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Original Article

Effect of twister wrap orthosis on foot pressure distribution and balance in diplegic cerebral palsy

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Abstract

Objectives: To evaluate the effectiveness of twister wrap orthosis (TWO) on foot pressure distribution and postural balance in children with spastic diplegic cerebral palsy (CP). **Methods:** Thirty children with spastic diplegic CP, with ages ranging from 6 to 8 years, were assigned randomly into two groups. The control group received the conventional physical therapy and ankle foot orthosis (AFO), whereas the study group received the same program as the control group in addition to TWO. Measurement of foot pressure distribution using a pressure platform as well as stability indices using the Biodex Stability System was performed before and after 12 weeks of the treatment program. **Results:** Both groups showed a significant increase in mean and peak planter pressure on forefoot and rear foot with a significant decrease on mid foot after treatment (P<0.05). The study group showed a significant improvement in balance after treatment (P<0.05) while there was no significant difference in the control group. After treatment, the study group showed significant improvement in planter pressure and balance compared with the control group (P<0.05). **Conclusions:** TWO could provide correction of foot pressure distribution and improve postural balance in children with spastic diplegic CP.

Keywords: Cerebral Palsy, Spastic Diplegia, Twister Wrap Orthosis, Foot Pressure Distribution; Balance

Introduction

Cerebral palsy (CP) is a group of motor disorders resulting from a non-progressive injury during early brain development leading to impairments of movement and posture[1]. Children with CP have several symptoms due to affection of the nervous and musculoskeletal systems, such as spasticity, contracture, and incoordination of movement[2,3]. These symptoms can affect movement ability, functional independence and quality of life[4]. Balance control in children with spastic diplegic CP is mostly affected when compared with their healthy peers, due to impaired development of neural motor control mechanisms in addition to musculoskeletal abnormalities[5,6].

Spastic diplegia represents the most common form of CP in which lower extremities are more affected than upper extremities and accompanied by a wide range of ambulatory outcomes[7]. In spastic diplegia, motor deficits and spasticity of the lower limbs typically produce a walking pattern that is characterized by equinus ankle position, exaggerated knee flexion with genu valgus, and increased hip adduction and internal rotation[8]. In children with spastic diplegic CP, abnormal muscle tone can lead to medial femoral torsion and compensatory external tibial torsion, which in turn result in toe-in gait and crouch gait and thus decreases the stability during walking[9]. This gait disorder decreases the base of support in the stance phase and increase crossing of the legs in the swing phase that increase the risk of falling and lead to functional balance problems[10].

Foot pressure distribution was used to observe abnormal alignment of the lower limbs and body weight transmission across the lower extremities and foot[11]. Torsional deformities of the long bones and foot deformities in children with CP reduces the effectiveness of muscle action and produced slow gait pattern with high-energy expenditure[12].

Ankle foot orthosis (AFO) was often used in children with CP as a solid correcting method, which is formed from

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polypropylene and consisted of molded plastic and fabricated orthosis[13]. It was prescribed to improve ankle joint stability, gait speed and reduces energy expenditure during walking[14]. Currently, TWO is used as a transverse plane corrective orthosis and it is considered one of the dynamic elastomeric fabric orthosis and could increase lateral torque in gait[15].

Few studies discussed the effects of TWO on spatiotemporal gait parameters and gait function in children with CP[13,16] and in-toeing in children with spina bifida[15]. However, the effects of TWO on planter pressure distribution and postural balance in children with CP were still unclear. Therefore, this study aimed to assess the effectiveness of TWO on foot pressure distribution and balance in children with diplegic CP. We hypothesized that TWO would not have an effect on planter pressure distribution and postural balance in children with CP.

Materials and methods

Participants

Thirty children (17 boys and 13 girls) with spastic diplegic CP, with ages ranging from 6 to 8 years, participated in a randomized controlled study. They were recruited from the outpatient clinic of physical therapy department, College of applied medical sciences, Najran University, Najran, Saudi Arabia. Children in both groups were selected with inclusion criteria, including children with toe-in gait and the degree of spasticity was determined according to the Modified Ashworth Scale (MAS)[17] to be grade 1^+ to 2. Gross Motor Function Classification System (GMFCS) scores I and II[18] as the child was required to be able to stand and walk independently. Children who had vision or hearing problems, previous surgery of the lower extremities, and Botulinum injections of the lower limb muscles within the preceding 6 months were excluded. They were assigned randomly, using sealed envelopes, into two groups. The control group consisted of 15 children (9 boys and 6 girls) and received the conventional physical therapy program and AFO. Whereas, the study group consisted of 15 children (8 boys and 7 girls) and received the same program given to the control group in addition to TWO.

