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Long-term success after trabeculectomy in open-angle glaucoma: results of a retrospective cohort study

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ABSTRACT

Objective To evaluate the long-term outcomes of trabeculectomy (TE) surgery in a large cohort with a minimum follow-up of 3 years.

Design Retrospective cohort study.

Setting University Eye Hospital, Germany.

Participants Three hundred and seventy-nine patients with open-angle glaucoma underwent TE with mitomycin C (MMC) between January 2013 and February 2017 with a minimal follow-up of 3 years. Eligible patients were identified via an electronic surgical case register.

Interventions All patients had undergone TE with MMC following a set surgical protocol. To assess the influence of cataract surgery following TE, eyes which underwent cataract surgery at least 6 months after TE were matched 1:3 by sex and age to eyes who did not undergo cataract surgery during the follow-up period.

Main outcome measures Primary outcome was the proportion of surgical success based on intraocular pressure (IOP), surgical complications, the need for revision surgery, loss of light perception and the need for additional pressure-lowering medication.

Results The mean follow-up time was 6 (±0.8, IQR: 5.4–6.5) years. Seventy-three per cent of eyes achieved qualified surgical success at the last follow-up (IOP≥5 mm Hg and ≤18 mm Hg, without surgical complications or complete loss of vision) but necessitated additional medical therapy, complete surgical success with no additional medical therapy was achieved in 69% of eyes. There was no significant difference in the success probability between eyes that had undergone cataract surgery after TE and those that had not (p=0.45).

Conclusions The results demonstrate a high and stable success rate of TE after a mean follow-up time of approximately 6 years, that is, not affected by later cataract surgery.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study evaluates the long-term outcomes of one of the most performed interventions in glaucoma surgery with a mean follow-up of 6 years.
⇒ The study cohort is relatively large, with 379 patients evaluated.
⇒ This study is a single-centre study, with surgery performed by few glaucoma specialists, and may thus not be representative of trabeculectomy success rates in other settings.
⇒ Its retrospective nature does not allow for the determination of causal relationships.

INTRODUCTION

Globally, glaucoma affects about 60.5 million people worldwide.[1] It accounts for 8% of all cases of blindness and is the second leading cause of irreversible blindness.[2] Initial therapy for glaucoma typically consists of topical eye drops or laser trabeculoplasty, both of which aim to lower the intraocular pressure (IOP) and have similar efficacy.[3] When pharmacological and/or laser treatment fail to control IOP, pressure lowering surgery is required. Trabeculectomy (TE), first described more than 50 years ago,[4] is considered the reference standard in the surgical treatment of glaucoma[5] due to its effective reduction of the IOP and its cost efficiency.

To reduce the risk of complications such as hypotony and endophthalmitis, alternative surgical procedures, such as glaucoma drainage devices, deep sclerectomy or viscocanalostomy, have been proposed as alternatives to TE.[6–8] Moreover, Minimal Invasive Glaucoma Surgery (MIGS) was introduced several years ago, expanding the surgical spectrum. The term MIGS includes a variety of interventions, extending from miniaturised versions of TE to minimally invasive shunt or bypass operations, differing from traditional tube shunt procedures through limited surgical manipulation of the sclera and the conjunctiva.[9]

These alternatives notwithstanding, TE remains the most performed surgical procedure for medically uncontrolled glaucoma. Moreover, its procedure has also evolved over time. In the 1990s, the chemotherapeutic agents mitomycin C (MMC) and 5-fluorouracil (5-FU) were introduced as an addition to the surgical procedure due to their antifibrotic effect, in order to counteract scarring and thereby reduce surgical failure.[10 11] Other

advancements include the use of anterior chamber maintainers, placement of releasable or adjustable sutures and improved sutures for a fornix-based conjunctival flap.[12] Postoperative interventions have equally evolved and comprise the adjustment or removal of scleral flap sutures, modification of postoperative bleb scarring with 5-FU injection, and bleb needling.[13] These so-called safer TE techniques, including perioperative and postoperative modifications, have reduced complications and improved outcomes of TE surgery.[14]

To date, only few studies have yet assessed the long-term results after more than 3 years, and mostly in smaller cohorts.[15–17] The aim of this study was thus to evaluate the long-term outcomes of TE surgery in a large cohort with a minimum follow-up of 3 years.

