What's New in the Surgical Management of Glaucoma

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Introduction

Although trabeculectomies and tube shunts remain mainstays of glaucoma management, the last decade has seen an unprecedented expansion in the surgical armamentarium for glaucoma. Several minimally invasive glaucoma surgeries (MIGS) have been introduced into practice or are in pipeline. These devices provide moderate reduction in IOP and are indicated in patients with mild to moderate open-angle glaucoma (OAG), either as a stand-alone procedure or at the time of cataract extraction. In select patients, more robust IOP reduction may also be attained with the Xen gel stent (Allergan, Dublin, Ireland), InnFocus MicroShunt (InnFocus Inc, Miami, FL), and gonio-assisted transluminal trabeculotomy (GATT). These procedures show promise for patients with advanced glaucoma who may have traditionally needed a filtration procedure.

Because they target angle-based outflow pathways, most MIGS are indicated for use in the open-angle glaucomas. Although fewer surgical options are available for primary angle-closure glaucoma (PACG), several recent clinical trials have clarified the indications for stand-alone cataract extraction in these patients for whom the mechanism of angle closure is related to the anatomical size or position of their lens.

This chapter summarizes the indications for glaucoma surgery as dictated by the mechanism of the glaucoma, its severity, and the level of IOP control needed. The current literature is reviewed regarding the relative efficacy and safety profile of the various glaucoma surgeries, as well as patient factors that need to be considered when choosing a surgical approach.

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Trabecular Bypass Procedures

For patients with mild to moderate OAG and a visually significant cataract, a trabecular bypass stent can be considered at the time of cataract surgery. There are no long-term studies regarding the impact of trabecular bypass procedures on disease progression, but several MIGS procedures have proven evidence of modest IOP reduction with a favorable safety profile.

iStent

The iStent (Glaukos, Laguna Hills, CA) was approved by the FDA in 2012. It is approved for use at the time of cataract surgery in patients with mild to moderate OAG on one to three medications. It bypasses the trabecular meshwork (TM) to create a direct communication between the anterior chamber and Schlemm's canal (SC) and is therefore contraindicated in angle-closure glaucoma and neovascular glaucoma and in patients with elevated episcleral venous pressure [1, 2]. A recent meta-analysis of 37 studies including 2495 patients found iStent implantation with concurrent phacoemulsification to be superior to phacoemulsification alone in reducing IOP and dependence on antiglaucoma medications. Patients undergoing phacoemulsification experienced a 4% IOP reduction from baseline with a mean reduction of 1.01 medications, compared to an IOP reduction of 9% and 27% and a medication reduction of 1.33 and 1.1 with one and two iStents, respectively [3].

Kahook Dual Blade

The Kahook dual blade (KDB) (New World Medical, Rancho Cucamonga, CA) is a novel ab interno goniotomy device (Fig. 6.1). It is a single-use device that allows the surgeon to cleave the trabecular meshwork for approximately 120°.

The dual blade is designed in a way to achieve a more complete goniotomy. Its sharp tip is designed with a taper to allow for smooth entry of the blade through TM

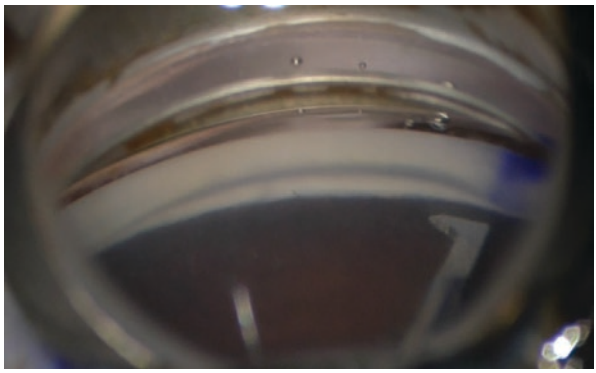

Fig. 6.1 Gonioscopic view of the Kahook dual blade

and into SC, and the heel fits within the SC and thus allows smooth advancement of the blade within the canal while preventing collateral damage during treatment. The ramp of the blade generates a gentle stretch of the TM as the blade is advanced. The dual blades create parallel incisions of the TM allowing excision of a strip of TM which achieves a near-complete removal of TM. Additionally, there are no implant-related risks.

Greenwood et al. studied 71 eyes with glaucoma that underwent goniotomy with the Kahook dual blade at the time of cataract surgery. The study subjects had a mean IOP reduction of 26% with a reduction of 0.7 medications. The most common adverse event observed was postoperative hyphema [4].

