Impact of Preoperative Intraocular Pressure on Trabectome Outcomes

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Purpose:

To evaluate the impact of preoperative intraocular pressure (IOP) on the efficacy and safety of Trabectome® surgery in open angle glaucoma patients.

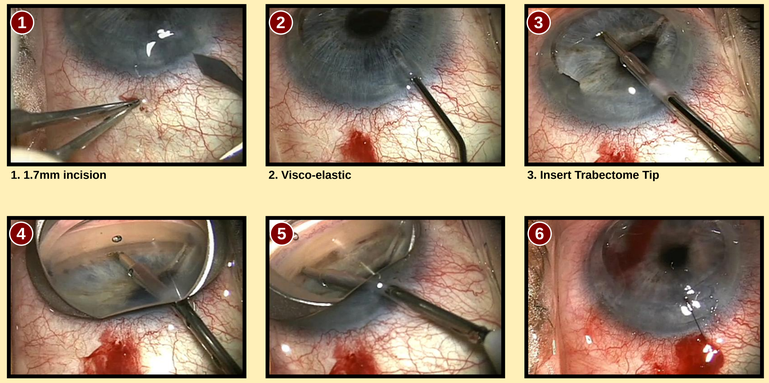
Setting:

Multicenter clinical study involving 53 academic and private ophthalmology practices to adopt Trabectome surgery.

Methods:

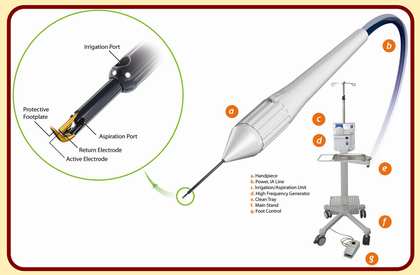
This is a retrospective study of consecutive Trabectome surgery cases with 6 months follow-up. All cases performed by participating surgeons were included. The eyes were stratified into four groups on preoperative IOP. Baseline demographic and medical data were collected. Main outcome measures were intraocular pressure (IOP), number of glaucoma medications, and the occurrence of complications or secondary procedures.

Surgical Technique:



1. 1.7mm incision
2. Visco-elastic
3. Insert Trabectome Tip
4. Identify angle view and begin ablation
5. Complete ablation 60-120 degree arc
6. Irrigate and aspirate with Simco, suture

Trabectome System:

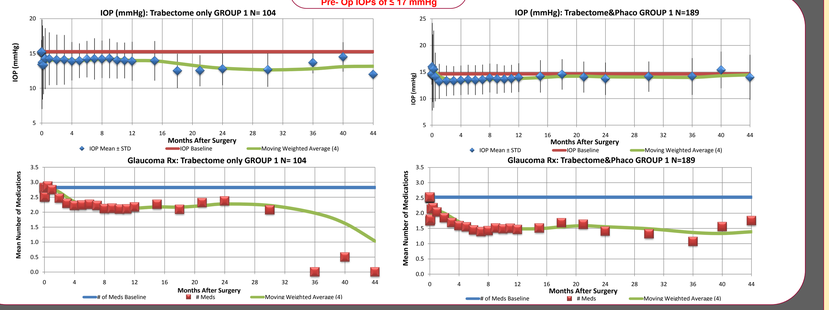


Technique Advantages

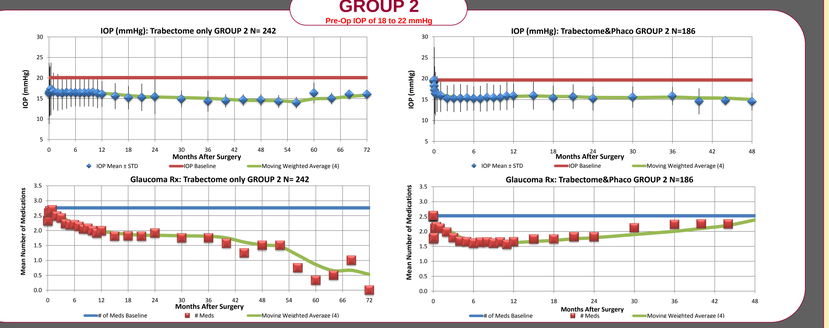
- Continual infusion deepens & maintains anterior chamber
- AC viscoelastic optional – can deepen & stabilize AC
- Footplate acts as guide within Schlemm's
- Ablation & aspiration of TM debris should reduce inflammatory stimuli
- Ceramic coated footplate & infusion protect from thermal & mechanical injury
- Minimally Invasive & low complication rate
- In theory re-establishes/enhances physiological drainage
- No conjunctival manipulation & does not preclude subsequent standard filtering surgery

Results:

