

Kahook Dual-Blade goniotomy combined with phacoemulsification in primary open-angle glaucoma patients: long-term results

Antônio Lucas Oliveira Correia^{1,2} , Breno Santos Holanda¹ , Vital Paulino Costa² ,

José Paulo Cabral de Vasconcelos² 

1. Hospital Geral de Fortaleza, Fortaleza, CE, Brazil.

2. Universidade Estadual de Campinas, Campinas, SP, Brazil.

ABSTRACT | Purpose: Glaucoma is a chronic and progressive disease that requires long-term treatment and continuous monitoring. The Kahook Dual Blade, a device used to perform goniotomy in adults, is designed to improve intraocular pressure control in patients with glaucoma. This study aimed to evaluate the long-term efficacy and safety of kahook dual blade goniotomy in glaucoma patients undergoing cataract surgery over a 36-month follow-up. **Methods:** This was a retrospective case series including 56 eyes from 56 patients with mild-to-moderate primary open-angle glaucoma who underwent phacoemulsification combined with kahook dual blade goniotomy. Mean intraocular pressure values, number of preoperative and postoperative hypotensive eye drops, procedure survival, and complications were evaluated over 36 months. Surgical success was defined as either a reduction in intraocular pressure of $\geq 20\%$ with intraocular pressure between 6 and 18 mmHg without additional medication or a reduction of ≥ 1 eye drop with intraocular pressure between 6 and 18 mmHg. **Results:** The mean preoperative intraocular pressure decreased from 15.96 ± 2.83 mmHg to 13.14 ± 2.11 mmHg at 36 months, representing a 14.9% reduction ($p < 0.001$). The mean number of eye drops decreased from 1.91 ± 0.75 to 1.34 ± 0.92 , a 29.8% reduction ($p < 0.001$). The overall success rate was 69.6% at 36 months. **Conclusion:** Kahook dual blade goniotomy combined with cataract surgery significantly reduced

intraocular pressure and the number of hypotensive eye drops required in patients with mild-to-moderate primary open-angle glaucoma, with a favorable success rate maintained at 36 months.

Keywords: Glaucoma, open-angle/surgery; Gonioscopy/methods; Intraocular pressure/physiology; Lens implantation, intraocular; Phacoemulsification/methods; Trabeculectomy/instrumentation; Treatment outcome

INTRODUCTION

Glaucoma is the leading cause of irreversible blindness worldwide, with its prevalence continuing to rise in recent years⁽¹⁾. It is estimated that approximately 112 million people will be affected by the disease by 2040⁽²⁾. Lowering intraocular pressure (IOP) remains the only proven strategy to slow disease progression⁽³⁻⁵⁾. In recent years, considerable efforts have been made to develop less invasive surgical techniques and devices that can reduce IOP and control glaucoma while minimizing surgical complications and allowing faster postoperative recovery.

Several of these procedures target the trabecular outflow pathway, which has traditionally been used for goniotomy in patients with congenital glaucoma, demonstrating favorable outcomes in IOP control⁽⁶⁾. However, the efficacy of goniotomy in adults has been limited, with failures often attributed to the development of goniosynechiae^(7,8). Consequently, newer techniques have been introduced to lower IOP with improved efficacy and safety profiles.

The Kahook Dual Blade (KDB; New World Medical, Rancho Cucamonga, California) is a dual-blade surgical knife specifically designed to perform ab interno goniotomy with minimal structural damage⁽⁹⁾. The procedure is most often performed in conjunction with cataract surgery. Previous studies have reported IOP reductions ranging from 11% to 36% and a decrease of 11% to 92%

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Corresponding author: Antonio L. O. Correia
Email: correiaantoniolucas@gmail.com

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Data Availability Statement:

The datasets generated and/or analyzed during the study are available from the corresponding author upon reasonable request and can be provided by referees if required.

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in the number of hypotensive eye drops after 12 months of follow-up⁽¹⁰⁻¹²⁾.

However, evidence on the long-term outcomes of this procedure remains limited, with most studies restricted to follow-up periods of 12 to 18 months⁽¹¹⁻¹⁵⁾. The present study therefore aims to evaluate the long-term efficacy and safety of KDB goniotomy combined with cataract surgery over a 36-month follow-up.

METHODS

This was a retrospective case series of patients who underwent phacoemulsification combined with KDB goniotomy at the General Hospital of Fortaleza, Ceará, Brazil, between January 2018 and December 2020. The study protocol was approved by the Ethics Committee of the General Hospital of Fortaleza in January 2023 (CAAE: 64265522.1.0000.5040) and conducted in accordance with the tenets of the Declaration of Helsinki.

