

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

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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 <u>make better treatment recommendations</u>	Maybe
Help patients with glaucoma <u>understand their disease better</u>	Maybe
Help physicians and patients <u>plan for future outcomes</u>	No

CURRENT CLASSIFICATION SYSTEMS

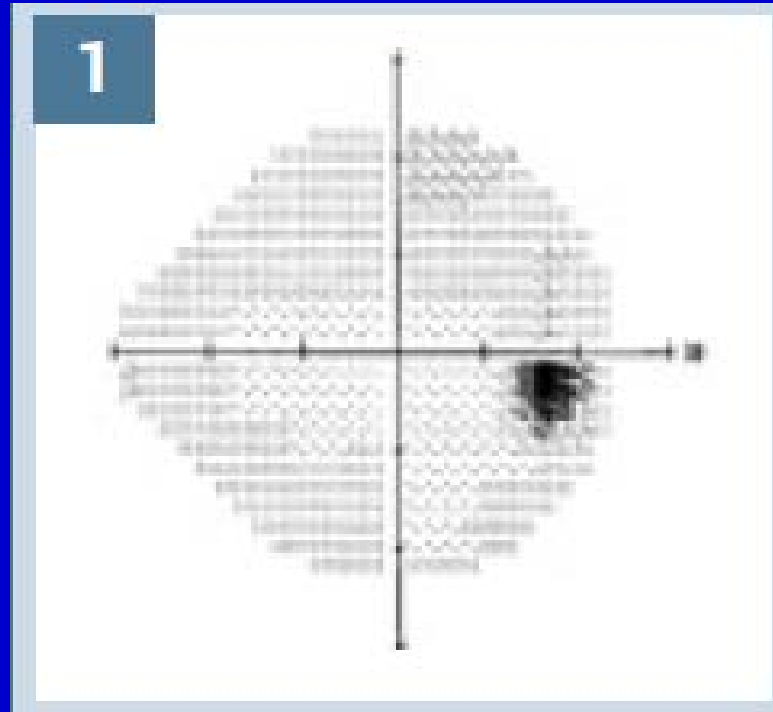
Based on severity of glaucomatous optic nerve damage and visual field loss (Fellman/Mattox et al)