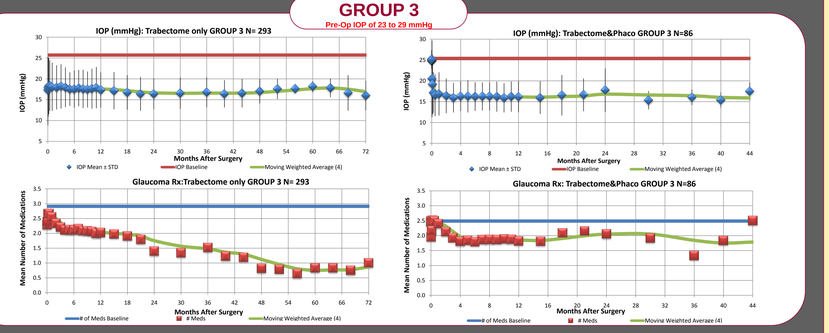
GROUP 1
Pre- Op IOPs of ≤ 17 mmHg



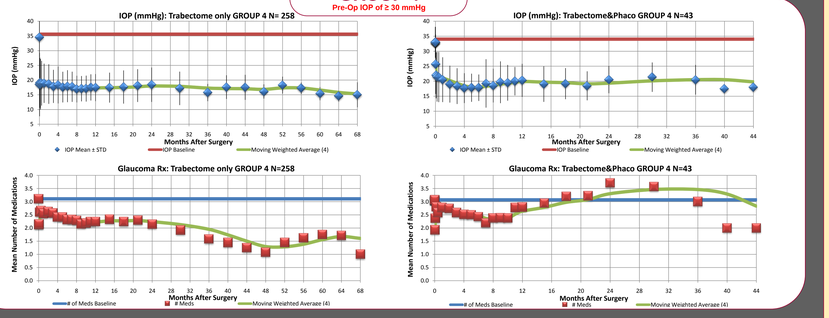
GROUP 2
Pre-Op IOP of 18 to 22 mmHg



GROUP 3
Pre-Op IOP of 23 to 29 mmHg



GROUP 4
Pre-Op IOP of ≥ 30 mmHg



Results Contd.:

Table 1: Demographic Data in T and T+P Surgery Types Within GROUPS 1, 2, 3, 4

	Group 1		Group 2		Group 3		Group 4	
	T	T+P	T	T+P	T	T+P	T	T+P
Number(n)	104	189	242	186	293	86	258	43
Age	69±15	75±10	70±15	73±10	66±16	75±10	64±18	69±14
Gender								
Males	50	71	91	74	115	28	137	16
Females	54	113	143	110	166	57	118	25
NR	0	5	8	2	12	1	3	2
Race								
African-American	3	12	12	8	13	4	19	1
Asian	7	31	29	30	32	15	33	8
Caucasian	79	113	164	128	182	56	143	23
Hispanic	0	7	12	4	30	0	31	7
Other/NR	15	26	25	16	36	11	32	4
Diagnosis								
POAG&COAG	85	145	195	139	226	58	149	15
PEX	7	18	17	25	13	9	41	8
JRA	1	0	0	0	2	0	1	0
Myopic Degeneration	1	0	0	0	3	0	1	0
Steroid Induced	0	1	2	1	2	0	9	1
Pigmentary Glaucoma	3	3	9	5	10	4	12	3
Uveitic	2	0	0	2	5	2	17	3
Other/NR	5	22	19	14	32	13	28	13
Pre-op Snellen Activity								
20/20-20/40	59	62	143	62	165	26	123	9
20/50-20/70	13	51	27	46	31	19	28	12
20/80-20/100	4	22	6	14	12	8	11	6
20/200-20/400	7	17	8	13	20	12	25	7
>20/400	5	5	9	6	6	4	15	0
Not recorded	16	32	49	45	59	17	56	9
Lens Status								
Pseudo-Phakic	50	0	125	0	137	0	100	0
Phakic	45	189	98	186	126	86	135	43
Aphakic	0	0	3	0	1	0	3	0
Not Recorded	9	0	16	0	29	0	20	0
Shaffer Grade								
I	2	1	2	4	4	0	3	1
II	5	17	10	20	17	7	19	6
III	26	67	68	53	81	28	76	13
IV	45	53	111	71	126	27	106	11
Not Recorded	26	51	51	38	65	24	54	12

Table 2: IOP Results In Trabectome Only (T) Cases And Combined Surgery Cases(T+P) In Each Of The 4 Groups

