Research Article

Clinical Results of an Extended Ab Interno Trabeculotomy Using KDB and Indirect Gonioscopy in Open Angle and Angle Closure Glaucoma

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Abstract

***Purpose**: To characterize the safety profile, intraocular pressure (IOP) lowering effect, and reduction in glaucoma medication use of an extended ab interno trabeculotomy technique using a Kahook Dual Blade and indirect gonioscopy combined with phacoemulsification (phaco KDB) in primary open-angle glaucoma (POAG) and primary angle-closure glaucoma (PACG) patients.*

***Methods**: A retrospective case notes review of all consecutive glaucoma patients (88 eyes of 63 patients) who underwent phaco KDB or phacoemulsification alone by a single experienced glaucoma surgeon was performed.*

Results *: Phaco KDB significantly lowered the IOP in both PACG and POAG groups at all time points (1 week, 3 months, 6 months, 12 months, 18 months) except week 1 in the POAG group. Success was defined as IOP reduction of at least 20% from the preoperative IOP and/or reduction in at least one glaucoma medication at 18 months compared with baseline. Seventy-one percent of all eyes treated with phaco KDB achieved IOP-related surgical success compared with 41% of eyes treated with phacoemulsification alone. Surgical success rates increased to 77% in the phaco KDB group if the reduction in medication by at least one drop was also factored in and decreased to 5% in the control group.*

Conclusion*: Combined phaco KDB with extended angle ab interno trabeculotomy facilitated by indirect gonioscopy is an effective and safe surgical option in the management of POAG and PACG patients and can lead to a significant reduction in medication burden in the medium term.*

Keywords*: extended ab interno trabeculotomy; indirect gonioscopy.*

Introduction

Goniotomy via trabecular meshwork excision performed with the Kahook Dual Blade (KDB, New World Medical, Rancho Cucamonga, CA) has recently been reported as an effective and method for trabecular bypass and intraocular pressure (IOP) lowering in patients with primary open-angle glaucoma **(**1**)**–**(**6**)** and congenital glaucoma **(**7**)**. The technique involves the controlled removal of a strip of trabecular meshwork (TM) tissue under direct visualization, thereby removing large areas of TM as a site of resistance to aqueous outflow and facilitating aqueous drainage from the anterior chamber into Schlemm's canal without the need for an in situ drainage device. This is in contrast to other ab interno procedures such as the Trabectome or gonioscopy-assisted transluminal trabeculotomy (GATT) which aim to incise the trabecular meshwork only with significant outflow resistance from the TM remaining. A histological study on human donor corneoscleral rims showed that there was less surrounding tissue damage with the KDB compared to both Trabectome and an MVR blade trabeculotomy **(**8**)**.

The minimally invasive technique also confers some advantages over trabeculectomy filtration surgery which provides significant IOP lowering but can be associated with potentially blinding complications

such as hypotony maculopathy and endophthalmitis(9) and requires intensive management in the post-operative period with multiple clinic visits and re-intervention.

Goniotomy with the KDB is an effective IOP lowering method both when combined with cataract surgery (6) or as a stand-alone procedure (4). Concomitant goniosynechiolysis and viscogonioplasty have also rendered the procedure feasible in patients with primary angle-closure glaucoma, with favorable outcomes reported at 6 months (10) and 12 months follow up (11), (12).

Here we report that the KDB technique is safe and effective in reducing IOP and the number of glaucoma medications in the medium-term in both open-angle and angle-closure glaucoma patients relative to controls.

We use an indirect gonioscopic view rather than the traditional direct view and insert an additional turn in the conventional KDB instrument to allow up to 360o access. The indirect gonioscopic view does not require a microscope or patient head repositioning and provides a superior view of the angle for surgery. We believe this facilitates a greater degree of TM excision in the majority of patients, theoretically leading to greater aqueous outflow and IOP reduction and also renders the procedure more efficient.

