An innovative gait rehabilitation device for improving gait parameters of a child with Cerebral Palsy

Keywords:
Cerebral Palsy
Gait
Rehabilitation
Motor Adaptation
Motor Learning

Abstract

Background: Cerebral Palsy (CP) is an umbrella term that covers a group of non-progressive, but often changing, motor impairment syndromes secondary to lesions or anomalies of the brain arising in early stages of development (Mutch 1992). Anomalies of gait are dominant and one of the most evident functional goal of therapists and parents alike is to improve or maintain walking (Hoffman 2017). Gait training is an acceptable mode of preserving and improving gait abilities among children with CP. Our aim in this in this single subject case study is to present our clinical experience with Salute's Just Walk device for improving the gait of a diplegic Cerebral Palsy patient over a 3-week period training. In addition, gait analysis results performed in a gait laboratory will be presented.

Methods: This is a single-subject case-study of a 10-year old diplegic CP patient. The subject participated in a 3-week training protocol with the system. In addition, gait analysis was performed using a Vicon Motion Capture gait analysis lab. Records for the gait analysis were taken pre- training and post-training. Three-week training included 10 minutes of walking with the system every day for the first week, and 20 minutes in the following two weeks. Timed-up and go test (TUG) and 10-meter walk test (10MWT) were taken in the first session and after 3 weeks. They were performed first without Salute's *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: Timed-up and Go (TUG) and 10 meter walk test showed an improvement in gait speed both in each session pre and post treatment as well as between the first and second session. Gait analysis results showed an improvement in temporal parameters of hip, knee and ankle flexion, as timing of both legs became more symmetrical post-treatment compared to pre-treatment.

Conclusions: Our results imply that Salute's *Just Walk* device is an effective therapeutic device which can lead to an improvement in gait speed, basic activities and gait temporal symmetry among children with diplegic spastic paresis Cerebral Palsy.

Background

The term cerebral palsy (CP) refers to a group of disorders in the development of posture and motor control as a result of a non-progressive lesion of the developing central nervous system. CP is the leading cause of childhood physical disability worldwide, occurring in 1.5 to 2.5 per 1000 livebirths (Aicardi, 1992). Individuals with CP may also have disturbances of sensation, cognition, communication, perception, and/or behavior, and/or a seizure disorder (Bax, 1964; Bax et al., 2005). In terms of movement disorder, the spastic-paresis is the most common disorder (85%) (McManus et al., 2006; Hagberg B et al., 2001) the two other disorders are the diskinetic paresis and the ataxic-paresis. The most important clinical symptom of spastic paresis is the increase in muscle tone when standing, walking or running, depending on the degree of involvement. Spastic paresis can further be classified as unilateral or bilateral, according to the body parts involved. The unilateral group is referred to as hemiplegia, in which one arm and one leg on the same side of the body are involved, and the bilateral group is referred to as diplegia (e.g. the primary involvement is in the legs) and quadriplegia (e.g. all four extremities are involved: the arms are just as severely, or more severely, involved as the legs, or more) (Scholtes, 2007). One of the most disabling mobility impairments in CP is gait impairment, clinically characterized by reduced speed and endurance, as well as reduced step, stride length, and toe clearance during gait (Pirpiris, 2003; Jean, 2006). The severity of these impairments has been suggested to promote restrictions in the child's participation across a broad range of life domains, including self-care, education and recreation (Imms, 2008). A recent meta-analysis and systematic review has indicated that gait training has a good chance of improving the walking speed of children with CP (Moreau et al., 2016)

Motor Learning theories suggest that when encountering a new motor skill or adapting a new motor skill to a specific situation, a group of interconnected neurons is selected from a primary neuronal repertoire based on prior experience of the task (Willoughby, 2009). Generated movement patterns and postural adjustments are then refined via afferent feedback (Hadders-Algra, 2000). Therefore, it has been argued that to develop and improve a motor skill such as walking, opportunities for repetitive practice of the skill need to be offered (Shumway-Cook, 2007). Treadmill training either with full body weight, body-weight supported or robotic-assisted offer such conditions and is commonly used in rehabilitation centers. Gait training using treadmill allows postural support and fall prevention; however, it still bears several disadvantages. One of them is that it is clinic bound and the presence of a healthcare team member is required. This by itself limits the availability of the practice. Another point to consider is that when relating to specificity of practice, treadmill versus over-ground gait differ in the lower limbs kinematic parameters (joint angles) as well as differences in cadence (rhythmicity of gait) and step lengths (Jung, 2016). Mehrholz et al. (2017) found that walking speed and walking distances were better after over-ground training compared to robotic-assisted gait training. There is a need to practice gait in variable and as close to real-life scenarios as possible. Therefore, 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 Salute's *Just Walk* device and how it can be used as a gait training technology. This device is based on the clinical principle of motor adaptation. 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 over-ground 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 over-ground. The adaptation was manifested in temporarily improved over-ground step length and improved over-ground 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).

