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Unparalleled Versatility in Implant-Free MIGS

A panel discussion and case studies on the OMNI® Surgical System.

Dan Lindfield, BM, PGCME, FRCOphth

Andrew Tatham, MD, MBA, FRCOphth, FEBO, CertLRS

Francesco Stringa, MD, MRCOphth, FEBOS-GL

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PANELISTS

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INTRODUCTION

The OMNI Surgical System (Sight Sciences) provides the opportunity for clinicians to perform a MIGS procedure that combines three mechanisms—ab-interno canaloplasty, distal outflow dilation, and trabeculotomy—into a single surgery. It can address and alleviate the three sources of outflow resistance in the conventional outflow pathway, which, from proximal to distal, include the trabecular meshwork, Schlemm's canal, and collector channels. The procedure leaves no implant behind.

The OMNI procedure is versatile. The trabeculotomy and canaloplasty procedures can be performed sequentially in a single surgery, allowing the treatment of up to 360° of Schlemm's canal. Alternatively, canaloplasty can be performed on its own. OMNI can also be performed in combination with cataract surgery or as a standalone procedure.

The handheld instrument (Figure) includes a cannula, a microcatheter for viscodilation and cutting tissue, an internal reservoir for OVD, and a finger wheel for advancing the microcatheter into the Schlemm's canal. Most surgeons report a short learning curve with the device.

The following dialogue from three surgeons who have amassed significant early experience with the OMNI Surgical System helps substantiate the value of the implant-free procedure in everyday clinical practice. Each panelist also provides a case study to illustrate the different ways in which the OMNI can be used.

Figure. The OMNI Surgical System.

How long have you been using the OMNI Surgical System in your practice?

Dan Lindfield, BM, PGCME, FRCOphth: I was fortunate enough to be one of the first surgeons in the United Kingdom to use OMNI. I now have 2 years of experience with the procedure, and at the time of the interview performed just shy of 100 cases. Most of these cases were for patients with mild to moderate open-angle glaucoma. I have performed OMNI both as a combined procedure with phacoemulsification and as a standalone procedure. Most often, I combine it with cataract surgery. The results patients have had thus far have exceeded what I can achieve with other devices that treat only the trabecular meshwork with a similar safety profile.

Andrew Tatham, MD, MBA, FRCOphth, FEBO, CertLRS: I've been using the OMNI Surgical System for about 18 months. Before then,

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– Francesco Stringa, MD, MCOphth, FEBOS-GL

I used a range of Schlemm's canal–based MIGS procedures to remove trabecular meshwork and increase aqueous humor outflow into the aqueous veins. What attracted me to OMNI, however, is that it's an implant-free option with three mechanisms of action (ab-interno canaloplasty, distal outflow dilation, and trabeculotomy). I like that it addresses the three sources of outflow resistance in the conventional outflow pathway and that I can complete two IOP-lowering procedures in one surgery.

Francesco Stringa, MD, MCOphth, FEBOS-GL: Viscocanaloplasty and trabeculotomy are two well-established procedures for the treatment of open-angle glaucoma. They are part of the MIGS universe. I like that OMNI combines both into a single implant-free procedure. I started using OMNI in the beginning of 2022. I appreciate that I can treat different degrees of the trabecular meshwork and that I can combine two different procedures into one surgery.

What do you see as the key benefits of the OMNI system?

Dr. Lindfield: For me, the key benefit is that I see and feel when I'm in the right place in Schlemm's canal. This gives me the confidence that, as the microcatheter slides into the canal, I am treating the target tissue that I want to treat. I think this differentiates OMNI from other devices that don't provide physical or visual feedback. Furthermore, I like that the device allows me to adjust the extent of the treatment that I can achieve with one device by treating either 180° or 360° of Schlemm's canal and that I can either spare or cut the trabecular meshwork. I regularly treat 360° of Schlemm's canal and trabecular meshwork, and the beauty of the OMNI Surgical System is it does so without leaving a device behind in the eye.

