Online Journal Club-Article Review Brain Injury SIG July 2013

Background/Overview	
Article Citation	Esquenazi A, Lee S, Packel AT, Braitman L. A randomized comparative study of manually-assisted versus robotic-assisted body weight supported treadmill training in persons with a traumatic brain injury. PM R 2013; 5(4):280-90.
Study Objective/Purpose (hypothesis)	(1) To compare the effects of robotic-assisted treadmill training (RATT) and Manually-assisted treadmill training (MATT) in participants with traumatic brain injury (TBI) and (2) to determine the potential impact on the symmetry of temporal walking parameters, 6-minute walk test, and the mobility domain of the Stroke Impact Scale, version 3.0 (SIS)
Brief Background (why issue is important; summary of previous literature)	Persons with TBI may experience a wide range of activity and participation limitations and for many, the barriers are particularly related to mobility. Many rehabilitation paradigms have been developed to promote recovery of lower extremity function and walking through task specific training. Although mixed evidence exists supporting the effectiveness of both MATT and RATT in other patient populations, no literature has been reported that compares the effectiveness of RATT and/or manually assisted treadmill training (MATT) in subjects with a TBI.
Methods	
Study Design (type of trial, randomization, blinding, controls, study groups, length of study, follow-up)	Randomized prospective study; 16 subjects with TBI, 8 were randomly assigned to the RATT group and 8 were randomly assigned to the MATT group.
Target Population (dx, acuity, inclusion/exclusion criteria)	Sixteen participants with chronic limitations in ambulation resulting from a TBI were recruited. Participants were at least 18 years of age and had sustained a TBI more than 12 months before the study began. Participants were able to ambulate at a self-selected velocity (SSV) of between 0.2 m/s and 0.6 m/s. If needed, braces (ankle/foot or knee orthoses) or upper extremity assistive devices (eg, canes or walkers) were used. All 16 participants had a cardiorespiratory status and medical stability sufficient to tolerate aerobic exercise for inclusion in the study.

Interventions (if applicable): (specificity of interventions, ability to replicate, frequency, duration)	Participants for both training groups received 18 sessions of training during a 6- to 8-week period. Participants were seen an average of 3 times per week for sessions of 60-75 minute durations. The time spent on actual locomotor activity (RATT or MATT) was 45 minutes per session. Participants were supported 10 to 20% of their body weight and this amount was reduced across time however the manner in which this was done was not standardized. All participants began their locomotor training with speeds set at their self-selected velocity (SSV). Every third sessions, both SSV and maximal velocity (MV) were reassessed. Subsequent training speeds were increased in a standardized manner, based on the reassessment findings. Standardized verbal encouragement was provided every 6 minutes throughout the training. Overall, the interventions were highly specific to the motor act being studied and the protocol offers good replicability.
Outcome Measures (relevant to purpose of the study; reliable, valid, clinical utility)	<u>Primary Measures:</u> • Self-selected Velocity (SSV) and maximal velocity (MV) collected via a 4-m electronic gait mat. Both measures have been studied in the target population and found to be reliable. Both also have good clinical utility. <u>Secondary Measures:</u> • Walking endurance (6 Minute Walk Test) has been studied found to be both valid and reliable. • The mobility domain of the Stroke Impact Scale (SIS version 3.0) was used to measure the impact of mobility deficits on participation. The SIS has not been validated for this population and no other psychometric information is available for subjects with TBI. • Three-dimensional gait analysis was performed to collect kinematic and spatiotemporal data to determine joint motion symmetry using participants' SSV. Changes in step-length asymmetry ration and single-support asymmetry ration were recorded for analysis. This measure has much less clinical utility and informs clinical decisions to a smaller degree that the other measures chosen. All measures were collected at an initial baseline sessions and post-intervention.

