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Coarsened Exact Matching of Trabectome Surgery Combined with Baerveldt to Baerveldt: Same Session Trabectome Negates Tube Fenestration

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Abstract

Purpose: To evaluate the efficacy and survival rates of trabectome-mediated ab interno trabeculectomy combined with non-fenestrated Baerveldt glaucoma implants (BT) in comparison to Baerveldt glaucoma implant alone (B).

Method: A total of 175 eyes undergoing primary glaucoma surgery (60 eyes BT and 115 B) were enrolled in this retrospective comparative case series. Participants were identified using the procedural terminology codes. Groups were then matched using Coarsened Exact Matching (51 eyes in each group). The primary outcome measure was surgical success, defined as 5 mmHg < IOP ≤ 21 mmHg, and IOP reduction ≥ 20% from baseline, and no reoperation for glaucoma. Secondary outcome measures were intraocular pressure, the number of glaucoma medications, and best corrected visual acuity (BCVA).

Results: The cumulative probability of success at one year was 61% in BT, and 50% in B. IOP decreased significantly from 23.5±2.4 mmHg at baseline to 14.1±2.7 mmHg at the final follow up in BT (P= 0.001). The corresponding numbers for B were 23.2± 2.0 and 13.9± 1.6, respectively (P= 0.001). There was no significant difference in IOP at the final follow-up (P=0.56). The number of medications at baseline was 2.3±0.3 in both groups. However, BT needed significantly fewer drops at all postoperative time intervals and used 1.1±0.3 (BT) and 2.0±0.4 eye drops (B) at the final follow-up visit (P= 0.004). No dangerous hypotony or hypertension occurred in BT.

Conclusion: Similar rates of success and IOP reduction were observed in BT and B. BT needed significantly fewer glaucoma medications. Tube fenestration was not necessary in BT resulting in less postoperative hypotony and hypertension.

Keywords: Trabectome Surgery, ab interno trabeculectomy, glaucoma drainage devices, Baerveldt Glaucoma Implantation, tube ligation

Introduction

Primary surgical interventions for refractory glaucoma with a low target IOP are often trabeculectomy and large glaucoma drainage devices (GDD). Both allow to bypass the impaired conventional outflow route and are therefore theoretically capable of achieving pressures below that of episcleral veins. Trabeculectomy is associated with a relatively high rate of failure and potentially sight-threatening complications [1–4]. Recent studies indicate glaucoma drainage devices have the same or higher success rate than trabeculectomy in the management of end-stage glaucoma with a better safety profile [1, 2, 5]. As such, GDDs are increasingly used for refractory glaucomas or as primary procedures.

One of the most frequently implanted GDDs is the Baerveldt implant (Advanced Medical Optics, Santa Ana, California, USA). In contrast to the Ahmed glaucoma implant (New World Medical Inc, Rancho Cucamonga, California, USA), another commonly used device, the Baerveldt implant does not have a flow restrictor and requires a ligature suture that ties off the lumen completely [6] until a capsule has formed around the implant around four to six weeks [7] that limits flow sufficiently to prevent hypotony. Since GDDs are often implanted in severe cases of glaucoma with advanced optic neuropathy, a high postoperative IOP can be detrimental. Slit-shaped fenestrations are often created anterior to the ligature with spatulated needles to allow limited flow [8–10]. Unfortunately, this strategy can be poorly titrated and has a variable effect from no IOP reduction to frank hypotony [9].

To address this problem we combined Baerveldt device implantations with trabectome-mediated ab interno trabeculectomy surgery (NeoMedix, Tustin, CA, USA) to allow a complete tube ligature without fenestration. We hypothesized that this would provide appropriate IOP reduction until the ligature dissolves and the Baerveldt implant starts to function. To achieve a balanced comparison, we used *Coarsened Exact Matching (CEM)* a computation-intense, modern statistics method [11–14] as we have done before [15, 16]. Although a randomized controlled trial remains the most effective tool to reduce bias and patient selection, modern statistical matching strategies can deliver a highly-balanced assessment of already existing, real-world patient data.

