J. Paediatr. Child Health (1999) **35**, 71–77

Botulinum toxin A versus fixed cast stretching for dynamic calf tightness in cerebral palsy

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Objective: To compare botulinum toxin A injections with fixed plaster cast stretching in the management of cerebral palsied children with dynamic (i.e. non-fixed) calf tightness.

Methods: The settings were the Women's and Children's Hospital (WCH) and the Crippled Children's Association of South Australia (CCA), Adelaide, South Australia. Twenty children were selected by two paediatric rehabilitation specialists. A prospective, randomized, single-blind controlled study, was carried out, with 10 children in each arm. The clinicians were blinded as to the allocated interventions.

The outcome measures for 6 months post intervention were clinical assessment, modified Ashworth Scale, Gross Motor Function Measure, 2 D-video ratings using a modified Physical Rating Scale and a global scoring scale and a parent satisfaction questionnaire.

Results and Conclusion: Botulinum toxin A injections were of similar efficacy to serial fixed plaster casting in improving dynamic calf tightness in ambulant or partially ambulant children with cerebral palsy. The ease of outpatient administration, reduction of muscle tone and safety with botulinum toxin A was confirmed. Parents consistently favoured botulinum toxin A and highlighted the inconvenience of serial casting.

Key words: botulinum toxin A; calf tightness; cerebral palsy; fixed cast stretching.

Currently there are a number of interventions, both conservative and surgical, which are being offered to the child with cerebral palsy in an effort to reduce spasticity and its effects in the lower limb. Few studies have rigorously evaluated interventions and approaches to treatment.

The primary objective of conventional treatment of calf tightness in cerebral palsy is to maintain or regain range of motion in order to prevent or reduce contracture and to maximize functional mobility. Current non-surgical approaches include passive and active stretching, positioning, muscle strengthening exercises, facilitating the development of balance and coordination of movement, and the use of casts and ankle-foot orthoses (AFO) to prevent secondary deformities and to improve function. For children < 6 years of age, it has generally been considered that the above-mentioned non-surgical approaches are preferable, not only because such measures could be successful, but also to avoid the potential risks associated with surgery, such as overlengthening, infection, scarring and anaesthesia. Another recognized complication of surgical lengthening of the Achilles tendon in children with spastic diplegia is a crouched gait pattern. In addition, a 50% recurrence rate after Achilles tendon lengthening has been reported in those children treated under 3 years of age.[1] If surgery can be delayed until 5–7 years of age, the risk of recurrence of contracture would be low.[2]

Orthopaedic surgery has an important part to play in the management of spasticity in cerebral palsy, particularly in the lower limbs, by appropriately selected and timed releases of tight muscles, e.g. fixed calf contractures. Neurosurgery in the form of selective dorsal root rhizotomy is still being evaluated, but appears to be effective in reducing spasticity and in improving function in a carefully selected group of patients.

Pharmacologic agents in common use to reduce spasticity are diazepam, baclofen and dantrolene; however, each has potential significant side-effects and unknown efficacy for the individual.

Serial inhibitive casting has been used effectively for non-surgical treatment of calf tightness. Proving the efficacy of casting has been difficult, but Watt *et al.*[3] showed a temporary improvement in passive range of ankle dorsiflexion. It may be necessary to repeat casting several times during the growing years, particularly between 2 and 6 years of age. Thus serial inhibitive casting effectively increases ankle dorsiflexion, but the effect is known to be transient. Whilst AFO can then be used to prevent or delay recurrence of deformity, they are of no value for fixed deformity.

Selective chemical neurectomy has been known to decrease or eliminate gastrocnemius and soleus spasticity, in the absence of contracture. Neuromuscular blockade by local injection of phenol or alcohol has been used to improve active and passive range of motion in children with cerebral palsy. Unfortunately, alcohol and phenol may require general anaesthesia for administration, their effectiveness is short-lived and they have also been associated with irreversible nerve injury, skin necrosis and permanent muscle damage and fibrosis.

