Two-Year Retrospective Analysis: Standalone Use of the OMNI Surgical System

A promising procedure to lower IOP in aphakic and pseudophakic patients with open-angle glaucoma.

BY KARSTEN KLABE, MD

Glaucoma care is evolving rapidly. The introduction of MIGS devices and procedures has lowered the threshold for surgical intervention; it is now an accepted early disease treatment option.

In the normal eye, the conventional outflow pathway is responsible for most aqueous humor egress and plays a key role in the maintenance of healthy IOP. In the glaucomatous eye, however, pathologic changes to the pathway in the trabecular meshwork, Schlemm's canal, and collector channels can introduce resistance to outflow with consequent increase in IOP.

The OMNI Surgical System (Sight Sciences) is a relatively new surgical device and the only one that combines two ab interno minimally invasive treatments, canaloplasty and trabeculotomy, in a single procedure.

I have been using the OMNI Surgical System (Sight Sciences) since 2018. This technology allows practitioners to target all three points of outflow resistance via two implant-free procedures that are performed with one device. OMNI can be performed as a standalone procedure or in combination with cataract surgery.

My colleague and I conducted a 24-month, single-center, open-label, retrospective study to characterize the reduction in IOP and IOP-lowering medication following standalone treatment with the OMNI Surgical System in patients with medically uncontrolled mild to moderate open-angle glaucoma. This article reviews our findings, which were published in *Clinical Ophthalmology*.[1]

> **"Our study demonstrates the long-term benefits of the OMNI Surgical System as a standalone procedure across a large patient base, including those with primary open-angle and pseudoexfoliation glaucoma as well as in phakic patients."**

STUDY DESIGN

A total of 38 eyes of 27 patients with a mean age of 67.3 years were included in the study. Nearly half of the patients were female (48.2% vs 51.8%). Particularly interesting, most of the patients (74%) were phakic, most had primary open-angle glaucoma (71%), and some had pseudoexfoliation glaucoma (29%). Our positive results in this study confirm that the OMNI Surgical System is an excellent standalone procedure in these populations.

Preoperative IOP and medication data for all patients was recorded; IOP was measured following a medication washout. IOP and medication usage was recorded at regular intervals post-surgically through the 24 months of follow-up. The primary statistical goal of this analysis was to characterize changes in IOP and IOP medication use. Two-sided paired t-tests were used to compare values at each follow-up with baseline values, with P = 0.05 taken as the level of significance. Secondary outcomes included the proportions of eyes achieving minimum IOP reductions of >20%, using fewer medications, and medication-free at each time point. We also tracked the number of secondary surgical interventions required for IOP control after 12 and 24 months.

RESULTS

The results of our study indicated that, when used as a standalone MIGS procedure, OMNI statistically significantly reduced both IOP and IOP-lowering medication use at 24 months in patients with mild to moderate open-angle glaucoma.

Mean baseline IOP. Before surgery, mean IOP was 24.6 ±3.0 mm Hg. On day 1, IOP immediately dropped to 12.6 mm Hg. At 12 and 24 months postoperatively, mean IOP was 14.7 mm Hg and 14.9 mm Hg, respectively. This represented approximately a 40% reduction of IOP. All eyes in the study had at least a 20% reduction in IOP by 24 months postoperative, and the reductions ranged from 12.6 to 14.9 mm Hg over the course of the study ($P < .0001$).

Mean baseline IOP-lowering medication. The

mean medication usage was reduced from 1.9 at baseline to 0.4 and 0.5 at 12 and 24 months postoperative, respectively ($P < .0001$). At the 24-month timepoint, 84.6% of eyes were treated with 1 (or more) fewer medications than at baseline; 57.7% were medication free.

Differences between baseline and month 24 for both IOP and medication use were statistically significant.

Adverse events. In this study, adverse events included transient postoperative hyphema of no more than 1 mm (17 eyes), choroidal effusion (three eyes), anterior synechiae (two eyes), and transient lens-cornea touch associated with a shallow anterior chamber (one eye). These adverse events are all consistent with the adverse events that occur with angle surgery and with MIGS procedures, all were reported to resolve spontaneously without intervention and with no sequelae, and no secondary procedures were required to address them. Only one patient underwent a secondary IOP-lowering surgery procedure. In my experience, prescribing pilocarpine 0.5% four times a day for 2 weeks postoperatively reduced the risk for anterior synechiae.

DISCUSSION

Our study demonstrates the long-term benefits of the OMNI Surgical System as a standalone procedure across a large patient base, including those with primary open-angle and pseudoexfoliation glaucoma as well as in phakic patients. Our research supports use of OMNI regardless of lens status to reduce not only IOP but also the medication burden in patients with open-angle glaucoma.

Compared to other procedures that target only one or two points of outflow resistance, OMNI is a unique procedure because it enables surgeons to address all three points of resistance in the conventional outflow pathway with two implant-free procedures (canaloplasty and trabeculotomy). As a result, outflow resistance can be addressed with OMNI wherever it occurs. Of further note, the OMNI procedure can be performed through a single, minimally invasive clear corneal incision.

CONCLUSION

Our study demonstrated that the OMNI Surgical System has a good safety profile with a very low number of second surgeries performed to lower IOP.

Further, patients in our study experienced a statistically significant reduction in the number of medications required to control IOP, and of particular note was that 57.7% no longer required IOP-lowering medication.

Our study confirmed that the OMNI Surgical System is an effective option to treat open-angle glaucoma in both phakic and pseudophakic patients outside the setting of cataract surgery. ■

1. Klabe K, Kaymak H. Standalone trabeculotomy and viscodilation of Schlemm's canal and collector channels in open-angle glaucoma using the OMNI Surgical System: 24-month outcomes. *Clin Ophthalmol.* 2021;15:3121-3129.

KARSTEN KLABE, MD
- Breyer – Kaymak – Klabe Augenchirurgie
  Düsseldorf, Germany
- k.klabe@augenchirurgie.clinic
- Financial disclosure: Consultant (Sight Sciences)