

EFFECTS OF GAIT TRAINING WITH A
BODY WEIGHT SUPPORT DEVICE AND TREADMILL IN
PATIENTS WITH IMPAIRED AMBULATORY ABILITY FROM A TBI

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ABSTRACT

Background and Purpose: The purpose of this study is to determine whether Body Weight Supported Treadmill Training (BWSTT) is more effective than conventional gait training for improving gait velocity, endurance, stride length differential and level of functional independence among persons who sustained a TBI within the last year. **Participants:** Twenty-seven subjects diagnosed with a TBI whose mean age was 35.6 ± 17.4 years. **Methods:** Participants were randomly assigned to an experimental (n=12) and control group (n=15). Both the experimental and control group received one hour of physical therapy interventions split into two 30 minute sessions, five days per week for a duration of four weeks. The control group therapy consisted of conventional therapy and over-ground gait training, while the experimental group received conventional therapy and one 20 minute BWSTT session per day at least four times a week. Treatment outcomes were assessed on the basis of the 3 minute walk test, 5 meter walk test, stride length differential, and Motor FIM score. **Results:** The results of MANOVA testing revealed that there was no significance difference between the groups at posttest ($p = .127$), however both the experimental and control groups improved from pretest to posttest. **Conclusion:** Conventional gait training and BWSTT are equally effective in improving recovery of ambulatory ability in patients who have sustained a TBI.

Key Words: Body Weight Supported Treadmill Training, Body Weight Support, Gait, Partial Weight Bearing, Traumatic Brain Injury, Over-ground, Treadmill, Rehabilitation, Physical Therapy, Ambulation

INTRODUCTION

Traumatic brain injury (TBI) is defined as a “nondegenerative, non congenital insult to the brain from an external mechanical force, possibly leading to permanent or temporary impairments of cognitive, physical and psychosocial functions, with associated diminished or altered state of consciousness.”¹ According to the Centers for Disease Control ², approximately 1.4 million individuals in the United States sustain a TBI each year. Fifty thousand die; 235,000 require hospitalization;² and 2% require long-term assistance to perform activities of daily living.³ Therefore, TBI is identified as a leading cause of death and disability among Americans. Principle causes of TBI include motor vehicle accidents, acts of violence, falls, and sports injuries with males between the ages 15-24 and older adults over the age of 75 most affected.^{2,4}

One of the most debilitating aspects of TBI is loss of ambulation. Approximately 25% of those who sustain a TBI fail to achieve independent ambulation within the first six months. Of those who do achieve independent ambulation, 94% do so within the first 3 months but often demonstrate persistent gait deviations such as decreased step length, decreased velocity and increased medial-lateral displacements which may compromise balance.⁵ Therefore a primary focus of rehabilitation involves facilitation of recovery of ambulation through emphasis on gait components such as posture, balance, weight-bearing, endurance, and bilateral lower limb coordination.⁶

Conventional gait training techniques may be limited by the subsequent biomechanical and neurological deficits following TBI. For example, inability to initiate and sustain upright posture and balance may inhibit task specific training therefore these patients are often excluded from early gait-retraining. Similarly, gait-retraining is often initiated through use of

assistive devices or stabilization of therapists, both of which may facilitate abnormal gait biomechanics. Additionally, conventional gait-retraining often requires several staff to ensure safety and proper positioning of the patient and may be unsafe or impractical in some rehabilitation settings. Optimal gait retraining must assist the patient's nervous system in regaining control over a multi-joint biomechanical system which requires the therapeutic environment provide proper patient biomechanics and task specific training to ensure appropriate return of function.⁶

Seif-Naraghi and Herman⁶ describe a therapeutic window early in acute rehabilitation when neuroplasticity is most pliable. Similarly, Page and Levine⁷ found that early and intense rehabilitation following TBI facilitates optimal neuroplastic changes and recovery. This emphasizes the need for maximal functional training early on during rehabilitation. Body weight supported treadmill training (BWSTT), which utilizes a vertical suspension system to facilitate appropriate upright postural control, balance, and safety during treadmill walking, may enhance the ability to practice walking earlier in the rehabilitation process.

The Motor Program Theory provides a neurobiological framework that supports the use of BWSTT in the rehabilitation of patients with TBI. Studies have suggested that spinally mediated programs or central pattern generators (CPGs) present in spinalized cats requires no activation or regulation from higher central nervous system (CNS) levels in order to independently generate complex movement patterns such as reciprocal gait, gallop, and trot.^{8,9} In humans the combination of various sources of afferent feedback, such as weight shift and cutaneous input from therapist(s), during BWSTT, may provide the synergy needed to promote the activation and modulation necessary to retrain CPG's in the spinal cord.¹⁰ The spine may then interpret this information and respond with appropriate efferent signals

to facilitate ambulation.¹¹ During BWSTT when the treadmill belt is sustained at a constant rate of speed, facilitation of rhythmic input is achieved. This may reinforce a coordinated reciprocal pattern of movement activating and modulating CPGs and promoting neuroplasticity in the spinal cord and cortical and sub-cortical areas of the CNS necessary for recovery of both motor control and ambulation.^{6,9,10,12} Additionally BWSTT is a repetitive task specific exercise that promotes proper lower extremity coordination through therapist mediated facilitation of foot placement and weight shifting, which may further retrain CPGs and promote neuroplasticity.¹²

