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The Effectiveness of Casting and Botulinum Toxin A for Treating Equinus Gait in Children with Cerebral Palsy

Amy Smith
Pacific University

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The Effectiveness of Casting and Botulinum Toxin A for Treating Equinus Gait in Children with Cerebral Palsy

Disciplines

Physical Therapy

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The Effectiveness of Casting and Botulinum Toxin A for Treating Equinus Gait in Children with Cerebral Palsy

Clinical Scenario: The patient who has led me to pursue this question is a 5 year-old girl, with a diagnosis of spastic diplegic cerebral palsy. She is ambulatory with a reverse walker. She has undergone botulinum toxin A treatments in the past and has shown some improvements, but continues to exhibit equinus gait, with limited ankle dorsiflexion range of motion, both active and passive, and bilateral lower extremity spasticity.

Introduction: For the purposes of my clinical question, I want to analyze available research regarding the use of serial casting and botulinum toxin A on patients with cerebral palsy. The typical ambulation presentation is a crouch, equinus gait, which can significantly interfere with function. These two interventions are commonly used to treat these impairments, but there is some controversy as to their effectiveness. Botulinum toxin A and casting have been used alone for treatment, and sometimes in combination. Previous research has found botulinum toxin A to be both effective (Corry et al. 1998; Sutherland et al. 1999; Boyd et al. 2000; Ubhi et al. 2000), and ineffective (Ackman et al. 2005; Glanzman et al. 2004) when used alone. Casting alone has been found to be effective for treating both fixed equinus (Kay et al. 2004), and dynamic equinus (Ackman et al. 2005; Cottalorda et al. 2000). When used in combination, research has shown these two treatments to be more effective than casting alone (Booth et al. 2003), but also as effective as casting alone (Ackman et al. 2005; Glanzman et al 2004). My goal is to review the literature in order to clarify the effectiveness of these interventions.

My Clinical Question:

Is serial casting an effective treatment for equinus gait in children with cerebral palsy and does the addition of botulinum toxin A augment this intervention?

My PICO:

Population: Children with cerebral palsy and dynamic equinus gait

Intervention: casting

Comparison: botulinum toxin A combined with serial casting

Outcome: ankle ROM, GMFM, modified Ashworth scale

Overall Clinical Bottom Line: Based on the results of the outcomes from Flett et al. and Hayek et al. both serial casting and botulinum toxin A plus casting significantly improve equinus gait in children with spastic cerebral palsy. Flett et al. found a significant increase in dorsiflexion range of motion, of 8.87 degrees and a significant decrease in spasticity of 0.66 on the modified Ashworth scale using serial casting over a 6-month period. There is some uncertainty to the

significance of Gross Motor Function Measure (GMFM) improvements, although there was a mean GMFM change of 7.47. With botulinum toxin A alone, there was only a significant improvement in dorsiflexion, by 6.15 degrees. The two groups were not significantly different in any outcome measure. This study had good internal and external validity, with the exception of a small sample size, which slightly compromises the ability to generalize results.

Hayek et al. found that the addition of serial casting to botulinum toxin A injections significantly improves active dorsiflexion and GMFM scores. Botulinum toxin A alone resulted in a significant increase in active dorsiflexion range of motion of 5.1 degrees and in GMFM scores, of 7.7. Botulinum toxin A with casting resulted in a significant increase in active and passive dorsiflexion, of 12.4 and 6.4 degrees respectively, along with GMFM scores, of 9.7. Authors reported both groups experienced a significant decrease in spasticity using the modified Tardieu scale, but not the modified Ashworth scale, however no raw data was provided for this outcome measure. This study did have some threats to internal and external validity, including a lack of randomization, blinding, intention-to-treat analysis and a small sample size, which limits the ability to generalize the results to a larger population. Additional research using larger sample sizes with randomization and blinding is needed to help fully answer my clinical question.

Search Terms: serial casting, botulinum toxin A, cerebral palsy, equinus

Appraised By: Amy Smith, SPT, February 13, 2011

School of Physical Therapy

Pacific University

Hillsboro, OR 97123

smit7984@pacificu.edu

Rationale for Chosen Articles:

I searched in multiple databases on Pacific University's website including Medline-Ovid, Medline-Pubmed, CINAHL, and PEDro using the search terms mentioned above. After sifting through everything my comprehensive search came up with, I narrowed it down to these three articles. I tried to pick articles that matched my PICO the closest, while also being of high quality, as determined by the PEDro scale.

