• Clinical Research •

Performances of glaucoma operations with Kahook Dual Blade or iStent combined with phacoemulsification in Japanese open angle glaucoma patients

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Abstract

● **AIM:** To compare surgical outcomes of phacoemulsification combined with glaucoma surgical techniques performed with either Kahook Dual Blade (KDB) or iStent for Japanese patients with either primary open angle glaucoma or exfoliation glaucoma.

● **METHODS:** We retrospectively evaluated the surgical outcomes of 129 eyes of 84 Japanese patients with glaucoma who underwent KDB or 44 eyes of 34 patients who underwent phacoemulsification with iStent procedures combined with cataract surgery. The primary outcome was surgical success or failure [with surgical failure being indicated by <20% reduction from preoperative intraocular pressure (IOP) or IOP>18 mm Hg as criterion A; IOP>14 mm Hg as criterion B on two consecutive study visits; or reoperation requirement]. In addition, we assessed the number of postoperative glaucoma medications and the resulting complications.

● **RESULTS:** The probability of success was significantly higher in the KDB group than in the iStent group for criterion A (60.2% *vs* 46.4%, *P*=0.019). In the KDB group, the mean preoperative IOP of 19.8±7.3 mm Hg decreased significantly to 13.0±3.1 mm Hg (*P*<0.01), and the mean number of glaucoma medications at 2.5±1.4 decreased significantly to 1.6±1.6 (*P*<0.01) 12mo postoperatively. In the iStent group, the mean preoperative IOP of 17.8±2.9 mm Hg significantly decreased to 14.3±2.3 mm Hg (*P*<0.01), and the mean number of glaucoma medications at 2.2±1.1 decreased significantly to 0.9±1.4 (*P*<0.01) 12mo postoperatively. The overall IOP reduction percentage was higher in the KDB group (26.2%) than in the iStent group (19.0%) 12mo postoperatively (*P*=0.03). Hyphema occurred significantly more frequently in the KDB group (16.3%) than in the iStent group (2.3%, *P*=0.017).

● **CONCLUSION:** KDB and iStent procedures combined with cataract surgery both result in significant IOP and glaucoma medication reductions after the 12-month follow-up. The patients in the KDB group have a higher success rate for the target IOP of less than 18 mm Hg and a higher complication rate than those in the iStent group.

● **KEYWORDS:** glaucoma surgery; surgical outcome; Kahook Dual Blade; iStent

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INTRODUCTION

Trabeculotomy is effective for intraocular pressure (IOP) reduction in patients with glaucoma[1-4]. The trabecular meshwork (TM) and inner walls of the Schlemm's canal are the main point of aqueous outflow resistance. During trabeculotomy, removal of that resistance results in IOP reduction. Conventional trabeculotomy is performed by an ab-externo approach with metal trabecular probes, which requires conjunctival and scleral incisions and sutures. Newer techniques performed using an ab-interno approach are becoming popular because of their minimal invasion. The Kahook Dual Blade (KDB), iStent, the Trabectome, Microhook, and the 360° suture trabeculotomy provide more safety and shorter recovery periods than the ab-externo approach[5-7].

The KDB (New World Medical, Rancho Cucamonga, CA, USA) is designed to excise a strip of TM and the inner walls of the Schlemm's canal to decrease aqueous outflow resistance. Similarly, the iStent (Glaukos Corporation, Laguna Hills, CA, USA) is a bypass implant between the anterior chamber and Schlemm's canal to decrease aqueous outflow resistance. Although studies about surgical outcomes for iStent and KDB have been published, few studies have compared surgical outcomes after glaucoma procedures with either the iStent or

KDB[8-10]. Moreover, no surgical outcome reports on Japanese patients with glaucoma have been conducted. Our aim was to assess the surgical outcomes after iStent and KDB procedures in Japanese patients and to compare results between the two groups.

SUBJECTS AND METHODS

Ethical Approval The institutional review board of University of Fukui Hospital and Obama Hospital in Fukui (Japan) approved this retrospective clinical cohort study. The protocol adhered to the tenets of the Declaration of Helsinki. We obtained written informed consents for the surgery from all patients after a detailed explanation of the procedures involved.

We obtained data from patients treated with phacoemulsification in combination with either single first-generation iStent or KDB procedures between February 2017 and July 2018 at the University of Fukui Hospital and Obama Hospital in Japan. We included data from patients older than 19 years with either primary open angle glaucoma or exfoliation glaucoma without a history of intraocular surgery. We excluded data from patients with primary angle-closure glaucoma, neovascular glaucoma, secondary glaucoma (except for exfoliation glaucoma), and congenital glaucoma. In total, we included data from 129 eyes of 84 patients who underwent combined phacoemulsification with KDB and from 44 eyes of 34 patients who underwent phacoemulsification with iStent.