Methods

The protocol of this study was approved by the institutional review board of the University of Pittsburgh Human Subjects Research Committee (Approval number is: PRO13120466). An informed consent was not required for this retrospective comparative case series. Our research adhered to the tenets of the Declaration of Helsinki and regulations of the Health Insurance Portability and Accountability Act. Patients who underwent either Baerveldt with trabectome surgery (BT) or Baerveldt implant alone (B) between 2008 and 2015 were identified using Current Procedural Terminology codes. All procedures were performed by four glaucoma fellowship-trained surgeons. Patients older than 18 years old with medically uncontrolled IOP were included in this study. Exclusion criteria were neovascular glaucoma, uveitic glaucoma, and history of prior ocular surgery (except uncomplicated phacoemulsification).

Data were collected from patients' electronic medical record and included basic demographic information, type of glaucoma and preoperative diagnosis, preoperative IOP and number of glaucoma medications, baseline best corrected visual acuity (BCVA), type of operation, postoperative IOP, number of medications, and BCVA.

The primary outcome measure was success defined as 5 mmHg < IOP ≤ 21 mmHg or ≥ 20% reduction of IOP from baseline at two consecutive visits, no need for further glaucoma surgery, and no loss of light perception. The secondary outcome measures were IOP, BCVA, and the number of medications.

In all cases, the IOP was measured with Goldmann applanation tonometer (GAT; Haag-Streit, Konig, Switzerland) at 1 day, 1 week, 4 ±1 week, 2-4 months, 5-7 months, 8-10 months, and 11-13 months. If more than one visit was found at these intervals, the visit closest to month 6, 9, or 12 was chosen.

Surgical technique

In BT, trabectome surgery was performed first. The patient's head was tilted 30˚ away from the surgeon and the microscope was tiled in the opposite direction. A temporal 1.6 mm clear corneal incision was created, and the handpiece was advanced into the anterior chamber. The tip of the trabectome was engaged with trabecular meshwork (TM) at the nasal angle and advanced parallel to Schlemm's canal for 90˚ counterclockwise followed by a 90˚ clockwise move to opposite direction for a total of 180˚ TM ablation. The handpiece was withdrawn from the anterior chamber, and the incision was hydrated to seal.

Baerveldt implantation: a fornix-based conjunctival flap was created, and tenon's dissection was advanced toward the equator until enough space was created for the implant. The lateral wings of the 350 mm*mm Baerveldt implant were advanced under the superior and lateral rectus muscles. The plate was sutured to the sclera 10 mm posterior to the limbus. The tube was cut short with the bevel up to have approximately 2-3 mm intracameral length. The tube was completely ligated near the plate junction with a 7-0 polyglactin 910 suture (coated VICRYL, Ethicon, Somerville, NJ, United States) and tested with BSS to confirm water tightness. The tube was then inserted into the anterior chamber through a tunnel created with 23-gauge needle and secured to the sclera with a 7-0 polyglactin loop stitch. In B, but not in BT, the tube portion anterior to the ligature was fenestrated with a pass of the spatulated 7-0 needle. A patch graft was used to cover the tube. The conjunctiva and Tenon's layer were pulled back over the shunt and sutured to the limbus.

At the conclusion of the surgery, an antibiotic (moxifloxacin) and steroid (1% prednisolone acetate) drop were applied. The antibiotic was used four times per day for one week while the steroid eye drops were used four times per day for one month and then tapered by one drop application per week.

Statistical analysis

Demographics were compared by the Mann-Whitney U test and chi-squared test for continuous and categorical variables, respectively. To avoid eliminating data with missing values, *Multiple Imputation* in R was used. Missing values of the incomplete dataset were imputed $m>1$ times, thus creating m completed datasets. Second, each of the m completed datasets were independently analyzed. Finally, the results from each of the m analysis were pooled into a final result. Missing data like age, gender, and race were imputed by generating five similar but non-identical datasets. Groups were then matched by utilizing *Coarsened Exact Matching* in R [17], based on age, race, type of glaucoma, baseline IOP, and number of preoperative glaucoma medications.

Univariate linear regression was used to examine IOP reduction after surgery. Variables statistically significant were included in the final multivariate regression model. A p-value of less than 0.05 was considered statistically significant. Continuous variables were expressed as mean±SD. All analyses were performed using R.

To compute the survival of subjects in the groups, Kaplan-Meier survival plots were determined and compared using the log-rank test. Statistical significance was set at $p< 0.05$. Success was defined as the IOP <21 mmHg and a >20% reduction from baseline with no need to further surgery.

