Do dynamic ankle foot orthotics (DAFO) improve gait in pediatric patients with spastic diplegic cerebral palsy (CP)?

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Do dynamic ankle foot orthotics (DAFO) improve gait in pediatric patients with spastic diplegic cerebral palsy (CP)?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not dynamic ankle foot orthotics (DAFO) improve gait in pediatric patients with spastic diplegic cerebral palsy (CP).

STUDY DESIGN: Review of two randomized controlled trials with crossover from 2009 and 2015 and one blinded randomized controlled trial from 2006.

DATA SOURCES: All articles were presented in English and were taken from peer reviewed sources using PubMed and Google Scholar. All articles were published between 2006-2016.

OUTCOMES: Outcomes of investigation measured are quantitative walking velocity measured via gait analysis and functional ability during ambulation using the Gross Motor Function Measurement-88 scoring system.

RESULTS: Wren et al found that there was a statistically significant increase in walking velocity while wearing DAFOs when compared to walking barefoot and also with different type of ankle foot orthoses. Bjornson et al found statistically significant improvements in the Gross Motor Function Measurement-88 scores when wearing DAFOs than when barefoot or wearing a simulated placebo device. Smith et al. found overall improvements in gait while wearing DAFOs and an increase in velocity after consistent month-long use of DAFOs, but the increase was not statistically significant.

CONCLUSIONS: These three studies show that DAFOs provide tangible benefit to individuals with spastic diplegic cerebral palsy. All 3 studies showed overall gait or functional improvements in those wearing dynamic ankle foot orthotics when compared against either themselves or age-matched controls regardless of the length of time the devices were worn with 2 of the studies showing statistically significant results. Further research can help to further clarify the efficacy of DAFOs within the pediatric population as a whole.

KEYWORDS: cerebral palsy, dynamic ankle foot orthotic

INTRODUCTION

Cerebral palsy (CP) is an overarching term for a non-progressive group of congenital neuromuscular conditions that present with universal themes of muscle hypo/hypertonicity and abnormalities in movement and ambulation.[1] It is often commonplace to see other symptoms, such as cognitive delay, respiratory comorbidities and epilepsy in individuals with CP, but it is not a requirement to have those features in order to make a diagnosis of cerebral palsy. One specific type of cerebral palsy, spastic diplegic cerebral palsy, contains hypertonicity, spasticity and movement challenges that are localized to the lower extremities bilaterally.[1] Hypertonic muscles in the lower extremities contribute to challenges in ambulation that may impair one's ability to ambulate, overall function and ultimately their quality of life.

Unfortunately, cerebral palsy is one of the most common congenital birth defects with an incidence of 2.11 per 1000 births.[2] While there are many types of CP, spastic diplegia is the most common.[2] Although it is not known exactly what mechanism causes CP, each case does have one thing in common: brain injury immediately prior or during delivery that causes an anoxic or hypoxic state leading to neuronal injury or death.[3] Most individuals with cerebral palsy are born premature and subsequently require specialized care within neonatal intensive care units due to underdevelopment of critical structures, most commonly their lungs and its ability to produce surfactant. Although non-progressive nor terminal, cerebral palsy does require additional management throughout a person's life in order to maintain functionality and quality of life.[4] While the condition as a whole does not progress, symptomatic management is the main focus. To achieve this, individuals with cerebral palsy must utilitze healthcare services more frequently than the average individual. Data shows that pediatric patients with cerebral palsy visit outpatient providers 2.2 times more and are hospitalized 4.3 more often than their able-bodied peers.[5] In fact, it is estimated that it costs an extra $80,000 in addition to normal lifetime costs to care for someone with cerebral palsy.[6]

There are no true diagnostic tests or studies that can diagnose cerebral palsy as a whole. It is instead a clinical diagnosis that in the very young can be subtle. It is often not picked up until individuals begin to miss age-related milestones that clinicians often suspect cerebral palsy.[7] While it is often a diagnosis of exclusion, the criteria to classify cerebral palsy are defined and uniform. First, the amount of resting muscle tone that an individual has is evaluated to be either spastic (hypertonic) or non-spastic (hypotonic).[7] For spastic individuals, the body region affected is then classified (diplegia, hemiplegia, or quadriplegia).[7] Individuals with non-spastic CP are broken down by whether their movements are voluntary, involuntary or involve their whole body (ataxia, dyskinetic or athenoid).[7]

