

Long-Term Clinical Results of Trabectome Surgery

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Research Article

Keywords: Trabectome, ab interno trabeculectomy, open angle glaucoma, pseudoexfoliative glaucoma, intraocular pressure.

Posted Date: June 16th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-599761/v1>

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Version of Record: A version of this preprint was published at Beyoglu Eye Journal on March 1st, 2023. See the published version at <https://doi.org/10.14744/bej.2023.13540>.

Abstract

Purpose: To analyze the long-term results of trabectome surgery and to characterize risk factors for failure.

Method: This is a single-center retrospective study including 66 eyes of 56 patients who underwent trabectome alone (TA) or phacotrabectome (TP) surgeries between 2012-2016. Surgical success was defined as intraocular pressure (IOP) drop by 20% or IOP \leq 21 mmHg and no further glaucoma surgery. Risk factors for further surgeries were analyzed with Cox proportional hazard ratio models. Cumulative success analysis of subgroups was completed with the Kaplan Meier analysis.

Results: Mean follow-up period was 59.7 \pm 14.1 months. During the follow-up period, 15 of 62 (24.2%) eyes had additional glaucoma surgery. The mean preoperative IOP was 26.8 \pm 6.5 mmHg. The mean last visit IOP was 18.7 \pm 4.5 mmHg (p <0.01). IOP decreased 30.1% from baseline at the last visit. Average numbers of medications used were 3.42 \pm 0.76 (range 1-4) and 2.45 \pm 1.33 (range 0-4) at preoperative and last visit, respectively (p <0.01). The risk factors for further surgery requirements were higher baseline IOP (HR:1.12, p :0.01), higher central corneal thickness (CCT) (HR:1.01, p :0.04), and higher amounts of preoperative drugs (HR:2.22, p :0.08). The cumulative probability of success was 93.5%, 90.5%, 85.5%, 80.6%, and 77.4% at 3, 12, 24, 36, and 60 months, respectively. Kaplan Meier survival plots indicating the time of additional glaucoma surgery in the subgroups showed higher survival probability in primary open angle glaucoma (POAG), males, phacotrabectome cases, early stage glaucoma, and eyes without previous glaucoma surgery.

Conclusion: Trabectome success ratio was 50% at 59 months. Higher baseline IOP and thicker CCT are associated with an increased risk of further glaucoma surgery.

Key Message

Trabectome is one of the MIGS on the way of proving itself in the long-term. A lot of studies find trabectome surgery safe and effective over many years. The factors leading to failure are subject to recent studies. We find out that higher preoperative IOP and higher CCT is strongly suggestive of late failure. Almost every study reported better outcomes with pseudoexfoliative glaucoma but we did not find out any superior outcomes in long term. On contrary, POAG seems to survive better.

Introduction

Glaucoma is an optic neuropathy characterized by specific optic disc findings reflecting retinal nerve fiber loss and certain visual field defects in which intraocular pressure (IOP) is the only modifiable risk factor to retard disease progression [1, 2]. It is one of the challenging diseases of the eye necessitating lifelong follow –up and is the leading cause of irreversible vision loss worldwide [3].

Treatment choices include medical treatment and surgical treatment [4]. Among surgical options, trabeculectomy with an antimetabolite application is still the gold standard [5]. Artificial drainage implants are among the other filtering surgical options. These procedures are highly effective in lowering intraocular pressure but are not perfect therapeutic options with sight-threatening complications like prolonged hypotony, bleb-related endophthalmitis, cataract formation, suprachoroidal hemorrhage, and high rate of revision surgery requirements [6, 7].

Minimally invasive glaucoma surgeries (MIGS) try to lower IOP without leading to serious complications as in filtering procedures. Saheb and Ahmed defined MIGS as a group of surgical interventions sharing common characteristics including an ab interno approach with clear corneal incision sparing conjunctiva and sclera, minimal trauma to target tissues, lowering IOP, high safety profile without exposing the eyes to serious complications, and rapid recovery [8]. In this regard, trabectome surgery (TS) with Trabectome (Neomedix Corp., Tustin, CA, USA) is one of MIGS which was approved by the Food and Drug Administration in 2004.