Inclusion and exclusion criteria

Eligible patients were older than 18 yr and had a diagnosis of mild-to-moderate primary open-angle glaucoma, defined according to the Hodapp-Parrish-Anderson classification⁽¹⁶⁾. Patients with a mean deviation (MD) better than -6 dB were classified as having mild glaucoma, and those with MD between -6 and -12 dB were classified as having moderate glaucoma. Additional requirements included gonioscopy showing an open angle without signs of prior angle closure and evidence of typical glaucomatous optic nerve damage.

Only patients who underwent phacoemulsification with KDB goniotomy and had a minimum follow-up of 36 months were included. Exclusion criteria were use of systemic medications affecting IOP, intraoperative complications during phacoemulsification, or history of previous ocular surgeries. For patients who underwent bilateral surgery, only the first operated eye was included in the analysis.

Surgical technique

All patients underwent standard cataract surgery with phacoemulsification through a 2.75-mm clear corneal incision, followed by in-the-bag intraocular lens (IOL) implantation under local anesthesia. After IOL placement, 1% acetylcholine was instilled to induce miosis and enhance visualization of angle structures, and the anterior chamber was filled with viscoelastic.

The surgeon was positioned temporally, with the patient's head rotated 45° in the opposite direction and the microscope tilted 25° toward the surgeon. Under direct gonioscopic visualization, the KDB was inserted into the trabecular meshwork (TM), excising approximately 90°-100° of TM tissue. The blade and viscoelastic were then removed. All procedures were performed by one of three experienced glaucoma specialists.

Follow-up and outcomes

Patients were evaluated preoperatively and at 1, 6, 12, 24, and 36 months postoperatively. The following parameters were assessed: IOP, number of hypotensive eye drops, best-corrected visual acuity, pachymetry, and glaucoma staging.

Surgical success was defined as either an IOP reduction of >20% from baseline with IOP between 6 and 18 mmHg without additional medications or a reduction of ≥1 eye drop from baseline with IOP between 6 and 18 mmHg. Patients who did not meet these criteria or required further IOP-lowering interventions after phaco-KDB were considered failures.

Statistical analysis

Descriptive statistics included minimum, maximum, median, mean, standard deviation, and coefficient of variation for continuous variables, and frequency and percentage for categorical variables. To evaluate the effects on IOP and the number of eye drops, a one-sample proportion test was applied. Kaplan-Meier survival analysis was used to determine the proportion of patients achieving surgical success over time. Complications were recorded by type and frequency.

Statistical analyses were performed using SPSS software (version 23; IBM Corp., Armonk, New York) and LibreOffice Community 7.1.0.3. A p-value ≤0.05 was considered statistically significant.

RESULTS

The medical records of 56 consecutive eyes from 56 patients who underwent phacoemulsification combined with KDB goniotomy (phaco-KDB) between April 2019 and March 2020 were reviewed. All patients had complete follow-up data for 36 months.

The demographic and preoperative characteristics are summarized in table 1. The mean age was 62.9 years; most patients were male (55.4%) and self-identified as mixed race (80.4%). All patients had mild-to-moderate

primary open-angle glaucoma. The mean visual field mean deviation (MD) was -4.75 ± 2.08 dB, assessed with the 24-2 SITA Standard strategy on the Humphrey Visual Field Analyzer (HFA 740i, ZEISS Medical Technology). Approximately 36% of patients had MD values worse than -6 dB, meeting the criteria for moderate glaucoma, although the overall mean was within the mild range.

The mean preoperative IOP was 15.96 ± 2.83 mmHg. On the first postoperative day, IOP increased to 17.45 ± 5.78 mmHg. By 1 month, mean IOP decreased significantly to 12.93 ± 3.08 mmHg ($p < 0.001$) and remained consistently reduced throughout follow-up: 12.21 ± 1.95 mmHg at 6 months, 12.41 ± 1.91 mmHg at 12 months, 12.98 ± 1.92 mmHg at 24 months, and 13.14 ± 2.11 mmHg at 36 months (all $p < 0.001$; Table 2). Compared with baseline, all follow-up points showed statistically significant reductions in IOP, with absolute decreases ranging from 3.75 to 2.82 mmHg, corresponding to a 22% to 14% decline.

