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Immediate effects of orthotic garment and strapping system on balance and gait in children with spastic diplegia

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Abstract

TheraTogs, a orthotic garment and strapping system that is known to improve postural alignment, joint stability, and movement efficiency. However, few studies on children with cerebral palsy have investigated its effect on the balance and gait. The purpose of the study is to investigate the immediate effects of TheraTogs used as orthoses on the balance and gait of children with spastic diplegic cerebral palsy. This study used a cross-over design. A total of 24 children (aged 3–14 years) with spastic diplegic cerebral palsy participated. Balance and gait were analyzed using the force plate and GAITRite pre- versus post-TheraTogs use. Sway velocity, sway path, and sway area post-TheraTogs use significantly improved compared to pre-TheraTogs use ($p < 0.05$). Regarding spatiotemporal gait parameters, post-TheraTogs use, gait velocity, cadence, step length, stride length, single support time, and double support time significantly improved ($p < 0.05$). Our results suggest that TheraTogs could be utilized as a useful posture orthosis to help improve the balance and gait of children with spastic diplegic cerebral palsy. However, further high-quality studies are required to validate our findings.

Keywords : Cerebral palsy, orthotic garment and strapping system, balance, gait, TheraTogs

INTRODUCTION

Cerebral palsy (CP) is a group of disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing fetal or infant brain.[1] With posture and movement problems as cardinal symptoms, CP is accompanied by various dysfunctions including muscle weakness, sensory and coordination dysfunction, cognitive impairment, language disorders, behavior pattern changes, epilepsy, and problems with the secondary musculoskeletal system.[2] In addition, participation in daily life is limited due to motor and postural dysfunction.[3,4]

The commonest type of CP is spastic CP. Children with spastic CP are characterized by a lack of muscle control due to increased spasticity, abnormal flexibility, muscle weakness, and insufficient development.[5] Accordingly, their posture control for sitting, standing, and gait deteriorate, severely limiting activities of daily life. Postural control is very important to one's independence[6], and its deficiency is among the largest problems for children with CP.[7]

Towards improvements in postural control through intervention, the use of orthoses has stood out, and studies of their effects have been reported.[8] Chang *et al*.[9] reported that the use of a customized external strap orthosis affects plantar pressure and gait in children with CP. Dureja and Verma[10] reported that therapeutic taping improves posture (sitting posture of the Gross Motor Function Measure) of children with CP. These previous studies noted the significance of the application of an orthosis to improve postural control and gait in the rehabilitation of children with CP. One such method is a therapeutic suit. Elshafey[11] investigated the impact of suit therapy on abnormal gait patterns of children with spastic diplegic CP and reported that a suit that can correct posture can effectively improve gait. Hemayattalab and Rostami[12] noted that a therapeutic suit could be used to correct posture in real time and promote normal movement patterns in children with CP. These studies stated that the therapeutic suit could improve the proprioception,

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postural alignment, balance ability, and gait patterns of children with CP.[13] However, a study by Martins *et al*.[14], suggested a lack of scientific evidence and effectiveness of therapeutic suits, and another study also suggested that TheraTogs had a positive effect on posture alignment and walking functions in CP, but lacked research to support them.[15] TheraTogs developed by TheraTogs Co., Ltd., consists of a flexible garment and stripping system and provides repetitive sensory feedback. Unlike other therapeutic suits, it is known to be worn comfortably as a garment in daily life, enabling long-term daily activities. These technologies are intended to improve postural alignment, joint stability, and movement efficiency.[16]

Children with cerebral palsy have difficulty with balance and gait due to problem in postural control. TheraTogs can have a positive effect on posture alignment and control. However, there is a lack of study to support whether TheraTogs have a positive effect on the balance and gait of children with spastic diplegic CP. Thus, this study investigated immediate effects of TheraTogs use as a orthotic garment and strapping system on the balance and gait of children with spastic diplegic CP.

METHODS

Participants

This study included children diagnosed with spastic diplegic CP. The volunteers were recruited through the offline bulletin boards of a developmental institute and a rehabilitation center located in South Korea. The inclusion criteria were: 1) A diagnosis of spastic diplegic CP confirmed by a neurologist; 2) age 3–14 years; 3) Gross Motor Function Classification System level I or II; 4) ability to walk > 10 meters without a gait orthosis; and 5) never used TheraTogs before. The exclusion criteria were: 1) history of contact allergic reactions; 2) inability to understand or follow the researcher's instructions; and 3) currently taking a drug that affects balance or gait. Thirty-six children applied through recruitment, of which a total of 12 children were excluded, including two who were not diagnosed with cerebral palsy by a neurologist, nine who did not follow instructions, and one who did not meet the age criteria. Finally, 24 individuals were included. The participants' general characteristics are shown in Table 1.

