A systematic review of the effects of casting on equinus in children with cerebral palsy

An AACPDM Evidence Report

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Summary

This systematic review examines the effects of casting, either alone or in combination with botulinum toxin type A (BtA), on equinus in children with cerebral palsy (CP). Comparisons are made between casting alone and no treatment, between casting alone and BtA alone, between combined casting and BtA and each treatment by itself, and between casting followed by BtA and BtA followed by casting. We searched the databases PUBMED, CINAHL, Proquest Health and Medical Complete, Cochrane Database of Systematic reviews, Physiotherapy Evidence Database (PEDro), OTseeker, Database of Reviews of Effectiveness (DARE), and Infotrieve. Articles were included if they reported the effects of an intervention using casting for equinus in participants with CP, aged 20 years or less, and if the article appeared in a peer-reviewed scholarly journal in 1970 or later, with no language restriction. Articles were excluded if casting was used in conjunction with surgery. Of 12 studies on casting only, there was only one RCT (Bertoti). This study found that casting improved stride length significantly more than no casting, but with a casting protocol no longer in common use. Three RCTs comparing casting with BtA (Corry, Flett, Ackman) reported no differences at post-test, though Corry reported significant differences at 12 weeks follow-up in favour of BtA. Three RCTs, comparing casting plus BtA with casting only (Booth, Kay, Ackman) produced diverse results. Two RCTs (Bottos and Ackman) comparing combined casting and BtA with BtA only produced differing results. One study (Desloovere) found no significant differences between treatment with BtA followed by casting and treatment with casting followed by BtA. There is little evidence that casting is superior to no casting (with significant improvements only in stride length), but the protocols of casting in current use have not been compared with no treatment in any RCT. There is no strong and consistent evidence that combining casting and BtA is superior to using either intervention alone, and in fact, there is some evidence that casting alone may be better at reducing spasticity 6 to 12 months post-treatment. Nor is there any strong and consistent

evidence that either casting or BtA is superior immediately after treatment. Finally, there is no evidence that order of treatment (casting before BtA versus BtA before casting) affects outcome. In the light of current evidence, treatment choices between casting, BtA and the combination will depend upon other considerations, such as availability, cost, convenience, family preference, and therapists' experience with the treatments. Future research needs to use adequate sample sizes, long-term follow-ups, and broader and more global measures. (419 words)

RUNNING HEAD: Systematic review on casting for equinus

The AACPDM has undertaken the development of systematic reviews to summarize the literature about specific intervention strategies used to assist children with developmental disabilities. These reviews are not best practice documents or practice guidelines, but rather they gather and present the best evidence – for and against – the effectiveness of an intervention. Their goal is to present the evidence about interventions in an organized fashion to identify gaps in evidence and help address new research that is needed. The Academy is neither endorsing nor disapproving of an intervention in these reviews. Every effort has been made to assure that AACPDM systematic reviews are free from real or perceived bias. Details of the disclosure and consensus process for AACPDM outcomes reports can be viewed at www.AACPDM.org. Nevertheless, the data in an AACPDM Systematic Review can be interpreted differently, depending on people's perspectives. Please consider the conclusions presented carefully.

Introduction

Casting has been recommended as a treatment option in the management of equinus in children with cerebral palsy (CP) for several decades (1, 2). Casting is the application of fibreglass and/or plaster to the lower limb to immobilize the ankle. Equinus, defined as increased plantarflexion (PF) at the ankle and standing or walking with increased weight bearing on the metatarsal heads, is one of the most frequent reasons for intervention in children with CP (3). Dynamic, or non-fixed, equinus is attributed to spasticity in the calf muscles (4) and imbalance between action of the gastrocnemius-soleus and pre-tibial muscles. Fixed equinus is caused by muscle contracture, attributed to faster growth in the tibia than the spastic calf muscle-tendon unit (5).

There are several interventions used to treat equinus and calf spasticity in children with CP, and, clinically, many are used in combination. Options include static and prolonged muscle stretching, casts, ankle foot orthoses (AFO), botulinum toxin type A (BtA) and orthopaedic surgery (2, 4, 6).

When casting is used, either a single cast or multiple casts may be applied. Serial or progressive casting involves the successive application of a series of casts, progressively increasing the amount of dorsiflexion with each cast (7). Over the past 10-15 years, it has become common clinical practice to combine serial casting with BtA injections, which is thought to achieve optimal improvement in equinus (3, 4, 8). Casting is applied either before or, more commonly, after BtA injections. Clinical reasoning suggests BtA addresses spasticity (and reduces dynamic equinus), with serial casting applied to treat any early contracture (3, 4).

Many rationales for the effects of casting on ankle range of motion (ROM) and calf muscle shortening have been postulated, but have not been well substantiated in research (7). Results from animal studies suggest that immobilisation of muscle in a lengthened position increases sarcomere number, with changes reverting to baseline four weeks after cast removal (9). Other animal experimental models exposed to incrementally applied static stretch over several weeks resulted in an increase in weight, muscle length, number of sarcomeres in series and cross sectional area of the type 1 fibres (10).

