

Beyond IVUS: OCT, NIRS, and Beyond

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Conflict of Interest Disclosure

- Akiko Maehara
 - Personal: Consultant for ACIST, Boston Scientific Corporation
 - Cardiovascular Research Foundation: Boston Scientific Corporation

OCT

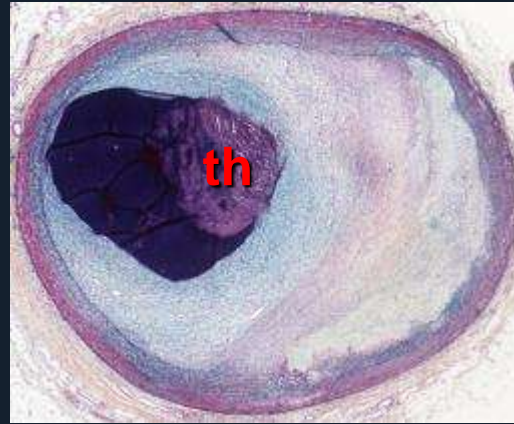
- *in vivo* Pathology -

Unstable Plaque=Causing Thrombosis

Plaque Rupture



Plaque Erosion



Calcified Nodule



Stable Plaque=Not Causing Thrombosis

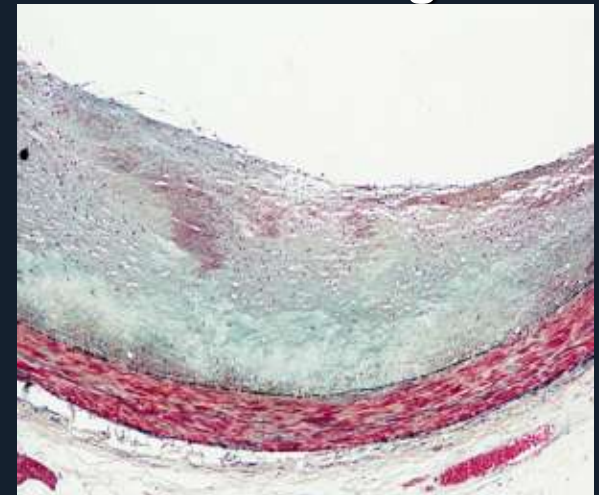
Fibrocalcific Plaque



Healed Rupture



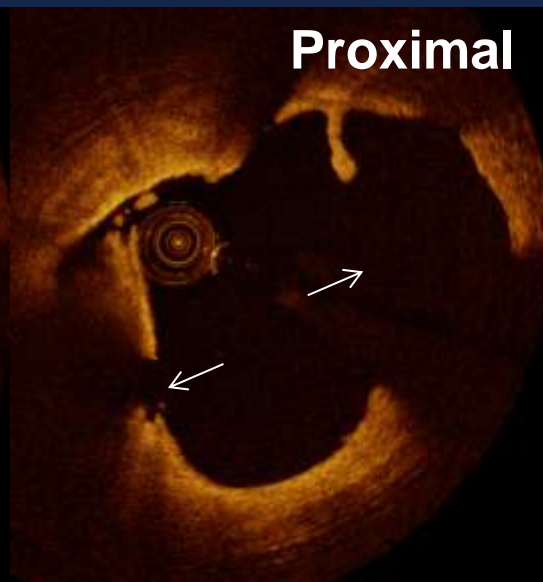
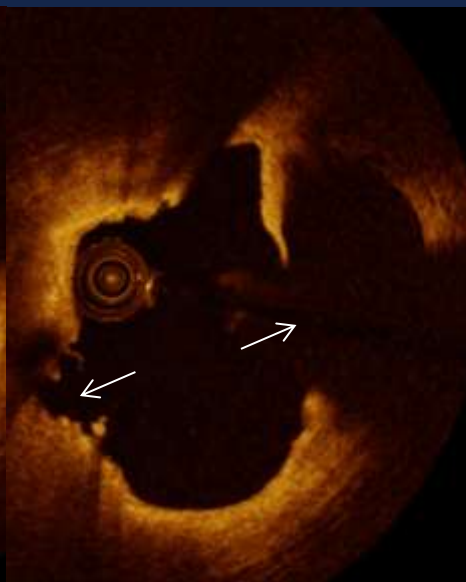
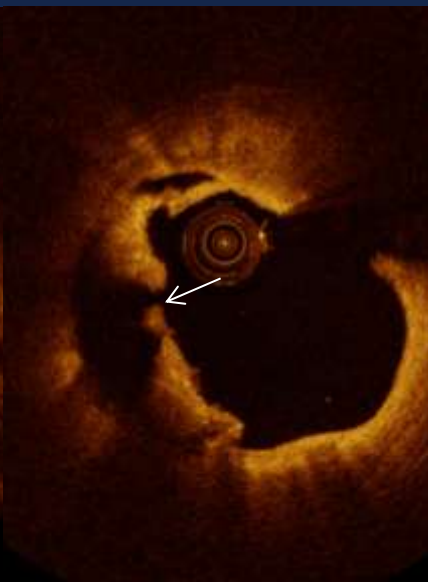
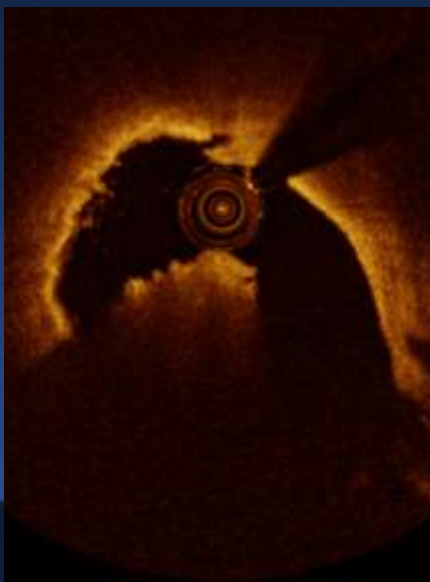
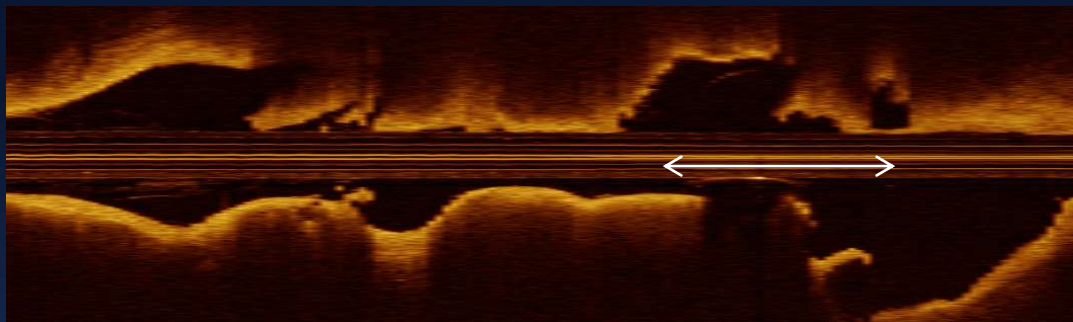
Pathological Intimal Thickening



Post-Thrombectomy

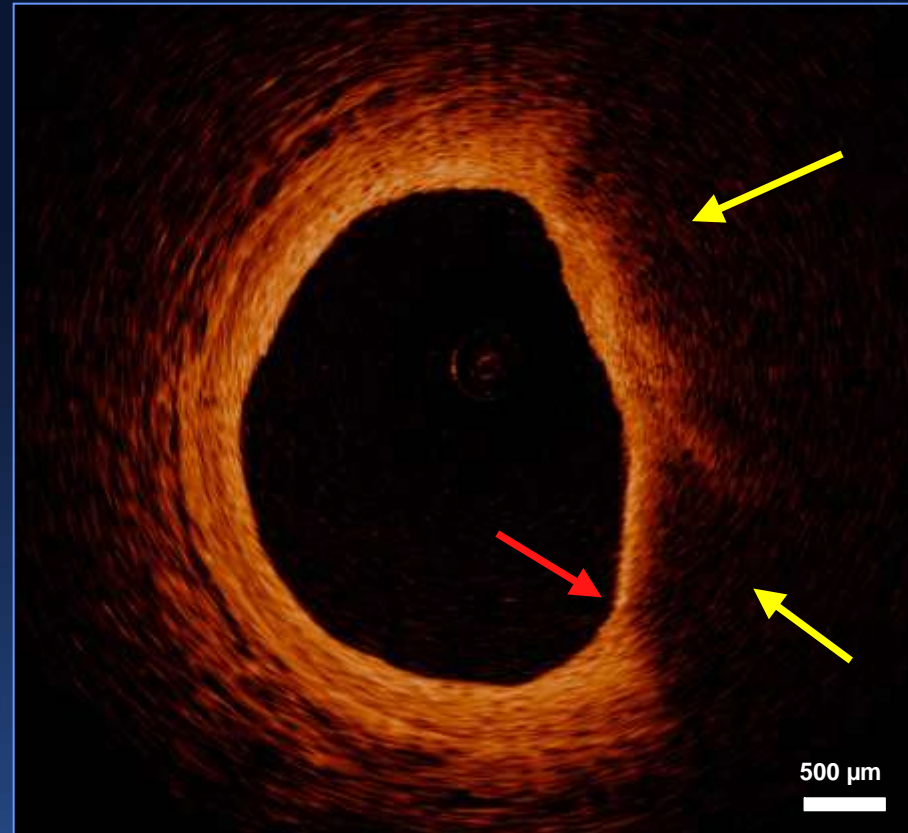


Representative Case of Rupture



OCT Thin Capped Fibroatheroma (OCT-TCFA)

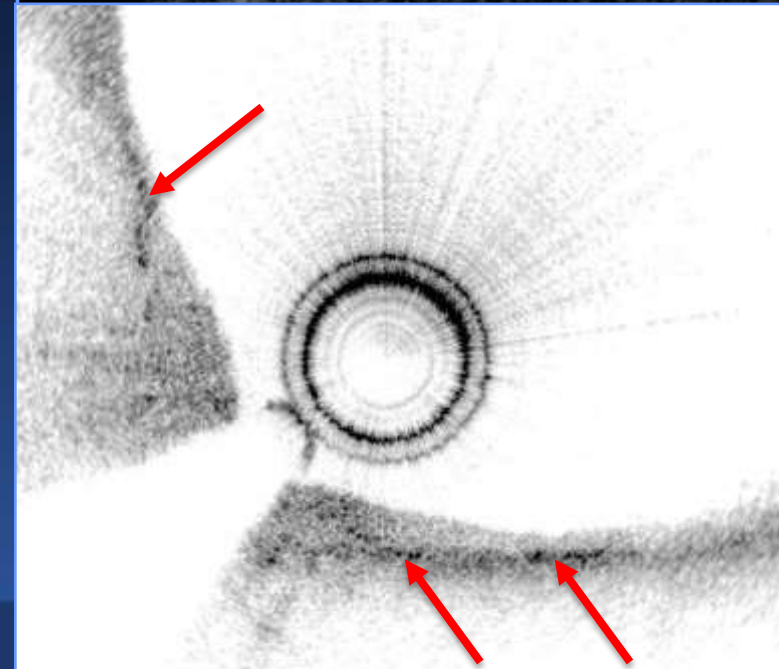
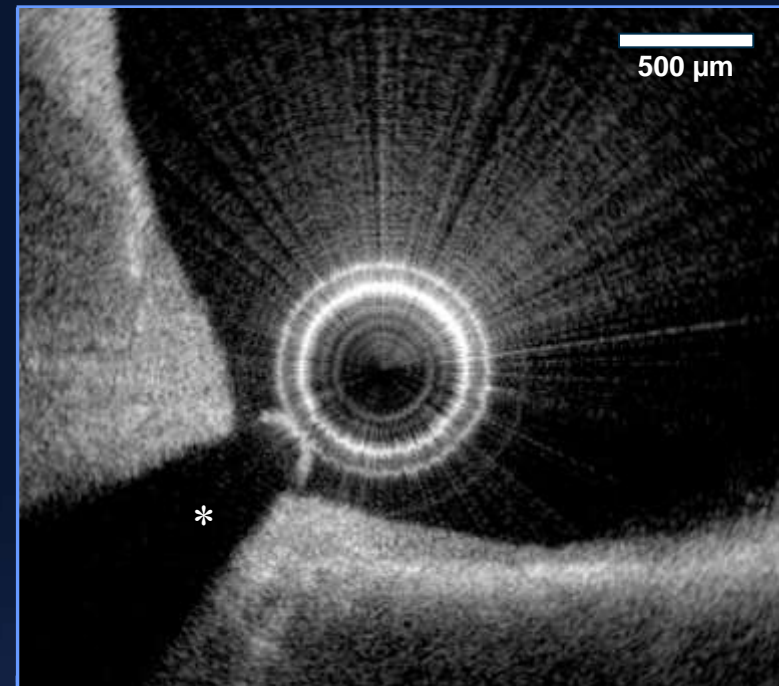
- **Description:**
 - OCT-delineated necrotic core
 - Overlying fibrous cap
 - Minimum thickness of the fibrous cap is less than a predetermined threshold
- **Level of Evidence:**
High
- **Unknown:**
 - Relevance of number of quadrants



TD-OCT; Takashi Akasaka, Wakayama; Lightlab/St. Jude M2 system.

