2023 45th Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC) | 979-8-3503-2447-1/23/$31.00 ©2023 IEEE | DOI: 10.1109/EMBC40787.2023.10340452

Intensity Modulated Exoskeleton Gait Training Post Stroke

Karen J. Nolan, Member, *IEEE*, Gregory R. Ames, Christina M. Dandola, Joshua E. Breighner, Sharon Franco, Kiran K. Karunakaran, Member, *IEEE*, Soha Saleh, Member, *IEEE*

***Abstract*— Stroke is a leading cause of long-term disability. While major advances have been made in early intervention for the treatment of patients post stroke, the majority of survivors have residual mobility challenges. Recovery of motor function is dependent on the interrelationship between dosing, intensity, and task specific practice applied during rehabilitation. Robotic exoskeleton (RE) based gait training utilizes progressive repetitive task-oriented movements to promote functional recovery. The purpose of this investigation was to demonstrate the utilization of intensity modulated exoskeleton gait training on functional outcomes and walking speed post stoke. Preliminary data is presented for individuals diagnosed with stroke who received RE gait training. The intensity modulated RE gait training was delivered by a physical therapist and participants trained at 75-85% of calculated max heart rates at each session, over 10 weeks (30 sessions). After 10 weeks of training participants increased walking speed (10 meter walk test) and functional measures (timed up and go, berg balance assessment, dynamic gait index and functional ambulation category). These preliminary results demonstrate the utilization of intensity modulated gait training for improved functional ambulation and motor recovery using a robotic exoskeleton overground gait training post stroke.**

***Clinical Relevance*— Preliminary data provides initial evidence for intensity modulated exoskeleton gait training as a therapeutic intervention post stroke. More research is needed to demonstrate the potential relationships between intensity based gait training, exoskeletons and improved functional ambulation in post stroke rehabilitation.**

I. INTRODUCTION

Stroke is a leading cause of long-term disability. While major advances have been made in early intervention for the treatment of patients post stroke, the majority of survivors have residual mobility challenges [1]. Post stroke gait rehabilitation involves relearning gait and balance skills required for independent ambulation. Though conventional physical therapy results in improvements in ambulation post stroke, high intensity, high dose training, has been suggested to promote walking recovery and neuroplasticity. Recovery of motor function is dependent on the interrelationship between dosing, intensity [2], and task specific practice [3] applied during rehabilitation. Recent research suggests maximizing the amount of task-specific (walking) practice, particularly at higher cardiovascular intensities up to 75-85% calculated maximum heart rate, may result in superior gains in locomotor capacity and performance [4]. Throughout the rehabilitation landscape, we need to find effective modalities to deliver individualized high-intensity rehabilitation for gait training. Lower extremity exoskeletons are currently being utilized for stroke gait rehabilitation and recent research has demonstrated improvements in functional recovery [5, 6, 7, 8]. Robotic exoskeletons (REs) are electromechanical devices that provide assistance as needed by the user to ambulate while providing stability and balance. REs provide the user with consistent, and goal-directed repetition of movement [9, 10]. In addition, REs also have the potential to provide increased number of steps in a session (dosing) as well as intensity (heart rate) in a consistent and controlled training environment, which is ideal to induce neuroplasticity [6, 11]. Previous research in stroke motor rehabilitation has demonstrated that increasing the dosing and intensity is a critical variable of rehabilitation interventions that can facilitate plasticity of neuromuscular system and result in improved locomotor function [12]. REs may provide an additional modality to provide more intensive, repetitive, and task-oriented training than it would be possible with the conventional overground walking alone [5, 8]. Therefore, the purpose of this investigation was to demonstrate the utilization of intensity modulated exoskeleton gait training on functional outcomes and walking speed post stroke.

