

# Ophthalmology Times<sup>®</sup>

All the Clinical News In Sight

## Special Section: Glaucoma

### Pilot study

## Micro-shunt, laser duo a novel glaucoma therapy

### Opening channels of drainage device can regulate aqueous flow for long-term IOP control

By Nancy Groves

Reviewed by Gabriel Simon, MD, PhD

Washington, DC—In a pilot study involving three centers, patients with mostly end-stage glaucoma were able to achieve an average IOP reduction of 12 mm Hg after implantation of an ultrathin gold micro-shunt (GMS). Patients were followed for up to 2 years.

The drainage device contains numerous microtubular channels that control the flow of the aqueous humor from the anterior chamber into the natural drainage pathway of the suprachoroidal space. The micro-shunt is one component of the investigational DeepLight Glaucoma Treatment System (SOLX), which also includes a long-wavelength, deep-penetrating titanium sapphire laser.

“When the two devices are used in combination, an additional reduction of 1 to 3 mm Hg can be achieved for each additional microtubular channel on the shunt opened with the laser,” said Doug Adams, president and chief executive officer of SOLX, a privately held company that is part of the Photonics Center at Boston University. “We think that we have another 10 mm Hg of potential reduction in IOP available to the doctor and the patient at some other point in time.”

Ten of the 20 channels on the GMS are open upon implantation, with each representing about a 1-mm Hg reduction in IOP when functioning.

Titration to lower levels is accomplished by activating additional channels with the laser.

“In 3, 4, or 5 years from now, rather than adding that second, third, or fourth medication or whatever the number may be, the surgeon can open up another channel and try to get incremental reduction in IOP without adding medication,” Adams explained.

**The shunt is also novel because it allows surgeon control of the amount of fluid that flows from one area to another, a feat made possible in part by the selection of gold for its construction.**

### Study outcomes

Outcomes from the pilot study of the GMS were based only on treatment with the shunt as initially implanted, with 10 channels open.

All 59 eyes had no longer responded to maximal medical therapy and had at least one failed surgical intervention. The mean best-medicated IOP before treatment with the shunt was 28.12 mm Hg. At 24 months, the mean medicated IOP was 18 mm Hg.

Patients, who were treated at sites in Spain and Israel, were typically treated with maintenance therapy of at least one medication following implantation of the micro-shunt.

In a separate study, the laser was used to open additional channels in the shunt in five eyes of patients who had the device im-

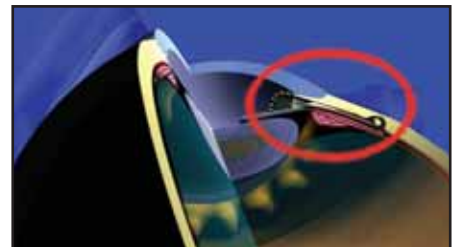


Illustration shows a Gold Micro-Shunt in place between the anterior chamber and the suprachoroidal space.

planted 12 months earlier. This action resulted in an average drop of an additional 5 mm Hg of IOP, Adams said.

### Investigational devices

The DeepLight Glaucoma Treatment System consists of a 790-nm titanium sapphire, flashlamp-excited, solid-state laser and a 24-karat gold biocompatible implant that creates a conduit between the anterior chamber and the suprachoroidal space to reduce IOP.



Both the micro-shunt and the laser are classified as investigational devices and can be used individually or together as a treatment system. The SOLX system has been in development for about 5 years, but no data have been released until recently.

Robert M. Kershner, MD, MS, FACS, pre-

### Take-Home Message

A pilot study of an ultrathin gold micro-shunt has shown that it can reduce IOP an average of 12 mm Hg over 2 years and that phototitration of channels on the shunt with a titanium sapphire laser could achieve further reductions. The micro-shunt and laser are components of the DeepLight Glaucoma Treatment System from SOLX.

sented a paper on a pilot study of the GMS at the American Society of Cataract and Refractive Surgery annual meeting in Washington, DC. Co-author Gabriel Simon, MD, PhD, of Madrid, Spain, director of ophthalmic research at SOLX, and SOLX's Adams later discussed the pilot study and the treatment system in more detail. Dr. Simon leads the SOLX scientific team that includes researchers in Israel, Europe, the United States, and Canada and is a professor of biomedical engineering at Boston University.

