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ÓRTESES NA MARCHA DE CRIANÇAS COM PARALISIA CEREBRAL: ESTUDO CLÍNICO ALEATORIZADO CONTROLADO

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ÓRTESES NA MARCHA DE CRIANÇAS COM PARALISIA CEREBRAL: ESTUDO CLÍNICO ALEATORIZADO CONTROLADO

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DEDICATÓRIA

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RESUMO

INTRODUÇÃO: A principal alteração presente nas crianças com PC é o comprometimento motor. Para isso, diferentes intervenções terapêuticas buscam favorecer o controle motor seletivo, entre elas, as órteses. Diferentes tipos de orteses são utilizadas com esse objetivo, destacando o uso das órteses fixas e articuladas. Considerando que as palmilhas posturais tem o objetivo de reorganizar a mecanica postural e reorganizar o tonus muscular, essa pode exercer um papel semelhante as das órteses convencionais. **OBJETIVO:** Avaliar e comparar diferentes tipos de órteses na marcha de crianças com paralisia cerebral. **METODOLOGIA:** Inicialmente foi realizada uma revisão sistemática da literatura considerando os seguintes critérios de inclusão: (1) desenho: ensaio clínico controlado; (2) população: crianças e adolescentes com paralisia cerebral; (3) intervenção: órteses rígidas ou articuladas; (4) desfecho: melhora da função motora e desempenho da marcha. Em seguida, foi realizado um ensaio clínico aleatorizado controlado duplo cego no qual após cumprimento dos aspectos legais e os critérios de elegibilidade, 10 crianças entre 4 e 12 anos foram divididas aleatoriamente em grupo controle (12) e grupo experimental (12). As crianças do grupo controle fizeram uso da palmilha placebo e as crianças do grupo experimental das palmilhas posturais. Essas palmilhas foram confeccionadas em etilvenilacetato, que no caso das palmilhas posturais, receberam termomoldagem para fixação das peças podais relacionadas a correção postural e no caso das palmilhas placebos não receberam as peças de correção. Com relação a avaliação, essa foi composta pela análise tridimensional da marcha e foi realizada antes, imediatamente após, 3 meses após o uso a aplicação das palmilhas e após um mês sem o uso das mesmas. Essa avaliação foi realizada através do sistema SMART-D 140® - BTS *Engineering* com oito câmeras e foram considerados para a análise estatística os parâmetros temporais da marcha. A análise dos dados considerou a aderência a curva de Gauss, pelo teste Kolmogorov- Smirnov e como esses apresentaram-se paramétricos, foram expressos em média (desvio padrão ou intervalo de confiança de 95%). Para análise intergrupos foi utilizado o teste t independente e para análise intragrupo foi utilizada ANOVA de medidas repetidas. **RESULTADOS:** Na revisão sistemática, foram encontrados sete estudos controlados que compararam o efeito das órteses fixas e articuladas apontando diferentes indicações terapêuticas para cada uma delas. Já, com relação ao efeito imediato das palmilhas posturais pode se observar um aumento significativo dos parâmetros relacionados a cadência e velocidade da marcha nas crianças do grupo experimental quando comparado as crianças do grupo controle, bem como, melhora funcional do tornozelo, joelho e quadril. **CONCLUSÃO:** Considerando essa fase preliminar do estudo, observa-se que as crianças classificadas como nível I e II da escala GMFCS que apresentam pequena espasticidade e contratura muscular se beneficiam mais das órteses que favorecem a função visto que essas possibilitam maior liberdade funcional associada a estimulos corretivos.

Palavras-chave: Paralisia cerebral, marcha, órteses, palmilha postural

ABSTRACT

INTRODUCTION: The main change present in children with CP is the motor impairment. For this, several therapeutic interventions seek to promote the selective motor control, among them the orthoses. Different types of orthotics are used for this purpose, highlighting the use of fixed and articulated orthoses. Whereas the postural insoles aims to reorganize and rearrange mechanical postural muscle tone, that may play a role similar to the conventional orthoses. **OBJECTIVE**: To evaluate and compare different types of orthoses on gait of children with cerebral palsy. **METHODS**: a systematic review of the literature considering the following inclusion criteria was done: (1) design: a controlled clinical trial, (2) population: children and adolescents with cerebral palsy (3) Intervention: rigid or articulated orthoses, (4) outcome: improvement in motor function and gait performance. Next, we conducted a randomized controlled double blind in which after meeting the legal aspects and the eligibility criteria, 10 children between 4 and 12 years old were randomly divided into a control group (12) and experimental group (12). Children in the control group used the placebo insole and children in the experimental group used postural insoles. These insoles were made in ethylene vinyl acetate, which in the case of postural insoles, received thermoforming to fasten the foot problems related to postural correction and in the case of placebos insoles did not receive the correct parts. In relation to evaluation, this was composed of three-dimensional gait analysis and it was performed before, immediately after, 3 months later and 1 month without application of insoles. This evaluation was performed using the SMART-D 140 ® - BTS Engineering with eight cameras and were considered for statistical analysis the temporal parameters of gait. Data analysis considered the adherence to the bell curve, by Kolmogorov-Smirnov and how they were presented parametric, were expressed as mean (standard deviation or confidence interval of 95%). For intergroup analysis it was used the independent t test and intragroup analysis was used repeated measures ANOVA. **RESULTS**: In the systematic review, seven controlled studies comparing the effect of orthoses fixed and articulated were found and they showed different therapeutic indications to each one. In relation to the immediate effect of postural insoles it is possible to observe a significant increase in parameters related to gait velocity and cadence in children in the experimental group compared to control group. **CONCLUSION**: Considering this preliminary phase of this study, it was observed that children classified as level I and II of the GMFCS scale showing small spasticity and muscle contracture benefit more of orthoses that favor function since these allow greater freedom associated with functional stimuli correctives.

Key words: Cerebral palsy, gait, orthoses, postural insole

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LISTA DE ABREVIATURAS

PC	Paralisia cerebral
GMFCS	*Gross Motor Function Classification System for Cerebral Palsy*
ANOVA	Análise da variação
AFO	Órtese tornozelo-pé

1.0 – CONTEXTUALIZAÇÃO

1.1 – PARALISIA CEREBRAL

A prevalência da Paralisia Cerebral (PC) varia entre 1,5 e 2,5 por 1000 nascidos vivos (HIRATUKE, 2010). No Brasil, existem poucos dados específicos em relação ao número de casos de PC, no entanto, o censo de 2000 registrou 24,5 milhões de pessoas com algum tipo de deficiência, representando 14,5% da população brasileira, entre os quais 23% tinham deficiências motoras, incluindo indivíduos com PC (Ministério da Saúde, 2009).

Em uma definição atual, a paralisia cerebral (PC) é uma doença crônica com um distúrbio do movimento, da postura e da função motora, mas não progressiva, devido às lesões ou às anormalidades do cérebro imaturo (BONONO, 2007).

A principal alteração presente nas crianças com PC é o comprometimento motor, que ocasiona várias modificações decorrentes da encefalopatia, com consequentes alterações na biomecânica corporal. Além disso, a criança pode apresentar distúrbios intelectuais, sensitivos, visuais e auditivos que, somados às alterações motoras, às restrições da tarefa e do ambiente, repercutirão de diferentes formas no seu desempenho funcional (VASCONCELOS et al., 2009; MANOEL et al., 2000).

1.2 – CLASSIFICAÇÃO DAS CRIANÇAS COM PARALISIA CEREBRAL

O comprometimento neuromotor dessa doença pode envolver partes distintas do corpo resultando em classificações topográficas específicas como quadriplegia, hemiplegia e diplegia (SCHWARTZMAN, 2004).

Porém, atualmente as crianças com PC são classificadas de acordo com a sua funcionalidade pois essa engloba, além das funções do corpo, as atividades e a participação social. O Sistema de Classificação da Função Motora Grossa (*Gross Motor Function Classification System for Cerebral Palsy* – GMFCS) classifica a criança de acordo com a idade (0-2, 2-4, 4-6, e 6-12 anos) e os respectivos níveis funcionais (PALISANO et al., 1997; HIRATUKA et al., 2010) (Anexo 1).

Entre os itens descritos como parte importante da funcionalidade destaca-se a marcha. Essa função pode ser avaliada através da análise tridimensional da marcha que permite uma avaliação detalhada dos aspectos cinéticos, cinemáticos e eletromiográficos de cada fase da marcha, representando uma importante ferramenta no processo de avaliação dos resultados obtidos pelas intervenções clínicas nessa população, (HIRATUKA et al., 2010) que apresenta limitações funcionais importantes devido a fraqueza muscular excessiva, alteração cinemática articular e a alteração das reações posturais (LEONARD et al., 1991).

1.3 PALMILHAS POSTURAIS

Diferentes intervenções terapêuticas buscam favorecer o controle motor seletivo e a coordenação da ação muscular na realização da função, entre elas, destaca-se a utilização das órteses de posicionamento, que segundo Lucarelli et al. (2007) tem a finalidade de melhorar o padrão da marcha.

Podem ser prescritas para esses pacientes diferentes tipos de órteses, entre elas, as órtese tornozelo-pé (AFO) que auxiliam no alinhamento e na qualidade da deambulação. Segundo Cury et al. (2006), esse tipo de órtese proporciona uma diminuição da flexão plantar do tornozelo durante o contato inicial com o solo, o que levará à maior estabilidade na fase de apoio da marcha.

Outros tipos de órteses também apresentam bons resultados no que diz respeito a funcionalidade. Romkes, Hell & Brunner (2006) em um trabalho com 10 crianças hemiplégicas, ao compararem a marcha com e sem órteses articuladas, observaram que ocorreu mudança em todos os parâmetros da marcha, concluído que esse tipo de órtese oferece a criança uma marcha mais funcional.

Com objetivos semelhantes, as palmilhas posturais buscam reorganizar o tônus das cadeias musculares e influenciar na postura corporal por meio de reflexos de correção. Estas agem na propriocepção muscular e levam as modificações nas cadeias proprioceptivas ascendentes (BRICOT, 1999).

Segundo Gagey & Weber (2000) existem regiões específicas na planta dos pés cuja estimulação provoca uma modificação do tônus postural e um reposicionamento do nivelamento da pelve e das assimetrias musculares da coluna vertebral.

A reprogramação postural ocorre quando os mecanorreceptores da região plantar são ativados por uma deformação na pele proporcionada por relevos descritos como peças podais e que são fixadas nas palmilhas. Estas peças são divididas em elementos, barras, calços e cunhas (PRZYSIEZNY & SALGADO, 2002).

1.4 JUSTIFICATIVA

Sabe-se que as AFOs são utilizadas para favorecer a função e previnir deformidades. Com esse mesmo objetivo as palmilhas posturais podem ser empregadas oferecendo a vantagem de serem mais funcionais, ou seja, oferecendo benefícios semelhantes às AFOs porém com menor limitação funcional favorecendo a performance na marcha.

Além disso, a palmilha postural deve ser utilizada dentro de sapatos tradicionais, não ficando visivel externamente, fato esse que gera um menor constrangimento ao usuário.

Outro aspecto a ser considerado é que as palmilhas posturais apresentam um custo baixo de produção, tendo um custo final 80% menor do que as AFOs sendo uma opção importante para a população de baixa renda.

2.0 – OBJETIVOS

2.1 - OBJETIVO GERAL

Verificar o efeito da associação das palmilhas posturais e das AFOs na na funcionalidade das crianças com paralisia cerebral.

2.2 - OBJETIVOS ESPECÍFICOS

- Comparar os resultados relacionados à funcionalidade das crianças com paralisia cerebral imediatamente após a aplicação das palmilhas posturais.
- Comparar os resultados relacionados à funcionalidade das crianças com paralisia cerebral três meses após a aplicação das palmilhas posturais.
- Comparar os resultados relacionados à funcionalidade das crianças com paralisia cerebral após um mês de *follow up (*sem o uso das palmilhas)*.*

3.0 - RESULTADOS

3.1 – ARTIGO 1

Pasini Neto H, Grecco LAC, Galli M, Oliveira CS. Comparison of articulated and rigid ankle-foot orthoses in children with cerebral palsy: a systematic review. **Pediatric Physical Therapy**, v. 24, p. 308-312, 2012.

COMPARISON OF THE EFFECTS OF ARTICULATED AND RIGID ANKLE-FOOT ORTHOSES ON GAIT IN CHILDREN WITH CEREBRAL PALSY: A SYSTEMATIC REVIEW

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ABSTRACT

Objective: The aim of the present study was to perform a systematic review of the literature in order to compare the effect of rigid and articulated ankle-foot orthoses on gait in children with cerebral palsy. Method: A systematic review was carried out in four databases. The papers identified were evaluated based on the following inclusion criteria: 1) design – controlled clinical trial; 2) population – children and adolescents with cerebral palsy; 3) intervention – rigid or articulated ankle-foot orthoses; and 4) outcome – improved motor function and gait performance. Results: Seven controlled studies comparing the effect of different ankle-foot orthoses were found. The studies achieved scores of 3 and 4 (PEDro scale) for methodological quality. Conclusion: There is evidence supporting the use of an articulated ankle-foot orthosis by children with cerebral palsy due to the improved function this type of orthosis provides. However, other studies point out the advantages of a rigid orthosis for children with greater impairment related to spasticity and contractures.

