THE EFFECT OF A NOVEL REHABILITATION PROGRAM ON WALKING PERFORMANCE IN PERSONS WITH MULTIPLE SCLEROSIS

Alyssa J. Rebensburg[1], Olivia D. Perrin[1], Ine Mylle[1], Cathy Ruprecht[2], Lynn Vanwelsenaers[3], Kim Spranger[2], Randall L. Jensen[1] and Sarah Breen[1]

School of Health & Human Performance, Northern Michigan University, Marquette, USA[1]
Upper Peninsula Health System Rehab Services, Marquette/Gwinn, USA[2]
Teter Orthotic and Prosthetic, Marquette, USA[3]

The current study examined the effects of the NewGait™ device on walking performance in persons with multiple sclerosis (MS). Eight MS patients participated in this study. Pre- and post-testing assessed kinematic gait variables (step width, length, and speed), ankle range of motion, and rating of perceived exertion (RPE). Participants completed an 8-week physical therapy (PT) protocol aimed to improve gait and balance, with the experimental group wearing the NewGait™ device. Repeated measures mixed ANOVA showed no main effects between the gait variables or between groups. Post-hoc paired t-tests indicated that the NewGait™ device elicited meaningful change in left and right step length and speed. The NewGait™ device may be a promising rehabilitation device to help induce positive walking performance changes in persons with MS.

KEYWORDS: Gait, physical therapy, Newgait™.

INTRODUCTION: Multiple sclerosis (MS) is a progressive, degenerative neurological disease that affects approximately 2 million people worldwide; symptoms of MS are highly variable between individuals, and include sensory, cognitive, and motor impairment (National Multiple Sclerosis Society, 2018; Socie & Sosnoff, 2013). LaRocca (2011) found that 70% of people with MS, who had difficulty walking, agreed that walking was the most challenging aspect of the disease. Walking and gait impairments can have a high negative impact on motor and lifestyle activities, with impairments that are associated with a low quality of life and an increased risk of falls (Cattaneo et al., 2002).

Several therapy techniques have been effective in improving gait and mobility. Beer et al. (2008) showed that robot-assisted gait training significantly improved distance walked and walking velocity versus a conventional walking therapy program when compared to baseline values. Colombo et al. (2000) developed a body-weight supported treadmill device that utilized a driven gait orthosis and allowed the user to focus on the walking motion . However, these therapy techniques are expensive and physically demanding for therapists who have the task of controlling and assisting the walking movements. Separate reviews by Kjølhede et al. (2012) and Dalgas et al. (2008) have shown that less expensive rehabilitation strategies incorporating resistance and endurance training to strengthen or re-train weakened muscles, are effective at improving walking gait.

The NewGait™ device is a modification of a resistance training device called Speedmaker™, which was designed to provide resistance to the muscle groups most responsible for speed production (Elite Athlete Products, 2017). The NewGait™ device consists of a harness that extends over the chest and waist, as well as straps that wrap around the lower thighs and below the knees. Elastic resistance bands are strategically placed to offer assistance to various joints, typically connecting between the harness and the leg straps and between the leg straps and the patient's shoes. The NewGait™ device is primarily an assistive device guiding the wearer into an optimal walking form. User-specific customization can add or remove bands to produce the desired assistance. This device has shown anecdotal clinical improvements in walking performance for a variety of populations, but requires more rigorous controlled research, especially in MS patients. This device may be more cost effective for persons with MS to use, in addition, it is more practical than other gait devices as it is light, compact, and is easy to carry.

The purpose of this study was to compare if the addition of the NewGait™ device to traditional therapy in comparison to traditional therapy alone would be more effective at improving walking technique and walking performance in persons with multiple sclerosis.

METHODS: Eight female participants (height = 164.4 cm ± 5.89; mass = 78 kg ± 24.64) were recruited to participate in an 8-week rehabilitation intervention. Approval for this study was granted by the Human Subjects Institutional Review Board of Northern Michigan University, Marquette, Michigan, USA (IRB# HS17-870). Inclusion criteria required participants to be in a stable phase of their MS, have chronic progressive pattern or relapsing-remitting MS with no relapse during the past three months, and have an Expanded Disability Status Scale (EDSS) score between 5 and 7 (Kurtzke, 1983). Participants were excluded if they had any cardiac related risk factor, major orthopedic problems or contractures of the lower limbs, complete inability to stand or walk for a longer period than three months, significant medical comorbidities, and cognitive or psychiatric problems that could compromise compliance with physical therapy (PT). Participants who met all the inclusion criteria completed an informed consent.

