Assessment Protocol for Serial Casting After Botulinum Toxin A Injections to Treat Equinus Gait

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Purpose: The purpose of this study was to investigate feasibility of an assessment protocol for a trial of post-Botox casting to treat equinus gait in cerebral palsy. **Methods:** Ten children (ages, 26–75 months) were recruited. Nine were assessed 1 week before botulinum toxin-A injections and reassessed 1 week after removal of the final cast. The assessment protocol included Modified Ashworth Scale (MAS), Modified Tardieu Scale (MTS), Gross Motor Function Measure-66 (GMFM-66), Pediatric Evaluation of Disability Inventory (PEDI), and GAITRite. Feasibility was based on acceptability of the protocol, inter-rater reliability, and responsiveness of outcome measures. **Results:** The assessment protocol was acceptable and practical. Inter-rater reliability for MAS, MTS, and GMFM ranged from moderate to excellent. Improvements were found in MTS and MAS scores for dorsiflexion and hamstring ($p < 0.01$), GMFM-66 ($p = 0.01$), and Pediatric Evaluation of Disability Inventory mobility ($p = 0.01$), self-care ($p = 0.01$), and social function ($p = 0.00$). GAITRite revealed reductions in speed ($p = 0.00$) and cadence ($p = 0.01$). **Conclusions:** Feasibility was confirmed. Recommendations include raising minimum age and delaying gait analysis. **(Pediatr Phys Ther 2008;20:233–241)** *Key words: botulinum toxin type A/therapeutic use, casts/plaster, child, disability evaluation, equinus deformity/drug therapy, equinus deformity/therapy, gait, outcome assessment (healthcare) methods, psychometrics, spasticity*

INTRODUCTION

Equinus is one of the most common gait disorders in children with cerebral palsy.[1] The equinus deformity is caused by hypoextensibility in the gastrocnemius-soleus complex and results in an unstable and inefficient gait pattern. Failure to address this problem at an early stage can result in decreased walking ability and an increased risk of developing deformities. Goldstein and Harper[1] observed that equinus deformity increases the risk of pain and early cessation of walking.

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During the past 10 years botulinum toxin (BTX)-A, a derivative of BTX, has been increasingly used in the management of equinus gait in children with cerebral palsy (CP). When injected into the muscle, BTX-A blocks the release of acetylcholine, causing temporary paralysis of the muscle and a localized reduction in spasticity.[2] The response occurs within 2 to 3 days, the effect reaching its maximum at 2 weeks and waning by 3 to 6 months.[2]

Clear and consistent protocols for optimal management post-BTX-A are not available. "Physiotherapy" (ie, strengthening and gait training in combination with orthoses and night splinting) has been cited widely as an essential component of the post-BTX-A care.[3,4] More recently, attention has turned to the addition of casting as a management option. Serial casting, a sequence of consecutive cast applications and removals, has been used as an adjunct to BTX-A to gain additional range of motion (ROM).[5] Tissue elongation is achieved through physiological adaptation to prolonged stretch; each cast contributes to an incremental increase in the desired ROM.[6–8]

The use of casting after BTX-A injections has been shown to result in improved ankle kinetics[9] and walking performance.[5] Booth et al[10] reported that the time to achieve the desired ROM was shorter using BTX-A followed by serial casting than with serial casting alone. In a trial comparing physiotherapy and orthotics after BTX-A versus post-BTX-A casting followed by physiotherapy and orthotics, greater improvements in time-distance gait parameters and spasticity were found with the latter intervention.[11] Two recent studies comparing BTX-A alone, casting alone, and the combination of both reported no significant differences in passive ROM, ankle kinematics, spasticity, and dorsiflexor strength in the BTX-A only group but significant differences in the other two groups.[12,13]

Although it is apparent that the combination of BTX-A and casting has beneficial effects, clear guidelines for casting protocols are lacking. Published casting procedures differ in terms of the duration of casting—from a single cast for 3 weeks[12,14] to changing casts after 2 weeks,[5] to serial casting until attainment of a target ROM.[10] Another source of variability is the minimum age considered appropriate for BTX-A and casting. Corry et al[11] included participants as young as 2 years whereas the minimum age in other studies has been 3 years.[10,12,14]

Assessment protocols used in previous studies of the combined effects of BTX-A and casting have been both varied and limited. None of the studies reported on outcomes across all domains of disability identified in the International Classification of Functioning, Disability, and Health (ICF)[15] framework. The majority of trials restricted measurement to impairments of body functions and structures (ie, physiological functions of body systems and anatomical parts such as organs, limbs, and their components[15]), including the Modified Ashworth Scale (MAS), Modified Tardieu Scale (MTS), ROM, and gait analysis.[5,11–13,16] A single study[14] included the Gross Motor Function Measure (GMFM) as a measure of activity (ie, execution of a task or action by an individual[15]) and no studies were cited that included outcomes in the domain of participation (ie, involvement of an individual in life situations[15]).

