WORKSHOP:

LE NUOVE TECNOLOGIE PER LA CHIRURGIA OFTALMICA. ASPETTI INNOVATIVI E DI SICUREZZA PER IL PAZIENTE

Forlì, 12 Aprile 2019 – Hotel Globus City, Sala Congressi America

iOCT Intra-operative OCT
La Quarta Dimensione nell'Imaging intraoperatoio

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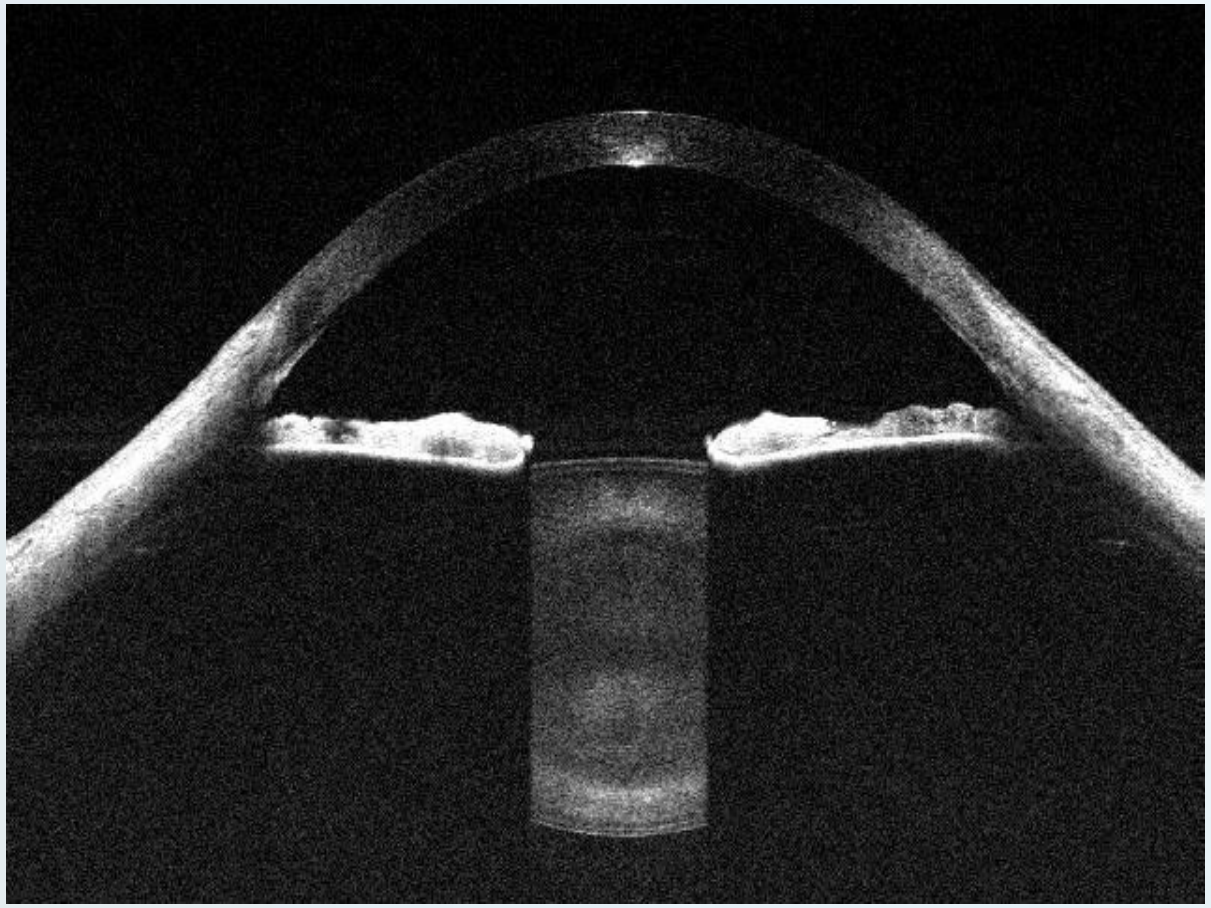
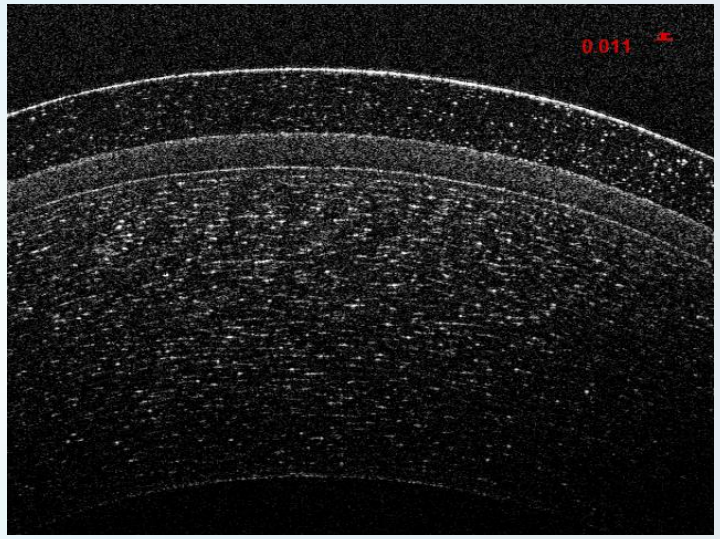
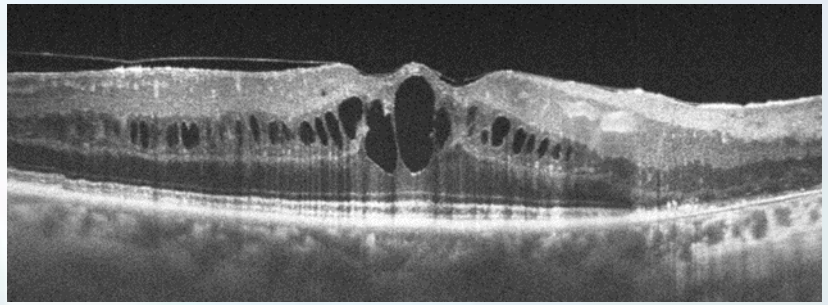
Leica Microsystems

