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CLINICAL INVESTIGATION



# Evaluation of fornix-based trabeculectomy outcomes in Japanese glaucoma patients based on concrete long-term preoperative data

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**Abstract**

**Purpose** To investigate the outcomes of fornix-based trabeculectomy in Japanese patients with glaucoma based on more than five years of preoperative data.

**Study design** Retrospective case series

**Methods** This study consisted of 35 eyes of 35 Japanese glaucoma patients (mean age: 60.6, standard deviation (SD) 11.5 years) who received initial fornix-based trabeculectomy from a single ophthalmology clinic, with one or more reliable visual field test results per year from at least five years before and after the surgery. Measurements included postoperative mean intraocular pressure (IOP), standard deviation of IOP, medication scores, mean deviation slope, and total deviation slope were evaluated based on preoperative data. The relationship between mean IOP, SD-IOP and the visual field (VF) deterioration speed was also analysed.

**Results** The mean follow-up period before surgery was 6.15 (SD 0.97) years and post surgery it was 5.95 (SD 0.63) years. The preoperative mean IOP of 14.6 (SD 2.3) mmHg significantly decreased to 9.2 (SD 2.2) mmHg ($P$ <.001). The preoperative medication score 2.7 (SD 0.5) significantly decreased to 0.1 (SD 0.4, $P$ <.001). The preoperative MD slope of −0.52 (SE 0.047) dB/year significantly improved to −0.31 (SE 0.14) dB/year ($P$ <.01), with improvement in the superior hemifield ($P$ ≤.018). Inferior hemifield ($P$ >.10) did not follow the trend. Neither mean IOP nor SD-IOP correlated with the VF deterioration speed.

**Conclusions** Fornix-based trabeculectomy is an acceptable procedure for initial surgical management of glaucoma, especially for maintenance of superior VF.

**Keywords** Glaucoma · Trabeculectomy · Fornix-based · Visual field · Japanese

## Introduction

Glaucoma is a leading cause of blindness worldwide [1] and the main cause of blindness in Japan [2]. Although glaucoma is sight-threatening, its onset and progression can be prevented or delayed by proper management of intraocular pressure (IOP) [3, 4]. A first-choice treatment strategy for glaucoma involves administration of IOP-lowering eye drops. However, if sufficient IOP reduction cannot be achieved or whenever the rate of deterioration is relatively rapid despite maximum usage of eye drops, surgical intervention is necessary. Trabeculectomy with antimetabolites, a procedure in which IOP is lowered by partial excision of the trabecular meshwork, is widely regarded as the most effective IOP reduction surgery for all types of glaucoma. There are two types of conjunctival incisions used in this procedure, limbal-based and fornix-based flaps [5]. A recent meta-analysis reports that there were no significant differences in postoperative IOP control or bleb failure between these two techniques [6].

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In addition to IOP reduction, the efficacy of trabeculectomy in suppressing the progression of visual field defects is reported in previous studies [7–11]. However, some of these studies were performed without a consistent surgical technique (limbal-based flap or fornix-based flap) or antimetabolite (5-fluorouracil [5-FU] or mitomycin C [MMC]). While a recent report supports the use of a fornix-based flap surgical technique with MMC, although its sample size is relatively small (N = 13) [12]. Other relevant studies cannot be systematically compared because they did not include detailed descriptions of the procedures or antimetabolites used [13, 14]. Furthermore, the evaluation criteria for preoperative data (i.e. preoperative follow-up periods) involving the number of reliable visual field (VF) results were not typically described. As a result, even when progression in VF defects is reported to be significantly suppressed with trabeculectomy, it remains controversial whether this conclusion is based on long-term and reliable preoperative data. Generally, reliable VF data are essential for the identification of clinically meaningful rates of VF deterioration in glaucoma patients [15]. These data provide the information required for the detection of VF changes over a period of several years.

