# RESULTS OF ORTHOSES USED ON AMBULATORY PATIENTS WITH BILATERAL CEREBRAL PALSY

RESULTADOS DO USO DE ÓRTESES EM PACIENTES DEAMBULADORES COM PARALISIA CEREBRAL

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## ABSTRACT

Objective: To investigate the impact of ankle-foot orthoses (AFO) on subjects diagnosed with bilateral cerebral palsy (CP) using the gait index and temporal data parameters. Methods: Twenty-four subjects, 14 male and 10 female, with a mean age of 11 (5-17 years old), underwent a comprehensive gait analysis under both barefoot (BF) and braced walking conditions. All children had been wearing the orthoses for at least 2 months before the gait analysis. Results: The overall values for the left and right Gait Profile Scores (GPS) did not show statistically significant variations when comparing the same individuals with and without orthoses. Gait velocity increased by 19.5% (p < 0.001), while the cadence decreased by 4% with use of orthosis, although it was not statistically significant (p > 0.05). The stride and the step lengths on both the right and left sides, however, resulted in statistically significant increases, when wearing AFO. Conclusion: AFO, prescribed for assistance by professionals without using gait data. did not significantly affect the gait index (GPS), but improved temporal data. The determination of quantitative clinical parameters for the prescription of orthotics in patients with bilateral CP, as well as orthotics that meet the specific requirements are points to be addressed in the future to obtain more significant effects. Level of evidence III, Case control study.

#### RESUMO

Objetivo: Investigar o impacto das órteses suropodálicas (AFOs) utilizando índices da análise computadorizada da marcha (ACM) e dados de tempo e espaço, em indivíduos com diagnóstico de paralisia cerebral (PC) bilateral. Métodos: 24 indivíduos, 14 do sexo masculino e 10 do sexo feminino, com média de idade de 11 anos (5-17 anos), foram submetidos a uma análise da marcha, tanto na condição de andar descalço (AD) quanto com uso das órteses. Todas as crianças usavam as órteses há no mínimo 2 meses antes da ACM. Resultados: Os valores do perfil global da marcha (GPS) dos lados direito e esquerdo não apresentaram variações estatisticamente significativas guando os mesmos indivíduos foram comparados, com e sem órteses. Com o uso de órtese a velocidade da marcha aumentou 19,5% (p < 0,001), enquanto a cadência diminuiu 4%, embora não tenha sido estatisticamente significativa (p > 0.05). No entanto, com o uso da órtese, a passada e o comprimento do passo dos lados direito e esquerdo tiveram aumentos estatisticamente significativos. Conclusão: As AFOs, guando prescritas por profissionais sem o uso de dados da ACM, não alteraram significativamente o índice da marcha (GPS), mas melhoraram os dados de tempo e espaço. A determinação de parâmetros clínicos quantitativos para a prescrição de órteses em pacientes com PC bilateral, bem como órteses que atendam a requisitos específicos, são pontos a serem abordados no futuro, a fim de obter efeitos mais significativos. Nível de evidência III, Estudo de caso e controle.

Keywords: Cerebral Palsy. Foot Orthoses. Gait.

Descritores: Paralisia Cerebral. Órteses do Pé. Marcha.

**Citation:** Melanda AG, Pauleto AC, lucksch DD, Cunha RFM, Smaili S. Results of orthoses used on ambulatory patients with bilateral cerebral palsy. Acta Ortop Bras. [online]. 2020;24(1):137-41. Available from URL: http://www.scielo.br/aob.

### INTRODUCTION

Cerebral Palsy (CP) is the most common cause of physical disability affecting children in developed countries, with an incidence rate between 2.0 and 3.5 per every 1,000 live births,<sup>1-3</sup> while in developing countries this index may reach 7 for every 1,000.<sup>4</sup> The explanation for the difference between these two groups of countries is attributed

to poor conditions of antenatal care and primary care for pregnant women. Functionally, approximately 60% of patients with CP can walk independently, approximately 10% use a mobility device, and approximately 30% have limited or no walking ability.<sup>5</sup>

Efficient walking is an important treatment goal for children with CP.<sup>6</sup> Orthotic management is a significant and useful treatment

