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GLAUCOMA

# Change in visual acuity 12 and 24 months after transscleral ab interno glaucoma gel stent implantation with adjunctive Mitomycin C

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## Abstract

**Purpose** To analyze changes in best-corrected visual acuity (BCVA) after implantation of the transscleral ab interno glaucoma gel stent (XEN Gel Stent; Allergan, Dublin) in patients with open-angle glaucoma.

**Methods** In a single-center, prospective, non-randomized study of 137 eyes with open-angle glaucoma which underwent implantation with XEN, 69 eyes underwent XEN implantation alone (group 1) and 68 eyes underwent XEN implantation and cataract surgery (group 2). BCVA (Bailey–Lovie chart, logMAR scale) was evaluated at baseline, postoperative day 1, weeks 1 and 2, and months 1, 3, 6, 12, and 24. Risk factors for decline in BCVA were analyzed in multivariate models.

**Results** Baseline BCVA in group 1 was 0.21 ± 031; the group's mean BCVA did not change at any postoperative visit, although a ≥ 2-line loss of BCVA was detected in 15% (95% CI 7–29%) and 4% (95% CI 0–20%) after months 12 and 24, respectively. Baseline BCVA in group 2 was 0.33 ± 031; vision increased significantly at months 3 (0.22 ± 0.29, $p = 0.015$), 6 (0.20 ± 0.26, $p = 0.006$), 12 (0.18 ± 0.29, $p = 0.001$), and 24 (0.18 ± 0.29, $p = 0.005$). A ≥ 2-line loss of BCVA was reported in 4% (95% CI 1–15%) and 7% (95% CI 1–24%) after months 12 and 24, respectively.

**Conclusions** There was no deterioration of BCVA in group 1; those in group 2 had an overall significant increase in BCVA. BCVA decrease was lower than is typically reported in the literature post-trabeculectomy.

**Keywords** XEN · Transscleral ab interno glaucoma gel stent · Best-corrected visual acuity · MIGS · Minimally invasive glaucoma surgery

## Introduction

Glaucoma is the second leading cause of irreversible visual function loss worldwide [1, 2], and medical/topical therapy to control intraocular pressure (IOP) often is the first-line treatment option for patients with open-angle glaucoma (OAG). However, even with topical medical treatment, there will be some patients in whom IOP remains uncontrolled [2–5]. These patients often require surgery to manage IOP successfully, and trabeculectomy has become the gold standard for glaucoma filtration surgery over the decades [6]. Several studies have shown subjective changes in vision after surgery, with 8.3 to 18.8% losing ≥ 2 lines of vision 3 months post-trabeculectomy [1, 7–10]. The 5-year Collaborative Bleb-Related Infection Incidence and Treatment Study found that after trabeculectomy in 649 eyes, 12.2% ($n = 79$) went blind and 0.9% ($n = 6$) lost light perception [1]. The same study found that best-corrected visual acuity (BCVA) steadily deteriorates post-trabeculectomy [1], and others have found that cataract development and vision loss are common late complications post-trabeculectomy [10, 11].

Recently, minimally invasive glaucoma surgery (MIGS) devices have been commercially introduced as another option to reduce IOP and topical medication use in a less invasive technique than traditional glaucoma filtration surgery (trabeculectomy) [12, 13]. A transscleral ab interno glaucoma

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gel stent (XEN Gel Stent; Allergan Plc., Dublin, Ireland) is but one of these MIGS devices; it bypasses aqueous humor from the anterior chamber to the subconjunctival space and creates comparable outflow paths similar to classic trabeculectomy while minimizing conjunctival trauma during the process of implantation [14, 15]. Further, conjunctival dissection and suture wound closure are unnecessary, giving this device a good safety profile [15, 16].

To date, there is little in the published literature that describes the BCVA results post-MIGS compared to traditional trabeculectomy outcomes. The purpose of this study was to determine both the incidence of visual impairment after implantation with the transscleral ab interno glaucoma gel stent (with or without combined cataract surgery) and the risk factors for visual impairment post-implantation.

## Methods

In this prospective, single-arm, single-center, longitudinal study, patients with open-angle glaucoma (OAG defined as primary OAG, pseudoexfoliation glaucoma, and pigmentary dispersion glaucoma) and insufficiently controlled IOP or intolerance to topical glaucoma therapy were treated with the transscleral ab interno glaucoma gel stent (XEN 45 μm; Allergan Plc., Dublin, Ireland) with or without combined cataract surgery. The determination to combine surgery was at the discretion of the surgeon; if the patient had clinically significant cataract, the surgeon recommended a combined procedure. The XEN device and implantation techniques had been described in detail elsewhere [14, 17].

The study and data accumulation were carried out with prospective approval from the local ethics committee. Informed consents were obtained, and the study was in adherence to the tenets of the Declaration of Helsinki.

