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Two-year outcomes of ab interno trabeculectomy with the Trabectome for Chinese primary open angle glaucoma: a retrospective multicenter study

Authors: Yalong Dang, [1,2,3,#] Xiao Wang, [1,#] Yujie Cen, [1] Ying Hong, [1,2] Ping Huang, [1] Nils Loewen, [2] Chun Zhang[1]

# these authors contributed equally to this work.

Affiliations:

1. Department of Ophthalmology, Peking University Third Hospital, Beijing, China

2. Department of Ophthalmology, University of Pittsburgh, Pittsburgh, Pennsylvania, USA

3. Department of Ophthalmology, Sanmenxia Central Hospital, Henan University of Science and Technology, Henan, China

*** Corresponding author:**

Chun Zhang

49 Huayuan N Rd, Haidian District,

Beijing 100191, China

Email: zhangc1@yahoo.com

Phone: 86-010-82266699

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Abstract

To evaluate the 2-year efficacy and safety of ab interno trabeculectomy with the Trabectome in Chinese primary open-angle glaucoma (POAG) patients. This was a multicenter, retrospective study and included POAG patients with or without visually-significant cataracts. The primary outcome was intraocular pressure (IOP) reduction. Secondary outcomes included reduction of glaucoma medications, surgical complications, and success at 2-years. Success was defined as: 1) IOP < 21 mmHg and at least 20% IOP reduction from baseline after 3 months at any two consecutive visits, and 2) no additional glaucoma surgery required. A total of 42 patients were enrolled; thirteen had a history of failed glaucoma surgery. Twelve patients underwent Trabectome surgery combined with phacoemulsification while the remainder underwent Trabectome surgery alone. Overall, the mean preoperative IOP was 21.4±1.23 mmHg. The Trabectome lowered IOP to 18.5± 0.94 mmHg at 2 years (P<0.05). The number of glaucoma medications also decreased from a baseline of 2.0±0.9 to 1.2± 0.21 at 2 years (P=0.04). The overall success was 78%, with patients undergoing combined surgery having a higher success than those with Trabectome surgery alone (100% vs. 76%). No major complications were seen. The Trabectome appears to be an efficient and safe procedure in Chinese POAG patients in the long-term.

Keywords: primary open-angle glaucoma; minimally invasive glaucoma surgery; ab interno trabeculectomy; intraocular pressure; success rate

Introduction

Primary open-angle glaucoma (POAG) is a leading cause of irreversible blindness[1], affecting more than 40 millions of people worldwide[2]. Intraocular pressure (IOP) is the only modifiable risk factor for POAG[3]. Traditional trabeculectomy and tube-shunt surgery efficiently reduce IOP in patients with moderate to advanced glaucoma but have a high incidence of complications[4,5] and surgical failure in the long-term[6]. In

contrast, microincisional glaucoma surgery provides a safe IOP reduction with a short recovery time[7], has become an ideal option for early to moderate POAG[8].

Most minimally invasive glaucoma surgeries can be combined with cataract surgery through an ab interno approach. These procedures reduce IOP by different mechanisms: 1) ablate or bypass the trabecular meshwork (TM) using instruments such as the Trabectome (Neomedix Corporation, Tustin, CA, USA)[9–11], iStent (Glaukos Corp., Laguna Hills, CA, USA)[12], or the Hydrus mini-stent (Ivantis Inc., Irvine, CA, USA)[13]; 2) establish a new route for suprachoroidal drainage (CyPass Micro-Stent; Transcend Medical, Menlo Park, CA, USA[14]; 3) reduce the production of aqueous humor[15]; or 4) create a subconjunctival filtration route [16]. Developed by Neomedix (Tustin, CA, USA) more than a decade ago[9], the Trabectome ablates 60–120 degrees of TM and the inner wall of Schlemm's canal by high-frequency electrosurgery [17]. The Trabectome provides active irrigation and aspiration, which maintains better stability and temperature in the anterior chamber, compared with passive chamber management [18]. No hypotony or bleb-related complications occur[10,11,19,20].

First introduced in China in 2013, the Trabectome shows promise for open-angle glaucoma patients[19,21]. Our previous study suggested that Trabectome surgery significantly reduced IOP from a baseline of 22.5 ± 8.1 mm Hg to 17.6 ± 6.4 mm Hg 1 year postoperatively[19], while the number of glaucoma medications was reduced by 40.0% with no major complications [19]. However, in that study, we included different types of open-angle glaucomas, which might have different responses [10,22]. Also, the follow-up in that study was only 1 year. The aim of the current study was to evaluate the 2-year efficacy and safety of ab interno trabeculectomy with the Trabectome in Chinese POAG patients.

