REVIEW ARTICLE

A Review of Excisional Goniotomy Performed with the Kahook Dual Blade for Glaucoma Management

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Abstract

Aim: To review the published literature describing clinical outcomes of excisional goniotomy using the Kahook Dual Blade (KDB) for the management of glaucoma.

Background: A family of less invasive glaucoma procedures—including excisional goniotomy with the KDB—has been developed to provide moderate reductions in intraocular pressure and/or medication burden in eyes with therapeutic needs that may not warrant the risks associated with more traditional procedures such as trabeculectomy and tube-shunt implantation. This review's goal is to synthesize the existing literature into a compendium of excisional goniotomy's indications, technique, efficacy and safety outcomes, and optimal place in glaucoma management.

Review results: Excisional goniotomy with the KDB effectively lowers IOP and reduces the medication burden in eyes with POAG and other forms of glaucoma across the spectrum of both baseline IOP and disease severity. The procedure exhibits a safety profile that is on par with other angle-based surgical interventions and enhanced safety compared to filtration procedures. It can be performed by comprehensive ophthalmologists as well as glaucoma specialists. This procedure as a standalone operation delivers IOP reductions consistent with filtration surgery, and in combination with cataract surgery delivers both IOP and medication reductions at least as great as other minimally invasive procedures.

Conclusion: Given the broad base of evidence supporting its use in a wide variety of clinical scenarios, excisional goniotomy with the KDB can play a meaningful role in the achievement of patient-specific glaucoma therapy goals.

Clinical significance: These aggregate findings support the efficacy and safety of excisional goniotomy with the KDB and clarify the patient profiles best suited for this procedure.

Keywords: Glaucoma, Glaucoma surgery, Goniotomy, Kahook Dual Blake, Systematic review.

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Background

Goniotomy Then and Now

Goniotomy was first described by Barkan as the incision of one quarter to one-third of the nasal trabecular meshwork (TM) *via* a temporal peripheral corneal incision under intraoperative gonioscopy in a series of 11 adult eyes in 1936.[1] The first PubMed-indexed case of goniotomy in a child came in 1944.[2] Scheie subsequently more fully characterized goniotomy in congenital glaucoma,[3,4] and by 1953 in the Jackson Memorial Lecture, Barkan conceded that this procedure's indication was limited to congenital glaucoma.[5] In the late 20th century, several variations of goniotomy for adult glaucoma (both laser[6,7] and incisional[8]) were described but did not gain traction clinically. Amidst recent rapid expansion of glaucoma surgical options, and with a focus on minimally invasive approaches, goniotomy for adult eyes with glaucoma has reemerged as a viable option.

Excisional goniotomy using the Kahook Dual Blade (KDB, New World Medical, Rancho Cucamonga, CA) is one of several innovative glaucoma procedures developed in recent years to satisfy unmet needs in the surgical glaucoma arena for a safer surgical option. Traditional procedures such as trabeculectomy and tube-shunt implantation are highly effective in both lowering intraocular pressure (IOP) and achieving low target IOPs, but these procedures are associated with well-described safety issues[9,10] and have historically been reserved for cases recalcitrant to less invasive interventions.

Recently, novel surgical techniques have arisen from the need for a safe procedure with a benefit/risk profile acceptable for deployment earlier in the treatment sequence.[11-14] These procedures as initially described had five distinct attributes: they were performed *via* an ab interno microincision; were minimally traumatic to both target and neighboring ocular tissues; delivered at least modest efficacy; had a favorable safety profile that avoided hypotony and bleb-related complications; and permitted rapid recovery, particularly with regard to visual acuity.[15] More recently, hybrid procedures have sought to bridge the gap between minimally invasive and more traditional procedures by utilizing subconjunctival filtration; these procedures deliver greater efficacy than TM-based procedures but are associated with bleb-related risks.[11-14]

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The ever-expanding array of novel glaucoma surgeries and the growing body of literature make a full review of all procedures impractical. Further, as distinct efficacy and safety profiles are clarified, indications for the various procedures are diverging. This review focuses on excisional goniotomy performed using the KDB. The goal of this paper is to review the current status of the procedure, including its indication, surgical technique and instrumentation, efficacy and safety results, and its role in the surgical management of glaucoma.

