

Six-month outcomes of combined conventional needle goniotomy and phacoemulsification in eyes with early to moderate primary open-angle and pseudoexfoliation glaucoma and ocular hypertension

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Purpose: Angle-based surgeries for the treatment of open-angle glaucoma have gained popularity in recent years. This study aimed to evaluate the efficacy of combined phacoemulsification and goniotomy in primary open-angle and pseudoexfoliation glaucoma (POAG and PXG) and ocular hypertension (OHTN). **Methods:** In this interventional case series in the setting of the Glaucoma Service at the Farabi Eye Hospital, 32 eyes of 30 patients with early-to-moderate POAG and PXG and OHTN were enrolled. All eyes underwent combined phacoemulsification and needle goniotomy. Intraocular pressure (IOP) and the number of antiglaucoma medications as well as demographic data were recorded at baseline and one day, one week, one month, three months, and six months after the surgery. Generalized Estimating Equation (GEE) was used to compare the values of IOP and the number of medications at different time points. Kaplan–Meier graph was used to demonstrate the survival status of the eyes. **Results:** Mean IOP at baseline was 21.8 ± 4.6 mmHg on mean 1.2 ± 1.5 topical medications. There was a 25.2% (16.3 ± 4.5 mmHg) and 32.1% (14.8 ± 3.9 mmHg) reduction in IOP at three and six months after procedure, respectively ($P < 0.001$). Meanwhile, the decline in medications was 66.7% (0.4 ± 0.9) and 50.0% (0.6 ± 1.1) at the same time points ($P = 0.002$ and $P = 0.048$, respectively). Post-operative complications were clot hyphema ($n = 1$, 3.1%), fibrinous inflammation ($n = 1$, 3.1%) and distorted pupil ($n = 2$, 6.3%). **Conclusion:** Combined phacoemulsification and needle goniotomy as a procedure for mild and moderate POAG and PXG and OHTN is as effective as other modified goniotomies in the setting of minimally invasive glaucoma surgeries (MIGS).

Key words: Early to moderate glaucoma, goniotomy, ocular hypertension, primary open-angle glaucoma, pseudoexfoliation glaucoma

Glaucoma is the second leading cause of blindness globally^[1] and intraocular pressure (IOP) is the only modifiable risk factor.^[2] The main goal in surgical and medical treatment of glaucoma is IOP reduction.^[2] As the sites of resistance to aqueous outflow in open-angle glaucoma (OAG) are juxtacanalicular tissue and the inner wall of Schlemm's canal^[3] surgical reduction of IOP should bypass these parts of the outflow pathway somehow.

Since the introduction of trabeculectomy by Cairns in 1968,^[4] this method has been used as a standard surgery for the treatment of glaucoma for many years. Trabeculectomy has myriad complications and in recent two decades has been replaced by glaucoma drainage devices (GDD) in the vast majority of patients.^[5–8] These surgeries violate the conjunctival tissue and may not be appropriate for mild-to-moderate cases of OAG.

Recently minimally-invasive glaucoma surgeries (MIGS) have been introduced and filled the gap between medical therapy and filtration and tube surgeries.^[9] MIGS have common features. They are usually done by the ab-interno approach and have modest efficacy. Low complication rates, sparing

the conjunctiva, and rapid recovery are other advantages of MIGS.^[10] Also, they can easily be used in combination with phacoemulsification.^[11]

One of the mechanisms of MIGS is trabecular bypass^[12] which is used in ab-interno trabecular bypass surgery with iStent (Glaukos Corporation, Laguna Hills, CA, USA), gonioscopy-assisted transluminal trabeculotomy (GATT), goniotomy by Kahook dual-blade (KDB, New World Medical, Rancho Cucamonga, CA) and ab-interno trabeculotomy by trabectome (NeoMedix, Tustin, CA, USA). The last two are, in fact, modified goniotomy and are dependent on expensive equipment.

