REVIEW/UPDATE

Visual outcomes of combined cataract surgery and minimally invasive glaucoma surgery

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Minimally invasive glaucoma surgery (MIGS) has become a reliable standard of care for the treatment of glaucoma when combined with cataract surgery. This review describes the MIGS procedures currently combined with and without cataract surgery with a focus on visual outcomes based on the literature and the experience of the ASCRS Glaucoma Clinical Committee.

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Minimally invasive (sometimes referred to as microinvasive) glaucoma surgery (MIGS) is a procedure that lowers intraocular pressure (IOP) without significantly altering the tissue, allows for rapid visual recovery, is moderately effective, and can be combined with cataract surgery in a safe and efficient manner.[1,2] This is in contrast to more conventional glaucoma surgery (eg, trabeculectomy or large glaucoma drainage device implantation), which requires conjunctival and scleral incisions as well as suturing.

We describe currently used MIGS procedures, both as stand-alone surgeries and combined with cataract extraction, as well as the postoperative visual outcomes. We also describe significant complications reported with the use of a supraciliary microstent. Although mention is made of IOP results and medication use after these procedures, it is not our intent to compare IOP-lowering outcomes, but to focus primarily on visual outcomes.

ENDOSCOPIC CYCLOPHOTOCOAGULATION

Endoscopic cyclophotocoagulation (ECP) is a laser treatment of the ciliary processes performed via direct intraocular application under viewing with a surgical endoscope. The procedure is designed to reduce aqueous humor production and thereby lower IOP. The endoscope consists of a fiberoptic camera, light source, and laser aiming beam with an 832 nm diode laser. The endoscope probe is introduced into the globe via a limbal corneal or pars plana incision. The anterior approach requires inflation of the ciliary sulcus with an ophthalmic viscosurgical device, whereas the posterior approach uses a pars plana or anterior chamber irrigation port. Although the anterior approach can be used in a phakic eye, it is typically performed with cataract extraction as a combined procedure or in a pseudophakic or aphakic eye. The pars plana approach cannot be used in the setting of a phakic intraocular lens (IOL).

ECP is appropriate for use in mild to moderate glaucoma combined with cataract extraction, in more advanced disease with failed filtration surgery, and in ultra-refractory glaucoma with multiple failed surgeries.[3–9] The IOP-lowering efficacy of ECP in these scenarios is well characterized; however, there is not as much information about the visual acuity and refractive outcomes, even in studies of ECP combined with cataract extraction. This section discusses studies that report data on visual recovery after combined ECP and cataract extraction.

Lopes Lima et al. performed a large retrospective analysis of 368 eyes of 243 patients with primary open-angle glaucoma (OAG) and cataract that had combined

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phacoemulsification and ECP.[10] There was a significant improvement in visual acuity from 0.6 ± 0.6 logarithm of the minimum angle of resolution (logMAR) to 0.4 ± 0.6 logMAR over the same period.

In another retrospective study, Siegel et al. compared 261 eyes that had combined phacoemulsification and 52 eyes that had phacoemulsification alone.[6] The median visual acuity at baseline was 20/50 in the ECP–phaco group and 20/60 in the phaco-alone group; the median at 36 months was 20/30 in both groups.

Morales et al. retrospectively reported 1-year outcomes in 104 eyes with more advanced glaucoma that had combined ECP and cataract.[11] The corrected distance visual acuity (CDVA) improved by 2 Snellen lines or more in 73% of patients, with a decrease in 6%. The decreased vision was the result of corneal decompensation in 3 cases, diabetic macular changes in 2 cases, and progression of macular degeneration in 1 case.

In a retrospective case series of 63 eyes that had ECP combined with phacoemulsification, Clement et al. found that at the last follow-up, the mean visual acuity improved from a baseline of 1.01 ± 0.98 logMAR to 0.33 ± 0.22 logMAR, with 94% of eyes achieving improved or stable vision after 1 year.[4] The decreased vision was caused by glaucoma progression in 3 eyes and corneal decompensation in 1 eye.

Ishida performed a review of complications of transscleral cyclophotocoagulation and of ECP.[12] In transscleral procedures, which include mostly stand-alone surgery, the incidence of visual acuity loss of 2 or more Snellen lines ranged from 0% to 55% (mean 22.5%). The ECP Collaborative Study reported a 1% incidence of visual decrease of more than 2 Snellen lines. The rate of vision loss of 2 or more lines is as high as 6%; however, these higher rates include cases of stand-alone ECP as well as ECP combined with cataract extraction in eyes with more refractory glaucoma.[13]

In a retrospective analysis of OAG, Kang et al. assessed the effects on refractive outcomes of combined ECP and phacoemulsification (62 eyes) and phacoemulsification alone (62 eyes).[14] The CDVA improved or was maintained in 95% in the ECP–phaco group and 98% in the phaco-alone group. Complications in the ECP–phaco group included uveitis (6.5%), pupillary membrane (1.6%), and macular edema (1.6%). In the ECP–phaco group, 90% of eyes achieved a postoperative refraction within ±1.0 diopter (D) of the target vs 100% in the phaco-alone group. The authors concluded that ECP does not affect the target refractive outcome when combined with cataract surgery and should not require adjustment of the IOL calculation.

In contrast, Sheybani et al. found that the postoperative refractive error was more variable in patients who had ECP and phacoemulsification (83 patients) than in those having cataract surgery alone (53 patients).[15] In this retrospective study, the refractive change from that predicted by IOL formulas was higher in the ECP–phaco group (−0.169 D vs 0.029 D for SRK/T, −0.325 D vs −0.110 D for Hoffer Q, and −0.312 D vs −0.095 D for Holladay 1).[16–18] The mean arithmetic error (F test of variance) was also significantly greater in the ECP–phaco group.