Before the study, interviews were conducted with the parents of all children to explain the purpose, procedures as well as potential benefits and risks of the study and signed a consent form prior to participation. The ethical committee of the University approved this study. All aspects of the research complied with the World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects.

Randomization

Forty-three children with diplegic CP were recruited for this study; 9 children did not meet the inclusion criteria, and the parents of 4 children refused to participate in the study. Following the baseline measurements of foot pressure distribution and balance, randomization process was performed for 30 children using closed envelopes. Children were stratified with regard to age and gender to be equally distributed in both groups. The investigator prepared 30 closed envelopes with each envelope containing a card labeled with either control or study. Each child was asked to draw a closed envelope that contains weather he/she was allocated to the control or the study group. The experimental design is shown as a flow diagram in Figure 1.

Procedures

Prior to baseline measurements, all children were familiarized with the assessment procedures and the protocol of the study. Weight and height were recorded using a calibrated floor scale (ZT-120 model, Hangzhou Tianheng Technology Co., Ltd. Hangzhou, China). Each child was evaluated for static and dynamic foot pressure distribution of both feet and postural balance before and after 12 weeks of the treatment by the same examiner who was blinded regarding the group to which each child was assigned.

Foot pressure distribution

Static and dynamic planter pressure measurements were performed by using a pressure platform (FDM-S, Zebris Medical GmbH, Germany), composed of 2560 capacitive sensing elements arranged in a 64×40 matrix. The obtained data were recorded through a personal computer connected to the pressure sensor platform via a USB interface and processed using a custom Matlab® routine. The sampling frequency was set at 50 Hz for static measurements and at 100 Hz for dynamic measurements.

The assessment procedures for both groups were performed while the children were barefoot without orthotic intervention. Familiarity sessions were performed for all children in both groups before testing procedures to establish a preferred walking speed and facilitate platform striking with the entire foot.

During static planter foot pressure measurements, the children in both groups were asked to stand as still as possible on the pressure sensor platform in a self-selected comfortable position for 10 s. They were instructed to look forward with straight ahead and both arms were relaxed beside their bodies. Measurements of the static planter pressure were done simultaneously for both feet and recording a valid trial only in which the children remained stationary during collecting data. The output from the platform was exported as ASCII file and processed to obtain the following measures:

- Peak plantar pressure for forefoot, mid-foot and rear-foot (the maximum pressure value detected by a single sensor in a given sub-region, expressed in kPa).
- Mean plantar pressure for each sub-region (the mean value across all sensors in a given sub-region, expressed in kPa).

Measurements were collected from 3 valid trials and the mean was obtained for data analysis.

During dynamic planter foot pressure measurements, the children were asked to walk at a steady and normal velocity back and forth on the middle of the pressure platform that