In 2005, the first clinical results reported by Minckler et al. [9] showed the effectiveness of TS for open-angle glaucoma. Later on, many subsequent studies showed the safety and effectiveness of TS in periods from 6 to 48 months. Recently, Mosaed et al. and Efsandiari et al. published long-term results for 90 months and 5 years follow-up, respectively [10, 11].

In this study, we aimed to evaluate the long-term results of trabectome surgery and compare with other studies.

Materials And Methods

This is a retrospective-single center study to investigate whether trabectome surgery is successful in the long term and which factors influence the success or lead to failure. This study was approved by the local ethics committee and adhered to the tenets of the Declaration of Helsinki.

We enrolled all patients who underwent trabectome surgery alone (TA) or combined with phacoemulsification (TS) between 2012–2016 in one tertiary center. Data was collected from patient files and hospital records. Demographic data including age, gender, laterality of eye, best-corrected visual acuity using logMar system, lens status, type of glaucoma, glaucoma stage according to Hoddap-Parrish-Aderson criteria using Goldmann visual field analysis [12], central corneal thickness (CCT) measured by Pentacam (rotating Scheimpflug camera; Oculus, Wetzlar, Germany) intraocular pressure (IOP) measured with Goldmann applanation tonometry, number of antiglaucomatous drug molecules used, type of surgery, and any previous surgery were noted.

Outcome measures were the 6th month and last visit records including IOP, number of glaucoma drugs, if any additional glaucoma or ocular surgery was performed and at which time point after the index surgery, last visit visual acuity, and any additional ocular pathology affecting visual acuity. We defined surgical

success as IOP drop by 20% or IOP \leq 21 mmHg and no further glaucoma surgery. Patient loss due to death or loss of follow-up was also noted.

All surgeries were performed by one well-experienced glaucoma surgeon. This procedure was performed under topical anesthesia through a 1.7 mm clear corneal temporal incision, using a modified Swan-Jacobs surgical gonioscopy lens (Ocular Instruments, Bellevue, WA, USA). To get the best angle visualization, the head is rotated 30–40° counter clockwise and the microscope tilted 30–40° clockwise towards the surgeon. Using viscoelastic, the trabectome tip is advanced and nasally approximately 60–100° strip of the inner wall of trabeculum, and Schlemm's canal (SC) is removed. Routine anterior chamber antibiotic prophylaxis is applied. When the combined procedure is performed, trabectome is performed first. All the patients were instructed to use antibiotics for 10 days and steroid and pilocarpine treatment for 1 month.

All statistical analyses were carried out using SPSS (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.). For all tests, $p < 0.05$ was considered statistically significant. Frequency, percent, mean \pm SD, median, and range were used to describe the data. Compliance to normal distribution was investigated with Kolmogorov–Smirnov and Shapiro Wilk tests. Normally distributed (parametric) paired groups were compared using correlated groups t-test, while paired groups not showing normal distribution (nonparametric) were compared using the Wilcoxon test. The odds ratio was used to quantify the strength of the association between two parameters. Kaplan-Meier survival plots were constructed to assess the long-term survival rates and compared using the log-rank test. A Cox proportional hazard model was used to find risk factors for failure.

Results

A total of 66 eyes from 56 patients were included in the study. Of the 66 surgeries performed, 48 (72.7 %) were trabectome alone (TA) and 18 (27.3%) were trabectome combined with phacoemulsification (TP). Of 66 eyes operated, 33 (50%) were right eyes. Of patients, 23 (41.1%) were female and 33 (58.9%) were male. The mean age was 69 years (range 21–85 years).

The mean follow-up time was 59.7 ± 14.1 months.

Baseline characteristics of operated eyes are shown in Table 1.

