• Clinical Research •

Efficacy and safety of combined Kahook Dual Blade goniotomy with phacoemulsification in Chinese patients with primary open angle glaucoma

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Received: 2024-03-28 Accepted: 2024-09-18

Abstract

● **AIM:** To report the one-year surgical outcome Kahook Dual Blade goniotomy combined with phacoemulsification (KDB-Phaco) in Chinese patients with primary open angle glaucoma (POAG).

● **METHODS:** This is a retrospective study included 43 eyes of 28 Chinese POAG patients with cataract who accepted KDB-Phaco and followed-up for 12mo. Intraocular pressure (IOP), glaucoma medications and surgical complications were recorded. Success 1 and success 2 was defined as 5-21 mm Hg and 5-18 mm Hg, and success plus was determined if additional criteria of IOP reduction ≥20% from baseline was reached. A corrected IOP by adding 3 mm Hg for each medication was used to do correlation test. Cox's proportional hazards regression model was used to test the hazard ratio for factors associated with surgical success.

● **RESULTS:** After a 12-month follow up, the IOP decreased from 28.1±6.3 to 13.8±3.0 mm Hg (47.92% reduction, *P*<0.001), and the medications used decreased from 2.0 (1.0) to 0.0 (0.0) (95% reduction, *P*<0.001). The mean IOP of all postoperative visits were lower than preoperative IOP (all *P*<0.001), so as the number of glaucoma medications (all *P*<0.001). Complete success 1 and qualified success 1 were 87.80% and 100.00% respectively. The complete success 1 plus and qualified success 1 plus were 85.37% and 97.56%, respectively. Totally 82.93% and 90.24% of patients got complete success 2 and qualified success 2 while 80.49% and 87.80% of patients satisfied complete success 2 plus and qualified success 2 plus. Age (*r*=-0.511, *P*=0.001) and visual acuity (VA; *r*=-0.321, *P*=0.041) were negatively correlated with postoperative corrected IOP at 12mo, while anterior chamber depth (*r*=0.432, *P*=0.005), mean deviation (*r*=0.617, *P*<0.001) and visual field index (*r*=0.524, *P*<0.001) were positively correlated with it. Preoperative VA (OR=33.092, *P*=0.004) and MD (OR=1.481, *P*=0.018) were hazard factors associated with failure based on qualified success as 18 mm Hg. The main complications of KDB were hyphema (9.30%), IOP spike (11.63%) and peripheral anterior synechia (6.98%).

● **CONCLUSION:** KDB goniotomy is a safe and effective in the treatment for Chinese POAG patients. Preoperative VA and mean deviation may predict the surgical success.

● **KEYWORDS:** Kahook Dual Blade goniotomy; primary open angle glaucoma; success rate; risk factors

DOI:10.18240/ijo.2025.02.10

Citation: Fu L, Lou JT, Guo Y, Wang PJ, Le RR, Xu SX, Li GX, Liang YB. Efficacy and safety of combined Kahook Dual Blade goniotomy with phacoemulsification in Chinese patients with primary open angle glaucoma. *Int J Ophthalmol* 2025;18(2):268-274

INTRODUCTION

Primary open angle glaucoma (POAG), the most common subtype of glaucoma, is a progressive and irreversible optic neuropathy. It is typically characterized by disc cupping and progressive retinal ganglion degeneration, which can lead to irreversible loss of vision[1]. For glaucoma disease, intraocular pressure (IOP), as the only factor that can be modified with further intervention, has been shown to slow the progression of blindness[2]. In the treatment of glaucoma, local medication, laser therapy or surgery are usually used, among which, due to drug resistance and compliance, local medication cannot meet the recovery of glaucoma patients. Minimally invasive glaucoma surgery (MIGS) has been widely accepted and popularized since it provides a safe, effective,

and less invasive method that can reduce compliance with local medications. Kahook Dual Blade (KDB) goniotomy is one of the trabecular procedure surgeries for glaucoma patients[3]. It was first reported by Kahook in 2013 as a novel dual-blade device incising the trabecular meshwork (TM) in cadaveric eyes[4]. When compared to the microvitreoretinal blade and trabectome, this dual-blade device showed a more complete TM removal and IOP reduction in human perfusion eye[4]. Then in 2015, the KDB (New World Medical, Rancho Cucamonga, CA, USA) was approved by the American Food and Drug Administration for use. As an *ab interno* procedure for glaucoma, KDB goniotomy showed a promising IOP reduction and minimal complications than other *ab externo* procedures.