Dr. Tatham: Compared to other MIGS procedures, there are several advantages with OMNI. The first is that no device is left in the eye. Second, it can be performed as a standalone treatment or combined with cataract surgery, and it is customizable to the patient. Third, I like that I can choose how many degrees to treat with canaloplasty alone or combined with trabeculotomy, and I can do so depending on the patient's needs.

Dr. Stringa: I agree with Drs. Lindfield and Tatham that a main advantage is that I can choose how many degrees of treatment I want to perform. It's also extremely beneficial that two different

CASE STUDY NO. 1

Presented by Dan Lindfield, BM, PGCME, FRCOphth

A 72-year-old man presented with moderate primary open-angle glaucoma about 5 years ago. At that time, his IOP was 23 mm Hg, and he was on two medications. The patient underwent combined phacoemulsification with a trabecular meshwork bypass stent. Postoperatively, his IOP reduced to 15 mm Hg with two medications but rose to 18 mm Hg when we reduced his medications to one. His IOP remained at 18 mm Hg for approximately 18 months to 2 years. After that time, the patient's IOP slowly crept up to 21 mm Hg on two medications with evidence of glaucoma progression on OCT.

The patient was very keen about a minimally invasive surgical option and wanted to have the same quick return to daily activities that he experienced after surgery in 2018. A standalone pseudophakic OMNI procedure was planned. During surgery, a 360° viscocanaloplasty without trabeculotomy was successfully performed. The microcatheter was inserted (Figure) between two trabecular bypass stents and slid behind them smoothly with no feeling of obstruction and minimal stent movement. The microcatheter was able to pass through Schlemm's canal both left and right. The trabecular stents were left in situ because they were believed to be functioning as suggested by the initial IOP reduction in 2018. It was suspected, however, that they may not be fully in canal.

One month after OMNI, the patient's IOP was 13 mm Hg on one medication. At 6 months, he was off medication completely, and the IOP was 16 mm Hg. At 1 year, the IOP was 17 mm Hg, and the patient remained off any medication.

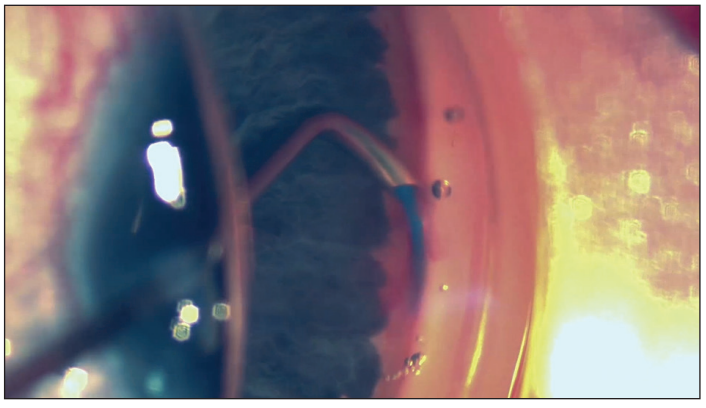

Figure. The OMNI microcatheter is inserted.

CASE STUDY NO. 2

Presented by Francesco Stringa, MD, MRCOphth, FEBOS-GL

A 67-year-old White woman with a family history of glaucoma (father) underwent uneventful cataract surgery in her right eye. A 22.50 D IOL was implanted, and the refractive target was emmetropia. The standard postoperative treatment included guttae chloramphenicol 0.5% four times a day for 2 weeks and guttae dexamethasone 0.1% four times a day for 4 weeks.

At the 4-week postoperative visit with her local optician, the patient's IOP was 41 mm Hg OD and 20 mm Hg OS. There were no signs of infection or active inflammation. The patient was referred to the hospital eye service, where topical treatment with guttae latanoprost once a day, guttae apraclonidine 1% three times a day, fixed combination guttae dorzolamide and timolol 2%/0.5% twice a day, and oral acetazolamide 250 mg three times a day was initiated. The iridocorneal angle was fully open upon gonioscopy; the visual acuity was 6/7.5 OU, and the central corneal thickness was 539 µm OD and 542 µm OS. The visual field test (Humphrey 24-2) and the retinal nerve fiber layer on OCT showed no clinically significant abnormalities in either eye. Diagnosis of steroid response was made based on the clinical information.