Traditional goniotomy is the procedure of choice for congenital glaucoma and needs simple and inexpensive equipment. At present, due to the advances in microsurgical

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techniques and studies that have shown the efficacy of modified goniotomies in OAG,^[13-16] we decided to give a chance to goniotomy in adults.

Our intention in this study was to combine goniotomy with phacoemulsification in OAG patients needing cataract extraction and to evaluate the IOP trend after this procedure.

Methods

In this prospective interventional case series, 32 eyes of 30 consecutive patients with high-risk ocular hypertension (OHTN) and early-to-moderate primary open-angle and pseudoexfoliation glaucoma (POAG and PXG) were enrolled. All patients had visually significant cataracts and were newly diagnosed in the glaucoma clinic of Farabi Eye Hospital from September 2019 to April 2020. The local ethics committee approved the study and the tenets of the Declaration of Helsinki have been adhered to.

High-risk OHTN was arbitrarily defined as IOP more than 25 mmHg, central corneal thickness (CCT) ≤ 556 -micron,^[17] and presence of an open angle on gonioscopy without glaucomatous optic neuropathy and associated visual field defects.

To be classified as early to moderate POAG and PXG the following criteria should be met:

1. Presence of an open angle on gonioscopy.
2. IOP >21 mmHg without antiglaucoma medications or IOP <21 mmHg for eyes on topical medications.
3. Presence of glaucomatous optic neuropathy (neuroretinal rim notching) or retinal nerve fiber layer (RNFL) defects (slit-like defects extending to optic nerve head (ONH)).
4. Presence of visual field defects defined by abnormal pattern standard deviation (PSD) ($P < 5\%$) or abnormal glaucoma hemifield test (GHT) in at least two reliable (fixation loss and false positive rate $< 15\%$) central 24-2 perimetries examined by Humphrey Field Analyzer (HFA, model 750; Carl Zeiss Meditec, Inc) with Swedish interactive thresholding algorithm (SITA) standard strategy. To fulfill the criteria for early to moderate POAG and PXG mean deviation (MD) better than -12 dB was obligatory.
5. Detection of pseudoexfoliation material on pupillary margin, anterior lens capsule, and/or angle was necessary for labeling as PXG.

Patients with visually significant cataracts and older than 18 years who satisfied the definition criteria of high-risk OHTN and early-to-moderate POAG and PXG were enrolled in the study. History of previous intraocular surgeries and other secondary glaucomas were considered as exclusion criteria.

All patients underwent comprehensive and thorough ophthalmic examination including corrected distance visual acuity (CDVA), measurement of IOP by Goldmann applanation tonometry, gonioscopy, and funduscopy. Demographic and ocular data, and the number of antiglaucoma medications were recorded. Decimal CDVA was converted to LogMAR according to ($\text{LogMAR} = -\text{Log}(\text{Decimal acuity})$) for statistical analysis.

Surgical technique

All surgeries were done by one attending ophthalmologist (Y.E.). Anesthesia for surgery was established with local and intracameral tetracaine 0.5% and lidocaine 1%, respectively. Phacoemulsification was done by either a temporal or

superior approach. After performing continuous curvilinear capsulorhexis and hydrodissection, phacoemulsification was done by stop-and-chop technique. A foldable intraocular lens (IOL) was injected into the capsular bag at the end of the procedure. In the case of the superior approach for phacoemulsification, the position was changed to the temporal side for performing a nasal goniotomy. All goniotomies were done with a 25-gauge needle which was bent from its hub for better handling. Also, the needle was connected to the irrigation fluid for maintaining the anterior chamber depth. To get an enface image of the nasal angle the microscope was tilted toward the surgeon while the patient's head was tilted away from the surgeon. By using a Swan-Jacob gonioscope and applying some dispersive ophthalmic viscosurgical device on the cornea, an enface image of the nasal angle was obtained. The central point of the nasal angle was penetrated with the tip of the needle. Thereafter, the needle was advanced for at least 45 degrees in superior and inferior directions. The goal was to incise the pigmented part of the trabecular meshwork and expose the Schlemm's canal into the anterior chamber for 90 degrees. In the case of hyphema, the irrigation was continued until the clearance of blood from the anterior chamber. At the end of the procedure, a drop of topical pilocarpine 1% was instilled on the ocular surface. After surgery, topical antibiotics and pilocarpine 1% (4 times daily) and topical steroids were prescribed. Topical antibiotics and pilocarpine were continued for one week and one month, respectively and topical steroid was continued in a tapering fashion during the first month after the procedure.