Keywords: cerebral palsy, rigid ankle-foot orthosis, articulated ankle-foot orthosis, gait

INTRODUCTION

Cerebral palsy (CP) is a permanent but not immutable posture and movement disorder stemming from a non-progressive brain abnormality due to hereditary factors or events during pregnancy, childbirth, the neonatal period or the first two years of life. CP limits motor activities and is often accompanied by sensation, cognition, communication, perception and behavioral disorders.[1] In a more current definition, CP is a non-progressive chronic disease with a movement, posture and motor function disorder stemming from lesions or abnormalities in the immature brain.[2,3,4]

Neuromotor impairment may involve different parts of the body, resulting in specific topographic classifications, such as quadriplegia, hemiplegia and diplegia.[5]

Children with CP experience important functional limitations due to excessive muscle weakness, kinematic joint abnormalities and reduced postural reactions.[6,7,8,9] Different therapeutic interventions seek to favor selective motor control and the coordination of muscle activity. One such intervention is the use of a positioning orthosis (brace), which, according to Lucarelli et al., is used to facilitate and improve the gait pattern. Different types of orthoses may be prescribed for these patients, such as an ankle-foot orthosis, which can help in alignment and gait quality. An ankle-foot orthosis provides a reduction in the plantar flexion of the ankle, leading to greater stability in the support phase of gait due to the alignment of the joint.[11]

There are different types of orthoses for different therapeutic indications. The rigid ankle-foot orthosis is the most often employed and maintains the ankle in a neutral position, thereby avoiding plantar flexion deformities. Another option is the use of articulated orthoses, which allow dorsiflexion movement, thereby promoting the stretching of the posterior musculature and a consequent reduction in electrical activity in this muscle group.[12]

The aim of the present study was to perform a systematic review of the literature in order to compare the effect of rigid and articulated ankle-foot orthoses on gait in children with cerebral palsy.

METHODS

Searches were carried out in four databases (Medline, Pubmed, Embase and Pedro) using the following keywords: cerebral palsy combined with rigid orthosis, articulated orthosis and gait.

The papers located in the initial search were evaluated by two blinded evaluators based on the following inclusion criteria: 1) design – controlled clinical trial; 2) population – children and adolescents with cerebral palsy; 3) intervention – rigid or articulated ankle-foot orthoses; and 4) outcome – improved motor function and gait performance.

The papers selected were then analyzed with regard to methodological quality using the PEDro scale[13], which has 11 items for the assessment of the internal validity and statistical information of randomized controlled studies. Each adequately satisfied item contributes to a maximal score of 10 points (except Item 1, which is related to external validity). The official score of the articles offered in the electronic address of the databases was used. In cases in which this score was not offered, the manuscript was evaluated independently by two blinded researchers, with divergences between these two evaluators settled by a third evaluator.

The following items were used as the basis for scoring the papers:

Eligibility criteria: origin of subjects and list of requirements used to determine the subjects eligible for participation in the study;

Randomized allocation: random distribution of subjects into different groups;

Confidential allocation: the researcher who determined the eligibility of the subjects had no prior knowledge regarding to which group each subject would belong;

Similar prognosis: based on the initial prognosis, it would not be possible to predict clinically significant differences between groups;

Blinded subjects: the subjects had no knowledge regarding to which group they belonged;

Blinded therapists: the researcher who administered the therapeutic intervention had no knowledge regarding to which group each subject belonged;

Blinded evaluators: the researcher in charge of the evaluation had no knowledge regarding to which group each subject belonged;

Key results: the measurement of at least one key result among more than 85% of the subjects distributed among the different groups;

Comparisons between groups: data analysis of at least one of the key results;

Results of precision and variability: presentation of measures of precision and variability for at least one of the key results.

RESULTS

The initial search of the databases resulted in nine titles and abstracts addressing the comparison of rigid and articulate ankle-foot orthoses, two of which were case studies[14,15] and did not achieve the necessary score on the PEDro scale in order to be part of the present review. Seven papers achieved a minimum of 3 points and were therefore considered methodologically adequate (Tables 1 and 2).

Table 1: Data on articles included in review

Article	Author and year published	PEDro	Type of study
1	Buckon CE et al. 2004 (15)	3/10	Clinical trial
2	Rethlefsen S et al. 1995 (18)	3/10	Clinical trial
3	Rethlefsen S et al. 1998 (19)	3/10	Clinical trial
4	Radtka AS et al. 2004 (16)	4/10	Clinical trial
5	Smiley SJ et al. 2002 (17)	3/10	Clinical trial
6	Rethlefsen S et al.1999 (20)	4/10	Clinical trial
7	Buckon CE et al. 2001 (21)	4/10	Clinical trial

Table 2: Methodological quality score of articles included in review

	Articles						
PEDro	1	2	3	4	5	6	7
Eligibility	YES	NO	NO	YES	YES	NO	YES
Randomized allocation	YES	NO	NO	YES	YES	YES	YES
Confidential allocation	NO	NO	NO	NO	NO	NO	NO
Similar prognosis	NO	NO	NO	NO	NO	NO	NO
Blinded subjects	NO	NO	NO	NO	NO	NO	NO
Blinded therapists	NO	NO	NO	NO	NO	NO	NO
Blinded evaluators	NO	NO	NO	NO	NO	NO	NO
Key results	NO	YES	YES	YES	NO	YES	YES
Comparison between groups	YES	YES	YES	YES	YES	YES	YES
Results of precision and variability	YES	YES	YES	YES	YES	YES	YES
Score	3/10	3/10	3/10	4/10	3/10	4/10	4/10

The seven studies[16,17,18,19,20,21,22] involved a total of 120 individuals. The majority of studies used the same volunteers for the experimental and control groups, alternating only the condition of the data collection. The number of participants ranged from 12 to 30 volunteers. The participants were children and adolescents with cerebral palsy (spastic diplegia or hemiplegia) between four and 15 years of age.

The studies offer divergent results regarding the comparison of rigid and articulated ankle-foot orthoses. Some report significant differences in gait parameters, such as velocity, cadence, step length and stride length, as well as kinetic and kinematic differences in the ankle and knee, whereas other studies found no significant differences between the two types of orthosis (Table 3).

The significant differences in the comparison between articulated and rigid orthoses were in the increase in peak dorsiflexion,[16,19,20,21,22] reduction in double-support time,[19] increase in gait speed[22] and reduction in energy expenditure[22] with the use of the articulated orthosis (Table 3).

Table 3 – Characteristics of studies included in review.

Article	number of volunteers	Characteristics of sample	Orthosis	Analysis	Results
1	16	Spastic diplegia.	Rigid, articulated and posterior leaf spring	Gait analysis: kinetics, kinematics and gait parameters	- no significant differences in gait parameters - no change in kinetics or kinematic of pelvis and hip - no significant difference in degree of knee extension at initial contact - increase in peak dorsiflexion with articulated orthosis
2	15	Spastic diplegia	Rigid and articulated	Gait analysis: kinetics, kinematics and gait parameters	- improved bipedal support and shorter unipedal support with articulated orthosis - no significant difference in degree of knee extension at initial contact - no difference in peak dorsiflexion
3	12	Spastic diplegia	Rigid and articulated	Gait analysis: kinetics, kinematics and gait parameters	- increase in peak dorsiflexion with articulated orthosis - no significant difference in degree of knee extension at initial contact

4	12	Spastic diplegia	Rigid and articulated	Gait analysis: kinetics, kinematics, gait parameters and EMG	- no significant differences in gait parameters or muscle activity in different phases - increase in peak dorsiflexion with articulated orthosis - no significant difference in degree of knee extension at initial contact
5	14	Spastic diplegia	Rigid, articulated and posterior leaf spring	Gait analysis: kinetics, kinematics, gait parameters and energy expenditure	- no significant differences in gait parameters, kinetics, kinematics or energy expenditure
6	21	Spastic diplegia	Rigid and articulated	Gait analysis: kinetics, kinematics and gait parameters	- increase in peak dorsiflexion with articulated orthosis - no significant difference in range of motion of knee
7	30	Spastic hemiplegia	Rigid, articulated and posterior leaf spring.	Gait analysis: kinetics, kinematics, gait parameters and energy expenditure	- increase in peak dorsiflexion with articulated orthosis - significant increase in gait velocity with articulated orthosis - reduction in energy expenditure with articulated orthosis.

It should be stressed that the present study only considered results regarding comparisons between rigid and articulated ankle-foot orthoses and did not address aspects related to the benefits of using an orthosis, as this topic is widely discussed in the literature.

All papers compared the effects of rigid and articulated ankle-foot orthoses during gait. Two studies included a third type of orthosis (posterior leaf spring),[16,18] which was not considered in the presentation and discussion of the results of the present study.

Gait performance was the parameter used for comparisons in all papers, which mainly investigated data on kinematic variations in the ankle, knee and hip joints as well as differences in temporal-distance gait parameters, such as velocity, cadence, step length and stride length. Moreover, three papers included an analysis of electromyographic activity in muscles related to gait, determining the degree of muscle activation in the different phases of gait with different orthoses.[17,19,20] Other aspects analyzed included energy expenditure with different orthoses[16,18,22] and the preference of the individuals regarding the choice of orthosis.[18]

DISCUSSION

According to Cury et al.,[11] orthoses are part of the daily routine of children with cerebral palsy and offer benefits mainly in locomotion in outdoor environments. The author also states that orthoses significantly enhance gait quality in these children when compared to a control group, regardless of the topographic diagnosis of the lesion.

The studies analyzed in the present systematic review address gait characteristics with the use of rigid and articulated orthoses and offer divergent results regarding differences in gait parameters (velocity, cadence, step length and stride length) between these two types of orthosis. It should be stressed that both types of orthosis lead to an improvement in gait parameters when compared to a control group without the use of an orthosis.

Buckon et al.,[16] Radtka et al.[17] and Smiley et al.[18] found no significant differences in gait parameters between orthoses. In contrast, Rethlefsen et al.[21] found significant differences between three types of orthosis (rigid, articulated and posterior leaf spring). The discrepancies in the results may be related to methodological differences between studies. Rethlefsen et al.[19] collected data with three orthoses in a single session, whereas the other studies cited allowed an adaptation period for the participants with the different orthoses prior to data acquisition.

In agreement with other findings, Rowkes et al.[25] compared gait with and without an articulated orthosis among 10 children with hemiplegic CP and found changes in all gait parameters, stressing the improvement in step length, cadence and gait speed as well as greater hip flexion upon initial contact and a reduction in plantar flexion in the swing phase. The authors concluded that this type of orthosis offers children a more functional gait.

However, Rethlefsen et al.[19] found that a rigid orthosis allowed greater stability during gait and suggest that this type of orthosis be used for patients with more severe locomotor impairment, as it assists in the prevention of muscle contractures. The authors state that the articulated orthosis, while achieving a more functional gait pattern, should be used with patients that have better hip and knee control.

It should be stressed that the results described by Romkes et al. [25] were obtained from a gait analysis of hemiplegic children, whereas Rethlefsen et al.[19] analyzed diplegic children. This may explain the differences in the findings regarding the significant increase in the quality of the gait variables, as these two conditions present different limitations.

Other studies comparing the use of rigid and articulated orthosis during locomotion on stairs report a significant increase in the quality of gait parameters as well as the kinetic and kinematic aspects of lower limb joints with the use of an articulated orthosis.[23] Moreover, Wilson et al.[23] report that an articulated orthosis offers a better transition between sitting and standing. More complex tasks require a greater range of motion in the joints, which respond more efficiently when allowed to move freely. Therefore, a rigid orthosis is more limiting for certain tasks and an articulated orthosis offers greater functional freedom for more complex tasks. However, the biomechanical advantages of such devices may not be made evident in gait analyses.

Another conflicting finding in the studies was the change in the kinematics of the ankle. Five of the papers report better ankle dorsiflexion with the use of an articulated orthosis,[16,17,20,21,22] whereas two papers found no difference between orthoses regarding this parameter.[18,19] Among the inclusion criteria in the majority of the studies, the following are cited: absence of muscle shortening in flexor group of the hip or knee; contracture of less than 15 degrees in the hip;[20] and 10 degrees of hip extension or five degrees of dorsiflexion with the knees extended.[17] The two papers that found no significant differences between did not include these criteria, which may explain the discrepancy in the results.

According to Radtka et al.,[17] the improvement in dorsiflexion achieved with an articulated orthosis (especially in the final support phase) in comparison to a rigid orthosis constitutes an important clinical benefit, as this type of orthosis allows a more functional gait pattern.[15,24] This corroborates findings described by Middleton et al.,[13] who published a case study and concluded that an articulated orthosis offers a more natural, symmetric gait pattern. This type of orthosis may therefore be an important resource for the prevention of deformities in plantar flexion.[17] The maximal dorsiflexion allowed by an articulated orthosis may promote an increase in knee flexion, thereby increasing energy expenditure and negatively affecting gait.[(17)] According to Carmick[15], a change from a rigid orthosis to an articulated orthosis is enough to alter the entire biomechanics of the body.

Regarding the knees, no significant differences are found between articulated and rigid orthoses during gait. However, the results demonstrate a tendency toward greater knee flexion upon initial contact among subjects using an articulated orthosis. One explanation for this is that muscle shortening in the triceps surae group, together with the distal fixation generated by the orthosis, may lead to a compensation in knee flexion due to the bi-articular characteristic of this muscle group.[18,22]

CONCLUSION

There are a large number of studies that report the advantages of rigid and articulated orthoses, but few have compared the effects of these types of orthosis on gait. Moreover, methodological differences hinder the comparison of the results between studies. There is evidence supporting the use of an articulated ankle-foot orthosis by children with cerebral palsy due to the improved function this type of orthosis provides. However, other studies point out the advantages of a rigid orthosis for children with greater impairment related to spasticity and contractures.