The efficacy of BWSTT in the recovery of ambulatory abilities in patients' who sustained a cerebral vascular accident (CVA) has been well documented in current literature and many studies indicate that BWSTT may facilitate improvements in gait velocity and stride length better than conventional gait training methods.^{13,14} BWSTT has also been shown to be effective in improving gait velocity, endurance, and stride length in those with spinal cord injury, Parkinson's Disease and Cerebral Palsy.¹⁵⁻²⁰

To date there is a paucity of evidence related to the efficacy of the BWSTT in persons with TBI. In three separate case studies, participants with TBI showed improvements in ability to ambulate after treatment with BWSTT.^{6,21,22} In a fourth case study BWSTT was also shown to increase cardiorespiratory capacity in a patient with TBI.²³ Two randomized control trials comparing BWSTT and conventional over-ground gait training for persons with TBI found no significant difference between the BWSTT and conventional over-ground gait training for improvements in gait function.^{24,25} However several limitations such as small sample size, use of outcome measures with limited sensitivity to change as well as unaccounted for differences in initial gait impairments of participants and placement of the

BWSTT harness below the greater trochanter may have affected the outcomes. Our study attempted to address these types of limitations by utilizing outcome measures sensitive to change such as the 3-minute and 5-meter walk tests, the motor FIM and stride length differential as measured by the GAITRite® Computerized Gait Analysis System (GAITRite®). Additionally the treating therapists received individualized training on the use of BWSTT to ensure appropriate harness placement. As there is currently no research available which provides objective data relating to the effectiveness of BWSTT in improving gait parameters such as velocity and stride length in person's with TBI or relating to length of stay and number of treating therapists this study seeks to increase available evidence.

The goal of this randomized control trial is to determine whether BWSTT improves recovery of ambulatory ability among individuals following TBI. Specifically, the primary purpose is to determine whether BWSTT is more effective than conventional gait training for improving gait velocity, endurance, stride length differential and level of functional independence among persons who have lost these abilities due to a TBI within the last year. A secondary purpose is to determine whether a relationship exists between group assignment and number of treating therapists or length of stay (LOS). We hypothesize that following a TBI participants receiving four weeks of BWSTT will demonstrate greater functional outcomes and ambulatory abilities, as measured by increases in gait velocity, gait endurance, stride length differential and motor FIM, than participants receiving four weeks of conventional gait training. In addition, we hypothesize that LOS or number of therapists needed to treat the participants will predict group assignment.

METHODS

Participants

Participants were recruited from Sunnyview Rehabilitation Hospital's Traumatic Brain Injury Program in Schenectady, NY by consecutive sampling. Inclusion criteria was as follows: (1) at least 16 years of age, (2) hospitalized with a diagnosis of TBI (3) permission by the attending MD, (4) 4 week projected LOS and (5) initial Glasgow Coma Scale of less than or equal to 8 indicating severe TBI. Exclusion criteria included: (1) combative behavior, (2) comatose, (3) pregnancy, (4) unable to follow simple commands at least inconsistently and (5) lower extremity weight-bearing restrictions related to musculoskeletal complications.

Informed consent was obtained for each participant via a signed document from the participant and/or the participant's guardian or proxy if the participant was unable to give consent. Human subjects' approval was obtained through The Sage Colleges and Northeast Health IRB committees. Confidentiality was maintained throughout the study according to the Health Insurance Portability and Accountability Act (HIPAA).

Research Design

A pretest post test experimental design, which is effective at demonstrating if a causal relationship exists between the independent and dependent variables, was utilized. The independent variable in the study was method of gait training and the dependent variables were gait endurance, gait velocity, stride length differential, functional independence, LOS, and number of treating therapists. Participants were randomly assigned to the experimental or control group to ensure similar characteristics in both groups.²⁶

Instrumentation

Demographic information and relevant clinical data were collected from participants' medical records and included age, gender, time post injury, type of paresis, initial Glasgow

Coma Scale, number of treating therapists, and LOS. This information was collected so differences between the experimental and control groups could be examined and to ensure the randomization process effectively formed equal groups.

All participants were evaluated at the beginning and end of the four week intervention period or at discharge by a team of two trained physical therapists blinded to participant group assignment. The outcome measures utilized were the 3-minute walk test, the 5-meter walk test, stride length differential, and the motor FIM.

The 3-minute walk was utilized to measure endurance. It is the distance, in feet, the participant is able to walk in 3 minutes. One trial for each participant was conducted and participants were allowed assistance to walk as needed by the evaluating therapist. The 3-minute walk test is derived from the 6-minute walk test (ICC= 0.94-0.99) and has been shown to have high concurrent validity ($r= 0.847$)²⁷

The 5-meter walk test was used to measure gait velocity.²⁸ An average of two trials were taken and gait velocity was determined by dividing the distance, by the time to complete. The 5-meter walk test is derived from the 10-meter walk test which is a reliable outcome measure for patients with TBI with excellent test-retest reliability (ICC=0.98).²⁹

