

Real-World Outcomes of Combined Phacoemulsification and STREAMLINE[®] Canaloplasty: Interim Analysis of a Longitudinal Single-Center Retrospective Study

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Purpose: To report the clinical outcomes of a novel ab interno minimally invasive procedure with the STREAMLINE[®] Surgical System for creation of incisional goniotomies and canaloplasty in eyes with primary open-angle glaucoma (POAG).

Methods: In a retrospective analysis of all consecutive cases performed and followed for up to 12 months, 51 eyes of 51 subjects with mild, moderate, and severe primary open-angle glaucoma (POAG) underwent canaloplasty and incisional goniotomy following phacoemulsification cataract extraction. The procedure was performed according to the manufacturer's instructions for use. However, in contrast to other studies where the technique involved solely incisional goniotomy during viscoelastic delivery, in this study, a 1–2 clock hour goniotomy was created with the cannula after 3–6 injections of viscoelastic into Schlemm's canal. Outcomes in this interim analysis included mean reduction in IOP and medications through month 12, as well as the proportion of eyes achieving IOP reduction $\geq 20\%$ from baseline.

Results: Mean preoperative IOP was 16.9 mmHg using a mean of 1.2 medications ($n = 51$). At 30 days post-op, mean IOP was 15.3 mmHg using a mean of 0.2 medications; 21.6% (11/51) had IOP reduction $\geq 20\%$ from baseline; 90.2% (46/51) were medication-free. At 6 months post-op, mean IOP was 15.6 mmHg using a mean of 0.2 medications; 21.6% (11/51) had IOP reduction $\geq 20\%$ from baseline; 90.2% (46/51) were medication-free. At 12 months post-op, mean IOP was 17.0 mmHg using a mean of 0.2 medications, 37.3% (19/51) had IOP reduction $\geq 20\%$ from baseline; 88.2% (45/51) were medication-free. No adverse events were reported. No secondary surgical interventions were required in any patient.

Conclusion: Canaloplasty and incisional goniotomy combined with phacoemulsification safely and effectively reduced dependence on IOP-lowering medications while adequately managing IOP in eyes with primary open-angle glaucoma through 12 months of follow-up.

Plain Language Summary: This study examined the real-world outcomes of a device called the STREAMLINE Surgical System. The device was used in combination with cataract surgery to treat glaucoma patients. The study followed 51 eyes of patients with mild to severe primary open-angle glaucoma for 12 months to assess how well the procedure reduced IOP and the need for glaucoma medications.

The results showed that the surgery was safe and effective. On average, patients experienced a significant reduction in their need for medications, with nearly 90% of participants medication-free for up to 12 months after surgery while maintaining stable intraocular pressure. Additionally, no serious adverse events or additional surgeries were required during the study period. These findings provide valuable insights into how this technique can be used in real-world clinical settings to improve patient outcomes.

Keywords: glaucoma, goniotomy, canaloplasty, viscodilation, MIGS, trabecular meshwork

Introduction

Surgical treatments for glaucoma are evolving in response to the persistent desire to avoid the risks associated with traditional filtration procedures.^{1,2} One such strategy utilizes the STREAMLINE® Surgical System (New World Medical, Rancho Cucamonga, CA), which was cleared via the 510(k) pathway by the US Food and Drug Administration (FDA) on October 8, 2021. It is a single-use, disposable instrument consisting of a surgical grade stainless-steel cannula and a polymer handset. The cannula features a long thin neck, which allows for access to the trabecular meshwork (TM) through a clear corneal incision. Prior to use, the system is loaded with ophthalmic viscoelastic. There is an actuator button on the hand-piece that, when fully depressed, retracts the polymer outer sleeve and facilitates positioning of the stainless-steel inner cannula. This inner cannula creates an incisional goniotomy of 150 µm in diameter and simultaneously delivers ~7µL of viscoelastic into the canal of Schlemm, which stretches the TM and flushes the distal collector channels. The system allows the surgeon to tailor the number of and placement of goniotomies and the number of applications of ophthalmic viscoelastic (up to 8 deliveries) into Schlemm's canal.

