

The Next Generation of Glaucoma Surgeries

Expanding the options for treating this chronic disease.

Canaloplasty



By Brian Flowers, MD

This is an exciting time in glaucoma. The focus has shifted from medical therapy to surgical glaucoma, where trabeculectomy with antimetabolites has been the standard of care for many years. Although the procedure is an effective means of lowering IOP, numerous intraoperative and postoperative complications are known to occur.¹⁻³ Glaucoma drainage implants are another effective and firmly entrenched means of reducing IOP, but they significantly limit the patient's future surgical options.

For those seeking to advance glaucoma surgery, the goal is to achieve IOP lowering similar to with trabeculectomy but with greater safety. Many new procedures show promise in this area, including, in my estimation, the Ex-Press Glaucoma Filtration Device (Alcon Laboratories, Inc., Fort Worth, TX). This procedure still produces a filtering bleb, however, with its associated problems. The search for an effective means of lowering IOP without the formation of a filtering bleb continues. Currently, canaloplasty is the only option for decreasing the IOP to a similar level as trabeculectomy but with greater safety and no filtering bleb.

TECHNIQUE

In canaloplasty, the surgeon seeks to create flow into Schlemm canal through a Descemet window. This is combined with viscodilation and stenting open of Schlemm canal to improve flow into the aqueous collector channels. The procedure involves creating a half-thickness triangular or parabolic scleral flap, followed by dissection of a second deep scleral flap to expose Schlemm canal and create a Descemet window. The surgeon then inserts the 250- μ m flexible iTrack micro-catheter (iScience Interventional, Menlo Park, CA) into Schlemm canal and passes it for 360°. The catheter has fiber optic illumination for guidance and a lumen for the injection of a viscoelastic.

The surgeon attaches a Prolene suture (Ethicon, Inc., Somerville, NJ) to the distal tip of the catheter after retrieving it from the opposite cut end of Schlemm canal. The catheter's direction is then reversed, and viscoelastic is injected to viscodilate the canal and to thread the Prolene suture into the canal. The surgeon ties the suture tightly to stent open the canal. Next, the deep scleral flap is removed, and the superficial scleral flap and conjunctiva are closed in a watertight fashion.

SURGICAL OBJECTIVES

The important surgical goals are the adequate distention of the canal and the creation of a sufficiently sized Descemet window. In a published study, the final IOP at 24 months correlated with the degree to which the canal was distended. Eyes with excellent distention had an IOP of 15.7 mm Hg \pm 3.1 versus 18.3 mm Hg \pm 4.2 in eyes with lesser distention.⁴ Achieving adequate distention requires appropriate tension on the suture. I have found using a slipknot with 9-0 or 10-0 Prolene after depressurizing the eye to be an effective way of ensuring adequate tension. As a simpler alternative, using a 4/1/1 knot also improves my ability to produce adequate tension.

Most ophthalmologists find creating an adequately sized window to be the most challenging surgical step, but new instruments are helping. A modified Drysdale nucleus rotator (Rhein Medical, Inc., Tampa, FL) allows safer dissection

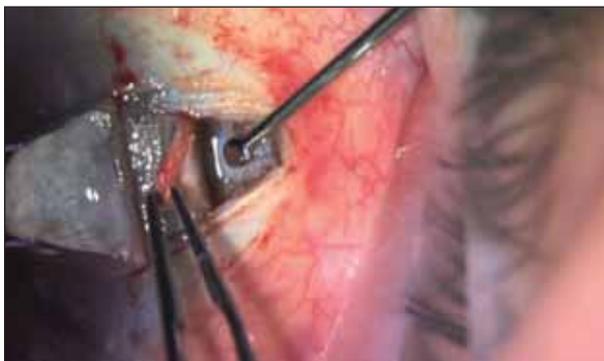


Figure 1. The surgeon uses a modified Drysdale nucleus rotator to create and advance the Descemet window.

beyond Schwalbe line into the cornea. Separating the overlying corneal stroma from Descemet membrane with the Drysdale allows the surgeon to safely extend the deep scleral flap far into the cornea without the fear of cutting through Descemet membrane and entering the anterior chamber (Figure 1). The surgeon will immediately notice improved aqueous flow from extension of the window far into the cornea.