After 1 week, IOP in the right eye decreased to 25 mm Hg, but the patient reported significant side effects with the oral acetazolamide, including an extreme sense of fatigue and loss of appetite, which could not be tolerated. Oral acetazolamide was stopped and guttae brimonidine 0.2% twice a day in the right eye was added to the topical treatment course.

At 3 weeks, IOP in the right eye increased to 29 mm Hg despite the use of four glaucoma agents. The right conjunctiva was hyperaemic with signs of ocular surface disease potentially linked to the multiple topical drug therapy. The patient reported discomfort and a subjective deterioration of vision in her right eye. At that time, the patient was offered surgical treatment, including ab-interno viscocanaloplasty/trabeculotomy with OMNI.

The patient elected to undergo 360º viscocanaloplasty and 180º trabeculotomy inferiorly (Figures 1 and 2). No significant intraoperative complications were encountered.

On day 1 postoperative, IOP in the right eye was 19 mm Hg. The presence of red blood cells was noticed, and there was minimal inflammation in the anterior chamber. The patient expressed good comfort, and visual acuity in the right eye was 6/12. Topical treatment included guttae chloramphenicol 0.5%, guttae dexamethasone 0.1% four times a day, guttae dorzolamide and timolol, and guttae apraclonidine 1%.

Two weeks later, IOP in the right eye was 17 mm Hg with no anterior chamber cell activity. Visual acuity in that eye was 6/7.5. Guttae dexamethasone 0.1% was reduced to three times a day for 1 week, then twice a day for 2 weeks, and finally once a day for 2 weeks. Guttae apraclonidine 1% was stopped, but guttae dorzolamide and timolol were continued.

By 8 weeks postoperative, the IOP in the right eye was 15 mm Hg. There were no signs of inflammation, and the patient reported good comfort and stable visual acuity. At this stage, the only topical drug in use was guttae dorzolamide and timolol, which was discontinued. Consecutive 4-week checks revealed right eye IOPs of 18 mm Hg with no topical treatment, good comfort, and stable visual acuity.

This case shows a significant steroid response following uneventful cataract surgery. Steroid responses may present with different magnitude. About 5% of healthy adults develop an IOP increase of more than 15 mm Hg following the use of topical steroids. People with glaucoma or a family history of glaucoma are at higher risk for developing a significant steroid response. The mechanism of the response involves both intra- and extracellular changes in the trabecular meshwork. These are usually reversible but may lead to trabecular sclerosis, sustained high IOP, and, if left uncontrolled, glaucomatous damage.

Targeting the trabecular meshwork addresses the pathophysiological mechanism and therefore treats increased IOP at its root. Ab-interno viscocanaloplasty/trabeculotomy with OMNI is an effective and minimally invasive treatment for steroid-induced glaucoma and can significantly reduce both IOP and the need for glaucoma drops.

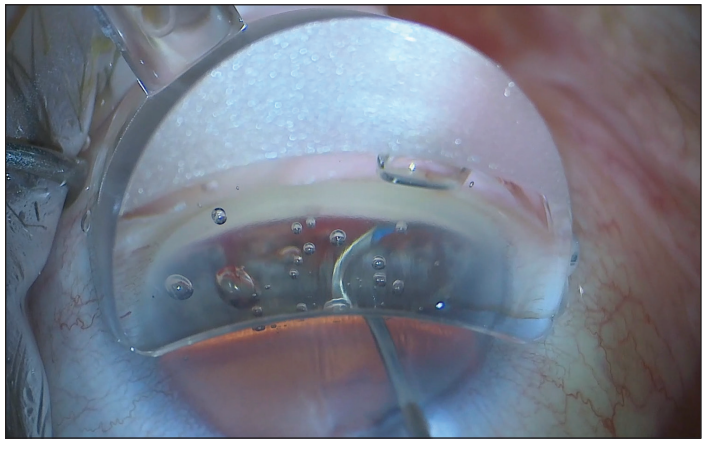

Figure 1. An inferonasal trabeculotomy was performed.

