

REVIEW ARTICLE

Open-angle glaucoma management with Kahook Dual Blade – A perspective based on available evidence and 5 years of surgical experience

Tiago Santos Prata^{1,2,3,4}, Laura Silva Reis³, Isabella Cristina Tristão Pinto Resende³, Syril Dorairaj², Fábio Nishimura Kanadani^{1,2,3}

¹Department of Ophthalmology, UNIFESP/EPM, São Paulo, Brazil, ²Mayo Clinic, Rochester, Minnesota, USA, ³Department of Ophthalmology, Glaucoma Institute, São Paulo, Brazil, ⁴Glaucoma Preceptor, Opty Group, São Paulo, Brazil

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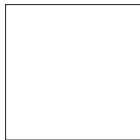
Address for correspondence:

Tiago Santos Prata, Department of Ophthalmology, UNIFESP/EPM, São Paulo, Brazil. E-mail: tprata0807@gmail.com

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**Abstract**

Minimally invasive glaucoma surgeries (MIGS) are surgical procedures developed for open-angle glaucoma (OAG) management, with the advantages of less tissue manipulation, faster recovery, and lower complication rates compared to conventional procedures. Excisional goniotomy using the Kahook Dual Blade (KDB) is an example of Schlemm's canal-based MIGS, whose efficacy and safety have been demonstrated in several studies. In this short review - based on available evidence and 5 years of surgical experience - we discuss KDB surgical technique, main indications and clinical outcomes. Overall, the procedure has been performed associated with cataract surgery in most of our cases. In this context, best indications are patients with requiring cataract extraction with ocular hypertension or mild to moderate OAG. In these cases, the goal is to lower intraocular pressure (IOP) or reduce hypotensive medications. Most studies have shown an average IOP reduction of approximately 20% with a positive impact on medication burden (average reduction of one medication). Regarding its safety profile, the main postoperative complication is hyphema (approximately 1/3 of the cases). In general, the hyphema is transient and self-limited. Eyes with a relatively higher baseline IOP and a more pronounced initial response to the procedure appear to have better midterm outcomes. We believe that more prospective studies are needed to better assess the long-term efficacy and safety profile of the procedure.

Introduction

Glaucoma is one of the leading causes of irreversible blindness worldwide. By the year 2020, the estimate of people with glaucoma was 80 millions and the estimate of people with consequent bilateral blindness was 11.4 millions.^[1] Notwithstanding the glaucomatous optic neuropathy pathophysiology is still not fully understood, elevated intraocular pressure (IOP) is a well-established risk factor for the development and progression of the disease.^[2,3] Therefore, effective IOP reduction is the main goal of clinical and surgical treatment of glaucoma.

Having in mind the glaucoma surgical procedures available up to 15 years ago, there were only more invasive procedures,

normally reserved for end stage glaucoma or cases with poorly controlled IOP.^[4] Since then, new surgical procedures have been developed, with less tissue manipulation, faster recovery, and lower complication rates compared to conventional filtration procedures.^[5] The technique of ab interno trabeculotomy with Kahook Dual Blade (KDB) is an example of these minimally invasive glaucoma surgeries (MIGS), whose efficacy and safety have been demonstrated in several studies in the last 6–7 years.^[6–11] In the next sections, we will address the main aspects related to the KDB procedure, from the surgical concepts to the most common indications, focusing mainly on those looking forward to starting the technique.

Surgical Technique

Tips to start learning the technique

The KDB surgery technique follows most concepts already used in angular surgeries. Therefore, we believe that those with previous surgical experience with other MIGS procedures (GATT or iStent, for example) will not have difficulties in learning it. In our routine, KDB procedure has been performed associated with cataract surgery in most of the cases. To make the learning curve shorter, a valuable suggestion is to train some of the KDB surgical steps at the end of routine cataract surgeries. After implantation of the intraocular lens, we tilt the patient's head and position the microscope for the KDB procedure. Positioning ourselves in the temporal region of the eye, we can not only train intraoperative gonioscopy (probably the most difficult step in the initial training phase), but also simulate the movement of the KDB with a Sinsky or a cannula, for example (taking care not to touch the trabecular meshwork). We believe that this type of training should be performed at the end of approximately 15–20 cataract surgeries so that the surgeon gains the necessary dexterity to perform intraoperative gonioscopy without difficulties.