Amputating the deep flap is another challenge for surgeons new to canaloplasty. A recently developed instrument with a guarded blade (Mastel Precision, Inc., Rapid City, SD) can assist the surgeon with extending the deep flap anteriorly and, ultimately, with amputating the flap. Unpublished data on file with iScience Interventional suggest that the optimal length of the window is between 250 and 500 μm .

EFFICACY

Thirty-six month data have been published from an ongoing multicenter study of canaloplasty.⁵ Of the 157 enrolled patients, 134 reached the 36-month visit. Subjects were divided into two groups, canaloplasty alone versus phacoemulsification combined with canaloplasty. In the canaloplasty-alone group, the baseline IOP was 23.5 mm Hg \pm 4.5 on 1.9 \pm 0.8 medications. The IOP at 36 months was 15.5 mm Hg \pm 3.5 on 0.9 \pm 0.9 medications. It was lower in patients who underwent canaloplasty combined with phacoemulsification: 13.6 mm Hg \pm 3.6 on 0.3 \pm 0.5 medications.

Complete and qualified success, defined as an IOP of less than 18 mm Hg with or without medication, respectively, was 36% and 77.5% for canaloplasty alone and 63% and 88.9% for phacocanaloplasty at 36 months. These numbers are surprisingly similar to long-term data on trabeculectomy.⁶ In addition, it is important to consider the effect of hypotony on mean IOP data in trabeculectomy studies. Patients who would be considered failures because of low IOP reduce the mean IOP in studies that have hypotony as a potential outcome.

COMPLICATIONS

The goal of nonpenetrating surgery is to minimize the complications associated with conventional filtering surgery. Excluding mild transient hyphema, no complications occurred in more than 8% of patients.^{4,5} The most common complications were hyphema and elevated IOP. There was one case of transient hypotony and no choroidal detachments. Visual acuity was well preserved.

BENEFIT

By adding canaloplasty to his or her surgical armamentarium, the ophthalmologist can offer a procedure

that provides reasonable IOP lowering and a smoother postoperative course than trabeculectomy. In my experience, patients typically recover their vision more rapidly and require fewer postoperative visits after canaloplasty, which is more satisfying to both patients and physicians. I perform canaloplasty on patients for whom an IOP in the midteens would be satisfactory.

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The Ex-Press Glaucoma Filtration Device



By Leon W. Herndon, MD

Surgical intervention is considered when maximal medical therapy or laser treatment fails to achieve adequate IOP control in patients with glaucoma. The initial incisional surgery most commonly performed is the conventional trabeculectomy. Used for more than 40 years, trabeculectomy lowers IOP to a greater degree than medication alone, and the procedure reduces fluctuations in pressure.^{1,2} Trabeculectomy with adjunctive antimetabolites such as mitomycin C has been associated with even higher success rates.³ Conventional trabeculectomy is still associated with a significant rate of postoperative complications, however, including early hypotony, blebitis, and endophthalmitis, particularly when antimetabolites are used.⁴

The Ex-Press Glaucoma Filtration Device (Alcon Laboratories, Inc., Fort Worth, TX) offers an alternative (Figure 1).

TECHNIQUE

The Ex-Press is a small, stainless steel, nonvalved shunt designed to lower IOP. An animal study using rabbits demonstrated that the device was associated with little to no inflammatory reaction once implanted.⁵ The Ex-Press apparatus was originally tested and placed directly under the conjunctiva, and it drained aqueous from the anterior chamber into the subconjunctival space. This resulted in a conjunctival filtering bleb much like that produced by a conventional trabeculectomy.⁶ The aforementioned method was associated with conjunctival erosion above the Ex-Press device and scar formation resulting in the bleb's failure.^{7,8}

Today, the device is routinely implanted under a partial-thickness scleral flap, as first described by Dahan and Carmichael,⁹ and has been associated with minimal untoward effects. The implantation technique is relatively simple to perform for experienced glaucoma surgeons. Placement of the Ex-Press is considered to be less traumatic to the eye than traditional trabeculectomy.¹⁰

