RESEARCH ARTICLE

Single-Subject Design Study of 2 Types of Supramalleolar Orthoses for Young Children With Down Syndrome

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Purpose: This study examined the effects of 2 types of supramalleolar orthoses on gross motor skills of young children with Down syndrome. **Methods:** Two children participated in this prospective single-subject, alternating treatment design with 3 conditions: baseline phase with shoes but without orthoses (A), first intervention phase (B1), and second intervention phase (B2). The Gross Motor Function Measure was used to collect data on motor skills. The 2-standard deviation band method was used for data analysis. **Results:** Both children demonstrated improvement, using the SureStep compared to shoes only, and 1 child also improved with the DAFO #4. Both families chose to continue using the SureStep at the conclusion of the study. **Conclusions:** Orthoses for young children with Down syndrome continue to be the standard of care; however, research has yet to confirm the most effective type of orthosis or when developmentally to introduce orthoses. **(Pediatr Phys Ther 2012;24:278–284)** *Key words: child, Down syndrome, foot, motor skills, orthoses, postural balance*

INTRODUCTION

Down syndrome (DS) is a genetic condition with an incidence estimated at 1 in 800 live births.[1] Physical deficits inherent with DS include hypotonia, joint instability from ligamentous laxity, postural control deficits,[2,3] musculoskeletal deformities,[4] and cardiopulmonary anomalies.[5] Although the sequence of skill acquisition in children with DS is similar to that in children who are developing typically, achievement of early motor milestones has been estimated to take an average of twice as long for a child with DS when compared with age-matched peers who are developing typically.[2,3,6,7] Proper lower extremity alignment and strength and the interplay of the various body systems are required to achieve efficient upright mobility. Joint laxity, hypotonia, and disturbances in postural control contribute to delayed mastery of skills in the upright posture for children with DS and these impairments persist beyond childhood.[2,3,6,8] Reports have indicated that delays are greatest in skills that are dependent upon postural control.[2,3,8]

In children with DS, decreased muscle tone and ligamentous laxity may lead to lower extremity malalignment and have a direct effect on the foot and ankle's shock-absorbing, propulsive, and stabilizing roles. The foot and ankle complex of a child with DS may be unable to maintain adequate stability for biomechanical efficiency. This is most often demonstrated by excessively pronated feet in standing, resulting in hind foot valgus, midfoot eversion, and forefoot abduction. This posture places the bones in an abnormal position for loading. This abnormal loading may have a detrimental effect over time on growing and remodeling bone.

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The application of forces can either improve or worsen musculoskeletal deformities, depending on the direction and amount of force and the resultant bony remodeling. Since immature bone can be extensively remodeled, correct positioning may lead to improved alignment.[9] The accelerated period of musculoskeletal growth between birth and 5 years provides a crucial period for intervention to maintain proper alignment for bony remodeling.[9] Because orthoses may improve lower extremity alignment as well as other factors, such as body awareness that may contribute to delayed acquisition of functional motor skills, the orthoses may positively affect bony remodeling, postural control, and upright activities, including gait.[4,10-12] Orthoses have been used to effectively address these issues in other populations, including children with cerebral palsy or spina bifida.[11,13,14]

The literature specifically addressing the use of orthoses for children with DS, however, provides minimal evidence of the benefits or disadvantages.[4,10,12] Genaze[10] recommends orthoses for children with DS but does not cite evidence to support this opinion. Selby-Silverstein et al[4] found that custom foot orthoses trimmed proximal to the metatarsal heads had a positive effect on gait and standing foot posture, and Martin[12] determined that immediate improvement in postural stability was noted with the use of SureStep (Midwest Orthotic and Technology Center, Inc, South Bend, Indiana) supramalleolar orthoses (SMOs).

Although the latter 2 studies included young children who were already independently walking, neither study addressed the effect of orthoses for children with DS who were not yet independently ambulating. Looper and Ulrich[15,16] studied this population, combining SureStep SMOs with a treadmill training protocol. While these authors showed that the SMOs did have a positive effect on decreasing the time spent with the trunk leaning on a support in standing[15] and the rate of walking development,[16] they suggested that SMOs should not be introduced until after the development of independent gait. Their rationale for this recommendation is based in motor learning theory and their concern that the SMOs constrain early exploration.

