

Botulinum toxin augmented bilateral lateral rectus recession versus three muscles surgery in large-angle intermittent exotropia

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Abstract

• **AIM:** To report the surgical outcomes of correcting large angle intermittent exotropia in adult patients by bilateral lateral rectus muscle recession with intraoperative use of botulinum toxin and to compare the results with those of bilateral lateral rectus muscle recession and unilateral medial rectus resection.

• **METHODS:** The medical records of patients who underwent surgical correction of large angle intermittent exotropia [exotropia >50 prism dioptre (PD)] were retrospectively reviewed. Two groups of patients were identified; Group I (21 patients) had bilateral lateral recti recession augmented with intraoperative botulinum toxin A (BTA) injection into the recessed muscles and group II (30 patients) were treated by bilateral lateral recti recession with unilateral medial rectus muscle resection. Preoperative data were extracted for age, gender, refraction, type of exotropia, angle of stereopsis and angle of deviation. The main outcome measures were the postoperative angle of deviation and stereoacuity angle by Titmus test measured at the end of one year of postoperative follow up.

• **RESULTS:** By the end of the first postoperative year, 10 patients in group I (47.6%) and 20 patients in group II (66.7%) achieved esotropia/esophoria <5 PD or exotropia/exophoria <10 PD. The difference in surgical success rate was not statistically significant ($P=0.1$) but there was a statistically significant higher rate of undercorrection in group I ($P=0.03$). On the other hand, 3 patients in group I (14.3%) and 5 patients in group II (16.7%) had improved stereopsis; this difference in the sensory outcome was not statistically significant ($P=0.8$). In

the BTA augmented surgery group, good stereoacuity and smaller preoperative angle of deviation were associated with significantly higher surgical success rate ($P=0.004$, 0.01 respectively).

• **CONCLUSION:** BTA augmented bilateral lateral recti recession is associated with higher rate of undercorrection as compared to bilateral lateral recti recession with unilateral medial rectus resection in the correction of large angle intermittent exotropia. The surgical success rate in BTA augmented surgery group is observed to be higher in patients with preoperative smaller angle of deviation and in patients with good stereoacuity.

• **KEYWORDS:** botulinum toxin; intermittent exotropia; large angle deviation; augmented surgery

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INTRODUCTION

Large angle exotropia is defined as exotropia of more than 50 prism dioptres (PD)^[1]. The surgical correction of large angle intermittent exotropia presents a dilemma due to the variability of surgical options ranging from large bilateral lateral recti recession, or unilateral recession-resection to three or even four muscles surgery^[2-5]. All these options aim towards adequate postoperative ocular alignment that may come at the expense of abduction which becomes limited in large recessions or resections. Other drawbacks include narrowing of the palpebral fissure, long intraoperative time and prolonged patient convalescence in three or four muscles procedures^[3,6]. Attempts to add more surgical effect without operating on more muscles led the surgeons to the adjunctive use of botulinum toxin in surgery for large angle ocular deviations.

Botulinum toxin is a potent neurotoxin produced by bacterium, *Clostridium botulinum*, it has many antigenic types but only type A is used in ophthalmology^[7]. It works by blocking the

release of acetylcholine from the cholinergic synapses without causing damage to the myotendinous nerve endings^[8]. It was first introduced for strabismus treatment by Scott^[9] in 1980, since then, its application has widened to include most types of strabismus in both adults and children^[10]. Botulinum toxin A (BTA) was found to have a long term effect on ocular alignment due to structural changes occurring in the muscles after injection and this after-effect is apparently more marked in patients with good fusion potential^[11]. Its use in exotropia was investigated either alone or as a surgical adjunct to recession-resection or bilateral lateral recti recession procedures^[12]. Adjunctive intraoperative use of botulinum toxin in bilateral lateral recti recession procedure offers the advantage of injection under direct vision thus minimizing undesired effects of botulinum toxin diffusion such as ptosis and vertical deviations or the rare event of inadvertent globe perforation. Moreover, it minimizes the surgical time and decreases the risk of complications that can arise when working on the medial rectus muscle including muscle slippage, postoperative fibrosis and sparing more muscles for later intervention if needed^[12-14]. This retrospective cohort study aims to report the surgical outcomes of correcting large angle intermittent exotropia by bilateral lateral rectus muscle recession with intraoperative use of botulinum toxin and to compare the results with those of bilateral lateral rectus muscle recession and unilateral medial rectus resection.

SUBJECTS AND METHODS

Ethical Approval This retrospective study was carried out in accordance with the tenets of the Declaration of Helsinki of 1964, as revised in 2013. All patients were operated by HKM at the Delta Eye Hospital (Dakahleya, Egypt) and the study was approved by the Ethics Committee of the Delta Medical Center. A written informed consent was provided by all patients before the procedure.

