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Achieving Single-Digit Intraocular Pressure Targets with Filtration Surgery in Eyes with Progressive Normal-Tension Glaucoma

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Abstract

Purpose—Whereas achieving intraocular pressure (IOP) targets ≤ 10 mm Hg typically requires surgical intervention, we sought to examine the safety and efficacy of trabeculectomy in normal-tension glaucoma (NTG).

Methods—Patients with progressive NTG undergoing trabeculectomy with preoperative IOP ≥ 15 mm Hg during the 12-month period prior to surgery were identified at a single academic institution. Failure was defined as IOP reduction $< 20\%$ below baseline (criteria A), $< 30\%$ (criteria B), or $< 40\%$ (criteria C), reoperation for glaucoma, or loss of light perception vision.

Results—Thirty eyes of 28 patients (mean age 73 ± 8.7 years) were enrolled with a mean follow-up period of 50 ± 31 mos. Mean postoperative IOP (8.6 ± 2.9 mm Hg) and medications (0.6 ± 1.0) at final follow-up was significantly ($p < 0.001$) reduced compared to prior to surgery (13.2 ± 1.4 mm Hg and 2.5 ± 1.2 , respectively). The cumulative probability of failure during 5 years of follow-up was 32% (criteria A), 48%, (criteria B), and 67% (criteria C). The probability of successfully achieving an IOP goal ≤ 10 mm Hg was 68% at 4 years follow-up.

Conclusions—Trabeculectomy is a safe and effective method for achieving single digit IOP targets in NTG eyes with progression at low IOP.

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Keywords

Normal-tension glaucoma; filtration surgery; intraocular pressure; visual field; glaucoma

Introduction

Glaucoma is a progressive disorder characterized by structural and functional abnormalities of the optic nerve.[1-3] Even though intraocular pressure (IOP) is the most important modifiable risk factor for disease onset and progression,[4-8] glaucoma can exist even among individuals for whom IOP measurements are within the statistically defined “normal range”. [9-12] Although an artificial construct, normal-tension glaucoma (NTG) is a widely used term to classify the disease in patients with glaucomatous optic neuropathy with or without visual field loss whose pressures are within the 95th percentile of the normal distribution of IOP measurements in the healthy population (IOP <22 mm Hg using Goldmann applanation tonometry).[1,2] NTG is a common disorder and accounts for approximately 20-30% of open-angle glaucoma cases in the United States 1-4 and a significantly higher proportion in other parts of the world, particularly Korea (77%) [13] and Japan (92%).[5]

The beneficial effect of reducing intraocular pressure (IOP) by 30% in eyes with NTG has been demonstrated.[7-11] Most patients achieve this therapeutic target using non-surgical therapy including anti-glaucomatous medication and laser trabeculoplasty. The Collaborative Normal-Tension Glaucoma Study reported that 50% of NTG patients achieved a 30% reduction in IOP using conservative measures without the use of medications such as topical beta-blockers, alpha-2 adrenoreceptor analogues, or prostaglandin inhibitors which were unavailable or contraindicated based upon the study protocol.[7]

The treatment of progressive NTG that fails to respond to medical therapy represents a therapeutic challenge, particularly in eyes in which progression has occurred at low IOP levels. Glaucoma filtration surgery in NTG eyes has been well described.[9,12,14-16] A recent study demonstrated that visual field progression in NTG patients was halted in a large proportion of patients after trabeculectomy when IOP was reduced by at least 20%; with better efficacy if lowered by 30%.[12] However, the risk-to benefit ratio must be carefully considered given that trabeculectomy in eyes with NTG carries an increased risk of hypotony, hypotony maculopathy, and choroidal effusion,[15-17] particularly in eyes with very low preoperative IOP in which the therapeutic window is considerably more narrow. Whereas achieving IOP targets 10 mm Hg typically requires surgical intervention, we sought to examine the safety and efficacy of trabeculectomy with anti-fibrosis therapy in NTG patients with preoperative IOP of 15 mm Hg. The purpose of this study was to examine the long-term outcomes of glaucoma filtration surgery in patients with progressive NTG at low IOP.

