Chapter

Ab-Interno Canaloplasty and Ab-Interno Canaloplasty/ Trabeculotomy in Glaucoma Patients Using the OMNI Surgical System

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Abstract

Eyes with Primary Open Angle Glaucoma (POAG) show anatomical changes within the trabecular outflow tract that increase aqueous humor outflow resistance and thus Intraocular Pressure (IOP). In these glaucomatous eyes, approximately 50–70% of the total outflow resistance is attributed by changes in the tissue of the Trabecular Meshwork (TM) and 30–50% by changes in Schlemm's canal and/or the collector canals. In the last decade, a number of Minimally Invasive Glaucoma Surgeries (MIGS) have been developed to target the different tissue changes particularly. For example, goniotomy, trabeculotomy, and trans-TM implants target TM resistance, whereas canaloplasty, viscodilation, and stenting procedures target Schlemm's canal and collector channels. Therefore, a procedure targeting multiple pathways of aqueous humor outflow might be more effective in lowering IOP. In a limited number of studies to date using the OMNI Surgical System either combined with phacoemulsification or as standalone system, IOP reductions of 20–35% and medication reductions of 25–75% have been reported. In this chapter, the experience in performing canaloplasty/trabeculotomy of Schlemm's canal and distal collector channels using the OMNI Surgical System is described.

Keywords: primary open-angle glaucoma, canaloplasty, trabeculotomy, OMNI Surgical System

1. Introduction

Glaucoma is still the second leading cause of blindness. The most important risk factors for glaucoma-related blindness are the severity of the disease at diagnosis, bilateral disease, and age. Currently, the only effective approach to preserving visual function in glaucoma is the reduction of the intraocular pressure (IOP) [1]. The first-line therapy for lowering intraocular pressure is usually the administration of medication in the form of eye drops. Poor compliance and tolerability can sometimes lead to

treatment failure. For progressive glaucoma with surgical intervention, ab-externo filtration surgery is still considered the gold standard, but the procedure can lead to significant complications [2].

Within the last decade new surgical procedures have been established, which are summarized under the term Minimally Invasive Glaucoma Surgery (MIGS). MIGS have been developed as safer and less traumatic surgical interventions for patients with mild to moderate glaucoma or who are intolerant to standard medical therapy. They are characterized by an ab-interno approach, inducing minimal trauma and disruption of eye anatomy with conjunctiva sparing and a rapid recovery [3, 4]. These surgical procedures play an increasing role in the care of patients with mild to moderate glaucoma. To improve physiologic outflow, a variety of different glaucoma surgeries target the structures in the chamber angle.

The implementation of the therapeutic goal varies from patient to patient and requires the use of individual procedures to achieve maximum intraocular pressure reduction. Compared to trabeculectomy with the use of cytostatics, the achievable pressure reduction with MIGS is usually slightly lower. However, the major advantage of MIGS is the significantly improved intra- and postoperative complication rate. In addition, more individualized glaucoma therapy is possible due to the broad spectrum of MIGS procedures available today.

The OMNI Surgical System (Sight Science) is a single-handed device.

designed to introduce pre-dosed viscoelastic fluid into Schlemm's canal and incise trabecular meshwork tissue with a microcatheter. The device integrates an access cannula, a microcatheter, an internal fluid resorvoir, and a wheel mechanism for advancing and retracting the catheter. The device allows stretching of Schlemm's canal and trabeculotomy in the entire circumference (2 × 180°) by ab-interno technique with a single clear cornea incision [4]. This feasible combined surgery of trabeculotomy and viscodilation ab-interno was a new approach for which the device was developed and has been on the market since 2018 (original clearance Dec 21, 2017; updated August 11, 2020 and March 1, 2021) by the US Food and Medication Administration) [5].

