

Primary baerveldt versus trabeculectomy study after 5 years of follow-up

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ABSTRACT.

Purpose: Although the Baerveldt glaucoma implant (BGI) initially was reserved for refractory glaucoma, its role in the surgical management of glaucoma has shifted towards a primary treatment choice. We performed a randomized prospective study to compare BGI surgery and trabeculectomy (TE) in patients without previous ocular surgery.

Methods: We included 119 glaucoma patients without previous ocular surgery. One eye of each subject was randomized to either a BGI or TE. Follow-up visits were at 1 day, 2 weeks, 6 weeks, 3 months, 6 months and 1, 2, 3, 4 and 5 years postoperatively. Primary outcomes were intraocular pressure (IOP) and failure rate. Secondary outcomes were medication, anterior chamber laser flare value and complications.

Results: After 5 years, an IOP of 12.7 ± 3.9 mmHg (mean \pm SD) was achieved in the TE group and 12.9 ± 3.9 mmHg in the BGI group. We found no statistically significant difference in failure rate between the groups ($p = 0.72$). More BGI patients needed additional medication to control their IOP (85%; 1.9 ± 1.2 types of glaucoma medication) compared to the TE patients (57%; 0.5 ± 0.9 types of glaucoma medication). Diplopia was significantly more present in the BGI group than in the TE group (27% versus 4%; $p < 0.001$). The self-limiting complication rate was similar in both groups.

Conclusions: Our study demonstrates that, in the long term, the final IOP and failure rate are similar after TE and BGI surgery. However, the need for additional medication after BGI surgery is higher than after TE. Also, the increased risk of developing diplopia after BGI surgery must be taken into consideration.

Key words: Baerveldt – glaucoma – intraocular pressure – trabeculectomy

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Introduction

Glaucoma drainage devices (GDD) have obtained an important role in the treatment of glaucoma. The Tube Versus Trabeculectomy (TVT) study

has contributed to this increased use of GDD (Gedde et al. 2012). Its long-term results demonstrated that, with a history of ocular surgery such as prior trabeculectomy (TE) or cataract

surgery, patients had a higher success rate with GDD surgery compared to TE with Mitomycin-C (MMC). Currently, however, glaucoma implants are increasingly used as a primary surgical choice when pharmacological therapy is insufficient (Bar-David & Blumenthal 2018).

In a randomized clinical trial, we compared TE and Baerveldt glaucoma implant (BGI) in patients, who never had previous ocular surgery (Islamaj et al. 2018b). Our 1-year results suggested that, overall when complications and the use of medication into account, TE had a higher success rate than the BGI. This outcome corresponds to the 1-year results of the primary TVT study (Gedde et al. 2018). In contrast with the tendency of using GDD as primary surgery, both studies favour TE as primary surgical treatment choice. Until now, however, the long-term outcome of the BGI as primary surgical treatment choice had not been investigated. Here, we report the long-term (5 years postoperative) results of the TE versus BGI study for patients without previous ocular surgery.

Methods

The study procedures have been described previously in detail (Islamaj et al. 2018b) In short, we performed a prospective, randomized study at the Rotterdam Eye hospital, the Netherlands, to evaluate two surgical procedures for the treatment of glaucoma. The study was approved by the medical ethical committee of the Erasmus Medical Center (Rotterdam) and is registered at www.trialregister.nl (identifier

NTR1142). The study protocol adhered to the tenets of the Declaration of Helsinki. We selected 119 patients at the outpatient department of glaucoma of the Rotterdam Eye Hospital, and eligibility was independently confirmed by our research team.

Inclusion criteria comprised age (18–75 years), primary open-angle glaucoma, normal-tension glaucoma (NTG), pseudo exfoliative glaucoma or pigmentary glaucoma and the need for intraocular pressure (IOP) lowering surgery. Patients with a history of any ocular surgery, such as TE, strabismus surgery or cataract extraction were excluded from the study. Other exclusion criteria were history of active uveitis or diabetic retinopathy, pregnancy or lactation, anticipated glaucoma surgery combined with other ocular procedures (i.e. cataract surgery), narrow anterior chamber angle interfering with tube implantation, best-corrected visual acuity <0.1 in the study eye or fellow eye and history of ocular motility disturbances. All patients received a full explanation of the study, and written informed consent was obtained. We assigned patients randomly to either TE with MMC or implantation of a 350 mm² BGI.

Surgical procedure

As the surgical procedures have also been described previously (Islamaj et al. 2018b), only a summary is provided here. Trabeculectomy with MMC superotemporally: the surgeon created a limbus-based conjunctival flap and applied sponges soaked with MMC (0.2 mg/ml) for 1 min to the sclera. The tissue was then rinsed with saline. A scleral flap was fashioned and a limbal block was removed (1.5 mm in diameter) from underneath the scleral flap with a Crozafon-De Laage punch (Moria, Paris, France). Following a peripheral iridotomy, the scleral flap was then sutured with 3–4 interrupted nylon 10.0 sutures. The conjunctiva and Tenon's capsule were closed with a running suture (nylon 10.0).

