

Effects of supramalleolar orthoses on postural stability in children with Down syndrome

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This study explored the effects of a flexible supramalleolar orthosis (SMO), indicated to decrease pronation associated with hypotonia, on postural stability in children with Down syndrome. Seventeen children with Down syndrome (nine males, eight females; mean age 5 years 10 months, SD 17.2 months; range 3 years 6 months to 8 years) were tested three times in a 10-week period (weeks 1, 3, and 10) using the Standing and the Walking, Running, and Jumping dimensions of the Gross Motor Function Measure (GMFM), and the Balance subtest of the Bruininks-Oseretsky Test of Motor Proficiency (BOTMP). Range of motion measurements were used to explore the influence of joint laxity. Significant improvement was found with SMOs compared with shoes only in the Standing dimension ($p=0.001$) and the Walking, Running, and Jumping dimension ($p=0.0001$) of the GMFM, both at the time of fitting (week 3) and after 7 weeks of wearing SMOs (week 10). For the BOTMP Balance subtest, significant improvement ($p=0.027$) was seen only at the end of the 7-week study period. Amount of joint laxity did not influence response to orthotic intervention. This study showed that young children with Down syndrome showed immediate and longer-term (after 7 weeks of use) improvement in postural stability with the use of flexible SMOs.

Down syndrome, a genetic disorder occurring in 1.3 per 1000 live births in North America, is a common cause of neurodevelopmental disability (Harris and Shea 1991) that includes hypotonia, joint laxity, delayed achievement of motor milestones, and disturbances in postural control (Rast and Harris 1985, Shumway-Cook and Woollacott 1985, Lauteslager et al. 1998, Russell et al. 1998). In a longitudinal study, Connolly et al. (1993) found that children with Down syndrome continued to have problems with postural stability into adolescence. The neuropathology associated with Down syndrome, including a smaller cerebellum and brainstem, is thought to be a factor in these deficits (Shumway-Cook and Woollacott 1985, Connolly et al. 1993).

Improving postural stability leads to better functional motor performance (Westcott et al. 1997, Lauteslager et al. 1998). Anecdotal reports from physical therapists and parents indicate that children with Down syndrome have improved postural stability when they use orthoses. However, this belief has not consistently been supported in the literature (Knutson and Clark 1991). Only one study has investigated the use of orthoses during gait in children with Down syndrome and it showed decreased external rotation in the foot progression angle, more consistent foot function during gait, and decreased heel eversion in standing with foot orthoses (Selby-Silverstein et al. 2001).

Genaze (2000) recommended supramalleolar orthoses (SMOs) for children with Down syndrome as conventional foot orthoses are usually not sufficient to control pronation secondary to hypotonia and joint laxity; yet no study has investigated the use of SMOs in children with Down syndrome. The purpose of this study, therefore, was to determine the immediate and longer-term effects of a flexible SMO on postural stability and physical disability in children with Down syndrome. In addition, the influence of joint laxity on response to the orthoses was investigated. The primary research hypothesis was that flexible SMOs would improve postural stability in children with Down syndrome, as measured by dimensions of the Gross Motor Function Measure (GMFM; Russell et al. 1993) and the Bruininks-Oseretsky Test of Motor Proficiency (BOTMP; Bruininks 1978). Secondary hypotheses were that this effect would be greater after several weeks of wearing the orthoses and that children with Down syndrome with greater joint laxity would benefit more from SMOs.

Method

PARTICIPANTS

Participants were recruited from central and northern Indiana, USA through local parent support groups. They were eligible for the study if they met the following criteria: aged between 3 years 6 months and 10 years; diagnosis of Down syndrome; no parent-reported history of inner ear impairment or uncorrected visual impairment; ability to follow simple commands; no history of seizures; and independent ambulation for 30 yards. This study was approved by the Committee on Research Involving Human Participants at the University of Indianapolis, USA. Informed, written consent was obtained from a parent or guardian before participation in the study.

Seventeen children (nine males, eight females) with Down syndrome participated in the study between July 2002 and January 2003. Data from three children were eliminated from the final analysis: one was unable to participate appropriately in the testing, one did not tolerate the orthoses, and one was

See end of paper for list of abbreviations.

a low-scoring outlier on all dependent variables. For the 14 remaining participants, mean age at initial testing was 5 years 10 months (standard deviation [SD] 17.2 months) and range was 3 years 6 months to 8 years.