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3.2 – ARTIGO 2

Pasini Neto H, Grecco LAC, Christovão TCL, Ferreira LAB, Giannasi LC, Salgado ASI, Correa JCF, Franco RC, Carvalho PTC, Sampaio LMM, Galli M, Oliveira CS. Effect of posture-control insoles on function in children with cerebral palsy: Randomized controlled clinical trial. **BMC Musculoskeletal Disorders** (Online), v. 13, p. 193-197, 2012.

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ABSTRACT

Introduction

Cerebral palsy (CP) is a posture and movement disorder and different therapeutic modalities, such as the use of braces, have sought to favor selective motor control and muscle coordination in such patients. The aim of the proposed study is to determine the effect of the combination of posture-control insoles and ankle-foot orthoses (AFOs) on improving functional limitation in children with CP.

Methods/Design

The sample will be composed of 24 children with CP between four and 12 years of age. After the signing of the statement of informed consent, the children will be randomly allocated to two groups: a control group using AFOs alone and an experimental group using both posture-control insoles and AFOs. Evaluations will be performed on five occasions: without any accessory (insoles or AFOs), immediately after, one month after, six months after and one year after AFOs or insole and AFOs use. The evaluation will involve the analysis of gait, static and functional balance, mobility and hypertonia. The three-dimensional assessment of gait will involve the eight-camera SMART-D 140® system (BTS Engineering), two Kistler force plates (model 9286BA) and an eight-channel, wireless FREEEMG® electromyography (BTS Engineering). Static balance will be assessed using a Kistler force plate (model 9286BA). Clinical functional balance and mobility will be assessed using the Berg Balance Scale, Timed Up-and-Go Test and Six-Minute Walk Test. The posture-control insoles will be made of ethylene vinyl acetate, with thermal molding for fixation. The fixed orthoses will be made of polypropylene and attached to the ankle region (AFO). The results will be analyzed statistically, with the level significance set to 5% ($p < 0.05$).

Trial Registration

Trial Registration Number: RBR6d342s
(http://www.ensaiosclinicos.gov.br/news/)

Keywords

Cerebral palsy, Posture-control insoles, Ankle-foot orthosis, Electromyography, Gait, stabilometry, Rehabilitation

Introduction

Cerebral palsy (CP) is a permanent but not immutable posture and movement disorder resulting from a non-progressive cerebral disorder due to hereditary factors or events occurring during pregnancy, child birth, the neonatal period or in the first days of life, leading to limited motor activity and often accompanied by sensory, cognition, communication, perception and behavioral disorders. [1] The most current definition states that CP is a chronic, non-progressive disease with movement, posture and motor function disorders stemming from lesions or abnormalities in the immature brain.[2]

Motor impairment is the major manifestation of CP, with consequent changes in bodily biomechanics. Moreover, children with CP may exhibit intellectual, visual and hearing disorders, which, when added to motor impairment and both task and environment restrictions, affect functional performance in a variety of different ways.[3, 4]

Neuromotor impairment in this disease involves different parts of the body, resulting in specific topographic classifications, such as quadriplegia, hemiplegia and diplegia.[5] However, children with CP are currently classified based on functionality, which encompasses the functions of the body, activities and social participation. The Gross Motor Function Classification System for Cerebral Palsy (GMFCS)[6] classifies children with CP based on age (0–2, 2–4, 4–6 and 6–12 years) and respective functional levels. Children classified as Level I can walk without restrictions, but tend to be limited in more advanced motor skills, whereas children classified as Level V are very limited in their ability to walk, even with a gait-assistance device.[7] The GMFCS is an extremely important tool for physical therapists who work with children with CP, as it allows the establishment of adequate therapeutic goals based on the patient's age and motor level.[7, 8]

Functional mobility can also be assessed using the Berg Balance Scale and the Timed Up-and-Go Test. These scales allow a quantitative assessment of functional balance.

With regard to gait, a three-dimensional analysis allows a detailed evaluation of the kinetic, kinematic and electromyographic aspects of each phase of the gait cycle and is an important tool for the assessment of the results of clinical interventions in children with CP, who exhibit functional limitations due to excessive muscle weakness, abnormal joint kinetics and abnormal postural reactions.[9]

Different therapeutic interventions seek to improve selective motor control and muscle coordination in these patients. The use of an orthosis (brace) is one such method, the aim of which, according to Lucarelli et al. (2007), is to improve the gait pattern.[10] Different types of orthosis may be prescribed, such as an ankle-foot orthosis (AFO), which assists in the alignment and quality of ambulation. This type of brace provides a reduction in plantar flexion of the ankle during initial contact with the ground, which leads to greater stability in the stance phase.[11]

Similarly, the aim of posture-control insoles is to reorganize the tonus of muscle chains and influence body posture through correction reflexes. These insoles affect muscle proprioception, leading to changes in the ascending proprioceptive chains.[12] According to Gagey & Weber (2000),[13] the stimulation of specific regions of the sole of the foot leads to a change in postural tonus and a repositioning of the pelvis and muscle asymmetries along the spinal column. Postural reprogramming occurs when mechanoreceptors in the plantar region are activated by deformation of the skin due to the topographic relief of the support surface, as occurs with posture-control insoles.[14]

The aim of the proposed study is to determine the effect of the combination of posture-control insoles and ankle-foot orthoses (AFOs) on functionality in children with CP. The hypothesis is that posture-control insoles lead to a change in sensitive afference, thereby stimulating a new postural reaction that favors better biomechanical alignment and allows greater efficiency in functional tasks, especially those related to locomotion and balance.

Methods

Type of study

A randomized, controlled, clinical trial will be carried out.

In compliance with Resolution 196/96 of the Brazilian National Health Council, the proposal was sent for the analysis of the Human Research Ethics Committee and received approval (August 8, 2011).

The children will participate on a volunteer basis and legal guardians will sign a statement of informed consent.

Sample description and characterization

The sample size will be calculated based on the study carried out by Buckon et al. (2004)[15] with results on gait cadence in children with CP (GMFCS Levels I and II) with and without a fixed AFO. For an expected size effect of 17 steps/minute, with a standard deviation of 15 steps/minute and assuming an α risk of 0.05 and an 80% power, the sample was estimated at 12 children per group. Thus, the sample will be composed of 24 male and female children with CP aged four to 12 years**.**

The participants will be recruited and selected for eligibility based on the criteria listed below.

Inclusion criteria

Diagnosis of CP; classification in Levels I and II of the GMFCS; and independent ambulation with no need for gait assistance devices (walker or crutches)

Exclusion criteria

History of surgical procedures or application of phenol in previous 12 months; history of neurolytic blocks in previous six months; cognitive or visual impairment that might impede the performance of the tasks; ankle deformities not reducible to zero; and obesity [16]

Sample composition

After fulfilling the eligibility criteria, the children will be randomly divided into two groups: 1) a control group that will make use of AFOs exclusively and 2) an experimental group that will make use of AFOs combined with posture-control insoles.

Children in therapy at rehabilitation centers will be recruited and instructed to maintain their normal therapy throughout the study. Randomization with involve a series of sealed opaque envelopes to ensure confidentiality. Each envelop will contain a card stipulating to which group the child will be allocated.

Equipment

Body mass and stature will be determined using a duly calibrated mechanical scale (Welmy brand) with a 150-Kg capacity and precision of 0.1 Kg and stadiometer coupled to the scale with a precision of 0.1 cm.

Static balance will be evaluated using a force plate (Kistler, model 9286BA), which allows stabilometric analysis based on oscillations of the center of pressure. The acquisition frequency will be 400 Hz, captured by four piezoelectric sensors positioned at the ends of the platform, measuring 400/600 mm. The data will be recorded and interpreted using the SWAY software program designed by BTS Engineering, integrated to and synchronized with the SMART-D 140® system.

The SMART-D 140® system (BTS Engineering) will be used for the three-dimensional evaluation of gait, using eight cameras with an infrared-sensitive response and the 32-analog channel SMART-D INTEGRATED WORKSTATION®. The kinetic data will be collected using two force plates (Kistler, model 9286BA) for recording displacement from the center of pressure and the contact time between the foot and surface of the platform. An eight-channel, wireless-transmission electromyograph (FREEEMG® – BTS (Engineering) will also be used, with bipolar electrodes with a total gain of 2000 x and within a frequency of 1000Hz. The impedance and common rejection mode will be $>10^{15}$ Ω//0.2 pF and 60/10Hz 92 dB.

The posture-control insoles to be used by the children in the experimental group have surface, middle and deep portions. The surface portion is composed of fabric that covers the other portions and serves to absorb sweat and provide comfort. The middle portion is made of ethylene vinyl acetate (EVA) with a thickness of 3 mm. The lowest portion is made by material formed by a network of cotton fibers and resin with a thickness of 1 mm in which the podal pieces are located (bars, wedges and shims), made from EVA with respective thicknesses, densities and resilience, the aim of which is to stimulate the skin in predetermined regions and promote postural reprogramming.[14] In the study proposed, the pieces to be used will be the hard postural half moon, wedge and outer anti-rotator, with the aim of acting on the re-equilibrium of a common motor pattern (Figure 1).

Figure 1: Representation of podal piece to be used in making of the posture-control insoles

After the different portions and the foot piece to be used are positioned, thermal molding of the insole will be performed for the fusion of the different sections and pieces (Figure 2). All material used for the confection of the insoles are from the brand name Podaly®.

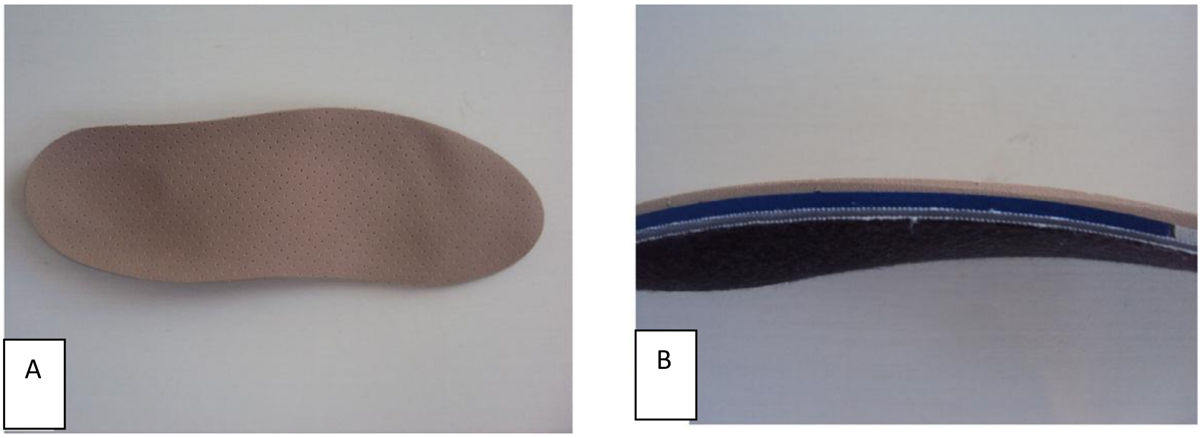

Figure 2: Representation of insoles after thermal molding; A – Front view; B- Side view, showing three portions

Instruments

The Gross Motor Function Classification System for Cerebral Palsy (GMFCS) will be used to classify the children based on the level of gross motor function.[17] This system classifies children between Levels I and V. Only children classified at Levels I and II will participate in the proposed study.

The motor growth curves[18] referring to GMFCS Levels I, II and III will be used as a complement to the classification of gross motor function. The curves have the scoring of the GMFM-66[19, 20] on the vertical axis and age on the horizontal axis for each GMFCS level. Using these curves, the child is functionally classified as being within the expected range, better than expected or poorer than expected.

The Berg Balance Scale will be used for the assessment of functional balance. This scale consists of 14 tasks that are similar to different activities of daily living. The items are scored on a five-point scale ranging from 0 (inability to perform task) to 4 (ability to perform task independently). The maximal score is 56 points. The point system is based on the time in which a position is maintained, the distance to which the upper limb is capable of reaching out in front of the body and the time needed to complete a task. The execution time is approximately 20 minutes. A chronometer, stool and chair are needed for the assessment. The evaluation is performed with the child dressed and making use of his/her habitual orthosis and/or gait assistance device.[21, 22]

The Timed Up-and-Go Test will be performed and distance will be measured using a metric tape. This fast, practical, easy-to-apply test is widely used for the assessment of functional mobility and dynamic balance. The test quantifies functional mobility through the time (in seconds) in which an individual performs the task (stand up from a standardized chair with back and arm supports, walk three meters, turn around, walk back to the chair and sit down again).[23, 24]

The Six-Minute Walk Test will be performed. This test is a reliable measure for the assessment of physical fitness[25, 26] and quantifies (in meters) functional mobility through the distance traveled walking in six minutes. This test will be performed based on the guidelines of the American Thoracic Society.

The modified Ashworth Scale will be used for the classification of hypertonia. This scale consists of Item 1+ and a five-point scoring system ranging from 0 (absence of tonic alteration) to 4. The classification of severity is related to range of motion at which increased resistance to rapid passive movement is detected.[27]

Procedures

The children selected (whose legal guardians agreed to their participation by signing a statement of informed consent) will be evaluated regarding their anthropometric data and GMFCS classification and randomly allocated to the experimental and control groups. The control group will make daily and constant use of the AFOs. The experimental group will make use of the posture-control insoles for six hours daily during the most active period of the day and will remain using the AFOs the rest of the day.

The evaluation process (before, immediately after, one month after, six months after and one year after insole use) will be performed under two different conditions. Under the first condition (evaluation 1), the children will not use an assistance device and under the second condition (evaluation 2), the children will use either the posture-control insoles or the AFOs, depending on the group to which they belong. Evaluation 1 and evaluation 2 will be performed by different examiners. Examiner 1 will not be aware of which group the children belong, thereby characterizing the investigation as a blind study.

