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Original Article

LOCOMOTOR TREADMILL TRAINING PROGRAM USING DRIVEN GAIT ORTHOSIS VERSUS MANUAL TREADMILL THERAPY ON MOTOR OUTPUT IN SPASTIC DIPLEGIC CEREBRAL PALSY CHILDREN

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Abstract:

Purpose : This study intended to understand and compare the effect of loco-motor treadmill training program using robot-assisted gait therapy (Driven gait-orthosis DGO) and manual treadmill therapy on motor function in children with spastic diplegic cerebral palsy on their gross motor skills related to walking speed, ambulation and endurance.

Subjects and Methods : Twelve spastic diplegic cerebral palsy children with the age under 5 years were participated in different ambulation training 3 times per week for 30 - 40 minutes sessions consisting of 2 different treadmill walking programs, for 10 weeks, and were tested pre and post intervention. The outcome measures included were; a timed 10-m walk test, ground walking speed, walking distance, and balance which were measured before and after treatment.

Results & Conclusion : The results of this study suggests preliminary findings that children with CP under the age of 5 years can benefit their gross motor function, gait variables after intensive ambulation training using Driven gait orthotis (DGO).

Keywords : Spastic Diplegic Cerebral Palsy, Driven Gait Orthosis, Motor Function.

Introduction:

Cerebral palsy (CP) is the most common physical disability occurs in childhood. The recent data show that the incidence of CP is 3.6 on every 1000 live births. As there is no cure for the CP, the motor disability continues throughout the life and interacts with normal developmental and aging processes which alter its presentation over time[1]. In spastic CP, spasticity develops because of the damage to the descending motor nerve tracts and there will be resistance and limitation of normal muscle movements[2]. Thereby it leads to muscle contractures which limit joint movement and hence, develop abnormal pattern of motor control[3]. Until recently, treatment for spasticity of muscles in children with cerebral palsy has consisted of physical therapy, bracing and surgery to lengthen and release tight tendons of contracted muscles and correct muscle contractures[4].

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Most of the children with CP have ambulatory difficulties. Because normal walking is essential for orthopedic and cardiopulmonary development, and for normal activities of daily living, the achievement of independent, effective, and safe gait is therefore the most important goal of rehabilitation in children with CP. Their walking energy expenditure is increased up to 3 times that of typically developing children, particularly for children with poorer locomotor function, classified as level III (reliant on a hand-held mobility device for ambulation) or IV (can walk only short distances with a body support walker) by the GMFCS (Appendix 1). Improving walking function for children with moderate to severe walking difficulty is particularly important because it has the potential to increase their mobility and positively influence their societal participation at home, at school, and in the wider community. The benefits of ambulation are many whether with or without assistance like; muscle activity and weight bearing during walking increase bone mineral density (Wilmshurst, Ward, Adams, Langton, & Mughal, 1996) and can decrease the risk of hip subluxation or dislocation (Metaxiotis, Accles, Siebel, & Doederlein, 2000). Other benefits gained from ambulation are improved endurance of cardiopulmonary system and control of obesity (Chien, DeMuth, Knutson, & Fowler, 2006) [1,5,6].

With a growing body of research evaluating the efficacy of training on treadmill for adults with neurologic disorders, most notably after injury to spinal cord, clinicians and researchers in pediatric CP field have begun to turn their attention to the potential benefits of treadmill training for benefitting walking in CP children. This interest is on the basis of the principle that task-specific and repetitive practice is needed to develop and improve a motor skill such as walking. Using a mechanical treadmill, with or without supporting the body weight, may improve gait in children with CP because it gives an opportunity to intensively and repetitively train the entire cycle of gait and facilitate an improved gait pattern during walking. Preliminary work suggests that body weight supported treadmill training is feasible in CP children and may improve their gait variables and general gross motor skills[6].

Locomotor treadmill training (LTT) is relatively new concept that is used to train the CP children on ambulation in a more efficient manner. LTT with or without body weight support, is one method that is followed in the rehabilitation of CP children. The central nervous system (CNS), through mechanisms of brain plasticity, has the capacity to learn and adapt. The goal of therapeutic exercise for the re education of muscles and facilitation is to get back the body positions and movements voluntary control after injury or disease has affected the motor control mechanism. Motor control may be affected by damage to either or both the afferent and efferent neural pathways, as well as damage to central control centers in the motor and premotor cortex. Although, exact mechanisms are not clear, the nervous system is continually adapting to environmental stimuli. This re-organization is termed as neural plasticity[7]. Brain plasticity may be intensified by exercise, including movement activities, and the effect of motor learning depends on the intensity and regularity of performing these[5].