To explore the influence of joint laxity, participants were placed in two groups by creating a single variable that was the total of six range of motion measurements (right and left knee hyperextension, elbow hyperextension, and ankle dorsiflexion). The two groups were defined as more lax (those with a total laxity score of 60° or more) and less lax (those with a score of less than 60°). Because no precedent exists in the literature to grade severity of joint laxity in children with Down syndrome, these operational definitions were set after examination of the data. The range of scores for the less lax group ($n=8$) was 33 to 56° (mean 42.5, SD 9.1) and for the more lax group ($n=6$) was 64 to 124° (mean 88.2, SD 23.7).

INSTRUMENTS

Gross Motor Function Measure

The GMFM can document change over time in gross motor function. Scores are reported as a percentage of items completed (Russell et al. 1993). Only dimensions D (Standing) and E (Walking, Running, and Jumping) were used in this study because one criterion for participation was independent ambulation, thus the other dimensions had little clinical relevance. The Standing dimension examines skills that progress from pulling to stand to independent standing and picking an object up off the floor without support. The Walking, Running, and Jumping dimension examines skills that include various aspects of gait, kicking a ball, jumping, and going up and down stairs. Recommended modifications to the standard testing procedure, such as demonstration and simplified verbal cues (Gémus et al. 2001) and use of parent-report (Russell et al. 1998), were used. Russell et al. (1998) established the test-retest reliability (within 2 weeks) of the GMFM for a sample of children with Down syndrome with an intraclass correlation coefficient of 0.98 for the Standing



Figure 1: Flexible supramalleolar orthosis.

dimension and 0.95 for the Walking, Running, and Jumping dimension.

Bruininks-Oseretsky Test of Motor Performance

The BOTMP is an evaluative tool that has shown that children with Down syndrome perform poorly in the areas of Running Speed and Agility, Balance, Strength, and Visual Motor Control (Connolly and Michael 1986, Connolly et al. 1993). The current study used only Balance and Running Speed and Agility because they are the subtests that examine skills requiring postural stability. These two subtests include a shuttle run (for a distance of 45 feet, pick up an object, and run back, timed) and static and dynamic balance activities on the floor and on a low balance beam. Only 11 of the 14 participants were tested with the BOTMP, as three children were younger than the minimum age requirement. Testing and scoring followed the procedures as described by the BOTMP manual (Bruininks 1978). Results are reported as raw point scores (number of points achieved). The BOTMP manual reports test-retest reliability for the Running Speed and Agility subtest of $r=0.78$, and for the Balance subtest of $r=0.56$ (Bruininks 1978).

Table I: History and maturation effect test results (shoes only condition)

| Dependent variable | F | p |
|--|--------------------|--------------------|
| BOTMP Balance subtest | 1.320 | 0.289 |
| GMFM Standing dimension | 2.330 ^a | 0.141 ^a |
| GMFM Walking, Running, and Jumping dimension | 0.329 | 0.722 |

BOTMP, Bruininks-Oseretsky Test of Motor Proficiency; GMFM, Gross Motor Function Measure; ^aGreenhouse-Geisser adjusted values.

Table II: Results of repeated measures ANOVA

| Dependent variable | F | p |
|--------------------------------|--------|---------------------|
| GMFM Standing | | |
| Session | 0.798 | 0.388 |
| Condition | 17.666 | 0.001 ^a |
| Interaction | 0.140 | 0.714 |
| GMFM Walking, Running, Jumping | | |
| Session | 2.844 | 0.116 |
| Condition | 27.911 | 0.0001 ^a |
| Interaction | 3.668 | 0.078 |
| BOTMP Balance | | |
| Session | 1.208 | 0.298 |
| Session for 'shoes only' | 1.000 | 0.341 |
| Session for 'shoes+SOMs' | 11.029 | 0.008 ^a |
| Condition | 5.450 | 0.042 ^a |
| Condition at second session | 1.369 | 0.269 |
| Condition at third session | 6.675 | 0.027 ^a |
| Interaction | 5.641 | 0.039 ^a |

GMFM, Gross Motor Function Measure; BOTMP, Bruininks-Oseretsky Test of Motor Proficiency; SOMs, supramalleolar orthoses; ^asignificant at $p=0.05$.