As a trabecular approach surgery, the KDB was designed to cut the TM as complete as possible with minimal invasive to the adjacent tissue. The KDB was consisted of a distal footplate with a pointed tip which widens posteriorly, an extended ramp with bilateral elevated blades which cut the stretch of TM cleanly. The footplate was 230-micron wide and was well seated into the approximate 250-micron wide Schlemm's canal[5-6]. Based on this precise design, the histological examination of TM strips from KDB goniotomy showed a high yield (70%) of TM[7] compared to the traditional trabeculectomy which showed a low yield of TM (20%)[8].

The IOP reduction ranged from 11%-36%, and the glaucoma medication reduced from 15% to 92% after KDB standalone surgery[9-13]. It was reported as a safe surgery without sight-threatening complications. Previous literature reported patients underwent KDB goniotomy ranged from moderate to severe glaucoma and most of them are retrospective designed studies[13-16]. The surgical results of the KDB goniotomy on Chinese patients are scarce. Therefore, in the present study, we recruited POAG and investigate the efficacy and safety of KDB goniotomy in Chinese patients.

PARTICIPANTS AND METHODS

Ethical Approval This is a retrospective study conducted in the Eye Hospital, Wenzhou Medical University, according to the tenets of Declaration of Helsinki. It was approved by the Ethics Committee of the Eye Hospital of Wenzhou Medical University (No.2023-214-K-171) and informed consent was waived.

Study Design and Participants Selection The patients who had accepted combined KDB goniotomy with phacoemulsification and intraocular lens implantation (KDB-Phaco) from September 2021 to July 2022 were included if 12-month postoperative follow-up data were available. Inclusion criteria were as follows: a diagnosis of POAG and cataract by an experienced glaucoma surgeon (Li GX), with age older than 40y. Exclusion criteria were a history of intraocular surgery, or ocular trauma, or underwent other ocular surgery unrelated to glaucoma management during the one-year postoperative follow-up.

Baseline Measurements For all included patients, the following demographics and clinical characteristics were collected: age, gender, glaucoma diagnosis, visual acuity (VA) in logMAR, best corrected visual acuity (BCVA) in logMAR, IOP, glaucoma medications, axial length, the depth of anterior chamber (AC), corneal endothelium cell density, central corneal thickness, mean deviation (MD) and pattern standard deviation (PSD) of visual field, retinal nerve fiber layer thickness from optical coherence tomography (OCT).

Surgical Procedure After satisfactory anaesthesia, a cataract surgery was done first. Briefly, a main incision was made at the temporal side. This was followed by capsulorhexis, nucleus division and emulsification. After aspiration of the capsular, an intraocular lens was implanted. Once the cataract procedure was completed, viscoelastic was injected into the AC again to maintain its stability. The patient's head was then tilted towards the opposite side of the surgeon by 30°-40°, while adjusting the surgical microscope to the surgeon by 30°-40° to clearly visualize the structure of AC angle. A direct gonioscope was placed over corneal with viscoelastic. The KDB was inserted to the AC and reached the AC angle under visualization of direct gonioscope. An incision of the TM was done by the tip of KDB, placing the footplate against the inner wall of Schlemm's canal and advancing the blade along the TM in both clockwise and anticlockwise directions to get a 100° to 180° KDB according to the surgical design. The KDB knife was retreated and the excised TM was floated at the AC angle which was removed by the forceps firstly, if not succeed, the floated TM was aspirated by the irrigation-aspiration during viscoelastic removal. Any viscoelastic and possible AC hemorrhage were removed before hydrating the corneal incision. After the surgery, the operated eyes were treated with tobramycin and dexamethasone eye ointment and then bandaged.