1.1 Medical therapy and the problem of patient adherence to therapy

The target of currently available glaucoma medications is to preserve visual function by lowering intraocular pressure to prevent further damage to the optic nerve. Glaucoma is a chronic disease, so medication or non-medication therapy is a long-term treatment. This requires continuous and reliable cooperation of the patient (adherence). One of the difficulties of glaucoma is the asymptomatic nature of the disease in the early stages of the disease. Initial visual field defects are not yet perceived or they are compensated by the other eye. To improve patient adherence, persistence, and concordance, a high level of organization and motivation is required, both on the part of the physician and the patient. This is especially true when the patient does not directly perceive the effect of therapy due to the asymptomatic nature of glaucoma. The non-administration of medication leads to a stronger progression of glaucoma. Since overall adherence to medical therapy is rather poor, especially in glaucoma patients, good cooperation between physician and patient is beneficial for successful therapy. For example, a 2005 publication showed that only 50% of patients with newly diagnosed open-angle glaucoma attended immediate follow-up examinations. After 24 months, only 30% of patients adhered to the proposed medicinally treatment plan [6, 7].

Currently, there are a large number of publications describing a variety of problems and difficulties in taking glaucoma medications, these range from the number of medications to the drip mechanism to the affordability of the medications. Further publications deal with modern control mechanisms for adherence to the drip schedule (e.g., reminder via phone-app) [8–11]. In summary, a complicated treatment regimen with multiple different medications is counterproductive to increasing patient adherence; the simpler the treatment regimen, the more likely patients are to adhere to it. Surgical interventions such as MIGS are one way to reduce multiple medication administration.

1.2 Surgical interventions and minimally invasive glaucoma surgery (MIGS)

If medication treatment proves insufficient to achieve the targeted IOP or the drops are not well tolerated, laser or surgical treatment must be considered to prevent irreversible progression of the glaucomatous damage.

In the EGS guidelines [1], the indication for a glaucoma surgery is described as follows: Surgery should be considered whenever medical or laser treatment is unlikely to maintain sight in the glaucomatous eye. It should not be as a last resort. The indications for the different surgical techniques depend on the type of glaucoma, the target pressure, the medical history, the patients' risk profile, preferences and experience of the surgeon, and the patients' preference, expectation and postoperative adherence.

According to recommendations from Sweden and England, the use of surgical procedures may be considered as initial therapy or very early after initiation of medication therapy if the patient has a very high baseline pressure, early progression, persistent intolerance of medication alternatives, or apparent lack of compliance with therapy [7, 12].

Trabeculectomy is still considered the surgical gold standard, but it is not free of potentially serious complications. In addition, strict postoperative care is required to achieve clinically successful outcomes. To minimize the risks of conventional filtering surgery, MIGS have been developed as safer and less invasive techniques. Trabectome, approved in 2006, ushered in the new era of minimally invasive glaucoma surgery. Since then, a variety of MIGS devices and procedures have been developed and are currently available [4, 13–15].

The success of MIGS is significantly influenced by the preoperative conjunctival situation. Long-term drop application leads to a proven inflammation of the conjunctiva with an increase of lymphocytes, mast cells, and fibroblasts, among others. Therefore, it is recommended to discontinue local anti-glaucomatous drop therapy prior to surgery and allow regeneration of the ocular surface.

Most surgical procedures target the structures of physiologic aqueous humor outflow (trabecular meshwork, Schlemm's canal, collector channels) to lower IOP. Procedures fall into three categories:

a. Procedures that use stents to reduce outflow resistance (iStent, Hydrus microstent).

b. Procedures that cause viscodilation of Schlemm's canal and dilation of the trabecular meshwork (ab-interno canaloplasty, iTrack Advance, OMNI Surgical System).

c. Procedures that open or resect all or part of the trabecular meshwork (ab-interno trabeculotomy, Gonioscopy-Assisted Transluminal Trabeculotomy (GATT), OMNI Surgical System, ELIOS excimer laser trabeculotomy, high-frequency deep sclerotomy) [16].

Some MIGS, particularly implantable microstents, are approved for use in mild to moderate glaucoma at the time of cataract surgery. In patients with early glaucoma, cataract surgeons can perform a MIGS in the same surgical session as cataract surgery, knowing that they are associated with low-risk surgery and offer some benefit in lowering intraocular pressure beyond the benefit of lens extraction alone.

The patient's personal situation should also be considered when choosing the MIGS procedure. The usually reduced number of IOP-lowering medications after MIGS (compared to pre-surgery) often leads to a simpler treatment regimen and thus to better adherence to therapy and thus to an increased quality of life for the patient.

