

Goniotomy with a single-use dual blade: Short-term results



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Purpose: To evaluate the intraocular pressure (IOP)-lowering efficacy and safety of a single-use dual blade (Kahook) in patients with mild to end-stage glaucoma.

Setting: International multicenter ophthalmic care centers.

Design: Prospective interventional case series.

Methods: Consecutive patients with glaucoma who had phacoemulsification plus goniotomy with the single-use dual blade were enrolled in this study. Each center collected deidentified clinical data, including preoperative and postoperative IOP, medication use, adverse events, and whether additional surgery was required during a 6-month follow-up.

Results: Of the 71 eyes included in this study, 70% had primary open-angle glaucoma. Other diagnoses included angle-closure,

pigmentary, pseudoexfoliative, and normal-tension glaucoma. Sixty-five percent of eyes were classified as having mild to moderate glaucoma and 35%, severe glaucoma. The mean baseline IOP decreased from 17.4 mm Hg \pm 5.2 (SD) to 12.8 \pm 2.6 mm Hg 6 months postoperatively and the hypotensive medication use decreased from 1.6 \pm 1.3 to 0.9 \pm 1.0, respectively ($P < .001$ and $P = .005$, respectively). The most common observation was blood reflux during surgery (39.4%).

Conclusion: Single-use dual blade goniotomy plus phacoemulsification resulted in a significant and sustained reduction in IOP and a decrease in glaucoma medications after 6 months of follow-up.

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At present, the treatment of glaucoma involves lowering intraocular pressure (IOP) pharmacologically, by laser, with incisional surgery, or a combination. The trabecular meshwork, in particular the juxtacanalicular portion adjacent to Schlemm canal, along with more distal outflow structures are considered to be the main sites of resistance to aqueous outflow.^{1–3} Although the reasons for this are unclear, they might be related to changes in trabecular meshwork composition with age. In theory, incising or removing trabecular meshwork should lower this resistance, leading to improved IOP control.⁴ Rather than an incision through the trabecular meshwork, more complete tissue removal could allow the surgically created opening to resist closure, yielding a more sustained reduction in IOP.

Preclinical studies have shown that nearly complete removal of the trabecular meshwork without damage to

adjacent tissues can be achieved with the single-use dual blade (Kahook, New World Medical, Inc.).⁵ The aim of this study was to assess the clinical experience with the single-use dual blade for performing goniotomy in adult glaucomatous eyes having cataract extraction with intraocular lens (IOL) implantation.

PATIENTS AND METHODS

Study Design

Consecutive patients who were age 18 years or older and had phacoemulsification in combination with goniotomy using the single-use dual blade were included in this international multicenter prospective observational study. Indications for goniotomy were a need for a reduction in IOP or a reduction in the reliance on IOP-lowering medications while avoiding the formation of a filtering bleb and its associated risk profile.

Baseline and operative data were collected on the day of surgery, and the clinical course was assessed 1 day, 1 week,

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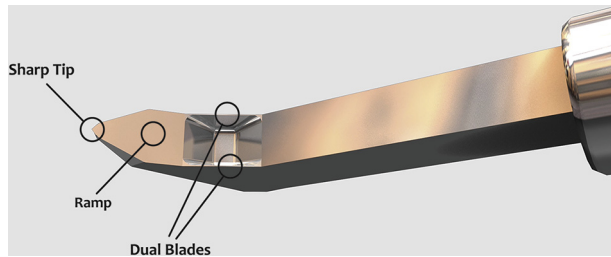


Figure 1. Schematic of the single-use dual blade.

and 1, 3, 6, and 12 months postoperatively. Data collected included glaucoma type and severity using the Hodapp-Parrish-Anderson disease classification system,⁶ IOP, medication use, operative details, adverse events, postoperative course, and surgeon experience using the device. No personal identifying data were collected; a deidentified dataset was analyzed. This study included data through 6 months of follow-up. Demographic data were not collected in this deidentified dataset in accordance with the U.S. Health Insurance Portability and Accountability Act requirements.

Single-Use Dual Blade

The Kahook single-use dual blade (Figure 1) has a sharp distal tip designed for smooth entry of the blade through the trabecular meshwork and into Schlemm canal. After the blade is properly seated against the anterior wall of the canal, the device is advanced along the trabecular meshwork and a ramp, which rises from the distal tip, elevates trabecular meshwork tissue above its natural position, and guides the tissue toward 2 blades (Figure 2). The blades then create parallel incisions in the trabecular meshwork for removal of an intact trabecular meshwork strip. According to the manufacturer, elevating the trabecular meshwork above its natural position and stretching it before cutting it removes the tissue more cleanly and minimizes damage to adjacent structures. The angle of the distal cutting surface and the size of the device shaft were designed to allow maximum angle treatment through a single clear corneal incision (CCI). Although intended for use as a stand-alone treatment for removing trabecular meshwork in eyes requiring a goniotomy, the single-use dual blade can also be used to perform a goniotomy in combination with other intraocular surgical procedures such as cataract extraction.

