Goniotomy Using the Kahook Dual Blade in Severe and Refractory Glaucoma: 6-Month Outcomes

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Purpose: The purpose of the study is to describe short-term efficacy and safety of goniotomy with trabecular meshwork excision using the Kahook Dual Blade (KDB, New World Medical Inc., Rancho Cucamonga, CA) in patients with severe or refractory glaucoma.

Method: Retrospective multicentric case series of 53 eyes with severe or refractory glaucoma as defined by ICD-10 conducted in the United States, Mexico, and Switzerland. Primary efficacy outcome was a $\geq 20\%$ decrease in intraocular pressure (IOP) from baseline at 6 months. Secondary efficacy outcome measures were probability of achieving an IOP ≤ 14 or 18 mm Hg at 6 months and the mean IOP change from baseline at 6 months. Medication use required to obtain target IOP at last follow up and adverse effects were analyzed.

Results: The proportion of eyes achieving an IOP reduction of $> 20\%$ from preoperative baseline at 6 months was 57.7% (n = 30). The mean IOP decreased from 18.4 ± 6.1 mm Hg at baseline to 13.9 ± 3.5 mm Hg at month 6 (23.9% reduction; $P < 0.001$). At 6 months, 63.5% and 92.3% achieved an IOP ≤ 14 and ≤ 18 mm Hg, respectively, and the mean number of glaucoma medications was reduced by 1.2 ± 1.3 (36.6%) compared with baseline ($P < 0.001$). The most common adverse event was hyphema (n = 29, 34.9%) with spontaneous resolution in all cases. No severe complications were reported. One case presented with uncontrolled IOP and required glaucoma drainage device surgery at 1 month.

Conclusions: Goniotomy with trabecular meshwork excision using the KDB could be an alternative surgery for severe or refractory glaucoma, significantly reducing IOP and medication use at 6 months, with a low rate of complications.

Key Words: Kahook dual blade, goniotomy, trabecular meshwork, severe glaucoma, refractory glaucoma, MIGS

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Glaucoma is a major cause of blindness in the world.[1] All available treatment options aim to lower intraocular pressure (IOP). These include medical treatment, laser procedures, and surgical treatment. Standard treatments of severe and refractory glaucoma include filtering surgery, glaucoma drainage devices (GDDs), and cyclodestructive procedures. These surgeries have an unfavorable safety profile, but generally provide a more effective IOP reduction than less invasive alternatives.[2] Trabeculectomy, deep sclerectomy, and GDDs result in bleb formation, with the risk of excessive scarring, leading to failure of surgery; or leakage, potentially leading to hypotony or infection.[2]

Recently, minimally invasive glaucoma surgeries (MIGS) were developed as an efficient and safer alternative to standard surgery for lowering IOP.[3] Some methods pursue the subconjunctival filtration pathway with the creation of a filtering bleb, whereas others avoid bleb formation by shunting aqueous humor through an enhanced the Schlemm canal by stents or routing aqueous into the suprachoroidal space. The trabecular microbypass stent (iStent; Glaukos Corps, San Clemente, CA) works by bypassing the trabecular meshwork (TM) and accessing directly the Schlemm canal. [4,5] It has been used since 2012 in the United States for the treatment of mild-to-moderate open-angle glaucoma, combining it with the cataract surgery. In July 2016, the Food and Drug Administration (FDA) approved a supraciliary microstent (CyPass Micro-Stent; Alcon, Fort Worth, TX) for mild-to-moderate primary open angle glaucoma in patients who require cataract surgery.[6] It creates a channel from the anterior chamber to the suprachoroidal space, bypassing the TM and the Schlemm canal. Another device, a gelatin stent (XEN 45 Gel Stent; Allergan plc, Dublin, Ireland) which provides an ab interno approach to the subconjunctival space, was cleared by the FDA in 2016 for the management of refractory glaucoma.[7,8] Most of these studies included patients with mild-to-moderate glaucoma. Currently, it is not known whether MIGS procedures are a viable alternative for the treatment of severe and refractory glaucoma.

