

Predictive Factors of Outcomes in Kahook Dual Blade Excisional Goniotomy Combined with Phacoemulsification

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ABSTRACT

Aim: To identify factors that were significant predictors of Kahook Dual Blade (KDB) excisional goniotomy outcomes.

Materials and methods: One hundred and thirty-two eyes from 99 adult glaucoma patients who underwent combined KDB and phacoemulsification (KDB-phaco) with a minimum 6-month follow-up were assessed for baseline patient characteristics to determine correlation to the success of KDB-phaco at 6 and 12 months postoperatively. Success was defined as $\geq 20\%$ intraocular pressure (IOP) reduction or ≥ 1 medication reduction as well as IOP ≤ 18 mm Hg without any additional IOP-lowering procedures after KDB-phaco.

Results: 63.6% (84/132) and 46.1% (41/89) of cases were successful at the 6- and 12-month follow-ups, respectively. KDB-phaco reduced patient's preoperative IOP (in mm Hg) from 17.6 ± 4.6 to 14.9 ± 3.2 at 6 months (15.3%, $p < 0.001$) and 15.4 ± 4.7 at 12 months (12.5%, $p = 0.001$). KDB-phaco reduced patient's preoperative IOP-lowering medications from 2 ± 1.2 to 1.1 ± 1.2 at 6 months (45%, $p < 0.001$) and 1.32 ± 1.3 at 12 months (34%, $p < 0.001$). At 6 months, patients on >1 IOP lowering medication had a greater chance of meeting our success criteria ($p = 0.037$). Visually significant postoperative hyphema was not associated with the use of anticoagulation ($p = 0.943$) but was significantly associated with postoperative day 1 IOP ≤ 10 mm Hg ($p = 0.011$).

Conclusion: Patients who underwent KDB-phaco significantly reduced their IOP and medication burden at both 6 and 12 months compared with their baseline preoperative values. KDB-phaco outcome was associated with higher baseline IOP-lowering medications and increased rate of hyphema was associated with lower postoperative day 1 IOP, regardless of anticoagulation status. Age, ethnicity, prior laser trabeculoplasty, type and severity of glaucoma, and baseline preoperative IOP were not associated with surgical success.

Clinical significance: Patients with a higher number of baseline medications may experience a greater probability of success following KDB-phaco.

Keywords: Kahook dual blade, Outcomes, Retrospective study, Risk factors.

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INTRODUCTION

Glaucoma is the leading cause of irreversible blindness around the world and is estimated to affect 76 million people between the ages of 40 to 80 this year.¹ Medications have long been first-line treatment to safely lower intraocular pressure (IOP) in these patients. However, there is evidence that surgical treatment of glaucoma may lower IOP more effectively and address the well-known adherence issues with eye drop administration.²⁻⁶ Correctly identifying characteristics of patients most likely to achieve lower IOP and a reduced medication burden postoperatively is important in surgical planning.

Kahook Dual Blade (KDB) excisional goniotomy (New World Medical, Rancho Cucamonga, CA, USA) has recently been shown to be successful in lowering IOP and decreasing the medication burden of patients with glaucoma both as a standalone procedure⁷⁻⁹ and combined with phacoemulsification (KDB-phaco).¹⁰⁻¹⁴ Although initially intended to treat primary open-angle glaucoma (POAG), KDB goniotomy success has also been seen in pigment dispersion glaucoma (PDG),¹⁵ congenital glaucoma,¹⁶ and primary angle-closure glaucoma (PACG).^{17,18} The KDB lowers IOP by precisely excising a segment of the diseased trabecular meshwork (TM), which has long been thought to be a critical component of the pathophysiology of POAG.¹⁹⁻²¹ Despite the research that has been conducted on the safety and efficacy of the KDB, we lack data on discrete patient factors that may be predictive of success or failure.²² A better understanding of predictive

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factors for a successful angle surgery may serve a significant role in proper patient selection and informed consent.²³ Therefore, this study was designed to assess the association of commonly shared preoperative patient factors to KDB-phaco outcomes up to the 12-month postoperative time point.

MATERIALS AND METHODS

Data Collection

The Institutional Review Board at the University of Missouri approved a waiver of informed consent because of the retrospective nature of this study (IRB # 201,4201). This study was conducted in accordance with the institutional and national research committee ethical principles as well as the 1964 Helsinki declaration and its subsequent amendments.

