SCHLEMM CANAL MICROSTENTING


Recent updates on MIGS combined with phacoemulsification.

BY JON WILLIAMS, MD, AND MANJOOL SHAH, MD

PROSPECTIVE, RANDOMIZED CONTROLLED TRIAL OF CATARACT SURGERY VS COMBINED CATARACT SURGERY WITH INSERTION OF ISTENT INJECT

Fan Gaskin JC, Bigirimana D, Kong GYX, et al[1]

Industry support for this study: Glaukos

ABSTRACT SUMMARY

A prospective randomized controlled clinical trial compared the safety and efficacy of cataract surgery combined with implantation of an iStent Inject (Glaukos; treatment group, n = 56 patients) versus cataract surgery alone (control group, n = 48 patients). All patients had mild to moderate open-angle glaucoma (OAG) and a preoperative IOP ranging from 12 to 30 mm Hg on zero to three ocular hypotensive medications. Secondary outcomes included patient-reported outcomes to gauge quality of life 24 months after surgery via the Ocular Surface Disease Index and the Glaucoma Activity Limitation Questionnaire.

At 24 months, the number of ocular hypotensive medications was 0.7 ±0.9 in the treatment group and 1.5 ±1.9 in the control group. No glaucoma medications were required by 57% and 36% of the eyes in the treatment and control groups, respectively. The IOP did not differ significantly between groups beyond 4 weeks postoperatively. No differences in patient-reported outcomes were observed between groups.

STUDY IN BRIEF

- A prospective randomized clinical trial compared the safety and efficacy of cataract surgery combined with implantation of an iStent Inject (Glaukos) versus cataract surgery alone. Primary outcomes included the number of ocular hypotensive medications and IOP 2 years postoperatively. Compared to cataract surgery alone, the combined procedure yielded a statistically significantly greater reduction in the number of glaucoma medications patients required 24 months postoperatively. No difference in IOP was observed between the cohorts at 2 years.

WHY IT MATTERS

Unlike earlier studies involving the iStent, this trial lacked a medication washout period and therefore more closely reflects common clinical practice. The results provide support for implanting the device to, at a minimum, blunt IOP spikes following phacoemulsification and, at most, reduce the medication burden of patients with mild to moderate open-angle glaucoma and cataracts.

DISCUSSION

How did the medication burden compare between groups?

The treatment group showed a clear reduction in medication burden 2 years postoperatively. Ten percent of patients in the control group required four ocular hypotensive agents 24 months after surgery; no one in the treatment group required this many glaucoma medications.

Was there a medication washout?

Participants in this study did not undergo medication washout before surgical intervention, which could explain why no statistically significant difference in IOP was observed between the two cohorts. Gaskin et al noted that a washout period is useful for measuring an absolute IOP reduction after cataract surgery combined with trabecular bypass microstenting but is difficult in everyday practice. The study simulated typical clinical practice and offers support for implanting an iStent Inject in patients undergoing cataract surgery who have mild to moderate OAG.

Was a difference in patient-reported outcomes found?

No statistically significant difference in patient-reported outcomes was observed 2 years after surgery. This may seem counterintuitive given the reduced medication burden postoperatively. As Gaskin et al noted, however, several landmark trials that employed similar patient-reported outcomes found no difference between study cohorts for otherwise effective interventions.[2,3]

THREE-YEAR OUTCOMES OF A SCHLEMM CANAL MICROSTENT (HYDRUS MICROSTENT) WITH CONCOMITANT PHACOEMULSIFICATION IN OPEN-ANGLE GLAUCOMA

Salimi A, Kassem R, Santhakumaran S, Harasymowycz P[4]

Industry support for this study: None

STUDY IN BRIEF

- A single-surgeon consecutive case series evaluated 3-year outcomes of phacoemulsification combined with implantation of a Hydrus Microstent (Alcon) in patients with open-angle glaucoma, including secondary open-angle glaucomas and severe disease.

WHY IT MATTERS

Published data on the long-term outcomes of Hydrus implantation combined with phacoemulsification are lacking. Aside from the 5-year outcomes of the pivotal HORIZON trial published in 2022,[5] there is limited evidence on the device's efficacy beyond 2 years after implantation. This case series provides valuable insight into the long-term safety and efficacy of the implant combined with cataract surgery outside the setting of a randomized clinical trial.

ABSTRACT SUMMARY

A longitudinal case series compared the 3-year outcomes of phacoemulsification combined with insertion of a Hydrus Microstent (Alcon). A single surgeon performed the combined procedure on a total of 106 eyes at a single academic center in Montreal. There was no control arm. Success was defined as the absence of specific failure criteria:

- Glaucoma reoperation;
- Selective laser trabeculoplasty;
- An IOP below 5 mm Hg or above 18 mm Hg, an increase in the number of ocular hypotensive medications, or a loss of light perception due to glaucoma; and
- Aggregation of the first three criteria.

Ninety-six eyes met the minimum follow-up threshold of 3 years. The percentage of eyes that achieved an IOP below 18, 15, and 12 mm Hg was 97%, 86%, and 42%, respectively. The use of ocular hypotensive medication decreased from an average of three preoperatively to an average of two at 3 years. Factors associated with treatment failure included a higher preoperative IOP, a greater number of ocular hypotensive medications, and prior incisional glaucoma surgery.

DISCUSSION

What does this study add to the current long-term evidence on implantation of the Hydrus Microstent combined with phacoemulsification?

Before 5-year results from the HORIZON trial were published in 2022,[5] little evidence on the device's efficacy beyond 2 years had been published in the peer-reviewed literature. The 5-year data showed that an IOP lower than 18 mm Hg was achieved by almost 50% of the eyes that underwent Hydrus implantation combined with phacoemulsification and 33.8% of those that received phacoemulsification alone.

Salimi and colleagues found that, 3 years after the combined procedure, 91% of patients had an IOP lower than 18 mm Hg. The average medication burden, however, was higher than in the HORIZON trial (2.0 ±1.2 at 3 years vs 0.5 ±0.9 at 5 years).

The case series by Salimi et al provides a snapshot of results with a single surgeon at a single site. It will be interesting to see whether future reports outside the confines of a randomized clinical trial find that a similarly high proportion of patients achieve surgical success.

Is Hydrus implantation justifiable in patients who have severe disease or secondary forms of OAG?

The US FDA-approved use of the Hydrus is limited to patients with mild to moderate primary OAG. Notably, 31% of patients analyzed in the retrospective study by Salimi et al had disease that would be classified as severe based on Canadian Ophthalmology Society glaucoma clinical practice guidelines. In addition, the study included patients with pigment dispersion glaucoma, pseudoexfoliative glaucoma, and normal-tension glaucoma. The study's results are encouraging, but a higher-powered prospective clinical trial is required to confirm the device's safety beyond its US FDA-approved indications. It is also important to consider that the hazard ratio for failure was higher among the patients in this study who had a history of incisional surgery or higher preoperative IOPs. ■

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