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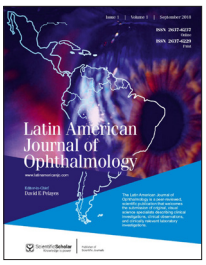

Original Article *Glaucoma*

One-year outcome of goniotomy with Kahook Dual Blade in primary open-angle glaucoma patients

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ABSTRACT

Objectives: The objective is to describe a -year outcome of goniotomy using the Kahook Dual Blade (KDB, New World Medical Inc., Rancho Cucamonga, CA) in patients with primary open-angle glaucoma (POAG) either as a standalone or plus phacoemulsification (phaco).

Material and Methods: We reviewed 12 eyes of 9 patients who had goniotomy with KDB either as a standalone or combined with cataract surgery by phaco from April 2017 to July 2018 at Eye Foundation Hospital, Ikeja, Lagos. The patients were followed for a minimum of 12 months.

Results: The mean age of the patients was 66.4 ± 8.8 years. The mean pre-operative intraocular pressure (IOP) for all eyes was 18.58 ± 5.42 mmHg. After 12 months of follow-up, the mean IOP was 14.27 ± 5.22 mmHg, representing a drop of 4.31 mmHg (23.2%) from baseline. For the Phaco+KDB group, the mean IOP changed from 19.25 ± 4.56 mmHg to 15.0 ± 6.03 mmHg for the same period, representing a reduction of 4.25 mmHg (22.1%) from baseline, and for the KDB as a standalone, the mean IOP change was 4.25 mmHg (24.6%) from baseline (17.25 ± 7.45 to 13.0 ± 3.83 mmHg). For all eyes, the mean number of topical antiglaucoma medications dropped by 0.88 (36.4%) from 2.42 ± 0.90 to 1.54 ± 1.51, whereas for the Phaco+KDB group, the topical antiglaucoma medications were reduced by 1.17 (46.8%) from 2.50 ± 0.93 to 1.33 ± 1.50. However, there was no change in the number of topical antiglaucoma medications in the KDB group after 12 months of follow-up (2.25 ± 0.96 to 2.25 ± 1.50). Transient hyphema in one and posterior capsular opacity (PCO) were the only recorded post-operative complications.

Conclusion: KDB, either as a standalone or with phaco, recorded at least a 20% reduction in IOP after one year of follow-up in these series.

Keywords: Outcome, Goniotomy, Kahook Dual Blade, Primary open-angle glaucoma

INTRODUCTION

The traditional goniotomy done with a microvitreoretinal blade in adults has been shown to have a mixed long-term result because of incomplete removal of the trabecular meshwork (TM) and inflammation attendant to damage to the surrounding structure.[1] The recent renewed desire to enhance aqueous outflow through the conventional pathway with minimal injury to ocular structures has led to the development of minimally invasive surgical devices. One of such devices is the Kahook Dual Blade (KDB by New World Medical, Rancho Cucamonga, California), a novel goniotomy blade designed for complete removal of the TM through a minimally invasive approach.[2] Minimally invasive glaucoma surgeries (MIGSs) are gradually becoming more widespread. Their

usage has been found to be effective in mild-to-moderate open-angle glaucoma and reducing the need for multiple topical medications.[3] KDB can be used as a standalone or in conjunction with phacoemulsification (phaco).

We have earlier reported a 6-month outcome of this study and found that in the short term, KDB goniotomy, either as a standalone or in combination with phaco, was effective in the management of primary open-angle glaucoma (POAG) with varied severity.[4] This is to report the 1-year outcome of this procedure for the management of POAG with varied severity.

MATERIAL AND METHODS

This was a retrospective analysis of data collected from medical records of patients with POAG of varying severity who had goniotomy with KDB (New World Medical Inc., Rancho Cucamonga, CA) either as a standalone or with cataract surgery using phaco at the Eye Foundation Hospital, Ikeja, Lagos, Nigeria, from April 2017 to July 2018.

The procedures carried out in this study involving human subjects followed the ethical standards of the hospital and the tenets of the Helsinki Declaration. Informed consent for the study was taken from every individual in this study.

Pre-operative data collected included patient demographic information (age and gender), glaucoma type and severity, current intraocular pressure (IOP)-lowering medications, past ocular surgical history, relevant systemic medical history, and baseline visual acuity and IOP. Post-operative data collected included type of surgery, post-operative visits, ocular and systemic medications, visual acuity, IOP, any new adverse events, and any secondary surgical interventions for IOP control. Data from day 1 to 12 months of follow-up are included in this analysis. Means were reported as ± standard deviation (SD).