The TM, particularly the juxta-canalicular TM adjacent to the Schlemm canal, along with more distal outflow structures are considered to be main sites of resistance to aqueous outflow.[9,10] In theory, incising or removing TM should lower IOP. Traditionally, trabeculotomy and goniotomy are used in the treatment of congenital glaucoma. Angle-based surgeries have a lower success rate in adult patients, which could be related to changes in TM composition with age or scarring.[11–13] The classic goniotomy knife is a microvitreoretinal blade, which incises the TM ab interno. It causes scleral injuries and exhibits minimal removal of TM. Rather than a simple incision through TM, a more complete tissue removal or ablation could allow the surgically created cleft to remain open, leading to more sustained IOP control. The Trabectome (NeoMedix, Tustin, CA) was approved by FDA in 2004 for the treatment of adult and juvenile open-angle glaucoma. It consists of an ab interno trabeculectomy, using a handpiece connected to a console that provides irrigation, aspiration and eletrocautery.[14] A meta-analysis found a reduction in IOP by approximately 36%, to a final average of around 16 mm Hg on <1 medication.[15] However, the relatively high cost of trabectome may be a barrier to its use in some settings, whereas it has been shown to cause thermal damage to nearby tissues.[16] Gonioscopy-assisted transluminal trabeculotomy (GATT), described in 2014, is a form of ab interno 360 degrees trabeculotomy. Grover et al[16] reported a case series with an IOP decrease of 30% and an average decrease in glaucoma medications of 0.9 ± 1.3 in POAG eyes at 12 months.

The Kahook Dual Blade (KDB, New World Medical Inc., Rancho Cucamonga, CA) is a recent device which aims to perform a safe and efficacious goniotomy with TM excision (GTE), minimizing collateral damage.[17] In 2015, it received FDA approval. It is designed with a taper at the tip to allow for smooth entry of the blade into the Schlemm canal. In contrast to a standard goniotomy knife, the KDB enters the Schlemm canal and excises a strip of TM. Once properly seated in the canal, the device is advanced along the TM. The ramp at the distal end of the instrument elevates TM tissue and guides it toward the blades on either side of the device, which then incises the tissue to allow for removal.[18] It can be used in combination with other surgical procedures such as cataract extraction.

The purpose of this study was to evaluate the short-term (6-month) efficacy and safety of GTE using the KDB in patients with severe or refractory glaucoma.

METHODS

Study Design

In this prospective and multicenter case series, data were collected from 11 surgeons in 11 centers in the United States, Mexico, and Switzerland using standardized deidentified data forms, from January to September 2017. Informed consent was obtained from all patients.

Participants

Consecutive patients included were aged 18 years or older. They presented with severe or refractory glaucoma and underwent GTE with a single-use dual blade. Severe glaucoma was defined by the ICD-10 definition as optic nerve abnormalities consistent with glaucoma, and glaucomatous visual field abnormalities in both hemifields and/or loss within 5 degrees of fixation in at least one hemifield.[19] Refractory glaucoma was defined as eyes with glaucoma that were uncontrolled by medical therapy and failed one or more incisional intraocular glaucoma surgeries/cycloablative procedures.[20]

Indication for GTE was the reduction of IOP and IOP-lowering medications. Gonioscopy was performed on each eye before surgery to ensure there was adequate visualization of the angle necessary for the GTE. Exclusion criteria were mild-to-moderate glaucoma, IOP < 6 mm Hg or > 40 mm Hg, a poor visualization of the angle, age below 18 years.