Among operated eyes, 45 (68.2%) were primary open-angle glaucoma, 14 (21.3%) were pseudoexfoliative glaucoma and 7 (10.6%) were secondary glaucoma including traumatic, post vitrectomy, and neovascular. Of the eyes, 15 (22.7%) had early, 23 (34.8%) had moderate and 28 (42.4%) had severe glaucomatous visual field changes. Mean CCT was 537.38 microns (443–648).

Among operated eyes, 14 (21.2%) had previously undergone trabeculectomy surgery, 5 (7.6%) had been vitrectomized and 3 (4.5%) had previous SLT.

During the follow-up period, 2 patients died and 1 patient with bilateral trabectome surgery did not adhere to follow-up. So last visit data include 62 (91.1%) eyes of patients.

No serious complication related to trabectome surgery was seen in the long term, but early postoperative hyphema which resolved within the first week postoperative was nearly universal, seen in 90% of patients.

The mean preoperative IOP was 26.8 ± 6.5 mmHg. The mean postoperative 6th month IOP was 18.8 ± 5.1 mmHg ($p < 0.01$). The last visit mean IOP was 18.7 ± 4.5 mmHg ($p < 0.01$). IOP decreased by 29.8% and 30.1% from the baseline in the 6th month and at the last visit, respectively.

The mean medication number was 3.42 ± 0.76 (range 1–4), 1.98 ± 1.42 (range 0–4), and 2.45 ± 1.33 (range 0–4) at preoperative, 6th month and last visit, respectively ($p < 0.01$). At the final visit, 8 (12.9%) patients were not using any antiglaucomatous drug and among them just one had additional glaucoma surgery.

The mean best-corrected visual acuity was 0.46 ± 0.53 logMAR (range 0–2) and 0.65 ± 0.76 logMAR preoperatively and at the last visit, respectively ($p < 0.01$). During the follow-up, other ocular pathologies including senile macular degeneration, diabetic maculopathy, branch retinal vein occlusion, and retinal detachment developed in 9 (14.5%) patients leading to vision loss, apart from glaucoma progression. Five (8.0%) eyes needed phacoemulsification surgery and were treated appropriately in the follow-up period.

According to surgical success criteria determined as IOP drop by 20% or $IOP \leq 21$ mmHg and no further glaucoma surgery, success ratio was 72% and 50% at 6th month and last visit, respectively.

During the follow-up period, 15 of 62 (24.2%) eyes had additional glaucoma surgery. Further glaucoma surgeries were as follows; trabeculectomy with mitomycin c in 10 eyes, Ahmed Glaucoma Valve (AGV) implantation in 5 eyes, and diode laser cyclophotocoagulation in 1 eye which previously had AGV. The mean interval between trabectome surgery and additional glaucoma surgery was 22.07 ± 20.4 months (range 1–63 months).

Kaplan Meier survival analysis showed mean survival of 69.01 ± 3.5 months according to further glaucoma surgery. The cumulative probability of success was 93.5%, 90.5%, 85.5%, 80.6%, and 77.4% at 3, 12, 24, 36, and 60 months, respectively (Fig. 1). Kaplan Meier survival plots indicating the time of additional glaucoma surgery in case failure (Fig. 2).

Multivariate Cox regression analysis was stratified by age, preoperative IOP, preoperative drugs, and CCT. The risk factors for further surgery requirements were higher baseline IOP (HR:1.12, $p:0.01$), higher CCT (HR:1.01, $p:0.04$), and higher number of preoperative drugs (HR:2.22, $p:0.08$) (Table 2).

Half of POAG failures were within the first year, whereas just 25% of PEX glaucoma failures were in the first year after trabectome surgery. The Odds ratio of POAG for early failure is 3.0 (95 % confidence interval: 0.21–42.6).

Discussion

The Trabectome device uses high frequency-microelectrocautery with infusion and aspiration simultaneously to ablate the inner wall of the trabeculum and Schlemm's canal providing direct access for aqueous fluid to collector channels [11]. In 2006, Minckler et al. reported an 84% success rate and high safety profile in a prospective study including 101 eyes over 30 months [13].

