

Three-year clinical outcomes of phacoemulsification combined with excisional goniotomy using the kahook dual blade for cataract and open-angle glaucoma in Saudi Arabia

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Abstract:

PURPOSE: The aim of this study was to describe the changes in intraocular pressure (IOP), IOP-reducing drugs, and visual acuity (VA) through up to 3 years of follow-up in patients undergoing combined phacoemulsification and excisional goniotomy with the Kahook Dual Blade (KDB-phaco) by a single surgeon in Saudi Arabia.

METHODS: The health records of 55 eyes of 47 patients undergoing KDB-phaco by a single surgeon were reviewed. Data were extracted from visits occurring preoperatively ($n = 55$), intraoperatively ($n = 55$), and 1-day ($n = 55$), 2 weeks ($n = 55$), 4–6 weeks ($n = 49$), 2–3 months ($n = 55$), and 6 ($n = 55$), 9 ($n = 55$), 12 ($n = 55$), 18 ($n = 49$), 24 ($n = 46$), and 36 months ($n = 16$) postoperatively. Data collection included IOP, IOP-lowering medications, and VA at each time point. Adverse events were also collected. Paired *t*-tests were used to compare IOP, medications, and VA at each time point to preoperative values.

RESULTS: Mean (standard error) baseline IOP was 20.4 (0.7) mmHg and through up to 36 months of follow-up (minimum 12 months, mean 26.1 [1.0] months) ranged from 13.6 to 14.1 mmHg; significant reductions ($P < 0.0007$) of 5.7–7.0 mmHg (23.0%–29.5%) were achieved at every time point. Medications were reduced from 3.2 (0.1) to 0.2–2.0 (reductions of 1.2–3.1 medications [50.0%–94.9%]; $P < 0.0001$ at every time point). At months 24 and 36, the mean IOP was 13.9 (0.3) and 13.9 (0.5) mmHg and mean medications were 1.4 (0.2) and 2.0 (0.4). Mean logMAR VA improved from 1.0 (0.1) preoperatively to 0.2 [0.0]; $P < 0.001$ by month 6 and remained stable thereafter through the duration of follow-up.

CONCLUSION: KDB-phaco significantly lowered IOP approximately 30% by day 1 with consistency and durability through 3 years. Medication use was reduced by >50% through 36 months. Mean logMAR VA improved from 1.0 to 0.2 (Snellen equivalent 20/200–20/32). This procedure provides meaningful long-term reductions in IOP and the need for IOP-lowering medications without compromising visual rehabilitation in Saudi Arabian eyes with cataract and glaucoma.

Keywords:

Ab interno, combined phacoemulsification, glaucoma, goniotomy, Kahook Dual Blade, microinvasive glaucoma surgery, Schlemm's canal

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INTRODUCTION

The prevalence of visual impairment in Saudi Arabia has been estimated at 7%–25%,^[1] with cataract being the leading cause of reversible blindness and glaucoma being the second leading cause of irreversible blindness behind diabetic retinopathy.^[2] Of the various glaucoma subtypes,

primary open-angle glaucoma (POAG) was the most common (27.7%) in a recent review of newly diagnosed glaucoma patients in Eastern region Saudi Arabia, followed by secondary glaucomas (26.7%), primary angle-closure glaucoma (18.2%), primary congenital glaucoma (2.7%), and juvenile open-angle glaucoma (2.2%), which were the most frequent glaucoma subsets.^[3] In contrast, at a tertiary eye

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hospital in the capital city of Riyadh, primary angle-closure glaucoma (46.6%) and primary angle-closure (17.2%) were most common, with POAG (including normal-tension glaucoma) comprising only 18.7% of all glaucoma.^[4] Approximately half of the patients are legally blind in at least 1 eye at the time of diagnosis.^[3]

Combined cataract and glaucoma surgery addresses two common sources of vision loss in Saudi Arabia. Bleb-based surgeries such as trabeculectomy and tube-shunt implantation are effective procedures but have attendant risks, including endophthalmitis.^[5] In recent years, a variety of novel glaucoma procedures have been developed to provide lower-risk surgical intraocular pressure (IOP) reduction and improve the quality of life.^[6-8] Among these procedures is the excisional goniotomy, a procedure performed with the Kahook Dual Blade (KDB, New World Medical, Rancho Cucamonga, CA). This specially-designed instrument has a pointed tip that pierces the trabecular meshwork (TM) to enter Schlemm's canal; as the KDB is advanced along the canal, an integrated ramp lifts and stretches the TM onto two parallel blades that excise a narrow strip of TM.^[9] In published studies, excisional goniotomy combined with phacoemulsification (KDB-phaco) lowers IOP by 12%–27% and reduces the medication burden by 21%–71% through 6–12 months with a favorable safety profile and low reoperation rates.^[10-19]

In this study, we report the clinical outcomes of patients in Saudi Arabia with visually significant cataract and medically treated open-angle glaucoma who underwent KDB-phaco and were followed for up to 3 years.

