Two-Year Clinical Outcomes of Combined Phacoemulsification, Goniosynechialysis, and Excisional Goniotomy For Angle-Closure Glaucoma

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Purpose: The aim of this study was to describe changes in intraocular pressure (IOP) and IOP medications after phacoemulsification with Kahook Dual Blade-assisted goniosynechialysis and excisional goniotomy in eyes with angle-closure glaucoma and cataract.

Design: Retrospective case series.

Methods: Data were collected retrospectively through 24 months of follow-up in 42 eyes of 24 subjects.

Results: Preoperative mean (SE) IOP was 25.5 (0.7) mm Hg using a mean of 2.3 (0.1) medications per eye. At month 24, mean IOP had decreased to 13.5 (0.4) mm Hg [a reduction of 12.0 mm Hg (47.1%); P < 0.0001]. Medication use declined to a mean of 0.6 (0.2) medications per eye [a reduction of 1.7 medications per eye (76%); P < 0.0001]. At month 24, 40 of 42 eyes (95.2%) achieved IOP ≤18 mm Hg, 42 of 42 eyes (100%) achieved IOP reduction of ≥20%, 36 of 42 eyes (85.7%) required ≥1 fewer medications for IOP control, and 29 of 42 (69.0%) were medication-free. No eyes required additional glaucoma surgery throughout 24 months of follow-up.

Conclusions: Phaco plus Kahook Dual Blade-assisted goniosynechialysis/excisional goniotomy provides statistically and clinically meaningful reductions in both IOP and medications in eyes with angle-closure glaucoma throughout 2 years of follow-up. These findings are consistent with our previously reported outcomes in this cohort at months 6 and 12 postoperatively, demonstrating a significant and sustained benefit of this procedure in eyes with angle-closure glaucoma and cataract.

Key Words: angle-closure, glaucoma, goniosynechialysis, goniotomy, MIGS


A ngle-closure glaucoma (ACG) is projected to afflict 21 million people worldwide by 2020.¹ This complex form of glaucoma represents only 25% of all glaucoma but accounts for nearly half of all glaucoma blindness worldwide.¹ The proportion of total glaucoma that is ACG varies among global regions, being approximately 11% in Europe but nearly 50% in China, where half of all global ACG cases occur.¹

The management of ACG is challenging and controversial. Recent clinical trials have cast doubt on the role of laser peripheral iridotomy (LPI) in primary angle-closure suspects with anatomically narrow angles,² and lens extraction may be more efficacious then iridotomy in eyes with primary angle-closure glaucoma.³ Procedures that deepen the anterior chamber angle do not always result in lower IOP, as the trabecular meshwork (TM) in eyes with ACG can be rendered permanently dysfunctional by chronic synechialization, inflammation, and/or proliferation of iris or fibrous tissue even upon angle deepening procedures such as LPI or lens extraction.⁴ Even mechanical reopening of the angle by goniosynechialysis to disrupt peripheral anterior synechiae (PAS) does not always lower intraocular pressure (IOP).⁴ Trabeculectomy, often the first-line surgery when laser or lens procedures fail to control IOP, may lower IOP but does not deepen the angle or prevent further PAS formation, and can in fact exacerbate progressive angle-closure through anterior rotation of the lens-iris diaphragm.⁵

We have recently described a combined procedure consisting of phacoemulsification, goniosynechialysis, and excisional goniotomy developed to address the multiple pathological processes that occur in eyes with ACG. Lens extraction deepens the angle to enhance trabecular outflow and reduce the risk of progressive PAS formation; goniosynechialysis disrupts existing PAS; and excisional goniotomy with the Kahook Dual Blade (KDB, New World Medical, Inc, Rancho Cucamonga, CA) removes dysfunctional TM to enhance aqueous egress through Schlemm canal. At 6 and 12 months, this combined procedure lowered IOP by ~50% and IOP-lowering medication use was in excess of 90%.⁶ In this report, we present the clinical outcomes of the same cohort now followed through 24 months postoperatively.

METHODS

This is a retrospective analysis conducted on a de-identified data set generated from the health records of adult subjects with angle-closure glaucoma and visually significant cataract undergoing combined phacoemulsification with intraocular lens implantation, goniosynechialysis, and goniotomy using the
KDB. The data set contained no protected health information as defined by the Health Information Portability and Accounting Act, and the analysis was conducted under an ethics committee’s waiver of consent.