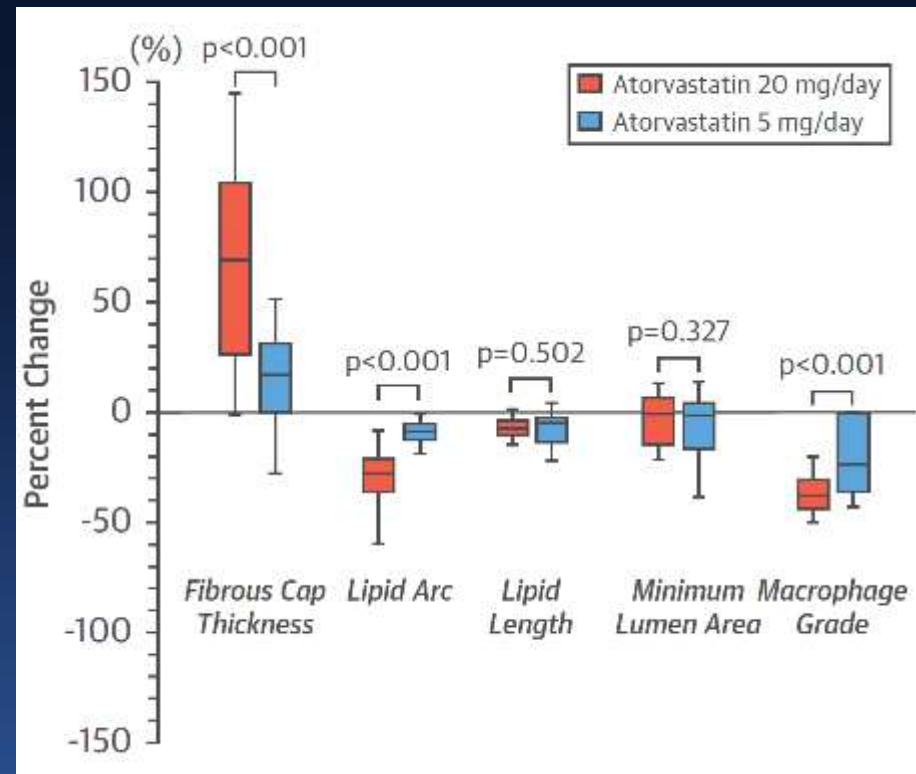
Macrophage Accumulations

- **Description:**
 - Defined only in plaque
 - Signal-rich, distinct or confluent punctate regions
 - Exceed the intensity of background noise
 - Can create shadows
- **Level of Evidence: Med**
- **Unknown:**
 - IVOCT ability to discriminate microcalcifications from macrophages



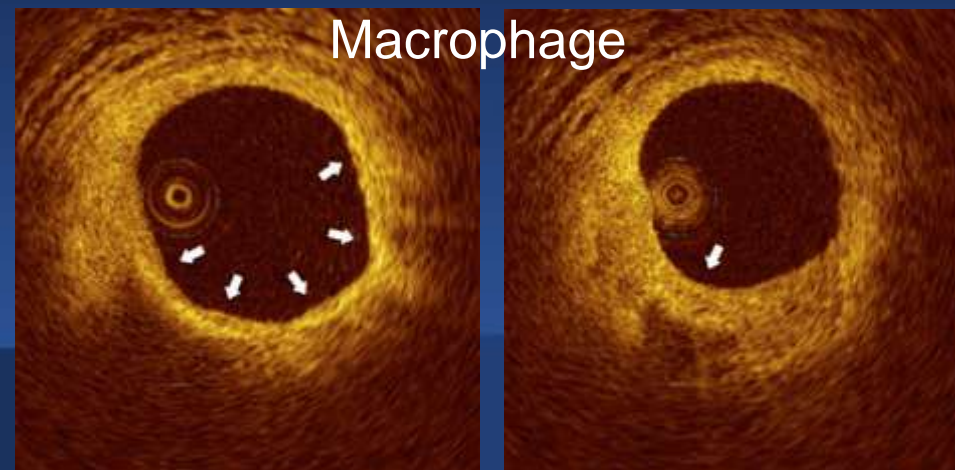
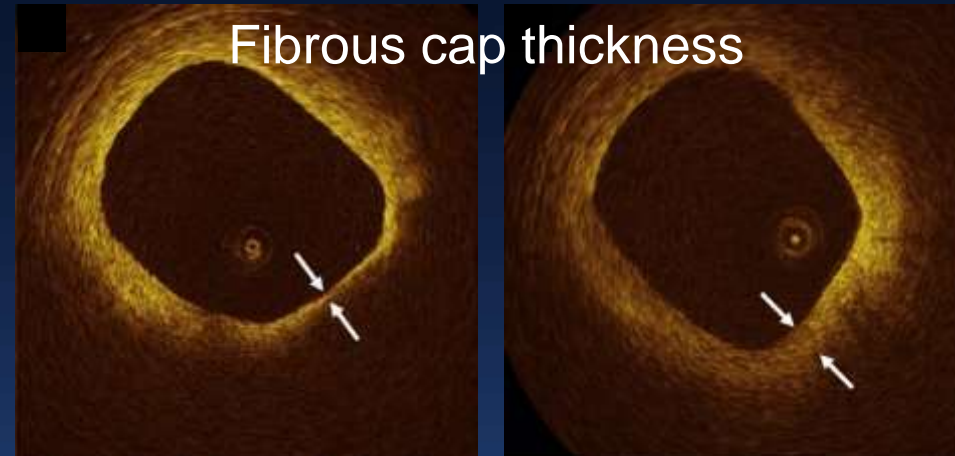
EASY-FIT Study

- Single center, randomized Atrovastatin 20mg vs 5mg in non-treated HL pts
- Intermediate non-culprit lesion in culprit vessel
- Fibrous cap thickness by OCT at 12 month
- 30 pts in each cohort



Baseline

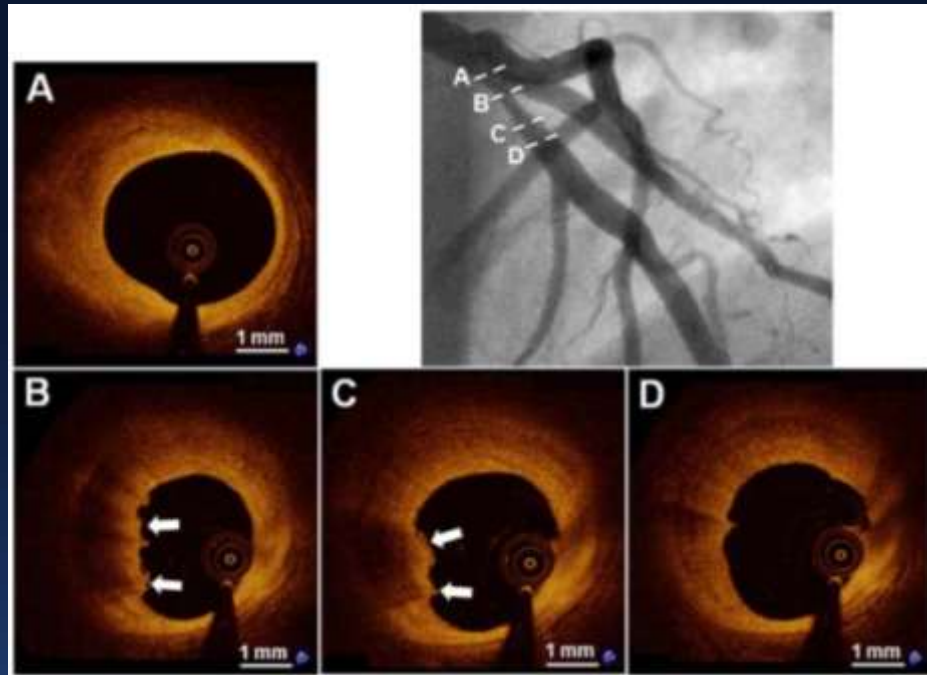
12-Month FU



Komukai et al. JACC 2014

OCT Erosion: Level of Evidence **Low**

Definite OCT-Erosion



Presence of attached thrombus overlying an intact and visualized plaque

Probable OCT-Erosion

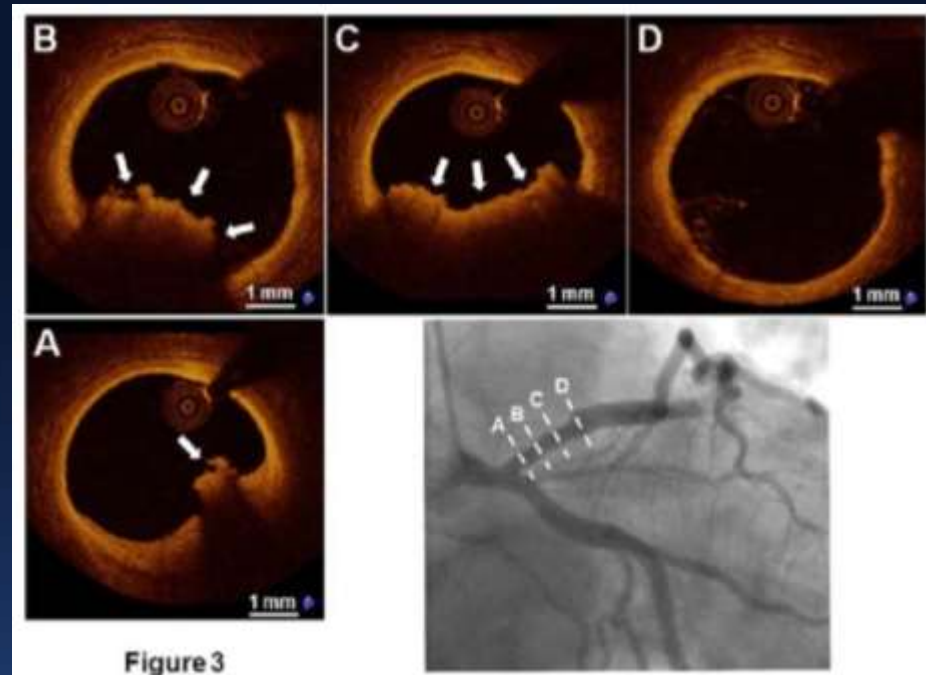
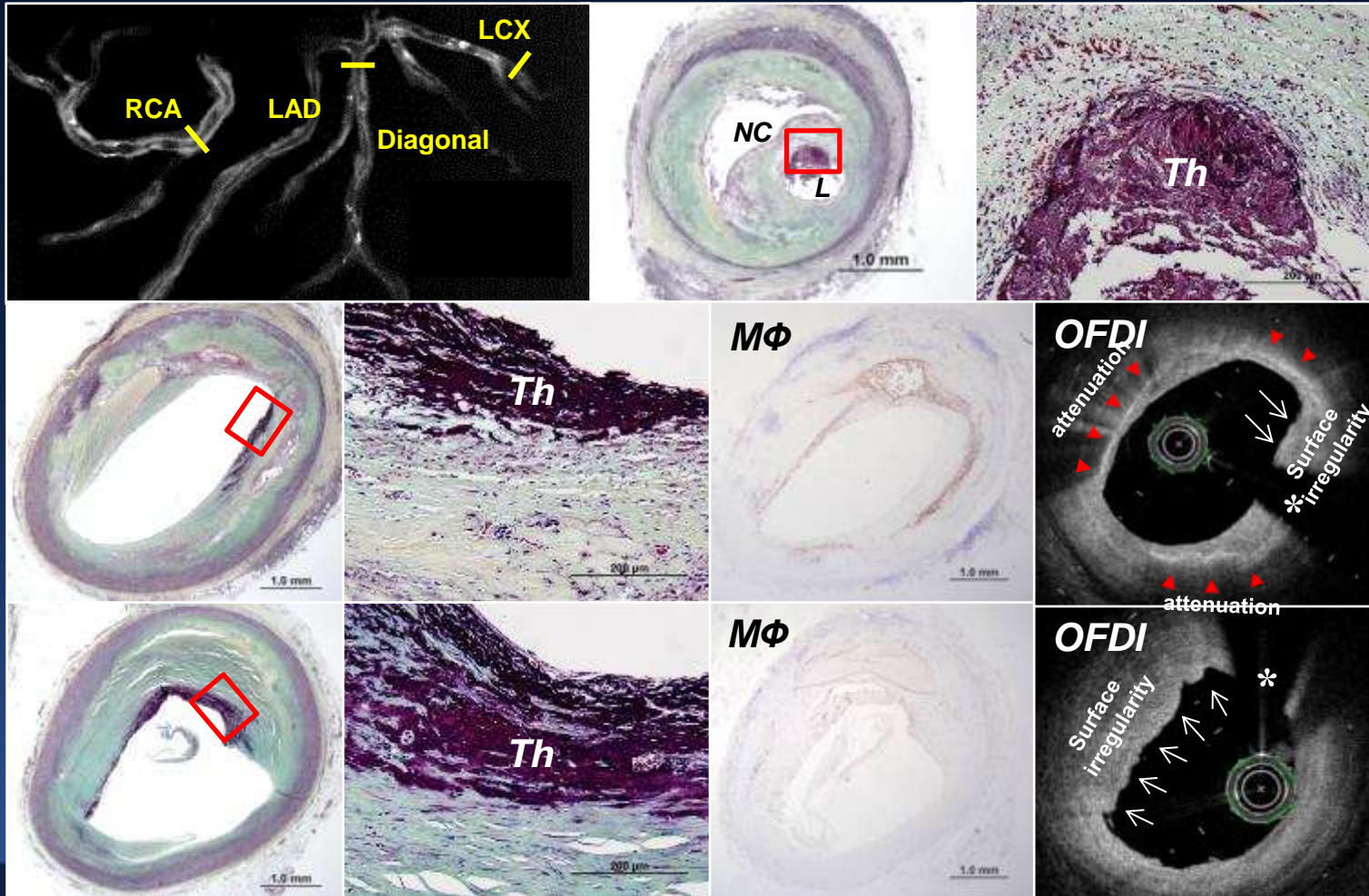