### All authors declare no potential conflict of interest related to this article.

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Article received on 09/18/2019, approved on 11/07/2019.



option for a number of conditions that affect gait and posture, and usually forms part of an overall rehabilitation program established for patients with CP. $^{6}$ 

Orthoses are commonly prescribed to address both structural and functional deficiencies.<sup>7</sup> Eighty-five percent of children with CP have had at least one orthotic device.<sup>8</sup> The most commonly used lower-limb orthoses in CP are AFO that provide direct control of the ankle and foot to improve gait.<sup>9</sup> Orthoses influence the ankle and foot by providing a control moment opposing ankle motion, and also stabilize the motions of the mid and forefoot joints.<sup>10</sup>

In children with CP, the aim of orthotic management in the form of ankle-foot orthoses (AFO) is to produce a more natural gait pattern. AFO may be used to protect the outcome of a surgical procedure during the healing and rehabilitation phases, to prevent the development or worsening of musculoskeletal deformities with growth and to improve gait.<sup>11</sup>

The prescription of rehabilitation treatments and recommendation of orthoses is generally performed after a clinical evaluation. The use of three-dimensional gait analysis (3DGA) contributes to defining strategies for the treatment of patients with cerebral palsy.<sup>12-14</sup> However, even with the assistance of gait analysis, the degree to which a patient's gait improves after an intervention remains difficult to assess. Considering not only how each feature of the gait pattern has changed, but also how the relationship between the features changed is important to accurately assess the changes in gait resulting from a specific treatment.<sup>15</sup> For such, the gait profile score (GPS) will be used, in order to produce an overview of the gait.<sup>16</sup> The gait index summarizes the kinematic data, helping the clinician to understand the general changes in gait pathology after a specific treatment.<sup>17</sup> Our study seeks to verify the outcome of the use of orthoses by patients with cerebral palsy that were prescribed through clinical criteria due to the unavailability of gait laboratories in most cities around the world. We must question if we are really improving the gait of patients with cerebral palsy by prescribing orthoses without using 3DGA. It was hypothesized that gait index and spatial-temporal data parameters could improve with the use of orthoses.

### **METHODS**

This retrospective cross-sectional study was conducted using the database of the gait laboratory at the Rehabilitation Center of Paraná in Curitiba, Paraná, Brazil. All participants and parents/guardians signed an informed consent form before the study. The approval of the local research ethics committee (number: 2.447.001) to conduct the study had been previously obtained. A search was conducted for all children with spastic CP who had underwent 3DGA, both barefoot (BF) and for those who were using orthoses during a single visit to the gait analysis laboratory between 2011 and 2017.

# Participants

The inclusion criteria were: children with a clinical diagnosis of spastic CP, with bilateral involvement of the lower limbs, using rigid or articulated AFO (the same design worn bilaterally), who had undergone 3DGA with and without orthoses.

Previous treatments such as single event multilevel surgery or botulinum toxin type A injections were allowed, as well as the use of walkers and crutches. All children had been wearing the orthoses for at least 2 months before the gait analysis. The walking motion trials were conducted on those wearing orthoses during the same visit as the barefoot trials.

#### Measurements

The Gross Motor Classification System (GMFCS) and Functional Mobility Scale (FMS) were assigned by a senior clinical physical therapist and a pediatric orthopedist in appointment with the child and their parents.<sup>18,19</sup>

The kinematic data was collected using reflective markers strategically placed on specific anatomical points on the participants, as described by Kadaba et al.,<sup>20</sup> and recommended by the software user's manual (Cortex Version 1.1.4.368 – User's Manual; Motion Analysis Corporation, Santa Rosa, CA, USA). Three-dimensional kinematic gait data was collected bilaterally using 6 infrared cameras and a motion capture system (infrared digital Hawk; Motion Analysis Corporation, Santa Rosa, CA) sampling at 60 Hz.

Three-dimensional gait kinematics data was used to estimate the GPS and temporal data was used to quantify the overall deviation of an individual's gait from normal gait.

