12-Month Intraocular Pressure and Hypotensive Medications Outcomes After Phaco-ELIOS Procedure–A Real World Study

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Précis: Combined phaco-ELIOS in ocular hypertension and glaucoma showed a statistically significant reduction in the number of hypotensive medications of 1.5 compared with baseline, with 78.4% of eyes being medication-free at 12 months.

Purpose: To describe the change in medication and intraocular pressure 12 months after the combined phacoemulsification-ELIOS procedure.

Methods: Retrospective, multicenter interventional case series of adults with ocular hypertension or glaucoma undergoing phaco-ELIOS. Clinical data were collected and analyzed from preoperative baseline up to 12 months postoperatively. The primary outcome was the mean change in medication compared with baseline. Secondary outcomes were intraocular pressure change from baseline, incidence of acute postoperative intraocular pressure elevation, and surgical success at 1 year, defined as intraocular pressure reduction of $\geq$20% compared with baseline with no increase in medications, or reduction of $\geq$1 medications compared with baseline with intraocular pressure equal or below baseline, with no secondary glaucoma surgeries and no loss of light perception.

Results: One hundred twelve eyes were included. Forty-two patients (51.2%) were female. Mean ($\pm$SD) age was 70.6 ($\pm$9.6) years. The most frequent diagnosis was primary open angle glaucoma (71.4%). The mean number of medications at baseline and 12 months was 1.8 ($\pm$0.8) and 0.4 ($\pm$0.7), respectively, representing a reduction of 1.5 ($\pm$1.0) ($P < 0.0001$). At the end of follow-up, 78.4% of eyes were medication-free. Mean intraocular pressure at baseline and 12 months was 19.9 ($\pm$4.0) mm Hg and 16.7 ($\pm$2.6) mm Hg, respectively, a significant decrease of 3.2 mm Hg ($\pm$4.0) or 13.7% ($P < 0.0001$). Surgical success was achieved in 75.9% of eyes at 12 months.

Conclusions: Combined phaco-ELIOS in glaucoma significantly reduced medication use and IOP, with over 75% of eyes being medication-free at 12 months.

Key Words: excimer laser trabeculostomy, phacoemulsification, glaucoma, ocular hypertension, ELIOS, MIGS

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Glaucoma is a progressive neurodegenerative disease that remains the leading cause of irreversible blindness worldwide.[1] Intraocular pressure (IOP) lowering is currently the only evidence-based treatment for glaucoma.[2] While topical IOP-lowering medications are considered first-line therapy, surgical intervention may be necessary when these

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medications reach their therapeutic limits or are not tolerated by the patient. Between 50% and 60% of glaucoma patients on topical hypotensive medications have ocular surface disease, leading to poor adherence and compliance from associated symptoms, such as burning sensation, irritation, itching, and a decrease in visual acuity.[3]

Minimally invasive glaucoma surgery (MIGS) procedures have been introduced in the surgical landscape in the past decade and have begun to replace traditional techniques. The IOP-lowering effect of MIGS is dependent on physiological outflow as compared with traditional filtering surgery, but these procedures have a more favorable safety profile, positioning them well for early deployment in patients with mild-to-moderate disease and modest treatment goals.[3] Cataract surgery has limited benefit in lowering IOP in open angle glaucoma,[4] but can provide a surgical window of opportunity to add a procedure with this objective. However, the predictability of the IOP-lowering effect varies among the different MIGS, and previous studies indicate that there are additional risks of intraocular IOP-lowering implants that include endothelial cell loss, implant malposition, and synechia.[5–8]

ELIOS (Elios Vision Inc., Irvine, CA) is an excimer laser device specifically designed for treating open angle glaucoma, allowing for intraoperative application during cataract surgery. A single-use 500 μm diameter fiber optic probe is inserted into the anterior chamber through the cataract surgery incisions. Under gonioscopic visualization, this probe creates a series of 10 laser trabeculostomies. Utilizing a 308 nm laser, 10 microchannels are created, each ~500 μm apart, passing through the juxtacanalicular trabecular meshwork and the inner wall of Schlemm canal in the nasal quadrant. This process significantly reduces resistance to aqueous outflow.[9,10]

