

# Ab interno trabeculotomy combined with cataract extraction in eyes with primary open-angle glaucoma

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## Abstract

**Objective:** To investigate the efficacy and safety of ab interno trabeculotomy using the VISCO360<sup>®</sup> Viscosurgical System (Sight Sciences, Inc., Menlo Park, CA, USA) combined with cataract extraction in the treatment of primary open-angle glaucoma (POAG).

**Methods:** Patients with POAG who underwent ab interno trabeculotomy combined with cataract extraction were retrospectively analyzed. Best-corrected visual acuity (BCVA), intraocular pressure (IOP), the number of antiglaucomatous medications, and complications were recorded preoperatively and 1 week, 1 month, 3 months, 6 months, 1 year, and 2 years postoperatively.

**Results:** Thirty-four patients (40 eyes) with POAG were included in this study, including 20 men (22 eyes) and 14 women (18 eyes). Compared with the preoperative IOP, the postoperative IOP was significantly lower at each time point. The greatest reduction in IOP was 60.7% at 1 month after surgery. The BCVA was also significantly improved at each postoperative time point. The number of antiglaucomatous medications used by the patients was significantly lower postoperatively than preoperatively.

**Conclusion:** Ab interno trabeculotomy combined with cataract extraction is effective and safe for treatment of POAG.

## Keywords

Trabeculotomy, glaucoma, VISCO360<sup>®</sup>, cataract extraction, intraocular pressure, best-corrected visual acuity

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## Introduction

Glaucoma has been classified as the second most common cause of blindness by the World Health Organization. The number of patients with glaucoma worldwide is estimated to increase to 80 million by 2020.<sup>1</sup> Of these patients, 74% are expected to have primary open-angle glaucoma (POAG).<sup>1</sup> By 2040, the total number of patients with glaucoma worldwide will reach an estimated 111.8 million.<sup>2</sup> Reducing the intraocular pressure (IOP) is currently the only effective treatment for glaucoma. Trabeculectomy combined with antimetabolites remains the classic procedure in the surgical treatment of glaucoma. However, as a bleb-dependent procedure, trabeculectomy often fails because of scarring of the filtration passage and poor formation of functional filtration blebs.<sup>3</sup> Therefore, many glaucoma physicians seek non-bleb-dependent filtering techniques; i.e., new surgical methods that divert or restore normal aqueous humor pathways to drain aqueous humor or increase outflow from physiological pathways.

Trabeculotomy is a newly developed operation aimed at the level of Schlemm's canal and the trabecular meshwork. By expanding Schlemm's canal and cutting the trabecular meshwork and the inner wall of Schlemm's canal, a natural channel of aqueous humor outflow can be created. This operation can avoid the problems of conjunctival scarring and filtration bleb-related complications. Trabeculotomy is more in line with the characteristics of minimally invasive glaucoma surgery, giving it good prospects for clinical application.

In this study, we retrospectively analyzed the efficacy and safety of trabeculotomy using the VISCO360<sup>®</sup> Viscosurgical System (Sight Sciences, Inc., Menlo Park, CA, USA) combined with cataract extraction in patients with POAG. Our aim is to

report the surgical outcomes of this new procedure in a consecutive case series.

## Methods

This study was approved by the Ethics Committee of the Shandong Provincial Qianfoshan Hospital and was performed in accordance with the Helsinki Declaration. Written informed consent was obtained from all patients.

Patients who had POAG and underwent ab interno trabeculotomy combined with cataract extraction from January 2017 to June 2017 in the Department of Ophthalmology, Shandong Provincial Qianfoshan Hospital were included in this retrospective study. These patients either had insufficiently controlled IOP or could not tolerate long-term medication. The indication for cataract extraction was the presence of a visually significant cataract coexisting with glaucoma.

The exclusion criteria were types of glaucoma other than POAG, the presence of other intraocular diseases (e.g., lens dislocation or retinal detachment), and a history of eye surgery (e.g., antiglaucoma surgery or cataract surgery).

## Surgical procedures

All surgical procedures were performed by the same senior doctor. Ab interno trabeculotomy was performed after cataract extraction, and implantation of a hydrophobic acrylic foldable intraocular lens was successfully completed. A microcatheter was introduced into the anterior chamber by way of a single, self-sealing, 2.4-mm clear corneal incision made for cataract extraction. Using an anterior chamber angle mirror to determine the position of the trabecular meshwork, the VISCO360<sup>®</sup> cannula was aligned with the incision and inserted into Schlemm's canal for 360° expansion. As the microcatheter continued to exit the

anterior chamber, the trabecular meshwork and the inner wall of Schlemm's canal were cut for 360°.

