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Outcomes of Kahook Dual Blade Goniotomy with and without Phacoemulsification Cataract Extraction

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Purpose: To determine the effectiveness and safety of Kahook Dual Blade (KDB) goniotomy in reducing intraocular pressure (IOP) and medication need in glaucoma patients when combined with phacoemulsification or as a standalone procedure.

Design: Retrospective study.

Participants: A total of 197 eyes from 143 patients were reviewed.

Methods: Thirty-two eyes underwent KDB goniotomy alone and 165 eyes underwent KDB goniotomy combined with phacoemulsification cataract surgery (phaco-KDB).

Main Outcome Measures: Surgical success, defined as IOP reduction of at least 20% from baseline at 12 months, and/or reduction of at least 1 glaucoma medication.

Results: At 12 months, the success rate was 71.8% for the phaco-KDB group and 68.8% for the KDB-alone group. In the phaco-KDB group at 12 months (n = 124), mean IOP was significantly reduced from 16.7 (standard error [SE] 0.4) mmHg on 1.9 (SE 0.1) medications to 13.8 (SE 0.4) mmHg on 1.5 (SE 0.1) medications. In the KDB-alone group at 12 months (n = 16), mean IOP was significantly reduced from 20.4 (SE 1.3) mmHg on 3.1 (SE 0.2) medications to 14.1 (SE 0.9) mmHg on 2.3 (SE 0.4) medications. The most common complications were transient hyphema (17.3% at day 1) and IOP spike >10 mmHg from baseline at 1 week (10.2%). LogMAR visual acuity at 12 months was unchanged from baseline in the KDB-alone group (0.218 [SE 0.07] and 0.306 [SE 0.09], respectively, $P = 0.244$) and significantly improved in the phaco-KDB group (0.184 [SE 0.02] and 0.340 [SE 0.03], $P < 0.001$).

Conclusions: Goniotomy with the KDB has a favorable safety profile and is an effective procedure at reducing IOP and medication burden as a standalone procedure or combined with phacoemulsification. *Ophthalmology Glaucoma 2018;1:75-81 © 2018 by the American Academy of Ophthalmology*

Glaucoma, a progressive optic neuropathy, is one of the leading causes of blindness worldwide.[1] Lowering intraocular pressure (IOP) remains the only modifiable risk factor in the disease process. The demand for glaucoma care and IOP reduction is expected to rise as the population continues to age. Current treatment methods for IOP reduction include topical agents, laser procedures, and incisional surgeries that either decrease aqueous humor production or increase its outflow.

The juxtacanalicular trabecular meshwork (TM) is the primary site of resistance to aqueous outflow.[2] In an attempt to overcome this resistance, goniotomy or trabeculotomy have been used with success in congenital glaucoma.[3,4] These have classically been performed by incising TM ab externo with a trabeculotome or ab interno with a microvitreoretinal blade.[3,5] In adults, there have historically been mixed long-term results with these procedures, which is likely the result of incomplete removal of the TM and inflammation from damage to surrounding structures.[6] Therefore, traditional surgical procedures in adult glaucoma have sought to completely bypass the TM outflow pathway through the creation of a subconjunctival filtration bleb. Although effective, these filtration surgeries are limited by failure through subconjunctival fibrosis or vision-threatening complications such as infection and hypotony from overfiltration.

Novel devices and surgical instrumentation have redirected recent attempts toward improving conventional outflow through the TM by goniotomy or trabeculotomy in adults.[7] The Kahook Dual Blade (KDB, New World Medical, Rancho Cucamonga, CA) is a novel goniotomy blade that was designed for a more complete removal of TM through a minimally invasive approach. After the tip is inserted through the TM, the ramp of the device gently stretches the TM and guides it toward the dual blades, which create parallel incisions, allowing excision of a strip of TM. The procedure achieves a near-complete removal of TM, instead of incision only, and avoids damage to surrounding structures.[8] Minimizing residual TM leaflets may lead to less fibrosis and potentially enhance outcomes after goniotomy in the adult population.