Due to some drawbacks in these previous studies, we reasoned that it was necessary to verify the outcomes of trabeculectomy performed using a single technique and with the same antimetabolite, and that these outcomes should be analysed using concrete long-term preoperative data, including VF assessments. Therefore, in the present study, we evaluated the outcomes of fornix-based trabeculectomy performed with MMC in Japanese patients with glaucoma over preoperative and postoperative follow-up periods of at least 5 years.

## Materials and methods

### Study design and inclusion and exclusion criteria

We retrospectively evaluated the medical records of Japanese patients with glaucoma who underwent an initial trabeculectomy at Yotsuya Shirato Eye Clinic in Tokyo, Japan between January 2011 and December 2013. All protocols and methods adhered to the tenets of the Declaration of Helsinki, and this study was approved by the ethics committee of Riverside Internal Medicine Cardiology Clinic (approval ID: RSC-1811RB01). Since it was a retrospective study, informed consent was waived by the Research Ethics Board.

The inclusion criteria for this study were as follows: (1) a diagnosis of glaucoma based on typical glaucomatous optic disc changes with corresponding VF damage; (2) an initial fornix-based trabeculectomy with MMC (including cataract surgery); (3) between the ages of 20 to 80 years at the time of surgery; (4) regular follow-up for more than five years before and after surgery; (5) VF results from tests performed using a Humphrey visual field analyser (Carl Zeiss Meditec) with the standard 30-2 program of the Swedish Interactive Threshold Algorithm from at least five different evaluations (at least once per year) before and five evaluations after surgery; (6) VF test results within the following reliability limits: fixation loss < 20%, false-positive rate < 15%, and false-negative rate < 15%; and (7) eyes without clinically significant cataracts that developed during the preoperative or postoperative follow-up periods.

The exclusion criteria were as follows: (1) patients with any other ocular or specific systemic disorders, including systemic use of calcium-channel blockers or β-blockers and (2) eyes with a previous history of any incisional or laser surgeries.

### Ophthalmic examinations

Slit lamp and fundus examinations were routinely conducted at every visit. IOP measurements were performed with a calibrated Goldmann applanation tonometer (Haag Streit) during office visits after administration of a topical anaesthetic while the patient was in a seated position. Refractive error was measured with an Autorefractor Keratometer (ARK-900; Nidek).

### Surgical technique

All assessments of surgical indications and subsequent surgery were performed by a single well-trained surgeon (S.S.). The surgical technique was as follows: after instillation of anaesthetic into the sub-Tenon space, a 5- to 6-mm fornix-based conjunctival incision was made along the limbus at the temporal side. This process was followed by cauterisation, formation of a single rectangular scleral flap (3 × 3 mm), soaking with 0.05% MMC for 1.5 minutes, washout of residual MMC with 100 mL of a balanced salt solution, excision of a sclerocorneal block (vertical 0.5 × horizontal 2.0 mm), peripheral iridectomy, placement of four 10-0 nylon scleral flap sutures, adjustment of aqueous humour flow with an occasional additional suture, and placement of a wing conjunctival suture with ophthalmic 10-0 nylon sutures (MANI). In cases with a combined cataract surgery, a clear corneal incision was made at the superior quadrant with viscoelastic materials (Viscoat 0.5 Ophthalmic Viscoelastic Substance [Alcon] and 1% Healon Ophthalmic Viscoelastic Substance [AMO]). Postoperative treatment after simple trabeculectomy consisted of four applications of 0.1% betamethasone and moxifloxacin ophthalmic solution. For the combined surgery, diclofenac sodium ophthalmic solution was also applied. Laser suture-lysis or bleb needling were performed at the surgeon's discretion to increase the flow rate of the aqueous humour if IOP was elevated after surgery.

### Outcome measures and statistical analysis

The main outcome measures assessed in the present study were mean IOP, IOP fluctuation defined by the standard deviation of IOP (SD-IOP) during the follow-up period, medication scores, and the rate of VF deterioration. Each item was surveyed both preoperatively and postoperatively. We also investigated the correlations between preoperative and postoperative IOP (mean IOP and SD-IOP) and the rate of VF deterioration. The IOP data recorded within six months after surgery were excluded from IOP analyses because of unstable IOP conditions. We determined medication scores by evaluating the number of components present in the main agent of the medication.

