ARTICLE

Long-term effectiveness and safety of trabecular microbypass stent implantation with cataract surgery in patients with glaucoma or ocular hypertension: Five-year outcomes

Tobias H. Neuhann, MD, Dana M. Hornbeak, MD, MPH, Raphael T. Neuhann, MD, Jane Ellen Giamporcaro, MS

Purpose: To assess 5-year outcomes after implantation of 1 trabecular microbypass stent during cataract surgery in eyes with open-angle glaucoma (OAG) or ocular hypertension.

Setting: Private ophthalmology clinic (AaM Augenklinik am Marienplatz, Munich, Germany).

Design: Prospective nonrandomized consecutive case series.

Methods: One trabecular microbypass stent was implanted after phacoemulsification cataract surgery by one surgeon over 4 years. Evaluations included intraocular pressure (IOP), medications, corrected distance visual acuity, cup-to-disc ratio, complications, and adverse events.

Results: This case series included 65 eyes of 43 patients with OAG (including primary, n = 39; pseudoexfoliative, n = 14; secondary uveitic, n = 1; posttraumatic, n = 1) or ocular hypertension (n = 10). Thirty-eight percent of eyes had previous trabeculectomy and/or glaucoma laser procedures, and 68% were on 2 or more preoperative medications. Twenty-six eyes completed follow-up through 5 years, and follow-up is ongoing. Among eyes without additional glaucoma surgery, the mean year 5 IOP decreased by 38% to 14.7 mm Hg ± 3.0 (SD) versus 23.7 ± 7.4 mm Hg preoperatively; 92% of eyes had a mean year 5 IOP of 18 mm Hg or lower and 65% had an IOP of 15 mm Hg or lower. Medications were reduced by 75% to 0.5 ± 0.9 medications versus 2.0 ± 1.0 preoperatively, with 4% of eyes on 3 to 4 medications versus 28% preoperatively, and 69% medication-free versus 5% preoperatively. The mean IOP at all postoperative visits was 16.0 mm Hg or lower and the mean medication number was 0.5 or less. Safety was favorable throughout the follow-up.

Conclusions: In a real-life cohort of eyes with OAG or ocular hypertension, substantial, durable, and safe IOP and medication reductions were achieved through 5 years after trabecular microbypass stent implantation with cataract surgery.

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Glaucoma is the leading cause of irreversible blindness worldwide, and its prevalence will continue to increase as the population ages.[1] At present, the glaucoma surgeon's armamentarium might include medical treatment, laser procedures, and/or incisional glaucoma surgery. In most cases, topical medications are the initial intervention for patients in the early stages of open-angle glaucoma (OAG).[2] Medications have an overall favorable safety profile and moderate success in lowering intraocular pressure (IOP), but they rely on a high level of adherence, which is widely known to be low[3]; moreover, their use might be limited by side effects, toxicities, cost, and/or difficulty with instillation.[3,4] As an alternative initial therapy in selected patients, or as an option for patients in whom medication use is inappropriate (because of any or a number of the aforementioned issues), laser trabeculoplasty (either argon laser trabeculoplasty [ALT] or selective laser

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From the AaM Augenklinik am Marienplatz (T. Neuhann, R. Neuhann), Munich, Germany; Glaukos Corp. (Hornbeak, Giamporcaro), San Clemente, California, USA.

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Corresponding author: Tobias H. Neuhann, MD, Medical Director, AaM Augenklinik am Marienplatz, Marienplatz 18/19, Munich 80331, Germany. Email: tneuhann@web.de.

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trabeculoplasty [SLT]) might be employed. However, several studies[5–7] have documented that the beneficial effects of ALT and SLT could wane over time.

For patients with more advanced and/or recalcitrant glaucoma, the most frequent incisional procedures traditionally have been filtering surgeries such as tube shunt implantation or trabeculectomy. However, the lifelong possibility of complications after such surgeries, such as endophthalmitis, hypotony, bleb infections, bleb leaks, or fibrosis,[8–10] remains a very real concern for patients and physicians. The cumulative risk of many complications accumulates over time, making the long-term safety profile increasingly relevant in light of rising life expectancies and glaucoma prevalence worldwide.[1]

Over the past decade, the glaucoma treatment landscape has benefited from the introduction of microinvasive glaucoma surgery procedures. These procedures typically produce more modest IOP and medication reductions than traditional filtering surgeries, but they have lower rates of serious complications; thus, they are usually considered to be most suitable for patients with mild-to-moderate disease.[2,11] The iStent trabecular microbypass stent (the first approved microinvasive glaucoma surgery device) and the second-generation iStent *inject* trabecular microbypass stent (both Glaukos Corp.) are microscale trabecular stents that are implanted ab internally either with or without cataract surgery. A significant body of evidence[12–19] has shown meaningful IOP and medication reductions after implantation of one or multiple iStent devices in mild-to-moderate OAG, with an excellent safety profile. Similarly, numerous studies have demonstrated the clinical utility and safety of iStent *inject* when implanted either with[20] or without[21–24] cataract surgery.