METHODS

This was a retrospective analysis of data drawn from the medical records of consecutive patients undergoing KDB-phaco at a single practice in Saudi Arabia. Data collection was performed after review and approval of the study plan by a local ethics committee, which also granted a waiver of consent.

Patients whose data were included in this analysis were adults 18 years or older with medically managed glaucoma and visually significant cataract undergoing KDB-phaco for reduction of IOP and/or medication burden. IOP was measured by Goldmann tonometry twice, once each by a glaucoma specialist and a glaucoma fellow, at each visit; the mean of these two measurements represented the IOP at that visit for purposes of analysis. The combined KDB-phaco procedure has been previously described.^[10,12] In brief, after regular phacoemulsification and intraocular lens implantation, the anterior chamber was filled with ophthalmic viscosurgical device (OVD), a cohesive viscoelastic to keep anterior chamber angle deeper. The KDB was inserted into the anterior chamber and under intraoperative gonioscopy advanced to the nasal TM. The instrument's tip engaged TM until the heel of the device rested within Schlemm's canal. The blade was then advanced along the TM, which became elevated and stretched as it was

guided up the ramp to the two parallel cutting blades that removed an intact TM strip. Using the dip and strip technique in which the TM is punctured with the KDB at one end of the intended excision, the KDB then entered TM at the opposite end of the intended excision and was advanced to the first puncture site, typically removes 3–4 clock hours of TM. The KDB was then removed from the eye, and the excised strip of TM removed from the eye with forceps.

Information gathered including baseline demographic data as well as visual acuity (VA), IOP, and IOP-reducing drugs at each time point. Intraoperative and postoperative side events were also documented. Postoperative information were gathered on day-1, weeks 2 and 4–6, and months 2–3, 6, 9, 12, 18, 24, and 36 after surgery. VA was best-corrected VA (BCVA) preoperatively and beginning 4–6 weeks postoperatively. IOP was measured with Goldmann tonometry. In defining the number of IOP-reducing drugs used at each time point, compound medications were recorded by the number of constituents, and oral carbonic anhydrase inhibitors were also entered into the count.

The co-primary conclusions of this study were the reductions of both IOP and IOP-reducing drugs from baseline at each postoperative time point. These conclusions were assessed using paired *t*-tests. Secondary conclusions included the difference in BCVA from baseline (also assessed using paired tests), as well as the proportion of patients with >20% IOP reduction, with IOP <18 mmHg and <15 mmHg, with >1 medication reduction, and medication-free at each time point beginning at month 2–3 (after postoperative stabilization). No specific hypotheses were tested and formal power and sample size calculations were not undertaken. The level of significance was taken to be 0.05. Means are reported with standard errors. Data were analyzed using SAS version 9.4 (SAS Institute Inc., Cary, NC).

RESULTS

Data from 55 eyes of 47 patients undergoing KDB-phaco and followed for a minimum of 12 months and up to 36 months (mean 26.1 [1.0] months) were analyzed. Demographic and baseline glaucoma status data are given in Table 1. Patients' mean age was approximately 65 years and slightly more were men than women. All were natives of Saudi Arabia.

IOP data at each time point are given in Table 2 and Figure 1. Mean IOP was 20.4 (0.8) mmHg at baseline and through 36 months of follow-up ranged from 13.6 to 14.1 mmHg ($P < 0.0007$ at all time points). At months 24 and 36, mean IOP was 13.9 (0.3) and 13.9 (0.5) mmHg, respectively. Overall, 69.1%–75.0% of eyes attained IOP reductions >20%, 92.7%–100% attained IOP <18 mmHg, and 71.7%–81.8% of eyes attained IOP <15 mmHg [Table 3].

IOP medication data at each time point are given in Table 2 and Figure 2. The mean number of medications used per eye

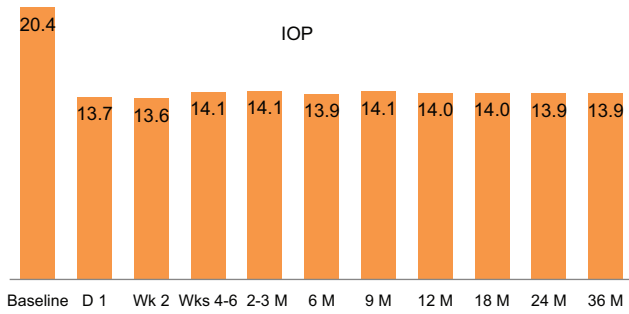


Figure 1: Mean IOP at each visit, $P < 0.0001$ at all time points, D 1: Day one, WK: Week, M: Month. IOP: Intraocular pressure