Surgical Procedure Experienced glaucoma specialists (Inatani M and Iwasaki K) performed all surgeries. They performed the standard phacoemulsification with intraocular lens implantation through a clear temporal corneal incision using topical anesthesia. Each patient's head and the microscope were tilted to visualize the nasal angle with a gonioprism. The surgeons then filled the anterior chamber with additional viscoelastic material. In the iStent group, the surgeons inserted the iStent device into the anterior chamber and implanted the stent into the Schlemm's canal through the TM. In the KDB group, the surgeons inserted the tip of the KDB into the Schlemm's canal and moved circumferentially to excise the TM over the 3-4 clock hours. After these procedures, the surgeons removed the viscoelastic material and filled the anterior chamber with balanced saline solution.

Postoperative Care and Data Collection All patients received similar postoperative topical medications with 0.3% gatifloxacin for 1-2wk and 0.1% betamethasone phosphate for 3-4wk. The glaucoma medications were discontinued after surgery, then added in the postoperative follow-up visits if the IOPs were elevated compared to the preoperative IOP values.

We collected patient data including gender, age, type of glaucoma, severity of glaucoma, preoperative IOP, postoperative IOP, the number of glaucoma medications taken, and any postoperative complications. We classified the severity of glaucoma into three stages using the mean defect (MD) score on Humphry visual field tests (MD≥−6.0 dB, mild; −6.0>MD≥−12.0 dB, moderate; and MD<−12.0 dB, severe). As for postoperative complications, we defined hyphema as formation of a blood niveau in the anterior chamber; and an IOP spike as a transient elevation of the IOP to ≥30 mm Hg within 1mo after surgery.

Primary Outcome Measure The primary outcome measure was surgical success or failure defined according to two IOP criteria. We defined failure according to the postoperative IOP levels with or without glaucoma medication at ≥1mo after surgery: <20% reduction from the preoperative IOP value, or IOP>18 mm Hg as criterion A; and IOP>14 mm Hg as criterion B on two consecutive study visits. In addition, we declared surgical failure in cases that required reoperation for glaucoma. We considered all cases lacking failure criteria as successful. We then compared the probability of success between KDB and iStent groups.

Secondary Outcome Measures Secondary outcome measures included IOP, the number of glaucoma medications taken, and postoperative complications.

Statistical Analysis We performed univariable comparisons between groups using the Chi-square test, Fisher's exact test, paired *t*-test, and unpaired *t*-test with Bonferroni correction. We used Kaplan-Meier survival curves to analyze the probability of success and compared them using the log-rank test. We considered *P*-values <0.05 as statistically significant.

RESULTS

Patients Characteristics In total, we analyzed data from 129 eyes of 84 patients who underwent combined phacoemulsification with KDB and from 44 eyes of 34 patients who underwent phacoemulsification with iStent for the study. Table 1 summarizes the patients' baseline characteristics for the 173 eyes of our study population. As for the severity of glaucoma, severe glaucoma was more frequent in the KDB group than in the iStent group (P<0.01). We found no other statistically significant differences in preoperative status between the two groups.

Primary Outcome Measures Figure 1 shows Kaplan-Meier survival curves comparing surgical outcomes in the KDB and iStent groups according to failure criteria. The probability of success was significantly higher in the KDB group than in the iStent group for criterion A (P=0.019). However, we found no significant difference between the groups in terms of criterion B (P=0.41). The probabilities of success for criterion A 12mo after the operation were 60.2% in the KDB group and 46.4% in the iStent group (P=0.019), and for criterion B they were 44.9% and 43.8%, respectively (P=0.41).

Secondary Outcome Measures Table 2 shows the comparisons of IOP values and the number of glaucoma medications at follow-up time points between the KDB and iStent groups. The

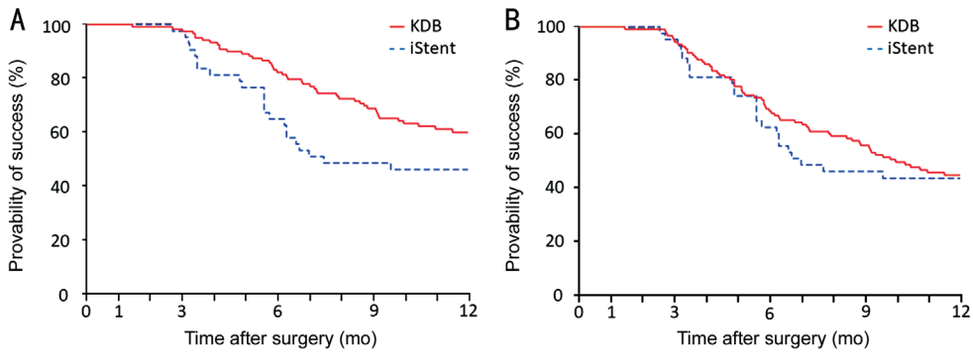

Figure 1 Kaplan-Meier survival curves for the failure criteria, comparing the KDB and iStent groups A: IOP>18 mm Hg, <20% reduction from preoperative IOP value, or reoperation for glaucoma. B: IOP>14 mm Hg, <20% reduction from preoperative IOP value, or reoperation for glaucoma. The cumulative success rates for the KDB and iStent groups were 60.2% and 46.4%, respectively for A (P=0.019), and 44.9% and 43.8%, respectively for B (P=0.41).