Satisfactory results have been seen in patients with secondary open-angle glaucoma such as pseudoexfoliation glaucoma and pigmentary glaucoma since the mechanism of elevated IOP in these patients is related to accumulation of extracellular material and pigment within the TM, respectively. The KDB goniotomy has also shown success in congenital glaucoma, in patients with uveitic and/or steroid-induced glaucoma [5]. However, given the relative novelty of this blade, most studies are limited to 12-month follow-up.

Hydrus Microstent

The Hydrus microstent (Ivantis Inc., Irvine, CA, USA) is a trabecular bypass stent intended for use in patients with mild to moderate OAG at the time of cataract surgery. It is made of nitinol and is 8 mm in length. Its curved shape facilitates scaffolding and dilation of SC for 3 clock hours ("intracanalicular scaffold") (Fig. 6.2).

Although not yet approved by the FDA, Phase 3 clinical trials are underway. A prospective randomized trial of 100 patients demonstrated that combined cataract and Hydrus surgery resulted in a 36% reduction in washed-out mean diurnal IOP vis-a-vis a 27% reduction for the cataract surgery group [6]. The Hydrus group also used 1.5 fewer medications at 2 years of follow-up, compared to one fewer medication for the control group. The only adverse event reported in the Hydrus group was

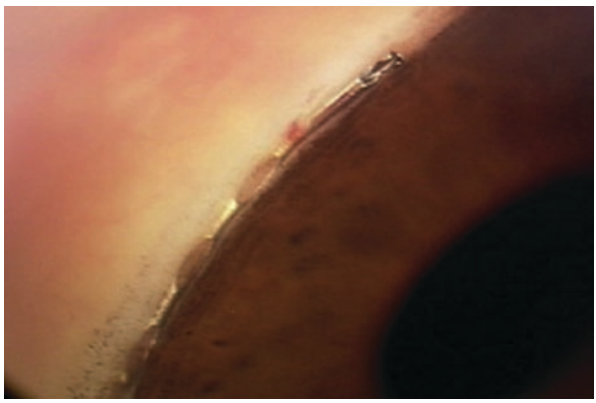

Fig. 6.2 Gonioscopic view of the Hydrus microstent after implantation in Schlemm's canal (From SooHoo JR, Seibold LK, Radcliffe NM, et al. Minimally invasive glaucoma surgery: current implants and future innovations. Can J Ophthalmol 2014;49:530; with permission)

the formation of focal PAS, which did not appear to affect the IOP outcomes. Recently, Fea et al. compared the efficacy of stand-alone Hydrus microstent implantation to selective laser trabeculoplasty in a cohort of 56 patients with uncontrolled POAG. Although both groups experienced significant reduction in IOP, only the Hydrus group experienced a reduction in number of medications, with 47% of patients remaining medication free at 12 months (vs. 4% in the SLT group) [7].

Gonio-Assisted Transluminal Trabeculotomy

For patients with OAG requiring significant IOP reductions, gonio-assisted transluminal trabeculotomy (GATT) may be tried. GATT is a form of ab interno trabeculotomy in which an illuminated fiber-optic microcatheter (iScience International, Menlo Park, CA) is advanced circumferentially through SC and then externalized to open the TM for a full 360° (Fig. 6.3). Grover et al. published the largest retrospective case series of 85 OAG patients who underwent GATT alone or in combination with cataract surgery. They found a 30% reduction in IOP with an average decrease of 0.9 medications at 1 year of follow-up for patients with POAG, while patients with secondary open-angle glaucoma experienced a 57% IOP reduction with a decrease of 1.9 medications [8]. Early reports indicate that GATT may also be more efficacious in younger patients with congenital or juvenile open-angle glaucoma (46% IOP reduction with a decrease of 1.8 medications) [9]. Thus in select patients for whom the TM is the primary site of outflow obstruction, GATT is a potentially efficacious primary procedure which still preserves the conjunctiva for incisional glaucoma surgery should it be required at a later date. GATT can also be performed after a failed trabeculectomy or glaucoma drainage device [10]. As with other procedures, which create an open pathway to the episcleral venous system, the main adverse event associated with GATT surgery is postoperative hyphema. This is usually self-limited but can rarely result in intractable IOP elevation necessitating incisional glaucoma surgery. Thus inability to stop anticoagulant medications and history of a bleeding diathesis are contraindications for GATT.

