Erasmus MC
University Medical Center Rotterdam

Current Consensus Standards for OCT

Evelyn Regar

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Erasmus MC

Coregistration: Tu, Regar et al. Int J Cardiovasc Imaging 2012

Intravascular OCT
Expert Review & Consensus Documents

Erasmus MC

European Heart Journal
doi:10.1093/eurheartj/ehp433

REVIEW

Expert review document on methodology, terminology, and clinical applications of optical coherence tomography: physical principles, methodology of image acquisition, and clinical application for assessment of coronary arteries and atherosclerosis

Francesco Prati[1*], Evelyn Regar[2], Gary S. Mintz[3], Eloisa Arbustini[4], Carlo Di Mario[5], Ik-Kyung Jang[6], Takashi Akasaka[7], Marco Costa[8], Giulio Guagliumi[9], Eberhard C
Expert's O

European Heart Journal
doi:10.1093/eurheartj/ehs095

CURRENT OPINION

Expert review document part 2: methodology, terminology and clinical applications of optical coherence tomography for the assessment of interventional procedures

Francesco Prati[1,2*], Giulio Guagliumi[3], Gary S. Mintz[4], Marco Costa[5], Evelyn Regar[6,7], Takashi Akasaka[8], Peter Barlis[9], Guillermo J. Tearney[10,11], Ik-Kyung Jang[12], Elosia Arbustini[13], Hiram G. Bezerra[5], Yukio Ozaki[14], Nico Bruining[6,7], Darius Dudek[15], Maria Radu[6,7], Andrejs Erglis[16], Pascale Motreff[17], Fernando Alfonso[18], Kostas Toutouzas[19], Nieves Gonzalo[20], Corrado Tamburino[21], Tom Adriaenssens[22], Fausto Pinto[23], Patrick W.J. Serruys[6,7], and Carlo Di Mario[24,25], for the Expert's OCT Review Document

EHJ 2010 & 2012

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MINI-FOCUS ISSUE: OPTICAL COHERENCE TOMOGRAPHY — Clinical Research

Consensus Standards for Acquisition, Measurement, and Reporting of Intravascular Optical Coherence Tomography Studies

A Report From the International Working Group for Intravascular Optical Coherence Tomography Standardization and Validation

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Boston, Massachusetts; Rotterdam, the Netherlands; and Wakayama, Japan

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Intravascular OCT
Details of the Consensus Document

- **Print**
  - Introduction
  - Physical principles of IVOCT
  - Imaging protocols
  - Qualitative image interpretation
  - Quantitative assessment

- **Online**
  - Levels of evidence
  - Equipment for IVOCT imaging
  - IVOCT display techniques
  - Artifacts
  - Expanded info for protocols & assessment
  - Validation, specialized techniques
  - Reporting of IVOCT studies, all appendices


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Intravascular OCT
Details of the Consensus Document

The International Working Group
For Intracoronary OCT Standardization And Validation

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For Intracoronary OCT Standardization And Validation

Achieve Widespread Utilization of Intracoronary OCT

Standardization and validation of the technology

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The International Working Group
For Intracoronary OCT Standardization And Validation

International committee

- Over 300 members
- Academia
- Clinical community
- Industry
- All OCT manufacturers

Organizers

G. Tearney, T. Akasaka, E. Regar

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Intravascular OCT
Details of the Consensus Document

The International Working Group
For Intracoronary OCT Standardization And Validation

The International Working Group
For Intracoronary OCT Standardization And Validation

- **11 International meetings held 2008-2012:**

  Prague, San Francisco, Barcelona, San Francisco, London, Kobe, Paris, Miami
- **DICOM Standard IV OCT**
- **Consensus document**

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Intravascular OCT
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For Intracoronary OCT Standardization And Validation

The International Working Group
For Intracoronary OCT Standardization And Validation

The format is patterned after the JACC Clinical Expert Consensus Document on "Standards for Acquisition, Measurement and Reporting of Intravascular Ultrasound Studies" by Mintz et al. 2001

Because of the similarities terminology and methods that exist for IVUS have been adopted for IVOCT, whenever possible.

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Intravascular OCT
Details of the Consensus Document

The International Working Group
For Intracoronary OCT Standardization And Validation

- **IWG-IVOCT subgroups were tasked with summarizing:**
- **what is known to date**
- **common pitfalls or roadblocks**
- **what is not known to date within their respective topic area.**

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Intravascular OCT Consensus
Level of Evidence

The International Working Group
For Intracoronary OCT Standardization And Validation

High

Homogeneous evidence from multiple, well-designed, cohort (descriptive) trials, each involving a number of samples to be of sufficient statistical power or multiple histopathologic correlative studies of sufficient statistical power.

Medium

From at least 1 well-designed trial, or a single histopathologic correlative study involving a number of samples to be of sufficient statistical power.

Low

Evidence based on clinical experience, descriptive studies, or reports of expert committees or histopathologic correlative case studies.