Although the aforementioned studies primarily address mild-to-moderate OAG, several recent studies have begun to examine iStent or iStent *inject* in more advanced OAG[25–27] and in pseudoexfoliation glaucoma (PXG).[28] For example, Ferguson et al.[26] reported 22% IOP reduction, 28% medication reduction, and avoidance of secondary glaucoma surgery in 93% of eyes with severe primary open-angle glaucoma (POAG) through 2 years after iStent implantation with cataract surgery. These investigators also published 2-year outcomes of iStent implantation with cataract surgery in 115 eyes with mild to severe PXG, constituting the largest cohort to date of trabecular microbypass performance in PXG patients.[28] At 2 years postoperatively, the study showed a 27% IOP reduction, 50% medication reduction, and favorable safety parameters, including avoidance of secondary glaucoma surgery in all but 1 eye.

Adding to this body of research, the present report provides long-term data after single iStent implantation with cataract surgery in a heterogeneous glaucoma population within a real-life clinical setting. The study's 5-year outcomes are some of the longest of any publication in the literature to date. The previous report from this cohort showed substantial 3-year reductions in mean IOP (14.9 mm Hg at 3 years versus 23.4 mm Hg preoperatively) and medication burden (0.3 medications at 3 years versus 1.9 preoperatively), together with favorable safety.[29] The present report continues to track these outcomes through 5 years postoperatively. Importantly, the cohort includes eyes with various etiologies of glaucoma (notably including POAG and PXG), as well as ocular hypertension, a moderate-to-high preoperative medication burden, and a relatively high prevalence of previous incisional or laser glaucoma surgery. Furthermore, the extended follow-up allows for long-term comparisons with therapies such as laser trabeculoplasty that are known to wane in effectiveness over time.

PATIENTS AND METHODS

Study Design

This was a prospective nonrandomized consecutive case series of surgeries completed by a single surgeon (T.N.) over a 4-year period at a private ophthalmology clinic in Munich, Germany. Qualified patients were required to have OAG (including POAG, PXG, secondary uveitic, or posttraumatic glaucoma) or ocular hypertension, and to be eligible for trabecular microbypass stent implantation and cataract surgery. Patients were included regardless of whether they had undergone previous glaucoma surgery, and regardless of the number of preoperative medications they were using. Patients were excluded if they were inappropriate candidates for trabecular microbypass stent–cataract surgery, such as if they had active intraocular inflammation, corneal opacities preventing gonioscopic view, or angle closure. All visits were conducted according to the tenets of the Declaration of Helsinki and the ethical standards of the responsible committee on human research; informed consent was completed for all patients.

Trabecular Microbypass Stent and Surgical Technique

iStent implantation was completed after standard phacoemulsification and intraocular lens (IOL) implantation through a single temporal limbal incision. Previous publications, including the former report from this study, have described the iStent and iStent implantation technique in detail.[12,29] Briefly, this L-shaped, single-piece, heparin-coated, titanium stent has a 0.33 mm height, 1.00 mm length, and 0.25 mm snorkel length; it is preloaded into a single-use stainless steel inserter that facilitates precise ab interno stent implantation into the Schlemm canal (Figure 1). The stent is designed to decrease IOP by increasing trabecular outflow from the anterior chamber (where the snorkel resides) to the Schlemm canal (where the stent body resides).

Postoperative Medication and Follow-Up

The complete postoperative medication and examination regimen was described in the previous report.[29] During follow-up, a patient's preoperative topical ocular hypotensive medication was

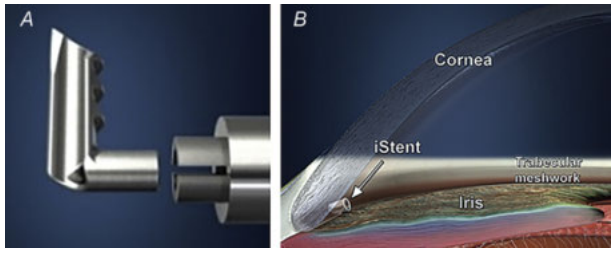


Figure 1. *A*: Trabecular microbypass stent (iStent, Glaukos Corp). *B*: Implantation location.

