ARTICLE

Trabecular microbypass stents as minimally invasive approach after conventional glaucoma filtration surgery

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Purpose: To evaluate long-term efficacy and safety of 2 trabecular microbypass stents in patients with advanced primary open-angle glaucoma (POAG) and insufficient intraocular pressure (IOP) after previous filtration surgery.

Setting: Vivantes Klinikum Neukölln, Augenklinik, Berlin, Germany.

Design: Retrospective case series.

Methods: Eyes with uncontrolled and advanced POAG since 2014 were assessed. All eyes previously had at least 1 filtration surgery procedure. The anatomical landmarks and configuration of the anterior chamber angle had to be identified easily. Two iStents were placed nasally into Schlemm canal.

Results: The study comprised 42 patients (42 eyes); 18 eyes had 1 previous glaucoma filtration surgery. During the follow-up of 12 months, the mean IOP in cases of primary failure of filtration surgery decreased from preoperative 23.8 mm Hg $\pm$ 3.9 (SD) to 15.2 $\pm$ 2.7 mm Hg. For cases with more than 1 previous filtration surgery, the mean IOP decreased from preoperative 26.1 $\pm$ 5.7 mm Hg to 16.3 $\pm$ 3.3 mm Hg. Medications were reduced from 2.7 $\pm$ 0.9 to 2.0 $\pm$ 1.1. No intraoperative or perioperative complications occurred.

Conclusions: For eyes with previous filtration surgery and medically uncontrolled IOP, the implantation of 2 stents provided a minimally invasive and safe reduction of mean IOP to less than 18 mm Hg at 12 months. The number of medications was also reduced.

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By 2020, blindness from glaucoma will affect approximately 11.2 million people worldwide and 80 million people will suffer from glaucoma with visual field defects.[1] In Germany, glaucoma (15%) is the second-most common cause for loss of sight.[2] According to an analysis in 2016, cyclodestructive glaucoma surgery has been applied to 27% of German cases without filtration surgery.[A] In 38% of cases, filtration surgery was performed. Interventions to improve aqueous humor circulation have been applied in 27% of cases (trabecular shunt implants, surgical iridectomy, trabeculoplasty and iridotomy). Nonfiltering surgery is less common with 8% of the total of surgeries (viscocanalostomy, canaloplasty).[A] All types of glaucoma are primarily treated with topical glaucoma medication. In case of progressive damage to the optic nerve and failure of conservative therapy, intolerance, or compliance issues, several types of glaucoma surgery have been applied.

In 30% of cases after conventional glaucoma filtration surgery, the effect of lowering the intraocular pressure (IOP) is insufficient; repeated filtration procedures are limited. As an alternative to conventional glaucoma surgery, microinvasive glaucoma surgery has been developed. It is primarily performed for mild to moderate primary open-angle glaucoma (POAG). It aims at reactivating efficient pressure reduction by intervention near the chamber angle and the suprachoroidal space around the natural outflow system, regardless of a filtering bleb. This approach is characterized by a high safety profile with uncomplicated healing and rapid rehabilitation of the patient. Often it is combined with cataract surgery.[3] Among the minimally invasive procedures, the iStent supra and the Cypass

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microstent implants have been approved in Europe since 2013. They support the uveoscleral outflow by probing the suprachoroidal space. The titanium iStent (first-generation) or iStent inject (second-generation) implants are inserted transtrabecularly to facilitate the outflow of aqueous humor via Schlemm canal and downstream collector channels. The iStent (GTS100,Glaukos Corp.), an L-shaped titanium implant, was approved by the U.S. Food and Drug Administration in 2012. Its successor, iStent inject, has been available in Europe since March 2014. This heparin-coated titanium implant is 360 μm long, has a base of 230 μm in width, and 4 orifices of 50 μm diameter. Because of its symmetrical design, it can be used in both eyes.[3]

Filtration surgery with drainage of the aqueous humor by a filtering bleb is still the gold standard for lowering the IOP by 20% to 30%. Minimizing wound-healing disorders with filtering bleb scarring requires medium- or long-term intensive postoperative care and the application of antimetabolites with a specific side-effect profile. In up to one third of cases, the target pressure is not reached subsequently. The purpose of this study was to examine, in cases with complex conjunctival conditions, whether revision surgery can be avoided by applying transtrabecular microbypass stents after previous filtering glaucoma surgery has failed, and whether the IOP can be sufficiently lowered.

PATIENTS AND METHODS

Study Design

The study design was a retrospective single-center open-label nonrandomized trial. Eyes with POAG, pseudoexfoliation syndrome, or pigment dispersion glaucoma that had filtration surgery were examined from July 2014 to July 2015 in the Department of Ophthalmology at the Vivantes Klinikum Neukölln, Augenklinik, Berlin, Germany.

