

Efficacy and Safety of Gold Micro Shunt Implantation to the Supraciliary Space in Patients With Glaucoma

A Pilot Study

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Purpose: To evaluate the safety and efficacy of Gold Micro Shunt (GMS) implantation to the supraciliary space in patients with glaucoma.

Methods: A total of 38 patients with glaucoma with uncontrolled intraocular pressure (IOP) underwent implantation of the GMS in this prospective 2-center study.

Main Outcome Measures: Intraocular pressure and surgical complications.

Results: A total of 38 patients with glaucoma participated. The mean follow-up time was 11.7 months. The IOP decreased a mean (SD) of 9 mm Hg from 27.6 (4.7) to 18.2 (4.6) mm Hg ($P < .001$). Surgical success was

achieved in 30 patients (79%) (IOP >5 and <22 mm Hg, with or without antiglaucoma medication). Eight patients had mild to moderate transient hyphema.

Conclusions: Implantation of GMS to the supraciliary space is a safe and effective method of controlling IOP in patients with glaucoma. Use of the GMS resulted in a significant decrease in IOP.

Application to Clinical Practice: The GMS could be an alternative surgical device to standard trabeculectomy.

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THE ACCEPTED SURGICAL approaches for treating glaucoma are filtration procedures such as trabeculectomy, implants connecting the anterior chamber (AC) to the subconjunctival space. Such procedures are considered effective in many cases,¹⁻⁴ but require the formation of a filtering bleb and, as a consequence, are associated with a variety of complications, mostly related to filtration bleb formation (which is closely associated with their success).^{5,6} Complications such as shallow AC, bleb leaks with hypotony, endophthalmitis, and subconjunctival fibrosis that indicate failure of intraocular pressure (IOP) control are among the most common.¹ As a result, there is a great deal of effort under way to design a safe “blebless” procedure that will be less prone to these complications and will not rely on conjunctival manipulation or integrity to form a bleb. Even procedures like nonpenetrating deep sclerectomy and viscocanalostomy require the opening of the inner wall of the Schlemm canal. Such ruptures of the inner wall have been reported after viscocanalostomy in monkeys⁷ and may explain the communica-

tion with the AC and functioning blebs detected in such cases.

Uveoscleral outflow is an alternative aqueous outflow route accounting for 10% to 15% of flow in the human eye.^{8,9} Spaces within the ciliary muscle, along with the suprachoroidal space and scleral vessels, take part in this outflow, which can be increased with drugs such as atropine¹⁰ and prostaglandin analogues¹¹ or surgery such as cyclodialysis.¹² Cyclodialysis has been abandoned by most ophthalmologists because of a high rate of complications such as hyphema, hypotony, cataract formation, and suprachoroidal hemorrhage. In addition, cyclodialysis cleft closure accounted for severe pressure spikes in many patients.¹³

It has been reported¹⁴ that there is a 1- to 5-mm Hg natural pressure differential between the AC and the suprachoroidal space. Emi et al,¹⁴ in their study of nonglaucomatous cynomolgus monkeys, report that a change in IOP produced a corresponding change in suprachoroidal space pressure when the AC and the suprachoroidal space were connected by cannulation. It is therefore assumed that communication between the AC and the suprachoroidal space should reduce IOP. Such attempts have been described using a silicone tube.¹⁵

In this study we describe the results from a novel approach that enhances uveoscleral outflow to reduce IOP in patients with glaucoma. This concept involves implantation of an ultrathin 24-karat (K) gold shunt that contains tubules to facilitate aqueous flow between the AC and the supraciliary/suprachoroidal space without the creation of a bleb.

Gold is known to be biocompatible, with no known long-term toxicity in the human eye.¹⁶ Implantation of the Gold Micro Shunt (GMS) in rabbits was found to be safe, with high biocompatibility of the gold.¹⁷ This shunt is implanted through a scleral incision and dissection, with placement in the suprachoroidal space and the AC to create aqueous flow between the compartments.

The design of the GMS, the surgical procedure, and the results of the pilot study evaluating the efficacy and safety of the device are presented.