Single-Use Dual Blade

The Kahook Dual Blade has a microengineered profile which allows for insertion into the eye through a clear corneal microincision. The surgical grade stainless steel body is comprised of a long, thin shaft that allows for access across the anterior chamber. The device has a sharp distal tip designed for smooth entry of the blade through the TM and into the Schlemm canal. Its ramp rises from the distal tip, elevates and stretches the TM tissue, guiding it toward 2 parallel blades. The dual blades excise a strip of TM and the foot plate prevents damage to anterior wall of the canal and facilitates smooth motion. The device is described in more detail elsewhere.[21]

Surgical Technique

The surgical procedure was performed under topical anesthesia in the operation room. A clear corneal incision was made with a 15-degree knife temporally. Viscoelastic was injected in the anterior chamber and angle to provide clearance and maintenance of anterior chamber. For a better angle approach and visibility, 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 gonioprism was placed on the clear cornea and the surgeon identified the TM in the nasal quadrant. The KDB was then inserted through the incision and introduced into the Schlemm canal through the TM. The device was advanced along the Schlemm's canal and TM was removed in the nasal quadrant. After excising sufficient TM, the dual blade was rotated 180 degrees and positioned a few clock hours away from the original location previously treated. The reverse procedure was performed to meet the initial excision. The total treatment area was approximately 90 to 110 degrees. A floating strip of TM was created and visible in the angle, as well as the back of the Schlemm canal. The KDB was removed and the free-floating TM strip was aspirated by irrigation-aspiration handpiece during removal of the viscoelastic. The decision to hospitalize the patient for 1 day or to treat in ambulatory surgery, was at surgeon's discretion.

Postoperative Medications

There was no standardized preoperative and postoperative medication protocol. Patients were treated at the discretion of each surgeon. This typically included a topical antibiotic combined with a steroid or a nonsteroidal anti-inflammatory drug for 1 to 2 months after surgery, with the addition of necessary IOP-lowering medication or pilocarpine.

Assessments and Outcomes

After a preoperative visit (day 0), follow-up visits were scheduled at day 1, week 1 (7 ± 2 d), months 1 (28 ± 7 d), 3 (84 ± 14 d), and 6 (182 ± 14 d). Data collected at baseline were age, sex, ethnicity, glaucoma type, IOP, medication use, pachymetry, visual field parameters, mean retinal nerve fiber layer thickness (RNFL), and best-corrected visual acuity (BCVA) in logMAR. Baseline IOP was defined by

the preoperative visit IOP, without washout of medication. Data collected at each point follow up were IOP, adverse events, BCVA, and medication use. IOP was assessed using the Goldmann applanation tonometry and the IOP value represented the mean of 2 consecutive measurements. Fixed combination medications were documented according to the number of active ingredients.

Primary efficacy outcome measures were the proportion of eyes achieving an IOP reduction of $\geq 20\%$ at 6 months versus baseline medicated IOP. Success rate and the mean IOP change from baseline at 6 months were secondary efficacy outcome measures. The success criteria was defined as the proportion of patients achieving an IOP ≤ 14 or ≤ 18 mm Hg. Complete success was defined as an IOP ≤ 14 mm Hg or ≤ 18 mm Hg without any treatment. Qualified success was defined as an IOP ≤ 14 mm Hg, or ≤ 18 mm Hg with or without medical treatment. Failure was defined as an IOP > 14 mm Hg or > 18 mm Hg on two consecutive study visits or if a reoperation was necessary. Other secondary outcome measures included reduction in the number of IOP-lowering medications and the proportion of patients whose regimen decreased by > 1 medication. The safety of the procedure was assessed using descriptive analysis of adverse events observed by the surgeons.

Statistical Analysis

A sample size of 53 achieves 89.6% power to detect a difference (P1−P0) of 0.227 using a 2-sided binomial test. Descriptive statistics included mean and SD for normally distributed variables, and median and interquartile range (IQR) for variables that were not normally distributed. Categorical variables were described using percentages. The Kaplan-Meier survival curves were used to assess the cumulative probability of success. Two cut-off levels for calculation of success probabilities were used. Associations between failure and factors such as patient's age, sex, type of glaucoma, ethnicity, number of preoperative medications, and previous ocular procedures were assessed using a logistic regression model. All tests were 2-tailed and a P-value < 0.05 was considered statistically significant. This statistical analysis was performed using the SPSS version 17.0 software package (SPSS Inc., Chicago, IL).