Brief description of the technique

As commented above, in our routine, the KDB procedure has been performed in conjunction with cataract surgery in most of the cases. In brief, after intraocular lens implantation, the anterior chamber is refilled with viscoelastic. It is important to avoid an excessive amount of viscoelastic at this time to avoid collapse of the Schlemm's canal. After correctly positioning the patient's head (approximately 45° inclination to the opposite side of the surgeon) and the surgical microscope (approximately 45° inclination toward the patient's face), viscoelastic is instilled over the cornea and the gonioscopy lens is used intraoperatively to visualize the nasal angle under high magnification. Using the KDB® (New World Medical, Rancho Cucamonga, CA), the nasal trabecular meshwork is excised to the greatest possible extension (approximately 90°). Methylcellulose is removed and the corneal incision is sealed to keep the eye slightly hypertonic at the end of the procedure, to minimize post-operative hyphema. For more details, we suggest the following link (<https://www.youtube.com/watch?v=3vNhnzLlK6s>) and the webinar on glaucoma surgeries provided by the Brazilian Society of Glaucoma (<https://www.youtube.com/channel/UCqgU8pSdXR-0fsyI9l94ncQ>).^[11,12]

Critical Analysis of Available Literature

Overview of the studies

There are very different study profiles when comparing the available data on the different types of MIGS, with a clear

dichotomy. On one side, there are studies with device based-MIGS, sponsored by companies that directly influence all steps of the research project, from the study design to the production of the final manuscript. They are usually expensive multicenter trials with a larger number of participants and a more robust design (many are randomized clinical trials). However, these characteristics are usually accompanied by some disadvantages, such as the adoption of unconventional inclusion and exclusion criteria, which makes it difficult to externally validate their results. In addition, one can note a clear discrepancy between statistical significance and clinical relevance in some of these studies, as authors often tend to overestimate even relatively poor results.^[13]

On the other side, we have MIGS studies without device implantation. Usually, these are small retrospective non-sponsored studies, with a shorter follow-up time and a less robust design. On the other hand, they usually include patients whose clinical profile is closer to our daily clinical practice and provide a more realistic discussion regarding their findings. Most KDB studies pertain to this second group. Therefore, despite the nearly 100 studies with KDB to date, the vast majority have a mean follow-up of one year or less, and randomized clinical trials are rare.^[14] Next, we will analyze the main results available on KDB, always focusing on the procedure associated with cataract surgery.

Summary of the main results

When we think about the effectiveness of cataract surgery associated with KDB surgery, we are generally talking about a pressure reduction of approximately 20% (4 mmHg for patients with a pre-operative IOP of 18 mmHg), with an average reduction of one hypotensive medication.^[6-8,11-16] Success rates after 1 year are around 80%, depending on the criterion adopted. Regarding success predictors, we have observed better results in eyes with glaucoma secondary to trabecular mechanisms, such as pigmentary, pseudoexfoliative, and steroid induced glaucomas.^[17,18] Furthermore, our group recently demonstrated that eyes with relatively higher baseline IOP and those with an initial good response in the first few weeks seem to have a greater chance of future success.^[8] In other words, it does not seem reasonable to expect a significant late IOP reduction in eyes whose initial response to the procedure was poor. Regarding its safety profile, the main KDB post-operative complication is hyphema. Although transient and self-limited in most patients, hyphema occurs in approximately 1/3 of the cases.^[6,8,18,19]

Comparison with other trabecular bypass MIGS procedures

Since KDB surgery involves a pressure reduction mechanism similar to other minimally invasive glaucoma procedures (trabecular bypass), some studies sought to compare the results of KDB with those of other MIGS, especially with iStent.^[20] In general, when it comes to effectiveness, some initial retrospective

studies already showed better success rates with KDB versus iStent.^[21,22] More recently, these findings were confirmed in a randomized clinical trial with a 12-month follow-up, in which success rates were 93.7% with KDB and 83.3% with iStent.^[14,15] Regarding safety, when comparing the two techniques, we clearly have more hyphema with KDB. On the other hand, some recent prospective data have suggested a better endothelial safety profile with KDB versus iStent, documenting a greater endothelial cell loss with the latter (-3.4% versus -9.0%; mean follow-up of 18.2 months).^[23]

Finally, in comparison with other minimally invasive procedures, the effectiveness of KDB versus gonioscopy-assisted transluminal trabeculotomy (GATT) has also been compared, with no significant differences between the results.^[7] We do not believe that these findings are definitive, since the mean pre-operative IOP of included patients was relatively lower than the usual baseline pressure in surgical studies in glaucoma.^[7] As we know that there is a limit for the final post-operative IOP after trabecular bypass procedures due to the distal outflow resistance and episcleral venous pressure, the fact that the pre-operative IOP was already lower than usual in this study may have mitigated the authors ability to investigate a possible greater pressure reduction with GATT.^[24] Therefore, we believe that further longitudinal studies are warranted to better investigate and compare KDB outcomes with those from GATT.