Inclusion criteria included patients who had been using at least 2 IOP-lowering medications for at least 6 months after previous filtration surgery but still required additional IOP lowering, with visual field defects caused by glaucoma, preoperative corrected distance visual acuity of 20/200 or better, scleral spur clearly visible by gonioscopy, and follow-up visits for 1 year postoperatively. Anticoagulation did not constitute a contraindication and could be continued.

Exclusion criteria included patients with glaucoma other than POAG, angle-closure glaucoma, or secondary glaucoma (except pseudoexfoliative and pigmentary); eyes with previous canaloplasty, suprachoroidal shunt systems or epibulbar drainage implants; eyes with peripheral anterior synechiae, corneal opacities or disorders inhibiting visualization of the nasal angle; elevated episcleral venous pressure; and chronic or active ocular inflammation.

Surgical Technique

To gain the best view of the chamber angle region, the patient's head was bent toward nasal by 30 degrees and the microscope was tilted in the opposite direction. After topical anesthesia, access was established through lateral paracentesis, the anterior chamber was stabilized with an ophthalmic viscosurgical device (OVD), and the nasal and superior trabecular meshwork were made visible by a goniolens (Ocular Instruments). Two stents were preloaded in the G2-M-IS injector with a 23-gauge tip. The injection trocar was exposed by a push mechanism to position the stents in the nasal superior and nasal inferior trabecular meshwork at a relative distance of 1 to 2 clock hours (Figure 1). Both stents were extruded from the injector with an integrated push button mechanism. Then, the OVD was thoroughly aspirated and irrigated and the eye was stabilized. In the first 2 weeks after surgery, all patients received a combination of pilocarpine 2.0% and timolol eyedrops (Fotil sine) twice a day to prevent the iris base from adhering to the stents and a resulting occlusion or unregulated IOP.

RESULTS

The study comprised 42 patients (42 eyes) with a mean age of 74.7 ± 7.3 years. Of these, 14 patients (33%) were women and 28 (67%) were men. There were 25 right eyes and 17 left eyes. Eleven eyes (26%) were phakic. Informed consent was obtained and the study adhered to the tenets of the Declaration of Helsinki.

Patients presented with glaucoma for a mean duration of 9.6 years ± 7.3 (SD). The visual field defects, measured preoperatively with the Swedish Interactive Thresholding Algorithm 24-2 full-threshold Humphrey visual field (Carl Zeiss Meditec AG), had a mean deviation of −14.8 ± 9.3 dB.

The mean cup-to-disc ratio was 0.9 ± 0.1. Patients were taking a mean of 2.7 ± 0.9 medications.

The mean medicated IOP of primary failures preoperatively was 23.8 ± 3.9 mm Hg, for patients with more than 1 previous filtering surgery; the mean medicated preoperative IOP was 26.1 ± 5.7 mm Hg.

The number of drugs and the IOP were preoperatively and postoperatively recorded after 2 and 6 weeks, and 3, 6, and 12 months. Moreover, the positioning of the stents (pretrabecular, transtrabecular, or posttrabecular), their actual position (normal depth, level, tilted), and the degree of synechia (open, partial synechia, complete synechia) were described postoperatively.

Eleven eyes (26%) had combined cataract surgery and 33 eyes (74%) were pseudophakic. Eighteen eyes (43%) had filtration surgery once, 15 eyes (36%) twice, 7 eyes (17%) 3 times, and 2 eyes (4%) 4 times. The IOP of primary failures could be lowered from 23.8 ± 3.9 mm Hg preoperatively to 15.2 ± 2.7 mm Hg postoperatively and in the other patients from preoperative 26.1 ± 5.7 mm Hg to 16.3 ± 3.3 mm Hg after 12 months (up to 18 months) (Figures 2 and 3). The number of medications decreased from 2.7 ± 0.9 to 2.0 ± 1.1. There were no complications. Four eyes (10%) showed partial synechia of 1 stent, 3 eyes (7%) a post-trabecular position, and in 2 eyes (5%), only 1 implant was visible after surgery. Fifteen eyes (36%) required filtering bleb revision, a drainage device, or cyclophotocoagulation within 6 months (the mean preoperative IOP was 27.1 ± 7.4 mm Hg). In 14 of these patients, the implant was perfectly placed; only 1 had synechia. Five of these eyes had combined surgery and 10 eyes were already pseudophakic.

