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Middle East Afr J Ophthalmol. 2015 Jan-Mar; 22(1): 45–52. PMCID: PMC4302476
doi: 10.4103/0974-9233.148348

Suprachoroidal Devices in Glaucoma Surgery

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Abstract

While conventional glaucoma filtration surgery provides excellent intraocular pressure (IOP) lowering effect, this comes at the expense of significant risks. As the physiology of the suprachoroidal space has become better understood, its potential as a source for aqueous drainage has generated significant interest. This has resulted in the creation of several suprachoroidal glaucoma devices with excellent IOP lowering ability and a much more favorable side effect profile.

Keywords: CyPass, Glaucoma, Shunt, SOLX, Suprachoroidal, Surgery

INTRODUCTION

Conventional glaucoma surgery targets the subconjunctival space as the preferred site for aqueous drainage. This strategy is steeped with tradition and has become a comfortable choice for most surgeons. Despite the benefits of familiarly and relatively good intraocular pressure (IOP) lowering efficacy, these procedures have equally well known risks including ocular discomfort, intraocular bleeding, and a lifetime risk of infection. These issues have prompted surgeons to seek surgical alternatives that have equal efficacy with a lower risk profile compared to traditional glaucoma surgeries. The suprachoroidal space - a virtual space between the external surface of the choroid and the internal surface of the sclera - has been identified as an intraocular location that can be modified to increase outflow facility.

The idea of accessing the suprachoroidal space as an alternative drainage pathway dates back over one century. In 1900, Fuchs described the incidental creation of a cyclodialysis cleft following some cataract extractions. Due to the difference in the hydrostatic pressure in the anterior chamber and suprachoroidal space, the IOP decreased significantly following cleft formation.[1] In 1905, Leopold Heine developed the cyclodialysis spatula so that he could deliberately and reproducibly create a cyclodialysis cleft that would effectively shunt aqueous out of the anterior chamber. Unfortunately, this procedure was complicated by variable postoperative IOP with a high rate of hypotony, along with episodes of dramatic and painful IOP spikes upon spontaneous closure of the clefts.[2] Due to the unpredictable IOP response and associated complications, this technique was never able to usurp the popularity from the alternative treatment at that time, iridectomy.

In 1967, Gills *et al*. renewed interest in the suprachoroidal space when he proposed inserting a Teflon implant within the cleft to maintain consistent aqueous drainage and to prevent sudden closure. While the short-term results were encouraging, onerous insertion, excessive inflammation and episodes of IOP spikes hampered this procedure's long-term success.[3]

Armed with a better understanding of the suprachoroidal space, we have once again focused our attention on this enticing outflow pathway. With high-powered microscopes, improved optics and finely crafted microinstruments, we are now positioned to access the suprachoroidal space in a minimally invasive

fashion. Moreover, extended cleft function is much more likely as improved bioengineering and microtechnology have made creating functional microshunts a realistic endeavor.

RATIONALE FOR TARGETING THE SUPRACHOROIDAL SPACE IN GLAUCOMA SURGERY

Overview

Aqueous humor, produced by the ciliary processes in the pars plicata of the ciliary body, may exit the eye through the trabecular meshwork (conventional pathway) or by the uveoscleral route (unconventional pathway). Previously, egress of aqueous humor via the trabecular meshwork has been studied in much greater depth than the uveoscleral pathway. However, recent advances indicate that the uveoscleral pathway and suprachoroidal space may provide opportunities for micro-invasive glaucoma surgery (MIGS). MIGS is presently an area of significant interest among clinicians as it offers the potential for reduction in IOP, less dependence on medical therapy, and an excellent safety profile. As such, suprachoroidal MIGS approaches are an area of tremendous innovation and growth in the arena of glaucoma drainage devices.[4] Blebless ab-externo glaucoma surgery (BAGS) is another technique that is used to access the suprachoroidal space and lower the IOP. BAGS involves scleral dissection, and it tends to be used in patients with more advanced glaucoma who require lower target IOPs.

Physiology

Anders Bill first demonstrated the uveoscleral pathway in radioactive tracer studies conducted on cynomolgus monkeys in the 1960s.[5,6] Subsequently, human experiments have demonstrated that anywhere from 20 to 54% of aqueous outflow occurs via the uveoscleral pathway.[7,8]

Aqueous humor flows with ease through the face of the ciliary body and iris root due to the absence of an epithelial barrier.[9] From there, it is able to access the interstitium of the ciliary muscle which then directs the aqueous to a potential space between the choroid and sclera known as the suprachoroidal space. This space acts as a molecular sieve as the aqueous humor enters scleral blood vessels, choriocapillaris, or scleral pores to access episcleral tissue.[6,10,11,12] Aqueous humor is carried to the orbit by choroidal and scleral vessels. From the orbit, it is then able to enter the systemic circulation by way of lymphatic vessels.[13]

Several physiologic differences exist between the conventional and unconventional pathways. Given the description of the anatomical pathway above, it is not surprising that the uveoscleral outflow is largely driven by differences in hydrostatic pressure between the anterior chamber and suprachoroidal space.[14] This contrasts with the traditional pathway, which demonstrates a largely linear dependence on IOP. The site of greatest resistance to outflow is another difference between the two pathways. In the traditional pathway, Schlemm's canal provides the greatest barrier to outflow where it appears that the ciliary body plays an analogous role in the uveoscleral pathway.