Baerveldt glaucoma implant (BG-101-350 mm²; Advanced Medical Optics Inc., Santa Ana, CA, USA): the BGI plate was placed in the superotemporal quadrant underneath the lateral and superior rectus muscles and sutured to the sclera. The tube was occluded with a single vicryl 7.0

suture and sized to fit in the anterior chamber of the patients. Through an incision into the anterior chamber behind the limbus, the tip of the tube was positioned at a maximal distance of the corneal endothelium, just anterior to the iris. The extraocular part of the tube was then covered with a graft of donor sclera, which was sutured to the recipient sclera with interrupted vicryl 7.0 sutures. The surgeon closed the conjunctiva and Tenon's capsule with a running suture (vicryl 7.0).

At the end of both surgical procedures, a Celestone Chronodose (betamethasone phosphate/betamethasone acetate) injection was administered in the inferior subconjunctival space and Dexamytrex (Dexamethasone/gentamycin) eye ointment was applied to the eye.

Until 3 months after the surgery, the patient's preoperative medication regimen was continued when the IOP exceeded the target pressure. In most cases, postoperative steroids (preserved prednisolone acetate 1% or unpreserved prednisolone phosphate 0.5%) were continued for 6 weeks at six times daily in the operated eye. After 6 weeks, the drops were tapered over 5 weeks. The pressure-lowering medication was adjusted so that the IOP remained below the target pressure, but without yielding hypotony (IOP <6 mmHg). Topical alpha mimetic agents were avoided as much as possible to reduce the amount of hyperaemia.

Study procedures

Study measurements were performed before surgery and 1 day, 2 and 6 weeks, 3 and 6 months and 1, 2, 3, 4 and 5 years after surgery. Each visit, slitlamp and Seidel tests were obtained. The IOP was measured with a Goldmann applanation tonometer, taking the mean of three measurements. Also, gonioscopy (Volk 4 mirror gonioscopy) and ophthalmoscopic fundus examinations were performed. Anterior chamber Laser flare was determined with a Kowa FM-600 (Kowa Company Ltd., Tokyo, Japan), i.e. by taking the mean value of five out of seven measurements, discarding the highest and lowest values. An orthoptist interviewed the patients about the presence of any diplopia and evaluated the motility of the eye (s). All postoperative complications at

both scheduled or unscheduled visits were recorded.

Failure was defined as persistent intraocular hypertension (IOP >21 mmHg), hypotony (IOP ≤ 5 mmHg) or less than 20% reduction relative to baseline IOP for at least two consecutive examinations. Reoperation for glaucoma was also defined as a failure. We applied the failure criteria from 3 months postoperative onwards, and not earlier because the BGI only starts controlling the IOP after 4–6 weeks. Failure rates were also evaluated for more restricted IOP ranges (i.e. 5–17 and 5–14 mmHg). Success was defined as 'qualified' when additional medication was needed and as 'complete' when not.

Statistical analysis

Possible differences between the two treatments were examined using the unpaired two-sided *t*-test for independent samples (age and IOP) or the Mann–Whitney *U*-test (flare count). Categorical variables were evaluated with either the chi-square or Fisher's exact test. Kaplan–Meier analysis (log-rank test) was performed to compare failure rates of the two treatment groups. Within-group comparisons were evaluated with either the paired *t*-test or the Wilcoxon signed-rank test. Analysis was performed according to intention-to-treat. All statistical calculations were done in spss version 23 (SPSS Inc., Chicago, IL, USA).

Results

Baseline

Between July 2008 and September 2014, we enrolled a total of 119 glaucoma patients, of whom 60 patients underwent TE surgery and 59 patients received a BGI. During 5 years of follow-up, eight patients received a first or additional BGI in their study eye, two patients died and four patients withdrew their informed consent (Fig. 1). Eventually, at 5 years after surgery, 105 patients (88%) remained for analysis.

At baseline, we found no statistically significant differences in patient characteristics between the two treatment groups. Additional preoperative information on the study patients was presented in an earlier publication (Islamaj et al. 2018b).

