



Outcomes and risk factors for Kahook Dual Blade excisional goniotomy with concomitant phacoemulsification: a multicentre Canadian study

Ali Salimi,* Oscar Kasner,*[†] Steven Schendel,[‡] Marc Mydlarski,*[†] Dima Kalache,[§] Lautaro Vera,* Rob Pintwala,[‡] Paul Harasymowicz^{||,¶}

Objective: To assess the outcomes and failure risk factors for Kahook Dual Blade (KDB) excisional goniotomy with cataract surgery (phaco-KDB) in eyes with various glaucoma subtypes and severities.

Methods: This multisurgeon consecutive case series included glaucomatous eyes with cataract that underwent phaco-KDB and had a minimum follow-up of 12 months postoperatively. Efficacy was assessed by absolute and qualified surgical success (defined by different criteria) and changes in intraocular pressure (IOP) and antiglaucoma medication (AGM) at the last postoperative follow-up. Safety included best-corrected visual acuity, cup-to-disc ratio, visual field mean deviation, retinal nerve fibre layer thickness, and adverse events.

Results: A total of 108 eyes of 89 patients with a median follow-up of 18 months (range, 12–47 months) were included. IOP decreased by 26% from 19.1 ± 5.0 mm Hg to 14.1 ± 3.5 mm Hg ($p < 0.001$), AGM use decreased by 29% from 2.4 ± 1.3 medications to 1.7 ± 1.3 ($p < 0.001$), and 25% of eyes became free of AGMs (vs 3% at baseline). Qualified success rates achieved for IOP cutoffs of 18, 15, and 12 mm Hg were 87%, 68%, and 46%, respectively. Higher baseline IOP and postoperative incidence of IOP spikes were associated with a higher risk of surgical failure. Best-corrected visual acuity improved postoperatively ($p < 0.001$), and visual field mean deviation, cup-to-disc ratio, and retinal nerve fibre layer thickness remained stable. Overall, safety was favourable, and adverse events were transient and not sight threatening.

Conclusion: This multicentre Canadian study provides real-world data that support the safety and efficacy of phaco-KDB in reducing IOP and AGM use with no evidence of disease progression during the follow-up period.

Filtering glaucoma surgeries offer excellent efficacy in reducing intraocular pressure (IOP), but the relatively high rate of complications has limited their use to refractory or advanced disease.¹ In recent years, the advent of minimally invasive glaucoma surgery has shifted the paradigm of glaucoma treatment toward earlier surgical intervention. Compared with more traditional glaucoma surgeries, minimally invasive glaucoma surgery offers a better safety profile, albeit with more modest efficacy.²

Trabeculotomy is an established surgical treatment option for glaucoma. However, this ab externo technique is relatively invasive, necessitating conjunctival and scleral flaps. Compared with the traditional ab externo trabeculotomy, the Kahook Dual Blade (KDB; New World Medical, Rancho Cucamonga, Calif.) excisional goniotomy is a safer surgical technique that employs a less invasive conjunctiva-sparing ab interno approach.³ This conjunctiva-sparing approach allows for future glaucoma surgeries. KDB goniotomy employs a single-use surgical blade to excise a strip of the trabecular meshwork (TM), creating a direct pathway for aqueous humour outflow into Schlemm's canal and distal collector channels.³

Outcomes of KDB goniotomy with and without cataract surgery have been established previously. However, most of the evidence is limited to short-term outcomes,^{4–8} with very few studies assessing surgical outcomes beyond 1 year postoperatively. Most of these studies had a limited sample size,^{9–14} except for 1 study reporting 18-month outcomes¹³ and a second study assessing 36-month outcomes in reasonably sized populations.⁹ Nonetheless, the postoperative change in structural and functional measures of disease stability, such as visual field (VF) and retinal nerve fibre layer (RNFL) thickness, was not reported. Therefore, we believe that there exists a gap in the KDB literature that warrants further studies with follow-up beyond 12 months postoperatively in a fairly large sample of eyes at this point in time reporting not only on the routinely reported efficacy and safety outcomes but also on less commonly reported measures of disease stability such as VF and RNFL thickness.

This study aims to fill this gap by assessing the medium-term efficacy and safety of KDB excisional goniotomy with concomitant cataract surgery (phaco-KDB) in a large sample of eyes across various glaucoma subtypes and severities. Additionally, this study focuses on less commonly reported

measures, such as the structural and functional measures of disease stability, as well as the risk factors for failure.

Methods

Study design and subjects

This single-arm, retrospective, multicentre interventional case series consisted of consecutive glaucoma patients who underwent phaco-KDB at different surgical centres across Canada from 2017 to 2020. Patients were adults (≥ 18 years of age) with symptomatic cataracts and had a minimum of 12 months of follow-up data. To enhance the study's generalizability, various glaucoma types and severities were included. Patients with a history of cataract, cornea, or retinal surgery were excluded.

All procedures performed were in accordance with the ethical standards of the institutional research committee and the tenets of the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Advarra Institutional Review Board (Pro00037667). Written informed consent was not required given the retrospective nature of the study.

Surgical technique

Under sterile conditions, patients underwent ab interno excisional goniotomy using KDB with standard phacoemulsification. Phacoemulsification was performed before or after the goniotomy according to each surgeon's practice pattern. For goniotomy, the anterior chamber was filled using a viscoelastic ophthalmic device, and the KDB blade was inserted into the anterior chamber and advanced toward the nasal TM under direct visualization using a gonioscope. After piercing the TM, the blade was advanced along the canal in a clockwise or counterclockwise direction, elevating and excising a strip of TM before engaging the opposite end of the intended treatment area and advancing toward the starting position. The treatment area spanned between 90 and 100 degrees depending on the surgeon. At the end of surgery, the anterior chamber was filled with balanced salt solution to an estimated pressure of 20–25 mm Hg to prevent reflux hyphema.

Postoperative medications consisted of a combination of topical antibiotic and corticosteroid drops, with nonsteroidal anti-inflammatory drops being prescribed at the discretion of the surgeon. Glaucoma medications were not routinely discontinued; rather, the regimen was modified based on the surgeon's preference and the eye's characteristics, including glaucoma type, disease severity, preoperative IOP, tolerance to eye drops, and the drops used in the contralateral eye.

Outcome measures

Clinical data were extracted at baseline and all postoperative visits. Primary outcomes included surgical success and

postoperative change in IOP and antiglaucoma medication (AGM) use. Surgical success was defined by IOP thresholds of 18, 15, or 12 mm Hg on no AGMs (absolute success) or irrespective of AGM use (qualified success) in the absence of secondary glaucoma surgery. Failure was considered if the criterion was not met at ≥ 2 consecutive visits following the third postoperative month (POM) or if the patient lost light perception. Secondary outcomes included predictors of surgical success, proportional analyses of eyes with certain IOP and AGM cutoffs, markers of disease stability, and the safety profile.