RESULTS

Anecdotally, a growing number of glaucoma surgeons are using the Ex-Press modified trabeculectomy instead of the conventional trabeculectomy. My colleagues and I compared the success and complication rates associated with standard trabeculectomy and trabeculectomy augmented by the Ex-Press device.¹¹ We reviewed the records of 76 eyes of 69 consecutive patients who received the implant and 77 eyes of 65 consecutive controls who underwent a standard trabeculectomy. The difference in the percentage of cases of postoperative hypotony between the standard trabeculectomy group (16%) and the Ex-Press group (4%) was statistically significant ($P = .023$). Our study demonstrated that the Ex-Press is at least as effective in the management of glaucoma as standard trabeculectomy, and our results support the device's use as a viable alternative to standard trabeculectomy.

Just one article has compared trabeculectomy with the Ex-Press to standard trabeculectomy in a prospective fashion.¹² Seventy-eight patients (80 eyes) were enrolled in the study. A total of 84.6% of patients receiving the Ex-Press and 60.0% of patients undergoing trabeculectomy ($P = .023$) achieved complete success. At the 1-year follow-up visit, complete success rates were 81.8% for the Ex-Press and 47.5% for trabeculectomy ($P = .002$). In a 5-year extension of this study,¹³ the Ex-Press Glaucoma Filtration Device controlled IOP more effectively without medication for more patients to year 3 (66.7% vs 41.0%, $P = .02$) than trabeculectomy. At year 1, only 12.8% of patients required IOP-lowering medication after implantation of the Ex-Press compared with 35.9% after trabeculectomy. The propor-



Figure 1. Shown under high magnification, this eye underwent the placement of an Ex-Press Glaucoma Filtration Device 2 weeks earlier.

tions became closer at year 5 (41% vs 53.9%). The response rate was higher with the Ex-Press, and the time to failure was longer in this group. In addition, surgical interventions for complications were fewer after implantation of the device.

One compelling article for me in support of the use of the Ex-Press device was published by Good and Kahook.¹⁴ For this retrospective, case-controlled series, the investigators collected information from the charts on 35 consecutive Ex-Press procedures and 35 consecutive trabeculectomy procedures with at least 2 years of follow-up. Mean IOP measurements were similar after 6 months, but they became slightly higher in the Ex-Press group at 1 year and at the final follow-up ($P = .004$ and $P = .008$, respectively). The final percentage of IOP lowering was similar between groups ($P = .209$). An unqualified success was achieved in 77.14% of Ex-Press and 74.29% of trabeculectomy procedures at the last follow-up ($P = 1.00$). There were fewer cases of early postoperative hypotony and hyphema and quicker visual recovery in the Ex-Press group. These patients also required fewer postoperative visits than the trabeculectomy group.

CONCLUSION

The Ex-Press Glaucoma Filtration Device is a viable alternative to standard trabeculectomy, and a growing number of studies are showing the device's efficacy and safety for the treatment of various types of glaucoma. The quicker visual recovery and fewer postoperative visits associated with the Ex-Press are beneficial to patients and their physicians alike.

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The Trabectome



By Sameh Mosaed, MD

The Trabectome (NeoMedix Corporation, Tustin, CA) was introduced in the United States in early 2006, when the FDA cleared the procedure for the broad indication of adult and juvenile glaucoma. Since then, more than 14,000 patients have undergone the surgery worldwide. The procedure is an ab interno trabeculotomy using microelectrocautery to ablate the trabecular meshwork (TM) and inner wall of Schlemm canal without damaging the surrounding tissues or collector channels. The ablation results in a cleft that allows the direct access of aqueous into the aqueous collector channels, thus bypassing the resistance in the TM. This restores the natural outflow pathway in the eye without the use of an implant or alternative drainage passageway.

THEORETICAL PRINCIPLE

The scientific rationale for the Trabectome is based on the concept that one of the main sites of resistance to

the outflow of aqueous is the TM. Bypassing this structure improves aqueous outflow and thus reduces IOP. The IOP in eyes thus treated would depend on the pressure in the collector channels and the episcleral venous pressure (EVP). The possibility of hypotony is therefore minimal, given that the EVP is typically thought to be in the range of 8 to 12 mm Hg. The final IOP in individual patients, however, is the result of a complex interplay of multiple factors, of which EVP is only one.

