Disclosures

As an inventor of Optical Coherence Tomography (OCT), Dr. Schuman receives royalties for intellectual property owned by Massachusetts Institute of Technology and Massachusetts Eye and Ear Infirmary and licensed to Carl Zeiss Meditec, Inc., and has received royalties for intellectual property owned by University of Pittsburgh and licensed to Bioptigen, Inc.

Introduction to Optical Coherence Tomography (OCT) Technology

Time-Domain and Spectral-Domain Including Similarities and Differences between these Technologies

FDA AGS WORKSHOP

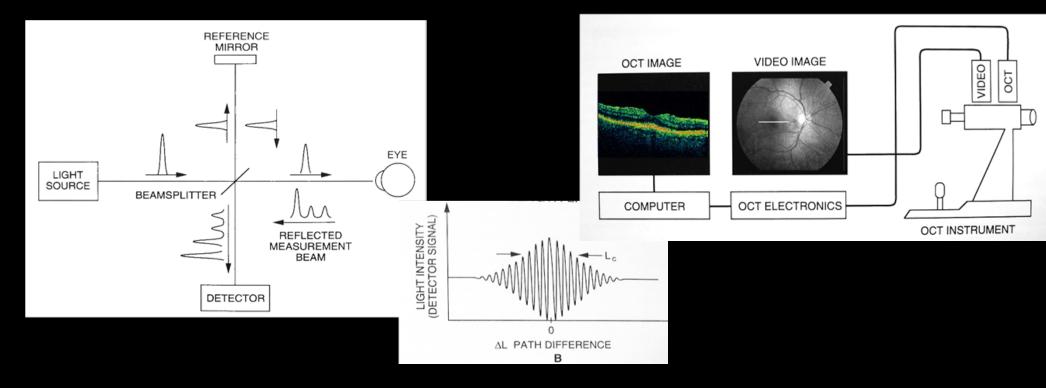
The Validity, Reliability, and Usability of Glaucoma Imaging Devices 5 October 2012

JOEL S. SCHUMAN, MD

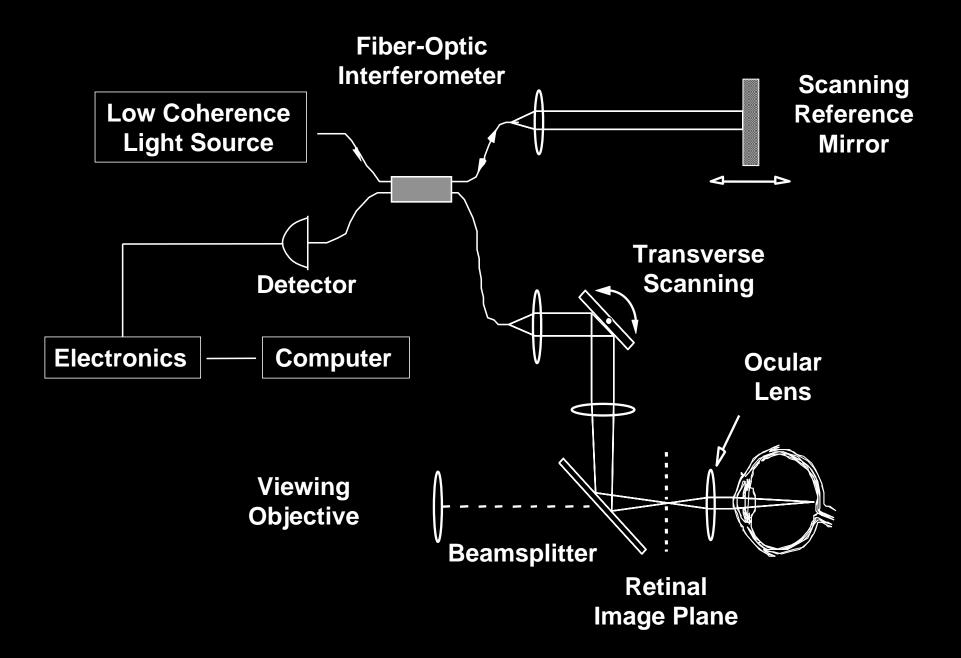
EYE AND EAR FOUNDATION PROFESSOR AND CHAIRMAN DEPARTMENT OF OPHTHALMOLOGY, UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE DIRECTOR, UPMC EYE CENTER PROFESSOR OF BIOENGINEERING, SWANSON SCHOOL OF ENGINEERING FOX CENTER FOR VISION RESTORATION MCGOWAN INSTITUTE FOR REGENERATIVE MEDICINE UPMC & UNIVERSITY OF PITTSBURGH CENTER FOR THE NEURAL BASIS OF COGNITION UNIVERSITY OF PITTSBURGH & CARNEGIE MELLON UNIVERSITY PITTSBURGH, PA USA

