• Clinical Research •

Kahook Dual Blade: six-month results in uncontrolled open angle glaucoma

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Abstract

● **AIM:** To investigate the intraocular pressure (IOP)-lowering efficacy of bleb-free *ab interno* trabeculectomy by means of the Kahook Dual Blade (KDB).

● **METHODS:** This retrospective cohort study enrolled patients with uncontrolled open angle glaucoma (OAG) who underwent standalone KDB *ab interno* trabeculectomy. Changes in IOP, the number of preoperative and postoperative IOP-lowering medications, as well as intraoperative and postoperative surgical profiles were analyzed. All participants completed a 6-month follow-up. Arithmetic mean, standard deviation (SD) and frequency were calculated, and the Wilcoxon test was used for statistical analysis.

● **RESULTS:** A total of 23 participants (15 males) were included, with a mean age of 69.3±9.6y. The baseline mean IOP was 21.7±5.6 mm Hg, with patients taking an average of 3.1±1.0 topical IOP-lowering medications, and 10 patients received adjuvant systemic acetazolamide preoperatively. At the 3-month follow-up, the mean IOP decreased to 12.7±4.3 mm Hg, with a mean medication score of 2.9±1.8. At the 6-month follow-up, mean IOP was reduced by 40.6% from the baseline level (P<0.01), with a mean medication requirement of 2.8±1.0; one-fifth of all participants discontinued glaucoma medications completely. Only mild postoperative hyphemata occurred in 10 cases, and no other surgery-related adverse complications were observed.

● **CONCLUSION:** Standalone *ab interno* trabeculectomy with KDB yields significant IOP reduction and favorable surgical safety in patients with uncontrolled OAG, meanwhile decreasing the requirement of topical IOP-lowering medications. Long-term therapeutic efficacy remains to be further validated. Distinct from previous published studies, this study focuses on a Caucasian population and confirms surgical efficacy of KDB as a single glaucoma procedure.

● **KEYWORDS:** Kahook Dual Blade; intraocular pressure; open angle glaucoma; *ab interno* trabeculectomy; glaucoma surgery

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INTRODUCTION

Glaucoma is still one of the main causes of blindness worldwide. Although neuroprotective approaches exist[1-2], most available treatment options are aimed at reducing intraocular pressure (IOP). If medication therapy or laser treatment for IOP lowering are not sufficient, glaucoma surgery is indicated; other reasons may include manual inability to apply drops or reduced adherence to therapy. Established standard procedures include filtering surgeries such as trabeculectomy. Typical problems in the early postoperative phase include hypotony with shallow anterior chamber, choroidal detachment and hypotony maculopathy; in the late phase, scarring processes with loss of filtration function or, in the worst case, an infectious event with blebitis and endophthalmitis, especially after the use of antimetabolites.

In open angle glaucoma (OAG), IOP is often elevated due to impaired outflow of aqueous humour[3-4]. In particular, the juxtacanalicular trabecular meshwork (TM) adjacent to Schlemm's canal, in connection with other distal outflow structures, is considered to be primarily responsible for the increased resistance to aqueous humour outflow[5].

Theoretically, incision or excision of the TM should lead to lower IOP. Classically, angle-based glaucoma surgery (goniotomy, trabeculotomy) is used in pediatric glaucoma, which is also based on a different pathogenesis. These operations show a lower success rate in adult patients, which could be due to age-related changes or scarring of the TM[6-7].

An ablation of the TM could enable a permanent opening of the surgically induced opening in the TM and, furthermore,

lead to a lower IOP, *i.e.,* gonioscopy-assisted 360° transluminal trabeculotomy or the trabectome (NeoMedix, Tustin, CA, USA), which works as an *ab interno* trabeculotomy over several clock hours by means of aspiration, irrigation and electrocautery[8]. Potential complications include heat damage to adjacent tissue structures[9]. Both techniques result in a reduction in IOP of 30%–36% and thus enable a reduction in IOP-lowering medication postoperatively[9-11].