METHODS

SHUNT DESIGN

The GMS (SOLX Ltd, Boston, Massachusetts) is a nonvalved flat-plate drainage device made from 24-K medical-grade (99.95%) gold. The shunt is 3.2 mm wide, 5.2 mm in length, and 44 μm thick. It has a long rectangular shape, with rounded edges and fin-like tabs on the distal end for anchoring the device in the suprachoroidal space. The proximal end provides the ingress for aqueous humor. The distal end provides drainage through the microchannels of the fluid from the AC into the suprachoroidal space. The current design of the GMS contains 19 tubules, of which 10 are closed and 9 are open, with a lumen width of 24 μm and height of 50 μm .

The posterior end of the shunt contains a grid of 117 holes 110 μm in diameter on each side of the implant to allow fluid to flow from the device. On the anterior end there are 60 holes 100 μm in diameter and one 300- μm through-hole that allows flow into the device. The proximal end contains 12 additional 50- μm lateral channels for increased flow, and the distal end contains 10 similar channels for the same purpose. A detailed schematic drawing of the GMS is shown in **Figure 1**.

CLINICAL STUDY

The aim of the clinical study was to evaluate the efficacy and safety of the GMS in patients with glaucoma. All patients signed an informed consent form to participate in the study.

The inclusions criteria were (1) age of 21 years or older (both men and women were included); (2) 1 or both eyes diagnosed with primary open-angle glaucoma, pseudoexfoliation glaucoma, pigmentary dispersion, or uveitic glaucoma; (3) ability and willingness to return for up to 24 months of scheduled visits; (4) an average baseline IOP of 22 mm Hg or more while on maximally tolerated medical treatment; (5) at least 60 days since prior incisional glaucoma surgery; and (6) visual field defect (mean deviation [MD] score, <0 dB on the Swedish Interactive Threshold Algorithm [SITA] Standard 24-2 Humphrey analysis).

The exclusion criteria were (1) either eye with best-corrected visual acuity worse than counting fingers; (2) being on a systemic corticosteroid (prednisone) regimen of more than 5 mg/d; (3) intolerance to gonioscopy, slitlamp examination, tonometry, or other study procedures; (4) mental impairment conflicting with informed consent or follow-up; (5) pregnancy; (6) known sensitivity to medication needed during and after surgery; (7) significant comorbid disease that may interfere with follow-up; (8) currently using any other investiga-

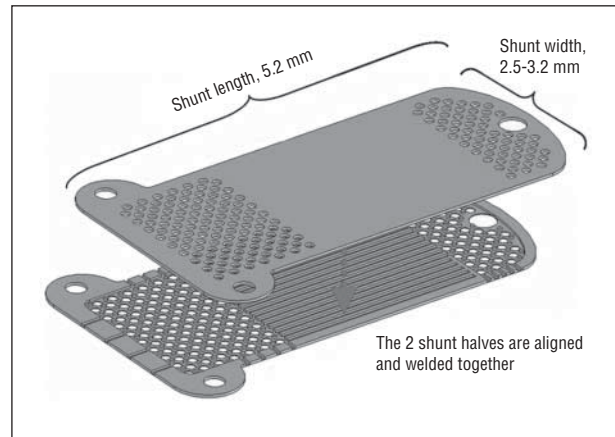


Figure 1. Schematic drawing of the Gold Micro Shunt (GMS), with the shunt dimensions used in the current study. The GMS consists of 9 open tubules and 10 closed tubules of 24 \times 50 μm .

tional drug or device; and (9) the intended study eye not having a history of acute angle closure glaucoma within the past 12 months, evidence of significant ocular disease other than glaucoma or cataract, a history of previous ocular surgery (except glaucoma, cataract, or cosmetic), active clinical ocular infection requiring treatment, a nonglaucomatous ocular condition likely to require surgery during study, or all quadrants unavailable owing to significant scarring or prior implant.

The study was approved by each of the local institutional review boards in Israel and Spain and conformed to all parts of the Helsinki Agreement.

Preoperative evaluation included visual acuity, slitlamp biomicroscopy, IOP measurement with a Goldmann applanation tonometer, ophthalmoscopy after pupil dilation, gonioscopy, and visual field analysis when applicable (24/2 program, Humphrey Field Analyzer HFA II-I; Carl Zeiss Inc, Jena, Germany). If the average of 2 IOP measurements was more than 22 mm Hg and the patient met the inclusion criteria, implantation of the GMS was performed as described. Each procedure was video recorded.