2. OMNI Surgical System: surgery procedure

Traditional canaloplasty procedures required an invasive ab-externo approach requiring full thickness scleral incisions. In many modern MIGS procedures, the surgery is performed through an ab-interno approach, thus there is significant protection of the conjunctiva and sclera.

The OMNI Surgical System (Sight Sciences, Inc., Menlo Park CA, USA) is indicated for catheterization and transluminal viscodilation of Schlemm's canal and incision into the trabecular meshwork to reduce intraocular pressure in adult patients with Open-Angle Glaucoma (OAG). The device should not be used in glaucoma patients in whom the chamber angle is compromised or damaged, nor in patients with chamber angle recession, neovascular glaucoma, chronic chamber angle closure, narrow-angle glaucoma, traumatic glaucoma, or malignant glaucoma.

The device allows repeated penetration of the Schlemm's canal with the microcatheter included. The surgeon gets the possibility to perform a complete 360° treatment or a partial treatment of less than 360° adapted to the medical needs of the patient. The system consists of a hand grip that opens into a curved cannula. The microcatheter is firmly integrated into the system, as is a reservoir that holds the viscoelastic (**Figure 1**). The surgical procedure itself has been well described in a number of previous publications [4, 5, 15, 17–20].

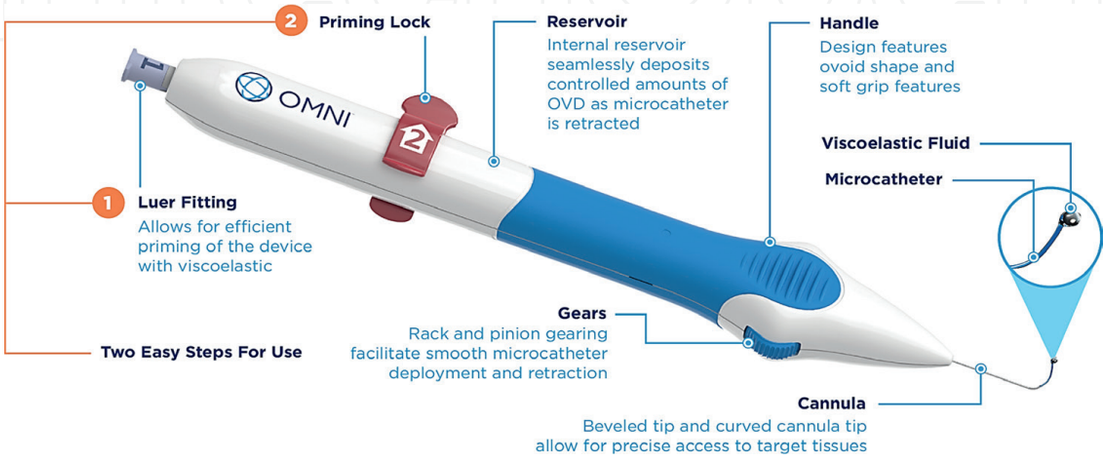

Figure 1.
OMNI Surgical System (figure used with permission from Sight Sciences, Inc. 2023).

2.1 Canaloplasty (viscodilation)

A small (1.5–2 mm) temporal free corneal incision is performed. After irrigation of the anterior chamber and deepening with viscoelastic, the head is tilted away from the surgeon and the microscope is tilted toward the surgeon for gonioscopic visualization (both approx. 30°–40°). The OMNI Surgical System is prepared by removing the retaining pin on the back of the handle and filling the reservoir with Healon. The cannula of the OMNI device is introduced through the incision into the anterior chamber and positioned at the desired location. Under gonioscopic view the cannula tip is brought near the nasal trabecular meshwork and a small <1 mm goniotomy was created. The microcatheter is then advanced into Schlemm's canal up to 180°. After then the microcatheter is slowly withdrawn while a fixed volume of approximately 11 μl of viscoelastic is automatically dispensed into Schlemm's canal and the collector channels. The procedure is then repeated for the second 180° of the canal. To avoid undesirable suprachoroidal tip advancement, the surgeon must ensure that the trabecular meshwork is penetrated at the correct location. The blue microcannula must be clearly visible in Schlemm's canal (**Figure 2**). Blood reflux indicates successful catheterization of Schlemm's canal. After the cannula is withdrawn from the eye, the anterior chamber is irrigated to entirely remove the Healon.

