Purpose

Significant IOP and ocular hypotensive use have been shown following micro-invasive glaucoma surgery (MIGS) in which single or multiple trabecular micro-bypass stents are implanted subInternally in conjunction with cataract surgery. The iStent creates a bypass through the trabecular meshwork to Schlemm’s canal to restore natural physiologic aqueous outflow. Over 4,100 iStents have been evaluated in over 30 studies worldwide in >10 years. It is the smallest device known to be implanted in humans. The MIGS study group undertook a prospective evaluation to assess IOP and medication reduction following implantation of two trabecular micro-bypass stents as the only surgical procedure followed by postoperative administration of a single ocular hypotensive medication. The study population was comprised of patients diagnosed with open angle glaucoma that was not controlled with the use of two medications prior to surgery.

Methods

Subject enrollment criteria were open-angle glaucoma, current use of two medications, and medication IOP between 20 and 30 mmHg. Additional qualification criteria was preoperative unmedicated IOP ranging between 22 mmHg and 38 mmHg following medication washout. Eyes could be either phakic or pseudophakic. A total of 42 eyes that met these criteria underwent implantation of two trabecular micro-bypass stents (iStent, Glaukos Corporation, Laguna Hills, CA) through a 1 mm clear corneal incision followed by postoperative administration of Travoprost. The primary effectiveness endpoint was IOP reduction of ≥20% at 12 months with reduction of one ocular hypotensive medication. The secondary effectiveness outcome was IOP ≤18 mmHg at 12 months with reduction of one ocular hypotensive medication. Safety assessments at postoperative visits through 25 months included slit-lamp, gonioscopy fundus/ocular nerve exam, surgical/postoperative complications and best corrected visual acuity. Twenty-one eyes have been followed for at least 12 months.

Inclusion Criteria:
- Phakic or pseudophakic
- On 2 topical hypotensive medications
- IOP between 20 -30 mmHg
- Glaucomatous visual field defects or nerve abnormalities
- On top one hypertensive medications
- Medicated IOP ≥18 mmHg at screening
- After medication washout, baseline IOP ≥22-38 mmHg

Exclusion Criteria:
- Aphakia or pseudophakia w/ AC IOLS
- Traumatic, acute, or chronic pseudoexfoliation, or optic nerve atrophy
- Open angle Glaucoma associated with vascular disease
- Prior glaucoma surgery other than iridotomy

Demographics

The average age of was 64 years (SD 1.2), and 86% of eyes were phakic. Mean preoperative IOP was 22.3 mmHg (SD 1.2, Table 1). All subjects were taking moderate glaucoma medications prior to surgery. In this population of eyes with moderate to advanced glaucoma, the mean CD ratio was 0.7 (SD 0.1), and 62% of eyes had a C/D ratio of 0.7 or more. After washout medication, baseline IOP was 25.2 mmHg (SD 1.9).

Results – IOP and Medication Reduction

Mean IOP decreased from preoperative IOP of 22.3 mmHg (SD 2.5) to 14.1 mmHg or less at all postoperative time periods (Figure 3). In the subset of 21 eyes with data available at 12 months, mean IOP was 14.0 mmHg (SD 1.8). In a hundred percent of these eyes the achieved the primary efficacy endpoint of ≥20% reduction with reduction of one medication, and 62% achieved reduction of ≥ 40%, with a mean IOP reduction of 43% (Figure 4). All 21 eyes met the secondary efficacy endpoint of IOP ≤ 18 mmHg with reduction of one medication, and 81% had IOP ≤ 15 mmHg (Figure 5).

Discussions and Conclusions

- The iStent is an ob-intestrient stent manufactured from titanium (Ti6Al4V ELI) and heparin coated. The stent has a single piece design, in 1 mm in length, 0.33 mm in height, with a snorkel length of 0.25 mm, and a snorkel bore diameter of 120 µm (Figure 1).

- The iStent has an “L”-shaped structure with a snorkel (inlet) on the short side which resides in the anterior chamber, and an open half-pipe body which resides in Schlemm’s canal. The convex side of the body (Figure 1) sits against the inner wall of Schlemm’s canal. The concave side of the body (Figure 1) sits against the inner wall of Schlemm’s canal, and the open part of the body (Figure 2) against the outer wall in order to access collector channels.

- The MIGS study group comprised of visiting surgeons and staff surgeons at one investigational site (S.V. Malayian Ophthalmo-Pathological Center, Yerevan, Armenia). Most visiting surgeons had not previously implanted iStent. The goal of the MIGS study group is to evaluate iStent technology as trinitable therapy in a series of studies in over 2000 patients.

- One subject experienced transient hypotony at one week, this resolved without intervention or further sequelae by one month. Two subjects experienced BCVA loss due to normal progression of pre-existing cataract or the duration of postoperative follow-up and with last reported BCVA of 20/200 and better (Figure 6). One eye had BCVA loss to worse than 20/40 (also see postop AE).

- In this study of MIGS implantation of two iStents and one postoperative prostaglandin in OAG subjects not controlled on two medications, significant IOP and medication reduction was achieved. All subjects were able to eliminate one medication and achieve IOP ≤18 mmHg (81% ≤ 15 mmHg) with a mean IOP reduction of 43%. In this series, phakic/pseudophakic eyes with OAG not controlled on two medications achieved IOP control with reduced medication burden through 12 months postoperatively after MIGS implantation of two trabecular micro-bypass stents as the sole surgical procedure.

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