Erasmus MC
Universitair Medisch Centrum Rotterdam

Clinical Utility of Intracoronary Imaging, Today and Tomorrow:

Grayscale, VH-IVUS and OCT Assessment of BVS

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Thoraxcenter
Erasmus Medical Center
Rotterdam, NL

20th CARDIOVASCULAR SUMMIT
TCTAP 2015

Clinical Utility of Intracoronary Imaging: BVS – Experience from Clinical Trials

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COHORT A

First in Men, n=30

Single de-novo lesion

OCT:
Single center,n=16

Academic analysis
Thoraxcenter

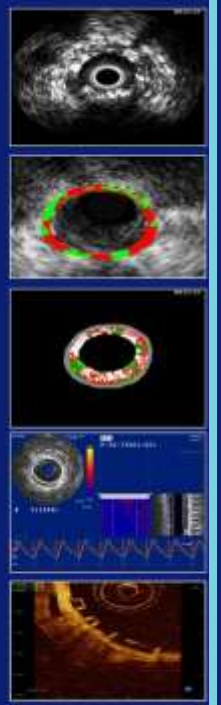
A bioabsorbable everolimus-eluting coronary stent system for patients with single de-novo coronary artery lesions (ABSORB): a prospective open-label trial

Ormiston et al. Lancet 2008
Serruys et al. Lancet 2010

ABSORB Cohort A - Study Design
Imaging Follow-Up (6m and 2y)

- QCA
- Echogenicity
- IVUS, IVUS-VH
- Palpography
- OCT
- MSCT

18 months



Clinical Utility of Intracoronary Imaging: BVS – Experience from Clinical Tri

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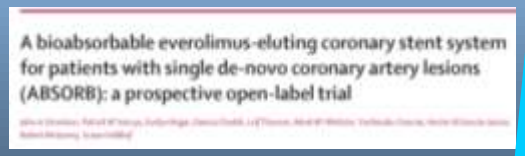
Thoraxcenter



Ormiston et al. Lancet 2008
Serruys et al. Lancet 2010

COHORT B

First in Men, n=101

Sir

C

EXTEND

Clinical trial, n=1000

Multiple de novo-lesio
Long lesions

OCT:
Multi-center, n=50

Corelab analysis
Cardialysis

ABSORB II

Clinical trial, n=500

Multiple de novo-lesions
Stable angina & ACS

RANDOMIZED 2:1
(BVS vs Xience)

B-SEARCH

Thoraxcenter Registry

All-comer
Real-world use

Simsek et al. Eurointerv 2013
Diletti et al. Eur Heart J 2014

Clinical Utility of Intracoronary Imaging: BVS – Experience from "Real Life" Registries

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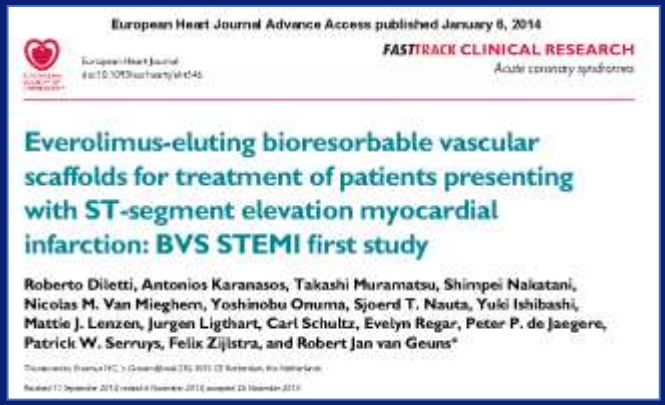
Thoraxcenter BVS registries

BVS STEMI first


European Heart Journal Advance Access published January 6, 2014

FASTTRACK CLINICAL RESEARCH

Acute coronary syndromes

Everolimus-eluting bioresorbable vascular scaffolds for treatment of patients presenting with ST-segment elevation myocardial infarction: BVS STEMI first study

Roberto Diletti, Antonios Karanasos, Takashi Muramatsu, Shimpei Nakatani, Nicolas M. Van Mieghem, Yoshinobu Onuma, Sjoerd T. Nauta, Yuki Ishibashi, Mattie J. Lenzen, Jurgen Ligthart, Carl Schultz, Evelyn Regar, Peter P. de Jaegere, Patrick W. Serruys, Felix Zijlstra, and Robert Jan van Geuns*

BVS EXPAND

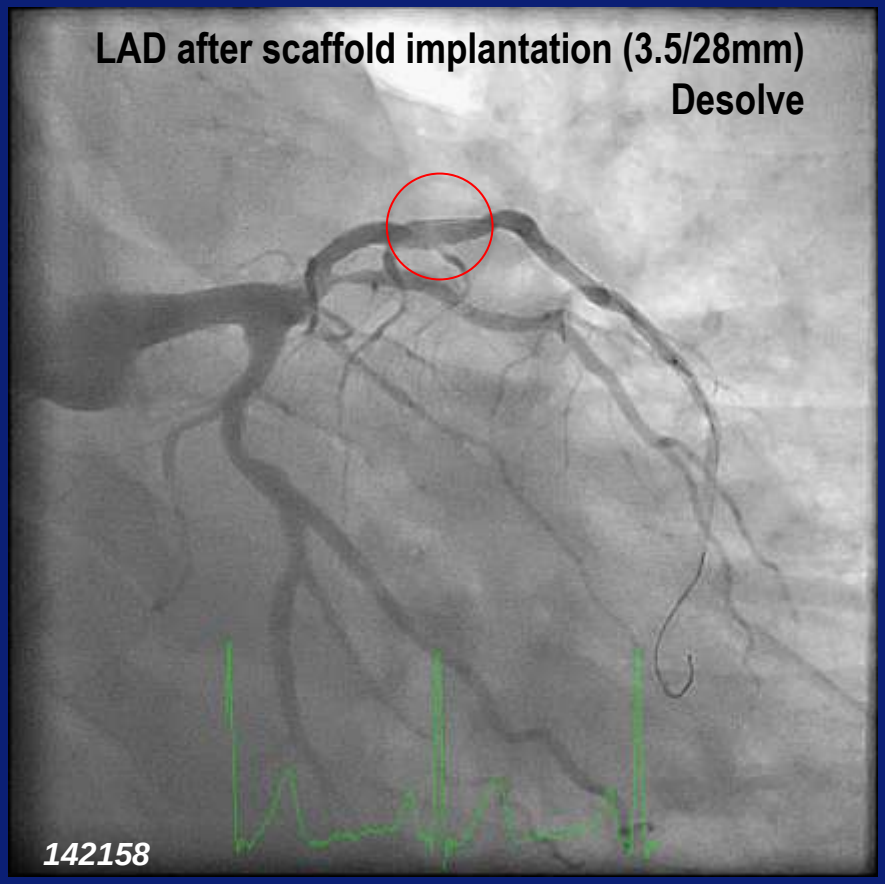
- Larger diameter up to 4.0 mm
- Longer length: > 32 mm
- Bifurcations
- Calcified lesions
- ACS patients (non-STEMI)
- No previous CABG
- No metallic stent in target vessel

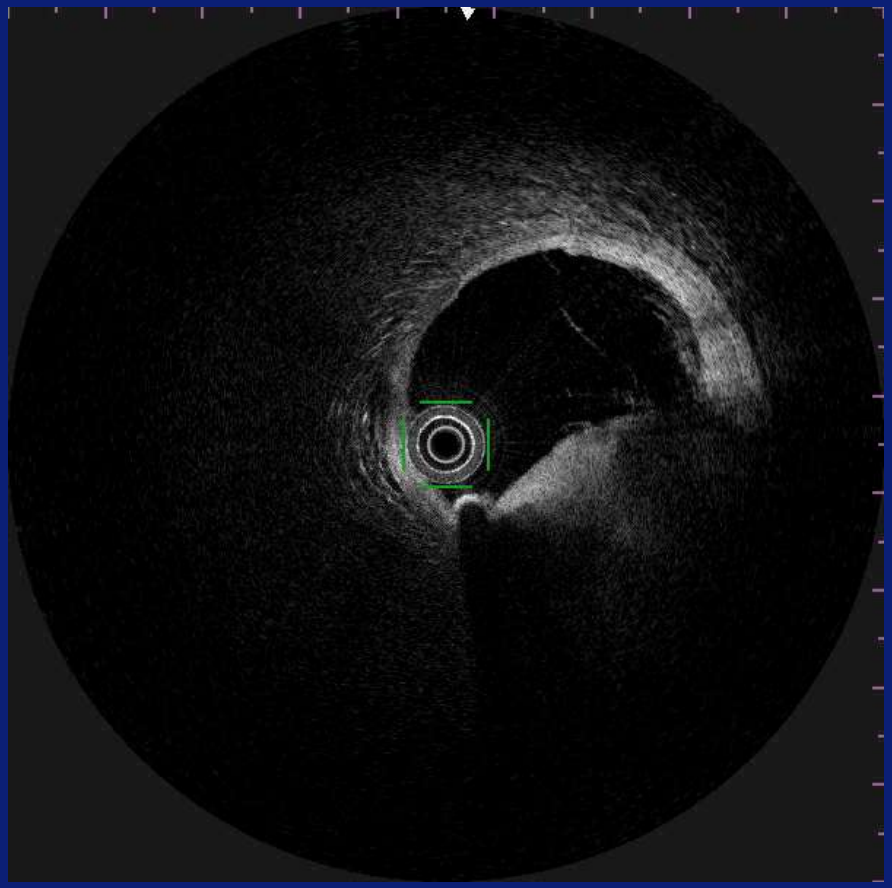
Clinical Utility of Intracoronary Imaging: BVS

