



Narrative review of goniotomy with the Kahook Dual Blade for the treatment of glaucoma

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Abstract: Glaucoma is a group of eye diseases that seriously threaten human visual health. Increased intraocular pressure is the main clinical manifestation and diagnostic basis of glaucoma and is directly related to increased resistance to aqueous circulation channels. The trabecular meshwork (TM) is a multi-layer spongy tissue that filters aqueous humor. Its structure changes and the filtering capacity decreases, leading to an increase in intraocular pressure. Surgical methods for TM are constantly updated. Compared with traditional glaucoma surgical techniques, such as external trabeculectomy, the development of a new surgical technique—minimally invasive glaucoma surgery (MIGS)—enables the operation to reduce intraocular pressure efficiently while further reducing damage to the eye. MIGS achieves the purpose of surgery mainly by optimizing the TM outflow pathway, uveoscleral outflow pathway, and subconjunctival outflow pathway. A new surgical instrument, the Kahook Dual Blade, appears to optimize the TM outflow pathway in the surgical technique. The Kahook Dual Blade is a new type of angle incision instrument. Because of its unique double-edged design, in the process of goniotomy, it can effectively reduce the damage to the anterior chamber angle structure and accurately remove the appropriate amount of TM so that the aqueous humor can flow out smoothly. Kahook Dual Blade goniotomy has the advantages of avoiding complications and foreign body sensation caused by intraocular implants. The operation time is relatively short, the surgical technique is easy to master, and the TM resection scope can be determined based on the patient's condition. It can be used to treat some clinically meaningful glaucoma. This article is organized as follows. We present the following article following the Narrative Review reporting checklist.

Keywords: Glaucoma; Kahook Dual Blade; goniotomy; minimally invasive glaucoma surgery (MIGS)

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Background

Glaucoma is the second prevalent blinding eye disease worldwide. Over 60 million people suffer from it, and their quality of life declines to varying degrees (1). Among them, there are more than 44 million people, most of them are important family laborers, and they have primary open-angle

glaucoma (POAG) (2). POAG is an occult eye disease (3); usually when diagnosed, severe loss of visual field and vision is present (4,5), which is closely related to increased intraocular pressure or retinal damage (6,7). In IOP-related POAG, IOP can be reduced by a variety of methods, including local eye drop treatment, laser trabeculoplasty, and invasive ophthalmic surgery (8). Local IOP-lowering

drugs can control IOP elevation in patients (9). When the above measures cannot sufficiently reduce IOP, we consider performing invasive ophthalmic surgery.

Trabecular meshwork (TM) is an important control structure for aqueous humor circulation. When glaucoma occurs, the resistance of the aqueous humor outflow will increase significantly (10). Observation and elimination of obstruction to improve aqueous effluent is the fundamental purpose of modern trabeculectomy. Initially, to remedy this problem, the approach is to cut off the appropriate part of the trabecular tissue to make the atrial water flow and restore normal circulation (11). However, many clinically effective trabeculectomy procedures do not remove TM tissue (12,13). In fact, trabeculectomy reduces the IOP by forming a filtration bleb in the subconjunctival space, but at the cost of increased lens opacity, and, more seriously, damage to non-renewable corneal endothelial cells (14), and potential long-term blinding complications, such as low intraocular pressure, filtration bleb leakage, macular degeneration, and endophthalmitis (14,15). We present the following article in accordance with the Narrative Review reporting checklist (available at <http://dx.doi.org/10.21037/aes-20-95>).

Minimally invasive glaucoma surgery (MIGS)

In addition to trabeculectomy and topical medication, tube-based implants such as Molteno, Baerveldt, and Ahmed have been developed (16-18). However, the 5-year failure rate of these surgeries reached nearly 50% (19), and the reoperation rates for these implant surgeries and trabeculectomy were relatively high, i.e., 9% and 29% respectively (20). Therefore, new shapes of implants and drainage technology have become the frontier of exploration; at present, these types of technology are referred to as MIGS. According to the anatomical position and the method of reducing intraocular pressure, MIGS can be divided into optimizing the conventional TM outflow route (GATT, iStent, Hydrus, etc.) and optimizing the uveal scleral outflow route (CyPass, iStent Supra, etc.) through the suprachoroidal shunt subconjunctival outflow route (Xen Gel implant, InnFocus, etc.).