A retrospective study by Wang et al. assessed patients with a diagnosis of primary angle-closure suspect, primary angle closure, or primary angle-closure glaucoma (ACG).[19] Of interest, they found a decrease in postoperative refraction predictability and a myopic shift in patients treated with combined ECP and phacoemulsification (68 eyes) compared with those having phacoemulsification alone (71 eyes). The mean absolute error (average of absolute differences between actual refractive outcome and predicted refractive outcome) was higher in the ECP–phaco group (0.62 ± 0.43 D) than in the phaco-only group (0.47 ± 0.53 D). In addition, the mean arithmetic error showed that the ECP–phaco group had a greater myopic shift than the phaco-only group (−0.54 ± 0.53 D vs −0.26 ± 0.52 D).

In a retrospective study of 223 eyes, Edmiston et al. evaluated the incidence of persistent anterior uveitis after ECP and cataract extraction and its relationship to race, IOP, and visual acuity outcomes.[20] Preoperatively, the mean visual acuity was 0.43 ± 0.40 logMAR, and the mean IOP was 15.3 ± 3.7 mm Hg. The mean postoperative visual acuity improved to 0.27 logMAR in Black patients, 0.23 logMAR in Asian patients, 0.13 logMAR in Hispanic patients, and 0.22 logMAR in White patients, with no statistical difference between the groups. The incidence of persistent anterior uveitis (22.4%) was correlated with race, in particular with the black race. However, the authors did not find a difference in visual acuity, IOP, or glaucoma medications between those with persistent anterior uveitis and those without persistent anterior uveitis. Of patients with persistent anterior uveitis, 80% had an improvement in vision compared with 76% of those with no persistent anterior uveitis.

One advantage of ECP is its utility in eyes with ACG, in which a scarred trabecular meshwork makes angle-based trabecular surgeries more unpredictable. A study of ECP with phacoemulsification, viscogoniosynechialysis, and ECP in 29 eyes of 22 patients reported a mean baseline CDVA improved from 0.4 to 0.3 logMAR by 6 months postoperatively, with no recorded significant visual complications.[21]

Lin et al. reported the results of a retrospective comparison of combined ECP and phacoemulsification in eyes with OAG (n = 41) and eyes with ACG (n = 22).[22] The visual acuity recovery was better in the open-angle group than in the angle-closure group (baseline, 0.27 ± 0.20 logMAR vs 0.29 ± 0.26 logMAR; at 1-year follow-up, 0.14 ± 0.20 logMAR vs 0.28 ± 0.29 logMAR).

Reducing aqueous humor production remains an effective way to treat many types of glaucoma in eyes with varying anatomy, disease severity, and previous glaucoma surgery. ECP is a method of decreasing aqueous production using laser treatment of the ciliary processes via a direct, titrated, endoscopic intraocular approach. It is especially popular for use with combined cataract extraction in eyes with mild to moderate glaucoma and in patients who are medically controlled or uncontrolled. Many studies have shown the beneficial effects of decreasing the IOP and the number of glaucoma medications. Fewer studies have

addressed visual acuity outcomes, which are summarized here. In general, the procedure has an excellent safety profile but a greater incidence of anterior chamber, corneal, and retinal inflammation. Visual recovery is longer and slightly worse than with cataract surgery alone, and the postoperative refractive error is minimal but less predictable.

TRABECULAR MICROBYPASS

iStent

The first U.S. Food and Drug Administration (FDA)-approved ab interno MIGS device was the iStent (Glaukos Corp.), a titanium, L-shaped trabecular microbypass stent 1.0 mm in length and 0.33 mm in height. In 2011, Samuelson et al. published a large multicenter prospective randomized study comparing cataract extraction alone and cataract extraction with iStent placement in patients with mild to moderate OAG.[23] The overall safety profile of the stent-plus-cataract arm was similar to that of cataract surgery alone, supporting the approval of the iStent. Since this time, numerous studies have reported the outcomes of iStent placement, concomitant with cataract surgery and as a stand-alone procedure, in a variety of clinical settings. In addition, a second-generation iStent, the iStent inject, was developed and studied, receiving FDA approval in 2018. This section reviews the reported visual outcomes of the iStent with the hopes of further elucidating how this implant meets the tenets of MIGS.

First-Generation iStent Placement with Cataract Extraction In the 2-year prospective randomized open-label multicenter U.S. Investigational Device Exemption clinical trial performed at 29 U.S. investigational sites, multiple safety and visual outcome measures were evaluated.[23] In the cataract-only (control) arm, 6 patients (5%) reported blurry vision or visual disturbance compared with 1 patient (1%) in the stent-plus-cataract (study) arm. Other potential visual problems included macular edema (2% and 1%, respectively) and posterior capsule opacification (7% and 3%, respectively).

Overall, patients in both arms had improved visual acuity postoperatively as a result of the cataract surgery. Preoperatively, the CDVA was 20/40 or better in only 45% of patients in the study group and 44% of patients in the control group. However, 1 year postoperatively, 94% of patients and 90% of patients, respectively, achieved a CDVA of 20/40, with most patients attaining 20/32 or better (85% in the study group; 79% in the control group). Finally, 97% in the study group had improved CDVA vs 95% in the control group. The differences between groups were not statistically significant, leading to the conclusion that placement of the iStent did not have an impact on visual recovery or postoperative visual function compared with cataract surgery alone.

