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European Journal of Physical and Rehabilitation Medicine 2021 August;57(4):577-84
DOI: 10.23736/S1973-9087.21.06566-7

ORIGINAL ARTICLE

Effectiveness comparison between carbon spring and hinged ankle-foot orthoses in crouch gait treatment of children with diplegic cerebral palsy: a randomized crossover trial

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ABSTRACT

BACKGROUND: Children with cerebral palsy (CP) often present a loss of effectiveness of the plantarflexors/knee-extensors couple that leads to crouch gait. When treating a child with crouch gait by means of ankle foot orthoses, preserving or restoring push off power is a key issue.
AIM: To compare carbon-fiber spring (Carbon Ankle Seven® [CAFO], Ottobock® HealthCare, Duderstadt, Germany) and hinged ankle-foot orthoses (HAFO) effectiveness in improving functionality and walking ability in children with diplegic CP and crouch gait.
DESIGN: Randomized crossover trial.
SETTING: Hospital center.
POPULATION: Ten children with diplegic CP and crouch gait, 5 males and 5 females, aged 11 (4) years.
METHODS: The gait of each child was evaluated by means of instrumental gait analysis with both CAFO and HAFO, in a randomized order and after a 4-week adaptation period. The primary outcome measure was the change in ankle power generation. As secondary outcome measures, knee joint kinematics, stride length, walking speed, Observational Gait Scale, and preferred orthosis were considered.
RESULTS: The median of the energy produced in stance was superior with CAFO (+2.2 J/kg, IQR 4.7, P=0.006), and the energy absorbed inferior (-3.3 J/kg, IQR 4.3, P=0.011). No statistically significant difference was found for any other parameter. Preference of the children was equally distributed between the two orthoses.
CONCLUSIONS: No evident superiority of CAFO with respect to HAFO was found in improving gait performance of children with CP and crouch gait. Nevertheless, the results suggest the possibility that CAFO permits an energy saving and reduction of the more compromising deficits.
CLINICAL REHABILITATION IMPACT: The final choice of the participants indicates that CAFOs are preferred by older and heavier children, but the preference does not correlate with the performance of the orthoses during gait.

(*Cite this article as*: Borghi C, Costi S, Formisano D, Neviani R, Pandarese D, Ferrari A. Effectiveness comparison between carbon spring and hinged ankle-foot orthoses in crouch gait treatment of children with diplegic cerebral palsy: a randomized crossover trial. Eur J Phys Rehabil Med 2021;57:577-84. DOI: 10.23736/S1973-9087.21.06566-7)

Key words: Cerebral palsy; Gait; Foot orthoses; Gait analysis.

Crouch gait is one of the most frequent pathological gait patterns in children and adolescents with cerebral palsy (CP).[1] It is described as the maintenance of an excessive knee flexion during stance phase of gait.[1-3]

Crouch gait increases energy costs during walking.[4] Without treatment, it worsens rapidly,[5] leading to greater functional disability, up to loss of walking.[6]

One of the basic components of crouch gait is the loss of effectiveness of plantarflexion/knee-extension couple, which is closely linked to muscle weakness.[3] In fact, even if quadriceps are usually vigorous, lack of tibia stability does not allow knee extension. A primary role of this couple in producing tibia stability is performed by the soleus.[3]

Ankle foot orthoses (AFOs) are often recommended,[7, 8] even if results are variable and with a weak level of evidence.[9-12] The fundamental goal of AFOs is providing a stabilization of the tibia, supporting plantarflexion and facilitating knee extension.[13] Nevertheless, in stabilizing the tibia, many common AFOs usually reduce not only the excessive dorsiflexion during support, but also the active plantarflexion, since they have a rigid connection between shank and foot (*i.e.* solid AFO, ground reaction AFO).