Clearly, further investigation of the parameters of casting is warranted to establish the optimal management protocol. This perceived gap in clinical practice has prompted us to plan a controlled trial to study more systematically and comprehensively the effects of the combination of BTX-A injections and casting for management of equinus gait in children with CP. However, before conducting such a study, it was deemed necessary to carry out a preliminary investigation, the purpose of which was to assess the feasibility of our ICF-based assessment protocol in terms of acceptability, practicality (time, resources), inter-rater reliability, and responsiveness of the selected outcome measures to change over time.

METHODS

Design

A single cohort was studied using a test-retest design with pretesting conducted 1 week before administration of BTX-A and the second, 1 week after completion of the casting protocol. All assessments were conducted at the IWK Health Centre. The study was approved by the Research Ethics Board, IWK Health Centre and all parents/guardians gave informed written consent.

Participants

Participants were recruited from the CP Clinic by physiotherapists not directly involved in the study. Inclusion criteria were diagnosis of CP, ages 2 to 6 years, presence of equinus gait, and Gross Motor Function Classification System (GMFCS) level I and II (ie, independent in ambulation).[17] Exclusion criteria were injection of BTX-A within the past 6 months, serial casting in the last 6 months, and lower extremity surgery within the past 12 months.

Intervention Protocol

The BTX-A and casting protocols selected for this study were based on standard procedures currently used at our facility. BTX-A was injected into 4 sites of the spastic gastrocnemius-soleus complex. In addition, 7 patients received hamstring injections. BTX-A was injected into 4 sites of the spastic hamstring muscle, 3 into the medial hamstring, and 1 into the lateral hamstring. Under general anesthetic and sterile conditions, the same physician injected 2 units of BTX-A/kg/site into the muscle to a depth of 5 to 7mm using a 23-gauge, 4 cm needle, and 3 mL syringe. The location of the injection site was determined according to anatomical landmarks and palpation.

Casting was delayed until 1 week after BTX-A administration because it has been hypothesized that motor activity enhances the uptake of the toxin.[18] A below-knee fiberglass walking cast was applied with the participant in supine, the hip and knee supported in 90° of flexion, the ankle in maximum passive dorsiflexion, and the subtalar joint in neutral position. A layer of stockinette and Webrite® Undercast Padding was applied over the foot and calf, followed by an inner layer of 3M Soft Cast™ semirigid casting tape and outer layer of rigid 3M Scotchcast™ Plus. Posting was added when necessary. The participants used cast shoes when walking. Caregivers were provided with verbal and written instructions on cast care and precautions. Casts were reapplied weekly for 3 weeks and the last cast remained on for 2 weeks.

Assessment Protocol

The assessments and reassessments were performed consistently in terms of the time of the day and testing environment by an experienced evaluator who was not directly involved in the study. Before testing the evaluator was trained in the standardized protocols for all measures by a physiotherapist with 30 years of experience. Figure 1 illustrates the assessment schedule. Based on clinical experience, it was anticipated that the time to conduct these assessments would be 60 to 90 minutes. The assessment tools used are outlined below according to the ICF framework.

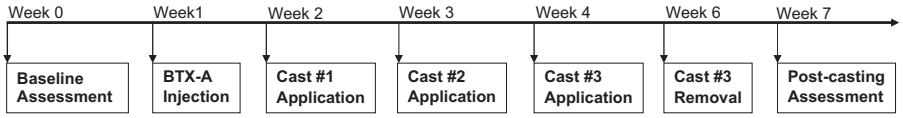

Fig. 1. Assessment and intervention schedule.

Measures of Body Functions and Structures

MAS documented the presence and extent of hypertonia of the hamstrings and gastrocnemius-soleus muscles. The MAS grades resistance to stretch on a 6-point scale (from 0, indicating no increase in tone, to 4, indicating rigidity in flexion or extension)[19] by passively moving the limb through ROM, at a count of "one, one thousand." To assess the hamstrings, the hip was flexed 90° and the knee was moved from full flexion to maximal extension.[20–22] To test the plantarflexors, the hip and knee were maintained in extension and the ankle joint was moved from maximal plantarflexion to maximal dorsiflexion, maintaining the correct joint alignment through the range.[20–22] In children with CP the MAS has demonstrated good inter-rater and intrarater reliability for the hamstrings [intraclass correlation coefficient (ICC) = 0.79; confidence interval (CI) = 0.67–0.88 and ICC = 0.80; CI = 0.69–0.88, respectively][23] and moderate intrarater reliability for gastrocnemius (ICC = 0.64; CI = 0.44–0.77).[23] In terms of validity, the MAS has been found to be correlated with the myotonometer (r = 0.64–0.81)[24] and isokinetic dynamometer (r = 0.53–0.73).[25]