METHODS

We conducted a retrospective cohort study including patients unresponsive to maximally tolerated IOP-lowering pharmacological therapy with open-angle glaucoma (primary open-angle glaucoma, secondary open angle or normal-tension glaucoma) who underwent TE with MMC between January 2013 and February 2017 at the University Eye Hospital Mainz, Germany. Identification of eligible patients was achieved by searching an electronic surgical case register. Eligible subjects were then confirmed by manual chart review. We identified 452 patients in the corresponding time period, of which six persons had died before the minimal follow-up of 3 years and 67 were lost to follow-up.

All data were fully pseudonymised before they were accessed. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[18]

Patient and public involvement

As this was a retrospective study, patients' priorities, experience and preferences were not part of the research development.

Collected characteristics included demographics and ocular characteristics, such as preoperative IOP used for decision for surgery (preoperative IOP), number of different glaucoma medications, glaucoma diagnosis and history of cataract surgery. Follow-up data were obtained through chart review and correspondence with ophthalmologists engaged in patients' follow-ups.

Inclusion and exclusion criteria

Patients above the age of 18 with primary open-angle glaucoma, secondary open-angle glaucoma and normal-tension glaucoma with a minimum follow-up of 3 years were included. Only patients after standalone TE were included. Patients who did not meet these criteria or had prior filtering glaucoma surgery were excluded.

Surgical protocol

The following surgical protocol was followed for all procedures at the University Eye Hospital Mainz, Germany: first, a fornix-based flap of the conjunctiva was dissected, and Tenon's capsule was mobilised. A shallow groove was created directly behind the former conjunctival insertion—to anchor the conjunctiva and Tenon's capsule later on—, and a 7×7 mm sponge soaked with 0.02 mg MMC in 0.1 mL was placed posteriorly under the conjunctiva for 3 min, followed by intensive rinsing (30 mL) with saline solution. A 3.5×3.5 mm scleral flap of partial thickness was prepared, and a temporal paracentesis was made. An anterior placed sclero-cornectomy was created and a peripheral iridectomy was performed. The scleral flap was closed with four 10-0 nylon sutures, two edge sutures and two side sutures stitched tangentially through the scleral flap and the adjacent sclera to allow aqueous humour to flow posteriorly whereby side sutures were pulled tighter than edge sutures.[19] Additionally, the knots of the posteriorly placed sutures were buried under the scleral flap to increase the area of posteriorly directed aqueous humour flow. The conjunctiva was closed with improved sutures in a meander-like fashion for fornix-based conjunctival flaps as described by Pfeiffer and Grehn.[12] The presence of a bleb and tightness of the sutures was confirmed by anterior chamber inflation with balanced salt solution. Surgeries were performed by glaucoma-specialised consultants who had performed at least 100 TE beforehand.

Perioperative management

According to the University Eye Hospital Mainz protocol, all patients were instructed to stop the use of antiglaucomatous eye drops on the treated eye 2–4 weeks preoperatively. In order to reduce conjunctival inflammation, patients were advised to use unpreserved topical steroids for 5 days four times a day preoperatively. In case of an IOP increase, patients and treating ophthalmologists were instructed to treat IOP spikes with oral acetazolamide. Patients were hospitalised for surgery and were seen daily in the postoperative course. The postoperative topical regimen included topical antibiotic prophylaxis for 1 week and unpreserved prednisolone eye drops six times a day, tapering off over a period of 6 weeks. Subconjunctival 5-FU injections were given at the discretion of the treating surgeon. Indication for 5-FU injections was a non-leaking bleb with an IOP of 5 mm Hg or above with no clinical signs of hypotony beginning at second day after surgery. Any necessary interventions (including laser suture lysis, and digital ocular compression posterior to the scleral flap increasing the scleral outflow) were performed on site during the inpatient stay.