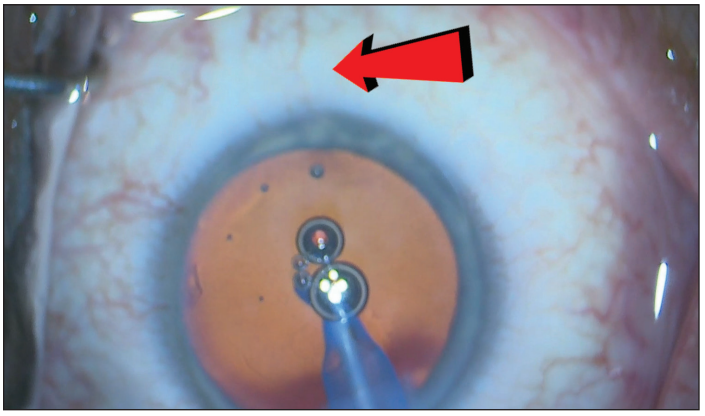

Figure 2. Blanching of the episcleral vessels (red arrow) is seen during irrigation/aspiration, confirming improved drainage and decreased resistance of the collector channels.

types of procedures can be performed with the same device. I can plan whether I want to treat 360º of Schlemm's canal, perform a viscocanaloplasty alone, or plan a combined viscocanaloplasty/trabeculotomy procedure.

How would you describe the ease of use of OMNI?

Dr. Lindfield: My learning curve with OMNI was similar to other MIGS procedures I have experience with. Additionally, there are translatable skills. I think for those who have used a trabecular microbypass device, OMNI would be a perfect fit for their practice. The handpiece is nicely designed, and I find that it slides into Schlemm's canal neatly and nicely. I tilt the handpiece upward about 30º, as a flat position can lead to the device diving down toward the iris. The tactile and visual feedback that OMNI provides helps me know I'm treating the right area. I don't always feel that with other devices.

Once inserted in Schlemm's canal, it only takes a few cases to get used to how to advance the OMNI device smoothly and carefully. If the catheter meets resistance momentarily, I retract the wheel slightly. It should then slide into Schlemm's canal easily without resistance.

Dr. Tatham: I position the handpiece similarly to Dr. Lindfield. I angle the device at about 20º, and I aim for the roof of Schlemm's canal so that the microcatheter brushes across the roof and passes through the canal without resistance. It took some practice for me to balance movement of the device's wheel to retract the microcatheter in a controlled manner during trabeculectomy. I learned that shortening the catheter slightly and pausing between movements ensures successful completion of the maneuver.

Overall, I find the OMNI Surgical System fairly easy to use. The length of the learning curve depends on the clinician's previous exposure to Schlemm's canal–based MIGS procedures. As with any MIGS procedure, it's important to have a good grasp of intraoperative gonioscopy to ensure good visualization.

The ideal position for the patient's head is to be turned away from the surgeon about 30º to 40º. The microscope should be positioned toward the surgeon by a similar number of degrees. Consider practicing these positions in patients who may not even need a MIGS procedure. Once these basics have been grasped, I think performing OMNI is just like performing other canal-based MIGS procedures.

Dr. Stringa: The OMNI procedure requires approximately 10 to 20 initial cases to become confident and efficient with the device. I agree with what Drs. Lindfield and Tatham have shared. Positioning of both the patient and microscope and being comfortable with intraoperative gonioscopy are extremely important for the procedure, as is having a clear view of the trabecular meshwork. In fact, placing the catheter correctly in Schlemm's canal as soon as the trabecular meshwork is engaged by the cannula tip is the key for a successful procedure. With these things mastered, the safety profile with OMNI is comparable to other ab-interno MIGS devices.

In your opinion, what patient groups make good candidates for OMNI?