As the tissue interaction from excimer laser is photoablative and nonthermal, ELIOS produces scant collateral damage to the surrounding tissue, resulting in minimum inflammatory reaction,[9–11] ensuring long-term patency of microchannels, and thus sustained IOP-lowering effect.[12–14] ELIOS can be performed in combination with cataract surgery or as a standalone procedure in accordance with its EU label indication.[9,11,12]

Previous studies with ELIOS technology have shown promising results in terms of medication and IOP reduction, with a favorable safety profile.[9,10] Considering the need for more real-world efficacy results across all MIGS procedures, the purpose of this study was to describe the change in medication use and IOP 1 year after ELIOS combined with phacoemulsification.

MATERIALS AND METHODS

This study reports 1-year outcomes from an investigator-initiated, multicenter, retrospective interventional case series of consecutive patients receiving ELIOS in combination with phacoemulsification between September 1, 2017, and June 1, 2021. Patients underwent surgery in one of 2 private surgical centers in Albacete and Barcelona, Spain. The institutional ethical approval for this study was granted by the Research Committee of the University Hospital of Albacete, Spain (Number: 2018/12/144). All patients were diagnosed of clinically significant cataracts and being treated with antihypertensive drugs who underwent phaco-ELIOS procedure during the study period were consecutively enrolled and their clinical data collected. Baseline preoperative characteristics recorded include demographics (age, eye, and sex) and ocular characteristics, such as best-corrected visual acuity (BCVA), IOP at which the decision for surgery was made (decision IOP), glaucoma medications, glaucoma diagnosis, and glaucoma severity.

Phaco-ELIOS Procedure

The procedure for phaco-ELIOS has been previously described.[9,12,15] In summary, the surgical approach consisted of phacoemulsification combined with ELIOS, which could be completed before or after phacoemulsification. Surgeries were performed by AMV, NPA, and MIC. All procedures were performed under topical and intracameral anesthesia and Elios was applied after Phacoemulsification in all cases. For the ELIOS procedure, the probe was inserted into the viscoelastic-filled anterior chamber through the main phacoemulsification incision and advanced under gonioscopic visualization, towards the trabecular meshwork until "light" apposition is achieved. The lower edge of the probe was positioned at the upper margin of the scleral spur. The 308 nm excimer laser was delivered through a fiberoptic probe to create 10 microchannels over the nasal quadrant at 500 μm distance from each other. Microbubbles and blood reflux were visualized around the location of laser energy delivery. Finally, the probe was removed from the eye, viscoelastic was irrigated, and the surgery was completed as per routine phacoemulsification procedure.

Postoperative Management

Postoperative management and follow-up were identical to standalone phacoemulsification, as per the preferred routine regimen for each of the surgeons. After the surgery, patients were instructed to cease all glaucoma medications and return for examination on day 1 (POD1), week 1 (POW1), month 1 (POM1), month 3 (POM3), month 6 (POM6), and month 12 (POM12), with any nonscheduled study visits as per clinical need. Glaucoma medications were added postoperatively based on the surgeon's discretion if IOP was above the target.

Primary Outcome

The main outcome measure was the mean change in hypotensive medication use as compared with baseline.

Secondary Outcomes

Secondary outcomes included mean postoperative IOP and IOP change compared with baseline at 1 year, occurrence of acute postoperative IOP elevation in the first 3 months after surgery, and proportion of eyes maintaining surgical success at 1 year. Surgical success was defined as either (1) IOP reduction of 20% or more compared with baseline with no increase in medication use or (2) a reduction of one or more medications as compared with baseline with IOP equal or below baseline, with no secondary surgical interventions for glaucoma.