This systematic review examines the effects of casting, either alone or in combination with BtA, on equinus in children with cerebral palsy. Comparisons are made between casting alone and no treatment, between casting alone and BtA alone, between combined casting and BtA and each treatment by itself, and between casting followed by BtA and BtA followed by casting.

Method

Search strategy

Using the search term “cerebral palsy AND cast*”, or, in those databases where the asterisk was not accepted “cerebral palsy AND (cast OR casts OR casting OR casted)”, a search of PUBMED, CINAHL, Proquest Health and Medical Complete, Cochrane Database

of Systematic reviews, Physiotherapy Evidence Database (PEDro), OTseeker, Database of Reviews of Effectiveness (DARE), and Infotrieve was conducted.

SELECTION OF ARTICLES

The selection criteria were as follows. An article was included: if it reported the effects of an intervention using casting for equinus; if the study participants were aged 20 years or less and diagnosed with CP (with separate results for the participants with CP if the sample included participants without CP); and if the article appeared in a peer-reviewed scholarly journal in 1970 or later, with no language restriction. Articles were excluded if casting was used in conjunction with surgery, and if the article was a review, survey, anecdote, letter or comment.

Using the inclusion and exclusion criteria, two of the authors independently reviewed the articles' titles and abstracts. Where there was uncertainty, the full article was obtained. The reference lists of all selected articles were also reviewed, and any articles that met the selection criteria were included. One hundred and eighty-four citations were examined, and 162 were excluded because casting was used in conjunction with surgery (n=55), articles were reviews, comments or letters (n=10), participants did not have CP (n=10), casting was not used for equinus (n=33), casting was not being investigated (n=51), the articles were pre-1970 (1, 11) (n=2), or some of the participants did not have CP and no separate results were given for the subgroup with CP (12) (n=1).

Twenty-two articles met the inclusion criteria. There was one French article, which was translated, formatted like the original French article, and placed among the English articles. All articles were copied and distributed to the four authors.

DATA EXTRACTION

The American Academy of Cerebral Palsy and Developmental Medicine's (AACPDM) Methodology to develop systematic reviews of treatment interventions (Revision 1.1) (13) was used for extracting data from the articles. Each article was coded independently by the

four authors and any disagreements were resolved by discussion. Methodological data were extracted to describe the population, sample size, and interventions. The outcomes in the articles with levels I, II or III of evidence were coded according to the International Classification of Function (ICF) components (14) shown in Table 1. Level of evidence was rated from I to V according to the rating system presented in Table 2.

Insert Tables 1 and 2 about here

Descriptions of the samples and interventions used in each study, their research designs and ratings of their levels and quality, are shown in Table 3. The table is divided into five sections: (1) Casting only studies, (2) Casting only versus BtA only studies, (3) Casting plus BtA versus casting only studies, (4) Casting plus BtA versus BtA only, and (5) Casting then BtA versus BtA then casting studies.

Insert Table 3 about here

Quality assessment

The AACPDM conduct questions were used to rate the quality of all original studies. Tables 4a and 4b show the ratings for each of these questions for studies with levels I, II or III of evidence.

Insert Tables 4a and 4b about here

Outcomes

The outcomes of studies at levels I, II or III of evidence are summarized under the three ICF components in Table 5.

Insert Table 5 about here

Results

Description of studies

Since two articles reflect short reports of studies published subsequently at length (15-18) and one article assessed the economics of casting with BtA (19), 19 original studies were

identified which met the inclusion criteria. These are listed in Table 3, and divided into five categories: casting only (12 studies), casting only versus BtA only (3 studies), casting plus BtA versus casting only (3 studies), casting plus BtA versus BtA only (2 studies), and casting then BtA versus BtA then casting (1 study). These numbers sum to 21 because one study (20) had three groups (Casting only, BtA only and combined), so all three comparisons are considered, each under the relevant section of the results.

ADVERSE EFFECTS

Table 6 summarizes the adverse effects of casting reported in the studies in this review.

Insert Table 6 about here

Discussion

1. WHAT EVIDENCE EXISTS ABOUT THE EFFECTS OF THE INTERVENTION IN THE COMPONENTS OF ICF IN WHICH IT WAS EXPECTED TO WORK?

Most investigators of the effects of casting and BtA have looked for changes in calf spasticity, ankle ROM and gait parameters. These outcomes are represented by the components of body function and structure in the ICF.

Spasticity

The effects of casting on spasticity have not been compared with the effects of no casting. When casting was compared with BtA, there was no significant difference in spasticity (6, 20). There were conflicting findings when casting plus BtA was compared with casting only (18, 20), the latter reducing spasticity more 6, 9 and 12 months after treatment in one study (18). When casting plus BtA was compared to BtA alone, casting plus BtA was superior 4 months after treatment in one study (21), but no significant difference was found in another study (20).