Arriola-Villalobos et al. performed a small study of 20 patients with ocular hypertension or glaucoma and cataract having first-generation iStent placement with cataract extraction.[24] No visual acuity loss was recorded, and the decimal CDVA increased significantly from 0.4 ± 0.12 preoperatively to 0.8 ± 0.17 by the last postoperative visit at 1 year ($P < .001$).

Neuhann presented 3-year data from a cohort of 62 eyes (43 patients) after concomitant cataract extraction with iStent placement.[25] Preoperatively, only 44% of patients had a CDVA of 20/40 or better, and 7% had a CDVA of 20/200 or worse. Through 36 months, 93% of patients achieved a CDVA of 20/40 or better, with 49% achieving 20/20 or better.

Placement of Multiple First-Generation iStent Concomitant with Cataract Extraction Belovay et al. reported a retrospective comparative case series of 53 eyes (47 patients) with cataract and mild to advanced glaucoma having cataract extraction with the concomitant placement of 2 (n = 28) or 3 (n = 25) first-generation iStents.[26] The CDVA was maintained or improved in 89% of patients at 1 year. At baseline, 25% of all patients had a visual acuity of 20/200 or worse, and the mean visual field mean deviation was 11.5 ± 7.6 (dB). Five patients did not maintain or have improved visual acuity at 1 year; however, at subsequent examinations, 4 of those patients had improved visual acuity, whereas the fifth patient was lost to follow-up. Of the eyes, 76% in the 3-stent group and 64% in the 2-stent group achieved a CDVA of 20/40 or better (compared with 32% and 21%, respectively, at baseline), providing evidence of good visual improvement and some support for the idea that the number of stents is not associated with visual outcomes.

Stand-Alone iStent Placement with Multiple First-Generation Stents Katz et al. reported the results of an ongoing prospective randomized study of 119 phakic patients with OAG randomized to have placement of 1 (n = 38), 2 (n = 41), or 3 (n = 40) stand-alone iStents.[27] By 42 months postoperatively, 8 eyes receiving 1 stent, 5 eyes receiving 2 stents, and 7 eyes receiving 3 stents had a CDVA loss of 1 line or more; the loss was attributed to cataract. Of the 8 eyes not having cataract extraction, the CDVA was 20/40 or better in all cases and better than 20/30 in 7 cases. A proportional analysis at 42 months found a CDVA of 20/40 or better in 79% of 1-stent eyes, 68% of 2-stent eyes, and 74% of 3-stent eyes, suggesting that number of stents placed was not a major factor in the postoperative visual acuity.

In 2014, Ahmed et al. published a prospective study of 39 phakic patients with OAG who had stand-alone placement of 2 first-generation iStents with concomitant nightly travoprost eyedrop therapy.[28] Although there were no adverse intraoperative events, 4 patients developed cataract with a reduction in CDVA. In these 4 patients, the baseline CDVA at baseline was 20/20, 20/22, 20/40, and 20/40, respectively; postoperatively, it was 20/33, 20/29, 20/67, and 20/67, respectively. One patient had transient worsening of CDVA; the acuity returned to normal by 3 months postoperatively. In general, the CDVA was stable; the CDVA was 20/40 or better in 89.7% of patients (n = 35) preoperatively and in 84.6% (n = 33) 18 months postoperatively.

In a randomized prospective study by Vold et al., 101 patients with newly diagnosed OAG were randomized to

receive 2 first-generation iStents or topical travoprost nightly.[29] At baseline, the CDVA was 20/40 or better in 74% in the 2-stent group and 83% in the travoprost group. However, at 36 months 77% in the 2-stend group and 74% in the travoprost group had a CDVA of 20/40 or better. Thus, the visual acuity outcomes of stand-alone multiple stent placement were similar to those of topical therapy with a prostaglandin analog.

iStent Inject (Second Generation) Placement with Cataract Extraction In a follow-up prospective uncontrolled nonrandomized interventional case series of 20 patients with ocular hypertension or glaucoma and cataract having 2 second-generation iStent inject placements with cataract extraction, Arriola-Villalobos et al. reported no visual acuity loss.[30] The decimal CDVA increased significantly from 0.42 ± 0.16 preoperatively to 0.18 ± 0.16 by the last postoperative visit at 1 year ($P < .001$).

Lindstrom et al. presented 18-month data from a prospective interventional study of 57 phakic eyes with OAG having placement of 2 second-generation iStents.[31] One patient developed cataract associated with a CDVA decrease of greater than 1 line. At 18 months, all patients were accounted for; 93% had a CDVA of 20/40 or better, and 98% had a CDVA of 20/100 or better.

The Synergy Trial was a European, multicenter, prospective, open-label study in which 99 patients with OAG on at least 2 medications had implantation of 2 iStent inject devices as a stand-alone procedure and were follow to 12 months.[32] At baseline, 84% of patients had a CDVA of 20/40; the postoperative CDVA was stable, with 86% achieving 20/40 at 12 months.

In conclusion, data from studies of combined cataract surgery–stent placement or stand-alone stent procedures support the safety of single or multiple iStent placement. Both procedures yielded standard outcomes in a variety of settings, with the majority of patients achieving a return to their preoperative visual acuity. The available data support the role of iStent placement in maintaining excellent visual function while lowering IOP and medication use in patients with cataract.

Hydrus

The Hydrus implant is an ab interno trabecular microstent designed to enhance aqueous outflow by bypassing the trabecular meshwork and scaffolding the Schlemm canal. Approximately 8.0 mm long, the implant consists of a short inlet segment and an extended stent segment. The inlet resides in the anterior chamber and provides a portal for aqueous flow. The stent portion sits within the Schlemm canal; it stretches the trabecular meshwork and scaffolds 3 clock hours of the canal. In tissue models, these characteristics enhanced outflow to aqueous veins.[33] Thus, the Hydrus implant was designed to address OAG, for which trabecular dysfunction and collapse of the Schlemm canal are thought to be main pathophysiologic factors.

