

International outlook

CLASS act: Why a new CO₂ laser is competing with the gold standard

by Matt Young EyeWorld Contributing Writer



Over the past several decades we have seen significant innovation in ophthalmology, and often this growth is concentrated in one area. Cataract surgery was transformed by IOLs and phacoemulsification. Not that long ago, refractive surgery was an exciting new subspecialty that underwent explosive growth. The treatment of macular degeneration was forever changed by the use of intravitreal injections to inhibit vascular growth. Glaucoma treatment, however, has remained largely unchanged. That is, until now. The next wave of innovation is occurring in the management of glaucoma. New devices have reduced the risk of complications associated with traditional trabeculectomy. Now a new laser is showing promise that could change the way we surgically manage elevated IOP. Is this the new age of glaucoma treatment?

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Trabeculectomy has had its day, but the CO₂ laser may be here to stay

The term “minimally invasive” is all the rage in glaucoma surgery, but one Israel-based technology called CO₂ Laser-Assisted Sclerectomy Surgery (or CLASS) really is non-invasive, especially around water.

While deeper evidence exists showing the safety and efficacy of CLASS (IOptima, Tel Aviv, Israel), a video presented by **Ehud I. Assia, MD**, inventor of the CLASS technology, and director, Department of Ophthalmology, Meir Medical Center, Kfar Saba, Israel, easily captures one’s attention.

Presented at the 2104 International Congress on Glaucoma Surgery (ICGS) in Singapore, the video shows that the laser is absorbed by a drop of water (instead of causing a burn on underlying wood),

suggesting it will not penetrate into unnecessary parts of the eyeball.

“If you apply the CO₂ laser energy on the piece of wood, we can ablate and penetrate through the wood,” Prof. Assia said during his ICGS presentation. “But if you apply just one drop of water and laser both of them, the effect would only be on the wood portion where the water droplet is not present. The CO₂ laser doesn’t work in water. The energy is almost completely absorbed by water.”

In a clinical setting during glaucoma surgery, the laser ablates the tissue above Schlemm’s canal until adequate percolation is achieved. The laser energy is then absorbed by the percolating fluid, completely avoiding penetration into the eyeball.

The procedure is approved in Europe, Mexico, and Israel, and also recently received approval from the China Food and Drug Administration (CFDA). Given that it is no easy task to pass this regulatory authority nowadays, it may be coming to a market near you sooner than you think.

Here is what you should know about CLASS now.

A CLASS act

With a wavelength of 10,600 μm, the CO₂ laser is highly absorbed by water and effectively ablates dry tissue, according to **Shlomo Melamed, MD**, Zucker-Sussman Chair for Glaucoma Research, Tel Aviv University Medical School, Israel.

Not unique to ophthalmology, the laser has been applied in cosmetic facial resurfacing procedures, Prof. Melamed said.

“In most glaucoma cases, Schlemm’s canal is flattened with bulging, herniated trabecular meshwork,” Prof. Melamed said at the 2014 World Ophthalmology Congress (WOC) in Tokyo. “Most knives, when used to enter Schlemm’s canal laterally from the scleral spur, are too large for this space and entry is associated with collateral damage. Unroofing of the canal with the CO₂ laser allows gentle entry and exposure of Schlemm’s canal lumen.”

Further, he said, anti-fibrosis properties of the CO₂ laser hopefully would reduce late failures of surgery.

What physically encompasses CLASS is the IOptiMate System (IOptima), made up of the laser and touch-screen control unit, and a scanner, which helps to ablate sclera based on a preselected area and pattern.

After creation of a conjunctival flap, scleral flap, and scleral bed, “the laser beam is scanned rapidly in a preselected ablation pattern and repeatedly ablates thin layers of sclera, ‘unroofing’ Schlemm’s canal,” Prof. Melamed said.

While fluid percolates through intact trabecular meshwork, the procedure avoids penetration of the eye. Scleral and conjunctival flaps are then closed and sutured.

“The laser works very nicely on a dry surface,” Prof. Assia said. “We were looking to how we can take advantage of this quality. We thought we can use it for glaucoma surgery and non-penetrating techniques, in which we need to ablate tissue and take it out layer by layer by layer.”

This is where water’s ability to absorb the laser energy really comes into play.

“Fluid comes up, and you can keep shooting on the tissue,” Prof. Assia said. “It is effective only on the dry areas, and this is why it does not penetrate.”

The procedure is performed in a hospital-based setting in order to maintain sterility.

Supportive evidence

To date, more than 700 procedures have been performed worldwide. In a multi-national controlled study, 111 patients have been treated by CLASS at 9 sites with more than 3 years of follow-up, Prof. Melamed said in his WOC presentation. These sites were located in Mexico, Spain, Italy, Switzerland, Russia, Israel, and India.

These patients all had glaucomatous optic neuropathy with reliable, reproducible evidence of a correlated typical visual field defect, he said. The mean age of patients was 69.3 years with the average age at diagnosis being 64.2 years. They

were fairly evenly split between males and females, and had a mixture of primary open-angle glaucoma (76%) and pseudoexfoliation glaucoma (24%).

Regarding results, CLASS safety shined over trabeculectomy (comparing the CLASS multicenter study to the literature).

For example, in the follow-up period up to 1 month, no CLASS patients experienced a flat or shallow anterior chamber, while 10% of trabeculectomy patients did. Choroidal detachment, hyphema, and wound leak occurred in greater percentages of trabeculectomy cases (13.0%, 8.0% and 11.0%, respectively) vs. CLASS cases (3.6%, 3.6% and 4.5%, respectively).

Late postoperative complications favored CLASS. While 57.0% of trabeculectomy cases developed cataract, only 8.0% did with CLASS. Vision loss occurred in 34.0% of trabeculectomy cases, but in only 0.9% of CLASS patients. Finally, encapsulated blebs occurred in 6.0% of trabeculectomy patients, but in no CLASS patient.

Meanwhile, efficacy was very similar between the groups. With IOP virtually identical between the groups preoperatively, it was lowered in both CLASS and trabeculectomy groups at 1 year (13.6 and 12.7 mm Hg, respectively), 2 years (13.1 and 12.1 mm Hg, respectively), and 3 years (14.6 and 13.5 mm Hg, respectively).

CLASS patients only had an average number of medications of 0.5 to 0.6 over the 3-year period.

“You need to be a master surgeon to do the manual [glaucoma] technique,” Prof. Assia said. “But with the laser technique, it does the work for you. You can control it with more or less application of the laser. It’s quite safe. If you can do a flap, then you can do non-penetrating [CO₂ laser] surgery.” **EW**

Editors’ note: Prof. Assia has no financial interests related to his comments. Prof. Melamed has financial interests with IOptima.

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