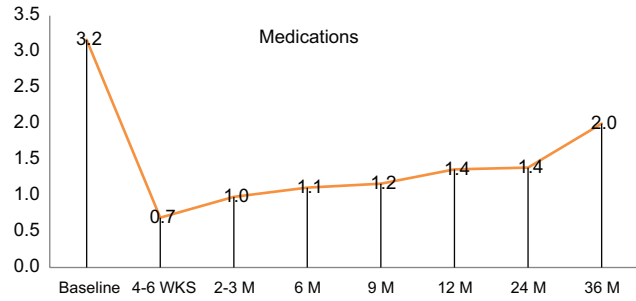


Figure 2: Mean number of IOP-lowering medications at each visit. $P < 0.0001$ at all-time points, WK: Week, M: Month. IOP: Intraocular pressure

Table 1: Demographics and baseline glaucoma status in 55 eyes of 47 subjects

Parameter	Value
Subject-level	
Age (years), mean (SE)	64.9 (1.4)
Gender, <i>n</i> (%)	
Male	30 (54.5)
Female	25 (45.5)
Eye-level	
Follow-up (months), mean (SE)	26.1 (1.0)
Operative eye, <i>n</i> (%)	
Right	31 (56.4)
Left	24 (43.6)
Cup-disc ratio, mean (SE)	0.7 (0.0)

SE: Standard error

was 3.3 at baseline and through 36 months of follow-up ranged from 0.2 to 2.0 ($P < 0.0001$ at all time points). At months 24 and 36, mean medication use was 1.4 (0.2) and 2.0 (0.4), respectively. The proportion of eyes attaining >1 medication reduction ranged from 87.5% to 100%, and the proportion that was medication-free ranged from 31.2% to 50.9% at each time point [Table 3].

VA data at each time point are given in Table 2. Mean logMAR BCVA was 0.98 (0.12) at baseline and was significantly improved ($P < 0.0019$ at all time points) through 36 months of follow-up. At months 24 and 36, mean BCVA was 0.20 (0.03) and 0.17 (0.07), respectively. All eyes but 1 (20/40 preoperatively and 20/50 at month 36) had improved or stable BCVA at last follow-up.

The procedure was safe and well-tolerated. Six eyes (10.9%) had transient hyphema that cleared spontaneously in all cases, and 1 eye (1.8%) had raised IOP on the first postoperative day related to retained OVD which likewise cleared spontaneously.

DISCUSSION

In what we believe to be the longest study of KDB-phaco reported to date, we have demonstrated significant and persistent reductions in IOP and the need for IOP-lowering medications through up to 36 months in Saudi Arabian patients with glaucoma. The procedure was well tolerated by all eyes,

with few adverse events, all of which resolved spontaneously without intervention.

The IOP reductions witnessed in this analysis are consistent with IOP reductions described in other studies of KDB-phaco (12%–27%) in predominantly POAG eyes.^[10-19] Likewise, drugs reductions in the current analysis are similar to previously described conclusions in POAG eyes (21%–71%).^[10-19] These previous benchmarks were described in studies mostly of 6–12 months' extent. The current study included data from all subjects through 12 months, from 46 subjects (83.6%) through 24 months, and from 16 subjects (29.1%) through 36 months. At these longer follow-up periods, IOP reductions persisted steadily while drugs reductions lessened slightly, although both IOP and drugs reductions were significant from baseline at both 24 to 36 months.

In addition to its longer duration, this study differs from prior reports in that its sample was composed exclusively of Saudi Arabian patients. Little is known of outcomes of KDB as a standalone procedure or in combination with phacoemulsification in populations outside the United States. In a recent retrospective analysis from Saudi Arabia that included 10 standalone and 40 KDB-phaco cases, mean IOP reduction of 29% and mean medication reduction of 86% was reported 4–7 months postoperatively; medication reductions were similar in combined and standalone cases, although greater IOP reductions were seen in KDB-phaco compared to standalone KDB eyes.^[20] A pair of reports from a data set comprised of both American and Vietnamese angle-closure glaucoma patients undergoing KDB-phaco combined with goniosynechialysis found 6- and 12-month IOP reductions of 49% and 47%, respectively, and medication reductions of 92% at both time points.^[21,22]

Strengths of this study, discussed above, include its length of follow-up and its patient population of Saudi Arabian glaucoma patients. Limitations of this study are those inherent to retrospective studies, including among others selection bias and lack of standardization of clinical assessments. We attempted to mitigate the former by including consecutive eligible patients. Furthermore, the lack of a control group – common to many retrospective analyses of novel glaucoma procedure outcomes – precludes benchmarking our results to other

