

Severity cutoffs for inclusion in MIGS studies

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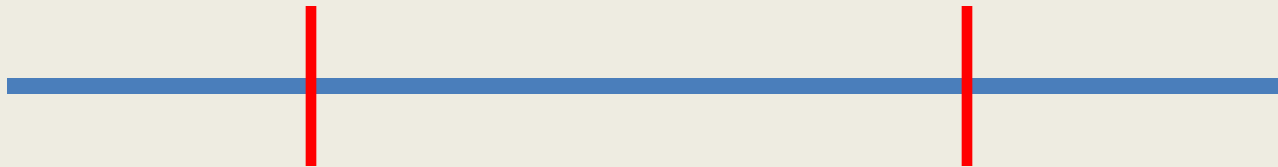
Disclosures

- Ivantis (Hydrus)
- Transcend (CyPass)
- Endo-optics (endolaser)

Clinical measures of severity

- Visual field loss
- Structural measures of ganglion cell loss
 - Optic nerve appearance
 - RNFL thickness
 - Macular thickness
- Associated measures
 - IOP (as a surrogate for outflow damage)
 - Number of IOP lowering medications

Eligible for inclusion



Too
severe

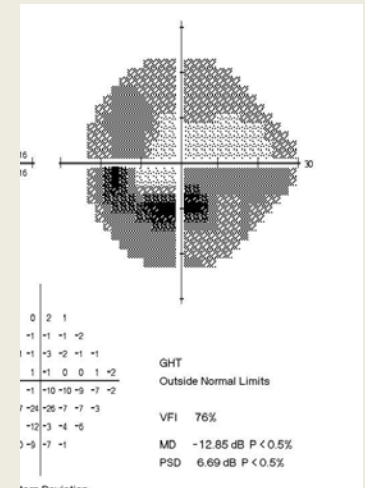
Too
mild

We need a “too severe” cutoff

- Prevent subjecting patients to a procedure unlikely to be effective enough
- Allow inclusion of patients in a control arm such as phaco alone
- Allow for safe washout of medications

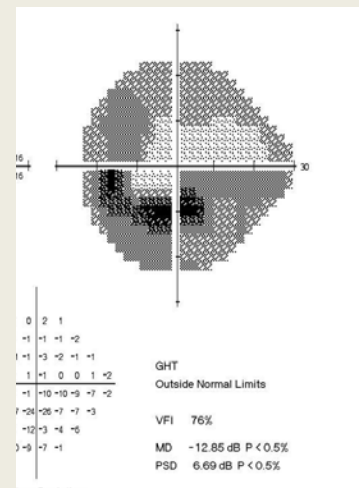
What “too severe” cutoffs are in use?

- VF MD no worse than -12 dB
- Optic nerve C/D ratio of > 0.8
- IOP Treated IOP > 24 mm Hg
- # of meds No more than 3