Esempi Tipici d’immagini OCT





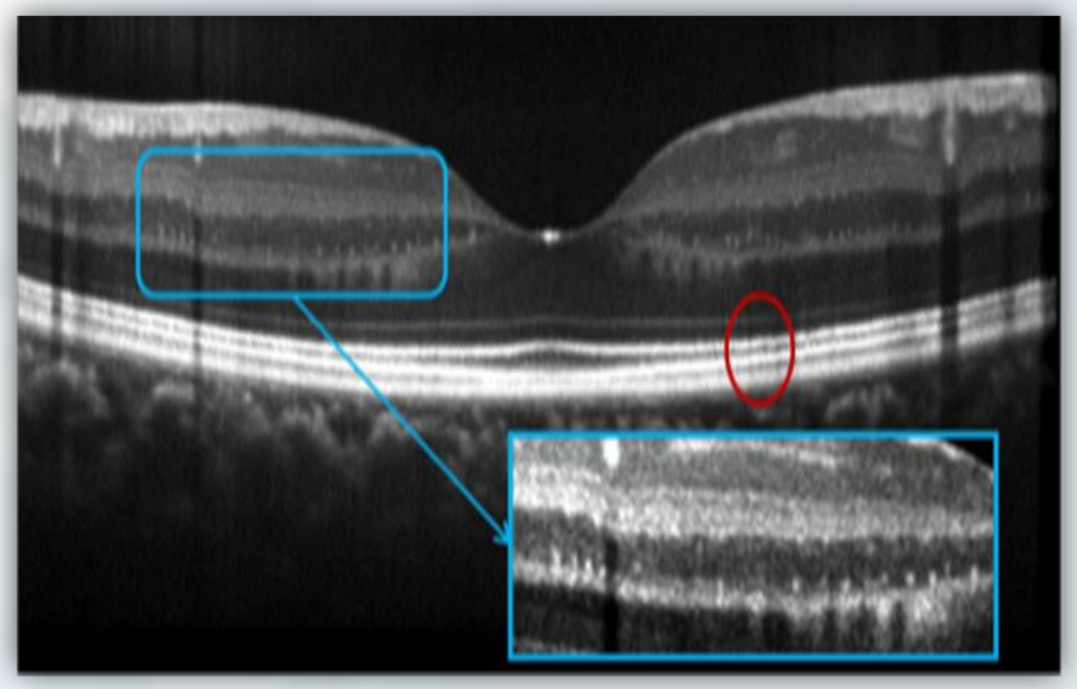
Esempi Tipici d’immagini OCT



What is OCT?

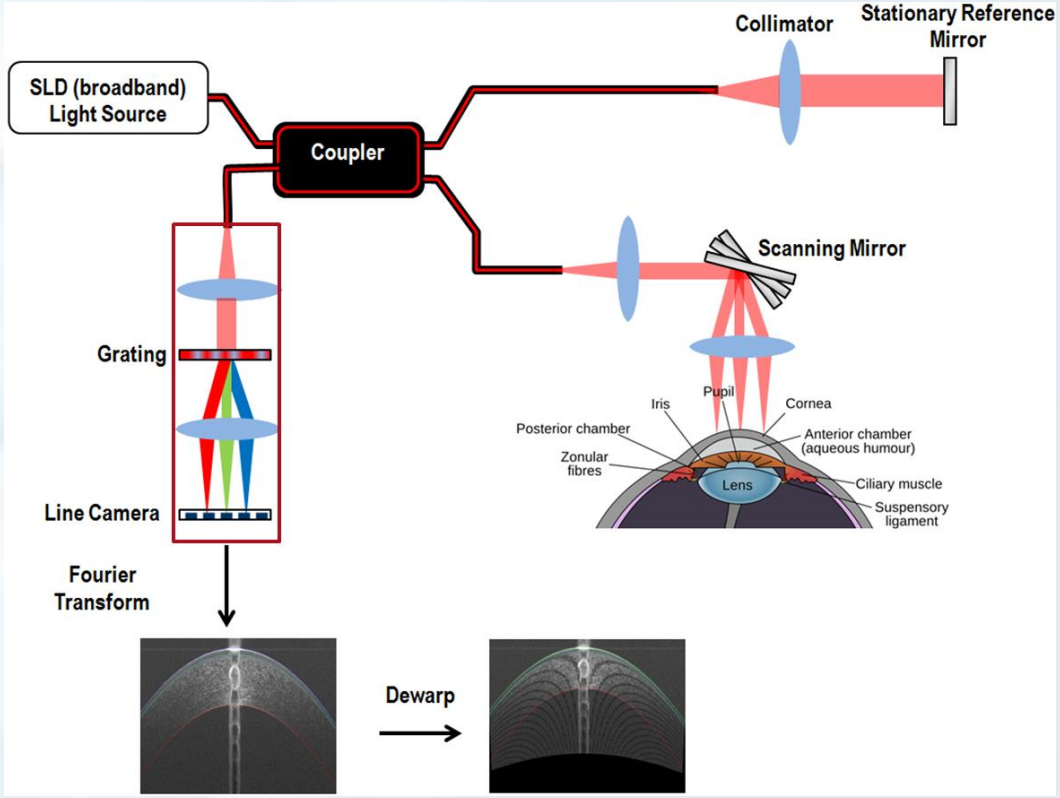
- Optical Coherence Tomography
  - Optical -> a light based imaging technology
  - Coherence -> signal is based on interferometry
  - Tomography -> produces 3D tomograms (volumes) composed of 2D slices (B-scans)

