Stratification of phaco-trabectome surgery results using a glaucoma severity index in a retrospective analysis

Pritha Roy[1], MD; Ralitsa T. Loewen[1], MD; Yalong Dang[1], MD; Hardik A. Parikh[1,2], BS; Igor I. Bussel[1], MD, MHA; Nils A. Loewen[1]*, MD, PhD

1: Department of Ophthalmology, School of Medicine, University of Pittsburgh, Pittsburgh, United States of America
2: Institute of Ophthalmology and Visual Science, Rutgers, New Jersey Medical School, Newark, NJ, United States of America

* corresponding author:
Igor I. Bussel, MD, MHA
UPMC Eye Center
Eye and Ear Institute
203 Lothrop St. Suite 819
Pittsburgh, PA 15213
Email: Igor.Bussel@gmail.com

Abstract

Background: To stratify the outcomes of phacoemulsification combined with trabectome surgery (PT) using glaucoma severity index (GI).

Methods: This is a retrospective, observational cohort study performed in the Department of Ophthalmology, University of Pittsburgh Medical Center. Inclusion criteria were subjects with primary or secondary open angle glaucoma along with a visually significant cataract and the need to lower IOP or the number of glaucoma medications. Only cases that had undergone trabectome surgery combined with phacoemulsification were included. Exclusion criteria were follow-up less than 12 months, any other surgery during this time or diagnosis of neovascular or active uveitic glaucoma. The main outcome measures were IOP, medications, and success when stratified by GI. This index incorporated preoperative IOP, medications and visual field. Linear regression was used to detect the association between GI group with IOP and medication reduction at one year. Log-rank was used for survival analysis.

Results: Of 1374 patients, a total of 498 cases of PT with 12 month follow-up were included in the study after applying the exclusion criteria. Mean IOP reduction after one year was 2.9±4.4, 3.6±5.0, 3.9±5.3, and 9.2±7.6 mmHg for GI groups 1 to 4, respectively. Linear regression showed patients in a higher GI group had an IOP reduction greater by 1.69±0.2 mmHg than patients in a lower GI group. Survival rate at 12 months was 98%, 93%, 96% and 88% for GI groups 1 to 4 ($p<0.05$).

Conclusions: A substantial IOP reduction was seen in subjects with more advanced glaucoma suggesting that the trabecular meshwork is the primary impediment to outflow and its ablation benefits those eyes relatively more than in mild glaucoma. Higher GI groups are expected to have a greater reduction of IOP.

Key Words: Glaucoma, Open-Angle, Trabecular Meshwork, Phacoemulsification, Minimally Invasive Glaucoma Surgery

Introduction

Cataract and glaucoma are the two main causes of visual impairment worldwide [1] but while vision can be recovered by cataract extraction and intraocular lens implantation, vision loss from glaucoma is irreversible. Co-existence of open-angle glaucoma and cataract are frequently seen in the elderly population. Incidence and prevalence of both increase with age [2]. Elevated IOP and use of glaucoma medications can increase the risk of development of a nuclear cataract [3]. Similarly, glaucoma surgery can also accelerate cataract progression [4]. Removal of cataracts can confer a modest IOP reduction and have occasionally been recommended as a first intervention towards controlling pressure in glaucoma [5–7]. In countries where access to more advanced and more expensive technology exists, phacoemulsification is the most frequently performed type of cataract surgery [8] and produces the better visual results [9].

Ab interno trabeculectomy (AIT) belongs to the family of microincisional glaucoma surgeries [10] that are relatively standardized and have a favorable safety profile compared to traditional filtering surgeries [11]. AIT lowers IOP by ionizing and disrupting the diseased trabecular meshwork and creates a direct pathway for aqueous to exit the anterior chamber [10,12]. Depending on the severity of the respective diseases and the additional requirement for lowering IOP, phacoemulsification can be combined with trabectome (PT) benefitting the patient with fewer procedures and better cost effectiveness compared to long-term use of drops or to two separate operating room procedures [13]. Glaucoma can be graded according to the visual field function, optic nerve damage, or both [14–16].