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Intravascular OCT Consensus
Example

The International Working Group
For Intracoronary OCT Standardization And Validation

Fibrous plaque
- high backscattering and
- relatively homogeneous IVOCT signal

Evidence level: High

Sometimes the IEM or EEM may be identified in fibrous plaques.

Caution should be exercised when characterizing a lesion as fibrous plaque if the IEM or EEM cannot be identified. Sometimes, the limited penetration depth of IVOCT does not allow the accurate detection of deep signal-poor areas possibly representing necrotic core or calcium behind fibrous tissue.

Fibrous plaques by IVOCT may be composed of collagen or smooth muscle cells. Although it has been postulated that proteoglycans and type III collagen have a lower OCT signal intensity, the relationship between the OCT signal and type III collagen and proteoglycans has **not yet been established**.

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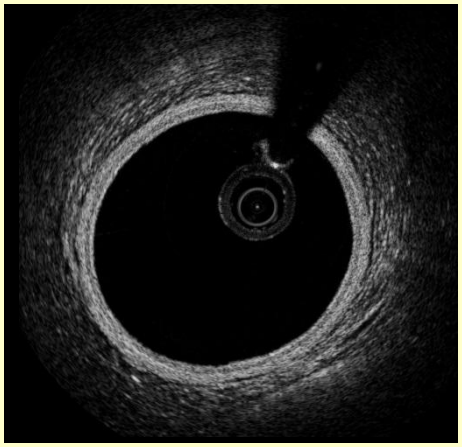
Intravascular OCT Consensus
Atherosclerotic Plaque Assessment

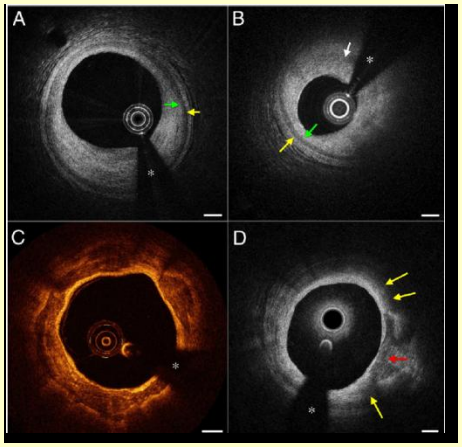
The International Working Group
For Intracoronary OCT Standardization And Validation

Evidence level: High

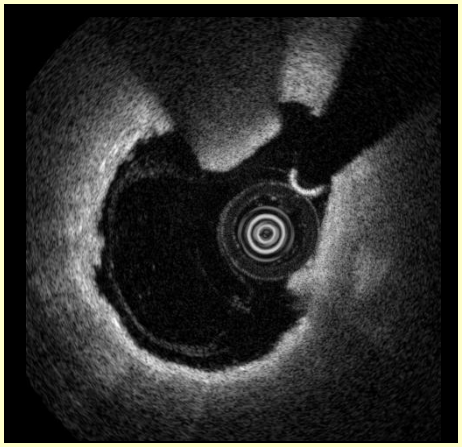
Normal vessel wall



Atherosclerosis



Thrombus



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Intravascular OCT Consensus
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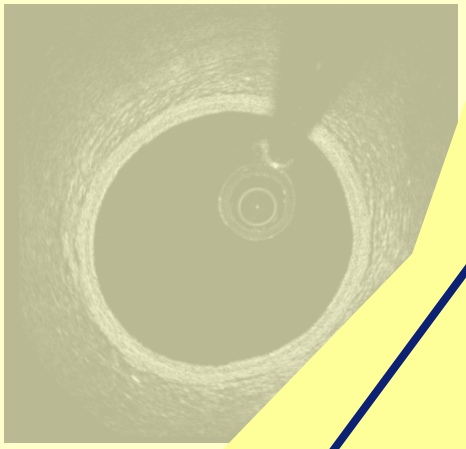
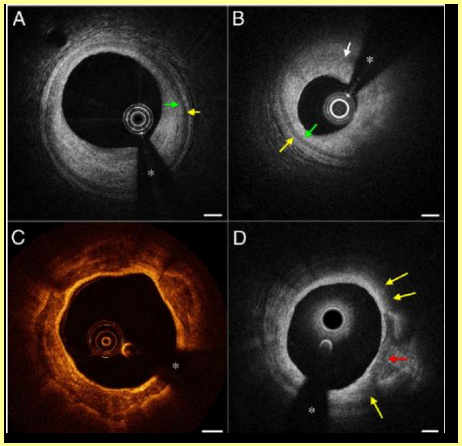
Evidence level: High