Outcome measures

The primary outcome was the proportion of surgical success; we distinguished between strict success, complete success and qualified success.

Failure

The procedure was considered as a failure if one of the following criteria was met: IOP>18 mm Hg, hypotony (IOP below 5 mm Hg), surgical complications, revision surgery

or loss of light perception. Revision surgery was defined as additional surgery required, including needling procedures. Postoperative in-clinic manoeuvres, including laser suture lyses, were not considered failures.

Complete success

The procedure was considered a complete success if it did not fail by these criteria and did not require supplemental medical therapy to lower the IOP.

Qualified success

If postoperative pharmaceutical treatment was necessary to achieve adequate IOP lowering (IOP≤18 mm Hg) but no additional surgery was necessary, these cases were considered a qualified success.

To enable comparability with studies using different success definitions, success was also measured in a stricter manner.

Strict success

In addition to the aforementioned criteria, the IOP had to be reduced at least 20% compared with the preoperative IOP. Patients who met the stricter criteria are referred to as strict success.

Cataract surgery after TE

To assess the influence of cataract surgery following TE, we matched patients who underwent cataract surgery at least 6 months after TE 1:3 by sex and age to eyes who did not undergo cataract surgery during follow-up. To enable adequate comparison, the time of cataract surgery after TE was set as baseline both for the eye after cataract surgery and the matched counterparts. Only eyes that met the criteria of success at the time of this new baseline were included in this analysis.

Statistical analysis

Subjects' demographic and ocular characteristics, including age, sex, IOP, IOP lowering medication and visual acuity were described with mean and SD for approximately normally distributed continuous data, otherwise with median and IQR for continuous variables, and with absolute and relative frequencies for categorical variables.

Categorical data were compared using the χ^2 test. Continuous data of paired samples were compared by Wilcoxon signed-rank test. Log-rank test and Cox regression analysis including clustering on patient level were used to evaluate the survival probabilities of surgical success. For survival analysis, Cox proportional hazards modelling was applied and the following covariates were included: adjusted for sex, age, type of glaucoma, lens status prior to surgery, number of IOP lowering medication prior to surgery and IOP prior to surgery. Proportional hazard assumption was checked. Correlation coefficients between transformed survival time and the scaled Schoenfeld residuals were computed.

This is an explorative study and a p value of 0.05 or less was considered as statistically significant. Statistical analyses were carried out with R (V.4.0.3,[20] the packages ggplot2,[21] dplyr[22] and rstatix[23]).

Table 1 Baseline characteristics

Eyes (patients) (n)	435 (379)
Age, median (IQR), years	67.0 (62.0–75.0)
Female sex % (n)	49.3 (187)
Glaucoma type % (n)	
Primary open-angle	75.2 (327)
Pseudoexfoliative glaucoma	15.9 (69)
Normal tension glaucoma	6.7 (29)
Pigmentary glaucoma	2.3 (10)
Eye laterality, right % (n)	48.5 (211)
Pseudophakia % (n)	61.7 (253)
Preop IOP in mm Hg, mean (SD)	25.8 (9.77)
Preop IOP in mm Hg, range	10.0–50.0
Visual field (MD in dB (SD))	10.4 (6.5)
Number of medications, mean (SD)	3.11 (1.06)
Visual acuity, logMAR (SD)	0.48 (0.52)

db, decibel; IOP, intraocular pressure; MD, mean deviation.

