Phantoms and Test Targets in the OCT ISO Standard and in Product Development

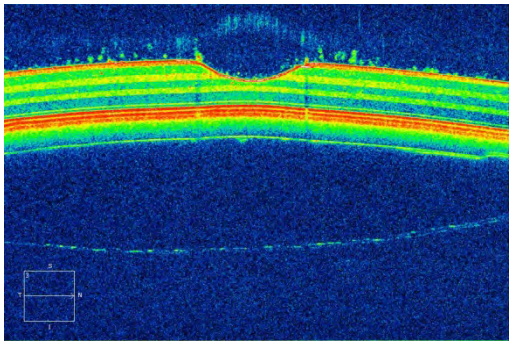
Disclaimer

Views expressed in this presentation are my own, and do not necessarily represent the views of my employer, Carl Zeiss Meditec, Inc.

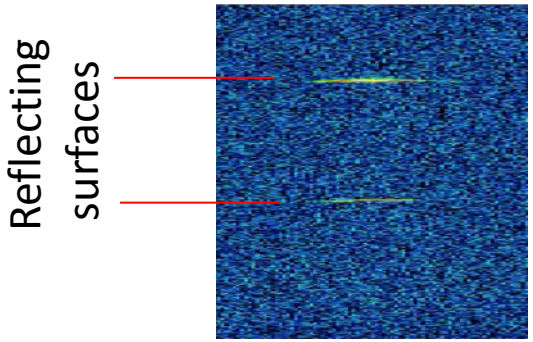
Imaging Phantoms and Test Targets - Definition

How I am using the terminology

- Imaging Phantom – (from Wikipedia)
  - A specially designed object that is scanned or imaged in the field of medical imaging to evaluate, analyze, and tune the performance of various imaging devices.
  - A phantom used to evaluate an imaging device should respond in a similar manner to how human tissues and organs would act in that specific imaging modality.
- Test Target (my definition)
  - Similar to Imaging Phantom, but without requirement to respond like tissue



FDA Tissue phantom image*



Axial scaling test target

*J. Baxi et al., "Retina-simulating phantom for optical coherence tomography," J. Biomed. Opt. 2014

ISO Ophthalmic Imaging Standards

ISO 10940 Ophthalmic instruments – Fundus cameras

ISO 16971: Ophthalmic instruments – OCT for the posterior segment of the human eye

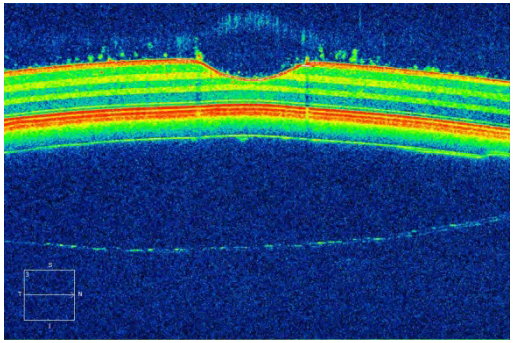
- ISO 10940 – Fundus cameras
  - Well established standard
  - Released more than 10 years ago
  - Publicly available
- ISO 16971 – OCT
  - Standard in draft, being voted on
  - Not publicly available

Phantoms and Test Targets in ISO Ophthalmic Imaging Standards

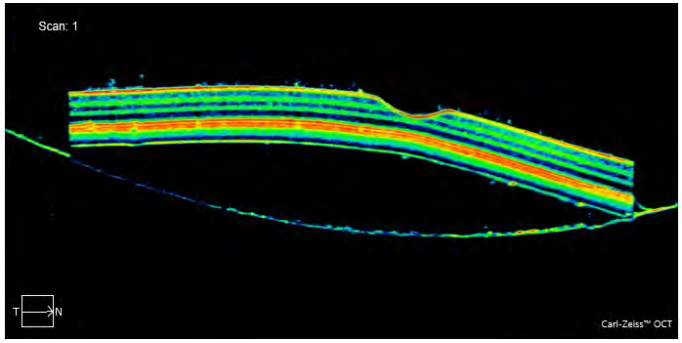
- Both ISO 16971 (OCT) and 10940 (Fundus cameras)
  - Contain descriptions of use of test targets for evaluation of instruments
  - Contain no text regarding use of phantoms
- Use of phantoms:
  - Is potentially more relevant for OCT than fundus cameras
  - Have been discussed for ISO 16971 (OCT)
  - Was not yet embraced

Use in OCT Product Development

- Both test targets and phantoms reduce scanning of humans and associated safety and paperwork issues
- Test targets are used for calibration, alignment, and testing
- Phantoms are used for evaluating and comparing prototype performance
  - Generally qualitative, not quantitative



FDA Phantom scanned on Cirrus.



