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Introduction

Supramalleolar orthoses (SMOs) are commonly prescribed devices for young children who present with benign hypotonia and excessive pronation, or *flexible pes planus*. Flexible pes planus is one of the most common deformities in young children. It can be described as "generalized ligamentous laxity in the foot... in which the foot has an abnormally low or absent arch. The heel shows excessive eversion during weightbearing, and the forefoot is usually abducted, producing a midfoot sag with lowering of the longitudinal arch, so that the talar head and navicular tuberosity appear to be in contact with the floor and to participate excessively in weightbearing (1)." Although clinicians and parents have reported anecdotal improvements in function with the use of SMOs, there is a lack of research demonstrating their effect in the pediatric low tone population.

Among clinicians, ideas on the proper treatment of flexible pes planus without other associated pathologies vary from observation only, to physical therapy, to orthotic management. There is disagreement among researchers as to whether foot orthotics (FOs) change the course of development of the arch. Bordelon found that custom molded FOs help allow an improved arch to develop with growth (2). In contrast, controlled prospective studies by Gould et al. and Wenger et al. failed to demonstrate any influence of the effect of shoe modifications and FOs on the development of the arch (3,4). However, none of these studies examined the effect on the child's function while wearing the foot orthotics, nor did they investigate the effect of SMOs.

Some studies have investigated the functional effect of orthoses on excessive pronation in children (5,6,7,8). Martin specifically targeted the Down syndrome population wearing flexible SMOs (SureStep^{TM1}), and used subjective measures (Gross Motor Function Measure and Bruininks-Oseretsky Test of Motor Proficiency) to evaluate the effect on postural stability. Martin found that postural stability improved immediately with use of SMOs and further improved after seven weeks of wear (5). Pitetti et al. studied the effect of non-custom dynamic FO's (PattiBob®²) on locomotor skills of children with motor delays secondary to cerebral palsy, Down syndrome, and developmental delay. Pitetti et al. also used a subjective evaluation measure (Peabody Developmental Motor Scales Test, 2nd edition), which showed a small improvement in the developmental delay group after one week of using FOs, and further improvement after two months (6). Small but non-significant improvements were seen in the Down syndrome and cerebral palsy population (6). Selby-Silverstein et al. investigated the immediate effect of custom-molded FOs on foot alignment in children with Down syndrome using force plates and a motion analysis system. Custom FOs were found to reduce heel eversion, increase internal rotation of the leg, and decrease

¹ SureStep is a product of Midwest Orthotic & Technology Center. South Bend, IN.

² PattiBob is a product of Cascade Dafo, Inc. Ferndale, WA.

walking speed (7). Selby-Silverstein also reported more consistent foot function in gait (7). Through a video and force plate gait analysis, Leung et al. showed that maximum hindfoot eversion and the percentage of stance time spent in hindfoot eversion were decreased in children with flexible pes planus using custom University of California Berkeley Laboratory (UCBL) orthoses (8).

The purpose of this study was to examine the gait of children with flexible pes planovalgus associated with benign hypotonia who are using bilateral SMOs, compared to a baseline shoes-only condition. It is hypothesized that, in-orthosis, velocity, cadence, and step length will increase, whereas step time will decrease as compared to the shoes only condition.

Methods

Six children, two males and four females, were recruited from the offices of Scheck and Siress Prosthetics, Orthotics, and Pedorthics in the Chicago metropolitan area. The mean age of the subjects was 4.2 years old (range: 2.5 to 5.5 years old). Subjects had a diagnosis of bilateral flexible pes planovalgus and associated low muscle tone and developmental delay. All subjects were required to be independent ambulators and existing users of bilateral SMOs. Subjects were screened and excluded if any of the following were present: soft tissue contractures, knee hyperextension, congenital bony anomalies, neurological involvement or any confounding diagnoses such as Down syndrome, cerebral palsy, or spina bifida. Legal guardians of the subjects provided informed consent prior to participating in the study.

The design characteristics of the SMOs were controlled and maintained consistent. All SMOs were custom-made and cast using similar techniques. The SMOs were fabricated with 3/32" copolymer³ plastic and had dorsum flaps, flexible toe plates, toe pads, and vertical hindfoot posts.

