CO_2 laser-assisted procedure showing long-term efficacy, safety

Simplified filtration procedure has short learning curve; reduced need for topical drugs

By Cheryl Guttman Krader; *Reviewed by Noa Geffen, MD, and Michael Mimouni, MD*

TEL AVIV, ISRAEL ::

CO_2 LASER-ASSISTED sclerectomy (CLASS, IOPtima) is a safe technique providing long-term IOP control with a reduced need for topical medications, show findings from follow-up to 5 years in a multinational trial.

"We are fortunate to be caring for patients in an era of glaucoma surgical innovation, and newer microinvasive procedures offer benefits in terms of their safety profiles," said Michael Mimouni, MD, Department of Ophthalmology, Rambam Health Care Campus, Haifa, Israel. "However most do not provide adequate IOP control over time in eyes with more advanced glaucoma."


Dr. Mimouni

CLASS, developed by Professor Ehud Assia, MD, Department of Ophthalmology, Meir Medical Center, Kfar- Saba, Israel, is a simplified filtration procedure that has a short learning curve.


Dr. Geffen

Outcomes from the studies published by Noa Geffen, MD, principal investigator, and the international CLASS group, show that it can be performed with repeatable efficacy and safety in the hands of different surgeons, Dr. Mimouni noted.

"Now we look forward to confirming these promising results with more data," he said.

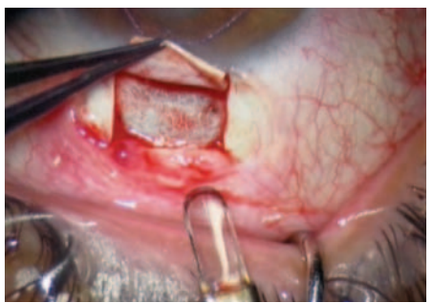
MORE ABOUT CLASS

CLASS is performed with a proprietary laser system (IOPtiMate, IOPtima) that includes a 10.6 µm CO_2 laser, a control unit, and a micromanipulating scanner integrated with the surgical microscope.

After creating a peritomy and half-thickness scleral flap, the laser is used to ablate the zone directly above Schlemm's canal in order to achieve deep scleral ablation and unroofing of Schlemm's canal. The laser ablates tissue layer by layer until percolation of fluid is visualized.

CLASS requires a manual creation of a partial thickness scleral flap but overcomes the need to manually create the deeper flap,

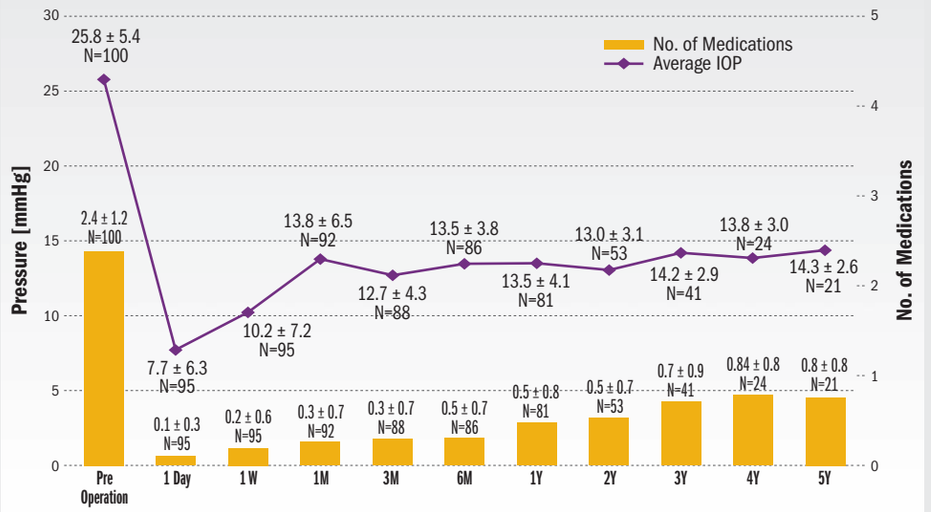
WATCH THE PROCEDURE



VIDEO The CLASS procedure is highly efficacious, with minimal learning curve. *(Video courtesy of IOPtima)*

