

**Effect of postoperative pilocarpine eyedrops in the outcomes of Gonioscopy-assisted
transluminal trabeculotomy (GATT) surgery**

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Précis: Postoperative pilocarpine use did not significantly alter IOP reduction or medication burden following GATT in patients with OHT and POAG. Furthermore, it had no effect on reducing IOP spikes or the development of PAS.

ABSTRACT

Purpose: To evaluate the effect of postoperative pilocarpine use on intraocular pressure (IOP), glaucoma medications, and complications in patients undergoing Gonioscopy-assisted transluminal trabeculotomy (GATT).

Methods: This retrospective study included patients with ocular hypertension or primary open-angle glaucoma who underwent stand-alone GATT or combined with cataract extraction between June 2021 and April 2023. Participants were divided into a pilocarpine group (n=28) and a control group (n=25). Pilocarpine 2% was administered twice daily for 4 weeks following surgery in the pilocarpine group. Outcomes including IOP, visual acuity, glaucoma medication use, and complications were assessed at multiple postoperative intervals up to 12 months.

Results: Baseline characteristics were similar between groups. Surgical success rates at 12 months were 80.8% for the pilocarpine group and 79.2% for the control group ($P=0.999$). No significant differences in IOP reduction were found at any follow-up visit. Considering pilocarpine as 1 drug, the mean number of medications was higher in the pilocarpine group from day 1 to month 1 after surgery ($P<0.001$). However, from the third month through the 12-month follow-up, the study groups were comparable. Although postoperative

complications were similar, on the first postoperative day, five patients (17.9%) in the pilocarpine group exhibited hyphema $\geq 25\%$, whereas none in the control group did ($P=0.053$).

Conclusions: Routine postoperative pilocarpine use following GATT did not appear to significantly impact surgical outcomes or complication rates. However, given its potential association with greater hyphema extension in the early postoperative period, a rational and selective use, rather than routine administration, might be more appropriate.

Key Words: gonioscopy-assisted transluminal trabeculotomy, pilocarpine, minimally invasive glaucoma surgery, glaucoma, hyphema

INTRODUCTION

Minimally Invasive Glaucoma Surgery (MIGS) have revolutionized the management of glaucoma since it was first described in 2012.¹ Among these innovations, Gonioscopy-assisted transluminal trabeculotomy (GATT), introduced by Grover *et al* in 2014, stands out as a notable procedure.² This technique aims to address elevated intraocular pressure (IOP) by creating a 360-degree trabeculotomy through an ab interno approach, providing a safer alternative to traditional incisional surgeries without compromising the conjunctiva. Moreover, it can be performed utilizing various methods and materials, such as an illuminated microcatheter, or different sutures (i.e. 5-0 prolene or 5-0 nylon with a thermally modified blunted tip).

The efficacy of GATT has been well documented across various types of glaucoma, including primary open-angle glaucoma (POAG), congenital glaucoma, juvenile open-angle glaucoma, exfoliation glaucoma, uveitic glaucoma, and steroid-induced glaucoma.³⁻⁷ As a MIGS technique, GATT offers reduced recovery time and short surgical time. Although its efficacy in lowering IOP is less potent compared to traditional trabeculectomy, GATT still demonstrates substantial IOP reduction and success rates.⁸ Previous studies reported success rates ranging from 80% to 90% in terms of IOP reduction over 12 to 24 months, making it a feasible option for stand-alone treatment or in combination with cataract surgery.⁹⁻¹¹

Despite its efficacy, GATT can present some challenges. Complications, such as hyphema, peripheral anterior synechiae (PAS), and postoperative IOP spikes, have been observed.¹² When addressing these concerns, some strategies have been proposed to mitigate adverse outcomes. In particular, the use of pilocarpine might be useful in the management of IOP spikes, by theoretically inhibiting any potential anterior chamber angle wound healing. Additionally, some authors have described its use routinely during the first postoperative month to reduce PAS formation.^{8,9,10,13} Therefore, this study aims to evaluate the effect of postoperative use of pilocarpine on IOP, glaucoma medications, and complication rates in patients undergoing GATT.