In summary, the evidence on the use of orthoses for children with DS is mixed. Neither the optimal type of orthosis nor the ideal time to introduce the orthosis has been conclusively proven. Thus, the purpose of this study was to examine the efficacy of and compare 2 styles of dynamic orthoses on functional gross motor skills of young children with DS. Because the literature supports the use of orthoses to improve postural stability,[4,12] it was hypothesized that participants wearing orthoses would demonstrate improved functional gross motor skills when compared with baseline performance wearing shoes only.

METHODS

Participants

Participants, recruited from an early intervention program, were 2 young children (aged 24 months and 19 months) with DS who met the following criteria: independent sitting, absence of independent ambulation, sufficient cognitive level to follow one-step commands, and absence of chronic ear infections. Independent ambulation was operationally defined as taking 3 consecutive steps without support.[16] Exclusion criteria included chronic ear infections, acute upper respiratory tract infection, or other medical conditions that impaired balance; lower extremity orthopedic issues affecting postural control; uncorrected visual impairment; and sensory deficits or tactile defensiveness that precluded the use of an orthosis.

Design

This single-subject, alternating treatment design (A1, B1, A2, B2) study lasted approximately 6 months, with 3 conditions: 2 baseline phases with shoes only (A1 and A2), the first orthotic intervention (B1), and the second orthotic intervention (B2) (Table 1). The alternating treatment design was selected to evaluate performance of functional skills with each orthosis as well as to compare performance with and without any orthoses, regardless of cooperation by the child. The independent variables were the conditions of shoes only, orthosis 1 and orthosis 2. The dependent variable was change in gross motor function over time as measured by the Gross Motor Function Measure (GMFM).

Outcome Measure

The GMFM is a criterion-referenced tool that uses typical gross motor milestones as the basis for items included for examination.[17] Originally developed for children with cerebral palsy, the 88-item version of the GMFM has been shown to be valid[18,19] and reliable[18] as a measure of change over time for children with DS. Two of the 5 dimensions (D-Standing and E-Walking, Running and Jumping) were used to evaluate upright skills. The skills in these 2 dimensions include items such as pulling to stand, cruising, independent standing, transferring from bench sitting to standing, walking, squatting, running, kicking, jumping, hopping, and going up- and downstairs. These 2 dimensions were chosen because they assess skills that might be influenced by the use of orthoses.

The test-retest reliability (within 2 weeks) of the GMFM with a sample of children with DS has been established with an intraclass correlation coefficient of 0.98

TABLE 1
Study Design and Timeframes

	Phase	Participant 1	Participant 2
Weeks 1-4	A1	Shoes	Shoes
Weeks 5-12	B1	DAFO	SureStep
Weeks 13-16	A2	Shoes	Shoes
Weeks 17-24	B2	SureStep	DAFO

Abbreviations: A1, first baseline (shoes only); A2, second baseline (shoes only); B1, first intervention; B2, second intervention.

for dimension D and 0.95 for dimension E.[19] In our study, modifications to testing procedures included the use of a parent report as recommended by Russell et al[19] in order to improve reliability of using the GMFM with children with DS. In this study, parent report was accepted to score an item if the child refused to perform the item during the testing session and when the informed clinical opinion of the researcher was congruent with what the parent reported. In addition, verbal cues and/or demonstrations were used as modifying strategies for administration of the GMFM.[18] One examiner (J.T.) performed all of the GMFM data collection. To establish intrarater reliability, all of the first baseline sessions and the initial 4 sessions in the first intervention phase for each child were videotaped and subsequently scored 1 week later (review of videotape). Session scores and videotaped scores were then compared, with a resultant intraclass correlation coefficient of 1.0.