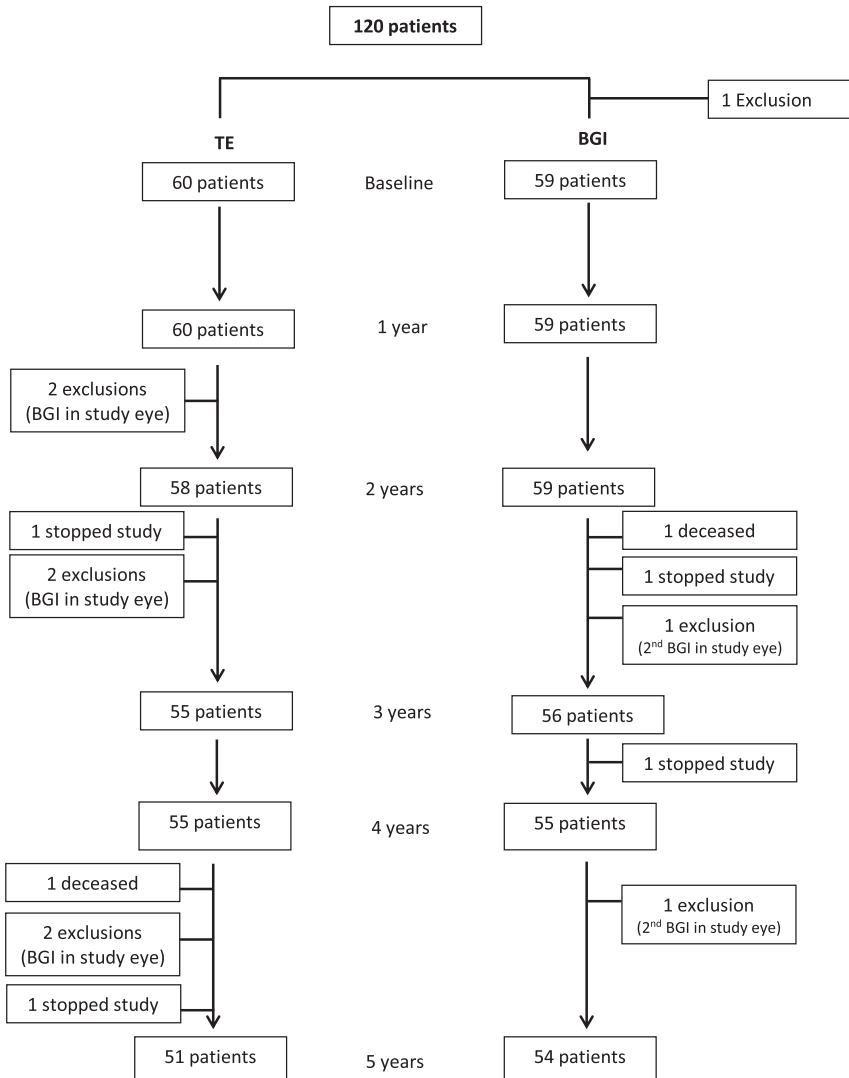


Fig. 1. Flowchart of patient progress during 5 years of follow-up.

Intraocular pressure

Five years after surgery, the two treatment groups were equally successful in lowering IOP compared to baseline ($p < 0.001$, paired t -test). In the TE group, an IOP of 12.7 ± 3.9 mmHg (mean \pm SD) was achieved and in the BGI group an IOP of 12.9 ± 3.9 mmHg. Among the TE patients, IOP decreased with 7 ± 6 mmHg (mean \pm SD) from baseline and in the BGI group with 9 ± 7 mmHg (Fig. 2). Until 6 months, a significant difference in mean IOP was noted between the TE and the BGI group ($p < 0.001$ at 2 weeks, 6 weeks, 3 and 6 months; unpaired t -test). From 1 year until 5 years postoperatively, no significant difference was found between the two treatment groups ($p = 0.63$ at 5 years postoperatively, unpaired t -test).

Pharmacological therapy

At 5 years after surgery, we observed a significant reduction in pharmacological therapy in both groups. In the TE group, medication use was reduced from 2.5 ± 0.7 (mean \pm SD) at baseline to 0.5 ± 0.9 at 5 years postoperatively ($p < 0.001$, paired t -test), while in the BGI group, medication use dropped from 2.8 ± 0.8 to 1.9 ± 1.2 ($p < 0.001$, paired t -test). Compared to the TE group, significantly more patients in the BGI group needed additional pharmacological therapy to control their IOP (Table 1), starting immediately after surgery and lasting until the end of follow-up ($p < 0.001$, Fisher exact test).

Failure

After 5 years of follow-up, failure rates were similar between the TE group (24

out of 60; 40%) and the BGI group (22 out of 59; 37%; $p = 0.72$, Log-rank test; Fig. 3). The most common reason for failure was an IOP reduction of less than 20% relative to baseline for at least two consecutive visits. With the follow-up period of 5 years, 12 study patients (10% of the total study group) required resurgery as a result of inadequate IOP control. In the TE group, three patients required a revision of their bleb (two due to a leaking bleb and one due to avascular bleb) and six patients received a BGI in their study eye. In the BGI group, two patients needed a secondary BGI in their study eye to maintain a stable IOP. Another BGI patient developed a choroidal detachment due to hypotony and was treated by placing a ligature around the drain of the BGI. Overall, resurgery due to failure did not differ significantly between the TE and BGI group ($p = 0.13$, chi-square test with Yates correction).

Hypertension (IOP > 21 mmHg) was more common in BGI patients (7%) than in the TE patients (2%).

