BRS
BioResorbable Scaffold

Revolution in PCI

ADVANCEMENTS IN THE TREATMENT OF HEART DISEASE

1977 BALLOON ANGIOPLASTY

1988 BARE METAL STENT

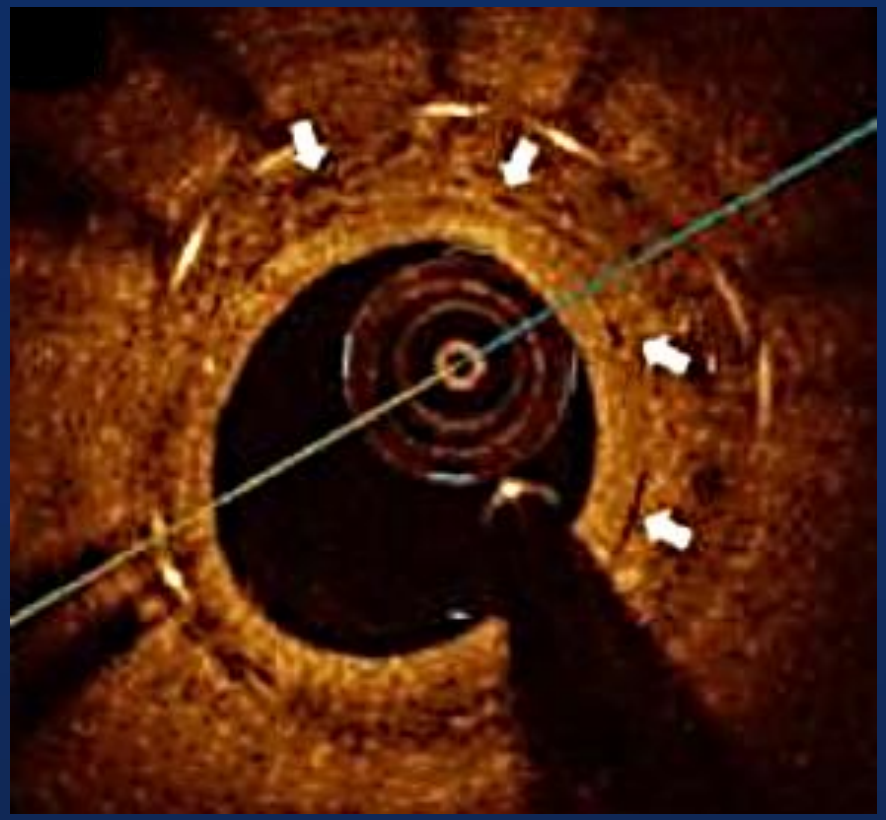
2001 DRUG ELUTING STENT

TODAY

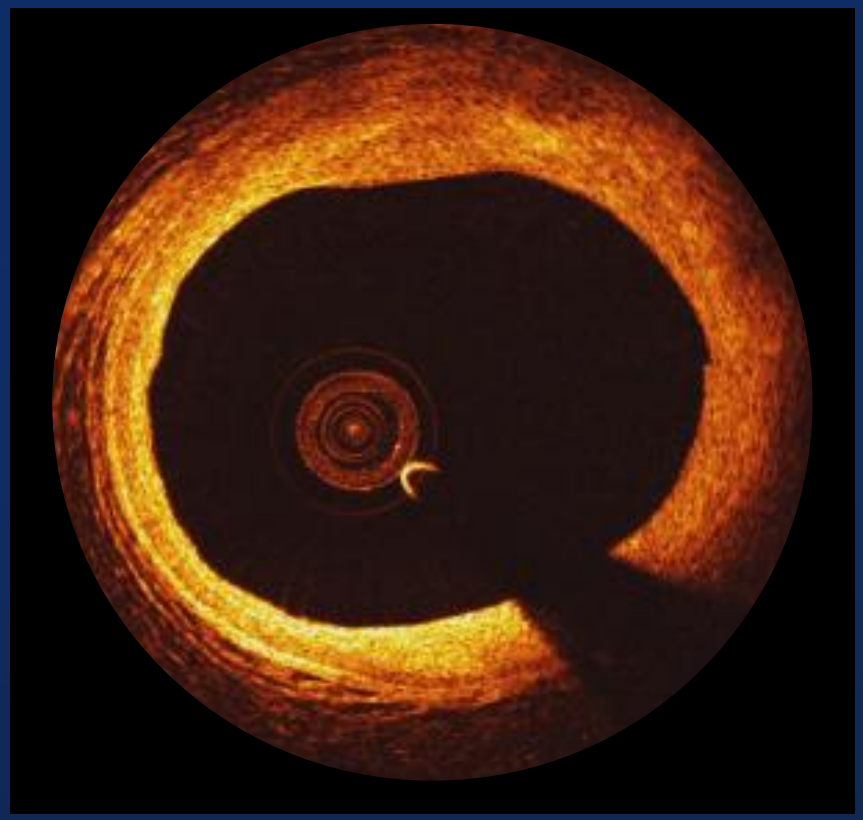
DISSOLVING STENT
– ABBOTT'S ABSORB™

Disappear !

Human Imaging at 5 Year



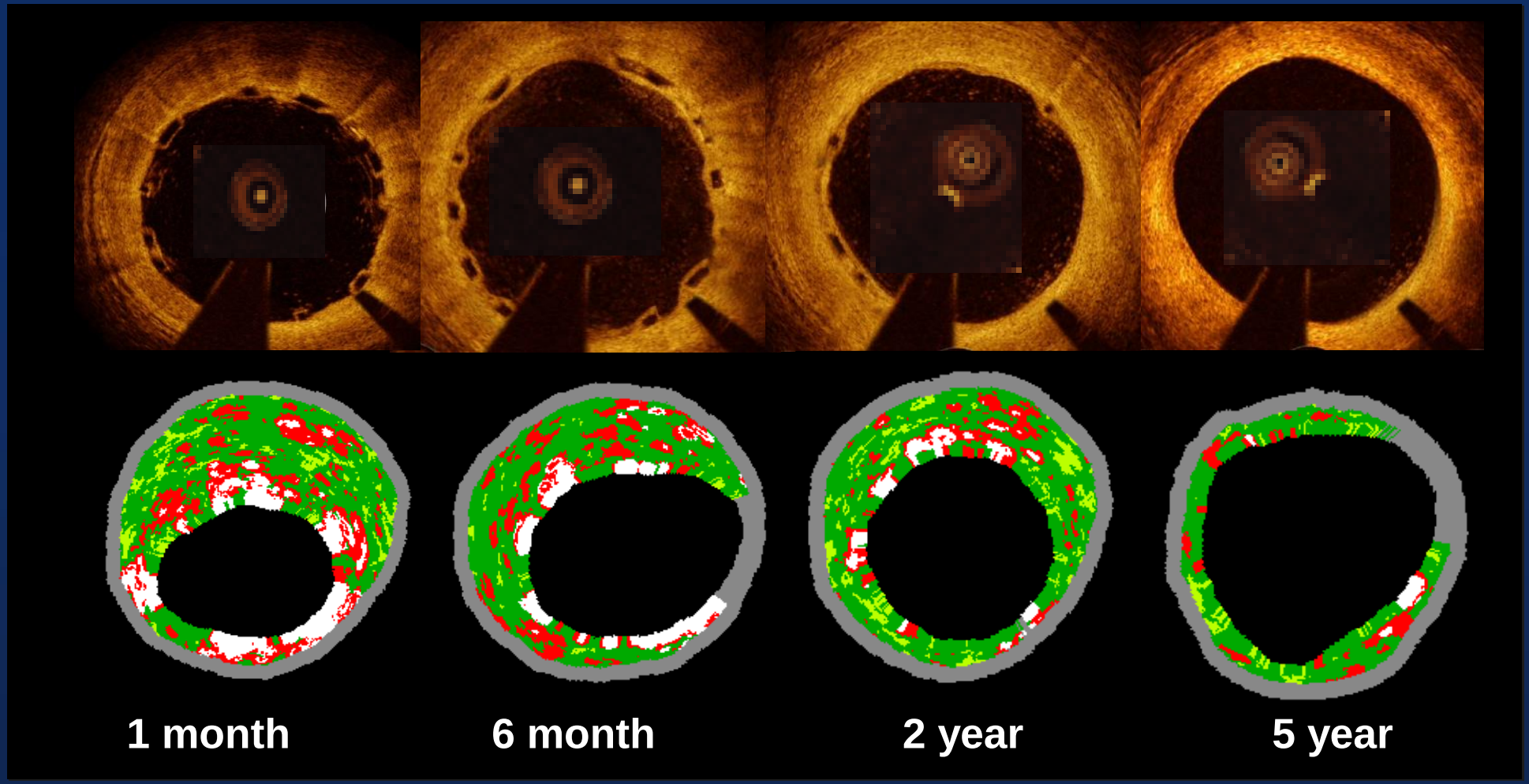
Metallic DES



BVS

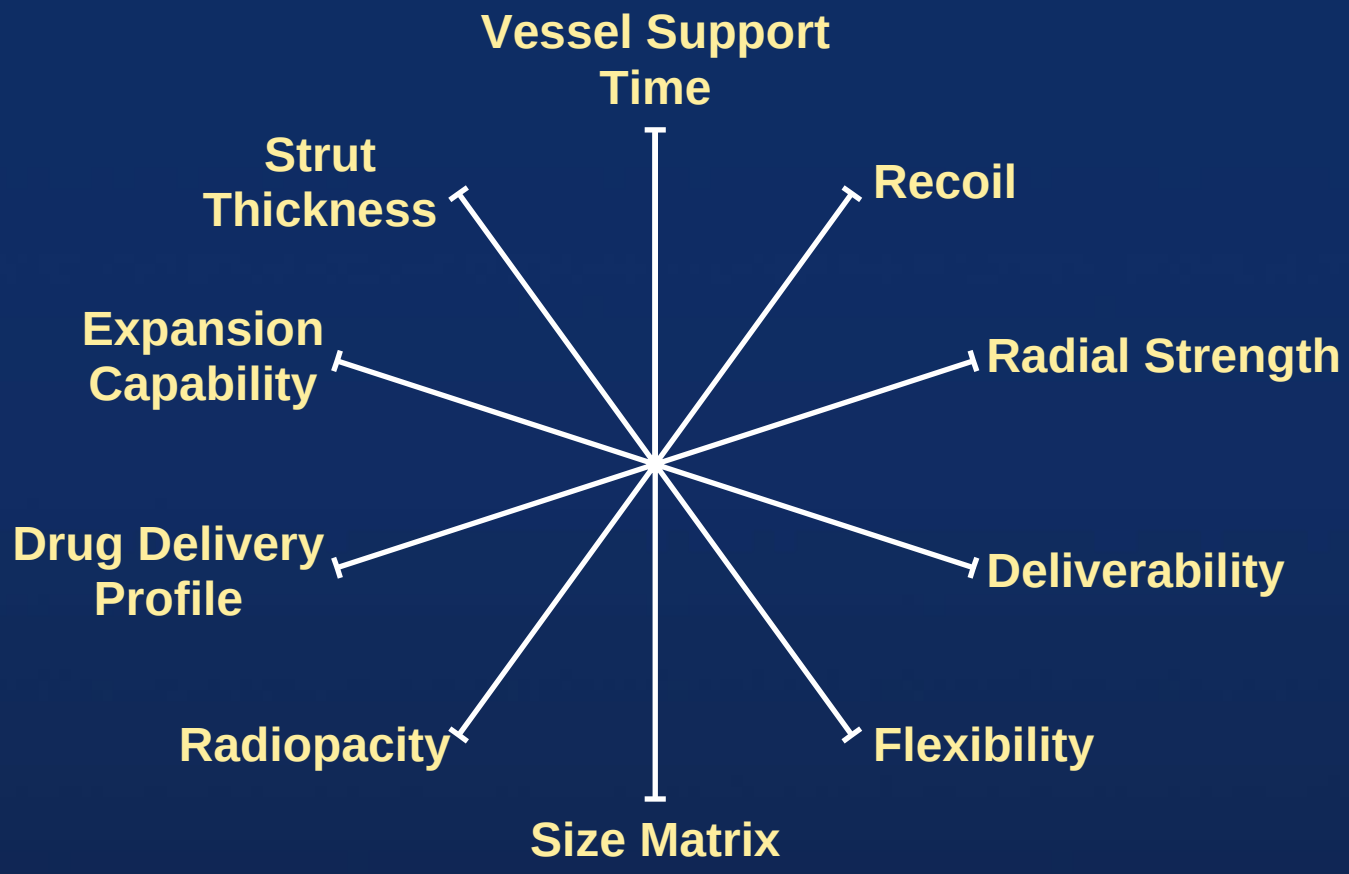
Atherosclerosis 2014;237:23e29

Plaque Stabilization and Lumen Enlargement



c/o Patrick Serruys

BRS Design Considerations

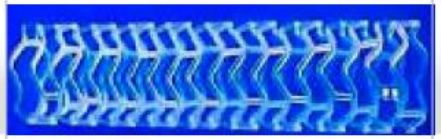


Design and Structure of Clinically Tested BRS

Scaffold (manufacturer)	Strut material	Coating material	Eluted drug	Radial support	Resorptio (months)
Metallic					
AMS-1 (Biotronik)	Mg alloy	None	None	Weeks	<4
DREAMS-1 (Biotronik)	Mg alloy with some rare metals	PLGA	Paclitaxel	3–6 months	9
DREAMS-2 (Biotronik)	Mg alloy with some rare metals	PLLA	Sirolimus	3–6 months	9
Polymeric					
Igaki-Tamai (Kyoto Medical)	PLLA	None	None	6 months	24–36
BVS 1.0 (Abbott Vascular)	PLLA	PDLLA	Everolimus	Weeks	18–24
BVS 1.1 (Abbott Vascular)	PLLA	PDLLA	Everolimus	6 months	24–48
DESolve (Elixir)	PLLA	None	Myolimus	N/A	12–24
REVA (Reva Medical)	PTD-PC	None	None	3–6 months	24
ReZolve (Reva Medical)	PTD-PC	None	Sirolimus	4–6 months	4–6
ReZolve2 (Reva Medical)		None	Sirolimus		
ART 18AZ (ART)	PDLLA	None	None	3–6 months	3–6
Fortitude (Amaranth)	PLLA	None	None	3–6 months	3–6
IDEAL BTI (Xenogenics)	Polylactide and salicylates	SA/AA	Sirolimus	3 months	6–9

Iqbal J et al. Eur Heart J 2014;35:765

Design of BRSs in Clinical or Preclinical use

Company / Device	Design of the biorsorbable device	Strut thickness, (μ m)	Polymer / Drug	Absorption time	Late loss, (mm)
Kyoto Medical/ Igaki-Tamai		170	PLLA	2 years (y)	0.48 (6m)
Biotronik / DREAMS		125	Mg alloy (AMS-4) / sirolimus	4 to 6 months (m)	0.68 (6m)*
Abbott / ABSORB BVS		150	PLLA / everolimus	2y	0.19 (6m)
Reva Medical / ReSolve		200	Tyrosine poly carbonate with iodine / sirolimus abluminal	2y	1.81 (6m)
-/ BTI		200	Salicylic acid into polymer (PLA or adipic acid) / sirolimus	6m	NA
Elixir / DESolve		150	PLLA / novolimus	1 to 2y	NA

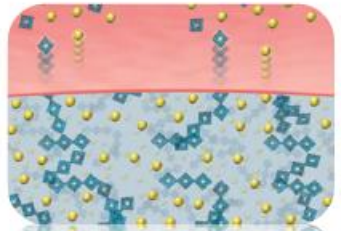
BRS System

Bioresorbable Scaffold

- Poly (L-lactide) (PLLA)
- Based on proven MULTI-LINK pattern
- Naturally resorbed, fully metabolized*

Bioresorbable Coating

- Poly (D,L-lactide) (PDLLA)
- Naturally resorbed, fully metabolized

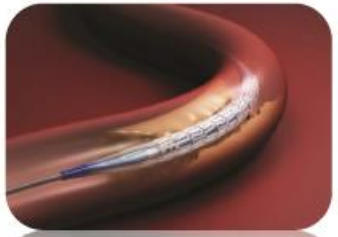


Everolimus

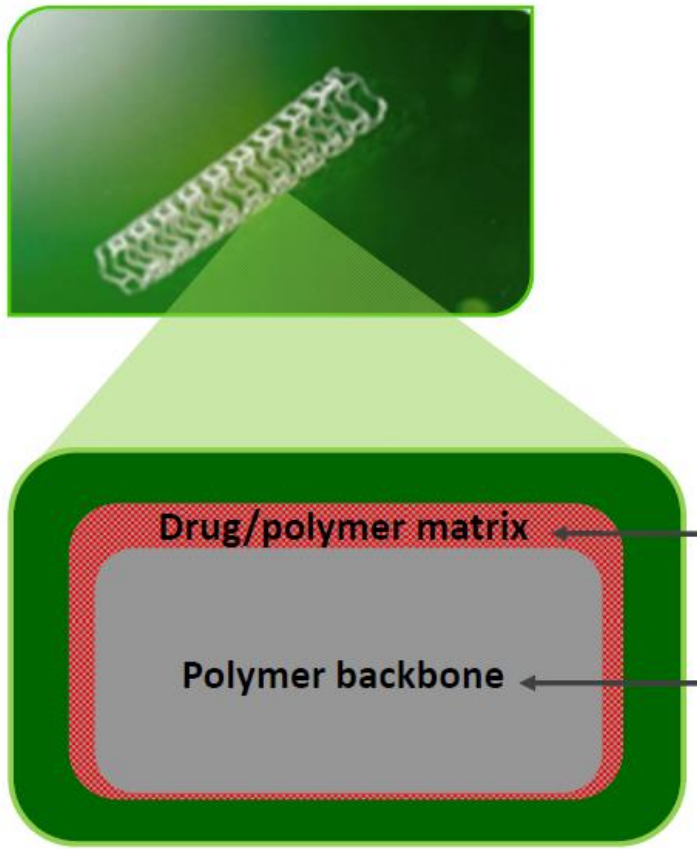
- Similar dose density and release rate to XIENCE V

XIENCE V Delivery System

- World-class deliverability



Bioresorbable Polymer



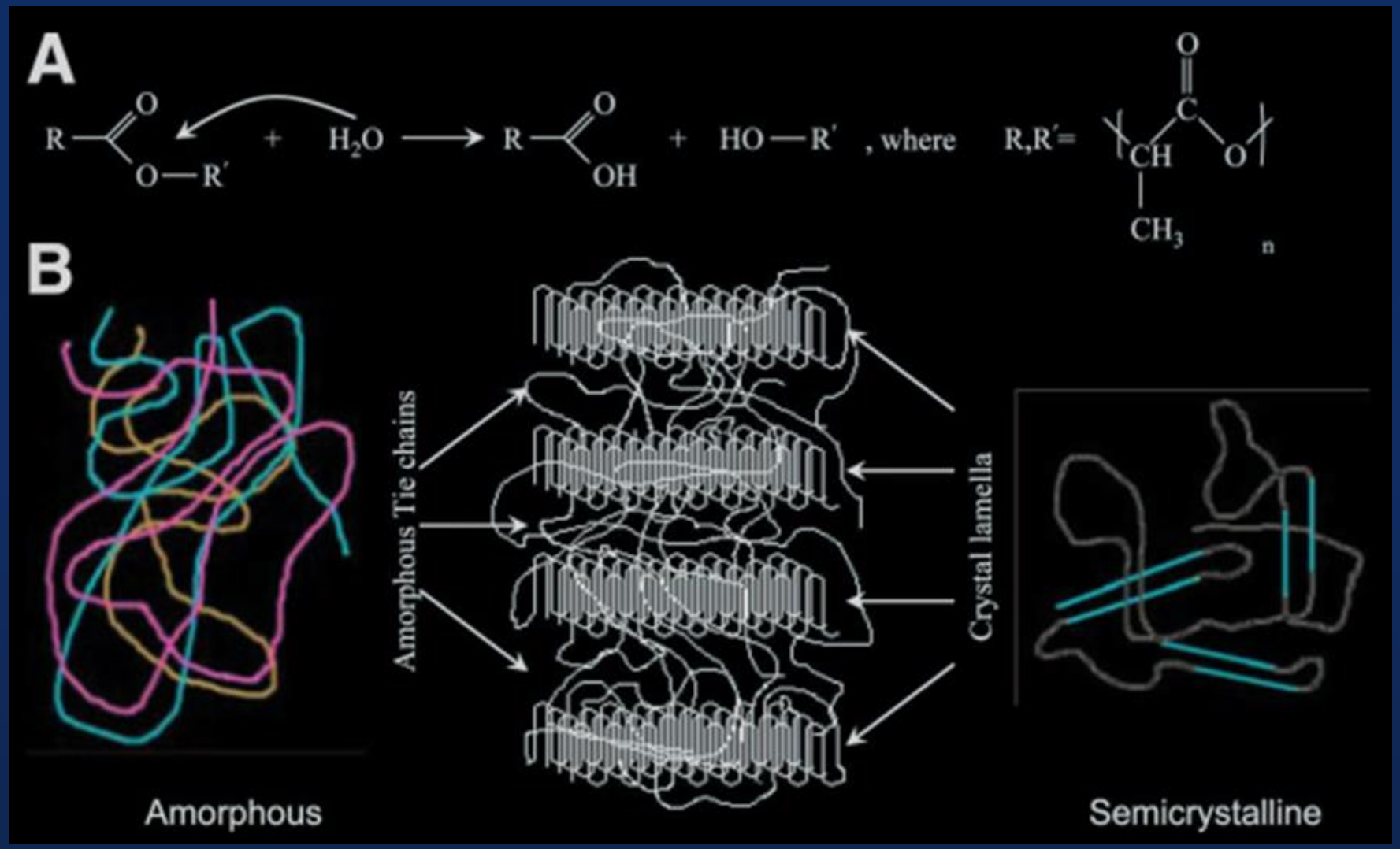
Everolimus/PDLLA Matrix Coating

- Thin layer
- Amorphous (non-crystalline)
- 1:1 ratio of Everolimus/PDLLA matrix
- Conformal coating, 2-4 μm thick
- Controlled drug release

PLLA Scaffold

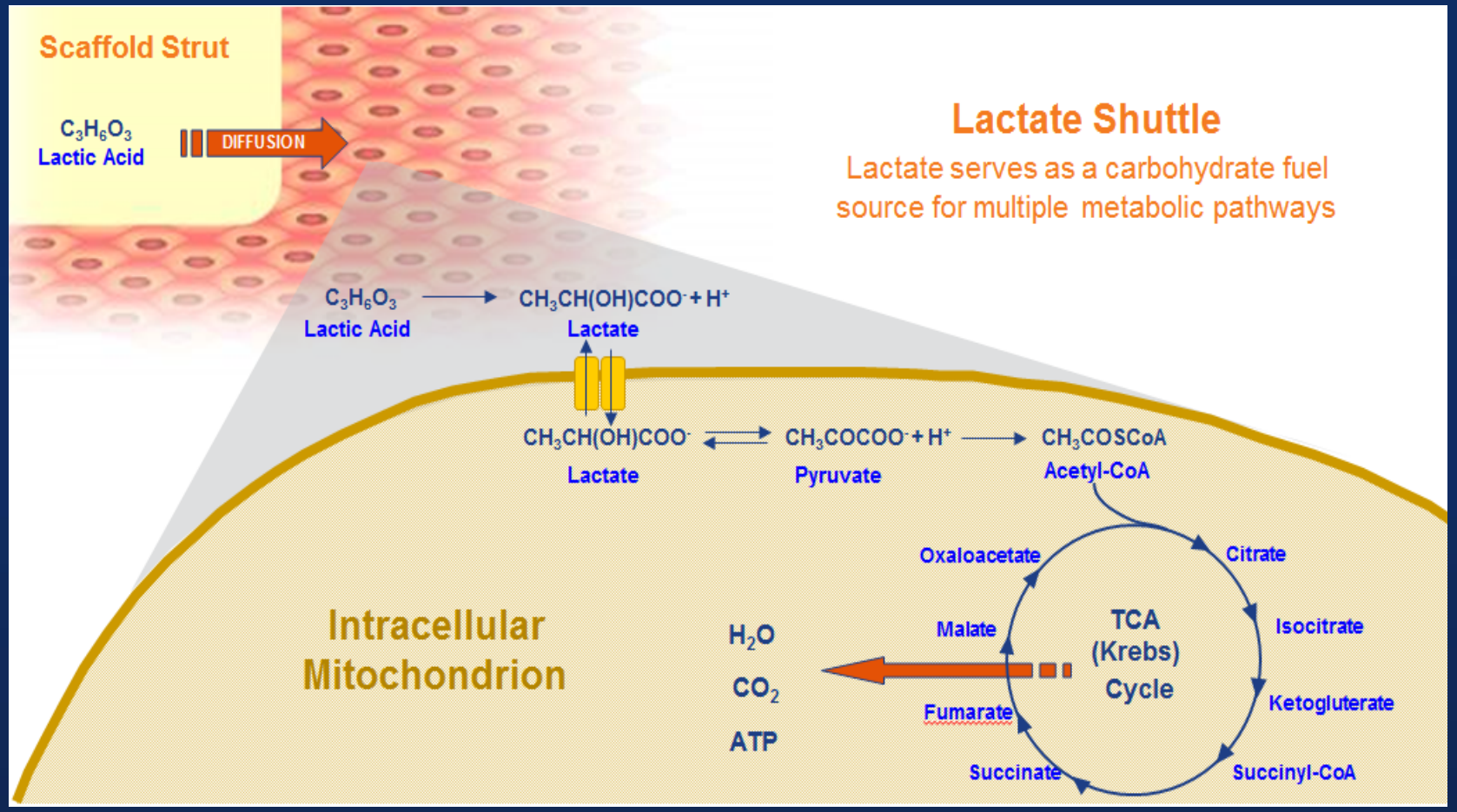
- Semi-crystalline
- Provides device structure
- Processed for required radial strength

Poly-L-Lactic Acid (PLLA)



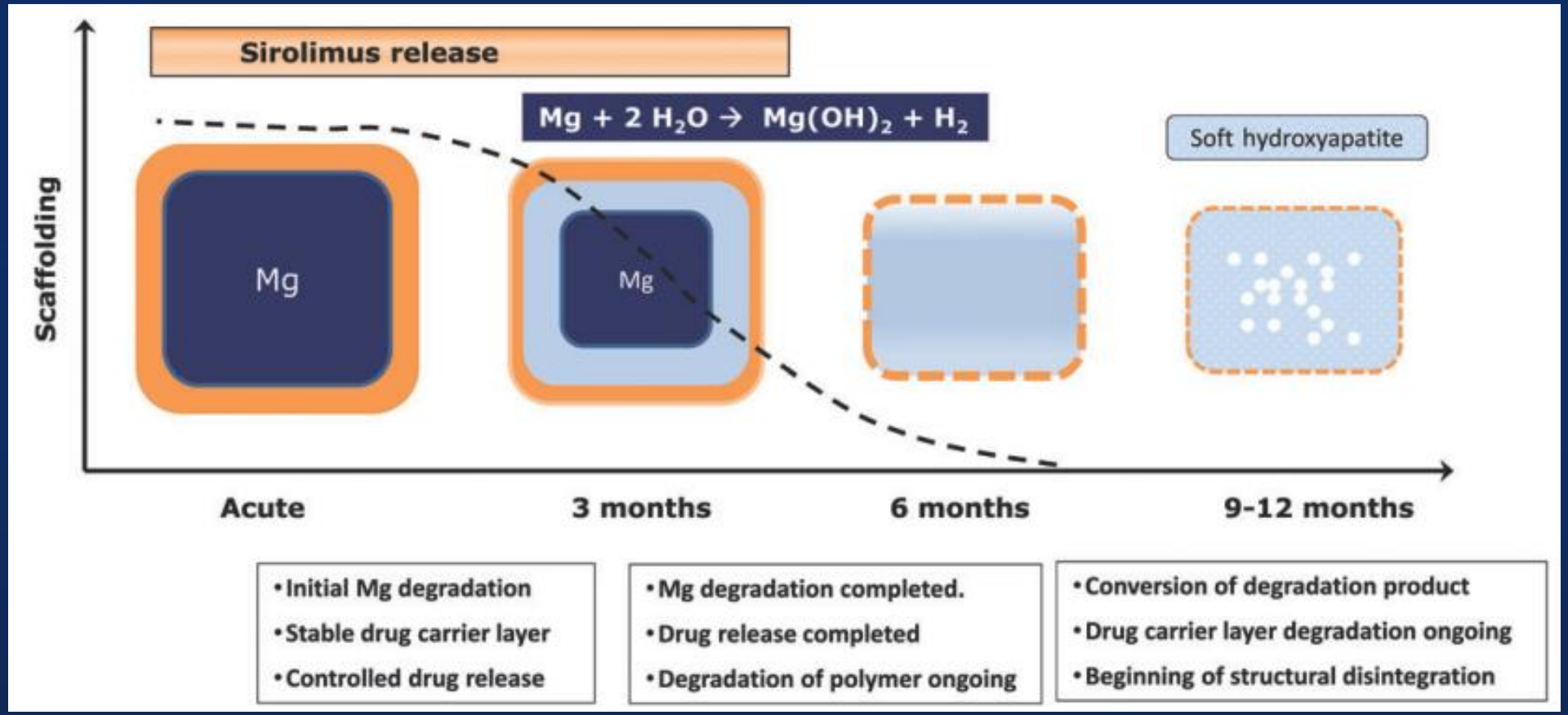
Onuma Y et al. Circulation 2011;123:779

Degradation of PLLA



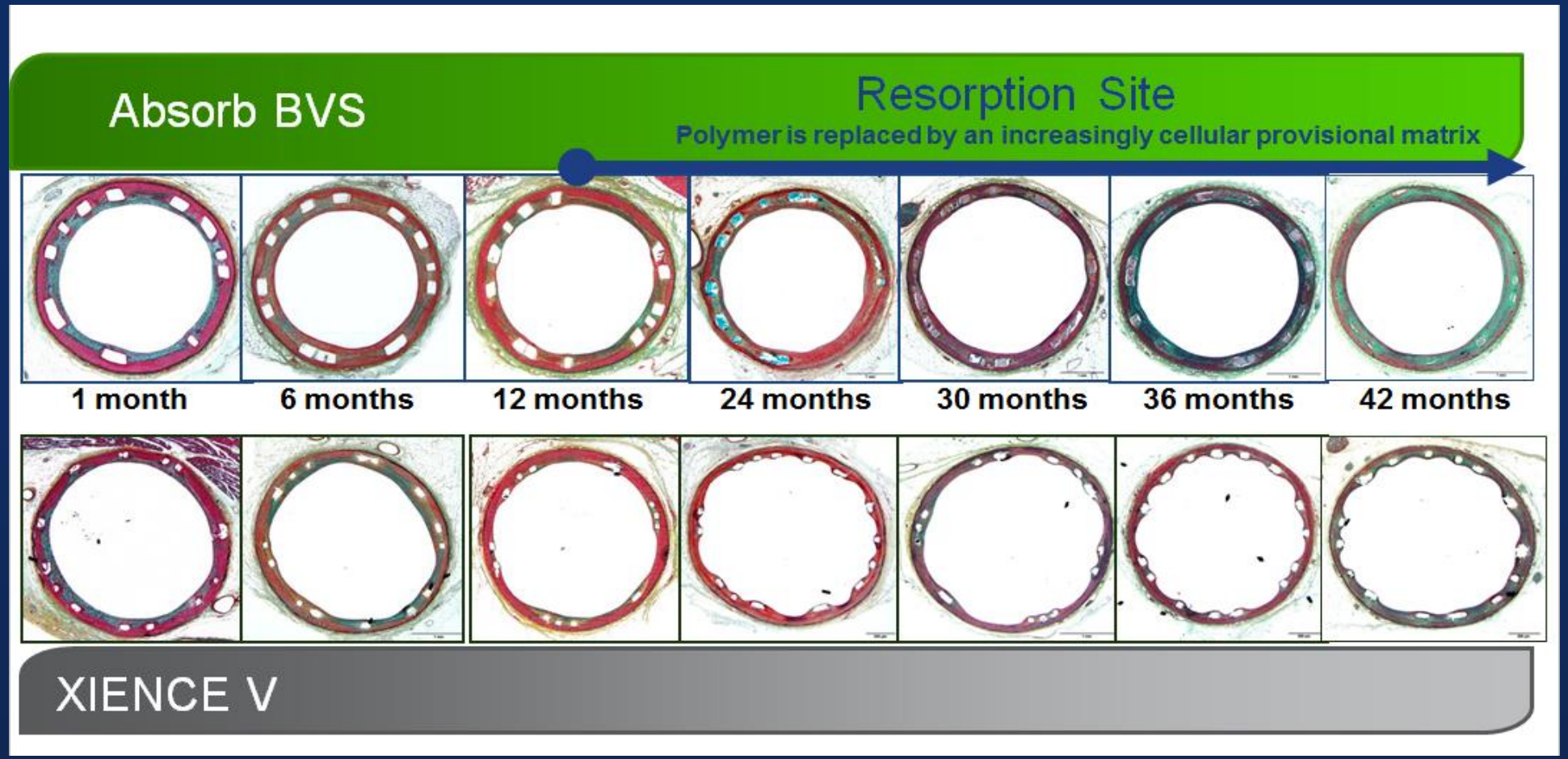
Philp, A., et.al. J. Exp. Biol. 2005; 208: 4561-4575

Bioresorption of Metal scaffold

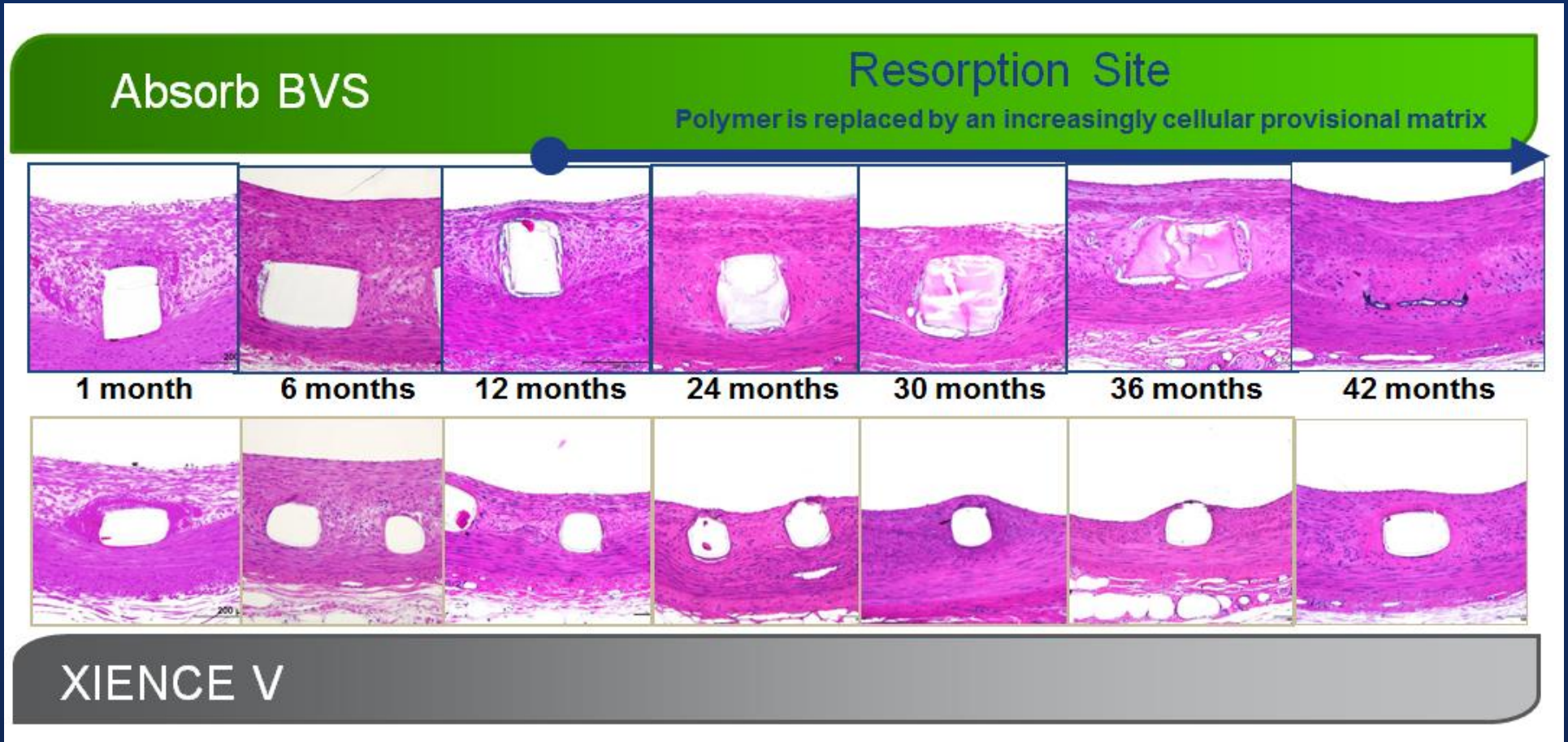


Iqbal J et al. Eur Heart J 2014;35:765

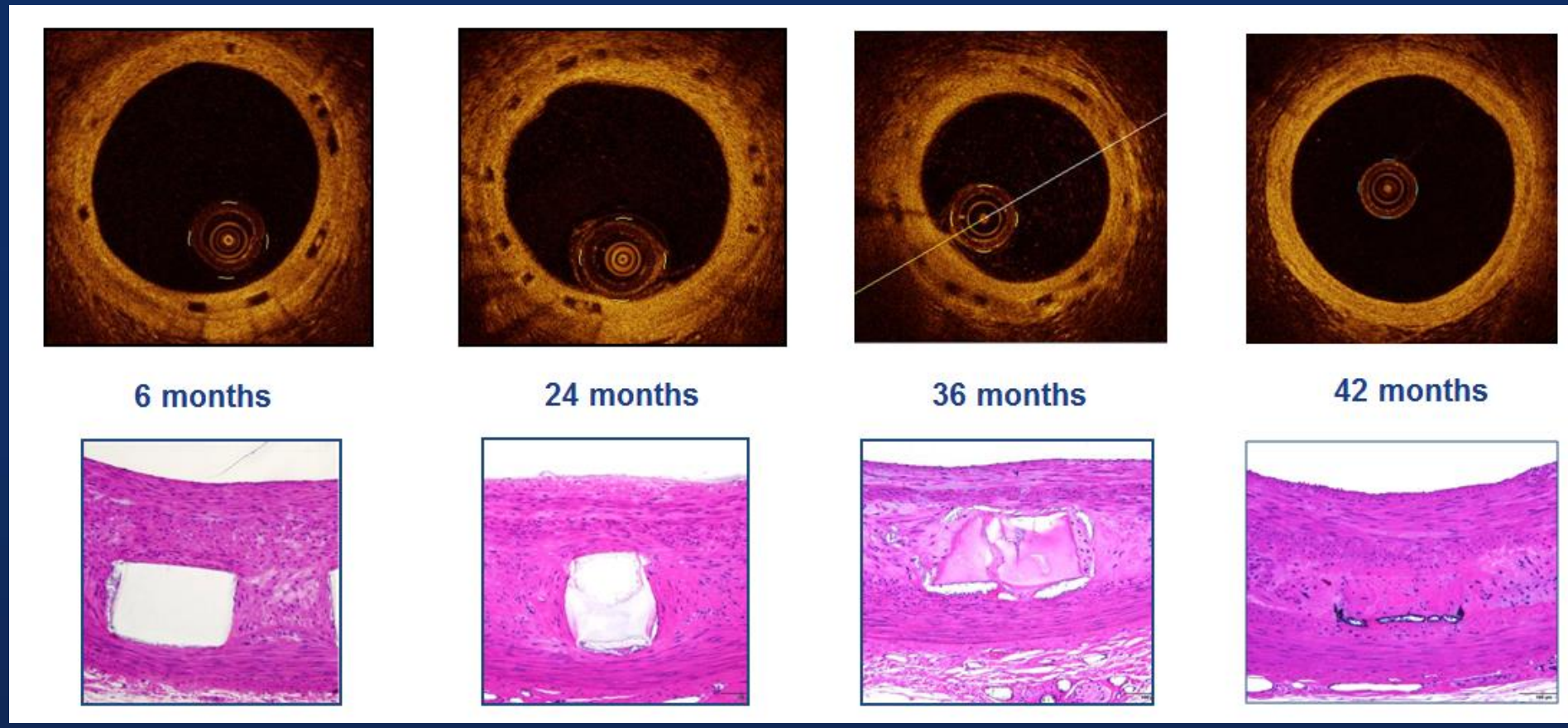
Resorption: Vascular response



Resorption: Vascular response



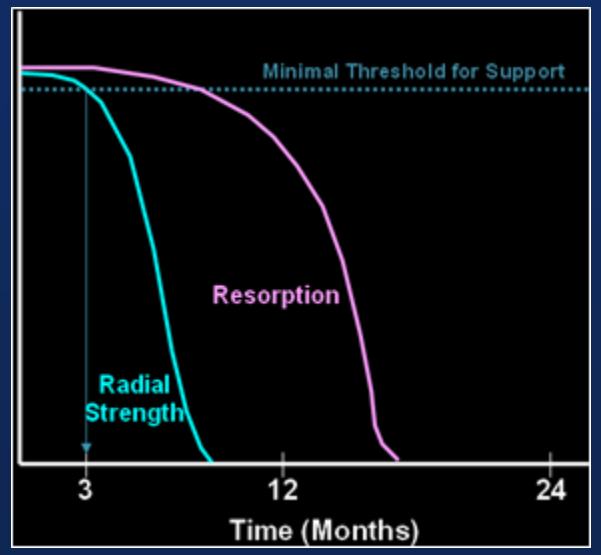
Resorption: Vascular response



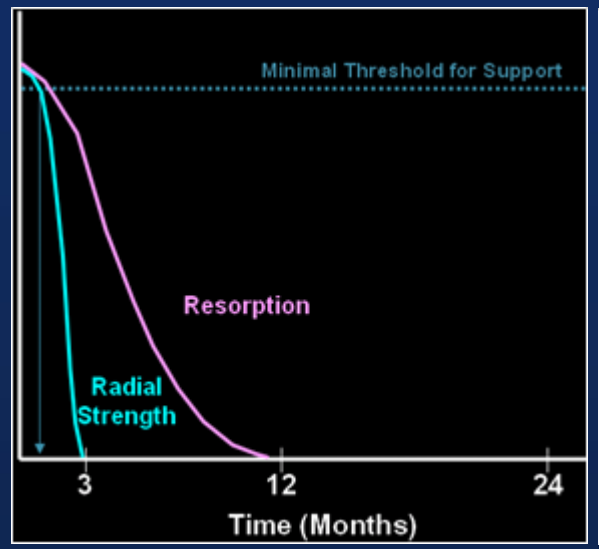
Vessel Healing

The timing of scaffold degradation and resorption are critical for directing the vessel toward optimal healing, functionality and stability

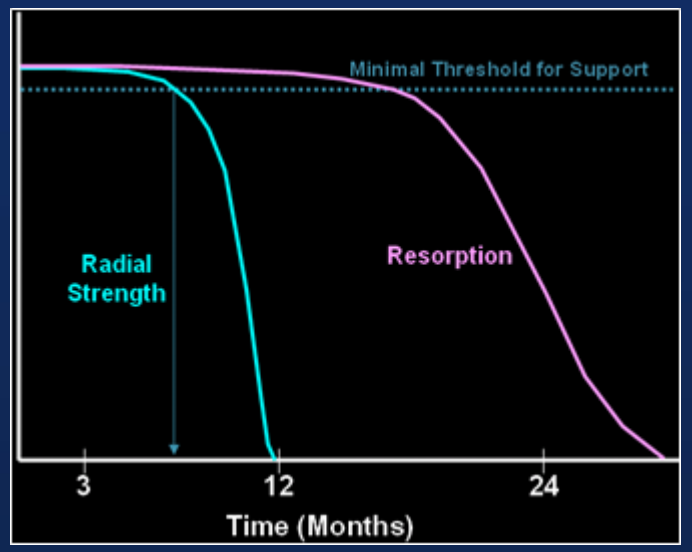
Insufficient vessel support



Resorbs too rapidly

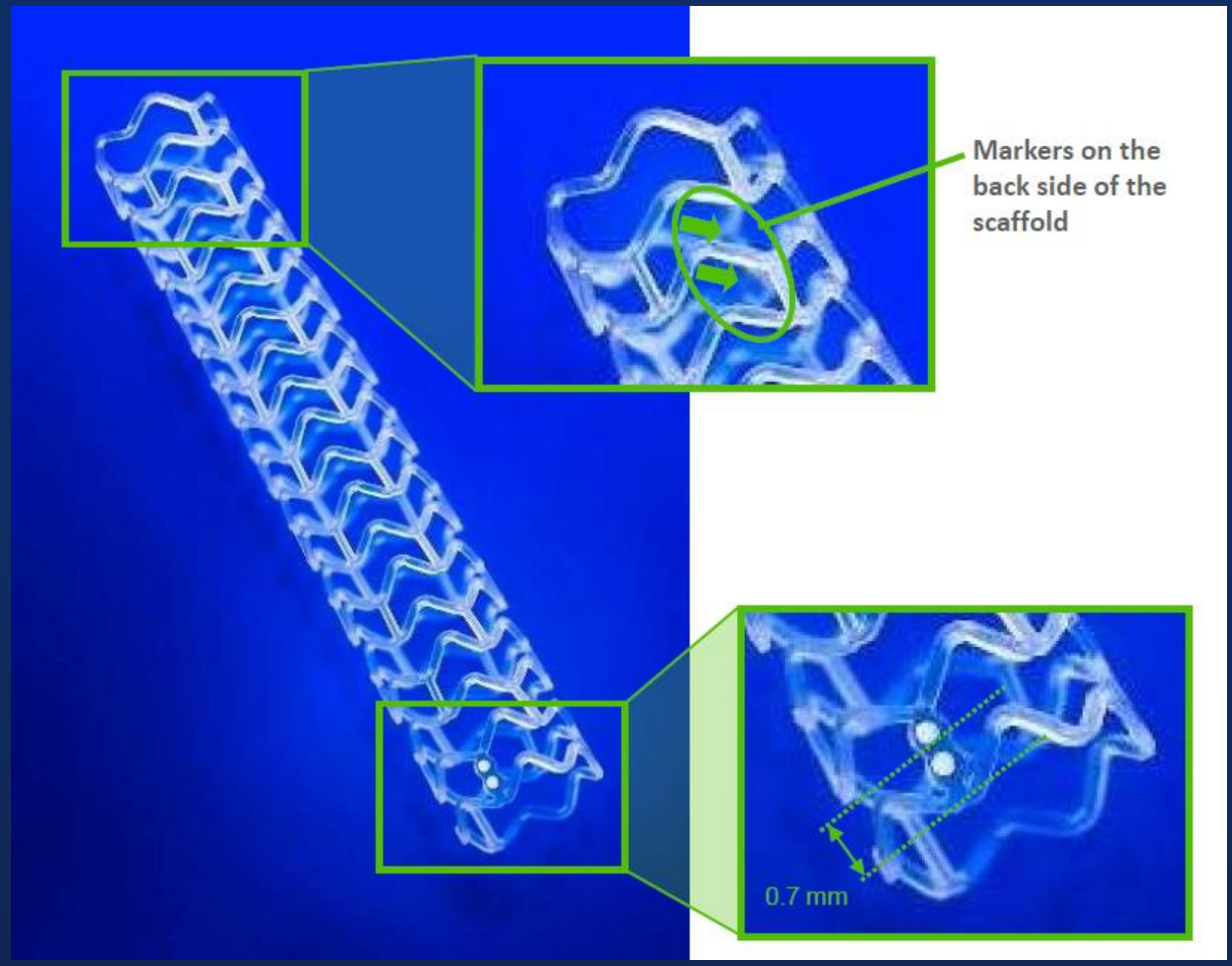


Ideal timing

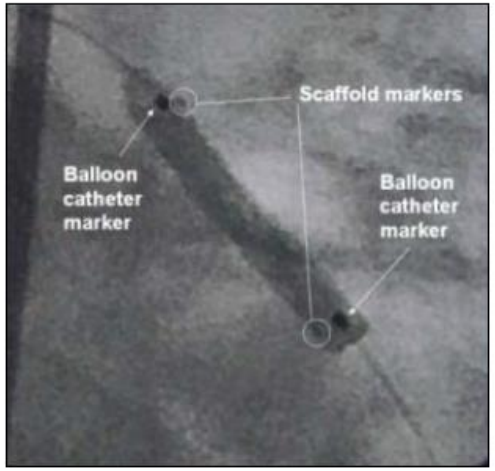


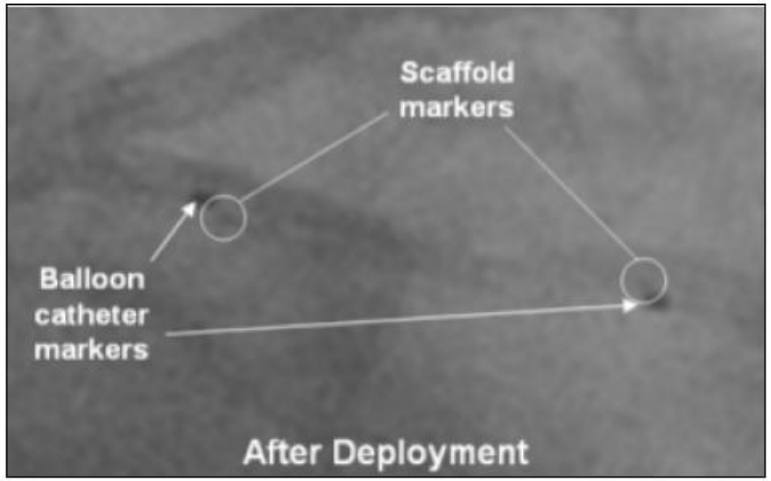
Scaffold Marker Beads

- Two pairs of platinum marker – one pair at each end of the scaffold
- The marker on the scaffold lie near the inner edge of the balloon markers



Locating Scaffold Marker Beads



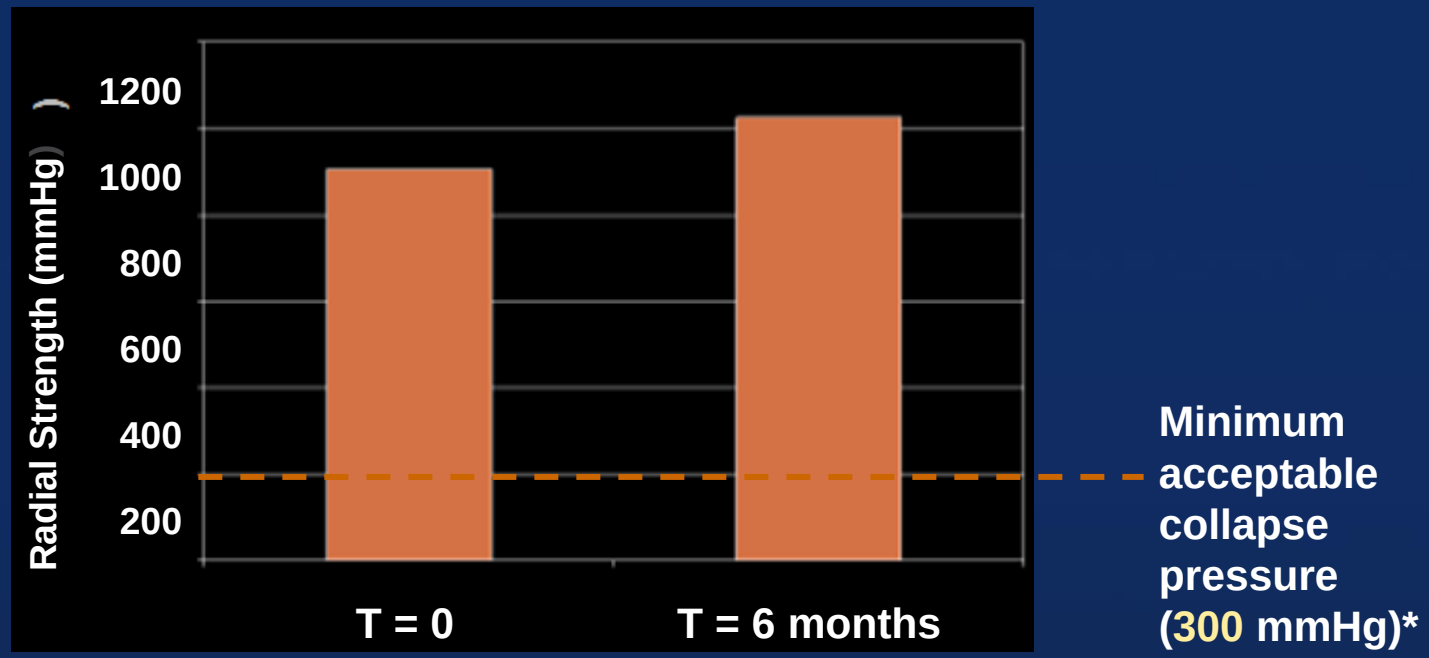


How Much Radial Strength is Needed?

- **Industry standards for stent radial from animal studies:**
  - Maximal transluminal pressures of canine artery: 200 – 275 mmHg
  - Human arteries pressures around 100 mmHg
  - Stents withstand the difference between transluminal and intraluminal pressures: up to 175 mmHg
  - Adding a factor of safety the minimum acceptable collapse pressure for stents is **300** mmHg

Agrawal, CM, et.al. Biomaterials. 1992; 13: 176-182

Radial Strength

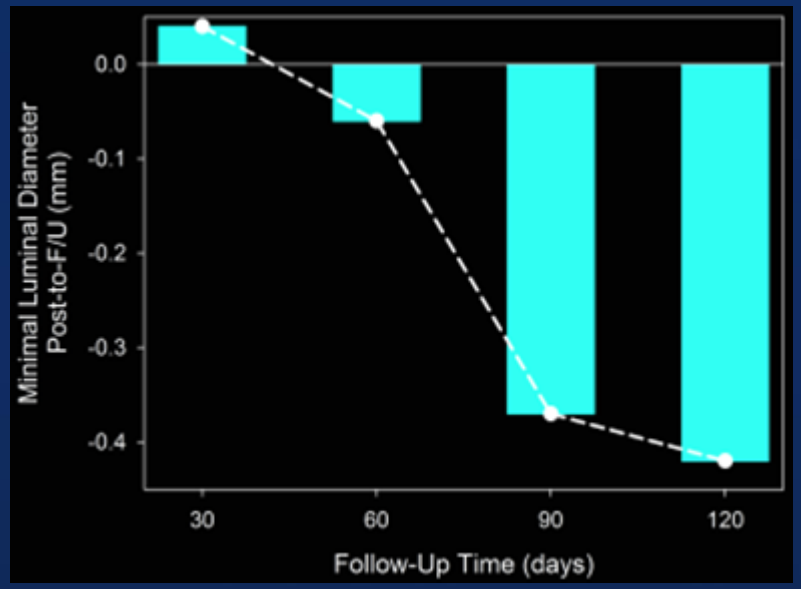


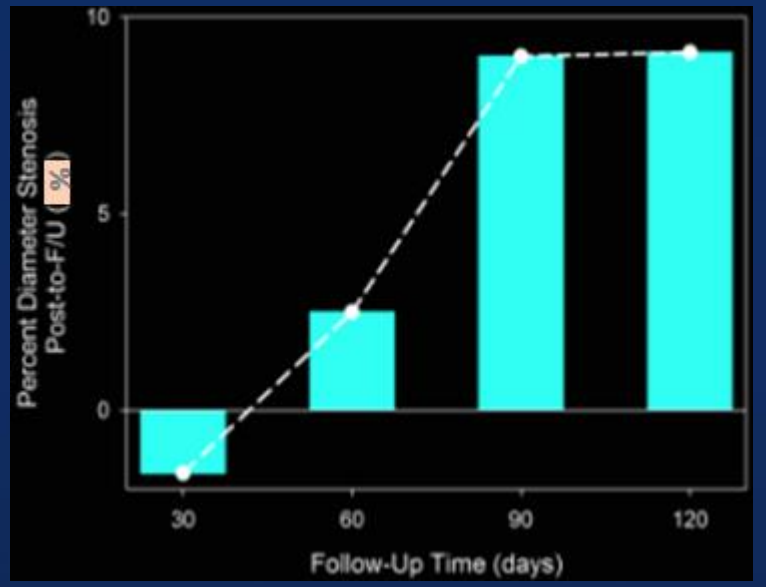
BVS maintains adequate support for at least as long as is needed

Agrawal, CM, et.al. Biomaterials. 1992; 13: 176-182.

What is the Minimum Duration of Radial Support?

Quantitative angiographic study in 342 consecutive patients

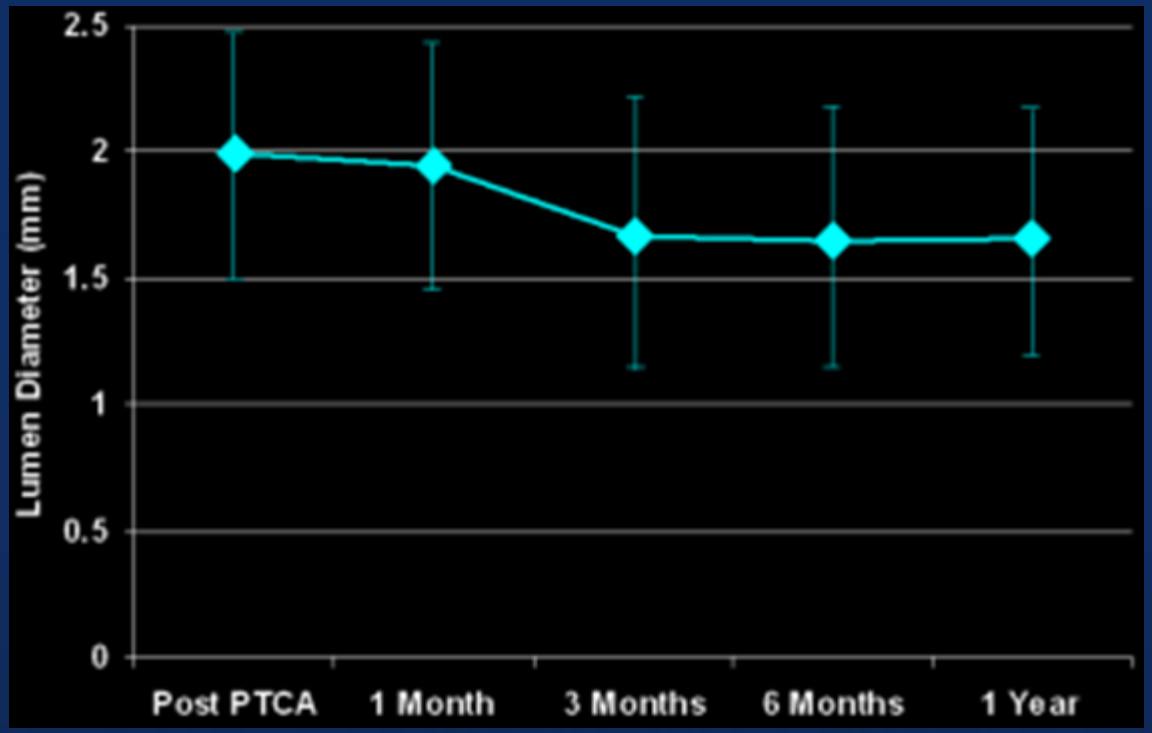




The lumen appears to stabilize 3 months after PTCA

Serruys PW, et al., Circulation 1988; 77: 361

What is the Minimum Duration of Radial Support?



Changes in MLD following PTCA stabilize at 3 months

Temperature Requirements

- Polymer based scaffold
- Polymers' performance is affected by temperature, as temperature affects the polymer material characteristics
- BVS needs to be maintained between -20°C and 25°C at all
  - Transported, received and stored in a temperature controlled environment

Available Sizes of the Absorb BRS

		Lengths (mm)				
		8	12	18	23	28
Diameters (mm)	2.5	X	X	X	X	X
	3.0	X	X	X	X	X
	3.5		X	X	X	X

Leaving Nothing Behind !

