

The First Decade of Global Trabectome Outcomes

Sameh Mosaed

Associate Professor, Cataract and Glaucoma Surgery, Ophthalmology, Director of Glaucoma Services, Department of Ophthalmology, Director of Glaucoma, Long Beach Veterans Hospital; Director of Glaucoma Fellowship, Department of Ophthalmology, Gavin Herbert Eye Institute, Department of Ophthalmology, School of Medicine, University of California, Irvine, US

Abstract

Purpose: To present available primary outcome results of global Trabectome experience for patients receiving Trabectome procedure including cases with up to 90 months of follow-up. **Method:** A total of 5,435 cases were included in the study. Baseline demographics were collected and outcome measures included intraocular pressure (IOP), number of glaucoma medications and secondary glaucoma surgery, if any. Survival analysis was performed and success was defined as IOP ≤ 21 mmHg, at least 20 % of IOP reduction from baseline, and no additional glaucoma surgery. **Results:** At 90 months, IOP was reduced from 23.0 ± 7.9 mmHg to 16.5 ± 3.8 mmHg (29 %) and the number of glaucoma medications was reduced from 2.6 ± 1.3 to 1.6 ± 1.3 (38 %). At 90 months, the survival rates were 60 % for all cases, 76 % for combined cases and 50 % for Trabectome alone cases. **Discussion:** These results are generally consistent with previously published outcome results for patients receiving the Trabectome procedure. **Conclusion:** Considering this outcome analysis of the available global Trabectome experience in combination with outcome data surveyed from the literature, patients receiving Trabectome on average have about a 30 % reduction in IOP and a 60 % reduction in glaucoma medication. The Trabectome procedure can be considered for initial glaucoma therapy, as well as for end-stage patients who have been refractory to other surgical and medical treatments.

Keywords

Trabectome, trabecular meshwork, glaucoma, ab-interno trabeculotomy, surgery, MIGS, trabecular bypass, Schlemm's canal surgery, trabeculotomy

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Correspondence: Sameh Mosaed, Gavin Herbert Eye Institute, Department of Ophthalmology, University of California, Irvine, CA 92697, US. E: smosaed@uci.edu

Glaucoma is a disease that results in degeneration of the optic disc and can lead to reduced vision and even blindness if left untreated. The purpose of this article is to provide summary results of Trabectome procedures performed between 2004 to 2014. Glaucoma remains one of the leading causes of blindness worldwide. Globally, 60.5 million people were estimated to have glaucoma in 2010, and the number is expected to increase to 79.6 million by 2020.¹ Based on population-based surveys, it is indicated that one in 40 adults older than 40 years of age has glaucoma with loss of visual function, equating to about 8.4 million being bilaterally blind.²

Intraocular pressure (IOP) is considered to be one of the main risk factors for optic nerve damage. Hence, one of the goals of glaucoma treatment is to lower and maintain IOP control.^{3–6} Available treatments for glaucoma include surgical procedures and topical eye drops. Traditional filtering surgeries, such as trabeculectomy and aqueous tube shunt, are associated with potential complications. Complications associated with trabeculectomy include hypotony, hypotony maculopathy, bleb leaks, late blebitis, choroidal effusion and haemorrhage, bleb-related endophthalmitis, peripheral anterior synechiae formation, posterior synechiae and cataract formation.^{7,8} The complication rates are increased when antifibrotics are used, but the short-term failure rate of trabeculectomy in the absence of antifibrotics is relatively high.^{8–10} The rate of endophthalmitis is 1 % per year.⁹ Aqueous tube shunt surgery has the

risk of early hypotony, choroidal effusion, suprachoroidal haemorrhage, shallow anterior chamber, diplopia, tube obstruction, conjunctival erosion, tube migration, corneal decompensation, plate encapsulation and late failure.^{7,8} Due to these high complication rates associated with filtering surgeries, the Trabectome surgical device was developed in attempt to lower IOP while minimising the risks typically associated with filtering surgeries.¹¹ Trabectome also has the advantage of not affecting the success rate of subsequent trabeculectomy, but same effect is not found in selective laser trabeculoplasty (SLT) after Trabectome.^{12,13}