Orthoses and Shoes

Two styles of SMOs were used in this study: the SureStep SMO (Midwest Orthotic and Technology Center, Inc, South Bend, Indiana) and the Cascade DAFO #4 Free Plantarflexion Orthosis (Cascade DAFO, Inc, Ferndale, Washington). According to the manufacturer of the SureStep (Figure 1), this orthosis is recommended for children weighing less than 85 pounds, have hypotonia, display pronation with walking or standing, and display general instability with pulling to stand and during cruising, and for children with developmental delays. It supports the foot using thin, flexible plastic that allows the device to be tightened around the foot.[20] This creates hydrostatic pressure from compression of the soft tissue, which may promote improved alignment of the lower extremity. Medial and lateral trim lines for the SureStep are unique, with the medial trim line proximal to the first metatarsal head, and the lateral trim line distal to the fifth metatarsal head to help control forefoot abduction that occurs with pronation. Each child was measured and fitted for the SureStep orthosis in his or her home by the orthotist who developed it.

The Cascade DAFO #4 Free Plantarflexion Orthosis (Figure 2) has a full-length, custom-contoured footplate fabricated from cast molds of the child's feet. Rear foot and forefoot posting is often added to the plantar surface of the footplate to achieve a neutral foot position. According to the manufacturer, the DAFO #4 is for patients who demonstrate delayed development, hypotonia, pronation, and sensory issues, and for use with high levels of floor activities requiring ankle mobility.[21] Each child was casted and fitted for the DAFO #4 by a physical therapist who attended a training session given by the Cascade company. The casts were then sent to Cascade, Inc, for manufacturing.

To diminish the effect of 1 type of orthosis upon the other, counterbalancing was implemented by randomly selecting the orthosis to use first with participant 1 and then using the other orthosis first for participant 2. In addition, properly fitting shoes were required for data collection during all phases. To negate the effect of the shoe over the orthosis, both participants wore a low cut athletic-type, lace-up style of sneaker, the soles of which were soft rubber. The same model of sneaker was worn throughout the study by both participants, with larger sizes worn to accommodate the greater bulk of the DAFO #4.

Procedures

Gross Motor Function Measure performance was recorded 1 time per week, with each session lasting approximately 30 minutes. Each testing session was performed the same day and time each week, beginning with dimension D and then dimension E. Each session also began in the same room of the house so that testing surfaces were consistent.

During the intervention phases (B1 and B2), parents were provided with a daily log sheet on which to record the duration and frequency of orthotic wearing time, with

Fig. 1. SureStep supramalleolar orthosis.

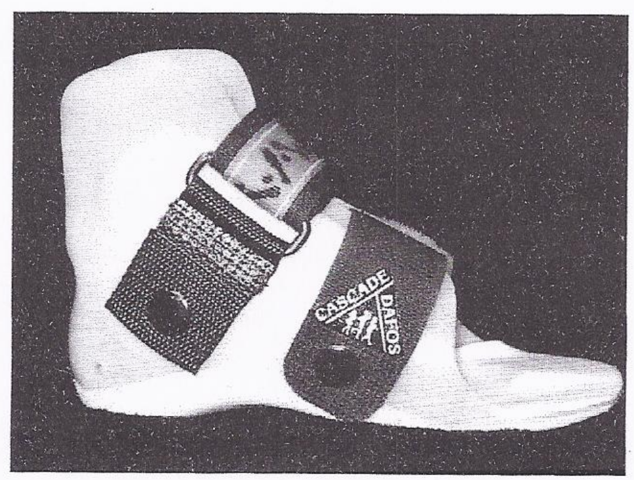

Fig. 2. Cascade DAFO #4.

a space provided for parent comments. Qualitative observations by parents regarding their child's response to the orthoses were encouraged. It was recommended that each pair of orthoses be worn daily for a minimum of 6 hours.

Data Analysis

The 2-standard deviation (2SD) band method was used to analyze the data.[22] This technique for data analysis represents the probable distribution of scores if the intervention does not produce a change in skill level. Data for each participant were first analyzed by calculating the mean and standard deviation of the raw point score of each dimension of the GMFM for each phase (Tables 2 and 3). The data points were then plotted on a graph and the 2SD band method was used to identify significant differences between the scores of the baselines and corresponding intervention phases.