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Accepted for publication 21 July 1998.

Previous randomized, double-blind placebo-controlled studies[4,5] have shown botulinum toxin A to be safe and effective in children with cerebral palsy. Botulinum toxin A, one of the most potent biological agents, may be injected directly into muscle to produce a dose-dependent and reversible weakness/paralysis; it works by blocking the release of acetylcholine at the neuromuscular junction. Recovery is slow over 3–6 months as new terminal axon sprouts form and restore transmission. The high affinity binding of the toxin to neuromuscular junctions and its safety from limited systemic absorption make it an excellent neuromuscular blocking agent. Botulinum toxin A was first used in humans in 1979,[4] and has since been used as an accepted and routine form of treatment in many conditions including blepharospasm and dystonias.[5]

Cosgrove *et al.*[4] studied botulinum toxin A in the management of the lower limb in cerebral palsy. They found no systemic side-effects and no cases of induced systemic toxicity despite using larger doses of botulinum toxin A in children than previously reported. They showed a reduction in spasticity as well as improvement in ambulatory status. They did not initially employ night ankle splints after injecting calves with botulinum toxin A, but subsequently intended to use night splints routinely. Koman *et al.*[5,6] further evaluated the efficacy of local intramuscular injections of botulinum toxin A in the management of dynamic equinus deformity associated with cerebral palsy, in a randomized double-blind placebo-controlled study. They concluded that botulinum toxin A injections appeared to be safe and effective in children, and merited further prospective study.

In this study we compared botulinum toxin A injections with fixed plaster cast stretching in the management of cerebral palsied children with dynamic (non-fixed) calf tightness.

MATERIALS AND METHODS

Subjects were 20 patients selected for treatment eligibility by two rehabilitation specialists.