MTS was used to explore, in a preliminary manner, potential contributors to the anticipated reduction in hypertonia in the hamstrings and plantarflexors.[26] Two levels of passive ROM (R2 and R1) were documented—R2 referring to the total passive ROM available into knee extension and ankle dorsiflexion with knee extension and with knee flexion, and R1 referring to the point in the ROM where a "catch" was felt during a quick stretch of the hamstrings or plantarflexors. An angle finder was used for ROM into knee extension and a universal goniometer (2° increments) was used to measure ROM into dorsiflexion. To test knee extension, the hip was flexed to 90° and the opposite leg in was placed in extension. To assess dorsiflexion with knee extension, the hip and knee were positioned in extension.[20–22,27] To test dorsiflexion with knee flexion, the knee was flexed to 90° and the talocrural joint was maintained in neutral to avoid calcaneal varus or valgus.[20–22,27] Two trials for each movement were performed with the average used in data analysis.

The MTS has been used previously to monitor the effects of BTX-A in children with CP.[3,12,14] Fosang et al[21] reported acceptable inter-rater reliability for hamstrings [ICC = 0.72; CI = 0.52–0.87; standard error of measurement (SEM) = 9.0] and plantarflexors (ICC = 0.71; CI = 0.53–0.87; SEM = 5.5), and acceptable test-retest reliability for hamstrings (ICCs = 0.68–0.90; SEM = 6.4–9.6) but poor test-retest reliability for plantarflexors (ICC = 0.38–0.90; SEM = 4.0–7.5).[21] In contrast, Yam and Leung[20] recently reported inter-rater reliability ICCs of less than 0.75 for plantarflexors. No studies investigating the validity of the MTS were found in the literature.

Spatiotemporal parameters of gait (ie, walking speed, cadence, and stride length) were measured on the GAITRite, a 4.6-m, portable, computerized walkway system (Fig. 2). The average of 3 trials was used in data analysis. The GAITRite has been found to be a valid and reliable tool (ICCs > 0.93) for measuring these parameters.[28] A recent reliability study using the GAITRite reported that in the 1 to 4 years old age group, test-retest reliability was excellent for stride length (ICCs = 0.86–0.89); fair to good for speed and cadence (ICCs = 0.57–0.70); in the 4 to 8 years old age group test-retest reliability was excellent for cadence and stride length (ICCs = 0.81–0.84) and fair to good for speed (ICCs = 0.57–0.74).[29]

Measures of Activity and Participation

GMFM-66, a 66-item observational instrument designed specifically for children with CP, was used to assess motor function. It is divided into 5 dimensions of motor function (dimension A: lying and rolling; dimension B: sitting; dimension C: crawling and kneeling; dimension D: standing; and dimension E: walking, running and jumping). Given that the children were classified as being at GMFCS level I and II, a ceiling effect would be reached in dimensions A, B, and C; thus dimensions D and E were chosen for this study. Dimension D has 13 items (for a total

Fig. 2. GAITRite computerized walkway.

score of 39) that examine various aspects of standing and dimension E has 24 items (for a total score of 72) that examine walking, running, and jumping skills. The GMFM-66 has excellent reliability (ICC = 0.99), construct validity, and is responsive to change.[30]

Pediatric Evaluation of Disability Inventory (PEDI) was used to assess activity and participation levels using a structured interview with the participants' caregivers.[31] The PEDI was selected as a measure of participation because of the age range of the participants. A review of other common and more comprehensive measures revealed that they are designed for children ages 6 to 21 years (Children's Assessment of Participation and Enjoyment and Preferences for Activities of Children)[32] or as a measure of participation in the school setting (School Function Assessment).[33] The PEDI involves 3 measurement scales: functional skills, caregiver assistance, and modifications to the environment and each scale has 3 domains: self-care, mobility, and social function. An overall summary index is not calculated because the domains comprise independent scales.[31] Given the high functional level of the participants in this study, only the results of the 3 domains in the Functional Skills Scale were analyzed and reported. The PEDI has excellent inter-rater reliability (ICCs = 0.74–0.96),[31] as well as excellent internal consistency (r = 0.95–0.99)[31] and concurrent validity (r = 0.70–0.80).[34]

Feasibility of Assessment Protocol

The criteria used to assess feasibility of the assessment protocol for a future, multisite trial included the following.