- Initial scaffolding similar to metallic stents
- Restore vessel to natural state with normal function and healing response
  - Preservation of vascular geometry
  - Restoration of vascular physiology
  - Eliminate source of inflammation/irritation
  - Vessel free for future interventions
- Prevention of very late thrombotic events
- Passivation of vulnerable plaques

Comparison of BRS with Other Angioplasty Technique/Devices

	POBA	BMS	DES	BRS
Acute occlusion	+	-	-	-
Acute recoil	+	-	-	-
Acute ST	+	+	+	+
Subacute ST	+/-	+	+	+
Late ST	-	+	+	+/- ?
Constrictive remodeling	-	+	+	+
Neointimal hyperplasia	-	++	+	+/-
Expansive remodeling	+	-	-	+
Late luminal enlargement	+	-	-	+
Vasomotion Restoration	+	-	-	+

Iqbal J et al. Eur Heart J 2014;35:765

Limitations of BRS

- Thickness of strut
- Post-dilatation with a balloon diameter more than 0.5 mm bigger than the scaffold diameter
- Limited sizes and diameters currently available
- Slow and prolonged dilatations
- Lack of visibility on X-ray imaging

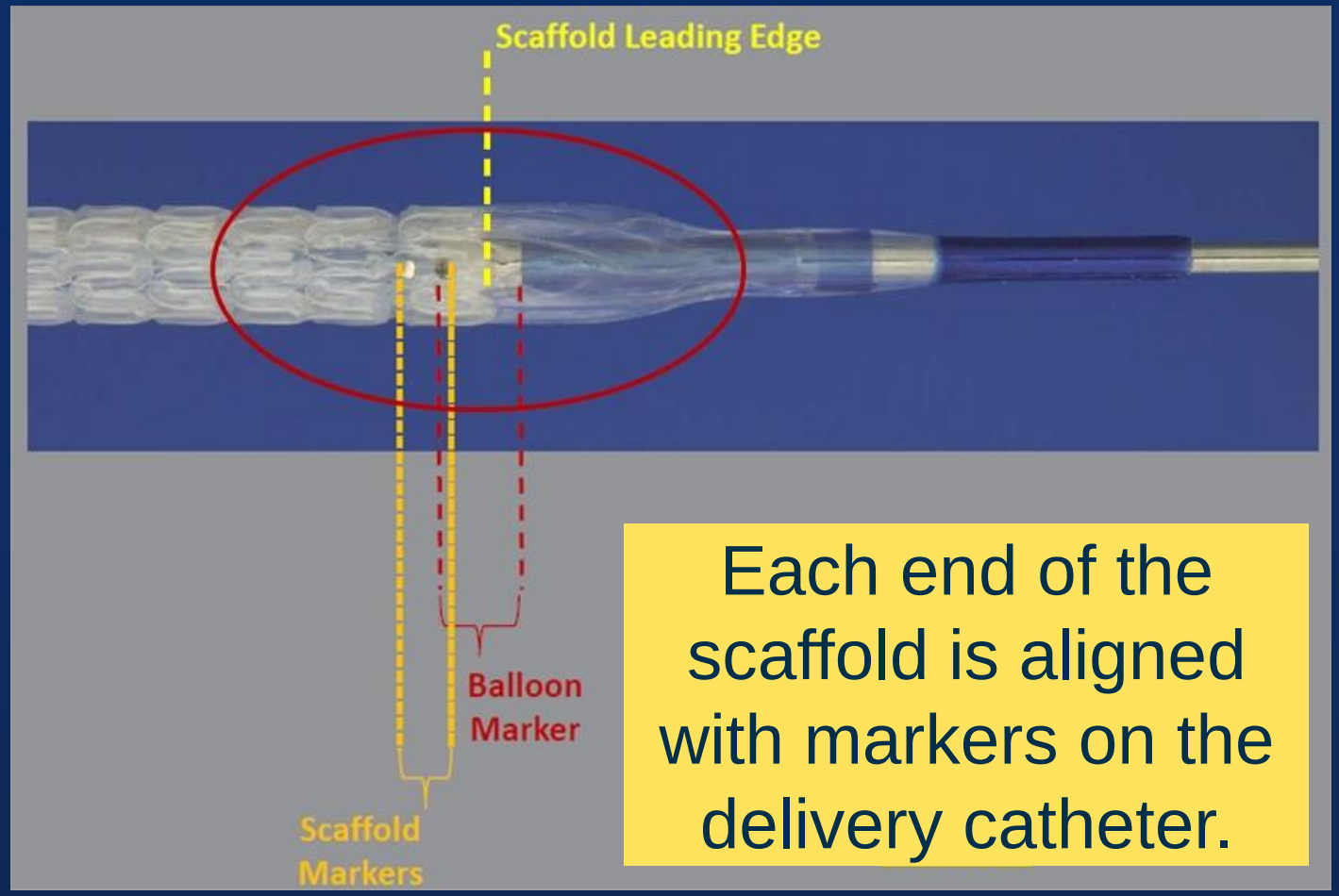
Technical Considerations of BRS Implantation

Unique characteristics of BRS

Considering technical aspects

- The struts are not visible under fluoroscopy or cine. Only IVUS or OCT will allow visualization of struts.
- To provide sufficient radial strength, BVS has thicker struts (156μm) than contemporary metallic stents (~80μm). This results in larger crossing profile (1.4mm for Absorb) and reduced deliverability or trackability.
- Over-dilatation can result in strut disruption and loss of radial strength.

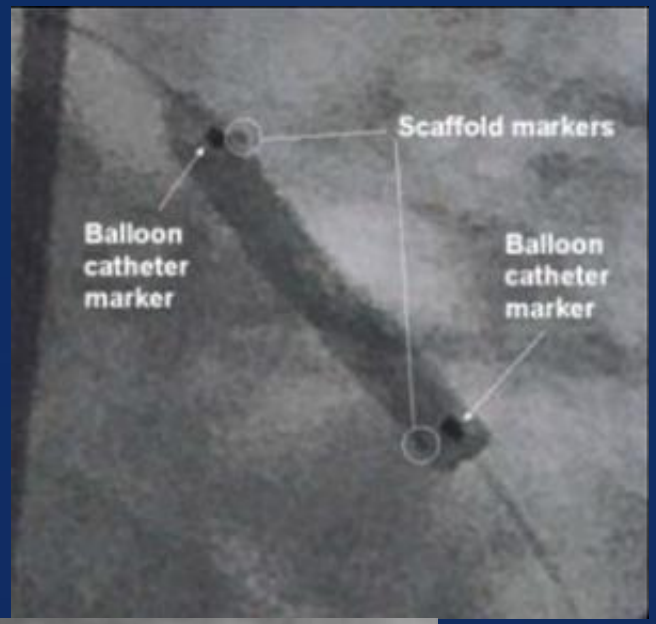
Scaffold mounted on the balloon

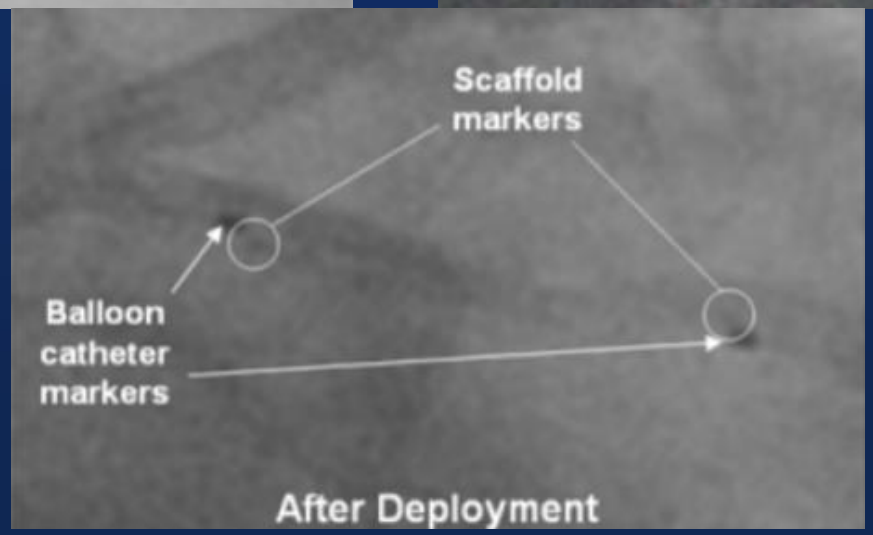


Use balloon markers to position scaffold

Scaffold design

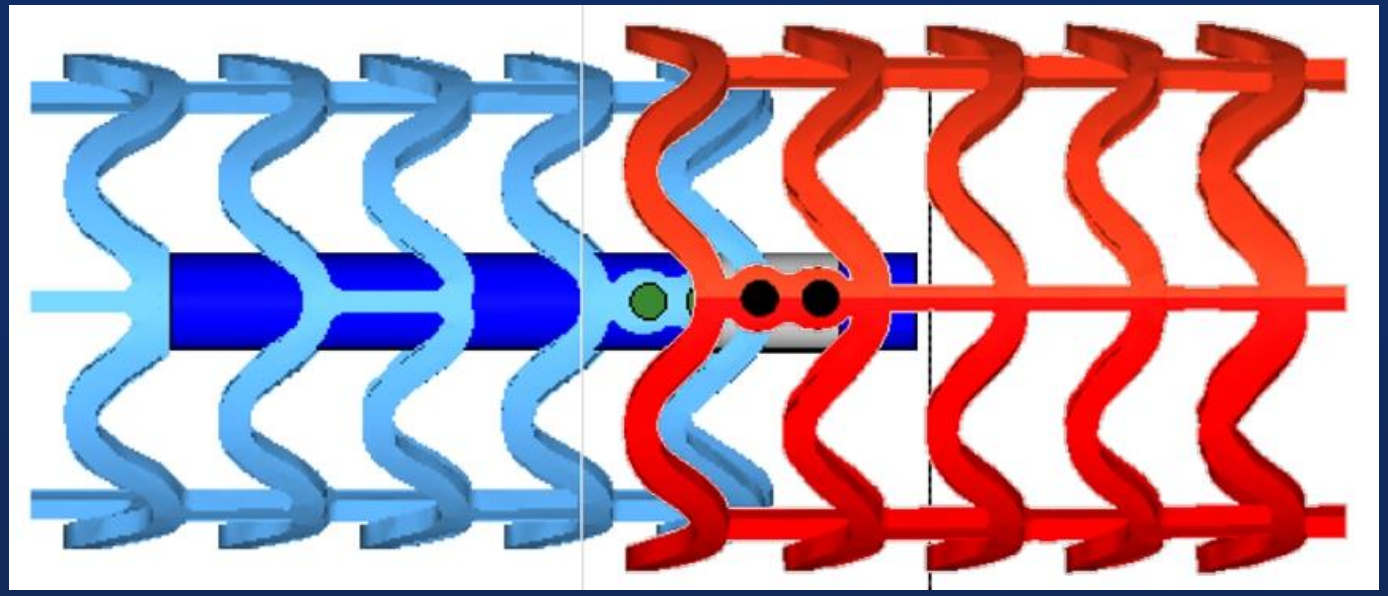
Locating Scaffold Marker Beads





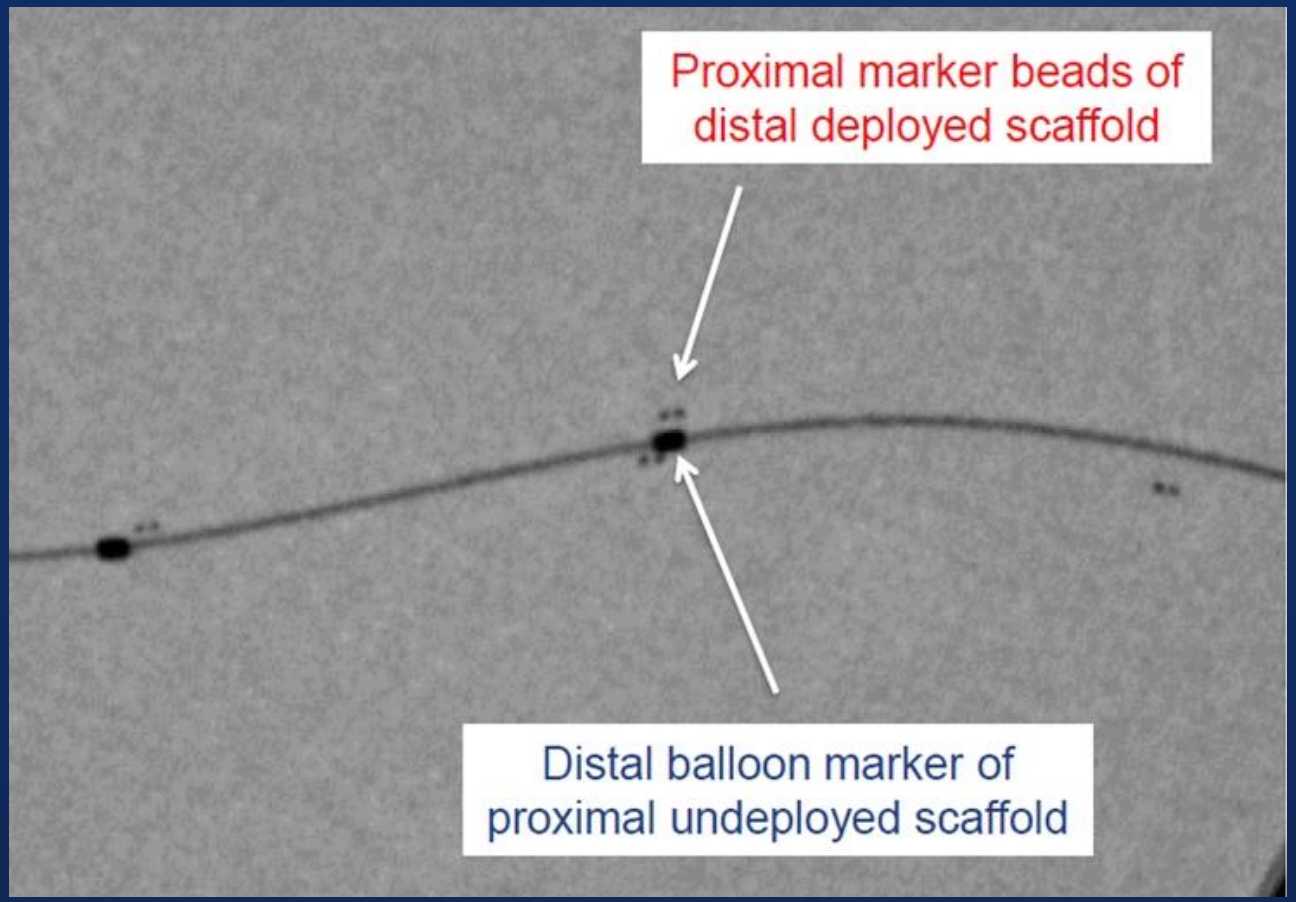
Scaffold overlap

The distal balloon marker (BLUE) lines up with the proximal marker beads of the implanted scaffold



Balloon Marker under Scaffold Markers
The result will be ~ 1mm of overlap

Scaffold Overlap



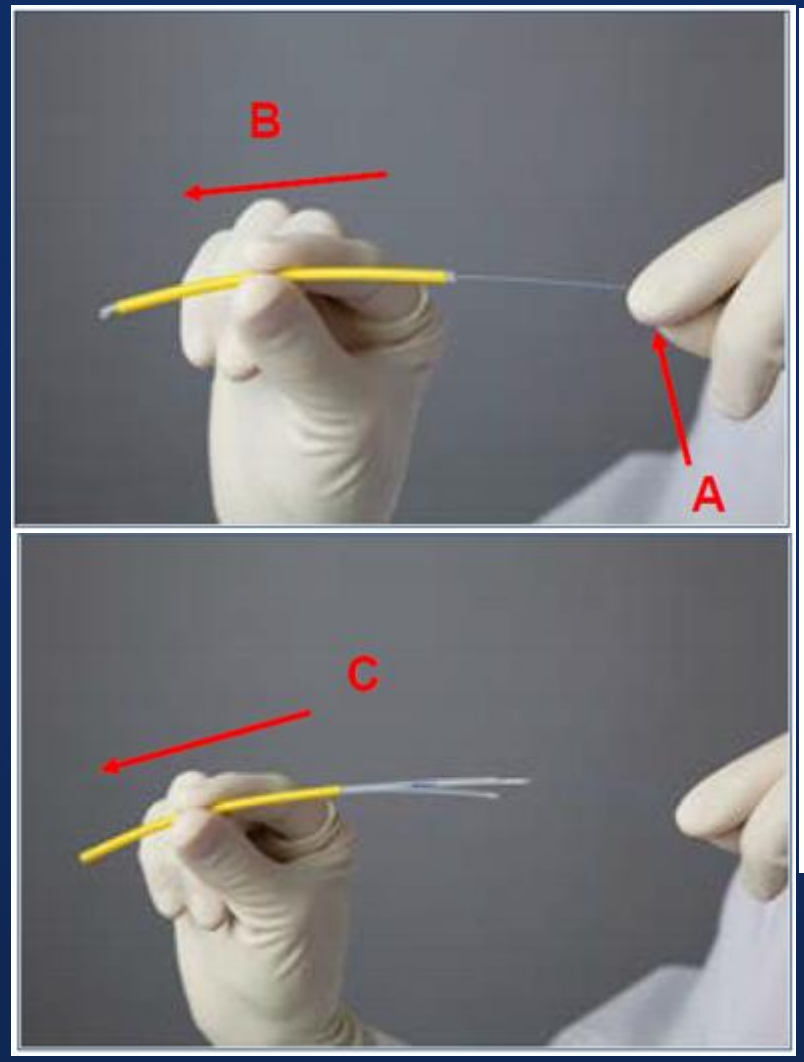
Line up the balloon marker band with the deployed scaffold marker beads; this will result in ~1mm overlap

Scaffold design

Guiding Catheter Compatibility

- At least ≥ 6F / 0.070” / 1.8mm minimum inner diameter
- If challenges with crossing the lesion are anticipated
  - consider an extra back-up support guide catheter
  - consider a more supportive guide-wire
- Do not insert a guide sheath into a guiding catheter, as doing so will result in an inner diameter that is too small for use with Absorb

Dual Layer Sheath Removal



- **DO NOT** grab/pinch both the outer and inner sheaths together at the most proximal end as damage to the proximal balloon seal may occur.

Optimal Implantation of ABSORB: *5P*

1. ***P***repare the lesion
2. ***P***roperly size the Vessel
3. ***P***ay Attention to Expansion Limits
4. ***P***ost-Dilate with a Non-Compliant Balloon
5. ***P***rescribe Dual Anti-Platelet Therapy

Prepare the lesion

- Absorb has a larger crimped profile than XIENCE; therefore, lesion preparation is key.
- Pre-dilatation is strongly recommended.
- Use of a non-compliant balloon is recommended.
- For highly resistant/calcified lesions, consider the use of cutting balloons, scoring balloons, or rotablator to optimize scaffold deployment.

Crossing the lesion

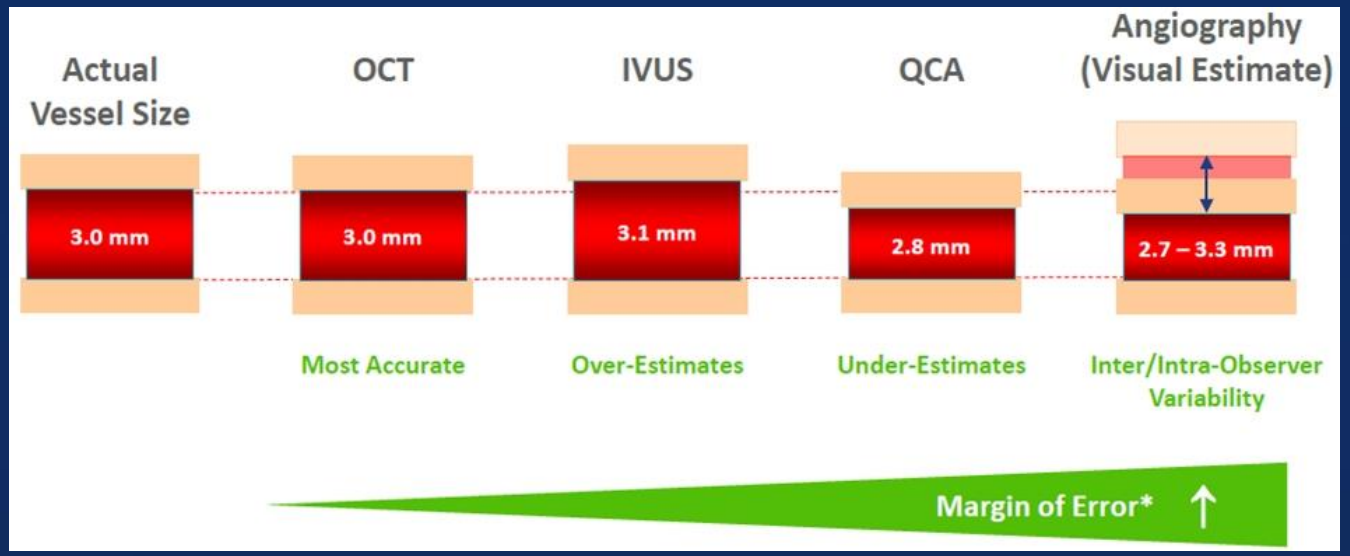
- Following pre-dilatation, consider evaluating the vessel pathway with the deflated pre-dilatation balloon to assess to deliver scaffold to the lesion.

- An unexpanded scaffold should not be reintroduced into the artery once it has been pulled back into the guiding catheter or removed from the body.

- Use constant forward pressure to cross the lesion (Avoid the Dottering technique)

Properly size the vessel

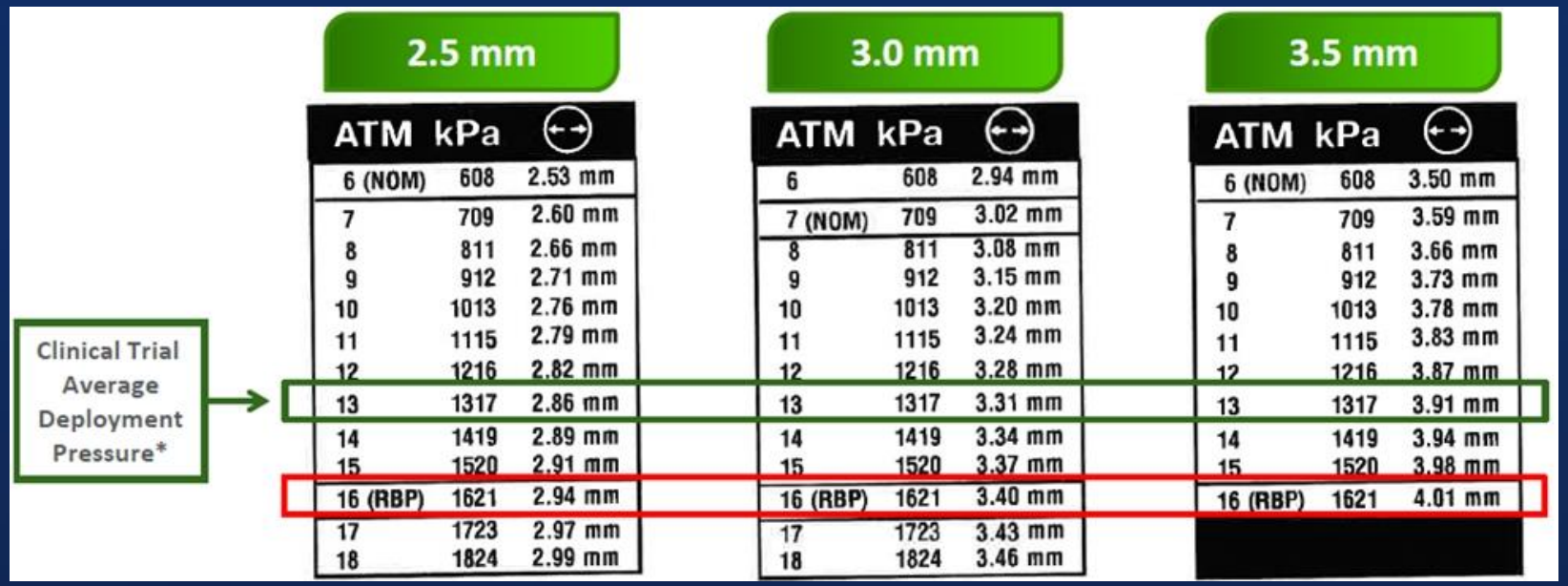
- IVUS or OCT are strongly recommended to size the vessel, particularly during the initial experience with the device



- When visually estimating vessel size, use the pre-dilatation balloon size when inflated in the lesion to more accurately size the vessel.
- It is recommended to administer a standard dose of intracoronary nitroglycerine prior to finalizing the RVD within the target zone.

Pay attention to expansion limits

- It is important to stay within the expansion limits to avoid strut disruption and minimize the loss of radial strength.
- Scaffold expansion limits are nominal scaffold diameter + 0.5mm



2.5 mm

ATM	kPa	↔
6 (NOM)	608	2.53 mm
7	709	2.60 mm
8	811	2.66 mm
9	912	2.71 mm
10	1013	2.76 mm
11	1115	2.79 mm
12	1216	2.82 mm
13	1317	2.86 mm
14	1419	2.89 mm
15	1520	2.91 mm
16 (RBP)	1621	2.94 mm
17	1723	2.97 mm
18	1824	2.99 mm

3.0 mm

ATM	kPa	↔
6	608	2.94 mm
7 (NOM)	709	3.02 mm
8	811	3.08 mm
9	912	3.15 mm
10	1013	3.20 mm
11	1115	3.24 mm
12	1216	3.28 mm
13	1317	3.31 mm
14	1419	3.34 mm
15	1520	3.37 mm
16 (RBP)	1621	3.40 mm
17	1723	3.43 mm
18	1824	3.46 mm

3.5 mm

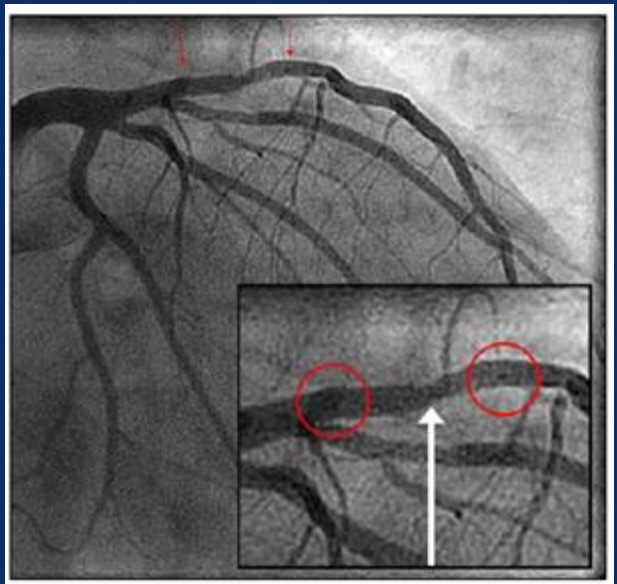
ATM	kPa	↔
6 (NOM)	608	3.50 mm
7	709	3.59 mm
8	811	3.66 mm
9	912	3.73 mm
10	1013	3.78 mm
11	1115	3.83 mm
12	1216	3.87 mm
13	1317	3.91 mm
14	1419	3.94 mm
15	1520	3.98 mm
16 (RBP)	1621	4.01 mm

Clinical Trial Average Deployment Pressure*

- Maintain target deployment pressure for 30 seconds

Post-Dilate with an NC Balloon

- If residual stenosis is >10%, then consider using a non-compliant balloon that is up to + 0.5 mm lager than the nominal scaffold diameter (i.e. use a 3.5 mm NC balloon with a 3.0 mm scaffold)



Sub-optimal result – should be post-dilated

Delivery system balloon removal Troubleshooting

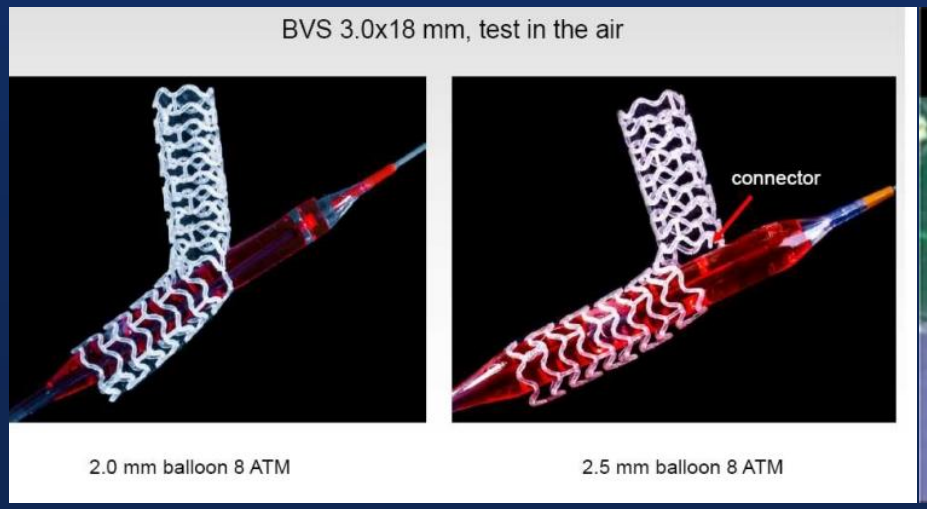
- If resistance is experienced upon removal of the Absorb delivery system balloon from the deployed scaffold, re-inflate the balloon up to nominal pressure, deflate, and change pressure to neutral as balloon folds relax and soften allowing for easier withdrawal

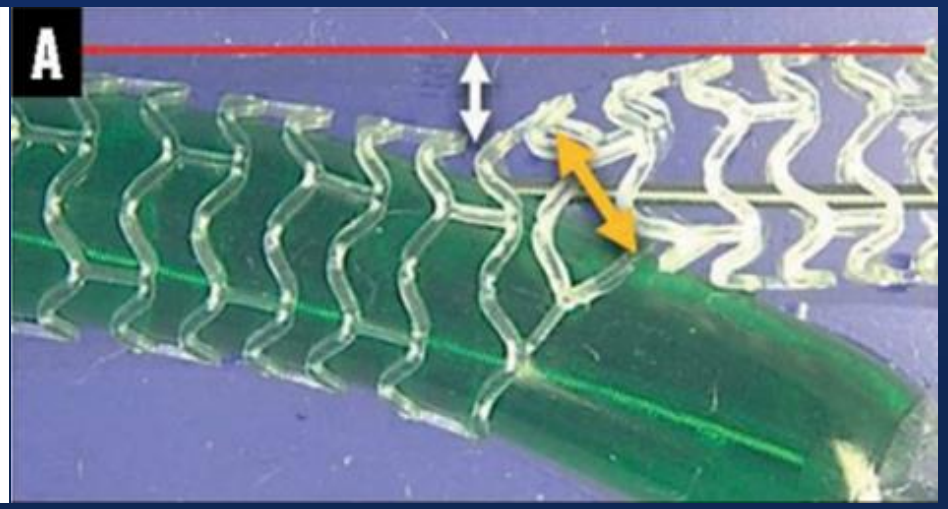
Negative Pressure

Neutral Pressure

Treating side branches

- If a clinical decision is made to dilate a side branch, use sequential balloon inflations
- Avoid scaffolding across any side branch ≥ 2.0mm
- Always finish with main branch balloon inflation

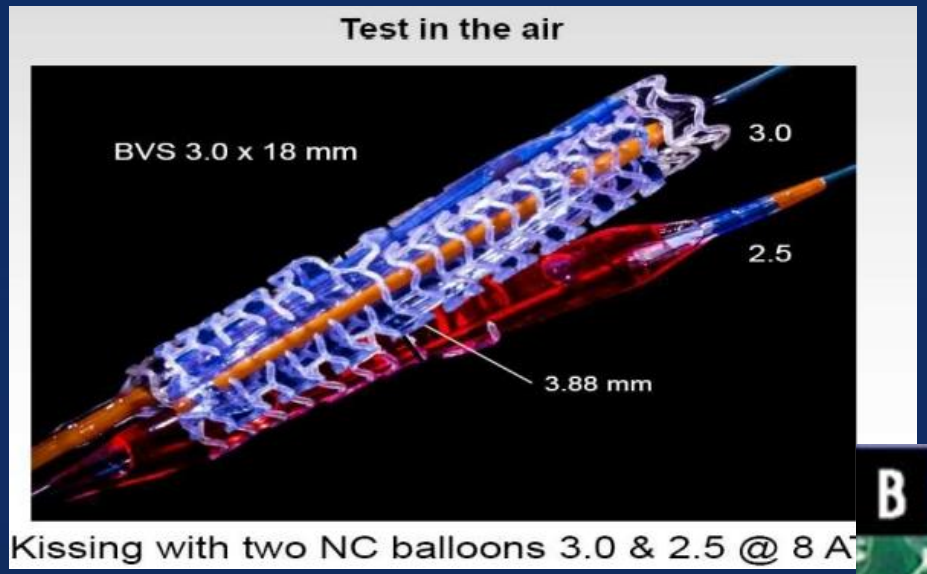


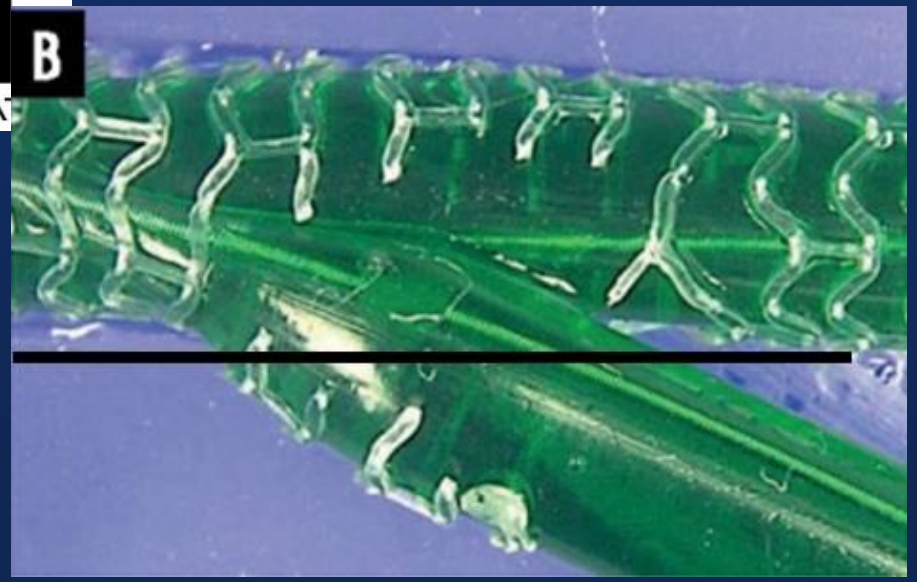


Post-dilate with an NC balloon

- High pressure post-dilatation with a non-compliant balloon is ideal (<10% RS)
  - To achieve optimal scaffold apposition
  - Do not dilate the scaffold beyond its maximum expansion limit
- If residual stenosis is >10%, then consider using a non-compliant balloon that is up to + 0.5 mm lager than the nominal scaffold diameter
- Use imaging guidance (IVUS or OCT)

Conventional kissing is prohibited



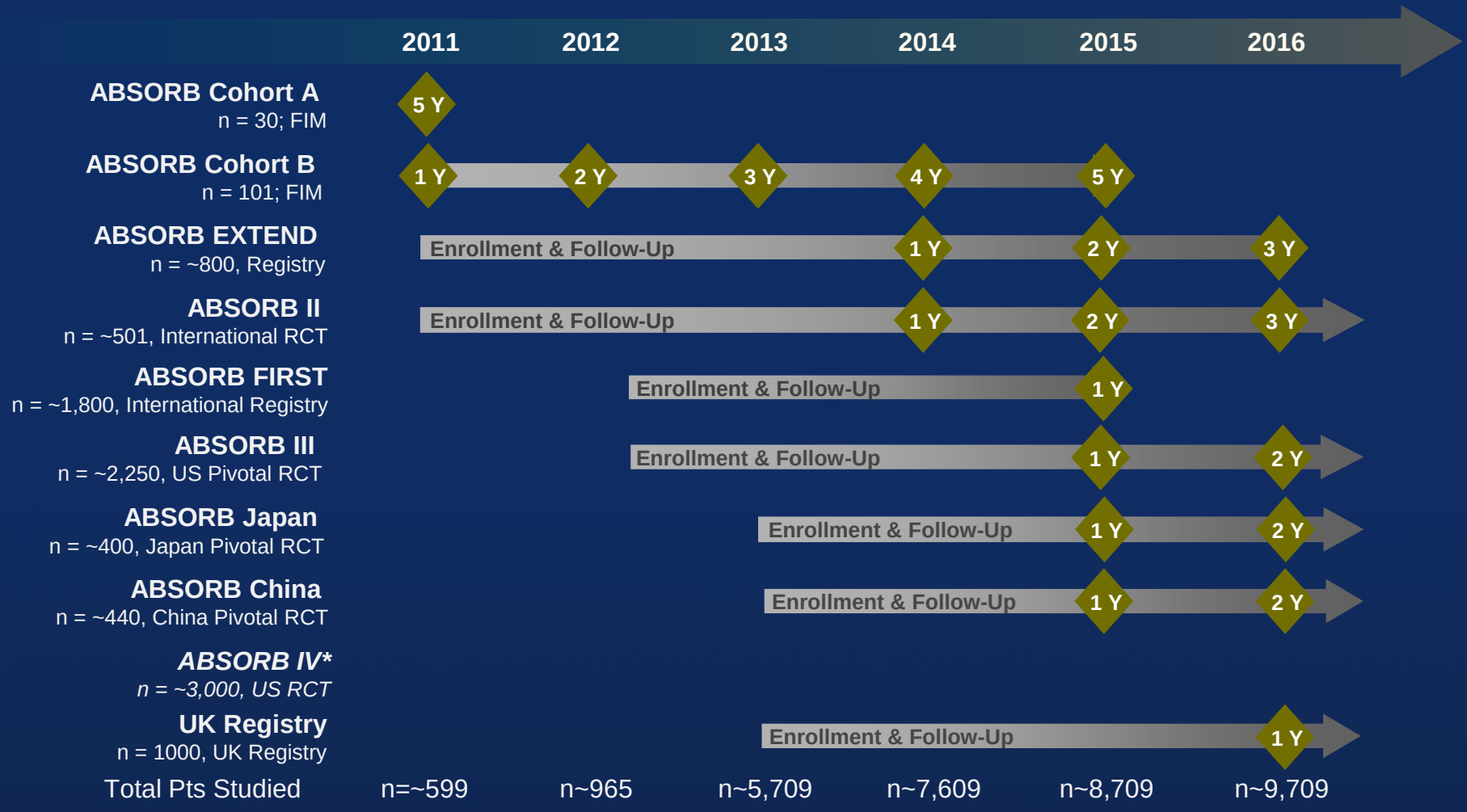


DAPT prescription

- Consider current ACC/AHA and ESC DAPT guidelines
- More potent P2Y12 inhibitors (Ticagrelor or Prasugrel) are highly recommended for complex lesions requiring extensive lesion prep, ACS/STEMI patients, and overlapped scaffolds

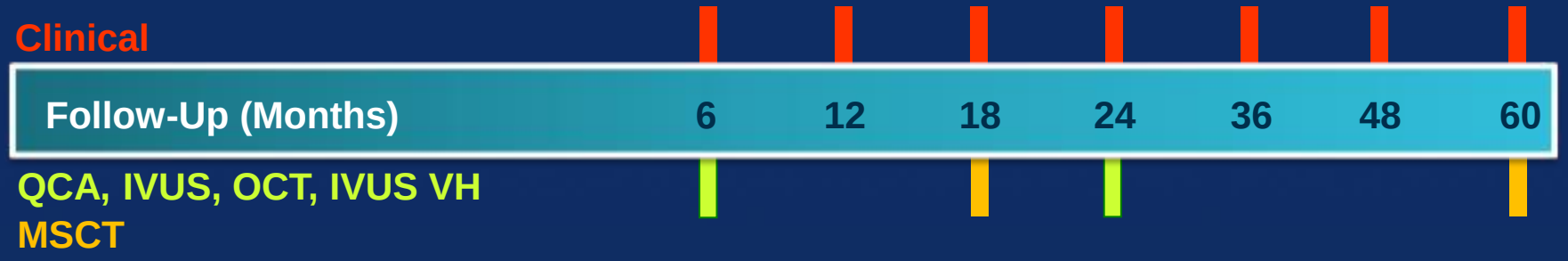
Clinical outcomes of BRS

Absorb Comprehensive Abbott Vascular Sponsored Clinical Trial Program



ABSORB Cohort A
Introduction

30 subjects
(Non-randomized) 4 sites in Europe & New Zealand



Study Objective	**First In Man, Single Arm – safety/performance**
Endpoints	**Typical PCI clinical and imaging endpoints**
Treatment	**Single, *de novo* native coronary lesion in a vessel with a reference vessel diameter of 3.0 mm**
Device Sizes	**3.0 x 12 mm scaffolds (3.0 x 18 mm scaffolds available after enrollment start and used in 2 pts)**

ABSORB Cohort A

Baseline Demographics and Lesion Characteristics

Male	58%
Diabetes Mellitus	4%
Location of Lesions	
LAD	50%
LCX	23%
RCA	27%
Lesion Classification	
Type B1	65%
Type B2	35%
Pre-Procedure	
Lesion length (mm)	8.66 ± 3.97
RVD (mm)	2.78 ± 0.47
MLD (mm)	1.10 ± 0.26
DS (%)	59 ± 12

Adapted from Serruys, PW, ABSORB Cohort A 2-year IVUS and OCT results; ACC 2009.

ABSORB Cohort A

Excellent Long-Term Data Out to 5 Years

ABSORB Cohort A Clinical Results at Each Phase: Intent to Treat

Hierarchical	6 Months 30 Patients	1 year 29 Patients**	2 Year 29 Patients**	5 Year 29 Patients**
Ischemia Driven MACE***	1 (3.3%)*	1 (3.4%)*	1 (3.4%)*	1 (3.4%)*
Cardiac Death	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MI	1 (3.3%)*	1 (3.4%)*	1 (3.4%)*	1 (3.4%)*
Q-Wave MI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non Q-Wave MI	1 (3.3%)*	1 (3.4%)*	1 (3.4%)*	1 (3.4%)*
Ischemia Driven TLR	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
by PCI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.%)
by CABG	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.%)

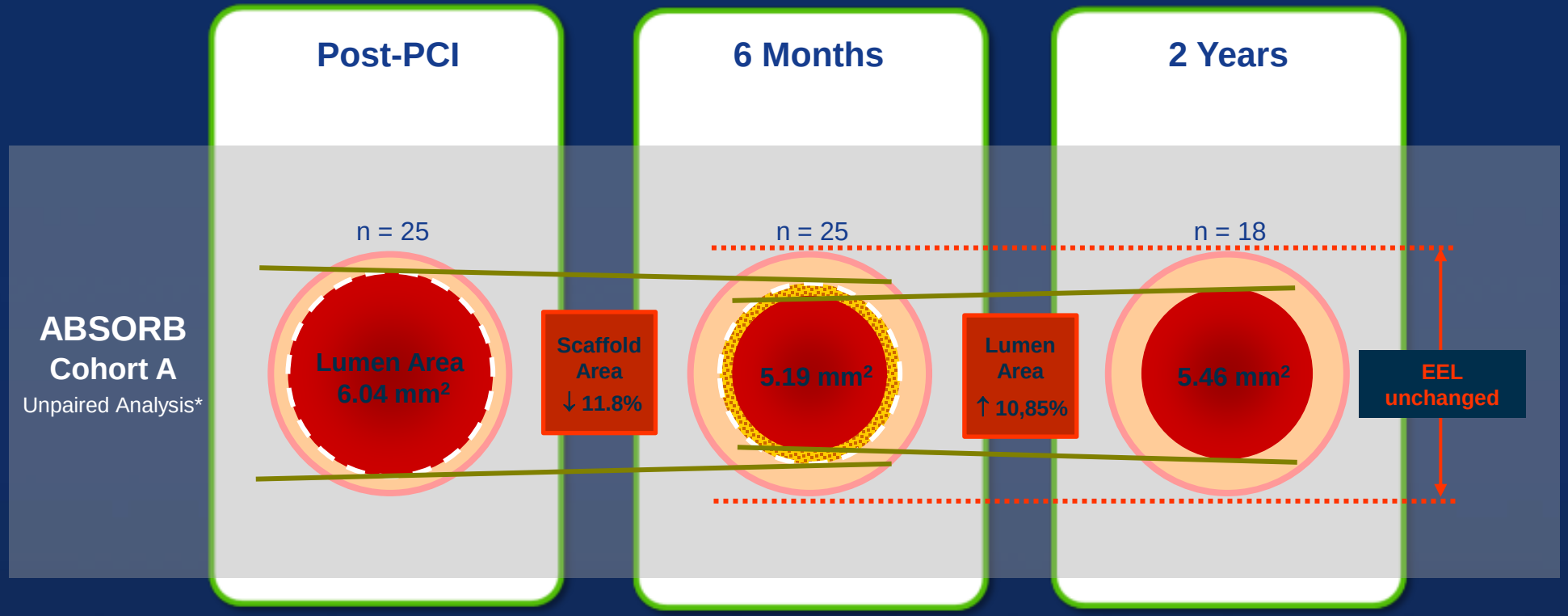
Serruys, ABSORB Cohort A 5-year results; TCT, 2011

No scaffold thrombosis by ARC or Protocol

Adapted from Serruys, PW, ABSORB Cohort A 2-year IVUS and OCT results; ACC 2009.

ABSORB Cohort A

Temporal Lumen Dimensional Changes, Per Treatment

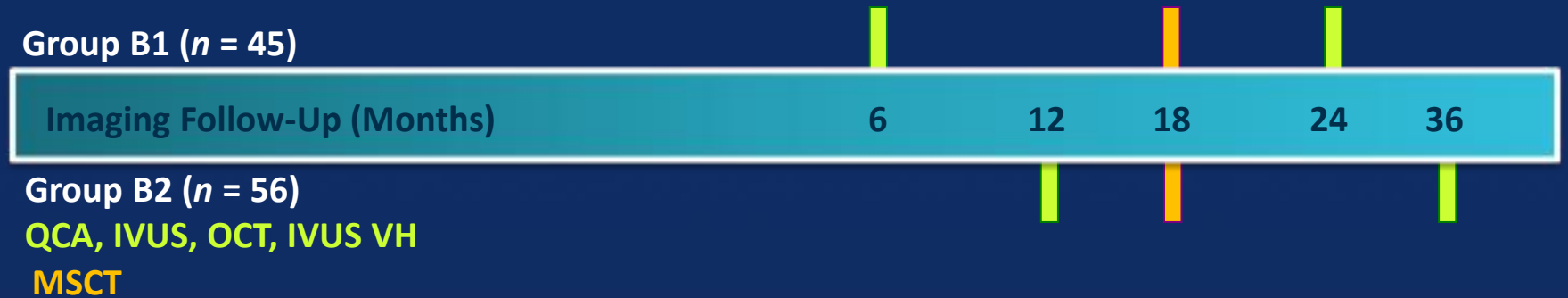


- Late lumen loss at 6 months mainly due to reduction in scaffold area
- Very late lumen gain noted from 6 months to 2 years

Adapted from Serruys, PW, ABSORB Cohort A 2-year IVUS and OCT results; ACC 2009.

ABSORB Cohort B
Introduction

101 subjects
(Non-randomized) 12 sites in Europe, Australia, New Zealand



Study Objective	First In Man, Single Arm – safety/performance
Endpoints	Typical PCI clinical and imaging endpoints
Treatment	Up to 2 *de novo* lesions in different epicardial vessels Reference vessel diameter of 3.0 mm, lesions ≤ 14 mm in length
Device Sizes	3.0 x 18 mm devices

ABSORB Cohort B

Baseline Lesion Characteristics/ Acute Success

Location of lesion (%)	
LAD	43
RCA	33
LCX	22
Ramus	1
Lesion classification (%)	
A	1
B1	55
B2	40
C	4
Clinical Device Success (%)	**100**
Clinical Procedure Success (%)	**98**

Serruys, PW., ABSORB Cohort B 9-month and 1-year results; AHA 2010.

ABSORB Cohort B

Clinical Results - Intent to Treat

Non-Hierarchical	30 Days	1 Year	2 Years	3 Years
	N = 101	N = 101	N = 100*	N = 100*
Cardiac Death %	0	0	0	0
Myocardial Infarction % (n)	2.0 (2)	3.0 (3)	3.0 (3)	3.0 (3)
Q-wave MI	0	0	0	0
Non Q-wave MI	2.0 (2)	3.0 (3)	3.0 (3)	3.0 (3)
Ischemia driven TLR % (n)	0	4.0 (4)	6.0 (6)	7.0 (7)
CABG	0	0	0	0
PCI	0	4.0 (4)	6.0 (6)	7.0 (7)
Hierarchical MACE % (n)	2.0 (2)	6.9 (7)	9.0 (9)	10.0 (10)
Hierarchical TVF % (n)	2.0 (2)	6.9 (7)	11.0 (11)	13.0 (13)

MACE: Cardiac death, MI, ischemia-driven TLR, TVF: Cardiac death, MI, ischemia-driven TLR, ischemia-driven TVR

No scaffold thrombosis by ARC or Protocol

Dr Whitbourn, TCT 2013

ABSORB Cohort B1

Clinical Results - Intent to Treat

Non-Hierarchical	30 Days	6 Months	12 Months	2 Years	3 Years	4 Years
	N = 45	N = 45	N = 45	N = 44*	N = 44*	N = 44*
Cardiac Death %	0	0	0	0	0	0
Myocardial Infarction % (n)	2.2 (1)	2.2 (1)	2.2 (1)	2.3 (1)	2.3 (1)	2.3 (1)
Q-wave MI	0	0	0	0	0	0
Non Q-wave MI	2.2 (1)	2.2 (1)	2.2 (1)	2.3 (1)	2.3 (1)	2.3 (1)
Ischemia driven TLR % (n)	0	2.2 (1)	4.4 (2)	4.5 (2)	4.5 (2)	4.5 (2)
CABG	0	0	0	0	0	0
PCI	0	2.2 (1)	4.4 (2)	4.5 (2)	4.5 (2)	4.5 (2)
Hierarchical MACE % (n)	2.2 (1)	4.4 (2)	6.7 (3)	6.8 (3)	6.8 (3)	6.8 (3)
Hierarchical TVF % (n)	2.2 (1)	4.4 (2)	6.7 (3)	6.8 (3)	9.1 (4)**	9.1 (4)**

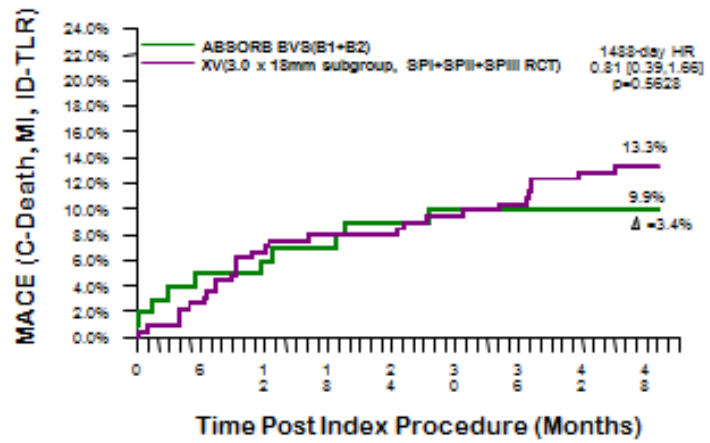
No new MACE between 1-year and 4-years

No scaffold thrombosis by ARC or Protocol

Dr Whitbourn, TCT 2013

ABSORB Cohort B
-Year Follow Up – B. Chevalier

KM Estimate of MACE Rate in Patients Treated with Absorb vs. Patients Treated with a Single 3.0x 18 mm Metallic XIENCE V



Time After Index Procedure (days)								
	0	37	194	284	393	758	1123	1488
ABSORB BVS(B1+B2) At Risk	101	99	96	96	94	91	89	39*
XV(3.0 x 18mm subgroup, SPI+SPII+SPIII RCT) At Risk	227	224	219	211	204	191	182	178

Absorb Demonstrates Similar Safety to XIENCE

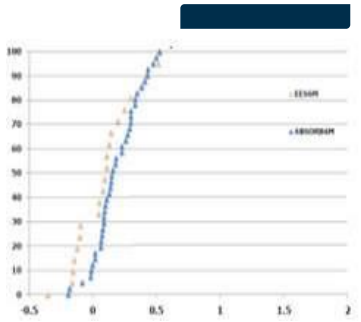
ABSORB Cohort B

6, 12, 24 and 36-Month QCA – Intent to Treat (Groups 1 & 2)

The Evolution of Cumulative Frequency Distribution Curves for Late Loss Over Time: Absorb BVS and XIENCE V (Non-Matched Population)

Angiographic late loss similar to XIENCE V and remains relatively unchanged between 12 and 36 months*

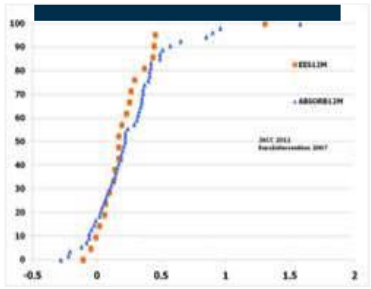
6 Months[1]



BVS: 0.19 ± 0.18 mm (n=42)

XIENCE V: 0.10 ± 0.23 mm (n=22)

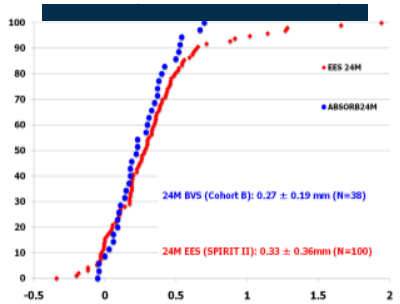
12 Months[1]



BVS: 0.27 ± 0.32 mm (n=56)

XIENCE V: 0.23 ± 0.29 mm (n=22)

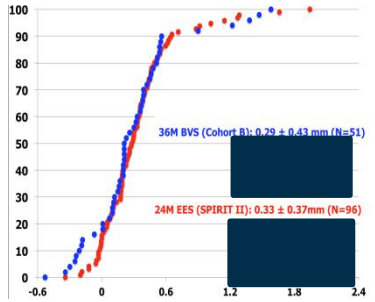
24 Months[1]



BVS: 0.27 ± 0.19 mm (n=38)

XIENCE V: 0.33 ± 0.36 mm (n=100)

36 Months[2]



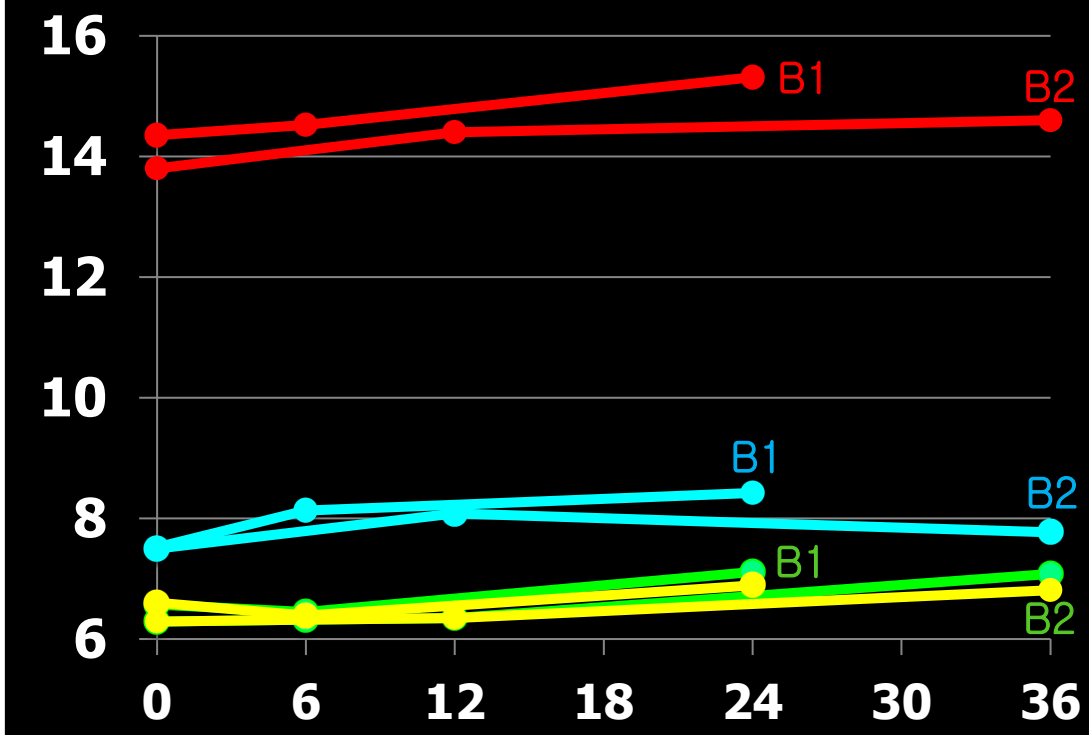
BVS: 0.29 ± 0.43 mm (n=51)

XIENCE V: 0.33 ± 0.36 mm (n=100)‡

1. Serruys, PW., 5-year ABSORB Cohort A and 2-year Cohort B results: integrated insights; TCT 2011
2. Serruys, PW., First report of the ABSORB Cohort B 3-year clinical and multi-modality imaging results; ACC 2013

ABSORB Cohort B

Serial IVUS Analysis (N=45)



Mean Vessel Area

Δ 6–24 Months: ↑ 0.90 mm²; p<0.001

Δ 12–36 Months: ↑ 0.15 mm²; p=0.39

Total Plaque Area

Δ 6–24 Months: ↑ 0.41 mm²; p<0.001

Δ 12–36 Months: ↓ 0.30 mm²; p=0.005

Mean Scaffold Area

Δ 6–24 Months: ↑ 0.66 mm²; p=0.003

Δ 12–36 Months: ↑ 0.73 mm²; p<0.001

Mean Lumen Area

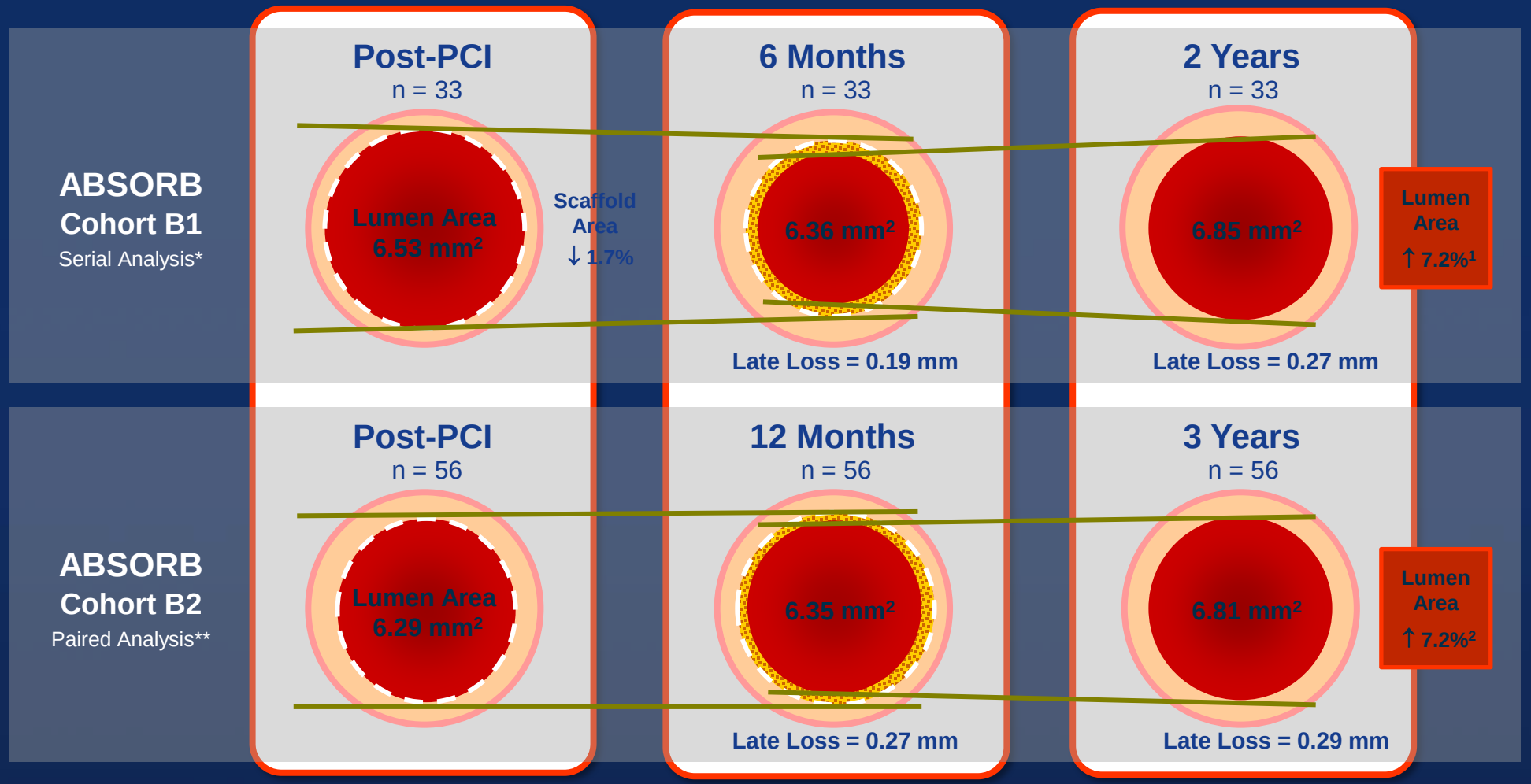
Δ 6–24 Months: ↑ 0.49 mm²; p=0.01

Δ 12–36 Months: ↑ 0.46 mm²; p=0.002

Serruys PW, ABSORB Cohort B 3Year Data, Rotterdam EuroPCR Focus on BVS 2013

ABSORB Cohort B

Temporal Lumen Dimensional Changes



1. Patient-level serial analysis
2. Calculated from overall mean values

Serruys, PW., ABSORB Cohort B 2-year results; TCT 2011
**Serruys, PW., ABSORB Cohort B 3-year results; ACC 2013*

ABSORB EXTEND

Non-Randomized, Single-Arm., Continued assess

~1,000 subjects
Up to 100 global sites (non-US)