The rate of VF deterioration was calculated using a regression line relative to the time axis of the mean deviation (MD) value for the 30-2 VF test, which comprised the overall rate of progression (MD slope: dB/year). These analyses were also performed using the mean of the total deviation in each of the four subfields, which were clustered in accordance with the approach described by Suzuki et al. [16] and Mataki et al. [10]. The four subfields consisted of the superior cecocentral field (Sector 1), superior arcuate field (Sector 2), inferior cecocentral field (Sector 3), and inferior arcuate field (Sector 4) (Fig. 1).

Since observations from the same eye were correlated with each other, a linear mixed model analysis was used to compare the regression coefficients of the mean total deviation of each subfield both before and after surgery. Data from left eyes were converted to mirror images of the right eyes. The Wilcoxon signed-rank test was used to compare the mean IOP, SD-IOP, medication scores, and MD slope values before and after surgery. The relationship between IOP and the rate of VF deterioration was evaluated using a linear mixed model. All statistical analyses were performed using R software (version 3.4.3; The Foundation for Statistical Computing). A $P$ value <.05 was considered statistically significant.

## Results

Thirty-five eyes of 35 patients met the inclusion criteria during the study period and were included in the study. The mean age of patients was 60.6 (SD: 11.5) years, with 9 men and 26 women. Detailed demographic data for the study patients are shown in Table 1. Six eyes (18%) required needling for postoperative bleb revisions.

The mean preoperative IOP of 14.6 (SD: 2.3) mmHg significantly decreased to 9.2 (SD: 2.2) mmHg after surgery ($P$ <.001) with a sufficient decrease of medication score. No significant changes were observed between pre- and postoperative SD-IOP values. The preoperative MD slope of −0.52 (SE: 0.047) dB/year significantly decreased to −0.31 (SE: 0.14) dB/year ($P$ <.01) (Table 2).

Sectoral analysis showed that the rate of deterioration in the superior hemifield (Sectors 1 and 2) significantly

