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ORIGINAL RESEARCH

Comparison of Superior versus Inferior Canaloplasty and Trabeculotomy Using the OMNI Surgical System

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Purpose: To compare outcomes of ab-interno canaloplasty and trabeculotomy of the superior versus inferior angle.

Patients and methods: This was a prospective, non-randomized, interventional comparison study done at the Veteran Affairs Hospital in Long Beach, California. All patients underwent cataract surgery with intraocular lens implantation combined with ab-interno canaloplasty and trabeculotomy with the OMNI Surgical System (SightSciences, Menlo Park, CA, USA), either superiorly or inferiorly. Pre- and post-operative intraocular pressure using Goldmann applanation tonometry and best corrected visual acuity were obtained and compared using paired t-tests. Patients were excluded if they had any prior intraocular surgery or prior laser trabeculoplasty procedures.

Results: 38 eyes from 29 patients were analyzed. 19 eyes were included in the superior group and 19 eyes in the inferior group. Mean pre-operative IOP in the superior group was 17.6 ± 5.2 mmHg and in the inferior group was 17.6 ± 4.6 mmHg ($p > 0.99$). At 12 months, mean postoperative IOP for the superior group decreased 24% to 13.3 ± 2.8 mmHg while the inferior group decreased 26% to 13.1 ± 2.2 mmHg ($p = 0.92$). Mean preoperative medications in the superior group were 2.2 ± 1.3 and in the inferior group was 2.4 ± 1.3 ($p = 0.88$). At 12 months, this decreased to 1.3 ± 1.5 post-operatively in the superior group and 2.2 ± 1.6 post-operatively in the inferior group ($p = 0.64$).

Conclusion: There was no statistical difference in efficacy between superior versus inferior canaloplasty/trabeculotomy with OMNI. Therefore, surgeons can perform the procedure in the direction that is most comfortable for them without affecting outcomes.

Keywords: OMNI, canaloplasty, trabeculotomy, goniotomy, MIGS

Introduction

The development of minimally invasive glaucoma surgeries (MIGS) has provided safe and efficacious interventions to lower IOP for glaucoma patients.[1–3] The arc length and location of trabeculotomy procedures have long been speculated to impact outcomes. Recent studies suggest that variable arc lengths may not have a major impact on outcomes,[4–8] however the location of the treatment arc has not been studied until now. The OMNI Surgical System (OMNI) is a MIGS device developed to perform ab-interno microcatheterization and transluminal viscodilation of Schlemm's canal (canaloplasty) followed by ab-interno transluminal trabeculotomy. The device addresses outflow resistance at the level of the collector channels (CC), Schlemm's canal (SC), and the trabecular meshwork (TM). Recently, the GEMINI and ROMEO 2 trials demonstrated both the safety and efficacy of this device in reducing IOP and medication use.[9–12] However, potential differences in IOP-lowering effectiveness as a consequence of which hemisphere (inferior or superior) is treated using this or other MIGS devices have not been evaluated.

The device is equipped with a microcatheter designed to enter and catheterize SC for 180 degrees. Once the canaloplasty and goniotomy are completed in one direction for 180 degrees, the surgeon then has the option of turning

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the device over to treat the other 180 degrees of the outflow system. However, a surgeon may choose to treat only 180 degrees rather than 360 degrees of the outflow system for various reasons. Firstly, a certain direction may be easier for the surgeon to cannulate than another. For a right-handed surgeon, entrance into the canal from the right to left direction with a forehand approach tends to be more comfortable, compared with the backhand approach. Furthermore, some clinicians suggest that leaving residual TM tissue intact may aid the eye in regulating IOP.[13] Additionally, the arc length of treatment may not impact the outcomes of IOP reduction or decrease in the number of glaucoma medications.[4,5] Lastly, treating more than 180 degrees may increase the risk of post-operative complications, such as hyphema and inflammation, which could lead to less favorable outcomes or more complicated post-operative recovery periods.[7,13]