Postoperative Management A steroid anti-inflammatory eye drop was administered for 3d post-surgery after which it was replaced with a nonsteroid anti-inflammatory eye drop for 1mo. Patients were scheduled for follow-up visits at 1wk, 1, 3, 6, and 12mo postoperatively.

Outcome Measures IOP spike was defined as an IOP>21 mm Hg with/without medication in the first 3mo postoperatively. Complete success 1 was defined as 5-21 mm Hg without any glaucoma medications. Qualified success 1 was defined as IOP met the same thresholds with or without glaucoma medications. Complete success 1 plus or qualified success 1 plus was determined if additional criteria of IOP reduction ≥20% from baseline IOP was reached. Correspondingly, if the IOP upper limit was changed to

18 mm Hg, complete success 2, qualified success 2, complete success 2 plus, and qualified success 2 plus were defined correspondingly.

Statistical Analysis Normally distributed variables were described as mean and standard deviation (SD) while non-normally distributed variables were described as median and interquartile range (IQR). The difference between the postoperative and preoperative were compared with paired *t*-test or Wilcoxon signed-rank test. To test the correlations between postoperative IOP and preoperative characteristics, we calculated corrected IOP by adding 3 mm Hg[17] for each medication at the basis of IOP with medication. And the correlations were tested by Pearson or Spearman test. Cox's proportional hazards regression model was used to test the hazard ratio for factors associated with failure based on qualified success as 21 or 18 mm Hg. All tests were two-tailed and $P<0.05$ was considered statistically significant.

RESULTS

A total of 43 eyes of 28 POAG patients who accepted KDB-Phaco goniotomy were included in this study. The baseline demographic characteristics of patients were presented in Table 1. The preoperative highest IOP was 28.1±6.3 mm Hg and 2.0 (1.0) medications were used before surgery. After a 12-month follow up, the IOP decreased from 28.1±6.3 to 13.8±3.0 mm Hg (47.92% reduction, $P<0.001$), and the medications used decreased to 0.0 (0.0) accordingly (95% reduction, $P<0.001$).

Compared to preoperative IOP, the IOP all decreased significantly at postoperative visits. They were 13.2±4.6, 13.8±4.2, 13.4±3.7, 13.3±2.4, 13.7±2.4, and 13.8±3.0 mm Hg at 1-day, 1-week, 1-month, 3-month, 6-month and 12-month postoperatively (all $P<0.001$; Figure 1). Similarly, the number of glaucoma medications at each visit were all significantly lower than that of preoperative (all $P<0.001$; Figure 2). The medications were 0.0 (0.0), 0.0 (0.0), 0.0, 0.0, 0.0, 0.0 (0.0) at 1-day, 1-week, 1-month, 3-month, 6-month and 12-month postoperatively. At the 12-month visit, BCVA improved significantly with 0.30 (0.50) compared to that of 0.50 (0.40) logMAR at baseline ($P=0.003$).

Following successful KDB goniotomy, complete success rates were 100.00%, 100.00% and 87.80% at 3, 6, and 12mo with the definition of 5-21 mm Hg and the qualified success rates were all 100.00%. Based on the successful criteria of IOP reduction ≥20% from baseline IOP, the success plus rates are detailly shown in Table 2. Complete success 1 and qualified success 1 were 87.80% and 100.00% respectively. And complete success 1 plus and qualified success 1 plus were 85.37%, 97.56% respectively. 82.93% and 90.24% of patients got complete success 2 and qualified success 2 while 80.49% and 87.80% of patients got complete success 2 plus and qualified success 2 plus.