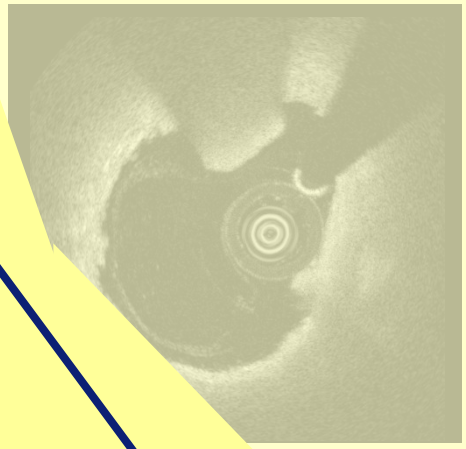
Normal vessel wall



Atherosclerosis



Thrombus



Fibrous **Fibrocalcific** **Lipid pool** **Fibrous cap** **Rupture**

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Intravascular OCT Consensus
Atherosclerotic Plaque Assessment

The International Working Group
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Evidence level: High

Atherosclerosis

Fibrous **Fibrocalcific** **Lipid pool** **Fibrous cap** **Rupture**

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Intravascular OCT Consensus
Atherosclerotic Plaque Assessment

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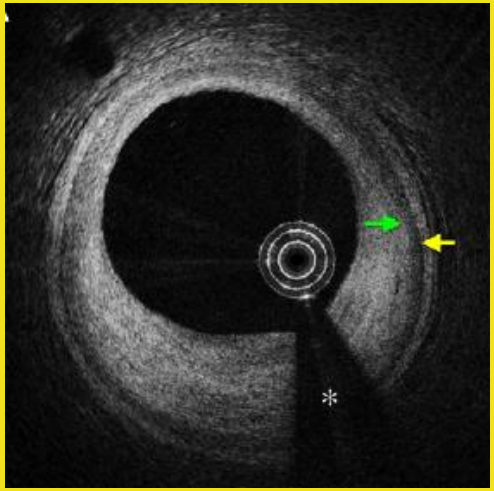
Evidence level: High

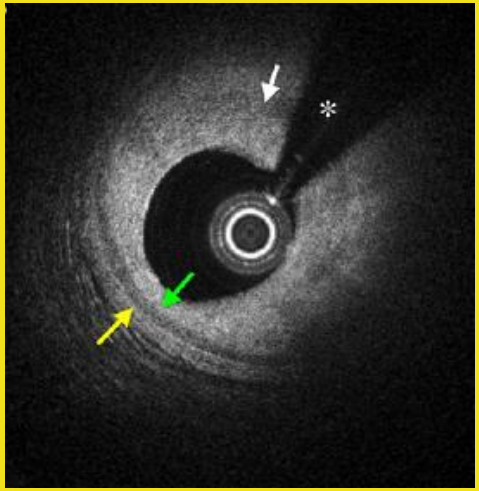
Fibrous

Atherosclerosis

Fibrocalcific Lipid pool Fibrous cap Rupture

Fibrous plaque with IEM (green) and EEM (yellow)





Fibrous plaque without IEM and EEM (white)

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Intravascular OCT Consensus
Atherosclerotic Plaque Assessment

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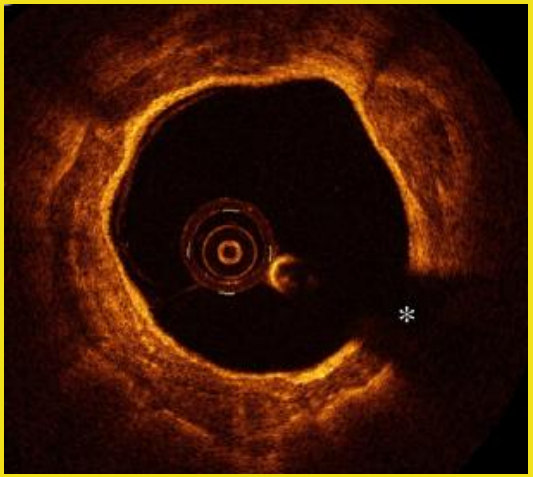
Evidence level: High

therosclerosis

Fibrous | **Fibrocalcific** | Lipid pool | Fibrous cap | Rupture



Fibrocalcific plaque showing circumferential signal-poor heterogeneous region with well-delineated borders.

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Intravascular OCT Consensus
Atherosclerotic Plaque Assessment

The International Working Group
For Intracoronary OCT Standardization And Validation

Evidence level: High

A

Fibrous | Fibrocalcific | **Lipid pool** | Fibrous cap | Rupture

IVOCT histopathologic correlative studies showed a good correspondence between signal-poor IVOCT regions with poorly defined or diffuse borders and a broader histopathologic category known as “lipid pool”

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Intravascular OCT Consensus
Atherosclerotic Plaque Assessment

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Evidence level: High

Fibrous | Fibrocalcific | **Lipid pool** | Fibrous cap | Rupture

In these studies, a lipid pool corresponds histologically to either a necrotic core or a region within pathological intimal thickening that contains extracellular lipid or proteoglycans.