RESULTS

Demographics, Baseline Characteristics

Data from 83 eyes of 74 patients were included, but overall 52 eyes of 45 patients were analyzed because of missing follow-up data. There were 19 men (42.2%) and 26 women (57.8%) and mean age was 74.5 ± 10.5 (range, 45 to 94). The majority of patients (n = 25, 55.6%) were Caucasian. Most eyes (n = 28, 62.2%) had primary open-angle glaucoma; 21 eyes (40.4%) were pseudophakic. Laser were previously performed in 15 eyes (28.8%), including 13 selective or argon laser trabeculoplasty and 2 goniopunctures. Twelve eyes (23.1%) had previous glaucoma surgery, including 3 combined phacoemulsification-glaucoma surgeries, 3 standalone trabecular microbypass stents, 2 GDDs, and 1 endocyclophotocoagulation.

Mean preoperative IOP was 18.4 ± 6.1 mm Hg (range, 7 to 39 mm Hg), using a mean [median (IQR)] number of 2.6 ± 1.1 [3 (2 to 3)] IOP-lowering medications. Median (IQR) visual acuity at baseline was 0.2 (0.1 to 0.5) logMAR. Preoperative data are presented in Table 1.

TABLE 1. Demographics and Baseline Ocular Parameters of the Study Population

Parameters	Total (53 Eyes of 45 Patients)
Age (y)	
Mean ± SD	74.5 ± 10.5
Range	Min 45; max 94
Sex [n (%)]	
Female	26 (57.8)
Male	19 (42.2)
Study eye [n (%)]	
Right	28 (53.8)
Left	24 (46.2)
Ethnicity [n (%)]	
Caucasian	25 (55.5)
African	8 (17.8)
Hispanic	12 (26.7)
Glaucoma diagnosis [n (%)]	
POAG	34 (64.2)
Pseudoexfoliative	6 (11.3)
Pigmentary	3 (5.6)
Angle closure	9 (17.0)
Normal tension	1 (1.9)
Previous ocular procedures [n (%)]	
Laser	15 (28.3)
Glaucoma surgery	13 (24.5)
Cataract surgery	21 (39.6)
Pachymetry (mean ± SD) (μm)	540.3 ± 38.3
Baseline BCVA [median (IQR)] (logMAR)	0.2 (0.1-0.5)
Visual field [median (IQR)] (dB)	
MD	15.3 (8.9-22.3)
PSD	9.3 (5.3-11.6)
OCT RNFL thickness (μm)	66 (51.1-75.3)
Medicated IOP at baseline (mm Hg)	
Mean ± SD	18.4 ± 6.1
Median (IQR)	18 (14-22)
No. IOP medications at baseline	
Mean ± SD	2.5 ± 1.0
Median (IQR)	3 (2-3)
No. medications (N = 49) [n (%)]	
0	0 (0)
1	7 (14.3)
2	16 (32.7)
3	16 (32.7)
4	10 (20.3)

BVCA indicates best-corrected visual acuity; IOP, intraocular pressure; IQR, interquartile range; MD, mean deviation; OCT, optical coherence tomography; POAG, primary open-angle glaucoma; PSD, pattern standard deviation; RNFL, retinal nerve fiber layer.

Effectiveness

IOP data at baseline and each follow-up visit are given in Figure 1. Mean difference between preoperative and postoperative IOP was significant at every postoperative time point through 6 months of follow up ($P < 0.05$). Six months after surgery, mean IOP was 13.9 ± 3.5 mm Hg (a mean reduction of 4.4 mm Hg or 23.9% from baseline, $P < 0.001$). Difference between follow-up time points was statistically significant ($P = 0.02$) between IOP at 1 month and 3 months. The proportion of patients achieving an IOP reduction of $> 20\%$ from preoperative baseline at 6 months was 30 (57.7%) eyes. At 6 months, complete and qualified success were achieved in 21.2% and 92.3%, respectively, using the ≤ 18 mm Hg threshold, and in 19.2% and 63.5%, respectively, using the ≤ 14 mm Hg threshold (Table 2).

