BOTULINUM TREATMENT OF STRABISMUS IN CHILDREN*

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INTRODUCTION

TREATMENT OF STRABISMUS BY BOTULINUM TOXIN INJECTION OF EXTRAocular muscles with reasonable follow-up was first reported in 1981.[1] Data on the effects of injection in children, however, have emerged only recently.[2,3] This paper reports the results with 6 months or greater follow-up since the last injection from the four most active investigators in an open, multi-investigator study involving children.

METHODS

Children treated were age 2 months to 12 years. Appropriately informed consent was obtained on all children. Table I shows the age ranges and conditions of these patients.

A total of 413 children were treated. Follow-up is available for 356 (86%), of which 124 patients had undergone prior surgery.

Topical drugs provided anesthesia.[4] Intravenous ketamine or inhaled nitrous oxide sedation was usually used for children aged 1 to 7 years. Topical anesthesia without sedation, as used in adult strabismus injection, was often possible on older children. Topical anesthesia with restraint was usually possible on children under 1 year of age. Dosages of drugs for individual muscles ranged from 1.0 to 12.5 U. A pilot series of injections with smaller doses were ineffective and are excluded.

Alignment data is expressed in prism diopters (PD) and is for distance fixation by the reflex or cover test with optimum refractive correction. Final deviation is the latest measurement and is at least 6 months after the last injection. Twenty patients received surgery prior to 6 months after injection. We used their preoperation deviation as the final deviation, or,

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TABLE I: RESULTS OF BOTULINUM TOXIN INJECTION BY CONDITION

		AGE (MO)		PRIOR SURGERY		AVERAGE DEVIATION		%	FINAL WITHIN 10 PD OF ORTHO		NO. OF	EVENTUAL SURGERY		FOLLOW-UP SINCE LAST INJECTION (MO)	
	NO.	AVG	RANGE	NO.	%	INITIAL	FINAL	CHANGE	NO.	%	INJS	NO.	%	AVG	RANGE
Total	356	58	2–144	124	35	30	11	65	223	63	1.6	66	19	27	6–65
Total esotropia															
No prior operation	183	47	3–141	0	0	34	10	70	123	67	1.7	31	17	29	6–65
Prior operation	78	64	6–144	78	100	26	9	65	55	71	1.6	16	21	25	6–53
Infantile esotropia															
No prior operation	58	23	4–96	0	0	43	12	73	38	66	2.1	12	21	30	6–55
Prior operation	44	51	6–114	44	100	29	10	64	29	66	1.6	9	21	25	6–53
Sensory esotropia	14	58	13–123	3	21	32	17	48	5	36	1.6	4	29	33	7–65
Residual accommodative esotropia	92	67	8–141	8	9	28	8	72	67	73	1.5	11	12	28	6–63
Other esotropia															
No prior operation	14	38	8–96	0	0	31	10	67	9	64	1.7	1	7	26	8–50
Prior operation	21	83	36–144	21	100	20	7	64	18	86	1.8	5	24	22	6–52
Total exotropia															
No prior operation	49	73	2–140	0	0	32	15	53	20	41	1.4	7	14	25	7–50
Prior operation	46	73	12–144	46	100	20	11	48	25	54	1.5	12	26	23	6–54
Intermittent exotropia	22	66	14–134	3	14	39	15	49	8	36	1.4	4	18	20	7–50
Sensory exotropia	3	118	111–126	1	33	25	5	81	3	100	1.3	0	0	15	6–32
Other exotropia															
No prior exotropia	25	78	10–140	0	0	32	15	54	10	40	1.3	1	4	29	12–49
Prior operation	41	71	12–144	41	100	20	11	45	22	54	1.6	12	29	23	6–54
Paralytic	15	43	3–133	2	13	35	10	72	9	60	1.3	5	33	20	6–56
Neurological	7	45	2–96	1	14	28	10	64	5	71	1.4	2	29	29	7–65

INJS = injections; AVG = average.

if this preoperation deviation measurement was unavailable, the initial deviation as the final deviation.

Infantile esotropia patients were neurologically normal, had onset before 6 months of age and no paralytic component.

