An innovative Neuro-Motion Learning™ device for improving gait speed and basic activities after stroke

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

Background: Stroke is a leading cause of disability and death. Disability following a stroke has an enormous effect on many functions. Regaining mobility is one of the most important functions for the patients; however alterations in the normal gait pattern are very common and complicate the rehabilitation process. The variety of treatment strategies aimed to improve these alterations (such as decreased gait speed and gait asymmetries) is very large. For gait speed, no treatment method was found to be superior to others. Instead, repeatability and intensity of the intervention program seem to matter. Gait asymmetries post stroke seem to be well improved by using locomotor adaptation strategies. Our goal in this single-subject case study is to present our clinical experience with the Salute Just Walk device for improving the hemipartic gait pattern of a chronic stroke patient, over a 4 week period. We wish to observe if the Salute system can improve basic activities, gait speed and step length of the affected limb, by inducing a strong proprioceptive stimulus and by creating a swing phase perturbation.

Methods: This is a single-subject case-study of a chronic stroke patient. The subject participated in a 4 week training protocol with the system. Training included 10 to 15 minutes of walking with the system every day for two weeks, and 20 minutes in the following two weeks. In addition, the subject participated in a 30-minutes physical therapy session twice a week, which included functional exercises with the system. Timed-up and go test (TUG) and 10-meter walk test (10MWT) were taken in the first session and after 4 weeks. They were performed first without the Salute 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 the training protocol while still connected the system.

Results: improvement was found in both the TUG test and the 10MWT, when the largest difference was seen at the second session (i.e. after 4 weeks of training). Improvement in step-length asymmetry was observed as well.

Conclusions: Our results imply that Salute's Just Walk device is an effective therapeutic device which can lead to improvement in basic activities and gait speed 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). Disability following a stroke has an enormous effect on many functions. One of the most important functions for the patients is mobility (Bijleveld-Uitman et. al, 2013). Therefore, regaining walking ability is a primary goal in rehabilitation (Lutz et al, 2011; Reisman et al 2013) and is often considered as a measure of success of the treatment (Dickstein, 2008).

Gait retraining following a stroke is complicated since it usually involves many alterations in the normal gait pattern, such as decreased speed, asymmetric step lengths and single-limb support (SLS) times (Savin et al 2013, 2014). Improving these alterations is of great importance since they are all related to reduced balance abilities and increased rate of falls following stroke (Savin et al 2013).

The variety of treatment strategies for post-stroke gait rehabilitation is very large. Different kinds of interventions such as lower extremity strengthening exercises, treadmill training; with or without body weight support, electrical stimulations and robotics all aim to improve gait speed as well as gait asymmetry parameters. For improving gait speed and achieving functional community walking, it appears that the essential characteristics of the intervention program are repeatability and intensity rather than the type of the intervention itself (Dickstein, 2008). Among the different strategies for improving post stroke gait asymmetry, it has been recently shown that motor adaptation strategies can be effective (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). The perturbation causes movement errors that initially increase the asymmetry (e.g. step length asymmetry), however with short practice adaptation is created and asymmetry is improved (Reisman et. al, 2010, Savin et al, 2014). Locomotor adaptation (i.e. motor adaptation applied to walking) allows flexibility and enables the adaptation of walking to novel circumstances (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.

In this report we present the Salute Just Walk device and how it can be used to create a very similar swing phase perturbation. The system 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. The system 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). 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 the hemipartic gait pattern of a chronic stroke patient, over a 4 weeks period. We wish to observe if the Salute system can improve gait speed and step length of the affected limb.

Methods

Participants and Study design

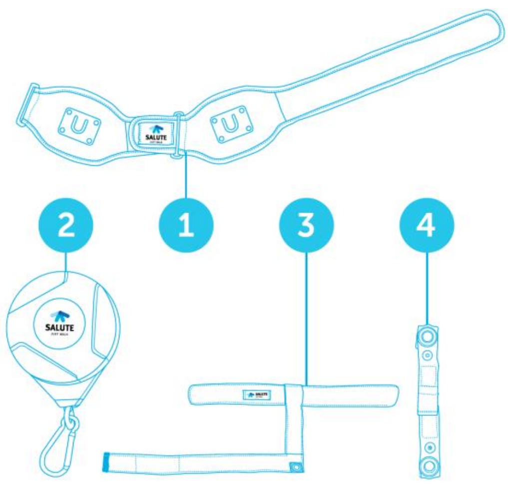
This study design was a single-subject case-study. The subject participating in this study is a 68-year old male, 9 months post stroke with resultant right hemiparesis. The subject walks independently without assistive devices and uses an off-the-shelf AFO brace because of a foot-slap (i.e. reduced eccentric control of dorsi-flexors muscles). The main alterations in the subject's gait, as observed while performing observational gait analysis, were reduced gait speed, reduced knee control during terminal stance, and shorter step length (all regarding his paretic limb).

Experimental protocol

The subject participated in a 4 week training protocol with the Salute Just Walk device, which was connected above the ankle to the posterior part of his leg. Training included 10 to 15 minutes of walking with the system every day for the first two weeks, and 20 minutes in the following two weeks. In addition, two times a week the subject participated in a 30-minutes physical therapy session with a well-trained physical therapist with over 10 years of experience in neurological rehabilitation. The physical therapy session included functional exercises such as stepping in different directions, exercises in standing in front of a step and climbing up and down the stairs, all performed with the Salute system. Functional tests were performed in the first session and once again after 4 weeks of training in the following order; without the Salute system (pre-tests-without), then with the system (tests-with), and once again at the end of the session without the Salute system (post-tests-without). Between the second and third tests the subject practiced the training protocol while still connected the system.

