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The Effect of Ankle-Foot Orthoses on Community-Based Walking in Cerebral Palsy: A Clinical Pilot Study

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Abstract

Purpose—Examine effect of ankle-foot orthoses (AFO) on walking activity in children with cerebral palsy (CP).

Methods—We used a randomized cross-over design with 11 children with bilateral CP, mean age 4.3 years. Subjects were randomized to current AFO-ON or AFO-OFF for 2 weeks and then crossed over. Walking activity (average total steps/day), intensity and stride rate curves were collected via ankle accelerometer. Group effects were examined with the Wilcoxon signed-rank test and within subject effects examined for > 1 standard deviation change.

Results—No significant group difference was found in average total daily step count between treatment conditions ($P = .48$). For the AFO-ON condition, 2 subjects (18%) increased total steps/day; 4 (36%) increased walking time; 2 (18%) had more strides at rate >30 strides/min; and 2 (18%) reached higher peak intensity.

Conclusions—Clinically prescribed AFO/footwear did not consistently enhance walking activity levels or intensity. Larger studies are warranted.

Keywords

ambulation; ankle foot orthoses; cerebral palsy; child; gait

Background

Ankle-foot orthoses (AFO) are an essential rehabilitation strategy employed to enhance the walking limitations seen in children with cerebral palsy (CP) who are ambulatory.¹ A consensus conference of the International Society for Prosthetics and Orthotics (ISPO)

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identified the aims of lower extremity orthotic management in children with CP: 1) to correct and/or prevent deformity, 2) provide a base of support, 3) facilitate training of motor skills, and 4) improve efficiency of walking.²

A literature review revealed some low level evidence that AFOs enhance walking activity through a combination of biomechanical and physiological mechanisms.² The solid AFO (SAFO) specifically limits dynamic ankle equinus and mid foot pronation allowing for foot flat contact with the surface during the stance phase of gait. This increased base of support (foot flat versus forefoot/toe contact during stance phase of gait) improves balance and stability as the tibia and body move over the foot during midstance of each step. Preventing dynamic equinus (plantar flexion) has been shown to facilitate ground clearance by the swing foot, increase step length and walking speed, improve stability during stance phase, and pre-position the foot in terminal swing phase.² Various AFO designs have been documented to improve stride length, walking speed, single limb stance, dorsiflexion at heel strike, and ankle moment at push-off; reduce equinus posturing and ankle excursion during loading; and enhance ankle power at push-off in children with CP.²

Clinically, lower extremity impairments (passive range of motion, segment alignment) and gait patterns (kinematics) are examined in the process of orthotic prescription, but are not consistently identified and/or agreed upon in the literature. The goal of each AFO prescribed for a child with CP is the collective improvement of these biomechanical variables to increase the ease of taking an individual step, with the potential to enhance walking activity and functional skills. For example, Buckon and colleagues documented normalized ankle kinematics, improved stride length and walk/run/jump skills with either the posterior leaf spring or hinged AFO as compared to a rigid or SAFO in children with CP who are ambulatory.³

Physiologically, we know that children with CP expend more energy to walk than children who are typically developing (TD), and that energy cost increases as functional level decreases.⁴ Recently, lower physical activity levels were also found to be associated with higher oxygen cost of walking in 10 children with CP who were ambulatory.⁵ However, Maltais et al. reported lower oxygen cost for walking in children with spastic CP while wearing a hinged AFO with no effect on standing and walking/running/jumping skills.⁶ Thus, AFO use might affect walking activity levels by decreasing the oxygen cost of walking.

The use of AFOs has developmental and psychosocial implications for children with CP and their families. Children with physical disabilities are at risk for delayed social development.^{7, 8} Facilitation of an upright posture positively supports acquisition of cognitive, visual perceptual, play, and social interaction skills, as well as walking independence. Naslund et al. described parental perceptions of the use of Dynamic Ankle Foot Orthoses (DAFO) using structured parental interviews.⁹ Parents noted positive functional effects of the DAFO for foot support, balance, standing and sitting posture as well as overall physical activity. Parents also reported foot pain with new orthoses and the need to change socks often due to excessive sweating when wearing plastic orthoses.⁹ Finding shoes that fit over the AFO was also a problem. Some parents noted that the DAFO seemed

to make younger, smaller children more clumsy, as they got in the way of floor play.⁹ Having to don and doff orthoses was noted as a burden of care.

Orthotic intervention has large economic implications for children with CP and their families and insurers. Given that approximately 53,000 AFOs are fabricated each year in the United States at an average Medicare reimbursement of \$417, more than \$2.2 million per year are spent on them.^{10,11} Thus, potential orthotic costs range from \$6,400 to \$15,400 for casting and fabrication (depending on speed of growth) for children from 2–9 years old.