1. Any intracoronary imaging is superior to angio!

Clinical Utility of Intracoronary Imaging: BVS

1. Intracoronary Imaging is Superior to Angio!





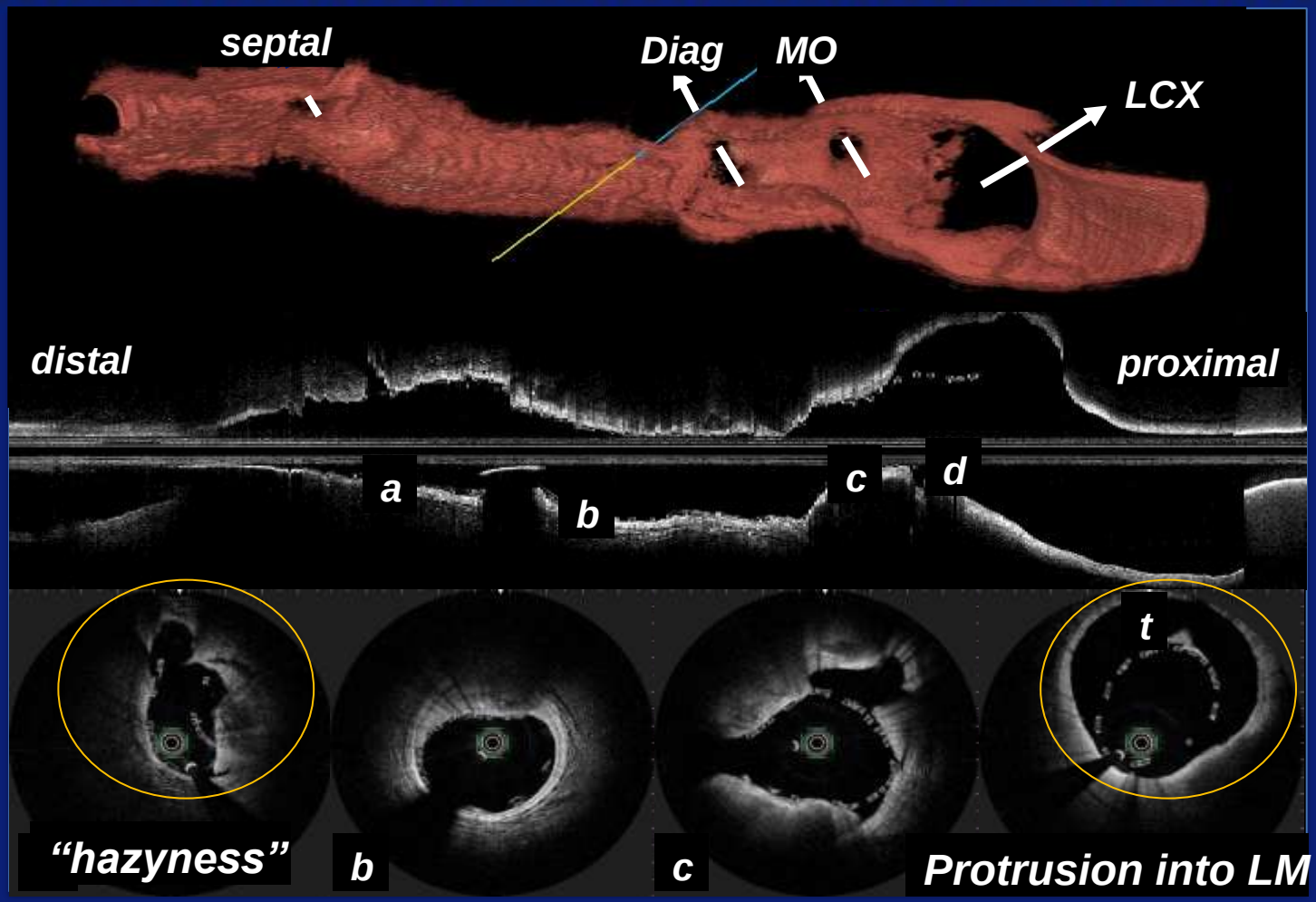
OCT Terumo Fastview™

51 yrs, male, CCS 3, smoker
History: 2003 STEMI: pPCI RCA, 2014 STEMI: LAST RCA

Clinical Utility of Intracoronary Imaging: BVS

1. Intracoronary Imaging is Superior to Angio!

Online
3D rendering
in the cathlab:
30 sec



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Clinical Utility of Intracoronary Imaging: BVS

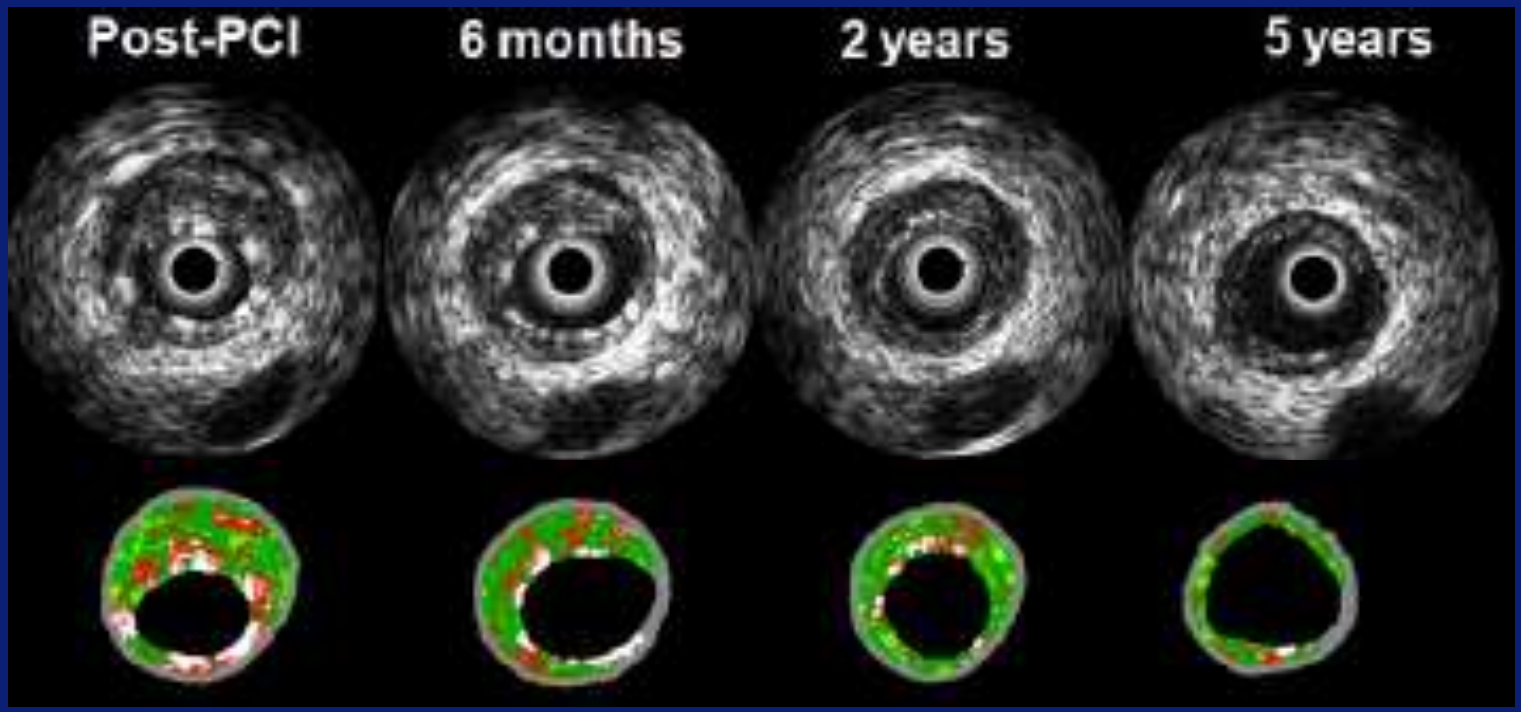
1. Any intracoronary imaging is superior to angio!

2. IVUS is superior to visualize plaque burden

Clinical Utility of Intracoronary Imaging: BVS

2. IVUS is Superior to Visualize Plaque Burden

IVUS: Scaffold, lumen, plaque burden



IVUS-VH: Struts as artefacts (white color)

Simsek C et al, Eurointervention 2014

Clinical Utility of Intracoronary Imaging: BVS

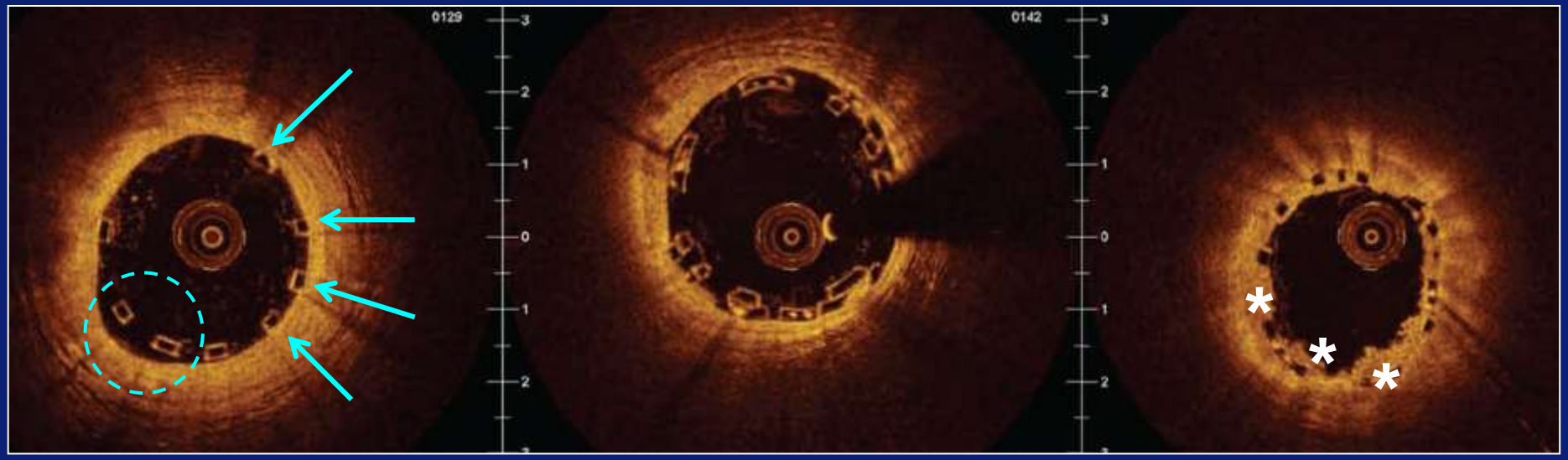
1. Any intracoronary imaging is superior to angio!
2. IVUS is superior to visualize plaque burden
3. OCT is superior to visualize struts & apposition

coverage

changes over time

Clinical Utility of Intracoronary Imaging: BVS

3. OCT is Superior to Visualize Struts & Apposition



incomplete strut apposition

scaffold strut overlap

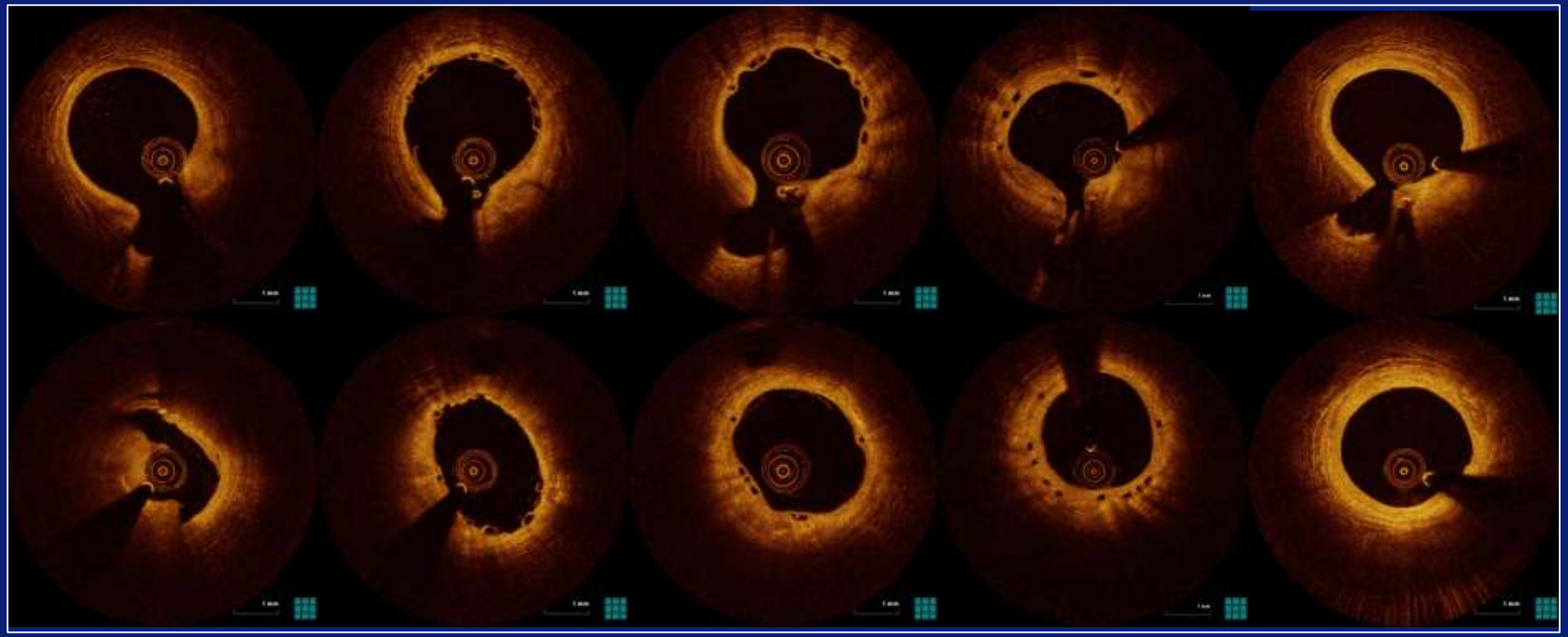
tissue protrusion

Modified from
Nammas W et al. Expert Rev. Cardiovasc. Ther. 11(5), 577–588 (2013)