The Trabectome device was cleared by the US Food and Drug Administration (FDA) in 2004. It is designed to address the outflow resistance problems in open angle glaucoma (OAG). The device ablates a strip of trabecular meshwork and the inner wall of Schlemm's canal and thus re-establishes outflow to the natural pathway.¹⁴ Since the procedure does not involve manipulation of the conjunctiva, tenon or external eye wall, the typical complications seen in filtering surgeries are not observed after Trabectome procedures.¹⁵ In addition, the procedure is minimally invasive and performed through a clear-corneal incision and thus can be combined with phacoemulsification and intraocular lens implantation.^{16,17}

A number of peer-reviewed Trabectome publications.^{7,11,12,14–46} are summarised in *Table 1* representing different comparative analyses of

Table 1: Peer-reviewed Journals

Ref.	Year	Author	Title	IOP Reduction (%)	Meds Reduction (%)	Follow-Up Period (M)	Total Number of Cases
18	2005	Minckler et al.	Clinical Results with the Trabectome for Treatment of Open-Angle Glaucoma	~31 %	~90 %	12	<ul style="list-style-type: none"> • 37 at baseline • 15 at 12M
19	2006	Minckler et al.	Clinical Results with the Trabectome, A Novel Surgical Device for Treatment of Open-Angle Glaucoma	~40 %	NA	30	<ul style="list-style-type: none"> • 101 at baseline
14	2006	Francis et al.	<i>Ab Interno</i> Trabeculectomy: Development of a Novel Device (Trabectome) and Surgery for Open-Angle Glaucoma	NA	NA	NA	NA
11	2007	Mosaed	<i>Ab Interno</i> Trabeculectomy with the Trabectome Surgical Device	42 %	~75 %	36	<ul style="list-style-type: none"> • 201 at baseline • 5 at 30M
20	2008	Gunderson	Trabeculectomy <i>Ab Interno</i> , Using the Trabectome: A Promising Treatment for Patients with Open-Angle Glaucoma	40 %	~67 %	52	<ul style="list-style-type: none"> • 434 at baseline • 52M: NA
21	2008	Filippopoulos and Rhee	Novel surgical procedures in glaucoma: advances in penetrating glaucoma surgery	6M: 29 % 12M: 34 % 24M: 30 % 48M: 30 %	NA	Up to 52	<ul style="list-style-type: none"> • 679 at baseline • 106 at 6M • 65 at 12M • 30 at 24M • 13 at 48M
16	2008	Francis et al.	Combined cataract extraction and trabeculectomy by the internal approach for coexisting cataract and open-angle glaucoma: Initial results	12M: 16 % 21M: 25 %	12M: 36 % 21M: 32 %	Up to 21	<ul style="list-style-type: none"> • 304 at baseline • 12M: 34 • 21M: 7
