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Efficacy and safety of inferonasal goniotomy with an MVR blade in open-angle glaucoma

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利用 MVR 刀行鼻下前房角切开术治疗开角型青光眼的疗效和安全性

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摘要

目的:探究使用显微玻璃体视网膜(MVR)刀行 90°鼻下节段性前房角切开术治疗轻中度原发性开角型青光眼(POAG)及假性剥脱性青光眼(PEXG)患者的疗效及安全性。

方法:回顾性纳入 2021 年 6 月至 2023 年 1 月接受单纯前房角切开术或前房角切开术联合超声乳化白内障吸除术的患者 60 例 60 眼,其中,45 眼行前房角切开术联合超声乳化白内障吸除术,15 眼行单纯前房角切开术。收集患者术后 1、3、6、12 mo 眼压(IOP)及用药次数,并记录患者术后 1 d、1 wk、1、3、6、12 mo不良反应。主要指标为 IOP 较术前降低 20%且术后 1 a 抗青光眼药物使用次数减少,次要指标为手术成功率,即术后 1 a IOP<18 mmHg(不限抗青光眼药物使用与否)。

结果:术后 1 a,78%患者 IOP 及用药次数降低 20%,63%患者手术成功。最常见的并发症为微前房积血,均未出现需要手术干预的并发症。

结论:MVR 刀行节段性鼻下前房角切开术可显著降低 POAG 及 PEXG 患者 IOP 及用药次数,且术后 1 a 显著减少或延缓需行青光眼滤过术的患者。

关键词:青光眼;微创青光眼手术;原发性开角型青光眼;假性剥脱性青光眼;前房角切开术

Abstract

• AIM: To investigate the efficacy and safety of 90° inferonasal sectoral goniotomy with an micro-vitreoretinal (MVR) blade in patients with mild-to-moderate primary open-angle glaucoma (POAG) and pseudoexfoliation glaucoma (PEXG).

• METHODS: This retrospective study included data from 60 patients (60 eyes) who underwent stand-alone goniotomy or goniotomy with phacoemulsification between August 2021 and January 2023, and 45 eyes underwent goniotomy combined with phacoemulsification, and 15 eyes underwent goniotomy as a stand-alone procedure. Postoperatively, intraocular pressure (IOP) and the number of medications were collected at 1, 3, 6, and 12 mo. The side effects of surgery were recorded 1 d, 1 wk, and 1, 3, 6, and 12 mo postoperatively. The primary outcomes were a reduction in IOP of at least 20% from baseline and a decrease in the number of antiglaucomatous medications in 1 a postoperatively. The secondary outcome was surgical success, defined as an IOP<18 mmHg with (qualified) or without (complete) antiglaucomatous medication at 1 a postoperatively.

• RESULTS: At the end of 1 a, 78% of patients achieved both a >20% reduction in IOP and a reduction in the number of medications used. Overall success was achieved in 63% of patients. Microhyphaema was the most common complication, none of the patients experienced a complication requiring surgical intervention.

• CONCLUSION: Sectoral inferonasal goniotomy with an MVR blade significantly reduced IOP and the number of medications required in patients with POAG and PEXG, and 1-year follow-up after goniotomy showed that the need for filtering surgery was either eliminated or delayed in a significant number of patients.

• KEYWORDS: glaucoma; minimally invasive glaucoma surgery; primary open-angle glaucoma; pseudoexfoliation glaucoma; goniotomy
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INTRODUCTION

Glaucoma is one of the leading causes of irreversible blindness worldwide[1], with its prevalence estimated to exceed 100 million by 2040[2]. Among all forms of glaucoma, primary open-angle glaucoma (POAG) is the most common[2], while pseudoexfoliation glaucoma (PEXG) is the most common form of secondary glaucoma[3]. The primary objective of glaucoma treatment is to reduce intraocular

pressure (IOP), which is the only modifiable risk factor[4]. Thus, pharmacotherapy to lower IOP is usually the first option for glaucoma management[4]. If pharmacotherapy is unsuccessful in reducing high IOP or glaucoma progression persists despite IOP reduction, laser and surgical options may be considered.

Surgical options for glaucoma include deep sclerectomy, trabeculectomy, and tube shunt surgery, which can effectively reduce IOP and prevent disease progression in patients with glaucoma[5].

