Long Term Outcome of Combined Phacoemulsification and Excisional Goniotomy with the Kahook Dual Blade in Different Subtypes of Glaucoma

Ahmed Al Habash (ahmedalhabash@gmail.com)
Imam Abdulrahman Bin Faisal University
Abdulrahman Al Buainain
Eye & Laser Centre, Bahrain Defence Force Hospital, Royal Medical Services

Research Article

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Abstract

Purpose: To characterize changes in intraocular pressure (IOP), IOP-lowering medications, and visual acuity (VA) through 3 years of follow-up in patients undergoing combined phacoemulsification and excisional goniotomy with the Kahook Dual Blade (phaco-KDB), with simultaneous goniosynechialysis in cases of angle-closure glaucoma, by a single surgeon (A.H.) in King Fahd Hospital of the University, Dammam, Saudi Arabia.

Methods: Prospective, non-comparative, uncontrolled, non-randomized interventional case series. Consecutive patients with medically-treated glaucoma and visually-significant cataract underwent combined surgery. Subgroup analysis of glaucoma subtypes was performed.

Results: Fifty-seven eyes (48 patients) including 29 eyes with primary open-angle glaucoma, 15 with pseudoexfoliation glaucoma, and 13 with angle-closure glaucoma, were enrolled. Mean (standard error) baseline IOP was 20.3 (0.7) mmHg and through up to 36 months of follow-up (minimum 12 months, mean 26.2 [1.0] months) ranged from 13.5-14.0 mmHg (13.7 mmHg at Month 36); significant reductions ($p \leq 0.0002$) of 23.6-29.9% were achieved at every time point. Medications were reduced from a mean of 3.3 (0.1) to 0.2-1.9 (reduction 51.4-94.7%; $p<0.0001$ at every time point). Mean logMAR VA improved from 0.97 (0.11) preoperatively to 0.25 (0.04) by Month 6 ($p<0.0001$), remaining stable thereafter. Outcomes were similar in POAG, pseudoexfoliation, and ACG subgroups. Hyphema occurred and resolved spontaneously in 6 eyes; 1 eye had elevated IOP on postoperative day 1.

Conclusions: Phaco-KDB significantly improved VA, lowered IOP ~25-30%, and lowered medications by >50% through 36 months. This combined procedure provides meaningful long-term reductions in IOP and need for IOP-lowering medication without compromising visual rehabilitation in eyes with cataract and glaucoma.

Introduction

Cataract is the world's most common cause of blindness,[1] and glaucoma represents an important cause of blindness worldwide as well.[2] Effective and safe intraocular pressure (IOP)-lowering treatments appropriate for patients with all types and severities of disease would help to halt progression of glaucomatous optic nerve damage and subsequent decline in quality of life.[3] Conventional surgical techniques for the treatment of glaucoma typically provide greater IOP reductions than more conservative medical and laser therapies,[4,5] but trabeculectomy and tube shunts have a higher risk of vision-threatening complications, including early postoperative complications such as hypotony and lifetime risk of bleb or device-related complications.[6,7] Longer visual recovery times, activity limitations, need for frequent follow-up, and secondary office-based or surgical interventions in the early postoperative phase also compromise the patient's quality of life as well as healthcare costs.

In recent years, a series of novel and less-invasive surgical techniques have been developed to provide meaningful IOP reductions with lower risk of complications compared to conventional glaucoma surgery. Most of these procedures avoid the formation of a filtering bleb—and its complications—by shunting aqueous humor across the obstructed trabecular meshwork (TM) into Schlemm's canal (SC) or into the suprachoroidal space, although a few techniques rely on subconjunctival filtration.[8,9] These procedures are considered safe and effective options that can be combined with cataract extraction and may prevent or delay the need for more invasive and higher-risk filtering or shunt surgeries, especially when used in early or moderate stages of the disease.[10,11]

The Kahook Dual Blade (KDB; New World Medical, Rancho Cucamonga, CA, USA) is an ophthalmic knife which is used to perform surgical ab interno trabeculectomy (commonly referred to as excisional goniotomy or gonioectomy).[12] Since the development of the KDB in 2015, a rising number of studies have established its efficacy and safety in reducing IOP and medication burden.[13,14] Unlike conventional goniotomy, which is frequently implemented in congenital glaucoma, the KDB's design allows complete resection of diseased TM on the inner wall of SC, allowing the flow of aqueous from the anterior

chamber to the distal outflow system.[12] The KDB also has a favorable safety profile.[13,14] The most common complication is intraoperative or early postoperative blood reflux that is to be expected with the unroofing of several collector channels and is generally transient.[15]

