• Clinical Research •

One year clinical outcomes with a novel canaloplasty device in mild to severe open angle glaucoma

Iden M. Amiri, Heran W. Gebreyesus, Nathan Grove, Jennifer L. Patnaik, Malik Y. Kahook, Leonard K. Seibold

Department of Ophthalmology, University of Colorado School of Medicine, Aurora, Colorado 80045, USA

Correspondence to: Leonard K. Seibold. Department of Ophthalmology, University of Colorado School of Medicine, 1675 Aurora Court, Aurora, CO 80045, USA. leonard.seibold@cuanschutz.edu

Received: 2025-01-09 Accepted: 2025-05-21

Abstract

• **AIM:** To evaluate the one-year clinical outcomes of a novel canaloplasty device used in combination with cataract extraction (CE) in patients with mild to severe open angle glaucoma (OAG).

• **METHODS:** This study reviewed patients diagnosed with mild to severe OAG, who underwent canaloplasty with the STREAMLINE® Surgical System combined with CE. The primary outcome was surgical success, defined as achieving ≥20% intraocular pressure (IOP) reduction and/or a reduction of ≥1 glaucoma medication compared to baseline. Secondary outcomes included mean IOP, average number of glaucoma medications, and best-corrected distance visual acuity (BCDVA). Data was collected preoperatively and at multiple postoperative time points up to one year.

• **RESULTS:** A total of 68 eyes of 47 patients were included with mean age was 73.1±7.0y and 60% were females. Surgical success at one year was achieved in 68.8% of eyes, with 67.6% success in mild, 80.0% in moderate, and 66.7% in severe OAG cases. IOP was significantly reduced from a baseline of 16.1±0.5 to 14.7±0.4 mm Hg at one year (P=0.0004). The number of medications decreased significantly in all eyes from a baseline of 1.2±0.1 to 0.6±0.1 at one year (P<0.0001). When stratified by glaucoma severity, only the mild group experienced a statistically significant decrease from a baseline of 1.1±0.1 to 0.4±0.1 (P<0.0001). BCDVA improved significantly from baseline to one year. No sight-threatening complications were reported.

• **CONCLUSION:** Canaloplasty using the STREAMLINE® surgical system combined with CE effectively reduces IOP at one year in mild to severe OAG with minimal complications. IOP lowering efficacy, reduction in IOP lowering medications, and safety in moderate to severe OAG require further study.

• **KEYWORDS:** open angle glaucoma; STREAMLINE Surgical System; microinvasive glaucoma surgery; canaloplasty

DOI:10.18240/ijo.2025.09.08

Citation: Amiri I, Gebreyesus H, Grove N, Patnaik JL, Kahook MY, Seibold LK. One year clinical outcomes with a novel canaloplasty device in mild to severe open angle glaucoma. *Int J Ophthalmol* 2025;18(9):1673-1680

INTRODUCTION

Glaucoma remains a leading cause of irreversible blindness worldwide, presenting a significant clinical challenge due to its progressive nature and chronicity[1]. All current treatment options, such as medications, laser trabeculoplasty, and incisional surgery aim to reduce intraocular pressure (IOP) to slow or prevent further optic nerve damage. The effectiveness of medical therapy is limited by adverse effects and nonadherence, while traditional filtering surgeries for glaucoma carry the risk of vision-threatening surgical complications[2-4].

In recent years, microinvasive glaucoma surgeries (MIGS) have emerged as a promising approach to manage glaucoma, offering the potential for reduction in IOP while also reducing medication dependence[5]. Most of the currently available MIGS procedures including trabecular bypass stents and scaffolds, excisional goniotomy, and canaloplasty seek to augment the traditional outflow pathway through the trabecular meshwork and canal of Schlemm[6]. These procedures are typically performed in conjunction with cataract extraction (CE). However, there is a growing body of evidence to support their use as standalone procedures as well[7]. Recent literature has demonstrated that canaloplasty using different catheter-based devices effectively lowers IOP in patients with open angle glaucoma (OAG)[8-10]. One study reported significant and sustained IOP reduction over a three-year follow-up period in patients undergoing canaloplasty using a circumferential catheter, with a favorable safety profile[11].