- OCT produces beautiful, high-resolution images with micron-scale resolution



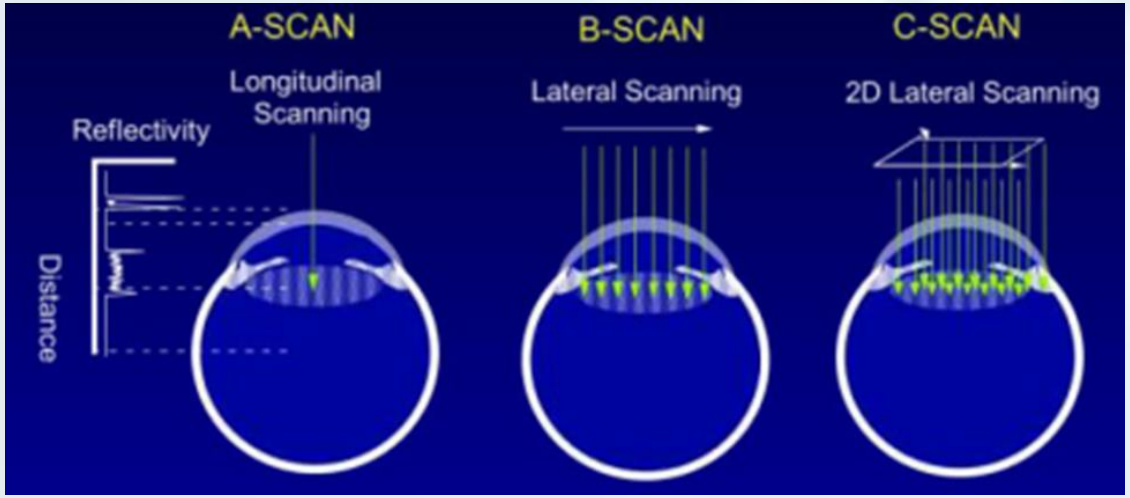
How does it work?

- OCT is an optical analogue of ultrasound
  - Send light into tissue and measures the time it takes for the light to come back
  - This time of flight is too fast to be measured directly, so we use interferometry
  - Light from the reference arm interferes with light from the sample arm (in this case, ‘the eye’)
  - When the two arms are matched, we get an interference signal, allowing us to measure time of flight by scanning the reference arm

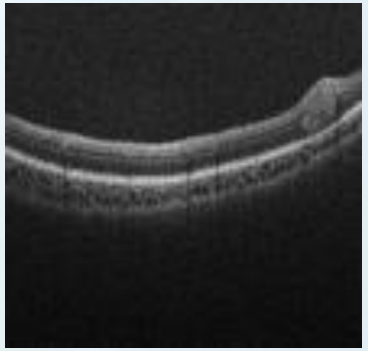


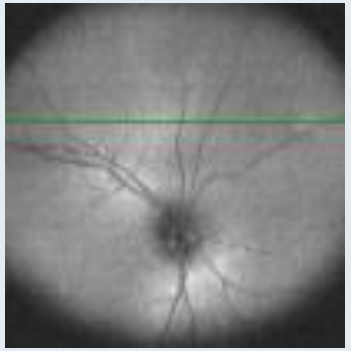
A-scans, B-scans, C-scans

- OCTs builds up images one “depth scan” (A-scan) at a time
- The beam is scanned in one dimension to produce a cross-sectional slice (B-scan)
- The beam is then scanned in the orthogonal dimension to build up multiple slices into a volume (or C-scan)



OCT
B-Scan

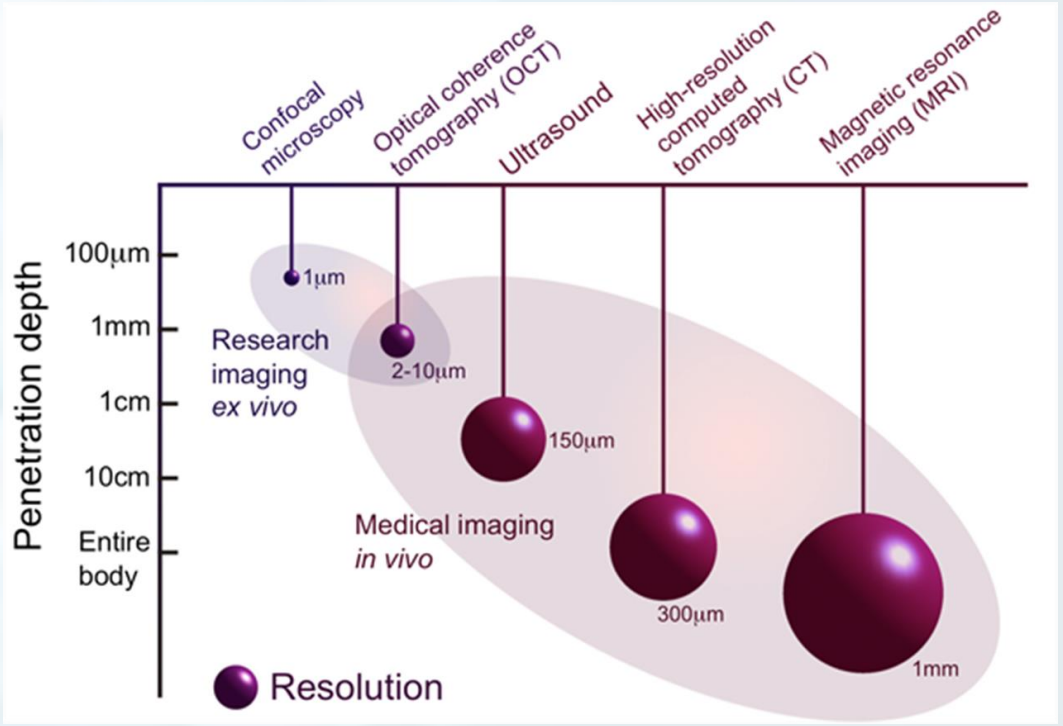




OCT
B-Scan
Location
in volume

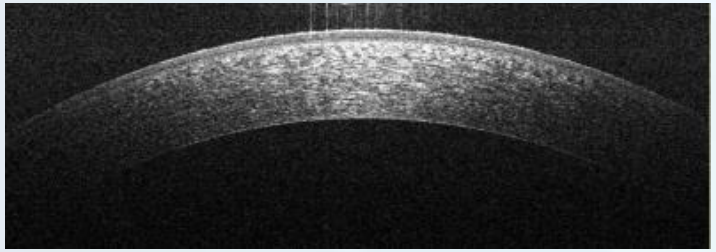
Resolution

- Axial and lateral resolution are decoupled, enabling each to be optimized independently for a particular application
  - Axial resolution: along the beam path (A-scan direction), distinguishes the layers of the cornea and retina
  - Lateral resolution: transverse to the beam path is similar to the resolution of the microscope view
- Axial resolution is dependent on the bandwidth and on wavelength of light source
  - Broader bandwidth & Short wavelength -> finer resolution -> shallower depth
  - Narrower bandwidth & Long wavelength -> coarser resolution -> deeper depth