Methods

After Institutional Review Board approval was obtained from the University of Miami Miller School of Medicine Clinical Research Ethics Board, a retrospective chart review was conducted. Consecutive open-angle glaucoma patients that had undergone trabeculectomy by a single surgeon (DSG) at Bascom Palmer Eye Institute, Palm Beach Gardens, Florida between February 2006 and October 2010 were identified. Patients with NTG had glaucomatous optic neuropathy consisting of neuroretinal rim narrowing, progressive visual field (VF) loss, and initial untreated IOP <21 mm Hg, with no single reading >22 mm Hg. The baseline IOP of each patient was reported as the average of consecutive IOP measurements during the 12-month period prior to surgery. Patients with mean preoperative IOP 15 mm Hg during the 12-month period prior to surgery were enrolled. Exclusion criteria consisted of age 18 years, recorded IOP >22 mm Hg on any visit, ocular disease other than glaucoma, prior incisional surgery except uncomplicated cataract extraction, or follow-up period of <12 months.

Glaucoma surgery was indicated in patients with VF progression and in whom the IOP was considered unsatisfactory for the extent of glaucomatous damage. Trabeculectomy was performed in a standardized fashion. A superior limbus-based or fornix-based flap was created, and a fluid retaining sponge soaked with MMC (0.4 mg/ml) was applied to the superior sclera for 1-3.5 minutes. A single highly myopic patient received intraoperative 5-Fluorouracil (50 mg/ml, 5 minute duration) at the time of trabeculectomy. A partial-thickness scleral flap was dissected, and a paracentesis was made. A block of limbal tissue was excised underneath the trabeculectomy flap. The scleral flap was reapproximated to the scleral bed with interrupted 10-0 nylon sutures. The conjunctiva was closed, and Seidel testing was performed at the conclusion of the case.

Failure was defined as inadequate IOP reduction, reoperation for glaucoma, or loss of light perception vision. Inadequate IOP reduction was defined using 3 criteria: IOP reduction <20% below baseline (criteria A), <30% (criteria B), or <40% (criteria C), on two consecutive follow-up visits after 3 months. The use of postoperative laser suture lysis was not considered as failure. Eyes that had not failed and were not on supplemental medical therapy were considered complete successes. Eyes that had not failed but required supplemental medical therapy were defined as qualified successes. We also evaluated failure based upon a threshold numeric criteria defined as a postoperative IOP 10 mm Hg on two consecutive follow-up visits after 3 months. IOP reduction was calculated at postoperative month three and all follow-up intervals thereafter. Final change in BCVA, IOP, and number of IOP lowering medications was calculated at last follow up compared to baseline. Early postoperative complications were defined as surgical complications developing within the first month after trabeculectomy; late postoperative complications occurred more than 1 month following surgery. Hypotony was defined as IOP 5 mm Hg on two consecutive follow-up visits occurring after postoperative month 3.

Kaplan-Meier survival curve was used to analyze the cumulative probability of maintaining a postoperative IOP reduction of 20%, 30%, or 40% from baseline. Two-sided Student *t*-test was used for continuous variables, and the χ^2 or Fisher exact test was used for categorical

variables using SPSS 21.0. A Mann-Whitney U Test was used to compare the visual acuities. BCVA was converted to logMAR equivalent for statistical analysis. A p-value of 0.05 was considered statistically significant for all variables.