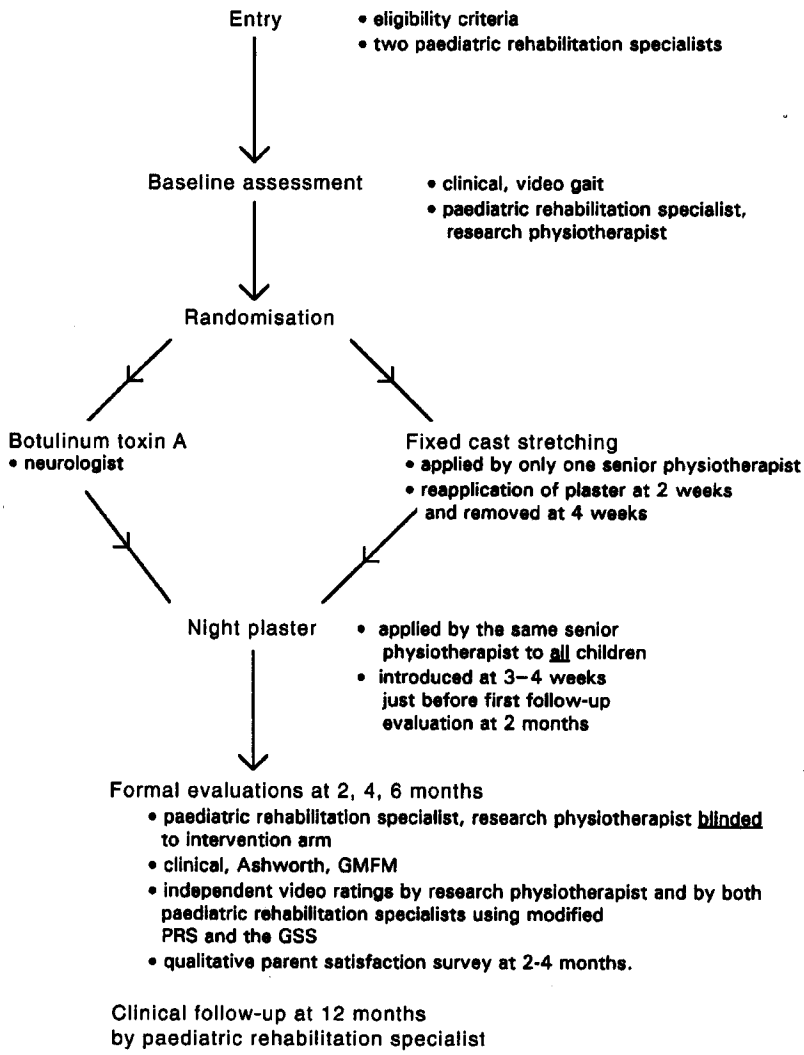

Fig. 1 Study design.

Inclusion criteria

1. Ambulatory patients (including those using walkers), diagnosed with cerebral palsy and muscle spasticity of the lower extremity, associated with dynamic muscle tightness and equinovarus or equinovalgus positioning of the foot, and who were unresponsive to physical therapy, orthotics or other non-operative modalities, and who did not currently require surgery for the condition.
2. Subjects had to exhibit forced passive dorsiflexion of the ankle of the target limb(s) with the subtalar joint locked and the knee in flexion.
3. Aged 2–8 years.

Exclusion criteria

1. Previous or current surgery on the foot, calf muscle, or hamstring muscles and previous alcohol injections into the muscles of the target limb(s).
2. Presence or evidence of fixed contracture or severe athetoid movements in the target limb(s).
3. Significant difference in leg length between right and left legs (greater than 5 cm).
4. Significant muscle weakness or atrophy predominantly in the calf muscles of the target limb(s).
5. Children over the age of 8 years at the commencement of treatment; and *withdrawal* criteria would be concurrent use of neuromuscular blocking and aminoglycoside drugs.

The study was undertaken at the Women's and Children's Hospital (WCH) and the Crippled Children's Association of South Australia Inc. (CCA), Adelaide, SA.

A prospective, randomized controlled study design was utilized, with the research clinicians blinded to the intervention arms. Once inclusion and exclusion criteria were met, random allocation to either intervention arm was carried out by the WCH Pharmacy Department (Fig. 1). The study was approved by the Research Ethics Committee and the Drug Advisory Committee of the WCH. After detailed explanation, information sheets were handed to the parents or legal guardians and informed consent obtained.

Method

Twenty patients were randomly assigned to either a single course of treatment with botulinum toxin A (two or more injections into targeted calf muscles) or a course of fixed plaster casting for 4 weeks (2×2 weeks). Both intervention arms received night plasters simultaneously in time for first follow-up evaluations at 8 weeks.

EMLA local anaesthetic cream and intranasal Midazolam were used for those receiving botulinum toxin A (Botox, Allergan), dosage 4–8 units kg^{-1} and maximum of 20 units per

Table 1 Abbreviated physician rating scale (PRS) for video gait analysis

Dynamic function (ROM)	Score right	Score left
Crouch		
Severe (> 20° hip, knee, ankle)	0	0
Moderate (5–20° hip, knee, ankle)	1	1
Mild (< 5° hip, knee, ankle)	2	2
None	3	3
Foot contact		
Toe	0	0
Toe – heel	1	1
Flat	2	2
Occasional heel – toe	3	3
Heel – toe	4	4

Table 2 Global scoring scale (GSS) for video gait analysis

Score	Analysis
0	Normal gait (gait now virtually normal and not requiring any treatment)
1	Significantly better (i.e. optimal improvement with control of gait)
2	Partially improved (i.e. a little better than before)
3	No change in gait (i.e. treatment unsuccessful but no worse)
4	Gait worse (i.e. current treatment has not been successful at all and obviously deteriorated)

Table 3 Basic background data of subjects

Subject characteristics	Subjects receiving botulinum toxin A ($n = 8$) $n = 10$ originally but two withdrew plaster ($n = 10$)	Subjects receiving fixed
Gender	Males: 5; females: 3	Males 6; females: 4
Age	Mean, 3.89 years (SD, 1.44 years)	Mean, 3.56 years (SD, 1.32 years)
Medical diagnosis		
Spastic diplegia	6	4
Spastic quadriplegia	1	1
Right hemiplegia	1	3
Left hemiplegia		1
Spastic triplegia		1
No. of right legs treated	8	9
No. of left legs treated	7	7

*The difference between botulinum toxin A and fixed-plaster subjects in terms of age and baseline measurements, for all tables, was assessed with *t*-tests. No significant differences were found.