RESULTS

Of the 452 patients initially identified, we included 435 eyes of 379 Caucasian patients with open-angle glaucoma with a mean follow-up time of 6 (SD: 0.8, IQR: 5.4–6.5, range: 3.3–7.7) years (16% loss to follow-up). The study population consisted of 187 women (49.3%) and 192 men (50.7%) with a median age of 67 years. The study group included 435 eyes: 327 eyes with primary open-angle glaucoma, 29 eyes with normal-tension glaucoma, 69 eyes with exfoliative glaucoma and 10 eyes with pigmentary glaucoma. Table 1 summarises the baseline characteristics of our study sample. Ninety-seven per cent of the eyes were receiving medical treatment before surgery, with a mean of 3.1 medications (±1.1).

Primary outcome: surgical success

According to the definition, qualified surgical success and IOP control (≥5 mm Hg and ≤18 mm Hg, without surgical complications or complete loss of vision) was achieved in 316/435 (73%) of eyes at the last available follow-up visit. Complete surgical success (no additional medical therapy to lower IOP necessary) was achieved in 301/435 (69%) of eyes, and strict surgical success (complete success+IOP reduction ≥20%) in 288/435 (66%) at the last follow-up. The reasons for failure are shown in table 2.

Based on the success proportions, Kaplan-Meier survival analysis was used to describe the surgical success in all cases. Since all failures due to IOP rise in our sample, except for one eye, had an IOP rise >18 mm Hg prior to receiving IOP lowering medication, we did not distinguish between complete and qualified success in the survival

Table 2 Reasons for failure—n (%)

Surgical complication	14 (3.2)
Bleb leak	5 (1.1)
Scleral thinning	4 (1.0)
Iris incarceration	2 (0.5)
Malignant glaucoma	2 (0.5)
Retinal detachment	1 (0.2)
Surgical revision	50 (11.5)
Flap suture	33 (7.6)
Anterior chamber revision	2 (0.5)
Open revision	8 (1.8)
Cyclodestructive surgery	6 (1.4)
Preserflo-Implantation	1 (0.2)
Needling	73 (16.8)
IOP<5 mm Hg	13 (3.0)
IOP>18 mm Hg	23 (5.3)

IOP, intraocular pressure.

rate analysis and therefore refer only to complete success. According to the Kaplan-Meier survival curve, success rates for surgical success, including both complete and qualified successes for the whole series, were 86% (95% CI 83% to 90%) at 1 year, 83% (95% CI 80% to 87%) at 2 years, 82% (95% CI 78% to 85%) at 3 years, 78% (95% CI 75% to 82%) at 4 years and 75% (95% CI 71% to 80%) at 5 years (figure 1). A Cox regression model showed no significant influence of sex, age, type of glaucoma, lens status prior to surgery, number of IOP lowering medication prior to surgery or IOP prior to surgery on the probability of surgical success. Individual Schoenfeld residuals for the model showed no pattern with time.

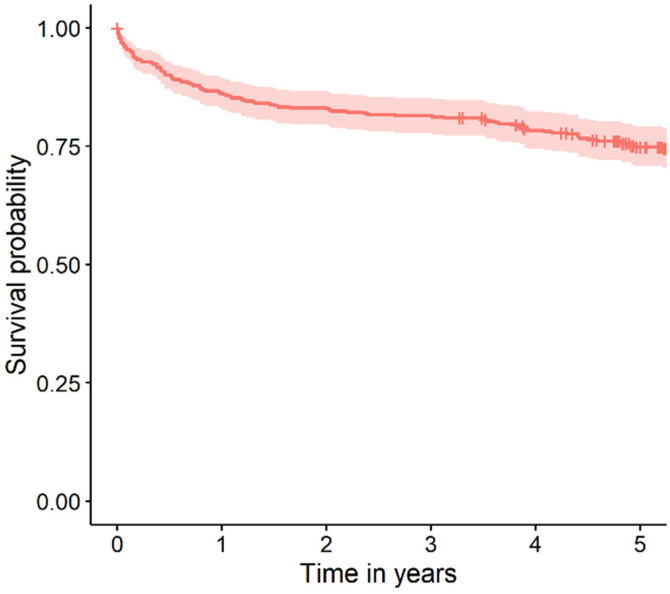

Figure 1 Kaplan-Meier survival analysis of complete success in all cases.