As surgical treatment for glaucoma has evolved, so has the technology and technique of these procedures. Canaloplasty and goniotomy are two of the leading methods used for the surgical treatment of glaucoma today. Canaloplasty uses a microcatheter to access and dilate Schlemm's canal with viscoelastic, improving the flow of aqueous humor. A popular device used for canaloplasty in the United States is the iTrack®.³ Goniotomy removes a portion(s) of the trabecular meshwork to improve the drainage of aqueous humor. The Kahook Dual Blade® is a common device used in the United States for goniotomy.⁴ The OMNI Surgical System® utilizes a catheter to perform both canaloplasty and trabeculotomy, which differs from the canaloplasty and goniotomy of STREAMLINE®.⁵ STREAMLINE is unique in its ability to provide small, precise 150µm goniotomies in the trabecular meshwork, disrupting less tissue, while simultaneously delivering viscoelastic into Schlemm's canal without the use of a catheter. Thus, surgeons may consider STREAMLINE a faster and less invasive method of delivering viscoelastic into Schlemm's canal. Phacoemulsification has also been shown to lower IOP in numerous studies. A cataract can obstruct the flow of aqueous humor from the posterior to the anterior chamber, and the removal of a cataract deepens the anterior chamber and promotes increased flow through the trabecular meshwork.⁶

In this preliminary analysis of an ongoing longitudinal study, we characterize 12-month efficacy and safety following phacoemulsification cataract extraction and incisional goniotomy and canaloplasty using the STREAMLINE surgical system in eyes with primary open-angle glaucoma (POAG). This study uniquely follows 1–2 clock hour goniotomies, creating larger incisional sites than those typically made with STREAMLINE. Our study aims to provide data for the comparison of STREAMLINE after cataract surgery in a real-world clinical setting to other micro-invasive glaucoma procedures used to treat primary open-angle glaucoma.

Materials and Methods

In this retrospective study, case records of consecutive patients who underwent phacoemulsification and intraocular lens (IOL) implantation followed by incisional goniotomies and canaloplasty using the STREAMLINE Surgical System for POAG of any stage at BVA Advanced Eye Care (Oklahoma, United States) from 1/26/22 to 9/1/22 were included. Criteria from the Center for Medicare and Medicaid Services (CMS) were used to define the stage of glaucoma as mild (code H40.1131), moderate (Code H40.1132), or severe (Code H40.1133).⁷

The study was conducted in accordance with the tenets of the Declaration of Helsinki and its amendments and was approved by Sterling Independent Review Board with a waiver of informed consent as the data were recorded in patient charts as a part of routine clinical practice and only de-identified patient data were analyzed.

Primary efficacy endpoints included mean reduction in IOP and medications through month 12, as well as the proportion of eyes achieving IOP reduction $\geq 20\%$ from baseline. Secondary endpoints included sub-group analysis at 12 months of patients with baseline IOP > 18 mmHg versus patients with baseline IOP ≤ 18 mmHg. The incidence and characterization of adverse events (AE) were also recorded. Patients were excluded if they had any prior incisional glaucoma surgery, did not have 12-month follow-up data, or if they had combined Streamline plus stenting procedures. Consecutive cases that met study inclusion and no exclusion criteria were included to reduce bias. Since this was

a retrospective study, power analysis was not conducted prior to data collection for the purpose of identifying an adequate sample size.

All procedures were performed by a single surgeon according to the manufacturer's instructions for use⁸ following cataract extraction by phacoemulsification cataract surgery and intraocular lens implantation. The procedure was performed after phacoemulsification in every case. Prior to use, the device was loaded with ophthalmic viscoelastic fluid. The device tip was advanced through the phacoemulsification incision to the nasal drainage angle using intraoperative gonioscopy for visualization. The outer sleeve of the device was placed adjacent to the TM, and the actuator button was depressed, delivering 7uL of viscoelastic fluid into the canal. This procedure was repeated over approximately 4 clock hours until 3–6 applications of viscoelastic were administered. Additionally, a 1–2 clock hour goniotomy connecting areas of prior incisional goniotomies was performed using the inner cannula in every case. The precise number of viscoelastic applications and size of goniotomy were dependent upon patient status prior to surgery. Patients with more advanced disease or greater medication burden typically received more applications and a larger goniotomy. Additionally, if no obvious visual cues were identified during initial viscoelastic injection to confirm delivery into Schlemm's canal (such as blanching of the trabecular meshwork), then additional viscoelastic applications were administered. This study is the first to report outcomes with this novel technique.

Because this was a retrospective, real-world study, there was no washout period. For most patients (and for all patients on a single medication prior to surgery), all medications were held starting at post-op day 0. Medications were only added back if the IOP was deemed above target pressure, which was at the discretion of the physician. Patients were seen at routine post-operative intervals, and any adverse events or secondary surgical interventions were noted in the electronic medical record.