Exclusion criteria included previous glaucoma surgery, a lack of free and mobile conjunctiva in the quadrant of implantation, congenital glaucoma, neovascular glaucoma or secondary glaucoma related to uveitis, as well as other previous intraocular surgery (except selective laser trabeculoplasty or uncomplicated phacoemulsification with intraocular lens implantation).

A total of 137 consecutive eyes (137 patients) were enrolled and were implanted with a single transscleral ab interno glaucoma gel stent with adjuvant Mitomycin C (MMC) use, as per previously published techniques [16]. To review briefly, 20 min before the MIGS device implantation, a combination of balanced salt solution and MMC was injected into the subtenon's space using a 30-gauge needle (0.05–0.1 ml, 4–8 μg MMC total). Postoperatively, the patients received preservative-free topical corticosteroids for a minimum of 6 weeks (dexamethasone, minimum three times a day) and preservative-free topical antibiotics for 1 week (ofloxacin, three times a day).

Visits were scheduled at baseline, postoperative day 1, weeks 1 and 2, and months 1, 3, 6, 12, and 24.

Manifest refraction was performed on each patient at all follow-up visits before evaluating BCVA. Subsequently, BCVA was tested during a single seating by an experienced orthoptist (6 m distance, standardized low light conditions, etc.). Patients were scored using line assignment scoring using the value of the lowest line, where at least half the letters were correctly identified deriving the patient's BCVA. Decimal BCVA was converted to logMAR as previously described by Holladay [18].

Patients were evaluated for the following at each postoperative visit: IOP, number of glaucoma medications, BCVA (and reason for decreased vision if any), and secondary surgical procedures (i.e., second IOP-lowering procedure or cataract removal/intraocular lens implantation). Patients who underwent secondary IOP-lowering surgical procedures (except needlings) were no longer assessed for BCVA, were exited from the study, and were followed as per routine clinical protocols. Patients undergoing subsequent cataract surgery were further assessed for BCVA post-cataract surgery. A clinically significant change in BCVA was defined as 0.2 units of logMAR (≥ 2 lines). If patients underwent a decrease of ≥ 2 lines, BCVA impairment was further classified as reversible or permanent (except of 24 months visit). "Reversible impairment of BCVA" was defined as a deterioration of BCVA during any postoperative visit of ≥ 2 lines (gain of at least 0.2 units of logMAR [e.g., from 0.10 to 0.30]) but an improvement at a following examination such that the patient would not fulfill the criteria of a BCVA decrease (logMAR at subsequent postoperative visit < baseline logMAR + 0.2). "Permanent impairment of BCVA" was defined as a deterioration of BCVA of ≥ 2 lines (gain of ≥ 0.2 units of logMAR [e.g., from 0.10 to 0.30]) until the final observation with no final recovery of BCVA (logMAR at every subsequent postoperative visit ≥ baseline logMAR + 0.2). Risk factors that could potentially explain a decrease in BCVA were analyzed at the month 12 and 24 visits.

Eyes were characterized into four groups as follows: (a) blind—BCVA worse than 20/400 (logMAR > 1.3); (b) low vision—BCVA ≥ 20/400 (logMAR ≤ 1.3) and < 20/60 (logMAR > 0.5); (c) intermediate vision—BCVA ≥ 20/60 (logMAR ≤ 0.5) and < 20/40 (logMAR > 0.3); and (d) high vision—BCVA ≥ 20/40 (logMAR ≤ 0.3). Risk factors for low vision or blindness were assessed at months 12 and 24.

The influence of glaucoma stage and the presence of pseudoexfoliation were assessed in subgroup analysis on the postoperative course of BCVA. Glaucoma stages were defined by the mean deviation of baseline visual field examination according to the Hodapp Classification described in the recent European Glaucoma Society Guidelines [19]: mean

deviation > − 6 dB was classified as early glaucoma, − 6 to − 12 dB as moderate glaucoma, and < − 12 dB was classified as advanced glaucoma.

### Statistical analysis

We used logistic regression analysis with odds ratios and 95% confidence intervals for odds ratios and Pearson's correlation coefficients with corresponding tests at all follow-up visits. We used Student's *t* tests with and without the assumption of variance homogeneity. We tested probabilities using Fisher's exact test. We used Pearson–Clopper confidence intervals to determine percentage of loss of BCVA ≥ 2 lines. Odds ratios with a corresponding confidence interval and test were computed for loss of BCVA ≥ 2 lines at 12 months and then compared to published results in the literature.

All reported tests were two sided, and $p$ values < 0.05 were considered as statistically significant. All statistical analyses in this report were performed by use of STATISTICA 13 (StatSoft, Tulsa, OK), Wolfram Research, Inc., Mathematica, Version 11.3, Champaign, IL (2018), and PASW 21 (IBM SPSS Statistics for Windows, Version 21.0, Armonk, NY).

