An Exploratory Study of Wearable Vibration Therapy on Gait and Mobility in People with Multiple Sclerosis

Hongwu Wang[1,2], Carol Dionne[1], Nidhiben A Anadani[1], Sarah C Brown[1], Morgan Shuping[1], Leonard Wilson[1]

[1]*University of Oklahoma Health Sciences Center,* [2]*University of Oklahoma*

INTRODUCTION

As of 2010, nearly one million adults are affected by multiple sclerosis (MS). There is a steady rise in prevalence of MS in United States (US). [1] MS is among the most common causes of neurological disability in young adults and occurs at least twice as frequently in women as in men. [2] MS is a complex, progressive, inflammatory, degenerative, and autoimmune demyelinating disease of the central nervous system (CNS), causing destruction of myelin and degradation of neurons. [3] Three of four people with MS report reduced mobility due to impaired walking function at some point during their lifetime. [4] Walking impairment is perceived as the most restricting of symptoms by 75% of patients with MS that may be present at the very early stages of the disease, significantly impacting patients' functional status and quality of life. [5]

Detailed evaluation of gait disorders in MS is vital, but research on sustainable interventions for MS-related gait abnormalities is imperative.[4] There is a growing array of interventions, such as medications, disease-modifying therapies, physical therapy, virtual reality, functional electrical stimulation (FES), tele-rehabilitation and robotics to improve walking.[6] However, there is a lack of consensus on the effectiveness and efficacy of those interventions in gait performance by patients with MS, as well as the notable deleterious side effects and sustainability of the interventions.

Vibration therapy, an established physiotherapy treatment well supported by clinical research, has multiple benefits. [7] Previous studies have found that focal vibration reduces muscle spasticity, facilitates muscle contraction, and stimulates the proprioceptive system to enhance efficient motor control during functional activities. [7] Additionally, studies show focal vibration can augment sensorimotor organization through proprioceptive training in patients with movement disorders. [7] Patients with Parkinson's disease, stroke, and incomplete spinal cord injuries have shown improvement in gait performance linked to this application.

Early evidence has shown that vibration therapy applied to lower limb muscles shows promise to improve walking in MS patients with postural instability and/or spasticity. [8,9] However, short treatment times with small samples, using varying doses and durations limited robust generalization. Therefore, the purpose of this study was to examine the effect of focal muscle vibration on gait and mobility in patients with MS on the short and longer term (1 month) following this intervention.

METHODS

Design

This was a single site, single group within-subjects design with a focus on measures of gait and mobility.

Participants

The incursion criteria for the study were: 1) MS diagnosis defined by the McDonald revisited criteria; [10] 2) age between 18 and 65; 3) subjects reporting impaired walking, assessed by clinical examination; 4) no clinical relapse in past 6 months; 5) able to understand English instructions; 6) able to sign an inform consent; and 7) have normal or corrected vision. Individuals with other symptoms or signs suggestive of peripheral neuropathy or other superimposed neurological or psychiatric condition that could interfere with walking assessment, medical condition preventing use of the vibration device,

pregnancy, and clinically diagnosed with dementia greater than mild (screened using Montreal Cognitive Assessment (MOCA) <24) were excluded. A physician with relevant training in MS care confirmed eligibility of subjects. All subjects interested in the study were informed about the procedure and the aim of the research. Eligible and willing patients signed an institutional review board-approved informed consent prior to screening. All subjects were recruited from Oklahoma City and surrounding area.

Figure 1 MyoVolt™ device applied to the three muscles

Equipment

The Myovolt™ wearable vibration device was used for this study. Myovolt™ is registered with the U.S. Food & Drug Administration (Regulation Number: 890.5660) under the "therapeutic massager" category. Myovolt™ has been used as a muscle stimulation device in a similar way as sports massage. Studies using the device for athletes had reported positive effect on increasing peripheral blood circulation, reducing muscle soreness. We have been using the device for patients with diabetic peripheral neuropathy (DPN), and found improved gait, mobility, and pain without any adverse events.