resumed if IOP remained at 25 mm Hg or higher after 1 month postoperatively. If the IOP still remained at 25 mm Hg or higher after restarting a patient's previous regimen, further medication was added on a case-by-case basis according to patients' tolerance and/or medical contraindications. Throughout follow-up, if a patient's clinical examination and/or adjunctive testing suggested disease progression, the IOP target was reduced to 15 mm Hg or lower. Patients completed follow-up examinations at 1 day, 7 days, and 1, 3, 6, 12, 24, 36, 48, and 60 months postoperatively. Examinations included IOP, number of ocular hypotensive medications, cup-to-disc ratio, corrected distance visual acuity (CDVA), complications, and adverse events. Specific visual field parameters were not part of the inclusion or efficacy criteria, and complete preoperative and postoperative visual field data were not available for all patients in the study.

Data Analyses

Effectiveness and safety parameters were analyzed for all available eyes at each visit, both for the consistent cohort and for the POAG and PXG subgroups. Efficacy analyses included mean IOP and number of medications over time, proportional analyses of eyes with IOP of 18 mm Hg or lower and 15 mm Hg or lower, and proportional analysis of medication use for all patients who did not undergo additional glaucoma surgery during follow-up. For eyes undergoing secondary surgery, postoperative effectiveness data were included up until the operation date, whereas safety measures were included from all timepoints. Safety evaluations included CDVA, cup-to-disc ratio, and complications and adverse events through 5 years postoperatively. Descriptive statistics (mean ± SD) were completed for continuous variables such as IOP and number of medications over time. No inferential statistics were employed.

RESULTS

Accountability and Demographics

All eyes (65 eyes of 43 patients) underwent successful implantation of a single trabecular microbypass stent (iStent) after phacoemulsification cataract surgery. Table 1 shows the demographics and preoperative characteristics of the overall cohort. Diagnoses included POAG (n = 39), PXG (n = 14), secondary uveitic glaucoma (n = 1), posttraumatic glaucoma (n = 1), or ocular hypertension (n = 10). Of note, the present report includes data from three patients with PXG whose data were not available for analysis at the time of the previous manuscript.[29] The current report also contains augmented and/or corrected data for existing patients, which resulted from continued clinical monitoring and data verification within this real-life, ongoing patient population. Of the 65 eyes, 26 have completed 5 years of follow-up.

In this consecutive cohort of 31 male eyes and 34 female eyes, the mean age was 72.7 ± 7.7 years and all patients were white. Preoperatively, the disease burden and degree of glaucomatous optic nerve damage varied from minimal to advanced, with a predominance of more advanced cases: more than one third (25 [38%]) of the 65 eyes had undergone previous trabeculectomy and/or glaucoma laser procedures, 44 (68%) of the eyes were being treated with 2 or more medications, and the mean cup-to-disc ratio was 0.7 ± 0.2. All 65 eyes had visually significant cataracts, with 37 eyes (58%) having baseline CDVA of 20/50 or worse.

Table 1. Demographics and preoperative characteristics, overall cohort (65 eyes of 43 patients).

Parameter	Number of Eyes (%)
Glaucoma diagnosis	
POAG	39 (60)
PXG	14 (22)
Ocular hypertension	10 (15)
Secondary uveitic	1 (1.5)
Posttraumatic	1 (1.5)
Previous glaucoma surgery	
No	40 (62)
Yes	25 (38)
Surgery type, n*	
LPI	4†
ALT	6
SLT	8*
Trabeculectomy	8*
Preop medication use	
0 meds	3 (5)*,‡
1 med	18 (28)
2 meds	26 (40)
3 meds	14 (22)
4 meds	4 (6)
CDVA§	
20/40 or better	27 (42)
20/50–20/100	33 (52)
20/200 or worse	4 (6)

ALT = argon laser trabeculoplasty; CDVA = corrected distance visual acuity; IOP = intraocular pressure; LPI = laser peripheral iridotomy; POAG = primary open-angle glaucoma; PXG = pseudoexfoliation glaucoma; SLT = selective laser trabeculoplasty

*25 eyes with 26 surgeries. One eye had both SLT and trabeculectomy, and it is included in the number of eyes for both procedures. This patient was on 0 medications

†Completed in eyes suspected to be at slight risk for mixed mechanism glaucoma. The IOP did not change after LPI, indicating that open-angle mechanisms were entirely responsible for the IOP elevation, and thus trabecular microbypass stent–cataract surgery was determined to be an appropriate intervention