The STREAMLINE® Surgical System (New World Medical, Rancho Cucamonga, CA, USA) is a novel canaloplasty device that targets the trabecular meshwork (TM) and canal of Schlemm as well as the downstream outflow channels to enhance aqueous outflow, thereby lowering IOP and/or reducing medication dependence. The Streamline canaloplasty procedure involves the creation of several TM punctures to access the canal of Schlemm, while delivering ophthalmic viscoelastic device (OVD) to viscodilate the canal, and downstream outflow pathways. The delivery of OVD across several clock hours improves aqueous outflow through multiple mechanisms including stretching of the TM, dilating the canal of Schlemm, and flushing the distal collector channels. The procedure can be performed either in combination with CE or as a standalone procedure, broadening its applicability to both phakic and pseudophakic eyes[12]. In the first clinical study published, Lazcano-Gomez *et al*[13] reported 6-month surgical outcomes with a 37% mean IOP reduction from baseline in mild to severe primary open angle glaucoma (POAG) patients undergoing canaloplasty with the STREAMLINE® surgical device combined with CE. Mean preoperative topical IOP-lowering medication burden was reduced by 50% at 6mo.

While the initial use of the STREAMLINE® surgical system has shown promising short-term outcomes in a small sample, there remains a need for comprehensive and longitudinal assessments of larger sample sizes to evaluate the sustained efficacy and safety of this procedure. In this study we describe the one-year clinical outcomes of patients with glaucoma who underwent canaloplasty with the STREAMLINE® procedure in conjunction with CE.

PARTICIPANTS AND METHODS

Ethical Approval This was a single-site, retrospective review of eyes diagnosed with mild to severe OAG. Prior to the start of study, approval was obtained from the Colorado Multiple Institutional Review Board (COMIRB, protocol 16-1345) and the protocol adhered to the tenets of the declaration of Helsinki. Due to the retrospective nature of the study and the analysis of a deidentified database, the study was granted a waiver of consent by our institutional ethics committee (COMIRB).

Consecutive eyes that underwent canaloplasty surgery with the STREAMLINE® Surgical System device combined with CE from November of 2021 to September of 2022, were included in the study. All surgeries were performed at the Sue Anschutz-Rodgers Eye Center at the University of Colorado School of Medicine.

All patients were over the age of 40y and diagnosed with OAG and visually significant cataracts necessitating surgery for vision improvement. The indication for canaloplasty with the STREAMLINE® Surgical System was the need for further IOP reduction and/or desire to reduce medication burden, consistent with long-term evidence supporting canaloplasty as an effective and durable surgical option[14]. Glaucoma subtypes were classified based on standard clinical criteria: POAG was defined as the presence of characteristic optic nerve damage and visual field loss with an open angle on gonioscopy and no history or clinical signs of secondary glaucoma causes, normal tension glaucoma (NTG) as OAG with baseline IOP consistently ≤21 mm Hg, pigmentary glaucoma as OAG with iris transillumination defects and pigment deposition on anterior segment structures, pseudoexfoliative glaucoma as OAG with clinically visible pseudoexfoliation material on the anterior lens capsule and/or pupillary margin, and uveitic glaucoma as elevated IOP and glaucomatous optic nerve damage in the setting of a known or suspected history of intraocular inflammation. Patients with varying severity levels of OAG, ranging from mild to severe, were included in this review. Glaucoma severity was classified according to the International Classification of Diseases, tenth revision (ICD-10) staging system. Eyes excluded from this study included those displaying any form of closed angle on gonioscopy, prior intraocular surgery, or procedures that were combined with procedures other than canaloplasty and CE.