Scanned on prototype system

Characterizing Ophthalmic OCT instruments

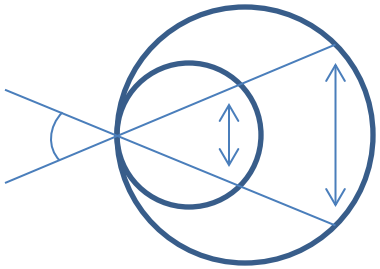
- Ophthalmic OCT instruments have a significant number of key attributes
- Some attributes are difficult to measure with test targets
- Performance is often affected by the specific human eye being measured

-> Opportunity and Challenge for Tissue Phantoms

Key Characteristics of Ophthalmic OCT Instruments

- Image scaling
  - Transverse
  - Axial
- Imaging performance
  - Transverse resolution
  - Axial resolution
  - Sensitivity
  - Ability to identify tissue layers and features
  - “Image appearance”
- Tissue segmentation results
  - Thickness accuracy
  - Thickness reproducibility
  - Robustness to human variability
  - Robustness to pathology

Dependence on Human Eye



- Image scaling
  - Transverse -> Eye length/refractive error
  - Axial -> Refractive index of tissue
- Imaging performance
  - Transverse resolution -> Optical aberrations/focus
  - Axial resolution -> Optical dispersion (small effect)
  - Sensitivity -> Scattering properties of tissue
  - Ability to identify tissue layers and features –> state of tissue
  - Image appearance -> Cataract, disease
- Tissue segmentation results -> state of tissue
  - Thickness accuracy
  - Thickness reproducibility
  - Robustness to human variability
  - Robustness to pathology

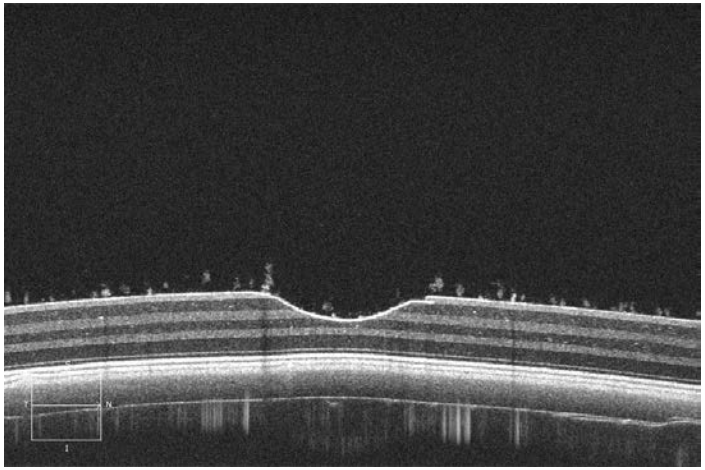
Ways that Phantoms could potentially be used

- Image evaluation
  - Qualitative?
  - Quantitative?
- Comparison between systems
- Testing of segmentation algorithms

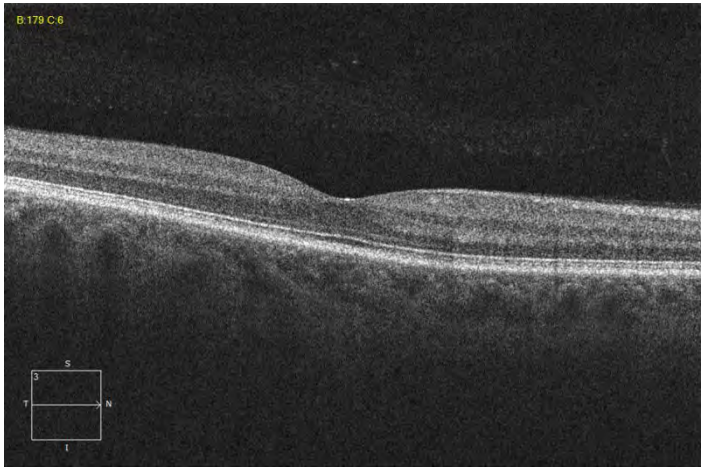
Phantoms for Tissue Segmentation Evaluation