To minimize the effect of regression toward the mean, the baseline IOP was calculated as the average of the last 2 preoperative IOP values,¹⁵ provided that the second-to-last visit was within 3 months of the surgery. The number of AGMs was calculated based on the number of active pharmacologic classes included in formulations.^{16,17} Glaucoma severity was classified according to the Canadian Ophthalmological Society's evidence-based clinical practice guidelines for the management of glaucoma in the adult eye.^{18,19} IOP spike was defined as an IOP increase by > 10 mm Hg or 50% relative to the baseline IOP until POM 2.^{17,20}

Data analysis

Kaplan–Meier curves assessed surgical success, and Cox proportional hazard ratios assessed the predictors of failure according to qualified success with an IOP threshold of 18 mm Hg. Generalized estimating equation models assessed the changes in continuous variables, including IOP, AGM use, best-corrected visual acuity (BCVA), cup-to-disc ratio (CDR), VF mean deviation (VF-MD), and RNFL thickness, from baseline to the last available follow-up visit. Postoperative outcomes of those who underwent secondary glaucoma surgeries were censored in subsequent visits. All statistical analyses accounted for inter-eye correlation and were performed using SPSS Statistics 27.0 (IBM Corp, Armonk, NY) with alpha set at 0.05 for statistical significance.

Results

The median follow-up duration was 18 months, ranging from 12 to 47 months (25%–75% interquartile range, 14–24 months). A total of 108 eyes from 89 patients were included, with the majority being primary open-angle glaucoma (POAG; 54%) patients. The average preoperative IOP was 19.1 ± 5.0 mm Hg on 2.4 ± 1.3 AGMs. **Table 1** presents the baseline clinical characteristics.

The rate of qualified success was 87% for IOP ≤ 18 mm Hg, 68% for IOP ≤ 15 mm Hg, and 46% for IOP ≤ 12 mm Hg. The corresponding rate of absolute success was 19% for both 18 and 15 mm Hg cutoffs and was 13% for IOP ≤ 12 mm Hg (**Fig. 1**). A total of 7 eyes (6%) underwent secondary glaucoma surgery, including XEN Gel Stent (Allergan Inc, Dublin, Ireland; $n = 3$), laser

Table 1—Demographic and preoperative ocular characteristics

Variable	n = 108 eyes of 89 patients
Median follow-up (months)	18
Age (years)	73.6 ± 8.6
Sex (male:female)	49%:51%
Eye (OD:OS)	53%:47%
Central corneal thickness (μm)	545.5 ± 44.3
History of prior glaucoma interventions	
Selective laser trabeculoplasty	52%
Laser peripheral iridotomy	16%
Type of glaucoma	
Primary open angle	54%
Secondary open angle	19%
Primary angle closure	17%
Normal tension	10%
Glaucoma severity	
Mild	38%
Moderate	25%
Advanced	37%
Goniotomy performed (%)	
Before cataract surgery	73%
After cataract surgery	27%
Intraocular pressure (mm Hg)	19.1 ± 5.0
Glaucoma medications	2.4 ± 1.3
Use of oral carbonic anhydrase inhibitors	7%
Best-corrected visual acuity (logMAR)	0.28 ± 0.27
Cup-to-disc ratio	0.73 ± 0.15
Visual field mean deviation (dB)	-7.2 ± 6.9
Retinal nerve fibre layer thickness (μm)	72.0 ± 16.4

Note: Mean ± SD are presented where applicable.

cyclophotocoagulation (n = 2), and Ahmed Glaucoma Valve (AGV; New World Medical, Cucamonga, Calif.) implant (n=2). The median interval time to undergo the second glaucoma surgery was 9 months (25%–75%

interquartile range, 4.5–10.5 months). Selective laser trabeculoplasty was performed in 4 eyes. No eye lost light perception.

Overall, the models showed significant reductions in both IOP and AGM use (Table 2). IOP decreased from 19.1 ± 5.0 mm Hg to 14.1 ± 3.5 mm Hg at last follow-up (5.0 mm Hg absolute reduction; 26% relative reduction; p < 0.001; Fig. 2). The proportion of eyes with IOP ≤18 mm Hg increased from 51% at baseline to 90% at last follow-up, those with IOP ≤15 mm Hg increased from 24% to 63%, and those with IOP ≤12 mm Hg increased from 2% to 35% (Fig. 3). AGM use decreased from an average of 2.4 ± 1.3 medications at baseline to 1.7 ± 1.3 medications at last follow-up (0.7 absolute reduction; 29% relative reduction; p < 0.001; Fig. 4). At last follow-up, AGM use decreased by at least 1 medication in 47% and by ≥2 medications in 13% of the eyes (Fig. 5). Notably, a quarter of eyes (25%) were completely medication free at last follow-up (vs 3% at baseline), and none of the eyes were on oral carbonic anhydrase inhibitors (CAIs) at last follow-up (vs 7% at baseline; Fig. 5).

Failure was associated with a higher preoperative IOP (p < 0.001) and a higher postoperative incidence of IOP spikes (p = 0.014). Other factors such as glaucoma type, disease severity, history of selective laser trabeculoplasty treatment, timing of goniotomy relative to lens extraction, and the surgeon were not associated with surgical success or failure (Table 3).

Safety was overall favourable, although 4 eyes experienced intraoperative complications, including tears in