Results

175 eyes were included consisting of 51 BT and 51 B. Using case matching, there was no significant difference in ethnicity, IOP, the number of IOP-lowering medications, glaucoma type, the degree of VF loss and GI between AIT and AGI ($p>0.05$). Table 1 shows the baseline characteristics of each group.

The mean age of the study participants was 70.7±11.1 years in BT and 67.2±15.7 years in B (P= 0.116). Thirty patients (59%) underwent phacoemulsification at the time of glaucoma surgery in each group (P=1.00). Primary open-angle glaucoma was the most common diagnosis in both groups (65.0% and 56.5% in BT and B, respectively, P=0.516) There were no significant differences between the study groups in terms of gender, preoperative intraocular pressure, baseline number of glaucoma medications, ethnicity, and type of glaucoma (Table 1).

Kaplan-Meier survival curves (Figure 1) indicated a mean duration of survival of 261.9±21.9 days in BT group and 220.28±17.5 in B group with no statistically significant difference between two groups (log rank=2.53 p= 0.11). The cumulative probability of qualified success at 3 months, 6 months, and 12 months was 74%, 64%, and 61% respectively in the BT, and 66%, 52%, and 50% in the B.

In subgroup analysis, although BT combined with phacoemulsification had longer survival than B +phacoemulsification, the difference was not statistically significant. The mean survival duration was 285.5±25.8 in BT with phacoemulsification versus 225.8±25.9 in B with phacoemulsification, log Rank= 2.17, P= 0.14). Corresponding values for glaucoma surgery alone were 221±37.2 and 215.5±23.6 in BT and B group, respectively (log-Rank= 0.24, p= 0.624, Figure 1). BT combined with phacoemulsification had longer survival than BT, but the difference was not statistically significant (285.5±25.8 versus 221±37.2, Log-Rank= 1.18 P= 0.18). Corresponding values for B were 225.8±25.9 and 215.5±23.6 in B with phacoemulsification and B alone, respectively (log-Rank = 0.45, P= 0.50).

IOP was decreased significantly from 23.5±2.4 mmHg at baseline to 14.1±2.7 mmHg at final follow up in BT (P= 0.001, Figure 2). The corresponding numbers for B were 23.2± 2.0 and 13.9± 1.6, respectively (P= 0.001). IOP varied more in B than in BT during the early postoperative phase with 6.3% of hypotony in BT versus 12.8% hypotony in B. During the 1-year follow-up, 7 (13.7%) patients in BT and 18 (35.2%) patients in B group experienced hypotony (P=0.04). Most of the hypotony episodes were within the first month before suture opening.

There was no significant difference in IOP at final follow-up (P=0.98). Eyes in BT experienced a 9±9.1 mmHg reduction in IOP within one week after the surgery compared to a 6±12.3 mmHg reduction in B (P= 0.09). IOP was comparable on day one between BT with phacoemulsification and BT (20.3±11.1 mmHg versus 18.6±12.7 mmHg, P= 0.56). B with phacoemulsification had a significantly higher IOP on day 1 compared to B (23.2±14.3 versus 17.9±11.4, P=0.041).

The baseline number of glaucoma medications was 2.3±0.3 in both groups (Figure 3). However, BT needed statistically significantly fewer drops in all postoperative visits. At the final follow-up visit, the number of glaucoma medications was 1.1±0.3 drops in BT and 2.0±0.4 in B (p=0.003, Figure 3).

The mean BCVA at the baseline was 0.64±0.85 logMAR in BT and 0.55±0.75logMAR in B (P=0.663). Corresponding numbers for final follow-up visit was 0.72±1.07 logMAR and 0.63±0.97 logMAR, respectively (P= 0.668).

Discussion

BT and B were both effective in reducing IOP. The IOP reduction of 31% at the 1-year follow-up was similar to previous reports [18–20]. There was a trend toward greater IOP reduction following BT compared to B, but the difference did not reach statistical significance. However, BT required significantly fewer medications postoperatively. The number of glaucoma medications at 1 month postoperative visit was nearly three times as high in B as surgeons struggled to control the pressure in this phase of the bleb maturation.