Orthoses

The flexible SMO used in this study was made from a hybrid plastic (Fig. 1), and is different from other flexible SMOs in that it is thinner and has a shorter footplate (approximately three-quarters length). This orthosis is thought to use compression to promote midline positioning and enhance joint receptor function, as opposed to the more traditional concept of wedging the foot into a neutral position through posting of the footplate. It can also be fabricated from girth, length, and width measurements, thus eliminating the need for a cast mold of the child's foot. This orthosis was chosen for this study because it was specifically designed for use by children with hypotonia, whereas other SMOs are used by children with either high or low tone.

PROCEDURE

This study used a repeated measures design with three testing sessions over a 10-week period. Testing was done either in the child's home or in a clinic. At the initial meeting, children were

measured for the orthoses by using the tools and protocol established by the SMO manufacturer (Midwest Orthotic and Technology Center, South Bend, Indiana). Passive ROM measurements for ankle dorsiflexion, knee hyperextension, and elbow hyperextension were taken, using the standard positions and protocol described in Norkin and White (1995). The children were then tested with the BOTMP (if older than 4 years 6 months) and the GMFM in random order, in the 'shoes only' condition.

Approximately 2 to 3 weeks later, the children were first tested in their shoes only. Then the children were fitted with their SMOs and were allowed to walk around the testing area until they felt comfortable enough in the orthoses to proceed with the selected GMFM and BOTMP tests. Parents were instructed as follows: how to apply the orthoses correctly and monitor skin integrity; that their child should wear the SMOs 8 hours per day, every day until the final testing session after approximately 6 weeks; to discontinue use of the SMOs and call the author if their child experienced any problems with the orthoses; and to continue with their current daily routine, including physical therapy and recreational activities. Adherence with the SMO-wearing schedule was monitored by having parents complete a daily log sheet.

After approximately 6 weeks of wearing the SMOs, the children returned for a final testing session. The child was first tested in the 'shoes+SMOs' condition, then the SMOs were removed and the child was tested in the 'shoes only' condition. Parents were asked to hand in the daily log sheet and instructed on how to determine when the orthosis no longer fitted their child.

Most participants were unable to run fast enough to obtain a score on the BOTMP Running Speed and Agility subtest. This created a large floor effect for this variable; therefore, it was not considered to be a useful measure for the purposes of this study and was eliminated from further analysis.

Data analysis

Statistical analysis was done with SPSS (version 10.0). Statistical significance was set at $p=0.05$ for all tests. First, data were examined for normality, then the GMFM and BOTMP scores from the 'shoes only' condition in each of the three sessions were compared for maturation and history effects by using a one-way repeated measures analysis of variance (ANOVA).

A two-way repeated measures ANOVA was used to look for differences within participants over time (second and third sessions) and across conditions (wearing 'shoes only' or 'shoes+ SMOs') for both GMFM dimensions and the BOTMP Balance subtest. Significant interactions between time and condition were explored with tests of simple main effects by using a Bonferroni correction of alpha.

To explore the contribution of joint laxity to the findings, the more lax group was analyzed separately from the less lax group, and they were compared for age and amount of time the orthoses were worn. Mean difference in scores attributed to the orthotic intervention (third session 'shoes+SMOs' minus the second session 'shoes only') between the two groups was calculated for each dependent variable and compared by using independent t -tests.

Individual responses to the orthoses were explored by calculating a 'total response' score for each child. This score was obtained by first converting the BOTMP scores to a percentage of points available so they would be on the same scale as the

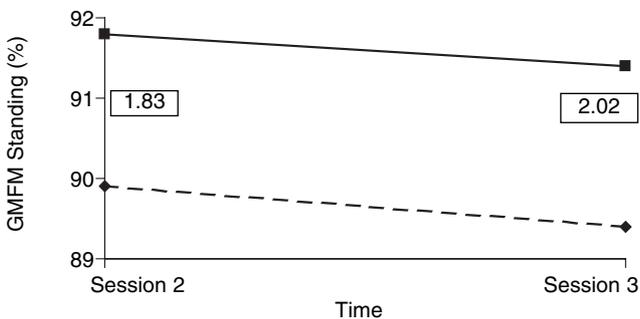


Figure 2: Gross Motor Function Measure (GMFM) Standing dimension results. Numbers in boxes represent mean change with supramalleolar orthoses (SMOs) intervention at each session. ■, shoes+SMOs; ◆, shoes only. Condition significant at $p=0.001$.