Regardless of the reason, performing 180 degrees of ab-interno canaloplasty and trabeculotomy leads to treating either the superior or inferior outflow system while leaving the other untreated. Histopathology evaluations of the outflow system have shown that a larger proportion of the aqueous CC are located inferonasally.[14,15] Additionally, imaging of aqueous outflow has demonstrated more aqueous outflow in the nasal and inferior regions of the limbus as compared to the superior and temporal regions.[16–20] Given these anatomical differences, it has been hypothesized that targeting treatment over the inferior and nasal regions of the outflow system would prove to be more beneficial than the superior and nasal region when using the OMNI device. Alternatively, it has also been suggested that liberating under-utilized collector channels in the superior angle might improve IOP outcomes of MIGS surgery in cases where the inferior angle is already functioning maximally. This study seeks to tease out this query by comparing the efficacy of 180 degrees ab-interno canaloplasty and goniotomy in the superior versus inferior outflow system.

Methods

This was a prospective study that was approved by the Institutional Review Board at the Veteran Affairs Hospital in Long Beach, California and adhered to the Declaration of Helsinki. HIPAA regulations were followed. All patients underwent cataract surgery with intraocular lens implantation combined with ab interno canaloplasty and trabeculotomy with the OMNI and informed consent was obtained from all participants. All eyes in this study completed 180 degrees of canaloplasty and trabeculotomy. Procedures were performed between March 2022 and February 2023. Patients with ocular hypertension, mild to severe open angle glaucomas, including those with pseudoexfoliation and pigmentary glaucoma, were included; however, 90.4% of the patients had a diagnosis of primary open angle glaucoma. Patients were excluded if they had any prior intraocular surgery or prior laser trabeculoplasty procedures.

Preoperative Assessment

All patients underwent a complete preoperative examination within 30 days of surgery which included best-corrected visual acuity (BCVA), IOP measurement using Goldmann applanation tonometry, un-dilated gonioscopy, and dilated fundus examination. All patients were deemed to have a visually significant cataract before surgery. Each patient was required to have open angles based on the gonioscopic exam (Shaffer grade 3 or 4) to be included. The IOP measurement and the number of ocular hypotensive medications in use at this appointment were recorded as the patient's preoperative baseline. Patients' medical charts were reviewed and each patient's age, sex, and ethnicity were recorded.

Procedure in Detail

After cataract extraction with intraocular lens implantation was completed, intracameral Acetylcholine Chloride was administered. Next, the microscope was tilted approximately 30 degrees away from the surgeon sitting temporally, the patient's head was rotated away from the surgeon, and a goniolens was placed on the cornea. The OMNI handpiece was introduced through the main clear cornea incision toward the nasal TM. A small goniotomy was made with the tip of the device, the catheter was inserted into SC, and advanced for 180 degrees using the gear wheel on the handpiece. As the catheter was retracted into the device, viscoelastic was injected to perform viscodilation of SC. The catheter was then re-introduced into SC through the original goniotomy site and advanced again to the full extent of the catheter in the same direction as the original canaloplasty. As the device was removed from the clear corneal incision, the ab interno trabeculotomy was completed. After completion, viscoelastic was then removed from the eye and water-tight closure of the incisions as typically performed after cataract surgery was accomplished. Patients were treated with topical moxifloxacin and prednisolone acetate four times

per day for one week, after which the antibiotic was discontinued and the steroid was tapered by one drop per week for a total treatment of one month. Glaucoma medications were adjusted post-operatively to maintain individual target IOP. The choice of treatment hemisphere was left to the surgeon's preference so as to remove any influence on intra-operative technical challenges or incomplete treatment arcs.