Results

Fifty-one eyes of 51 subjects were analyzed. Demographic and baseline glaucoma data are given in Table 1. Thirty-seven eyes (72%) had mild glaucoma, ten eyes (20%) had moderate glaucoma, and four eyes (8%) had severe glaucoma. Seven patients had history of SLT in the study eye. Of those seven, three patients were on zero pre-operative medications, three were on one medication, and one patient was on three medications. The mean pre-operative Humphrey Visual Field among participants ($n = 47$) was -2.96 (SD 4.72).

Mean IOP data at each time point are given in Table 2 and Figure 1. Mean (standard deviation) medicated IOP at baseline was 16.9 (3.9) mmHg. Mean IOP was significantly reduced from baseline to 1 month postoperative, to 15.3 (3.9) mmHg ($p < 0.001$), with 21.6% (11/51) achieving IOP reduction $\geq 20\%$ from baseline. Mean IOP was significantly reduced from baseline to 6 months postoperative, to 15.6 (2.8) mmHg ($p < 0.01$), with 21.6% (11/51) achieving IOP reduction $\geq 20\%$ from baseline. Mean IOP was not significantly reduced from baseline to 12 months postoperative.

Table 1 Demographic and Baseline POAG Status Data for the Study Sample ($N = 51$)

Age (years), mean (SD)	71 (6)
Gender, n (%)	Male 15 (29%) Female 36 (71%)
Ethnicity, n (%)	White 38 (75%) Black 5 (10%) Hispanic 2 (4%) Did not say 6 (12%)
Glaucoma severity, n (%)	Mild 37 (72%) Moderate 10 (20%) Severe 4 (8%)

Abbreviation: POAG, Primary Open Angle Glaucoma.

Table 2 Mean IOP and Medication Changes from Baseline at Each Visit (N = 51)

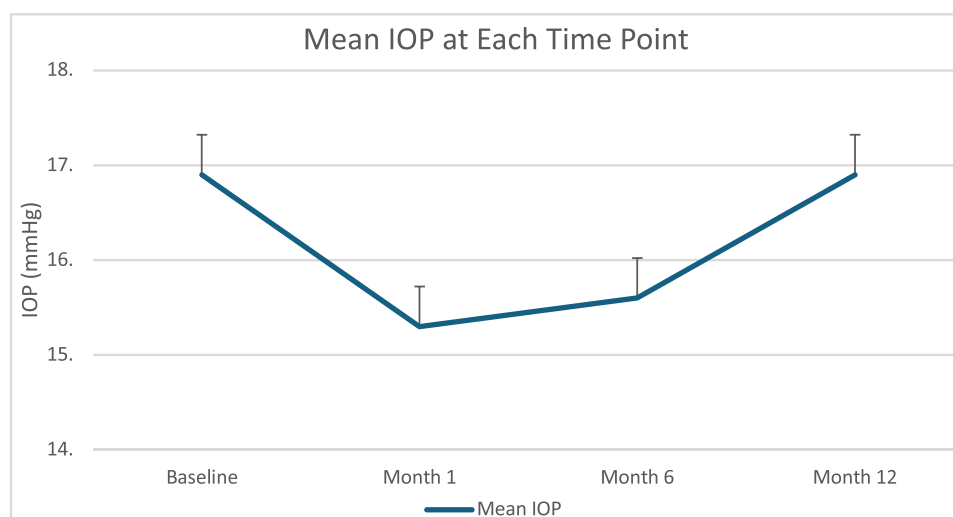
	Baseline	Month 1	Month 6	Month 12
Number of Eyes	51	51	51	51
IOP				
• Mean SD	16.9 (3.9)	15.3 (3.9)	15.6 (2.8)	17.0 (3.0)
• Mean (SD) Change from baseline	–	–1.6 (3.5)	–1.3 (3.5)	0.1 (3.5)
• Mean (SD) % change from baseline	–	–7.9 (0.2)	–5.0 (0.2)	0.7 (0.5)
• Significance	–	<0.001	<0.01	0.41
Number of Medications				
• Mean SD	1.2 (0.8)	0.2 (0.7)	0.2 (0.7)	0.2 (0.7)
• Mean SD (change from baseline)	–	–1.0 (0.6)	–1.0 (0.7)	–1.0 (0.7)
• Mean (SD) % change from baseline	–	79.0 (39.0)	79.0 (39.0)	79.0 (39.0)
• Significance	–	<0.001	<0.001	<0.001

Abbreviations: IOP, Intraocular pressure; SD, Standard Deviation.