A significant reduction in the number of hypotensive eye drops was also observed. At 1 month, the mean number of drops decreased to 0.95 ± 0.84 ($p < 0.001$), with a gradual increase thereafter: 1.11 ± 0.89 at 6 months, 1.16 ± 0.91 at 12 months, 1.29 ± 0.91 at 24 months, and 1.34 ± 0.92 at 36 months (all $p < 0.001$; Table 3).

Table 1. Sociodemographic and preoperative clinical characteristics of study patients

	n	Percentage (%)	Mean
Age	56	100	62.91 (± 4.01)
Sex			
Female	25	44.6	-
Male	31	55.4	-
Race			
White	6	10.7	-
Mixed	45	80.4	-
Black	5	8.9	-
Eye			
Right eye	37	66.1	-
Left eye	19	33.9	-
Glaucoma staging			
Mild glaucoma	36	64.2	-
Moderate glaucoma	20	35.8	-
Best-corrected visual acuity			
20/30	29	51.8	-
20/40	27	48.2	-
Visual field mean deviation	56	100	$-4.78 (\pm 2.08)$

Compared with baseline, medication use decreased by 56.3% at 1 month and by 32.7% at 36 months, with all reductions statistically significant ($p < 0.05$).

When applying the combined success criterion (IOP reduction $\geq 20\%$ and/or ≥ 1 medication reduction, with final IOP between 6 and 18 mmHg), the success rate was 91.1% ($n=51$) at 1 month ($p < 0.001$), declining gradually to 82.1% at 6 months, 80.4% at 12 months, 78.6% at 24 months, and 69.6% at 36 months (Figure 1). Conversely, failure rates increased to 30.4% at 36 months.

When success was defined strictly as $\geq 20\%$ IOP reduction from baseline without additional medication and a final IOP between 6 and 18 mmHg, success rates were 58.9%, 53.5%, 51.2%, 46.4%, and 39.3% at 1, 6, 12, 24, and 36 months, respectively (Figure 2). Alternatively, when defined as a reduction of ≥ 1 medication

Table 2. Mean intraocular pressure (IOP) of patients at all time intervals

Variable	n	Mean IOP \pm SD (mmHg)	Range (mmHg)	Absolute reduction (mmHg)	Percentage reduction (%)	p^a
Preoperative IOP (mmHg)	56	15.96 (± 2.83)	10–22	15.96	2.83	<0.001
IOP 1 day (mmHg)	56	17.45 (± 5.78)	9–30	17.45	5.78	<0.001
IOP 1 month (mmHg)	56	12.93 (± 3.08)	10–26	12.93	3.08	<0.001
IOP 6 months (mmHg)	56	12.21 (± 1.95)	10–17	12.21	1.95	<0.001
IOP 12 months (mmHg)	56	12.41 (± 1.91)	10–16	12.41	1.91	<0.001
IOP 24 months (mmHg)	56	12.98 (± 1.92)	10–18	12.98	1.92	<0.001
IOP 36 months (mmHg)	56	13.14 (± 2.11)	10–18	13.14	2.11	<0.001

^aCompared with baseline.

Table 3. Mean number of hypotensive eye drops used by patients at all time intervals

Number of eye drops	n	Mean number of eye drops (\pm SD)	Range	Absolute Reduction	Percentage Reduction (%)	p^a
Preoperative	56	1.91	1–3	-	-	-
First month	56	0.95 (± 0.84)	0–3	0.96	56.26	<0.001
Sixth month	56	1.11 (± 0.89)	0–3	0.8	46.13	<0.001
12th month	56	1.16 (± 0.91)	0–3	0.75	43.45	<0.001
24th month	56	1.29 (± 0.91)	0–3	0.62	36.01	<0.001
36th month	56	1.34 (± 0.92)	0–3	0.57	32.74	<0.001

^aCompared with baseline.

from baseline with a final IOP between 6 and 18 mmHg, success rates were higher: 75% at 1 month, 67.8% at 6 months, 66.6% at 12 months, 57.1% at 24 months, and 51.8% at 36 months (Figure 3).

The most common complications included transient IOP spikes (defined as postoperative IOP exceeding baseline by >10 mmHg), hyphema, and posterior capsule opacification. Hyphema occurred in 57.1% of patients during the early postoperative period but was mild in all cases and resolved spontaneously within the first week without medical or surgical intervention. One patient

experienced a small intraoperative iris dialysis, which resolved uneventfully without further treatment. No cases of hypotony, malignant glaucoma, choroidal effusion, or other severe complications were reported (Table 4). No patient required reoperation to control IOP. All treatment failures were due to the reintroduction or escalation of hypotensive eye drops.

