A Suprachoroidal Gold Shunt for Glaucoma

a report by
Gabriel Simon

Gabriel Simon Institute of Ophthalmology, Barcelona and Madrid

DOI: 10.17925/EOR.2009.02.01.42

Glaucoma is an irreversible ocular disease in which elevated intraocular pressure (IOP) leads to a slow degeneration of retinal ganglion cells and eventually to optic nerve death, or complete blindness if left untreated. Although several factors may contribute to advanced glaucoma, one primary cause is the eye's inability to provide sufficient outflow for the aqueous humour produced by the ciliary body. When aqueous humour is produced at a greater rate than it can be removed, IOP increases. Reducing the IOP is the only proven treatable characteristic of glaucoma.

The first course of treatment following diagnosis usually involves pharmaceuticals such as prostaglandin analogues, α-adrenergic agonists, carbonic anhydrase inhibitors, β-adrenergic blockers and cholinergic agonists, each associated with its own mechanism of action, potential side effects and financial cost to the patient. When the pharmaceutical course of action fails to stop the progression of the disease, other non-pharmaceutical options are available.[1] In many cases the next choice for the glaucoma specialist is to lower the IOP using laser trabeculoplasty. Several types of laser have been tested and developed for trabeculoplasty over the past few decades, with the most common today being argon laser trabeculoplasty (ALT),[2] selective laser trabeculoplasty (SLT)[3] and titanium:sapphire laser trabeculoplasty (TLT).[4]

When laser trabeculoplasty and pharmaceuticals fail to control glaucoma progression and concomitant loss of vision, surgical intervention is commonly the next option. Trabeculectomy is still considered the gold standard of glaucoma surgical treatment; however, complications and bleb failures are well documented. Deep sclerectomy and non-penetrating procedures offer surgical choices with or without the use of an antimetabolite agent such as mitomycin C. Additionally, an increasing number of glaucoma drainage devices have been developed, including the Molteno,[5] Baerveldt,[6] Ahmed[7] and ExPRESS[8] implants, all of which provide an artificial channel to drain excess aqueous humour from the anterior chamber to the outside of the eye (supporting the formation of a bleb), and the Trabectome[9] device, which is designed to increase aqueous outflow through Schlemm's canal.

This article will focus on another relatively new glaucoma drainage device: the SOLX Gold Shunt (GMS+, SOLX Inc., Waltham, Massachusetts, US).

Gabriel Simon is Director of the Gabriel Simon Institute of Ophthalmology, with clinics in Barcelona and Madrid. He is an honorary member of the Barraquer Institute of America (Bogota, Colombia). Dr Simon received his medical degree from the Central University of Barcelona and conducted his medical training at Bascom Palmer Eye Institute at the University of Miami.

Device Description

The Gold Shunt is a miniature flat drainage device designed for implanting in the eye to reduce IOP. Unlike most other glaucoma drainage devices, which direct aqueous humour from the anterior chamber of the eye to the outside of the eye or into the sub-conjunctival space, creating a bleb, the Gold Shunt establishes a pathway for flow from the anterior chamber to the suprachoroidal space, enhancing a naturally occurring drainage pathway in the eye without creating a bleb. With maximum outer dimensions of 6mm long, 3.5mm wide and 0.12mm thick, the Gold Shunt is substantially smaller than other glaucoma drainage devices, and is fabricated from highly biocompatible 99.95% pure gold (see *Figure 1*).

The proximal or 'head' end of the device has openings to allow aqueous to flow into the device from the anterior chamber. The distal or 'tail' end is positioned in the suprachoroidal space and has openings that allow aqueous to flow out through that end of the device. Larger reinforced openings aligned along the centre-line of the device are designed to aid positioning of the device during surgical implantation. A protective stainless steel insertion tool is supplied with each device to aid with handling and positioning of the implant. The Gold Shunt has been commercially available in the EU with CE approval since 2006.