In this report we examine Salute's *Just Walk* device and how it can be used to create a very similar swing phase perturbation. The influence of the device is examined on a 10-year-old diplegic Cerebral Palsy patient. 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 both affected lower limbs of the patient 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 Salute's *Just Walk* device for improving the gait pattern of a 10-year-old diplegic Cerebral Palsy patient. Clinical gait tests were performed in baseline and after 3 weeks of daily training with the device. In addition, gait analysis was performed in a gait laboratory pre and post treatment during baseline and results will be presented.

Methods

Participants and Study design

This study design was a single-subject case-study. The subject participating in this study is a 10-years old diplegic Cerebral Palsy patient, right leg is more spastic than the left leg. The subject walks independently without assistive devices. The subject went through Achilles tendon elongation procedure of both legs two years ago with a repetition of the procedure on the right leg alone one year ago. An Ankle foot orthosis was prescribed in order to assist ankle elevation of the right leg, as well as a means of preservation of Achilles tendon length. However, the subject avoids using it due to foot pain. When observing the subject's gait, diminished right foot elevation is noticeable as well as thigh internal rotation in both legs. The sound of both forefeet chafing the floor can be heard during swing phase.

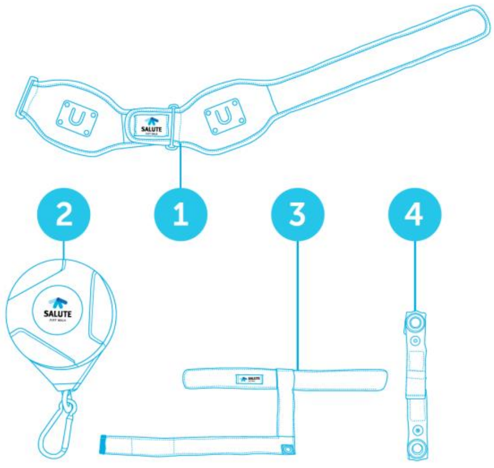
Experimental protocol

The subject participated in a 3-week training protocol with Salute's *Just Walk* device, which was connected to the forefoot of both his legs. Training included 10 minutes of walking with the system every day for the first week, and 20 minutes in the following two weeks. Functional tests were performed in the first session and once again after 3 weeks of training in the following order; without Salute's *Just Walk* system (pre-tests-without), then with the system (tests-with), and once again at the end of the session without Salute's *Just Walk* system (post-tests-without). Between the second and third tests in every session, the subject trained walking while being connected to the system.

In addition, gait analysis was performed in baseline pre-treatment and post-treatment. Subject walked on a treadmill. His gait parameters were recorded pre-training. Salute Just Walk device was fitted, and subject walked on the treadmill wearing the device for 12 minutes. Then, system was removed and gait analysis was performed once again while subject walked on the treadmill post-training. Gait was captured, recorded and analyzed by Vicon Motion Capture System using eleven sensors that were mounted on the subject on the pelvis and on each joint of the lower limb.

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 on 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 extends from the device and is quickly connected to the patient's foot / shoe via an adjustable foot/ankle strap (3). Adjustable resistance applies 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 strap 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 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). Each measurement was recorded 3 times and the average was calculated. (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 was asked to walk as fast as he could during all tests taken. Again, each measurement was taken 3 times and the average was calculated.

Gait analysis data in the gait laboratory was edited, calculated and graphically presented using Polygon Software.

Results

Safety

No adverse events or side effects were reported by the subject. The subject reported that 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, was further improved after disconnecting it. As for the 10-meters walk test, improvement was noted when comparing the end of each session to its beginning. Furthermore, improvement in gait speed is noted between the second and first sessions. In the second session, improvement in gait speed continued after the removal of the device. According to the 10-meter walk test, gait speed kept on improving throughout the training.