Study Objective	**FPI: Jan 11, 2011**
Endpoints	**Typical PCI clinical endpoints**
Treatment	**Up to 2 *de novo* lesions in different epicardial vessels Planned overlapping allowed in lesions >22 and ≤ 28 mm**
Device Sizes	**Scaffold diameters: 2.5, 3.0, 3.5 mm Scaffold lengths: 12*, 18, 28 mmContinued Access trial**

Pooled ABSORB Cohort B and EXTEND 1-Year, Propensity Score Adjusted Analysis vs. SPIRIT I/II/III – B. Chevalier

Propensity Adjusted Clinical Outcomes At 1 Year

Non-Hierarchical	Absorb BVS (N = 558)	XIENCE V (N = 672)	P value
Cardiac Death %	0.3	0.6	0.35
Myocardial Infarction %	3.9	2.1	0.06
Ischemia Driven TLR %	1.6	3.2	0.08
Hierarchical MACE %	5.2	5.5	0.81
Hierarchical TVF %	5.5	8.6	0.04
Hierarchical TLF %	5.2	5.0	0.91
Scaffold Thrombosis (ARC Def/Prob) %	0.5	0.5	0.93

Information contained herein for presentation outside the U.S. only. Absorb is authorized for sale in CE Mark and certain independently regulated countries outside the United States. Please check the regulatory status of the device in your geographical location before distribution. AP2939135-OUS Rev. A 10/13

Absorb BVS Cohort: Pooled from ABSORB EXTEND and ABSORB Cohort B trials
XIENCE V Cohort: Pooled from XIENCE V arms of SPIRIT FIRST, II, and III trials

Dr. Chevalier TCT 2013

ABSORB EXTEND

Clinical Results – Intent to Treat; Interim Snapshot

Non-Hierarchical % (n)	12 Months* (N = 250)	24 Months* (N = 250)
Cardiac Death % (n)	**0.4**	**0.4**
Myocardial Infarction % (n)**	**2.8**	**4.0**
Q-wave MI	1.2	1.2
Non Q-wave MI	1.6	2.8
Ischemia driven TLR % (n)	**2.0**	**4.0**
CABG	0.0	0.4
PCI	2.0	4.0
Hierarchical MACE % (n)	**4.4**	**7.3**
Hierarchical TVF %	**4.8**	**8.1**
Hierarchical TLF %	**4.4**	**6.9**
Scaffold Thrombosis (ARC Def/Prob) % (n)	**0.8**	**0.8**

Whitbourn, TCT 2013

2-Year Propensity Scored Analysis ABSORB EXTEND vs. SPIRIT I/II/III - R. Whitbourn

Absorb has comparable safety to XIENCE

ABSORB EXTEND Propensity Score Matched Clinical Outcomes: 2 Years

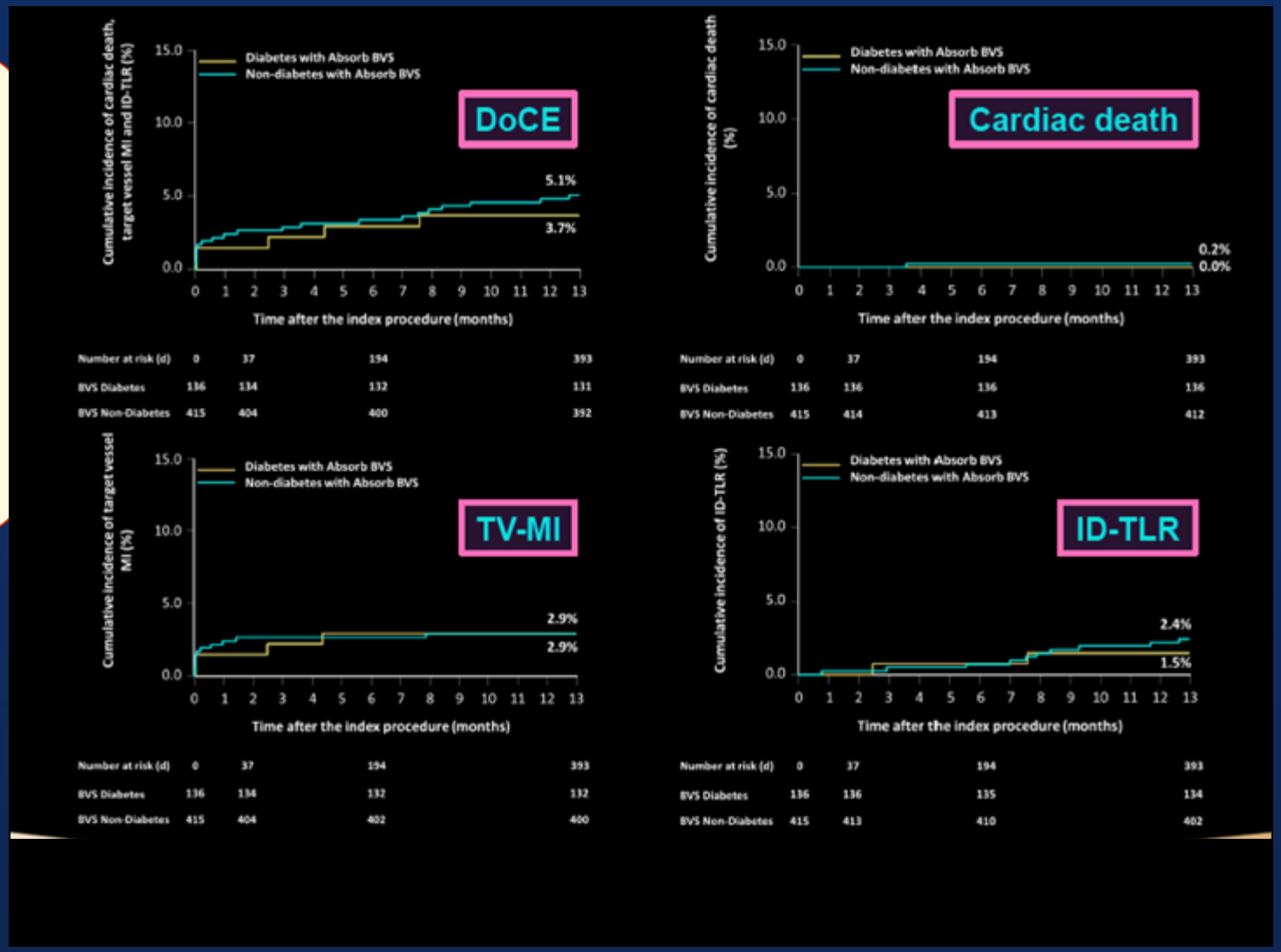
	Absorb (EXTEND, N = 178)	XIENCE V (SP123, N = 293)	P Value
NON-HIERARCHICAL COMPONENTS			
Cardiac Death %	0.0	1.4	0.30
Myocardial Infarction %	4.5	4.4	1.00
Ischemia Driven TLR %	3.4	3.8	1.00
MACE %	6.7	8.9	0.49
TVF %	7.3	12.3	0.09
TLF %	6.2	8.2	0.47
Scaffold Thrombosis (ARC Def/Prob) %	0.6	1.4	0.65

Dr. Whitbourn, TCT 2013

Pooled Analysis From ABSORB Cohort B and EXTEND 1-Year, Clinical Outcomes of Diabetic Patients vs. SPIRIT I/II/III/IV at 1-Year– T. Muramatsu

Absorb Demonstrates Similar Safety to XIENCE

Absorb
Patients with Diabetes
vs.
Absorb
Patients without Diabetes



Dr. Muramatsu, TCT 2013

ABSORB EXTEND / XIENCE V
Propensity Score Matched Aalysis

BEFORE
Propensity Matched

812 ABSORB EXTEND

6074 XIENCE
- SPIRIT II
- SPRIIT III
- SPIRIT IV*
- XIENCE V

Case-controlled
1:1 match ratio

AFTER
Propensity Matched

812 Absorb

812 XIENCE

ABSORB EXTEND / XIENCE V

Propensity Score Matched 1 Year Clinical Outcomes

	Absorb (EXTEND, N = 812)	XIENCE V (N = 812)	P Value
NON-HIERARCHICAL COMPONENTS			
Cardiac Death %	0.7	0.6	0.80
Myocardial Infarction %	3.3	1.5	0.02
Ischemia Driven TLR %	2.3	3.0	0.38
MACE %	5.0	4.8	0.83
TVF %	5.5	6.2	0.57
TLF %	5.0	4.7	0.74
Scaffold Thrombosis (ARC Def/Prob) %	1.0	0.3	0.11

A. Abizaid – EuroPCR 2015

Propensity Score Matched Analysis of Site Diagnosed Angina
Significant Difference in SDA at 1-Year

Unadjusted

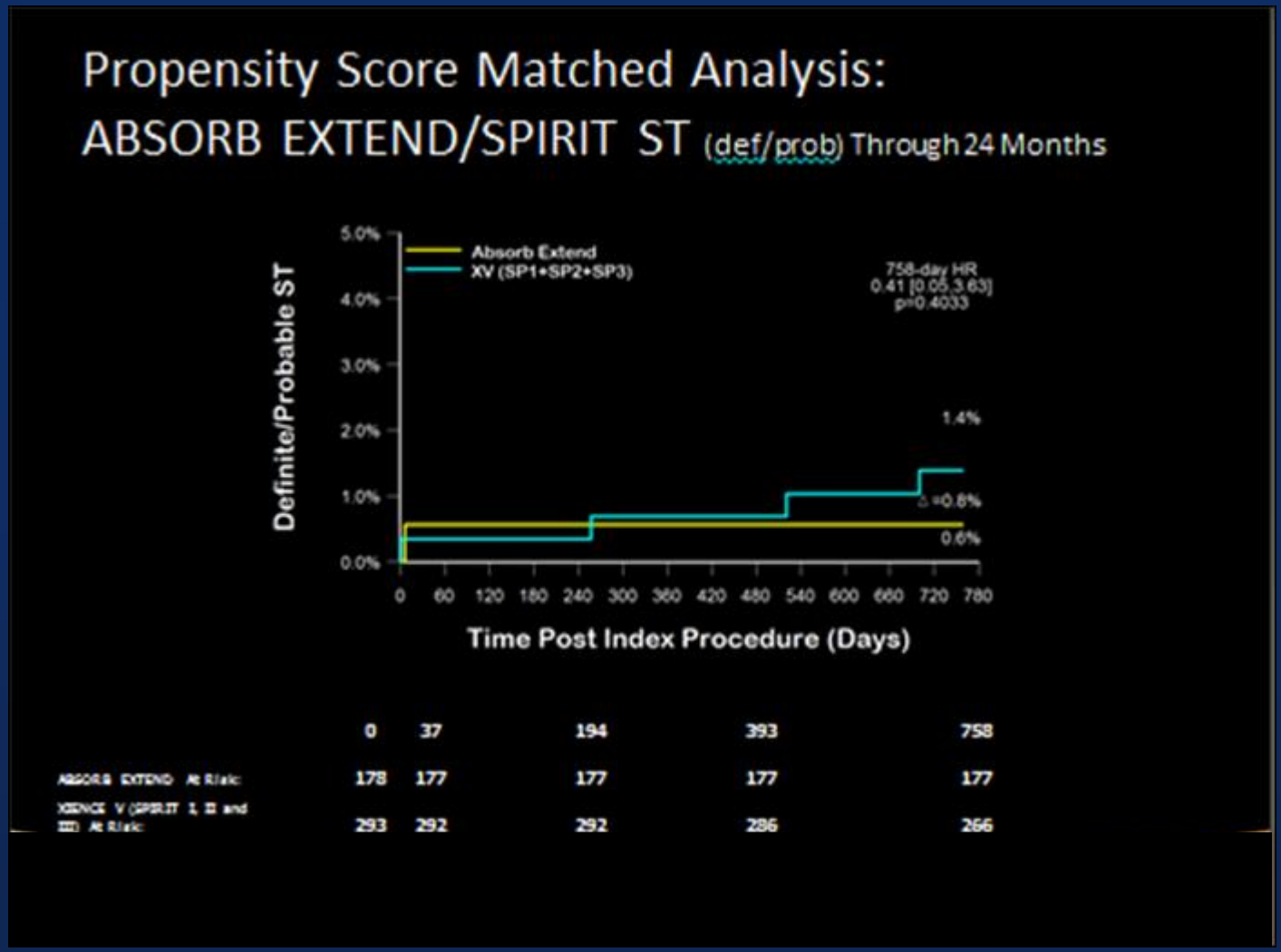
Unadjusted	Absorb (EXTEND)	XIENCE V (SPIRIT IV)	Difference [CI]
1-Year	15.9% (60/378)	27.1% (542/2000)	11.2% [7.1%, 15.4%]

Propensity Score Matched

PS Matched	Absorb (EXTEND)	XIENCE V (SPIRIT IV)	Difference [CI]
1-Year	16.0% (46/287)	27.9% (168/602)	11.9% [6.3%, 17.4%]

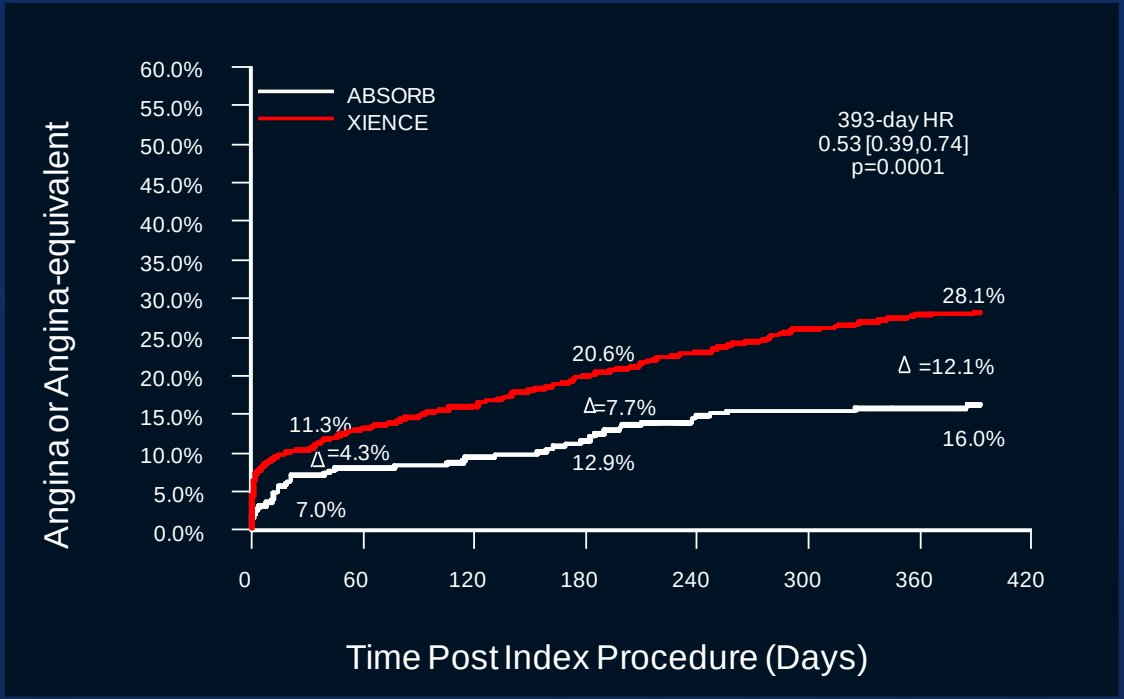
Dr. Stone, TCT 2013

Propensity Score Analysis ABSORB EXTEND vs. SPIRIT I/II/III
Definite/Probable ST Through 24-Months – R. Whitbourn
Absorb has comparable safety to XIENCE



Dr. Whitbourn, TCT 2013

Absorb Propensity Score-Matched Angina Through 1-Year ABSORB EXTEND vs. SPIRIT IV

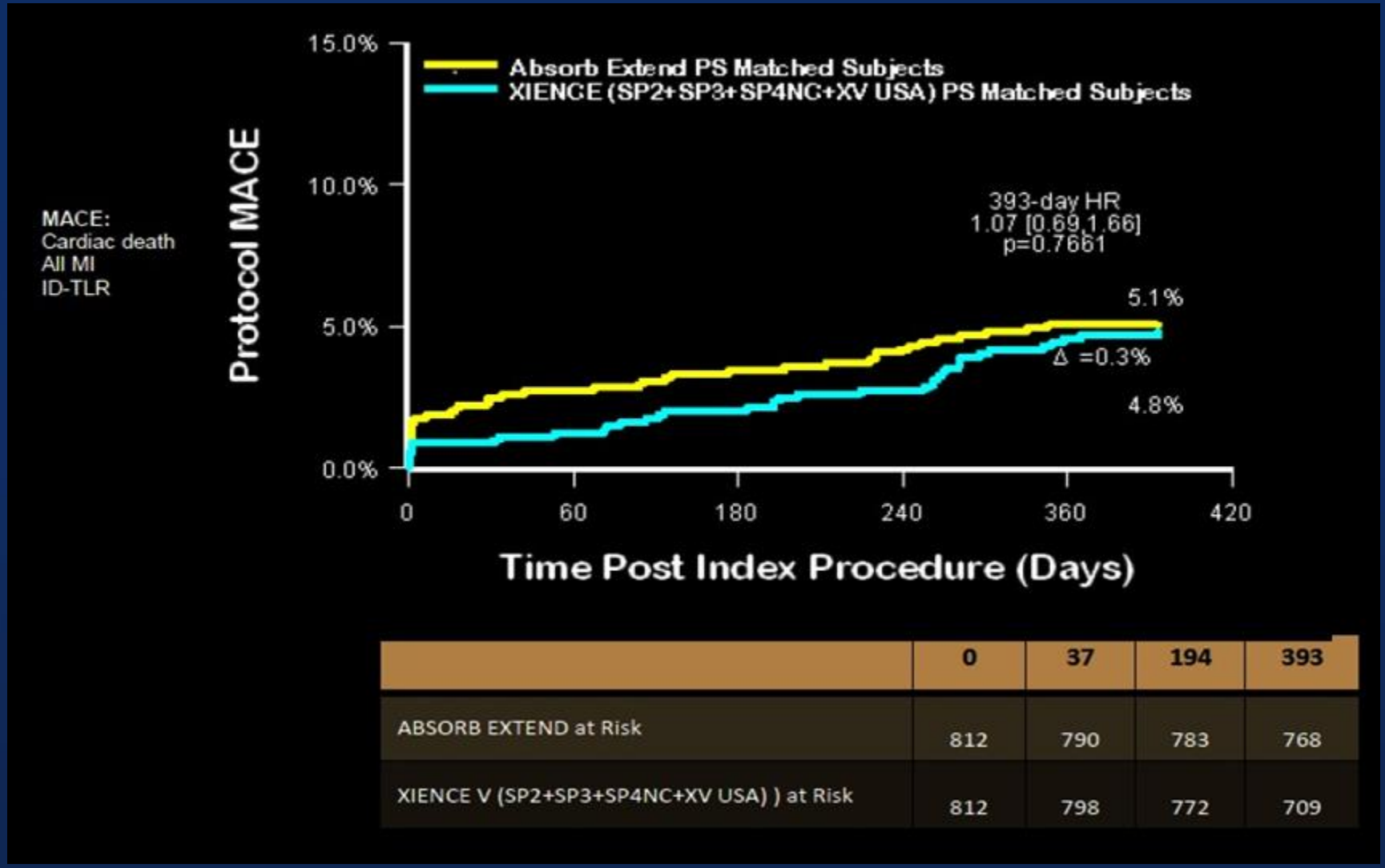


Time post-Index Procedure (days)	0	37	194	393
Absorb Subjects At Risk:	287	267	250	240
# Events	5	20	37	46
XIENCE Subjects At Risk:	602	535	478	429
# Events	26	68	124	169

Dr. Stone, TCT 2013

ABSORB EXTEND / XIENCE V

Propensity Matched 1 Year Clinical Outcomes



	0	37	194	393
ABSORB EXTEND at Risk	812	790	783	768
XIENCE V (SP2+SP3+SP4NC+XV USA)) at Risk	812	798	772	709

ABSORB II RCT

501 subjects
(Randomized 2:1 Absorb versus XIENCE PRIME) Up to 40 European sites

Study Objective	Randomized against XIENCE PRIME control. FPI 28-Nov-2011
Co-primary Endpoints	• Vasomotion assessed by change in Mean Lumen Diameter between pre- and post-nitrate at 2 years (superiority) • Minimum Lumen Diameter (MLD) at 2 years post nitrate minus MLD post procedure post nitrate (non-inferiority, reflex to superiority)
Treatment	Up to 2 *de novo* lesions in different epicardial vessels Planned overlapping allowed in lesions ≤ 48 mm

ABSORB II

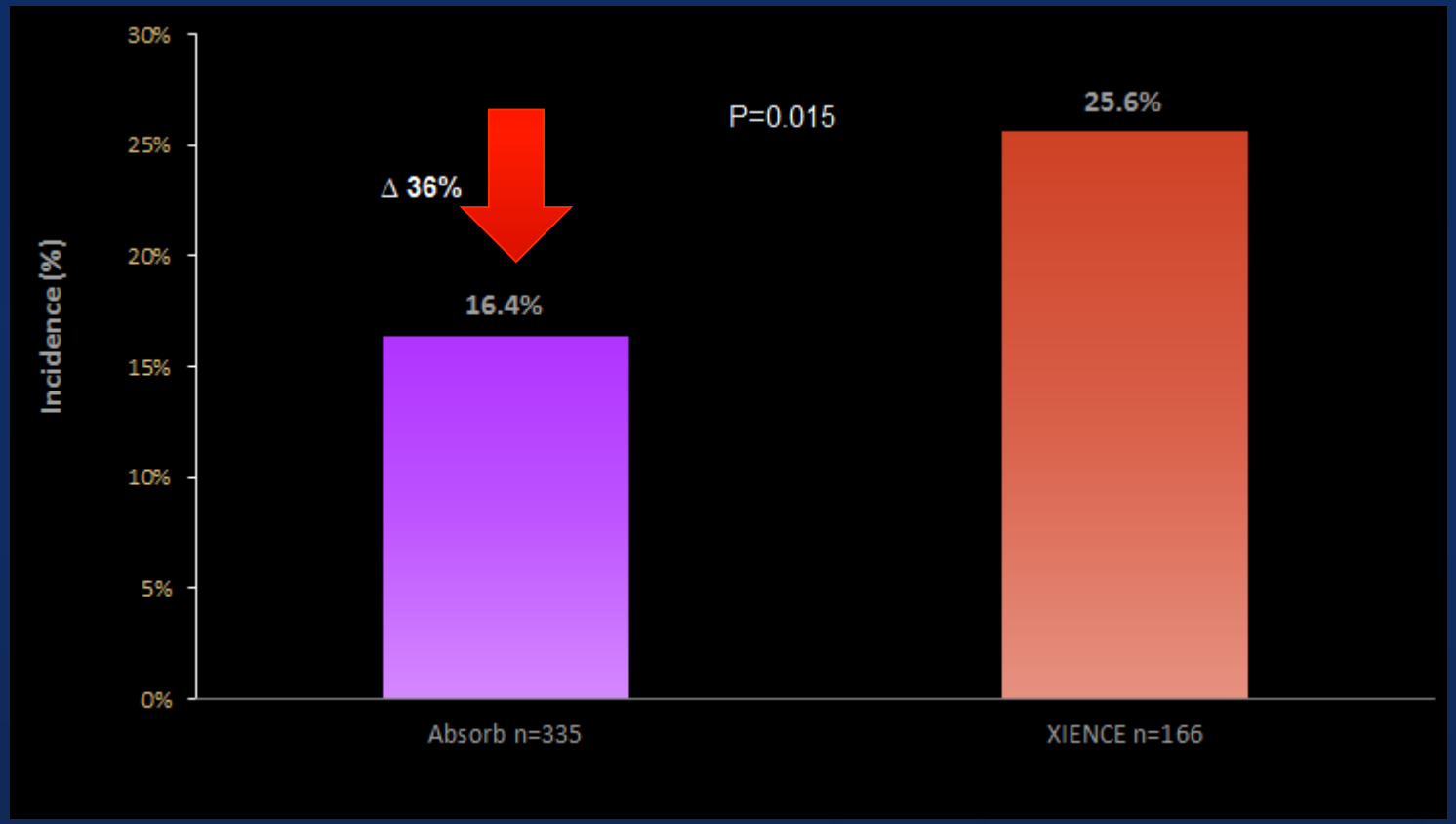
One Year Clinical Results

	Absorb (N=335 patients)	XIENCE (N=166 patients)	P-value
DoCE (Device-Oriented Composite Endpoint)	**4.8**	**3.0**	**0.35**
Cardiac Death (%)	0	0	1.00
Target Vessel MI (%)	4.2	1.2	0.07
Clinically Indicated TLR (%)	1.2	1.8	0.69
All TLR (%)	1.2	1.8	0.69
Definite Scaffold/Stent Thrombosis (%)	0.6	0.0	1.00
PoCE (Patient-Oriented Composite Endpoint)	**7.3**	**9.1**	**0.47**
All Death (%)	0	0.6	0.33
All MI (%)	4.5	1.2	0.06
All NQMI (%)	3.9	1.2	0.16
All QMI (%)	0.6	0	1.00
All Revascularizations (%)	3.6	7.3	0.08

P.W. Serruys, TCT 2014

ABSORB II

One Year Angina Outcome



P.W. Serruys, TCT 2014

ABSORB II 2-years

	2 years		
	Absorb BVS N=335	XIENCE N=166	*p* value
Death* (%)	1.2	0.6	0.67
Cardiac	0.6	0.0	0.55
Non cardiovascular	0.6	0.6	1.00
Myocardial Infarction (%)	5.8	2.4	0.10
Q-wave	1.5	0.6	0.67
Non Q-wave	4.3	1.8	0.16
Definite/Probable ST* (%)	1.5	0.0	0.17
Acute/sub-acute (0-30 days)	0.6	0.0	1.00
Late (31-365 days)	0.3	0.0	1.00
Very late (365 – 758 days)	0.6	0.0	0.55
TLR (%)	2.7	1.8	0.76
NTL-TVR (%)	1.5	2.4	0.49
NTVR (%)	2.7	5.5	0.13
All revascularization	5.8	9.1	0.17

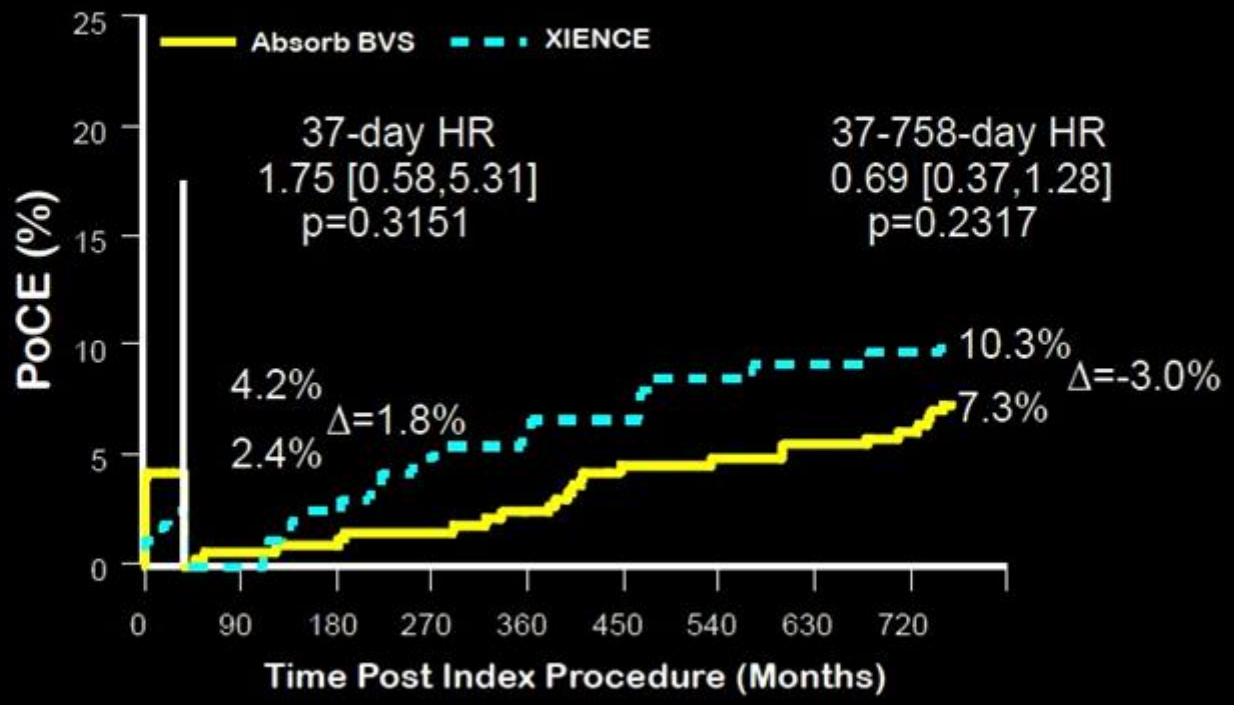
ABSORB II 2-years

	Absorb BVS N=335	XIENCE N=166	*p* value
PoCE (%)	11.6	12.8	0.70
MACE (%)	7.6	4.3	0.16
DoCE, TLF (%)	7.0	3.0	0.07
TVF (%)	8.5	6.7	0.48

PoCE (Patient oriented Composite Endpoint):
All death, all myocardial infarction, and all revascularisation
MACE (Major Adverse Cardiac Events):
Cardiac death, all myocardial infarction, and clinically indicated target-lesion revascularisation (TLR)
DoCE (Device oriented Composite Endpoint)/ TLF (Target Lesion Failure):
Cardiac death, target-vessel myocardial infarction, and clinically indicated target-lesion revascularisation (TLR)
TVF (Target Vessel Failure):
Cardiac death, all myocardial infarction, clinically indicated target-vessel revascularisation (TVR)

ABSORB II 2-years

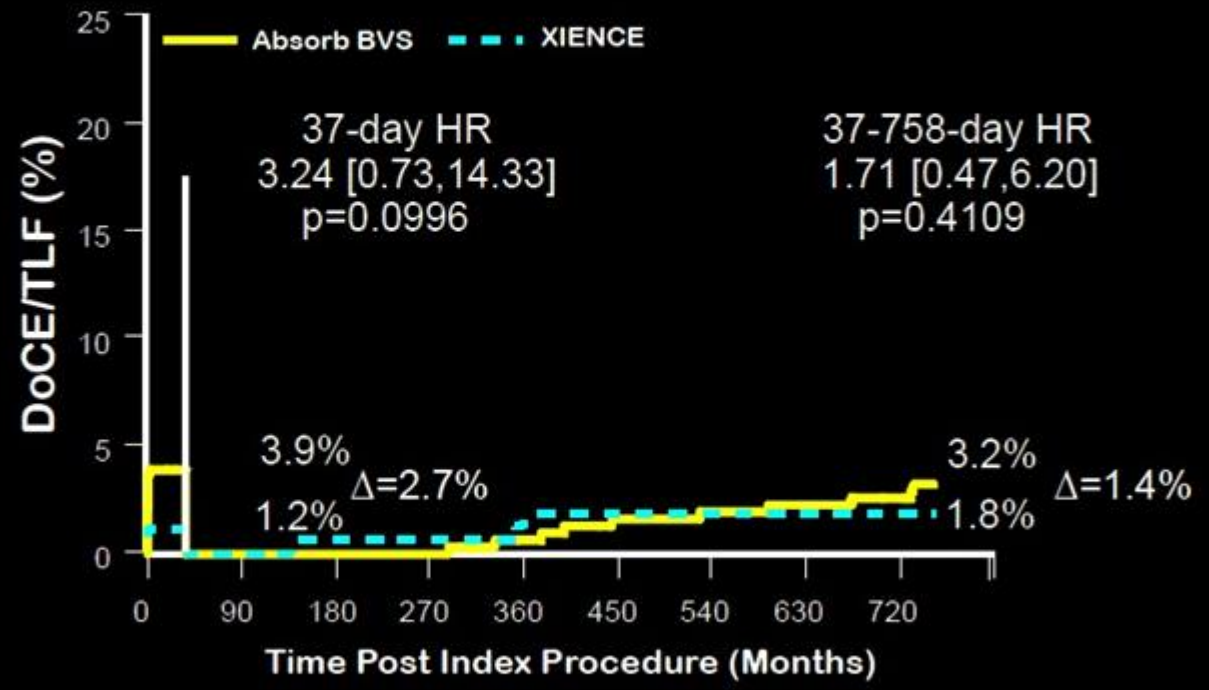
Patient oriented Composite Endpoint (PoCE)



PoCE: All death, all myocardial infarction, and all revascularisation

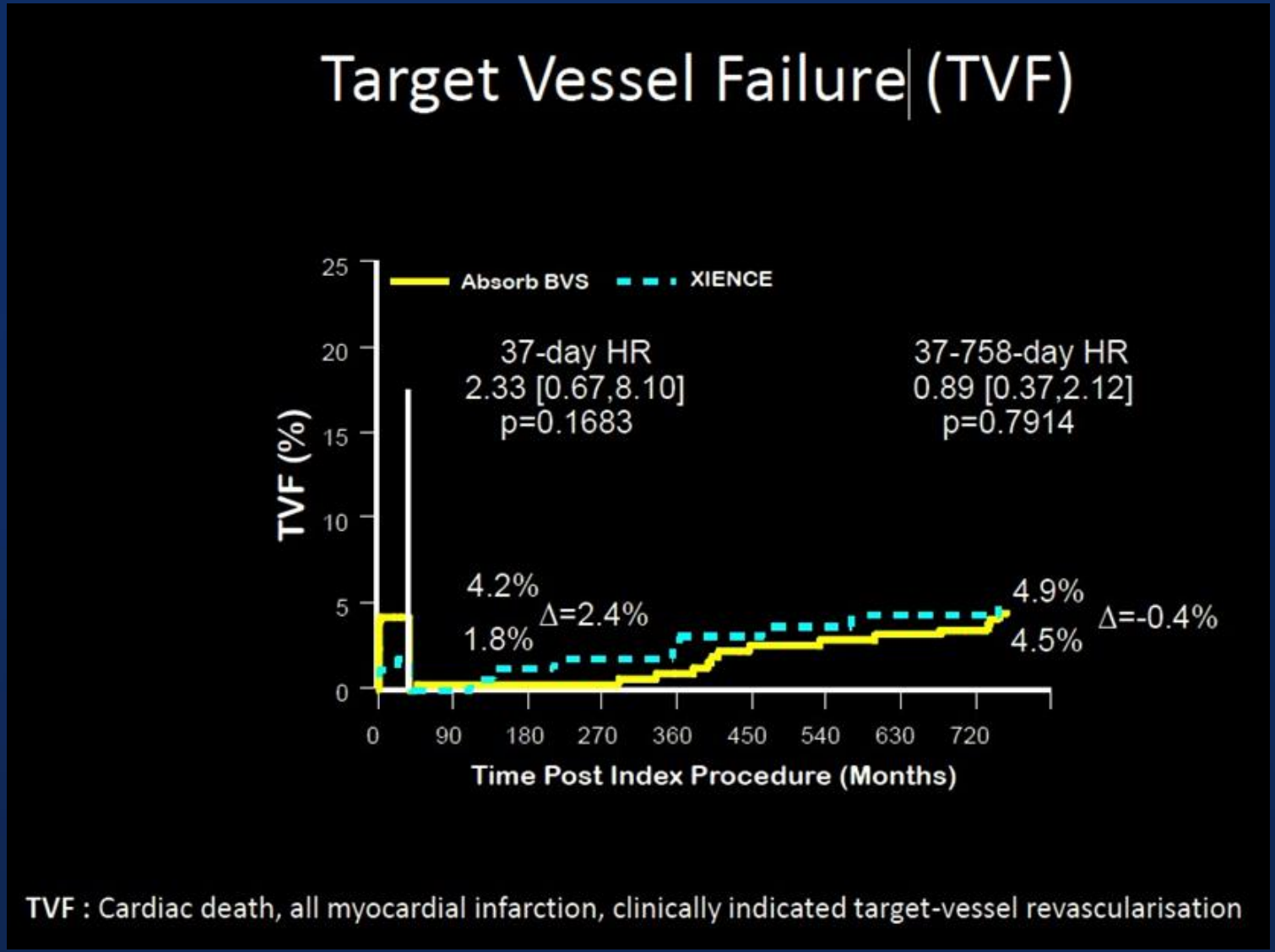
ABSORB II 2-years

Device oriented Composite Endpoint (DOCE)/ Target Lesion Failure (TLF)



DoCE/TLF : Cardiac death, target-vessel myocardial infarction, and clinically indicated target-lesion revascularisation (TLR)

ABSORB II 2-years

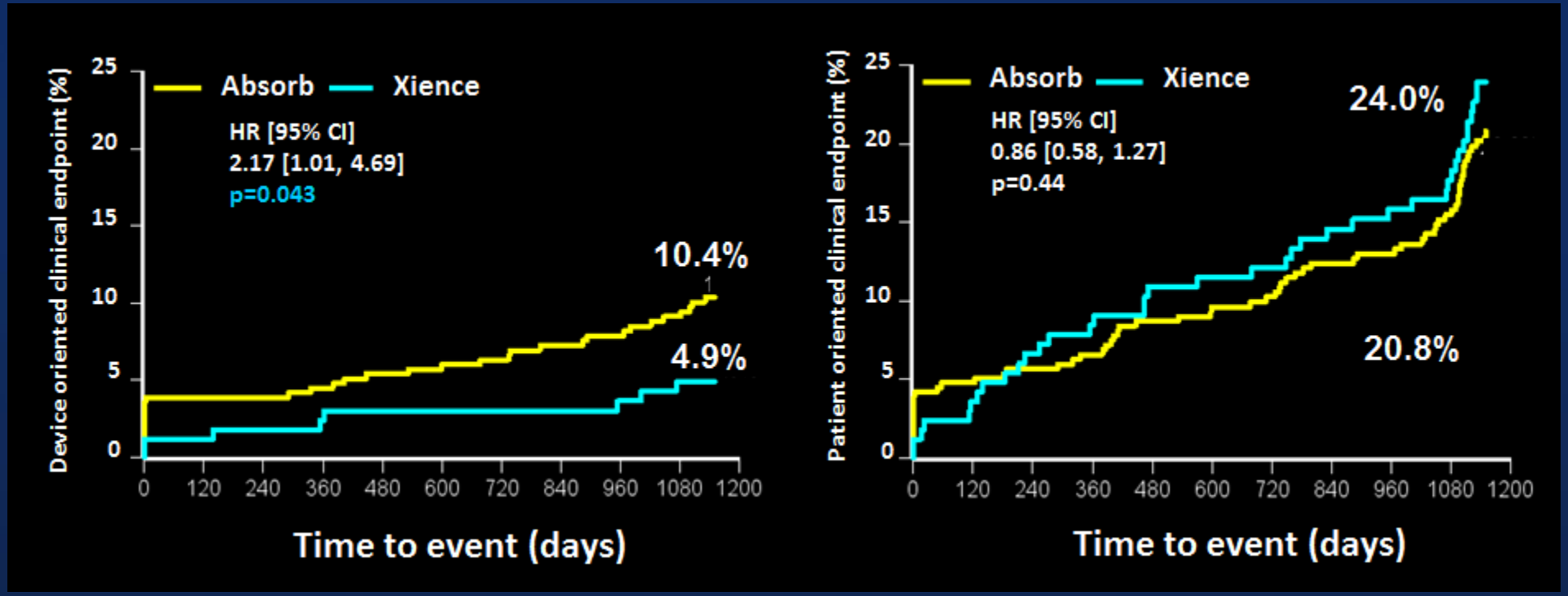


TVF : Cardiac death, all myocardial infarction, clinically indicated target-vessel revascularisation

ABSORB II 3-years

Device-Oriented Composite Endpoints (Cardiac Death, TV-MI, CI-TLR)

Patient-Oriented Composite Endpoints (Any Death, Any-MI, Any Revascularization)



Lancet 2016; 388: 2479–911

ABSORB II 3-years

Scaffold or Stent Thrombosis

	Absorb 335 patients	Xience 166 patients	p value
Definite	2·5% (8)	0·0% (0)	0·06
Acute (0–1 day)	0·3% (1)	0·0% (0)	1·0
Sub-acute (2–30 days)	0·3% (1)	0·0% (0)	1·0
Late (31–365 days)	0·0% (0)	0·0% (0)	1·0
Very late (>365 days)	1·8% (6)	0·0% (0)	0·19
Definite or probable	2·8% (9/320)	0·0% (0/159)	0·03
Acute (0–1 day)	0·3% (1)	0·0% (0)	1·0
Sub-acute (2–30 days)	0·3% (1)	0·0% (0)	1·0
Late (31–365 days)	0·3% (1)	0·0% (0)	1·0
Very late (>365 days)	1·8% (6)	0·0% (0)	0·19

Lancet 2016; 388: 2479–911

ABSORB II 3-years

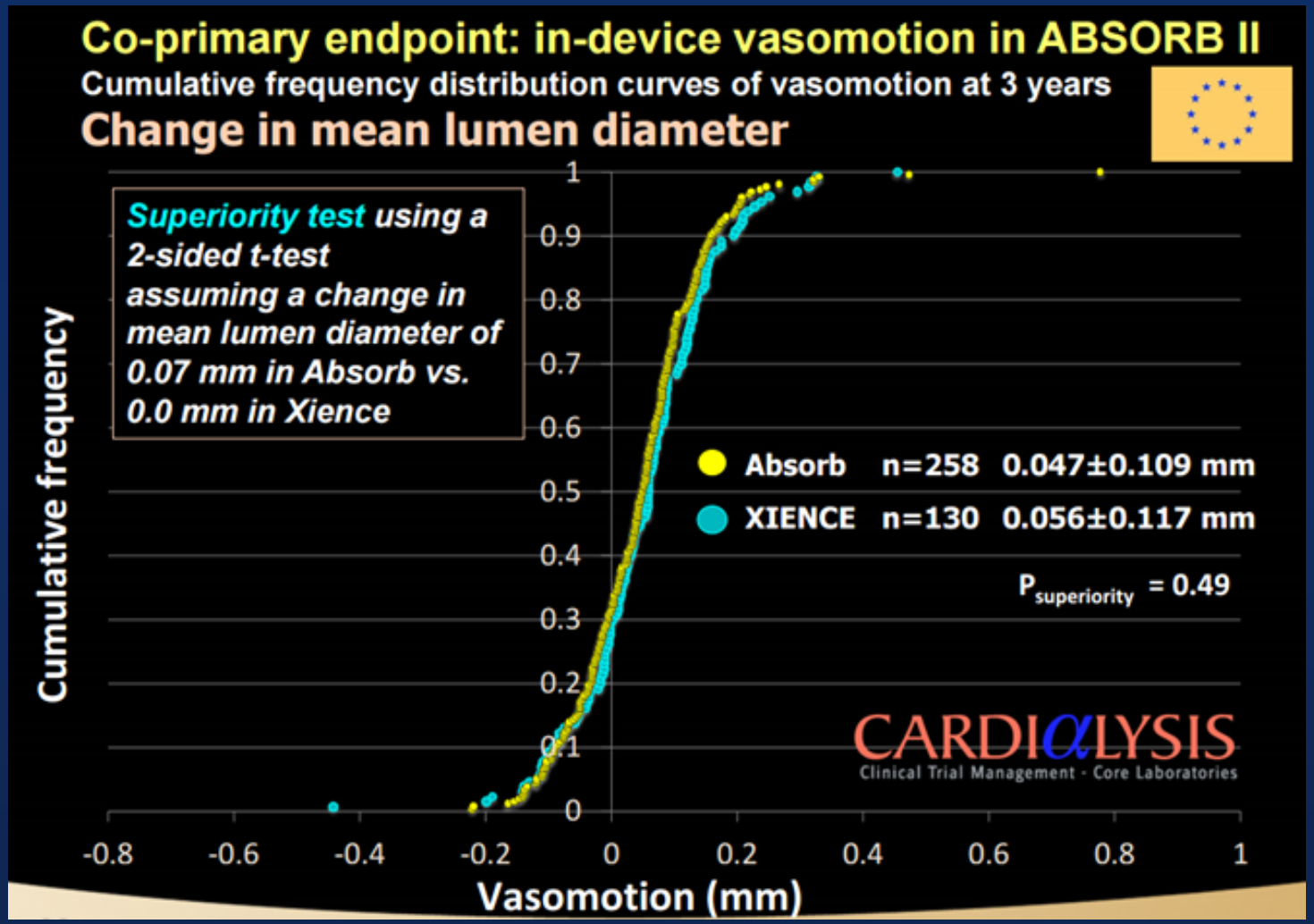
Secondary Clinical Endpoints

	Absorb 325 patients	Xience 161 patients	Relative Risk	p value
Device-oriented composite endpoint [DOCE]	10.5%	5.0%	2·11 [1·00, 4·44]	0·04
Cardiac death	0.9%	1.9%	0·50 [0·10, 2·43]	0·40
Target vessel MI	7.1% (23)	1.2% (2)	5.70 [1.36, 23.87]	0.0061
Periprocedural MI (WHO)	3.9%(13)	1.2% (2)	3.22 [0.74, 14.11]	0.16
Spontaneous MI (WHO extended)	3.1% (10)	0% (0)	NC [NC]	0.06
Clinically indicated TLR	6.2%(20)	1.9% (3)	3.30 [1.00, 10.95]	0.036
Patient-oriented composite endpoint [POCE]	20.9%	24.2%	0·86 [0·61, 1·22]	0·40
All-cause death	2.5%	3.7%	0·66 [0·23, 1·87]	0·57
Any MI	8.3%	3.1%	2.68 [1.05, 6.82]	0.03
Any revascularization	15.1%	20.5%	0.74 [0.49, 1.10]	0.13

Lancet 2016; 388: 2479–911

ABSORB II 3-years

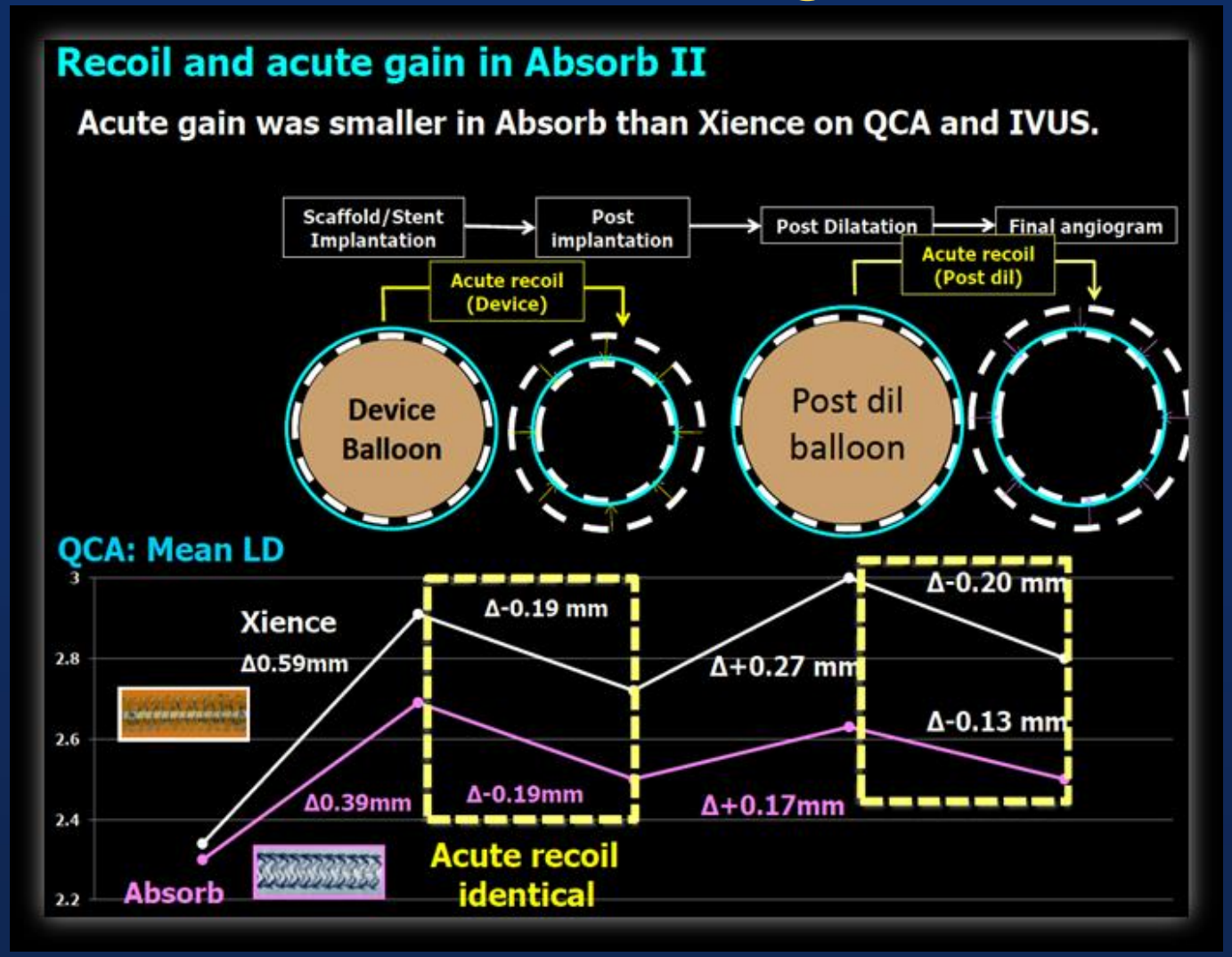
In-device Vasomotion



PW Serruy, TCT 2016

ABSORB II 3-years

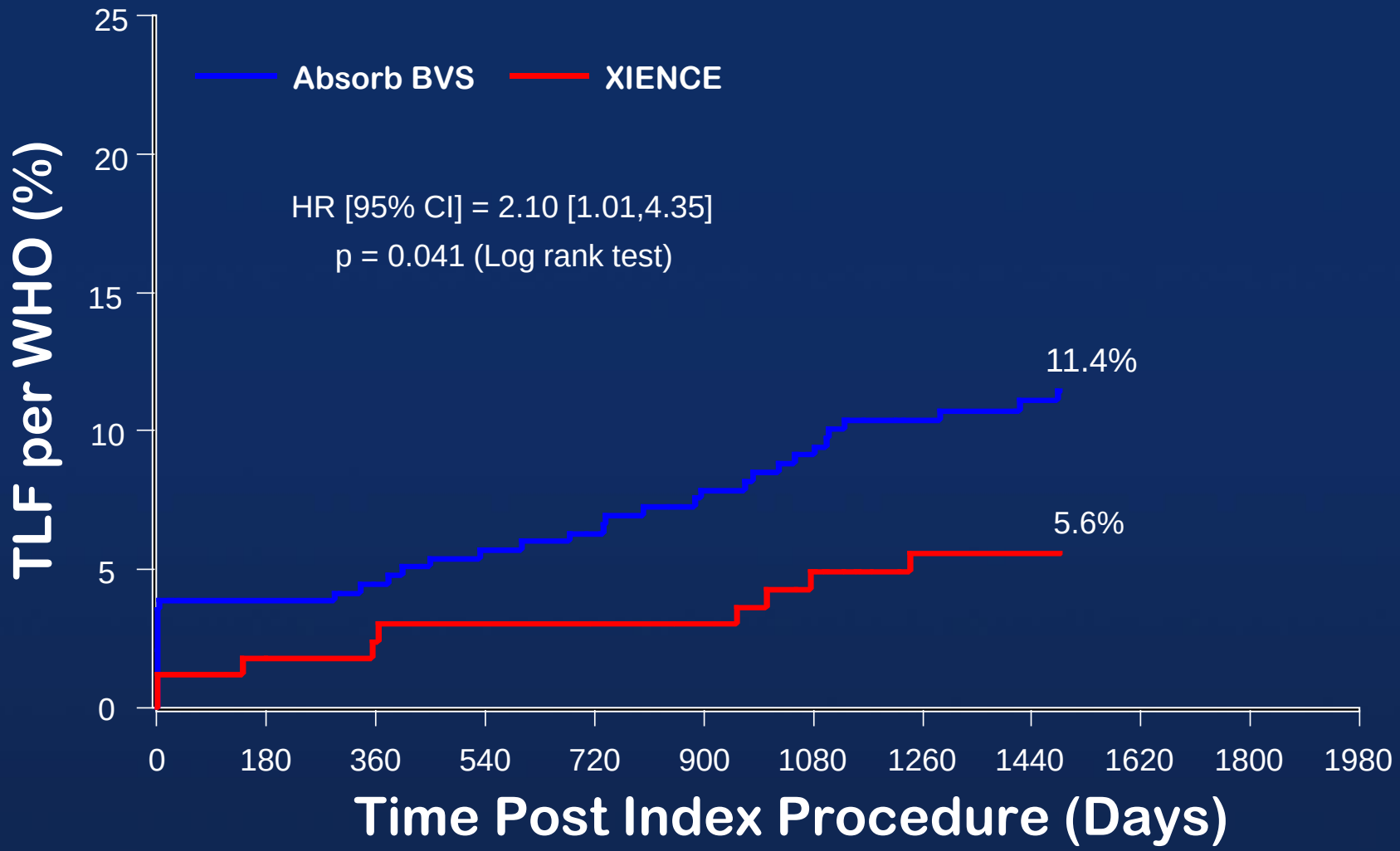
Radial Strength



Serruys, PW. JIM 2016

ABSORB II 4-years

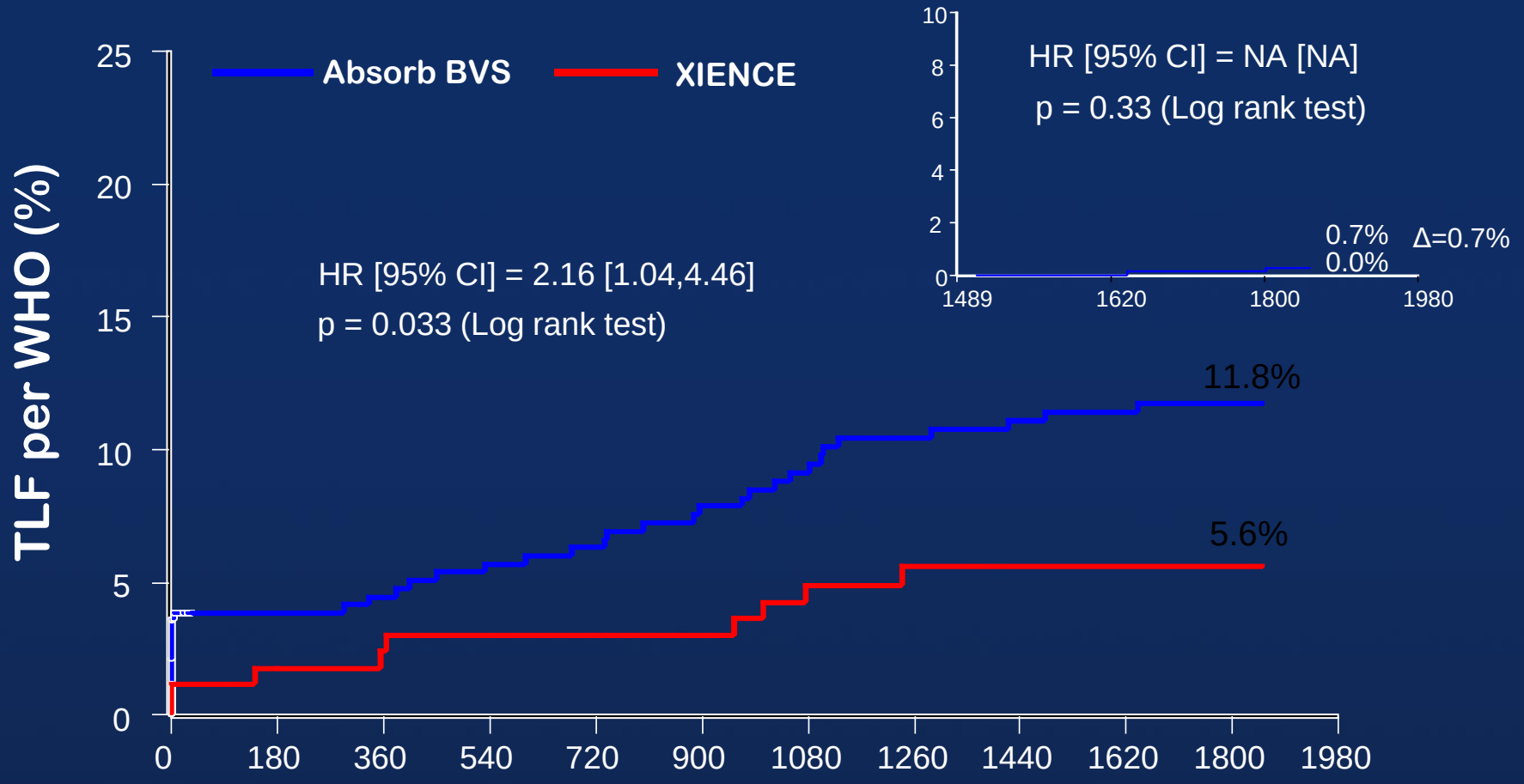
Device-oriented Composite Endpoint(DoCE) at 4 Years
Target Lesion Failure (TLF)



CI=confidence interval, DoCE=device-oriented composite endpoint, HR=hazard ratio, TLF=target lesion failure, WHO=World Health Organization

ABSORB II 5-years

Device-oriented Composite Endpoint (DoCE) at 5 Years
Target Lesion Failure (TLF)



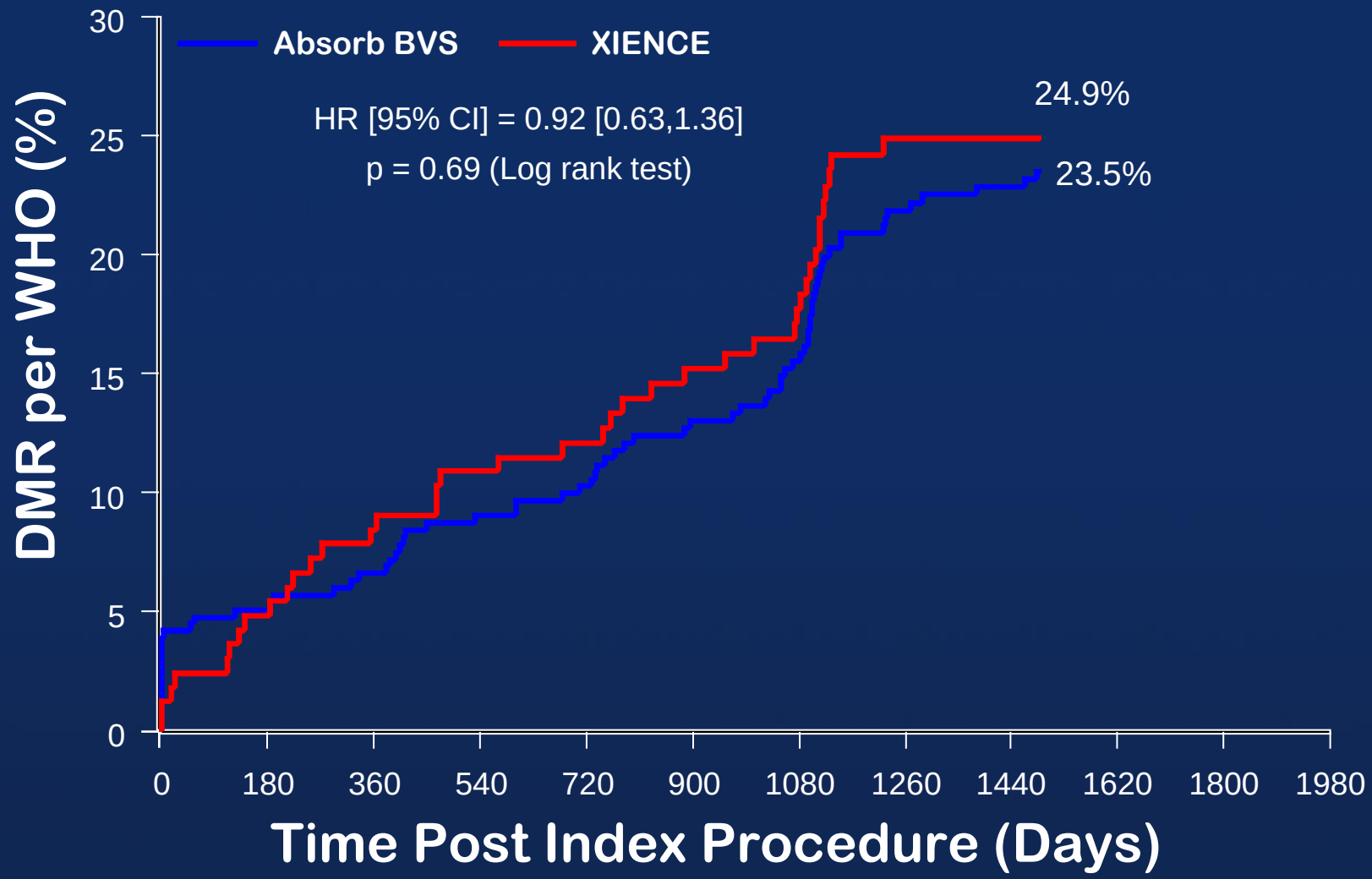
Time Post Index Procedure (Days)

DoCE/TLF : Cardiac death, target-vessel myocardial infarction, and clinically indicated target-lesion revascularisation (TLR)

CI=confidence interval, DoCE=device-oriented composite endpoint, HR=hazard ratio, TLF=target lesion failure, WHO=world health organization