Clinical Utility of Intracoronary Imaging: BVS

3. OCT is Superior to Visualize Changes Over Time

5-year follow-up of BVS 1.1

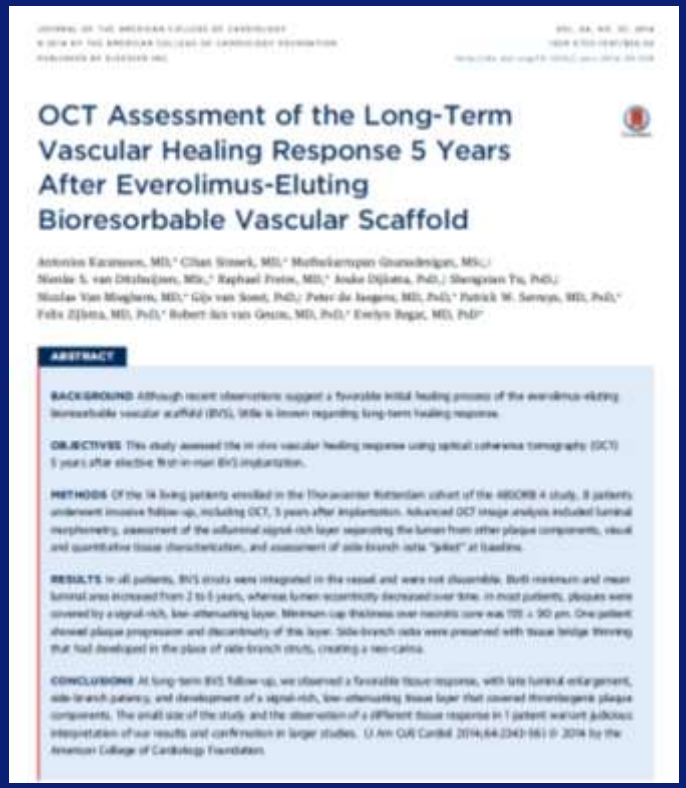


Pre *Post* *6 months* *2 years* *5 years*

Clinical Utility of Intracoronary Imaging: BVS

3. OCT is Superior to Visualize Changes Over Time

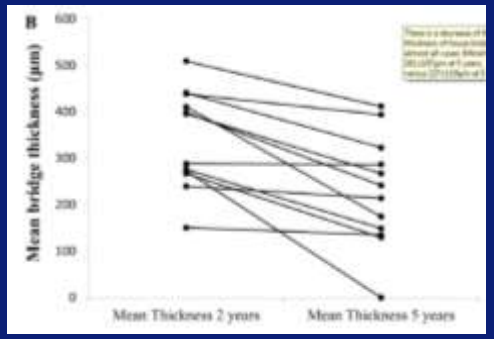
5-year follow-up of BVS 1.0

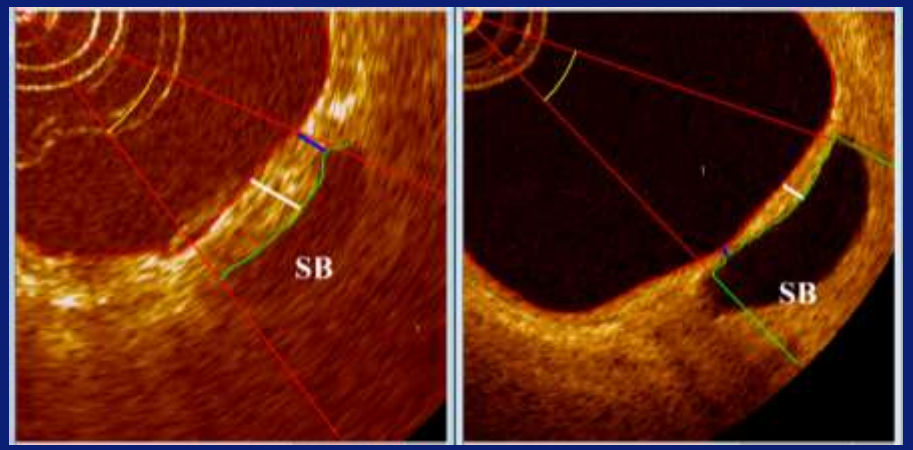


OCT Assessment of the Long-Term Vascular Healing Response 5 Years After Everolimus-Eluting Bioresorbable Vascular Scaffold

ABSTRACT

Fate of side branches?
All patent at 5y fup!





2 years *5 years*

Karanasos A et al. JACC 2014

Clinical Utility of Intracoronary Imaging: BVS

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BVS

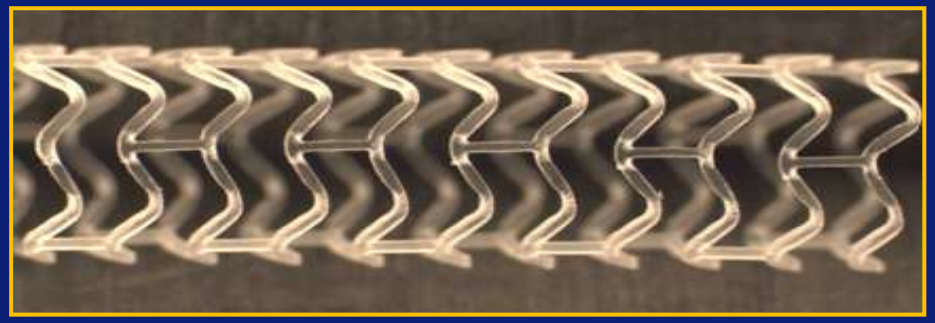
Clinical Utility of Intracoronary Imaging:

- Guidance of Implantation Procedure
- Insights in Failure/ Thrombosis

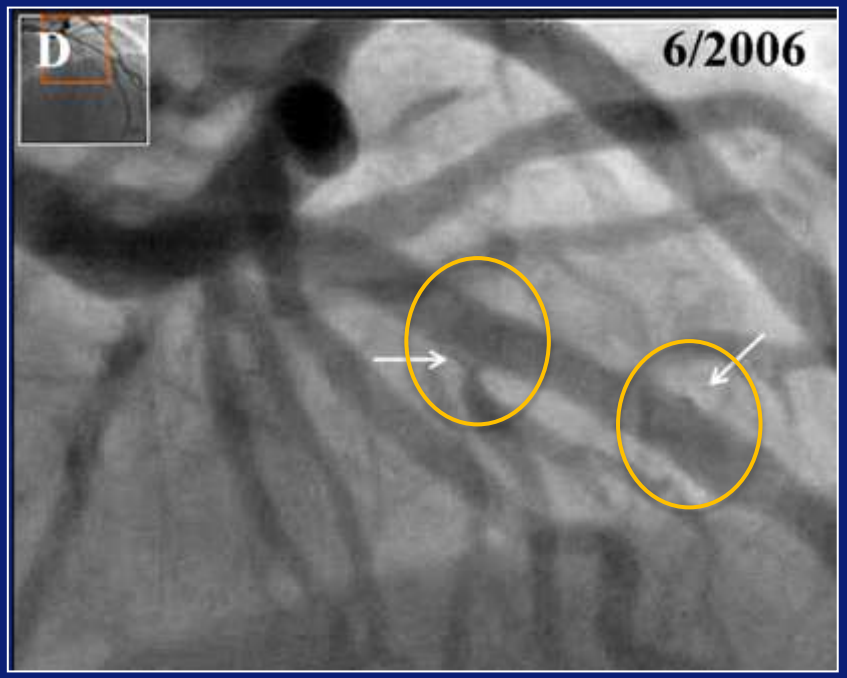
Intracoronary Imaging to Guide BVS Implantation: A Number of Good Reasons

- **Scaffolds are poorly visible on angiogram!**

BVS Absorb



Tiny markers at the edges of the scaffold



Intracoronary Imaging to Guide BVS Implantation: A Number of Good Reasons

- **Scaffolds are relatively bulky**
- **Lesion preparation is important!**

Strut thickness 150 µm
Crossing profile 1.4-1.5mm

BVS Absorb

Intracoronary Imaging to Guide BVS Implantation: A Number of Good Reasons

- **Adequate BVS sizing is crucial**

Key issue with the ABSORB scaffold
Limited range of expansion

2.5 mm scaffold → up to 3.0mm
3.0 mm scaffold → up to 3.5mm
3.5 mm scaffold → up to 4.0mm

Beyond that range, struts can break.

Therefore sizing pre-implantation is of paramount importance.