Figure 3

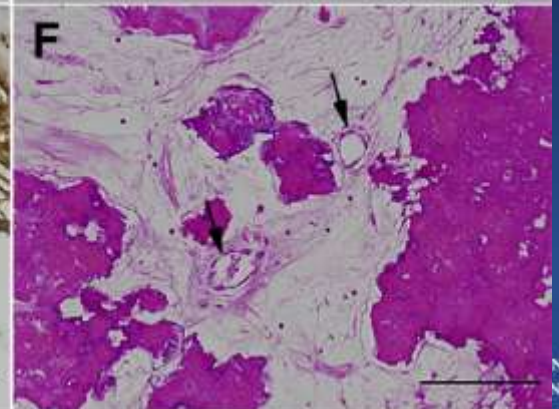
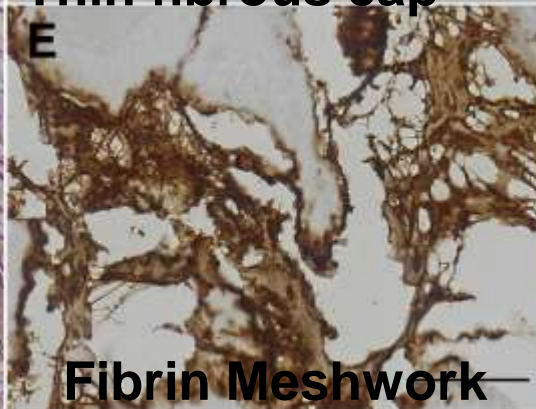
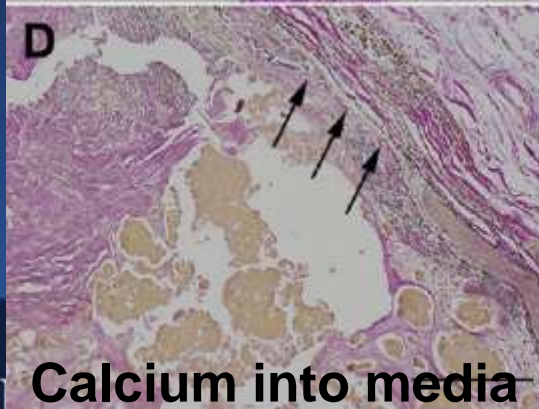
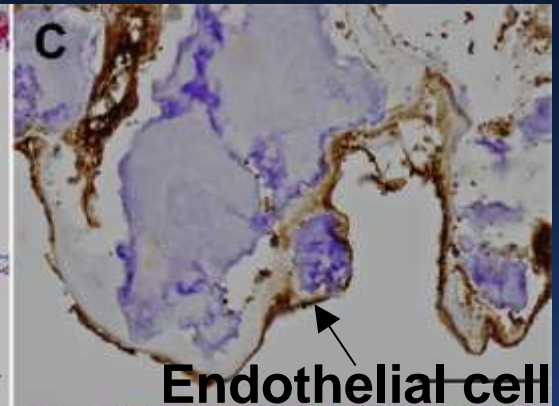
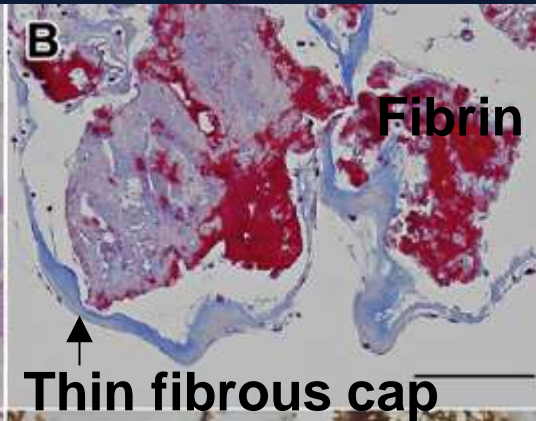
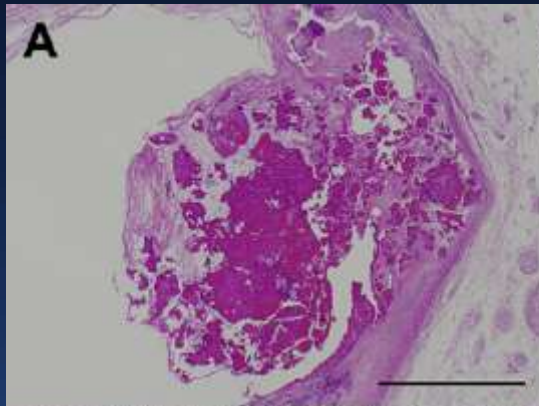
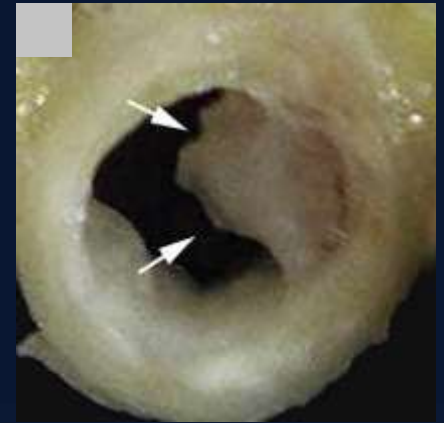
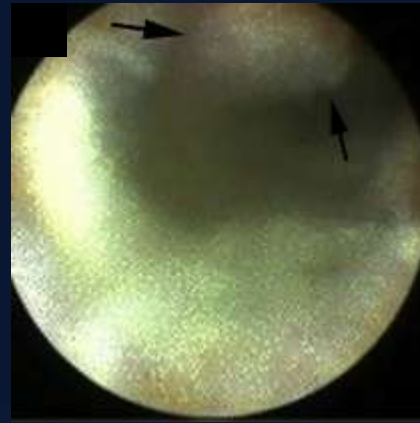
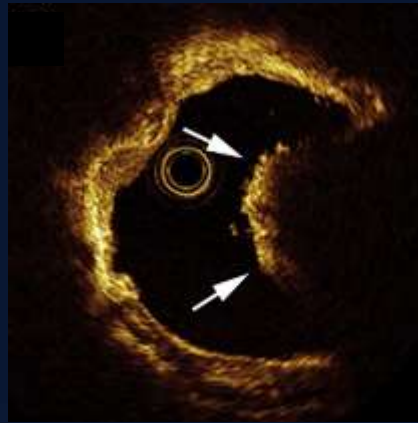
- 1) Luminal surface irregularity without thrombus
- 2) Attenuation of underlying plaque by thrombus without superficial lipid or calcification immediately proximal or distal site

Erosion - Thrombus in the Absence of Rupture

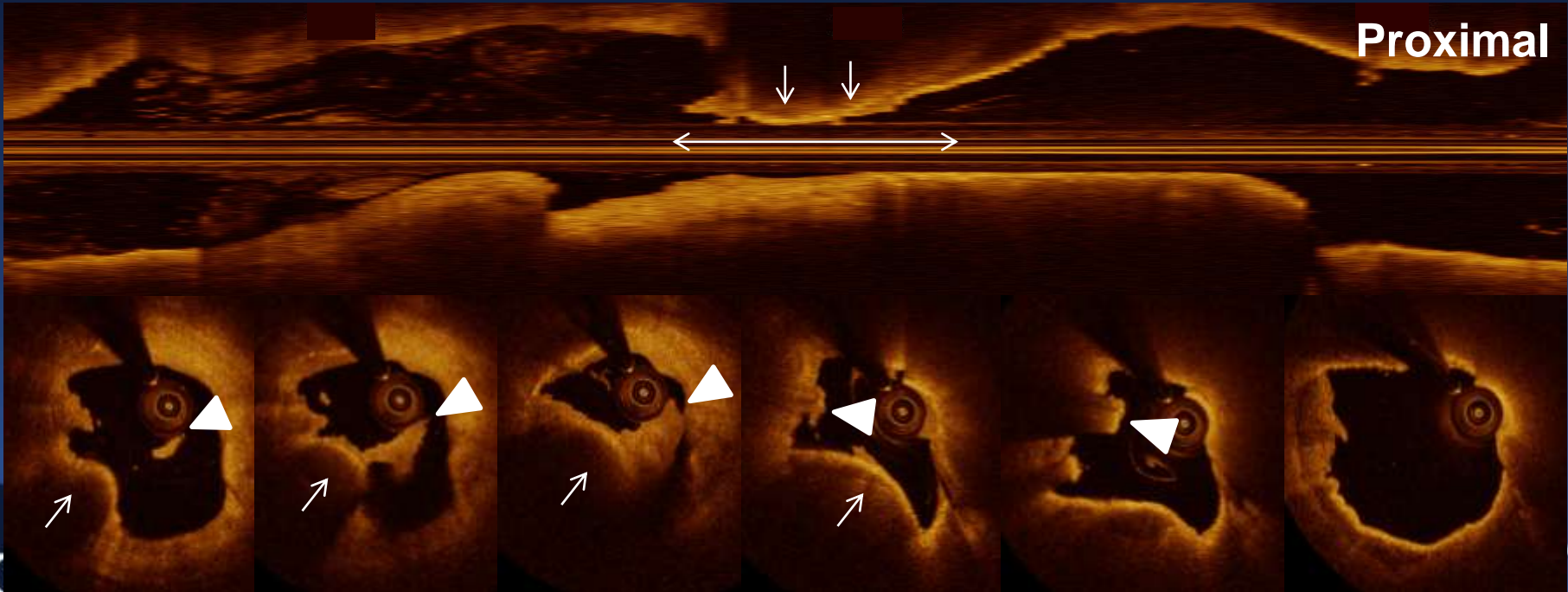
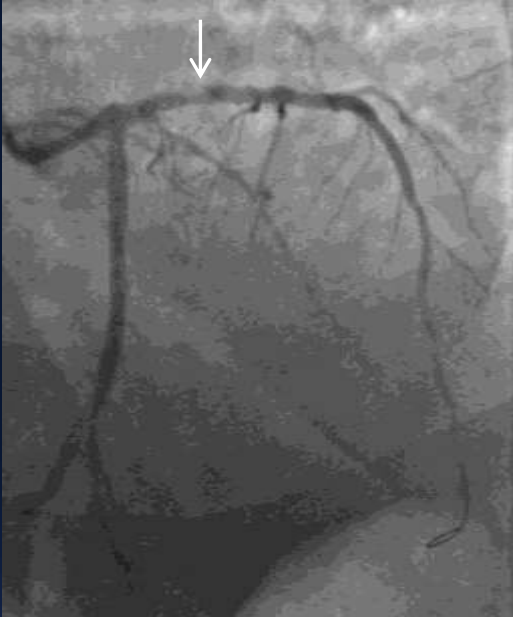
34-year old man with history of smoking and untreated hyperlipidemia, had epigastric pain and was found dead at home