Latest developments in clinical neuroscience give lot of hope that the institution of effective functional therapies on the basis of on enhanced activity can improve the level of functioning in children with CP[8, 9]. Recent concepts of motor learning assume that repetitive, task-specific training, enabled by a driven gait orthosis, may be a cost-effective means allowing for an improvement in walking ability [10, 11]. One of the latest solutions in this area is the Lokomat (Hocoma AG, Volketswil, Switzerland), which was designed for adults and shown to facilitate significant improvements in individuals with injury to spinal cord[12–13]. A paediatric device for children age of 4 years and over has been available since 2006; however, there are only a few studies assessing body-weight-supported treadmill therapy applied to paediatric patients. Robot-assisted walking training can increase the duration of training and the intensity for the patients while the therapist's physical strain also can be minimized.

Aim of the work:

The purpose of the current study was to compare the effect of an intensive, loco-motor treadmill training program using robot-assisted gait therapy (Driven gait-orthosis DGO) and manual treadmill therapy on gross motor skills related to ambulation, walking speed and balance in children with diplegic cerebral palsy (CP) under the age of 5 years.

Subjects and Methods:

Subjects:

Twelve subjects (7 male and 5 female) with neurological walking disorders due to spastic diplegic cerebral palsy participated in the study. The participants had an average weight of 28 kg (SD±4.3), an average height of 89 cm

(SD±6.7), and their age ranged from 3 to 5 years, with an average age of 4.2 years (SD±0.7). All children were being treated as either inpatients or outpatients in pediatric clinics. The subjects were randomly divided into two equal groups, control group and study group. The control group received manual treadmill therapy and the study group received intensive, loco-motor treadmill training program using robot-assisted gait therapy (Driven gait-orthosis DGO), and each comprised of six patients. Both groups used computerized visual feedback and verbal instructions of a physical therapist. After explaining the need of the study to the subject's parties, informed written consent for this study was obtained. The study was approved by the Institutional Review Board.

The inclusion criteria for recruiting the subjects were; All children with cerebral palsy had a pediatrician's diagnosis of spastic diplegia, the subjects were recruited with at least minimal voluntary control of their lower-extremity muscles for the ability to respond and to adapt their walking, the treating physical therapists judge the ability of the subjects to voluntarily control their lower extremities (ie, at least minimal movement in hip and knee joints was observed upon instruction), the subjects were having mild spasticity, which has been confirmed clinically according to Ashworth's scale, the subjects were having Level III or IV of Gross Motor Function Classification System (GMFCS), subjects were having sufficient cognition should be demonstrated to understand the requirements of the study and all subjects have never received treadmill gait training at any time before the study. The exclusion criteria were: children treated with botulinum toxin during the last 6 months; children treated surgically within a 1-year period before the date of the examination; anatomical leg length discrepancy larger than 2 cm (due to the Lokomat system limitations); fixed contractures; bone and joint deformities; bone-articular instability (joint dislocation); baclofen therapy using an implanted infusion pump; inhibiting casts during the last 6 months; significant amblyopia and hearing loss; contra-indications for training on a treadmill; any significant endurance impairments due to cardiovascular limitation based on patient's health history and lack of patient cooperation[5].

Materials:

For the experimental group we have instituted the Lokomat Driven gait-orthosis LDGO (Lokomat® Pro Version 4, by Hocoma AG, Volketswil, Switzerland). The Lokomat system consists of; a treadmill, a body weight support system, a harness, a driven gait orthosis. The Lokomat DGO is a bilateral robotic gait orthosis that is used in conjunction with a body weight–support system to control a patient's leg movements in the sagittal plane. The hip and knee joints of the DGO are actuated by linear drives, which are integrated into an exoskeletal structure with force sensors in the hip and knee linear drives. The legs of the patient are moved with predefined hip and knee joint trajectories. A passive foot lifter induces an ankle dorsiflexion during the swing phase. The legs of the patient are moved with highly repeatable predefined hip and knee joint trajectories on the basis of an impedance control strategy. Knee and hip joint torques of the subject are determined from force sensors integrated in the drives of the DGO[3].

