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12-month interim results of a prospective study of patients with mild to moderate open-angle glaucoma undergoing combined viscodilation of Schlemm's canal and collector channels and 360° trabeculotomy as a standalone procedure or combined with cataract surgery

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Abstract

Purpose: To characterize clinical outcomes of combined viscodilation of Schlemm's canal and collector channels and 360° trabeculotomy as a standalone procedure or combined with cataract surgery in eyes with mild to moderate open-angle glaucoma (OAG).

Methods: In this prospective case series, the OMNI glaucoma surgical platform (Sight Sciences, Menlo Park, CA) was utilized to perform the procedure either combined with phacoemulsification or as a standalone procedure. Changes from baseline in intraocular pressure (IOP) and IOP-lowering medications were evaluated through the first 12 months of a planned 24-month follow-up period.

Results: Among 17 eyes of 15 subjects, mean IOP was reduced from 20.4 mmHg to 12.7–13.7 mmHg through 12 months of follow-up ($p < 0.001$ at every time point) and mean medications reduced from 2.5 to 0.1–0.6 ($p < 0.001$ at every time point). IOP reductions in eyes undergoing standalone surgery were approximately 2–4 mmHg greater at each time point compared to eyes undergoing surgery combined with phacoemulsification; this may be related to a higher baseline IOP in the former eyes (22.1 vs 18.5 mmHg). Six eyes developed hyphema, of which three required washout for elevated IOP on the first postoperative day; six additional eyes had IOP elevations that resolved with medical management.

Conclusion: Viscodilation of Schlemm's canal and collector channels paired with ab interno trabeculotomy performed with a single integrated instrument (OMNI), whether as standalone or combined with phacoemulsification, effectively lowers both IOP and the need for IOP-lowering medications through 12 months of follow-up.

Keywords

Glaucoma, trabeculotomy, viscodilation, phacoemulsification, OMNI

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Introduction

Surgical intervention for glaucoma management had historically been reserved for patients whose disease is inadequately controlled with less invasive means, such as medications or laser therapy. In recent years, however, innovation has revolutionized the surgical management of glaucoma. The development of a growing family of minimally invasive glaucoma surgeries (MIGS) has greatly

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expanded the options for incisional surgery for intraocular pressure (IOP) reduction. These procedures are generally considered to be safer alternatives to more traditional procedures such as trabeculectomy and tube-shunt implantation.[1–4] Common attributes of most MIGS procedures include an ab interno approach, minimal tissue trauma, faster visual recovery time, and a more favorable safety profile than trabeculectomy or tube-shunts, albeit with a generally lesser efficacy profile.[1–4]

The general approach to MIGS procedures—as well as traditional surgeries—is to aid the egress of aqueous humor from the eye while bypassing the diseased trabecular meshwork (TM) and its associated outflow impairment. Traditional surgeries rely on subconjunctival filtration, while MIGS generally bypass the TM and deliver aqueous humor to Schlemm's canal, where it flows through the post-TM distal outflow channels.[1–4] Efforts to tap the suprachoroidal space and take advantage of uveoscleral outflow have been largely unsuccessful, and newer MIGS procedures have returned to subconjunctival filtration.[1–4]

The OMNI glaucoma system (Sight Sciences, Menlo Park, CA) is a novel surgical platform that combines two MIGS procedures: viscodilation of Schlemm's canal and the distal collector channels, and ab interno trabeculotomy of the TM. Together this system features three mechanisms of action for IOP reduction: excision of the TM to overcome the known increased resistance to aqueous outflow through the TM in OAG, along with viscodilation of Schlemm's canal and the distal collector channels, which are secondary points of outflow resistance.[5–8] Each procedure alone has been shown to effectively and safely lower IOP in eyes with primary open-angle glaucoma (POAG),[9–19] and the combination of both procedures using the OMNI system was recently reported to lower IOP by an average of ~35% and medications by ~25–50% in retrospective studies.[9,20,21]

In this paper, we describe the 12-month interim analysis of an ongoing prospective 24-month evaluation of combined viscodilation/trabeculotomy with or without phacoemulsification in eyes with mild to moderate OAG.

