

Handling refractory glaucoma

Gold microshunt implantation may be an option for lowering IOP

Study showed a mean pressure reduction of 34% from baseline at 18 months

By Nancy Groves

Reviewed by Shlomo Melamed, MD

Chicago—Glaucoma patients whose condition is nonresponsive to traditional therapies may have another treatment option, the gold microshunt (GMS) from SOLX. Outcomes of a study of the novel implant placed in the supraciliary space, which were conducted at sites in Israel and Spain, showed that 61% of patients had achieved IOP reduction of 30% or more by 6 months, with a mean reduction of 34% at 18 months after implantation.

“The outcome so far looks very promising,” said Shlomo Melamed, MD, director of the Sam Rothberg Glaucoma Center, Goldschleger Eye Institute at Sheba Medical Center, Tel-Hashomer, Israel, one of the principal investigators. More than 70 cases have been performed, and investigators are very encouraged by the results, he added.

In the study presented in a poster at the American Academy of Ophthalmology annual meeting, unpaired glaucomatous eyes

Take-Home Message

Implantation of a gold microshunt (SOLX) in the eyes of patients with refractory glaucoma resulted in a mean reduction in IOP of 34% at 18 months. Findings from this study of 60 patients were promising, investigators reported. The device has received the CE mark in Europe, and FDA trials are being planned.

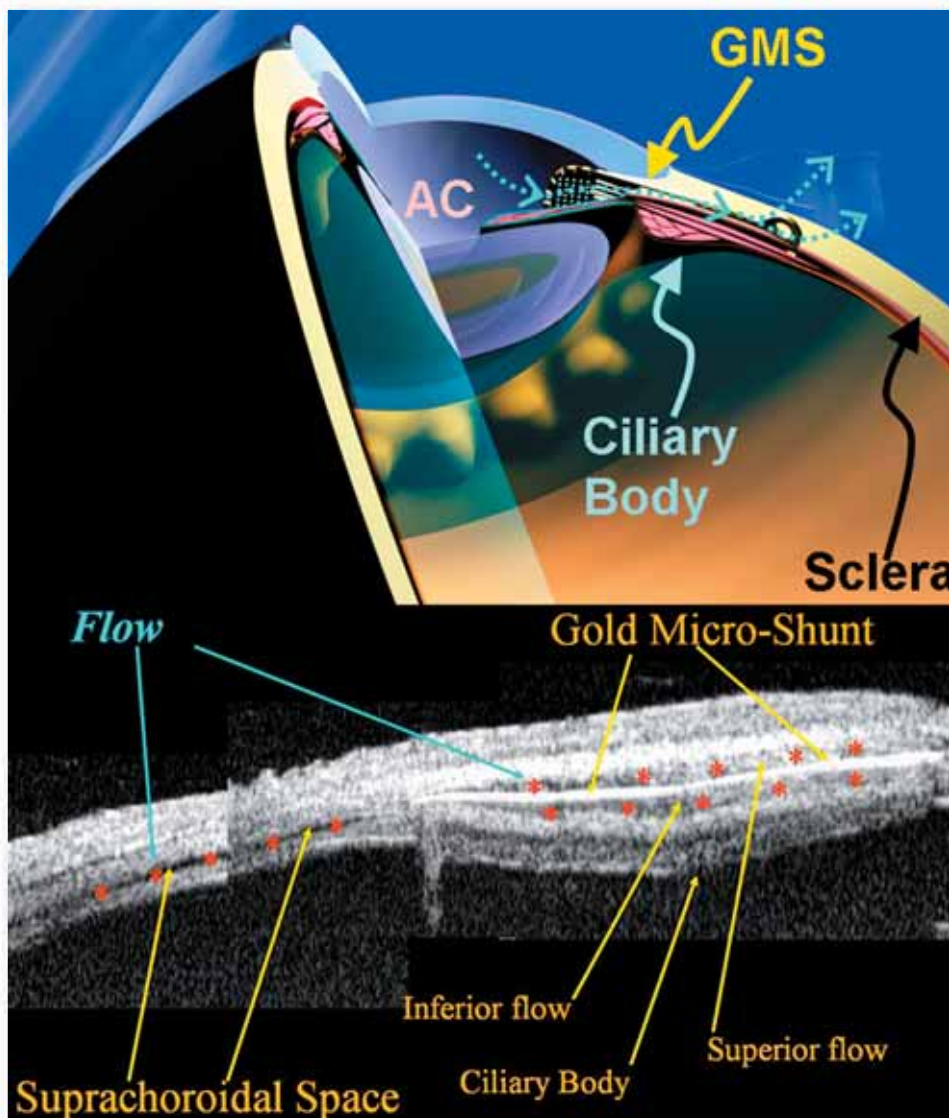


Figure 1 The gold microshunt (GMS) is implanted in the supraciliary space to enhance aqueous outflow between the anterior chamber (AC) and the suprachoroidal space.