Group #	Surgery Type	Pre-op IOP	6 Month IOP	% Change	p-IOP
Group 1	T	15.3±1.7	14.2±2.6	-6%	<0.001
	T+P	14.6±2.0	13.5+2.8	-7%	<0.001
		0.003#	0.04#		
Group 2	T	20.1±1.3	16.4±3.3	-18%	<0.001
	T+P	19.6±1.4	15.2±2.9	-22%	<0.001
		<0.001#	<0.001#		
Group 3	T	25.7±1.9	17.5±4.5	-31%	<0.001
	T+P	25.4±1.8	16.2±3.4	-36%	<0.001
		0.19#	0.018#		
Group 4	T	35.6±5.7	17.9±5.4	-48%	<0.001
	T+P	34.0±4.2	17.8±4.4	-47%	<0.001
		0.079#	0.91#		

p-IOP is p value from t test for comparing 6 month IOP to pre-op IOP within each surgery group.
# denotes p value from t test for comparing various characteristics between surgery groups.
T: Trabectome surgery only, T+P : Trabectome combined with phacoemulsification surgeries.

Table 3: Complications & 2nd Surgeries In T and T+P Surgery Types Within Groups 1, 2,3 4

	Group 1		Group 2		Group 3		Group 4	
	T	T+P	T	T+P	T	T+P	T	T+P
Total # cases	104	189	242	186	293	86	258	43
Sec. Surgeries								
Trabeculectomy post Trabectome	5	1	19	4	39	2	39	6
Shunt post Trabectome	1	0	10	1	20	2	18	2
DCP	1	0	5	0	0	0	1	0
ECP post Trabectome	0	1	1	0	2	0	3	0
T post Trabectome#	0	0	2	0	6	0	5	0
Total Secondary Surgeries %	7 (7%)	2 (1%)	37 (15%)	5 (3%)	67 (23%)	4 (5%)	66 (25%)	8 (19%)
Patients death (not related to Trabectome)	0	0	0	0	0	0	0	0
Eyes out of study (Patient moved)	0	0	0	0	0	0	0	0
Complications:								
Sustained Hypotony (IOP<5 mmHg) 1 month post op	0	0	0	0	0	0	0	0
Hypotony (IOP<5mmHg) 1 day post op	3	3	2	3	4	0	5	0
IOP-10>10 mmHg from pre op IOP	7	20	15	17	13	7	10	2
Aqueous Misdirection	0	0	0	0	1	0	0	0
Infection	0	0	0	0	0	0	0	0
Bleb Formation	0	0	0	0	0	0	0	0
Wound Leaks	0	0	0	0	0	0	0	0
Problematic Pain	0	0	0	0	0	0	0	0
Choroidal Effusion	0	0	0	0	0	0	0	0
Choroidal Hemorrhage	0	0	0	0	0	0	0	0
Visual Acquity Decrease(>2 lines)	0	0	0	0	0	0	0	0
Intra Operative Blood Reflux:								
Yes	80	154	199	160	238	66	199	32
No	3	5	8	4	15	4	7	1
Not reported	21	30	35	22	40	16	52	10

DCP is Diode Cyclo Photo Coagulation
T post Trabectome is repeat Trabectome that happens on patient request

Table 4 Medication Usage In Trabectome (T) Only And In Combined Cases (T+P) In Each Of The 4 Groups

Group#	Surgery Type	Pre-op Rx	6 Month Rx	p-Rx
Group 1	T	2.83±1.16	2.26±1.29	0.001
	T+P	2.52±1.09	1.45±1.22	<0.001
		0.023#	<0.001#	
Group 2	T	2.76±1.28	2.20±1.26	<0.001
	T+P	2.53±1.06	1.60±1.32	<0.001
		0.048#	<0.001#	
Group 3	T	2.91±1.44	2.11±1.41	<0.001
	T+P	2.49±1.19	1.79±1.29	<0.001
		0.014#	0.07#	
Group 4	T	3.11±1.30	2.32±1.49	<0.001
	T+P	3.07±0.91	2.43±1.17	0.008
		0.846#	0.68#	

p-IOP is p value from t test for comparing 6 month IOP to pre-op IOP within each surgery group.
# denotes p value from t test for comparing various characteristics between surgery groups.
T: Trabectome surgery only, T+P : Trabectome combined with phacoemulsification surgeries.

Results:

A total of 1401 eyes were included in the study. In GROUP 1 eyes with preoperative IOPs of ≤ 17 mmHg, mean reductions in IOP and glaucoma medication 6 months after surgery were 7% and 35% respectively. In GROUP 2 eyes with preoperative IOPs of 18 to 22 mmHg, these mean reductions were 20% and 28%. In GROUP 3 eyes with IOPs of 23 to 29 mmHg, mean reductions measured 33% and 28%. In GROUP 4 eyes with IOPs of ≥ 30 mmHg, mean reductions were 48% and 25%. The number of complications and secondary surgeries were proportional to the pre-op IOP levels.

Conclusions:

Preoperative IOP appears to influence Trabectome surgery outcomes in regards to lowering of IOP and number of glaucoma medications.

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