

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

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Received: 2017-12-18 Accepted: 2018-04-28

## Abstract

• **AIM:** To evaluate the 2-year efficacy and safety of ab interno trabeculectomy with the Trabectome in Chinese primary open angle glaucoma (POAG) patients.

• **METHODS:** This was a multicenter, retrospective, observational study and included POAG patients with or without visually-significant cataracts. The Chinese patients were enrolled from three glaucoma centers and a group of comparable Japanese POAG patients was analyzed from our international Trabectome database. The patients received Trabectome or a combined surgery with phacoemulsification and intraocular lens implantation. The primary outcome was intraocular pressure (IOP) reduction. Secondary outcomes included reduction of glaucoma medications, surgical complications, and success at 2y. Success was defined as: 1) IOP $\leq$ 21 mm Hg and at least 20% IOP reduction from baseline after 3mo at any two consecutive visits; 2) no additional glaucoma surgery required.

• **RESULTS:** A total of 42 Chinese POAG patients from three glaucoma centers were enrolled. Twelve patients underwent Trabectome surgery combined with phacoemulsification and intraocular lens implantation while the remainder underwent Trabectome surgery alone. Thirteen patients had a history of failed glaucoma surgery and were

considered as complicated cases. In China data, the mean preoperative IOP was 21.4 $\pm$ 1.23 mm Hg. The Trabectome lowered IOP to 17.9 $\pm$ 1.8 mm Hg at 2y ( $P=0.05$ ). The number of glaucoma medications also decreased significantly from a baseline of 2.0 $\pm$ 0.9 to 1.1 $\pm$ 0.8 at 2y post-surgery ( $P=0.04$ ). The overall 2-year success rate was 78%, with patients undergoing combined surgery having a higher success rate compared with those undergoing Trabectome surgery alone (100% vs 76%). In Japan data, the mean preoperative IOP was 20.8 $\pm$ 7.7 mm Hg. The Trabectome lowered IOP to 12.20 $\pm$ 2.0 mm Hg at 2y. The number of glaucoma medications also decreased significantly from a baseline of 2.1 $\pm$ 0.9 to 3.4 $\pm$ 0.6 at 2y post-surgery. In all patients, no major complications were seen.

• **CONCLUSION:** Surgery with 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 surgeries; intraocular pressure; surgical complications

DOI:10.18240/ijo.2018.06.08

**Citation:** Dang YL, Wang X, Dai WW, Huang P, Loewen NA, Zhang C, China Trabectome Study Group, International Trabectome Study Group. Two-year outcomes of ab interno trabeculectomy with the Trabectome for Chinese primary open angle glaucoma: a retrospective multicenter study. *Int J Ophthalmol* 2018;11(6):945-950

## INTRODUCTION

Primary open angle glaucoma (POAG) is a leading cause of irreversible blindness<sup>[1]</sup>, affecting more than 40 millions of people worldwide<sup>[2]</sup>. Intraocular pressure (IOP) is the only modifiable risk factor for POAG<sup>[3]</sup>. Traditional trabeculectomy and tube-shunt surgery efficiently reduce IOP in patients with moderate to advanced glaucoma but have a high incidence of complications<sup>[4-5]</sup> and surgical failure in the long-term<sup>[6]</sup>. In contrast, microincisional glaucoma surgery provides a safe IOP reduction with a short recovery time<sup>[7]</sup> has become an ideal option for early to moderate POAG<sup>[8]</sup>.