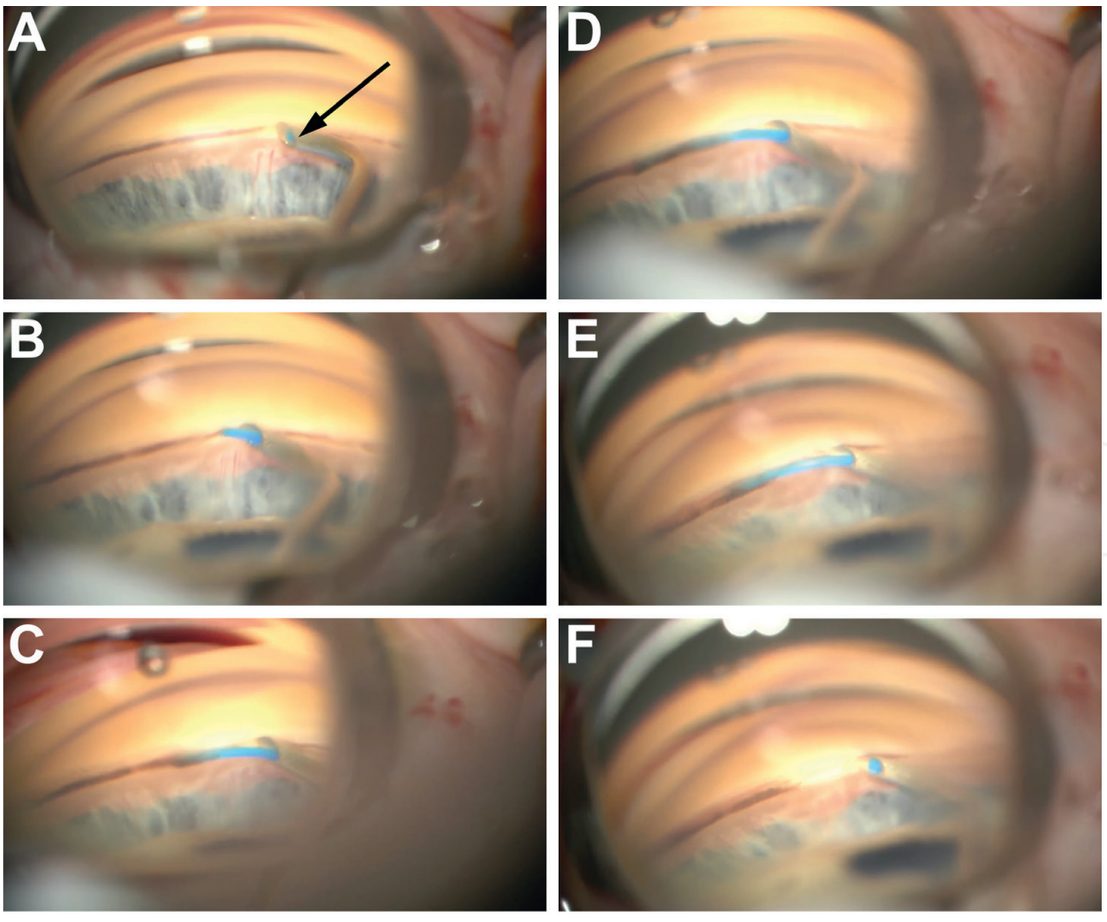

Figure 2.
Gonioscopic view of circumferential viscodilation of Schlemm's canal with the OMNI Surgical System. The black arrow marks the tip of the device's cannula. Through the blue microcatheter, viscodilation of Schlemm's canal (brownish shading) is clearly visible chronologically (A–F).

2.2 Canaloplasty + trabeculotomy

To perform the trabeculotomy, the same catheter is advanced once again through 180° of Schlemm's canal and withdrawn using a cheese-wire technique to unroof the canal.