MATERIALS AND METHODS

Study design

This was a retrospective comparative study from a consecutive series of patients with ocular hypertension (OHT) and POAG who underwent stand-alone GATT or combined with cataract extraction (CE) with or without postoperative use of pilocarpine at “Fundacion Oftalmologica de Santander – FOSCAL” (Santander, Colombia) from June 2021 to April 2023. All consecutive eyes that underwent surgery between June 2021 and March 2022 did not receive pilocarpine (control group), whereas all consecutive eyes that underwent GATT between April 2022 and April 2023 received pilocarpine (pilocarpine group). In the pilocarpine group, pilocarpine 2% was prescribed twice a day starting after the surgery and continuing for 4 weeks. Informed consent was obtained from all patients before surgery and the study was in accordance with the Declaration of Helsinki. This study was approved by the Research Ethics Committee of FOSCAL (reference: 008739).

Patients aged ≥ 18 years with OHT or POAG were included. Indications for GATT were to reduce IOP and/or to reduce the number of hypotensive medications at the time of CE. Exclusion criteria were other types of open-angle glaucoma, history of prior glaucoma surgery, glaucoma laser procedure within the last 3 months, patients on anticoagulant therapy, corneal disease that reduced visualization of the angle structures or difficulted IOP measurements and follow-up < 3 months.

Surgical technique

All procedures were carried out by a single surgeon (GE) with the same standardized technique. The GATT surgery has been described previously.² Briefly, a 2.2 mm temporal paracentesis was created and ocular viscoelastic device (sodium hyaluronate) was injected in the anterior chamber. Subsequently, a 23G needle paracentesis track, oriented tangentially, was placed in either the supero-nasal or infero-nasal quadrant. A 5-0 prolene suture with a thermally modified blunted tip was introduced through the tangential paracentesis and patient's head and microscope were tilted about 35° each to allow a clear view of the nasal angle structures with a surgical gonioprism. A small goniotomy was created under direct visualization with a 23G MVR blade and the suture was inserted into the Schlemm's canal using a 23G microsurgical forceps and passed circumferentially around the entire canal. After passing the suture 360° , the distal tip was retrieved within the anterior chamber using the microsurgical forceps and trabeculotomy was performed by pulling the suture. Finally, viscoelastic was removed and the anterior chamber was filled with an air bubble of approximately 70%.

Postoperative management

Postoperative treatment included: broad-spectrum antibiotics and non-steroidal anti-inflammatory drugs (NSAID) for both stand-alone GATT and GATT combined with CE. Moreover, in cases of combined GATT with CE, steroids were prescribed five times a day during the first week after surgery and were tapered over a three-week period. Glaucoma medications used prior to surgery were suspended. In cases of IOP spikes, aqueous suppressants were prescribed according to surgeon discretion. In the pilocarpine group, pilocarpine 2% was prescribed twice a day starting after the surgery and continuing for four weeks, whereas those in the control group did not receive pilocarpine, even in the event of IOP spikes.

Clinical information, obtained through chart review, was collected for the following post-operative visits: day 1, week 1, month 1, month 3, month 6 and month 12. At every follow-up visit, the following data were collected: Snellen best corrected visual acuity (BCVA) converted into logarithm of the minimum angle resolution (logMAR), IOP measurement with Goldmann applanation tonometer, gonioscopic findings, number of glaucoma medications, optic nerve evaluation and surgery-related complications. An IOP spike was defined as an IOP >30 mmHg or >10 mmHg compared to baseline IOP within the first postoperative month. The extent of hyphema was assessed as the percentage of the anterior chamber involved, and anterior chamber cell inflammation was evaluated using the SUN International Workshop grading scale.

Outcome measures

The primary outcome measure was the cumulative rate of surgical success at 1 year.

Secondary outcome measures included IOP, use of glaucoma medical therapy, BCVA, and

surgical complications. Failure was defined as IOP >21 mmHg or less than 20% reduction below baseline on 2 consecutive follow-up visits after 3 months; IOP \leq 5 mmHg on 2 consecutive follow-up visits after 3 months; or further glaucoma surgery. Eyes that had not failed by the previous criteria and were not receiving supplemental medical therapy were considered as complete successes. Eyes that had not failed but received supplemental medical therapy were categorized as qualified successes.