Optimizing the outflow path of the TM

iStent

iStent is a non-ferromagnetic titanium device coated with heparin. A disposable implant is usually used under a

gonioscope to implant it into the Schlemm's canal through the TM via an internal route. Since its first application, after 16 years of development, many documents have regarded it as a device that can act alone or in combination, and cataract surgery and implant procedures can be performed simultaneously. The iStent clinical randomized controlled trial showed that within 12 months after surgery (21), 72% of 240 patients could maintain IOP ≤ 21 mmHg; at 24 months (22), 61% of patients still met the standard. The compliance rate of patients undergoing cataract surgery was 50%. In clinical applications, the use of iStents is not limited to open-angle glaucoma with mild symptoms (23). Neuhann (24) Studies have shown that iStent still has an effect for moderate to severe glaucoma, even for eyes that have undergone surgery. The safety of the operation is very good, and no serious complications have been reported during or after the operation; however, due to its early appearance, the operation requires at least a 1.7mm corneal incision, which is relatively traumatic in MIGS.

Hydrus

The Hydrus Microstent is a trabecular bypass implant device used to restore the normal structure of the Schlemm's canal. It is made of a nickel-titanium alloy and has an overall crescent shape of 8 mm. It has an open rear surface and three window-front surfaces. The microstent is implanted through the TM using a preloaded handheld syringe, then entered into the anterior chamber through the clear corneal incision, and the TM is incised with the tip of the cannula. The microstent is then advanced to span approximately 90° of Schlemm's canal. Its length is larger than that of iStent and can increase the aqueous humor collection channel, expand the Schlemm's canal, and prevent it from being compressed. In vitro experiments prove that its drainage effect is twice that of iStents (25). The clinical results of Pfeiffer *et al.* (26) showed that 100 eyes were randomly treated with cataract alone or combined with Hydrus implantation. Two years after surgery, the proportion of Hydrus patients (80%) was higher in eyes with a 20% reduction in intraocular pressure compared to cataract surgery alone (46%). Despite the relatively large volume of the implant, electron microscopy showed that it did not cause significant damage to the TM (27). Hydrus is larger and has a stronger drainage effect on the aqueous humor. It is mainly used in patients with stronger IOP-lowering needs. MIGS causes relatively large damage to the eyeballs. Although there are few reports of adverse events of Hydrus, in terms of

actual usage, its application is relatively limited.

GATT

Traditional trabeculectomy only opens part of the TM channel. Anterior chamber gonioscopy-assisted transluminal trabeculotomy (GATT) aims to open the TM in a ring shape, thereby greatly reducing the resistance of aqueous effusion. The microcatheter was inserted into the anterior chamber. The tip of the instrument was used to make an initial incision into the TM. The catheter was then fed into Schlemm's canal 180° circumferentially, grasped through the TM, and pulled to unroof the TM and the inner wall of the Schlemm's canal. This was repeated on the remaining 180° of the angle, creating a total of 360° circumferential TM incision. GATT was performed using an iTrack illuminated microcatheter according to the procedure's original description (28). A clinical study of 32 patients showed that with cataract combined with GATT surgery, the average intraocular pressure before surgery was 34.2 ± 10.6 mmHg (mean \pm standard deviation), and the average intraocular pressure during the sixth month after surgery was 11.2 ± 2.4 mmHg. During all postoperative follow-ups, IOP decreased significantly ($P < 0.05$). Because of the surgical method, anterior chamber hemorrhage was often complicated, and very few patients had failed surgery due to the development of deep hypotonia (29).