Passive Ankle Dorsiflexion

The RCTs found no significant differences in this outcome between casting and BtA (6, 20), between casting plus BtA and casting alone (8, 18, 20), or between casting plus BtA and BtA alone (20, 21)

Gait Parameters

Children who received casting showed significantly greater improvements in stride length than children who received no casting (22). When casting was compared to BtA (6, 20) and to casting plus BtA (18, 20), no immediate differences were found. However, one study (17) tested participants 12 weeks later and found significant differences (in maximum ankle dorsiflexion in stance and maximum plantarflexion) in favour of BtA. Studies comparing casting plus BtA with BtA alone had conflicting outcomes, one showing no differences (20), and the other favouring the combined treatment in measures of stride length and speed of progression (21). Investigation of the order of treatment (casting followed by BtA versus BtA followed by casting) did not show either order to be superior (23).

2. WHAT EVIDENCE EXISTS ABOUT THE EFFECTS OF THE INTERVENTION IN THE OTHER COMPONENTS OF ICF?

Activity and Participation

Three RCTs (6, 18, 21) investigated activities using the Gross Motor Function Measure (GMFM) (24). One compared casting with BtA (6) and another compared combined casting and BtA with casting only (18). Neither of these studies showed any effects of treatment on this outcome measure. The third (21) compared combined casting and BtA with BtA only, and found a significant difference at 4 months follow-up in favour of the combined treatment, but no other differences.

There were no attempts in any of the studies to investigate any broader measures of participation than gross motor function, such as mobility and how it affects day-to-day activities at home, at school, and in the community.

Contextual Factors

Apart from a few comments from parents on how they liked the treatments, contextual or environment factors (such as attitudes and supports from family and peers and need for further services) have not been examined.

A systematic review of the efficacy, parent satisfaction, and relative costs of casting and BtA (19), which included two of the RCTs reviewed here (6, 17), concluded that efficacy is similar (though the effects of BtA may last longer), that parents are more satisfied with BtA because they find it less inconvenient, and that, in Australia, the costs of BtA are 37% higher than casting for children with hemiplegia and 20% higher for children with diplegia.

3. What evidence exists for linkages of effects within and between these components?

Limited evidence exists on linkages between ICF components because measures of activity and participation are rarely included in the studies and objective measures of contextual and environmental factors are never included. One study found improvements in gross motor function in walking (using the GMFM) in association with improvements in spasticity, stride length and speed of progression in walking (21) —which may suggest linkages between body functions and activities. This would need to be confirmed in other studies.

4. What kinds of magnitude of complications have been documented?

The commonest reported adverse effects of casting are skin irritation and breakdown and foot and calf pain. (See Table 6.) Reported adverse reactions to casting were usually minor and rarely required discontinuation of treatment. However, long-term adverse effects were not assessed in these studies, as follow-ups never exceeded 12 months. The effects of casting and BtA (especially when combined) and their contribution to weakening muscles in children with CP are rarely considered (25).

5. What is the strength of the evidence?

Although a substantial number of studies was located, only a few had adequate internal validity (Level of Evidence I-III) to be informative (6, 8, 17, 18, 20-23). These studies varied in the treatments compared (e.g., casting versus no treatment, casting versus BtA, casting plus BtA versus casting only).

Three limitations were pervasive: small sample sizes and lack of power calculations, lack of blinding, and inadequate treatment of dropouts. Only one study (20) conducted a power analysis, and this study determined a need for 25 children per group to give a 90% probability of detecting at least 5^{o} change in ankle kinematics. The maximum group size in any RCT was 17 (23). Study assessors were blinded in only four studies (6, 17, 20, 23). Blinding of study participants was achieved with BtA in one study (20) by the use of a placebo injection but never with casting (which would be extremely difficult). No study conducted an intention-to-treat analysis and dropout rates were as high as 12.5% for casting (2) and 25% for BtA (20).

Generalizability is limited because protocols varied (e.g., angle of dorsiflexion in which the cast was applied; whether the cast was once-off, serial or progressive; use and timing of co-interventions; dosage of BtA) and because current practice differs from that in early studies (e.g., in treatment intensity and duration of daily wear (22)).

Conclusions

IMPLICATIONS FOR PRACTICE

The decision regarding the use of casting for equinus in children with cerebral palsy is a complex one owing to differences in protocols. Several generalizations, however, are possible: There is little evidence that casting is superior to no casting (with significant improvements only in stride length) (22), but the protocols of casting in current use have not been compared with no treatment in any RCT. There is no strong and consistent evidence that combining casting and BtA is superior to using either intervention alone, and in fact, there is some evidence that casting alone may be better at reducing spasticity 6 to 12 months

post-treatment (18). Nor is there any strong and consistent evidence that either casting alone or BtA alone is superior to the other immediately after treatment, though BtA may have the edge after 12 weeks (17). Finally, there is no evidence that order of treatment (casting before BtA versus BtA before casting) affects outcome.