Testing took place before and after the 8-week PT intervention. On both the pre- and post-testing days, participants performed six 10-meter walk trials. Participants had 34 reflective markers placed on their left and right ASIS and PSIS, lateral and medial knees, lateral and medial ankles, metatarsals (1^{st} and 5^{th}), and calcaneus, with additional 4 marker clusters placed mid-thigh and mid-shank. Kinematics were measured using a 10 camera analysis system sampling at 250 Hz, digitized and Butterworth filtered at 10 Hz using Cortex Motion Analysis software (Motion Analysis Corporation, Santa Rosa, CA, USA). Ten-meter walk time was assessed using four timing gates (Witty Wireless Training Timer system, Mahopac, NY, USA). For the first three walking trials, participants walked under normal conditions and were instructed to "walk as quickly and as safely as you can". After the three trials, participants were fitted with a NewGait™ device for their particular gait abnormality by a licensed PT and/or a certified prosthetist. The participants then repeated the three 10-meter walk trials wearing the device. For the purpose of this research, data from the control walks (not wearing the NewGait™ device) were reported. Rating of perceived exertion (RPE) using Borg's RPE scale of 0-10 was recorded following each set of three walking trials.

Following pre-testing, participants were matched to another individual with similar gait impairments and EDSS score. Participants were then randomly assigned into either the control or experimental group based on a coin flip. The experimental group wore the NewGait™ device during PT, while the control participants did not. Participants began PT within one week of pre-testing. PT sessions occurred twice a week, for 60 minutes each, and included gait, balance, functional balance, and mat exercises, as well as neurological tests.

Kinematic gait variables (step width, step length (SL), speed, and ankle range of motion (ROM)) were calculated by creating a conventional gait model using a CODA pelvis created in Visual 3D (Version 4.0, C-Motion, Inc., Germantown, MD, USA), and by following standard Visual 3D protocol for recognition of gait events (Zeni, Richards, & Higginson, 2008). Range of motion of the ankle was calculated using the minimum and maximum angles of the ankle joint during the swing and stance phases of the gait cycle. A repeated measured mixed ANOVA was used to analyse kinematic variables. Statistical analyses were completed with SPSS (version 24). Cohen's D effect size was calculated to assess change across time for each group. Additional paired t-tests were run to investigate pre-post comparisons within groups when large effect sizes were present.

RESULTS: Repeated measures mixed ANOVA revealed no main effects between the gait variables or between the control and experimental conditions (Table 1). In addition, there was no interaction between the variables ($p > 0.05$). Post-hoc paired t-tests run based on large effect size indicated that the experimental group showed meaningful change in left and right step length and speed (Table 2). The control group showed meaningful change in left step length and left ankle ROM during the swing phase (Table 2).

Table 1: Mean ± SD, p-values and effect sizes for gait variables and rating of perceived exertion (RPE) pre- and post-intervention for the control and experimental groups.

		Control Group (n = 4)		Experimental Group (n = 4)		p-value	
		Pre	Post	Pre	Post	Time	Time*Group
Step Width (m)		0.14	0.15	0.16	0.14	0.67	0.22
Left SL (m)		0.46	0.54	0.52	0.69	0.02	0.33
Right SL (m)		0.53	0.57	0.54	0.69	0.03	0.19
Speed (m/sec)		0.90	0.98	0.99	1.36	0.03	0.13
RPE		3	2.9	4	2.1	0.05	0.08
SWING	Left Ankle ROM (°)	21.85	18.41	19.89	22.96	0.91	0.09
SWING	Right Ankle ROM (°)	22.47	16.41	15.51	21.04	0.95	0.17
STANCE	Left Ankle ROM (°)	24.59	25.09	26.26	26.33	0.49	0.91
STANCE	Right Ankle ROM (°)	31.73	31.62	27.39	26.42	0.73	0.78

Table 2: Difference, p-value, and effect size for left and right SL, speed, and ankle ROM during swing for the control and experimental groups.

Variable	Control Group (n = 4)			Experimental Group (n = 4)		
	Diff	p	d	Diff	p	d
Left SL (m)	-0.082	0.060	-0.947	-0.158	0.098	-0.884
Right SL (m)	-	-	-	-0.149	0.117	-0.777
Speed (m/sec)	-	-	-	-0.368	0.103	-0.717
SWING Left Ankle ROM (°)	3.439	0.246	0.896	-	-	-

DISCUSSION: The main finding was that an 8-week PT intervention that focused on gait and balance was effective at improving walking technique and performance, as seen by the differences in left step length and left ankle ROM during the swing phase in the control group. However, there is evidence to suggest that the addition of the NewGait™ assistive device to PT may also be effective at further improving walking gait and performance, as shown by the differences in left and right step length, and speed in the experimental group.

These findings are in agreement with Beer et al. (2008) and Schwartz et al. (2012) who both used robot-assisted gait training and reported improvements in walking distance and velocity. Although the NewGait™ device differs greatly from that technique in terms of cost and versatility; the current findings also agreed with Kjølhede et al. (2012), Dalgas et al. (2008), and Gutierrez (2005) who note that less expensive rehabilitation techniques are also effective at improving walking gait. Gutierrez et al. (2005), found that two months of resistance training could elicit a significant increase in step length and foot angle.