Methods

This was a prospective interventional case series of eyes undergoing ab-interno viscodilation of Schlemm's canal and collector channels followed by trabeculotomy using the OMNI Surgical System as a standalone procedure or in combination with cataract extraction in patients with open-angle glaucoma (OAG). The protocol was reviewed and approved by ethics committee of Centre of Postgraduate Medical Education in Warsaw on 11th April 2018 and all subjects provided written informed consent to participate. All patient data were treated with confidentiality, in accordance with the Declaration of Helsinki. All surgeries were performed by the same surgeon. The study was registered at ClinicalTrials.gov (NCT04503356).

Participating subjects were adults aged 45 years or older, with either visually significant cataract or pseudophakia, and open-angle glaucoma (including primary, pigmentary, and pseudoexfoliative) with intraocular pressure (IOP) >21 mmHg using up to three topical IOP-lowering medications. The diagnosis of OAG was based on the presence of characteristic optic nerve findings (concentric cupping, focal rim thinning, notching, and/or retinal nerve fiber layer bundle defects) and an abnormal glaucoma hemifield test on automated perimetry with mean deviation <0 dB but not worse than -12 dB. Subjects were excluded from participation for use of oral carbonic anhydrase inhibitors for IOP control, for prior glaucoma surgery (laser trabeculoplasty or trabecular microbypass implantation within the prior 6 months; any other glaucoma procedures at any time in the past), and for any co-existing ocular pathology that could affect treatment or assessment of outcomes. Both eyes in a given subject could be enrolled if both met all eligibility criteria.

At a screening visit, following the obtainment of informed consent, potential subjects provided medical history and underwent a comprehensive examination including best-corrected visual acuity (BCVA), intraocular pressure (IOP) using Goldmann tonometry, corneal pachymetry, gonioscopy, slit-lamp examination of the anterior segment, automated perimetry, dilated fundoscopic examination of the posterior segment including cup-disc ratio determination, and stereoscopic optic nerve photography. Subjects meeting eligibility criteria described above were enrolled. A separate baseline assessment was conducted to establish baseline IOP, without criteria for participation, to minimize the effect of regression to the mean.

All eyes underwent the viscodilation/trabeculotomy procedure using the OMNI glaucoma surgical system (Sight Sciences, Inc., Menlo Park, CA). This system is a handheld instrument featuring a cannula tip through which a microcatheter for trabeculotomy can be advanced (and through which ophthalmic viscosurgical device [OVD] can be injected for viscodilation), a gear wheel for deployment and retraction of the microcatheter, a reservoir for OVD, and a port for loading the handpiece with OVD. Via a peripheral incision in the temporal cornea, the handpiece tip is introduced into the anterior chamber under intraoperative gonioscopy, advanced to the nasal angle, and its sharp tip used to pierce the trabecular meshwork (TM). Through this micro-goniotomy, the flexible microcatheter is advanced around 180° of SC and slowly retracted as a fixed volume of ophthalmic viscosurgical device is automatically dispensed to dilate SC and the collector channels in a controlled fashion. The microcatheter's blue color aids visualization during these canal passages. The viscodilation portion of the procedure is completed by repeating this sequence of steps through the same TM entry point in the opposite direction along the remaining 180° of SC. The microcatheter is then

reinserted sequentially into each 180° of now-dilated SC and the instrument's tip drawn slowly away from the TM entry point to unroof each 180° of TM via a cheesewire technique. The handpiece is then withdrawn from the eye. The incision requires no sutures. A standard postoperative regimen of topical pilocarpine 2% once daily for 1–2 weeks, dexamethasone 0.1% six times daily and tapering by 1 drop per week until discontinued, a nonsteroidal anti-inflammatory drug (nepafenac 0.1% three times daily for 1 month in diabetic patients, bromfenac 0.09% twice daily for 1 month in non-diabetic patients), and levofloxacin three times daily for 1 week was prescribed in every case. The surgical protocol was revised after the first six eyes developed hyphema, three of which required surgical washout, to include the intraoperative administration of a single dose of tranexamic acid 1 g intravenously to reduce the risk of subsequent hyphema.