GPS represents the root mean square (RMS) difference between particular gait trials and averaged data from people with no gait pathology. The overall GPS is based upon 15 clinically important kinematic variables including, gait variable score (GVS): Pelvic Tilt (Ant/Post), Pelvic Obliquity (Up/Dn) and the rotation of the left side and hip flexion, abduction, internal rotation, knee flexion, ankle dorsiflexion and foot progression for the left and right sides, as shown in Table 2. In this analysis, a GPS score for each side was used based on all nine GVS for each side. As the GPS uses all the gait features representing the root mean square difference between the patient's data and the average from the reference dataset obtained from all of the relevant kinematic variables for the entire gait cycle, the higher the GPS value the less physiological the gait pattern.<sup>21</sup>

Temporal data, GPS and GVS were used to quantify the changes of the gait with and without orthoses.

Three different analyses were conducted. First, all 24 participants were analyzed while walking barefoot using orthoses. Second, the participants were divided according to the use of rigid or articulate orthoses. Third, they were divided by functional status (GMFCS), classified into levels I, II, III and IV.

### Statistical analysis

Data was presented as median and interquartile range, according to the Shapiro-Wilk test for normality. For intragroup analyses (with or without orthoses) the paired t-test or Wilcoxon test was performed, and for the analyses between groups (GMFCS classification and type of orthosis), the t-test for independent samples or Mann-Whitney test was used, according to the normality distribution of the data. Statistical analyses were conducted using SPSS 22 for Windows (SPSS Inc., Chicago, IL), adopting a 5% significance level.

# RESULTS

The sample consisted of 24 subjects, 14 male and 10 female, with a median age of 11 [5-17 years old] and with GMFCS as follow: 1 participant at level I, 13 at level II, 9 at level III and 1 at level IV. Regarding orthosis characteristics, 10 patients used rigid AFO and 14 articulated AFO.

No significant differences were found for outcomes considering GPS overall, GPS right and GPS left side when comparing the walking tests with the individuals using or not using the orthoses (Table 1).

**Table 1.** Median [quartile range] of gait profile scores overall, left and right sides for bilateral cerebral palsy group when walking barefoot and with ankle-foot orthoses.

Variable	Barefoot	AFO	Р
GPS overall	14.96 [13.11-18.18]	15.54 [14.05-16.40]	0.25
GPS right	13.06 [11.50-16.13]	14.15 [11.77-15.62]	0.73
GPS left	14.80 [13.00-16.85]	14.62 [12.70-16.30]	0.87

Considering GVS variables such as pelvic tilt, pelvic rotation, pelvis obliquity, hip flexion, hip rotation, hip abduction, knee flexion, ankle dorsiflexion, and foot angle of advancement, no statistically significant differences were observed between BF and with use of orthoses, except for one parameter: GVS Hip Abduction-Adduction left- barefoot = 5.76 [4.42-8.85] and with AFO = 6.44 [5.31-8.97] - p = 0.01. All results are shown in Table 2.

Table 2. Median [quartile range] of gait variable scores for the bilateral cerebral palsy group when walking barefoot and with ankle-foot orthoses

cerebral parsy group when walking bareloot and with ankie-loot orthoses.						
Parameter	Barefoot	AFO	Р			
GVS Pelvic Tilt (°)	5.76 [4.24-8.77]	6.77 [4.49-9.79]	0.19			
GVS Pelvic Rotation (°)	10.16 [8.52-12.84]	9.87 [7.11-13.60]	0.19			
GVS Pelvic Obliquity (°)	4.45 [3.07-5.53]	4.66 [3.24-5.67]	0.39			
GVS Hip Flex-Extension right (°)	11.96 [8.24-19.91]	12.06 [10.02-17.61]	0.64			
GVS Hip Flex-Extension left (°)	13.26 [6.65-20.16]	12.41 [7.41-15.25]	0.08			
GVS Hip Ab-Adduction right (°)	6.60 [5.26-7.45]	6.14 [5.13-8.53]	0.84			
GVS Hip Ab-Adduction left (°)	5.76 [4.42-8.85]	6.44 [5.31-8.97]	0.01			
GVS Hip Rotation right (°)	9.52 [7.92-14.73]	10.52 [7.92-15.16]	0.27			
GVS Hip Rotation left (°)	13.84 [8.12-20.51]	11.67 [8.00-15.83]	0.66			
GVS Knee Flex-Extension right (°)	21.48 [15.28-27.93]	20.87 [18.51-27.94]	0.62			
GVS Knee Flex-Extension left (°)	22.53 [19.17-29.34]	22.12 [19.72-29.72]	0.58			
GVS Ankle Dorsi- Plantarflexion right (°)	10.83 [7.80-14.80]	10.98 [8.74-14.34]	0.97			
GVS Ankle Dorsi- Plantarflexion left (°)	11.31 [7.88-15.82]	9.42 [7.07-12.89]	0.24			
GVS Foot Progression right (°)	11.88 [9.19-20.71]	15.98 [9.59-24.47]	0.06			
GVS Foot Progression left (°)	15.05 [8.28-26.05]	12.85 [8.13-26.98]	0.36			