The GAITRite® system was used to measure stride length differential and consisted of a carpeted electric walkway embedded with pressure sensors which detect a series of footfalls and allow calculation of temporal and spatial parameters of gait.³⁰ The GAITRite® has shown high levels of concurrent validity when compared to the Clinical Stride Analyzer (ICC=0.99) as well as excellent test-retest reliability for stride length at preferred and fast walking speeds.³⁰

The Motor FIM Score was used to measure functional independence. [See Appendix A] The Motor FIM is one of two subscales of the Functional Independence Measure (FIM)³¹ The Motor FIM score was calculated based on the participants' ability to perform 13 tasks which include eating, grooming, bathing, dressing upper body, dressing lower body, toileting, bowel and bladder management, transfers from bed, chair, wheelchair, toilet and tub/shower, walking, wheelchair mobility, and stair negotiation. Each item on the Motor FIM was scored on a 7-point Likert scale indicating the amount of assistance required.³¹ The FIM has been shown to be a reliable and valid measure for persons with TBI.^{32,33} Additionally the FIM had good inter-rater reliability with a squared weighted Kappa of 0.75-0.80 and intraclass correlation coefficient of 0.75-0.92.³²

Procedure

Data was collected by the primary investigators and the initial and final evaluations were conducted by two trained outpatient therapists, each with five years of neurorehabilitation experience. These therapists were blinded to participant assignment. The interventions for the experimental and control groups were conducted by the participant's primary physical therapist, who were individually trained on BWSTT and the use of the LiteGait System. Both the control and experimental groups received one hour of physical therapy interventions, split into two 30-minute sessions, five days per week, for a duration of four weeks.

Control Group

The control group received conventional physical therapy for two 30-minute sessions, five days a week for a duration of four weeks. Conventional physical therapy included, but was not limited to gait training, strength and balance training, range of motion, neurodevelopmental techniques and aquatic therapy. See Appendix B for examples.

Experimental Group

The experimental group received a combination of one conventional physical therapy session five times a week and one 20 minute BWSTT session per day at least four times a week utilizing the LiteGait I-350 and TRUE S.o.f.t. treadmill model #725. During the BWSTT sessions the amount of body weight support utilized was based on clinical judgement and visual observation of the point at which symmetrical weight bearing is achieved but never exceeded 40% of the participant's weight.¹⁴ One or two physical therapists provided assistance as needed for stepping and weight shifting. Initial treadmill speed was determined by the fastest speed that both the therapist(s) and participant could maintain a reciprocal gait pattern as increased speeds have been shown to improve ambulatory abilities^{34,35} Each BWSTT session consisted of up to 20 minutes of total walking time with rest breaks as needed.

Statistical Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences Version 16.0 (SPSS 16.0). To test the first hypothesis, multivariate analysis of variance (MANOVA) was used to determine whether there was a difference between the experimental and control groups on the 3 minute walk test, 5 meter walk test, stride length differential and motor FIM score at the post test. MANOVA was also utilized to determine whether the experimental and control groups were identical on all pretest variables. The following assumptions for MANOVA were tested and met: independence, random sampling, multivariate normality, and homogeneity of covariance matrices. To test the second hypothesis, logistic regression analysis was performed. Group assignment was chosen as the outcome variable and length of stay and number therapists as the predictor variables to

determine if there was a relationship between the two variables and group assignment. An alpha value of 0.05 was deemed statistically significant for all parametric testing.

RESULTS

Twenty-seven subjects participated in the study; 15 subjects were randomly assigned to the control group and 12 to the experimental group. The study sample was mostly male (74%), Caucasian (100%), and were of low ambulating status (96%). The mean age of the subjects was 35.6 ± 17.4 years. The average length of stay at the hospital for each subject was $62.4 \text{ days} \pm 33.7$. See Table 1 for demographic variables.

Histograms and results of the Kolmogorov- Smirnov test of normality indicate the data was not normally distributed for the 3 minute walk test, stride length differential, and Motor FIM score. Therefore, a log transformation was performed on all dependent variables which was successful in normalizing the data. See Table 2 for pre-test/post-test measures for both groups.

The results of MANOVA testing revealed no significant difference between the experimental and control group in the full model $F(4,27) = 1.77, p = .127$. There was no difference between the experimental and control groups at post-test for the 3 minute walk test, 5 meter walk test, stride length differential and Motor FIM. See Table 4 for results of MANOVA testing.

Non-parametric testing using the Wilcoxon Signed Ranks Test was performed on all four dependent variables to determine whether there were any significant differences from pre-test to post-test within the experimental and control groups. A Bonferroni correction was performed to account for the potential of a Type 1 error and an alpha value of .0125 was deemed statistically significant. In the experimental group the 3 minute walk test ($p=.010$), 5

meter walk test ($p=.005$), and motor FIM ($p=.003$) was found to be statistically significant. The stride length differential was not found to be statistically significant ($p=.612$). In the control group the 3 minute walk test ($p=.001$), 5 meter walk test ($p=.002$), and motor FIM ($p=.001$) was found to be statistically significant. The stride length differential was not found to be statistically significant ($p=.333$). See Table 5 for results of Wilcoxon Signed Ranks Test.

A test of the full model logistic regression analyses with both predictors was not statistically significant $X^2(2, 27) = .667, p = .716$. Group assignment could not be predicted by length of stay or number of therapists needed to treat the patients. See Table 6 for results of logistic regression analysis.

