



Glaucoma surgery with CLASS

Proving to be a promising procedure, according to clinical results

By Adrienne Resek

Reviewed by Professor Ehud

I. Assia, MD, and Professor

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Doctors and researchers continuously seek new ways to improve treatments and outcomes for patients by applying new and existing technology in novel ways. Known in the medical industry for high power and efficiency, particularly in the field of skin resurfacing, carbon dioxide (CO₂) lasers are now finding a place in the world of ophthalmology. CO₂ laser assisted sclerectomy surgery (CLASS) is proving to be a highly effective, minimally invasive, safe and simple method to surgically treat glaucoma patients. As participants in a prospective, multicentre study of 111 patients, Prof. Ehud I. Assia, MD, and Prof. Shlomo Melamed, MD, are at the forefront in the research, development and implementation of this approach.

Globally, glaucoma is the second most common cause of blindness. An estimated 8.4 million people in the world suffer from glaucoma-induced blindness and an additional 60 million are affected by optic neuropathy.¹ Traditional treatment for glaucoma begins with hypotensive topical medications. Although these medications are proven effective at lowering intraocular pressure (IOP) when used as directed,² a significant number of patients are not fully compliant, severely limiting efficacy of the treatment regimen.³

"We resort to traditional penetrating surgical methods such as trabeculectomy and tube shunts when the state of the disease is dire enough to exceed the high risks associated with these treatments," explained Prof. Assia.

"Although quite efficient at reducing the IOP, trabeculectomy is associated with too many complications, ranging from foreign body sensation and dellen formation, to leaking blebs, hypotony, blebitis and endophthalmitis,"⁴ said Prof. Melamed.

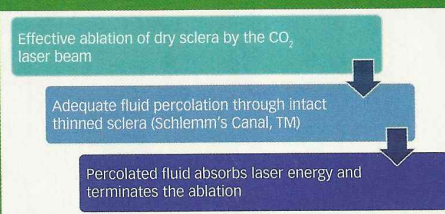
A new surgical option

CLASS is best suited for patients with mild to moderate primary open-angle glaucoma (POAG) and pseudo exfoliative glaucoma (PEXG) with baseline IOP between 20 mmHg and 35 mmHg, and even higher. Using the IOPtimate (IOPtima, Israel) system, which uses CO₂ laser of a 10.6 µm wavelength accompanied by a micro-manipulating



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Figure 1: Principle of operation.



scanner and a control unit, the sclera of the eye is thinned to allow percolation of the aqueous. The eye globe is not penetrated, and there is no need to insert and leave a foreign object in the eye.

"...CLASS may be most suitable for patients with uncontrolled glaucoma where a less invasive approach is preferred."
(Prof. Melamed)

The surgeon begins by creating a conjunctival flap using the fornix base method and a standard scleral flap 5.0 x 5.0 into the clear cornea to expose the limbus. A scleral bed is created as a fluid reservoir. The CO₂ laser beam rapidly ablates thin layers of dry sclera in a pre-selected pattern to 'un-roof' Schlemm's Canal. Fluid then percolates through the intact trabecular meshwork. The percolated fluid absorbs laser energy and terminates the ablation; there is no penetration of the eye globe. The scleral flap and conjunctiva are closed and sutured (see Figure 1).

In short...

Carbon dioxide laser assisted sclerectomy surgery (CLASS) is being used as an effective and safe, minimally invasive treatment for glaucoma. In this article, two surgeons at the forefront of research, development and implementation of this approach discuss this surgical option and its benefits for the ophthalmic market.

Figure 2: 5 year post-op results of mean IOP. (Figure courtesy of IOPTima.)

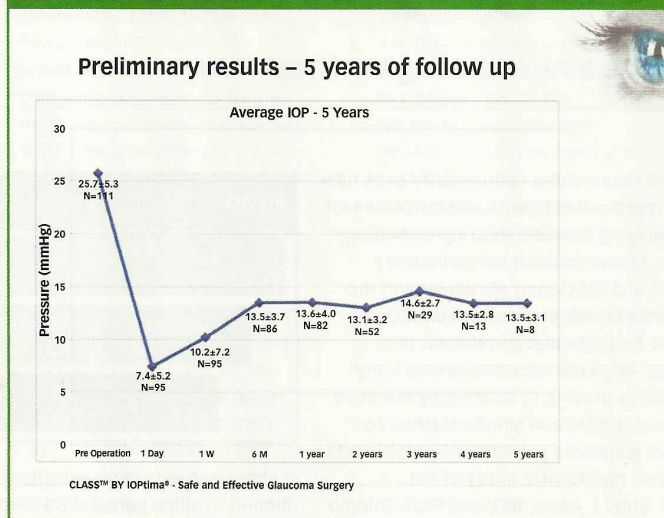
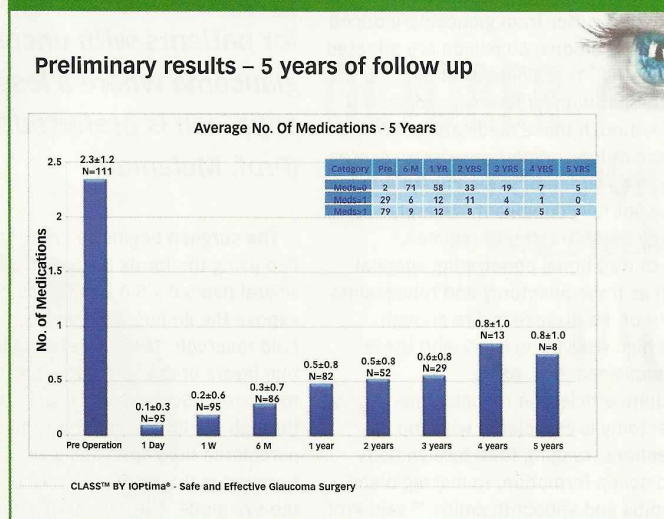