Results

The charts of 274 patients were evaluated for enrollment. Two hundred forty-four patients were excluded with preoperative IOP mean > 15 mm Hg, inadequate follow-up, secondary glaucoma, prior ocular surgery, or co-morbid ocular disease. Thirty eyes of 28 NTG patients (mean age 73 ± 8.7 years) were enrolled with a mean follow-up period of 50.3 ± 30.8 months. Baseline clinical characteristics are presented in Table 1. The mean preoperative IOP during the year prior to surgery was 13.3 ± 1.4 mm Hg using a mean of 2.5 ± 1.2 IOP lowering medications.

Mean postoperative IOP and number of IOP lowering medications at all follow-up time points are illustrated in Table 2. The mean postoperative IOP at 4-years, 7.23 ± 3.7 mm Hg, and number of IOP lowering medications, 0.1 ± 1.0 , were significantly lower compared to baseline ($p < 0.01$). Figure 1 illustrates the Kaplan-Meier plot of the cumulative probability of Qualified Success at various postoperative follow-up time points, with or without anti-glaucomatous medications. At 96 months of postoperative follow-up, the proportion of eyes classified as successful was 68%, 52%, and 26% for Criteria A, B, and C, respectively. Figure 2 illustrates the Kaplan-Meier plot of the cumulative probability of Complete Success at various postoperative follow-up time points, without anti-glaucomatous medications. We examined the overall cumulative probability of achieving a near single-digit IOP target goal during the follow-up period. Failure was defined as a postoperative IOP > 10 mm Hg on two consecutive follow-up visits after 3 months. The probability of successfully achieving this numeric IOP goal was 90%, 79%, 79%, 68% at 1, 2, 3, and 4 years, respectively.

Twenty eyes (66%) were phakic at the time of trabeculectomy. Two eyes (7%) had a combined phaco-trabeculectomy; 8 of the remaining 18 (44%) eyes had worsening of cataract requiring subsequent cataract extraction during the follow-up period. The mean time from trabeculectomy to cataract extraction was 27.4 ± 12.0 months (range 5-40). At final follow-up, the mean IOP and number of supplemental glaucoma medications in phakic eyes who required cataract surgery (7.0 ± 4.3 mm Hg, 0.25 ± 0.71) was not statistically different ($p = 0.10$, 0.23) compared with phakic eyes who did not require cataract surgery (8.7 ± 2.0 , 0.8 ± 1.3). In the subset of patients that required cataract surgery, the mean IOP (7.7 ± 4.1 mm Hg) and supplemental medication requirement (0.3 ± 0.7), was not significantly different ($p = 0.18$) compared to prior to cataract surgery (6.0 ± 3.0 , 0), with a mean follow-up post cataract surgery of 30 ± 15.5 months.

Early and late postoperative complications are presented in Table 3. Sixteen eyes (53%) experienced at least one early or late postoperative complication. There were no surgical failures based upon the need for reoperation for glaucoma or loss of light perception vision. A total of 9 eyes (30%) experienced hypotony during the postoperative period; 2 (6%) of which developed hypotony maculopathy. No surgical intervention was required in the 2 eyes with hypotony maculopathy based upon unchanged postoperative visual acuity compared to

preoperative levels (20/25 and 20/50). One eye with ocular hypotony and no macular folds required bleb revision for reduced visual acuity associated with irregular astigmatism. The characteristics of eyes with and without hypotony are presented in Table 4. There was no significant difference ($p=0.45$) in postoperative BCVA (logMAR) between eyes that developed hypotony (0.29 ± 0.23) compared to eyes without hypotony (0.20 ± 0.32); the mean change in visual acuity from baseline was similar ($p=0.33$). Among eyes with hypotony ($n=9$), the mean change in BCVA in eyes with hypotony maculopathy (-0.1 ± 0.19 , $n=2$) was similar ($p=0.33$) compared to hypotony without maculopathy (-0.03 ± 0.17 , $n=7$).