In addition, as a significant proportion of glaucoma patients are elderly, changes in the uveoscleral pathway associated with aging are of particular interest. It has been estimated that there is an increase in connective tissue of >50% by age 60 on the ciliary body segment facing the anterior chamber.[15] Considering the previous discussion of the ciliary body as the main source of outflow resistance, this may have significant implications for IOP by decreasing the surface area of the ciliary body that is available to facilitate drainage by the uveoscleral pathway.

Surgical approaches to the suprachoroidal space

Historically, cyclodialysis was the first surgical approach to increase aqueous humor drainage via the uveoscleral pathway. Cyclodialysis involves separation of the ciliary body from the scleral spur, which eliminates the natural barrier between the anterior chamber and the suprachoroidal space. Although classic ab-externo cyclodialysis is an effective means of IOP reduction, it is plagued by significant complications including severe postoperative hypotony and bleeding from scleral vessels. In addition, the cyclodialysis cleft has a propensity to scar, which eliminates the communication between the anterior chamber and the suprachoroidal space. Ab interno approaches have been explored in an attempt to reduce scarring with less disruption of conjunctiva, but the evidence for the procedure's efficacy is not convincing at this time -

particularly in light of the paucity of long-term follow-up.[16] Innovative ab-externo procedures are also being investigated, but these techniques also need more consistently positive data.

Less invasive procedures with more effective implants have been an area of extensive research and innovation recently. For the purposes of this discussion, we will focus on suprachoroidal devices, but it should be noted that several devices exist that may affect other pathways (facilitating drainage via the conventional pathway by way of Schlemm's canal) and anatomical spaces (subconjunctival aqueous drainage). MIGS procedures have been previously defined by a constellation of features including a microincisional ab interno approach, minimal trauma, efficacy, a high safety profile, and rapid recovery. Currently, available MIGS devices appear to be well suited for situations in which a mild to moderate decrease in IOP is the desired outcome. More traditional aqueous drainage devices remain the standard for advanced disease requiring a significant reduction in IOP. The BAGS procedures fall somewhere between MIGS and traditional filtering surgeries in respect to safety and efficacy. These surgeries may provide a more robust IOP lowering compared with MIGS albeit at the expense of being more invasive and with a slightly greater side effect profile.

As the use of MIGS and BAGS procedures continues to grow, it will become increasingly important for ophthalmologists to become well acquainted with the variety of devices as each has certain situations to which it may be most amenable. An understanding of the anatomy relevant to these devices, indications for their use, and the skill set necessary for implantation will guide ophthalmologists through an exciting period in the development of novel surgical techniques for the treatment of glaucoma.

THE CYPASS SUPRACHOROIDAL MICRO-STENT

Background

The CyPass device (Transcend Medical, Menlo Park, CA, USA) is a supraciliatry microshunt designed to create controlled aqueous outflow from the anterior chamber into the suprachoroidal space. The fenestrated micro-stent is constructed from a biocompatible, nonbiodegradable polyimide material that has demonstrated excellent biocompatibility in preclinical testing.[17] The flexible implant is 6.35 mm in length, with a 300 mm lumen and a 510 mm external diameter. The micro-shunt is designed so that the curve of its body follows the natural contour of the potential space between the sclera and the ciliary body. When properly positioned in the supraciliary space, the implant is stabilized by a combination of its inherent mechanical strength coupled with the tri-layered retention rings at the tip of the device.

CyPass micro-stent implantation is performed using a transcameral approach through a clear corneal incision [Figure 1]. After filling the anterior chamber with viscoeleastic, visualization of the angle is achieved with a surgical goniolens. The implant is loaded onto the curved, retractable guide wire and then carefully directed across the anterior chamber towards the drainage angle. The blunt tipped guide wire is strategically designed to disinsert the ciliary body from the sclera and then gently create a controlled cyclodialysis that is maintained by the micro-shunt. Fenestrations along the body of the tube facilitate aqueous egress as the fluid flows from the anterior chamber into the suprachoroidal space [Figure 2]. Once the micro-stent is implanted, the guidewire is retracted and removed from the eye. Correct positioning can be confirmed by visualization of the proximal end of the tube with the underlying retention rings or using anterior segment optical coherence tomography.[18]

Recently, a novel insertion protocol has been described that advocates gonio-free insertion of the CyPass micro-stent. To facilitate this technique, a tactile gonioprobe was designed to measure the depth of the angle from the ciliary body insertion to the limbus at the site of implantation. Measurement scales on both the inserter and probe allow for precise implantation and accurate depth of stent insertion.[19]