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Successful lowering of IOP has been demonstrated in perfusion studies of human cadaver eyes that underwent KDB goniotomy.[8] In previous clinical data published on the KDB, Greenwood et al[9] showed successful IOP lowering and a reduction in medication burden at 6 months with the use of the dual-blade goniotomy combined with phacoemulsification performed on 71 eyes. In this study, we present clinical data on the efficacy and safety of KDB goniotomy both as a combined procedure with cataract surgery and as a standalone procedure.

Methods

The Colorado Multiple Institutional Review Board approved this study. A retrospective chart review of all patients undergoing KDB goniotomy alone or in combination with phacoemulsification cataract surgery between 2015 and 2017 at the University of Colorado Health Eye Center was conducted. Inclusion criteria were age >18 years and a minimum follow-up of at least 1 month after surgery. All glaucoma subtypes and disease severities were included. Glaucoma severity was determined using the International Statistical Classification of Diseases and Related Health Problems, Ninth Revision (ICD9) criteria.[10] Patients were included regardless of previous glaucoma surgeries or lasers. Exclusion criteria included any patient <18 years of age and any additional glaucoma surgery performed at the time of KDB goniotomy alone or in combination with cataract surgery.

Patient demographics and ocular characteristics were gathered for each patient. Data were collected on IOP and number of medications at baseline and postoperatively at 1 day, at 1 week, and at months 1, 3, 6, and 12. Postoperative complications, including IOP spikes at 1 week, the presence or absence of hyphema, the time of presentation, time to resolution, and the use of systemic anticoagulants, were noted. An IOP spike was defined as an increase in IOP greater than 10 mmHg above baseline. Hyphema was defined as the presence of layered blood in the anterior chamber and time to resolution of hyphema as the number of days until there was no layered hyphema. Success was defined by IOP reduction of at least 20% and/or reduction in at least 1 glaucoma medication from baseline level to each follow-up time period.

Kahook Dual Blade Surgical Technique

Four different glaucoma-trained specialists (L.S., M.K., J.S., M.P.) performed all of the surgeries. If combined with phacoemulsification, the KDB goniotomy was performed after completion of uncomplicated cataract surgery with intraocular lens implantation. Carbachol was instilled into the anterior chamber upon completion of lens implantation to constrict the pupil. The primary clear corneal wound from the cataract surgery was utilized for the KDB procedure. If goniotomy was performed as a standalone procedure, a 1.0 mm keratome was used to make a clear corneal incision temporally and widened to 1.5 to 2.5 mm in width to allow entry of the blade and subsequent irrigation/aspiration handpiece. Hereafter, the procedures with and without phacoemulsification are identical. A cohesive viscoelastic was inserted into the anterior chamber to deepen the nasal anterior chamber angle. The patient's head was then rotated 30 to 45 degrees away from the surgeon while the microscope was tilted 30 to 45 degrees towards the surgeon. A Swan-Jacobs gonioprism was placed on the corneal surface with the nondominant hand to bring the TM into direct gonioscopic view. In cases of chronic angle closure, goniosynechialysis was first performed with the footplate of the KDB so as to access TM.

Table 1. Characteristics of Kahook Dual Blade Study Population

	N	%
Patients	143	
Gender		
Female	86	60.1%
Male	57	39.9%
Age, years		
Mean (SD)	71.5 (9.9)	
Median	73.0	
Range	32–90	
Total eyes	197	
Eyes		
Left	100	50.8%
Right	97	49.2%
Glaucoma severity		
Mild	51	25.9%
Moderate	70	35.5%
Severe	51	25.9%
Indeterminate	25	12.7%
Glaucoma type		
Primary open-angle	141	71.6%
Pseudoexfoliation	33	16.8%
Pigmentary	7	3.5%
Steroid-induced/uveitic	6	3.0%
Closed-angle	3	1.5%
Low-tension	3	1.5%
Ocular hypertension	3	1.5%
Traumatic	1	0.5%

The dominant hand was used to insert the KDB through the temporal corneal wound and advance the blade to the nasal angle. The tip of the KDB would then pierce the TM, and the heel was seated within the canal of Schlemm. The blade was advanced within the canal to allow the dual blades to create parallel incisions along the TM, resulting in excision of approximately 3 to 5 clock hours of TM. The strip of TM was either removed with intraocular forceps or during irrigation/aspiration of the viscoelastic. The blade was removed from the eye, and irrigation/aspiration was used to remove the remaining viscoelastic from the eye. All wounds were hydrated and checked to ensure water-tight closure. If necessary, a 10-0 nylon suture was placed through the main wound to achieve water-tight closure. Postoperatively, patients were started on a standard regimen of 1% prednisolone acetate suspension, 0.5% moxifloxacin solution, 0.5% ketorolac solution, and 1% pilocarpine solution dosed 4 times a day for 1 week. After 1 week, moxifloxacin was discontinued, and the remaining 3 medications were tapered off over the following 3 to 4 weeks. In standalone KDB surgeries, the same postoperative regimen was used, except that ketorolac was omitted.

