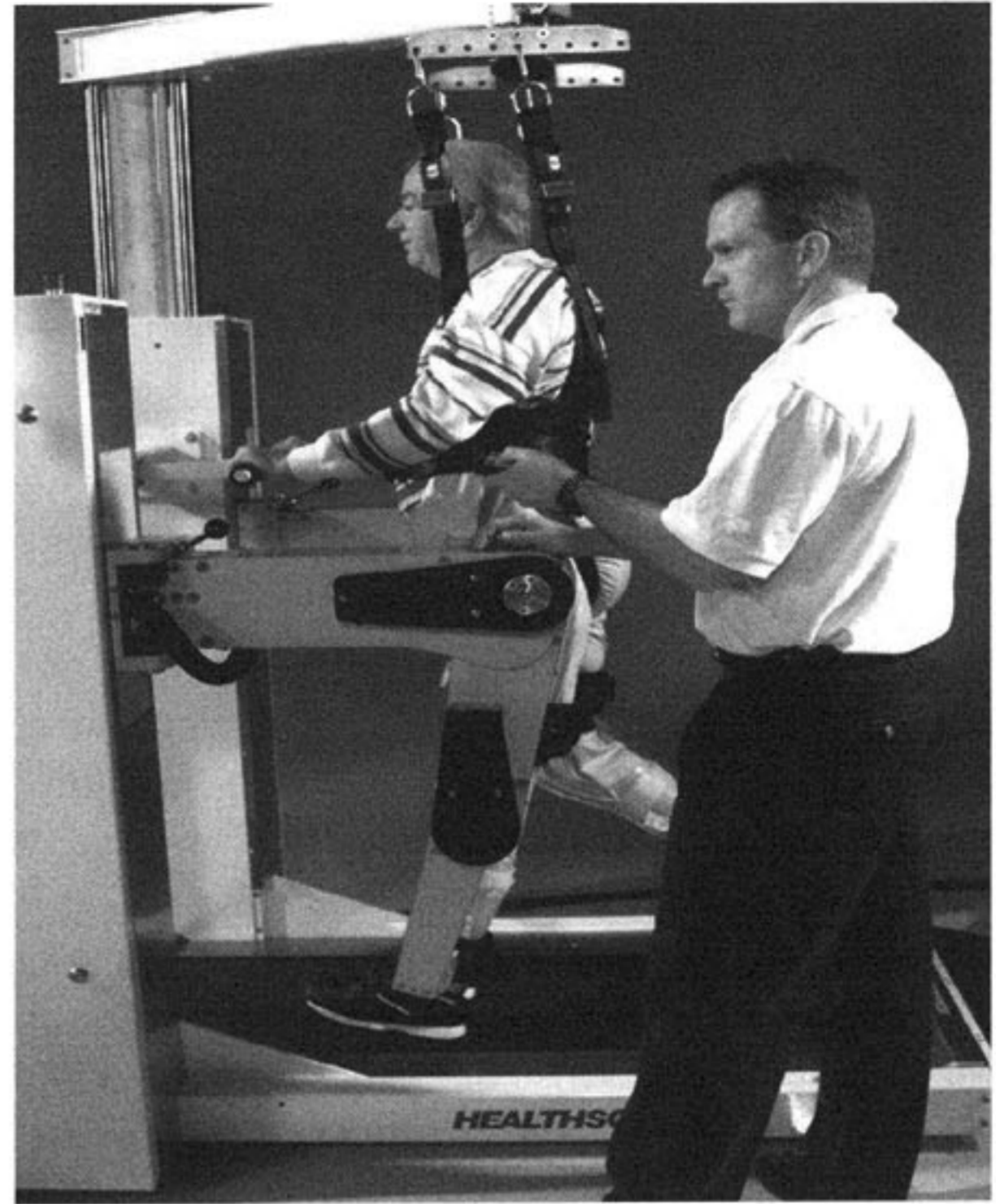


Figure 1. Autoambulator.

Figure 1, the Autoambulator is a device consisting of a treadmill, an overhead lift, a pair of articulated arms, and 2 upright structures housing the computer controls and parts of the mechanism.¹⁴ Individuals, when placed in the machine and fitted with a special harness, are attached to the overhead lift and raised to a standing position over the treadmill where weight-bearing can be assessed. The articulated robot arms mounted to the upright structures are hinged outward and are mechanically driven for vertical adjustment.

