How to Classify Disease Severity in Clinical Trials of New Glaucoma Surgical Procedures

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FINANCIAL DISCLOSURES

Consultant: Allergan, Aquesys, Bausch and Lomb, Genentech

Research Funding: NIH, Genentech
Why Classify

• Provide better guidance to physicians to make better treatment recommendations
• Help patients with glaucoma understand their disease better
• Help physicians and patients plan for future outcomes
CURRENT CLASSIFICATION SYSTEMS

**Refractory:** Uncontrolled IOP despite maximal medical treatment, and/or laser surgery and/or incisional glaucoma surgery.

**Non-Refractory:** IOP can be controlled by medical management.
## CURRENT CLASSIFICATION SYSTEMS

### Refractory/Non-Refractory

| Provide better guidance to physicians to make better treatment recommendations | Maybe |
| Help patients with glaucoma understand their disease better | Maybe |
| Help physicians and patients plan for future outcomes | No |
CURRENT CLASSIFICATION SYSTEMS

Based on severity of glaucomatous optic nerve damage and visual field loss (Fellman/Mattox et al)

Mild

Moderate

Severe
CURRENT CLASSIFICATION SYSTEMS

365.71 **Mild or early-stage glaucoma:**
optic nerve abnormalities consistent with glaucoma but no visual field abnormalities on any white-on-white visual field test, or abnormalities present only on short-wavelength
365.72 **Moderate-stage glaucoma**: optic nerve abnormalities consistent with glaucoma and glaucomatous visual field abnormalities in one hemifield, **and not** within 5 degrees of fixation.
365.73 **Severe, advanced, end-stage glaucoma:** optic nerve abnormalities consistent with glaucoma and glaucomatous visual field abnormalities in both hemifields, and/or loss within 5 degrees of fixation in at least one hemifield.
## CURRENT CLASSIFICATION SYSTEMS

### Mild/Moderate/Severe damage

<table>
<thead>
<tr>
<th></th>
<th>Maybe</th>
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<tbody>
<tr>
<td>Provide better guidance to physicians to <strong>make better treatment recommendations</strong></td>
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</tr>
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<td>Help patients with glaucoma understand their disease <strong>better</strong></td>
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</tr>
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<td>Help physicians and patients plan for future outcomes</td>
<td><strong>Yes</strong></td>
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PROPOSED CLASSIFICATION SYSTEM

• Goal: Classify disease severity for clinical trials of novel glaucoma surgical procedures
  
  – Potential magnitude of IOP lowering
  – Potential for pre-, intra- and post-operative (short and long term) risk
  – Based on at least 1 year follow-up data
PROPOSED CLASSIFICATION SYSTEM

Target IOP lowering needed

- IOP lowering $\leq 4\text{mmHg}$
- IOP lowering $\geq 5\text{mmHg}$

Ability to tolerate Complications

- Low (mod/advanced damage)
- Moderate (minimal damage)
## Proposed Classification System

<table>
<thead>
<tr>
<th>Group</th>
<th>IOP lowering level</th>
<th>Glaucoma Damage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>≤4 mmHg</td>
<td>Minimal</td>
</tr>
<tr>
<td>2</td>
<td>≥5 mmHg</td>
<td>Minimal</td>
</tr>
<tr>
<td>3</td>
<td>≥5 mmHg</td>
<td>Mod/Adv</td>
</tr>
</tbody>
</table>
**PROPOSED CLASSIFICATION SYSTEM**

**Group 1-3**

| Provide better guidance to physicians to **make better treatment recommendations** | Yes |
| Help patients with glaucoma **understand their disease better** | Yes |
| Help physicians and patients **plan for future outcomes** | Yes |
PROPOSED CLASSIFICATION SYSTEM

- THIS IS A PROPOSED **DRAFT** FOR CONSIDERATION, INUT AND MODIFICATION

- INCORPORATES LEVEL OF IOP REDUCTION AND THEREFORE HELPS WITH THE SELECTION OF FUTURE TREATMENT

- INCORPORATES GLAUCOMA DAMAGE WHICH CAN PROGNOSTICATE FUTURE COURSE

- PROVIDES A SIMPLE APPROACH TO HELP PATIENTS UNDERSTAND MANAGEMENT OF THEIR DISEASE