



AMERICAN GLAUCOMA SOCIETY

FDA-AGS Workshop on the Validity, Reliability, and Usability of Glaucoma Imaging Devices

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DISCLOSURE

Research Support

- NIH: EY14267, EY10427
- New York Glaucoma Research Institute
- Carl Zeiss Meditech, Inc.
- Diopsys, Inc.
- Glaukos, Inc.
- Heidelberg Engineering, GmbH
- Optovue, Inc.
- Topcon, Inc.
- Reichert, Inc.

Consultant

- Alcon Laboratories, Inc.
- Allergan, Inc.
- Diopysis, Inc.
- Merz, Inc.
- Optovue, Inc.
- Quark Pharmaceuticals, Inc.
- SOLX, Inc.
- Topcon, Inc.

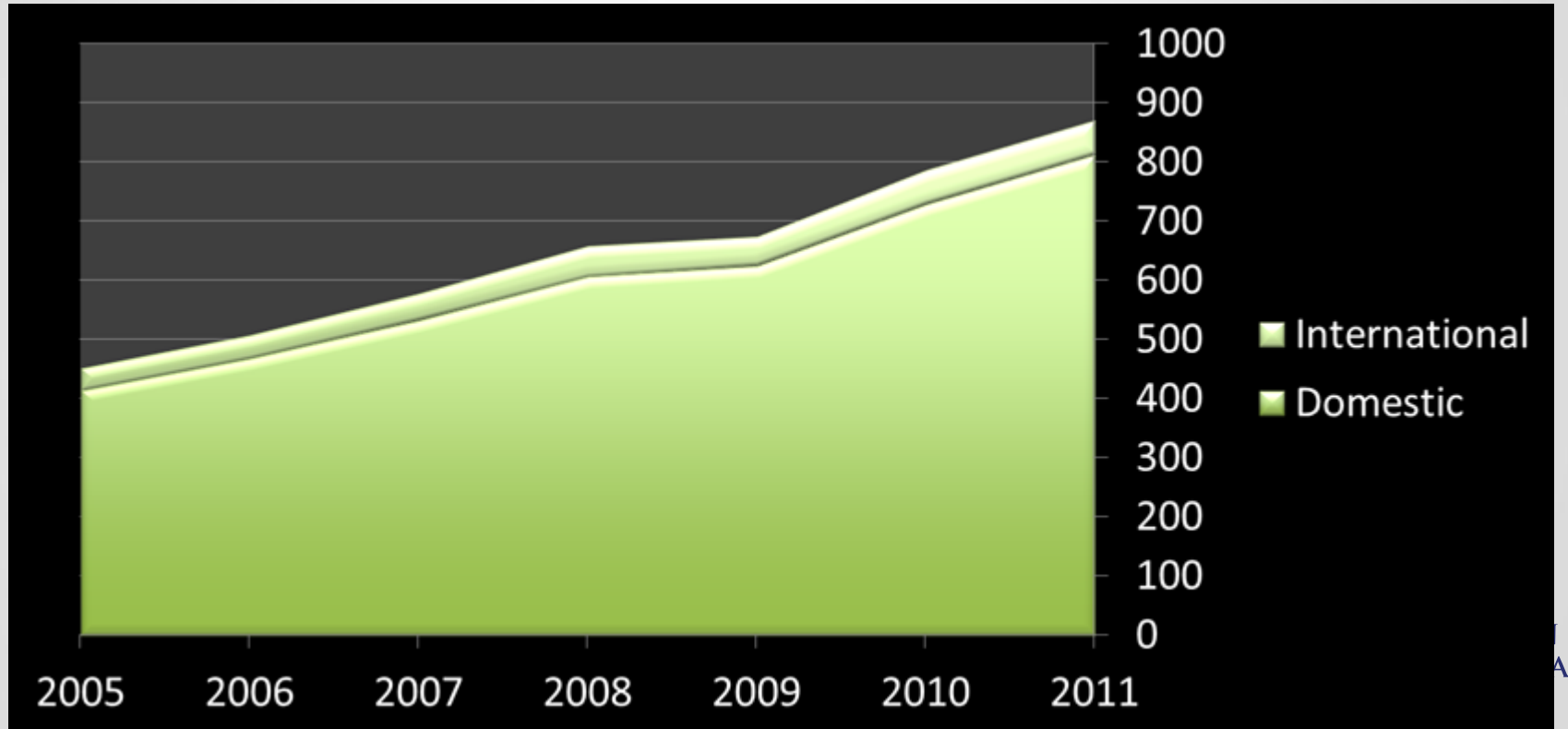
MISSION STATEMENT

The mission of the American Glaucoma Society is to promote excellence in the care of patients with glaucoma and preserve or enhance vision by supporting glaucoma specialists and scientists through the advancement of education and research.



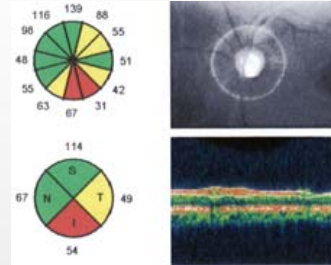
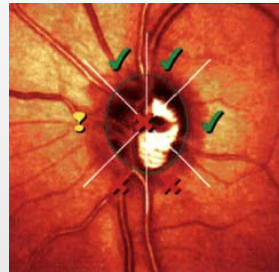
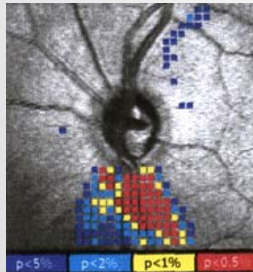
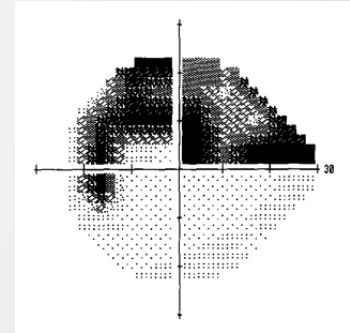
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MEMBERSHIP



GLAUCOMA

- Optic neuropathy
- Characterized by progressive injury to retinal ganglion cells and their axons (*optic nerve structure*)
- Visual field deficit (*optic nerve function*)
- IOP-dependent and IOP-independent risk factors



IMAGING AND GLAUCOMA

- Provides quantitative information about optic nerve structure
- Clinical practice^{1,2,3}
- Stage disease (better assess suspects for the presence of disease)
- Aid in detection of progression