Intracoronary Imaging to Guide BVS Implantation: A Number of Good Reasons

- **Adequate BVS sizing is crucial**

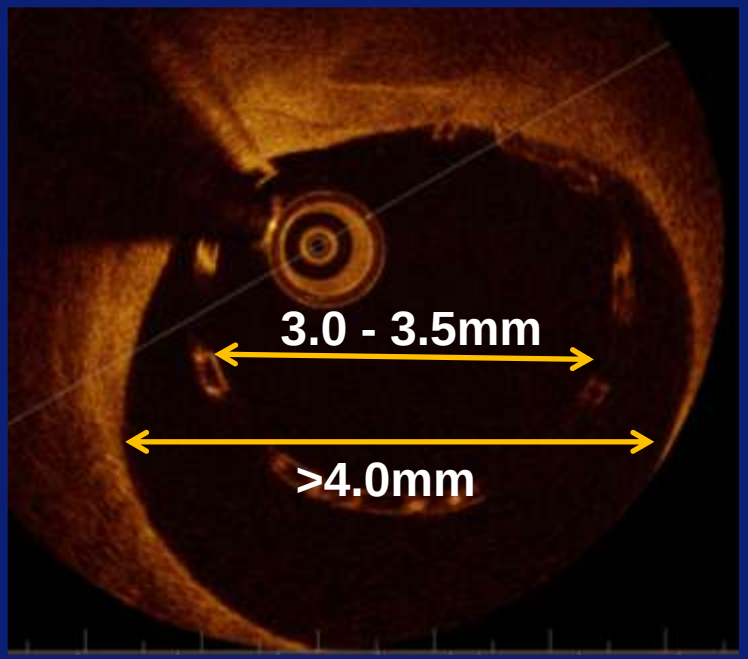
Small malapposition

- Correctable by post dilatation
- Resolve at FUP

Large malapposition

- Uncorrectable (Persistent at FUP)
- Overexpansion by a large balloon

  → Acute disruption



Post procedural

Courtesy Y Onuma

Intracoronary Imaging to Guide BVS Implantation: A Number of Good Reasons

- **Adequate BVS sizing is crucial**

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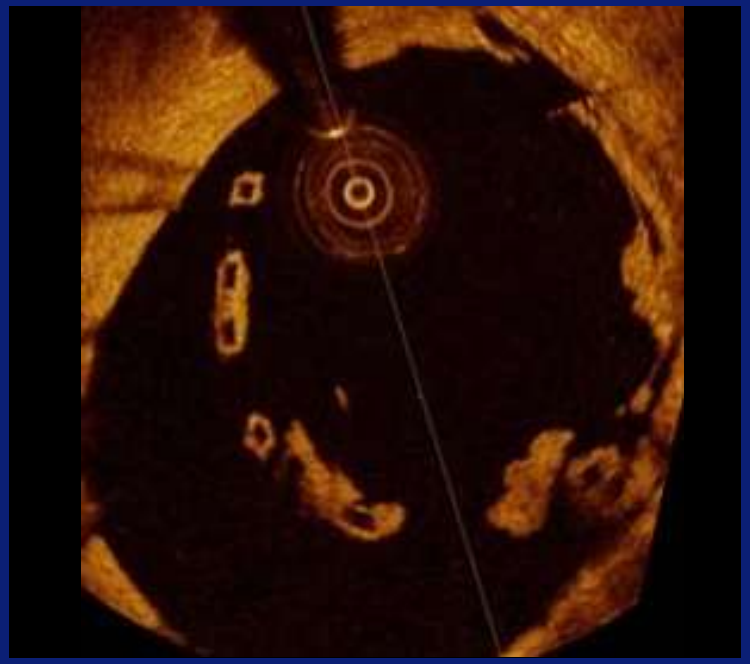

12M Follow-up

Courtesy *Y* Onuma

Intracoronary Imaging to Guide BVS Implantation: A Number of Good Reasons

- **Adequate BVS sizing is crucial**

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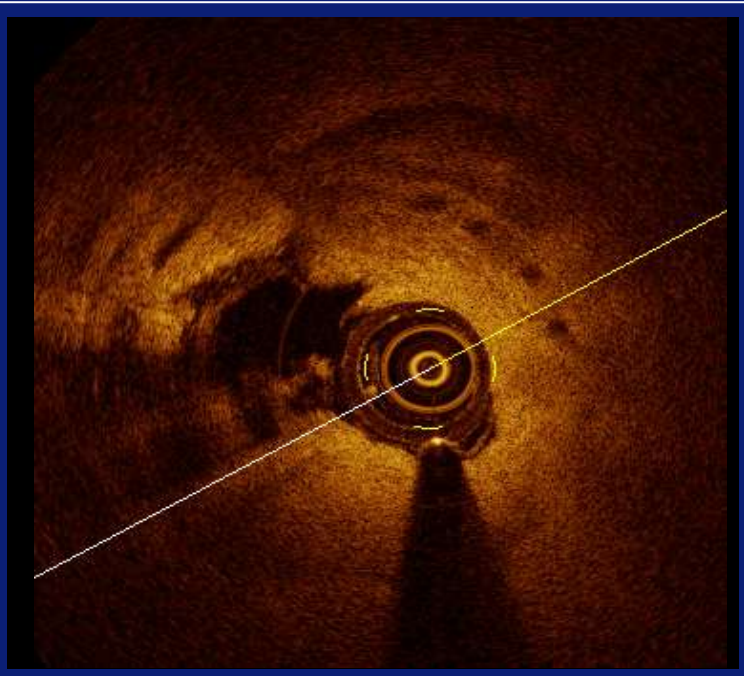


18M Follow-up

Courtesy *Y* Onuma

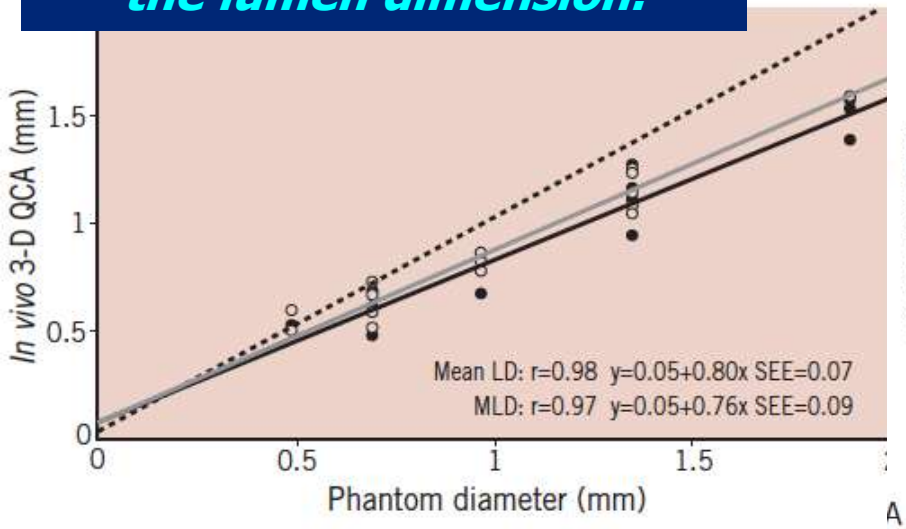
OCT to Guide BVS Implantation: Advantages

- **Angiography is inaccurate! Lumen diameter**

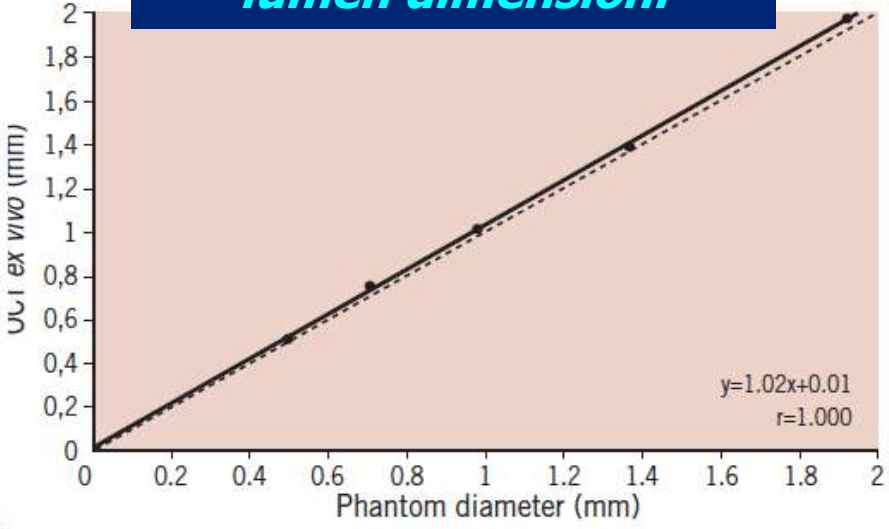
In vivo validation of a novel three-dimensional quantitative coronary angiography system (CardiOp-B™): comparison with a conventional two-dimensional system (CAAS II™) and with special reference to optical coherence tomography

Kelichi Tsuchida, MD, PhD; Willem J. van der Giessen, MD, PhD; Mark Patterson, MRCP; Shuzou Tanimoto, MD; Héctor M. García-García, MD, MSc; Evelyn Regar, MD, PhD; Jurgen M. R. Ligthart, BSc; Anne-Marie Maugenest; Gio Maatrijn; Jolanda J. Wentzel, PhD; Patrick W. Serruys*, MD, PhD, FACC, FESC

QCA underestimates the lumen dimension.



OCT provides the correct lumen dimension.



Tschuchida et al. EuroIntervention

OCT to Guide BVS Implantation: Advantages

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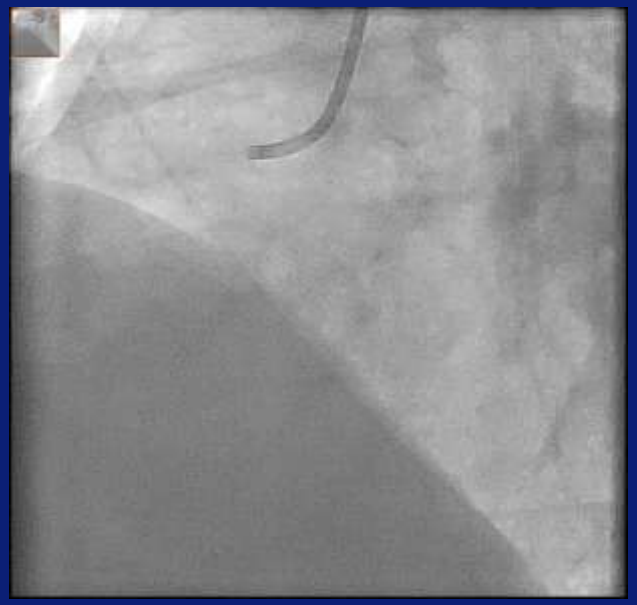
Accuracy

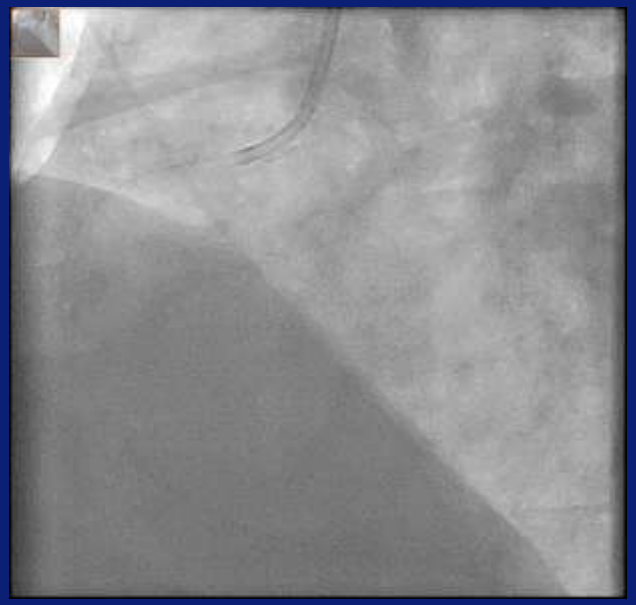
	QCA	IVUS	OCT
Dimension assessment	underestimation	overestimation	correct
Detection of malapposition	none	poor	optimal
Detection of fracture	none	none/poor	optimal
Option for co-registration	none	yes	yes
Regulatory labeling	no	yes	yes

Modified from
Nammas W et al. Expert Rev. Cardiovasc. Ther. 11(5), 577–588 (2013)

