Evaluation of Short-Term Intensive Orthotic Garment Use in Children Who Have Cerebral Palsy

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Purpose: To evaluate the effectiveness of an orthotic undergarment on gait, balance, and life skills of children who have diplegic cerebral palsy (CP). **Methods:** Five subjects (ages 7–13 years) with CP at Gross Motor Function Classification Scale level I wore a TheraTog™ undergarment for 12 weeks. Data collection included Vicon® Motion Analysis, Bruininks-Oseretsky Test of Motor Proficiency, and Canadian Occupational Performance Measure at baseline; in and out of the garment after 12 weeks of wear; 2 months and 4 months after garment wear. **Results:** Kinematic data indicated increased peak hip extension and correction of anterior pelvic tilt in stance during wear time. Composite gross motor scores on the Bruininks-Oseretsky Test of Motor Proficiency and Canadian Occupational Performance Measure scores improved significantly at the end of wear time. **Conclusion:** When worn for a 12-week time frame, an individualized orthotic garment can improve gait and functional skills in some children with CP. **(Pediatr Phys Ther 2009;21:201–204)** *Key words: cerebral palsy, child, clothing, gait, human movement system, orthotic device, outcome assessment, physical therapy*

INTRODUCTION

Children with cerebral palsy (CP) are a heterogeneous group, but by using the Gross Motor Function Classification System (GMFCS), they can be classified into 5 levels of gross motor function, ranging from ambulation without limitations (level 1) to complete dependence in mobility and self-care, even with the use of assistive technology (level 5).[1] For those children classified at GMFCS level 1, 90% of motor development potential is reached at approximately 5 years of age with a plateau of function reached around 7 years.[2] This classification system does not discriminate quality of movement or how function may be improved as a result of interventions including aids or orthoses.[2]

The use of lycra compression garments as an orthotic device has been suggested to improve the ability to stabilize posture and improve function, and with correction of deformity, to advance the user to a more normal functional capacity.[3] Studies using full-body lycra garments, worn at least 6 hours/day for 6 weeks, have suggested improvements in proximal stability,[4] leading to some improvements in self-help and mobility; however, difficulties in donning/doffing and toileting made the garments impractical for daily use by caregivers and the children.[5]

TheraTogs™, an orthotic undergarment fabricated from Delta-flex, a lightweight, breathable fabric that is Velcro sensitive, have been developed to provide a gentle, passive force to correct imbalance or alignment through the combination of a trunk and shorts system along with a customized external strapping system. It is suggested that this system, like the lycra bodysuit, can improve joint stability, posture, and gait skills.[6] This system, unlike the full-body lycra suit, provides access for toileting when the system is worn during the day, improving the ease of wear. To the best of our knowledge, there have been no studies published in peer-reviewed journals regarding TheraTogs™ as a treatment modality.

The purpose of this study was to assess the effectiveness of short-term intensive use of a dynamic orthotic undergarment system (TheraTogs™) on gait, balance, and function in a group of children with CP classified at GMFCS level 1.

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METHODS

Participants

The participants, who represented a sample of convenience, were 5 children (4 boys, 1 girl; 7–13 years) with diplegic CP, GMFCS level I. None of the children had surgery or Botox injections in the past. The children did not receive additional physical therapy services during the study and were all enrolled in regular education classes in the community. The parents completed consent forms for their child to participate in the study, which was approved by the Institutional Review Board of our facility.

Design

A single, preintervention baseline assessment was performed before the orthotic under garments were provided. Following the 12-week intervention phase, assessments were performed in and out of the garment. The same assessments were also completed 2 and 4 months postintervention.

The intervention phase of this study consisted of wearing an individualized TheraTog™ garment system for 12 weeks, 10 to 12 hours per day. During the first 2 weeks, the vest and shorts were worn alone, per the developer's recommendation, to allow the child and family to become acclimated to the system. Based on the visual and photographic findings from formal gait analysis, standing posture, and biomechanical lower extremity assessment, a strapping system was individually designed for each child by consensus of the team. The subjects all received strapping for activation of oblique abdominals and paraspinals as well as individualized lower extremity strapping as indicated. This strapping system was worn for the rest of the intervention phase.

Testing

One investigator consistently administered a single evaluation tool throughout the study.

Gait Analysis. Reflective markers were affixed to the skin with double-sided tape at anatomic landmarks on the subject's pelvis and lower limbs as determined by the Vicon® Plug-in Gait Model. When the garment was worn, the garment was moved out of the way to accommodate the reflective marker on the skin. Marker placement was performed by the same clinician who had 14 years of experience in a pediatric Motion Analysis Laboratory. A 14-MX camera three-dimensional motion analysis system (VICON®, Motion Analysis, Santa Rosa, Calif.) was used to collect kinematic data of the lower extremities. The system underwent calibration assuring accuracy of less than 1 mm and all of the gait data were run through a Woltring Filter with a mean squared error value of 20 to assure reliability of the data. The subjects walked at a self-selected speed for a total of 6 walking trials and 3 representative trials were selected. Computer analysis of the data was completed by the biomedical engineer used by the Motion Analysis Laboratory.

