INTRODUCTION

Medical therapies that treat glaucoma and cataract surgery by reducing aqueous production or increasing the outflow of aqueous via the trabecular meshwork are available. Trabecular bypass has been found to enhance the facility of outflow and reduce IOP to physiological levels. To that end, the iStent® (Glaukos Corp., Laguna Hills, CA) was developed to address some of the limitations of current medical and surgical therapies for treating glaucoma including inability to control outflow resistance, need for frequent, invasive, hypotensive and curative measures. The trend seems to bypass the trabecular meshwork, which is considered to be responsible for the increased outflow resistance leading to glaucoma. This procedure attempts to re-establish fully-developed physiological steady-state outflow, increase the conduction unblocked, and relieve the risk of complications associated with both therapies. This prospective study was designed to test the safety and efficacy of the iStent® Trabecular Micro-Bypass Stent in patients undergoing cataract and glaucoma surgery.

METHODS

• This was a prospective, non-randomized, single-center, multi-center, 24-month clinical evaluation of the safety and efficacy of the Glaukos iStent® Trabecular Micro-Bypass Micro-Stent for the treatment of open-angle glaucoma (POAG) or pseudoexfoliation glaucoma (pEXG) in patients (n=51) with IOP controlled by their current standard hypertensive medications.
• No washout of patients’ current hypertensive medications was required.
• Patients discontinued use of all agents immediately postoperatively and were instructed to resume treatment only if the investigator determined additional IOP lowering was needed.

Outcome measures

• The primary outcome measures were OIP by Goldmann applanation tonometry.
• The secondary outcome measures were number of glaucoma medications pre- and postoperatively.

Inclusion criteria

• Diagnosis of open-angle glaucoma, including pseudoexfoliation glaucoma or pigmentary glaucoma.
• Current use of at least one glaucoma medication.
• IOP ≥ 14 mmHg (as measured at least two consecutive office visits).
• Concomitant diagnosis of cataract requiring cataract surgery and intraocular lens implantation.
• Female gender with gonioscopy.
• No prior ocular hypotensive procedures.
• Availability and willingness to attend follow-up visits for 2 years study duration.
• Signed informed consent.

Exclusion criteria

• Any type of glaucoma other than open-angle glaucoma, pseudoexfoliation, or pigmentary glaucoma.
• Medical therapy, compliance with study determined follow-up, and medical intervention within the last year.
• History of any ocular or systemic glaucoma surgery or the study eye.
• History of any cataract surgery in the study eye.
• History of iris surgery (excluding goniotomy).
• History of prior laser trabeculoplasty.
• History of laser or intraocular photocoagulation for optic nerve damage.
• Prior history of trabecular bypass procedures.
• Prior history of trabecular bypass procedures that may present acute IOP measurements (i.e., 0, PKP, USAHP).

Surgical procedure

• Patients underwent implantation of the Glaukos iStent® Trabecular Micro-Bypass Micro Stent at the conclusion of standard clear cornea cataract surgery with a 2.0 to 3.0 mm incision.
• The iStent® was guided into its tunnel using a sterile technique. The stent was inserted under topical anesthesia using a 25-gauge needle.

Follow-up evaluations

• Preoperative examination visits were at days 1-2 days post-operatively and months 1, 3, 6, 12, 18, and 24. Study visits included OIP measurement, slit-lamp examination, grading of number of glaucoma medications, and adverse event assessment.

Patient demographics

• Most patients were:  o Female (66.1%)  o Caucasian (98.3%)
• Mean age was 75 years (range: 28-87).
• Preoperative study visits were at days 1-2 days post-operatively and months 1, 3, 6, 12, 18, and 24.
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• Stent location and condition were evaluated gonioscopically.

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