Early complications of glaucoma drainage devices include hyphema, shallow or flat anterior chamber, tube-corneal touch, corneal edema, and suprachoroidal effusion [6, 21]. These complications are caused by postoperative hypotony, more common in non-valved devices when the flow is not restricted and when fenestration of the tube yields excessive flow [22]. Complete ligation of the tube can prevent postoperative hypotony [23–26], but high postoperative IOPs can be dangerous to eyes with advanced glaucoma damage. Therefore, tube ligation is mostly carried out in conjunction with intraoperative longitudinally oriented 2 mm fenestrations proximal to the ligation [22]. Despite this, a postoperative hypertensive spike may develop secondary to fibrotic growth around the fenestration, malfunction of the slit valves, or insufficient fenestrations [8, 27]. Considering the limitations of fenestration, we proposed to perform trabectome surgery in the same session to prevent postoperative IOP spikes. Trabectome enhances outflow by plasma-mediated ablation of the trabecular meshwork and has a long track record of efficacy and safety in several types of glaucomas [28–32].

Although trabectome is in the family of minimally invasive glaucoma surgeries and primarily proposed for mild open-angle glaucoma cases [32], recent studies suggest it is also effective in more severe glaucomas [33] but it requires a patent conventional drainage system downstream of the trabecular meshwork. Although the success rate of trabectome after failed trabeculectomy and tube shunt procedure supports its role in the management of severe glaucoma [34, 35], many eyes at that stage cannot afford a surgical failure. The effect of trabectome is immediate and controls IOP until absorbable ligation sutures dissolve, and B begins to function. In contrast to fenestration, the IOP lowering effect of trabectome also persists after the ligature suture is absorbed and has the additive effect of reducing the need for glaucoma medications. This is no small feat as nearly half of all glaucoma patients experience local and systemic side effects of glaucoma medications [36]. Adverse effects from medication are an important reason for non-adherence [37] and can also jeopardize the success of glaucoma surgery [38, 39]. Conversely, reducing eye drops can considerably improve the quality of life [40].

Since cataract and glaucoma frequently coexist, many individuals in both groups underwent cataract surgery concurrently. IOP in BT with phacoemulsification was not significantly different from BT alone, reflecting our prior results that phacoemulsification does not add to the IOP lowering effect when combined with trabectome surgery [15]. Although phacoemulsification has been advocated as providing a trabeculoplasty-like, additional IOP reduction [41], glaucomatous trabecular meshwork is often unpredictable and can result in IOP spikes [42, 43]. We observed this on day 1 in patients in B with phacoemulsification. The results of our study and previous reports on this subject show that this potentially dangerous IOP spike could be prevented by the same session trabectome surgery [44]. Conversely, no severe hypotony was seen in BT that did not require tube fenestration.

Limitations of this study are inherent to the retrospective nature compared to randomized controlled trials. However, the *CEM* strategy used here reduces imbalances without discarding valid data. Although observational data is easy to collect compared to randomized experiments, how the treatments were assigned and other aspects of data generation are often ambiguous and difficult to control. *CEM* is a newer form of automatic, nonparametric matching to control the confounding influence of pretreatment control variables by achieving an acceptable balance between treated and control groups [17]. Additionally, this study was conducted at a single tertiary academic center, so the results cannot easily be generalized to other practice facilities.

In summary, we found that Baerveldt implants with same-session trabectome surgery had a significantly decreased number of glaucoma medications and avoided both severe hypertension and hypotension, thereby negating the need for tube fenestration.

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Tables

Table 1. Baseline clinical characteristics of patients in BT and B group

		Group		
		BT	**B**	**P**
Age	Mean±SD	70.7±11.1	67.2±15.7	0.116†
BCVA	Mean±SD	0.64±0.85	0.55±0.75	0.663‡
IOP	Mean±SD	23.4±2.4	22.8±2.1	0.871†
Medications	Mean±SD	2.3±0.3	2.3±0.3	1.00‡
Gender	Female	32 (63%)	27 (53%)	
	Male	24 (47%)	55 (47.8%)	0.32*
Phaco	Yes	30 (59%)	30 (59%)	1.00*
	No	21 (41%)	21 (41%)	
Ethnicity	White	37 (61.7%)	70 (60.9%)	0.99**
	African American	21 (35.0%)	42 (36.5%)	
	Other	2 (3.3%)	3 (2.6%)	
Glaucoma	POAG	39 (65.0%)	65 (56.5%)	
	XFG	3 (5.0%)	8 (7.0%)	
	PACG	7 (11.7%)	10 (8.7%)	0.516**
	PG	3 (5.0%)	5 (4.3%)	
	Other	8 (13.3%)	27 (23.5%)	