Gross Motor Assessment. The gross motor scales of the Bruininks-Oseretsky Test of Motor Proficiency (BOTMP)[7] were used to assess gross motor skills and balance. The gross motor scale is made up of 4 subtests including running speed and agility, balance, strength, and bilateral coordination. A composite score was used from these subtests.

Biomechanical Assessment. A standing postural evaluation in the frontal and sagittal plane was performed to assess trunk, lower extremity and pelvic alignment. A lower extremity biomechanical assessment included Ryder's test for femoral torsion, Staheli test for hip extension, popliteal angle for hamstring length, hip rotation, ankle dorsiflexion range of motion with knee flexed and extended, and thigh foot angle to assess tibial torsion. This information was used to evaluate the garment strapping needs of the child before the study.

Functional Skills/Goals. The Canadian Occupational Performance Measure (COPM),[8] an interview tool for the child and family was used to measure the perceived satisfaction and performance of functional, goal-directed activities of daily living skills using a 10-point Likert scale.

Parent Satisfaction. At the end of the intervention phase, a parent satisfaction survey, developed by one of the investigators, was completed. A 5-point Likert scale was used to evaluate satisfaction with ease of use of the garment and parent perception of the child's quality of movement.

Compliance. The families kept a daily log of compliance and comments during the intervention phase.

RESULTS

The subjects, as a whole, ambulated at baseline with a gait pattern most consistent with a "jump-type pattern" observed in the sagittal plane. This kinematic profile consists of an anterior pelvic tilt and decreased peak hip extension in stance phase. As a result, each child received strapping for abdominals and back extensors to address these impairments.

The only kinematic gait parameters that were significantly affected with the garment on, for the subjects as a group, were peak hip extension and pelvic alignment. Postintervention kinematic gait data showed that peak hip extension at terminal stance increased during the wear period and did not return to baseline at the 2- and 4-month follow-up (Fig. 1). Pelvic alignment in the sagittal plane though, was only affected with the garment on causing the pelvis to tilt more posterior throughout stance and swing phase (Fig. 2).

Only 2 subjects required any additional lower extremity strapping based on kinematic findings following gait analysis and physical examination measurements. One subject walked with a single bent knee throughout the gait cycle and a knee extension strap was added to the garment. On postintervention gait analysis, this subject's knee extension angle did not change with the garment on but did demonstrate a loading response that was maintained at subsequent follow-ups. Another subject had rotation straps added to the lower extremities in an attempt to decrease the amount of internal rotation with gait. With the garment on and at follow-up visits, the amount of internal rotation of the hips decreased overall, but the findings were not significant.

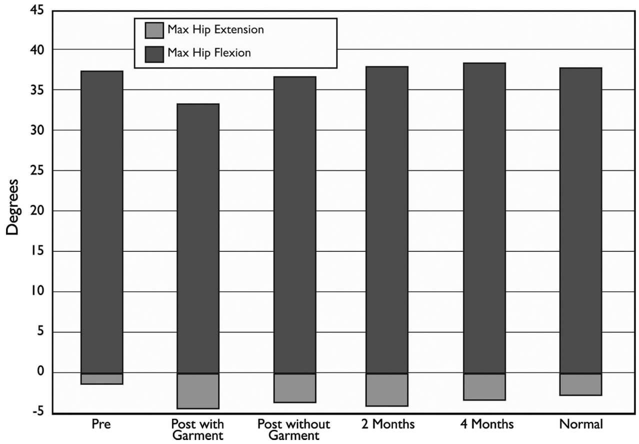

Fig. 1. Peak hip flexion/extension during gait.

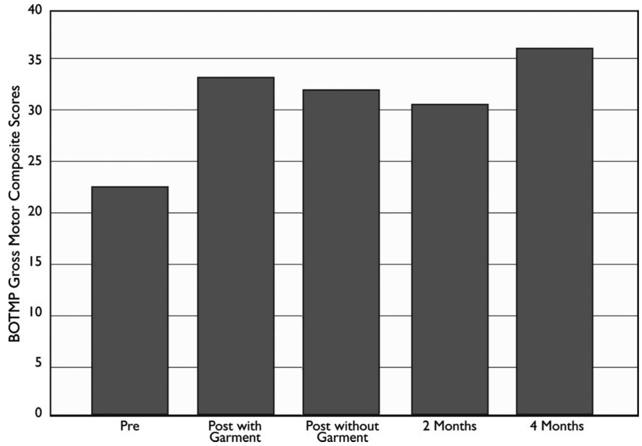

Fig. 3. BOTMP scores.