DISCUSSION

This study evaluated the outcomes of cataract surgery combined with goniotomy using the KDB in patients with primary open-angle glaucoma treated within the public health system. The primary objective was to assess efficacy and safety over a 3-year follow-up.

With respect to IOP reduction, an average decrease of 20% was maintained throughout the first year of follow-up. This result is consistent with previous studies reporting reductions between 11% and 34% when KDB is combined with cataract surgery^(10,13,14). At 36 months, the IOP reduction was 14.8%, which is lower than the 34.7%-36.9% reductions described elsewhere^(16,17). This difference may be explained by the baseline characteristics of our cohort, in which most patients already had well-controlled IOP (<18 mmHg) and lacked major predictors of large reductions, such as high baseline IOP, short axial length, pseudoexfoliation syndrome, or dense cataracts^(18,19). Despite this, the procedure provided consistent IOP-lowering benefits, even in patients with mild-to-moderate, stable disease.

The IOP-lowering effect of cataract surgery alone must also be considered. Phacoemulsification by itself has been shown to reduce IOP modestly-by approximately 1 to 1.4 mmHg after 12 months-and this effect tends to diminish over time^(20,21). Although this study did not include a control group undergoing phacoemulsification alone, the greater and sustained IOP reduction observed suggests that phaco-KDB confers additional benefit. Removal of TM by the KDB likely enhances aqueous outflow beyond the effect of cataract surgery alone.

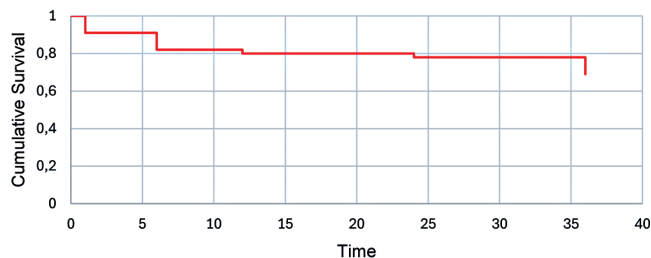


Figure 1. Kaplan-Meier survival curve of PHACO-KDB considering the combined success criterion: IOP reduction $\geq 20\%$ from baseline and/or reduction of ≥ 1 hypotensive medication, with final IOP between 6 and 18 mmHg, without the introduction of new medications.

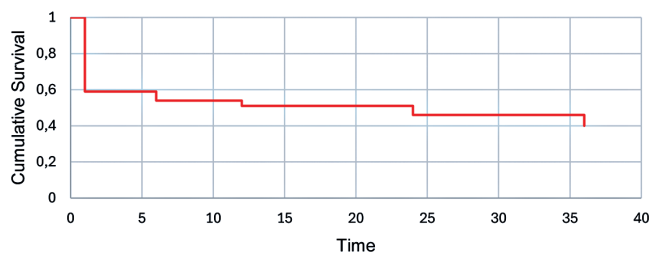


Figure 2. Kaplan-Meier survival curve of PHACO-KDB, considering success defined as IOP reduction $\geq 20\%$ from baseline, with final IOP between 6 and 18 mmHg, without the introduction of new medications.

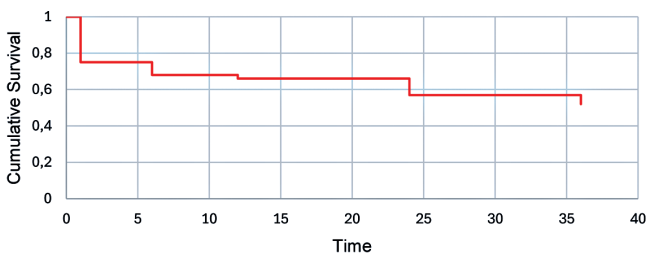


Figure 3. Kaplan-Meier survival curve of PHACO-KDB, considering success defined as reduction of ≥ 1 hypotensive medication, with final IOP between 6 and 18 mmHg.

Table 4. Postoperative complications observed after the PHACO-KDB procedure (total number of eyes = 56)

Complication	n	%
Hyphema	32	57.1
IOP spikes (>10 mmHg)	13	23.2
Posterior capsule opacification	6	10.7
Iridodialysis	1	1.7

In terms of medication use, a 39.2% reduction was observed in the first year, with a 29.8% reduction sustained at 36 months. These findings fall within the 11%-79% reduction reported in the literature^(10,13,14). Although medication use gradually increased over time, the reduction remained statistically significant at all follow-up points. This outcome is clinically meaningful, as reducing the medication burden improves adherence, lowers the risk of side effects, and enhances quality of life.