A retrospective analysis was performed on consecutive patients who underwent KDB-phaco between February 2017 and June 2019 with a minimum of 6-month postoperative follow-up (132 eyes in 99 adult patients). Eyes that received additional procedures, with the exception of adjunctive viscocanalostomy, were excluded. The indications for KDB-phaco included visually significant cataracts with the need for IOP reduction and/or the desire to reduce the medication burden. Baseline characteristics were collected as follows: age, ethnicity, glaucoma type, glaucoma severity [defined via ICD-10 guidelines²⁴], surgeon training level (resident vs attending surgeon), IOP, IOP-lowering medications, prior laser trabeculoplasty, anticoagulation or antiplatelet medications, and adjunct intraoperative viscocanalostomy. Outcomes collected were IOP, number of IOP-lowering medications, and any adverse events including reflux hyphema recorded on day 1, week 1–2, month 1, month 3, month 6, and month 12.

Success was defined as IOP reduction $\geq 20\%$ or ≥ 1 medication reduction and IOP ≤ 18 mm Hg at each postoperative time point. Inability to meet these criteria or the need for any secondary surgical intervention to lower IOP were considered surgical failures.

Surgical Procedure

KDB-phaco was performed by a glaucoma fellowship-trained ophthalmologist or a senior (PGY-4) ophthalmology resident under the direct supervision of the attending. Patients received topical anesthesia with mild sedation. Goniotomy with the KDB was completed through a 2.4 mm temporal corneal incision before phacoemulsification. A Swan Jacob-style gonioscope was used to visualize the iridocorneal angle, after which the KDB was utilized to excise approximately 4 clock hours from the nasal TM.²⁵ The strip of excised TM was then removed from the anterior chamber with microforceps. In select patients, a viscocanalostomy was performed by injecting sodium hyaluronate (cohesive viscoelastic) via a 27-G cannula into the exposed collector channel entrances and both cut ends of Schlemm’s canal after trabecular unroofing.^{26,27} Phacoemulsification with intraocular lens placement was performed via a standard approach after completion of the KDB excisional goniotomy. Viscoelastic was then completely removed from the anterior chamber and a balanced salt solution and Moxifloxacin was injected into the anterior chamber to attain an IOP in the mid-20s to minimize postoperative blood reflux. Patients were advised to keep the head of the bed elevated and avoid straining for the first 2 weeks after surgery. Patients used prednisolone acetate 1% four times daily and tapered over 4 weeks. Preoperative IOP-lowering medications were continued until target IOP was reached and the steroid was discontinued. Additional medications were added per the surgeon’s discretion.

Data Analysis

Differences between preoperative and postoperative IOP and medication reduction at 6 and 12 months were compared using Wilcoxon rank-sum tests. A mixed model (age and preoperative IOP) and binomial logistic regression (surgeon training level, baseline IOP and IOP-lowering medications, prior laser trabeculoplasty,

adjunct viscocanalostomy, type and severity of glaucoma, and postoperative hyphema) with a random patient effect to accurately account for individuals who contributed two eyes to the study was used to determine factors predictive of success. Binomial logistic regression was also used to determine predictive factors for hyphema development (preoperative anticoagulation/antiplatelet use, type of glaucoma, surgeon training level, age, and day 1 IOP). In addition, a Mann–Whitney *U* test and Welch’s *T*-test were used to compare baseline medications and IOP for successful and unsuccessful patients. All normally distributed values were reported as mean \pm standard deviation and percentage (*n*) for categorical variables unless otherwise stated.

RESULTS

Baseline Demographic and Glaucoma Data

Demographic and glaucoma status data are reported in Table 1. The average age was 69.2 ± 8.9 years and 57% of the eyes belonged to females. Primary open-angle glaucoma was the most common diagnosis (*n* = 71, 53.8%). Baseline IOP and IOP-lowering medications were 17.6 ± 4.6 mm Hg and 2.0 ± 1.2 , respectively.

IOP, IOP-lowering Medications, and Success At 6 and 12 Months
84/132 (63.6%) eyes and 41/89 (46.1%) eyes satisfied the success criteria at the 6- and 12-month postoperative follow-up, respectively. Baseline IOP and IOP-lowering medications were significantly reduced at both 6 and 12 months (Table 2). KDB-phaco success is compared to mean IOP-lowering medications and IOP in Figures 1 and 2, respectively.