Methods

This was a multicenter, retrospective, observational study approved by the Institutional Review Board of Peking University Third Hospital in compliance with the Declaration of Helsinki. The need for patient informed consent was waived. POAG patients undergoing Trabectome surgery included those with or without visually-significant cataract except those who: 1) has concurrent keratitis, conjunctivitis or uveitis in the study eye, and, 2) has other abnormalities preventing reliable applanation tonometry, and, 2) had a follow-up of less than 3 months.

The Trabectome surgery was performed as we described previously [10,19]. IOP was measured by Goldmann applanation tonometry. The target IOP was determined individually by the treating physician. Patients with a visually-significant cataract underwent phacoemulsification after the Trabectome surgery. Visual field defects were categorized as mild, moderate, and advanced based on Humphrey visual field testing. Gonioscopy, Snellen visual acuity, and stereoscopic optic nerve evaluation were performed routinely before surgery.

The primary outcome was IOP reduction, while the secondary outcomes included reduced number of glaucoma medications, surgical complications, and 2-year success rate. Success was defined as: 1) IOP < 21 mm Hg and at least 20% IOP reduction from baseline after 3 months at any two consecutive visits, and 2) no additional glaucoma surgery required.

Quantitative data were presented as mean ± standard error and were statistically analyzed using R (statistical package version 3.0.0, Free Software Foundation, Boston, MA, USA) [23]. The Wilcoxon's test was used to compare postoperative IOPs and the number of glaucoma medications with their respective baseline values. We computed Kaplan-Meier curves and compared them using the log-rank test. We could not determine the risk factors associated with Trabectome surgery failure by logistic regression because of the small sample size. A p-value ≤ 0.05 was considered statistically significant.

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Results

After excluding 2 cases without postoperative information, a total of 42 POAG patients from three independent glaucoma centers (Peking University Third Hospital, Beijing Tongren Hospital, and Peking University People's Hospital) were enrolled in this study. Patients' demographics and characteristics are summarized in **Table 1**. The mean age was 55 ± 21 years, and more patients were male. Half of the patients had preoperative best-corrected visual acuity better than 20/40; 76% of these patients (n=32) were phakic and 12 underwent combined surgery of Trabectome and phacoemulsification. Thirteen patients with a history of previous failed glaucoma surgery were considered complicated cases, and had previously undergone trabeculectomy (n=10), or Trabectome (n=2) or tube-shunt surgery (n=1) (**Table 1**).

Table 1. Demographics

	Primary open angle glaucoma (n=42)
Age (years)	
Mean±SD	55±21
Range	19 - 87
Gender	
Female	11/42 (26%)
Male	31/42 (74%)
Pre-Op Snellen visual acuity	
>20/20	0/42 (0%)
20/20-20/40	21/42 (50%)
20/50-20/70	6/42 (14%)
20/80-20/100	4/42 (10%)
20/200-20/400	5/42 (12%)
<20/400	1/42(2%)
NR	6/42 (14%)
Visual field	
Mild	6/42 (14%)
Moderate	9/42 (21%)

Advanced	11/42 (26%)
MD/Other	16/42 (38%)
Disc C/D ratio	
<0.7	6/42 (14%)
0.7 to 0.8	20/42 (48%)
>0.8	13/42 (31%)
NR	3/42 (7%)
Lens Status	
Phakic	32/42 (76%)
Pseudophakic	4/42 (10%)
Aphakic	0/42 (0%)
NR	6/42 (14%)
Shaffer angle grade	
I	0/42 (0%)
II	0/42 (0%)
III	0/42 (0%)
IV	26/42 (62%)
NR	16/42 (38%)
Prior glaucoma surgery	
SLT	0/42 (0%)
ALT	0/42 (0%)
Shunt	1/42 (2%)
Trabeculectomy	10/42 (24%)
Trabectome	2/42 (5%)
Surgery combination	
Trabectome + Phaco	12/42 (29%)
Trabectome alone	30/42 (71%)

Mean preoperative IOP was 21.4 ± 1.23 mm Hg, and on the first day post-surgery, the mean value dropped to its lowest value of 15.5 ± 1.06 mm Hg ($P<0.01$, compared with baseline). Then, mean IOP increased slightly but remained statistically lower than baseline value throughout the study (all comparisons, $P<0.05$) (**Fig. 1**).