The Kahook Dual Blade (KDB; New World Medical Inc., Rancho Cucamonga, CA, USA) is a single-use instrument for complete excision of the TM. Hence, the site of highest outflow resistance is removed (exception: increased venous pressure in fistulas). The function of this surgical technique is independent of bleb-formation with corresponding complications. Cytotoxic and fibrosis-inhibiting substances such as mitomycin C, 5-fluorouracil or bevacizumab are not needed.

The KDB (Figure 1) consists of a long, thin shaft (handle). At its end is a tapered "ramp", which is bordered by two blades. Inserted *via* a paracentesis under viscoelastic, the tip can be used to penetrate the TM on the opposite nasal side. The TM is loaded onto the "ramp" and thereby pre-tensioned. The penetration depth in the drainage angle is limited by the defined height of the cutting edge. This is intended to prevent injury to adjacent structures. The Schlemm's canal should be protected from trauma by this design (the blades are turned away from the wall of the Schlemm's canal). The excision can be carried out by advancing the KDB in both directions and thus several clock hours can be excised[12].

There have been several studies that demonstrate the effectiveness of KDB. In most studies, however, the procedure is used in combination with cataract surgery, or the stand-alone group has only a few patients included. Nevertheless, it is known that cataract surgery itself has an IOP-lowering effect[13-14]. In addition, numerous studies were conducted with an Asian patient population, which is why the results cannot be easily transferred to Caucasian patients[11,15-20].

Therefore, this retrospective cohort study investigates the efficacy and safety of the KDB as a stand-alone procedure with a follow-up period of 6mo in patients with uncontrolled OAG in Europe.

PARTICIPANTS AND METHODS

Ethical Approval This study was reviewed and approved by the local ethics committee (approval no. 72/21). All methods were carried out in accordance with relevant guidelines and regulations. Due to its retrospective nature, no informed consent was necessary. It adhered to the tenets of the Declaration of Helsinki, and its later amendments.

Data Collection The IOP was assessed preoperatively as well as 3 and 6mo after surgery. The number of IOP-lowering medications, visual acuity and complications were also recorded descriptively. To assess the severity of glaucoma, perimetry was performed preoperatively using the Zeiss Humphrey Field Analyser 3 and mean deviation (MD) was determined in decibels (dB). Gonioscopy was also performed preoperatively and repeated at 1, 3, and 6mo postoperatively. Visual field checks were carried out 3 and 6mo postoperatively. Inclusion criteria were patients with medically uncontrolled OAG (IOP >18 mm Hg and <30 mm Hg on treatment; IOP higher than target IOP despite medical or laser treatment), who were thought to be eligible for sufficient IOP reduction by means of surgery using the KDB. In seven patients, the IOP was lower (n=6) or higher (n=1) than listed in the inclusion criteria. However, these patients were included into the study due to allergy to their topical medications, not having reached their target IOP or worsening of the visual fields. Patients with active inflammation, significant opacification of optical media, drainage angle <Shaffer 2° nasally or changes that do not allow excision, high IOP levels that are not expected to allow sufficient IOP reduction, age <18y, previous drainage angle surgery or incisional glaucoma surgery, furthermore laser iridotomy, laser trabeculoplasty, vitrectomy or other glaucoma surgery within 3mo prior to study inclusion, pseudophakia by means of anterior chamber lens or a lens status that suggests cataract surgery within the next 6mo (after baseline visit) were excluded.

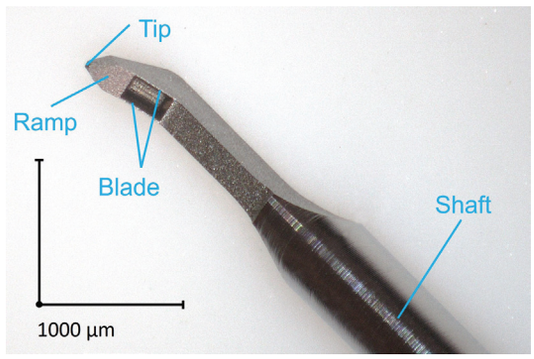

Figure 1 Highly enlarged illustration of the Kahook Dual Blade with the key elements tip, ramp, the two blades and the shaft.

