An innovative Neuro-Motion Learning[™] device for gait and balance rehabilitation after stroke

Keywords: Stroke, Cerebrovascular Accident (CVA), Gait, Rehabilitation, Motor Adaptation

Abstract

Background: Stroke is a leading cause of disability and death. Regaining walking ability is one of the primary concerns of the patients and their caregivers. Alterations in the normal gait pattern are very common after stroke. Gait asymmetries post stroke seem to be affected by using locomotor adaptation strategies. Our aim is to present our clinical experience with the Salute Just Walk device when used as a perturbation to the hemipartic gait pattern of a chronic stroke patient, over a 3 weeks period. We wish to observe if the Salute Just Walk device can improve step length and clearance of the paretic limb and if it can affect dynamic stability as measured by the performance on the modified Four Square Step Test (mFSST). Methods: This is a single-subject case-study of a chronic stroke patient. The subject participated in a 3 week training protocol with the Salute Just Walk device. Training included 15 minutes of functional exercises and walking with the Salute Just Walk device every day. mFSST was taken at the first session and at the last. At both sessions the test was taken at the beginning of the session without the system, then with the system on the paretic limb, and once again after practice without the system. Results: Improvement was found in the mFSST test, both in the pre/post-test during each session and also when comparing scores of each test mode at the first and the last session. The reports of the subject indicate on a better ability to take longer steps with the paretic leg along with an improvement in walking distances and in walking on different surfaces. Conclusions: Our objective results, along with the subjective reports of the subject participating, imply that the Salute Just Walk device is an effective therapeutic device which can lead to an improvement in walking abilities and dynamic balance among chronic stroke patients.

Background

Stroke is a leading cause of disability and death. In 2013, stroke was the fifth leading cause of death in the United States (Mozaffarian et al., 2016). Each year, approximately 795,000 people in the United States continue to experience a new or recurrent stroke (ischemic or hemorrhagic) and approximately 1 of every 20 deaths is caused by stroke (Mozaffarian et al., 2016). Disability following stroke has an enormous functional effect in many aspects such as impaired cognition, communication and mobility (Reisman et al, 2013). For the patients, one of the primary goals during rehabilitation is to be able to walk again (Lutz et al, 2011; Reisman et al 2013). Therefore, significant effort is focused on gait retraining (Reisman et al 2013).

Gait retraining following a stroke is complicated since alterations in the normal gait pattern, such as decreased speed, asymmetric step lengths and single-limb support (SLS) times are very common (Savin et al 2013, 2014). These alterations have an influence on balance and are related to increased rate of falls following stroke (Savin et al 2013).

Recently it has been shown that gait asymmetries post stroke can be affected by using locomotor adaptation strategies (Savin et. al, 2013; 2014). Motor adaptation is defined as a process of adjusting a well-learned movement pattern (e.g. walking), that occurs over a period of trial and error practice, when exposing the movement to a novel sensorimotor perturbation (Martin et al 1996, Reisman et al 2010, Savin et al 2014).

So far, interventions which implemented this approach used very massive and expensive systems such as split-belt treadmills, or treadmill with cable and weight system attached to it (Reisman et al, 2009; Reisman et al, 2013; Savin et al, 2014). These systems can be used in large rehabilitation centers, however their accessibility to the patients is low. In addition, the number of training sessions and the environment in which the gait training is performed are very limited under these circumstances. The ability to enhance the number of repetitions and to practice in different environments are well-known motor learning principles (Kleim and Jones, 2008). Hence, the need for an accessible system that will

enable the patients to enhance practice frequency at home and other different environments, is significant.

Similar to the studies of Savin et al, (2013; 2014), and according to the definition of motor adaptation as mentioned above, it seems that the Salute Just Walk device can be used as a sensorimotor perturbation during walking. It can be used on a daily basis, on any type of surface, at home or outside. The device works on the affected lower limb and provides assistance in the initial swing and resistance in the terminal swing of the gait (for more details see the description in Methods). This resistance is creating 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 Just Walk device when used as a perturbation to the hemipartic gait pattern of a chronic stroke patient, over a 3 weeks period. We wish to observe if the Salute Just Walk device can improve step length and foot-slap of the paretic limb and if it can affect dynamic stability.

Methods

Participants and Study design

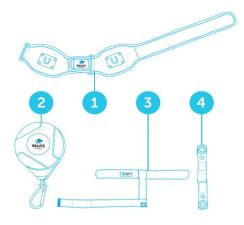
This study design was a single-subject case-study. The subject participating in this study is an 81-year old chronic stroke patient, 23 years following a left hemorrhagic stroke with resultant right hemiparesis. The subject is able to walk independently without assistive devices or orthotic devices, even though he suffers from a mild foot slap in walking.