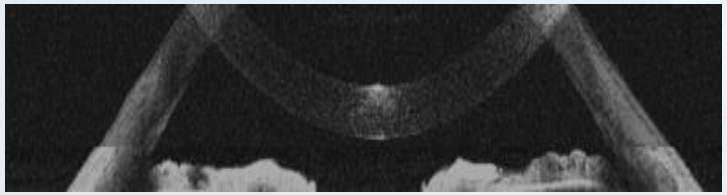


OCT Depth & Resolution Trade-Off

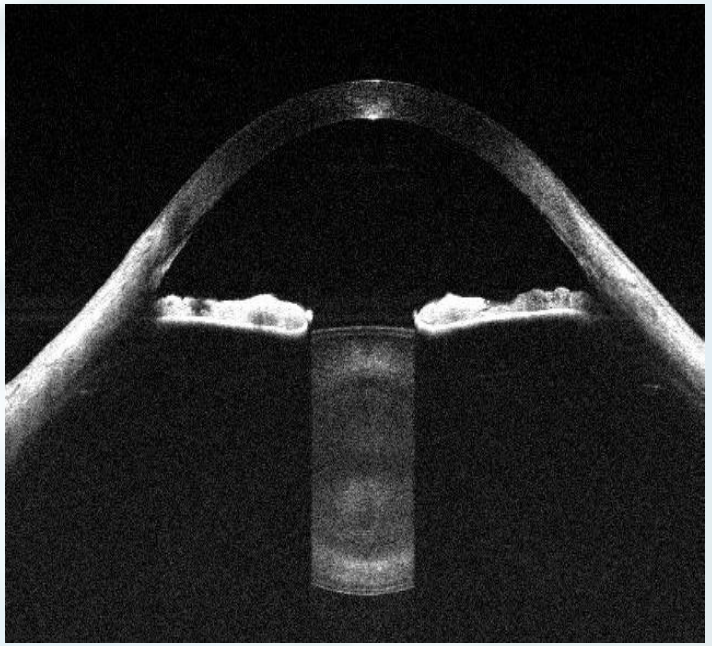
Low dispersion spectrometer:
less depth, greater resolution



Fold-over artifact



High dispersion spectrometer:
greater depth, less resolution

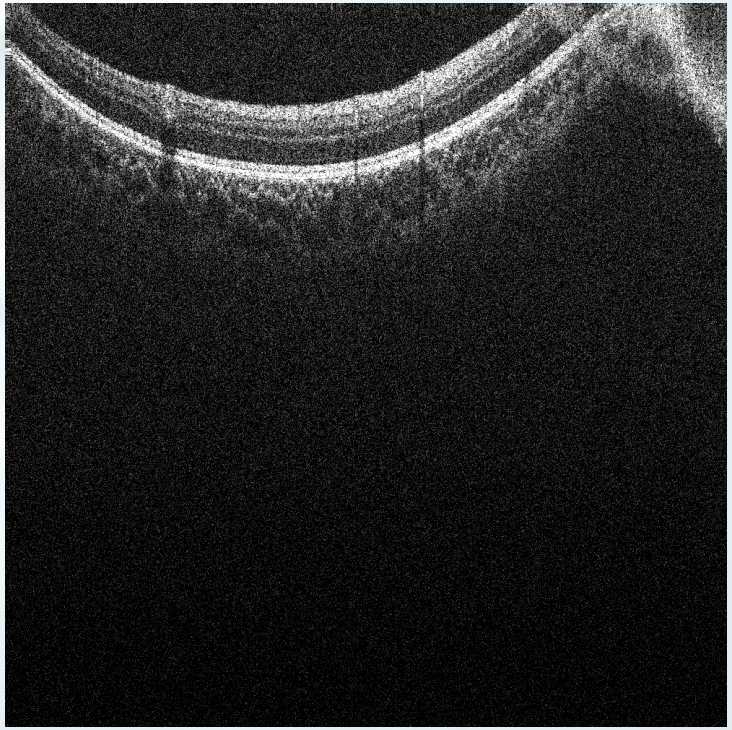


OCT Depth & Resolution Trade-Off

Low dispersion spectrometer:
less depth, greater resolution

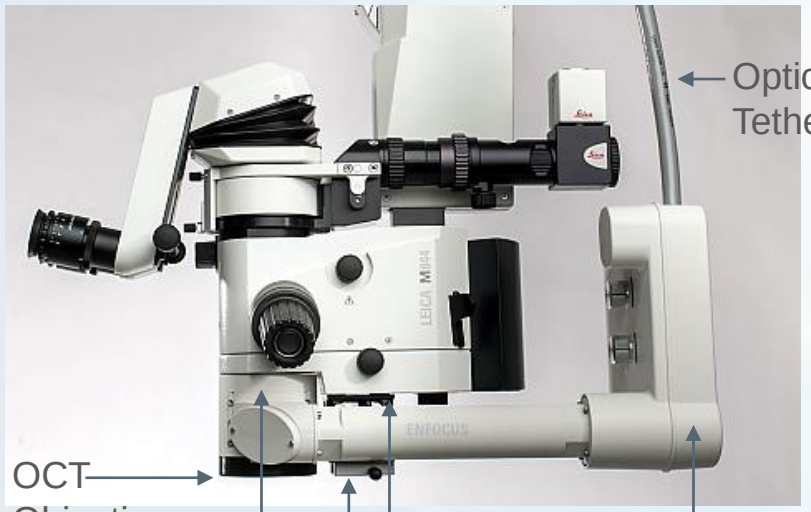
11.1 mm - 9 microns resolution
Traction Retinal Detachment