Previous data on AIT with phacoemulsification after a failed trabeculectomy suggested that eyes with more advanced glaucoma may experience a larger IOP reduction although this did not reach statistical significance [17]. When trabectome surgery is performed as a single procedure to lower IOP a bigger pressure decrease can be observed [18]. We recently described that the impact of phacoemulsification on IOP reduction is negligible when PT is compared to trabectome surgery in eyes that remain phakic [19]. In this study, we analyzed IOP reduction from cataract surgery combined with trabectome as a function of a glaucoma index (GI) [18,20,21]. We also stratified outcomes by glaucoma severity based on preoperative IOP, number of preoperative medications, and visual field damage. We hypothesized that outcomes of PT would be similar regardless of GI.

Methods

Data for this retrospective, observational cohort study was collected after approval by the Institutional Review Board of the University of Pittsburgh, in accordance with the Declaration of Helsinki and the Health Insurance Portability and Accountability Act (IRB# REN15100055). Informed consent was not required. Only cases that had undergone trabectome surgery combined with phacoemulsification were included. Exclusion criteria was follow up less than 12 months, any other surgery during this time or diagnosis of neovascular or active uveitic glaucoma. For each patient, a specific target IOP was established by the treating glaucoma specialist deemed to prevent further nerve damage.

The indications for PT consisted of IOP above target with progressive glaucoma on maximally tolerated medical therapy, or stable glaucoma with the need to decrease the number of medications and a visually significant cataract with at least 0.4 logMAR (20/50 Snellen) visual acuity testing. AIT was completed before same session phacoemulsification in phaco-AIT [10]. The visual acuity was expressed as the logarithm of the minimum angle of resolution (logMAR). Based on the most recent Humphrey visual field exam (Carl Zeiss Meditec, AG, Jena, Germany), visual fields were grouped into four categories of up to mild, up to moderate, up to advanced, and more than advanced visual field damage [22], and designated 1, 2, 3 and 4 points, respectively. All patients received a comprehensive slit lamp and ophthalmoscopy exam before surgery. Anterior chamber angles in all patients were graded by Shaffer grade (SG) [23,24], a classification system in which '0' to 'slit' represents a totally or partially closed angle with potential for angle closure that is present or very likely, '1' an angle width of 10° (very narrow) and closure potential that is probable, '2' representing 20° and possible potential for closure, '3' standing for 20° to 45° with unlikely closure and grade '4' indicating a wide open angle and improbable potential for angle closure.

GI was defined using the following variables: 1) Preoperative IOP, 2) numbers of medications used prior to surgery, 3) visual field status. Visual field was separated into four categories: mild, moderate, advanced and end stage where mild was assigned 1 point, moderate with 2, advanced with 3 and end stage with 4. Preoperative number of medications were divided into 4 categories: 0-1, 2, 3 or 4+, and assigned with a value of 1 to 4, respectively. Baseline IOP was divided into 3 categories: <20 mmHg, 20-29 mmHg, and greater than 30 mmHg and assigned with 1 to 3 points respectively. These categories were chosen based on IOP distribution and designed not to underrate low pressure glaucoma and to include the small number of eyes with a baseline IOP above 40. GI was then defined as preoperative IOP $\times$ preoperative number of medications $\times$ VF. GI was separated into 4 groups: <3 (group 1), 3-5 (group 2), 6-11 (group 3) and >12 (group 4). Linear regression was used to determine if there was an association between GI group and IOP reduction after one year.

Baseline characteristics were compared by the Kruskal-Wallis and chi square tests for continuous and categorical variables between GI groups, respectively. Univariate linear regression was performed first and those variables that were found to be statistically significant were included into multivariate regression. Success was defined as IOP$\leq$21 mmHg, at least 20% IOP reduction from baseline in any two consecutive visits after three months, and no secondary glaucoma surgery. Log-rank test was used to compare survival distributions of GI groups. Continuous data was reported as mean ± standard deviation.