Sensory includes patients with corneal scars, severe amblyopia, and retinal or optic nerve pathology.

Residual accommodative ET includes patients with strabismus onset after 6 months of age who wore hyperopic spectacle correction.

Paralytic includes III nerve (2 cases), VI nerve (12 cases), and Duane's syndrome (1 case).

Neurological includes those patients with overt microcephaly, ataxia, and similar neurological defect.

Other includes constant exotropia, consecutive esotropia or exotropia, and strabismus of unknown origin.

RESULTS

Of the 356 children treated by injections, 223 (63%) had a successful alignment outcome with correction to 10 PD or less. It took an average of 1.6 injections per patient to achieve these results, with follow-up of 6 to 65 months (average, 27 months) after the last injection (Table I). The likelihood of success from the first injection alone was 37% (133 of 356). The likelihood of success from additional injections in 144 patients was 63% (90 of 144). Sixty-seven patients (19%) were left with alignment exceeding 10 PD and were not operated upon. Sixty-six patients (19%) received eventual surgery for residual strabismus.

Table II shows results broken down by number of injection treatments and by length of follow-up over 6 months. Patients who received more than one injection had a larger average initial deviation (34 PD) than patients who received a single injection (27 PD).

Table III shows that age did not greatly influence overall outcome, but that large deviations were less well corrected by injection.

Sixty-seven percent of esotropes with no prior surgery, and 71% of esotropes who did have prior surgery, had correction to 10 PD or less. Forty-one percent of exotropes with no prior surgery and 54% of exotropes who did have prior surgery had correction to 10 PD or less.

Twenty patients had initial deviations of 10 PD or less (19 of these had 10 PD). Seventeen of these 20 patients had final deviations of 10 PD or less. None of these small angle strabismus cases achieved demonstrable binocular fusion.

Residual strabismus following prior surgery was corrected to 10 PD or less in the following categories: overcorrected exotropia (n = 15), 87%;

TABLE II: RESULTS OF BOTULINUM TOXIN INJECTION BY LENGTH OF FOLLOW-UP AND NUMBER OF INJECTIONS

	NO.	AGE (MO) AVG	AGE (MO) RANGE	PRIOR SURGERY NO.	PRIOR SURGERY %	AVERAGE DEVIATION INITIAL	AVERAGE DEVIATION FINAL	% CHANGE	FINAL WITHIN 10 PD OF ORTHO NO.	FINAL WITHIN 10 PD OF ORTHO %	NO. OF INJS	EVENTUAL SURGERY NO.	EVENTUAL SURGERY %	FOLLOW-UP SINCE LAST INJECTION (MO) AVG	FOLLOW-UP SINCE LAST INJECTION (MO) RANGE
Total															
1 injection	212	62	1–144	82	39	27	10	64	133	63	1.0	33	16	26	6–65
2+ injections	144	51	3–144	42	29	34	11	66	90	63	2.5	33	23	27	6–63
Follow-up (mo)															
6–12	72	62	6–135			28	19	65	42	58	1.6	18	25	9	6–12
13–24	107	59	6–144			30	11	64	65	61	1.6	11	10	18	13–24
25+	157	59	4–144			30	8	73	115	73	1.6	17	11	40	25–65
Esotropia															
1 injection	146	59	5–144	49	34	28	9	68	101	69	1.0	23	16	27	6–65
2+ injections	115	44	3–135	29	25	35	11	70	77	67	2.5	24	21	28	6–63
Follow-up (mo)															
6–12	46	56	6–132			30	8	72	32	70	1.7	10	22	9	6–12
13–24	82	57	6–144			30	10	65	54	66	1.7	9	11	19	13–24
25+	118	49	4–135			32	7	77	91	77	1.7	13	11	41	25–65
Prior overcorrection of XT	15	85	36–144			21	6	74	13	87	1.6	2	13	26	6–52
Prior undercorrection of ET	44	51	6–114			29	10	64	29	66	1.6	9	21	25	6–53
Exotropia															
1 injection	66	70	2–140	33	50	26	12	53	32	49	1.0	10	15	24	6–50
2+ injections	29	80	12–144	13	45	27	15	47	13	45	2.5	9	31	23	6–54
Follow-up (mo)															
6–12	26	73	16–135			25	13	50	10	39	1.5	8	31	9	6–12
13–24	25	65	18–134			29	12	58	11	44	1.2	2	8	18	13–24
25+	39	83	10–144			24	12	53	24	62	1.6	4	10	37	25–54
Prior overcorrection of ET	35	70	12–144			20	10	49	20	57	1.6	8	23	25	6–54
Prior undercorrection of XT	1	73				18	11	39	0	0	2.0	1	100	8	

