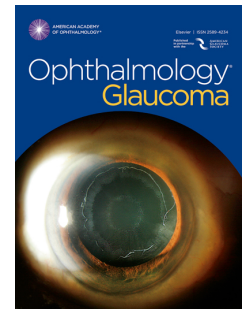


ELIOS Excimer Laser Trabeculostomy with Phacoemulsification in Primary Open-Angle Glaucoma: 24-Month Outcomes of Pivotal Trial

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PII: S2589-4196(26)00141-9

DOI: <https://doi.org/10.1016/j.ogla.2026.08.006>

Reference: OGLA 859

To appear in: *Ophthalmology Glaucoma*

Received Date: 29 May 2026

Revised Date: 11 August 2026

Accepted Date: 24 August 2026

Please cite this article as: Gallardo M, Sarkisian SR Jr., Reiss G, Lee A, Singh P, Borisuth N, Yassine M, Swaim K, McCabe C, Duh YJ, Ling HY, Nangia R, Ahmed IIK, on behalf of the ELTGTS Study Investigators, ELIOS Excimer Laser Trabeculostomy with Phacoemulsification in Primary Open-Angle Glaucoma: 24-Month Outcomes of Pivotal Trial, *Ophthalmology Glaucoma* (2026), doi: <https://doi.org/10.1016/j.ogla.2026.08.006>.

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ELIOS Excimer Laser Trabeculostomy with Phacoemulsification in Primary Open-Angle Glaucoma: 24-Month Outcomes of Pivotal Trial

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Journal Pre-proof

Financial Support:

This study was sponsored by Elios Vision, a wholly owned subsidiary of Bausch + Lomb. The sponsor was involved in the study design, data collection, data management, data analysis, and interpretation, and contributed to the preparation, review, and approval of the manuscript.

Conflict of Interest:

M.G.: Consultant/advisor — AbbVie/Allergan, Alcon, Bausch + Lomb, Glaukos, Alcon, Sight Sciences, Nova Eye Medical, Aerie Pharmaceuticals.

S.S.: Consultant/advisor — AbbVie/Allergan, Alcon, Bausch + Lomb, Beaver-Visitec International, Carl Zeiss Meditec USA, Glaukos, Icare USA, Iantrek, iStar Medical, Johnson & Johnson Surgical Vision, Katena Products Inc, MicroSurgical Technology, New World Medical, Novartis, Ocular Science, RadiusXR, RxSight, Santen, Sight Sciences, TearLab Corp, Thea Pharma. Grant support — AbbVie/Allergan, Alcon, Allysta Pharmaceuticals, Bausch + Lomb, Glaukos, iStar Medical, Ocular Therapeutix, Sights Sciences, Spyglass Pharma, Virtual Field. Equity Owner — Iantrek, Ocular Science, Sight Sciences. Lecture Fees — AbbVie/Allergan, Alcon, Bausch + Lomb, Glaukos.

G.R.: Consultant/advisor — AbbVie/Allergan, Glaukos, New World Medical, Nova Eye Medical, NICOX, RL Gore, Sight Sciences.

A.L.: Consultant/advisor — Bausch + Lomb.

P.S.: Consultant/advisor — AbbVie/Allergan, Glaukos, Alcon, New World Medical, Nova Eye Medical, NICOX, iStar Medical, Sight Sciences.

N.B.: Consultant/advisor — Alcon, Bausch + Lomb, Glaukos, New World Medical, NICOX, Spyglass Pharma.

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I.I.A.: Consultant/advisor — multiple ophthalmic companies including Alcon, Allergan/AbbVie, Bausch + Lomb, Glaukos, Alcon, Sight Sciences, Carl Zeiss Meditec, and others; Research support and speaking honoraria — select companies.

Running head: Excimer laser trabeculostomy 24-month outcomes

This article contains additional online-only material. The following should appear online-only: Figures S1A and S1B, and Tables S1, S2, S3, and S4.

Address for reprints: Bausch + Lomb. 400 Somerset Corporate Blvd. Bridgewater, NJ 08807, USA

Trial registration: ClinicalTrials.gov, NCT04899063

Keywords

Excimer laser trabeculostomy; intraocular pressure (IOP) reduction; minimally invasive glaucoma surgery (MIGS); combined phacoemulsification and minimally invasive glaucoma surgery (phaco-MIGS); glaucoma

Abbreviations

AC = anterior chamber; AE = adverse event; C/D = cup-to-disc; CDVA = corrected distance visual acuity; CI = confidence interval; CV = coefficient of variation; DIOP = diurnal intraocular pressure; ECD = endothelial cell density; FA = full analysis; FDA = US Food and Drug Administration; IDE = Investigational Device Exemption; IOP = intraocular pressure; MIGS = minimally invasive glaucoma surgery; POAG = primary open-angle glaucoma; PP = per

80 protocol; SD = standard deviation; SE = standard error; SLT = selective laser trabeculoplasty;
81 SSI = secondary surgical intervention; TM = trabecular meshwork; VFMD = visual field mean
82 deviation.
83

Abstract

Purpose: To evaluate 24-month safety and effectiveness of excimer laser trabeculostomy combined with phacoemulsification in patients with mild-to-moderate primary open-angle glaucoma (POAG).

Design: Prospective, multicenter, non-randomized pivotal investigational device exemption trial (NCT04899063).

Participants: Adults (≥ 45 years) with mild-to-moderate POAG, operable age-related cataract, medicated intraocular pressure (IOP) ≤ 24 mmHg on 1–3 ocular hypotensive medications, and unmedicated diurnal IOP (DIOP) 22–34 mmHg after washout.

Methods: Patients underwent phacoemulsification with intraocular lens implantation followed by excimer laser trabeculostomy (ELIOS System; Bausch + Lomb) and were followed for 24 months. Coprimary effectiveness endpoints were compared with prespecified performance goals derived from phacoemulsification-only control arms of other pivotal minimally invasive glaucoma surgery (MIGS) trials.

Main Outcome Measures: Coprimary endpoints were proportion of patients achieving $\geq 20\%$ reduction in unmedicated mean DIOP from baseline at months 12 and 24 (performance goals $>79\%$ and $>68.5\%$) and mean change in unmedicated DIOP at the same timepoints (performance goals ≤ -7.2 and ≤ -6.15 mmHg). Safety outcomes included adverse events, endothelial cell density (ECD), corrected distance visual acuity, visual field, and pachymetry.

Results: A total of 318 patients underwent the procedure (mean $\pm$ SD age, 70.3 $\pm$ 7.3 years; medicated IOP at screening, 17.05 $\pm$ 3.01 mmHg; unmedicated DIOP at baseline, 24.53 $\pm$ 2.51 mmHg). Both coprimary endpoints were met at months 12 and 24: a $\geq 20\%$ reduction in unmedicated DIOP was achieved by 84.2% and 76.1% of patients ($P=0.0116$ and $P=0.0018$ vs. performance goals), respectively, and the mean $\pm$ SE change in unmedicated DIOP was -8.17 ± 0.21 mmHg and -7.35 ± 0.22 mmHg (both $P<0.0001$ vs. performance goals), respectively.

Mean DIOP decreased to 15.98 mmHg at month 12 and 16.76 mmHg at month 24. At month 23, 82.0% of patients were medication-free. No intraoperative adverse events occurred during the ELIOS procedure, and the postoperative safety profile in this population was consistent with that expected following phacoemulsification alone. ECD reduction occurred early and stabilized from month 3 through month 24.

Conclusions: Through 24 months, excimer laser trabeculostomy with phacoemulsification provided sustained, clinically meaningful reductions in unmedicated DIOP and medication use, with a favorable safety profile, supporting its use as a MIGS option in patients with mild-to-moderate POAG undergoing cataract surgery.

Glaucoma is the leading cause of irreversible vision loss, affecting approximately 4 million people in the United States and projected to rise rapidly with the aging population.^{1,2} Primary open-angle glaucoma (POAG) is the most common subtype of glaucoma in the US and is characterized by an open anterior chamber angle and progressive optic neuropathy without identifiable cause, and is associated with elevated intraocular pressure (IOP). Lowering IOP remains the only established intervention that modifies the course of disease progression.³

Management of POAG generally follows a stepwise approach, beginning with topical hypotensive glaucoma medications or laser trabeculoplasty, escalating to incisional surgical interventions as required.³⁻⁵ However, long-term pharmacological therapy is limited by medication-related side effects, treatment cost, insufficient IOP control, and poor patient adherence.^{6,7} Fewer than half of patients maintain adequate medication compliance at 1 year,⁸ and chronic exposure to preservatives contributes to ocular surface disease and is cytotoxic to the trabecular meshwork (TM) endothelium, further compromising both quality of life and the success of future filtering surgery.^{3,9} The effects of selective laser trabeculoplasty (SLT) have been shown to diminish substantially over time,^{10,11} and incisional surgeries have a high rate of complications and substantial postoperative burden, which typically limits their use to advanced or severe disease.^{7,12}

Cataract commonly coexists with glaucoma, reflecting the shared age-related nature of both conditions,¹³ and approximately 1 in 5 cataract procedures is performed in patients with glaucoma or ocular hypertension.¹³ Minimally invasive glaucoma surgery (MIGS) encompasses a group of procedures that target different aqueous outflow pathways, and have been shown to provide adequate IOP control and reduce medication burden in mild-to-moderate glaucoma, with fewer complications and faster healing than incisional surgery.¹⁴ Further, combining phacoemulsification with MIGS has shown numerous benefits, including sustained IOP lowering, reduced secondary surgical interventions (SSIs), and reduced dependence on topical

drops, thereby improving patient quality of life.¹⁴⁻¹⁸ Consistent with this, the 5-year HORIZON trial demonstrated that combined phacoemulsification with a trabecular MIGS device achieved significantly greater preservation of the visual field than phacoemulsification alone.¹⁹ However, conventional MIGS procedures targeting the trabecular outflow pathway each carry mechanism-specific limitations: goniotomy and trabeculotomy achieve outflow access through irreversible excision of TM and alteration of the Schlemm's canal pump mechanism along with increased hyphema risk; trans-trabecular stents require precise placement and are permanently retained in the angle²⁰; and canaloplasty viscodilates Schlemm canal without removing tissue or implanting hardware, relying on mechanical dilation rather than the creation of a discrete outflow channel.²¹ Surgical approaches that overcome these limitations may expand the population of glaucoma patients eligible for combined intervention at the time of phacoemulsification.