Statistical Analysis

Subjects were divided into those who underwent the procedure in the superior direction (Superior Group) and those who underwent the procedure in the inferior direction (Inferior Group). Patients were followed for 6 to 12 months after surgery. Postoperative IOP was recorded at months 1, 3, 6, and 12. Number of medications and BCVA were recorded at the patient's last visit. Mean IOP and number of medications were calculated for each group. The mean percent change of IOP was calculated for postoperative months 1, 3, 6, and 12. Percent change in the number of medications was also calculated. Paired *t*-tests were run to compare pre- and postoperative mean IOP and number of medications for each group. Next, paired *t*-tests were used to compare pre- and post-operative IOP and number of medications between the two groups. The *t*-tests were two tailed, and p-value was set at 0.05.

The percentage of patients with BCVA of 20/30 or better and those with BCVA worse than pre-operative BCVA were calculated for each group. LogMAR visual acuity and baseline mean deviation on Humphrey visual fields were also recorded and compared with paired *t*-tests.

Results

38 eyes from 29 patients met the inclusion criteria. 19 eyes were included in the superior group and 19 eyes in the inferior group. The average age for the superior and inferior group was 73.8 years old and 72.0 years old, respectively ($p = 0.45$). The baseline mean deviation on Humphrey visual fields was -4.8 ± 5.0 dB for the superior group and -7.2 ± 7.3 dB for the inferior group ($p = 0.22$). Baseline logMAR visual acuity was 0.36 for the superior group and 0.32 for the

Table 1 Patient Demographics

	Superior	**Inferior**
Number	19	19
Age in years (p = 0.45)	73.8	72.0
Race		
Black	8 (42%)	8 (42%)
White	8 (42%)	6 (32%)
Asian	1 (5%)	0
Hispanic	1 (5%)	2 (11%)
Unspecified	1 (5%)	3 (16%)
Glaucoma Severity		
Mild	11 (58%)	9 (47%)
Moderate	4 (21%)	5 (26%)
Severe	2 (11%)	4 (21%)
OHTN	2 (11%)	1 (5%)
Baseline MD (p = 0.22)	−4.8	−7.2
Baseline logMAR visual acuity (p = 0.76)	0.36	0.32

Abbreviations: OHTN, ocular hypertension; MD, Mean deviation on Humphrey visual fields.

Table 2 12-Month Outcomes

	Superior	Inferior	P-value
Mean Pre-op IOP in mmHg	17.6 ± 5.2	17.6 ± 4.6	0.99
Mean Post-op IOP in mmHg	13.3 ± 2.8	13.1 ± 2.2	0.92
Percent Change	24%	26%	–
Number of Pre-op Meds	2.2 ± 1.3	2.4 ± 1.3	0.88
Number of Post-op Meds	1.3 ± 1.5	2.2 ± 1.6	0.64

Abbreviation: IOP, intraocular pressure.

inferior group (p = 0.76). Additional baseline patient characteristics are compared in Table 1. 89.5% of the eyes had final BCVA of 20/30 or better in the superior and inferior groups. There was a statistically significant improvement in visual acuity (logMAR) in both the superior and inferior groups (p < 0.01). There was no statistically significant difference between post-operative logMAR visual acuity in the superior versus inferior groups (p = 0.39).

The mean preoperative IOP for all patients was 17.6 ± 4.9 mmHg which was reduced to 13.2 ± 2.5 mmHg (p < 0.01) at 12 months. The mean pre-operative IOP in the superior group was 17.6 ± 5.2 mmHg and in the inferior group was 17.6 ± 4.6 mmHg (p > 0.99) (Table 2). At 12 months, the mean postoperative IOP for the superior group decreased by 24.0% to 13.3 ± 2.8 mmHg while the inferior group decreased 26.0% to 13.1 ± 2.2 mmHg (p = 0.92) (Figure 1). Mean preoperative medications in the superior group were 2.2 ± 1.3 and in the inferior group was 2.4 ± 1.3 (p = 0.88). At 12 months, this decreased to 1.3 ± 1.5 post-operatively in the superior group and 2.2 ± 1.6 post-operatively in the inferior group (p = 0.64) (Figure 2).