Although conventional surgeries for glaucoma are highly effective, they are mostly invasive and associated with serious short - and long - term postoperative complications[5]. Minimally invasive glaucoma surgery (MIGS) is the preferred surgical approach for mild - to - moderate glaucoma. It is a safer, easier, and less invasive alternative to conventional incisional surgeries, particularly in the early stages of the disease when trabeculectomy or tube shunts are not necessary. Recently, this approach has gained popularity owing to its minimally invasive nature and low risk of complications[6]. MIGS can lower IOP by increasing outflow *via* bypassing, removing, or incising the trabecular meshwork, which is the main cause of resistance to normal aqueous outflow.

Goniotomy is a procedure within the MIGS spectrum that aims to treat the trabecular meshwork[7]. Due to advances in MIGS, goniotomy, which has long been preferred for pediatric glaucoma, has reemerged as a treatment option for adult glaucoma[8], and several studies have demonstrated the efficacy of different types of goniotomies[9-11]. To the best of our knowledge, no studies have explored the efficacy of goniotomy using a micro vitreoretinal (MVR) blade for POAG and PEXG. This study investigated the efficacy and safety of 90° inferonasal sectoral goniotomy using an MVR blade in patients with mild-to-moderate open-angle glaucoma.

SUBJECTS AND METHODS

Ethical Approval This retrospective study included data of 60 patients (60 eyes) who underwent stand-alone goniotomy or goniotomy with phacoemulsification at a single center between August 2021 and January 2023 and were followed-up for 1 a postoperatively. The study protocol was approved by the Institutional Review Board of the Ethical Committee of the University (No. DNR. E1 - 23 - 4411). The study adhered to the ethical tenets of the Declaration of Helsinki.

Subjects Patients aged 18-85 years with mild-to-moderate POAG or PEXG and IOP >21 mmHg despite maximal medical anti - glaucomatous therapy were included herein. Patients were excluded if they had advanced glaucoma, angle-closure glaucoma, congenital or juvenile open - angle glaucoma, neovascular glaucoma, active uveitis with secondary glaucoma, increased episcleral venous pressure, or a history of glaucoma surgery.

All patients received a full ophthalmologic evaluation, including measurement of best-corrected visual acuity, slit-lamp biomicroscopy, gonioscopic examination, dilated fundus assessment, and analysis of the optic nerve head. IOP was measured three consecutive times at each visit using Goldmann applanation tonometry, and the average of these readings was documented. Preoperative baseline IOP values were defined based on the final visit prior to surgery. Following surgery, information on IOP and the number of antiglaucoma medications was recorded at 1, 3, 6, and 12 mo. Postoperative adverse events were documented at 1 d, 1 wk, and 1, 3, 6, and 12 mo.

The diagnosis of glaucoma was established by identifying characteristic glaucomatous damage to the optic nerve, detecting retinal nerve fiber layer abnormalities with swept-source optical coherence tomography (Topcon Healthcare), and confirming corresponding visual field loss using 24 - 2 central automated perimetry with a Humphrey Field Analyzer (model 750; Carl Zeiss Meditec, Inc.).

Patients with glaucoma with an open, normal - appearing anterior chamber angle on gonioscopy and no other underlying diseases were considered to have POAG. Patients with glaucoma with pseudoexfoliation material at the pupillary margin, anterior lens capsule, or angle were considered to have PEXG. Disease severity was classified as mild, moderate, or advanced according to the Hodapp - Parrish - Anderson criteria[12].

The occurrence of an IOP-spike was delineated as an IOP-elevation of $\geqslant$10 mmHg from the baseline measurement, or an IOP of $\geqslant$30 mmHg recorded at the first postoperative week[13]. Microhyphema was considered present when the anterior chamber contained flare or a blood layer measuring 1 mm or less, whereas macrohyphema was defined as the accumulation of layered blood exceeding 1 mm.

Surgical Technique Surgery was performed by two experienced ophthalmologists following the same protocol (MA and CZF). For the combined procedures, phacoemulsification was performed before goniotomy. All goniotomies were performed with an MVR blade. The microscope was tilted at a 45° angle toward the surgeon, while the patient's head was tilted 45° away from the surgeon. An ophthalmic viscoelastic material was placed on top of the cornea to obtain an optimal direct image of the inferonasal angle using a Swan - Jacob goniolens. After entering the anterior chamber *via* the superotemporal paracentesis, the inferonasal angle was penetrated using the tip of the MVR blade (Figure 1). The blade was then advanced by at least 45° in both the superior and inferior directions. The aim was to excise the pigmented portion of the trabecular meshwork without harming the inner wall of Schlemm's canal (Figure 2). After cleaning the viscoelastic material, sterile air was injected into the anterior chamber to prevent or reduce hyphema formation. Following surgery, topical antibiotics and steroids were prescribed. Topical antibiotics were continued for 1 wk, and topical steroids were tapered off at 1 mo postoperatively.

