

Six months' follow-up of combined phacoemulsification–kahook dual blade excisional goniotomy

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Abstract:

PURPOSE: This study reports on the combination of excisional goniotomy and cataract extraction in the management of glaucoma in terms of intraocular pressure (IOP) and glaucoma medication reduction.

METHODS: This is a retrospective case series. Twenty-eight eyes of 22 patients with the diagnosis of cataract and ocular hypertension or glaucoma of any stage underwent combined phacoemulsification and Kahook Dual Blade (KDB) goniotomy, between March 2019 and September 2020. The parameters evaluated were postoperative best-corrected visual acuity, mean IOP reduction, number of IOP-lowering medications, and the surgical success rate defined as IOP reduction >20% and/or reduction in glaucoma medications >1.

RESULTS: The mean IOP reduction at 6 months was 4.5 mmHg ($P = 0.0007$), which translates to 24.9% reduction from preoperative IOP. The mean preoperative number of glaucoma medications was 2.9 ± 1.0 (median of 3). It was reduced to 1.1 ± 1.1 (median of 1.5), 1.46 ± 1.17 (median of 2), 1.44 ± 1.28 (median of 2), and 1.56 ± 1.28 (median of 2) at 1 week, 1 month, 3 months, and 6 months, respectively. Twenty-nine percent (8/28) of the patients were off glaucoma medications at 6 months and 46% (13/28) had a reduction of more than 50% of their glaucoma medications.

CONCLUSION: Combined phacoemulsification–KDB excisional goniotomy may be an effective and safe alternative to more invasive filtering surgery in glaucoma patients of any stage.

Keywords:

Glaucoma, goniotomy, Kahook Dual Blade, phacoemulsification

INTRODUCTION

Glaucoma is the most frequent cause of irreversible blindness worldwide.^[1] Global prevalence of glaucoma is expected to reach 3.54% in 2040, and the number of people with glaucoma will likely increase from 64.3 million in 2013 to 111.8 million in 2040.^[2] Classically, medical treatment and trabeculectomy are the first-line options in glaucoma management as these noninvasive treatment modalities are associated with a lower risk than traditional glaucoma surgeries. In fact, according to major glaucoma trials, the complication rates of conventional incisional glaucoma surgeries range between 37% and 63%.^[3-5]

Hence, minimally invasive glaucoma surgical procedures (MIGS) have been developed, with the aim of achieving better safety profiles.^[6] These modalities are also associated with faster recovery than traditional glaucoma surgeries.^[7] However, intraocular pressure (IOP) reduction is usually less with MIGS than with other traditional glaucoma procedures; this is why these new procedures are indicated in cases of mild-to-moderate glaucoma.^[8] MIGS are categorized into surgeries that increase the trabecular outflow, surgeries that increase suprachoroidal outflow, and conjunctival bleb-forming procedures.^[9]

Recent studies have shown that goniotomy with trabecular meshwork (TM) excision using the Kahook Dual Blade (KDB, New World Medical Inc., Rancho Cucamonga, CA) offers good IOP

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reductions in early, moderate, and severe glaucoma.^[10,11] In fact, the inner wall of Schlemm’s canal, which is formed by the juxtacanalicular TM, and the endothelium of Schlemm’s canal inner wall are the main sites of resistance to aqueous outflow.^[12] The KDB enables the surgeon to perform a safe and reliable goniotomy with TM excision over 3–5 clock hours,^[13] without damaging surrounding tissues.^[14] The tapered end at the tip enters smoothly into Schlemm’s canal, and when the device is advanced, the blades on either side create parallel incisions in the TM, thus allowing for the removal of a strip of the meshwork. KDB was registered by the FDA in 2015. Goniotomy with the KDB is effective in reducing IOP and medication burden, both as a standalone procedure and when combined with phacoemulsification.^[15,16]

The present study aims at assessing the efficacy of KDB goniotomy combined with phacoemulsification, and evaluating postoperative outcome in terms of IOP reduction, improvement in visual acuity, intra- and postoperative complications, and the number of postoperative glaucoma medications or need for additional surgical procedures.