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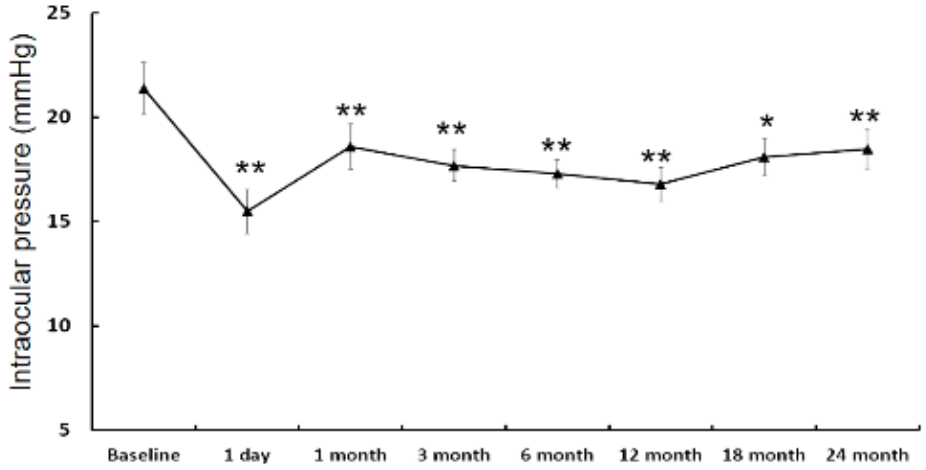

Figure 1. Intraocular pressure reduction. A total of 42 POAG patients were enrolled in this study. Mean preoperative intraocular pressure (IOP) was 21.4 ± 1.23 mm Hg. After Trabectome™, mean IOP decreased significantly to its lowest value of 15.5± 1.06 mm Hg on the first postoperative day (P<0.01), then increased slightly but remained statistically lower than baseline throughout the study (all comparisons, P<0.05). Wilcoxon's test was used to compare postoperative IOPs with baseline values. * and ** indicate *P*<0.05 and *P*<0.01, respectively.

Trabectome surgery also decreased patients' number of glaucoma medications from a baseline of 2.0 ± 0.9 to 0.5 ± 0.7 on the first postoperative day. At the last follow-up at 24 months, the number of glaucoma medications was still significantly lower than baseline (P=0.04) (**Fig. 2**).

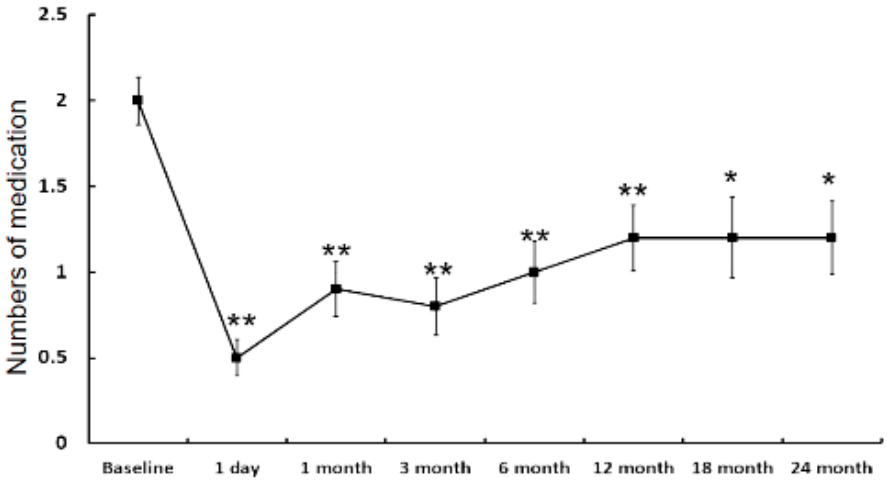

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Figure 2. Reduction in the number of glaucoma medications. Trabectome™ dramatically decreased the number of glaucoma medications from a baseline of 2.0 ± 0.9 to 1.2 ± 0.21, 2 years postoperatively (P=0.04). Wilcoxon's test was used to compare the number of postoperative glaucoma medications with the number at baseline. * and ** indicate P<0.05 and P<0.01, respectively.