2.3 Canaloplasty (+ trabeculotomy) + cataract surgery

In ab-interno canaloplasty combined with cataract surgery, the surgical steps are almost unchanged. Only the microincision of 2.2 mm is slightly larger and access to the anterior chamber with the OMNI Surgical System is via the cataract incision.

3. OMNI Surgical System: scientific status

The first single-incision approaches to trabeculectomy for glaucoma treatment only allowed trabeculectomy over 120° [21, 22]. A further development of this approach allowed trabeculectomy over a full 360° range. In the new approach, entry and exit from Schlemm's canal is through a single incision. A blue coloration of the suture material used made it possible to control with a gonioscope the exact placement and the accurate penetration of Schlemm's canal with the suture material. The first application of this technique was developed for congenital glaucoma. Furthermore, better results were obtained in direct comparison with the 360° technique than with the 120° technique [23–25].

Canaloplasty is based on the finding that the IOP-lowering effect of canalostomy is more likely due to viscodilation of Schlemm's canal and the resulting disruption of the lateral walls, inner wall endothelium, and bridging structures. Thus, in contrast to trabeculotomy, canaloplasty targets not only the inner wall and trabecular meshwork but also distal outflow resistance [26].

Ab-interno canaloplasty differs from ab-externo canaloplasty in that Schlemm's canal is accessed through the anterior chamber via a small goniotomy, and therefore only a small clear corneal incision is required, rather than conjunctival dissection and scleral flap. There is no tensioning suture [22].

3.1 Ab-interno canaloplasty

To prevent the sometimes serious side effects of trabeculectomy, such as shallow anterior chamber, uncontrolled hypotony, choroidal detachment, and macular wrinkles, non-penetrating filtering techniques have been proposed.

Non-penetrating filtering surgery, such as canaloplasty, involves techniques that focus on widening the Schlemm's canal to facilitate aqueous humor outflow via the physiologic pathway. The aim is to remove mechanical obstructions in the collector channels by improving aqueous humor outflow and creating additional pathways. Viscodilation separates the trabecular lamellae and creates microperforations in the inner wall of Schlemm's canal, allowing improved diffusion of aqueous humor through the proximal system into the distal system [4, 27].

The goal of this ab-interno canaloplasty is to restore physiologic aqueous humor outflow pathways independent of external wound healing. Numerous studies have demonstrated that canaloplasty is a relatively safe and effective surgical procedure that lowers intraocular pressure with continued pressure control over several years.

Additionally, postoperative management is simpler and fewer complications occur than with trabeculectomy [28–30].

In 2022, Toneatto et al. published retrospective interim results on ab-internal viscodilation of Schlemm's canal with the OMNI Surgical System in primary open-angle glaucoma (POAG) [4]. The primary endpoint at 12-month follow-up was defined as the proportion of eyes achieving an intraocular pressure of 18 mmHg or below, with an IOP reduction of more than 25% from baseline, either with the same number or fewer IOP-lowering medications and without additional IOP-lowering surgery or laser. In their cohort, the mean IOP reduction at 12 months compared to baseline was of 26.8% (from 23.0 ± 5.7 mmHg to 15.6 ± 3.6 mmHg). The mean number of medications at 12 months decreased from 3.0 ± 1.1 to 2.0 ± 1.4. Further publications reported comparable results [17, 31–33]. The results showed that surgery resulted in effective control and reduction of intraocular pressure. Only a few adverse events have occurred. Due to physiological blood regurgitation from Schlemm's canal, microhyphema was frequently observed; however, these microhyphema were not considered adverse events. 2 of 73 eyes showed clinically significant hyphema with more than 1 mm. In these two eyes, anterior chamber irrigation was performed without further postoperative complications affecting vision. Hyphema rates reported in the literature for ab-internal canaloplasties range from 0 to 20%, with the higher rates based mostly on studies that included milder hyphema. Mild postoperative hypotony (4–5 mmHg) occurred in 4 of 73 eyes within the first month but resolved without any intervention. No shallow anterior chambers or choroidal detachments were noted. IOP fluctuated widely during the first 30 days after surgery because antiglaucoma drops were discontinued after surgery and steroids were administered during the first weeks.