Using the 2SD band method, if at least 2 consecutive data points in a phase fall outside of the 2SD band, a statistically significant change in performance occurred at $P < .05$. In addition, the parental logs of qualitative observations were consulted for tolerance to and performance of skills while wearing each orthosis. Parental logs also included daily wear time for each orthosis, with raw mean time values calculated for each orthosis for each participant.

RESULTS

Overall visual inspection of the data comparing the A1 baseline data with the first intervention phase (B1) indicated improvement in skills with the first orthosis in both GMFM dimensions for both participants (Figures 3 through 6). Both participants then remained stable in both GMFM dimensions during the second baseline phase (A2). However, in the final intervention phase (B2), participant 1 continued to show significant improvement, while participant 2 showed a significant decline in performance in both GMFM dimensions. When comparing orthotic devices, participant 1 improved with both types of orthoses but showed a larger improvement with the SureStep. Participant 2 showed improvement with the SureStep but regression of skills with the DAFO #4.

TABLE 2

GMFM Raw Point Scores for Case 1

Phase	No. of Trials	Dimension D Mean	Dimension D SD	Dimension D 2 SD	Dimension E Mean	Dimension E SD	Dimension E 2 SD
A1	4	11.00	0	0	9.0	0	0
B1	8	14.88	1.73	3.45	11.50	0.54	1.07
A2	4	15.00	.82	1.63	10.00	0.82	1.63
B2	8	23.13	3.38	6.76	14.88	2.10	4.20

Abbreviations: A1, first baseline (shoes only); A2, second baseline (shoes only); B1, first intervention (Cascade DAFO #4); B2, second intervention (SureStep); GMFM, Gross Motor Function Measure.

TABLE 3

GMFM Raw Point Scores for Case 2

Phase	No. of Trials	Dimension D Mean	Dimension D SD	Dimension D 2 SD	Dimension E Mean	Dimension E SD	Dimension E 2 SD
A1	4	0	0	0	0	0	0
B1	8	4.88	3.09	6.18	2.00	2.62	5.24
A2	4	10.25	0.50	1.0	4.75	0.96	1.91
B2	8	5.63	2.50	5.0	3.63	2.83	5.65

Abbreviations: A1, first baseline (shoes only); A2, second baseline (shoes only); B1, first intervention (SureStep); B2, second intervention (Cascade DAFO #4); GMFM, Gross Motor Function Measure.

Participant 1

Prior to the study, participant 1 was able to pull to stand and was cruising around furniture. In the first intervention phase, participant 1 wore the DAFO #4 for a mean of 7.96 hours per day. Table 2 presents the GMFM raw point score data for this child. Since the standard deviation for the baseline (A1) was zero, the 2SD band for this intervention phase is a straight line. Improvement in gross motor skills with the DAFO #4 was statistically significant for both dimensions D and E (Figures 3 and 4) when compared with the A1 phase.

During the A2 phase, the child maintained a similar level of performance from the previous phase (B1) for dimension D. The A2 mean raw score for dimension E was

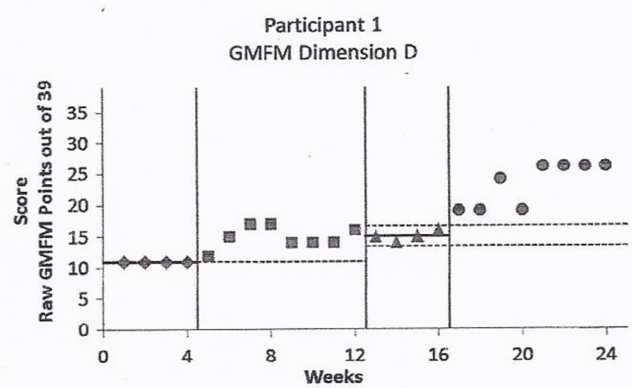

Fig. 3. Case 1–GMFM—dimension D: 2SD band analysis. GMFM indicates Gross Motor Function Measure.