The literature examining the effect of orthoses on walking in children with CP has focused primarily on measures of activity ‘capacity’ (defined by the International Classification of Functioning and Disability [ICF] as what a child can do in a lab/clinic environment)¹² using computerized 3 dimensional gait analysis, gross motor function tests, energy cost, and clinical gait analysis. To date, activity ‘performance’ (what a child does in the day to day environment according to the ICF) has not been reported.¹³ Hence, this pilot study aims to examine the effect of AFOs on walking activity within community based settings in children with CP.

METHODS

This study is a prospective randomized cross-over design with a convenience sample of 11 participants. With prior approval from the human subjects review committee, a focused mailing was addressed to potential participants from a specialty care pediatric facility in the US Pacific northwest and local therapy providers. Children having a diagnosis code of ambulatory CP and ages 2 to < 10 years made up the initial mailing list. This list was further screened prior to mailing to confirm ambulatory status and use of English as the primary language.

After obtaining informed consent and/or assent, participants were enrolled who met the additional inclusion criteria of: 1) Gross Motor Function Classification System (GMFCS) Level I – III, 2) bilateral CP, 3) wearing bilateral AFOs more than 8 hours per day for more than 1 month, 4) the primary goal of current AFOs was to facilitate balance and walking, and 5) the family was willing to discontinue AFO use for 2 weeks. Exclusion criteria included having visual impairment that limited physical activity, lower extremity injection therapy in the past 3 months, medication changes planned during the study period, an uncontrolled seizure disorder that affected mobility skills, neurosurgical or orthopedic surgeries in the past 6 months, or other surgeries or procedures in the past 2 weeks.

At a center-based baseline study visit, demographics, current AFO prescription, and shoe design were documented (Table 1). Participants then underwent sagittal plane video vector gait analysis (Contemphas Motion Analysis, Templo Version 7, zFlo Motion Analysis Systems, Inc., Boston, MA) with shoes only, and shoes with current AFOs. Footwear shoe profiles were similar between conditions but were not the same shoe due to size differences. After these assessments were completed, the subject was assigned to an initial intervention wear phase (currently prescribed AFO-ON/footwear or AFO-OFF/footwear) by opening a sealed opaque randomization envelope. After the child was assigned to an intervention wear

phase, the StepWatch (SW) multi-axis accelerometer (Orthocare Innovations, Mount Lake Terrace, WA) was fitted to the lateral side of the left ankle in a knit cuff (either with or without the AFO per randomization) and calibrated to the child's walking pattern per manufacturer guidelines by adjusting sensitivity and cadence settings to suit individual walking patterns in each condition (AFO-ON or AFO-OFF). Calibration of the SW accelerometer is essential to accurately document differences in walking activity levels between conditions for each child. Participants were instructed to wear the SW all their waking hours for 14 days except when bathing or swimming. A home visit by the primary author was then carried out wherein the SW data were downloaded to a laptop computer. Participants then changed to the opposite intervention wear phase, and the SW recalibrated to the walking pattern of the new condition. Participants then wore the SW for 14 days and returned the monitor and cuff to study staff via postage paid envelope.

Functional gross motor level was documented using the GMFCS¹⁴ (Table 1). Sagittal plane barefoot video from the baseline visit was viewed to classify type of gait pattern according to the criteria described by Rodda et al.¹⁵ (e.g. jump, equinus or crouch) by observation of shoes only gait at midstance. Video vector gait analysis was used to assess the influence of the AFO and footwear on lower extremity alignment.¹⁶ A still picture of midstance was printed from the sagittal video and bilateral shank-to-vertical angles (SVAs) manually measured (Figure 1). Inter-rater reliability (percent of absolute agreement) of SVA measures between the primary author and a research assistant was 95% across 66 pictures.

Community-based walking activity was examined with the SW. The SW is designed to record steps in each time interval by identifying the magnitude and timing of multi-axial accelerations that occur with each step, usually foot-off, but sometimes other gait events. Accuracy of calibration to individual walking patterns and treatment conditions was checked against visual observation of stride counts during a 100+ stride walking trial wearing the SW. Strides were manually counted with a hand held counter and compared to the SW recording of strides. A ratio of agreement was taken and averaged. Accuracy to manual counts and comparison to other pedometers confirms the accuracy and precision of the SW for detecting strides taken.¹⁷ The primary outcome of walking activity level was summarized through average total strides per day. Secondary outcomes were percent daytime hours walking and walking intensity captured by number of strides taken at a rate greater than 30 strides/min, peak activity index (the average of the top 30 one-minute stride counts/day), and stride activity curves.¹⁸