This constraint has the counter-effect of hindering the power generation of ankle plantar flexors in late stance,[3, 8, 9, 14-17] that is one of the two (with hip flexors activation) primary mechanisms used to increase walking speed.[18, 19] Moreover, AFOs add a limitation to an ankle push-off power (*i.e.* the power generated by the ankle in late stance) often already compromised by the pathology,[3] in a context of severely limited speed.[4-6]

Hinged AFOs (HAFOs) and Carbon Spring AFOs (CAFOs) are two different possible attempts to overcome this limitation. HAFOs allow a free plantar/dorsiflexion movement within a defined range, by means of a flexible element hinged at the anatomical ankle joint level. A positive effect of HAFOs on ankle power has been demonstrated in children with hemiplegic[8, 20] and diplegic[21, 22] CP, with a positive impact on speed.

CAFOs have been specifically developed to restore insufficient push-off power. Theoretically, CAFOs are designed to store energy during the loading phase and release it during toe-off one. Deeslovere *et al*.[9] found higher push-off with a CAFO in hemiplegic children with respect to a leaf spring AFO. In a group of patients with stroke and multiple sclerosis, Bregman *et al*.[17] determined that CAFOs provide energy advantages not by increasing net push-off, but partially taking over ankle work. CAFOs application in patients with myelomeningocele seems to improve spatio-temporal gait parameters and ankle power production.[23, 24]

To our knowledge, there is a lack of studies regarding CAFO application in children with diplegic CP, especially concerning crouch gait patterns, and comparison with HAFO effectiveness.

The aim of this study was to compare CAFOs and HAFOs impact on ankle push-off power in children with diplegic CP and crouch gait. Besides, the effects on walking ability and gait effectiveness will be investigated.

Materials and methods

Ten children participated in this interventional randomized-crossover study. The children, all with diplegic CP, Italian and between 6 and 18 years old, were recruited among patients treated at Children Rehabilitation Specialized Unit (UDGEE), Santa Maria Nuova Hospital, USL-IRCCS of Reggio Emilia, Reggio Emilia, Italy. The research design and protocol were approved by the institutional Review Board and Ethics Committee (approval #CE 951, 12/07/2012, chair: Nicola Magrini) and the study was carried out in accordance with the World Medical Association's code of Ethics (Declaration of Helsinki, 1967). Participant parents provided written informed consent. This study has been registered in ClinicalTrials.gov database under the Identifier: NCT03333434.

Inclusion criteria were as follows: 1) children with diplegic CP and crouch gait; and 2) clinical indication for wearing AFO, and in particular for AFO renewal (children joined this study when their AFOs had to be renewed).

Exclusion criteria were as follows: 1) disability (cognitive or sensorial) or other diseases that could affect participation and effectiveness of orthoses; 2) functional surgery of lower limbs or botulinum toxin injections in the previous 6 months; and 3) indication for surgical treatment to be carried out within 6 months after the date of inclusion in this study.

In order to compare CAFO (Carbon Ankle Seven Orthosis, Ottobock® HealthCare, Ottobock, Duderstadt, Germany; GmbH=A7) and HAFO performance, the gait of each patient was evaluated with both A7 and HAFO (AB/BA design). Children were examined wearing the same orthotic footwear (Figure 1). The sole of the footwear provides a forward foot tilt of 5° relative to the ground, when the shoe is fully leaning on the ground. Both HAFO and A7 were fabricated by the same orthotics technician at med-tech company OttoBock® in Reggio Emilia and tailored for each patient. HAFO ankle angle was set at 90°, with 20° of free range of motion (5° of dorsiflexion - 15° of plantarflexion). A7 was composed by a posterior shell embracing the calf, a foot shell and a carbon spring connecting the two parts. The calf and foot shells were made of homopolymer polypropylene and extruse (3-6mm of thickness). The geometry of the carbon spring displays a neutral angle of plantarflexion and an external rotation of 7° between leg and foot parts. Springs are available in 10 prefabricated sizes based on patient body weight, each size covering a 10kg weight range.