At present, there are no definitive published studies directly comparing IVOCT lipid pool–containing plaques with necrotic core by histology, and as a result, the evidence level was determined to be LOW for IVOCTdelineation of NECROTIC CORE.

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Intravascular OCT Consensus
Atherosclerotic Plaque Assessment

The International Working Group
For Intracoronary OCT Standardization And Validation

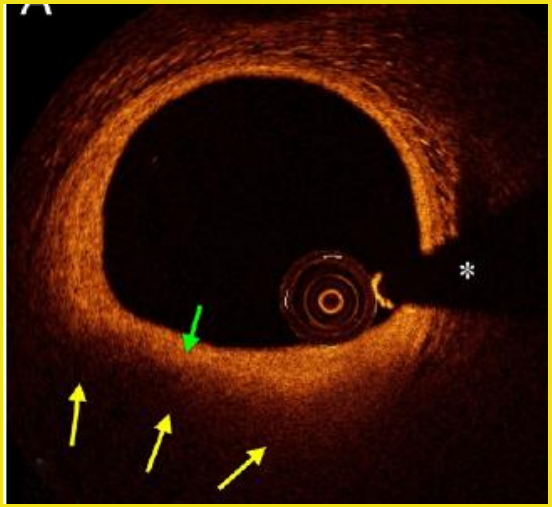
Evidence level: High

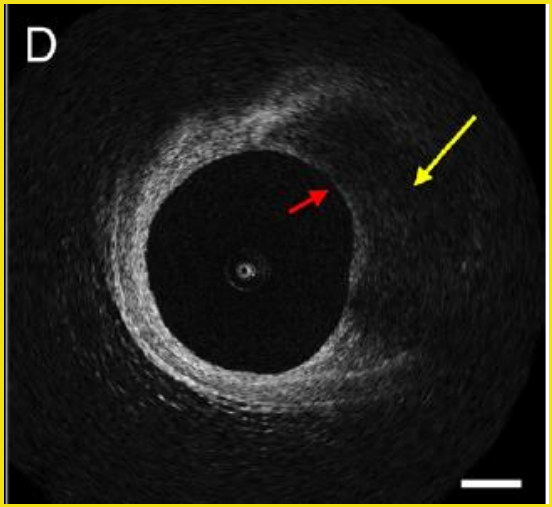
Atheroscleros

Fibrous | Fibrocalcific | Lipid pool | **Fibrous cap** | Rupture

OCT thin-capped fibroatheroma (OCT-TCFA)

Fibroatheroma with poorly defined borders and a cap





Fibroatheroma with thin fibrous cap

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Intravascular OCT Consensus
Atherosclerotic Plaque Assessment

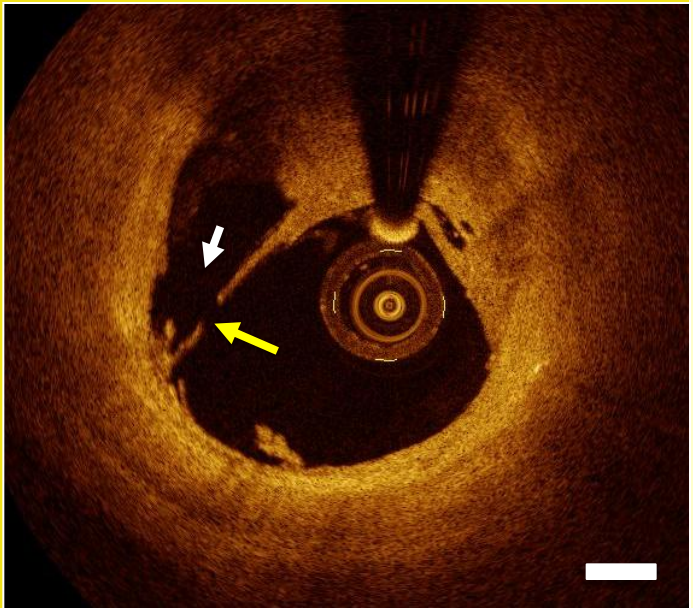
The International Working Group
For Intracoronary OCT Standardization And Validation

Evidence level: High

Atherosclerosis

Fibrous | Fibrocalcific | Lipid pool | Fibrous | **Rupture**

Ruptured plaques frequently occur in the context of OCT-TCFAs and show features of intimal tearing, disruption, or dissection of the cap



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Atherosclerotic Plaque Assessment