Discussion

Normal-tension glaucoma represents a subgroup of open-angle glaucoma with measured untreated IOP in the statistically normal range. Although most patients respond favorably to IOP reduction of 30% below the untreated baseline,[7] a subset of NTG eyes continue to progress despite achieving and maintaining IOP control in the low teens. The management of such eyes represents a clinical challenge given that non-surgical approaches typically cannot lower IOP below episcleral venous pressure, and a narrow therapeutic window exists in which further IOP lowering may be achieved while avoiding ocular hypotony. Glaucoma filtration surgery is often required in eyes with, or at high risk for, disease progression. [9,12,14-16] To our knowledge, surgical outcomes in eyes specifically requiring single-digit target IOP levels have not been described.

We found that trabeculectomy with anti-fibrosis therapy is an effective method for achieving long-term IOP reduction of 20-40% in NTG eyes with progression at low IOP, defined in the present study as ≥ 15 mm Hg. The proportion of patients achieving complete success without supplemental glaucoma therapy as defined using Criteria A, B, and C at 4 years was 59%, 52%, and 39%, respectively. This is consistent with other studies,[12,15,16] which have reported that approximately 40%-60% of patients achieved a 20-30% reduction in postoperative IOP. For many clinicians, the target goal in eyes with progressive NTG at low IOP that approximates episcleral venous pressure is to achieve a near single-digit IOP level. In a series of Japanese persons with progressive NTG, Aoyama et al recommended a goal IOP of 10 mm Hg or less.[12] We found that the cumulative success rate of achieving a numeric IOP goal ≤ 10 mm Hg was 90% at 1 year and 68% at 4 years, which remained stable throughout the remainder of the follow-up period. A more important outcome after filtering surgery is the prevention of further visual field deterioration; the overall impact of IOP reduction on visual progression in this cohort is currently under investigation and will be reported as a separate paper.

As with all surgical procedures, the benefits of aggressive IOP lowering must be interpreted in the context of the associated adverse events. The patients in our study had progressive visual field loss and were therefore considered to have a favorable risk-to-benefit ratio. The types and frequency of complications in the present series (Table 3) were consistent with the literature.[17-20]

Not surprisingly, given the mean preoperative IOP of 13 mm Hg and goal to obtain single-digit target IOP levels, we observed a high overall rate (9 patients, 30%) of early and late

postoperative hypotony. Jampel et al reported that hypotony after trabeculectomy with anti-fibrosis therapy occurred in 15-20% of patients during the postoperative follow-up.[20] In our study, the development of hypotony did not appear to have a deleterious affect on visual acuity. Goodkin and colleagues reported that hyptonous eyes without disruption of the foveal pit visible on spectral-domain optical coherence tomography imaging often retain good central acuity.[21] However, clinicians should carefully consider several important factors. Since patients in this series were not selected in a prospective randomized fashion, surgeon bias to avoid eyes at high risk for hypotony maculopathy may have influenced our results. Although many eyes tolerate low IOP, ocular hypotony is an important cause of visual loss following glaucoma surgery. The absence of a statistically significant reduction in visual acuity should not be interpreted as clinically irrelevant. One patient in our study with a mean postoperative IOP of 1 mm Hg had reduced visual acuity requiring bleb revision that resulted in a postoperative IOP of 8 mm Hg and improvement in visual acuity to 20/60.

Consistent with other studies,[15-17,22] we found that a large proportion (27%) of phakic eyes had worsening of cataract following filtration surgery, requiring subsequent cataract extraction during the follow-up period. The development of cataract following glaucoma filtration surgery with MMC was reported to be 22.6% by Yamamoto et al.[23] and 29% in a series by Hagiwara et al.[17] Intercurrent cataract surgery did not represent a risk factor for trabeculectomy failure in this population of eyes with low preoperative IOP. The mean IOP (7.7 mm Hg) and supplemental medication requirement (0.3) was similar compared to prior to cataract surgery (6.0 mm Hg, 0 medications). Chen et al. found that when cataract extraction was performed after trabeculectomy, preoperative IOP greater than 10 mm Hg was associated with worsened postoperative IOP control.[22] Other risk factors identified were age > 50 years, intraoperative iris manipulation, and early postoperative IOP greater than 25 mm Hg.