Study Outcome Measures The primary outcomes of the study were as follows: 1) a reduction in IOP of at least 20% from baseline without an increase in the number of glaucoma

medications; 2) a decrease in the number of antiglaucomatous medications in the first postoperative year.

Surgical success was evaluated as a secondary outcome. Complete surgical success was defined as maintaining an IOP below 18 mmHg at the 1-year follow-up without the need for antiglaucoma therapy, while qualified success referred to achieving an IOP below 18 mmHg at the same time point with the use of antiglaucomatous medication.

Statistical Analysis Descriptive statistical methods were applied to summarize the study variables. For continuous outcomes, mean, standard deviation, median, and interquartile range (IQR), as well as minimum and maximum values, were reported. Categorical variables were expressed as frequencies and percentages. The Shapiro-Wilk test was performed to evaluate the normal distribution of continuous data. Comparisons between preoperative and postoperative measurements were conducted using Friedman's ANOVA, and post-hoc pairwise differences between specific time points were assessed with Friedman's Multiple Comparison test. Differences in longitudinal changes between the POAG and PEXG groups were evaluated with the Mann-Whitney *U* test. Categorical group comparisons were carried out using the Chi-square test. All analyses were performed in IBM SPSS Statistics version 20 (Chicago, IL, USA), with statistical significance defined as $P<0.05$.

RESULTS

The study population comprised patients who were able to attend all scheduled visits during the 1-year follow-up period. Patients who were absent at scheduled visits during the 12-month follow-up period were excluded. The mean age of the patients who underwent goniotomy was 67.05±9.09 years. Table 1 summarises the patients' demographic data and baseline findings. Herein, 45 eyes (75%) underwent goniotomy combined with phacoemulsification, and 15 eyes (25%) underwent goniotomy as a stand-alone procedure. Among patients who underwent goniotomy alone, 6 were diagnosed with POAG and 9 with PEXG. In contrast, the phacoemulsification-combined goniotomy group consisted of 18 patients with POAG and 27 patients with PEXG.

Efficacy At the baseline, the mean IOP was 31.07±6.96 mmHg. There was a significant difference between the mean preoperative IOP values at 1, 3, 6, and 12 mo postoperatively ($P<0.001$; Table 2).

At the 12-month follow-up, mean IOP decreased from 29.84±7.16 mmHg to 17.20±5.15 mmHg in the combined phacoemulsification and goniotomy group, and from 34.73±4.87 mmHg to 19.73±3.17 mmHg in the stand-alone goniotomy group. Postoperative IOP values were significantly reduced compared with preoperative measurements at 1, 3, 6, and 12 mo (all $P<0.001$), whereas no significant differences were observed among the IOP values at these postoperative time points (all $P>0.05$).

Similarly, the number of antiglaucoma medications was significantly lower at 1, 3, 6, and 12 mo postoperatively compared with the preoperative period (all $P<0.001$; Table 3), with no significant differences noted between the

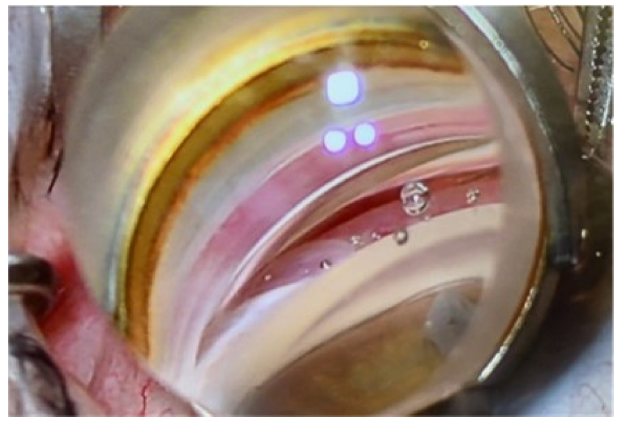

Figure 1 At the beginning of the goniotomy procedure, the tip of the micro-vitreoretinal blade is observed to be positioned within the pigmented trabeculum.