Statistical analysis

A descriptive univariate analysis was conducted. Quantitative variables were described using mean and standard deviation, while qualitative variables were reported as absolute and relative frequencies. A bivariate analysis was performed by stratifying variables based on the use of pilocarpine. Fisher's exact test was used for qualitative variables, while comparisons of quantitative variables were conducted using the Student's t-test. The preoperative mean IOP and the number of glaucoma medications were compared with subsequent follow-up measurements using the Student's t-test. Pilocarpine was included as an IOP-lowering medication in the analysis. A significance level (alpha) of 0.05 was used for all analyses, and the statistical software Stata 16.0 (StataCorp LLC, College Station, TX, USA) was used to conduct the calculations.

RESULTS

Demographic characteristics

A total of 61 medical charts of patients who were diagnosed as having POAG or OHT and underwent stand-alone GATT or combined with CE were reviewed. Of the 61 medical charts, forty-one patients (53 eyes) fulfilled the inclusion criteria and were analyzed in this

study. Pilocarpine group included 28 eyes (52.8%) and control group included 25 eyes (47.2%). Five eyes were excluded from the pilocarpine group and three from the control group due to various reasons: follow-up duration of less than 3 months (5 eyes), insufficient data in the medical chart (2 eyes), and previous glaucoma surgery (1 eye).

The participants had a mean age of 71.3 ± 8.5 years (range: 52-88 years) and 54.7% were females. Sixteen eyes (30.2%) had OHT and 37 (69.8%) had POAG. Thirty-five eyes (66%) were combined with CE and 18 eyes (34%) were stand-alone GATT. Table 1 summarizes the baseline characteristics for both groups. There were no statistically significant differences between the two groups in these baseline characteristics.

IOP reduction and medical therapy

Table 2 summarizes mean IOP changes and mean number of glaucoma medications at baseline and at each follow-up visit for both groups. A significant IOP and medication reduction from baseline was observed in both groups ($P < 0.001$). At 12 months, mean IOP was 14.9 ± 3.7 mmHg in the pilocarpine group and 14.2 ± 3.3 mmHg in the control group. There was no statistically significant difference observed between the two groups regarding IOP reduction at any of the follow-up visits (Figure 1). Concerning glaucoma medications, considering pilocarpine as 1 drug, the mean number of medications was higher in the pilocarpine group from day 1 to month 1 after surgery ($P < 0.001$). Nonetheless, from the third month through the 12-month follow-up, the study groups were comparable (Figure 2). At 12 months, the mean number of glaucoma medications was 0.8 ± 1.3 in the pilocarpine group and 0.7 ± 1.1 in the control group.

Surgical Success

At 12 months, success was achieved in 21 eyes (80.8%) in the pilocarpine group and 19 eyes (79.2%) in the control group ($P=0.999$, Fisher exact test). In the pilocarpine group, 15 eyes (57.7%) were classified as complete successes, and 6 eyes (23.1%) were qualified successes. In the control group, 15 eyes (62.5%) were classified as complete successes, and 4 eyes (16.7%) were qualified successes. No significant differences were observed between the groups regarding complete, qualified, or overall success at any interval (all $P>0.05$).

Postoperative complications

Table 3 details the complications in each group. The overall number of complications did not differ between the study groups, and most of them were self-limiting. The most common adverse event was PAS in both groups with 15 eyes (53.6%) in the pilocarpine group and 13 eyes (52%) in the control group ($P=0.999$). Additionally, there was no difference in the extent of PAS between the two groups. Notably, the inferior quadrant was the most affected by PAS, accounting for 85.7% of the general cohort. In 9 eyes (32.1%) of pilocarpine group and 6 eyes (24%) of the control group, early IOP spikes were observed ($P=0.511$). Although hyphema was most frequent in the pilocarpine group (50%) compared to the control group (36%), this did not reach statistical significance ($P=0.407$). During the first month of Pilocarpine use, we assessed the rate and extent of hyphema and anterior chamber inflammation. Despite no significant differences between the groups, the pilocarpine group tended to show a greater extent of hyphema at the first postoperative day and week. Specifically, on the first postoperative day, five patients in the pilocarpine group showed hyphema $\geq 25\%$, whereas no patients in the control group exhibited this condition ($P=0.053$). Furthermore, one eye in the pilocarpine group had significant hyphema

requiring anterior chamber washout at week 1. At the one-month follow-up visit, three eyes in the pilocarpine group showed $\geq 2+$ cells of anterior chamber inflammation, while no eyes in the control group exhibited this level of inflammation ($P=0.235$).