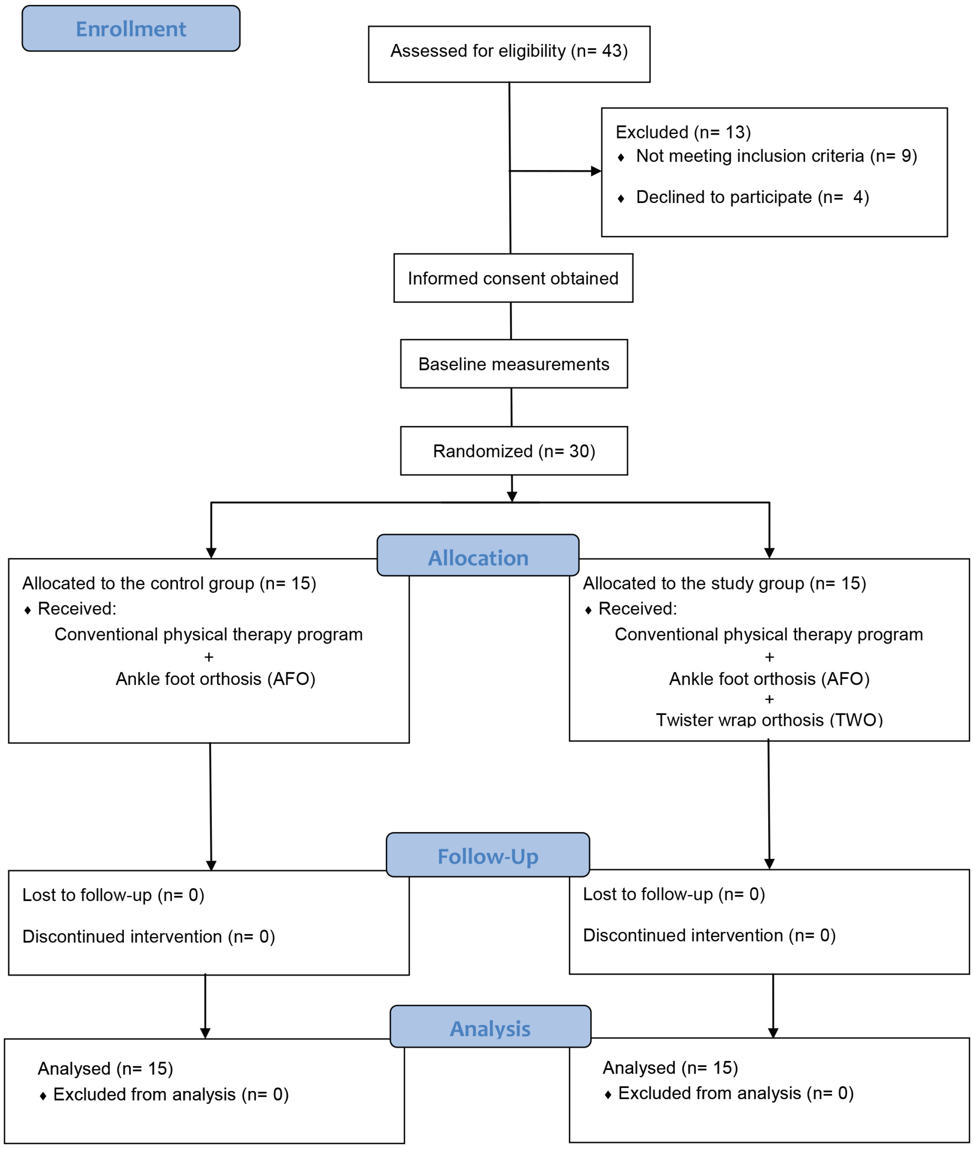

Figure 1. Flow diagram showing the experimental design of the study.

was embedded in a 5-m walkway. Sometimes, we used the foot prints to guide the children to understand how to step over the platform by a single foot contact. The obtained data was processed as described in the static procedure. The measurement test was repeated 3 times and the ideal 2-step method was obtained for data analysis[19].

Balance

Balance assessment was carried out using the Biodex Stability System (BSS; Biodex, Inc, Shirley, NY) that enables objective assessment of balance[20]. The intertester intraclass correlation coefficients (ICCs) were 0.70 and the intratester ICCs were 0.82[21].

The BSS consists of a dynamic balance platform that allows movements around the anterior-posterior (AP) and medial-lateral (ML) axes simultaneously. The dynamic balance platform has eight levels of stability, extending from the most stable level (level 8) to the least stable level (level 1). In addition, the BSS consists of a support handle and a display screen in front of the child that can be adjusted according to the height of each child. The screen provides visual feedback about the degree of tilting that guides the child to maintain the cursor in the center of the screen to obtain a good score of balance. The BSS measures the degree of tilting about each axis during dynamic conditions and calculates a medial-lateral stability index (MLSI), an anterior-posterior stability index (APSI) and overall stability index (OSI), which is a composite of the MLSI and the APSI[22]. The BSS calculates the

Table 1. Comparison of the mean age, weight and height between the study and the control groups.

	Study group	Control group			
	X̄ ± SD	X̄ ± SD	MD	t- value	p- value
Age (years)	7.34 ± 0.7	7.62 ± 0.64	-0.28	-1.14	0.26*
Weight (kg)	29.2 ± 2.88	30.13 ± 2.85	-0.93	-0.89	0.38*
Height (cm)	126.53 ± 3.09	127.06 ± 2.63	-0.53	-0.5	0.61*

*X̄, mean; SD, standard deviation; MD, mean difference; p-value, level of significance; * non-significant.*

Table 2. Plantar pressure for forefoot, mid foot and rear foot during standing before and after treatment in the study and the control groups.