II. METHODS

A. Participants

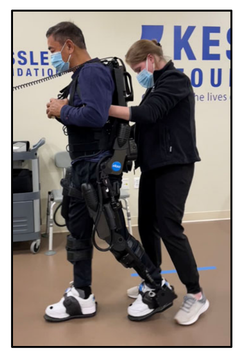

Figure 1: Participant completing RE gait training session.

Individuals (n=2) diagnosed with acute stroke (<30 days), and unilateral hemiplegia were recruited for participation (Table I). Participants had no: (1) history of injury or pathology (unrelated to their stroke) to the unaffected limb; (2) skin issues that would prevent wearing the device; (3) pre-existing condition that caused exercise intolerance; (4) hospitalization for heart attack, heart surgery or acute heart failure (< 3 months); (5) uncontrolled seizure disorder; or (6) neuromuscular, neurological or orthopedic pathologies that would interfere with neuromuscular function, ambulation or limit range of motion of the lower limbs. Participants had to physically fit into the RE device (height between 1.5 and 1.8m; weight <99.7 kg). The Fugl-Meyer assessment was completed as a measure of lower extremity motor function during the baseline visit; participant RE-A had

* Research supported by the NIH R01 NICHD -1R01HD099200-01,

K. J. Nolan, K. K. Karunakaran, and S. Saleh are with Kessler Foundation (KF), West Orange, NJ & Rutgers-NJMS, Newark, NJ. (Corresponding author phone: 973-324-3544; email: knolan@kesslerfoundation.org).

G.R. Ames, and S. Franco are with KF, West Orange, NJ. C.M. Dandola is with KF and Kessler Institute for Rehabilitation (KIR), West Orange, NJ. J. E. Breighner is with KIR, West Orange, NJ.

an initial Fugl-Meyer score of 28 and RE-B had a score of 33.

Data from this investigation is part of a larger randomized clinical trial and preliminary data is presented. All procedures performed in this investigation were approved by the Human Subjects Review Board and informed consent was obtained prior to participation in the study. All participants continued their prescribed outpatient therapy during this period.

TABLE I. PARTICIPANT DEMOGRAPHICS

Condition	*Gender*	*Age at Consent (years)*	*Time Since Stroke (days)*	*Weight (kgs)*	*Height (m)*	*CMH (bpm)*	*Target HR (bpm)*
RE- A	M	60	24	58.5	1.57	166	125-141
RE- B	F	55	16	77.4	1.57	170	127-144

B. Overground Gait Training

Intensity modulated RE gait training was provided to participants by a licensed physical therapist using a commercially available FDA approved robotic exoskeleton (EksoNR, Ekso Bionics, Inc. Richmond, CA, USA). During gait training sessions the physical therapist adjusted the RE control strategies (Figure 2) in real time to modify robotic control and assistance to increase participant effort and modulate intensity (measured by heart rate). The RE allowed patient-driven volitional movement of both limbs but sufficient guidance and support was still provided by the RE to ensure successful walking [12]. The physical therapist was able to modify the RE control strategy as well as change the direction of walking (side stepping or backwards walking) to modulate intensity.

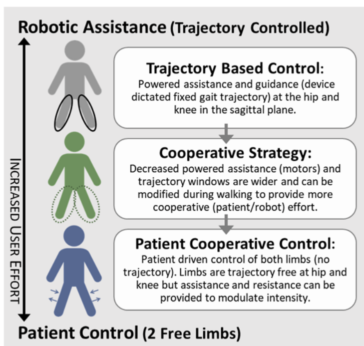

Figure 2: Training paradigm for modulating intensity utilizing RE control strategies.