## Results

There were 137 eyes (137 patients) enrolled: 69 received the transscleral ab interno glaucoma gel stent only (group 1) and 68 eyes received the transscleral ab interno glaucoma gel stent plus standard cataract operation. Patient characteristics and major postoperative efficacy outcome parameters are listed in Table 1; differences at baseline were not statistically significant with the exception of patient age and BCVA. Subjects in group 2 (who received the combined procedure) were about 10 years older than those in group 1.

### BCVA results

At baseline, no patient had BCVA of logMAR > 2.0 (< 20/800). There was a statistically significant difference at baseline between the two groups in BCVA ($p = 0.003$, see Table 1). In group 1, the mean baseline logMAR was 0.21 (95% CI 0.16–0.26): 2.9% (2/69) were blind, 11.6% (8/69) were low vision, 8.7% (6/69) were intermediate vision, and 76.8% (53/69) were high vision. In group 2, the mean baseline BCVA logMAR was 0.33 (95% CI 0.27–0.41): 2.9% (2/68) were blind, 19.1% (13/68) were low vision, 26.5% (18/68) were intermediate vision, and 51.5% (35/68) were high vision. Group 1 showed no significant change in BCVA at any postop visit ($p = 0.09$–$0.36$; Fig. 1).

Group 2 had no detectable decrease of BCVA at any postoperative period. Beginning at month 3 and continuing through month 24, there was a statistically significant increase of BCVA detected (logMAR baseline: 0.34; month 3: 0.22 [$p = 0.015$], month 6: 0.20 [$p = 0.006$], month 12: 0.18 [$p = 0.001$], month 24: 0.18 [$p = 0.005$]; Fig. 2).

In group 1, baseline BCVA was worse in advanced glaucoma subgroup (0.29 ± 0.33) compared to moderate (0.12 ± 0.13, $p = 0.042$) and early glaucoma subgroups (0.11 ± 0.15, $p = 0.015$). In group 2, baseline BCVA was also worse in advanced glaucoma subgroup (0.43 ± 0.38) compared to early glaucoma subgroup (0.20 ± 0.18, $p = 0.001$). In groups 1 and 2, the BCVA did not deteriorate over a period of 24 months compared to baseline in early, moderate, and advanced glaucoma subgroups ($p > 0.19$).

### Risk factors for vision changes

In group 1, a lower baseline BCVA was later identified as a risk factor for a decrease in BCVA postoperatively at 12 months, with an odds ratio of 1.5 (95% CI 1.3–1.99). The odds ratio is normalized with an increase of 0.1 logMAR. Further in this group, the number of IOP-lowering medications at baseline was identified as a positive risk factor for improvement in BCVA post-surgery ($p < 0.001$).

In group 2, baseline BCVA ($r = 0.71$, $p < 0.001$) and mean deviation of visual field ($r = 0.43$, $p = 0.003$) were identified as risk factors for a decrease of BCVA at month 12.

Age at time of surgery was not a risk factor influencing BCVA. At baseline, there was no difference in BCVA when quantified by age (≤ 65 years or > 65 years) in group 1 ($p = 0.57$) or group 2 ($p = 0.20$). In both the early postoperative period (postop day 1 through week 2) and then in the later postoperative period (month 1 onward), there were no differences in postoperative BCVA between younger patients (≤ 65 years) and older patients (> 65 years) when quantified by age.

### Loss of BCVA

There was a BCVA loss of ≥ 2 lines of 15% (8/51, 95% CI 7–29%) and 4% (1/26, 95% CI 1–15%) at 12 months and 4% (2/46, 95% CI 0–20%) and 7% (2/28, 95% CI 1–24%) at 24 months in groups 1 and 2, respectively. See Figs. 3 and 4.

At month 12, there were several causes of BCVA loss of ≥ 2 lines in group 1: cataract (affecting 7.4% [4/51] of the overall group) was the leading cause, followed by vitreomacular traction (affecting 3.7% [2/51] of the overall group), and by CME (affecting 2% [1/51] of the overall group). Unknown causes were responsible for BCVA loss of ≥ 2 lines in 1.9% [1/51] of group 1. At month 24, cataract formation was the cause for all patients with BCVA loss of ≥ 2 lines in group 1. At month 24, expulsive bleeding and visual field progression (each affecting 3.5% [1/28] of patients) were the causes for patients with BCVA loss of ≥ 2 lines in group 2.