Figure 3: Average number of hypotensive medications over post-op follow up period of 5 years. (Figure courtesy of IOPTima.)



"One of the greatest benefits of CLASS is the ease of performing the procedure. The technique for unroofing the canal is very safe, yet productive. IOP is significantly reduced without the risk of hypotony and impact on vision is minimal, if at all. I continue to use a variety of glaucoma procedures, but find that CLASS

may be most suitable for patients with uncontrolled glaucoma where a less invasive approach is preferred," emphasized Prof. Melamed.

Prof. Assia added, "Patients with mild to moderate glaucoma are often seen by comprehensive-care ophthalmologists rather than by glaucoma specialists. The

precision of the CLASS procedure provides a solution that is very accessible to all surgeons. The laser beam is precisely guided by the micro-manipulating beam, and will ablate exactly what is chosen according to the defined shape and dimensions. Physicians simply have to exercise confidence in the device. Keeping the eye intact significantly reduces the risk of intraoperative and postoperative complications, as well as the follow-up interventions commonly associated with penetrating surgical alternatives."

"The precision of the CLASS procedure provides a solution that is very accessible to all surgeons." (Prof. Assia)

Clinical results

In a prospective, multicentre study of 111 patients, the procedure was performed on 85 eyes with POAG and 26 eyes with PEXG, with an average IOP of 25.7 ± 5.3 mmHg. Mean IOP dropped to 13.5 ± 3.7 mmHg at six months postoperative (N = 86) and remained stable through three years (N = 29) and five years postoperative (N = 8). Average number of hypotensive medications dropped from a mean of 2.3 ± 1.2 at baseline to 0.3 ± 0.7 at six months postoperative, 0.6 ± 0.8 after three years and 0.78 ± 1.0 after five years. At three years postoperative, 87.5% of patients achieved a reduction in IOP of 20% or greater, maintaining an IOP less or equal to 18 mmHg; 59.4% of patients were able to maintain the IOP goals without use of any medication.

Conclusion

CLASS is proving to be a very promising technology based on data from over 700 procedures

performed to date worldwide. Melamed concluded, "We know it works well, providing significant, long-term reductions in both IOP and hypotensive medication requirements. It also has a very low postoperative complication rate. I anticipate that future studies will continue to show the benefits of using CO₂ lasers for the treatment of glaucoma."

References

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Special contributors

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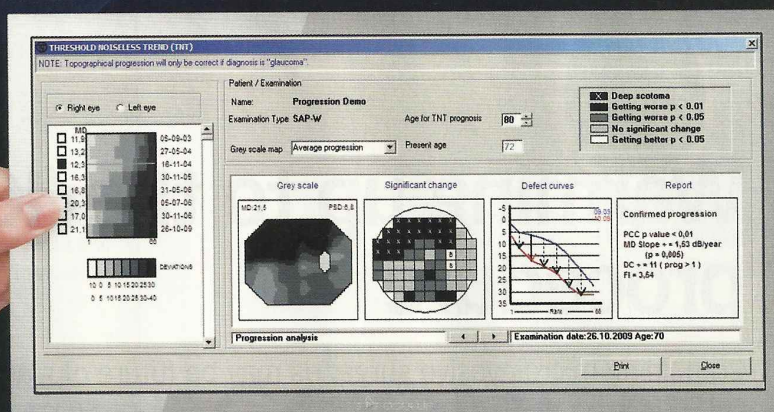
Professor Shlomo Melamed, MD, is full professor of Ophthalmology, Incumbent of the Zuker-Sussman Chair for Glaucoma Research at the Tel Aviv University Medical School. He is also the Director of the Sam Rothberg Glaucoma Center, Tel Hashomer, Israel.

Prof. Assia has indicated he has financial interest in APX Ophthalmology, BioTechnology General, Hanita Lenses, IOptima.

Prof. Melamed receives consultancy fees or grants from Allergan, Solx, Ellex, IOptima.

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