Surgical Technique Surgeries were performed either under local or general anaesthesia, depending on patient's needs. Miosis was achieved by preoperative application of pilocarpine eye drops. A temporal clear corneal incision of approximately 2.4 mm in width was made. The anterior chamber was filled with cohesive viscoelastic. The TM was then excised over 4 clock hours using the KDB and then the viscoelastic was rinsed out. If there was no contraindication, 0.1 mL cefuroxime was applied intracamerally and the access was then hydrated. Postoperatively, topical antibiotics were applied 4 times a day for 5d as well as pilocarpine eyedrops for 10d and topical steroid eye drops for 6wk, which were gradually tapered.

The IOP-lowering treatment was initially continued and then adjusted depending on the IOP readings.

Statistical Analysis The statistical analysis of the study data was performed by descriptive methods using arithmetic mean and standard deviation (SD) or frequencies. A $P<0.05$ was assumed as the exploratory significance threshold. The *P*-value was calculated using the non-parametric Wilcoxon test for dependent samples.

After data analysis, the surgical outcome was categorised into failure, qualified success and complete success based on the tube versus trabeculectomy study[21]. The criteria for this were determined retrospectively. Failure: IOP>21 mm Hg or less than 20% pressure reduction at the last visit compared to the mean preoperative IOP, IOP<5 mm Hg at one of the visits, further glaucoma surgery or loss of light perception. Further glaucoma surgery was defined as any glaucoma surgery performed in the operating theatre, with the exception of anterior chamber irrigation. If none of the above criteria applied and no further topical/systemic IOP-lowering medications were required, it was considered a complete success; if topical/systemic IOP-lowering therapy was required, it was considered a qualified success.

RESULTS

Between May 2021 and February 2022, 23 patients were included. Table 1 shows an overview of the patients included, of which 16 had a primary OAG, two a secondary glaucoma due to uveitis, four patients a pseudoexfoliation glaucoma and one patient a secondary glaucoma due to multiple previous surgeries. In the 30-2 perimetry, the MD preoperatively was -7.71±8.47 dB and in the 24-2 perimetry -15.39±6.00 dB.

Seven patients had not yet undergone ophthalmological surgery, 15 patients were already pseudophakic and 6 patients had already been treated using laser surgery for IOP lowering, *i.e.,* selective laser trabeculoplasty.

On therapy with an average of 3.1±1.0 topical IOP-lowering medications, the mean preoperative IOP was 21.7±5.6 mm Hg. Ten patients also received systemic IOP-lowering medication (acetazolamide).

In all 23 patients, the procedure was performed without any significant complications by two experienced surgeons-intraoperative bleeding, which is to be expected when excising the TM, was not categorized as a complication. Postoperative treatment was carried out with the above-mentioned medication. IOP-lowering medication was also continued according to the surgeon's instructions. In the postoperative course, ten patients showed a mild hyphaema (<2 mm in height) in the first two weeks, which was treated with anterior chamber irrigation. Three months after trabeculectomy using the KDB, there was a mean IOP reduction of 41% to 12.7±4.3 mm Hg on 2.9±1.8 medications. Two patients required systemic acetazolamide due to multiple eye drop intolerance and refusal of other IOP-lowering surgery.

Table 1 Demographic and ocular baseline values of the included patients

Parameters	Data
Age, mean±SD, y	69.3±9.6
Sex	
Male	15 (65%)
Female	8 (35%)
Study eye	
Right	10
Left	13
Number of topical IOP lowering medication at baseline per patient	
1	3
2	0
3	10
4	9
Mean±SD	3.1±1.0
Systemic IOP-lowering medication at baseline	
Number of patients	10
BCVA, mean±SD, logMAR	0.40±0.72
VF, dB, mean±SD	
24-2 VF (*n*=13)	-15.39±6.00
30-2 VF (*n*=7)	-7.71±8.47
Baseline IOP (mm Hg), mean±SD (min, max)	21.7±5.6 (13, 34)

SD: Standard deviation; logMAR: Logarithm of the minimum angle of resolution; dB: Decibel; IOP: Intraocular pressure; BCVA: Best corrected visual acuity; VF: Visual field.