†SD, standard deviation.

site. Botulinum toxin A was administered in the Accident and Emergency Department, WCH, whilst the fixed and night plaster casts were applied in the Physiotherapy Department of CCA. EMG guidance was not used for the injections, but rather the 'Kerr Graham' technique,[4] whereby the needle is placed in gastrocnemius; as the ankle is dorsiflexed, the muscle belly is pulled distally, moving the needle tip with it; the skin acts as a fulcrum and the external end of the needle moves in the opposite direction.

Two months following intervention, additional therapy (e.g. AFO) could be introduced, depending on clinical indications.

Outcome measures included clinical and goniometric examination of the degree of ankle dorsiflexion in equinovarus or equinovalgus deformity, modified Ashworth Scale and Gross Motor Function Measure (GMFM)[7] score preintervention, and at 2, 4 and 6 months. The chief investigator (rehabilitation specialist) and research physiotherapist, who were blinded, carried out these clinical examinations. Follow-up by the chief investigator, including description of clinical progress, was continued 12 months post-intervention. Video ratings using a modified Physician Rating Scale (PRS, Table 1) and a Global Scoring Scale (GSS, Table 2) were conducted by three scorers

Table 4 Ashworth scores, physiotherapist and doctor ratings

Condition (rater)	Baseline mean (SD)	2 months mean (SD)	4 months mean (SD)	6 months mean (SD)
Botulinum toxin A (physio)	2.41 (0.65)	1.40 (0.51)	1.57 (1.13)	2.13 (1.06)
Botulinum toxin A (doctor)	2.69 (0.75)	1.40 (0.51)	1.92 (1.26)	1.92 (1.26)
Fixed plaster (physio)	2.53 (0.64)	1.60 (1.12)	1.78 (0.97)	1.87 (1.19)
Fixed plaster (doctor)	2.55 (0.69)	1.47 (1.19)	1.60 (0.83)	2.07 (1.22)
Pearson's correlation between doctor and physio Ashworth scores, for subjects from both conditions combined	0.68*	0.87*	0.94*	0.91*

*$P < 0.01$

†SD, standard deviation.

‡Results were: change across time in the botulinum toxin A condition: $P < 0.03$. Changes across time in the fixed plaster condition: $P < 0.001$. Difference between the botulinum toxin A and fixed plaster conditions: not significant.

Table 5 Range of movement scores (degrees), physiotherapist and doctor ratings

Condition (rater)	Base line mean (SD)	2 months mean (SD)	4 months mean (SD)	6 months mean (SD)
Botulinum toxin A (physio)	6.85 (5.65)	15.47 (5.38)	14.62 (8.03)	13.00 (6.49)
Botulinum toxin A (doctor)	5.90 (4.98)	12.00 (3.80)	13.65 (8.20)	10.96 (10.68)
Fixed plaster (physio)	6.00 (5.41)	13.70 (10.95)	14.00 (10.04)	14.87 (8.96)
Fixed plaster (doctor)	8.17 (5.13)	15.00 (8.76)	15.00 (8.13)	13.03 (9.23)
Pearson's correlation between doctor and physio Ashworth scores, for subjects from both conditions combined	0.37	0.79*	0.91*	0.84*

*$P < 0.01$.

†SD, standard deviation.

‡Results were: changed across time in the botulinum toxin A condition: $P < 0.001$. Changes across time in the fixed plaster condition: $P < 0.001$. Difference between the botulinum toxin A and fixed plaster conditions: not significant.