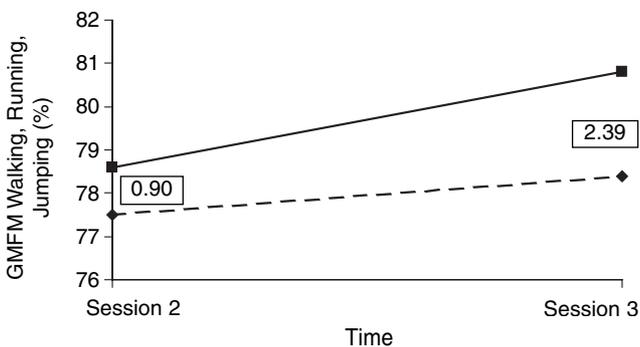


Figure 3: Gross Motor Function Measure (GMFM) Walking, Running, and Jumping dimension results. Numbers in boxes represent mean change with supramalleolar orthoses (SMOs) intervention at each session. ■, shoes+SMOs; ◆, shoes only. Condition significant at $p=0.0001$.

GMFM scores. Then the per cent change attributable to the orthoses (third session 'shoes+SOMs' minus second session 'shoes only') was calculated for each of the three dependent variables and summed, indicating the percentage point improvement (or decline) in function experienced by each child.

Results

For this study, test-retest reliability intraclass correlation coefficients for each dependent variable for the first and second testing sessions (2 to 3 weeks) were as follows: 0.67 for the Standing dimension, 0.93 for the Walking, Running, and Jumping dimension of the GMFM, and 0.81 for the Balance subtest of the BOTMP.

The 14 children wore the SOMs for an average of 5.68 hours per day (SD 1.96) for a mean of 49.07 days (SD 8.45). Table 1 indicates that there was no significant difference in the dependent variables in the 'shoes only' condition across the three testing sessions.

For both GMFM dimensions, significant differences were found between orthotic conditions but not between testing sessions (Table II; Figs. 2, 3), and there was no significant interaction between conditions and sessions. For the BOTMP Balance subtest, a significant interaction between condition and sessions ($p=0.039$) required exploration of simple main effects (Table II; Fig. 4). This analysis showed that the SOMs offered a mean improvement of 0.64 points over the 'shoes only' at the second session, and a larger effect with a mean improvement of 2.64 points by the third session.

Overall, the group that was more lax scored lower on all dependent measures compared with the less lax group (Fig. 5). When the two groups were compared for age and amount of time the SOMs were worn, they were significantly different only in age ($t=2.18, p=0.05$). The more lax group had a mean age of 5 years 2 months whereas the less lax group had a mean age of 6 years 6 months. Mean difference attributed to the orthotic intervention was not significantly different between the two groups on any variable (GMFM Standing, $p=0.271$; GMFM Walking, Running, and Jumping, $p=0.210$; BOTMP Balance $p=1$).

Individual 'total response' scores showed that percentage point changes ranged from -2.6 to 32.5% (Table III). Seven of the 14 children improved by at least 8 percentage points, and four children improved from 2 to 4 percentage points.

Discussion

ORTHOTIC INTERVENTION

This study supports the hypothesis that flexible SOMs have a positive effect on measures of postural stability in children with Down syndrome. Because the data from the three 'shoes only' conditions (Table I) were not significantly different, the changes seen in this study were unlikely to be a result of maturation or outside activity. Significant changes in performance were detected immediately and after 7 weeks by the two GMFM dimensions, and by the end of the study for the BOTMP Balance subtest. The skills in the GMFM Standing dimension required less postural stability and were more likely to have already been mastered. The GMFM Walking, Running, and Jumping dimension tested skills that were more challenging, and the BOTMP Balance subtest tested skills that were the most difficult and complex. Thus the tendency was that when the task was more challenging, more time was needed for significant improvement to be seen. The trend in this

study is supported by Palisano et al. (2001), who also noted that more time is required to learn movements that are more complex and thus require greater motor control and limb coordination.