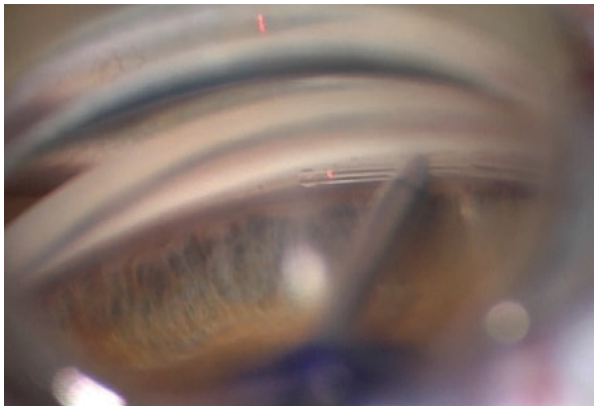

Fig. 6.3 Gonioscopic view of gonio-assisted transluminal trabeculotomy just prior to insertion of the illuminated fiber-optic microcatheter into Schlemm's canal

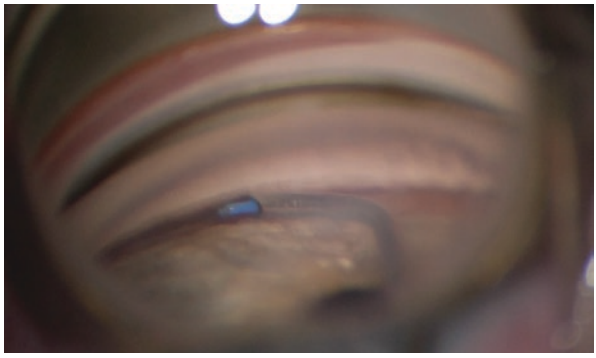

Fig. 6.4 Gonioscopic view of the TRAB360 just prior to insertion into Schlemm's canal (Courtesy of Jonathan S. Myers, MD, Wills Eye Hospital, Philadelphia, PA)

The disadvantages of GATT include its technical difficulty to perform, the expense of the fiber-optic probe, and the rare but significant postoperative IOP spikes. Modifications have been suggested to overcome these limitations.

Ab interno canaloplasty (ABiC) describes the procedure in which a microcatheter is passed through SC for 360°. Viscoelastic is injected to dilate the SC during its passage; however the catheter is not externalized, and so the TM remains intact. No clinical study has yet been published regarding this procedure; however it is expected to have a reduced incidence of hyphema as compared to GATT [11]. Grover and Fellman have also described a simple modification of the GATT procedure in which a thermally blunted 4-0 or 5-0 nylon suture is used to cannulate SC, thus obviating the need for the fiber-optic probe [12].

Finally, the TRAB360 (Sight Sciences, Menlo Park, CA, USA) is a single-use device, which allows completion of a 360-degree goniotomy (Fig. 6.4) through a clear corneal incision, just like cataract surgery. With the exception of viscodilation, this is theoretically equivalent to the GATT, although no studies have yet been performed to confirm its effect.

Supraciliary Procedures

The CyPass microstent (Transcend Medical, Inc., Menlo Park, CA) has been approved by the FDA for implantation at the time of cataract surgery in patients with mild to moderate OAG. It is a fenestrated microstent that is inserted into the supraciliary space after creation of a small cyclodialysis cleft (Fig. 6.5).

In a prospective randomized clinical trial of 505 POAG patients, combined cataract and CyPass surgery resulted in a 30% IOP reduction and 1.2 fewer medications. These results were superior to the control group, which experienced a 22% IOP reduction with 0.6 fewer medications from cataract surgery alone. In this study, main adverse events associated with CyPass implantation were transient hypotony, which in three patients (1%) was associated with signs of maculopathy but no visual acuity loss and transient IOP rise >10 mmHg in 16 patients (4.3%) [1, 13].