When surgical success was defined as $\geq 20\%$ IOP reduction or a decrease of ≥ 1 hypotensive medication with IOP maintained between 6 and 18 mmHg, success rates were 91.1% at 1 month, 80.4% at 12 months, and 69.6% at 36 months. These results are comparable with outcomes of other minimally invasive glaucoma surgeries (MIGS) targeting the trabecular outflow pathway⁽¹⁹⁻²²⁾. However, success rates were lower when IOP reduction alone was considered, with only 39% of patients achieving $\geq 20\%$ reduction at 36 months. This likely reflects a ceiling effect, as most patients had low baseline IOP, limiting the extent of possible reduction. Importantly, this should not be interpreted as treatment failure but rather as a function of baseline disease stability.

By contrast, reduction in medication burden was more consistent, particularly in the first year. At 36 months, more than half of patients were still using fewer drops than at baseline. This suggests that, in real-world settings, especially for patients with mild-to-moderate glaucoma, the principal benefit of KDB may be medication-sparing rather than aggressive IOP lowering. This aligns with evolving treatment goals that emphasize quality of life and adherence.

Comparisons with other MIGS procedures must be interpreted cautiously due to differences in study criteria. Gonioscopy-assisted transluminal trabeculotomy combined with cataract surgery has shown greater IOP reduction than phaco-KDB over 12 months (37%-44% vs. 22.9%), although success rates were similar in the first year (87% vs. 80%)⁽²²⁻²⁴⁾. Compared with the iStent bypass (Glaukos, San Clemente, California), which produces 27%-38% IOP reductions at 12 months, our findings (22.9%) are within a comparable range⁽²⁵⁻²⁷⁾. Success rates were also similar (83% iStent vs. 80% KDB)⁽²⁷⁾. While stent-based procedures minimize trabecular disruption, KDB goniotomy offers a lower-cost, stent-free alternative, avoiding risks such as implant obstruction, migration, or fibrosis. Moreover, by excising a segment of TM, KDB may provide broader access to Schlemm's canal and potentially more durable IOP control.

Postoperative complications were generally mild and self-limited. Hyphema was the most frequent (57.1%), followed by transient IOP spikes (23.2%) and posterior capsule opacification. All hyphema resolved spontaneously within 1 week without intervention. A single case of minor intraoperative iridodialysis was reported and resolved uneventfully. No hypotony, malignant glaucoma, or reoperations were observed.

Transient IOP spikes occurred in 23.2% of cases, typically within the first two postoperative weeks. These elevations, defined as > 10 mmHg above baseline, may be related to residual viscoelastic, postoperative inflammation, or temporary outflow resistance at Schlemm's canal^(10,14). Although self-limiting, such spikes could pose a risk in patients with advanced optic nerve damage. For this subgroup, close postoperative monitoring and early use of IOP-lowering medications are advisable.

This study has several limitations. The absence of a control group (e.g., phacoemulsification alone) precludes definitive attribution of efficacy to KDB. All procedures were performed by experienced glaucoma specialists in patients with mild-to-moderate disease, which may limit generalizability. Additionally, while surgical success remained significant across follow-up, the survival rate declined from 91.1% at 1 month to 69.6% at 36 months, highlighting the need for continued monitoring and individualized management.

In conclusion, phacoemulsification combined with KDB goniotomy is a safe and moderately effective option for patients with mild-to-moderate primary open-angle glaucoma, particularly in public health settings. While efficacy diminishes gradually, the procedure provides meaningful short- and intermediate-term benefits, primarily by reducing medication burden, with a favorable safety profile.

AUTHORS' CONTRIBUTIONS:

Significant contribution to conception and design: José Paulo Cabral de Vasconcelos; Antônio Lucas Oliveira Correia. **Data acquisition:** Antônio Lucas Oliveira Correia; Breno Santos Holanda. **Data analysis and interpretation:** José Paulo Cabral de Vasconcelos; Antônio Lucas Oliveira Correia. **Manuscript drafting:** Antônio Lucas Oliveira Correia. **Significant intellectual content revision of the manuscript:** José Paulo Cabral de Vasconcelos; Vital Paulino Costa. **Final approval of the submitted manuscript:** Antônio Lucas Oliveira Correia; Breno Santos Holanda; Vital Pau-

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