Several studies have assessed the effectiveness of this implant in lowering IOP and reducing dependence on medications and how it compares with alternative approaches; however, none of these studies had vision as an end point.[34] Fea et al. found that combined phacoemulsification and Hydrus implantation, even in patients with failed previous incisional glaucoma surgeries, led to a significant reduction in IOP and a high medication-free rate 24 months postoperatively.[35] In their study, they suggested that the Hydrus implant has comparable safety to cataract surgery alone, with iris adhesion to the implant the most frequently reported (9.8%) adverse event.

Two prospective multicenter randomized trials evaluated Hydrus placement combined with cataract surgery and compared the results with those of cataract surgery alone.[36,37] In a study of 100 eyes, Pfeiffer et al. found that the IOP was significantly reduced at 2 years in the combined Hydrus–cataract surgery group compared with the group having cataract surgery alone; the safety profile was similar as well.[36]

In addition to the IOP-lowering effect, Fea et al. reviewed the effect of the device on endothelial cell loss (ECL) in combined phacoemulsification–Hydrus placement compared with phacoemulsification alone.[38] They found no change in endothelial parameters after implantation of the device and that phacoemulsification was the main factor in determining the loss of endothelial cells in all groups at 6 months. Fea et al. also compared the results of selective laser trabeculoplasty with those of Hydrus implantation.[39] They found that Hydrus implantation led to a significant further reduction in medication dependence at 12 months.

In conclusion, the Hydrus microstent had no reported adverse visual outcomes compared with cataract surgery alone, and the rate of endothelial cell loss with the device when combined with cataract surgery was similar when compared with cataract surgery alone.

SUPRACHOROIDAL AND SUPRACILIARY IMPLANTS

A newer class of IOP-lowering surgery is placement of a supraciliary or suprachoroidal drain. Several suprachoroidal implant stents have been described recently, including the CyPass microstent (Alcon), iStent Supra, and STARflo (iStar Medical).[40] These implants vary in size and shape as well as in material composition and insertion technique. All suprachoroidal or supraciliary implants shunt aqueous humor from the anterior chamber across the junction of the ciliary body face and sclera into the suprachoroidal space.

Given that suprachoroidal shunts are a new class of surgical implant, little available data exist on their impact on the endothelial cell count (ECC). The most robust dataset is derived from the COMPASS trial and COMPASS-XT trial, which compared the outcomes of combined cataract extraction and polyamide CyPass supraciliary stent placement with those of cataract extraction alone.[41,42,A,B]

CyPass

The CyPass supraciliary microstent received FDA approval in 2016 for the treatment of mild to moderate glaucoma in

conjunction with cataract surgery. The device is composed of a biocompatible polyimide material that conforms to the shape of the sclera with fenestrations. It is 6.35 mm × 510 μm with a 300 μm lumen. The surgical technique consists of ab interno insertion between the scleral spur and ciliary body into the suprachoroidal space, essentially creating a controlled cyclodialysis cleft to enhance uveoscleral outflow.

In the COMPASS trial, 505 patients with cataract and OAG were randomized 3:1 to cataract extraction with CyPass placement (study group; n = 374) or cataract extraction alone (control group; n = 131).[41] Although the ECC was recorded in the trial, these results were not directly reported in the accompanying article. At 2 years, only 1.1% of eyes in the study group and 0.0% of eyes in the control group had a CDVA that was 2 lines or more below the baseline value. There were no significant differences in the rate of adverse events between the 2 arms, including in the proportion of patients with corneal edema (study group, 3.5%; control group, 1.5%) (P = .37).

When the FDA approved the device, Alcon and the FDA, exercising caution, agreed to initiate an extension of the COMPASS study. In this study, known as the COMPASS-XT trial, data were collected out to 5 years postoperatively.[42,A,B] The COMPASS-XT trial followed a smaller number of patients than the COMPASS trial. By 60 months, roughly 200 patients had CyPass placement with cataract extraction (study group), and 53 patients had cataract extraction alone (control group).

In the COMPASS trial, hypotony was initially reported in 2.9% of patients who received the CyPass device combined with cataract extraction.[41] Vision loss from hypotony can be secondary to corneal edema, astigmatism, cystoid macular edema, or maculopathy.

Soon after the introduction of the CyPass into mainstream use, isolated case reports began to appear on various forums regarding myopic surprises after combined CyPass placement and cataract extraction. Although no published reports are available, cases on the forums reported a myopic shift between 1.00 D and 3.00 D.[C–F] The causes of the induced myopia are presumed to be ciliary body swelling and forward rotation of the lens–iris diaphragm. There were no cases of induced myopia in the initial COMPASS trial. This led many to believe that the medication washout period initiated in all cases in the clinical trial might protect against the development of ciliary body swelling because it eliminated the pressure-lowering effects of medications that remain in the eye without a proper washout. It is the experience of surgeons on the ASCRS Glaucoma Committee that all cases of induced myopia from ciliary body swelling after combined CyPass placement–cataract extraction resolve within 1 to 2 months after a course of topical steroids and cycloplegics.

Glaucoma is associated with corneal endothelial disease. Although the etiology of ECL in glaucoma is unknown, the literature provides strong evidence of the impact of direct contact between tube shunt implants and the ECC.[43–45] Supraciliary or suprachoroidal implants might share a common mechanism for endothelial damage with the tube shunt by initiating direct trauma or turbulent aqueous flow against the corneal endothelium.