Follow-up visits

All patients were followed one day, one week, one month, three months, and six months after surgery. IOP and the number of antiglaucoma medications were recorded at each visit. The mean of two consecutive IOP measurements at each visit, by Goldmann applanation tonometer, was recorded as the IOP. If the IOP was greater than the target pressure, the appropriate medication for the patient would be started. Fixed combination drugs were considered as two medications. CDVA at six-month and post-operative complications were also recorded. Due to the emerging COVID-19 pandemic during the study, all follow-up visits took place at the glaucoma clinic at the weekends concerning the social distancing rules.

Success and failure

Complete and qualified success was defined at three levels (15 mmHg, 18 mmHg, and 21 mmHg). Achieving the IOP lower than 15, 18, and 21 mmHg without the use of antiglaucoma medications was categorized as a complete success. Eyes taking topical medications with the IOP lower than 15, 18, and 21 mmHg were considered to have qualified success.

IOP lower than 6 mmHg and more than 21 mmHg despite topical medications and the need for additional glaucoma procedures were defined as failures.

Statistical analysis

To present data, we used mean, standard deviation, median, range, frequency, and percentage. To present the precision of the estimation, we used 95% confidence interval (CI). To compare the visual acuity in baseline with the final, Wilcoxon signed-rank test was used. We use the generalized estimating equation (GEE) to compare the values of IOP and the number of medications in different follow-up times. Kaplan-Meier

graph was used to demonstrate the survival status of the eyes. All statistical analyses were performed by SPSS (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.). *P* values less than 0.05 were considered statistically significant.

Results

32 eyes of 30 patients were recruited for this study. The mean ± standard deviation (SD) age was 69.81 ± 8.59 years. 16 patients (18 eyes, 71.9%) were male and 14 patients (14 eyes, 28.1%) were female. The diagnosis was PXG in 13 (40.6%) eyes, POAG in ten (31.3%) eyes, and high-risk OHTN in nine (28.1%) eyes [Table 1].

Mean ± SD CDVA at baseline was 0.7 ± 0.56 LogMAR which significantly improved six months (0.44 ± 0.54 LogMAR) after the procedure (*P* < 0.001) [Table 2]. Mean ± SD IOP at baseline was 21.8 ± 4.6 mmHg. Mean ± SD IOP at one-day (13.8 ± 4.4 mmHg), one-week (13.4 ± 4.3 mmHg), one-month (16.9 ± 6), three-month (16.3 ± 4.5 mmHg) and six-month (14.8 ± 3.9 mmHg) visits was significantly lower than baseline (*P* < 0.001) [Fig. 1 and Table 2]. There was a 25.2% and 32.1% IOP reduction at three months and six months after surgery, respectively.

Also, the number of antiglaucoma medications was significantly declined from 1.2 ± 1.5 (Mean ± SD) at baseline to 0.4 ± 0.9 at three-month and 0.6 ± 1.1 at six-month visits (*P* = 0.002 and *P* = 0.048, respectively), a 66.7% and 50% reduction, respectively. There was no statistically significant difference between number (Mean ± SD) of medications at one-week (1 ± 0) and one-month (1 ± 0.2) in comparison to baseline (*P* = 0.545 and *P* = 0.621, respectively) [Fig. 2 and Table 2].