In 2014, Mosaed et al. published a large data pool obtained from the Trabectome Study Group Database, including 5436 patients and 90 months follow-up time [14]. The average IOP reduction was 29% from 23.0 ± 7.9 mmHg to 16.5 ± 3.8 mmHg, and medications were reduced from 2.6 ± 1.3 to 1.6 ± 1.3 (38%). In the report, the survival rates were 60% for all cases, 76% for combined cases, and 50% for trabectome-only cases. Secondary glaucoma surgery was reported as 7%. A limitation of this report is that it was unclear how many eyes were still included in 90th-month data.

In 2019, Efsandiari et al. reported 5-year outcomes for a combined phacotrabectome case series including 93 patients [15]. In this report, the cumulative probability of success at 5 years was 67.5%. Risk factors for failure were reported as lower baseline IOP, younger age, and higher CCT. Exfoliative glaucoma was associated with a higher success rate. IOP dropped from 20 ± 5.6 to 15.6 ± 4.6 mmHg at 5 years.

In 2019, Avar et al. reported 3.5-year outcomes of 81 trabectome cases, in which IOP decreased by 28% and 26% for POAG and PEX glaucoma, respectively [16]. In the report, the Cox proportional hazard model showed nearly 2 times increased risk of failure in POAG cases compared to PEX glaucoma.

In 2020, Kono et al. published long-term results of 305 trabectome cases, using IOP ≤ 21 mmHg and $\geq 20\%$ reduction as criterion A; IOP ≤ 18 mmHg and $\geq 20\%$ reduction as criterion B; and IOP ≤ 16 mmHg and $\geq 20\%$ reduction criterion as C [17]. Success probabilities for all cases were found as 44%, 35%, and 17% for Criteria A, B, and C, respectively, at 72 months. Baseline IOP dropped from 29.2 ± 9.8 mmHg to 16.4 ± 5.8 mmHg at 72 months. There was no significant difference in success probability at 72 months for glaucoma type in terms of criterion A. On the other hand, the report emphasized that the combined procedure significantly reduced failure risk, whereas POAG and past SLT history significantly increased the failure risk. In this report, it was noted that 44.6% of eyes required subsequent glaucoma surgery.

In our report, we found trabectome was successful in reducing baseline IOP from 26.83 ± 6.5 mmHg to 18.7 ± 4.5 mmHg ($p < 0.01$) with a mean follow-up of 59 months. The mean IOP decreased by 30.1% and the mean medication quantity decreased from 3.42 ± 0.76 to 2.45 ± 1.33 ($p < 0.01$). These results are compatible with other reports in the literature.

If we assume surgical success criteria as IOP drop by 20% or IOP ≤ 21 mmHg without additional glaucoma surgery, the success rate was 50% at last visit. During the follow-up period, 24.2% of eyes had additional glaucoma surgery. This is relatively higher than the ratio reported by Mosaed et al., but lower than that of Kono et al. In our report, Kaplan Meier analysis for reoperation time showed mean survival of 69.01 ± 3.5 months (Fig. 1) Cumulative probability of success was 93.5%, 90.5%, 85.5%, 80.6%, and

77.4% at 3, 12, 24, 36, and 60 months, respectively. This is important to see what happens in real life and shows us the benefit of trabectome surgery. This probable success rate is higher than the rate reported by Efsandiari at 5 years which was 67.5% [15].

Kaplan Meier survival plots indicating the time for additional glaucoma surgery with the subgroups showed higher survival probability with combined surgery and in male patients and lower survival probability in eyes with advanced glaucoma and vitrectomized eyes (Fig. 2). The analysis according to glaucoma types showed better survival for POAG and lower survival for PEX glaucoma and lowest with secondary glaucoma (post-vitrectomy, neovascular, traumatic) at 80 months which seems not to be compatible with the literature. But if the plot is examined in detail, it seems that within the first 25 months, PEX glaucoma had better survival and then the survival probability curve for PEX glaucoma crosses and then declines. In the report by Kono et al. [17], no significant difference in success probability was found regarding glaucoma type, but in the plot PEX glaucoma had lower survival at 72 months and similarly higher survival at earlier time points. Whereas in the report by Avar et al. [16] with a mean follow-up of 3.5 years, PEX glaucoma had significantly better survival than POAG. The incompatibility of the reports may be related to the follow-up time as other reports indicating better results for PEX glaucoma had shorter follow-up periods [18–22]. Because PEX glaucoma is associated with fibrillary protein deposition in the trabeculum [23], it may have a better response to surgeries bypassing trabecular resistance. This may be the reason why early reports had better outcomes for PEX glaucoma.