Much like there being no true diagnosis of CP of any type, there is no definitive treatment. Instead this condition is treated solely symptomatically. By definition, spastic diplegic CP contains hypertonic muscles (spastic) and affects the lower extremities bilaterally (diplegic) with little to no involvement in the upper extremities. There are many different modalities employed to limit or decrease one’s tone and improve overall function all with varying successes. While each treatment is tailored to the severity of one’s spasticity, there are many types of standard treatments that can be done for a patient ranging from physical therapy to stretching and strengthening, assistive devices (crutches, wheelchairs, orthotics), medications to reduce spasms, and various types of orthopedic surgery.[4] Of all the treatments, one of the least invasive and most commonly employed is the use of ankle foot orthotics. The orthotics are custom fitted to the patient and provide a continuous stretch of specific muscle groups, while providing support.[8] There are many different variations of these orthotics that a clinician can prescribe for a patient to serve individual needs depending on their specific gait and muscle tone. Ankle foot orthotics can range from flexible (dynamic), solid, adjustable or hinged at the talocalcaneal joint.[8,9] One orthotic type used is a dynamic ankle foot orthotic (DAFO), a non-hinged single piece flexible brace that provides support at the malleoli, while still allowing a patient to ambulate through a full gait cycle.[9] Dynamic ankle foot orthotics serve as a noninvasive way to augment other long term modalities (i.e. surgery) in improving patient’s walking speed and ambulatory function.

OBJECTIVE:

The objective of this selective EBM review is to determine whether or not dynamic ankle foot orthotics (DAFO) improve gait in pediatric patients with spastic diplegic cerebral palsy (CP).

METHODS:

Two randomized controlled trials with a crossover and a blinded randomized controlled trial were chosen for review. The patient population selected for review was ambulatory patients under the age of 18 years old with a diagnosis of spastic diplegic cerebral palsy. Interventions employed included use of dynamic ankle foot orthotics bilaterally. Depending on the study, subjects were either aged matched to controls or to themselves with appropriate washout periods. Outcomes measured were patient oriented and focused on: ambulatory velocity and functional changes in ambulation using the Gross Motor Function Measurement-88 objective scoring system.

Both Google Scholar and PubMed databases were utilized to select studies. Keywords used to search were “cerebral palsy” and “dynamic ankle foot orthotics.” The three studies selected were published in peer reviewed journals between 2006-2016 and all were written in English. In general, inclusion criteria for all three studies was the same: ambulatory pediatric patients under 18 years old with a primary diagnosis of spastic diplegic cerebral palsy. Two of the three studies provided the same exclusion criteria, subjects over 18 years of age and/or those that have undergone an orthopedic/neurosurgical or botulinum toxin A injection within 12 or 6 months of participation, respectively. Detailed inclusion and exclusion criteria, as well as other individual study characteristics, are provided in Table 1. The statistics reported in the studies and utilized for the review were p-values, X^2 and ANOVA.

Table 1. - Demographics & characteristics of included studies

Study	**Type**	**# Pts**	**Age (yrs.)**	**Inclusion Criteria**	**Exclusion Criteria**	**W/D**	**Interventions**
Smith (2009)[9]	RCT with Crossover	15 subjects 20 controls	Mean age: 7.5 ± 2.9 years (Age range not disclosed)	-Age: ≤13 years -Ambulate without assistive devices (crutches/cane etc.) - “Jump gait” pattern of walking -Baseline GMFCS-88 Score: 1 -Ability to dorsiflex ankle to neural position on PE	1. Any orthopedic or neurological surgical intervention within 12 months 2. Botulism toxin A injections within 6 months	0	Daily use of dynamic or hinge ankle foot orthotic for 4 weeks. Washout period of 2 weeks. Daily use of other ankle foot orthotic for 4 weeks
Wren (2015)[10]	RCT with Crossover	10 subjects	Ages: 4-12 years old	-Age: 0-18 years old -Crouch and/or equinus gait -Baseline GMFCS-88 Level I—III	None provided	0	Wearing dynamic ankle foot orthotics daily for 4 weeks, then wearing ADR-AFOs for another 4 weeks