BCVA: best corrected visual acuity; IOP: intraocular pressure; POAG: primary open angle glaucoma; XFG: exfoliation glaucoma; PACG: primary angle closure glaucoma; PG: pigmentary glaucoma. ch† Based on t-test. ‡ Based on Mann-Whitney test. * Based on Chi-Square test.** Based on Fisher exact test.

Figures

Figure 1

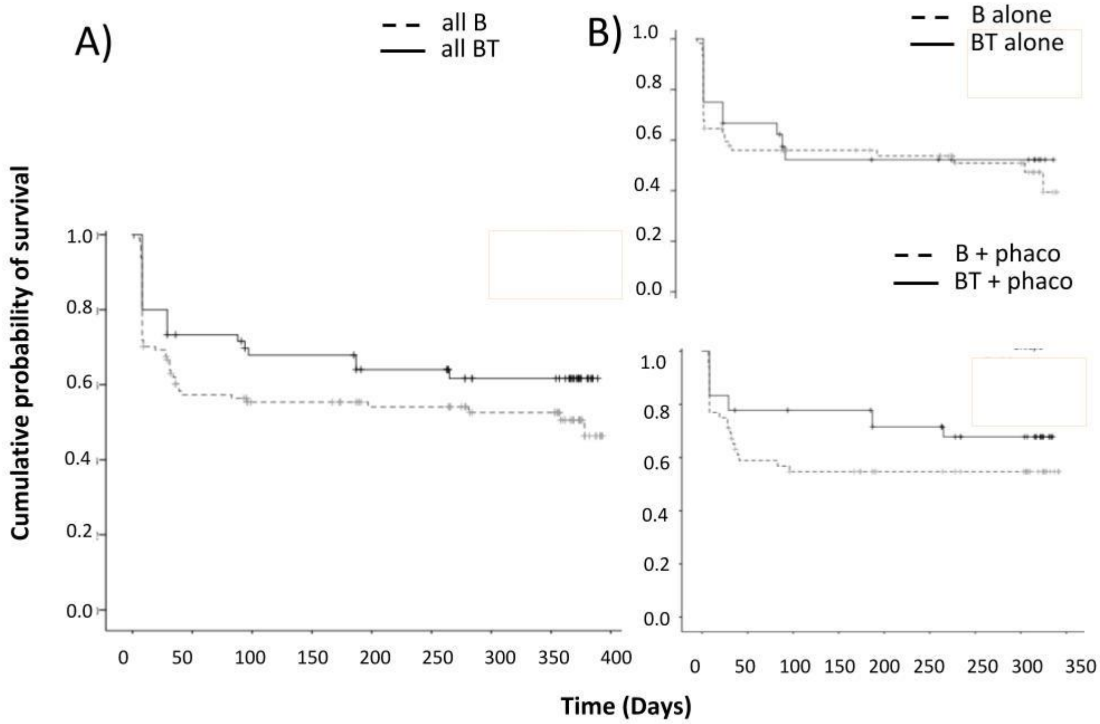

Figure 1. A) Kaplan-Meier survival plots for BT and B with success defined as a final IOP of ≤ 21 mmHg and a 20% reduction from baseline. Success rates of (BT) and B was similar in both groups. B) survival plots of BT and B for subgroup analysis separated by B) glaucoma surgery alone and C) same session phacoemulsification (lower right).