METHODS

Study design

This is a retrospective, single-center case series study. Data were collected from two glaucoma specialists (ZK and KFT) at the Beirut Eye and ENT Specialist Hospital, Beirut, Lebanon. Informed consent was obtained from all patients.

Participants

Twenty-eight eyes of 22 patients who underwent combined phacoemulsification and KDB goniotomy between March 2019 and September 2020 were included. The enrolled patients presented with the diagnosis of cataract and ocular hypertension or glaucoma of any stage. Combining KDB goniotomy with the phacoemulsification aimed at achieving better IOP control, and/or removing all or part of the glaucoma medications in case of intolerance or poor compliance. Gonioscopy was performed preoperatively to assess the iridocorneal angle. Exclusion criteria were age below 18 years, congenital glaucoma, and prior incisional glaucoma surgeries.

Surgical technique

Day surgery is performed in the operating room under topical or regional anesthesia. The patient’s head is rotated around 30° away from the surgeon, and the microscope is tilted 30°–45° toward the surgeon in order to visualize and access the angle. A temporal clear corneal incision is made with a 3-mm keratome. Viscoelastic is injected into the anterior chamber. The TM in the nasal quadrant is directly viewed by using a surgical gonioscope (Volk Vold Gonio, previously known as *VTSTVG/AVG*, Volk, USA) placed on the clear cornea. The surgeon then inserts the KDB [Figure 1] through the incision into Schlemm’s canal.^[13] The device is advanced along the Schlemm’s canal so that the TM moves up the ramp from the distal point toward the dual cutting blades. This movement

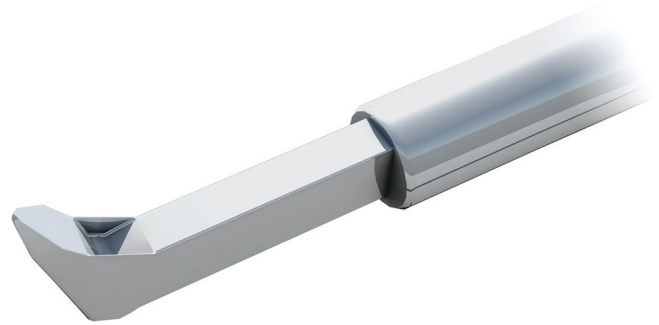


Figure 1: Kahook Dual Blade: Two lateral dual cutting blades (black arrows) and one distal point (white arrow) that are designed to pierce the trabecular meshwork and enter into the Schlemm’s canal. The distance between the dual blades is designed to closely match that of the width of the trabecular meshwork¹³

excises a strip of TM and creates a floating strip of TM visible in the angle. Classical techniques include “outside-in” [Figure 2a], “inside-out” [Figure 2b], and the “mark and meet” [Figure 2c]. Our technique is similar to the “mark and meet” but without the initial trabecular marking [Figure 2d]. This results in a residual trabecular strip that remains attached to the end of the goniotomy cleft. The total treatment area extends approximately along 3–5 clock hours. After completing the excisional goniotomy, cataract extraction by phacoemulsification (phaco-chop technique) and implantation of an intraocular lens in the capsular bag was performed. Depending on surgeon’s preference, phacoemulsification is performed before the KDB goniotomy in some cases.

Postoperative medications

Patients were treated postoperatively with topical antibiotic (tobramycin) combined with a steroid (dexamethasone) for 1 month after surgery. Glaucoma medications were suspended the day of the surgery and potentially resumed on day 1 postoperatively whenever necessary. In fact, if measured IOP at each follow-up visit was higher than the target IOP set to the patient, glaucoma medication (s) was (were) added. The amount of medications required (before and after surgery) was computed taking into account the number of medications within fixed-combination drops.

