An innovative gait rehabilitation device for improving functional mobility and basic activities of a person with Multiple Sclerosis

Keywords:
Multiple Sclerosis
Gait
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Abstract

Background: Multiple sclerosis (MS) is a chronic inflammatory demyelinating disease of the central nervous system (CNS) that affects approximately 2.5 million worldwide. The etiology of MS is unknown, but it is likely the result of a complex interaction between genetic and environmental factors and the immune system. The clinical manifestations of MS are highly variable, but most patients initially experience a relapsing-remitting course. Patients accumulate disability as a result of incomplete recovery from acute exacerbations and/or gradual disease progression (Tullman, 2013). Although MS affects a variety of daily functions, Gait impairment is considered a clinical hallmark, often resulting from the combination of multiple common symptoms and deficits such as fatigue, weakness, spasticity, ataxia, and balance problems (Kelleher, 2009; Pearson, 2004). Gait training has become a leading rehabilitative tool for managing walking impairment and improving function among people with MS.

Methods: This is a single-subject case-study of a person with MS, first diagnosed 21 years ago. The subject participated in a 2-week training protocol with the system. Training included 10 to 15 minutes of walking with the Salute's *Just Walk* system every day for the first week and 20 minutes in the second week. Timed-up and go test (TUG) and four square step test (FSST) were taken in the first session and after 2 weeks. They were performed first without the *Just Walk* system (pre-tests-without), then with the system (tests-with), and once again at the end of the session without the system (post-tests-without). Between the second and third tests the subject practiced walking while connected to the system.

Results: improvement was found in both the TUG test and FSST. Subject reported on an increase in her motivation to practice gait in general which manifested itself in longer periods of walking per day since receiving the *Just Walk* device.

Conclusions: Our results imply that Salute's *Just Walk* system is an effective therapeutic device which can lead to improvement in the mobility and balance among people with Multiple Sclerosis. For patients with a long chronic disabling disease it may increase the motivation to practice gait, thus preserving their functional mobility.

Background

Multiple sclerosis (MS) is a chronic inflammatory demyelinating disease of the Central Nervous System (CNS) that affects approximately 400,000 people in the United States and approximately 2.5 million worldwide. The etiology of MS is unknown, but it is likely the result of a complex interaction between genetic and environmental factors and the immune system. The clinical manifestations of MS are highly variable, but most patients initially experience a relapsing-remitting course. Patients accumulate disability as a result of incomplete recovery from acute exacerbations and/or gradual disease progression (Tullman, 2013). The majority of people with MS are diagnosed between 20 and 50 years of age, and women are affected 2-3 more often than men. (Koch-Henriksen, 2010). The demyelinating process that occurs in the CNS is expressed in a variety of impairments that involve muscle weakness, sensory disturbances, cognitive aspects and dysfunction in balance and walking (Noseworthy, 2000).

Gait impairment is a clinical hallmark of MS, often resulting from the combination of multiple common symptoms and deficits such as fatigue, weakness, spasticity, ataxia, and balance problems (Kelleher, 2009; Pearson, 2004). People with MS with difficulty walking report that this problem not only affected their mobility, but also significantly restricted their activities and affected their emotional health. These people referred to the impact of walking difficulty on their ability to perform daily tasks, their self-esteem, their work life, and their ability to travel (LaRocca, 2011).

The variety of treatment strategies for walking difficulties of people with MS is very large. Exercise-based therapy is commonly used. This includes traditional therapeutic balance exercises and muscle strengthening. Another option presented in literature is the use of exergaming, such as Wii-based balance challenges (Sonsoff, 2015). Walking training using treadmill in the purpose of promoting aerobic ability is also an effective treatment mode. Studies have demonstrated that aerobic treadmill walking improved over-ground walking speed and endurance among people with MS (Van der Berg, 2006; Newman, 2007). Walking aids such as walking sticks, rollators and ankle-foot orthosis are commonly utilized among people with MS. The first two allow a wider base of support to the walker, thus promoting stability. The ankle-foot orthosis allows foot clearance to patients suffering from foot drop. Foot drop is defined as a deficit in active dorsiflexion and/or eversion resulting in the foot touching the ground in the swing phase (Esnouff JE, 2010). Overcoming foot drop is an important fall prevention factor among people with MS (Peterson, 2013). Among the different approaches mentioned here, motor adaptation is an additional strategy that was investigated among people with neurological deficits, mostly people post-stroke, and was found effective at improving gait (Savin et al., 2013; 2014).