Within the first 3 postoperative months, IOP outside the threshold and glaucoma medication use were not regarded as failures for survival analysis. Loss of light perception or surgical reoperations for glaucoma at any point during postoperative follow-up were defined as immediate failures.

Statistical Analysis

Microsoft Excel (Microsoft 365, Redmond, Washington), Prism 9 (Version 9.1.2, GraphPad Software, LLC), and SAS statistical software were used to conduct all

TABLE 1. Demographic and Baseline Characteristics of Subjects Undergoing Phaco-ELIOS Procedure

	Patients, N = 82; eyes, n = 112, n (%)
Demographic	
Age, mean (SD), y	70.6 (9.6)
Age, median (IQR), y	72 (66–76)
> 70 y	65 (58.0)
Left eye	51 (45.5)
Female	42 (51.2)
Glaucoma type and severity	
Medication classes, mean (SD)	1.8 (0.8)
Medication classes, median (IQR)	2 (1–2)
Decision IOP, mean (SD)	19.9 (4.0)
Decision IOP, median (IQR)*	20 (18–22)
Preop BCVA (logMAR), mean (SD)	0.3 (0.2)
Preop BCVA (logMAR), median (IQR)	0.3 (0.15–0.40)
Preop BCVA ≥0.4 logMAR	22 (27.5)
Disease type	
POAG	80 (71.4)
PXG	1 (0.9)
ACG	9 (8.0)
CMG	11 (9.8)
OHT	10 (8.9)
Other glaucoma	1 (0.9)
Disease severity†	
Mild	80 (71.4)
Moderate	19 (17.0)
Advanced	13 (11.6)

*IOP measured at the visit when the decision was made to proceed with surgery.

†On the basis of visual field mean deviation: mild = 0 dB to > −6 dB; moderate = −6 dB to > −12 dB; and advanced = −12 dB or worse.

BCVA indicates best-corrected visual acuity; IOP, intraocular pressure; IQR, interquartile range; logMAR, logarithm of the minimum angle of resolution; MD, mean deviation; OAG, open angle glaucoma; VA, visual acuity. Other glaucoma includes neovascular glaucoma, elevated episcleral venous pressure, traumatic, uveitic.

statistical analyzes and to create graphs. Categorical variables were represented as proportions and compared using the Fisher exact tests where appropriate. Continuous outcomes were described as means ± SD, and then compared using Wilcoxon tests or 2-sided *t* tests, as indicated by data distribution. To statistically account for loss to follow-up, overall treatment success was evaluated using survival analysis and visualized with Kaplan-Meier curves. Cohort of patients with nonmedicated IOP value available preoperatively underwent distinct analysis of medication use and IOP for the duration of the study.[15]

RESULTS

Study Population and Baseline Characteristics

This study enrolled 112 phakic eyes from 82 patients undergoing phaco-ELIOS procedure between September 1, 2017 and June 1, 2021 and followed them for 12 months postoperatively, with a follow-up rate of 100%. Table 1 summarizes the baseline characteristics of all included patients. The mean age of the enrolled patients was 70.6 ± 9.6 years, and 51.2% were female. Among the included eyes, 71% had mild glaucoma, with the majority (71%) diagnosed with primary open angle glaucoma (POAG). Other glaucoma types included combined mechanism glaucoma (CMG) in 10%, ocular hypertension (OHT) in 9%, angle closure glaucoma (ACG) in 8%, and pseudoexfoliative glaucoma (PXG) in 1%. The mean ± SD best-corrected visual acuity (BCVA) in the sample was 0.3 ± 0.2 logMAR. The mean preoperative intraocular pressure (IOP) was 19.9 ± 4.0 mm Hg, and the average number of medications used at the time of the decision to undergo surgery was 1.8 ± 0.8.