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

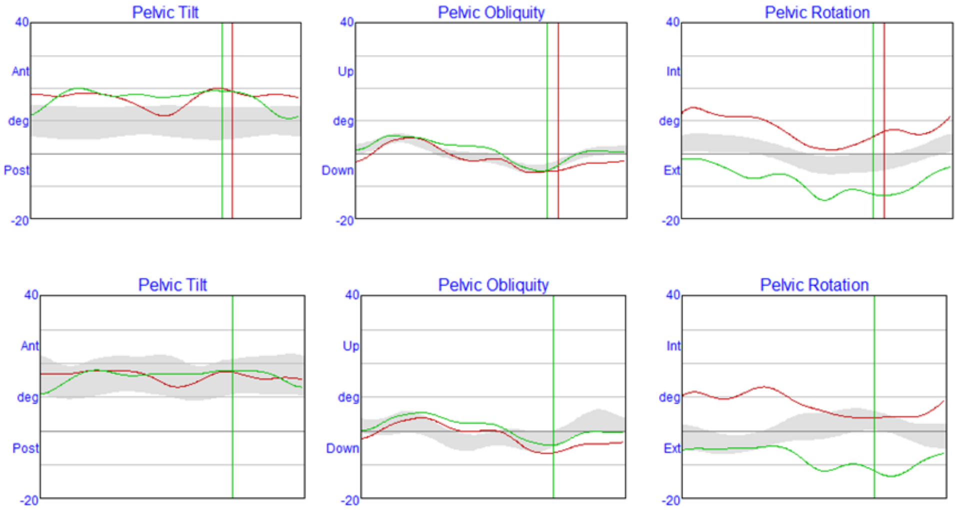
	TUG (sec) 1st session	**TUG (sec) 2nd session**	**Difference in TUG 2nd -1st session**	**10 MWT (m/sec) 1st session**	**10 MWT (m/sec) 2nd session**	**Difference in 10 MWT 2nd -1st session**
pre-test-without	5.7	5.2	**-0.5**	1.5	1.8	**0.3**
test-with	5.5	5.2	**-0.3**	1.7	2	**0.3**
post-test-without	4.8	4.4	**-0.4**	1.7	2.3	**0.5**
Difference between *pre-* and *post-* score (without)	**-0.9**	**-0.8**	**-0.1**	**0.2**	**0.5**	**0.2**

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

Gait Laboratory Results

Figure 1-4 display the differences in the results of pre and post treatment of a single session in the pelvis, hip, knee and ankle joints. Right leg is displayed by a green line, left leg is displayed by a red line and the norm is displayed in gray.

Figure 1- Gait Laboratory Results of pre-treatment vs. post-treatment of a single session in the **pelvis**

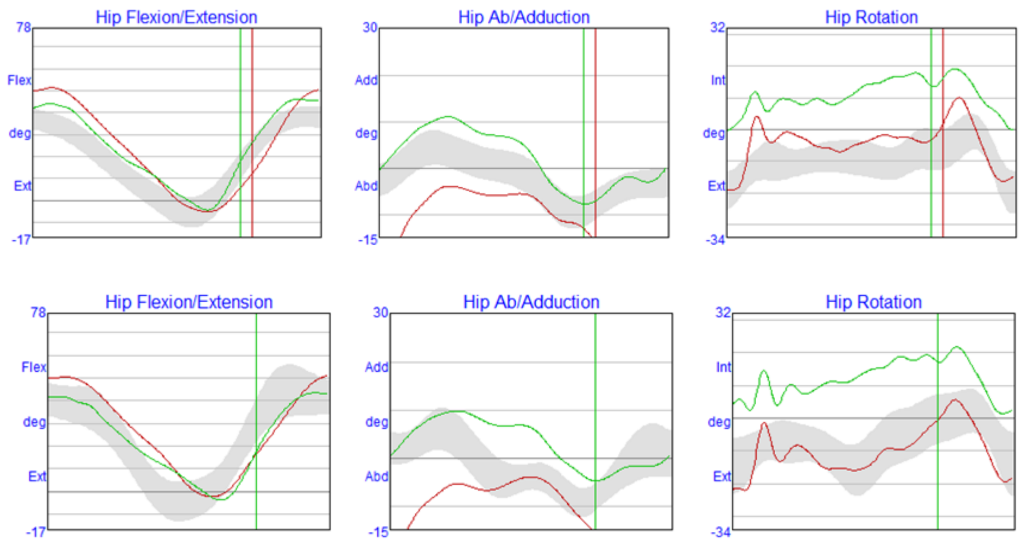


Pre-treatment

Post-treatment

Figure 1 shows that when comparing the pre and post-treatment Pelvic Tilt, the post treatment graph shows that the right and left sides of the pelvis have entered the norm. Pelvic Obliquity shows a better symmetry of both sides in the post-treatment vs. pre-treatment, as both lines move parallel to each other; Pelvic rotation post-treatment shows the approximation of the right pelvis (green line) to the norm, meaning a lesser excessed pelvic external rotation at the beginning of the cycle.