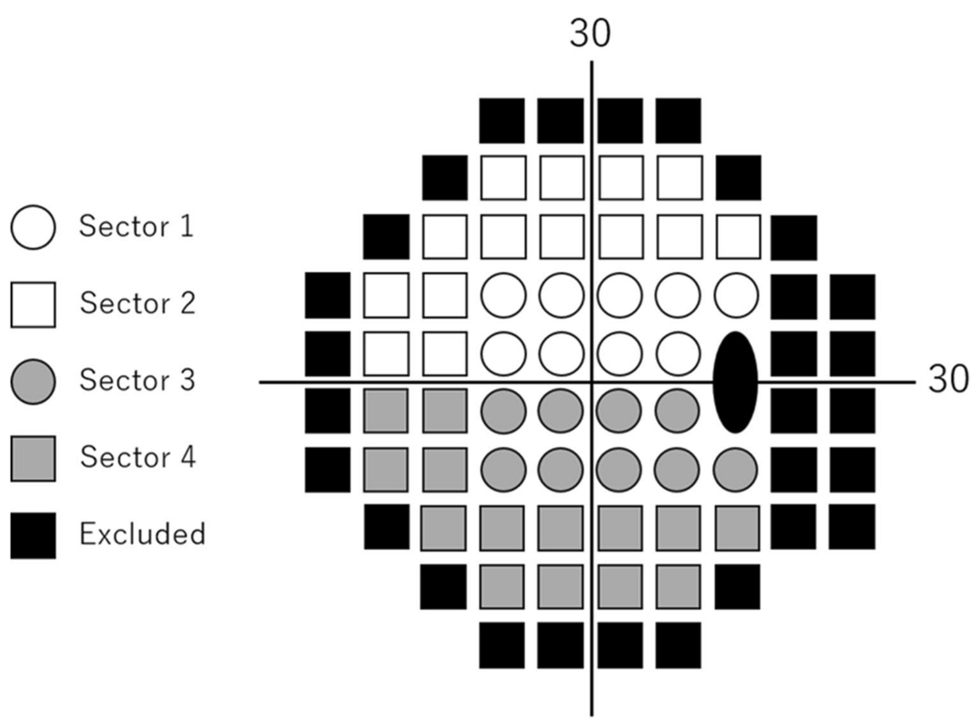


**Fig. 1** Test Points in each Subfield based on the Right Eye. The white circle indicates Sector 1 (superior cecocentral subfield), the white square indicates Sector 2 (superior arcuate subfield), the grey circle indicates Sector 3 (inferior cecocentral subfield), and the grey square indicates Sector 4 (inferior arcuate subfield). The black square indicates excluded test points

**Table 1** Patient characteristics and clinical backgrounds[a]

| Characteristics | Value |
|---|---|
| Age (y) | 60.6±11.5 [35–82] |
| Sex | Male (n = 9), Female (n = 26) |
| Laterality | Right (n = 17), Left (n = 18) |
| Refraction (diopters) | −3.87±4.48 [−14.5–2.50] |
| IOP (mmHg) | 14.6±2.30 [10.9–21.6] |
| Medication score | 2.66±0.54 [1–3] |
| Last MD before operation (dB) | −13.0±7.18 [−2.21 to −28.3] |
| Type of glaucoma | NTG (n = 28), POAG (n = 2)<br>PACG (n = 3), SOAG (n = 2) |
| Type of surgery | Trabeculectomy (n = 20)<br>Phaco-trabeculectomy (n = 15) |
| Preoperative follow-up period (y) | 6.15±0.96 [5.02–8.51] |
| Postoperative follow-up period (y) | 5.95±0.63 [5.03–7.39] |

Abbreviations: IOP, intraocular pressure; MD, mean deviation; NTG, normal tension glaucoma; PACG, primary angle-closure glaucoma; POAG, primary open-angle glaucoma; SOAG, secondary open-angle glaucoma; y, year; dB, decibel

[a]Data are shown as mean ± SD [range]

**Table 2** Comparisons of main preoperative and postoperative parameters

| | Pre-op. | Post-op. | *P* value[a] |
|---|---|---|---|
| Mean IOP (mmHg) | 14.6±0.39[b] | 9.20±0.37[b] | <.001 |
| SD-IOP (mmHg) | 1.90±0.13[b] | 1.87±0.14[b] | .59 |
| Medication score | 2.66±0.09[b] | 0.086±0.063[b] | <.001 |
| MD slope (dB/year) | −0.52±0.047[c] | −0.31±0.14[c] | .005 |

Abbreviations: MD, mean deviation; Mean-IOP, mean intraocular pressure; Pre-op., preoperative values; Post-op., postoperative values; SD-IOP, standard deviation of intraocular pressure; dB, decibel

[a]Wilcoxon signed rank test

[b]Data are shown as mean±SD

[c]Data are shown as mean±SE

slowed ($P \leq .018$), whereas the deterioration rate in the inferior hemifield (Sectors 3 and 4) did not change ($P > .10$) (Table 3). Neither the mean IOP nor the SD-IOP were correlated with the MD slope before surgery (r = 0.0019, $P$ =.93; r = −0.022, $P$ =.72, respectively) or after surgery (r = −0.090, $P$ =.17; r = −0.23, $P$ =.19, respectively).

## Discussion

In the present study, we evaluated the clinical outcomes of fornix-based trabeculectomy in Japanese patients with glaucoma based on long-term and reliable preoperative data. For patients with a confirmed preoperative progress evaluation, the rate of VF deterioration decreased significantly after surgery and the TD slope in the superior hemifield improved significantly, whereas it did not change in the inferior hemifield.