Primary Outcome

At baseline, most eyes (56.3%) were using 2 medication classes for IOP control (Table 2, Fig. 1). The mean ± SD number of medications decreased significantly from 1.8 ± 0.8 preoperatively to 0.4 ± 0.7 at 12 months postoperation (POM12), representing a mean ± SD reduction of 1.5 ± 1.0 medications at the end of the follow-up period ($P < 0.0001$). This indicates a highly significant and sustained decrease in medication use from the point of surgical decision throughout the entire follow-up, with 78.4% of eyes being medication-free at the study's conclusion.

Secondary Outcomes

The changes in IOP, the occurrence of acute postoperative IOP elevation, postoperative BCVA, and the proportion of eyes maintaining surgical success at one year postoperatively are detailed below.

TABLE 2. Baseline and Postoperative Data

	Patients, N = 82; eyes, n = 112					
Medications	**0 meds, (%)**	**1 med, (%)**	**2 meds, (%)**	**3 meds, (%)**	**4 meds, (%)**	***P***
Baseline	5.3	23.2	56.3	11.6	3.6	
POD1	82.7	14.4	2.9	0	0	
POW1	68.0	23.7	8.2	0	0	
POM1	74.2	18.3	6.5	1.1	0	
POM3	78.2	11.5	10.3	0	0	
POM6	78.5	12.7	7.6	1.3	0	
POM12	78.4	9.0	10.8	1.8	0	
Vision, (LogMAR), mean (± SD)						
Preoperative			0.302 ± 0.240			$P < 0.0001$
Postoperative (POM12)			0.054 ± 0.098			
Vision, ≥0.4 logMAR						
Preoperative			22 (27.5)			$P < 0.0001$
Postoperative (POM12)			2 (2.0)			

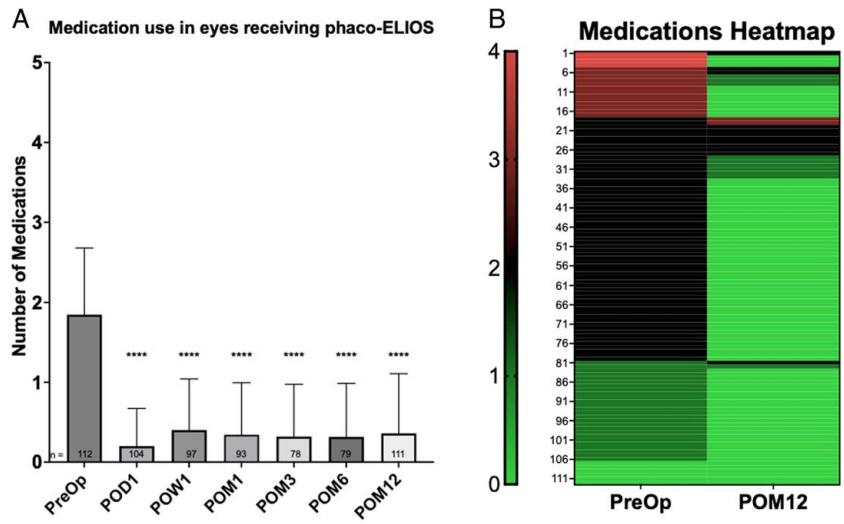

FIGURE 1. Medication use in patients undergoing phaco-ELIOS procedure, (A) bar graph, (B) heatmap representing matched medication use in patients receiving phaco-ELIOS, at the time of surgical decision and at postoperative month 12. Each eye included in the study is indicated by an individual line on the heatmap, with preoperative and postoperative number of medications (0–4) indicated by color. * $P<0.05$; ** $P<0.01$, *** $P<0.001$; **** $P<0.0001$. Figure 1 can be viewed in color online at www.glaucomajournal.com.

Intraocular Pressure

At the time of the decision to undergo surgery, the mean ± SD medicated IOP was 19.9 ± 4.0 mm Hg (Table 2, Fig. 2). Postoperatively, IOP significantly decreased to 16.3 ± 3.1 mm Hg at POM3, 16.5 ± 2.5 mm Hg at POM6, and 16.7 ± 2.6 mm Hg at POM12. This represents a significant decrease of 3.2 ± 4.0 mm Hg or 13.7% from baseline to POM12 ($P<0.0001$).