Participants received gait training three days per week (30 minutes per session) for 10 weeks (total of 30 sessions). The intensity of training was continuously adjusted throughout each session to target 75-85% of the participant's individually calculated maximum heart rate (CMH). Intensity for the purposes of this investigation was measured by heart rate using an optical based monitor (photoplethysmography) (Polar OH1, Polar USA, Lake Success, NY, USA) attached to the biceps and sampling at 1 Hz. The physical therapist was able to view real time feedback of the participant's heart rate on a tablet computer to modulate intensity. Heart rate data was recorded using an Android App (MyWorkouts, version 1.6.2, Aduilio Eduardo da Silva, Brazil). CMH was determined for each participant using either equation 1 or 2.

$$\begin{gathered}Calculated\ Max\ Heart\ Rate\ was\ computed\ as\ follows: \\ 207 - 0.7 * Age = CMH\ beats\ per\ minute\ (bpm) \quad \text{----- (1)}\end{gathered}$$

$$\begin{gathered}Calculated\ Max\ Heart\ Rate\ for\ indivduals\ taking\ beta \\ - blocker\ medication\ was\ computed\ as\ follows: \\ 164 - 0.7 * Age = CMH\ beats\ per\ minute\ (bpm) \quad \text{----- (2)}\end{gathered}$$

C. Data Collection

Functional walking assessments were completed at baseline and follow up (10 weeks post training). All assessments were performed without RE. Outcome measures for functional ambulation included:

- *Walking speed* (10 meter walk test, 10MWT) – a performance measure of functional mobility, provides a measure of walking speed in meters/second (m/sec). The instructions for this assessment included walking as fast as possible, safely, to complete the test.
- *Timed up and go* (TUG) – a measure of gait and balance dysfunction and locomotor performance; participants rise from a chair, perform a 3-meter walk, and return to a seated position, the time to complete the task is recorded (sec).
- *Berg balance assessment* (BBA) – a task performance test of static and dynamic balance consisting of 14 items of increasing difficulty graded on a five-point ordinal scale of 0 to 4 (maximum score is 56).
- *Dynamic gait index* (DGI) – a performance measure that assesses the ability to modify balance while walking in the presence of external demands (maximum score is 24).
- *Functional Ambulation Category* (FAC) – an observed measure of functional mobility and gait. Walking ability is rated on a scale from 0 (cannot walk) to 5 (independent ambulatory).

D. Data Analysis

Intervention Session Data

A) *Mean Heart Rate Progression* was calculated from continuous heart rate data throughout each training session. Mean heart rate data (bpm) per session was plotted across 30 sessions and the individualized target intensity zone (75-85% of the participants individual CMH) was indicated as a reference.

B) Gait Speed Progression (m/sec) was computed from a 10MWT test at the beginning of each training session (without the RE device). This measurement was used as an indication of the trajectory of gait speed changes throughout the intervention and plotted over 30 sessions.

C) Total Step Count was quantified at each intervention session using a wireless insole measurement system (Loadsol, Pedar USA, Saint Paul, Minnesota) and included the number of steps while walking in RE.

Functional Ambulation Measures

Comparisons were made from baseline to follow up to measure changes in walking speed, functional ambulation and motor recovery using intensity modulated robotic exoskeleton as well as standard of care overground gait training post stroke.

III. RESULTS

Preliminary data is presented for two participants diagnosed with stroke and unilateral hemiplegia who received intensity modulated RE gait training (30 sessions over 10 weeks) delivered by a physical therapist.

A. *Mean Heart Rate Progression*

Participants were able to train within 75-85% of calculated max heart rates throughout the 30 training sessions (Figure 3). Participant RE-A was able to reach the target HR zone and train at or above the target range for 100% of the training sessions. Participant RE-B was able to reach the target zone and train at or above the target range for 86% of the training sessions. Participant RE-B only missed training in the target zone in 4 sessions. Overall participants were training in the target HR zone for approximately 40% of each 30 minute session throughout the 10 weeks (30 sessions).