Patients were examined after 3 hours, 1 day, 1 week, 3 months, 6 months, and 1 year postoperatively. At 1 day or 1 week after surgery, a 20-MHz ultrasound examination and anterior segment optical coherent tomography (AS-OCT) (Visante OCT; Carl-Zeiss Inc) were performed to evaluate the exact position of the implant. Slitlamp photography and gonioscopy photographs were also taken and recorded in selected patients. Ophthalmoscopy with pupil dilation was performed after 1 day and 3, 6, and 12 months after surgery. When applicable, visual fields were performed within 3 months before surgery and then 6 months and 1 year after surgery.

GOLD SHUNT SURGICAL TECHNIQUE

Patients were operated on under local anesthesia using either a sub-Tenon or a peribulbar injection. A bridle suture was placed around the superior rectus muscle; alternatively, a corneal traction suture was placed at 12 o'clock. A fornix-based conjunctival flap was fashioned, followed by meticulous cautery of episcleral vessels. A 4-mm, full-thickness, scleral incision was created that was located 2 mm posterior to the limbus to expose the supraciliary space. Following the placement of an AC maintainer via a peripheral paracentesis, the AC was entered at a plane of 90% scleral thickness using a crescent knife and careful dissection to avoid cyclodialysis. Dissection was then continued posteriorly into the suprachoroidal space for 2 to 3 mm using the same crescent blade or blunt spatula.

Table. Demographics of 38 Patients With Glaucoma Who Underwent Gold Micro Shunt Implantation

| | Mean (SD) Value [Range] n = 38 |
|---------------------------|-----------------------------------|
| Age, y | 67 (10) [45-81] |
| Sex | |
| Male | 15 (40) |
| Female | 23 (60) |
| Glaucoma type | |
| Primary open-angle | 25 (66) |
| Aphakic | 2 (5.3) |
| Pseudoexfoliation | 4 (10.5) |
| Pigmentary | 1 (2.6) |
| Uveitic | 4 (10.5) |
| Other | 2 (5.2) |
| Lens status | |
| Phakic | 7 (18.4) |
| Pseudophakic | 26 (68.4) |
| Aphakia | 5 (13.2) |
| Previous glaucoma surgery | |
| Trabeculectomy | 12 (32) |
| Glaucoma drainage device | 3 (8) |
| Laser trabeculoplasty | 6 (16) |
| Follow-up, mo | 11.7 (1.3) [6-12] |

Next, the anterior segment of the GMS was introduced into the AC and the posterior segment was placed into the suprachoroidal space, making certain that the implant was placed posteriorly so 1 to 1.5 mm of the GMS was visible in the AC. In case of leakage from the scleral dissection, two 10-0 nylon sutures were used to close the wound tightly. Leakage through the scleral wound was detected by evaluating the rate of flow of balanced salt solution through the anterior chamber maintainer into the AC and out through the wound. Only 2 cases did not require suturing of the scleral wound, as no leaking fluid was detected after positioning of the GMS. In all other cases, suturing was required and the conjunctiva was closed with 10-0 nylon sutures. The eyes were patched at the end of the procedure. All eyes were treated with Dexamethasone-Neomycine eye drops 4 times daily postoperatively for at least 2 weeks.

STATISTICAL ANALYSIS

The paired samples *t* test was used to calculate differences in visual acuity, IOP, and antiglaucoma medications preoperatively and postoperatively in all patients. The Wilcoxon signed ranks test was used to compare the visual field MD index preoperatively and postoperatively. Conversion of Snellen visual acuity to the logarithm of minimal angle of resolution was performed. The last follow-up data were compared with the baseline values in all parameters including visual acuity, IOP, and antiglaucoma medications.

Surgical success was defined as an IOP greater than 5 mm Hg and less than 22 mm Hg, with or without antiglaucoma medication. Complete success was defined as an IOP between more than 5 mm Hg and less than 22 mm Hg without antiglaucoma medications.

Statistical analysis was carried out using SPSS version 13.0 (SPSS Inc, Chicago, Illinois) programs.