Clinical studies

Before committing to human studies, the biocompatibility of the CyPass micro-shunt was confirmed in rabbit eyes.[17] The first report of CyPass micro-shunt placement in humans was a prospective study of 81 primary open-angle glaucoma (POAG) patients who underwent combined cataract extraction and CyPass micro-stent insertion. After 6 months of follow-up, the study documented a 29% drop in IOP from a preoperative mean value of 22.9 mmHg. The only recorded complications were transient hyphema and a

shallow anterior chamber.[20] Soon thereafter, Craven *et al*. published their report on the clinical safety of the device. In this prospective study, 121 patients with concomitant POAG and cataract who underwent combined phacoemulsification and CyPass placement were followed for 6 months. This group reported a 30% IOP reduction with a 60% reduction in medication load at the end of the study. Study related complications were mild and included: Transient intraoperative hyphema ($n = 8$), postoperative hyphema ($n = 2$), persistent inflammation ($n = 1$), branch retinal vein occlusion ($n = 11$), and exacerbation of diabetic macular edema ($n = 1$).[21]

The first large-scale study to evaluate the long-term safety and efficacy of the CyPass micro-stent is the CyCLE (CyPass Clinical Experience) study. This prospective, open-label, interventional, multicenter clinical trial recruited 460 patients, with 222 patients undergoing CyPass implantation alone and 238 patients receiving the CyPass device in conjunction with cataract extraction.

As of 2014, 136 of the combined cataract/CyPass patients have reached the 24-month postoperative time point. In this study, patients were classified preoperatively as either being uncontrolled (IOP ≥ 21 mmHg, Cohort 1, $n = 51$) or controlled (<21 mmHg, Cohort 2, $n = 85$). In Cohort 1, the mean IOP decreased 37%, from a 25.5 ± 4.9 mmHg baseline to 15.8 ± 3.8 mmHg ($P \leq 0.0001$) and the mean medication use dropped from 2.2 to 1.0 at the last follow-up. In Cohort 2, where the therapeutic objective was a reduction of the medication burden, the mean IOP experienced a slight reduction from 16.4 mmHg to 15.8 mmHg at the 24-month visit ($P > 0.05$). In this group, the mean number of required antiglaucoma medications decreased from 2.0 to 1.1 ($P < 0.0001$) at 24 months.

Adverse events related to CyPass implantation were generally mild and relatively infrequent. The most commonly reported adverse events were transient hypotony (15.4%), stent obstruction (8.8%) and postoperative IOP spike (4.4%). Most importantly, there were no reports of endophthalmitis, suprachoroidal hemorrhage or hypotony maculopathy. Certainly, the side effect profile was much more benign compared to traditional glaucoma filtering surgeries.[22]

The second group of patients in the CyCLE clinical trial underwent CyPass micro-shunt implantation as a stand-alone treatment for patients with POAG. The patients in this arm of the study were also subdivided into the same two cohorts, depending on whether their IOP was uncontrolled (Cohort 1) or controlled (Cohort 2) preoperatively. The patients in Cohort 1 with inadequately controlled baseline IOP experienced a 26% mean reduction in IOP (from 27.4 ± 6.9 mmHg to 18.9 ± 8.1 mmHg) at the 12-month follow-up. This group also experienced a 48% reduction in topical medication use from 2.1 ± 1.1 to 1.1 ± 1.2. The IOP in Cohort 2 remained stable, but they were able to decrease the medication burden by 40% (from 2.3 ± 1.3 to 1.4 ± 1.4) at the 1-year time point.[23] These results were fundamental in demonstrating the inherent efficacy of this device, even in patients with good baseline IOP.

Whereas a sub-group of the patients in the CyCLE study were treated with the CyPass device as a stand-alone procedure for their glaucoma, the true focus of that study was to demonstrate safety and efficacy of this new device in glaucoma patients. A subsequent study (DUETTE) sought to evaluate the IOP lowering efficacy of CyPass when it is implanted as an independent procedure in glaucoma patients whose IOP is recalcitrant to at least one medication. This prospective, multicenter interventional case series recruited 65 patients with elevated eye pressure (IOP ≥ 21 mmHg and ≤ 35 mmg) on 1-4 glaucoma medications. The mean baseline medicated IOP was 24.5 mmHg, with 68% of the patients on ≥ 2 glaucoma drops. At 12 months after surgery, the mean IOP had decreased to 16.7 mmHg, which represented a 32% reduction from baseline. A further analysis of the data revealed that 86% of patients had a ≥ 20% reduction in IOP with a corresponding 32% reduction in the medication load (from a mean baseline of 2.2 glaucoma medications to a mean of 1.5 glaucoma medications at 1-year). The most common adverse events included a persistent IOP spike > 30 mmHg ($n = 7$), transient hyphema ($n = 4$) and cataract progression ($n = 5$). Once again, there were no cases of suprachoroidal hemorrhage, bleb related infections, or hypotony maculopathy associated with CyPass implantation.[24,25]

The only active CyPass micro-stent study is the US based COMPASS clinical trial.

This prospective, comparative, multicenter study randomized patients with concomitant cataracts and glaucoma to either receive (1) Phacoemulsification alone or (2) combined phacoemulsification and CyPass insertion. The study was able to successfully recruit 505 subjects, which is significantly more patients than

have been recruited in any previous MIGS study. With a large sample size and a robust clinical design, compelling results should be forthcoming.

