CLASS: CO₂ Laser-Assisted Sclerectomy Surgery: A novel filtration procedure for glaucoma treatment

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INTRODUCTION

CO₂ laser was used to perform CLASS procedure - a filtering procedure for the treatment of glaucoma.

CLASS utilizing CO_2 laser is a self regulatory procedure due to CO_2 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-Descemet'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 IOPtiMateTM System (by IOPtima, Israel) in conjunction with CO₂ laser in performing Laser Assisted Sclerectomy (CLASS) in primary open angle and pseudoexfoliation glaucoma patients.

SUBJECTS & METHODS

Study design and settings:

A prospective, single-arm, non-randomized clinical study was conducted at 9 sites: Israel, Ramat Gan; Israel, Kfar Saba; Mexico, Mexico City; India, Madanapelle; Russia, Moscow; Italy, Ancona; Spain, Valencia; Switzerland, Genève, Switzerland, Lausanne

Subjects:

Primary open angle glaucoma (POAG) or pseudoexfoliative glaucoma (PEXG) patients, with baseline IOP > 21mmHg on maximally tolerated medical treatment, who were candidates for glaucoma filtration surgery.

Devices Used:

IOPtiMateTM system (by IOPtima, Israel), and CO_2 laser system. The IOPtiMateTM is attached to the ophthalmic microscope and includes a scanner and micromanipulator.

Surgical procedure:

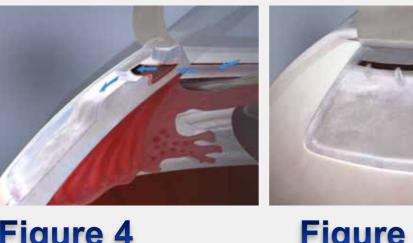
- (1) Creation of the standard scleral flap
- (2) Creation of scleral bed
- (3) The laser beam is scanned rapidly in a pre-selected ablation pattern and repeatedly ablates thin layers of sclera, "un-roofing" the Schlemm's canal
- (4) Fluid percolation through intact thinned sclera
- (5) A thin layer remains intact; penetration of the eye is avoided
- (6) The scleral flap is closed and sutured





Figure 2









ure 5

Outcome measures:

- 1. Intra-ocular pressure (IOP) at 1/2/3 years after surgery. Qualified and complete success rates were defined as IOP < 21 mmHg with or without anti-glaucoma medications, respectively.
- 2. Number of anti-glaucoma medications per patient.
- 3. Intra-operative and post-operative complications.

RESULTS

Total № of patients: 111 were recruited and underwent the procedure

Mean age ± SD 69.3 ± 12.8 years

Gender: Men 62 (55%); women 49 (45%).

Race: Hispanics- 14, Asians (Indians) – 13, Caucasians – 82, African - 2

Glaucoma types: POAG – 85 (76%) patients; PEXG - 26 (24%) patients

Performance

Adequate aqueous percolation was achieved in all cases.

Mean IOP values are presented in table 1 and in figure 7.

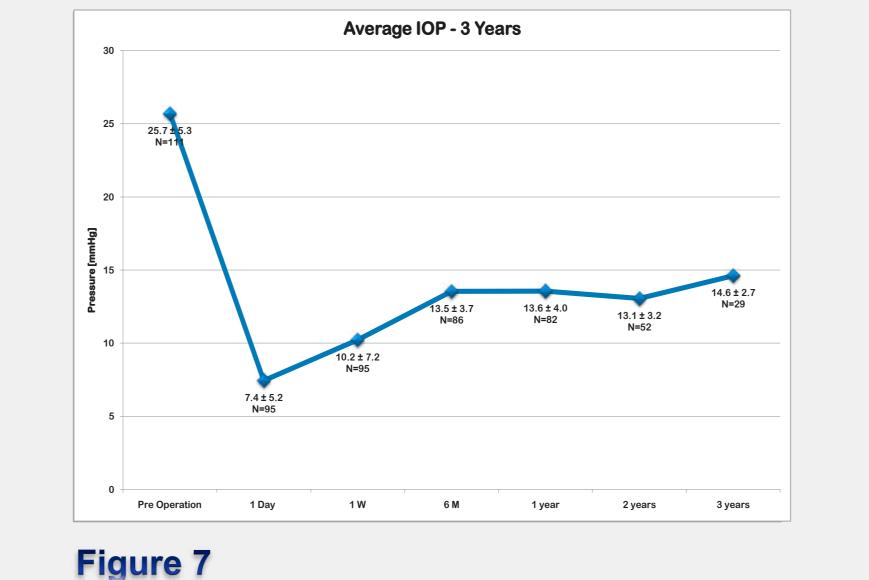
Mean # of medications per subject was reduced from 2.3±1.2 to 0.6±0.8 (p<0.0001)- **figure 8**.