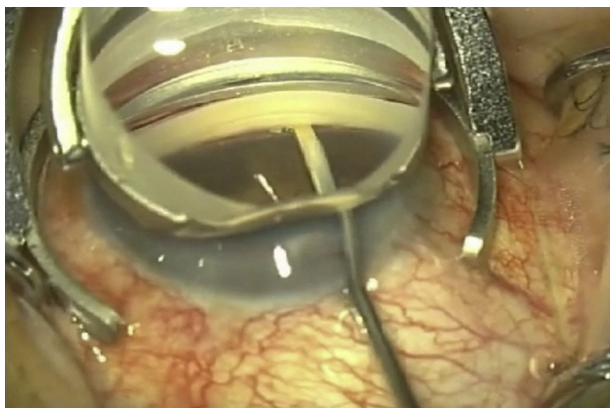


Figure 3. The dual blade is being advanced in Schlemm canal under gonioscopic view.

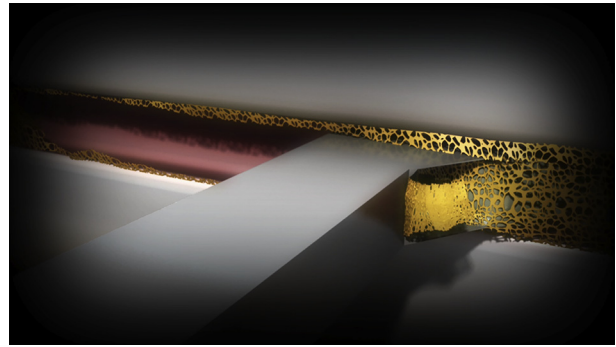


Figure 2. The dual blades are used to cut trabecular meshwork.

Surgical Technique

The single-use dual blade portion of the procedure was performed as follows: The device was introduced via the temporal CCI used for phacoemulsification and IOL placement. If necessary, additional ophthalmic viscosurgical device (OVD) was used to provide clearance and maintenance of the anterior chamber. The patient's head was rotated 30 to 45 degrees away from the surgeon, and the microscope was tilted 30 to 45 degrees toward the surgeon. A direct gonioscope was placed on the cornea with the nondominant hand and the anatomic landmarks, including the trabecular meshwork, were brought into focus. The dual blade was then inserted through the CCI with the dominant hand. The tip of the dual blade was used to pierce the trabecular meshwork, and the footplate heel was seated against the anterior wall of Schlemm canal. The device was then advanced along Schlemm canal in a clockwise or counterclockwise manner (Figure 3). After sufficient trabecular meshwork removal was performed in 1 direction, the dual blade was rotated 180 degrees and the tip of the dual blade was positioned a few clock hours away from the original location that was treated. The device was advanced again until the previously treated trabecular meshwork was reached and a free-floating trabecular meshwork strip was created so that the back of Schlemm canal was visible (Figure 4). The dual blade was then removed from the eye and the free-floating trabecular meshwork was removed with an intraocular forceps or aspirated with the irrigation/aspiration handpiece during removal of the OVD.

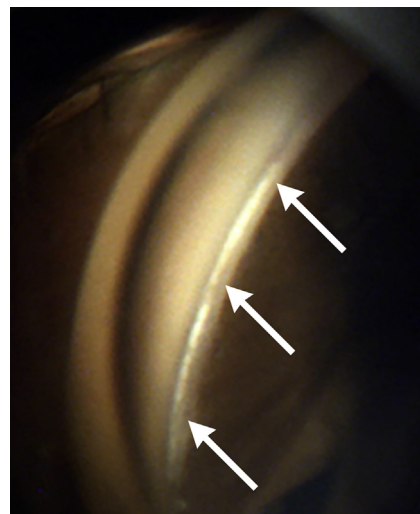


Figure 4. The anterior wall of Schlemm canal (white tissue indicated by the white arrows) is visible after the trabecular meshwork was excised with the dual blade.

Table 1. Mean IOP over time.