In the COMPASS-XT trial, 8.7% of patients had a 30% ECC loss from baseline compared with 3.0% of control patients.[42,A,B] At 5 years, the ECL was more pronounced in the study group than in the control group. The baseline ECC was 2432 cells/mm^2 in the study group and 2434 cells/mm^2 in the control group. The ECC decreased to 1992 cells/mm^2 in the study group (n = 116) and 2303 cells/mm^2 in the control group (n = 33) at 48 months and to 1931 cells/mm^2 in the study group (n = 163) and 2189 cells/mm^2 in the control group (n = 40) at 60 months. This represented a reduction in ECL of 18.4% in the study group and 7.5% in the control group at 48 months and of 20.5% and 10.5%, respectively, at 60 months. The difference in ECL between the 2 groups decreased slightly between 48 months and 60 months. American National Standards Institute Z80:27 standards consider a 30% ECL at 5 years to be meaningful.[46] At 5 years, 27.2% of patients in the study group and 10% in the control group had an ECL loss of 30%.

The rate of ECL per year was 1.39% in eyes with no rings showing (n = 69), 2.74% in eyes with 1 ring showing (n = 98), and 6.96% in eyes with 2 to 3 rings showing (n = 27). No patient in the COMPASS-XT trial required corneal surgery by 5 years. A CyPass trimming procedure was performed in 4 patients with 3 rings visible in the anterior chamber; the rings were observed in the first postoperative week. In all cases, the corneas remained clear, and the ECC remained stable at 60 months. One patient in the initial COMPASS trial (2-year follow-up) had Descemet stripping endothelial keratoplasty at 13 months; the procedure was thought to be related to the cataract extraction and not to the CyPass device, which was well positioned with 1 ring visible. Some eyes with more than 2 rings visible in the anterior chamber had minimal ECL.

Alcon voluntarily withdrew the CyPass device from the market on August 29, 2018, because of safety concerns, reportedly based on 5-year data from the COMPASS-XT study. The data indicated that the rate of ECL was higher in patients receiving cataract extraction plus CyPass implantation than in patients receiving cataract extraction alone. The FDA recommended that surgeons not implant CyPass microstents and that they return unused devices to Alcon.

In conclusion, visual outcomes after CyPass implantation can be affected by hypotony, myopic shifts, and ECL. Hypotony and myopic shifts tend to be transient and self-resolve or can be corrected with intervention. To date, no published reports of deceased visual acuity have been directly attributed to the statistically significant loss of ECL reported in the COMPASS-XT trial. It is recommended that all patients who have had CyPass implantation have a thorough corneal assessment to determine whether there are signs of ECL. No intervention is likely required if there are no signs of corneal decompensation. If corneal decompensation develops and more than 1 ring of the device is visible, surgeons should consider repositioning or trimming the device.

iStent Supra

The iStent Supra (Glaukos) is made of polyethersulfone and titanium. It is currently undergoing U.S. FDA trials and has the Conformité Européenne mark. The device is 4.0 mm long and is intended for placement in the suprachoroidal space via ab interno surgery in association with cataract surgery or as a stand-alone procedure. The manufacturer completed enrollment of a 24-month outcome study in February 2017. The study included 505 patients at 35 sites with mild to moderate glaucoma. The pending results are to be submitted for premarket approval of the device.

At present, there are little available data about the device in the published literature. Jünemann reported the outcomes of a 12-month study of 42 eyes with advanced glaucoma that had iStent Supra placement and received travaprost postoperatively.[G] There were no long-term complications, and no patient had a decrease in CDVA at the 1-year visit. Myers et al. also published a long-term series of 80 patients with refractory glaucoma who had inadequate IOP after a previous trabeculectomy.[47] The patients received 1 iStent Supra and 2 trabecular bypass stents, with travaprost administered postoperatively, with no reported long-term visual complications.

In conclusion, there are little published data concerning the iStent Supra. The material, size, and position within the angle are different for the Supra compared with the CyPass, but without data or experience beyond the clinical trial, the rate of endothelial cell loss with this implant is unknown.

AB INTERNO TRABECULOTOMY/GONIOTOMY

OMNI Surgical System and Trabectome

The TRAB360 device is the predicate to the OMNI Surgical System (Sight Sciences, Inc.) and is used for advancing the microcatheter into and 360 degrees around the Schlemm canal to tear the trabecular meshwork and the inner wall of the Schlemm canal. The TRAB360 device is no longer available because most surgeons choose to perform ab interno viscodilation of the canal as well as the goniotomy; therefore, the manufacturer developed a device that combines both functions. The Trabectome (NeoMedix) uses thermal ablation of the trabecular meshwork and the inner wall of the Schlemm canal to improve the outflow of aqueous.

