Long Term Multi Center Evaluation of CO2 Laser Assisted Sclerectomy Surgery (CLASS) in Open Angle Glaucoma Patients

Shlomo Melamed[1], MD; Noa Geffen[2], MD; Ehud I. Assia[2], MD
[1]The Goldschleger Eye Institute, Sheba Tel Hashomer, Israel, [2]Meir Medical Center, Kfar-Saba and Ein-Tal Eye Center, Tel-Aviv, Israel

Background:

To evaluate the long term efficacy and safety of CO2 Laser Assisted Sclerectomy Surgery (CLASS) in primary and pseudoexfoliative open-angle glaucoma.

Methods:

A prospective, single-arm, non-randomized clinical trial at 9 centers worldwide. Patients with Primary Open Angle Glaucoma (POAG) or Pseudo-Exfoliative Glaucoma (PEXG), baseline IOP >18 mmHg on maximally tolerated medical treatment who are candidates for primary filtration surgery were included. The CLASS procedure ("IOPtiMate"; IOPtima Ltd, Israel) was performed. A half- thickness scleral flap was created and the CO2 laser was used to achieve deep scleral ablation and un-roofing of Schlemm's Canal.

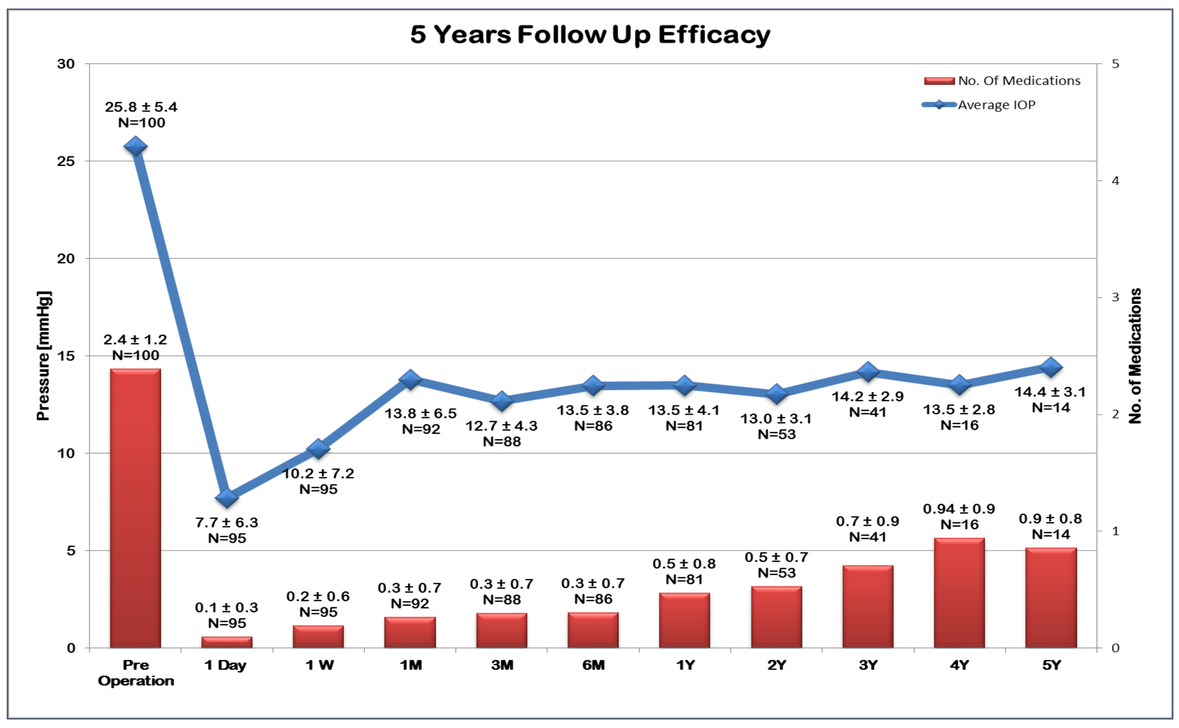
Intraocular pressure (IOP) and use of glaucoma medications were collected at baseline and up to 5 years follow up. Complete success was defined as 5≤ IOP≤ 18 mmHg and 20% IOP reduction with no medications, and qualified success as the same IOP range with or without medications. All adverse events were recorded and analyzed.