Participants were randomized to start with (AFO-ON) or without (AFO-OFF, with footwear only) AFO for 2 weeks, and then switch to the opposite condition for another 2 weeks. Participants wore the SW during the entire 4-week study period, therefore each participant contributed 2 weeks of SW data to AFO-ON condition and 2 weeks of SW data to the AFO-OFF condition. Consistent with published SW monitoring protocols for children,^{18–21} 5 days (4 week days and 1 weekend day) from the second week of monitoring were selected for analysis of walking activity variables.²¹ StepWatch data were considered valid for analysis if less than 3 hours of inadequate monitoring was found (e.g., monitor worn upside down) or no stride counts that were unexplained (e.g., bathing) during daytime hours (6:00 am–10:00

pm). All participants maintained their typical daily activities for the 4 weeks of monitoring (i.e., school was in session).

Demographics and clinical impairments were reported descriptively. Due to the small sample size and paired nature of outcomes, between treatment group condition (AFO-ON vs. AFO-OFF) effects were examined with the non-parametric Wilcoxon signed-rank test for paired data (α set at 0.05). To capture individual effects, between treatment condition data were plotted and examined for greater than 1 standard deviation change from the AFO-OFF condition, based on the hypothesis that the current AFO prescription would positively enhance community walking.

RESULTS

Eleven participants (S1–S11) were enrolled and completed the protocol. Average age was 4.3 years (range 3.0 to 6.0 years, Table 1). These children were classified as GMFCS levels I (n=1), II (n=9) and III (n=1) with gait patterns characterized as equinus (n=5), jump (n=3) and crouch (n=3). Current orthoses included SAFOs (n=4) with ankle angle in the AFO ranging from -5° (plantar flexion) to 0° (neutral/plantigrade), non-articulated AFOs with plantar flexion (PF) stop at neutral (i.e., 90°) and free dorsiflexion (DF) (n=3), hinged AFOs with a range of 0° PF to 15° DF (n=3), and supramalleolar orthoses (n=1). All participants wore tennis shoes with round soles and negative heels, except 1 who had a flat sole and point loading rocker at approximately 85% of shoe length (S11).

Two participants (S3, S11) had wedging of the sole of their shoes to optimize the SVA during static standing and midstance per their clinical orthotist/therapist prescription. Based on a published orthotic management algorithm, an optimized SVA during static standing and midstance of walking is when the shank is inclined to allow the knee to be over the toes and thigh vertical.²² For the AFO-OFF condition, midstance SVAs ranged from -5° (reclined) to 32° (inclined) across all limbs (Table 1). Calibration accuracy of SW stride count to manual stride count averaged 100% (range 94–108) across all treatment conditions.

No significant difference was found in the primary outcome of average daily total step count between AFO-ON and AFO-OFF ($P = .48$). The between treatment condition comparison of the secondary outcomes percent of time walking each day, average number of strides each day > 30 strides/min, peak activity index, and stride rate curves showed no significant differences ($P = .33 - 0.79$, Table 2, Figure 2).

Within subject comparison using the criterion of greater than 1 standard deviation change from AFO-OFF condition identified 2 children (18%) who took a greater number of steps/day with AFO-OFF (S4 & S10) and 2 (18%) who did better with AFO-ON (S3 & S11, Figure 3A). For percent time walking each day, 4 (36%) participants walked more each day with AFO-ON (S1, S3, S8 & S11) and 1 (9%) walked more with AFO-OFF (S10, Figure 3B). Number of strides/day > 30 strides/min and peak activity index were greater during the AFO-ON condition for 2 participants (S3 & S11) and less for 1 (S2, Figure 3C/D). Only 2 subjects (S3 & S11) increased both walking activity level (number steps/day, percent time

walking) and intensity (number of strides/day > 30 strides/min, peak activity index) with AFO-ON.

DISCUSSION

We did not find consistently favorable community based walking activity outcomes for the AFO-ON condition compared to the AFO-OFF condition. The within subject analysis showed large variability in outcomes between the 2 conditions. This variability may be a function of a general lack of consistency in orthotic prescription based on gait pattern and biomechanical impairments. This includes multiple orthoses employed for the same gait pattern, heterogeneity of the study sample and/or the general population of children with CP that are ambulatory, and the lack of individualization of shoes and SVAs. The results of this pilot study suggest that the majority of participants were not currently wearing orthoses and/or footwear prescriptions that positively influenced their daily walking activity levels or the secondary outcomes of walking intensity. The 2 subjects for whom the SVA was explicitly optimized (1 with a shoe modified to have a point loading rocker) demonstrated a positive effect of AFO/footwear use on daily walking levels. This positive effect was also documented for the secondary outcomes of walking time and walking intensity for these 2 subjects.