Optimizing the route of uveal sclera outflow

Cypass

Cypass is a perforated polyamide tube with a 6.35-mm length. Its role is to increase the inflow of aqueous humor in the suprachoroidal space. Studies on cataract extraction combined with Cypass device implantation (30) showed that 2 years after surgery, in eyes with uncontrolled open-angle glaucoma, IOP decreased by 37%, and the average drug use was reduced from initial 2.2 to 1.0 (31), and in patients controlled by glaucoma but wishing to reduce eye drop dependence, drug dependence dropped from 2.2 to 1.0. Eighty-three percent of patients who did not receive glaucoma control when the Cypass stent was inserted alone avoided further glaucoma surgery (32). No major adverse events were reported in the literature.

iStent Supra

iStent Supra is made of a titanium-containing material and is a tubular implant with a 4 mm length. The treatment principle and surgical method are different from those of iStent, but almost the same as Cypass. Clinical studies conducted by the Myers team showed that in 80 patients implanted with iStent or iStent Supra, the preoperative drug control IOP was 22.0 ± 3.1 mmHg, while the average IOP without drug control was 26.4 ± 2.4 mmHg. During the 4-year follow-up, the average IOP is ≤ 13.7 mmHg in the drug control group, and the annual average non-drug IOP is ≤ 18.4 mmHg, and no eyes required additional glaucoma surgery. The clinical results of iStent Supra alone have not been reported in the literature (33). It is easier to operate because it can be positioned without lateral sliding brackets, and two devices can be injected at the same time without leaving the eye.

Optimize subconjunctival outflow pathway

XEN GEL

The XEN GEL implant is a collagen-derived gelatin cylinder with a length of 6 mm. It will never degrade and has good chemical stability, and is pre-installed in a bolus, implanted internally to drain the aqueous humor below the conjunctiva. Intraoperative injection of a mitotic inhibitor under the conjunctiva can enhance this effect. Animal studies have shown that Xen implants are relatively stable during the first few years (34). The follow-up results of 40 patients (implanted with XEN45) and 34 patients (implanted with XEN63) showed that during the period of 12 to 36 months, the average changes in the XEN45 group at 1, 2, and 3 years were 70%, 74.3%, and 37.5%, respectively, while in the XEN63 group, the average decline was 75%, 79.8%, and 71.9%, respectively. As the leading achievement of MIGS, XEN GEL's clinical application value still needs further exploration (35).

InnFocus

InnFocus, formerly known as MIDI arrow, is made of polystyrene block isobutylene block styrene (SIBS), using a micro-shunt design, implanted externally. Superficial scleral pocket dissection is required in the surgery, which is more similar to conventional trabeculectomy than other MIGS implants (36). Continued follow-up of 23 eyes after the implantation of InnFocus showed that regardless of whether or not they had cataract surgery, more than 80%

of patients had IOP ≤ 14 mmHg at 3 years (37). The 3-year average IOP compliance rate for the entire group was 95%. Complications such as transient hypotonicity and transient choroidal effusion may occur, and they may disappear spontaneously without serious long-term adverse events.

New MIGS surgical method—Kahook Dual Blade (KDB)

Ab-interno trabeculectomy

The principle of the traditional ab-externo approach is to remove the TM after forming the scleral flap and then using metal trabeculotomes to perform trabeculectomy (38,39). A new technique, ab-interno trabeculectomy, has been reported to be applied to the clinic in recent years. It can use specialized devices to incise or excise TM while directly observing the anterior chamber angle structure. These innovative trabeculotomy methods include trabectome surgery, microhook ab-interno trabeculotomy, and GATT and KDB goniotomy.

In Trabectome, with the aid of a gonioscope, the ophthalmologist uses a small diathermy/irrigation/suction handpiece to remove the TM and directly ablate the trabecular tissue. The 90° – 120° trabecular tissue can be removed in one operation. In clinical application (40), the average preoperative intraocular pressure was 28.2 ± 4.4 mmHg ($n=37$), and it was 17.4 ± 3.5 mmHg ($n=25$) at 6 months after surgery. The number of adjuvant medications was lower than that of patients who received preoperative medication ($n=34$) 1.2 ± 0.6 decreased to 0.4 ± 0.6 (6 months after surgery, $n=25$). There are no significant adverse events reported in the literature, but corneal incisions can cause delayed iris hyperplasia. This technology requires the ophthalmologist to be familiar with a handpiece, and the operation time cannot be too long; otherwise, it will cause thermal damage to the eye tissue. Compared with the Trabectome, KDB has a smaller incision and physical resection, which causes less damage to the anterior segment and is safer.

