Original Article

Safety and Efficiency of Trabectome-mediated Trabecular Meshwork Ablation for Chinese Glaucoma Patients: A Two-year, Retrospective, Multicentre Study

Ya-Long Dang[1], Yu-Jie Cen[1], Ying Hong[1], Ping Huang[1], Ning-Li Wang[2], Chao Wang[3], Chun Zhang[1], China Trabectome Study Group

[1]Department of Ophthalmology, Peking University Third Hospital, Beijing 100191, China
[2]Department of Ophthalmology, Beijing Tongren Hospital, Capital Medical University, Beijing 100005, China
[3]Department of Ophthalmology, University of Pittsburgh, Pittsburgh, Pennsylvania 15213, USA

Abstract

Background: The aim of the study was to evaluate the long-term safety and efficacy of the Trabectome for Chinese glaucoma patients.
Methods: This was a multicenter, retrospective, observational study. Glaucoma patients, except those with neovascular glaucoma, with/without a visually significant cataract were enrolled. The patients received Trabectome or a combined surgery with phacoemulsification and intraocular lens implantation. The primary outcome evaluation was a reduction in intraocular pressure (IOP), and the secondary outcomes were a reduction in glaucoma medication, the 2-year success percentages, and complications. Success was defined as an IOP <21 mmHg and at least a 20% IOP reduction from baseline after 3 months for any two consecutive visits, without additional glaucoma surgery. The data were processed using the R Stats Package version 3.0.0. The Wilcoxon test was used to compare the postoperative IOP and the number of glaucoma medications with baselines. The Kaplan–Meier test was used to calculate the 2-year success percentage. The risk factors related to Trabectome failure were determined by logistic regression.
Results: A total of 120 glaucoma patients were enrolled. The Trabectome efficiently reduced the IOP from a baseline of 22.8 ± 1.34 mmHg to 17.6 ± 0.96 mmHg, and the use of glaucoma medications from 2.2 ± 0.17 mmHg to 1.4 ± 0.21 in a 2-year follow-up (both, $P < 0.01$). The overall success percentage was 80%. No risk factor related to Trabectome failure was identified. No vision-threatening complication was observed. Ten patients, who required secondary glaucoma surgery, all reached the target IOP.
Conclusions: In a 2-year follow-up, Trabectome was an efficient and safe procedure for Chinese glaucoma patients.

Key words: Glaucoma; Intraocular Pressure; Minimally Invasive Surgical Procedures; Trabecular Meshwork

Introduction

Glaucoma is a degenerative disease of the optic nerve, affecting millions of people[1] and causing huge economic burdens worldwide.[2] Neuroprotection strategies (including gene therapy and medical therapy), which alleviate the deterioration of glaucomatous optic neuropathy, have shown promising effects *in vitro* and in glaucoma animal models but are still in preclinical stages.[3-5] Currently, reducing intraocular pressure (IOP) is the only clinically proven treatment for glaucoma management.[6]

Conventional glaucoma surgeries such as trabeculectomy and tube shunt implantation can effectively reduce the IOP and the use of glaucoma medications but also have significant complications.[7,8] In recent decades, minimally invasive glaucoma surgeries have shown comparable IOP-lowering effects when compared with conventional glaucoma surgeries, but with a better safety profile, thus becoming the first-line treatment for glaucoma patients with the maximum tolerance of medication.[9] Invented and patented by George Baerveldt and Roy Chunk in 2002,[10]

Access this article online

Quick Response Code:

Website: www.cmj.org

DOI: 10.4103/0366-6999.225050

Address for correspondence: Prof. Chun Zhang, Department of Ophthalmology, Peking University Third Hospital, Beijing 100191, China
E-Mail: zhangc1@yahoo.com

Received: 22-09-2017 **Edited by:** Yi Cui
How to cite this article: Dang YL, Cen YJ, Hong Y, Huang P, Wang NL, Wang C, Zhang C, China Trabectome Study Group. Safety and Efficiency of Trabectome-mediated Trabecular Meshwork Ablation for Chinese Glaucoma Patients: A Two-year, Retrospective, Multicentre Study. Chin Med J 2018;131:420-5.

the Trabectome (NeoMedix, Tustin, CA, USA) is a United States Food and Drug Administration-approved minimally invasive glaucoma surgery designed to remove the trabecular meshwork (TM) using a high-frequency bipolar electrode.[11] With more than 5000 successful cases worldwide in the past decade, its safety and efficiency have been comprehensively investigated.[12,13]