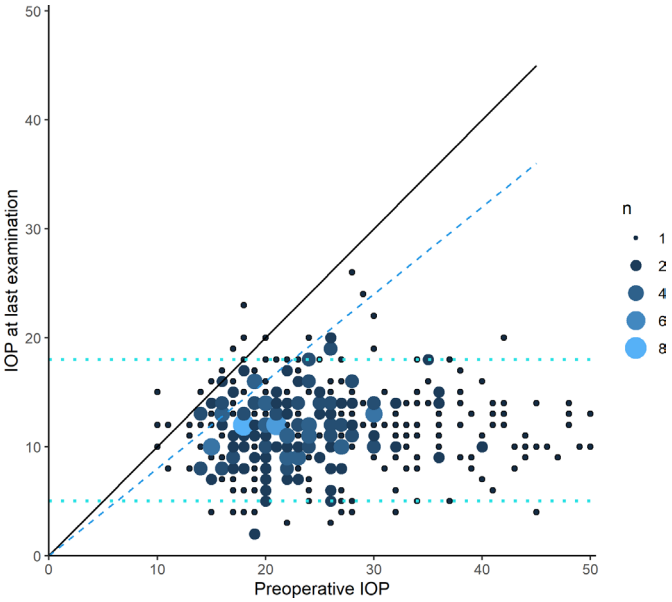

Figure 2 Scattergram showing preoperative and last postoperative intraocular pressure (IOP), illustrated by frequency; blue dashed line displays 20% IOP-reduction.

IOP development

The mean preoperative IOP was 25.80±9.77 mm Hg. The mean maximum IOP was 31.15±9.88 mm Hg. At the last examination, the IOP was significantly reduced to a mean of 12.06±4.33 mm Hg (p<0.001). An IOP reduction below preoperative levels was achieved in 91% of all eyes (figure 2).

Influence of cataract surgery after TE

A total of 53 patients underwent cataract surgery at least 6 months after TE, these were matched by sex and age with 157 patients who did not undergo cataract surgery. There was no significant difference in the survival probability between the groups (log-rank p=0.45). Figure 3 shows the survival curves of the two groups.

Visual acuity

The median preoperative best corrected visual acuity (BCVA) was 0.30 (IQR 0.70–0.10) logMAR. At the last examination, median BCVA hast not deteriorated and was still 0.30 (IQR 0.52–0.10) (p=0.99).

IOP lowering medication

Preoperatively, the mean number of topical IOP lowering medications used was 3.11±1.06 and declined to 0.07±(0.26) at the last examination (p<0.001).

DISCUSSION

In this retrospective cohort study examining 435 eyes in 379 patients, we could show that TE was completely successful in an estimated 75% of cases after 5 years. Although some studies have reported similarly high success rates,[15] others have reported considerably lower survival rates without the use of IOP-lowering medication, for example, approximately 35% after 5 years[16] or 45.8%