Subjects were re-evaluated 1 week and 1, 3, 6, 12, and 24 months postoperatively. Goldmann IOP and slit-lamp examination were performed at every visit; perimetry, dilated fundus examination, and optic disc photography were repeated annually; and gonioscopy was repeated at Month 24. In addition, adverse events were recorded intraoperatively and at every postoperative visit.

This is a 12-month interim analysis of a planned 24-month study. The primary efficacy outcome was the proportion of eyes with IOP reduction $\geqslant$20% from baseline using the same number or fewer IOP-lowering medications compared to baseline at Month 24. In this interim analysis, we report the same outcome at the Month 12 time point. Secondary efficacy outcomes included the proportion of eyes with IOP $\leqslant$18 mmHg and the proportion with IOP $\leqslant$15 mmHg (and IOP $\geqslant$6 mmHg in both cases) at Month 12; the proportion of eyes that were medication-free or on at least one fewer medication compared to baseline at Month 12; changes from baseline in IOP and the number of IOP-lowering medications at each visit; and the number of secondary surgical interventions performed for IOP control. Safety endpoints included the nature and incidence of ocular adverse events.

The primary efficacy endpoint and most secondary endpoints were analyzed using descriptive statistics. Changes from baseline in IOP and IOP medication use were evaluated using paired t-tests. Subgroup analysis of standalone and combined operations was undertaken. The level of significance was taken to be 0.05, with Hom-Bonferroni correction applied for multiplicity. Means are reported with standard errors. Safety outcomes were analyzed by tabulating the nature and incidence of adverse events. Given that this was not a hypothesis-testing study, the sample size was determined quasi-arbitrarily based on the number of eligible patients who enrolled within the study enrollment period. Formal power and sample size calculations were not undertaken for this reason.

Table 1. Demographic and glaucoma severity data for the study sample ($N = 17$).

Parameter	Value
Subject-level variables	$n = 15$
Age (year), mean (SE)	69.5 (1.9)
Gender, *n* (%)	
Male	2 (13.3)
Female	13 (86.7)
Ethnicity, *n* (%)	
Caucasian	15 (100)
Eye-level variables	$n = 17$
Diagnosis, *n* (%)	
POAG	15 (88.2)
Pseudoexfoliation OAG	2 (10.8)
Glaucoma severity, *n* (%)	
Mild	9 (52.9)
Moderate	8 (47.1)
Cup-disc ratio, mean (SE)	0.75 (0.03)
Number of medications at baseline, *n* (%)	
1	2 (11.8)
2	3 (17.6)
3	12 (70.6)
Operation performed, *n* (%)	
Standalone	9 (52.9)
Combined with phacoemulsification	8 (47.1)
Study eye, *n* (%)	
Right eye	8 (47.1)
Left eye	9 (52.9)

Results

Overall, 17 eyes of 15 subjects participated in this study, of which 14 have now completed the first 12 months of follow-up. One patient was lost to follow-up 5 weeks postoperatively. Demographic and glaucoma status data are given in Table 1. Subjects were all Caucasian, were on average 69.5 years of age, and were predominantly female (13/15, 86.7%). Most eyes (15/17, 88.2%) had POAG, the severity of which was evenly distributed between mild (9/17, 52.9%) and moderate (8/17, 47.1%) based on the Hodapp-Parrish-Anderson schema, and most eyes (12/17, 70.6%) were using three IOP-lowering medications at the time of surgery. Roughly half of eyes (9/17, 52.9%) underwent standalone surgery and the remaining eyes underwent surgery in combination with phacoemulsification. Mean baseline IOP was numerically greater for the standalone cohort than for the combined with cataract surgery eyes (22.1 vs 20.4 mmHg) but the difference did not reach statistical significance ($p = 0.085$). There was no difference in the baseline mean number of medications between these two groups (2.6, both groups).