Our team published the first clinical results of the Trabectome for Chinese open-angle glaucoma patients in a 12-month follow-up.[14] We found that the Trabectome sufficiently reduced the IOP from a baseline of 22.5 ± 8.1 mmHg to 17.6 ± 6.4 mmHg at 12 months without serious complications. The overall success was 85.0%. Only 9.8% of patients required a secondary glaucoma surgery. However, the long-term effects of the Trabectome for Chinese glaucoma patients remain unclear. In addition, the small sample size in the previous study also made it difficult to determine the risk factors related to Trabectome failures.

Methods

Ethical approval

This was a multicenter, retrospective, observational study approved by the Institutional Review Board of Peking University Third Hospital in accordance with the 1964 *Declaration of Helsinki*. Due to the retrospective nature of the study design, no informed consent was required.

Patients

According to a previous study,[15] patients with primary or various secondary open-angle glaucomas as well as narrow angles were included, except neovascular glaucoma and those with postoperative follow-ups <3 months. All patients received either Trabectome alone or Trabectome with phacoemulsification/intraocular lens implantation. Trabectome was performed as previously described.[16] Briefly, a 1.6 mm iris, parallel, clear, corneal incision was made at the nasal side. After the insertion of the Trabectome tip into the anterior chamber, the eye was pressurized with active irrigation. The goniolens 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°C of the 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 1 day, 1 week, 1, 3, 6, 12, 18, and 24 months.

The primary outcome evaluation was the reduction in the IOP, and the secondary outcomes were reductions in glaucoma medications, 2-year success percentages, and surgical complications. The IOP was measured using Goldmann applanation tonometry. The target IOP was determined individually by the progression of the visual field loss and the preoperative IOP. The visual field was categorized as mild, moderate, or advanced according to a Humphrey visual field test. Slit lamp, Snellen best-corrected visual acuity, gonioscopy, and stereoscopic optic nerve photography were regularly performed during the follow-up.

Statistical analyses

The quantitative data were presented as the mean ± standard error (SE) and analyzed using the R Stats Package software version 3.0.0 (Free Software Foundation, Boston, MA, USA). The Wilcoxon test was used to compare the postoperative IOP and number of glaucoma medications with the baselines. The Kaplan–Meier test was used to calculate the 2-year success percentage. The surgical success was defined as an IOP <21 mmHg and at least 20% of the IOP reduction from baseline after 3 months for any two consecutive visits with no additional glaucoma surgery required. The risk factors correlating with Trabectome failure were determined by logistic regression.

Results

Demographics

A total of 120 patients from five glaucoma centers were enrolled in the study. The majority of patients were diagnosed with primary open-angle glaucoma (78%), followed by juvenile glaucoma (7%), angle closure glaucoma (2%), and other types of glaucoma. The mean age of these patients was 50 ± 19 years (range: 11–87 years) and 65% of them were male. Thirty of 84 phakic eyes with visually significant cataracts received combined surgery with phacoemulsification and intraocular lens implantation. Sixteen patients had previous glaucoma surgeries including 13 with trabeculectomy, 2 with Trabectome, 1 with selective laser trabeculoplasty, and 1 with tube shunt implantation [Table 1].

Reductions in intraocular pressure and glaucoma medications

The preoperative IOP was 22.8 ± 1.3 mmHg. It dramatically decreased to a maximum level of 16.4 ± 1.05 at the 1st postoperative day ($P < 0.01$, compared to the baseline). While a small IOP fluctuation was observed, the postoperative IOPs were all statistically lower than the baseline IOPs (all $P < 0.01$), with a range of 22.4–28.1% reduction [Figure 1 and Table 2]. Similar to the patterns of IOP reduction, Trabectome significantly reduced the number of glaucoma medications from 2.20 ± 0.17 at the baseline to a range of 1.20–1.40 during the 2-year follow-up (all $P < 0.01$) [Figure 2 and Table 3].

