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3-Year Outcomes of Excisional Goniotomy with the Kahook Dual Blade for Glaucoma in Bolivia

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Abstract

Purpose: To characterize long-term Intraocular Pressure (IOP) and IOP-lowering medication reductions through 3 years following Excisional Goniotomy (EG) using the Kahook Dual Blade (New World Medical) combined with phacoemulsification in Bolivia.

Methods: This was a single-surgeon, retrospective analysis. Preoperative and postoperative IOP and medication use data were collected through 3 years of follow-up. Changes from baseline were analyzed using paired t-tests.

Results: Overall, 30 eyes of 25 patients were included; all were seen through 3 years of follow-up. The mean (standard deviation) age was 66.4 (7.7) years and most had primary open-angle glaucoma (63.3%) or pseudoexfoliative glaucoma (33.3%). Mean preoperative IOP was 20.8 (2.9) mmHg with subjects using a mean of 2.0 (1.2) medications per eye. Across time points (1 week, 1, 3 and 6 months and 1, 2 and 3 years), mean IOP ranged from 13.4-15.2 mmHg ($p < 0.0001$ at all-time points). At 3 years postoperatively, mean IOP was 14 (1.8) mmHg (a reduction of 6.8 mmHg, 32.1%, $p < 0.0001$) and mean medication use was 0.4 (0.7) medications per eye (a reduction of 1.6 medications, 85%, $p < 0.0001$). At 3 years, 86.7% of eyes had IOP reductions >20% from preoperative baseline and 70% were medication-free.

Discussion: Consistent with prior reports, excisional goniotomy lowered IOP by 36% and medications by 75% three years postoperatively. These are both statistically significant and clinically significant therapeutic outcomes.

Conclusions: Excisional goniotomy combined with phacoemulsification provides long-term (3-year) reductions in both IOP and the need for IOP-lowering medications in eyes with primary open angle glaucoma or pseudoexfoliative glaucoma in Bolivia.

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Introduction

The traditional glaucoma treatment cascade reserves traditional filtering surgery-trabeculectomy and tube-shunt implantation-for eyes with severe, advanced, or medically recalcitrant disease. In recent years, numerous minimally invasive glaucoma procedures have been developed with the goal of expanding the surgical indications for glaucoma surgery to include patients with mild-moderate disease whose surgical goals are more modest than are typically derived from filtering procedures [1-3]. Excisional goniotomy, performed using the Kahook Dual Blade (KDB, New World Medical, Rancho Cucamonga, CA), is an ab interno procedure in which a region of the Trabecular Meshwork (TM) is excised to facilitate drainage of aqueous humor from the anterior chamber into the canal of Schlemm. The KDB features a ramped dual-blade configuration that stretches TM before excision to ensure removal of a wide enough strip to prevent re-approximation of the residual tissue flaps [4,5].

In clinical studies, excisional goniotomy with the KDB lowers IOP by 11-35% and medications by 15-92% as a standalone procedure [6-1]. And lowers IOP by 11-34% and medications by 11-87% when combined with phacoemulsification [6,9-24]. Of note, the longest study of excisional goniotomy with the KDB is a 24-month retrospective study conducted in Hispanic patients in the United States [24]. Given the lifelong chronicity of glaucoma, there exists significant unmet need for longer-term data for excisional goniotomy and other novel glaucoma procedures, to more fully inform surgeons and their patients of long-term prognoses following these procedures. Also, given that all but one published study of excisional goniotomy with the KDB to date were conducted in the United States (a single study of combined phacoemulsification/goniosynechialysis/excisional goniotomy for angle closure included some eyes from Vietnam [25]), there also exists unmet need for outcomes data in international samples with greater heterogeneity of ethnicity.

In this report, we present 36-month outcomes of a cohort of Bolivian patients with glaucoma who underwent excisional goniotomy with the KDB in combination with phacoemulsification (KDB-phaco).

Methods

This was a retrospective analysis of patients undergoing KDB-phaco at Clínica de Ojos Norte in Santa Cruz de la Sierra, Bolivia, between January 2016 and April 2020. The protocol for data collection and analysis was reviewed and approved by the Bolivian Glaucoma Society Ethics Committee, which granted a waiver of consent.

Subjects were adults aged 18 years or older with visually significant cataract and medically treated mild or moderate open-angle glaucoma who underwent KDB-phaco in one or both eyes to reduce IOP, the IOP-lowering medication burden, or both. To characterize long-term outcomes, only patients with a minimum of 3 years of follow-up without further surgical interventions for additional IOP control were included. All patients meeting these criteria in the author's clinical practice were included in this analysis.