22	2008	Nguyen	Trabectome: A Novel Approach to Angle Surgery in the Treatment of Glaucoma	~36 %	~67 %	Up to 56	<ul style="list-style-type: none"> • 679 at baseline • 106 at 6M • 65 at 12M • 30 at 24M • 13 at 48M
23	2008	Minckler et al.	Trabectome (Trabeculectomy-Internal Approach): Additional Experience and Extended Follow-Up	TA: ~35 % TP: ~42 %	TA: ~83 % TP: ~30 %	Up to 60	<ul style="list-style-type: none"> • TA: 738 at baseline and 2 at 60M • TP: 366 at baseline and 2 at 30M
24	2009	Godfrey et al.	Canal Surgery in Adult Glaucomas	NA	NA	NA	NA
25	2009	Patel and Sit	A Practice Model for Trabecular Meshwork Surgery	NA	NA	NA	NA
26	2009	Minckler and Hill	Use of novel devices for control of intraocular pressure	NA	NA	NA	NA
7	2009	Liu et al.	<i>Ab interno</i> trabeculectomy Trabectome surgical treatment for open-angle glaucoma	~30 %	~64 %	Up to 60	<ul style="list-style-type: none"> • 1,688 at baseline • 60M: NA
15	2009	Mosaed et al.	Comparative outcomes between newer and older surgeries for glaucoma	~37 %	~48 %	Up to 60 (graph only)	<ul style="list-style-type: none"> • 102 at baseline • 12M: NA
27	2010	Vizzeri and Weinreb	Cataract surgery and glaucoma	NA	NA	NA	NA
28	2010	Vold and Dustin	Impact of laser trabeculectomy on Trabectome outcomes	~32 % ~39 %	~55 % ~29 %	Up to 36	<ul style="list-style-type: none"> No LTP • 852 at baseline • 36M: 47 LTP • 493 at baseline • 36M: 3
29	2010	Mosaed et al.	Trabectome Outcomes in Adult Open-Angle Glaucoma: One Year Follow-Up	TA: 31 % TP: 18 %	TA: 28 % TP: 33 %	Up to 12	<ul style="list-style-type: none"> TA • 538 at baseline • 12M: 363 TP • 290 at baseline • 12M: 266
30	2010	Francis	Trabectome combined with phacoemulsification versus phacoemulsification alone: a prospective, non-randomised controlled surgical trial	TP: 28 % PCE: 12 %	40 %	Up to 24	<ul style="list-style-type: none"> TP • 114 at baseline • 24M: 67 PCE • 145 at baseline • 24M: 41
31	2010	Vold	Impact of pre-operative intraocular pressure on trabectome outcomes: A prospective, non-randomised, observational, comparative cohort outcome study	Group 1: 7 % Group 2: 20 % Group 3: 33 % Group 4: 48 %	Group 1: 35 % Group 2: 28 % Group 3: 28 % Group 4: 25 %	Up to 6	<ul style="list-style-type: none"> Group 1 • 293 at baseline Group 2 • 428 at baseline Group 3 • 379 at baseline Group 4 • 301 at baseline