Bjornson (2006)[11]	RCT with Crossover & Double Blinding	23 subjects	Ages: 1.9-7.3 years old	-Age: 12-96 months -GMFCS-88 levels 1-3 -Current use of bilateral dynamic foot orthotic with free plantarflexion -Minimum orthotic use of 4 hours per day for at least one month	1.Orthopedic or neurological surgical intervention within 12 months 2. Botulism toxin A injections within 6 months	0	Wearing sock covered DAFOs and undergoing GMFM scoring 2x and then repeating test with placebo (sock cover mimicking DAFO)

<u>OUTCOMES MEASURED</u>:

This review examined both ambulatory velocity and changes in Gross Motor Function Measurement – 88 (GMFCS-88) scores when using DAFOs bilaterally. Using a motion analysis program to track, measure and video record body motion while ambulating, velocity was calculated both with and without a DAFO. To measure GMFCS-88 scores, a licensed pediatric physical therapist scored patients both with and without the device. This objective scoring system scores patients by ability and ease to do a variety of specific functional motions (rolling, sitting, crawling, kneeling, standing, walking, running and jumping).

<u>RESULTS</u>:

Smith et al., conducted a randomized controlled trial age matched comparing 15 subjects and 20 age matched controls that were 13 years of age or younger who did not use any assistive devices to ambulate on a daily basis.[9] The authors reported a mean age of 7.5 ± 2.9 years of age. Additional inclusion and exclusion criteria are provided in Table 1. This trial examined ambulatory velocity of individuals after using DAFOs daily for 4 weeks, which allowed the participants time to adjust and become accustomed to the device. [9] Velocity was measured via motion analysis three times at the end of the 4 weeks while the participant wore DAFOs bilaterally and compared to patient's barefoot baseline and also while wearing another ankle foot orthotics after a 2-week washout period. The order in which a participant wore a DAFO or the other type of ankle foot orthotic included in the study was randomized. There was a 0% loss to follow up at the conclusion of the research.[9] The researchers used continuous data, which is provided in Table 2. The results of this study show that patient's ambulatory velocity minimally increased if one was wearing a dynamic foot orthotic or if they were barefoot. Using ANOVA, examiners found that there were no statistically significant changes in ambulatory velocity when comparing the DAFO and barefoot conditions using a $P \leq 006$ as being statistically significant but did not provide individual P-values.[9]

Table 2. – Ambulatory Velocity (m/s) at baseline and with DAFO use

Condition:	**Mean and Standard Deviation**
Baseline (Barefoot)	1.01 ± 0.6
DAFO	1.11 ± 0.6
Mean Change in Velocity	0.10 ± 0.0 ($P \leq 006$)

Wren et al. directed a randomized controlled trial with crossover that looked at ambulatory velocity of 10 children (40% male, 60% female) between 4-12 years old with differing baseline GMFCS-88 scores against age matched controls while wearing custom fitted DAFOs, other custom fitted orthotics and barefoot.[10] Both orthotic types were worn for 4 weeks without a washout period. As is shown in Table 1, the inclusion criteria included baseline gross motor function scores of I-III and either a crouch or equinus pattern gait.[10] The distribution of GMFCS-88 baseline classifications is shown in Table 3. 4 of the subjects who were classified as GMFCS-88 level III and used assistive devices as their baseline and were permitted to use them during the testing.[10] There was 0% loss to follow up throughout the trial and participants reported no adverse effects. The data was reported as continuous and is shown in Table 4. This research shows that there was a statistically significant increase (P = .006; CI: 95%) in ambulatory velocity when using DAFOs than when compared to their barefoot baseline.