In our report, multivariate Cox regression analysis showed an increased risk of further surgery with higher baseline IOP (HR:1.12, p:0.01), higher CCT (HR:1.01, p:0.04), and higher number of drugs (HR:2.22, p:0.08). Patients with higher baseline IOP are expected to have higher IOP reduction after trabectome surgery. Many reports found higher baseline IOP was associated with higher IOP reduction after trabectome [15, 24]. The data may be biased by the floor effect in normotensive eyes. The higher baseline IOP reflects how aggressive glaucoma is. A recent report published by Kono et al. also found high baseline IOP was associated with a significant increase in failure risk, as in our study [17].

We observed higher CCT led to increased requirements for further surgery. Efsandiari et al. also reported an association between thicker cornea and risk of failure [15]. Thicker corneas may reflect ultrastructural and biomechanical properties of eyes which may defer more distal outflow facility [25–27].

Limitations of our study are the retrospective design, low patient numbers, and inadequate follow-up data especially in an intermediate period. But the study gives an objective view about the long-term survival after trabectome surgery. Higher baseline IOP, higher drug numbers, higher glaucoma stage, and secondary glaucoma (traumatic, post-vitrectomy, neovascular) reflect the aggressive nature of glaucoma. Combined phacotrabectome was shown to have no additional effect on IOP reduction [24, 28], but it biases patient selection towards the earlier stages [22].

In conclusion, trabectome surgery achieved 50% success rate at 59 months follow-up. The probability of success was 77.4% if reoperation is a criterion for failure. Higher CCT and higher baseline IOP significantly increase the failure rate in the long term.

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Tables

Table 1. Baseline characteristics of operated patients. POAG: primary open-angle glaucoma, PEX: pseudoexfoliative glaucoma, TA: trabectome alone, TP: trabectome with phacoemulsification, CCT: central corneal thickness, SLT: selective laser trabeculoplasty.

Baseline characteristics		
Age (years)	Mean±SD	66.9±12.7
	Median(range)	69 (21-85)
Gender	Female	23 (41.1%)
	Male	33 (58.9%)
Eye	Right	33 (50%)
	Left	33 (50%)
CCT (micron)	Mean±SD	537.3±39
	Median(range)	531 (443-648)
Lens	Phakic	34 (51.5%)
	Pseudophakic	32 (48.5%)
logMAR	Mean±SD	0.46±0.53
	Median (range)	0.3 (0.00-2)
Baseline medications	Mean±SD	3.42±0.76
	Median(range)	4 (1-4)
Baseline IOP (mmHg)	Mean±SD	26.8±6.5
	Median(range)	27 (12-48)
Glaucoma stage	Early	15 (22.7%)
	Moderate	23 (34.8%)
	Severe	28 (42.4%)
Glaucoma type	POAG	45 (68.2%)
	PEX	14 (21.3%)
	Secondary	7 (10.6%)
Surgery	TA	48 (72.7%)
	TP	18 (27.3%)
Prior surgery	SLT	14 (21.2%)
	Trabeculectomy	5 (7.6%)
	Vitrectomy	3 (4.5%)

Table 2. Cox proportional hazard regression model. CCT: central corneal thickness.