### **Postoperative evaluation**

Best-corrected visual acuity (BCVA), IOP (Goldmann tonometer), the number of anti-glaucomatous medications, and complications were analyzed preoperatively and 1 week, 1 month, 3 months, 6 months, 1 year, and 2 years postoperatively. The efficacy endpoint was the mean reduction in IOP from baseline. Safety measures were the rate of adverse events (intraoperative and postoperative) and re-interventions to treat glaucoma. The criteria for success were a postoperative IOP of  $\leq 15$  mmHg (criterion A) or  $\leq 12$  mmHg (criterion B) without an increase in the number of IOP-lowering medications at or after 6 months of follow-up. IOP values measured within 3 months postoperatively were not considered to indicate surgical failure because the occurrence of postoperative IOP fluctuations after trabeculotomy is well known.<sup>4</sup> All decimal visual acuity values were converted to the logarithm of the minimum angle of resolution (logMAR) for analyses.

### **Statistical analysis**

The statistical analysis was performed using IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, NY, USA). The paired t-test was used to compare BCVA, IOP, and the number of antiglaucomatous medications before and after surgery. A  $P$  value of  $<0.05$  was considered statistically significant.

## **Results**

Thirty-four patients (40 eyes) with POAG were included in this study. The patients comprised 20 men (22 eyes) and 14 women (18 eyes) with a mean age of  $68 \pm 7.58$  years.

### **Preoperative and postoperative IOP**

The preoperative and postoperative IOP of the patients are shown in Table 1. Figure 1 shows the mean IOP at each follow-up time point, and the vertical lines represent the standard errors. The postoperative IOP at each time point was significantly different from the preoperative IOP ( $P < 0.05$ ). Compared with the preoperative results, the IOP was markedly lower at 1 week after the operation. The lowest IOP occurred 1 month after operation, and the reduction rate of IOP was 60.1%. The surgical success rate at 6 months and 2 years after surgery was 100% for criterion A and 65% for criterion B.

### **Preoperative and postoperative BCVA**

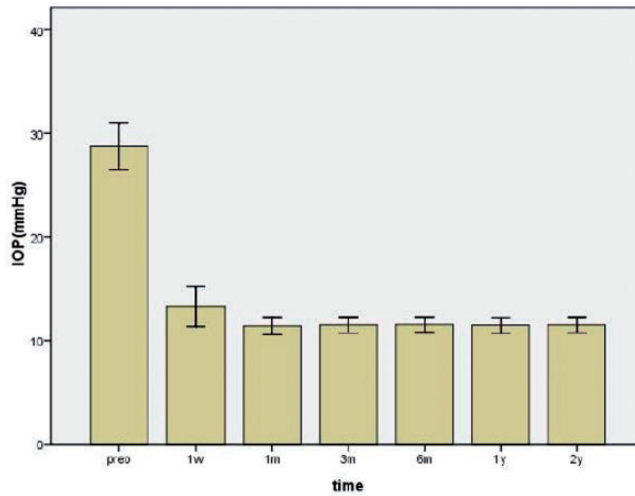
Preoperative and postoperative BCVA of the patients are shown in Table 2. Figure 2 shows the mean BCVA at each follow-up time point, and the vertical lines represent the standard errors. Compared with the preoperative BCVA, the BCVA was improved at each postoperative time point, and the difference was statistically significant ( $P < 0.01$ ). The best vision was achieved 3 months after the operation, and the patients' vision remained stable after 2 years of follow-up.

### **Preoperative and postoperative antiglaucomatous medications**

Table 3 shows the number of antiglaucomatous medications before and after surgery. Figure 3 shows the average number of antiglaucomatous medications used before and after surgery at each follow-up time point, and the vertical lines represent the standard errors. The number of antiglaucomatous medications was significantly lower after surgery than before surgery, and the difference was statistically significant ( $P < 0.01$ ). The patients were using the fewest IOP medications at 3 months postoperatively.

**Table 1.** Preoperative and postoperative intraocular pressure (mmHg).

	Preoperatively	1 week	1 month	3 months	6 months	1 year	2 years
Mean	28.75	13.3	11.4	11.5	11.5	11.5	11.5
Standard deviation	6.98	6.05	2.56	2.29	2.26	2.26	2.28
Minimum	15	7	7	8	8	8	8
Maximum	45	30	15	15	15	15	15
P		<0.01	<0.01	<0.01	<0.01	<0.01	<0.01

**Figure 1.** Preoperative and postoperative IOP.

IOP, intraocular pressure; preo, preoperatively; w, week; m, month; y, year.