Children wore A7s and HAFOs in successive periods. A randomization with an automatic generator determined the first orthosis to be assigned. Allocation was concealed and communicated by telephone to investigators (by a third person).

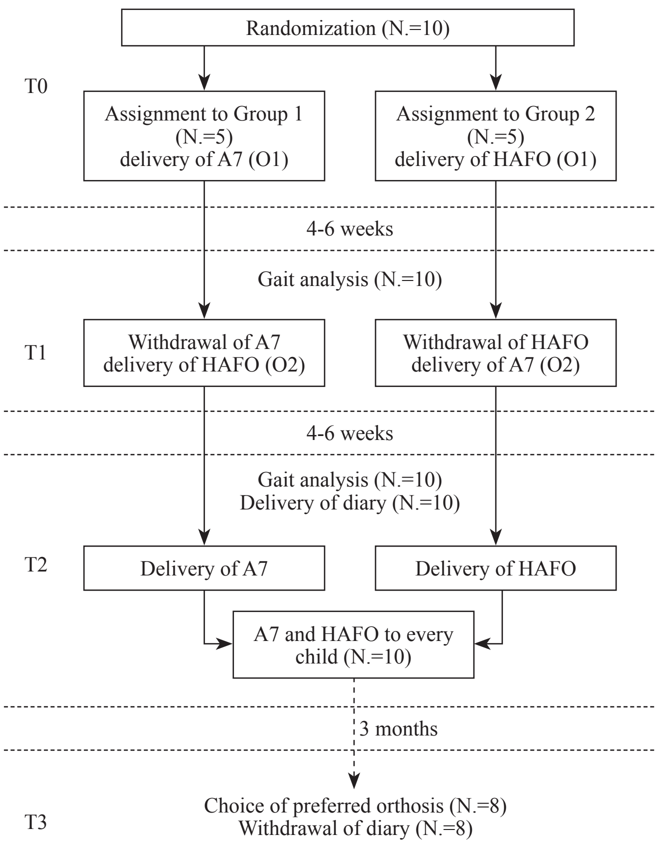

Figure 1.—Flow chart of randomization and phases of the study.

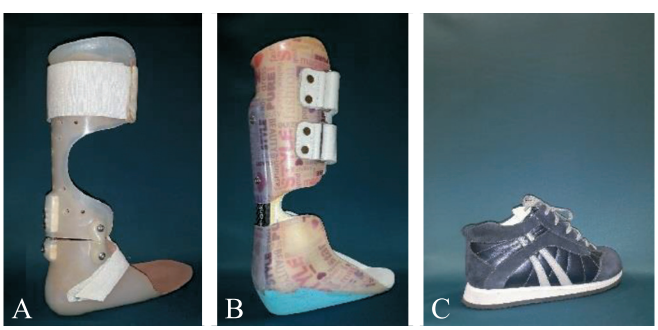

Figure 2.—Examples of orthoses and footwear utilized in the study: A) HAFO; B) A7; and C) orthotic footwear.

The study consisted of 4 phases (Figure 2).

- T0: randomization of first orthosis assignment (O1); collection of measures and production of the orthotic devices (OttoBock headquarters of Reggio Emilia); delivery of a diary to collect data about orthoses use;
- T1: after a period of 4-6 weeks, during which patients got accustomed to their assigned orthosis (O1), execution of instrumental gait analysis and video recording during walking; followed by O1 withdrawal and second orthosis assignment (O2);
- T2: 4-6 weeks after T1, 3D gait analysis and video recording during walking with O2; return also of O1 to the patient; delivery of a diary to collect data about orthoses use;
- T3: after 3 months during which the children were free to use both O1 and O2, collection of the self-compiled diary and final assignment of preferred orthosis.

No “washout period” between assignments of the two orthoses was introduced since the children involved in this study had never walked without orthoses.