Acceptability and Practicality of the Protocol. Participants and caregivers were asked at post-testing 2 open-ended questions: (1) How was the experience for you in terms of level of comfort with physiotherapy assessment, BTX-A injections, and casting procedures?; (2) How did you feel about the amount of time needed for the physiotherapy assessment? Responses to these questions as well as adverse events (eg, development of postcast discomfort, pressure sores or falls) were recorded. We also recorded responses to 2 close-ended questions asked of the evaluator: (1) Was the assessment protocol easily administered? and (2) Did you need assistance to complete the assessment? Time to complete each assessment was documented.

Responsiveness of Assessment Tools to Change from Baseline to Post-Testing. Utility of an outcome measure is dependent on its capacity to reflect change in a particular attribute over time. We were interested in both statistically significant and clinically meaningful differences. However, given that this was a pilot study with only 6 weeks between BTX-A injection and post-testing and no follow-up assessment, we anticipated that the magnitude of change at post-testing could fall short of being clinically relevant.

Inter-Rater Reliability. A second, experienced evaluator joined the primary evaluator to score the MAS, MTS, and GMFM-66 during the same assessment session. The MAS and MTS were repeated 5 minutes after the initial assessment and scored independently, without discussion between the evaluators. The GMFM was scored by the second evaluator whereas the primary evaluator was carrying out the assessment, also without discussion between evaluators.

Data Analysis

Normality of distribution of the dependent variables was determined using standard errors of kurtosis and skewness. GMFM-66 scores were calculated with the Gross Motor Ability Estimator software and the combined scores for dimensions D and E were expressed in percentages. The 95% CIs of the means for GMFM-66 scores were calculated. Raw scores on the PEDI were converted into scaled scores, on a scale from 0–100, to provide an indication of the level of capability in a domain along a continuum of relatively easy to relatively difficult, independent of the age of the child. For participants with diplegia, MTS, and MAS data on the limb with the greatest restriction in ankle ROM were analyzed. Scores of the MAS, MTS, and GMFM-66 obtained by the primary evaluator were used in the analyses. Wilcoxon signed-ranks test was used to analyze MAS data. Paired-samples t tests were used to compare baseline and post-casting scores on the MTS, GAITRite, GMFM-66, and PEDI. To correct for alpha inflation resulting from the large number of comparisons under analysis, an alpha level of $p < 0.01$ was used.

To determine the clinical relevance of statistically significant differences in measures, effect size (ES) was estimated by taking the difference between pre-testing and post-testing means and dividing it by the pretest standard deviation of the same measure.[35] The interpretation of ES developed by Cohen[36] was used, whereby a large effect is defined as 0.8 or higher, medium effect is 0.5, and a small effect is 0.2.

Differences between the MTS R2 and R1 ROM into knee extension and dorsiflexion ($R2$–$R1$) from baseline to post-casting were compared using paired-samples t tests. Alpha level was set at $p < 0.05$.

Inter-rater reliability coefficients for MAS, MTS, and GMFM-66 were determined using the ICC model 2[2][37] The closer the ICC is to one; the better the agreement is between raters. Using the guidelines suggested by Portney and Watkins,[37] we interpreted ICCs greater than 0.75 as "good" and those from 0.50 to 0.75 as "moderately acceptable." To determine the extent of error that would be expected with repeated measurements of MTS by different raters, the SEM was derived from the square root of the mean square error term in the analysis of variance table.[38] The Statistical Package for Social Sciences (version 11.0) was used for all analyses.

RESULTS

Subjects

Four males and 6 females were recruited, ranging in age from 26 to 75 months (mean = 49.0 months, standard deviation = 14.8 months). Seven participants had hemiplegia and 3 had diplegia. The background characteristics of the participants are presented in Table 1.

TABLE 1
Background Characteristics of the Participants

Participant	Sex	Age (mo)	GMFCS	BTX-A Injections
1	M	36	I	R calf, R hamstrings
2	F	46	I	R calf, R hamstrings
3	F	48	I	R calf, R hamstrings
4	F	36	I	R/L calf, R/L hamstrings
5	F	66	I	R calf, R hamstrings
6	M	54	I	L calf, L hamstrings
7	F	58	I	L calf, L hamstrings
8	F	75	II	R/L calf, R/L hamstrings
9	M	26	I	R calf
10	M	45	I	L calf

GMFCS indicates Gross Motor Function Classification System; BTX, botulinum toxin; M, Male; F, Female; R, right; L, left.