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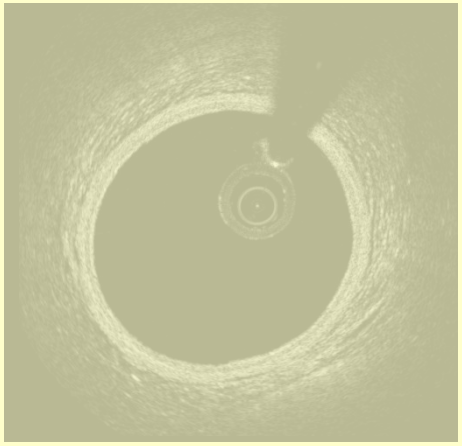
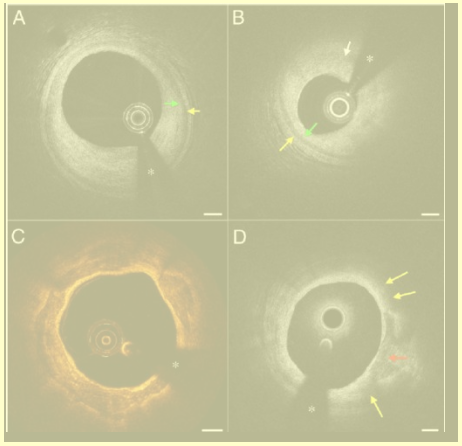
For Intracoronary OCT Standardization And Validation

Evidence level: High

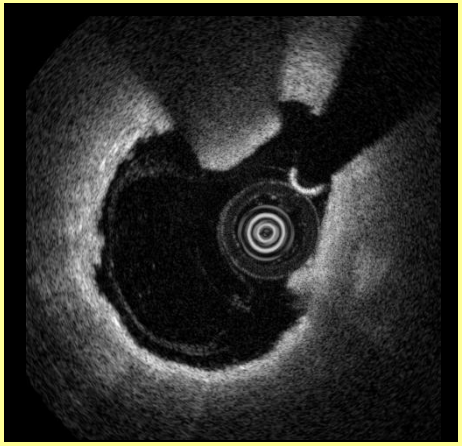
Normal vessel wall



Atherosclerosis



Thrombus



Differentiation
Red vs White

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Intravascular OCT Consensus
Atherosclerotic Plaque Assessment

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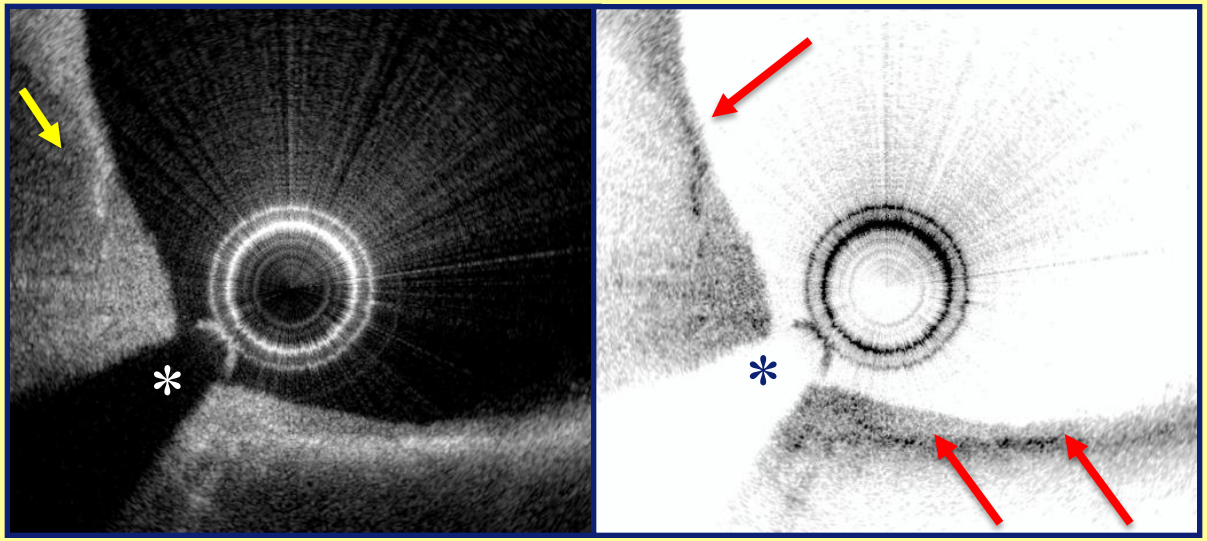
For Intracoronary OCT Standardization And Validation

Evidence level: Medium

Macrophages

may be seen as signal-rich, distinct, or confluent punctate regions that exceed the intensity of background *speckle* noise



Gray scale look-up table Inverse gray scale look-up table

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Intravascular OCT Consensus
Atherosclerotic Plaque Assessment

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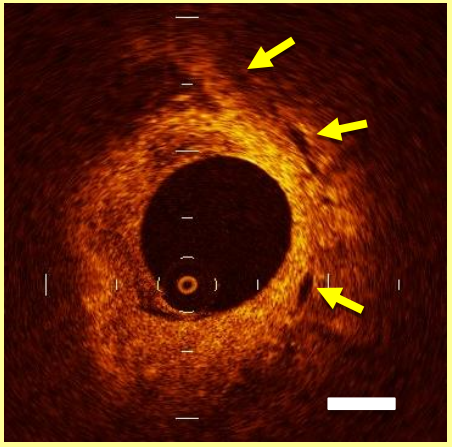
Evidence level: Low