The Kahook Dual Blade

The KDB was authorized for marketing by the United States Food and Drug Administration in 2015 *via* a 510(k) class I exemption as an ophthalmic knife[16] indicated to manually cut TM in pediatric and adult patients.[17] The instrument is a handheld knife designed to engage, stretch, and excise a strip of TM. The KDB features a specialized distal footplate consisting of a pointed tip that widens posteriorly, a ramp extending from the tip, and a pair of elevated parallel blades incorporated into the posterior aspect of the ramp (Fig. 1). This design facilitates the excision procedure: the pointed tip engages and penetrates TM, the 230-micron wide footplate is seated in Schlemm's canal (the width of which is ~250 microns[18-20]), and as the tip/footplate advances along the canal, the TM is put on stretch as it feeds up the ramp and encounters the dual blades which cleanly excise a strip of stretched TM. The angle of the distal cutting surface and the diameter of the device shaft are designed for maximum angle treatment through a single clear corneal incision.[21] In a laboratory experiment, the KDB demonstrated more complete TM removal than either a microvitreoretinal (MVR) blade or trabecular ablation using the Trabectome (Microsurgical Technology, Redmond, WA), with minimal residual leaflets of TM and no damage to neighboring tissues.[22] A histological analysis of excised TM strips from adult eyes with glaucoma confirmed the presence of TM in all samples,[23] in contrast to trabeculectomy in which up to 40% of cases do not excise TM.[24] A second-generation KDB instrument (KDB Glide, New World Medical) is in development that features beveled edges and rounded corners on the footplate to facilitate greater ease of passage along the canal while preserving ramp and blade dimensions and configuration. In a second laboratory experiment, the Glide produced more reliable TM excision than an MVR blade, 360°trabeculotomy with 5–0 prolene suture, or the TrabEx device (Microsurgical Technology).[25]

Surgical Technique

The KDB tip enters the anterior chamber through a temporal peripheral clear corneal incision and, under direct gonioscopic visualization, is advanced to the nasal TM. The instrument's sharp tip then engages TM, fashioning an opening through which the heel at the base of the footplate is seated in Schlemm's canal. The tip is then advanced within the canal along with the TM, which is elevated onto the ramp and stretched as it is guided to the two cutting blades that remove an intact TM strip. The strip is then removed from the eye with the KDB or with forceps. This elevation and stretching of the TM before excision maximizes the width of the excised strip and protects adjacent structures from collateral injury.[17,21] Three excisional approaches have been described:

- Mark and meet: The KDB tip fashions an opening at one end of the planned strip of TM to be excised to mark the location and is then withdrawn from the TM. The tip then engages TM at the opposite end of the planned excision with the device tip pointed toward the initial TM opening and advanced until the strip between the two points is fully excised. A single tissue strip is excised.
- Outside-in: The KDB tip engages TM at one end of the planned excision and is advanced to the approximate midpoint of the planned excision. The tip then engages TM at the opposite end of the planned excision and is advanced to meet the first pass at the midpoint. A single tissue strip is excised.
- Inside-out: The KDB tip engages TM at the approximate center of the planned excision and is advanced to one end of the planned excision. The tip is then rotated 180° and reseated in the canal at the initial (central) point, then advanced to the opposite end of the planned excision. The two half-length tissue strips are either excised or remain in place according to surgeon preference.