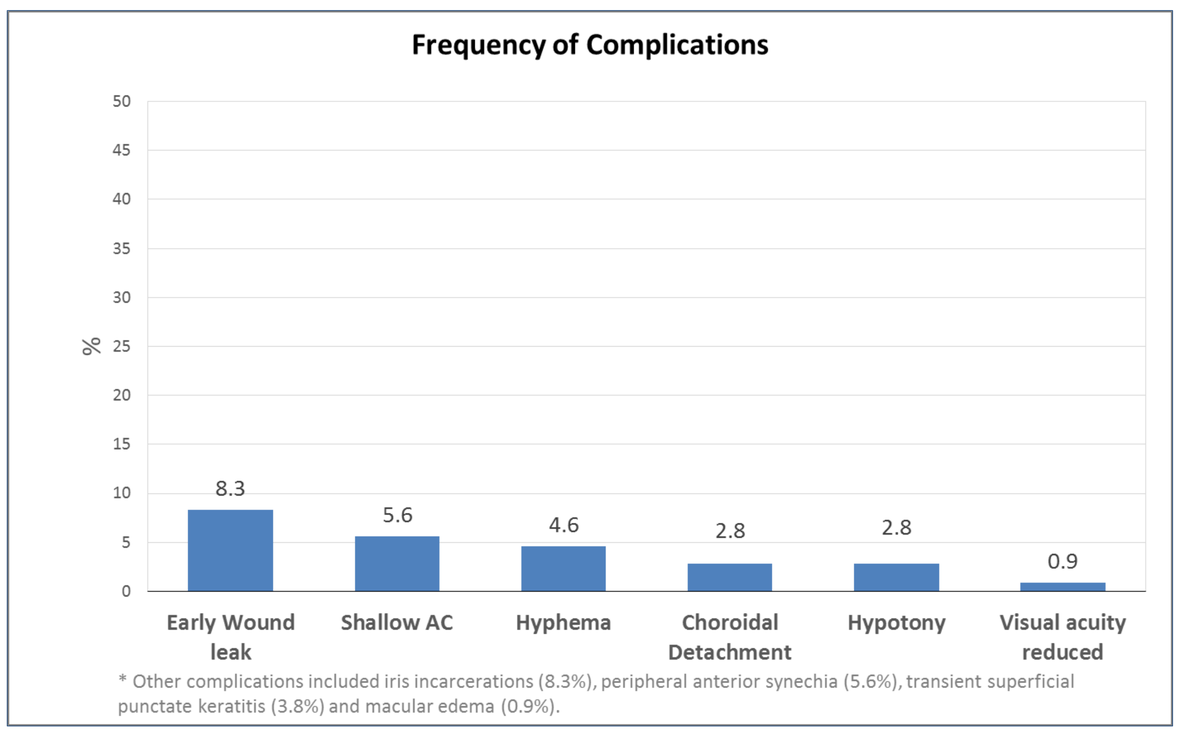
Results:

111 consecutive eyes were enrolled in the study. 11 were excluded from the study, 5 cases of protocol deviations and 6 cases operator failure. The mean age was 69.3 ± 12.8 years. 73.9% were Caucasians. Mitomycin C was used in 88.9% of CLASS procedures. IOP was reduced from 25.8 ± 5.4mmHg at baseline to 13.5 ± 4.0mmHg, 14.2±2.9mmHg and 14.1±3.1mmHg at 1, 3 and 5 years follow up respectively. The qualified success rates after 1, 3 and 5 years were 79.6%, 86.7% and 80.0% respectively. The average number of medications dropped from 2.41 ± 1.25 at baseline to 0.5 ± 0.8, 0.7 ± 0.9 and 0.9 ± 0.8 at 1, 3 and 5 years follow up respectively (P < 0.001). No technical device malfunctions occurred and complications were mostly mild and transitory with no significant sequela.

Conclusions:

Long term results suggest that CLASS procedure is a safe, effective, and simple technique for treating patients with open-angle glaucoma.





* Other complications included iris incarcerations (8.3%), peripheral anterior synechia (5.6%), transient superficial punctate keratitis (3.8%) and macular edema (0.9%).

Procedure Steps


Creation of a rectangular scleral flap (following conjunctival flap)


CO_2 laser application – Tissue ablation
Creation of a scleral bed


CO_2 laser application – Tissue ablation
Unroofing of the Schlemm's Canal


Fluid percolation through the intact trabecular meshwork


Flap closure and suture


Conjunctiva closure and suture