(1) Flett PJ, Stern LM, Waddy H, Connell TM, Seeger JD, & Gibson SK. Botulinum toxin A versus fixed cast stretching for dynamic calf tightness in cerebral palsy. *Journal of Pediatrics Child Health* 1999; 71-77.

PEDro Score: 7/10

P: 20 children with cerebral palsy, aged 2-8 years old

I: serial casting

C: botulinum toxin A injections

O: range of motion, modified Ashworth scale, Gross Motor Function Measure, video ratings using modified Physical Rating Scale and global scoring scale, parent satisfaction questionnaire

(2) Ackman JD, Russman BS, Thomas SS, Buckon CE, Sussman MD, Masso P, Sanders J, D'Astous J, & Aiona MD. Comparing botulinum toxin A with casting for treatment of dynamic equinus in children with cerebral palsy. *Developmental Medicine & Child Neurology* 2005; 620-627.

PEDro score: 3/10

P: 39 children with spastic cerebral palsy, aged 3-9 years old

I: serial casting

C: botulinum toxin A alone, botulinum toxin A with casting

O: ankle kinematics, velocity, stride length, spasticity, strength, range of motion, and kinetics

(3) Hayek S, Gershon A, Wientroub S, & Yizhar Z. The effect of injections of botulinum toxin type A combined with casting on the equinus gait of children with cerebral palsy. *Journal of Bone and Joint Surgery* 2010; 1152-1159.

PEDro score: 4/10

P: 20 young children with cerebral palsy

I: botulinum toxin A

C: botulinum toxin A with casting

O: ankle range of motion, observational gait score, selective motor control

When comparing these three articles, I looked at similarity of PICO's and overall quality. All of these articles used similar subjects to my patient, subjects diagnosed with cerebral palsy with equinus gait. All studies used serial casting and botulinum toxin A as interventions. The comparison interventions were slightly different between these studies, but all three addressed my clinical question. When comparing the PEDro scores that I came up with, displayed in Table 1 below, the article by Flett et al. is of the highest quality. The other two articles are of lower quality, scoring 3 and 4. The article by Hayek et al. had similar subjects at baseline, adequate follow-up, and included the availability of point estimates and variability, which is important when analyzing the data for comparison. The article by Ackman et al. lacked all three of these components.

Based on the above comparisons, I have chosen to write this critically appraised paper on the articles by Flett et al. and Hayek et al.

Table 1. Comparison of PEDro Scores

	Flett et al.	Ackman et al.	Hayek et al.
Random	1	1	
Concealed Allocation	1		
Baseline Comparability	1		1
Blind Subjects			
Blind Therapists			
Blind Assessors	1	1	
Adequate Follow-up	1		1
Intention-to-Treat			
Between Group	1	1	1
Point Estimates & Variability	1		1
Total Score	7	3	4

Article 1 of 2: Flett PJ, Stern LM, Waddy H, Connell TM, Seeger JD, & Gibson SK. Botulinum toxin A versus fixed cast stretching for dynamic calf tightness in cerebral palsy. *Journal of Paediatrics Child Health* 1999; 71-77.

Clinical Bottom Line: Based on the results of this study, there is strong evidence to suggest that for children with cerebral palsy, an intervention of serial casting results in clinically meaningful improvements in equinus gait. On average, study subjects experienced significant improvements in ankle spasticity, 0.66 on modified Ashworth scale, and range of motion, 8.87 degrees, over a 6-month period. Researchers found a mean improvement in GMFM scores of 7.47, however it seems to be of low statistical power. Botulinum toxin A was not found to result in significant improvements in spasticity or GMFM scores, but did result in significant improvements in range of motion, 6.15 degrees, however there was no statistically significant difference between the groups in any outcome measure. No MCIDs were provided for any outcome measures so there is some uncertainty to the level of significance. This study has good internal and external validity, however the sample size was small, which could limit the ability to generalize the results to a larger population. More research with larger sample sizes would be beneficial to fully explore the effectiveness of these interventions on equinus gait.