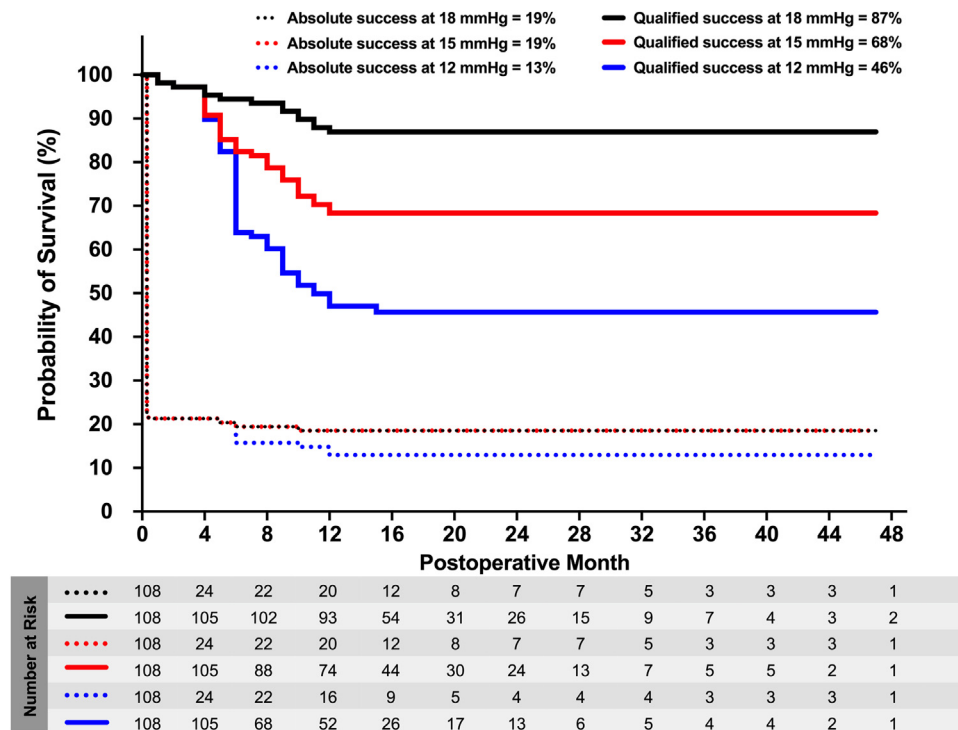


Fig. 1—Kaplan–Meier survival chart. Dotted lines represent absolute success at 18 mm Hg (black), 15 mm Hg (red), and 12 mm Hg (blue). Solid lines represent qualified success at 18 mm Hg (black), 15 mm Hg (red), and 12 mm Hg (blue).

Table 2—Efficacy and safety measures (n = 108 eyes of 89 patients)

Variable	Mean ± SD	Change vs Baseline		
		Percent change	Absolute change	p Value
Intraocular pressure (mm Hg)				
– Baseline	19.1 ± 5.0			
– POD 1	18.5 ± 8.5	–3	–0.6	0.335
– POM 1	16.0 ± 5.3	–16	–3.1	<0.001*
– POM 6	15.5 ± 5.3	–19	–3.6	<0.001*
– POM 12	14.6 ± 4.0	–24	–4.5	<0.001*
– Last follow-up	14.1 ± 3.5	–26	–5.0	<0.001*
Glaucoma medications				
– Baseline	2.4 ± 1.3			
– POD 1	1.3 ± 1.3	–46	–1.1	<0.001*
– POM 1	2.0 ± 1.2	–17	–0.4	<0.001*
– POM 6	1.9 ± 1.2	–21	–0.5	<0.001*
– POM 12	1.8 ± 1.3	–25	–0.6	<0.001*
– Last Follow-up	1.7 ± 1.3	–29	–0.7	<0.001*
Best-corrected visual acuity (logMAR)				
– Baseline	0.28 ± 0.27			
– POD 1	0.53 ± 0.61	89	0.25	<0.001*
– POM 1	0.16 ± 0.17	–43	–0.12	<0.001*
– POM 6	0.14 ± 0.23	–50	–0.14	<0.001*
– POM 12	0.11 ± 0.11	–61	–0.17	<0.001*
– Last Follow-up	0.12 ± 0.12	–57	–0.16	<0.001*
Visual field mean deviation (dB)				
– Baseline	–7.2 ± 6.9			
– Last follow-up	–6.7 ± 6.5	7	0.5	0.351
Cup-to-disc ratio				
– Baseline	0.73 ± 0.15			
– Last follow-up	0.73 ± 0.16	0	0.0	0.936
Retinal nerve fibre layer thickness (µm)				
– Baseline	72.0 ± 16.4			
– Last follow-up	70.8 ± 18.0	–2	–1.2	0.374

Note: Median duration to last follow-up was 18 months (25%–75% interquartile range: 14–24 months).

*Statistical significance.

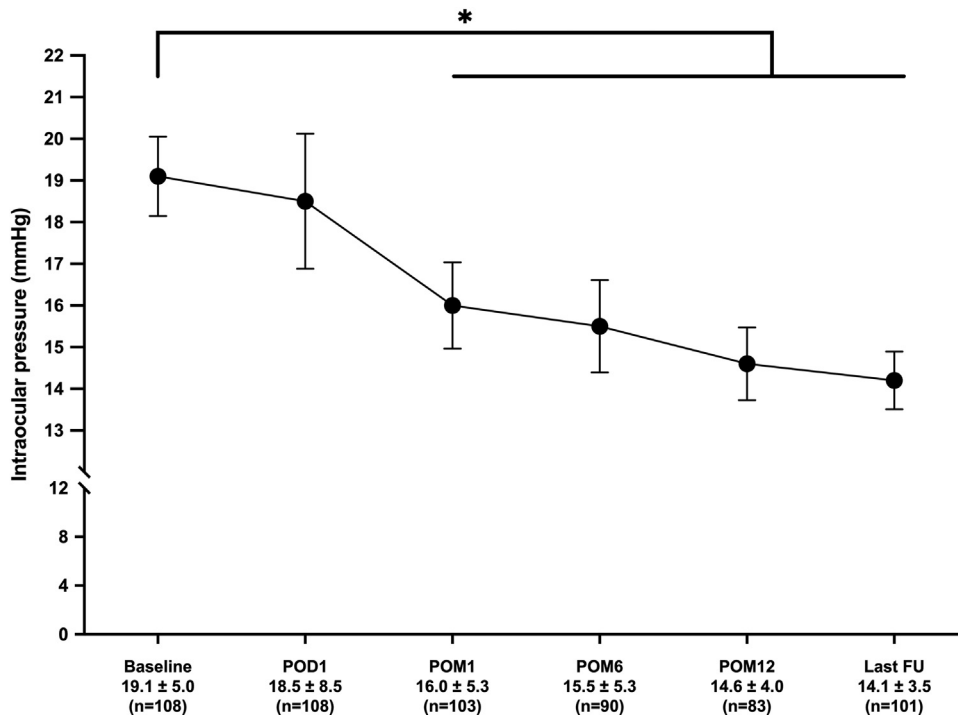


Fig. 2—Postoperative change in intraocular pressure. Asterisk (*) denotes statistical significance at $p < 0.05$, and error bars represent 95% CIs. POD = postoperative day; POM = postoperative month.