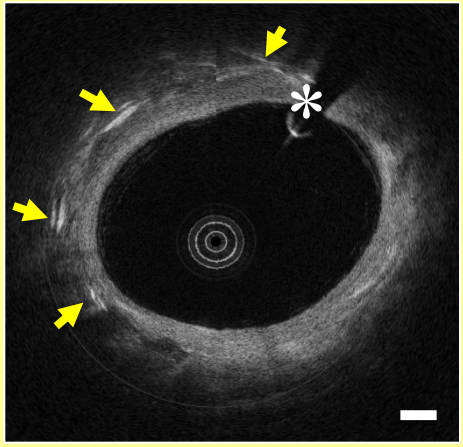
Intimal Vasculature

Can appear as signal-poor voids that are sharply delineated and can usually be followed in multiple contiguous frames



Cholesterol Crystals

- May appear as thin, linear regions of
- high intensity, usually associated with a fibrous cap or necrotic core



Erosion

May be composed of IVOCT evidence of thrombus, an irregular luminal surface, and no evidence of cap rupture evaluated in multiple adjacent frames

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Intravascular OCT Consensus
Qualitative Assessment

The International Working Group
For Intracoronary OCT Standardization And Validation

The definitions of Lesion and Reference Segment from JACC IVUS Consensus Document have been adopted for IVOCT.

- **Proximal reference.**

  The site with the **largest lumen** proximal to a stenosis but within the same segment (usually **within 10 mm of the stenosis**, with no major intervening branches). This may not be the site with the least plaque.
- **Distal reference.**
- **Largest reference.**
- **Lesion.**
- **Stenosis.**
- **Worst stenosis (T-1).**
- **Secondary stenoses (T-2, T-3, and so on).**

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Intravascular OCT Consensus
Quantitative Measurements

The International Working Group
For Intracoronary OCT Standardization And Validation

Measurements should be made on good-quality images that do not contain artifacts. The image should be correctly calibrated for *z-offset* and refractive index.

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Intravascular OCT Consensus
Quantitative Measurements

The International Working Group
For Intracoronary OCT Standardization And Validation

Lumen Measurements
Once the lumen has been traced, the measurements by IVOCT are similar to that for IVUS (see Mintz et al. JACC 2001)

IEM Measurements
For plaques in which the IEM can be identified, the preceding measurements can be made for the IEM, including the IEM CSA similar to that for IVUS (see Mintz et al. JACC 2001)

EEM Measurements
Note that IEM measurements can also be measured for the EEM, if it is identified in the IVOCT image.
It is therefore recommended that when reporting these measurements, the use of either IEM or EEM be clearly specified.

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Intravascular OCT Consensus
Unstable Lesions & Ruptured Plaques

The International Working Group
For Intracoronary OCT Standardization And Validation

TCFA diagnosed by histology has been associated with plaque rupture and coronary thrombosis at autopsy.

Future natural history studies should be conducted to demonstrate the risk of OCT-TCFAs and macrophage-rich plaques for enabling the identification of patients at higher risk for future coronary events.

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Intravascular OCT Consensus
Stent Assessment

The International Working Group
For Intracoronary OCT Standardization And Validation

Evidence level: High

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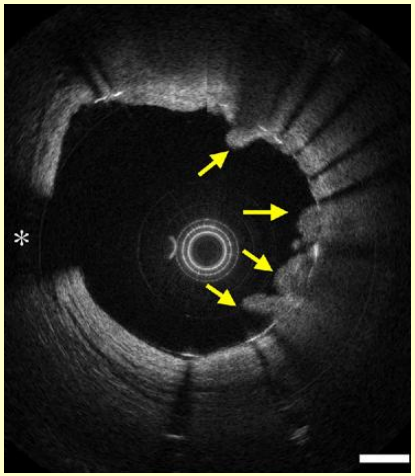
Intravascular OCT Consensus
Stent Assessment

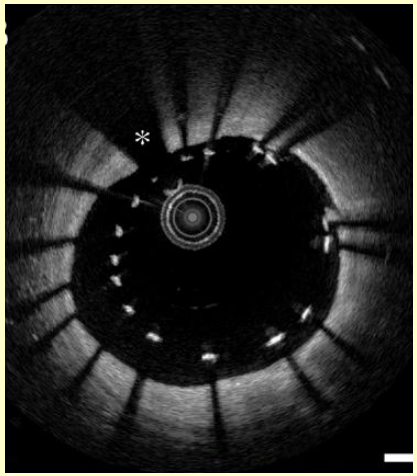
The International Working Group
For Intracoronary OCT Standardization And Validation