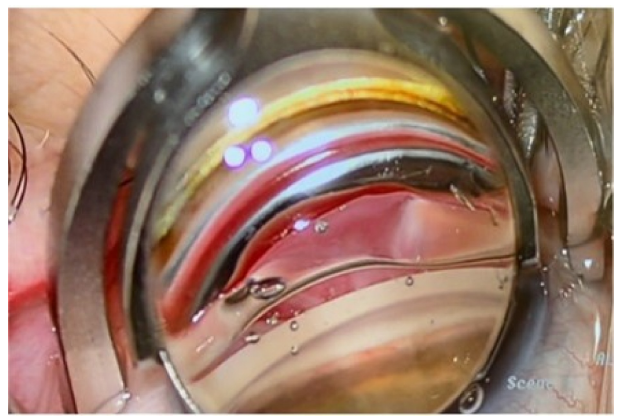

Figure 2 The appearance of the angle at the end of the surgery.

Table 1 Patient's demographics and baseline characteristics

Parameters	Patients ($n=60$)
Age ($\bar{x}\pm s$, year)	67.05±9.09
Sex (n, %)	
Female	(25, 42)
Male	(35, 58)
Surgery type (n, %)	
Phaco+goniotomy	(45, 75)
Goniotomy	(15, 25)
Glaucoma type (n, %)	
PEXG	(36, 60)
POAG	(24, 40)
Glaucoma severity (n, %)	
Mild	(33, 55)
Moderate	(27, 45)
Systemic disease (n, %)	
No	(19, 32)
Yes	(41, 68)
Side (n, %)	
Right	(36, 60)
Left	(24, 40)

Phaco: Phacoemulsification; PEXG: Pseudoexfoliation glaucoma; POAG: Primary open-angle glaucoma.

postoperative time points (all $P>0.05$).

There was no significant difference in the degree of IOP reduction between the POAG and PEXG groups at 1, 3, 6, and 12 mo postoperatively (all $P>0.05$; Table 4). There was no significant difference in the reduction of medication use between the PEXG and POAG groups at 1, 3, 6 and 12 mo postoperatively (all $P>0.05$; Table 4).

Herein, 78% of patients achieved both a >20% reduction in IOP and a decrease in the number of medications, while 62% achieved both a >30% IOP reduction and reduced medication use. Overall surgical success was observed in 63% of patients, comprising 48% qualified success and 15% complete success. No significant differences were found in success rates between patients with PEXG and those with POAG. At 12 mo postoperatively, IOP was significantly lower in the combined phacoemulsification and goniotomy group compared with the stand-alone goniotomy group.

At 12 mo postoperatively, the number of medications used in the combined phacoemulsification and goniotomy group was significantly lower than that in the goniotomy alone group ($P<0.01$; Table 5).

Safety and Adverse Events No cases of cyclodialysis cleft, persistent hypotony, or infection were reported within 1 month of surgery. On 1 d postoperatively, the incidence of microhyphema was 45%, while the incidence of corneal edema was 42%. A total of 17% of patients exhibited IOP spikes during the first postoperative mo. These were treated by either the addition or increase of antiglaucomatous medications. One eye presented severe inflammation with membrane formation and another developed macrohyphema, which resolved in the first postoperative wk.

DISCUSSION

Since the introduction of MIGS more than a decade ago, various devices and techniques have been developed for its

Table 2 Intraocular pressure measurements preoperatively, at 1, 3, 6 and 12 months postoperatively for the entire study group

Time ($n=60$)	IOP ($\bar{x}\pm s$, mmHg)	P	Post hoc
Preop IOP	31.07±6.96	<0.001[a]	
Postop 1 month IOP	14.55±5.09		$P<0.001$
Postop 3 month IOP	15.73±4.47		$P<0.001$
Postop 6 month IOP	16.63±4.52		$P<0.001$
Postop 12 month IOP	17.83±4.84		$P<0.001$

[a]Friedman's multiple comparison test. IOP: Intraocular pressure.

Table 3 The number of medications used preoperatively, at 1, 3, 6 and 12 months postoperatively

Time ($n=60$)	Number of medications ($\bar{x}\pm s$, times)	P	Post hoc
Preoperative	3.28±1.16	<0.001[a]	
Postoperative 1 month	2.33±1.28		$P<0.001$
Postoperative 3 month	2.22±1.30		$P<0.001$
Postoperative 6 month	2.07±1.21		$P<0.001$
Postoperative 12 month	2.07±1.21		$P<0.001$

[a]Friedman's multiple comparison test.

