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OMNI Surgical System

One MIGS Device.

Two implant-free procedures.

Three points of resistance.

► **Advantage No. 6: It simplifies the surgical intervention.** For surgeons with familiarity of the anatomical structures of the chamber angle, the learning curve with the OMNI is short. It is a sophisticated procedure, but most surgeons should become comfortable performing the procedure within about the first five cases. This is not like learning trabeculectomy, which can take years.

CONCLUSION

Viscodilation and trabeculectomy are highly efficacious. Due to the complexity of the surgeries, however, many doctors are not comfortable offering these procedures to their patients.

The availability of an equally efficacious procedure that is easier to perform and that targets all three points of resistance in the conventional outflow pathway has

changed the way in which we can provide care to our glaucoma patients.

The OMNI Surgical System offers the efficacy of viscodilation and trabeculotomy but in a MIGS platform. It is a powerful tool for glaucoma and cataract surgeons to use in combined and standalone surgeries. ■

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FRITZ H. HENGERER, MD, PHD

- Director and Chief Medical Officer, Department of Ophthalmology, Bürgerhospital Eye Clinic, Frankfurt, Germany
- f.hengerer@buergerhospital-ffm.de



Standalone Trabeculotomy and Viscodilation of Schlemm Canal and Collector Channels in Open-Angle Glaucoma

One-year results with the OMNI Surgical System.

BY KARSTEN KLABE, MD

OP elevation in eyes with primary open-angle glaucoma (POAG) is caused by the alteration of tissue within three structures of the eye: the trabecular meshwork (TM), Schlemm canal, and distal collector channels.¹⁻⁴ These mechanisms of change within the trabecular outflow pathway increase aqueous outflow resistance. Approximately 50% to 70% of total outflow resistance in glaucomatous eyes occurs within the TM,^{1,2} and 30% to 50% within Schlemm canal and the collector channels.^{3,4}

MIGS has transformed the way that we approach glaucoma care, and in many cases it is the preferred management strategy for patients with POAG. Various MIGS techniques can be used to target aqueous outflow resistance in one or two structures at best. Goniotomy, trabeculotomy, and trans-TM implants address TM resistance, whereas canaloplasty, viscodilation, and some stenting procedures address Schlemm canal and/or the collector channels.⁵⁻⁸ A standalone procedure targeting all three mechanisms could effectively reduce IOP by removing all sources of aqueous

TABLE 1. DEMOGRAPHIC AND BASELINE GLAUCOMA STATUS DATA FOR THE STUDY SAMPLE

Patient: Level Parameters		Value
Number (n)		27
Age, mean (SD)		67.3 (6.4)
Gender, n (%)		
	Male	14 (51.8)
	Female	13 (48.2)
Ethnicity, n (%)		
	White	27 (100%)
	Other	0 (0%)
Eye: Level Parameters		
Number (n)		38
Study eye, n (%)		
	Right eye	22 (57.9)
	Left eye	16 (42.1)
Glaucoma diagnosis, n (%)		
	Primary open-angle	27 (71.1)
	Pseudoexfoliation	11 (28.9)
Cup-disc ratio, mean (SD)		0.65 (0.16)
Visual field mean deviation (dB), mean (SD)		-3.60 (2.59)
Phakic status, n (%)		
	Phakic	28 (73.7)
	Pseudophakic	10 (26.3)
Prior SLT, n (%)		10 (26.3)
Abbreviations: SD, standard deviation; SLT, selective laser trabeculoplasty		

outflow resistance. The OMNI Surgical System (Sight Sciences) allows practitioners to perform two implant-free procedures and target all three points of resistance with one device. And it also allows us to intervene earlier in the disease state because the device’s indications for use are not restricted by disease severity.

RETROSPECTIVE ANALYSIS

Study design. My colleagues and I recently conducted a study to characterize the reduction in IOP and IOP-lowering medication use following trabeculotomy and viscodilation with the OMNI Surgical System. The procedure was performed as a standalone intervention in eyes with medically uncontrolled mild-moderate open-angle glaucoma (OAG).

A total of 38 eyes (27 patients) were enrolled in this retrospective analysis (Table 1). Patients were approximately 67 years of age, with similar representation of both genders. Most (71%) had POAG of moderate severity (mean cup-disc ratio 0.65, mean visual field mean deviation -3.6 dB), most (74%) were phakic, and 26% had undergone prior selective laser trabeculoplasty.

Patients consecutively underwent MIGS with the OMNI since I began offering the procedure. IOP, medication use, and safety (intra- and postoperative adverse events and the need for additional surgery) data were collected pre-operatively and at every postoperative visit through 12 months of follow-up.

Results. Mean (standard deviation) baseline IOP was 24.6 (3.0) mm Hg. Through 12 months of follow-up, this ranged from 12.6 to 14.7 mm Hg ($P < .0001$ at all time points), representing mean IOP reductions of 10.2 to 12.0 mm Hg (39.8% to 47.9%). Mean medication use was 1.9 (0.7) at baseline; through 12 months of follow-up, this ranged

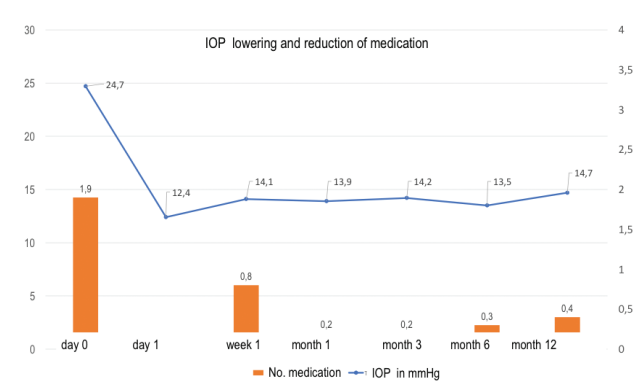


Figure. IOP-lowering effect and reduction of medication with the OMNI Surgical System.