Two-year success

Figure 3 shows that the surgery success declined at all times during the 2-year follow-up. Overall, 80% of the patients had a postoperative IOP <21 mmHg with over 20% of the patients showing an IOP reduction from the baseline and no secondary glaucoma surgery at any two consecutive visits [Figure 3a]. All patients ($n = 30$) who received combined surgery with phacoemulsification and intraocular

Table 1: Demographics of the patients (n = 120)

Characteristics	n (%)
Age (years)	
Mean ± SD	50 ± 19
Range	11–87
Gender	
Female	42 (35.0)
Male	78 (65.0)
Diagnosis	
Primary open angle glaucoma	93 (77.5)
Pseudoexfoliation	1 (0.8)
Juvenile	8 (7.0)
Angle closure glaucoma	2 (2.0)
Steroid-induced glaucoma	1 (0.8)
Pigmentary glaucoma	1 (0.8)
Other	14 (11.7)
Preoperative Snellen visual acuity	
>20/20	1 (0.8)
20/20–20/40	49 (40.8)
20/50–20/70	11 (9.2)
20/80–20/100	5 (4.2)
20/200–20/400	13 (10.8)
<20/400	5 (4.2)
NR	36 (30.0)
Visual field	
Mild	21 (17.5)
Moderate	16 (13.3)
Advanced	27 (22.5)
NR	56 (46.7)
Disc C/D	
<0.7	24/120 (20)
0.7–0.8	43 (35.8)
>0.8	25 (20.8)
NR	28 (23.3)
Lens status	
Phakic	84 (70)
Pseudophakic	14 (11.7)
Aphakic	1 (0.8)
NR	21 (17.5)
Shaffer grade	
I	2 (1.7)
II	4 (3.3)
III	21 (17.5)
IV	62 (51.7)
NR	31 (25.8)
Prior surgeries	
SLT	1 (0.8)
ALT	0
Tube shunt	1 (0.8)
Trabeculectomy	13 (11.0)
Trabectome	2 (2.0)
Combined surgeries	
Trabectome + phacoemulsification	30 (25)
Trabectome alone	86 (72)
Trabectome with other surgeries	4 (3)

SLT: Selective laser trabeculoplasty; ALT: Argon laser trabeculoplasty; NR: Not recorded; SD: Standard deviation.

lens implantation matched the success criteria after 2 years of follow-up, in contrast to only 77% of those (n = 90) who received Trabectome alone (P = 0.264) [Figure 3b]. In addition, patients with a history of trabeculectomy or tube shunt implantation (n = 14) had a similar success percentage, compared to those without such histories (n = 106) (79% vs. 82%; P = 0.887) [Figure 3c]. No risk factor including age, surgery type, or cup/disc ratio correlated with the surgical failure using univariate logistic regression [Table 4]. Due to the small sample size, multivariate logistic regression was not performed.

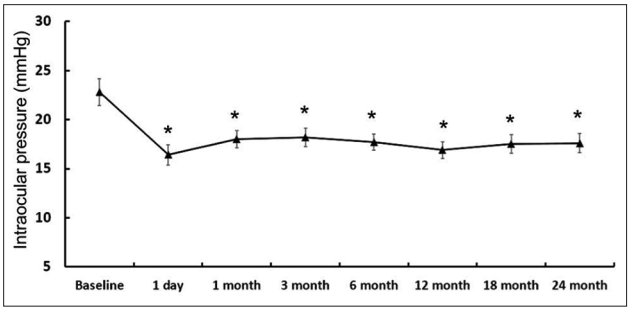

Figure 1: Reduction in the IOP. The baseline IOP was 22.8 ± 1.3 mmHg, which was reduced to 16.4 ± 1.1 mmHg at day 1 and sustained at statistically lower levels throughout the study (all P < 0.01, compared to the baseline). The Wilcoxon test was used for statistical analyses. *Indicates a statistical difference with P < 0.01. IOP: Intraocular pressure.

Complications and secondary glaucoma surgery

The only surgical complication identified in the study was transient blood reflux, which occurred in almost all cases but resolved spontaneously within a few days. No vision-threatening complication such as sustained hypotony defined as an IOP <5 mmHg, aqueous misdirection, endophthalmitis, wound leakage, or choroidal hemorrhage occurred. A total of ten patients required secondary glaucoma surgeries including four express shunt implantations, four trabeculectomies, and two Trabectomes at the opposite quadrant of the eye. All these cases reached the target IOP at the first follow-up.