Table 4 The reduction in intraocular pressure and number of medications at 1, 3, 6 and 12 months postoperatively in patients with pseudoexfoliation glaucoma and primary open-angle glaucoma Median (Min-Max)

Parameters	Total	PEXG	POAG	P
IOP difference at 1 month compared to preop	−14.5 (−34)- (−2)	−15 (−34)- (−3)	−14 (−27)- (−2)	0.815[a]
IOP difference at 3 month compared to preop	−13.5 (−33)- (−2)	−13 (−33)- (−2)	−14 (−26)- (−4)	0.809[a]
IOP difference at 6 month compared to preop	−13 (−30)- (−3)	−14 (−30)- (−8)	−12.5 (−26)- (−3)	0.329[a]
IOP difference at 12 month compared to preop	−11 (−31)- (+4)	−11 (−31)- (+4)	−10 (−25)- (−1)	0.285[a]
Reduction in number of medications at 1 month	−1 (−3)- (+2)	−1 (−3)- (+2)	−1 (−3)- (0)	0.751[a]
Reduction in number of medications at 3 month	−1 (−3)- (+4)	−1 (−3)- (+4)	−1 (−3)- (+1)	0.501[a]
Reduction in number of medications at 6 month	−1 (−3)- (+2)	−1 (−3)- (+2)	−1 (−4)- (0)	0.602[a]
Reductionin number of medications at 12 month	−1 (−3)- (+2)	−1 (−3)- (+2)	−1 (−4)- (0)	0.602[a]

[a]Mann Whitney-U test. IOP: Intraocular pressure; PEXG: Pseudoexfoliation glaucoma; POAG: Primary open-angle glaucoma.

Table 5 The intraocular pressure and number of medications used at 12 month postoperatively $\bar{x}\pm s$

Parameters	Phaco+goniotomy	Goniotomy	P
Postop 12 month-IOP levels (mmHg)	17.20±5.15	19.73±3.17	0.003[a]
Postop 12 month-number of medications (times)	1.80±1.23	2.87±0.74	0.002[a]

[a]Mann Whitney-U test. IOP: Intraocular pressure; Phaco: Phacoemulsification.

improvement. However, a significant proportion of equipment used in the MIGS is expensive and not readily available in all countries. This study aimed to examine the efficacy of goniotomy performed with an MVR blade, which is a cost-effective and commonly used tool in ophthalmic procedures.

A previous study[13] has shown that aqueous outflow in the trabecular meshwork is not homogeneous; the high- and low-flow regions are strongly related to the active collector channels. As they are predominantly located in the nasal and inferior parts of the trabecular meshwork[14], these are the areas most often targeted by goniotomy. Several studies have shown that partial sectoral goniotomy, including 60° nasal goniotomy[15], can effectively reduce the IOP as much as 360° goniotomy[16]. Herein, we performed a 90° partial goniotomy that included the inferior and nasal quadrants, either alone or in combination with phacoemulsification. When using the MVR blade to open the trabecular meshwork, it is crucial to create a smooth incision that does not harm Schlemm's canal or surrounding tissues. To ensure this, the incision must be in the correct plane and the white sheen of the Schlemm's canal should be visible.

The Trabectome (Micro Surgical Technology, USA), the iTrack canaloplasty microcatheter (Nova Eye Medical, USA), and the OMNI trabeculotomy system (OMNI Surgical, USA) are some of the devices utilised for the purpose of opening the trabecular meshwork[17].

Kono *et al*[18] demonstrated that after a 6-year follow-up period, trabectome surgery resulted in a decrease in the baseline IOP from 29.2±9.8 mmHg with a 5.3±1.7 medication score to 16.4±5.8 mmHg with a 4.2±1.5 medication score in patients with POAG, secondary open-angle glaucoma, and childhood glaucoma. Herein, IOP decreased by 43%, from 31.07±6.96 mmHg at the baseline to 17.83±4.84 mmHg after goniotomy, and the number of medications decreased from 3.28±1.16 at the baseline to 2.07±1.21 after surgery.

The Kahook dual blade (KDB) (New World Medical, USA) is a widely used MIGS option for goniotomies. Sieck *et al*[19] demonstrated that combined phacoemulsification and KDB surgery resulted in a >20% reduction in IOP and/or a decrease in the number of antiglaucoma medications in 71% of patients. Herein, at the end of the first year, 78% of the patients attained a >20% reduction in IOP, with a significant reduction in medication use.