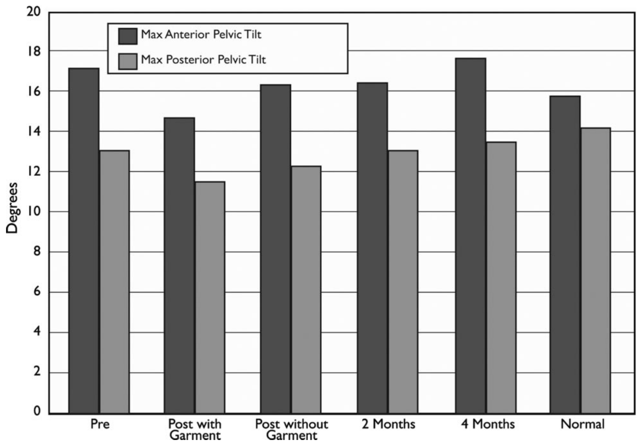

Fig. 2. Kinematic pelvic motion during gait.

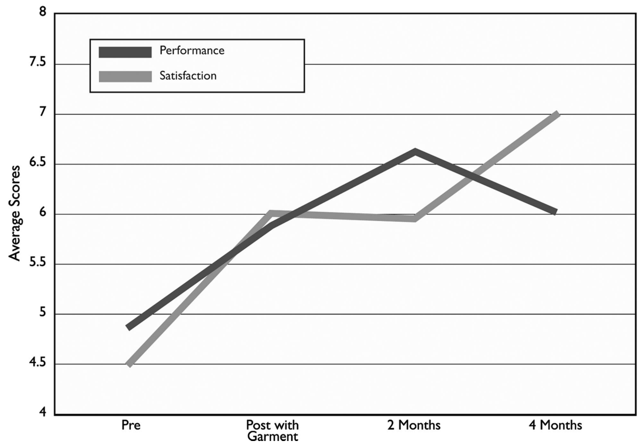

Fig. 4. COPM results.

Temporal spatial gait parameters such as speed, cadence, step, and stride length were unchanged from the beginning to the end of the study. Each individual subject's walking speed resembled that of children who are developing typically before the intervention and remained consistent throughout the study. Step and stride lengths were reduced compared with children who are developing typically but again were unchanged throughout the duration of the study.

The subjects' mean composite score on the BOTMP was 22.4 (SD ± 12.7) at baseline, which improved to 35.2 (SD ± 15.9) with the garment on and 33.6 (SD ± 16.3) with the garment off (Fig. 3). After 2 months of not wearing the garment, the composite score was 32.0 (SD ± 14.4) and 38.0 (SD ± 19.1) after 4 months. Because this was a small sample size, a paired t test analysis was used to determine significance of the results. With paired t test analysis ($p \leq 0.05$), the scores were significant for all testing conditions. At 2 months of wear with the garment, $p = 0.023$; without the garment, $p = 0.025$; 2 months postwear, $p = 0.007$; and 4 months postwear, $p = 0.020$.

The COPM rated the parent's perceived performance and satisfaction of parent selected activity of daily living goals for their child. Goals were rated on a scale of 1 to 10. A performance score of 1 signifies the child is not able to do it and a score of 10 signifies the child is able to do it extremely well. Likewise, a satisfaction score of 1 means the parent is not satisfied at all and a score of 10 shows the parent is extremely satisfied.

The mean performance on the COPM at baseline was 4.7 (±0.65) and at 2 months after wear was completed measured 6.63 (±1.53). At the completion of the study, mean performance was 6.0 (±2.49). Mean satisfaction on the COPM at baseline was 4.55 (±0.79) and 6.0 (±0.66) after wearing the garment. At 4 months, satisfaction was 7.02 (±2.51). With a paired t test analysis ($p \leq 0.05$) of the COPM performance and satisfaction domains, results were not statistically significant with the exception of satisfaction after 2 months of wear ($p = 0.03$) (Fig. 4).

The parent satisfaction survey was measured on a 5-point Likert scale with 1 = strongly agree and 5 = strongly disagree (Table 1). Generally the parents found the garments easy to don and care for with limited problems toileting. The parents reported that walking and confidence level was improved, but the comfort of the child and the child's energy level were more of an issue.