Parameter	Preop	Postop				
		1 Day (1–3 Days)	1 Wk (4–14 Days)	1 Mo (15–59 Days)	3 Mo (60–120 Days)	6 Mo (121–270 Days)
Eyes (n)	71	60	59	67	58	60
Mean IOP (mm Hg) \pm SD	17.4 \pm 5.2	13.3 \pm 3.9	13.5 \pm 4.8	13.7 \pm 3.6	12.5 \pm 2.7	12.8 \pm 2.6
Mean difference (mm Hg)	Reference	–4.1*	–3.9*	–3.7*	–4.9*	–4.6*
IOP change (%)	Reference	24	22	21	28	26

IOP = intraocular pressure

* $P < .001$ compared with preoperative measurement

Postoperative Medications and Follow-Up

Postoperatively, patients were managed per each surgeon's preferred protocol, which was relatively consistent across centers. This typically included a topical fourth-generation fluoroquinolone, a steroid, and a nonsteroidal antiinflammatory drug (NSAID). These medications were given primarily in the form of topical drops; however, intracameral drugs or a combination of topical and intracameral drugs were used in a few eyes. Because this was an observational study, medication addition or removal was based on clinical judgment, and there were no specific guidelines to determine when to add or discontinue ocular hypotensive medications.

Outcome Measures

The primary outcome measure in the study was IOP reduction measured by Goldmann applanation tonometry and the proportion of patients achieving an IOP reduction of more than 20% from baseline. Secondary outcome measures included the number and type of ocular hypotensive medications and the proportion of patients whose regimen decreased by more than 1 medication. The safety of the procedure was assessed using descriptive analysis of adverse events observed by the surgeon, reported by the patient, or both; this included whether a reoperation was necessary. The surgeon's experience with the single-use dual blade was assessed by asking surgeons to indicate whether they strongly agreed, agreed, were undecided/neutral, disagreed, or strongly disagreed with the following 3 statements: (1) Performing goniotomy with the single-use dual blade was straightforward. (2) Entry into Schlemm canal with the single-use dual blade was uncomplicated. (3) Once in Schlemm canal, advancement of the single-use dual blade in the canal was efficient.

Statistical Analysis

Longitudinal IOP and IOP medication reduction from baseline were assessed using mixed modeling with a diagonal covariance matrix, adjusted for multiplicity using the Bonferroni method. Mixed models ($\alpha = 0.05$) were used for analyses with adjustment for multiple comparisons with a Bonferroni significant at $\alpha 0.05$. The proportion of patients meeting success criteria (IOP reduction more than 20%, medical regimen reduced by more than

1 medication) at each timepoint was determined using descriptive statistics. Statistical analysis was performed with SPSS statistics software (version 24.0, IBM Corp.).

RESULTS

This study included data from 71 eyes of patients. Eight surgeons who were experienced with angle-based surgery participated in the study. Of the 71 eyes, 50 (70%) had primary open-angle glaucoma (OAG), 12 (17%) had angle-closure glaucoma, 4 (6%) had pigmentary glaucoma, 2 (3%) had pseudoexfoliative glaucoma, and 3 (4%) had normal-tension glaucoma. The glaucoma was classified as mild in 30 eyes (42%), as moderate in 16 eyes (23%), and as severe in 25 eyes (35%).

The mean amount of trabecular meshwork excised was 118.9 degrees \pm 18.6 (SD). The trabecular meshwork was removed from the anterior chamber in 65 (91.5%) of the cases with the remaining cases having successful goniotomy with some degree of residual trabecular meshwork tethered in the angle.

Tables 1 and 2 and Figures 5 and 6 show the mean IOP and number of medications at each visit. The mean IOP and the mean number of hypotensive medications decreased significantly from baseline to 6 months postoperatively ($P < .001$ and $P = .005$, respectively). Table 3 shows the proportion of patients who had a reduction in IOP of 20% or more from baseline and the proportion whose regimen was reduced by 1 medication or more at each timepoint.

The safety profile of the single-use dual blade was favorable. Table 4 shows the adverse events, the most common of which was intraoperative blood reflux from collector channels. The reflux resolved spontaneously in all cases. An IOP spike higher occurred at 1 week in 1 case and at 1 month in another case; 1 eye was treated

Table 2. Mean medication use over time.