Basic OCT Principles

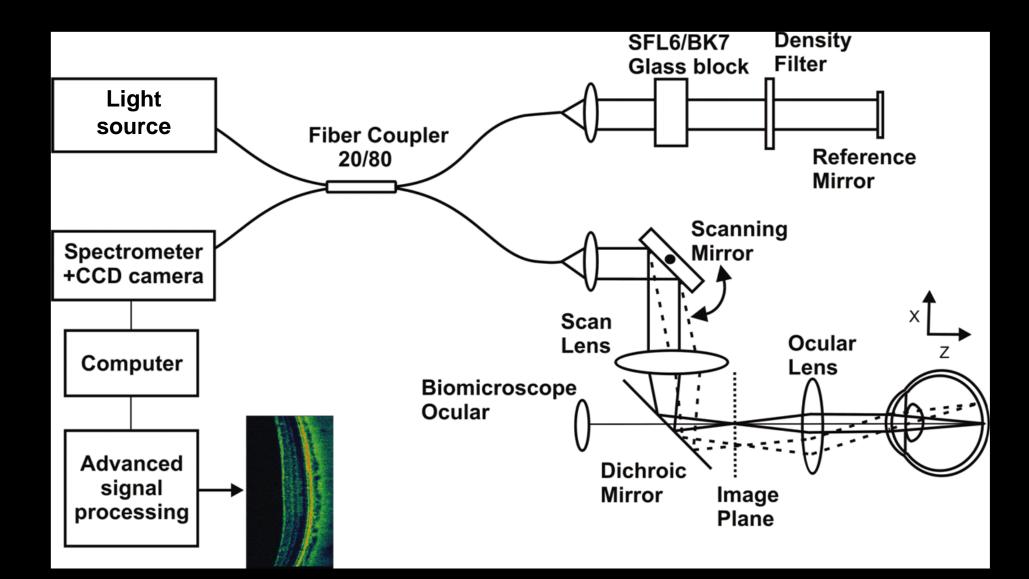
- Uses near-infrared light (~800-1310nm)
- Michelson type interferometer
 - Measures time-of-flight of light (Time-Domain)
 - Measures wavelengths of backreflected light (Spectral-Domain)
- Low coherence allows high resolution



Ophthalmic OCT Imaging System



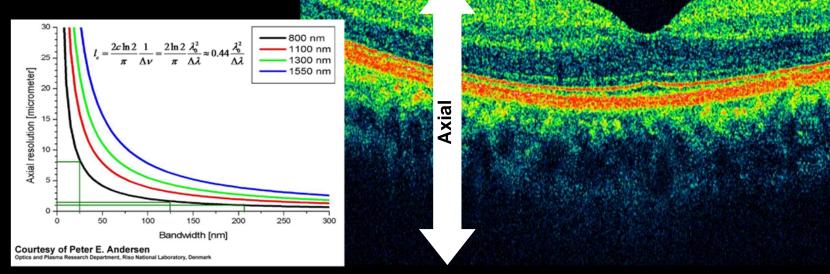
High Speed OCT with Spectral/Fourier Domain Detection



What determines OCT resolution?

OCT has 2 independent directions of resolution

- Lateral resolution determines accuracy with which size and separation of features can be identified. It is based on:
 - $_{\odot}$ Width of the beam waist and is limited by optics of eye (~10-20 $\mu m)$
- Axial resolution determines which layers can be distinguished. It is based on:
 - o Wavelength of light source
 - ${\rm o}$ Bandwidth of light source



Resolution

TD-OCT

- In TD-OCT, there is a mechanical moving part, which performs the A-scan, and the information along the longitudinal direction is accumulated over the course of the longitudinal scan time
- Due to the nature of the slow mechanical moving speed, the scan time in TD-OCT is slow
 - Stratus can perform 400 A-scans/second
- Because of the eye motion, it is not feasible to use TD-OCT to precisely map retinal tissue in three dimensions

SD-OCT

- Broadband source is employed and the entire signal (at all wavelengths) is recorded in parallel by a spectrometer
- Acquire the signal in the wavelength space and Fourier-transform it to get the spatial information
- All done at same time, so speed dramatically increased (50-1000x faster than TD)

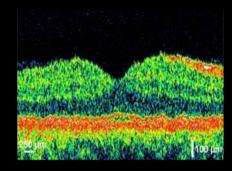
Spectral Domain Advantages

- Improved resolution
- Improved acquisition speed
 - Reduces motion artifacts
 - Digital processing not required to align adjacent axial scans = More accurate retinal scans
- 3D views
- More accurate segmentation
- Precise registration/orientation

OCT Imaging Speeds and Technologies

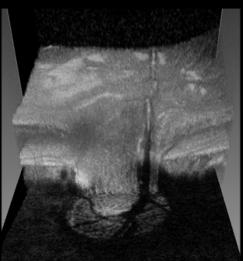
Time Domain OCT 400 axial scans per second (Zeiss Stratus - 2002) 8-10 um axial resolution Spectral / Fourier Domain OCT – spectrometer 25,000 - 50,000 axial scans per second (2006) 5 - 7 um axial resolution **Next Generation Spectral / Fourier OCT** 70,000 – 100,000 axial scans per second ~3 - 5 um axial resolution 100,000 – 250,000 axial scans per second ~5 - 10 um axial resolution Swept Source / Fourier OCT – swept laser 200,000 + axial scans per second ~5 - 7 um axial resolution at 1050 nm wavelengths

Zeiss StratusOCT



512 A-scan Image, ~1.3 seconds

Ultrahigh Speed



500 x 500 A-scans, ~2 seconds

OCT – The Next 5 Years?

- Competition between manufacturers will drive rapid innovation of technology
- Ophthalmologists will have the possibility to assess retinal pathology like pathologists
- Software advances will enable advanced quantitative assessment and display of 3D OCT data
- Subtle changes in pathology will be measurable, enabling more accurate monitoring of disease progression and response to therapy
- New, lower cost OCT instruments will enable wider spread access, especially in the international community

Summary

- OCT performs "optical biopsy" imaging tissue pathology in situ and in real time
- Retinal pathology can be examined at the level of individual retinal layers
- 3D OCT provides comprehensive information about structure
- Reproducible registration, longitudinal follow up, quantitative assessment
- Many new clinical studies are possible to develop biomarkers for earlier diagnosis, track disease progression and response to therapy