When narrowing down the failure criterion from IOP > 21 mmHg to IOP > 17 mmHg, both study groups, again, showed equivalent failure rates ($p = 0.67$, Log-rank test). At 5 years postoperatively, 33 patients (55%) failed in the TE group and 32 patients (54%) failed in the BGI group.

With the upper limit defined as IOP > 14 mmHg, 36 TE patients (60%) did not remain below this upper limit versus 38 BGI patients (64%) ($p = 0.36$, log-rank test).

When only those patients were inspected who had not failed (failure criterion IOP > 21 mmHg) after 5 years (36 out of 60 in the TE group; 60%) (37 out of 59 in the BGI group; 63%), a similar tendency in IOP development in both groups was seen as for the total study population. Concerning their medication use, these successful TE patients hardly needed any additional medication to control their IOP until 2 years after surgery, while the medication use of the successful BGI patients was similar to that of the entire BGI group (Fig. 4).

Complete successes occurred more frequently in the TE group than in the BGI group ($p < 0.001$, Fisher Exact test). In the TE group, 31 patients (86%) were classified as complete successes and five patients (14%) as

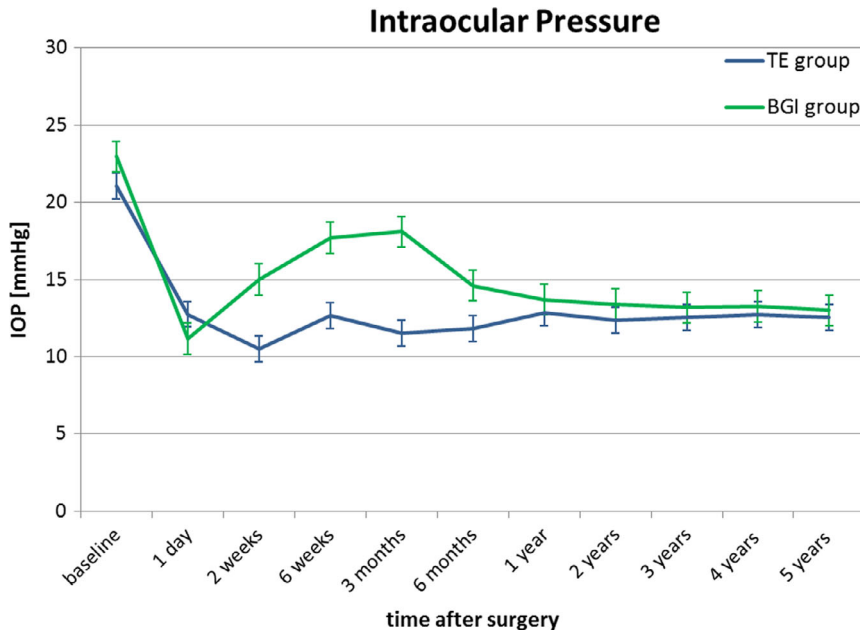


Fig. 2. Intraocular pressure at baseline and during 5 years of follow-up (mean ± SE).

Table 1. Table 1. Summary of the comparative use of types of glaucoma medication at baseline and during follow-up

Time of follow-up	Number of active substances						p Value*
	0	1	2	3	4	≥5	
Baseline							
Trabeculectomy	0	5	21	33	1	0	0.17
Baerveldt	0	3	17	31	6	2	
Day 1							
Trabeculectomy	60	0	0	0	0	0	0.006
Baerveldt	52	4	2	1	0	0	
Week 2							
Trabeculectomy	58	0	2	0	0	0	0.001
Baerveldt	43	4	7	5	0	0	
Week 6							
Trabeculectomy	57	1	1	0	0	1	<0.001
Baerveldt	32	7	11	8	1	0	
Month 3							
Trabeculectomy	55	1	0	2	1	1	<0.001
Baerveldt	23	13	16	6	1	0	
Month 6							
Trabeculectomy	51	1	3	4	0	0	<0.001
Baerveldt	10	14	24	11	0	0	
Year 1							
Trabeculectomy	51	2	1	5	1	0	<0.001
Baerveldt	15	11	21	12	0	0	
Year 2							
Trabeculectomy	47	3	2	6	0	0	<0.001
Baerveldt	17	6	24	12	0	0	
Year 3							
Trabeculectomy	40	8	3	3	0	1	<0.001
Baerveldt	11	6	26	11	0	1	
Year 4							
Trabeculectomy	38	5	8	3	1	0	<0.001
Baerveldt	14	2	20	18	0	0	
Year 5							
Trabeculectomy	36	4	7	4	0	0	<0.001
Baerveldt	13	0	22	17	2	0	

* Fisher exact test.

qualified successes. In the BGI group, on the other hand, 11 patients (30%) were labelled as complete successes and 26 patients (70%) as qualified successes.

Visual function

No statistically significant decrease in visual field was observed in the TE group (mean deviation (MD) change of -0.41 ± 2.40 dB; $p = 0.508$, Wilcoxon test). In the BGI group, this decrease was statistically significant (MD change of -1.92 ± 4.15 dB; $p = 0.008$).