Article PICO

Population: 20 children with cerebral palsy, aged 2-8 years old

Intervention: serial casting

Comparison: botulinum toxin A injections

Outcome: range of motion, modified Ashworth scale, Gross Motor Function Measure, video ratings using modified Physical Rating Scale and global scoring scale, parent satisfaction questionnaire

Blinding: Both the rehabilitation specialist and the research physical therapist, who carried out all assessments, were blinded to group allocation. Subjects and individuals carrying out interventions, therapists and physicians, were not blinded. The lack of blinding in these two groups does not pose a significant threat to the study because it would be impossible to blind subjects to these interventions and knowing which group each child was in would not change the administration of the intervention and should not affect reliability of outcome measures. The important component to blinding is the assessors, which were blinded, therefore eliminating any bias.

Controls: All subjects acted as their own control, as there was no true control group, to detect change due to treatment. Each group was then compared to each other to determine which intervention was more effective.

Randomization: Subjects were randomly assigned to either the botulinum toxin A group or the casting group, and randomization was concealed from assessors. This randomization appeared to be effective, as subjects were similar at baseline.

Study: This was a prospective, randomized controlled trial, which included 20 subjects with a diagnosis of cerebral palsy. To be included in this study, subjects had to be ambulatory, exhibit dynamic calf tightness and equinus gait for which physical therapy and other non-surgical interventions were not effective. They also had to exhibit forced dorsiflexion of ankle and aged 2-8. Subjects were excluded if they had previous surgery or alcohol injections, fixed contracture or severe athetoid movements in affected limbs, significant leg length discrepancies, or would be over 8 years of age by the end of study. Subjects were not allowed to use neuromuscular blocking or aminoglycoside drugs. Of these subjects, 10 received a single treatment of botulinum toxin A, while the other 10 received serial casting. Those in the botulinum toxin A group received injections of 4-8 units/kg into the calf muscles using the Kerr Graham technique with a maximum of 20 units per site. They also received a local anesthetic prior to injections. The casting group received 2 successive casts, 2 weeks per casts, for a total of 4 weeks. Both groups received night plasters prior to the first follow-up visit.

Outcome measures: The outcome measures relevant to my clinical question include range of motion, modified Ashworth scale, and the Gross Motor Function Measure (GMFM). Measurements were taken at baseline, 2, 4, and 6 months. There was also a follow-up at 12 months by the rehabilitation specialist, but no data from this was included in the study. The

authors reported good inter-rater reliability of the Ashworth scoring and the range of motion measurements, which they tested themselves. The authors also reported that the modified Ashworth and the GMFM were valid tools for their study. There was no other mention of the reliability and validity of these tests, nor was there mention of minimal clinically important differences (MCIDs) for any of the outcome measures. Range of motion measurements using goniometry does have face validity.

Study Losses: Two subjects from the botulinum toxin A group withdrew from the study, one child for social reasons and the other for parental request of a different intervention. There was no mention of an intention-to-treat analysis performed.

Summary of Internal Validity: Overall, this study has good internal validity. Subjects were randomly assigned to groups, with concealed allocation, and were similar at baseline. There was blinding of the assessors and use of valid and reliable outcome measures. The only threats to internal validity include the lack of subject and therapist blinding and the lack of intention-to-treat analysis, which are minor threats and do not compromise the results of this study.

Evidence: In order to assess the effectiveness of serial casting, the range of motion, modified Ashworth, and GMFM measurements were analyzed at baseline and at 6 months. Change over time within this group was assessed to determine efficacy of this treatment. It should be noted that the authors did not state whether there was a significant difference within the groups, but only that there was not significant difference between the groups.

Table 2, below, displays the authors' data of spasticity changes made within each group over the course of the treatment as well as my calculations of the 95% confidence interval with the corresponding effect sizes. From this data, it appears that the casting group improved their scores by an average of .66, however the confidence interval, although small, crosses zero, meaning while most of the children did improve their scores, some may have experienced increased spasticity. The effect size is large, meaning that casting did seem to significantly reduce their spasticity, although no MCID was provided. When looking at the botulinum toxin A data, this group experienced a mean improvement of .28 on the modified Ashworth scale with a confidence interval of -0.65 to 1.21. Although this interval is small, it crosses zero, which means some subjects improved while some worsened. The effect size is small, meaning that this treatment did not have a significant change on the subjects' spasticity.

Table 2: Analysis of modified Ashworth scores within groups.

