

# Ab interno trabeculectomy: Outcomes in exfoliation versus primary open-angle glaucoma

Jessica L.M. Ting, MD, Karim F. Damji, MD, Michael C. Stiles, MD,  
on behalf of the Trabectome Study Group

**PURPOSE:** To compare outcomes in exfoliation glaucoma versus primary open-angle glaucoma (POAG) after ab interno trabeculectomy alone (Trabectome) or in combination with cataract surgery and intraocular lens (IOL) implantation.

**SETTING:** Trabectome Study Group institutions.

**DESIGN:** Prospective nonrandomized cohort study.

**METHODS:** Outcomes included intraocular pressure (IOP), glaucoma medications, complications, secondary procedures, and success, defined as no secondary surgery and IOP less than 21 mm Hg and a greater than 20% reduction from baseline.

**RESULTS:** In the ab interno trabeculectomy-alone group, the mean preoperative IOP was 29.0 mm Hg  $\pm$  7.5 (SD) in exfoliation glaucoma cases and 25.5  $\pm$  7.9 mm Hg in POAG cases ( $P < .01$ ). At 1 year, the mean decrease in IOP was  $-12.3 \pm 8.0$  mm Hg and  $-7.5 \pm 7.4$  mm Hg, respectively ( $P < .01$ ); the secondary procedure rate was 20.9% and 34.9%, respectively ( $P = .02$ ); and the cumulative probability of success was 79.1% and 62.9%, respectively ( $P = .004$ ). In the combined ab interno trabeculectomy-IOL group, the mean preoperative IOP was 21.7  $\pm$  8.4 in exfoliation glaucoma cases and 19.9  $\pm$  5.4 mm Hg in POAG cases ( $P = .06$ ). At 1 year, the mean decrease in IOP was  $-7.2 \pm 7.7$  and  $-4.1 \pm 4.6$ , respectively ( $P < .01$ ); the secondary procedure rate was 6.7% and 6.1%, respectively ( $P = .88$ ); and the cumulative probability of success was 86.7% and 91.0% ( $P = .73$ ), respectively.

**CONCLUSION:** Ab interno trabeculectomy using this new incisional procedure safely lowered IOP to the mid teens, with an overall greater reduction in exfoliation glaucoma and improved success when combined with cataract surgery.

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Exfoliation syndrome is an age-related disorder characterized by an abnormal accumulation of extracellular elastin-related microfibrillar material throughout the anterior segment of the eye.<sup>1</sup> It is considered the most common identifiable cause of open-angle glaucoma (OAG) worldwide and has been associated with polymorphisms in the lysyl oxidase-like 1 gene.<sup>1,2</sup>

When exfoliation glaucoma develops in the context of exfoliation syndrome, it typically has a more serious clinical course and worse prognosis compared with primary OAG (POAG). Exfoliation glaucoma is associated with greater intraocular pressure (IOP)

fluctuations, visual field loss, and severity of optic nerve damage as well as an increased frequency of treatment failure requiring surgical intervention.<sup>1</sup>

In exfoliation glaucoma, the underlying mechanism of OAG appears to be the accumulation of exfoliation material and/or liberated iris pigment that obstructs the trabecular meshwork.<sup>1</sup> In theory, if this source of outflow resistance were removed with no further distal obstruction, aqueous drainage should proceed relatively unimpeded. Historically, ab interno surgical procedures directed at the trabecular meshwork include goniotomy, goniotomy, and gonio

curettage; however, all have had limited success in adult glaucoma.<sup>3,4</sup> A more recently developed procedure, trabecular aspiration, is specifically directed at exfoliation glaucoma; it appears to lower IOP to the high teens but has a regression in effectiveness over time.<sup>5</sup>

A relatively new incisional procedure is Trabectome (Neomedix Corp.), in which ab interno trabeculectomy is performed by removing an arc of trabecular meshwork and inner wall of Schlemm canal and therefore may be a promising new approach for exfoliation glaucoma. It appears to effectively lower IOP in different OAG types with a lower risk for complications than standard trabeculectomy.<sup>6,7</sup>

The purpose of this study was to compare the 12-month postoperative outcomes in exfoliation glaucoma cases and POAG cases treated with ab interno trabeculectomy alone or combined with cataract extraction and intraocular lens (IOL) implantation. The main outcome measures included mean IOP, number of glaucoma medications, complications, and secondary procedures. Kaplan-Meier survival analysis was also performed to determine the 1-year success rate.

## PATIENTS AND METHODS

This was a prospective nonrandomized observational comparative cohort outcome study of exfoliation glaucoma cases and POAG cases with a minimum follow-up of 1 year. Data were obtained from the Trabectome Study Group Database inclusive from May 2003 to May 2011.

### Data Collection

All research was performed with institutional review board approval and in accordance with the Declaration of Helsinki and the U.S. Health Insurance Portability and Accountability Act.

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From the Department of Ophthalmology (Ting, Damji), University of Alberta, Edmonton, Alberta, Canada; University of Kansas Medical Center (Stiles), Kansas City, Kansas, USA.