Discussion

TM is a filter-like structure, accounting for 90% of the aqueous outflow resistance.[17] Diseased TM is present in almost all types of glaucoma including primary open-angle glaucoma, primary angle-closure glaucoma, and congenital glaucoma.[18] Ablation of this tissue either by surgery[14,19,20] or other methods[21,22] increases outflow facility and decreases the IOP. In the present study, the results showed that Trabectome-mediated TM ablation efficiently reduced the IOP from a baseline of 22.8 ± 1.3 mmHg to 17.6 ± 1.0 mmHg and decreased the use of glaucoma medications from 2.20 ± 0.17 to 1.40 ± 0.21 with an 80% overall success percentage after 2 years of follow-up. No vision-threatening complication occurred. These results were consistent with our previous findings,[14] and this study described the long-term results of Trabectome for Chinese glaucoma patients.

IOP reduction was the major goal of this surgery, although it varied depending on the glaucoma type and preoperative IOP. Steroid-induced glaucoma and pseudoexfoliation glaucoma, which are usually disorders primarily affecting the TM, have a higher IOP reduction than primary open-angle glaucoma, which has a more complicated mechanism involving ocular hypertension.[16,23,24] Patients with a higher preoperative IOP and glaucoma severity are also likely to achieve a greater IOP reduction.[25,26] However, it needs to be noted that the expected postoperative IOP should not be lower than 10 mmHg, which is the estimated pressure of the episcleral vein,[27] indicating outflow resistance also exists in the downstream outflow tracts.[13,28]

Reducing the use of glaucoma medication is another benefit of the Trabectome, especially for those with intolerable glaucoma medication. An average of 0.3[29] to 1.2[30] less medication can be achieved by different patient populations. Patients with refractory glaucoma have less medication reduction.[29,30] In the present study, glaucoma medications were reduced from a baseline of 2.20 ± 0.17 to 1.40 ± 0.21 at the end of the 2-year follow-up, which was comparable to our previously reported results.[14]

In a similar manner as other minimally invasive glaucoma surgeries,[31-33] Trabectome may be performed with phacoemulsification/intraocular lens implantation, and the combined surgery usually is more successful than the Trabectome alone.[16,19,25] In the present study, all thirty patients who received combined surgery were successfully treated when compared with only 77% of the patients in the Trabectome alone group. These results were consistent with a recent meta-analysis by Okeke *et al*.,[12] showing that combined surgery had a 78% lower risk of surgical failure. However, it is important to note that patients with the combined surgery usually had lower baseline IOPs, so the absolute IOP reduction might be lower than with Trabectome

Table 2: Reduction of intraocular pressure (mmHg)

IOP	Mean ± SE	*P*
Baseline	22.8 ± 1.34	–
1 day	16.4 ± 1.05	<0.01*
1 month	18.0 ± 0.90	<0.01*
3 months	18.2 ± 0.95	<0.01*
6 months	17.7 ± 0.80	<0.01*
12 months	16.9 ± 0.85	<0.01*
18 months	17.5 ± 0.94	<0.01*
24 months	17.6 ± 0.96	<0.01*

Wilcoxon test were applied by comparing with baseline IOP or number of medications. *Significant level is 0.05. IOP: Intraocular pressure; SE: Standard error.

Table 3: Reduction of glaucoma medication

Numbers of medication	Mean ± SE	*P*
Baseline	2.2 ± 0.17	–
1 day	1.2 ± 0.19	<0.01*
1 month	1.4 ± 0.18	<0.01*
3 months	1.3 ± 0.25	<0.01*
6 months	1.4 ± 0.24	<0.01*
12 months	1.4 ± 0.21	<0.01*
18 months	1.4 ± 0.26	<0.01*
24 months	1.4 ± 0.21	<0.01*

Wilcoxon test were applied by comparing with baseline IOP or number of medications. *Significant level is 0.05. IOP: Intraocular pressure; SE: Standard error.

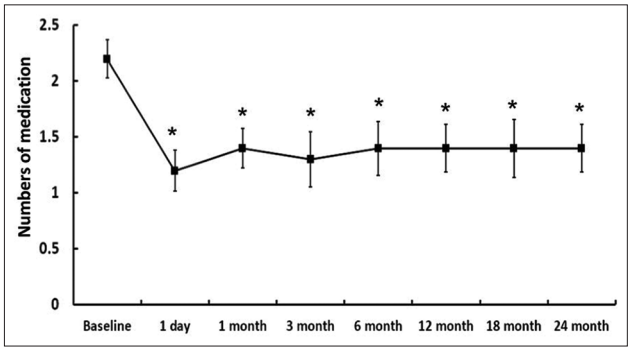

Figure 2: Reduction of glaucoma medication. Patients had an average of 2.20 ± 0.17 glaucoma eye drops before surgery. Trabectome significantly decreased the use of glaucoma medication throughout the study (all $P < 0.01$, compared to the baseline). The Wilcoxon test was used for statistical analyses. *Indicates a statistical difference with $P < 0.01$.