For the control group it was trained on a Manual treadmill therapy consists of; a treadmill, a Biodex unweighing system with hydraulic lift and a harness. The visual feedback is presented and displayed as line graphs on the patient monitor and on the monitor for the physical therapist[9,10].

For the evaluation of the outcome we have used the following tools; Walking sheet: 10 meters long, divided at 1-cm intervals, Recording and displaying system consists of; Video set, camera and tapes, Color TV and Stop watch, Tape measure, The Bruininks-Oseretsky Test of Motor Proficiency Subset 2 for Balance (Form 1), and 10 meter Walk Test (time in sec or msec)

Among the timed walking tests, the simplest to administer is the ten-meter walk test (10mWT). It is simply a documented measure of the time required for the patient to traverse ten meters at his self-selected walking speed. Properly administered, the test is performed with a flying start and finish. Specifically, the patient should be allowed several meters of ambulation immediately before and after the ten-meter walkway to ensure that there are no periods of acceleration or deceleration within the timed event itself. Additionally, clinicians should walk behind the patient rather than at his or her side or in front of him or her to ensure that they are not pacing the patient at a speed other than the patient's true, self-selected walking speed.

Methods of Evaluation:

Age, Sex, height, weight and body mass index (BMI) were done according to standardized methods. Gait evaluation was performed as follows; the walking sheet was positioned on the floor of the gait evaluation area and fastened on both sides. The children were asked to walk as normally as they used to, from the start to the end of the walkway. This was repeated three successive times. Then, the subjects were videotaped along the ten-meter long of the sheet. The videotape was then played back on the TV for the measurement of the temporal and distance gait - parameters, as follows:

- Stride length: The distance between two successive placements of the same foot.
- Cadence: The number of steps taken per minute.
- Velocity: The distance covered in a minute. (Whittle, 1993)

The Balance evaluation was done using the Bruininks-oseretsky Test of Motor Proficiency Subset 2 for balance. Each test was repeated two times, after which the final score was calculated. All evaluation procedures were conducted by the same investigator for each patient before and after the suggested period of treatment.

The following steps were taken before starting the treatment; upon arriving to the treatment area, all the subjects were given an overview of the treatment procedure and were also instructed on how to safely step onto and off the treadmill. The subjects of the control group were fitted with the harness with support across the buttocks, around the thigh and around the rib cage, while allowing free movements of the arms, the harness suspended from an overhead support and the support allowed free movement of the lower extremities.

The subjects of the study group were fitted with a bilateral robotic orthosis that is used in conjunction with a body-weight support system to control the patient's leg movements in the sagittal plane. The DGO's hip and knee joints are actuated by linear drives, which are integrated in an exoskeletal structure. A passive foot lifter induces an ankle dorsiflexion during the swing phase. The legs of the patient are moved with highly repeatable predefined hip and knee joint trajectories on the basis of an impedance control strategy. Knee and hip joint torques of the patient are determined from force sensors integrated in the drives of the DGO[3].

The treating physical therapists judged the ability of the subjects to voluntarily control their lower extremities (ie, at least minimal movement in hip and knee joints was observed upon instruction). The subjects then walked on the treadmill to become familiar with treadmill and determine their self-selected walking speed (Their preferred speed), then the treadmill was stopped, and appropriate amount of unweighting of each subject was adjusted. The treadmill speed was set for each subject individually according to his/her preferred speed. The average speed was 0.55 m/s (SD±0.08 m/s) with the lowest possible body-weight support (where knee buckling was still prevented for passively behaving subjects). The impedance for the DGO control program was set to maximum (ie, the “guidance force” was set at 100%). Then the subjects were weighed on the previously calibrated Tefal Electronic Device (weight scale), this weight was used to calculate the support needed for each subject. The investigator was positioned next to the treadmill to guard the subjects from falling. Treatment for both groups continued for ten successive weeks, thrice a week. Each session lasted about 30 - 40 minutes[3].

Results :

Twelve subjects (n=12) were participated in this study and the statistical comparison between values obtained before and after training were done using “t tests”. Results are presented as means ± standard deviation (SD) and the differences were considered significant by keeping the confidence interval at 5% ($p<0.05$).