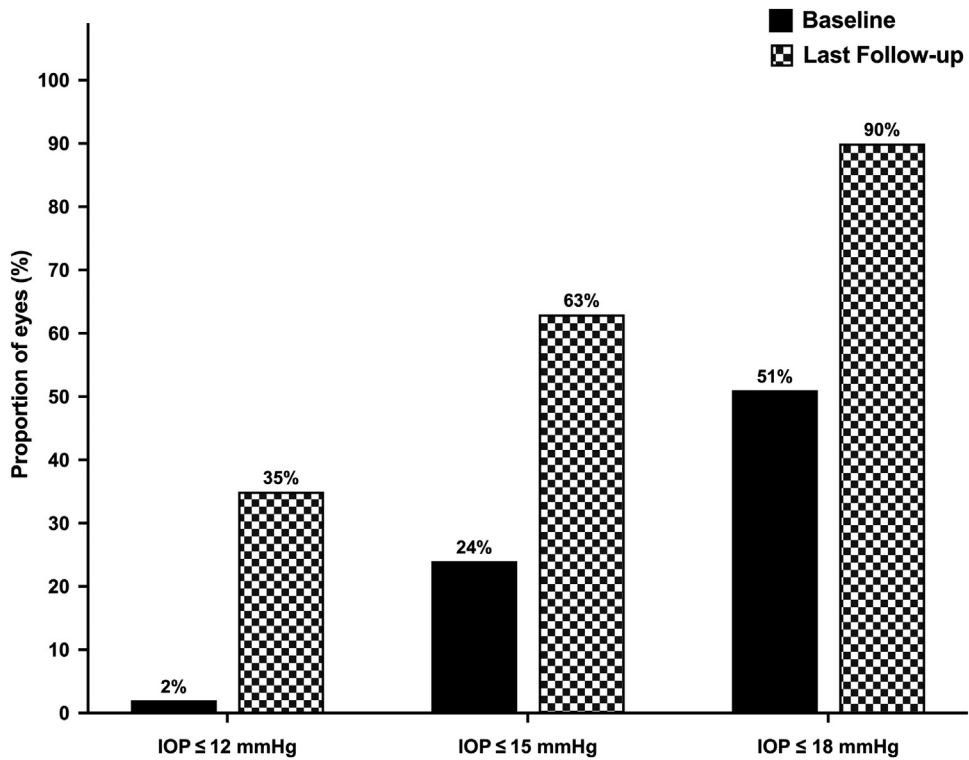


Fig. 3—Percentages of eyes with intraocular pressure ≤ 18 mm Hg, ≤ 15 mm Hg, and ≤ 12 mm Hg at baseline (solid bars) and follow-up (checked bars). IOP = intraocular pressure.

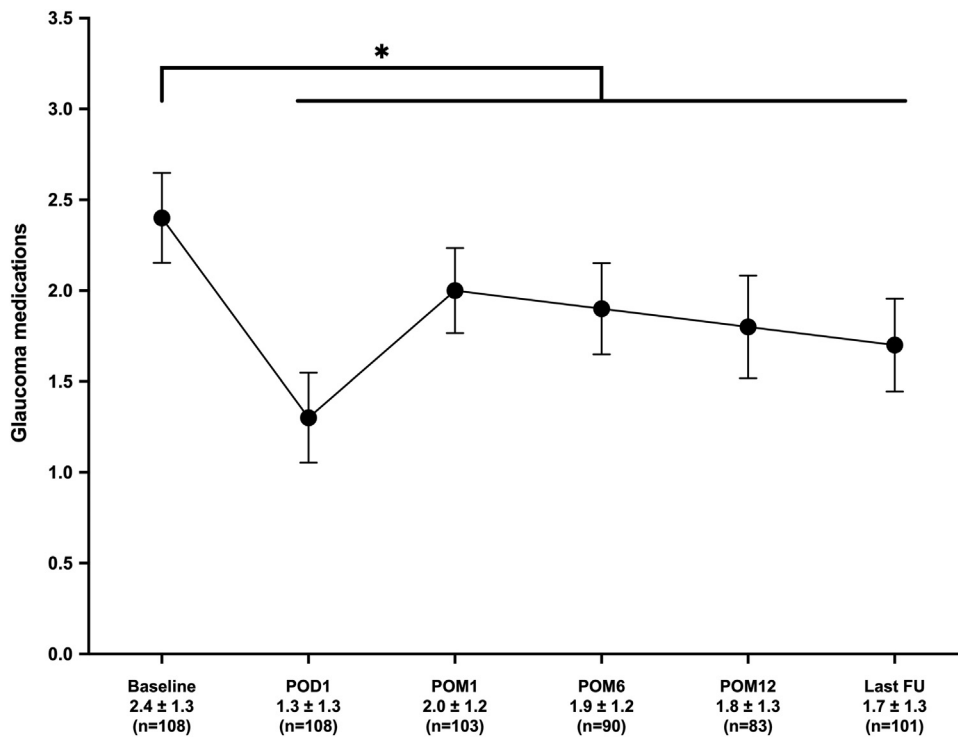


Fig. 4—Postoperative change in the number of glaucoma medications. Asterisk (*) denotes statistical significance at $p < 0.05$, and error bars represent 95% CIs. POD = postoperative day; POM = postoperative month.

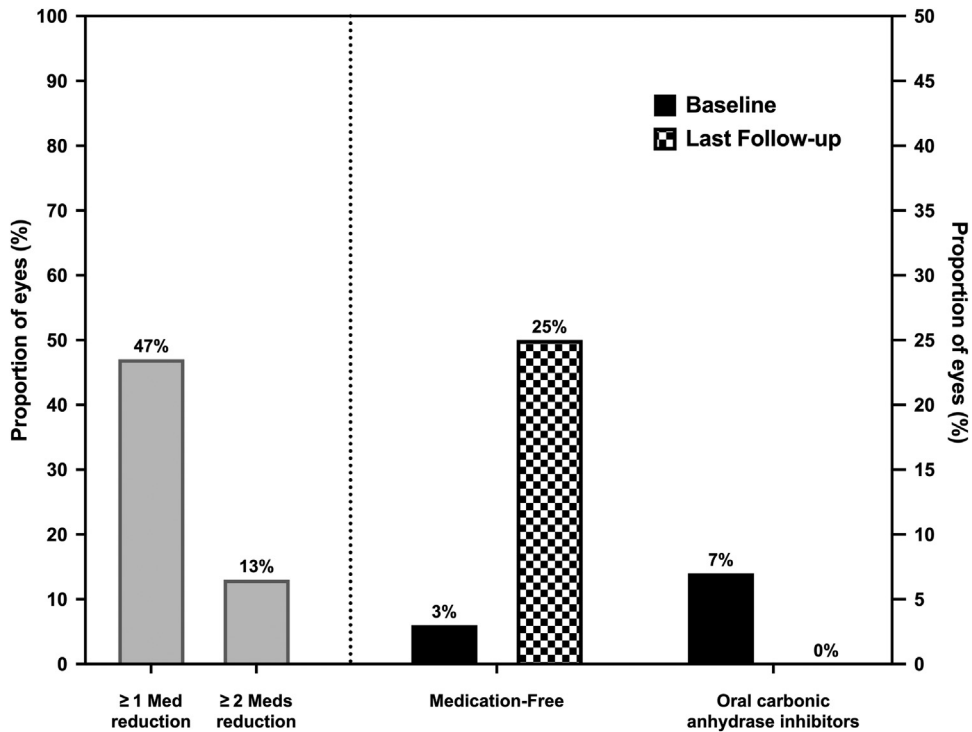


Fig. 5—Left panel shows the percentage of eyes with ≥ 1 and ≥ 2 medication reductions. Right panel shows the percentage of eyes that were medication-free or were on oral carbonic anhydrase inhibitors, at baseline (solid line) and follow-up (checked bars). Med reduction = reduction in the number of antiglaucoma medications.