The ELIOS System (Bausch + Lomb) uses a precision non-thermal 308 nm XeCl excimer laser system to create ten 210- μ m diameter "microchannels" in the TM, without the use of a retained device.^{15,22,23} The use of excimer lasers is well established in ocular surgery, and operate via a photoablative mechanism, delivering high-energy light that is strongly absorbed at the surface of the tissue.²⁴ Absorption of this energy causes molecular bonds to break and results in the tissue vaporizing in extremely thin, precise layers.²⁴ The ablated material is released as a plume, consisting of a variety of organic fragments and water. The absence of adjacent tissue interaction leads to well-delineated treatment areas, and results in limited inflammation and consequent wound-healing response.^{16,25,26} Unlike SLT, which lowers IOP through biologic remodeling of the TM, the ELIOS procedure creates direct microchannels to improve outflow and lowers IOP while preserving the majority of the delicate physiology of the TM,^{22,27,28} which allows this specialized pump to maintain its active role in aqueous outflow.²⁸

The ELIOS System has been CE-marked since 2014, with up to 8 years of European follow-up data;¹⁵ however, prospective multicenter data in a US population have been lacking prior to

the present study. Furthermore, a robust comparison to a cataract surgery only control group is needed. The objective of this study was to evaluate the safety and effectiveness of the ELIOS procedure to reduce IOP in adult patients with mild-to-moderate POAG undergoing cataract surgery.

Methods

Study Design

This was a 24-month, prospective, multicenter, non-randomized clinical trial (ClinicalTrials.gov, identifier: NCT04899063) conducted at 20 sites in the US. This study was designed to evaluate the safety and effectiveness of the ELIOS procedure to reduce IOP in patients with mild-to-moderate POAG undergoing cataract surgery.

The study received Investigational Device Exemption (IDE) granted by the US Food and Drug Administration (FDA) and received institutional review board approval at each participating site. All procedures were performed in accordance with Good Clinical Practice, the Declaration of Helsinki, and applicable FDA regulations. Investigators were experienced cataract and glaucoma surgeons and received standardized training on device setup and use.

Coprimary effectiveness endpoints were assessed at 12 months and 24 months using prespecified performance goals based on historical control data from cataract-only arms of pivotal MIGS studies. The objective was to demonstrate superiority of the ELIOS procedure performed concomitantly with cataract surgery over cataract surgery alone.

The coprimary endpoints were (1) proportion of patients with $\geq 20\%$ diurnal IOP (DIOP) reduction versus performance goal of $>79\%$ (12 months) and $>68.5\%$ (24 months), and (2) mean change in DIOP versus performance goal of ≤ -7.2 mmHg (12 months) and ≤ -6.15 mmHg (24 months) in the full analysis (FA) population. Performance goals were defined using the upper bound of the 95% confidence interval (CI) for the responder rates and DIOP reduction

from pooled weighted historical phacoemulsification-only control arms of three pivotal MIGS trials (see **Table S1** available at www.opthalmologyglaucoma.org for more information).

The study hypothesis tested whether outcomes following the ELIOS procedure combined with cataract surgery exceeded these thresholds. Other effectiveness outcomes included IOP by visit and medication use. Safety outcomes included corrected distance visual acuity (CDVA), rates of ocular adverse events (AEs), central endothelial cell density (ECD) change, visual field mean deviation (VFMD) change, and slit lamp and fundus findings.

Historical Control Comparison

The single-arm design using historical control data is consistent with FDA guidance for evaluating medical device safety and effectiveness, which supports a less burdensome approach of using non-concurrent controls where valid scientific evidence allows for adequate evaluation of device performance where sources of bias are appropriately addressed or minimized (**Supplemental Methods**, available at www.opthalmologyglaucoma.org).²⁹ To account for the well-established confounding effect of phacoemulsification alone on intraocular pressure outcomes that have been observed in prior MIGS studies, this study incorporated a comparison to a historical control arm of patients undergoing cataract surgery only. Each performance goal was intentionally set at the upper limit of the 95% confidence interval of the corresponding cataract-only estimate, rather than at the point estimate. This conservative construction requires the combined procedure to exceed the most favorable plausible outcome attributable to cataract surgery alone, thereby isolating the incremental contribution of excimer laser trabeculostomy and protecting against misattributing the phacoemulsification effect to the device. Three similar prospective, well-designed studies were used to establish the historical control for this study, Alcon Hydrus Microstent Pivotal Study, Glaukos iStent Inject Trabecular Micro-Bypass System Pivotal Study, and Alcon Cypass System.³⁰⁻³² This relevant and reliable body of historical data on cataract surgery alone was collected under the oversight of the FDA

within the IDE framework with comparable glaucoma treatment endpoints and patient populations.

Baseline characteristics (including age, sex, and race), medicated IOP at screening, and washout DIOP at baseline were generally similar between the comparison studies, supporting the comparability of the historical control data set (**Table S2** available at www.opthalmologyglaucoma.org). Notable differences included a higher proportion of Hispanic/Latino patients in this study (19.8% vs approximately 5–7% in comparator studies) and a higher proportion of patients receiving a single medication at screening (69.8% vs. predominantly ≥ 2 medications in comparator cohorts). These differences may reflect a broader and more contemporary US glaucoma population. Key elements of the study design, including eligibility criteria, were modeled on FDA-approved premarket approval studies in the public domain, most notably the HORIZON trial.³³ The proportion of eyes with $\geq 20\%$ reduction in washed-out DIOP from baseline at 24 months for the cataract surgery control group are similar across all 3 studies, with an approximate difference of 4%. The mean reduction in washed-out DIOP from baseline at 24 months is also similar across the 3 studies (**Table S1**, available at www.opthalmologyglaucoma.org). The consistency in the outcomes increases the validity as a historical control data set and therefore it would be reasonable to expect that if a concurrent control was used in this study of a cataract-only arm, it would have achieved similar outcomes to the data observed in the three pivotal studies.

In addition, the availability of FDA-approved MIGS devices and procedures as well as the current standard of care in the US, raises questions regarding the ethics of randomizing subjects with glaucoma to a cataract-only arm when they have the potential to achieve IOP reduction with less medication burden. Moreover, the availability of these devices and procedures would have impeded the ability to enroll patients into the trial, as patients as well as the physicians would be reluctant to be randomized to an option that does not offer further potential for IOP reduction.

Eligibility Criteria

Eligible patients were aged ≥ 45 years with operable, age-related cataract and mild-to-moderate POAG. Key inclusion criteria included medicated IOP ≤ 24 mmHg on 1–3 ocular hypotensive medications at screening and unmedicated DIOP ≥ 22 and ≤ 34 mmHg at baseline, with an IOP increase of ≥ 3 mmHg between screening and baseline. Additional inclusion criteria included visible TM on gonioscopy with Shaffer angle grade $\geq III$ in all quadrants; observable glaucomatous optic nerve damage; observable glaucomatous field defect (measured on a Humphrey SITA Standard 24-2 field, with mean deviation not worse than -12 dB, with at least one of a cluster of ≥ 3 points depressed below the 5% level [≥ 1 below the 1% level] on the pattern-deviation plot or a Glaucoma Hemifield Test outside normal limits); a cup to disk (C/D) ratio ≤ 0.8 ; minimum central ECD determined by age group with a maximum coefficient of variation (CV) ≤ 0.45 ; and CDVA of 20/40 or worse (if CDVA was better than 20/40, eyes were tested with a brightness acuity test meter on a medium setting and included if CDVA was 20/40 or worse). Exclusion criteria included closed-angle or secondary glaucoma, congenital or developmental glaucoma, severe glaucoma (MD ≤ -12 dB with defined perimetric deficits) or fixation-threatening field loss, prior incisional glaucoma surgery, intraocular surgery, corneal surgery, iridectomy, laser iridotomy, or ocular laser treatment (with the exception of SLT more than 6 months prior to screening), clinically significant trauma to the eye, and patients at high risk for AEs as determined by the investigator. High risk features included the need for oral ocular hypotensive medication for IOP control, fixation-threatening glaucoma, or a CDVA of 20/200 or worse. Femtosecond laser-assisted cataract surgery was prohibited.

Study Visits and Assessments

Patients who agreed to participate, were able to provide informed consent, and complete clinical follow-up were enrolled and screened. Patients who met screening criteria underwent IOP examination followed by washout of all ocular hypotensive medications in the potential study

eye before baseline assessment; the minimum washout period was specified by drug class (range 4–28 days), with longer-acting agents (beta-blockers, prostaglandin analogs, Rho kinase inhibitors) requiring 28 days. Patients were scheduled for surgery within 80 days of the screening visit and at ≥ 1 day after the baseline visit. One eye per patient was treated under the study protocol. If both eyes qualified for surgery, the eye with the worse CDVA was designated as the study eye. If both eyes had the same visual acuity, the non-dominant eye was selected. After screening, participants were examined at baseline, day 1, week 1, month 1, month 3, month 6, month 11, month 12, month 18, month 23, and month 24. Study examinations included IOP measurement, visual acuity, slit lamp biomicroscopy, dilated ophthalmoscopy, gonioscopy, specular microscopy, visual field, and pachymetry. Medication use, AEs, and changes in medical status were recorded at all visits. IOP was measured using Goldmann applanation tonometry by 2 observers at all visits; 1 observer adjusted the slit lamp dial while masked to the reading and the other recorded the value. At least 2 measurements were obtained, with a third taken if values differed by >2 mmHg, and IOP was defined as the mean of 2 (or the median of 3) readings. Washed-out DIOP was evaluated at baseline, month 12, and month 24 by taking the mean of 3 IOP measurements over an 8-hour period at intervals of approximately 4 hours (± 30 minutes).