Statistical Analysis

Percent changes in IOP were calculated by eye for each follow-up time (IOP at follow-up minus preoperative IOP, divided by preoperative IOP). A linear model with generalized estimating equations using an exchangeable correlation structure was used to compare the mean IOP and number of medications preoperatively and postoperatively. Given that patients could have surgery on either eye, this statistical method was used to adjust for correlation within patients who had surgery on 2 eyes. Follow-up IOP and medication burdens were compared with the preoperative time point for patients who had data at each particular follow-up time point. Means are reported with standard errors.

Table 2. Intraocular Pressure at Baseline and Follow-up Times for All Patients, Patients with Kahook Dual Blade Goniotomy Combined with Phacoemulsification Cataract Surgery, and Standalone Kahook Dual Blade Goniotomy Patients

	Preoperative	Day 1	Week 1	Month 1	Month 3	Month 6	Month 12
All patients							
Eyes, n	197	197	194	194	169	162	140
IOP, mean (SE)	17.3 (0.4)	13.6 (0.4)	17.2 (0.6)	14.8 (0.4)	13.7 (0.3)	14.2 (0.3)	13.9 (0.3)
P value		<0.0001	0.9204	<0.0001	<0.0001	<0.0001	<0.0001
KDB/phaco							
Eyes, n	165	165	162	162	143	139	124
IOP, mean (SE)	16.7 (0.4)	13.7 (0.5)	17.5 (0.7)	14.3 (0.4)	13.5 (0.3)	13.9 (0.3)	13.8 (0.4)
P value		<0.0001	0.1949	<0.0001	<0.0001	<0.0001	<0.0001
KDB only							
Eyes, n	32	32	32	32	26	23	16
IOP, mean (SE)	20.4 (1.3)	12.9 (0.9)	15.5 (1.3)	17.4 (1.7)	14.7 (0.8)	15.3 (0.8)	14.1 (0.9)
P value		<0.0001	<0.0028	<0.0780	<0.0001	<0.0001	<0.0001

IOP = intraocular pressure; KDB = Kahook Dual Blade goniotomy; KDB/phaco = Kahook Dual Blade goniotomy combined with phacoemulsification.

Surgery success was defined as IOP reduction of at least 20% and/or reduction in at least 1 glaucoma medication. Associations between potential predictors of surgery success (gender, age, type and severity of glaucoma) were tested with logistic regression modeling with generalized estimating equations. Owing to the number of tests, a Bonferroni adjustment was performed to correct for multiple comparisons, such that a P value <0.005 was considered statistically significant.

Results

A total of 197 eyes from 143 patients was included in the analysis. Thirty-two eyes underwent KDB goniotomy alone, and 165 eyes underwent KDB goniotomy combined with phacoemulsification cataract surgery (phaco-KDB). Patient demographics for the entire study population are presented in Table 1. The average patient age was 71 years (range, 32–90 years). Of the eyes undergoing goniotomy alone, 6 were phakic and the remaining 26 were pseudophakic. A wide range of glaucoma types were included. The most common subtypes were primary open-angle glaucoma (POAG; 71.6%) and pseudoexfoliation glaucoma (16.8%). In addition, surgeries were performed for 3 eyes with ocular hypertension.

As demonstrated, there was significant attrition from the cohort, which went from 197 eyes preoperatively to 140 eyes at month 12. The most common reason for attrition was being lost to follow-up, need for additional surgery, or following up with an outside provider. Follow-up rates were higher in the phaco-KDB group at 75.2% at 12 months, with only 50% of KDB-only patients following up at 12 months. Patients who followed up at 12 months did not differ from the original cohort in terms of gender, age, type of glaucoma, baseline IOP, and number of baseline medications.