The medical records of patients diagnosed with large angle intermittent exotropia between January 2017 and January 2020 were reviewed retrospectively. Patients included in this analysis were those who had large angle intermittent exotropia with no history of previous strabismus surgeries, no associated vertical deviations nor neurologic impairment, age above 18y and those who attended their follow up visits.

Based on the surgical procedure performed, two groups of patients were identified; the first group included patients who had received bilateral lateral recti recession augmented with intraoperative BTA injection into the recessed muscles (Group I) and the second group included patients who had bilateral lateral recti recession with unilateral medial rectus muscle resection in the non-dominant eye (Group II). No cases of repeated BTA injections were included in this study.

Preoperative data collected from patient's records included: history, cycloplegic refraction, best corrected visual acuity (BCVA), and the results of ocular motility, anterior segment and posterior segment examinations. Data extracted also included the angle of exotropia measured for distance (6 m) and for near (30 cm) using alternate prism cover method with best optical correction, the subtype of intermittent exotropia, the ocular fixation dominance and measurement of near stereopsis angle by Titmus test. Exotropia was classified into two main broad categories according to the difference between distance and near deviation: Basic type where the difference was less than 15 PD and divergence excess type (either true or simulated) in which the difference was more than 15 PD. Cases of convergence insufficiency were not included in this analysis.

Surgeries were performed in all patients under general anaesthesia by the conventional standard techniques based on distance deviation. The amount of recession-resection was determined based on the guidelines suggested by Cifuentes *et al*^[3] who recommended performing bilateral lateral recti recession of 9 mm to correct 50 PD of exotropia then added 1 mm of medial rectus resection in the non-dominant eye for every remaining 5 PD of exotropia. Patients of the first group received BTA intraoperatively in a dose of 2.5 U injected into the belly of each lateral rectus muscle before being recessed. To minimize inadvertent spread of the BTA to other muscles; the surgeon adopted a routine of surgical sponge application over the muscle just after injection for 1min followed by thorough wash with balanced salt solution to flush any leaking toxin. The amount of bilateral lateral recti recession performed in the BTA augmented surgery group was determined based on the preoperative deviation as follows: 9 mm recession of each lateral rectus muscle for 50-60 PD exotropia, 9.5 mm for 60-70 PD exotropia and 10 mm for >70 PD of exotropia.

The surgery ratio was calculated for each patient [(preoperative distance deviation angle in PD)/(sum of mm of bilateral lateral recti recession and medial rectus resection when it was done)]. Follow up data were collected after 1wk, 1, 6mo, and 1y following the procedure.

The evaluated outcome measures were: 1) Motor outcome in the form of distance deviation angle as measured at 1wk, 1mo, 6mo and 1y postoperatively. Surgical success was defined as esotropia or esophoria of <5 PD to exotropia or exophoria of <10 PD as measured at the end of the first post-postoperative year. Values above 5 PD esodeviation and 10 PD exodeviation were defined as overcorrection and undercorrection respectively. The surgical effect on alignment was also calculated at one year after surgery, as the net change in alignment in PD per amount of surgery in mm (PD/mm). 2) Sensory outcome in the form of Titmus stereoacuity measured at

Table 1 Preoperative data of the studied groups

Variables	BTA augmented surgery (n=21)	Three muscles surgery (n=30)	P
Age (y), mean±SD	27.5±5.86	27.7±5.31	0.8
Sex			0.8
Male	11 (52.4%)	15 (50%)	
Female	10 (47.6%)	15 (50%)	
Refraction			
Emmetropia	11 (52.4%)	15 (50%)	0.8
Myopia	6 (28.6%)	9 (32%)	0.9
Hypermetropia	4 (19%)	6 (18%)	0.9
BCVA (median)			
OD	0.2 (0-0.5)	0.2 (0-0.6)	0.8
OS	0.2 (0-0.6)	0.2 (0-0.5)	0.8
Near deviation (PD), mean±SD	59.3±6.7	60.8±7.6	0.6
Distance deviation (PD), mean±SD	71.9±6.7	72.7±7.7	0.7
Type of exotropia			0.8
Basic	11 (52.4%)	15 (50%)	
Divergence excess	10 (47.6%)	15 (50%)	
Stereopsis angle degrees			0.7
Bifoveal	10 (47.6%)	14 (46.7%)	
Gross	11 (52.4%)	16 (53.3%)	

the end of one postoperative year. The sensory fusion tested by Titmus stereoacuity was classified as bifoveal (≤ 60 seconds of arc) or gross (70-3000 seconds of arc). Significant change in stereopsis was defined as change of at least 2 octaves from the previous examination to overcome any test-retest variability^[15].