Predictive Factors of Success

Patients taking >1 medication were more likely to meet our success criteria (68.3%) compared with those taking 0–1 medications (56.6%) at 6 months (*p* = 0.037). The mean number of baseline medications

Table 1: Baseline demographic and glaucoma status data (*n* = 132)

Age (years), mean \pm SD	69.2 \pm 8.9
Range (years)	43–90
Gender, <i>n</i> (%)	
Female	75 (56.8)
Male	57 (43.2)
Ethnicity, <i>n</i> (%)	
Caucasian	104 (78.8)
Other	28 (21.2)
Baseline IOP (mm Hg), mean \pm SD	17.6 \pm 4.6
Baseline medications, mean \pm SD	2.0 \pm 1.2
Glaucoma type, <i>n</i> (%)	
POAG + NTG	84 (63.6)
ACG (1°, 2°, and combined), <i>n</i> (%)	36 (27.3)
PXG and PDG, <i>n</i> (%)	10 (7.6)
Traumatic, <i>n</i> (%)	2 (1.5)
Glaucoma severity, <i>n</i> (%)	
Mild	67 (50.8)
Moderate	15 (11.4)
Severe	50 (37.8)

KDB, Kahook dual blade; SD, standard deviation; IOP, intraocular pressure; POAG, primary open-angle glaucoma; NTG, normal tension glaucoma; ACG, angle closure glaucoma; PXG, pseudoexfoliation glaucoma; PDG, pigment dispersion glaucoma



for successful cases at 6 months was 2.1 ± 1.2 , compared with 1.8 ± 1.2 in unsuccessful cases ($p = 0.235$). Eyes operated on by resident surgeons were more likely to be successful than those

operated on by attendings at 12 months (61.5 vs 39.7%, $p = 0.019$). No other baseline factors were associated with KDB-phaco success (Table 3).

Table 2: Results of KDB-phaco

		<i>n</i>	<i>p</i> value
IOP (mm Hg), mean \pm SD			
Baseline	17.6 \pm 4.6	132	–
6 months	14.9 \pm 3.2	132	<0.001
12 months	15.4 \pm 4.7	89	0.001
IOP-lowering medications, mean \pm SD			
Baseline	2 \pm 1.2	132	–
6 months	1.1 \pm 1.2	132	<0.001
12 months	1.32 \pm 1.3	89	<0.001

Predictive Factors of Hyphema

Postoperative hyphema was significantly associated with postoperative day 1 IOP ≤ 10 mm Hg ($p = 0.011$). It was not associated with the use of anticoagulants or antiplatelet agents even though they were not stopped before surgery ($p = 0.943$). Predictive factors of hyphema are reported in Table 4.

DISCUSSION

Kahook Dual Blade goniotomy has presented new treatment strategies not previously available for adult glaucoma patients. The safety profile and postoperative recovery of KDB goniotomy are superior to that of traditional glaucoma surgery, inspiring its