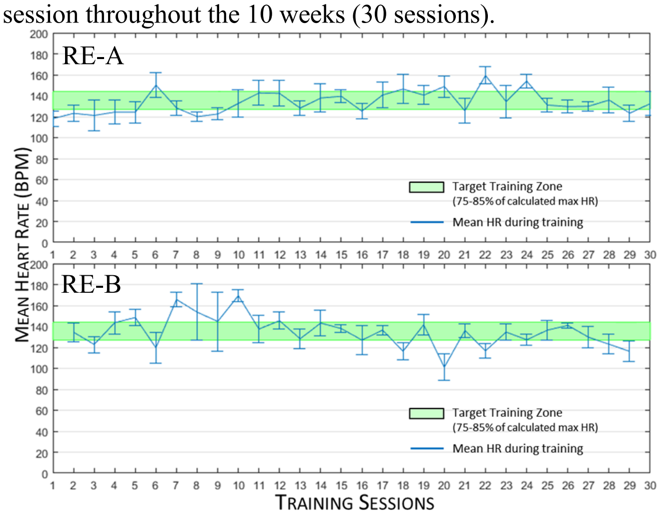

Figure 3: Mean heart rate progression (and standard deviations) across 30 intensity modulated exoskeleton gait training sessions.

B. *Gait Speed Progression*

Walking speed (10MWT) increased from session 1 to session 30 for both participants (Figure 4). Although there was some session-to-session variability, walking speed trajectory progressively increased from session 1 to session 30 over the 10 weeks of training. Participant RE-A reached a maximum walking speed of 1.9 m/sec and participant RE-B had a maximum walking speed of 2.1 m/sec. After 30 sessions of walking participant RE-A increased their walking speed 0.74 m/sec and participant RE-B increased their walking speed 1.0 m/sec, both meeting the MCID criteria for a meaningful change in walking speed.

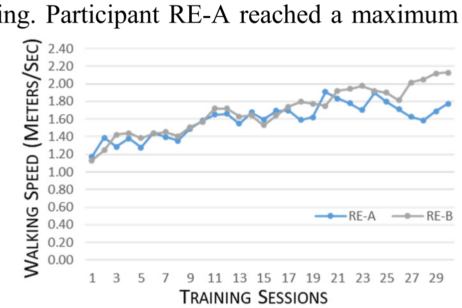

Figure 4: Total step count at session 1 and session 30 for both participants.

C. *Total Step Count*

Participants increased the number of steps per session from session 1 to session 30 (Figure 5). Participant RE-A increased by 1014 steps and participant RE-B increased by 510 steps, which is a 71.9% and 25.4% increase in steps per session respectively.

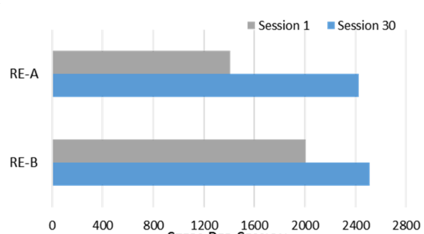

Figure 5: Total step count at session 1 and session 30 for both participants.

D. *Functional Ambulation*

After 10 weeks of training participants increased motor function and improved overall functional ambulation as measured by increases in walking speed (10MWT) and improvements in functional measures (TUG, BBA, DGI and FAC). Measures of functional ambulation TUG, 10MWT, BBA, DGI and FAC at baseline and follow-up (post 10 weeks of gait training) post stroke are presented in Table II.

TABLE II. Measures of Functional Ambulation Post Stroke.

Subject		***10MWT (sec)***	***TUG (sec)***	***BBA***	***DGI***	***FAC***
RE - A	**pre**	8.01	10.00	50	20	3
	post	5.76	7.82	53	23	5
RE - B	**pre**	8.03	11.46	47	16	3
	post	5.52	9.45	54	24	5