Conclusion

In all of these studies, the CyPass implant was able to significantly lower the IOP and decrease the medication burden both as a stand-alone procedure and in combination with cataract surgery. Equally important is the benign side effect profile with minimal risk of catastrophic visual loss. The early results are certainly very encouraging, and we wait for additional follow-up to better gauge long-term efficacy.

THE SOLX GOLD SHUNT

Background

The SOLX gold shunt (SOLX Ltd., Waltham, MA) is designed to transmit aqueous from the anterior chamber to the suprachoroidal space, where it will ultimately be redistributed and/or reabsorbed by the scleral channels or the choriocapillaris.[6,11] The concept for this device has its origin in two unique observations.[26] The first key element is a fundamental relationship between the anterior chamber and the adjacent suprachoroidal space. There is evidence to suggest that a 1-5 mmHg pressure differential exists between the two regions, with the pressure in the suprachoroidal space always negative in comparison with the anterior chamber.[14] This creates a hydrostatic pressure differential that favors unidirectional flow into the suprachoroidal space if the two regions are connected. The second observation relates to the excellent biocompatibility of gold in the human eye. This finding was highlighted by a clinical report of a goldsmith who had a gold particle removed from his anterior chamber after a 9-year incubation. There was no evidence of any active or past inflammation, nor was there any indication of chalchosis from the small amount of copper that was part of the gold alloy.[27]

The SOLX gold micro shunt (GMS) was developed based upon these aforementioned principles. The device is composed of two leaflets fused together vertically, concealing microchannels within its body that connect the anterior inflow channels to the posterior outflow openings. The unit is fabricated from 24-kt medical grade (99.95%) pure gold, which is known for being inert and biocompatible. The original GMS was 3.2 mm wide, 5.2 mm long and weighed 6.2 mg. A revised model (GMS Plus) was released that is slightly longer (5.5 mm), heavier (9.2 mg), with larger channels that effectively increase its tensile strength. The shunt is designed to increase uveoscleral outflow from the anterior chamber into the suprachoroidal space. This hypothesis is corroborated by ultrasound biomicroscopy and anterior segment optical coherence topography findings.[28]

Implantation of the GMS is typically performed under topical anesthesia, sometimes augmented with subconjunctival lidocaine. The gold shunt can be inserted in any quadrant. It is important to select an area with healthy sclera and conjunctiva, to ensure a watertight closure and prevent bleb formation. Following the creation of a conjunctival peritomy, a 3–4 mm, full thickness scleral incision is created 2–3 mm posterior to the limbus to expose the supraciliary space. A scleral pocket at 95% depth is then fashioned, using a crescent knife to extend all of the way to the scleral spur. While the eye is still pressurized, the dissection is continued posteriorly into the suprachoroidal space. Subsequently, the anterior chamber is entered after the anterior chamber is stabilized with viscoelastic or by anterior chamber maintainer. The GMS is then delicately positioned with the proximal end in the anterior chamber and the distal end in the suprachoroidal space [Figure 3]. Finally, the scleral incision is closed with multiple 10–0 nylon sutures and the conjunctiva is reapproximated with a 10–0 vicryl suture. Given the ab-externo approach with the conjunctival dissection, this procedure falls into the category of surgeries commonly referred to as BAGS.

Clinical studies

In the 2009 pilot study, Melamed *et al*. reported the results of prospective noncomparative case series wherein one eye from 38 patients with advanced glaucoma underwent surgical placement of a GMS. In this study, the IOP decreased 32.6%, from a mean baseline value of 27.6 ± 4.7 mmHg to 18.2 ± 4.6 mmHg at the 1-year (11.7 ± 1.3 months) postoperative visit. While 92% (35/38) of the patients had a final IOP <22 mmHg, 86% (30/35) of these patients required glaucoma medications to achieve an acceptable IOP. On a positive note, the visual field and visual acuity parameters did not change during the course of this

study. Moreover, the side effect profile was encouraging, with the most common complications being mild hyphema (n = 6), moderate hyphema (n = 2), shunt exposure (n = 1), and exudative retinal detachment (n = 1).[28]

In a prospective uncontrolled case series, Figus *et al*. evaluated the efficacy of GMS in 55 eyes with refractory glaucoma. At the 2-year follow-up, the mean IOP decreased from 27.6 ± 6.9 mmHg at baseline to 13.7 ± 2.98 mmHg. With success defined as an IOP > 5 and < 22 mmHg, 67.3% (n = 37) of the patients achieved that goal with adjunctive medications and 5.5% (n-3) were in that range without additional glaucoma therapy. While mild to moderate hyphema (n = 12) was the most commonly reported side effect, they also documented other postoperative complications including choroidal detachment (n = 6), corneal edema (n = 2) and over-filtration (n = 1). An evaluation of those cases that did not reach the target IOP range found that the most common cause of GMS failure was a thin inflammatory membrane (n = 4) blocking the inflow channels.[29] Two additional papers corroborated this finding when they reported that histological evaluation of failed GMS surgeries identified connective tissue proliferation as the main cause of surgical failure for these devices.[30,31]