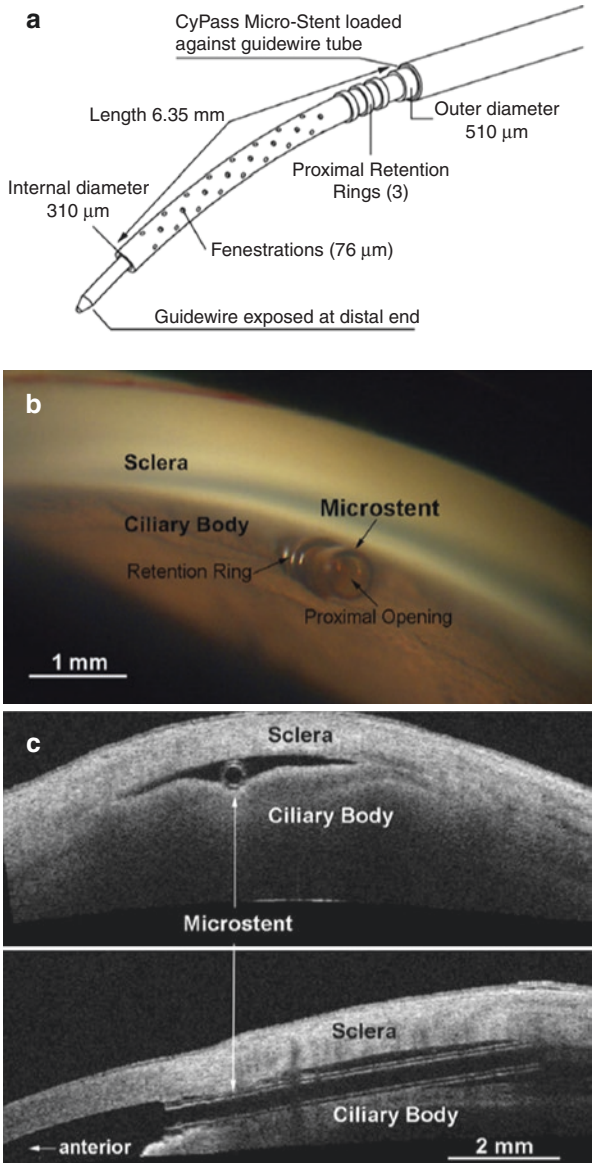

Fig. 6.5 CyPass microstent. (**a**) Illustration of the CyPass microstent threaded on the guidewire of the applier. (**b**) Gonioscopic view of the CyPass microstent and (**c**) positioning on ocular coherence tomography (From Vold S, Ahmed IIK, Craven ER, et al. Two-Year COMPASS Trial Results: Supraciliary Microstenting with Phacoemulsification in Patients with Open-Angle Glaucoma and Cataracts. Ophthalmology 2016;123:2103–2112; with permission)

A retrospective study has shown that that IOP-lowering effect of CyPass may be more pronounced for patients with a baseline IOP ≥ 21 mmHg [14]. Although no direct comparisons have been made, the CyPass thus appears to have similar efficacy to the trabectome.

The iStent G3 Supra (Glaukos, Laguna Hills, CA) is a similar suprachoroidal stent, made of a biocompatible polymer with a titanium sleeve. It is a 4-mm-long curved stent with a lumen of 0.165 mm. It is currently being studied for use with

concurrent cataract surgery in a multicenter randomized controlled trial in the USA. The iStent Supra has received CE Mark approval in Europe.

Subconjunctival Filtration Procedures

For patients with advanced glaucoma or those requiring more aggressive IOP control typically obtained with trabeculectomy or tube shunt, new approaches to filtration via the subconjunctival space are available or in development.

Xen Gel Stent

The Xen gel stent is a collagen implant that is inserted ab interno through the scleral spur into the subconjunctival space (Fig. 6.6). A prospective multicenter clinical trial of 65 glaucoma patients whose IOP was uncontrolled on maximum tolerated medical therapy demonstrated a 64% reduction in IOP with 1.8 fewer medications at 12 months. The most common complications were subconjunctival fibrosis requiring bleb needling (32%) and transient hypotony (IOP < 6 mmHg not requiring surgical intervention, 24%). Only four patients (6%) had persistent loss of ≥2 lines of BCVA [15]. Implantation of the stent at the time of cataract surgery has also been studied, with similar outcomes [16]. One retrospective study has compared the efficacy and safety of the Xen gel stent to trabeculectomy in 354 eyes (293 patients) with uncontrolled glaucoma and no prior incisional surgery. Outcomes were similar between the two groups, with no significant difference in failure rates or visually significant complications. The investigators identified preoperative IOP > 21 mmHg, nonwhite race, and preoperative BCVA better than 0.4 logMAR as factors that trended toward better outcomes with the Xen gel stent [17].