Table 1: Peer-reviewed Journals (Continued)

Ref. Year	Author	Title	IOP Reduction (%)	Meds Reduction (%)	Follow-Up Period (M)	Total Number of Cases	
12	2011	Jea et al.	Effect of a Failed Trabectome on Subsequent Trabeculectomy	Study group: 47.1 % Control group: 52.1 %	Study group: 75 % Control group: 81 %	Up to 24	Study group • 34 at baseline • 24M: 15 Control group • 42 at baseline • 24M: 22
32	2011	Francis et al.	Novel glaucoma procedures	NA	NA	NA	NA
17	2011	Francis and Winarko	Combined Trabectome and Cataract Surgery versus Combined Trabeculectomy and Cataract Surgery in Open-Angle Glaucoma	TP: 30 % TLE+PCE: 52 %	TP: ~46 % TLE+PCE: ~81 %	Up to 12	TP • 89 at baseline • 12M: 85 TLE+PCE • 23 at baseline • 12M: 20
33	2012	Ting et al.	<i>Ab interno</i> trabeculectomy: Outcomes in exfoliation vs primary open angle glaucoma	POAG TA: ~34 % POAG TP: ~22 % PEX TA: ~44 % PEX TP: ~35 %	POAG TA: ~21 % POAG TP: ~31 % PEX TA: ~28 % PEX TP: ~38 %	Up to 12	POAG TA • 450 at baseline • 12M: 293 POAG TP • 263 at baseline • 12M: 247 PEX TA • 67 at baseline • 12M: 53 PEX TP • 45 at baseline • 12M: 42
34	2013	Iordanous et al.	Projected Cost Comparison of Trabectome, iStent, Endoscopic Cyclophotocoagulation versus Glaucoma Medication in the Ontario Health Insurance Plan	NA	NA	NA	NA
35	2013	Maeda et al.	Evaluation of Trabectome in Open-Angle Glaucoma	31 %	43 %	Up to 12	• 80 at baseline • 12M: 27
36	2012	Oterrendorp et al.	The Trabectome as Treatment Option in Secondary Glaucoma Due to Intraocular Lymphoma	NA	NA	NA	NA
37	2010	Pantchevan and Kahook	<i>Ab Interno</i> Trabeculectomy	38 %	~67 %	Up to 6	• 34 at baseline • 6M: 25
38	2013	Jordan et al.	Trabectome surgery for primary and secondary open angle glaucomas	POAG: 25 % PEX: 32 %	POAG: 50 % PEX: 40 %	Up to 40	POAG • 261 at baseline • 40M: 76 PEX • 173 at baseline • 40M: 46
39	2013	Kaplowitz and Loewen	Techniques and outcomes of minimally invasive trabecular ablation and bypass surgery	NA	NA	NA	NA
40	2013	Klamann et al.	Combined clear cornea phacoemulsification in the treatment of pseudoexfoliative glaucoma associated with cataract: significance of trabecular aspiration and <i>ab interno</i> trabeculectomy	NA	NA	Up to 12	28
41	2013	Maeda et al.	Comparisons of the Outcomes of Trabectome with Trabeculectomy with Deep Sclerectomy: <i>Ab Interno</i> vs <i>Ab Externo</i> Trabeculectomy				
42	2013	Hwang et al.	Assessment of the Anterior Chamber Angle after Trabectome Glaucoma Surgery by Optical Coherence Tomography, Histopathology, Ultrasound Biomicroscopy and Scanning Electron Microscopy	NA	NA	NA	NA
43	2014	Mosaed	The First Decade of Global Trabectome Outcomes	25 %	~60 %	Up to 90	4,659 at baseline
44	2014	Klamann et al.	Influence of Selective Laser Trabeculoplasty (SLT) on combined clear cornea phacoemulsification and Trabectome outcomes	POAG: 38 % PEX: 46 % PG: 36 %	NA	NA	NA
45	2014	Anton et al.	Trauma-related secondary glaucoma in childhood: A therapeutic challenge	NA	NA	12M	1 (case report)
46	2014	Bussel et al.	Outcomes of <i>ab interno</i> trabeculectomy with the trabectome after failed trabeculectomy	28–33 %	14–27 %	Up to 12	AIT: 58 Phaco-AIT: 15

AIT = *ab interno trabeculectomy*; M = months; NA = not applicable; PCE = phacoemulsification cataract extraction; PEX = pseudoexfoliation glaucoma; PG = pigmentary glaucoma; POAG = primary open angle glaucoma; TA = trabectome alone; TP = trabectome combined with phacoemulsification.