If performing the KDB excision goniotomy technique following phacoemulsification, steps should be taken to ensure that the corneal epithelium and endothelium are adequately protected to maintain the angle view needed for KDB. We recommend the use of a dispersive viscoelastic throughout the procedure rather than the traditionally described cohesive viscoelastic to maintain corneal clarity and optimize the angle view for KDB excisional goniotomy following phacoemulsification.

Methods

A retrospective case notes review of glaucoma patients (88 eyes of 63 patients) who underwent consecutive KDB excision goniotomy combined with phacoemulsification or phacoemulsification alone by a single experienced glaucoma specialist over 9 months at the Colchester Eye Department was performed.

IOP was measured at 1 week, 3 months, 6 months and 12 months and 18 months post-operatively. Patients that had previous glaucoma surgery were excluded from the analysis. Treatment with selective laser trabeculoplasty was considered equivalent to one glaucoma medication. Success was defined as IOP reduction of at least 20% from the pre-operative IOP at each measured time point where data was available, and/or reduction in at least one glaucoma medication at 18 months compared with baseline.

Data are shown as mean ± SEM unless otherwise indicated and were analyzed using Student's two-tailed t-tests.

KDB excision goniotomy procedure

The KDB excision goniotomy procedure is performed following IOL insertion after uneventful phacoemulsification (see Video, Supplementary file 1). We insert an additional turn in the KDB instrument to facilitate up to 360o access and use either of two paracentesis ports created for bimanual irrigation and aspiration of cortical material and posterior capsule polishing during cataract surgery (temporal approach). The utilisation of the main corneal incision created during phacoemulsification for KDB entry has been described but we feel is more likely to lead to anterior chamber instability, intraoperative IOP fluctuations and hyphaema due to loss of positive anterior chamber pressure and reflux from the collector channels following TM excision.

A dispersive viscoelastic (Viscoat, Alcon) is used throughout the phacoemulsification procedure, to maintain a formed anterior chamber and corneal hydration. Viscoat is also used following IOL implantation to perform viscogonioplasty in all cases and goniosynechiolysis in the presence of peripheral anterior synechiae in angle-closure patients. An indirect gonioprism is used in the non-dominant hand to visualise the angle, taking care to minimize corneal distortion and striations which could obscure TM view. The modified KDB is inserted into the first paracentesis wound and the blade advanced to the angle opposite under indirect gonioscopic view. TM excision is performed as has previously been described**(**6**)**. The modified KDB has then inserted into the second paracentesis and the blade advances to the opposite nasal angle and further TM excised, aiming to meet the initial trabeculotomy, maximizing the degree of excision. Collector channels often become visible as blood-filled round channels are seen periodically along the trabeculotomy groove as the roof of Schlemm's canal is removed (see Video, Supplementary file 1) with the concomitant increased aqueous flow into the episcleral venous circulation. The collector channels may bleed slowly but a large bleed often signifies damage to the angle or iris.

The blade is then removed from the anterior chamber and the strip of excised TM is either removed using capsulorrhexis forceps or during irrigation and aspiration of the viscoelastic. If after completion significant bleeding is still present then continued irrigation and aspiration are performed as necessary. In our experience, most small bleeds will stop if adequate anterior chamber pressure is maintained.

Careful wound construction and post-operative hydration are essential to maintain IOP above episcleral venous pressure and reduce the risk of post-operative hyphaema.

Post-operative regime

Post-operatively patients are given a standard regime of 500 mg of oral Acetazolamide as a stat dose to prevent IOP spikes, Maxitrol (Alcon) 4 times a day for 4 weeks and Nevanac (Alcon) twice a day for 4 weeks. Patients are advised to continue their usual glaucoma medications for the initial post-operative period and then stop 1 week before clinic review to assess the IOP lowering effect of the surgery. Glaucoma medications are restarted if the IOP control was not sufficient following post-operative clinic review.