The newer glaucoma procedures are most commonly utilized in mild-to-moderate glaucoma, due to moderate efficacy compared to subconjunctival filtering procedures.[8-11] Therefore, most studies of these procedures have been limited to these populations. However, a previous study on stand-alone KDB goniotomy has shown promising efficacy and safety in severe glaucoma patients.[15] Another study demonstrated the efficacy of KDB combined with phacoemulsification (Phaco-KDB) in glaucoma patients across the spectrum of disease severity, of whom 22 had severe glaucoma.[14] To our knowledge, no study has specifically examined the long-term efficacy of KDB goniotomy combined with cataract surgery in patients with different types of glaucoma in our region of the world. In this study, we describe long-term (up to 36 months) outcomes of phacoemulsification and excisional goniotomy using the KDB, combined with goniosynechialysis in cases of angle-closure glaucoma, in patients with cataract and different types and stages of glaucoma.

Methods

Study Design

This was a prospective, non-comparative, uncontrolled, non-randomized interventional case series of consecutive patients undergoing combined Phaco-KDB, with simultaneous goniosynechialysis in cases of angle closure glaucoma. All the surgeries were performed by a single surgeon (A.H.) at King Fahd Hospital of the University, Dammam, Saudi Arabia over the course of three years. The protocol was reviewed and approved by Imam Abdulrahman Bin Faisal University IRB. Approval was given on the understanding that the "Guidelines for Ethical Research Practice" were adhered to, and all patients provided written informed consent to participate. Participating patients were adults 18 years or older with medically-managed glaucoma and visually significant cataract undergoing Phaco-KDB for reduction of IOP and/or medication burden, combined with goniosynechialysis in cases of angle-closure glaucoma. Patients undergoing any other combined procedures, active uveitis, coexisting retinopathy that limits visual acuity potential, active neovascularization, angle dysgenesis and those with less than 12 months of follow-up, were excluded.

Surgical Technique

The combined Phaco-KDB procedure has been previously described.[9,11] Briefly, following standard phacoemulsification and intraocular lens implantation, the anterior chamber was filled with ophthalmic viscosurgical device (OVD). The KDB was inserted into the anterior chamber and under intraoperative gonioscopy advanced to the nasal TM. In eyes with angle-closure glaucoma, goniosynechialysis was performed first, as described by Dorairaj.[16,17] The KDB's pointed tip engaged the peripheral iris at the base of each peripheral anterior synechia (PAS) and dissected the PAS with gentle radial pressure within the iris plane toward the pupillary center to reveal the trabecular meshwork. The excisional goniotomy was then performed as previously described.[13,14] The instrument's tip engaged TM until the heel of the device rested within SC. 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. The KDB was then removed from the eye and the excised strip of TM removed from the eye with forceps.

Statistical Analysis

Data collected in this study included baseline demographic information as well as visual acuity (VA), IOP, and IOP-lowering medications at every time point. Intraoperative and postoperative adverse events were also recorded. Postoperative data were collected at Day 1, Weeks 2, 4 and 6, and Months 2-3, 6, 9, 12, 18, 24, and 36 post-surgery. VA was best-corrected VA (BCVA) preoperatively and beginning 4-6 weeks postoperatively. IOP was measured with Goldmann applanation tonometry.

In determining the number of IOP-lowering medicines used at each time point, combination products were counted by the number of constituents and oral carbonic anhydrase inhibitors were also included in the count. The co-primary outcomes of this analysis were the reductions of both IOP and IOP-lowering medications from baseline at each postoperative time point. These outcomes were assessed using paired t-tests. Secondary outcomes included change 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). Subgroup analysis was undertaken to evaluate the co-primary endpoints separately in eyes with open-angle and closed-angle glaucoma; these outcomes were evaluated through 24 months of follow-up; the last time point at which sample sizes were adequate to characterize results. 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 57 eyes of 48 subjects undergoing Phaco-KDB with or without goniosynechialysis and followed for a minimum of 12 months and up to 36 months (mean 26.2 [1.0] months) were analyzed. Demographic and baseline glaucoma status data are given in Table 1. Subjects' mean age was 64.32 (1.4) years and slightly more were men (56%) than women (44%). Approximately half of the eyes (51%) had primary open-angle glaucoma (POAG), and a quarter each had pseudoexfoliation glaucoma (PXFG) (26%) and angle-closure glaucoma (ACG) (23%).

Table 1. Demographics and baseline glaucoma status in 57 eyes of 48 subjects.