**Table 1** Patient population

| | Group 1 (MIGS device only) | Group 2 (combined procedure) | *p* value |
|---|---|---|---|
| *N* | 69 | 68 | |
| Right eye (%) | 34 (47%) | 38 (53%) | 0.50 |
| Left eye (%) | 35 (54%) | 30 (46%) | 0.50 |
| Female (%) | 34 (49%) | 36 (51%) | 0.73 |
| Male (%) | 35 (52%) | 32 (48%) | 0.73 |
| Primary open angle (%) | 40 (58%) | 45 (66%) | 0.22 |
| Pseudoexfoliation (%) | 27 (39%) | 23 (34%) | 0.59 |
| Pigmentary (%) | 2 (3%) | 0 (0%) | 0.50 |
| Age (mean ± SD) | 65.8 (13.9) | 75.2 (7.0) | < 0.001 |
| Baseline BCVA logMAR (Snellen's equivalent) | 0.21 (20/32) | 0.33 (20/43) | 0.003 |
| Central corneal thickness (mean ± SD) | 540 (33) | 534 (40) | 0.38 |
| Baseline IOP (mean ± SD) | 22.5 (6.5) | 23.4 (6.3) | 0.39 |
| Baseline medication (mean ± SD) | 3.0 (0.9) | 2.9 (1.0) | 0.43 |
| Baseline visual field mean deviation (mean ± SD) | − 10.2 (8.1) | − 11.9 (8.5) | 0.25 |
| M12 IOP (mean ± SD) | 14.6 (5.5) | 14 (4.7) | 0.53 |
| M12 medication (mean ± SD) | 1.02 (1.21) | 0.93 (1.75) | 0.76 |
| M24 IOP (mean ± SD) | 13.0 (5.15) | 12.7 (6.88) | 0.85 |
| M24 medication (mean ± SD) | 0.76 (0.91) | 1.4 (1.28) | 0.06 |
| Secondary procedures exkl. cat. operations within 24 months (%) | 5 (7%) | 0 (0%) | 0.058 |
| Secondary cat. operations within 24 months(%) | 10 (15%) | 0 (0%) | n/a |

IOP, intraocular pressure; SD, standard deviation

Figure 4 shows the proportion of patients having a loss of BCVA ≥ 2 lines after ab interno glaucoma gel stent implantation combined with cataract operation at follow-up visits. Of those with a loss of BCVA ≥ 2 lines (overall comprising 2% [1/46] of group 2), half of the patients had expulsive bleeding and half reported dry eye syndrome.

## Blindness and low vision

No patient had a loss of light perception acuity postoperatively. At baseline, however, two patients had been classified as blind in group 1, with vision between 20/400 and 20/800. These two patients were subsequently classified as low vision postoperatively. The proportion of blindness and low vision can be seen in Fig. 5. The majority of patients has a high or intermediate vision at months 12 and 24 in both groups.

## Risk factors for blindness and low vision

No risk factors were identified for "blindness" at months 12 or 24 in group 1. A history of past cataract operation ($p = 0.012$) and baseline BCVA ($p < 0.001$) were risk factors for "low vision" at month 12 in group 1. Of those in group 1, 30% (21/69) were pseudophakic at baseline. The risk for low vision