Another option for goniotomy is bent-*ab interno*-needle goniectomy. This procedure is performed using a simple bent hypodermic needle. Several studies have demonstrated that bent-*ab interno*-needle goniectomy can effectively reduce IOP and the number of required medications[20-21], with efficacy comparable to other, more expensive goniotomy options.

Gonioscopy-assisted transluminal trabeculotomy is a common option for MIGS. According to Wan *et al*[22], there was a 43.97% reduction in IOP at the 12-month follow-up after gonioscopy-assisted transluminal trabeculotomy. Similarly, we observed a 43% reduction in IOP at the 12-month follow-up after goniotomy with an MVR blade.

In this study, the combined phacoemulsification and goniotomy group exhibited a lower IOP and a lower drug consumption rate in comparison to the stand-alone goniotomy group following a 1-year period. This phenomenon may be attributable to the additional IOP-lowering effect of phacoemulsification, higher baseline IOP, the greater number of medications in the stand-alone goniotomy group, or a combination of these factors.

Studies comparing the results of MIGS in patients with POAG and PEXG are limited. Hengerer *et al*[23] observed no significant difference in the efficacy of the XEN45 device for POAG and PEXG 12 mo after its implantation. Similarly, herein, no statistically significant differences were observed in the success rates of MVR blade goniotomy between patients with POAG and those with PEXG. The study demonstrated statistically similar outcomes for both types of open-angle glaucoma following MVR blade goniotomy.

MIGS aims to reduce both IOP and the need for antiglaucomatous medications. Barkander *et al*[24] reported that 24 months after phacoemulsification-iStent and phacoemulsification-KDB surgery, approximately half of the patients experienced over 20% reduction in IOP, with a postoperative IOP value ≤18 mmHg. Herein, the qualified success rate was 48.3%, and the complete success rate was 15% at the the end of the first year.

Dorairaj *et al*[25] reported a 20.8%-26.2% reduction in IOP 12 mo after combined phacoemulsification and KDB goniotomy. Herein, at 12 mo postoperatively, 61.6% of the patients experienced >30% reduction in IOP and a decrease in the number of antiglaucoma medications.

Barkander *et al*[24] reported total hyphema requiring anterior chamber washout after KDB goniotomy. Herein, microhyphaema was the most common complication; however, no surgical intervention was required. KDB goniotomy involves tissue excision, whereas MVR blade goniotomy involves an incision in the trabecular meshwork, which may lead to less hyphema formation. During the 1-year follow-up period, none of the patients experienced serious complications requiring surgical intervention.

MIGS has been demonstrated to be a safe and effective treatment for mild-to-moderate glaucoma in adults[26]. Our study provides evidence that goniotomy using an MVR blade is also a safe and well-tolerated procedure for mild-to-moderate open-angle glaucoma in adults, either in combination with phacoemulsification or as a stand-alone procedure.

No significant difference was observed in the IOP values measured at 1 and 12 mo postoperatively. Additionally, there was no significant difference in the number of medications used by patients at 1 and 12 mo postoperatively, indicating that MVR blade goniotomy resulted in a stable decrease in IOP, at least in the early and medium terms.

To our knowledge, this is the first study to examine the results of goniotomy performed with an MVR blade 1 a postoperatively

in patients with mild-to-moderate open-angle glaucoma.

This study has some limitations, including the lack of long-term follow-up and the relatively small number of patients in the stand-alone goniotomy group, which precluded direct statistical comparisons. These factors should be considered when interpreting the results, and future prospective studies with larger cohorts and longer follow-up are warranted to confirm and extend our findings.

In conclusion, this study demonstrated that sectoral inferonasal goniotomy using an MVR blade with or without phacoemulsification significantly reduced IOP and the number of medications required in patients with POAG and PEXG. It may be an alternative to more expensive goniotomy options when these are not available. This study suggests that goniotomy may reduce or delay the need for filtering surgery during the first postoperative year.

Conflicts of Interest: Asfuroglu M, None; Fikret CZ, None; Asfuroglu Y, None.

Authors' contributions: Asfuroglu M and Asfuroglu Y conceptualized the manuscript; Asfuroglu M prepared the original draft; Fikret CZ and Asfuroglu Y reviewed and edited the manuscript. Fikret CZ did the supervision. All authors read and agreed to the published version of the manuscript.

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