For eyes with glaucomatous progression even at lower IOP values (under 15 mmHg), the achievement of a single-digit IOP following trabeculectomy had beneficial effects on the reduction of global and localised rates of VF progression [17]. A mean IOP of approximately 9 mmHg after trabeculectomy in our study cohort, where the majority of the population (80%) had NTG, was considered sufficient for delaying VF deterioration. Notably, the SD-IOP, an indicator of IOP fluctuation in the present study, did not change after trabeculectomy. The SD-IOP may have been underestimated when the postoperative IOP was smaller than the preoperative IOP, although the percentage of fluctuation relative to the mean IOP was consistent.

In the present study, the mean preoperative progression rate of VF defects decreased from −0.56 dB/year to −0.31 dB/year after surgery. Table 4 summarizes the comparison with previous similar reports. Since this study adopted a longer preoperative follow-up period compared to those studies, it is possible that the progression rate (−0.56 dB/year) tended to be slower than previously reported because patients with more rapid progress during a shorter time period were excluded from our study and underwent an operation. There is another study lacking descriptive details about the follow-up duration, surgical methods and antimetabolites used reported [13, 14]. This makes it difficult to compare with the results of our study.

The post-operative diminished speed of the superior hemifield of VF needs to be discussed. This has been pointed out before, but it can be taken as suggesting that the inferior part of the optic disc is more vulnerable to IOP changes than the superior part [18]. The fact that the inferior rim width of the optic disc corresponding to the superior hemifield correlates with IOP, while the superior rim width corresponding to the inferior hemifield correlates not only with IOP but also with age, central corneal thickness and ocular perfusion pressure [19]. Taking all of this into account, it can be assumed that the load on the upper half of the visual field is reduced by lowering the IOP. On the other hand, the fact that the progression of the inferior hemifield of VF was not delayed despite sufficient IOP reduction (also indicated in previous reports [7, 9, 10]) may be related to the structural characteristics of that portion of the optic nerve head that is not easily affected by IOP changes [20].

Few reports regard the respective correlation between IOP parameters (mean IOP or SD-IOP) and glaucoma progression rate (trend analysis). In a report on Japanese patients with NTG, correlations between the mean IOP values recorded during the course of treatment and the progression rates were investigated [21]. The results show that, in the high IOP group (≥ 21 mmHg), there was a significant

**Table 3** Total deviation of deterioration rates before and after trabeculectomy and last total deviation values for the four subfields before trabeculectomy

| | Pre-op. TD value[a] | Pre-op. TD deterioration rate[b] | Post-op. TD deterioration rate[b] | *P* value[c] |
|---|---|---|---|---|
| Sector1: Superior cecocentral | −16.4±7.34 [−32.8 to −4.44] | −0.70±0.16 [−3.90–1.18] | −0.18±0.11 [−1.47–1.61] | .018 |
| Sector2: Superior arcuate | −17.3±10.3 [−33.7 to −0.07] | −0.94±0.14 [−2.76–0.65] | −0.30±0.13 [−2.06–1.21] | <.001 |
| Sector3: Inferior cecocentral | −9.62±6.79 [−23.7–0.67] | −0.42±0.11 [−2.31–1.10] | −0.41±0.15 [−3.03–1.41] | .85 |
| Sector4: Inferior arcuate | −13.1±9.34 [−28.8–0.57] | −0.52±0.10 [−1.59–1.02] | −0.31±0.14 [−3.97–1.29] | .10 |

Abbreviations: Pre-op., preoperative values; Post-op., postoperative values; TD, total deviation

[a]Data are shown as mean±SD [range] (dB)

[b]Data are shown as mean±SE [range] (dB/year)

[c]Wilcoxon signed rank test

**Table 4** The effect of trabeculectomy on the rate of visual field deterioration, comparison with previous reports

| Author | N | Surgical method | Antimetabolite | Pre-op. (f/u duration) | Post-op. (f/u duration) |
|---|---|---|---|---|---|
| Koseki (1997) | 21 | Unknown | 5-FU or MMC | −1.48 dB/year (2.0 y) | 0.13 dB/year (2.0 y) |
| Daugeliene (1998) | 32 | Limbal-based | MMC | −0.97 dB/year (3.8 y) | −0.32 dB/year (4.5 y) |
| Shigeeda (2002) | 23 | Unknown | 5-FU or MMC | −1.05 dB/year (unknown) | −0.44 dB/year (6.0 y) |
| Mataki (2014) | 34 | Unknown | 5-FU or MMC | −0.70 dB/year (4.6 y) | −0.25 dB/year (5.7 y) |
| Bertrand (2014) | 52 | Fornix-based | 5-FU or MMC | −0.36 dB/year (3.9 y) | −0.16 dB/year (3.8 y) |
| Present study (2020) | 35 | Fornix-based | MMC | −0.52 dB/year (6.2 y) | −0.31 dB/year (6.0 y) |