Figure 2- Gait Laboratory Results of pre-treatment vs. post-treatment of a single session in the **hip**



Pre-treatment

Post-treatment

Figure 2 shows the improvement in the symmetry of both legs in Hip Flexion/Extension in the post-treatment vs. pre-treatment, as both lines meet during the 2nd hip flexion (2nd upper curve). The Hip Abduction/Adduction analysis shows ambiguous results: post treatment right hip abduction (green line), when compared to pre-treatment, enters the norm at the beginning of the cycle but then moves away from the norm at the middle of the cycle. The left hip (red line) abduction shows an improvement as the graph enters the norm. Hip Rotation graph shows an improvement of the left hip (red line) as the line enters the norm during post-treatment. A slight improvement in the right leg rotation is noticed towards the end of the cycle, as the green line moves closer to the norm.

Figure 3- Gait Laboratory Results of pre-treatment vs. post-treatment of a single session in the **knee.**

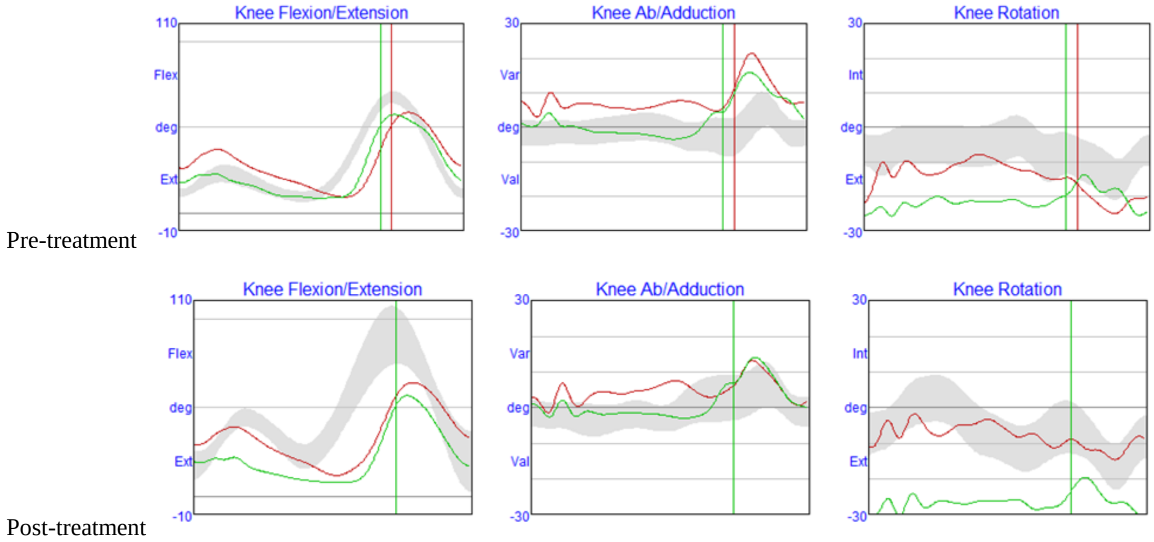


Figure 3 shows that the Knee Flexion/Extension post treatment is more symmetrical temporally speaking, as the right knee corrects the timing of flexion movement and both legs flex at the same point (see the x axis). Knee Abduction/Adduction shift noticeably into the norm, from knee varus towards neutral position. The left knee rotation shifts from external rotation towards the norm. The right knee rotation does not improve but moves even further from the norm.

Figure 4- Gait Laboratory Results of pre-treatment vs. post-treatment of a single session in the **Ankle.**