In microhook ab-interno trabeculotomy, using three different microhooks, straight [M-2215S] hooks were used to cut the corners of the nose, and the right oblique [M-2215R] and left oblique [M-2215 L] hooks (all from Inami And Co., Ltd.) for the incision of the temporal horn. A gonioscope was used to observe the relative angle between the microhook and the corneal incision and complete the TM incision. The incision can be 180° – 240°

in one operation. Clinical results (41–43) showed TM nasal cut (6 eyes, 3.6 ± 0.5 clock hours), temporal cut (6 eyes, 3.8 ± 0.8 clock hours), or bilateral (56 eyes, 6.5 ± 0.5 clock hours). At 9.5 months after the operation, the average preoperative IOP (16.4 ± 2.9 mmHg) and the use of antiglaucoma drugs (2.4 ± 1.2) were reduced to 11.8 ± 4.5 and 2.1 ± 1.0 mmHg. Anterior chamber hemorrhage is the most prone complication, and ophthalmologists need to pay attention to the insertion depth of the microhook throughout the operation. KDB operation is easier than microhooks, the depth after insertion is more certain, and the relative damage is relatively small.

GATT has been described above, and the latest ab-interno trabeculectomy technique is the KDB.

Operation principle

KDB goniotomy is an emerging trabecular surgery method. Its double-edged design allows the sharp end of the blade to smoothly enter the angled tissue. Before completing the resection (38), the blade must be accurately fixed on the front wall of the Schlemm's canal, inserted into the TM and raised, observed and the position of the blade corrected, and the tissue guided toward the two blades. After the resection is completed, a complete trabecular mesh tissue strip is set aside to artificially establish a channel in the TM, and skilled cutting techniques can minimize damage to nearby structures. Before cutting, the cutting angle and resection range are designed such that a single clear corneal incision (CCI) can be used for maximum efficiency.

Indications

Since its original design was to treat glaucoma by removing the TM in the eyes that required anterior chamber angle incision, the best indication is open-angle glaucoma, but according to the actual clinical application, KDB can also treat congenital glaucoma, angle-closure glaucoma, and other types of glaucoma and has good performance. KDB surgery does not conflict with cataract surgery and can enhance the effect of lowering intraocular pressure and has gradually developed into a conventional glaucoma treatment.

Surgical technique

Instill local anesthetic into the eyes and cover the sterile sheet. The patient's heads were rotated 30° , which was

conducive to KDB entry and removal. The tilt of the microscope corresponded to it, and the eyelid device kept the eyelid open. Performing anterior chamber puncture and filling the anterior chamber with viscoelastic agent, a 2.4 mm incision was made in the temporal region, and then KDB was inserted along the CCI into the preoperatively selected position so that the heel was closely attached to the front wall of the Schlemm's canal. Then, a TM strip was cut along the circumference, spanning 4 clock hours, using micro tweezers to remove the TM strip. At the end, the anterior chamber is filled with a balanced salt solution, and IOP can be maintained early after surgery, thereby reducing early blood reflux. The operation is terminated after ensuring that there is no viscoelastic residue in the anterior chamber.

Comparison of surgical effects

KDB for anterior chamber angle incision or combined cataract surgery

Anterior chamber angle incision was performed with KDB, and KDB combined with cataract surgery in 100 eyes in 111 eyes (39). The average IOP before the operation was 17.1 ± 4.7 mmHg, and the average drug use was 2.4 ± 1.3 . In the course of one year after surgery, the intraocular pressure was reduced to 20% of the preoperative measurement value, and the proportion of eyes treated with drug reduction was 75–90%. It is suggested that KDB goniotomy anterior chamber angle incision alone or combined with cataract surgery can achieve good surgical results. At the same time, KDB has a lower economic burden on patients than other implantable MIGS operations, so it is more in the choice of surgical methods, with advantages.