DISCUSSION

The trabecular meshwork of the healthy eye is a contractile dynamic tissue that can actively adjust the aqueous humor outflow.[4] In eyes with POAG, remodeling in the area of elastic fibrils, the extracellular matrix, and the trabecular meshwork has been shown. This results in an outflow resistance, most commonly via the juxtacanalicular meshwork

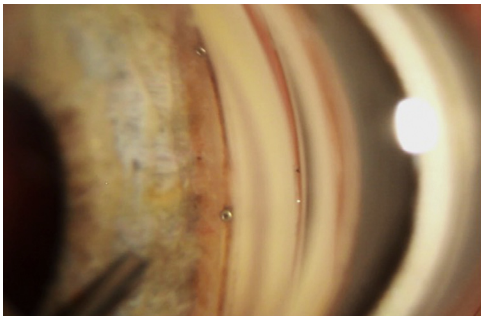

Figure 1. Two second-generation microbypass stents in the nasal trabecular meshwork at a 1 clock hour distance.

that connects the corneoscleral meshwork with the endothelium of the inner wall of Schlemm canal.[5] This is known as 1 of the most crucial factors for the development of chronic open-angle glaucoma (OAG) with elevated IOP. Schlemm canal is located behind the juxtacanalicular trabecular meshwork. A link to the episcleral vessel system is established via the scleral posterior wall by 20 to 30 collector channels.[6]

As early as 1974, Lütjen-Drecoll and Barany,[7] in experimental studies with macaque monkeys, found that Schlemm canal collapses widely after filtration surgery (Figure 4). The same effect was confirmed for the human eye in a study by Johnson et al. in 2000.[8] On average, eyes that had filtration surgery had a smaller diameter of Schlemm canal than eyes that were treated with glaucoma medication without surgery (178 ± 71 μm versus 261 ± 61 μm).[8]

After traditional filtration surgery, the target pressure is not reached over time in up to 30% of cases, requiring a revision of the filtering bleb. In such cases, bleb scarring might occur in up to 29% of cases.[9] Further postoperative complications of the conjunctival tissue include external fistulation with perioperative hypotonia and filtering bleb infection. A cyclodestructive intervention or the

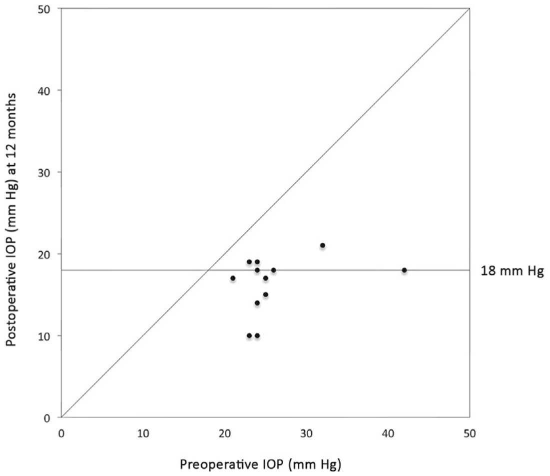

Figure 3. Preoperative IOP compared with postoperative IOP at the 12-month visit in cases of several preceding filtering surgery procedures. Each spot indicates a patient (IOP = intraocular pressure).

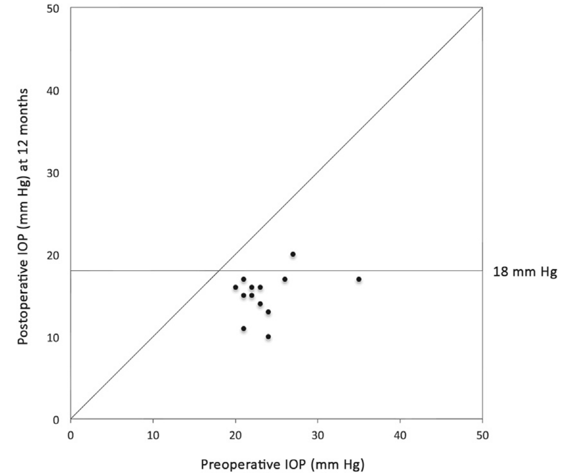

Figure 2. Preoperative IOP compared with postoperative IOP at the 12-month visit in cases of primary failure of filtration surgery. Each dot indicates a patient (IOP = intraocular pressure).

implantation of epibulbar drainage implants might be alternative options.