Statistical Analysis (statistics used, appropriate application)	Changes in outcomes from before to after training were assessed using Wilcoxon signed-rank tests for each training method (within groups). The Wilcoxon rank-sum test was used to compare changes from before to after training (between groups). Effect sizes and percent change were calculated to determine whether a statistically significance difference was of practical importance.
Results	
Enrollment/Subject Characteristics (sample size, gender, age, functional level; were groups similar on important variables prior to application of the intervention)	The mean age was 37 years (range, 24-58 years) for the RATT group and 42 years (range, 24-69 years). Five women were enrolled in the RATT group and 4 in the MATT group. Mean time since injury (months) were 140.3 and 150.4 for the RATT and MATT respectively. There appeared to be no significant differences between groups for any of the important subject characteristics recorded.
Summary of Primary and Secondary Outcomes (include aggregate and sub-group findings if reported); note results that were statistically significant; How many reached a level of clinical significance (exceed MCID if known); Was there retention of changes following intervention (if studied)	<u>Primary Outcomes</u>: No statistically significant differences were noted between groups for either SSV or MV. Within group comparisons showed a significant increase in SSV for the robotic group (*P* = .01). The authors report that both groups produced significant increases in MV [MV in the MATT group (*P* = .01, effect size 0.92) and the RATT group (*P* = .06, effect size 0.38)] however the p-value reported for the RATT group was actually greater than the threshold established for the study. Results for these primary measures were not discussed in terms of known MCD or MCID. Incorporating the values for MCID established by vanLoo and Moseley,[1] only the robotic group exceeded MCID for SSV and neither group exceeded MCID for MV. <u>Secondary Outcomes:</u> No significant between-group differences were found for joint motion symmetry data. Within group comparisons showed a significant decrease in average step-length asymmetry for the robotic group (*P*=.01) only. The single-support asymmetry ratio increased at SSV for both groups, but neither reached significance. The 6MWT and self-perceived assessment of function did not reveal statistical significance for between-group differences. Within group comparisons showed a significant increase walking endurance for the MATT (*P*=.03) and an insignificant increase in endurance for the RATT group.
Authors' Discussion and Conclusions	
Brief Summary of Authors' Main Discussion	The authors acknowledge that comparable studies in patients with TBI are scarce and, as such, they

Points; Authors' Conclusion	drew from published evidence with other populations to support the study's findings. Their overall impression was that improvements in gait speed, symmetry, distance, and self-perceived assessment of function occurred similarly in the training modes. Regarding the SIS, the authors report that, "participants in our study exceeded both the minimally detectable change and the minimally clinical important difference for the mobility domain as defined by Lin et al [68]." The study referenced included only subjects with stroke and, to my knowledge, the SIS has not been validated for clients with TBI. As such, we do not know what constitutes MDC or MCID for this population.
Reviewer's Discussion and Conclusion	
Study Strengths	Randomized prospective methodology; standardization of protocol between training conditions, although the authors acknowledge that their inability to control certain variables (e.g., the time between the baseline assessment and first training sessions) as limitations.
Study Limitations and Potential for Bias	Interventions and outcome assessments were not performed in a blind manner. Available MDC and MCID values for some measures were either not incorporated in the analysis or were reported from other populations. We often carryover outcome measure psychometrics from different but similar populations, but it must be done in an equitable manner. For example, much in the same way the authors borrowed SIS properties from studies conducted on subjects with stroke, the authors could have incorporated data published on the 6MWT from similar, post-stroke studies.[2,3] Doing so, the reader would interpret that neither RATT nor MATT produced changes in gait endurance that approached MDC levels. The study size was rightly noted as a limitation by the authors. They also correctly suggest that, "The results of this study provide a basis for a larger clinical trial designed to provide more definitive results."
Applicability: • Types of patients (dx) that results apply to • Types of settings or patient acuity that the results apply to • Can interventions be reproduced? Can results be applied to other pt populations?	The results of this study apply to clients with chronic TBI having severely impaired gait abilities. The settings most likely to apply these findings to similar clients are outpatient and day rehabilitation. The ability to implement robotic locomotor training or to attempt to reproduce the study's findings will be limited by the availability of a robotic locomotor training system.

How will study results impact PT management of this patient population?; List suggestions for how to implement changes in your clinic/department to integrate study findings into patient care	The findings of this study will not have a direct impact on most facilities treating the TBI population given the technology limitations noted above. Expanding this line of research, however, could be useful in further elucidating the different advantages of the two types of locomotor training in question. Additionally, larger studies may help shed light on important motor learning topics such as motor adaptation and variability of training.

References:

1. van Loo, M. A., Moseley, A. M., et al. (2004). "Test-re-test reliability of walking speed, step length and step width measurement after traumatic brain injury: a pilot study." Brain Inj 18(10): 1041-1048. Find it on PubMed

2. Eng, J. J., Dawson, A. S., et al. (2004). "Submaximal exercise in persons with stroke: test-retest reliability and concurrent validity with maximal oxygen consumption." Arch Phys Med Rehabil 85(1): 113-118. Find it on PubMed
3. Flansbjer, U. B., Holmback, A. M., et al. (2005). "Reliability of gait performance tests in men and women with hemiparesis after stroke." J Rehabil Med 37(2): 75-82. Find it on PubMed