In Tables 2 and 3, we include the mean IOP and mean number of glaucoma medications for all patients at baseline and during the course of follow-up, respectively. Apart from the mean IOP at week 1, there was a significant reduction in the mean IOP among all eyes, from 17.3 (standard error [SE] 0.4) mmHg (range, 8–33 mmHg) at baseline to 13.9 (SE 0.3) mmHg at 12 months. The mean number of glaucoma medications also dropped significantly, from a preoperative high of 2.1 (SE 0.1) to 1.6 (SE 0.1) at month 12. Table 4 includes success rates for each study group broken down by success parameter. At the 1-year mark in all eyes, 71.4% of eyes achieved surgical success by either or both measures of success. Of these, 29.3% of eyes had an IOP reduction ≥20% from baseline, 27.1% of eyes had a reduction of at least 1 medication, and 15.0% of patients met both criteria.

Table 3. Number of Glaucoma Medications at Baseline and Follow-up for All Patients, Patients with Kahook Dual Blade Goniotomy Combined with Phacoemulsification Cataract Surgery, and Standalone Kahook Dual Blade Goniotomy Patients

	Preoperative	Day 1	Week 1	Month 1	Month 3	Month 6	Month 12
All patients							
Eyes, n	197	197	194	194	169	162	140
No. meds, mean (SE)	2.1 (0.1)	1.5 (0.1)	1.6 (0.1)	1.1 (0.1)	1.3 (0.1)	1.4 (0.1)	1.6 (0.1)
P value		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
KDB/phaco							
Eyes, n	165	165	162	162	143	139	124
No. meds, mean (SE)	1.9 (0.1)	1.4 (0.1)	1.5 (0.1)	1.0 (0.1)	1.1 (0.1)	1.3 (0.1)	1.5 (0.1)
P value		<0.0001	<0.0028	<0.0001	<0.0001	<0.0001	0.0011
KDB only							
Eyes, n	32	32	32	32	26	23	16
No. meds, mean (SE)	3.1 (0.2)	1.7 (0.3)	1.8 (0.3)	1.4 (0.3)	2.1 (0.3)	2.2 (0.3)	2.3 (0.4)
P value		<0.0001	<0.0001	<0.0001	<0.0001	0.0012	0.0079

KDB = Kahook Dual Blade goniotomy; KDB/phaco = Kahook Dual Blade goniotomy combined with phacoemulsification; meds = medications.

Table 4. Success Rates at Follow-up for All Patients, Patients with Kahook Dual Blade Goniotomy Combined with Phacoemulsification Cataract Surgery, and Standalone Kahook Dual Blade Goniotomy Patients

	Day 1	Week 1	Month 1	Month 3	Month 6	Month 12
All patients						
Eyes, n	197	197	194	169	162	140
Any success	77.7%	66.5%	77.3%	79.9%	73.5%	71.4%
Success by both IOP and medications	30.5%	19.1%	23.7%	18.3%	14.8%	15.0%
Success by IOP only	26.9%	16.5%	20.1%	24.3%	25.9%	29.3%
Success by medications only	20.3%	30.9%	33.5%	37.3%	32.7%	27.1%
KDB/phaco						
Eyes, n	165	165	162	143	139	124
Any success	75.8%	63.6%	77.2%	80.4%	74.1%	71.8%
Success by both IOP and medications	23.6%	14.2%	22.8%	17.5%	13.7%	13.7%
Success by IOP only	29.7%	17.9%	21.6%	23.8%	25.9%	29.0%
Success by medications only	22.4%	31.5%	32.7%	39.2%	34.5%	29.0%
KDB only						
Eyes, n	32	32	32	26	23	16
Any success	87.5%	81.2%	78.1%	76.9%	69.9%	68.8%
Success by both IOP and medications	65.6%	43.8%	28.1%	23.1%	21.7%	25.0%
Success by IOP only	12.5%	9.4%	12.5%	26.9%	26.1%	31.2%
Success by medications only	9.4%	28.1%	37.5%	26.9%	21.7%	12.5%

IOP = intraocular pressure; KDB = Kahook Dual Blade goniotomy; KDB/phaco = Kahook Dual Blade goniotomy combined with phacoemulsification. Success defined by IOP reduction of at least 20% or reduction in at least 1 glaucoma medication.