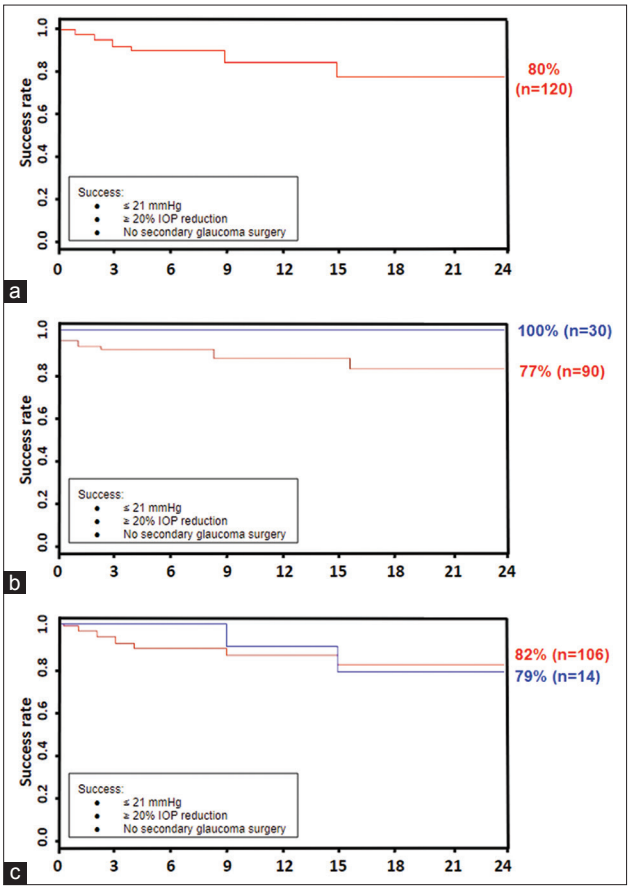

Figure 3: Two-year success percentage. Overall success rate during 2-year follow-up (a). The combined surgery versus Trabectome alone (b). Patients with history of glaucoma surgery versus patients without history of glaucoma surgery (c).

Table 4: Risk factor with trabectome failure

Variables	*OR*	*P*
Age (years)		
30< age ≤50 (reference 10< age ≤30)	0.285	0.12
50< age ≤90 (reference 10< age ≤30)	0.167	0.06
Surgery		
Combined surgery with phaco	<0.01	0.99
Cup/disk ratio		
C/D >0.8	4.66	0.06
Preoperative visual acuity		
20/50 or worse	3.12	0.06
Prior surgery		
Prior glaucoma surgery history	0.600	0.56

OR: Odds ratio.

alone.[13,23,24] In our recent study, we found that combined surgery had 1.29 ± 0.39 mmHg less IOP reduction than that of Trabectome alone.[24] A meta-analysis by Kaplowitz *et al*. also reported similar results.[13]

A relatively safe profile is a significant feature of Trabectome surgery.[13,14,16,29,34] In the present study, no vision-threatening complication was observed, including sustained hypotony and bleb-related complications, which are common in conventional glaucoma filtering surgeries. Transient blood reflux was reported in all cases, indicating the opening of Schlemm's canal.[35] Temporary hypotony occurred in two of 101 pigmentary glaucoma patients.[36] Peripheral anterior synechiae were reported in 24% of open-angle glaucoma patients[37] but not in the present study. Secondary glaucoma surgery might be needed for 10.5–34.9% of open-angle glaucoma patients.[23,34,38] Patients who received the combined surgery with phacoemulsification and intraocular implantation were likely to have a lower percentage of secondary procedures.[23]

This study had some limitations. First, no risk factors related to Trabectome failure were found possibly because of the small sample size. We have found $P = 0.06$ in terms of age >50 years, high cup/disk ratio, and worse preoperative best-corrected visual acuity using univariate logistic regression, suggesting a high risk of Trabectome failure. A future study enrolling more patients should, therefore, be conducted. Second, recent studies suggested that advanced and refractory glaucoma may also be indications of Trabectome surgery,[25,26,29] so studies investigating the effect of Trabectome for these patients are necessary.