It is generally accepted that the utility of trabeculotomy or goniotomy in adults is limited compared with the outcomes in congenital glaucoma. One explanation for these findings may be that the cut ends of the TM often form peripheral anterior synechiae and develop fibrosis and hence that IOP control is often poor. The idea with the Trabectome is to minimize these complications by ablating the tissue such that the exposed ends of the TM and inner wall of Schlemm canal do not reappose. In addition, the handpiece of the device is designed such that there is a protective footplate behind the electrocautery, which lessens the possibility of collateral trauma to the adjacent tissues (Figure 1). With goniotomy, it is often challenging to determine the depth of the incision with the goniotome, and collateral damage to the back wall of Schlemm canal is expected. Unlike in trabeculotomy, goniotomy does not require a conjunctival or scleral incision; these tissues are left undisturbed, which permits more aggressive surgical treatments in the future, if required.

SURGICAL STEPS

In brief, the surgeon sits temporal to the patient, whose head is directed away from the surgeon. The microscope is tilted slightly to allow for an optimal view.



Figure 1. The tip of the Trabectome's handpiece inside the eye.

The surgeon uses a 1.7-mm keratome to create a temporal, clear corneal incision and then injects viscoelastic to deepen the anterior chamber. A special goniolens is placed on the eye, and the handpiece is inserted across the chamber to the nasal angle. The tip of the handpiece is inserted into the TM. The surgeon activates the cautery and advances the handpiece to create the arc of ablation until visualization limits further advancement (typically between 90° and 120°; Figure 2). The procedure can be combined with phacoemulsification, if indicated.

RESULTS

Several published studies have evaluated the safety and efficacy of the Trabectome procedure. In the first, Minckler and colleagues reported on a group of 37 patients with an average preoperative IOP of 28.2 ± 4.4 mm Hg on maximum tolerated medical therapy. The postoperative IOP at 12 months was 16.3 ± 2.0 mm Hg, representing a 40% reduction in IOP from baseline.¹ Further studies on larger groups of subjects have supported these early findings.^{2,3} Most recently, investigators examined patients treated with the Trabectome alone and observed for a minimum of 1 year. The IOP decreased from 26.3 ± 7.7 mm Hg to 16.6 ± 4.0 mm Hg. The success rate at 1 year was 64.9%, with success defined as at least a 20% reduction in IOP, an IOP of less than 21 mm Hg, and no additional glaucoma surgery.⁴

Francis and Winarko examined the results of Trabectome combined with phacoemulsification. They observed patients for 1 year and found a similar 1-year postoperative IOP in the midteens (15.4 ± 3.1 mm Hg) compared with the preoperative IOP of 22.1 ± 5.5 mm Hg.⁵

If Trabectome surgery does not reduce the IOP adequately, future incisional glaucoma surgery remains an option. A recent study by Jea et al found no difference in the success rate of trabeculectomy 2 years after Trabectome surgery (60.2%) compared with a surgically naïve eye (55.5%).⁶

COMPLICATIONS

Common complications of the Trabectome procedure include transient hyphema and mild postoperative inflammation. Site-threatening complications have rarely been reported and include intractable IOP spikes, usually within 2 to 5 days postoperatively. These elevations are likely due to hyphema or retained viscoelastic that is occluding the drainage system. Inadvertent trau-