For both the phaco-KDB and KDB-alone groups, there was a sustained reduction in mean IOP and medications over the course of follow-up, with the exception of week 1 for phaco-KDB and month 1 for KDB only (Table 2). Figures 1 and 2 illustrate the change in mean IOP and glaucoma medication use, respectively, over the course of follow-up for each group. In the phaco-KDB group at 12 months (n = 124), mean IOP was significantly reduced, from 16.7 (SE 0.4) mmHg on 1.9 (SE 0.1) medications to 13.8 (SE 0.4) mmHg on 1.5 (SE 0.1) medications, with 71.8% surgery success. In the KDB-alone group at 12 months (n = 16), mean IOP was significantly reduced, from 20.4 (SE 1.3) mmHg on 3.1 (SE 0.2) medications to 14.1 (SE 0.9) mmHg, with 68.8% surgery success. At 12 months, patients were on an average of 2.3 (SE 0.4) medications; however, given the low number of patients at 12 months, this reduction was not statistically significant after Bonferroni adjustment.

Success rates did not differ at the 12-month time points by gender or age. The success rate was 77.1% in mild glaucoma, 68.1% in moderate glaucoma, 60.0% in severe glaucoma, and 77.8% in indeterminate glaucoma. These differences between glaucoma severity were not significant. Among glaucoma subtypes, success was highest in pseudoexfoliation glaucoma (84.6%) and lowest for POAG (66.0%), yet this difference did not reach statistical significance after Bonferroni correction ($P = 0.03$). Baseline IOP and number of preoperative medications did not significantly predict surgery success.

In the phaco-KDB group, mean (SE) logMAR visual acuity was significantly improved at 12 months, from 0.340 (0.03) to 0.184 (0.02), $P < 0.0001$. In the KDB-alone group, mean (SE) visual acuity was unchanged from baseline at 12 months (0.306 [0.09] and 0.218 [0.07], respectively, $P = 0.244$). No patient in the KDB-alone group had a decrease of 2 or more Snellen lines of visual acuity at 12 months compared with baseline. There were 2 patients in the phaco-KDB group that lost greater than 2 lines of Snellen visual acuity; 1 had cystoid macular edema, and the other developed a central retina vein occlusion.

Complications included postoperative IOP spike and hyphema. IOP spike occurred in 2 eyes at postoperative day 1 and 20 eyes at week 1. Most IOP spikes were controlled with topical and oral antihypertensive agents as needed. Three IOP spikes occurred with an associated hyphema, 1 requiring anterior chamber washout on postoperative day 2 for control. Four patients underwent additional surgery for uncontrolled IOP within the first postoperative month: Ahmed valve (n = 2) and EX-PRESS glaucoma drainage device (n = 2) at 3 weeks follow-up. There was no relation between IOP spikes and surgical failure at 12 months or need for further surgical intervention.

Hyphema occurred in 17.3% of patients, with the majority (30 of 34) noted on postoperative day 1. The additional 4 presented within 1 week of the surgery. Hyphemas took an average of 6.8 days to resolve (range, 3–14 days). Patients on anticoagulants

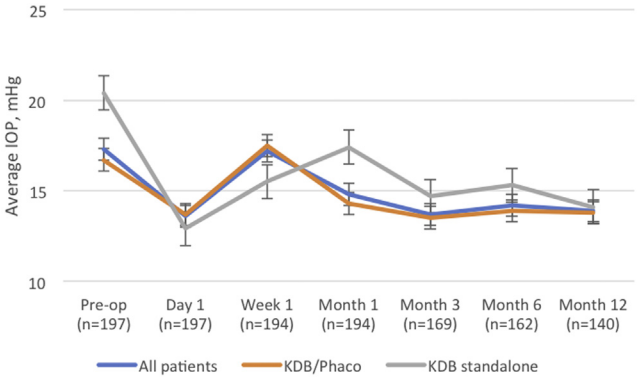

Figure 1. Average intraocular pressure in all patients, Kahook Dual Blade (KDB) goniotomy combined with phacoemulsification cataract surgery (phaco-KDB) group, and standalone KDB group with or without intraocular pressure (IOP)–lowering medications. Error bars represent standard error.