Included eyes had documented comprehensive clinical assessment including prior medical and ocular history, and ophthalmic examination including IOP, gonioscopy, and perimetry. Baseline demographic data and ocular history were collected by manual chart reviews and included IOP, visual acuity, and number of glaucoma medications at the visit prior to the surgery. Visual acuity was measured by Snellen charts with the best corrected visual acuity used. IOP was measured by Goldmann applanation tonometry when possible, and with iCare rebound tonometry (iCare, Vantaa, Finland) when unable to reliably perform applanation. All anterior and posterior segment examinations were performed with slit lamp microscopy. Visual field testing was performed with standard automated perimetry using the Humphrey visual field (HVF) 24-2c protocol (Zeiss, Oberkuchen, Germany). Combination medications were counted as 2 medications.

All eyes included in the study underwent a standardized surgical approach involving the use of the STREAMLINE® Surgical System, an MIGS approach consistent with techniques that enhance natural aqueous outflow through Schlemm's canal, in conjunction with CE[15-16]. Participating investigators were board-certified ophthalmologists with glaucoma fellowship training and substantial experience performing glaucoma angle surgery.

The procedure was performed after phacoemulsification surgery with intraocular lens implantation in the capsular bag and encompassed transluminal visco-dilation across

greater than 90 degrees of the canal of Schlemm, in line with refined canaloplasty methods that aim to maximize outflow through physiologic pathways[17-18]. Prior to the surgery, the device was primed with a cohesive OVD. Uncomplicated clear cornea phacoemulsification was performed first, with in-the-bag intraocular lens placement. The microscope was tilted 45 degrees towards the surgeon, and the participant's head was tilted 45 degrees contralaterally. The outer sleeve of the STREAMLINE® Surgical System device was inserted in the eye through an existing temporal corneal incision and advanced across the anterior chamber, reaching the nasal angle structures—an *ab-interno* approach shown to be effective across glaucoma subtypes[19]. The single use device consists of an outer handle with button and a long outer cannula that is inserted into the eye. The sleeve is positioned so that it gently abuts the trabecular meshwork, and the actuator button was fully engaged for 2s without moving position, retracting the outer sleeve and allowing the inner cannula to inject approximately seven microliters of OVD. The actuator button is then disengaged, and the aforementioned steps are repeated over several clock hours in the nasal angle totaling 4-8 times. The postoperative medication regimen consisted of moxifloxacin 0.5% four times daily for one week, and ketorolac tromethamine 0.4% and prednisolone acetate 1% four times daily with a weekly taper schedule over four weeks.

The primary outcome measure for this study was surgical success, defined as achieving an IOP reduction of ≥20% and/or a reduction of ≥1 topical glaucoma medications compared to preoperative baseline. Secondary outcomes included mean IOP, average number of glaucoma medications, and best-corrected distance visual acuity (BCDVA) following the surgical intervention. Patient demographic data, preoperative assessments, surgical details, and postoperative outcomes were systematically collected and analyzed. In accordance with the World Glaucoma Association, visual acuity, IOP, and glaucoma medication data were collected postoperatively on day 1, week 1, months 1, 3, 6, and year 1.

Statistical Analysis Characteristics of the cohort were described with frequencies, percentages, means, and standard deviations. Linear regression using generalized estimating equations with an exchangeable correlation structure was used to model the trajectories of IOP, number of medications used, and BCDVA following the Streamline procedure. Visual acuity was converted to logMAR for statistical analysis. Empirical means and standard errors (SE) of measurements are presented for preoperative and follow-up time points. *P*-values from the linear regression models were used to compare estimates at each timepoint with respect to the preoperative timepoint. For eyes with one year of follow-up, logistic regression using generalized estimating equations with an exchangeable correlation structure was used to compare eye-level baseline characteristics between successful and non-successful outcomes at one year after surgery. Statistical analysis was performed using R version 4.4.2, and generalized estimating equations were fit using the geepack package. $P<0.05$ was considered statistically significant.