**Table 2.** Preoperative and postoperative best-corrected visual acuity.

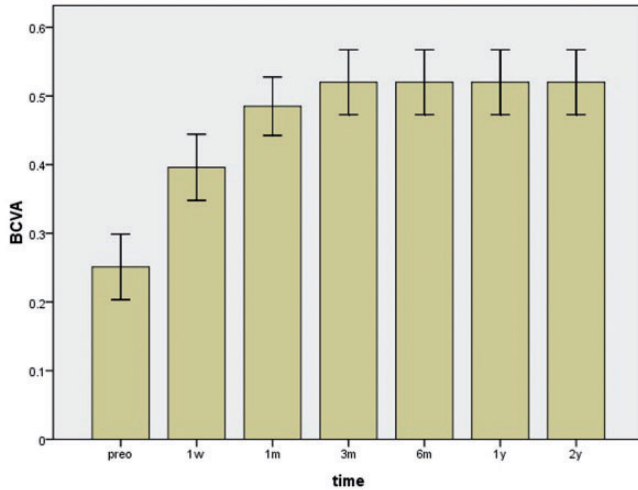
	Preoperatively	1 week	1 month	3 months	6 months	1 year	2 years
Mean	0.25	0.39	0.49	0.52	0.52	0.52	0.52
Standard deviation	0.14	0.15	0.13	0.15	0.15	0.15	0.15
Minimum	0.05	0.12	0.2	0.25	0.25	0.25	0.25
Maximum	0.5	0.6	0.6	0.8	0.8	0.8	0.8
P		<0.01	<0.01	<0.01	<0.01	<0.01	<0.01

The number of antiglaucomatous medications remained stable during the 2-year follow-up.

### Complications

One patient developed a small amount of anterior chamber hemorrhage during the

operation, and the blood absorbed within 1 day postoperatively. The postoperative complications examined in this study were hyphema, a shallow anterior chamber, choroidal detachment, endophthalmitis, lens subluxation, and hypotony (IOP of <5 mmHg). None of these postoperative complications developed in any eyes.



**Figure 2.** Preoperative and postoperative BCVA.

BCVA, best-corrected visual acuity; preo, preoperatively; w, week; m, month; y, year.

**Table 3.** Number of preoperative and postoperative antiglaucomatous medications.

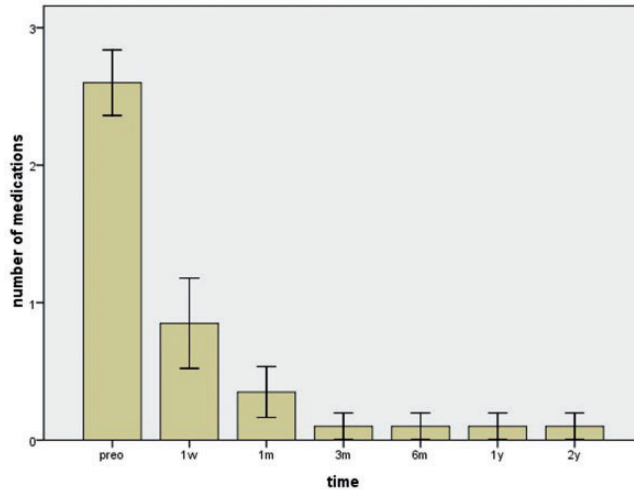
	Preoperatively	1 week	1 month	3 months	6 months	1 year	2 year
Mean	2.6	0.85	0.35	0.1	0.1	0.1	0.1
Standard deviation	0.73	1.01	0.57	0.3	0.3	0.3	0.3
Minimum	1	0	0	0	0	0	0
Maximum	4	3	2	1	1	1	1
<i>P</i>		<0.01	<0.01	<0.01	<0.01	<0.01	<0.01

## Discussion

Despite the new progress that has been made in the pathogenesis of glaucoma during the past few decades, surgeons still have few choices for the surgical treatment of glaucoma. Trabeculectomy is still considered the main treatment for glaucoma. Although the effect of trabeculectomy is good, it is associated with many complications such as filtration bleb scarring, late filtration bubble leakage, filtering blebitis, endophthalmitis, and low IOP.<sup>5</sup> To avoid complications of filtering surgery and reducing injuries, reconstructing the natural passage of aqueous humor outflow is the ultimate goal of glaucoma surgery. Establishing the aqueous humor outflow

channel is an important part of ab interno trabeculotomy and one of the most effective surgical procedures.

Structural changes of Schlemm's canal play an important role in the occurrence and development of glaucoma. Age and IOP are important factors that can influence the structure of Schlemm's canal. Ainsworth and Lee<sup>6</sup> found that the length of the inner wall of Schlemm's canal decreased with age. By observing specimens of trabecular tissue removed from patients with glaucoma, Lee<sup>7</sup> found that a small stenosis of Schlemm's canal was present in 50% of cases. Allingham et al.<sup>8</sup> found that the length of Schlemm's canal and the inner wall were significantly smaller in eyes with



**Figure 3.** Number of preoperative and postoperative antiglaucomatous medications. preo, preoperatively; w, week; m, month; y, year.