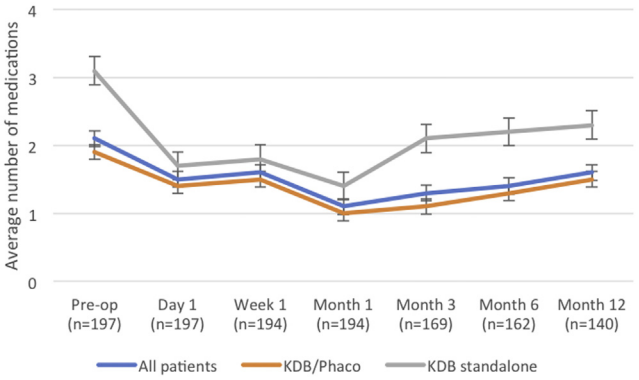

Figure 2. Average number of glaucoma medications in all patients, Kahook Dual Blade (KDB) goniotomy combined with phacoemulsification cataract surgery (phaco-KDB) group, and standalone KDB group. Error bars represent standard error.

(20.8%) had a higher rate of hyphema (24.4%) than patients not taking an anticoagulant (15.4%); however, this difference was not statically significant ($P = 0.19$). Only 1 patient required an anterior chamber washout for a hyphema with concurrent elevated IOP. There were no vision-threatening complications such as endophthalmitis, hypotony, or phthisis.

Discussion

In this study, we demonstrate the utility of KDB goniotomy as an effective and safe angle-based glaucoma procedure in adults and provide the first published results of procedure outcomes as a standalone procedure. KDB goniotomy achieved significant lowering of IOP and reduction in medication burden both as a standalone procedure and in combination with phacoemulsification cataract surgery. The procedure achieved success in a majority of eyes (71%) across a variety of glaucoma subtypes and severities. The IOP-lowering effects were seen early after the procedure and results were maintained at 12 months of follow-up for all groups.

We speculate that this IOP-lowering effect may be secondary to a near-complete removal of TM while avoiding damage to surrounding structures. The limited inflammation of surrounding tissue and near-absent TM remnants reduce the risk of scarring or closure of the opening created into the canal of Schlemm. In a preclinical study of perfused cadaver eyes at our institution, the KDB was shown to be successful in reducing IOP and removing TM.[8] In the first published clinical data, there was an average 26.4% decrease in IOP at 6 months with KDB goniotomy combined with phacoemulsification. In addition, the study showed a significant decrease in medication burden at 6 months.[9] In our study, we found a similar level of reduction in mean IOP for the combined procedure with longer follow-up. Furthermore, the IOP-lowering efficacy of KDB alone was similar to that of the phaco-KDB group. This finding is key to validate the effect of KDB goniotomy in isolation from the known IOP-lowering effect of phacoemulsification cataract surgery alone.[11] However, it should be noted that our sample size at 1 year for the KDB-alone group was limited to only 16 patients.

This study population included multiple forms of glaucoma, with POAG being the most common. Although the sample sizes were not adequate to show a significant difference in success after Bonferroni adjustment, pseudoexfoliative eyes achieved an 84.6% success rate in our study. Other studies have suggested that this is owing to the removal of TM and pseudoexfoliative material, which is known to obstruct outflow at the level of the TM.[12] The final mean IOP of 13.9 mmHg at 12 months for all eyes was not surprising. Although the TM has been identified as the primary outflow obstruction, outflow is still subject to episcleral venous pressure (EVP). Average EVP is around 8 to 10 mmHg[13] and is not bypassed with the KDB procedure. Although KDB goniotomy was successful in all severities of glaucoma, it will not replace traditional filtering procedures that bypass EVP and may reduce IOP below physiologic EVP levels.

There have been several recent advancements in the ab interno approach to angle surgery. Ab interno angle surgery, like the KDB goniotomy, offers a number of advantages over filtration surgery in terms of safety, surgical time, and recovery time, and only requires a small clear corneal incision to perform. These angle-based procedures can thus be easily performed at the time of cataract surgery.[14] One unique feature of the KDB is that it can be performed at the time of cataract surgery or as a standalone procedure. Other ab interno glaucoma procedures are approved to be performed only at the time of cataract surgery. Thus, given the success with and without phacoemulsification, KDB goniotomy is a viable treatment for both phakic and previously pseudophakic patients. This provides an additional IOP-lowering procedure for glaucoma specialists and comprehensive ophthalmologists for a wide variety of patients.