3.2 Ab-interno canaloplasty and trabeculectomy

In 2021 Klabe et al. [17] published a retrospective analysis of data drawn from existing health records. Prior surgery, patients were washed out of their ocular hypertensive medications according to generally accepted wash-out periods for prostaglandin analogs, beta blockers, alpha antagonists, and carbonic anhydrase inhibitors. All operations were performed by the same surgeon. In the sample of 38 eyes of 27 patients with open-angle glaucoma undergoing trabeculotomy/viscodilation using the OMNI Surgical System. 28 eyes were pseudophakic. 12- and 24-month results revealed statistically significant and clinically relevant reductions in intraocular pressure and medications. IOP decreased from 24.6 ± 3.0 mmHg to 14.7 ± 1.6 mmHg (40% IOP reduction from baseline) and 14.9 ± 2.0 mmHg (39%), respectively. Number of medications decreased from 1.9 ± 0.7 to 0.4 ± 0.6 and 0.5 ± 0.7, respectively. All retrospectively examined eyes showed a reduction in intraocular pressure of more than 20% from baseline. In addition, 83 and 85% of eyes required less medication than before MIGS treatment, and 63 and 58% of eyes were even medication-free. These outcomes were achieved without significant adverse events.

Another retrospective observation with a 12-month outcome was the ROMEO study [32]. This was a multicenter, retrospective, observational, single-arm study to evaluate the safety and effectiveness of canaloplasty and trabeculotomy with the OMNI Surgical System in pseudophakic eyes with OAG. Eyes were stratified by baseline IOP, with group 1 > 18 mmHg and group 2 ≤ 18 mmHg. Each group included 24 eyes of 24 patients. Surgeries were performed in 10 multi-subspecialty ophthalmic practices. Primary success was defined as the proportion of patients with at least 20% reduction in IOP from baseline or an IOP between 6 and 18 mmHg and on the same

or fewer medications without secondary surgical intervention up to 12 months after MIGS. Mean IOP was reduced in group 1 from 21.8 ± 3.3 mmHg to 15.6 ± 2.4 mmHg (28%) and in group 2 from 15.4 ± 2.0 mmHg to 13.9 ± 3.5 mmHg (10%). Medications went from 1.7 ± 1.3 to 1.2 ± 1.3 and from 2.0 ± 1.3 to 1.3 ± 1.3, respectively. 91 and 90% of eyes, respectively, required less medication than before MIGS treatment.

Further results of retrospective observations after trabeculotomy/viscodilation with the OMNI Surgical System are comparable and in the same range as results reported here [18, 33].

The observed reduction in intraocular pressure and medication are clinically relevant to glaucoma progression and patient adherence. In eyes with progressive open-angle glaucoma despite medication therapy, a 20% or greater reduction in intraocular pressure has been shown to significantly reduce the risk of further progression of glaucoma [34]. This is one reason why the FDA accepts a 20% reduction in intraocular pressure as an endpoint in MIGS registry studies [35]. Reducing medication offers patients several benefits such as: increased treatment adherence, reduced exposure to topical glaucoma medications, slower progression of dry eye symptoms, and also time and money savings.

3.3 Ab-interno canaloplasty/trabeculectomy standalone or combined with cataract surgery

Previous studies have shown that cataract surgery (phacoemulsification) alone results in an average IOP reduction of 1.4 mmHg in glaucoma patients up to 3 years out from surgery [36]. To date, there have been no randomized clinical trials in which cataract surgery was performed with and without a MIGS with the OMNI Surgical System or in which cataract surgery was combined with the OMNI Surgical System device and then compared with cataract surgery combined with another MIGS procedure. Therefore, the effect of phacoemulsification on IOP lowering cannot be accurately determined or compared when the procedure is performed in combination with canaloplasty or canaloplasty/trabeculoplasty using the OMNI Surgical System.

A retrospective, consecutive case series from a single center reported a smaller but statistically non-significant reduction in intraocular pressure and medication use after combined surgery compared with MIGS surgery alone [31]. A total of 89 eyes were examined, the surgery was performed as standalone with OMNI Surgical System in 17 eyes and in 72 eyes in combination with a phacoemulsification. After 18 months, 5 and 17 eyes could still be analyzed, respectively. The observation was not randomized, therefore the influence of confounding variables cannot be ruled out. In addition, the small sample size may not have been powered adequately to show any difference. This study is also limited by the weaknesses inherent to retrospective studies including selection bias and variable follow-up.