The next question that must be addressed is how the GMS compares to traditional glaucoma surgeries in regards to safety and efficacy. Moroz *et al*. addressed this very question when they prospectively compared the performance of the proven Ahmed glaucoma valve (AGV) with the cutting-edge GMS technology. In this study,[32] patients with refractory glaucoma were randomly assigned to have either AGV or GMS implantation with 5-year of planned follow-up. Considering the target IOP in this study (>5 mmHg and <22 mmHg), the cumulative success rate was reported at 0.78 for the AGV group and 0.67 for the GMS group based on Kaplan-Meier survival analysis (P = 0.83). From a more practical standpoint, patients with AGV implantation enjoyed a 48% reduction in IOP while those with the GMS experienced a 35% decrease in IOP. While both devices produced a nice drop in IOP, the mean number of glaucoma medications did not change during the course of the study for either group.[32]

Most of the GMS clinical trials produced positive results, but one paper presented a contrasting report. This retrospective study evaluated the efficacy of GMS in 31 patients with refractory glaucoma who were followed for up to 4-year. In this study, criteria for treatment failure consisted of: (1) IOP <5 mmHg and >22 mmHg at 6 months after GMS insertion, (2) serious complications, and (3) need for additional glaucoma surgery. Based on these criteria, 97% of the eyes (30/31) met the criteria for surgical failure. Moreover, within 1-year of GMS placement, 77% (24/31) of the eyes required additional glaucoma surgery because of elevated IOP or adverse events.[33] While the authors could not definitively explain why their results were so different from other similar studies, this report highlights the fact that we should exercise caution before rendering a final judgment on the efficacy of GMS.

Conclusion

The GMS is an exciting new technology that exploits the untapped IOP lowering potential of the suprachoroidal space. This procedure has produced impressive IOP lowering efficacy with a favorable side effect profile in most of its early clinical trials. That being said, it does require a conjunctival peritomy and scleral dissection, which introduce potential difficulties and complications not seen in other glaucoma surgeries that target the suprachoroidal space.

EMERGING SUPRACHOROIDAL TECHNOLOGY

Stent Supra

The iStent Supra (Glaukos Corporation, Laguna Hills, CA, USA) is the third generation in the lineage of Glaukos devices to bear the iStent moniker. It remains investigational in the United States but has been CE marked for use in Europe. As its name implies, the iStent Supra is engineered to increase suprachoroidal drainage. Since it is implanted via an ab interno route, the iStent Supra may be placed in conjunction with cataract surgery or as a stand-alone procedure in both phakic and pseudophakic eyes. The device is a ridged tube that is curved to conform to the contour of the globe within the suprachoroidal space [Figure 4]. The ridges are designed to improve implant retention in its desired location. The 0.16-0.17 mm lumen allows for transport of aqueous from the anterior chamber to the suprachoroidal space. The device is composed of a polymer selected in part for excellent biocompatibility.

Outcomes data continue to emerge that shows favorable efficacy and risk profile. 12 months postoperative data in open angle glaucoma subjects previously uncontrolled on two topical hypotensive medications demonstrate the iStent Supra to be safe and capable of a significant reduction in IOP and medication burden. In 73 subjects, the mean preoperative medicated diurnal IOP was 20.4 mmHg, and the unmedicated baseline IOP was 24.8 mmHg. Following uncomplicated placement of the stent and administration of postoperative travoprost, 42 subjects were followed through 12 months. Of this group, 98% met the primary endpoint of a 20% reduction in IOP with one medication. The mean IOP decreased by 47% to 13.2 mmHg. Of equal importance, there were no documented adverse events during the course of the study.[34] Similar results have been reported by others that confirm the utility of the iStent Supra as a safe, effective means of IOP reduction.[35]

In addition, this device has been successfully used in combination with other MIGS devices (trabecular bypass stents) in cases of the open angle glaucoma refractory to conventional filtration surgery and medication. Thirsty subjects with persistently elevated IOP following trabeculectomy were followed for 18 months after placement of 2 iStents and 1 iStent Supra in addition to postoperative travoprost. Mean medicated preoperative IOP was 22.0 mmHg and mean unmedicated IOP was 26.4 mmHg. At 18 months, mean IOP was 13.2 mmHg without any reported adverse events or complications.[36] These reports suggest a possible synergistic effect between suprachoroidal shunts and other MIGS devices, particularly in glaucoma patients refractory to conventional treatment modalities.