Parameter	Value
Subject-Level (n=48)	
Age (yr), mean (SE)	64.3 (1.4)
Gender, n (%)	
Male	27 (56.3%)
Female	21 (43.8%)
Eye-Level (n=57)	
Follow-up (months), mean (SE)	26.2 (1.01)
Operative eye, n (%)	
Right	33 (58%)
Left	24 (42%)
Glaucoma type, n (%)	
Primary open-angle	29 (51%)
Pseudoexfoliation	15 (26%)
Angle closure	13 (23%)
Cup-disc ratio, mean (SE)	0.69 (0.02)

SE, standard error

IOP outcomes

IOP data at each time point for the full sample are given in Table 2 and Figure 1. Mean IOP was 20.3 (0.7) mmHg at Baseline and through 36 months of follow-up ranged from 13.5 to 14.0 mmHg ($p<0.0002$ at all-time points). IOP reductions ranged from 5.8-7.1 mmHg, representing percent IOP reductions of 23.6-29.9%. IOP reductions remained stable throughout follow-up, and at Months 24 and 36 mean IOP was 13.8 (0.3) and 13.7 (0.5) mmHg, respectively. Overall, across all time points, 68.6-77.8% of eyes attained IOP reductions >20%, 93.0-100% attained IOP <18 mmHg, and 72.9-82.5% of eyes attained IOP <15 mmHg (Table 3).

Table 2. Intraocular pressure, medication, and visual acuity data at each time point.

	Baseline	Day 1	Week 2	Week 4-6	Month 2-3	Month 6	Month 12	Month 18	Month 24	Month 36
Number of eyes	57	57	57	51	57	57	57	51	48	18
Mean (SE) IOP, mmHg	20.3 (0.7)	14.0 (0.9)	13.5 (0.5)	14.0 (0.5)	14.0 (0.4)	13.8 (0.4)	13.9 (0.3)	13.9 (0.3)	13.8 (0.3)	13.7 (0.5)
Mean (SE) IOP change from baseline, mmHg	--	-6.4 (1.1)	-6.9 (0.9)	-5.8 (0.9)	-6.3 (0.8)	-6.5 (0.8)	-6.5 (0.8)	-6.5 (0.7)	-7.1 (0.7)	-6.2 (1.3)
Mean (SE) % IOP change from baseline	--	-25.9 (5.4)	-27.8 (4.5)	-23.6 (4.1)	-25.7 (3.6)	-26.1 (3.8)	-25.9 (3.7)	-26.9 (3.3)	-29.9 (3.2)	-26.3 (6.0)
p (IOP mean change from baseline)	--	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	0.0002
Mean (SE) medications, n	3.3 (0.1)	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)	1.9 (0.4)
Mean (SE) medication change from baseline, n	--	-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)	-2.00 (0.2)	-1.3 (0.2)
Mean (SE) % medication change from baseline	--	-94.7 (2.3)	-90.5 (2.9)	-81.7 (3.5)	-74.3 (3.8)	-70.9 (3.9)	-65 (4.4)	-64.6 (4.7)	-65.2 (4.9)	-51.4 (8.9)
P (medication mean change from baseline)	--	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001
Mean (SE) BCVA, logMAR	0.97 (0.11)	1.11 (0.14)	0.60 (0.08)	0.40 (0.07)	0.32 (0.05)	0.25 (0.04)	0.24 (0.04)	0.21 (0.03)	0.2 (0.03)	0.18 (0.06)
Mean (SE) BCVA change from baseline, logMAR	--	0.14 (0.13)	-0.37 (0.09)	-0.43 (0.07)	-0.66 (0.09)	-0.72 (0.09)	-0.74 (0.09)	-0.71 (0.10)	-0.69 (0.10)	-0.42 (0.10)
Mean (SE) % BCVA change from baseline, logMAR	---	76 (36.1)	-15.6 (11.6)	-44.8 (8.95)	-61.7 (5.79)	-72.3 (3.93)	-74.4 (3.54)	-75.7 (3.77)	-76.8 (3.79)	-74.1 (8.69)
P (BCVA mean change from baseline)	---	0.2862	0.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	0.0005

BCVA, best-corrected visual acuity; IOP, intraocular pressure; logMAR, logarithm of the minimum angle of resolution; mmHg, millimeters of mercury; SE, standard error

Table 3. Pre-specified IOP and medication outcomes at each time point.

