

Immediate Effect of Postural Insoles on Gait Performance of Children with Cerebral Palsy: Preliminary Randomized Controlled Double-blind Clinical Trial

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Abstract. [Purpose] Improved gait efficiency is one of the goals of therapy for children with cerebral palsy (CP). Postural insoles can allow more efficient gait by improving biomechanical alignment. The aim of the present study was to assess the effect of postural insoles on gait performance of children with CP classified as levels I or II of the Gross Motor Function Classification System (GMFCS). [Subjects and Methods] the study was a randomized controlled double-blind clinical trial. After meeting the legal aspects and the eligibility criteria, 10 children between four and 12 years old were randomly divided into a two groups: a control group (n=5), and an experimental group (n=5). Children in the control group used a placebo insoles, and children in the experimental group used postural insoles. Evaluation consisted of three-dimensional gait analysis under three conditions: barefoot, shoes without insoles and shoes with postural insoles or shoes with placebo insoles. [Results] Regarding the immediate effects of insole use, significant improvements in gait velocity and cadence were observed in the experimental group in comparison to the control group. [Conclusion] The use of postural insoles led to improvements in gait velocity and cadence of the children with cerebral palsy classified as levels I or II of the GMFCS.

Key words: Cerebral palsy, Orthoses, Postural insole

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INTRODUCTION

Cerebral palsy (CP) is a term to describe a permanent, mutable motor development disorders stemming from a primary brain lesion that cause secondary musculoskeletal problems leading to limitations in activities of daily living¹⁾. Motor impairment is the main manifestation of cerebral palsy (CP), and it has a consequent effect on the biomechanics of the body. Children with CP may also exhibit cognitive, visual and hearing impairments, which, along with motor impairment, task restrictions and environmental restrictions, have a negative effect on functional performance^{2, 3)}.

Neuromotor impairment in this disease can involve different parts of the body, has led to development of specific

topographic classifications, such as quadriplegia, hemiplegia and diplegia⁴⁾. However, children with CP are currently classified based on their degree of functional independence, which encompasses the functions of the body, activities and social participation. The Gross Motor Function Classification System (GMFCS) for Cerebral Palsy⁵⁾ classifies children according to age (0–2, 2–4, 4–6 and 6–12 years) and respective functional levels.

Three-dimensional gait analysis is used to assist in the functional characterization of children with CP, allowing a detailed evaluation of kinetic and kinematic aspects of each phase of the gait cycle. This form of analysis is an important tool in the evaluation of the results of clinical interventions for CP sufferers, who have functional limitations due to excessive muscle weakness and abnormalities in both joint kinematics and postural reactions⁶⁾.

Different therapeutic interventions have been employed in an attempt to favor selective muscle control and coordination in children with CP. Lucarelli et al.⁷⁾ reported that the use of an ankle-foot orthosis assists with gait improvement. In a systematic review of the influence of rigid and articulated orthoses, Pasini Neto et al.⁸⁾ reported numerous benefits are derived from the use of rigid orthoses. How-

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ever, this type of orthosis is directed at children with accentuated motor impairment, spasticity and contractures. On the other hand, articulated orthoses offer the benefits of stability and freedom during gait, raising the functional potential of children with CP.

The aim of postural insoles is to reorganize the tonus of the muscle chains and influence body posture through correction reflexes. These insoles affect muscle proprioception and lead to changes in the ascending proprioceptive chains⁹⁾. According to Gagey and Weber⁹⁾, the stimulation of specific regions of the soles of the feet causes a change in postural tonus, and repositions of the leveling of the pelvis and muscle asymmetries along the spinal column. Postural reprogramming occurs when the mechanoreceptors of the plantar region are activated by a deformation in the skin caused by the bars, wedges, half-moons and shims incorporated into postural insoles¹⁰⁾. In a study of such postural insoles used by children with CP, the kinetic, kinematic and electromyographic analyses revealed a reduction in plantar flexion as well as better coordination between the tibialis and gastrocnemius muscles and improved force distribution during the support phase¹¹⁾.

The hypothesis guiding the present study was that postural insoles would generate a change in sensory afference, stimulating a postural reaction which improves a gait performance. Therefore, the aim of this study was to assess the effect of postural insoles on gait performance of children with CP using the gait variables of cadence and velocity as the primary outcomes.