DISCUSSION

The results of this randomized control trial did not support our primary hypothesis that individuals receiving BWSTT will demonstrate greater improvements than those receiving conventional gait training in gait velocity, gait endurance, stride length differential, and level of functional independence. Results of MANOVA testing showed there was no significant difference between the experimental and control group in the 3 minute walk test, 5 meter walk test, stride length differential, and Motor FIM. However, for both groups there was a significant improvement from pretest to posttest in the 3 minute walk test, 5 meter walk test, and Motor FIM. Our data also demonstrates that a relationship does not exist between group assignment and length of stay or number of treating therapists.

Our findings are consistent with the results of a randomized control trial (RCT) by Wilson et al²¹; in which BWSTT was compared to conventional physical therapy for participants with TBI. Wilson²¹ found significant improvements for both groups in balance, walking ability, and functional independence; however no difference existed between the experimental and

control groups. We also found that both groups improved in walking ability and functional independence without a difference between groups.

For all outcome measures, with the exception of stride length differential, our study showed improvements in both groups without a significant difference between groups. In addition, our study showed a trend towards increased stride length differential in the experimental group and a decrease in stride length differential in the control group. This is consistent with the results of the RCT by Brown et al²⁴ in which BWSTT was compared to overground gait training for individuals with chronic TBI. This study found improvements for both groups in step width, gait velocity, gait ability, functional ambulation, and dynamic standing balance. The only significant difference between groups found was greater improvement in gait symmetry with conventional gait training.

Stride length differential decreased in the control group from an average of 3.64 cm to 2.83 cm and increased in the experimental group from an average of 3.44 cm to 4.26 cm, which is consistent with findings in the study by Brown et al²⁴ involving individuals with TBI. The control group in our study had the advantage of specificity of training with overground ambulation during treatments and post test measurements. The experimental group however ambulated differently during treatment and testing sessions, possibly resulting in less carryover.

Studies involving participants who have sustained a CVA demonstrate greater improvements in gait symmetry, gait velocity, quality of ambulation, and gait endurance with the use of BWSTT when compared to conventional overground training.^{13,14,36} However, these findings do not correlate with the results of our study in which there was no difference between groups. Greater effectiveness of cortical reorganization for repairing lesions in

those who have sustained a CVA as compared to individuals with TBI could be a cause for the differing results between studies.

Similarly, the amount of cortical reorganization in individuals with TBI may be more limited than those with CVA. Diffuse axonal injury which occurs in individuals who have sustained a TBI consists of not only localized damage in a restricted area but also white matter injury in the cerebral hemispheres, corpus callosum, and brainstem.³⁷ However, damage to the brain following a CVA is generally more localized to the area of the brain lacking blood flow resulting in more focal lesion.¹³ Cortical reorganization therefore may be more likely to occur and lead to greater motor recovery in individuals post CVA. For example, Whishaw³⁸ has demonstrated that animals with larger lesions show noticeably less return of function and the function that does return may take many weeks or months to maintain.

Our data further supports this idea as greater improvements were found in individuals with unilateral involvement. Participants with hemilateral impairment performed better in several outcome measures when compared to participants with bilateral impairment. Median values for the 3 minute walk test, 5 meter walk test, and gait speed improved to 348 feet, 43.5 m/s and .41 m/s respectively in those with hemilateral impairment and only 111 feet, 31 m/s and .28 m/s respectively in those with bilateral impairment. These findings are more consistent with the research involving individuals post CVA who have hemilateral impairment.^{13,14,36,39} Additional support is found in the Constraint Induced Movement Therapy literature. Taub et al³⁹ found that those with TBI who had unilateral upper limb motor deficits performed better than the subject with bilateral upper limb motor deficits. With appropriate participant stratification a significant difference between groups may have

been found. However, our sample size was not large enough to control for unilateral versus bilateral involvement statistically.

Several therapists are often required to assist with positioning of a patient with TBI when safety and postural control are limited.⁶ Anecdotally, fewer therapists are required to assist a patient during gait training in the acute stages of rehabilitation with the use of BWSTT. However, our data analysis does not support this statement since group assignment could not be predicted by the number of treating therapists.

Another trend in our data was a negative relationship between time since injury and amount of improvement in the 3 minute and 5 meter walk test. As the time post injury increased, improvement in the 3 minute and 5 meter walk test decreased. Mussico et al⁴⁰ has shown that individuals who initiated the rehabilitation process within 7 days post CVA had better long term outcomes than those who began rehabilitation between 15 to 30 days or more post CVA. When comparing two case studies in which subjects received the same treatment, Wilson and Swaboda²¹ found that the subjects with less time between injury and therapy showed greater improvements in the different dimensions of walking ability including standing balance and amount of independence.