Neomedix Corp., Tustin, California, USA, coordinated the data collection and assisted with statistical analysis.

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Corresponding author: Jessica L.M. Ting, MD, Department of Ophthalmology, University of Alberta, 10240 Kingsway Avenue, Royal Alexandra Hospital, Edmonton, Alberta, T5H 3V9, Canada. E-mail: [jting@ualberta.ca](mailto:jting@ualberta.ca).

The Trabectome Study Group database consists of data submitted by Trabectome surgeons on standardized reporting forms. Participating surgeons are listed in the Appendix (available at <http://jcrsjournal.org>). Neomedix requires mandatory reporting to a 1-year follow-up on the initial 20 surgeries performed by each surgeon. Data collected include patient demographics and baseline measures, intraoperative details and complications, and postoperative measures and complications. After 1 year of follow-up, continued data submission is encouraged but voluntary.

Inclusion criteria were all patients diagnosed with exfoliation glaucoma or POAG with and without visually significant cataract who had ab interno trabeculectomy alone (ab interno trabeculectomy-alone group) or combined with cataract extraction and IOL implantation (ab interno trabeculectomy-IOL group). Patients were excluded if they did not reach a minimum follow-up of 1 year, had missing preoperative IOP data, or had previous incisional procedures (trabeculectomy, tube shunts, Trabectome, endoscopic cyclophotocoagulation, and vitrectomy or other retinal procedures).

### Surgical Technique

Details of the surgical technique have been published.<sup>8-10</sup> Briefly, a 1.6 to 1.8 mm near limbal temporal corneal incision is made and an ophthalmic viscosurgical device is injected into the anterior chamber for stability. Under gonioscopic view, the Trabectome handpiece is advanced nasally and inserted through the trabecular meshwork. Selective electrosurgical ablation is activated to remove approximately a 60- to 120-degree arc of trabecular meshwork and inner wall of Schlemm canal while protecting the surrounding tissue and collector channels with the ceramic-coated footplate. The ablated tissue is aspirated via the irrigation/aspiration (I/A) lumens of the handpiece.