Calcified Nodule

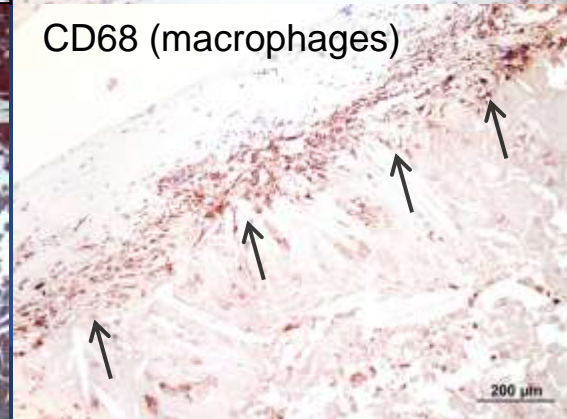
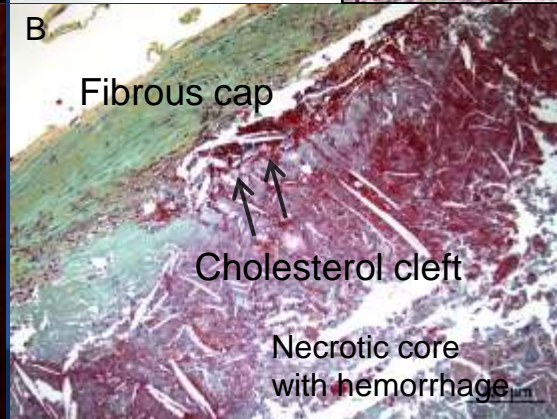
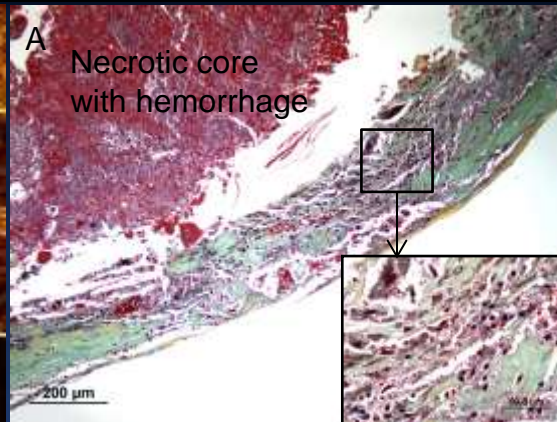
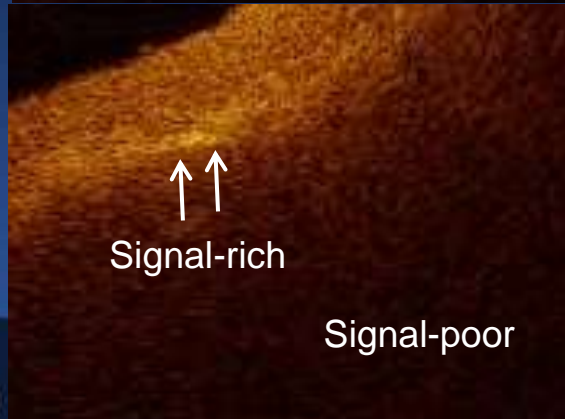
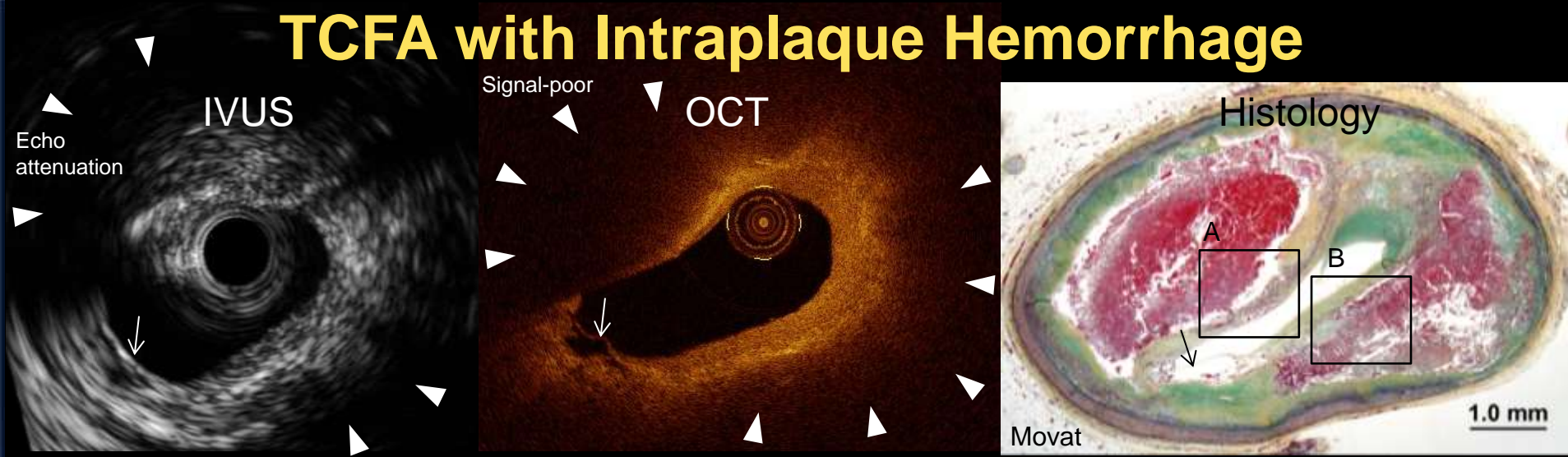