Table 3: Number of Participants based on GMFCS-88

Baseline Gross Motor Function Classification Score	**I**	**II**	**III**
Classification Level Interpretation[11]	Walks without restrictions; some limitations with running/jumping	Walks with assistance from surrounding and /or crutches	Walks with assistance of walker and/or crutches
Number of Participants	6	0	4

Table 4: Mean Ambulatory Velocity (m/s)

	Barefoot (Mean ± SD)	**DAFO (Mean ± SD)**	**Mean Change**
Velocity (m/s)	0.72 ± 0.34	0.78 ± 0.34	0.06 ± 0.00
Statistical Measures			P =.006 (CI: 95%)

Using a double blinded randomized controlled trial, Bjornson et al examined 23 participants with differing GMFCS-88 score baselines to evaluate any changes in GMFCS-88 scores when barefoot and while wearing bilateral DAFOs.[12] Each participant had used bilateral DAFO daily prior to participation in the research. DAFOs or placebo orthotics were applied to the participant and covered with athletic wear to allow for blinding from a physical therapist scoring each participant.[12] Subjects ranged from 1.9 –7.3 years of age. Each participant was scored on 3 different activity categories using the GMFCS-88 scoring system: crawling/kneeling, standing, and walking/running/jumping. Each category contains a certain number of specific tasks and movements that patients are asked to complete. Continuous data was collected and the results of the "walking/running/jumping" category are shown in Table 5. [12] This research shows that there was an increase in the participants' level of function in terms of running, jumping and walking. The p-value and chi squared calculation demonstrate that the increase is statistically significant and that participants demonstrating higher scores on the GMFCS-88 are not due to chance, but instead due to an association between the intervention (DAFO use) and ambulation.

Table 5: Average GMFCS-88 Scores for Walking/Running/Jumping

Condition	**(Mean ± SD)**
Barefoot	19.9 ± 17.7
DAFO	26.4 ± 23.6
Difference (DAFO – Barefoot)	6.5 ± 5.9
P- Value:	<.001
X^2	6.7

Unlike other medical treatments, in which treatments are invasive or absorbed via a medication, dynamic ankle foot orthotics are noninvasive and external. Their effects are immediate and the effectiveness is dependent on wearing the devices. As a result, none of the reviewed studies reported any adverse effects or safety concerns.

DISCUSSION:

The content of this evidence based systematic review focused on if dynamic ankle foot orthotics affect ambulatory function and speed of pediatric patients with spastic diplegic pattern cerebral palsy. Orthotics, as a whole, are considered exempt from regulation by the Food and Drug Administration.[13] Instead, indications for the appliances originate directly from insurance companies. Generally, dynamic foot orthotics are indicated for individuals with a plantar flexion spasticity and contracture upon passive dorsiflexion.[14] From the perspective of cerebral palsy, DAFOs are indicated in ambulatory individuals who require ankle support due to weak dorsiflexor muscles, but are able to plantarflex without assistance.[8] There are no absolute contraindications for the use of dynamic ankle foot orthotics as they will not cause harm to a patient, but they are ineffective in certain cases, such as individuals with a "foot drop" that do not have ankle contractures.[13]

Through researching the topic, there were a few study limitations that could have impacted the review. One limitation revolved around the fact that there are many types of ankle foot orthotics making selection of studies that met all criteria challenging. Additionally, each of the studies chosen had small sample sizes and none of them utilized patients between 14-18 years of age, which would still be considered pediatric patients. As the age ranges of the selected studies examined young children through adolescents, it may be difficult to generalize the results towards teenagers. Larger sample sizes with a wider age range would provide more evidence about the effects or lack thereof of DAFOs on ambulation in the pediatric spastic diplegic cerebral palsy population.