Mild

Moderate

Severe

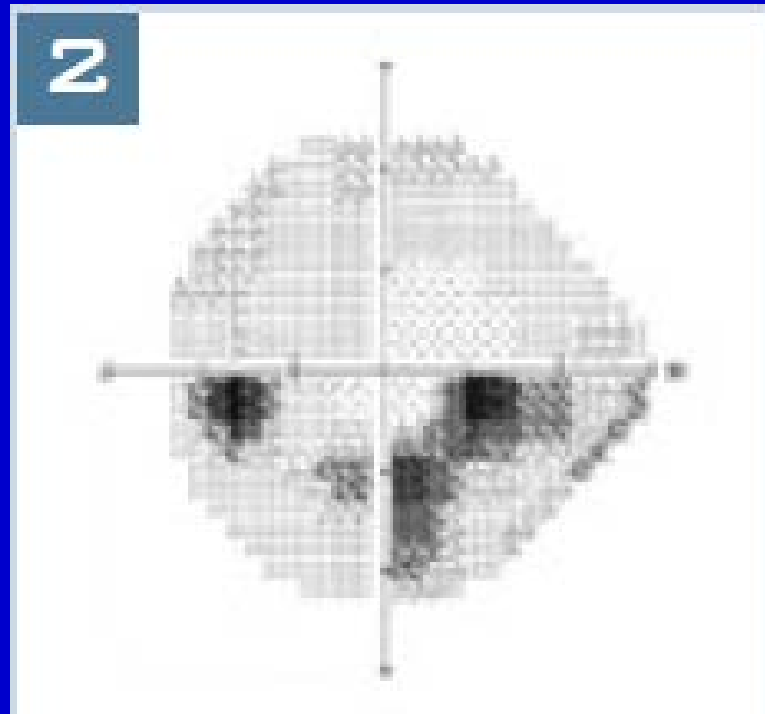
CURRENT CLASSIFICATION SYSTEMS



365.71 **Mild or early-stage glaucoma:**

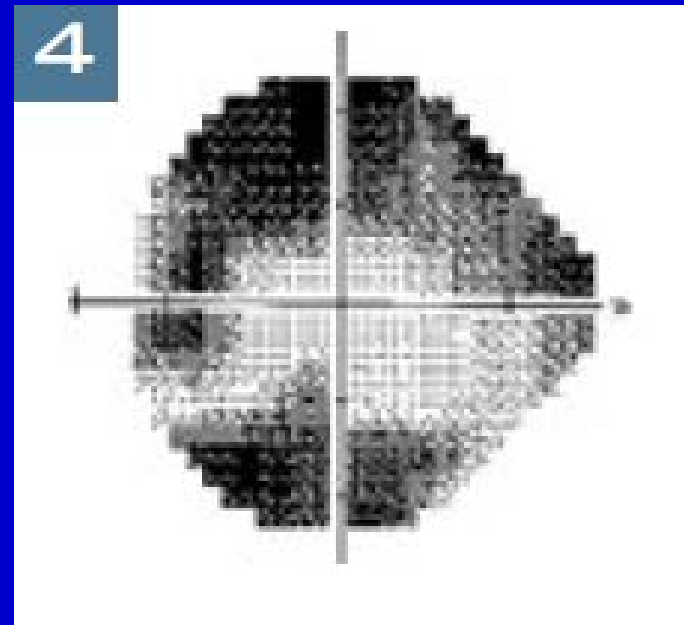
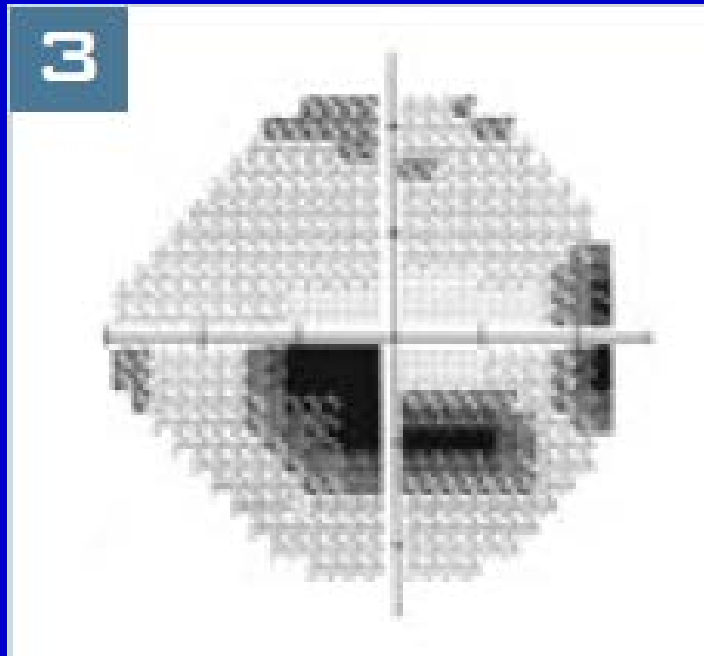
optic nerve abnormalities consistent with glaucoma but no visual field abnormalities on any white-on-white visual field test, or abnormalities present only on short-wavelength

CURRENT CLASSIFICATION SYSTEMS



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

CURRENT CLASSIFICATION SYSTEMS



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

Provide better guidance to physicians to <u>make better treatment recommendations</u>	Maybe
Help patients with glaucoma <u>understand their disease better</u>	Yes
Help physicians and patients <u>plan for future outcomes</u>	Yes

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

Group	IOP lowering level	Glaucoma Damage
1	≤ 4 mmHg	Minimal
2	≥ 5 mmHg	Minimal
3	≥ 5 mmHg	Mod/Adv

PROPOSED CLASSIFICATION SYSTEM

Group 1-3

Provide better guidance to physicians to <u>make better treatment recommendations</u>	Yes
Help patients with glaucoma <u>understand their disease better</u>	Yes
Help physicians and patients <u>plan for future outcomes</u>	Yes

PROPOSED CLASSIFICATION SYSTEM

- THIS IS A PROPOSED DRAFT FOR CONSIDERATION, INPUT 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