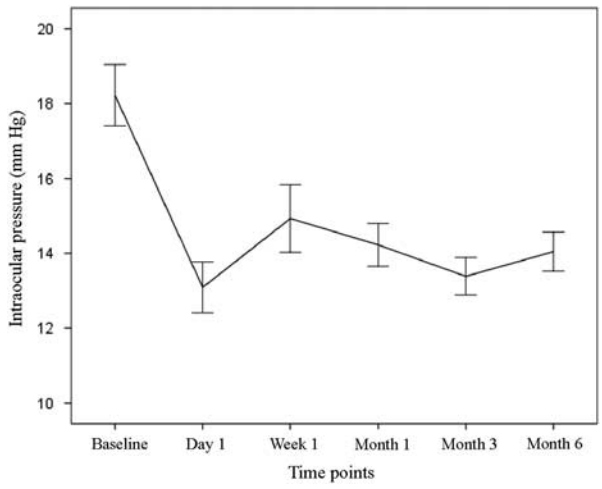

FIGURE 1. Mean intraocular pressure at baseline and over 6 months follow up. Vertical lines on each curve represent standard error (SE) bars.

The Kaplan-Meier survival curves are presented in Figure 2. None of the analyzed factors (age, sex, ethnicity, glaucoma diagnosis, previous laser, previous glaucoma surgery, previous phacoemulsification, number of baseline medications, baseline MD, PSD, and RNFL) were statistically significantly ($P > 0.05$) associated with failure, using the > 14 and the > 18 mm Hg thresholds.

Table 3 shows the mean number of IOP-lowering medications at each visit. All comparisons to baseline data remained statistically significant ($P < 0.001$). Mean differences between follow-up time points were not significant. At the month 6 assessment, mean [median (IQR)] medications were reduced by 1.2 ± 1.3 [1 (2 to 0)] or $36.6 \pm 56.9\%$ reduction from baseline ($P < 0.001$). The proportion of patients whose regimen decreased by > 1 medication at 6 months was 63.3% (n = 31). Three eyes (6.1%) required more antiglaucoma medication postoperatively compared with preoperative baseline. Variation of IOP between 1 day and 1 week was correlated with variation of medications between 1 day and 1 week, and between 1 week and 1 month ($P = 0.001$ and 0.008, respectively).

Safety

Most eyes (n = 34, 64.1%) underwent uncomplicated surgery. In 36.5% (n = 19 eyes), peroperative hyphema was present, with spontaneous regression at week 1 in 90.5%, and in 100% at month 1. One day after surgery, 2 eyes had corneal edema. Seven cases (13.5%) and four cases (7.7%) presented an IOP increase of > 5 mm Hg and ≥ 10 mm Hg at week 1, respectively. For one case IOP increase of > 5 mm Hg was persistent at month 1, resolving with medical therapy. One case of intravitreal hemorrhage and one case of iritis were reported at 1 day and 3 months after surgery, respectively, with spontaneously resolution. For one eye, a reintervention (GDD) was necessary at 1-month follow-up because of uncontrolled IOP. No severe, sight threatening complications were reported. Table 4 shows the ocular adverse events observed in the study.

Variation of median visual acuity (logMar) was significant between baseline (0.2) and day 1 (0.4, $P = 0.009$) but was not significant for other follow-up time points.

TABLE 2. Success Rates at 6 Months, by Surgery Group

	D1	W1	M1	M3	M6
Eyes (n)	46	48	51	52	52
Complete success (%)					
≤ 14 mm Hg	26.1	20.8	23.5	15.4	19.2
≤ 18 mm Hg	37.0	25.0	29.4	21.2	21.2
Qualified success (%)					
≤ 14 mm Hg	65.2	54.2	56.9	67.3	63.5
≤ 18 mm Hg	89.1	77.1	88.2	98.1	92.3

D1 indicates 1 day postoperative; M1, 1 month postoperative; M3, 1 months postoperative; M6, 6 months postoperative; W1, 1 week postoperative.