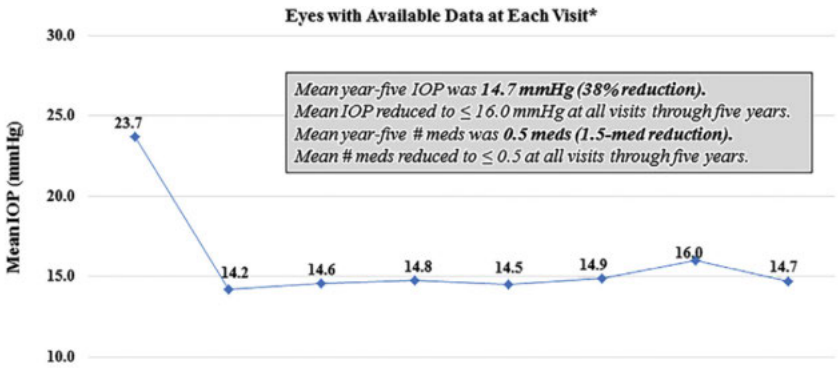
‡The remaining 2 eyes on 0 medications had ocular hypertension

§Not measured in 1 eye

Figures 2, 3, and 4 show the mean IOP and medication use from baseline to 60 months postoperatively in the overall cohort, the POAG subgroup, and the PXG subgroup, respectively. The baseline mean IOP was 23.7 ± 7.4 mm Hg on a mean of 2.0 ± 1.0 medications in the overall cohort, 22.8 ± 4.4 mm Hg on a mean of 1.9 ± 0.8 medications in the POAG subgroup, and 27.1 ± 6.7 mm Hg on a mean of 2.5 ± 1.0 medications in the PXG subgroup.

Efficacy

The IOP and medications were analyzed at every visit through 5 years postoperatively for all available eyes without secondary glaucoma surgery. Five years after the iStent implantation with cataract surgery, the mean IOP decreased by 38% (Figure 2); 24 (92%) of 26 eyes had a



Exam	PRE	M3	M6	M12	M24	M36	M48	M60
n	65	64	63	64	44	39	41	26
IOP (mmHg)	23.7 ± 7.4	14.2 ± 3.7	14.6 ± 3.4	14.8 ± 4.2	14.5 ± 2.0	14.9 ± 2.3	16.0 ± 2.8	14.7 ± 3.0
# meds	2.0 ± 1.0	0.2 ± 0.4	0.3 ± 0.7	0.4 ± 0.9	0.2 ± 0.5	0.3 ± 0.5	0.5 ± 0.7	0.5 ± 0.9

* *Excludes data from time points after secondary glaucoma surgery.*

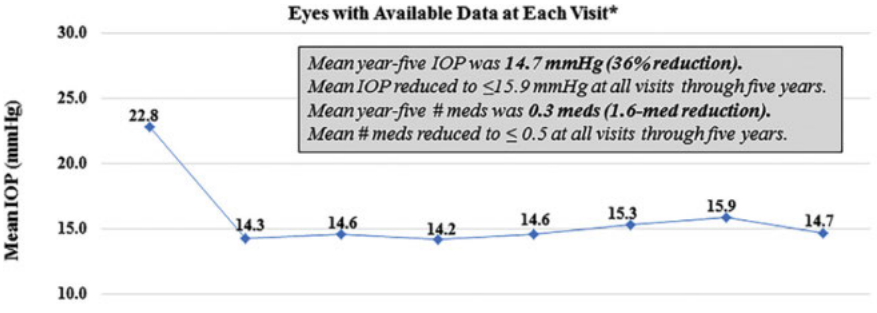
Figure 2. Mean IOP and medications over time, overall cohort (IOP = intraocular pressure; M = month; Med = medication; Pre = preoperative).

year 5 IOP of 18 mm Hg or lower and 17 eyes (65%) had an IOP of 15 mm Hg or lower (Figure 5). Medications were reduced by 75% to 0.5 ± 0.9 versus 2.0 ± 1.0 medications preoperatively (Figure 2). Figure 6 shows the medication use through 5 years. The percentage of eyes on 3 to 4 medications at 5 years decreased to 4% versus 28% preoperatively; inversely, 69% of eyes became medication-free versus 5% preoperatively. At all visits through 60 months, the mean IOP was maintained at 16.0 mm Hg or lower and the mean number of medications remained at 0.5 or fewer. Notably, the IOP-lowering and medication-lowering impact of the iStent seemed consistent over time, with no indication of diminishing effectiveness (Figures 2 to 4).