Results

Eighty-eight eyes from 63 patients were included in the analysis. Fifty-five eyes underwent phaco KDB and 33 eyes underwent phacoemulsification cataract surgery alone. Patient demographics are presented in **Table 1**.

	n	%
Patients	63	
Gender		
Female	35	56
Male	28	44
Age, years		
Mean	80.7	
Median	83	
Range	21-95	
Total eyes	88	
Eyes		
Left	45	51%
Right	43	49%
Glaucoma type		
Primary angle closure glaucoma	46	52%
Primary open angle glaucoma	42	48%

Table 1: Patient demographics

Phaco KDB significantly lowered the IOP in both PACG and POAG groups at all time points except week 1 in the POAG group (**Table 2**). The reduction in IOP was sustained through to 18 months, with a reduction from 27.7 (SEM 2.50) mmHg to 14.4 (SEM 0.84) mmHg in the PACG group and a reduction from 21.3 (SEM 1.00) mmHg to 15.3 (SEM 0.61) mmHg in the POAG group (**Figure 1**). There was also a significant IOP reduction in the control phacoemulsification alone group for primary angle-closure patients. However, this did not lead to a reduction in medication burden (**Figure 2**).

P value		0.0036	<0.0001	<0.0001	<0.0001	0.0107
Phaco POAG						
Eyes, n	13	10	6	7	4	5
IOP, mean (SEM)	18.3 (2.44)	13.7 (0.94)	14.8 (0.60)	14.1 (0.74)	14.5 (1.55)	16.8 (1.07)
P value		0.1293	0.3575	0.238	0.4182	0.7154
Phaco KDB POAG						
Eyes, n	29	11	27	25	24	7
IOP, mean (SEM)	21.3 (1.00)	19.5 (3.6)	16.5 (1.03)	16.1 (0.75)	14.7 (0.64)	15.3 (0.61)
P value		0.588	0.0016	0.0002	<0.0001	0.0064

Table 2: Intraocular pressure at baseline and post-operative time points following combined phaco KDB or phacoemulsification alone. Data analysed using Student's t-test.

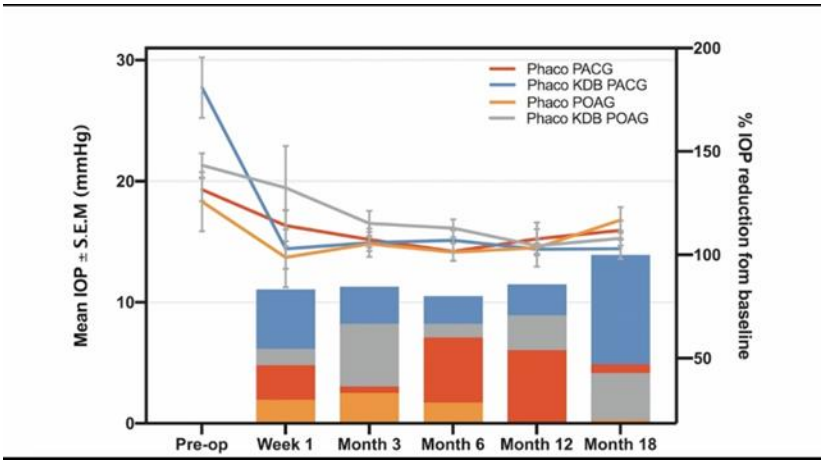

Figure 1: Mean intraocular pressure profile and percentage IOP reduction following combined phaco KDB or phacoemulsification alone. Error bars represent SEM.

