Canaloplasty and Trabeculotomy with the OMNI System in Pseudophakic Patients with Open-Angle Glaucoma: The ROMEO Study

Steven D. Vold, MD,1 Blake K. Williamson, MD,2 Louis Hirsch, MD,3 Ardalan E. Aminlari, MD,4 Andrew S. Cho, MD,5 Cade Nelson, BS,2 Jaime E. Dickerson, Jr., PhD6,7

**Purpose:** Provide outcomes up to 12 months postsurgically for sequential canaloplasty and trabeculotomy with the OMNI surgical system (Sight Sciences, Inc) in pseudophakic patients with mild to moderate open-angle glaucoma.

**Design:** Retrospective, multicenter, single-arm study conducted at 10 multi-subspecialty ophthalmology practices and surgery centers located in 7 states (Arkansas, California, Kansas, Louisiana, Missouri, New York, and Texas).

**Participants:** Eligible patients were pseudophakic, with mild/moderate open-angle glaucoma, 12-month follow-up, and medicated intraocular pressure (IOP) ≤36 mmHg on ≤4 medications preoperatively. One eye per patient was enrolled.

**Methods:** Institutional Review Board approved. All available cases meeting eligibility criteria were enrolled. Analysis of secondary end points was stratified by baseline (BL) IOP (>18 mmHg in group 1 and ≤18 mmHg in group 2) recognizing that treatment goals differed depending on BL IOP.

**Main Outcome Measures:** Primary success was defined as the proportion of patients with ≥20% reduction in IOP from BL or IOP between 6 and 18 mmHg (inclusive) and on the same or fewer medications without secondary surgical intervention (SSI). Other effectiveness end points included mean IOP and number of medications at 12 months. Safety end points were best-corrected visual acuity (BCVA), adverse events (AEs), and SSl.

**Results:** Forty-eight patients were enrolled, 24 in each group. Primary success was met by 73%. Mean IOP was reduced in group 1 (21.8 to 15.6 mmHg, P < 0.0001) and remained controlled in group 2 (15.4 to 13.9 mmHg, P = 0.24). Medications went from 1.7 ± 1.3 to 1.2 ± 1.3 (P = 0.024) in group 1 and from 2.0 ± 1.3 to 1.3 ± 1.3 (P = 0.003) in group 2. Adverse events were typical for the patient population undergoing angle surgery. Those reasonably related to the procedure were mild inflammation (13%), IOP spikes (6%), hyphema, corneal edema, and BCVA loss (all 4%). Five patients (10%) required an SSI.

**Conclusions:** The sequential combination of canaloplasty followed by trabeculotomy performed as stand-alone procedures using the OMNI system in pseudophakic patients with open-angle glaucoma provides effective IOP reduction or sustained IOP control and meaningful medication reduction for up to 12 months postoperatively. Ophthalmology Glaucoma 2021;4:173-181 © 2020 by the American Academy of Ophthalmology. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

The development of microinvasive glaucoma surgery (MIGS) has shifted standards of treatment for glaucoma and established surgical intervention as an accepted early disease treatment option.1-3

The favorable safety profile, demonstrable efficacy, and minimal disruption and trauma to ocular tissues have driven this shift and defined the category.3 In many instances, MIGS is conjoined to cataract surgery; in the United States, this is the only approved use for trabecular implants.4,5 Combination procedures with cataract surgery invite early surgical intervention as cataract surgery creates the opportunity to also intervene with MIGS without adding significant risk to the patient.5 Conversely, MIGS as a stand-alone procedure is a deterministic as opposed to an opportunistic decision. The procedure is not an add-on but is the reason for going into the eye. Candidate patients may be phakic, without cataracts or the need for lens exchange, or pseudophakic having already undergone cataract surgery in the past. Modest efficacy may justify MIGS added to cataract surgery but not when used as a stand-alone procedure. Moreover, cataract surgery alone provides some limited intraocular pressure (IOP) reduction, which would not contribute to effectiveness in a stand-alone procedure.7 Surgeon and patient expectations are greater because they must be for a procedure carried out solely to manage glaucoma. The selection of a MIGS that can meet these expectations should maximize the potential for effectiveness without sacrificing the favorable MIGS safety profile.

One such technique is the ab interno microcatheterization and transluminal viscodilation of Schlemm’s canal (“canaloplasty,” “transluminal canal viscodilation,” or “canal viscodilation”) followed by ab interno transluminal trabeculotomy (“trabeculotomy” or “goniotomy”) with the OMNI surgical system (Sight Sciences, Inc). The OMNI surgical system facilitates the microcatheterization of Schlemm’s canal circumferentially from a single clear

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corneal incision allowing the surgeon to perform ab interno cananoplasty followed by trabeculotomy using a single fully integrated handheld system. Combining the 2 different mechanistic modalities successively addresses multiple points of outflow resistance in the conventional outflow pathway, both proximal (i.e., juxtacanalicular and inner wall of Schlemm’s canal) and distal (i.e., Schlemm’s canal and the collector channels). By first performing cananoplasty, an open distal outflow pathway including collector channel ostia is obtained while subsequent trabeculotomy removes the resistance residing in the trabecular meshwork.