	Baseline	6 Months	Change	95% CI	Effect Size
Casting	2.53 (0.64)	1.87 (1.19)	-0.66	-0.25 – 1.57	1.03 (large)
Botulinum Toxin A	2.41 (0.65)	2.13 (1.06)	-0.28	-0.65 – 1.21	0.43 (small)

p < 0.001 for casting data; p < 0.03 for botulinum toxin A data. Data collected by physical therapists were used, as they were the assessors of other outcome measures.

Table 3, below, compares the two group’s mean post-intervention Ashworth scores, which were 1.87 for the casting group and 2.13 for the botulinum toxin A group. The mean difference between them is 0.26, with a confidence interval of -0.87 to 1.39. This means the true difference lies between these two numbers, but the range crosses zero, making the true difference hard to determine. The effect size is considered small, so there does not appear to be a significant difference between the groups.

Table 3: Between group analysis of modified Ashworth scores post treatment.

Casting	Botulinum Toxin A	Mean Difference (95% CI)	Effect Size (95% CI)
1.87	2.13	0.26 (-0.87 – 1.39)	0.23 (-0.70 – 1.16)

Table 4, below, displays the authors’ data of range of motion changes made within each group over the course of the treatment as well as calculations of the 95% confidence interval with the corresponding effect sizes. Looking at ankle dorsiflexion, both groups appear to have made significant improvements over a 6-month period. The casting group improved by an average of 8.87 degrees, being 95 percent confident that the true change is between 1.85 degrees and 15.89 degrees. Although this is a fairly large range of change, the large effect size of 1.64 suggests that casting did in fact have a big impact on range of motion. Similarly, the botulinum toxin A group improved by an average of 6.15 degrees, with a confidence interval of -0.30 to 12.60. Because the confidence interval crosses zero, despite the large effect size, this intervention may not have had as favorable effects as the mean change suggests. While some subjects improved by as much as 12.6 degrees, some may not have improved at all and some actually lost 0.3 degrees. The effect size is large, which tells us that this intervention did have a large impact on ankle range of motion, and most subjects did improve.

Table 4: Analysis of ankle range of motion (dorsiflexion) within groups.

	Baseline	6 Months	Change	95% CI	Effect Size
Casting	6.00 (5.41)	14.87 (8.96)	8.87	1.85 – 15.89	1.64 (large)
Botulinum Toxin A	6.85 (5.65)	13.00 (6.49)	6.15	-0.30 – 12.60	1.09 (large)

p < 0.001 for all data

When comparing mean ankle range of motion post-intervention, as shown in Table 5 below, there does not appear to be a significant difference between groups. The mean difference is 1.87 degrees, with a confidence interval of -6.10 to 9.84. This is a wide interval, so there is some uncertainty as to where the true difference lies. There is also a small effect size of 0.23, so the difference between the groups is not of much magnitude.

Table 5: Comparison of ankle range of motion (dorsiflexion) post treatment between groups.

Casting	Botulinum Toxin A	Mean Difference (95% CI)	Effect Size (95% CI)
14.87	13.00	1.87 (-6.10 – 9.84)	0.23 (-0.70 – 1.17)

Table 6, below, displays the authors' data of GMFM changes made within each group over the course of the treatment as well as my calculations of the 95% confidence interval with the corresponding effect sizes. The casting group experienced a mean change of 7.47 on the GMFM with a confidence interval of -19.67 to 34.61. This huge range of change, which crosses zero, means that while some subjects experienced a 34.61 improvement on the test, some may have experienced a 19.67 decline. Additionally, the effect size of 0.27 is considered small, so the magnitude of change is small. This leads to the conclusion that there is not strong evidence to suggest casting improves scores on the GMFM. The data also leads us to the same conclusion for botulinum toxin A, as the mean change is 8.84, with an even wider confidence interval than that of the casting group and a corresponding small effect size.

Table 6: Analysis of dynamic Gross Motor Function Measure (GMFM) scores (%) within groups.

	Baseline	6 Months	Change	95% CI	Effect Size
Casting	42.62 (27.17)	50.09 (29.97)	7.47	-19.67 – 34.61	0.27 (small)
Botulinum Toxin A	40.61 (24.00)	49.45 (30.27)	8.84	-20.13 – 37.81	0.37 (small)

p < 0.01 for all data.

When comparing intervention groups to each other regarding GMFM scores, as shown below in Table 7, there appears to be no significant difference between them. The mean difference of 0.64 is small, and the confidence interval of -29.46 to 30.74 is extremely large and crosses zero, suggesting uncertainty of the true difference between groups. The effect size is very small, being only 0.02, which suggests a small difference between groups. With this data, the evidence is not strong enough to say there is a difference between groups.