The visual acuity (LogMAR) did become significantly worse at 5 years of follow-up in both groups; in the TE group with 0.16 ± 0.22 ($p = 0.008$) and in the BGI group with 0.09 ± 0.24 ($p = 0.01$).

When both study groups were compared to each other at 5 years of follow-up, no significant difference was found in MD ($p = 0.067$; Mann-Whitney test) nor in visual acuity ($p = 0.318$).

Flare count

In both treatment groups, anterior chamber laser flare values increased significantly after surgery (Fig. 5). In the TE group, flare returned to baseline value after 6 weeks (6.5 ± 3.6 photons/ms, mean ± SD). After 2 years, however, flare slightly increased until the end of follow-up (9.5 ± 5.7 photons/ms, mean ± SD). In the BGI group, flare stayed elevated until the end of 5 years of follow-up (19.1 ± 12.3 photons/ms, mean ± SD).

Complications

Table 2 lists the complications that occurred in the first postoperative year and between 1 and 5 years of follow-up. In the first year, hyphema was more often observed in TE patients than in BGI patients. Other short-term complications that occurred after TE, and not after BGI, were corneal dellen (three patients), anterior uveitis (1), hypotony (1) and ptosis (1). In the BGI group, we found some cases of dyscoria (4) and central or branch retinal vein occlusion (1), which did not occur in the TE group. Within the 5 years follow-up period, BGI patients developed significantly more cataract and dyscoria

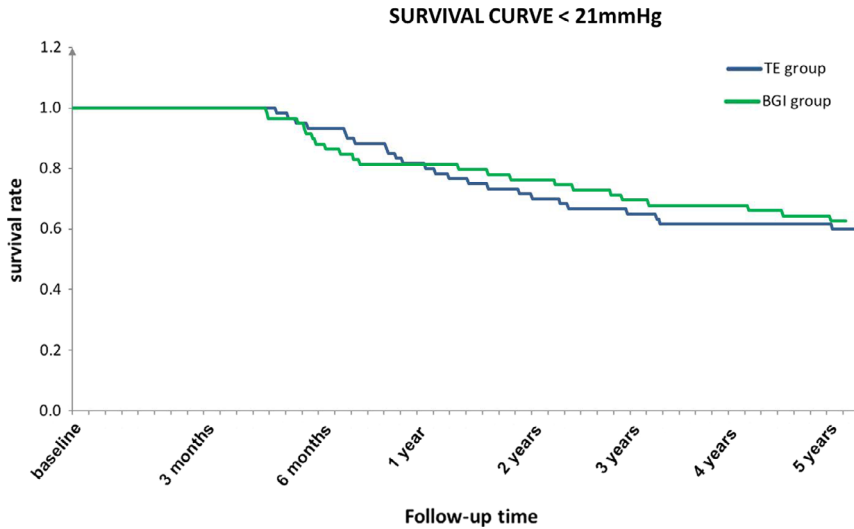


Fig. 3. Survival rates during 5 years of follow-up. Failure is defined as inadequate intraocular pressure (IOP) reduction as IOP > 21 mmHg or a reduction of less than 20% below baseline. Both criteria have to be present on two consecutive visits after 3 months to qualify as failure. Reoperation for glaucoma or persistent hypotony (IOP < 5 mmHg) are also defined as failures.