	Month 2-3	Month 6	Month 12	Month 18	Month 24	Month 36
Number of eyes (n)	57	57	57	51	48	18
Proportion achieving IOP reduction ≥20% compared to baseline	70.2%	70.2%	71.9%	68.6%	75%	77.8%
Proportion achieving IOP ≤18 mmHg	93%	93%	98%	98%	97.9%	100%
Proportion achieving IOP ≤15 mmHg	77.2%	82.5%	77.2%	82.3%	72.9%	77.8%
Proportion using ≥ 1 fewer medication compared to baseline	100%	100%	96.5%	98%	97.9%	88.9%
Proportion medication-free	50.9%	45.6%	42.1%	41.2%	43.7%	33.3%

IOP, intraocular pressure; mmHg, millimeters of mercury

Medication Outcomes

IOP medication data for the full sample at each time point are given in Table 2 and Figure 2. The mean number of medications used per eye was 3.3 (0.1) at baseline, and through 36 months of follow-up ranged from 0.2 to 1.9 ($p<0.0001$ at all-time points). Medication reductions ranged from 1.3 to 3.1, representing percent medication reductions of 51.4-94.7%. As anticipated, medication use dropped immediately after surgery and increased gradually throughout follow-up; at Months 24 and 36, mean medication use was 1.4 (0.2) and 1.9 (0.4), respectively. The proportion of eyes attaining >1 medication reduction ranged from 88.9 to 100%, and the proportion that were medication-free ranged from 33.3 to 50.9% at each time point (Table 3).

Visual Acuity Outcomes

Visual acuity data at each time point are given in Table 2. Mean logMAR BCVA was 0.97 (0.11) at baseline and was significantly improved ($p< 0.0005$ at all-time points after Day 1) through 36 months of follow-up. At Months 24 and 36, mean BCVA was 0.20 (0.03) and 0.18 (0.06), respectively. All eyes but 1 (20/40 preoperatively and 20/50 at Month 36) had improved or stable BCVA at last follow-up.

Outcomes in Subgroups

Mean IOP and IOP-lowering medication reductions from baseline were separately evaluated in the subgroups with POAG, PXFG, and ACG through 24 months of follow-up (Figures 1 and 2). In eyes with POAG, mean IOP reductions were 6.1-7.8 mmHg (25.2-34.5%; $p<0.0002$ at all-time points), and medication reductions were 1.6-2.9 (59.4-92.2%; $p<0.0001$ at all time points). At Month 24, mean IOP in eyes with POAG was reduced by 7.8 mmHg (34.5%; $p<0.0001$) and medications were reduced by 1.2 (55.8%; $p=0.0006$). In eyes with PXFG, mean IOP reductions were 5.5-6.9 mmHg (18.5-27.2%; $p<0.0409$ at all-time points), and medication reductions were 2.3 3.1 (74.3-96.7%; $p<0.0001$ at all-time points). At Month 24, mean IOP in eyes with pseudoexfoliation glaucoma was reduced by 6.4 mmHg (25.6%; $p=0.0007$) and medication use was reduced by 2.5 (74.3%; $p<0.0001$). In eyes with ACG, mean IOP reductions were 4.9-7.3 mmHg (18.5-32.7%; $p<0.0103$ at all-time points except Week 4-6 [18.5%; $p=0.0506$]), and medication reductions were 2.2-3.6 (63.6-100%; $p<0.0001$ at all-time points). At Month 24, mean IOP in eyes with ACG was reduced by 6.5 mmHg (25.7%; $p=0.0093$) and medication use was reduced by 2.3 mmHg (63.6%; $p<0.0001$). Improvements in BCVA in each subgroup were comparable to the overall sample finding.

Safety Outcomes

The combined procedure was safe and well tolerated. Six eyes (10.9%) developed transient hyphema that resolved spontaneously in all cases, and 1 eye (1.8%) developed elevated IOP on the first postoperative day attributed to retained OVD which also resolved spontaneously. No eyes required any secondary surgical interventions for IOP control throughout the follow-up period.

Discussion

In 2015, The Kahook Dual Blade (KDB, New World Medical, Rancho Cucamonga, CA) was launched in the United States. The KDB is a novel goniotomy blade produced to create a more complete removal of TM through a minimally invasive technique without any adjacent tissue injury.[12] The design of KDB has several key features to achieve a complete goniotomy. The tip is sharp, the heel fits comfortably within SC which allows smooth advancement of the blade without any collateral injury, the ramp of the blade stretches TM gently while blade advancement and the dual blades create parallel incisions facilitating excision of a strip of TM.[12,18] An additional benefit of the KDB is that it is a single-use, disposable instrument that does not require any additional special surgical equipment, without implant-related risks as no implant is left behind with this procedure.[18]

Reducing IOP or the medication burden are two main indications for combining glaucoma surgery with elective cataract surgery (as in most cases of POAG or pseudoexfoliation glaucoma) or in more urgent cases (as in acute ACG). Our prospective study is a real-world study that reveals the long experience of a single surgeon performing combined phaco-KDB demonstrates the safety, efficacy with a significant and persistent reduction in the IOP and the need for IOP-lowering medication throughout 36 months which is the longest reported follow up to date of which we are aware.