ABSORB II 4-years

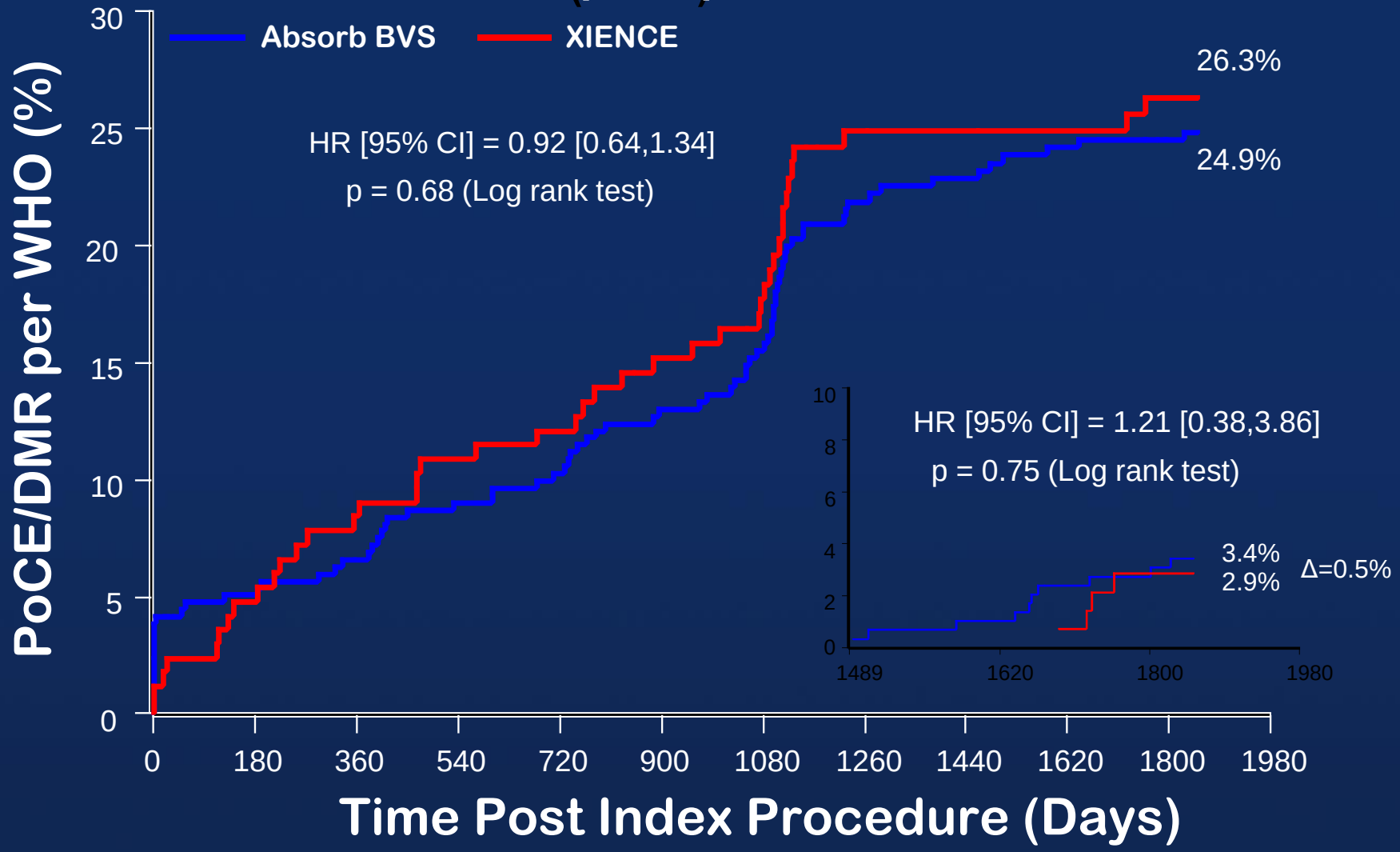
Patient-oriented Composite Endpoint at 4 Years (PoCE) / DMR



CI=confidence interval, HR=hazard ratio, PoCE=DMR: All Death, all Myocardial infarction, and all Revascularization, WHO=World Health Organization

ABSORB II 5-years

Patient-oriented Composite Endpoint at 5 Years (PoCE) / DMR



ABSORB II 5-years

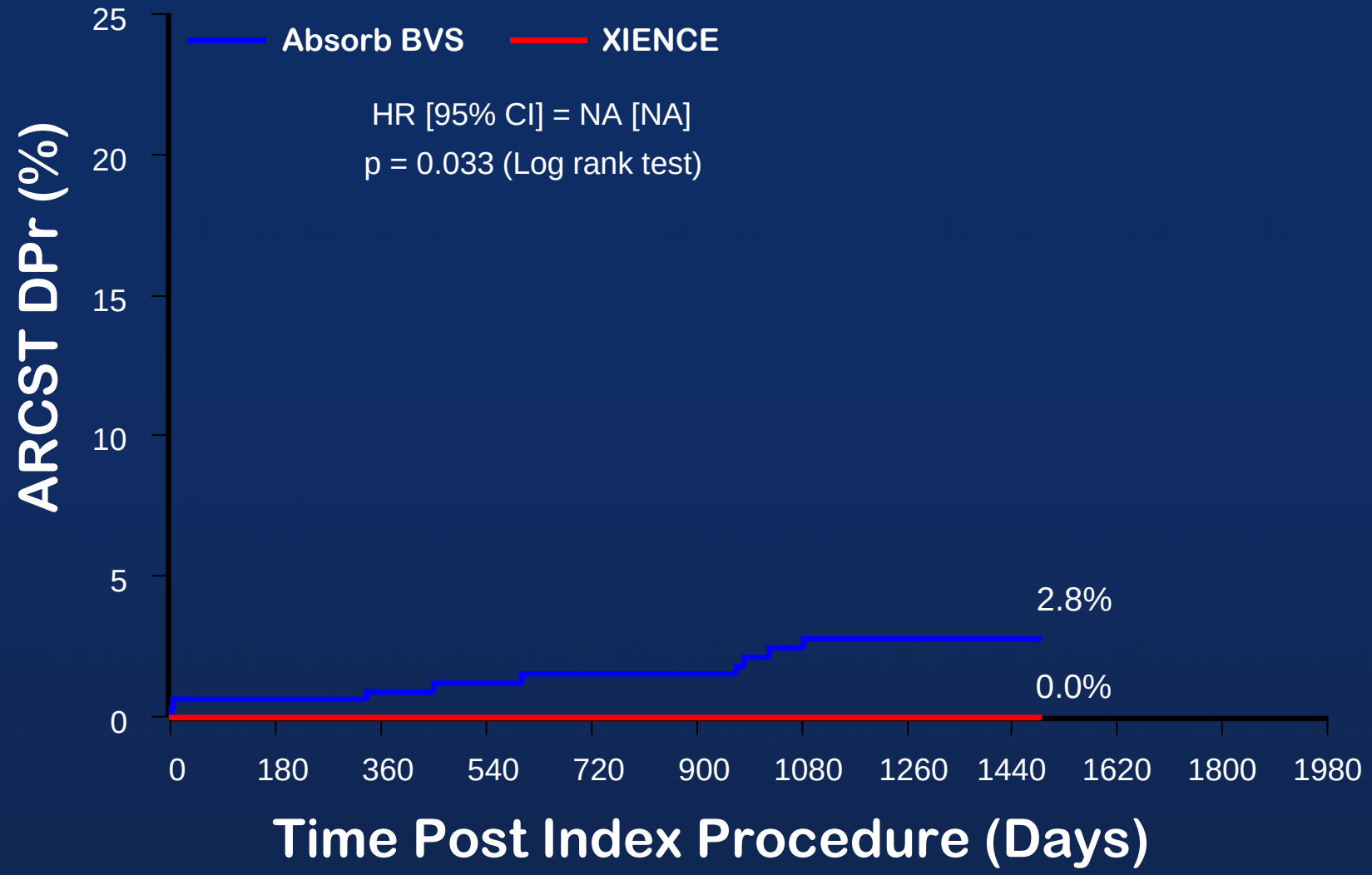
Clinical Outcomes Composite Endpoints at 5 Years

	Absorb BVS N=335	XIENCE N=166	*p* value
PoCE (%)	26.3	28.6	0.6132
MACE (%)	13.5	8.8	0.1545
DoCE, TLF (%)	12.5	6.1	0.0377
TVF (%)	15.5	15.0	0.8912

PoCE (Patient-oriented Composite Endpoint):
All death, all myocardial infarction, and all revascularisation
MACE (Major Adverse Cardiac Events):
Cardiac death, all myocardial infarction, and clinically indicated target-lesion revascularisation (TLR)
DoCE (Device-oriented Composite Endpoint)/ TLF (Target Lesion Failure):
Cardiac death, target-vessel myocardial infarction, and clinically indicated target-lesion revascularisation (TLR)
TVF (Target Vessel Failure):
Cardiac death, all myocardial infarction, clinically indicated target-vessel revascularisation (TVR)

ABSORB II 4-years

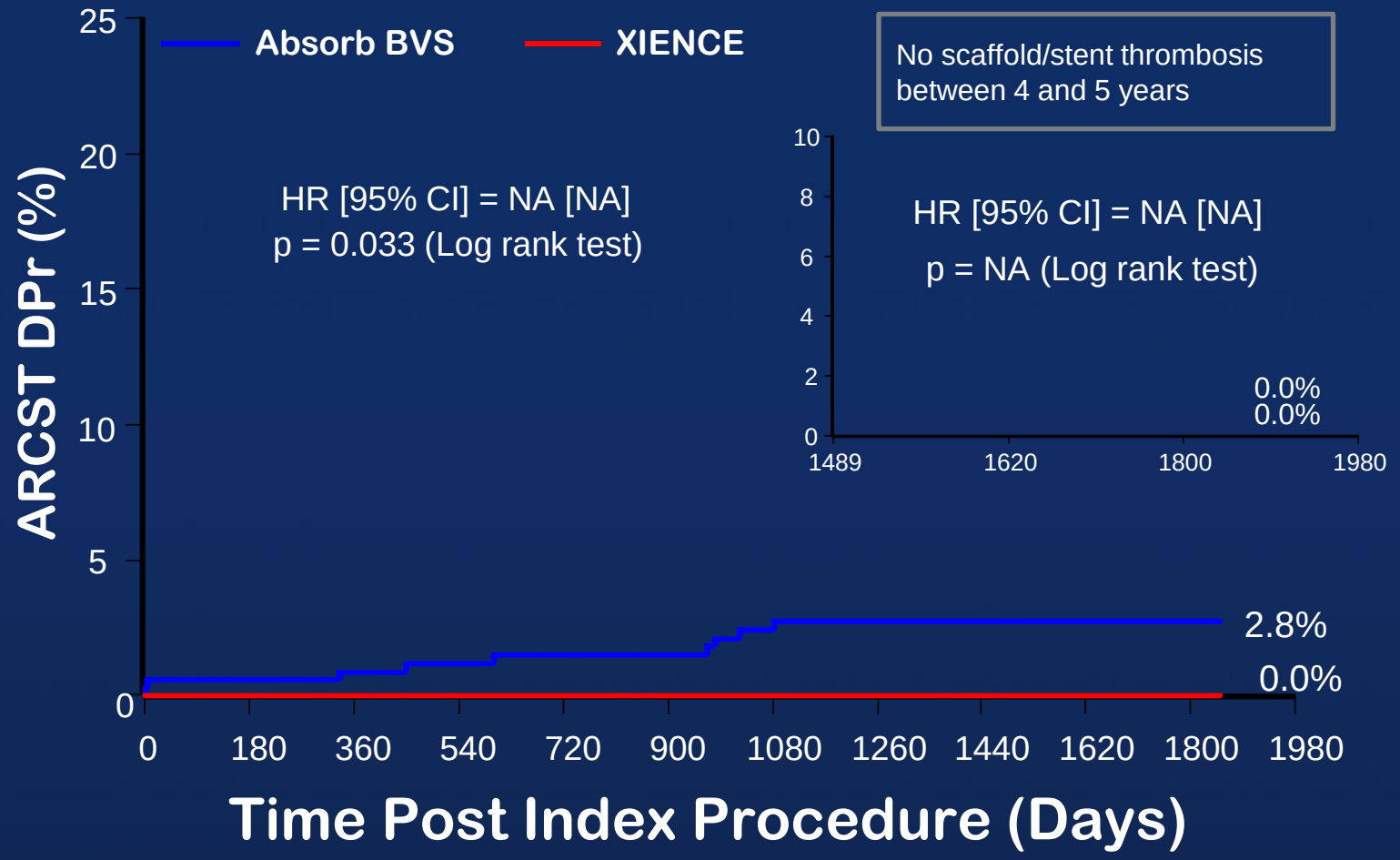
Definite/Probable Scaffold/Stent Thrombosis* at 4 Years



ARCST=academic research consortium scaffold/stent thrombosis, CI=confidence interval, DPr=definite/probable, HR=hazard ratio, NA=not applicable

ABSORB II 5-years

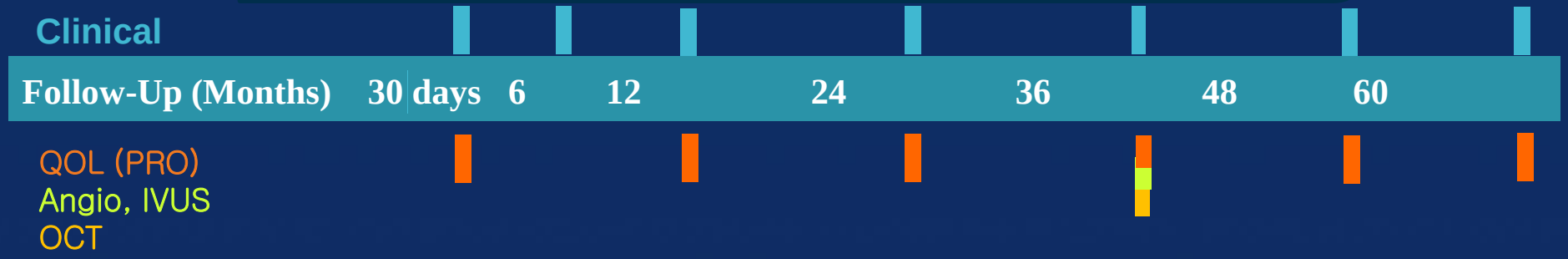
Definite/Probable Scaffold/Stent Thrombosis* at 5 Years



ARCST=academic research consortium scaffold/stent thrombosis, CI=confidence interval, DPr=definite/probable, HR=hazard ratio, NA=not applicable

ABSORB III RCT

~2250 subjects in up to 220 sites (predominantly US)
Lead-in (n≤50); Clinical (n~2000); Imaging (n~200)
PI: Dean Kereiakes, Steve Ellis; Chairman: Gregg Stone



Study Objective	Randomized against XIENCE control. 2:1. FPI Lead-in 28 Dec 201230
Primary Endpoint	Target Lesion Failure at 1 year, non-inferiority to XIENCE (n~2000)
Major Secondary Endpoints	• Vasomotion assessed by change in angiographic Mean Lumen Diameter between pre- and post-nitrate at 3 years (superiority) • Change in Mean Lumen Area by IVUS, from post-procedure to 3 years (Mean Lumen Area measured post-nitrate, superiority)
Treatment	Up to 2 *de novo* lesions in different epicardial vessels, Lesion lengths ≤ 24 mm, RVD ≥ 2.5 mm and ≤ 3.75 mm

ABSORB III

Baseline Characteristics

Characteristic	Absorb (N=1322)	Xience (N=686)	p-value
Age (mean)	63.5 ±10.6	63.6±10.3	0.75
Male	70.7%	70.1%	0.80
Race (Caucasian)	87.1%	88.3%	0.44
Current tobacco use	21.3%	20.7%	0.77
Hypertension	84.9%	85.0%	0.95
Dyslipidemia	86.2%	86.3%	0.97
Diabetes	31.5%	32.7%	0.60
Insulin-treated	10.5%	11.2%	0.60
Prior MI	21.5%	22.0%	0.79
Prior coronary intervention	38.7%	38.0%	0.75
Stable angina	57.3%	60.8%	0.13
Unstable angina	26.9 %	24.5%	0.25
Silent ischemia	10.0%	10.2%	0.88
Single vessel disease	69.5%	67.2%	0.29

Kereiakes D, ABSORB III trial, TCT 2015

ABSORB III

Angiographic Characteristics

Characteristic	Absorb (N=1322) (L=1385)	Xience (N=686) (L=713)	p-value
ACC/AHA lesion class B2/C	68.7%	72.5%	0.08
# of target lesions treated	1.0 ± 0.2	1.0 ± 0.2	0.38
One	95.1%	96.1%	0.32
Two	4.8%	3.9%	0.36
Target lesion			
LAD	44.5%	42.2%	0.31
RCA	29.2%	27.2%	0.35
Circumflex	26.2%	30.6%	0.03
Lesion length, mm	12.60 ± 5.41	13.12 ± 5.82	0.05
RVD, mm	2.67 ± 0.45	2.65 ± 0.46	0.36
RVD <2.25 mm	18%	19%	0.39
MLD, mm	0.92 ± 0.37	0.90 ± 0.34	0.11
%DS	65.3 ± 12.5	65.9 ± 11.7	0.24

Kereiakes D, ABSORB III trial, TCT 2015

ABSORB III

Procedural Characteristics

Characteristic	Absorb (N=1322) (L=1385)	Xience (N=686) (L=713)	p-value
Per Subject			
Bivalirudin use	60.7%	58.7%	0.39
GP IIb/IIIa inhibitor use	10.1%	12.4%	0.11
Only unassigned devices implanted	4.4%	0.6%	<0.001
Unplanned overlapping devices	6.2%	8.5%	0.06
Post-dilatation performed	65.5%	51.2%	<0.001
Intravascular imaging guidance	11.2%	10.8%	0.81
Procedure duration (min)	42.2 ± 23.1	38.3 ± 20.9	<0.001
Per Lesion			
Total study device length (mm)	20.5 ± 7.2	20.7 ± 9.0	0.56
Max device/balloon diameter (mm)	3.18 ± 0.43	3.12 ± 0.45	0.007
Max device/balloon to vessel diameter ratio	1.21 ± 0.15	1.19 ± 0.14	0.05
Maximum device/balloon pressure (atm.)	15.4 ± 3.0	15.4 ± 3.2	0.83

Kereiakes D, ABSORB III trial, TCT 2015

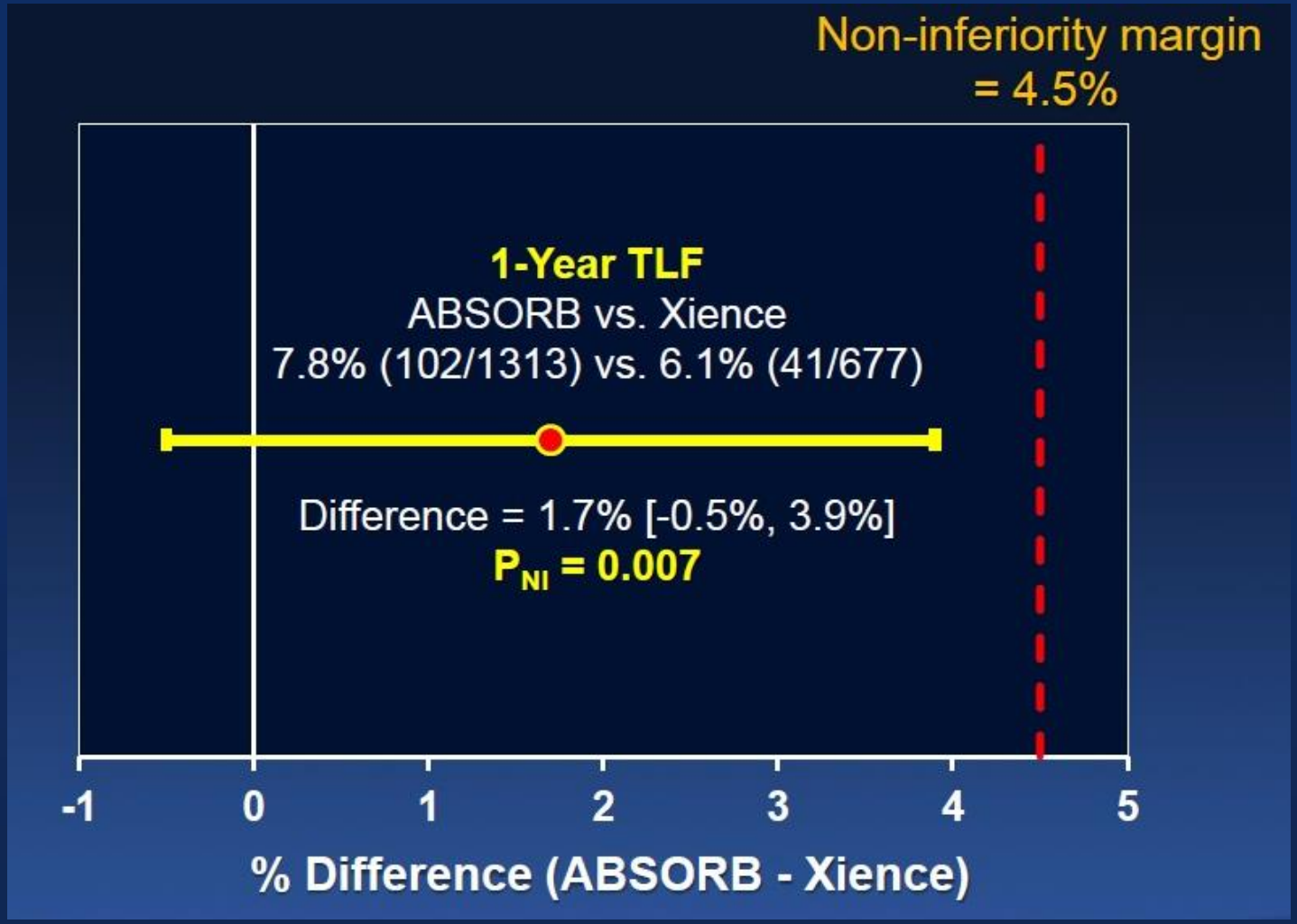
ABSORB III

Postprocedural QCA

Measurement	Absorb (N=1322) (L=1385)	Xience (N=686) (L=713)	p-value
RVD	2.70 ± 0.45	2.68 ± 0.47	0.33
In-Device			
MLD	2.37 ± 0.40	2.49 ± 0.40	<0.0001
Acute gain	1.45 ± 0.45	1.59 ± 0.44	<0.0001
%DS	11.6 ± 8.77	6.4 ± 8.91	<0.0001
In-Segment			
MLD	2.15 ± 0.41	2.14 ± 0.43	0.58
Acute gain	1.23 ± 0.46	1.24 ± 0.44	0.50
%DS	20.0 ± 7.94	19.8 ± 8.20	0.55

Kereiakes D, ABSORB III trial, TCT 2015

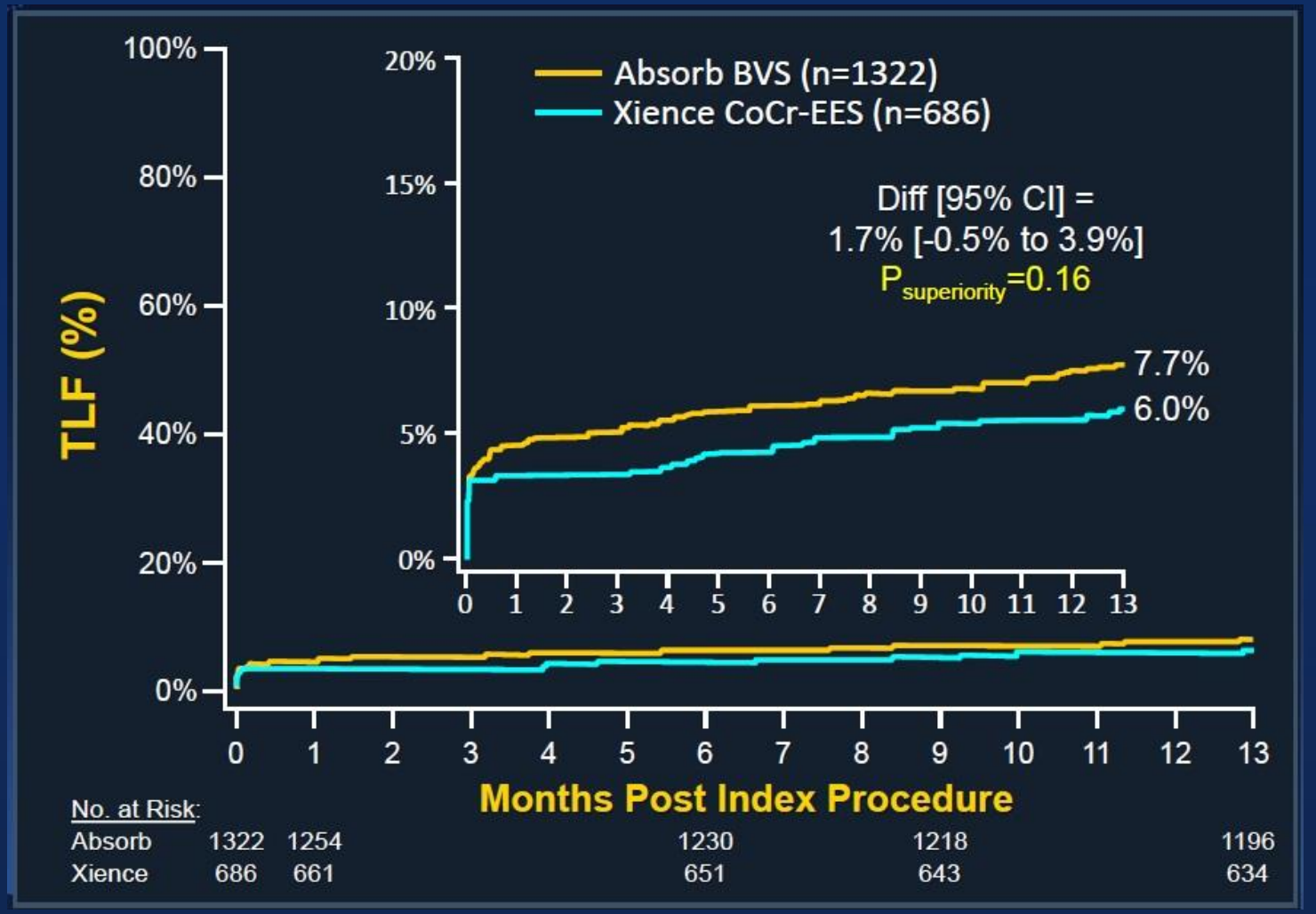
ABSORB III
Primary Endpoint-TLF



Kereiakes D, ABSORB III trial, TCT 2015

ABSORB III

Primary Endpoint-TLF

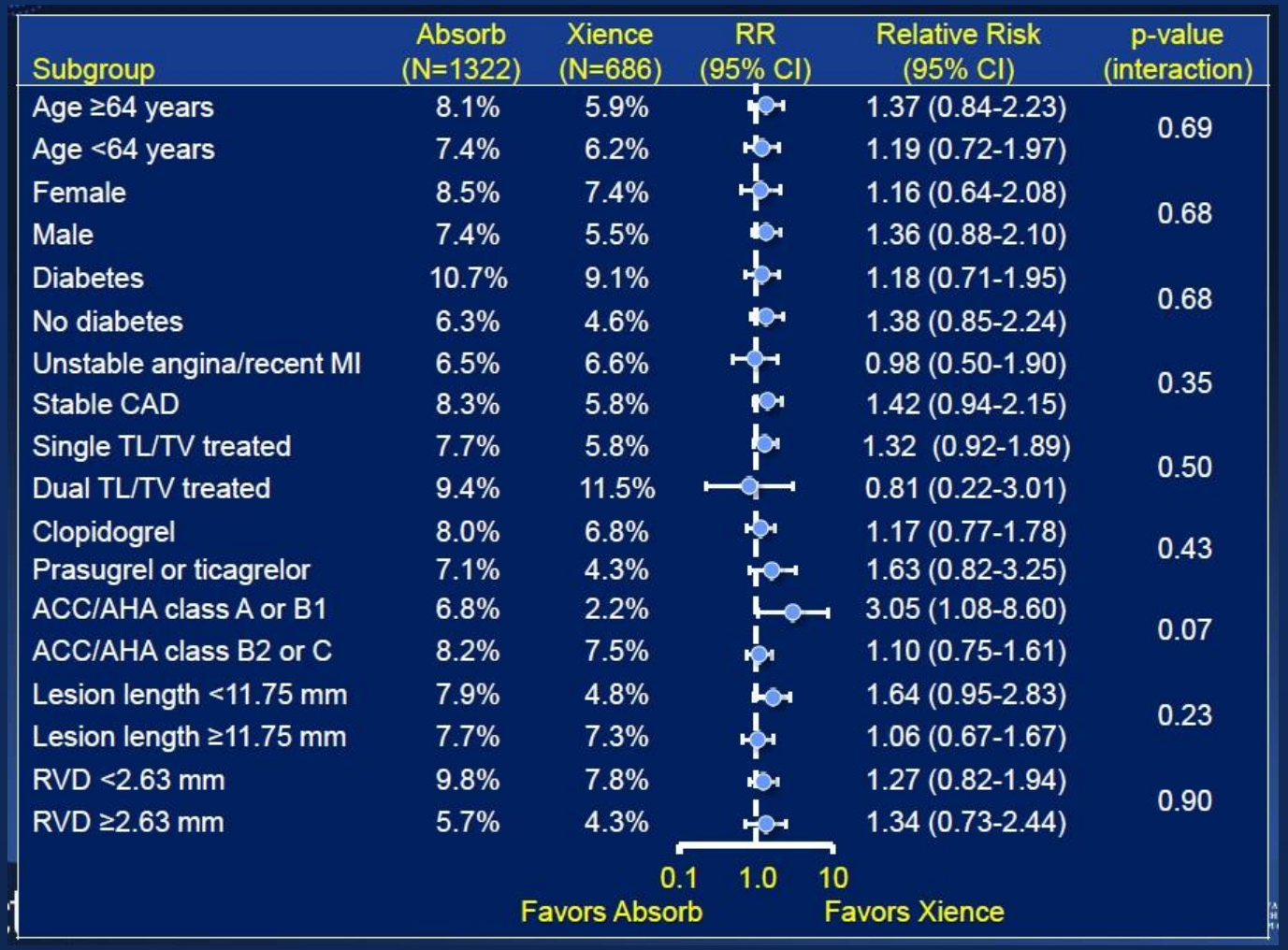


Kereiakes D, ABSORB III trial, TCT 2015

ABSORB III

Primary Endpoint-TLF

Subgroup	Absorb (N=1322)	Xience (N=686)	RR (95% CI)	Relative Risk (95% CI)	p-value (interaction)
Age ≥64 years	8.1%	5.9%		1.37 (0.84-2.23)	0.69
Age <64 years	7.4%	6.2%		1.19 (0.72-1.97)	
Female	8.5%	7.4%		1.16 (0.64-2.08)	0.68
Male	7.4%	5.5%		1.36 (0.88-2.10)	
Diabetes	10.7%	9.1%		1.18 (0.71-1.95)	0.68
No diabetes	6.3%	4.6%		1.38 (0.85-2.24)	
Unstable angina/recent MI	6.5%	6.6%		0.98 (0.50-1.90)	0.35
Stable CAD	8.3%	5.8%		1.42 (0.94-2.15)	
Single TL/TV treated	7.7%	5.8%		1.32 (0.92-1.89)	0.50
Dual TL/TV treated	9.4%	11.5%		0.81 (0.22-3.01)	
Clopidogrel	8.0%	6.8%		1.17 (0.77-1.78)	0.43
Prasugrel or ticagrelor	7.1%	4.3%		1.63 (0.82-3.25)	
ACC/AHA class A or B1	6.8%	2.2%		3.05 (1.08-8.60)	0.07
ACC/AHA class B2 or C	8.2%	7.5%		1.10 (0.75-1.61)	
Lesion length <11.75 mm	7.9%	4.8%		1.64 (0.95-2.83)	0.23
Lesion length ≥11.75 mm	7.7%	7.3%		1.06 (0.67-1.67)	
RVD <2.63 mm	9.8%	7.8%		1.27 (0.82-1.94)	0.90
RVD ≥2.63 mm	5.7%	4.3%		1.34 (0.73-2.44)	



Kereiakes D, ABSORB III trial, TCT 2015

ABSORB III
Component of TLF

Kereiakes D, ABSORB III trial, TCT 2015

ABSORB III
Device Thrombosis

	Absorb (N=1322)	Xience (N=686)	p-value
Device Thrombosis (def/prob)	1.54%	0.74%	0.13
- Early (0 to 30 days)	1.06%	0.73%	0.46
- Late (> 30 to 1 year)	0.46%	0.00%	0.10
- Definite* (1 year)	1.38%	0.74%	0.21
- Probable (1 year)	0.15%	0.00%	0.55

Kereiakes D, ABSORB III trial, TCT 2015

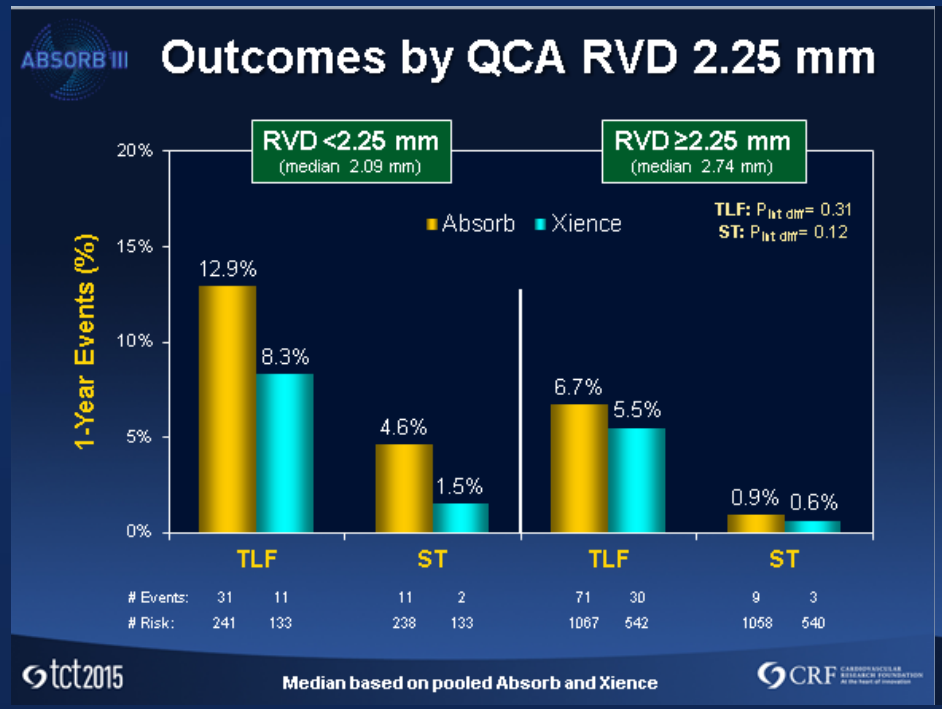
ABSORB III

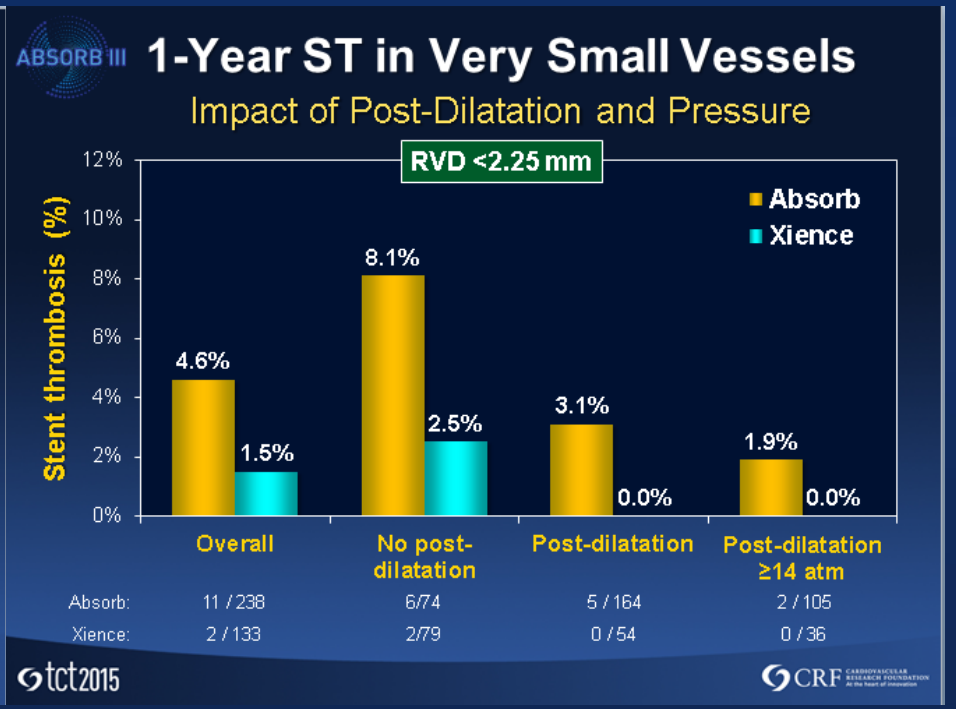
Secondary Endpoints

	Absorb (N=1322)	Xience (N=686)	p-value
Angina	18.3%	18.4%	0.93
All Revascularization	9.1%	8.1%	0.50
ID-TVR	5.0%	3.7%	0.21

Kereiakes D, ABSORB III trial, TCT 2015

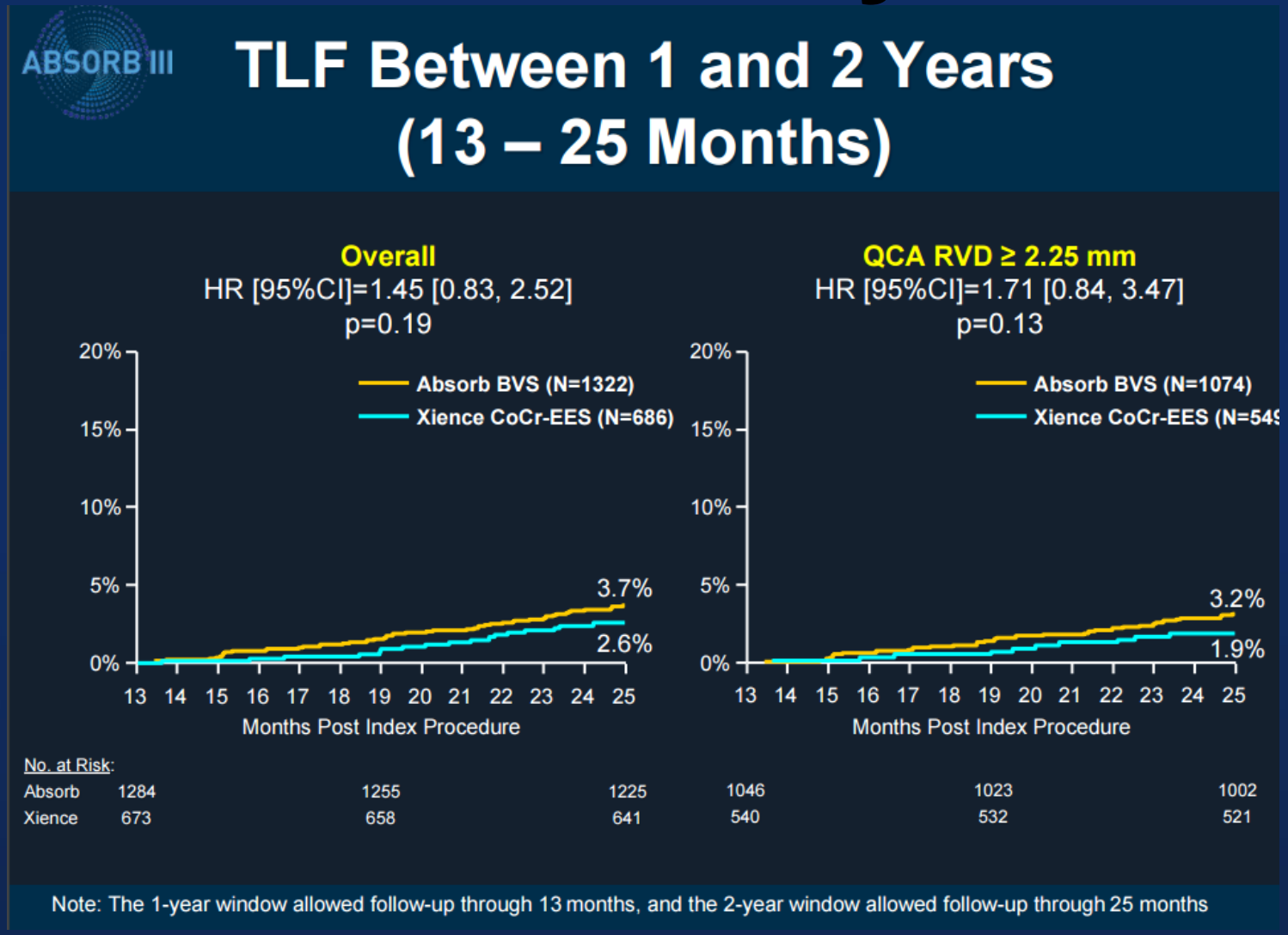
ABSORB III, 1-year outcome





Kereiakes D, ABSORB III trial, TCT 2015

ABSORB III 2-years



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ABSORB III 2-years

ABSORB III

Clinical Endpoints from 1 to 2 Years (13 to 25 Months)

	Overall		QCA RVD ≥ 2.25mm	
	Absorb (N=1322)	XIENCE (N=686)	Absorb (N=1074)	XIENCE (N=549)
TLF	3.7% (47)	2.5% (17)	3.2% (33)	1.9% (10)
Cardiac Death	0.5% (6)	0.4% (3)	0.4% (4)	0.2% (1)
TV-MI	1.3% (17)	0.7% (5)	1.3% (14)	0.4% (2)
ID-TLR	2.6% (33)	1.8% (12)	2.2% (23)	1.5% (8)
ST (Def/Prob)	0.3% (4)	0.0% (0)	0.4% (4)	0.0% (0)

P-value >0.05 for all comparisons

Note: The 1-year window allowed follow-up through 13 months, and the 2-year window allowed follow-up through 25 months

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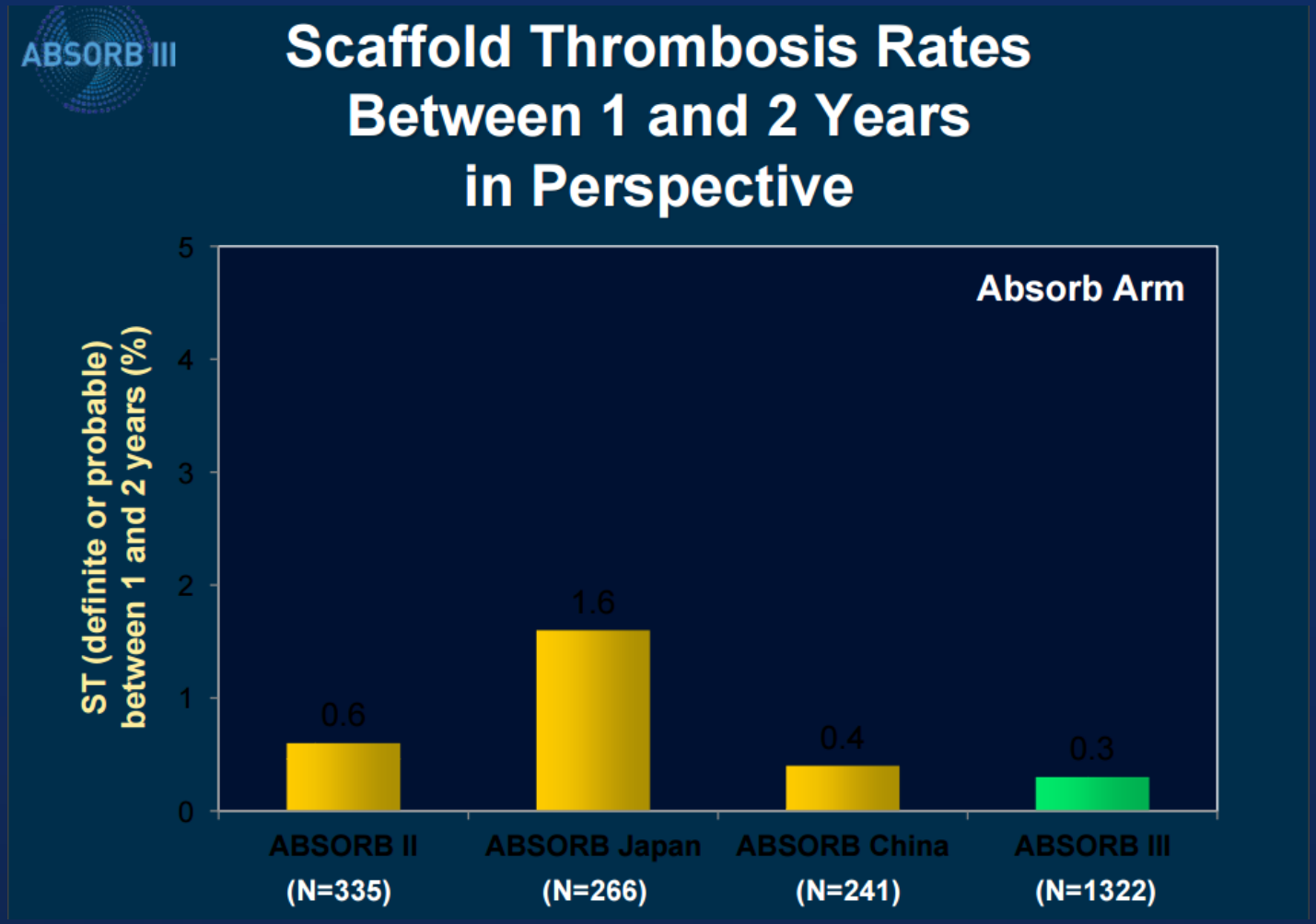
ABSORB III 2-years



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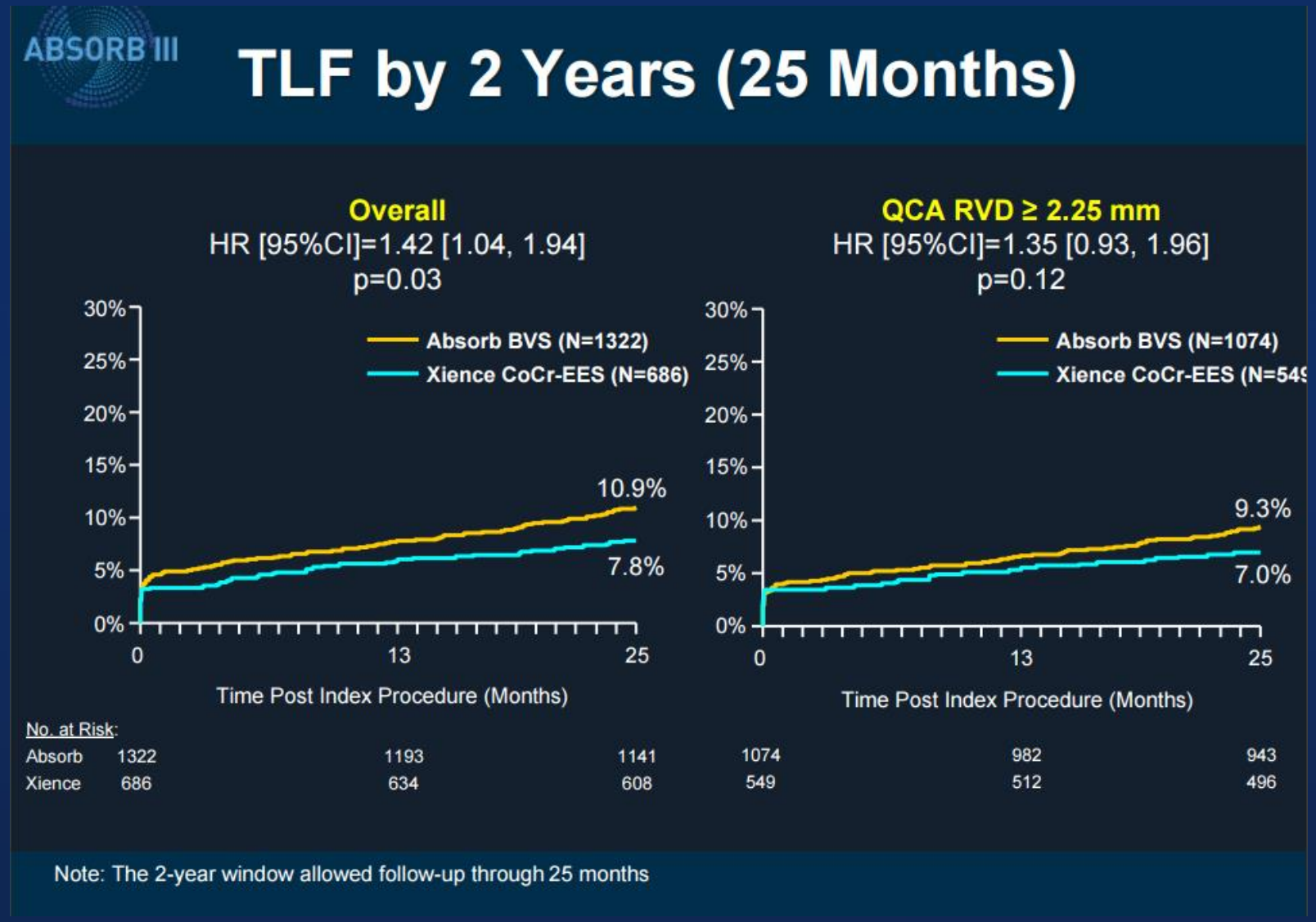
ABSORB III 2-years



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ABSORB III 2-years

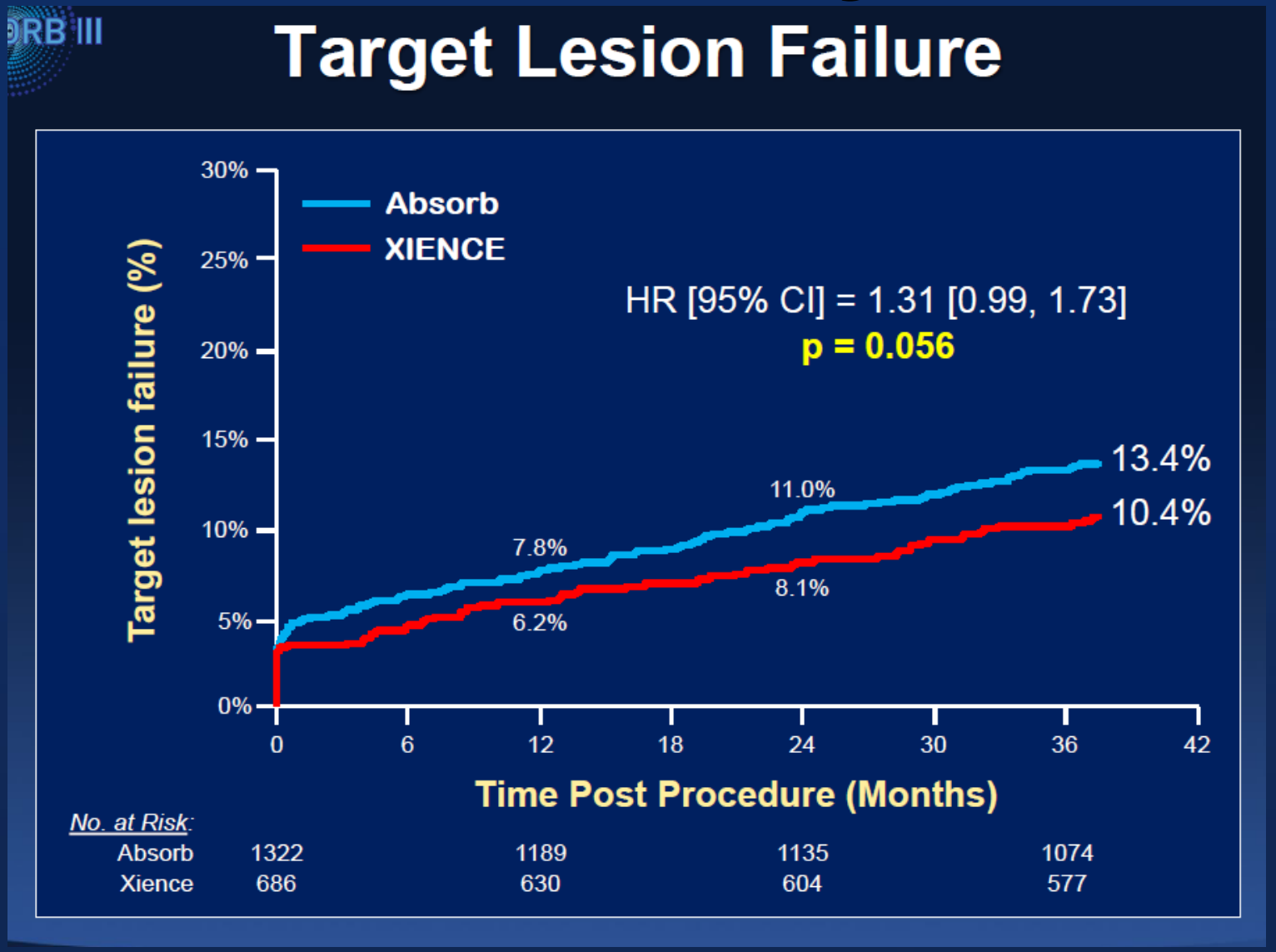
Clinical Endpoints by 2 Years (25 Months)

	Overall		QCA RVD ≥ 2.25mm	
	Absorb (N=1322)	XIENCE (N=686)	Absorb (N=1074)	XIENCE (N=549)
TLF	11.0% (143)*	7.9% (53)*	9.4% (99)	7.0% (38)
Cardiac Death	1.1% (14)	0.6% (4)	0.9% (10)	0.4% (2)
TV-MI	7.3% (95)**	4.9% (33)**	6.5% (68)	4.8% (26)
ID-TLR	5.3% (69)	4.3% (29)	4.1% (43)	3.0% (16)
ST (Def/Prob)	1.9% (24)	0.8% (5)	1.3% (13)	0.6% (3)

* P-value=0.03. ** P-value=0.04. P-value >0.05 for all other comparisons
Note: The 2-year window allowed follow-up through 25 months

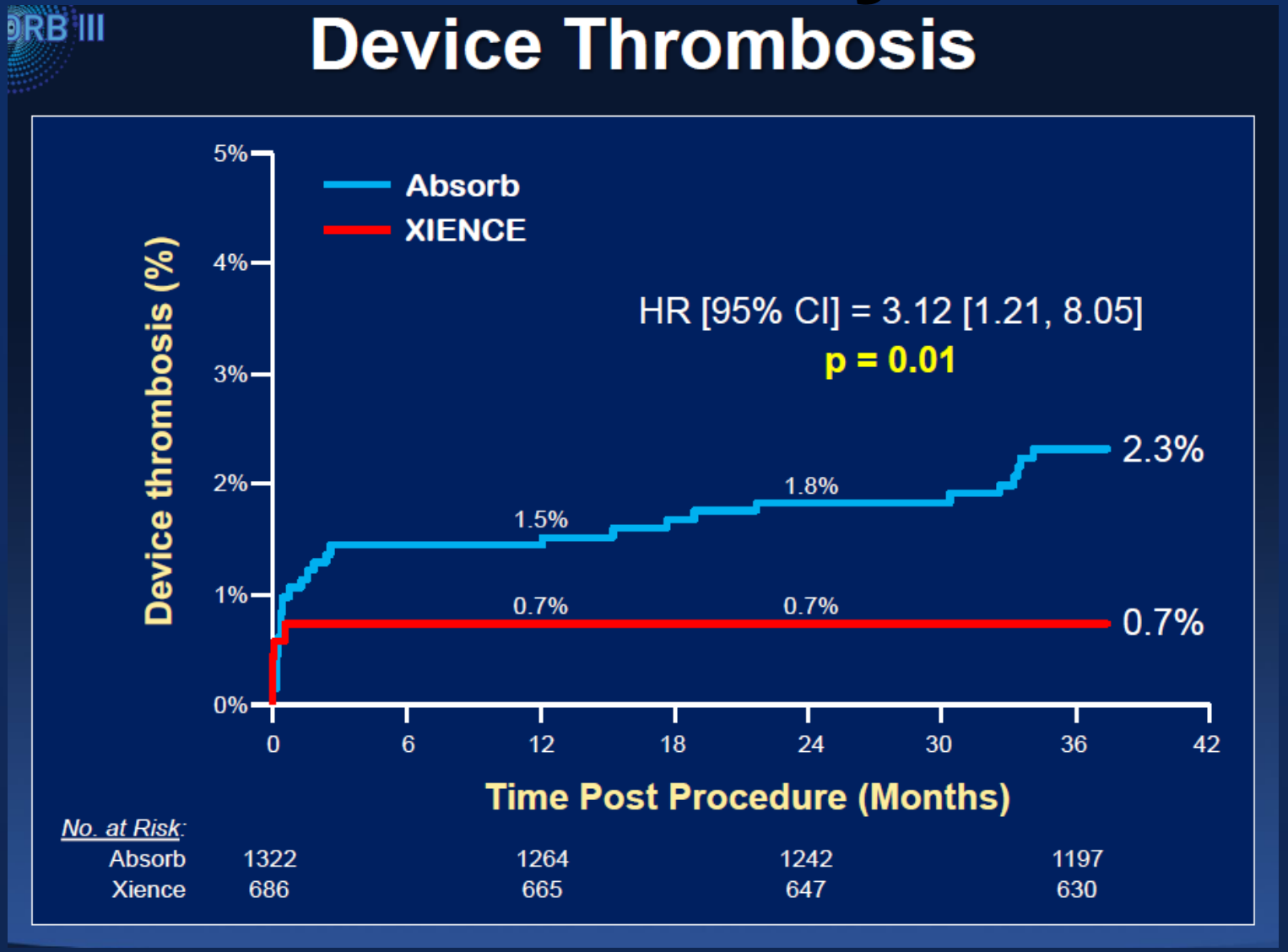
Stephen G. Eelis ACC 2017

ABSORB III 3-years



Stephen G. Eelis TCT 2017

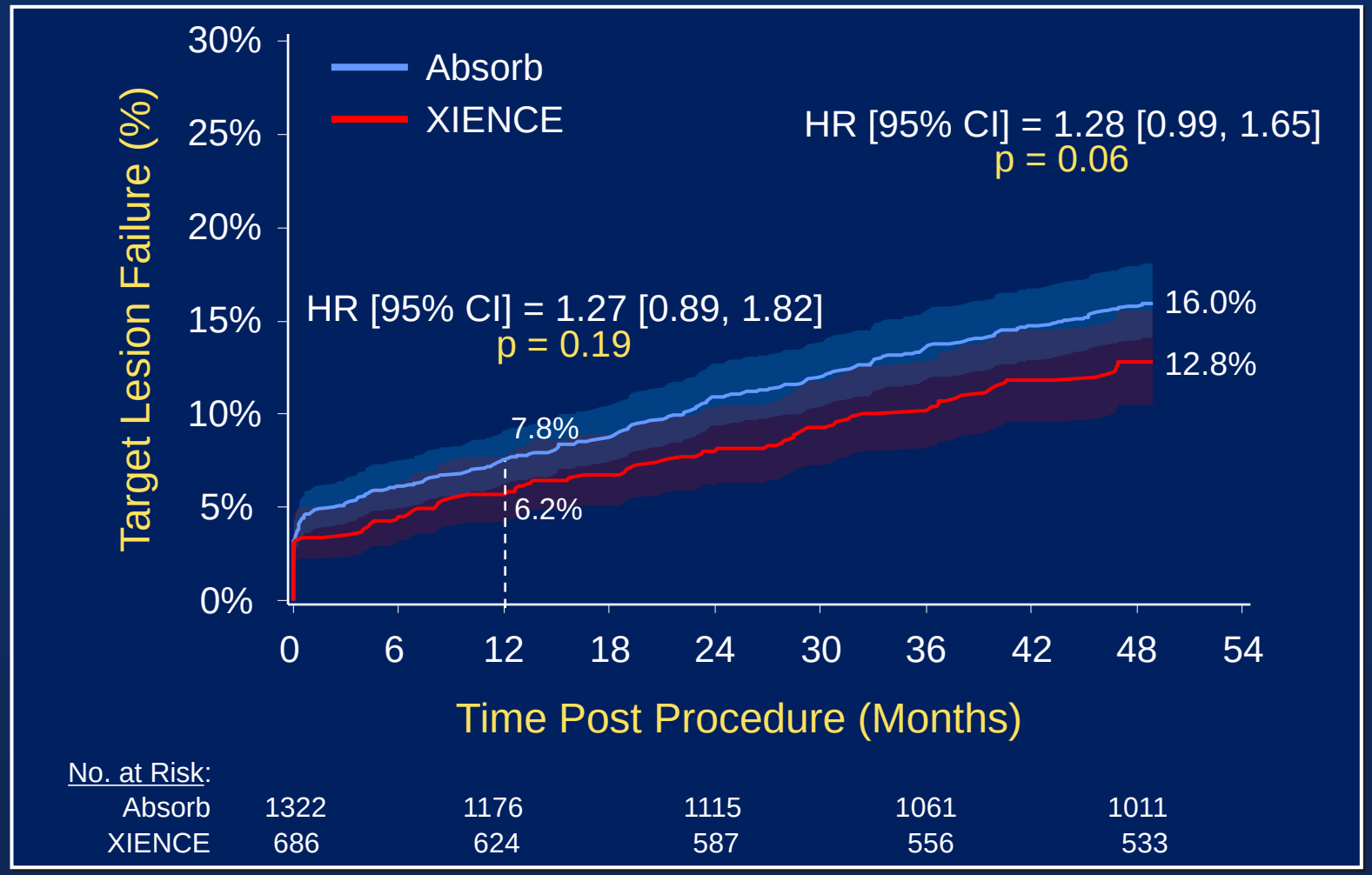
ABSORB III 3-years



Stephen G. Eelis TCT 2017

ABSORB III 4-years

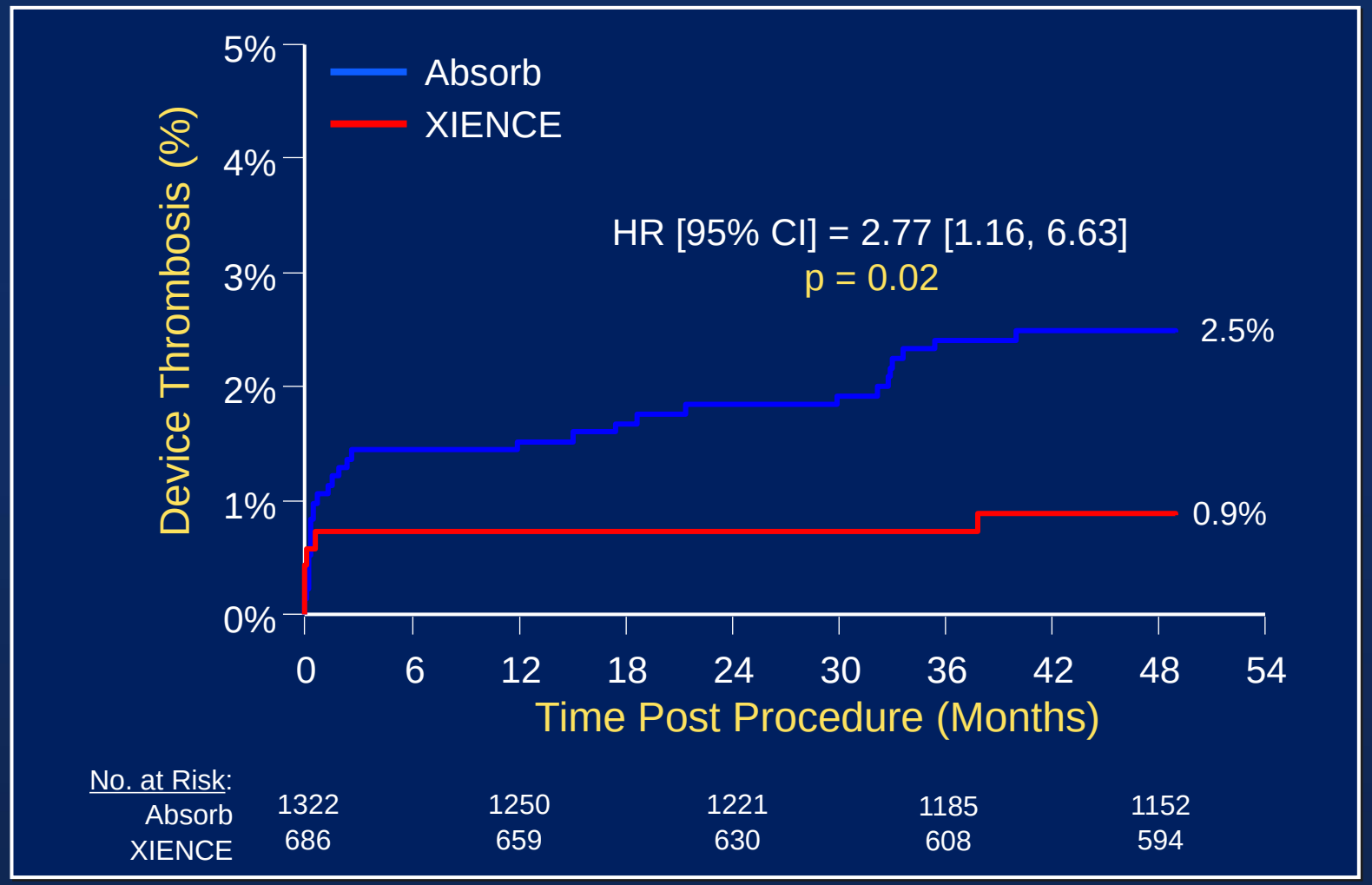
4-Year Target Lesion Failure



Note: 4-year window includes follow-up through 49 months.