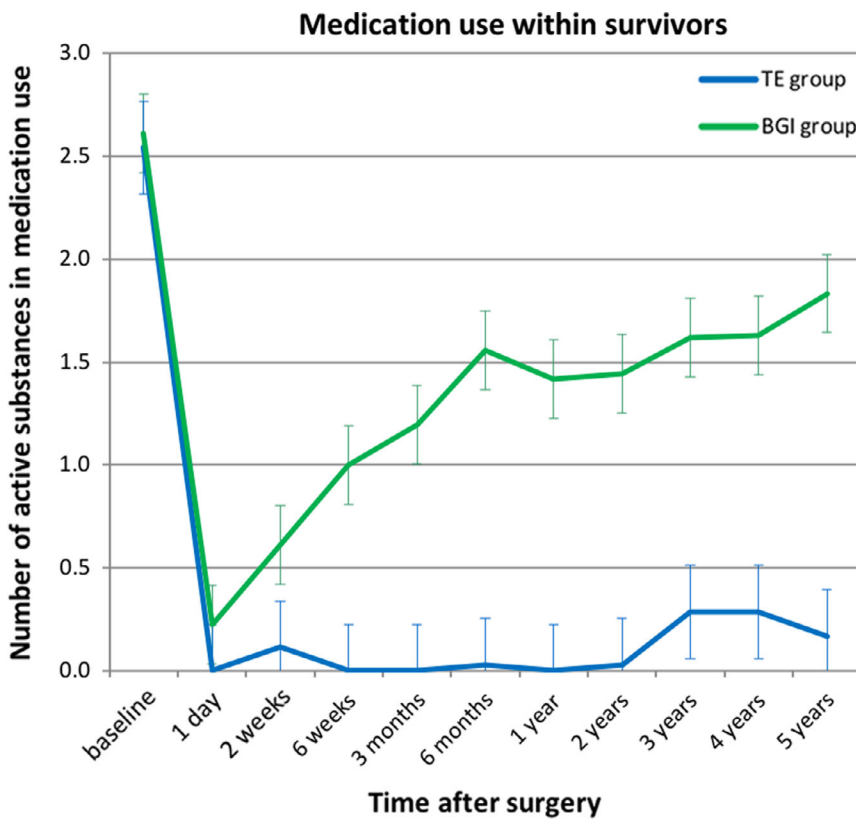


Fig. 4. Medication use of patients who did not fail within 5 years of follow-up.

than TE patients ($p < 0.001$, Fisher Exact test).

In total, 18 TE patients and 27 BGI patients received additional surgery within 5 years of follow-up (Table 3): 20 BGI patients and six TE patients underwent cataract extraction and received an intraocular lens, and one

BGI patient was vitrectomized for a macular hole, and one TE patient received a tarsomullerectomy (for insufficient tear film due to a large bleb). An aqueous leak was present in two TE groups, for which they received resurgery. No cases of blebitis were found.

Diplopia occurred significantly more often in the BGI group than in the TE group ($p < 0.001$, Fisher Exact test). Five years after surgery, 15 BGI patients (28%) reported diplopia, in four of whom diplopia complaints started after implantation of a BGI in their fellow eye. In the TE group, two patients (4%) had diplopia, one of whom already had diplopia complaints before surgery and the other developed diplopia after receiving a BGI in his/her fellow eye.

Discussion

Five years after surgery, TE and BGI surgery proved equally effective in lowering the IOP in our study population, i.e. patients without previous ocular surgery. However, BGI patients required more additional medication to maintain their IOP within therapeutically desirable limits (see below).

In general, our results appear to be in agreement with earlier reports (Wilson et al. 2003; Molteno et al. 2011; Gedde et al. 2012, 2018; Panarelli et al. 2016). At 1 year, IOP differences between the TE and glaucoma drainage device groups may or may not be statistically significant, but after that initial period, IOP differences (cf. Fig. 2) appear to become insignificant (Gedde et al. 2012, 2018; Panarelli et al. 2016). The BGI needed more time to regulate the patient's IOP, i.e. approximately 1 year. Thereafter, the IOP is well maintained by the drainage glaucoma device until the end of the follow-up period. This confirms our expectation from a previous publication that the ophthalmologist should be patient and wait until at least 1 year after surgery before considering any further surgical intervention (Islamaj et al. 2018b). An important difference between the TE and the GDD group of our study was the substantial need for medication in the latter group. This was also observed by Gedde and coworkers (in their 1-year results) (Gedde et al. 2012) and by Panarelli's team (Panarelli et al. 2016). Our study shows that the use of glaucoma medication in the BGI group steadily continued at a higher level after the initial postoperative year up to 5 years.

When comparing the failure rates of our study with the TVT study, also with a follow-up time of 5 years, differences are not statistically

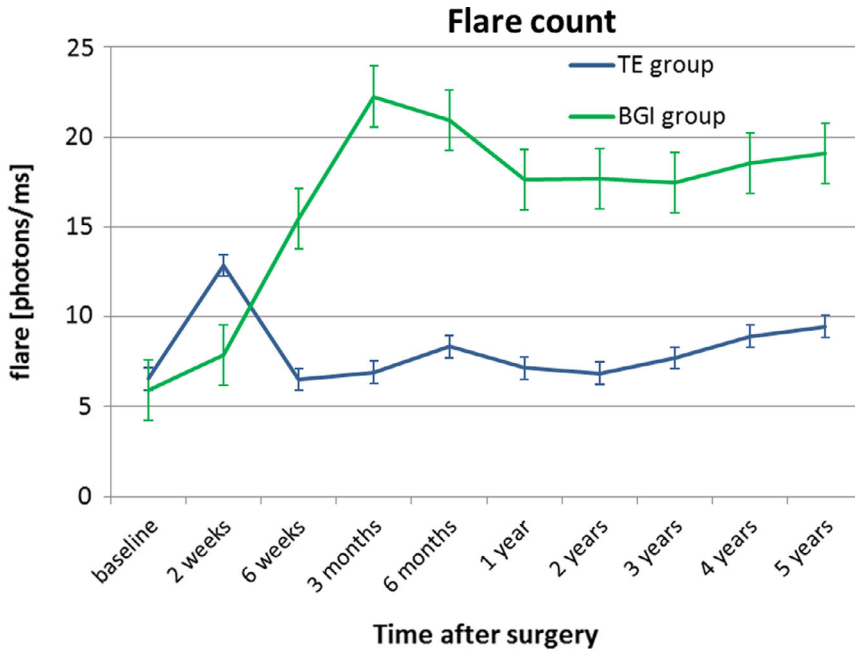


Fig. 5. Flare count (mean ± SE) at baseline and during 5 years of follow-up.