Dr. Lindfield: The ideal candidate for OMNI is someone with mild to moderate open-angle glaucoma. Consider starting with patients who present with pigmented angles because it is easier to identify landmarks than in eyes with pale angles. Additionally, look to perform OMNI first as a combined procedure with phacoemulsification or in pseudophakic patients to reduce concerns about touching the crystalline lens.

Dr. Tatham: Because OMNI can be used as a standalone procedure or combined with cataract surgery, it can be a good option for a broad range of scenarios (Editor's note: the sidebars by Drs. Lindfield, Tatham, and Stringa include examples of scenarios for which they chose the OMNI Surgical System). Personally, I think the procedure is a good option for patients with concomitant cataract and glaucoma who wish to potentially reduce the medication burden. These patients often also have ocular surface disease. Compliance is a problem for patients on multiple medications, and their quality of life improves drastically after OMNI surgery when the medication burden is reduced. Another scenario in which I find OMNI useful is in phakic patients who have suboptimal IOP control. In these patients, I often perform OMNI as a standalone procedure.

In my early experience with OMNI, I selected cases that I knew I would have a good view of the angle. This helped me learn how to place the microcatheter in

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– Dan Lindfield, BM, PGCME, FRCOphth

the correct location and move it along the correct path. The bright blue color of the microcatheter helps with tracking its course, especially over the first 60° to 70°.

Dr. Stringa: As mentioned previously, the views of the angle and trabecular meshwork is important. Therefore, ideal candidates for the OMNI procedure are those with open angles and, particularly for the first cases, those with a well-defined angle anatomy. In terms of glaucoma stage, good candidates are those with early to moderate glaucoma and a target IOP in the mid to low teens. ■

CASE STUDY NO. 3

Presented by Andrew Tatham, MD, MBA, FRCOphth, FEBO, CertLRS

The following case illustrates successful use of OMNI (Sight Sciences) to perform a 360º canaloplasty and 180º trabeculotomy in a patient with primary open-angle glaucoma (POAG).

A 52-year-old woman presented with POAG in both eyes, but the diagnosis was worse in the left. At presentation, IOP was 25 mm Hg OU, and corneal thickness was average. The introduction of topical therapy with a prostaglandin analogue achieved a decrease in IOP to 18 mm Hg in the left eye. A topical beta-blocker was added as a fixed-dose combination, and a further reduction in IOP to 16 mm Hg was achieved. The patient was monitored over the subsequent 4 years without any significant change in retinal nerve fibre layer (RNFL) thickness or visual field (Figure 1A). IOP in the left eye remained between 15 and 17 mm Hg during this period.

Six years after presentation, however, IOP in the left eye was 23 mm Hg despite apparently good adherence and substantial progression on visual field testing (Figure 1B). The mean deviation had declined from -2.39 dB in 2020 to -5.82 dB in 2022. There was paracentral involvement and evidence of significant progressive RNFL thinning on OCT. The visual acuity had also declined to 6/9, improving with pinhole to 6/6. An early nuclear sclerotic cataract was evident. In the left eye, a myopic shift with the spherical equivalent refraction was noted (-3.50 D of sphere in 2020 to -5.00 D of sphere in 2022). The patient was still driving due to the relatively well-preserved visual field in the right eye. Options for treatment including adding a third medication, performing selective laser trabeculoplasty (SLT), and performing trabeculectomy were discussed with the patient. The last was considered an option given the degree of progression, paracentral involvement, relatively young age of the patient, and low target IOP. The patient was not keen to take additional medication due to symptoms of dry eye disease. When the patient learned that SLT would probably not offer a good long-term option, she expressed the desire for more immediate and sustained IOP lowering.

We decided to combine cataract surgery with a canal-based MIGS procedure. The patient was well informed of the options and preferred to avoid the use of an implant-based treatment and the chance for a substantial IOP drop, which would be greater with a 360º treatment. Cataract extraction combined with 360º canaloplasty and 180º trabeculotomy was performed using the OMNI system (Figure 2).