The surgeries were performed by an experienced glaucoma surgeon (OA) and a glaucoma fellow (GIN). The surgical technique used in this study was reported by Sieck *et al.*[2] Postoperatively, patients who had combined KDB and phaco were started on Guttae Maxitrol 2 hourly, Guttae Ciloxan (Novartis) 4 hourly, and Maxitrol ointment nocte daily, which were tapered over 8 weeks. Guttae Pilocarpine 2%, four times a day, was given, for 1 week. For the standalone KDB, the eyes were placed on Guttae Maxitrol 6 hourly and Guttae Ciloxan 6 hourly, which were tapered down within 4 weeks. The primary efficacy outcome measure was a ≥20% decrease in IOP from baseline. The secondary outcome was an IOP-lowering medical regimen reduced by ≥1 medication compared with pre-operative therapy.

Statistical analyses

All data were cross-checked for accuracy and entered in a pro forma, and were analyzed using commercially available statistical data management software, Statistical Package for Social Sciences (IBM-SPSS) version 25. Continuous variables were illustrated in the form of mean ± SD, and categorical variables were shown in the form of frequency and percent. Comparisons among continuous data were done using analysis of variance, whereas categorical data were analyzed using the χ^2-test. A comparison between pre-operative and post-operative IOP was done using a *t*-test; $P < 0.05$ was considered statistically significant.

RESULTS

A total of 12 eyes from 9 patients were included in the study. The mean age of the patients was 66.4 ± 8.8 years. Eight eyes had goniotomy with KDB plus phaco with posterior intraocular lens implantation, while four eyes had goniotomy with KDB as a standalone. The other demographic and clinical characteristics are shown in Table 1. The majority of the eyes (7, 58.3%) have severe POAG.

Table 1: Demographic and clinical characteristics of the patients.

Characteristics	Type of surgery	
	KDB	Phaco+KDB
Age (years)		
Mean±SD	68.0±8.83	64.5±8.23
Range	63–77	54–82
Gender (%)		
Male	2 (22.2)	3 (33.3)
Female	1 (11.1)	3 (33.3)
Eye (%)		
Right	3 (25)	4 (33.3)
Left	1 (8.3)	4 (33.3)
Glaucoma severity		
Mild	2	0
Moderate	1	2
Severe	1	6

KDB: Kahook Dual Blade, Phaco: Phacoemulsification, SD: Standard deviation

IOP at baseline and follow-up for all eyes, eyes with phaco-cataract surgery, KDB goniotomy, and standalone KDB goniotomy eyes

At the end of the 1-year follow-up, 11 eyes of 8 patients were available for analysis. The mean IOP for these 11 eyes at 1-year follow-up was 14.27 ± 5.22, representing a drop of 4.31 mmHg (23.2%) in IOP from baseline. From day 1 through the 12th month of post-operative follow-up, the mean IOP ranged from 18.58 ± 9.26 mmHg to 12 ± 2.20 mmHg, representing a reduction of 0–6.38 mmHg (0–34.3%; $P < 0.05$ at each time point versus baseline except for day 1), with peak reduction occurring at the 9-month post-operative period, as seen in Table 2. For the Phaco+KDB group, the baseline mean IOP was 19.25 ± 4.56 mmHg while the mean IOP post-operatively from day 1 to 12 months ranged from 19.13 ±

8.99 mmHg to 11.43 ± 3.36 mmHg, representing a reduction of 0.12 mmHg to 7.82 mmHg (0.6–40.6%; $P < 0.05$ only from day 1 to 12 months), with peak reduction also occurring at the 9-month post-operative period. The mean IOP at baseline for the eyes that had KDB goniotomy as a standalone was 17.25 ± 7.45 mmHg. From day 1 to 12 months of follow-up, the mean IOP ranged from 17.50 ± 11.09 mmHg to 12.67 ± 1.15 mmHg, which represented reductions of −0.25–4.58 mmHg (−1.45–26.6%; $P < 0.05$) compared with baseline [Table 2]. The highest IOP reduction for the KDB group occurred at the 6-month post-operative period.

For all eyes and eyes that had KDB goniotomy as a standalone, IOP reduction was not evident on day 1, whereas for the eyes that had Phaco cataract surgery plus KDB goniotomy, reduction of IOP was evident from day one and maintained throughout the follow-up period.

The mean number of antiglaucoma medication usage at baseline and follow-up for all eyes, eyes with phaco cataract surgery, KDB goniotomy, and standalone KDB goniotomy eyes.

After 12 months of follow-up [Table 3] for all eyes, the mean number of topical medications was 1.54 ± 1.51, representing a drop of 0.88 (<1, 36.4%, $P = 0.06$). For the Phaco+KDB group, the pre-operative mean antiglaucoma topical medication was 2.50 ± 0.93, and after 12 months of follow-up, it was 1.33 ± 1.50, representing a 1.17 reduction in the number of topical medications (>1, $P < 0.05$; 46.8%). The pre-operative mean number of antiglaucoma topical medication for the KDB group was 2.25 ± 0.96, while the 12-month post-operative mean number was 2.25 ± 1.50, indicating no change in the usage of topical antiglaucoma [Table 3]. Except for week 1, a sustained drop in the number of topical antiglaucoma

Table 2: Intraocular pressure at baseline and follow-up for all eyes, eyes with phaco cataract surgery and KDB goniotomy and standalone KDB goniotomy eyes.