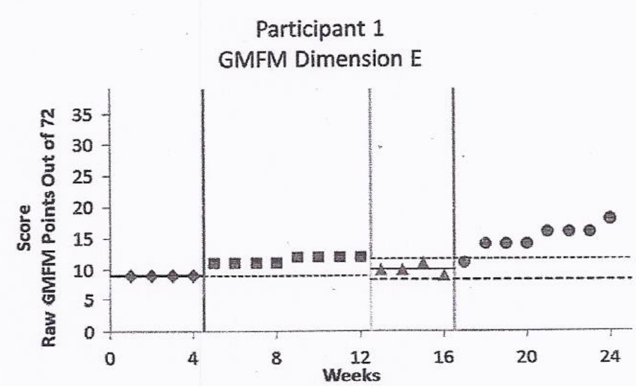

Fig. 4. Case 1–GMFM—dimension E: 2SD band analysis. GMFM indicates Gross Motor Function Measure.

lower than the mean score from B1 but was still greater than the mean score for the initial baseline phase (A1).

Following the second baseline phase, participant 1 then wore the SureStep for the B2 phase, with a mean wearing time of 10.0 hours per day. Immediately, scores increased for both dimensions D and E. Because more than 2 consecutive data points are outside the 2SD band, the improvement in gross motor skills with the SureStep was determined to be statistically significant for both dimensions D and E compared with the A2 phase.

At the conclusion of the study, this child was able to stand independently, transfer independently from sitting on a bench to standing, transfer independently from the floor to standing through plantigrade, pick up a toy from the floor and return to standing, and independently ambulate 10 steps. Parental reports indicated that the SureStep was preferred over the DAFO #4 because of the ease of donning the device, ability to use the same shoe without needing a larger size, and improved mobility in the home. The child reportedly did not demonstrate a preference.

Participant 2

Participant 2 was 4½ months younger than participant 1 and had not yet begun to bear weight in supported standing. No measurable skills were demonstrated with the GMFM during the first baseline phase (A1) for either dimension D or E (Table 3).

The first intervention phase (B1) began with the use of the SureStep, and the child wore them a mean of 7.92 hours per day. Scores immediately improved in dimension D, with scores increasing in dimension E halfway through this phase. Because the SD for A1 was zero, the 2SD band is a straight line and the changes in scores were statistically significant for both dimensions D and E with the use of the SureStep compared with the A1 phase (Figures 5 and 6).

During the second baseline phase (A2) in shoes only, performance of skills remained similar to the level of skill at the end of the first intervention phase (B1). In the second intervention phase (B2), inconsistent performance was noted for participant 2 with the DAFO #4. The child only wore the DAFO #4 an average of 0.65 hours per day during

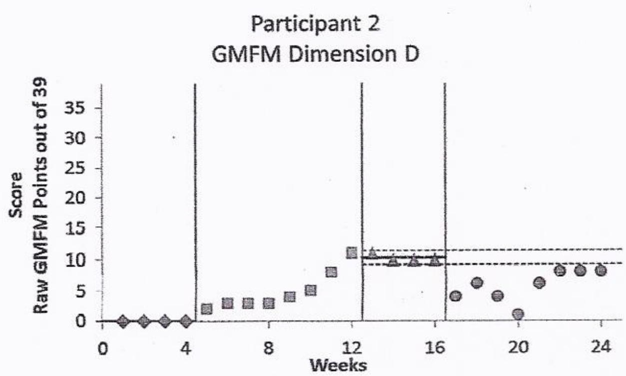

Fig. 5. Case 2–GMFM—dimension D: 2SD band analysis. GMFM indicates Gross Motor Function Measure.

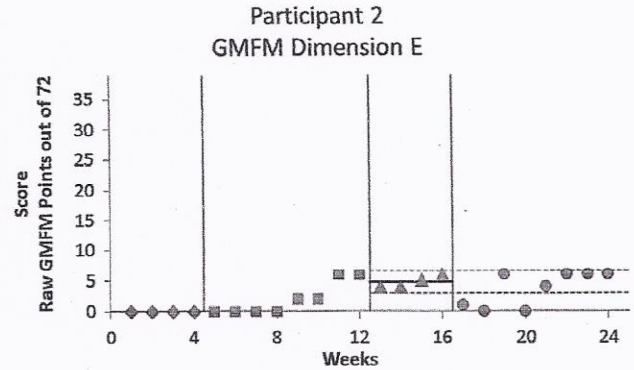

Fig. 6. Case 2–GMFM—dimension E: 2SD band analysis. GMFM indicates Gross Motor Function Measure.

the final intervention phase and, according to her mother, was very resistant to wearing this set of orthoses. By definition, a statistically significant decrease in gross motor skills was found for both dimensions during the B2 phase with the DAFO #4 compared with the A2 phase.