Results

Of 1374 patients, a total of 498 cases of phaco-AIT were included in the study after applying the exclusion criteria. The average age of the patients was 73±10 years. The average preoperative IOP was 20.6±6.6 mmHg and the average number of preoperative medications used was 2.4±1.1. The percentage of cases with mild, moderate and advanced visual field status were 33%, 33%, 34% respectively. The demographics table does not show any significant differences in age among the GI groups (Table 1).

The patient distribution across GI groups was relatively even and only reached a significant difference in visual acuity and cup disc ratio (Table 1). Most patients were Caucasian, followed by Asians, and then by African Americans and Hispanics. Amongst the GI groups, the majority of the patients had the diagnosis of primary open angle glaucoma with Shaffer grade above 2 followed by pseudoexfoliative glaucoma. Pigmentary and steroid induced glaucoma were amongst the least common diagnosis. PEX and steroid induced glaucoma patients had a greater IOP reduction by 3.75±0.79, 4.27±1.25 mmHg than OAG patients. The cup to disc (C/D) ratio increased significantly from a mean of 0.66 to 0.81 from GI1 to GI4. In contrast, visual acuity showed a significant decrease from GI1 to GI4 with GI4 nearly half of that of GI1.

At the end of 12 months, visual acuity showed a significant improvement for all the GI groups (Table 2).

Most patients had a preoperative IOP below 20 mmHg and most of them used three drops to achieve that (Figure 1). The visual field damage was relatively evenly distributed among mild, moderate and advanced damage. There were no patients with end stage visual fields (Figure 1).

At one year, glaucoma index groups 1 through 3 had an IOP reduction of about 4 mmHg in average while group 4, with the most advanced glaucomas, had a reduction near 10 mmHg (Figure 2).

Univariate linear regression (Table 3), which was performed first, identified age, diagnosis of pigmentary glaucoma and steroid induced glaucoma, and visual acuity to be most significant. These variables were then included in the multivariate regression.

In the multivariate regression analysis (Table 4), GI group, the diagnosis of pseudoexfoliation glaucoma and steroid induced glaucoma, were found to be significantly associated with IOP reduction. We examined the glaucoma index variables and their individual relationships to postoperative IOPs at the different time points. Patients in a higher glaucoma index group had a larger absolute IOP decrease (Figure 3). While there was an overall decrease in the number of medications in all glaucoma index groups (GI), GI3 and GI4 showed the most significant changes ($p<0.05$) after 6 months postoperatively (Figure 4). Individuals with more advanced visual field damage had the largest IOP reduction (Figure 5). Kaplan-Meier survival rate at 12 months was 98%, 93%, 96% and 88% for GI group 1 to 4. Log-rank test suggested a significant difference in survival distributions between GI groups. Patients in lower GI groups had a higher survival rate than those in the highest GI group (Figure 6).

Discussion

In this study, we stratified the outcomes of PT by a glaucoma index and found that there is a modest correlation to the severity of open angle glaucoma indicating that a larger IOP reduction is achieved in more severe glaucoma. Phacoemulsification on its own can produce a small but significant pressure drop by 1.5 to 3 mmHg and eyes with higher preoperative IOP often a greater reduction [25,26]. This effect may be the result of a trabeculoplasty-like effect [27,28], brought on by a stress response [29] or at other times due to a resolved phacomorphic component [30]. On the other hand, it is not uncommon for glaucoma patients who already have a compromised trabecular meshwork to experience pressure spikes after cataract surgery [31,32]; those can be prevented by combining trabecular ablation with cataract surgery [33]. Combining phacoemulsification with AIT has many advantages that include functional vision improvement, reduction of cost and efforts and good safety [11].