	Pre-operative	Day1	WK1	MO1	MO3	MO6	MO9	MO12
All patients								
Eye, *n*	12	12	12	12	12	12	11	11
IOP, mean (SD)	18.58±5.42	18.58±9.26	15.55±5.65	14.75±3.75	13.0±1.34	12.27±1.68	12.20±3.43	14.27±5.22
P-value	0.864	0.01*	0.01*	0.02*	0.001*	0.001*	0.001*	
Phaco/KDB								
Eye, *n*	8	8	8	8	8	8	7	7
IOP, mean (SD)	19.25±4.56	19.13±8.99	15.88±6.33	13.63±2.62	13.0±1.51	12.13±1.89	11.43±3.36	15.0±6.03
P-value	0.910	0.002*	0.001*	0.001*	0.001*	0.001*	0.001*	
KDB alone								
Eye, *n*	4	4	4	4	4	4	4	4
IOP, mean (SD)	17.25±7.45	17.50±11.09	14.67±4.16	17.0±4.97	13.0±1.0	12.67±1.15	13.5±2.38	13.0±3.83
P-value	0.842	0.001*	0.808	0.04*	0.04*	0.003*	0.003*	

*Statistically significant ($P<0.05$). WK: Week, MO: Month, Phaco/KDB: Kahook Dual Blade combined with phacoemulsification, KDB: Kahook Dual Blade, SD: Standard deviation, IOP: Intraocular pressure, Phaco: Phacoemulsification

Table 3: Mean number of antiglaucoma medications usage at baseline and follow-up for all eyes, eyes with phaco cataract surgery, and KDB goniotomy and standalone KDB goniotomy eyes.

	Pre-operative	WK1	MO1	MO3	MO6	MO9	MO12
All patients							
Eye, n	12	12	12	12	12	11	11
No. of meds mean (SD)	2.42±0.90	3.33±0.58	1.15±1.07	1.08±0.79	0.90±0.57	1.0±1.10	1.54±1.51
P-value		0.02*	0.006*	0.002*	0.01*	0.02*	0.06
Phaco/KDB							
Eye, *n*	8	8	8	8	8	7	7
No. of meds mean (SD)	2.50±0.93	3.50±0.71	1.11±1.05	0.88±0.35	0.88±035	1.57±0.98	1.33±1.50
P-value		0.02*	0.003*	0.001*	0.001*	0.03*	0.02*
KDB alone							
Eye, n	4	4	4	4	4	4	4
No. of meds mean (SD)	2.25±096	3.0±0.11	1.0±1.22	1.50±1.29	1.0±1.41	1.75±0.95	2.25±1.50
P-value		0.146	0.01*	0.11	0.01*	0.22	0.948

*Statistically significant ($P<0.05$). WK: Week, MO: Month, Phaco/KDB: Kahook Dual Blade combined with phacoemulsification, KDB: Kahook Dual Blade, SD: Standard deviation, IOP: Intraocular pressure, Phaco: Phacoemulsification, Meds: Medications

medications was observed for all 3 groups until 12 months post-operative period, except for the KDB group, where no change was noted. After 12 months of follow-up, the use of antiglaucoma medication declined at least by one in only the Phaco+KDB group in this study.

Eight eyes achieved at least a 20% reduction in the mean IOP from baseline, as shown in Table 4. Therefore, 8 eyes (66.67%) achieved the primary objective of ≥20% reduction in IOP from baseline with or without topical medications. For the KDB standalone group, 3 (37.5%) achieved ≥20% reduction, and for the Phaco+KDB group, 5 (62.5%) achieved ≥20% reduction in IOP from baseline with or without topical medications.

Table 4: Proportion of eyes with≥20% reduction in IOP.

Type of surgery	≥20% drop in IOP from pre to post		Total	Fisher's exact P
	Yes Freq (%)	No Freq (%)		
Kahook	3 (37.5)	**1 (25.0)**	**4 (33.33)**	1.00
Phaco-Kahook	5 (62.5)	3 (75.0)	8 (66.67)	
All (Total)	**8**	**4**	**12**	

IOP: Intraocular pressure

Out of the eight eyes that achieved ≥20% reduction in IOP from baseline, only two eyes were not on topical medications. Therefore, eight eyes achieved qualified success, while two eyes achieved complete success after 1-year of follow-up.