ABSORB III 4-years

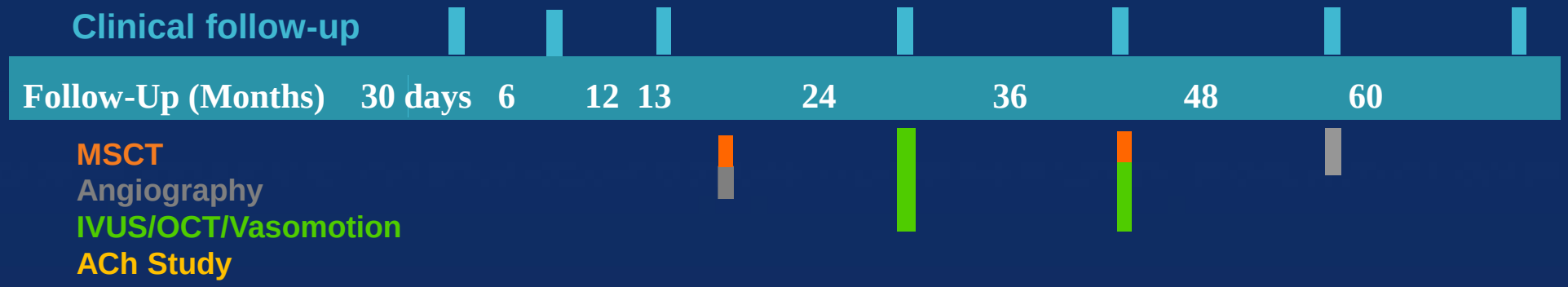
4-Year Device Thrombosis



Note: 4-year window includes follow-up through 49 months.

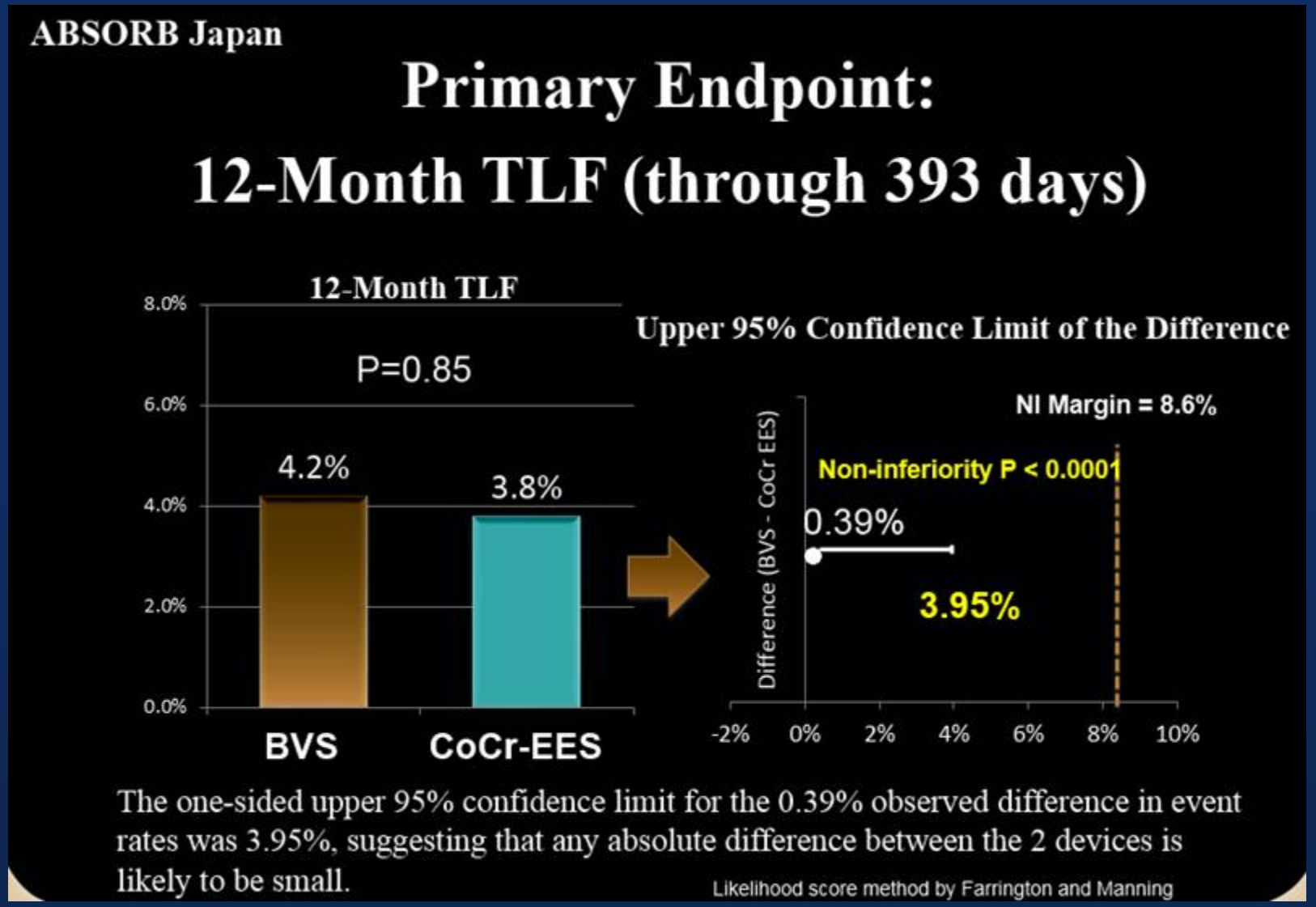
ABSORB JAPAN RCT
JAPAN Approval Trial

~400 subjects (267 Absorb, 133 XIENCE)
~30 Japan Sites. Follow-up out to 5 years
PI: Takahashi Kimura



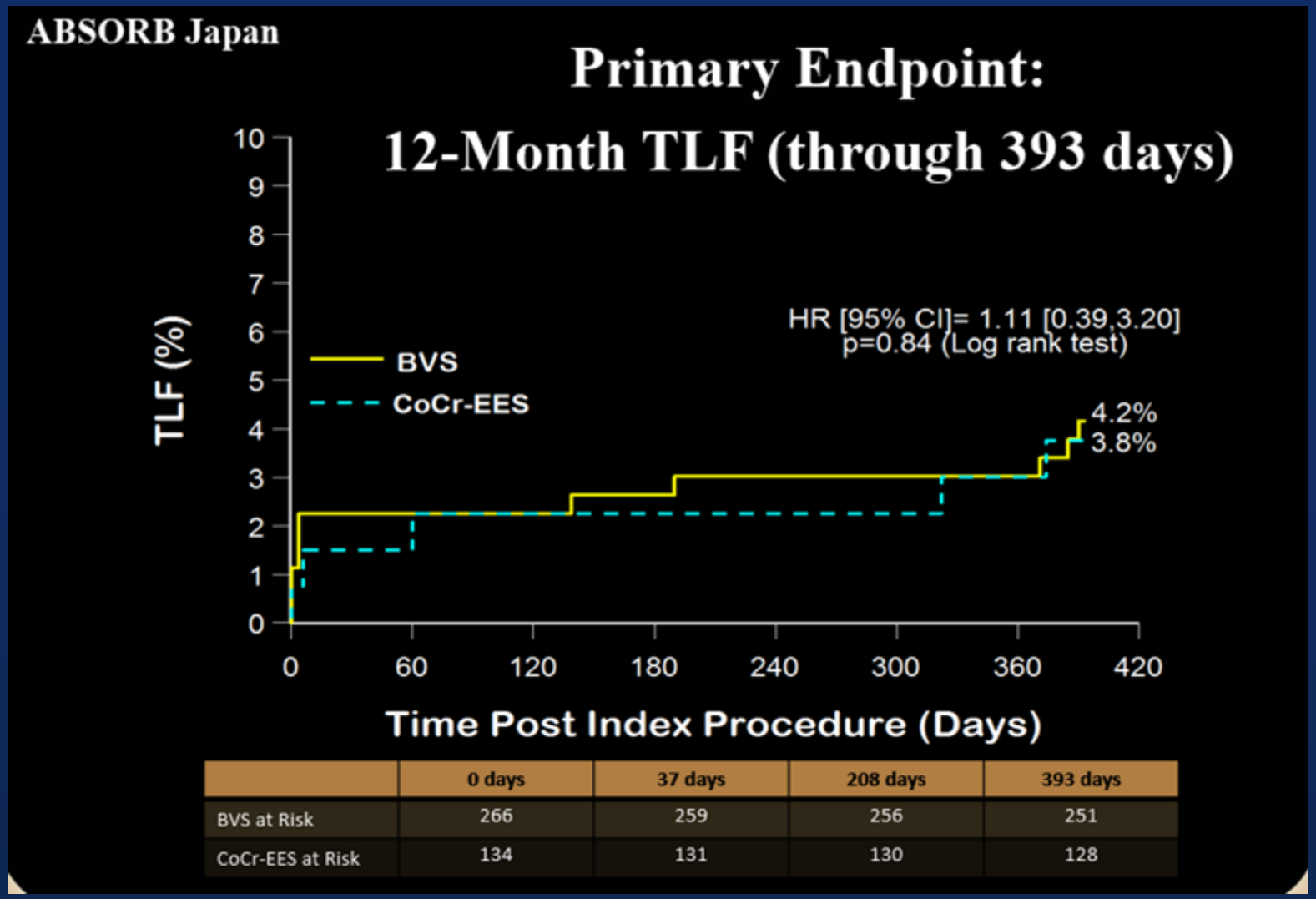
Study Objective	Randomized against XIENCE V 2:1
Primary Endpoint	Clinically indicated target lesion failure at 1-year (composite of cardiac death, target vessel MI or clinically indicated TLR)
Treatment	Up to two *de novo* lesions in different epicardial vessels. No planned overlap allowed

ABSORB Japan



Kimura, ESC 2015

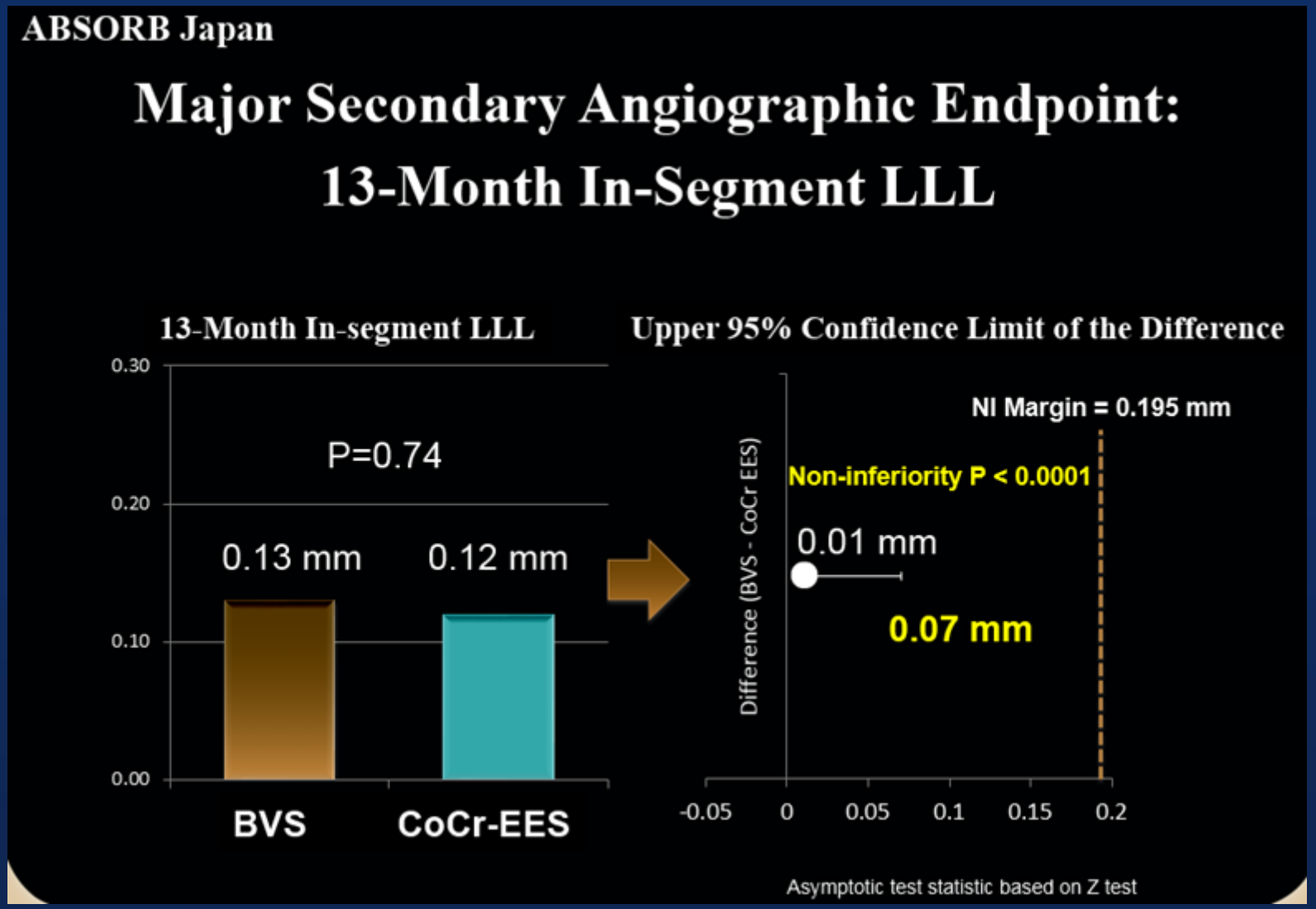
ABSORB Japan



	0 days	37 days	208 days	393 days
BVS at Risk	266	259	256	251
CoCr-EES at Risk	134	131	130	128

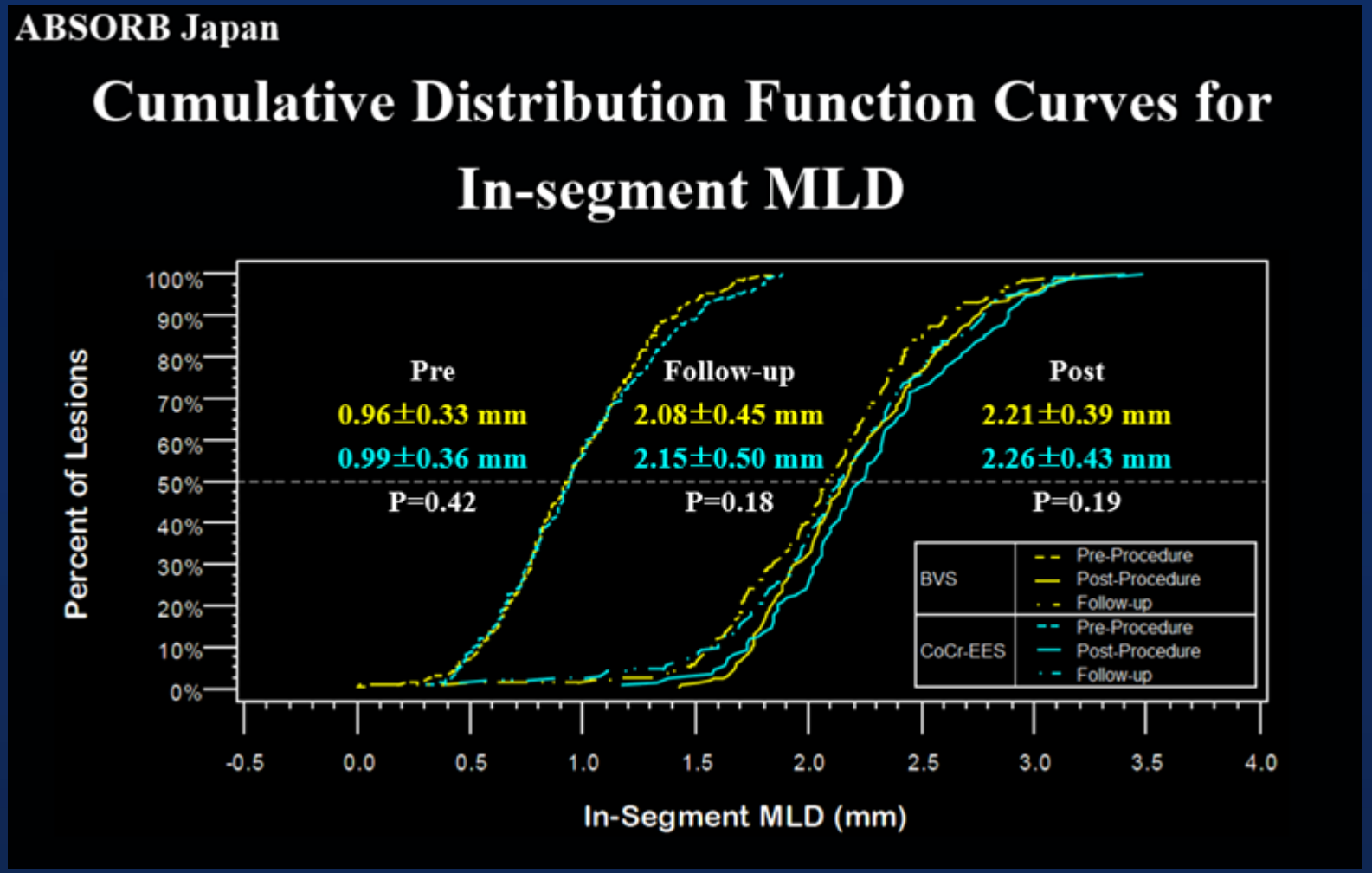
Kimura, ESC 2015

ABSORB Japan



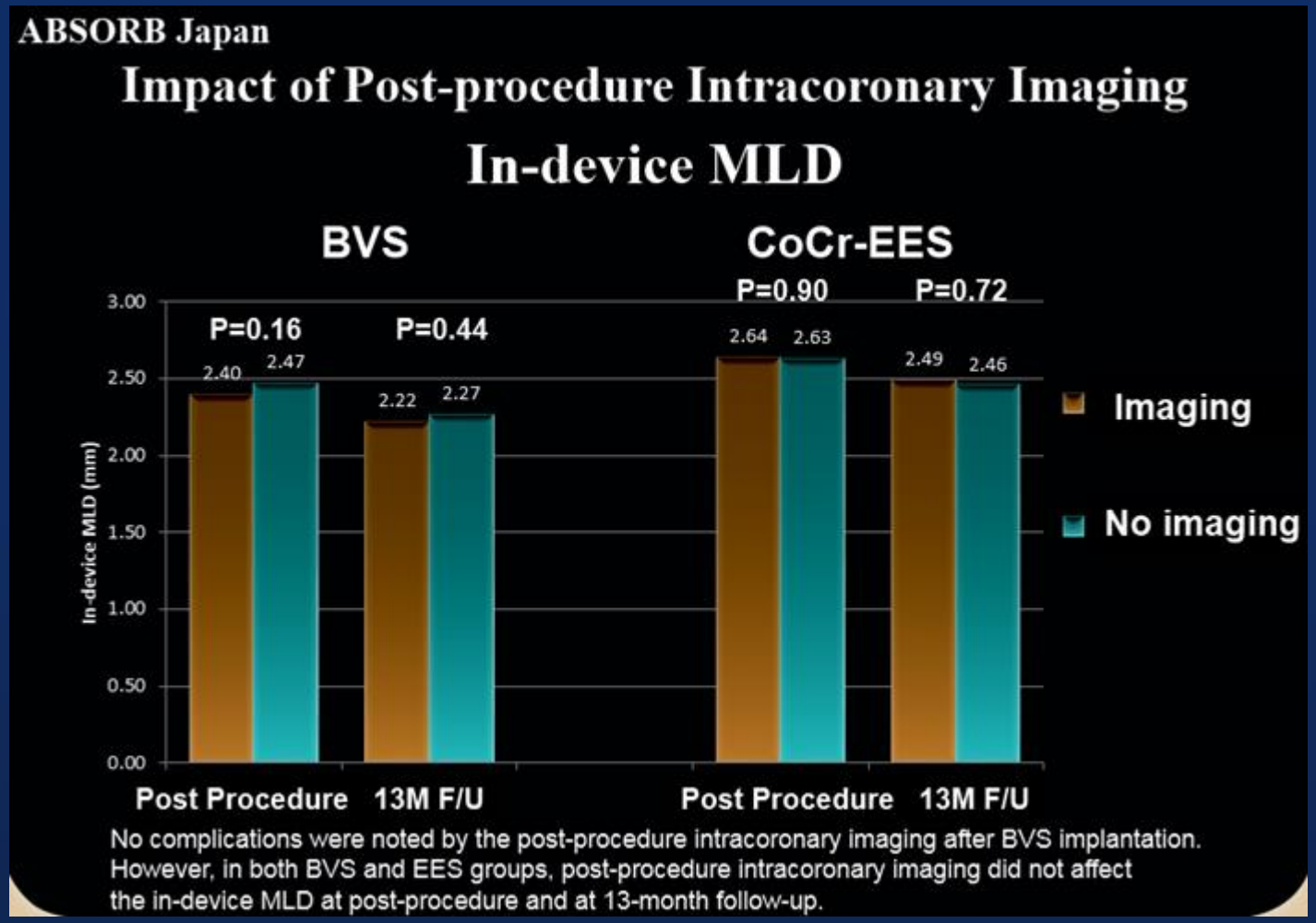
Kimura, ESC 2015

ABSORB Japan



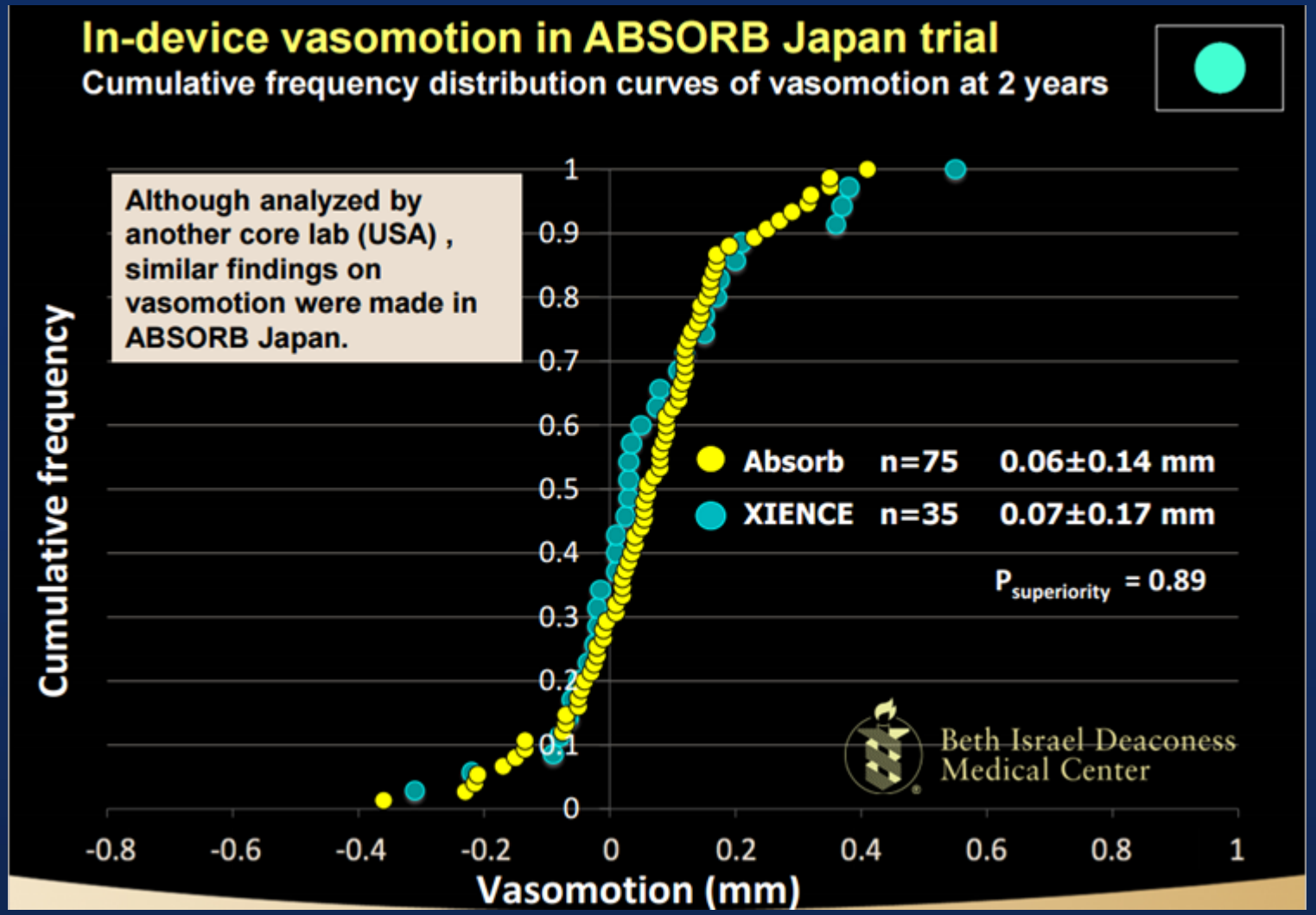
Kimura, ESC 2015

ABSORB Japan



Kimura, ESC 2015

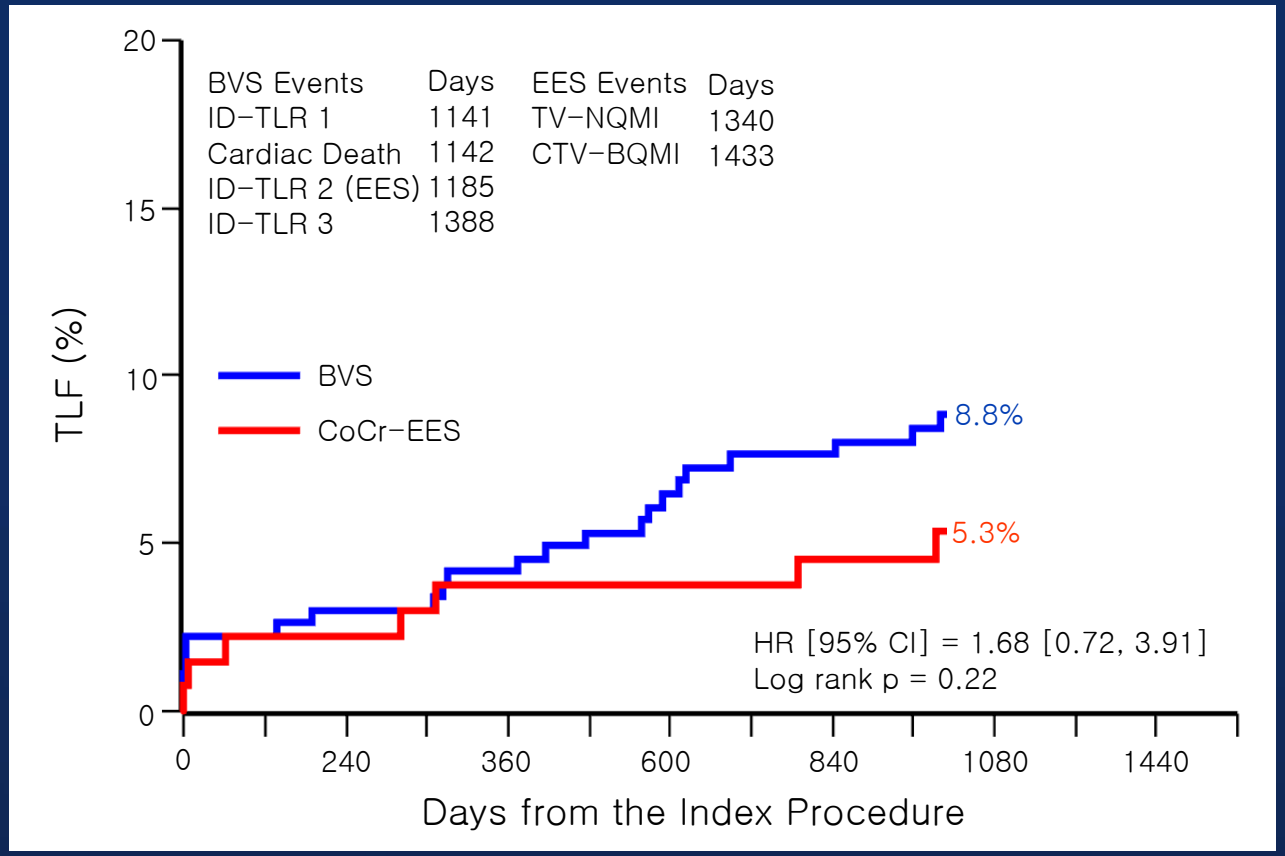
ABSORB Japan



Onuma, Sotomi, Serruys, Kimura et al. EuroIntervention 2016

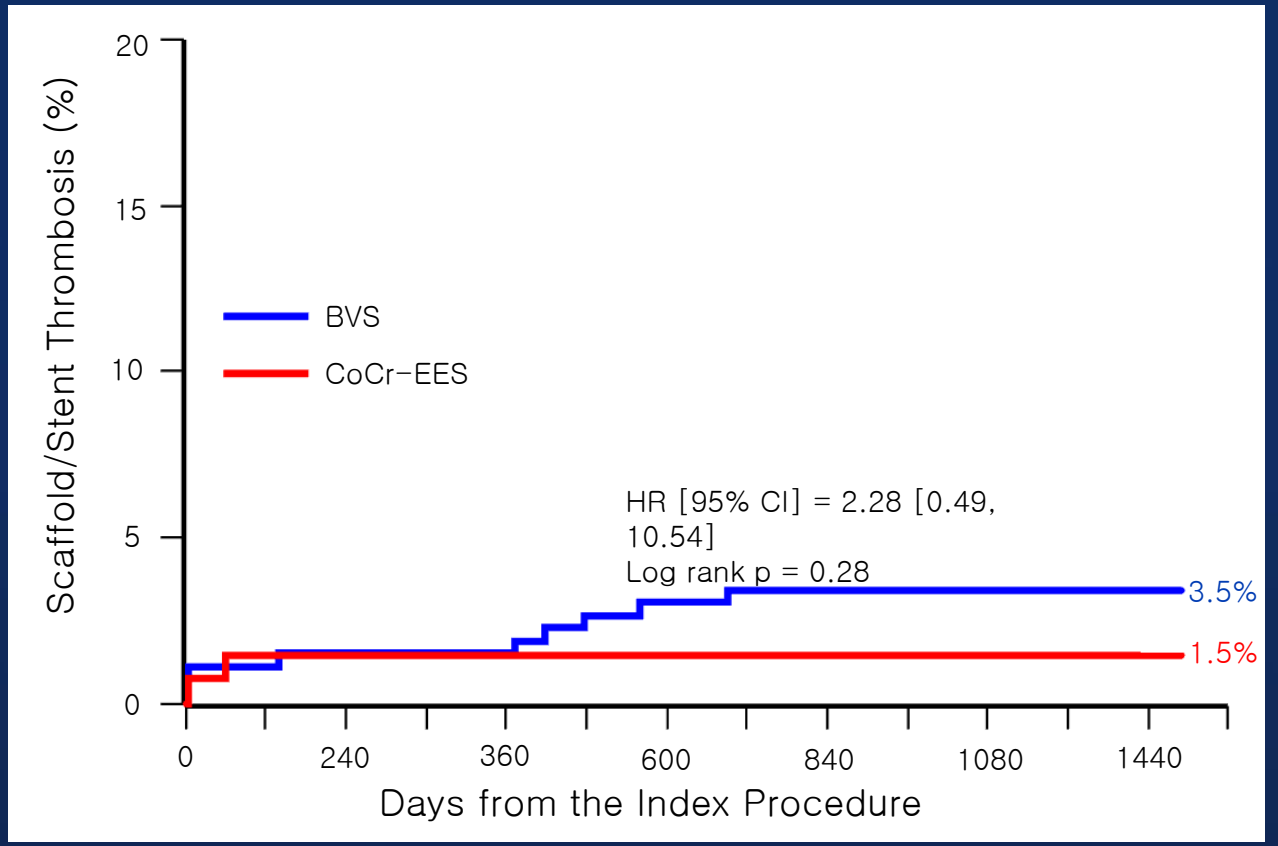
ABSORB Japan

Kaplan-Myer TLF to 4 Years



ABSORB Japan

Kaplan-Myer Stent/Scaffold Thrombosis to 4 Years



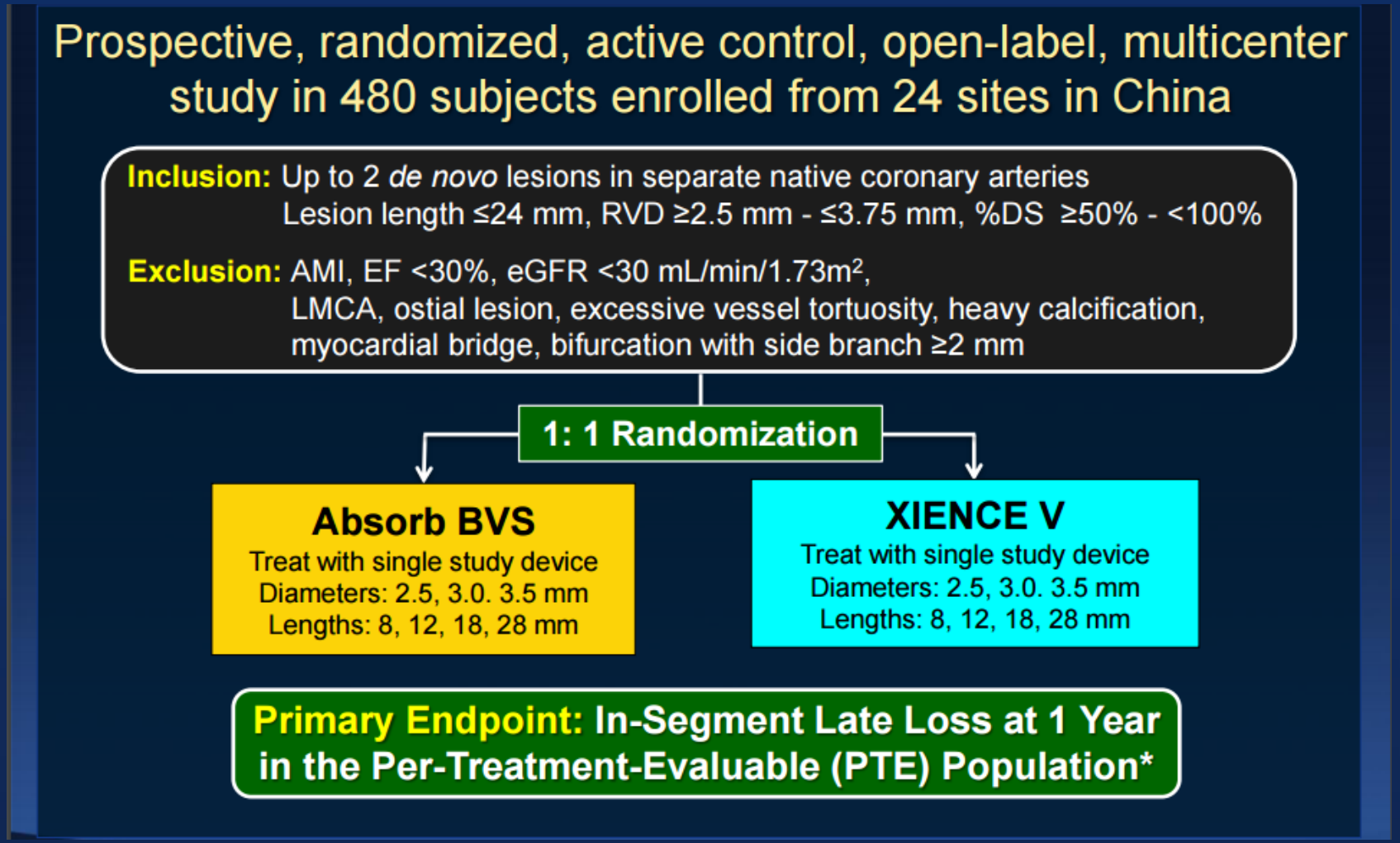
ABSORB Japan

Clinical Outcomes at 4 Years

	BVS N=255	EES N=127	*P*
Cumulative TLF	10.6% (27)	7.1% (9)	0.27
- Cardiac Death	0.8% (2)	0.0% (0)	1.00
- TV-MI	5.9% (15)	4.7% (6)	0.64
- ID-TLR	8.2% (21)	3.9% (5)	0.12
Cumulative ST	3.7% (9)	1.6% (2)	0.35
TLF 3-4 Years	2.1% (5)	1.6% (2)	1.00
- Cardiac Death*	0.3% (1)	0.0% (0)	1.00
- TV-MI*	0.4% (1)	1.6% (2)	0.27
- ID-TLR	1.7% (4)	0.0% (0)	0.30
- Primary ID-TLR**	1.2% (3)	0.0% (0)	0.55
- Secondary ID-TLR	0.3% (1)	0.0% (0)	1.00
VLST 3-4 years	0.0% (0)	0.0% (0)	1.00

* Cardiac death due to aortic rupture after AVR and CABG to the target vessel incorporated with peri-procedural TV-MI. Target lesion was patent.
** One of ID-TLR patient in BVS arm was treated by EES due to delivery failure of BVS.

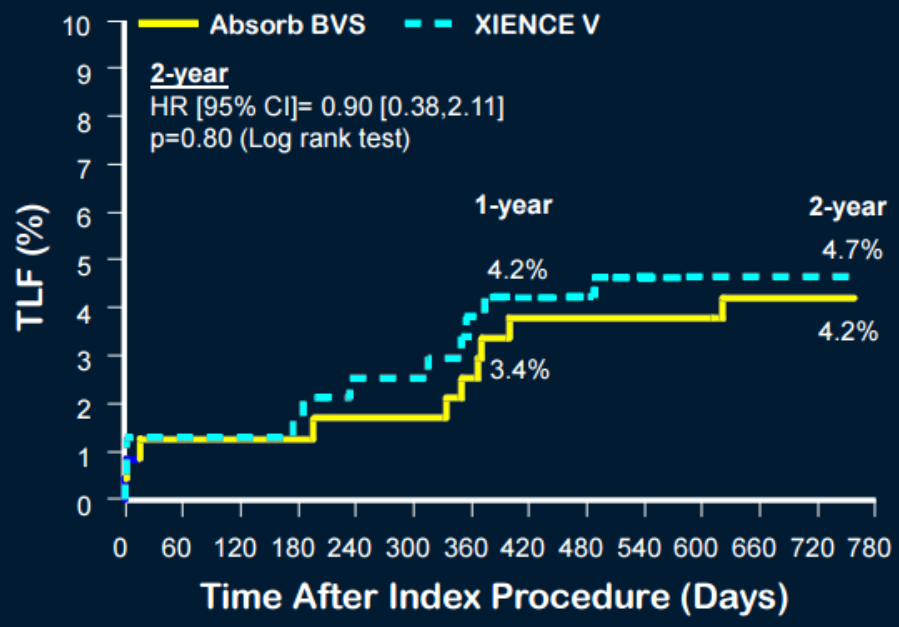
ABSORB China 2-years



Gao R, TCT 2016

ABSORB China 2-years

Target Lesion Failure (TLF)



Time (days)	0	37	208	298	393	758
Absorb BVS (# At Risk)	238	235	234	234	230	227
XIENCE V (# At Risk)	237	234	230	229	225	223

Gao R, TCT 2016

ABSORB China 2-years

Scaffold/Stent Thrombosis

	Absorb BVS (N=241)	XIENCE V (N=239)	P-Value
All (0 - 730 days)	0.8% (2/237)	0.0% (0/231)	0.50
Definite	0.4% (1/237)	0.0% (0/231)	1.00
Probable	0.4% (1/237)	0.0% (0/231)	1.00
Early (0 – 30 days)	0.4% (1/238)	0.0% (0/236)	1.00
Late (31- 365 days)	0.0% (0/238)	0.0% (0/232)	1.00
Very Late (366- 730 days)	0.4% (1/237)	0.0% (0/231)	1.00

There were 1 probable, subacute (1-30d) ST and 1 definite, very late ST in the Absorb BVS arm.

Gao R, TCT 2016

ABSORB China 2-years

PSP Analysis for TLF & ST

		PSP*	Non-PSP
TLF	0-1 Year	0% (0/32)	3.9% (8/205)
	1-2 Year	0% (0/32)	1.5% (3/204)
ST	0-1 Year	0% (0/32)	0.5% (1/205)
	1-2 Year	0% (0/32)	0.5% (1/204)

This is a post-hoc analysis for hypothesis-generating only.

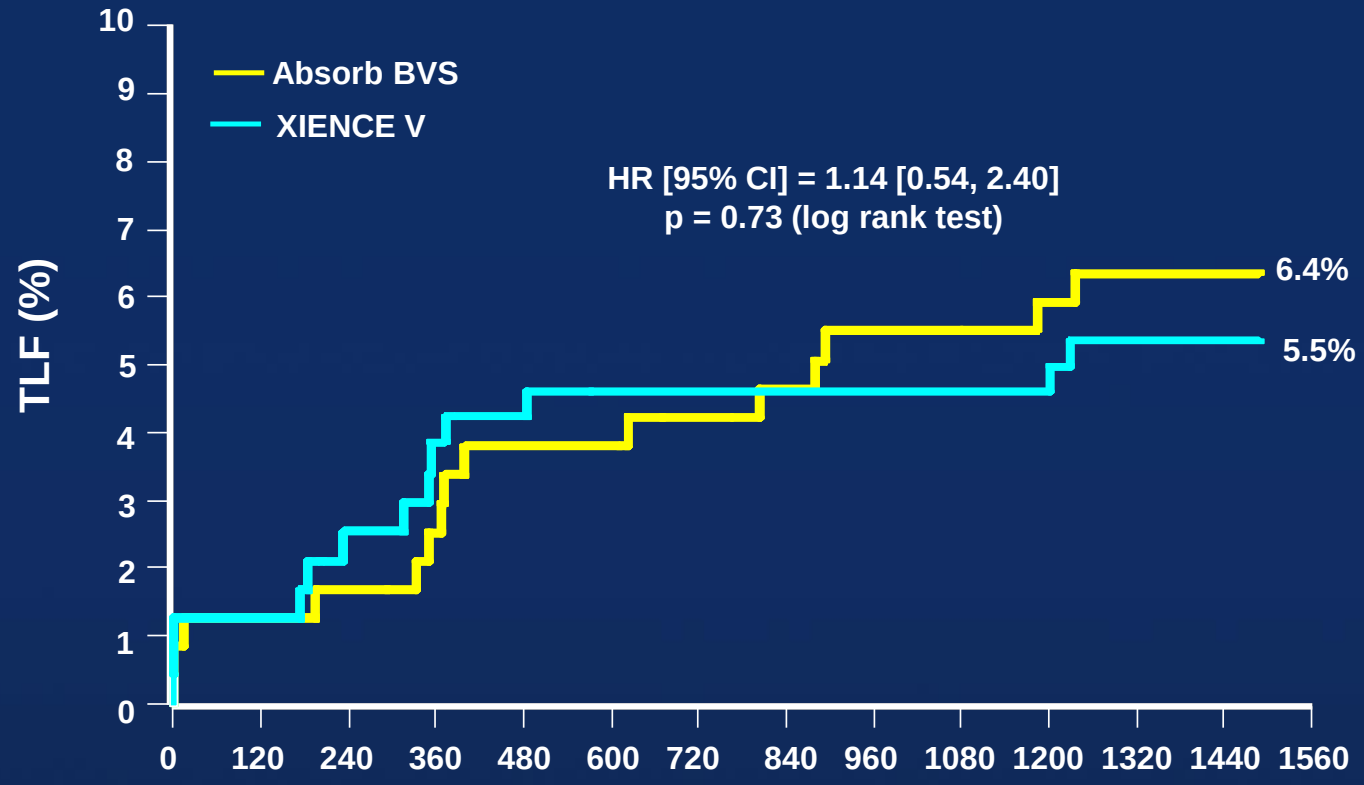
*PSP analysis (all lesions must satisfy all the criteria below) based on as-treated population:

- Pre-dilatation
- Sizing (vessel): 2.25mm ≤ QCA RVD ≤ 3.5 mm
- Post-dilatation:
  -Pressure > 16 atm
  -Balloon diameter: scaffold diameter > 1:1 and balloon diameter ≤ scaffold diameter + 0.5mm

Gao R, TCT 2016

ABSORB China 4-years

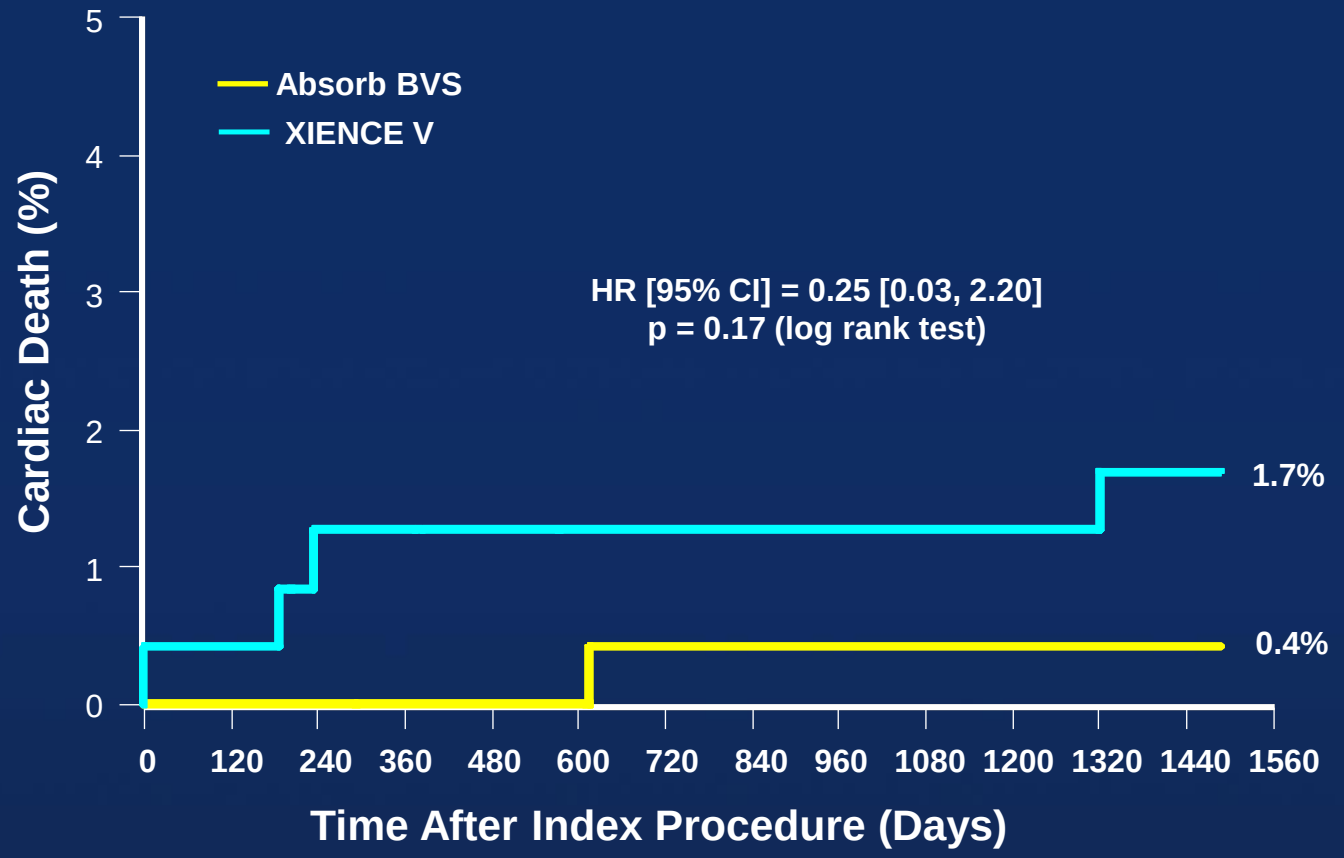
Target **Lesion Failure Through 4 Years**



Time (days)	0	37	208	298	393	758	1123	1488
Absorb BVS (# At Risk)	238	235	234	233	229	225	220	217
XIENCE (# At Risk)	237	234	230	229	223	221	221	219

ABSORB China 4-years

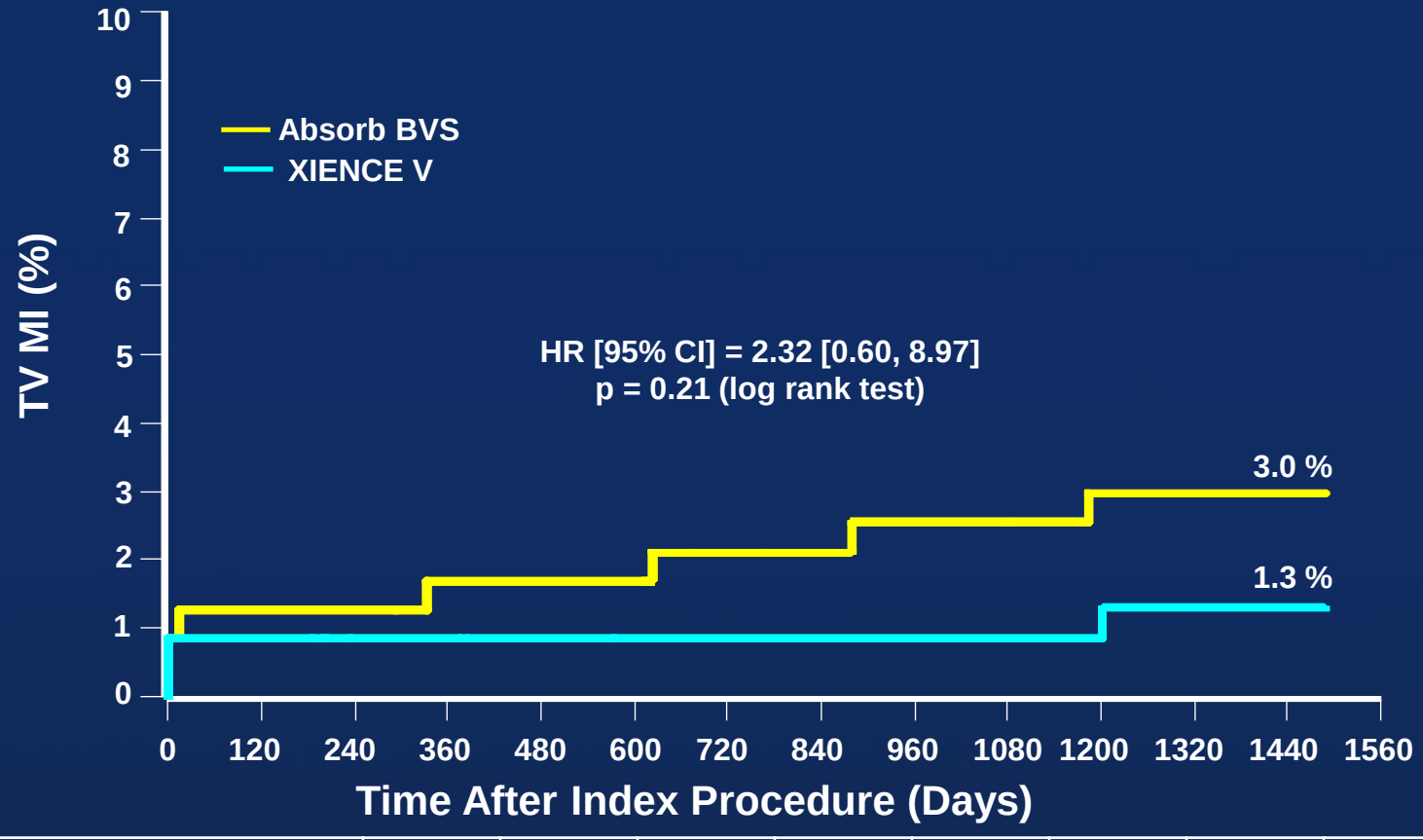
Cardiac Death Through 4 Years



Time (days)	0	37	208	298	393	758	1123	1488
Absorb BVS (# At Risk)	238	238	238	237	237	234	232	231
XIENCE (# At Risk)	237	236	233	232	230	229	229	228

ABSORB China 4-years

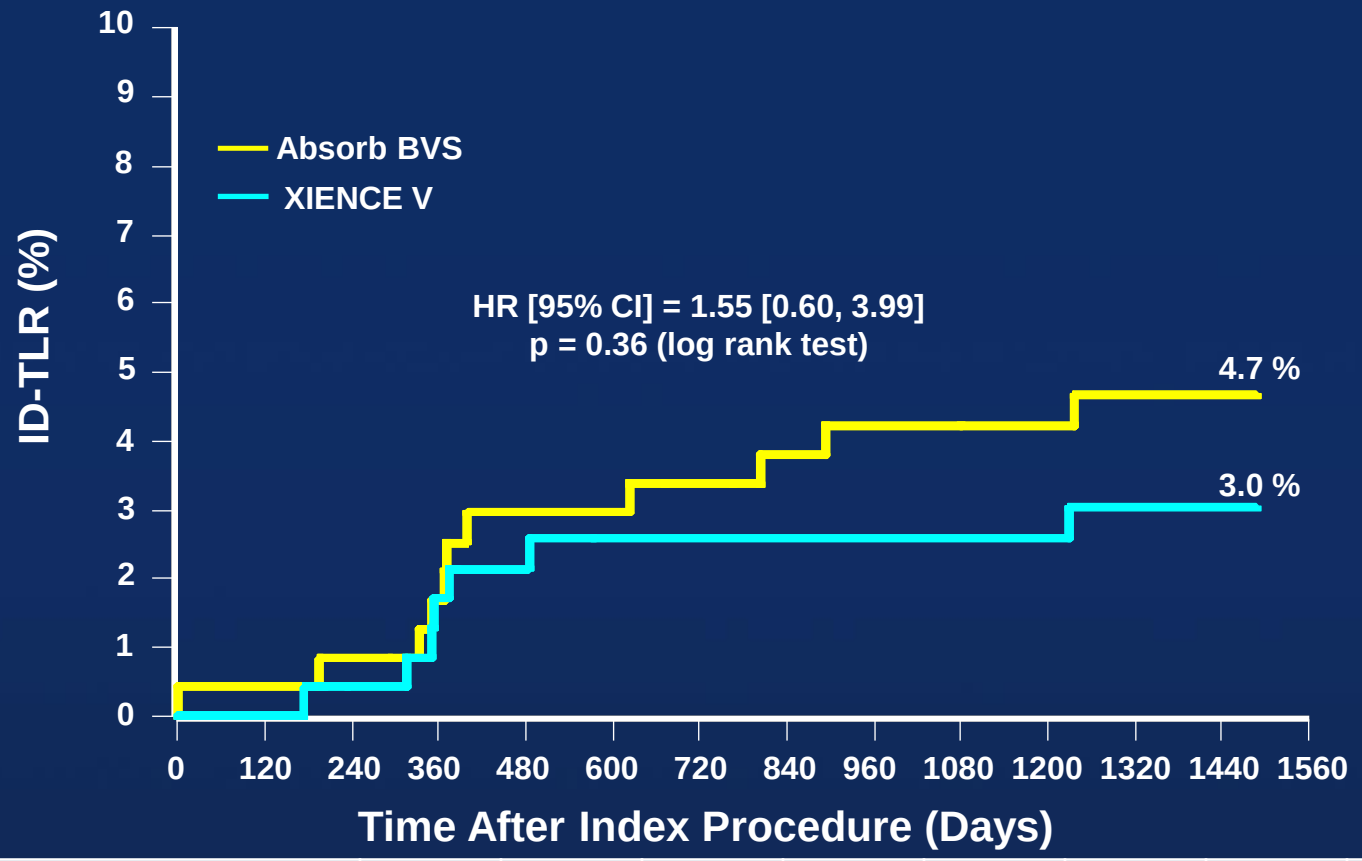
Target-Vessel Myocardial Infarction Through 4 Years



Time (days)	0	37	208	298	393	758	1123	1488
Absorb BVS (# At Risk)	238	235	235	234	233	229	226	224
XIENCE (# At Risk)	237	234	231	230	228	227	227	226

ABSORB China 4-years

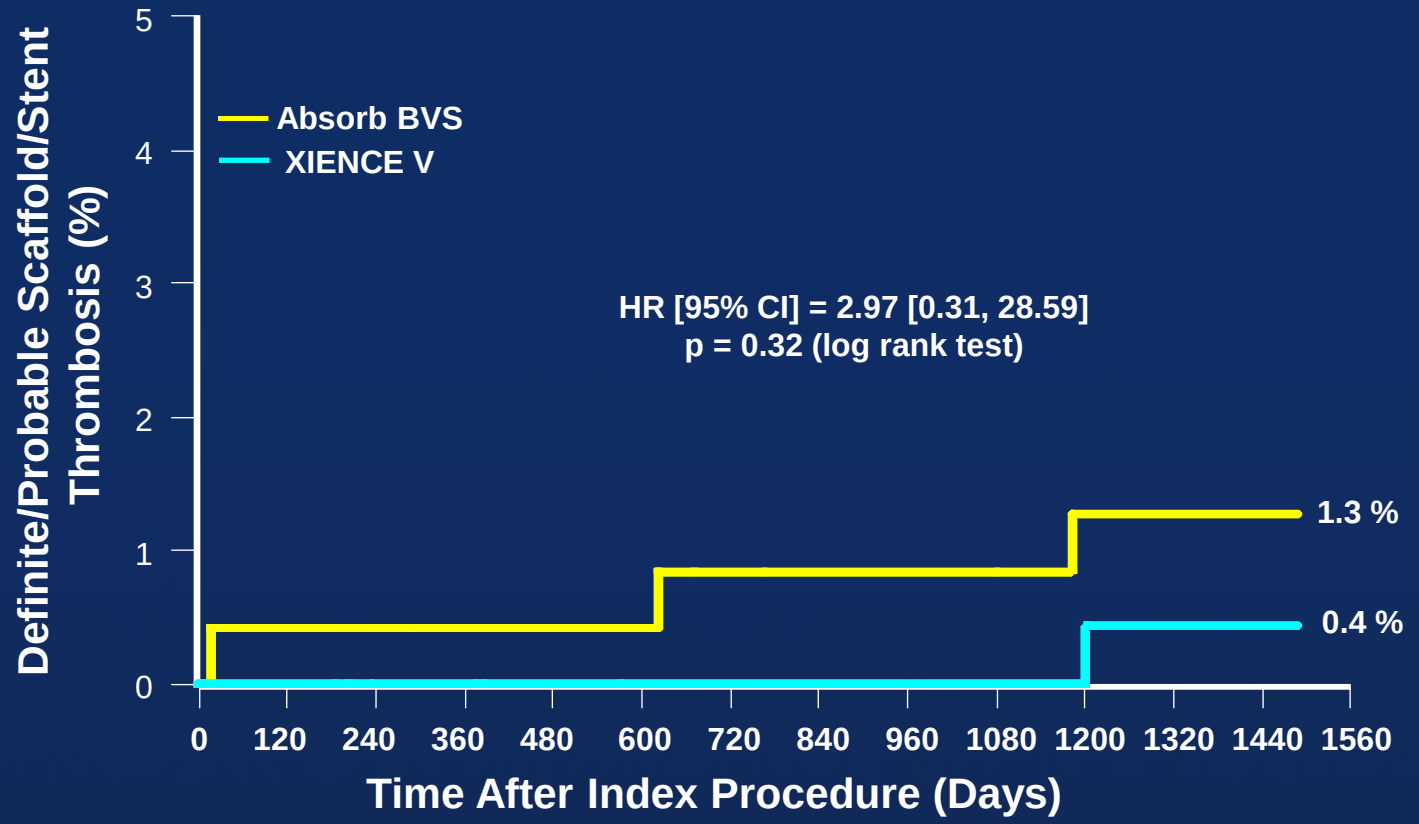
Ischemia-Driven Target Lesion Revascularization Through 4 Years



Time (days)	0	37	208	298	393	758	1123	1488
Absorb BVS (# At Risk)	238	237	236	235	231	227	223	221
XIENCE (# At Risk)	237	236	232	231	225	223	223	221

ABSORB China 4-years

Definite/Probable Scaffold/Stent Thrombosis Through 4 Years

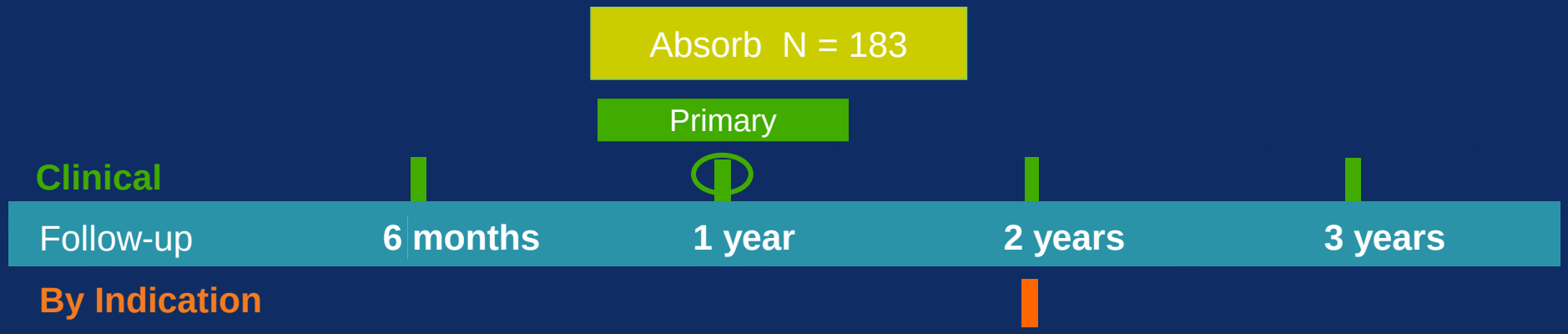


Time (days)	0	37	208	298	393	758	1123	1488
Absorb BVS (# At Risk)	238	237	237	236	236	232	230	228
XIENCE (# At Risk)	237	236	233	232	230	229	229	228

ASSURE (D. Mathey)

Objective: Measure Absorb safety, efficacy and performance in all-comers over 3 years

Design: Prospective, observational multi-center registry, 183 patients, 6 sites in Germany



Primary Endpoints:

- Death (cardiovascular)
- MI
- TLR, TVR, TVF
- Angiographic parameter (QCA)

Twelve Months ASSURE, T. Schmitz, PCR 2014

ASSURE (D. Mathey)
Twelve Months Clinical Results

Baseline Charactaristics	N = 183
Hypertension	82.0%
Diabetes	25.7%
Dyslipidemia	76.0%
Angina (not stable)	21.3%
ACC/AHA B2 or C lesions	64.6%
Moderately to heavy Ca-lesions	15.7%
Diameter stenosis	64.4%

12 Months Results	N = 183
Death*	0.5%
Target lesion revascularization**	2.8%
Myocardial infarction***	1.6%
MACE	5%
Stent Thrombosis	0%

*Patient died due to major gastrointestinal bleeding
** Restenosis in complex lesions
*** MI's were caused by non-TVF

Dr. Schmitz' conclusion: One-year ASSURE results suggest that BVS for de novo coronary artery disease are associated with favorable clinical and functional outcomes in all day clinical practice without mandatory IVUS or OCT guidance.