As shown in table 1, the mean value of the stride length in study group before treatment was 59.4cms, which increased after the suggested period of treatment to 66.0cms. The improvement was 11 %, which revealed a highly significant difference ($t = 7.92$, $p < 0.001$) and the mean value of the stride length in control group before treatment was 59.0cms, which increased after the suggested period of treatment to 61.4 Cm. The improvement was 4 %, which revealed a non significant difference ($t = 2.714$, $p < 0.025$).

As shown in Table 2, the mean values of cadence in the study group before and after the suggested period of treatment were 74.16 ± 7.386 and 80.92 ± 6.369(in steps/min), respectively. The mean difference was 6.76, which was statistically highly significant ($p < 0.001$) whereas the mean value of cadence in the control group increased from 74.96 ± 7.295(in steps/min) to 79.57 ± 8.135 (in steps/min) after treatment, which indicated a non-significant improvement ($p < 0.815$).

As it is shown in the table 3, the mean value of velocity in the study group before treatment was 36.03 ± 4.495 cms/sec which was increased to 41.8 ± 3.705cms after 10 weeks of treatment. The mean difference was 5.75, which represented a highly significant difference ($p < 0.001$). In the control group, the mean value of velocity has increased from 38.45 ± 4.272cms to 39.67 ± 3.637cms after application of the traditional physical therapy program, with a mean difference of 1.22, which was shown as statistically not significant ($p<0.032$).

From the table 4, it can be shown that in the study group, the mean values of the grades of stability before and after treatment were 14.6 ± 0.966 and 16.4 ± 2.75 (grades), respectively where the mean difference was.1.8 grades, which was statistically highly significant ($p< 0.001$). Meanwhile, the mean values of these grades in the control group before and after treatment were 15.3 ± 1.494 and 16.6 ± 1.577(grades) respectively, showing a mean difference of 1.3 (grades) which was also statistically significant ($p < 0.005$).

APPENDIX

1. The Bruininks-Oseretsky Test of Motor Proficiency Subset 2 for balance. (Form 1)

Action	Duration	Point Score		Total Score
		Trial 1	Trial 2	
Standing on preferred leg on floor	10 seconds maximum per trial	( ) seconds 0 1 2 3 4	( ) seconds 0 1 2 3 4	
Standing on preferred leg on balance beam	10 seconds maximum per trial	( ) seconds 0 1 2 3 4 5 6	( ) seconds 0 1 2 3 4 5 6	
Standing on preferred leg on balance beam-eyes closed	10 seconds maximum per trial	( ) seconds 0 1 2 3 4 5 6 7	( ) seconds 0 1 2 3 4 5 6 7	
Walking forward on walking line	6 seconds maximum per trial	( ) steps 0 1 2 3	( ) steps 0123	
Walking forward on balance beam.	6 seconds maximum per trial	( ) steps 01 2 3 4	( ) steps 0123	
Walking forward heel-to-toe on walking line	6 seconds maximum per trial	( ) steps 0123	( ) steps 0123	
Walking forward heel-to-toe on balance beam.	6 seconds maximum per trial	( ) steps 0 1 2 3 4	( ) steps 0123 4	
Stepping over response speed Stick on balance beam	10 seconds maximum per trial	( ) steps 0123	( ) steps 01	

Adopted from Bruininks (1987)

TABLES:

Table1 : Shows mean values of stride length (in cms) in both control and study group after treatment

Comparison	Study		Control	
	Pre	After	Pre	After
Mean	59.4	66.0	59.0	61.4
SD	5.92	5.436	6.342	7.662
MD	6.6		2.4	
t	7.92		2.714	
p	< 0.001		0.025	

Table 2: Shows mean values of cadence (in steps/min) in both study and control groups before and after treatment.

Comparison	Study		Control	
	Pre	Post	Pre	Post
Mean	74.16	80.92	74.96	79.57
SD	7.386	6.369	7.295	8.135
MD	6.76		0.39	
t	6.002		0.241	
p	< .001		<0.815	

Table 3: Shows mean values of gait velocity (in cms /sec) in both study and control groups before and after treatment.

Comparison	Study		Control	
	Pre	Post	Pre	Post
Mean	36.05	41.8	38.45	39.67
SD	4.495	3.705	4.272	3.637
MD	5.75		1.22	
t	8.4		2.542	
p	< 0.001		< 0.032	

Table 4: Shows mean values of Stability (in grades) in both study and control groups before and after treatment.