Gait analysis was performed by means of a Vicon® system (Oxford Metrics Group, Oxford, UK). The system was equipped with eight optoelectronic cameras, two force plates (AMTI, USA), and two video cameras. A 10-meter walkway allowed children to reach and maintain a constant self-selected walking speed during acquisitions. Marker-set followed the Total3DGait protocol.[25] Children walked until they effectively struck the force plates three times with each foot. No indications of striking the force plates were given to the patients. Kinematic and dynamic data were recorded. Averaged parameters of all the recorded gait cycles (at least six for each leg) were calculated.

The outcome measures were selected to explore four main aspects of AFO effectiveness: effect on ankle power generation (primary outcome, that should be the specific result of CAFO application); effect on knee extension during stance (specific focus of AFOs for children in crouch); general gait performance; patient perspective.

The first aspect, *i.e.* ankle power generation, should provide information on whether the children are capable to exploit the A7 carbon spring. Is it possible for them to increase ankle power during push-off phase? To answer this question the following parameters regarding power and energy exchanges at the ankle level were evaluated (Figure 3): propulsion power peak in preswing, energy produced during the entire stance and push-off, and total energy absorbed during stance. Energy expended was calculated both for each ankle and each patient (in this last case, by adding the energy produced/absorbed by right and left limb). Ankle power was calculated as $P=\mathbf{M}\times\boldsymbol{\omega}$, where $\mathbf{M}$ is the moment of the ground reaction force with respect to the ankle center (midpoint between the two malleoli), and ω the angular velocity of the foot relative to the shank. Calculation was performed with Aurion® software (Aurion, Brisbane, Australia) and based on Total3DGait protocol.[25] Since ankle movement is permitted by the AFOs only in the sagittal plane (relative to the shank), the power in this

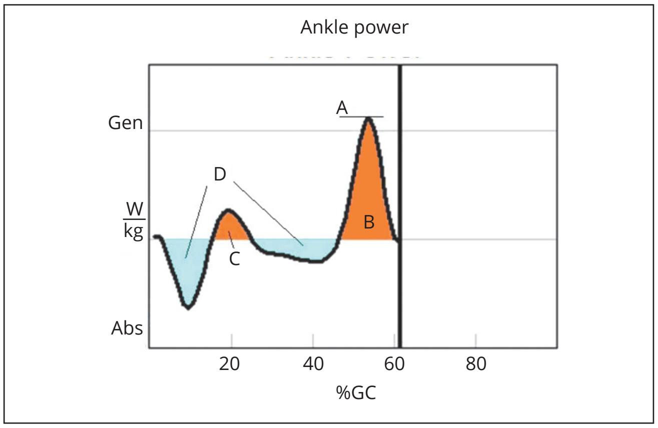

Figure 3.—An example of normalized ankle power during a gait cycle (GC) is shown. The following parameters were analyzed: propulsion power peak in preswing A value; energy produced during the entire stance (B area + C area, *i.e.* all possible areas where the power is generated); energy produced during push-off phase (B area); and total energy absorbed during stance (D area; *i.e.* all the areas relative to absorbed power).

plane (around the medio-lateral axis) represents almost the entire power at the ankle. Energy was computed by adding the power for each instant of the phase of interest.

Power generation at the ankle is a fundamental component of the propulsive push in the push-off phase,[8, 18, 19] but it is not automatically transferred to a better global gait performance.

In order to evaluate the effects of these AFOs on a more general gait performance, stride length (normalized to height), and walking speed (self-selected, normalized to height), were measured. Moreover, the Observational Gait Scale[26] (OGS, compiled by blinded evaluators) was applied.

In crouch gait, supporting knee extension is a fundamental goal. Therefore, even if the focus of this work is on ankle power, knee joint kinematics was analyzed (average extension during initial contact, loading response and mid-stance; calculated for each leg).

Finally, patients' and parents' perspectives were considered by recording the time of usage and the preferred orthosis (from a self-compiled diary during a 3-month follow-up).