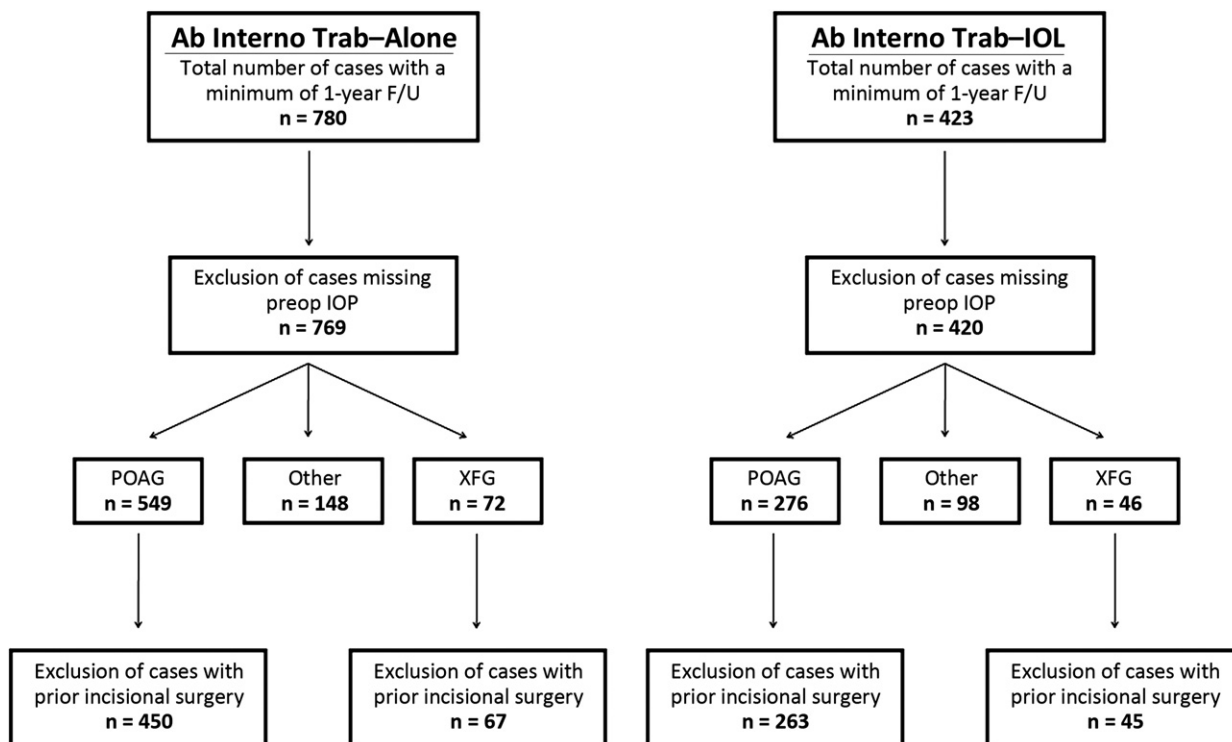
### Statistical Analysis and Outcomes

For study outcomes, comparison of preoperative and postoperative values was performed using the unpaired *t* test. Postoperative complications were compared using the Z test on proportions assuming equal variances. The association between various attributes of patients and their type of glaucoma was performed using the chi-square test. R statistical software (R Project) and Excel software (Microsoft Word Corp.) were used for statistical analysis. Kaplan-Meier survival analysis was used to compare success rates between exfoliation glaucoma and POAG. Success was defined as no secondary surgery and an IOP less than 21 mm Hg and a greater than 20% reduction from baseline on the last 2 consecutive follow-up visits after 3 months, similar to the success definition in the Tube versus Trabeculectomy Study.<sup>11</sup>

## RESULTS

After applying exclusion criteria, 825 cases were analyzed. In the ab interno trabeculectomy-alone group, there were 67 cases of exfoliation glaucoma and 450 cases of POAG. In the combined ab interno trabeculectomy-IOL group, there were 45 cases of exfoliation glaucoma and 263 cases of POAG (Figure 1).

Tables 1A and 1B show the patients' baseline demographics. The only significant difference was age; that



**Figure 1.** Trabectome Study Group Database. Cases analyzed after accounting for exclusion criteria. Prior incisional surgery includes standard trabeculectomy, tube shunts, Trabectome, endoscopic cyclophotocoagulation, and vitrectomy or other retinal procedures (F/U = follow-up; IOL = intraocular lens; IOP = intraocular pressure; POAG = primary open-angle glaucoma; Trab = trabeculectomy; XFG = exfoliation glaucoma).

is, patients with exfoliation glaucoma had a significantly higher mean age than patients with POAG in each treatment group.

Table 2 and Figures 2 and 3 show the preoperative and postoperative IOP measurements. In both treatment groups, there was significantly greater IOP lowering in exfoliation glaucoma cases than in POAG cases.

In the ab interno trabeculectomy-alone group, exfoliation glaucoma cases had a significantly higher preoperative IOP than POAG cases ( $P < .01$ ); however, the 2 subgroups had a similar mean 12-month IOP (approximately 16 mm Hg) ( $P = .23$ ). In contrast, in the ab interno trabeculectomy-IOL group, there was a borderline significant difference in preoperative IOP between exfoliation glaucoma cases and POAG cases ( $P = .06$ ); however, the 12-month IOP was significantly lower in exfoliation glaucoma cases than in POAG cases ( $P = .009$ ). Furthermore, in both treatment groups, the mean decrease in IOP was significantly greater in exfoliation glaucoma cases than in POAG cases at all postoperative endpoints except at 1 day.

Table 3 shows the change in the number of glaucoma medications over time. In the ab interno trabeculectomy-alone group, the mean decrease in

medications was significantly greater in exfoliation glaucoma cases than in POAG cases 6 months and 12 months postoperatively. The mean number of preoperative medications was also significantly higher in exfoliation glaucoma cases. In contrast, in the ab interno trabeculectomy-IOL group, there were no significant differences in the mean decrease in medications or the mean number of medications at any endpoint. Overall, the decrease in medications ranged from 30% to 40% in the ab interno trabeculectomy-alone group, except in POAG cases in which the decrease was approximately 15%.

Table 4 shows the incidence of secondary surgeries and complications. In the ab interno trabeculectomy-alone group, the incidence of secondary surgeries was significantly higher in POAG cases than in exfoliation glaucoma cases ( $P = .02$ ) and the surgeries consisted primarily of standard trabeculectomies. In the ab interno trabeculectomy-IOL group, the incidence of secondary surgeries in exfoliation glaucoma cases and POAG cases was not significantly different ( $P = .88$ ).

Overall, the most common complication was intraoperative blood reflux. There was a low incidence of 1-day postoperative hypotony and IOP spikes. There were no reported incidences of sustained hypotony,

**Table 1A.** Patient demographics in the ab interno trabeculectomy-alone group.

Parameter	POAG (n = 450)	XFG (n = 67)	P Value
Mean age (y) ± SD	68 ± 15	73 ± 9	.008*
Sex (n)			.1 <sup>†</sup>
Male	181	21	
Female	256	45	
Not indicated	13	1	
Race (n)			.2 <sup>†</sup>
White	276	40	
Hispanic	50	8	
Asian	51	12	
African-American	26	0	
Other	47	7	
CDVA (n)			.8 <sup>†</sup>
20/20–20/40	261	40	
20/50–20/70	57	6	
20/80–20/100	15	4	
20/200–20/400	29	4	
<20/400	21	2	
Not indicated	67	11	
Lens status (n)			.2 <sup>†</sup>
Pseudophakic	192	21	
Phakic	220	39	
Aphakic	3	0	
Not indicated	35	7	
Cup-to-disc ratio			.2 <sup>†</sup>
<0.7	98	13	
0.7–0.8	145	29	
>0.8	151	21	
Not indicated	56	4	
Schaffer grade (n)			.3 <sup>†</sup>
I	8	1	
II	27	4	
III	152	17	
IV	182	36	
Not indicated	81	9	
Previous surgery (n)			.7 <sup>†</sup>
SLT	149	29	
ALT	75	17	