IV. Discussion

Wearable robotic exoskeletons for overground walking provide task specific, high repetitive practice for individuals with acute and chronic stroke [7, 8, 13]. Wearable robotic exoskeletons in stroke rehabilitation can provide patient-driven, volitional movement of both limbs as well as some degree of guidance/support provided by the RE to ensure successful walking [12]. Intensity modulated exoskeleton gait training was delivered by a physical therapist during the acute stage of recovery. The goal of the gait training sessions were to achieve high cardiovascular intensities, measured by real time heart rate measurements (bpm) during overground walking. Participants were able to train within the target training zone (75-85% of calculated max heart rates) throughout the 30 training sessions over 10 weeks. The physical therapist was able to modulate gait training intensity using RE control strategies and feedback from real time HR information. The physical therapist modified robotic control and assistance/resistance during walking sessions to increase participant effort and intensity. Modulating the RE control strategy can provide variations in training intensity (e.g., walking speed and HR) but also provides the ability to increase or decrease the assistance and resistance to modulate training intensity. Increasing the amount of cardiovascular intensity during gait training throughout stroke rehabilitation may lead to improvements motor recovery and improved functional ambulation [4].

Recovery of motor function is dependent on the interrelationship between dosing, intensity [2], and task specific practice [3] applied during rehabilitation. In the current investigation, overground gait training at a high intensity resulted in improved functional ambulation. Walking speed continuously improved throughout the 30 weeks of the intervention and both participants reached a peak walking speed of over 1.9 m/sec. The minimal clinically important difference (MCID) scores for walking speed post stroke range from a small meaningful change of 0.06 m/sec and a large meaningful change score of 0.10–0.16 m/sec. The MCID is a commonly used criterion to evaluate the clinical significance of an intervention. After 30 sessions of walking overground in the RE individuals increased their walking speed 0.74 m/sec and 1.0 m/sec respectively, both meeting the MCID criteria for a meaningful change in walking speed [14]. Walking speed is an indicator of community ambulation and community participation.

Step count has previously been used as a measure of gait rehabilitation dosing, increasing the dosing during motor rehabilitation is a critical variable for interventions that can facilitate plasticity of neuromuscular system and result in improved locomotor function [11, 15]. Total step count increased for both participants throughout the 10 weeks of intensity modulated gait training and participants took an average of 1,938 steps per session in the RE. Previous research reported individuals post stroke averaging only 250-500 steps per session and trained at 30-50% of calculated max heart rate during acute and sub-acute gait rehabilitation. Increasing the number steps (dosing) at higher cardiovascular intensities (HR) may facilitate plasticity of the neuromuscular system and result in improved locomotor function [4].

Gait training at high intensity with RE, with increased step counts may have resulted in improved functional ambulation and decreased motor impairment. Individuals improved balance post RE intervention (BBA) which indicates a decrease in fall risk. Post training individuals also improved their ability to modify balance while walking in the presence of external demands (DGI). Participants met the MCID criteria for a meaningful clinical change in DGI score of 0.6 points [16]. The TUG score correlates with balance, gait speed, and functional capacity and is a widely used reliable measure of physical mobility. Participants improved their performance on the TUG after 30 weeks of training (decreased the time to complete the test) and met the minimal detectable change (MDC) of 2.9 seconds [17].

The FAC is a functional walking test that evaluates ambulation ability. This 6-point scale assesses ambulation status by determining how much human support the patient requires when walking. Individuals in the current investigation went from an ambulatory dependent on supervision to an independent ambulator. The FAC increased from 3 to 5 for both participants after intensity modulated RE training. Previous research has demonstrated improvements in FAC after RE utilization post stroke [18].

The limitations of the current investigation are the small sample size and acute stroke participants that were independent ambulators with residual mobility impairments. More research is needed in a larger sample with individuals with varying levels of impairment to fully understand how to use robotic exoskeletons to modulate intensity and dosing to maximize functional recovery.

V. Conclusion

Gait training at high intensity and dosing may have resulted in improved functional ambulation and decreased motor impairment during RE gait training. Intensity or dose meaningfully impacts functional mobility recovery post stroke. Our results are in accordance with previous research that increased dosing also results in improved motor function. These preliminary results are the first to demonstrate intensity modulated exoskeleton gait training post stroke using RE control strategies and feedback from real time HR information. More research is needed to demonstrate the potential relationship between intensity based gait training and improved functional ambulation in rehabilitation medicine.