OCT to Guide BVS Implantation: Advantages



Pre



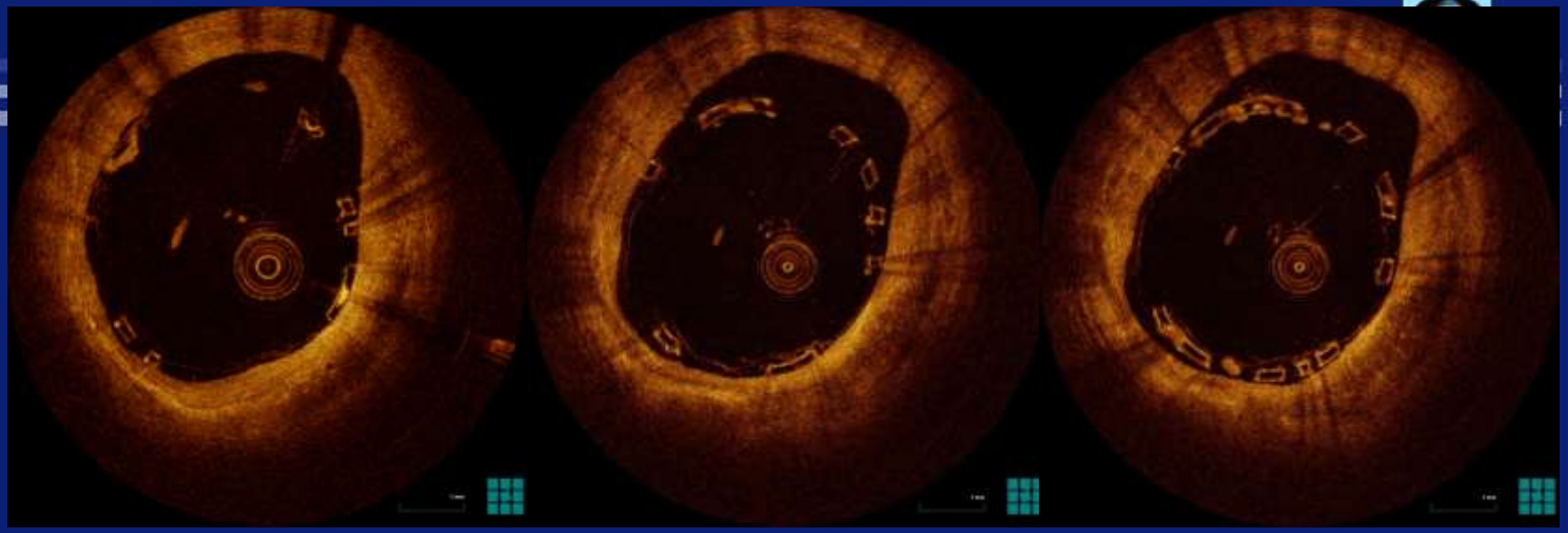
After thrombusaspiration

Online QCA
MLD: 1.42mm
RVD: 4.02mm
DS: 65%
Dmax: 3.89mm

BVS 3.5/18mm

56 yo man, inferior STEMI, no CV history

OCT to Guide BVS Implantation: Advantages



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OCT to Guide BVS Implantation: Advantages

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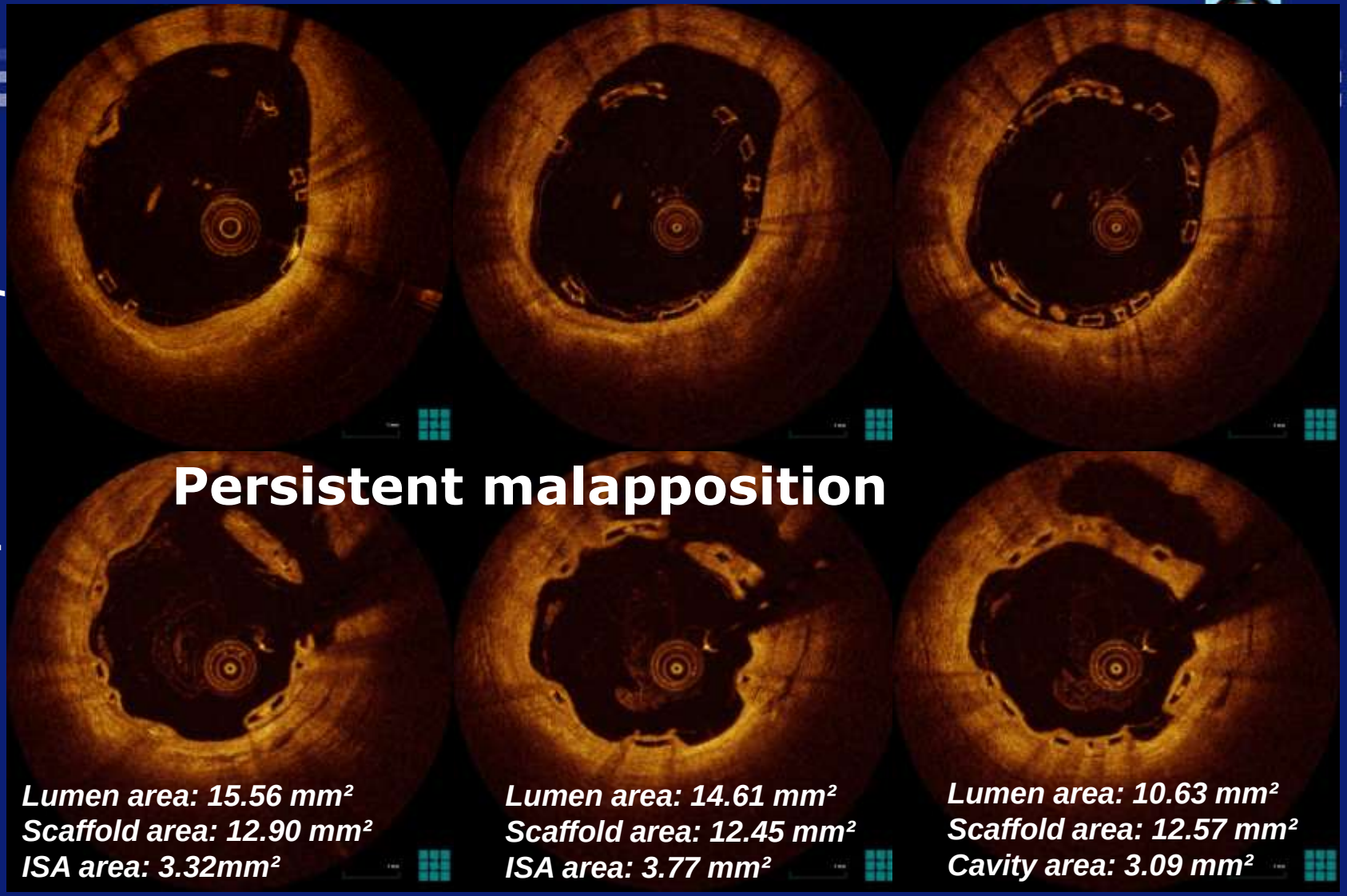
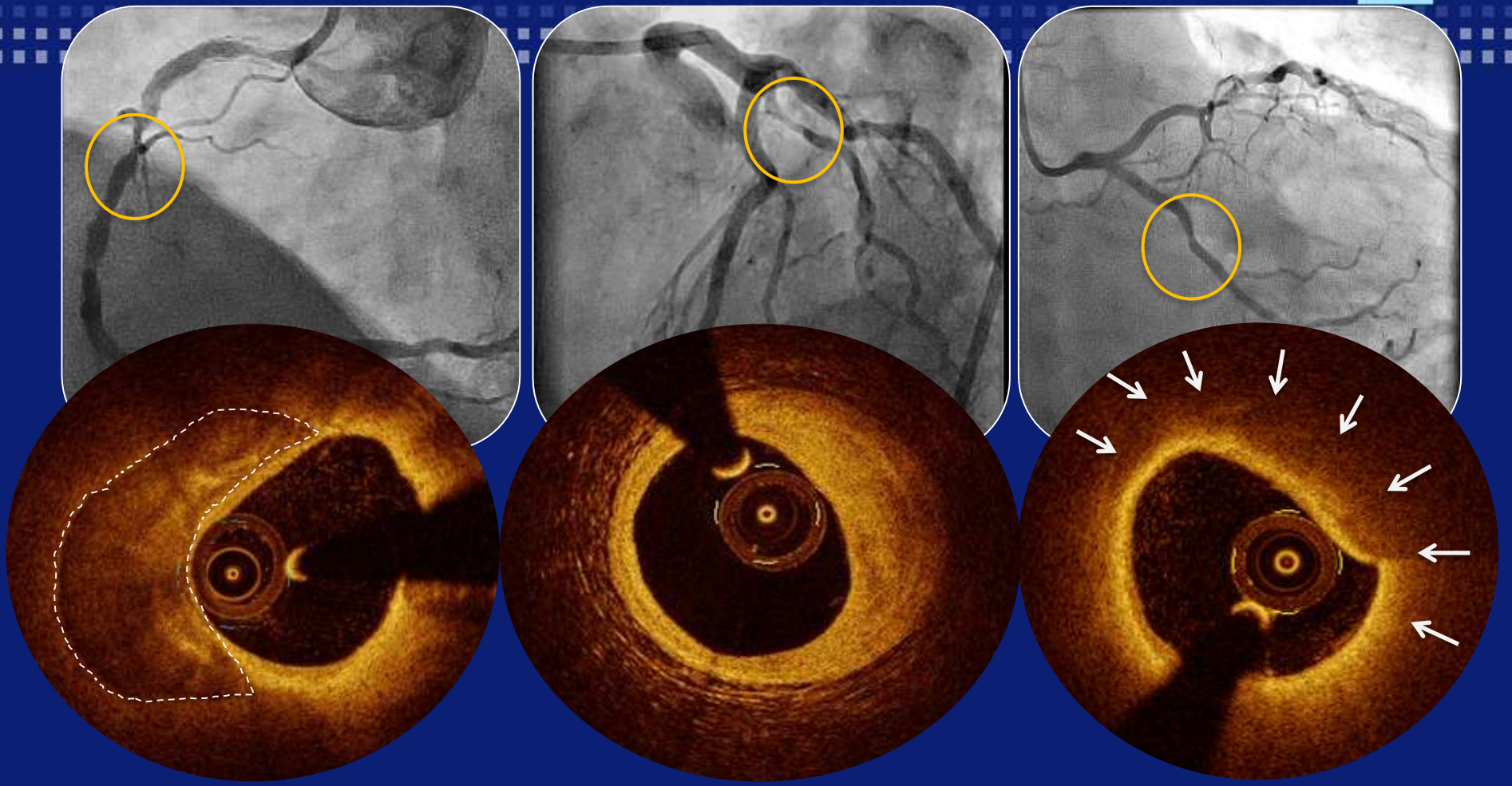


56 yo man, inferior STEMI, no CV history

OCT to Guide BVS Implantation: Advantages Lesion- and Plaque Characteristics

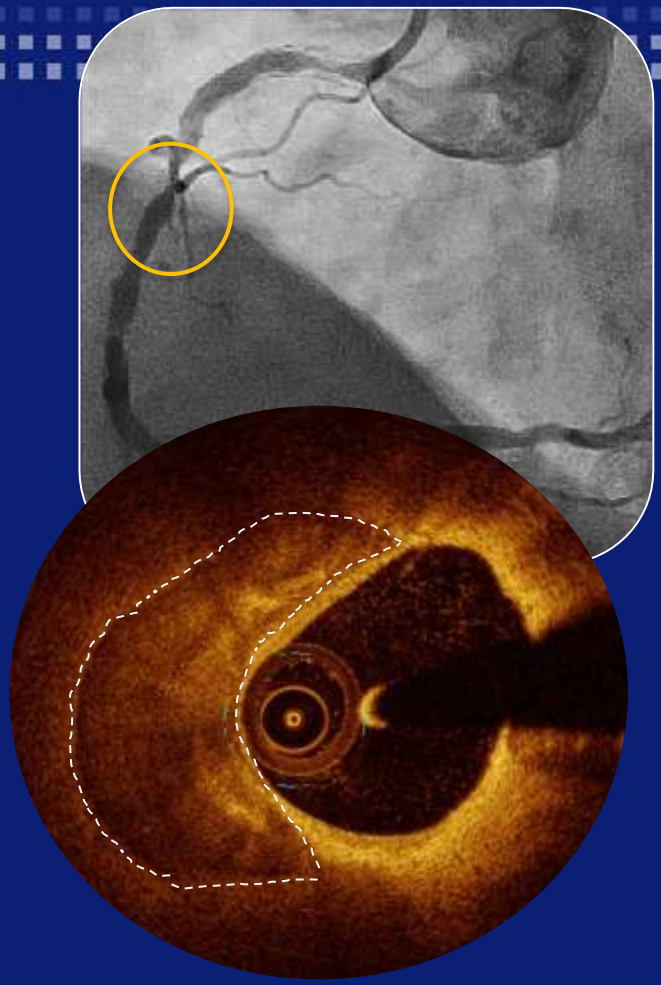


Calcific

Fibrous

Lipid-rich Fibroatheroma

OCT to Guide BVS Implantation: Advantages Lesion- and Plaque Characteristics



Calcific

Role of OCT

Location: ***superficial*** *vs deep ?*
Extent: ***circumference*** *(≥270)?*
Location of MLA
Lesion length