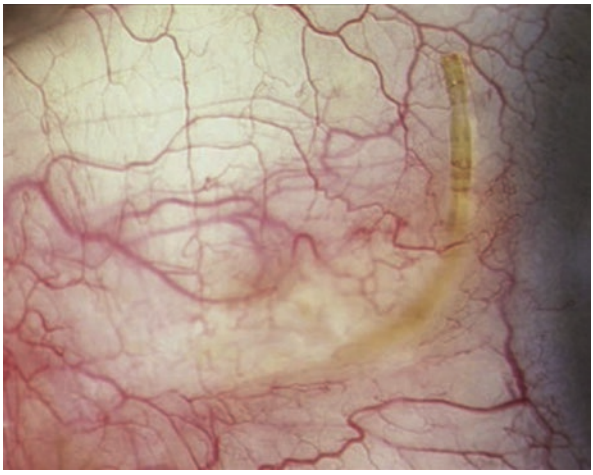

Fig. 6.6 The Xen gel stent in the subconjunctival space (From Lewis RA. Ab interno approach to the subconjunctival space using a collagen glaucoma stent. J Cataract Refract Surg 2014;40:1305; with permission)

InnFocus MicroShunt

The InnFocus MicroShunt is an aqueous drainage device made of an ultra-stable synthetic polymer of poly(styrene-block-isobutylene-block-styrene) or SIBS. It has been approved in Europe since 2012 but is yet to get US FDA approval. It is implanted through an ab externo modified filtering procedure. It drains aqueous fluid 3 mm posterior to the limbus to a subconjunctival flap created with adjunctive mitomycin C.

A cohort of 14 patients, nine of whom underwent InnFocus placement in combination with cataract surgery, were followed for 3 years. These patients had 55% reduction of IOP from a baseline of 23.8 mmHg with the use of 1.5 fewer topical medications. This translated to a 95% qualified success rate using the relatively stringent criteria of an IOP $\leq$ 14 mmHg and IOP reduction $\geq$20%. Serious adverse events that included hypotony (13%) and transient choroidal effusion (8.7%) have been noted [18]. Although these rates are similar to those reported in studies of the Ex-Press shunt and trabeculectomy, all cases of hypotony in this cohort resolved spontaneously. There were also no cases of shunt erosion, bleb leak, or infection. Prospective randomized trials comparing the InnFocus MicroShunt to trabeculectomy in patients with refractory glaucoma are now underway. If these results are confirmed in these appropriately powered prospective trials, the InnFocus MicroShunt may provide another avenue for the treatment of advanced glaucoma in conjunction with cataract surgery.

Special Considerations for Angle-Closure Glaucoma

Stand-Alone Cataract Extraction for Angle-Closure Glaucoma

Patients with primary angle-closure glaucoma (PACG) derive a significant IOP-lowering benefit from cataract extraction. A meta-analysis of patients with angle closure demonstrated a 30% reduction in IOP and a 58% reduction in number of medications after stand-alone cataract extraction through 16 months of follow-up [19]. Several recent prospective trials have helped to clarify which of these patients may do well with cataract surgery alone.

Tham et al. in a study of 72 patients with medically controlled PACG (IOP $\leq$ 21 mmHg on 1–3 medications) found that phacoemulsification alone was equivalent to combined phacotrabeculectomy in IOP control at 2 years of follow-up [20]. The patients in the combined surgery group required 0.8 fewer medications, however, at the cost of significantly more postoperative complications. There were no differences in visual acuity or progression of optic nerve cupping or visual field defects between the two groups. Only one patient in the phacoemulsification group required a trabeculectomy through 2 years of follow-up.

MIGS for Angle-Closure Glaucoma

Thus in patients with mild to moderate angle-closure glaucoma, stand-alone phacoemulsification results in significant reductions in IOP [21]. These patients may derive further benefit with an acceptable safety profile from a concurrent MIGS procedure. In aiming to bypass the trabecular meshwork, most MIGS discussed previously are best suited for patients with OAG. Because it targets aqueous production at the ciliary body, however, endoscopic cyclophotocoagulation (ECP) can theoretically be effective for any type of glaucoma. It may be particularly well suited for patients with chronic PACG because it causes the ciliary body to rotate posteriorly with a resultant deepening of the anterior chamber angle [22]. Multiple retrospective studies have found that combined phaco-ECP consistently lowers IOP with a safety profile that is similar to that of cataract surgery alone [23–26]. Recently, one prospective nonrandomized study confirmed this finding. In a study of 80 eyes with medically controlled OAG, Francis et al. found that mean reduction in IOP was modest but statistically superior in the phaco-ECP group as compared to the phacoemulsification group alone (1.1 mmHg and 0.8 mmHg at 2 years, respectively) [27]. The combined phaco-ECP patients also used statistically fewer glaucoma medications, while visual acuity and complication rates were similar between the two groups. Thus, ECP is an appropriate adjunct for patients with mild-moderate glaucoma who require phacoemulsification surgery for a visually significant cataract. It is best avoided in patients at increased risk for postoperative inflammation or macular edema, given its pro-inflammatory side effects.