In the case of pseudoexfoliation, removing the cataractous lens also reduces production of pseudoexfoliation material [34] that may produce obstruction of the collector openings. It is for these reasons that patients examined here have a fundamentally different indication compared to patients who undergo trabectome surgery for the sole purpose of IOP reduction [18]. It is therefore not surprising that the regression analysis in the current study only agrees with our prior study on secondary, steroid induced glaucoma and age as significantly correlated. The average age of the patients displayed the increased incidence of cataract with advancing age [1] which is also a risk factor for glaucoma [35]. The percentage of patients with cataract were equally distributed amongst the different GI groups. Pseudoexfoliation can cause both earlier and more severe cataracts and may also lead to glaucoma. Pseudoexfoliation was significant in the present multivariate analysis but not in the prior, trabectome-only, study [18]. Pseudoexfoliation glaucoma is often more aggressive than primary open angle glaucoma and experiences a more profound IOP reduction [36]. It is therefore fitting that such patients were found more commonly in the higher GI group and had greater reduction of IOP following PT. Interestingly, pigment dispersion glaucoma is also seen to be significantly correlated here but not in the prior trabectome-only study. The reason for this observation is most likely that such patients often have a reverse pupillary block and friction between ciliary processes, the posterior iris and the crystalline lens and may undergo cataract surgery [37] sooner than other patients. Outcomes of trabectome surgery in pigment dispersion syndrome are otherwise relatively similar to outcomes in primary open angle glaucoma [38].

We found that patients in a GI group higher had an IOP reduction that was better by 1.69±0.24 mmHg. As could be expected, this is less than the 2.98±0.28 mmHg in trabectome-only patients [18]. There was an overall decrease in the number of medications in all the groups but GI3 and

GI4 showed the largest change at 12 months. We had previously applied a vigorous statistical matching method, Coarsened Exact Matching, which makes up for the shortcomings of nonrandomized studies and found that the impact of cataract surgery on IOP reduction in combination with cataract surgery is negligible [19]. The results here are consistent with this and indicate that, contrary to common believe, cataract removal does not confer any additional IOP reduction in ab interno trabeculectomy.

Conclusions

In conclusion, PT had a mixed indication of a visually significant cataract and the need to lower IOP *or* an interest in reducing the number of glaucoma medications. Despite a less absolute indication to lower IOP, a substantial pressure reduction was seen in patients with more advanced glaucoma which suggests that the trabecular meshwork is the primary impediment to outflow. The ablation benefits eyes with more challenging glaucoma relatively more than those with mild disease. Although patients with advanced glaucoma had a slightly lower success rate, PT does appear to make for a reasonable first line of treatment and is recommendable over phacoemulsification alone for visually significant cataracts.

Declarations

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Competing Interests:

NAL has received honoraria from NeoMedix, Corp. for wet labs and lectures. All other authors declare they have no competing interest.

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Figure legends

Figure 1. Distribution of glaucoma index variables.

Most patients had a preoperative intraocular pressure in the range below 20 mmHg. Three medications was the most common median number of eye drops used. Visual field score distribution was even and included a relatively large number of eyes with advanced visual field damage.

†IOP: Intraocular pressure

Figure 2. IOP reduction at one year by glaucoma index group.

The largest IOP reduction was observed in GI 4 with more severe glaucoma.

†GI = Glaucoma Index, ‡IOP: Intraocular pressure

Figure 3. Individual IOPs by glaucoma index group.

Patients in a higher glaucoma index (GI) group had a larger absolute reduction of IOP (table: mean±SD).

†GI = Glaucoma Index, ‡IOP: Intraocular pressure, §D: Day, ¶M: Month

Figure 4. Mean number of medications by glaucoma index group.

While there was an overall decrease in the number of medications in all glaucoma index groups (GI), GI3 and GI4 showed the most significant changes ($p<0.05$) after 6 months postoperatively.

†GI = Glaucoma Index, ‡IOP: Intraocular pressure, §D: Day, ¶M: Month

Figure 5. Intraocular pressure by visual field.

Patients with advanced visual field damage had the lowest intraocular pressures starting at 1 month.

†GI = Glaucoma Index, ‡IOP: Intraocular pressure, §D: Day, ¶M: Month

Figure 6. Survival plot by glaucoma index group.

Subjects had relatively similar survival rates.