Table 2: Intraocular pressure, medication, and visual acuity data at each time point in eyes with open-angle glaucoma (n=55)

	Baseline	Day 1	Week 2	Week 4-6	Month 2-3	Month 6	Month 12	Month 18	Month 24	Month 36
Number of patients	55	55	55	49	55	55	55	49	46	16
IOP (mmHg), mean (SE)	20.4 (0.8)	14.1 (0.9)	13.6 (0.5)	14.1 (0.5)	14.1 (0.4)	13.9 (0.4)	14.0 (0.3)	14.0 (0.3)	13.9 (0.3)	13.9 (0.5)
IOP change from baseline, (mmHg), mean (SE)	-	-6.2 (1.1)	-6.8 (0.9)	-5.7 (0.9)	-6.2 (0.8)	-6.5 (0.9)	-6.4 (0.8)	-6.5 (0.8)	-7.0 (0.8)	-6.0 (1.4)
Percentage IOP change from baseline, mean (SE)	-	-25.1 (5.6)	-27.3 (4.6)	-23.0 (4.3)	-23.3 (3.7)	-25.7 (3.9)	-25.4 (3.8)	-26.6 (3.4)	-29.5 (3.3)	-24.7 (6.6)
P (IOP mean change from baseline)	-	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	0.0007
Medications (n), mean (SE)	3.3 (0.2)	0.2 (0.1)	0.4 (0.1)	0.7 (0.1)	1.0 (0.2)	1.1 (0.2)	1.4 (0.2)	1.4 (0.2)	1.4 (0.2)	2.0 (0.4)
Medication change from baseline (n), mean (SE)	-	-3.1 (0.2)	-2.9 (0.2)	-2.6 (0.2)	-2.3 (0.1)	-2.2 (0.1)	-1.9 (0.1)	-2.0 (0.2)	-2.0 (0.2)	-1.2 (0.2)
Percentage medication change from baseline, mean (SE)	-	-94.9 (2.2)	-91.1 (2.9)	-81.9 (3.6)	-74.7 (3.8)	-71.2 (3.9)	-65.1 (4.5)	-64.7 (4.7)	-65.3 (5.0)	-50.0 (9.4)
P (medication mean change from baseline)	-	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
BCVA (logMAR), mean (SE)	0.98 (0.12)	1.04 (0.12)	0.60 (0.08)	0.43 (0.09)	0.33 (0.06)	0.25 (0.04)	0.24 (0.04)	0.21 (0.03)	0.20a (0.03)	0.17 (0.07)
BCVA change from baseline, logMAR, mean (SE)	-	0.06 (0.12)	-0.38 (0.09)	-0.41 (0.07)	-0.65 (0.09)	-0.74 (0.10)	-0.75 (0.10)	-0.72 (0.10)	-0.71 (0.10)	-0.41 (0.11)
Percentage BCVA change from baseline (logMAR), mean (SE)	-	66.7 (35.1)	-15.6 (12.0)	-43.5 (9.34)	-61.6 (6.06)	-72.5 (3.96)	-74.2 (3.62)	-75.7 (3.87)	-77.0 (3.98)	-73.4 (9.62)
P (BCVA mean change from baseline)	-	0.6579	0.0002	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	0.0019

*Number of patients data for logMAR at month 24 is n=45. BCVA: Best-corrected visual acuity, IOP: Intraocular pressure, logMAR: Logarithm of the minimum angle of resolution, SE: Standard error

Table 3: Prespecified intraocular pressure and medication outcomes at each time point

	Month 2-3 (%)	Month 6 (%)	Month 12 (%)	Month 18 (%)	Month 24 (%)	Month 36 (%)
Number of patients (n)	55	55	55	49	46	16
Proportion achieving IOP reduction ≥20% compared to baseline	69.1	69.1	70.9	69.4	73.9	75.0
Proportion achieving IOP ≤18 mmHg	92.7	92.7	98.2	98.0	97.8	100
Proportion achieving IOP ≤15 mmHg	76.4	81.8	76.4	81.6	71.7	75.0
Proportion using ≥1 fewer medication compared to baseline	100	100	96.4	98.0	97.8	87.5
Proportion medication-free	50.9	45.4	41.8	40.8	43.5	31.2

IOP: Intraocular pressure

procedures in a head-to-head fashion, which we have attempted to mitigate by comparing our results to those of other published studies of similar design.

Altogether, KDB-phaco significantly reduced IOP almost 30% by day 1 with consistency and durability through

3 years. Drugs use was lowered by >50% at 24 months and 38% at 36 months. Mean logMAR VA enhanced from 1.0 to 0.2 (Snellen equivalent 20/200–20/32). This practice affords significant visual recovery with long-term reductions in IOP and the demand for IOP-reducing drugs in Saudi Arabian eyes with cataract and glaucoma.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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