Acute postoperative IOP elevation within the first 3 months after surgery, defined as an IOP increase of at least 10 mm Hg from baseline or an IOP above 30 mm Hg, occurred in 6 eyes (5.4%) on postoperative day 1 (POD1), in 3 eyes (2.7%) at postoperative week 1 (POW1), and in 1 eye (0.9%) at postoperative month 1 (POM1).

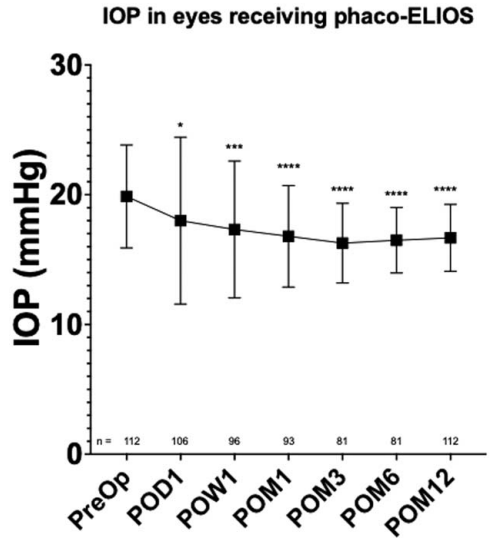

FIGURE 2. IOP values were measured in the clinic using GAT in patients undergoing phaco-ELIOS procedure. * $P<0.05$; ** $P<0.01$, *** $P<0.001$; **** $P<0.0001$.

Nonmedicated IOP (obtained through washout or recorded before treatment initiation) was available for 47 of the 112 included eyes, showing a mean ± SD value of 26.1 ± 3.5 mm Hg. For this subgroup, IOP at POM12 was 16.9 ± 2.2 mm Hg, demonstrating a significant decrease from the mean preoperative value ($P<0.0001$), which corresponds to a 35% reduction from baseline. Medication use in this group was consistent with the overall patient sample, decreasing from 1.6 ± 0.7 preoperatively to 0.3 ± 0.7 at POM12 ($P<0.0001$).

Best Corrected Visual Acuity

Mean ± SD BCVA (LogMAR) improved significantly from 0.3 ± 0.2 preoperatively to 0.05 ± 0.09 at POM12 ($P<0.0001$). Before surgery, 22 eyes (27.5%) had a BCVA of 0.4 LogMAR or worse, while at POM12, only 2 eyes (2.0%) had a BCVA in this range.

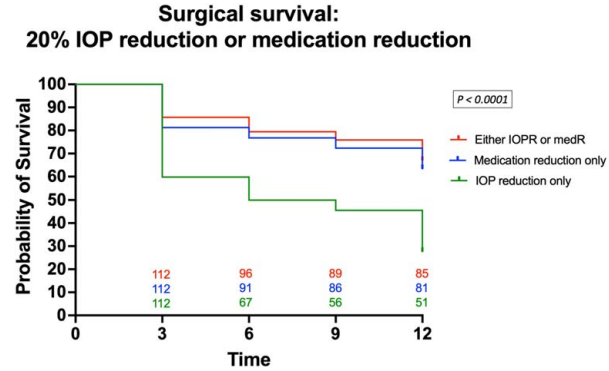

FIGURE 3. Surgical survival. Kaplan-Meier survival curves for surgical success through 12 months. Success was defined as patients achieving either (1) IOP reduction of 20% or more compared with baseline with no increase in medication use or (2) a reduction of one or more medications as compared with baseline with IOP equal or below baseline, with no secondary surgical interventions for glaucoma.