Aquashunt

The Aquashunt (OPKO Health Inc., Miami, FL, USA) is a suprachoroidal device that is presently in development by OPKO Health that is used as part of a BAGS protocol. The polypropylene device is designed to be inserted through a full thickness scleral incision with an integrated insertion tool. The Aquashunt is curved to conform to the globe and has a shearing lead edge [Figure 5]. The key difference between the Aquashunt and the gold shunt is a single large lumen for the Aquashunt rather than several small channels. Results data are limited at this time, but some early phase I trial information has been made available. The initial trial enrolled 15 patients with an open angle glaucoma refractory to medical therapy and previous failed surgery. Early results suggest that almost 80% of those patients with Aquashunt implants had IOP lowering at 1-month postoperative, with several patients demonstrating single digit IOPs. At 6 months postimplantation, 75% of the patients ($n = 4$) experienced a >20% reduction in IOP. Equally important, the shunt was generally well tolerated with few adverse events initially.[37] Long-term data, for both efficacy and safety, remains pending at this time.

STARflo

The STARflo (iSTAR Medical, Isnes, Belgium) is another suprachoroidal device that remains investigational in the United States, but has been CE marked in Europe since 2012. It is constructed using a proprietary silicone microporous material (known as STAR) designed to reduce fibrotic response and maximize long-term performance. The STARflo shunt is 11 × 5 mm with an anvil-like head that helps prevent extrusion [Figure 6]. The device is inserted through an ab-externo approach into the suprachoroidal space via a scleral flap with its head positioned in the anterior chamber and the body of the device resting primarily between the sclera and choroid. At this point in time, antifibrotic agents (such as mitomycin C or 5-fluorouracil) are not part of the protocol. Although a small, transient bleb may form immediately postoperatively, the device does not rely upon a bleb for filtration.[38] After encouraging results from rabbit and canine studies, a human trial was initiated. In this prospective, multicenter, feasibility clinical trial, four patients with advanced open-angle glaucoma underwent STARflo implantation. Mean IOP dropped from a preoperative baseline of 37.0 mmHg to 14.3 mmHg at 1-year. In addition, reliance upon medical therapy was significantly reduced and no visually devastating perioperative or device-related complications were reported.[39] Further investigation is necessary given the paucity of data and small sample sizes within the existing body of information.

CONCLUSION

The suprachoroidal space has the physical characteristics and the accessibility that make it an attractive source for less invasive procedures that can achieve significant IOP reduction. In practice, the early results

with several techniques that target this space have been very encouraging. That being said, the published reports lack the stringency and follow-up that the Food and Drug Administration likes to see before approving a new device. At this time, these stents remain investigational (in the United States) until data from long-term, randomized controlled trials are performed and released.

Footnotes

Source of Support: Nil

Conflict of Interest: None declared.

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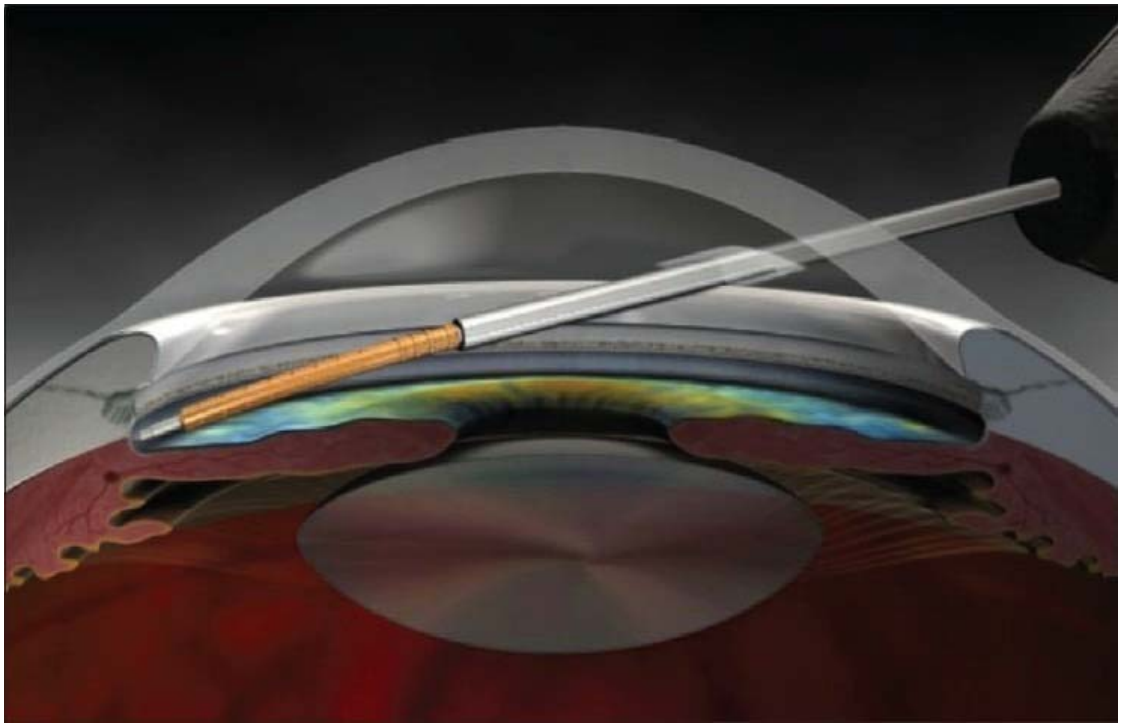
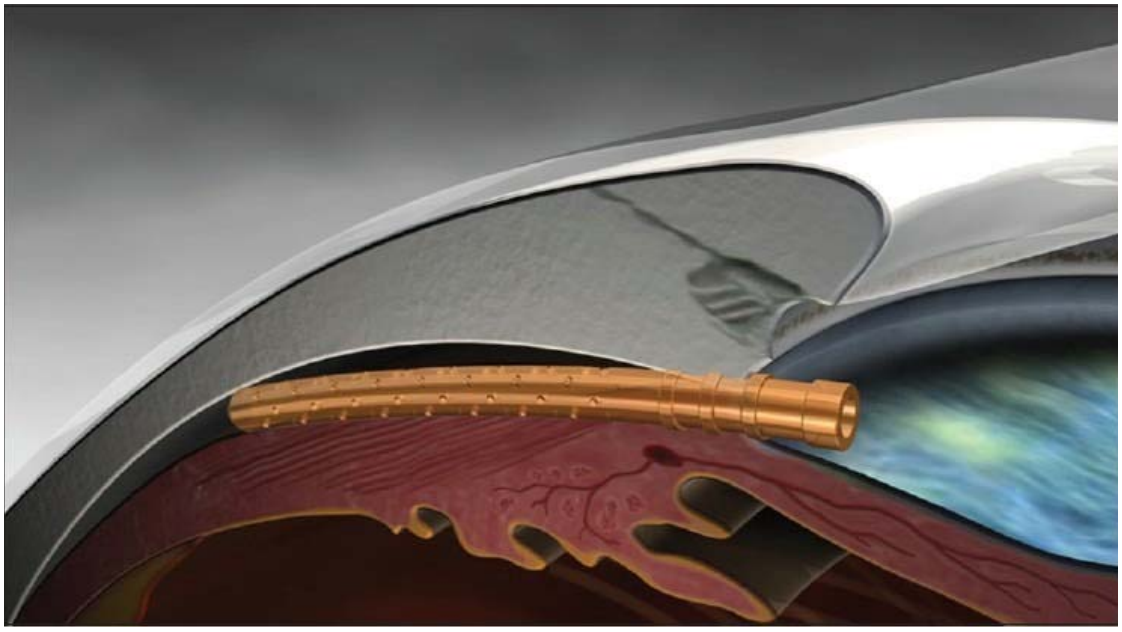
Figures and Tables