Prior to gait testing, a physical evaluation of each subject was conducted including a passive range of motion test and an estimate of calcaneal valgus in a weight bearing position. Additionally, the guardians were asked to complete a subjective survey on the efficacy of the SMOs.

Two different conditions were tested with six subsequent trials each: walking in shoes only and walking in bilateral SMOs and shoes. All data was collected on the same day using the GaitRite®⁴ electronic walkway (9). For all trials, the subjects were instructed to walk at a natural comfortable velocity beginning one meter before the walkway and continuing for one meter beyond the end of the walkway. Cueing a subject to begin walking was permitted but no contact with the subject was allowed. If a subject began to run during a trial, data was discarded and the trial repeated. Subjects were allowed to rest for five minutes between the two test conditions. The order of the two tests was alternated to ensure randomization of the data collection. Guardians were present for all testing.

Velocity, cadence, step time, and step length were analyzed. Averages and standard deviations were calculated for each subject, and paired t-tests were implemented to determine statistical significance.

³ Copolymer plastic 3/32" from Cope Plastics, Inc. Godfrey, IL.

⁴ GaitRite® is a product of MAP/CIR, Inc. Haverton, PA.

Results

At the time of testing, subjects had been using SMOs for an average of 22.0 months (range: 5 to 40 months). The mean age at which the subjects began to walk independently was 19.1 months (range: 18 to 21 months). The means and standard deviations for velocity, cadence, step length, and step time for both testing conditions are presented in Table 1.

The results show that, with SMOs, mean velocity increased by 12%, cadence increased by 8%, stride length increased by 7%, and left and right step times decreased by 5%. The increases in cadence, left step length and stride length were statistically significant ($p \le 0.05$). The increase in velocity was not found to be statistically significant, however, *p*-values were approaching statistical significance. There was no significant difference in the change in step time. Plots of velocity, cadence, bilateral step length and bilateral step time comparing the two conditions are presented in Figure 1.

Additionally, in the subjective surveys on the effect of the SMOs, all guardians reported that the SMOs improved the child's quality of life in one or more capacities including improved balance, greater endurance, ability to better keep up with peers, and ability to jump when wearing SMOs.

Discussion

The purpose of this study was to examine the effect of SMOs on the gait of children with excessive pronation. The hypotheses that cadence and step length would increase have been supported, however, there was not statistical significance to support the hypotheses that velocity would increase and that step time would decrease.

This is the first study known to these authors to investigate the changes in gait of children using SMOs to control excessive pronation associated with benign hypotonia in the absence of other pathologies such as Down syndrome. Increased cadence and step length are evidence that SMOs have a positive functional impact on the gait of these children. Although not significant, a trend in increased velocity was seen, which can also improve function and the ability of patients to keep pace with their able-bodied peers. Due to the limited number of subjects, statistical significance may not have been achieved for some of the changes observed. Continuation of subject recruitment is necessary to achieve appropriate statistical power.

Confirmation of these hypotheses would provide objective, empirical data to support the use of SMOs for children with benign hypotonia and flexible pes planovalgus. The long-term effect of FOs and SMOs on a child's arch may remain unknown, but these children may derive an immediate functional benefit that justifies the prescription of SMOs.

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associated percent changes between test conditions						
	Shoes		Shoes and		Percent	<i>p</i> -
Variable	Only		SMOs		Change	value*
	Mean	<u>SD</u>	Mean	<u>SD</u>		
Velocity (cm/s)	95	10	107	9	+ 12%	0.08
Cadence (steps/min)	130	10	140	8	+ 8%	0.03
Lt Step Length (cm)	44	3	47	3	+ 6%	0.04
Rt Step Length (cm)	45	4	48	3	+ 6%	0.08
Stride Length (cm)	89		94		+ 7%	0.05
Lt Step Time (s)	0.48	0.04	0.45	0.04	- 5%	0.27
Rt Step Time (s)	0.47	0.47	0.44	0.03	- 5%	0.29

Table 1: Means and standard deviations for gait variables and associated percent changes between test conditions

*Calculated from paired t-tests comparing shoes only to SMO condition

Figure 1.



Figure 1: Six plots representing the means and standard deviations for velocity, cadence, bilateral step length and bilateral step time with SMOs compared to a shoes-only baseline for each individual subject.