INFLUENCE OF JOINT LAXITY

Children with Down syndrome with greater joint laxity did not show a greater treatment effect with the flexible SOMs. Even though the more lax group scored lower on all dependent measures, the magnitude of change attributed to the

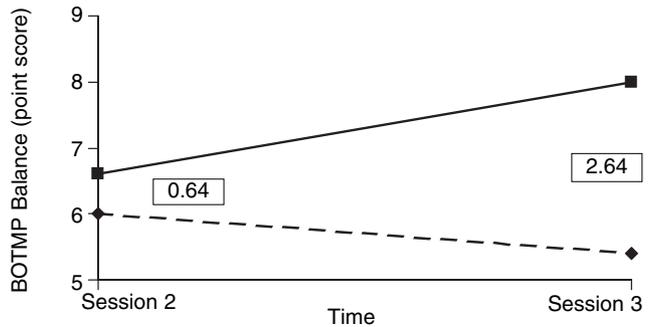


Figure 4: Bruininks-Oseretsky Test of Motor Proficiency (BOTMP) Balance subtest results. Numbers in boxes represent mean change with supramalleolar orthoses (SOMs) intervention at each session. ■, shoes + SOMs; ◆, shoes only. Interaction significant at $p=0.039$. Condition at session 3 significant at $p=0.027$.

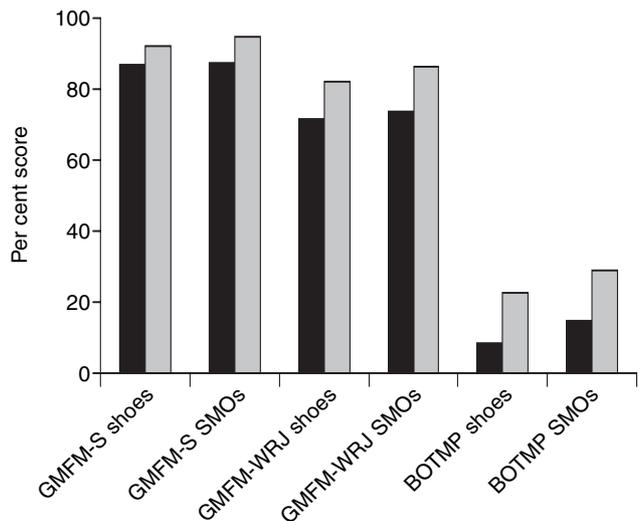


Figure 5: Comparison of mean scores when grouped by laxity category. Sessions labelled 'shoes' are session 2, sessions labelled 'SOMs' are session 3. GMFM-S, Gross Motor Function Measure, Standing dimension; GMFM-WRJ, Gross Motor Function Measure, Walking, Running, and Jumping dimension; BOTMP, Bruininks-Oseretsky Test of Motor Proficiency; SOMs, supramalleolar orthoses; ■, more lax; ■, less lax.

orthotic intervention was similar between groups. These findings are consistent with two previous studies that have attempted to examine the impact of joint laxity on children with Down syndrome (MacNeill-Shea and Mezzomo 1985, Livingstone and Hirst 1986). Both of these studies concluded that the orthopaedic and motor skill problems commonly seen in children with Down syndrome were related to hypotonia but not joint laxity.

CLINICAL RELEVANCE

For the GMFM Standing dimension, the mean improvement in score seen with the orthoses of approximately 2 percentage points could mean completing a floor to stand transition without support, or an increase of single leg balance by as much as 7 seconds (Russell et al. 1993). For the GMFM Walking, Running, and Jumping dimension, the mean improvement with orthoses of approximately 3 percentage points could mean stepping over a tall obstacle independently, running with control versus walking quickly, being able to hop on one foot at least three times, or being able to consistently go up or down stairs reciprocally versus a step-to-step pattern (Russell et al. 1993). For the BOTMP Balance subtest the mean improvement with orthoses of 17% could reflect a 2- to 3-fold increase in single-leg standing balance or the ability to take two to three times as many steps on a balance beam (Bruininks 1978). All of these changes seem to be clinically important, particularly in enabling school-aged children with Down syndrome to more readily keep up with their peers.

The rate of change in this study also seems notable. Two studies have reported that improvement in gross motor skills occurred at a slower rate in children with Down syndrome over the age of 3 years (Russell et al. 1998, Palisano et al. 2001). Yet in this study, significant improvement in postural stability was found within minutes for less complex skills and

within 7 weeks of intervention with flexible SMOs for more challenging skills.