Figure 1



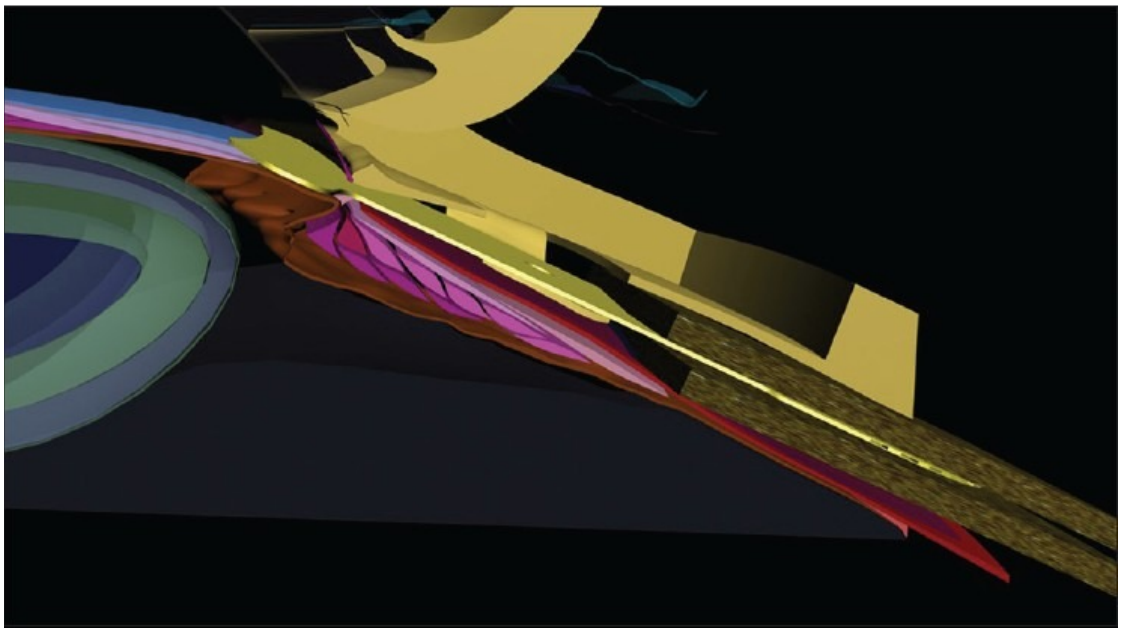
The CyPass micro-shunt is inserted into the suprachoroidal space in a transcameral fashion through a clear corneal incision (image courtesy of Ravi Pamnani, Transcend Medical, Inc.)

Figure 2



The CyPass micro-shunt creates and maintains a localized cyclodialysis cleft with the body of the stent while the proximal collar remains positioned in the anterior chamber as the inflow site (image courtesy of Ravi Pamnani, Transcend Medical, Inc.)