Descemet’s membrane (n = 2), posterior capsular rupture (PCR) requiring anterior vitrectomy (n = 1), and vitreous prolapse due to zonulopathy requiring anterior vitrectomy (n = 1). Disease stability was maintained, as evidenced by both functional and structural measures, including VF-MD

(p = 0.351), CDR (p = 0.936), and RNFL thickness (p = 0.374).

Table 3—Cox proportional hazard ratio for factors associated with failure according to qualified success at 18 mm Hg

Factor	Hazard ratio	95% CI	p Value
Age (years)	0.971	0.918–1.027	0.296
Central corneal thickness (μm)	1.008	0.996–1.020	0.202
Intraocular pressure (mm Hg)	1.157	1.062–1.261	<0.001*
Glaucoma medications	1.413	0.953–2.095	0.085
Carbonic anhydrase inhibitor use	2.655	0.594–2.655	0.201
History of selective laser trabeculoplasty	0.898	0.315–2.560	0.841
Sex			0.493
Male (reference)	—	—	—
Female	0.690	0.240–1.990	0.493
Glaucoma type			0.733
Primary open-angle glaucoma (reference)	—	—	—
Secondary open-angle glaucoma	0.824	0.227–2.996	0.769
Primary angle-closure glaucoma	0.307	0.039–2.401	0.261
Normal-tension glaucoma	0.001	0.000–0.001	0.981
Glaucoma severity			0.726
Early (reference)	—	—	—
Moderate	1.072	0.277–4.147	0.919
Advanced	0.639	0.187–2.182	0.474
Timing of goniotomy			0.688
Before lens extraction (reference)	—	—	—
After lens extraction	0.770	0.215–2.760	0.688
Surgeon	0.893	0.638–1.250	0.510
Postoperative intraocular pressure spike	3.784	1.311–9.921	0.014*
Postoperative hyphema	0.382	0.050–2.923	0.354
Postoperative peripheral anterior synechiae	0.609	0.080–4.653	0.632

*Statistically significant values (p < 0.05).

The most common postoperative adverse event was hyphema, defined as ≥ 2 mm layered blood in the anterior chamber.²¹ It was noted in 18 eyes (17%), primarily on postoperative day 1. Most cases of hyphema were self-limiting and resolved spontaneously within 1 week without the need for any interventions. IOP spike was the second most common postoperative adverse event, noted in 17 eyes (16%), predominantly within the first postoperative week. The average IOP at the time of the spike was 34.7 ± 11.5 mm Hg (median, 30 mm Hg; range, 23–60 mm Hg), and the IOP was controlled through either pharmacologic therapy (n = 9) or anterior-chamber paracentesis (n = 8). Peripheral anterior synechiae were observed in 13 eyes (12%), ranging from 1 to 3 o’clock. Although BCVA improved postoperatively (p < 0.001), 3 eyes lost ≥ 2 lines of acuity. This included the eye that experienced PCR intraoperatively, 1 eye with advanced glaucoma that had uncontrolled IOP postoperatively and underwent AGV implantation, and another eye with advanced glaucoma and VF deficit within the central 10 degrees of fixation but normal postoperative IOP. Other adverse events included anterior uveitis (n = 3; controlled using topical steroids), corneal edema (n = 2; the 2 eyes that experienced Descemet’s membrane tear intraoperatively), cystoid macular edema (n = 2; POMs 3 and 7), central retinal vein occlusion (n = 1; POM 10), branch retinal vein occlusion (n = 1; POM 2), and posterior vitreous detachment (n = 1; POW 2).

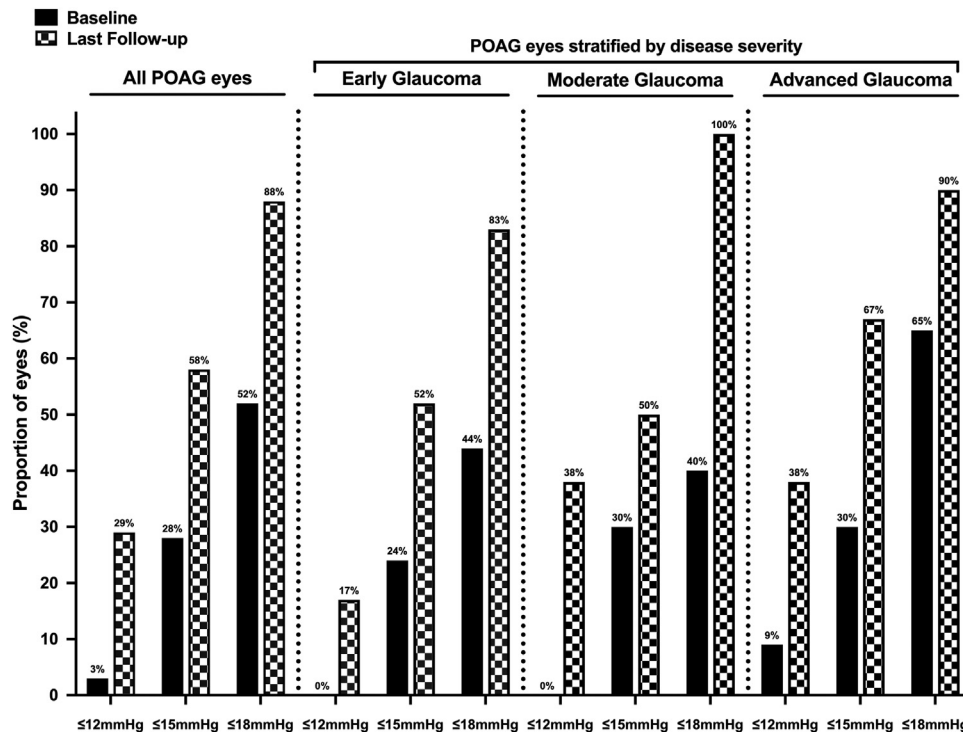


Fig. 6—Percentages of primary open-angle glaucoma eyes with intraocular pressure ≤ 18 mm Hg, ≤ 15 mm Hg, and ≤ 12 mm Hg at baseline (solid bars) and follow-up (checked bars), stratified by glaucoma severity (early, moderate, and advanced). POAG = primary open-angle glaucoma.