In summary, Trabectome was an efficient and safe procedure for Chinese glaucoma patients in a 2-year follow-up study.

Acknowledgment

The authors thank for the help in patient data collection from Professor Hui-Juan Wu (Department of Ophthalmology, Peking University People's Hospital), Professor Huai-Zhou Wang (Department of Ophthalmology, Beijing Tongren Hospital), Professor Ding Lin (Glaucoma Center, Changsha Aier Eye Hospital), and Professor Ping Zhao (Glaucoma Center, Shenyang Aier Eye Hospital). The authors appreciate the Trabectome training provided by Prof. Nils Loewen (Department of Ophthalmology, University of Pittsburgh).

Financial support and sponsorship

This study was supported by a grant from National Natural Science Foundation of China (No. 81670851).

Conflicts of interest

There are no conflicts of interest.

References

1. Tham YC, Li X, Wong TY, Quigley HA, Aung T, Cheng CY, *et al.* Global prevalence of glaucoma and projections of glaucoma burden through 2040: A systematic review and meta-analysis. Ophthalmology 2014;121:2081-90. doi: 10.1016/j.ophtha.2014.05.013.
2. Varma R, Lee PP, Goldberg I, Kotak S. An assessment of the health and economic burdens of glaucoma. Am J Ophthalmol 2011;152:515-22. doi: 10.1016/j.ajo.2011.06.004.
3. He S, Stankowska DL, Ellis DZ, Krishnamoorthy RR, Yorio T. Targets of neuroprotection in glaucoma. J Ocul Pharmacol Ther 2017; Ahead of print. doi: 10.1089/jop.2017.0041.
4. Song W, Huang P, Zhang C. Neuroprotective therapies for glaucoma. Drug Des Devel Ther 2015;9:1469-79. doi: 10.2147/DDDT.S80594.
5. Dang Y, Mu Y, Wang K, Xu K, Yang J, Zhu Y, *et al.* Papaverine inhibits lipopolysaccharide-induced microglial activation by suppressing NF-κB signaling pathway. Drug Des Devel Ther 2016;10:851-9. doi: 10.2147/DDDT.S97380.
6. Lusthaus JA, Goldberg I. Investigational and experimental drugs for intraocular pressure reduction in ocular hypertension and glaucoma. Expert Opin Investig Drugs 2016;25:1201-8. doi: 10.1080/13543784.2016.1223042.
7. Giovingo M. Complications of glaucoma drainage device surgery: A review. Semin Ophthalmol 2014;29:397-402. doi: 10.3109/08820538.2014.959199.
8. Condon GP, Moster MR. Minimizing the invasiveness of traditional trabeculectomy surgery. J Cataract Refract Surg 2014;40:1307-12. doi: 10.1016/j.jcrs.2014.03.023.
9. Kerr NM, Wang J, Barton K. Minimally invasive glaucoma surgery as primary stand-alone surgery for glaucoma. Clin Exp Ophthalmol 2017;45:393-400. doi: 10.1111/ceo.12888.
10. Trabectome: Ab Interno Trabeculectomy – EyeWiki. Available from: http://www.eyewiki.aao.org/Trabectome%3A_Ab_Interno_Trabeculectomy. [Last accessed on 2017 Sep 21].
11. Francis BA, Singh K, Lin SC, Hodapp E, Jampel HD, Samples JR, *et al.* Novel glaucoma procedures: A report by the American Academy of Ophthalmology. Ophthalmology 2011;118:1466-80. doi: 10.1016/j.ophtha.2011.03.028.
12. Okeke CO, Miller-Ellis E, Rojas M, Trabectome Study Group. Trabectome success factors. Medicine (Baltimore) 2017;96:e7061. doi: 10.1097/MD.0000000000007061.
13. Kaplowitz K, Bussel II, Honkanen R, Schuman JS, Loewen NA. Review and meta-analysis of ab-interno trabeculectomy outcomes. Br J Ophthalmol 2016;100:594-600. doi: 10.1136/bjophthalmol-2015-307131.
14. Huang P, Wang H, Wu H, Sun Y, Wang M, Cui Y, *et al.* Preliminary investigation on the safety and efficacy of trabectome (in Chinese). Chin J Ophthalmol 2015;51:115-9. doi: 10.3760/cma.j.issn.0412-4081.2015.02.011.
15. Vinod K, Gedde SJ. Ab interno trabeculectomy: Patient selection and perspectives. Clin Ophthalmol 2016;10:1557-64. doi: 10.2147/OPTH.S99746.
16. Dang Y, Kaplowitz K, Parikh HA, Roy P, Loewen RT, Francis BA, *et al.* Steroid-induced glaucoma treated with trabecular ablation in a matched comparison with primary open-angle glaucoma. Clin Exp Ophthalmol 2016;44:783-8. doi: 10.1111/ceo.12796.
17. Llobet A, Gasull X, Gual A. Understanding trabecular meshwork physiology: A key to the control of intraocular pressure? News Physiol Sci 2003;18:205-9. doi: 10.1152/nips.01443.2003.