Based on the success criteria (IOP ≤ 21 mmHg and > 20% IOP reduction from baseline without additional glaucoma surgery), the overall success rate was 78% at 24 months (**Fig. 3**). Patients undergoing combined Trabectome surgery and phacoemulsification (n=12) had a higher success rate than did those undergoing Trabectome surgery alone (n=30) (100% vs. 76%, respectively). Patients who underwent prior Trabectome surgery (n=2) achieved their target IOP at 24 months while 2/10 patients undergoing previous trabeculectomy suffered surgical failure; one patient at 9 months and one at 15 months.

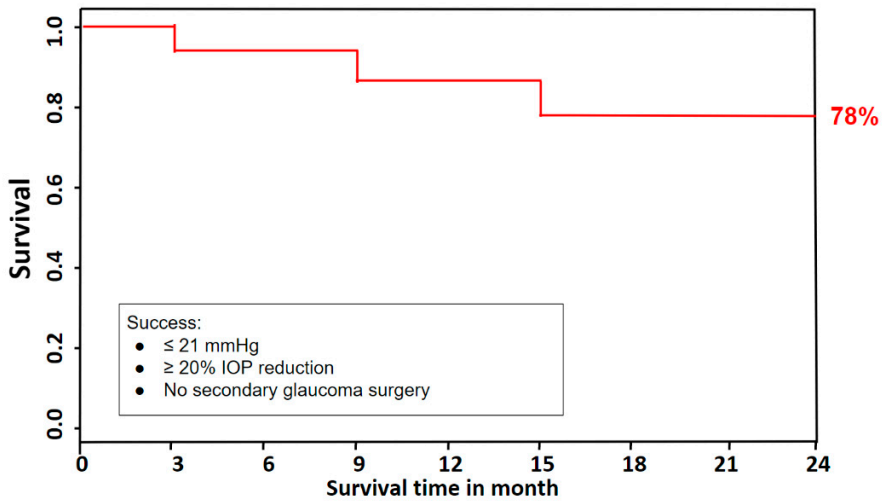

Figure 3. Two-year success rate. Applying the success criteria, defined as IOP < 21 mm Hg and at least 20% IOP reduction from baseline without secondary glaucoma surgery at any two consecutive visits, the overall success rate was 78% at 24 months. Kaplan-Meier curves were used for survival analysis.

By the end of the 24-month follow-up, one patient had undergone repeat Trabectome surgery at 6 o'clock and four patients had undergone EX-PRESS (Alcon Laboratories, Inc., Fort Worth, TX, USA) shunt implantation. All

patients had achieved their IOP goals at the last visit. No vision-threatening complications were encountered, and no patients experienced visual acuity loss of more than two lines **(Table 2)**.

Table 2. Postoperative observations.

	Numbers of patient	%
Secondary glaucoma surgery	5	12%
Sustained hypotony (IOP < 5 mmHg)	0	0%
Aqueous misdirection	0	0%
Infection	0	0%
Bleb formation	0	0%
Wound leaks	0	0%
Problematic pain	0	0%
Choroidal effusion	0	0%
Choroidal hemorrhage	0	0%

Discussion

TM is a complex multilayer structure that regulates aqueous outflow in a pressure dependent fashion[24]. In glaucomatous eyes, diseased TM has a reduced facility and shows reduced phagocytosis[25,26], increased stiffness[27], and stress fiber formation[26]. Either removing TM surgically[28] or rehabilitating TM function by stem cells[29] can restore normal outflow and decrease IOP in previous studies. In the current study, our results showed that ab interno trabeculectomy with the Trabectome efficiently reduced IOP and the number of glaucoma medications with an overall success rate of 76% during a 2-year follow-up. No major complications were seen highlighting the safety aspects of this procedure.