After three months, complete successes with 15, 18, and 21 mmHg levels were 37.5%, 65.6%, and 65.8%, respectively. 43.8%, 81.3% and 90.6% of eyes had qualified success with the aforementioned levels three months after surgery, respectively. The proportion of eyes with IOP less than 15, 18, and 21 mmHg without medication six months after the procedure was 46.9%, 65.6%, and 65.6%, respectively. Concerning the qualified success 62.5%, 84.4%, and 90.6% of eyes had IOP less than 15, 18, and 21 mmHg at the six-month visit, respectively [Table 3].

Failure due to hypotony didn't occur in our study. Three eyes had IOP more than 21 mmHg on topical medications and

were categorized as failure. In one eye, failure was detected after three months and trabeculectomy was planned but the patient refused to undergo the surgical procedure due to the COVID-19 pandemic. Two other failures were detected after six months and scheduled for surgery [Fig. 3].

Gonioscopy was done for each eye during the follow-up period. 23 eyes (71.9%) had a quite normal appearance in the nasal quadrant of the angle where the goniotomy was done. Four eyes (12.5%) had peripheral anterior synechiae (PAS) and Schlemm's canal was exposed in five eyes (15.6%) [Fig. 4].

Concerning postoperative complications, one eye (3.1%) had clot hyphema, one eye (3.1%) had fibrinous inflammation in the anterior chamber and two eyes (6.3%) showed distorted pupils. Except for pupillary distortion, the hyphema was transient and self-healing, and the fibrinous reaction was managed with oral steroids for one week.

Table 1: Demographic and clinical characteristics of the study eyes

Number of eyes	32
Age (years, Mean±SD)	69.81±8.59
Sex (Patients, Male/Female)	16/14
Systemic Disease (Eyes, %)	
DM	6 (18.8)
HTN	2 (6.3)
DM & HTN	2 (6.3)
Baseline IOP (mmHg, Mean±SD)	21.8±4.6
Number of Antiglaucoma Medications (Mean±SD)	1.2±1.5
Diagnosis (Eyes, %)	
PXG	13 (40.6)
POAG	10 (31.3)
High-Risk OHTN	9 (28.1)
CCT (µm, Mean±SD)	541.03±26.34
Phaco Approach (Eyes, %)	
Temporal	17 (53.1)
Superior	15 (46.9)

DM, Diabetes Mellitus; HTN, Hypertension; IOP, Intraocular Pressure; IQR, Interquartile Range; PXG, Pseudoexfoliation Glaucoma; POAG, Primary, Open-Angle Glaucoma; OHTN, Ocular Hypertension; CCT, Central Corneal, Thickness

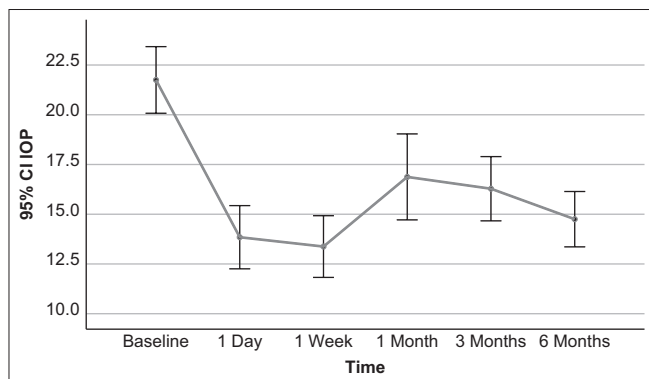


Figure 1: Change of intraocular pressure at different time points during the study