Refractive results after cataract surgery independently or in combination with KDB goniotomy

Glaucoma patients undergo significant refractive changes after cataract surgery. A retrospective analysis showed that in 385 eyes, phacoemulsification cataract surgery combined with KDB goniotomy (phaco-KDB) in 76 eyes showed that more than 26% of patients in the phaco-KDB group had refractive errors greater than 0.5 D (40), and 36.2% of patients in the phacoemulsification group (phaco) developed refractive errors ($P=0.11$). Univariate analysis evaluated preoperative intraocular pressure, axial length, corneal curvature, or KDB goniotomy. The results showed that

there was no statistical difference between the two groups. Hirabayashi's clinical case showed (41) that the patient's right eye was implanted with phaco-KDB combined with a toric intraocular lens (IOL), and the only phaco combined with a toric intraocular lens in the other eye. After the operation, almost all corneal astigmatism disappeared in the right eye, while the other eye was almost the same as before the operation. It is suggested that phaco-KDB may reduce refractive changes after glaucoma. Compared with traditional trabeculectomy and other MIGS surgical methods, patients may have better vision, but the specific principles and scope of KDB affecting refractive power still need to be further studied.

The effect of treating open-angle glaucoma

After 42 eyes of 36 glaucoma patients received phaco-KDB operation (42), the baseline average intraocular pressure before IOP was 17.1 ± 4.8 mmHg. At 6 months after surgery, 64.3% of the patients achieved the goal ($IOP \leq 15$ mmHg), and within 6 months after surgery, only 7.1% of the eyes required additional reduction in IOP. Of the 52 eyes undergoing surgery (43), at 12 months, the average IOP decreased from the initial 16.8 ± 0.6 to 12.4 ± 0.3 mmHg, a decrease of 26.2%, and 63.5% of the eyes decreased by ≥ 1 medicine for lowering intraocular pressure. Phaco-KDB surgery can significantly reduce intraocular pressure and reduce the dependence of OAG patients on lowering intraocular pressure drugs. Compared with traditional incision surgery, the use of KDB for surgery has a stable treatment effect and greatly reduces eye damage in patients.

The effect of treating angle-closure glaucoma

Phaco-KDB surgery can treat angle-closure glaucoma (44). The average intraocular pressure before surgery was 25.5 ± 0.7 mmHg, and the intraocular pressure decreased by 12.3 ± 0.73 mmHg (47.2%) in December, $P < 0.0001$. The average amount of drugs used to lower intraocular pressure before surgery decreased from 2.3 ± 0.1 to 2.2 ± 0.12 (91.7%; $P < 0.0001$). Phaco-KDB safely reduces the intraocular pressure and drug burden of patients with angle-closure glaucoma, while improving vision. This proves that phaco-KDB also has better performance in angle-closure glaucoma, which may replace traditional trabeculectomy with cataract surgery, but the main pathogenesis of angle-closure glaucoma is angle-closure, and further comparison between KDB surgery and other angle closure types is

needed. The effects of other glaucoma surgery methods (such as angle separation) determine the prospects of KDB surgery in angle-closure glaucoma treatment.

The effect of treating uveal-associated ocular hypertension

KDB underwent simple TM resection or combined phacoemulsification cataract surgery (45) to treat uveal-associated intraocular hypertension (OHTN). The results showed that the average maximum IOP of 12 patients (16 eyes) was 35.6 ± 5.8 mmHg. The average intraocular pressure before surgery was 28.1 ± 8.5 mmHg after drug treatment. During the recent follow-up (mean time 9.6 ± 5.6 months), IOP remained stable in ten eyes. The average drug application for glaucoma also decreased (3.6 ± 0.9 to 2.1 ± 1.7). The traditional method of treating severe OHTN is usually to control inflammation and then perform filtering surgery. This study suggests that KDB surgery can also be used to treat OHTN, and the effect is significant. KDB surgery causes less irritation of the uvea than traditional filtering surgery. Less damage to the eyeball may make it a better alternative to traditional OHTN filtration surgery.