ALT = argon laser trabeculectomy; CDVA = corrected distance visual acuity; Not indicated = data excluded from chi-square test calculations; POAG = primary open-angle glaucoma; SLT = selective laser trabeculectomy; XFG = exfoliation glaucoma

\*Unpaired *t* test

<sup>†</sup>Chi-square test

choroidal effusion or hemorrhage, visual acuity decrease greater than 2 lines, infection, aqueous misdirection, or wound leak.

Figures 4 and 5 show the Kaplan-Meier survival analysis results. In the ab interno trabeculectomy-alone group, the 1-year cumulative probability of success was significantly higher in exfoliation glaucoma cases than in POAG cases (79.1% versus 62.9%) ( $P=.004$ , log rank test). In the ab interno

**Table 1B.** Patient demographics in the combined ab interno trabeculectomy-IOL group.

Parameter	POAG (n = 263)	XFG (n = 45)	P Value
Mean age (y) ± SD	74 ± 9	78 ± 7	.005*
Sex (n)			.05 <sup>†</sup>
Male	104	11	
Female	155	33	
Not indicated	4	1	
Race (n)			.4 <sup>†</sup>
White	137	30	
Hispanic	70	7	
Asian	19	2	
African-American	7	1	
Other	30	5	
CDVA (n)			.3 <sup>†</sup>
20/20–20/40	73	17	
20/50–20/70	74	8	
20/80–20/100	34	2	
20/200–20/400	19	5	
<20/400	11	2	
Not indicated	52	11	
Cup-to-disc ratio			.09 <sup>†</sup>
<0.7	48	9	
0.7–0.8	91	21	
>0.8	84	14	
Not indicated	40	1	
Schaffer grade (n)			.4 <sup>†</sup>
I	1	1	
II	30	4	
III	95	13	
IV	76	14	
Not indicated	61	13	
Previous surgery (n)			.97 <sup>†</sup>
SLT	49	10	
ALT	30	6	

ALT = argon laser trabeculectomy; CDVA = corrected distance visual acuity; Not indicated = data excluded from chi-square test calculations; POAG = primary open-angle glaucoma; SLT = selective laser trabeculectomy; XFG = exfoliation glaucoma

\*Unpaired *t* test

<sup>†</sup>Chi-square test

trabeculectomy-IOL group, there was no significant difference in the 1-year cumulative probability of success between exfoliation glaucoma cases and POAG cases (86.7% versus 91.0%) ( $P=.73$ , log rank test).

## DISCUSSION

In this prospective nonrandomized cohort study of ab interno trabeculectomy using the Trabectome technique, we compared the outcomes of ab interno trabeculectomy-alone versus combined ab interno trabeculectomy-IOL in exfoliation glaucoma cases and POAG cases. Overall, there was a greater IOP reduction in exfoliation glaucoma cases in both treatment groups. The 1-year survival was greater in

**Table 2.** Change in IOP.

Treatment Group	POAG			XFG			P Value*	
	n	Mean (mm Hg) ± SD		n	Mean (mm Hg) ± SD		IOP	Δ IOP
		IOP	Δ IOP		IOP	Δ IOP		
<b>Ab interno trab-alone</b>								
Preop	450	25.5 ± 7.9	—	67	29.0 ± 7.5	—	<.01	—
<b>Postop</b>								
1 day	450	16.5 ± 7.9	-8.9 ± 9.9	67	17.8 ± 9.8	-11.2 ± 12.8	.22	.09
1 month	420	18.1 ± 5.8	-7.1 ± 8.2	66	16.9 ± 5.6	-12.1 ± 8.8	.11	<.01
3 months	384	17.6 ± 5.3	-7.3 ± 8.1	59	16.3 ± 4.5	-12.1 ± 8.0	.07	<.01
6 months	327	17.3 ± 4.0	-7.3 ± 7.5	55	16.0 ± 3.4	-12.4 ± 7.6	.02	<.01
12 months	293	16.8 ± 3.9	-7.5 ± 7.4	53	16.1 ± 4.0	-12.3 ± 8.0	.23	<.01
<b>Ab interno trab-IOL</b>								
Preop	263	19.9 ± 5.4	—	45	21.7 ± 8.4	—	.06	—
<b>Postop</b>								
1 day	263	18.4 ± 9.0	-1.5 ± 9.2	45	20.2 ± 10.1	-1.4 ± 10.9	.22	.94
1 month	258	15.5 ± 4.4	-4.3 ± 5.4	43	13.4 ± 4.7	-8.1 ± 8.2	.004	<.01
3 months	258	15.2 ± 3.6	-4.7 ± 5.0	42	13.6 ± 4.5	-7.9 ± 6.9	.01	<.01
6 months	252	15.3 ± 3.4	-4.4 ± 4.8	42	14.1 ± 3.0	-7.4 ± 7.5	.03	<.01
12 months	247	15.6 ± 3.2	-4.1 ± 4.6	42	14.2 ± 3.1	-7.2 ± 7.7	.009	<.01