The second part of the ROMEO study (see Section 3.2 above) provides 12-month results after combined surgery of canaloplasty/trabeculotomy with the OMNI Surgical System and cataract surgery in patients with mild to moderate OAG [37]. Group 1 included 24 eyes and group 2 included 57 eyes. Surgeries were performed in 11 multi-subspecialty ophthalmic practices. Mean IOP was reduced in group 1 from 21.9 ± 3.7 mmHg to 15.1 ± 3.7 mmHg (31%) and in group 2 from 14.1 ± 2.5 mmHg to 13.4 ± 3.1 mmHg (7%). Medications went from 2.0 ± 1.3 to 1.1 ± 1.1 and from 1.6 ± 1.3 to 0.9 ± 1.2, respectively. 88% and 91% of eyes, respectively, required the same or less medication than before MIGS treatment. No safety issues were identified based on the analysis of adverse events and visual acuity.

The GEMINI clinical trial evaluated the efficacy of combined canaloplasty/trabeculotomy surgery with the OMNI Surgical System and cataract surgery in patients with mild to moderate glaucoma. 113 eyes with POAG were treated in 15 multi-subspecialty ophthalmic practices. Mean unmedicated diurnal IOP was reduced from 23.9 ± 3.0 mmHg at baseline to 15.4 ± 3.8 mmHg (36%) at month 12. Medications went from 1.8 ± 0.9 to 0.3 ± 0.9. 78% of eyes required less medication than before MIGS treatment.

Nevertheless, these and similar results [4] show that there are no significant disadvantages for the glaucoma patient when the OMNI Surgical System is combined with phacoemulsification. Rather, the advantage for both patient and physician is the ability to treat both cataract and aqueous humor outflow with only one surgical procedure, just one scleral incision.

3.4 Other glaucoma than primary open-angle glaucoma

There is limited data available on the performance of OMNI Surgical System in pseudoexfoliation glaucoma and pigmentary glaucoma [5]. One retrospective observation included only six patients diagnosed with pseudoexfoliation and one with pigmentary glaucoma [32] and another clinical study includes nine and one patients, respectively [20]. In general, the demographics of these patients were unremarkable compared with the pooled study populations. No clinically significant differences were observed compared to the results from patients with primary open-angle glaucoma. This observed effect suggests that OMNI Surgical System is also effective in secondary open angel glaucoma. However, the number of patients in these two studies is too small to draw any conclusions about the relative efficacy of the OMNI Surgical System for treating these types of glaucoma.

Although OMNI Surgical System is primarily used for open-angle glaucoma in adults, the combination of ab-interno canaloplasty and trabeculotomy is also useful for childhood glaucoma. Ab-interno trabeculotomy is the treatment of choice for primary congenital and other pediatric glaucoma. A retrospective study evaluated the results of a group of 46 eyes with various pediatric glaucoma treated with TRAB360, a precursor to OMNI Surgical System without canaloplasty function. Success was achieved in 81% of eyes with primary congenital glaucoma [38].

3.5 Combined MIGS

To date, few data are available on the combined use of the OMNI Surgical System with another MIGS technique. At the 2022 Annual Meeting of the American Society of Cataract and Refractive Surgery, a case series of 16 glaucomatous eyes undergoing combined surgery with the Hydrus Microstent (Ivantis, Irvine, CA, USA) and a canaloplasty with OMNI Surgical System was presented for the first time. In 2022 [39], there was another case report of 8 eyes in which the two devices were used during one glaucoma surgery [40]. In both case series, a significant and clinically meaningful reduction in IOP occurred in the majority of patients. Only in some patients in the case series could the number of IOP-lowering agents be reduced to achieve the target IOP. In patients with uncontrolled IOP who are already receiving maximally tolerated medication therapy, implantation of a hydrus microstent alone with OMNI Surgical System canaloplasty may not be an effective means of reducing medication burden.