In the POAG subgroup, the mean year 5 IOP reduced to 14.7 ± 2.4 mm Hg versus 22.8 ± 4.4 mm Hg preoperatively (36% reduction); and the mean medication burden was 0.3 ± 0.6 medications versus 1.9 ± 0.8 preoperatively (1.6 medication reduction) (Figure 3). At all visits through 5 years, the mean IOP in POAG eyes was maintained at 15.9 mm Hg or lower and the mean medication number remained at 0.5 or fewer. For the PXG subgroup, the mean year 5 IOP reduced to 15.5 ± 4.5 mm Hg versus 27.1 ± 6.7 mm Hg preoperatively (43% reduction); and the mean number of medications decreased by approximately one half to 1.3 ± 1.2 medications versus 2.5 ± 1.0 preoperatively (1.2 medication reduction) (Figure 4). At all visits through 5 years, the mean IOP in PXG eyes was maintained at 17.3 mm Hg or lower and the mean medication number remained at 1.3 or fewer.

Safety

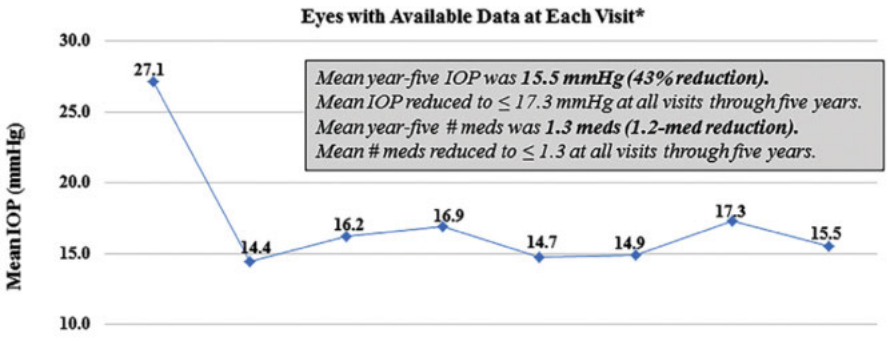
All patients had uneventful implantation of a single iStent device after standard phacoemulsification cataract surgery. No operative or perioperative complications typically seen



Exam	PRE	M3	M6	M12	M24	M36	M48	M60
n	39	38	37	38	28	24	16	18
IOP (mmHg)	22.8 ± 4.4	14.3 ± 3.8	14.6 ± 3.1	14.2 ± 2.1	14.6 ± 2.3	15.3 ± 2.3	15.9 ± 2.6	14.7 ± 2.4
# meds	1.9 ± 0.8	0.2 ± 0.4	0.2 ± 0.4	0.3 ± 0.6	0.2 ± 0.4	0.4 ± 0.5	0.5 ± 0.5	0.3 ± 0.6

* *Excludes data from time points after secondary glaucoma surgery.*

Figure 3. Mean IOP and medications over time, primary open-angle glaucoma subgroup (n = 39) (IOP = intraocular pressure; M = month; Med = medication; Pre = preoperative).



Exam	PRE	M3	M6	M12	M24	M36	M48	M60
n	14	14	14	14	10	9	8	6
IOP (mmHg)	27.1 ± 6.7	14.4 ± 2.2	16.2 ± 4.3	16.9 ± 7.7	14.7 ± 1.3	14.9 ± 1.7	17.3 ± 3.4	15.5 ± 4.5
# meds	2.5 ± 1.0	0.3 ± 0.7	0.8 ± 1.1	0.9 ± 1.3	0.4 ± 0.7	0.3 ± 0.5	0.8 ± 1.2	1.3 ± 1.2

** Excludes data from time points after secondary glaucoma surgery.*

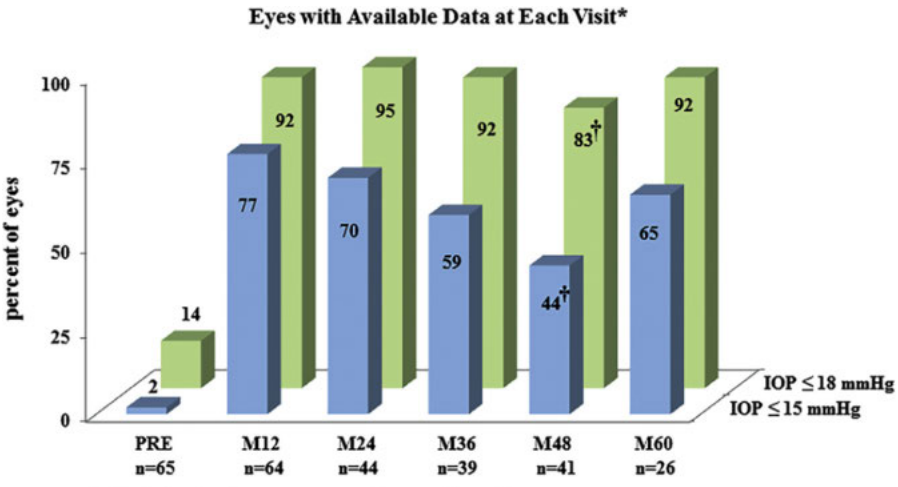
Figure 4. Mean IOP and medications over time, pseudoexfoliation glaucoma subgroup (n = 14) (IOP = intraocular pressure; M = month; Med = medication; Pre = preoperative).