Table 1 Preoperative characteristics *n* (%)

Parameters	KDB (n=129)	iStent (n=44)	P
Age (y)	76.8±7.5	75.4±7.8	0.24
Gender			0.29
Male	63 (49)	17 (39)	
Female	66 (51)	27 (61)	
Type of glaucoma			0.82
Primary open angle glaucoma	75 (58)	25 (57)	
Exfoliation glaucoma	30 (23)	9 (20)	
Normal tension glaucoma	24 (19)	10 (23)	
Severity			<0.01
Mild	31 (24)	17 (39)	
Moderate	23 (18)	27 (61)	
Severe	75 (58)	0	

KDB: Kahook Dual Blade.

mean preoperative IOP in the KDB group was 19.8±7.3 mm Hg with a mean use of 2.5±1.4 glaucoma medications, and these values were significantly decreased to 13.0±3.1 mm Hg (P<0.01) and 1.6±1.6 medications (P<0.01), respectively, 12mo postoperatively. The mean preoperative IOP in the iStent group was 17.8±2.9 mm Hg with a mean use of 2.2±1.1 glaucoma medications and these values were significantly decreased to 14.3±2.3 mm Hg (P<0.01) with 0.9±1.4 medications (P<0.01), respectively, 12mo postoperatively. The postoperative IOPs at 12mo were significantly lower in the KDB group than in the iStent group (P=0.04). We found no significant differences in IOP values at any other time points. The overall IOP reduction percentage was significantly higher in the KDB group (26.2%) than in the iStent group (19.0%) 12mo postoperatively (P=0.03). The numbers of medications at 1, 3, 6, 9 and 12mo were significantly lower in the iStent group than in the KDB group (P=0.01, <0.01, 0.02, 0.03, and 0.02; respectively). The number of medication reduction was significantly greater in the iStent group (1.3±1.6) than in the KDB group (0.9±1.3) 12mo postoperatively (P<0.01).

Table 2 IOP and glaucoma medications at preoperative and follow-up visits

Time	KDB	iStent	P
Preoperative			
IOP (mm Hg)	19.8±7.3	17.8±2.9	>0.99
No. of medications	2.5±1.4	2.2±1.1	>0.99
No. of patients	129	44	
1d			
IOP (mm Hg)	16.9±8.1	16.4±5.6	>0.99
No. of medications	0.0±0.0	0.0±0.0	NA
No. of patients	129	44	
1wk			
IOP (mm Hg)	17.8±7.7	16.7±4.9	>0.99
No. of medications	0.3±0.9	0.1±0.6	>0.99
No. of patients	129	44	
1mo			
IOP (mm Hg)	14.1±4.3	15.2±3.5	0.33
No. of medications	1.3±1.6	0.5±1.0	0.01
No. of patients	129	44	
3mo			
IOP (mm Hg)	13.2±3.6	14.4±3.4	0.11
No. of medications	1.5±1.6	0.6±1.1	<0.01
No. of patients	124	43	
6mo			
IOP (mm Hg)	13.3±3.4	14.5±3.6	0.23
No. of medications	1.6±1.6	0.8±1.3	0.02
No. of patients	119	42	
9mo			
IOP (mm Hg)	13.4±4.4	14.2±2.9	0.42
No. of medications	1.6±1.7	0.8±1.3	0.03
No. of patients	107	42	
12mo			
IOP (mm Hg)	13.0±3.1	14.3±2.3	0.04
No. of medications	1.6±1.6	0.9±1.4	0.02
No. of patients	104	42	
Reduction from preoperative IOP %	26.2±21.4	19.0±14.0	0.03

IOP: Intraocular pressure; KDB: Kahook Dual Blade; NA: Not applicable.

Table 3 compares postoperative complications between the KDB and iStent groups. Hyphema occurred significantly more frequently in the KDB group (16.3%) than in the iStent group (2.3%; *P*=0.017), but it was cleared spontaneously without intervention in all cases. Although IOP spikes occurred more frequently in the KDB group (14.0%) than in the iStent group (6.8%), we found no significant differences between the two groups. Additional glaucoma surgery was required within 12mo after surgery in the KDB group only 3 of 129 eyes (trabeculectomy for two eyes, tube shunt surgery for one eye).