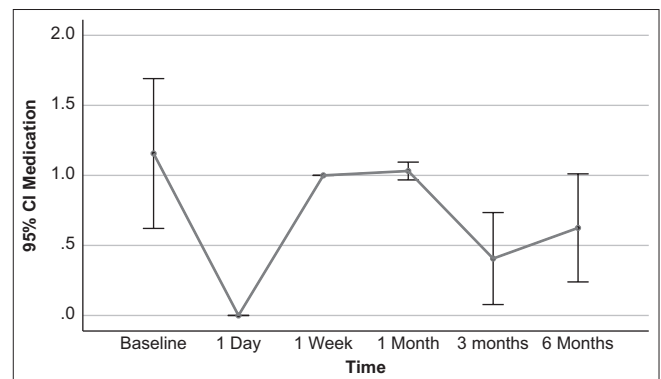
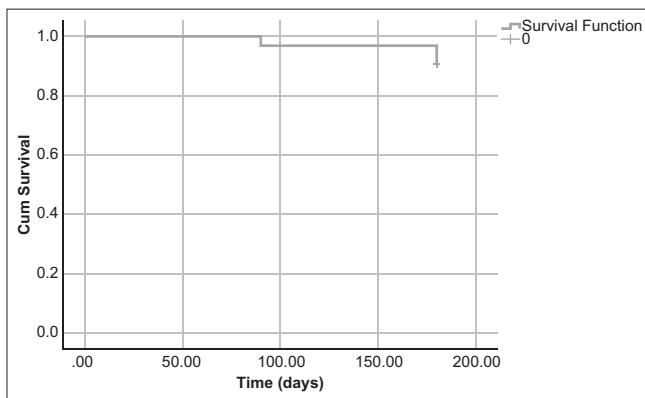


Figure 2: Change of the number of antiglaucoma medications at different time points during the study

Table 2: Comparison of IOP, number of antiglaucoma medications and CDVA at different time points with baseline

	Time	Mean±SD	Median (range)	P for change from baseline
IOP (mmHg)	Baseline	21.8±4.6	22 (10 to 30)	-
	1 Day	13.8±4.4	14 (5 to 24)	<0.001 [†]
	1 Week	13.4±4.3	12 (8 to 24)	<0.001 [†]
	1 Month	16.9±6	16 (9 to 40)	<0.001 [†]
	3 Months	16.3±4.5	16 (10 to 34)	<0.001 [†]
	6 Months	14.8±3.9	14 (8 to 23)	<0.001 [†]
Antiglaucoma Medications	Baseline	1.2±1.5	0 (0 to 4)	-
	1 Day	0±0	0 (0 to 0)	<0.001 [†]
	1 Week	1±0	1 (1 to 1)	0.545 [‡]
	1 Month	1±0.2	1 (1 to 2)	0.621 [†]
	3 Months	0.4±0.9	0 (0 to 4)	0.002 [‡]
	6 Months	0.6±1.1	0 (0 to 4)	0.048 [‡]
CDVA (LogMAR)	Baseline	0.7±0.56	0.5 (0.1 to 2.3)	-
	6 Months	0.44±0.54	0.3 (0 to 1.9)	<0.001 [‡]

[†]Pairwise comparisons of estimated marginal means based on the original scale of dependent variable IOP. [‡]Based on Wilcoxon Signed-Ranks Test. IOP, Intraocular Pressure; CDVA, Corrected Distance Visual Acuity

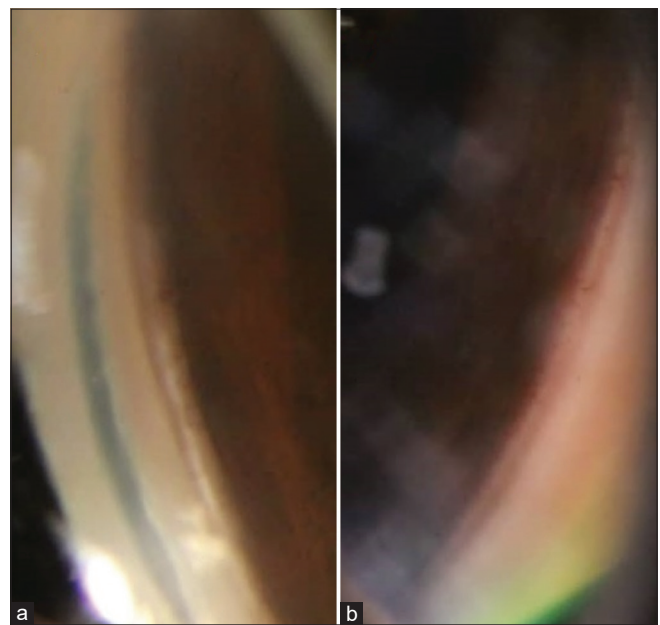
**Figure 3: Kaplan–Meier survival curve for the study eyes**

Discussion

Our study showed that combined phaco-goniotomy in early-to-moderate POAG, PXG, and OHTN will effectively reduce the IOP (25.2–32.1%) and antiglaucoma medications (50%–66.7%) without serious complications.