T. Schmitz, PCR 2014

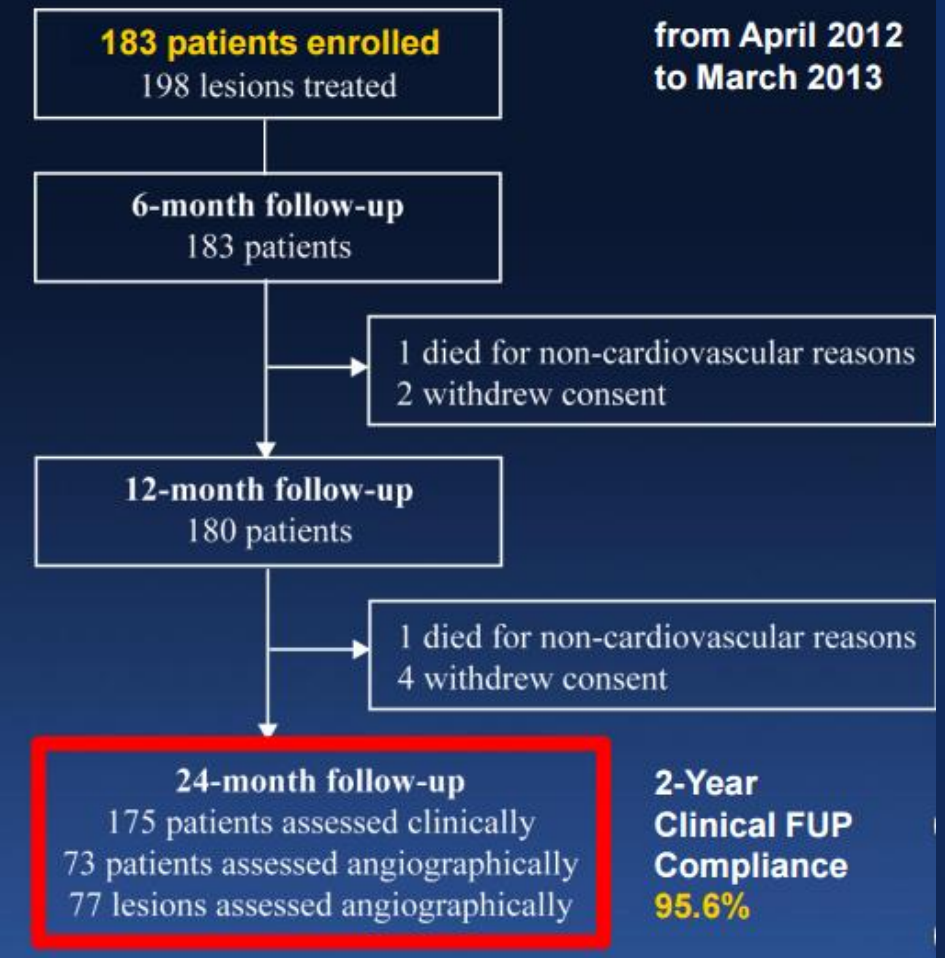
ASSURE 2-years

DESIGN
Prospective, observational, single-arm, multi-center

OBJECTIVE
To investigate safety and effectiveness of the Absorb bioresorbable vascular scaffold for de novo coronary artery lesions in real-world practice

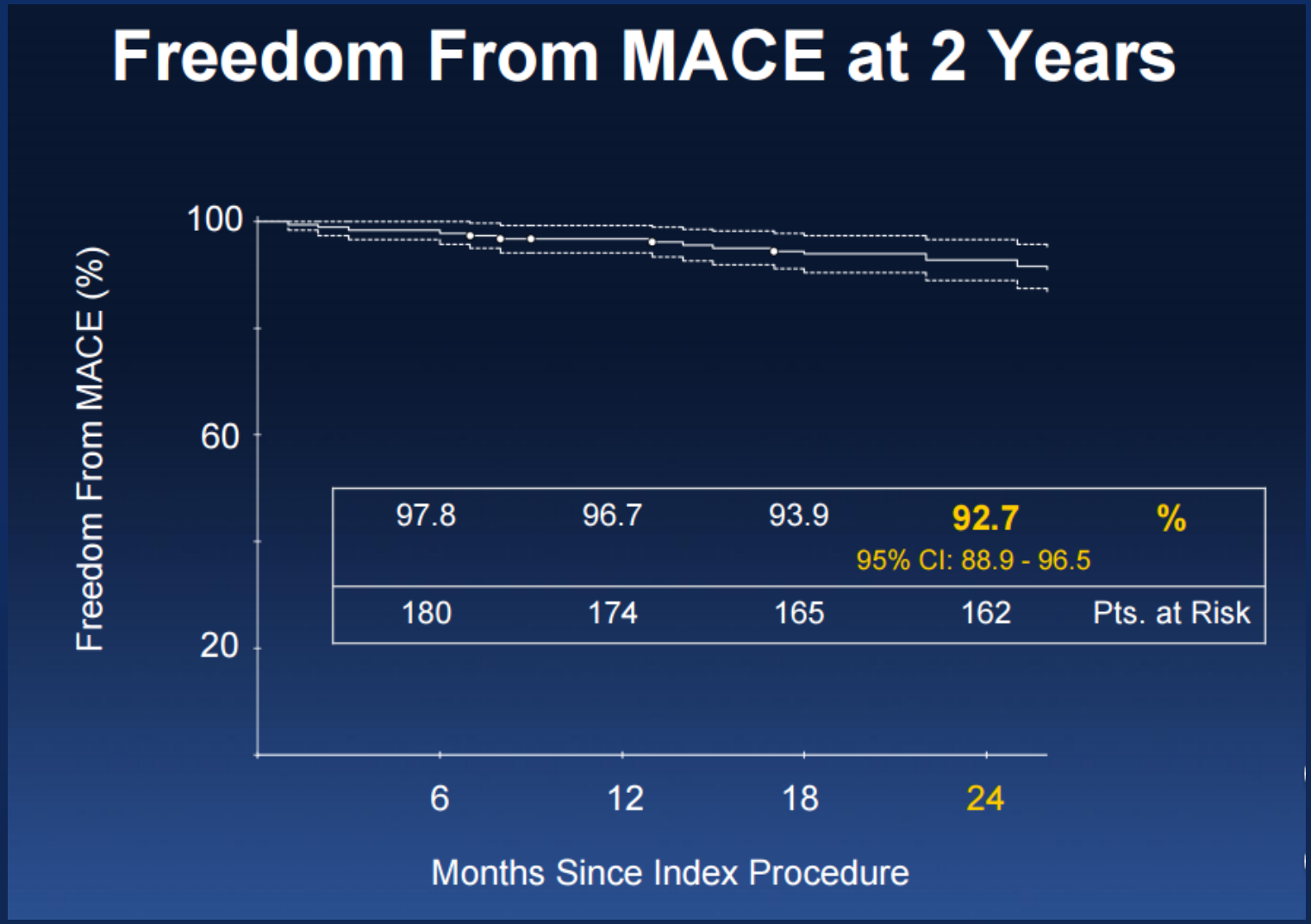
COORDINATING CLINICAL INVESTIGATOR
Detlef Mathey, MD, University Cardiovascular Center Hamburg, Germany

CORE LAB University of Ulm



Dr. Mathey, TCT 2016

ASSURE 2-years



Dr. Mathey, TCT 2016

ASSURE 2-years

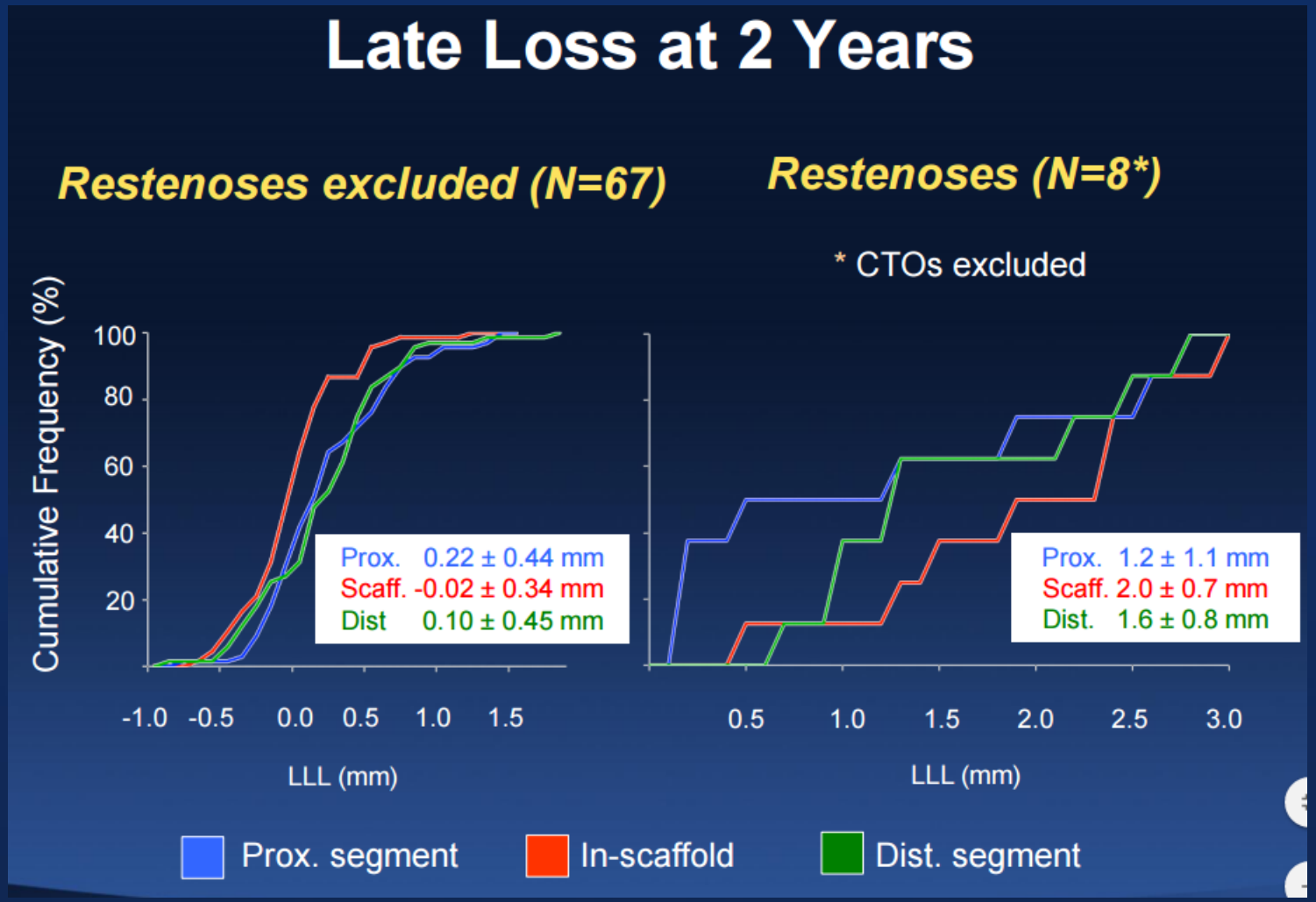
Angiographic Findings

2-Year FU (22.2 ± 6 Months)

	77 lesions
Post Procedure (mean)	
Acute gain, mm	1.7
% DS in-scaffold	14.6
Acute gain, %	61.8
2-Year FU (mean)	
LLL in-scaffold, mm	0.24
% DS in-scaffold	20.8
Net gain, %	47.2

Dr. Mathey, TCT 2016

ASSURE 2-years



Dr. Mathey, TCT 2016

ABSORB IV

ABSORB III + IV Clinical Trial Program

ABSORB IV

~3,000 pts randomized 1:1 ABSORB v XIENCE

RVD: 2.50 - 3.75 mm; Lesion length: ≤24 mm

Scaffold diameters: 2.5, 3.0 and 3.5 mm
Scaffold lengths: 12, 18, and 28 mm

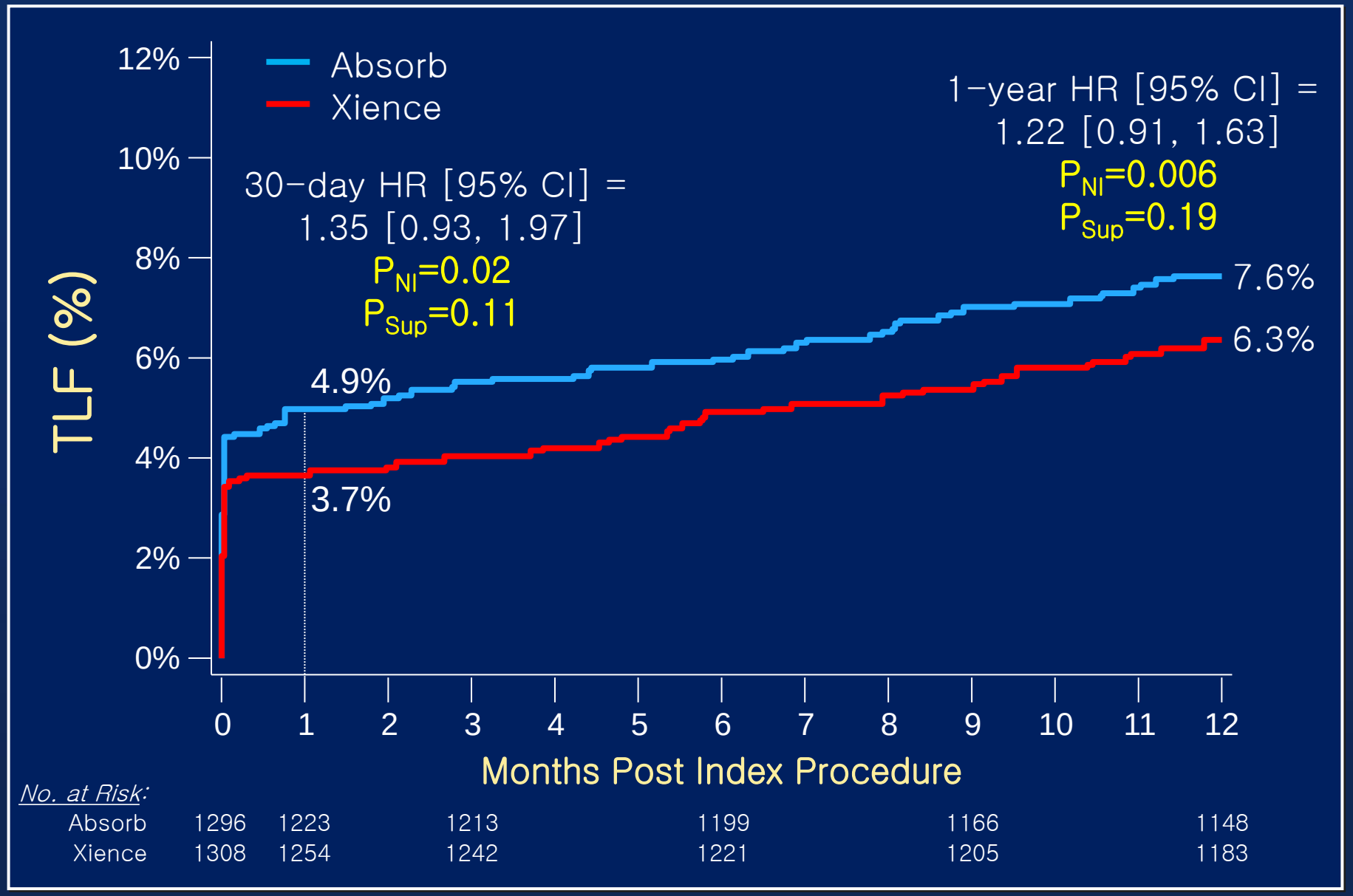
~5,000 total pts (ABSORB III + IV) with up to 2 de novo lesions in different epicardial vessels randomized, with FU for at least 5 years, at up to 160 US and non-US sites

Primary endpoints:

1. Angina at 1 year (ABSORB IV)
2. TLF between 1 and 5 years (landmark analysis)

G W. Stone, TCT 2013

ABSORB IV


Absorb
Xience
30-day HR [95% CI] = 1.35 [0.93, 1.97]
P_{NI}=0.02
P_{Sup}=0.11
1-year HR [95% CI] = 1.22 [0.91, 1.63]
P_{NI}=0.006
P_{Sup}=0.19
TLF (%)
12%
10%
8%
6%
4%
2%
0%
4.9%
3.7%
7.6%
6.3%
0 1 2 3 4 5 6 7 8 9 10 11 12
Months Post Index Procedure
No. at Risk:
Absorb 1296 1223 1213 1199 1166 1148
Xience 1308 1254 1242 1221 1205 1183

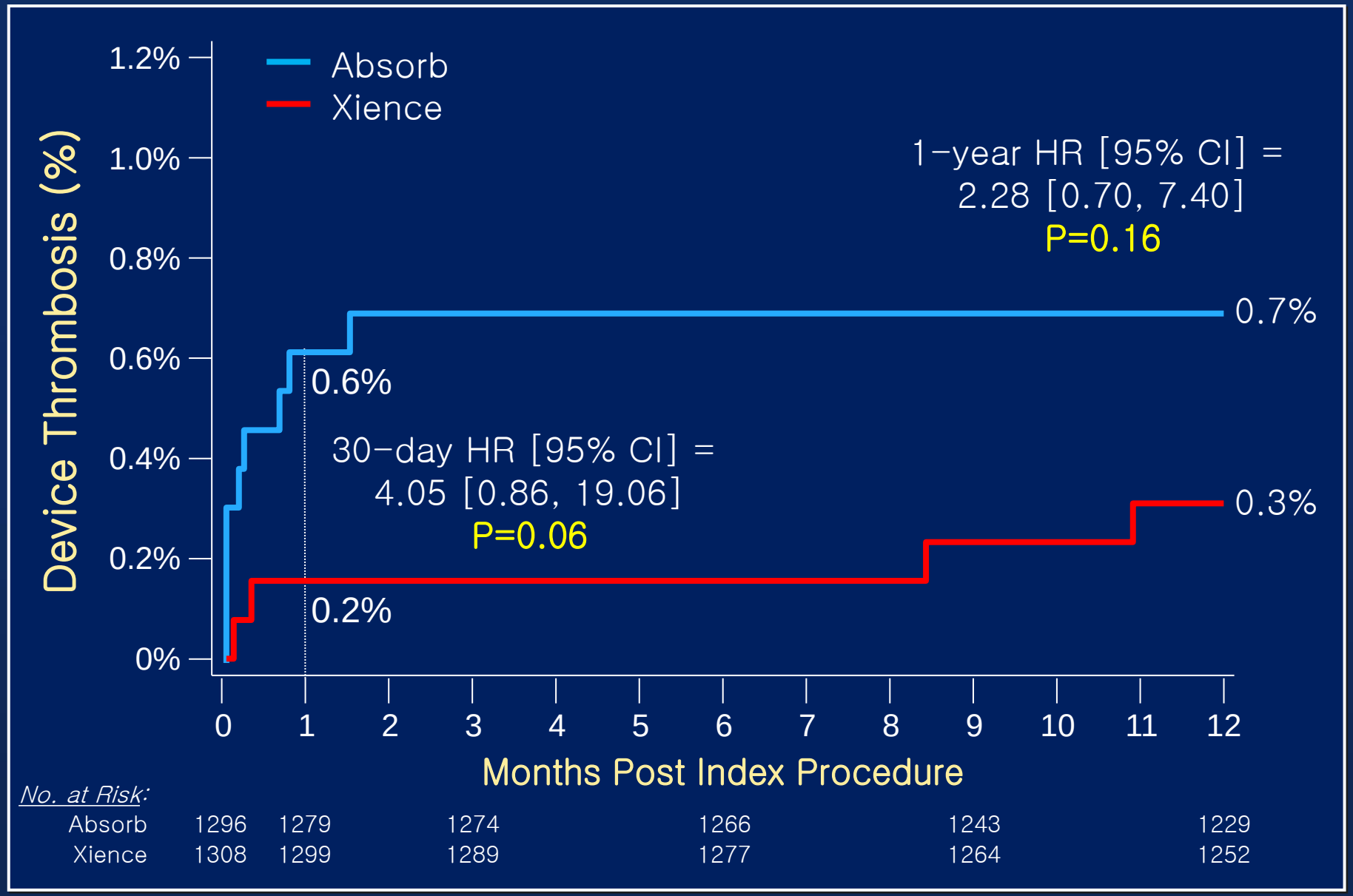
ABSORB IV 1-Year Endpoints

	Absorb (N=1296)	Xience (N=1308)	p-value
TLF	7.6% (98)	6.3% (82)	0.19
- Cardiac death	0.8% (10)	0.6% (8)	0.62
- TV-MI	5.8% (75)	4.5% (58)	0.12
- ID-TLR	2.9% (37)	1.9% (24)	0.08
TVF (CD, MI, ID-TVR)	8.7% (111)	7.6% (99)	0.33
PoCE (death, MI, revasc)	9.7% (124)	8.6% (112)	0.35
- All-cause death	1.3% (16)	1.1% (14)	0.69
- MI	6.2% (80)	5.0% (65)	0.18
- Peri-procedural MI	3.8% (49)	3.4% (44)	0.56
- Spontaneous	2.6% (33)	1.7%(22)	0.12
- All revascularization	4.9% (63)	3.9% (50)	0.19
- ID-TVR	4.0% (51)	2.9% (37)	0.11

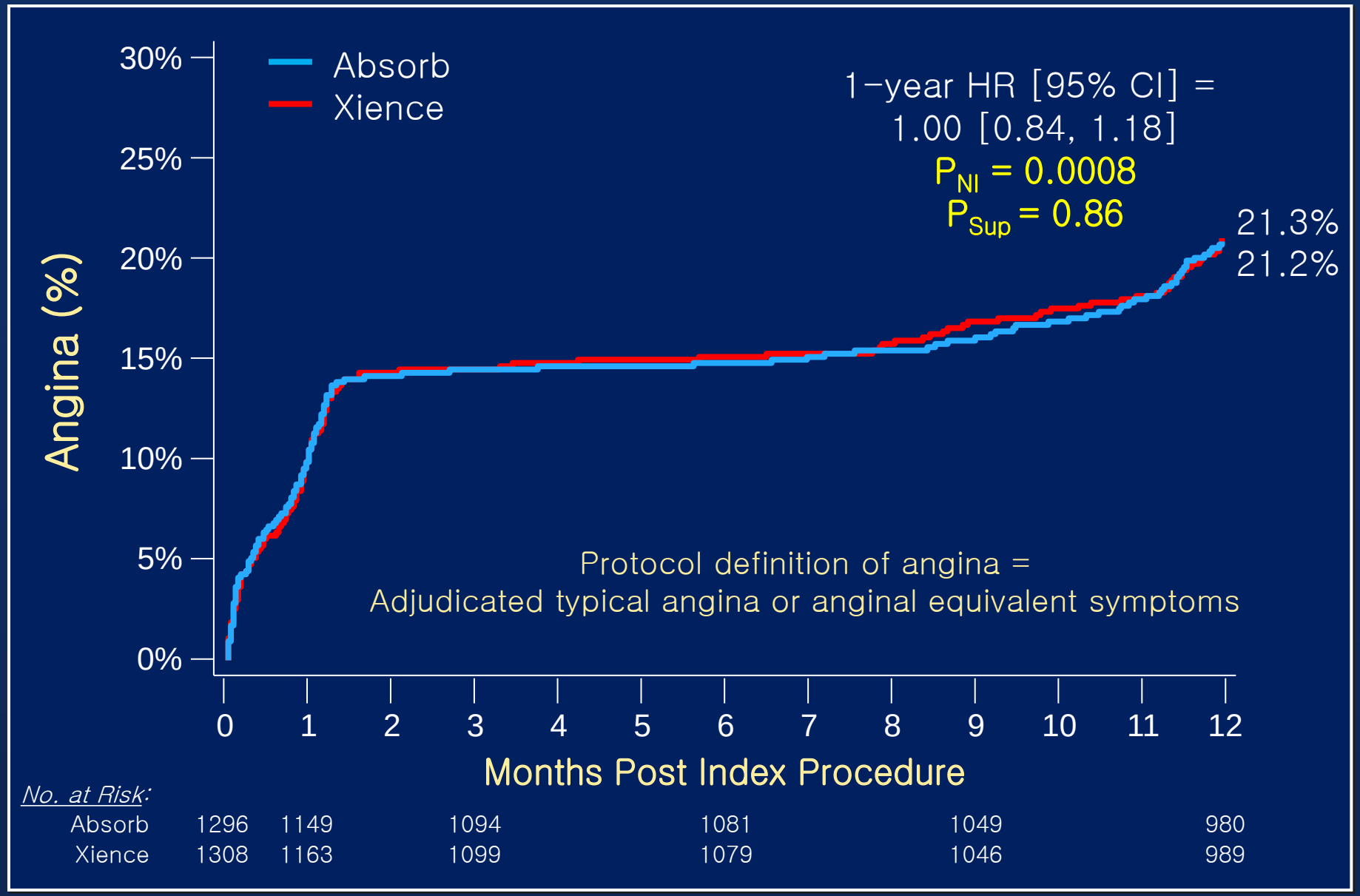
ABSORB IV 30-Day Endpoints

	Absorb (N=1296)	Xience (N=1308)	p-value
TLF	4.9% (64)	3.7% (48)	0.11
- Cardiac death	0.1% (1)	0% (0)	0.32
- TV-MI	4.4% (57)	3.6% (47)	0.29
- ID-TLR	1.0% (13)	0.2% (3)	0.02
TVF (CD, MI, ID-TVR)	5.1% (66)	3.7% (48)	0.08
PoCE (death, MI, revasc)	5.2% (67)	4.1% (53)	0.17
- All-cause death	0.1% (1)	0.1% (1)	0.99
- MI	4.5% (58)	3.6% (47)	0.25
- Peri-procedural MI	3.8% (49)	3.4% (44)	0.56
- Spontaneous	0.8% (10)	0.2% (3)	0.05
- All revascularization	1.5% (19)	0.6% (8)	0.03
- ID-TVR	1.2% (16)	0.2% (3)	0.003

ABSORB IV

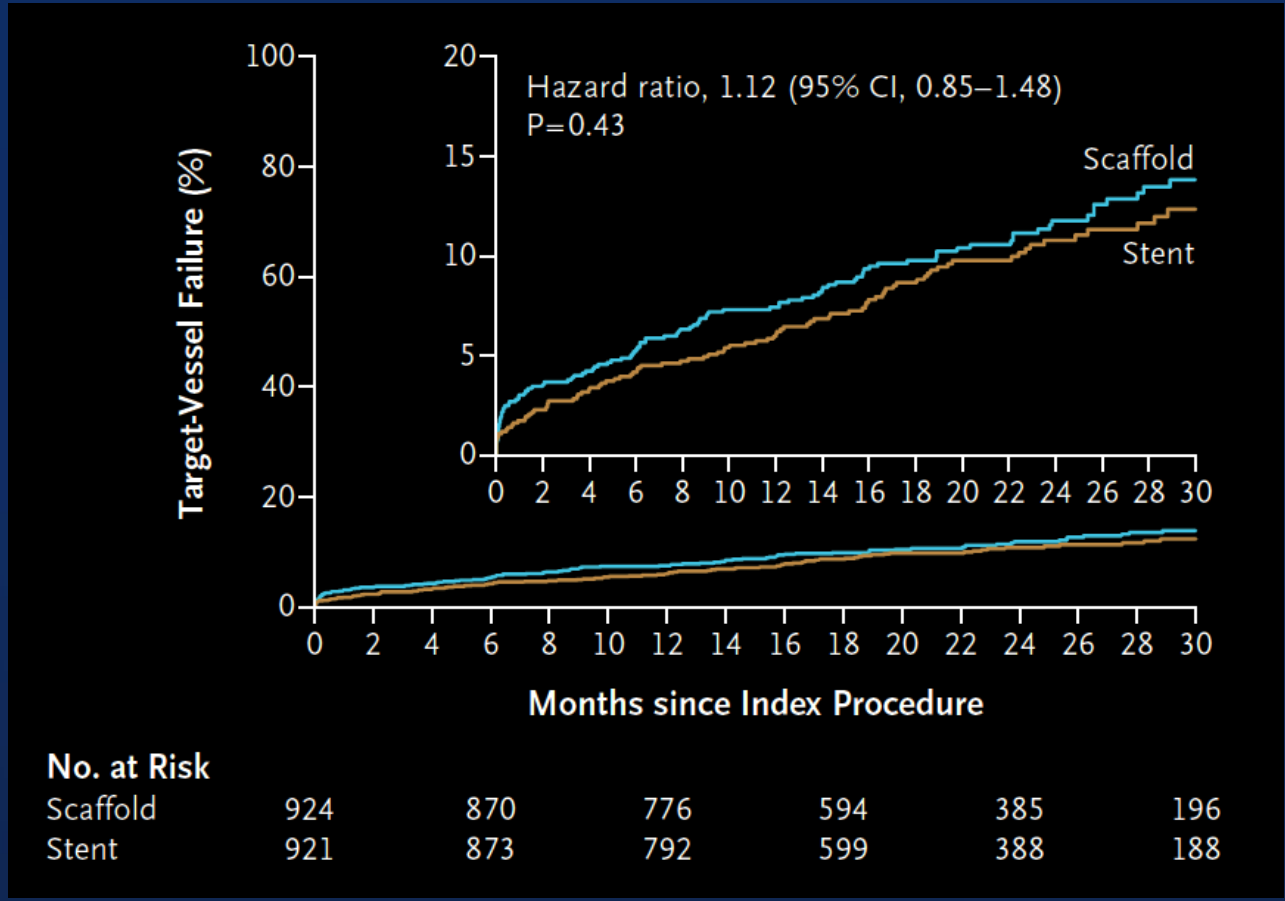

Absorb
Xience
1.2%
1.0%
0.8%
0.6%
0.4%
0.2%
0%
Device Thrombosis (%)
1-year HR [95% CI] =
2.28 [0.70, 7.40]
P=0.16
0.7%
0.6%
30-day HR [95% CI] =
4.05 [0.86, 19.06]
P=0.06
0.3%
0.2%
0 1 2 3 4 5 6 7 8 9 10 11 12
Months Post Index Procedure
No. at Risk:
Absorb 1296 1279 1274 1266 1243 1229
Xience 1308 1299 1289 1277 1264 1252

ABSORB IV


Absorb
Xience
1-year HR [95% CI] =
1.00 [0.84, 1.18]
P_{NI} = 0.0008
P_{Sup} = 0.86
21.3%
21.2%
Angina (%)
30%
25%
20%
15%
10%
5%
0%
Protocol definition of angina =
Adjudicated typical angina or anginal equivalent symptoms
0 1 2 3 4 5 6 7 8 9 10 11 12
Months Post Index Procedure
No. at Risk:
Absorb 1296 1149 1094 1081 1049 980
Xience 1308 1163 1099 1079 1046 989

AIDA 2-years

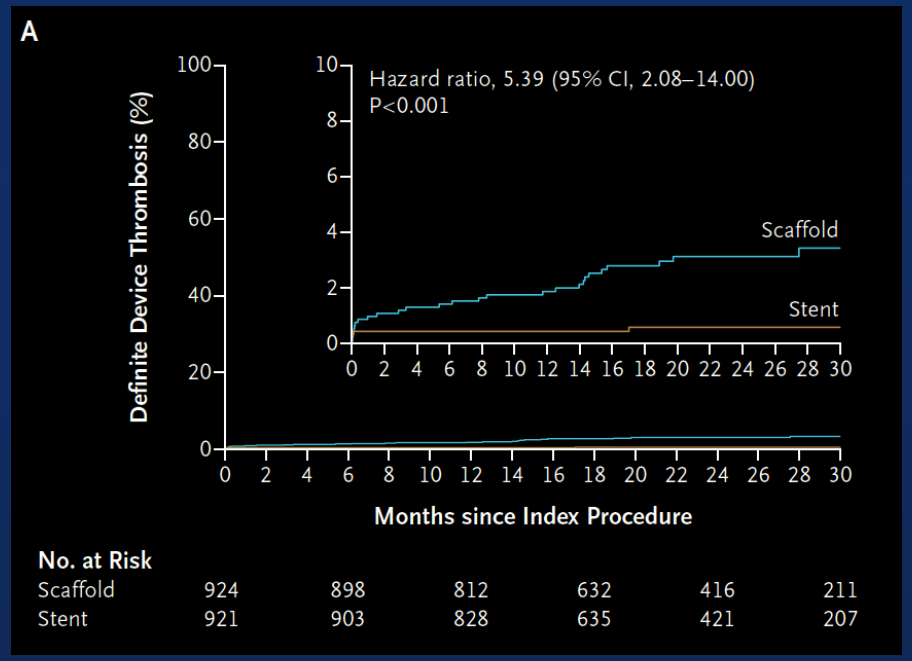
Target-vessel Failure



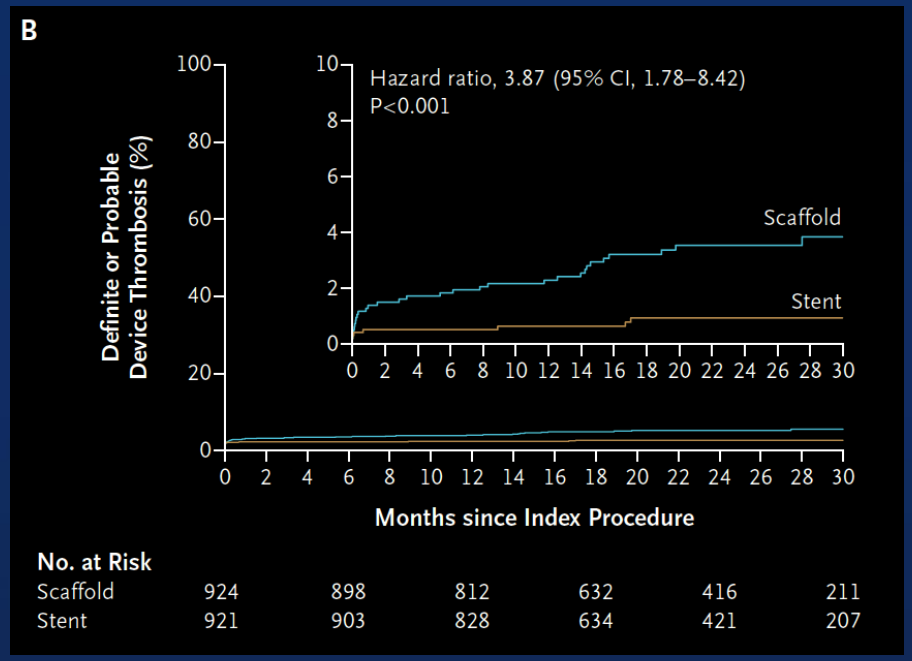
J J. Wykrzykowska et al., NEJM 2017

AIDA 2-years

Definite device thrombosis



Definite or probaable device thrombosis



J J. Wykrzykowska et al., NEJM 2017

COMPARE-ABSORB

Primary endpoint
1 year TLF non-inferiority analysis

- Assumed difference between Xience and Absorb : 0 %
- Non inferiority margin : 4.5 %
- One sided 2.5% significance level
- TLF rate Xience 4.2%
- TLF rate Absorb 5.1%

Δ Prim. EP: Absorb - Xience = 0.9 % (95% CI: -1.2 – 3.0 %)

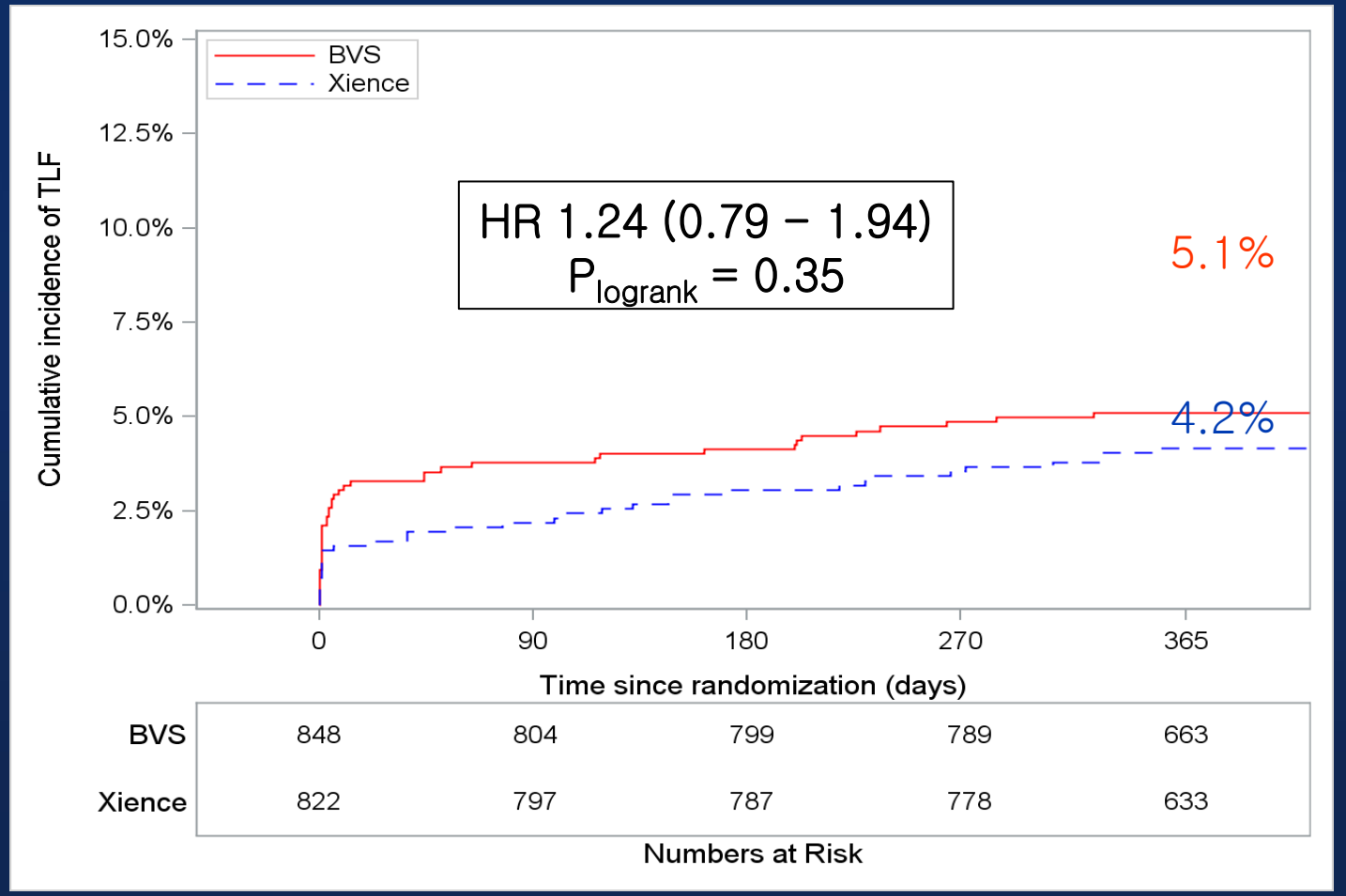
Absorb is non-inferior compared to Xience

P < 0.001

COMPARE-ABSORB

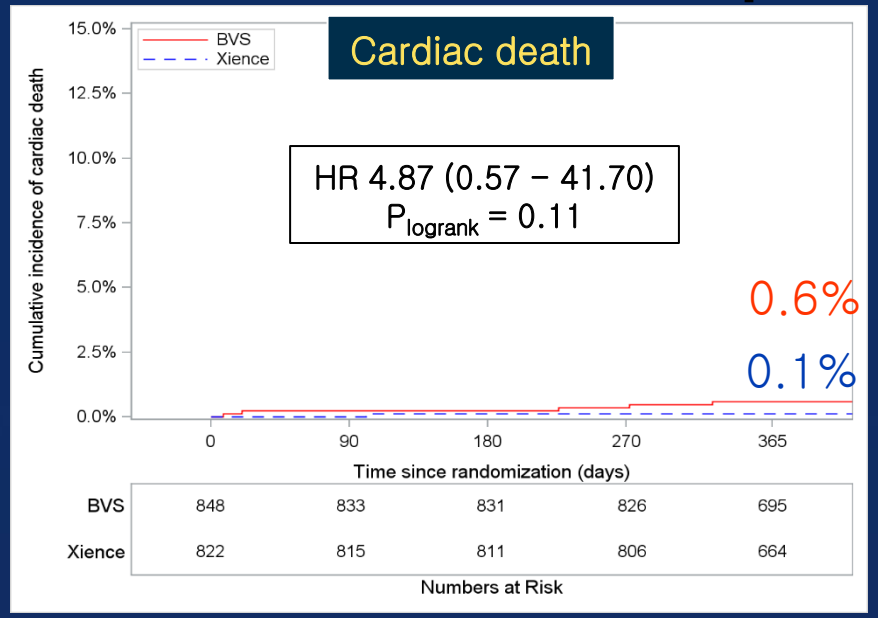
TLF at 1 year

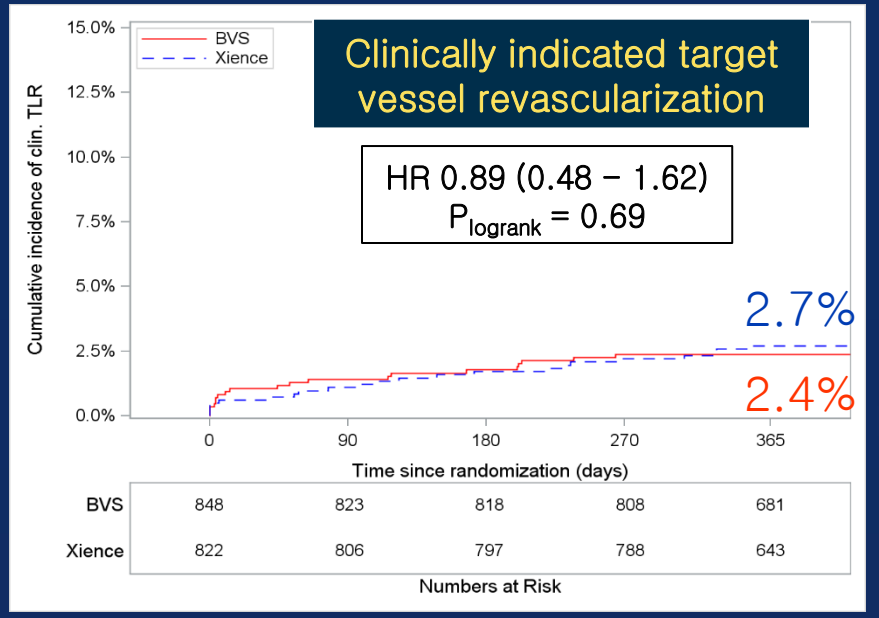
Cardiac death, target vessel myocardial infarction, clinically-indicated target lesion revascularization

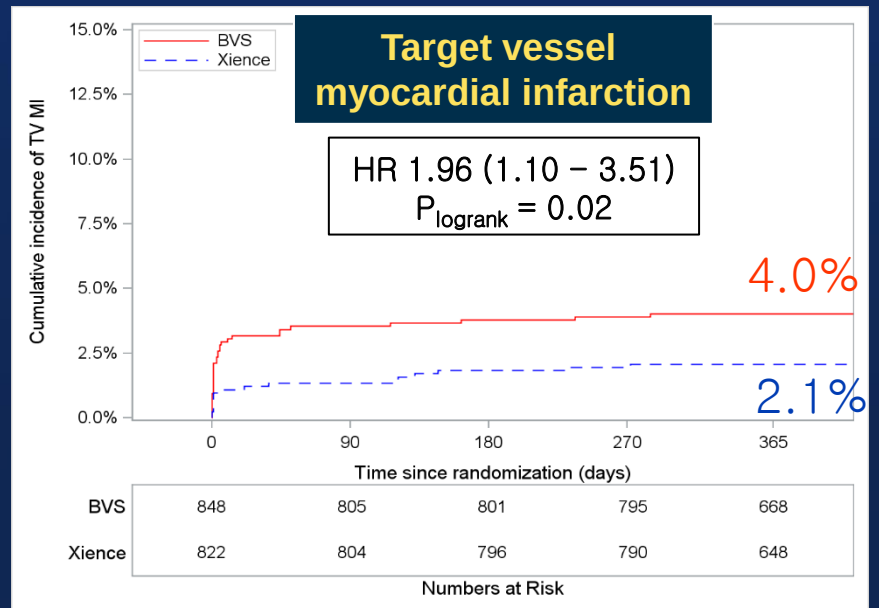


COMPARE-ABSORB

Components of TLF







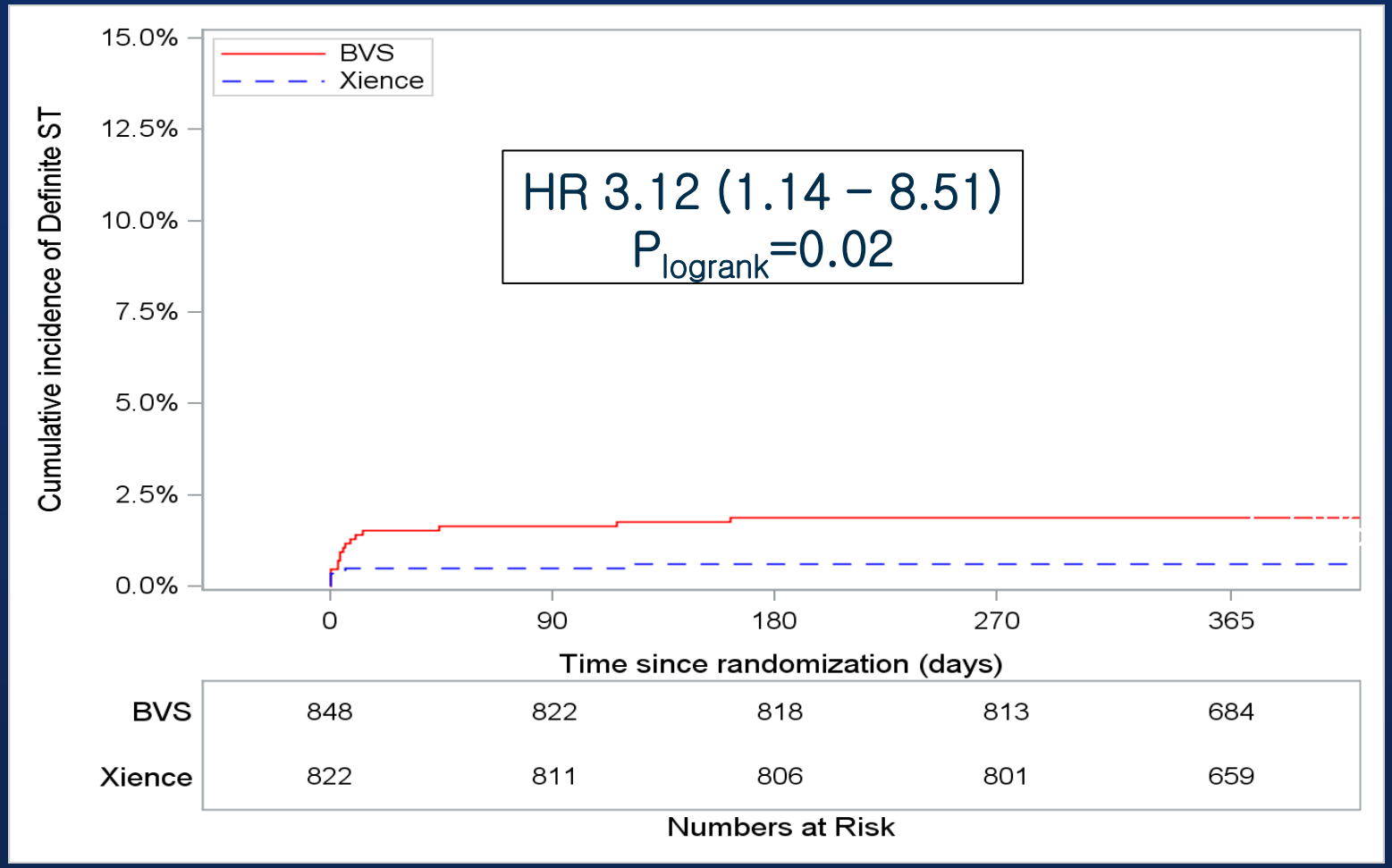
MI definition:

- SCAI (peri-procedural)
- TUD (spontaneous)

COMPARE-ABSORB

Stent/Scaffold Thrombosis @ 1 year

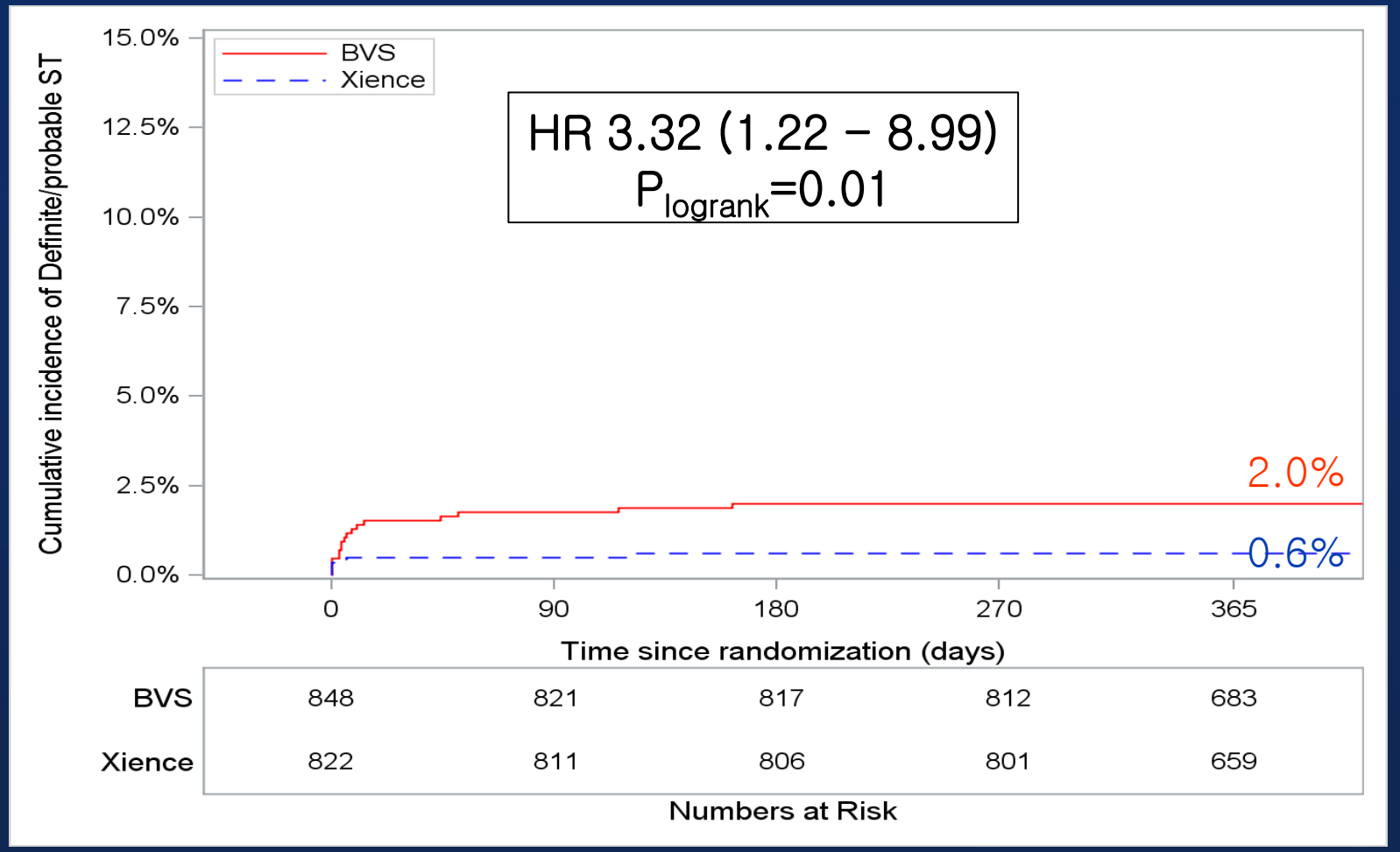
Definite Stent/Scaffold Thrombosis (ARC definition)



COMPARE-ABSORB

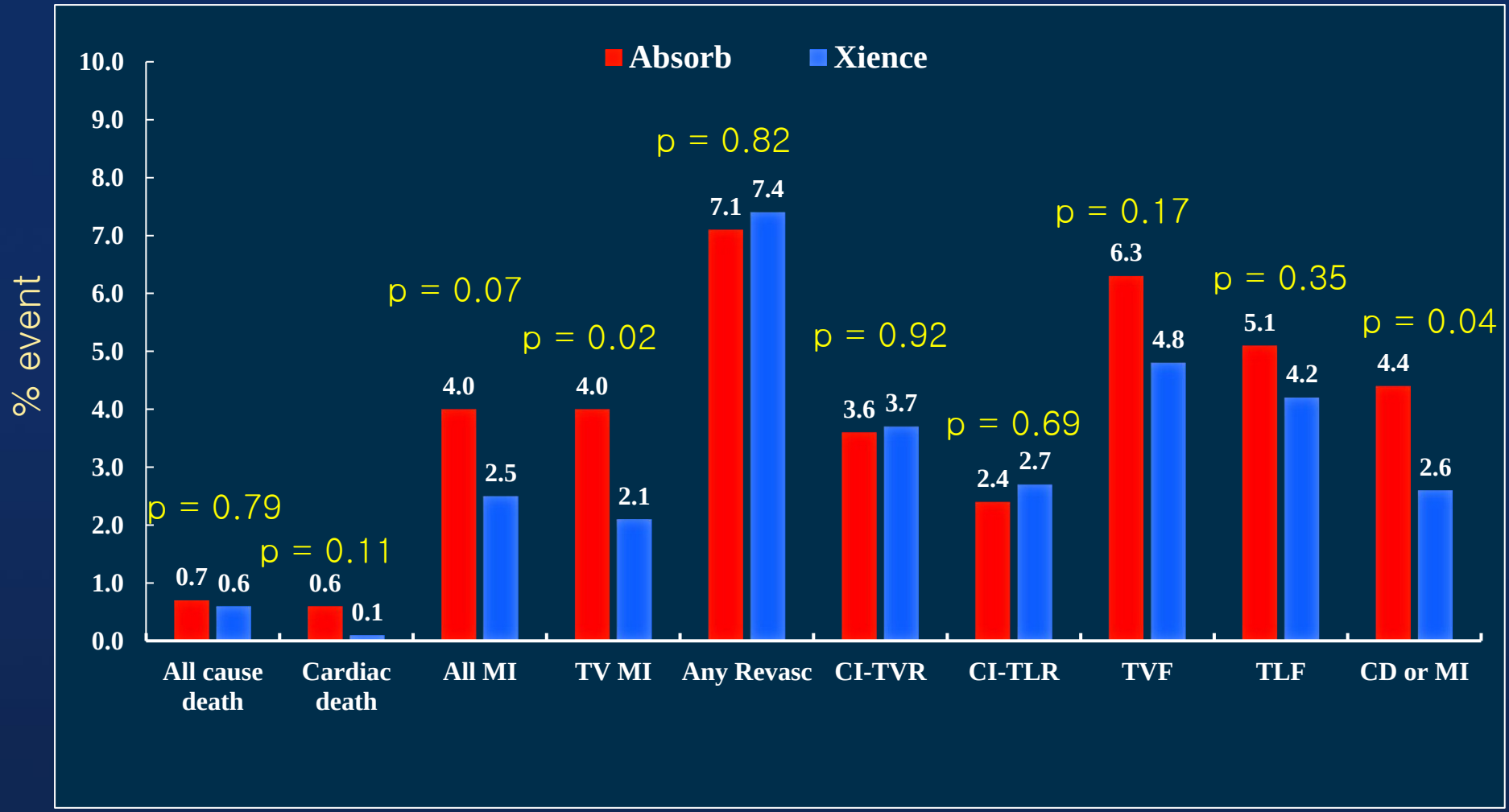
Stent/Scaffold Thrombosis @ 1 year

Definite and Probable Stent/Scaffold Thrombosis (ARC definition)