DISCUSSION

Results of this study show a significant reduction of IOP (by 24%) and IOP-lowering medications (by 36%) over the 6-month follow up after GTE with KDB in severe and refractory glaucoma. These results support the efficacy of GTE with KDB and provide direction for further long-term evaluation. To the best of our knowledge, no other study has investigated the efficacy of GTE with KDB specifically in patients with severe and refractory glaucoma, and none is available for comparison with these results. Greenwood et al,[21] studied the IOP after phacoemulsification in combination with GTE using KDB and found a reduction of 26% at 6 months postoperatively. The mean baseline IOP decreased from 17.4 ± 5.2 mm Hg to 12.8 ± 2.6 mm Hg, and 58.3% of eyes had an IOP reduction $\geq$ 20% from baseline, and 35% of eyes were classified as having severe glaucoma.

The initial clinical report using the Trabectome followed 37 patients with uncontrolled open-angle glaucoma.[22] Twenty-five patients had at least 6 months of follow up, and mean IOP was reduced in this cohort by 38% from baseline, which is similar to our results. Filippopoulos et al[23] reported a study of 679 consecutive patients who underwent treatment with the Trabectome, which showed similar results: the average reduction of IOP was 29% at 6 months postoperatively (n = 106) and a reduction in the use of adjunctive glaucoma therapy by an average of 2 medications. A study evaluated the Trabectome after failed trabeculectomy and found at 6 months a reduction of 33% of IOP compared with baseline and a reduction of 23% of medications in advanced glaucoma.[24] Histologic analyses comparing KDB with Trabectome and microvitreoretinal (MVR) blade found that KDB removes a more complete TM without injury to surrounding tissues. MVR blade exhibited minimal removal of TM and obvious injury to the adjacent sclera, and Trabectome caused thermal injury and leaflets of residual tissue remained.[17] Furthermore, the dual blade is more economical than Trabectome.[18] A recent study showed good efficacy and the safety of trabecular microbypass stent combined with phacoemulsification in patients with severe glaucoma.[25] In this study, IOP was <18 mm Hg and ≤ 15 mm Hg in 83% and 66% of eyes 1 year after surgery, respectively. IOP was reduced by 20% in 55% of eyes, and medication was reduced in 62% from baseline. At 6 months, IOP decreased from 19.25 mm Hg to 14.26 mm Hg, and medication was reduced from an average of 2.27 medications to 1.36, which is similar to our results. Grover et al[26] published a study on the performance and safety of the gelatin stent in refractory glaucoma: 75.4% had a ≥20% IOP lowering from baseline at 12 months on the same or fewer medications.