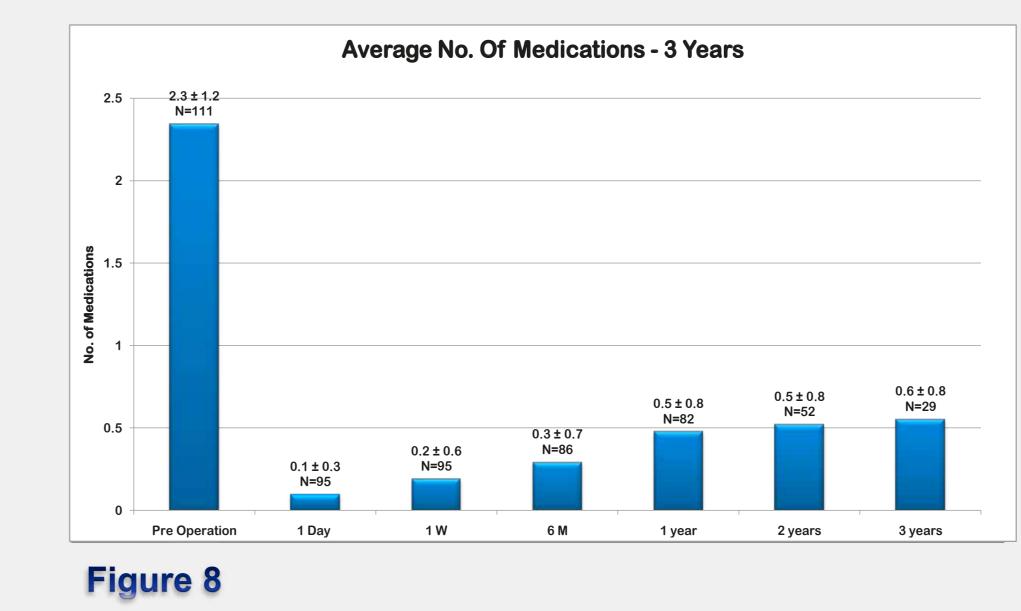
Qualified / complete success rates figure 9 and IOP from all sites is in figure 10.

Table 1: Mean IOP ± SD & Success rates	
Baseline IOP	25.7±5.3 mmHg
IOP at 1 year (N=82)	13.6±4.0 mmHg, p< 0.0001
IOP at 2 years (N=52)	13.1±3.2 mmHg, p< 0.0001
IOP at 3 years (N=29)	14.6±2.7 mmHg, p< 0.0001
Qualified success at 3 years	90.6%
Complete success at 3 years	59.4%

Complications

No Intra-operative device related complications were recorded Post-operative procedure-related complications were mild and resolved: Hypotony (2.7%), choroidal detachment (3.6%), wound leak (4.5%) and hyphema (3.6%).



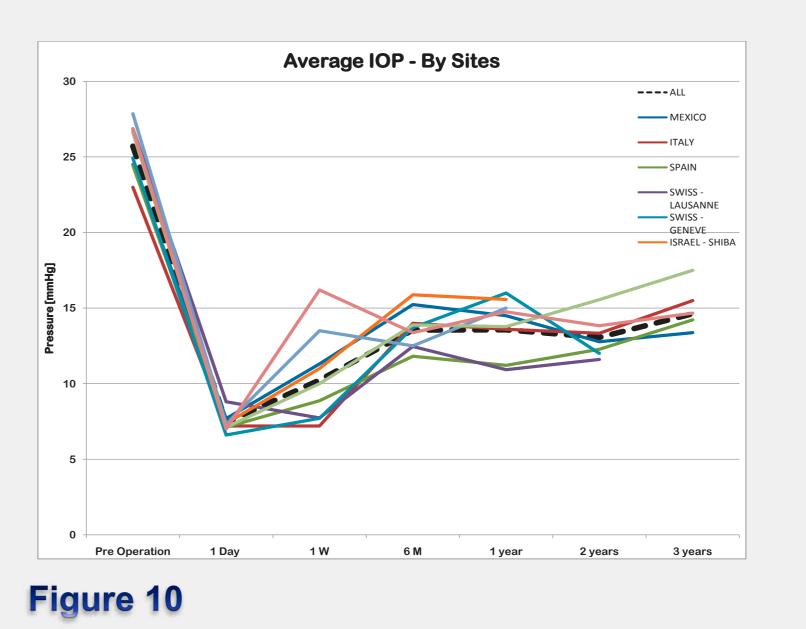


Success Rate (IOP<21) - 3 Years

100%
90%
89.7%
90.6%

70%
60.0%
566.9%
59.4%
1 year
N=95
1 years
N=58
3 years
N=32

Figure 9



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

DISCUSSION

CLASS is an easy to perform procedure with a short learning curve.

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

The rate and type of post-operative complications were significantly lower compares to those published in the literature for Trabeculectomy (3).

Conclusion:

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

REFERENCES

1. Assia EI, Rotenstreich Y, Barequet IS et al., Experimental studies on nonpenetrating filtration surgery using the CO_2 laser. Graefes Arch Clin Exp Ophthalmol., 2007 Jun, 245:847-54,

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