Surgical Success

Surgical success at 1 year, defined as either (1) an IOP reduction of 20% or more compared with baseline with no increase in medication use, or (2) a reduction of one or more medications compared with baseline with IOP equal to or below baseline, and no secondary glaucoma surgeries, is shown in Table 2 and Figure 3A. Surgical success was achieved in 85.7% of eyes at POM3, 79.9% at POM6, and 75.9% at POM12. Among the surgical failures, 2 patients (1.8%; both diagnosed with POAG, 1 moderate and 1 severe) required rescue glaucoma surgery during the follow-up period: nonpenetrating deep sclerectomy was performed in both cases, at POM4 and POM11, respectively.

DISCUSSION

The use of ELIOS for glaucoma has garnered increasing attention in recent years. The current study investigated the efficacy of the ELIOS procedure in combination with phacoemulsification as an intervention for patients with ocular hypertension or glaucoma. In 112 eyes included in this study, there was a significant reduction in medication use, with 78.4% of eyes being medication-free at 1 year postoperatively. There was also a significant reduction in IOP of 3.18 mm Hg, sustained over the entire duration of the follow-up period, with only a small percentage of patients experiencing acute postoperative IOP elevations. Mean BCVA improved from 0.30 preoperatively to 0.05 LogMAR at POM12. Decrease in medication use carries relevance as studies have shown that inadequate drop instillation can range from 25% to 90%, which can result in disease progression and drop wastage carrying important economic implications,[16] not to mention the well-known challenges with adherence, persistence, and ocular surface adverse effects.[17]

It has been published that 11% of the 5 million people with dry eye disease in America, also have glaucoma.[3] The coexistence of glaucoma, glaucoma therapy, and ocular surface disease is an important consideration for patients and physicians, hence making the decrease of topical medication burden a critical point in the care of these patients.[3] Several recent studies have investigated the efficacy of the Excimer Laser Trabeculostomy procedure in reducing hypotensive medication use. Hommayada (2022) found medication drop from 2 to 1.3–1.8,[10] Berlin (2021) reported medication use at 1 year after Excimer Laser Trabeculostomy combined with phacoemulsification with a significant decrease from 1.85 to 1.19,[15] and Riesen (2022) from 2.3 to 1.5.[11] In a prior study, our group identified a reduction in medication by 1.3 with 82% of patients being medication-free 1 year after phaco-ELIOS,[9] similar to the decrease of 1.49 medications and 78.4% eyes medication-free at POM12 found in the current study.

Similarly, previous studies report a consistent 1-year IOP reduction after phaco-ELIOS. Hommayda (2022), in a study of 314 eyes that underwent phaco-ELIOS procedure, identified an IOP decrease between 21% and 37%.[10] Our group previously reported results of 34 eyes who underwent phaco-ELIOS procedure and experienced a decrease in IOP between 13.3% and 26.6% over 1 year of follow-up.[9] Berlin (2021) conducted a long-term study involving 74 eyes that underwent phaco-ELIOS and reported sustained IOP reduction over an 8-year follow-up period, with significant IOP reduction over the first year of follow-up, from 21.9 mm Hg to 14.4 mm Hg.[15] Similarly, Riesen (2022) in a study of 161 eyes undergoing phaco-ELIOS, identified an IOP reduction of 20.2% from medicated IOP.[11] These numbers are in line with our findings of 3.18 mm Hg or 13.7% IOP reduction.

Surgical success defined as either (1) IOP reduction of 20% or more compared with baseline with no increase in medication use or (2) a reduction of one or more medications as compared with baseline with IOP equal or below baseline, with no secondary surgical interventions for glaucoma or loss of light perception, was considered to be more fitting with the IOP-lowering effect of MIGS being dependent on physiological pathways[4] as compared with bleb-forming procedures, where the traditional success criteria has commonly made a target IOP with a 20% reduction from baseline a mandatory requirement to achieve success.[18] With the definition used in the current study, success was achieved in 75.9% of eyes at POM12, similar to another MIGS procedure (iStent trabecular microbypass), that also used an alternative surgical success criteria definition, and reported a success rate as high as 90% at the end of the 8-year follow-up period.[19]

Furthermore, past studies reporting surgical success for ELIOS demonstrated success rates of 70%–80% over intermediate and long-term follow-up ranging between 12 months and 8 years, when success was defined as IOP < 21 mm Hg with 20% IOP reduction.[10] Similarly, Riesen et al[11] (2022) defined treatment success as IOP ≤ 21 mm Hg and medication reduction, and at 1 year of follow-up, 81.3% of patients achieved success.