†GI = Glaucoma Index

Tables

Table 1. Demographics. Group 1: GI<3; group 2: 3≤GI<6; group 3: 6≤GI<12; group 4: GI≥12

	Group 1 n=103	Group 2 n=101	Group 3 n=168	Group 4 n=126	p-value
Age					0.33
Mean±SD	73±10	72±10	72±10	74±10	
Range	16 - 90	36 - 91	27 - 90	50 - 93	
Gender					0.42
Female	65 (63%)	58 (57%)	85 (51%)	75 (60%)	
Male	37 (36%)	43 (43%)	81 (48%)	49 (39%)	
Undocumented	1 (1%)	0 (0%)	2 (1%)	2 (2%)	
Race					0.08
African American	9 (9%)	5 (5%)	7 (4%)	4 (3%)	
Asian	29 (28%)	43 (43%)	61 (36%)	50 (40%)	
Caucasian	61 (59%)	49 (49%)	83 (49%)	63 (50%)	
Hispanic	1 (1%)	0 (0%)	2 (1%)	4 (3%)	
Other	3 (3%)	4 (4%)	15 (9%)	5 (4%)	
Diagnosis					0.19
POAG	77 (75%)	75 (74%)	121 (72%)	89 (71%)	
Pseudoexfoliation Glaucoma	10 (10%)	8 (8%)	24 (14%)	25 (20%)	
Pigment Dispersion	4 (4%)	5 (5%)	6 (4%)	1 (1%)	
Steroid induced Glaucoma	4 (4%)	3 (3%)	9 (5%)	6 (5%)	
Others	8 (8%)	10 (10%)	8 (5%)	5 (4%)	
Visual Acuity (logMAR)					0.01*
Mean±SD	0.34±0.31	0.41±0.36	0.35±0.35	0.54±0.62	
Range	0.00 - 2.00	-0.19 - 2.00	-0.19 - 2.00	-0.19 - 3.00	
Disc Cup/Disk					<0.01*
Mean±SD	0.66±0.17	0.70±0.19	0.75±0.15	0.81±0.14	
Range	0.1 - 0.99	0.2 - 1.0	0.4 - 1.0	0.25 - 1.0	
Shaffer Grade					0.8
I	2 (2%)	2 (2%)	0 (0%)	2 (2%)	
II	9 (9%)	5 (5%)	18 (11%)	14 (11%)	
III	32 (31%)	33 (33%)	60 (36%)	38 (30%)	
IV	46 (45%)	47 (47%)	66 (39%)	55 (44%)	
Undocumented	14 (14%)	14 (14%)	24 (14%)	17 (13%)	

†GI = Glaucoma Index, ‡POAG = Primary Open-Angle Glaucoma
*p<0.05

Table 2. Visual acuity (logMar) at baseline and after phaco-trabectome surgery.

	GI1	GI2	GI3	GI4
Baseline	0.34±0.31	0.41±0.36	0.35±0.35	0.54±0.62
12 Month	0.11±0.17	0.09±0.19	0.16±0.26	0.27±0.46
p-value	p<0.01*	p<0.01*	p<0.01*	p<0.01*

†GI = Glaucoma Index
*p<0.05

Table 3. Univariate regression result.

	Coefficient	Standard Error	p-value
Age	0.06	0.03	0.03*
Male	-0.08	0.60	0.90
Race			
Asian	1.26	1.33	0.34
Caucasian	-0.21	1.31	0.87
Hispanic	3.88	2.65	0.14
Other	0.50	1.73	0.77
Diagnosis			
Others	0.00	1.12	1.00
Pseudoexfoliation Glaucoma	-1.72	1.57	0.27
Pigmentary Dispersion	4.52	0.82	<0.01*
Steroid Induced Glaucoma	4.25	1.32	<0.01*
Cup/Disk Ratio	1.33	1.76	0.43
Visual Acuity (logMAR)	1.96	0.75	0.01*
Shaffer Grade	0.31	0.39	0.42