Table 6 Gross motor function measure (GMFM) scores (%)

Condition (GMFM subscale)	Baseline mean (SD)	2 months mean (SD)	4 months mean (SD)	6 months mean (SD)
Botulinum toxin A (standing)	55.75 (24.20)	62.16 (23.93)	61.41 (26.52)	62.55 (23.77)
Botulinum toxin A (dynamic)	40.61 (24.00)	46.63 (32.14)	46.68 (28.20)	49.45 (30.27)
Fixed plaster (standing)	52.45 (29.03)	60.15 (30.87)	61.78 (30.59)	64.57 (29.98)
Fixed plaster (dynamic)	42.62 (27.17)	45.36 (28.12)	46.22 (29.56)	50.09 (29.97)

‡Results for the GMFM standing subscale were: change across time in the botulinum toxin A condition: $P < 0.01$. Changes across time in the fixed plaster condition: $P < 0.04$. Difference between the botulinum toxin A and fixed plaster conditions: not significant. Results for the GMFM dynamic subscale were: change across time in the botulinum toxin A condition: $P < 0.01$. Changes across time in the fixed plaster condition: $P < 0.01$. Difference between the botulinum toxin A and fixed plaster conditions: not significant.

†SD, standard deviation.

Table 7 Total PR scale

Condition (rater)	Baseline mean (SD)	2 months mean (SD)	4 months mean (SD)	6 months mean (SD)
Botulinum toxin A (physio)	2.80 (1.32)	3.60 (1.55)	3.62 (1.50)	3.40 (1.45)
Botulinum toxin A (doctor 1)	2.20 (1.08)	2.87 (1.92)	3.38 (2.26)	3.13 (2.10)
Botulinum toxin A (doctor 2)	2.27 (0.96)	3.20 (1.21)	3.15 (1.21)	3.13 (1.46)
Fixed plaster (physio)	2.07 (1.44)	3.07 (1.49)	3.00 (1.65)	3.20 (1.53)
Fixed plaster (doctor 1)	1.87 (0.83)	2.87 (1.60)	2.73 (1.62)	2.67 (1.68)
Fixed plaster (doctor 2)	2.13 (1.13)	2.93 (1.28)	2.73 (1.44)	2.80 (1.57)
r (physio and doctor 1)	0.68*	0.75*	0.73*	0.74*
r (physio and doctor 2)	0.65*	0.83*	0.75*	0.60*
r (doctor 1 and doctor 2)	0.69*	0.86*	0.82*	0.82*

*$P < 0.01$.
†SD, standard deviation.
‡Results were: change across time in the botulinum toxin A condition: $P < 0.001$. Changes across time in the fixed plaster condition: $P < 0.001$. Difference between the botulinum toxin A and fixed plaster conditions: not significant.

Table 8 Global scoring scale

Condition (rater)	Baseline mean (SD)	2 months mean (SD)	4 months mean (SD)	6 months mean (SD)
Botulinum toxin A (physio)		2.28 (0.52)	2.57 (1.13)	2.75 (1.04)
Botulinum toxin A (doctor 1)		2.25 (0.89)	1.86 (1.07)	2.38 (1.41)
Botulinum toxin A (doctor 2)		2.25 (0.71)	2.14 (0.69)	2.50 (0.76)
Fixed plaster (physio)		2.10 (0.99)	2.00 (0.94)	2.00 (0.82)
Fixed plaster (doctor 1)		1.90 (0.88)	2.20 (0.79)	2.20 (0.92)
Fixed plaster (doctor 2)		1.70 (0.82)	2.00 (0.71)	2.00 (0.82)
r (Physio and doctor 1)		0.73**	0.66**	0.72**
r (Physio and doctor 2)		0.65**	0.65**	0.58*
r (Doctor 1 and doctor 2)		0.68**	0.54*	0.57*

*$P < 0.05$, **$P < 0.01$.
†SD, standard deviation.
‡Results were: change across time in the botulinum toxin A condition: not significant. Changes across time in the fixed plaster condition: not significant. Difference between the botulinum toxin A and fixed plaster condition: not significant.

independently (two rehabilitation specialists and the research physiotherapist). After the final clinical and gait scoring analysis at 6 months, the code for the intervention arm for each child was broken by the research clinicians. A parent satisfaction questionnaire was used to measure parental perception of change and to seek their comments.

