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OMNI Surgical System

One MIGS device.

Two implant-free procedures.

Three points of resistance.



Early Experience With the OMNI Surgical System

Analysis of my first 24 patients.

BY PAOLO BRUSINI, MD

I am an anterior segment surgeon with a special interest in glaucoma surgery. My favorite surgical management techniques are deep sclerectomy and canaloplasty.

The latter procedure is particularly fascinating to me; it offers equivalent IOP-lowering efficacy to traditional filtering surgery without the bleb-related complications. Ab externo canaloplasty is, however, technically challenging to perform. Several innovations over the years have helped to simplify the procedure, including the OMNI Surgical System (Sight Sciences). This technology has once again changed the way we can help our patients to decrease their dependence on medication with a much better safety profile.

BACKGROUND

Some years ago, it was proposed to use an ab interno approach to cannulate and viscodilate the Schlemm canal by using the same type of microcatheter from a standard canaloplasty procedure but without leaving the prolene suture inside the canal. In addition to lowering IOP, another advantage of ab interno canaloplasty is that it leaves the conjunctiva untouched and ready for other surgical interventions, including MIGS procedures.^{1,2} The main drawback of this approach, however, is that it was not easy to perform and required the surgeon to use both hands to manage the microcatheter in the anterior chamber.

The introduction of the VISCO 360 Viscosurgical System (Sight Sciences) and more recently the OMNI Surgical System has dramatically improved the ab interno canaloplasty technique. These devices are specifically designed for ab interno viscodilation of the Schlemm canal, enabling surgeons with experience in angle-based procedures to perform these techniques more efficiently than ever before.³

MY EXPERIENCE

I have been using an ab interno canaloplasty approach for almost 4 years, first with the VISCO 360 and now with OMNI. The technique is extremely efficient and intuitive. The OMNI device is easily inserted into the anterior chamber, through a 1-mm clear corneal incision (Figure 1), with a curved cannula tip filled with a high molecular weight OVD such as Healon GV (Johnson & Johnson Vision) or similar. A gonio lens with or without a handle is placed on the cornea to enable proper visualization of the angle. The tip of the cannula is then moved

across the pupil, toward the iridocorneal angle, and the cannula tip is pressed against the trabecular meshwork (TM) to create a small opening in the Schlemm canal. The microcatheter is then inserted by turning the small wheel located on the handle of the device (Figure 2). Upon retraction of the microcatheter, the OVD is injected in a consistent and measured amount to dilate the Schlemm canal and address any possible herniations or blockages of the distal collector channels.

The catheter is deployed within the Schlemm canal for 180° or one hemisphere at a time (Figure 3). The same maneuver can be repeated in the opposite hemisphere by removing the cannula from the anterior chamber (AC), rotating the cannula 180°, and reentering the AC to treat the remaining hemisphere. Once complete, the surgeon has circumferentially dilated the entirety of the canal. After completing the viscodilation, the cannula is then removed from the anterior chamber and the OVD is forced out by injecting balanced saline solution until it has been completely removed.

Since transitioning to the OMNI device from VISCO 360 2.5 years ago, I have already performed 24 procedures. I have been extremely impressed with early results, which I share below.

LEARNING CURVE AND POINTERS

The learning curve for the average surgeon is quite short. The only difficulties, at the beginning, are related to the use of the gonio lens, which the surgeon should quickly get used to, and the opening of the Schlemm canal to introduce the tip of the device. After a few operations, the procedure becomes easy and can usually be completed in less than 10 minutes.

Ab interno canaloplasty can be successfully combined with phacoemulsification^{4,5} and other MIGS procedures.⁶ The mid-term results with VISCO 360/OMNI canaloplasty are encouraging. In the 35 standalone surgeries of this type that I

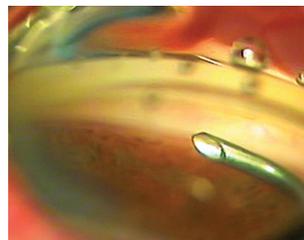


Figure 1. The curved cannula tip in the anterior chamber.

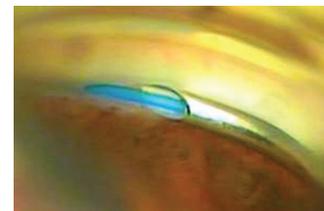


Figure 2. The microcatheter enters into the Schlemm canal, which was previously opened with the tip of the cannula.