	Before treatment			After treatment			Before vs After	
	Study group	Control group		Study group	Control group		Study	Control
	X̄ ± SD	X̄ ± SD	P value	X̄ ± SD	X̄ ± SD	P value	P value	P value
Mean pressure								
Forefoot (kPa)	31.67 ± 6	32.73 ± 7.62	0.67*	40.06 ± 6.48	33.93 ± 7.3	0.02**	0.0001**	0.0001**
Mid foot (kPa)	28.68 ± 9.24	27.6 ± 8.08	0.73*	19.46 ± 6.2	25.13 ± 7.43	0.03**	0.0001**	0.0001**
Rear foot (kPa)	54.41 ± 14.56	52.94 ± 15.84	0.79*	67.8 ± 15.56	54.5 ± 16.09	0.02**	0.0001**	0.02**
Peak pressure								
Forefoot (kPa)	73.92 ± 12.72	70.76 ± 14.32	0.52*	87.46 ± 12.39	74.6 ± 14.43	0.01**	0.0001**	0.18*
Mid foot (kPa)	59.58 ± 17.9	60.26 ± 15.95	0.91*	42.06 ± 16.06	56.26 ± 17.65	0.02**	0.0001**	0.17*
Rear foot (kPa)	97.32 ± 16.63	94.98 ± 13.65	0.95*	113.53 ± 12.78	102.86 ± 11.99	0.02**	0.0001**	0.1*

*X̄, Mean; SD, standard deviation; p-value, level of significance; * Non significant; ** Significant.*

Table 3. Plantar pressure for forefoot, mid foot and rear foot during walking before and after treatment in the study and the control groups.

	Before treatment			After treatment			Before vs After	
	Study group	Control group		Study group	Control group		Study	Control
	X̄ ± SD	X̄ ± SD	P value	X̄ ± SD	X̄ ± SD	P value	P value	P value
Mean pressure								
Forefoot (kPa)	80.43 ± 15.6	78.46 ± 19.63	0.76*	108.73 ± 17.31	86.83 ± 21.79	0.005**	0.0001**	0.0001**
Midfoot (kPa)	74.66 ± 22.84	73 ± 9.14	0.79*	51.26 ± 14.61	66.8 ± 12.35	0.004**	0.0001**	0.01**
Rearfoot (kPa)	133.13 ± 21.61	129.6 ± 19.97	0.64*	174.73 ± 18.7	146.06 ± 25.92	0.002**	0.0001**	0.0001**
Peak pressure								
Forefoot (kPa)	211.33 ± 35.47	204.06 ± 20.25	0.49*	247.93 ± 28.42	215.46 ± 19.54	0.001**	0.0001**	0.004**
Midfoot (kPa)	168.53 ± 33.98	167.73 ± 27.88	0.94*	126 ± 35.21	158.4 ± 29.18	0.01**	0.0001**	0.0001**
Rearfoot (kPa)	279.93 ± 38.78	273.66 ± 28.8	0.61*	317.26 ± 34.57	285.4 ± 29.39	0.01**	0.0001**	0.01**

*X̄, Mean; SD, standard deviation; p-value, level of significance; * Non significant; ** Significant.*

Table 4. Stability indices before and after treatment in the study and the control groups.

	Before treatment			After treatment			Before vs After	
	Study group	Control group		Study group	Control group		Study	Control
	$\bar{X} \pm SD$	$\bar{X} \pm SD$	P value	$\bar{X} \pm SD$	$\bar{X} \pm SD$	P value	P value	P value
OSI	2.91 ± 0.29	2.86 ± 0.28	0.66*	2.08 ± 0.24	2.78 ± 0.39	0.0001**	0.0001**	0.18*
APSI	2.37 ± 0.31	2.44 ± 0.29	0.51*	1.88 ± 0.29	2.38 ± 0.33	0.0001**	0.0001**	0.17*
MLSI	2.24 ± 0.34	2.23 ± 0.27	0.92*	1.75 ± 0.29	2.15 ± 0.24	0.0001**	0.0001**	0.1*

*$\bar{X}$, Mean; SD, standard deviation; p-value, level of significance; * Non significant; ** Significant.*

average position for the child during all motions throughout the test. The higher the scores in all these outcomes, the poorer the balance of the child.