Representative Case with Calcified Nodule



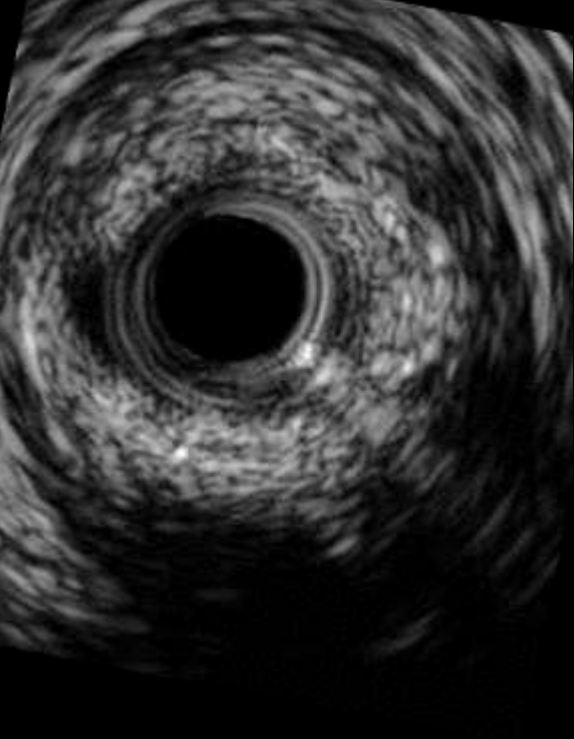
Proximal

TCFA with Intraplaque Hemorrhage

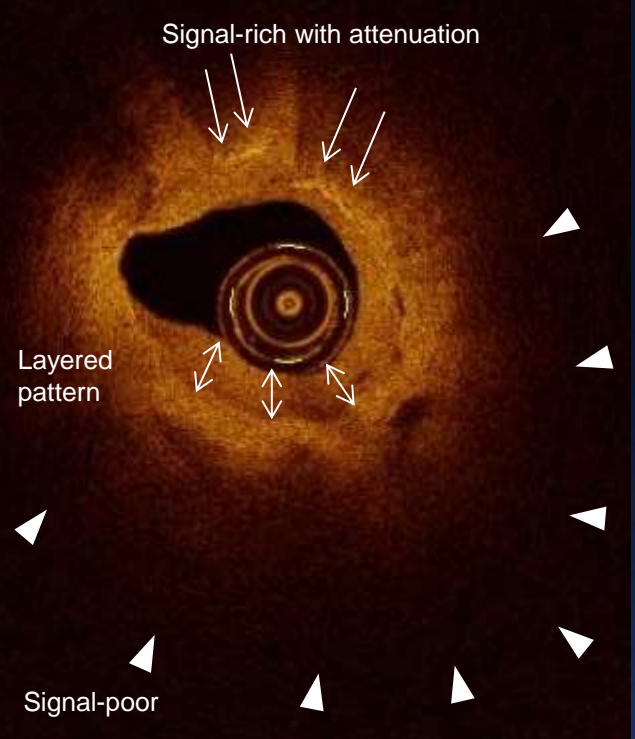


Healed Plaque Rupture

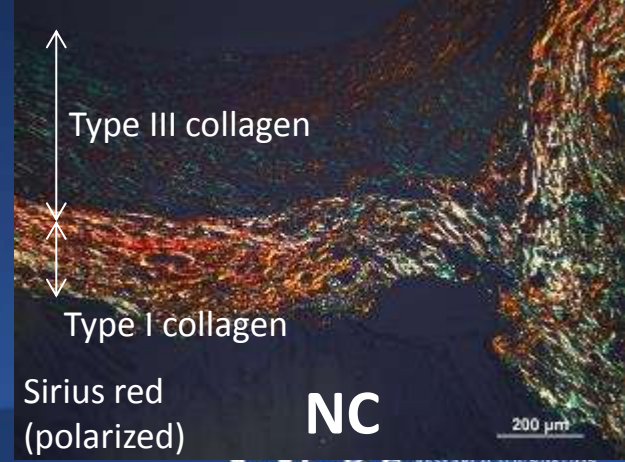
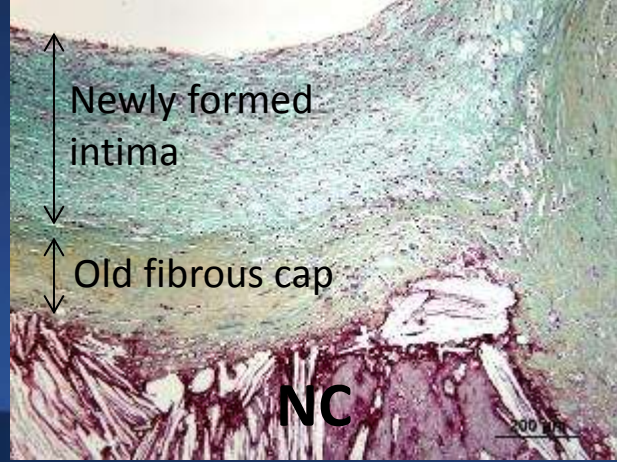
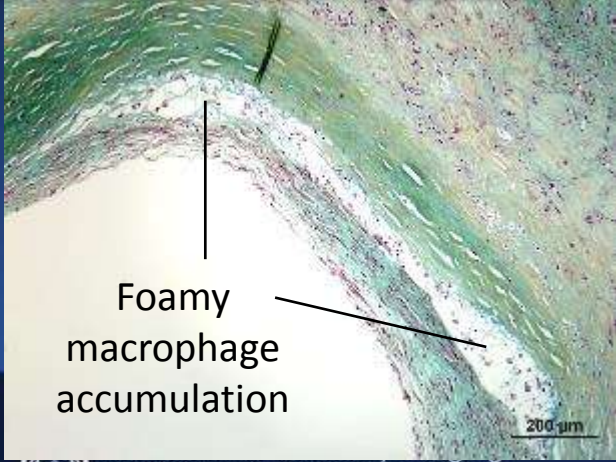
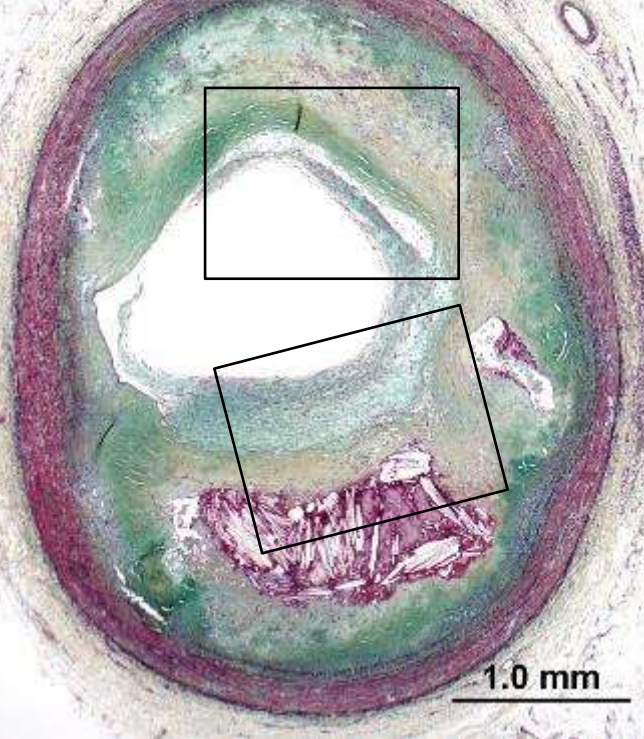
IVUS



OCT

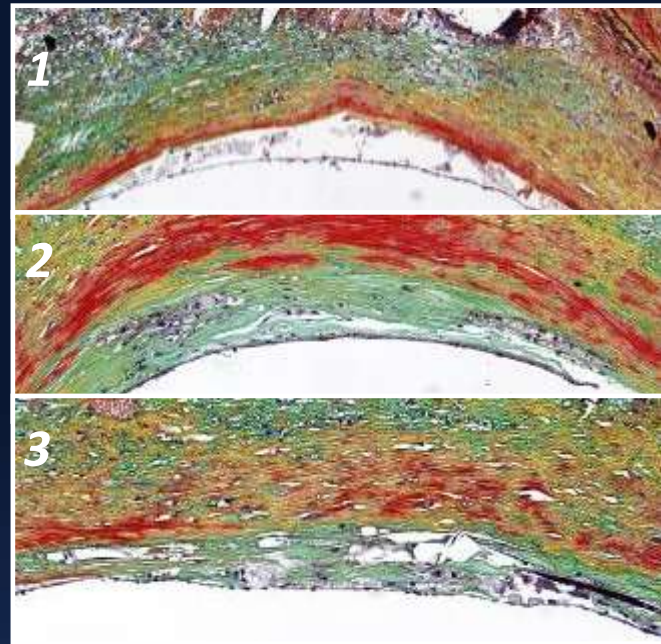
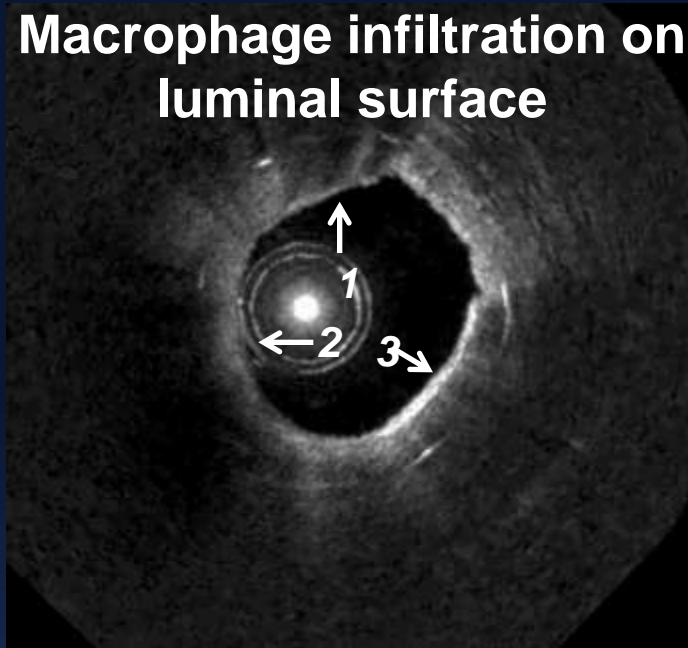


Histology

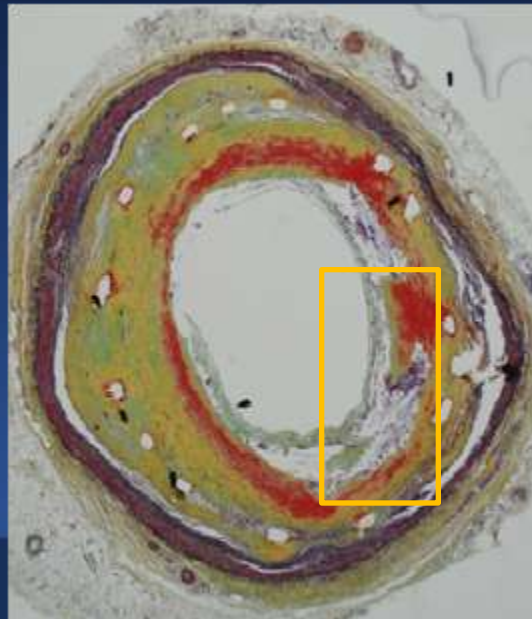
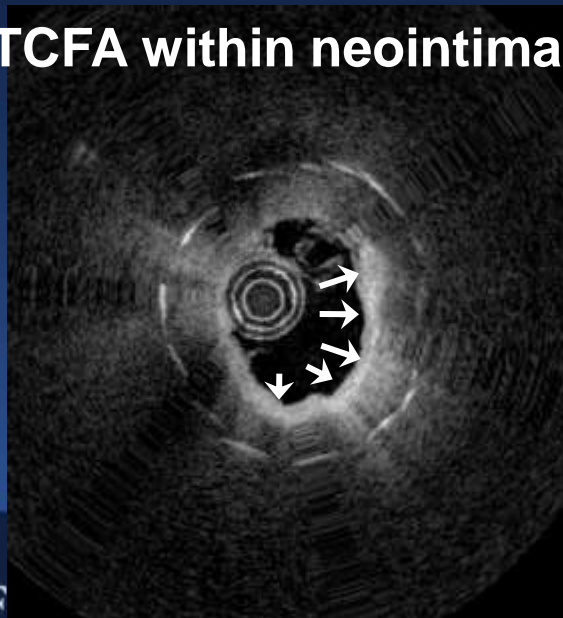


Neoatherosclerosis

Macrophage infiltration on luminal surface

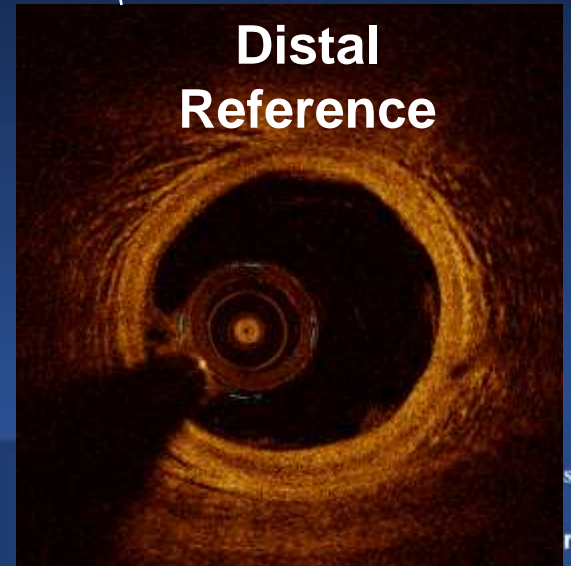
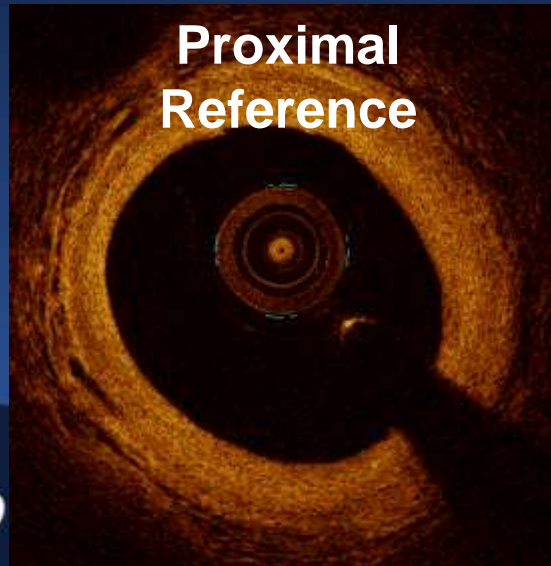
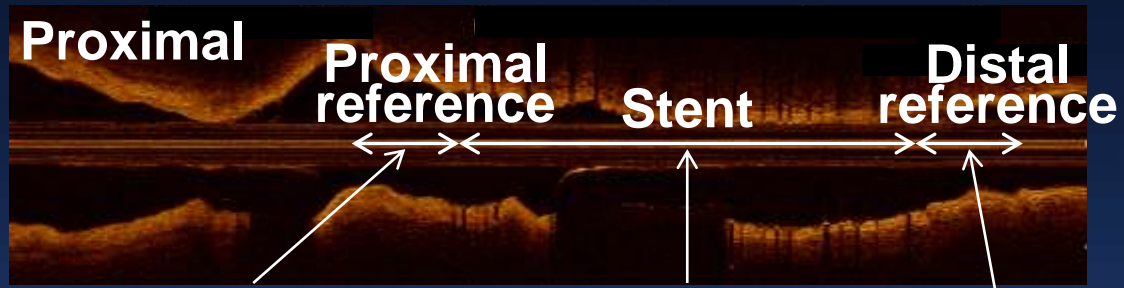
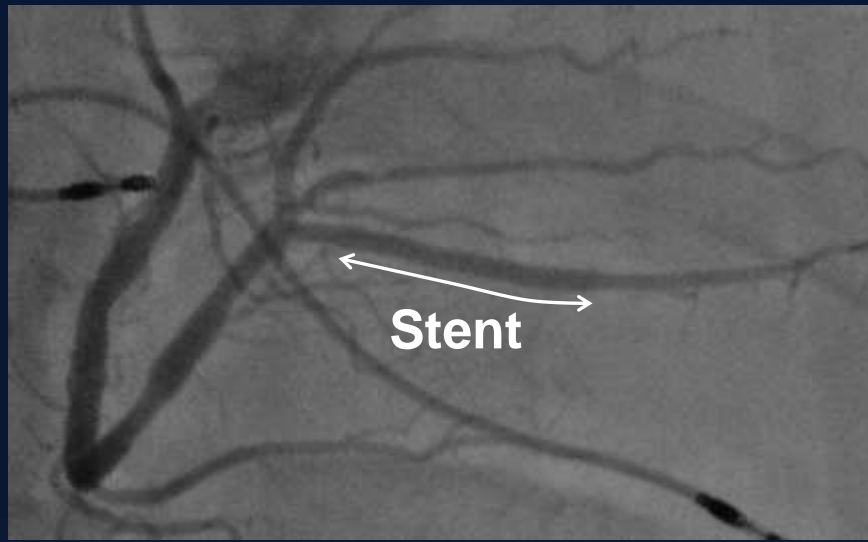