Acceptability and Practicality of Assessment Protocol

Nine of the participants and caregivers did not indicate any concerns with the physiotherapy assessment, BTX-A injections, and casting procedures when questioned about comfort level and time commitment. No adverse events (undue fatigue, discomfort, pressure sores) were reported. Participant 9 (see Table 1), the youngest participant, was unable to tolerate the initial assessment and was withdrawn from the study. In addition, post-casting PEDI assessment for participant 6 was not conducted because the participant did not attend the testing session with his primary caregiver. The evaluator indicated that the assessment protocol took on average 59 minutes (range, 52–70 minutes) to complete and was easily administered without the assistance of a second person.

Responsiveness of Measures to Change Over Time

Measures of Body Functions and Structures. As anticipated, reductions in MAS values for both plantarflexors and hamstrings were observed at post-testing ($p = 0.01$, ES = 1.30; $p = 0.01$; ES = 0.84, respectively) (Fig. 3). Improvements in the MTS were also seen in R1 and R2 values for dorsiflexion with the knee in extension ($p = 0.01$, ES = 1.35; $p = 0.00$, ES = 2.0, respectively) and R1 and R2 values for dorsiflexion with the knee in flexion ($p = 0.01$, ES = 1.0; $p = 0.00$, ES = 1.78, respectively) (Fig. 4). In addition, significant improvements were found in R1 values for knee extension ($p = 0.01$; ES = 0.77) but not in R2 values. From pretesting to post-testing, differences between R2 and R1 were demonstrated only for movement into knee extension ($p = 0.03$, ES = 0.93) (Fig. 5). GAITRite measures at post-testing revealed reductions in speed ($p = 0.00$; ES = −0.77) and cadence ($p = 0.01$; ES = 0.89) but not in stride length (Fig. 6).

Measures of Activity and Participation. The 95% CIs for the GMFM mean scores for pretesting and post-testing were 66.2 to 76.5 and 68.5 to 78.6, respectively. GMFM-66 scores increased modestly but significantly at post-testing ($p = 0.01$; ES = 0.46) as did PEDI self-care ($p = 0.01$; ES = 0.99) and PEDI Social Function scores ($p = 0.00$; ES = 0.35) (Fig. 7). The change in the PEDI mobility score (ie, $p = 0.03$) did not meet the level of significance set a priori (ie, $p < 0.01$) (Fig. 7).

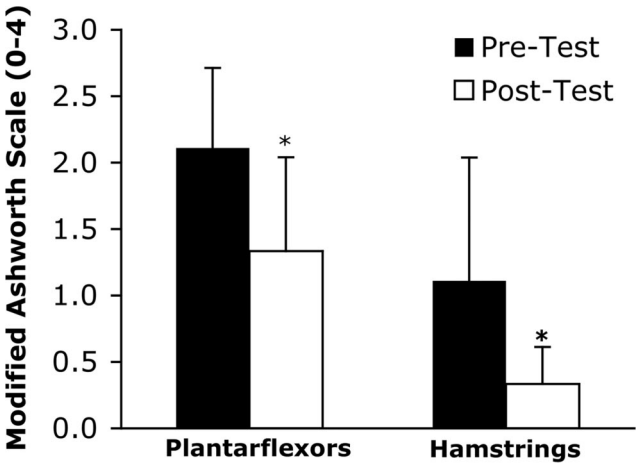

Fig. 3. Pretesting versus post-testing comparison of Modified Ashworth Scale. Error bars represent 1 standard deviation and asterisks indicate $p < 0.01$.

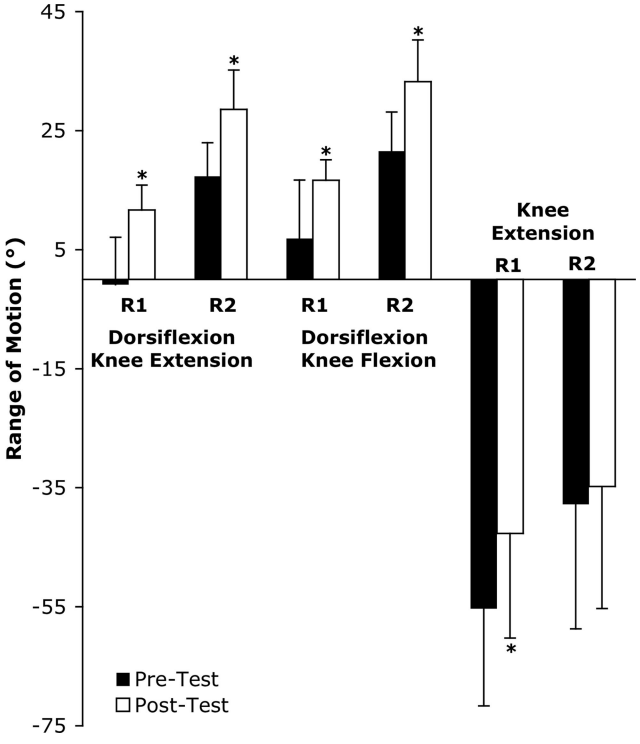

Fig. 4. Pretesting versus post-testing comparison of Modified Tardieu Scale measures. Error bars represent 1 standard deviation and asterisks indicate $p < 0.01$.