Supplementary analyses

Supplementary subgroup analyses were performed for POAG eyes, which showed similar trends to those observed for the whole cohort. Among the 58 included eyes, 43% had early glaucoma, 17% had moderate disease, and 40% had advanced disease. In this subgroup, IOP decreased by 23% from 19.0 ± 5.2 mm Hg to 14.6 ± 3.7 mm Hg ($p < 0.001$). The proportion of eyes with IOP ≤ 18 mm Hg increased from 52% to 88% at last follow-up, IOP ≤ 15 mm Hg increased from 28% to 58%, and IOP ≤ 12 mm Hg increased from 3% to 29%. The proportion of eyes achieving the 3 IOP cutoffs, stratified by disease severity, is demonstrated in Figure 6. AGM use decreased from 2.3 ± 1.3 medications to 1.8 ± 1.3 medications at last follow-up ($p < 0.001$). The proportion of medication-free eyes increased from 2% to 21% at the last follow-up, and none of the eyes were on oral CAIs (vs 5% preoperatively).

Discussion

KDB goniotomy reduces the IOP by removing a portion of the TM, allowing aqueous humour to bypass the dysfunctional TM into Schlemm's canal and downstream collector channels.³ The 5 mm Hg absolute IOP reduction observed in our study is consistent with the phaco-KDB literature, which has reported reductions ranging from 2.1 to 7.1 mm Hg.^{4,22} Additionally, 90% of eyes achieved an IOP of

≤ 18 mm Hg, with 63% reaching ≤ 15 mm Hg. It is important to note that cataract surgery also can contribute to postoperative IOP reductions, as shown in studies such as the Ocular Hypertension Treatment Study.^{23,24} A recent meta-analysis reported a mean IOP reduction of 2.7 mm Hg following cataract surgery in open-angle glaucoma patients.²⁵ However, in our study, the combined nature of phaco-KDB makes it difficult to determine the isolated IOP-lowering effect of KDB goniotomy. Previous studies have reported outcomes for standalone KDB goniotomy and phaco-KDB, but baseline inter-group differences make it difficult to draw concrete conclusions.¹³

The use of AGMs decreased by 0.7 medications, which is consistent with the range of 0.4–1.5 medications reported in previous similar studies.^{7,22} While this decrease may appear modest, it is important to note that 62% of patients had moderate to advanced glaucoma, which could have potentially limited the surgeon's risk tolerance for decreasing AGMs. Of note, a quarter of patients were medication-free at follow-up. Eliminating AGMs is valuable given their ocular surface toxicity, systemic side effects, cost, and association with decreased quality of life.^{26–28} Oral CAIs are associated with a range of side effects, some of which can be life threatening.²⁹ Postoperatively, the use of oral CAIs was discontinued in all patients (7%) who were taking them preoperatively.

The *Guidelines on Design and Reporting of Glaucoma Surgical Trials*, published by the World Glaucoma Association, recommend the use of Kaplan–Meier survival analysis.³⁰ However,

there is no consensus on the definition of surgical success, and criteria vary between studies. In this study, surgical success was defined as both absolute (without AGMs) and qualified (with or without AGMs) using 3 IOP cutoffs at 18, 15, and 12 mm Hg. In our cohort, 7 eyes (6%) underwent secondary glaucoma surgeries, which compares well with the rates reported in similar studies, ranging from 2% to 22%.^{4,6,7,9,13,31–33} It is important to note that unlike in prospective trials where the AGMs are generally discontinued postoperatively, in our study, AGMs were not routinely stopped postoperatively. This fact explains the significantly low rates of absolute success in our study, which should be interpreted with extra caution. Furthermore, KDB only bypasses part of the proximal outflow system, leaving the distal parts intact, which means that the IOP is still somewhat buffered by the floor effect of episcleral venous pressure. Therefore, the limited success rate according to the IOP threshold at 12 mm Hg should be interpreted with caution.

Assessing predictors of surgical success is essential for appropriate patient selection and surgical planning. A few papers have explored this area of study. Two studies found no association between surgical success and any baseline clinical characteristics such as age, sex, IOP, or AGM use.^{7,34} In our study, higher preoperative IOP and postoperative incidence of IOP spikes were associated with a higher risk of surgical failure. Following glaucoma surgery, a higher baseline IOP typically results in a greater degree of IOP reduction.³⁵ Nevertheless, as demonstrated by the Ocular Hypertension Treatment Study, starting with higher pressures generally lead to higher postoperative pressures,³⁶ likely explaining the observed association between higher baseline IOP and surgical failure in our study. IOP spikes can occur for several reasons, including postoperative hyphema, retained viscoelastic, and steroid response.³⁷ The association between the incidence of IOP spikes and surgical failure observed in eyes with partially excised TM can indicate pathology downstream to the TM. Therefore, we suggest that patients with a postoperative incidence of IOP spikes be followed more closely.

The safety outcomes of phaco-KDB were overall favourable. Regarding intraoperative complications, we attribute the incidence of PCR to cataract surgery and not KDB goniotomy. Conversely, the incidence of tears in Descemet's membrane is rare⁵ and can be avoided by meticulous attention to the orientation of the KDB blade when traversing the corneal wound. BCVA improved in line with the expected effect of cataract surgery. Among the 3 eyes that lost ≥ 2 lines of acuity, we attribute 1 to PCR during cataract surgery and the remaining 2 eyes likely to KDB goniotomy. Of note, both eyes had advanced disease, including 1 with uncontrolled IOP postoperatively requiring AGV implantation and the other with a VF deficit within the central 10 degrees of fixation preoperatively and postoperative IOP in the high teens. This case highlights the importance of aggressive IOP control in advanced glaucoma patients, especially those with threatened central vision. All cases of

hyphema resolved spontaneously through conservative management. IOP spikes are another common complication reported in the KDB literature.⁵ The incidence of IOP spikes was 16%, which is consistent with other similar studies reporting rates between 3% and 32%.^{8,38} Depending on the suspected cause and severity of the IOP spike, management may include pharmacotherapy, rapid taper of steroid drops, or anterior-chamber paracentesis with frequent follow-up.