Δ = mean of differences; IOL = intraocular lens; IOP = intraocular pressure; n = number of cases remaining after survival accounted for at each endpoint; POAG = primary open-angle glaucoma; trab = trabeculectomy; XFG = exfoliation glaucoma

\*Unpaired *t* test

exfoliation glaucoma cases than in POAG cases in the ab interno trabeculectomy-alone group; however, the survival was similar in the ab interno trabeculectomy-IOL group.

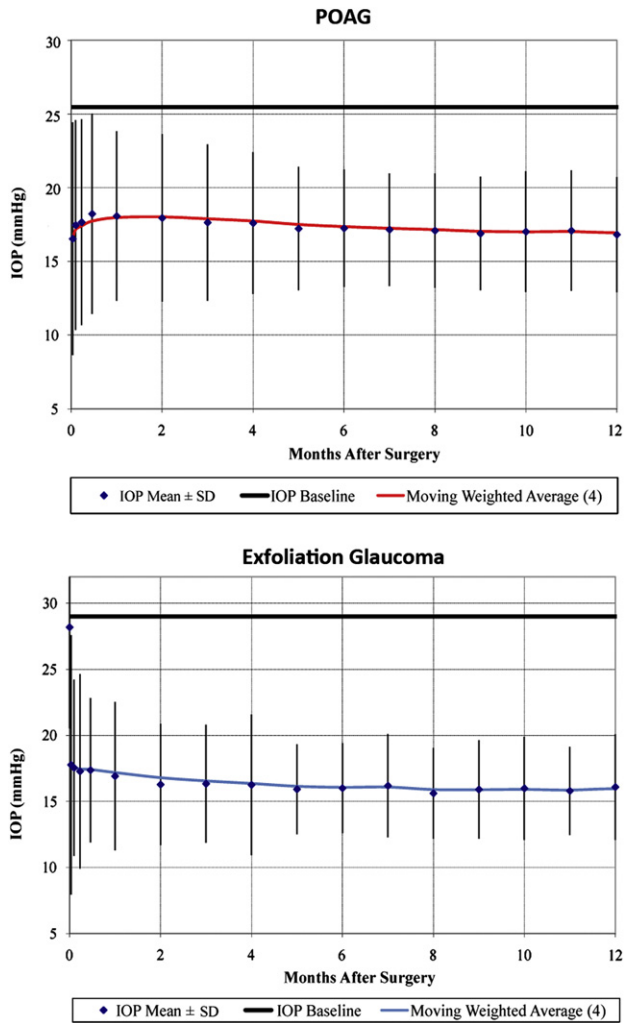
In POAG, although the level of obstruction is thought to be trabecular, there is also speculation of more distal obstruction in the drainage pathway.<sup>12</sup> In exfoliation glaucoma, the level of obstruction appears to be primarily trabecular and the greater IOP lowering seen with ab interno trabeculectomy using the Trabectome technique may reflect the mechanical removal of trabecular meshwork as well as mechanical and/or inflammatory effects that wash out exfoliation material in and around the meshwork and elsewhere in the anterior segment.<sup>1,13</sup> In this study, the removal of trabecular obstruction with ab interno trabeculectomy appeared to consistently lower IOP to the mid teens in both treatment groups. However, there was a significantly greater mean decrease in IOP in exfoliation glaucoma cases than in POAG cases, which may reflect this washout mechanism.

In a previous prospective study that compared the IOP-lowering effect of cataract surgery between exfoliation glaucoma and POAG, greater IOP lowering occurred in the exfoliation glaucoma cases, and this was correlated with irrigation volume.<sup>13</sup> The authors hypothesize that this was the result of 1 or more of the following: deepening of the anterior chamber angle, reduction in the iridolenticular

friction that releases pigment and exfoliation material, washout of exfoliation material, or low-grade inflammation that enhances aqueous outflow, similar to laser trabeculoplasty. In a small case series, Jacobi et al.<sup>5</sup> evaluated the effects of trabecular I/A to remove trabecular exfoliation material in eyes with exfoliation glaucoma. Although they found a significant reduction in IOP, there was a 14% incidence of postoperative hematoma of the anterior chamber angle. In addition, mild regression in IOP lowering that was thought to result from reaccumulation of exfoliation material was seen over a 2- to 4-year follow-up.

In our study, irrigation volume was not recorded; therefore, further study would be needed to confirm the correlation with IOP reduction. With the ab interno trabeculectomy-IOL technique, cataract extraction would provide additional irrigation; therefore, we would expect more pronounced IOP lowering than with ab interno trabeculectomy alone. However, it is difficult to evaluate whether IOP lowering was greater in exfoliation glaucoma cases in ab interno trabeculectomy-IOL than in ab interno trabeculectomy-alone because of the difference in baseline IOP (21.7 ± 8.4 mm Hg versus 29.0 ± 7.5 mm Hg).