Experimental protocol

The subject participated in a 3 week training protocol with the Salute Just Walk device which was placed on his right leg (paretic limb) and was connected to the forefoot. Training was performed daily, 2 times a day (morning and evening) and included 15 minutes of functional exercises (i.e. stepping sideways, forward and backward) and walking with the Salute Just Walk device. Functional tests were performed by a physical therapist at the first session and after 3 weeks in the following order; first without the Salute system (pre-test-without), then with the system (test-with), and once again at the end of the session (after training) without the Salute system (post-test-without).

Salute 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 in the belt. The device provides continuous linear and adjustable tension by creating a magnetic force that is converted into kinetic energy. A tension cord in the device quick connects to the patient's foot / shoe via an adjustable foot strap that fits the feet and ankle strap (3). Variable resistance puts tension and pressure on the leg as the person walks. An extra strap (4) is supplied, that can be attached in alternative locations on the foot strip 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 in a clockwise direction. The foot belt is adjusted around the feet and ankles. The patient then pulls the tension cord from the device and attaches the D-clip in the cord to the foot strap. The patient then walks with the device on.

Outcome measures

The modified Four Square Step Test (mFSST) was performed in order to evaluate the improvement in dynamic stability. It was found as a test which can identify progress in people with stroke in varied settings. The test requires subjects to rapidly change direction while stepping forwards, backwards, and sideways. Time to complete the test is measured. The test was found to be reliable (intraclass correlation coefficient ranges: 0.81–0.99) and valid (Roos et al, 2016). The minimal detectable change was 6.73 s. (Roos et al, 2016).

Results

<u>Safety-</u>No adverse events or side effects were reported by the subject, except for tiredness after the first practice. The subject reported he managed to place the belt, ankle and foot strap and to attach the tension cord with the D-clip to the foot strap without any assistance.

<u>Efficacy-</u>Improvement was found in the mFSST test, both in the pre/post-test during each session and also when comparing scores of each test from the first session with the second, as described in Table 1. The improvements in the scores of the mFSST in pre- and post-test of the first session were above the minimal detectable change (MDC) as found by Roos et al, (2016). The difference in the scores of the mFSST of the pre-tests that were taken in the first and second sessions, without the Salute Just Walk device, was also above the MDC.

Table 1- Functional scores of the mFSST.

Measurement mode	mFSST (sec) at 1 st session	mFSST (sec) after 3 weeks	Difference between scores
pre-test-without	18.45	8.9	9.55
test-with	14.88	9.43	5.45
post-test-without	10.58	7.26	3.32
Difference between pre- and post- score (without)	7.87	1.64	-

mFSST= modified four square step test, pre-test-without= pre-test without the Salute Just Walk device, pre-test-with=with the Salute Just Walk device

Subjective outcome measurements – improvement in step length of the paretic limb along with an improvement in foot-slap, were seen immediately after a few minutes of practice, when the device was still placed on the subject. At the first session this improvement lasted only a few minutes after removing the system. However, after 3 weeks of practice these improvements were maintained and were also reflected when the subject performed the mFSST at pre-test mode, without the device.

Subjective report of the subject – at the first few minutes of the first practice, the subject reported on an odd feeling of a restricted ability to step with his right leg. However, after 15 minutes of practice he reported on a lightness feeling of lifting his leg while walking. After the 3 weeks period of practice with the device, the subject reported that this feeling of lightness lasts for almost half of the day after his morning practice. He also reported on an improvement which was manifested mostly in longer walking distances and on a better ability to walk on faulty surfaces, inclines and slopes. He explained his improvement by a better ability to take a longer step with his right leg (i.e. the paretic leg), since he was able to flex his hip and knee more easily during walking. He also specifically described a significantly improvement in the feeling of dragging his right foot.

Discussion and conclusions

Our results in this single-subject case-study imply that the Salute Just Walk device can be an effective therapeutic device for gait and balance rehabilitation.

While the results seem to fit with the locomotor adaptation approach, it seems that there might be another explanation to this improvement seen in the mFSST scores which was also described by the subject. The subject explained his improvement in walking and dragging his foot by an improved ability to flex his hip and knee while walking. However, the subject didn't seem to have a significant weakness which can explain the lack of sufficient hip and knee flexion during walking before using the Salute Just Walk device. One explanation for this improvement may be the proprioceptive stimuli created by the system during practice. There is an assumption that in locomotion, load afferent input and hip-joint position afferent input has an important role in the activation pattern of the leg muscles (Dietz, 2002). It is possible that the assistance provided by the system enabled enhanced proprioceptive input by affecting on the joint position of the hip as well as on the load receptors while walking. This may have affected the movement pattern of the subject's walking, which was manifested in longer and higher steps and improved clearance.

In future studies, we wish to examine these outcomes in a gait laboratory where step parameters and kinematic analysis of joints range of motion can be measured accurately. We see our encouraging results as the foundation for future studies, with larger subject populations which will establish the Salute Just Walk device as an innovative therapeutic device for gait rehabilitation among chronic stroke patients.

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