The OMNI surgical system received US Food and Drug Administration (FDA) clearance in December 2017 and was launched in the United States in March 2018. The aim of the present retrospective chart review was to report the immediate postlaunch clinical experience of a geographically diverse group of 10 surgeons with up to 12-month effectiveness outcomes for patients treated with the OMNI as a stand-alone procedure in pseudophakic patients.

Methods

Study Design

This was a multicenter, retrospective, observational, stratified, consecutive study of all eyes meeting eligibility criteria treated with the OMNI system from 10 multi-subspecialty ophthalmic practices in 7 states (Arkansas, California, Kansas, Louisiana, Missouri, New York, and Texas). Patients were stratified into 2 groups: baseline (BL) IOP >18 mmHg (group 1) and BL IOP ≤18 mmHg (group 2). All surgeries were performed between June 27, 2018, and May 29, 2019.

Design of the study protocol, including datapoints collected, subject eligibility, and 100% source data verification, was informed by the FDA guidance document, “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices,” August 31, 2017. This study was consecutive/sequential based on the date of surgery with the OMNI surgical system and included all eligible patients. Study sites and surgeons were selected on the basis of experience with the device and in having a sufficient volume of cases to provide confidence that enrollment targets could be met.

Eligibility criteria were as follows: underwent canaloplasty and trabeculotomy using the OMNI at least 273 days and no more than 456 days before start of the study; a minimum of 180° viscodilation and a minimum of 90° of trabeculotomy; diagnosis of open-angle glaucoma including pigmentary glaucoma and pseudoexfoliative glaucoma; visual field mean deviation not worse than −12 decibels; cup:disc not worse than 0.9; 0–4 topical ocular hypotensive medications at preoperative BL with fixed combinations counted as the number of individual components; and open angles (Shaffer grade ≥3). Patients were ineligible if there was a laser trabeculoplasty, trabecular bypass or supraciliary stent, cyclodestructive/ciliary ablation procedure ≤6 weeks before surgery with the OMNI; any history of trabeculectomy or other bleb-forming procedure, prior canaloplasty, goniotomy, or trabeculotomy; concurrent IOP-lowering procedure other than the OMNI at the time of surgery; preoperative medicated IOP >36 mmHg; forms of glaucoma other than open-angle glaucoma; and clinically significant concurrent intraocular pathology other than glaucoma at the time of surgery. Patients with a history of narrow angles but with open angles after cataract extraction were not excluded.

Twelve months (273–456 days) of follow-up were required for eligibility because the intent of the study was to demonstrate effectiveness and document adverse events (AEs) over a 1-year period postoperatively. For each participating patient, only 1 eye could be enrolled. In case both eyes were eligible, the right eye was selected as the study eye.

Medical records were reviewed for demographic and medical history information, preoperative and postoperative IOP, medication use data, best-corrected visual acuity (BCVA), and AEs. Surgical information including clock hours of canaloplasty and trabeculotomy, and any intraoperative complications were abstracted from the operative notes. The reporting time windows for each of the study follow-up visits (months 1, 6, 12) were purposely broad given the “real world” nature of the study and are those recommended as “acceptable” by the World Glaucoma Association in Guidelines on Design and Reporting of Glaucoma Surgical Trials (2009).

The study was reviewed by the Institutional Review Board (Aspire Institutional Review Board, Santee, CA), and waiver of consent was granted because of the retrospective noninterventional nature of the study. All patient data were treated with confidentiality in accordance with the Declaration of Helsinki. This study is not considered an “Applicable Clinical Trial” under 42 CFR 11.22(b) and was therefore not required to be listed on clinicaltrials.gov.

Preoperative Assessments

All subjects had undergone a complete ophthalmic examination including slit-lamp and dilated fundus examinations, Goldmann applanation tonometry, gonioscopy, and automated perimetry before surgery. For most patients, this preoperative examination was within 30 days of surgery (mean, 19 days; median, 13 days; 90th percentile, 38 days). The IOP measured at this examination was used as the BL IOP.

Surgical Technique

The OMNI procedure was performed as follows with only minor variation between surgeons. A single small clear corneal incision (~2 mm) was created temporally. The anterior chamber (AC) was irrigated with 2% lidocaine and deepened with viscoelastic, the head was tilted away from the surgeon, and the microscope was tilted toward the surgeon for gonioscopic visualization (generally 30–40 degrees, head; 30–40 degrees, microscope). The OMNI was introduced through the incision into the AC. The device was advanced across the AC and positioned at the desired location nasally, and a small <1-mm goniotomy was created with the cannula tip. The cannula was placed into the goniotomy, and the microcatheter was advanced into Schlemm’s canal for 180°. As the microcatheter was retracted, a controlled amount of viscoelastic was delivered providing viscodilation of the canal and distal outflow pathway. To perform the trabeculotomy, the microcatheter was again advanced to the desired extent and subsequently withdrawn by removal of the device through the corneal incision causing the microcatheter to unroof Schlemm’s canal. If both hemispheres were treated, the device was withdrawn from the eye and rotated, and the process was repeated for the second 180°. On completion of the procedure, the AC was irrigated with balanced salt solution to remove viscoelastic, and the chamber was pressurized. In most cases, a standard postoperative regimen of topical steroid and antibiotic was prescribed. Viscoelastic delivery was 180° in 56% of eyes, and both hemispheres were treated in 44%. The overwhelming majority of trabeculectomies were 180° (85%).