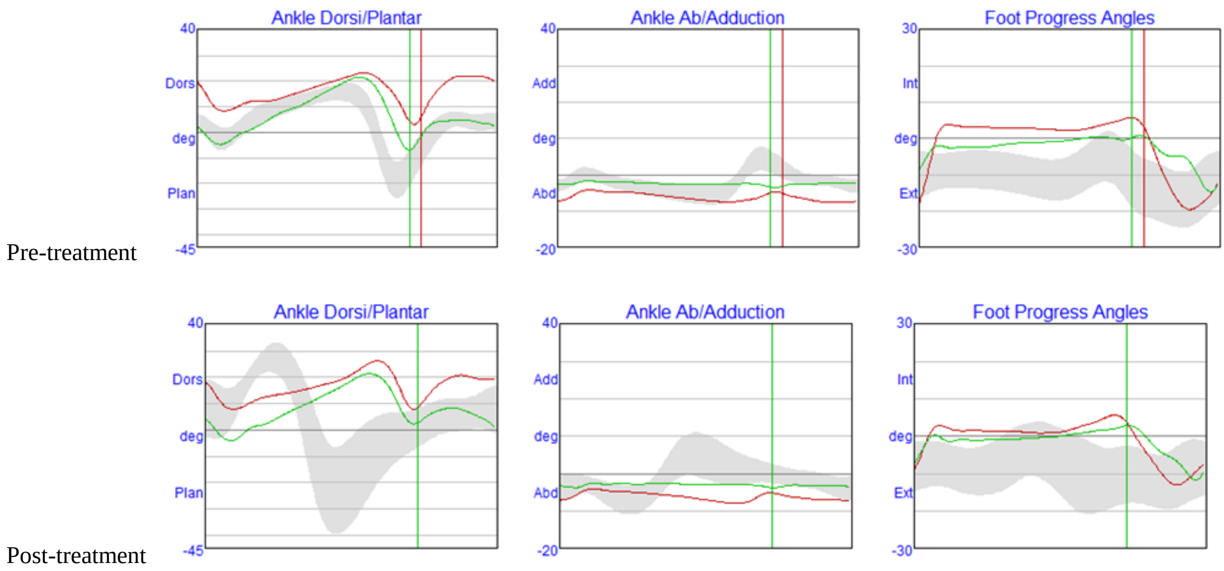


Figure 4 shows that in Ankle Dorsi/Plantarflexion there is an improvement in symmetry, temporally speaking, as both legs start plantarflexing at the same spot on the x axis; during pre-treatment, the right leg began plantarflexing earlier than the left leg. Ankle Ab/Adduction shows no noticeable change pre vs. post treatment. Foot Progress Angles show once more an improvement in the symmetry of the legs, as the graphs of the right and left leg improve in similarity of wave form.

Discussion and conclusions

Our results in this single-subject case-study imply that when using the *Just Walk* device for 3 weeks on a daily basis, a person with diplegic spastic paresis due to Cerebral Palsy may improve gait symmetry, gait speed and basic activities.

We attached the system to the forefoot, as it was noticeable during baseline that an assistance to dorsiflexion is required. Throughout the 3 weeks practice, the subject has reported a sensation of muscle stretch in his Calf muscles whenever using the device. This sensation continued also after removing the device. Considering that the subject went through Achilles tendon release procedure once in his left leg and twice in his right, a daily treatment which enables the preservation of the Achilles tendon length is crucial for him. Moreover, during normal walking, the subject's mother and the subject himself reported on a chafing sound produced with each new swing of the both legs. This sound was produced due to an insufficient dorsiflexion of the feet. According to the subject and his mother, when using the *Just Walk* device, no chafing sound could be heard during the swing phase of both feet; this implies good clearance of the feet off the floor.

Gait analysis records an improvement in the symmetry of hip flexion/extension, knee flexion/extension and ankle dorsiflexion/plantarflexion on the x axis, meaning on the temporal aspect. During pre-treatment, the right leg which is more spastic tended to start movement earlier than the left leg. This difference was lessened post-treatment, as both lines representing both legs aligned to a more parallel position on the x axis. Unlike our expectations, no improvement in the sagittal plane was demonstrated, meaning an improvement in dorsiflexion of ankle and flexion of the hip were not marked. Further improvement could be spotted in pelvic parameters of both legs, left hip abduction/adduction and rotation, both knees alignment in the medio-lateral plane and both legs foot progression angles. The right hip abduction/adduction showed ambiguous results as it improved at the beginning and at the end of the cycle and showed a tendency further from the norm at the middle of the cycle when compared to pre-treatment. Right knee rotation is the only component which showed lesser results post-treatment when compared to pre-treatment.

We assume that the enhanced proprioceptive stimulus enabled by the *Just Walk* device caused the motor adaptation which enabled the correction in the timing of the joints' sagittal movements (hip, knee and ankle flexion/extension). 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).

As for the improvement in gait speed manifested in the results of the TUG and 10 meters walk test, it was expected. The assistance to ankle dorsiflexion together with the resistance to the knee extension and heel strike applied by the *Just Walk* device is considered by us as a sensory-motor perturbation to which the nervous system is required to adapt itself. Based on Savin et al. (2014) we expected that adaptation to the new resistance will occur and that it will be manifested in increased gait speed. Gait speed is a valid and reliable measure of walking ability in children with or without neuromuscular disability (Sutherland, 1988; Boyd, 1999).

Finally, the advantage of our system 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 *Just Walk* device by Salute as an intuitive gait rehabilitation device for improving gait parameters as well as an intuitive neuro-motion learning therapeutic device for improving basic activities, gait speed and gait symmetry among children with Cerebral Palsy.

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