Table 7: Analysis of dynamic GMFM scores post treatment between groups.

Casting	Botulinum Toxin A	Mean Difference (95% CI)	Effect Size (95% CI)
50.09	49.45	0.64 (-29.46 – 30.74)	0.02 (-0.91 – 0.95)

Applicability of study results:

Benefits vs. Costs: The authors reported no adverse effects of either treatment, however parents did report the casting was more inconvenient. The financial costs of the botulinum toxin A treatment were much more than that of casting. The costs of each cast was \$70, thus the two casts for one leg would be \$140, but if both legs were casted, it would have been \$280. The reported cost of the injection was reported as \$450 per injection, thus it would also be doubled if it were given in both legs. It should be noted that these costs were reported in 1999, and costs have likely increased since then. These costs were reported in Australian dollars, however the current exchange rate to USA dollars is 1:1. The time of each intervention was likely the similar, with casting taking slightly more time since it was applied twice as the injections were only given once. The benefits reported were similar for each group, so one must weigh the financial costs and convenience of each treatment to determine which would be a better fit for the individual and family.

Feasibility of Treatment: Both treatments appear to be feasible in the United States, and should be covered by most health insurances. If insurance is not available, there are also other options such as Shriner’s Hospitals, which provide charity care. The procedures were described well enough to be reproduced, and both of these treatments are well known and accepted among the health care community. The casting could be done in the outpatient physical therapy department by a physical therapist, while the injections would have to be done by a physician during an outpatient visit. Neither treatment required adherence to a home program, however the casting group did require more care and precautions at home.

Summary of External Validity: This study has good internal validity and patients used in this study appear to be similar to those treated in the clinic, which allows generalization of the results. The sample size, however, is small which does limit our ability to extrapolate the results to a larger patient population to some degree.

Article 2 of 2: Hayek S, Gershon A, Wientroub S, & Yizhar Z. The effect of injections of botulinum toxin type A combined with casting on the equinus gait of children with cerebral palsy. *Journal of Bone and Joint Surgery* 2010; 1152-1159.

Clinical Bottom Line: Based on the results of this study, there is strong evidence to suggest that for young patients with spastic diplegic or hemiplegic cerebral palsy, an intervention of botulinum toxin A with casting results in significant improvements in ankle range of motion, 12.4 degrees (active), 6.4 degrees (passive), and GMFM scores, 9.7. Botulinum toxin alone also resulted in significant improvements with active dorsiflexion, 5.1 degrees, and GMFM scores, 7.7. When compared to botulinum toxin A alone, the combined treatment resulted in significantly greater improvements in active dorsiflexion and GMFM scores. There were some threats to internal validity, such as a lack of blinding, randomization, intention-to-treat analysis and no MCIDs reported for any outcome measures. There was also a small sample size. All of these factors limit the ability to generalize the results to larger patient populations. Additional research would be beneficial in clarifying the effects of these interventions, using larger sample sizes, with randomization and blinding.

Article PICO

Population: 22 young children with cerebral palsy, aged 3-5 years old

Intervention: botulinum toxin A

Comparison: botulinum toxin A with casting

Outcome: ankle range of motion, observational gait score, selective motor control

Blinding: There was no blinding of subjects, therapists/physicians, or assessors. The lack of blinding of assessors poses a threat to the internal validity of this study, as that allows a possible bias of measurements.

Controls: All subjects acted as their own control, as there was no true control group, to detect change due to treatment. Each group was then compared to each other to determine which intervention was more effective.

Randomization: There was no randomization of subjects and allocation was not concealed. Subjects were alternately assigned to groups, which seemed to be an effective strategy as groups were similar at baseline.

Study: This was a prospective study, which included 22 children aged 3-5 years old with cerebral palsy, both hemiplegic and diplegic distribution. Inclusion criteria were ambulatory children with an equinus gait. Exclusion criteria was previous botulinum toxin A injections or

injections to other sites, previous surgical treatment, fixed contractures, and spasticity-reducing medication. There were 11 subjects in group A, who received botulinum toxin A and casting, and 11 subjects in group B, who received just botulinum toxin A injections. All subjects received a local anesthetic before two botulinum toxin A injections to the heads of gastrocnemius. This procedure was repeated at four months and each subject received a total of 20 IU per kg/body weight of botulinum toxin A. Group A also received casts on the day of the injections and wore them for 2 weeks. Casts were applied with the ankle in neutral position. Both groups also received physical therapy 3 times a week, however specific interventions were not discussed.