Modification of parameters towards "typical gait pattern" was deemed by performance improvement. Typical gait pattern was determined by a group of 22 typically developing children (mean age 12 years) acquired with the same protocol in the same laboratory.

Statistical analysis

Descriptive statistics were performed to investigate the sample characteristics; median and interquartile range (IQR) were chosen to summarize continuous variables. Wilcoxon signed-rank test was used to compare scores obtained from the same patients who wore A7s and HAFOs in sequential periods. The scores were calculated both for each leg and each patient.

Threshold for statistical significance was set at $P<0.05$. IBM SPSS Statistics 23 (SPSS, Chicago, IL, USA) for Windows (Microsoft, Albuquerque, NM, USA) was used for statistical analyses.

Data availability

The data associated with the paper are not publicly available but are available from the corresponding author on reasonable request.

Results

Patient characteristics and randomization of first and second assignment orthoses are shown in Table I. Average use of the assigned orthoses was six weeks, with no significant temporal differences between A7 and HAFO.

TABLE I.—*Characteristics of the children included in the study. Gross motor function classification system (E&R) and random sequence of AFO assignment are also reported.*

Subject ID	Age	Gender	Weight [kg]	height [cm]	GMFCS (E&R)	Assistive devices	1st assign.	2nd assign.
1	11	F	33	140	II	no	HAFO	A7
2	15	F	41	142	II	no	HAFO	A7
3	7	F	19	113	II	no	HAFO	A7
4	9	F	35	123	II	no	A7	HAFO
5	7	M	28	126	II	no	A7	HAFO
6	15	M	82	170	II	no	A7	HAFO
7	17	M	45	157	II	no	HAFO	A7
8	14	M	58	164	II	no	HAFO	A7
9	14	F	44	154	II	no	A7	HAFO
10	6	M	19	107	II	no	A7	HAFO

TABLE II.—*Section A shows energy and power at the ankle. Push off energy, energy produced and absorbed during the whole stance phase, and push off power peak are reported. Results are shown both for the 20 legs of the children, considered separately, and for the 10 children considered as a unit, adding the energy of right and left limb. Since it has poor physical meaning adding right and left power peak, for this variable only the results related to the 20 legs separately are indicated. Section B shows knee flexion during stance for the 20 legs. Knee flexion is identified by the average value at initial contact (IC), loading response (LR) and mid-stance (MS). Section C shows spatio-temporal parameters for the 10 subjects. Self-selected speed and stride length, both normalized to height, are reported. Statistics is express by median, interquartile range and p-value relative to the increase of the parameter with A7(A7-HAFO). Values related to typically developing children (TD) are calculated on a sample of 22 healthy children.*

Section A		Push off energy [J/kg]			Absorbed energy [J/kg]			Produced energy [J/kg]			Power peak [W/kg]		
		HAFO	A7	A7-HAFO	HAFO	A7	A7-HAFO	HAFO	A7	A7-HAFO	HAFO	A7	A7-HAFO
Each leg separately (N.=20)	Median	5.6	6.8	1.7	17.4	13.8	-3.3	6.9	9.5	2.2	0.74	0.81	0.12
	IQR	2.5	2.4	3.0	7.4	8.3	4.3	5.0	7.8	4.7	0.34	0.31	0.54
	P value			0.052			0.011			0.006			0.601
	TD		14.9			-8.3			15.0			1.8	
		HAFO	A7	A7-HAFO	HAFO	A7	A7-HAFO	HAFO	A7	A7-HAFO			
Right+left Leg (N.=10)	Median	11.3	14.4	2.2	36.1	29.3	-7.4	15.1	20.5	6.3			
	IQR	4.4	5.9	5.9	10.5	16.2	7.9	9.3	10.2	5.5			
	P value			0.114			0.022			0.013			
	TD		29.9			-16.5			30.0				
Section B		IC [deg]			LR [deg]			MS [deg]					
		HAFO	A7	A7-HAFO	HAFO	A7	A7-HAFO	HAFO	A7	A7-HAFO			
Knee flexion (N.=20)	Median	36.0	34.7	2.0	38.6	37.9	-0.3	28.8	28.3	-1.7			
	IQR	10.8	9.8	10.6	12.3	12.3	5.8	12.5	10.7	8.1			
	P value			0.940			0.654			0.550			
	TD		6.0			11.2							
Section C		SPEED [%h/s]			STRIDE [%h]								
		HAFO	A7	A7-HAFO	HAFO	A7	A7-HAFO						
Spatio-temporal parameters (N.=10)	Median	65.6	65.6	0.1	71.9	69.4	0.3						
	IQR	18.1	15.4	10.0	11.4	9.3	9.4						
	P value			0.959			0.678						
	TD		85.9			82.6							