Postoperatively, the fixed-dose combination medication was continued to achieve a low target IOP with such a high preoperative IOP. Topical dexamethasone eye drops were prescribed twice hourly for 1 week and then four times per day for 4 weeks. On day 1, week 1, and month 1, IOP was 12 mm Hg, 11 mm Hg, and 13 mm Hg, respectively. The patient was still using topical dexamethasone. At 6 months, IOP in the left eye was 12 mm Hg, and it remained stable at the 12-month review, though the fixed-dose combination medication was continued. The patient's UCVA improved to 6/6 with emmetropia targeted and achieved. The visual field remained stable.

It remains to be seen whether this patient might still require a filtering procedure in the future, but canaloplasty/trabeculotomy combined with phacoemulsification enabled safe removal of the cataract and a substantial reduction in IOP that was sustained at least in the medium term. The patient has subsequently undergone the same procedure in the right eye.

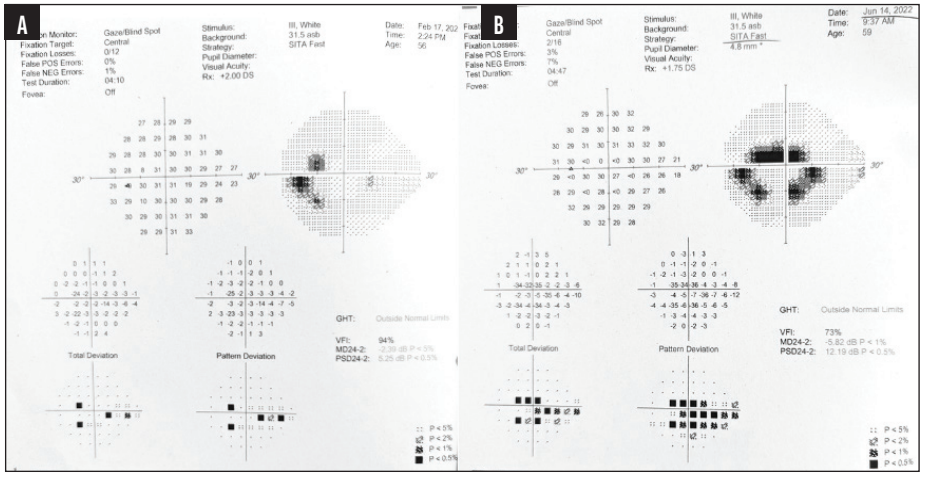

Figure 1. Visual field tests at ages 56 (A) and 59 (B) showing marked progression with paracentral involvement (tested with contact lenses).

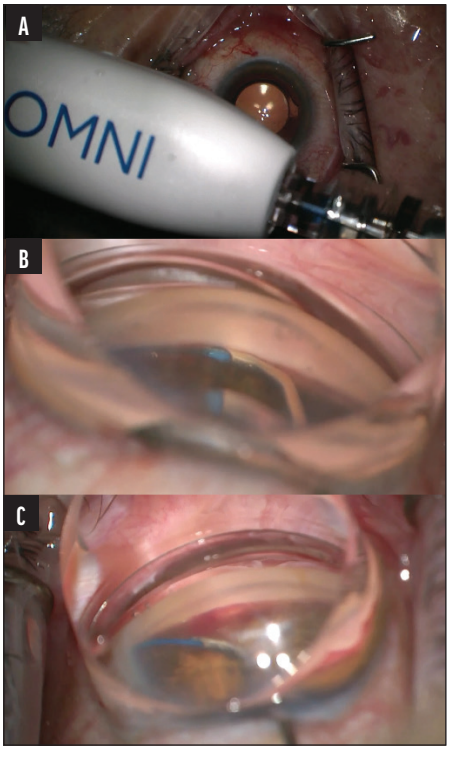

Figure 2. Photographs from the surgical video showing the OMNI device being primed with a cohesive OVD (A), entry of the OMNI catheter into Schlemm's canal and canaloplasty (B), and trabeculotomy with withdrawal of the microcatheter and deroofing of Schlemm's canal (C).

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IMPORTANT PRODUCT INFORMATION:

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

Surgeons are paid consultants of Sight Sciences

This information is intended solely for the use of ophthalmic clinicians - Patients should contact their eyecare professional.