Advanced Angle-Closure Glaucoma

Although the aforementioned studies provide important insights into the effects of stand-alone cataract extraction on IOP control in PACG, it is important to note that they predominately included patients with mild to moderate disease, and were not designed to assess its long-term impact on glaucomatous progression. Guidance regarding patients with more severe disease is found in another prospective trial by Tham et al. [28]. They randomized a group of medically uncontrolled PACG patients (IOP > 21 mmHg on maximally tolerated medications) to either phacoemulsification alone or phacotrabeculectomy. This cohort represented the full spectrum of disease severity, with mean MD of −17.1 dB (range, −2.1 to −32.1 dB). The phacotrabeculectomy group had consistently superior IOP control by a margin of 2 mmHg and used an average of 1.25 fewer topical medications. Also, at 2 years of follow-up, only 25.9% of patients in the phacoemulsification group required no medications, while 70.8% of patients in the combined surgery group met this goal. Four eyes (14.8%) in the phacoemulsification group subsequently required trabeculectomy. Although the phacotrabeculectomy group endured more complications during the postoperative period, this did not result in any significant differences in visual acuity between the two groups.

Thus, for patients with advanced or medically uncontrolled glaucoma, combined cataract and glaucoma surgery provides superior IOP control with the use of fewer topical medications. A concurrent trabeculectomy may also decrease the likelihood of a perioperative spike in IOP, which is an important consideration in patients with very advanced disease. Finally, results from these studies indicate that patients with any severity of chronic angle closure are more likely to require a subsequent trabeculectomy if their IOP is uncontrolled.

Single-Pass Four-Throw (SFT) Pupilloplasty for Angle Closure

Angle crowding is an associated feature with ACG, and in long standing cases, it causes formation of peripheral anterior synechiae (PAS), and the extent of PAS correlates with the level of IOP.

Surgical pupilloplasty has recently been attempted to break PAS [29]. The procedure involves taking a significant area of iris tissue into the loop/knot of pupilloplasty in order to relive traction exerted to break the PAS. In cases with more than 270° synechiae, it is recommended to do a 6-point traction that translates into making three passes with SFT for achieving pupillary knots. In cases with <270° of PAS, a 4-point traction is sufficient. This procedure has also been used for the management of secondary ACG due to trauma [30]. Post-SFT pharmacological pupil mydriasis can be achieved that can aid in adequate fundus examination to monitor glaucoma, unlike surgical pupilloplasty.

Phacoemulsification with Intraocular Implantation of Lens, Endocyclophotocoagulation, and Endoscopic Goniosynechialysis (PIECES)

This new technique combining phacoemulsification with intraocular lens (IOL) implantation (PI), endocyclophotocoagulation (EC), and endoscopic GSL (ES) has been suggested to control IOP in extensive (>270°) synechial angle-closure glaucoma [31]. This approach addresses both the inflow and outflow of the aqueous humor simultaneously. It minimizes the need for glaucoma medications and drainage surgery. Conjunctiva is also preserved, so future drainage surgery can still be done, if needed.

New Drainage Devices

New Susanna Glaucoma Drainage Device (SGDD)

The new SGDD is a nonvalved silicone device with a plate having area of 200 mm^2 and two extensions measuring 4 × 1 mm. The anterior portion is fixed at 6 mm from limbus, allowing the plate to be located at 10 mm, decreasing the possibility of extrusion.

The new SGDD plate is better than its older version that had a larger area of 350 mm^2 and an elliptical form and thus was difficult to implant in many cases. New SGDD is thinner (0.5 mm) than Ahmed (1.9 mm) and Baerveldt (0.84 mm) and also has a thinner tube [32].