Study Device

The ELIOS System was developed by Elios Vision Inc (now Bausch + Lomb) and is designed to perform excimer laser trabeculostomy, either as a standalone procedure or concomitantly with cataract surgery, to lower IOP in adults with open-angle glaucoma. The ELIOS System consists of a mobile console and single-use disposable laser probe accessory (**Fig 1A**). The mobile console houses the laser source, electrical system, optical system, control systems, cooling system, and all user controls. The ELIOS probe is a sterile, single-use disposable device designed for use with the ELIOS console only. It comprises a steel cannula with a 210- μ m diameter fiber core that transmits ultraviolet laser pulses from the ELIOS console to the targeted

tissue under gonioscopic guidance. The probe tip is beveled with an angle to allow the probe tip to be placed in direct contact with the TM.¹⁵

Procedure

All investigators received training on ELIOS prior to study initiation. Participants underwent standard phacoemulsification cataract extraction with monofocal intraocular lens implantation (in the capsular bag in all but 1 case), immediately followed by the ELIOS procedure, performed under topical or local anesthesia. Preoperative and intraoperative medications were prescribed as customary for the investigator. After the cataract surgery was completed, a cohesive viscoelastic was injected into the anterior chamber (AC), the ELIOS probe was inserted through a clear corneal incision and manually guided to the iridocorneal angle under gonioscopic guidance. The probe tip was placed in direct contact with the TM (**Fig 1B**), and the console foot pedal was depressed and held to deliver a 20-pulse laser sequence lasting approximately 1 second, resulting in formation of a precise microchannel immediately proximate to the probe tip. The console is programmed to repeat this process to create a total of 10 microchannels distributed over approximately 90° of the inferonasal quadrant, a region known to have a higher density of collector channels that enable fluid outflow via Schlemm canal.³⁴ After completion of the procedure, the probe was removed, and the viscoelastic was irrigated and aspirated from the AC. All incisions were inspected for integrity and hydrated for a tight seal. Postoperatively, topical moxifloxacin 0.5% was prescribed 4 times daily for 1 week, and prednisolone acetate 1% was administered 4 times daily during weeks 1–2, tapered to 3 times daily in week 3 and twice daily in week 4. The postoperative medication regimen could be adjusted per investigator discretion.

Statistical Analysis

The primary effectiveness outcomes were analyzed within the FA population, which consisted of all patients treated with the ELIOS procedure. This study was designed and executed during the COVID-19 pandemic environment; therefore, the recommendations from the FDA guidance

document “Statistical Considerations for Clinical Trials during the COVID-19 Public Health Emergency,” were followed. The Medical Monitor reviewed cases in which patients missed a study visit or assessment, or cases considered washout non-compliant. If the cause of the missing visit/assessment or non-compliance was deemed related to the performance of the study procedure, a non-responder imputation was applied. In all other cases, the multiple imputation approach (Markov Chain Monte Carlo) was used to impute missing ocular hypotensive medication numbers (based on the number at each scheduled visit prior to the endpoint visit) and DIOPs (based on all available DIOPs and standard IOPs, except for day 1 and week 1). Cases with an imputed medication number of ≥ 1 were categorized as non-responders for the first coprimary effectiveness endpoint and the corresponding baseline unmedicated DIOP was used to calculate the second coprimary effectiveness endpoint. Otherwise, the imputed unmedicated DIOP data were used to calculate the first and second coprimary effectiveness endpoints. Patients who were unable to complete medication washout due to safety concerns or those who received IOP-related SSIs prior to the endpoint timepoint were treated as non-responders.

Eligibility criteria required baseline unmedicated DIOP ≥ 22 mmHg, resulting in a left-truncated baseline distribution; descriptive statistics should be interpreted accordingly. Inferential analyses (one-sample *t*-test, confidence intervals) are expected to remain valid in this sample size (central limit theorem). An exact binomial test was applied for the first coprimary effectiveness endpoint and a 1-sample *t*-test was applied for the second coprimary effectiveness endpoint, each compared with their respective performance goals. A 2-sided significance level of 0.025 was used for each coprimary endpoint based on the Bonferroni adjustment. CIs were calculated at the 97.5% level to account for prespecified analyses at more than 1 timepoint.

A target sample size of 286 eyes and 257 eyes was calculated for the coprimary effectiveness endpoints at 12 and 24 months, respectively, assuming enrollment of 640 eyes, a

screening failure rate of up to 50%, a dropout rate of 10% by 12 months, and an additional 10% dropout by 24 months.

The primary analyses were also performed in the per protocol (PP) population, a subset of the FA population with no major protocol deviations and a 12-month and 24-month DIOP measurement for the 12- and 24-month analysis, respectively. Covariate and subgroup analyses were also conducted in the PP population to assess the prognostic impact of baseline characteristics on achieving the coprimary effectiveness endpoints. Each potential prognostic factor was evaluated using Fisher's exact test (significance level 0.15) for the first coprimary effectiveness endpoint and 1-way analysis of variance (significance level 0.15) for the second coprimary effectiveness endpoint.

Safety outcomes were assessed in the FA population for all available data through 24 months. AEs were classified as intraoperative or postoperative. The following outcomes were summarized descriptively: change in ECD and percentage change in ECD from baseline at each scheduled visit; pachymetry and VFMD values with corresponding changes from baseline; and findings from slit lamp, fundus examination, and gonioscopy.

Results

Patient Flow and Baseline Characteristics

Twenty sites enrolled and screened 575 patients. A total of 318 patients underwent the procedure between June 2021 and July 2023 (FA population). **Figure 2** shows the patient disposition. The database lock occurred on February 11, 2026, when all patients had completed the 24-month visit or had prematurely exited the study prior to 24 months. Full patient baseline demographics and characteristics are shown in **Table 1**. Mean age was 70 years, 83% were White, and 54% were female. Mean $\pm$ SD medicated IOP was 17.05 ± 3.01 mmHg at screening, and mean unmedicated DIOP was 24.53 ± 2.51 mmHg at baseline. Seventy percent were on 1 ocular hypotensive medication, with the remainder on either 2 or 3 medications; the most

commonly prescribed medication classes were prostaglandin analogs (59.4%), topical carbonic anhydrase inhibitors (36.8%), and beta-adrenergic blocking agents (25.8%). The PP population at 12 and 24 months comprised 295 and 288 patients (92.8% and 90.6% of the FA population), respectively.

Effectiveness Outcomes

Both coprimary effectiveness endpoints were met with statistical significance at 12 months. A $\geq 20\%$ reduction in unmedicated DIOP from baseline at month 12 was achieved in 84.2% of patients (97.5% CI: 79.6, 88.8; N=318), which was statistically significant compared with the prespecified performance goal of $>79\%$ ($P=0.0116$). The mean $\pm$ standard error (SE) change in unmedicated DIOP from baseline at month 12 was -8.17 ± 0.21 mmHg (97.5% CI: -8.7 to -7.7 ; N=318), which was statistically significant compared with the prespecified performance goal of a reduction ≥ 7.2 mmHg ($P<0.0001$) (**Fig 3**).

Both coprimary effectiveness endpoints were also met with statistical significance at 24 months. A $\geq 20\%$ reduction in unmedicated DIOP from baseline at month 24 was achieved in 76.1% of patients (97.5% CI: 70.7%, 81.6%), which was statistically significant compared with the prespecified performance goal of $>68.5\%$ ($P=0.0018$) (**Fig 3**). The mean $\pm$ SE change in unmedicated DIOP from baseline at month 24 was -7.35 ± 0.22 mmHg (97.5% CI: -7.85 to -6.84 mmHg), which was statistically significant compared with the prespecified performance goal of a reduction of ≥ 6.15 mmHg ($P<0.0001$) (**Fig 4**).

Sensitivity analyses of the coprimary endpoints in the PP populations at 12 and 24 months were consistent with those observed in the FA population. At 12 months, 84.7% (250/295) of patients achieved a $\geq 20\%$ reduction in unmedicated DIOP from baseline ($P=0.0153$ vs. the prespecified performance goal), with a mean change from baseline of -8.2 ± 3.7 mmHg ($P<0.0001$). At 24 months, 77.1% (222/288) of patients achieved a $\geq 20\%$ reduction in unmedicated DIOP ($P=0.0016$ vs. the performance goal), and the mean change from baseline was -7.5 ± 3.9 mmHg ($P<0.0001$).

Prespecified covariate analyses demonstrated generally consistent treatment effects across all subgroups evaluated in the 12-month and 24-month PP populations, including baseline DIOP category, number of preoperative medications, age, sex, and race (24 months: **Figs 5A and 5B**; 12 months: **Figs S1A and S1B**, available at www.opthalmologyglaucoma.org). Higher baseline DIOP was associated with greater absolute reductions in IOP. Patients using 3 ocular hypotensive medications at screening demonstrated numerically lower response rates than those receiving fewer, and those with prior SLT exhibited a smaller IOP change than those who not received prior SLT. Although responder rates varied across medication strata, mean DIOP reduction remained consistent, and the overall study conclusions were robust across medication groups. Hispanic/Latino ethnicity did not affect the endpoints, with 78.9% $\geq 20\%$ DIOP reduction compared with 76.6% in non-Hispanic/Latino ($p=0.860$), and -8.46 vs. -7.24 mmHg change ($p=0.032$), respectively.