All surgical procedures were performed by a single surgeon (MJJ). The surgical procedure has been described previously [4,20]. Briefly, following uncomplicated phacoemulsification, the KDB was passed through the corneal incision to the nasal angle, where its tip engaged and passed through TM so that the heel of the instrument rested against the outer wall of Schlemm's canal. The instrument was then advanced along the canal until the desired amount of TM had been excised. Postoperatively, all IOP-lowering medications were discontinued and a standard regimen of difluprednate and fixed combination gatifloxacin and dexamethasone was prescribed for 10 days. Data collected from health records included demographic and baseline glaucoma status data, Best-Corrected Visual Acuity (BCVA), IOP, and medication data at baseline and every postoperative visit (week 1 and months 1, 3, 6, 12, 24 and 36), and all intra- and postoperative adverse events. IOP was measured by fellowship-trained glaucoma specialists using Goldmann tonometry.

The primary outcomes analyzed in this report were reductions from baseline in IOP and IOP-lowering medications at each postoperative time point. Secondary outcomes included the proportions of eyes at 36 months attaining IOP reductions of >20%, target IOP of <18 mmHg and <15 mmHg, reduction of the medication regimen by 1 or more drugs, and medication-free. Safety assessment included changes in BCVA from baseline (analyzed in logMAR form) as well as the nature, frequency, and timing of adverse events. Changes from baseline in IOP, medications, and BCVA were assessed using paired t-tests, with $p = 0.05$ taken as the level of significance. Means are reported with their standard deviations. Absent the testing of any hypotheses, power and sample, size calculations were not undertaken; instead, the sample size consisted of the number of cases meeting eligibility at the time of data analysis.

Results

This analysis includes data from 30 eyes of 25 subjects undergoing combined KDB-phacoemulsification. Demographic and baseline glaucoma status data are given in Table 1. The majority were men (60%), of Hispanic/Latino ethnicity (92%), and the average age was 66.4 (7.7) years.

Table 1: Demographics and baseline glaucoma status in 32 eyes of 26 subjects.

Parameter	Value
Subject-Level (n=25)	
Age (yr), mean (SD)	66.4 (7.7)
Gender, n (%)	
Male	15 (60.0)
Female	10 (40.0)
Ethnicity, n (%)	
Hispanic - Latino	23 (92.0)
Other	2 (8.0)
Eye-Level (n=30)	
Operative eye, n (%)	
Right	15 (50.0)
Left	15 (50.0)
Diagnosis, n (%)	
Primary open-angle	19 (63.3)
Pseudoexfoliation	10 (33.3)
Narrow-angle	1 (3.3)
Severity, n (%)	
Mild	22 (73.3)
Moderate	8 (26.7)

Mean IOP data at each time point are given in Table 2. Mean IOP was 20.8 (2.9) mmHg at baseline and was significantly reduced at every postoperative time point through 3 years of follow-up. Significant IOP reductions manifested as soon as week 1 (mean IOP 15.2 [3.1], p < 0.0001), and upon postoperative stabilization, IOP remained consistent, ranging from 13.4-14.0 mmHg from months 3 through 36 (p < 0.0001 at every time point). Secondary outcomes are given in Table 3. At 36 months postoperatively, IOP reductions of >20% were achieved in 86.7% of eyes (26/30), final IOP <18 mmHg was achieved in 100% of eyes (30/30), and IOP < 15 mmHg was achieved in 76.7% of eyes (23/30).

Table 2: Intraocular pressure, medication, and visual acuity data at each time point (n=30 eyes).

	Baseline	Week 1	Month 1	Month 3	Month 6	Month 12	Month 24	Month 36
Intraocular pressure, mmHg								
Mean (SD)	20.8 (2.9)	15.2 (3.1)	14.6 (2.5)	13.6 (1.9)	13.4 (1.7)	13.4 (1.8)	13.5 (2)	14 (1.8)
Mean (SD) change from baseline	---	-5.6 (3.4)	-6.2 (2.5)	-7.2 (2.5)	-7.4 (2.3)	-7.8 (2.5)	-7.3 (2.5)	-6.8 (2.8)
Mean (SD) % change from baseline, %	---	-25.6 (14.2)	-29.7 (10.6)	-34.2 (8.8)	-35.1 (7.5)	-34.8 (9.1)	-34.4 (9)	-32.1 (10.1)
p (mean change from baseline)	---	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001
Medications, n								
Mean (SD)	2 (1.2)	0	0.2 (0.5)	0.2 (0.5)	0.3 (0.6)	0.3 (0.6)	0.3 (0.6)	0.4 (0.7)
Mean (SD) change from baseline	---	-2 (1.2)	-1.8 (1.1)	-1.8 (1.1)	-1.7 (1.0)	-1.7 (1.0)	-1.7 (1.1)	-1.6 (1.1)
Mean (SD) % change from baseline, %	---	-100 (0)	-92.7 (21.4)	-91.7 (21.7)	-88 (23.7)	-88 (23.7)	-87.3 (24.5)	-84.7 (26.6)
P (mean change from baseline)	---	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001

mmHg: Millimeters of mercury; SD: Standard Deviation

Mean medication use data at each time point are also given in Table 2. The mean number of medications used per eye at baseline was 2.0 (1.2) and was significantly reduced at every postoperative time point, ranging from 0-0.4 medications per eye (p < 0.0001 at every time point). At 36 months postoperatively, 96% of eyes on >1 medication at baseline (24/25) and 80% of all eyes (24/30) were using at least 1 fewer medication at month 36 compared to baseline (Table 3). Also, 68% of eyes were medicated at baseline (17/25) and 70% of all eyes (21/30) were medication-free at month 36 (Table 3).