In the light of current evidence, treatment choices between casting, BtA and the combination will depend upon other considerations, such as availability, cost, convenience, family preference, and therapists' experience with the treatments.

IMPLICATIONS FOR RESEARCH

The apparent contradictions in the studies reviewed here highlight some significant gaps in current knowledge of the effects of casting. Over the past 25 years, there have been enormous improvements in the quality of research designs investigating casting. If this trend continues, then more robust findings should start to emerge.

The ubiquitous challenge in these studies has been obtaining a sufficient sample size. Adequate comparisons of groups receiving casting alone, BtA alone and the combination will probably be possible only in a multi-centre trial. In addition, future researchers may consider the use of long-term follow-ups to determine the long-term positive and adverse effects of the treatment; and the inclusion of broader and more global measures to investigate ICF areas other than body functions and structures, such as activity and participation outside the clinic, and measures from families and peers.

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Table 1. ICF Components and Definitions

ICF Component	Definition
Body Function	Body functions are the physiological functions of body systems including psychological functions
Body Structure	Body structures are the anatomical parts of the body such as organs, limbs, and their components
Activity	Activity is the execution of a task or action by an individual
Participation	Participation is involvement in a life situation
Context/Environmental Factors	Environmental factors make up the physical, social and attitudinal environment in which people live and conduct their lives

Table 2. Levels of Evidence used in AACPDM reviews

Level	Intervention (Group) studies
I	Systematic Review of randomized controlled trials (RCTs)
	Large RCT (with narrow confidence intervals) (n>100)
II	Smaller RCTs (with wider confidence intervals) (n<100)
	Systematic Reviews of cohort studies
	"Outcomes research" (very large ecological studies)
III	Cohort studies (must have concurrent control group)
	Systematic reviews of Case Control Studies
IV	Case series
	Cohort study without concurrent control group (e.g. with historic control group)
	Cast-control Study
V	Expert Opinion
	Case study or report
	Bench research
	Expert opinion based on theory or physiologic research
	Common sense/anecdotes

Table 3. Summary of studies – interventions and participants

Study	Level of evidence Research design	Intervention		Population	Total n	Ages
CASTING ONLY STUDIES		***Casting group***	***No casting group***			
Sussman and Cusick 1979 (26)	IV-W (2/7) Case series	TR PC with toes extended for average of 42d, followed by orthotic devices and physiotherapy.	None	CP; functional (not fixed) equinus correctable to neutral; SD or SQ; at least able to stand on prone board.	52	10mo-14y 9mo (median=2y 6mo)
Tardieu et al. 1982 (5)	IV-W (1-2/7) Case series	Progressive PC above or below knee; generally 3 casts over 3w; 18 chn also had surgery; many had diazepam.	None	CP; spastic hypoextensibility of Triceps surae, classified by presence (n=18) or absence (n=11) of persistent sustained contraction of triceps surae.	29	4-14y
Otis et al. 1985 (27)	IV-W (1/7) Case series	PC or FGC in neutral ankle position bivalved; worn daytime for median of 5w after short period of full-time use.	None	Boys with SD.	8	3-6y

Bertoti 1986 (22)	II-M (5/7) Small RCT	Bilateral PC with footplates bivalved same day and worn during physiotherapy, daily home program and at least 4h play/d for 10w; plus therapy as for other group.	Physical therapy 2x/w for 10w and home program.	CP; Cast SD (3), SH (3), SQ (2); Ctl SD (4), SH (3), SQ (1); ambulatory or able to accept full weight with support; flexible equinus or equinovarus; passive ankle df to at least 5^{o} with knee extended; normal intelligence; no other medical complications.	16 Cast=8 Ctl=8	Cast 1y 3mo-6y 4mo (M=2y 9mo); Ctl 10 mo-11y 0mo (M=4y 1mo)
Watt et al. 1986 (2)	IV-M (5/7) Case series	Bilateral inhibitive PC ankles plantigrade and toes extended worn for 3w with physiotherapy 2x/w & daily home program; after removal daytime AFOs & physiotherapy, and/or home program for 6 mo.	None	CP; SD (17); SQ (8); SH (3); no fixed equinus; at least 5^{o} passive ankle df with knees extended; no static varus or valgus; able to stand with support; 15 walked independently; 12 normal, 16 below average intelligence.	28	1y 6mo-5y (M=2y 7mo)