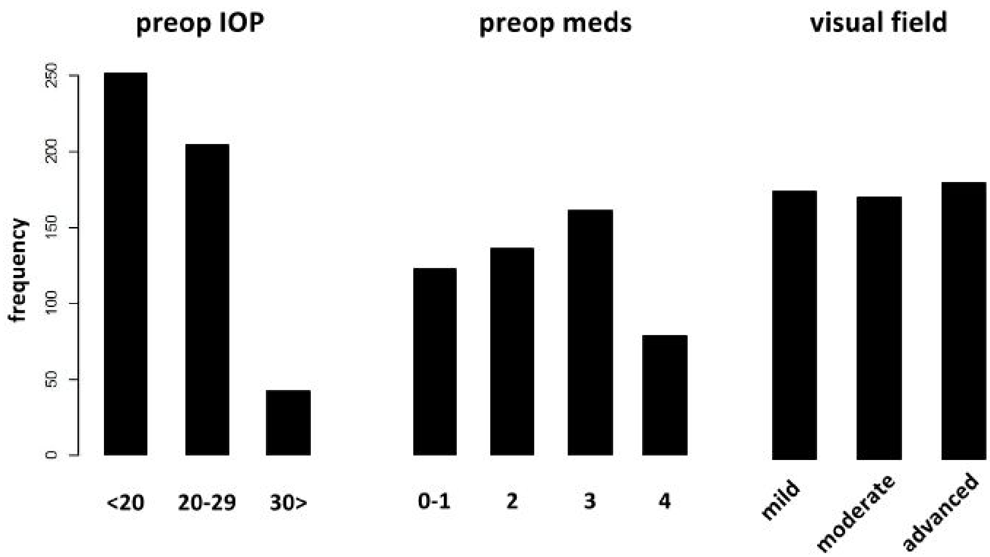
*p<0.05

Table 4. Multivariate regression result.

	Coefficient	Standard Error	p-value
GI Group	1.69	0.24	<0.01*
Age	0.05	0.03	0.08
Diagnosis			
Other	0.47	1.06	0.66
Pigmentary Dispersion	-0.64	1.51	0.67
Pseudoexfoliation Glaucoma	3.75	0.79	<0.01*
Steroid Induced Glaucoma	4.27	1.25	<0.01*
Visual Acuity (logMAR)	1.32	0.69	0.06

[†]GI = Glaucoma Index
*p<0.05

Figure 1.



preop IOP
preop meds
visual field
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50
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200
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<20
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2
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4
mild
moderate
advanced

Figure 2.