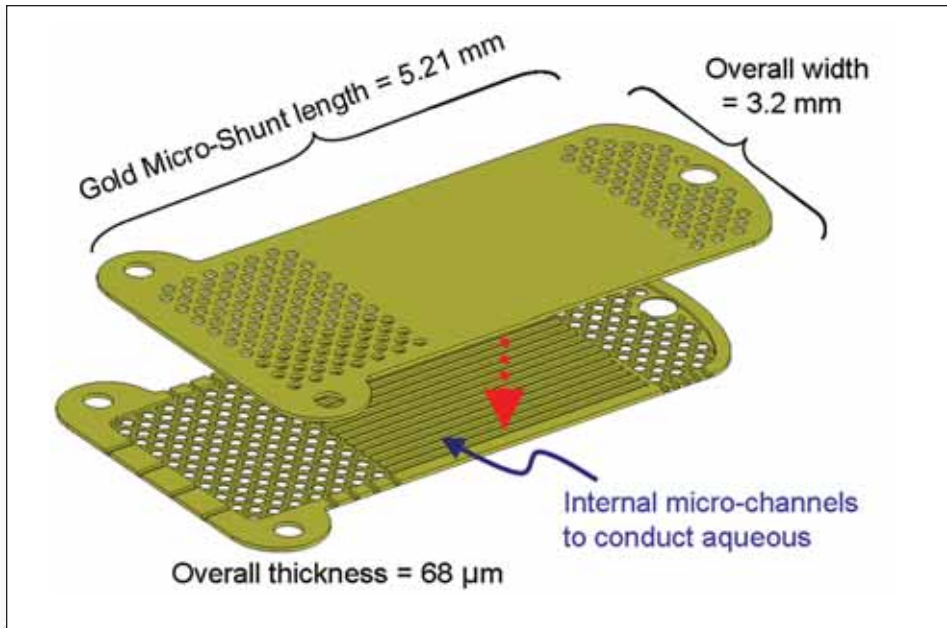


Figure 2 The gold microshunt (GMS) measures 5.21 mm long, 3.20 mm wide, and 45 μm thick. It has 19 internal channels, which direct flow from the anterior end to the distal (suprachoroidal) end. (Figures courtesy of SOLX Inc.)

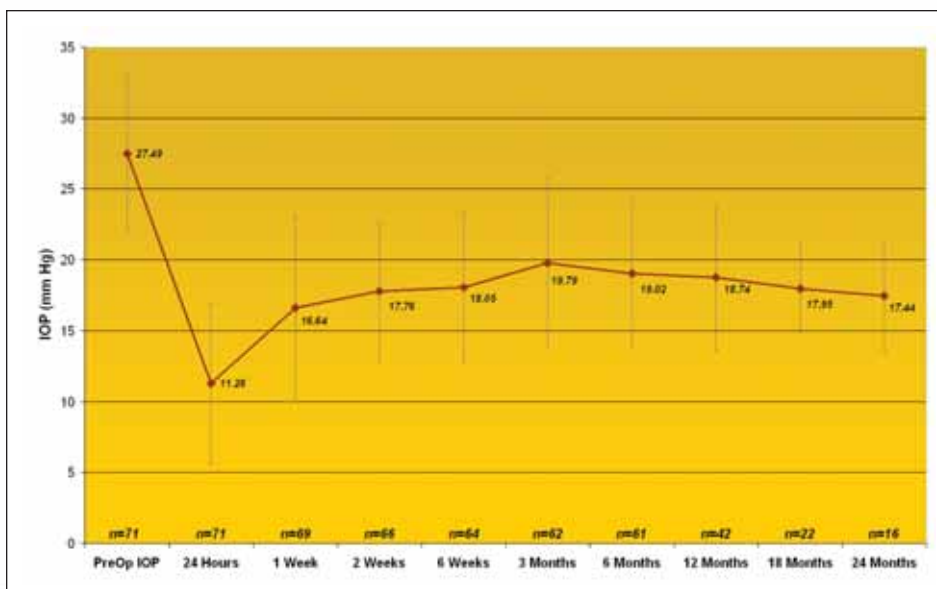
of 60 patients, ages 23 to 85, had the GMS implanted. The mean preoperative IOP was 27.72 mm Hg (n = 60), and the mean postoperative IOP at 18 months was 18.38 mm Hg (n = 8). The IOP reduction attained with the GMS stabilized at 6 weeks and reached 34% at 18 months.