Figure 3

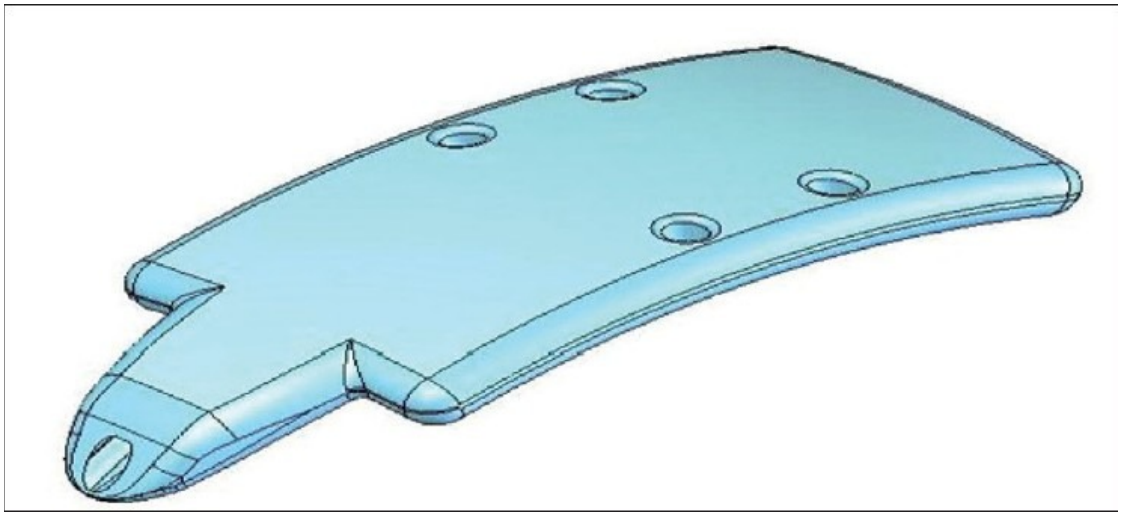


This is a three-dimensional representation of the correct positioning of the gold shunt within a pillow of collagen in the suprachoroidal space (image courtesy of Gabriel Simon, M.D.)

Figure 4

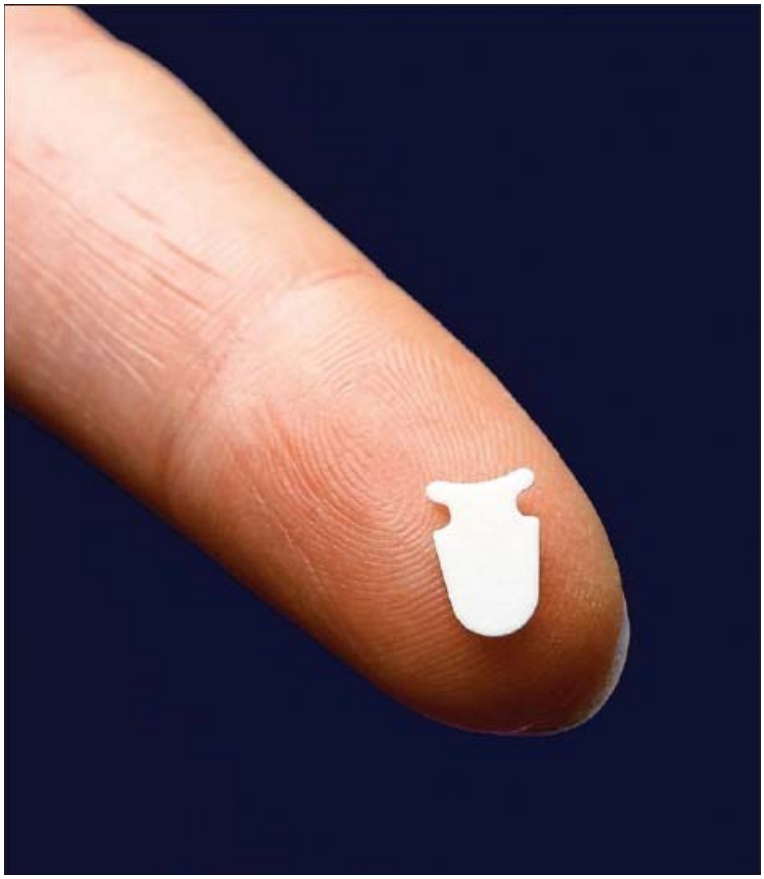
The iStent Supra is a heparin-coated, slightly curved polyethersulfone stent that is designed to create and maintain a lumen within the suprachoroidal space (image courtesy of Chris Calcaterra, Glaukos)

Figure 5



The Aquashunt is a 10 × 0.75 × 0.75 mm polypropylene shunt with a tapered leading edge (image courtesy of M. Bruce Shields)

Figure 6



The STARflo device is composed of a single continuous sheet of porous silicon STAR scaffold that is implanted in the supraciliary space and provides a controlled fluid path for aqueous egress (image courtesy of Cecile Roy Ph.D., iStar Medical)