Complications were reported whether they were a result of the cataract extraction portion or glaucoma portion of the surgery (Table 3). One eye (2.6%) encountered a posterior capsular tear during cataract surgery requiring anterior vitrectomy and sulcus intraocular lens placement and one eye (2.6%) had post-op macular edema that resolved with topical anti-inflammatory drops. Two eyes (5.3%) had transient hyphema in the early post-operative period that resolved by the week 1 visit. Both hyphemas measured less than 1 mm and neither were associated with IOP elevations. One eye (2.6%) had an IOP spike which resolved after re-starting topical aqueous suppressant medications. A focal iridodialysis occurred in two eyes (5.3%), which were asymptomatic and not visible without slit lamp biomicroscopy. There were no incidences of cyclodialysis cleft formation or hypotony.

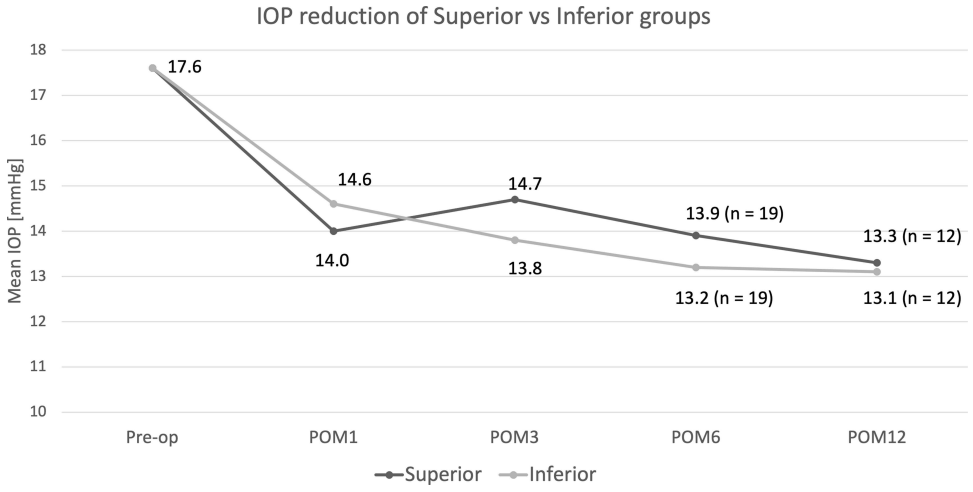

Figure 1 IOP reduction in Superior versus Inferior groups.
Abbreviation: IOP, intraocular pressure.

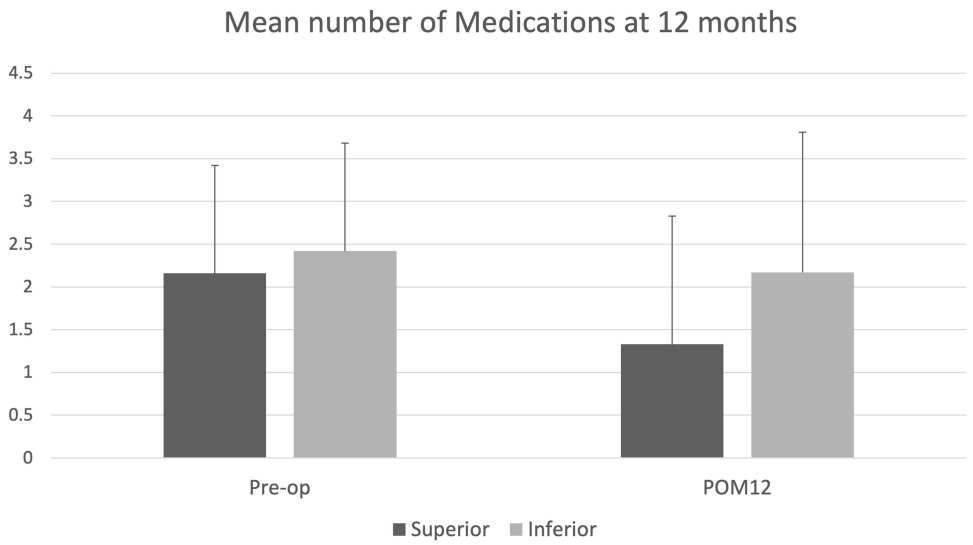

Figure 2 Number of ocular hypotensive medications at 12 months compared to pre-op.