The gait drive components are computer controlled through position, time, and distance to provide a smooth, accurate, and coordinated movement of the legs and treadmill through variable speeds. The control interface is through a touch screen computer display that can collect, process, display, and archive pertinent session data. The device is equipped with safety interlocks, redundant travel limits, variable torque limits, and other means to detect and clear inordinate safety situations.

The robot arms move with 4 degrees of freedom corresponding to hip flexion/extension and knee flexion/extension bilaterally. The robot arms

provide assistance in the sagittal plane only. The patient is physically connected to the robot via a set of cuffs worn at the mid-thigh and calves. The device produces symmetrical reciprocal gait by providing forces throughout the entire gait cycle, including swing phase. A handlebar is fixed to the chassis of the device in front of the patient, which he or she can hold onto as though pushing a cart.

Treatment began immediately following group assignment. All participants started the study as inpatients and were scheduled for 5 therapy sessions per week with at least a 1-day interval between sessions. Most participants were discharged from inpatient care before completing all 24 sessions. At discharge, participants were moved to a residence outside of the hospital and transferred immediately to an outpatient schedule of 3 sessions per week. Participants completed the study in roughly 6 to 8 weeks, according to the duration of their inpatient stay, which depended on factors not controlled by this study.

Following the completion of all treatment sessions, participants repeated the 8-m walk test, 3-minute walk test, and Tinetti balance assessment.

Analysis

To ensure balanced randomization, we tested differences between the control group and RAGT group at baseline using a chi-square test for gender and Mann-Whitney *U* tests for age, days post stroke, and all baseline assessments (Tinetti balance score, 3-minute walk test, and 8-m walk test). A 2×2 repeated measures analysis of covariance with factors of treatment (RAGT vs conventional PT) and time was used to identify effect of treatment with respect to the outcome measures. Stroke duration at the time of enrollment into the study was used as a covariate. The level of significance for all statistical tests was set to $\alpha = 0.05$.

Results

Twenty stroke patients participated in this study. Ten were assigned to the control group and 10 to the RAGT group. There were no statistical differences between groups in gender ($P = 1.000$), age ($P = .154$), stroke duration ($P = .261$), or baseline 8-m walk ($P = .652$), baseline 3-minute walk ($P = .472$), or baseline Tinetti balance score ($P = .409$), indicating an equitable randomization. Demographic and treatment data for all participants are shown in **Table 1**.

All participants successfully completed 24 therapy sessions. Significant improvements over time were seen in both groups for the 8-m walk ($F_{1,18} = 14.02$; $P = .0015$), the 3-minute walk ($F_{1,18} = 18.66$; $P = .0004$), and the Tinetti score ($F_{1,18} = 53.55$; $P < .0001$). However, the difference between groups was not significant for the 8-m walk ($F_{1,18} = 0.29$; $P = .5967$), the 3-minute walk ($F_{1,18} = 0.63$; $P = .4385$), or the Tinetti score ($F_{1,18} = 0.40$; $P = .5354$). A summary of the changes in outcome measures are given in **Table 2**.

Table 1. Participant data

Characteristics	Control group (n = 10)	RAGT group (n = 10)
Gender		
Male	7	7
Female	3	3
Age, mean (\pm SD), years	60 (14)	60 (14)
Stroke duration, mean (\pm SD), days	81 (106)	57 (73)
Side of hemiparesis	4L/6R	3L/7R
No. of sessions, mean (\pm SD), as:		
Inpatient	11 (5.0)	11 (6.5)
Outpatient	13 (5.0)	13 (6.5)

Note: L = left; R = right; RAGT = robot-assisted gait training.

Table 2. Outcome measures, mean (\pm SD)

Measure	RAGT group		Control group	
	Baseline	Posttreatment	Baseline	Posttreatment
8-m walk, s	143 (105)	56 (73)	105 (95)	57 (65)
3-minute walk, ft	120 (157)	290 (340)	62 (82)	213 (166)
Tinetti score	8.3 (8.4)	17.7 (9.9)	7.4 (8.5)	13.9 (7.7)

Note: RAGT = robot-assisted gait training.