Inter-Rater Reliability

The inter-rater reliability ICCs for MAS of plantarflexors and hamstrings were 0.85 and 0.68, respectively and for GMFM was 0.96. The ICCs for the MTS ranged from 0.87 to 0.96 (Table 2). The amount of error for the MTS measures ranged from 3.3° to 6.1° (see Table 2).

DISCUSSION

Acceptability of the assessment protocol is perhaps the most critical aspect of feasibility, given the young age of

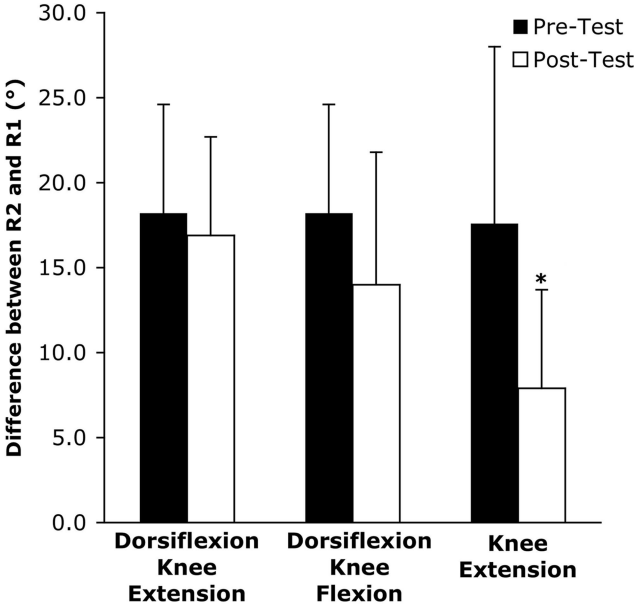

Fig. 5. Pretesting versus post-testing comparison of differences between *R2*/*R1* for Modified Tardieu Scale measures. Error bars represent 1 standard deviation and asterisks indicate $p < 0.05$.

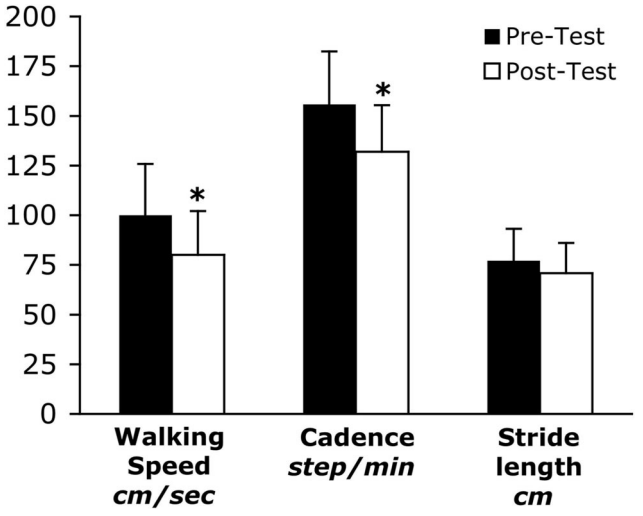

Fig. 6. Pretesting versus post-testing comparison of temporal-spatial parameters of gait. Error bars represent 1 standard deviation and asterisks indicate $p < 0.01$.

the participants and the absolute need for caregiver cooperation. Although a standardized satisfaction questionnaire was not administered, the assessments, BTX-A injections, and casting protocols were generally well accepted and there were no adverse events. One participant, the youngest in the group (26 months), was unable to tolerate the assessments. He was an active child and had difficulty in attending tasks. This observation calls into question the feasibility of recruiting 2-year-old children into the future trial. In a previous BTX-A and casting trial, Corry et al[11] did not report any difficulty with this age group but the assessment protocol contained fewer measures. Most studies included children older than 3 years.[4,5,12,13] In an investigation examining the effect of BTX-A alone, Sutherland et al[39] suggested that children younger than 4 years may have difficulty cooperating during assessments.