RESULTS

Thirty-eight patients with glaucoma with uncontrolled IOP under maximally tolerated medical treatment and/or

after failed trabeculectomy or glaucoma drainage device participated in the study (23 women [60%]; mean [SD] age, 67 [10] years). Twenty-five patients (66%) had primary open-angle glaucoma. Twenty patients (53%) had previous glaucoma surgery or a glaucoma drainage device. Demographics of the study population are summarized in the **Table**. The mean follow-up was 11.7 (1.3) months (range, 6-12 months).

POSTOPERATIVE EVALUATION OF GOLD SHUNT

In most patients, slitlamp and gonioscopic photography indicated good position of the device in the AC (**Figure 2**); only 3 patients missed photography, owing to technical reasons. In all eyes operated on, 20-MHz ultrasound biomicroscopy confirmed the implant position in the suprachoroidal space with hypoechogenic space around the tail of the device (**Figure 3**). Anterior segment OCT disclosed a spongy appearance of the sclera above the plate that may suggest fluid absorption (**Figure 4**). In a few cases, a comparison was performed with the sclera in the nonoperated region (of the same eye) in which these findings could not be detected (**Figure 5**).

Postoperatively, IOP decreased a mean (SD) of 9 (7.5) mm Hg from 27.6 (4.7) to 18.2 (4.6) mmHg in the last follow-up visit ($P < .001$, paired samples *t* test; this was an average decrease of 32.6% from baseline) (**Figure 6**). The mean (SD) IOP at day 1, week 1, months 1, 3, and 6, and the last follow-up were 12.5 (7.2), 18.1 (6.7), 19.7 (5.9), 19.7 (6.5), 18.5 (5.4), and 18.2 (4.6) mm Hg, respectively. The mean (SD) number of antiglaucoma medications decreased from 2.0 (0.8) preoperatively to 1.5 (1.0) postoperatively in the last follow-up visit ($P = .02$, paired samples *t* test). Visual acuity remained unchanged (average visual acuity, 20/50 preoperatively and at last follow-up).

Surgical success (defined as an IOP greater than 5 mm Hg and less than 22 mm Hg with or without antiglaucoma medications in the last follow-up) was achieved in 30 patients (79%) (**Figure 7**). Complete success (defined as an IOP > 5 and < 22 mm Hg without antiglaucoma medication in the last follow-up) was achieved in 5 patients (13.2%). Two-thirds of the patients still used some form of antiglaucoma medication to achieve adequate IOP control.

Visual field remained unchanged, with an MD (SD) of 12.5 (7.9 and 6.7) dB preoperatively and postoperatively ($P = .55$, Wilcoxon signed rank test).

Complications included shunt exposure in 1 patient (3%); synechia formation, 1 patient (3%); mild hyphema, 6 patients (16%); moderate hyphema, 2 patients (5%); and exudative inferior retinal detachment, 1 patient (3%). The last patient had an IOP of 8 mm Hg, with low visual acuity of finger counting preoperatively and postoperatively; he declined further treatment.

COMMENT

Implantation of the GMS into the supraciliary space was found to be safe and effective. The surgical technique had