RESULTS

The study included 68 eyes of 47 patients with a majority having primary OAG (POAG, 85%), and mild disease (72%). The mean age of patients was 73.1y [standard deviation (SD): 7.0], and 60% were female. There was a mean preoperative average retinal nerve fiber layer (RNFL) value of 76.1 μm (SD=10.4). The preoperative HVF mean deviation was -3.0 dB (SD=3.9). Study participants all underwent canaloplasty with the STREAMLINE® Surgical System and CE, of which 13% (n=9) were considered complex phacoemulsification procedures. About half of all patients (51%) underwent bilateral procedures with contralateral surgeries occurring on a separate date (Table 1). The mean preoperative IOP was 16.1 mm Hg [standard error (SE): 0.5; Table 2] with a mean of 1.2 (SE: 0.1) medications (Table 3).

Surgical success was achieved in 31 of 47 (66%) eyes assessed at 3mo, 39 of 54 eyes (72.2%) assessed at 6mo, and 33 of 48 (68.8%) eyes assessed at one year. Success varied by severity with success rates of 67.6% in mild, 80% in moderate, and 66.7% in severe OAG cases at one year. For the entire cohort, mean IOP was significantly reduced at postoperative day 1 and all timepoints after postoperative week 1 compared to baseline. At postoperative year one, mean IOP was significantly reduced to 14.7 mm Hg (SE=0.4) for all eyes, P=0.0004. When analyzing by disease severity group, mean IOP at one year was 14.9 mm Hg (SE=0.5, P=0.0042) for mild, 13.4 mm Hg (SE=1.6, P=0.2853) for moderate, and 14.3 mm Hg (SE=1.0, P=0.0049) for severe (Table 2).

Mean medication use for the entire cohort was significantly reduced at all timepoints through one year (0.6, SE=0.1, $P<0.0001$ at 1y). Mean medication use was significantly reduced at all time points in eyes with mild disease (0.4, SE=0.1, $P<0.0001$ at 1y). In the moderate group, mean medication use was only significantly reduced through postoperative month 1, and then returned to values similar to baseline. In the severe disease group, mean medication use was significantly reduced at all time points up until postoperative year 1 (1.5, SE=0.5, P=0.4565 at 1y; Table 3). At one year, 31 of 48 (65%) eyes were medication free.

No baseline covariatae were predictors of surgical success at one year. Eyes that achieved success did not differ significantly from those that did not with respect to baseline age, sex, race, disease severity, IOP, visual field mean deviation, and average RNFL thickness (Table 4).

Table 1 Patient- and eye-level characteristics

Variable	*n*=47
Age (y), mean±SD	73.1±7.0
Sex, *n* (%)	
Male	19 (40)
Female	28 (60)
Race, *n* (%)	
White/Caucasian	31 (66)
Black/African American	9 (19)
Asian	1 (2.1)
Other	6 (13)
Ethnicity, *n* (%)	
Hispanic	7 (15)
Non-Hispanic	40 (85)
Procedure laterality, *n* (%)	
Right	15 (32)
Left	8 (17)
Bilateral	24 (51)
Glaucoma type, *n* (%)	
POAG	40 (85)
NTG	3 (6.4)
Pigmentary	2 (4.3)
Pseudoexfoliative	1 (2.1)
Uveitic	1 (2.1)
Glaucoma Severity, *n* (%)	
Mild	34 (72)
Moderate	8 (17)
Severe	5 (11)
Number of preop. medications, *n* (%)	
0	12 (26)
1	18 (38)
2	9 (19)
3	8 (17)
Eye level variables	*n*=68
Glaucoma severity, *n* (%)	
Mild	49 (72)
Moderate	11 (16)
Severe	8 (12)
Preop. IOP (mm Hg), mean±SD	16.1±3.9
Preop. VF mean deviation (dB), mean±SD	-3.0±3.9
Preop. average RNFL (μm), mean±SD	76.1±10.4
Complex phacoemulsification, *n* (%)	9 (13)

SD: Standard deviation; NTG: Normal tension glaucoma; POAG: Primary open angle glaucoma; Preop.: Pre-operative; IOP: Intraocular pressure; VF: Visual field; RNFL: Retinal nerve fiber layer.