The initial study with 58 patients reported a qualified success rates for neovascular glaucoma group and failed trabeculectomy group to be 73% and 86%, respectively. Significant complications noted were two cases of conjunctival erosion and two cases of late hypotony [33].

Future Directions

Randomized controlled trials will be necessary to directly compare the aforementioned procedures to each other and to trabeculectomy in the setting of advanced or uncontrolled glaucoma.

Prospective trials are also needed to identify the specific demographic and clinical factors, which may be indicative of success in each type of surgery. For example, the patency of downstream collector channels has been suggested as one factor that may determine the efficacy of canal-based surgeries. The presence of an episcleral venous fluid wave may indicate that this system is intact, but at the time, there is no way to assess this factor preoperatively [33, 34].

In the future, improved diagnostic approaches may allow surgeons to predict which patients will benefit from procedures that target SC and the supraciliary space or subconjunctival filtering procedures.

Finally, there is very limited data at this time on cost-effectiveness and quality-of-life measures for these procedures. Stand-alone cataract surgery has well-defined positive effects on performance-based measures and quality of life [35]. Its cost-effectiveness is also well established, including for surgery on the second eye [36]. Studies regarding the cost-effectiveness of MIGS are limited, but two analyses performed in Canada and the UK indicate that the cost of the iStent may be superior to topical ocular medication in long-term follow-up of greater than 5 years. Modest cost-effectiveness for trabectome and ECP has also been established in comparison to medical therapy [37, 38]. Additional research is needed to compare the cost-effectiveness and quality-of-life impact of the various MIGS and to delineate these effects from the already well-known benefits of cataract extraction.

Conclusions

Several new minimally invasive surgical procedures are now available for use in mild to moderate POAG at the time of cataract extraction. As reviewed here, the iStent, Hydrus, CyPass, and ECP have demonstrated evidence of modest improvements in IOP control. Although this benefit is largely reflected in a lower medication burden for these patients, the favorable safety profile of these interventions

makes them an attractive adjunct to cataract surgery. Given the many barriers to long-term compliance with topical medications, it can be argued that any intervention that decreases this medication burden is likely to be beneficial. Formal economic and quality-of-life analyses are necessary to confirm the validity of this approach, but the few studies, which have been conducted so far in this regard, are promising. Since these procedures involve minimal tissue manipulation, they theoretically should not change the success rate of subsequent filtering surgery. This has been confirmed in one cohort study involving patients who underwent a trabeculectomy following trabectome surgery [39]. Several other devices including the Kahook dual blade and Hydrus trabecular bypass stent await further study or FDA approval but are also likely to be useful for the treatment of mild to moderate POAG at the time of cataract surgery. Although a superficial analysis of the available literature indicates that the CyPass and Hydrus stents may be more effective than the other MIGS, direct comparisons in randomized controlled trials are necessary to fully explore these differences. It may be too that individual demographic and clinical factors will predispose certain patients to success with a particular procedure.

Due to their modest efficacy, these MIGS are not appropriate for patients with advanced or medically uncontrolled glaucoma. GATT, the Xen gel stent, and the InnFocus MicroShunt do show promise for these patients. Each of these procedures has the benefit of sparing at least the majority of the conjunctiva for future incisional surgery, and so far each seems to have a relatively favorable safety profile. However, it is important to bear in mind that both the Xen and InnFocus stents still involve the formation of a conjunctival bleb and require the use of mitomycin C. Given the limited results published on each of these surgeries to this point, additional study with larger patient populations is necessary to capture the full range of complications that may occur with these devices. Randomized controlled trials are also necessary to compare these procedures to the current gold standard surgical approaches to refractory glaucoma.

An abundance of research in the past decade has also clarified the importance of the native lens in the regulation of intraocular pressure and the pathogenesis of angle-closure glaucoma. This research as well as improvements in cataract surgical technique has paved the way for a paradigm shift in the management of concurrent cataract and PACG. Patients with mild to moderate PACG may achieve sufficient IOP control with cataract surgery alone, although they may derive additional benefit from combination with ECP. Finally, for patients with advanced PACG, combined cataract extraction with trabeculectomy has also been shown to provide superior IOP control with a lower medication burden than stand-alone cataract surgery and is still the preferred approach.

In conclusion, there have never been more avenues for surgical management and thus greater opportunity to individualize care for patients with glaucoma. In the years to come, additional prospective trials will more fully characterize the long-term efficacy, safety profiles, and cost-effectiveness of these procedures.

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