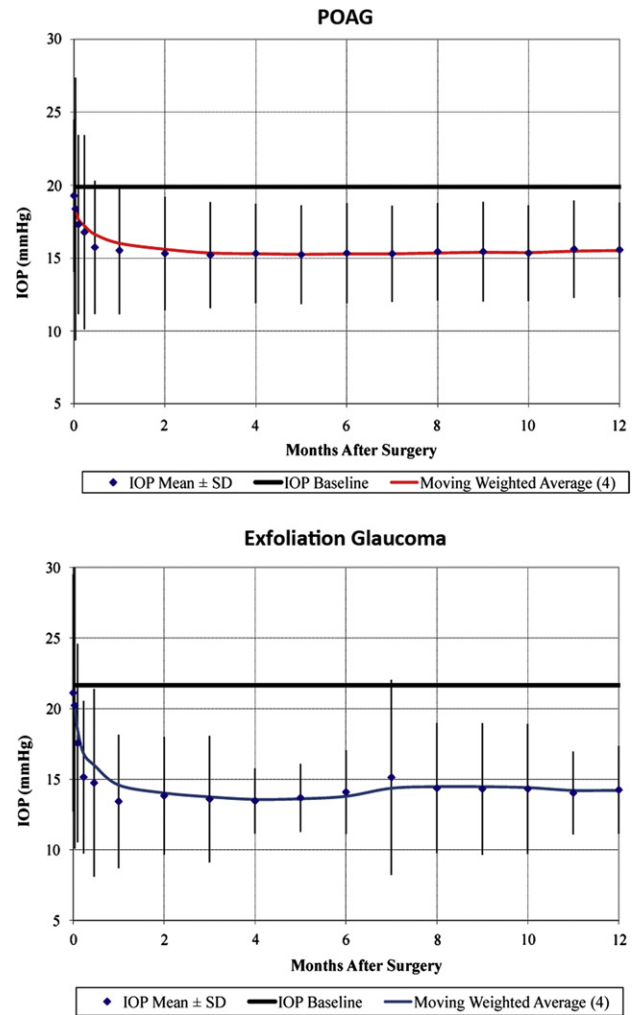
In our ab interno trabeculectomy-alone group, the rate of secondary surgeries, primarily standard trabeculectomy, was significantly higher in POAG cases than in exfoliation glaucoma cases. This may reflect



**Figure 2.** Top: Mean IOP  $\pm$  SD in POAG cases in the ab interno trabeculectomy-alone group; IOP baseline indicates mean preoperative intraocular pressure in 450 cases. Bottom: Mean IOP  $\pm$  SD in exfoliation glaucoma cases in the ab interno trabeculectomy-alone group; IOP baseline indicates mean preoperative intraocular pressure in 67 cases (IOP = intraocular pressure; POAG = primary open-angle glaucoma).

an unaddressed distal obstruction in POAG cases or increased wound healing, resulting in closure of the cleft. Once again, it is possible that the outcomes in the exfoliation glaucoma cases were better due to washout of exfoliation material, leading to greater 1-year survival (79.1% in exfoliation glaucoma and 62.9% in POAG).

In contrast, in our ab interno trabeculectomy-IOL group, the need for secondary surgery was lower and the survival rates at 1 year were higher (86.7% in exfoliation glaucoma and 91.0% in POAG). This may be related to the increased aqueous drainage resulting from deepening of the anterior chamber angle with lens removal or from a lower baseline IOP and lower number of glaucoma medications in exfoliation



**Figure 3.** Top: Mean IOP  $\pm$  SD in POAG cases in the ab interno trabeculectomy-IOL group; IOP baseline indicates mean preoperative intraocular pressure in 236 cases. Bottom: Mean IOP  $\pm$  SD in exfoliation glaucoma cases in the ab interno trabeculectomy-IOL group; IOP baseline indicates mean preoperative intraocular pressure in 45 cases (IOP = intraocular pressure; POAG = primary open-angle glaucoma).

glaucoma cases and POAG cases than in the corresponding subgroups in the ab interno trabeculectomy-alone group.

Furthermore, because ab interno trabeculectomy does not violate the conjunctiva, subsequent procedures that rely on intact and healthy conjunctiva, such as filtering and/or aqueous shunt devices, can likely be performed without difficulty.