Across subgroups, 95% CIs for both coprimary endpoints met or encompassed the prespecified performance goals, indicating that the observed baseline differences did not materially influence the primary effectiveness outcomes.

In descriptive analyses of observed (on-treatment) IOP, mean $\pm$ SD observed IOP decreased from 24.5 ± 2.5 mmHg at baseline ($N=318$) to 16.0 ± 3.9 mmHg at month 12 ($n=304$), and 16.8 ± 4.0 mmHg at month 24 ($n=290$), corresponding to a mean reduction $\pm$ SD of 8.5 ± 3.9 mmHg (34.5%) and 7.7 ± 3.7 mmHg (31.5%), respectively. The largest reduction in observed IOP occurred between baseline and month 3 (-9.0 mmHg, -36.5%), with a stable plateau maintained from month 3 through month 24 (**Fig 6**).

The mean $\pm$ SD number of medications decreased from 1.5 ± 0.7 at screening ($N=318$) to 0.2 ± 0.6 at month 6 ($n=310$), which remained stable through month 23 (0.3 ± 0.8 ; $n=289$), the last visit prior to medication washout for month 24 IOP assessment (**Fig 6**). Medication-free rates were consistently high from month 3 onward, peaking at 87.4% at month 6 and sustained

thereafter (82.0% at the 23-month visit). Compared with screening, 87.9% (254/289) of patients reduced their ocular hypotensive medications by at least 1 medication at month 23.

Safety Outcomes

Early postoperative visual recovery was observed, with 98.1% of patients (307 of 313) achieving CDVA 20/40 or better at month 1, increasing to 100% at month 12 (n=307), and remaining stable through month 24 (99.3%, 297 of 299). At month 24, mean CDVA was 0.013 ± 0.079 logMAR (Snellen equivalent approximately 20/20.6), and CDVA was stable or improved in 98.3% of patients (294 of 299). Visual field outcomes were stable or improved in 93.2% of patients (274 of 294) at 24 months. Mean VFMD remained stable over time, measuring -3.36 ± 2.67 dB at screening (N=318), -2.66 ± 3.19 dB at month 12 (n=302), and -3.03 ± 3.77 dB at month 24 (n=294). Mean corneal thickness also remained stable, from 551.8 ± 34.7 μ m at screening (N=318), 556.0 ± 35.9 μ m at month 12 (n=306), and 557.9 ± 36.4 μ m at month 24 (n=299).

Five AEs were reported during cataract extraction and intraocular lens implantation, with no intraoperative complications or AEs reported during the ELIOS procedure. Through 24 months, 115 postoperative ocular AEs were reported in 69 of 318 patients (21.7%). Non-IOP postoperative ocular AEs are summarized in **Table 2**. The most common postoperative AEs were worsening of visual field (6.3% persisting at month 24) and AC cell and/or flare (5.7%; classified based on the need for increased or re-initiated postoperative steroid therapy). AEs were largely mild or moderate (92.1%) and resolved without sequelae or SSI. Five patients (1.6%) experienced 8 AEs involving a loss of 2 or more lines of CDVA at or after the 3-month postoperative visit. Five of the events were due to dry eye, of which 4 were transient. Seven patients (2.2%) experienced 8 AEs resulting in SSI after the ELIOS procedure, including XEN placement (n=4), SLT (n=2), and both paracentesis and XEN placement (n=1).

The protocol-defined AE of visual-field worsening was based on an MD decrease of ≥ 2.5 dB, confirmed on repeat testing, relative to the single field used for study eligibility, and therefore

reflects deviation from one baseline measurement rather than adjudicated glaucomatous progression. Five of the 23 confirmed cases subsequently improved, consistent with the recognized variability of automated perimetry. Global visual-field status remained stable or improved in 93.2% of patients, mean VFMD was essentially unchanged through Month 24 (-3.36 vs. -3.03 dB), and only three eyes required a secondary intervention (two SLT for field worsening and one XEN for IOP control). A case-by-case review found no visual-field worsening event attributable to the ELIOS procedure; all events were consistent with perimetric variability, the natural history of glaucoma, or other patient-specific factors.

Corneal edema occurred predominantly in the early postoperative period, with only 1 event persisting at >1 month postoperative; this event was related to elevated IOP and was present at the 1-month visit and resolved without sequelae 3 days later. Hyphema was also predominantly observed in the early postoperative period and was self-limited: microhyphema was present in 9.4% of eyes at day 1, 3.5% at week 1, 0.3% at month 1, and absent from month 3 onward. Layered hyphema >2 mm at >1 day postoperative was reported as an AE in one patient (0.3%) and resolved without sequelae by month 1 (reported in **Table 2**).

As expected following phacoemulsification, reduction in central ECD occurred almost entirely between screening and Month 3 and remained stable thereafter, with no evidence of progressive endothelial loss through Month 24. The median percentage change in ECD from screening was -8.90% at month 3 ($n=307$; range -69.30% to $+5.90\%$), -8.90% at month 6 ($n=309$; range -63.40% to $+10.90\%$), -9.10% at month 12 ($n=307$; range -68.80% to $+38.00\%$), -9.90% at month 18 ($n=297$; range -61.50% to $+8.10\%$), and -9.60% at month 24 ($n=297$; range -66.00% to $+8.90\%$). The proportion of eyes with $\geq 30\%$ ECD loss from screening was 17.6% at month 3, 15.2% at month 6, 15.3% at month 12, 13.8% at month 18, and 12.8% at month 24 (**Table S3**, available at www.ophtalmologyglaucoma.org). This temporal pattern is consistent with the expected endothelial response to phacoemulsification cataract surgery. The

lack of implanted device in the anterior chamber or iridocorneal angle from the ELIOS procedure means no mechanism for chronic endothelial interaction exists, and no evidence of device-related progressive endothelial loss was observed.

Discussion

In this 24-month prospective, multicenter FDA study of the ELIOS procedure combined with phacoemulsification, both coprimary effectiveness endpoints were met with statistical significance relative to their prespecified performance goals at both month 12 and month 24. At 24 months, a $\geq 20\%$ reduction in unmedicated DIOP was achieved in 76.1% of patients, and the mean change in DIOP was -7.35 mmHg, exceeding the corresponding performance goals. As the performance goals were developed in-line with outcomes reported for phacoemulsification alone as well as other MIGS procedures, this demonstrates clinically meaningful and long-lasting IOP reduction through 24 months, and improved IOP control versus cataract surgery alone. The performance goals were themselves derived from similar cataract-only historical control arms used in the Hydrus, iStent inject, and CyPass pivotal prospective trials: the 12-month performance goal of -7.2 mmHg corresponds to the upper 95% confidence limit of the mean medication-free DIOP reduction observed with cataract surgery alone in the Hydrus pivotal trial (approximately -6.5 mmHg; 95% CI: -5.96 to -7.13 mmHg), and the 24-month performance goal of -6.15 mmHg corresponds to the upper 95% confidence limit of the sample-size-weighted mean reduction across the 3 cataract-only control arms (-5.76 mmHg; 95% CI: -5.37 to -6.15 mmHg). Demonstrating mean DIOP reductions that exceed these performance goals therefore represents a conservative, statistically significant comparison versus cataract surgery alone, and are consistent with FDA-recognized use of performance goals for single-arm device investigations when a concurrent control is not feasible. Notably, the baseline characteristics were very similar, including those known to impact outcomes such as prior SLT (16.0% ELIOS, 15% HORIZON),³³ with medicated screening IOP and the unmedicated 24-

month observed IOP were nearly identical in the three pivotal FDA trials and this current study, indicating that the ELIOS procedure achieved an IOP reduction equivalent to the patient's preoperative medication regimen.

The 20% IOP-reduction endpoint was selected in accordance with US FDA recommendations for implantable MIGS devices even though the ELIOS procedure does not involve an implant.³⁵ Additionally, the 31.5% reduction in mean DIOP to 16.8 mmHg at month 24 aligns with the American Academy of Ophthalmology target IOP guidelines for $\geq 25\%$ reduction to slow progression of POAG³⁶ and therefore represents a clinically meaningful outcome.