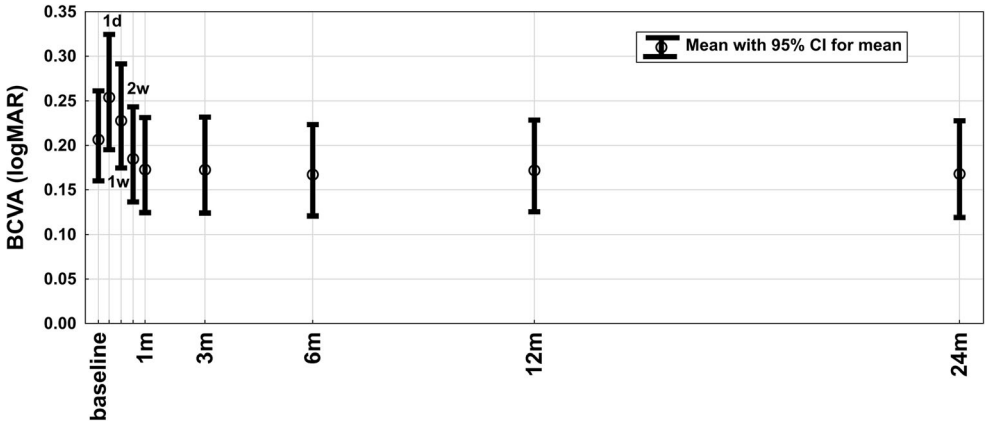


**Fig. 1** LogMAR from baseline to 24 months in transscleral ab interno glaucoma gel stent only group

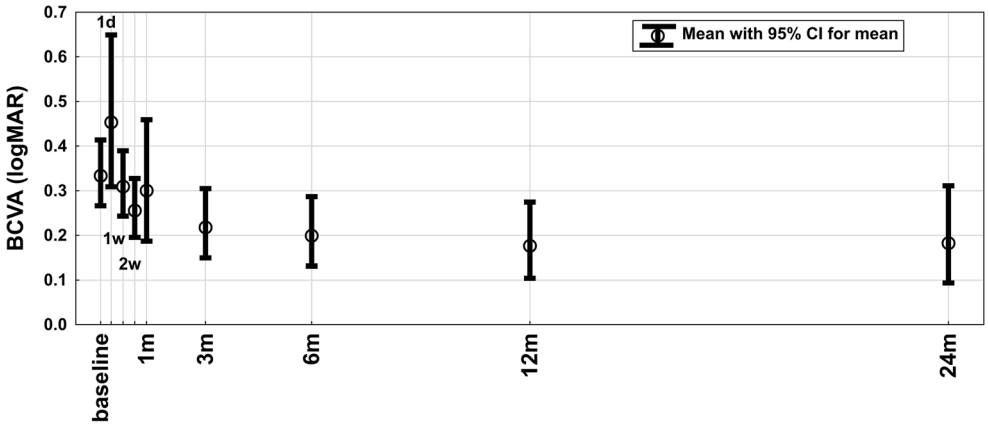


**Fig. 2** LogMAR from baseline to 24 months in transscleral ab interno glaucoma gel stent and cataract surgery group

in pseudophakic patients in group 1 was 31% at 12 months; for the remaining patients in group 1, the risk for low vision at 12 months was 2.6% (odds ratio 16.4 [95% CI 1.6–166]). The risk of having low vision at 12 months is associated with a lower preoperative BCVA with an odds ratio of 1.5 (95% CI 1.3–1.99) whereby the odds ratio refers to an increase of 0.1 units (i.e., loss of 1 line) of BCVA. There were no risk factors identified in group 1 for low vision at month 24.

We could not identify any risk factors for blindness in group 2 at either month 12 or month 24. However, the mean deviation in the baseline visual field examination was identified as a risk factor for low vision at 12 months ($p = 0.036$). Patients with severe visual field defects were at a higher risk for low vision (odds ratio 0.86, 95% CI 0.76–0.99). We were unable to identify any risk factors for low vision in group 2 at month 24.

### Pseudoexfoliation

The presence of pseudoexfoliation was not found to be a significant risk factor for a different BCVA at all visits (generalized estimation equation model, $p = 0.41$, Fig. 6). Additionally, pseudoexfoliation was also not found to be significant in any of the BCVA interaction terms in which pseudoexfoliation was involved, e.g., pseudoexfoliation ∗ type of surgery ($p = 0.27$), pseudoexfoliation ∗ time ($p = 0.55$), pseudoexfoliation ∗ type of surgery ∗ time ($p = 0.52$).

## Discussion

This study showed that there was little effect on BCVA with the implantation of an ab interno glaucoma gel stent independently of glaucoma stage. In this study, 78 and 85% of patients in group 1 and 78 and 71% of patients in group 2 were considered to have "high vision" (BCVA of ≥ 20/40 or logMAR ≤ 0.3) at months 12 and 24, respectively. In this study, 90 and 85% of patients in group 1 and 87 and 89% of patients in group 2 were considered to have "intermediate vision" or "high vision" (BCVA of ≥ 20/60 or logMAR ≤ 0.5) at months 12 and 24, respectively. Patients in these two categories are able to maintain their independence (e.g.,

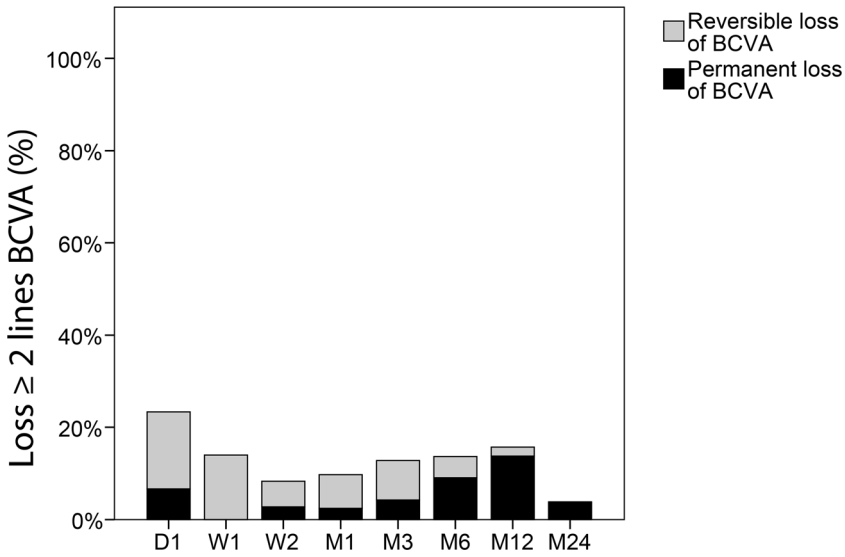


**Fig. 3** Loss of best-corrected visual acuity ≥ 2 lines in transscleral ab interno glaucoma gel stent only group. Overview of proportions of patients with reversible loss (gray shaded) of best-corrected visual acuity (BCVA) and permanent loss (black shaded) after transscleral ab interno glaucoma gel stent implantation within 2 years after surgery. Total loss of BCVA ≥ 2 is the sum of reversible and permanent loss of BCVA