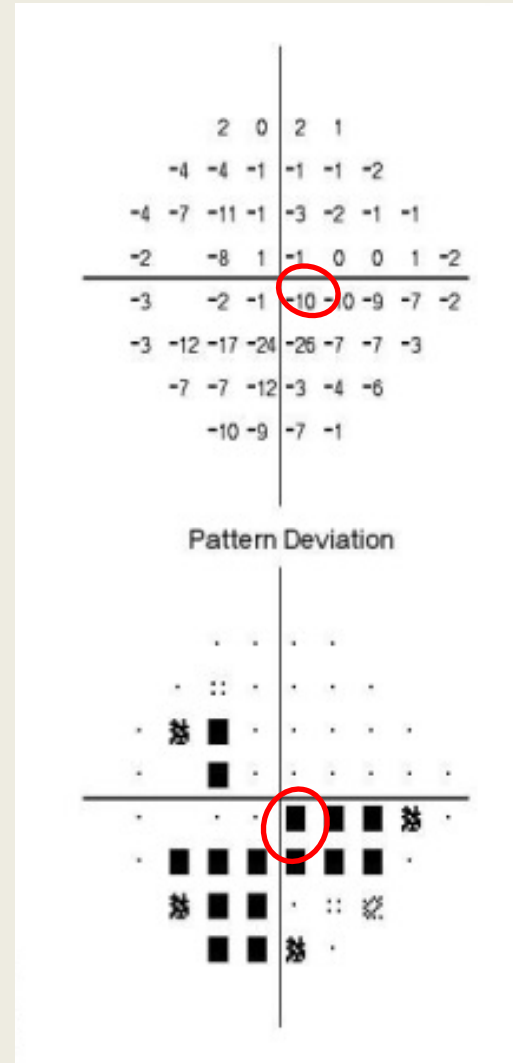
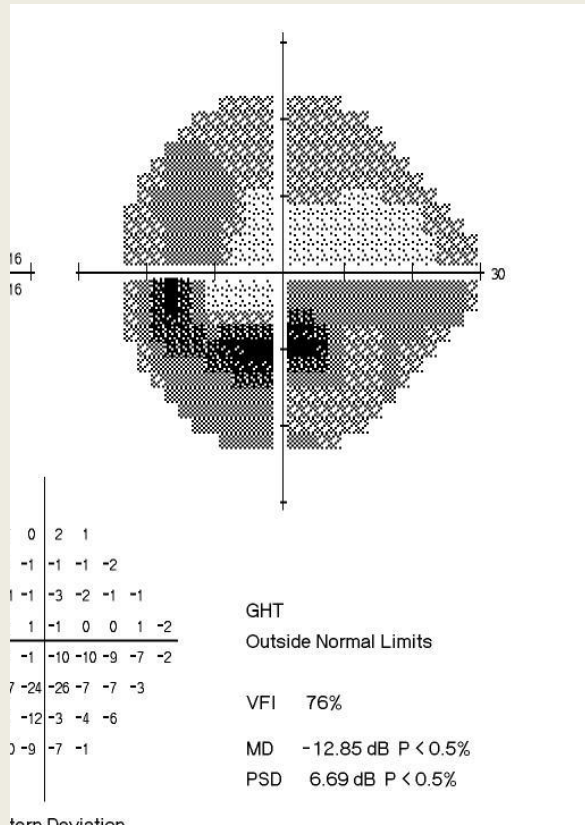


Proposed modification of “too severe” cutoffs

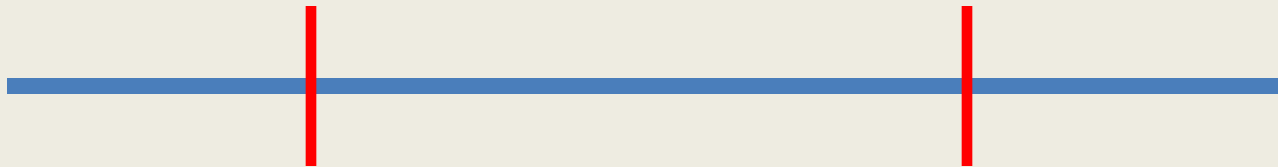
- VF MD no worse than -12 dB
Fixation not threatened
- ~~Optic nerve~~ ~~C/D ratio of > 0.8~~
- IOP Treated IOP > 24 mm Hg
- # of meds No more than 3



Fixation threatened criterion



Eligible for inclusion



Too
severe

Too
mild

We need a “too mild” cutoff
to prevent recruitment of
individuals without disease

“Too mild” cutoffs currently in use

Too permissive

- VF MD greater than 0

Too subjective

- Optic nerve No characteristic signs of damage

OK

- IOP ≤ 21 mm Hg after washout

Proposed modifications of “Too mild” cutoffs

- VF ~~MD greater than 0~~
Defined VF loss
 - GHT ONL?
 - 3 statistically abnl contiguous points?
- Optic nerve ~~No characteristic signs of damage~~
Objective OCT evidence of nerve
fiber layer thinning if VF does not meet criteria
 - average RNFL abnl ($p < 0.01$)?
 - inf or sup sector or segment abnl ($p < 0.01$)?
- IOP IOP \leq 21 mm Hg after washout

Recommendations

- **Too mild side**
 - Defined VF loss
 - If no VF loss, OCT-defined structural damage
- **Too severe side**
 - Don't need optic nerve criteria
 - Include a fixation threatened criterion in addition to mean deviation