The modest attenuation in effectiveness from 12 to 24 months (imputed mean DIOP change: -8.17 to -7.35 mmHg) remained above the performance goals, within recommended target IOP ranges, and is consistent with the expected trajectory following combined phacoemulsification and MIGS. This attenuation likely reflects conservative analytical assumptions and the progressive nature of disease-related IOP dynamics over time. Similar patterns have been reported with other MIGS procedures; for example, in the HORIZON trial, mean DIOP reduction in patients receiving the Hydrus Microstent decreased from -8.4 at 12 months to -7.6 mmHg at 24 months.³³

More than 80% of patients were medication-free from 3 months through 23 months, despite all patients receiving 1–3 medications at screening (mean 1.5 medications). Given the well-documented challenges with long-term adherence in glaucoma management,^{4,6} reduction in medication burden represents an important indicator of treatment utility. Lowering medication burden decreases reliance on patient adherence to achieve desired visual outcomes, and is associated with improved patient quality of life, an important treatment goal.^{3,12,37} Patients using a greater number of ocular hypotensive medications at screening demonstrated numerically lower response rates (60.5% meeting co-primary endpoint 1 at 24 months), and those with prior SLT exhibited a smaller IOP reduction (-5.42 vs. -7.83 mmHg at 24 months). These findings

are consistent with established evidence suggesting that eyes with more advanced disease or prior trabecular intervention may derive a reduced magnitude of response to trabecular MIGS procedures; however, treatment benefit may still be achieved.^{18,19}

When interpreted within the limitations of cross-trial comparisons, the effectiveness profile of the ELIOS System is broadly consistent with that observed for commercially available trabecular stenting or disrupting MIGS procedures.^{33,38} For example, at 12 and 24 months, the proportion of patients achieving $\geq 20\%$ reduction in unmedicated DIOP was similar for the ELIOS System (84% and 76%) and the Hydrus Microstent (86% and 77%); the iStent inject pivotal study reported this metric only at 24 months (76%). Mean reductions in unmedicated DIOP at 12 and 24 months were comparable across the 3 studies (-8.2 and -7.4 ; -8.5 and -7.6 ; and -7.0 mmHg [24-month data only], respectively).^{33,38} Similarly, medication-free status was achieved in 82% of patients who underwent the ELIOS procedure at month 23, compared with 78% for Hydrus Microstent and 84% among responders for iStent inject.^{33,38}

ECD change occurred early in the study period and stabilized from month 3 onward, with no evidence of a progressive decline through 24 months. This temporal pattern is consistent with endothelial changes typically observed following phacoemulsification, characterized by an initial postoperative decrease followed by long-term stabilization.^{38,39} To determine whether the decline in eyes with $\geq 30\%$ ECD loss reflected differential loss to follow-up, we performed within-eye longitudinal analyses. Median ECD loss remained stable after Month 3 (-8.9% , -9.1% , and -9.6% at Months 3, 12, and 24), with no further decline in paired within-eye analyses. The same pattern was observed in the 24-Month Consistent Cohort ($n=276$ eyes with complete ECD data at all visits), confirming stability in the absence of attrition. These findings indicate that endothelial cell loss stabilized after the early postoperative period rather than reflecting preferential dropout. These findings are relevant in the context of long-term corneal endothelial safety considerations following combined cataract surgery and MIGS. Long-term endothelial safety signals among MIGS devices have been device-specific: a progressive endothelial cell-

loss signal was observed with the CyPass Micro-Stent implant,⁴⁰ whereas longer-term follow-up of the Hydrus Microstent and iStent platforms has not demonstrated incremental endothelial cell loss relative to phacoemulsification alone.^{39,41} The ELIOS procedure does not implant a retained device, eliminating the potential for chronic endothelial interaction.

No intraoperative complications or unexpected device-related AEs were reported during the ELIOS procedure, and most postoperative AEs were mild or moderate and resolved without sequelae or SSI. The SSI rate of 2.2% through 24 months is in the range reported for other MIGS devices, including approximately 2.4% for the Hydrus Microstent in HORIZON; the previously published 24-month SSI rate for iStent inject was 5.4%.^{33,38} The low overall need for surgical reintervention provides further evidence of lasting IOP reduction through at least 24 months. Compared with trabecular stenting or TM-disrupting MIGS procedures, the ELIOS System uses a non-thermal, photoablative laser that may minimize adjacent tissue injury and inflammatory response.^{22,23,27} Reduced postoperative inflammation may, in turn, limit wound healing activity, hypothesized to support microchannel patency and sustained enhancement of TM permeability.^{22,42,43} The TM and inner wall of the Schlemm canal adjacent to the treated areas maintain their anatomy and physiologic function, and the absence of a retained device eliminates risks associated with implantation error, device migration, or localized tissue reactions that may necessitate SSI.^{22,23,25,44}

This study employed a non-randomized design without a concurrent control group and relied on historical controls to assess relative effectiveness, which may introduce bias related to differences in patient populations, clinical practices, and other confounding factors.

Randomization to cataract surgery alone was considered but not pursued due to widespread availability and established use of MIGS procedures in contemporary clinical practice compared with previous MIGS randomized clinical trials which were performed in a different era. In this setting, randomization to phacoemulsification alone was considered challenging, given evidence

from prior studies indicating that additional IOP reduction and potential reductions in medication burden could be achieved when MIGS is performed adjunctively.

This consideration also had implications for the IDE study feasibility, as both patients and study investigators may be reluctant to participate in a randomized design where assignment to phacoemulsification alone could limit access to adjunctive MIGS procedures that are otherwise routinely available to them in standard practice. Additionally, since the study was initiated during the COVID-19 pandemic, reducing the required number of in-person clinic visits was an important consideration in the study design. Outcomes reported in historical control populations (i.e., the cataract-only arms of pivotal MIGS trials)^{33,38,45} were highly consistent across studies with 24-month data, reinforcing the longer-term clinical relevance of the observed effects. The historical control arms were enrolled between 2012 and 2016 and therefore reflect the practice patterns of that era. Although contemporary patients may be treated earlier and with newer therapies, eligibility criteria and baseline IOP were closely matched across studies (washed-out DIOP: 24.53 vs. 24.4–25.5 mmHg; medicated screening IOP: 17.05 vs. 17.4–18.1 mmHg). Because treatment effects were referenced to washed-out baseline IOP, differences in medication use are unlikely to have materially affected the comparison. The consistency of cataract-only responder rates (57.8–61.9%) and mean unmedicated DIOP reductions (5.3–5.4 mmHg) across the three historical control arms further supports the robustness of the performance goals. The close alignment of study designs and patient populations, as discussed in the methods and demonstrated in **Table S2** (available at www.opthalmologyglaucoma.org), further supports the validity of these comparisons. Additionally, because both co-primary endpoints were met within each subgroup defined by the characteristics that differed from the comparator trials (number of medications and ethnicity), with all prespecified subgroup confidence intervals meeting or containing the performance goals, the results do not depend on the specific baseline distribution of the cohort, supporting the robustness of the primary

effectiveness findings. Nevertheless, as with any historical comparison, residual confounding from unmeasured differences cannot be excluded.

These comparisons are further supported by the robust prospective multicenter design of the study. As with many prospective clinical trials, eligibility criteria were applied that may limit representation of the broader US glaucoma population and, therefore, generalizability. However, the racial distribution of enrolled patients remained comparable to that reported in other pivotal MIGS studies. Future investigations incorporating broader inclusion criteria, such as patients with other glaucoma subtypes (e.g., secondary open-angle glaucoma) or ocular comorbidities, will be important to further define the role of this procedure across a wider and more heterogeneous clinical population.

In summary, these 24-month results demonstrate that the ELIOS procedure combined with phacoemulsification produces clinically meaningful and durable reductions in IOP and medication burden in patients with mild-to-moderate POAG, with a safety profile consistent with phacoemulsification alone. The implant-free, non-thermal approach of the ELIOS System, which minimizes disruption to angle anatomy and physiology, offers a mechanistically distinct alternative within the MIGS landscape.

Acknowledgments

We acknowledge S. Ari Zak for ongoing support and guidance, as well as Melissa Moe and the clinical monitors for their contributions to the conduct of the study.

Medical writing assistance in the preparation of this manuscript was provided by Robyn Foster, PhD, of Panacea 85 Ltd, and Eeke Romo, MSc, who also served as the clinical study report medical writer and contributed to data categorization and analysis. The authors were responsible for manuscript development and interpretation, and provided critical revisions.

Medical writing support was funded by Bausch + Lomb.

Finally, we thank the principal investigators and their study staff for their contributions to patient enrollment, data collection, and overall study execution (see **Supplementary Table S4**).

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Figure Legends

Figure 1. A Depiction of the ELIOS Console and Probe. **B** Depiction of the ELIOS Probe at the trabecular meshwork site.

Figure 2. Patient disposition. *16 patients were treated with the ELIOS System and included in the full analysis set, but subsequent monitoring revealed they had not satisfied all eligibility criteria: glaucomatous field defect on reliable visual field (n = 3); prior incisional surgery, intraocular surgery or ocular laser treatment of any type except for SLT >6 months prior to screening (n = 7); unable to undergo medication washout in the study eye or severe glaucoma in either eye (n = 1); degenerative visual disorders (n = 1); systemic medication that may cause an increase in IOP (n = 2); a well-centered monofocal intraocular lens placed in the capsular bag (n = 1); evidence of zonular dehiscence/rupture (n = 1); vitreous in the anterior chamber (n = 1). †At Month 12, 307 patients were available for analysis (308 remained in follow-up); one patient missed the 12-month visit but continued in the study and completed subsequent visits. 12-month DIOP was available for 306 patients, as one patient did not complete 12-month DIOP assessment due to a medical concern (specifically, pancreatic cancer) prohibiting an extensive, prolonged visit. ‡One patient attended the 24-month visit but refused to complete the DIOP observations. CI = confidence interval; DIOP = diurnal intraocular pressure; IOP = intraocular pressure; SD = standard deviation; SLT = selective laser trabeculoplasty.

Figure 3. Proportion of patients achieving $\geq 20\%$ reduction in unmedicated DIOP from baseline at 12 months and 24 months (full analysis population). CI = confidence interval; DIOP = diurnal intraocular pressure.

Figure 4. Mean change in unmedicated DIOP from baseline at 12 and 24 months (full analysis population). CI = confidence interval; DIOP = diurnal intraocular pressure.

Figure 5. A Proportion achieving $\geq 20\%$ DIOP reduction at 24 months by covariate (per protocol population). **B** Mean DIOP change at 24 months by covariate (per protocol population)

CI = confidence interval; DIOP = diurnal intraocular pressure; SD = standard deviation; SLT = selective laser trabeculoplasty.