Review Results

Clinical Efficacy Outcomes

Standalone vs Combined with Phacoemulsification

Excisional goniotomy with the KDB can be performed either as a standalone procedure or in combination with phacoemulsification in eyes with coexisting visually significant cataracts. It is important to consider the different indications and surgical goals likely applicable to these two scenarios. Standalone glaucoma procedures are typically performed in the setting of elevated IOP with the goal

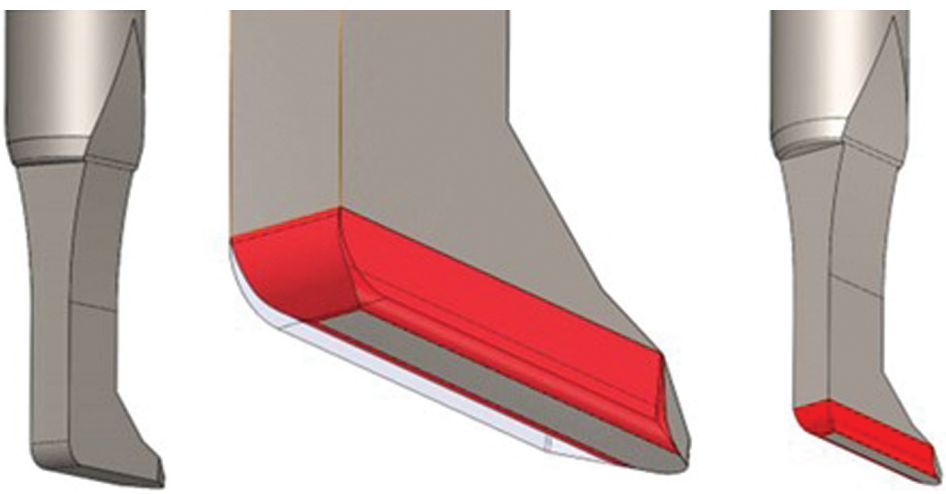


Fig. 1: Left: Kahook Dual Blade. Right: second-generation KDB Glide. Center: highlighted differences between the two designs

of lowering IOP; less commonly standalone surgery is performed to reduce the medication burden. Conversely, when combined with phacoemulsification, the surgical goal is usually to reduce the medication burden; less commonly, the need for visual rehabilitation and IOP reduction arise contemporaneously in eyes with coexisting cataracts and glaucoma. Outcomes in standalone vs combined surgeries are therefore presented separately and summarized in Table 1.

Standalone: IOP and medication reductions following standalone surgery have been characterized in one prospective and five retrospective studies of 4–18 months in duration.[26-31] In these studies, mean IOP reductions of 11–36% and mean medication reductions of 15–92% (note: one study reported a medication increase of 14% at 18 months[30]) were reported. These wide ranges likely represent variable proportions of patients in each study undergoing surgery for IOP versus medication reductions.

Combined with phacoemulsification: Efficacy outcomes in samples composed chiefly of eyes with open-angle glaucoma undergoing combined surgery have been reported in one randomized clinical trial,[32] six retrospective controlled studies (one reported at two time points[33,34]),[35-39] and seven retrospective uncontrolled studies [one reported at two time points[26,40]; another reported a pooled sample of primarily combined cases (90%)[41]].[21,29-31,42] In these 17 reports with follow-up ranging from 4–18 months, mean IOP reductions of 11–34% and mean medication reductions of 11–79% were described. These ranges were generally consistent across the various study designs with the exception of the randomized trial (17% IOP reduction, 79% medication reduction), which enrolled primarily patients with mild disease (79%) whose baseline IOP was quite low (18.5 mm Hg) suggesting medication reduction as the goal of surgery in most cases.[32] Importantly in eyes undergoing concurrent cataract surgery for visual rehabilitation, visual acuity outcomes were not compromised with the addition of excisional goniotomy with the KDB in the studies cited above, and the combined procedure was not associated with refractive surprise (Table 1).[43]

Across the Spectrum of IOP

In an effort to better characterize patient-specific surgical goals, three investigative groups conducted subgroup analyzes stratifying subjects by baseline IOP above vs below the mean or median preoperative IOP, with the assumption being that patients with higher baseline IOP likely underwent surgery to achieve IOP reduction while those with lower baseline IOP more likely sought to achieve medication reduction.[26,34,40] As might be expected, IOP reductions were greater in eyes with higher baseline IOP than with lower baseline IOP, while medication reductions were generally similar in the two groups (Table 2).