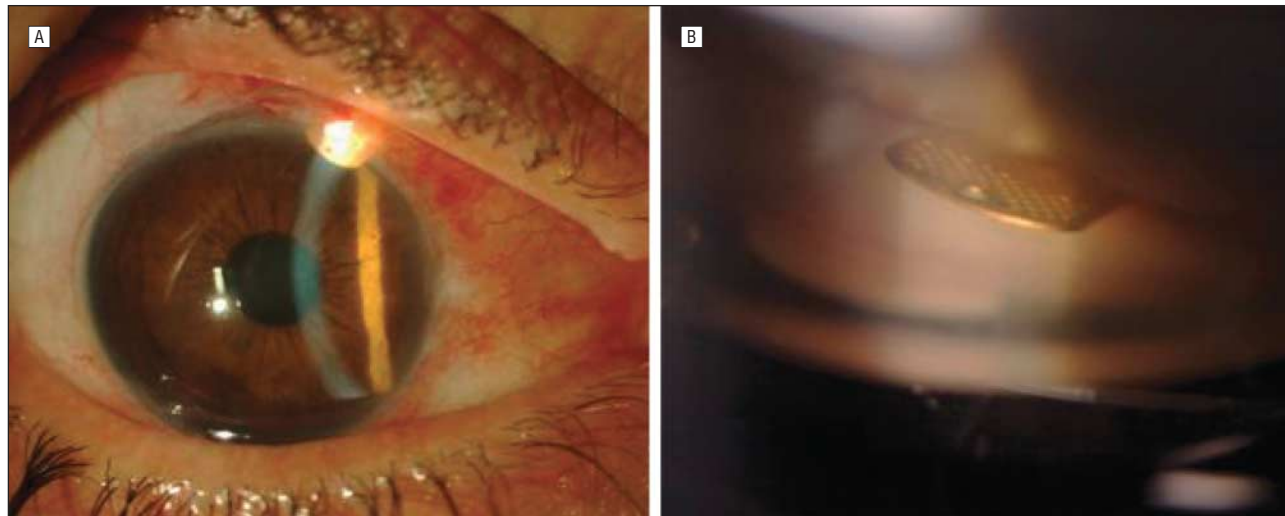


Figure 2. Postoperative clinical image of a patient after Gold Micro Shunt implantation. Note the good position of the shunt in the anterior chamber (A), with no shunt-corneal or shunt-iris touching, as seen in the gonioscopic view (B).

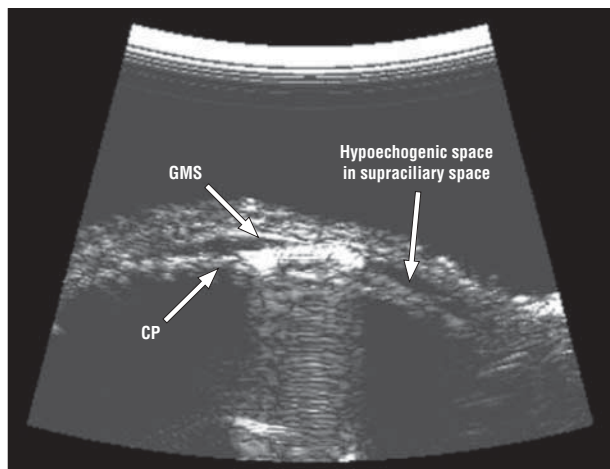


Figure 3. Ultrasound biomicroscopy 20-MHz ultrasound of the Gold Micro Shunt (GMS) in the suprachoroidal space. Note the hypoechoic space around the shunt implying aqueous humor flow. CP indicates ciliary processes.

no major intraoperative or postoperative complications. Verification of GMS position in the suprachoroidal space was confirmed in all cases by ultrasound and anterior segment OCT. The literature regarding gold toxicity is scarce; however, based on our experience using the GMS, the gold is inert to the human eye and is not associated with any exceptional inflammatory response.

The mechanism of IOP reduction by GMS is yet to be determined. Although no measurements of uveoscleral flow were performed, it is our assumption that increased uveoscleral outflow through the suprachoroidal space is the main mechanism for IOP reduction in this procedure. The hypoechoic space around the device detected by 20-MHz ultrasound and AS-OCT may suggest increased flow through the supraciliary and suprachoroidal space. From there, aqueous humor can drain into the choroidal vascular system or permeate through the sclera. Analysis performed with AS-OCT disclosed a spongy appearance of the sclera that may suggest in-

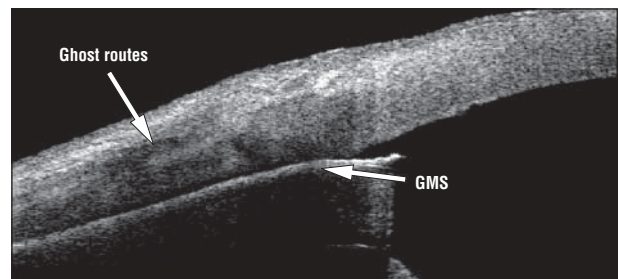


Figure 4. Anterior segment optical coherence tomography showing the Gold Micro Shunt (GMS) in the suprachoroidal space. Note the spongiform appearance of the sclera, suggesting aqueous humor flow.

creased scleral permeability for aqueous flow. In scleral tissues *in vitro*, such an increase of scleral permeability has been described by Kim et al¹⁸ and Lindsey et al¹⁹ following the application of prostaglandin analogues that are known to increase uveoscleral outflow. However, we did not evaluate the contribution of each process to the mechanism of IOP reduction in our cases.