The IOP reductions observed in this study are consistent with IOP reductions reported in other studies of phaco-KDB in POAG eyes (12-27%). Similarly, medication reductions in the current study are similar to previously reported outcomes in POAG eyes (21-71%).[13,14,19-26]These prior benchmarks were reported in studies generally of 6-12 months' duration. The current study included data from all subjects through 12months, from 48 (84.2%) through 24 months, and from 18 (31.6%) through 36 months. At these more extended follow-up periods, IOP reductions remained stable, while medication reductions diminished somewhat in each of the three glaucoma type subgroups. However, both IOP and medication reductions were significant from baseline at both 24 and 36 months in the full sample and 24 months in each glaucoma subtype group. Two previous prospective studies have been achieved. In multicenter interventional case series, Greenwood and colleagues evaluated 71 eyes undergoing phacoemulsification with goniotomy.[14] At six months, 58.3% of patients had at least a 20% reduction of IOP from baseline, and 61.7% were using at least one fewer IOP lowering medication. Similar results were observed in a subsequent prospective interventional case series of 52 patients undergoing phaco-KDB. At 12 months, a 26.3% reduction of IOP was observed in addition to a 50% reduction in the number of medications used.[13]

In addition to its efficient IOP lowering and medication reduction, KDB goniotomy furthermore shows a well-tolerated and safe profile. Overall, most complications were transient hyphemia with spontaneous resolution in only six eyes, and one eye with transient high IOP due to retained OVD as we usually intend to leave some OVD in the end of the surgery, which also resolved spontaneously and were non-sight threatening. These results correspond with prior reports in the literature. [13-15,20,26]

Earlier studies have hypothesized that angle procedures targeting the TM may be more effective among the pseudoexfoliation glaucoma patient population as the pseudoexfoliative material may be obstructing TM outflow.[19] Only one prior study to date has compared the success rates of KDB goniotomy between POAG and PXFG. In their study, Sieck et al. reported a higher success rate among PXFG (84.6%) compared to POAG (66.0%). However, this difference did not reach statistical significance after .[19] Nonetheless, given the small sample sizes in this study, a definite conclusion cannot be drawn. In our subgroup analysis, there were no clinically significant differences between each type of glaucoma enrolled in the study.

Strengths of this study include its length of follow-up and its patient population of Saudi Arabian glaucoma patients. The lack of a control group—common to many retrospective analyses of novel glaucoma procedure outcomes—is a limitation that precludes benchmarking our results to other procedures in a head-to-head fashion.

Conclusions

In summary, Phaco-KDB significantly improved VA, lowered IOP ~25-30%, and lowered medications by >50% through 36 months. This combined procedure provides meaningful long-term reductions in IOP and need for IOP-lowering medication without compromising visual rehabilitation in eyes with cataract and glaucoma.

Declarations

Data Availability

The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest

The authors declare that they have no competing interests.