Go to **http://bit.ly/2aw5iQb**

Efficacy Results: Average IOP and Medications



IOP was reduced from 25.8 ± 5.4 mm Hg to 13.5 ± 4.1, 14.2 ± 2.9, and 14.3 ± 2.6 mm Hg at 1, 3, and 5 years. The average number of medications dropped from 2.41 ± 1.2 to 0.5 ± 0.8, 0.7 ± 0.9, and 0.8 ± 0.8 at 1, 3, and 5 years ($p < 0.001$). *(Figure courtesy of IOPtima)*

which is the more challenging step in the standard non-penetrating deep sclerectomy procedures.

"The CO_2 laser was chosen for this procedure because its wavelength effectively ablates dry tissue, but is highly absorbed by water," Dr. Mimouni said. "The laser is used to ablate the deeper scleral layer until percolation is achieved, without perforation."

STUDY RESULTS

The multinational prospective study enrolled patients at nine sites in seven countries across three continents. It followed earlier testing in animal models showing that CLASS could be performed without causing perforation [Ton Y, et al. *J Glaucoma*. 2012;21:135-140] and after achieving positive results in an initial clinical trial including 37 eyes [Geffen N, et al. *J Glaucoma*. 2012;21:193-198].

Patients were eligible for study participation if they had primary open-angle glaucoma or primary exfoliation glaucoma with an IOP >18 mm Hg despite maximum tolerated medical therapy, Shaffer angle >grade 2, no ocular disorders other than cataract, and no surgical intervention in the study eye other than clear corneal cataract surgery. About three-fourths of the study participants had primary open-angle glaucoma.

> 'The laser is used to ablate the deeper scleral layer until percolation is achieved.'
> — *Michael Mimouni, MD*

Mitomycin-C was used in 89% of procedures. During the first year after the laser treatment, there were 12 needling procedures and 18 goniopunctures.

Efficacy results analyzed data from 100 eyes, of which 81 were seen at 1 year, 41 at 3 years, and 21 at 5 years. Mean IOP was 25.8 ± 5.4 mm Hg at baseline, 7.7 ±9.5 mm Hg on the first day after surgery and averaged 13.5 ± 4.1, 14.2 ± 2.9, and 14.3 ± 2.6 mm Hg at 1, 3, and 5 years, respectively.

Prior to CLASS, patients were on an average of 2.4 ± 1.2 medications daily, and the average number was reduced significantly to 0.5 ± 0.8, 0.7 ± 0.9, and 0.8 ± 0.8 at 1, 3, and 5 years, respectively.

Complete success, defined as IOP between 5 and 18 mm Hg with a ≥20% reduction from baseline on no medications, was achieved in 59.1% of eyes seen at 1 year, 43.5% at 3 years, and in 40.9% of eyes followed to 5 years.

Qualified success, which was defined using the same IOP criteria but with or without medication, was achieved at rates of 78.5%, 84.8%, and 86.4% at 1, 3, and 5 years, respectively.

Complications were mostly mild without any significant sequelae. The most common procedure-related complications were early wound leak (8.3%), shallow anterior chamber (5.6%), and hyphema (4.6%).

"Although some of the patients experienced complications during follow-up, most were transient and mild," Dr. Mimouni said. "In addition, they compared favorably with trabeculectomy if we consider the trabeculectomy arm of the Tube versus Trabeculectomy Study in which 87% of eyes developed at least one complication by 5 years." ■

take-home

- **CO_2 laser-assisted sclerectomy performed with a proprietary laser system is a simplified filtration procedure that is showing good IOP-lowering efficacy and safety in eyes followed to 5 years.**

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