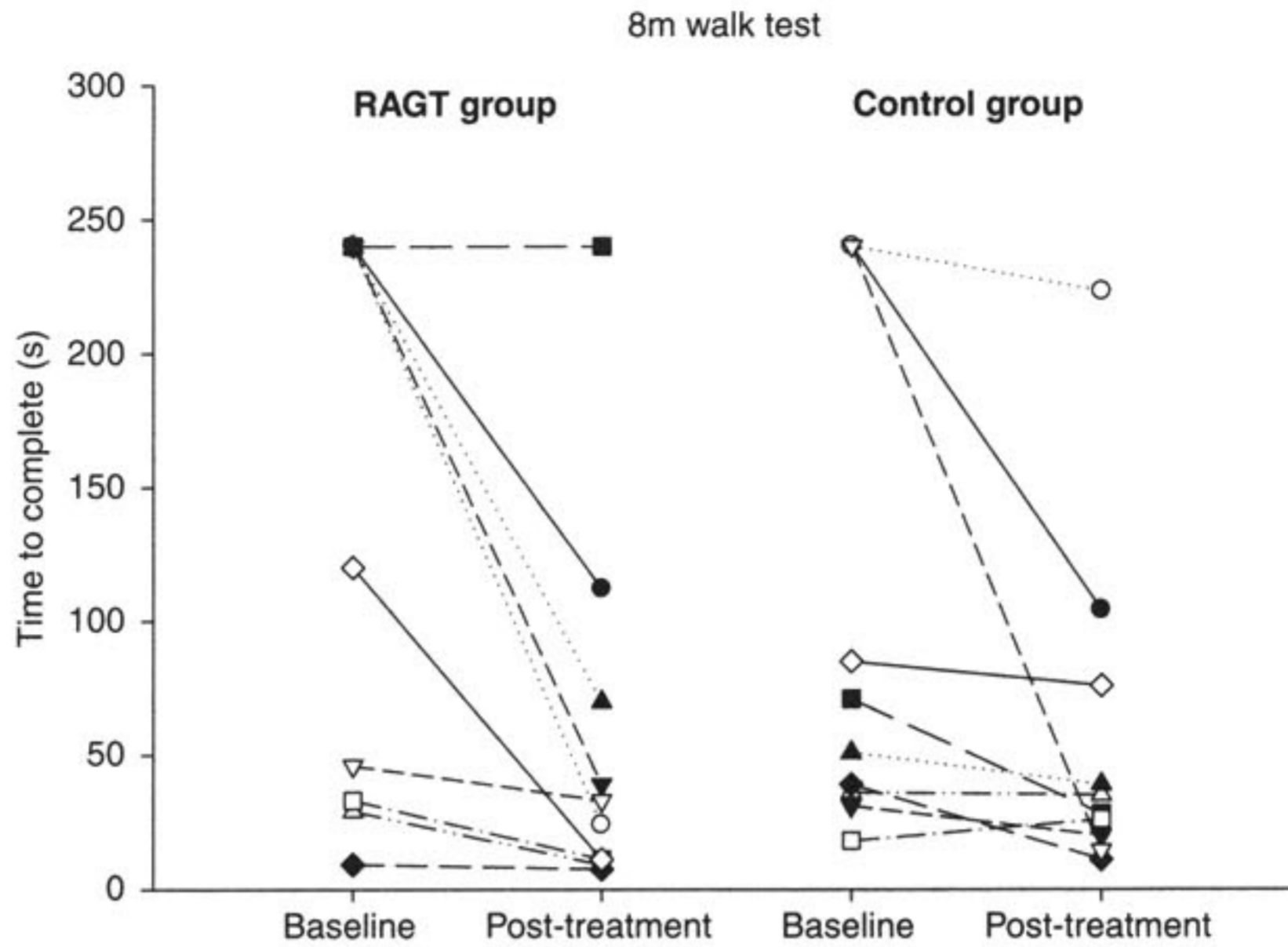


Figure 2. Individual participant scores on the 8-m walk test for the robot-assisted gait training (RAGT) group and control group.