Table 3 Postoperative complications in KDB and iStent eyes *n* (%)

Complications	KDB (*n*=129)	iStent (*n*=44)	*P*
Hyphema	21 (16.3)	1 (2.3)	0.017
IOP spikes	18 (14.0)	3 (6.8)	0.29
Tear in Descemet's membrane	0	1 (2.3)	0.25
Implant lost	NA	1 (2.3)	NA
Additional glaucoma surgery	3 (2.3)	0	0.57

IOP: Intraocular pressure; KDB: Kahook Dual Blade; NA: Not applicable.

DISCUSSION

The aim of our study was to compare the surgical outcomes between the KDB and iStent procedures combined with cataract surgery. The probability of success was significantly higher in the KDB group than in the iStent group for criterion A (60.2% *vs* 46.4%, *P*=0.019). Both the KDB and iStent procedures resulted in significant reductions in IOP values and glaucoma medications during the 12-month follow-up period. The overall IOP reduction percentage was higher in the KDB group (26.2%) than in the iStent group (19.0%) 12mo postoperatively (*P*=0.03). The KDB group required more glaucoma medications than the iStent group 12mo postoperatively (*P*=0.02). The KDB group caused higher rate for hyphema (16.3%) than in the iStent group (2.3%, *P*=0.017).

Three studies had retrospectively compared surgical outcomes between KDB and iStent procedures combined with cataract surgery[8-10]. Their results showed surgical outcomes including IOP, number of glaucoma medication, and complications. Our study evaluated surgical success between the two procedures using survival curves in addition to the direct comparison of two angle-based glaucoma surgeries.

One study reported that the mean IOP reduction percent from baseline was significantly higher in the KDB group (23.7%) than in the iStent group (16.4%) 6mo postoperatively, and their mean glaucoma medications reduction was also significantly higher in the KDB group (1.1 medications) than in the iStent group (0.9 medications) at the same time-point[8]. Another study reported that the mean IOP reduction percent from baseline was significantly larger in the KDB group (27.5%) than in the iStent group (13.7%) 12mo postoperatively, but that the mean glaucoma medications reductions were equal between the KDB group (1.0 medications) and the iStent group (1.0 medications) at the same time-point[10]. Our results are consistent with the those on IOP reductions in those studies, while our patients in the KDB group required more glaucoma medications than those in the iStent group. This might be explained by the KDB group having more cases of severe glaucoma than the iStent group, and probably needing more medications to maintain the postoperative IOPs. Another explanation may be the difference in IOP spikes, with patients in the KDB group presenting more (14.0%) than those in the iStent group (6.8%); and thus, requiring more glaucoma medications.

We evaluated the probability of success for 12mo after surgery and found it to be significantly higher in the KDB group (60.2%) than the iStent group (46.4%) for IOP<18 mm Hg (*P*=0.019). The probabilities of success for IOP<14 mm Hg were similar (KDB *vs* iStent, 44.9% *vs* 43.8%, respectively, *P*=0.41). In conventional trabeculotomy ab externo combined with cataract extraction, the probability of success was 58.7% for IOPs>17 mm Hg and 30.0% for IOPs>15 mm Hg 1y after surgery[11]. The data indicate that KDB is almost as effective as conventional trabeculotomy ab-externo, but more effective than iStent for targeting high-teen IOPs.

However, iStent caused significantly less hyphemas and a lower tendency of IOP spikes than KDB. Including our data, KDB causes hyphema in 16.3% to 34.9% of patients[10,12] and IOP spikes in 1.0% to 14.0% of patients[8,10,12-16]. iStent seems to have the advantage of reducing the frequency of postoperative complications, which are common after trabecular surgeries.

Our study has some limitations, mostly because of its retrospective nature. First, we could not standardize preoperative characteristics especially in terms of the glaucoma severity. Severe glaucoma is usually refractory to surgical treatment, therefore the difference in severity between two groups may have affected the surgical outcomes. Second, we lacked some clinical data. Postoperative inflammation in the anterior chambers and postoperative peripheral anterior synechia may have affected the surgical outcomes because of the elevation of aqueous outflow resistance[17-18]. We think gonioscopic examinations and the measurements of flare values by flare cell meter should have been performed. A further prospective study would be required to dispel concerns raised by these limitations.

In conclusion, the KDB and iStent procedures combined with cataract surgery achieved a significant reduction in IOP and glaucoma medications 12-month after the operations in Japanese patients with open angle glaucoma. The KDB group had a higher IOP reduction and higher rate for hyphema compared with the iStent group.

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Conflicts of Interest: Iwasaki K, None; **Takamura Y,** None; **Orii Y,** None; **Arimura S,** None; **Inatani M,** None.

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