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Figures

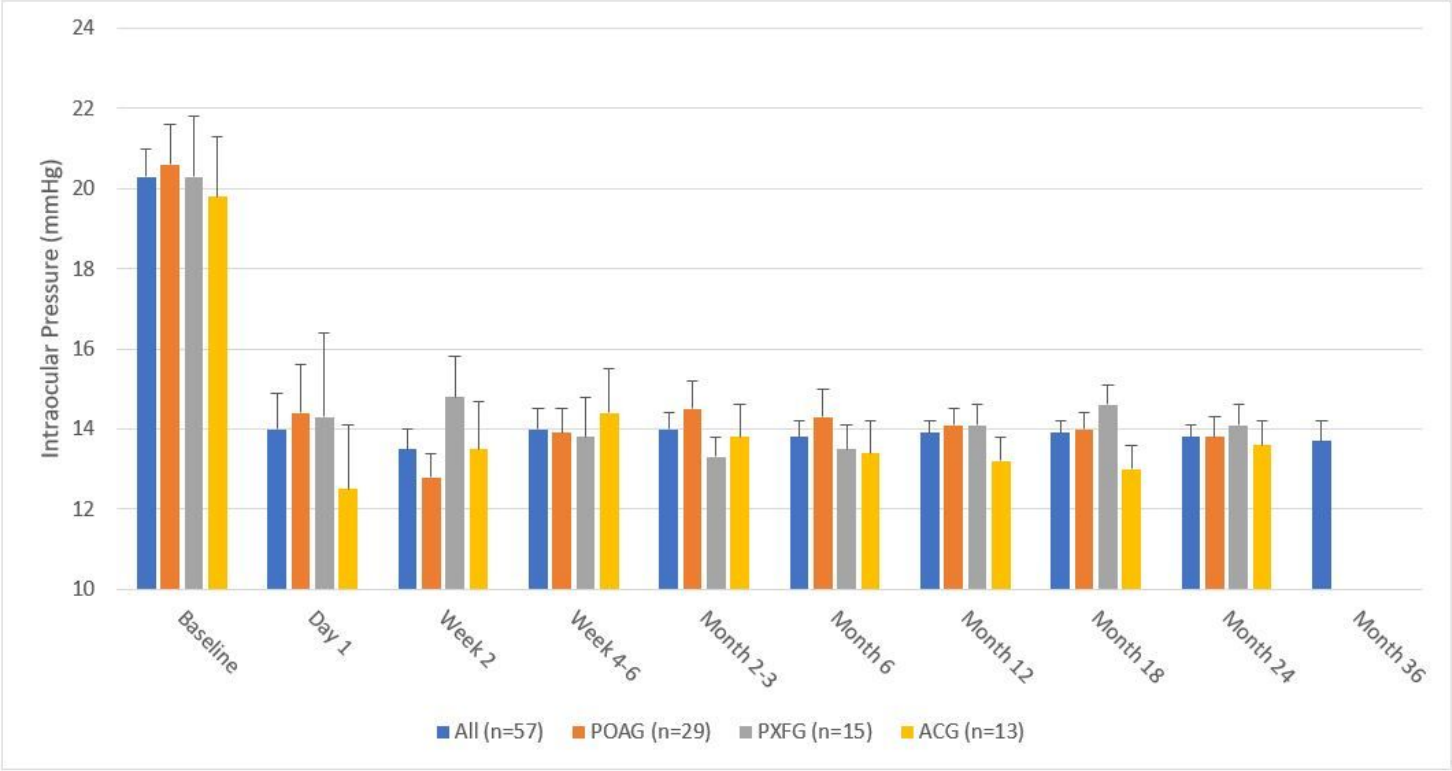
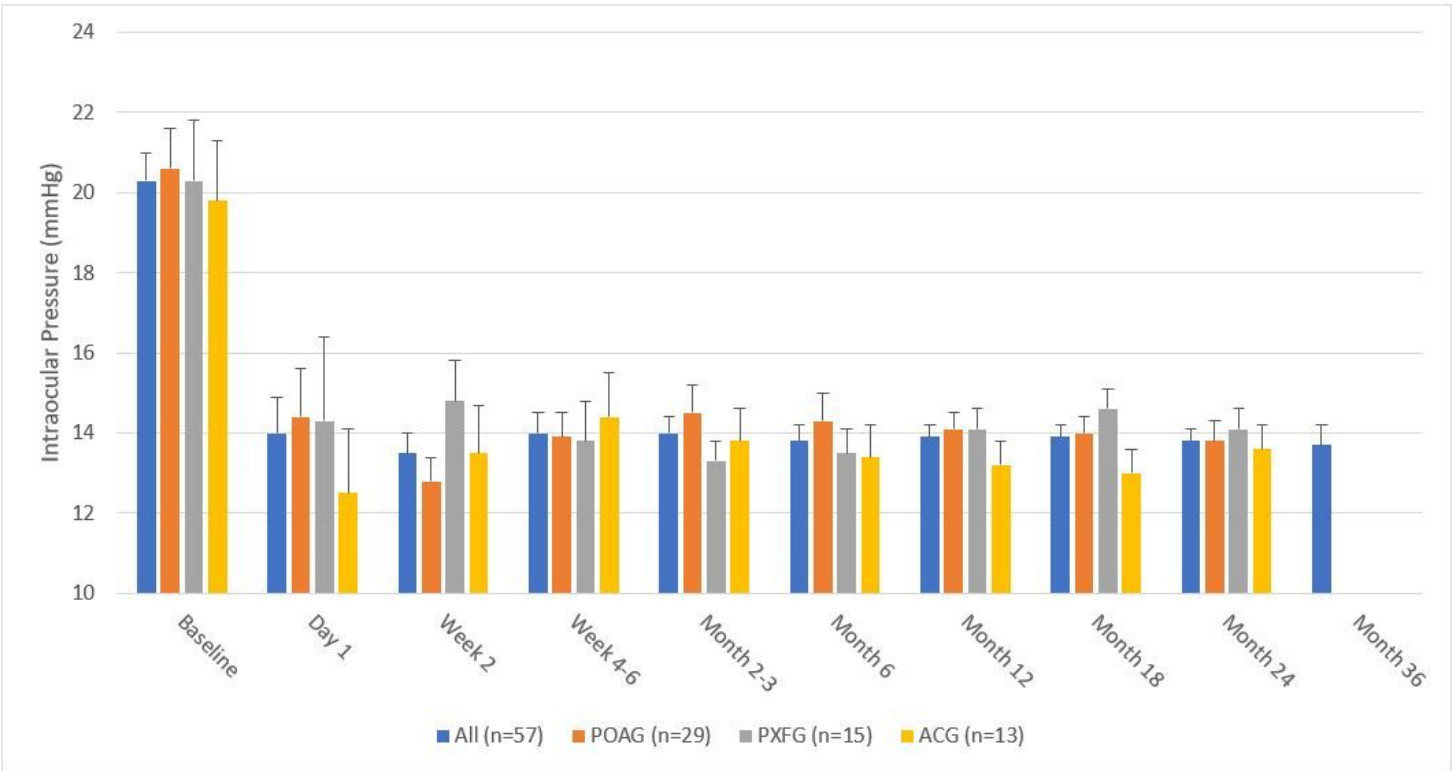


