ARTICLE

Microbypass stent implantation with cataract extraction and endocyclophotocoagulation versus microbypass stent with cataract extraction for glaucoma

Tanner J. Ferguson, BS, Russell Swan, MD, Ramu Sudhagoni, PhD, John P. Berdahl, MD

Purpose: To compare the outcomes of combined microbypass stent implantation, cataract extraction, and endocyclophotocoagulation (ECP) with those of implantation of the same microbypass stent with concomitant cataract surgery in patients with open-angle glaucoma (OAG).

Setting: Private Practice, Sioux Falls, South Dakota, USA.

Design: Retrospective consecutive case series.

Methods: Patients from January 2015 to August 2016 were included. The study group comprised eyes that had implantation of a microbypass stent in combination with cataract extraction and ECP. To compare outcomes, a control group of eyes with similar baseline characteristics that had implantation of a stent in combination with cataract surgery was established. Data were collected preoperatively and postoperatively at 1 day, 1 week, and 1, 3, 6, and 12 months. Data included intraocular pressure (IOP) and number of glaucoma medications.

Results: The mean preoperative IOP was 21.49 mm Hg ± 9.56 (SD) in the study group (51 eyes) and 20.66 ± 3.23 mm Hg in the control group (50 eyes). Twelve months postoperatively, the mean IOP reduction was 7.14 mm Hg in the study group and 4.48 mm Hg in the control group and the medication reduction was 38% (0.68) and 63% (1.06), respectively.

Conclusions: Patients who had implantation of the microbypass stent in combination with cataract surgery and ECP had significantly better IOP reduction than those who did not have ECP. The combination procedure was also effective in patients with severe OAG.

J Cataract Refract Surg 2017; 43:377–382 © 2017 ASCRS and ESCRS

Glaucoma is a leading cause of irreversible blindness worldwide, and at present intraocular pressure (IOP) is the single proven modifiable risk factor for the development and progression of glaucoma.[1,2] In early stages of the disease, ocular hypotensive drugs have traditionally been considered the first-line treatment.[3] However, the recent emergence of the microinvasive glaucoma surgery (MIGS) procedures has shifted the algorithm of glaucoma treatment.[4]

Microinvasive glaucoma surgery procedures using ab interno trabecular microbypass stents have a high safety profile, produce minimal trauma, and are an attractive option for patients with mild to moderate disease. Microinvasive glaucoma surgery procedures also preserve the option for additional surgery in the future.[5] The iStent (Glaukos Corp.), the first U.S. Food and Drug Administration (FDA)–approved MIGS implant, is an ab interno device designed to serve as a bypass through the trabecular meshwork to improve physiological aqueous outflow and lower IOP. The titanium L-shaped trabecular microbypass stent is 1.0 mm in length and 0.33 mm in height and is the smallest medical device ever approved by the FDA.[6]

The iStent, approved for use at the time of cataract surgery, has been shown to have long-term safety and efficacy in numerous trials including a large multicenter study that showed a decrease in IOP and hypotensive medication use compared with cataract surgery alone up to 5 years postoperatively.[7,A] Studies[8–11] have also shown it can be implanted as a sole procedure (without concomitant cataract surgery) and that multiple stents can be used to enhance the IOP-lowering abilities of the device. Furthermore, the excellent safety profile of the stent enables it to be combined with

Submitted: October 31, 2016 | Final revision submitted: December 5, 2016 | Accepted: December 7, 2016

From the Sanford School of Medicine (Ferguson) and the Master of Public Health Program (Sudhagoni), School of Health Sciences, University of South Dakota, and Vance Thompson Vision (Swan, Berdahl), Sioux Falls, South Dakota, USA.

Presented at the ASCRS Symposium on Cataract, IOL and Refractive Surgery, New Orleans, Louisiana, May 2016.

Corresponding author: Tanner J. Ferguson, BS, Vance Thompson Vision, 3101 West 57 Street, Sioux Falls, South Dakota 57108, USA. E-mail: tannerferguson@me.com.

0886-3350/$ - see frontmatter
http://dx.doi.org/10.1016/j.jcrs.2016.12.020

other microinvasive glaucoma procedures such as endocyclophotocoagulation (ECP).

Both the microbypass stent and ECP have independently been shown to be safe and efficacious in combination with cataract surgery.[6,12] Combining multiple procedures might provide a greater reduction in medication dependence and in IOP. Endocyclophotocoagulation is a cyclodestructive procedure that decreases aqueous production by delivering laser energy to the ciliary processes. Like other MIGS procedures, ECP spares the conjunctiva and does not create a bleb. Combined ECP and cataract surgery provided a greater reduction in IOP and medication use than cataract surgery alone.

A combined procedure, which includes the microbypass stent, cataract surgery, and ECP, provides a dual mechanism approach to glaucoma treatment. This procedure, which has been discussed previously,[B–D] simultaneously reduces inflow while increasing outflow. Although this can also be accomplished with the simultaneous use of multiple medications, this procedure offers a dual-mechanism surgical option.

The purpose of this study was to evaluate the combined procedure and compare it with the results of microbypass stent implantation with concurrent cataract surgery but with no ECP. Data evaluating the safety and efficacy of the procedure are limited. To our knowledge, this study presents the first data published on the safety and efficacy of the combined procedure.