High dispersion spectrometer:
greater depth, less resolution

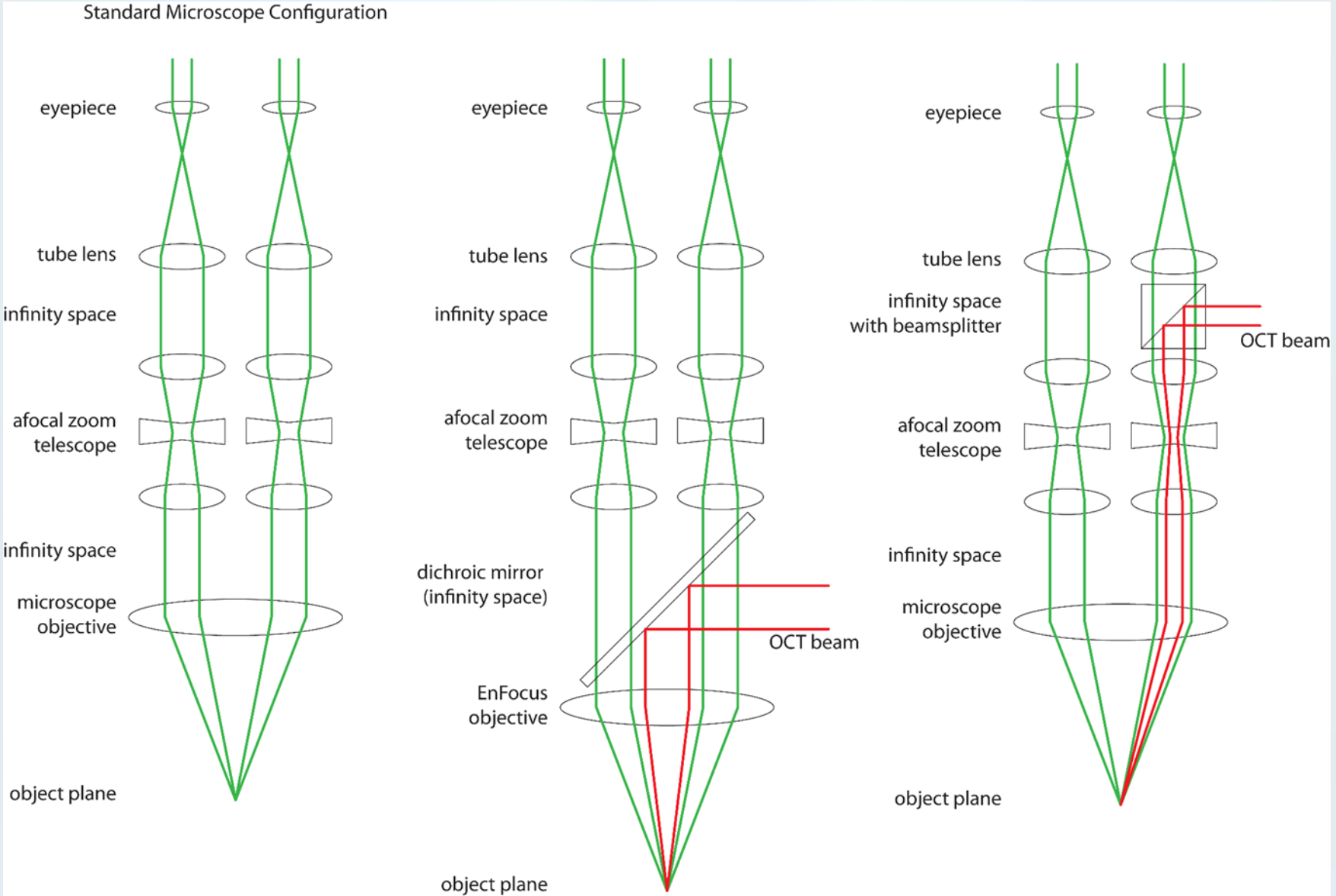


2.5mm - 4 microns resolution
Retinoblastoma

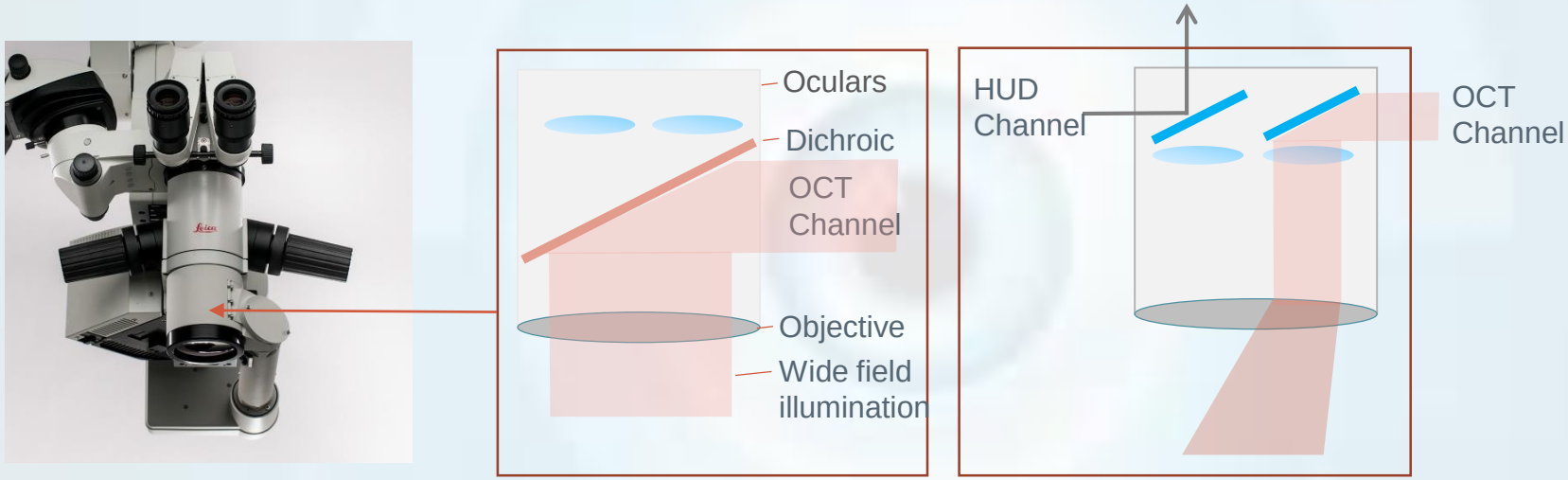
Setup Example on Microscope



Main alternatives on OCT beam injection



Main alternatives on OCT beam injection

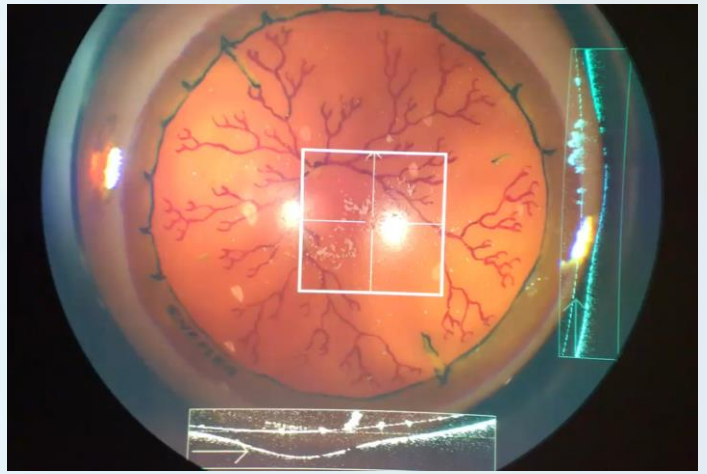


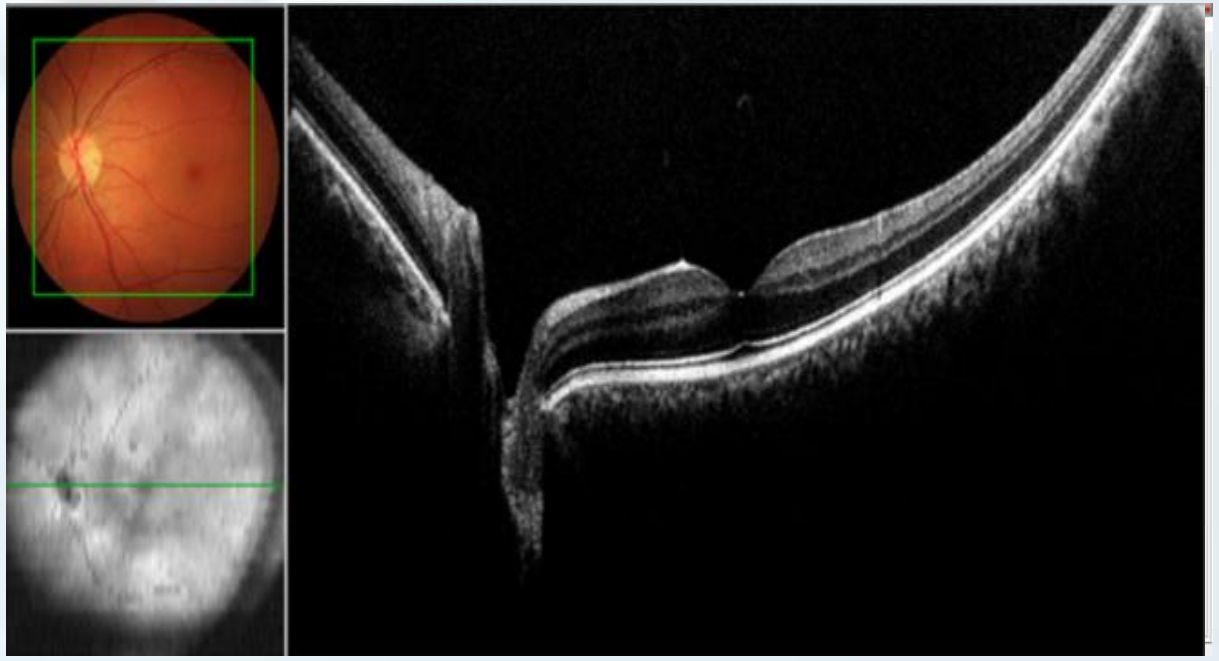
Surgical Workflow Management

OCT Use:

- On-screen procedural pre-set modes
- Customizable scan management
- Image-guided dynamic scan control
- Integrated footpedal control
- On-screen caliper measurements

Example of Intrasurgical OCT image management software



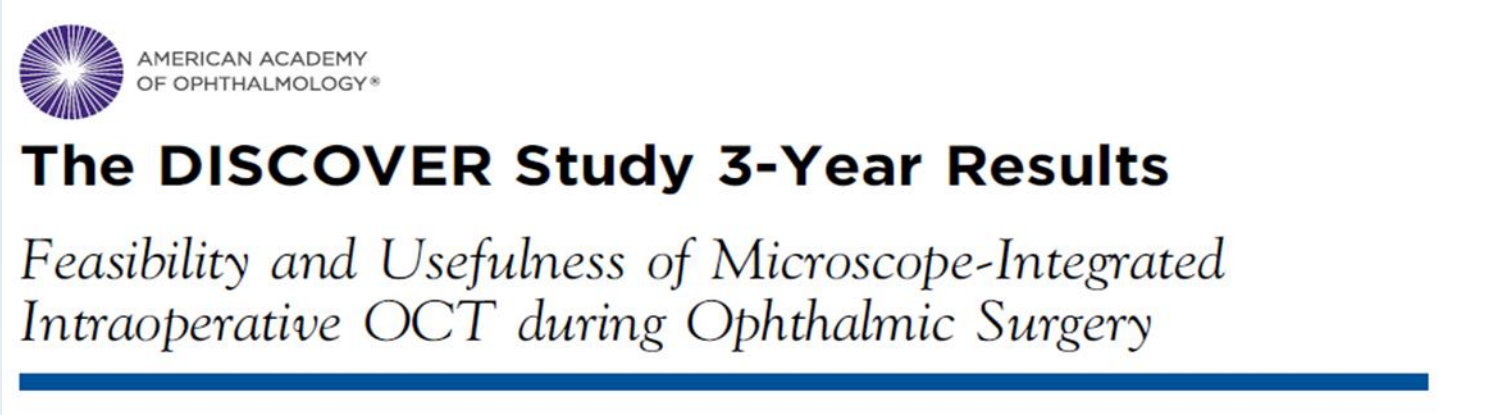


Advantages and Clinical information Intraoperative Use Cases for OCT

- 29.2% of posterior cases had decisions change intraoperatively due to real time visualization of OCT