Comparison	Study		Control Group	
	Pre	Post	Pre	Post
Mean	14.6	16.4	15.3	16.6
SD	.966	2.75	1.494	1.577
MD	1.8		1.3	
t	1.765		3.545	
p	< 0.001		< 0.005	

Discussion:

The purpose of the current study was to compare the effect of an intensive, loco-motor treadmill training program using robot-assisted gait therapy (Driven gait-orthosis DGO) and manual treadmill therapy on gross motor skills related to ambulation, walking speed and balance in children with diplegic cerebral palsy (CP) under the age of 5 years.

Walking ability, which is extremely important for the quality of life and participation in social and economic life, can be adversely affected by neurological disorders[5]. Rehabilitation of patients with such disorders should include gait training, due to evidence that the desired function or movement has to be developed in a task-specific training programme[14, 15]. Recently, gait rehabilitation methods in patients with neurological impairments have relied on technological devices, which drive the patient's gait in a body-weight support condition and emphasize the beneficial role of repetitive practice[11]. The rationale for these approaches originates from animal studies, which have shown that repetition of gait movements may enhance spinal and supraspinal locomotor circuits[16].

In this study we examined the changes in gait parameters associated with DGO and supported body weight tread mill training. We Utilized gait evaluation parameters, including, stride length, cadence, velocity and the Bruininks-Oseretsky Test Motor Proficiency Subtest 2 for balance. The results at the end of the treatment period indicated significant improvement in cadence, stride length, gait velocity and balance in the study group who received a bilateral robotic orthosis that is used in conjunction with a body-weight support system whereas in the control group only the balance has shown a significant improvement. Such significant differences reflect the great influence of the bilateral robotic orthosis that is used along with body-weight support system training in treatment of diplegic CP.

The use of DGO in patients with CNS disorders has many benefits. These include: providing a safe environment to practice walking[17], making repetitive training more feasible, increasing safety of standing and ambulation training, and decreasing the work reducing the number of therapists[18,19]. However, the limitations and controversial findings in published research suggest the need for further studies[19, 20]. Unfortunately we could not find much of published articles on the effect of DGO in CP children to have a comparison of the current study; meanwhile we could find many articles on the effect of body weight supported treadmill training (BWSTT) in different neurological conditions. In our study it was found that both these treatment techniques are found to be effective but DGO had a slightly better edge on the parameters tested in CP children.

The study by Chrysagis N et al, found in their study on effect of treadmill training on CP children that, children receiving treadmill training had higher mean posttest GMFM and walking speed scores compared with the control group receiving conventional physiotherapy. Therefore, patients with CP exposed to treadmill training may improve their motor function and gait speed to a greater extent, without an adverse effect on spasticity, compared with their counterparts after conventional physiotherapy. This supports the theory of motor learning through task-specific repetitive movements. According to this approach, training should be customized around a treatment goal demanding the participant's active motivation[21]. Another study by Richards et al.(1997)[22] who have stated that, pattern of walking seen in children with CP is very similar to the leg muscle activity described in stepping newborns. They assumed that in children with cerebral palsy, the locomotor pattern cannot mature because of impaired supraspinal influence, and the impact of BWSTT is shown to have a greater effect on neuronal connections in spinal cord.

Schindl et al,(2000)[23], reported that stretching the hip flexors in terminal stance stimulates the primary nerve ending of the muscle spindles, thereby activating the muscles and initiating the leg to come forward. In addition, the increased tension placed on the triceps surae muscle by loading the limb in mid-stance during BWSTT, has also found to facilitate muscle activation. Hesse et al. (1999)[11], stated that BWSTT is beneficial as a treatment method because the movement of the lower extremities into extension afforded by the treadmill assists in stimulating a stepping response not otherwise able to be elicited. While upright and safe position of the patient not only functional for the patient, but it also allows the therapist to be more effective.

Even though therapists are using BWSTT because of its clinical effectiveness, evidence supporting the clinical significance of the treatment method still rather limited. Some limitations do not allow for generalizations of the present findings without adequate caution. An additional secondary outcome variables like muscle strength and energy expenditure, were not assessed in the current study and in addition, the effect of the training program on the participants' psychologic parameters, like quality-of life, was not examined.

Conclusion :

From the results of the present study we can conclude that, the study group CP children who were receiving DGO were showing slightly better improvement in all the gait variables tested except the balance as compared with the BWSTT group.

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Conflict of Interest

Authors agree that there was no source of conflict of interest.

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