The baseline and posttreatment scores for the 8-m walk test are shown in **Figure 2**. At baseline, 5 participants in the RAGT group and 3 participants in the control group were unable to walk 8 m in 4 minutes. All of these participants except for 1 in the RAGT group were able to complete

the 8-m walk test after treatment. The general trend of improvement following treatment can be seen clearly in **Figure 3**, which illustrates the baseline and posttreatment scores from the Tinetti balance assessment. All participants improved during the treatment period; however, there was

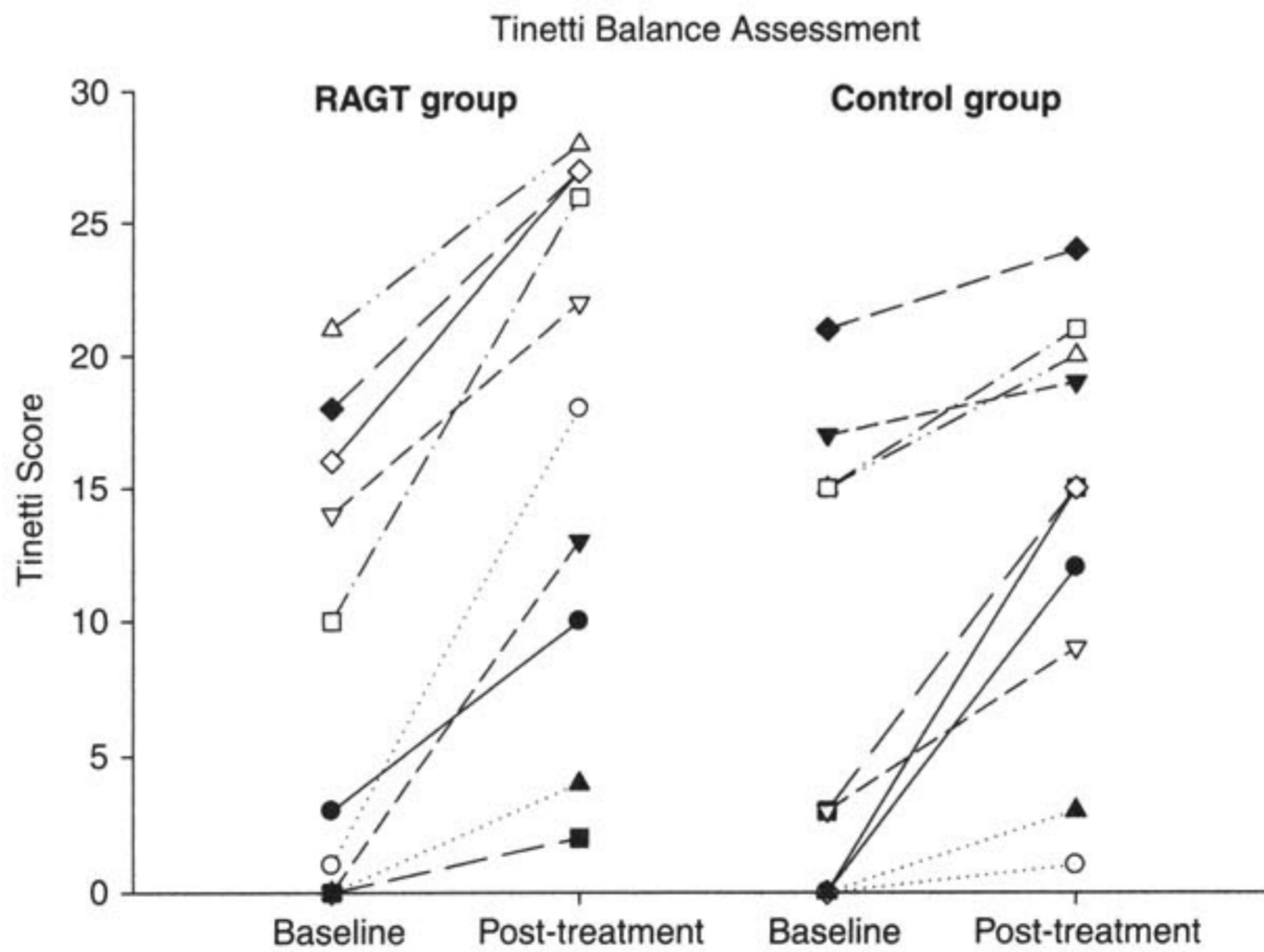


Figure 3. Individual participant scores on the Tinetti balance assessment for the robot-assisted gait training (RAGT) group and control group.