Few publications have specifically assessed the refractive and visual outcomes after combined cataract and Trabectome surgery, and no study has evaluated the effect of combined cataract and TRAB360 surgery on these parameters. Luebke et al. performed a retrospective study to compare the visual outcomes in 137 eyes having combined cataract and Trabectome surgery and 1702 eyes having cataract surgery alone.[48] The refractive and visual outcomes 2 months postoperatively were not statistically different between the 2 groups. The mean biometry prediction error was 0.48 ± 0.01 D (range −4.00 to 5.13 D) for cataract surgery alone and 0.53 ± 0.04 D (range −1.47 to 2.23 D) for combined cataract–Trabectome surgery. The mean decimal CDVA was 0.78 ± 0.01 and 0.81 ± 0.02, respectively. The mean postoperative axial length was not significantly different between combined surgery (23.60 mm; range 21.12 to 29.91 mm) and cataract surgery alone (23.26 mm; range 17.16 to 27.54 mm). However, the combined surgery group had a slightly higher rate of postoperative cystoid macular edema than the stand-alone cataract surgery group (2.2% vs 1.9%), although the difference did not reach statistical significance. In a study by Esfandiari et al., 2 of 93 patients who had combined cataract–Trabectome surgery lost 2 lines of visual acuity over a 5-year follow-up as a result of advanced glaucoma.[49]

In conclusion, although studies have reported the results of combined cataract–Trabectome surgery at various postoperative time points, they did not primarily examine the refractive and visual outcomes. Rather, they mainly focused on the effect of combined surgery on the reduction in IOP and number of medications.[49–51] These limited data suggest that combined cataract–Trabectome surgery does not change the visual results conferred by cataract surgery alone. However, additional studies are warranted.

Kahook Dual Blade and Gonioscopy-Assisted Transluminal Trabeculotomy

The Kahook dual blade (KDB) (New World Medical Inc.) removes the entire nasal aspect of the trabecular meshwork and the inner wall of the Schlemm canal. In a prospective case series, Dorairaj et al. reported that 52 eyes receiving combined the Kahook blade and cataract surgery had a significant improvement in the mean visual acuity from 0.439 ± 0.041 logMAR before surgery to 0.137 ± 0.016 logMAR 12 months postoperatively.[52] Two eyes (3.8%) developed posterior capsule opacification. The study lacked a control group of cataract surgery alone. In a retrospective study, Dorairaj et al. compared combined Kahook blade and cataract surgery with combined iStent and cataract surgery.[53] During 6 months of postoperative follow-up, both groups had a significant improvement in the mean CDVA from 0.4 ± 0.3 logMAR at baseline to 0.1 ± 0.2 logMAR at 6 months; there were no significant differences in CDVA between the 2 groups. In another study, Sieck et al. evaluated visual outcomes comparing KDB with cataract surgery and cataract surgery alone and demonstrated that refractive surprise greater than ±0.5 D occurred in 26.3% of eyes in the phaco-KDB group and 36.2% in the phacoemulsification group ($P = .11$). Refractive surprise greater than ±1.0 D occurred in 6.6% for the phaco-KDB group and 9.7% for the phacoemulsification group ($P = .08$). There was no significant difference in risk of refractive surprise when preoperative IOP, axial length, keratometry or performance of KDB goniotomy were assessed in univariate analyses.[54]

In a retrospective study, Grover et al. found that gonioscopy-assisted transluminal trabeculotomy alone or combined with cataract surgery effectively reduced IOP and the number of medications over a 24-month follow-up.[55] The mean preoperative and postoperative visual acuities were reported for the entire cohort. Thus, the effect of the combined surgery on visual acuity is not yet known.

In conclusion, although there are few publications on this topic, future studies will likely be performed to examine the

effect on the refractive and visual outcomes of cataract surgery combined with either GATT or Kahook dual blade.

AB INTERNO VISCODILATION/CANALOPLASTY

An evolution of viscocanalostomy, traditional canaloplasty uses circumferential (360 degrees) catheterization of the Schlemm canal along with gentle viscodilation. It is theorized that it breaks adhesions in the canal, allows the compressed tissue planes of the trabecular meshwork and sclera to separate, and causes herniated trabecular meshwork tissue to withdraw from collector channels. In traditional canaloplasty, a 9-0 or 10-0 polypropylene tensioning suture is used to ensure the patency of the Schlemm canal. However, a review of 3-year data by Lewis et al. indicated that 360-degree viscodilation alone (ie, canaloplasty without a suture) successfully lowered IOP.[56]

Suture-free canaloplasty, known as ab interno canaloplasty, is a treatment option for mild to moderate primary OAG, mainly based on its ease of use, comprehensive approach, and low-risk profile. Ab interno canaloplasty also spares conjunctival manipulation and thus does not obviate future conjunctival surgery.[57] Ab interno canaloplasty can be performed with an illuminated microcatheter (iTrack, Ellex) (which was originally used for ab externo canaloplasty) or more recently with the OMNI system (Sight Sciences). Both are used to access, catheterize, and viscodilate the proximal and distal outflow system, whereas the OMNI system was designed to also perform partial or full 360-degree goniotomy/trabeculotomy; however, the iTrack can also do this if the catheter is reinserted after the viscodilation is completed. Because the OMNI is a newer device, no published study has measured the visual outcomes. However, when ab interno canaloplasty alone is performed with the OMNI system, visual outcomes should be similar to those of the iTrack microcatheter. However, if the OMNI system is used to also perform a goniotomy, the risk for hyphema might be higher because of the loss of trabecular meshwork.

Körber published findings from a study of 23 patients who had stand-alone ab interno canaloplasty or ab interno canaloplasty combined with cataract extraction.[3,58] There were reductions in medication dependence and IOP through 12 months postoperatively with no difference in visual outcomes presented.

Gallardo et al. have published results of ab interno canaloplasty and compared the 1-year efficacy and safety profile of ab interno canaloplasty performed as a stand-alone procedure or as an adjunct to cataract extraction in reducing IOP and glaucoma medication dependence.[59,60] Visual acuity was significantly improved at the 1-year follow-up in the cohort as a whole as well as in the combined group ($P \leq .001$). In the stand-alone group, the visual acuity was unchanged ($P = .849$).