Six months after the procedure, the mean IOP was 12.9±4.0 mm Hg on 2.8±1.0 topical IOP-lowering medications. IOP was 8.8 mm Hg or 40.6% ($P<0.01$) lower. The IOP-lowering medications were reduced by a mean of 0.3 medications or 9.7% ($P=0.099$). Systemic IOP-lowering medication by means of acetazolamide was necessary in one patient. Subsequently, the indication for an additive glaucoma surgery by means of implantation of a glaucoma drainage implant was given. Complete success was achieved in 5, qualified success in 11 and a failure in 7 patients.

Figure 2 shows the preoperative and postoperative IOP values of all 23 patients, Figure 3 indicates the number of topical IOP-lowering medications.

DISCUSSION

In summary, trabeculectomy *ab interno* using the KDB avoids the risk of bleb leakage, hypotony, blebitis and even endophthalmitis. The idea of improved aqueous humour outflow by excision of TM has already been implemented with other surgical procedures, such as the trabectome. Filippopoulos and Rhee[22] reported of 679 patients who underwent surgical IOP-lowering using the trabectome with

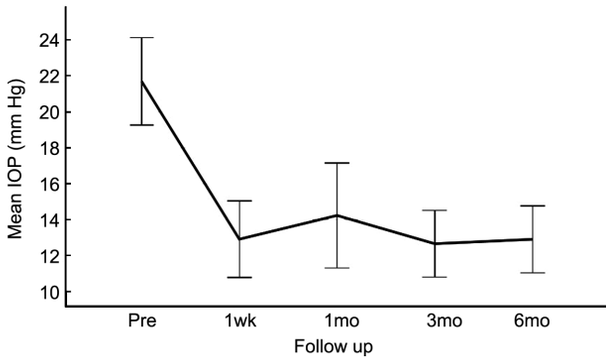

Figure 2 Progression of IOP before (pre), 1wk, 1, 3, and 6mo after surgery (*n*=23) Mean value with 95% confidence interval. IOP: Intraocular pressure.

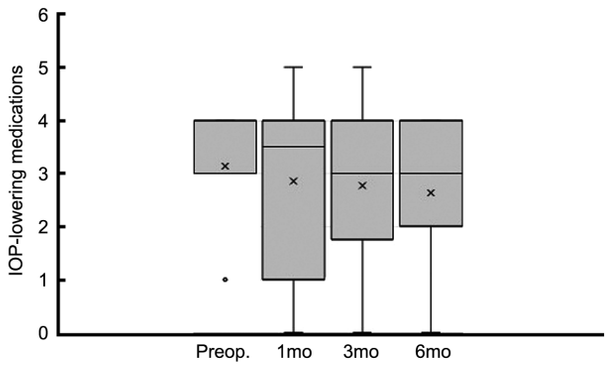

Figure 3 Number of topically applied IOP lowering medications before (pre), 1wk, 1, 3, and 6mo after the operation of all 23 patients Median: Horizontal line. Mean value: x. IOP: Intraocular pressure.

an IOP reduction of 29% on average and a reduction in IOP-lowering adjuvant therapy of two medications on average six months postoperatively. Even in patients who underwent trabeculectomy first and then a trabectome surgery, a 33% reduction in IOP and a 23% reduction in medication after 6mo was demonstrated[23].

Histologically, there are differences in the excised TM depending on the surgical instrument used. In a comparison of trabectome, KDB and microvitreoretinal blade, it was found that a larger and more complete piece of TM is excised using KDB without damaging the surrounding tissue. In contrast, when using the microvitreoretinal blade, only a small piece of TM is excised and damage to the neighbouring sclera is documented. The trabectome causes thermal damage, residual TM parts remain in the drainage angle after excision[24-26].

The patients included in this study had moderate to advanced glaucoma damage according to the Hodapp classification[27]. A significant reduction in IOP was measured at all time points, and this continued to be statistically significant 6mo after the operation with a reduction of 40.6%. The number of topical IOP-lowering medications was also reduced, although no statistical significance was achieved here. This could be due to the small study population. After all, 5 patients achieved freedom from drops.