In regard to intra-operative complications, there was one case of a Descemet's membrane detachment. This was small, peripheral, and self-resolved by the one week visit. Postoperatively, there were no cases of hyphema, and one case of an IOP spike (>20 mm Hg) that resolved following one week of dorzolamide/timolol administration. Postoperatively, one eye underwent selective laser trabeculoplasty at postoperative month six and one eye underwent Ahmed glaucoma valve implantation at 9mo. There were no serious or vision threatening complications. The average preoperative BCDVA (logMAR) was 0.28 (SE=0.05), which decreased to 0.37 (SE=0.05) at 1d postoperatively and improved gradually thereafter. At one year, average BCDVA (logMAR) significantly improved to 0.13 (SE=0.02, *P*=0.0002).

DISCUSSION

One year follow-up after canaloplasty with the STREAMLINE® Surgical System combined with CE resulted in clinically and statistically significant reduction in IOP and dependence on IOP lowering medications over one year in eyes with OAG. This case series expands on prior data that demonstrated successful IOP reduction from canaloplasty with the STREAMLINE® Surgical System in combination with CE[11-12]. Data from this prior study demonstrated IOP reduction through postoperative month 6 and surgical success by IOP reduction (≥20% reduction from baseline IOP) of 68.8%, with over 40% of eyes having a reduction in topical medication burden. Extending follow-up data to one year in the present study, we see efficacy that is consistent with earlier results, with a statistically significant decrease in IOP and number of glaucoma medications at one year of follow-up.

In a previously published study using STREAMLINE® Surgical System, Lazcano-Gomez *et al*[12] found the procedure to be successful in lowering IOP at 6-months postoperatively in eyes with mild to severe POAG when combined with CE. In that prospective study, the authors found that 89.5% of all eyes (17/19) had IOP reduction ≥20% from their unmedicated baseline, and 42.1% of eyes (8/19) were medication-free. A subsequent study by Lazcano-Gomez *et al*[12] demonstrated 1-year outcomes of the STREAMLINE Surgical System. The findings of that study were similar to ours in demonstrating effective and safe reduction of IOP and use of IOP-lowering medications in patients with mild to moderate POAG. By month 12, 80% of eyes achieved a ≥20% IOP reduction, and 51.4% of eyes were medication-free[13]. Differences in methodology compared to our study include its prospective design, a higher baseline IOP (after a washout period) and less advanced disease in study participants. It is also worth mentioning that study participants in the Lazcano study were mostly female (85%) and younger (mean age=66.0y), in an exclusively Hispanic population. The percentage of eyes achieving surgical success by IOP reduction was somewhat less in the present cohort compared to the Lazcano-Gomez *et al*'s[12] study, however this may be due, at least in part, to the lack of a washout IOP at baseline in our study. It is important to note that the second Lazcano-Gomez *et al*'s[13] study study of

Table 2 IOP at baseline and follow-up times mean±SE

Parameters	Preop.	Postop. 1d	Postop. 1wk	Postop. 1mo	Postop. 2-4mo	Postop. 4-8mo	Postop. 9-14mo
All eyes, *n*	68	68	65	61	47	54	48
IOP	16.1±0.5	13.9±0.5	16.6±0.8	14.5±0.5	13.6±0.4	14.4±0.4	14.7±0.4
P	-	0.0001	0.5271	0.0010	<0.0001	0.0002	0.0004
Mild glaucoma, *n*	49	49	48	47	37	40	37
IOP	16.2±0.6	14.3±0.7	16.8±1.1	14.4±0.6	13.4±0.4	14.2±0.5	14.9±0.5
P	-	0.0030	0.5402	0.0082	<0.0001	0.0006	0.0042
Moderate glaucoma, *n*	11	11	9	7	6	7	5
IOP	15.2±1.3	12.2±1.3	15.2±0.9	14.7±1.6	14.2±1.5	14.6±1.3	13.4±1.6
P	-	0.0264	0.8788	0.5321	0.2529	0.5110	0.2853
Severe glaucoma, *n*	8	8	8	7	4	7	6
IOP	16.6±1	14.2±0.6	16.6±1	14.6±1.5	14±1.9	15.6±0.8	14.3±1
P	-	0.0319	1	0.0261	0.0114	0.2048	0.0049

P: IOP at follow-up times *vs* preop. IOP: Intraocular pressure; SE: Standard error; Preop.: Preoperative; Postop.: Postoperative.