Table 2: Demographics

n=5,435	
Age	
Mean±SD	70±14
Range	0–99
Gender	
Female	2,875 (53 %)
Male	2,433 (45 %)
NR	127 (2 %)
Race	
African American	306 (6 %)
Asian	258 (5 %)
Caucasian	2,448 (45 %)
Chinese	41 (1 %)
Japanese	1,345 (25 %)
Hispanics	172 (3 %)
Other	1,037 (19 %)
Diagnosis	
POAG	3,650 (67 %)
Pseudoexfoliation glaucoma	710 (13 %)
Juvenile	47 (1 %)
ACG	82 (2 %)
Myopic degeneration	8 (0 %)
Steroid	70 (1 %)
Pigment dispersion	160 (3 %)
Uveitic glaucoma	83 (2 %)
Ocular hypertension	25 (0 %)
Normal tension glaucoma	178 (3 %)
Traumatic glaucoma	15 (0 %)
Secondary glaucoma	157 (3 %)
Others	250 (5 %)
Pre-Op Snellen Acuity	
20/20–20/40	2,705 (50 %)
20/50–20/70	840 (15 %)
20/80–20/100	264 (5 %)
20/200–20/400	358 (7 %)
<20/400	168 (3 %)
NR	1,100 (20 %)
VF	
Mild	1,226 (23 %)
Moderate	1,210 (22 %)
Advanced	1,335 (25 %)
MD/Other	1,664 (31 %)
Disc C/D	
<0.7	1,136 (21%)
0.7–0.8	1,722 (32 %)
>0.8	1,371 (25 %)
NR	1,206 (22 %)
Lens Status	
Phakic	3,637 (67 %)
Pseudophakic	1,368 (25 %)
Aphakic	40 (1 %)
NR	390 (7 %)
Shaffer Grade	
I	66 (1 %)
II	511 (9 %)
III	1,475 (27 %)
IV	1,985 (37 %)
NR	1,398 (26 %)
Prior Surgeries	
SLT	1,161 (21 %)
ALT	555 (10 %)
Shunt	50 (1 %)
Trabeculectomy	312 (6 %)

Table 2: Demographics (continued)

Trabectome	45 (1 %)
Vitrectomy	18 (0 %)
LI	16 (0 %)
ECP	28 (1 %)
YAG	25 (0 %)
Retina Surgery	21 (0 %)
CRVO	4 (0 %)
Combined Surgeries	
Trabectome + phaco	2,250 (41 %)
Trabectome + goniosynechialysis	21 (0 %)
Trabectome + shunt	6 (0 %)
Trabectome + penetrating keroplasty	1 (0 %)
Trabectome + ECP	15 (0 %)
Trabectome + bleb revision	3 (0 %)
Trabectome only	3,057 (56 %)
Trabectome + other surgeries	82 (2 %)

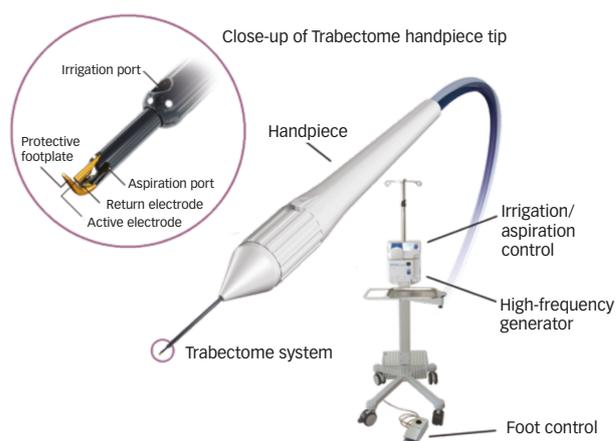
ACG = angle closure glaucoma; ALT = argon laser trabeculoplasty; C/D = cup-disc ratio; CRVO = central retinal vein occlusion; ECP = endocyclophotocoagulation; LI = laser iridotomy; MD = macular degeneration; NR = non response; POAG = primary open angle glaucoma; SD = standard deviation; SLT = selective laser trabeculoplasty; VF = visual field; YAG = capsulotomy.

Table 3: Intraocular Pressure and Number of Medications

	Intraocular Pressure	Number of Medications	n
Baseline	23.0±7.9	2.6±1.3	5,435
12M	16.2±4.0 (p<0.01*)	1.9±1.3 (p<0.01*)	1,546
24M	16.4±4.4 (p<0.01*)	1.9±1.3 (p<0.01*)	804
36M	16.4±4.3 (p<0.01*)	1.9±1.3 (p<0.01*)	444
48M	16.0±3.7 (p<0.01*)	1.7±1.3 (p<0.01*)	200
60M	15.7±3.3 (p<0.01*)	1.7±1.3 (p<0.01*)	129
72M	16.0±3.2 (p<0.01*)	1.9±1.3 (p=1.00)	76
84M	15.9±2.7 (p<0.01*)	1.8±1.3 (p=1.00)	47
90M	16.5±3.8 (p<0.01*)	1.6±1.3 (p=1.00)	37