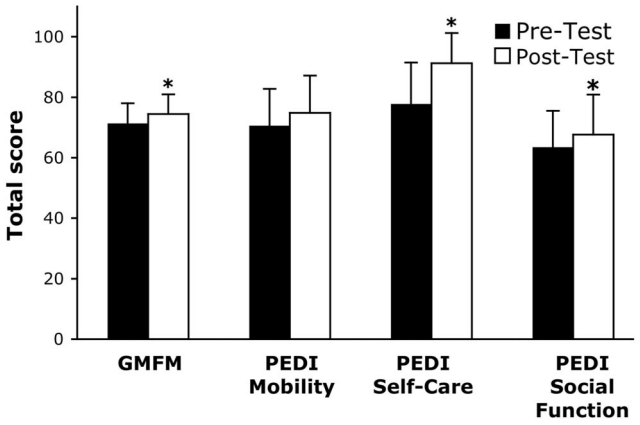

Fig. 7. Pretesting versus post-testing comparison of Gross Motor Function Measure (GMFM) and Pediatric Evaluation of Disability Inventory (PEDI). Error bars represent 1 standard deviation and asterisks indicate $p < 0.01$.

TABLE 2
Inter-Rater Reliability Interclass Correlations for the Modified Tardieu Scale

Variable Tested	ICC Coefficient	CI	SEM (°)
Knee extension *R1*	0.96	0.93–0.98	4.5
Knee extension *R2*	0.95	0.92–0.97	4.1
Dorsiflexion with knee extension *R1*	0.87	0.81–0.92	3.9
Dorsiflexion with knee extension *R2*	0.88	0.84–0.93	3.3
Dorsiflexion with knee flexion *R1*	0.94	0.89–0.97	5.2
Dorsiflexion with knee flexion *R2*	0.92	0.86–0.95	6.1

ICC indicates intraclass correlation; SEM, standard error of measurement; CI, confidence interval; *R1*, passive range of movement following a quick stretch; *R2*, passive range of movement available.

Practicality issues (time, resources) from the perspective of the evaluators were not a concern. The requirements were in keeping with the time normally allotted for BTX-A-serial casting physiotherapy assessments at our facility. However, direct costs (ie, cost of BTX-A, casting material, and physician/physiotherapist/orthopedic technician time) and indirect costs (ie, time off work for caregiver to attend and travel expenses) were not formally assessed in the present study.

When planning a clinical trial, a psychometric property of outcome measures that is of utmost importance is responsiveness to change over time. All of the measures demonstrated statistically significant differences and most reflected clinically meaningful differences. The extent of change in muscle tone in both the plantarflexors and the hamstrings mirrors the findings for MAS scores in previous studies investigating the combined effects of BTX-A and casting.[9,12,14] Similarly, the magnitude of change in the MTS for dorsiflexion with the knee in extension and flexion was consistent with the results in other studies.[5,12,13]

Neither MAS nor MTS findings alone can be used to discern the relative contribution to hypertonia of neural components of tone (spasticity or hyperexcitability of the

stretch reflex arc) versus non-neural components (passive restraint). However, Boyd and Hays[40] suggested that a large difference between R2 and R1 could be used for this purpose—a large difference indicating a greater contribution from the neural components. Thus, the significant and clinically relevant reduction in the R2–R1 difference for ROM into knee extension at post-testing would imply that the neural component of hamstrings hypertonia was more affected by the intervention whereas the lack of change in the R2–R1 differences for ROM into dorsiflexion would imply that the non-neural component of the plantarflexor hypertonia was targeted. It is possible that BTX-A had a greater effect on hamstring tone and serial casting had a greater effect on plantarflexor tone. More rigorous investigation of the mechanisms underlying tonal differences is planned for the controlled trial.

The significant and clinically meaningful reductions observed in walking speed and cadence were contrary to those found in recent studies.[5,12,14] This unexpected finding may be explained by the scheduling of the post-test, which was carried out sooner after cast removal than was the case in previous studies.[5,12,14] However, authors of a study reported that gait speed was decreased initially post-treatment (2 months) in 50% of the participants but at 6 months there was a significant increase in walking speed for all participants.[5] Thus, decreased speed and cadence may be due to the combined effects of the temporary weakness that occurs with BTX-A, the weakness that results from immobilization in a cast, and the imbalance between the agonist and antagonist muscles.[5]

It could be argued that clinically meaningful change scores in measures within the ICF components of activity and participation are more important to consider than statistically significant differences. The results for the GMFM-66 and the PEDI are clear illustrations of this point. Although a statistically significant change in total GMFM-66 was realized, the clinical significance of this finding is questioned from a few perspectives. The ES of the GMFM-66 change score fell short of the criterion for a "medium effect." Although a 6% change in the total score of the original version of the GMFM is considered clinically significant[41] the cutoff for the GMFM-66 has not yet been determined. However, examination of the 95% CIs for the GMFM mean scores can be used as an alternative assessment of clinically meaningful change. In the present study the CIs overlapped, suggesting that the degree of change was not clinically meaningful. Given the short period between BTX-A injection and post-testing (6 weeks) this finding is not surprising. Slawek et al[42] noted that a clinically significant change in GMFM scores was not observed until 3 months post-BTX-A injections. Similarly, another study reported improvements in GMFM scores after 4 months.[14]