Outcome Measures

The overall primary success end point was selected to fairly acknowledge a successful outcome given that there were 2 different subgroups of patients with different treatment goals: patients with medically controlled IOP in whom the primary goal was maintaining
IOP control and reducing medications, and patients with IOP above the target in whom pressure reduction was paramount. Therefore, the primary success end point was defined as the proportion of all subjects at 12 months postoperatively with IOP \(\leq 18\) mmHg and \(>6\) mmHg or with a \(\geq 20\%\) reduction from preoperative BL IOP and on the same number of or fewer ocular hypotensive medications compared with the preoperative BL, and with no additional IOP-lowering surgery or laser. There was no stratification for the primary end point. Intraocular pressure of \(18\) mmHg or below is an accepted benchmark for control of glaucoma progression and acknowledges that maintenance of IOP control is “success” for patients already controlled on medication. A 20% reduction in IOP after an IOP-lowering intervention is the recommended primary success end point in the US FDA Guidance for Industry: Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices. Reduction in IOP was the main goal for uncontrolled patients, and 20% reduction from BL is a fair measure of meeting this goal. The qualifiers “same or fewer ocular hypotensive medications and no additional IOP-lowering surgery or laser” are necessary so that either way of achieving “success” can be fairly assessed without confounding influences.

The secondary end points included median percent change in IOP from preoperative BL, mean IOP, and mean number of ocular hypotensive medications. These are standard parameters for the assessment of the effectiveness of a treatment aimed at reduction of IOP. Secondary end points were planned to be stratified by BL IOP to evaluate the effect on patients with IOP \(>18\) mmHg (group 1: \(\leq 18\) mmHg, group 2) to better assess effectiveness in these 2 subgroups with different treatment goals. The selection of \(18\) mmHg as the boundary between these 2 strata was made a priori and based on the findings of The Advanced Glaucoma Intervention Study (AGIS) regarding the overall lack of progression when IOP is consistently below \(18\) mmHg.

The incidence of all ocular AEs for the study eye was recorded, including loss of 2 or more lines of BCVA (Snellen), IOP elevation \(>10\) mmHg above preoperative BL at \(>30\) days postoperatively, secondary surgical or laser intervention for IOP control (secondary surgical intervention [SSI]), and slit-lamp and fundus abnormalities. The BCVA was assessed for each time point, and the proportion of patients with \(20/20\) or better, \(20/25\) or better, \(20/32\) or better, \(20/40\) or better, between \(20/40\) and \(20/80\), between \(20/80\) and \(20/200\), and worse than \(20/200\) was tabulated for each time point.

Statistical Analysis

The full analysis set included all subjects meeting all inclusion criteria and no exclusion criteria. Because all subjects are screened for eligibility before inclusion in the study, the full analysis set was composed of all study subjects. For subjects who required an SSI, IOP measurements and medication use data subsequent to the SSI were excluded from the analysis set; these patients were treatment failures for binary end points.

Demographics and BL characteristics were analyzed with descriptive statistics (mean, maximum, minimum, standard deviation). The proportions for the primary binary outcome and corresponding standard errors and confidence bounds at each time (1 month, 6 months, 12 months) were calculated. The mean IOP profile over time was computed using a repeated measure (mixed) model to account for correlations over time. The mean of the number of ocular hypotensive medications is reported at each time and compared with BL using the nonparametric Wilcoxon signed-rank test for paired data.

Missing data due to a procedure not being done (e.g., BCVA) or a missed visit were treated as missing. No imputation was carried out. Treatment failures due to SSI with missing IOP data at month 12 were treated as failures for the primary end point.

The sample size was not based on statistical power calculations but instead on the number of available cases. With the actual sample size of \(n = 48\) and 72.9% success at 12 months, the observed standard error was \(\pm 6.4\%\), corresponding to a 95% confidence interval width of \(\pm 12.8\%\).

Results

Patient Demographics and Baseline Characteristics

The study included 48 eyes of 48 patients. Ten investigative sites contributed cases: Fayetteville, Arkansas (23); Baton Rouge, Louisiana (11); Springfield, Missouri (3); Encinitas, California (3); Los Angeles, California (3); Buffalo, New York (1); New York, New York (1); El Paso, Texas (1); Laredo, Texas (1); and Wichita, Kansas (1). Twenty-four eyes had BL IOP \(>18\) mmHg (group 1), and 24 eyes had BL IOP \(\leq 18\) mmHg (group 2). Average follow-up time was 335 \(\pm 54.8\) days. Mean age at the time of surgery was 75 years, both genders were equally represented, and most patients (79%) were White. Baseline characteristics and demographics stratified by BL IOP (Table 1) were overall similar between strata. Baseline medication use was similar between the 2 groups; however, at each level of medication use, the BL IOP for patients in the group 1 cohort was higher than for patients in group 2 (Table 2).