The evaluations will be held on two non-consecutive days. The Berg Balance Scale, Timed Up-and-Go Test, Six-Minute Walk Test and modified Ashworth scale will be administered on the first day. The three-dimensional gait analysis and the static balance test on a pressure plate will be performed on the second day.

For the three-dimensional gait analysis, the equipment will be introduced to the children and the procedures will be explained. The children will be submitted to an initial practice gait exam to become familiarized with the procedure (no data will be collected on this training run). The children will wear bathing suits to facilitate the placement of the markers. The skin will be cleaned with alcohol for better attachment of the markers on the exact sites. The markers will be enveloped in adhesive tape lined with microscopic glass spheres and attached to a plastic base with double-sided adhesive tape. The markers will be attached to the children in the orthostatic position, as suggested by Davis et al. (1991),[28] on the following anatomic structures:

Pelvis: Three markers will be positioned on the anterior superior iliac spines (right and left) and one between the posterior superior iliac spines.

Thigh: One marker will be placed laterally to the greater trochanter. A second marker will be placed laterally to the lateral condyle of the femur. A third marker will be positioned on an appendicular line midway between the two previous points.

Leg: One marker will be placed laterally to the head of the fibula. A second marker will be placed laterally to the lateral malleolus. A third marker will be positioned on an appendicular line midway between the two previous points.

Foot: A marker will be placed laterally to the head of the fifth metatarsus. One adjunctive marker will be placed bilaterally on heel only for the standing acquisition, before the walking test.

The markers will be used as reference for the eight-camera SMART-D BTS$^{@}$ system which will acquire the 3D coordinates (x,y,z) of each marker .[29] The set of markers will be used to estimate the position of the joint centers and calculate the three-dimensional kinematics of the pelvis, hips, knees and ankles.[30] This will be performed through the combination of coordinates, which will take the information obtained from the positioning of the markers into consideration.[29]

For such, the children will walk on a track marked on the ground measuring 90 centimeters in width and four meters in length, with two force plates (model 9286A) positioned in the center. Upon stepping on the force plates while walking, the kinetic gait data will be collected and calculated using a video system (BTS, Milan, Italy) synchronized to the two force plates.

The electrical activity stemming from the activation of the rectus femoris, tibialis anterior and soleus muscles (on right and left leg) will be collected using a signal conditioner (FREEEMG®, BTS). For the placement of the six channels, the motor point of the muscles will be identified and the area will be cleaned with 70% alcohol to reduce impedance, based on the recommendations of the Surface Electromyography for the Non-Invasive Assessment of Muscles.[31] All electromyographic data will digitized in 1000 frames/second using the BTS MYOLAB® software program. The kinematic and kinetic data will be collected simultaneously and managed using the BTS® system and Smart Capture® software program.

Static balance will be analyzed using a Kistler force plate (model 9286BA). The evaluation will be performed with the individuals in the orthostatic position on the force plate with no restriction regarding the foot base. Readings will be taken three times under two conditions (eyes open and eyes closed), with each reading lasting 30 seconds. A rest period will be respected between each application of the instrument and the child will be allowed to interrupt the evaluation to rest at any time.

Flowchart

The project will be carried out in accordance with the following flowchart (Figure 3):

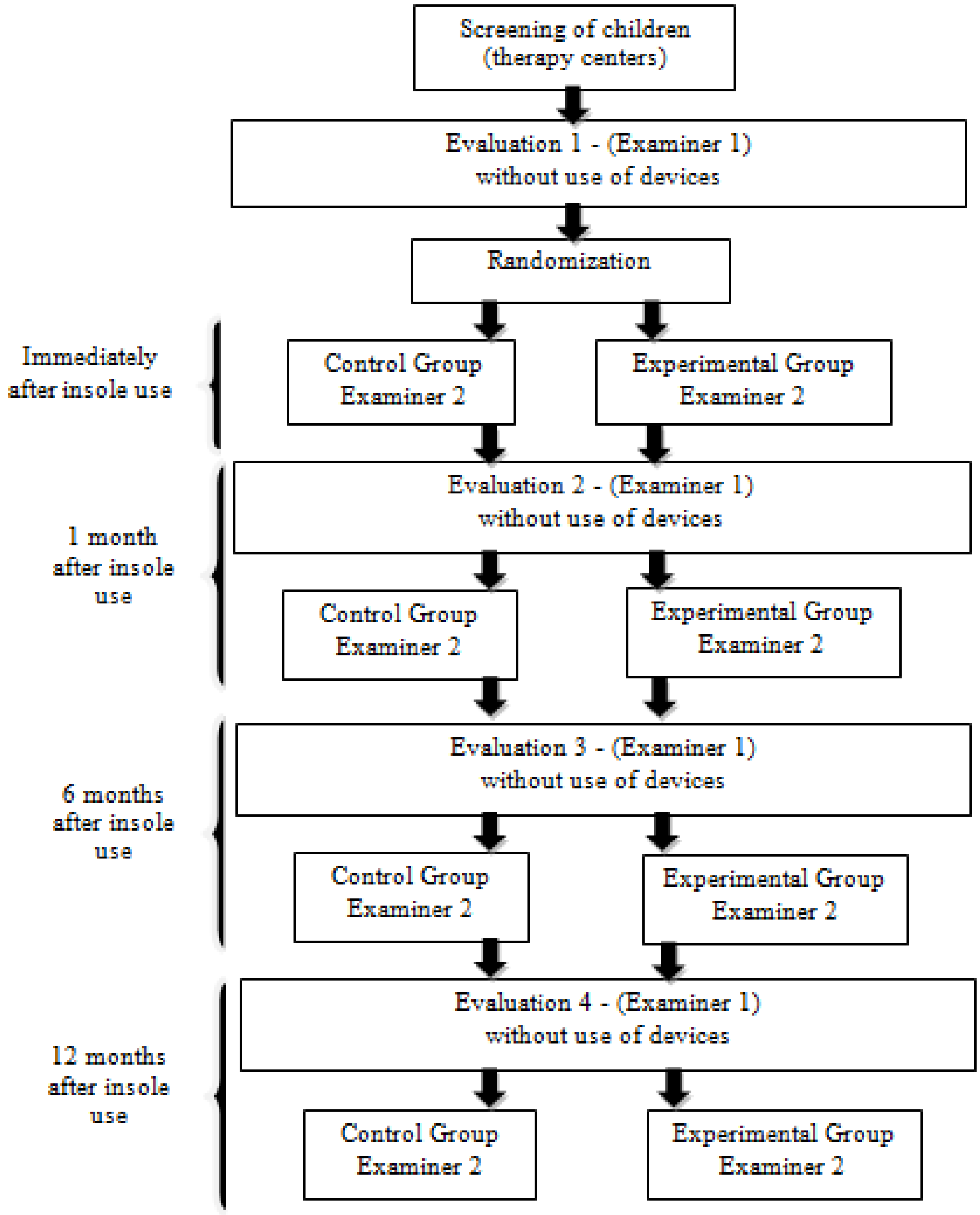

Figure 3 Flowchart of project

Flowchart of project

Statistical analysis

The Kolmogorov-Smirnov test will be used to test the data with regard to Gaussian distribution. Central tendency and dispersion measures will be expressed as mean and standard deviation values or median and inter-quartile interval when exhibiting parametric and non-parametric distribution, respectively. Either repeated-measure ANOVA or Friedman's test will be used for the intra-group analysis and either one-way ANOVA or the Kruskal-Wallis test will be used for the inter-group analysis for data with parametric and non-parametric distribution, respectively. The data will be organized and tabulated using the Statistical Package for the Social Sciences (SPSS v.19.0). The level of significance will be set to 5% ($p < 0.05$).

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

All authors contributed to the conception and design of the study. CSO provided the idea for the study and established the hypothesis. HPN and LACG significantly contributed to drafting the manuscript. All authors read and approved the final manuscript.

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3.3 – ARTIGO 3

Pasini Neto H, Grecco LAC, Christovão TCL, Galli M, Oliveira CS. **Immediate effect of postural insoles on gait performance in children with cerebral palsy: preliminary randomized controlled double-blind clinical trail. Submetido à Prothetics and Orthotics International.**

IMMEDIATE EFFECT OF POSTURAL INSOLES ON GAIT PERFORMANCE IN CHILDREN WITH CEREBRAL PALSY: PRELIMINARY RANDOMIZED CONTROLLED DOUBLE-BLIND CLINICAL TRAIL.

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ABSTRACT

INTRODUCTION: The main change present in children with CP is the motor impairment. For this, several therapeutic interventions seek to promote the selective motor control. Whereas the postural insoles aims to reorganize and rearrange mechanical postural muscle tone, that may play a role similar to the conventional orthoses. **OBJECTIVE**: The aim of this study was to assess the effect of postural insoles on gait performance in children with CP **METHODS**: We conducted a randomized controlled double blind in which after meeting the legal aspects and the eligibility criteria, 10 children between 4 and 12 years old were randomly divided into a control group (5) and experimental group (5). Children in the control group used the placebo insole and children in the experimental group used postural insoles. These insoles were made in ethylene vinyl acetate, which in the case of postural insoles, received thermoforming to fasten the foot problems related to postural correction and in the case of placebos insoles did not receive the correct parts. In relation to evaluation, this was composed of three-dimensional gait analysis and it was performed before and immediately after application of insoles. This evaluation was performed using the SMART-D 140 ® - BTS Engineering with eight cameras and were considered for statistical analysis the temporal parameters of gait. Data analysis considered the adherence to the bell curve, by Kolmogorov-Smirnov and how they were presented parametric, were expressed as mean (standard deviation or confidence interval of 95%). For intergroup analysis it was used the independent t test and intragroup analysis was used repeated measures ANOVA. **RESULTS**: The immediate effect of postural insoles it is possible to observe a significant increase in parameters related to gait velocity and cadence in children in the experimental group compared to control children. **CONCLUSION**: Postural insoles proved effective for the treatment of children with cerebral palsy classified at GMFCS levels I and II.

Key words: Cerebral palsy, gait, orthoses, postural insole

INTRODUCTION

Motor impairment is the main manifestation of cerebral palsy (CP) and has a consequent effect on the biomechanics of the body. Children with CP may also exhibit cognitive, visual and hearing impairment, which, along with motor impairment, task restrictions and environmental restrictions, have a negative effect on functional performance.[1,2]

Neuromotor impairment in this disease can involve different parts of the body, which results in specific topographic classifications, such as quadriplegia, hemiplegia and diplegia.[3] 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 (GMCFS) for Cerebral Palsy[4] 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 for evaluating the results of clinical interventions in this population, which has functional limitations due to excessive muscle weakness and abnormalities in both joint kinematics and postural reactions.[5]

Different therapeutic interventions have been employed in an attempt to favor selective muscle control and coordination in children with CP. Lucarelli et al. (2007)[6] report that orthoses assist in improving gait. In a systematic review on the influence of rigid and articulated orthoses, Pasini Neto et al. (2012)[7] report numerous benefits from the use of rigid orthoses. However, 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, thereby potentiating function in children with CP.

With a similar finality, 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 chains.[(8)] According to Gagey & Weber (2000),[(8)] the stimulation of specific regions of the soles of the feet causes a change in postural tonus and repositioning 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 insoles.[(9)]

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

MATERIALS AND METHODS

A preliminary randomized, controlled, double-blind, clinical trial was conducted at the Movement Analysis Laboratory of the Universidade Nove de Julho (Sao Paulo, Brazil) following approval from the Human Research Ethics Committee of the institution under process number 436960 dated August 8, 2011, in compliance with Resolution 196/96 of the Brazilian National Board of Health. This study is registered with the Brazilian Registry of Clinical Trials (Registration Number: RBR6d342s - http://www.ensaiosclinicos.gov.br/news/). Parents/guardians signed a statement of informed consent agreeing to the participation of the children.

Twenty-five children were recruited and selected based on the eligibility criteria. The inclusion criteria were a diagnosis of CP and classification on levels I and II of the 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 interfere in the performance of the procedures; and ankle deformities non-reducible to neutral.

The participants were randomly allocated to two groups. The control group (CG) made use of an insole without correction elements and the experimental group (EG) made use of an insole with correction elements. Neither the children nor their guardians were aware of the group to which the participants were allocated, thereby characterizing a blind study for the placebo effect of the insole in the CG. 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 acetate.[14] The pieces used in the present study were half-moon and anti-valgus (Figure 1).

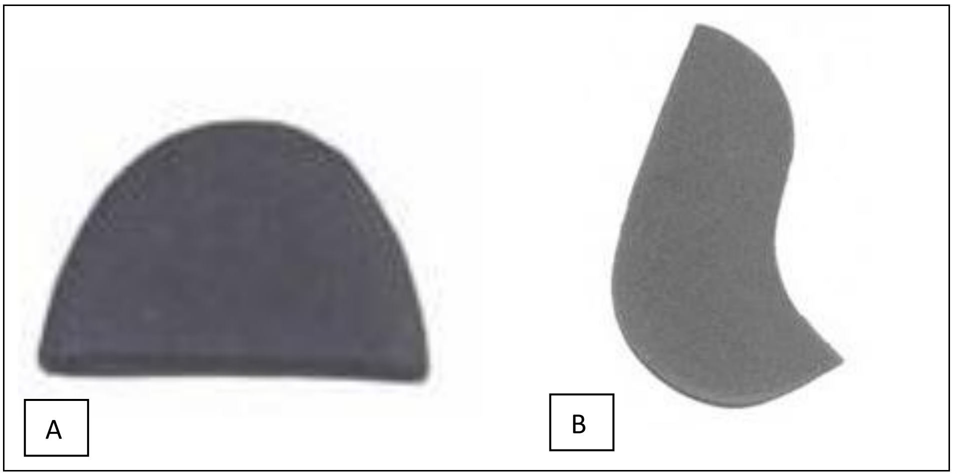

Figure 1 – Representation of elements used in postural insoles; A- half-moon; B- anti-valgus (Podaly®)

The CG used smooth insoles without corrective pieces (Figure 2).