Table 3 Glaucoma medications at baseline and follow-up times mean±SE

Parameters	Preop.	Postop. 1d	Postop. 1wk	Postop. 1mo	Postop. 2-4mo	Postop. 4-8mo	Postop. 9-14mo
All eyes, *n*	68	68	64	61	47	54	48
Medications, *n*	1.2±0.1	0	0.4±0.1	0.6±0.1	0.6±0.1	0.5±0.1	0.6±0.1
P	-	<0.0001	<0.0001	0.0002	<0.0001	<0.0001	<0.0001
Mild glaucoma, *n*	49	49	47	47	37	40	37
Medications, *n*	1.1±0.1	0	0.4±0.1	0.7±0.1	0.5±0.1	0.4±0.1	0.4±0.1
P	-	<0.0001	0.0001	0.0172	0.0003	<0.0001	<0.0001
Moderate glaucoma, *n*	11	11	9	7	6	7	5
Medications, *n*	1.2±0.3	0	0.4±0.2	0.6±0.3	0.8±0.5	1±0.5	0.6±0.4
P	-	<0.0001	0.0124	0.0273	0.3106	0.7721	0.4690
Severe glaucoma, *n*	8	8	8	7	4	7	6
Medications, *n*	2±0.5	0	0.1±0.1	0.4±0.3	1±0.7	0.4±0.3	1.5±0.5
P	-	<0.0001	<0.0001	0.0003	0.0409	0.0090	0.4565

P: Medications at follow-up times *vs* preop. SE: Standard error; Preop.: Preoperative; Postop.: Postoperative.

1-year outcomes only encompassed eyes with mild to moderate POAG. Furthermore, our study's demographic profile varied greatly from the prior two studies, as study participants were predominantly non-Hispanic (41/48, 85%), included a more equal distribution of males and females, and were on average older than those enrolled in the Lazcano-Gomez *et al*'s[12-13] study studies. Despite these study differences, it is encouraging to see similar significant improvements in IOP and medication burden in both studies. Moreover, our study demonstrated a similar safety profile with minimal adverse effects and no sight-threatening complications. Notably, when evaluating predictors of surgical success at one year, we found no significant associations between baseline demographic or clinical characteristics and treatment outcomes. Neither glaucoma severity, baseline IOP, nor complex phacoemulsification were predictive of success at one year. This suggests that the STREAMLINE® procedure may offer consistent efficacy across a diverse patient population regardless of baseline characteristics. Moreover, these findings align with the stepwise, individualized treatment approach emphasized in the American Academy of Ophthalmology's Preferred Practice Pattern for POAG, which supports early interventional options like MIGS when clinically appropriate[20].

A recent Meta-analysis further supports the role of MIGS combined with cataract surgery in reducing both IOP and medication burden in patients with coexisting OAG and cataracts, although substantial heterogeneity in techniques and outcomes were noted[21]. This variability underscores the importance of evaluating individual MIGS approaches—particularly canaloplasty-based procedures, which differ significantly in terms of mechanism, complexity, and extent of outflow pathway engagement. Recent studies have evaluated the efficacy of canaloplasty procedures utilizing catheter-based devices such as the iTrack and OMNI systems. A 2024 study by Koerber and Ondrejka[22] demonstrated that *ab-interno* canaloplasty with the iTrack microcatheter (Nova Eye, Adelaide, Australia), performed either as a standalone procedure or combined with cataract surgery, resulted in a