Pre- and postoperative assessment

The patients were seen preoperatively for a baseline examination including applanation IOP without washout of glaucoma medication. Baseline collected data also included age, sex, best-corrected visual acuity (BCVA) in logMAR, glaucoma type, IOP, topical and systemic medication use, in particular IOP-lowering medications and anticoagulants, and visual field (VF) defects on Humphrey 24-2 VF. VF abnormalities were classified as early (mean deviation [MD] >–6 decibels [dB]), moderate (–12 dB < MD ≤–6 dB), or severe (MD ≤–12 dB). Patients were then followed up at day 1, week 1, and months 1, 3, and 6. Data collected at each follow-up visit were BCVA, applanation IOP, adverse events, and medication use.

Outcomes

We evaluated postoperative outcomes in regard to BCVA, mean IOP reduction, number of IOP-lowering medications, and the surgical success rate defined as IOP reduction >25% and/or reduction in glaucoma medications >1.

Statistical analysis

The data were analyzed using paired sample two-tailed *t*-tests to compare mean baseline and 1-, 3-, and 6-month IOP, and the Wilcoxon signed-rank test to compare the number of medications after checking assumptions. Tests were two-tailed with $\alpha=0.05$. Values are reported as mean \pm SD for the data with normal distribution. SPSS version 24.0 (IBM Corporation, Armonk, NY, USA) was used for statistical analysis.

RESULTS

Baseline data

The average age of the patients was 72.5 ± 6.6 years (range: 59–83). Glaucoma types were as follows: 78.6% (22/28) of the eyes had primary open-angle glaucoma, 10.7% (3/28) had pseudoexfoliation, 7.1% (2/28) had ocular hypertension, and 3.6% (1/28) had chronic angle-closure glaucoma. The mean baseline defect by Humphrey VF SITA-Standard 24-2 was -11.1 ± 8.3 dB [Table 1]. Twelve eyes (43%) had early VF defects, 3 eyes had moderate VF defects, 10 eyes (36%) had severe VF defects, and 3 eyes (11%) did not have preoperative Humphrey VF: one patient (2 eyes) presented cognitive

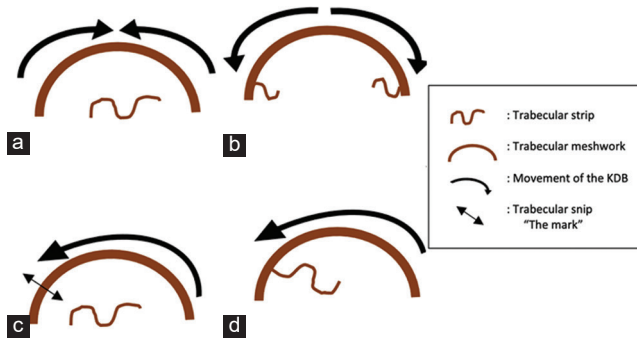


Figure 2: Schematic gonioscopic representation of different surgical techniques of Kahook Dual Blade excisional goniotomy: (a) Outside-in technique: Kahook Dual Blade goniotomy starts at the periphery of the visualized nasal angle and moves centrally. This technique consists of both a forehand and backhand excision. This leads to a complete excision with a trabecular strip floating in the anterior chamber. (b): Inside-out technique: Kahook Dual Blade goniotomy starts at the center of the visualized nasal angle and moves peripherally. This technique consists of both a forehand and backhand excision. This technique leaves two trabecular meshwork strips attached at the periphery of the cleft. (c): Mark and meet: This technique avoids the backhand pass. Kahook Dual Blade enters the trabecular meshwork/SC off-center to create a small initial snip, “the mark.” It is then moved to the opposite end of the nasal angle and advanced until it meets the initial area marked, also creating a floating strip in the anterior chamber. (d) Our technique, which is a modification of the mark and meet technique without the initial “mark.” This technique leaves a floating leaflet of trabecular meshwork attached to the end of the created cleft

impairment and was not cooperant, and the second patient lives abroad and was referred to our hospital in Lebanon for cataract surgery. The mean preoperative IOP was 18.1 ± 6.8 (range: 10–41 mmHg), and the mean (median) baseline number of glaucoma drops was 2.9 ± 1 (3) (range: 0–4).