Statistical Analysis The collected data was analysed using Statistical Package of Social Services, version 25 (SPSS; IBM, 2017). Shapiro-Wilk test was used to determine the distribution characteristics of variables. Normally distributed data were described using mean and standard deviation (SD), while heterogenous non-normally distributed data were described using median and interquartile range (IQR).

Independent samples *t*-test was used for analysis of normally distributed variables, while heterogenous variables were analysed using Mann-Whitney test. Fisher exact test and Pearson's Chi-squared test were used to analyse qualitative data. In all the tests, $P < 0.05$ was taken as significant.

RESULTS

Record review identified 51 patients meeting the inclusion criteria: 21 patients were treated by bilateral lateral recti recession augmented with BTA injection into the recessed muscles (Group I: BTA augmented surgery group), 30 patients were treated by bilateral lateral recti recession with unilateral medial rectus muscle resection in the non-dominant eye (Group II: Surgery only group). The mean follow-up period for all patients was 14.6±4.7mo.

Table 1 shows the demographic data of both groups with no statistically significant difference regarding their preoperative characteristics.

Table 2 Motor and sensory outcomes of the studied groups 1y post-operative

Variable	BTA augmented surgery (n=21)	Three muscles surgery (n=30)	P
Motor outcome			
Success	10 (47.6%)	20 (66.7%)	0.1
Under correction	11 (52.4%)	7 (23.3%)	0.03 ^a
Over correction	0	3 (10%)	0.1
Sensory outcome			
Stable	17 (81%)	23 (76.7%)	0.7
Improved	3 (14.3%)	5 (16.7%)	0.8
Deteriorated	1 (4.7%)	2 (6.6%)	0.8

^aStatistically significant.

Table 2 shows the postoperative motor and sensory outcomes at the end of first postoperative year. The success rate in both groups was not statistically different ($P=0.1$). However, there was higher incidence of undercorrection in the BTA augmented group that was statistically significant when compared to the 3-muscle surgery group. No significant differences between both groups were detected for sensory outcomes.

The data presented in Table 3 shows the association between the surgical success in BTA augmented surgery group and the different preoperative patient characters. Among all the enlisted variables, only the preoperative stereoacuity and the mean preoperative angle of distance deviation showed a significant association with surgical success.

The postoperative deviation at the end of the first week, the first month, the sixth month and the first year showed a significant difference between both groups. The median

Table 3 Effect of different preoperative variables on the surgical success in the BTA augmented surgery group

Variables	Surgical success (n=10)	Surgical failure (n=11)	P
Mean age (y)	27±7.8	27.9±7.5	0.4
Sex			0.3
Male	4 (40%)	6 (54.5%)	
Female	6 (60%)	5 (45.5%)	
Error of refraction			
Emmetrope	4 (40%)	5 (45.5%)	0.8
Myope	3 (30%)	4 (36.4%)	0.7
Hypermetrope	3 (30%)	2 (18.1%)	0.5
Type of exotropia			0.3
Divergence excess	4 (40%)	5 (45.5%)	
Basic	6 (60%)	6 (54.5%)	
Stereoacuity			0.004 ^a
Bifoveal	9 (90%)	3 (27.3 %)	
Gross	1 (10%)	8 (72.7 %)	
Mean angle of distance deviation (PD)	68.5±5.3	75±6.7	0.01 ^a

^aStatistically significant.

angle of deviation in the BTA augmented group was 25 PD of esotropia in the first week due to the transient BTA induced overcorrection and 20 PD of exotropia at the end of the first postoperative year. These results are presented in Table 4.

Table 5 shows the surgery ratio (the surgical dose) and the surgical effect at the end of the first postoperative year; the surgical ratio was significantly higher in the BTA augmented surgery group than in the surgery only group with no significant difference in the surgical effect between both groups. The records showed that only one patient injected with BTA (4.7%) had suffered postoperative mild ptosis that resolved completely after 2mo with no reported vertical deviation nor intraoperative complications in all the treated patients. The frequency of postoperative diplopia was significantly higher ($P=0.03$) in the BTA group (9 patients; 42.9%) than the surgery group (5 patients; 16.7%); but this diplopia declined markedly after 2wk and was completely resolved within one month. All patients had been consulted before the procedure about the possibility of postoperative diplopia and were managed by occlusion or temporary relieving prisms in selected cases of troublesome diplopia interfering with normal daily activities.

DISCUSSION

Large angle intermittent exotropia can be managed by different surgical techniques with variable success rates^[16-19]. Previous studies evaluated the BTA use to augment the effect of surgery in recession-resection procedures for the correction of different types of exotropia^[12-14,20], other studies have evaluated the use of BTA alone for the treatment of intermittent exotropia with variable success rates^[21-23]. To the best of our knowledge, this is the first study to compare the effect of BTA augmented bilateral lateral recti recession with the effect of surgery on three recti muscles for the correction of the large angle intermittent exotropia.