	Hazard ratio	P value
Age	0.993 (0,951-1.038)	0,766
Preoperative IOP	1,127 (1.024-1.241)	0,015
Preoperative drugs	2,221 (0.892-5.531)	0,087
CCT	1,018 (1.000-1.035)	0,045

Figures

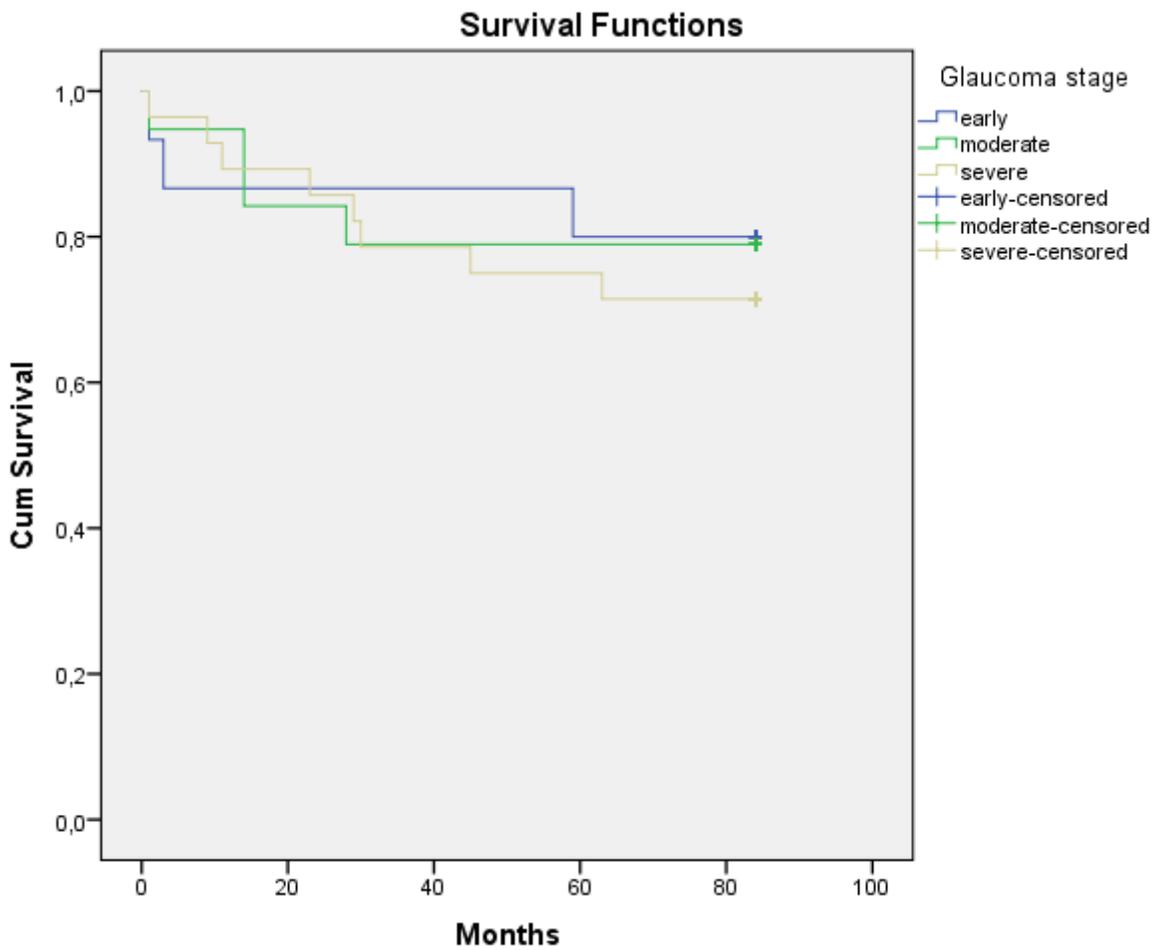


Figure 1

Kaplan Meier survival plots based on the need for further glaucoma surgery

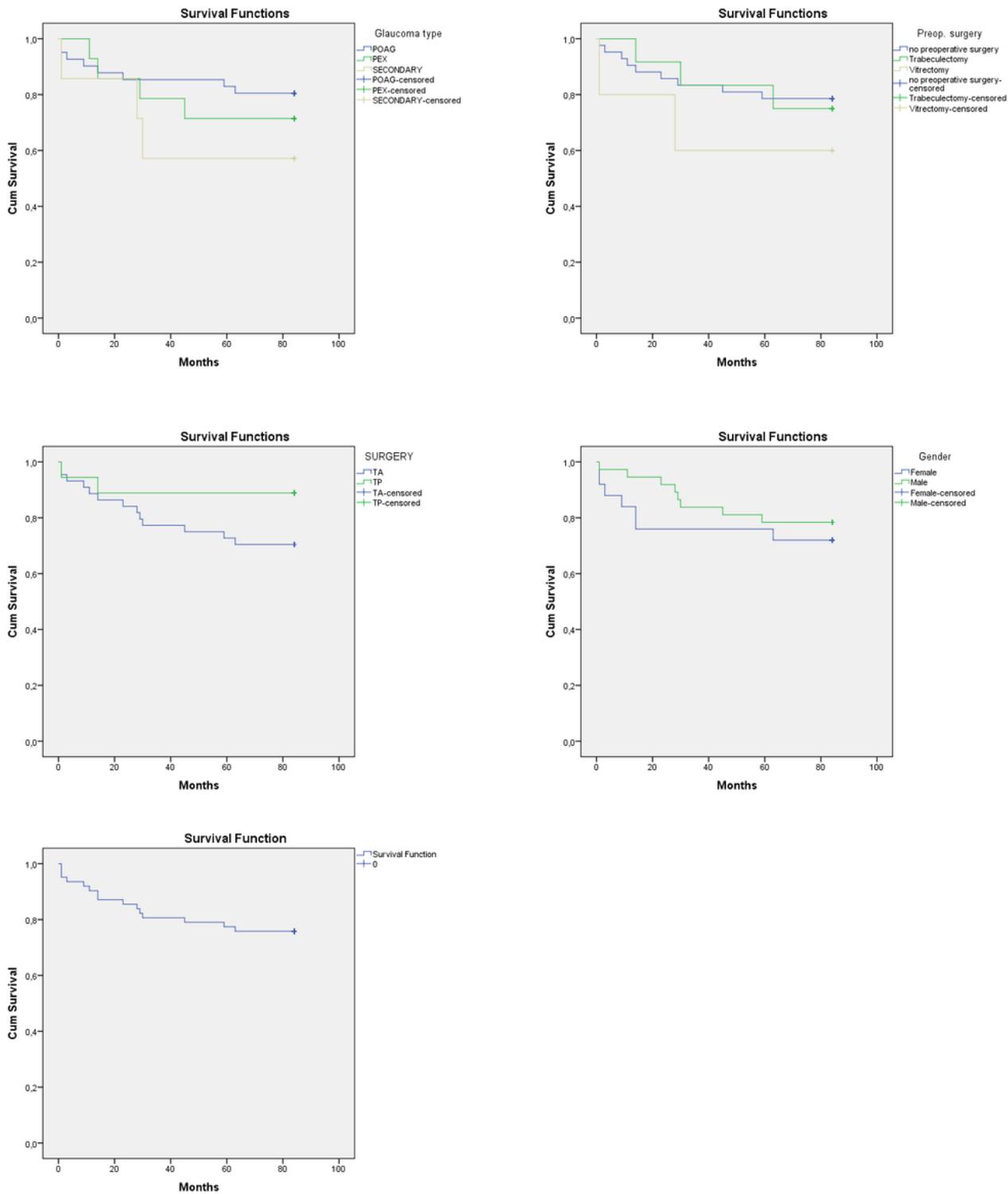


Figure 2

Kaplan Meier survival plots indicating the time of additional glaucoma surgery in case failure. a. Survival according to glaucoma type, b. Trabectome alone versus phacotrabectome, c. Survival according to the glaucoma stage, d. Survival functions according to pretrabectome surgeries of eyes, e. Male versus female POAG: Primary open-angle glaucoma, PEX: pseudoexfoliative glaucoma, TA: trabectome alone, TP: trabectome with phacoemulsification