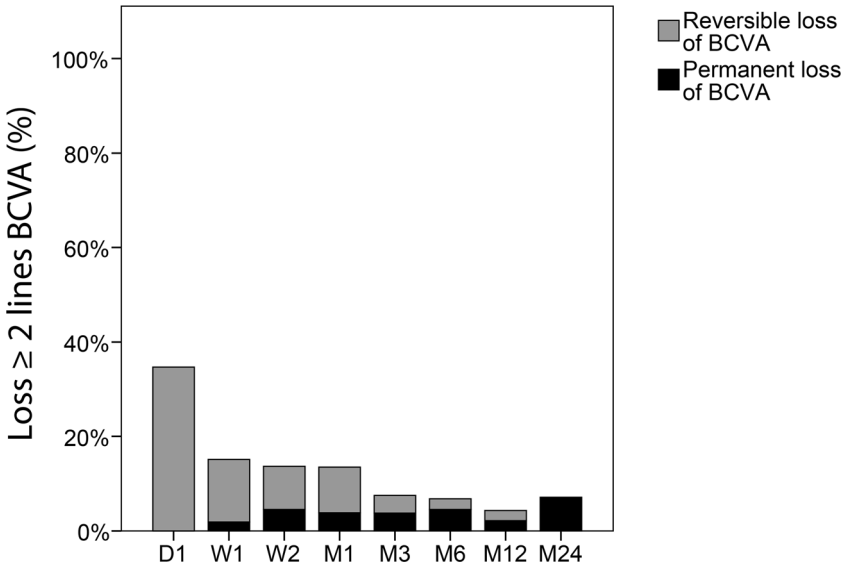


**Fig. 4** Loss of best-corrected visual acuity ≥ 2 lines in transscleral ab interno glaucoma gel stent and cataract surgery group. Overview of proportions of patients with reversible loss (gray shaded) of best-corrected visual acuity (BCVA) and permanent loss (black shaded) after transscleral ab interno glaucoma gel stent implantation combined with cataract operation within 2 years after surgery. Total loss of BCVA ≥ 2 is the sum of reversible and permanent loss of BCVA

driving, reading). In this study, the percentage of patients who had a decline in vision post-surgery was less than it is reported in the literature post-trabeculectomy. We here have to point out that comparing to trabeculectomy literature is not easy. Although in a huge number of studies it was shown that some patients undergoing MMC trabeculectomy experience vision deterioration, the occurrence of changes in visual function after trabeculectomy has not been reported consistent in previous studies. Reasons for variability of results are differences in the surgical technique, disease stage of the studied population, preoperative visual function requirements, and definitions of visual impairment amongst these studies. Edmunds et al. [10] who reported a rate of 18.8% with a significant decrease of BCVA 12 months after trabeculectomy highlighted the impact of trabeculectomy on visual acuity in the first year following trabeculectomy; our data showed a stable BCVA after stent implantation (both studies included open-angle glaucoma eyes undergoing first-time filtering glaucoma surgery).

We believe that this study adds to the growing body of literature that finds these MIGS procedures efficacious and safe [12, 13, 20, 21].

In trabeculectomy, factors including surgical technique and ocular comorbidities can cause a decrease of vision in up to 34% of patients over the long term [10, 11, 22]; e.g., Kashiwagi et al., who investigated a mixed cohort including patients with history of filtering glaucoma surgery, reported that 8.1% of patients with OAG went blind post-trabeculectomy [1]. In another prospective study with a long follow-up period including patients for primary trabeculectomy, Bevin et al. reported a decline of visual acuity at the final follow-up in 32% (mean follow-up was 7.5 years) [23]. Post-surgery both the transscleral ab interno glaucoma gel stent and trabeculectomy will create a bleb. However, bleb appearance after this MIGS device has been reported to differ from that of traditional trabeculectomy [24].

In this study, 4% of patients in group 1 and 7% of patients in group 2 lost ≥ 2 lines of vision at 24 months. Although patients in group 1 did not gain a significant amount of vision post-implantation, those in group 2 did, an expected outcome given the cataract removal. In our study, some patients in group 1 also improved from blind at baseline to at least low vision during the postoperative period.

When we look at our results compared to published literature on trabeculectomy, we find several differences. In our study, there was no deterioration of BCVA in group 1 from baseline to week 2 and there was no significant difference detected at any follow-up visit. Kobayashi et al. reported "a significant decrease" in logMAR at 2 weeks in their post-trabeculectomy group [22], and Kashiwagi et al. reported the mean BCVA "significantly and steadily deteriorated" post-trabeculectomy [1]. Although a comparison of these studies to ours may be difficult due to differences in study population baseline characteristics, overall age of the study populations, and MIGS device used, an early visual recovery seems to be more likely after transscleral ab interno gel stent compared to trabeculectomy literature.