with conventional filtering surgeries were seen with the iStent implantations. Over the duration of follow-up, no sight-threatening or device-related adverse events occurred, including no hypotony maculopathy, endophthalmitis, retinal detachment, or choroidal detachment or hemorrhage. Figure 7 shows the preoperative and 5-year CDVA readings. Improvement in CDVA after cataract surgery was preserved, with mean year 5 CDVA of 20/40 or better in 100% of the 24 eyes with CDVA measurement at that time point, and 20/25 or better in 19 eyes (79%). Consistent with the previous report of 3-year data, the mean cup-to-disc ratio continued to be stable through 5 years postoperatively (Table 2). During the follow-up, two non-ocular adverse events occurred (non-study-related deaths in two patients aged 75 years and 90 years), and two ocular sequelae occurred (posterior capsular opacification and non-visible stent in 2 eyes of the same patient). These four events were discussed in the previous publication. No additional adverse events were reported from 3 to 5 years postoperatively.

A total of 7 eyes in the overall cohort (including 3 with PXG, 3 with POAG, and 1 with secondary uveitic glaucoma), 5 of which had a history of previous glaucoma surgery, underwent eight secondary glaucoma surgeries during the follow-up; five of these surgeries were discussed in the 3-year report.[29] The eight total surgeries included shunt surgery (n = 2), cyclophotocoagulation (n = 2), gel stent (Xen, Allergan, Inc.) implantation (n = 2), and one patient (with secondary uveitic glaucoma) had both cyclophotocoagulation and trabeculectomy (Table 3).

DISCUSSION

The current report presents data with one of the longest follow-up periods documented in the literature to date.



** Excludes data from time points after secondary glaucoma surgery.*
† Mean M48 IOP impacted by data from two eyes with IOP > 21 mmHg that subsequently were treated with medication (n=1) or XEN surgery (n=1).

Figure 5. Proportional analysis of IOP of 15 mm Hg or lower and 18 mm Hg or lower through 5 years, overall cohort (IOP = intraocular pressure; M = month; Pre = preoperative; XEN = Xen gel stent [Allergan, Inc.]).

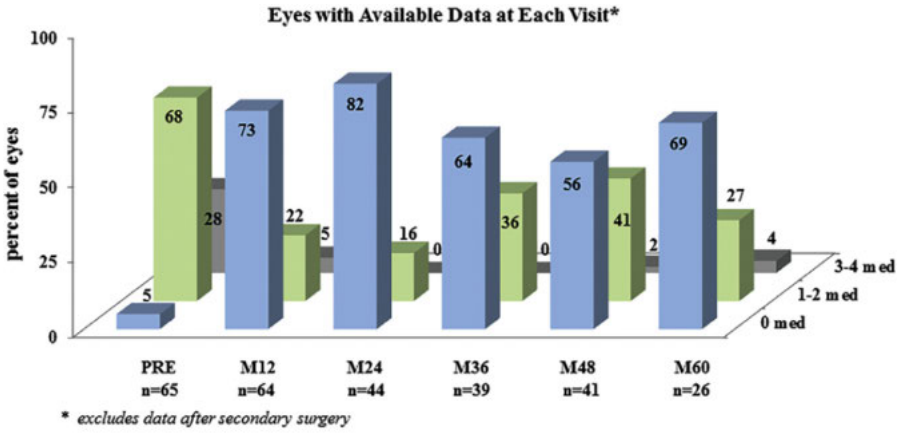


Figure 6. Proportional analysis of medication use through 5 years, overall cohort (M = month; Med = medication; Pre = preoperative).

Specifically, this 5-year dataset evaluates outcomes of iStent implantation with cataract surgery in a heterogeneous patient population with a considerable preoperative medication burden and surgical history. The study includes a variety of glaucoma types (including primary, pseudoexfoliative, secondary uveitic, and posttraumatic) and ocular hypertension, and eyes both with and without previous surgery, as seen in routine clinical practice. This realistic scenario makes the outcomes particularly relevant to practicing ophthalmologists who are evaluating surgical treatment options for their glaucoma patient population.