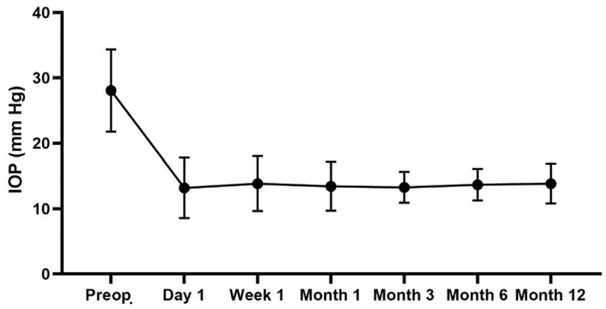

Figure 1 All postoperative IOP values were significantly lower than the preoperative level (all *P*<0.001) Error bars represent the standard deviation. IOP: Intraocular pressure.

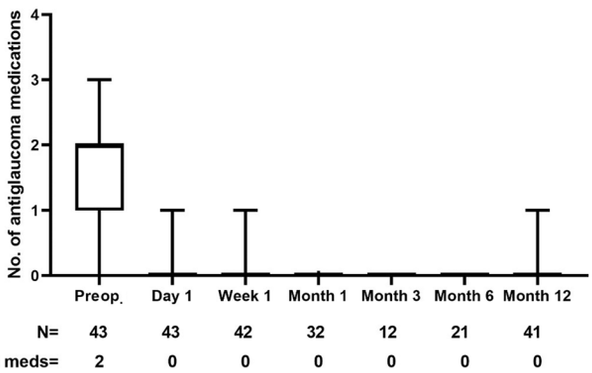

Figure 2 Number of glaucoma medications at all postoperative visits were less than preoperative N: Number of patients; Median meds: Median of glaucoma medications.

Table 1 Baseline demographic characteristics of patients

Clinical characteristics	Surgical eyes
Age	72.79±9.10 (50 to 86)
Sex (male/female)	17/11
Right/left eye	21/22
VA, logMAR	0.70 (0.90)
BCVA, logMAR	0.50 (0.40)
Preoperative highest IOP without medications (mm Hg)	28.1±6.3 (17.8 to 42.5)
Preoperative highest IOP with medications (mm Hg)	20.3±5.8 (11.8 to 34.5)
Preoperative medications, *n*	2.0 (1.0)
ACD (mm)	3.11±0.35
MD	-16.46 (19.89)
PSD	5.44 (4.98)
VFI	0.57 (0.80)
Corneal endothelium cell density (cells/mm^2)	2631±268

Data are presented as the mean±SD (range) for normal distribution and median (interquartile range) for abnormal distribution or absolute value. VA: Visual acuity; BCVA: Best-corrected visual acuity; IOP: Intraocular pressure; ACD: Anterior chamber depth; MD: Mean deviation; PSD: Pattern standard deviation; VFI: Visual field index.

We also calculated the distribution of IOP of 12-month postoperatively. As shown in Table 3, 100%, 90.24%, 73.17% and 29.27% of patients got a IOP≤21, ≤18, ≤15, and ≤12 mm Hg respectively with/without medication. The rates were 87.80%, 82.93%, 70.73% and 29.27% respectively without medication.

Postoperative corrected IOP at 12mo were negatively correlated with age ($r=-0.511$, $P=0.001$) and VA ($r=-0.321$,