Figure 3. The microcatheter is completely inserted in one half circumference of the Schlemm canal.

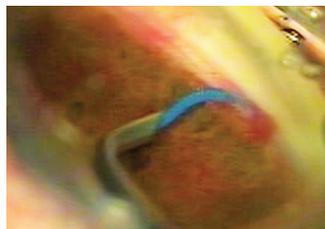


Figure 4. The microcatheter is removed, producing an ab-interno trabeculotomy.

have performed, all were done in pseudophakic patients. The main indications were primary open-angle glaucoma and pseudoexfoliation glaucoma that was insufficiently controlled with medical therapy. Most patients had mild to moderate glaucoma. I have also performed the procedure in eyes with a previous failed trabeculectomy or deep sclerectomy.

The OMNI device can be used not only to dilate the Schlemm canal but also to perform an ab interno titratable trabeculotomy. This is achieved by pulling the microcatheter through the TM to unroof the tissue, creating a direct path for the outflow of aqueous through the Schlemm canal and distal collector channels (Figure 4).

The trabeculotomy can be performed in both hemispheres, opening the Schlemm canal for 360°, or can be titrated to one (180°) or even a portion of one hemisphere (~90°). An important benefit of the OMNI Surgical System is that the amount of trabeculotomy performed can be titrated to match the surgical plan for patients. Slight reflux in the anterior chamber is usually observed after this maneuver and can sometimes disturb visibility of the angle, especially if both sections of the canal have been opened. For this reason, I prefer to perform trabeculotomy in one hemisphere of the canal only.

I have also performed the procedure in eyes with a previous failed trabeculectomy or deep sclerectomy. The mean preoperative IOP of all operated cases was

24.8 ±5.6 mm Hg (range, 16-40 mm Hg) with an average of 3.1 medications. The IOP values after 6 and 12 months were 17.3 ±5.0 mm Hg (range, 7-34 mm Hg) and 17.2 ±3.6 mm Hg (range, 14-26 mm Hg), respectively, with an average of 1.4 and 1.7 medications, respectively. Mean IOP reduction after 6 and 12 months was 7.5 mm Hg (30.2%) and 7.6 mm Hg (30.6%), respectively. Seven eyes required a reoperation over time because of insufficiently controlled IOP.

An additional benefit of ab interno canaloplasty is that it could likely be repeatable if the TM is still intact. If a patient does not achieve the target IOP or medication reduction, a repeat procedure could be attempted. Of course, canaloplasty is not possible when an ab interno trabeculotomy was combined with canaloplasty. Even in that case, however, using the OMNI preserves the ability to move to more aggressive procedures such as deep sclerectomy or, in rare cases, a trabeculectomy.

CONCLUSION

I have had a positive early experience with the standalone ab-interno canaloplasty and partial trabeculotomy procedure with the OMNI device. Careful patient selection, however, is crucial for the success of this safe, effective, and efficient procedure. ■

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Implant-Free IOP Reduction Targeting All Points of Outflow Resistance

The OMNI procedure can be performed in combination with cataract surgery and as a standalone intervention.

BY FRITZ H. HENGERER, MD, PHD

Glaucoma is a complex disease that can lead to progressive and irreversible vision loss if left untreated. Its cardinal risk factor is elevated IOP due to increased outflow resistance in the conventional outflow pathway. Aqueous angiography studies have shown that, in addition to the trabecular meshwork

(TM) and Schlemm canal, outflow resistance also occurs through the distal collector channels.¹ Procedures that target all three areas of resistance provide patients with the best chance of controlling IOP and combatting glaucoma progression, but some are more invasive—and therefore riskier—than others.

Combined ab interno trabeculotomy and viscodilation of the Schlemm canal is a novel surgical approach that targets both proximal and distal points of resistance in the conventional outflow pathway in a single, implant-free, minimally invasive procedure. The OMNI Surgical System (Sight Sciences) can be used either in a standalone surgical procedure or in combination with cataract surgery to significantly reduce IOP from baseline levels. This article highlights its usefulness as a highly efficacious MIGS procedure.

BACKGROUND

When performing any glaucoma procedure, identifying where resistance occurs in the conventional outflow pathway can be challenging. Addressing the TM alone, or isolating a single point, may not be enough to achieve the desired IOP-lowering effect. The possibility of resistance occurring at any point suggests that a surgical option that addresses all three points of possible resistance (TM, the Schlemm canal, and the distal collector channels) may offer the best chance of surgical success.