- Brings the clinician to the level of expert observer with respect to diagnosis and progression
- Research²
 - Longitudinal studies of structure and function
 - Endpoint determination
 - Study inclusion parameters
- Computerized imaging in glaucoma enjoys widespread use

1. Vessani et al. JoG 2009;18:253

2. Greenfield, Weinreb AJO 2008;145:698

3. Lin et al, AAO. Ophthalmol 2007;114:1937



FDA-AGS WORKSHOP GOALS

- Provide a platform for direct discussion between physicians, physician-scientists, researchers, and FDA colleagues in the field of glaucoma imaging
- Discuss the construction, reliability, and usability of OCT normative databases.
- Enhance the proper use of these databases and imaging technologies in clinical practice
- Elucidate standards for accuracy, validity, precision, and reproducibility of measurement
- Advance and clarify the regulatory science in the field of glaucoma imaging devices



FDA-AGS WORKSHOP

- Please participate in the discussion and panels – this is your opportunity to provide feedback
- Comments and ideas will be incorporated in the publication

THANK YOU

Program Planning Group

AGS

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Support

American Glaucoma Society

American Glaucoma Society Foundation



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San Francisco 2013

AGS

ANNUAL MEETING

FEB 28–MAR 3

americanglaucomasociety.net

Meeting Information and Registration Materials:

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**Abstracts accepted
until October 29**