Motor adaptation is known to be referred as a short term, error-driven motor learning process (Reisman et al., 2010). It is defined as a process of adjusting a well-learned movement pattern (e.g. walking) to a novel sensorimotor perturbation (Martin et al., 1996; Reisman et al., 2010; Savin et al., 2014). The adjustment process occurs over a period of trial and error practice (which can last a few minutes to hours) (Reisman et al., 2010). Savin et al. (2014) examined if adaptation to a swing phase perturbation during treadmill gait transferred from treadmill to overground walking, and if it improved step length asymmetry and gait velocity in persons with hemiparetic stroke (occurring >9 months). In their results they found that adaptation had occurred during treadmill walking and that it was transferred to overground. The adaptation was manifested in temporarily improved overground step length and improved overground gait speed (Savin et al., 2014). In order to create a swing phase perturbation, they used a rope which was attached to a cuff on the subject's leg on one end, and at the other end was attached a set of pulleys which was connected to a weight. The pulley resisted forward movement of the leg during its swing phase (Savin et al, 2014).

Current interventions such as mentioned in the study of Savin et al (2014) use very massive, expensive systems (Reisman et al., 2009; 2013; Savin et al., 2014) and therefore, they are usually not accessible to the patients on a daily basis. This also sets a limitation on the number of training sessions and the environment in which the gait training can be performed. Thus, an accessible system which will enable patients to increase the number of repetitions, practice in different environments and most importantly in their own home, is significant.

Among people with MS, very few works examined the effect of motor adaptation on gait improvement. Bret (2015) presented motor adaptation as feasible in a study that examined postural adaptation and Ahn et al. (2011) showed an improvement in cadence of a single MS patient after a repetitive perturbation of the ankle by a robot while walking. Van der Berg (2017) examined the effects of walking on sand on people with MS and has shown that they adapted by increasing their hip, knee and ankle flexion. During post-adaptation period (walking on a solid surface again), the MS participants returned to their baseline joint flexion angles, meaning no successful after-effects were recorded. However, the author mentioned that the sand walking was of short duration and that a more prolonged perturbation is needed

In this report we present Salute's *Just Walk* device. It is a simple, mechanical, easily fitted device that produces a swing phase perturbation. Salute's *Just Walk* device enables walking training, as well as the performance of functional strengthening exercises against an adjustable resistance. It is relatively small and mobile and therefore enables enhancement of the number of repetitions. Dickstein (2008) has shown that any intervention program should include repetitive training for the improvement of gait speed and functional community walking. Salute's *Just Walk* system works on the lower limbs and provides assistance in the initial swing and resistance in the terminal swing of the gait (for more details see the description in Methods). The tension and pressure created by the resistance induces a strong proprioceptive stimulus which is known to be important in gait rehabilitation (Dietz et al., 2002; Lam et al., 2006).

Our aim in this single-subject case study is to present our clinical experience with the Salute system for improving functional mobility and dynamic balance of a chronic Multiple Sclerosis patient, over a practice of 2 weeks period. We expect an improvement in the results of mobility and balance tests following the use of Salute's *Just Walk* device.

Methods

Participants and Study design

This study design was a single-subject case-study. The subject is a 58-year old female, first diagnosed with of Multiple Sclerosis 21 years ago. Her ambulatory EDSS score is 6.5 (constant bilateral assistance (canes, crutches, or braces) and is able to walk 20 meters without resting (Kurtzke, 1983)). The patient walks independently in house with two crutches and ambulates outside the house using a mobility scooter. When performing gait observation, one can notice the slow walking pace, lack of foot clearance of both legs accompanied by lack of hip and knee flexion, as both legs slide on the floor with full contact with the floor during swing phase.