		Casting conditions	***No casting condition***			
Hinderer et al. 1988 (28)	W (3/7) Single subject ABAC design	Two interventions: (1) Bivalved standard PC with ankle plantigrade worn for >6h/d for about 5w; (2) Bivalved tone-reducing PC with inhibitive footplate with ankle plantigrade worn for >6h/d for about 5 w. Plus NDT-based physical therapy throughout.	NDT-based physical therapy and no casts.	Boy with mild SD and below average intelligence who walked independently; girl with mild asymmetric SD, ataxia and average intelligence who walked independently.	2	3y 6mo boy and 5y 9mo girl
		Casting group	***No casting group***			
Dvir et al. 1991 (29)	IV-W (3/7) Case series	Bilateral TR PC applied in neutral ankle position with toes df for 3w, plus 1h NDT sessions twice weekly.	None	CP; SD (6), SQ (7); equinus but no fixed contracture; no previous surgery; only one ambulatory without support; 4 with ID, 7	13	3-5y

				borderline, 2 normal intelligence.		
Cottalorda et al. 1997 (30)	IV-M (5/7) Case series	Serial PC: 1 cast/w for 2w (n=4) or 3w (n=16) plus 3 physiotherapy sessions/w plus night orthosis.	None	CP; 10 with hemiplegia, 8 with diplegia, 2 with quadriplegia; one used walker, others walked independently.	20	2y 4mo-8y (M=4y 6mo)
Cameron and Drummond 1998 (31)	IV-M (4/7) Case series	Progressive FGC: 1 cast/w for 4w until at least 20^{o} df plus daily therapy; AFO after cast removal worn 1.5-2h/d.	None	CP; SD (6), SH (4); loss of primary heel strike, reduced active and passive ankle df; able to walk independently; able to follow instructions.	10	3y 6mo-11y 9mo (M=6y 4mo)
Brouwer et al. 1998 (32)	IV-W (3/7) Case series	Progressive FGC cast midway between R1 and R2: 1 cast/w for 3w.	None	CP; SD (4), SH (3); restricted ankle df.	7	4-14y
Cottalorda et al. 2000 (33)	IV-M (4/7) Case series	Progressive FGC at maximal df: 1 cast/w for 3w followed by below knee night splint and physiotherapy with repeated passive stretching of tendon.	None	CP; SD (10) or SH (10); able to walk independently without aids; toe-walking; fixed triceps surae contracture no more than 10^{o} of fixed equinus with knees extended and no static ankle varus or valgus	20	2y 4mo-5y 11mo (M=4y 1mo)

				deformity; no previous surgery.		
Brouwer et al. 2000 (34)	IV-W (3/7) Case series	Serial FGC midway between R1 and R2: 1 cast/1-2w for 3-6w.	None	Limited ankle df; CP (8) with SD (5) or SH (3); ITW (8)**.	16	3-12y CP (M=7y 1mo) ITW (M=7y 6mo)
CASTING ONLY VERSUS BTA ONLY STUDIES		***Casting only***	***BtA only***			
Corry et al. 1998 (17)	II-M (4/7) Small RCT	Lightweight casts if possible in neutral ankle position for 4-6w, changed at 2w if neutral not achieved; plus normal physiotherapy.	BtA injected into gastrocnemius and soleus at 4 points/calf; 8 children had Botox (6-8 U/kg) and 2 had Dysport (15U/kg); plus normal physiotherapy.	CP; ambulant; with dynamic component to calf equinus; 11 with diplegia, 8 with hemiplegia, 1 with quadriplegia.	20	2-9y (M=4y 7mo)
Flett et al. 1999	II-S (6/7) Small	Progressive PC: 1 cast/2w for 4w; plus	Injection of 4-	CP; Cast: SD (4) SH (4) SQ (1) ST	18	Cast M=3y 7mo,

(6)	RCT	night plasters.	8U/kg BtA into targeted calf muscles; plus night plasters.	(1); Ctl: SD (6) SH (10) SQ (1); ambulatory (some with aids); dynamic muscle tightness and equinovarus or equinovalgus foot positioning; not currently requiring surgery; no previous calf/foot surgery; no LLD >5cm; no significant muscle weakness in calf.	Cast=10 Ctl=8	s=1y 4mo; Ctl M=3y 8mo, s=1y 5mo
Ackman et al. 2005* (20)	II-S (6/7) Small RCT	3 3-monthly P and FGC applied with ankle in 0-5^{o} df, each for 3w; followed by AFOs removed only 2-4h in evening.	3 3-monthly injections of 4U/kg BtA into gastrocs plus AFOs as for cast group.	CP; Cast: SH (10), SD (4), SD (4); BtA: SH (8), SD (4); Cast+BtA: SH (8), SD (5); ambulant without devices; ankle neutral when knee extended; all but one child at GMFCS level 1.	39 Cast=14 BtA=12 Cast+BtA=13	Cast: 3y 0mo-9y 0mo (M=5y 8mo) BtA: 3y 4mo-8y 9mo (M=5y 9mo) Cast+BtA: 3y 5mo-8y 3mo (M=6y 0mo)