Those findings seem to continue through longer-term follow-up (> 3 months) as well. Patients in this study showed a stable BCVA during the late postoperative phase. In our study, we found a BCVA of 0.17 ± 0.26 in group 1 at 2 years, which did not change significantly from baseline (0.21 ± 31, $p$ = 0.32). This suggests a favorable long-term BCVA course after a transscleral ab interno gel stent.

There are several potential causes for the loss of vision between weeks 2 and month 12 in group 1. Some patients developed a visually significant cataract, which may or may not be directly attributable to the surgery or to the corticosteroid drops used in each eye in the postoperative phase. Our

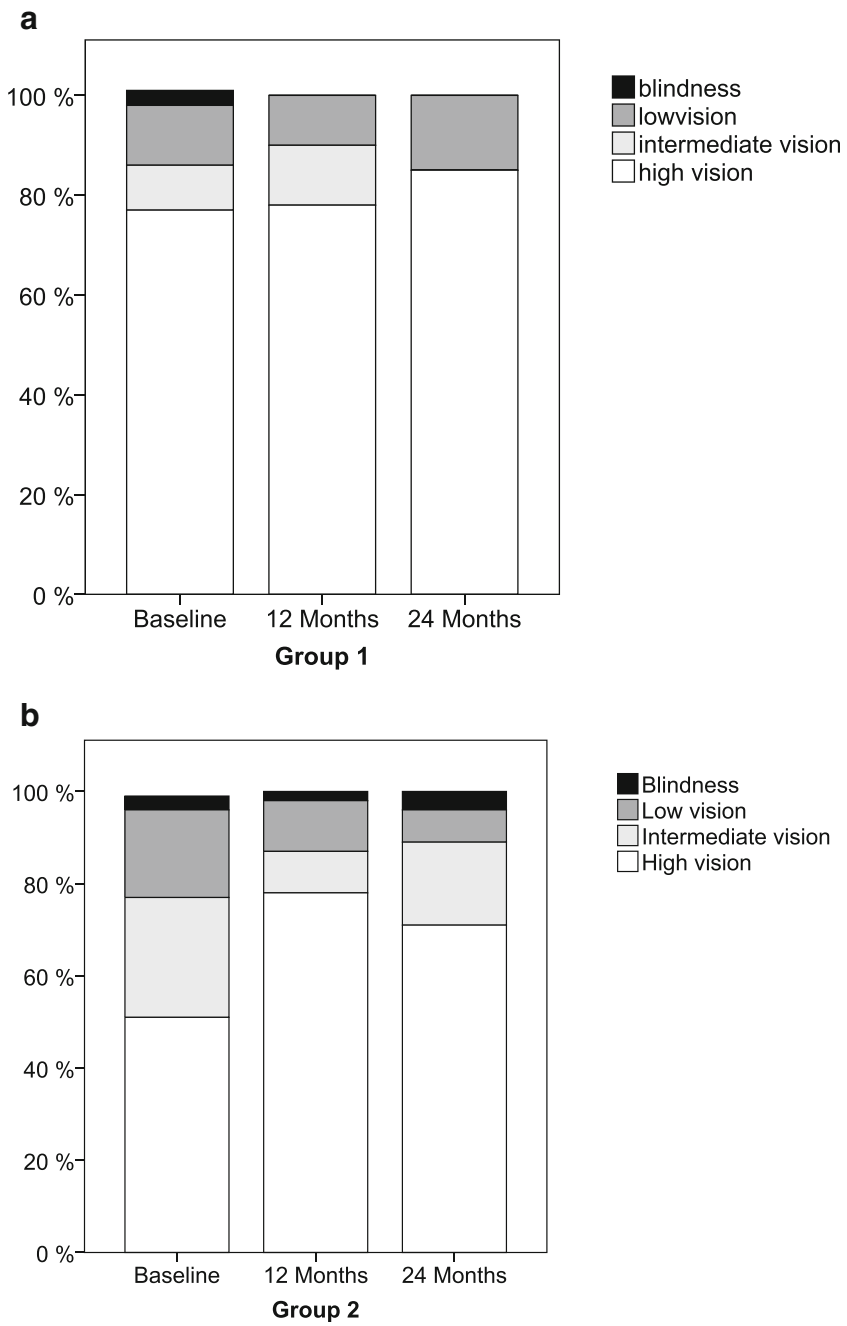


**Fig. 5** Proportion of blindness and low vision after transscleral ab interno glaucoma gel stent implantation without (group 1) or with (group 2) combined cataract operation. Panels **a** (top) and **b** (bottom): bar graphic shows the proportion of high vision, intermediate vision, low vision, and blindness at baseline, month 12, and month 24

study found that after 2 years, 4% of patients in group 1 and 7% of patients in group 2 had a ≥ 2 line loss of BCVA after implantation with the transscleral ab interno glaucoma gel stent, while the literature notes a much higher long-term risk (8–34%) of decreasing BCVA post-trabeculectomy [9, 25]. Cataract formation after traditional filtration surgery also has been reported [10, 11, 22]. Others also have reported decreases of ≥ 2 lines of BCVA after the transscleral ab interno gel stent in uveitic glaucoma and, also, attributed that vision loss to cataract formation [26].