Evidence level: High

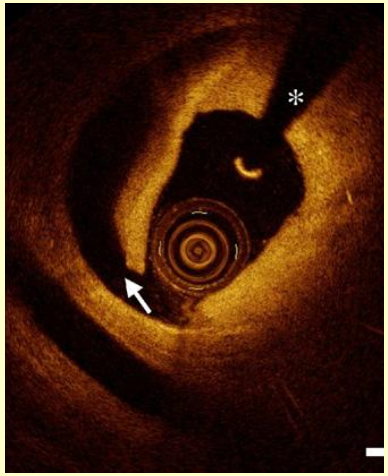
Prolapse



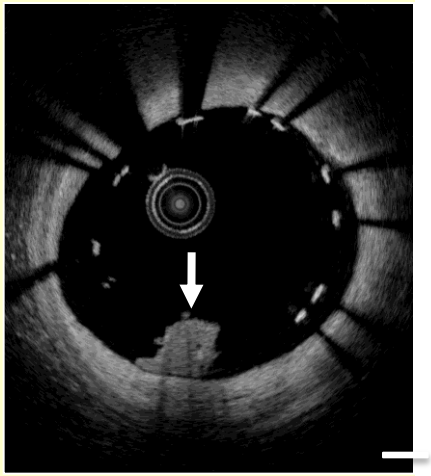
Apposition Malapposition



Dissection



Thrombus



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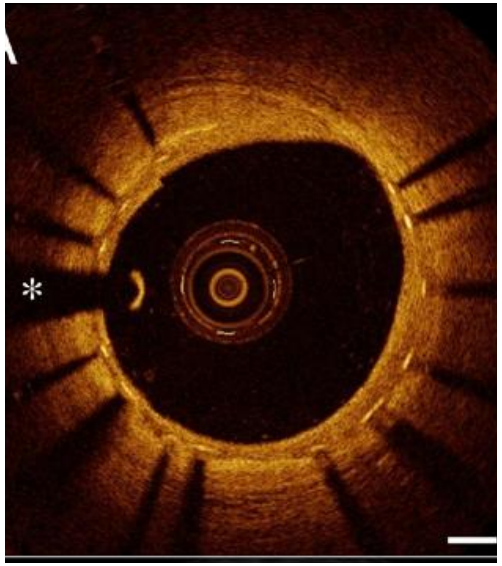
Intravascular OCT Consensus
Stent Assessment: Strut Coverage

The International Working Group
For Intracoronary OCT Standardization And Validation

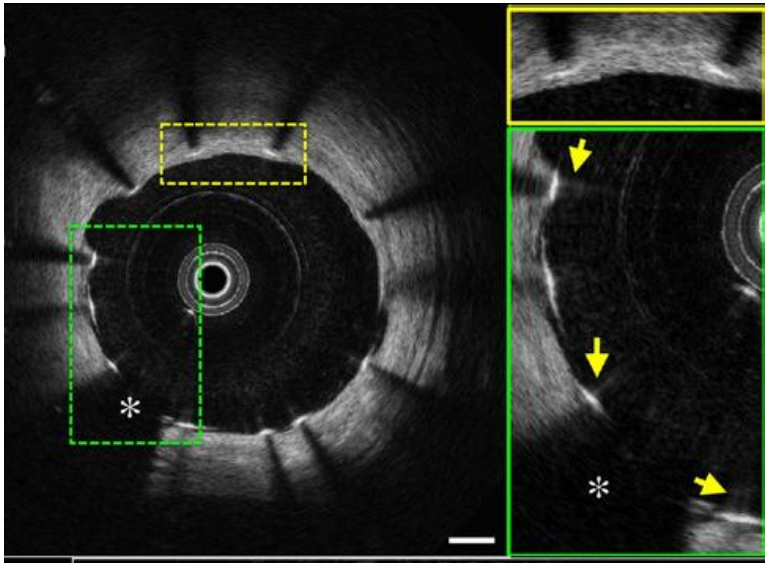
Struts are termed *covered* by IVOCT if tissue can be identified above the struts.

Struts are dubbed *uncovered* by IVOCT if no evidence of tissue can be visualized above the struts.

Covered struts



Uncovered struts



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Intravascular OCT Consensus
Stent Assessment: Strut Coverage

The International Working Group
For Intracoronary OCT Standardization And Validation

At present, IVOCT has not been shown to allow the visualization of endothelium, but this question is still under investigation.

Additionally, the precise nature of tissue coverage has not been demonstrated, be it fibrin, endothelium, thrombus, neointimal, or other.

It has been postulated that IVOCT strut coverage tissue characteristics such as backscattering intensity may provide further discrimination of IVOCT strut coverage tissue type; however, it was believed that this topic merited further investigation. In addition, the significance of the intensity of the strut's backscattering has not been established.