The study cohort and procedures have been described previously. Eligibility criteria included age ≥18 years, presence of both visually significant cataract and angle-closure glaucoma, and having undergone the combined procedure as described above. All eyes had elevated IOP, classic glaucomatous optic nerve and visual field changes, and at least 180 degrees of anterior chamber angle-closure on indentation gonioscopy in a darkened room. Eyes with previous acute angle-closure were excluded. After a standard phacoemulsification and intraocular lens implantation procedure, the pupil was pharmacologically constricted and an ophthalmic viscosurgical device was injected into the anterior chamber to dissect the iris from the angle as much as possible. The KDB instrument was then inserted into the anterior chamber through the surgical incision and, under direct gonioscopy, its pointed tip was utilized to engage peripheral iris at the base of each PAS. Gentle radial force was applied within the iris plane toward the pupillary center to dissect the peripheral adhesions and expose the TM for excisional goniotomy. Then, under direct gonioscopy, the KDB’s tip was guided to the nasal angle, inserted through the TM into Schlemm canal, and advanced for several clock hours, excising a narrow strip of TM. A second pass in the opposite direction removed several additional clock hours of TM, producing a free-floating strip of TM that was then removed from the eye with either the KDB or forceps. The extent of TM excision was in the range of 110 to 140 degrees per eye. The ophthalmic viscosurgical device was then evacuated from the anterior chamber. Postoperative care included a standard course of antimicrobial prophylaxis for 1 week and anti-inflammatory therapy tapered over 4 weeks. Although there was no protocol governing IOP-lowering medication use in this retrospective analysis, in general medications were continued postoperatively and discontinued as indicated by resulting IOP at each visit. Given the highly variable nature of acute postoperative IOP, medication use and withdrawal are also highly variable in the acute postoperative period. For this reason, medication use was reported upon stabilization at the month 1 time point.

The following data were collected preoperatively, intraoperatively, and 1, 3, 6, 9, 12, 18, and 24 months postoperatively as applicable: age, sex, severity of glaucoma, Snellen best-corrected visual acuity (BCVA), Goldmann IOP, the IOP-lowering medication regimen, and adverse events.

The primary statistical goal of this analysis was to characterize the long-term (24-month) reduction in both IOP and IOP-lowering medication use following the combined procedure. Additional endpoints included IOP reduction of ≥20% from baseline, the proportion of eyes with IOP ≤18 mm Hg, and the proportion of eyes requiring ≥1 fewer medication, all assessed at each postoperative time point, with the exception that medication use in the immediate postoperative period (1 day and 1 week) was not analyzed as it was highly variable between patients and not indicative of long-term outcomes. As no specific hypothesis testing was planned, formal power and sample size calculations were not performed. Arithmetic means and changes from baseline are presented ± standard error (SE). Paired t tests were used to analyze the change from baseline for IOP, number of IOP-lowering medications, and logMAR BCVA at each time point.

### RESULTS

The cohort of 42 eyes of 24 subjects has been previously described (Table 1). Subjects were predominantly Asian (41.7%) or white (29.2%) (all Asian patients were recruited from the study site in Vietnam) and had a mean (SE) age of 66.5 (2.4) years, and the majority (54.2%) were female. Most eyes had moderate (31.0%) or severe (61.9%) ACG and were treated with 2 (47.6%) or 3 (42.9%) IOP-lowering medications. All eyes of all subjects were examined at 24 months postoperatively.

Mean (SE) IOP at baseline was 25.5 (0.7) mm Hg (Table 2, Fig. 1), decreased immediately after surgery, and remained consistently low through 24 months of follow-up. Mean IOP reductions of 11.8 to 12.7 mm Hg, representing 45.4% to 48.8% reductions from baseline, were seen across time points (P < 0.0001 at all-time points). At month 24, mean IOP was 13.5 mm Hg (a 46.2% reduction, P < 0.0001). At month 24, 95.2% (40/42) of eyes achieved IOP ≤18 mm Hg, and 100% (42/42) achieved a minimum IOP reduction of 20% from baseline (Table 3).

The mean (SE) number of IOP medications used at baseline was 2.3 (0.1) (Table 2, Fig. 2) and was significantly reduced in 24 months of follow-up. Mean medication reductions of 1.8 to 2.2 meds, representing 69.4% to 91.7% reductions from baseline, were seen across time points (P < 0.0001 at all-time points). At month 24, mean medication use was 0.6 medications/eye (a 69.4% reduction, P < 0.0001). At month 24, 85.7% (36/42) of eyes required ≥1 fewer medications for IOP control, and 69.0% (29/42) were medication-free (Table 3).