*p value <0.05. M = months

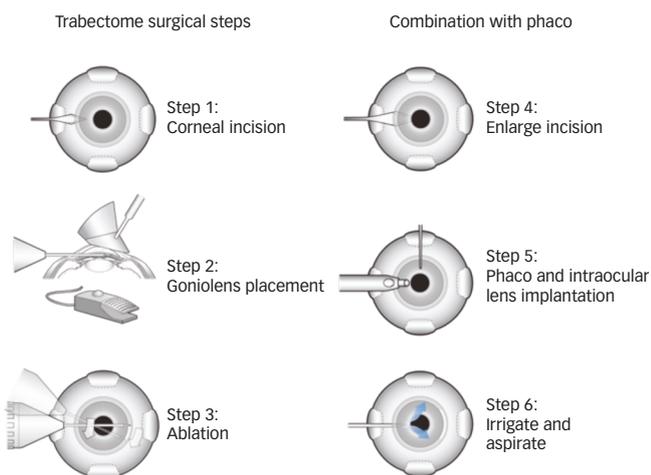
Figure 1: Trabectome Device



Trabectome outcomes. For each cited study, the parameters shown in the table include: year of publication, journal, author(s), title, average IOP reduction (%), average glaucoma medication reduction (%), duration of follow-up and total number of cases.

This paper is a summary of the first 20 cases of Trabectome surgeons who chose to contribute their initial cases on a voluntary basis globally.

Figure 2: Trabectome Surgical Steps



Some surgeons continued to provide additional cases that are also included, but the majority of the data are based on the first 20 cases of Trabectome surgeons. Each Trabectome surgeon was trained consisting of didactic, wet-Lab and surgical observation prior to performing Trabectome surgery. Therefore, this report represents the Trabectome surgeon’s experience and Trabectome outcomes of their initial cases (generally the first 20 cases).

Patients and Methods

Data were obtained from the Trabectome Study Group Database. The database consists of de-identified data submitted by Trabectome surgeons on standardised forms. Data collected include patient demographics and baseline measures such as pre-operative IOP, glaucoma medication use, surgical history of operative eye, as well as intraoperative details and complications. Outcome measures include IOP, number of glaucoma medications and secondary glaucoma surgery, if any.

All research was conducted with local institutional review board approval and in accordance with the Declaration of Helsinki and the US Health Insurance Portability and Accountability Act.

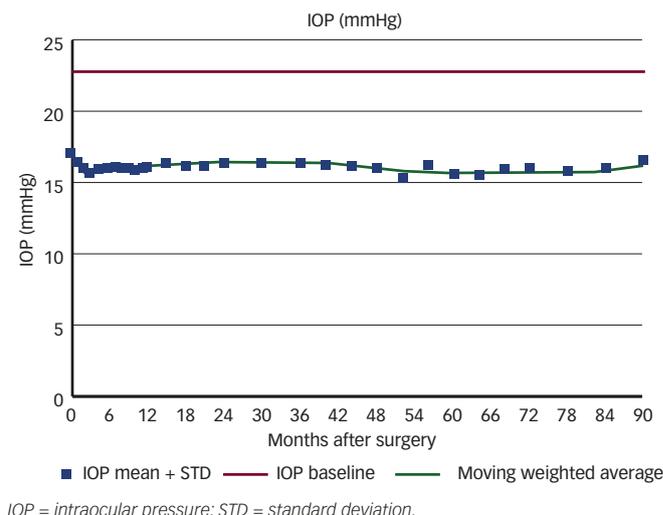
Details of the device and surgical procedures have been published.^{14,18} In brief, a 1.6–1.8 mm temporal corneal incision is made, the Trabectome handpiece is inserted into the anterior chamber and advanced nasally. Under gonioscopic view, the handpiece tip is inserted through the trabecular meshwork and into Schlemm’s canal. Once in appropriate position, approximately a 60 to 120 degree arc of trabecular meshwork and inner wall of Schlemm’s canal is ablated. Remnants of ablated tissue are removed via the handpiece’s aspiration flow. In most combined cases, Trabectome is generally performed first and followed by phacoemulsification. *Figure 1* shows the device; *Figure 2* indicates the basic surgical steps.