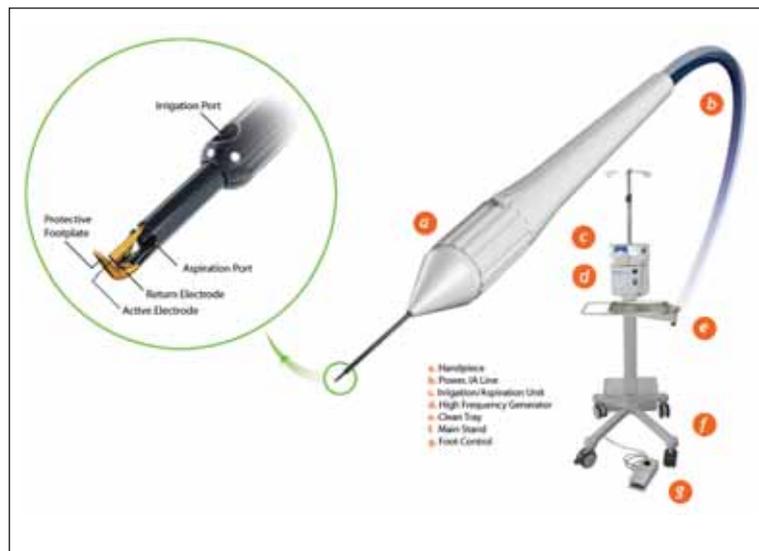


Figure 2. The Trabectome system.

ma to the native lens from the handpiece has also been reported, as have two cases of transient cyclodialysis cleft formation. No cases of endophthalmitis have been reported.¹⁻³

CLINICAL PERSPECTIVES

The Trabectome rarely achieves a single-digit IOP for the long term, so patients with this requirement are currently better served by a trabeculectomy. For patients with a target IOP in the midteens, however, the device offers the appealing option of a low-risk procedure that causes minimal disruption to the eye's natural anatomy. Further research is underway to better elucidate mechanisms by which to enhance outcomes.

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The iStent



By Jason Bacharach, MD

The past 2 decades have brought enormous advances in the pharmacologic management of glaucoma. Topical therapy has evolved from pilocarpine dosed q.i.d. and β -blockers b.i.d. to prostaglandin analogues dosed q.d. and a great armamentarium of ancillary drugs. For a long time, the surgical side of glaucoma treatment was almost stagnant, but at long last, that seems to be changing. Advances have been made on the laser front, and a whole new category of devices for minimally invasive glaucoma surgery (MIGS) is being created to customize glaucoma treatment to the needs of the individual patient.

ABOUT THE DEVICE

The MIGS device positioned to reach the market first is the iStent from Glaukos Corporation (Laguna Hills, CA). The titanium, L-shaped, trabecular microbypass stent is designed to facilitate physiologic outflow and thus lower IOP. The iStent is placed in Schlemm canal directly after cataract surgery through the same clear corneal incision. The procedure requires ophthalmologists to use intraoperative gonioscopy, which a comprehensive cataract surgeon should feel comfortable performing after just a few cases (Figure 1).

RESULTS

A prospective, randomized, multicenter study across 29 US sites enrolled 240 patients with cataract and mild-to-moderate open-angle glaucoma. Investigators compared the outcomes of patients undergoing cataract surgery alone to those of patients who received the iStent in addition to undergoing cataract surgery.¹ Primary efficacy was determined to be a pressure of 21 mm Hg or less without medicine at month 12; 72% of iStent subjects reached that target versus 50% of the patients who underwent cataract surgery alone. Secondary efficacy was a reduction of IOP greater than 20% at month 12; 66% of patients in the treatment group versus 48% in the control group reached this goal.

From a clinical standpoint, these results mean that patients who receive the iStent need less medication than those who do not, which is extremely meaningful to my patients. Equally important, postoperative complications were the same in both the treated and the control group. Implantation of the iStent did not compromise the

excellent safety profile and quick visual recovery of cataract surgery. High benefits and low risk profiles are the essential characteristics of the new MIGS.

WHERE IT FITS IN THE TREATMENT PARADIGM

In the large and growing population of glaucoma patients, an effective treatment paradigm requires diverse options. The iStent fulfills an important need by reducing the burden of medication on patients with mild-to-moderate glaucoma and cataracts.

Ophthalmologists have a healthy skepticism in their approach to new procedures, so initially, the iStent will likely be used for the precise parameters I have described. Once surgeons have performed the procedure for a couple of years, however, I am confident that they will see other potential applications for the device. For example, the iStent may be beneficial for patients with ocular hypertension who have difficulty adhering to or tolerating prescribed medical therapy. Likewise, patients whose mild-to-moderate glaucoma is medically controlled but who have difficulty paying for topical drops might be good candidates for the iStent.