Postoperative intraocular pressure reduction

The mean IOP was 18.1 ± 6.8 mmHg at baseline (range: 10–41 mmHg). It was reduced to 14.3, 13.9, and 13.6 mmHg at 1, 3, and 6 months postoperatively (range: 10–18 mmHg), respectively, and the difference was statistically significant at all times of the follow-up ($P < 0.05$) [Table 2]. This translates to a mean IOP reduction at 6 months of 24.9% from baseline IOP. Figure 3 is a graphic representation of mean IOP progression in millimeters of mercury over the consecutive follow-up: it shows a postoperative reduction that remained relatively stable throughout the postoperative period. The percentage of patients who exhibited a reduction of IOP of more than 20% at 6-month follow-up was 54% (15/28 eyes).

Postoperative medication reduction

The mean preoperative number of glaucoma medications was 2.9. It was reduced to 1.46, 1.44, and 1.56 at 1, 3, and 6 months, respectively [Table 3]. The number of glaucoma medications was significantly lower than baseline at all follow-up visits ($P < 0.001$). Twenty-nine percent (8/28) of the patients were off glaucoma medications at 6 months and 46% (13/28) had a reduction of more than 50% of their glaucoma medications. Figure 4 shows the decline in topical glaucoma medication from baseline to 6 months, reflecting the postoperative decrease in IOP. Compared to preoperative mean number of glaucoma medications, the mean medication reduction was 1.75 ± 1.32 , 1.5 ± 1.29 , 1.46 ± 1.26 , and 1.36 ± 1.31 at 1 week, 1 month, 3 months, and 6 months, respectively. These values translate to 61%, 49%, 49.5%, and 46% reduction of glaucoma medications at 1 week, 1 month, 3 months, and 6 months, respectively.

Surgical success rate

The overall surgical success rate in our series was 82.1% (23/28 eyes). Fifty percent of the patients (14/28 eyes) had either one success criterion (>1 glaucoma medication reduction or >20% IOP reduction). Thirty-two percent of the eyes (9/28 eyes) met both postoperative success criteria (>1 glaucoma medication reduction and >20% IOP reduction). Eighteen percent did not reach the definition of surgical success.

Table 1: Demographic characteristics of patients
SD=standard deviation

Mean age (years) \pm SD	72.5 \pm 6.6 years
Male/Female	60.7%/39.3%
Systemic anticoagulation	11 patients (39.3%)
Mean defect (Humphrey SITA-Standard 24-2) \pm SD	11.1 \pm 8.3 dB
Mean pre-operative IOP \pm SD	18.1 \pm 6.8 mm Hg
Mean pre-operative BCVA \pm SD	0.29 \pm 0.39
Mean pre-operative number of glaucoma medications \pm SD	2.9 \pm 1.0

Table 2: Intraocular pressure (IOP) values in millimeters of mercury (mm Hg) at baseline, 1 week, 1 month, 3 months and 6 months post-operatively

	Pre-operative IOP	IOP day 1	IOP week 1	IOP month 1	IOP month 3	IOP month 6
N valid/missing	28/1	23/6	26/3	24/5	28/1	28/1
Mean	18.11	14.09	13.42	14.29	13.89	13.57
Median	16	13	13	14	14	13.50
Std. deviation	6.79	4.621	3.501	3.141	2.331	2.348
Minimum	10	5	8	8	10	8
Maximum	41	25	24	20	20	18

Table 3: Number of glaucoma medications (Topical Meds) required to control intraocular pressure at baseline (pre-operative), 1 week, 1 month, 3 months and 6 months post-operatively.