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)<sup>[9-11]</sup>, iStent (Glaukos Corp, Laguna Hills, CA, USA)<sup>[12]</sup>, or the Hydrus mini-stent (Ivantis Inc., Irvine, CA, USA)<sup>[13]</sup>; 2) establish a new route for suprachoroidal drainage (CyPass Micro-Stent; Transcend Medical, Menlo Park, CA, USA)<sup>[14]</sup>; 3) reduce the production of aqueous humor<sup>[15]</sup>; or 4) create a subconjunctival filtration route<sup>[16]</sup>. Developed by Neomedix (Tustin, CA, USA) more than a decade ago<sup>[9]</sup>, Trabectome ablates 60-120 degrees of TM and the inner wall of Schlemm's canal by high-frequency electrosurgery<sup>[17]</sup>. Trabectome provides active irrigation and aspiration, which maintains better stability and temperature in the anterior chamber, compared with passive chamber management<sup>[18]</sup>. No hypotony or bleb-related complications occur<sup>[10-11,19-20]</sup>.

First introduced in China in 2013, Trabectome shows promise for open angle glaucoma patients<sup>[19,21]</sup>. 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 at 1y postoperatively<sup>[19]</sup>, while the number of glaucoma medications was reduced by 40.0% with no major complications<sup>[19]</sup>. However, in that study, we included different types of open-angle glaucomas, which might have different responses<sup>[10,22]</sup>. Also, the follow-up in that study was only 1y. 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.

### SUBJECTS AND 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) had concurrent keratitis, conjunctivitis or uveitis in the study eye; 2) had other abnormalities preventing reliable applanation tonometry, and had a follow-up of less than 3mo.

Trabectome surgery was performed as we described previously<sup>[10,19]</sup>. Briefly, a 1.6-mm iris parallel clear corneal incision was made at the temporal side. After the insertion of the Trabectome tip into the anterior chamber, the eye was pressurized with active irrigation. The gonioscope was then placed on the cornea, and the TM was engaged with the instrument at a 45° upward angle to facilitate the best visualization to the surgeon. A total of 120°-180° of the nasal TM was ablated for each patient. After removal of the TM debris, a few viscoelastic materials were injected to minimize postoperative hyphema. The patients with visually significant

cataracts received phacoemulsification with intraocular lens implantation immediately after Trabectome. The patients were followed up at 1d, 1wk, 1, 3, 6, 12, 18, and 24mo. 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 defined as by Hodapp-Parrish-Anderson criteria<sup>[23]</sup>. 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 3mo at any two consecutive visits; 2) no additional glaucoma surgery required.

**Statistical Analysis** Quantitative data were presented as mean±standard deviation and were statistically analyzed using R (statistical package version 3.0.0, Free Software Foundation, Boston, MA, USA)<sup>[24]</sup>. 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.

### 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. A group of comparable Japanese POAG patients was analyzed from our international Trabectome database. Patients' demographics and characteristics are summarized in Table 1. In China data, the mean age was 55±21y, and most of 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).

In China data, the mean preoperative IOP was 21.4±1.23 mm Hg, and at one year post-surgery, the mean value dropped to the lowest value of 16.5±2.8 mm Hg (*P*<0.01, compared with baseline). Then, mean IOP increased slightly but remained statistically lower than baseline value throughout the study

Parameters	n (%)	
	China group (n=42)	Japan group (n=35)
Age, mean±SD (range), y	55±21 (19-87)	63±9 (21-92)
Gender (F/M)	11/31	14/21
Preop. Snellen acuity		
>20/20	0 (0)	5 (14)
20/20-20/40	21 (50)	15 (43)
20/50-20/70	6 (14)	4 (11)
20/80-20/100	4 (10)	1 (3)
20/200-20/400	5 (12)	0 (0)
<20/400	1 (2)	0 (0)
NR	6 (14)	10 (29)
VF		
Mild	6 (14)	3 (9)
Moderate	9 (21)	11 (31)
Advanced	11 (26)	10 (29)
NR	16 (38)	11 (31)
Disc C/D		
<0.7	6 (14)	4 (11)
0.7 to 0.8	20 (48)	6 (18)
>0.8	13 (31)	11 (31)
NR	3 (7)	14 (40)
Prior surgeries		
SLT/ALT/LI/ECP	0 (0)	0 (0)
Trabeculectomy/trabeculotomy	10 (24)	3 (9)
Trabectome	2 (5)	0 (0)
Shunt	1 (2)	0 (0)
Retina surgery	0 (0)	0 (0)
Combined surgeries		
Trabectome+phaco	12 (29)	12 (34)
Trabectome only	30 (71)	23 (66)

SD: Standard deviation; NR: Not recorded; VF: Visual field; SLT: Selective laser trabeculoplasty; ALT: Argon laser trabeculoplasty; IL: Laser iridectomy; ECP: Endoscopic cyclophotocoagulation.