Ethical consideration

This study was conducted after receiving approval from the institutional review board of Kyungnam University. The participants were children aged < 18 years, and consent was obtained from them or their legal guardians after the study purpose and procedures were explained. The participants signed an assent form and the parents signed a consent form.

Procedure

The general information of participants including sex, age, height, weight, and onset period were collected by brief interview or medical record review. Balance and gait were measured using a force plate and GAITRite pre- and post- orthotic garment and strapping system (TheraTogs) use. TheraTogs (TheraTogs, Inc., Telluride, USA), a class I medical device registered with the United States Food and Drug Administration, is a clothing system consisting of a garment (top and bottom) and strap made of a patented soft-foam material designed to aid with functional recovery. In the study, TheraTogs full body system was used. Participants wore a TankTop and a Hipster and added limb cuffs and striping. (Figure 1). Before the TheraTogs were applied, the garment was adjusted for the participant's height and weight. Participants had no experience of wearing TheraTogs before the experiment and

Table 1: General information of the participants

Variables	
Gender (male / female)	16 / 8
Age (year)	6.17 (2.64)
Height (cm)	108.67 (28.77)
Weight (kg)	27.33 (21.87)
Disease duration (month)	78.42 (32.09)
GMFCS (Level I/II)	16 / 8

The values are presented as frequency or mean (SD).

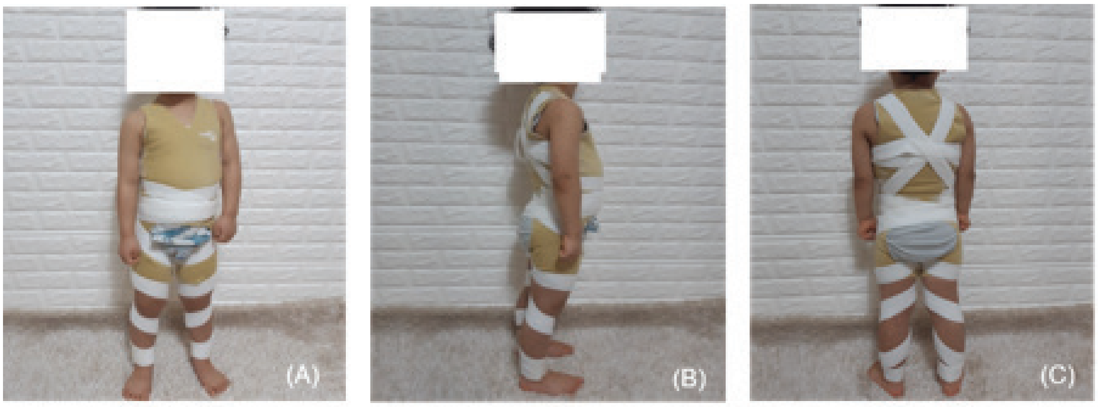

Figure 1. TheraTogs ULTRA Posture and Torso Alignment System: (A) Front view, (B) Side view, (C) Back view

had 30 minutes of experience wearing TheraTogs before the experiment. The participants were randomly assigned by the research assistant to undergo measurements of balance before putting on the TheraTogs, walking before putting on the TheraTogs, balance after putting on the TheraTogs, or walking after putting on the TheraTogs. All measurements were made by two research assistants and were blinded by a barrier so that the participants did not know if it was before or after application of the TheraTogs. The statistical analysis was performed by another research assistant who was blinded to the participants' identity and measurement order.

Outcome measures

Balance was measured by a force plate (AMTI, Waterton, MA, USA), a 50 cm × 46 cm static balance measuring instrument containing four 6-axis load cells. The signals recorded on the force plate are amplified to a signal that can be recognized by an amplifier and transmitted to a computer through a cable. The transmitted signals are converted into digital format by a 12-byte converter and stored in a numeric form on the computer. The sampling rate was set at 100 Hz, and 12 Hz low-pass filtering was performed. The participants were asked to stand at the center of the force plate with their arms comfortably at either side and stare at a small dot on the wall located 1 m in front of them. The pre- and post-TheraTogs use conditions were repeated 3 times with the participant standing on two legs for 90 sec. A 5-min break was given after each trial, and a minimum 5-min break was assumed for changing the task. Using the force plate, sway path, sway velocity, and sway area were collected as variables. The average value of 3 measurements for each task was used in the statistical analysis.[17]