Table 2. Complications – the cumulatively observed events during any follow-up visit

	During the first year of follow-up		Between 1 and 5 years of follow-up	
	TE n = 60	BGI n = 59	TE n = 60	BGI n = 59
Number of patients without complications*	54 (91%)	49 (82%)	45 (89%)	42 (79%)
Frequency of complications†				
Hyphema	19	10	2	1
Shallow anterior chamber (<3 months)	3	4	0	0
Conjunctiva tear temporal	1	1	0	0
Sclera perforation (peroperative)	0	1	0	0
Choroidal effusion	7	7	0	3
Macula oedema	0	0	0	2
Corneal dellen	3	0	0	0
High IOP (steroid response) (<3 months)	0	2	0	0
Peripheral anterior synechiae	2	4	0	2
Synechiae posterior	0	0	0	2
Tube erosion	n/a	1	0	0
Avascular bleb	0	0	7	n/a
Filter failure (leaking bleb)	0	0	2	n/a
Punctata near bleb	0	0	1	n/a
Fibrine on lens	0	2	0	0
Cataract formation	2	5	5	18
Anterior uveitis	1	0	0	0
Hypotony	1	0	0	1
Ptosis	1	0	0	0
Dyscoria	0	4	0	18
Venous occlusion	0	1	0	1
Eye lid retraction			0	1
Intermittent or persistent diplopia‡	2	10	2	15

* Number of patients without complications at 1 and between 1 and 5 years respectively after surgery.

† Patient can have more than 1 complication. Number depends on duration of the complication and intervals between the visits.

‡ In primary and/or reading position.

BGI = Baerveldt glaucoma implant; IOP = intraocular pressure; TE = trabeculectomy.

significant. For the BGI, we recorded 37% (22/59) failures versus 33% (24/73) in the TVT study ($p = 0.28$, χ^2 -test); for TE, these figures were 40% (24/60) versus 50% (42/84) failures ($p = 0.24$).

Although statistically significant, the reduction of visual acuity after 5 years for both surgical procedures, TE and BGI, was just of marginal clinical significance. These findings do not fundamentally differ from the (non-significant) visual acuity results reported by Junoy Montolio and colleagues (Montolio et al. 2019).

Remarkably, even until 5 years after surgery, flare remained elevated in the BGI group. Presumably, the presence of foreign substances, i.e. the Baerveldt plate and silicone tube, causes a chronic low-grade inflammatory response. Another suggestion could be the higher use of medication in the BGI group. Selen et al. (2017) found a statistically significant increase in the flare values after the use of bimatoprost or latanoprost. Physicians should be aware of this, particularly because previous studies suggest that an elevated flare value could be a predictor for developing posterior synechiae, cataract or macular oedema in (uveitis) patients (Gonzales et al. 2001; Holland 2007). In our study, cataract developed three times more often after BGI surgery ($n = 23$) than after TE ($n = 7$). Also, macular oedema and posterior synechiae were more frequently observed after BGI surgery (two patients each) than after TE (none).

In the first postoperative year, slightly more short-term complications (corneal dellen, hyphema and anterior uveitis) seem to occur after TE than after BGI. Although this might be an argument for more early postoperative consultations, most of these complications were transient and resolved without further intervention. Development of diplopia was significantly higher after BGI surgery than after TE. Patients who reported diplopia within 1 year postoperatively still had complaints 4 years later. Diplopia should be considered as a severe complication because it can cause impairment of normal daily activities such as driving, reading or working (Wen Ying et al. 2011). Although it may seem obvious that the implantation of a BGI plate changes ocular alignment and/or

Table 3. (re)surgeries during follow-up

	1 year		2 years		3 years		4 years		5 years		Total (re)surgeries during 5 years of follow-up	
	TE n = 60	BGI n = 59	TE n = 58	BGI n = 59	TE n = 55	BGI n = 56	TE n = 55	BGI n = 55	TE n = 51	BGI n = 54	TE	BGI
Number of patients without additional surgery (Re)surgeries (Patients can have more than 1 surgery)	59	54	53	49	47	43	45	35	42	32		
Additional BGI*	0	0	2	0	2	1	0	0	2	1	6	2
Cataract extraction	1	5	1	5	2	2	2	5	0	3	6	20
Vitrectomy	0	0	0	0	0	1	0	0	0	1	0	2
Blepharoplasty	0	0	0	1	0	0	0	0	0	0	0	1
Revision bleb	0	0	2	0	1	0	0	0	0	0	3	0
Revision BGI	N/A	0	N/A	1†	N/A	0	N/A	0	N/A	0	N/A	1
Tarsomullerectomy	0	0	1	0	0	0	0	0	0	0	1	0
Proptosis correction	0	0	0	0	1	0	0	0	1	0	2	0
Strabismus correction	0	0	0	0	0	0	1	0	0	0	1	0
Posterior vitreous detachment with retinal defect (laser treatment)	0	0	0	0	0	1	0	0	0	0	0	1

* Patients who received an additional BGI were excluded from the total n at follow-up time.