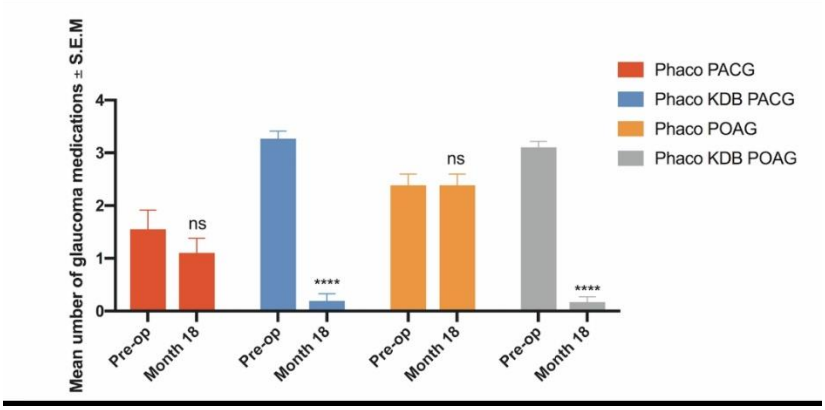

Figure 2: Mean number of glaucoma medications at 18 months following combined phaco KDB or phacoemulsification alone (****, p<0.0001, Student's t-test). Data displayed as mean ± SEM

Both groups of patients treated with the phaco KDB technique had a significant reduction in the number of glaucoma medications at 18 months post-surgery relative to control (**Figure 2**). The PACG group treated with phaco KDB had a reduction from a mean of 3.2 (SEM 0.14) glaucoma medications to a mean of 0.19 (SEM 0.16) glaucoma medications at 18 months, compared with a non-significant reduction in the PACG phacoemulsification alone control group from 1.55 (SEM 0.37) glaucoma medications pre-operatively to 1.1 (SEM 0.28) medications at 18 months postoperatively. The mean number of glaucoma medications in the POAG group decreased significantly from 3.1 (SEM 0.11) pre-operatively to 0.38 (SEM 0.14) at 18 months compared with no change in the number of medications in the control phacoemulsification alone group (2.38 (SEM 0.21) medications pre-operatively and 2.38 (SEM 0.21) medications at 18 months).

Seventy-one percent of all eyes treated with phaco KDB achieved surgical success as defined by a reduction of IOP of at least 20% at 18 months compared with 41% of eyes treated with phaco-emulsification alone (**Table 3**).

	Week 1	**Month 3**	**Month 6**	**Month 12**	**Month 18**
Phaco alone all eyes					
Eyes, n	25	17	17	17	22
Success by IOP only	40%	35%	47%	41%	41%
Success by both IOP and medications					5%

Phaco KDB all eyes					
Eyes, n	22	53	49	45	14
Success by IOP only	68%	75%	73%	78%	71%
Success by both IOP and medications					77%
Phaco alone PACG					
Eyes, n	15	11	10	13	17
Success by IOP only	47%	36%	60%	54%	47%
Success by both IOP and medications					7%
Phaco KDB PACG					
Eyes, n	12	26	25	21	7
Success by IOP only	83%	85%	80%	86%	100%
Success by both IOP and medications					100%
Phaco alone POAG					
Eyes, n	10	6	7	4	5
Success by IOP only	30%	33%	29%	0%	20%
Success by both IOP and medications					0%
Phaco KDB POAG					
Eyes, n	11	27	24	24	7
Success by IOP only	55%	67%	67%	71%	43%
Success by both IOP and medications					50%

Table 3: Success rates following combined phaco KDB or phacoemulsification alone

Surgical success rates increased to 77% in the phaco KDB group if the reduction in medication by at least one drop was also factored in and decreased to 5% in the control group. In the PACG group, all phaco KDB treated eyes achieved surgical success according to IOP alone or combined with a reduction in medication burden, compared with a 47% IOP reduction success rate in the control PACG group (Figure 1). The surgical success rate in the control group decreased to 7% at 18 months when medication reduction was also considered. Forty-three percent of POAG eyes achieved successful IOP reduction at 18 months in the phaco KDB group, increasing to 50% success when both IOP and medication reduction were included. compared to 20% successful IOP reduction in the control group. No patients in the control POAG group achieved surgical success defined by both IOP decrease and medication reduction at 18 months.