INJS = injections; AVG = average; XT = exotropia; ET = exotropia.

TABLE III: RESULTS OF BOTULINUM TOXIN INJECTION BY AGE AND BY INITIAL DEVIATION SIZE

AGE (MO)	NO.	% WITHIN 10 PD OF ORTHO	INITIAL DEVIATION	NO.	% WITHIN 10 PD OF ORTHO
3–12	41	54	10–20	121	74
13–24	49	69	21–30	104	58
25–144	266	63	31–50	108	56
			51–75	23	57

overcorrected esotropia (n = 35), 66%; undercorrected esotropia (n = 35) 56%; undercorrected exotropia (n = 1) 0%.

The incidence of side effects was: transient ptosis 31% and transient vertical deviation 16%. There was no globe perforation, amblyopia, or visual loss produced by injection in this series.

DISCUSSION

The data here are presented with a view towards providing insight into whether clinical use of botulinum injection is safe and effective in the therapy of childhood strabismus.

These results in children support the conclusion that both the drug and the injection procedure are safe, with no visual loss or major complication in any case. The essential statistic of these results is that 63% of 356 children treated with an average of 1.6 botulinum injections maintained an alignment correction within 10 PD of ORTHO position after an average 27 months (range, 6 to 65 months) of follow-up. Included in the overall figure are different categories of strabismus, some faring better than others. Better results were obtained when treating esotropia (70%) than exotropia (47%) regardless of whether previous surgery had been performed. Higher success rates realized upon injecting medial recti for surgical consecutive esotropia (87%) and surgically undercorrected esotropia (66%) may be related to the greater concentration of global layer singly innervated fibers in the medial rectus muscle, which are singularly and profoundly affected by botulinum.[5] Interestingly, the difference in outcome between previously operated and nonoperated cases was not great, suggesting only small influence from previous surgery. This was probably a result of retaining relatively normal extraocular movement elasticity in most of these patients, since injection treatment of the antagonist to surgically over-recessed muscles has limited effectiveness in adults.[6]

The side effects of partial ptosis (31%) and secondary vertical deviations over 2 PD (16%), although discomforting, were always transient and never resulted in amblyopia.

Magoon[7] showed that a subset of 50 patients under age 14 years, measured 2 years or more after injection, had the same alignment as had the original set of 85 patients measured earlier, 6 months to 2 years after injection. This stability is greater than that reported for adults after botulinum treatment of horizontal strabismus.[8,9]

These results in attaining alignment within 10 PD are comparable to those reported by Bartley et al[10] for one strabismus operation correction of childhood esotropia (66% for recess-resect, 46% for bilateral medial rectus recession), and comparable to results of surgery for infantile esotropia reported by Scott et al[11] (65%) and von Noorden[12] (66%). These results are not as good as those in recent reports on infantile esotropia with larger amounts of muscle surgery, eg, Kushner and Morton[13] (84%), Helveston et al[14] (84%), and Mims et al[15] (82%). With further refinement (bilateral injection, larger botulinum doses, use of antitoxin to prevent effects on the antagonist or adjacent muscles, and treatment of younger children, age 2 to 4 months) it is possible that injection results may be improved further for infantile esotropia. Botulinum treatment of exotropia, while useful in this series, was less impressive.