CONCLUSION:

As a whole, the evidence shows that dynamic ankle foot orthotics have a positive impact on ambulation velocity and functional ability in pediatric patients with spastic diplegic cerebral palsy but further research is necessary to confirm the relationship. Both of the studies examining ambulation velocity showed increases when wearing the orthoses, but only one study showed a statistically significant increase.[9,11] Smith et al, only used participants with a Gross Motor Function Classification Score of I, which may have influenced the outcomes as these participants are the highest functioning and may not benefit from the devices.[9] Bjornson et al, proved a statistically significant increase in the Gross Motor Function Classification System-88 score for the walking/running/jumping category.[12] While this is only one study showing significant improvements in functional scoring, it is important for future research to be completed to further validate this increase in ambulatory function. Additionally, it is important to examine more age groups (older adolescents and young adults) to determine whether the effects are as profound as they are in the young pediatric population.

Reference List

1. Rosenbaum P, Paneth N, Leviton A, et al. A report: The definition and classification of cerebral palsy April 2006. *Dev Med Child Neurol Suppl*. 2007; 109:8-14.

2. Oskoui M, Coutinho F, Dykeman J, Jette N, Pringsheim T. An update on the prevalence of cerebral palsy: A systematic review and meta-analysis. *Dev Med Child Neurol*. 2013;55(6):509-519. doi: 10.1111/dmcn.12080 [doi].

3. Barkoudah E, Glader L. Epidemiology, etiology, and prevention of cerebral palsy. UpToDate. 2017. Available at: https://www.uptodate.com/contents/epidemiology-etiology-and-prevention-of-cerebral-palsy. Accessed December 2, 2017.

4. Patterson MA. Management and prognosis of cerebral palsy. In: UpToDate, Bridgemohan C (Ed), UpToDate, Waltham, MA. Updated 2016 (Accessed on September 28, 2017.)

5. Young NL, Gilbert TK, McCormick A, et al. Youth and young adults with cerebral palsy: Their use of physician and hospital services. *Arch Phys Med Rehabil*. 2007;88(6):696-702. doi: S0003-9993(07)00198-0 [pii].

6. Centers for Disease Control and Prevention (CDC). Economic costs associated with mental retardation, cerebral palsy, hearing loss, and vision impairment--united states, 2003. *MMWR Morb Mortal Wkly Rep*. 2004;53(3):57-59. doi: mm5303a4 [pii].

7. Patterson MA. Evaluation and diagnosis of cerebral palsy. In: UpToDate, Bridgemohan C (Ed), UpToDate, Waltham, MA. Updated 2017. (Accessed on September 28, 2017.)

8. David K. Using evidence to select an ankle foot orthosis (AFO) for children with cerebral palsy. Alexandria: American Physical Therapy Association; 2008. Available at: https://pediatricapta.org/includes/fact-sheets/. Accessed December 3, 2017.

9. Smith PA, Hassani S, Graf A, et al. Brace evaluation in children with diplegic cerebral palsy with a jump gait pattern. *J Bone Joint Surg Am*. 2009;91(2):356-365. doi: 10.2106/JBJS.G.01369 [doi].

10. Wren TA, Dryden JW, Mueske NM, Dennis SW, Healy BS, Rethlefsen SA. Comparison of 2 orthotic approaches in children with cerebral palsy. *Pediatr Phys Ther*. 2015;27(3):218-226. doi: 10.1097/PEP.0000000000000153 [doi].

11. Daher M, Martins P, Esperidião A et al. Relationship between function and presence and type of deformity in patients with cerebral palsy. *Coluna/Columna*. 2016;15(4):275-278. doi:10.1590/s1808-185120161504157842.

12. Bjornson KF, Schmale GA, Adamczyk-Foster A, McLaughlin J. The effect of dynamic ankle foot orthoses on function in children with cerebral palsy. *J Pediatr Orthop*. 2006;26(6):773-776. doi: 10.1097/01.bpo.0000242377.10596.0f [doi].

13. Code of Federal Regulations. Silver Spring: U.S. Food and Drug Administration; 2001.

14. Ankle orthoses, ankle-foot orthoses (AFOs), and knee-ankle-foot orthoses (KAFOs). Clinical Policy Bulletins. 2001. Available at: http://www.aetna.com/cpb/medical/data/500_599/0565.html. Accessed December 3, 2017.