A brief look at the history of goniotomy reveals to us that, after De Vincentiis who introduced the “incision of iridic angle”, Otto Barkan performed goniotomy in eyes having chronic glaucoma and reported, “some good results”.^[18] After that, due to the good results of goniotomy in congenital glaucoma, this procedure remained a standard for this condition. In the last two decades, modified goniotomy has been raised again as procedures done by KDB and trabectome.

KDB, which is a tool for excisional goniotomy, has a blade with a sharp tip, a ramp, and two parallel blades. During goniotomy, the sharp tip enters Schlemm’s canal. By advancing the device circumferentially, a strip of trabecular meshwork will be excised and Schlemm’s canal will be exposed to the anterior chamber.^[19] In a study by Dorairaj *et al.*,^[13] 52 eyes having OAG underwent combined phaco-goniotomy by KDB. They reported a 20.8%–26.2% reduction in IOP during

**Figure 4: (a) Nasal quadrant of angle. Note the exposed canal with different light reflex. (b) The temporal quadrant of the angle has a normal appearance**

12 months after surgery while there was a 37.5%–68.8% reduction in the number of IOP-lowering drugs. In another study by Hirabayashi *et al.*,^[20] combined phaco-KDB was done in severe glaucoma cases and the patients were followed for six months. There was a 2.1 ± 4.67 mmHg IOP reduction from baseline (17.1 ± 4.8 mmHg) in their study and antiglaucoma medications were reduced by nearly 50%. Similar outcomes were reported in stand-alone excisional goniotomy using KDB in mild-to-severe glaucoma by Elmallah *et al.*^[14] They reported a 19.3%–27.7% and 12.5%–32.6% reduction in IOP and IOP-lowering drugs during 12 months after surgery, respectively. Our study almost had comparable results in the matter of IOP or medication reduction.

Table 3: Complete and qualified success after 3 and 6 months

Time	Success	IOP (mmHg)	n	%	95% CI	
					Lower	Upper
3 Months	Complete	Less than 15	12	37.5	21.9	53.1
		Less than 18	21	65.6	50	81.3
		Less than 21	22	65.8	53.1	84.4
	Qualified	Less than 15	14	43.8	28.1	59.4
		Less than 18	26	81.3	65.6	93.8
		Less than 21	29	90.6	78.1	100
6 Months	Complete	Less than 15	15	46.9	28.1	65.6
		Less than 18	21	65.6	50	81.3
		Less than 21	21	65.6	50	81.3
	Qualified	Less than 15	20	62.5	43.8	78.1
		Less than 18	27	84.4	71.9	96.9
		Less than 21	29	90.6	78.1	100

IOP, Intraocular Pressure; CI, Confidence Interval

Another tool for ab-interno trabeculotomy or modified goniotomy is the trabectome. This device has a handpiece that consists of footplate and electrocautery electrodes. The footplate enters into the Schlemm's canal. By applying energy from the electrode into the trabecular meshwork, the tissue will disrupt and disintegrate and the canal will expose to the anterior chamber.^[21] Francis and coworkers reported the outcome of combined phaco-trabectome in 304 consecutive eyes. The percentage of IOP reduction was 21.1%, 22.3%, 15.6%, and 25.1% at 3, 6, 12, and 21 months after the surgery, respectively. Meanwhile, there was a 27.3% to 35.9% reduction in IOP-lowering drugs at different time points.^[22] Ahuja and her colleagues reported similar results in eyes undergoing phaco-trabectome. After 3, 6, and 12 months, IOP reduction was 23.0%, 23.1%, and 24.3%, in their study, respectively. The drop in the number of antiglaucoma medications for the same time points was 40.5%, 42.8%, and 40.2%.^[23] Again, our outcomes are comparable.