The extent to which canaloplasty and trabeculotomy were performed was at the individual surgeon’s discretion. In 45 of 48 cases, trabeculotomy was performed on only 1 hemisphere. Baseline IOPs for the 3 cases in which both hemispheres were treated were near the overall group mean (18.6 mmHg): 17, 17, and 19 mmHg. The extent of canaloplasty was split between 1 (\(n = 27\)) or both (\(n = 21\)) hemispheres. There was no significant difference in BL IOP (\(18.0\ vs. 19.4, P = 0.244\)) and no difference in mean reduction in IOP based on extent of canaloplasty (\(-4.2\) mmHg, \(-23.3\%\), and \(-4.8\) mmHg, \(-24.8\%\)).

Effectiveness

Primary effectiveness was defined as the proportion of all subjects achieving a 20% reduction in IOP from the preoperative BL or an IOP between 6 and 18 mmHg (inclusive) at month 12 while on the same or fewer ocular hypotensive medications as at BL and without the need for an SSI for IOP control. The majority of subjects (72.9%; 95% confidence interval, 60.1–85.7) met this success criteria. A more stringent success criterion was also evaluated that required all patients in group 2 (with preoperative IOP \(\leq 18\) mmHg) to achieve a 20% reduction in IOP or a reduction in medications (for those patients on medication at BL) to be considered a “success.” In other words, group 2 patients could not be counted a success if both IOP and medications were essentially the same at month 12 as at BL. By applying this criterion, only 1 patient was affected, and the overall success rate was 70.8%.

Group 1: Baseline Intraocular Pressure \(>18\) mmHg

The median and mean percent change from BL in IOP are provided in Table 3. Median percent change from BL was \(\approx 26\%\) (all visits) and was statistically significant versus BL at all timepoints (\(P < 0.0001\)). A significant reduction in IOP was evident by month 1 (\(\approx 6\) mmHg, \(P < 0.0001\)), which was sustained through month 12 (21.8 \(\pm 3.3\) mmHg, BL;
15.6 ± 2.4 mmHg, month 12; \( P < 0.0001 \) (Fig 1). Although mean IOP was significantly different at BL between groups 1 and 2, the 2 groups were not significantly different at months 1, 6, and 12. Mean medication use was 1.7 ± 1.3 preoperatively declining to 1.2 ± 1.3 by month 12 (\( P = 0.024 \) (Fig 2). Twenty-two patients (91.7%) were on the same or fewer medications as at BL. Considering those patients on 1 or more hypotensive medications at BL (18/24), 9 (50.0%) were on fewer medications at month 12. The number of medication-free patients increased by 50%: from 6 (21.1%) to 9 (37.5%).

**Group 2: Baseline Intraocular Pressure \( \leq 18 \) mmHg**

Intraocular pressure remained stable and controlled for patients in group 2. There was a modest but statistically significant median percent change from BL in IOP (−11.1%, \( P = 0.039 \)) at month 12 (Table 3). The mean IOP profile over time is shown in Figure 1. Mean preoperative IOP was 15.4 ± 2.0 mmHg and 15.8 ± 10.5 mmHg, 15.1 ± 4.0 mmHg, and 13.9 ± 3.5 mmHg at months 1, 6, and 12, respectively. These decreases did not reach statistical significance. In contrast, medication use decreased significantly from an average of 2.0 ± 1.3 at BL to 1.3 ± 1.3 by month 12 (\( P = 0.003 \) (Fig 2). Seventeen patients (89.5%) were on the same or fewer medications, with 5 (26.3%) on the same number and 12 (63.2%) on fewer. There was a 3-fold increase in medication-free patients: 6 (31.6%) at month 12 compared with 2 (10.5%) at BL.

**Safety**

Adverse events were reported for the study eye whether or not they were considered related to the device or procedure. Adverse events were classified as intraoperative or postoperative. The number and percent of reported AEs of a given type are summarized in Table 4. Adverse events observed in this study were generally mild, nonserious, transient in nature, and consistent with those expected for patients with the study demographics and undergoing angle surgery. One AE, a dislocated IOL that was present before the surgery but corrected during the procedure, was intraoperative. Adverse events occurring at a frequency \( \geq 3\% \) included mild AC inflammation occurring more than 30 days postoperatively (12.5%), posterior capsule opacity (10.4%), IOP >10 mmHg above BL >30 days postoperatively (6.3%), cystoid macular edema (6.3%), and corneal edema