CASTING PLUS BTA VERSUS CASTING ONLY STUDIES		***Casting plus BtA***	***Casting only***			
Booth et al. 2003 (8)	III-M (4/7) Cohort with control group	Injection of 4-6U/kg BtA into gastrocnemius soleus followed by serial P and FGC after 7-10 days as for cast group.	Serial P and FGC: 1 cast/w until ankle df R2 reached 20^{o} or there was no increase in ROM on 2 consecutive casts.	CP; 2-18y; ambulatory; no surgery for spasticity.	30 Cast+BtA=15 Cast=15	Cast+BtA M=5y 7mo Cast M=7y 10mo
Kay et al. 2004 (18)	II-M (5/7) Small RCT	Injection of 8U/kg of BtA into gastrocnemius (and into soleus [n=1]) and medial hamstrings (n=2) followed by serial FGC after 1-3w as for cast group.	Serial FGC applied in maximum passive ankle df: 1 cast/2w until at least 5^{o} passive ankle df with knee extended	CP; SD (13) SD (9); ambulant (4 with walker, 1 with forearm crutches); <0^{o} passive ankle df with knee extended; no orthopaedic surgery or selective dorsal rhizotomy in previous 12 mo.	23 Cast+BtA=11 Cast=12	Cast+BtA M=6y 11mo s=2y 10mo Cast M=7y 4mo s-3y 4mo

			followed by bivalved FG night splints in maximum passive df and daytime AFOs.			
Ackman et al. 2005* (20)	II-S (6/7) Small RCT	3 3-monthly injections of 4U/kg BtA into gastrocs plus AFOs as for cast group plus serial casting and AFOs as for cast group.	3 3-monthly P and FGC applied with ankle in 0-5^{o} df, each for 3w; followed by AFOs removed only 2-4h in evening.	CP; Cast: SH (10), SD (4), SD (4); BtA: SH (8), SD (4); Cast+BtA: SH (8), SD (5); ambulant without devices; ankle neutral when knee extended; all but one child at GMFCS level 1.	39 Cast=14 BtA=12 Cast+BtA=13	Cast: 3y 0mo-9y 0mo (M=5y 8mo) BtA: 3y 4mo-8y 9mo (M=5y 9mo) Cast+BtA: 3y 5mo-8y 3mo (M=6y 0mo)

BTA PLUS CASTING VERSUS BTA ONLY STUDY		***BtA plus Casting***	***BtA only***			
Bottos et al. 2003 (21)	II-W (3/7) Small RCT	BtA as for BtA only group, followed immediately by inhibitory cast for 3w, then physiotherapy	15-20 U/kg BtA in both triceps surae followed by AFOs immediately and physiotherapy	Mild SD; independently ambulant; no fixed equinus; no orthopaedic surgery in past 12 mo; no joint or bone deformities	10 5 per group	4-11y (M=6y 4mo)
Ackman et al. 2005* (20)	II-S (6/7) Small RCT	BtA as for BtA group plus 3 3-monthly P and FGC applied with ankle in 0-5^{o} df, each for 3w; followed by AFOs as for BtA group.	3 3-monthly injections of 4U/kg BtA into gastrocs plus AFOs removed only 2-4h in evening.	CP; Cast: SH (10), SD (4), SD (4); BtA: SH (8), SD (4); Cast+BtA: SH (8), SD (5); ambulant without devices; ankle neutral when knee extended; all (except 2) at GMFCS level 1.	39 Cast=14 BtA=12 Cast+BtA=13	Cast: 3y 0mo-9y 0mo (M=5y 8mo) BtA: 3y 4mo-8y 9mo (M=5y 9mo) Cast+BtA: 3y 5mo-8y 3mo (M=6y 0mo)

CASTING THEN BTA VERSUS BTA THEN CASTING STUDY		***Casting then BtA***	***BtA then Casting***			
Desloovere et al. 2001 (23)	II-M (5/7) Small RCT	Serial casts applied in neutral or 5° df for 10-28d (M=20.3d) removed after at least 2w until at least 10° df. BtA into at least gastrocnemius and medial hamstrings, M=24.4U/kg in SD, M=16.4U/kg in SH. Plus physiotherapy and day and night orthoses.	BtA as for other group. Serial casts as for other group (M=18.5d). Plus physiotherapy and day and night orthoses.	CP, predominantly spastic; each group: SD (11), SH (6); ambulant without aids; passive df with knees extended not >10°; R2 M=5.7°, R1 M=-15.4°; no serial casting, BtA or surgery in previous 12mo.	34 17 per group	Cast 1st: M=6y 7mo BtA 1st: M=7y 7mo Total: 4y 6mo-9y 10mo (M=6y 9mo)

AFO ankle-foot orthoses; BtA Botulinum toxin A; chn children;CP Cerebral Palsy; Ctl control group; d days; df dorsiflexion; FGC fibreglass casts; gastrocs gastrocnemius;GMFCS Gross Motor Function Classification System; h hours; ID intellectual disability; ITW idiopathic toe-walkers; LLD leg length difference; M mean; mo months; NDT neurodevelopmental therapy; PC plaster casts; Q quadriplegia; R1 Point of initial resistance to rapid velocity stretch on Modified Tardieu Scale; R2 Static muscle length on Modified Tardieu Scale; ROM range of motion; s standard deviation; SD spastic diplegia; SH spastic hemiplegia; SQ spastic quadriplegia; TA Tendoachilles; TR tone-reducing; U/kg units per kilogram of body weight; w weeks; y years.

