Trabecular micro-bypass stent implantation during small-incision cataract surgery for open-angle glaucoma or ocular hypertension: Long-term results

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PURPOSE: To evaluate long-term safety and efficacy of iStent trabecular micro-bypass stent implantation during cataract surgery in patients with primary open-angle, pseudo-exfoliation glaucoma, ocular hypertension, or secondary or post-traumatic glaucoma.

SETTING: AaM Augenklinik am Marienplatz, Munich, Germany.

DESIGN: Prospective, open-label, non-randomized study.

METHODS: Preoperative and postoperative evaluations included intra-ocular pressure (IOP), topical ocular hypotensive medication use, cup/disc ratio, corrected-distance visual acuity (CDVA), complications, and adverse events.

RESULTS: A single trabecular micro-bypass stent was implanted through the same temporal, limbal incision used for cataract surgery via phacoemulsification in a consecutive series of 62 eyes of 43 patients. To date, a total of 41 eyes have been followed for 3 years postoperatively, whereas long-term postoperative follow-up on the remaining patients is ongoing. Mean preoperative IOP was 24.1 $\pm$ 6.9 mm Hg on a mean of 1.8 medications ($\pm$0.9). Analyses of eyes with no secondary surgical intervention showed mean IOP reduction to 14.8 $\pm$ 4.2 mm Hg at 12 months (n = 61), 14.5 $\pm$ 2.2 mm Hg at 24 months (n = 42), and 14.9 $\pm$ 2.3 mm Hg at 36 months (n = 39). Medications were eliminated in 74% of eyes at 36 months. Five eyes, 4 with previous glaucoma surgeries and 1 with pseudo-exfoliation syndrome, required additional glaucoma surgery after stent implantation. No intra-operative or postoperative complications typically seen with conventional glaucoma surgeries occurred after stent implantation. At 36 months, CDVA was 20/40 or better in 38 eyes (93%).

CONCLUSION: Trabecular micro-bypass stent implantation during cataract surgery was safe and effective in patients with ocular hypertension or glaucoma as measured by a sustained reduction in IOP and medication use and an excellent safety profile through 3 years after surgery.

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Glaucoma, one of the leading causes of blindness in the world, is expected to affect 78 million people by the year 2020.[1] This progressive disease requires a multitude of life-long therapeutic options and until recently has been treated with only medications, laser treatment, and incisional surgery. The clinical goals are prevention of visual field loss via control of intra-ocular pressure (IOP)[2] and neuroprotection. The practical objective is to use medical or surgical treatment options that minimize impact on a patient's quality of life and are not burdensome from a compliance perspective. However, the array of complications associated with conventional glaucoma medical and surgical treatments can hinder their conceivable therapeutic potential. The co-morbidity of certain procedures is of concern to clinicians who strive to actively manage this

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disease but who find that existing surgical options have limited the range of options for future treatment.

A promising advance in glaucoma surgery is micro-invasive glaucoma surgery (MIGS) with ab interno trabecular micro-bypass stents, proven to be safe and effective for mild-to-moderate glaucoma in conjunction with cataract surgery.[3,4] Experience in the last 8 years with trabecular micro-bypass stents has shown significant IOP and ocular hypotensive medication reduction. MIGS implantation of trabecular micro-bypass stents has shown a favorable safety profile and has not been associated with the complications experienced with earlier conventional treatments. Furthermore, long-term studies with greater than 4 years of postoperative follow-up have shown reduction in mean IOP and medication usage, thus providing a sustained efficacy profile and consequently an advantageous risk to benefit ratio.[5–8] Much of this work in trabecular micro-bypass stent implantation has focused on eyes at earlier disease states in patients who have undergone only initial medical therapy.

The author's experience with MIGS stent implantation began in 2010 in patients with glaucoma and in need of cataract surgery. The group of patients was not restricted to the numerous inclusion and exclusion criteria typically inherent in multi-centered clinical trials designed for product registration. The decision to implant a trabecular bypass stent during cataract surgery was based on (1) the wish of the patient to reduce or possibly eliminate the burden of topical ocular hypotensive medications and (2) the intention of the surgeon to offer surgical treatment for glaucoma with the lowest possible risk. Consequently, the author's experience amassed to date includes patients with ocular hypertension or primary open-angle, pseudo-exfoliation, or secondary or post-traumatic glaucoma who have never had surgical treatment or had previous surgery.

The goal of this prospective data collection was to assess long-term postoperative outcomes with one iStent trabecular micro-bypass stent (Glaukos Corp) implanted in conjunction with cataract surgery in a broader group of patients at risk for continued glaucoma progression in whom initial therapy had not been limited to medication only. This report summarizes IOP, ocular hypotensive medication use, and safety through up to 3 years after surgery in a heterogeneous set of eyes.

PATIENTS AND METHODS

Study Design

This was a prospective, consecutive series of surgeries performed by the same surgeon (T.N.) at a clinical facility in Munich, Germany. All patients were selected from the adult population with the need for cataract surgery and reduction of IOP. Patients had implantation of a single iStent trabecular micro-bypass device in conjunction with cataract surgery. All methods of data collection were followed in accordance with the Helsinki Declaration and ethical standards of the responsible committee on human research. Informed consent was obtained from all patients.

Trabecular Micro-Bypass Stent

The iStent is an L-shaped stent, 0.33 mm in height and 1.00 mm in length, with a snorkel length of 0.25 mm. The body of the stent resides in the Schlemm canal and the snorkel resides in the anterior chamber (Figure 1). This single-piece device is manufactured from titanium (Ti6A25V ELI) and coated with stearalkonium heparin. The trabecular micro-bypass stent is preloaded in a single-use, disposable inserter to allow for precise insertion of the device into the Schlemm canal.

Surgical Technique

The stent was implanted through a clear corneal incision after uncomplicated standard micro-invasive phacoemulsification and IOL implantation. An intracameral miotic was allowed if the pupil remained overly dilated subsequent to the cataract surgery. The angle was inspected with the use of a gonioprism to ensure a good view of the trabecular meshwork. A dual-property, visco-adaptive ophthalmic viscosurgical device (OVD) with 7 000 000 mPas viscosity and a molecular weight of 4.0 million Daltons was injected into the anterior chamber as needed to assist with chamber maintenance. The same temporal incision used for cataract surgery was used to insert the stent. The implant on the tip of

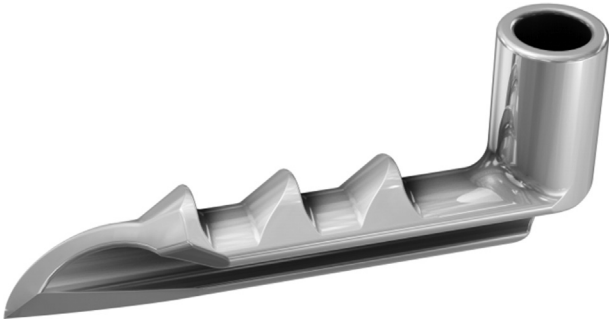

Figure 1. Trabecular micro-bypass stent.

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