Glaucoma is defined based on structural and functional measures such as RNFL thickness and VF abnormalities. Thus, studying these measures is crucial in evaluating disease evolution. Markers of disease stability have not been consistently reported in the KDB literature. Our results show that VF-MD, CDR, and RNFL thickness all remained stable throughout the medium-term postoperative period. However, it is possible that the stability in these measures is due to the limited follow-up duration of the study in the context of a relatively slowly progressive disease like glaucoma. Nevertheless, the absence of evidence for disease progression is reassuring.

Our study has limitations that are worth discussing. This cohort consisted of patients with mild to advanced glaucoma from several clinics across Canada, making the results generalizable across the spectrum of disease severity. The variations in surgical technique and perioperative protocols associated with the multisurgeon nature of this study can be seen as a limitation; however, it also adds to the generalizability of the results. Furthermore, failure of the Cox proportional hazard ratio model in identifying the surgeon variable as a predictor of surgical failure confirms that this factor likely has not had a significant effect on the results. Phacoemulsification alone can lead to substantial reductions in IOP. The absence of a control arm did not allow us to assess the isolated effect of KDB goniotomy relative to that of cataract surgery. Therefore, we focused our discussion on the phaco-KDB literature. It is imperative that the results of this study should be interpreted in the context of reported baseline clinical characteristics and the combined approach of phaco-KDB surgery and should not be generalized to standalone KDB goniotomy. Furthermore, inherent to retrospective studies, investigator bias related to postoperative measurements and documentation cannot be ruled out.

In summary, the results from our reasonably sized cohort of eyes with a broad range of glaucoma types and severities showed that phaco-KDB is effective in reducing IOP and AGM use, with no evidence of disease progression during the follow-up period. Recognizing the possible association between higher preoperative IOP and surgical failure can help inform patient selection and surgical decision making. Additionally, patients with postoperative IOP spikes should be followed closely. Lastly, although this ab interno blebless technique offered good safety, those with advanced disease and VF deficits in the central 10 degrees of fixation may benefit from more aggressive surgical options.

References

- Rathi S, Andrews CA, Greenfield DS, Stein JD. Trends in glaucoma surgeries performed by glaucoma subspecialists versus nonspecialists on Medicare beneficiaries from 2008 through 2016. *Ophthalmology* 2021;128:30–8.
- Saheb H, Ahmed II. Micro-invasive glaucoma surgery: current perspectives and future directions. *Curr Opin Ophthalmol* 2012;23:96–104.
- Seibold LK, Soohoo JR, Ammar DA, Kahook MY. Preclinical investigation of ab interno trabeculectomy using a novel dual-blade device. *Am J Ophthalmol* 2013;155:524–9 e2.
- Hirabayashi MT, King JT, Lee D, An JA. Outcome of phacoemulsification combined with excisional goniotomy using the Kahook Dual Blade in severe glaucoma patients at 6 months. *Clin Ophthalmol* 2019;13:715–21.
- Dorairaj SK, Seibold LK, Radcliffe NM, et al. 12-Month outcomes of goniotomy performed using the Kahook Dual Blade combined with cataract surgery in eyes with medically treated glaucoma. *Adv Ther* 2018;35:1460–9.
- Salinas L, Chaudhary A, Berdahl JP, et al. Goniotomy using the Kahook Dual Blade in severe and refractory glaucoma: 6-Month outcomes. *J Glaucoma* 2018;27:849–55.
- Sieck EG, Epstein RS, Kennedy JB, et al. Outcomes of Kahook Dual Blade goniotomy with and without phacoemulsification cataract extraction. *Ophthalmol Glaucoma* 2018;1:75–81.
- Greenwood MD, Seibold LK, Radcliffe NM, et al. Goniotomy with a single-use dual blade: Short-term results. *J Cataract Refract Surg* 2017;43:1197–201.
- Iwasaki K, Kakimoto H, Orii Y, Arimura S, Takamura Y, Inatani M. Long-term outcomes of a Kahook Dual Blade procedure combined with phacoemulsification in Japanese patients with open-angle glaucoma. *J Clin Med* 2022;11:1354.
- Al Habash A, Albuainain A. Long term outcome of combined phacoemulsification and excisional goniotomy with the Kahook Dual Blade in different subtypes of glaucoma. *Sci Rep* 2021;11:10660.
- Amljots TS, Economou MA. Kahook Dual Blade goniotomy vs iStent inject: Long-term results in patients with open-angle glaucoma. *Clin Ophthalmol* 2021;15:541–50.
- Dorairaj S, Tam MD, Balasubramani GK. Two-year clinical outcomes of combined phacoemulsification, goniosynechialysis, and excisional goniotomy for angle-closure glaucoma. *Asia Pac J Ophthalmol (Phila)* 2020;10:183–7.
- Wakil SM, Birnbaum F, Vu DM, McBurney-Lin S, ElMallah MK, Tseng H. Efficacy and safety of a single-use dual blade goniotomy: 18-month results. *J Cataract Refract Surg* 2020;46:1408–15.
- Albuainain A, Al Habash A. Three-year clinical outcomes of phacoemulsification combined with excisional goniotomy using the Kahook Dual Blade for cataract and open-angle glaucoma in Saudi Arabia. *Saudi J Ophthalmol* 2022;36:213–7.
- Salimi A, Watt H, Harasymowycz P. Long-term outcomes of two first-generation trabecular micro-bypass stents (iStent) with phacoemulsification in primary open-angle glaucoma: Eight-year results. *Eye Vis (Lond)* 2021;8(1):43.
- Salimi A, Watt H, Harasymowycz P. Three-year outcomes of second-generation trabecular micro-bypass stents (iStent inject) with phacoemulsification in various glaucoma subtypes and severities. *J Glaucoma* 2021;30:266–75.
- Salimi A, Nithianandan H, Al Farsi H, Harasymowycz P, Saheb H. Gonioscopy-assisted transluminal trabeculectomy in younger to middle-aged adults: One-year outcomes. *Ophthalmol Glaucoma* 2021;4:162–72.
- Canadian Ophthalmological Society Glaucoma Clinical Practice Guideline Expert C, Canadian Ophthalmological Society. Canadian Ophthalmological Society evidence-based clinical practice guidelines for the management of glaucoma in the adult eye. *Can J Ophthalmol* 2009;44 (Suppl 1):S7–93.
- Salimi A, Kassem R, Santhakumaran S, Harasymowycz P. Three-year outcomes of a Schlemm canal microstent (hydrus microstent) with concomitant phacoemulsification in open-angle glaucoma. *Ophthalmol Glaucoma* 2023;6:137–46.
- Salimi A, Winter A, Li C, Harasymowycz P, Saheb H. Effect of topical corticosteroids on early postoperative intraocular pressure following combined cataract and trabecular microbypass surgery. *J Ocul Pharmacol Ther* 2019;35:413–20.
- Chihara E, Chihara T. Development and application of a new T-shaped internal trabeculectomy hook (T-hook). *Clin Ophthalmol* 2022;16:3919–26.
- Murata N, Takahashi E, Saruwatari J, Kojima S, Inoue T. Outcomes and risk factors for ab interno trabeculectomy with a Kahook Dual Blade. *Graefes Arch Clin Exp Ophthalmol* 2023;261:503–11.
- Mansberger SL, Gardiner SK, Gordon M, Kass M, Ramulu P. Ocular hypertension treatment study group. Cataract surgery lowers intraocular pressure and medication use in the medication group of the ocular hypertension treatment study. *Am J Ophthalmol* 2022;9:53–62.
- Mansberger SL, Gordon MO, Jampel H, Bhorade A, Brandt JD, Wilson B, Kass MA. Ocular hypertension treatment study group. Reduction in intraocular pressure after cataract extraction: the ocular hypertension treatment study. *Ophthalmology* 2012;119:1826–31.
- Masis M, Mineault PJ, Phan E, Lin SC. The role of phacoemulsification in glaucoma therapy: A systematic review and meta-analysis. *Surv Ophthalmol* 2018;63:700–10.
- Joseph A, Pasquale LR. Attributes associated with adherence to glaucoma medical therapy and its effects on glaucoma outcomes: An evidence-based review and potential strategies to improve adherence. *Semin Ophthalmol* 2017;32:86–90.
- Baudouin C, Labbe A, Liang H, Pauly A, Brignole-Baudouin F. Preservatives in eyedrops: The good, the bad and the ugly. *Prog Retin Eye Res* 2010;29:312–34.
- Leung EW, Medeiros FA, Weinreb RN. Prevalence of ocular surface disease in glaucoma patients. *J Glaucoma* 2008;17: 350–5.
- Fraunfelder FT, Meyer SM, Bagby Jr. GC, Dreis MW. Hematologic reactions to carbonic anhydrase inhibitors. *Am J Ophthalmol* 1985;100:79–81.
- Heuer D, Barton K, Grehn F, Shaarawy T, Sherwood M. Consensus on definitions of success. In: Shaarawy TM, Sherwood MB, Grehn F, editors. Guidelines on design and reporting of glaucoma surgical trials. Amsterdam: Kugler Publications; 2009. p. 15.
- ElMallah MK, Berdahl JP, Williamson BK, et al. Twelve-month outcomes of stand-alone excisional goniotomy in mild to severe glaucoma. *Clin Ophthalmol* 2020;14:1891–7.