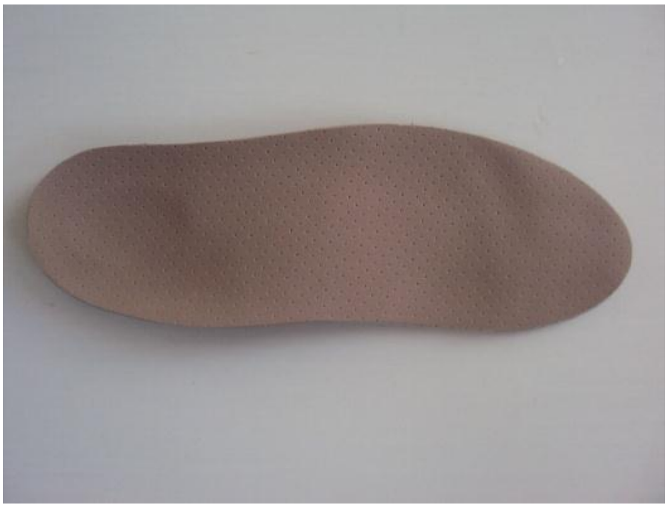

Figure 2 – Representation of smooth insole used in control group (Podaly®).

Following the positioning of the pieces, the insoles were submitted to thermal molding to fuse the different portions together (Figure 3).

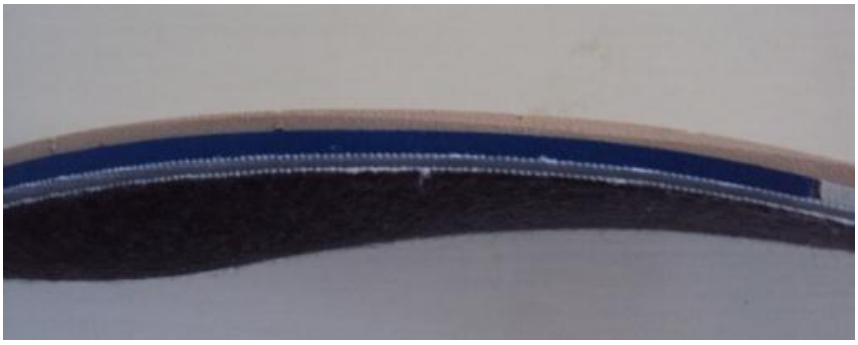

Figure 3 – Representation of three layers after thermal bonding (Podaly®).

The evaluation process was performed under three different conditions: barefoot, with shoes and with shoes and insoles. 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 with regard to the procedures to be carried out. A training session was then performed, simulating a regular gait exam, but without data collection. For such, the children were instructed to walk normally on a track demarcated on the floor measuring four meters in length and 90 centimeters in width. All children wore bathing suits to facilitate the placement of the markers. The markers were then placed on the children in the standing position, as suggested by Davis et al (1991).[(10)] The markers were enveloped in adhesive tape lined with microscopic glass spheres and attached to a plastic base with double-sided adhesive tape to favor visualization by the infrared cameras. The equipment used for the gait evaluation was the SMART-D 140® (BTS Engineering), with eight cameras sensitive to the infrared spectrum. 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, with shoes and with shoes and insoles). The researcher in charge of this phase was unaware of the group to which each child belonged (double-blind trial).

The data were first submitted to the Kolmogorov-Smirnov test to determine adherence to the Gaussian curve. As data were parametric, the results were expressed as mean and standard deviation or 95% confidence interval. The effect size was calculated considering the mean difference between the results obtained with the participants barefoot, with shoes and with shoes and insoles. 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 (Figure 4).

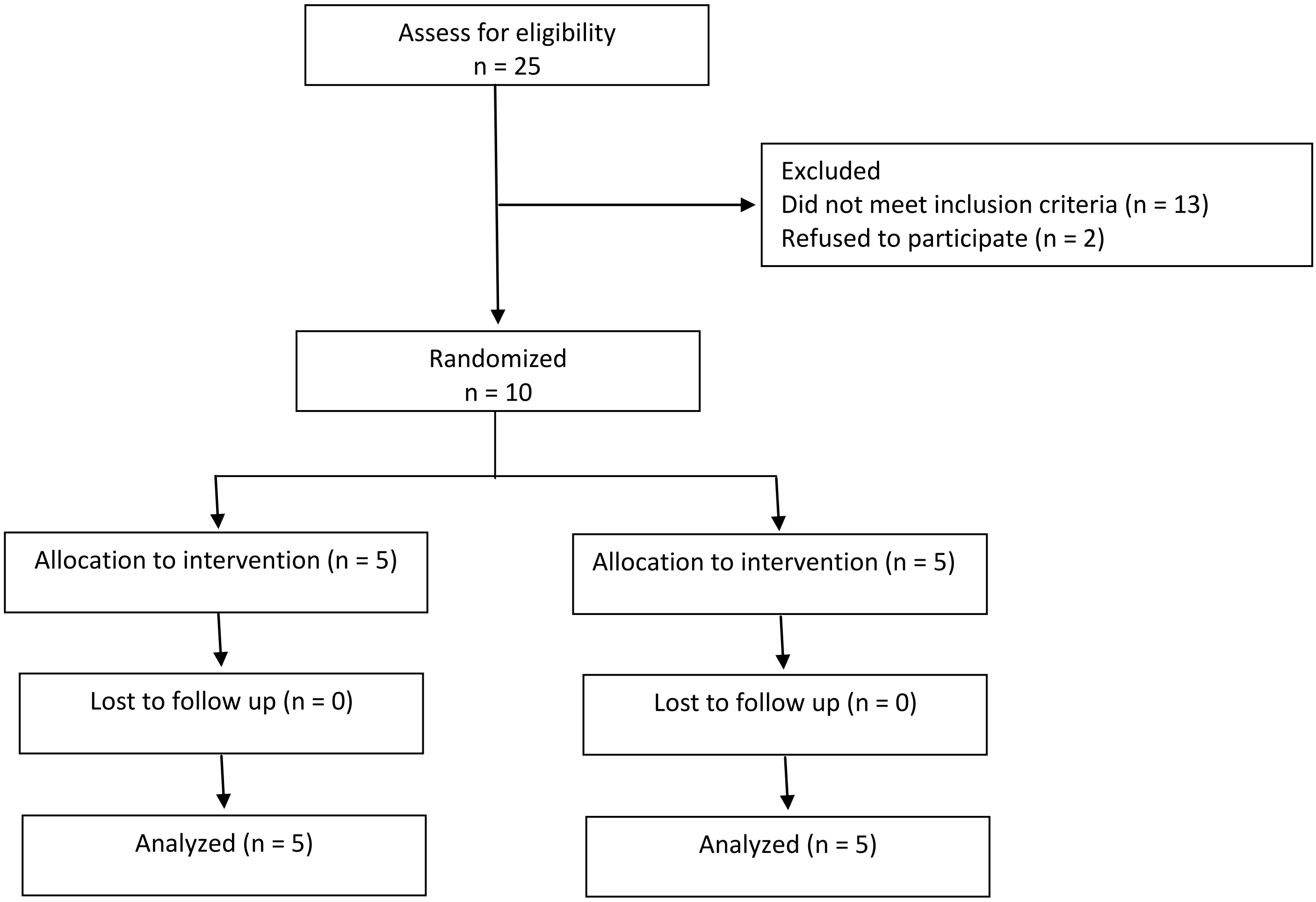

Figure 4 - Fluxogram

Table 1: displays 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

Table 1: Mean ± standard deviation of anthropometric data of participants

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

Table 2: Results of gait variables when barefoot, wearing shoes and wearing shoes with insoles

	Barefoot		Shoes		Shoes + insoles	
	EG	CG	EG	CG	EG	CG
Support phase	55.34(5.46)	55.32(2.34)	46.08(9.68)	48.68(11.29)	53.89(4.87)	51.44(5.35)
Swing phase	41.66(3.05)	42.08(3.73)	37.67(9.19)	41.98(4.35)	40.07(2.11)	43.17(6.74)
Double support phase	5.16(1.65)	6.28(1.69)	6.76(9.19)	6.41(1.60)	10.92(4.78)	20.03(28.69)
Step time	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	111.58(18.76)	111.08(20.74)	87.76(25.16)	99.98(27.48)	124.90(7.04)*	99.20(25.91)
Step length	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	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	0.89(0.10)	0.81(0.17)	0.83(0.13)	0.82(0.09)	0.98(0.13)*#	0.84(0.17)

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

In the analysis of the effect of the postural insoles in comparison to the other conditions (barefoot and shoes without insoles), 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 with regard to cadence and velocity (Table 3).

Table 3: Effect of treatment on all outcome measures

	Shoes without insoles				Shoes with insoles			
	EG	CG	Effect	P	EG	CG	Effect	P
Support phase	-3.9(-9.8-2.0)	-1.4(-6.4-3.5)	2.45	0.407	7.8(-7.3-22.9)	2.7(-5.8-11.3)	5.05	0.444
Swing phase	1.0(-7.4-9.5)	-1.5(-4.2-1.0)	-2.68	0.427	2.4(-11.0-15.0)	1.1(-4.0-6.4)	1.21	0.822
Double support phase	13.7(-20.2-47.7)	5.7(0.8-10.6)	-7.99	0.536	13.6(-21.1-48.3)	4.1(-1.6-9.9)	-9.46	0.478
Step time	0.02(-0.02-0.07)	0.06(-0.2-0.3)	0.04	0.705	-0.04(-0.1-0.1)	0.07(-0.1-0.3)	0.07	0.249
Cadence	13.3(-5.2-31.8)	-11.8(-26.0-2.2)	13.32	0.017*	37.1(11.0-63.2)	-0.78(-16.9-15.3)	37.92	0.019*
Step length	0.00(-0.02-0.02)	-0.01(-0.1-0.07)	-0.01	0.664	0.06(-0.00-0.02)	-0.1(-0.1-0.08)	-0.02	0.572
Stride length	0.00(-0.02-0.02)	-0.01(-0.01-0.07)	0.05	0.377	0.06(-0.008-0.02)	-0.01(-0.01-0.08)	0.12	0.664
Velocity	0.08(0.01-0.16)	-0.06(-0.11-0.04)	0.15	0.016*	0.14(-0.03-0.32)	-0.08(-0.02-0.04)	0.22	0.021*

Legend: 6'WT: *Independent t-test

DISCUSSION

The findings of the present study evidence a tendency toward an immediate positive effect on temporal gait variables with the use of postural insoles in 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 spatiotemporal gait variables in children with CP.[11,12] Redekop, Andrysek and Wright (2008)[13] assessed computerized gait analysis with regard to functional level in 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 Damiano (1996)[11],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 increase in gait velocity and cadence when taken together. According to Morita et al. (1995),[14] enhanced gait efficiency is directly related to an increase in velocity and children with CP use an increase in cadence as their main strategy for increasing velocity. This observation may explain the findings of the present study, in which significant changes were only found with regard to cadence and velocity.

Greater spatiotemporal variables are found in healthy children in comparison to those with CP. According to Holt et al. (2000)[15] ,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, allowing children with CP to come 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 0.98m/s when using the postural insoles, allowing children with CP to nearly reach the reference value for velocity in healthy children described by Holt et al. (2000)[15] (0.99 m/s).

It should be stressed that the present study offers preliminary findings on the effects of postural insoles on gait in 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, 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 developing a study involving an adequate sample size, three-dimensional gait analysis and an assessment of function in children with CP.

CONCLUSION

Postural insoles proved effective for the treatment of children with cerebral palsy classified at GMFCS levels I and II, allowing these children to approach values considered references for the determination of improvements in gait performance.

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3.4 – Artigo 4

Pasini Neto H, Grecco LAC, Christovão TCL, Galli M, Oliveira CS. **Effect of postural insoles on gait performance in children with cerebral palsy: randomized controlled double-blind clinical trail. <u>Submetido à</u> Clinical Rehabilitation.**

EFFECT OF POSTURAL INSOLES ON GAIT PERFORMANCE IN CHILDREN WITH CEREBRAL PALSY: RANDOMIZED CONTROLLED DOUBLE-BLIND CLINICAL TRAIL

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ABSTRACT

Study design: Randomized, controlled, double-blind, clinical trial.

Background: 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.

Objective: The aim of the present study was to assess the effect of postural insoles on gait performance in children with CP classified on levels I and II of the Gross Motor Function Classification System (GMFCS).

Methods: After meeting legal requirements and the eligibility criteria, 24 children between four and 12 years of age were randomly allocated either the control group (n = 12) or experimental group (n = 12). The control group used placebo insoles and the experimental group used postural insoles. Three-dimensional gait analysis was performed under three conditions: barefoot, in shoes and in shoes with insoles. Three evaluations were carried out: 1) immediately following placement of the insoles; 2) after three months of insole use; and 3) one month after suspending insole use.

Results: Regarding the immediate effects of insole use, significant improvements in gait velocity and cadence were found in the experimental group, along with an increase in dorsiflexion, a reduction in knee flexion and a reduction in internal rotation.