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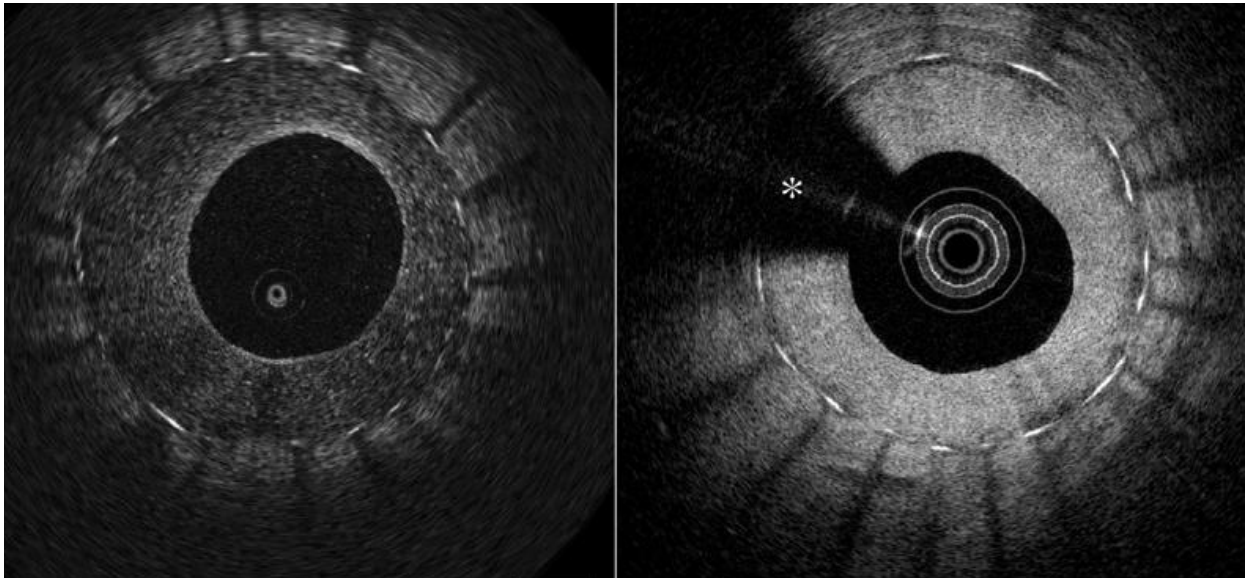
Intravascular OCT Consensus
Stent Assessment: Restenosis

The International Working Group
For Intracoronary OCT Standardization And Validation

Restenosis by IVOCT may be visualized as signal-poor, layered, or signal-rich tissue overlying stent struts.

The relationship between the signal intensity of restenosis seen by IVOCT and the underlying tissue composition has only been documented in rare cases and is not generally understood.



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Intravascular OCT Consensus
Stent Measurements

The International Working Group
For Intracoronary OCT Standardization And Validation

Stent area measurements

follow that of the JACC IVUS Consensus Document (Mintz et al. JACC 2001), modified in part

Strut apposition distance

Distance between the abluminal surface of the strut and the luminal surface of the artery wall.

Some investigators have estimated the location of the abluminal surface of the strut by drawing a line from the luminal surface of the strut toward the artery wall, where the line has a length that is equivalent to the known strut plus polymer (if present) thickness. The end of this line is an estimate of the location of the abluminal surface of the strut. If it is separated abluminally from the luminal *contour* of the vessel, the strut is considered to be malapposed.

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Intravascular OCT Consensus
Stent Measurements

The International Working Group
For Intracoronary OCT Standardization And Validation

Stent area measurements
follow that of the JACC IVUS Consensus Document (Mintz et al. JACC 2001), modified in part

Strut apposition distance
Distance between the abluminal surface of the strut and the luminal surface of the artery wall.

OCT strut coverage thickness
Distance between the luminal surface of the covering tissue and the luminal surface of the strut.

IVOCT is capable of measuring the tissue overlying a strut within the resolution of the OCT system. The biological and clinical significance of OCT strut tissue coverage thickness that is measured to be less than, equal to, or near the axial resolution of the OCT system is not well understood.

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Intravascular OCT Consensus
Summary & Outlook

- Consensus documents summarize current knowledge and put it into perspective.
- As such, they can be instrumental for the clinical application.
- OCT has high level of evidence when it comes to lesion assessment in native vessels as well as after PCI and stent implantation.
- Areas with need for further validation are clearly identified (especially the prospective validation of OCT findings).

- A broad participation is key to move the field forward!

Intravascular OCT Consensus
Next Steps

The International Working Group
For Intracoronary OCT Standardization And Validation

- **DICOM Structured Report (SR) Template**

  SR allows OCT specific measurements and findings to be exported to PACS and become part of the Patient's Electronic Medical Record

- **Phantoms** (Guy Lamouche)

  Industrial, Tech Research and Development
  Preclinical and clinical applications
  Training of (new) users

- **Bifurcations** (Tom Adriaenssens, Niels Holm)

  Assessment pre and post stent, follow-up
  Reporting

www.octstandardization.org