Results of this study should be interpreted with caution due to several limitations. A large variability existed among the participants especially in cognitive ability, area of the brain affected, and physical status. Variability may act as a limitation since the response to the treatment may be affected by participant characteristics resulting in the true relationship being undetectable. All subjects were rated less than or equal to 8 on the Glasgow Coma Scale at the time of diagnosis, yet the cognitive ability was not assessed or controlled for at the time of admission to the study. An individual's impairments can also vary greatly

depending on where in the brain the lesion is located. In our study 33.3% of the participants had right sided lesions, 18.52% had left sided lesions and 22.2% had bilateral lesions. People with TBI may have lesions located in various areas of the cortex therefore increasing the variability of possible deficits and potential for a treatment effect. In our study, there were wide variations in physical status as measured by motor FIM, gait velocity and gait endurance. This variability is demonstrated by the wide range in standard deviations (SD) for both the experimental and control groups on pre test measures. For the control group, the SD for the 3 minute walk test and stride length differential were 53.71 ± 55.0 feet and 3.64 ± 5.49 cm respectively and for the experimental group the SD were 39.9 ± 46.8 feet and 3.44 ± 4.18 cm respectively.

In our study, treadmill speed was increased by patient and therapist tolerance. The inability to progress the speed in a more aggressive structured step-wise progression may have limited the ability for improved gait recovery.³⁴ Pohl et al⁴¹ found that in individuals post CVA, increasing the treadmill speed stepwise resulted in better walking abilities than limited progressive treadmill training and conventional gait training. For each session the subjects began training at the maximum achieved belt speed, which was then increased by 10% for 10 seconds. A recovery period followed and then belt speed was increased by another 10%. The limited progressive training group speed was increased by no more than 5% each week resulting in a 20% increase over 4 weeks.⁴¹ Further support for the beneficial effects of increased training speed was demonstrated by Sullivan et al³⁴ who found that the greatest improvement in self selected overground walking velocity occurred in participants who trained at fast speed (2.0 mph) in comparison to those who trained at slow speed (0.5 mph) or variable speed (0.5 to 2.0 mph).

The therapists involved in the study were trained for approximately 30 minutes, yet consistent follow through was lacking. Inconsistencies involving treatment, harness placement, and record collections are a possible source of error. Due to human error, several participants were missing pre and/or post test measurements which resulted in up to 0% to 33% of the data missing depending on the variable. During the second year of the study there was an increase in missing data which corresponds to the absence of the head investigator who was on maternity leave. There were also inconsistencies involving treatment especially when untrained therapists filled in. These methodological limitations could be avoided with more thorough training and better development of a specific protocol.

Assigning a certified trainer to educate each treating therapist will provide more consistency even when the same therapist is not available to treat the same patient as well as ensuring that the therapists are trained in the proper techniques. This will assist in preventing inappropriate donning of the harness which could result in lack of efficient lower extremity movement and prevention of full hip extension which may hinder CPG activation.²¹ The protocol could account for maintaining control over the use of experimental variables such as rest periods, gait speed, percentage of unweighting, and the appropriate progression of each. These factors were not properly accounted for or recorded in our study. In addition, during the study the GaitRite® Mat was replaced due to malfunctioning and could have been a threat to internal validity if inaccurate results were produced.²⁶ The changes in stride length differential may have been altered because of flaws in our instrumentation as opposed to resulting from the intervention.

We did not meet our targeted goal of 50 subjects and therefore the small sample size acts as another limitation. A power analysis revealed that we had adequate power (>0.8) to

compute a simple MANOVA, however our sample was not large enough to statistically control for any factors. Although we were on target for reaching our goal sample size during the first year of the study, the number of participants recruited during the second year decreased. This may be due to the absence of the head investigator leading to recruitment error, and/or Medicare criteria changes affecting the number of patients admitted to the facility. In addition, the initial inclusion criteria did not allow for participants under the age of 18 years to be included and limited the part of the population which has a high prevalence of TBI. Nearly two thirds of individuals with TBI are under the age of 36 years and 39% are between the ages of 15 and 24 years.⁴² To attempt to account for the limitation, the inclusion criteria were changed to include participants age 16 years and older but unfortunately the change was made late in the study and resulted in a minimal increase for participant recruitment. Including other facilities in the study as opposed to only involving individuals of Sunnyview Rehabilitation Hospital would help in providing a larger sample. Future research should involve greater homogeneity in participant characteristics at baseline including initial physical status, age, cognitive level, unilateral impairment, and time since injury.

Other research to determine efficacy of BWSTT over conventional gait training for individuals with TBI could involve gait machines such as the GT I which is an electromechanical gait trainer. With the participant secured in harness and feet placed on foot plates, cadence and step length can be controlled while relieving therapist strain.⁴³ Center of mass movement in vertical and lateral directions is controlled using a pulley system connected to the GT I from the individual's pelvis. Using this equipment may allow for the step wise progression of walking speed described in the study by Pohl et al⁴¹ while allowing

for appropriate sinusoidal movement of the center of mass. This would provide more intense treatment for individuals with TBI in BWSTT and therefore may produce more significant and accurate results.

Outcome measures used in future studies should include the Functional Assessment Measure which has been shown to be more sensitive to changes which occur in individuals with TBI than the FIM and has high internal consistency and reliability.^{44,45} Possibilities for other research may include assessing the effects of BWSTT on other impairments experienced by those with TBI such as cardiovascular deficits and spasticity.

Conclusion

Our study has shown that there is no difference between BWSTT and conventional gait training in treating those with TBI for improving gait velocity, gait endurance, and functional independence. In addition we found that group assignment was not predicted by participant LOS and the number of treating therapists. Although the present study did not demonstrate significant differences between the experimental and control group for the 3 minute walk test, 5 meter walk test, or motor FIM, both treatments were effective in improving ambulation ability according to these measures.