ORTHOTIC MECHANISMS

The question of how and why a flexible orthosis produces an improvement in the postural stability of children with Down syndrome has not been answered. Biomechanical and neurological explanations have been offered in previous literature on orthoses. Orner et al. (1994) proposed that orthoses create an improved biomechanical alignment that allows muscles to work in a more appropriate length-tension relationship. The orthosis in this study is flexible and does not hold the subtalar joint rigidly in neutral, thus small increments of movement around midline are allowed while preventing fixation in an abnormal position or movements into the extreme end range of pronation. Because of the movement allowed, Hylton (1989) has hypothesized that flexible orthoses provide improved and more consistent proprioceptive feedback, which in turns improves control of movement.

The trimlines of the SMO are also different from traditional styles in that they are proximal to the first metatarsal head and just distal to the fifth metatarsal head, which is thought to decrease the forefoot abduction that often occurs with pronation. Another feature of the orthosis in this study is its lack of full-length footplate which, combined with its flexibility, allows the development of normal ankle strategies in response to balance perturbations and development of jumping skills. Traditional orthoses with a full-length rigid footplate may inhibit the graded shifting of weight that occurs with an ankle-strategy balance response. Shumway-Cook and Woollacott (1985) have recommended that treatment to improve the postural control of children with Down syndrome should focus on assisting development and refinement of postural synergies. The flexible SMO used in this study would seem to be consistent with accomplishing that goal.

LIMITATIONS

One limitation of this study was that participants were all children with Down syndrome between the ages of 3 years 6 months and 8 years; thus the results should not be generalized to children with other disorders or those who are outside this age range. This study did not limit any outside activities that may have contributed to the development of postural stability during the study period. Half of the participants were tested in their homes, thus the testing environment also varied. Another limitation of the study was the participants' cognitive understanding and ability to follow verbal directions for complex skills, such as walking between 2 lines on the floor. Finally, the analysis of influence of joint laxity lacked reliability analysis and justification from previous literature. However, given the lack of a definitive method for grading joint laxity, the method used in this study offered preliminary information about an interesting clinical question.

ADDITIONAL STUDY

The study could be broadened to include children with a diagnosis of hypotonia of any origin. Also, the age range could be lowered to look at the effect of orthoses on development of independent gait. Finally, many different types of orthotic devices are commercially available; a comparison of this SMO with other types with different features would help clinicians choose the orthoses that would most benefit their patients.

Table III: Individual total response scores with orthotic intervention^a

| Patient number | BOTMP Balance | GMFM Standing | GMFM WRJ | Total change |
|----------------|---------------|---------------|----------|--------------|
| 8 | 21.9 | 5.1 | 5.5 | 32.5 |
| 5 | 15.6 | 2.6 | 9.7 | 27.9 |
| 6 | 12.5 | 5.2 | 3.3 | 21.0 |
| 3 | 9.4 | 2.5 | 2.4 | 14.3 |
| 11 | 9.4 | 2.6 | 0 | 12.0 |
| 10 | 0 | 2.6 | 6.9 | 9.5 |
| 2 | - | 2.6 | 5.6 | 8.2 |
| 12 | 6.3 | -2.6 | 0 | 3.7 |
| 9 | 0 | 0 | 2.8 | 2.8 |
| 4 | - | 2.5 | 0 | 2.5 |
| 7 | -3.1 | 2.6 | 2.7 | 2.2 |
| 15 | - | -2.5 | 2.7 | 0.2 |
| 13 | -3.1 | 0 | 2.8 | -0.3 |
| 17 | 0 | -2.6 | 0 | -2.6 |

^aOverall percentage point change = session 3 'shoes+SMOs' minus session 2 'shoes only'. BOTMP Bruininks-Oseretsky Test of Motor Proficiency; GMFM, Gross Motor Function Measure; WRJ, Walking, Running, and Jumping dimension.

Conclusion

Improvements in the postural stability of children with Down syndrome, aged 3 years 6 months to 8 years, were seen with the use of a flexible SMO. Immediate and longer-term improvements were noted in skills that were less complex; more complex skills showed significant improvement by the end of the 7-week intervention period. Although the children with more lax joints scored lower on all dependent measures across all conditions, there was no difference in response to the orthoses between the groups with more or less joint laxity. Results of the current study show that improvement in postural stability of children with Down syndrome is possible through relatively short-term use of flexible SMOs. These results suggest that clinicians should consider the use of flexible SMOs for school-age children with Down syndrome as a way of improving their overall functional mobility.

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List of abbreviations

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|-------|---|
| BOTMP | Bruininks-Oseretsky Test of Motor Performance |
| GMFM | Gross Motor Function Measure |
| SMO | Supramalleolar orthosis |