- 43.4% of anterior segment cases had decision change intraoperatively due to real time visualization of OCT

https://www.ncbi.nlm.nih.gov/pubmed/29409662

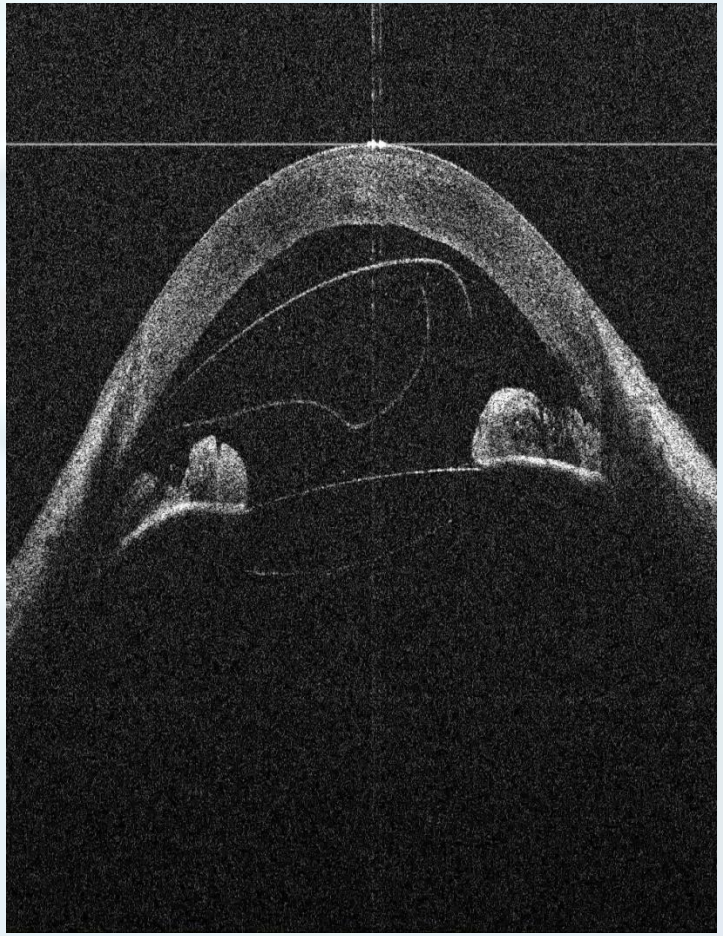


Advantages and Clinical information Intraoperative Use Cases for OCT

Procedure	Procedure Description	Relevant Anatomical Features Visualized by EnFocus OCT
DALK	**D**eep **A**nterior **L**amellar **K**eratoplasty – Removal of all corneal layers anterior to Descemet's membrane and replacement with donor tissue	• Visualization of air injection and measurement needle depth • Visualization of removal of recipient stroma • Caliper measurement of stromal thickness/trephine depth • Caliper measurement of graft thickness • Visualization of graft adherence and interface fluid
DSAEK	**D**escemet's **S**tripping **A**utomated **E**ndothelial **K**eratoplasty – Removal of Descemet's membrane and replacement with donor tissue, both stroma and Descemet's	• Visualization of removal of Descemet's membrane • Visualization of graft orientation • Visualization of graft adherence and interface fluid • Caliper measurement of post-op corneal thickness
DMEK	**D**escemet's **M**embrane **E**ndothelial **K**eratoplasty - Removal of Descemet's membrane and replacement with donor tissue, Descemet's only	• Visualization of removal of Descemet's membrane • Visualization of graft orientation (scroll) • Visualization of graft adherence
Cataract	Removal of cataract, implantation of IOL	• Visualization of residual epithelial cells in capsular bag • Visualize settling of IOL • Visualize adherence of posterior capsule to IOL
PPV	**P**ars **P**lana **V**itrectomy – removal of vitreous, indicated for a wide variety of conditions including macular hole/pucker, vitreomacular traction, macular edema, vitreous hemorrhage, tractional retinal detactment and others	• Visualization of separation of posterior hyaloid membrane • Visualization of retinal morphology including ERM, macular hole, edema, traction, etc. • Visualization and caliper measurement of macular edema • Visualization of macular hole and caliper measurement of hole thickness
Air/Fluid Exchange	Injection of air (or gas mixture) to seal retina, tamponade for macular hole	• Visualization of retinal morphology • Visualization of macular hole
ILM/ERM Peel	Peeling of inner limiting membrane or epiretinal membrane to release traction or facilitate macular hole closure	• Visualization of removal of ILM/ERM from macula • Visualization of residual ILM/ERM after peel • Visualization of retinal morphology including macular hole, edema, traction, etc.
EUA	Examination under anesthesia – visualization of retina under anesthesia for pediatric or uncooperative patients	• Visualization of retinal morphology • Visualization of retinoblastoma • Visualization of photocoagulation/laser burns
Macular buckle	Insertion of a macular buckle to support closure of a macular hole, particularly in high myopes	• Visualization of macular buckle positioning underneath macular
Retinal graft /scaffold **Research Use Only**	Experimental procedures where grafts or scaffolds are implanted	• Visualization of subretinal air injection and subretinal bleb • Visualization of graft location and orientation • Visualization of retinal morphology following gas exchange

Advantages and Clinical information Example Anterior Segment

- Intraoperative OCT cross-sectional view of thin DMEK donor tissue being positioned for graft