"The shunt is a new concept in glaucoma," Dr. Simon explained. "We are using a very small shunt that connects the anterior chamber with the suprachoroidal space, so we are draining aqueous inside the eye. We don't have any bleb on the outside."

Studies have shown a difference of about 5 mm Hg in pressure between the anterior chamber and the suprachoroidal space, and that is the scientific basis behind fluid flow and fluid mechanics in the shunt, Adams said.

However, it is constructed to allow fine-tuning of the channels so that pressure can be lowered incrementally rather than abruptly dropping to zero when the anterior chamber is opened, Dr. Simon said. If pressure dropped too low, the laser could be used at a lower energy level to close some of the channels.

The GMS is a flat plate that is approximately 5.2 mm long and 3.2 mm wide with a thickness of 60  $\mu\text{m}$ , about half the width of a human hair. The shunt is implanted through a single subscleral microincision with a special insertion tool provided by SOLX in a procedure that typically can be performed in less than 15 minutes. The shunt can be inserted through clear cornea, open sky, or sublimbal methodologies, although the clear cornea incision has been most frequently used during early studies of the device.

The shunt is also novel because it allows surgeon control of the amount of fluid that flows from one area to another, a feat made possible in part by the selection of gold for its construction. Gold is an inert biocompatible material that minimizes tissue ingrowth or protein adherence that could cause blockage of aqueous flow, Dr. Simon explained.

The GMS is made of 99.95% pure gold. Unlike gold implants used experimentally decades ago, it does not contain copper and therefore is nontoxic.

Gold is also a perfect chromophore for the 790-nm wavelength of the titanium sapphire DeepLight laser, Dr. Simon added. Since gold absorbs the light at this wavelength rather than reflecting it, the laser is ideal for titration of the microtubules in the shunt.

This fact was discovered accidentally during laboratory experiments, and after doing further research, investigators realized that the laser and shunt, originally intended for separate uses, could also be used jointly to achieve greater pressure reductions, Adams said.

### Long-lasting shunt

Clinical studies to date have demonstrated that the shunt is well tolerated and remains functional for up to 2 years. However, it is anticipated that it will continue to function much longer.

"We believe that the gold micro-shunt is equal to or better than existing shunts, and ideally what we would like to prove long term is that the gold micro-shunt is the ideal replacement for trabeculectomy," Adams said. "A procedure that is safer than trabeculectomy with better outcomes is the real goal."

The GMS and the insertion tool are sterile, single-use medical devices. The shunt can be removed by a trained surgeon, an action that should not prohibit administration of other standard glaucoma treatments.

The GMS should be approved for sale in the European Union by this fall. The DeepLight 790 laser has earned the CE Mark in Europe.

In the United States, the GMS is regulated by the FDA as an investigational device. In January, enrollment began for a randomized, controlled FDA clinical trial of the laser, assessing its equivalency to argon laser trabeculectomy.

Additional FDA trials will evaluate the shunt.  $\square$

### FYI

Robert M. Kershner, MD, MS, FACS, MD

E-mail: [Kershner@EyeLaserCenter.com](mailto:Kershner@EyeLaserCenter.com)

Dr. Kershner did not indicate any financial interest in any aspect of the material presented.

Gabriel Simon, MD, PhD

Phone: 011 34 915-237-575

E-mail: [gabrielsimon@dr-simon.net](mailto:gabrielsimon@dr-simon.net)

Dr. Simon did not indicate any financial interest in any aspect of the material presented.

Doug Adams

Phone: 617/353-1277

Fax: 978/443-3249

E-mail: [doug@solx.com](mailto:doug@solx.com)

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For More Information:

Web: [www.SOLX.com](http://www.SOLX.com)

Email: [info@solx.com](mailto:info@solx.com)

US Phone: 800.939.SOLX (7659)

International Phone: 001.978.717.9482