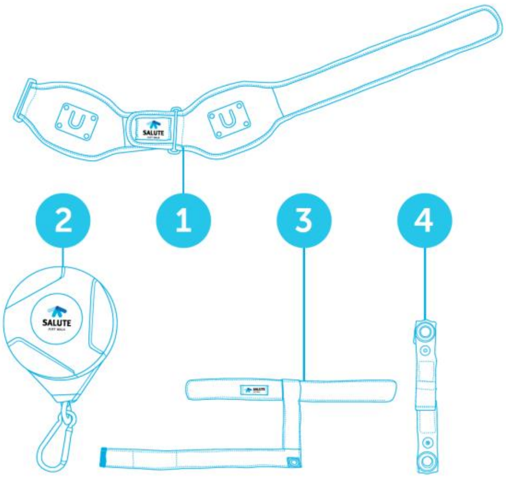
Experimental protocol

The subject participated in a 2-week training protocol with Salute's *Just Walk* device, which was connected to the forefoot via a special foot strap. Training included 10 to 15 minutes of walking with the system every day for the first week, and 20 minutes in the second week.

Functional tests were performed in the first session and once again after 2 weeks of training in the following order: without the *Just Walk* system (pre-tests-without), then with the system (tests-with), and once again at the end of the session without the *Just Walk* system (post-tests-without). Between the second and third tests the subject practiced walking for 10 to 15 minutes while being connected to the system.

Salute's Just Walk device description

The system is composed of a belt (1), placed around the patient's waist. The device (2) is



secured in a residence unit on the belt. The device provides continuous linear and adjustable tension to the muscles by creating a magnetic force that is converted into kinetic energy. A tension cord that extends from the device quickly connects to the patient's foot / shoe via an adjustable foot and ankle strap that fits the feet (3). Variable resistance produces tension and pressure on the leg as the person walks. An extra strap (4) which can be attached in alternative locations on the foot strap is also supplied for additional functions. All components are Salute's technology designed especially for "Home User" patients. To use the device, the patient or the patient's caregiver places the belt around the patient's waist. The device is then secured in a residence unit into the U sign. To change the level of difficulty (resistance), the residence unit is rotated clockwise. The foot belts are adjusted around the feet and ankles. The patient then pulls the tension cord from the device and attaches the D-clip at the end of the cord to the foot strap. Finally, the patient can walk with the device on.

Outcome measures

Primary outcome measures were: (1) Timed UP and Go (TUG), which is a widely used, reliable and valid performance test for the evaluation of functional mobility of people with MS (Sebastiao, 2016). The TUG requires participants to stand up from a chair, walk 3 meters, turn around, return to the chair, and sit down again. The time required to complete the test is recorded in seconds using a stopwatch (Hafsteinsdóttir et al., 2014). (2) Four Square Step Test (FSST) is a valid and reliable measure of dynamic standing balance in ambulant people with

MS (Wagner, 2013). The test requires subjects to rapidly change direction while stepping forwards, backwards, and sideways. Time to complete the test is measured.

Results

Safety

No adverse events or side effects were reported. The subject stated that she managed to place the belt independently in a sitting position, while her spouse helped with the attachment of the ankle/foot straps as well as the cord attachment to the straps.

Efficacy

As described in Table 1, improvement was found in both tests, the TUG and FSST, both in the pre/post-test during each of the sessions, and also when comparing scores of each test performed in the first and second session. In the TUG, results with the device were slower than the pre-test, as the *Just Walk* device applied resistance to leg extension when getting up from sitting to standing. However, when removing the device (post-test), results improved compared to pre-test in both sessions. The FSST improvement was achieved when testing with the device and continued also after its removal during both sessions. The differences in the FSST scores surpassed the minimal detectable change of 4.6 sec (Wagner, 2013) in each session, as well as between sessions.

Observational gait analysis – A faster walking speed was detected with full foot clearance during swing phase in both legs when using the device. Both legs returned to touch the floor post-treatment during swing phase; nevertheless, leg transfer from pre-swing to initial contact was easier and faster and step length seemed larger during post-treatment.

Table 1- Functional scores of the subject in the TUG and FSST.

	TUG (sec) 1st session	**TUG (sec) 2nd session**	**Difference in TUG 2nd -1st session**	**FSST (sec) 1st session**	**FSST (sec) 2nd session**	**Difference in FSST 2nd -1st session**
pre-test-without	25.2	21.5	**-3.7**	27.1	16.4	**-10.7**
test-with	31.9	22.7	**-9.2**	23.8	13.1	**-10.7**
post-test-without	23.7	19.9	**-3.8**	21.4	11.8	**-9.6**
Difference between *pre-* and *post-* score (without)	**-1.5**	**-1.6**	**-0.1**	**-5.7**	**-4.6**	-1.1

TUG= Timed up-and-go test, FSST= Four Square Step Test, pre-test-without= pre-test without Salute's *Just Walk* device, pre-test-with=with Salute's *Just Walk* device.

