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All the Clinical News In Sight

Investigational device in United States

Titanium-sapphire laser procedure reduces IOP by 25% This method causes less thermal damage to trabecular meshwork than ALT or SLT, studies find

By Nancy Groves

Reviewed by Gabriel Simon, MD, PhD

Las Vegas—Studies of a 790-nm titanium-sapphire laser (SOLX 790, OccuLogix) used to perform trabeculoplasty in human donor eyes and in patients suggest that the laser may be an important tool for treatment of open-angle glaucoma due to benefits such as an IOP-lowering effect, low complication profile, and ability to repeat treatment periodically, according to Gabriel Simon, MD, PhD. He presented a poster on the findings of his research here at the annual meeting of the American Academy of Ophthalmology in Las Vegas.

Dr. Simon and colleagues demonstrated that the laser provides clinically significant reduction of IOP of approximately 25% for up to 12 months following treatment. The titanium-sapphire laser also causes less thermal damage in the trabecular meshwork than argon laser trabeculoplasty (ALT) or selective laser trabeculoplasty (SLT), the studies showed.

The human donor eye study was performed to evaluate the tissue effects seen on the trabecular meshwork during laser trabeculoplasty as well as to study the subsequent histopathology, said Dr. Simon, director of ophthalmic research, Boston University Photonics Center, and research professor of biomedical engineering, Boston University.

Three donor eyes were exposed to pulses from the laser at parameters of 790 nm, 8 μ sec, 200- μ m spot size, and pulse energies of 30, 50, and 80 mJ. A single suture was placed centrally to aid in locating exposure sites during histologic study; the laser exposures were aimed at the trabecular meshwork below

the suture and 1 mm to either side.

Following laser exposure, the samples were fixed in 4% glutaraldehyde and sent for histologic study using eosin-staining techniques for subsequent analysis with light microscopy.

No thermal damage

The histologic analysis revealed some anatomic alterations in the trabecular meshwork at the laser exposure site and areas of slight depigmentation but no thermal damage, Dr. Simon said.

These findings suggested that the mechanism of action is non-thermal and that the effects of the laser may be due to dispersion of trabecular pigments without damage to the trabecular beams, he added.

“By creating less thermal damage in the trabecular meshwork, the titanium-sapphire laser may allow the same areas of the trabecular meshwork to receive treatment more than once, unlike, for example, ALT, which creates such a degree of thermal damage in the tissues that repeating treatment of the same area is not possible,” Dr. Simon said.

“This laser has very deep penetration into the trabecular meshwork,” he said. “It’s also very selective for the pigmented trabecular meshwork cells.”

The laser enables deeper penetration of clogged tissue with less scarring than ALT and has a stronger IOP-lowering effect, he added.

In the pilot clinical trial, 206 eyes received titanium-sapphire laser trabeculoplasty (TST) at the Gabriel Simon Ophthalmic Institutes in Madrid and Barcelona, Spain. Treatment consisted of 50 laser

exposures across 180° of trabecular meshwork. The lowest possible treatment energies, typi-

cally 30 to 80 mJ, were used. The endpoint was defined as small vapor bubble formation or visible dispersion of debris from the trabecular meshwork.

‘This laser has very deep penetration into the trabecular meshwork.’

Gabriel Simon, MD, PhD

Patients were seen for follow-up at day 1 and at 1, 3, 6, and 12 months. Results showed that an average IOP reduction from a baseline value of 22.5 ± 5.1 mm Hg to 17.6 ± 3.2 mm Hg at 6 months and 17.0 ± 3.3 mm Hg at 12 months ($n = 100$). Complications were minor and infrequent, Dr. Simon said.

The laser is approved for sale in the European Union and Canada. It is considered an investigational device in the United States. Enrollment began in June 2004 for a randomized, multicenter investigational device exemptions clinical trial comparing the safety and effectiveness of the titanium-sapphire laser against ALT for the treatment of open-angle glaucoma.

The study will include up to 180 eyes at 10 sites in the United States, Canada, Spain, and Israel. The primary outcome is IOP, and the secondary outcome is adverse event frequency. \square T

Take-Home Message

A 790-nm titanium-sapphire laser (SOLX 790, OccuLogix) produces clinically significant lowering of IOP in open-angle glaucoma. It also has few adverse effects and may allow for re-treatment because it causes minimal damage to the trabecular meshwork.

FYI

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The study of donor eyes and the clinical trial were supported by SOLX.

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