Table 3: Pre-specified IOP and medication outcomes at month 36 (N=30 eyes).

Outcome	n (%)
Proportion achieving IOP reduction≥20% compared to baseline	26 (86.7)
Proportion achieving IOP ≤18 mmHg	30 (100)
Proportion achieving IOP ≤15 mmHg	23 (76.7)
Proportion using≥1 fewer medication compared to baseline	24 (80)
Proportion medication-free	21 (70)

IOP: Intraocular Pressure; mmHg: Millimeters of Mercury.

The procedure was well tolerated by all patients. Intra-and postoperative complications were limited to several cases of transient anterior chamber blood-common to angle surgeries-all of which resolved spontaneously without sequellae. No re-operations for complications were performed within the 3-year follow-up period in any eye. Mean logMAR BCVA improved from 0.5 (0.16) preoperatively to 0.22 (0.13) at 36 months (p < 0.0001).

Discussion

Our data demonstrate that KDB-phaco safely provides clinically and statistically significant reductions in both IOP and the need for IOP-lowering medications that are sustained through at least 36 months. All eyes achieved final IOP <18 mmHg, 87% had IOP reductions from baseline >20%, 96% were able to discontinue the use of at least 1 medication, and 70% were medication-free 3 years after surgery. These results are consistent with prior reports of excisional goniotomy combined with cataract surgery and support broader generalizability of their findings to other populations [6-24]. Of particular interest, our findings are comparable to or better than those reported in a prior study of KDB-phaco in Hispanic patients in the United States, in which 24-month IOP and medication reductions were 23% and 47%, respectively, [24] compared to our 24-month IOP and medication reductions of 34% and 87%, respectively. The more favorable outcomes obtained in our patients compared to this prior study may be attributable in part to our patients having less severe glaucoma than those in the prior study.

Glaucoma is a leading cause of irreversible vision loss and blindness worldwide [26]. The epidemiology of glaucoma in South America has not been fully characterized, but it has been estimated that in 2010, 23,000-36,000 people in Andean South America (the western region along the Andes mountain range that includes Bolivia) were blind from glaucoma and another 62,00-107,000 suffered moderate to severe visual impairment from glaucoma [26]. Further, approximately 5% of all visual impairment and 12% of all blindness in the region is attributable to glaucoma [26].

Bolivia is a landlocked, lower middle income country in west central South America, where the World Health Organization estimates that 63% of the population lives below the poverty line [27]. As in many resource-limited regions, specialized healthcare-as for glaucoma-has limited availability throughout most of the country. Also, the geography of the country-Bolivia is the 5th largest country in South America with the western third being mountainous-makes travelling for healthcare difficult and limits the feasibility of follow-up at centralized specialty cen-

ters. For these reasons and others, the utilization of traditional filtering procedures such as trabeculectomy and tube-shunt implantation is limited by the need for close and extended postoperative follow-up.

Excisional goniotomy with the KDB is a useful surgical procedure in this setting. The procedure has a long track record of success, has a well-established safety profile, does not require a permanent implant that can cause late safety issues, [28] and requires minimal postoperative management. Its cost is less than many other novel procedures that require either permanent implants or equipment to operate the instruments; this factor is critical in low-resource regions such as Bolivia. Importantly, combining the procedure with cataract surgery enhances its cost-effectiveness and maximizes the likelihood that patients will perceive a benefit to surgery, which is critical in regions that depend on community advocates and word-of-mouth for health education and awareness as well as referrals for evaluation and care.

This study has several limitations. There was no control group, and cataract surgery alone is known to lower IOP, [29]. Although not to the extent observed consistently at every time point in this study. The sample size was modest; although the consistency of outcomes relative to the existing literature support that, the sample size was adequate to estimate the true effect size. Also, there is a selection bias in that only patients with continued successful outcomes through 3 years were included. This precludes assessment of surgical success rates and the need for secondary glaucoma interventions within the first 3 years. However, we believe there is value in the data presented herein. When counseling patients regarding surgical prognosis, the likelihood of surgical success can be derived from many prior studies. The current study describes the nature of success in patients for whom the procedure is successful-an important complement to results of prior studies.

Conclusions

Excisional goniotomy with the KDB can safety provide long-term reductions in IOP and the need for IOP-lowering medications in Bolivian patients with glaucoma. Given the limitations and barriers to healthcare in the region, this procedure can play an important role in delaying or preventing visual impairment and blindness.

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