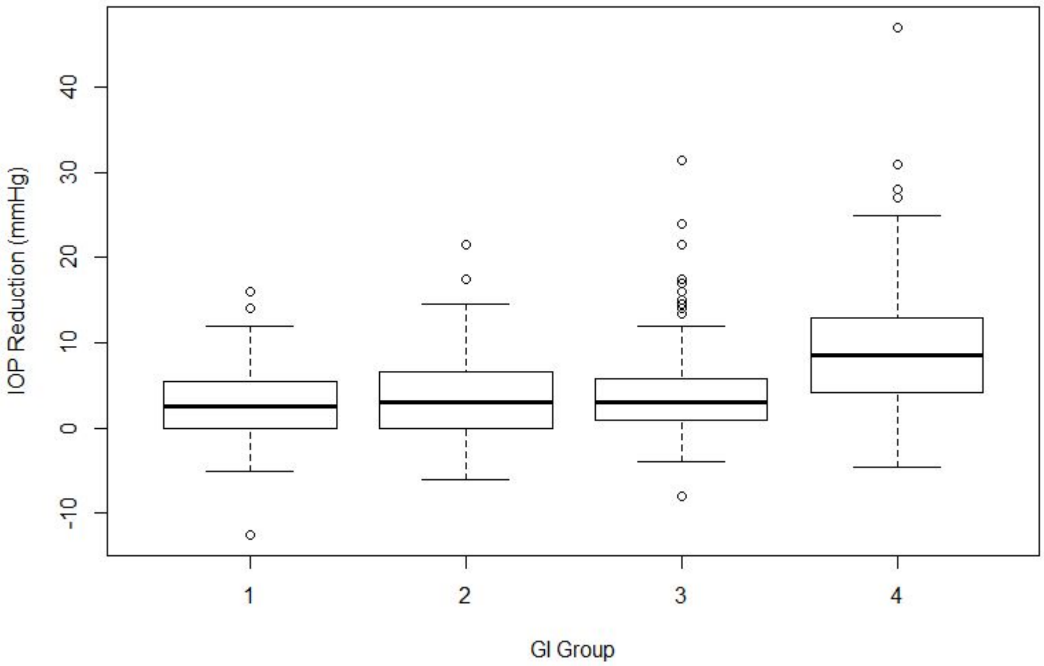
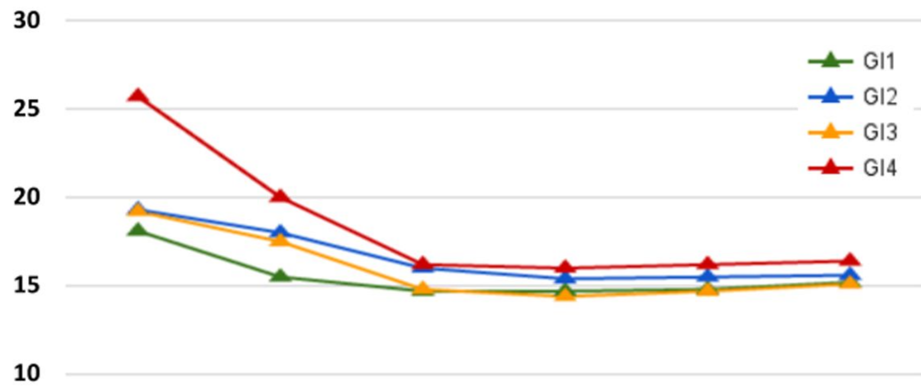
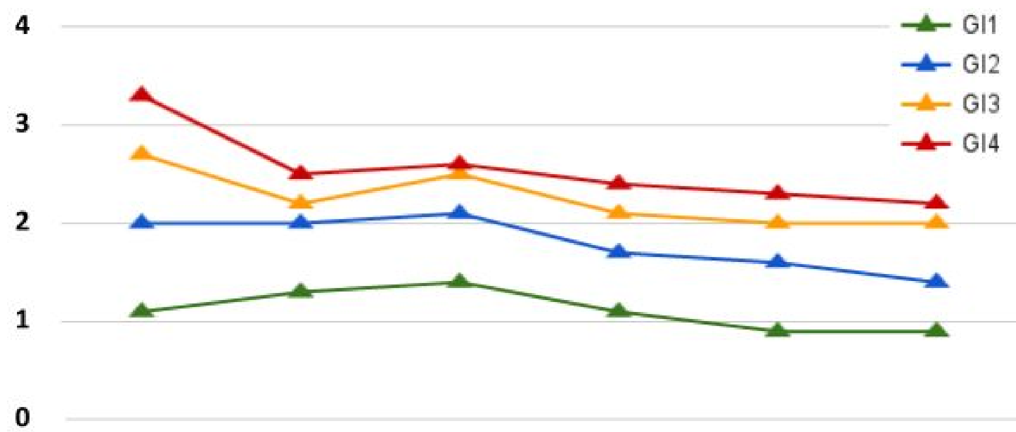


Figure 3.



IOP	Baseline	1D	1M	3M	6M	12M
GI1	18.1±4.3	15.5±6.4	14.7±3.9	14.7±3.4	14.8±2.7	15.2±3.0
GI2	19.3±5.0	18.0±9.0	16.0±4.6	15.4±4.1	15.5±3.8	15.6±3.5
GI3	19.2±6.0	17.5±8.8	14.8±4.2	14.4±3.5	14.7±3.8	15.1±3.6
GI4	25.7±7.4	20.0±8.5	16.2±5.2	16.0±4.4	16.2±3.6	16.4±4.1

Figure 4.