Across the Spectrum of Glaucoma Severity

While no study to date has reported outcomes stratified by baseline glaucoma severity, differences in the severity of glaucoma between study samples permit some inference on this point. A caveat of this approach is that the method of classifying glaucoma severity was not always described and may differ between studies. Eight studies had KDB groups with predominantly (≥75%) mild-moderate glaucoma[26,27,32,33,36] or moderate-severe glaucoma.[28,37,42] Both IOP and medication reductions were similar in studies at both ends of the severity spectrum (Table 3).

Table 1: IOP and medication reductions in standalone and combined procedures

	IOP reductions	*Medication reductions*
Standalone[26-31]	11–36%	15–92%*
Combined[21,29-40,42]	11–34%	11–79%

*one study reported a 14% increase in medication use[30]

In Comparison to Other Procedures

One randomized trial[32] and five retrospective studies[33-37] have compared excisional goniotomy to trabecular micro bypass implantation (iStent, Glaukos, San Clemente, CA) when each was combined with phacoemulsification. In the randomized trial, 164 eyes with mild to moderate open-angle glaucoma (OAG) were randomized to one of the two treatments.[32] The study's primary endpoint was IOP reduction ≥20% or IOP reduction ≥1 medication at 12 months and was achieved by 94% of excisional goniotomy eyes and 83% of micro bypass eyes ($p = 0.04$). At 12 months, mean IOP reductions were 17% in the excisional goniotomy group and 13% in the micro bypass group, while medication reductions were 79% and 70%, respectively; differences were statistically significant. Among the five retrospective studies, mean IOP reductions ranged from 13–27% for excisional goniotomy and 13–19% for micro bypass implantation [differences significant ($p < 0.05$) in three studies, insignificant in the remaining two], while medication reductions ranged from 27–79% and 6–70%, respectively (differences significant favoring KDB in two studies, micro bypass in one study, and insignificant in two studies) (Table 4). Retrospective comparative studies such as these must be interpreted with great caution, as physicians selected the procedure they felt was best for each patient at the time of surgery, and thus the patient characteristics of each treatment group may differ in important ways. This is illustrated in one of the retrospective studies cited above,[37] in which 58% of eyes undergoing excisional goniotomy had severe glaucoma at baseline while 0% of micro bypass eyes had severe glaucoma at baseline. While this reveals a clear bias on the investigators' part for excisional goniotomy in eyes with more severe glaucoma, it underscores the challenges of retrospective comparisons: in this case, significantly greater medication reductions were seen in micro bypass eyes (59% vs 36%, $p < 0.01$), but the patient characteristics suggest that far more micro bypass eyes underwent surgery at an earlier disease stage and may have preferentially sought medication reduction compared to the excisional goniotomy eyes that underwent surgery at a later stage and likely sought IOP reduction (which was greater in

Table 2: IOP and medication reductions stratified by baseline IOP

	IOP reductions	*Medication reductions*
Low baseline IOP[26,34,40]	4–21%	36–61%
High baseline IOP[26,34,40]	40–46%	33–84%

Table 3: IOP and medication reductions stratified by severity of glaucoma at baseline

	IOP reductions	*Medication reductions*
Mild-moderate (>75% of eyes with mild-moderate disease)[26,27,32,33,36]	14–36%	15–79%
Moderate-severe (>75% of eyes with moderate-severe disease)[28,37,42]	12–26%	36–50%

excisional goniotomy eyes—26% vs 19%, $p = 0.03$). There may also be differences in the nature of surgical failure between these two procedures. A study of TM tissue changes in three eyes undergoing micro bypass explanation for surgical failure revealed loss of TM cells, the collapse of collagen beams, an increase in fibrous material, and a basement membrane-like structure that were not seen in unimplanted glaucomatous or healthy eyes.[44]

A single study reported a retrospective comparison of excisional goniotomy with 360°trabeculotomy performed either *via* gonioscopy-assisted transluminal trabeculotomy or using the TRAB360 device (Sight Sciences, Menlo Park, CA) in eyes with primarily severe OAG.[38] At 6 months postoperatively, mean IOP reductions were 13% in excisional goniotomy eyes and 6% in eyes undergoing 360°trabeculotomy (p = ns). More eyes undergoing excisional goniotomy than 360°trabeculotomy achieved final IOP <18 mm Hg (80% vs 59%, $p = 0.04$) and <15 mm Hg 61% vs 26%, $p = 0.003$) (Table 4).