KDB surgery and iStent implantation

Mohammed's study showed that in the phaco-KDB group in comparison with the phaco-iStent group (46), the average preoperative baseline IOP was 18.2 ± 0.3 and 16.7 ± 0.3 mmHg ($P=0.001$). The average IOP decreased by -5.0 ± 0.3 and 2.3 ± 0.4 mmHg respectively after 12 months. In the former group, the decrease in average IOP was better and obvious. The effect of KDB surgical treatment was more significant, and leaving implants in the eye was not necessary, reducing the financial burden of patients. Under the premise of ensuring vision, it is a more economical and practical choice.

KDB surgery and 360° circular trabeculectomy or GATT

A comparison of partial anterior chamber angle resection with KDB to (Trab360 or GATT) post-ocular pressure (IOP) reduction and intraocular pressure-lowering drug use was conducted (47). The results showed that in the first 6 months after surgery, KDB and 360° trabeculectomy were effective in reducing the use of IOP and ocular hypotensive drugs. Among the patients who achieved the target IOP ≤ 18 and ≤ 15 mmHg, more eyes received KDB surgery than

Trab360. It is suggested that this type of MIGS surgery may not require 360° trabeculectomy to achieve maximum efficacy. Only a part of the TM is removed during the KDB operation, and multiple operations can be performed depending on the condition. Trab360 or GATT can open 360° TM in one operation and can only rely on other methods to control the condition. The same is the choice of the lighter economic burden on patients in MIGS surgery, and the efficacy of KDB is more stable and reliable.

Postoperative adverse events

The most frequently reported adverse events were increased intraocular pressure, dull pain, and blurred vision. Most of them recovered within 2–3 days after surgery. Less frequent complications were corneal deposits and anterior adhesions around the iris (48). If the patient's condition does not improve, secondary surgery may be necessary. Moreover, anterior chamber hemorrhage and subsequent TM clot coagulation are relatively rare and mostly caused by intraoperative operation (49). There are also few reports of ciliary body separation, mostly intraoperatively. Although ciliary body separation can also occur during cataract surgery (38,49), most of the reported cases occur at the location of the KDB cutting. Gonioscopy can examine and identify this, and the argon laser photocoagulation treatment can be repaired without causing serious complications. In addition, there are very few patients with macular cystoid edema (48), and the root of the iris is severed. In general, KDB has fewer adverse events after surgery and is a safer surgical method.

Conclusions

Anterior chamber angle incision performed by KDB is a novel type of MIGS surgical method, which is currently in clinical application. The surgical method relies on the unique design of the KDB. After the blade tip is inserted into the TM, the double-edged design can be used to complete the incision. The lower TM strip has less damage to the surrounding tissues so that the aqueous humor can directly enter the collection tube, thereby effectively reducing intraocular pressure and reducing the use of drugs. Depending on the site of action, KDB is most suitable for open-angle glaucoma (44), but current reports show that KDB can also treat angle-closure glaucoma. Moreover, a few case reports are demonstrating that KDB goniotomy is used for primary congenital glaucoma (50)

and adolescent open-angle glaucoma (51) and was also noted to perform well. Compared with other operations such as Trab360 or GATT, KDB surgery produces less damage and provides a good surgical effect. Compared with iStent trabecular stents and other implants, KDB surgery is a better option under similar conditions or even lower intraocular pressure. Most of the studies conducted on KDB are joint operations of KDB and cataract surgery. The principles of surgery were reviewed and most cases were open-angle glaucoma. KDB goniotomy has the advantages of a stable intraocular pressure-lowering effect, a wide range of application, and small surgical damage and can be performed multiple times depending on the postoperative performance. Although adverse events may still occur, as the latest MIGS technology, KDB's performance can be trusted. KDB surgery alone, the impact of KDB surgery on the refractive outcome, and the comparison of KDB surgery with other surgical methods still need further research and exploration.

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