Discussion and conclusions

Our results in this single-subject case-study imply that for a person with MS, Salute's *Just Walk* system can be an effective therapeutic device for the improvement of gait as well as basic activities that are usually performed numerous times during the day. Practicing with the device improved functional mobility by enabling swifter and more effective foot clearance compared to baseline.

When observing the subject walking, it was clear that she needed assistance with foot clearance. As a result, the *Just Walk* device was attached to the forefoot of both her legs. This way, the assistance of leg flexion at the pre-swing to mid swing was enabled, followed by resistance to the extension of the knee throughout the mid swing till initial contact. Based on Savin et al. (2014), we expected that adaptation to the altered gait pattern induced by the *Just Walk* system will occur and that it will be manifested in increased step length, gait speed and an overall better functional mobility as represented by both TUG and FSST scores.

The motor adaptation approach relies on the concept that the nervous system possesses an internal model of the movements of the limbs (Shadmehr and Mussa-Ivaldi 1994; Lam et al., 2006). The nervous system computes the necessary motor output for a desired movement based on this internal model. This is considered as a feedforward mechanism (Lam et al., 2006). The feedback mechanism is based on sensory input coming from the limbs interacting with the environment. Sensory input is known to have a significant role in shaping the motor output during walking (Dietz et al., 2002). It has an impact on timing the transition between stance and swing and has a role in regulating muscle activity (Lam et.al, 2006). Salute's system provides enhanced intrinsic proprioceptive feedback during practice and potentially may enable motor adaptation.

The results of both TUG and FSST show that motor adaptation did occur, as post-test scores surpassed pre-test scores in both sessions. When examining the TUG scores, although improved at pre-test vs. post-test and between sessions, the results did not surpass the minimal detection change which for people with MS stands on 10.6 seconds (Learmonth, 2012). This can be explained by the difficulty of the subject to stand up from the chair, followed by the need to insert both hands into the elbow cuffs of her crutches. This phase alone took long seconds to complete. The cut-off time that defines high risk of fall for this test is 14 seconds (Shumway-Cook, 2000). Our Subject, did not reach it after 2 weeks of practice; nevertheless, considering the ongoing improvement between sessions, it is fairly reasonable to assume that within several weeks of daily practice, this result may be reached.

As for the FSST, scores showed increasing improvement within each measurement. Minimal detectable change of 4.6 seconds was reached when comparing pre-test to post-test within each session as well as when comparing each test between sessions. In addition, the difference between the post-test of the 1st session and the pre-test of the 2nd session exceeded minimal detection change as well. This proves subject's progressive improvement in dynamic balance and mobility as represented by the FSST (Moore, 2017). The FSST does not include transferring from sitting to standing. This supports the claim that the transfer from sitting to standing using two crutches prevented the TUG scores to be higher and that the improvement reached in the TUG test reflects improvement in gait speed. In future studies, gait speed tests such as 2-minute walk or 10-meter walk should be performed in order to prove without a doubt that Salute's *Just Walk* device improves gait speed, which has been shown to have excellent correlation with dependence in self-care and domestic life among patients with MS (Paltamaa, 2007).

The subject reported of a lighter feeling when walking with the device that remained up to two hours after removing it. She spoke of a sensation of an increased muscle work around the thighs. Moreover, she reported of a boost in her motivation to walk in general that manifested itself by her initiating going out for strolls outdoors with and without the device, while being accompanied by her spouse. Walking outdoors was not practiced before by our subject for a long period of time due to her fear of falling and general sense of instability.

Gait practice is an important routine for people with MS (Larocca, 2011). A "Vicious Circle" is known to exist as a person encounters difficulty to walk, he/she reduces walking, which in turn worsens the competence and endurance to walk. Patients with high EDSS score such as our subject struggle with this issue on a daily basis. The advantage of Salute's *Just Walk* for this kind of patients lies within its accessibility together with the increased repetition of practice that the system allows. Since it is rather small and mobile it also enables practice of different tasks in different contextual environments. These are all well-known motor learning principles (Kleim and Jones, 2008).

In conclusion, based on findings of prior studies, we consider our results encouraging. We believe that our future studies will establish Salute's *Just Walk* system as an intuitive neuro-therapeutic device for improving basic activities, gait speed and functional mobility of people with MS.

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