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Blade lets nature take its own course

Single-use Kahook dual blade excises the TM so aqueous flows to distal channels.

While trabeculectomy and glaucoma drainage devices remain the gold standard for the surgical lowering of intraocular pressure, there has been a recent emergence of surgical techniques designed to lower pressure by re-establishing the natural aqueous humor outflow pathways.[1] One such device is the Kahook dual blade (KDB, New World Medical), a single-use goniotomy knife designed to make parallel incisions in the trabecular meshwork (TM). These incisions allow aqueous humor to have free communication between the anterior chamber and distal collector channels **(Figure 1)**. The key feature of the KDB is a ramp on the distal end that allows the TM to be stretched before the KDB's two blades cleanly remove a wide swath of tissue. The process of elevating the TM on the ramp is essential and represents a significant breakthrough in design efforts.

The research and development process involving the KDB was intended to provide a single-use device that was accessible to surgeons of various backgrounds that could be applied to patients in a safe and effective manner.

This article describes the steps taken from preclinical testing to clinical utility and describes surgical pearls that surgeons can leverage when adopting this novel goniotomy blade.

PRECLINICAL DEVELOPMENT

Preclinical testing of the KDB was completed in the early stages of development with specific attention to removing TM while minimizing residual leaflets left behind. A study that compared the performance of three different devices in cadaveric tissue was completed: (1) KDB; (2) a microvitreoretinal (MVR) blade; and (3)

IMAGE COURTESY NEW WORLD MEDICAL

Figure 1. The KDB device is a single-use ophthalmic blade that is precision engineered for removal of trabecular meshwork while minimizing residual leaflets.

Trabectome (NeoMedix Corporation).[2] The MVR blade incised the TM without removal of tissue but also resulted in collateral damage to adjacent sclera. While the Trabectome device removed a central portion of the TM, residual leaflets were significant and thermal damage was noted in the treatment pathway. The KDB device achieved a more complete removal of TM with minimal residual TM tissue and without injury to surrounding tissues. These preclinical data led to a collaboration with New World Medical to further refine the device and complete the requirements for launching KDB.

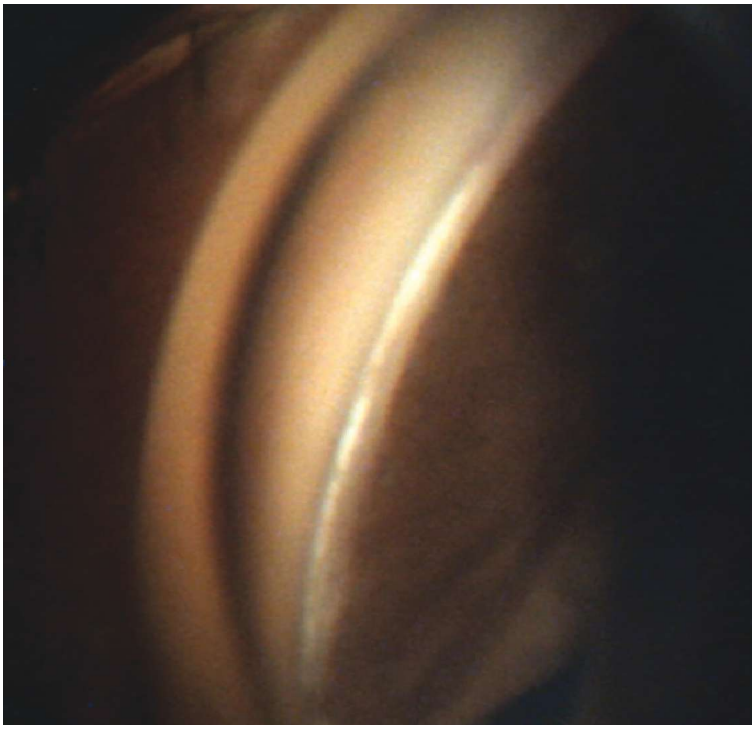

IMAGE COURTESY LEONARD K. SEIBOLD, MD

Figure 2. **The anterior wall of the canal of Schlemm (white) can be observed post KDB treatment revealing minimal residual TM remaining.**

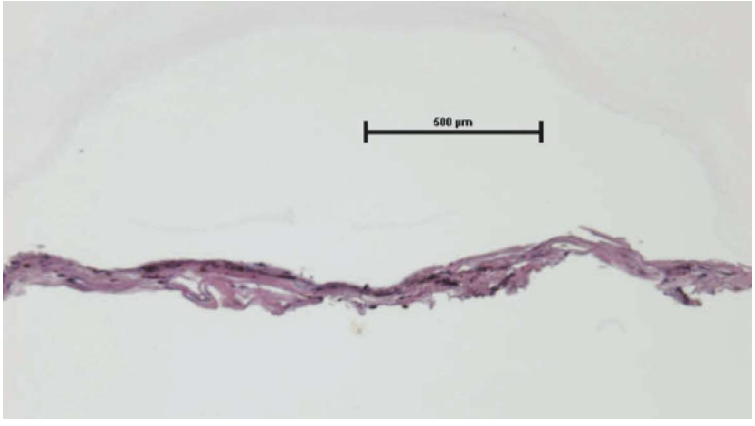

IMAGE COURTESY MALIK Y. KAHOOK, MD

Figure 3. **A histologically prepared strip of TM removed using KDB.**

CLINICAL DATA

The KDB device was launched in the United States in late 2015 and has subsequently been made available to several countries around the globe. This has allowed the collection of real world data regarding KDB's utility and safety in everyday practice.[3] One example of clinical data collection involves a review of the first 10 cases, either standalone KDB or KDB combined with cataract extraction, from several clinical sites around the country. Each surgeon also has completed a questionnaire to document ease of use and intraoperative experience. To date, more than 120 eyes have been included in this effort with continued follow-up over the next two years. A recent review of data from this cohort focused on those undergoing KDB with cataract extraction from eight different centers and involving 71 eyes with 12 months of follow-up.