REFERENCES

1. Traumatic brain injury definition resource page. Emedicine website. Available at: <http://www.emedicine.com/pmr/topic212.htm>. Accessed June 2, 2007.
2. National Center for Injury Prevention and Control. Centers for Disease Control. Available at <http://www.cdc.gov/ncipc/tbi/TBI.htm>. Accessed September 29, 2008
3. Traumatic brain injury in the United States: a report to congress. Available at: http://www.cdc.gov.mill1.sjlibrary.org/ncipc/tbi/tbi_congress/00_preliminary.htm. Accessed June 2, 2007.
4. National Institute of Neurological Disorders and Stroke. National Institutes of Health website. available at http://www.ninds.nih.gov/disorders/tbi/detail_tbi.htm. Accessed September 29, 2008
5. Katz DI, White DK, Alexander MP, Klein RB. Recovery of ambulation after traumatic brain injury. *Arch Phys Med Rehabil*. 2004;85(6):865-869.
6. Seif-Naraghi AH, Herman RM. A novel method of locomotion training. *J Head Trauma Rehabil*. 1999;14(2):146-162.
7. Page S, Levine P. Forced use after TBI: Promoting plasticity and function through practice. *Brain Inj*. 2003;17(8):675-684.
8. Grillner S. Locomotion in the spinal cat. In: Shumway-Cook A, Woollacott MH, eds. *Motor Control: Theory and Practical Applications*. Baltimore, MD: Williams and Wilkins, 2001:15-16.

9. Grillner S. Control of locomotion in bipeds, tetrapods, and fish. In: Shumway-Cook A, Woollacott MH, eds. *Motor Control: Theory and Practical Applications*. Baltimore, MD: Williams and Wilkins, 2001:15-16.
10. Harkema SJ, Hurley SL, Patel UK, et al. Human lumbosacral spinal cord interprets loading during stepping. *J Neurophysiol.* 1997;77(2):797-811.
11. Dietz V, Muller R, Colombo G. Locomotor activity in spinal man: significance of afferent input from joint and load receptors. *Brain.* 2002;125(Pt 12):2626-2634.
12. Dobkin BH. Functional rewiring of brain and spinal cord after injury: the three Rs of neural repair and neurological rehabilitation. *Curr Opin Neurol.* 2000;13(6):655-659.
13. Hesse S, Bertelt C, Jahnke MT, et al. Treadmill training with partial body weight support compared with physiotherapy in nonambulatory hemiparetic patients. *Stroke.* 1995;26(6):976-981.
14. Visintin M, Barbeau H, Korner-Bitensky N, Mayo NE. A new approach to retrain gait in stroke patients through body weight support and treadmill retraining. *Stroke.* 1998;29(6):122-128.
15. Barbeau H, Fung J. The role of rehabilitation in the recovery of walking in the neurological population. *Curr Opin Neurol.* 2001;14(6):735-740.
16. Behrman AL, Harkema SJ. Locomotor training after human spinal cord injury: A series of case studies. *Phys Ther.* 2000;80(7):688-700.
17. Behrman AL, Lawless-Dixon AR, David SB, et al. Locomotor training progression and outcomes after incomplete spinal cord injury. *Phys Ther.* 2005;85(12):1356-1371.
18. Miyai I, Fujimoto Y, Ueda Y, et al. Treadmill training with body weight support: its effects on Parkinson's disease. *Arch Phys Med Rehabil.* 2000;81(7):849-852.

19. Schindl MR, Forstner C, Kern H, et al. Treadmill training with partial body weight support in non-ambulatory patients with cerebral palsy. *Arch Phys Med Rehabil.* 2000;81(3):301-306.
20. Dodd KJ, Foley S. Partial body-weight-supported treadmill training can improve walking in children with cerebral palsy: a clinical controlled trial. *Dev Med Child Neurol.* 2007;49(2):101-105.
21. Wilson DJ, Swaboda JL. Partial weight-bearing gait retraining for persons following traumatic brain injury: preliminary report and proposed assessment scale. *Brain Inj.* 2002;16(3):259-268.
22. Scherer M. Gait rehabilitation with body weight-supported treadmill training for a blast injury survivor with traumatic brain injury. *Brain Inj* 2007;21(1):93-100.
23. Mossberg KA, Orlander EE, JL N. Cardiorespiratory capacity after weight-supported treadmill training in patient with traumatic brain injury. *Phys Ther.* 2008;88:77-87.
24. Brown TH, Mount J, Rouland BL, et al. Body weight supported treadmill training versus conventional gait training for people with chronic traumatic brain injury. *J Head Trauma Rehabil.* 2005;20(5):402-415.
25. Wilson DJ, Powell M, Gorham JL, Childers MK. Ambulation training with and without partial weightbearing after traumatic brain injury. *Am J Phys Med Rehabil.* 2005;85:68-74.
26. Domholdt E. *Rehabilitation Research: Principles and Applications.* 2nd ed. St. Louis: Elsevier Saunders; 2005.
27. Leerer P, Miller E. Concurrent validity of distance-walks and timed-walks in the well elderly. *Journal of Geriatric Physical Therapy.* 2002;25:3-7.

