CO2 Laser Assisted Sclerectomy Surgery (CLASS) – 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 CO2 laser is a self regulatory procedure due to this laser’s unique property of effectively ablating dry tissues while being highly absorbed by aqueous percolation. Upon achieving adequate percolation, laser energy is absorbed by the percolating fluid, automatically preventing further tissue ablation and inadvertent penetration into the anterior chamber.

Subjects & Methods
Study design and settings: A prospective, single-arm, non-randomized clinical trials were conducted at 5 sites: Mexico-City – Mexico, Madraps – India, Moscow – Russia, Ancona – Italy, Valencia-Spain
Subjects: Primary open angle glaucoma (POAG) or pseudoexfoliative glaucoma (PEXG) patients, with baseline IOP > 18mmHg on maximally tolerated medical treatment, who were candidates for glaucoma filtration surgery.
Devices Used: IOPtima™ system (by IOPtima, Israel), and CO2 laser system (40C by Lumenis). The IOPtima™ is attached to the ophthalmic microscope and includes a scanner and micromanipulator.
Surgical procedure: Peritomy and superficial scleral flap dissection extending 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:
• Intraocular pressure (IOP) at 1 year after surgery.
• Complete and qualified success rates. 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.

Results
Number of patients: 62
11 patients were excluded:
9 protocol deviations, 2 procedures converted to trabeculectomy.
Mean age ± SD: 68 ± 13 years
Gender: 38 were males (61%)
Race: Asians (Indian): 13 (21%)
Caucasians: 35 (56.4%)
Hispanics: 14 (22.6%)
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.

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 affective for treating primary open angle glaucoma and pseudoexfoliative 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 NPGS (2).
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.

References:

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Figure 1
Figure 2
Figure 3
Figure 4
Figure 5
Figure 6
Figure 7
Figure 8

Table 1

<table>
<thead>
<tr>
<th>Site</th>
<th>Number of patients</th>
<th>Mean age ± SD</th>
<th>Gender</th>
<th>Race</th>
<th>Glaucoma type</th>
<th>Mean # of medications per subject</th>
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</thead>
<tbody>
<tr>
<td>Valencia-Spain</td>
<td>11</td>
<td>68 ± 13 years</td>
<td>7 (64%)</td>
<td>1 (9)</td>
<td>POAG - 10 (91%)</td>
<td>1.35 ± 0.25</td>
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<tr>
<td>Ancona – Italy</td>
<td>14</td>
<td>70 ± 12 years</td>
<td>6 (43%)</td>
<td>3 (21%)</td>
<td>POAG - 13 (93%)</td>
<td>1.45 ± 0.26</td>
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<tr>
<td>Moscow – Russia</td>
<td>10</td>
<td>64 ± 11 years</td>
<td>4 (40%)</td>
<td>2 (20%)</td>
<td>POAG - 8 (80%)</td>
<td>1.50 ± 0.28</td>
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<tr>
<td>Valencia-Spain</td>
<td>12</td>
<td>61 ± 11 years</td>
<td>6 (50%)</td>
<td>2 (20%)</td>
<td>POAG - 10 (83%)</td>
<td>1.55 ± 0.30</td>
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<tr>
<td>Tel-Aviv, Israel</td>
<td>15</td>
<td>69 ± 13 years</td>
<td>7 (47%)</td>
<td>3 (20%)</td>
<td>POAG - 12 (80%)</td>
<td>1.60 ± 0.28</td>
</tr>
</tbody>
</table>

Complication Rates

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

<table>
<thead>
<tr>
<th>Site</th>
<th>Mean IOP ± SD</th>
<th>IOP at 1 year</th>
<th>Average IOP reduction (%)</th>
<th>Qualified success</th>
<th>Complete success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valencia-Spain</td>
<td>22.2 ± 3.4</td>
<td>13.7 ± 4.1</td>
<td>55.5%</td>
<td>71.1%</td>
<td>63%</td>
</tr>
<tr>
<td>Ancona – Italy</td>
<td>22.0 ± 4.1</td>
<td>15.0 ± 3.1</td>
<td>59.0%</td>
<td>71.1%</td>
<td>63%</td>
</tr>
<tr>
<td>Moscow – Russia</td>
<td>20.8 ± 2.9</td>
<td>14.0 ± 3.1</td>
<td>45.5%</td>
<td>71.1%</td>
<td>63%</td>
</tr>
<tr>
<td>Tel-Aviv, Israel</td>
<td>23.0 ± 3.5</td>
<td>15.0 ± 3.1</td>
<td>55.5%</td>
<td>71.1%</td>
<td>63%</td>
</tr>
</tbody>
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