At the conclusion of the study, this child was able to independently pull to stand, cruise around furniture, and was initiating sit to stand from a bench. She was not yet ambulating with 2 hand-held assist. Parental reports for participant 2 indicated that the child demonstrated a preference to the SureStep orthoses, being reluctant to move about the home environment when using the DAFO #4. In addition, the parent also reported preferring the SureStep because of ease of donning.

DISCUSSION

Overall Results

Findings from this study suggest that both participants benefited from the use of orthoses in that they both acquired more gross motor skills while using the orthoses than might have been expected in the given time frame. Participant 1 initially showed significant improvement with the DAFO #4 and then significantly improved again with the SureStep. Participant 2 showed significant improvement initially with the SureStep, but a significant decrease in gross motor performance with the DAFO #4. Whereas each participant responded differently, our results support previously published reports that orthotic intervention in children with DS may improve functional gross motor skills.[4,12,16]

The results of this study are most closely related to the results reported by Martin,[12] as the current study also found improvements in gross motor skills requiring postural stability in children with DS through the use of the more flexible SureStep orthoses. The results of both studies demonstrated immediate results while using the SureStep for skills measured by dimension D. Although results with the use of the SureStep in dimension E were also positive in both cases in this study, these skills took longer to develop likely because of the complexity of the skills. Martin[12] also found an increased amount of time for statistically significant changes in more challenging skills.

Looper and Ulrich[16] also studied children with DS who were nonambulatory using the SureStep; however, their study also included treadmill training as a part of the intervention. While their results support the use of the SureStep to improve the rate of walking acquisition, they question early introduction of the orthosis from a motor learning perspective. Selby-Silverstein et al[4] used custom-made foot orthoses and examined several body structure-level variables as well as standing and gait variables. While these studies have some similarities to ours, there are also substantial differences. Overall, there is no consensus in the current literature as to the best type of orthosis or when to introduce the orthosis for young children with DS.

Previous research reports have indicated that gross motor delays in children with DS were greatest in skills dependent upon postural control.[2,3,8] The growth motor curves as reported by Palisano et al[7] confirm that children with DS take longer to acquire these more complex skills. Although a clinically important change in score on the GMFM has not been reported for children with DS (Dr Dianne Russell, written communication, 2007), a 7% change is considered a clinically important change for children with cerebral palsy.[17] In general, children with DS tend to gain more skills and at a faster rate than children with cerebral palsy; therefore, the clinically important change for children with DS would be expected to be larger than 7%. The percent change for the GMFM scores in this study ranged from 20% to 50%, which is 3 to 7 times larger than the reported clinically important change for cerebral palsy. Therefore, the magnitude of the change in GMFM scores in this study suggest they are clinically important.

One of the more interesting results in this study was maintenance of skill level during the second baseline phase. If the orthoses were providing the stability necessary to improve gross motor skills, then their removal would have been expected to decrease skills. We hypothesize that the orthoses created the circumstances for the participants to develop the motor skills that allowed them to perform better even without the orthoses. From a motor learning perspective, perhaps the orthoses provided the right mix of individual/task/environment to allow a new motor behavior to "emerge" first with the orthoses, and then that skill level was carried over without the orthoses. No studies have addressed the carryover of skills in children with DS after the removal of orthoses or the optimal length of time children need to use orthoses to maximize their gross motor skill potential. This study was not designed to completely answer these questions.