### Table 1. Demographic and Baseline Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>All (N = 48)</th>
<th>Group 1 IOP &gt;18 mmHg (N = 24)</th>
<th>Group 2 IOP ( \leq 18 ) mmHg (N = 24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (n, %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22 (46)</td>
<td>9 (38)</td>
<td>13 (54)</td>
</tr>
<tr>
<td>Female</td>
<td>26 (54)</td>
<td>15 (63)</td>
<td>11 (46)</td>
</tr>
<tr>
<td>Age, yrs (mean, SD, minimum, maximum)</td>
<td>75.0 (8.7, 56, 94)</td>
<td>74.7 (8.5, 56, 88)</td>
<td>75.3 (8.9, 56, 94)</td>
</tr>
<tr>
<td>Diagnosis (n, %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POAG</td>
<td>46 (96)</td>
<td>23 (96)</td>
<td>23 (96)</td>
</tr>
<tr>
<td>PXG</td>
<td>1 (2)</td>
<td>1 (4)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>PG</td>
<td>1 (2)</td>
<td>1 (4)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Mean deviation, dB (mean, SD, minimum, maximum)</td>
<td>−5.4 (3.8, −13.9, 0.9)</td>
<td>−5.2 (3.8, −13.9, 0.9)</td>
<td>−5.7 (3.7, −12.5, 0.6)</td>
</tr>
<tr>
<td>Race (n, %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>38 (79)</td>
<td>19 (79)</td>
<td>19 (79)</td>
</tr>
<tr>
<td>Black</td>
<td>3 (6)</td>
<td>1 (4)</td>
<td>2 (8)</td>
</tr>
<tr>
<td>Asian</td>
<td>4 (8)</td>
<td>1 (4)</td>
<td>3 (13)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (2)</td>
<td>1 (4)</td>
<td>-</td>
</tr>
<tr>
<td>Not reported</td>
<td>2 (4)</td>
<td>2 (8)</td>
<td>-</td>
</tr>
<tr>
<td>Ethnicity (n, %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>3 (6)</td>
<td>2 (8)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Not Hispanic</td>
<td>38 (79)</td>
<td>18 (75)</td>
<td>20 (83)</td>
</tr>
<tr>
<td>Not reported</td>
<td>7 (15)</td>
<td>4 (17)</td>
<td>3 (13)</td>
</tr>
<tr>
<td>Comorbidities (n, %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>33 (69)</td>
<td>18 (75)</td>
<td>15 (63)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>14 (29)</td>
<td>8 (33)</td>
<td>6 (25)</td>
</tr>
<tr>
<td>Study eye (OD or OS)</td>
<td>25 OD (52)</td>
<td>12 OD (50)</td>
<td>13 OD (54)</td>
</tr>
<tr>
<td></td>
<td>23 OS (48)</td>
<td>12 OS (50)</td>
<td>11 OS (46)</td>
</tr>
<tr>
<td>BL IOP (mean, SD, minimum, maximum)</td>
<td>18.6 (4.2, 12, 31)</td>
<td>21.8 (3.2, 19, 31)</td>
<td>15.4 (2.0, 12, 18)</td>
</tr>
<tr>
<td>BL medications (mean, SD, minimum, maximum)</td>
<td>1.9 (1.3, 0, 4)</td>
<td>1.7 (1.3, 0, 4)</td>
<td>2.0 (1.3, 0, 4)</td>
</tr>
</tbody>
</table>

**Table 2. Baseline IOP by Ocular Hypotensive Medication Use**

<table>
<thead>
<tr>
<th>No. of Medications*</th>
<th>Group 1 IOP &gt;18 mmHg (N = 24)</th>
<th>Group 2 IOP ( \leq 18 ) mmHg (N = 24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>22.2 (6)</td>
<td>15.5 (2)</td>
</tr>
<tr>
<td>1</td>
<td>20.5 (4)</td>
<td>15.3 (9)</td>
</tr>
<tr>
<td>2</td>
<td>22.9 (8)</td>
<td>15.8 (4)</td>
</tr>
<tr>
<td>3</td>
<td>24.0 (3)</td>
<td>16.0 (4)</td>
</tr>
<tr>
<td>4</td>
<td>23.2 (3)</td>
<td>14.6 (5)</td>
</tr>
</tbody>
</table>

IOP = intraocular pressure.

*Fixed combinations were counted as the number of component drugs.
There were 2 (4.2%) AEs for clinically significant hyphema (>1 mm).

The number and percent of eyes with BCVA of 20/20 or better, 20/25 or better, 20/32 or better, 20/40 or better, worse than 20/40 to 20/80, worse than 20/80 to 20/200, and worse than 20/200 at each visit for all patients are summarized in Table 5. The BCVA was stable with no obvious trend.

Five subjects (10.4%) required an SSI for IOP in the medical judgment of the investigator. The reinterventions were selective laser trabeculoplasty (2, 40%), glaucoma drainage device (1, 20%), trabeculectomy (1, 20%), and EX-PRESS mini-shunt (Alcon, Fort Worth, TX) (1, 20%). Average time to SSI was 252.6 ± 78.5 days (minimum = 136, maximum = 343). The mean IOP and number of medications before the SSI were 26.4 ± 3.8 mmHg and 2.4 ± 1.5 medications, respectively.