Mean medication use data at each time point are given in [Table 2](#) and [Figure 2](#). Subjects used a mean of 1.2 (0.8) medications at baseline, and this was significantly reduced ($p < 0.001$) to a mean of 0.2 medications at one month postoperative, at which point 90.2% of subjects (46/51) were medication-free.

The reduction in mean medication usage persisted through to 12 months postoperative. After postoperative stability (month 1 and beyond), the mean number of medications persisted at 0.2, representing a mean reduction of 1.0 medications and a persistent percent reduction of 79.0%. At month 12, 84.3% (43/51) of subjects were using fewer medications than at baseline and 88.3% (45/51) were medication-free.

In the sub-group analysis ([Table 3](#)), which included sixteen patients with baseline IOP > 18 mmHg, the mean medicated IOP at baseline was 21.38 (3.18SD) mmHg. Mean IOP was significantly reduced from baseline to 12 months postoperative, to 17.75 (3.73SD) mmHg ($p < 0.0002$). Also in this group, subjects used a mean of 0.88 (0.81SD) medications at baseline, and this was significantly reduced ($p < 0.0004$) to a mean of 0.19 (0.54SD) medications at 12 months postoperative.

**Figure 1** Mean IOP at each time point.

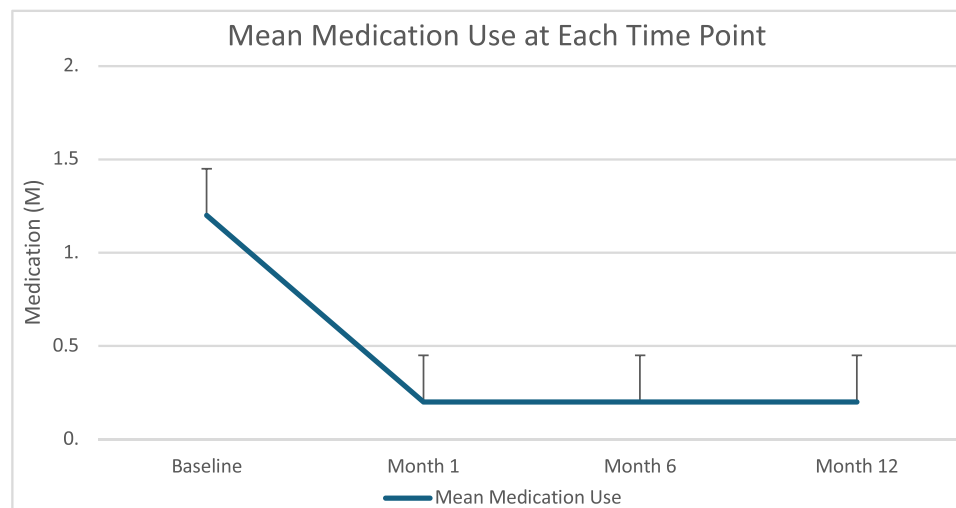


Figure 2 Mean medications at each time point.

In the sub-group analysis of thirty-five patients with baseline IOP ≤ 18 mmHg, mean medicated IOP at baseline was 14.80 (2.07SD) mmHg. Mean IOP increased from baseline to 12 months postoperative to 16.63 (2.65SD) mmHg, which was not statistically significant. Also in this group, subjects used a mean of 1.4 (0.81SD) medications at baseline. This was reduced to a mean of 0.23 (0.73SD) medications at 12 months postoperative, which was not statistically significant. The procedure was safe and well tolerated. No adverse events were reported, and no secondary surgical interventions were required in any patients.