Minimally invasive surgical techniques have gained interest and popularity among patients and surgeons over the past years because they claim to be safe and easily combined with cataract surgery. With transtrabecular microbypass stents (iStent and iStent inject), the collapsed Schlemm canal could be activated ab interno in the eyes with previous filtration surgery when the target IOP has not been achieved. In addition to a lower IOP, the number of medications could be reduced and compliance increased. In the literature, we found only 1 case report from 2014[10] that found an eye after multiple surgeries,

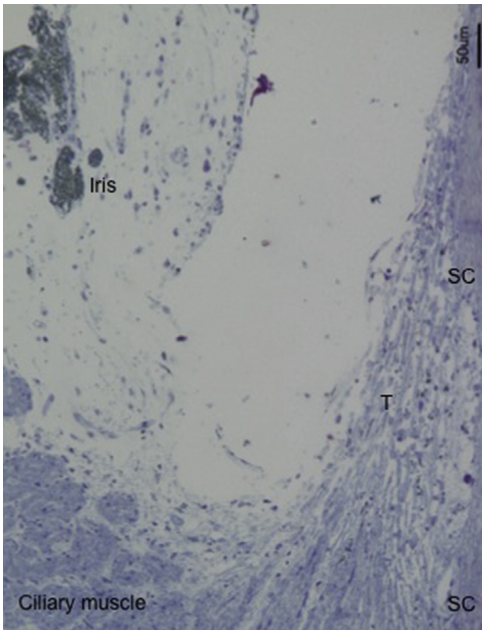

Figure 4. Schlemm canal: 1 μm semi-thin cut, toluidine blue staining (SC = Schlemm canal [mostly collapsed, inner and outer wall merged]; T = trabecular meshwork). (*Reproduced with permission of E. Lütjen-Drecoll, MD, University Erlangen-Nürnberg, Germany.*)

including trabeculectomy and epibulbar drainage implant, had not reached the target pressure under 4 medications and after having 2 stents implanted. The follow-up after 2 years resulted in an IOP of 17 mm Hg.[10] To our knowledge, larger studies of the effects of trabecular meshwork surgery with first- and second-generation microbypass stents implanted after previous filtration surgery have not yet been published.

In our study, 11 phakic eyes (26%) had combined cataract surgery. Many studies show that standalone cataract surgery of a POAG reduces the IOP by 1.5 to 3 mm Hg in comparison to a control group without surgery. In 2012, Mansberger et al.,[11] in a retrospective analysis of the Ocular Hypertension Treatment Study, showed that the pressure-reducing effect correlates with the preoperative IOP; that is, the higher the preoperative IOP, the more pronounced was the postoperative reduction.

Previously published data in the literature suggest a correlation of the number of implanted microbypass stents and IOP-lowering effect. The best effect is found when 2 or 3 stents are implanted.[12] In a 2015 prospective study, Katz et al.[13] showed that IOP reduction depends on the number of implants used. One microbypass stent was implanted in 38 eyes, 2 in 41 eyes, and 3 in 40 eyes. The IOP could be lowered to 15.9 $\pm$ 0.9 mm Hg, 14.1 $\pm$ 1.0 mm Hg, and 12.2 $\pm$ 1.1 mm Hg after 18 months, respectively. Histologic studies of the distribution of collector channels found that their major part is located in the nasal area. Today, the entire distal outflow system can be fully 3-dimensionally imaged by microcomputer tomography, down to the episcleral blood vessels.[14] Considering previously obtained findings on the distribution of the collector channels, we implanted the second-generation microbypass stent in our study in the superonasal area of the chamber angle region to allow for the highest pressure reduction.

In 2010, Fernández-Barrientos et al.[15] examined the influence of first-generation trabecular microbypass stents on the aqueous humor dynamics. In a prospective fluorophotometric study, 33 patients received 2 stents in combination with cataract surgery whereas the control group had only cataract surgery. The stent group showed a 275% higher aqueous outflow facility compared with the cataract surgery group, which had an approximately 46% outflow increase. The mean IOP could be lowered by 6.6 mm Hg versus 3.9 mm Hg, and the number of medications was 0.0 and 0.7, respectively.

In our study, the IOP could be lowered by 40% in eyes with single previous filtration surgery, from mean preoperative 23.8 $\pm$ 3.9 mm Hg to postoperative 15.2 $\pm$ 2.7 mm Hg. In patients with multiple previous filtration surgeries, IOP reduction was 38%, from mean preoperative 26.1 $\pm$ 5.7 mm Hg to postoperative 16.3 $\pm$ 3.3 mm Hg (Figures 3 and 4). The mean follow-up was 12 months. The mean number of medications decreased from 2.7 $\pm$ 0.9 to 2.0 $\pm$ 1.1. All patients in our study received a combination therapy of β-blockers and miotics for at least 2 weeks postoperatively to achieve a very low target IOP in cases of advanced glaucoma damage and to prevent synechia of the implant. The longest follow-up so far, more than 5 years, was reported by Arriola-Villalobos et al.[16] in 2012. They showed in 19 eyes that the first-generation microbypass stent reduced the IOP by 16.3% (from 19.4 to 16.3 mm Hg) and that the number of glaucoma medications could be decreased from 1.3 to 0.8.