**Discussion**

The increase of MIGS over the last 10 to 15 years has been transformative in the treatment and management of glaucoma. The bar for surgical intervention, once high, has been lowered.

![Figure 1](image_url)

**Figure 1.** Mean intraocular pressure (IOP) at the presurgical baseline (BL) and at each follow-up visit for group 1 (BL IOP >18 mmHg) and group 2 (BL IOP ≤18 mmHg). Error bars are 95% confidence interval. Grp 1 = group 1; Grp 2 = group 2; M 1, M6, M12 = months 1, 6, 12; ns = not significant; preop = preoperative.
Traditional bleb-forming surgery was reserved for patients with unacceptable disease progression despite maximum tolerated medical therapy, intervention with laser trabeculoplasty, or both. With the advent of MIGS, surgeons have been willing to intervene earlier given the excellent safety profile relative to traditional surgery.\textsuperscript{10,11} In the Ocular Hypertension Treatment Study, early medical intervention in ocular hypertensive patients was shown to reduce the likelihood of developing glaucoma by 50% over a 5-year period.\textsuperscript{12} The Early Manifest Glaucoma Trial showed an increase of 13% in the risk of glaucoma progression (median follow-up was 8 years) with each mmHg increase in IOP at 3 months postintervention.\textsuperscript{13} The Advanced Glaucoma Intervention Study showed the benefit of maintaining IOP below 18 mmHg.\textsuperscript{9} Similar to other MIGS, the OMNI is frequently used in patients who are medically well controlled. Although MIGS coupled with cataract surgery adds little or no additional risk, in the pseudophakic patient, the decision to take a patient to surgery is based on the favorable balance of risk-benefit for the glaucoma procedure alone. There is also the opportunity in these patients to reduce the burden of medication and allow for IOP control that is not reliant on patient adherence.

<table>
<thead>
<tr>
<th>AE (N = 48)</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild AC inflammation</td>
<td>6 (12.5)</td>
</tr>
<tr>
<td>Posterior capsule opacity</td>
<td>5 (10.4)</td>
</tr>
<tr>
<td>IOP increase ≥10 mmHg above BL &gt;30 days postoperatively</td>
<td>3 (6.3)</td>
</tr>
<tr>
<td>Cystoid macular edema</td>
<td>3 (6.3)</td>
</tr>
<tr>
<td>Worsening of visual field mean deviation ≥2 dB</td>
<td>3 (6.3)</td>
</tr>
<tr>
<td>Corneal edema</td>
<td>2 (4.2)</td>
</tr>
<tr>
<td>Hyphema &gt;1 mm\textsuperscript{*}</td>
<td>2 (4.2)</td>
</tr>
<tr>
<td>BCVA loss of ≥2 lines Snellen at or after 3 mos postoperatively</td>
<td>2 (4.2)</td>
</tr>
<tr>
<td>Dislocated IOL</td>
<td>1 (2.1)</td>
</tr>
<tr>
<td>Macular degeneration (dry)</td>
<td>1 (2.1)</td>
</tr>
<tr>
<td>Epiretinal membrane peel</td>
<td>1 (2.1)</td>
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<tr>
<td>Vitreous hemorrhage</td>
<td>1 (2.1)</td>
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<tr>
<td>Lid edema</td>
<td>1 (2.1)</td>
</tr>
<tr>
<td>Total</td>
<td>31</td>
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</tbody>
</table>

AC = anterior chamber; AE = adverse event; BCVA = best-corrected visual acuity; BL = baseline; dB = decibels; IOL = intraocular lens; IOP = intraocular pressure.\textsuperscript{*}Clinically significant hyphema (layered and >1 mm and/or persisting for 1 wk or more and/or required a secondary intervention). Limited and transient hyphema were expected and not considered AEs.