Fixed plaster casting at the CCA has usually been performed by dorsiflexing the ankle to neutral and applying lightweight walking plasters for 4–6 weeks according to individual circumstances. The plaster is reapplied at 2 weeks, with more stretch given to the calf muscle; and the whole treatment regime either stopped at 4 weeks or the plaster reapplied 2 weeks later for a total period of 6 weeks. In this trial, we elected to standardize casting to 4 weeks total, a factor which might have been better for compliance and more rapid return to normal function and bathing routines but which might not have treated all subjects adequately.

The modified Ashworth and GMFM scores are now regarded as standard and validated tools for the purpose of monitoring an intervention. The PRS[5] was modified (Table 1) for crouch and foot contact only, so as to eliminate the collection of extra data which was (in our view) unlikely to improve discrimination or inter-rater reliability.

Our GSS is very similar to other general scales devised for the evaluation of 'change' by 2D video gait analysis. Three raters independently rated the subjects using this scale in order to test its inter-rater reliability.

RESULTS

During the period from September 1995 to July 1997, 20 children underwent treatment as allocated and were followed for 12 months. However, two children withdrew from the trial after receiving botulinum toxin A for different reasons: one for social reasons, and the other at parental request because of the perceived need to treat differently by a combination of botulinum toxin A and fixed plaster treatment. The demographic characteristics of subjects in both intervention arms are summarized in Table 3. In Tables 4–8 each treated leg is included. Thus, diplegic children who had both legs treated contributed twice whilst, as expected, hemiplegic children had one leg treated and contributed only once. Significance of change across time in each treated leg was tested with the Repeated Measures Analysis of Variance (ANOVA), separately for botulinum toxin A subjects and fixed plaster subjects. Outcome measures used

in Tables 4, 5, 7 and 8 involved two or three raters (physiotherapist, doctor 1 and possibly doctor 2) rating each subject independently. Only the physiotherapist's ratings were used in the analyses. The doctors' ratings were used as an inter-rater reliability check only. Data from all four occasions of measurement were used (i.e. baseline, 2 months, 4 months and 6 months). Difference in effects achieved by botulinum toxin A intervention versus fixed plaster intervention were compared in another ANOVA, this time a between-subjects design involving only the last three occasions of measurement (i.e. 2, 4 and 6 months). There was no significant difference between the botulinum toxin A and fixed plaster conditions as measured by Ashworth scores, range of movement scores, GMFM scores, total PRS scores and GSS scores. On the GSS correlations between ratings from the three raters (the physiotherapist and doctors 1 and 2) are shown in Table 8. Two of the three raters appeared to achieve closer agreement (the physiotherapist and doctor 1), whilst the ratings provided by doctor 2 seemed less consistent with either of the other two raters. This suggests that future applications of this scale could be helped by the first two raters defining their hitherto only implicit but shared additional definitions of particular ratings. Certainly the general inter-rater agreement on this scale is less than strong, and efforts to achieve higher inter-rater agreement would make it a more useful measure.

Twenty (i.e. 100%) consumer questionnaires were returned. The majority (i.e. 17) were quite pleased with the service, information sheet and verbal explanations, and expressed satisfaction with the treatment service. Comments included:

Botulinum toxin A group

'Worked fast' (three patients), freedom and convenience regarded as positive (three patients), ability to walk with less stiffness (two patients), one treatment with no side-effects seen as beneficial (one patient).