DISCUSSION

Children with diplegic CP often ambulate with a "jump gait pattern"; demonstrating anterior pelvic tilt, decreased peak hip and knee extension, and persistent plantarflexion in stance phase.[9] Following the intervention

TABLE 1

Parent Satisfaction Survey (n = 5)

Statement	Mean Response (SD)
1. Garment was easy to doff/don	2.0 (1.4)
2. Child was comfortable with full day wear	2.8 (1.6)
3. Child liked wearing the garment all day	2.2 (0.5)
4. Child's balance was improved	2.4 (0.9)
5. Child's walking improved	1.6 (0.5)
6. Caring for the garment was easy	1.8 (0.8)
7. Child's energy level was improved	3.2 (1.1)
8. Child's confidence was improved	2.2 (1.6)
9. There were no problems toileting	2.0 (1.7)

1 = strongly agree, 2 = somewhat agree, 3 = neither agree or disagree, 4 = somewhat disagree, 5 = strongly disagree.

phase, when assessed without the garment on, the subjects demonstrated an increased anterior pelvic tilt and reduced stance phase peak hip extension when compared with children who are developing typically. During the same session, while wearing TheraTog™ garments and strapping, the subjects were noted to have pelvic and hip kinematic gait data that resembled children who are developing typically. It is believed that this may be due to the abdominal and back extensor strapping that attempts to facilitate the core trunk stabilizers.

Examining the subtest standard scores on the BOTMP, for which a 15% increase is considered significant,[7] scores with the garment on increased between 17% and 37%. Of note, on the same day testing occurred without the garment on, the balance score decreased 44% below the baseline measurement. This may have been due to altered body position sense upon garment removal. The percent change in balance then increased positively by 58% and 76% at 2 and 4 months, respectively, after discontinuing garment wear. These findings seem to suggest that motor learning took place while wearing the garments, which may have promoted more physical activity with their peer group during the study.

Performance improvements noted by the parents on the COPM included functional activities such as stepping in and out of the shower independently as well as up and down curbs. Parents also reported greater participation in gym class and improved handwriting, buttoning, and tying.

On the parent satisfaction survey, parents reported both positive and negative aspects of wearing the garment. Physically study participants spent more time participating in physically challenging activities including riding a bicycle and in physical education class. Confidence in the subjects own physical abilities increased. Parents did note, however, similar to Nicholson et al,[5] that the garments were too hot to tolerate in warm weather, in gym or in sports activities. Dressing and toileting were more challenging with the garment than without. Of the 5 subjects who participated in the study, the 2 who were 100% compliant requested to continue the use of the garment when the study was completed. The other 3 subjects wore the garment on average 75% of the time.

Limitations of this study include a small sample size, single baseline, and lack of a blinded examiner. Other potential limitations include possible kinematic gait alterations as a result of repositioning of the garment to accommodate for pelvic surface marker placement. Additionally, it has been reported that increasing gait velocity could account for changes in peak hip extension.[10] Future studies should also examine the optimum wear time for the garment to obtain the most benefit. The current study started with a relatively small intervention of 12 weeks to maximize compliance, but the ideal wear time is not known.

CONCLUSION

When worn over a 2-month period, an individualized orthotic garment and strapping system can improve gait, balance, and functional skills in some children with CP, GMFCS level I. Some of these improvements are maintained 2 to 4 months later. Wearing compliance is limited in some by the difficulties with heat, skin discomfort, and toileting. Further research is needed to determine if the same effect would be seen in a larger population and with those children who have greater disabilities. Optimum wear time and duration of wear will also require further study.

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REFERENCES

1. Palisano RJ, Rosenbaum PL, Walter SD, et al. Development and reliability of a system to classify gross motor function in children with cerebral palsy. *Dev Med Child Neurol.* 1997;39:214–223.
2. Rosenbaum PL, Walter SD, Hanna SE, et al. Prognosis for gross motor function in cerebral palsy. *JAMA.* 2002;288:1357–1363.
3. Blair E, Ballantyne J, Horsman S, et al. A study of a dynamic proximal stability splint in the management of children with cerebral palsy. *Dev Med Child Neurol.* 1995;37:544–554.
4. Rennie DJ, Attfield SF, Morton RE, et al. An evaluation of lycra garments in the lower limb using 3-D gait analysis and functional assessment (PEDI). *Gait Posture.* 2000;12:1–6.
5. Nicholson J, Morton RE, Attfield S, et al. Assessment of upper-limb function and movement in children with cerebral palsy wearing lycra garments. *Dev Med Child Neurol.* 2001;43:384–381.
6. Cusick, B. TheraTogsTM—the live-in orthotics system you've been waiting for! Available at: http://www.theratogs.com/descriptions.html. Accessed January 4, 2007.
7. Bruininks RH. *The Bruininks-Oseretsky Test of Motor Proficiency*. Circle Pines, MN: American Guidance Service; 1978.
8. Law M, Baptiste S, Carswell A, et al. *Canadian Occupational Performance Measure.* Ottawa, Ontario, Canada: CAOT Publications ACE; 2005.
9. Gage J. The Treatment of Gait Problems in Cerebral Palsy. London: Mac Keith Press; 2004.
10. Olney SJ, Griffin MP, McBride ID. Temporal, kinematic, and kinetic variables related to gait speed in subjects with hemiplegia: a regression approach. *Phys Ther.* 1994;74:872–885.