Survival curves were generated using Kaplan-Meier analysis. Success was defined as IOP less than 21 mmHg, at least 20 % reduction from baseline on any two consecutive visits after 3 months and no secondary glaucoma surgery. Analysis was performed using R statistical software (R Project).

Results

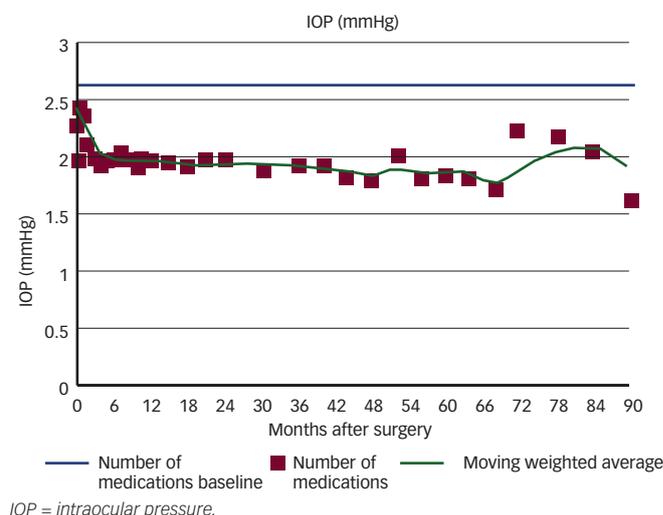
A total of 5,435 eyes in which patients received the Trabectome procedure were included in the total study group. Of these, 3,057 eyes (56 %)

Figure 3: Intraocular Pressure Trend



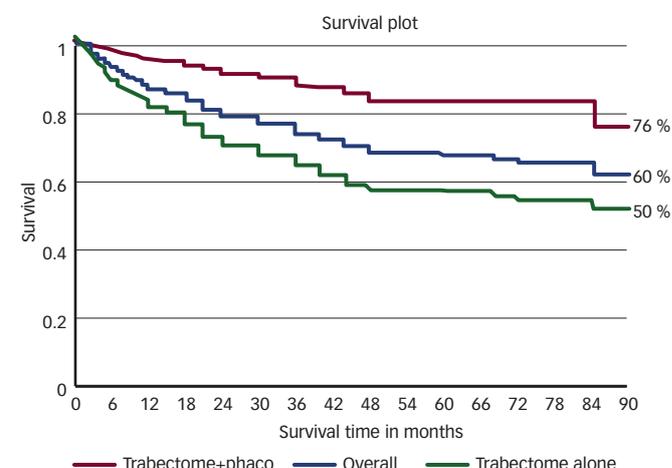
IOP = intraocular pressure; STD = standard deviation.

Figure 4: Number of Medications Trend



IOP = intraocular pressure.

Figure 5: Survival Plots for all Cases, Trabectome+Phaco and Trabectome Alone



received the Trabectome procedure alone, 2,250 eyes (41 %) received the Trabectome procedure combined with cataract extraction (phaco) and 82 eyes (2 %) received Trabectome combined with other surgical procedures.