*These studies appear three times in the table, representing the three two-way comparisons between casting, BtA and combined treatment.

**Separate results given for participants with CP.

Table 4a. Conduct of Study (Levels I, II and III evidence only)

Study	Level/Quality	1	2	3	4	5	6	7
CASTING ONLY STUDIES								
Bertoti 1986 (22)	II-M (4/7)	✓	✓	✓				✓
CASTING ONLY VERSUS BTA ONLY STUDIES								
Corry et al. 1998 (17); Corry et al. 1995 (15)	II-M (4/7)	✓		✓	✓			✓
Flett et al. 1999 (6)	II-S (6/7)	✓	✓	✓	✓		✓	✓
Ackman et al. 2005* (20)	II-S (6/7)	✓	✓	✓	✓	✓		✓
CASTING PLUS BTA VERSUS CASTING ONLY STUDIES								
Booth et al. 2003 (8)	III-W (3/7)		✓	✓			✓	
Kay et al. 2004 (18);	II-M (5/7)	✓	✓	✓			✓	✓
Ackman et al. 2005* (20)	II-S (6/7)	✓	✓	✓	✓	✓		✓
CASTING PLUS BTA VERSUS BTA ONLY								
Bottos et al. 2003 (21)	II-W (3/7)	✓		✓			✓	

Ackman et al. 2005* (20)	II-S (6/7)	✓	✓	✓	✓	✓	✓
CASTING THEN BTA VERSUS BTA THEN CASTING STUDY							
Desloovere et al. 2001 (23)	II-M (5/7)	✓	✓	✓	✓		✓

Conduct of the study is rated as “strong” (6-7 ticks), “moderate” (4-5 ticks) or “weak” (0-3 ticks).

1. Were inclusion and exclusion criteria of the study population well described and followed? 2. Was the intervention well described and was there adherence to the intervention assignment? (for two-group designs, was the control exposure also well described?) 3. Were the measures used clearly described, valid and reliable for measuring the outcomes of interest? 4. Was the outcome assessor unaware of the intervention status of the participants (i.e. were there blind assessments)? 5. Did the authors conduct and report appropriate statistical evaluation including power calculations? 6. Were dropouts/loss to follow-up reported and less than 20%? For two-group designs, was dropout balanced? 7. Considering the potential within the study design, were appropriate methods for controlling confounding variables and limiting potential biases used?

* These studies appear three times in the table, representing the three two-way comparisons between casting, BtA and combined treatment.

Table 4b. Conduct of Study (Levels I, II and III evidence only)

Study	**Level/Quality**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Houltram et al. 2001 (19)	I (10/10)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

1. Were the search methods reported? 2. Was the search comprehensive? 3. Were the inclusion criteria reported? 4. Was selection bias avoided? 5. Were the validity criteria reported? 6. Was validity assessed properly? 7. Were the methods used to combine studies reported? 8. Were the findings combined appropriately? 9. Were the conclusions supported by the reported data? 10. What was the overall scientific quality of the review?

Table 5. Summary of studies: outcomes, measures, and results.

Study	Outcome of interest	Measure	Components of Health		
			Body Structure/s Body Functions	**Activities and Participation**	**Contextual Factors**
CASTING ONLY STUDIES					
Bertoti 1986	Gait: Stride length	Vicon 3D Gait Analysis	p<.05 Cast		
(22)	Stride width		ns		
II-M (5/7)	Foot angle		ns		
Small RCT	Footprint clarity		ns		
CASTING ONLY VERSUS BTA ONLY STUDIES					
Corry et al.	Gait:	Vicon 3D Gait Analysis	2w 12w		
1998 (17)	Ankle angle at initial contact		ns ns		
II-M (4/7)	Maximum df in stance		ns p=.04 BtA		
Small RCT	Maximum plantarflexion		ns p=.01 BtA		
	Ankle range		ns ns		
Flett et al. 1999			PT Dr	PT Dr	

(6)	Muscle tone	MAS	ns	ns		
II-S (6/7) Small	Ankle df	Goniometry	ns	ns		
RCT	Gross motor function	GMFM			ns	ns
	Gait	Physician rating scale on video	ns	ns		
	Gait	Global scoring scale on video	ns	ns		
Ackman et al.	Gait velocity	Vicon 3D gait analysis	ns			
2005* (20)	Stride length	Vicon 3D gait analysis	ns			
II-S (6/7) Small	Ankle df at initial contact	Vicon 3D gait analysis	ns			
RCT	Peak df in stance	Vicon 3D gait analysis	ns			
	Peak df in swing	Vicon 3D gait analysis	ns			
	Triceps surae spasticity	MAS	ns			
		Tardieu	ns			
	Passive ankle df	Goniometry	ns			
	Active ankle df	Goniometry	ns			
	Ankle df strength	Manual muscle test	ns			
	Ankle pf strength	Manual muscle test	ns			