In analyzing the collected data, considering the 20 legs separately, the change in stance ankle dynamics was significant for the total energy, both produced and absorbed (Table II, Figure 4). The median of the energy produced increased with A7 from 6.9 to 9.5 J/kg, and the energy absorbed decreased from 17.4 to 13.8 J/kg. Push-off energy increase was at the limit of significance, from a median of 5.6 to 6.8 J/kg. Instead, no differences were found for the power peak. Adding right and left stance energy and considering one value for each subject (N.=10) did not considerably modify these findings. The only noteworthy change was related to a P value increase for push-off energy (from 0.052 to 0.11).

No statistically significant difference was found for any other gait analysis parameters (Table II). Speed and stride length medians were almost the same for both A7 and HAFO. No changes were revealed concerning knee kinematics: at initial contact, loading response and mid-stance, all the median values remained very similar to each other.

OGS showed a better score for A7 in 25% of cases, a better score for HAFO in 35%, and an equal score in the remaining 40%.

Diaries compiled by the patients showed that A7 was mainly used 5.4 days per week, and 7.27 hours per day; HAFO was used respectively 5.2 days and 6.61 hours. At the end of this study, four children (patients ID 1, 2, 7, 8) chose to keep A7 as their favorite orthosis, and four preferred HAFO (ID 3, 4, 9, 10). It was not possible to determine the final choice for the other two children since they did not return the diary during the 3-month follow-up.

Discussion

The aim of this study was to compare CAFOs (A7) and HAFOs effectiveness in improving functionality and walking ability in children with diplegic CP and crouch gait. The analysis was conducted in a highly homogeneous group of children not only for the pathology characteris-