† Choroidal detachment: a ligature was applied to the BGI.
BGI = Baerveldt glaucoma implant; TE = trabeculectomy.

restricts ocular motility, resulting in diplopia (Islamaj et al. 2018a), it is worthwhile to further investigate the cause of diplopia in more detail.

Due to the single-centre and single-surgeon (on average 125 glaucoma procedures per year) design, the surgical procedures in this study were fairly uniform. This design, however, also implies that results are dependent of the surgeon's surgical skills in the two glaucoma procedures involved. Therefore, the results of this study may not warrant extrapolation to other ophthalmologists or clinics. Also, this study may not warrant extrapolation to other patient groups.

From the point of view of clinical preference, the potential benefits and risks for TE and BGI (or any other GDD) as the primary surgical intervention for IOP reduction should be carefully weighed. Based on the findings of our study, TE seems superior to BGI: (i) IOP reduction is of sufficient magnitude and almost instantaneous, (ii) the need for adjunct medication is substantially less (this may even be the more advantageous when compliance is expected to be poor or in the presence of allergies or intolerance) and (iii) a BGI may provoke a chronic low-grade inflammatory response. Only if the patient's compliance towards visits is anticipated to be poor, a BGI seems a better option because less early post-operative consultations may be necessary.

In conclusion, primary TE shows better overall results when taking complications and the use of medication into account. Additionally, when TE fails, BGI still remains as an option. The TVT study already showed that, after a failed TE, successive BGI may lead to excellent results (Gedde et al. 2012). A TE secondary to BGI, on the other hand, is much less successful; actually, the options after failure of a BGI are limited. Hence, the position of the BGI/GDD in glaucoma surgery as primary choice (Bar-David & Blumenthal 2018) must be reconsidered.

References

Bar-David L & Blumenthal EZ (2018): Evolution of glaucoma surgery in the last 25 years. *Rambam Maimonides Med J* 9: e0024.

- Gedde SJ, Schiffman JC, Feuer WJ, Herndon LW, Brandt JD & Budenz DL (2012): Treatment outcomes in the tube versus trabeculectomy (TVT) study after five years of follow-up. *Am J Ophthalmol* **153**: 789–803.e2.
- Gedde SJ, Feuer WJ, Shi W et al. (2018): Treatment outcomes in the primary tube versus trabeculectomy study after 1 year of follow-up. *Ophthalmology* **125**: 650–663.
- Gonzales CA, Ladas JG, Davis JL, Feuer WJ & Holland GN (2001): Relationships between laser flare photometry values and complications of uveitis. *Arch Ophthalmol* **119**: 1763–1769.
- Holland G (2007): A reconsideration of anterior chamber flare and its clinical relevance for children with chronic anterior uveitis (an American Ophthalmological Society thesis). *Trans Am Ophthalmol Soc* **105**: 344–364.
- Islamaj E, Jordaen-Kuip CP, Vermeer KA, Lemij HG & de Waard PWT (2018a): Motility changes and diplopia after baerveldt glaucoma drainage device implantation or after trabeculectomy. *Transl Vis Sci Technol* **7**: 7.
- Islamaj E, Wubbels RJ & de Waard PWT (2018b): Primary Baerveldt versus trabeculectomy study after one-year follow-up. *Acta Ophthalmol* **96**: e740–e746.
- Molteno ACB, Bevin TH, Herbison P & Husni MA (2011): Long-term results of primary trabeculectomies and Molteno implants for primary open-angle glaucoma. *Arch Ophthalmol* **129**: 1444–1450.
- Montolio FGJ, Müskens RPHM & Jansonius NM (2019): Influence of glaucoma surgery on visual function: a clinical cohort study and meta-analysis. *Acta Ophthalmol* **97**: 193–199.
- Panarelli JF, Banitt MR, Gedde SJ, Shi W, Schiffman JC & Feuer WJ (2016): A retrospective comparison of primary baerveldt implantation versus trabeculectomy with mitomycin C. *Ophthalmology* **123**: 789–795.
- Selen F, Tekeli O & Yanik O (2017): Assessment of the anterior chamber flare and macular thickness in patients treated with topical antiglaucomatous drugs. *J Ocul Pharmacol Ther* **33**: 170–175.
- Wen Ying WC, Christoff A, Subramanian PS & Eggenberger ER (2011): Diplopia and quality of life. *Ophthalmology* **118**: 1481.e2.
- Wilson MR, Mendis U, Paliwal A & Haynatzka V (2003): Long-term follow-up of primary glaucoma surgery with ahmed glaucoma valve implant versus trabeculectomy. *Am J Ophthalmol* **136**: 464–470.

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