

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

CLASS utilizing CO2 laser is a self regulatory procedure due to CO2 laser’s unique property of effectively abating 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 IOPiMate™ System (by IOPtima, Israel) in conjunction with CO2 laser in performing Laser Assisted Sclerectomy (CLASS) in primary open angle and pseudosclerotic 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, Madanapalle; Russia, Moscow; Italy, Ancona; Spain, Valencia; Switzerland, Genève, Switzerland, Lausanne.

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

Devices Used:
IOPiMate™ system (by IOPtima, Israel), and CO2 laser system. The IOPiMate™ 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

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 N 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) - 12, Caucasians - 82, Africans - 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 IOP at 3 years was reduced during follow-up. The results suggest that CLASS is a simple, safe and effective means of choice for the treatment of open-angle glaucoma.

Compli cations
No intra-operative device related complications were recorded.
Post-operative procedure-related complications were mild and resolved.

DISCUSSION

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.

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 pseudosclerotic 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 compared to those published in the literature for Trabeculectomy (3).

CONCLUSION

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REFERENCES