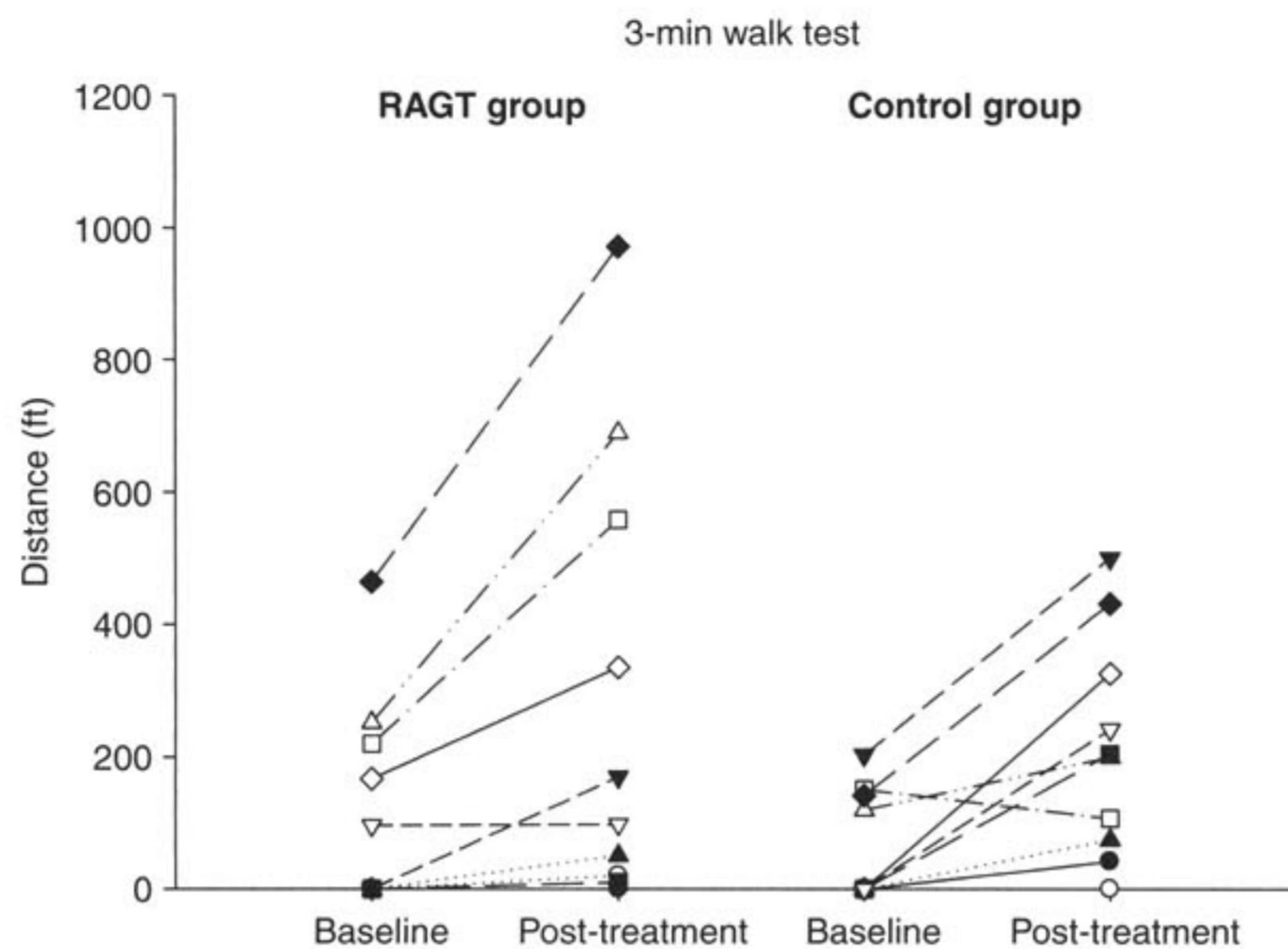


Figure 4. Individual participant scores on the 3-minute walk test for the robot-assisted gait training (RAGT) group and control group.

no significant difference between the magnitudes of improvement shown by each group. **Figure 4** shows the results of the 3-minute walk test. Four participants in the RAGT group and 5 participants in the control group were unable to take a single step during this test.