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 on the muscles by creating a magnetic force that is converted into kinetic energy. A tension cord in the device quick connects to patient 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

Primary outcome measures were: (1) The Timed UP and Go (TUG), which is a widely used, reliable and valid performance test for the evaluation of basic mobility skills after stroke and provides information on the abilities that facilitate living safely at home. 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) 10-meter walk test (10MWT), assesses walking speed in meters per second is also a well-known reliable and valid functional test. The subject is instructed to walk 10 meters and the time is measured. The distance covered is divided by the time it took the subject to walk the distance (Flansbjer et al, 2005). The subject in this case-study used his brace while performing the functional tests and was instructed to walk as fast as possible on both of the tests.

Results

Safety

No adverse events or side effects were reported by the subject. 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.

Efficacy

As described in Table 1, improvement was found in the TUG test, both in the pre/post-test during each of the sessions, and also when comparing scores of each test from the first session and the second. Also, in both the first session and the second, the improvement achieved in the TUG test while walking with the system connected, were maintained after disconnecting it. For the 10MWT, the main improvement was seen in the tests taken at the second session. When looking at the outcomes of the first session, there was an improvement in gait speed while walking with the system. However, after disconnecting, gait speed was the same as base-line. It is possible that the improvement wasn't maintained after disconnecting the system because the practice time was too short for a first time practice in this case (i.e.15 minutes). The fact that at the pre-test of the second session (after 4 weeks of training) the outcome on the 10MWT was already improved, and after disconnecting the system the score was even better, reinforces this assumption.

Observational gait analysis – improvements were seen in walking speed, as well as in step length asymmetry. Swing and stance times of the affected limb did not seem to change.

Table 1- Functional scores of the subject in the TUG and 10MWT.

	TUG (sec) 1st session	TUG (sec) 2nd session	Difference in TUG 2nd -1st session	10 MWT (m/sec) 1st session	10 MWT (m/sec) 2nd session	Difference in 10 MWT 2nd -1st session
pre-test-without	10.7	9.2	**-1.5**	1.06	1.23	**0.17**
test-with	9.6	7.3	**-2.3**	1.16	1.40	**0.24**
post-test-without	9.4	7.6	**-1.8**	1.05	1.49	**0.44**
Difference between *pre-* and *post-* score (without)	**1.3**	**1.6**		**0.01**	**-0.26**	

TUG= Timed up-and-go test, 10MWT= 10 meter walk test, pre-test-without= pre-test without the Salute Just Walk device, pre-test-with=with the Salute Just Walk device.

Discussion and conclusions

Our results in this single-subject case-study imply that following a chronic stroke Salute's system can be an effective therapeutic device for the improvement of gait speed, as well as basic activities that are usually performed numerous times during the day. It also seems to improve gait asymmetry parameters such as step length of the affected limb.

We attached the system to the posterior part of the ankle because based on the locomotor adaptation approach; we wanted to create a resistance to the forward movement of the leg during swing. Based on Savin et al, (2014) we expected that adaptation to the new resistance will occur and that it will be manifested in increased step length and gait speed. Indeed, our experiment results show an improvement in gait speed, as reflected by the scores of the 10MWT. Gait speed is one of the significant, reliable and valid measures of functional community walking ability (Dickstein, 2008; Bijleveld-Uitman et. al, 2013). The mean gait speed of chronic stroke patients reported is 0.53 (±0.22) m/sec (Dickstein, 2008). In our experiment, after 4 weeks of training with the Salute's system, the subject achieved a gait speed of 1.49 m/sec. This is above the reported mean gait speed of healthy subjects; 1.34 (±0.17) m/sec (Dickstein, 2008). The improved step-length of the paretic limb however, was only observed and not measured in this case-study. We intend to verify this in a future clinical trial with a large population of chronic stroke patients that will be performed in a gait laboratory with the ability to measure symmetry and step parameters.

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.

Lam et.al,(2006) applied a velocity-dependent resistance against hip and knee movements, by using an exosekeletal robotic gait orthosis device, mounted on the lower limbs of healthy subjects walking on a treadmill. In their experiment, Lam and his colleagues (2006), have shown that the adaptive modifications in the walking pattern to the applied resistance, involved both feedback and feedforward motor-control strategies. Feedback mechanisms were manifested in immediate reaction of increased muscle activity and reduced hip and knee range of motion, which occurred right with the first time a subject took a step against resistance (i.e. adaptation to the sensory input). While the subjects continued to walk with resistance, adaptation had occurred. This was reflected in returning to the baseline values of range of motion during swing although there was no change in resistance. However, after adaptation was observed, resistance was unexpectedly removed which resulted in a reaction of increased hip and knee range of motion. This implies a feedforward adaptive mechanism (Lam et.al, 2006). Meaning, the nervous system anticipated resistance during upcoming movement and attempted to produce the appropriate motor command (Shadmehr and Mussa-Ivaldi 1994; Lam et. al, 2006). These results reinforce the findings in this case-study and the expected effect of the Salute system.

Finally, the advantage of our system compared to the other systems mentioned above (Lam et al, 2006; Savin et al, 2014), is that it enables specificity, increased number of repetitions and adjusted intensity. 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 system as an Intuitive Neuro-Motion Learning therapeutic device for improving basic activities, gait speed and step length among chronic stroke patients.

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