Today, a novel MIGS approach that targets all three points of resistance is available. The OMNI Surgical System allows surgeons to combine ab interno trabeculotomy with viscodilation in an easy-to-perform, safe, and efficacious procedure that consistently and predictably lowers IOP in patients with open-angle glaucoma. OMNI can be performed in combination with phacoemulsification or as a standalone procedure, and it is titratable based on patient needs and surgeon preferences. It can be used in patients with mild, moderate, and severe primary and secondary open-angle glaucoma.

A STEPWISE APPROACH

I use a stepwise approach for management of open-angle glaucoma. The OMNI procedure closes the gap between conservative glaucoma therapy with eye drops and invasive stenting procedures that are typical in Schlemm canal surgery. I have been using the OMNI Surgical System for 4 years and find that it represents a psychological stepladder for my glaucoma patients who decide not to have conventional surgery because it is too invasive and risky.

I typically use the OMNI in patients with mild to moderate glaucoma (IOPs between 15 and 20 mm Hg), which is most of the glaucoma patients I treat. In patients with early-stage glaucoma, I perform the viscodilation portion of the procedure only to address the Schlemm canal and to enhance the natural outflow by reducing the resistance in the collector channels. The channel is widened with a viscoelastic alone, not by introducing a stent or other foreign body.

In patients with more severe open-angle glaucoma, I perform both the viscodilation and trabeculotomy portions of the OMNI procedure to simultaneously lower the resistance in the TM, the Schlemm canal, and the collector channels.

ADVANTAGES

There are several advantages of the OMNI procedure.

► **Advantage No. 1: It provides the opportunity for more consistent IOP-lowering outcomes.** The OMNI procedure addresses all three points of potential resistance in the conventional outflow pathway: the TM, Schlemm canal, and collector channels. This provides the opportunity to produce more consistent results, especially in combined cataract and MIGS cases.

► **Advantage No. 2: It creates the potential to use the procedure in a standalone fashion in a certain population of patients.** This includes patients who are not willing or able to use eye drops, pseudophakic patients with glaucoma, younger patients without cataract, and patients with a history of failed glaucoma surgery such as trabeculectomy.

► **Advantage No. 3: It is an implant-free system.** I like that the OMNI procedure ensures that the natural pathway for the outflow of aqueous humor is open without introducing a foreign body into the eye. I leave nothing permanently in the eye—only a viscoelastic is introduced into the eye, which disappears relatively quickly. No other technology is available today, besides a stent, that can widen the collector channels and create the potential opportunity to lower the IOP by restoring outflow.

► **Advantage No. 4: The OMNI Surgical System spares the conjunctiva and sclera.** Therefore, it becomes possible to perform other glaucoma surgeries in the future as needed.

► **Advantage No. 5: It produces consistent results in both combination surgery and in standalone procedures.** In our experience, the OMNI Surgical System produces similar results to stenting procedures, and this is true whether the surgery is combined with cataract surgery or performed in a standalone procedure. The benefit of a combined procedure, of course, is that we can enhance patients' quality of life twofold, by lowering their IOP and by providing better quality of vision, in a single procedure.

Interestingly, cataract surgery can indeed lower IOP on its own; however, its effect is minimal, at best only 1 or 2 mm Hg. In most glaucoma patients, this decrease is not significant enough to alter their need for glaucoma drops or therapy. Most of the lowering potential of a combined procedure originates from introduction of the stent² or from the OMNI procedure. Once the TM is opened and the Schlemm canal is functioning properly, the IOP will begin to decrease more significantly.

► **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 trabeculectomy 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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Standalone Trabeculectomy 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, trabeculectomy, 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 preoperatively 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 from 0.0 to 0.4 ($P < .0001$ at all time points), representing

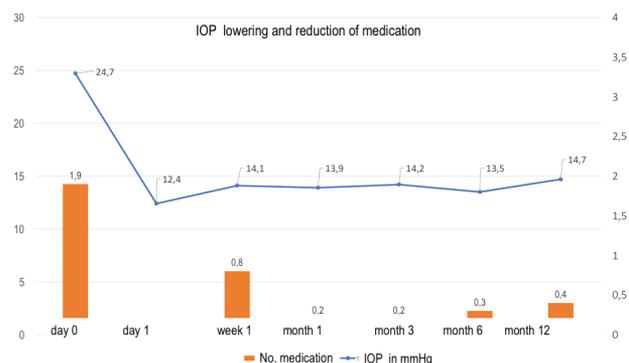


Figure. IOP-lowering effect and reduction of medication with the OMNI Surgical System.