Figure 6. Mean IOP and mean number of ocular hypotensive medications by study visit (full analysis population). Baseline IOP represents washed-out DIOP prior to study treatment. At selected follow-up visits (including months 12 and 24), unmedicated DIOP was evaluated following protocol-specified medication washout to assess IOP independent of ocular hypotensive therapy. Highlighted columns indicate visits at which unmedicated DIOP was required. Mean IOP calculations excluded eyes that underwent SSI prior to the corresponding visit. Some patients did not undergo washout at 12 and/or 24 months but were included in the analysis. CI = confidence interval; DIOP = diurnal intraocular pressure; IOP = intraocular pressure; M = month; SD = standard deviation; SSI = secondary surgical intervention.

Table 1. Demographics and Baseline Characteristics (Full Analysis Population)

Parameter	Cataract Surgery with ELIOS Procedure (N=318)
Age (years), mean $\pm$ SD (range)	70.3 $\pm$ 7.3 (45–87)
Age range, n (%)	
40 to <60	24 (7.5)
60 to <70	114 (35.8)
70 to <80	149 (46.9)
≥ 80	31 (9.7)
Sex, n (%)	
Male	146 (45.9)
Female	172 (54.1)
Race, n (%)	
American Indian or Alaska Native	3 (0.9)
Asian	4 (1.3)
Black or African American	49 (15.4)
Native Hawaiian or Other Pacific Islander	3 (0.9)
White	263 (82.7)
Other	2 (0.6)
Ethnicity, n (%)	
Hispanic or Latino	63 (19.8)
Not Hispanic and not Latino	255 (80.2)
Study eye, n (%)	
OS	170 (53.5)
OD	148 (46.5)
Number of ocular hypotensive medications at screening,* n (%)	
0	0 (0)
1	222 (69.8)
2	48 (15.1)
3	48 (15.1)
CDVA at screening, mean $\pm$ SD logMAR	0.197 $\pm$ 0.161
Snellen CDVA or BAT (if performed) at screening, n (%)	
Snellen 20/40	124 (39.0)
Snellen 20/50 to 20/80	157 (49.4)
Snellen 20/100 to 20/400	36 (11.3)
Visual field mean deviation (dB), mean $\pm$ SD	-3.36 $\pm$ 2.67
Visual field pattern standard deviation (dB), mean $\pm$ SD	3.51 $\pm$ 2.16
Medicated IOP at screening (mmHg), mean $\pm$ SD	
Mean $\pm$ SD	17.05 $\pm$ 3.01
Median (IQR)	17.0 (15.0–19.0)
Min, max	8.0, 24.0
Unmedicated DIOP at baseline (mmHg)	
Mean $\pm$ SD	24.53 $\pm$ 2.51
Median (IQR)	23.7 (22.7–25.7)
Min, max	22.0, 33.8
Gonioscopy: Shaffer angle grade	
3 - 21–34° angle	101 (31.8)
4 - 35–45° angle	217 (68.2)
C/D ratio, mean $\pm$ SD	0.610 $\pm$ 0.142
Pachymetry (μ m), mean $\pm$ SD	551.8 $\pm$ 34.7

*A combination medication is counted as 2 medications.

BAT = Brightness Acuity Test; C/D = cup-to-disc; CDVA = corrected distance visual acuity; DIOP = diurnal intraocular pressure; IOP = intraocular pressure; IQR = interquartile range.

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Table 2. Postoperative Ocular AEs at Any Time in the Study Eye, Full Analysis Population (N=318)

Postoperative Events	Events	Subjects	
	n	n	%
Any postoperative AE	115	69	21.7
Worsening of VFMD* compared to the MD used to determine subject eligibility	25	23	7.2
Resolved at month 24 visit	5	5	1.6
Present at month 24 visit	20	20	6.3
AC cell and/or flare requiring either an increase in the standard postoperative steroid regimen or re-initiation of steroid use following completion of the standard postoperative regimen	18	18	5.7
Slit lamp and fundus findings with no specified grading scale that are severe or clinically significant at or after 3 months postoperative	12	12	3.8
Disc hemorrhage	2	2	0.6
Epiretinal membrane	1	1	0.3
Keratic precipitates	1	1	0.3
Keratitis	1	1	0.3
Lid margin disease	4	4	1.3
Subconjunctival hemorrhage following XEN implant	1	1	0.3
Worsening age-related macular degeneration	1	1	0.3
Worsening of dry eye	1	1	0.3
Corneal edema	12	12	3.8
Mild to moderate, persisting >1 month postoperative	1	1	0.3
Severe persisting ≥ 1 day postoperative	11	11	3.5
Ocular surgical reintervention (other than paracentesis to relieve pressure <1 week postoperative or Nd:YAG capsulotomy)	8	7	2.2
Paracentesis >1 week	1	1	0.3
SLT	2	2	0.6
XEN placement	5	5	1.6
CDVA loss ≥ 2 lines (10 ETDRS letters) from baseline measured at or after 3 months postoperative [†]	8	5	1.6
Elevated IOP at >1 month requiring treatment with oral or intravenous medications or with surgical intervention	6	5	1.6
Oral medications and surgical intervention	2	2	0.6
Surgical intervention	2	2	0.6
Oral medications	2	1	0.3
Other postoperative event	5	5	1.6

Allergic reaction to ocular hypotensive medication	1	1	0.3
Corneal abrasion	2	2	0.6
Ocular injury due to foreign body	1	1	0.3
Wound dehiscence following XEN implant	1	1	0.3
Hypotony, defined as IOP <6 mmHg	5	5	1.6
Early (≤ 2 weeks postoperatively)	2	2	0.6
Following XEN implant	3	3	0.9
Chronic AC cell and/or flare [‡]	4	3	0.9
Following XEN implant	1	1	0.3
IOP ≥ 10 mmHg than the qualifying baseline mean DIOP at >1 month	4	3	0.9
Ptosis, significant	2	2	0.6
2-point worsening to severe on the slit lamp or fundus examination findings (other than cells and flare) at or after 3 months postoperative not associated with a preexisting condition	3	3	0.9
Conjunctival edema following XEN implant	1	1	0.3
Contact dermatitis	1	1	0.3
Punctate epithelial keratitis	1	1	0.3
Layered hyphema (>2 mm at >1 day postoperatively)	1	1	0.3
Vitreous hemorrhage - new or onset (not from spillover)	1	1	0.3
Cystoid macular edema	1	1	0.3

% = (# of subjects) / N $\times$ 100%.

Patients might have multiple reports of the same event or different subcategories of the same adverse event main category.

*MD worsening by 2.5 dB or more, confirmed by 2 repeat measurements.

[†]A loss of BCVA in conjunction with PCO, followed by Nd:YAG capsulotomy and subsequent improvement of BCVA is not considered an AE.

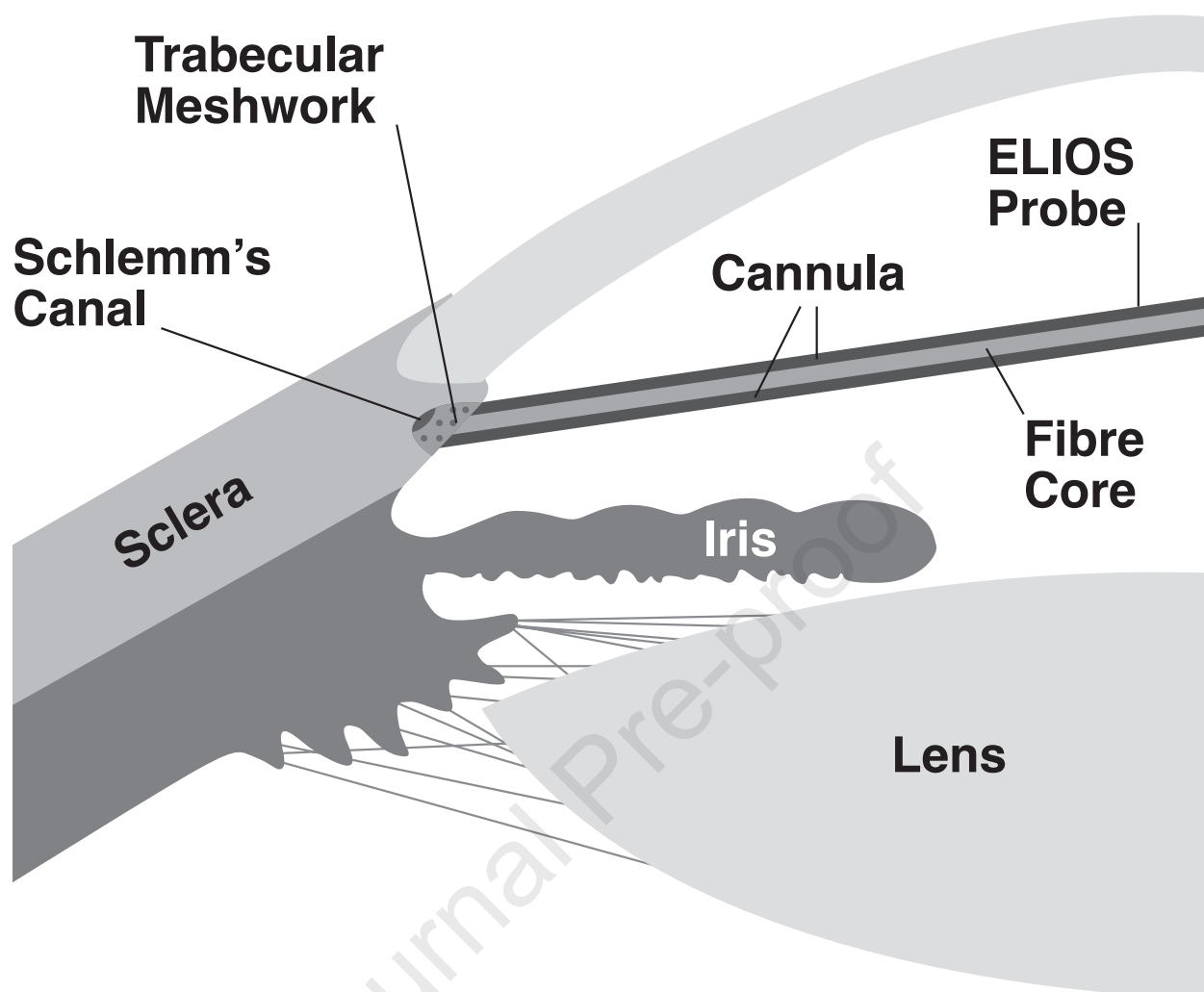
[‡]Defined as inflammation grade 1+ or worse persisting at more than 3 months postoperatively or that recurs less than 3 months after discontinuing treatment.