DISCUSSION

Pilocarpine is a nonselective muscarinic receptor agonist that has been extensively used in the medical management of glaucoma for nearly 150 years. It targets muscarinic M3 receptors on the ciliary muscle and iris sphincter. Activation of these receptors leads to contraction of the ciliary muscle, which pulls the scleral spur and expands the trabecular meshwork and Schlemm's canal, enhancing aqueous humor outflow.¹⁴ Additionally, Pilocarpine induces miosis by contracting the iris sphincter.¹⁵ Given these effects, Pilocarpine use after GATT has been suggested to potentially prevent PAS formation and IOP spikes by inhibiting anterior chamber angle wound healing.

Our study demonstrated that the use of pilocarpine during the first month following GATT surgery did not offer any advantage regarding the incidence of PAS or IOP spikes. Moreover, there were no significant differences in the success rate, IOP reduction, or the number of medications when comparing the pilocarpine group to the control group. Nonetheless, the pilocarpine group did show a trend towards greater hyphema extension during the first postoperative week and increased anterior chamber inflammation during the first postoperative month, although these did not reach statistical significance.

Although the effects of pilocarpine on GATT outcomes have not been previously investigated, earlier studies have examined its impact on other MIGS. In a retrospective

study, Esfandiari *et al* compared 101 eyes that received pilocarpine four times a day for one month following goniotomy with the Trabectome, to 86 eyes that did not receive pilocarpine postoperatively. At 12 months, no significant differences were observed between both groups in terms of IOP reduction, medication reduction, and surgical success. Additionally, the incidence of IOP spikes was similar between the two groups ($P=0.153$).¹⁶ In contrast, Birnbaum *et al* investigated the surgical outcomes of Kahook Dual Blade goniotomy, comparing patients treated postoperatively with difluprednate 0.05% to those receiving a combination of prednisolone 1% and pilocarpine 1%. Both groups showed significant IOP reduction at 6 months. However, the difluprednate group experienced an IOP increase at week 1, likely due to a higher incidence of IOP spikes, whereas the prednisolone-pilocarpine group demonstrated a consistent decline in IOP from day 1. Despite this finding could be attributed to the effects of pilocarpine, the authors suggested that the higher steroid potency of difluprednate could also have contributed to the observed outcomes.¹⁷

Intraocular pressure spikes are relatively common during the first postoperative month following GATT surgery. The reported incidence of these spikes in patients with open-angle glaucoma varies widely between studies, with rates ranging from 11.4% to 47%^{8,9,10,13} in those utilizing pilocarpine, and from 13.2% to 24.7%¹⁸⁻²¹ in those not using it. Several preoperative factors, including younger age and higher preoperative IOP, have been associated with an elevated risk of IOP spikes. Rao *et al* observed a correlation between PAS extension and the need for glaucoma medications after GATT in patients under 40 years old with juvenile open-angle glaucoma. Their findings suggest that intense bleeding and inflammation might account for the higher incidence of PAS and IOP spikes in young patients.¹² Postoperatively, the discontinuation of preoperative glaucoma

medications, the presence of retained viscoelastic, hyphema, topical steroids and PAS have all been linked to the occurrence of IOP spikes.^{12,22,23} Naftali *et al* observed an increased risk of surgical failure and a higher likelihood of requiring additional surgery in patients who experienced an IOP spike. Therefore, they recommend maintaining preoperative medications in patients at higher risk for IOP spikes, particularly younger individuals with high preoperative IOP.²²

Even though PAS are not usually reported as complications in GATT studies, this postoperative finding is frequently observed. In our study, PAS was the most common complication in both the pilocarpine (53.6%) and control groups (52%). However, no correlation was observed between PAS and surgical failure in either group. Most cases of PAS occurred in a single quadrant, which was usually the inferior quadrant. This is likely due to the accumulation of blood in the inferior angle and the subsequent inflammation it induces.²⁴ Similar to IOP spikes, PAS have been observed more frequently in younger patients, prompting recommendations for more aggressive use of steroids, atropine, or pilocarpine to modulate scarring in these cases.¹² Despite these recommendations, our study did not find any significant benefit from pilocarpine use.