Despite the fact that our technique of entry into the AC over a thin scleral plane was designed to prevent or minimize a cyclodialysis effect, we cannot rule out that some contribution of a cyclodialysis effect did occur. However, we have not encountered any of the complications reported after cyclodialysis: persistent hypotony, suprachoroidal hemorrhage, Descemet membrane detachment, and closure of the cyclodialysis cleft associated with IOP spikes. Also, gonioscopy did not reveal a cyclodialysis cleft in any of the operated eyes. In the unlikely case of a cyclodialysis effect contribution, it is likely that the presence of the gold shunt would prevent closure of the cyclodialysis cleft, thereby eliminating the possibility of postoperative IOP spikes. In addition, we encountered only one case of shunt exposure that required explanation. We believe the shunt design with the 2 tabs extending sideways anchors the shunt very firmly in the supraciliary space.

Other investigators have explored the use of a device to facilitate aqueous flow from the AC to the suprachor-

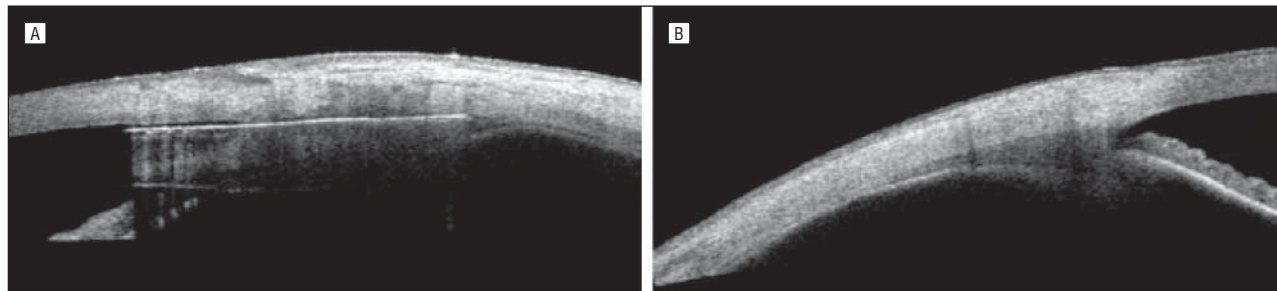


Figure 5. Anterior chamber optical coherence tomography of a Gold Micro Shunt (A) and of the opposite region in the same eye (B). Note the spongy appearance is missing in part B.

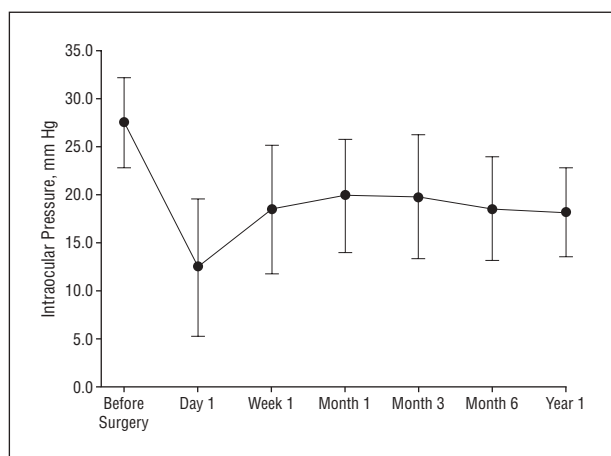


Figure 6. Mean (SD) intraocular pressure over time (12 months) in 38 patients with glaucoma who underwent Gold Micro Shunt implantation. A total of 36 patients (95%) completed the 1-year follow-up.