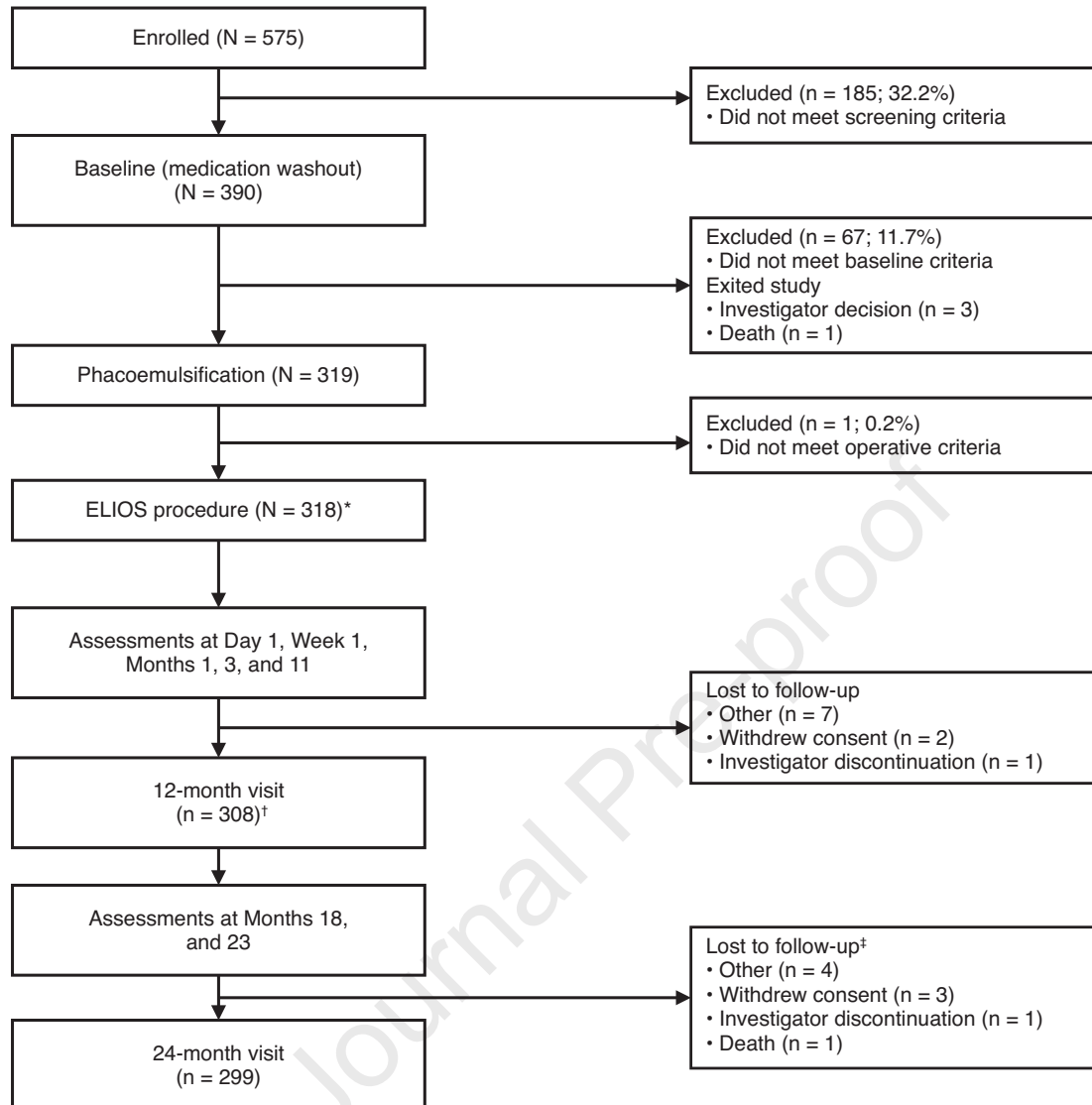
AC = anterior chamber; AE = adverse event; CDVA = corrected distance visual acuity; DIOP = diurnal intraocular pressure; ETDRS = Early Treatment Diabetic Retinopathy Study; IOP = intraocular pressure; MD = mean deviation; Nd:YAG = neodymium-doped yttrium aluminum garnet; PCO = posterior capsular opacification; SLT = selective laser trabeculoplasty; SSI = secondary surgical intervention; VFMD = visual field mean deviation.