Conclusion: The use of postural insoles led to improvements in gait performance in children with cerebral palsy classified on levels I and II of the GMFCS.

Key words: Cerebral palsy, gait, orthoses, postural insole

BACKGROUND

Different forms of therapy are employed to promote selective motor control and muscle coordination in children with cerebral palsy (CP).[1,2,3] According to Gage (2004),[4] the gait pattern in such children is a mixture of primary, secondary and tertiary abnormalities. Primary abnormalities consist of spasticity, the loss of selective control and balance disturbances, which are considered permanent abnormalities. Secondary abnormalities are related to biomechanical aspects that can be corrected or diminished through therapeutic, medicinal or surgical interventions. Tertiary abnormalities consist of compensations that disappear spontaneously when secondary abnormalities are corrected.

Children with CP exhibit functional limitations due to excessive muscle weakness, abnormal joint kinematics and abnormal postural reactions.[5] Three-dimensional gait analysis can be employed for the functional characterization of such children, allowing a detailed assessment of the kinetic and kinematic aspects of each phase of the gait cycle as well as an evaluation of the results of therapy. This analysis is performed with the use of video cameras that record light reflected from markers placed on bone prominences to capture the movement of different segments of the body during gait.[6,7]

Besides kinematic data, the analysis of spatial and temporal gait parameters is important to understanding how gait pattern variables are changed due to a clinical condition.[8] Gait speed, cadence, stride length and step length are important indicators of functional mobility and quality of life.

The use of an orthosis for improvements in gait performance is widely discussed in the literature. Different types of orthoses have different therapeutic indications. A rigid ankle-foot orthosis is the most often employed and maintains the ankle in a neutral position, thereby avoiding plantar flexion deformities. However, articulated ankle-foot orthoses have received a growing number of indications and allow dorsiflexion movement, which promotes stretching of the posterior musculature and a consequent reduction in spasticity in this muscle group.(9) In a systematic review on the influence of rigid and articulated orthoses, Pasini Neto et al. (2012)(10) report numerous benefits from the use of rigid orthoses. However, this type of orthosis is indicated for children with accentuated motor impairment, spasticity and contractures. On the other hand, articulated orthoses offer the benefits of stability and freedom during gait, thereby potentiating function in children with CP.

The aim of postural insoles is to reorganize the tonus of the muscle chains and influence body posture through correction reflexes. Such insoles affect muscle proprioception and lead to changes in ascending proprioceptive chains.(11) Postural reprogramming occurs when 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 insoles.(12) In a study involving the use of postural insoles by children with CP, 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 phase.(13)

The hypothesis guiding the present study was that postural insoles would generate a change in sensory afference, stimulating postural reactions and favoring gait performance. The aim of this study was to assess the effect of postural insoles on gait performance in children with CP through an analysis of velocity, cadence and kinematic variables during gait.

METHODS

A randomized, controlled, double-blind, clinical trial was conducted at the Universidade Nove de Julho (Sao Paulo, Brazil) following approval from the Human Research Ethics Committee of the institution under process number 436960 dated August 8, 2011, in compliance with Resolution 196/96 of the Brazilian National Board of Health. This study is registered with the Brazilian Registry of Clinical Trials (Registration Number: RBR6d342s - http://www.ensaiosclinicos.gov.br/news/). Parents/guardians signed a statement of informed consent agreeing to the participation of the children.

Twenty-four children were selected based on the eligibility criteria. The inclusion criteria were a diagnosis of CP spastic diplegia and classification on levels I and 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 affect the performance of the procedures; and ankle deformities non-reducible to neutral.

The sample size was calculated based on a study carried out by Buckon et al. (2004)[14] with results referring to gait cadence in children with CP (GMFCS I and II) with and without the use of a fixed ankle-foot orthosis. For an expected size effect of 17 steps per minute with a standard deviation of 15 steps per minute and assuming an α risk of 0.05 and 80% test power, a minimum of 12 children was determined for each group.

The participants were randomly allocated to two groups. The control group (CG) made use of an insole without corrective elements and the experimental group (EG) made use of an insole with corrective elements. Neither the children nor their guardians were aware of the group to which the participants were allocated, thereby characterizing a blind study for the placebo effect of the insole in the CG. 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 was to absorb sweat and provide comfort. The middle portion was made up of ethylene vinyl acetate measuring 3 mm in thickness. The lower portion was composed of material formed by a weave of cotton fibers and resin measuring 1 mm in thickness containing wedges and shims made of ethylene vinyl acetate.[11] Half-moon and anti-valgus elements were used in the present study (Figure 1).

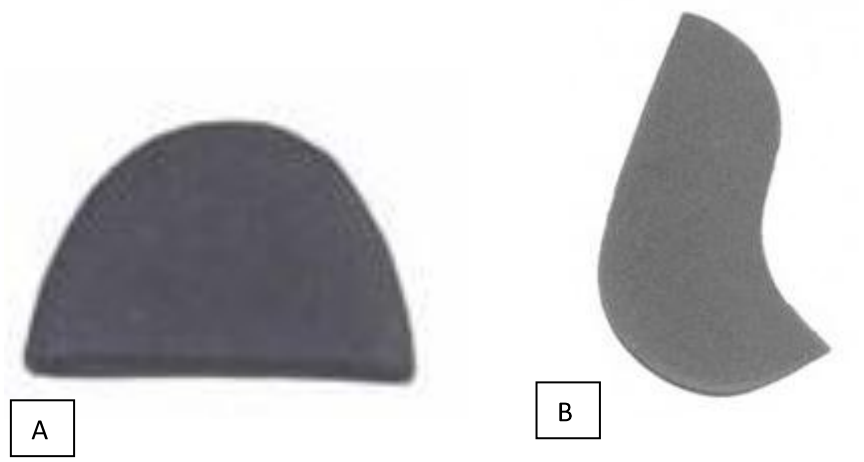


Figure 1 – Representation of elements used in postural insoles; A- half-moon; B- anti-valgus (Podaly®)

The CG used smooth insoles without corrective elements (Figure 2).

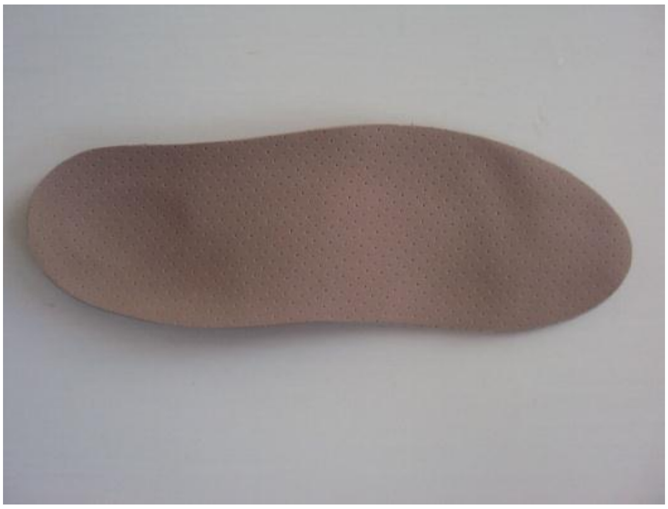


Figure 2 – Representation of placebo insole used in control group (Podaly®).

Following the positioning of the corrective elements, the postural insoles were submitted to thermal molding to fuse the different portions together (Figure 3).

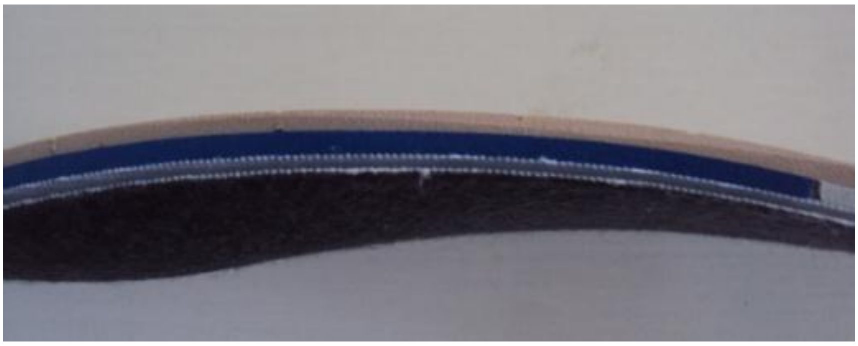


Figure 3 – Representation of three layers after thermal bonding (Podaly®).

Evaluations were carried out under three different conditions: barefoot, in shoes without insoles and in shoes with insoles. The children wore their habitual shoes under the latter two conditions. The order of the evaluations was randomly determined by lots to avoid standardization in the behavior of the sample. The children were first shown the equipment for the gait analysis and instructed with regard to the procedures to be carried out. A training session was then performed, simulating a regular gait exam, but without data collection. The children were instructed to walk normally on a track demarcated on the floor measuring four meters in length and 90 centimeters in width.

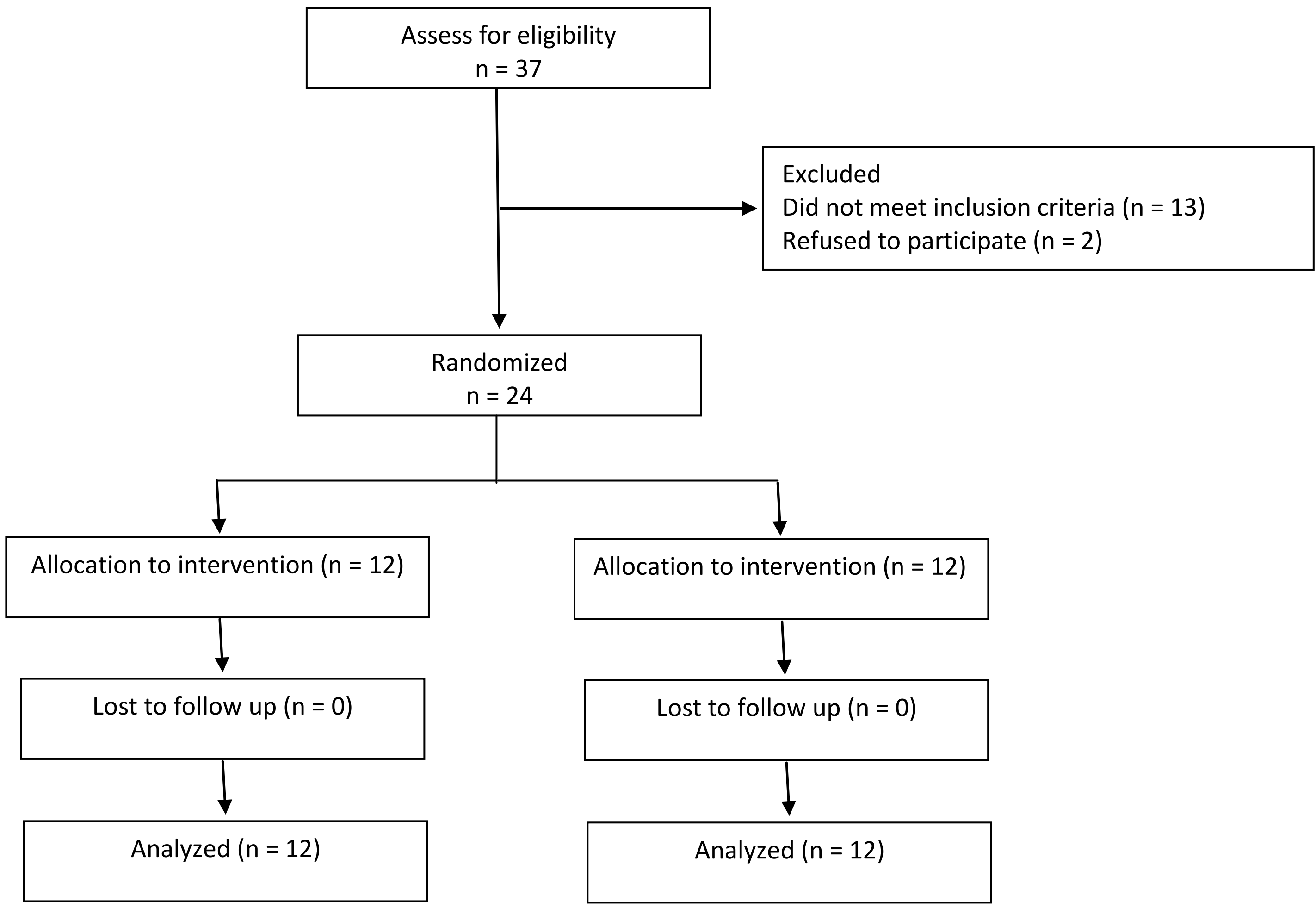
All children wore bathing suits to facilitate the placement of the markers. The markers were then placed on the children in the standing position, as suggested by Davis et al (1991).[15] The markers were enveloped in adhesive tape lined with microscopic glass spheres and attached to a plastic base with double-sided adhesive tape to favor visualization by the infrared cameras. The SMART-D 140® system (BTS Engineering) was used for the gait analysis, employing eight cameras sensitive to the infrared spectrum. The children were instructed to walk along the demarcated track six times for the data collection.

Evaluations were carried out on three separate occasions over a four-month period: Evaluation 1 – immediately following placement of the insoles; Evaluation 2 – after three months of insole use; and Evaluation 3 – one month after suspending insole use. The children were instructed to wear the insoles for six hours a day over a three-month period.