Table 4 Eye-level characteristics by success at postoperative 12mo

Variables	Overall, *n*=48	Success at postop. 12mo		Logistic regression[a]	
		No, *n*=15	Yes, *n*=33	OR (95%CI)	*P*
Age (y), mean±SD	72.7±7.2	71.5±9.1	73.3±6.2	1.05 (0.96 to 1.15)	0.31
Sex, *n* (%)					0.46
Male	18 (38)	7 (47)	11 (33)	Reference	
Female	30 (63)	8 (53)	22 (67)	1.69 (0.42 to 6.76)	
Race, *n* (%)					
White/Caucasian	38 (79)	12 (80)	26 (79)	Reference	
Black/African American	8 (17)	2 (13)	6 (18)	1.12 (0.19 to 6.64)	0.90
Asian	2 (4.2)	1 (6.7)	1 (3.0)		
Ethnicity, *n* (%)					
Hispanic	1 (2.1)	0	1 (3.0)		
Non-Hispanic	47 (98)	15 (100)	32 (97)		
Glaucoma type, *n* (%)					
POAG	40 (83)	14 (93)	26 (79)		
NTG	4 (8.3)	0	4 (12)		
Pigmentary	3 (6.3)	0	3 (9.1)		
Uveitic	1 (2.1)	1 (6.7)	0		
Glaucoma severity, *n* (%)					
Mild	37 (77)	12 (80)	25 (76)	Reference	
Moderate	5 (10)	1 (6.7)	4 (12)	3.11 (0.02 to 417)	0.65
Severe	6 (13)	2 (13)	4 (12)	0.55 (0.01 to 34.9)	0.78
Preop. IOP (mm Hg), mean±SD	16.2 (3.6)	16.7 (3.3)	15.9 (3.7)	0.92 (0.81 to 1.05)	0.22
Preop. VF mean deviation (dB), mean±SD	-2.8 (3.3)	-4.2 (4.4)	-2.1 (2.5)	1.20 (0.95 to 1.52)	0.13
Missing	5	1	4		
Preop. average RNFL (μm), mean±SD	75.1 (9.8)	72.8 (9.0)	76.2 (10.2)	1.02 (0.92 to 1.12)	0.75
Missing	9	2	7		
Complex phacoemulsification, *n* (%)	5 (10)	2 (13)	3 (9.1)	1.66 (0.26 to 10.5)	0.59

[a]Generalized estimating equations: Empty factor levels were not included in logistic regression models; Models for ethnicity and glaucoma type did not converge due to empty cells; Asian race excluded from Race model due to low sample size in Asian factor. SD: Standard deviation; OR: Odds ratio; CI: Confidence interval; POAG: Primary open angle glaucoma; NTG: Normal tension glaucoma; IOP: Intraocular pressure; Preop.: Preoperative; RNFL: Retinal nerve fiber layer; VF: Visual field.

significant reduction in IOP and a decrease in the number of glaucoma medications over a 6-year follow-up period. Specifically, the mean IOP (SD) decreased from 19.9 (5.2) mm Hg at baseline to 14.6 (3.3) mm Hg at 6y, and the average number of medications reduced from 1.9 (1) to 0.9 (0.9)[22]. While the STREAMLINE treated eyes in our study achieved a similar medication reduction and similar final IOP to this study, the percent IOP reduction was less, likely due to the lower starting pressure in our cohort. Earlier data on ab externo canaloplasty also demonstrated durable IOP and medication reductions over three years, confirming the long-standing efficacy of Schlemm's canal-based approaches in OAG[23]. Canaloplasty and trabeculotomy using the OMNI device—which combines 360-degree viscodilation with trabecular meshwork incision—demonstrated sustained IOP and medication reductions over 36mo in a large real-world IRIS Registry Study[24]. For example, combining canaloplasty using the iTrack microcatheter with a Hydrus Microstent in patients undergoing phacoemulsification yielded sustained IOP and medication reductions through 36mo, suggesting possible additive benefits when canaloplasty is paired with outflow-enhancing implants[18]. Similarly, the GEMINI studies assessed 12 and 36-month outcomes of combined phacoemulsification and *ab-interno* canaloplasty using the OMNI Surgical System (Sight Sciences, Menlo Park, California, USA) in patients with OAG. By 12mo, 84.2% of all eyes had ≥20% IOP reduction and 80% were medication free, highlighting the early efficacy of the combined OMNI procedure[25]. At 36mo, the GEMINI 2 study reported that 78% of eyes achieved ≥20% IOP reduction, with a 29% mean IOP reduction from baseline and 74% of eyes remaining medication-free, confirming the durability of the treatment effect[26]. While both devices aim to enhance aqueous outflow through Schlemm's canal, it is important to note that these approaches involve circumferential catheter-

based canaloplasty, which may differ in technique and outcomes compared to the STREAMLINE® procedure. The GEMINI study also utilized a washout period with a higher baseline mean IOP (23.8 mm Hg) making success comparisons with the present study difficult.