Outcome measures: Outcome measures relevant to my clinical question are the modified Ashworth scale, active/passive ankle range of motion via goniometry using modified Tardieu scale, and the gross motor function measure-66 dimension E (GMFM). All measurements were taken by the same physical therapist at baseline and at 4 other times, spaced out over 8 months, which authors referred to as phase 0-4. Phase 1 was at 6 weeks, phase 2 at 4 months, phase 3 at 5.5 months, and phase 4 at 8 months. The right side measurements were used for data analysis in the diplegic children. The authors did not mention the reliability or validity of any outcome measures, however these measures are frequently used clinically, have face validity, and have been reported as being valid per other studies (Flett et al. 1999). The authors did not mention any MCIDs.

Study Losses: Two subjects from group B were dropped from the study due to failure of completing the appropriate follow-up. Authors did not mention performing an intention-to-treat analysis.

Summary of Internal Validity: The internal validity of this study is fair. There was a lack of randomization, blinding and intention-to-treat analysis, however subjects and groups were similar at baseline and outcome measures appear to be valid. The randomization and lack of subject and therapist/physician blinding are minor threats, but the lack of assessor blinding does pose a significant threat to the study's validity, as measurements may have been under the influence of assessor bias in order to show improvements when perhaps there were none or improvements were less than what was reported.

Evidence: To determine the effectiveness of the combined treatment using botulinum toxin A and casting, the outcome measures of spasticity, active/passive ankle range of motion, and GMFM scores were analyzed at baseline and at 8 months for both groups. Spasticity data was not presented, however the authors reported that spasticity was not significantly improved using the modified Ashworth scale in either group, but was found to be significantly improved in both groups using the modified Tardieu scale, but no significant difference between groups ($p < 0.0001$ set for all data).

Table 8 below, displays the authors' data of active and passive range of motion (ROM) changes made within group A over the course of the treatment as well as calculations of the 95% confidence interval with the corresponding effect sizes. This data shows a mean change in active ROM of 12.4 degrees, with a confidence interval of 9.24 to 19.16. This is a substantial increase in ROM, which authors report as significant. The corresponding effect size is large, confirming that the change was of a large magnitude. Increases in passive ROM were less, averaging 6.3 degrees, with a confidence interval of -3.55 to 16.15 and effect size of 0.50, which is medium. Although this range does cross zero, the majority of subjects did experience an increase in passive ROM and authors report this to be a significant change.

Table 8: Analysis of active and passive ankle range of motion (dorsiflexion) within group A.

	Baseline	8 Months	Change	95% CI	Effect Size
Active DF	-28.1 (5.6)	-13.9 (5.37)	12.4	9.24 – 19.16	2.54 (large)
Passive DF	3.5 (12.5)	9.8 (9)	6.3	-3.55 – 16.15	0.50 (medium)

Table 9 below, displays the authors' data of active and passive range of motion (AROM & PROM) changes made within group B over the course of the treatment as well as calculations of the 95% confidence interval with the corresponding effect sizes. Mean changes were smaller in this group, only improving by a mean of 5.1 degrees in AROM and 3.2 degrees in PROM. Confidence intervals cross zero for both APROM and PROM, but the majority of subjects lie in the improvement range. This intervention was found to have a large effect on active dorsiflexion, but a small effect on passive dorsiflexion, which is consistent with authors' reports of a significant difference only in active ROM in this group.

Table 9: Analysis of active and passive ankle range of motion (dorsiflexion) within group B.

	Baseline	8 Months	Change	95% CI	Effect Size
Active DF	-27.1 (6.21)	-22 (6)	5.1	-1.01 – 11.21	0.82 (large)
Passive DF	8.7 (7.6)	11.9 (7.5)	3.2	-4.35 – 10.75	0.42 (small)

Even though both groups significantly improved their active dorsiflexion, the data in Table 10 below, shows a significant difference between groups, with the group receiving both interventions improving to a larger extent. There was a mean difference of 8.1 degrees between groups at the end of the study, which is considered to be a large difference according to the effect size of 1.43. Passive ROM did not appear to be significantly difference between groups at 8 months, even though only group A experienced a significant improvement during

the study. This could be explained by the baseline measurements, as group B started with more ROM than group A, however this was not considered a significant difference.