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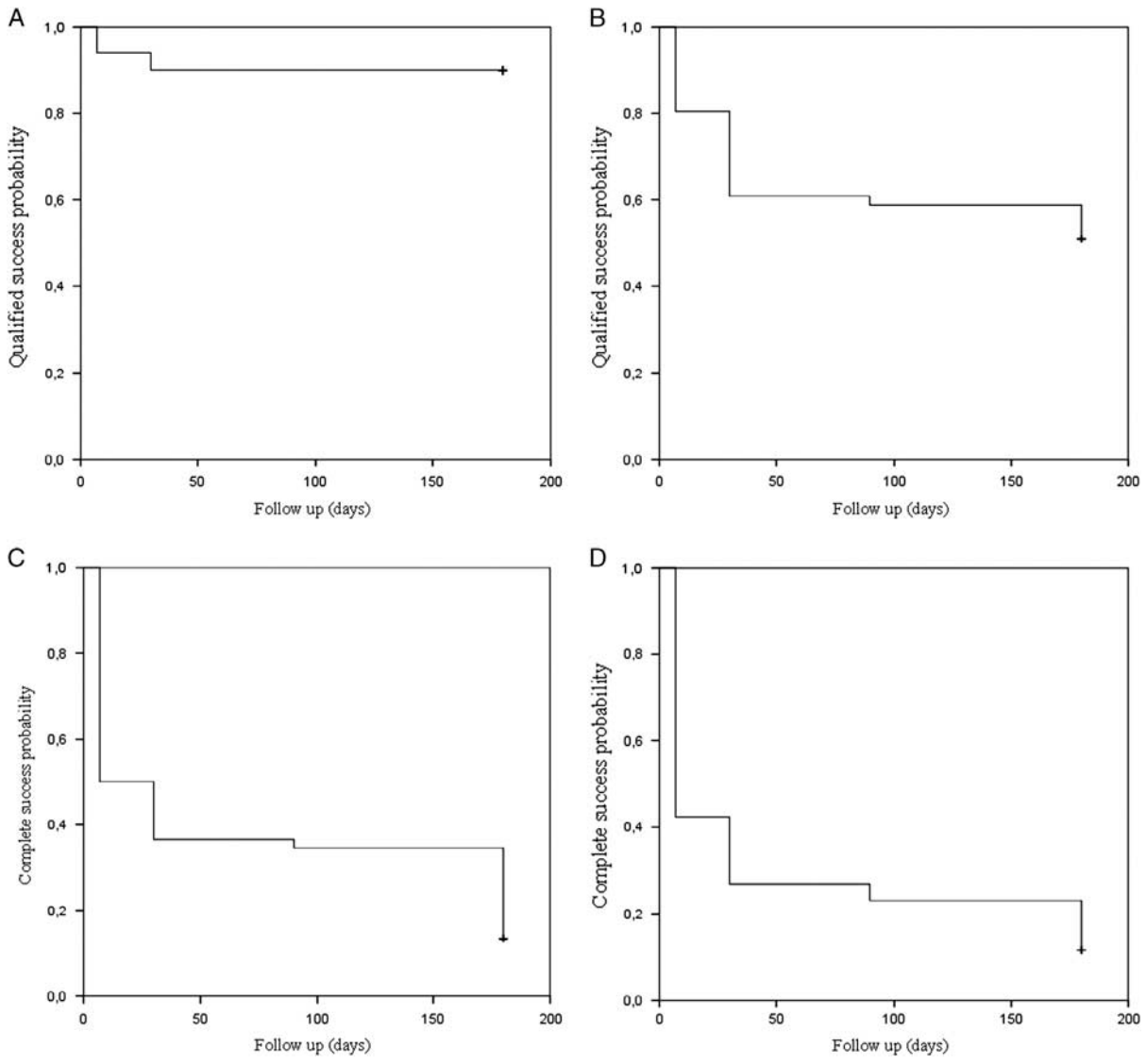

FIGURE 2. The Kaplan-Meier survival curves for eyes achieving qualified success using the ≤18 mm Hg cut-off (A) and the ≤14 mm Hg cut-off (B) at 6 months follow up, and achieving complete success using the ≤18 mm Hg cut-off (C) and the ≤14 mm Hg cut-off (D) at 6 months follow up.

In our study, the reduction of the mean number of IOP-lowering medications was statistically significant from baseline to 6 months postoperatively. Greenwood et al[21] found a mean reduction of 0.7 medications at 6 months postoperatively. These results compare well with Minckler et al's study,[27] which found an average reduction from 1.2 ± 0.6 medications before surgery using Trabectome to 0.4 ± 0.6 at 6 months postoperatively. Fewer medications are positively correlated with patient adherence and quality of life.[28] Furthermore, the reduction in chronic topical glaucoma medications might preserve the ocular surface from inflammation and its consequences.[29] In fact, patients with severe or refractory glaucoma often have scarred, thin, or inflamed conjunctiva. KDB, avoiding the formation of a bleb and its short and long-term complications such as leaks and infections would, therefore, be a potentially good alternative for these patients.