PATIENTS AND METHODS

Study Design

This retrospective study comprised consecutive patients diagnosed with open-angle glaucoma (OAG). The study included eyes with mild, moderate, and severe OAG. The University of South Dakota Institutional Review Board approved this study. This study used data from procedures performed by the same surgeon (J.P.B.) at a single site.

The stage of OAG was defined as optic nerve changes consistent with glaucoma and visual field changes (mild: no changes on white-on-white 24-2; moderate: changes in 1 hemifield and not within 5 degrees of fixation; severe: changes in both hemifields or changes within 5 degrees of fixation in at least 1 hemifield). These criteria are consistent with the American Academy of Ophthalmology Preferred Practice Pattern guidelines.[13]

The study group comprised eyes that had implantation of 1 microbypass stent (iStent) in combination with ECP during cataract surgery. A control group of eyes that had iStent implantation with concurrent cataract surgery but without ECP was randomly selected from a large data set of patients of the surgeon to allow comparison of the outcomes with those in the study group.

The only inclusion criterion for the control group was a diagnosis of primary OAG and 1 or more medications at baseline; the mean baseline IOP and medication use were similar between the 2 groups. The control group was not matched for age, sex, or disease severity.

Surgical Technique

After cataract removal and IOL implantation using phacoemulsification through a clear corneal incision (CCI), the eye was rotated nasally and the head was rotated approximately 30 degrees away from the surgeon. The microscope was also rotated 30 degrees away from the surgeon and the eye was left dilated. A cohesive ophthalmic viscosurgical device (OVD) was used to implant the intraocular lens (IOL) in the eye. A gonioprism was held on the cornea with the surgeon's nondominant hand, and the trabecular meshwork was brought into focus using the microscope. The microbypass stent, on a preloaded injector, was placed in the surgeon's dominant hand and inserted through the CCI. A right stent was used in right eyes and a left stent in left eyes. The stent, on the tip of the inserter, was guided into the trabecular meshwork at a 20-degree angle and advanced inferiorly. The stent was released, and the shaft of the insertion device was used to nudge the stent inferiorly and push the heel of the device into the trabecular meshwork. The secure placement of the device was confirmed by "strumming" the device with the injector tip in a posterior-to-anterior direction. If the stent was not properly secured, it was repositioned.

A cohesive OVD was injected into the ciliary space posterior to the iris and anterior to the lens capsule. An ECP probe (Endo Optiks, Inc.) was introduced into the eye through the main incision. The distal portion of the pars plicata was identified, and 270 degrees of ciliary body processes were treated using 0.2 mW. The remaining OVD was then removed with irrigation/aspiration (I/A), including from behind the IOL. If a hyphema or microhyphema were present at the end of surgery, it was removed as thoroughly as possible with I/A, although it was still common to see red blood cells in the anterior chamber at the end of the case. The cornea was hydrated and the pressure was left in the physiologic range. No pharmacologic constricting agents or ocular hypotensive agents were used during or immediately after the procedure.

Postoperative Medications and Follow-Up

Postoperative care was similar in both groups. In the study group, patients were treated with intravitreal triamcinolone–moxifloxacin–vancomycin (Tri-Moxi-Vanc) or intravitreal triamcinolone–moxifloxacin (Tri-Moxi) concurrent with the procedure. During the study period, the center switched to triamcinolone–moxifloxacin injections because of concerns regarding the use of vancomycin and risk for hemorrhagic occlusive retinal vasculitis,[14] although no cases of hemorrhagic occlusive retinal vasculitis have been reported with use of triamcinolone–moxifloxacin–vancomycin to date. Postoperatively, patients were prescribed nonsteroidal antiinflammatory drugs (NSAIDs) for 1 month and were kept on their preoperative ocular hypotensive medications for at least 1 week and until the patient's IOP was deemed clinically acceptable by the operating physician. The control group included eyes with both postoperative regimens, based on patient preference. A previous study[E] found no significant difference in postoperative IOP and medication reduction between the use of topical drops and intravitreal injections in this procedure. In eyes that received topical drops, patients were prescribed moxifloxacin 0.05% for 1 week, a daily NSAID (bromfenac 0.07% or nepafenac 0.3%) for 4 weeks, and steroid drops (difluprednate 0.05% or prednisolone acetate 1%) for 4 weeks that were used 4 times a day and then tapered to 2 times a day after 1 week. As opposed to the more restrictive clinical trials,[6] no specific guidelines were established to determine when to add or remove ocular hypotensive medications, and medication addition or removal was based on clinical judgment.

Preoperative data were used to establish a baseline, typically 1 to 2 weeks before the surgery. Postoperatively, data was collected from 1 day, 1 week and 1, 3, 6, and 12 months. At each timepoint, the data collected included IOP, number and type of medications used, and visual acuity.

Outcome Measures and Safety Evaluation

The main outcome measures in the study were IOP by Goldmann applanation tonometry and the number of glaucoma medications being used. To evaluate the safety of the procedure, the need for additional surgery and postoperative complications were noted. Whether patients had IOP pressure increases of 15 mm Hg or higher at any timepoint postoperatively was also recorded.

Statistical Analyses

A paired *t* test was used to compare the within-group mean change in IOP from baseline to 1 year. A Wilcoxon signed-rank