Figure 2. Mean number of ocular hypotensive medications preoperatively and at each follow-up visit. Error bars are 95% confidence interval. Group 1 = baseline (BL) intraocular pressure (IOP) >18 mmHg; Group 2 = BL IOP ≤18 mmHg. Wilcoxon signed-rank test was used for within-group comparisons, and Mann–Whitney rank-sum test was used for between-group comparisons. Grp 1 = group 1; Grp 2 = group 2; M 1, M6, M12 = months 1, 6, 12; ns = not significant; preop = preoperative.
result of contributions from distinct portions of the physiologic outflow pathway. In primates, up to 75% of the resistance comes from the trabecular meshwork and in particular the juxtacanalicular tissue. The inner wall accounts for <10% of resistance in normal eyes. Morphometric and perfusion studies show that the cross-sectional area of Schlemm’s canal averages 54% lower and mean outflow facility 55% lower in primary open-angle glaucoma eyes compared with normal, and that these measures are correlated implicating canal atrophy as a source of resistance. A third point of resistance is the collector channel ostia. In bovine eyes, light microscopy showed that increasing IOP resulted in herniation of the inner wall and juxtacanalicular tissue into the ostia of the collector channels. Addressing all 3 of these points of resistance by combining canaloplasty with trabeculotomy is appealing theoretically and practically. A single surgery with a minimally invasive approach has the potential to provide maximum safety and minimum tissue disruption, that is, no scleral and conjunctival dissection as with traditional glaucoma surgery. No implant is left behind. The conjunctiva is not injured. The promise of this multimodal, ab interno approach targeting all 3 sources of outflow resistance is supported by the results of the present study. Some 73% of all patients met the primary end point success criteria at month 12 (IOP <18 mmHg and ≥6 mmHg or a ≥20% reduction in IOP from preoperative BL IOP, and on the same number, or fewer, ocular hypotensive medications). Only 2% of patients required additional surgical or laser intervention through 230 days (>7 months) and 10% over the 12-month follow-up period. This is comparable to the SSI rate for trabecular bypass stents (6 months: 5.3%;20 12 months: 8%,21 4.3%;22 24 months: 4.7%;23 8.1%24). In the original iStent trial, Samuelson et al25 reported 28% of patients required paracentesis for IOP control (most in the perioperative period). Medication use in OMNI-treated patients decreased from a median of 2 medications preoperatively to 1 medication at month 12.

In addition to demonstrated effectiveness in reduction and control of IOP, there were few AEs, there were no serious or unanticipated AEs, and all AEs were mild and transient in nature. The incidence of reported hyphema was low compared with some published reports. Only clinically significant hyphemas (i.e., layered and >1 mm and persisting for 1 week or more and required a secondary intervention) were recorded as AEs in this study. Moreover, participating surgeons carefully screened for and avoided patient anticoagulant therapy during the perioperative period, whenever possible, and were careful to pressurize the globe at the close of the procedure. Sarkisian et al26 reported a 70% incidence of hyphema for eyes undergoing a similar trabeculotomy procedure; however, most of these were described as “mild and transient” with “clinically significant hyphema” occurring in only 5% of eyes, similar to the 4% rate reported in this article. Reported rates of hyphema for trabecular bypass stents are also variable depending on the definition used, with rates between 91% (intraoperative blood reflux) and zero (>10% of AC).2728 It is important to acknowledge that some degree of hyphema is commonplace and to be expected when the trabecular meshwork is cut; however, it is generally a short-term, self-limiting phenomenon that only infrequently requires additional intervention. The incidence of IOP spikes was also relatively low and likely reflects the nature of the procedure (e.g., in contrast to a cycloclysis that may close), the conservative approach many of the participating surgeons took in the discontinuation of IOP-lowering medications (note that the average number of medications at month 1 was intermediate between BL and month 6), and the generally short period of postoperative topical steroid use. Preoperative medications were generally continued until IOP reduction was confirmed and warranted discontinuation. The use of the OMNI did not affect visual acuity. Most patients had BCVA of 20/40 or better both preoperatively and at month 12.

Because the OMNI system has been available for use only since early 2018, there are limited published peer-reviewed data currently available. Brown et al29 reported on a series of 41 eyes from 24 patients undergoing cataract surgery and treated with the OMNI device. Consistent with the data in the present study, they found that the magnitude of IOP reduction was directly correlated with BL IOP. In their study, patients were grouped into <16 mmHg, >16 and <22 mmHg, and ≥22 mmHg. The lowest BL IOP group had an average IOP reduction of 0.6 mmHg, the group between 16 and 22 mmHg had a 4.5-mmHg reduction, and the highest-pressure group had a 9.6-mmHg reduction. Although the strata in the present study are broader and the series by Brown et al29 includes only combined with cataract surgery cases, the results are remarkably consistent. Group 2, which included BL IOP ≤18 mmHg, had a reduction in mean IOP of 1.5 mmHg, whereas group 1 (BL IOP >18 mmHg) showed a reduction of 6.2 mmHg. Post hoc analysis of only patients with BL IOP ≥22 mmHg showed an average reduction similar to that of Brown et al29 (8.8 vs. 9.6 mmHg). The patients in the present study achieved these

<table>
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<tr>
<th>Visit (n)</th>
<th>20/20 or Better</th>
<th>20/25 or Better</th>
<th>20/32 or Better</th>
<th>20/40 or Better</th>
<th>Worse than 20/40 to 20/80</th>
<th>Worse than 20/80 to 20/200</th>
<th>Worse than 20/200</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative BL</td>
<td>(47)</td>
<td>(32%)</td>
<td>(57%)</td>
<td>(79%)</td>
<td>(85%)</td>
<td>(13%)</td>
<td>(2%)</td>
</tr>
<tr>
<td>Month 1</td>
<td>(44)</td>
<td>(23%)</td>
<td>(52%)</td>
<td>(68%)</td>
<td>(80%)</td>
<td>(14%)</td>
<td>(5%)</td>
</tr>
<tr>
<td>Month 6</td>
<td>(46)</td>
<td>(33%)</td>
<td>(65%)</td>
<td>(74%)</td>
<td>(83%)</td>
<td>(15%)</td>
<td>(2%)</td>
</tr>
<tr>
<td>Month 12</td>
<td>(43)</td>
<td>(40%)</td>
<td>(60%)</td>
<td>(81%)</td>
<td>(81%)</td>
<td>(16%)</td>
<td>(2%)</td>
</tr>
</tbody>
</table>

BL = baseline.
significant and meaningful IOP reductions in the absence of cataract surgery. As stand-alone procedures, all IOP lowering could be ascribed to the OMNI intervention without a confounding contribution from phacoemulsification.