(all comparisons,  $P<0.05$ ; Table 2). Trabectome surgery also decreased patients' number of glaucoma medications from a baseline of  $2.0\pm 0.9$  to  $1.1\pm 0.9$  at one year. At the last follow-up at 24mo, the number of glaucoma medications was still significantly lower than baseline ( $P=0.04$ ; Table 2).

Based on the success criteria (IOP $\leq$ 21 mm Hg and >20% IOP reduction from baseline without additional glaucoma surgery), the overall success rate of China data was 78% at 24mo. Chinese 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; Figure 1). Patients who underwent prior Trabectome surgery ( $n=2$ ) achieved their target IOP at 24mo while 2/10 patients undergoing previous trabeculectomy suffered surgical failure; one patient at 9mo and one at 15mo. In China group, by the end of the 24mo follow-up, one patient had undergone repeat Trabectome surgery at 6 o'clock and

Table 2 Wilcoxon test were applied by comparing IOP and number of medications between two groups

Parameters	China group	Japan group	P
IOP			
Baseline	21.4±1.23 (42)	20.8±7.7 (35)	
1mo	17.8±6.7 (41)	14.5±4.2 (34)	0.01
3mo	17.0±3.8 (23)	14.1±4.1 (28)	0.01
6mo	17.1±3.2 (20)	13.8±3.6 (20)	<0.01
9mo	16.7±2.5 (19)	13.6±3.5 (17)	<0.01
12mo	16.5±2.8 (17) <sup>a</sup>	14.3±3.7 (17)	0.08
18mo	17.8±2.6 (14)	13.5±2.5 (8)	<0.01
24mo	17.9±1.8 (11) <sup>b</sup>	12.0±2.0 (5)	<0.01
No. of medication			
Baseline	2.0±0.9 (42)	2.1±0.9 (35)	
1mo	0.8±0.9 (41)	1.7±1.5 (34)	<0.01
3mo	0.7±0.9 (23)	1.9±1.3 (31)	<0.01
6mo	0.8±0.9 (20)	2.4±1.2 (20)	<0.01
9mo	1.0±0.9 (19)	2.4±1.2 (17)	<0.01
12mo	1.1±0.9 (17)	2.3±1.2 (17)	<0.01
18mo	0.9±0.7 (14)	2.5±1.1 (8)	<0.01
24mo	1.1±0.8 (11) <sup>c</sup>	3.4±0.6 (5)	<0.01

<sup>a</sup> $P<0.01$ , <sup>b</sup> $P<0.05$ , <sup>c</sup> $P=0.04$  vs Baseline.

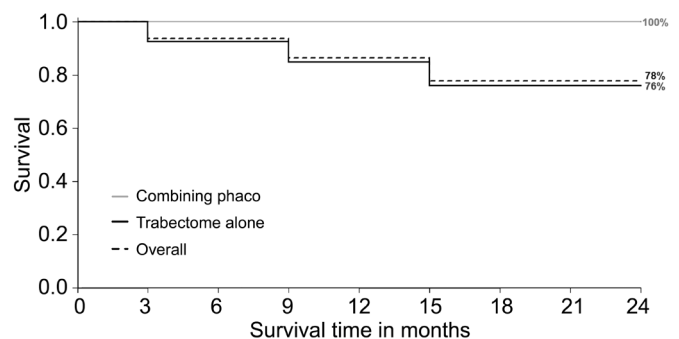


Figure 1 Two-year success rate Applying the success criteria, the overall success rate of China data was 78% at 24mo. Kaplan-Meier curves were used for survival analysis.