In general, it can be said that only a few studies are available on IOP reduction by means of trabeculectomy *ab interno* using the KDB; the comparison of these studies is also limited due to different and mostly small study populations.

Miller *et al*[28] demonstrated an IOP reduction of 62.5% at 6mo after trabeculectomy ab interno using KDB in patients with ocular hypertension due to uveitis. These results are similar to those in our study. In severe refractory glaucoma, Salinas *et al*[29] showed an IOP reduction of 24% and medication reduction of 36% after 6mo. Another group showed no significant difference in IOP and topical treatment reduction 12mo after KDB in patients with mild to moderate glaucoma compared to a control group with cataract surgery alone. Visual field, endothelial cell count, and best-corrected visual acuity remained unchanged in both groups[30]. Many studies investigate the combined IOP-lowering effect of phacoemulsification and trabeculectomy by means of KDB and could show a very good reduction in IOP as well as glaucoma medication[20,31-32]. One study compares iStent implantation combined with cataract surgery to KDB combined with cataract surgery. Both groups could show a significant reduction in IOP as well as in topical medication, with the patients in the KDB group having a higher success rate for the target IOP and a higher rate of complications[33]. However, our study focuses on the IOP-lowering effect of the KDB alone.

With an ageing population, healthcare systems are under increasing pressure to be cost-efficient. In our experience, the KDB is less expensive than minimally invasive glaucoma surgery (MIGS) implants. Especially with regard to the trabectome, which addresses the same target tissue, there is a clear cost advantage for the KDB, as no basic device, which also generates additional running costs, has to be purchased.

Due to the constantly increasing number of different MIGS techniques, good patient selection is important. Long-term data from large multi-centre studies with comparisons of all relevant parameters are desirable but are not currently available.

In our study, the failure rate of 30.4% is certainly high. However, especially against the background of the significantly lower spectrum of side effects, this surgical technique can be used as an option before a potential filtering operation with the need for intensified follow-up care from our perspective, even in advanced glaucomas. Seven patients needed additional IOP-lowering surgery. The procedure chosen was an individual decision according to patient's needs and included cyclodestructive procedures (*n*=3), trabeculectomy (*n*=3), and glaucoma drainage devices (*n*=1). Nonetheless, IOP-lowering medications are usually still required and further glaucoma interventions such as filtering operations may be necessary in the future. In particular, long-term results that allow conclusions to be drawn about the duration of the effect are still pending.

The limitations of our study are the lack of a control group, the small patient population and the short follow-up period as well as its retrospecitve nature. Furthermore, comparing subgroups of phakic and pseudophakic patients would add interesting insights to demonstrate the IOP-lowering effect by means of the KDB trabeculectomy. Nevertheless, there was a robust, statistically significant reduction in IOP 6mo after the procedure. In our study, there were no intraoperative complications, postoperative complications (hyphema in ten patients within 2wk) were treated with anterior chamber irrigation in 10 patients, recurrent bleedings or other complications did not occur. The visual field examinations were stable in 22 patients during the course of the study, one patient showed an increase in visual field defects and an insufficiently regulated IOP, which is why another glaucoma surgery (implantation of a glaucoma drainage device) was performed during the course of the study.

In summary, it can be said that trabeculectomy *ab interno* using the KDB achieved a very good IOP reduction in our Caucasian patient population, even as a stand-alone procedure. There were no serious complications-hypotony due to the trabeculectomy being too deep due to the KDB was not observed. Especially for patients with a difficult conjunctival situation, but also multiple drop intolerances and/or lack of acceptance of a major surgical glaucoma procedure-even with advanced glaucomatous damage-this MIGS technique offers an option for both surgical IOP reduction and reduction of the necessary IOP-lowering medication. The absence of need to use antifibrotic substances such as 5-fluoruracil or mitomycin C and therefore bleb-free surgery reduces the risk of feared complications like leakage, blebitis or endophthalmitis.

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