The modified (12-month rather than 24-month time point) primary efficacy outcome measure—the proportion of eyes with IOP reduction $\geqslant$20% from baseline using the

Table 2. Mean (SE) IOP (mmHg) at all study time points for all eyes as well as the standalone and combined surgery subgroups.

	Timeframe	*N*	Mean IOP (SE)	IOP change from baseline		IOP percent change from baseline (%)
				Mean	*p* Value (from baseline)	
All eyes	Baseline	17	20.41 (1.05)	–	–	–
	Week 1	17	13.44 (1.14)	−6.97	<0.001	−34
	Month 1	17	13.76 (0.72)	−6.65	<0.001	−33
	Month 3	14	13.43 (0.79)	−6.57	<0.001	−33
	Month 6	14	13.71 (0.69)	−6.29	<0.001	−31
	Month 12	14	12.71 (0.54)	−7.29	<0.001	−36
Standalone eyes	Baseline	9	22.11 (1.58)	–	–	–
	Week 1	9	14.17 (1.81)	−7.94	<0.001	−36
	Month 1	9	14.00 (1.13)	−8.11	<0.01	−37
	Month 3	6	13.17 (1.58)	−8.83	<0.05	−40
	Month 6	6	13.50 (0.92)	−8.50	<0.01	−39
	Month 12	6	13.33 (1.11)	−8.67	<0.01	−39
Combined eyes	Baseline	8	18.50 (1.07)	–	–	–
	Week 1	8	12.63 (1.39)	−5.88	<0.001	−32
	Month 1	8	13.50 (0.93)	−5.00	<0.001	−27
	Month 3	8	13.63 (0.82)	−4.88	<0.001	−26
	Month 6	8	13.88 (1.04)	−4.63	<0.001	−25
	Month 12	8	12.25 (0.45)	−6.25	<0.001	−34

same number or fewer IOP-lowering medications compared to baseline at Month 12—was attained by 14/14 eyes (100%). Mean IOP at baseline and each postoperative visit through Month 12 is given in Table 2. Mean IOP reductions from baseline (20.4 mmHg) of 6.7–7.7 mmHg were seen through 12 months of follow-up ($p < 0.001$ at all time points). The proportion of all eyes with IOP ⩽18 mmHg and ⩾6 mmHg was 100% (14/14), and the proportion with IOP ⩽15 mmHg and ⩾6 mmHg was 92.9% (13/14). IOP reductions for the standalone and combination subgroups are also given in Table 2. IOP reductions in standalone eyes ranged from 7.9 to 8.9 mmHg ($p < 0.05$ at all time points) from baseline (22.1 mmHg), and in combined eyes ranged from 4.6 to 6.3 mmHg ($p < 0.001$ at all time points) from baseline (18.5 mmHg).

Mean medication use data at baseline and every postoperative time point are given in Table 3. In the full data set, mean medications were reduced from 2.6 per eye at baseline by 2.0–2.5 per eye across all time points ($p < 0.001$ at all time points). The proportion of all eyes that were medication-free was 41.2% (7/17) and the proportion on at least one fewer medication compared to baseline at Month 12 was 92.9% (13/14). Medication reductions for the standalone and combination subgroups are also given in Table 3. Medication reductions in standalone eyes ranged from 1.9 to 2.4 medications per eye ($p < 0.01$ at all time points) from baseline (2.6 medications), and in combined eyes ranged from 2 to 2.6 medications per eye ($p < 0.01$ at all time points) from baseline (2.6 medications).

Regarding safety, six eyes developed hyphema (four standalone and two combined cases), of which three resolved spontaneously and three required anterior chamber washout procedures on the first postoperative day due to marked IOP elevations. These were among the first eyes enrolled, after which the surgical protocol was amended to include an intravenous injection of tranexamic acid, with no further eyes requiring washout thereafter. Six additional eyes manifested IOP elevations above 30 mmHg (four standalone and two combined cases), all of which resolved with topical medical management within the first postoperative week. Adverse events are listed in Table 4. No eyes required any secondary surgical interventions for glaucoma control due to surgical failure within the postoperative period through most recent follow-up.