TCFA within neointima



OCT

- Tool for PCI Guidance -



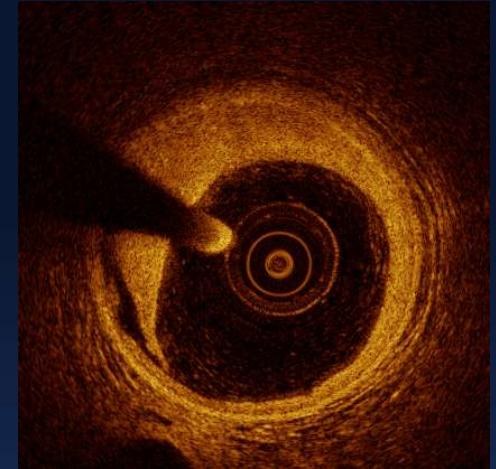
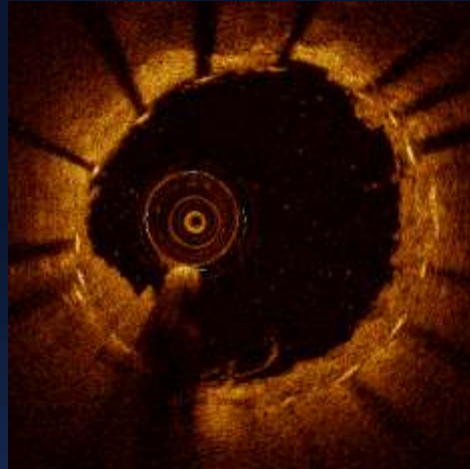
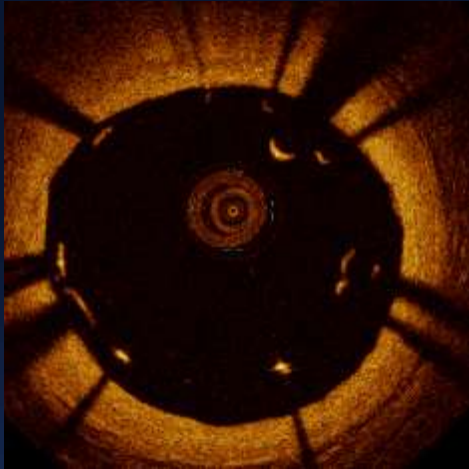
Difference between OCT and IVUS

Malapposition

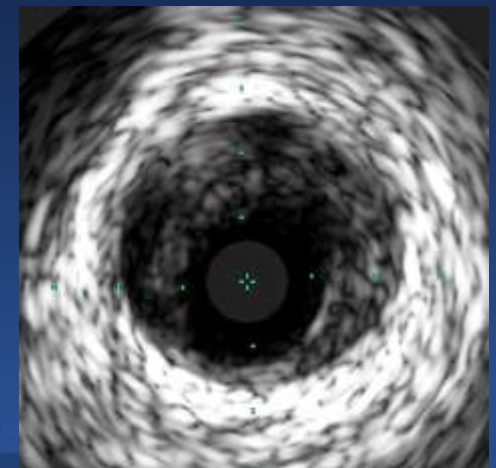
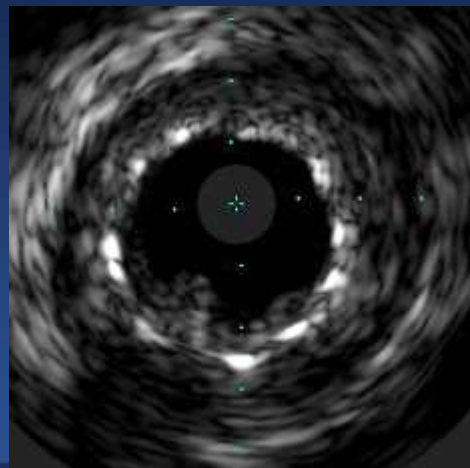
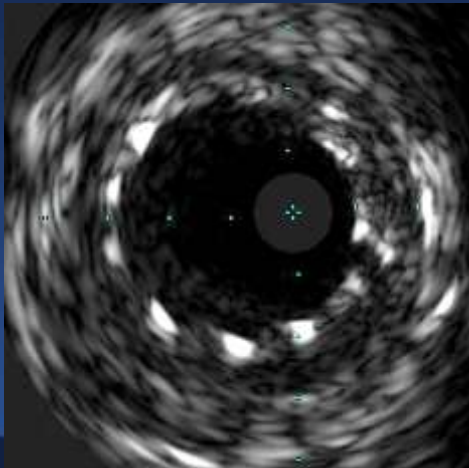
Tissue Protrusion

Stent Edge Dissection

OCT



IVUS



ILUMIEN III - OPTIMIZE PCI Trial - 420 Patients requiring PCI

R

```
graph TD; R((R)) --> OCT["OCT guided PCI  
N=140"]; R --> IVUS["IVUS guided PCI  
N=140"]; R --> Angio["Angio guided PCI  
N=140"];
```

OCT guided PCI
N=140

IVUS guided PCI
N=140

Angio guided PCI
N=140

OCT protocol to guide PCI
Optimal PCI criteria

Primary endpoint: Minimum stent area by OCT

- **Non-inferiority compared to IVUS arm**
- **Superiority compared to Angio arm**

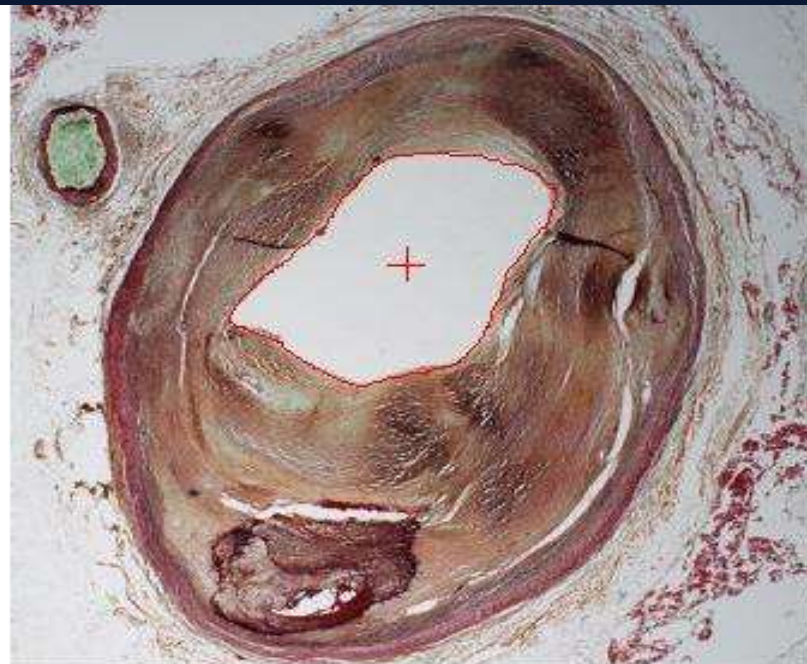
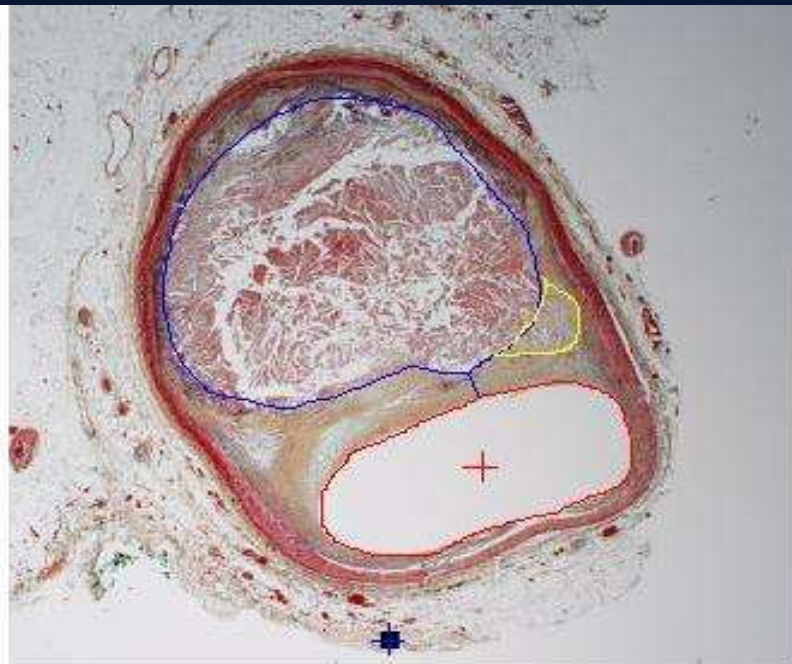
PI: Ziad Ali, Chair: Gregg Stone

Sponsor: St Jude Medical

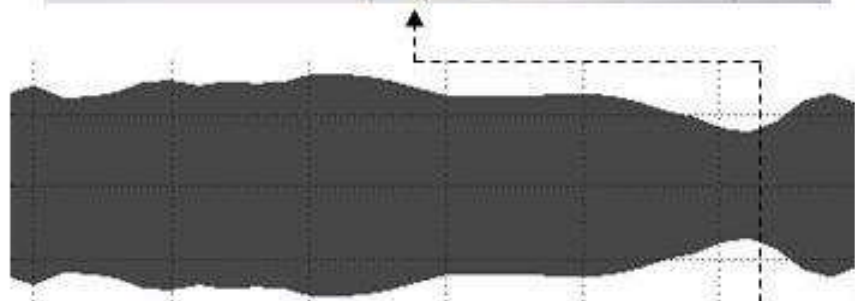
NIRS

- Prediction of Outcome -

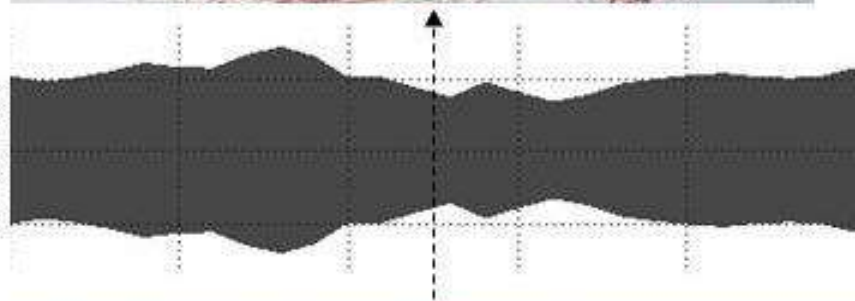
NIR can Distinguish Lipid-rich from Fibrotic Plaques