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DISCUSSION

DR GUNTER K. VON NOORDEN. Uncertainty prevails regarding the effectiveness and indications of chemodenervation in the treatment of strabismus. This uncertainty turned into controversy when Biglan and co-workers concluded at the last Academy meeting that chemodenervation was not as successful as surgery in the treatment of comitant strabismus (Biglan AW, et al: Management of strabismus with botulinum A toxin. *Ophthalmology*, in press). To determine whether chemodenervation is a safe and effective alternative to surgery Doctor Scott and coworkers have reviewed data from 356 children with various forms of comitant and incomitant strabismus.

In reviewing this study several questions arise. The first concerns the extraordinary heterogenicity of the study material which included strabismus forms with entirely different clinical characteristics, functional potential, tendency for recurrences or, as in the cases of a VIth nerve palsy or a surgically overcorrected exotropia, for spontaneous recovery. I would be most hesitant to generalize on the effects of surgery in patients as different as those pooled in this study and find such generalization equally problematic in assessing the effect of chemodenervation.

Another question concerns the method of pre- and postinjection assessment. The authors use the Hirschberg test and the "cover test," by which I assume they mean the prism and cover test. Both tests were applied only at distance fixation. The Hirschberg test allows at best an estimation but not an actual measurement of the angle of strabismus. It is difficult to perform in children at distance fixation and has a margin of error of ± 14 prism diopters (PD). This variation should have been taken into account when comparing before and after treatment deviations. Moreover, disregarding the near deviation entirely makes it practically impossible to evaluate the treatment effect in accommodative esotropia which was present in as many as 50% of the esotropes included in this study.

Using the reduction of a deviation to within 10 PD of orthotropia as the second method to evaluate strabismus therapy in this study raises another problem. If our therapeutic goal is cosmetic acceptability, this criterion may be acceptable. However, if our goal is ocular alignment and restoration of normal binocular vision when this potential exists, this criterion is of little value. From a functional point of view a patient with a residual eso- or exotropia of 10 PD or less is just as badly off as with a larger deviation. Unless one distinguishes clearly between residual

heterotropia and heterophoria and between residual eso-, exo- or hyperdeviations of 10 PD or less, no conclusions can be drawn whether a patient has been functionally improved. For instance, the authors stress the high success rate in surgically overcorrected exotropes by reporting that 13 of 15 patients had a final deviation of 10 PD or less. Unless we know whether these patients were able to fuse after the injection(s) we cannot determine whether the treatment was of benefit. The use of the 10 PD criterion also makes one wonder what was accomplished by chemodenervation in the 17 patients of this study whose initial deviation was only 10 PD or less and thus was not different from the final deviation.

Is chemodenervation safe? Whether it is safe or even appropriate to inject on different occasions into an extraocular muscle of a squirming infant, immobilized by physical restraint and under topical anesthesia is a question I leave for the audience to ponder. The complications encountered in this study were limited to transient ptosis and secondary vertical deviations. However, other authors have reported more serious problems with chemodenervation, such as perforation of the globe, retrobulbar hemorrhage, persistent diplopia and recurrence of the deviation (Biglan A, Gan XL: Experience with botulinum A toxin (Oculinum) in the treatment of strabismus. *Contemp Ophthalmol* 1987; 5:230). Although visual deprivation amblyopia from ptosis was not observed by the essayists this possibility remains a real concern in the age group under consideration. The induction of vertical diplopia from spread of the injected drug to the adjacent cyclovertical muscles is undesirable in patients with a potential for fusion. On the other hand, surgery also carries certain risks and the question whether chemodenervation is as safe as, safer than, or not as safe as surgery can only be answered by comparative studies.

Finally, we must ask whether chemodenervation is a viable alternative or just an adjunct to surgery? What are its indications? I find it difficult to answer these questions from the data reported here or from those reported in other studies. A definitive answer will only become available after comparing the results of surgery and chemodenervation in a randomized, prospective and matched study. In such a study the various strabismus forms with their differences in etiology, tendencies for recurrence or spontaneous improvement, changes of mechanical forces by previous operations, number of treatments, sensory state, etc, must be compared individually rather than lumped together. Likewise, for a valid assessment of this therapy the deviation at near as well as at distance, the state of comitance, the elimination of a compensatory head posture if such was present and, last but not least, the functional outcome must be recorded. Only then will we be able to judge whether chemodenervation should occupy a permanent place in our therapeutic armamentarium.