Casting group

'Liked choice of colours' [of plaster] (two patients), 'general improvement' (two patients) and 'smooth' [process] (one patient); negative comments were difficulty bathing and carrying child (four patients), legs weaker afterwards and slow to 'rebuild' all leg muscles again (three patients); one parent described casting as 'archaic and inconvenient' and another said the treatment 'was a waste of time'.

Some cost comparisons were undertaken. Given that fixed casting was carried out in this trial for 4 weeks only, and that some labour was delegated by the physiotherapist to her assistants, the cost per cast per leg was $70.00. Thus, if a child had two fixed plasters (e.g. spastic diplegia), the total cost of casting was $280.00. This does not, however, take into account the costs involved for the parents in terms of their work, time and travel over three visits. A single ampoule of botulinum toxin A (Botox, Allergan) costs $450.00.

DISCUSSION

Botulinum toxin A causes variable and reversible neuromuscular blockade or chemical denervation, produces clinical reduction of muscle spasticity and improvement of muscle balance and facilitates gait and gross motor function.[6] In our study botulinum toxin A injection was of similar efficacy to serial fixed plaster casting in improving dynamic calf tightness in ambulant or partially ambulant children. The ease of outpatient administration, the reduction of tone, the safety, and the lack of discernible local or systemic side-effects with botulinum toxin A are confirmed by this study.

Local intervention is more appropriate for topographically limited areas such as calf spasticity. Neither oral antispasticity drugs, nor selective dorsal rhizotomy, nor intrathecal baclofen are likely to be favoured in such situations. With similar efficacy between botulinum toxin A and serial fixed plaster casting for dynamic calf tightness, the possibility exists for tone reduction and prolongation of improvement in range of movement and for increase in muscle length to be better with a combination of both treatments. Careful patient selection is likely to maximize benefit; and a higher dosage of toxin (Botox, Allergan) at 8–10$^{\mu}$ kg^{-1} bodyweight followed by a 2-week course of fixed plaster casting may produce better results in some patients.

The results of this study are comparable to similar studies reported after the commencement of our trial by Corry *et al.*[8,9] They concluded that botulinum toxin A injections were of similar efficacy to serial casting in improving dynamic equinus. They also found that tone reduction in the botulinum toxin A group was greater and allowed a more prolonged improvement in passive dorsiflexion, which may allow more opportunity for increase in muscle length.

Our study, however, also included a parent (or consumer) satisfaction questionnaire. There are good reasons for an increasing emphasis on patient satisfaction with health services.[10–15] There is increasing evidence that patient satisfaction has a significant influence on the effectiveness of services: greater satisfaction with health services is associated with better treatment compliance, less premature 'drop-out' from treatment, and less delay in seeking further treatment. Health care providers have become increasingly aware of the potential negative impact of customer complaints on the public's perception of the quality of health care services. Increasing emphasis has been given to the use of 'Total Quality Improvement' as a method of managing health services. This approach places great emphasis on the use of good quality data to describe both the needs of patients and the extent to which their needs are met. The parents in this study consistently wrote about preference for a single event effective treatment (botulinum toxin A) and about the inconvenience of plaster treatment for child handling, especially bathing.

Cost comparisons were difficult, but seemed to be better for a single leg receiving fixed casting (i.e. two casts over 4 weeks) rather than toxin. Where two calves were being treated in the same individual, the costs involved were more comparable, and had we elected to evaluate toxin with casting over 6 weeks (i.e. three casts), then there would have been very little difference in those costs. This is what Corry *et al.*[9] found, and they also appropriately referred to the potential reduction in the cost of botulinum toxin A once licensing for this purpose and wider use occurs.

In this study botulinum toxin A was shown to be of similar efficacy to serial fixed plaster stretching in improving dynamic calf tightness in children with cerebral palsy. The toxin was also a preferred treatment option for parents in terms of single event treatment and the convenience compared to casting treatment.

ACKNOWLEDGEMENTS

We thank the Crippled Children's Association Research and Development Fund and the Women's and Children's Hospital Pharmacy Department.

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