The data were first submitted to the Kolmogorov-Smirnov test to determine adherence to the Gaussian curve. As parametric distribution was demonstrated, the data were expressed as mean and standard deviation or 95% confidence interval. The effect size was calculated considering the mean differences among the results obtained with the participants barefoot, in shoes and in shoes with insoles. The independent t-test was used for the inter-group analysis. Repeated-measures 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 37 children recruited for the present study, eleven children did not meet the eligibility criteria and two refused to participate. Thus, the sample was made up of 24 children with CP, 12 of whom were randomly allocated to the CG and 12 were randomly allocated to the EG (Figure 4).



No statistically significant differences between groups were found regarding anthropometric data (Table 1).

Table 1: displays the anthropometric characteristics of the sample.

Anthropometric data			
	Age (years)	Height (cm)	Body mass (kg)
Mean	7	127	21
Standard deviation	4,3	32	5,7

Table 1: Mean ± standard deviation of anthropometric data of participants

In the intra-group analysis of the CG, no statistically significant differences in temporal gait variables were found under the different test conditions (barefoot, in shoes without insoles and in shoes insoles) (Table 2).

Table 2: Gait variables in control group when barefoot, wearing shoes without insoles and wearing shoes with placebo insoles at Evaluation 1 (immediately following insole placement), Evaluation 2 (after 3 months of insole use) and Evaluation 3 (1 month after suspending insole use).

	Evaluation 1			Evaluation 2			Evaluation 3	
	Barefoot	Shoes	Insole	Barefoot	Shoes	Insole	Barefoot	Shoes
Support phase (%)	56.32(2.34)	48.68(11.29)	51.44(5.35)	55.32(2.34)	48.68(11.29)	51.44(5.35)	54.21(2.34)	48.68(11.29)
Swing phase (%)	40.08(2.71)	41.98(4.35)	43.17(6.74)	42.08(3.73)	41.98(4.35)	43.17(6.74)	41.18(3.25)	41.98(4.35)
Double support phase(%)	6.28(1.69)	6.41(1.60)	20.03(28.69)	7.13(1.69)	6.41(1.60)	20.03(28.69)	7.03(1.69)	6.41(1.60)
Step time (s)	0.96(0.18)	1.06(0.23)	0.98(0.17)	0.98(0.21)	1.06(0.23)	0.98(0.17)	0.96(0.18)	1.06(0.23)
Cadence(step/min)	111.08(20.74)	99.98(27.48)	99.20(25.91)	112.13(20.74)	99.98(27.48)	99.20(25.91)	114.08(21.05)	99.98(27.48)
Step length (m)	0.33(0.06)	0.33(0.09)	0.35(0.05)	0.31(0.06)	0.36 (0.06)	0.36(0.09)	0.33(0.02)	0.33(1,23)
Stride length (m)	0.75(0.15)	0.71(0.12)	0.71(0.13)	0.76(0.23)	0.72(0.12)	0.74(0.13)	0.75(0.32)	0.76(0.12)
Velocity (m/s)	0.81(0.17)	0.82(0.09)	0.84(0.17)	0.81(0.25)	0.81(0.19)	0.83(0.59)	0.81(0.18)	0.82(0.09)

Legend: *p ≤ 0.05 (intra-group analysis – repeated-measure ANOVA); # p ≤ 0.05 (inter-group analysis – independent t-test)

In the EG, significant increases in cadence (p = 0.05) and velocity (p = 0.04) were found with the use of postural insoles on Evaluations 1 and 2 in comparison to the other test conditions (barefoot and shoes without insoles) as well as in comparison to the CG (Table 3).

Table 3: Gait variables in experimental group when barefoot, wearing shoes without insoles and wearing shoes with postural insoles at Evaluation 1 (immediately following insole placement), Evaluation 2 (after 3 months of insole use) and Evaluation 3 (1 month after suspending insole use).

	Evaluation 1			Evaluation 2			Evaluation 3	
	Barefoot	Shoes	Insole	Barefoot	Shoes	Insole	Barefoot	Shoes
Support phase (%)	55.34(5.46)	46.08(9.68)	53.89(4.87)	53.32(5.46)	46.08(9.68)	54.69(4.87)	56.27(5.46)	46.08(9.68)
Swing phase (%)	41.66(3.05)	37.67(9.19)	40.07(2.11)	42.76(3,21)	37.67(9.19)	41.17(2.11)	41.66(5.09)	37.67(9.19)
Double support phase(%)	5.16(1.65)	6.76(9.19)	10.92(4.78)	6.16(1.73)	6.76(9.19)	11.03(4.78)	7.67(1.65)	6.76(9.19)
Step time (s)	0.83(0.12)	0.91(0.17)	0.90(0.20)	0.83(0.22)	0.91(0.17)	0.89(0.17)	0.83(0.12)	0.91(0.17)
Cadence(step/min)	111.58(18.76)	87.76(25.16)	124.90(7.04)*#	113.31(18.43)	87.81(24.10)	125.32(6.32)#	113.58(18.76)	87.76(25.16)
Step length (m)	0.34(0.10)	0.34(0.14)	0.32(0.91)	0.32(0.10)	0.34(0.14)	0.32(0.91)	0.34(0.10)	0.34(0.18)
Stride length (m)	0.78(0.21)	0.67(0.19)	0.79(0.19)	0.77(0.21)	0.67(0.25)	0.79(0.19)	0.77(0.21)	0.63(0.22)
Velocity (m/s)	0.89(0.10)	0.83(0.13)	0.98(0.13)*#	0.90(0.14)	0.81(0.23)	1.21(0.11)*#	0,92(0.10)	0.83(0.17)

Legend: *p ≤ 0.05 (intra-group analysis – repeated-measure ANOVA); # p ≤ 0.05 (inter-group analysis – independent t-test)

In the CG, no significant differences were found regarding kinematic variables under the different test conditions or among the different evaluation times (p > 0.05) (Table 4).

Table 4: Kinematic variables in control group when barefoot, wearing shoes without insoles and wearing shoes with placebo insoles at Evaluation 1 (immediately following insole placement), Evaluation 2 (after 3 months of insole use) and Evaluation 3 (1 month after suspending insole use).

	Evaluation 1			Evaluation 2			Evaluation 3	
	Barefoot	Shoes	Insoles	Barefoot	Shoes	Insoles	Barefoot	Shoes
Right ankle	14.1(4.6)#	17.7(7.1)	17.7(7.2)	14.8(5.2)	17.0(6.8)	17.7(7.2)	14.8(4.7)	17.7(7.2)
Left ankle	10.8(5.1)#	15.3(9.6	15.5(8.4)	10.5(5.1)	15.5(8.4)	16.7(8.0)	10.8(5.1)	15.5(8.4)
Right knee	62.8(12.7)	59.7(8.6)	62.2(8.4)	59.8(11.8)	61.9(7.9)	62.2(8.4)	59.8(11.8)	62.2(8.4)
Left knee	58.4(10.1)	61.0(7.8)	62.8(7.7)	52.6(14.1)	57.9(7.7)	44.8(8.1)	52.6(14.1)	62.8(7.7)
Right hip	42.5(11.1)	43.5(10.4)	43.8(11.6)	43.8(11.2)	43.4(11.8)	43.5(11.6)	43.8(11.2)	43.8(11.6)
Left hip	41.2(8.0)	44.3(7.8)	44.8(8.1)	42.4(9.0)	44.8(8.1)	38.2(7.2)	42.4(9.0)	44.8(8.1)
Right external rotation	20.0(10.0)	22.2(8.8)	21.4(9.5)	17.1(12.8)	21.8(10.1)	21.4(9.5)	17.1(12.8)	21.4(9.5)
Left external rotation	21.7(9.8)#	26.5(3.6)	26.3(3.6)	19.1(9.4)#	26.3(3.6)	23.5(5.0)	19.1(9.4)	26.3(3.6)

Legend: # Significant difference between “barefoot” and “shoes” conditions at Evaluation 1 ($p < 0.05$)

Furthermore, in the EG it is noted that the evaluation 2 was a significant increase range of motion in dorsiflexion of the ankle joint (p = 0.05), a decreased range of motion of knee flexion (right and left p = 0:03 p = 0:05) and a decrease in hip internal rotation (right and left p = 0:04 p = 0.01), the condition of your use of shoes with postural insole when compared to the other two conditions (barefoot and without insoles) (Table 5).

Table 5: Kinematic variables in experimental group when barefoot, wearing shoes without insoles and wearing shoes with postural insoles at Evaluation 1 (immediately following insole placement), Evaluation 2 (after 3 months of insole use) and Evaluation 3 (1 month after suspending insole use).

	Evaluation 1			Evaluation 2			Evaluation 3	
	Barefoot	Shoe	Insole	Barefoot	Shoe	Insole	Barefoot	Shoe
Right ankle	14,8(5,2)	17,7(7,2)	19,4(8,7)	13,6(6,5)	17,2(6,0)	21,7(6,9)#	14,4(4,4)	15,4(8,5)
Left ankle	19,1(9,4)	17,5(8,4)	19,2(5,1)	14,7(13,3)	18,5(10,5)	20,4(4,7)#	16,9(10,5)	13,8(9,3)
Right knee	59,8(11,8)	62,2(8,4)	56,0(10,6)	52,4(20,5)	56,1(13,7)	41,7(6,9)*#	51,6(15,3)	60,1(17,2)
Left knee	57,6(14,1)	62,8(7,7)	52,2(14,9)	57,6(11,9)	56,9(15,2)	42,6(18,2)*#	52,8(19,9)	59,5(13,9)
Right hip	43,8(11,2)	43,8(11,6)	44,3(10,7)	42,2(12,4)	38,3(10,2)	41,3(13,0)	40,5(11,0)	42,5(16,2)
Left hip	42,4(9,0)	44,6(8,1)	45,5(10,8)	46,0(9,8)	41,4(8,1)	45,8(14,3)	43,4(9,8)	44,8(9,6)
Right internal rotation	23,2(6,3)	21,4(9,5)	17,4(12,8)#	18,4(11,3)	20,0(8,6)	12,9(3,6)*#	17,4(12,5)	12,9(10,4)
Left internal rotation	19,1(9,4)	18,3(9,6)	17,3(7,6)#	16,7(13,3)	17,3(7,6)	13,5(6,8)*#	16,9(10,5)	18,6(10,1)

Legend: *Significant difference with insoles between Evaluations 1 and 2 ($p < 0.05$); # Significant difference from other test conditions (barefoot and shoes) ($p < 0.05$)

It is worth noting that there was a significant difference between the amplitude of motion of knee flexion ($p = 0.5$) and decreased hip external rotation ($p = 0.5$) in the condition of your use of insoles on postural different evaluation, and evaluation 2 the results were significantly lower than in the first assessment (Table 5).

DISCUSSION

In the present study, children with CP demonstrated improvements in gait velocity and cadence as well as the kinematics of the hips, knees and ankles with the use of postural insoles in comparison to walking barefoot, walking in shoes without insoles or wearing a placebo insole without corrective elements.

Redekop et al. (2008)[16] assessed the use of computerized gait analysis for children with CP (functional level based on GMFCS) and found adequate to excellent reliability for temporal, spatial and kinematic variables of the pelvis, hip, knee and ankle. A number of authors have demonstrated the importance of analyzing spatiotemporal gait variables in children with CP.[17] While Patterson et al. (2008)[18] state that the measurement of speed and other spatiotemporal variables is often used to evaluate gait function, an increase in walking speed alone does not improve the gait pattern.

According to Abel and Damiano (1996),[17] 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 a significant increase in gait velocity and cadence when taken together. According to Morita et al. (1995),[19] enhanced gait efficiency is directly related to an increase in velocity and children with CP use an increase in cadence as their main strategy for increasing velocity. This observation may explain the findings of the present study, in which significant changes were only found with regard to cadence and velocity.

Spatiotemporal values in healthy children are larger than those found in children with CP. According to Holt et al. (2000),[20] healthy four-year-olds have mean cadence and velocity of 152 steps/min and 0.99 m/s, respectively. In the present study, mean cadence among children with CP when barefoot and wearing shoes without insoles was 111 and 87 steps/min, respectively, and immediately increased to 124 steps/min when using postural insoles, which is 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 postural insoles, nearly reaching the reference value for velocity in healthy children described by Holt et al. (2000).[20]

Although a positive association has been reported between velocity and both range of motion and muscle strength, a kinematic evaluation is needed to determine the degree of gait impairment among children with CP classified on levels I and II of the GMFCS. The analysis of variables that describe movement, such as angular displacement, allows comparisons with normative data as well as the determination of an absence or excess of movement.[21,22] The kinematic analysis of gait in children with CP allows the determination of the angular differences stemming from biomechanical abnormalities that lead to different gait patterns.[23,24,25] According to Sutherland (1993),[23] the most important abnormalities in children with CP occur on the sagittal plane, as the movements of flexion and extension have the greatest range of motion. Winters et al. (1987)[26] report that children with CP exhibit an increase in knee flexion during gait, especially during the stance phase, and that a reduction in knee flexion closer to normative reference values indicates an improvement in gait performance.

In the present study, a significant increase in dorsiflexion, reduction in knee flexion and reduction in internal rotation were found with the use of postural insoles. These results differ from findings reported in previous studies involving more functional orthoses, such as an articulated ankle-foot orthosis,[27,28,29,30,31,32,33] indicating that postural insoles may exert a greater influence on gait.

According to Elis et al. (2002),[34] proprioceptive information from mechanoreceptors of the plantar region allow the planning of motor functions and these receptors can be considered the first sensory input, along with muscles, tendons, ligaments and joint capsules. According to Nurse et al. (1998),[35] the sensitivity of the plantar surface of the foot plays an important function in the selection of both local and distant dynamic responses, respectively evident in the present study by the increase in dorsiflexion and reduction in internal rotation during gait with the use of postural insoles.