Gait was measured using the electronic walkway (GAITRite, CIR System Inc., NJ, USA). The GAITRite, which has a length of 4.8 m and width of 0.9 m, is an electronic walkway that contains sensors arranged in a pattern to measure the pressure exerted by the feet on the contact surface. The equipment acquires data that are transmitted via connections to a laptop; software within the computer processes patterns from the soles of the feet. Participants walked about 10 m, which included the length of the GAITRite. The GAITRite was installed about 2 m past the starting line to reduce the participants' awareness of it. Participants were asked to stand at the front of the GAITRite and walk with it at a comfortable speed. At the researcher's signal, the participants ambulated 8.8 m. In the pre- and post-TheraTogs use conditions, 3 attempts were made. A 5-min break was given after each trial, and a minimum 5-min break was assumed for changing the task. Spatiotemporal gait variables (velocity, cadence, step length, stride length, single support time, and double support time) were collected. The average value of 3 measurements for each task was used in the statistical analysis. The test–retest reliability had an intraclass correlation coefficient of 0.91, indicating high reliability.[16]

Data analysis

SPSS version 18.0 (SPSS Inc., Chicago, IL, USA) was used for the statistical analyses. The participants' general characteristics are expressed as mean (standard deviation) or frequency (percentage). All the data were normally distributed. The differences in pre- versus post-TheraTogs use were analyzed using a paired t-test. The significance level was set at $\alpha = 0.05$.

Table 2: Comparison of balance variables between pre - and post- orthotic garment and strapping system (TheraTogs) use

	Pre-TheraTogs	Post-TheraTogs	Difference	*P*
Sway Velocity (cm/s)	10.55 (5.73)	8.91 (4.50)	-1.63 (2.14)	0.000*
Sway Path (cm)	292.13 (61.85)	251.15 (136.12)	-40.97 (53.14)	0.000*
Sway Area (cm^2)	54.45 (52.81)	31.91 (34.33)	-22.54 (40.46)	0.001*

The values are presented as mean (SD).
*p<0.05, between pre-TheraTog and post-TheraTog

RESULTS

Comparison of balance

Sway path, sway velocity, and sway area values were compared between pre- and post-TheraTogs use (Table 2). Significant differences were noted in all variables between the two conditions ($p < 0.05$).

Comparison of gait

Velocity, cadence, step length, stride length, single support time, and double support time values were compared between the pre- and post-TheraTogs use conditions (Table 3). Significant differences were noted in all variables between the two conditions ($p < 0.05$).

DISCUSSION

This study investigated the immediate effects of orthotic garment and strapping system (TheraTogs) as posture orthoses on the balance and gait of children with spastic diplegic CP by comparing the differences between pre- and post-use conditions. We noted significant differences in balance variables including sway path, sway velocity, and sway area. Flanagan *et al*.[18] reported that TheraTogs use affected pelvis, hip joint, and knee joint alignment and that strapping the abdominal and back extensors provided core trunk stabilization. According to Elsodany *et al*.[19], conventional physical therapy and TheraTogs used in parallel significantly affected postural stability. This effect was due to the stimulation of proprioception lengthening of muscle; the TheraTogs induced greater power generation and static and dynamic balance improvements by promoting hip abductor and extensor activities in addition to the normal muscle recruitment mechanism. In the standing posture of children with spastic diplegic CP using the TheraTogs, Ehlert *et al*.[20] found that trunk, knee, and hip extension improved and that the tension induced by the TheraTogs changed the postural adaptation. Thus, the increased balance noted in the present study, in other words, sway path, sway velocity, and sway area, indicated improved trunk stability as an ancillary role in the coordination of the trunk muscles and the ability to maintain posture alignment and control the movement by using the TheraTogs. As a result, the trunk sway was

Table 3: Comparison of gait variables between pre- and post- orthotic garment and strapping system (TheraTogs) use

		Pre-TheraTogs	Post-TheraTogs	Difference	*P*
Velocity (cm/sec)		64.79 (21.16)	91.05 (19.24)	26.26 (21.17)	0.000*
Cadence (step/min)		112.23 (34.86)	140.17 (27.95)	27.94 (26.49)	0.000*
Step (cm)	Rt.	35.29 (7.80)	40.21 (7.42)	4.92 (6.07)	0.001*
	Lt.	34.96 (6.63)	40.30 (6.74)	5.32 (5.64)	0.000*
Stride (cm)	Rt.	69.23 (17.15)	81.01 (13.62)	11.78 (14.38)	0.001*
	Lt.	70.59 (13.84)	81.12 (13.34)	10.52 (11.04)	0.000*
Single Support Time (sec)	Rt.	0.39 (0.08)	0.33 (0.05)	-0.06 (0.07)	0.000*
	Lt.	0.41 (0.11)	0.33 (0.05)	-0.08 (0.09)	0.000*
Double Support Time (sec)	Rt.	0.36 (0.23)	0.18 (0.10)	-0.17 (0.19)	0.000*
	Lt.	0.36 (0.24)	0.18 (0.10)	-0.17 (0.18)	0.000*

The values are presented as mean (SD).
*p<0.05, between pre-TheraTog and post-TheraTog

stabilized, and posture stability improved with the proper functional recovery of posture alignment and muscle with TheraTogs use. In addition, Lehman *et al*.[21] found that trunk stabilization helped functional activity, contributing to maintaining appropriate postural alignment and efficient movement control. In the present study, wrapping the trunk and pelvic muscles with the TheraTogs garment continuously stimulated the antigravity muscles, while connecting the strap to induce symmetrical alignment of the trunk and lower limbs affected postural control, resulting in significant differences in balance variables.