In the overall cohort, substantial reductions in both IOP (decreased by 38%) and medications (decreased by 75%) were observed through 5 years postoperatively. The IOP reduction is especially noteworthy given the absence of a preoperative medication washout before stent implantation. In addition, among eyes not undergoing secondary glaucoma surgery during follow-up, over two thirds (69%) became medication-free by 5 years postoperatively, thereby adding value for patients by eliminating the costs, time, and side effects associated with medication use.[3,4] The favorable effectiveness and safety seen in this study corroborate previous evaluations of trabecular microbypass stent–cataract surgery in mild-to-moderate glaucoma.[12–14,17] The data also are consistent with recent studies of iStent surgery in more moderate-to-severe cases of glaucoma.[25–27]

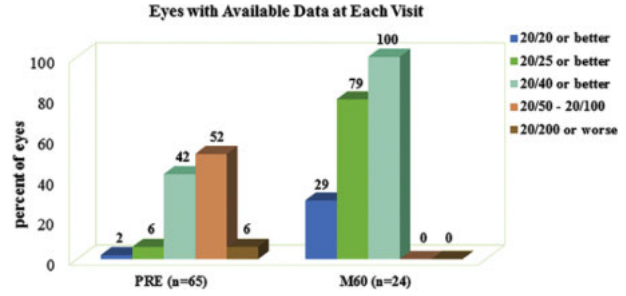


Figure 7. Preoperative and 5-year CDVA, overall cohort (CDVA = corrected distance visual acuity; M = month; Pre = preoperative).

Of particular importance to surgeons and patients planning long-term glaucoma treatment and disease prognosis, the present longitudinal study brings to the literature real-life information on the durability of iStent outcomes over an extended 5-year follow-up. The ongoing consistency of iStent efficacy over this 5-year period contrasts with the long-term outcomes of laser trabeculoplasty, which have been documented to wane in efficacy over time.[5–7] For example, one large 5-year study reported success rates after SLT to be 58%, 38%, and 31% at 1, 3, and 5 years respectively; and the success rates after ALT to be 46%, 23%, and 13% at 1, 3, and 5 years respectively.[5] Similarly, a prospective randomized 5-year study comparing ALT with diode laser trabeculoplasty showed surgical failure in 42% of eyes within 5 years after ALT[7]; and the landmark Glaucoma Laser Trial[6] found that 64% of laser trabeculoplasty-treated eyes required one or more medications over the course of follow-up because of IOP increase, visual field deterioration, and/or optic disc deterioration.[6] In contrast, the clinical outcomes observed after iStent implantation in the present study remained consistent throughout follow-up, as demonstrated by the maintenance of mean IOP at 16.0 mm Hg or lower and mean number of medications at 0.5 or fewer at all visits through 5 years in this cohort.

Although sample sizes are relatively small for subgroup analyses of PXG eyes (n = 14) and POAG eyes (n = 39) in this cohort, some preliminary trends could be observed. When analyzed separately, the PXG subgroup demonstrated a higher preoperative mean IOP (27.1 mm Hg) than that of the overall cohort (23.7 mm Hg) or the POAG subgroup (22.8 mm Hg), consistent with the more aggressive nature of this glaucoma type.[30] At 5 years postoperatively, PXG eyes experienced a similar to slightly greater degree of IOP reduction (43% reduction) as the overall cohort (38% reduction) or the POAG subgroup (36% reduction), corroborating the widely observed pattern of greater IOP reduction in eyes with higher preoperative pressures.[17] Eyes with PXG also experienced a similar reduction in the number of actual medications (1.2 medication reduction in PXG eyes versus 1.5

Table 2. Mean cup-to-disc ratio through 5 years, overall cohort.*

Parameter	Preop	12 Mo	24 Mo	36 Mo	48 Mo	60 Mo
Number of eyes†	64	61	43	37	39	24
Mean ± SD	0.7 ± 0.2	0.6 ± 0.2	0.6 ± 0.2	0.6 ± 0.2	0.6 ± 0.2	0.5 ± 0.2

*Not measured in 1 eye
†Eyes with available data at each visit

medication reduction in the overall cohort and 1.6 medication reduction in POAG eyes). In addition, the IOP and medication reductions in our study's PXG subgroup were directionally and quantitatively comparable to those of the larger PXG cohort published by Ferguson et al.[28]

The safety profile remained favorable through 5 years of follow-up, consistent with the widely documented durable safety observed in previous studies of iStent and iStent *inject*.[12–28] Of note, no complications typically seen with conventional filtering surgeries were seen, and no site-threatening or device-related adverse events were observed for the entirety of follow-up. Three surgical procedures were completed in addition to the 5 secondary glaucoma surgeries already discussed in the 3-year manuscript[29] for a total of 8 secondary glaucoma surgeries in 7 eyes (3 eyes with POAG, 3 eyes with PXG, and 1 eye with secondary uveitic glaucoma). This number is favorable given that many of these eyes might have undergone traditional filtering surgery otherwise because most of them (5 of 7) already had failed glaucoma surgical and/or laser intervention(s) before enrolling in the study. Considering that filtering surgeries carry an annual and cumulative lifelong risk for serious complications,[8–10] preventing such surgeries—or at least delaying them—has important value.