32. Omoto T, Fujishiro T, Asano-Shimizu K, et al. Comparison of the short-term effectiveness and safety profile of ab interno combined trabeculotomy using 2 types of trabecular hooks. *Jpn J Ophthalmol* 2020;64:407–13.
33. Kormmann HL, Fellman RL, Feuer WJ, et al. Early results of goniotomy with the Kahook Dual Blade, a novel device for the treatment of glaucoma. *Clin Ophthalmol* 2019;13:2369–76.
34. Pratte EL, Cho J, Landreneau JR, Hirabayashi MT, An JA. Predictive factors of outcomes in Kahook Dual Blade excisional goniotomy combined with phacoemulsification. *J Curr Glaucoma Pract* 2022;16:47–52.
35. Neiweem AE, Bussel II, Schuman JS, Brown EN, Loewen NA. Glaucoma Surgery Calculator: Limited additive effect of phacoemulsification on intraocular pressure in ab interno trabeculectomy. *PLoS One* 2016;11:e0153585.
36. Mansberger SL, Gordon MO, Jampel H, et al. Reduction in intraocular pressure after cataract extraction: the Ocular Hypertension Treatment Study. *Ophthalmology* 2012;119:1826–31.
37. Fang EN, Kass MA. Increased intraocular pressure after cataract surgery. *Semin Ophthalmol* 1994;9:235–42.
38. Falkenberry S, Singh IP, Crane CJ, et al. Excisional goniotomy vs trabecular microbypass stent implantation: A prospective randomized clinical trial in eyes with mild to moderate open-angle glaucoma. *J Cataract Refract Surg* 2020;46:1165–71.

Footnotes and Disclosure

Steven Schendel has worked as a consultant to Alcon, Abbvie, Bausch & Lomb, Labtician/Thea, Glaukos, and Santen. Dima Kalache has worked as a consultant to Abbvie, Alcon, and Labtician/Thea and on the ad board for Bausch & Lomb. Lautaro Vera has received research funds from ViaLase, Avisi Technologies, and iSTAR Medical. Paul Harasymowycz has worked as a consultant for Alcon, Allergan, Glaukos, Ivantis, J & J Vision, Santen, and Bausch &

Lomb. The remaining authors have no potential conflicts of interest to report.

This study was supported by a grant from Labtician Ophthalmics Inc, Oakville, Ontario. The sponsor had no role in study design, data collection/extraction, statistical analysis, data interpretation, drafting, or review of the manuscript or the decision to publish.

From the *Department of Ophthalmology, McGill University, Montreal, QC; †Ophthalmology Department, Jewish General Hospital, Montreal, QC; ‡Department of Ophthalmology, University of British Columbia, Vancouver, BC; §Department of Ophthalmology, Hospital Cité de la Santé, Laval, QC; ||Montreal Glaucoma Institute and Bellevue Ophthalmology Clinics, Montreal, QC; ¶Department of Ophthalmology, University of Montreal, Montreal, QC.

Presented as preliminary results at the Annual Meeting of the American Academy of Ophthalmology (AAO 2022), Chicago, IL, September 30–October 3, 2022; the Annual Meeting of the European Glaucoma Society (EGS 2022), Athens, Greece, June 4–8, 2022; and the Annual Meeting of the European Society of Cataract and Refractive Surgeons (ESCRS 2022), Milan, Italy, September 16–20, 2022. This study was presented at the Annual Meeting of the Canadian Ophthalmological Society (COS 2023), Quebec City, QC, June 15–18, 2023.

Originally received Feb. 14, 2023. Final revision Jul. 4, 2023. Accepted Aug. 11, 2023.

Correspondence to: Paul Harasymowycz, MD, Department of Ophthalmology, University of Montreal, 4135 de Rouen, Montreal, QC H1V1G5, Canada; pavloh@igmmtl.com.