SUBJECTS AND METHODS

The present study was a preliminary randomized, controlled, double-blind, clinical trial. The study method was conducted, conformed to the principles of the Declaration of Helsinki and the Regulating Norms and Guidelines for Research Involving Human Subjects formulated by the Brazilian National Health Council, Ministry of Health, established in October 1996. The study received approval from the ethics committee of the Universidade Nove de Julho (Sao Paulo, Brazil) under protocol number 436960/2011. All parents/guardians agreed to the participation of the children by signing a statement of informed consent.

Twenty-five children were recruited and ten were selected based on the eligibility criteria. The inclusion criteria were a diagnosis of spastic diplegic CP and classification on levels of I or II of the Gross Motor Function Classification System (GMFCS). The following were the exclusion criteria: surgical procedures or the administration of phenol in the previous 12 months; neurolytic block in the previous six months; cognitive or visual impairment that could have interfered with the performance of the procedures; and ankle deformities that were non-reducible to neutral.

The participants were randomly allocated to two groups. The control group (CG) made use of an insole without correction elements (placebo insole) and the experimental group (EG) made use of an insole with correction elements (postural insole). Neither the children nor their guardians were aware of the group to which the participants had been

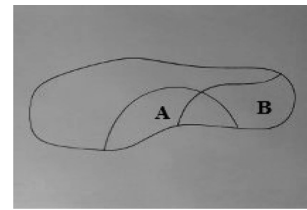


Fig. 1. Representation figure of the elements used in postural insoles A- half-moon; B- anti-valgus (Podaly®).



Fig. 2. The representation of placebo insole used by the control group (Podaly®).

allocated; thus conditions for a blind study for the placebo effect of the insole in the CG were satisfied. During the randomization procedure, a set of sealed, opaque envelopes was used to ensure the concealment of the allocation. Each envelop contained a card stipulating to which group the child would be allocated.

The postural insoles used in the EG were composed of three layers. The aim of the surface portion is to absorb sweat and provide comfort. The middle portion is made up of ethylene vinyl acetate measuring 3 mm in thickness. The lower portion is composed of material formed by a weave of cotton fibers and resin measuring 1 mm in thickness and contains wedges and shims made of ethylene vinyl acetate¹⁰⁾. The pieces used in the present study were half-moon and anti-valgus (Fig. 1). The CG used placebo insole (Fig. 2).

Following the positioning of the pieces, the insoles were submitted to thermally molded to fuse the different portions together.

The evaluation process was performed under three different conditions: 1) barefoot; 2) wearing shoes without insoles; and 3) wearing shoes with placebo insole (CG) or postural insoles (EG). The test order under the different conditions was randomly determined by lots to avoid standardization of the behavior of the sample. The evaluation consisted of gait analysis. The children were first shown the equipment and instructed on how to the procedures would be carried out. A training session was then performed, simulating a regular gait exam, but without data collection. In this, the children were instructed to walk normally on a track demarcated on the floor measuring four meters in length and 90 centimeters in width that was marked on the floor. All the children wore bathing suits to facilitate the placement of the markers. The markers were then fixed to the children in the standing position, as suggested by Davis