Finally, our study observed a slight trend towards increased bleeding and inflammation in the pilocarpine group. Regarding bleeding, although not statistically significant, there was a higher incidence of hyphema in the pilocarpine group, with an increased extent of hyphema from the first day through the first week. This might be associated with the traction mechanism exerted by the pilocarpine on Schlemm's canal, facilitating blood reflux through

the collector channels. In addition, Grover et al. have proposed that immediate postoperative hypotony may increase the risk of bleeding. Therefore, the IOP-lowering effect of pilocarpine could induce a transient IOP reduction, potentially exacerbating postoperative hemorrhage.³ In terms of inflammation, one month post-surgery, we noted that three eyes in the pilocarpine group had $\geq 2+$ anterior chamber cells, while no patients in the control group exhibited this finding. It is possible that the increased permeability of the blood-aqueous barrier could explain this, as previously suggested.²⁵ However, the precise mechanism by which pilocarpine use leads to an increase in anterior chamber flare remains unclear.²⁶

There are several limitations to our study that should be acknowledged. Firstly, the retrospective design inherently limits the ability to establish causality and is susceptible to selection bias. Additionally, the relatively small sample size and the single-center nature of the study may limit the generalizability of our findings. Finally, the absence of randomization between the pilocarpine and control groups could have introduced confounding variables that were not accounted for.

In summary, based on this small retrospective study, the use of pilocarpine during the first month following GATT did not appear to provide significant benefits in terms of surgical success or in preventing complications such as PAS and IOP spikes. While our findings do not support its routine use, they do not preclude the possibility that pilocarpine may be beneficial in specific cases. Its rational use in the postoperative period should be carefully considered, particularly given its potential to lower IOP and theoretically increase the risk

of hyphema. Further prospective randomized studies are warranted to determine whether pilocarpine may have a potential role in enhancing GATT outcomes.

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Figure 1. Intraocular pressure changes over time in the pilocarpine group and the control group