Impact on lesion preparation

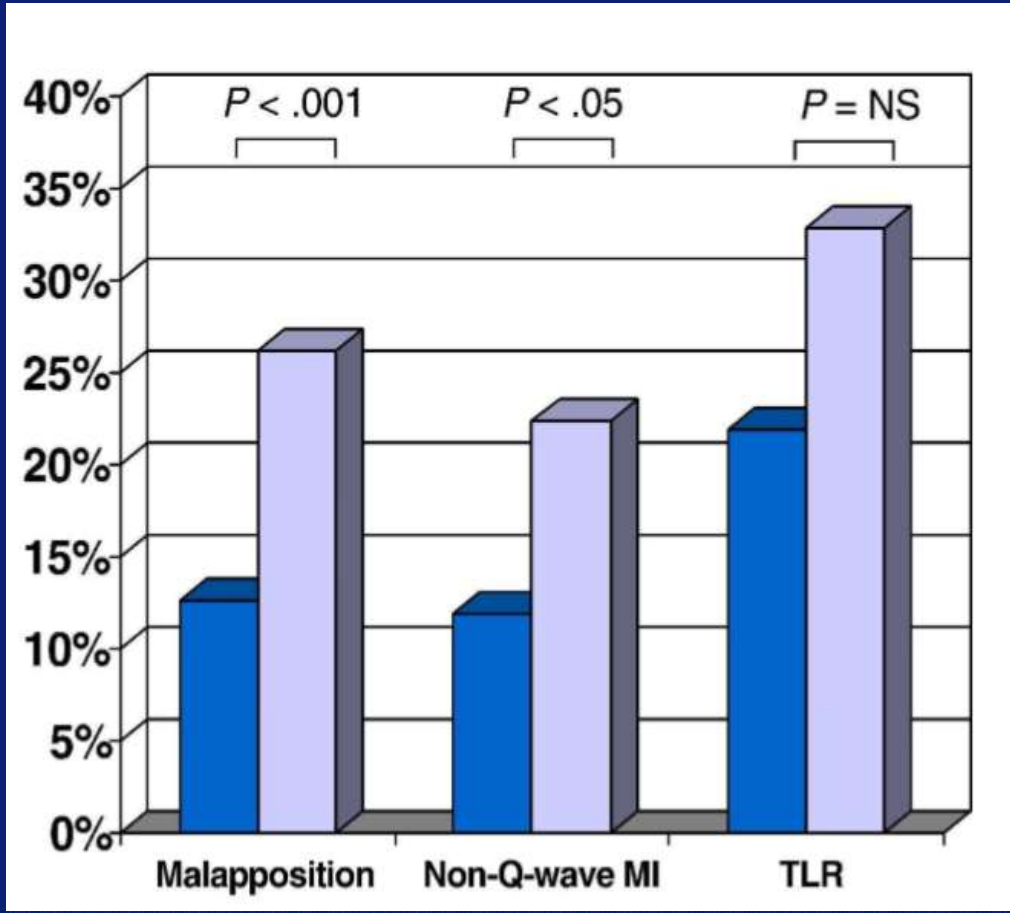
Rotational/orbital atherectomy
Scoring balloon?
Cutting balloon?
Adequate stent length
Adequate stent diameter

OCT to Guide BVS Implantation: Advantages Lesion- and Plaque Characteristics

Calcific lesions cause malapposition,MI & worse outcome

- *Calcium >271° circumference*
- *Calcium ≤270° circumference*

Registry
N= 540 pts
Retroscective IVUS analysis
Bare metal stents

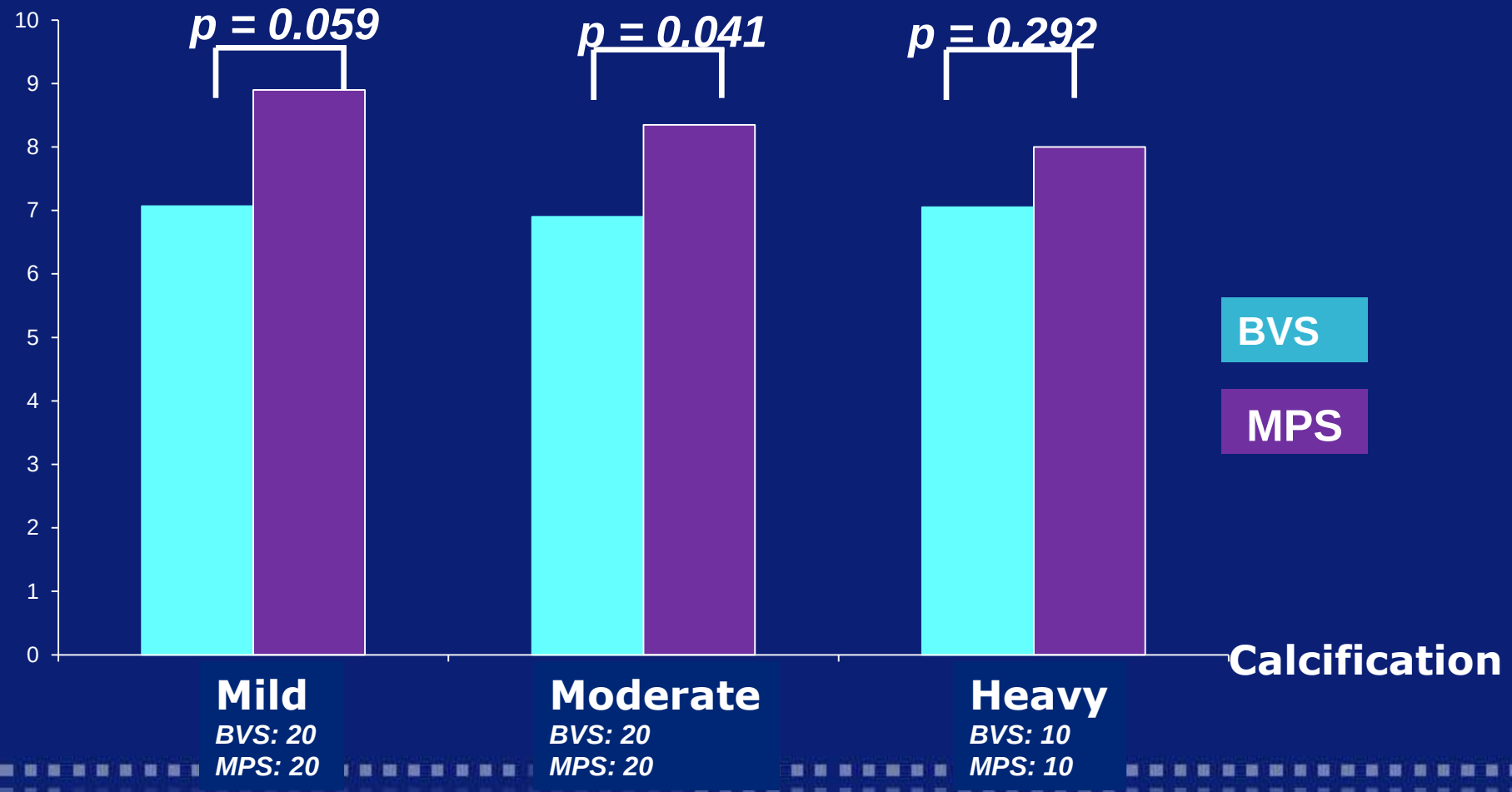


Mosseri et al. Cardiovasc Revasc Med 2005 147-153.

BVS – Thoraxcenter Experience

Does Lesion Calcification Affect Expansion?

Mean Scaffold Area (mm2)

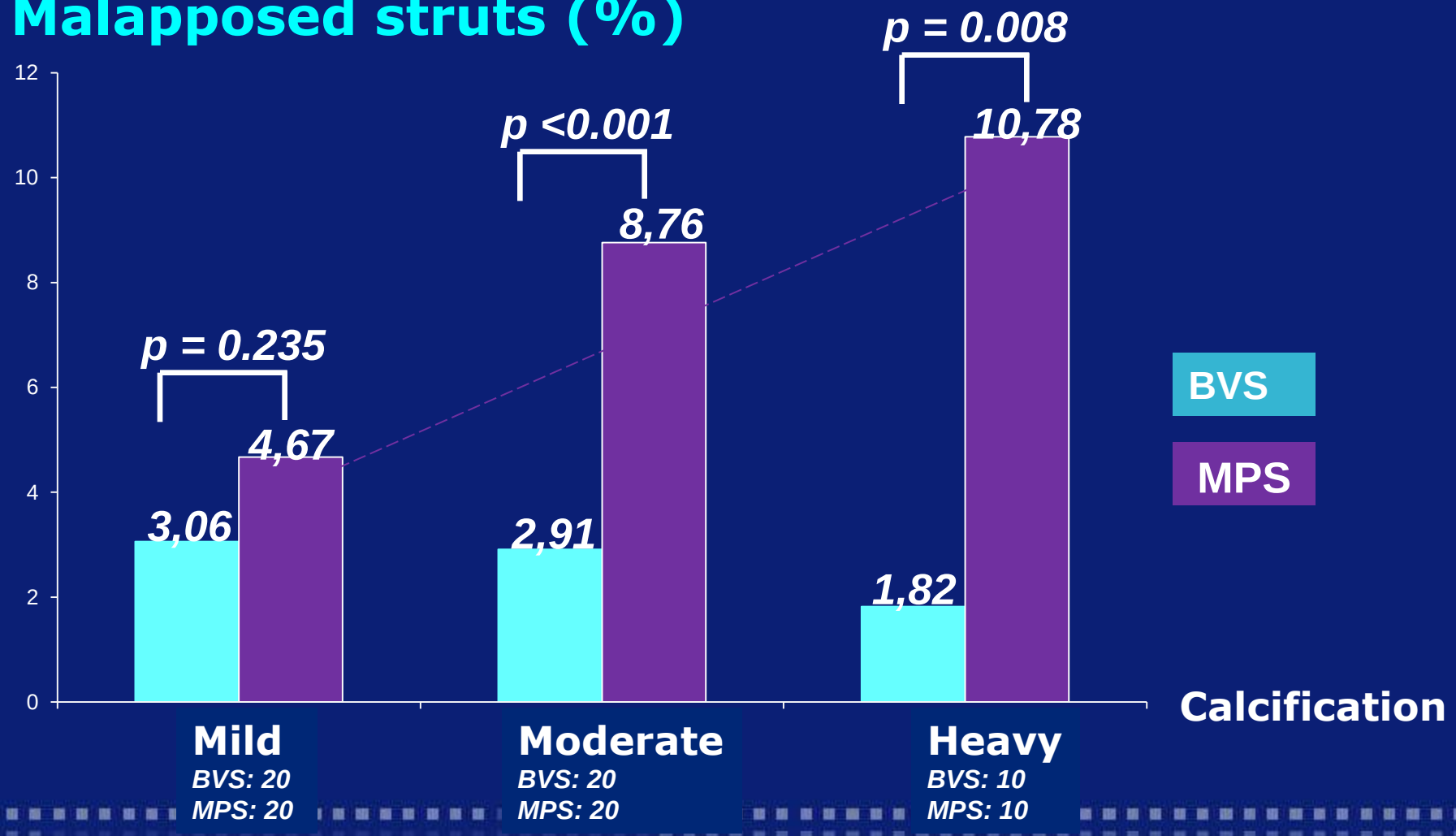


Fam JM, van Geuns RJ et al, presented 2015 Singapore

BVS – Thoraxcenter Experience

Does Lesion Calcification Affect Strut Apposition?