AFO management in CP must positively influence day to day walking activity. As compared to children who are TD, youth with CP take significantly fewer strides each day and spend less time walking.²⁰ Relative to intensity or patterns of walking, youth that are TD spend a similar number of strides and/or time at low (1–30 strides/min) and moderate rates (30–60 strides/min), whereas the day-to-day walking of youth with CP is predominately at low rates.²⁰ Recent work has documented a positive association between daily walking levels and intensity with mobility based participation in daily life for youth with CP.^{20,23} Also, from a public health perspective, youth with CP regardless of GMFCS level demonstrate maximal walking activity levels that are far below those recommended for overall health (60 minutes/day of moderately vigorous activity).^{20, 24}

The orthoses worn by the children in this study, were not in accord with previously published algorithms matching orthoses to gait pattern.¹⁵ Our data suggest that several subjects were currently wearing prescriptions that did not address the segmental biomechanical limitations of their presenting gait pattern (S2, S6, S9 and S10). For example, subjects 2 and 10 with crouch gait patterns were wearing hinged AFOs that would be unable to limit excessive tibial progression during stance. A child with a crouch gait pattern, per published algorithms, should be prescribed a device that limits shank inclination during midstance (e.g. a SAFO). Assuming that the remaining subjects (S1, S3, S4, S5, S7, S8, & S11) were wearing orthoses that had potential to address their individual gait impairments, only 2 participants (S3 & S11) had a greater than 1 standard deviation change in walking activity levels and intensity during the AFO-On versus the AFO-OFF condition.

Numerous authors have proposed theoretical guidelines for the optimal SVA for standing and walking in SAFOs.^{25–27} These proposed recommendations range from "slight incline" and "knee cap over metatarsalphalangeal joints", to specific ranges, e.g. 7 to 10° incline. In

1972, Glancy and Lindseth, based on visual gait analysis, proposed 3–5 degrees of incline.²⁸ In 1992, Hullin et al. proposed 0 degrees with a rocker sole and 10° incline without a rocker sole.²⁹ Owen reported SVA tuned to optimum alignment using video vector analysis of ~ 7–15° (mean 11.4°).³⁰ Most recently, Jagadamma et al. proposed an average SVA of 10.8° incline based on gait analysis in youth with CP.^{31,32} The individual SVA data for the 4 subjects in this study wearing SAFOs (S3, S7, S8 & S11) were broader than the values reported in the literature, which may have contributed to our observation of an inconsistent positive group effect on walking activity.

These results support the need for further research on the effect of AFO/footwear prescription relative to the gait pattern and physical and neuromotor impairments of each limb for each client. This concurs with emerging recommendations that the SVA needs to be individualized for each leg within each patient depending on their gait pattern and diagnosis.³³ Orthotic management also needs to account for footwear as an influencing factor in the functional outcomes of an individualized prescription. If future work confirms the influence of footwear on walking outcomes, fiscal and policy implications will follow since footwear are not traditionally reimbursed in some countries (e.g. United States).

Study limitations should guide the interpretation of these pilot data. First, the sample size is small and maybe under powered to find true differences between treatment conditions. While the randomized cross-over design does somewhat mitigate this issue, a larger sample size is needed to corroborate these findings. Clinical heterogeneity of this study sample and the broader population of children with CP who are ambulatory could confound the effect of AFO use on walking activity outcomes. More work is needed to understand the influence of the SVA and shoe modifications within orthotic management. Such studies would be enhanced by use of full kinetic and kinematic analyses in addition to step activity monitoring. A key strength of this project was that the type of monitoring used, which can be feasibly implemented in clinical practice, allowed walking activity to inform orthotic management. In contrast to much of the literature, this study describes specific components of each individual's AFO/footwear, facilitating interpretation and/or clinical translation of the results.

Monitoring of walking activity performance during orthotic management has the potential to document the functional effect of orthoses within the context of day-to-day life in children with CP who are ambulatory. Measurement of the SVA from still frames of sagittal plane video has potential as a relatively low tech clinical outcome to document the influence of orthotic prescription on shank alignment during midstance. These methods can be incorporated within the orthotic fitting process to ensure the correct prescription and/or shoe modifications based on observation of stance phase slow motion or freeze frame video. Shoe modifications and optimization of SVA during all phases of gait warrant further research to understand the biomechanical mechanisms of action and clinical indications.