When considering the spatio-temporal parameters of gait, there was a 19.5% increase in Gait velocity with the use of orthosis (p < 0.001). The Stride length and the step length of the right and left sides showed a statistically significant increase. No difference were observed in cadence. The values are shown in Table 3.

Table 3. Median [quartile range] of velocity and cadence. Mean (standard deviation) of stride length and step length of right and left sides for the bilateral cerebral palsy group when walking barefoot and with ankle-foot orthoses

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Parameters	Barefoot	AFO	Р			
Velocity (cm/sec)	68.85 [25.95-80.50]	82.31 [36.70-89.25]	0.01			
Cadence (steps/min)	112.25 [68.15-123.15]	107.50 [61.42-118.87]	0.46			
Stride Length (cm)	68.62 (4.15)	77.65 (4.58)	< 0.01			
Right Step Length (cm)	35.15 (2.16)	40.28 (2.28)	< 0.01			
Left Step Length (cm)	33.42 (2.20)	37.82 (2.49)	< 0.01			

When performing the detailed gait analysis with and without orthoses according to the functional classification – GMFCS 1-2 and GMFCS 3-4, as well as between subjects using rigid and articulated orthoses, we found the same results reported for the general sample. That is, no significant difference was found between the groups related to overall, right, left GPS and GVS. However, the significant increase in velocity and stride length was maintained.

## DISCUSSION

The most typical use of an AFO is to optimize the normal dynamics of walking by applying a mechanical constraint (control moment) to the ankle to control motion and, at the same time, to produce a more efficient gait.<sup>22</sup>

Different types of orthoses may be prescribed for children with CP, such as AFO, which can help with alignment and in improving gait quality. AFO in fact, reduce, plantarflexion of the ankle, leading to greater stability in the support phase of gait.<sup>22</sup>

The values for general, left and right GPS did not present statistically significant differences when comparing the same individuals with and without the use of orthoses. These results are in concordance with a previous study by Danino et al.,<sup>23</sup> that did not find any changes in GPS in subjects with cerebral palsy when walking BF and using AFO. The explanation for the non-improvement in GPS was postulated because the index mainly examined the general kinematics of gait as measured from normal, and despite some changes in distal parameters, the overall gait pattern did not change significantly.

Our study analyzed GVS variables and significant changes were not found when analyzing the subjects walking BF or with orthoses, except for, hip adduction/abduction at the left side, the only parameter that changed. However, this had no clinical significance. In contrast with our results, Galli et al.<sup>22</sup> reported improvement in GVS of the ankle and pelvic tilt with a small sample of 10 subjects diagnosed with bilateral cerebral palsy, walking barefoot and with AFO. It is important to remember that the GVS evaluates the area of the kinematic curve as a whole. However, the orthosis positions the ankle in such a way that it avoids extreme positions of plantar flexion and/or dorsiflexion, without necessarily making the ankle movements look close to normal.

On the other hand, the temporal parameters showed changes that included gait velocity increasing by 19.5% with the use of the orthoses, while the cadence decreased by 4%, although the latter is not statistically significant. The lengths of the stride and step of the right and left sides had a statistically significant increase.