The majority of eyes (70%) had primary open angle glaucoma while others were diagnosed with chronic angle closure, pigmentary and pseudoexfoliation glaucoma. Almost 60% of the eyes were documented to have severe or moderate glaucoma. In 96% of cases, surgeons either strongly agreed or agreed that use of the KDB was straightforward, entry into Schlemm's canal was uncomplicated and advancement along the treatment pathway was smooth. At 12 months, the mean IOP was significantly reduced to 13.0±2.5 mm Hg compared to 17.4±1.6 at baseline ($P<0.001$). The mean glaucoma medication burden was also significantly reduced compared to baseline ($p=0.001$). Further data collection is ongoing to understand the IOP-lowering efficacy of KDB when combined with cataract extraction beyond one year of follow-up.

An important aspect of this ongoing study is that many eyes that underwent the KDB procedure were not candidates for traditional trabecular microbypass implants. Many had angle closure glaucoma or secondary glaucomas for which trabecular stents are not indicated, or were not undergoing cataract surgery concomitantly. Also, it is important to note that the goniotomy procedure code (65820) has been established for decades, while other angle-based procedures may lack a category I code. Certain insurance companies may restricts these codes and may exclude underserved patient populations with Medicaid or managed Medicaid. These facts may be welcomed by surgeons who have made TM bypass procedures

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Disclosures: Dr. Kahook a consultant to New World Medical.

part of their repertoire, allowing them performed in patients who may not have been considered candidates for traditional stent implantation.

TECHNIQUE AND PRACTICE PEARLS

As with other angle-based surgeries, use of the KDB to perform goniotomy requires a goniolens. It also requires the patient to be repositioned to enhance alignment with the operating microscope. The patient's head is tilted 30° to 45° away from the surgeon and the microscope is tilted towards the temporally seated surgeon. The viscoelastic choice is variable depending on the surgeon, but we find a cohesive viscoelastic works best to maintain the anterior chamber and deepen the recess between the iris and cornea to expose the TM. The KDB is advanced through a clear cornea incision, recommended to be 2.0-2.4 mm wide, and the gonioscopic lens is placed over the cornea coupled with viscoelastic to bring the drainage angle into view under high magnification.

Once the distal end of the KDB reaches the TM, the surgeon should move the device 2 to 3 clock hours to the right and then enter the canal of Schlemm using the blade's piercing tip. Some surgeons find it beneficial to direct the distal tip of the KDB up 10° towards Schwalbe's line prior to piercing the TM. This may help with smoother entry through all TM layers. The heel of the KDB is then settled back on the anterior wall of the canal and advanced from right to left while ensuring the TM is rising over the ramp prior to engaging the dual blades to create parallel incisions.

The treatment is stopped after 2 to 3 clock hours and the same procedure is then repeated from left to right so that a strip of TM is amputated and subsequently removed with irrigation/aspiration or with capsulorhexis forceps **(Figures 2 and 3).** The viscoelastic is then evacuated and the anterior chamber is inflated to an IOP of 20 to 25 mm Hg (to help push back any refluxed blood) and the wounds are meticulously hydrated for a watertight seal.

The KDB procedure can be combined with cataract surgery or performed as a standalone intervention. When combined with cataract extraction, the order of procedures doesn't matter. A miotic may be used prior to the KDB procedure to enhance the view of the angle and is recommended for surgeons who are new to using a gonioscopic lens in surgery. When anatomic structures are not clear at the time of surgery, the surgeon may lower the anterior chamber pressure to allow for some blood to reflux into Schlemm's Canal and help outline the location of the TM. Alternatively, Trypan blue can also stain the TM and help identify landmarks for better visualization. These techniques are particularly useful in lightly pigmented TM.

The postoperative drop regimen is similar to that of standalone cataract extraction with some surgeons choosing to use pilocarpine 1% four times daily for two to four weeks to keep the angle wide open in the early postoperative period. Steroid-induced glaucoma can still occur after angle-based surgery and so early taper of the steroid drops is recommended as appropriate for each given case. Most surgeons choose to stop all previously used glaucoma drops when possible, then re-institute topical therapy as required depending on the response to the KDB treatment.

CONCLUSION

The goal of the translational research involving the KDB was to find a better and more efficient method for removing a complete strip of TM using an ab interno approach while minimizing collateral damage. The preclinical testing and subsequent clinical data collected to date reveal that the KDB can successfully remove the targeted TM and open a pathway for aqueous humor egress through the distal collector channels. Furthermore, the safety and efficacy profile of the device has made KDB a valuable part of our routine for the surgical care of glaucoma patients with disease ranging from mild to severe. The added versatility of combining KDB with cataract surgery or as a standalone treatment has further expanded its use. Multicenter studies are currently underway to better understand the role of KDB with longer-term follow-up in a wider range of patients (For a demonstration, visit https://www.youtube.com/watch?v=ruZw-WK_f34). **OM**

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