Differing Responses of Participants

Participant 1 did well with both orthoses, but participant 2 did not like the DAFO #4. The DAFO #4 was donned at the beginning of each testing session, but the child was very reluctant to be mobile while wearing the orthoses and her parents did not make her wear them. Repeated trials were implemented of donning the orthoses at various times during the day for use with functional skills. Each time, the child was reluctant to stand or even creep, yet would do so immediately upon removal of the DAFO #4. Because of this, the fit of the orthoses was reassessed. There were no problematic areas of pressure noted, and the fit, including trim lines and footplate length, was appropriate. It was thus determined that this behavior was because of preference rather than any problem with the DAFO #4, given the apparent fit and lack of skin irritation from the orthoses. The poor adherence to wearing the DAFO #4 for participant 2 makes any conclusions about its efficacy, or lack thereof, impossible.

The 2 orthoses used in this study vary in design and construction. The SureStep is thinner and more flexible than the DAFO #4. Trimlines and footplate length also vary in that the SureStep footplate ends proximal to the metatarsal heads while the DAFO #4 footplate is full length. These differences between the 2 orthoses may offer some explanation for the differences in results. The stiffer footplate and more distal medial trim line of the DAFO #4 does not allow for as much foot mobility within the orthotic device, when compared with the SureStep. This may have inhibited the use of ankle strategies for maintaining balance.

The circumferential pressure, trim lines, and flexibility of the SureStep may be the reason for the significant improvement with skills for both participants. The SureStep uses soft tissue compression to promote improved alignment yet is flexible enough to allow movement. The SureStep appears to prevent the child from being stuck in the end range of pronation and thus promotes more normal pronation and supination movements around midline. Because this flexibility allows the device to move with the foot, theoretically proprioception is also enhanced.

Additional parental qualitative observations were beneficial for identifying an overall preference by the children between the 2 orthoses. Both parents indicated in their daily logs that each child demonstrated positive behaviors when approached with the SureStep, such as lifting up a foot for donning the orthosis. In addition, the parents reported that in their opinion, their child performed overall balance and mobility skills better with the use of the SureStep. In fact, the parent for participant 1 reported that he immediately and independently transitioned from bench sitting to stand for the first time upon initial donning of the SureStep. Shoes were reportedly easier to don over the SureStep without having to increase in the shoe size, as was necessary with the DAFO #4. The parent of participant 1 reported that the DAFO #4 "slowed him down a lot so that he didn't seem to want to walk as much." Each family independently elected to continue with the SureStep following the conclusion of data collection for ease of use as well as for subjectively improved gross motor skills for their child.

Overall, the literature regarding the efficacy of orthoses for children with hypotonia continues to be sparse.

This study adds to the literature on orthoses for hypotonia by presenting the first comparison of 2 different types of SMOs; however, much is still unknown. The amount of orthotic support necessary, ideal trim lines and stiffness of the device, developmental time to introduce orthoses, and length of time for intervention are all questions that have not been fully addressed in the literature to date. Also, the available studies have primarily addressed the efficacy of orthoses at the activity level,[4,12] but no reports are available on the effect of orthoses for children with hypotonia on participation.

Limitations

Many variables are related to gross motor abilities in children with DS, such as amount of foot pronation, hypotonia, and joint laxity. The very small sample size creates a substantial limitation in that no generalization to other children with DS would be appropriate. In addition, this study does not address a comparison between orthoses above and below the malleoli. This study also does not compare custom-made versus off-the-shelf types of orthoses, and Cascade now has an off-the-shelf, more flexible SMO available that would be an interesting comparison to the SureStep. Benefit would be gained by conducting a similar study with a larger sample size and by including objective measures of gait as well. Finally, the inclusion criteria should be reconsidered in future studies. It might be appropriate to require children to be able to bear weight in supported standing and possibly cruise. This change in criteria would more closely match when orthoses are introduced typically in clinical practice. Clearly, additional research in this area is warranted.

CONCLUSION

The results for participant 1 support the hypothesis that the participant would demonstrate improved functional gross motor skills while wearing orthoses when compared with the baseline performances wearing shoes only. This was true for use with both the SureStep and the DAFO #4. The results for participant 2, however, support this hypothesis only with the use of the SureStep, as skills decreased with the use of the DAFO #4. However, no specific conclusions can be made for participant 2, given the very large differences in wear time between the 2 types of orthoses. While the use of orthoses for young children with DS continues to be the standard of care in the United States, the available evidence has yet to confirm the most effective style of orthosis or when developmentally to introduce the orthoses.

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