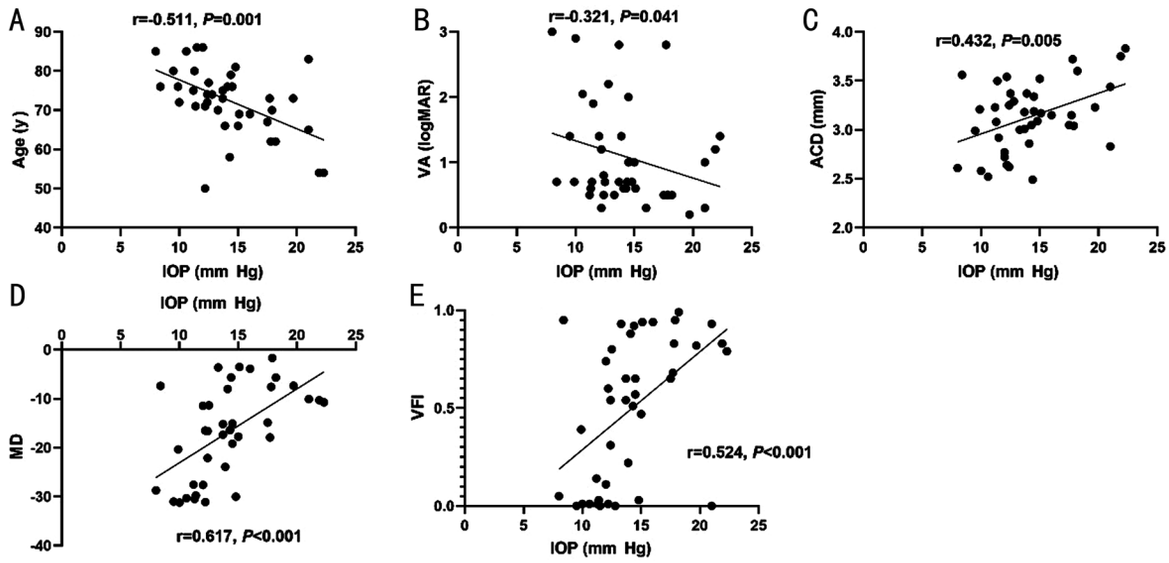

Figure 3 Correlations between postoperative 12-month IOP and preoperative characteristics IOP: Intraocular pressure; VA: Visual acuity; ACD: Anterior chamber depth; MD: Mean deviation; VFI: Visual field index.

Table 2 Success rates of different successful criterion in 12mo postoperatively

Success definition	Success rate
5-21 mm Hg	
Complete success 1	87.80% (36/41)
Qualified success 1	100.00% (41/41)
Complete success 1 & IOP reduction ≥20% from baseline	85.37% (35/41)
Qualified success 1 & IOP reduction ≥20% from baseline	97.56% (40/41)
5-18 mm Hg	
Complete success 2	82.93% (34/41)
Qualified success 2	90.24% (37/41)
Complete success 2 & IOP reduction ≥20% from baseline	80.49% (33/41)
Qualified success 2 & IOP reduction ≥20% from baseline	87.80% (36/41)

IOP: Intraocular pressure.

Table 3 Distribution of IOP of 12-month postoperatively

IOP range	Rate
5-21 mm Hg	
With/without medication	100.00% (41/41)
Without medication	87.80% (36/41)
5-18 mm Hg	
With/without medication	90.24% (37/41)
Without medication	82.93% (34/41)
5-15 mm Hg	
With/without medication	73.17% (30/41)
Without medication	70.73% (29/41)
5-12 mm Hg	
With/without medication	29.27% (12/41)
Without medication	29.27% (12/41)

IOP: Intraocular pressure.

P=0.041), positively correlated with AC depth (*r*=0.432, *P*=0.005), MD (*r*=0.617, *P*<0.001) and VFI (*r*=0.524, *P*<0.001), as shown in Figure 3. Corrected IOP at 12-month postoperatively were not correlated with BCVA, highest IOP without medication, highest IOP with medication, the number medications used, PSD, thickness of retinal nerve fiber layer or severity of glaucoma before surgery. Neither the reduction of IOP nor the range of KDB goniotomy was correlated with it in our experiment.

Table 4 Cox proportional hazard ratio for factors associated with failure based on qualified success as 18 mm Hg

Factors	Hazard ratio	95%CI	*P*
Age	0.940	0.865-1.023	0.151
VA, logMAR	33.092	2.995-365.583	0.004
MD	1.481	1.070-2.049	0.018

VA: Visual acuity; MD: Mean deviation; CI: Confidence interval.

According to the Cox's proportional hazards regression model, preoperative VA (OR=33.092, *P*=0.004) and MD (OR=1.481, *P*=0.018) were hazard factors associated with failure based on qualified success as 18 mm Hg (Table 4), which meant a 1.0 logMAR deterioration of preoperative VA or a 1.00 deterioration of preoperative MD led to 33.092 or 1.481 more likely surgical failure. But we did not get a significant Cox's proportional hazard regression model based on qualified success as 21 mm Hg (*P*=0.291).