28. Salbach NM, Mayo NE, Higgins J, et al. Responsiveness and predictability of gait speed and other disability measures in acute stroke. *Arch Phys Med Rehabil.* 2001;82(9):1204-1212.
29. Van Loo MA, Moseley AM, Bosman JM, et al. Test-re-test reliability of walking speed, step length and step width measurement after traumatic brain injury: a pilot study. *Brain Inj.* 2004;18(10):1041-1048.
30. Bilbey B, Morris M, Webster K. Concurrent related validity of the GAITRite® walkway system for quantification of the spatial and temporal parameters of gait. *Gait Posture.* 2003;17(1):68-74.
31. In depth review of FIM. Stroke Engine. Available at:
http://www.medicine.mcgill.ca/stroking-engine-assess/module_fim_indepth-en.html.
Accessed June 24, 2007.
32. van Ballen B, Odding E, van Woensel MPC, et al. Reliability and sensitivity to change of measurement instruments used in a traumatic brain injury population. *Clin Rehabil.* 2006;20:686-670.
33. Corrigan JD, Smith-Knapp K, Granger CV. Validity of the functional independence measure for persons with traumatic brain injury. *Arch Phys Med Rehabil.* 1997;78(8):828-834.
34. Sullivan KJ, Knowlton BJ, Dobkin BH. Step training with body weight support: effect of treadmill speed and practice paradigms on poststroke locomotor recovery. *Arch Phys Med Rehabil.* 2002;83:683-691.
35. O'Sullivan SB, Schmitz TJ. *Physical Rehabilitation.* Fifth Edition. Philadelphia: F.A. Davis Company; 2007.

36. Hesse S, Werner C, vonFrankenberg S, Bardeleben A. Treadmill training with partial body weight support after stroke. *Phys Med Rehabil Clin N Am*. 2003; 14(1 Suppl):S111-23.
37. Munoz-Cespedes JM, Rios-Lago M, Paul N, Maiestu F. Functional Neuroimaging studies of cognitive recovery after acquired brain damage in adults. *Neuropsychology Review*. 2005;15(4): 169-183.
38. Whishaw IQ. Loss of the innate cortical engram for action patterns used in skilled reaching and the development of behavioral compensation following motor cortex lesions in the rat. *Neuropharmacology*. 2003;39:842-51.
39. Taub E, Uswatte G, Pidikiti R. Constraint-induced movement therapy: a new family of techniques with broad application to physical rehabilitation-a clinical review. *J of Rehab Res*. 1999;38(3):237-251.
40. Musicco M, Emberti L, Nappi G. Early and long-term outcome of rehabilitation in stroke patients: the role of patient characteristics, time of initiation, and duration of interventions. *Arch Phys Med Rehabil*. 2003;84(4):551-558.
41. Pohl M, Mehrholz J, Ritschel C, Ruckriem S. Speed-dependent treadmill training in ambulatory hemiparetic stroke patients: a randomized controlled trial. *Stroke*. 2002;33(2):553-558.
42. Gordon WA, Mann N, Willer B. Demographic and social characteristics of the traumatic brain injury model system database. *J Head Trauma Rehabil*. 1993;8(2):26-33.
43. Hesse S, Schmidt H, Werner C. Machines to support motor rehabilitation after stroke: 10 years of experience in Berlin. *J Rehabil Res Dev*. 2006;43(5):671-678.

44. Hawley CA, Taylor R, Hellowell DJ, Pentland B. Use of the functional assessment measure (FIM+FAM) in head injury rehabilitation: a psychometric analysis. *J Neurol Neurosurg Psychiatry*. 1999;67(6):749–754
45. Bajo A, Hazan J, Fleminger S, Tay R. Rehabilitation on a cognitive behavioural unit is associated with changes in FAM, not FIM. *Neuropsychol Rehabil*. 1999; 9(3/4):413-419.

Table 1. Demographic Information Experiment and Control Groups

Experimental Group						
Subject	Gender	Initial ambulation status	Age	Time since post injury (days)	Paretic side	Race
1	0	0	28	29	2	0
2	1	0	21	30	0	0
3	0	1	51	32	2	0
7	0	0	28	22	0	0
8	0	0	61	30	0	0
10	1	0	19	44	3	0
14	0	0	30	43	1	0
15	0	0	33	78	3	0
16	0	0	29	61	0	0
17	0	0	47	54	3	0
23	0	0	50	25	0	0
24	1	0	24	109	1	0
Control Group						
Subject	Gender	Initial ambulation status	Age	Time since post injury (days)	Paretic side	Race
4	1	0	20	103	2	0
5	0	0	20	24	2	0
6	0	0	22	67	3	0
9	0	0	48	23	1	0
11	0	0	48	32	2	0
12	0	0	81	33	1	0
13	0	0	28	44	2	0
18	1	0	19	30	1	0
19	0	0	22	43	1	0
20	0	0	71	12	3	0
21	0	0	20	26	1	0
22	0	0	39	55	1	0
25	1	0	19	107	3	0
26	1	0	43	29	3	0
27	0	0	54	59	1	0

*Gender-0=male, 1=female
 *Initial Ambulation status - 0=low, 1=high
 *Paretic side- 0=right, 1=left, 2=bilateral, 3=Not Applicable
 *Race - 0=Caucasian