This study compared gait pre- versus post-TheraTogs use and found significant differences in spatiotemporal gait variables including velocity, cadence, step length, stride length, single support time, and double support time. Liao *et al*.[22] found that the gait of children with CP is closely related to improved standing posture stability. In the study of the relationship between standing posture balance and gait, a slow gait speed reflected decreased balance ability, loss of muscle strength, and abnormal biomechanics due to imperfect movement control. Willerslev-Olsen *et al*.[23] found that, in the stance phase of the gait cycle, it is important to increase lower-limb stability to allow the feet to swing smoothly. Gage, and Novacheck[24] also reported that stance phase stability should be maintained to enable an effective gait, an appropriate foot position should be chosen before contact in the terminal swing, and an appropriate stride length should be maintained. This study judged that the posture stability improvement with TheraTogs use positively impacted the balance variables. Thus, the results of the previous studies of posture stability and gait were consistent with those of the present study in that the spatiotemporal gait variables significantly increased. Maguire *et al*.[25] analyzed electromyography during gait in stroke patients wearing TheraTogs and found significant activation of the hip abductor and improved walking velocity in the group using TheraTogs.

When comparing pre- and post-TheraTogs use in children with spastic diplegic CP, Ehlert[20] noted that the use improved hip extension in the standing posture; this change increased the posteriorization of the plantar pressure that occurred in the initial contact, and asymmetry between the left and right feet decreased in the total contact area. The authors reported overall improvements in functional mobility. In the gait of children with spastic diplegic CP, Kafy *et al*.[26] reported that hip extension increased and stride length improved in the group that used the TheraTogs in parallel. Mahani *et al*.[27] noted that the therapeutic suit supports weakened leg muscles and secures a suitable length that can assist with lower-limb stability and mobility during gait. In the present study, spatial gait variables, step length, and stride length improved; during gait, the single and double support times significantly decreased. These results demonstrate that securing the stability and mobility of the limb muscles of children with CP may positively impact the spatial gait variables. In particular, significant changes in step and stride lengths improved balance and stability during gait. According to a report by Ko *et al*.[28] this change was possible because the therapeutic suit for posture correction provided external stability from the outside and allowed movement with appropriate stability and mobility on both legs. Securing lower-limb stability and mobility of symmetrical movement like gait resulted in mutually supportive lower-limb.

The current study demonstrated positive influences on balance and gait pre- versus post-TheraTogs use. This result shows that the therapeutic intervention can have greater synergy for maintaining postural balance and training complex gait patterns with the use of orthoses like TheraTogs. This device can reportedly maintain the correct posture and provide proper biofeedback using proprioception based on biomechanics and sensorimotor input. Since the garment itself has elasticity, it covers the participant's body snugly, providing proper compression and adherence to enable the sensorimotor enhancement. It also reportedly stimulates the muscles that maintain and stabilize posture, maintaining postural alignment. There may also be an effect of individuals undergoing continuous and repetitive training of movement skills in daily life that compensates for insufficient treatment time. In summary, TheraTogs use induced differences in the balance and gait of children with spastic diplegic CP; thus, it could be utilized as a useful posture orthosis.

This study has a few limitations. First, because it included a small number of subjects (24 children with spastic diplegic CP), it is difficult to generalize our findings to all children with CP. Second, it investigated only the immediate effect of TheraTogs use versus non-use. Thus, future long-term studies are needed to investigate the persistence of the therapeutic effect of TheraTogs. In addition, to develop an effective and efficient intervention program suitable for children with CP, continuous and repetitive training of movement skills in daily life will be needed.

In conclusion, this study investigated the balance and gait of children with spastic diplegic CP pre- versus post-TheraTogs use. We noted significant improvements in the balance and gait post-TheraTogs use. Our findings indicate that TheraTogs could be utilized as a useful posture orthosis to help improve the balance and gait of children with spastic diplegic CP. However, the result of the present study can only be utilized as basic guide regarding the influence of suit therapy on balance and gait.

DISCLOSURE

Conflict of interest: None

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