Acute postoperative IOP elevations after phaco-ELIOS have been previously reported at 13.4% on POD1, 1.0% at POW1 and 1.6% at POM1,[10] while Riesen et al[11] reported 11.3% on POD1, 4.3% at POW1 and 2.5% at POM1, which are similar to the rates in the current study: 5.3%, 2.7%, and 0.9%, respectively.

A review by Durr et al[12] (2020) provided a summary of 8 previous studies on ELIOS, highlighting its potential as an effective treatment option that offers significant IOP and medication reduction with a low-risk profile. ELIOS has a favorable safety profile, and significant IOP reduction potential for patients with mild-to-moderate glaucoma; moreover, ELIOS significantly reduces the medication burden, thereby improving the patient's quality of life.

One of the limitations of our study is that we are not reporting any safety data. Nonetheless, previous publications have reported on safety measures with the ELIOS procedure. ELIOS has a particular safety advantage as an implant-free procedure, since it avoids many adverse effects associated with IOP-lowering intraocular implants. Prior studies found that trabecular bypass microstents and Schlemm canal microstents may be associated with stent malposition and/or obstruction in 1.1%–4.3% of cases and may require surgical revision.[5,7,8] In rare cases, stent malposition has been associated with a serious complication of uveitis-glaucoma-hyphema syndrome.[20–22] Endothelial cell loss is another serious concern that has been associated with supraciliary micro-stent implant.[6] Postoperative synechia are a less serious, but significantly more common postoperative finding in implant-based MIGS, estimated to occur in 18%–19% of cases.[5,7,8] Implant-free, laser-based ELIOS procedure avoids these safety risks, while providing a similar efficacy profile.

Several limitations should be considered when interpreting the results of this study. First, the relatively short 1-year follow-up period might overestimate the effectiveness

due to potential regression to the mean. Conversely, we may underestimate the long-term effectiveness of ELIOS compared with studies with 8-year follow-up.[11,15] In addition, the present study lacked a control group for direct comparison, which is relevant as phacoemulsification alone has been shown to have a modest and transient IOP-lowering effect (~1 y postsurgery). However, when examining our primary outcome, the medication reduction in our study (78% of patients medication-free) is higher than the 51% reported in the phaco-alone cohort of the Horizon trial at 1 year.[23,24] Finally, current study focused on the combined procedure of phaco-ELIOS, thus it does not reveal distinct effects that phacoemulsification or ELIOS alone have on medication burden and IOP. However, prior studies of standalone ELIOS have demonstrated its safety and efficacy.

A direct comparison of ELIOS to implant-based MIGS may offer a quantitative assessment of the efficacy and safety profile of the procedure and may be a beneficial future research direction. As clinical use of the procedure would likely be in conjunction with phacoemulsification, the currently reported efficacy of the combination procedure is most relevant for clinical practice.

Further studies investigating the effects of ELIOS on patient satisfaction and quality of life outcomes would be of value. Cost-effectiveness analyzes will help in establishing the clinical and economic value of ELIOS as a treatment option for glaucoma patients. These efforts will help with obtaining agency approvals and securing funding in the public health care sector or insurance coverage, and will facilitate its integration into clinical practice to promote the widespread patient access to ELIOS.

In conclusion, the current study on phaco-ELIOS demonstrates promising results in terms of medication burden reduction, with 78.4% of eyes who underwent the procedure being medication-free at 1 year postoperatively. IOP reduction was also significant and sustained at 13.7% 1 year after the procedure. In conjunction with prior studies, current study suggests the efficacy benefit of phaco-ELIOS for treatment of patients with mild-to-moderate glaucoma.

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