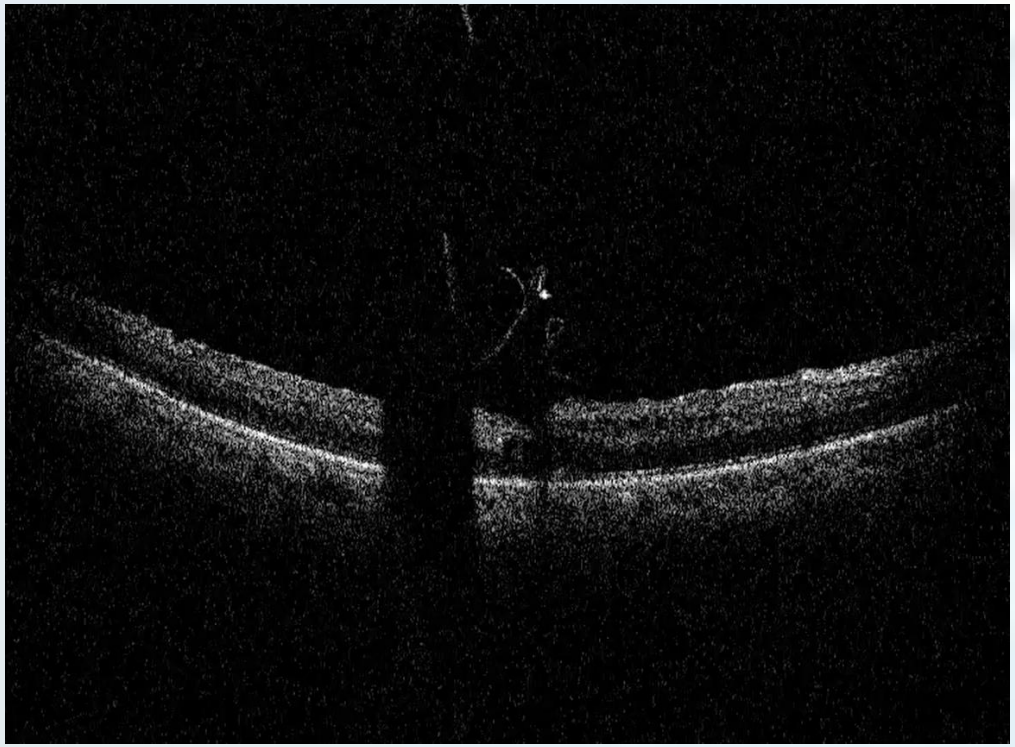


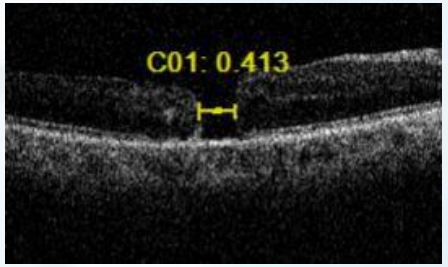
OCT Use:

- Visualization of removal of Descemet's membrane
- Visualization of graft orientation (scroll)
- Visualization of graft adherence

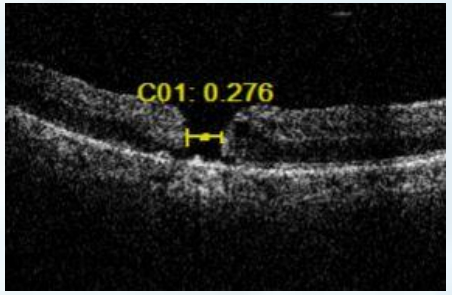
Advantages and Clinical information Example Posterior Segment

- Macular hole measurement and comparison.





Time Stamp 3:02 pm



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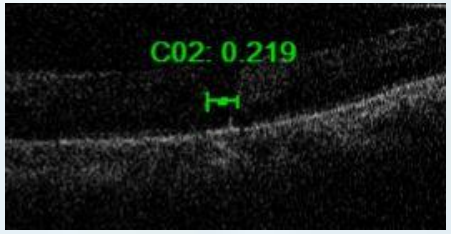

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Sicurezza per il paziente

- Dispositivo medicale Classe II
- EN ISO 134855, Medical devices -- Quality management systems -- Requirements for regulatory purposes
  - Scope: Design and Development, Production and Distribution, Installation and Servicing of Ophthalmic Imaging Systems
- EC Certificate (Directive 93/42/EEC on Medical Device)
- Spectral Domain Ophthalmic Imaging System (SDOIS) should comply with the Group 2 instrument requirements of ISO 15004-2:2007.

- iOCT systems are generally indicated for use as an aid in the visualization of physiologic and pathologic conditions of the eye through non-contact optical imaging.

Necessità Manutentive

- Scan head optics cleaning
  - Standard optics cleaning apply

Description	Cleaning
System	Alcohol wipe-down
Scanner	Cleaning required between uses.
Cart	Alcohol wipe-down
Foot pedal	Alcohol wipe-down
UPS	Alcohol wipe-down

- Regular Data Backup management

- Calibration:
  - iOCT might require calibration at installation time to fit the microscope it is coupled with. Changes to the microscope or camera might require re-calibration

Impatto Economico

- The iOCT can be purchased installed simultaneously to the microscope or at a later stage
- Impact of the iOCT system can have an order of magnitude of about 30% to 40% of the budget for a microscope plus iOCT
- Several levels of optional maintenance contracts are normally available

Diffusione

- The iOCT is a relatively recent technique with a limited but growing penetration mainly in US and in Europe

Thank you

(Backup slides)

Esempi di Specifiche Techniche

Method of operation		Spectral Domain Optical Coherence Tomography (SD-OCT)	
Internal light source		800nm band SLD: Very High Resolution (VHR) ≥ 90nm bandwidth FWHM 860nm center ±5 nm	800nm band SLD: High Resolution (HR) ≥ 40nm bandwidth FWHM 880nm center ±5 nm
Objective lens options		175mm (177.5mm) working distance (201.8mm focal length) 200mm (203mm) working distance (227mm focal length)	
Patient interface		Non-patient contact	
Optical power		≤ 750 µW	
Scanner ergonomics		Microscope mounted	
Scan patterns		Line, rectangular volume, circle, concentric rings (annular volume), radial lines (radial volume)	
Field of view	Axial (air/tissue)	3.4 ±0.1 mm / 2.5 ±0.1 mm	15.3 ±0.3 mm / 11.1 ±0.2 mm
	Lateral	≥ 20 mm	
Resolution	Axial (in tissue)	VHR: ≤ 4 µm	HR: ≤ 9µm
	Lateral	175mm Objective: < 31.5 µm (low NA) and < 15.0 µm (high NA) 200mm Objective: < 33.3µm (low NA) and < 15.7 µm (high NA)	
Scan rate (aka acquisition speed)		≥ 32,000 A-scans/s	≥ 18,000 A-scans/s
Scan pixels	Axial	1024 pixels	2048 pixels
	Lateral	User selectable, A-scans/B-scan: 2000 maximum	
		Maximum A-scans/volume: ≥ 1,000,000	Maximum A-scans/volume: ≥ 500,000
Pixel resolution, axial (air/tissue)		3.3 µm / 2.4 µm	7.5 µm / 5.4 µm
Sensitivity fall-off		–2.1 dB/mm	–0.84 dB/mm
Calipers		Manual placement of on-screen calipers	
Doppler		Qualitative blood flow visualization with color Doppler OCT	
Memory		16 GB	
Computer Storage		1TB Redundant Data Storage and 250GB Operating Drive	
Image Storage		Full volume OCT images	
Image Display Resolution		1920 x 1080	
Contrast Ratio		1000 : 1	