Doctor Scott deserves our admiration for having pioneered a novel approach to the treatment of strabismus. His tenacity in attempting to define the role of botulinum injections in the treatment of neuromuscular anomalies of the eye may well provide us one day with the answers we are searching for. I appreciate the courtesy of the authors for having made their manuscript available to me well in advance of this meeting.

PROF ALFRED HUBER. Let me take the occasion also to participate in the discussion of your excellent and most interesting paper. Thanks to your kindness, our research group at the Neurological University Clinic in Zurich has had the botulinum toxin at our disposal for 4 years. We have no experience in the treatment of strabismus in children but have used it for concomitant and paralytic strabismus of adults. In paralytic strabismus the toxin prevents contracture of the homolateral antagonist and thus facilitates binocular vision over small areas of gaze. In cases of total lateral rectus palsy, the toxin injection may thus facilitate a muscle transposition procedure without the need of ipsilateral weakening of the medial rectus or with a medial rectus recession of a smaller amount than usual. In cases of light lateral rectus paresis the toxin injection allows the paretic muscle to recover and thus normal alignment and recovery of the ocular function can be obtained, often without the need for muscle surgery. Very good results are also obtained in cases of IV nerve palsy where the injection of botulinum toxin in the overacting homolateral inferior oblique eliminates completely the disturbing hyperphoria. In concomitant strabismus of adults the method of muscle weakening with the toxin is effective above all in cases of small primary angles or residual angles following surgical intervention. We have the same experience that the best results are obtained with multiple small doses. Generally a 70% reduction of the horizontal angle of deviation can be obtained after two injections. Botulinum toxin injections can also be applied with success in ocular myopathies and ocular myasthenias to correct the disturbing deviations. Let me finish my remarks with the statement that botulinum toxin as introduced by Doctor Scott has a far wider application than presented here for it is the best temporary treatment for blepharospasm, hemifacial spasm, several types of dystonia like torticollis, and also for spasms of the vocal cords in spastic dysphonia where the toxin is directly injected into the vocal cords. Doctor Scott has opened with his botulinum treatment a wide area not only in ophthalmology but also in general neurology. In the name of many satisfied patients I would like to thank him here especially and congratulate him for his wonderful achievement.

DR THOMAS D. FRANCE. Mr President, members and guests. The work of Doctor Alan Scott and colleagues has given us the opportunity to test and perhaps answer a question that has been raised for certainly well over 100 years. That is, is the cause of infantile strabismus, so-called congenital esotropia, of a sensory or motor origin? Their methodology gives us for the first time an opportunity to change the motor input in infantile esotropia at a time much earlier than we are now able to do so surgically. The work of Hubel and Weisel in kittens in the early 60s showed that the induction of a strabismus would lead to the loss of binocular cortical cell response when done within a certain critical period, indicating that a strabismus by itself can lead to lack of sensory binocular function. Helveston and colleagues have found, however, that the so-called congenital esotropia is, in fact, not congenital. It is not present at the time of birth or within the first 3 or 4 days following birth. It apparently does not develop until 2 or 3 months of age. As Doctor Scott has pointed out, within that period of time binocular function is

developing. Therefore, we must endeavor to identify and treat those children with so-called "essential" esotropia after birth but before the loss of binocular function occurs. Doctors Magoon, Stager, McNeer, and Scott have shown that it is possible to do this in children using botulinum toxin. My question to the group is when and how do we identify these patients and at what point are we able to first inject these children since we know that some children with strabismus at the age of 1 or 2 months will lose it by the age of 3 months and will have straight eyes with good binocular function, whereas other children will go on and maintain their misalignment and appear to have no possibility of restoration of binocular function.