Because the risk profile of the iStent is low and because it leaves open all of the other treatment options, the device can play a flexible role in the management of glaucoma. It might be useful for patients with advanced disease in certain clinical situations. For example, a patient with relatively delicate health and dense cataracts might still wish to undergo cataract surgery but not to undertake the risks of a trabeculectomy. Elderly patients might also prefer the iStent to trabeculectomy. Although these uses are theoretical, what this new category of MIGS is giving ophthalmologists is the power to customize treatment to the individual patient. Cataract and glaucoma surgeons are assured of a greater possibility of pressure reduction for their patients, with little risk of pressure spikes during surgery or in the postoperative period.

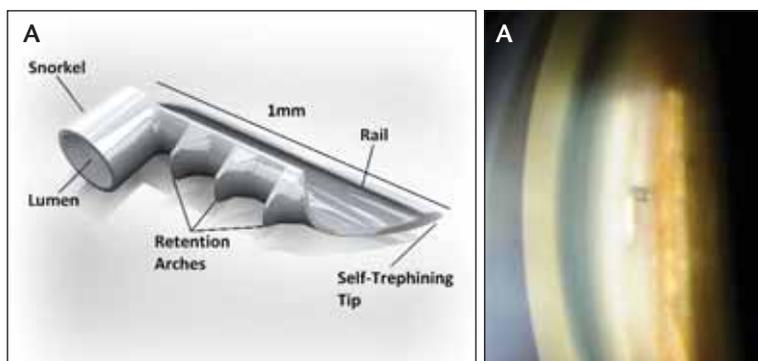


Figure 1. The iStent (A). A gonioscopic view of the implanted device (B).

(Courtesy of Glaukos Corporation.)

CONCLUSION

The recent expansion of options for glaucoma treatment is exciting. Although medical therapy is, and will continue to be, a mainstay of the treatment of glaucoma, it is impossible to ignore the growing body of literature that documents patients' lack of compliance with topical drops. Low-risk options for the treatment of glaucoma are a long-awaited addition to the specialty. For the appropriate patient, the iStent is a promising option for providing 24-hour control of IOP while reducing or eliminating the burden of medications.

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The Solx Gold Shunt



By Gabriel Simon, MD, PhD

In the search for alternative surgical therapies, glaucoma specialists have become increasingly interested in the drainage potential of the suprachoroidal space. In recent years, considerable effort has gone into developing technologies that target the eye's natural outflow pathway to achieve results similar to those of traditional trabeculectomy but without its associated complications. The Solx Gold Shunt (Solx, Inc., Waltham, MA) is one of the devices at the forefront of this research.

CONCEPT AND INITIAL RESULTS

The starting point for the Gold Shunt stemmed from two key observations. First, the investigation of uveoscleral outflow in monkeys revealed that IOP in the suprachoroidal space is always negative when compared with the IOP in the anterior chamber.¹ Researchers at Solx hypothesized that a device connecting these two areas might be able to take advantage of this negative gradient to lower IOP without creating a bleb. The second observation pertained to a jeweler who had a piece of gold removed from his eye after 10 years.² A laboratory analysis showed that the metal was completely free of proteins and cells. This discovery suggested that gold, if optimized, could provide a superior material base for a biocompatible device and minimize issues related to wound healing and the formation of scar tissue.

After several years of research and development, Solx introduced the Gold Shunt, the world's first biocompatible, pure gold implant that uses the eye's natural pressure differential to reduce IOP (Figures 1 and 2). Unlike with other surgical glaucoma options, the use of this device does not require the creation of a bleb, a well-known source of postoperative complications. Additionally, recent engineering advances have improved the device's tensile strength as well as optimized its performance and the ease of surgical implantation.

The Gold Shunt device has been implanted worldwide in the eyes of a variety of glaucoma patients, ranging from those in which trabeculectomy has failed to eyes with late-stage refractory disease. The results include outside US safety and efficacy data out to approximately 4 years (data on file with Solx, Inc.). Initial results inside and outside the United States in patients with refractory and nonrefractory disease suggest significantly decreased IOP from best-medicated baseline (ranging from 30% to 40% reductions at 1 year) and decreased use of medications. The complications seen to date most commonly include hyphema and hypotony, which are minor and transient in nature and normally resolve by 1 to 2 weeks. The Gold Shunt is cleared in Canada and has the CE Mark in Europe. Solx is currently enrolling a US pivotal study, the results of which the company will use to file for FDA 510(k) clearance.