Table 2 shows the baseline demographics of the study group. The average age of the study group was 70 years with the gender majority being female (53 %). The largest racial cohorts were Caucasians (45 %) and Japanese (25 %). The diagnosis of the majority of patients was primary open angle glaucoma (POAG) (67 %), followed by pseudoexfoliation glaucoma (13 %). The pre-op Snellen acuity of the largest cohort ranged from 20/20–20/40 (50 %). Measured visual fields were relatively evenly distributed among patients ranging from mild to advanced. The cup to disc ratio of the largest cohort was 0.7–0.8 (32 %), followed by >0.8 (25 %). Grade IV Shaffer represented the largest cohort of 1,985 eyes (37 %), followed by Shaffer grade III in 1,475 eyes (27 %). The largest cohort in terms of lens status was phakic in 3,637 eyes (67 %). Prior to receiving the Trabectome procedure, 1,716 eyes (31 %) had received argon laser trabeculoplasty (ALT) or SLT.

Table 3 shows average IOP and number of glaucoma medications at baseline and at different follow-up time periods. Figures 3 and 4 provide a graphical representation of these data. IOP was reduced from a baseline of 23.0±7.9 mmHg to 16.5±3.8 mmHg at 90 months, while number of glaucoma medications was reduced from 2.6±1.3 to 1.6±1.3 at 90 months. Post-operative observations are presented in Table 4. Three hundred and eighty-three eyes (7 %) required secondary glaucoma surgery. Of the 383 eyes, most underwent additional trabeculectomy or tube shunt. None of the sight-threatening complications associated with traditional filtering surgeries were observed. The survival curves are presented in Figure 5. At 90 months, the survival rates were 60 % for all cases, 76 % for combined cases and 50 % for Trabectome alone cases.

Discussion

Previous studies with the Trabectome procedure have been promising with the data available at various durations of follow-up. The purpose of this paper is focused on further providing global Trabectome outcomes, biased towards reflecting initial surgeon experience.

The data presented herein are provided on a voluntary basis by surgeons performing Trabectome procedures at centres around the world. Data are compiled based on receipt of de-identified data on standardised forms. There are no pre-defined exclusion criteria imposed for inclusion of cases into this analysis. This is an important factor. As such, these data reflect real-world use of Trabectome for the treatment

of glaucoma patients as determined by their physician providers. As indicated in the demographics presented in Table 2, patients receiving the Trabectome procedure in this study include various stages of glaucoma progression, with varying diagnoses and across a broad range of races. Furthermore, the database is biased towards inclusion of the first 20 Trabectome cases performed by starting surgeons, so results as presented would certainly include any early 'learning curve' impact without prejudice.

Considering the summary of outcomes for Trabectome patients previously published (see Table 1), it is apparent that most of these studies applied certain exclusion criteria for the purposes of performing certain defined comparative subgroup analyses. However, the intent of this paper is to analyse all available data without exclusion to provide insight into internationally observed Trabectome outcomes on a more universal and all-inclusive basis.

In terms of the primary outcome measures reported in this paper, average IOP was reduced from a baseline of 23.0 mmHg to 16.5 mmHg (28 %) at 90 months, and average number of glaucoma medications was reduced from 2.6 to 1.6 (38 %) at 90 months. These results are generally consistent with previously published outcome results as presented in Table 1.

Although none of the sight-threatening complications associated with traditional filtering surgeries were observed in this study, there have been risks associated with Trabectome procedure reported. Sit et al. reported 4.6 % of 262 cases have developed delayed hyphema, but most cases resolved within 1–2 weeks and only one case required additional surgery.⁴⁷ Cyclodialysis have also been observed with low incidence rate.⁴⁸

Conclusion

Considering this compilation and analysis of available data, as well as all of the outcome data surveyed from the literature, patients receiving Trabectome on average have about a 30 % reduction in IOP and a reduction in glaucoma medication use of about 40 %. Given the American Academy of Ophthalmology preferred practice pattern guidelines for at least 25 % initial IOP lowering, the procedure can be considered for initial therapy, as well as for end-stage patients that have been refractory to other surgical and medical treatments.⁴⁹ ■

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