Although there are limited published data available for canaloplasty combined with trabeculotomy, there is a large body of data for the individual procedures. In a group of patients with open-angle glaucoma and similar severity of disease, Gallardo et al.\(^5\) reported a 25% reduction in IOP at 12 months postoperative for canaloplasty alone. Using the GATT technique to perform trabeculotomy, Grover\(^11\) reported a 32% reduction in IOP at 12 months for a cohort of pseudophakic eyes with primary open-angle glaucoma, although the BL IOP was greater (23.8 mmHg) than for group 1 of the present study (21.8 mmHg).

**Study Strengths and Limitations**

This report is a detailed analysis of retrospective data collected from 10 clinical sites. Retrospective studies have both strengths and weaknesses when compared with prospective trials. Completely standardized methods for measurements (e.g., IOP), surgical procedure, and medication introduction or discontinuation are the norm in a prospective study but are not possible in a retrospective study. In considering the medication reductions observed in this retrospective study, it is important to understand that the decisions to decrease or increase medication for a patient were made solely as part of a surgeon’s practice of medicine. There were no protocol-mandated criteria or thresholds to be met because the study protocol did not exist at the time these decisions were taken. From this standpoint, the medication use and reductions observed may more accurately predict real-world outcomes for patients treated with the OMNI than for medication use outcomes observed under a prospective clinical trial where investigator medication decisions are restricted by protocol criteria. The retrospective nature of the study ensured that all IOP measurements and physician decisions regarding medication had already been made and recorded in the medical record outside of the context of the study preventing subconscious bias for favorable outcomes at the level of the investigative site. The patient population in a prospective trial is typically precisely and often narrowly defined to minimize any potential confounding variables. In contrast, a retrospective study usually has more inclusive subject eligibility criteria. Although in some sense these aspects may be viewed as weaknesses, they are also the strengths. Although prospective trials have strong intrinsic validity and can provide reliable insights in the performance of a treatment when it is used exactly as directed in patients who fit the study profile, the “real-world” data from a retrospective trial have strong extrinsic validity. That is, the results of a retrospective “real-world” study can provide valuable insight into the performance of a therapy as used in real surgical practice with real (nonstudy) patients. Real-world data such as the present study give insights into how a therapy is really used and the kinds of patients in whom it is used.

In conclusion, the OMNI surgical system was found to provide effective IOP reductions or sustained IOP control and meaningful reduction in medication use for up to 12 months postoperatively in pseudophakic patients with mild to moderate open-angle glaucoma. No safety issues were identified on the basis of the analysis of AEs and BCVA. The OMNI was found to be effective and safe for use in this patient population.

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**Footnotes and Disclosures**

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\(^1\) Vold Vision, Fayetteville, Arkansas.
\(^2\) The Williamson Eye Center, Baton Rouge, Louisiana.
\(^3\) Mercy Eye Specialists, Springfield, Missouri.
\(^4\) Morris Eye Group, Encinitas, California.
\(^5\) Serrano Eye Center Medical Group, Los Angeles, California.
\(^6\) North Texas Eye Research Institute, University of North Texas Health Science Center, Fort Worth, Texas.
\(^7\) Sight Sciences, Inc, Menlo Park, California.

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S.D.V. and B.K.W.: Speakers for Sight Sciences, Inc.
J.E.D.: Employee — Sight Sciences, Inc.

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**HUMAN SUBJECTS:** Human subjects were included in this study. The human ethics committees at Aspire approved the study, and a waiver of consent was granted due to the retrospective non-interventional nature of the study. All research adhered to the tenets of the Declaration of Helsinki.

No animal subjects were used in this study.

**Author Contributions:**
Conception and design: Dickerson
Analysis and interpretation: Hirsch, Dickerson
Obtained funding: N/A

Overall responsibility: Vold, Williamson, Hirsch, Aminlari, Cho, Nelson, Dickerson

**Abbreviations and Acronyms:**
AC = anterior chamber; AE = adverse event; BCVA = best-corrected visual acuity; BL = baseline; FDA = Food and Drug Administration; IOP = intraocular pressure; MIGS = microinvasive glaucoma surgery; SSI = secondary surgical intervention.
Keywords:
canaloplasty, trabeculotomy, MIGS, viscodilation, OMNI, ab interno, open-angle glaucoma, Schlemm’s canal, Minimally invasive glaucoma surgery.

References