- Use of Phantoms for Tissue Segmentation is highly desirable
- If we could use tissue phantoms, it would:
  - Greatly reduce testing on humans
  - Simplify comparison between instruments
  - Provide a standard to test against
  - Improve reproducibility of tests
- Tissue phantoms are beginning to look like healthy human eyes

Tissue phantoms can look similar to healthy eyes



FDA Phantom



Healthy eye

Challenges in using tissue phantoms for segmentation algorithm evaluation

Eyes are more complex and variable than tissue phantoms

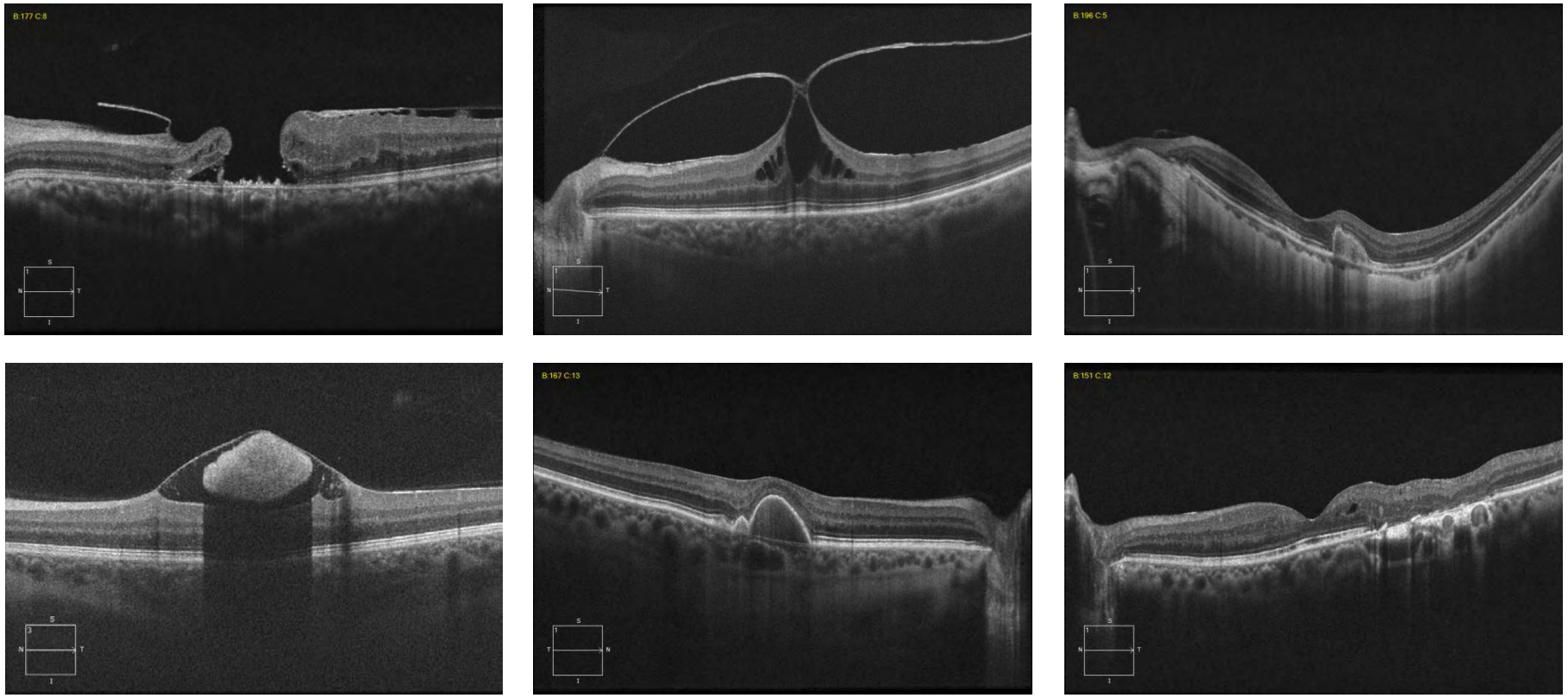
->

- Demonstration of algorithm success on phantom does not guarantee success on real tissue.
- Optimization of algorithm to generate best results on phantom is likely to impact performance on real eyes
- Claims based on testing on phantoms could overpromise results in real eyes