Clinical Studies

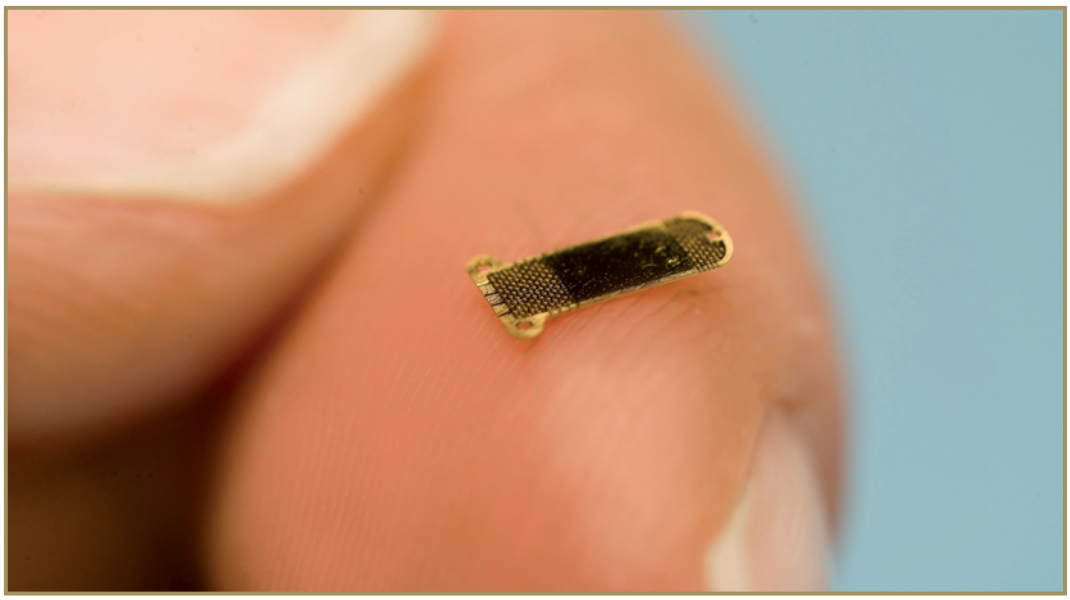
A prospective, multicentre clinical study was undertaken to evaluate the safety and efficacy of the Gold Shunt as a treatment for glaucoma. All patients in this study provided informed consent prior to inclusion in the trial, which was conducted under local Ethical Committee approval.

Materials and Methods

A total of 85 eyes were studied, including patients of both sexes, aged 18 years or older and diagnosed with glaucoma inadequately controlled on maximally tolerated medical therapy. Sixty-eight of 85 patients (80%) had also failed at least one prior laser or surgical intervention (see *Table 1*). All patients received a full ophthalmic examination prior to Gold Shunt implantation, with baseline records made of the patient's ocular history, diagnosis, glaucoma medications being used and IOP. All Gold Shunt surgeries were performed as an outpatient procedure using only topical or regional anaesthesia, such as a sub-Tenon's or retrobulbar block. Surgical implantation of the Gold Shunt consists of the following steps: a conjunctival flap is created; a 3–4mm incision is made to 95% scleral depth; a scleral tunnel incision at 95% depth is made into the anterior chamber; a full-thickness 3mm posterior incision is made into the suprachoroidal space; the anterior end of the device is inserted into the anterior chamber; the posterior end of the Gold Shunt is inserted into the suprachoroidal space; and the scleral incision and conjunctival flaps are sutured. The eyes were then post-operatively patched for one day.

Think of it as a
Gold Artificial Meshwork
to Reduce IOP

Who says you need a bleb?



The SOLX Gold Shunt reduces IOP without creating a bleb by acting as an artificial meshwork, harnessing the natural pressure differential between the anterior chamber and the suprachroidal space.
No bleb. No bleb-related complications. Simple.

Treat your first three patients free. Go to www.solx.com or contact us at (+1) 978.717.9482 so we can help get you started.

SOLX®
Gold Shunt

IOP reduction without a bleb

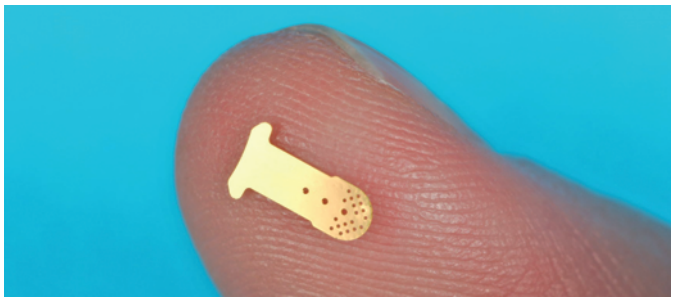
www.solx.com

CE 0473

U.S. 800.939.SOLX (7659)
International (+1) 978.717.9482
email info@solx.com

Caution: Investigational Device. Limited by Federal Law to Investigational Use.

Figure 1: SOLX Gold Shunt



Glaucoma medications were continued or re-started at the physician's discretion. Patients were asked to return for follow-up visits at day one and weeks one, four, 12, 26 and 52 for examination and re-measurement of IOP and visual acuity.

Results

The mean IOP measurements at follow-up for the Gold Shunt are shown in *Table 2*. The type and number of glaucoma medications already prescribed for use by the patient were also recorded for each patient at baseline and all follow-up visits. The mean IOP (standard deviation [SD]) at baseline was 27.6 (7.6) mmHg. Following Gold Shunt implantation, an immediate 65.5% drop in mean IOP to 9.2 (6.7) mmHg was observed on day one, which stabilised to 18.1 (6) mmHg and 18.2 (4.5) mmHg at 26 and 52 weeks, respectively, representing a mean IOP reduction of about 34%. Glaucoma medication use was seen to drop from a baseline average of 2.55 (0.94) medications to 1.03 (1.08) at 26 weeks and 1.16 (1.04) at 52 weeks.