In addition to excellent IOP-lowering efficacy, KDB goniotomy resulted in few complications in this clinical review. In contrast to other angle-based surgeries involving implants, KDB goniotomy does not contain inherent device risks such as obstruction or dislodgement. Hyphema was the most common postoperative finding, occurring in 17.3% of patients. The majority of hyphemas were noted on postoperative day 1 and resolved within 7 days of presentation. It was rarely associated with an increase in IOP and had no effect on best-corrected visual acuity once cleared. Intraoperative blood reflux and postoperative hyphema are common with any angle-based glaucoma procedure.

Despite a slight trend for more hyphemas in anticoagulated patients, our study failed to identify this as a significant risk factor for hyphema postoperatively. Patients were not asked to stop their anticoagulant use before the surgery. These findings might be skewed, as patients on therapeutic anticoagulation may have been selected by the surgeon for another procedure with a lower risk of postoperative hyphema. Given low rates of hyphema overall, more patients on anticoagulation will likely undergo KDB goniotomy, and the relationship should be further assessed.

The hyphema rate noted with KDB goniotomy is notably less than other angle-based surgeries. This may be attributable in part to variation in reporting, use of viscoelastic, and

definition of hyphema, ranging from microhyphema to layered hyphema. In 2 studies of gonioscopy-assisted transluminal trabeculotomy outcomes, 1-day hyphema rates were not reported, but at 1 week the hyphema rates were 30% and 38%, with the majority resolving within 1 month.[15,16] Hyphema was very common for ab interno trabeculectomy using Trabectome (Neomedix, Inc., Tustin, CA), with 1 study finding that 100% of patients developed a hyphema, which resolved in 1 to 7 days.[17] By comparison, iStent trabecular micro-bypass (Glaukos Corp., Laguna Hills, CA) studies often do not report hyphema or show rates less than 5%; however, 1 study found a hyphema rate of 70% at postoperative day 1. This study, however, only included 10 eyes.[18–20]

The limitations of this study include the retrospective nature, lack of long-term follow-up, and small sample size. Given that this was a retrospective study, there was no randomization and patients were selected as good candidates for this procedure. In addition, the majority of the patients underwent combined phaco-KDB. The KDB-alone group population was relatively smaller, yet still provides the first data on standalone outcomes with KDB. Lastly, there was limited follow-up at 12 months. The same original cohort will continue to be followed to better assess the duration of IOP-lowering effect at each time point and beyond the 1 year time point, as follow-up time continues to accrue. In addition, future prospective, controlled, and randomized studies will be crucial to validate the clinical results demonstrated here.

In conclusion, KDB goniotomy is an effective ab interno procedure for the reduction of IOP and/or medication burden in glaucomatous eyes. The procedure has an excellent safety profile, consistent with other ab interno procedures, yet has similar efficacy whether performed in conjunction with phacoemulsification cataract surgery or as a standalone procedure and across disease severities.

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Conception and design: Sieck, Epstein, Kennedy, Patnaik, Wagner, Lynch, Kahook, Seibold

Data collection: Sieck, Epstein, Kennedy, SooHoo, Pantcheva, Seibold

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Abbreviations and Acronyms:
EVP = episcleral venous pressure; **IOP** = intraocular pressure; **KDB** = Kahook Dual Blade; **POAG** = primary open-angle glaucoma; **SE** = standard error; **TM** = trabecular meshwork.