The log MAR visual acuity for all eyes dropped from 0.51 ± 0.25 to 0.57 ± 1.01 from baseline. This drop was not statistically significant ($P = 0.29$). For the KDB as a standalone, the mean LogMAR visual acuity of 0.00 ± 0.00 did not change from baseline to the last follow-up visit, while the VA of the phaco+KDB group changed from 0.51 ± 0.25 at baseline to 0.57 ± 1.01 at the last follow-up visit. This drop in LogMAR acuity was because of posterior capsular opacity in one eye.

The complications consisted of transient hyphema in 2 (16.7%) eyes and posterior capsular opacity in one eye. None of the eyes had an additional intervention to reduce the IOP during the period under review.

DISCUSSION

Goniotomy with KDB is an excisional ab interno trabeculectomy resulting in no residual TM tissue.[5] This contrasts with the traditional goniotomy, which is associated with the residual leaflet of TM. Therefore, the long-term outcome of the traditional goniotomy has been quite disappointing, primarily due to fibrosis of the outflow pathway occasioned by remnants of the TM.[5]

In this long-term outcome study, we reported a mean IOP drop of 4.31 mmHg (23.2%) from baseline after 12 months of follow-up for all eyes. Dorairaj *et al.*[6] reported a similar mean IOP drop of 4.4 mmHg (26.2%) from baseline after 12 months of follow-up in 52 eyes of 52 patients who had KDB and phaco. Theirs was a prospective study, while ours was a retrospective study. However, in a retrospective study of 197 eyes with varying degrees of severity of open-angle glaucoma, Sieck *et al.*[2] reported a lower mean IOP drop of 2.9 mmHg (17.3%) from baseline (17.3 ± 0.4 to 13.9 ± 0.3) at 12 months of follow-up. In another retrospective study by Kornmann *et al.*,[5] a mean IOP reduction of 1.6 mmHg (10%) from baseline at 12 months of follow-up in eyes that had KDB and phaco cataract surgeries and KDB alone. In our series, the mean IOP reduction for the Phaco+KDB group and KDB standalone group after 12 months of follow-up was 4.25 mmHg (22.1%) and 4.25 mmHg (24.6%), respectively, from the baseline. Sieck *et al.*,[2] in their own study, reported a mean IOP drop of 3.4 mmHg (19.7%) for the phaco+KDB group and 6.3 mmHg (30.9%).

Topical antiglaucoma medications were reduced by 0.88 (36.4%) for all eyes at 12 months of follow-up, which does not meet our secondary outcome measure. However, a 36.4% drop in the use of topical medication was statistically significant ($P = 0.06$); [Table 4]. For the Phaco+KDB group, the topical antiglaucoma medications reduced by 1.17 (46.8%) from baseline after 12 months of follow-up, while there was no change in the use of topical antiglaucoma medications in the KDB standalone group. Dorairaj *et al.*[6] in their study, reported a reduction in the use of topical antiglaucoma of 0.8 (50%) from baseline for eyes that had phaco+KDB after 12 months of follow-up (1.6 ± 0.2 to 0.8 ± 0.1). While our study involved only patients with POAG, the Dorairaj *et al.*[6] study consisted of POAG, pigmentary glaucoma, exfoliation glaucoma, and normal tension glaucoma. Although their study had a similar IOP reduction to our study, the number of topical medication uses was reduced by at least one in our study for the comparable group, which may be explained by the different types of glaucoma in their study compared with that in this study. Kornmann *et al.*[5] after 12 months of follow-up reported a drop in the use of antiglaucoma from 2.4 ± 1.3 at baseline to 1.1 ± 1.3, representing a reduction of 1.3 (54.2%) for all eyes that had phaco+KDB and KDB alone. At 12 months of follow-up, we observed that the mean number of topical antiglaucoma uses remained the same as the pre-operative number in the KDB standalone group. In general, the use of topical antiglaucoma dropped maximally at six months of follow-up for all three groups in this study.

After 12 months of follow-up, 8 (66.6%) of all the eyes achieved a success rate of ≥20% reduction in IOP. This finding is comparable to the finding by Dorairaj *et al.*,[6] who reported a success rate of 57.7% in their study. Sieck *et al.*[2] reported a success rate of 71.8% for phaco-KDB and 68.8% for KDB as a standalone after 12 months of follow-up.

One eye in the phaco+KDB group in our study developed significant posterior capsular opacity, which resulted in the drop in the mean LogMAR visual acuity noted. The complications reported in this study were essentially like those reported by the studies mentioned above.

The major drawback of this study is the small sample size. However, our findings will help enrich the body of knowledge concerning this relatively new procedure, especially among black eyes in Africa.

CONCLUSION

Goniotomy with KDB, either as a standalone procedure or in conjunction with cataract surgery using phaco, achieved at least a 20% reduction in IOP in these series with transient post-operative complications.

Ethical approval

The research/study complied with the Helsinki Declaration of 1964.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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