18. Weinreb RN, Aung T, Medeiros FA. The pathophysiology and treatment of glaucoma: A review. JAMA 2014;311:1901-11. doi: 10.1001/jama.2014.3192.
19. Francis BA, See RF, Rao NA, Minckler DS, Baerveldt G. Ab interno trabeculectomy: Development of a novel device (Trabectome) and surgery for open-angle glaucoma. J Glaucoma 2006;15:68-73. doi: 10.1097/IJG.0b013e31802d6e2b.
20. Wang C, Dang Y, Waxman S, Xia X, Weinreb RN, *et al.* Angle stability and outflow in dual blade ab interno trabeculectomy with active versus passive chamber management. PLoS One 2017;12:e0177238. doi: 10.1371/journal.pone.0177238.
21. Zhang Z, Dhaliwal AS, Tseng H, Kim JD, Schuman JS, Weinreb RN, *et al.* Outflow tract ablation using a conditionally cytotoxic feline immunodeficiency viral vector. Invest Ophthalmol Vis Sci 2014;55:935-40. doi: 10.1167/iovs.13-12890.
22. Dang Y, Waxman S, Wang C, Jensen A, Loewen RT, Bilonick RA, *et al.* Freeze-thaw decellularization of the trabecular meshwork in an *ex vivo* eye perfusion model. PeerJ 2017;5:e3629. doi: 10.7717/peerj.3629.
23. Ting JL, Damji KF, Stiles MC, Trabectome Study Group. Ab interno trabeculectomy: Outcomes in exfoliation versus primary open-angle glaucoma. J Cataract Refract Surg 2012;38:315-23. doi: 10.1016/j.jcrs.2011.08.043.
24. Dang Y, Roy P, Bussel II, Loewen RT, Parikh H, Loewen NA, *et al.* Combined analysis of trabectome and phaco-trabectome outcomes by glaucoma severity. F1000Res 2016;5:762. doi: 10.12688/f1000research.8448.2.
25. Roy P, Loewen RT, Dang Y, Parikh HA, Bussel II, Loewen NA, *et al.* Stratification of phaco-trabectome surgery results using a glaucoma severity index in a retrospective analysis. BMC Ophthalmol 2017;17:30. doi: 10.1186/s12886-017-0421-7.
26. Loewen RT, Roy P, Parikh HA, Dang Y, Schuman JS, Loewen NA, *et al.* Impact of a glaucoma severity index on results of trabectome surgery: Larger pressure reduction in more severe glaucoma. PLoS One 2016;11:e0151926. doi: 10.1371/journal.pone.0151926.
27. Rand Allingham R, Damji KF, Freedman SF, Moroi SE, Rhee DJ, Bruce Shields M. Shields Textbook of Glaucoma. Philadelphia, PA: Lippincott Williams & Wilkins; 2012.
28. Chow JTY, Hutnik CML, Solo K, Malvankar-Mehta MS. When is evidence enough evidence? A Systematic review and meta-analysis of the trabectome as a solo procedure in patients with primary open-angle glaucoma. J Ophthalmol 2017;2017:2965725. doi: 10.1155/2017/2965725.
29. Wecker T, Neuburger M, Bryniok L, Bruder K, Luebke J, Anton A, *et al.* Ab interno trabeculectomy with the trabectome as a valuable therapeutic option for failed filtering blebs. J Glaucoma 2016;25:758-62. doi: 10.1097/IJG.0000000000000492.
30. Ahuja Y, Ma Khin Pyi S, Malihi M, Hodge DO, Sit AJ. Clinical results of ab interno trabeculotomy using the trabectome for open-angle glaucoma: The mayo clinic series in Rochester, Minnesota. Am J Ophthalmol 2013;156:927-35.e2. doi: 10.1016/j.ajo.2013.06.001.
31. Spiegel D, García-Feijoó J, García-Sánchez J, Lamielle H. Coexistent primary open-angle glaucoma and cataract: Preliminary analysis of treatment by cataract surgery and the iStent trabecular micro-bypass stent. Adv Ther 2008;25:453-64. doi: 10.1007/s12325-008-0062-6.
32. Saheb H, Ianchulev T, Ahmed II. Optical coherence tomography of the suprachoroid after cyPass micro-stent implantation for the treatment of open-angle glaucoma. Br J Ophthalmol 2014;98:19-23. doi: 10.1136/bjophthalmol-2012-302951.
33. Lewis RA. Ab interno approach to the subconjunctival space using a collagen glaucoma stent. J Cataract Refract Surg 2014;40:1301-6. doi: 10.1016/j.jcrs.2014.01.032.
34. Lee JW, Yick DW, Tsang S, Yuen CY, Lai JS. Efficacy and safety of trabectome surgery in Chinese open-angle glaucoma. Medicine (Baltimore) 2016;95:e3212. doi: 10.1097/MD.0000000000003212.
35. Hashemian SJ, Miraftabi A, Jafari ME, Hemami MR. Combined cataract extraction and trabeculotomy by the internal approach for coexisting cataract and open-angle glaucoma. J Curr Ophthalmol 2017;29:17-22. doi: 10.1016/j.joco.2016.09.003.
36. Akil H, Chopra V, Huang A, Loewen N, Noguchi J, Francis BA, *et al.* Clinical results of ab interno trabeculotomy using the trabectome in patients with pigmentary glaucoma compared to primary open angle glaucoma. Clin Exp Ophthalmol 2016;44:563-9. doi: 10.1111/ceo.12737.
37. Minckler DS, Baerveldt G, Alfaro MR, Francis BA. Clinical results with the trabectome for treatment of open-angle glaucoma. Ophthalmology 2005;112:962-7. doi: 10.1016/j.ophtha.2004.12.043.
38. Shoji N, Kasahara M, Iijima A, Takahashi M, Tatsui S, Matsumura K, *et al.* Short-term evaluation of trabectome surgery performed on Japanese patients with open-angle glaucoma. Jpn J Ophthalmol 2016;60:156-65. doi: 10.1007/s10384-016-0433-5.