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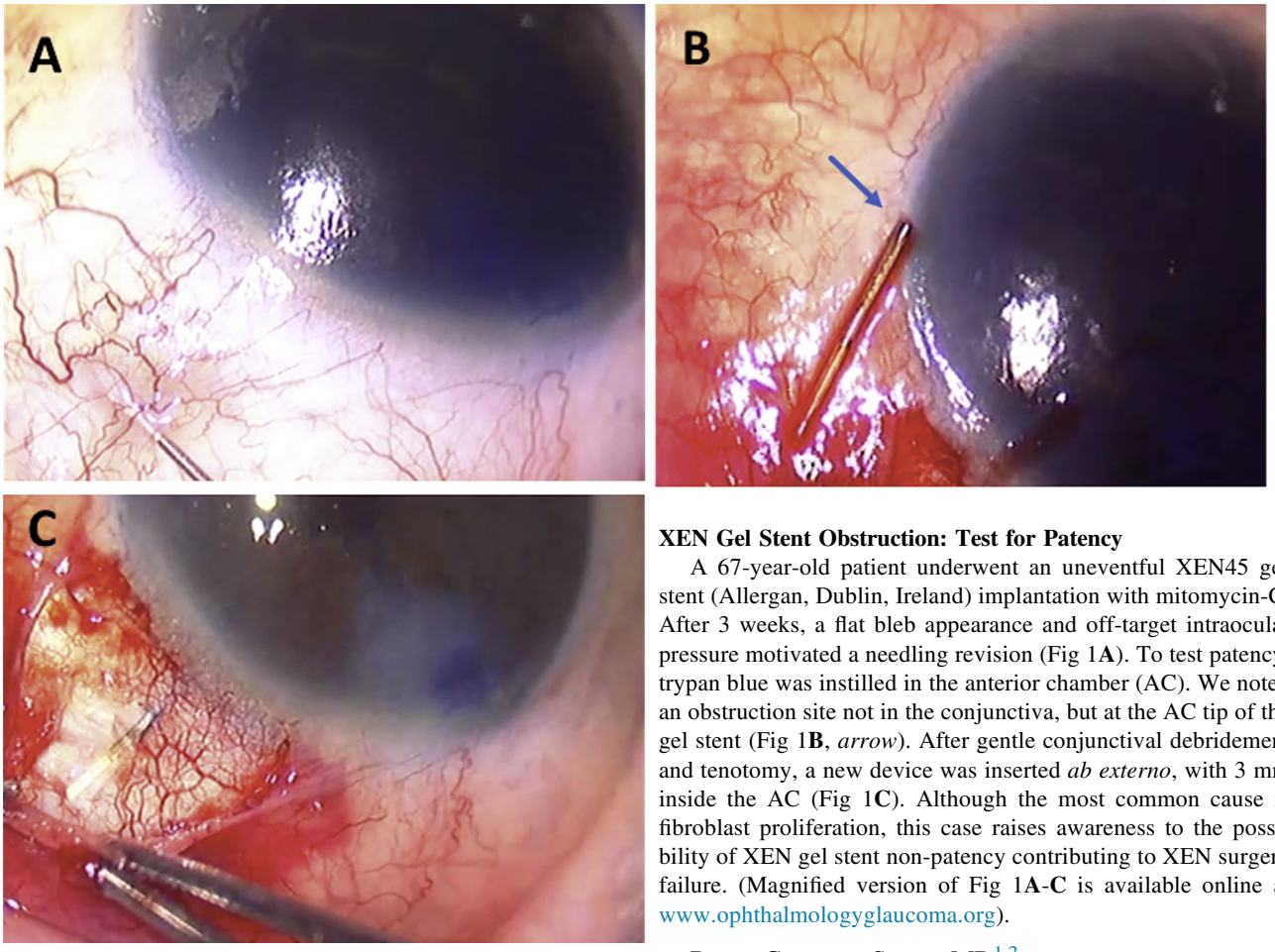
Pictures & Perspectives



XEN Gel Stent Obstruction: Test for Patency

A 67-year-old patient underwent an uneventful XEN45 gel stent (Allergan, Dublin, Ireland) implantation with mitomycin-C. After 3 weeks, a flat bleb appearance and off-target intraocular pressure motivated a needling revision (Fig 1**A**). To test patency, trypan blue was instilled in the anterior chamber (AC). We noted an obstruction site not in the conjunctiva, but at the AC tip of the gel stent (Fig 1**B**, *arrow*). After gentle conjunctival debridement and tenotomy, a new device was inserted *ab externo*, with 3 mm inside the AC (Fig 1**C**). Although the most common cause is fibroblast proliferation, this case raises awareness to the possibility of XEN gel stent non-patency contributing to XEN surgery failure. (Magnified version of Fig 1**A**-**C** is available online at www.ophthalmologyglaucoma.org).

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