	Pre-operative topical meds	Topical meds week 1	Topical meds month 1	Topical meds month 3	Topical meds month 6
N valid/missing	28/1	28/1	26/3	27/2	27/2
Mean	2.86	1.11	1.46	1.44	1.56
Median	3	1.5	2	2	2
Std. deviation	1.044	1.1	1.174	1.281	1.281
Minimum	0	0	0	0	0
Maximum	4	3	4	4	4

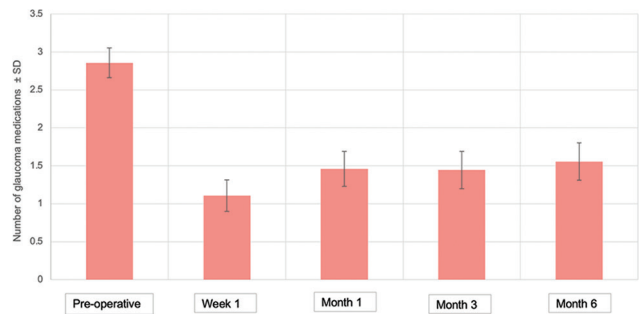


Figure 4: Mean number of glaucoma medications over the consecutive follow-up periods (± standard error of mean). X-axis represents the different follow-up periods. Y-axis represents mean medication number

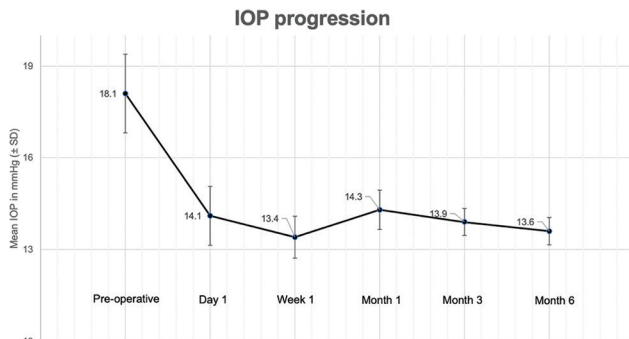


Figure 3: Mean intraocular pressure (± standard error of mean) progression curve in millimeters of mercury over the consecutive follow-up periods. X-axis represents the different follow-up periods. Y-axis represents mean intraocular pressure ± standard error of mean. Intraocular pressure indicates intraocular pressure

Intraoperative and postoperative complications

We recorded information on any adverse events at day 1, week 1, month 1, month 3, and month 6 postoperatively. On day 1, we recorded only 2 IOP values >20 mmHg (22 mmHg and 25 mmHg), both of which decreased on week 1 follow-up and did not affect the outcome nor the further need for topical glaucoma medication. No clinically significant hypotony was noted. Thirty-five percent of the eyes (10/28) presented with a microhyphema within the 1st week after surgery. These early hyphemas required no treatment and cleared spontaneously by the 1-month follow-up period. During the 6-month timeframe, no eyes had visual loss and no additional glaucoma procedures were needed.

DISCUSSION

Excisional goniotomy is a minimally invasive glaucoma procedure that is supposed to result in IOP reduction by decreasing the outflow resistance at the TM level. Our study population had a significant (24.9%) reduction of IOP, with a mean IOP of 13.6 mmHg at the 6-month follow-up after combined surgery. Hence, combining cataract extraction and KDB goniotomy seems to fulfill the American Academy of Ophthalmology recommendations as for the initial target of glaucoma management.^[17] Our results are comparable with what has been reported in the literature, whereby IOP reduction of 24%–26% and a mean IOP at 6 months ranging from 12.8–15 mmHg were reported at 6 months postoperatively.^[10,18–20] The mean IOP was reduced by 4.5 ± 6.3 mmHg from mean baseline IOP of 18.1 mmHg, comparable to what Dorairaj *et al.* reported (IOP was reduced by 4.4 mmHg from mean baseline IOP of 16.8 mmHg to 12.4 mmHg at 6 months).^[21]