Table 4 Postoperative data of the studied groups median (IQR)

Follow-ups	BTA augmented surgery (n=21)	Three muscles surgery (n=30)	P
After 1wk	+25 (10)	+5 (15)	<0.001 ^a
After 1mo	+10 (10)	- 2.5 (6.25)	<0.001 ^a
After 6mo	-10 (15)	-5 (10)	0.02 ^a
After 1y	-20 (22.5)	-6 (11.25)	0.04 ^a

^aStatistically significant; + indicates esotropia, - indicates exotropia. IQR: Interquartile range.

Table 5 Surgical effect and ratio in the studied groups Mean±SD

Variables	BTA augmented surgery (n=21)	Three muscles surgery (n=30)	P
Surgical ratio (PD/mm)	3.8±0.3	3.3±0.2	<0.001 ^a
Surgical effect (PD/mm)	3.1±0.7	3.03±0.4	0.4

^aStatistically significant.

In the present study both utilized techniques yielded favourable success rates, three muscle surgery had higher success rate but the difference was not statistically significant which could be attributed to the small sample size. However, the number of patients who were under corrected at the end of follow up period was significantly higher in the BTA augmented group. BTA was previously used by Tavakolizadeh and Farahi^[24] to augment the effect of bilateral lateral recti recession in a small case series of two exotropia patients with albinism and poor preoperative fusion; by the end of the fourth postoperative month both patients achieved acceptable alignment and demonstrated fusion by Bagolini lenses as well. Other studies evaluated adjunctive intraoperative use of BTA in exotropia in monocular recession-resection procedure rather than bilateral lateral recti recession surgery. A randomized controlled study conducted by Minguini *et al*^[20] compared the results of surgery plus BTA injection to surgery plus hyaline solution injection in patients undergoing monocular recession-

resection procedure for either esotropia or exotropia, they found no significant difference in surgical outcomes between the two treatment groups. In a short case series, Özkan *et al*^[12] evaluated the effect of BTA augmented surgery in three large angle exotropia patients who also underwent monocular recession–resection procedure for either basic or sensory exotropia with intraoperative injection of 5 U of BTA into the recessed lateral rectus muscle, all three patients developed successful motor outcome. Similar findings were reported by Owens *et al*^[13] when operating on a similar number of large angle sensory exotropia patients but with performing maximum recession-resection and injecting 10 U of BTA into the recessed lateral rectus muscle^[12-13].

Patients with intermittent exotropia are known to have good binocular potential with good stereoacuity in near distances where deviation is minimum alternating with suppression in far distances when the deviation is maximum. Moreover, successful surgical correction was found to be associated with improved binocularity and stereopsis in adults with large angle exotropia^[25-26]. In the current work, a significant association between good preoperative stereoacuity and successful motor outcome was found in exotropia patients treated with BTA augmented surgery. Accordingly, it can be assumed that a potent after effect of BTA and subsequently stable successful outcome can be obtained when using it in patients with pre-existing good sensory fusion. This assumption was previously suggested in other studies evaluating BTA injection for infantile esotropia^[27-31]. However, a different finding was presented by Owens *et al*^[13] who reported stable long term results in their three treated patients with poor sensory fusion^[13]. A recent study was conducted by Su *et al*^[32] to compare the BTA injection with the conventional surgery for the treatment of intermittent exotropia in children; they concluded that BTA was as effective as surgery, but the recovery of the fusion was lower in the BTA group than the surgery group.

The surgical effect after 6mo showed no significant difference between both groups which implies that the after-effect of BTA in successful cases compensated for the higher undercorrection rate in this group making the surgical effect comparable to that of the surgery only group and not significantly lower than it. The surgical dose is significantly higher in the BTA augmented surgery due to the smaller amount of muscle surgery performed in this group (2 muscles) in comparison to the three muscles surgery group.

In the present study, the records showed that only one patient injected with BTA had suffered postoperative ptosis. This relatively low rate of complication could be attributed to the accurate under direct vision injection of the BTA and the adopted intraoperative routine of injection. In other studies that evaluated intraoperative BTA injection, the incidence of ptosis

was variable ranging from zero cases as in small case series conducted by Özkan *et al*^[12] to 42% as reported by Minguini *et al*^[20].

A potential limitation of using botulinum toxin for correcting strabismus is its relatively low predictability. Another limitation of the study is being retrospective with relatively short follow-up period. Further multicentre prospective studies would support the results of this current research.

In conclusion, BTA augmented bilateral lateral recti recession is associated with higher rate of undercorrection as compared to bilateral lateral recti recession with unilateral medial rectus resection for the correction of large angle intermittent exotropia in adults. The surgical success in BTA augmented surgery was higher in patients with smaller preoperative angle of deviation and in patients with good stereoacuity.

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