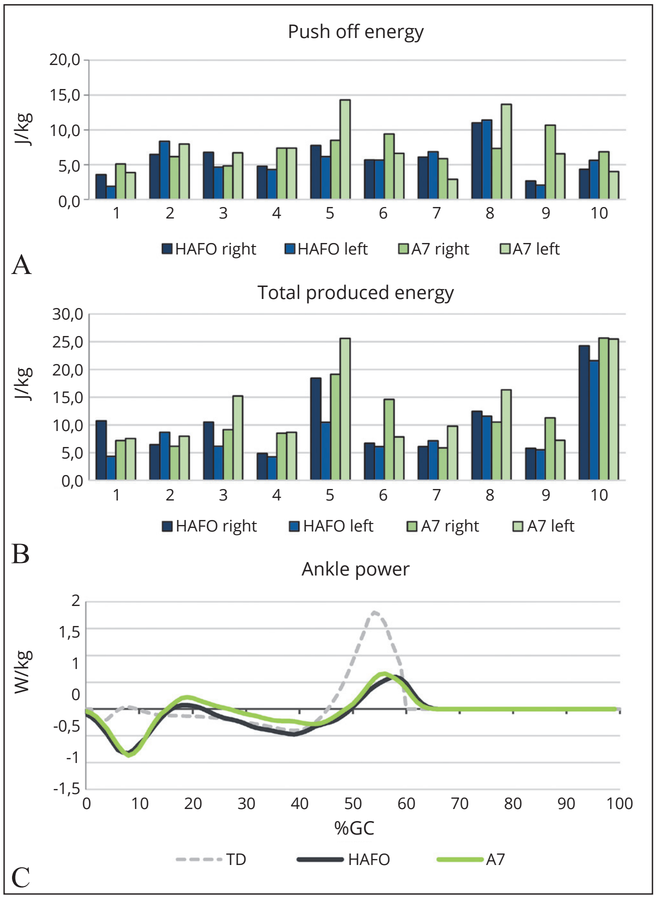

Figure 4.—Energy produced (normalized to weight) at the ankle level during push off phase (A) and during the whole stance phase (B). Push off energy was calculated considering the area subtended by the last positive power phase (push off peak). The energy produced by each ankle of each of the 10 subjects, both with HAFO and A7, is presented. The median of HAFO and A7 ankle power during gait cycle (GC) is shown (C). Power is normalized to weight. The dashed line refers to a group of 22 typically developing (TD) children (mean age 12). The power absorption in the early stance is determined by forefoot strike. This pattern is mainly caused by the excessive knee flexion, also in absence of equinus deformity.

tics, but also for the functional level. All participants were classified level II with the Gross Motor Function Classification System (E&R), and they did not use assistive devices.

The results do not highlight a clear superiority in performance of one of the two AFOs.

For what concerns ankle power generation, no differences were found for power peak during push-off. It was only possible to detect a trend of improvement in ankle push-off energy when considering all the legs separately, with no statistical significance. Energy exchanges represented the only significant difference between orthoses, both considering the 10 subjects and the 20 legs separately. At ankle level, the total amount of energy produced increased with A7 and total energy absorbed (*i.e.*, eccentric work) decreased. These two variations led to typical gait parameters.

This means that A7 supported the production of an extra-energy during mid-stance, and not during the push-off phase. Therefore, it could have other effects than propulsion. Is it useful for a more efficient gait?

We could advance the hypothesis that this energy facilitates segment alignment (*i.e.,* hip and knee extension in mid-stance).[17] In fact, during physiological mid-stance, plantarflexion occurs when the sole of foot (fixed point) is leaned on the ground, and results in a verticalization of the shank. Nevertheless, no difference was found for the improvement of knee extension during stance. Furthermore, no increase in speed and stride length was observed. Therefore, we do not have evidence that this extra-energy produced at the ankle during stance improve gait effectiveness. A further analysis of its possible effects should be performed.

Interesting considerations can emerge by comparing these results with the findings of the studies of Bregman *et al.*[17] They declare that a positive effect of a CAFO (with respect to barefoot walking) is not necessarily oriented to push-off power improvement, but to energy saving. In their research, this saved energy accounted for 22% of mechanical energy produced at the ankle, and for 9.8% of metabolic cost.

In that study, benchtop equipment (BRUCE - biarticular reciprocating universal compliance estimator) was used to assess the AFO stiffness.[27] Unfortunately, this tool was recently added to the clinical examination protocol, and it was not possible to exploit it in the present work, in order to calculate the exact energy contribution.

Nevertheless, in our study, we can state that there is a contribution of the A7 spring when the energy is produced at the ankle: at the beginning of push-off phase the carbon spring is already loaded by an external dorsiflexion moment, and during plantarflexion it releases the stored energy producing power in synergy with the plantar flexor muscle activity. On the other hand, when HAFO is employed, the energy produced at the ankle is almost entirely due to muscle force (since HAFO is mainly a passive mechanism).

Therefore, we can affirm that, during push-off phase, an unknown amount of energy is saved at the ankle using A7. This stored-and-released energy may lead to greater endurance and lengthen the maximum walking distance rather than produce any change in speed and stride length. Anyway, endurance and maximum walking distance cannot be adequately detected in a 3D gait analysis laboratory.