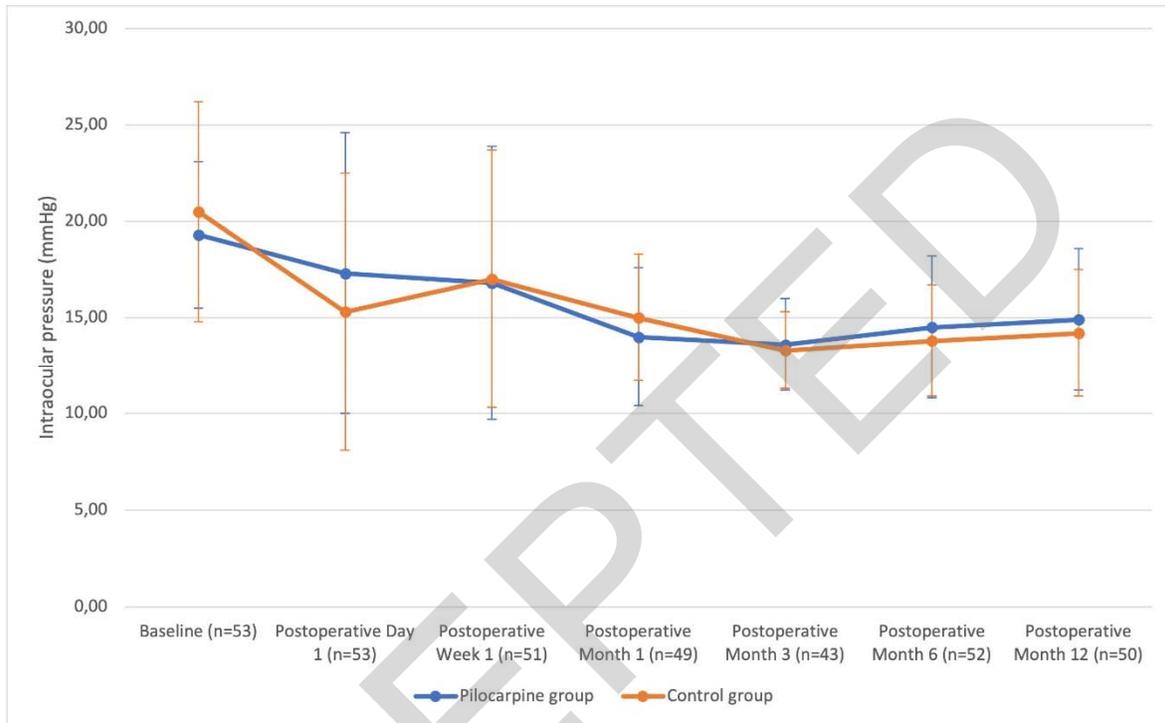


Figure 2. Number of glaucoma medications changes over time in the pilocarpine group and the control group

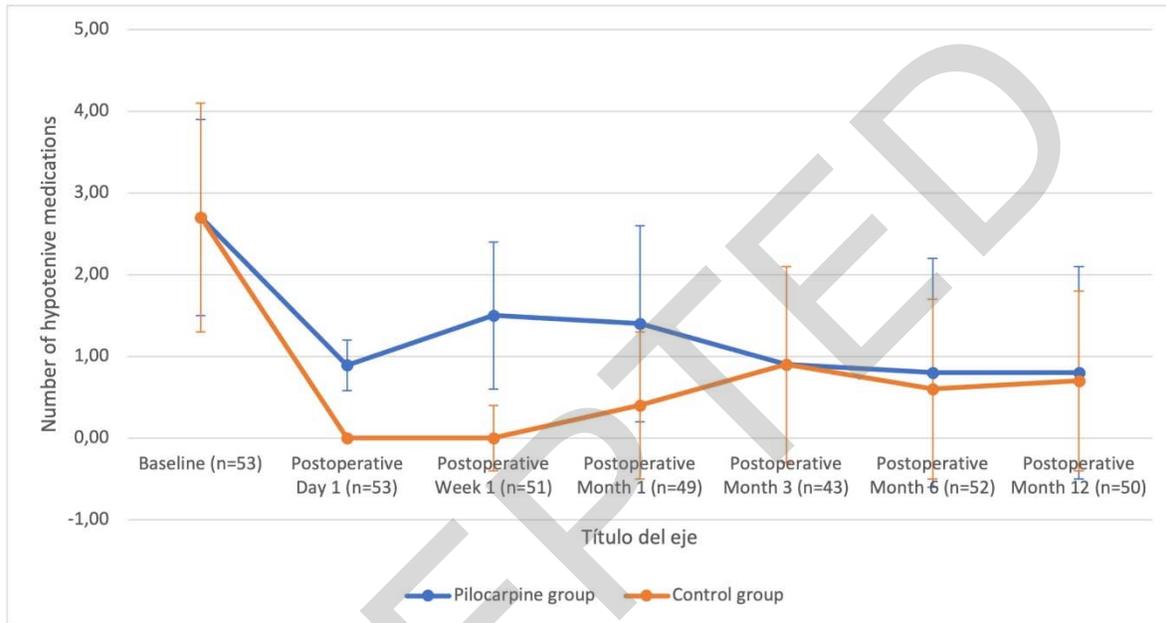


Table 1. Demographics characteristics at baseline.