Malapposed struts (%)



Fam JM, van Geuns RJ et al, presented 2015 Singapore

BVS – Thoraxcenter Experience

Does Lesion Calcification Affect Expansion?

When adequate* lesion preparation *has been performed

the degree of lesion calcification

- ***did not limit the expansion of BVS scaffolds***
  - ***as measured by scaffold area &***
  - ***incidence of strut malapposition.***

- ***only moderately affected the symmetry indices.***

in our small cohort

Fam JM, van Geuns RJ et al, presented 2015 Singapore

BVS

Clinical Utility of Intracoronary Imaging:

Insights in Failure/ Thrombosis

OCT to Guide BVS
What Happens in The Real World?

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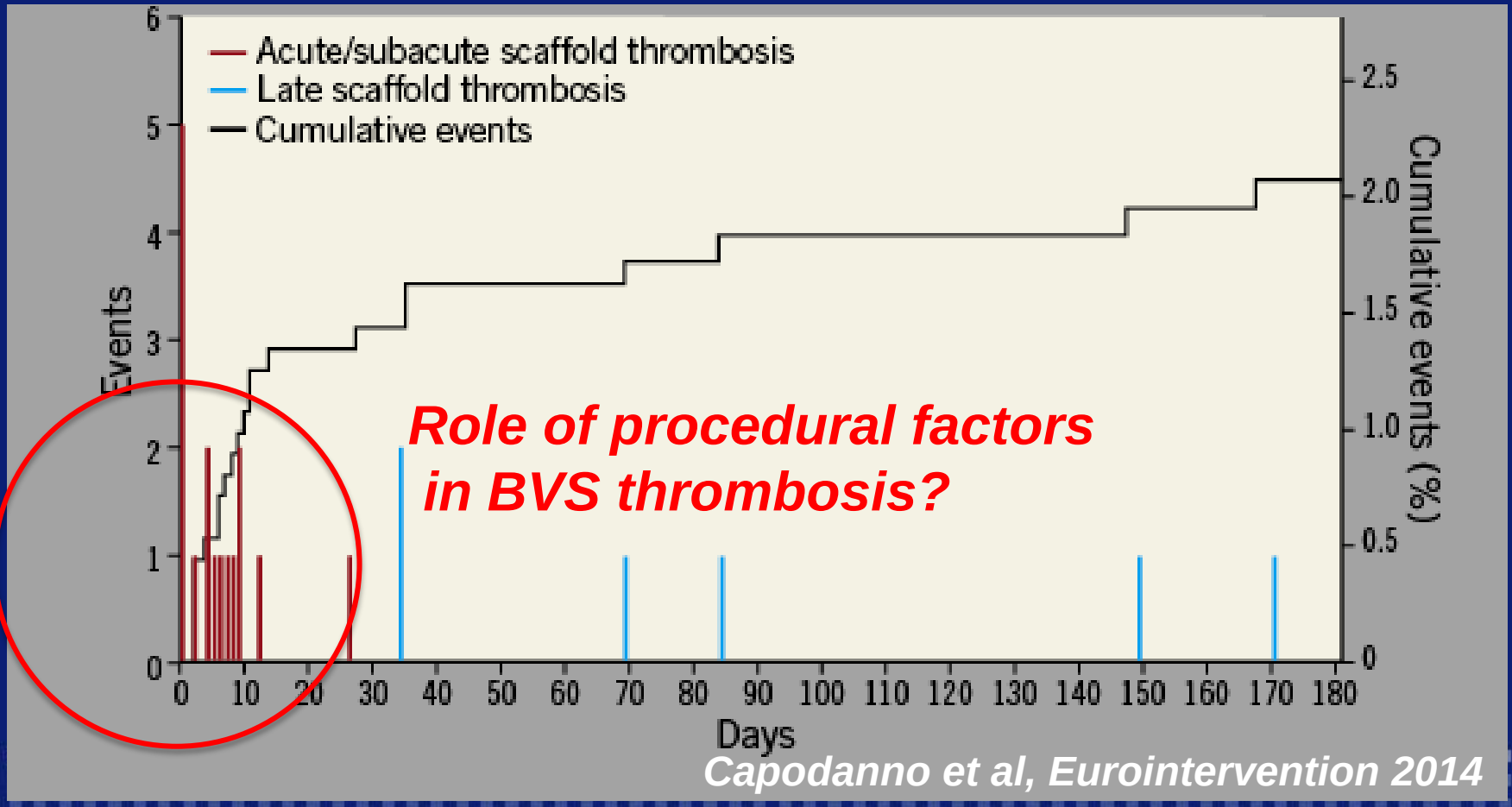
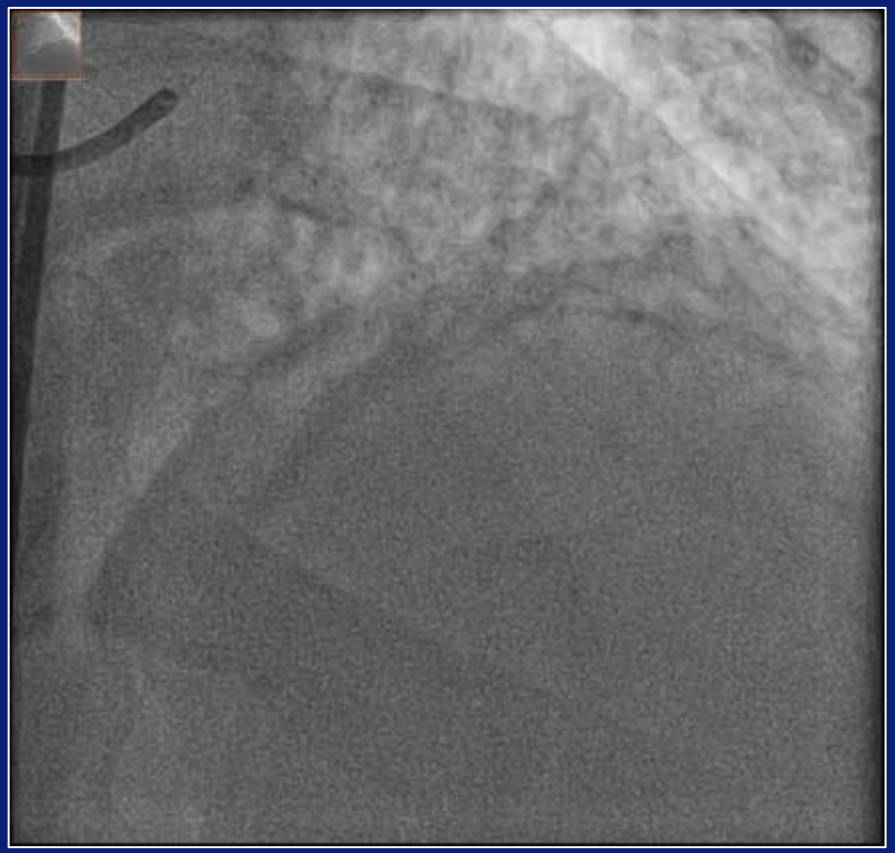
BVS perform less well in real world lesions?



Capodanno et al, Eurointervention 2014

OCT to Guide BVS
What Happens in The Real World?
BVS-Thrombosis at Day 2: STEMI

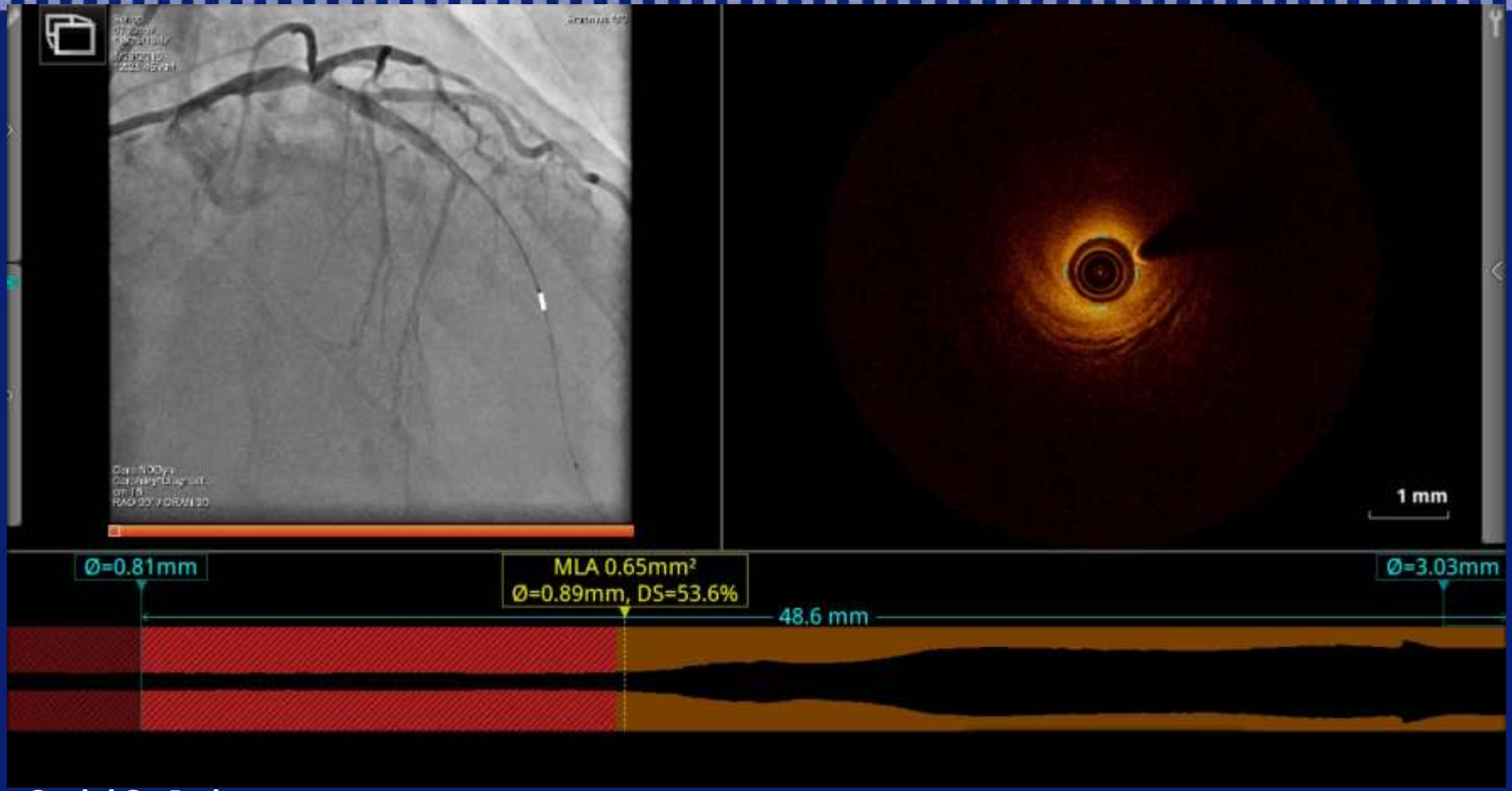
LAD: Event



STEMI 2d
after PCI LAD
(BVS 3.5x18mm)