Each child was allowed to stand in the center of the locked platform of the BSS with the two legs stance and with orthotic intervention. Certain parameters as the child's age, weight, height and stability level (platform firmness) were fed to the device. During the assessment period, the platform began to freely move and simultaneously calculate the degree of tilt about both axes (AP and ML). The balance measurement test was repeated 3 times and the mean was obtained for data analysis.

Treatment protocol

The control group

The children in the control group received the conventional physical therapy program which consisted of neurodevelopmental techniques, proprioceptive training, facilitation of muscle contraction for the anti-spastic muscles, gentle stretching exercises for the tight muscles, gait training, in addition to balance and postural control exercises. This program was given for 1 hour, 5 days a week for 12 weeks. In addition, the control group wore rigid AFOs to hold the ankles and feet in the neutral position during walking.

The study group

The children in the study group received the same physical therapy program given to the control group. In addition, the study group wore TWO with AFOs. TWO was elastic band that attached to the shoes covering AFO and wind circumferentially with a spiral pattern up the lower limb where it attached to a pelvic band at the other end by the way of a clip. It was not wrapped around the hip and knee joints. Both AFO and TWO were adjusted for each child by an occupational therapist to correct the alignment of the lower extremities. The children in both groups wore the orthoses for 8 to 10 hours per day for 12 weeks[15].

Statistical analysis

To avoid a type II error, a preliminary power analysis (power=0.8, α=0.05, effect size=0.5) determined a sample size of 30 for this study. t-test was carried out for comparison of participants' characteristics between both groups. The data showed normal distribution as checked using the Shapiro-Wilk test. Levene's test for homogeneity of variances revealed the homogeneity between groups. Mixed MANOVA was carried out to compare the mean values of plantar pressure parameters and stability indices between the study and the control groups and within each group. The level of significance for all statistical tests was set at p value less than 0.05. All statistical analyses were carried out using statistical package for the social studies (SPSS, version 19; IBM, Chicago, IL, USA).

Results

Demographic characteristics of participants:

Table 1, showed the mean ± SD age, weight and height of the study and control groups. There was no significant difference between both groups in the mean age, weight and height ($p<0.05$).

Effect of treatment on planter pressure distribution

There was a significant interaction of treatment and time (Wilks' Lambda = 0.39; F (12,17)=34.97, p=0.0001). There was a significant main effect of time (Wilks' Lambda=0.01; F (12,17)=98.47, p=0.0001). There was a significant main effect of treatment (Wilks' Lambda=0.35; F (12,17)=2.55, p=0.03). Table 2 and 3 showed descriptive statistics of planter pressure as well as the significant level of comparison between both groups in addition to the significant level of comparison between before and after treatment in each group.

There was no significant difference between the study and the control groups in standing and walking planter pressure before treatment ($p>0.05$). After treatment, the study group showed a significant increase in mean and peak planter pressure in standing and walking on forefoot and rear foot, and a significant decrease in mid foot compared with that of the control group ($p<0.05$). Both groups showed a significant increase in mean and peak planter pressure in standing and walking on forefoot and rear foot, and a significant decrease in mid foot after treatment compared with that before treatment ($p<0.05$).

Effect of treatment on stability indices

Mixed MANOVA revealed that there was a significant interaction of treatment and time (Wilks' Lambda=0.13; F (3,26)=58.07, p=0.0001). There was a significant main effect of time (Wilks' Lambda=0.08; F (3,26)=95.19, p=0.0001). There was a significant main effect of treatment (Wilks' Lambda=0.6; F (3,26)=5.73, p=0.004). Table 4 showed descriptive statistics of stability indices as well as the significant level of comparison between both groups in addition to the significant level of comparison between before and after treatment in each group.

There was no significant difference between the study and the control groups in OSI, APSI and MLSI before treatment (p>0.05). After treatment, there was a significant decrease in the OSI, APSI and MLSI of the study group compared with that of the control group (p<0.0001).

Comparison before and after treatment in the study group showed that there was a significant decrease in the OSI, APSI and MLSI after treatment compared with before treatment (p<0.0001). However, comparison between before and after treatment in the control group showed that there was no significant difference in the OSI, APSI and MLSI between before and after treatment (p>0.05).

Discussion

Ambulation disorders is an important limiting factors in children with spastic diplegic CP. About 90% of children with CP had instability problems during gait and 54% were unable to walk independently[23]. Therefore, the purpose of this study was to examine the effects of TWO on foot pressure distribution and postural balance in children with spastic diplegic CP. The main findings of this study suggested that using TWO in combination with AFO to overcome medial femoral torsion and compensatory tibial external rotation induced significant improvements in the distribution of planter pressure loading and postural balance in children with spastic diplegic CP.