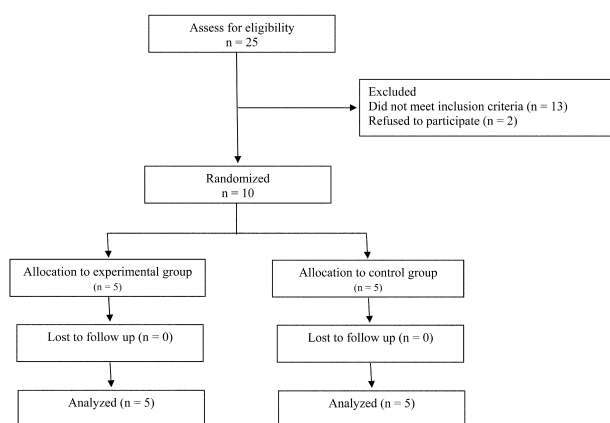


Fig. 3. Fluxogram

et al¹²). The markers were enveloped in adhesive tape lined with microscopic glass spheres and attached to a plastic base with double-sided adhesive tape to the skin allow better visualization by the infrared cameras. The equipment used for the gait evaluation was the SMART-D 140[®] system (BTS Engineering), with eight cameras sensitive to the infrared spectrum. The images were processed using the same system. The gait cycle was determined from the moment of initial contact of one foot (foot strike) through to the foot strike of the second foot and toe-off of the first foot until the second foot strike of the first foot (one complete stride). The children were instructed to walk along the demarcated track six times for the data collection. This procedure was performed under the three different conditions (barefoot, wearing shoes without insoles and wearing shoes with postural insoles or placebo insoles). The researcher in charge of this phase of the study was unaware of the group to which each child belonged (double-blind trial).

For data involving the analysis of the right and left legs (step length and stride length), means were calculated and used in the statistical analysis. The data were first submitted to the Kolmogorov-Smirnov test to determine if they were normally distributed. As data were parametric, the results were expressed as means and standard deviations or 95% confidence intervals. The effect size was calculated considering the mean difference of between the results obtained for the participants wearing shoes with postural insole. The independent t-test was used for the inter-group analysis. Repeated-measure ANOVA was used for the intra-group analysis under each condition. A p-value of ≤ 0.05 was considered significant. The data were organized and tabulated using the Statistical Package for the Social Sciences (SPSS v.19.0).

RESULTS

Among the 25 children recruited for the present study, thirteen children did not meet the eligibility criteria and two refused to participate. Thus, the sample was made up of 10 children with CP, five of whom were randomly allocated to the CG and five were randomly allocated to the EG (Fig. 3).

No statistically significant differences between groups

Table 1. The anthropometric characteristics of the sample

	Anthropometric data		
	Age (years)	Height (cm)	Body mass (kg)
Mean	8	123	20
Standard deviation	2.9	35	5.2

Mean \pm SD of anthropometric data of participants

were found for the anthropometric data (Table 1).

Regarding the temporal gait variables, the intra-group analysis revealed a significant improvement in cadence (number of steps per minute) ($p = 0.03$) and velocity ($p = 0.02$) in the EG when wearing the postural insoles in comparison to walking barefoot and with shoes alone. Moreover, no significant differences were found in temporal gait variables between the latter two conditions (barefoot and shoes alone) (Table 2). In the intergroup analysis, a significant increase in gait velocity ($p = 0.01$) was found in the EG in comparison to the CG. Moreover, no significant differences were found between groups under the conditions of barefoot and smooth insoles without corrective pieces, demonstrating the homogeneity of the sample (Table 2).

In the analysis of the effect of the postural insoles in comparison to the placebo insole, a tendency toward a positive effect was seen with the use of the postural insoles for the majority of gait variables analyzed. However, significant differences were only found for to cadence ($p = 0.019$) and velocity ($p = 0.021$) (Table 3).

DISCUSSION

The findings of the present study evidence a tendency toward an immediate positive effect on temporal gait variables when the use of postural insoles were worn by children with CP. However, the inter-group analysis revealed significant differences only with regard to cadence and velocity.

A number of authors have demonstrated the importance of analyzing temporal gait variables in children with CP^{13, 14}. Redekop, Andrysek and Wright¹⁵) assessed computerized gait analysis with regard to functional level on relation to the GMFCS and found adequate to excellent reliability considering temporal, spatial and kinematic variables of the pelvis, hip, knee and ankle.

According to Abel and Damiano¹³), spatiotemporal variables reflect the end result of small adjustments and adaptations. Thus, the positive results in the analysis of the effect demonstrated in Table 3, although individually not statistically significant, reflect the significant increases in gait velocity and cadence when taken together. According to Morita et al.¹⁶), enhanced gait efficiency is directly related to an increase in velocity, and children with CP used an increase in cadence as their main strategy for increasing velocity. This observation may explain the findings of our present study, in which significant changes were only found with regard to cadence and velocity.