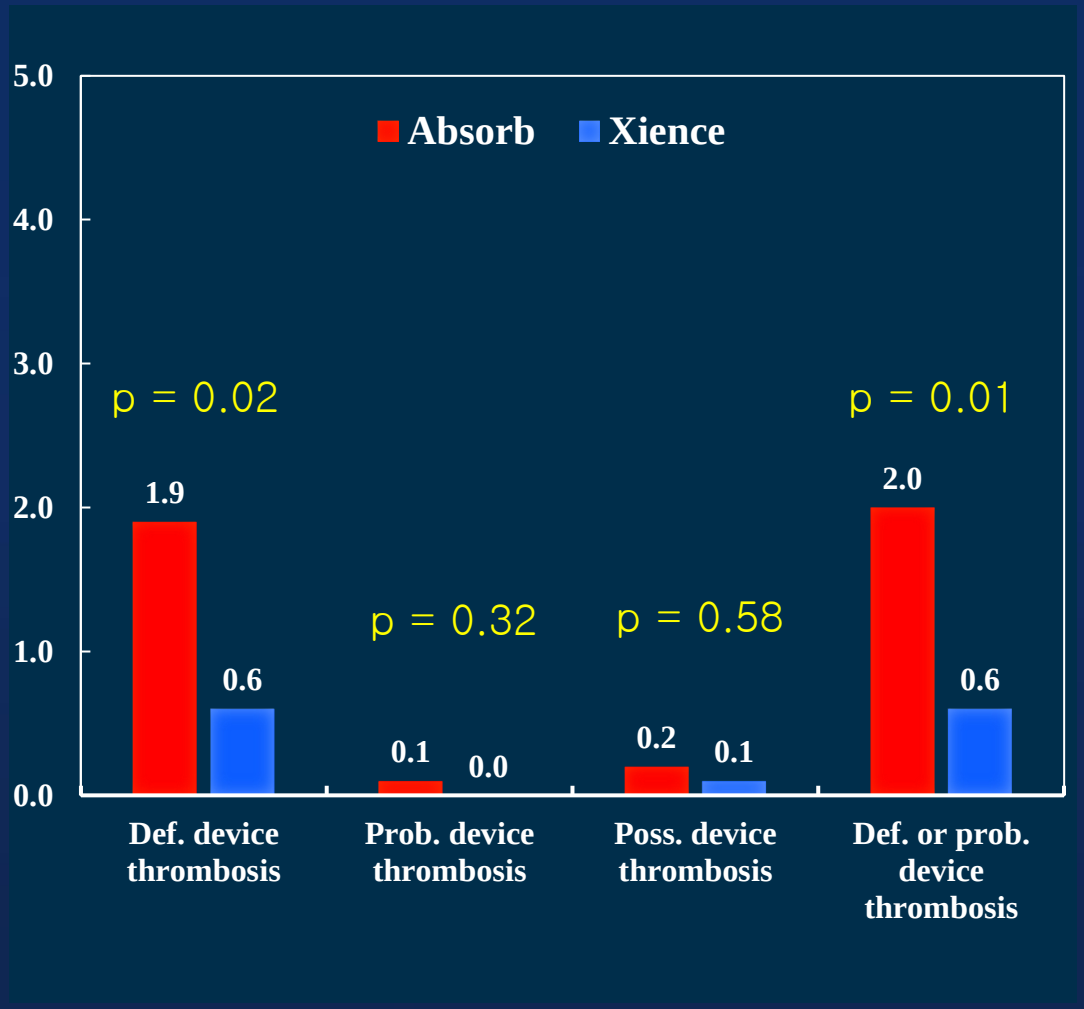
COMPARE-ABSORB

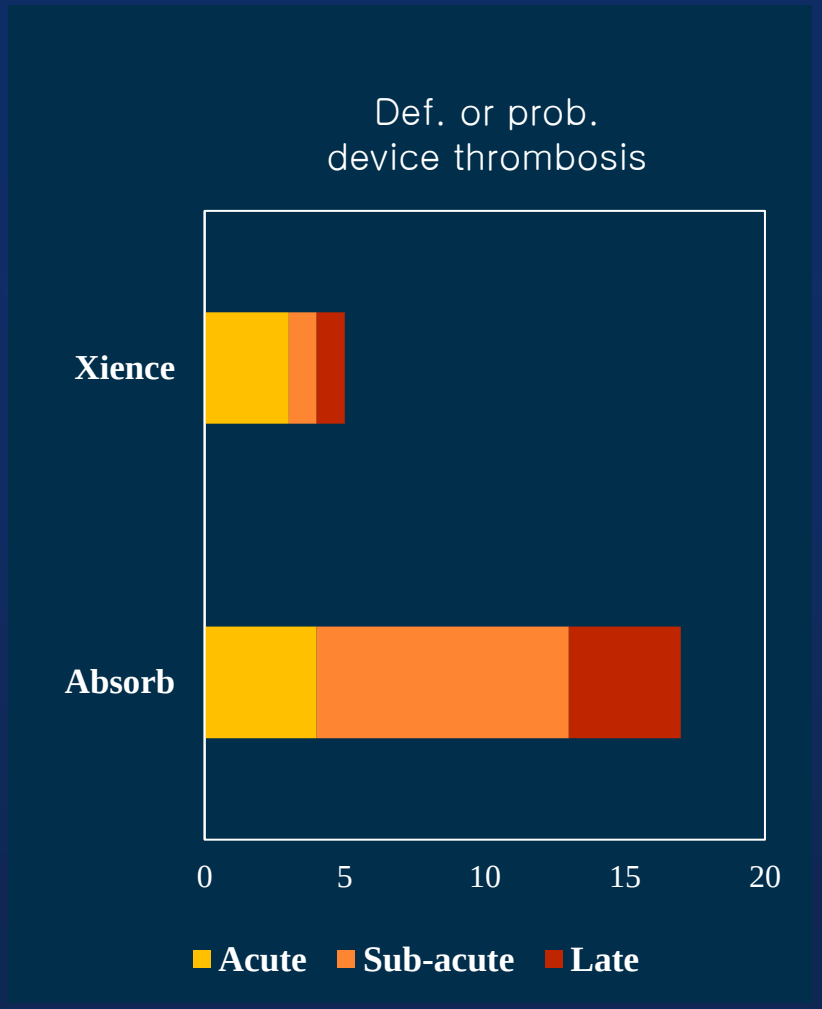
Clinical events



COMPARE-ABSORB

Device thrombosis

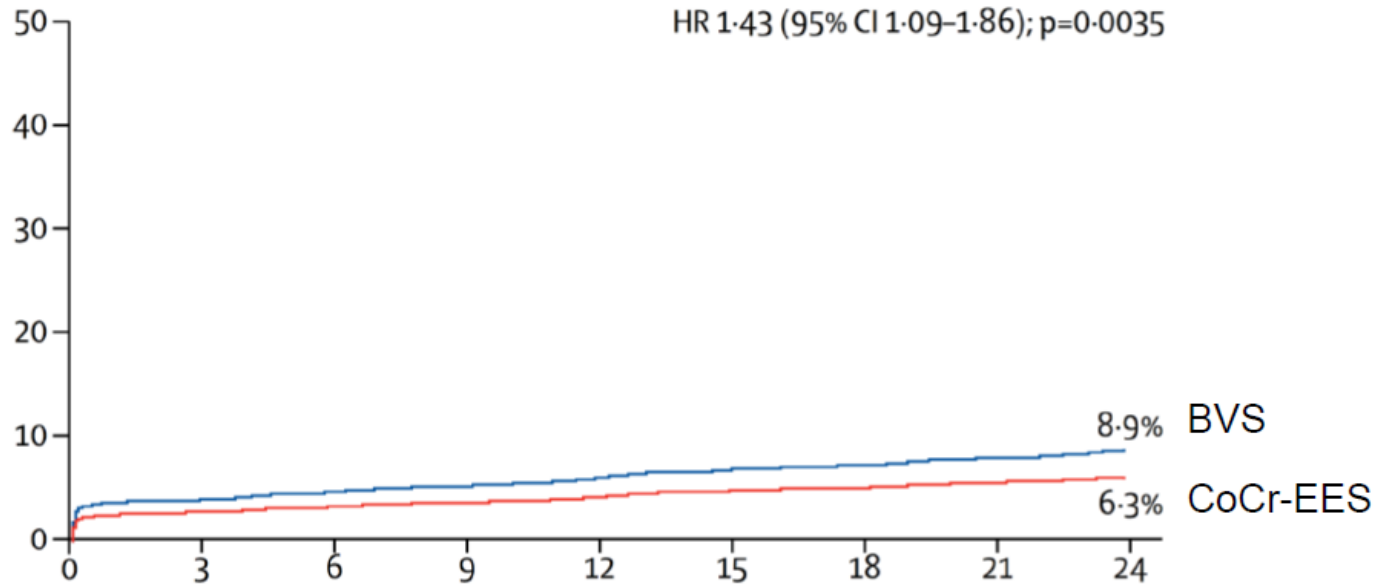




Meta-analysis of ABSORB

Indivitual pt data pooled analysis of 4 randomized trials of BVS vs. EES (ABSORB II, III, Japan, China; N=3389 pts)

2-year target lesion failure

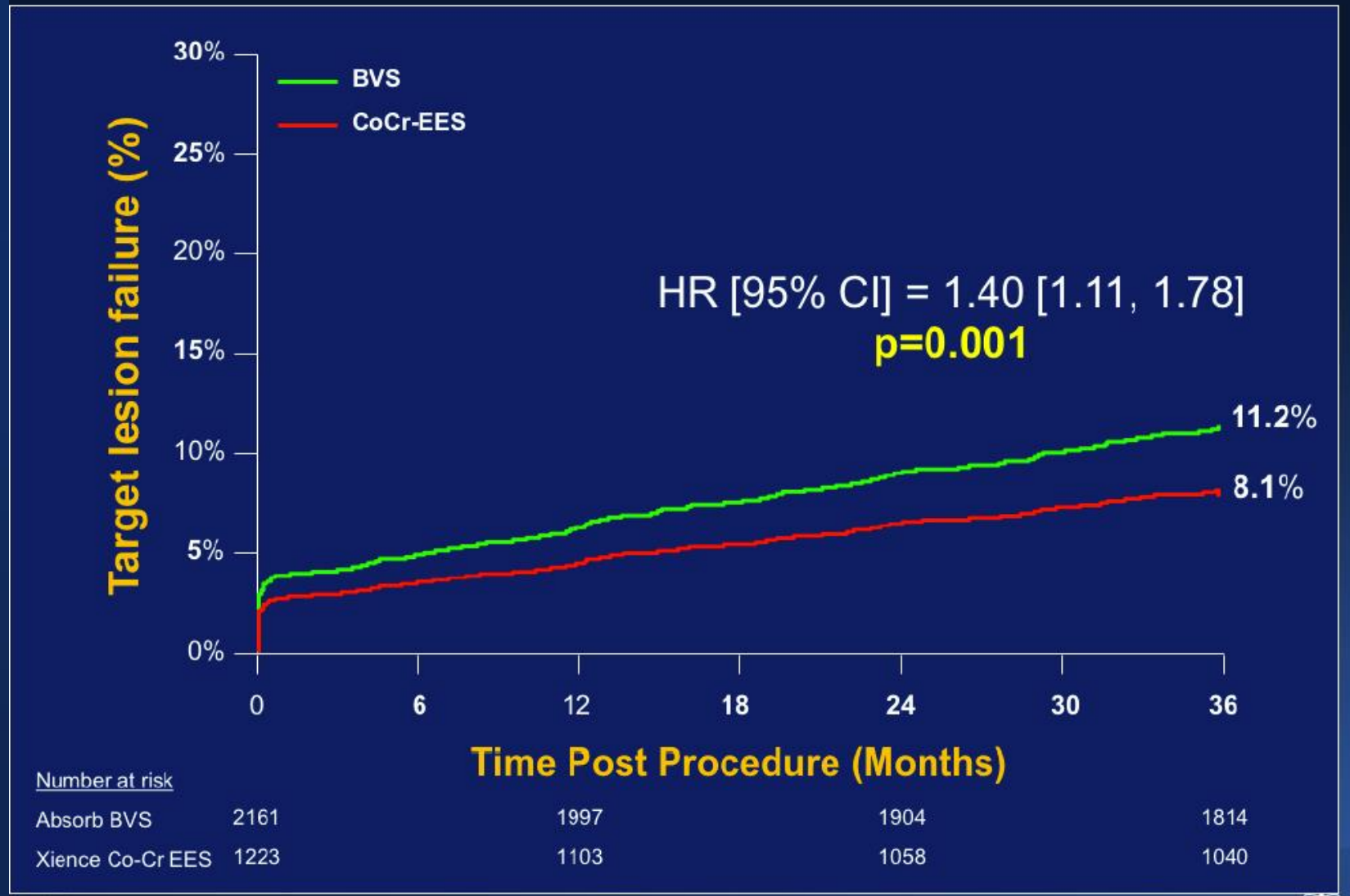


Ali Z etal. Lancet 2017

ABSORB: 3-year Outcomes

Meta-analysis of 4 BVS vs. EES RCTs (n=3,389 pts)

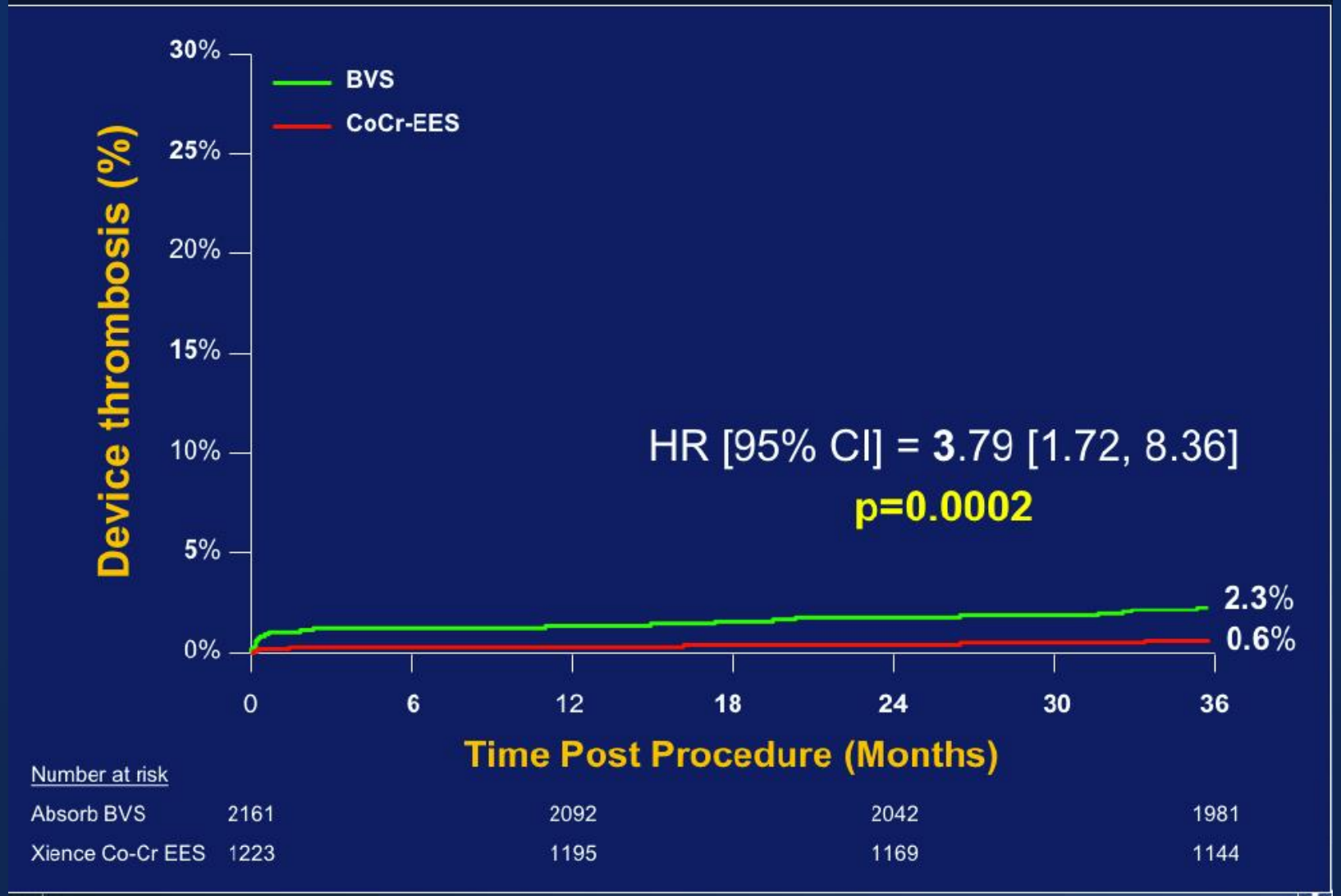
3-Year TLF



ABSORB: 3-year Outcomes

Meta-analysis of 4 BVS vs. EES RCTs (n=3,389 pts)

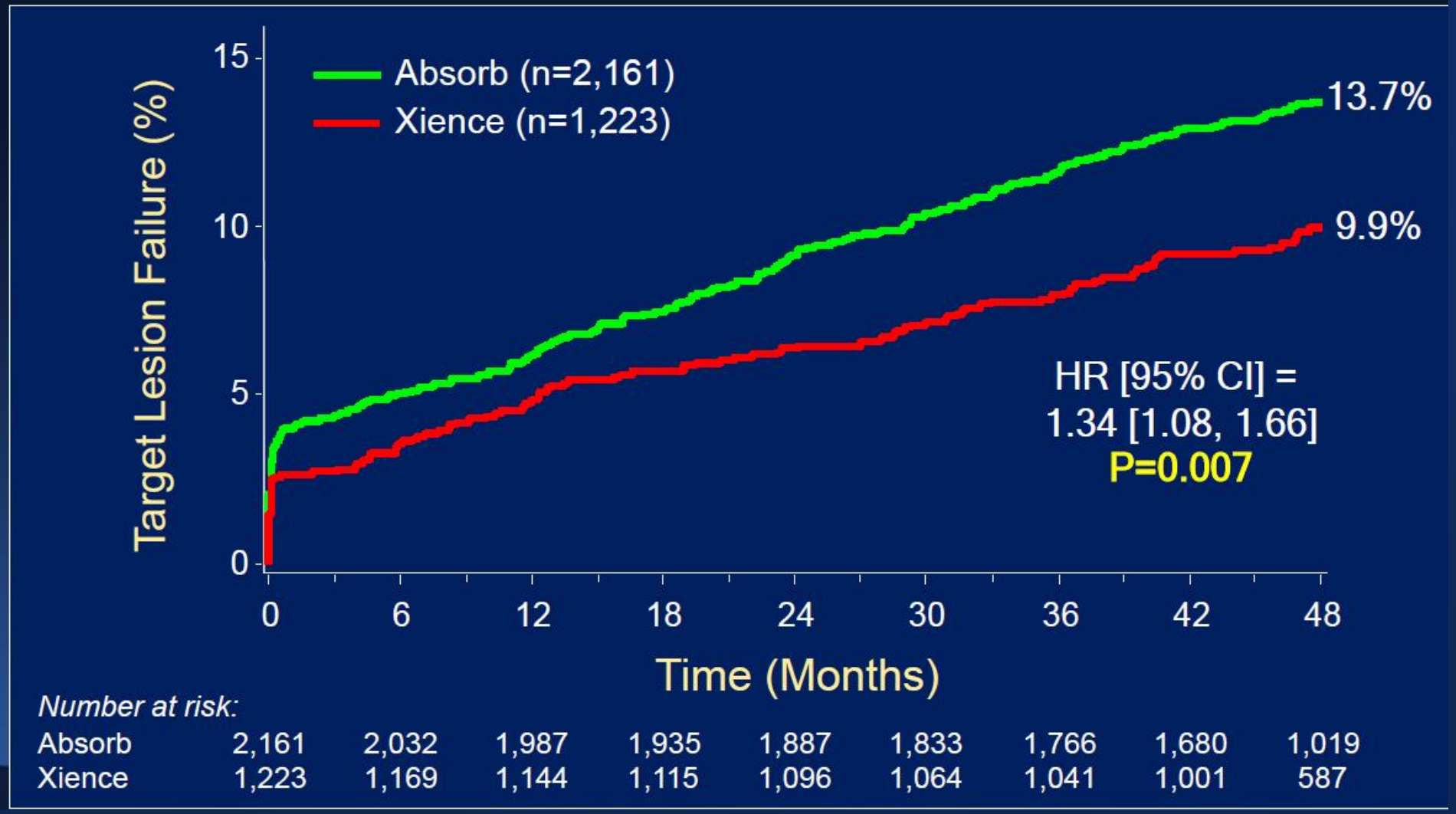
3-Year Device Thrombosis



ABSORB: 4-year Outcomes

Meta-analysis of 4 BVS vs. EES RCTs (n=3,389 pts)

4-Year TLF



Number at risk:

Absorb	2,161	2,032	1,987	1,935	1,887	1,833	1,766	1,680	1,019
Xience	1,223	1,169	1,144	1,115	1,096	1,064	1,041	1,001	587

ABSORB: 4-year Outcomes

Meta-analysis of 4 BVS vs. EES RCTs (n=3,389 pts)

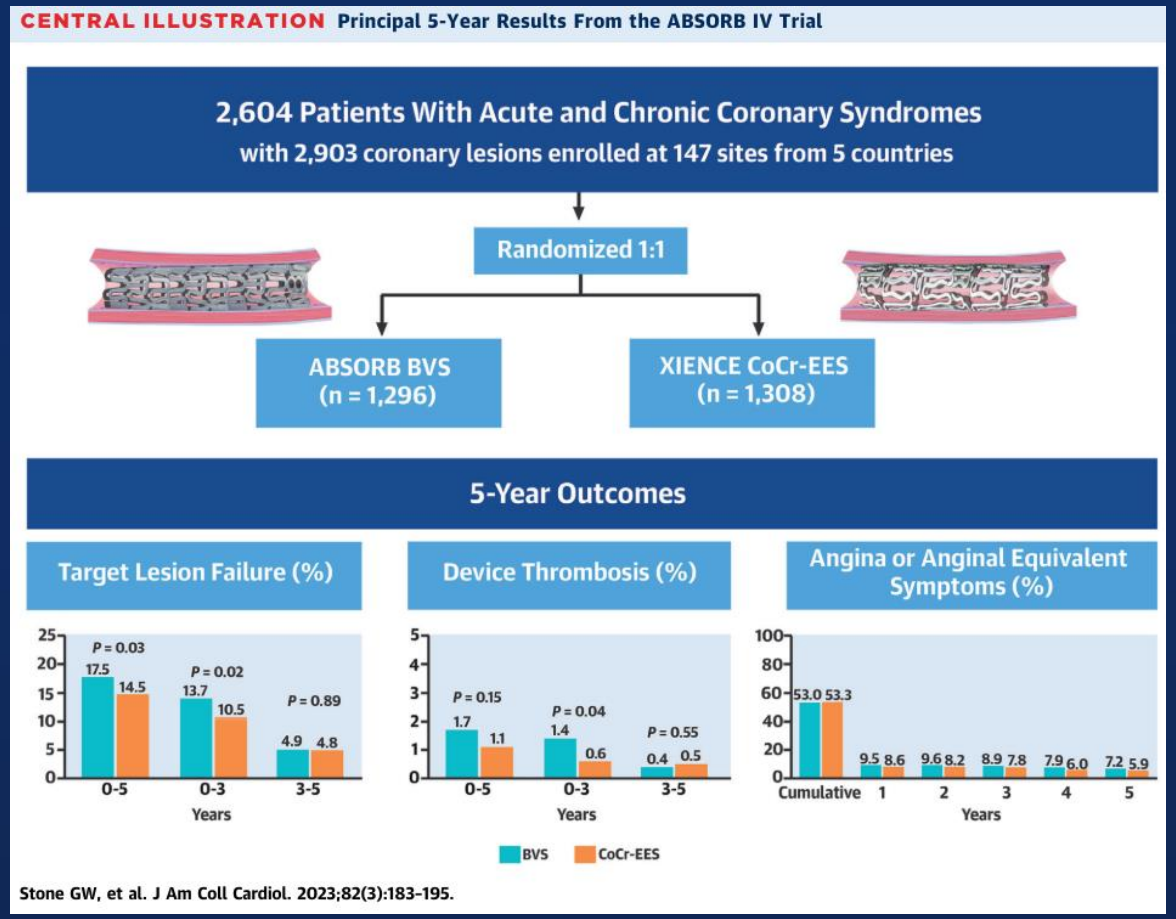
4-Year Device Thrombosis

ABSORB 4-Year Meta-analysis

Conclusions from 4 trials and 3,389 randomized patients

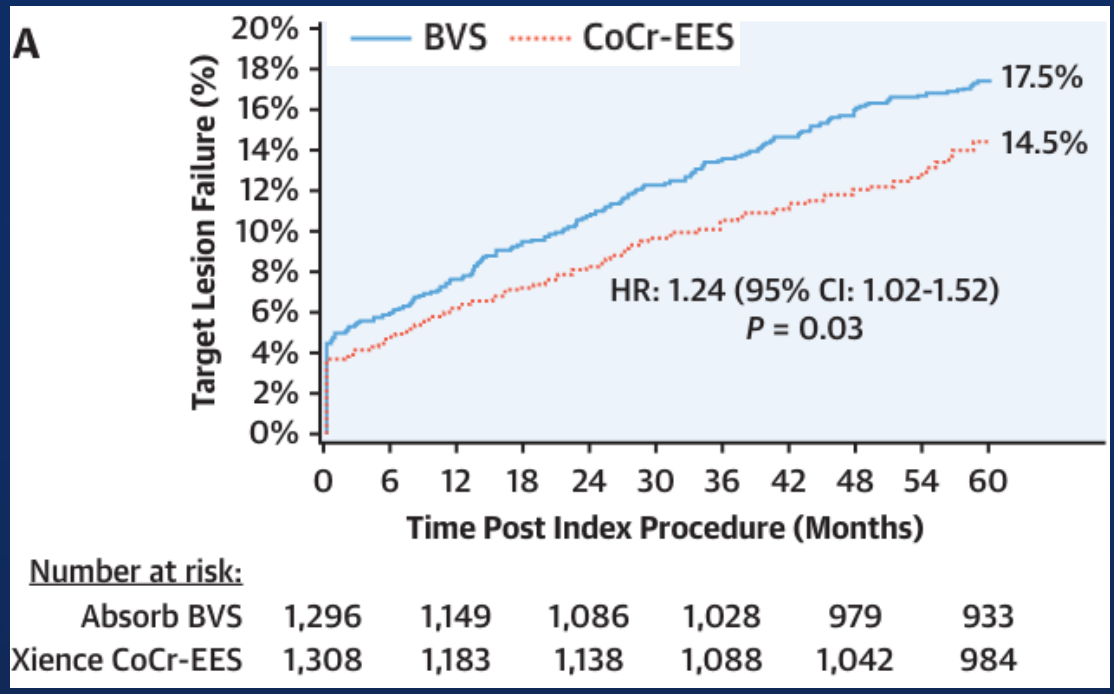
- Absorb BVS resulted in higher cumulative 4-year rates of TLF and device thrombosis compared with Xience CoCr-EES
- However, after 3 years, the point of complete polymer bioresorption, the excess risk from BVS has resolved, offering the potential for the long-term advantages of bioresorbable scaffold technology to emerge

ABSORB IV: 5 –Year Outcomes



Stone GW, et al. J Am Coll Cardiol. 2023;82(3):183-195.

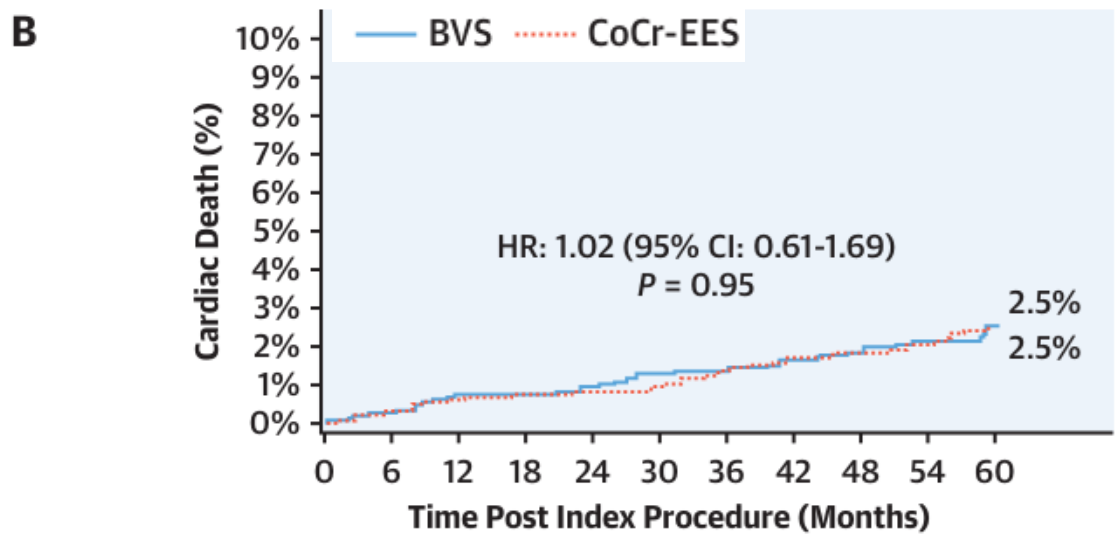
A) Target Lesion Failure



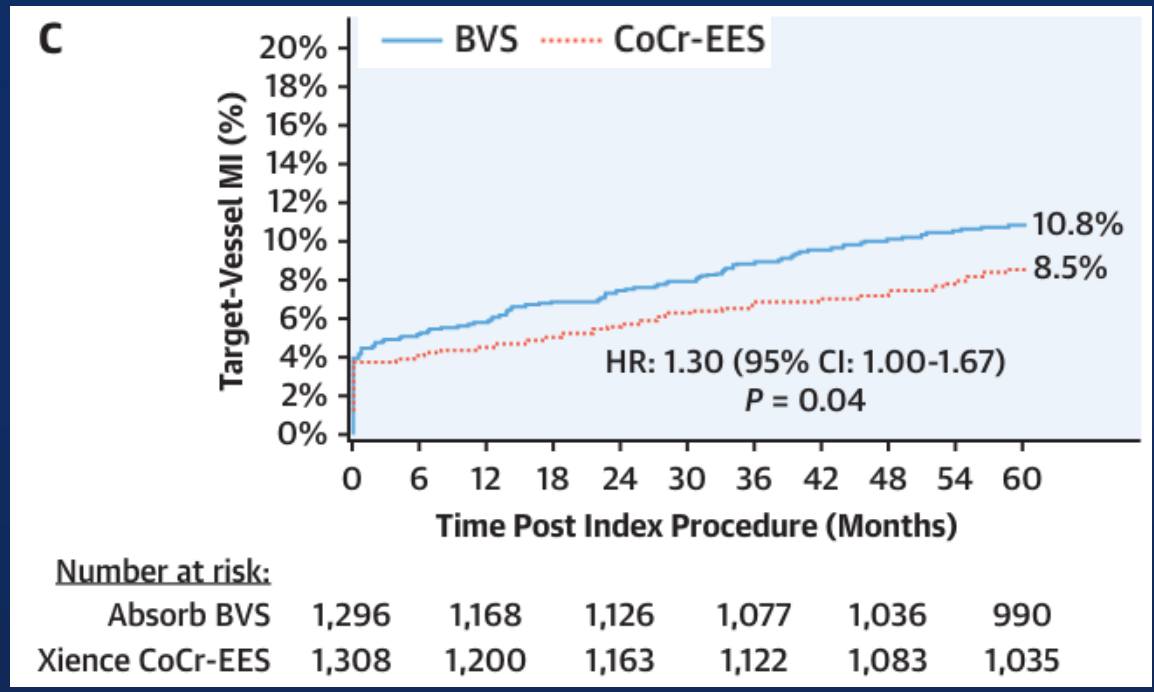
GW stone et al. J Am Coll Cardiol. 2023 Jul 18;82(3):183-195.

ABSORB IV: 5 –Year Outcomes

B) Cardiac Death



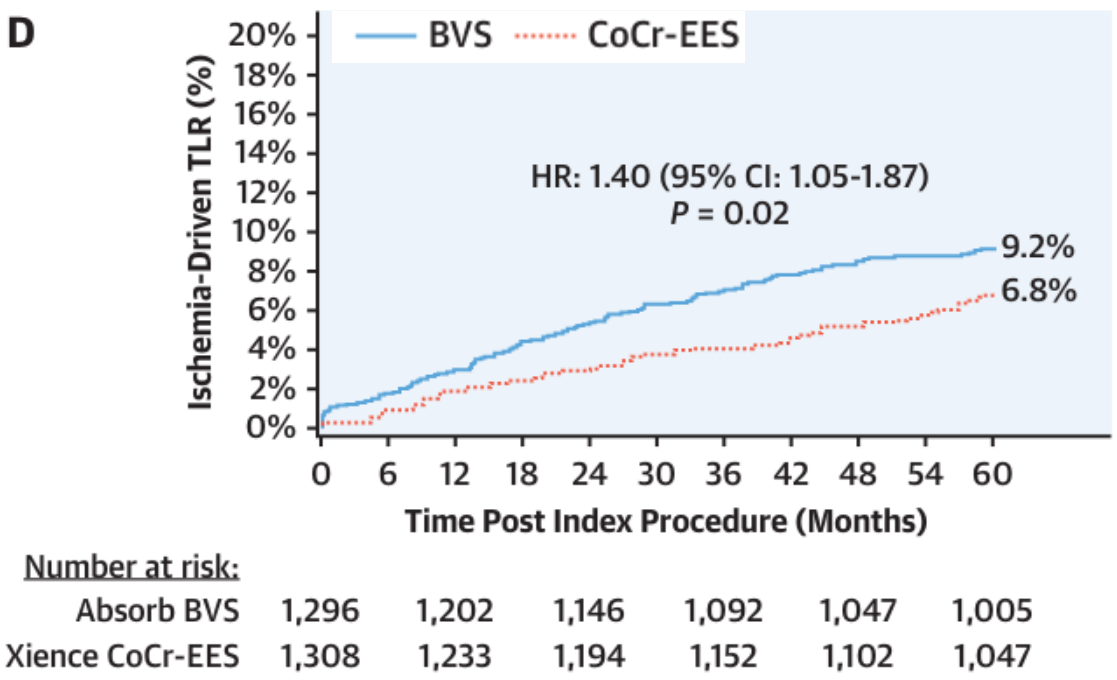
C) Target Vessel MI



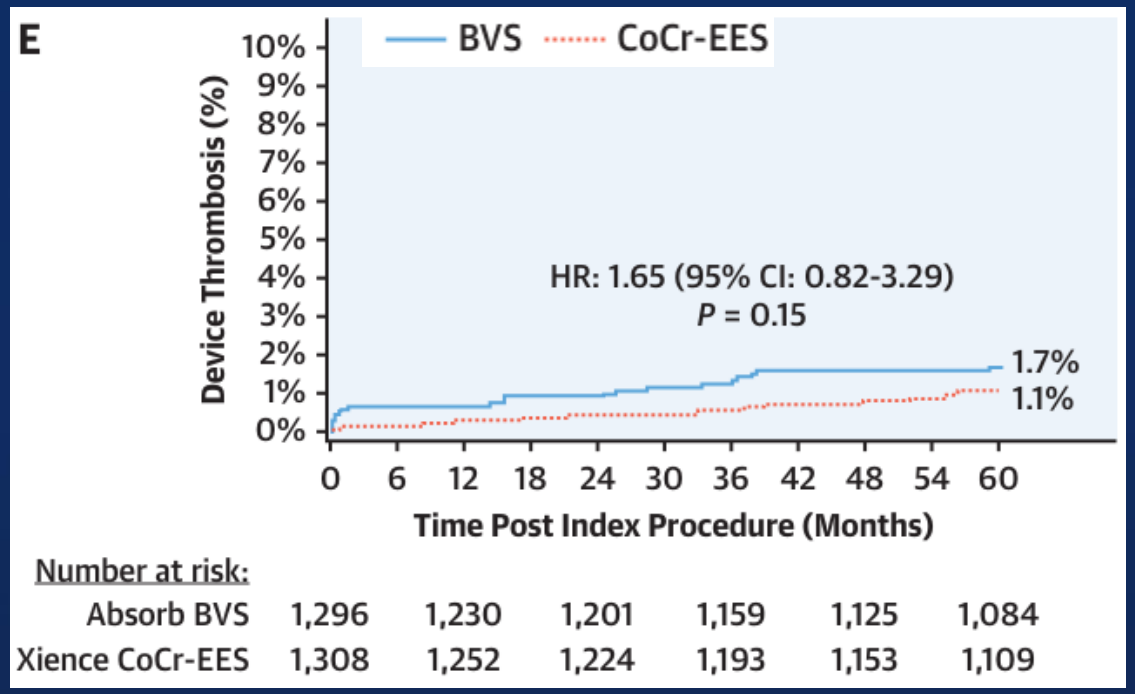
GW stone et al. J Am Coll Cardiol. 2023 Jul 18;82(3):183-195.

ABSORB IV: 5 –Year Outcomes

D) Ischemia-Driven TLR



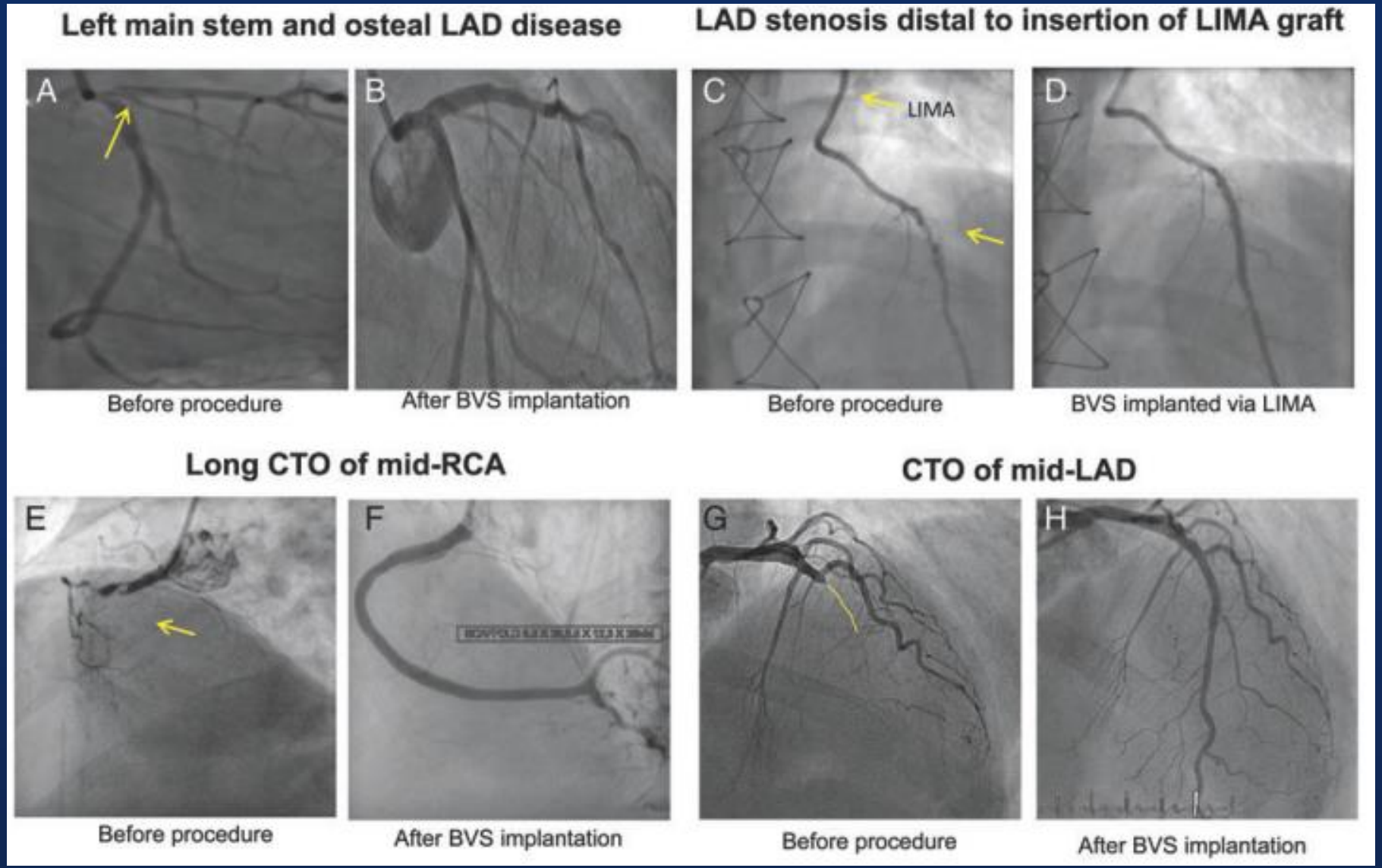
E) Device thrombosis



GW stone et al. J Am Coll Cardiol. 2023 Jul 18;82(3):183-195.

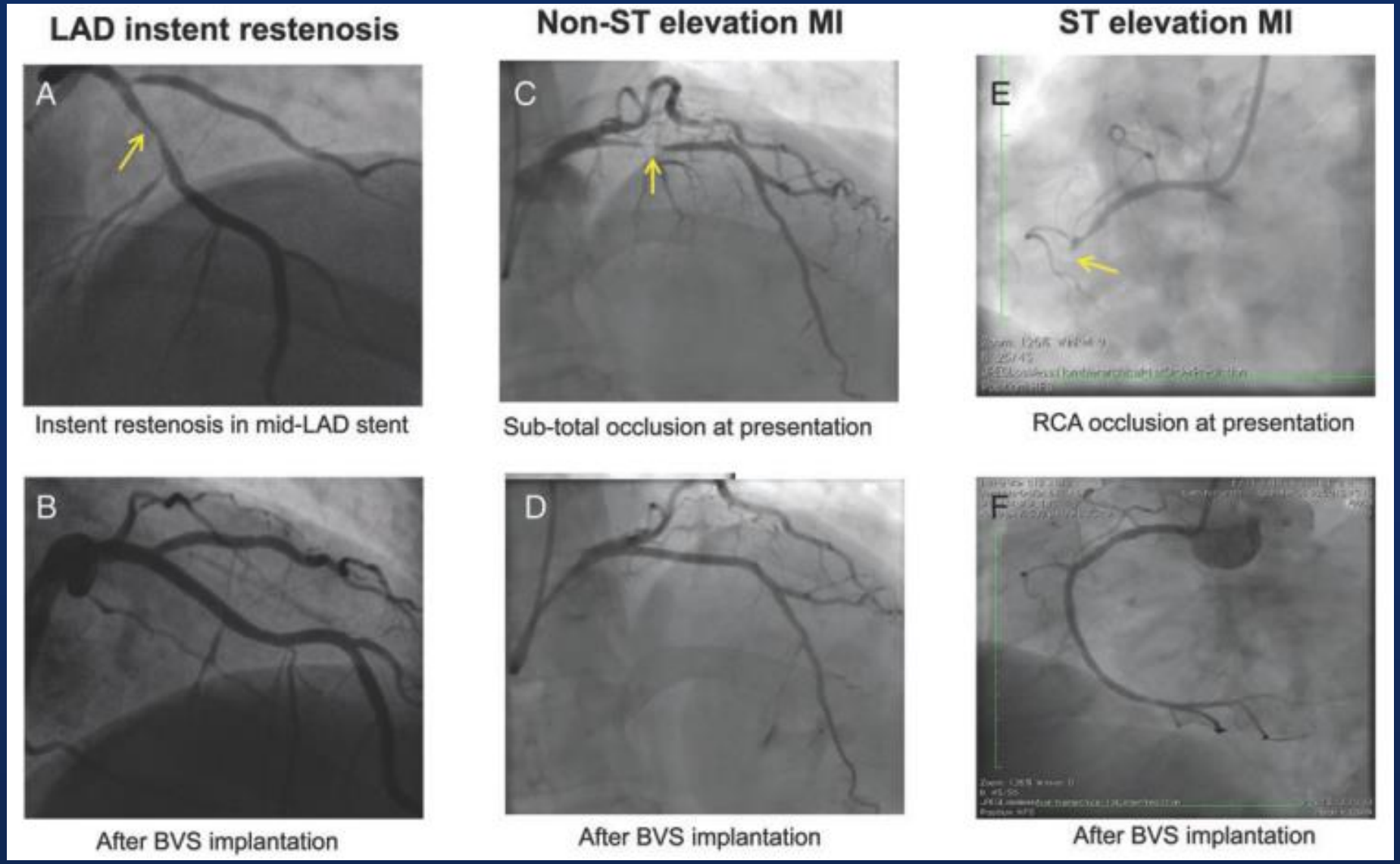
BRS and imaging

ABSORB



Iqbal J et al. Eur Heart J 2014;35:765

ABSORB

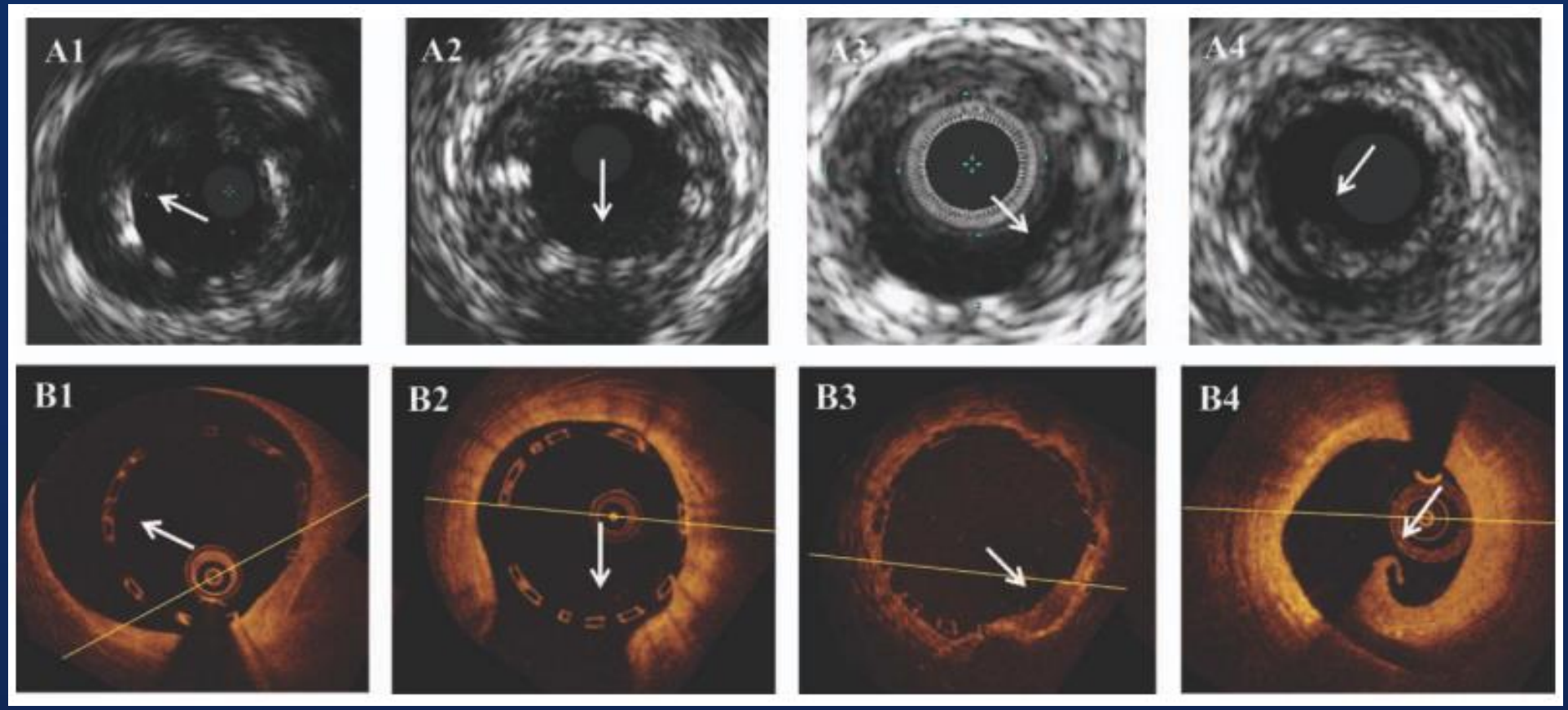


Iqbal J et al. Eur Heart J 2014;35:765

IVUS - Good penetration

- Critical to guide BRS deployment
- Useful information on vessel morphology, the need for lesion preparation and site selection

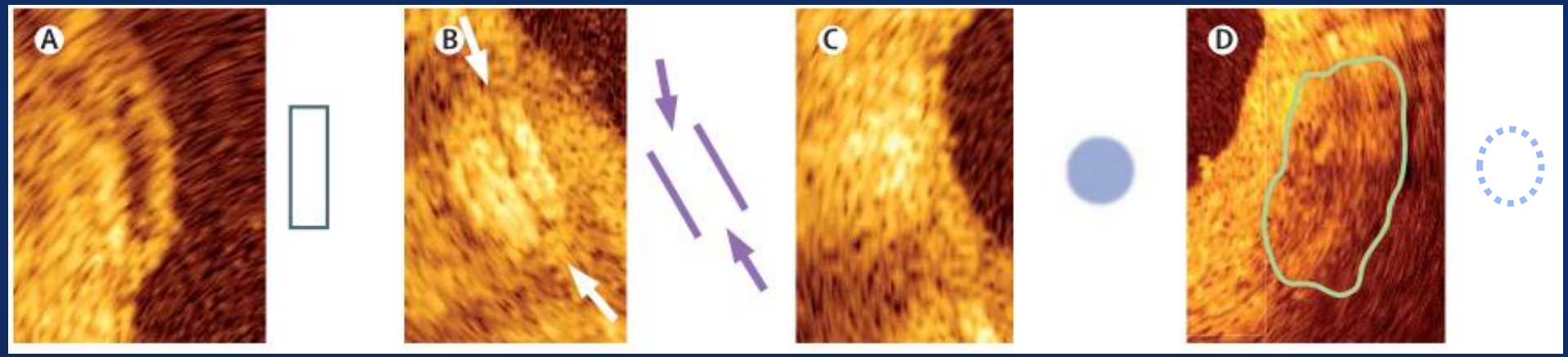
Poor resolution
→ Poor reproducibility



Gomez-Lara et al. CCI 2012;79:890

OCT

Morphologic changes in strut



Preserved Box

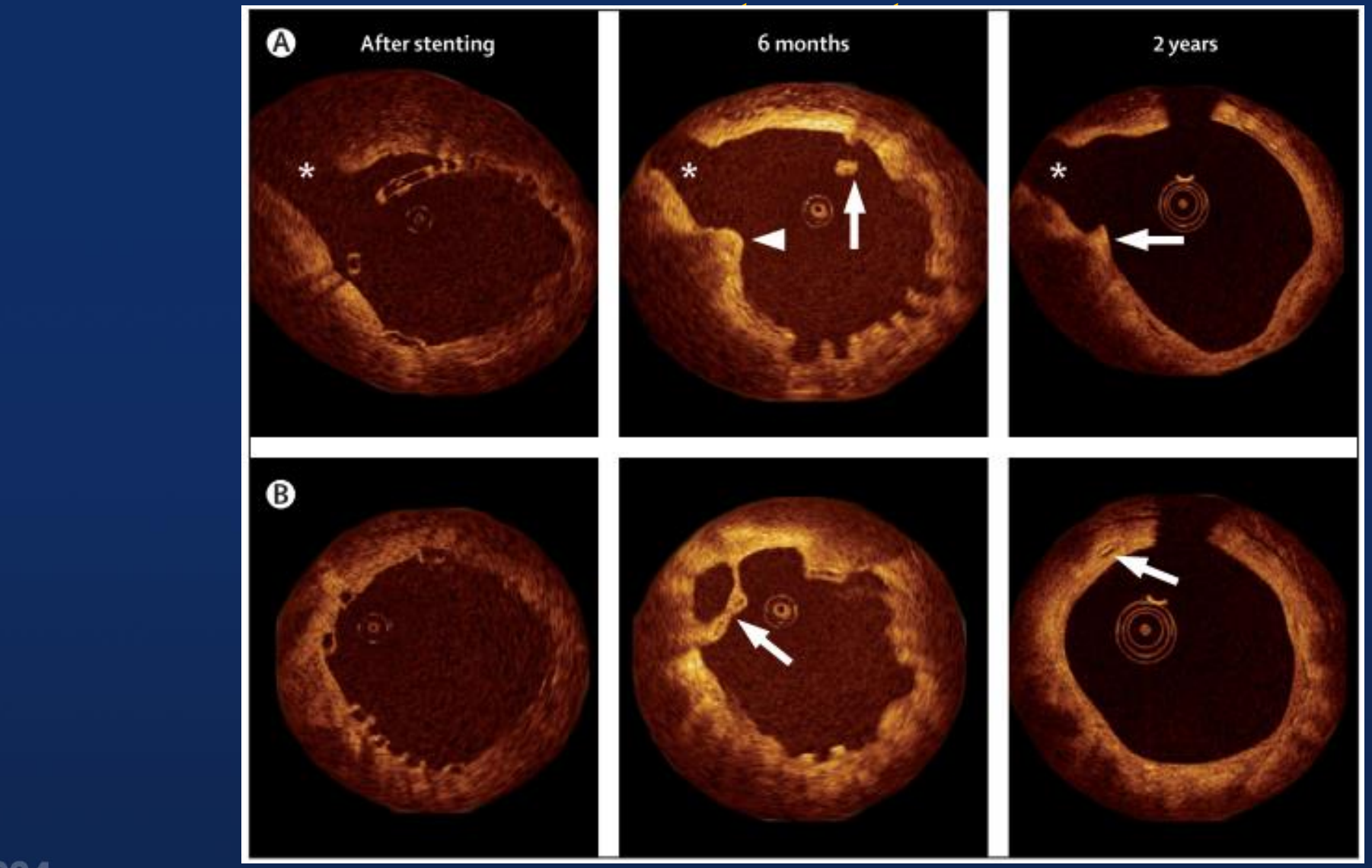
Open Box

Dissolved Bright Box

Dissolved Black Box

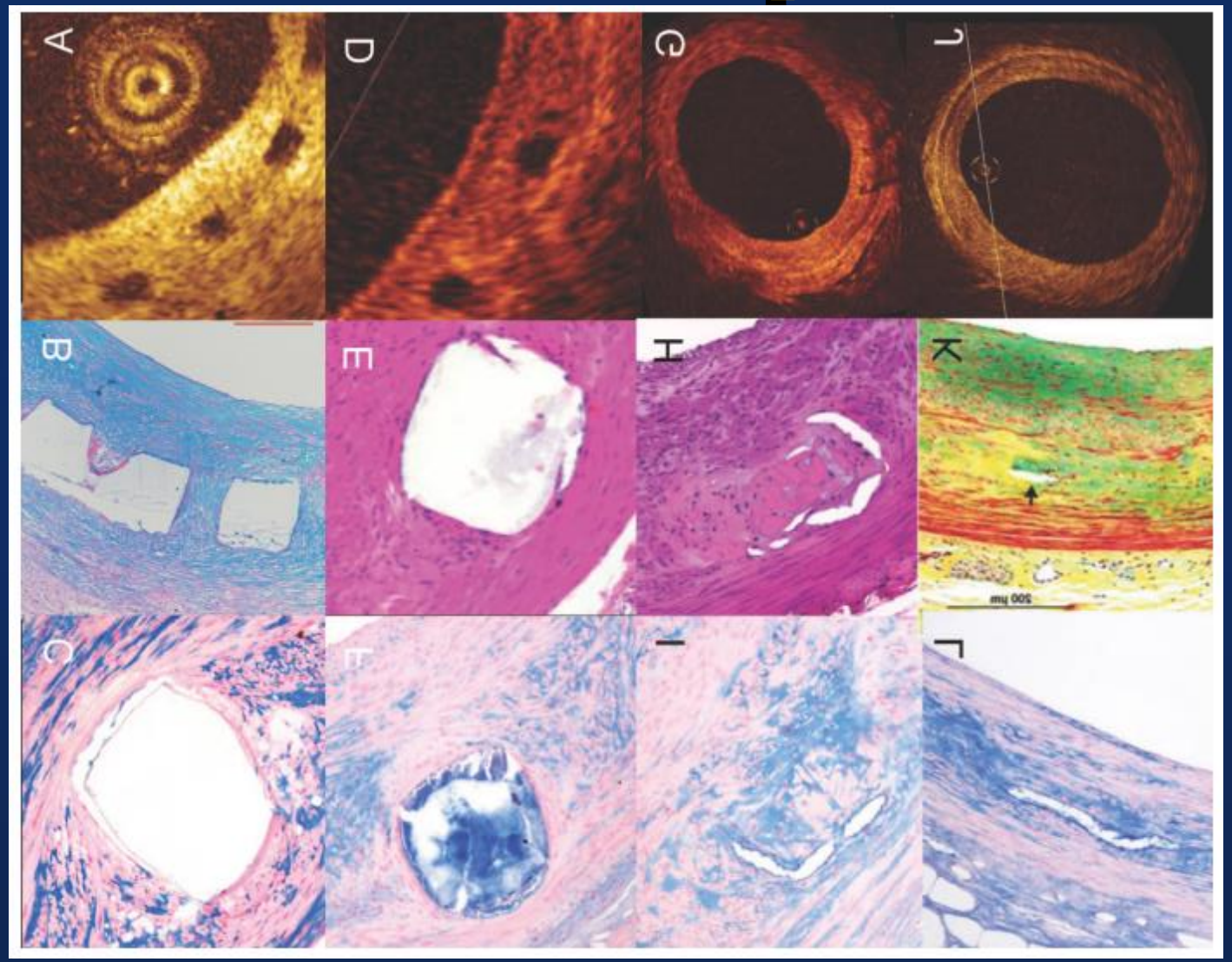
Ormiston JA et al. Lancet 2008;371:907

Resorption of malapposed



Serruys PW et al. Lancet 2009;373:897

BRS Resorption

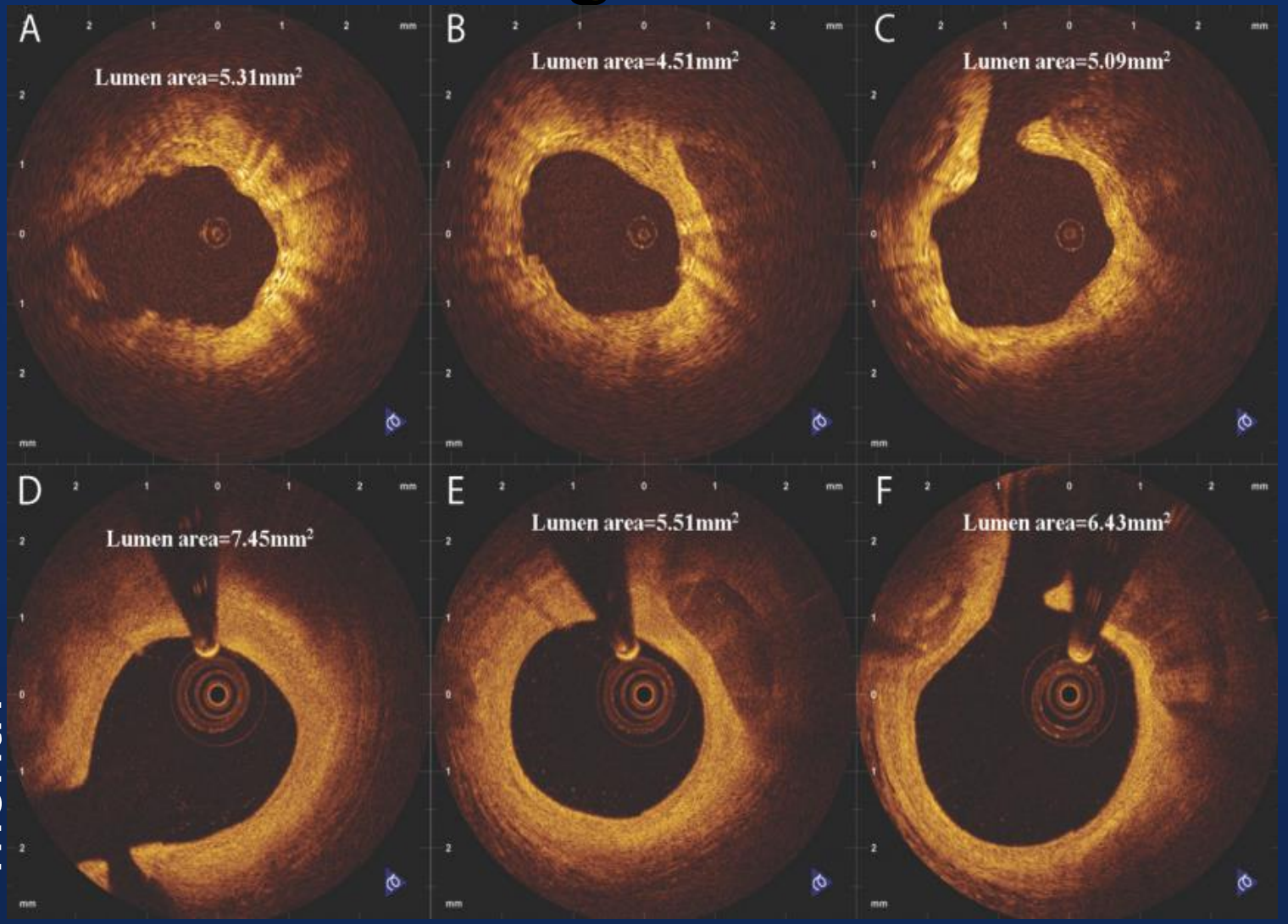


Onuma Y et al. Circulation 2011;123:779

Plaque Stabilization and Lumen Enlargement

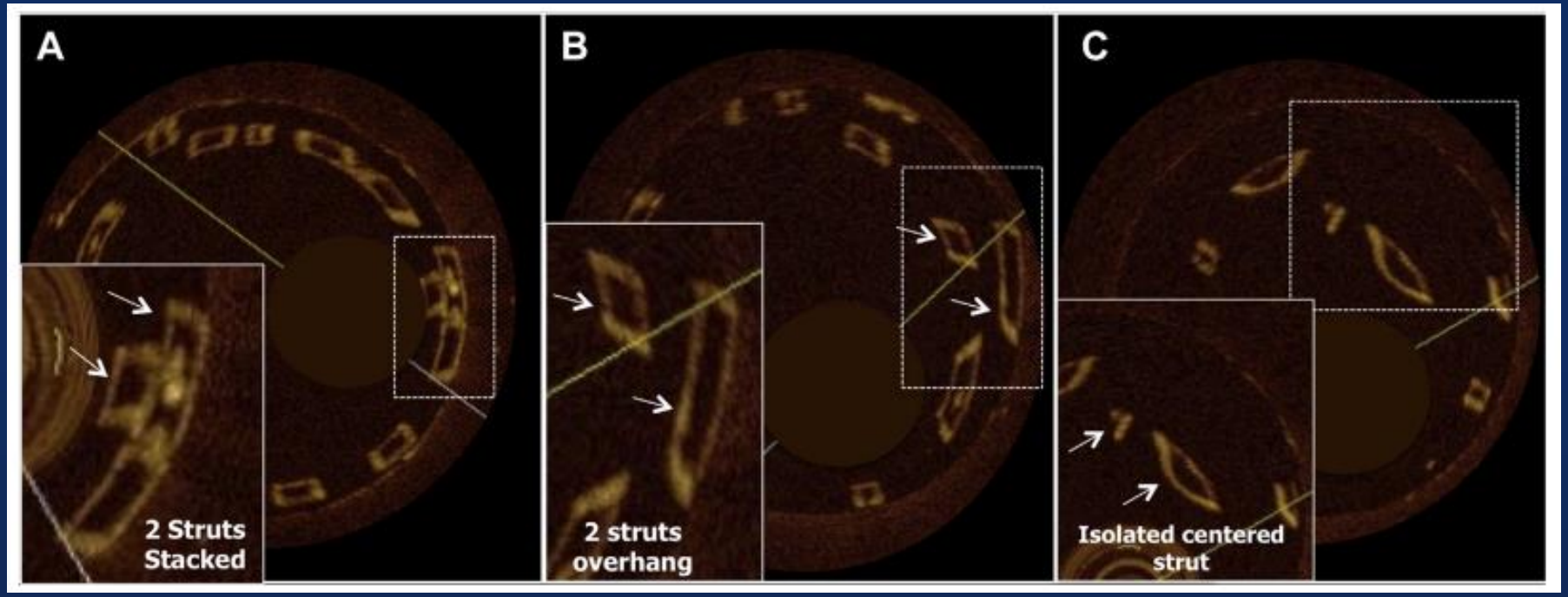
6 month

60 month



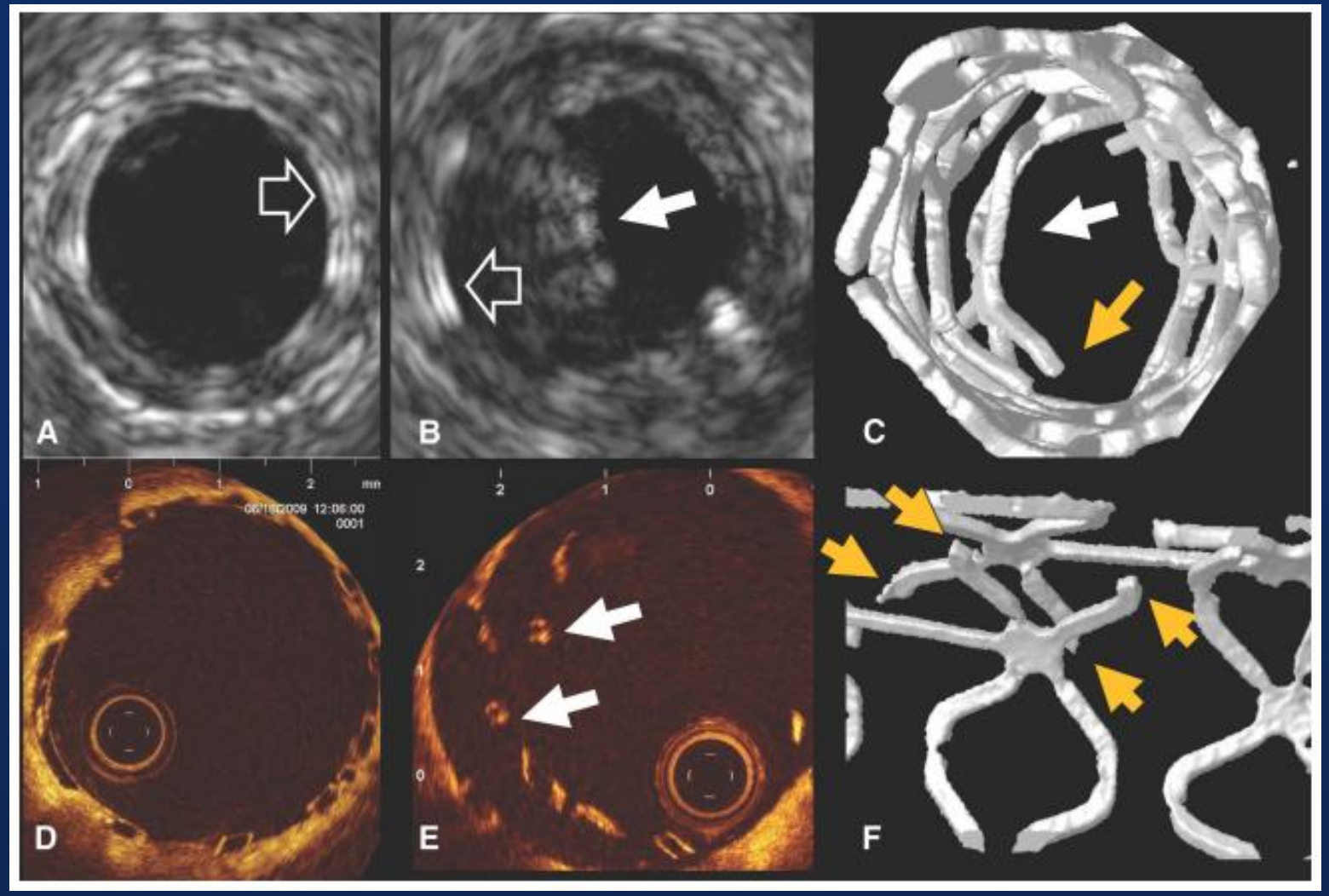
Karanasos A et al. Circulation 2012;126:e89