Figure 1

Mean IOP at each visit overall and by glaucoma subtype. Error bars represent standard error. P<0.0002 at all-time points in the full data set of all eyes (n=57).



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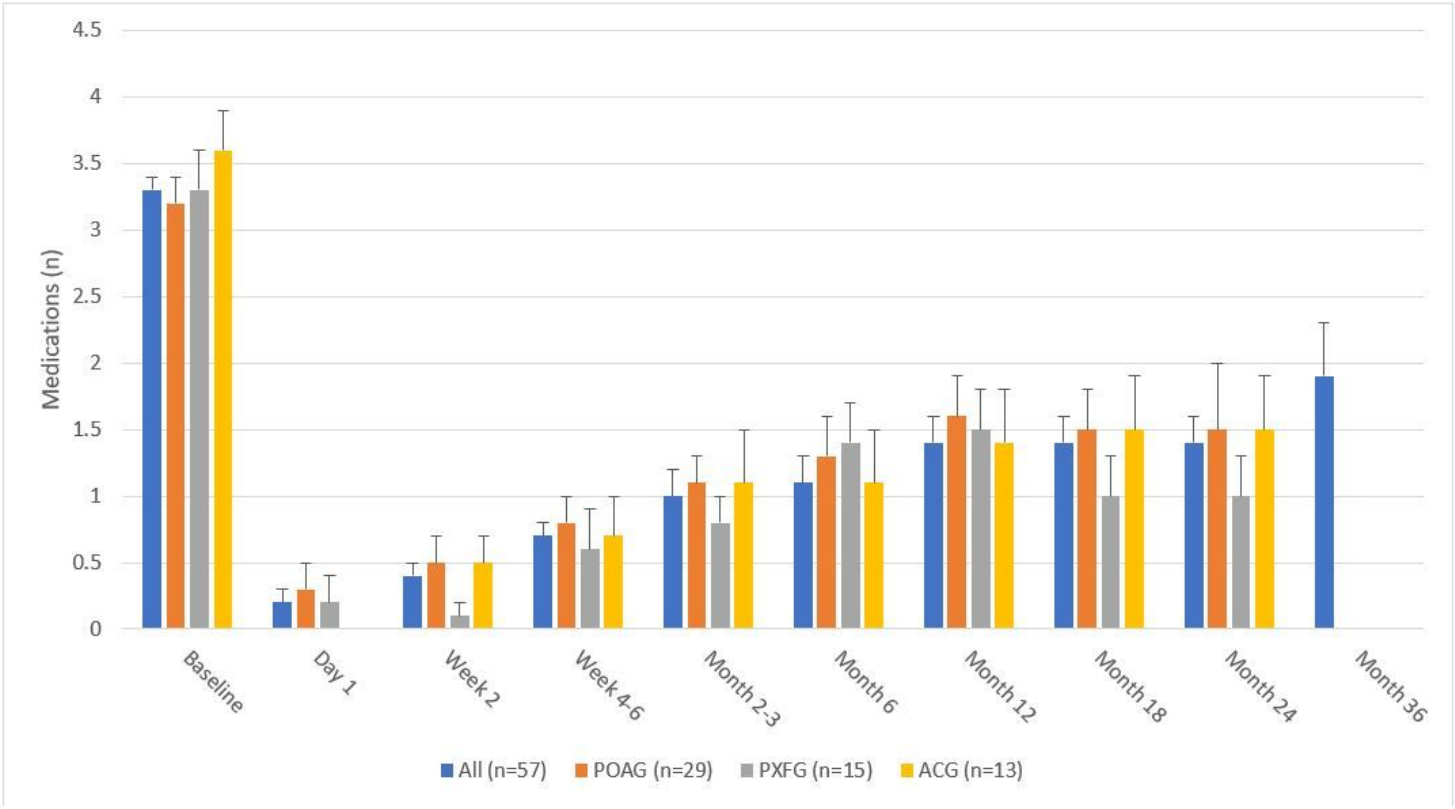