No longitudinal research has been conducted on the effectiveness of the NewGait™ device, but past research using robot-assisted gait training indicates that any improvements seen in gait function at the conclusion of the study were not detectable at 6 months post (Beer et al., 2008; Schwartz et al., 2012). However, an advantage of the NewGait™ device is that due to its low cost and portability, the device could be used outside a PT setting, meaning that individuals could continue using it long-term.

A limitation of the current study was the lack of power from a small sample size. However, it should be noted that the current study uses a subsample of participants from an ongoing study; future publications will include the entire sample. Another limitation may be the length of the PT intervention. If the intervention was longer or included more sessions, participants may have shown greater improvements in their walking performance. Day et al. (2002) indicate that there may be a positive correlation between results of balance therapy and number of sessions, with more sessions equating to more optimal results. Future research should use a longer PT intervention and study the longitudinal effects of the NewGait™ device.

CONCLUSION: The purpose of this study was to compare if the addition of the NewGait™ device to traditional therapy in comparison to traditional therapy alone would be more effective at improving walking technique and walking performance in persons with multiple sclerosis. Primary results showed no main effect between gait variables or between groups. Post-hoc t-tests indicated that the traditional therapy group experienced meaningful change in unilateral step length and ankle ROM however, the NewGait™ device demonstrated meaningful change in bi-lateral step length and walking speed. The NewGait™ is cost-effective and mobile, which makes it easy to use for physical therapists and patients. The ability to customize the device to each individual may also be an attractive quality for physical therapists who see a variety of patients with a multitude of impairments.

REFERENCES

Beer, S., Aschbacher, B., Manoglou, D., Gamper, E., Kool, J., & Kesselring, J. (2008). Robot-assisted gait training in multiple sclerosis: a pilot randomized trial. Multiple Sclerosis Journal, 14(2), 231–236.

Cattaneo, D., De Nuzzo, C., Fascia, T., Macalli, M., Pisoni, I., & Cardini, R. (2002). Risks of falls in subjects with multiple sclerosis. Archives of Physical Medicine and Rehabilitation, 83(6), 864–867.

Colombo, G., Joerg, M., Schreier, R., & Dietz, V. (2000). Treadmill training of paraplegic patients using a robotic orthosis. Journal of Rehabilitation Research and Development; Washington, 37(6), 693–700.

Dalgas, U., Stenager, E., & Ingemann-Hansen, T. (2008). Review: multiple sclerosis and physical exercise: recommendations for the application of resistance-, endurance- and combined training. Multiple Sclerosis Journal, 14(1), 35–53.

Day, L., Fildes, B., Gordon, I., Fitzharris, M., Flamer, H., & Lord, S. (2002). Randomised factorial trial of falls prevention among older people living in their own homes. BMJ, 325(7356), 128. https://doi.org/10.1136/bmj.325.7356.128

Elite Athlete Products. (2017). SpeedMaker. Retrieved October 16, 2017, from Available at:
http://speedmakerathletics.com/

Gutierrez, G. M., Chow, J. W., Tillman, M. D., McCoy, S. C., Castellano, V., & White, L. J. (2005).
Resistance training improves gait kinematics in persons with multiple sclerosis. Archives of Physical Medicine and Rehabilitation, 86(9), 1824–1829. https://doi.org/10.1016/j.apmr.2005.04.008

Kjølhede, T., Vissing, K., & Dalgas, U. (2012). Multiple sclerosis and progressive resistance training: a systematic review. Multiple Sclerosis Journal, 18(9), 1215–1228.

Kurtzke, J. F. (1983). Rating neurologic impairment in multiple sclerosis an expanded disability status scale (EDSS). Neurology, 33(11), 1444–1452. https://doi.org/10.1212/WNL.33.11.1444

LaRocca, N. G. (2011). Impact of walking impairment in multiple sclerosis: perspectives of patients and care partners. The Patient; Auckland, 4(3), 189–201.

National Multiple Sclerosis Society. (2018). Ms symptoms. Retrieved December 7, 2017, from http://www.nationalmssociety.org/Symptoms-Diagnosis/MS-Symptoms

Schwartz, I., Sajin, A., Moreh, E., Fisher, I., Neeb, M., Forest, A., Meiner, Z. (2012). Robot-assisted gait training in multiple sclerosis patients: a randomized trial. Multiple Sclerosis Journal, 18(6), 881–890.

Socie, M. J., & Sosnoff, J. J. (2013). Gait variability and multiple sclerosis. Multiple Sclerosis
International.

Zeni, J. A., Richards, J. G., & Higginson, J. S. (2008). Two simple methods for determining gait events during treadmill and overground walking using kinematic data. Gait & Posture, 27(4), 710–714.

ACKNOWLEDGEMENTS: This project was supported by grants from The Superior Health Foundation, and the Northern Michigan University PRIME and Travel Award.