In the ab interno trabeculectomy-alone group, the mean decrease in medication was significantly greater in exfoliation glaucoma cases than in POAG cases at the 6-month and 12-month endpoints. The medication requirements were more significantly decreased in exfoliation glaucoma cases, supporting the greater effectiveness of ab interno trabeculectomy in this

**Table 3.** Change in glaucoma medications.

Treatment Group	POAG			XFG			P Value*	
	n	Mean (n) ± SD		n	Mean (n) ± SD		Rx	Δ Rx*
		Rx	Δ Rx		Rx	Δ Rx		
Ab interno trab-alone								
Preop	450	2.73 ± 1.33	—	67	3.09 ± 1.15	—	0.04	—
Postop								
1 day	450	2.21 ± 1.73	-0.52 ± 1.81	67	2.09 ± 1.79	-1.00 ± 2.17	0.6	0.05
1 month	420	2.50 ± 1.45	-0.21 ± 1.40	66	2.68 ± 1.55	-0.39 ± 1.55	0.35	0.34
3 months	384	2.34 ± 1.42	-0.36 ± 1.31	59	2.46 ± 1.37	-0.66 ± 1.36	0.54	0.1
6 months	327	2.14 ± 1.34	-0.49 ± 1.28	55	2.24 ± 1.36	-1.00 ± 1.26	0.6	0.006
12 months	293	2.16 ± 1.29	-0.42 ± 1.33	53	2.21 ± 1.38	-1.00 ± 1.36	0.8	0.004
Ab interno trab-IOL								
Preop	263	2.40 ± 1.08	—	45	2.53 ± 0.99	—	0.45	—
Postop								
1 day	263	1.82 ± 1.55	-0.56 ± 1.67	45	1.80 ± 1.78	-0.73 ± 1.81	0.94	0.53
1 month	258	2.13 ± 1.35	-0.25 ± 1.31	43	2.40 ± 1.50	-0.14 ± 1.26	0.23	0.6
3 months	258	1.80 ± 1.27	-0.59 ± 1.14	42	1.81 ± 1.47	-0.69 ± 1.18	0.96	0.6
6 months	252	1.66 ± 1.24	-0.71 ± 1.16	42	1.69 ± 1.37	-0.81 ± 1.11	0.89	0.6
12 months	247	1.65 ± 1.26	-0.72 ± 1.19	42	1.57 ± 1.33	-0.93 ± 1.18	0.7	0.29

Δ = mean of differences; IOL = intraocular lens; IOP = intraocular pressure; n = number of cases remaining after survival accounted for at each endpoint; POAG = primary open-angle glaucoma; trab = trabeculectomy; XFG = exfoliation glaucoma

\*Unpaired t test

group. However, in the ab interno trabeculectomy-IOL group, the mean decrease in medication was not significantly different between exfoliation glaucoma

cases and POAG cases. This may be related to the additional benefit of cataract extraction and the possible greater washout of exfoliation material.

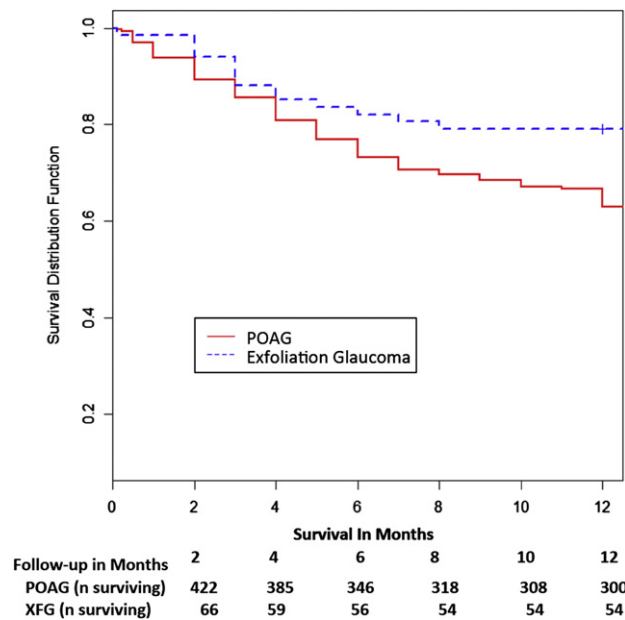
**Table 4.** Postoperative complications in first year of follow-up.

Complication	Ab Interno Trab-Alone			Ab Interno Trab-IOL		
	POAG	XFG	P Value <sup>†</sup>	POAG	XFG	P Value <sup>†</sup>
Total cases, n	450	67	—	263	45	—
Late complications, n (%)						
Standard trabeculectomy post ab interno trab*	100 (22.2)	7 (10.4)	0.03	9 (3.4)	1 (2.2)	0.67
Shunt post ab interno trab*	37 (8.2)	4 (6.0)	0.5	3 (1.1)	2 (4.4)	0.11
Diode cyclophotocoagulation	30 (6.7)	0	0.5	0	0	—
ECP post ab interno trab*	6 (1.3)	1 (1.5)	0.9	1 (0.4)	0	0.67
Express shunt	2 (0.4)	0	0.6	2 (0.8)	0	0.55
Ab interno trab* post ab interno trab* (patient request)	9 (2.0)	2 (3.0)	0.6	1 (0.4)	0	0.67
Total secondary surgery	157 (34.9)	14 (20.9)	0.02	16 (6.1)	3 (6.7)	0.88
Early complications, n (%)						
Hypotony (IOP <5 mm Hg) 1 day postop	3 (0.7)	1 (1.5)	0.5	0	1 (2.2)	0.02
IOP at 1 day >10 mm Hg from preop IOP	14 (3.1)	4 (6.0)	0.2	26 (9.9)	4 (8.9)	0.83
Intraoperative blood reflux, n (%)						
Yes	372 (82.7)	55 (82.1)	—	220 (83.7)	45 (100)	—
No	17 (3.8)	1 (1.5)	—	7 (2.7)	0	—
Not reported	61 (13.6)	11 (16.4)	—	36 (13.7)	0	—