In our population, 54% of the eyes achieved an IOP reduction ≥20% from baseline, even though the range of further IOP reduction was relatively narrow for most, as the mean baseline IOP was 18.1 mmHg and only 21% (6/28 patients) had a preoperative IOP of ≥20 mmHg. Nevertheless, combined phacoemulsification–KDB goniotomy was a successful treatment even in patients with baseline IOP ≥30 mmHg (4/28 eyes or 14%). It is noteworthy that our preoperative IOP (range: 10–41 mmHg) compares to previous reports in the literature^[16,22] and postoperative surgical success is comparable to what Salinas *et al.* published in “Goniotomy Using the

Kahook Dual Blade in Severe and Refractory Glaucoma: 6-Month Outcomes” in the *Journal of Glaucoma* 2018.

Excisional KDB goniotomy also decreases the number of glaucoma medications needed and, by doing so, reduces long-term noncompliance with glaucoma treatment. Glaucoma medications are known to have substantial local and systemic side effects, and one study has shown that only 31% (range: 10%–68%) of the new therapy users were still compliant at 1 year.^[23] Therefore, reducing the number of glaucoma medications should improve compliance, and thus probably decreases the likelihood of glaucoma progression. In our cohort, the mean reduction in medications was 46% at 6 months, and 46% of the patients were taken off medical treatment altogether. Glaucoma severity did not influence our ability to taper patients off glaucoma medications postoperatively, since half of the patients who stopped medications at 6 months had moderate-to-severe glaucoma at presentation (MD ranging between –10.9 dB and –19 dB).

Overall, our population exhibited a surgical success rate (defined by Sieck *et al.* as >20% IOP reduction and/or >1 medication reduction) of 82.1%, consistent with the reported success rates in the literature at 6 months of 74.1%.^[16]

Combining excisional goniotomy and cataract extraction is safe for chronic glaucoma management. In fact, cataract surgery is one of the safest procedures in ophthalmology and adding excisional goniotomy does not significantly alter the safety profile.^[18,21] Thirty-five percent of our patients had postoperative blood reflux, which is comparable to the range of 31%–39% reported in the literature.^[22] Early hyphema did not lead to any IOP spikes (>30 mmHg), nor did it affect the postoperative outcome. In fact, this blood reflux is a favorable sign that Schlemm’s canal and the collecting channels communicate freely with the anterior chamber, and is therefore an expected and welcome intraoperative event.^[24] In the present study, we included different types of chronic primary or secondary (pseudoexfoliative) open-angle glaucoma and chronic angle-closure glaucoma, since KDB goniotomy was shown to be successful in these types of glaucoma.^[25]

Several surgical techniques of excisional sectorial goniotomy were described in the literature [Figure 2]. Our technique leaves a residual trabecular strip that is attached to the goniotomy cleft. Some authors advocate complete excision of the TM and consider that near-absent TM remnants reduce the risk of scarring of the opening created in Schlemm’s canal.^[16] According to our cohort, keeping a nasally floating strip of TM does not modify surgical outcomes since our mean postoperative IOP and IOP reduction at 6 months were comparable to the literature. Therefore, even if anatomical healing process may differ if we leave a residual TM strip, this remodeling is not clinically significant and does not affect surgical outcomes.

The limitations of this study include lack of long-term follow-up, small sample size, and its retrospective nature. Patients were not selected randomly, and only eligible patients

were offered this surgical treatment. Surgical sequence differed according to a surgeon’s preference. Nonetheless, our cohort will continue to be followed up regularly to assess long-term surgical results and surgical sequence will be studied to determine its effect on postoperative outcome.

CONCLUSION

Combined phacoemulsification–KDB goniotomy reduces IOP by almost 25% and decreases the need for glaucoma medications by 46% at 6-month follow-up. According to our study, this procedure is a safe alternative to more elaborate combined cataract–glaucoma procedures and may be adopted as a first-line treatment in patients with chronic glaucoma of any stage that are also candidates for cataract extraction.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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