In our study, the overwhelming majority of patients in group 2 maintained or improved vision at 12 months (96%) and at 24 months (93%). The effect of disease stage on visual acuity course after stent implantation is not yet clear. Although in the subgroup analysis of glaucoma stages, no deterioration in all glaucoma stages—respectively, advanced glaucoma stage—has been longitudinally detected, we found baseline visual field defects to be a primary cause and risk factor of decreased BCVA in the combined group. Further prospective investigations on visual acuity with special consideration of advanced glaucomas are suggested.

In both groups, the presence of pseudoexfoliation was not found to be significant in any of the BCVA interaction terms, suggesting that the visual outcome after ab interno

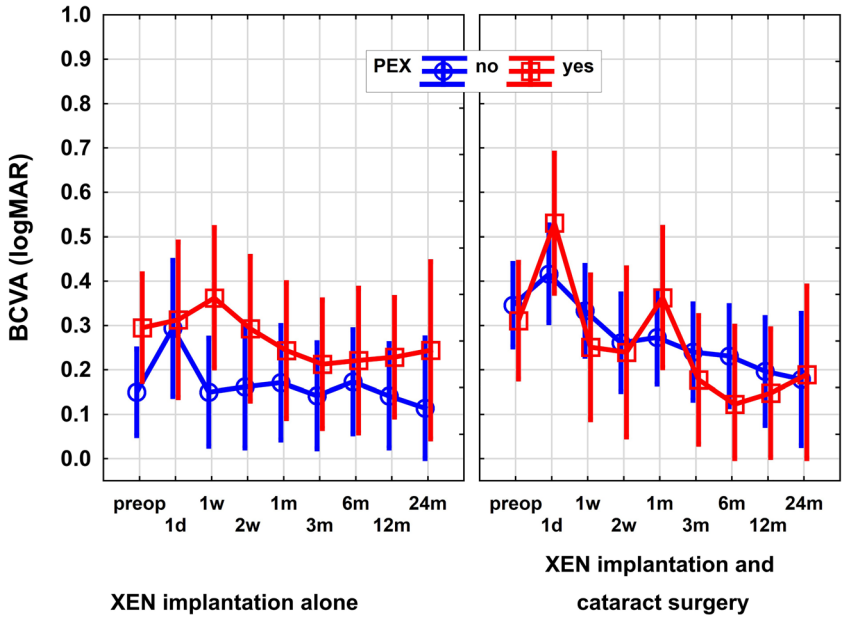


**Fig. 6** LogMAR from baseline to 24 months in transscleral ab interno glaucoma gel stent with and without combined cataract surgery stratified by the presence or absence of pseudoexfoliation. The presence of pseudoexfoliation was not found to be a significant risk factor for a different best-corrected visual acuity at all visits (generalized estimation equation model, $p = 0.41$). Error bars indicate the 95% confidence intervals

glaucoma gel stent implantation is not influenced by the absence or presence of pseudoexfoliation.

There are some limitations to this study, including our inability to compare outcomes between our two groups. At baseline, both the age and the lens status between our two groups were substantially different, and those who put into the combined group had a much lower BCVA due to cataracts. The decision to perform solo or combined procedures is at the discretion of the surgeon and patients, eliminating our ability to randomize patients. As this MIGS device is implanted into a different anatomic location (subconjunctiva) than other MIGS devices, it is unrealistic to compare our BCVA outcomes to those of other devices. However, a meta-analysis of published data on all MIGS devices (encompassing 2928 eyes) found no decrease in BCVA postoperatively [27], which our findings also support. Further, we did not exclude patients after secondary cataract operation, since this more likely reflects clinical observations. This has to be kept in mind when interpreting results.

There are an equal number of strengths to our study, however. We included consecutive patients from our clinic, which meant a wide range of baseline BCVA, including some who had low vision or were blind. We also included only one eye per patient. Our inclusion criteria better reflects what glaucoma specialists are realistically treating and reflects the postoperative burden of a secondary cataract operation in some patients.

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## Compliance with ethical standards

Referring to the Instructions for Authors of this journal, the manuscript complies with the Ethical Rules applicable for this journal.

**Conflict of interest** HR and ML received financial support from Allergan Plc as consultants. None of the other authors report that they have any conflicts of interest.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (Ethikkommission für das Bundesland Salzburg, Nr. 1702) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual participants included in the study.



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