ECP = endocyclophotocoagulation; IOL = intraocular lens; IOP = intraoperative pressure; POAG = primary open-angle glaucoma; trab = trabeculectomy; XFG = exfoliation glaucoma

\*Performed using Trabectome

<sup>†</sup>From Z test on proportions assuming equal variances



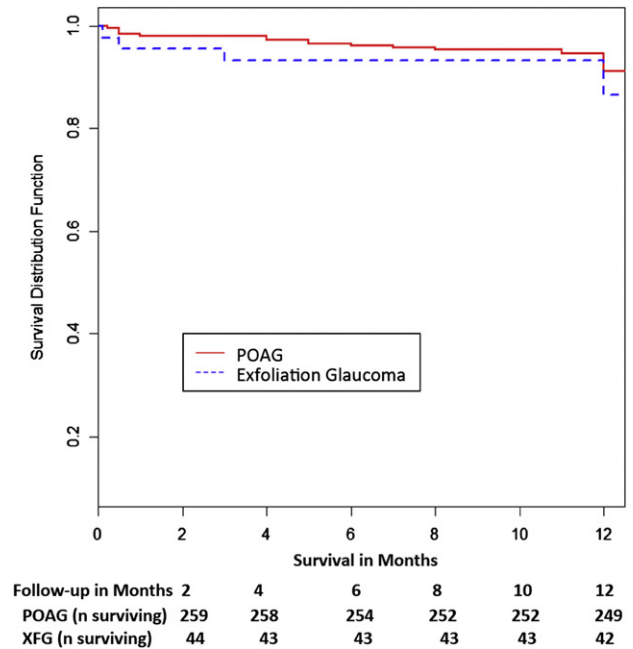
**Figure 4.** Kaplan-Meier survival curve of exfoliation glaucoma versus POAG in the ab interno trabeculectomy-alone group (POAG = primary open-angle glaucoma).

Although the most common complication was intraoperative blood reflux, this is expected when an arc of trabecular meshwork and inner wall of Schlemm canal are removed and likely indicates reflux from collector channels that communicate with the episcleral venous system. It typically clears within a few days, and previous evaluation of the Trabectome technique did not find a correlation with IOP spikes.<sup>7</sup>

Cataract-specific complications were not reported in our ab interno trabeculectomy-IOL group. However, future studies should evaluate this because exfoliation glaucoma is associated with an increased risk for zonular dialysis, capsule tears, and vitreous loss.<sup>1</sup>

Limitations of this study include selection bias because the Trabectome Study Group Database comprises mandatory reporting on the initial 20 patients operated on by each surgeon followed by subsequent voluntary data submission. Despite standardized reporting forms, there was also incomplete data submission.

We analyzed all applicable exfoliation glaucoma and POAG cases in the Trabectome Database. However, there was a large difference in sample sizes between these groups and the proportion of exfoliation glaucoma cases seemed to be lower than would be expected in the population. This may relate to the selection bias but also to the more severe clinical course often seen in exfoliation glaucoma, which may limit ab interno trabeculectomy as a first-line treatment. As a result, the exfoliation glaucoma cases



**Figure 5.** Kaplan-Meier survival curve of exfoliation glaucoma versus POAG in the ab interno trabeculectomy-IOL group (POAG = primary open-angle glaucoma).

may not reflect the normal distribution, as assumed in the parametric statistical tests used in our analysis.

For study outcomes, the method of IOP measurement was at the discretion of the surgeon and may have differed between single IOP measurements versus a mean of several measurements. The risk of regression to the mean would be higher with single IOP readings. Furthermore, the postoperative reduction in glaucoma medications could have been influenced by various factors, such as increased compliance.

Nevertheless, because there are limited studies of the Trabectome technique, the Trabectome Database provides the best data at this time to evaluate this relatively new surgical procedure.

In conclusion, ab interno trabeculectomy by the Trabectome technique safely and effectively lowered IOP to the mid teens in exfoliation glaucoma cases and POAG cases, with overall greater IOP lowering in exfoliation glaucoma cases. When performed alone, the rate of secondary procedures, such as standard trabeculectomy, was higher in POAG cases than in exfoliation glaucoma cases; however, when performed in combination with cataract surgery and IOL implantation, the rate of secondary surgery was overall lower and similar in both groups.

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First author:

Jessica L.M. Ting, MD

*Department of Ophthalmology,  
University of Alberta, Edmonton,  
Alberta, Canada*