In Other Forms of Glaucoma

Angle Closure Glaucoma: The application of angle-based surgery in an eye with angle-closure glaucoma (ACG) is not immediately intuitive. However, paired with goniosynechialysis (also performed with the KDB), excisional goniotomy has been shown to provide substantial reductions in both IOP and the need for IOP-lowering medications. A series of 42 eyes of a mixed ethnicity sample (half of whom were Asian) underwent combined phacoemulsification, goniosynechialysis, and excisional goniotomy with the KDB has been reported at 6,[45] 12,[46] and 24[47] months postoperatively. Initial IOP reductions of 49% and medication reductions of 92% persisted through 12 months (47% and 92%, respectively) and 24 months (47% and 76%, respectively). At 24 months, 95% of eyes achieved IOP ≤18 mm Hg, 100% had IOP reductions ≥20% from baseline, 86% were on fewer medications than at baseline, and 69% were medication-free.[47] The investigators explained their rationale for the combined procedure by pointing out that TM dysfunction can occur in eyes with ACG and thus opening the angle alone may not fully address outflow obstruction; coupling excisional goniotomy to the cataract extraction and goniosynechialysis procedures removes potentially dysfunctional TM and optimizes aqueous outflow through the TM outflow pathway.[47]

Uveitic Glaucoma: A series of 16 eyes with glaucoma associated with uveitis undergoing excisional goniotomy with the KDB either as a standalone procedure or in combination with phacoemulsification has been reported.[48] Patients in this series were younger than in studies of primary open-angle glaucoma (POAG) (mean age 43 years) and had a wide variety of underlying inflammatory ocular conditions underlying their uveitis. Survival analysis revealed a 68% 1-year success rate at achieving prespecified and patient-specific target IOP. Mean IOP was 28.1 mm Hg preoperatively and at last follow-up (mean 9.6 months) was 17.4 (p = 0.007); medication use was reduced from a mean of 3.6 preoperatively to 2.1 at last follow-up ($p = 0.004$).

Childhood Glaucoma: Several case reports have demonstrated the utility of excisional goniotomy using the KDB in the eyes of children with developmental glaucomas. In an infant with bilateral glaucoma, IOP was reduced from 35 mm Hg and 52 mm Hg to 17 mm Hg and 18 mm Hg in right and left eyes, respectively.[49] In a similar report, IOP was reduced from –21 mm Hg in the right eye of an infant but failed to lower IOP in the left eye following three excisional goniotomy procedures necessitating implantation of a tube-shunt.[50] In a 14-year-old with juvenile OAG, mean IOP was reduced from 28–15 mm Hg.[51]

Other Glaucomas: In a case of steroid-related IOP elevation following penetrating keratoplasty, excisional goniotomy with the KDB lowered IOP from 32–13 mm Hg.[52] In a case of glaucoma associated with transthyretin amyloidosis, IOP was lowered from 32 to < 14 mm Hg.[53]

Clinical Safety Outcomes

Excisional goniotomy with the KDB is generally a safe procedure without significant sight-threatening complications. Transient bleeding from the TM excision site is common, expected, and typical of most angle-based surgeries. The most common adverse event across the various studies was IOP elevation, occurring in 3–32% of eyes.[21,29,32,33,36,37,39,40] This may be attributable in part to a steroid response, although specific mechanisms remain elusive. The highest reported incidence in this range—32%, occurred in the randomized trial vs the micro bypass. In these eyes, the incidence of IOP elevations was 33%.[32] Among the retrospective comparisons of excisional goniotomy and micro bypass, IOP elevations were seen in 13–18% of the former and 2–7% of the latter.[33,36,37] Transient pain was reported in 8% of eyes in one study.[40] Also in the randomized trial the rates of posterior capsule opacification were 9% in incisional goniotomy eyes and 6% in micro bypass eyes.[32]