Discussion

The introduction of numerous MIGS devices has allowed surgeons to target the conventional outflow system safely and efficaciously in the treatment of glaucoma.[1–3] The OMNI device has previously been shown to significantly reduce IOP and maintain a favorable safety profile.[9–12,21] This study confirms the efficacy of using the OMNI to reduce IOP and the number of glaucoma medications. It further demonstrates that when treating 180 degrees, targeting the superior or inferior direction does not impact outcomes of IOP or reduction in glaucoma medications.

The nuances of using MIGS devices, such as any differences in IOP reduction when treating the superior versus the inferior angle, are not well studied. To the authors' knowledge, this is the first study to compare efficacy in treating different regions of the conventional outflow system with MIGS in glaucoma patients. Prior investigations have compared the amount (in degrees) of treatment of the conventional outflow system. For example, one non-surgical, randomized control trial found that performing selective laser trabeculoplasty on 360 degrees of the trabecular meshwork as compared to 180 degrees was more efficacious in lowering IOP at one year.[22] Additionally, comparisons of the larger Hydrus microstent and smaller iStent devices have shown varying results with possible increased IOP reduction with the Hydrus microstent, though this difference may be secondary to the inherent features of the stent itself rather than the degrees of treatment.[23,24] A recent study by Toris et al compared the outflow facility of one versus two iStents and the

Table 3 Number and Frequency of Adverse Events

Adverse Event	# (%)
Anterior chamber inflammation (beyond 1 month)	3 (7.9%)
Hyphema >1mm	2 (5.3%)
Focal iridodialysis	2 (5.3%)
Macular edema	1 (2.6%)
IOP spike >30 days post op	1 (2.6%)
Corneal edema	1 (2.6%)
Sulcus IOL due to PC rupture	1 (2.6%)

Abbreviations: IOP, intraocular pressure; IOL, intraocular lens; PC, posterior capsule.

Hydrus microstent versus two iStents, found that outflow facility increased with increasing number of iStents and was greatest with the Hydrus, suggesting that gains in Schlemm's canal dilation arcs resulted in increased outflow facility.[25]

Recent investigations have compared degrees of treatment with goniotomy/trabeculotomy using various MIGS devices including the Kahook Dual Blade (KDB), Tanito Microhook, Trab360, GATT, and OMNI—these studies have found no significant differences in IOP reduction despite larger areas of treatment.[4–8] For example, a recent study by Zhang et al concluded that there is little difference between IOP reduction or medication use after 120, 240, or 360 degrees of goniotomy.[4] Hirabayashi et al retrospectively compared 120 degrees of goniotomy performed by the Kahook Dual Blade and 360 degrees of goniotomy performed by the Trab360 device or GATT and found no difference in IOP reduction or adverse events at 6 months.[6] In another study, Song et al also found no significant difference in IOP reduction when performing goniotomy on 120 vs 360 degrees with or without phacoemulsification (Tanito Microhook or KDB for the 120 degree goniotomy and GATT for 360 degrees).[7] Similarly, Hughes et al found no difference in IOP reduction at 18 months in eyes treated with 180 or 360 degrees of canaloplasty using the Visco360 or OMNI device.[8] While further research is needed to delineate these outcomes, the potentially varying regions being targeted in these studies may be at least partially responsible for these results.