Zhang BC et al.
JACC Cardiovasc Interv . In press

OCT to Guide BVS
What Happens in The Real World?
BVS-Thrombosis at Day 2: STEMI



Optisi St.Jude

Zhang BC et al.
JACC Cardiovasc Interv . In press

STEMI 2d after PCI LAD (BVS 3.5x18mm)

OCT to Guide BVS
What Happens in The Real World?
BVS-Thrombosis at Day 2: STEMI

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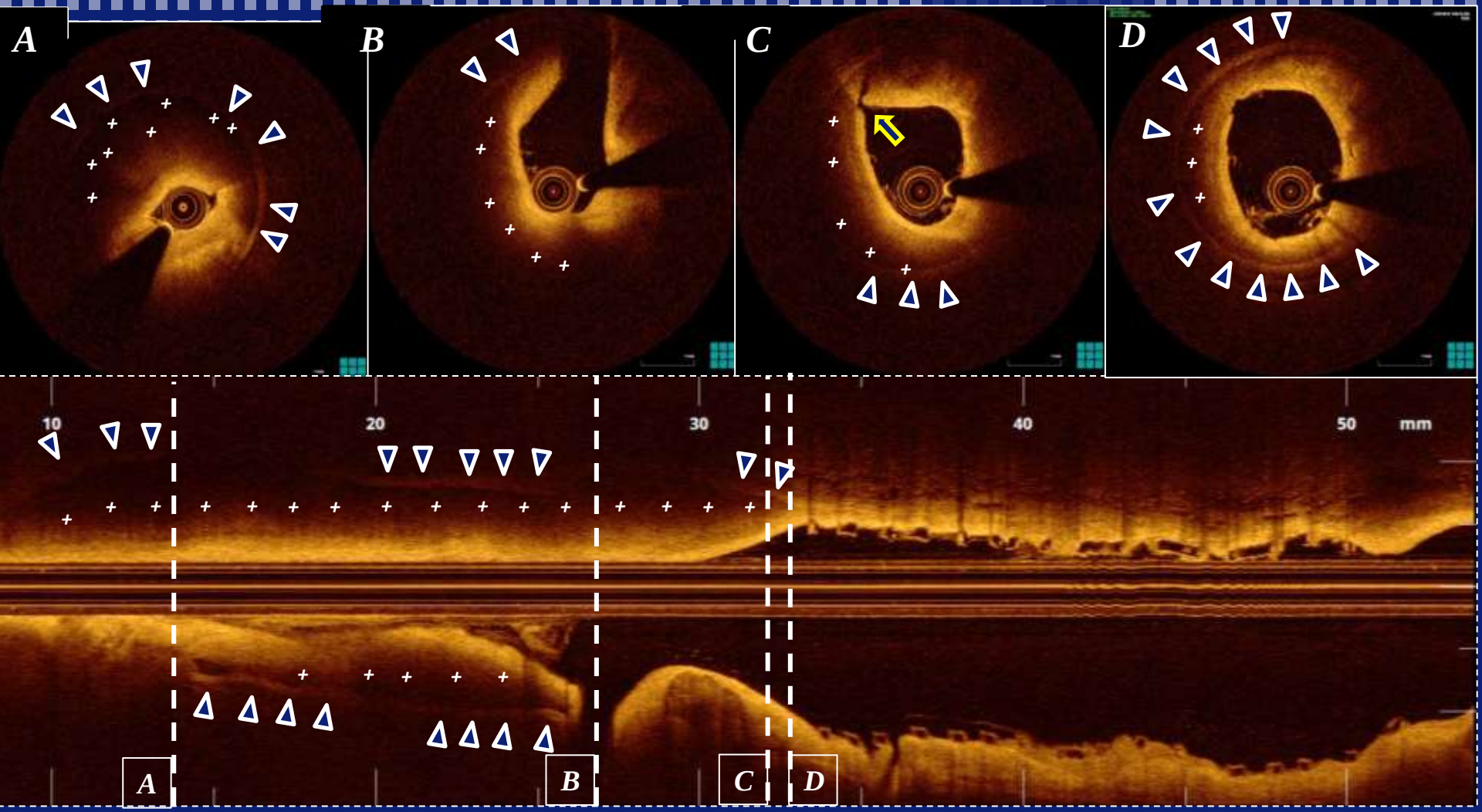

Zhang BC et al.
JACC Cardiovasc Interv . In press

STEMI 2d after PCI LAD (BVS 3.5x18mm)

OCT to Guide BVS
What Happens in The Real World?
BVS-Thrombosis at Day 2: STEMI

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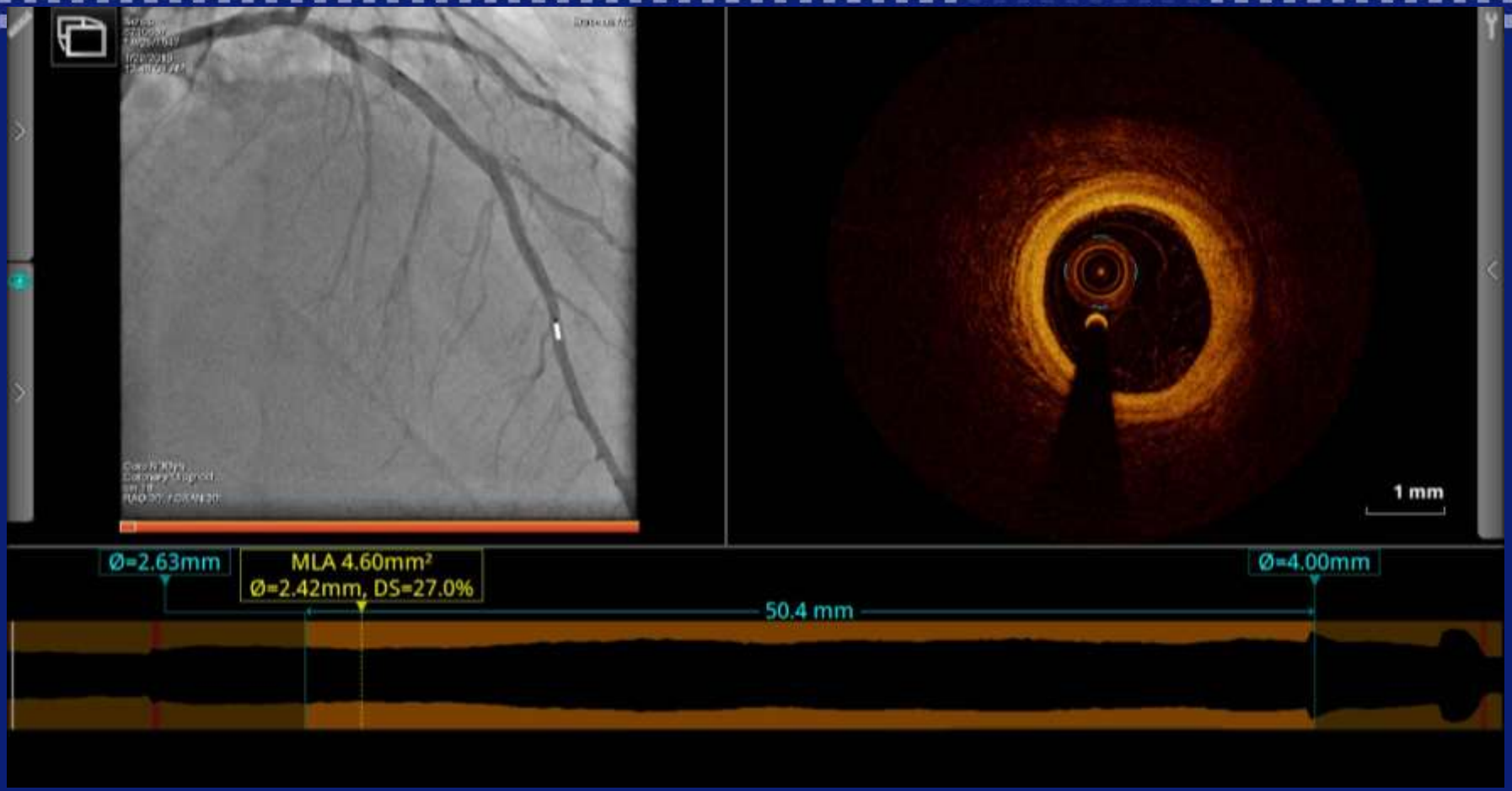

After implantation of distal overlapping BVS 3.5x23mm & 2.5x12mm

Zhang BC et al.
JACC Cardiovasc Interv . In press

STEMI 2d after PCI LAD (BVS 3.5x18mm)

OCT to Guide BVS
What Happens in The Real World?
BVS-Thrombosis: Thoraxcenter Experience

Erasmus MC

Case	Type/timing	Baseline OCT findings	OCT findings at event	Dual antiplatelet therapy
1	Acute/same day		Thrombus at proximal stent edge, deriving from an adjacent fibroatheroma **Incomplete lesion coverage**	Yes
2	Subacute/2 days		Thrombus overlying extensive overlap region (7.6mm) **Extensive overlap**	Yes
3	Late/40 days	Undersizing/residual thrombus/plaque prolapse	Incomplete scaffold apposition with thrombus **Incomplete expansion**	Yes
4	Late/4 months		Occlusive edge restenosis **Incomplete lesion coverage**	Yes
5	Late/4 months		Uncovered struts at the carina of a bifurcation treated with T-stenting **Incomplete lesion coverage**	No
6	Late/4 months	Scaffold fracture	Thrombus overlying overlap region with underexpansion/ scaffold fracture **Mechanical damage**	No
7	Late/7 months		Incomplete scaffold apposition/occlusive restenosis **Incomplete expansion**	Yes
8	Very late/2 years	Optimal scaffold expansion	Late scaffold discontinuity/incomplete scaffold apposition **Mechanical damage**	No

Karanasos A et al. JACC Cardiovasc interv. In press

Clinical Utility of Intracoronary Imaging: BVS Summary

IVUS, VH & OCT: Intracoronary imaging is superior to angio!

Intracoronary imaging is most efficient when used *before* scaffold placement

Lesion preparation & BVS selection

- ✓ **Correct assessment of plaque composition**
- ✓ **Correct assessment of lumen dimensions**
- ✓ **Correct assessment of lesion length**

Assuring optimal prognosis

In our limited experience, most BVS thromboses seem avoidable !

Thank you for your attention!

PhD Students

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