Personal Experience with the Procedure

Our group has been using KDB since the second half of 2017. In addition, we have been coordinating a multicenter MIGS study group dedicated to compare their efficacy and safety profile and to investigate possible success predictors. Our intention within this section is to share our surgical experience with KDB, in addition to our recently published results.^[7-9]

In general, the adaptation to the technique is not so time consuming, especially for those with previous experience with congenital glaucoma surgery. Comparatively, we believe that the technical difficulty with KDB could be subjectively classified as moderate, being more difficult than an iStent implant, and easier than a GATT procedure. Regarding the surgical procedure itself, we suggest starting with more simple and well-controlled cases (mild glaucoma with well controlled IOP under few topical medications) whose disease prognosis does not depend on the KDB procedure outcomes. We only recommend that surgical indications should be expanded as the surgeon gains more confidence and masters the technique. Regarding the post-operative period, we usually perform the first evaluation 2 h after the procedure. The focus of this first assessment is to identify possible pressure peaks and manage them accordingly. The fact that we perform the surgery with topical anesthesia facilitates the examination in the 1st h after the procedure. We do not suspend glaucoma medications neither on the 1st day, nor before the surgery. Our

preference has been to adjust patients' medication regimen according to documented IOP values throughout the post-operative period. When a significant pressure reduction is observed, medications are discontinued, in a stepwise fashion. Prostaglandin analogues are usually the first class to be removed. It is important to closely monitor every patient along the initial post-operative period. More frequent visits are required compared to a conventional cataract surgery post-operative period, since IOP peaks in the 1st weeks are not infrequent, likely due a combined mechanism of inflammation (blood-aqueous barrier breakdown), hyphema, and sensitivity to topical corticosteroids. Regarding the hyphema, we believe that it is always important to inform patients of this possibility before the procedure. In general, as aforementioned, hyphema cases are self-limited, and surgical revision is usually not necessary. As a tip to mitigate hyphema occurrence, we suggest proper sealing of the surgical wounds and to keep the eye relatively hypertonic at the end of the surgery. Whenever possible, patient's head should be positioned higher than usual in the final stages of the procedure, to minimize blood reflux to the anterior chamber.

Rationale for KDB use and Main Indications

Regarding the best KDB indications in the management of open-angle glaucoma, we see two main clinical scenarios: (a) patients with cataract surgery indication and ocular hypertension or mild-to-moderate well-controlled glaucoma: in this case, the main focus is to reduce the number of glaucoma medications; (b) patients with cataract surgery indication with ocular hypertension or mild-to-moderate glaucoma, whose treated IOP is slightly above target: in this case, pressure reduction is the main focus of the procedure. It is important to keep in mind that the magnitude of pressure reduction with the procedure is limited. As an example, a reasonable indication would be a patient with a preoperative IOP range between 16 and 17 mmHg, whose desired target pressure with KDB would range between 13 and 14 mmHg.

In this context, it is also important to highlight the clinical situations, in which we consider that KDB should not be recommended. As it offers a moderate magnitude of IOP reduction and there is a risk of IOP spikes in the initial post-operative period, we do not recommend KDB neither for eyes with advanced glaucoma, nor for any patient (regardless of disease stage) who needs an IOP reduction greater than the procedure can provide.^[11,16,25-27]

Finally, in phakic eyes with a good indication for KDB (based on the two clinical scenarios mentioned above), but without a symptomatic cataract, we usually do not perform KDB as solo procedure (nor any other trabecular bypass MIGS).^[25,26] In these cases, also aiming to reduce the number of medications or IOP control in eyes with mild-to-moderate glaucoma, we have routinely indicated selective laser trabeculoplasty, with comparable success rates and an excellent safety profile.^[28-32]

Conclusions

The results available to date suggest that phacoemulsification combined with excision of the trabecular meshwork with the KDB is an effective and safe alternative for the management of cataract in eyes with mild-to-moderate open-angle glaucoma, positively impacting IOP control and the number of medications. Eyes with a relatively higher baseline IOP and a more pronounced initial response to the procedure seem to have better 1-year outcomes. We believe that more prospective studies are needed to better assess the long-term efficacy and safety profile of the procedure.

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