

# CO<sub>2</sub> Laser Assisted Sclerectomy Surgery (CLASS) – A novel filtration procedure for glaucoma treatment

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## Introduction

CO<sub>2</sub> laser was used to perform CLASS procedure - a filtering procedure for the treatment of glaucoma.

CLASS utilizing CO<sub>2</sub> laser is a self regulatory procedure due to this laser's unique property of effectively ablating dry tissues while being highly absorbed by aqueous (1).

The sclera was ablated over the Schlemm's canal and trabecular meshwork zone while preserving an intact thin trabeculo-Desemet's membrane resulting in aqueous percolation (2).

Upon achieving adequate percolation, laser energy is absorbed by the percolating fluid, automatically preventing further tissue ablation and inadvertent penetration into the anterior chamber.

## Objective

To evaluate the clinical safety and efficacy of the IOPTiMate™ System\* in conjunction with CO<sub>2</sub> laser in performing CLASS procedure in primary open angle and pseudoexfoliation glaucoma patients. (\* By IOPTima, Tel-Aviv, Israel).

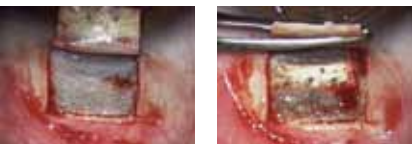


Figure 1

Figure 2

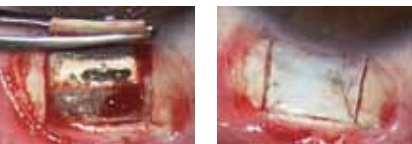


Figure 3

Figure 4

## Subjects & Methods

### Study design and settings:

A prospective, single-arm, non-randomized clinical trials were conducted at 5 sites:  
Mexico City – Mexico  
Madanapelle – India  
Moscow – Russia  
Ancona – Italy  
Valencia-Spain

### Subjects:

Primary open angle glaucoma (POAG) or pseudoexfoliation glaucoma (PEXG) patients, with baseline IOP > 18mmHg on maximally tolerated medical treatment, who were candidates for glaucoma filtration surgery.

### Devices Used:

IOPTiMate™ system (by IOPTima, Israel), and CO<sub>2</sub> laser system (40C by Lumenis). The IOPTiMate™ is attached to the ophthalmic microscope and includes a scanner and micromanipulator.

### Surgical procedure:

Peritomy and superficial scleral flap dissection extending to the clear cornea (Figure 1); Red aiming beams indicate and confine laser ablation zone distal to the limbus (Figure 2); Laser ablation aimed at Schlemm's canal (Figure 3); Scleral flap and conjunctival suturing (Figure 4).

Intra-operative Mitomycin C was used in 50 procedures (80.6%).

### Post-operative treatment and follow-up:

All patients were treated with anti-inflammatory and antibiotic eye drops.

### Follow up schedule:

1 day post-op, 1 week, 4 weeks, 6 weeks, and 3, 6, and 12 months post surgery.

### Outcome measures:

- Intra-ocular pressure (IOP) at 1 year after surgery.
- Complete and qualified success rates. Complete success was defined as ≤ IOP ≤ 18 mmHg and 20% IOP reduction with no medications, and qualified success as the same IOP range with or without medications.
- Number of anti-glaucoma medications per patient.
- Intra-operative perforations.
- Intra-operative and post-operative complications.

## Results

**Number of patients:** 62

**11 patients were excluded:** 9 protocol deviations, 2 procedures converted to trab during the primary surgery.

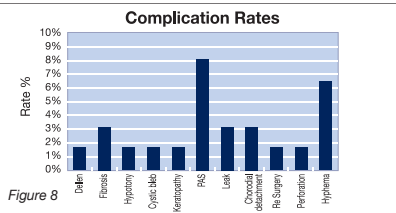
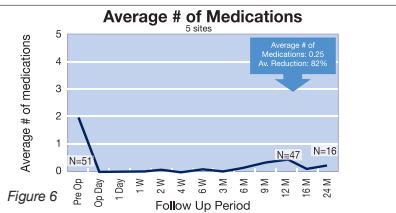
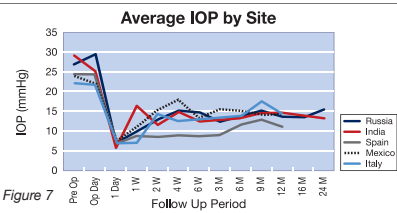
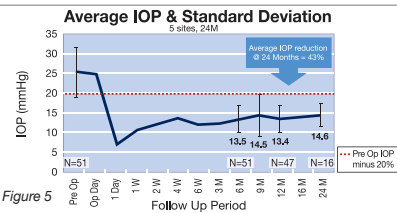
**Mean age ± SD:** 68 ± 13 years  
**Gender:** 38 were males (61%)  
**Race:** Hispanics: 14 (22.6%)  
Asians (Indians): 13 (21%)  
Caucasians: 35 (56.4%)  
**Glaucoma type:** POAG - 51 (82%)  
PEXG - 11 (18%)

### Performance:

Adequate aqueous percolation was achieved in all cases. Mean IOP values are presented in Table 1 and in Figure 5. Mean # of medications per subject was reduced from 1.98±0.15 to 0.45±0.82 (p<0.001) - Figure 6. Qualified and complete success rates are presented in Table 1. The average IOP by site is presented in Figure 7.

### Complications:

No Intra-operative device related complications were recorded. The complications rate is presented in Figure 8.



## Discussion

CLASS procedure was developed to turn minimally invasive filtration surgery a practical option for all surgeons, by utilizing simple self regulated laser scleral tissue removal.

CLASS procedure was relatively safe and effective for treating primary open angle glaucoma and pseudoexfoliation glaucoma. Average IOP and anti-glaucoma medications use were significantly reduced during follow-up.

The rate and type of post-operative complications were similar to those published in the literature for NPDS (3).

CLASS procedure is self-regulated and easy to perform, minimizing the possibility of perforation and related complications.

## Conclusion:

The results suggest that CLASS may become simple, safe and effective means of choice for the treatment of open-angle glaucoma.

### Mean IOP ± SD at baseline and at 12 months end point and success rates

Baseline IOP	25.2 ± 6 mmHg (range 18-48)
IOP at 1 year	13.7 ± 3.4 mmHg (range 8-21)
Average IOP reduction (%)	43.5% ± 19 (0 < 0.001)
Qualified success	88.9%
Complete success	71.1%
Failure	11.1%

Table 1

### References:

1. Assia EI, Rotenstreich Y, Barquet IS et al. Experimental studies on nonpenetrating filtration surgery using the CO<sub>2</sub> laser. Graefes Arch Clin Exp Ophthalmol. 2007 Jun;45:847-54.
2. Geffen N, Ton Y, Degani J, Assia EI. CO<sub>2</sub> Laser-Assisted Sclerectomy Surgery (CLASS) Part II: Multicenter Clinical Preliminary Study. JOG. Electronic publication ahead of print.
3. Honchar A, Onof M, Hasanreisoglu B. Nonpenetrating glaucoma surgery: meta-analysis of recent results. J Glaucoma. 2008;17:138-46.

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