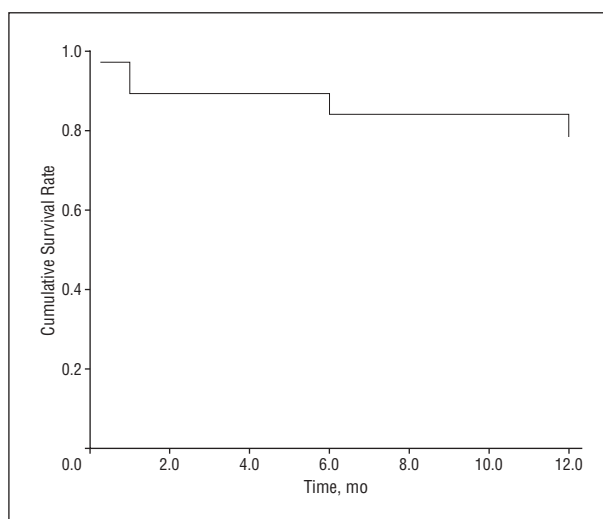


Figure 7. Kaplan-Meier survival analysis of surgical success in 38 patients with glaucoma who underwent Gold Micro Shunt implantation. Surgical success was defined as an intraocular pressure greater than 5 and less than 22 mm Hg, with or without antiglaucoma medication.

roidal space. Nesterov and Kolesnikova²⁰ implanted a scleral strip into the suprachoroidal space in patients with glaucoma. Jordan et al¹⁵ described implantation of a silicone tube from the AC into the suprachoroidal space. They reported a success rate of 71% in 51 patients after 12 to 23 months of follow-up, with only mild hyphema in 20% of cases and no major complications.

Despite the fact that more than 50% of the eyes in this series had at least one failed trabeculectomy, glaucoma drainage device, or laser trabeculectomy, it is encouraging that patients with a GMS achieved a decrease in IOP of more than 30%. Previous studies described similar decreases in IOP using the Ahmed Glaucoma Valve.²¹⁻²³

Our new methodology of using a thin 24-K gold device may offer some additional advantages: (1) no filtration blebs were detected in any of the patients with a GMS, thereby avoiding bleb-associated complications; and (2) gold is an inert metal, and the GMS was found to be well tolerated by the human eye. Previous studies of GMS implantation into the rabbit eye confirmed that the device was safe and did not trigger any inflammatory response in adjacent tissues.¹⁷

Immediately after surgery, in all cases without hyphema, there was minimal flare and cells in the AC typically resolved within a few days. In some cases, conjunctival congestion localized to the surgical site was evident, but this also disappeared within days after surgery. Some patients experienced slight dis-

comfort (mild stinging and burning), while most patients had no concerns at all. Eight patients had mild to moderate hyphema that resolved spontaneously within 1 to 2 days in all cases, and none required additional anterior segment surgery.

In summary, our preliminary experience with GMS implantation into the supraciliary space in patients with uncontrolled glaucoma is very encouraging. The procedure was found to be safe and well tolerated. Reduction of IOP was satisfactory for this group of patients with advanced glaucoma.

A large multicenter study that will evaluate this procedure in patients with all types of glaucoma and compare it with other routinely used implants is under way. Such a study will help to better define the role of this new methodology in glaucoma therapy.

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Financial Disclosure: Drs Melamed and G. Simon report being paid consultants for Solx.

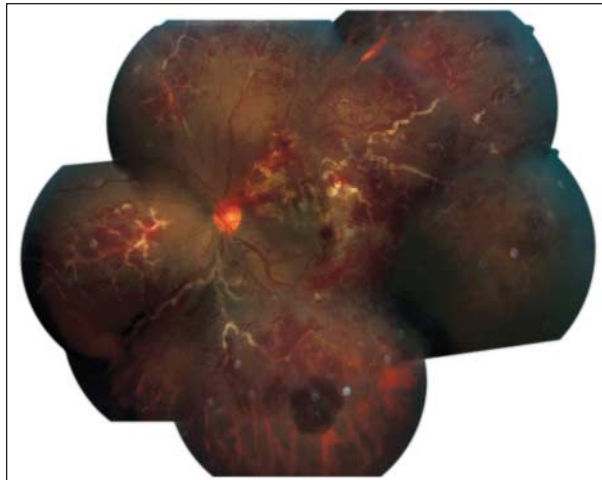
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Ophthalmic Images

Sarcoid Retinal Vasculitis

Christopher T. Hood, MD; Careen Y. Lowder, MD, PhD



A 21-year-old man with sarcoidosis had a 3-day history of visual loss in his left eye. Dilated funduscopy examination revealed extensive retinal periphlebitis associated with intraretinal hemorrhages. A diagnosis of retinal vasculitis secondary to sarcoidosis was made.