We acknowledge several limitations in this unmasked, nonrandomized study. The patients comprised a consecutive series of patients in the surgeon's clinical practice, and thus were not required to meet protocol-defined IOP or medication criteria for enrollment aside from needing and being eligible for trabecular microbypass stent–cataract surgery. Diurnal IOP measurements were not obtained, and visual field examinations were not available for every patient. The patients did not complete preoperative and postoperative medication washouts because these are not usually part of standard clinical practice and potentially could cause harm to patients with more moderate and advanced stages of glaucoma. However, as mentioned previously, the absence of washouts might be considered a strength because it makes the IOP reductions particularly noteworthy. As is the case in most studies from real-life clinical cohorts, there was no formal control group; however, we considered preoperative IOP and medication number to be valid comparators, given they are objective numeric measures. Because all patients underwent combined trabecular microbypass stent–cataract surgery, it was not possible to separate the IOP effect of cataract extraction versus stent implantation. As noted previously, the sample size was relatively small for the subgroups of POAG eyes (n = 39 at baseline, n = 18 at 5 years) and PXG eyes (n = 14 at baseline, n = 6 at 5 years). However, the long follow-up period makes the data valuable, even if only trends (rather than complete statistics) are possible. Further investigation could include a larger cohort of POAG and PXG patients from this surgeon, including surgeries completed more recently than the period in this study. Alternatively, the existing data could be combined with other colleagues' cohorts to allow for a larger pooled analysis.

Limitations notwithstanding, this study contributes some of the longest published follow-up data currently available

Table 3. Safety through 5 years, overall cohort. There were no intraoperative complications, and no postoperative sight-threatening or device-related adverse events through 5 years.

Additional Glaucoma Surgery During Follow-up (n = 7 Eyes)		
Preop Diagnosis	**Surgical History Before Procedure***	**Postop Course After Procedure***
POAG	SLT and Trabeculectomy	Intolerance to topical and systemic medications; shunt surgery at 3 months
POAG	SLT	Gel stent implant at 12 months
POAG	None	Gel stent implant at 48 months
PXG	Trabeculectomy	CPC at 24 months
PXG	None	CPC at 12 months
PXG	ALT	Intolerance to topical and systemic medications; shunt surgery at 12 months
Secondary uveitic glaucoma	LPI	CPC at 12 months; trabeculectomy at 24 months

ALT = argon laser trabeculoplasty; CPC = cyclophotocoagulation; LPI = laser peripheral iridotomy; POAG = primary open-angle glaucoma; PXG = pseudoexfoliation glaucoma; SLT = selective laser trabeculoplasty
*Trabecular microbypass stent–cataract surgery

on the sustained utility and safety of a single iStent trabecular microbypass stent combined with cataract surgery. Importantly, these longitudinal outcomes were observed within a realistic clinical setting and in a clinically heterogeneous patient population, including patients with different glaucoma types or ocular hypertension, various numbers of baseline medications and degrees of glaucomatous damage, and both previously operated and surgery-naïve eyes. Thus, the data might be applied to real-life clinical settings and physician–patient treatment decisions. The results demonstrate substantial, sustained reductions in both IOP and medication burden through 5 years postoperatively, together with excellent safety.

WHAT WAS KNOWN

- Considerable data have demonstrated that trabecular microbypass stent implantation during cataract surgery can safely reduce intraocular pressure and medication burden in open-angle glaucoma.
- To date, most publications have presented outcomes through 1 to 3 years postoperatively in mild-to-moderate glaucoma populations, often in the context of clinical trials with specific protocols and inclusion criteria, whereas relatively fewer published longitudinal datasets exist through 5 years in real-life heterogeneous clinical cohorts.

WHAT THIS PAPER ADDS

- With one of the longest follow-up periods of any existing publication on trabecular microbypass stent implantation with cataract surgery, the present study demonstrated appreciable reductions in IOP and medications, together with consistent safety through 5 years postoperatively.
- The results were observed in a clinically representative, diverse patient cohort, including multiple glaucoma subtypes and ocular hypertension, various disease severities (including moderate and advanced), and both surgery-naïve and previously operated eyes.

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First author:
Tobias H. Neuhann, MD

AaM Augenklinik am Marienplatz, Munich, Germany