Parameter	Preop	Postop				
		1 Day (1–3 Days)	1 Wk (4–14 Days)	1 Mo (15–59 Days)	3 Mo (60–120 Days)	6 Mo (121–270 Days)
Eyes (n)	71	60	59	67	58	60
Mean medication (n) \pm SD	1.6 \pm 1.3	0.5 \pm 0.9	0.6 \pm 1.0	0.7 \pm 0.9	0.9 \pm 1.1	0.9 \pm 1.0
Mean difference (n)	Reference	–1.1*	–1.0*	–0.9*	–0.7*	–0.7*

* $P = .005$ compared with preoperative measurement

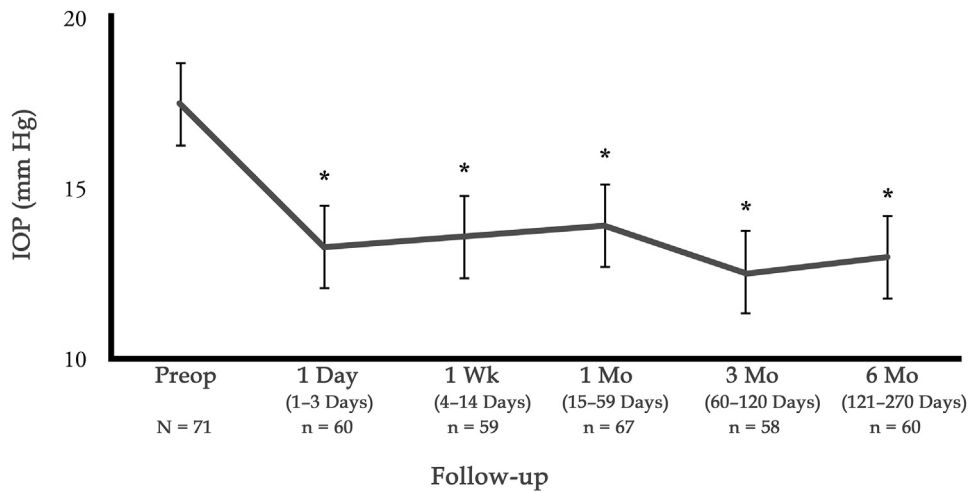


Figure 5. Mean IOP with 95% confidence intervals over time (N = 71) (* = statistically significant compared with baseline [$P < .001$]; IOP = intraocular pressure).

with topical IOP-lowering medication, and the other resolved with observation.

In 69 cases (98%), surgeons strongly agreed or agreed that the use of the single-use dual blade was straightforward and that advancement of the dual blade along the canal was efficient. In 68 cases (96%), surgeons strongly agreed or agreed that entry into the canal with the dual blade was uncomplicated.

DISCUSSION

Goniotomy with the Kahook single-use dual blade successfully reduced IOP and decreased medication dependence over the 6-month follow-up. The treated eyes had mild to end-stage glaucoma, and the goniotomy procedure was successfully combined with cataract extraction in all cases. Given that most of the obstruction of aqueous outflow from the anterior chamber appears at the level of the trabecular meshwork, removal of this diseased tissue is a natural target for surgeons seeking to lower pressure without resorting to full-thickness drainage procedures.¹⁻³ The results in this study support the early safety and efficacy of goniotomy with the

single-use dual blade and provide direction for further evaluation.

Studies⁷⁻⁹ have shown that phacoemulsification alone in patients with OAG can reduce IOP by 2 mm Hg, and the reduction seems to be proportional to the preoperative IOP. Our results indicate that the single-use dual blade procedure when combined with cataract surgery can provide a significant pressure reduction as shown by the mean decrease of 4.6 mm Hg 6 months postoperatively. This was a 26.4% decrease from baseline, with 58.3% of patients having a decrease of 20% or more. The mean baseline IOP was 17.4 mm Hg. In such cases, achieving a greater IOP-lowering effect can be difficult because the episcleral venous pressure.

In addition to the reduction in IOP, there was a significant decrease in the mean number of topical glaucoma medications from baseline to 6 months postoperatively. Patient compliance with topical medications continues to be a significant concern for most eye-care providers; reducing the requirement for topical medications minimizes this concern while alleviating the burden for patients postoperatively. In addition, the reduction in medications for chronic topical glaucoma might improve patients' ocular