In conclusion, the visual outcomes with ab interno canaloplasty have been rarely reported. This is most likely because no device left in the eye; therefore, no large RCT was needed, making comparisons with cataract surgery alone largely absent. However, based on the scarce data, and the experience of the authors, postoperative vision is typically unchanged from baseline. With all canal-based MIGS procedures discussed here, postoperative hyphema is common but is self-limited and usually resolves spontaneously. However, the primary focus of this article is the long-term visual outcomes, not transient loss of vision.

SUBCONJUNCTIVAL MIGS

XEN45 Gel Stent

The XEN45 gel stent (Allergan) consists of a 6.0 mm long porcine gelatin tube with a 45 μm lumen. The needle is placed through a clear corneal incision opposite the target site and then pierced though the angle, with the stent being delivered into the subconjunctival space. Mitomycin C is applied subconjunctivally to enhance bleb survival.

Unlike many other MIGS devices, the XEN45 stent is approved for use with or without cataract surgery. Like other MIGS devices, the stent can be implanted through standard cataract surgery wounds. It is believed that most MIGS are augmented by cataract surgery. Some have feared that because of the proinflammatory response associated with cataract surgery, the subconjunctival bleb would have an increased risk for failure in a combined case. Many studies, however, found no difference in failure between XEN45 placement alone and XEN45 placement combined with cataract surgery.[61–64]

When combined with cataract surgery, the IOP response to MIGS is a crucial tenet of success. In addition, visual acuity recovery is an important outcome of any combined surgery. Although limited data exist, XEN45 stent placement has been shown to be safe in combined surgery and as a stand-alone procedure. Evaluating the postoperative recovery in stand-alone cases, Schlenker et al. compared the visual recovery between placement of the gel stent and trabeculectomy.[65] In this study, 12.4% in the stent group and 21.9% in the trabeculectomy group lost more than 2 lines of CDVA. In addition, the rate of surgically induced astigmatism (SIA) was lower in the stent group, with 25.3% having less than 0.50 D of astigmatism compared with 40.7% in the trabeculectomy group. Of eyes with SIA, 8.0% in the gel stent group and 17.3% in the trabeculectomy group had less than 1.00 D of astigmatism. Combining the gel stent with cataract surgery thus improved visual recovery and reduced SIA.

A retrospective study by Ibáñez-Muñoz et al. evaluated eyes with pseudoexfoliative glaucoma without or with cataract that had XEN45 stent surgery alone or with cataract extraction, respectively.[66] Postoperatively, the mean decimal CDVA in the combined group improved significantly from 0.55 ± 0.31 at baseline to 0.68 ± 0.32 at the 12-month follow-up. They authors attributed the majority of the improvement to the combined surgery because patients who had a stand-alone procedure did not have a significant change in CDVA. Although other statistical data on visual recovery are limited, most studies report that visual recovery and improvement were rapid in patients having combined procedures.[62,64,67] The rates of complications in this procedure are low, with most studies reporting a loss

of CDVA of 2 lines in 2.0% to 3.5% or less and a low rate of choroidal effusions, hyphema, and sight-threating conditions.[62,64,67]

In another study, Lenzhofer et al., compared visual outcomes with the XEN45 alone (group 1), vs XEN45 combined with cataract surgery (group 2).[68] They demonstrated that baseline BCVA in group 1 was 0.21 ± 031; the group's mean BCVA did not change at any postoperative visit, although a ≥2-line loss of BCVA was detected in 15% (95% CI 7%-29%) and 4% (95% CI 0%-20%) after months 12 and 24, respectively. Baseline BCVA in group 2 was 0.33 ± 031; vision increased significantly at months 3 (0.22 ± 0.29, $P = .015$), 6 (0.20 ± 0.26, $P = .006$), 12 (0.18 ± 0.29, $P = .001$), and 24 (0.18 ± 0.29, $P = .005$). A ≥2-line loss of BCVA was reported in 4% (95% CI 1%-15%) and 7% (95% CI 1%-24%) after months 12 and 24, respectively. They concluded that there was no deterioration of BCVA in group 1; those in group 2 had an overall significant increase in BCVA. BCVA decrease was lower than is typically reported in the literature post-trabeculectomy.[68]

In conclusion, placement of a XEN45 gel stent is designed to be a safer trabeculectomy method. It is often reserved for patients with more advanced glaucoma vs more minimally invasive MIGS procedures. The speed of visually recovery often takes a backseat to efficacy and IOP control in these cases. Despite this, early data suggest that gel stent insertion, as a combined or stand-alone option, can provide safety and efficacy and yield better visual recovery than trabeculotomy.

PreserFlo

The PreserFlo (Santen) (formerly the InnFocus microshunt) is a minimally invasive drainage implant currently under FDA investigation. This 8.5 mm long implant has a 70 μm diameter internal lumen and is based on Poiseuille law. The PreserFlo is made of a polymer called polystyrene-block-isobutylene-block-styrene. This soft elastic material is used in cardiac stents and causes minimal ocular scarring and inflammation.[69] This thin tubular device drains aqueous from the anterior chamber into the subconjunctival space to form a bleb approximately 6.0 mm posterior to the limbus. The microshunt is biologically inert, and its design allows creation of low diffuse blebs that might require less postoperative needling and bleb management than other surgeries, such as XEN45 gel shunt placement or trabeculectomy.[70]

The PreserFlo implant might be an alternative to trabeculectomy. It showed promising results in early studies; the main findings were that in addition to lowering IOP, visual acuity quickly returned to baseline. Recent studies confirm that mitomycin C (0.2 mg/mL or 0.4 mg/mL) is necessary and is effective in preventing scarring around the bleb.[71]