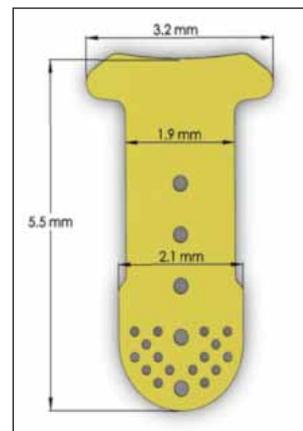


Figure 1. The Solx Gold Shunt.

THE SUPRACHOROIDAL SPACE: A NOVEL DRAINAGE PATHWAY

Over 40 years ago, Anders Bill, MD, PhD, first described the uveoscleral route for aqueous humor drainage.³ Since then, researchers and clinicians' understanding of this "alternative" physiologic pathway has advanced. First, it is now understood that the uveoscleral route works fundamentally due to the natural pressure gradient (-1 to -5 mm Hg) that exists between the anterior chamber and the suprachoroidal space. Second, it appears that the suprachoroidal space may spare patients wound-healing issues associated with filtering surgery. Third, clinical experience with several devices targeting the suprachoroidal space suggests that surgery in this location poses limited additional risk such as suprachoroidal hemorrhage.

ABOUT THE DEVICE

Material and Biocompatibility

In recognition of the unique potential of the suprachoroidal space, the Gold Shunt is designed with a shape and dimension to take advantage of this natural difference in pressure. The company has also refined the implant material. It developed a process by which to yield 99.95% pure gold, thereby eliminating any residual impurities such as copper. Much like PMMA, gold is extremely biocompatible and remains inert in the eye. In the immediate postoperative period, the eye remains quiet with very little inflammation.⁴ Based on my longer-term clinical experience, the material has shown resistance to postoperative wound-healing issues and the formation of scar tissue.

Optimization

Engineering advances have strengthened the device within its existing configuration. For example, replacing internal long channels in the device with posts has reduced its susceptibility to mechanical damage during implantation and prevents the unanticipated restriction of flow. The shunt now comes preloaded with an inserter, which protects the device and improves its placement and the reproducibility of its implantation. Based on my experience with several versions of the device, the current Gold Shunt appears to be more effective than earlier generations in terms of safety and efficacy. The procedure is relatively straightforward, with a typical learning curve of fewer than four cases.

FUTURE DIRECTIONS

In my opinion, glaucoma is a surgical disease currently treated with medications. The Gold Shunt is a novel, minimally invasive device that has the potential to advance the surgical treatment of glaucoma and become utilized prior to trabeculectomy and tube implants. In time, it may also become the first surgical option for some glaucoma patients, ahead of trabeculectomy. The Gold Shunt has evolved over the years and is distinguished by its novel mechanism of action, proprietary material, and simple surgi-

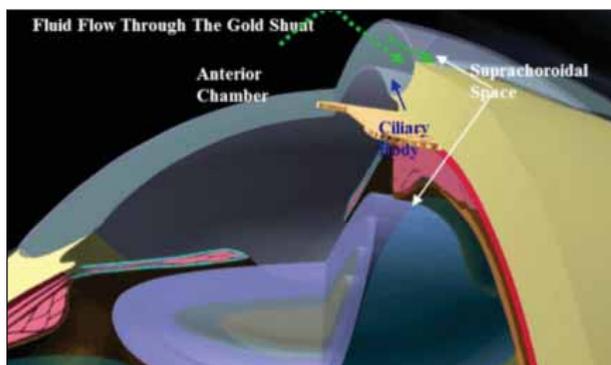


Figure 2. Fluid flow through the Gold Shunt.

cal technique as well as an extensive clinical database that includes a variety of glaucoma patients. I believe this technology and space will become the primary surgical tool and target, respectively, in the treatment of glaucoma. A new clinical study of the Gold Shunt in patients with refractory glaucoma is currently underway in multiple centers across the United States. Future research will assess other unmet needs in the management and treatment of glaucoma. □

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The Transcend CyPass System



By E. Randy Craven, MD

New approaches to microstents may be the biggest improvement ahead for glaucoma treatment in the next few years. Increasing outflow through either the trabecular system or the choroidal space are the options currently being studied for ab interno outflow. The Transcend CyPass System (Transcend Medical, Menlo Park, CA) has a 300- μ m–lumen stent that is 6 mm long. Fenestrations in the tube allow aqueous to egress throughout its length. The tube is placed through the angle, into the supraciliary space (Figure 1).