There are several limitations in this study. First, the sample size is relatively small, which may limit our ability to detect statistical differences, particularly when stratified by severity of glaucoma. In addition, the study was performed at one institution which may limit the generalizability of the findings to a broader population. Additionally, the study's duration of only one year does not allow us to assess long-term efficacy and safety outcomes. Moreover, it is important to note that there was not a control group of CE alone, which makes it difficult to attribute IOP and glaucoma medication reduction to the canaloplasty. Cataract extraction alone has been shown to reduce IOP in patients with OAG. One study by Majstruk *et al*[27] reported a mean IOP reduction of 1.15 mm Hg and no change in medication use at 1y postoperatively in patients with medically controlled POAG who underwent phacoemulsification. Another study by Shingleton *et al*[28] found a mean IOP reduction of 1.4 mm Hg and no change in medication 3y after CE in OAG eyes. We believe the greater IOP reduction in addition to a reduction in medication use observed in our cohort suggests that the STREAMLINE® Surgical System provides an additional and meaningful IOP-lowering benefit beyond what is expected from CE alone. It should also be noted that the procedure is relatively new, and there may be a learning curve associated with using a new surgical device, which could affect the consistency of the results across the study time period. This variability in surgical expertise and technique may have introduced additional confounding factors, potentially influencing the overall outcomes observed. In future work, involving more surgeons with varying levels of experience will help assess the learning curve and ensure that the procedure's outcomes are not overly dependent on individual expertise. Additionally, our study did not encompass any structural or functional assessments over time such as RNFL thickness and visual field analysis. Future studies exploring these variables as outcomes following canaloplasty by the STREAMLINE® Surgical System may be warranted to further characterize the long-term efficacy of this procedure.

Canaloplasty with the STREAMLINE® Surgical System combined with CE leads to clinically meaningful reduction in IOP and medication use in patients with mild to severe OAG for up to 12mo after surgery. Given that the STREAMLINE® Surgical System is a relatively recent addition as a commercial device, this study is noteworthy for reporting the real-world efficacy in a fairly diverse, older population. Future studies should aim to assess a longer duration of follow-up as well as prospectively compare STREAMLINE® Surgical System canaloplasty to other MIGS procedures, and to characterize its effects as a standalone procedure. This aligns with broader calls in the literature for higher-quality, comparative MIGS studies with standardized endpoints and long-term follow-up to better guide clinical decision-making[29].

ACKNOWLEDGEMENTS

Authors' Contributions: Seibold LK was responsible for the conceptualization, editing, and review of the manuscript. Gebreyesus H was responsible for data collection and review of the manuscript. Amiri I was responsible for the data collection, as well as writing and review of the manuscript. Kahook MY was responsible for the conceptualization and review of the manuscript. Grove N and Patnaik JL were responsible for the entirety of the data analysis and development of the tables within this manuscript, and review of the manuscript.

Artificial Intelligence Statement Disclosure: No generative artificial intelligence (AI), machine learning, or large language model tools were used in the writing or editing of this manuscript. The authors take full responsibility for the accuracy and originality of the content.

Foundation: Supported by Challenge Grant from Research to Prevent Blindness, Inc.

Conflicts of Interest: Amiri I, None; **Gebreyesus H,** None; **Grove N,** None; **Patnaik JL,** None; **Kahook MY,** consultant for New World Medical and receives patent royalties; owner of Spyglass Pharma and receives patent royalties; receives patent royalties from Alcon; **Seibold LK,** consultant for New World Medical.

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