Refractory cases

All cases involved refractory glaucoma, and

most patients had already undergone various procedures, such as trabeculectomy, implantation of an Ahmed valve, or laser cyclophotocoagulation.

During the follow-up phase of the study, patients received an ocular examination and Goldmann applanation tonometry at 24 hours, 1 week, 2 weeks, 3 weeks, 6 weeks, 3 months, 6 months, 12 months, and 18 months. An ultrasound study was performed



DeepLight Gold Micro-Shunt eyes treated and IOP measurements. (Figures courtesy of SOLX Inc.)

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within 1 week of surgery to verify that the GMS was properly positioned in the supraciliary space.

Glaucoma medication was discontinued following surgery but could be resumed at the physician's discretion. The average number of medications taken postoperatively was 1.06 ± 0.77 versus 2.0 ± 0.66 preoperatively.

In addition, a bench flow study was conducted using an artificial anterior chamber, and ADINA finite-element software was used to model the GMS' flow resistance and verify results of the flow test. In bench testing, the GMS flow resistance was similar to the simulated resistance.

All eyes tolerated the shunt well, and the procedure was easy to perform. "We did not see severe complications," Dr. Melamed said. "We were afraid at the beginning that dissection just above the ciliary body into the supraciliary space would be associated with bleeding and suprachoroidal hemorrhage. That has not happened in any of the cases so far. The eyes are very quiet. Immediately after the operation it looks as if the eyes had not been operated on because apparently the eye can tolerate the gold very nicely."

Seven cases of transient hypotony and 18 cases of transient hyphema occurred, all of which were less than 2 mm and resolved without further complications. One case of shunt extrusion was reported due to improper placement.

Study results indicate that pressure may fluctuate slightly, but in general the eye tolerates the device very well. For the first few days, the pressure may be so low that it is close to hypotony levels, but it tends to go back up and plateau between approximately 15 and 20 mm Hg, Dr. Melamed said.

The study was performed at the Sam Roth-



berg Glaucoma Center in Israel and the Gabriel Simon Ophthalmic Institutes in Barcelona and Madrid, Spain. A poster on the study was presented at the American Academy of Ophthalmology meeting, and a paper is in progress.

The GMS consists of two layers of electroplated 24-karat gold containing internal micro-channels to facilitate aqueous outflow and reduce IOP. The device is 5.21 mm long, 3.20 mm wide, and 45 μm thick. The 19 channels (24 μm by 50 μm by 2.21 mm long) direct flow from the anterior end to the distal or suprachoroidal end. The device has inlet and egress holes on each end and fin-like tabs on the posterior end to permit anchoring during implantation.

The device takes advantage of the gradient in the IOP difference between the anterior chamber and the supraciliary space to force the flow through the shunt, expanding the uveoscleral outflow, Dr. Melamed said.

The approach of communicating between the anterior chamber and the supraciliary space

has been attempted before through cyclodialysis, but that is a very aggressive procedure associated with complications such as bleeding, closure of the cyclodialysis cleft, and pressure spikes, he added. Implanting the GMS in the supraciliary space achieves a more controlled form of cyclodialysis without extended hypotony.

Dr. Melamed noted that trabeculectomy is the gold standard in glaucoma surgery, but this procedure is associated with many complications, such as hypotony, shallow anterior chamber, vitreous bleb leaks, and endophthalmitis. Because of these and other problems, many physicians are looking for a blebless operation.

"We strongly believe that the idea of implanting this miniature device may save the day and minimize most of the complications of trabeculectomy," Dr. Melamed said.

CE Mark approval

The GMS was awarded the CE Mark in October 2005. The FDA has given SOLX approval

to conduct a randomized study comparing the GMS with the Ahmed valve, and a large, multicenter, international trial is under way. A separate study of implantation of the GMS in patients with angle-closure glaucoma is also planned.

Studies are also necessary to determine the efficacy of the GMS in conjunction with the Ti-Sapphire laser, which would enable clinicians to perform phototitration for further controlled reduction of IOP, Dr. Melamed said.

As SOLX moves ahead with studies and clinical trials, the company is also modifying the device based on previous results. "There is room for improvement. There is no question about that," Dr. Melamed said. One adaptation will be that GMS devices implanted in eyes with IOP > 30 mm Hg will have channels 60 μm in diameter rather than 30 μm .

"We believe a larger flow through the 60- μm diameter will allow better control of the higher pressures, but it remains to be seen whether we are right," Dr. Melamed added.

In addition, the device can now be implanted either through the sclera or the cornea. Most cases done so far have been through the cornea, but the scleral approach, which may be easier, will be further tested in upcoming trials. \square

FYI

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The study was provided by SOLX, a privately held company based at the Boston University Photonics Center.



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