Mean (SE) BCVA (logMAR) was 0.55 (0.06) at baseline, improved immediately after surgery, and remained consistently improved through 24 months of follow-up (P < 0.0001 at all-time points). At month 24, mean logMAR BCVA was 0.18 (0.07) (P < 0.0001). Overall, final postoperative BCVA improved in 40 of 42 eyes (95.2%) and was unchanged in the remaining 2 eyes (4.8%); these 2 eyes had baseline VA of counting fingers and hand
TABLE 2. Mean IOP, Medication and Visual Acuity Data, and Changes From Baseline, at Each Study Time Point

<table>
<thead>
<tr>
<th></th>
<th>Baseline (N = 42)</th>
<th>Month 6 (N = 42)</th>
<th>Month 12 (N = 42)</th>
<th>Month 18 (N = 42)</th>
<th>Month 24 (N = 42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean IOP (SE)</td>
<td>25.5 (0.73)</td>
<td>12.8 (0.43)</td>
<td>13.3 (0.44)</td>
<td>13.7 (0.55)</td>
<td>13.5 (0.44)</td>
</tr>
<tr>
<td>Change from baseline</td>
<td>—</td>
<td>—</td>
<td>12.7 (0.75)</td>
<td>12.3 (0.73)</td>
<td>11.8 (0.77)</td>
</tr>
<tr>
<td>Percent change from baseline</td>
<td>—</td>
<td>—</td>
<td>48.8 (1.86)</td>
<td>47.2 (1.61)</td>
<td>45.4 (1.91)</td>
</tr>
<tr>
<td>Significance</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Mean number of IOP-lowering medications (SE)</td>
<td>2.33 (0.10)</td>
<td>0.14 (0.06)</td>
<td>0.14 (0.06)</td>
<td>0.45 (0.11)</td>
<td>0.55 (0.15)</td>
</tr>
<tr>
<td>Change from baseline</td>
<td>—</td>
<td>—</td>
<td>2.19 (0.12)</td>
<td>1.79 (0.12)</td>
<td>1.88 (0.16)</td>
</tr>
<tr>
<td>Percent change from baseline</td>
<td>—</td>
<td>—</td>
<td>91.7 (3.65)</td>
<td>89.7 (3.65)</td>
<td>75.8 (7.47)</td>
</tr>
<tr>
<td>Significance</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Mean logMAR best-corrected visual acuity (SE)</td>
<td>0.547 (0.06)</td>
<td>0.183 (0.07)</td>
<td>0.159 (0.07)</td>
<td>0.189 (0.07)</td>
<td>0.181 (0.07)</td>
</tr>
<tr>
<td>Change from baseline</td>
<td>—</td>
<td>—</td>
<td>0.364 (0.03)</td>
<td>0.388 (0.03)</td>
<td>0.367 (0.03)</td>
</tr>
<tr>
<td>Percent change from baseline</td>
<td>—</td>
<td>—</td>
<td>77.6 (4.32)</td>
<td>81.7 (4.45)</td>
<td>75.4 (4.97)</td>
</tr>
<tr>
<td>Significance</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
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</tbody>
</table>

IOP indicates intraocular pressure.

FIGURE 1. Mean intraocular pressure (IOP) over 24 months for eyes undergoing combined phacoemulsification, goniosynechialysis, and excisional goniotomy for angle-closure glaucoma (with SE bars).

TABLE 3. Prespecified IOP and Medication Outcomes at Each Study Time Point

<table>
<thead>
<tr>
<th></th>
<th>Month 6 (N = 42)</th>
<th>Month 12 (N = 42)</th>
<th>Month 18 (N = 42)</th>
<th>Month 24 (N = 42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion achieving IOP ≤18 mm Hg</td>
<td>39 (92.9)</td>
<td>39 (92.9)</td>
<td>39 (92.9)</td>
<td>40 (95.2)</td>
</tr>
<tr>
<td>Proportion achieving IOP reduction ≥20% compared to baseline</td>
<td>41 (97.6)</td>
<td>42 (100)</td>
<td>41 (97.6)</td>
<td>42 (100)</td>
</tr>
<tr>
<td>Proportion using ≥1 fewer medication compared to baseline</td>
<td>40 (95.2)</td>
<td>40 (95.2)</td>
<td>38 (90.5)</td>
<td>36 (85.7)</td>
</tr>
<tr>
<td>Proportion medication-free</td>
<td>36 (85.7)</td>
<td>36 (85.7)</td>
<td>29 (69.0)</td>
<td>29 (69.0)</td>
</tr>
</tbody>
</table>

IOP indicates intraocular pressure.