IVUS
DIAMETER



IVUS
DIAMETER



CHEMOGRAM



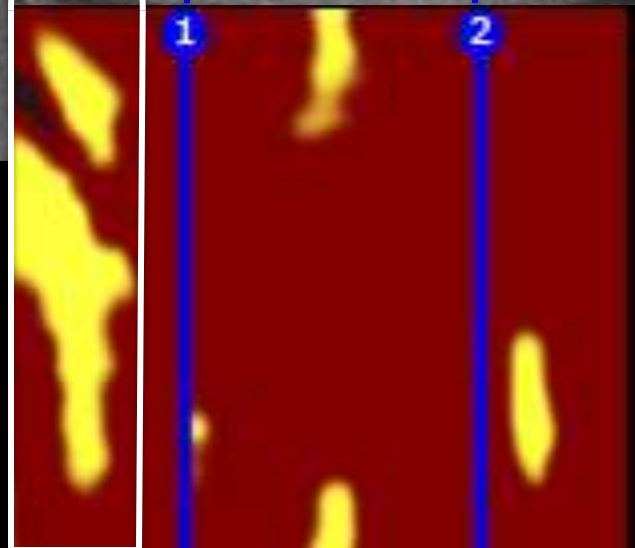
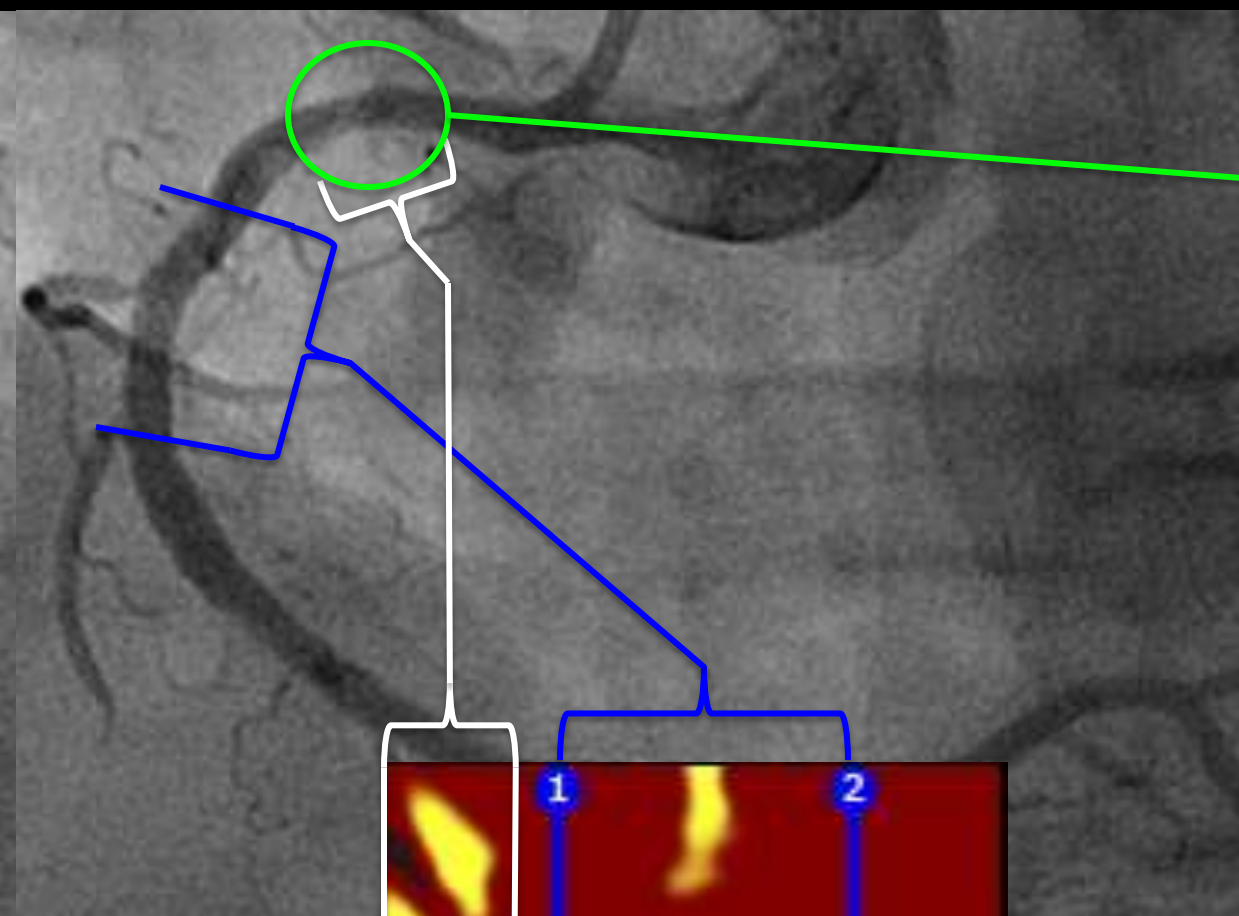
CHEMOGRAM



64 year old presents with STEMI in March 2012



Unstable angina October 2012



maxLCBI_{4mm}
694



Methods

Spectrum NIRS-IVUS Registry

- Single center, observational
- Prospectively enrolled patients undergoing NIRS-IVUS

Inclusion criteria

- Patients completing ≥ 1 year of follow-up

Exclusion criteria

- Prior CABG/referred for CABG
- Uninterpretable NIRS
- NIRS imaging performed only within a stented segment

January 2012 to April 2013

167 patients
NIRS-IVUS imaging
&
 ≥ 1 year of follow-up

→ Excluded

Prior CABG (7)

Referred for CABG (17)

Uninterpretable NIRS (15)

NIRS only in stent (7)

121 patients
included in this analysis

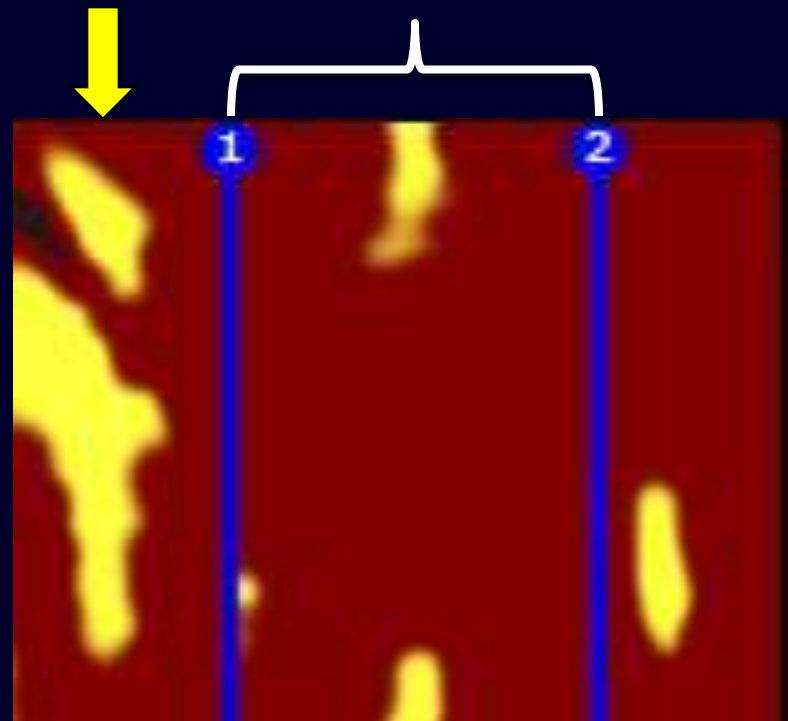


Methods

- Evaluated non-stented coronary segments for large LRP
 - defined as a $\max\text{LCBI}_{4\text{mm}} \geq 500$
- Patients followed for MACCE
 - Composite of all-cause mortality, recurrent ACS requiring revascularization, or acute cerebrovascular events
- Events related to previously stented segments were excluded
- All events adjudicated blinded to the NIRS-IVUS imaging

Large LRP
in
non-
stented
segment

Stented
segment
excluded
from
analysis

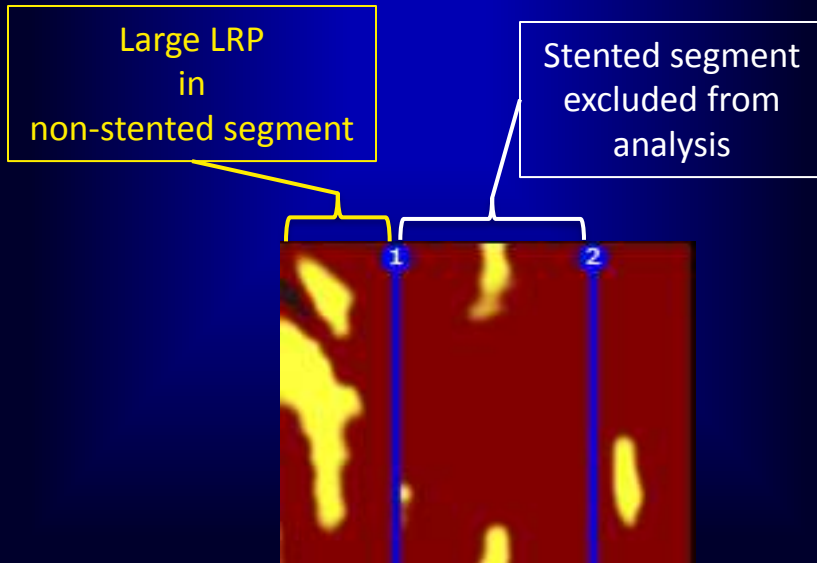




Results

Baseline NIRS Findings

- 462 non-overlapping 10-mm coronary segments analyzed
- A large LRP was detected in **15 (3.2%)** segments & in **12 (9.9%)** patients

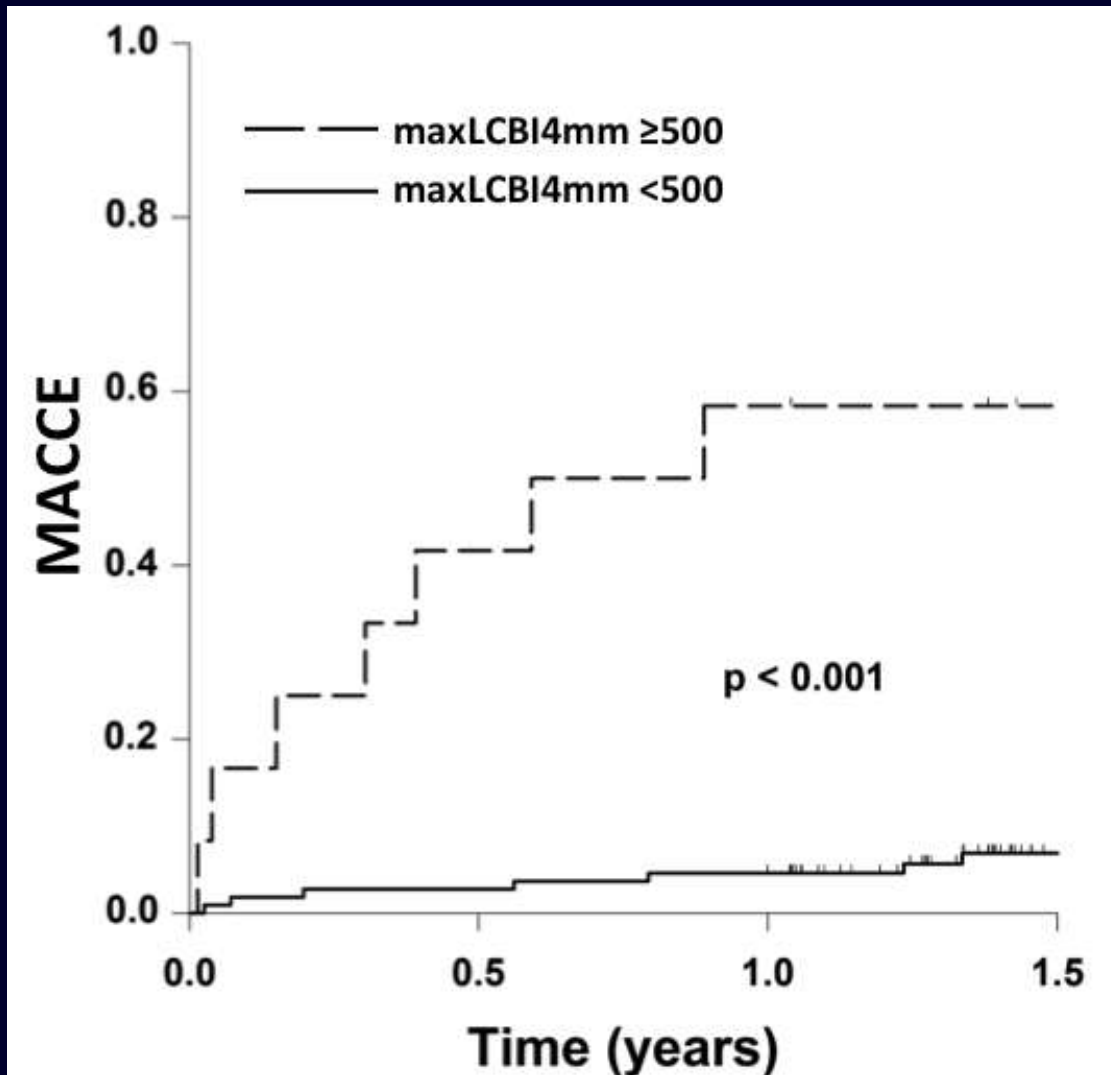


Follow Up Events

- Average follow-up duration was 603 ± 145 days (1.7 years)
- MACCE (unrelated to previously stented segments) occurred in **11.6%** of patients during follow up
 - ➔ All-cause death 4.1%
 - ➔ ACS requiring revascularization 6.6%
 - ➔ CVA 0.8%