Discussion

This interim analysis of an ongoing 24-month prospective study demonstrates that combined viscodilation/trabeculotomy using the OMNI system effectively lowers both IOP and the need for IOP-lowering medications through the first 12 months of follow-up. IOP reduction were greater in eyes undergoing standalone surgery, in which baseline IOP was higher and surgery was indicated primarily for IOP reduction, while medication reductions were similar in both standalone and combined phacoemulsification eyes.

Combining viscodilation of Schlemm's canal and the collector channels with trabeculotomy targets three distinct mechanisms by which IOP is elevated in eyes with OAG. First, TM outflow resistance is well known to be increased in eyes with OAG, with the juxtacanalicular TM accounting for most of the increased resistance.[22,23] Trabeculotomy

Table 3. Mean (SE) IOP-lowering medication use (*n*) at all study time points for all eyes as well as the standalone and combined surgery subgroups.

	Timeframe	*N*	Mean medications (SE)	Mean medication change from baseline		Medication percent change from baseline (%)
				Mean	*p* Value (from baseline)	
All eyes	Baseline	17	2.59 (0.17)	–	–	–
	Week 1	17	0.06 (0.06)	−2.53	<0.001	−98
	Month 1	17	0.18 (0.13)	−2.41	<0.001	−93
	Month 3	14	0.29 (0.16)	−2.29	<0.001	−89
	Month 6	14	0.43 (0.20)	−2.14	<0.001	−83
	Month 12	14	0.64 (0.20)	−1.93	<0.001	−75
Standalone eyes	Baseline	9	2.56 (0.24)	–	–	–
	Week 1	9	0.11 (0.11)	−2.44	<0.001	−96
	Month 1	9	0.33 (0.24)	−2.22	<0.001	−87
	Month 3	6	0.50 (0.34)	−2.00	<0.01	−80
	Month 6	6	0.50 (0.34)	−2.00	<0.01	−80
	Month 12	6	0.67 (0.21)	−1.83	<0.01	−73
Combined eyes	Baseline	8	2.63 (0.26)	–	–	–
	Week 1	8	0 (0)	−2.63	<0.001	−100
	Month 1	8	0 (0)	−2.63	<0.001	−100
	Month 3	8	0.13 (0.13)	−2.50	<0.001	−95
	Month 6	8	0.38 (0.26)	−2.25	<0.001	−86
	Month 12	8	0.63 (0.32)	−2.00	<0.01	−76

Table 4. Adverse events.

Adverse event	OMNI standalone (*n* = 9)	OMNI combined with cataract surgery (*n* = 8)	All (*n* = 17)
Hyphema[a]	4 (44%)	2 (25%)	6 (35%)
IOP elevation[b]	4 (44%)	2 (25%)	6 (35%)

[a]Less than 1 week duration, three washed out on Day 1 post surgery (first three cases).
[b]Resolved within first post-operative week.

effectively overcomes this outflow resistance by creating a direct channel between the anterior chamber and Schlemm's canal. The canal itself is also a point of resistance to aqueous outflow, with studies demonstrating an approximately 50% reduction in both cross-sectional diameter and outflow facility of Schlemm's canal in eyes with POAG compared to healthy eyes; this may be related to atrophy from overall reduced aqueous outflow in diseased eyes.[7] Distal to the canal, elevated IOP can cause herniation of inner wall tissue into the ostia of the collector channels, effectively blocking outflow through them.[8] Dilating Schlemm's canal and the collector channels effectively increases the canal's cross-sectional area and outflow facility while relieving focal blockage of channel ostia, further enhancing aqueous humor outflow and IOP reduction.