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Figure 2

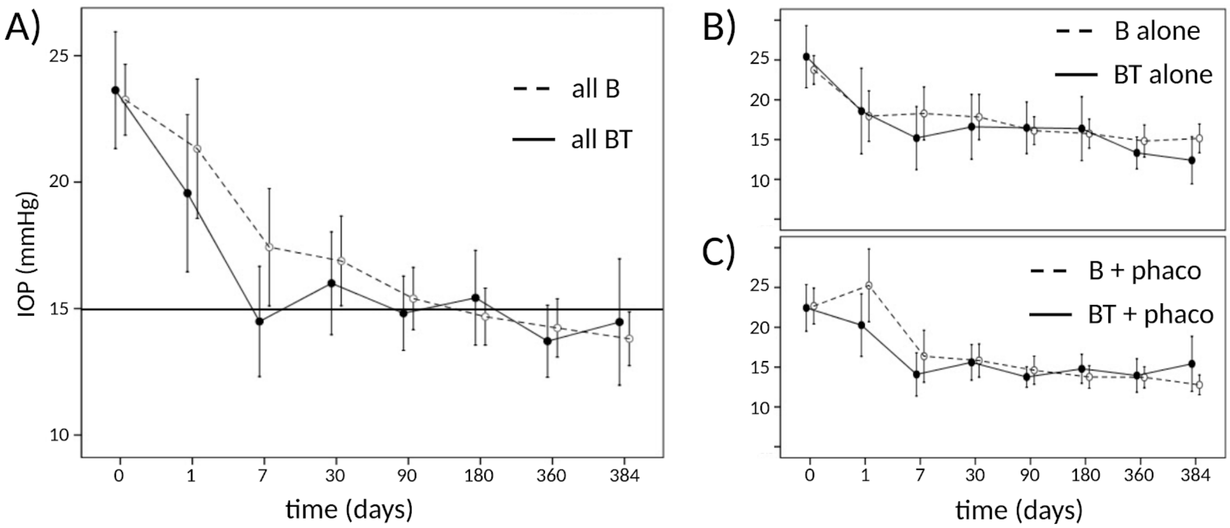

Figure 2. IOP in B and BT. A) IOP in BT was similar to B and trended towards a lower average although tubes in BT were not fenestrated and trended towards a lower average IOP. B) B and BT as standalone procedures. C) B + phaco had a higher IOP on day one compared to subsequent IOPs. No such peak was seen in BT. Mean±95% confidence interval.

Figure 3

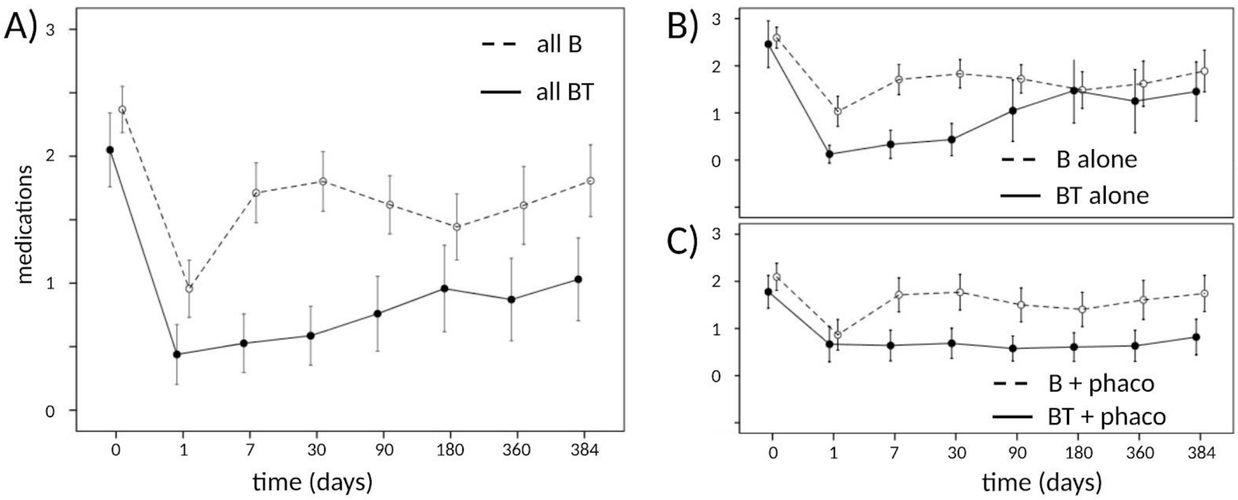

Figure 3. Preoperative and postoperative mean eyedrops for BT and B. Mean pre- and postoperative glaucoma medications for subgroup analysis separated by glaucoma surgery only (B) and same session phacoemulsification (C). Represented as mean±95% confidence Intervals.