Why segmentation success on phantom does not guarantee success on real tissue

- Phantoms can simulate human eyes, but will never be identical to them
- Tissue and eye variation among normals is significant
- Algorithms must also work on a large variety of diseased eyes
  - Purpose of instrument is to evaluate people with disease, and disease is highly variable

Diseased human eyes are highly variable



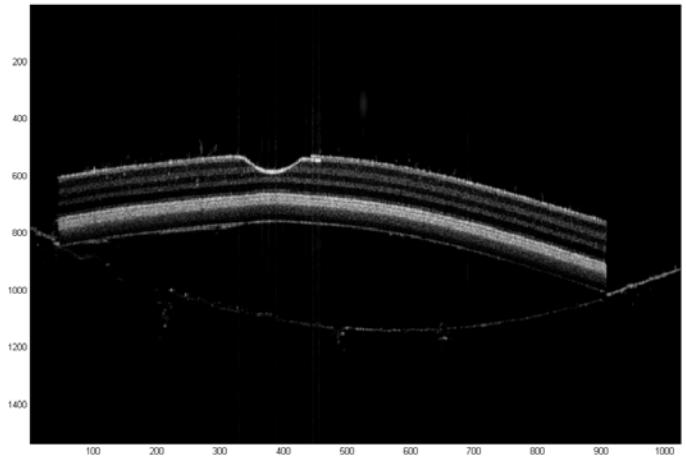
Why segmentation success on real tissue does not guarantee success on phantom

- Phantoms can simulate human eyes, but will never be identical to them
- Phantom is unlikely to contain all contrast mechanisms available in real eye
  - Depolarization to identify RPE
  - Motion to identify vascular structure
  - Birefringence to identify nerve fiber layer
  - Angle dependent scattering to identify photoreceptors.

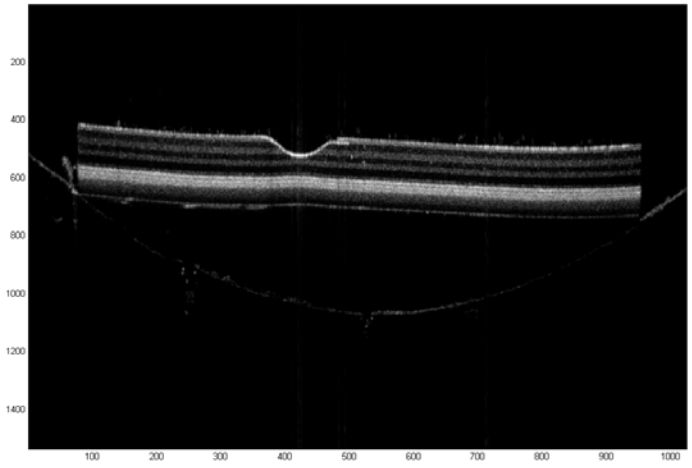
Design considerations for Phantoms and Test Targets

- Optical characteristics of the eye (eye model)
  - Optical aberrations on axis, and as function of position on retina
- Details of scattering behavior
  - Birefringence
  - Angle dependence
  - Wavelength dependence
- Variability between human eyes
  - Eye size and shape -> optical aberrations, scaling effects
  - Ethnicity -> melanin content -> imaging depth
  - Disease states
- Imaging protocol

Effect of Imaging Protocol



FDA phantom scanned properly



Scanning pivot point not at pupil

Conclusions

- Test targets are currently used in the ISO Ophthalmic imaging standards
- Tissue phantoms are not yet used in the ISO Ophthalmic imaging standards
- Development of tissue phantoms will benefit ophthalmology by reducing the need for scanning of humans
- Scanning of humans will continue to be needed for evaluating instruments.

THANK YOU