The main complications of KDB-Phaco goniotomy are hyphema (9.30%, 4/43), IOP spike (11.63%, 5/43) and peripheral anterior synechia (6.98%, 3/43). As for hyphema, they all occurred in the first day after surgery and three of them resolved in the 1st week postoperatively without medication, and one of them resolved in the one month after surgery. IOP spikes all occurred in the first postoperative month and all were lower than 30 mm Hg with a range of 21.2-26.2 (23.93±1.71) mm Hg. They all recovered to normal level during the subsequent postoperative follow-up within 3mo.

Three patients experienced a peripheral anterior synechia at the site of KDB goniotomy.

DISCUSSION

In the present study, we achieved promising surgical outcomes of KDB goniotomy in Chinese POAG patients. As different success criteria were used from literature, in order to better compare with other studies, we herein used eight criteria with two different cutoff values of 21 and 18 mm Hg, and the additional requirement of IOP reduction ≥20% from baseline, to clearly assess the efficacy of KDB goniotomy in Chinese POAG in this study.

Trabeculectomy and glaucoma drainage device implantation are the two most common traditional filtering surgeries for the past half a century. However, they are related with at least 30% complications especially postoperative bleb-related complications, including bleb encapsulation, bleb leak, and blebitis[18-19]. The complications induce frequent postoperative interventions and increased follow-up[20-22]. With the increasing popularity of MIGS, it is now more and more commonly applied for mild to moderate glaucoma in the last two decades. Non-bleb forming MIGS is favored by clinical surgeons. This is due to the less complications and less frequency of postoperative interventions.

Varies types of MIGS have been reported. The IOP reduction range was reported to be 32%-44% for the gonioscopy-assisted transluminal trabeculotomy[23-24], 23%-39% for the trabectome[25-26], 25%-40% for the *ab-interno* canaloplasty (ABiC)[27-28], and 15%-36% for the excisional goniotomy[9-11,14]. Currently there are little evidence of one superior to another. KDB is one with good recovery time and safety profile. A 12-month success rate of 84.3% of combined KDB-Phaco was reported in Latino patients with the cutoff of 21 mm Hg[29]. Herein, our study investigated the efficacy and safety of KDB goniotomy, and evaluate the factors associated with the postoperative IOP and success rate, to provide the surgical outcome information of KDB goniotomy in Chinese POAG patients. In this study, IOP was reduced 47.92% from baseline values 12mo after KDB-Phaco.

In order to compare the present success rates with other studies, only the results of 12mo surgical outcome after combined KDB-Phaco in POAG were retrieved. So far, there have been only no more than 10 reports showing the success rates of KDB in POAG at 12mo. Kuerten *et al*[30] presented that the complete success rate 1 was 64%, while in our study, it was 87.8%. For the qualified success 1 plus, the success rate was 62.2% in Aoki *et al*'s[31] study. In the present study, it was 85.37%. The qualified success rate 2 was 61% (11/18) in a Germany study[32]. However, in the current study, it was 90.24% which was also apparently higher. In Iwasaki *et al*'s[33] study, the success rate was 60.2% according to the qualified success 2 plus criteria, and it was 87.80% in this study. For the above studies, the reported success rates were all lower than in our study with the same definition of success rate. Only one study reported by Le *et al*[34] showed a 92% qualified success rete 2 which was slightly higher than in our study of 90.24%. However, the overall IOP reduction percentage was 14.3% in the study of Le *et al*[34], and it was 47.92% in our study. This indicates the baseline IOP was higher in our recruited patients.