While we hypothesized that there may be greater IOP reduction in the inferior treatment group, our study found that there was no significant difference in IOP outcomes when targeting the superior versus inferior TM. This finding was somewhat unexpected given the anatomy of the conventional outflow system. Histological examination reveals that more CCs are located nasally and inferiorly.[14,15] Episcleral venous fluid wave analyses also suggest that outflow is favored inferonasally.[16] Furthermore, ex-vivo and in-vivo aqueous angiography studies have shown that most eyes have preferential flow to the nasal regions of the outflow system.[17–20] However, favoring recruitment of low flow areas may have a greater impact on IOP reduction than high flow areas of the conventional outflow system as suggested by a recent study in which goniotomy performed in "low-flow" areas of the conventional outflow system in ex vivo porcine and human eyes, resulted in increased outflow facility and IOP reduction as compared to high flow areas.[26]

Since the procedures in our study all included the nasal angle, the results of this study suggest that the addition of trabeculotomy in the superior versus inferior quadrant does not result in significantly different outcomes. However, it should be noted that the reduction in number of glaucoma medications was greater in the superior group than the inferior group though the difference was not statistically significant. There are a few possible explanations for these findings. Firstly, performing canaloplasty may remove resistance in CC pathways that previously received less flow, allowing the IOP to better approximate episcleral venous pressure. Secondly, the degree of the goniotomy itself (180 degrees) may be sufficient to remove trabecular resistance for a critical mass of CCs, beyond which any further TM removal would not result in any further IOP reduction. Thirdly, perhaps the goniotomy in the nasal region regardless of targeting the superior or inferior outflow pathway is sufficient to reduce the IOP into the low teens.

This finding provides valuable information to adopters of the OMNI device in considering how to best apply the technology. When performing 180 degrees of treatment, the study suggests that the surgeon can target the direction, be it superior or inferior, that is most comfortable for them (ie, utilizing a "forehand pass" rather than a "backhand pass"). The forehand approach is generally how most surgeons adopt MIGS procedures in real-world applications, and these results allow each individual surgeon to proceed with their preferred arc direction and are helpful in surgical planning and intraoperative decision-making.

This study is not without limitations. Our subjects were not randomized pre-operatively to treatment hemispheres to allow for more patients with complete 180 degrees of treatment and to better approximate real-world results as surgeons will often perform the procedure in the most easily managed hemisphere based on patient positioning, individual angle anatomy, and other intraoperative factors. Although there was no statistically significant difference between the change in pre versus postoperative number of medications when comparing the two groups, there was only a mild reduction in number of post-operative medications in the inferior group compared to the superior group. We hypothesize that this difference may be due to the fact that the patients in the inferior treatment group had more moderate stage glaucoma (mean baseline deviation of −7.2 ± 7.3 dB versus −4.8 ± 5.0 dB for the superior group) and therefore required more medications postoperatively to maintain goal IOP.

Additionally, the patient population was all male, and these results may not be generalizable to female patients. However, our results were consistent with other studies of OMNI that included both sexes.[9–12] Each patient also underwent cataract extraction with intraocular lens implantation at the same time as ab-interno canaloplasty and trabeculotomy, and therefore the results may not be applicable to patients undergoing stand-alone procedures. Furthermore, these results were not directly correlated to aqueous angiography in individual eyes to assess whether an absolute number of CC is a factor in IOP reduction. Lastly, this study only looked at IOP outcomes from postoperative month 6 to 12 and future studies would be strengthened by longer follow up periods.

Conclusions

The salient findings of this study confirm the efficacy of using the OMNI device to reduce IOP in patients with primary open angle glaucoma undergoing simultaneous cataract extraction. Furthermore, this study also finds that when treating 180 degrees of the outflow system, targeting the superior direction or inferior direction did not make a statistically significant difference in IOP outcomes or reduction in the number of glaucoma medications at postoperative month 6 to 12. Therefore, when deciding to perform this procedure on 180 degrees of the conventional outflow system, surgeons can perform it in the direction that is most comfortable for them without compromising outcomes.

Data Sharing Statement

The authors do not intend to share the data of the participants. Requests should be directed to the corresponding author.

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Disclosure

Dr Sameh Mosaed reports personal fees from Alcon and Skye Bioscience; grants from Sightsciences, outside the submitted work. The authors report no other conflicts of interest in this work.

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