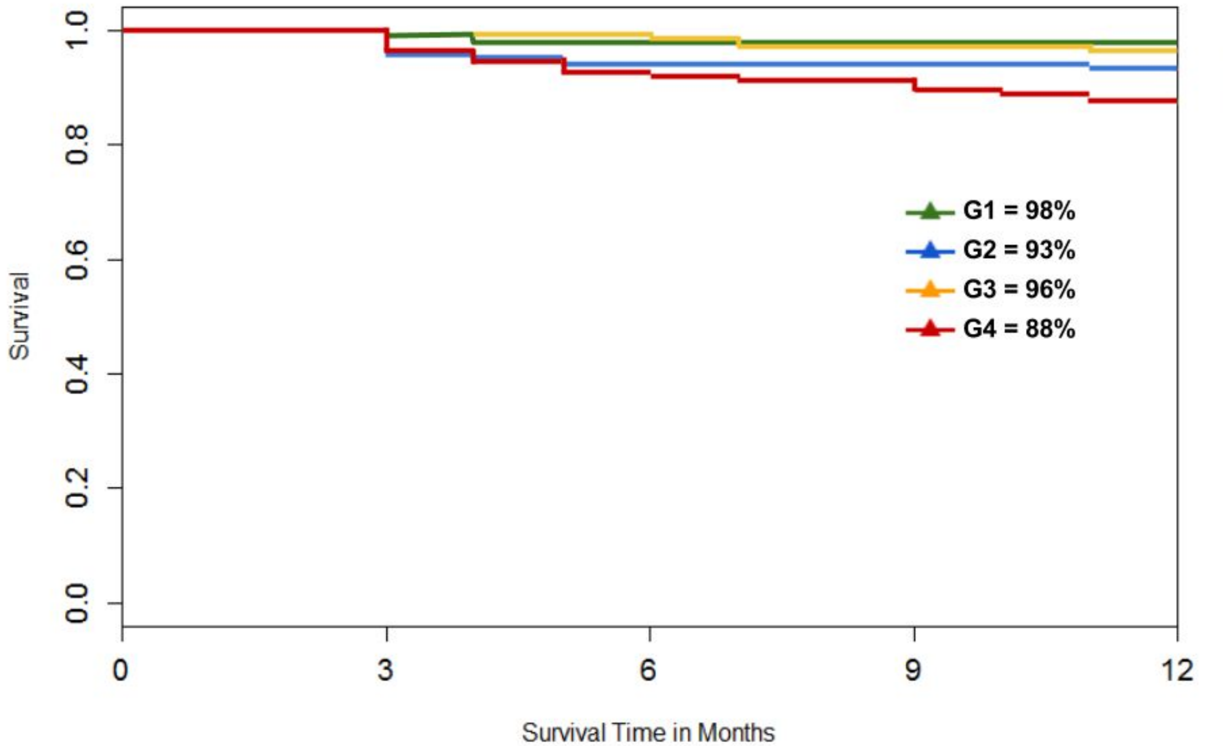


IOP	Baseline	1D	1M	3M	6M	12M
GI1	1.1±0.6	1.3±1.0	1.4±1.0	1.1±0.9	0.9±0.8	0.9±0.9
GI2	2.0±0.9	2.0±1.3	2.1±1.2	1.7±1.1	1.6±1.1	1.4±1.1
GI3	2.7±0.9	2.2±1.6	2.5±1.4	2.1±1.4	2.0±1.3	2.0±1.3
GI4	3.3±0.8	2.5±1.7	2.6±1.5	2.4±1.3	2.3±1.3=	2.2±1.3

Figure 5.

IOP	Baseline	1D	1M	3M	6M	12M
GI1	18.1±4.3	15.5±6.4	14.7±3.9	14.7±3.4	14.8±2.7	15.2±3.0
GI2	19.3±5.0	18.0±9.0	16.0±4.6	15.4±4.1	15.5±3.8	15.6±3.5
GI3	19.2±6.0	17.5±8.8	14.8±4.2	14.4±3.5	14.7±3.8	15.1±3.6
GI4	25.7±7.4	20.0±8.5	16.2±5.2	16.0±4.4	16.2±3.6	16.4±4.1

Figure 6.



1.0
0.8
0.6
0.4
0.2
0.0
Survival
0
3
6
9
12
Survival Time in Months
G1 = 98%
G2 = 93%
G3 = 96%
G4 = 88%