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 and bleb-related complications were encountered, and no patients experienced visual acuity loss of more than two lines.

## DISCUSSION

TM is a complex multilayer structure that regulates aqueous outflow in a pressure dependent fashion<sup>[25]</sup>. In glaucomatous eyes, diseased TM has a reduced facility and shows reduced phagocytosis<sup>[26-27]</sup>, increased stiffness<sup>[28]</sup>, and stress fiber formation<sup>[27]</sup>. Either removing TM surgically<sup>[29]</sup> or

rehabilitating TM function by stem cells<sup>[30]</sup> 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 78% 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*<sup>[31]</sup> showed that IOP decreased from a mean baseline of 24±5.5 to 18±6.1 mm Hg 204d after Trabectome surgery for a consecutive 261 POAG patients. The authors' results were similar to our findings as well as those of a Meta-analysis by Chow *et al*<sup>[32]</sup>. In POAG, the Trabectome has comparable or better IOP-lowering effects on secondary open-angle glaucoma, depending on the preoperative IOP. Akil *et al*<sup>[22]</sup> found that with similar preoperative values, IOP reduction in pigmentary glaucoma cases was similar to that in POAG. 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<sup>[10,33-34]</sup>. Even though preoperative IOP was higher in these patients, the overall success rate was unchanged<sup>[10,22,35-36]</sup> or even better<sup>[35,37]</sup> 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 2y 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<sup>[34,38]</sup>. 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<sup>[7,33-34,37-38]</sup>. A recent study by Tojo *et al*<sup>[38]</sup> suggested that a low preoperative IOP and combined surgery contribute to success with the Trabectome.

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<sup>[11,39]</sup>. 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 24mo follow-up. In another study, Wecker *et al*<sup>[40]</sup> found that the Trabectome efficiently decreased IOP in patients with

previously failed trabeculectomy from 24.5±3.5 to 15.7±3.4 mm Hg (36% reduction) over 415d observation.

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<sup>[7]</sup>. Consistent with our previous work<sup>[19]</sup>, 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<sup>[41]</sup> and transient hypotony (<5 mm Hg)<sup>[22]</sup>, which usually spontaneously resolves within a few days of surgery. Less than 1% vision-threatening complications were reported<sup>[7]</sup>, including one case of endophthalmitis<sup>[42]</sup>, and four cases of aqueous misdirection<sup>[29,31,43-44]</sup>. Previous studies suggested approximately 6.1% to 34.9% of patients required a secondary glaucoma surgery<sup>[35,37,40]</sup>. In this study, there was no bleb so bleb-related complications were avoided, and only five patients underwent additional glaucoma surgery; one patient underwent repeat Trabectome surgery and four underwent a luminal control glaucoma filtration device (EX-PRESS, Alcon Laboratories, Inc., Fort Worth, TX, USA) implantation.

In this study, trabectome showed an effective and safe procedure in lowering IOP and glaucoma medication. Since glaucoma treatment is a balance between lowering IOP and reducing glaucoma medication taking. Based on this analysis, glaucoma practice in Japan tended to lower IOP in comparison to practice in China where glaucoma practice tended to lower the glaucoma medication.

Actually, 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*<sup>[45]</sup> indicated that trabeculectomy might reverse the glaucomatous dysfunction of retinal ganglion cells and their central projections.

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.

### ACKNOWLEDGEMENTS

**Foundation:** Supported by the National Natural Science Foundation of China (No.81670851).

**Conflicts of Interest:** Dang YL, None; Wang X, None; Dai WW, None; Huang P, None; Loewen NA has received honoraria for wet labs and lectures from Neomedix Inc.; Zhang C, None; China Trabectome Study Group, None; International Trabectome Study Group, None.



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