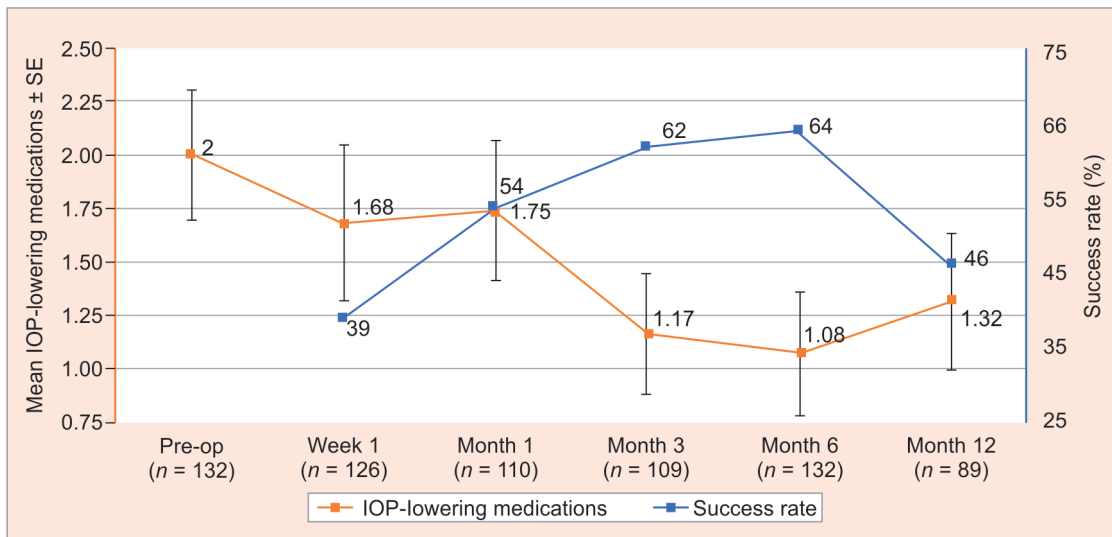


Fig. 1: Mean IOP-lowering medication use compared with KDB-Phaco success during the postoperative period