Few studies have described the outcomes of combined viscodilation/trabeculotomy using the OMNI system. A retrospective series of 15 eyes of 13 patients with OAG underwent the procedure either standalone (eight eyes) or in combination with phacoemulsification (seven eyes), and after 4 months of follow-up, mean IOP was reduced from 21.3 mmHg to 13.7 mmHg (35%) with a 25% reduction in IOP-lowering medication use; transient hyphema was noted in two eyes (13%).[20] In another series, 24 eyes of 19 patients with OAG underwent standalone (14 eyes) or combined (10 eyes) surgery; mean IOP was reduced from 21.4 mmHg to 13.9 mmHg (35%) and mean medications by ~50% 12 months postoperatively, and adverse events (IOP spikes, hyphema) were transient and resolved spontaneously in the first postoperative week.[21] In a recently published retrospective US study, mean IOP reduction after mean follow-up of 4 months in 41 eyes of 24 patients with OAG was 5.6 mmHg (baseline not reported) overall and 9.6 mmHg in eyes with baseline IOP > 22 mmHg; two eyes developed transient hyphema.[9] The procedure has also been reported to be effective in a child with congenital glaucoma associated with Sturge Weber syndrome.[24] These outcomes are consistent with the 36% IOP reductions and 75% medication reductions seen in our full data set at 12 months.

Numerous studies have described the outcomes of ab interno trabeculotomy or ab interno viscodilation separately. Gonioscopy-assisted transluminal trabeculotomy

(GATT) performed with either a suture or an illuminated microcatheter reportedly lowers IOP by ~30–45% and medications by ~30–70% as a standalone procedure, and IOP by ~30–70% and medications by ~45–90% in combination with phacoemulsification, in studies ranging from 6 to 24 months in duration.[11–16,19,25] Ab interno trabeculotomy performed with the TRAB360 device (Sight Sciences; the precursor to the OMNI system) lowers IOP ~30% and medications ~35–80% in a pair of retrospective studies.[17,18] Viscodilation of Schlemm's canal lowers IOP 30–41% and medications 0–89% in various studies.[10,26,27] Lacking are studies comparing the combined procedure to either of its components to demonstrate additive benefits of the dual procedure; however, this limitation is pervasive in the MIGS literature, with exceedingly few well-designed and appropriately-powered studies comparing two or more MIGS procedures in head-to-head fashion.

In this case series, an unexpectedly high rate of hyphema requiring surgical washout occurred within the first three eyes. Subsequently, the surgical protocol was revised to include the administration of tranexamic acid (1000 mg/i.v.) to reduce bleeding. Tranexamic acid (TA) is approved in Europe for prevention and treatment of hemorrhages following various types of surgery, including ENT procedures but not specifically ophthalmological procedures. A meta-analysis of five trials has demonstrated the efficacy of TA in reducing the rate of secondary hemorrhage in eyes with traumatic hyphema.[28] It was used off-label in this study, which greatly reduced intraocular hemorrhage and eliminated the need for further surgical washouts. The need for an antifibrinolytic agent was not reported in other studies of this procedure,[9,20,21] suggesting a surgical learning curve.

The prospective design of this study is an important strength. This is only the second publication of which we are aware evaluating the OMNI glaucoma surgical system and the first that describes prospectively collected data. Also, our plan to collect data through 24 months addresses the chronic nature of glaucoma and the need for long-term outcomes of new procedures. The inclusion of both standalone cases and those combined with phacoemulsification illustrates the diversity of the procedure and characterizes outcomes when used in either clinical scenario. Limitations include its relatively small sample size as well as the absence of a comparator group. This is a common limitation for studies of many of the MIGS procedures, particularly those cleared for marketing through the 510(k) equivalence-to-predicate pathway without the requirement for a pivotal trial, in which funding for well-designed and adequately-powered clinical trials is often not available.

Conclusion

In summary, viscodilation of Schlemm's canal and collector channels paired with ab interno trabeculotomy performed with a single integrated instrument (the OMNI surgical system), whether as standalone or combined with phacoemulsification, effectively lowers both IOP and the need for IOP-lowering medications through 12 months of follow-up. Further study is warranted to more robustly characterize outcomes and clarify the optimal use of this procedure. This study is ongoing and 24-month data will be reported when available.

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