Discussion

The findings in this investigation further demonstrate outcomes that favorably compare with clinical trials that have evaluated TM bypass devices^{9–12} and other transluminal dilation procedures.^{13–23} The current investigation also aligns with earlier prospective case series, which found that use of the STREAMLINE Surgical System combined with phacoemulsification safely and significantly decreased both IOP and the need for IOP-lowering medications.^{24,25} Specifically, in a 2022 study by Lazcano-Gomez et al, mean IOP was reduced by 36.9% and medication use by 49.1% at 6 months, with 42.1% achieving a medication-free status.²⁴ In a separate 2023 paper by Lazcano-Gomez et al looking specifically at Hispanic patients, mean IOP was reduced by 30.2% and medication use by 60.5% at 12 months, with more than half of subjects (51.4%) achieving a medication-free status.²⁵

In this most recent study, given there was no pre-operative washout period, mean IOP reduction was comparatively less pronounced; however, medication reductions were greater than what has been previously reported. In the current investigation, the 79% mean medication reduction at one-month post-operative persisted through 12 months, at which point 84.3% of subjects were using fewer medications and 88.3% were medication-free. Additional evidence of this is made apparent in the analysis of patients with baseline IOP ≤ 18 mmHg.

While medication dependence remained low at the 12-month post-op visit, the average IOP rose to levels comparable to those before surgery. The gradual increase in IOP between the 1, 6, and 12-month post-op visits raises the question of a potential waning of procedural efficacy. Medication reintroduction was based on physician discretion and that patients

Table 3 Subgroup Analysis of Mean IOP and Medication Changes from Baseline to Month 12

	Group 1 > 18 mmHg IOP Clinical Outcomes @ 12 Months (n = 16)		Group 2 ≤ 18 mmHg IOP Clinical Outcomes @ 12 Months (n = 35)	
	IOP (mmHg)	Medication	IOP (mmHg)	Medication
Mean Change	−3.63	−0.69	+1.83	−1.17
% Change	−16.96%	−78.57%	+12.36%	−83.67%

Abbreviation: IOP, Intraocular pressure.

whose IOP remained within an acceptable clinical range (even with an increase) did not require additional treatment. This reflects real-world decision-making, where therapeutic goals vary between patients. Further evaluation involves revisiting this same population at 24 months and beyond to determine the continual effectiveness of STREAMLINE.

This investigation adds to the growing body of research and longer-term follow-up of patients receiving canaloplasty and incisional goniotomy following phacoemulsification cataract extraction. In addition, it is the first to report on a real-world use that was not previously reported in the literature. In contrast to other studies using this device, where solely incisional goniotomies were created during viscoelastic delivery, in this study, a 1–2 clock hour goniotomy was created with the cannula after 3–6 injections of viscoelastic into Schlemm's canal. The technique was performed to evaluate potential benefits of increasing areas of outflow while assessing potential risks of increased inflammation or bleeding. Although we did not find a statistically significant benefit of IOP lowering compared to prior studies that only performed the incisional goniotomies, there was a higher percentage of medication-free patients. Notably, there were no increased rates of hyphema. The retrospective nature of this study provides a greater understanding by analyzing real-world, long-term data in a diverse population. This study design contains clear advantages compared to those that are shorter or more controlled. Furthermore, the retrospective study allows us to identify rare or delayed complications, offering a more comprehensive evaluation of the potential prolonged effects of the procedure.

As with all studies, some limitations are worth noting, beginning with the retrospective design. Although this limits generalizability due to uncontrolled baseline characteristics and protocols, it notably allowed for a deeper understanding of efficacy and safety in real-world settings, where physicians place variable degrees of importance on baseline IOP, IOP reduction preferences, and desire to reduce medication burden. Future real-world studies assessing outcomes from more than one surgeon would add to our understanding of best practices and strategies for optimizing outcomes. Additional limitations include the modest sample size and study duration, which are not reflective of the conic nature of a disease that patients often must treat for decades. Furthermore, the decreased number of patients with moderate-to-severe disease limits our ability to generalize our results to this population of patients.

Another limitation of this retrospective study is the lack of control groups. Since this study only evaluates a single group where all patients received goniotomy, canaloplasty, and cataract surgery simultaneously, it is difficult to discern the effects of each intervention compared to their synergistic effects. Further prospective studies evaluating STREAMLINE and cataract surgery versus cataract surgery alone and STREAMLINE as a standalone procedure are needed to evaluate the IOP and medication-lowering effects of these methods individually.

Conclusion

Canaloplasty and goniotomy with STREAMLINE combined with phacoemulsification safely and effectively reduced dependence on IOP-lowering medications while adequately managing IOP through 12 months of follow-up in patients with primary open-angle glaucoma. Further studies are required to evaluate the combined effects of the IOP-lowering methods used.

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Disclosure

Don Nguyen has financial interests and/or receives consulting fees from New World Medical, AbbVie, and Alcon. The authors report no other conflicts of interest in this work.

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