Kim *et al.*^[24] in a study compared combined phaco and conventional needle goniotomy with phaco alone in OAG patients. Mean IOP and number of medications at 3, 6, and 12 months after the procedure was not different between groups while the drop of IOP was significantly higher in the combined surgery group at 3 (13.7% versus 6.3%), 6 (17.5% versus 8.6%), and 12 (17.0% versus 8.0%) months. The decrease in medications was also greater in the combined surgery group. This study showed the efficacy of goniotomy despite the use of traditional methods. We had a greater IOP reduction in our study, probably due to greater baseline IOP in our patients.

As mentioned earlier, topical steroids were prescribed for all eyes during the first month after surgery. The highest mean IOP was observed at one month (not statistically significant, Fig. 1), most likely due to steroid response in the POAG subgroup. Multiple studies have shown that POAG is a risk factor for steroid-induced ocular hypertension.^[25-27] We recommend discontinuing topical steroids earlier after uncomplicated combined phaco-goniotomy.

As the included eyes had visually significant cataracts, CDVA improved significantly 6 months after the procedure (0.70 ± 0.56 versus 0.44 ± 0.54 ; $P < 0.001$). However, the post-operative CDVA

was not typical for the eyes with mild and moderate OAG and OHTN. Our patients didn't have ocular comorbidities other than cataracts and glaucoma or OHT. The presence of posterior capsular opacification in some eyes is the reason for the measured CDVA at six months. A fundamental difference between our study and previous studies^[20,22,24] was that we did phacoemulsification before goniotomy. Experimentally, we did direct gonioscopy before and after phaco alone surgery and recognized the angle is wider and more suitable for goniotomy after phacoemulsification and posterior chamber IOL implantation.

Five eyes (15.6%) in our study had exposed Schlemm's canal after the procedure. The mean IOP in this subgroup was 12.6 ± 3.13 mmHg. There wasn't a statistically significant difference between IOP in this subgroup and other eyes, probably due to the small sample size. However, we believe that this condition is optimal after goniotomy and will result in better control of IOP.

Albeit, the majority of eyes had a quite normal appearance in the nasal angle. By advancing the needle through the trabecular meshwork only an incision will be made and the leaflets of the trabecular meshwork may adhere together after a while. We believe that this adherence is incomplete in such conditions and large microscopic pores in the trabecular meshwork would facilitate the outflow.

Blood reflux from collector channels during goniotomy is expected and occurred in almost all eyes in this experiment. This phenomenon indicates the correct plane of incision rather than a complication. Two eyes in our study had a traumatic distorted pupil without visual complaints. Our insistence on proper incision of trabecular meshwork led to this situation. Complications such as clot hyphema and inflammation were resolved with proper management. Complications reported in other studies such as IOP spike > 10 mmHg, Descemet's tear, cystoid macular edema, epiretinal membrane, damage to the lens capsule, and aqueous misdirection didn't occur in our study.^[13,14,20,22,23]

The lack of a control group is the main limitation of this study. However, the effect of phaco alone in the reduction of IOP and medications in glaucomatous patients is less than our results. A meta-analysis reported a 12% reduction of IOP and 0.57 medication per patient after phaco alone surgery.^[28] The short duration of follow up was another limitation. Albeit, this study is continuing and more eyes with a longer follow up will be recruited.

Conclusion

In conclusion, this study revealed the efficacy of combined phaco-goniotomy with a needle in eyes with coexisting cataracts and early-to-moderate OAG. Also, this procedure is effective in the reduction of IOP and the burden of topical medications. The need for further studies with the control group and a longer follow-up period is quite clear.

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Conflicts of interest

There are no conflicts of interest.

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