Our study has limitations. NTG should not be considered a distinct disease entity but rather a spectrum of OAG in which the IOP producing optic nerve damage is in low-normal range. Since a proportion of NTG eyes do not progress, or progress slowly, surgical intervention to achieve the IOP targets described herein are not required in the majority of persons. Thus, our study population consisted of a relatively small number of eyes. Since surgery was not performed in a randomized masked fashion, there is a potential for selection bias that may affect our results. We recognize that the ideal measure of success for any glaucoma therapy is preservation of visual function and prevention of further glaucomatous optic nerve damage. This is a subject that will be addressed in a separate investigation. Success for individual patients cannot be defined a priori by an arbitrary IOP level as individuals vary in their susceptibility to the damaging effect of IOP. Nevertheless, since at the present time IOP reduction is the only form of treatment for glaucoma that has been shown to have any long-term effect on the course of the disease, IOP is a reflection of the efficacy of medical and surgical treatment.

In conclusion, trabeculectomy with anti-fibrosis therapy is a safe and effective method for achieving long-term IOP reduction of 20-40% in NTG eyes with progression at low IOP. An IOP of < 10 mm Hg was achieved in approximately 70% of eyes at 4 years of postoperative

follow-up. Hypotony is a common postoperative occurrence but did not result in a significantly greater degree of vision loss compared to patients without hypotony.

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Figure 1.

Kaplan-Meier plot of the cumulative probability of Qualified Success, defined as intraocular pressure (IOP) reduction 20% below baseline (criteria A), 30% below baseline (criteria B), 40% below baseline (criteria C), at the various postoperative follow-up time points, with or without anti-glaucomatous medications.

*Note: Total eyes at each follow-up.

Figure 2.

Kaplan-Meier plot of the cumulative probability of Complete Success, defined as intraocular pressure (IOP) reduction 20% below baseline (criteria A), 30% below baseline (criteria B), 40% below baseline (criteria C), at the various postoperative follow-up time points, without anti-glaucomatous medications.

*Note: Total eyes at each follow-up.

Table 1
Baseline clinical characteristics of the study population^a

Clinical Variable	No. of patients (%)
Age (years)	
Mean ($\pm$ SD)	73 ($\pm$ 8.7)
Median (range)	73.5 (53-89)
Gender	
Male	8 (26)
Female	22 (73)
Ethnicity	
Black	2 (7)
White	26 (87)
Hispanic	2 (6)
Intraocular pressure (mm Hg)	
Mean ($\pm$ SD)	13.27 ($\pm$ 1.4)
Range	10-15
Snellen VA	
Median	20/30
Range	20/20-20/400
LogMAR^b	
Mean ($\pm$ SD)	0.2 $\pm$ 0.1
Spherical equivalent (Diopters)^c	
Mean ($\pm$ SD)	-1.6 ($\pm$ 2.8)
Range	-7.8 to +1.5
Visual Field (decibels)	
Mean Deviation, Mean ($\pm$ SD)	-12.39 $\pm$ 7.6
Pattern Standard Deviation, Mean ($\pm$ SD)	9.71 $\pm$ 3.21
Glaucoma medications	
Mean ($\pm$ SD)	2.53 ($\pm$ 1.2)
Range	0-4
Prior surgery	
Cataract extraction	10 (33)
Laser Trabeculoplasty	16 (53)
Lens status	
Phakic	20 (66)
Pseudophakic	10 (33)
Duration of MMC (Minutes, 0.4 mg/cc)	
Mean ($\pm$ SD)	1.8 ($\pm$ 0.8)
Median, Minutes (range)	2 (1-3.5)

Clinical Variable	No. of patients (%)
Laser suture lysis	
Yes	16 (53)
Duration of follow-up (months)	
Mean ($\pm$ SD)	50.3 ($\pm$ 30.8)
Range	12-108