Procedure

Patients were asked to wear the Myovolt™ wearable device on both legs and apply the vibration in three muscles. Patients wore the Myovolt™ bilaterally on the distal quadriceps muscle/tendon close to the rectus femoris insertion at about 2 cm from the medial edge of the patella, as well as the gastrocnemius/soleus muscle tendon, then the tibialis anterior muscle. In a single day, each participant received focal vibration over quadriceps first, then the gastrocnemius, and then the tibialis anterior. For each muscle group, vibration was applied for 10 minutes, for 3 days per week for 4 weeks. There were three visits for each participant at baseline (visit 1), end of 4-week study (visit 2), and a 4 weeks post intervention follow-up (visit 3). Demographics were collected at visit 1 including age, gender, body mass index, disease duration and course, and current medications, co-morbidities and secondary conditions. Quantitative gait parameters were collected in the Center for Human Performance Measurement (CHPM) equipped with the Qualysis™ motion capture system and AMTI™ force plates at visit 1 and 2. Timed 25-Foot Walk (T25-FW) was used to assess the mobility and leg function performance at all three visits. The Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) questionnaire was used at end of visit 2 to assess participant's satisfaction with the wearable vibration technology. Patients' experience and impression over the whole 8 weeks were surveyed by semi-structured interviews at end of visit 2 and visit 3.

Analysis

Gait data were analyzed using Visual3D© and Excel™. Descriptive statistics were used for the demographic and other outcome variables. Due to the small sample size, no statistical test was conducted. Thematic analysis was used to analyze the semi-structured interview data.

RESULTS

Four patients with MS had completed all the three visits to date. The demographics, participants' satisfaction on the wearable device, and the time for completing Timed 25-Foot Walk at each visit were shown in Table 1. The spatial-temporal parameters of the gait were shown in Table 2.

Table 1. Patients demographics, QUEST scores, and Timed 25-Foot Walk performance of the three visits

Pt ID	Age (years)	Gender	Weight (lbs.)	Height (inches)	Ethnicity	Years with MS	QUEST V2.0	T-25FT pre (second)	T-25FT post (second)	T-25FT follow-up (second)

1	39	Female	245	67	African-American	1	38	9.1	8.25	9.1
2	63	Male	250	67	Caucasian	6	40	7.19	6.26	6.9
3	48	Female	265	68.5	African-American	7	40	3.55	6.2	5.05
4	56	Female	118	62	Caucasian	15	38	3.85	4.1	6.84

Table 2. Spatial-temporal parameters at baseline and post intervention

Pt ID	Gait speed (m/s) pre/post	Stride Length (m) pre/post	Stride Width (m) pre/post	Cycle Time (s) pre/post	Left Step Length (m) pre/post	Right Step Length (m) pre/post	Left Step Time (s)	Right Step Time (s)	Double Limb Support (s) pre/post
1	0.68/0.82	1.03/1.17	0.18/0.15	1.52/1.44	0.42/0.56	0.58/0.62	0.73/0.72	0.77/0.72	0.59/0.45
2	0.78/0.86	0.87/0.97	0.27/0.25	1.11/1.14	0.45/0.46	0.41/0.51	0.59/0.56	0.53/0.57	0.41/0.39
3	1.03/1.10	1.21/1.25	0.21/0.19	1.17/1.14	0.59/0.59	0.61/0.65	0.59/0.55	0.58/0.59	0.37/0.37
4	1.05/1.15	1.19/1.21	0.20/0.22	1.14/1.05	0.54/0.57	0.65/0.64	0.57/0.56	0.57/0.49	0.28/0.26

* The shadowed results were notable changes between pre and post measures

Three themes were identified from the interview data. The first theme was the application of the vibration therapy. All four patients used the device when seated or recumbent. Two patients applied the therapy at different times during the day, while two others always applied at evening time before sleep. The second theme was personal experience with the vibration therapy. All participants reported liking the vibration, felt comfortable while using it, and no pain was reported. Two patients with spasticity also reported reduced spasticity. Two patients reported increased sensation. One patient did not like applying the vibration on quadriceps because it sometimes increased her spasticity. Three patients reported no differences in feeling over the follow-up weeks. The third theme was the wearable device. All patients liked everything about the device. Two of them felt the vibration was good, and two others wanted stronger and more vibration. Three patients commented the strap of the wearable could be better designed. One patient commented the charging port of the device intermittently charged. All patients truly missed using the device when interviewed at the final visit.

DISCUSSION

This paper presented the pilot results of an ongoing study to investigate feasibility and effectiveness of wearable focal vibration on gait and functional mobility for individuals with MS. The preliminary results showed that participants were very satisfied with the wearable device and vibration therapy. The Timed 25-Foot Walk results showed that two patients participants the test faster after the 4-week vibration intervention, and did not worsen, even after the follow-up. For participant 3 with increased time to compete the test, we noticed that she had a relapsing event in the middle of the study. From participant 4's results, we can see that her disease progression was slowed due to the intervention.