CONCLUSIONS

This pilot study documented inconsistent influence of clinically prescribed AFO/footwear use on the primary outcome of day-to-day stride levels in a cohort of children with bilateral

CP presenting with the 3 common gait patterns observed in this population. Varying results were observed for secondary outcomes of time spent walking each day and walking intensity. Contrary to our clinical intuition, the within-subject analysis of this study sample suggests that use of clinically prescribed AFO/footwear may be negatively associated with daily stride activity. However, the 2 participants for whom SVA was explicitly optimized (1 with a shoe modified to include a point loading rocker) documented positive changes in both daily walking levels as well as intensity. Future work is warranted to document the outcomes of clinical orthotic management in children with CP. This work should focus on defining the essential clinical factors of individualized orthotic prescription in order to optimize daily walking activity and function.

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Figure 1.
Shank to vertical angle (SVA) at midstance phase of gait.

Figure 2.

Walking stride rate curves for AFO-ON and AFO-OFF conditions (n=11). These curves are the mean group trajectory of minutes spent at increased stride rates (solid and open circles) and 95% confidence interval (vertical lines).

Figure 3.

StepWatch walking activity data comparing AFO-ON and AFO-OFF. (A) Average daily total steps count. (B) Percent of active time walking. (C) Average number of strides > 30 strides/min. (D) Peak activity index. Red arrows indicate greater than 1 standard deviation improvement with AFO-ON. Yellow arrows indicate greater than 1 standard deviation improvement with AFO-OFF. Red circled data indicates participants with shank to vertical angle addressed in prescription. One standard deviation of change is based on the group AFO-OFF condition.

Table 1

Subject and intervention characteristics.

Subject	Age (y)	GMFCS	Gait Pattern ¹⁵	Bilateral Orthosis Design	Shoe Profile	Midstance SVA AFO-OFF/footwear ^{**} (Right/Left)	Midstance SVA AFO-ON/footwear ^{**} (Right/Left)
1	5.0	II	True Equinus	Non-articulated AFO 0° PF stop, free DF Flexible toe plate	Negative heel, round sole	-4°/-2°	3°/5°
2	6.0	II	Crouch	Hinged AFO 0° PF stop, 15° DF Flexible toe plate	Negative heel, round sole	20°/28°	20°/22°
3	3.0	I	True Equinus	Solid AFO (SAFO) Angle of ankle in AFO -5° Solid foot plate	Negative heel,## round sole	-5°/-2°	8°/10°
4	4.0	II	True Equinus	Non-articulated AFO 0° PF stop, free DF Flexible toe plate	Negative heel, round sole	0°/0°	5°/4°
5	3.8	III	True Equinus	Non-articulated AFO 0° PF stop, free DF Flexible toe plate	Negative heel, round sole	-3°/-3°	3°/5°
6	5.2	II	Jump	Hinged AFO 0° PF stop, 15° DF Flexible toe plate	Negative heel, round sole	28°/18°	28°/24°
7	3.8	II	Crouch	Solid AFO (SAFO) Angle of ankle in AFO 0° Flexible Toe plate	Negative heel, round sole	15°/20°	12°/20°
8	3.2	II	True Equinus	Solid AFO (SAFO) Angle of ankle in AFO 0° Flexible Toe plate	Negative heel, round sole	-3°/-3°	-3°/4°
9	5.8	II	Jump	Supramalleolar orthosis Flexible toe plate	Negative heel, round sole	12°/8°	10°/8°
10	4.3	II	Crouch	Hinged AFO 0° degrees PF stop, 15° DF Flexible toe plate	Negative heel, round sole	32°/15°	15°/13°
11	3.6	II	Jump Gait	Solid AFO (SAFO) Angle of ankle in AFO -5° Solid foot plate	Flat sole,## Point Loading Rocker	15°/20°	9°/9°

Abbreviations: GMFCS= Gross Motor Function Classification System; AFO = ankle foot orthosis; DF- dorsiflexion; PF- plantar-flexion; SVA= Shank-to-Vertical Angle

** Positive number in degrees from vertical = inclined shank, negative number in degrees from vertical = reclined shank.

- SVA optimized.²²

Table 2

Average (1 standard deviation) of StepWatch variables by intervention condition.

StepWatch Variables	AFO-ON	AFO-OFF	<i>P</i> value *
Primary Outcome: Average total strides/day	4660 (1421)	4897 (1438)	.48
Secondary Outcomes: Percent daytime hours walking	.49 (.07)	.46 (.08)	.33
Average number of strides > 30 strides/min	1918 (1025)	1986 (1075)	.66
Peak activity index	43.6 (6.5)	44.1 (7.4)	.79

* Paired Wilcoxon signed-rank test

Abbreviation: AFO = ankle foot orthosis