Complications following phaco KDB included corneal oedema (3 eyes), post-operative hyphaema <2mm (3 eyes), anterior chamber inflammation (5 eyes), Descemet's tear (2 eyes), iris root damage (1 eye). Six patients had intraoperative bleeding during the KDB procedure and 2 patients had a post-operative spike at week 1 in the KDB group. All postoperative complications were controlled with topical treatment or observation and did not require a return to theatre. One patient from the phaco KDB group required further trabeculectomy and one patient from the phacoemulsification alone group required subsequent trabeculectomy. There were no vision-threatening complications in the phaco KDB group such as phthisis, endophthalmitis or hypotony maculopathy. The course of phacoemulsification only treated eyes proceeded uneventfully.

Discussion

Our results indicate that combined phaco-KDB is a safe and effective approach in the initial surgical management of primary open-angle glaucoma and primary angle-closure glaucoma patients. There was a significant and sustained reduction in IOP and medication burden at 18 months relative to controls. The procedure as an adjunct to cataract surgery is cost-effective, requiring only a disposable blade in addition to equipment that is readily available in any glaucoma surgeon's practice, minimal additional theatre time and no stents or devices requiring implantation. The procedure is associated with fewer postoperative clinic visits overall with no requirement for needling, device repositioning, or the use of cytotoxic anti-scarring agents and did not require subsequent surgical intervention in the form of return to theatre to treat any complications. The ab interno approach preserves the integrity of the conjunctiva facilitating any future trabeculectomy or aqueous shunt insertion.

We report a greater success rate in IOP reduction and decrease in medication burden than has previously been described **(**6**)**. Although the variation inpatient population may contribute to this difference, the modification of the blade as described above with the use of an indirect gonioprism may also facilitate a greater degree of TM excision with improved efficacy. A direct comparison between the standard 90-degree ab-interno trabeculectomy using a direct swan-jacob style gonioscope and our KDB modified technique would be useful to evaluate this finding further.

A recent study comparing 90-degree sectoral ab-interno trabeculotomy using KDB to 360-degree ab-interno trabeculotomy using GATT or Trab360 showed no significant difference in IOP lowering effect and need for IOP lowering medications in the 6 month postoperative period **(**13**)**. However, both the GATT and Trab360 aim to incise the trabecular meshwork only with significant outflow resistance from the TM remaining and it remains conceivable that the larger area of TM removed using KDB with the modified blade may improve efficacy.

There is a learning curve associated with intraoperative use of the indirect gonioprism to perform angle surgery. However, we would argue that the benefits of surgeon, patient and microscope positioning, which do not require significant alteration with the indirect view, overall facilitate ease of surgery and improved outcomes, while also maximizing efficiency. A microscope inverter while using a direct gonioprism or the Mori surgical gonio lens, which redirects the oblique gonio image to the coaxial surgical position are alternative options. The use of a dispersive viscoelastic also maintains corneal clarity and optimizes the angle view.

Although the technique has been reported as effective for all stages of glaucoma severity(6) the absolute IOP reduction did not drop below 10 mmHg throughout the post-operative period in our experience. We would therefore consider the combined phaco KDB approach an effective and minimally invasive intervention to reduce the IOP and medication burden in patients with mild to moderate glaucoma. There is a continued role for more invasive intervention in the initial surgical management of glaucoma if a target pressure of below 10 mmHg is required. The long-term efficacy and safety profiles have not yet been characterized and remain a focus of future work.

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Conflict of interest statement: The authors report no conflict of interest

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Key messages:

What was known before:

1.KDB is an effective trabecular bypass technique to lower the intraocular pressure in glaucoma patients

What this study adds:

2.Longer term data in angle closure glaucoma patients

3.Safety and efficacy data of a modified KDB technique using indirect gonioscopy which facilitates trabecular meshwork excision in glaucoma patients undergoing cataract surgery.

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