In a study evaluating the effect of bandage taping of the plantar surface on postural stability in a sample of older adults, Perry et al. (2001)[36] found an increase in efferent information to the central nervous system and improved balance in the standing position and attributed this finding to improve biomechanics due to the new proprioceptive afference.

The present findings are in agreement with data described in previous studies, which report an increase in dorsiflexion using orthoses that provide better mobility and stability to the ankle.[27,29,30,32,33]

CONCLUSION

Postural insoles proved effective for the treatment of children with cerebral palsy classified at GMFCS levels I and II, allowing these children to approach normative reference values for temporal (velocity and cadence) and kinematic (dorsiflexion, knee flexion and internal rotation) variables.

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4.0) DISCUSSÃO

Os resultados observados nos estudos apresentados acima demonstraram a importância de associar a estabilidade de uma órtese com a liberdade funcional dessa.

No estudo de revisão sistemática observou-se que as órteses articuladas favorecem a função da marcha permitindo uma movimentação livres das articulações diretamente relacionadas a essa, evidenciados pelo incremento na performance da marcha.

Esses resultados corroboraram com os achados nos outros estudos relacionados ao efeito imediato e tardio (após 3 meses) do uso das palmilhas posturais durante a marcha. Esses estudos apresentados anteriormente demonstraram que as palmilhas posturais atuaram de forma positiva no incremento dos parâmetros temporais e cinemáticos da marcha, aproximando esses valores dos considerados como valores de referência.

Segundo Cury et al. (2006) as órteses estão inseridas na rotina diária das crianças portadoras de paralisia cerebral e que os benefícios desses dispositivos foram observados, principalmente, na locomoção em ambientes externos. Ainda, segundo o autor, as órteses favorecem significativamente a qualidade da marcha de crianças com paralisia cerebral independente do diagnóstico topográfico da lesão.

Romkes et al (2006), em um trabalho com 10 crianças hemiplégicas observaram que ocorreu mudança em todos os parâmetros da marcha durante o uso das órteses articuladas se comparado com órteses fixas, concluído que esse tipo de órtese oferece a criança uma marcha mais funcional.

Em outros estudos, que comparavam a órtese fixa e articulada em locomoção sobre escadas, destacou aumento significativo na qualidade dos parâmetros da marcha, bem como, nos aspectos cinemáticos e cinéticos das articulações do membro inferior durante a utilização das órteses articuladas (WILSON, 1997). Ainda nesse aspecto, os autores relataram que as órteses articuladas ofereceram melhor transição da posição sentada para a posição em pé.

Segundo Radtka et al. (2005), o uso da órtese articulada melhora a dorsiflexão evidenciada principalmente na fase final do apoio, quando compara com a órtese fixa, e isso é um importante benefício clínico para a indicação desse tipo de órtese pois permite uma marcha mais funcional (CARMICK, 1995).

Esses resultados corroboram com os achados de Middleton et al. (1998) que em um estudo de caso concluíram que a órtese articulada oferece uma marcha mais natural e mais simétrica nos movimento dos membros inferiores, podendo ser um importante recurso na prevenção de deformidades em flexão plantar (RADTKA et al., 2005).

Com objetivos semelhantes, as palmilhas posturais buscam reorganizar o tônus das cadeias musculares e influenciar na postura corporal através de reflexos de correção. Estas agem na propriocepção muscular e levam as modificações nas cadeias proprioceptivas ascendentes, ou seja, o ganho de estabilidade é garantido de forma proprioceptiva (GAGEY, 2000).

Moraes e Przynsiezny (2004) relataram que as informações cutâneas aferentes vindas do pé, informam ao sistema nervoso central sobre a posição do corpo e induzem uma resposta postural adaptativa, por meio da normalização do tônus. Ainda nessa linha, Silva (2006) afirmou a aplicação de peças podais sob a pele e músculos plantares desencadeiam respostas nas cadeias musculares e corrigem variáveis posturais através da normalização do tônus postural por ativação de receptores sensitivos musculares, articulares e cutâneos.

As palmilhas, segundo Bricot (1999) proporcionam correções efetivas por estimular e produzir reflexos de correção através de seus elementos podais, agindo assim na propriocepção muscular do pé levando a modificações na ativação de cadeias musculares ascendentes.

Nesse sentido, evidências teóricas associadas a resultados observados nos estudos apresentados, as palmilhas posturais demonstram oferecer uma estabilidade proprioceptiva com efeitos semelhantes aos da utilização de uma órtese articulada porém com maior liberdade funcional.

5.0) CONCLUSÃO

As palmilhas posturais oferecem um incremento na performance da marcha evidenciada pela melhora dos parâmetros temporais e cinemáticos dessa.

Além disso, conclui-se que as órteses que oferecem a estabilidade de forma mecânica, no caso das órteses articuladas, e proprioceptiva, no caso das palmilhas posturais, associadas a uma maior liberdade funcional, favorecem a realização da função da marcha.

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Anexo 1

SISTEMA DE CLASSIFICAÇÃO DA FUNÇÃO MOTORA GROSSA PARA PARALISIA CEREBRAL (GMFCS)

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Referência: Dev Med Child Neurol 1997; 39:214-223

Antes do aniversário de 2 anos

Nível I Os bebês sentam-se no chão, mantêm-se sentadas e deixam esta posição com ambas as mãos livres para manipular objetos. Os bebês engatinham (sobre as mãos e joelhos), puxam-se para levantar e dão passos segurando-se nos móveis. Os bebês andam entre 18 meses e 2 anos de idade sem a necessidade de aparelhos para auxiliar a locomoção.

Nível II Os bebês mantêm-se sentados no chão, mas podem necessitar de ambas as mãos como apoio para manter o equilíbrio. Os bebês rastejam em prono ou engatinham 3 (sobre mãos e joelhos). Os bebês podem puxar-se para ficar em pé e dar passos segurando-se nos móveis.

Nível III Os bebês mantêm-se sentados no chão quando há apoio na parte inferior do tronco. Os bebês rolam e rastejam para frente em prono.

Nível IV Os bebês apresentam controle de cabeça, mas necessitam de apoio de tronco para se sentarem no chão. Os bebês conseguem rolar para a posição supino e podem rolar para a posição prono.

Nível V As deficiências físicas restringem o controle voluntário do movimento. Os bebês são incapazes de manter posturas antigravitacionais de cabeça e tronco em prono e sentados. Os bebês necessitam da assistência do adulto para rolar.

Entre o segundo e o quarto aniversário

Nível I As crianças sentam-se no chão com ambas as mãos livres para manipular objetos. Os movimentos de sentar e levantar-se do chão são realizadas sem assistência do adulto. As crianças andam como forma preferida de locomoção, sem a necessidade de qualquer aparelho auxiliar de locomoção.
Nível II As crianças sentam-se no chão, mas podem ter dificuldades de equilíbrio quando ambas as mãos estão livres para manipular objetos. Os movimentos de sentar e deixar a posição sentada são realizados sem assistência do adulto. As crianças puxam-se para ficar em pé em uma superfície estável. As crianças engatinham (sobre mãos e joelhos) com padrão alternado, andam de lado segurando-se nos móveis e andam usando aparelhos para auxiliar a locomoção como forma preferida de locomoção.
Nível III As crianças mantêm-se sentadas no chão freqüentemente na posição de W (sentar entre os quadris e os joelhos em flexão e rotação interna) e podem necessitar de assistência do adulto para assumir a posição sentada. As crianças rastejam em prono ou engatinham (sobre as mãos e joelhos), freqüentemente sem movimentos alternados de perna, como seus métodos principais de locomoção. As crianças podem puxar-se para levantar em uma superfície estável e andar de lado segurando-se nos móveis por 4 distâncias curtas. As crianças podem andar curtas distâncias nos espaços internos usando aparelhos auxiliares de locomoção, necessitando de assistência do adulto para direcioná-la e virá-la.
Nível IV As crianças sentam-se no chão quando colocadas, mas são incapazes de manter alinhamento e equilíbrio sem o uso de suas mãos para apoio. As crianças freqüentemente necessitam de equipamento de adaptação para sentar e ficar em pé. A locomoção para curtas distâncias (dentro de uma sala) é alcançada por meio do rolar, rastejar em prono ou engatinhar (sobre as mãos e joelhos) sem movimento alternado de
pernas.
Nível V As deficiências físicas restringem o controle voluntário do movimento e a capacidade de manter posturas antigravitacionais de cabeça e tronco. Todas as áreas de função motora estão limitadas. As limitações funcionais do sentar e ficar em pé não são completamente compensadas por meio do uso de adaptações e de tecnologia assistiva. Neste nível, as crianças não mostram

sinais de locomoção independente e são transportadas. Algumas crianças atingem autolocomoção usando uma cadeira de rodas
motorizada com extensas adaptações.

Entre o quarto e o sexto aniversário

Nível I As crianças sentam-se na cadeira, mantêm-se sentadas e levantam-se sem a necessidade de apoio das mãos. As crianças saem do chão e da cadeira para a posição em pé sem a necessidade de objetos de apoio. As crianças andam nos espaços internos e externos e sobem escadas. Iniciam habilidades de correr e pular.

Nível II As crianças sentam-se na cadeira com ambas as mãos livres para manipular objetos. As crianças saem do chão e da cadeira para a posição em pé, mas freqüentemente necessitam de superfície estável para empurrar-se e impulsionar-se para cima com os membros superiores. As crianças andam nos espaços internos e externos, sem a necessidade de aparelhos auxiliares de locomoção, por uma distância curta numa superfície plana. As crianças sobem escadas segurando-se no corrimão, mas são incapazes de correr ou pular.

Nível III As crianças sentam-se em cadeira comum, mas podem necessitar de apoio pélvico e de tronco para maximizar a função manual. As crianças sentam-se e levantam se da cadeira usando uma superfície estável para empurrar-se e impulsionar-se para cima com os membros superiores. As crianças andam usando aparelhos auxiliares de locomoção em superfícies planas e sobem escadas com a assistência de um adulto. As crianças freqüentemente são transportadas quando percorrem longas distâncias e quando em espaços externos em terrenos irregulares.

Nível IV As crianças sentam em uma cadeira, mas precisam de um assento adaptado para controle de tronco e para maximizar a função manual. As crianças sentam-se e levantam-se da cadeira com a ajuda de um adulto ou de uma superfície estável para empurrar-se ou impulsionar-se com os membros superiores. As crianças podem, na melhor das hipóteses, andar por curtas distâncias com o andador e com supervisão do adulto, mas têm dificuldades em virar e manter o equilíbrio em superfícies irregulares. As crianças são transportadas na comunidade. As crianças podem alcançar autolocomoção usando cadeira de rodas motorizada.

Nível V As deficiências físicas restringem o controle voluntário de movimento e a capacidade em manter posturas antigravitacionais de cabeça e tronco. Todas as áreas da função motora estão limitadas. As limitações funcionais no sentar e ficar em pé não são completamente compensadas por meio do uso de adaptações e tecnologia assistiva. Neste nível, as crianças não mostram sinais de locomoção independente e são transportadas. Algumas crianças alcançam autolocomoção usando cadeira de rodas
motorizada com extensas adaptações.

Entre o sexto e o décimo segundo aniversário

Nível I As crianças andam nos espaços internos e externos e sobem escadas sem limitações. As crianças realizam habilidades motoras grossas, incluindo correr e pular, mas a velocidade, o equilíbrio e a coordenação são reduzidos.

Nível II As crianças andam nos espaços internos e externos e sobem escadas segurandose no corrimão, mas apresentam limitações ao andar em superfícies irregulares e inclinadas e em espaços lotados ou restritos. As crianças, na melhor das hipóteses, apresentam capacidade mínima para realizar habilidades motoras grossas como correr e pular.

Nível III As crianças andam em espaços internos e externos sobre superfícies regulares usando aparelhos auxiliares de locomoção. As crianças podem subir escadas segurando se em corrimões. Dependendo da função dos membros superiores, as crianças manejam uma cadeira de rodas manualmente. Podem ainda ser transportadas quando percorrem longas distâncias e quando em espaços externos com terrenos irregulares.

Nível IV As crianças podem manter os níveis funcionais alcançados antes dos seis anos de idade ou depender de cadeira de rodas em casa, na escola e na comunidade. As crianças podem alcançar autolocomoção usando cadeira de rodas motorizada. Nível V As deficiências físicas restringem o controle voluntário de movimento e a capacidade para manter posturas antigravitacionais de cabeça e tronco. Todas as áreas de função motora estão limitadas. As limitações funcionais no sentar e ficar em pé não são completamente compensadas por meio do uso de adaptações e tecnologia assistiva. Neste nível, as crianças não mostram sinais de locomoção independente e são transportadas. Algumas crianças alcançam a autolocomoção usando cadeira de rodas motorizada com extensas adaptações.

Apêndice 1

APROVAÇÃO DO COMITE DE ÉTICA E PESQUISA

UNINOVE
Universidade Nove de Julho

COMITÊ DE ÉTICA EM PESQUISA - CoEP

Certificamos que o Projeto de pesquisa intitulado Influência da palmilha postural na funcionalidade de crianças com paralisia cerebral: estudo clínico randomizado controlado sob número de protocolo 436960 e responsabilidade de **Hugo Pasini Neto** de acordo com a resolução 196/96 do Conselho Nacional de Saúde M/S, de 10/10/96, tendo sido aprovado pelo Comitê de Ética em Pesquisa - UNINOVE.

São Paulo, 22 de Agosto de 2011.

Profa. Dra. Claudia Santos Oliveira
Presidente do Comitê de Ética em Pesquisa