Table 10: Active/passive ankle range of motion (dorsiflexion) post treatment between groups.

		95% Confidence Interval
Mean Difference (active)	8.1	2.73 – 13.47
Effect Size (active)	1.43	0.45 – 2.42
Mean Difference (passive)	2.1	-5.84 – 10.04
Effect Size (passive)	0.25	-0.63 – 1.14

Table 11 below, displays the authors’ data of GMFM score changes made within each group over the course of the treatment as well as calculations of the 95% confidence interval with the corresponding effect sizes. This data shows that both groups significantly improved their scores, with group A having a mean change of 9.7 and group B of 7.7.

Table 11: Analysis of GMFM-66 dimension E scores within groups.

	Baseline	8 Months	Change	95% CI	Effect Size
Group A	54.6 (5.05)	64.3 (3.7)	9.7	5.70 – 13.70	1.92 (large)
Group B	50 (5.64)	57.7 (4.2)	7.7	2.73 – 12.67	1.37 (large)

The data displayed below in Table 12 shows a mean difference of 6.6 between groups in GMFM scores at 8 months. Although the authors reported no significant difference between groups, calculations show that group A improved significantly more than group B in this measure.

Table 12: Mean difference and effect size for GMFM-66 dimension E scores post treatment between groups.

		95% Confidence Interval
Mean Difference	6.6	2.87 – 10.33
Effect Size	1.68	0.66 – 2.70

Applicability of study results:

Benefits vs. Costs: The authors reported no adverse effects of either treatment. The financial costs of the botulinum toxin A treatment and that of the casting were discussed in the previous article. Using that data the total costs for group A would be approximately \$1,040 and total costs for group B would be approximately \$900. The time of each intervention was likely similar, with casting taking slightly more time. The group receiving both botulinum toxin A injections and casting seemed to experience more benefits than the botulinum toxin A only group. So for a slightly higher cost, the added benefits of casting appear to be worthwhile.

Feasibility of Treatment: Both treatments appear to be feasible, and should be covered by most health insurances. If insurance is not available, there are also other options such as Shriner's Hospitals, which provide charity care. The procedures were described well enough to be reproduced, and both of these treatments are well known and accepted among the health care community. The casting could be done in the outpatient physical therapy department by a physical therapist, while the injections would have to be done by a physician during an outpatient visit. Neither treatment required adherence to a home program, however the casting group did require more care and precautions at home.

Summary of External Validity: The ability to generalize the results of this study is slightly compromised due to the threats of internal validity as well as the small sample size. Although the subjects used in this study are similar to those seen in a typical pediatric clinic, caution should be used when extrapolating these results to a larger patient population of individuals diagnosed with cerebral palsy.

Synthesis/Discussion: These studies both looked at the effect of botulinum toxin A alone, but came up with slightly different results. This could be due to the difference in protocols of the injections, as Flett et al. only gave a single treatment of botulinum toxin A, while Hayek et al. gave two treatments 4 months apart, which likely enhanced the effect. Also Hayek et al. included physical therapy in both interventions, which also likely had an effect. The comparison groups in these studies were different, with Flett et al. comparing botulinum toxin A to serial casting and Hayek et al. comparing it to botulinum toxin A plus casting. Findings of both studies showed significant improvements with these comparison interventions, with regards to ankle range of motion, spasticity, and GMFM, although Flett et al.'s results on the GMFM are questionable. The casting was done with different protocols. Flett et al. used a true serial casting method, applying two successive casts immediately after botulinum toxin A injections, whereas Hayek et al. applied only one cast after the first injection, and another after the second injection. Even though the treatments were slightly different, similar outcomes were found. It

should also be noted that Flett et al. looked at outcome measures at 6 months post treatment, and Hayek et al. looked at them at 8 months post treatment, but this was only 4 months after the last injection. The methodology in both studies was decent, with the exception of Hayek et al. failing to blind assessors. Both studies used small sample sizes, of less than 12 subjects per group, which limits the statistical significance of all results. It seems to be difficult to recruit larger sample sizes with pediatric populations, as most studies I reviewed during this research process were of similar sizes. After critically appraising these two studies, it seems that both serial casting and botulinum toxin A injections are beneficial treatment options which should be considered for children with spastic cerebral palsy demonstrating a dynamic equinus gait.

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