In our study, partial goniosynechiae occurred in 1 stent injection in 4 eyes (10%) during the 2-week follow-up. Different studies report successful synechialysis with neodymium:YAG (Nd:YAG) or argon laser treatment in cases with postoperative elevated IOP.[17] This was not required in our cases because we had no case with a postoperative elevated IOP. Subsequently, the synechia recovered in 2 eyes (5%) without further intervention.

In 3 eyes (7%), we saw 1 post-trabecular-placed microbypass stent 2 weeks after surgery, but no elevated IOP. In 2 eyes (5%), we could only detect 1 microbypass stent postoperatively by gonioscopy. This might have been caused by too high pressure during the extrusion of the second-generation microbypass stent, resulting in deep penetration in the sclera. Thus, we were able to lower the IOP successfully in 8 of 9 patients, although only 1 microbypass stent was optimally positioned or had an open orifice. Synechia or suboptimal inserted stents belong with 2.6% to 18.0% of the most frequently reported postoperative complications in the literature.[18] There is a high safety profile with few complications for implantation of the first- and second-generation microbypass stents. Thus far, only 1 case of transient hypotonia, but without choroidal detachment or postoperative endophthalmitis, has been described in the literature.[18]

As Schlemm canal collapses after filtration surgery and the distally located outflow system with its collector channels might be irreversibly damaged up to the episcleral vein plexus, it obviously cannot be reactivated sufficiently in some cases. No studies of the implantation of first- and second-generation microbypass stents after filtration surgery have been published. The iStent Study Group[19] reported that 4.5% of patients required secondary surgical interventions after first-generation microbypass stent implantation. In 3 cases, 1 first-generation microbypass stent was repositioned; in 1 case, the stent was replaced and in another case, the patient was treated with the Nd:YAG-laser.[19]

The ideal positioning of the trabecular stents is not yet fully clarified. Several studies show that most collector channels are found nasally, which makes implantation in this area most promising. However, this is a complex construct and the outflow facility is based not only on the presence of collector channels but also on the subsequent structures. Hence, other factors in addition to ideal placement might be involved.[20] A reflux bleeding after the implantation of the stent is an indicator of correct placement in the collector channel. Visualization of the collector channels before surgery might help.[21] Indirect canalography allows displaying the outflow system intraoperatively. In 2010, Grieshaber et al.[22] found that after inducing a slight hypotonia via a paracentesis, Schlemm canal fills with blood. The reflux of blood helps to identify the position and the number of collector channels to achieve an ideal placement of the implant. A prospective study in 2015 with 30 patients,[B] used indirect canalography to assess the reflux and 2 second-generation microbypass stents were implanted in 65% of cases and a Cypass implant (supraciliary microstent) in 35% of cases. There was a significant mean IOP reduction of 25% in the second-generation microbypass stent group and of 42% in the supraciliary microstent group.[B]

Thus far, trabecular microbypass stents have been used only in the early stages of glaucoma with mild to moderate visual field defects, either as the primary surgery after a failed conservative therapy and/or in cases of intolerance to eyedrops. In the later stages, a very low target IOP, which is limited by the episcleral vein pressure when microbypass stents have been implanted, is often pursued. However, by adding local glaucoma medication, the IOP can be lowered down to a level that reduces further progression of the glaucomatous damage. It should be considered that the combined cataract and second-generation microbypass stent implantation might act as a confounder because standalone cataract surgery itself could cause an IOP reduction. Outcomes regarding long-term IOP reduction are pending. In case of therapy failure, canaloplasty or suprachoroidal shunt systems are viable options.

In conclusion, 12 months after the implantation of 2 second-generation microbypass stents in eyes with previous filtration surgery and advanced OAG, this minimally invasive and safe surgery resulted in a successful IOP lowering to less than 18 mm Hg and a better compliance by two thirds of the patients.

WHAT WAS KNOWN

- In the management of mild to moderate glaucoma, current data show that the trabecular microbypass stents are effective and have a high safety profile with rapid recovery time.

WHAT THE PAPER ADDS

- With the implantation of trabecular microbypass stents ab interno in eyes with insufficient IOP after previous filtration surgery, it was possible to reactivate the collapsed Schlemm canal, thus lowering the IOP.

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