From the spatial-temporal parameters of the gait, we noticed that for all of them, their self-paced walking speeds and stride length were improved after the intervention. These results agreed with previous studies on a single session or short-term effects of focal vibration on gait for MS. [8,9] We also noticed the decrease of the stride width which demonstrated improved dynamic stability. The increase of the speed could be explained partially by the increased stride length, and also the decreased cycle time. The differences between the gait data and Timed 25-Foot Walk data for participants 3 and 4 could be explained that when measuring the gait, the distance particpants walk (10 feet) was shorter. Due to the limitation on resources, we did not assess gait parameters at the follow-up visit. Future study should investigate the gait performance changes at the follow-up, which could better explain the changes on the Timed 25-Feet Walk data.

Patients overall felt comfortable with the vibration therapy and liked it. For this study we did not control when to use the device, and did not have specific requirement on posture or condition when using the device. We believe the advantage of the wearable device should be that patient could use it even when they are active, or performing other activities of daily living. In the future study, we will try to better track

the when and how the device is used. In our DPN study, most participants reported increased sensation while for this study only two of patients reported improved sensation. This could be the difference between the two diseases, or due to we did not include a good sensation measurement in this protocol. In addition, the reported decrease of spasticity from two patients agreed with previous studies. [8] As for the wearable device, it was suggested that the strap to secure the device should be redesigned and improved to make it easier for patient to wear. Furthermore, in the future we should try to modify the device to allow customizable vibration delivery based on the condition of the patients, and the stage of disease progression.

One limitation of this paper was the small sample size. As we are continuing recruitment and participant testing, hopefully we will be able to find statistically significant improvement as well as clinically meaningful changes on the outcome measures. Another limitation of this study was we did not include the kinematics and kinetics of the gait parameters, we are analyzing the data now, and will include those in the future analysis to better understand the changes in gait, which will be helpful to understand how and why vibration therapy affects walking of individuals with MS.

CONCLUSIONS

4 weeks of focal vibration delivered by a wearable vibration device improved the gait speed, stride length and width determined by 3-D motion analysis and improved the functional mobility measured by Timed 25FT Walk. The high satisfaction with the wearable device and positive patient experience and feedback suggests that focal vibration may benefit patients with MS. Given the ease of use and wearability of the technology, it may increase exercise tolerance by improving gait, mobility and extending the onset of relapsing and slow down the progression of MS; however, more participants will be needed to confirm the findings, and a randomized clinical trial study is required with more patients and different vibration dosages to fully understand the efficacy of wearable vibration by comparing it with other interventions, such as physical therapy.

We are grateful to the participants who gave their time and to the Department of Rehabilitation Sciences, Center for Human Performance Measurement for the use of their facilities and Presbyterian Health Foundation for funding this study.

REFERENCES

[1] Wallin, M.T., et al., The prevalence of MS in the United States: A population-based estimate using health claims data. Neurology, 2019. 92(10): p. e1029-e1040.

[2] Dimitrov, L.G. and B. Turner, What's new in multiple sclerosis? The British journal of general practice : the journal of the Royal College of General Practitioners, 2014. 64(629): p. 612-613.

[3] Alonso, A. and M.A. Hernan, Temporal trends in the incidence of multiple sclerosis: a systematic review. Neurology, 2008. 71(2): p. 129-35.

[4] Filli, L., et al., Profiling walking dysfunction in multiple sclerosis: characterisation, classification and progression over time. Scientific reports, 2018. 8(1): p. 4984-4984.

[5] Opara, J.A., K. Jaracz, and W. Brola, Quality of life in multiple sclerosis. Journal of medicine and life, 2010. 3(4): p. 352-358.

[6] Allushi, E. and I. Zekja, Physical Rehabilitation, An Important Factor On The Treatment Of Multiple Scleroses: A Literature Review. European Scientific Journal, ESJ, 2016. 12(9): p. 250.

[7] Murillo, N., et al., Focal vibration in neurorehabilitation. Eur J Phys Rehabil Med, 2014. 50(2): p. 231-42.

[8] Spina, E., et al., The effects of mechanical focal vibration on walking impairment in multiple sclerosis patients: A randomized, double-blinded vs placebo study. Restor Neurol Neurosci, 2016. 34(5): p. 869-76.

[9] Camerota, F., et al., Focal muscle vibration, an effective rehabilitative approach in severe gait impairment due to multiple sclerosis. Journal of the Neurological Sciences, 2017. 372: p. 33-39.

[10] Thompson, A.J., et al., Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. Lancet Neurol, 2018. 17(2): p. 162-173.