	Ankle power generation	Unilateral heel rises	ns
CASTING PLUS BTA VERSUS CASTING ONLY STUDIES			
Booth et al. 2003 III-M (4/7) Cohort with control group	Range of motion	Number of weeks to reach 20^{o} ankle df	p=.01 Cast + BtA
		Change in ankle df/w	p=.02 Cast + BtA
Kay et al. 2004 (18) II-M (5/7) Small RCT	Passive ankle df	Goniometry	ns
	Peak df in stance	Vicon 3D Gait Analysis	ns
	Peak df in swing	Vicon 3D Gait Analysis	ns
	Plantarflexion spasticity	MAS	ns at 3 mo p<.03 at 6, 9 & 12 mo Cast only
	Gross motor function	GMFM (Dimensions C,D&E)	ns
Ackman et al. 2005* (20)	Gait velocity	Vicon 3D gait analysis	ns
	Stride length	Vicon 3D gait analysis	ns

II-S (6/7) Small RCT	Ankle df at initial contact	Vicon 3D gait analysis	ns
	Peak df in stance	Vicon 3D gait analysis	ns
	Peak df in swing	Vicon 3D gait analysis	ns
	Triceps surae spasticity	MAS	ns
		Tardieu	ns
	Passive ankle df	Goniometry	ns
	Active ankle df	Goniometry	ns
	Ankle df strength	Manual muscle test	ns
	Ankle pf strength	Manual muscle test	ns
	Ankle power generation	Unilateral heel rises	ns

CASTING PLUS BTA VERSUS BTA ONLY					
Bottos et al.			1mo	4 mo	12 mo
2003 (21)	Triceps Surae spasticity	Ashworth	ns	.006 CBtA	ns
II-W (3/7)	Gross motor function: Standing	GMFM	ns	ns	ns
Small RCT	Walking	GMFM	ns	.007 CBtA	ns
	Passive ankle df	Not stated	ns	ns	ns
	Passive ankle pf	Not stated	ns	ns	ns
	Right stance, % of cycle	Gait analysis	ns	ns	ns
	Left stance, % of cycle	Gait analysis	ns	ns	ns
	Cycle time	Gait analysis	ns	ns	ns
	Stride length, % of height	Gait analysis	ns	.028 CBtA	ns
	Cadence	Gait analysis	ns	ns	ns
	Speed of progression	Gait analysis	ns	.04 CBtA	ns
	Sagittal ankle angle at initial contact	Gait analysis	ns	ns	ns
	Ankle df during stance	Gait analysis	ns	ns	ns

Ackman et al.	Gait velocity	Vicon 3D gait analysis	ns
2005* (20)	Stride length	Vicon 3D gait analysis	ns
II-S (6/7) Small	Ankle df at initial contact	Vicon 3D gait analysis	ns
RCT	Peak df in stance	Vicon 3D gait analysis	ns
	Peak df in swing	Vicon 3D gait analysis	ns
	Triceps surae spasticity	MAS	ns
		Tardieu	ns
	Passive ankle df	Goniometry	ns
	Active ankle df	Goniometry	ns
	Ankle df strength	Manual muscle test	ns
	Ankle pf strength	Manual muscle test	ns
	Ankle power generation	Unilateral heel rises	ns
CASTING THEN BTA VERSUS BTA THEN CASTING STUDY			
Desloovere et	Walking velocity	Gait analysis	ns
al. 2001 (23)			
II-M (5/7)			

Small RCT

BtA Botulinum toxin A; df dorsiflexion; Dr doctor; GMFM Gross Motor Function Measure; MAS Modified Ashworth Scale; mo months; pf plantarflexion; PT physiotherapist; w weeks.

Where significant, results are given as the probability level and the group that improved most (e.g., p<.05 Cast); where non-significant, results are given as ns. Results from different time periods or types of observers are shown in columns with subheadings (i.e., 2w or PT). Flett et al. obtained two sets of ratings, one from a doctor and one from a physiotherapist, and the table shows these separately.

*This study appear three times in the table, representing the three two-way comparisons between casting, BtA and combined treatment.

Table 6. Adverse effects of casting treatments

CASTING ALONE
Skin irritation or breakdown (2, 5, 12, 15, 30, 33)
Foot or calf pain (2, 17, 33)
Cast breakdown (2)
Continuing triceps surae contractions (5)
Oedema (30)
Persistent rearfoot varus (30)
Tendonitis (12)
Temporary ankle stiffness (15)
Weakness (6)
Tentative gait (15)
Difficulty bathing (6)
CASTING PLUS BTA
Falls (20)
Constipation (23)