Healthy children show greater spatiotemporal variables

Table 2. Gait variables when barefoot, wearing shoes without insoles and wearing shoes with postural insoles (EG) or shoes with placebo insole (CG)

	Barefoot		Shoes without insole		Shoes with insoles	
	EG	CG	EG	CG	EG	CG
Support phase (%)	55.3 (5.4)	55.3 (2.3)	46.0 (9.6)	48.6 (11.2)	53.8 (4.8)	51.4 (5.3)
Swing phase (%)	41.6 (3.0)	42.0 (3.7)	37.6 (9.1)	41.9 (4.3)	40.0 (2.1)	43.1 (6.7)
Double support phase (%)	5.1 (1.6)	6.2 (1.6)	6.7 (9.1)	6.4 (1.6)	10.9 (4.7)	20.0 (28.6)
Step time (s)	0.83 (0.12)	0.96 (0.18)	0.91 (0.17)	1.06 (0.23)	0.90 (0.20)	0.98 (0.17)
Cadence (step/min)	111.5 (18.7)	111.0 (20.7)	87.7 (25.1)	99.9 (27.4)	124.9 (7.0)*	99.2 (25.9)
Step length (m)	0.34 (0.10)	0.33 (0.06)	0.34 (0.14)	0.33 (0.06)	0.32 (0.91)	0.33 (0.05)
Stride length (m)	0.78 (0.21)	0.75 (0.15)	0.67 (0.19)	0.71 (0.12)	0.79 (0.19)	0.71 (0.13)
Velocity (m/s)	0.89 (0.10)	0.81 (0.17)	0.83 (0.13)	0.82 (0.09)	0.98 (0.13)*#	0.84 (0.17)

* $p \leq 0.05$ (intra-group analysis – repeated-measure ANOVA); # $p \leq 0.05$ (inter-group analysis – independent t-test)

Table 3. Effect of treatment on all outcome measures

	Shoes with postural insoles		
	EG	CG	Effect
Support phase (%)	7.8 (-7.3–22.9)	2.7 (-5.8–11.3)	5.05
Swing phase (%)	2.4 (-11.0–15.0)	1.1 (-4.0–6.4)	1.21
Double support phase (%)	13.6 (-21.1–48.3)	4.1 (-1.6–9.9)	-9.46
Step time (s)	-0.04 (-0.1–0.1)	0.07 (-0.1–0.3)	0.07
Cadence (step/min)	37.1 (11.0–63.2)	-0.78 (-16.9–15.3)	37.92*
Step length (m)	0.06 (-0.00–0.02)	-0.1 (-0.1–0.08)	-0.02
Stride length (m)	0.06 (-0.008–0.02)	-0.01 (-0.01–0.08)	0.12
Velocity (m/s)	0.14 (-0.03–0.32)	-0.08 (-0.02–0.04)	0.22*

* $p \leq 0.05$ (inter-group analysis – Independent t-test)

are found than those with CP. According to Holt et al.¹⁷⁾, healthy four-year-olds have mean cadence and velocity values of 152 steps/min and 0.99 m/s, respectively. In the present study, mean cadence when barefoot and wearing shoes without insoles was 111 and 87 steps/min, respectively, and immediately increased to 124 steps/min when using the postural insoles were worn, allowing the children with CP achieve a cadence closer to the cadence demonstrated by healthy children. Likewise, mean velocity when barefoot and wearing shoes without insoles was 0.89 and 0.83 m/s, respectively, and increased significantly to 0.98 m/s when using the postural insoles, allowing the children with CP to nearly reach the reference value for velocity of healthy children described by Holt et al.¹⁷⁾ (0.99 m/s).

It should be stressed that the present study offers preliminary findings on the effects of postural insoles on the gait of children with CP. Considering the mean velocity of 0.98 m/s (standard deviation: 0.13 m/s) in the EG and 0.84 m/s (standard deviation: 0.17 m/s) in the CG, giving for a bi-directional alpha of 0.05 and an 80% test power, 12 children per group would be needed to determine the effects of postural insoles more specifically in this population. Thus, our research group is currently preparing a study with an adequate sample size, three-dimensional gait analysis, and an assessment of function in children with CP.

The use of postural insoles led to improvements in gait performance (velocity and cadence) in children with cere-

bral palsy classified as levels I or II of the GMFCS.

The present investigation is a preliminary study and did not perform kinetic or kinematic analyses of the gait cycle and did not compare the effect of postural insoles with different types of orthosis during gait. Thus, further studies are needed along this line of research.

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