References

[1] Tsao, C. W., et al. Stroke Statistics, (2023). Heart Disease and Stroke Statistics-2023 Update. Circulation, 147(8), e93-e621.

[2] Hornby, T. G., Moore, J. L., et al. (2016). Influence of skill and exercise training parameters on locomotor recovery during stroke rehabilitation. Curr. Opin. Neurol. 29, 677– 683.

[3] Krishnan, C., et al. (2019). Learning new gait patterns is enhanced by specificity of training rather than progression of task difficulty. J. Biomech. 88, 33–37.

[4] Henderson CE, Plawecki A, et al. Increasing the Amount and Intensity of Stepping Training During Inpatient Stroke Rehabilitation Improves Locomotor and Non-Locomotor Outcomes. Neurorehabilitation and Neural Repair. 2022;36(9):621-632.

[5] Nolan KJ, Karunakaran KK, et al.. Robotic exoskeleton gait training during acute stroke inpatient rehabilitation. Front Neurorobot. 2020;14:581815.

[6] Yoo, H., Bae, C. R, et al. (2023). Clinical efficacy of overground powered exoskeleton for gait training in patients with subacute stroke: A randomized controlled pilot trial. Medicine, 102(4), e32761.

[7] Molteni, F., et al. (2021). Gait recovery with an overground powered exoskeleton: a randomized controlled trial on subacute stroke subjects. Brain Sci. 11, 1–14.

[8] Nolan, K. J., Karunakaran, K. K., et al. (2021). Utilization of Robotic Exoskeleton for Overground Walking in Acute and Chronic Stroke. Front Neurorobot, 15, 689363.

[9] Louie, D. R. and Eng, J. J., "Powered robotic exoskeletons in post-stroke rehabilitation of gait: A scoping review," *Journal of NeuroEngineering and Rehabilitation*. 2016.

[10] Dollar, A. M. and Herr, H., "Lower Extremity Exoskeletons and Active Orthoses:Challenges and State-of-the-Art," *IEEE Trans. Robot.*, vol. 24, no. 1, 144–158, 2008.

[11] Lang, C. E., Lohse, K. R., and Birkenmeier, R. L. (2015). Dose and timing in neurorehabilitation: prescribing motor therapy after stroke. Curr. Opin. Neurol. 28, 549–555.

[12] Bruni MF, Melegari C, et al. What does best evidence tell us about robotic gait rehabilitation in stroke patients: a systematic review and meta-analysis. J Clin Neurosci. (2018) 48:11–7.

[13] Karunakaran, K. K., et al. (2021). Effect of robotic exoskeleton gait training during acute stroke on functional ambulation. NeuroRehabilitation, 48(4), 493-503.

[14] Perera, S. et al., (2006). Meaningful change and responsiveness in common physical performance measures in older adults. J of the American Geriatrics Society, 54(5), 743-749.

[15] Hornby, T. G., et al., (2015). Feasibility of Focused Stepping Practice During Inpatient Rehabilitation Poststroke and Potential Contributions to Mobility Outcomes. Neurorehabilitation and Neural Repair, 29(10), 923-932.

[16] Pardasaney, P. K., et al., (2012). Sensitivity to change and responsiveness pf four balance measures for community-dwelling older adults. Phys Ther. 92(3), 388-397.

[17] Flansbjer U. B., et al., (2005). Reliability of gait performance tests in men and women with hemiparesis after stroke. J Rehabil Med., 37(2), 75-82.

[18] Goffredo, M et al. (2019) Overground Wearable powered exoskeleton for gait training in subacute stroke subjects: Clinical and gait assessments. Eur. J. Phys. Rehabil. Med. 55, 710–721