微创小梁消融术对中国青光眼患者安全性及有效性的多中心、回顾性研究

摘要

目的: 探讨微创小梁消融术对中国青光眼患者的长期安全性及有效性。
方法: 多中心、回顾性队列研究. 采集北京大学第三医院、北京同仁医院等国内六家眼科中心自2013年12月至2017年5月接受微创小梁消融术并随访超过2年的青光眼患者120例。 合并白内障的患者同时接受超声乳化及人工晶状体植入术。 手术效果评价的主要标准是眼压的下降。 次要评价标准包括: 青光眼用药的减少、2年的手术成功率及并发症。 手术成功的判定标准：(1) 术后3个月后的任意连续2次随访的眼压低于21mmHg; (2) 与术前眼压相比, 20%的眼压下降；(3) 无二次青光眼手术。术前与术后眼压和青光眼用药数量的比较采用Wilcoxon检验，术后2年成功率分析采用Kaplan Meier检验。我们还尝试使用回归分析寻找手术失败的危险因素。
结果: 经过2年随访, 接受微创小梁消融术的青光眼患者的眼压从术前的22.8 ± 1.34 mmHg下降到17.6 ± 0.96 mmHg ($P < 0.01$)。青光眼用药数量也从术前的2.2 ± 0.17降低到1.4 ± 0.21 ($P < 0.01$). 小梁消融术的2年总体成功率为80%, 合并白内障手术的小梁消融术患者的手术成功率高于单独接受小梁消融术的患者(100% vs. 77%). 由于样本量有限，导致小梁消融术失败的危险因素未被找到. 在安全性方面, 未发现术中及术后威胁视力的并发症. 10例患者接受了二次青光眼手术, 术后眼压均控制良好.
结论: 微创小梁消融术能够长期、安全、显著地降低青光眼患者的眼压和用药数量, 因此是一种有效的青光眼手术方法.