than without glaucoma. A study of the effect of IOP on the diameter of Schlemm's canal showed that when the IOP increased, the lumen of Schlemm's canal narrowed, and the trabecular meshwork protruded into the lumen of Schlemm's canal;<sup>8,9</sup> at 40 mmHg (1 mmHg=0.133 kPa), most of Schlemm's canal collapsed.<sup>10</sup> Narrowing or collapse of Schlemm's canal is not only caused by an increase in IOP but also reduces the outflow of aqueous humor, resulting in a further increase in IOP. In this study, by expanding Schlemm's canal and cutting the trabecular meshwork and the inner wall of Schlemm's canal, we removed obstacles at the level of the trabecular meshwork, facilitating treatment of POAG. Through the preliminary clinical observation in this study, we found that ab interno trabeculotomy combined with cataract extraction achieved the expected purposes: internal drainage, non-filtering bleb dependence, and stable surgical results. Three months after surgery, the mean IOP was  $11.5 \pm 2.28$  mmHg, which was 60.1% lower than that before surgery, and the

IOP was stable until 2 years after surgery. Khaimi<sup>11</sup> showed that when phacoemulsification was combined with canaloplasty and successful suture placement, 27 eyes had a 42% mean decrease in IOP ( $23.5 \pm 5.2$  to  $13.6 \pm 3.6$  mmHg). However, the postoperative IOP was lower in the present study, and the IOP was reduced to a greater extent, reaching 60.1%. Although intraoperative sutures are used to expand Schlemm's canal and simple canaloplasty stretched the trabecular meshwork, the maintenance time is limited, and the long-term effect of reducing the IOP may be affected. Compared with simple canaloplasty, the procedure in this study removed the inner wall of Schlemm's canal and part of the trabecular meshwork, directly removing the main resistance of the aqueous humor outflow. The outflow of aqueous humor does not depend on the trabecular meshwork. Better IOP reduction and a higher long-term success rate can be achieved. Bao et al.<sup>12</sup> reported that after 6 years of follow-up, the success rate of trabeculotomy was 44%. The criterion for success was defined as IOP of <16 mmHg.

The follow-up time in the present study was 2 years. With extension of the follow-up time, the development of adhesions in the surgical area and changes in the success rate can be further verified in future studies.

For patients with glaucoma, there is a significant benefit in reducing the number of medications used to lower IOP. Long-term use of IOP-lowering drugs can cause damage to the ocular surface and increase the patient's economic burden;<sup>13–16</sup> it can also increase the chance of failure of filtration surgery.<sup>17</sup> In the present study, the mean number of preoperative antiglaucomatous medications was  $2.6 \pm 0.73$ , and the mean number of antiglaucomatous medications 3 months after surgery was  $0.1 \pm 0.3$ . The number of antiglaucomatous medications decreased by 96.2% 3 months after surgery. No new type of antiglaucomatous medication increased during the 2-year follow-up. This operation can effectively reduce the number of antiglaucomatous medications that are used in the long term.

Cataract is the most common eye disease in the elderly population. Approximately 33% of patients worldwide are affected by blindness due to cataracts.<sup>18</sup> In patients with glaucoma, cataract surgery can more effectively reduce the IOP and the number of antiglaucomatous drugs.<sup>19–21</sup> Because elderly patients may have difficulties traveling frequently for hospital visits, they can be good candidates for trabeculotomy.<sup>22</sup> In this study, the mean BCVA before surgery was  $0.25 \pm 0.15$ , and that 3 months postoperatively was  $0.52 \pm 0.15$  ( $P < 0.01$ ). The patients' visual acuity remained stable 2 years after surgery. This study demonstrated that ab interno trabeculotomy can be safely and effectively performed in combination with cataract extraction.

The results of this study showed that few postoperative complications occurred, and only one patient developed a small amount of anterior hemorrhage that was absorbed 1 day after surgery. Therefore, the results of

this study indicate that ab interno trabeculotomy combined with cataract extraction is a safe procedure for patients.

Our data indicate that ab interno trabeculotomy combined with cataract extraction can be successfully performed in patients with POAG to facilitate aqueous humor outflow. After surgery, an ideal IOP was obtained and the number of antiglaucomatous medications was reduced. Because of its better IOP control and a lower rate of severe complications, ab interno trabeculotomy should undergo widespread utilization as a preferred surgical technique for POAG.

This study had certain limitations. It was a single-center with a relatively small sample size. Both eyes of some patients were included in the analysis when both eyes met the eligibility criteria. This is a potential confounder because of the lack of independence and should be considered in the interpretation of the results. Another limitation is the lack of morphological evaluation, such as assessment of postoperative changes in the surgical area. This was a retrospective and noncomparative case series, and the impact of cataract extraction on IOP cannot be ruled out.<sup>23</sup> The results should be verified through future prospective randomized clinical controlled studies. Despite these limitations, we believe that this study provides important new insights into novel, less invasive canal reconstruction approaches to treat POAG.

### Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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