from 0.0 to 0.4 ($P < .0001$ at all time points), representing medication reductions of 1.4 to 1.9 per eye (70.6% to 100%). At Month 12, mean IOP was 14.7 mm Hg, a reduction of 10.1 mm Hg (39.8%; $P < .0001$). Also at that time point, 96.7% of eyes achieved IOP reduction of 20% or more from baseline, and mean medication use was 0.4 medications per eye, representing a reduction of 1.4 medications (70.6%; $P < .0001$). A total of 83.3% of eyes were using at least one less medication than at baseline, and 63.3% were medication-free (Tables 2 and 3 and Figure).

Safety. The most common adverse event in this population of patients undergoing OMNI implantation for better control of IOP was intraoperative hyphema (44.7%); this resolved spontaneously in all cases. A transient lens touch associated with a shallow anterior chamber was seen in one eye (2.6%). No eyes required reoperation during follow-up.

Take-home points. This study confirmed that performing trabeculotomy and viscodilation with the OMNI Surgical

TABLE 2. IOP AND MEDICATION DATA AT EACH TIME POINT							
	Baseline	Day 1	Week 1	Month 1	Month 3	Month 6	Month 12
Number of eyes (n)	38	38	38	38	38	38	30
Mean IOP (SD)	24.6 (3.0)	12.6 (2.3)	13.8 (3.3)	14.0 (2.0)	14.2 (2.0)	14.2 (1.5)	14.7 (1.6)
Change from baseline	---	-12.0 (4.0)	-10.8 (4.1)	-10.7 (3.1)	-10.5 (3.5)	-10.4 (3.4)	-10.1 (3.7)
Percent change from baseline	---	-47.9 (11.7)	-43.4 (14.3)	-42.8 (9.2)	-41.6 (10.2)	-41.4 (9.5)	-39.8 (10.6)
Significance (P)	---	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001
Mean number of IOP-lowering medications (SD)	1.9 (0.7)	0.1 (0.2)	0 (0)	0.1 (0.4)	0.2 (0.4)	0.3 (0.6)	0.4 (0.6)
Change from baseline	---	-1.8 (0.8)	-1.9 (0.7)	-1.8 (0.6)	-1.7 (0.7)	-1.6 (0.9)	-1.4 (1.0)
Percent change from baseline	---	-96.1 (17.9)	-100 (0)	-95.2 (14.4)	-92.5 (21.1)	-80.7 (42.5)	-70.6 (48.3)
Significance (P)	---	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001
Abbreviations: SD, standard deviation							

TABLE 3. SECONDARY IOP AND MEDICATION OUTCOMES AT EACH STUDY TIME POINT

	Day 1	Week 1	Month 1	Month 3	Month 6	Month 12
Number of eyes (n)	38	38	38	38	38	30
Proportion achieving IOP reduction >20% compared to baseline (%)	97.4	97.4	100	97.4	97.4	96.7
Proportion using >1 fewer medication compared to baseline (%)	92.1	71.1	100	97.4	89.5	83.3
Proportion medication-free (%)	84.2	13.2	89.5	86.8	76.3	63.3

System as a standalone procedure provides clinically relevant and statistically significant reductions in both IOP and the IOP medication burden. The study also highlighted the procedure's excellent safety profile and established that it can be considered in phakic or pseudophakic eyes with mild to moderate OAG that require a safe and effective surgical intervention to achieve IOP reduction, medication reduction, or both.

CONCLUSION

Compared to other MIGS procedures, the combination of viscodilation and titrable trabeculotomy with the OMNI Surgical System addresses all three sources of physiological outflow resistance in a standalone procedure, which could result in longer-lasting IOP reduction. ■

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KARSTEN KLABE, MD

- Breyer – Kaymak – Klabe Augenchirurgie Düsseldorf, Germany
- k.klabe@augenchirurgie.clinic



Surgery of the Conventional Outflow Pathway

Treating proximal to distal is best.

BY IMRAN MASOOD, FRCOPHTH

The most important modifiable risk factor for the development and progression of primary open-angle glaucoma (POAG) is raised IOP. Elevated IOP is caused by increased resistance to aqueous humor flow through the conventional outflow pathway.^{1,2} The history of glaucoma surgery is replete with procedures targeting different anatomical structures along the outflow pathway. Surgeons now have the means to target multiple points in the outflow pathway in a safe and effective procedure performed with one single device.

In this article, I explain how the OMNI Surgical System (Sight Sciences, Figure) can be used to perform two distinct implant-free procedures—viscodilation and trabeculotomy—to target all three points of resistance in the conventional outflow pathway thought to be of importance in the pathology of raised IOP.

THREE POINTS OF RESISTANCE

Background. In glaucoma, the three points of resistance affecting the conventional outflow pathway are the trabecular meshwork (TM), Schlemm canal, and distal collector channels. Most of the resistance—somewhere between 50% and 70%—lies within the juxtacanalicular matrix of the TM,³ and potentially up to 50% is within the Schlemm canal and distal collector channels.² The aqueous humor flows out of the eye mainly segmentally, and it flows preferentially down the path of least resistance within the outflow pathway. Canal atrophy, herniation of the inner wall and juxtacanalicular connective tissue into the ostia of collector channels can increase the resistance to flow of aqueous humor within the conventional outflow pathway.⁴

The trabecular meshwork. In the TM, outflow resistance is normally generated in the juxtacanalicular connective tissue