The IOP distribution was also calculated and 100.00% were below 21 mm Hg, 82.93% below 18 mm Hg, 73.17% below 15 mm Hg, and 29.27% below 12 mm Hg. Previous report from Murata *et al*[35] showed that it was difficult to reduce the IOP below 15 mm Hg with only 19.9% for POAG 1y after KDB surgery. Bravetti *et al*[36] reported that the proportion of IOP≤16 mm Hg was 67.5%. For the cutoff of IOP≤16 mm Hg, the qualified success was 64% 6mo after KDB-Phaco and was 26% (5/19) 12mo after KDB-Phaco from Baumgarten *et al*'s study[37]. Nevertheless, in the present study, 73.17% were brought below 15 mm Hg.

Compared with other studies, either from the success rate or the IOP reduction percentage, the current results showed an overall promising outcome of KDB-Phaco in Chinese POAG. The results showed a more significant trend in the success rate of KDB goniotomy in terms of IOP reduction and medication reduction, which was mainly due to racial differences. So far as we know, this is the first study showing the 12mo results of POAG received KDB goniotomy, providing a more comprehensive patient population profile for clinical trials and refining the clinical data of patients with POAG in different countries following KDB goniotomy.

For a glaucoma patient, not only the IOP but also the glaucoma medication should be account for the treatment effect. Therefore, in this study, one glaucoma medication was converted to 3 mm Hg for the analysis of the relationships between the baseline characteristics and postoperative IOP[17]. In our study, six preoperative parameters were associated with post IOP, including the age, baseline VA, IOP, AC depth, MD, and PSD. Moreover, we also tested the risk factors for the success rate. Baseline VA and MD were found to be the risk factors of success rate 2. Deterioration of visual function is common in patients with glaucoma, so it is important to further test the preoperative examination of baseline MD and VA, and then control the risk factors to slow the further deterioration of the optic nerve function of glaucoma. As the success criteria varies according to different stages of glaucoma patients. Both VA and MD may reflect the severity of the optic nerve damage of the patient. Therefore, the worse preoperative visual function, the later to start surgical intervention, may result in higher risk of surgical failure. From the cox hazard ratio analysis, the age and baseline IOP were not the risk factors of

the surgical failure. This is consistent with the result of Le *et al*'s[34] study, that age, sex, race, baseline IOP were related with IOP reduction while were not associated with success rate. Higher baseline IOP was reported to be related with surgical failure from a Canadian study[38]. However, that study included various glaucoma types including POAG, secondary open angle glaucoma, primary angle-closure glaucoma and normal tension glaucoma and the risk factors for surgical failure in POAG were not analyzed separately.

There are several limitations of this study. The sample size is 43 eyes which is small and this is a retrospective designed study in which the investigator bias could not be avoided, and relied on measurements at each point in time, resulting in substantial attrition as we approached the 12-month mark. Moreover, it is a limitation that we did not include a control group of other surgical methods, to compare the surgical results. Mou *et al*[39] reported a 6-month follow-up results, which showed no differences of the success rate between the KDB-Phaco and phacoemulsification combined with trabectome. We may further compare the KDB goniotomy with other methods of goniotomy to investigate the outcome differences. Finally, this study only included POAG without other types of glaucoma including pseudoexfoliation glaucoma, unveitic glaucoma, and pigmentary glaucoma is also the limitation of this study. Secondary glaucoma requires further study with a prospective design, larger sample size, more glaucoma subtypes, a control group and longer follow-up duration is necessary to better evaluate the efficacy and safety of the KDB goniotomy.

In conclusion, we showed a favorable surgical outcome of KDB goniotomy in Chinese POAG in this one-year study. The baseline age, VA, IOP, AC depth, MD, and PSD were related with post IOP values. Baseline VA and MD were found to be the risk factors of success rate. Therefore, patients with severe visual function may need careful follow-up after surgery.

ACKNOWLEDGEMENTS

Foundations: Supported by the National Natural Science Foundation of China Youth Science Foundation Project (No.82201176); Zhejiang Provincial Medical & Health Science Technology Program (No.2023KY153).

Conflicts of Interest: Fu L, None; **Lou JT,** None; **Guo Y,** None; **Wang PJ,** None; **Le RR,** None; **Xu SX,** None; **Li GX,** None; **Liang YB,** None.

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