A similar trend was noted of statistically but not clinically meaningful differences in 1 of 3 PEDI domains. Despite finding statistically significant differences in social function, the ES was low (0.35). Moreover, the minimal clinical important difference for PEDI change scores has been reported to be 11%,[43] whereas the change scores in social function and self-care in the present study were 9.2% and 6.6%, respectively. This lack of clinically meaningful difference may have been due to the short interval between intervention and post-testing. The finding that the PEDI mobility change score was neither statistically significant nor clinically meaningful is consistent with the observed reduction in walking performance at post-testing.

The ICCs for MAS plantarflexors met the acceptable value of 0.75. ICCs for hamstrings however were moderately acceptable. Previously, Clopton et al[23] reported the opposite pattern—higher inter-rater reliability for hamstrings (ICC = 0.79) than for plantarflexors (ICC = 0.33–0.45). Yam and Leung[20] also reported lower inter-rater ICCs for plantarflexors (ICC = 0.46–0.56). Fosang et al[21] reported low inter-rater ICCs for both hamstrings (ICC = 0.37–0.48) and plantarflexors (ICC = 0.27–0.45). The disparity in these findings may be due to variability in participant profiles—the aforementioned studies included children with GMFCS levels I to V, who present with wide variation in muscle tone whereas all children in the present study were at GMFCS level I or II. Nonetheless, given the concerns about the reliability of the MAS, our results should be viewed with caution.

The inter-rater reliability for MTS exceeded the minimum of 0.75, indicative of good reliability.[37] This, along with our finding that the amount of error in degrees for the MTS was generally around 5°, is consistent with a previous report on the reliability among raters and degree of error when the MTS is used with children with CP.[21] The excellent inter-rater reliability ICCs for the GMFM are consistent with the findings in the literature.[30]

A number of limitations in this pilot study were identified, including the small sample size, inability to ensure stability of the baseline findings because of the lack of serial measurements, inconsistency in BTX-A protocol in that not all patients received injections in the hamstring musculature, and absence of documentation of indirect costs to the caregivers. In addition, quality of life (QOL) is an important construct to consider when investigating health-related interventions, particularly when children are involved becuase interventions often have broad implications for many people. The ICF framework does not encompass health-related QOL measures; thus QOL was not reflected in our assessment protocol. This gap in the comprehensiveness of outcome measurement will be rectified in the future trial.

In summary, the overall objective of investigating the feasibility of the assessment protocol was met. Although the protocol was well accepted by the patients, caregivers and the evaluator, several issues were identified that, if addressed, would enhance the protocol to be implemented in the controlled, multisite study. Recommended modifications include the following: (1) raising the minimum age of participants from 2 to 3 years; (2) establishing stability of baseline measurements by adding a series of initial test sessions before intervention; (3) delaying post-testing of gait until 8 weeks after removal of the last cast; (4) administering a standardized parent satisfaction questionnaire

post-intervention; (5) performing cost analysis of the interventions under investigation; (6) conducting follow-up assessments on all measures at 3 and 6 months post-injection; and (7) adding a QOL questionnaire designed for the CP population.

CONCLUSIONS

The results of this study confirm the feasibility of the assessment protocol in terms of acceptability and practicality of the protocol by the participants, caregivers and the evaluator, as well as the inter-rater reliability and responsiveness of most of the outcome measures to change from baseline to post-testing. Modest modifications to this protocol will be made in preparation for our upcoming trial to examine the effects of the combination of BTX-A injections and casting for management of equinus gait in CP.

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ERRATUM

In the article "Effectiveness of the Test of Infant Motor Performance as an Educational Tool for Mothers," by Lou Ann Goldstein, PT, MS, PCS, and Suzann K. Campbell, PT, PhD, FAPTA, appearing in the Summer 2008 issue of *Pediatric Physical Therapy* (volume 20, number 2, pages 152–159), reference 24 is incorrectly cited in the following sentence: "Campbell et al[24] found that scheduled 'tummy time' increased with parent education, and the frequency increased when a pictured brochure was given." The correct reference is 26, and the sentence should read as follows: "Jennings et al[26] found that scheduled 'tummy time' increased with parent education, and the frequency increased when a pictured brochure was given."