Open-angle glaucoma (except neovascular glaucoma) is the main indication for ab interno trabeculectomy with the Trabectome. A retrospective cohort study by Jordan et al showed that IOP decreased from a mean baseline of 24 ± 5.5 mm Hg to 18 ± 6.1 mm Hg 204 days after Trabectome surgery for a consecutive 261 POAG patients[30]. The authors' results were similar to our findings as well as those of a meta-analysis by Chow and

colleagues[31]. In POAG, the Trabectome has comparable or better IOP-lowering effects on secondary open-angle glaucoma, depending on the preoperative IOP. Akil et al found that with similar preoperative values, IOP reduction in pigmentary glaucoma cases was similar to that in POAG[22]. In our previous studies, patients with pseudoexfoliative- and steroid-induced glaucoma with higher preoperative IOP finally obtained more IOP reduction than age- and gender-matched POAG controls[10,32,33]. Even though preoperative IOP was higher in these patients, the overall success rate was unchanged[10,22,34,35] or even better[34,36] than for POAG patients. This is likely because the causes of secondary open-angle glaucoma are mostly TM-related diseases while POAG has a more complicated mechanism, including dysfunction of downstream outflow tracts.

In this study, 12 patients underwent Trabectome surgery combined with phacoemulsification. All of these patients achieved the success criteria at the 2-year follow-up, in contrast with only 76% in the Trabectome only group. This is consistent with previous findings by other groups showing that combined surgery has a lower risk of failure than for Trabectome alone[33,37]. However, it is worth noting that a higher success rate in patients undergoing combined surgery does not mean a greater IOP reduction. In fact, patients undergoing combined surgery consistently have less IOP reduction compared with the Trabectome only group because of the low preoperative IOP in the combined group[7,32,33,36,37]. A recent study by Tojo et al suggested that a low preoperative IOP and combined surgery contribute to success with the Trabectome[37].

Trabectome was once thought suitable only for mild or moderate glaucoma. Our previous studies indicated that patients with higher glaucoma severity achieved greater IOP reduction[11,38]. In the current study, we included 10 patients with advanced POAG and a history of previous trabeculectomy. Eight of these patients met the success criteria at the end of the 24-month follow-up. In another study, Wecker et al found that the Trabectome efficiently decreased IOP in patients with previously failed trabeculectomy from 24.5 ± 3.5 mm Hg to 15.7 ± 3.4 mm Hg (36% reduction) over 415 days' observation[39].

Reducing the number of medications is another benefit of Trabectome surgery; 0.99 ± 0.54 fewer medications are expected following Trabectome alone and 0.76 ± 0.35 fewer medications following Trabectome combined with phacoemulsification[7]. Consistent with our previous work[19], the POAG patients in this study obtained an average of 0.8 fewer medications (40% reduction) compared with baseline.

Similar to other microincisional glaucoma procedures, Trabectome surgery has a desirable safety profile. The most common complication is transient blood reflux[40] and transient hypotony (< 5 mm Hg)[22], which usually spontaneously resolves within a few days of surgery. Less than 1% vision-threatening complications were reported[7], including one case of endophthalmitis[41], and four cases of aqueous misdirection[28,30,42,43]. Previous studies suggested approximately 6.1% to 34.9% of patients required a secondary glaucoma surgery[34,36,39]. In this study, no serious complications were seen, and only five patients underwent additional glaucoma surgery; one patient underwent repeat Trabectome surgery and four underwent a lumenal control glaucoma filtration device (EX-PRESS, Alcon Laboratories, Inc., Fort Worth, TX, USA) implantation.

This study has several limitations. First, the small sample size was insufficient to determine the risk factors associated with Trabectome failure by logistic regression. Second, we focused on IOP reduction but not on restoration or improved visual function. A recent study by Caprioli et al indicated that trabeculectomy might reverse the glaucomatous dysfunction of retinal ganglion cells and their central projections[44].

In conclusion, our data suggested that ab interno trabeculectomy with the Trabectome is an efficient and safe procedure in Chinese POAG patients in the long-term. In future, a large-sample-size clinical trial with more visual function evaluations are desired to address the limitations of our study.

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Ethical Statement

This study was approved by the Institutional Review Board of Peking University Third Hospital in compliance with the Declaration of Helsinki. Because of the retrospective study design, the informed consent from patient was not required.

Author Contributions

Yalong Dang: data acquisition, data analysis, figure creation, manuscript preparation, manuscript review; Xiao Wang: data acquisition, data analysis; Yujie Cen: data acquisition, data analysis; Ping Huang: data acquisition, data analysis, manuscript preparation; Ying Hong: data acquisition, data analysis; Chun Zhang: funding, study design, data acquisition, data analysis, manuscript preparation, manuscript review. Nils Loewen: manuscript preparation, manuscript review.

Conflicts of Interest

N.A.L. has received honoraria for wet labs and lectures from Neomedix Inc. All other authors declared no conflict of interests.

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