Nevertheless, it can be concluded from these case series that a combination of ab-interno canaloplasty with the OMNI Surgical System with another MIGS technique is still a relatively safe and well tolerated method to control intraocular pressure. And in patients who have not achieved an adequate response of intraocular pressure despite the combined procedure, it is important to know that this does not preclude or prevent further glaucoma surgeries.

3.6 Clinical trials

The OMNI Surgical System has only been on the market for a few years. Therefore, only a few clinical studies are currently listed on the official website of the U.S. National Library of Medicine (ClinicalTrials.gov). By February 2023, 3, studies will be or have been conducted in the USA (NCT04530084, NCT03861169, NCT04872348) and one study in Poland (NCT04503356). No clinical trial is registered on the European website (clinicaltrialsregister.eu). All other peer-reviewed publications published to date are retrospective observations or case reports from single or multiple sites.

The first final 12-month analysis of a clinical trial was published in 2022 [20]. The GEMINI study was a prospective, multicenter, interventional, single-arm clinical study of patients with mild-moderate OAG undergoing 360° canaloplasty followed by 180° trabeculotomy with the OMNI Surgical System at the time of phacoemulsification. Final results from the 120 eyes analyzed showed that both IOP and the need for IOP-lowering medications were significantly reduced for at least 12 months postoperatively, with an excellent safety profile and no serious adverse event. Mean diurnal IOP without medication was reduced by 34%, with 84% of eyes having IOP reduced by more than 20% from baseline. Mean medication use was reduced by 78%, and 80% were medication-free at month 12. In this study, there was no control group, so the IOP-lowering effect of phacoemulsification alone or the effect of OMNI Surgical System compared with other MIGS could not be comparatively investigated.

3.7 Limitations

The current status of the clinical observations reported in this chapter is limited by some of the following factors:

Most are retrospective, uncontrolled studies with few or only one site (sometimes only one surgeon). Most are non-comparative, non-hypothesis-testing, descriptive studies with an inhomogeneous patient selection. Therefore, the occurring effects in terms of IOP and number of glaucoma medications are underestimated rather than overestimated compared to a prospective study with precisely defined inclusion and exclusion criteria.

Glaucoma is a chronic disease. In contrast, the longest observation period to date after MIGS with the OMNI Surgical System of 24 months is a relatively short period. However, this time frame is long enough to capture intraoperative and postoperative safety events as well as early surgical failures.

Completely standardized methods for ophthalmic measurements, surgical interventions, and medication initiation or discontinuation are the norm in a prospective study but not possible in a retrospective study. The decision to washout and to decrease or increase a patient's medication was made solely within the context of a surgeon's medical practice.

Some eyes had previously undergone other glaucoma surgery, such as trabeculectomy, deep sclerectomy, or also other MIGS. These patients were included based

on the results of previous studies showing that canaloplasty can be successfully performed even in patients with failed trabeculectomy in whom Schlemm's canal remained largely undamaged by previous filtering surgery [41, 42].

4. Conclusion

MIGS are considered for patients with mild to moderate visual field defects when medication therapy does not result in sufficient pressure reduction or IOP is above target pressure, patients do not adhere to therapy, or patients are suspected of not adhering to therapy, resulting in an increased risk of glaucoma progression. Especially, by reducing the number of different topical medications, MIGS are a useful tool to improve patient adherence and thus treatment outcomes. In addition, earlier intervention may help delay or avoid the need for more invasive surgery.

The OMNI Surgical System provides a practical approach to treating conventional outflow resistance by sequential canaloplasty and trabeculotomy, proximal to the juxtacanalicular trabecular meshwork and the inner wall of Schlemm's canal, and distal to Schlemm's canal and collecting channels.

Canaloplasty and trabeculotomy with the OMNI Surgical System as a standalone procedure or in combination with cataract surgery results in clinically relevant and statistically significant reductions in both IOP and IOP medication with an excellent safety profile. The procedure should be considered for eyes with mild to moderate open-angle glaucoma that require a safe and effective surgical intervention to achieve a reduction in intraocular pressure, a reduction in medication, or both. Phakic eyes can be treated as well as pseudophakic eyes.

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Conflict of interest

The authors declare no conflict of interest.

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