Complications were typically minor and infrequent. The most commonly reported complication was mild hyphema (grade 1 or 2, <3mm) in 37 of 85 eyes (44%), which typically completely resolved without intervention by four weeks post-operatively. Mild hypotony (IOP between 3 and 5mmHg) was reported in 12% of cases in the first week post-operatively, but also resolved completely by the week four follow-up visit. Seven cases of shunt–cornea touch were reported, primarily in the first patients to receive the shunt and less frequently reported as the surgeons gained more experience with the implantation technique. Instances of all other complications (choroidal effusion, haemorrhage or detachment, shunt migration and synechia) were low: typically <5% if recorded at all.

Table 1: Demographics of SOLX Gold Shunt Study Population

Patient Demographic		n=85	(%)
Mean age ± standard deviation		66.7±11.9	–
Gender	Male	36	42
	Female	49	58
Study eye	Right eye	41	48
	Left eye	44	52
Lens status	Phakic	24	28
	Aphakic	3	4
	Pseudophakic	55	65
Prior glaucoma surgery*	No	17	20
	Yes	68	80
Glaucoma type	Primary open angle	70	82
	Uveitic	4	5
	Pseudoexfoliative	11	13
	Closed angle	4	5
	Pigmentary	1	1
	Neovascular	1	1
	Pseudophakic	1	1
	Other	3	4

** Eyes may have had more than one prior surgery.*

Table 2: Follow-up Data After Gold Shunt Implantation

	Gold Shunt (n)	Mean IOP (mmHg ± SD)	Mean Reduction (%)	Mean Number of Medications ± SD
Baseline	85	27.6±7.6	–	2.55±0.94
Day 1	83	9.2±6.7	65.5	0.25±0.73
Week 1	83	13.±7.2	49.3	0.34±0.88
Week 4	83	18.2±7.2	30.1	0.69±0.91
Week 12	74	17.4±5.6	32.3	0.96±1.02
Week 26	71	18.1±6	32.0	1.03±1.08
Week 52	48	18.2±4.5	33.7	1.16±1.04

IOP = intraocular pressure; SD = standard deviation.

Discussion

In this study, the Gold Shunt demonstrated the capacity to reduce IOP an average of about 34% at the 52-week follow-up visit with a concomitant average reduction in glaucoma medication of about 1.4 medications. Choosing to leave patients on their baseline medications may produce lower target IOPs.

Overall, the Gold Shunt procedure is straightforward, much like a cataract procedure, leaving quiet eyes following surgery. Most physicians will find there is a learning curve of three to four implants to achieve consistent proficiency with implantation. Overall, post-operative complications were minor and easily managed, with the most commonly seen – mild to moderate hyphema and mild hypotony – self-resolving in a short period of time, thus supporting the safety profile of the device. Furthermore, the 24-carat gold material of the device was shown to be extremely well tolerated by the eye, without significant inflammatory response.

Early reports of new Gold Shunt designs that provide greater aqueous flow are encouraging as they may allow lower target IOPs to be reached. Furthermore, additional clinical studies will provide more experience with the Gold Shunt and a better understanding of its mechanisms of action, allowing new ways of improving clinical outcomes to be developed. ■

Acknowledgement

The author would like to recognise Judy Lin, MSME, for her assistance with the biostatistical analysis used in the preparation of this article.

1. Weinreb R, Khaw PT, Primary Open-Angle Glaucoma, *Lancet*, 2004;363:1711–20.
2. Wise JB, Witter SL, Argon Laser Therapy for Open-Angle Glaucoma: A Pilot Study, *Arch Ophthalmol*, 1979;97:319–22.
3. Latina MA, Sibayan SA, Shin DH, et al., Q-switched 532-nm Nd:YAG Laser Trabeculoplasty (Selective Laser Trabeculoplasty): A Multicenter, Pilot, Clinical Study, *Ophthalmology*, 1998;105(11):2082–90.
4. Simon G, Vivar A, Lowery JA, Clinical Results Following Gonioscopic Laser Trabecular Ablation (GLTA) with a Ti:Sapphire Laser for the Treatment of Glaucoma, *Invest Ophth Vis Sci*, 1995;36(4):5838.
5. Lloyd MA, Sedlak T, Heuer DK, et al., Clinical Experience with the Single-Plate Moteno Implant in Complicated Glaucomas: Update of a Pilot Study, *Ophthalmology*, 1992;99:679–87.
6. Smith SL, Starita RJ, Fellman RL, Lynn JR, Early Clinical Experience with the Baerveldt 350-mm2 Glaucoma Implant and Associated Extraocular Muscle Imbalance, *Ophthalmology*, 1993;100(6):914–18.
7. Ishida K, Netland PA, Costa VP, et al., Comparison of Polypropylene and Silicone Ahmed Glaucoma Valves, *Ophthalmology*, 2006;113(8):1320–26.
8. Maris PJ, Ishida K, Netland PA, Comparison of Trabeculectomy with Ex-PRESS Miniature Glaucoma Device Implanted Under Scleral Flap, *J Glaucoma*, 2007;16(1):14–19.
9. Francis BA, See RF, Rao NA, et al., Ab Interno Trabeculectomy: Development of a Novel Device (Trabectome™) and Surgery for Open-Angle Glaucoma, *J Glaucoma*, 2006;15(1):68–73.