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 (<i>P</i>)	---	<.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 (<i>P</i>)	---	<.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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Surgery of the Conventional Outflow Pathway

Treating proximal to distal is best.

BY IMRAN MASOOD, BSC, MB CHB, MRCS(ED) 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

Anterior Segment Procedures with the OMNI® Surgical System
Combines Two Distinct Implant-free Procedures in One Device

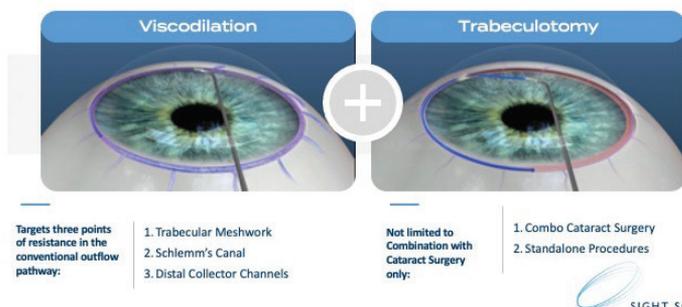


Figure. The OMNI Surgical System combines ab interno viscodilation with ab interno trabeculotomy.

and is modulated by endothelial cells in the inner wall of Schlemm canal.^{2,5-7}

The Schlemm canal. This part of the outflow pathway is a vascular channel that is believed to emanate from venous and lymphatic origins. As aqueous humor drains from the Schlemm canal, it travels into the intrascleral plexi and aqueous veins. Increased stiffness of the endothelial cells in the inner Schlemm canal wall and narrowing and collapse of the canal itself contribute to increased outflow resistance.⁸⁻¹¹ It is important to note that the Schlemm canal is not a perfect cylindrical tube but rather varies in size; the most outflow resistance generally occurs in the narrowest parts of the canal. Further, it is likely that the conjunctival lymphatic system plays a role in the conventional outflow pathway.

Distal collector channels. These channels connect the Schlemm canal to different points of the outflow pathway. Compared to normal controls, eyes with POAG have decreased blood reflux into the Schlemm canal. They also have an increased number of herniations of juxtacanalicular connective tissue and inner-wall tissue that partially or completely obstruct the collector channel ostia.⁴ This likely contributes to the increased outflow resistance and consequently elevated IOP.¹²

CHOOSING A PROCEDURE

There is increasing evidence that the areas of outflow resistance can vary depending on the type of glaucoma. This notion is extremely relevant when considering what type of procedure to perform. Further evidence has shown that, in high-pressure situations, the internal aspect of the TM can herniate into the collector channels. Therefore, when addressing the pathology of glaucoma, the situation is far more complex than simply bypassing the TM.

This is where the advantages of the OMNI Surgical System are realized because the procedure targets all three points of

resistance—the TM, Schlemm canal, and distal collector channels.

The procedure can be performed in a standalone fashion or in conjunction with cataract surgery to treat ocular hypertension, mild to moderate and more advanced glaucoma. The goals of the surgery are to reduce canal herniations, dilate the distal collector channels, and provide the option of an ab interno trabeculotomy. Further, compared with trabeculectomy and tube shunts (traditional glaucoma incisional surgeries that are highly effective but also come with higher rates of complication¹³), employing the OMNI device is less risky and spares the conjunctiva for future drainage surgery. One of the other advantages is that it is easy to access the

Schlemm canal with the OMNI device obviating the need for a large incision into the TM.

CONCLUSION

With the OMNI Surgical System, we can rejuvenate the entire outflow system. In my opinion, the greatest advantage of the OMNI is that it can be used to perform a trabeculotomy and canaloplasty to increase outflow facility and address all the potential points of resistance without leaving a device in the eye. ■

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INDICATIONS FOR USE: The OMNI Surgical System is indicated for the catheterization and transluminal viscodilation of Schlemm's canal and the cutting of trabecular meshwork to reduce intraocular pressure in adult patients with open-angle glaucoma.

For important safety information including contraindications, warnings, precautions and adverse events, please visit omnisurgical.com.

Doctors are paid consultants for Sight Sciences, Inc.