Children with spastic diplegia showed reduced hallux and lateral heel pressure but increased lateral, medial mid-foot and first metatarsal pressure[24]. Our results demonstrated increased forefoot and rear foot with decreased mid foot pressure. These results confirm those already reported by Pauk et al[25], who reported increased pressure distribution under the metatarsal heads and the heel in the typically developing children.

Our results confirm those already reported by Chang et al[13], who investigated the immediate effects of a customized external strap orthosis on planter pressure and gait parameters in children with mild CP. They reported that the customized external strap orthosis improves the static and dynamic balance and reduce planter pressure loading in children with mild CP when compared with AFO. External strap orthosis induced external rotation movements of the lower extremities.

Crouch gait adapted by children with spastic diplegic CP reduces the planter flexion moment arm of the soleus muscle, especially when the external tibial torsion is 30° or more above the normal limits[26]. Excessive femoral anteversion and the external tibial torsion reduce the capacity of the soleus to extend the knee and hip joints by more than 50%[27] as hip and knee extension are necessary for normal standing and walking patterns[28].

TWO induced a transverse plane correction of mal-alignment of the lower limb. Previous studies indicated the importance of orthotic management of lower limbs to provide transverse plane correction and facilitates the internal planter flexor moment that maintain knee extension in single support[29,30]. Many researchers proposed that the therapeutic strapping would increase proprioceptive and tactile awareness, restoring optimal muscle length, orienting the muscle force along normal vectors in the frontal and sagittal planes and reduce spasticity through sustained stretch and reflex inhibiting positions[31,32].

The improvement in postural balance and planter pressure loading in the study group could be attributed to the biomechanical action of the elastic TWO combined with AFO in achieving active rotational forces of the hip joint and can alter the foot progression angle[33]. These results are consistent with the study of Richards et al[15], who compared the effects of twister cables with Thera Togs on toe-in gait in a patient with spina bifida. They reported that Thera Togs induced external rotation of the hip joints in both lower extremities and corrected in-toeing gait measured dynamically through foot progression. Our results also are consistent with the study of Flanagan et al[34], who studied the effects of an orthotic undergarment on gait, balance and functional skills in children (age 7-13 yrs) with diplegic CP. They found that after 12-weeks, an individualized orthotic garment could improve balance and functional skills in some children with CP.

Regarding to the control group, a significant improvement in foot pressure distribution and non-significant improvement in postural balance were observed. The improvement in foot pressure distribution may be attributed to the effect of AFO in correcting foot progression angle by rotating the lower leg with respect to the thigh via the knee joint, which has a substantial effect on foot pressure distribution[35]. While, the non-significant improvement of the postural balance in AFO group could be explained as the changes of AFO in the more proximal joints were not markedly significant and had no effect on joint kinematics[36,37].

Children with spastic CP commonly have ankle equinus that strikes the ground with the forefoot during walking. As a result, the line of action of the ground reaction force passes in front of the knee and hip joints, causing knee extension moment and a flexion moment around the hip joint. AFOs prevents plantar flexion and induces knee extension that prevents excessive foreword movement of the tibia and keeps the ground reaction force anterior to the knee joint[38].

Some limitations of this study were recognized including, the relatively small sample size with only one type of CP that limit the generalizability of the findings. Moreover, lack of follow-up several months after training to evaluate the long lasting effect of the TWO. Therefore, future studies are recommended to investigate the long-term effect of TWO and to investigate the effect of treatment with a larger sample size and different types of CP.

Based on the obtained results, the present study concluded that the elastic force of the TWO combined with AFO could improve plantar pressure distribution and postural balance in children with spastic diplegic CP. These findings support the potential use of the TWO in the rehabilitation of children with spastic diplegic CP with in-toeing gait pattern.

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Authors' Contributions

M. Eid, S. Aly and R. Mohamed conceived and designed the study. S. Aly and R. Mohamed were involved in participant recruitment. M. Eid, S. Aly were involved in data collection and data entry. M. Eid and R. Mohamed provided access to research tools and input on analysis and interpretation. M. Eid accepts responsibility for integrity of the data. All authors have read and approved the manuscript.

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