Unlike other glaucoma procedures, excisional goniotomy does not require the implantation of a device, obviating secondary surgical procedures for device-related complications, and does not create a bleb, precluding the need for suture lysis, needling, and other routine postoperative bleb management procedures. Instead, reoperations following excisional goniotomy are necessitated by surgical failure. In the various studies cited above, the reoperation rate for surgical failure following excisional goniotomy ranged from 2–22%, with a trend toward higher reoperation rates in studies (and in patients within studies) with more severe glaucoma and/or higher baseline IOP.[27,28,30,37,41,42] The common complications of the procedure are summarized in Table 5.

Discussion

Considerations for Patient Selection

Given the vast array of new and traditional glaucoma procedures available today, a clear understanding of each procedure's features and limitations is essential in selecting the best procedure for each individual patient. Key features to consider when planning surgery include a procedure's indication, efficacy in the context of patient-specific surgical goals, safety including the rapidity of visual rehabilitation, ease of performance, and ability to pair with concurrent procedures, among others.

Table 4: IOP and medication reductions in comparative studies of excisional goniotomy with the KDB

	IOP reductions		*Medication reductions*	
Comparator	*KDB*	*Comparator*	*KDB*	*Comparator*
Trabecular microbypass[32-37]	13–27%	13–19%	27–79%	6–70%
360°trabeculotomy[38]	13%	6%	45%	58%

Table 5: Complications associated with excisional goniotomy

Complications	*Reported Incidence (%)*
Elevated intraocular pressure	3–32%[21,29,32,33,36,37,39,40]
Posterior capsule opacification (combined surgery)	9%[32]
Transient pain	8%[40]
Reoperation rate	2–22%[27,28,30,37-39,41]

Table 6: Contraindications to excisional goniotomy

Contraindications
Active uveitis
Neovascular glaucoma
Acute angle closure glaucoma
Corneal opacity precluding angle visualization

As discussed above the KDB instrument and not the procedure itself is regulated. Thus, the clinical indications of the procedure are determined by efficacy and safety profiles in various clinical settings. Multiple studies described in this review demonstrate the efficacy and safety of excisional goniotomy with the KDB in eyes with OAG across the spectrum of disease severity and baseline IOP. Further, its clinical utility has been demonstrated in eyes with angle-closure glaucoma, uveitic glaucoma, glaucomas of childhood, and other forms of glaucoma.

Patient-specific surgical goals may be IOP reduction, medication reduction, or both. Substantial medication reductions have been reported across the spectrum of baseline IOP and disease severity, and in eyes with high baseline IOP, IOP reductions of 40–46% with excisional goniotomy are on the order of those delivered by trabeculectomy in the Collaborative Initial Glaucoma Treatment Study (44–48%) without the attendant life-long risk of bleb-related complications.[54]

The procedure is straightforward to perform,[21] offers versatility as a standalone procedure or in combination with cataract surgery and has a favorable safety profile with rapid visual recovery and no refractive surprise. Clinical scenarios in which excisional goniotomy is contraindicated are given in Table 6.

Conclusion

In summary, excisional goniotomy with the KDB effectively lowers IOP and reduces the medication burden in eyes with POAG and other forms of glaucoma across the spectrum of both baseline IOP and disease severity. The procedure exhibits a safety profile that is on par with other angle-based surgical interventions and enhanced safety compared to filtration procedures. It can be performed by comprehensive ophthalmologists as well as glaucoma specialists. This procedure as a standalone operation delivers IOP reductions consistent with filtration surgery, and in combination with cataract surgery delivers both IOP and medication reductions at least as great as other minimally invasive procedures. Given the broad base of evidence supporting its use in a wide variety of clinical scenarios, excisional goniotomy with the KDB can play a meaningful role in the achievement of patient-specific glaucoma therapy goals.

Clinical Significance

These aggregate findings support the efficacy and safety of excisional goniotomy with the KDB in a broad array of clinical scenarios and clarify the patient profiles best suited for this procedure.

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