Discussion

In this pilot study, the data show that patients with hemiparesis due to stroke improved walking function following RAGT using a powered exoskeleton with partial body weight support. The functional gains were not significantly better than an equivalent dosage of conventional physical therapy. This suggests that RAGT and conventional physical therapy, as applied in this study, may produce similar clinical outcomes. The only difference is that the physical therapy program required significantly more therapist time (12 additional therapist-hours per patient) than the RAGT.

Our study was similar in design and objective to that of Husemann et al,¹⁸ who compared RAGT using the Lokomat with a conventional physical therapy program. Their study involved

30 patients, all of whom were nonambulatory prior to beginning treatment, and their findings were that neither RAGT nor physical therapy had an advantage in recovery of walking function. Our findings are the same. This does not rule out the possibility that there is a difference between the effectiveness of these 2 rehabilitation approaches; it may be that there is a small effect that requires a sample of much more than 30 participants to reveal.

A limitation of this study is the low number of participants. The lack of differences between groups could be due to low statistical power. Furthermore, it is not clear to what degree spontaneous recovery accounted for the improvements observed in both groups. This is a potential confound that is difficult to account for due to the ethical concerns of withholding treatment from a control group.

In this study, we chose to evaluate walking function using 3 tests that are common in research of this kind as well as in clinical practice. The 8-m walk test is designed to determine the overground walking speed of an individual by recording the time it takes to traverse a fixed distance. Although the 10-m walk test is the standard used in many studies on gait function poststroke, we used the

8-m walk test because of limited space in our clinic. A recent study by Lam et al²¹ reported that the 6-m walk test is valid and reliable for the assessment of walking ability of patients with hemiparesis due to stroke. The 3-minute walk test is a modification of the 6-minute walk test, which is commonly used to assess gait endurance in patient populations. Kosak and Smith²² compared the 2-minute walk test with the 6-minute walk test and found that both were highly reliable measurements of gait function post stroke. Although there are no reliability/validity studies that look specifically at the 8-m walk test or the 3-minute walk test, we believe that these are appropriate and meaningful measures of walking ability in the poststroke population. The Tinetti balance assessment provided a thorough evaluation of the static and dynamic balance function of the patients. Both groups of patients showed significant improvement for all 3 functional outcome measures, indicating that RAGT and physical therapy are effective in improving walking speed, endurance, and balance. These measurements were not performed by a blinded assessor, therefore the possibility of a bias exists. Furthermore, due to the nature of the study in an inpatient setting, the treating therapist and patient were not blinded to group assignment.

The treatment approach used with all participants was consistent with standard practice at our center. All of the day-to-day clinical decisions were based on the therapists' training, experience, and professional judgment as appropriate to

the individual needs of the patient. When the AutoAmbulator was used, parameters such as treadmill speed had to be selected by the operator (a trained physical therapist). The selection of these treatment parameters was again based on professional judgment and may have been somewhat arbitrary. Future studies should focus on developing evidence for selecting the most appropriate treatment parameters for a RAGT regimen.

Each patient in our study underwent individual therapy delivered by a team of highly trained therapists specializing in neurological rehabilitation. This degree of expertise and manpower may not be available in the typical setting of inpatient or outpatient rehabilitation. RAGT can provide a controlled, consistent level of therapy in many different settings. We conclude that RAGT may provide functional gains comparable with conventional physical therapy. This study justifies a larger multicenter trial to investigate the effectiveness of RAGT in hemiparetic stroke. Furthermore, a financial analysis weighing the large initial cost of RAGT against the long-term reduction in manpower should be pursued in the context of various health care funding models.