DR MALCOLM L. MAZOW. In a recent publication, Doctor Metz and I looked at both sixth and third nerve palsies. Those two groups included patients requiring surgery long before botulinum was available and those since the advent of botulinum. Elimination of patients developing sixth nerve palsy from diabetic and small vessel etiology left a relatively equal group of patients, in the treated and nontreated groups. Before the use of botulinum, 75% did not recover, requiring surgery. The group that was watched for a minimum of 3 months and then managed with botulinum injections, had approximately 75% cure with only a residual of a -1 abduction in lateral rectus function. This is a very significant group of individuals benefiting greatly by the use of botulinum for the restoration of binocular vision. The question that I would like to ask Doctor Scott and coauthors is are these results also possible in the infantile essential esotrope? The results of most surgeons is 85% to 90% cure with one operation. Cure being considered as less than 8 prism diopters of esotropia. Until we get the same results with botulinum, it seems that strabismus surgery, with good pediatric anesthesiology, allows excellent results, questioning the benefit of botulinum to correct congenital esotropia.

DR THOMAS D. DUANE. Mr Chairman, Mr Secretary. This discussion has a special meaning to me because it reminds me of an experience that I had after World War II. We had a course in Georgetown. Doctor Adler was one of the main speakers. It was a very interesting course. During the course the technician came in and showed lights vertical and horizontal. You have the child close his eyes and have him look at a blank wall and ask the position of the lines. A young child was presented who was crying and obviously upset which was very irritating. So, finally, one of the ophthalmologist in the audience taking the course said: "When I close my eyes all I can see is that Russian I was out with last night." The orthoptic technician said: "Vertical or horizontal?"

We had that problem when I was in the Navy as a flight surgeon. You had to take a test. You did a cover test on them but it would show a fairly strong deviation but with just the Maddox rod they don't have any difficulties. I don't think whether you have a floater or not makes any difference whether you can fly an airplane but the Navy does and I finally did a paper on the concerns of the Navy. They didn't pay any attention to it. I think you ought to know how much deviation you have

before you start treatment. So that was my experience in the Navy. Thank you for letting me discuss this paper.

DR GEORGE L. SPAETH. We have heard for some time that botulinum works very well; we've also heard cautions that it doesn't work so well as some would think. I'd like to give you an example from a different field to support the point I'm going to make.

We all know that lowering intraocular pressure helps some people with glaucoma, but one paper from Duke University reviewing the literature questioned this, because there were no controlled studies "proving" it. As a consequence, legislatures across the country started questioning whether, indeed, treatment for glaucoma was appropriate. The General Accounting Office (GAO) decided that since there appeared to be no appropriate, effective treatment for glaucoma, screening for glaucoma and diagnostic tests for glaucoma were inappropriate and, therefore, not be reimbursed. Fortunately, the GAO's material was passed on to the American Academy of Ophthalmology and others, and vigorous efforts started to report the available evidence showing that in fact treatment for glaucoma can be beneficial. As a result, the GAO changed position and some of the damage was reversed.

The time has come for us to realize that we are going to be challenged on whether treatments are really effective or not. If indeed a treatment is presented as "highly effective," we will be required to develop meaningful data to prove that.

What I would like to ask Doctor Scott, then, is that since botulinum treatment appears to be so effective, why not do a controlled study so that we can convince others that the treatment really works?

DR DAVID R. STAGER. First of all, Doctor Magoon, Doctor McNeer, my wife and I would like to thank Doctor Alan Scott and this society for having us as your guests at this very special meeting. Secondly, I think we speak for all of our subspecialty in expressing to this society our congratulations to Doctor Parks for being the recipient of the Howe Medal Award. We are very proud of Doctor Parks and his accomplishment.

I feel we should take a historical perspective of the present study. Chemical strabismus correction is in its infancy and will improve just as strabismus surgery has over the past century. The question is whether it holds enough promise to proceed judiciously. There is a great amount of hard data that was presented today, and more will be included in the published reports. Perhaps the answer to many of the questions that have been raised will be answered. Much work is still needed as Doctor von Noorden and Doctor Mazow have pointed out. In fact, I believe that Doctor Bill Scott is organizing a prospective study that will include botulinum in the study of congenital esotropia. With the help of Doctor France, Doctor Mazow, Doctor Huber, our distinguished guest, and many others, we look forward to helping to define the role of chemical treatment in strabismus.