With the concept of minimal clinically important difference (MCID), which means a limit to determine when significant changes occur, there is an increasing emphasis in clinical research into establishing whether outcomes are clinically meaningful, as well as statistically significant.<sup>24,25</sup> Oeffinger et al.,<sup>26</sup> reported that changes in gait velocity, cadence and stride length, respectively 9.1%, 8.1% and 5.8% from normal were MCID. The mean subject's velocity, cadence and stride length in our study changed 19.5%, -4.2% and 13%, respectively. When comparing these changes with normal values, we noted that the velocity and the stride lengths were MCID. The reported changes that reach statistical significance were also clinically meaningful (gait velocity and stride length). As walking velocity is often used as a surrogate measure for overall gait quality, we can say that orthoses in our sample produced functional benefits, agreeing with a systematic review and meta-analysis published by Lintanf et al.,<sup>27</sup> despite avoiding the appearance of musculoskeletal deformities. Furthermore, we can observe the results above point to an improvement in function, since the increase in velocity relates to an increase in the stride length, rather than an increase in cadence, as shown in Table 3.

The authors also performed the subdivision of the sample considering greater and lesser motor impairment (GMFCS 1-2 and GMFCS 3-4), and by the type of orthosis used (articulated or rigid). The results reported for the general sample were the same when the sample was divided using the level of motor impairment and type of orthosis. Therefore, the heterogeneity in the sample was not responsible for the changes.

For children with CP, Davids et al.,<sup>11</sup> argued that analogous with multilevel surgery decision making, optimal orthotic management

requires the physician to clearly identify the gait deviation and functional deficits to be addressed using the orthosis.

Recommendations for orthoses must meet specific requirements in physical exams and in gait performance. Adequate range of motion for typical alignment while walking is necessary to properly fit the orthosis and to expect good functionality. This requires at least a neutral ankle dorsiflexion with the knee extended and no knee flexion contractures. Femoral anteversion and tibial torsion decrease the effectiveness of a well-made orthosis and should be identified and corrected to maximize effectiveness.<sup>7</sup> Rodda and Graham,<sup>28</sup> proposed the use of articulated AFO in true equinus gait and jump gait as well as the use of rigid AFO for apparent equinus and crouch gait. This recommendation reveals the concern with keeping the ankle in a more neutral position during the stance phase of gait. Careful clinical evaluation of the patient by the professional is essential to avoid prescribing an orthosis under suboptimal conditions

for use. Clinical gait analysis may aid in orthosis recommendations. In our study, the fact that prescriptions for orthoses were issued without the aid of quantitative data (gait analysis), may have been a contributing factor for non-significant changes in some parameters such as ankle GVS.

The lack of evidence is also observed due to the scarcity of prescription guidelines.<sup>29</sup> In clinical practice, this lack of consensus observed due to differences in treatment paradigms regarding both the recommendations and the mechanical construction of AFO.<sup>9</sup> A systematic review on the quality of AFO studies in children with CP concluded that substantial variability in the quality or reporting was present in currently published studies.<sup>30</sup> The prevention of the occurrence of skeletal muscle dysfunction is one of the reasons to prescribe orthoses in this population. Studies such as these do not evaluate this important effect of the use of orthoses in patients diagnosed with CP.

The limitations of our study relate to the small study cohort sample, collected out of convenience and for the efficacy of orthoses, who were evaluated in a laboratory, and not in an environment where children participated in normal daily activities.

#### **Clinical implications**

The attending professional needs to carefully assess the recommendations and effects of orthoses on ambulatory patients with CP. This is because some predicted effects of orthoses recommendations may not be achieved, as occurred in the sample studied in which no changes were observed in the overall gait characteristics.

The determination of quantitative parameters for the prescription of orthotics in patients with bilateral CP, as well as orthotics that meet specific requirements are points to be addressed in the future to obtain more significant effects.

#### CONCLUSION

In this study, the AFO, prescribed for assistance by professionals without using gait data, did not significantly affect the gait index (GPS), but improved temporal data. Answering the question: are we improving the gait of patients with cerebral palsy by prescribing orthoses without using 3DGA? In the evaluated sample the patients using orthoses became more functional with increased velocity, step and stride length. However, the movements of the lower limbs were no closer to normality.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article: AGM: article design, project design and writing; ACP: data collection and review; DDI: data collection and review; RFMC: data collection and review; SS: statistical analysis, writing and review.

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