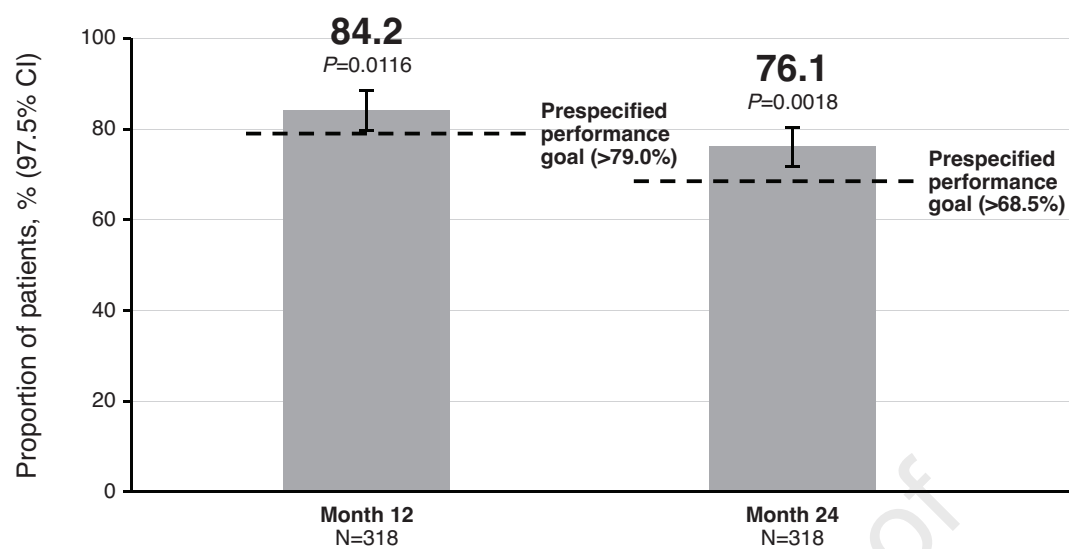
ELIOS Console

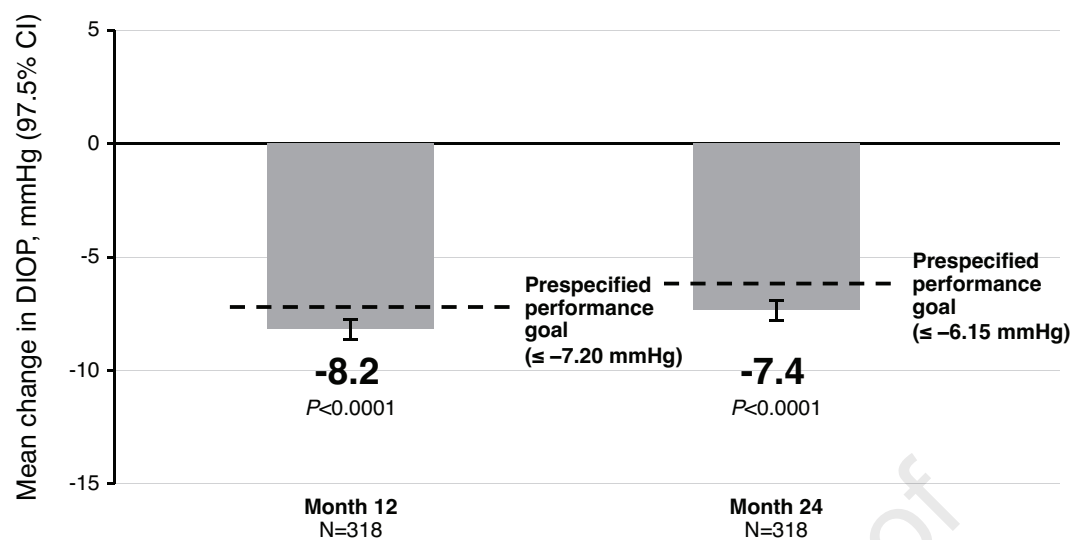


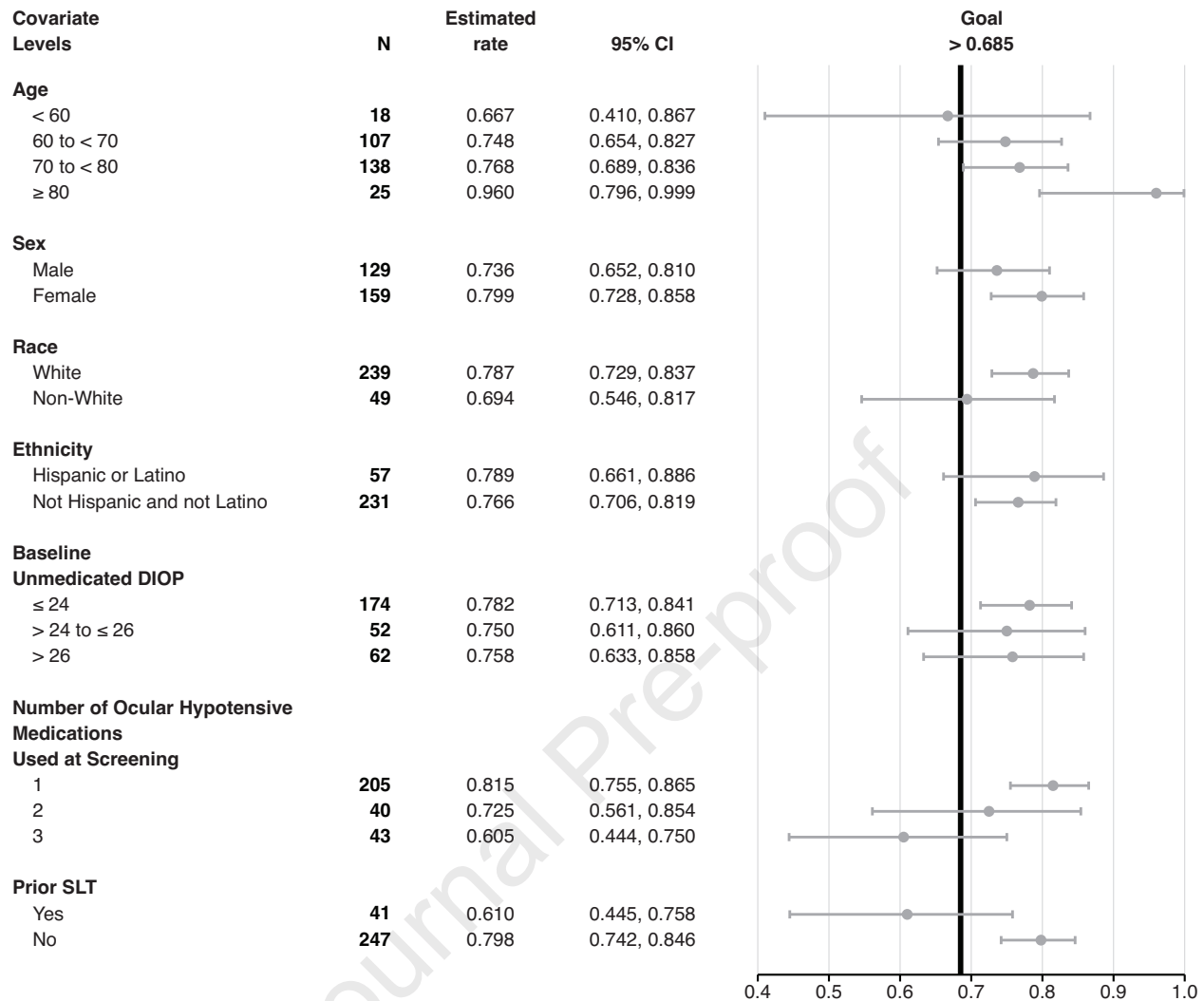
ELIOS Probe (Single-Use)

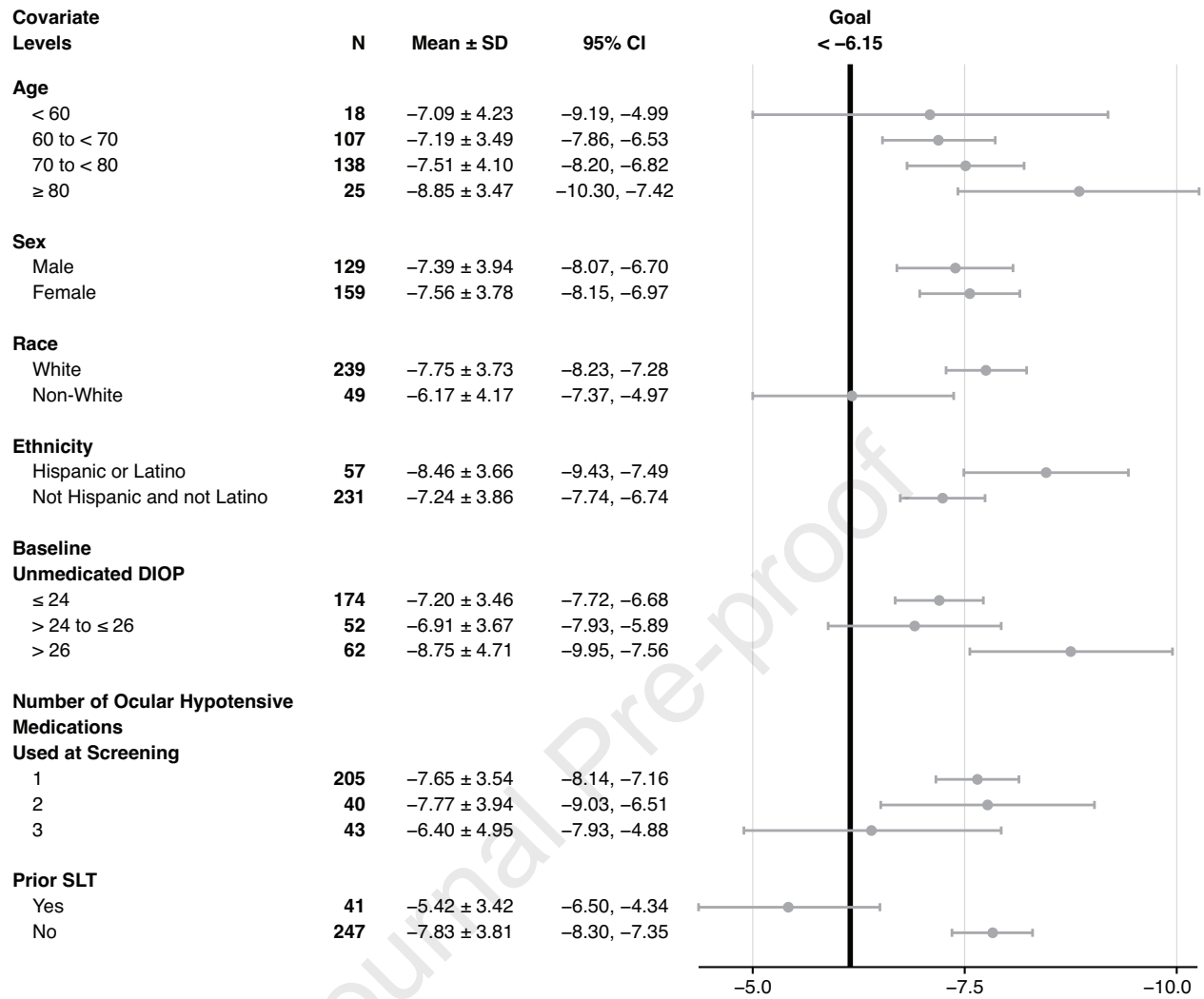


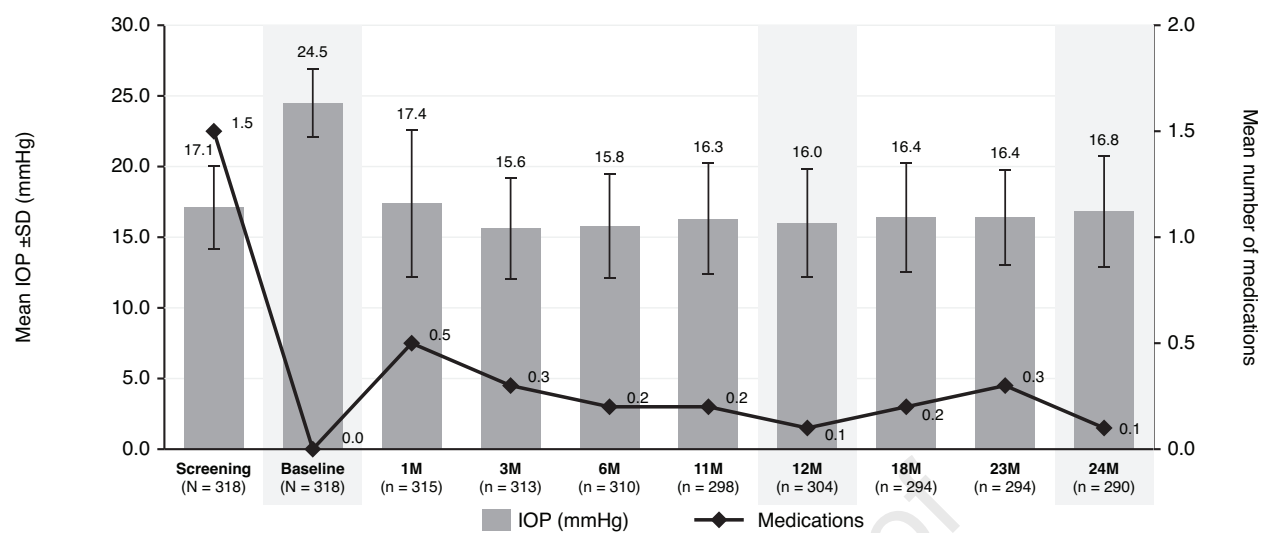












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This prospective, multicenter FDA pivotal trial evaluated ELIOS excimer laser trabeculostomy with phacoemulsification in mild-to-moderate primary open-angle glaucoma, demonstrating sustained, clinically meaningful reductions in intraocular pressure and medication use through 24 months.