FIGURE 2. Mean medication use 24 months for eyes undergoing combined phacoemulsification, goniosynechialysis, and excisional goniotomy for angle-closure glaucoma (with SE bars).
motions. No eye lost any BCVA compared to baseline at month 24.

The combined procedure was safe and well tolerated. No new adverse events were identified between months 12 and 24, and BCVA was not reduced in any eye at Month 12 compared to preoperatively. No eye required any further IOP-lowering surgery through 24 months of follow-up.

**DISCUSSION**

With extended follow-up now through 24 months, we have demonstrated that a combined procedure consisting of phacoemulsification, goniosynechialysis, and excisional goniotomy with the KDB provides persistent mean IOP reductions of approximately 50%, mean medication reduction of 70%, and improved VA in eyes with cataract and ACG. IOP reductions of ≥20% were achieved in all eyes, with 95% attaining IOP ≤18 mm Hg. Medication reduction was achieved in 85% of eyes, and 69% were medication-free at 24 months. No eye required any further surgery for IOP control.

This combined procedure’s success is likely related to its approach, addressing each of the mechanisms of IOP elevation that occur in eyes with ACG: lowering IOP, opening the anterior chamber angle, and removing dysfunctional TM. Less comprehensive approaches produce lesser outcomes. LPI deepens the angle and thus may lower IOP, but the procedure alone is typically inadequate for long-term IOP control and visual acuity improvement, with most eyes requiring additional surgery. Cataract surgery alone fails to address any peripheral anterior synchiae (PAS) present or the dysfunctional TM. In a Bayesian analysis of expected IOP reductions resulting from phacoemulsification alone in eyes with primary ACG, the probability of an IOP reduction of ≥5 to 6 mm Hg was approximately 50%. In the EAGLE clinical trial comparing lens extraction to LPI, lens extraction produced IOP reductions of approximately 50% and medication reductions of 60% at 36 months, both of which were superior to outcomes in LPI-treated eyes. These eyes had early-stage disease, however, with mean visual field mean deviation of −3.3 dB, whereas in our study, >60% had severe ACG. Also the IOP reductions in the current study were achieved from a more heavily medicated baseline, with >90% of eyes in our study using 2 or 3 medications, whereas 75% of EAGLE eyes were using 0 or 1 medication. Cataract extraction plus goniosynechialysis also fails to address TM dysfunction upon reopening of the angle. Studies of cataract extraction plus goniosynechialysis performed with devices other than the KDB show comparable IOP-lowering outcomes but not generally accompanied by sustained medication reductions on the order of 85% to 90% over 2 years as seen in the present study. The ultimate goal of glaucoma therapy is the preservation of quality of life, which can be enhanced by reducing or eliminating the need for daily eye drop therapy and the adverse events, costs, and inconvenience associated with topical medical therapy. Our combined approach produced a 69% medication-free rate at 24 months without the need for any further IOP-lowering surgery and while still producing mean IOP reductions on the order of 50% from medicated baseline. Furthermore, all but 2 eyes with preoperative low vision experienced improvement in BCVA over OR in 24 months of follow-up; KDB-Phaco has been shown to have no greater effect on postoperative refraction than phacoemulsification alone. Limitations of the current study are its retrospective nature and its size. The outcomes reported are from only 2 physicians and may not generalize widely. However, one of the surgeons practices in Vietnam, thus providing representation of native Asian eyes in the data set to improve generalizability to the region where ACG is most prevalent. The follow-up duration of 24 months is the strength of the study, as it demonstrates consistency of results from the immediate postoperative point through 2 years of postoperative observation.

In summary, phacoemulsification combined with KDB-assisted goniosynechialysis and excisional goniotomy safely reduces both IOP and the need for IOP-lowering medications in eyes with ACG, while also improving visual acuity. These benefits manifest immediately after surgery and are maintained through 2 years of postoperative follow-up.

**REFERENCES**