Right now, the CyPass is being evaluated in one of the largest FDA trials of a glaucoma device (the Compass Trial). The microstent already has CE Mark approval and is being used in multiple clinical trials in Germany, Spain, Italy, and other countries of the European Union. The US trial and much of the European experience with the CyPass involve patients undergoing concurrent cataract surgery. In Europe, the CyPass has also lowered IOP successfully when used as a stand-alone procedure for primary open-angle glaucoma.¹

IMPLANTATION

First, the surgeon removes the cataract and places the IOL. Next, he or she inserts the delivery device and

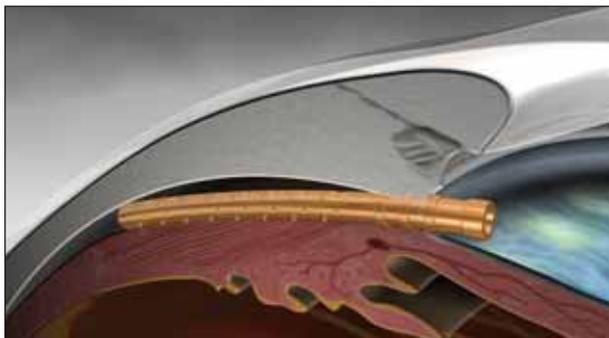


Figure 1. The CyPass microstent is placed in the supraciliary space, allowing outflow to the choroidal space.



Figure 2. The CyPass on the delivery guidewire, just before separation of the iris from the scleral spur.

microstent through the phaco incision, into the anterior chamber, and toward the opposite angle. The CyPass is positioned on a small guidewire that has an atraumatic tip with which to separate the iris from the scleral spur, thus facilitating the device's insertion (Figure 2). The surgeon then slowly advances the polyimide implant into the small cleft created by the guidewire.

While Transcend was first developing the stent, I had an opportunity to implant the device outside the United States and then gained further experience during the Compass Trial. I was surprised at how little bleeding occurs intraoperatively and postoperatively, and I observed no hypotony. Once the device is correctly positioned, the procedure is complete. (A video of the procedure is available at <http://eyetube.net/?v=kirek>.)

RESULTS

The results of the US trial have not been released, but other results were presented at the 2011 ASCRS annual meeting.² The data were gathered from one of the European CyPass studies called the CyCLE study. The patients included in the presentation underwent pha-

coemulsification with the placement of an IOL and then implantation of the CyPass. The intraoperative events and short-term postoperative observations at 1 and 7 days were recorded, as were the long-term postoperative data at 1, 3, 6, and 12 months.

The investigators evaluated 94 patients in this multicenter study. Ninety-three percent of the patients were on IOP-lowering medication, and going into surgery, one-third of them were using three or more drugs. The mean number of preoperative medications was 2.1. The average IOP was 20 mm Hg, and 40% of the patients had an IOP greater than 21 mm Hg.

None of the following complications occurred: choroidal detachment or hemorrhage, persistent hyphema, flat anterior chamber, or retinal detachment. Among patients whose baseline IOP was above 21 mm Hg, the reduction in IOP was 38%, 36%, and 35% at months 1, 3, and 6, respectively. Simultaneously, the number of medications per patient in this group dropped from 2.2 at baseline to under 0.4 medications at 3 months and 0.8 medications at 6 months.

CONCLUSION

The data from European clinical trials of the CyPass are encouraging. It appears that the device may serve a role in combined glaucoma and cataract procedures. This approach will avoid bleb formation and allow further options, if needed, because of the untouched conjunctiva. Some European surgeons feel that the CyPass may be an option for primary surgical intervention, even if simultaneous cataract surgery is not required. I eagerly await the results of the Compass Trial. □

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