Table 2. Pretest and Posttest Values for the Experimental and Control Groups

Experimental Group								
Subject	Pre3min (feet)	Pre5meter (m/s)	Prestride length differential (cm)	PreFIM	Post3min (feet)	Post5meter (m/s)	Poststride length differential (cm)	PostFIM
1	87	0.12	12.67	19	68	0.18	0.05	41
2	32.6	0.51	2.55	28	460	0.83	3.9	71
3	148	0.34	0.05	39	388	0.84	2.41	79
7	28	0.22	2.36	16	478	1.13	1.45	64
8	29	0.07	1.33	22	297	0.57	0.79	66
10	58	0.18	2.83	14	400	0.64	0.66	32
14	0	0	*	21	17	0.07	*	35
15	1	0	*	23	10	0.02	*	29
16	1	0	*	16	67	0.25	*	27
17	0	*	*	15	57	0.27	*	24
23	87	0.34	2.28	23	87	0.34	2.63	50
24	7.2	0.01	*	33	8	0.03	22.2	28
Control Group								
Subject	Pre3min (feet)	Pre5meter (m/s)	Prestride length differential (cm)	PreFIM	Post3min (feet)	Post5meter (m/s)	Poststride length differential (cm)	PostFIM
4	10	0.02	*	22	97	0.22	3.04	32
5	54	0.25	3.59	15	595	1.3	0.8	71
6	48	0.16	19.53	16	200	0.65	14.11	33
9	0	0		15	287	0.53	1.06	34
11	51	0.16	1.52	14	300	0.84	0.94	57
12	62	0.15	0.63	26	356	0.67	1.88	69
13	25	0.09	3.56	14	452	1.26	2.75	48
18	158.4	0.29	0.2	25	477	1.13	1.5	63
19	22	0.07	*	30	357	1.06	3.37	54
20	27	0.06	0.23	22	*	*	*	46
21	161	0.77	3.35	31	678	1.66	0.69	72
22	123	0.77	0.29	28	510	1.1	3.67	47
25	3.5	*	*	14	24	0.06	*	*
26	*	*	3.88	23	576	0.92	0.74	39
27	7	0.09	3.28	22	113	0.39	2.3	44

* = Missing Data

	Pre3min (feet)	Pre5meter (m/s)	Prestride length differential (cm)	PreFIM	Post3min (feet)	Post5meter (m/s)	Poststride length differential (cm)	PostFIM
Experimental Group	39.9	0.16	3.44	22.42	194.75	0.43	4.26	45.5
Standard Deviation for Experimental Group	± 46.8	± 0.17	± 4.18	± 7.63	± 191.67	± 0.37	± 7.36	± 19.66
Control Group	53.71	0.22	3.64	21.13	358.71	0.84	2.83	50.64
Standard Deviation for Control Group	± 55	± 0.26	± 5.49	± 6.11	± 201	± 0.45	± 3.55	± 14.06

Results of MANOVA			
	Value	F Value	P Value
Wilk's Lambda	0.693	1.771	0.184
Logistic Regression Analysis Significance			
	Chi-square	df	Significance
Model	0.667	2	0.716

	3 Minute Walk Test	5 Meter Walk Test	Stride Length Differential	FIM
Control Group	0.001	0.002	0.333	0.001
Experimental Group	0.01	0.005	0.612	0.003

APPENDIX A. Motor Subset of Functional Independence Measure

Rating Scale:

Independent

- 7. Complete Independence (timely, safely)
- 6. Modified Independence (extra time, devices)

Moderate Dependence

- 5. Supervision (cuing, coaxing, prompting)
- 4. Minimal Assist (patient performs 75% of more of task)
- 3. Moderate Assist (patient performs 50%-74% of task)

Complete Dependence

- 2. Maximal Assist (patient performs 25% to 49% of task)
- 1. Total Assist (patient performs less than 25% of task)

Scored Items:

Self Care Items:

- A. Eating
- B. Grooming
- C. Bathing
- D. Dressing Upper Body
- E. Dressing Lower Body
- F. Toileting

Sphincter Control

- G. Bladder Management
- H. Bowel Management

Transfers

- I. Bed, Chair, Wheelchair
- J. Toilet
- K. Tub, Shower

Locomotion

- L. Walk/Wheelchair
- M. Stairs

APPENDIX B. Handout of acceptable conventional physical therapy treatments

Treatment Ideas for Pregait and Gait Activities for Research Patients:

1. Tilt Table
2. Standing Frame
3. Standing at High Low Mat or Raised Table for UE Support
4. Standing in Parallel Bars
5. Work in Parallel Bars on Weight Shifting Activities, all directions
6. Work in Parallel Bars in staggered stance position, or stepping activities
7. Work outside of Parallel bars, with mat or wheelchair behind them for weight shifting and or stepping activities, with or without an assistive device
8. Balance Master for weight shifting activities
9. Ambulation with or without an assistive device, including hand hold assist, buddy style, shopping cart, walker, cane, etc.
10. Gait training with patient towards least restrictive assistive device and working to decrease gait deviations
11. Work with patient to increase distance, increase speed and fluidity of gait
12. Uneven surfaces, including stairs

If a patient is able to ambulate, even minimally, the training session should not exclusively include the tilt table or standing frame, and needs to include some pregait and gait activities.