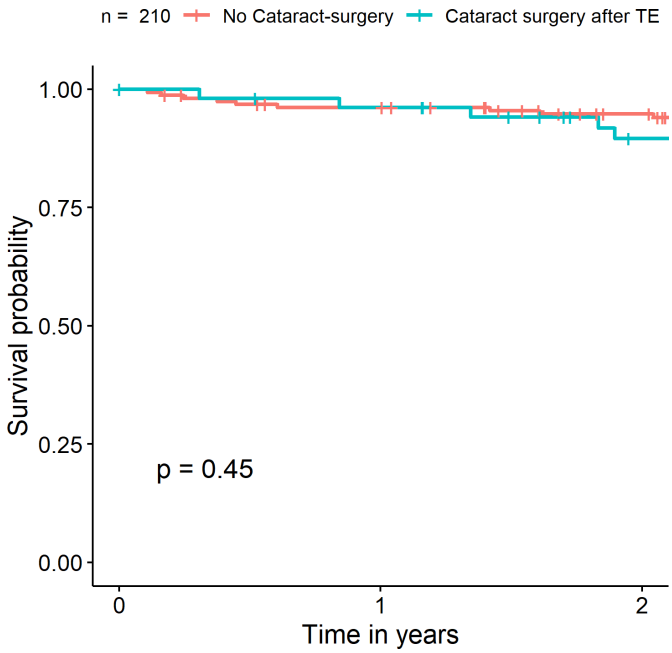

Figure 3 Comparison of Kaplan-Meier survival analysis for the matched cohort of eyes with and without cataract surgery at least 6 months after trabeculectomy (TE).

after 2 years.[24] In the latter study, surgery was performed by trainees, which may have influenced the success rates, as higher complication rates among less experienced surgeons have been reported.[25] In comparison, all trabeculectomies assessed in this cohort were performed by glaucoma specialists in the field. It must be noted, however, that most studies could not detect a decrease in postoperative success rates if trainees were adequately supervised.[25 26]

A critical aspect in comparing studies reporting success rates after TE are the different definitions of success used by various authors regarding, for example, the target IOP or what defines surgical revision.[27] We have therefore, decided to evaluate success with and without relative IOP reduction compared with preoperative values in order to enable comparability.

Several studies have reported an accelerated cataract development after filtration surgery, often necessitating cataract surgery after TE. To date, there is no scientific consensus on the potential influence of cataract surgery after TE on the outcome of the latter surgery. Husain *et al* and Arimura *et al* reported an increased risk of TE failure after cataract surgery,[28 29] while Mathew *et al* and Nguyen *et al* reported no influence of cataract surgery on success rates after TE.[30 31] Fontana *et al* even reported a decreased risk of failure after cataract surgery.[32] In our collective of eyes after TE, we could not detect a significant influence of cataract surgery performed at least 6 months after TE on success rates.

Moreover, few surgical complications occurred in this study cohort. The reported rate of hypotony (3%) is relatively low compared with values reported in other studies, ranging from 3% to 14%.[32–36] The low rate of hypotony in our cohort may be related to the use of tight scleral flap sutures (and subsequent laser suture lysis when necessary) to avoid early overfiltration with structural and functional complications.

Furthermore, there was no case of blebitis or endophthalmitis in our cohort. The reported incidence of endophthalmitis after TE ranges between 0.1% and 1.3% per year.[32 37–39] A possible explanation is the use of fornix-based watertight conjunctival sutures, which in turn may have the benefit of fewer bleb infections. The intensive rinse out of MMC intraoperatively might also contribute to a low blebitis rate in the course of follow-up.

Our study has several limitations. First, it is a single-centre study, with surgery performed by few glaucoma specialists, and may thus not be representative of TE success rates in other settings. Moreover, its retrospective nature does not allow for the determination of causal relationships. However, the results may underline the importance of centres of expertise in the treatment of glaucoma patients in order to reach safe and high-quality surgery with longstanding effectivity and thus preserving vision.

In conclusion, the results of this retrospective study with a mean follow-up time of approximately 6 years demonstrate a high and stable success rate of TE, that is not affected by later cataract surgery.

Contributors NP and EMH were responsible for the study conception and design and critically reviewed the final manuscript. FMW was responsible for data acquisition, analysis, interpretation of data, initial drafting and revising the manuscript. AKS was also responsible for the design of the study, analysis, interpretation of data and critically revised the manuscript. KK assisted with the data acquisition. JS assisted with the interpretation of the data. All the authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval According to regional laws, the requirement for informed consent was waived by the ethics committee of the medical board of Rhineland-Palatinate.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data is available from the corresponding author upon reasonable request.

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