	Pilocarpine group	Control group	Total	P Value
No. eyes	28	25	53	
Age (y), mean \pm SD	71.8 \pm 9.3	70.8 \pm 7.7	71.3 \pm 8.5	0.647 [†]
Range (y)	52 - 88	54 - 83	52 - 88	
Gender				0.583 [¶]
Males, <i>n</i> (%)	14 (50%)	10 (40%)	24 (45.3%)	
Females <i>n</i> (%)	14 (50%)	15 (60%)	29 (54.7%)	
Preoperative IOP (mmHg), mean \pm SD	19.3 \pm 3.8	20.5 \pm 5.7	19.9 \pm 4.7	0.397 [†]
Preoperative medications, mean \pm SD	2.7 \pm 1.2	2.7 \pm 1.4	2.7 \pm 1.2	0.856 [†]
Diagnosis				0.387 [¶]
OHT, <i>n</i> (%)	10 (35.7%)	6 (24%)	16 (30.2%)	
POAG, <i>n</i> (%)	18 (64.3%)	19 (76%)	37 (69.8%)	
Severity				0.619 [¶]
None, <i>n</i>	10	6	16	
Mild, <i>n</i>	9	7	16	
Moderate, <i>n</i>	5	5	10	
Severe, <i>n</i>	4	7	11	
Type of surgery				0.780 [¶]
Stand-alone, <i>n</i> (%)	9 (32.1%)	9 (36%)	18 (34%)	
Combined with CE, <i>n</i> (%)	19 (67.9%)	16 (64%)	35 (66%)	
BCVA logMAR, mean \pm SD	0.37 \pm 0.3	0.28 \pm 0.2	0.33 \pm 0.3	0.320 [†]

BCVA, best corrected visual acuity; CE, cataract extraction; OHT, ocular hypertension; POAG, primary-open angle glaucoma; SD, standard deviation; y, years.

[¶]Fisher exact test; [†]T-test.

Table 2. Mean IOP and number of glaucoma medications during the 12 months follow-up.

		Baseline (n=53)	Postoperative Day 1 (n=53)	Postoperative Week 1 (n=51)	Postoperative Month 1 (n=49)	Postoperative Month 3 (n=43)	Postoperative Month 6 (n=52)	Postoperative Month 12 (n=50)
IOP (mean ± SD)	Pilocarpine group	19.3 ± 3.8	17.3 ± 7.3	16.8 ± 7.1	14 ± 3.6	13.6 ± 2.4	14.5 ± 3.7	14.9 ± 3.7
	Control group	20.5 ± 5.7	15.3 ± 7.2	17.0 ± 6.7	15.0 ± 3.3	13.3 ± 2.0	13.8 ± 2.9	14.2 ± 3.3
	<i>P</i> value*	0.397	0.316	0.906	0.298	0.665	0.421	0.484
Number of glaucoma medications (mean ± SD)	Pilocarpine group	2.7 ± 1.2	0.89 ± 0.31	1.5 ± 0.9	1.4 ± 1.2	0.9 ± 1.2	0.8 ± 1.4	0.8 ± 1.3
	Control group	2.7 ± 1.4	0 ± 0	0.0 ± 0.4	0.4 ± 0.9	0.9 ± 1.2	0.6 ± 1.1	0.7 ± 1.1
	<i>P</i> value*	0.856	<0.001	<0.001	0.003	0.986	0.427	0.782

IOP, intraocular pressure; SD, standard deviation.

*T-test, significant *P* values are in bold.

Table 3. Postoperative complications.

	Pilocarpine group n (%)	Control group n (%)	Total n (%)	P Value*
PAS	15 (53.6)	13 (52)	28 (52.8)	0.999
1 quadrant	9 (32.1)	9 (36)	18 (34)	0.780
2 quadrant	3 (10.7)	1 (4)	4 (7.6)	0.613
3 quadrant	2 (7.1)	1 (4)	3 (5.7)	0.999
4 quadrant	1 (3.6)	2 (8)	3 (5.7)	0.597
IOP spikes	9 (32.1)	6 (24)	15 (28.3)	0.511
Hyphema	14 (50)	9 (36)	23 (43.4)	0.407
Vitreous hemorrhage	2 (7.1)	1 (4)	3 (5.7)	0.999
Intracapsular hemorrhage	3 (10.7)	0 (0)	3 (5.7)	0.238
BCVA loss (≥ 2 Snellen lines)	1 (3.57)	1 (4)	2 (3.8)	0.999
Macular edema	0 (0)	1 (4)	1 (1.9)	0.472

BCVA, best-corrected visual acuity; IOP, intraocular pressure; PAS, peripheral anterior synechiae.

*Fisher exact test.