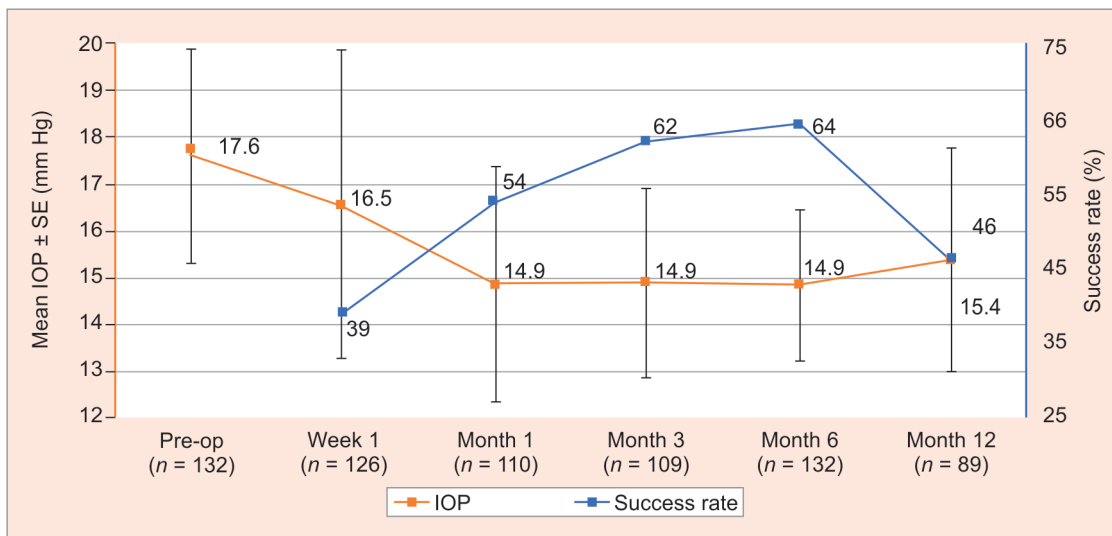


Fig. 2: Mean IOP compared with KDB-Phaco success during the postoperative period

Table 3: Predictive factors of KDB-phaco success

	6 months	12 months	6 months	12 months
Age (years), mean ± SD			0.479	0.472
Success	69.6 ± 8.6	69.6 ± 8.6		
Failure	68.4 ± 9.6	67.0 ± 8.1		
Ethnicity (successful cases)			0.393	0.805
African American, <i>n</i> (%)	16/23 (69.6)	7/13 (53.8)		
Asian, <i>n</i> (%)	3/3 (100)	0/1 (0)		
Caucasian, <i>n</i> (%)	63/104 (60.6)	31/73 (42.5)		
Hispanic, <i>n</i> (%)	0/1 (0)	0/1 (0)		
Other, <i>n</i> (%)	0/1 (0)	0/1 (0)		
Glaucoma type (successful cases)			0.626	0.147
POAG and NTG, <i>n</i> (%)	52/84 (61.9)	24/56 (42.8)		
ACG (1°, 2°, and combined), <i>n</i> (%)	24/36 (66.6)	13/26 (50.0)		
Traumatic, <i>n</i> (%)	1/2 (50)	–		
PXG and PDG, <i>n</i> (%)	7/10 (70)	4/7 (57.1)		
Glaucoma severity (successful cases)			0.194	0.172
Mild and moderate, <i>n</i> (%)	54/82 (65.9)	20/56 (35.7)		
Severe, <i>n</i> (%)	30/50 (60)	21/33 (63.6)		
Surgeon (successful cases)			0.133	0.019
Resident, <i>n</i> (%)	28/38 (73.7)	16/26 (61.5)		
Attending, <i>n</i> (%)	56/94 (59.6)	25/63 (39.7)		
Baseline IOP-lowering medications (successful cases)			0.037	.133
0–1 medication, <i>n</i> (%)	30/53 (56.6)	12/35 (34.3)		
>1 medication, <i>n</i> (%)	54/79 (68.3)	29/54 (53.7)		
Baseline IOP (successful cases)			0.188	0.670
>18 mm Hg, <i>n</i> (%)	26/45 (57.8)	19/34 (55.9)		
≤18 mm Hg, <i>n</i> (%)	58/87 (66.7)	26/55 (47.2)		
Prior laser trabeculoplasty* (successful cases)			0.921	0.142
Present, <i>n</i> (%)	31/49 (63.3)	14/36 (38.9)		
Absent, <i>n</i> (%)	53/83 (63.9)	27/53 (50.9)		
Intraoperative viscocanalostomy (successful cases)			0.895	0.353
Performed, <i>n</i> (%)	36/55 (65.4)	16/41 (39.0)		
Not performed, <i>n</i> (%)	48/77 (62.3)	25/48 (52.1)		
Postoperative hyphema (successful cases)			0.137	0.658
Present, <i>n</i> (%)	6/7 (85.7)	3/5 (60)		
Absent, <i>n</i> (%)	78/124 (62.9)	38/84 (45.2)		

KDB, Kahook dual blade; SD, standard deviation; IOP, intraocular pressure; POAG, primary open-angle glaucoma; NTG, normal tension glaucoma; ACG, angle closure glaucoma; PXG, pseudoexfoliation glaucoma; PDG, pigment dispersion glaucoma

*Prior laser trabeculoplasty included: SLT (*n* = 40), MLT (*n* = 6), and ALT (*n* = 3)

expanded use in all subsets of glaucoma,²⁸ including severe-stage POAG with target IOP in the low- to mid-teens.⁷¹¹ However, proper patient selection for this procedure remains challenging, and no study has assessed predictive factors of outcomes of KDB-phaco.

Similar to previously reported retrospective KDB-phaco outcomes-based reviews, our study showed a significant reduction in preoperative IOP and IOP-lowering medications at 6 and 12 months postoperatively.^{18,29} Our study population was mostly Caucasian (76.3%) with a relatively small representation of African

Americans (17.3%), which are representative of the demographics of the state of Missouri as reported by the census.³⁰ Most patients had POAG or NTG (65.6%). The severity of the disease was distributed evenly, with mild glaucoma representing 50.8% of the cases.

While utilizing a binomial logistic regression and controlling for other patient factors, having >1 baseline IOP-lowering medication significantly predicted success at 6 months (*p* = 0.037), although this effect disappeared at 12 months (*p* = 0.133). Similarly, the eyes with successful KDB-phaco were on more IOP-lowering medications



Table 4: Predictive factors of hyphema

	Values	p-value
Pre-op anticoagulation (cases with hyphema)		0.943
Patient using, n (%)	2/42 (4.8)	
Patient not using, n (%)	5/90 (5.6)	
Glaucoma type (cases with hyphema)		0.544
POAG + NTG, n (%)	2/84 (2.4)	
Other, n (%)	5/48 (10.4)	
Surgeon (cases with hyphema)		0.102
Resident, n (%)	4/38 (10.5)	
Attending, n (%)	3/94 (3.2)	
Age (cases with hyphema)		0.053
<70 years, n (%)	6/66 (9.1)	
≥70 years, n (%)	1/66 (1.5)	
Day 1 IOP (cases with hyphema)		0.011
≤10 mm Hg	5/29 (17.2)	
>10 mm Hg	2/101 (2.0)	

KDB, Kahook dual blade; IOP, intraocular pressure; POAG, primary open-angle glaucoma; NTG, normal-tension glaucoma

at baseline (2.2 ± 1.2) than those who were unsuccessful (1.8 ± 1.2) ($p = 0.235$). Therefore, there may be unintended bias created with this analysis, attributed to how we defined the KDB-phaco success criteria. Similarly, patients with a preoperative IOP of >18 mm Hg had a more significant average reduction in IOP (6.25 ± 3.4 mm Hg) when compared with patients with a baseline IOP of ≤ 18 mm Hg (0.85 ± 2.6 mm Hg) ($p < 0.001$). However, preoperative baseline IOP of 18 mm Hg or higher did not significantly predict KDB-phaco success.