The PreserFlo device aims to offer the IOP-lowering efficacy of trabeculectomy and tube shunt placement while avoiding the significant negative visual impact that often accompanies these traditional surgeries. The Primary Tube Versus Trabeculectomy Study reported similar findings at 1 year.[72] Of the eyes, 13% in the tube group and 11% in the trabeculectomy group lost 2 or more Snellen lines; in addition, cataract formation occurred in 20% of cases in each group. In contrast, in the longest prospective study of this microshunt, none of the 23 patients lost more than 1 Snellen line 3 years after microshunt placement combined with phacoemulsification and IOL implantation; 3 patients gained 2 or more lines.[73] Over a 3-year follow-up, the mean IOP decreased from 23.8 ± 5.3 mm Hg to 10.7 ± 3.5 mm Hg and the mean number of medications from 2.4 ± 0.9 to 0.7 ± 1.1. Several other short-term studies found similar IOP-lowering results; however, visual acuity was not specifically included as an outcome.[H]

The design and small size of the PreserFlo implant make it a promising and straightforward alternative to glaucoma surgery; it avoids the need for iridectomy, sclerotomy, patch grafting, or suturing to control flow. An advantage of this microshunt is that patients often to return to their baseline vision within days to weeks.

In conclusion, preliminary published results of the PreserFlo microstent are encouraging, especially given that the IOP remained in the very low teens at latest follow-up in these studies. The FDA has approved a 500+ patient multicenter clinical trial comparing the PreserFlo implantation and primary trabeculectomy in patients with glaucoma refractory to medication, and the study is fully enrolled.

DISCUSSION

MIGS is a rapidly expanding field. As we transition from eyedrops toward first-line interventional glaucoma treatments, the visual outcomes of all techniques and devices must be carefully assessed, with the results serving as a guide to surgeons.

In our review of the available data, and based on the collective experience of the ASCRS Glaucoma Committee, we believe that MIGS procedures approved by the FDA through rigorous clinical trials and in which cataract surgery serves as the control do not adversely affect visual outcomes. The extent to which devices that are not canal based and hold significant physical space in the anterior chamber might adversely affect longer-term visual outcomes should be carefully weighed against the risk for glaucoma progression. It is our majority opinion that devices such as the CyPass should be made available to surgeons with updated "directions for use" so that if the device is properly implanted, the risk for ECL can be mitigated. Moreover, endothelial cells can be replaced or transplanted, whereas optic nerve tissue cannot. Most, if not all, patients in the COMPASS-XT trial who were followed for 5 years maintained good vision, even if they had a reduced ECC.

MIGS procedures that have been approved and targeted for use in patients with refractory glaucoma (which should be differentiated from severe glaucoma) can also be combined with cataract surgery. Surgeons disagree whether any procedure that relies on the subconjunctival space for IOP lowering should be considered minimally invasive, in particular if a conjunctival incision must be made. Nonetheless, compared with conventional filtration surgery, the XEN45 get stent and PreserFlo microshunt clearly

yield improved visual outcomes. The significantly reduced rate of hypotony and induced astigmatism as well as the faster rate of visual recovery with these devices likely make them a safer choice when combined with cataract surgery for more refractory glaucoma.

Regarding IOL selection when combining cataract surgery and MIGS, it is important to remember that cataract surgery is a refractive procedure. Simply because a patient has the diagnosis of glaucoma does not preclude them from achieving the best possible postoperative visual outcomes, which may include the use of premium IOLs (toric, presbyopia correcting, or a combination of both). Unless there is compromised fixation, profound central vision loss, or a condition requiring rigid contact lenses, it always appropriate to correct corneal astigmatism at the time of cataract surgery, either with a toric IOL or with laser or arcuate incisions.

If a patient has elevated IOP, the decision of whether to implant a presbyopia-correcting IOL depends on the severity of the glaucoma, careful patient selection, and surgeon preference. Combining MIGS with cataract surgery should not necessarily influence a surgeon's IOL selection. Premium IOLs offer a clear benefit over monofocal models for the correction of astigmatism and presbyopia as well as for improving overall visual function. The once conservative approach of denying these technologies to patients who have or are suspected of having glaucoma is changing.

Cataract surgery is often complicated in eyes with glaucoma; however, concomitant cataract and glaucoma surgery is becoming much less so in the era of MIGS. Longer-term follow-up with these devices will show the slope in their survival curves regarding IOP; however, we expect that the visual outcomes will not be affected by the devices themselves but rather by the cumulative effect of glaucomatous and age-related optic nerve progression.

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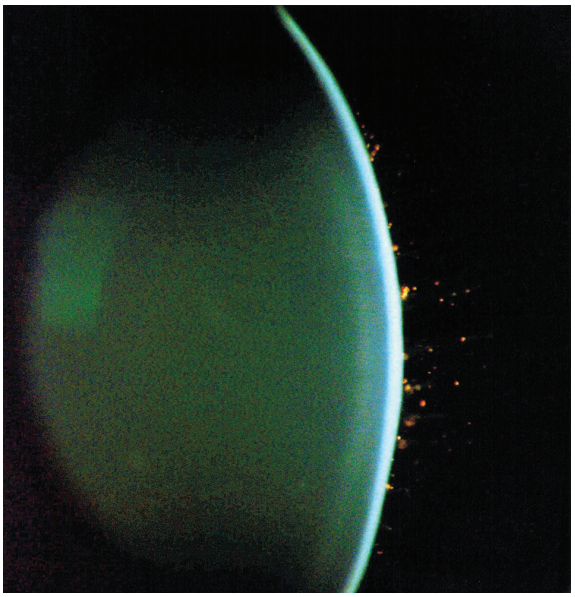

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