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

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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 ("IOPtMate", IOP'tma 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 IOPs 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±1.1mmHg 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.

Procedure Steps

- Creation of a rectangular scleral flap (following conjunctival flap)
- Creation of a virtual laser transection line
- CO2 laser ablation - laser is applied to the inferior/anterior canal
- Laser penetrating to the medial trabecular meshwork
- Partial closure at the center
- Complete closure and closure

Laser & Control Unit

5 Years Follow Up Efficacy

Frequency of Complications

Success Rate (IOP <18mmHg)

- Complete success (%)
- Qualified success (%)
- Failure rate (%)
- Failure rate (%)
- Failure rate (%)
- Failure rate (%)
- Failure rate (%)

0 10 20 30 40 50 60 70 80 90 100
0 0.9 2.8 3.8 4.6 5.6 8.3

- Early Wound leak
- Shallow AC
- Hypotony
- Choroidal Detachment
- Hypopyon
- Visual acuity reduced
- Other complications included intraocular hemorrhage (2.3%), peripheral anterior synechiae (5.0%), transient superficial punctate keratitis (5.3%) and macular edema (0.3%).