Our study found that eyes operated on by resident surgeons had higher success at 12 months than those operated on by the attending surgeon. Our previous study comparing outcomes of KDB-phaco performed by a resident vs attending showed similar results.³¹ D'Souza et al. performed a meta-analysis examining 14 specialties, including ophthalmology, which showed no significant differences in the duration of procedures or rate of complications between cases performed by residents and attending physicians.³¹ Although there may have been selection bias that favored resident cases (with more severe or refractory glaucoma cases operated by the attending), our findings may reinforce the concept that resident-performed surgeries do not compromise safety or efficacy.

While our 12-month success rate is lower than that of the 6-month time point, it was noted that patients with unsuccessful outcomes were more likely to follow-up at 12 months than those with successful outcomes (as they are often discharged from the subspecialty clinic), erroneously decreasing the success rate at this follow-up. Out of 84 eyes that were successful at 6 months (84/132, 62.6%), 53 followed up at the 12-month time point (53/84, 63.1%). Conversely, out of the 48 patients who were considered surgical failures at 6 months postoperatively, 35 patients followed up at the 12-month time point (35/48, 72.9%).

As can be expected in an excisional goniotomy procedure, blood reflux from Schlemm's canal is common,³² but is usually transient and mild without additional treatment.^{29,33-35} Our results show that day 1 postoperative IOP ≤ 10 mm Hg was significantly associated with the development of early and visually significant hyphema, whereas taking anticoagulant or antiplatelet medications

was not. Studies have shown the typical average episcleral venous pressure (EVP) to be 7 to 11 mm Hg.³⁶ When EVP exceeds patient IOP, blood reflux into the anterior chamber from the venous circulation has been shown in hypotonous eyes.³⁷ Based on these findings, there may be new postoperative strategies adopted to avoid hyphema in eyes with a higher risk for postoperative hypotony, and discontinuation of anticoagulation may not be necessary before goniotomy.

Manually washing the TM during phacoemulsification has been theorized to benefit immediate postoperative IOP.^{38,39} Tran et al. recently described a unique patented cannula to help irrigate and aspirate fibrillar material out of the iridocorneal angle and TM for long-lasting reduction of IOP.⁴⁰ In our study, select patients ($n = 55$) had their exposed collector channel entrances at the goniotomy site and the remaining intact Schlemm's canal "washed down" with cohesive viscoelastic at the end of the goniotomy procedure. This washout technique was not associated with greater success in our study. A randomized controlled trial with more standardized practice may be necessary to reveal the value of this technique.

Despite limitations inherent to a retrospective study design, our results support the existing literature on the effectiveness of KDB-phaco. In addition, our study provides data with clinically relevant implications to avoid early postoperative hyphema following KDB without discontinuing anticoagulation/antiplatelet therapy. Additional studies exploring predictive factors of success with KDB and other MIGS procedures will be important for patient selection and preoperative planning moving forward.

CONCLUSION

Patients who underwent KDB-phaco significantly reduced their IOP and medication burden at both 6 and 12 months compared with their baseline preoperative values. KDB-phaco success was associated with higher baseline IOP-lowering medications and an increased rate of hyphema was associated with lower postoperative day 1 IOP, regardless of anticoagulation status. Age, ethnicity, prior laser trabeculoplasty, type and severity of glaucoma, and baseline preoperative IOP had no association with surgical success.

CLINICAL SIGNIFICANCE

Determining preoperative characteristics that are predictive of outcomes are important in surgical planning and may influence patient selection. Patients with a higher number of baseline IOP-lowering medications may experience a greater probability of success following KDB-phaco. Additional effort to limit postoperative hypotony may decrease the risk of reflux hyphema after KDB-phaco and discontinuation of anticoagulation may not be necessary.

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