Acknowledgments

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REFERENCES

1. Bogey R, Hornby GT. Gait training strategies utilized in poststroke rehabilitation: are we really making a difference? *Top Stroke Rehabil.* 2007;14(6):1-8.
2. Barbeau H. Locomotor training in neurorehabilitation: emerging rehabilitation concepts. *Neurorehabil Neural Repair.* 2003;17(1):3-11.
3. Langhorne P, Coupar F, Pollock A. Motor recovery after stroke: a systematic review. *Lancet Neurol.* 2009;8(8):741-754.
4. Thrasher TA, Popovic MR. Functional electrical stimulation of walking: function, exercise and rehabilitation. *Ann Readapt Med Phys.* 2008;51(6):452-460.
5. Schmidt H, Werner C, Bernhardt R, Hesse S, Kruger J. Gait rehabilitation machines based on programmable footplates. *J Neuroeng Rehabil.* 2007;4:2.
6. Patton J, Small SL, Rymer WZ. Functional restoration for the stroke survivor: informing the efforts of engineers. *Top Stroke Rehabil.* 2008;15(6):521-541.
7. Laufer Y, Dickstein R, Chefez Y, Marcovitz E. The effect of treadmill training on the ambulation of stroke survivors in the early stages of rehabilitation: a randomized study. *J Rehabil Res Dev.* 2001;38(1):69-78.
8. Yagura H, Hatakenaka M, Miyai I. Does therapeutic facilitation add to locomotor outcome of body weight-supported treadmill training in nonambulatory patients with stroke?: a randomized controlled trial. *Arch Phys Med Rehabil.* 2006;87(4):529-535.

9. Werner C, von Frankenberg S, Treig T, Konrad M, Hesse S. Treadmill training with partial body weight support and an electromechanical gait trainer for restoration of gait in subacute stroke patients: a randomized crossover study. *Stroke*. 2002;33(12):2895–2901.
10. Westlake KP, Patten C. Pilot study of Lokomat versus manual-assisted treadmill training for locomotor recovery post-stroke. *J Neuroeng Rehabil*. 2009;6:18.
11. Huang VS, Krakauer JW. Robotic neurorehabilitation: a computational motor learning perspective. *J Neuroeng Rehabil*. 2009;6:5.
12. Hesse S, Schmidt H, Werner C, Bardeleben A. Upper and lower extremity robotic devices for rehabilitation and for studying motor control. *Curr Opin Neurol*. 2003;16(6):705–710.
13. Banala SK, Kim S, Agrawal SK, Scholz JP. Robot assisted gait training with active leg exoskeleton (ALEX). *IEEE Trans Neural Syst Rehabil Eng*. 2009;17(1):2–8.
14. Colombo G, Joerg M, Schreier R, Dietz V. Treadmill training of paraplegic patients using a robotic orthosis. *J Rehabil Res Dev*. 2000;37(6):693–700.
15. West RG, inventor; HealthSouth Corporation, assignee. Powered gait orthosis and method of utilizing same. US patent 6689075. February 10, 2004.
16. Veneman JF, Kruidhof R, Hekman EE, Ekkelenkamp R, Van Asseldonk EH, van der Kooij H. Design and evaluation of the LOPES exoskeleton robot for interactive gait rehabilitation. *IEEE Trans Neural Syst Rehabil Eng*. 2007;15(3):379–386.
17. Skvortsova VI, Ivanova GE, Kovrazhkina EA, et al. [The use of a robot-assisted Gait Trainer GT1 in patients in the acute period of cerebral stroke: a pilot study]. *Zh Nevrol Psikhiatr Im S S Korsakova*. 2008; 23(suppl):28–34.
18. Husemann B, Muller F, Krewer C, Heller S, Koenig E. Effects of locomotion training with assistance of a robot-driven gait orthosis in hemiparetic patients after stroke: a randomized controlled pilot study. *Stroke*. 2007;38(2):349–354.
19. Hornby TG, Campbell DD, Kahn JH, Demott T, Moore JL, Roth HR. Enhanced gait-related improvements after therapist- versus robotic-assisted locomotor training in subjects with chronic stroke: a randomized controlled study. *Stroke*. 2008;39(6):1786–1792.
20. Tinetti ME. Performance-oriented assessment of mobility problems in elderly patients. *J Am Geriatr Soc*. 1986;34(2):119–126.
21. Lam HS, Lau FW, Chan GK, Sykes K. The validity and reliability of a 6-metre timed walk for the functional assessment of patients with stroke. *Physiother Theory Pract*. 2010;26(4):251–255.
22. Kosak M, Smith T. Comparison of the 2-, 6-, and 12-minute walk tests in patients with stroke. *J Rehabil Res Dev*. 2005;42(1):103–107.