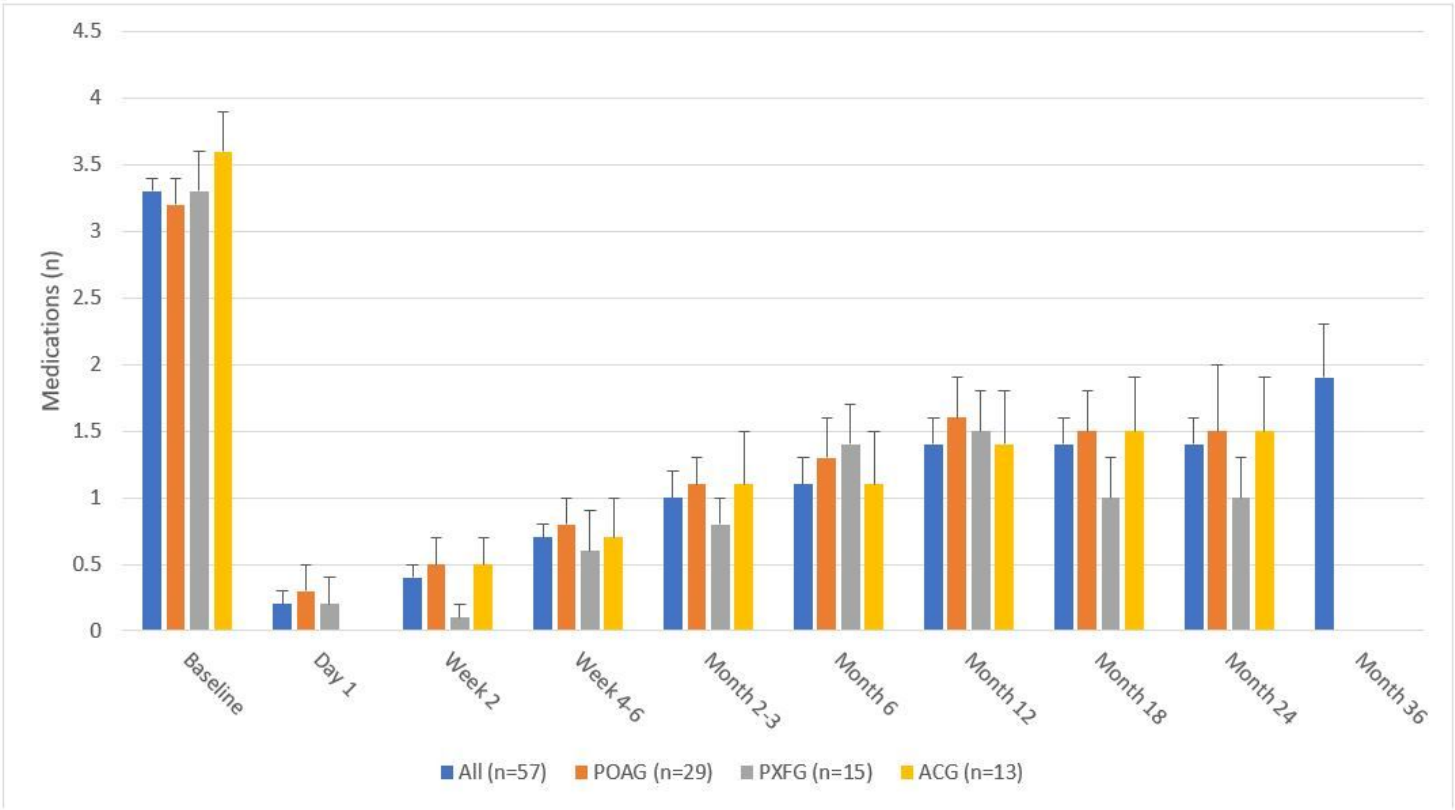


Figure 2

Mean number of IOP-lowering medications at each visit by glaucoma subtype. Error bars represent standard error. P<0.0001 at all-time points in the full data set of all eyes (n=57).



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