Large LRP by NIRS and MACCE



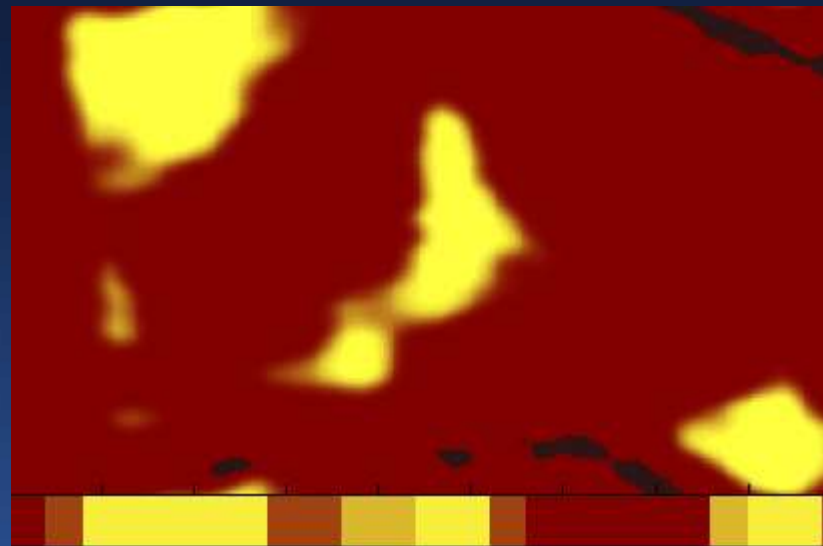
MACCE Rate
Large LRP 58.3%
vs
No large LRP 6.4%
($p < 0.001$)

ACS Requiring Revascularization
Large LRP 25.0%
vs
No large LRP 4.6%
($p < 0.001$)

Relationship between Lipid Rich Plaque detected by NIRS and Outcomes

- Prospective Single Center Study, 206 patients (ACS47%)
- Primary Endpoint: Composite of all-cause mortality, non-fatal ACS, stroke and unplanned PCI during one-year FU
- >40mm non culprit segment of NIRS

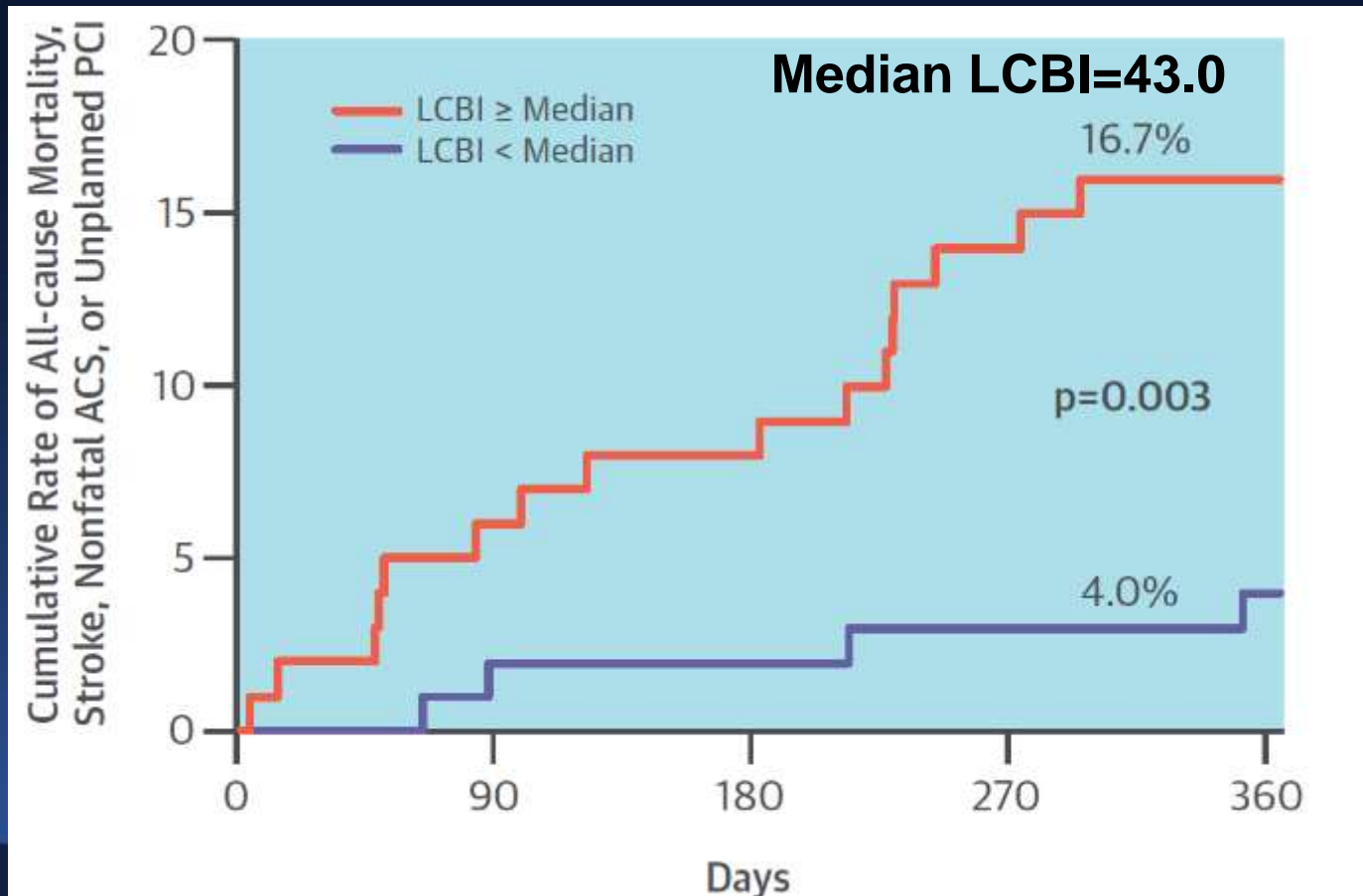
Lipid Core
Burden Index
(LCBI)=188



45mm

Relationship between Lipidic Plaque detected by NIRS and Outcomes

Primary Endpoint: Adjusted Hazard Ratio
= 4.0 (1.3-12.3), $p=0.01$



PROSPECT II Study

**900 pts with ACS at up to 20 hospitals
in Sweden, Denmark and Norway (SCAAR)**

NSTEMI or STEMI >12°

IVUS + NIRS (blinded) performed in culprit vessel(s)

Successful PCI of all intended lesions (by angio \pm FFR/iFR)

Formally enrolled

3-vessel imaging post PCI

Culprit artery, followed by non-culprit arteries

Angiography (QCA of entire coronary tree)

IVUS + NIRS (blinded) (prox 6-8 cm of each coronary artery)

PROSPECT II Study PROSPECT ABSORB RCT

900 pts with ACS after successful PCI

3 vessel IVUS + NIRS (blinded)

≥1 IVUS lesion with ≥65% plaque burden present?

Yes

(N=300)

No

(n=600)

R

1:1

**ABSORB BVS
+ GDMT** (N~150)

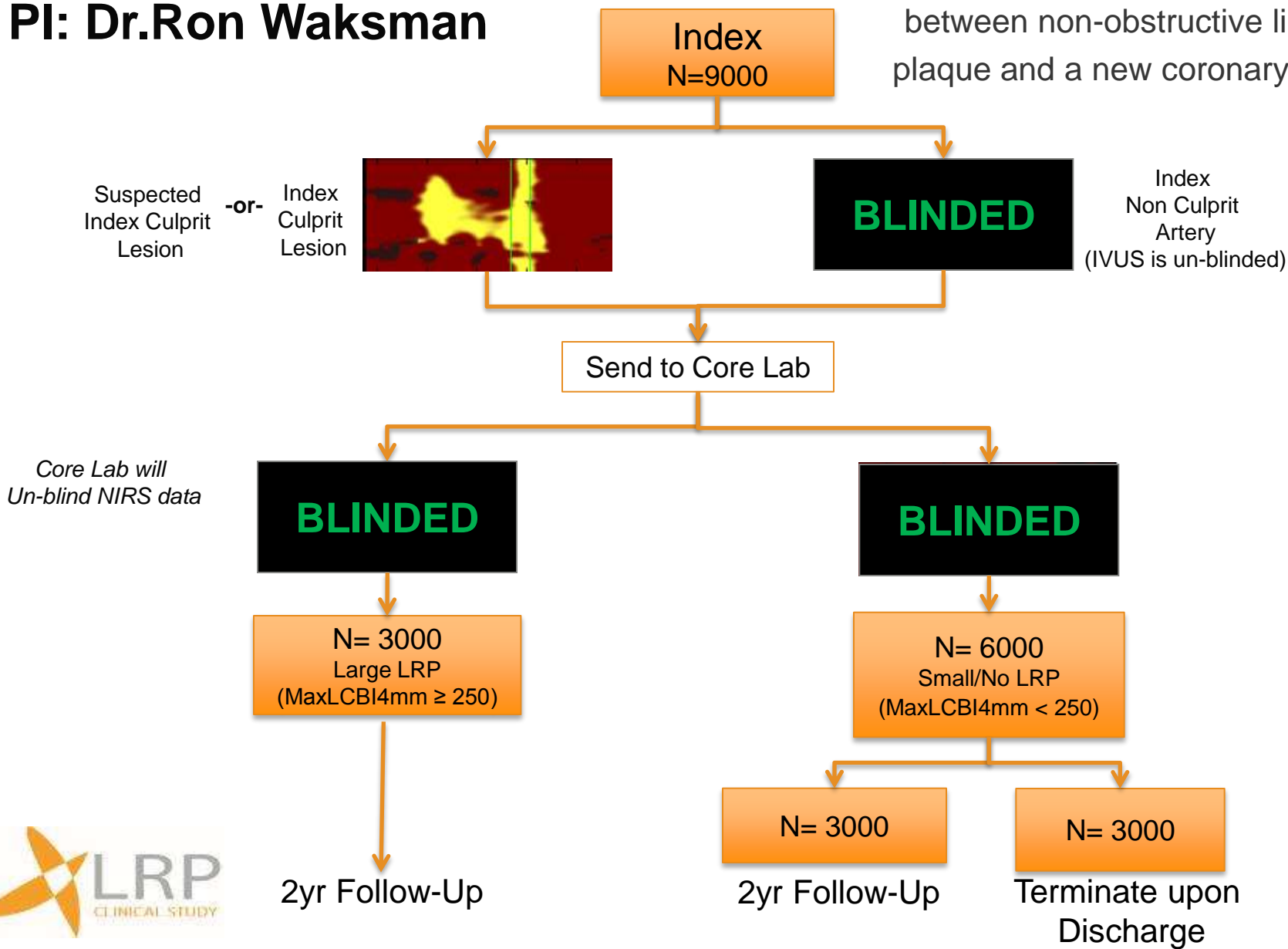
GDMT
(N=150)

Routine angio/3V IVUS-NIRS FU at 2 years

Clinical FU for ≥3 years

PI: Dr. Ron Waksman

“To evaluate the relationship between non-obstructive lipid-rich plaque and a new coronary events”



The *PREVENTive* Implantation of Bioresorbable Vascular Scaffold on Stenosis With Functionally Insignificant Vulnerable Plaque

SJ Park **PREVENT Trial**

Any Epicardial Coronary Stenosis
with FFR ≥ 0.80 and with Two of the following

1. IVUS MLA $\leq 4.0 \text{mm}^2$
2. IVUS Plaque Burden $> 70\%$
3. Lipid-Rich Plaque on NIRS ($_{\text{max}} \text{LCBI}_{4\text{mm}} > 500$)
4. OCT-TCFA or VH-TCFA



Primary endpoint at 2 years:
CV death, MI, Hospitalization d/t unstable angina

OCT sub-study/ NIRS sub-study, (300 patients in each arm at 2 years)

Summary

- 1.** By OCT, we can see *in vivo* pathology and we have been learning more about the pathophysiology of thrombotic events.
- 2.** We believe that OCT-guided PCI is non-inferior to IVUS guidance and have started a randomized trial to prove this.
- 3.** An accumulation of data shows the relationship between NIRS and clinical outcomes. On-going prospective studies will provide a definitive answer.