The most common adverse event was hyphema during surgery. In our study, it was observed in 34.9% of eyes, resolving spontaneously without complication. In the Greenwood et al study,[21] 39.4% of eyes presented hyphema, and there were 2 cases of IOP spike. The hyphema would come from an inversion of the pressure gradient between the anterior chamber and the Schlemm channel causing a blood reflux in the anterior chamber, thus confirming the complete removal of the TM, so it is an adverse event which points to the correct application of the procedure. Delayed-onset hyphemas in trabecular bypass procedures have been described, but we did not observe these complications in our study.[30] Others adverse events, as cystoid macular edema, iridodialysis, peripheral anterior synechia or tear in Descemet membrane, described in other studies using the single use dual blade were not reported in our study, maybe because of an under reporting of complications.[21] This study supports the safety of this procedure, which may be interesting for patients with severe or refractory glaucoma.

One of the merits of this study is that it covered a multicentric and heterogenous population. However, it was limited

TABLE 3. Medication Use Postoperatively

Parameter	D1	W1	M1	M3	M6
Eyes (n)	46	49	51	52	52
No. IOP medication					
Mean ± SD	1.3 ± 1.3	1.3 ± 1.3	1.5 ± 1.2	1.6 ± 1.2	1.4 ± 1.1
Median (IQR)	1 (0-2)	1 (0-2)	2 (0-2)	2 (1-2)	1 (1-2)
Patients taking medication [n (%)]					
0	20 (43.5)	19 (38.8)	17 (33.3)	11 (21.2)	11 (21.2)
1	5 (10.9)	7 (14.3)	3 (5.9)	14 (26.9)	16 (30.8)
2	12 (26.1)	13 (26.5)	21 (41.2)	18 (34.6)	18 (34.6)
3	6 (13.0)	7 (14.3)	8 (15.7)	5 (9.6)	5 (9.6)
4	3 (6.5)	3 (6.1)	2 (3.9)	4 (7.7)	2 (3.8)
Using ≥1 fewer medications from baseline	28 (65.1)	30 (65.2)	28 (58.3)	30 (61.2)	31 (63.3)

IOP indicates intraocular pressure.

by its retrospective design, the small sample size and the short-term follow up. Our study included consecutive patients who underwent GTE with the KDB, and a selection bias at enrollment may be possible. Surgery was performed by 11 surgeons, which is both a strength and a limitation. Even if this procedure is described as a simple and fast surgery, the difference of experience might influence the efficacy and safety of the procedure. Furthermore, the maximum treated area is 90 to 110 degrees, but the difference in treatment areas by different surgeons or in different patients, might affect the results. Our study was also limited by the absence of a control group, consistent to its design as a descriptive study rather than a hypothesis-testing trial. Our study aims to be observational, that explains why there was no washout of medications before surgery, and no standardized postoperative treatment. The difference of dose and duration of drug administration, especially corticosteroids, might influence the IOP and is an acknowledged limitation of this study.

The statistically significant reduction of IOP between 1 month and 3 months postoperatively was not correlated with medication use. However, variation of IOP between 1 day and 1 week, and between 1 week and 1 month was correlated with variation of medications between 1 week and 1 month. The discontinuation of IOP-lowering medications immediately after surgery seems to be a possible cause of this IOP rise at 1 week, with a consequent increase in medications, followed by a secondary IOP reduction.

In summary, this study shows that GTE using KDB significantly reduces IOP and mean number of IOP-lowering medications in severe or refractory glaucoma over a period of 6 months postoperatively. This procedure would be of value to patients with severe or refractory glaucoma, with thin, scarred, and inflamed conjunctiva. Further prospective and randomized studies are required to characterize long-term efficacy and safety of the dual blade as a standalone procedure.

TABLE 4. Ocular Adverse Events During Follow up

Adverse Event	N (%)
Blood reflux	
Peroperative	19 (36.5)
Day 1	4 (7.7)
Week 1	2 (3.8)
Corneal edema	2 (3.8)
IOP spike (increase ≥10 mm Hg from baseline)	7 (13.5)
Vitreous hemorrhage	1 (1.9)
Iritis	1 (1.9)

IOP indicates intraocular pressure.

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