^a All data are given as the number (percentage) of patients unless otherwise specified

^b logMAR = logarithm of minimum angle of resolution

^c spherical equivalent reported for phakic eyes only

Table 2
Patient characteristics at baseline and after trabeculectomy during the follow up period

	N	IOP mean, (SD), mm Hg	No. Glaucoma Meds, (SD)
Baseline	30	13.3 ($\pm$ 1.4)	2.5 ($\pm$ 1.2)
6 months	30	7.8 ($\pm$ 3.7)	0.1 ($\pm$ 0.3)
12 months	30	7.8 ($\pm$ 3.5)	0.2 ($\pm$ 0.6)
18 months	22	8.1 ($\pm$ 3.3)	0.1 ($\pm$ 0.4)
2 years	24	8.3 ($\pm$ 3.9)	0.3 ($\pm$ 0.9)
3 years	21	8.5 ($\pm$ 3.8)	0.4 ($\pm$ 1.1)
4 years	15	7.23 ($\pm$ 3.7)	0.1 ($\pm$ 1.0)
Last follow up	30	8.6 ($\pm$ 3.0)	0.7 ($\pm$ 1.2)

Table 3
Postoperative complications among the study group

Early postoperative complications^a	No. of patients (%)
Choroidal effusion	1 (3)
Hyphema	6 (20)
Hypotony ^c	6 (20)
Late postoperative complications^b	No. of patients (%)
Persistent corneal edema	2 (6)
Hypotony (total)	9 (30)
Hypotony maculopathy	2 (6)
Dysesthesia	3 (10)
Choroidal effusion	1 (3)
Cystoid macular edema	3 (10)
Diplopia	1 (3)
Bleb leak	2 (6)
Blebitis	1 (3)
Chronic or recurrent iritis	1 (3)

^a Onset 1 month after surgery

^b Onset was 1 month after surgery

^c Hypotony was defined as IOP 5 mm Hg on 2 consecutive postoperative visits

Table 4

Characteristics of hypotonous^a eyes with or without maculopathy^b compared to eyes without hypotony after trabeculectomy.

	Hypotony (n=9)	Without Hypotony (n=21)	
	No. Patients (%)	No. Patients (%)	p-value
Age , mean (± SD), years	71.8 (± 9.6)	73 (±8.6)	0.74
Gender			
Male	3 (33)	5 (24)	0.59
Female	6 (67)	16 (76)	
Ethnicity			
Black	1 (11)	1 (5)	0.54
White	8 (89)	18 (86)	
Hispanic	0 (0)	2 (10)	
Lens Status			
Phakic	4 (44)	16 (76)	0.09
Pseudophakic	5 (56)	5 (24)	
Hypotony Maculopathy	2 (22)	0	0.03
Snellen VA			
Mean	20/40	20/50	
Median	20/50	20/25	0.26
Range	20/20-20/70	20/20-20/250	
LogMAR^c			
Postop Mean (± SD)	0.29 (± 0.23)	0.20 (± 0.32)	0.45
Change in VA (± SD)	-0.1 (± 0.19)	-0.03 (± 0.17)	0.33
IOP			
Mean (± SD), mm Hg	6.22 (± 2.86)	9.59 (± 2.28)	0.002
Glaucoma Medications			
Mean (± SD)	0	0.8 (± 1.12)	0.04
Duration of MMC, minutes			
Mean, (± SD)	2.14 (± 0.85)	2.22 (± 1.53)	0.89
Laser Suture Lysis	9 (100)	12 (57)	0.02

^a Hypotony is defined as IOP < 5 mm Hg on 2 consecutive postoperative visits

^b Hypotony maculopathy was defined as macular chororetinal folds on 90 D dilated exam and/or on optical coherence tomography

^c logMAR = logarithm of minimum angle of resolution