N, number; Pre-op., pre operation; Post-op., post operation; f/u, follow-up; 5-FU, 5-fluorouracil; MMC, mitomycin C; dB, decibel

negative correlation between the mean IOP and the rate of progression. On the other hand, in the normal IOP group (NTG), there was no correlation between the two parameters. Another study of patients with primary open-angle glaucoma and with primary angle closure glaucoma (baseline IOP of 15.9 mmHg) showed no relationships between the mean IOP or between maximum IOP and progression rate, though long-term IOP fluctuations were significantly correlated [22]. In the present study, neither the mean IOP nor the SD-IOP were correlated with the MD slope pre- or postoperatively. This difference may be due to the small number of patients included, differences in IOP levels, and the shorter follow-up periods compared with those of previous studies [21, 22].

Another perspective has been studied with respect to IOP fluctuations and glaucoma progression (event analysis) [23–25]. In the randomised cohort analysis of the Advanced Glaucoma Intervention Study, the odds of VF progression are reported to increase with larger IOP fluctuations [23, 25]. On the other hand, a randomised study of data from the Early Manifest Glaucoma Trial shows an insignificant correlation between time-to-progression of glaucoma and IOP fluctuations, whereas the mean IOP had a significant negative correlation with progression [24]. In the present study, the association between mean IOP and/or mean SD-IOP and glaucoma progression was not examined because glaucoma progression in our study was judged only by trend analysis.

One of the strengths of our study is the extended duration of the follow-up period before trabeculectomy. These long-term and reliable VF assessments enabled us to perform more accurate evaluations of changes in VF [15, 26] and in IOP after surgery. Furthermore, because the same ophthalmologist examined the patients and performed the surgery, this study did not require consideration of the diagnostic ability, inter-examiner errors in IOP measurements [27], or variations in surgical skills.

This study does have some limitations. First, the number of patients was relatively small because we only included patients with reliable VF data followed for a total of 10 years, with more than five years before and after surgery. We excluded patients who showed more rapid progression of glaucoma leading to surgery within five years or patients who changed hospitals after surgery. Second, although this study included patients with multiple types of glaucoma, the majority had NTG (80%). Thus, the number of patients with angle closure or secondary glaucoma in the present study was insufficient for a separate analysis. We are planning to examine only NTG patients in our next study. In this study, we wanted to confirm the effect of trabeculectomy on glaucoma (regardless of disease type) with a stable course for more than 5 years before and after surgery. Trabeculectomy can be applied to any type of disease, so we did not distinguish between different types of disease. And lastly, this study included a few patients with high myopia. Previous cross-sectional, population-based studies identified myopia as a risk factor for primary open-angle glaucoma [28]; however, the extent to which myopia affects the progression of glaucoma remains unknown. In contrast, some prospective longitudinal studies have shown that refractive error does not play an apparent role in the development or progression of glaucoma [29, 30]. In a report examining the effects of trabeculectomy on highly myopic glaucoma eyes, myopia was not detected as a risk factor for worsening surgical performance, but rather a success factor [31]. Based on this, it is hard to believe the inclusion of myopia would have an effect on our results.

In conclusion, this study clearly demonstrated the effectiveness of fornix-based trabeculectomies with MMC in delaying VF deterioration based on concrete long-term preoperative data. Since this procedure is becoming increasingly common, a fornix-based trabeculectomy should be considered as a potential initial surgery for maintenance of VF in patients with glaucoma.

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