This interpretation is in line with the fact that A7 seemed to work better on the more affected leg. If we define as "more affected leg", the leg on the side where ankle push-off power is more compromised when wearing HAFO, we could notice that in 7 out of 10 cases, the push-off power peak increases on the more affected side with A7. This could indicate that instead of improving performance, the carbon spring may help in reducing more compromising deficits.

These 3D gait analysis results confirm what has been generally found in literature concerning AFO applications in children with CP, *i.e.* the difficulty in increasing ankle push-off power, especially in diplegia,[8, 9, 15, 16, 28] and the high variability in performance, that strongly depends on single child characteristics.[10, 11, 29]

No statistical change was found from the observational point of view. A general evaluation of gait produced by the OGS slightly favored HAFO. The diaries compiled by the patients indicate, on the contrary, a minimum longer time of use for A7. The choice of the children was anyway equally distributed between HAFO and A7. It is interesting to note that there is no correlation between patient choice and any performance parameters. Among children 1, 4 and 9, that had the best results in terms of ankle power production in late stance, only number 1 chose A7. The choice of the patients correlates, instead, to body weight (0.65) and age (0.72): older and heavier children tend to prefer A7. A possible explanation could be the importance given by these children to gait and, more in general, to standing. This importance increases with age (and consequently with weight), because as children acquire motor skills, their gait may become more relevant in social relationships. It is possible that older and active children appreciate the energy stored with A7 while walking.[30]

In general, these results indicate that the reasons of patient choice should be investigated also in aspects different from ankle push-off power increase. These aspects (for instance, aesthetics, weight, ease of wearing, standing stability, support when changing posture, etc.) may be more important for children with CP (and their parents) than improving gait performance.[12]

Limitations of the study

This study has several limitations. Because of small sample size, power of statistical analysis is low. Selection of measured parameters was adequate to verify a performance improvement over short distances, but not to fully understand energy exchanges and endurance performance, and therefore preference of the patients. It would be useful to investigate, on one hand, energy expenditure and absorption at other districts (*i.e.,* knee and hip), metabolic cost and energy contribution of orthoses, and, on the other hand, the psychological reasons for patient choices.

Conclusions

To our knowledge, this is the first research comparing a CAFO (A7) and a HAFO regarding functionality and walking improvement in children and adolescents with CP and crouch gait.

We can conclude that the use of A7 improved total energy exchanges at ankle level during stance phase, increasing total amount of energy produced and decreasing total energy absorbed. Anyway, this improvement does not correlate to changes in spatio-temporal and kinematic parameters as well as OGS and orthosis preference.

Future studies should investigate the effects of extra-energy stored and released with A7. Furthermore, given the high variability of response to a CAFO application even in a homogenous group of children, it would be important to define adequate parameters for the optimal ankle-foot orthosis prescription.

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Conflicts of interest.—Authors received research support from Otto Bock Italia; Otto Bock HealthCare Deutschland GmbH; Azienda USL-IRCCS di Reggio Emilia, Italy. The owner of the data is Azienda USL-IRCCS di Reggio Emilia (Department of Health ministerial decree 17/12/2004).

Funding.—The research was funded by Otto Bock Italia; Otto Bock HealthCare Deutschland GmbH; Azienda USL-IRCCS di Reggio Emilia, Italy.

Authors' contributions.—Corrado Borghi has given substantial contributions to investigation, methodology, visualization and original manuscript draft; Stefania Costi contributed to methodology, manuscript draft, review and editing; Debora Formisano gave contributions to formal analysis; Rita Neviani and Daniela Pandarese contributed to conceptualization, investigation, data curation and manuscript original draft; Adriano Ferrari has given contributions to manuscript draft, review, editing, project administration and supervision. All authors read and approved the final version of the manuscript.

History.—Article first published online: February 23, 2021. - Manuscript accepted: February 18, 2021. - Manuscript revised: February 10, 2021. - Manuscript received: August 28, 2020.