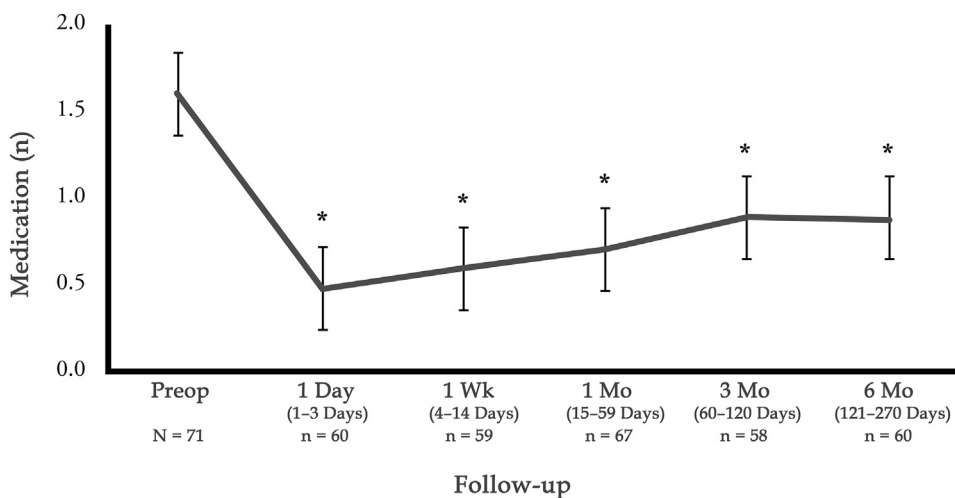


Figure 6. Mean number of glaucoma medications with 95% confidence intervals over time (N = 71) (* = statistically significant compared with baseline [$P = .005$]; IOP = intraocular pressure).

Table 3. Patients who met the success criteria for IOP reduction and a decrease in medication use postoperatively.

Parameter	1 Day (1–3 Days)	1 Wk (4–14 Days)	1 Mo (15–59 Days)	3 Mo (60–120 Days)	6 Mo (121–270 Days)
Eyes (n)	60	59	67	58	60
IOP reduction \geq 20% from baseline, n (%)	30 (50)	31 (52.5)	33 (49.3)	37 (63.8)	35 (58.3)
Using \geq 1 fewer medications from baseline, n (%)	36 (60)	37 (62.7)	40 (59.7)	36 (62.1)	37 (61.7)

IOP = intraocular pressure

surface by eliminating a source of inflammation.¹⁰ In our study, 66.2% of patients were using 1 or fewer medications and 61.7% eliminated 1 or more medications between baseline and 6 months postoperatively. Only 25.4% had no change in medications at 6 months.

Because this was an observational study, there was no preoperative washout of medications, no control over when drops were started or stopped, and no control over which hypertensive medicines were started or discontinued first. The use of steroids or NSAIDs as well as of topical antibiotics was not uniform across the study, although it was similar across sites. The study also lacked an active control group, consistent with its design as a descriptive study rather than a hypothesis-testing trial.

The findings in this study show a sustained IOP-lowering effect after phacoemulsification combined with single-use dual blade–assisted goniotomy through 6 months postoperatively. In addition, the mean number of medications was significantly reduced through 6 months of follow-up. Further prospective studies are warranted to more fully characterize long-term efficacy and safety of the Kahook single-use dual blade combined with cataract extraction and to characterize the safety and efficacy of dual-blade goniotomy as a standalone procedure. These studies are ongoing and will be reported in the near future.

Table 4. Incidence of adverse events through 6 months of follow-up (71 eyes).

Adverse Event	Number (%)
Blood reflux	28 (39.4)
Difficulty removing TM strip	2 (2.8)
IOP spike	2 (2.8)
Irritation	2 (2.8)
PCO	2 (2.8)
Tearing	1 (1.7)
Corneal edema	1 (1.4)
CME	1 (1.4)
Dull pain	1 (1.4)
Floater	1 (1.4)
Glare	1 (1.4)
Hazy vision	1 (1.4)
Iridodialysis	1 (1.4)
Pain	1 (1.4)
PAS in quadrant	1 (1.4)
Tear in Descemet membrane	1 (1.4)

CME = cystoid macular edema; IOP = intraocular pressure; PAS = peripheral anterior synechia; PCO = posterior capsule opacification; TM = trabecular meshwork

WHAT WAS KNOWN

- Incising the trabecular meshwork, which is the site of greatest resistance for aqueous outflow, has resulted in mixed success in terms of reducing IOP. This is thought to be the result of incomplete removal of the trabecular meshwork and the formation of membranes across the remaining trabecular meshwork leaflets.

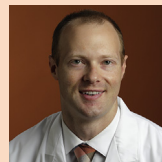
WHAT THIS PAPER ADDS

- Goniotomy using the single-use dual blade resulted in more complete removal of the trabecular meshwork, reducing IOP and the amount of IOP-lowering medications.
- Although designed for use as a standalone IOP-lowering procedure, goniotomy using the single-use dual blade can also be successfully combined with cataract extraction surgery.

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