OCT of acute scaffold disruption



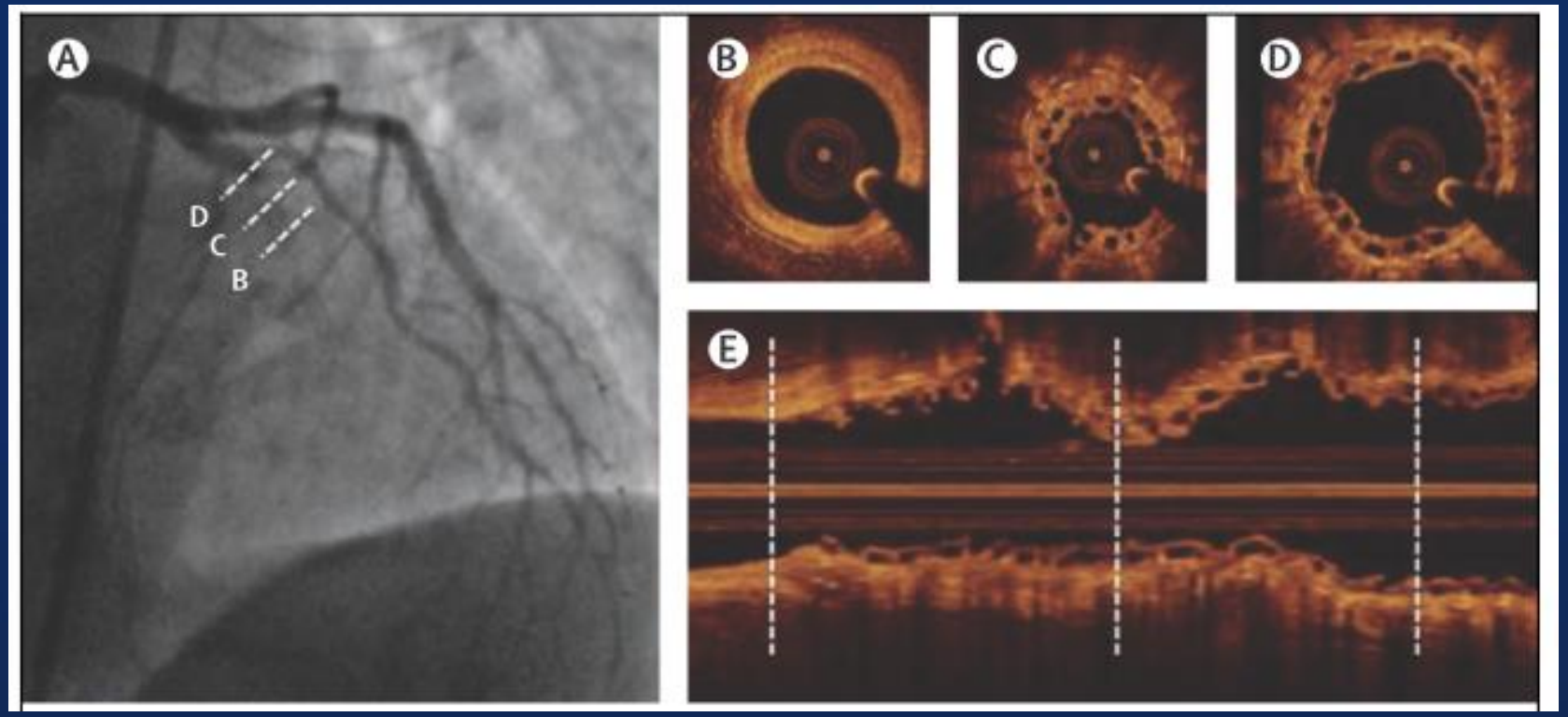
Onuma Y et al. JACC Int 2014;7:1400

Strut Fracture



Ormiston JA et al. Circ Cardiovasc Int 2011;4:535

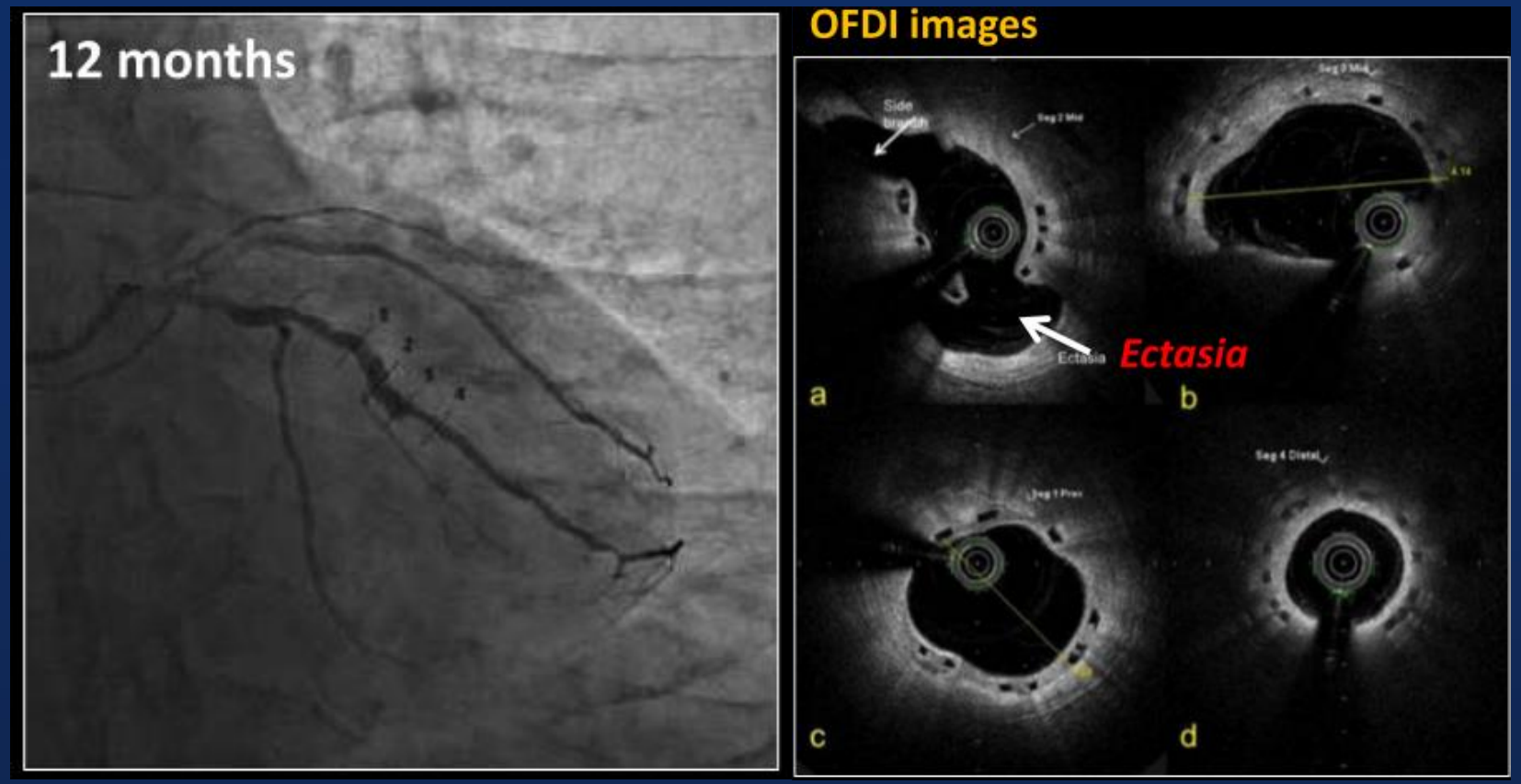
Scaffold thrombosis



Late Stent Thrombosis

Late Malapposition

- A 54 year-old man underwent PCI with Absorb 2.5 X 18mm



Cortese B. et al. 2014 Catheter Cardiovasc Interv

Two modalities seem to be complementary

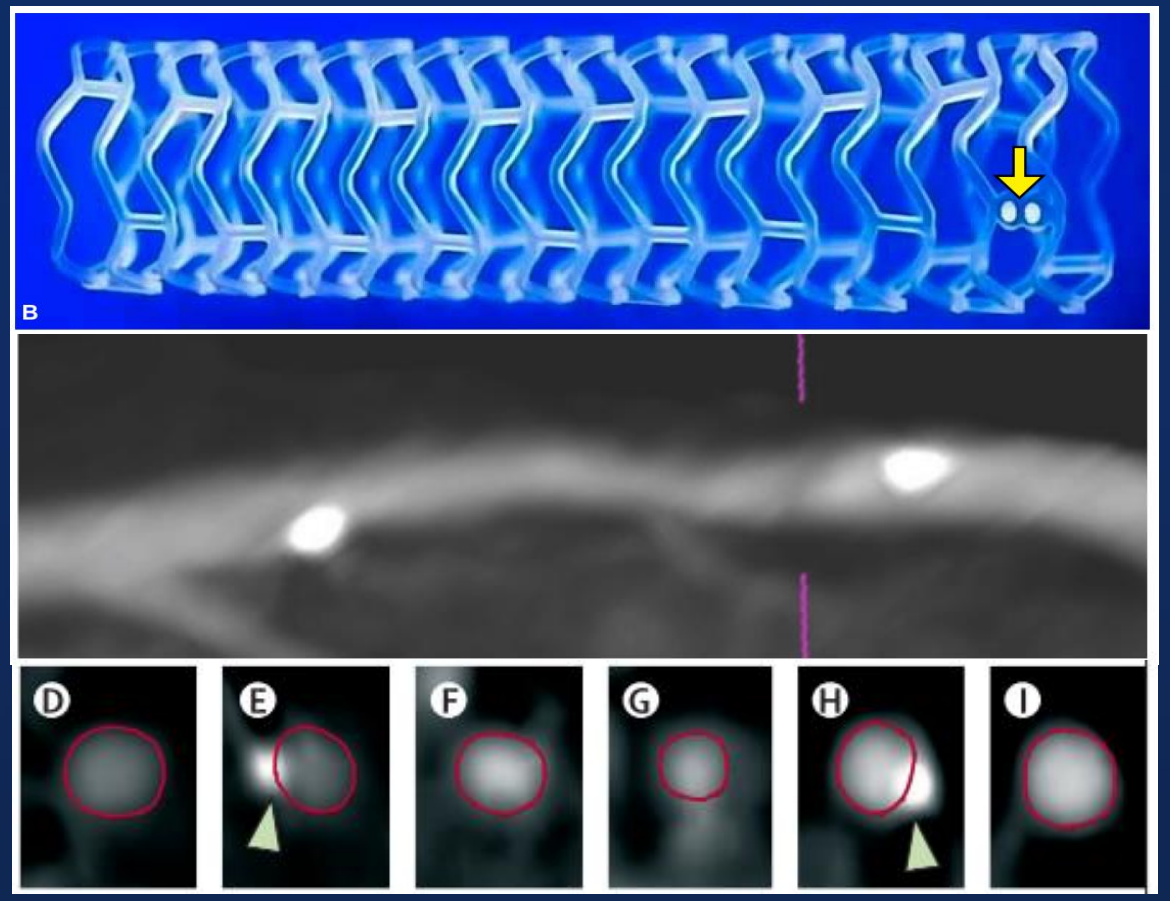
- While **IVUS** could be more helpful for the evaluation of the plaque morphology and in the preparation phase,

- **OCT** allows better qualitative scaffold analysis and follow-up evaluations.

Coronary CT

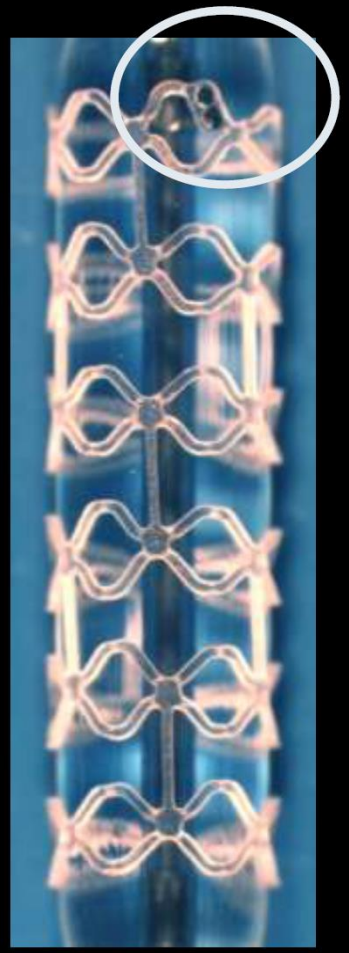
Radiolucent, with radiopaque platinum markers

No blooming artifact !

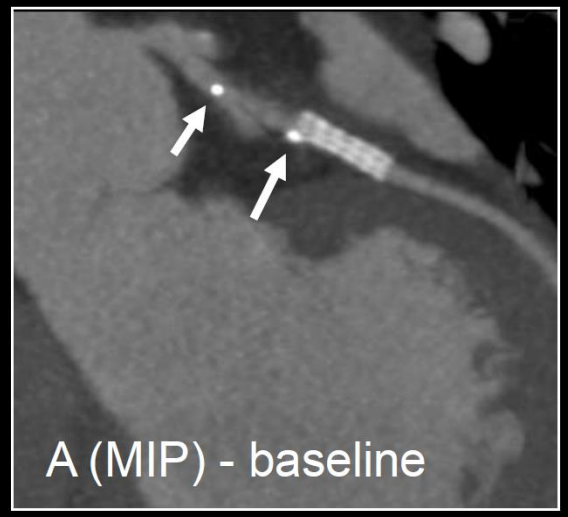


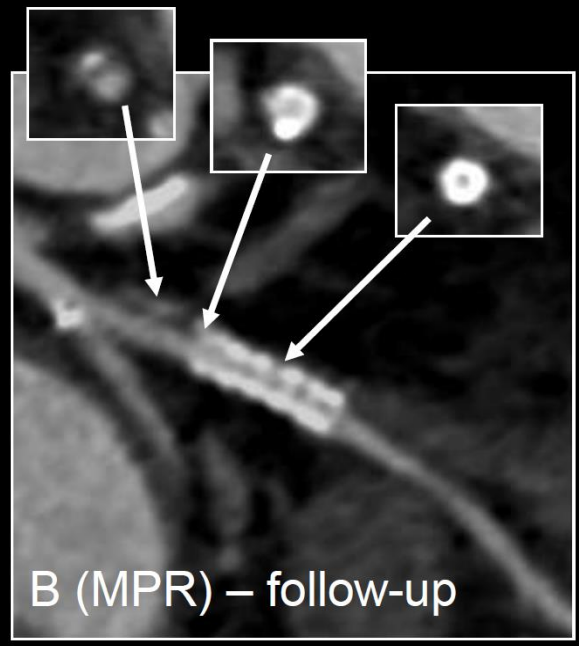
Gogas BD et al. Hellenic J Cardiol 2012;53:309

Metal vs Bioresorbable scaffold by MSCT



*marker





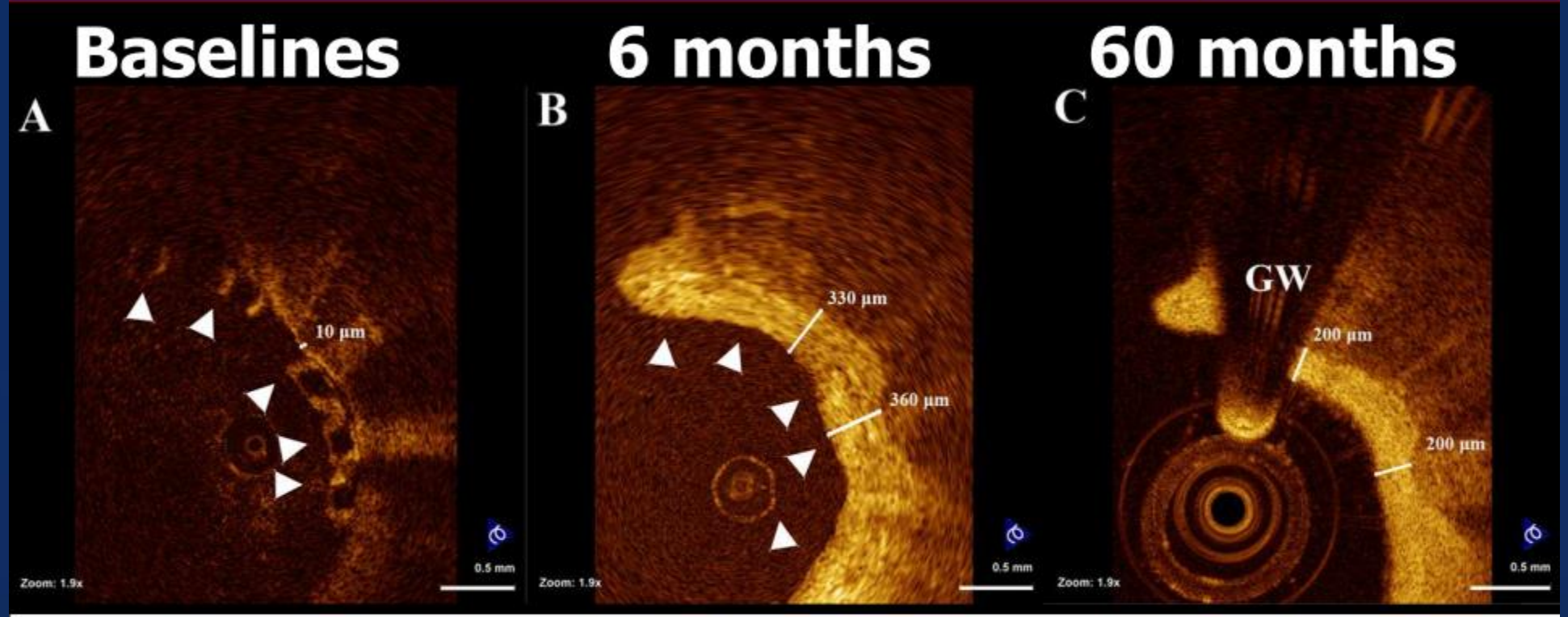
- Absorbable and metal stent implantation (bail-out)
- Highly attenuating distal metal stent well visible
- Only prox./dist. markers absorbable stent detectable
- In-stent plaque remains visible

Cohort A

Serial imaging at 6m,24m and 60m

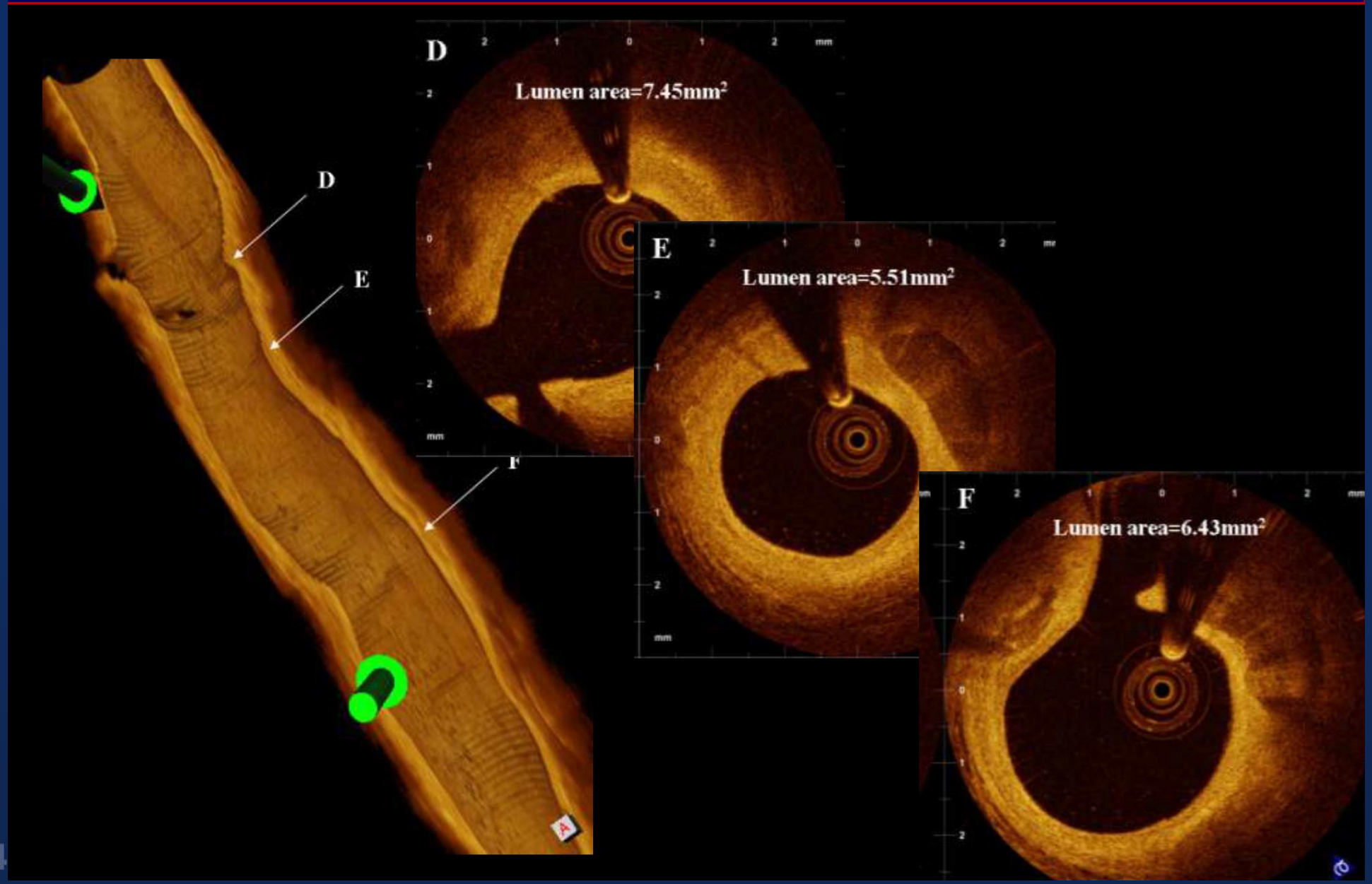
- MSCT – feasibility of functional assessment
- OCT –Plaque reduction and Vasomotion restoration

. Sealing and shielding of plaques as a result of scaffold implantation : can the scaffold cap the plaque? 60 Months Follow up



ABSORB cohort A (n=30)

5-Year Follow-up OCT of ABSORB A



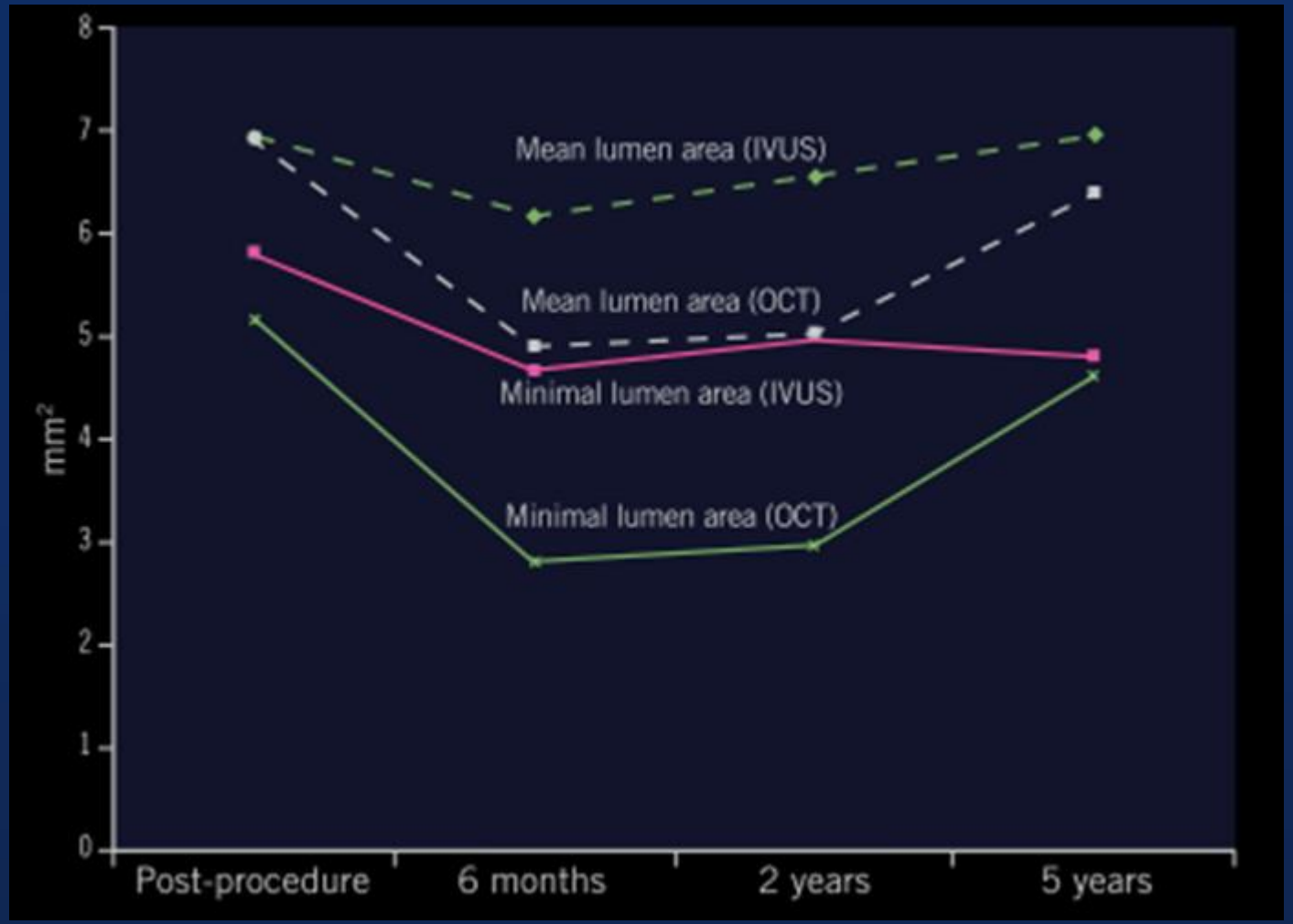
OCT optimization

	Not requiring OCT Optimization (n=21)	Requireing OCT optimization (n=8)	P-value
Age	50.8 ± 11.1	56.1 ± 17.8	0.34
Female	2 (9.5%)	1 (12.5%)	0.82
Target vessel			
LAD	9 (75%)	3 (25%)	0.80
LCx	6 (66%)	3 (33%)	0.66
RCA	5 (71%)	2 (29%)	0.95
Lesion type, A	10 (66%)	5 (33%)	0.49
Lesion type, B or C	11 (79%)	3 (21%)	0.49
Mean n. POBA	8.7 ± 3.3	16.5 ± 11.3	<0.01
Length of procedure (min)	83.7 ± 26.5	113.7 ± 39.0	<0.05

Allahwalla et al. EuroInt 2015;10:1154

ABSORB Cohort A

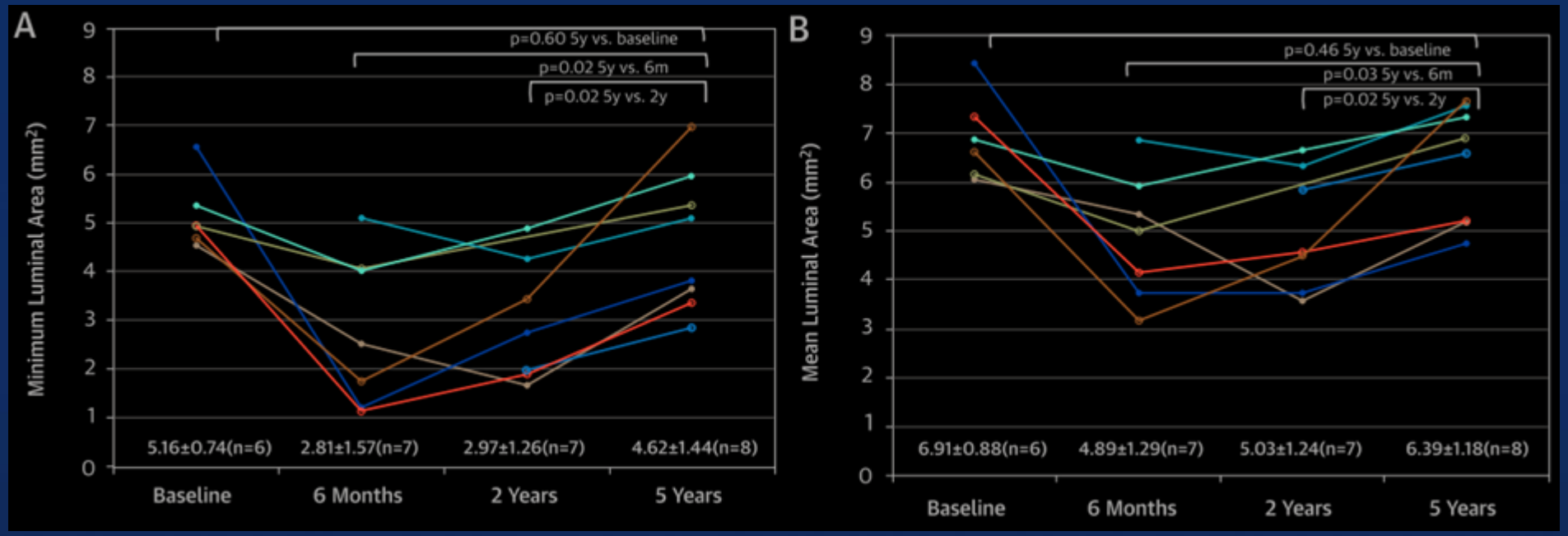
IVUS and OCT



Simsek C et al. EuroInt 2014;10 e-pub

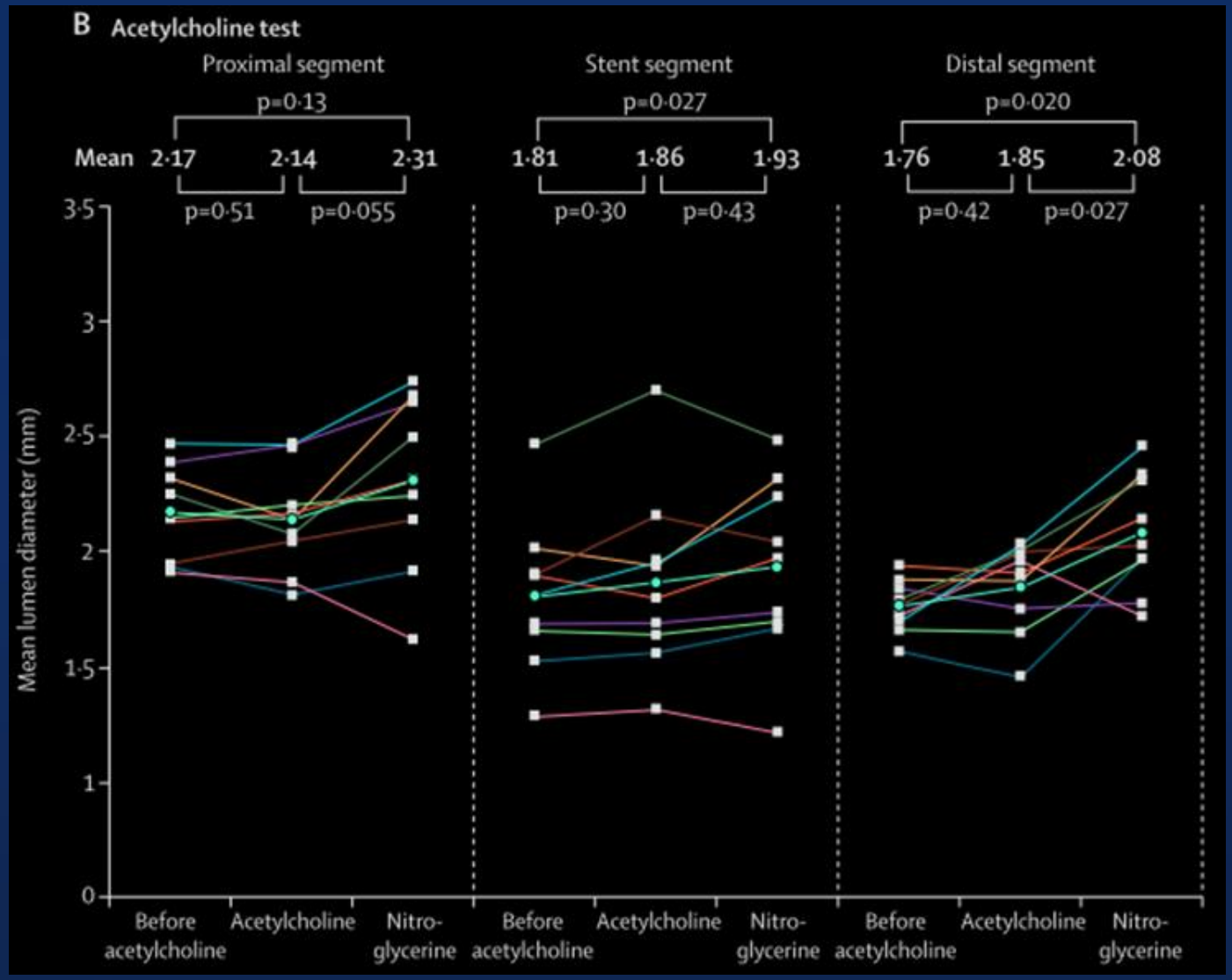
ABSORB Cohort A

Serial Luminal Measurement



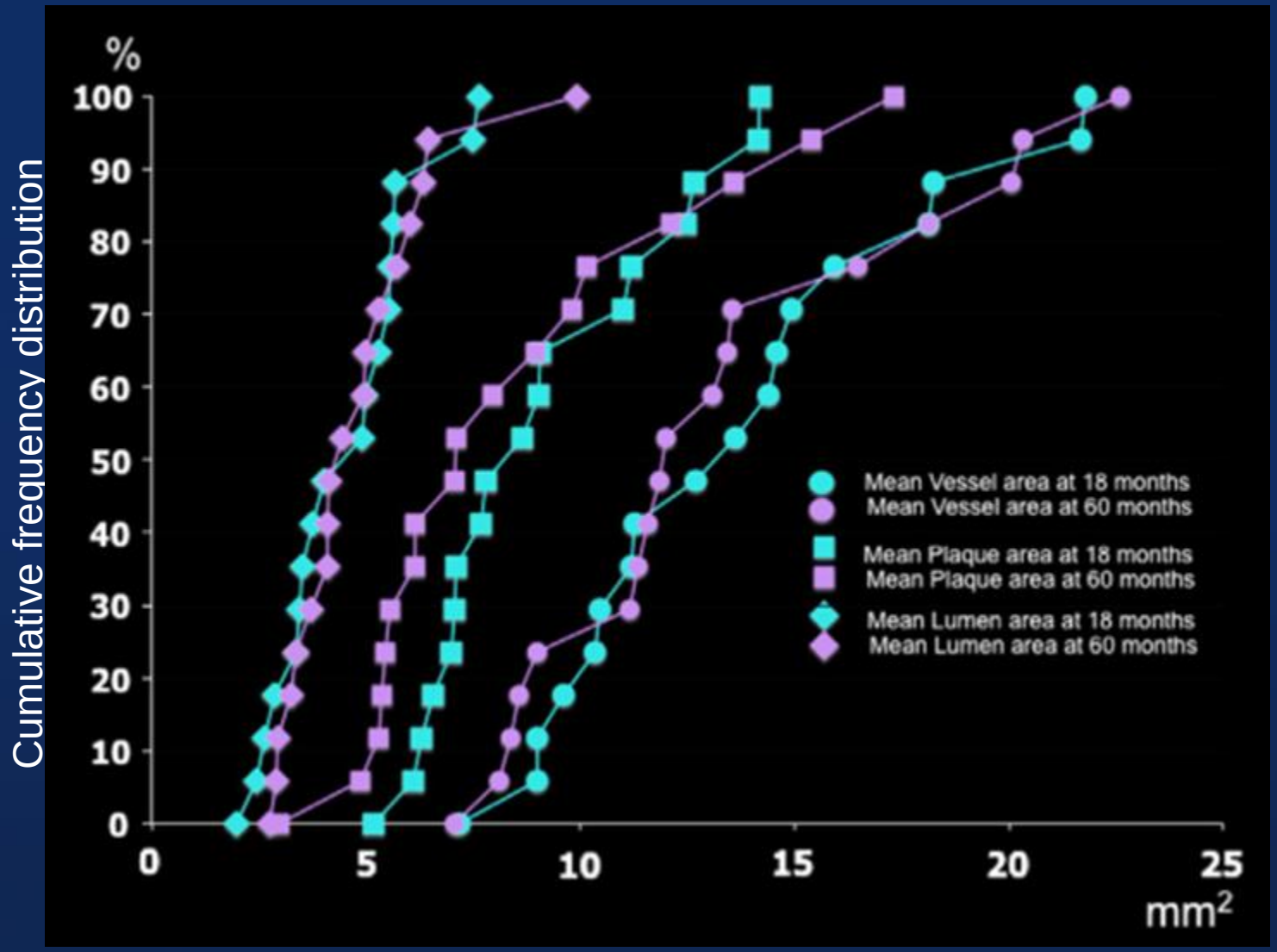
Karanasos A et al. JACC 2014;64:2343

Vasomotion Restoration



ABSORB Cohort A

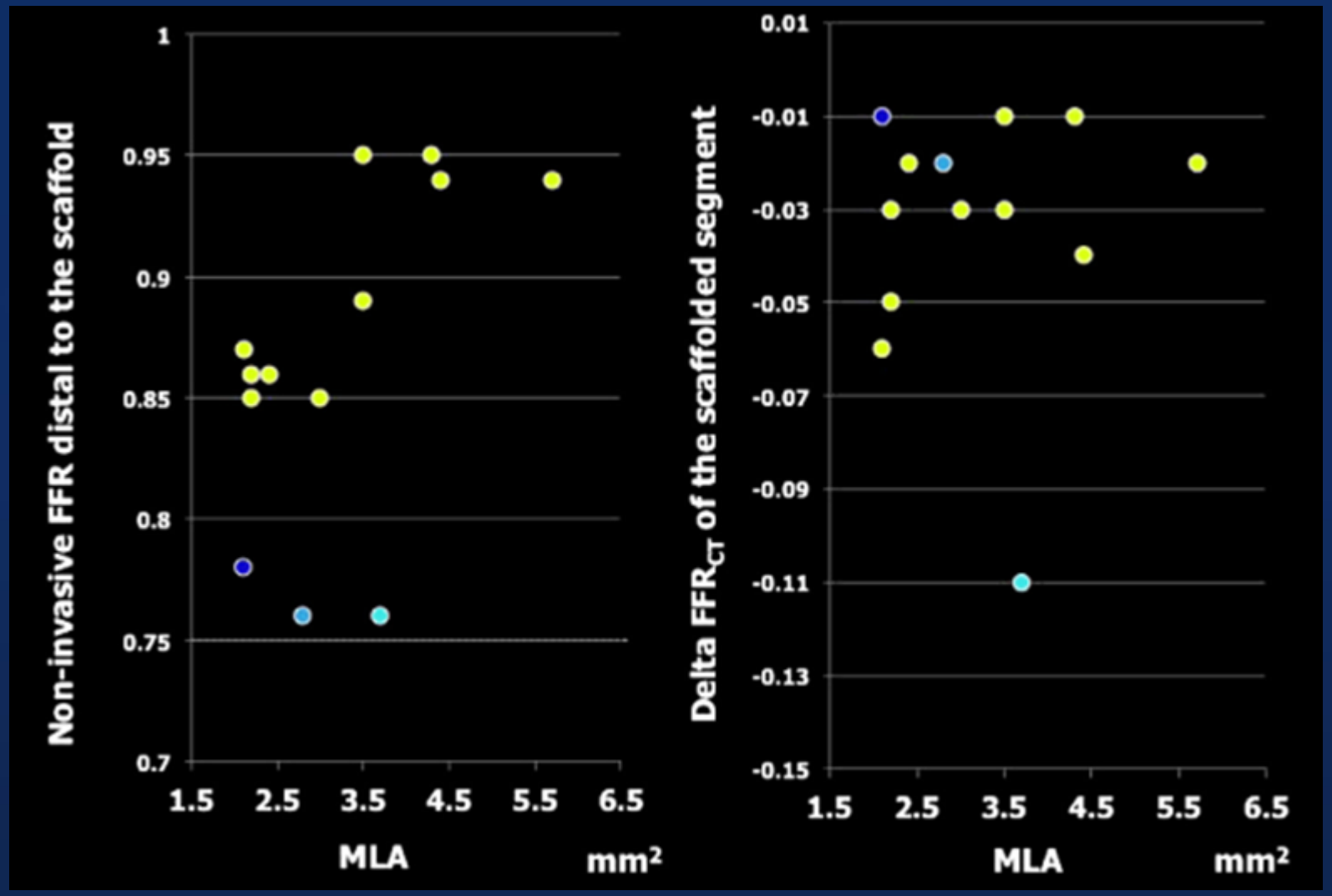
MLA, Plaque area, Vessel area



Onuma Y et al. JACC Interv 2013;6:999

ABSORB Cohort A

MLA vs FFR_{CT}



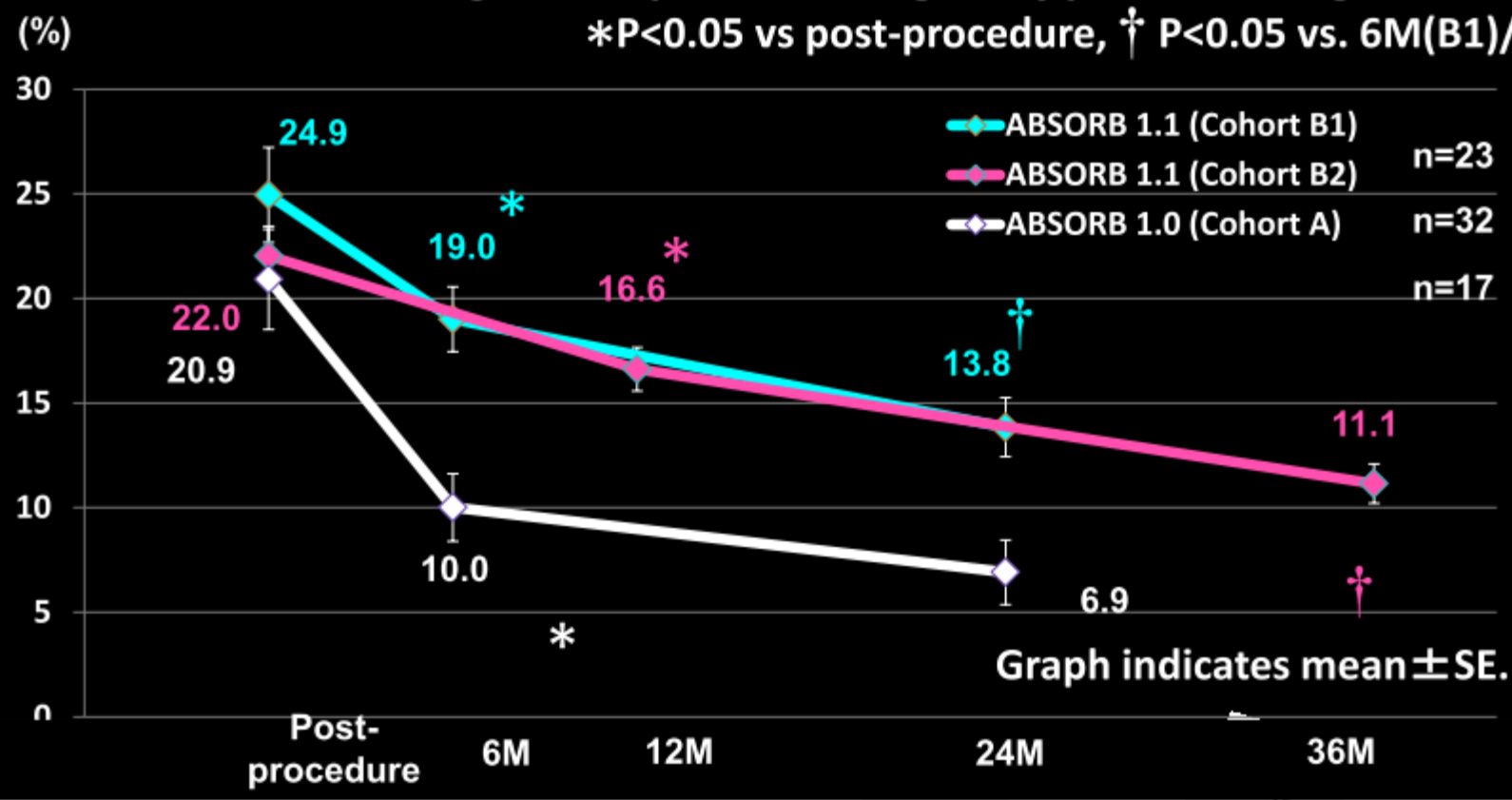
Onuma Y et al. JACC Interv 2013;6:999

Cohort B

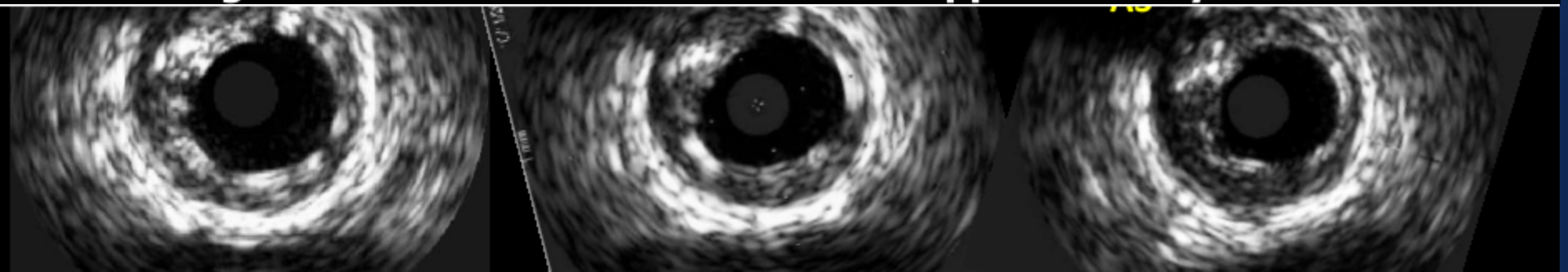
Imaging at 3 year

- Advanced bioresorption of BVS (VH / IVUS echogenicity)
- Acceptable angiographic late luminal loss between 1 and 3 yr (binary 6%)
- Increased MLA (IVUS and OCT)
- Biphasic change of total plaque area
  - ↑ bewteen 1 and 2 yr but ↓ between 2 and 3 yr

True-serial changes in percentage hyper-echogenic area

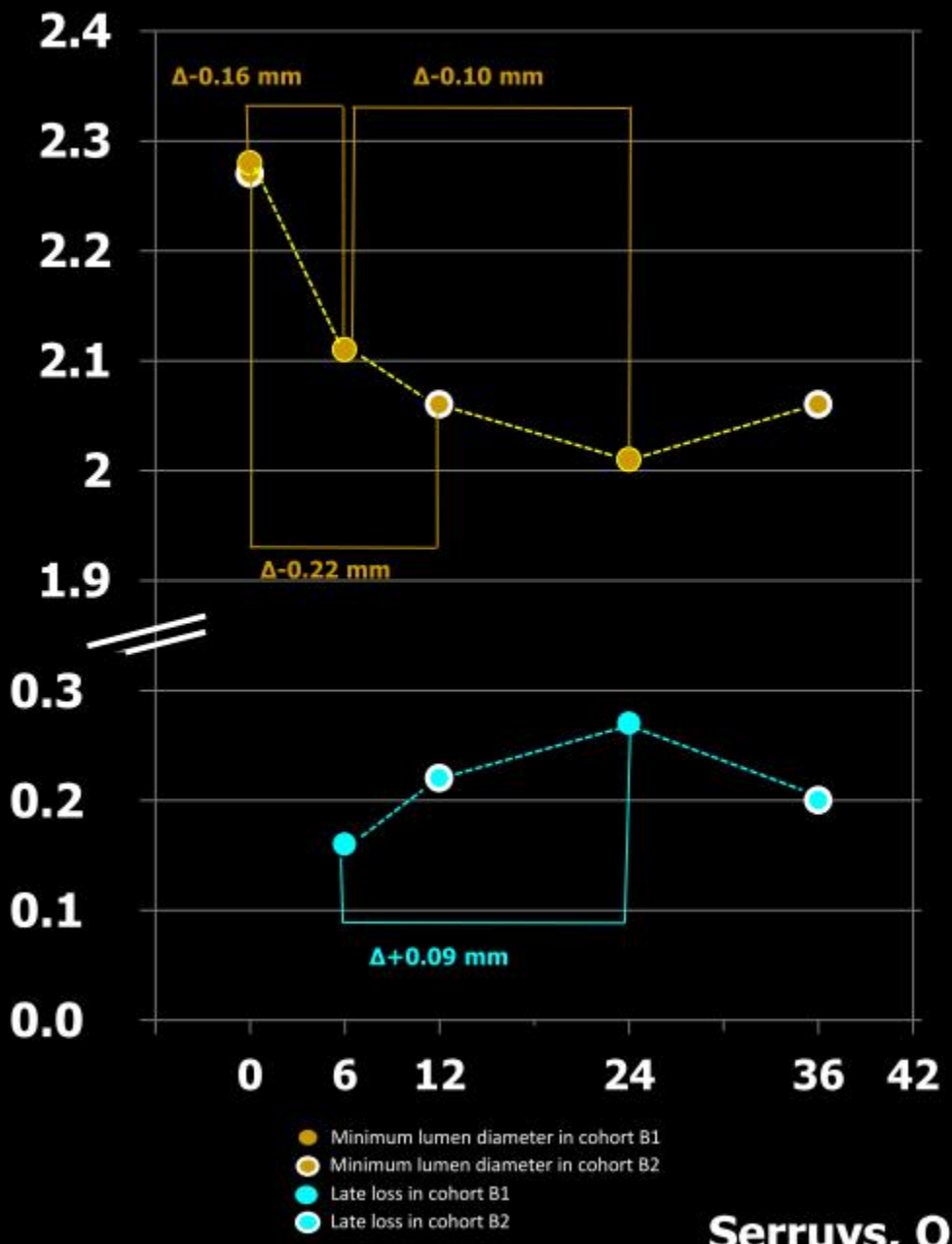


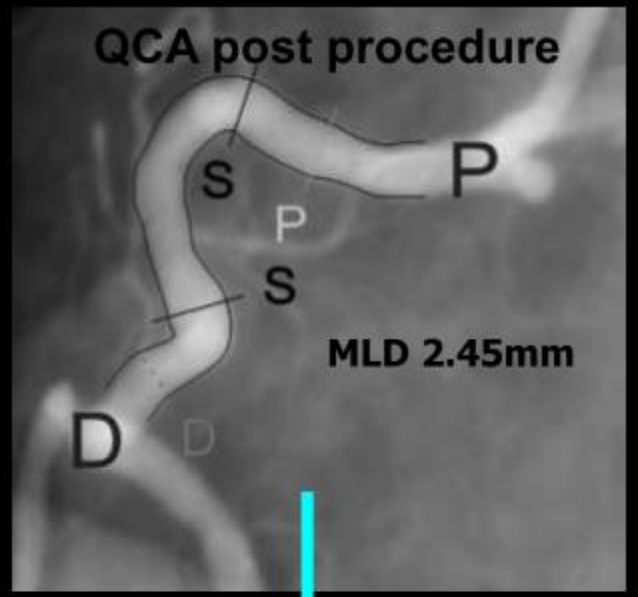
The actual duration of resorption of the second generation is in vivo approximately 18 months longer than the first generation, and the mass loss of 2nd generation ABSORB scaffold takes approximately 36 months

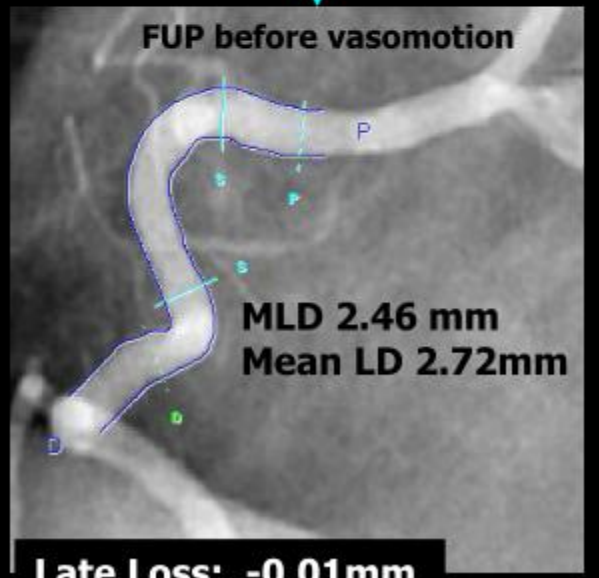


A

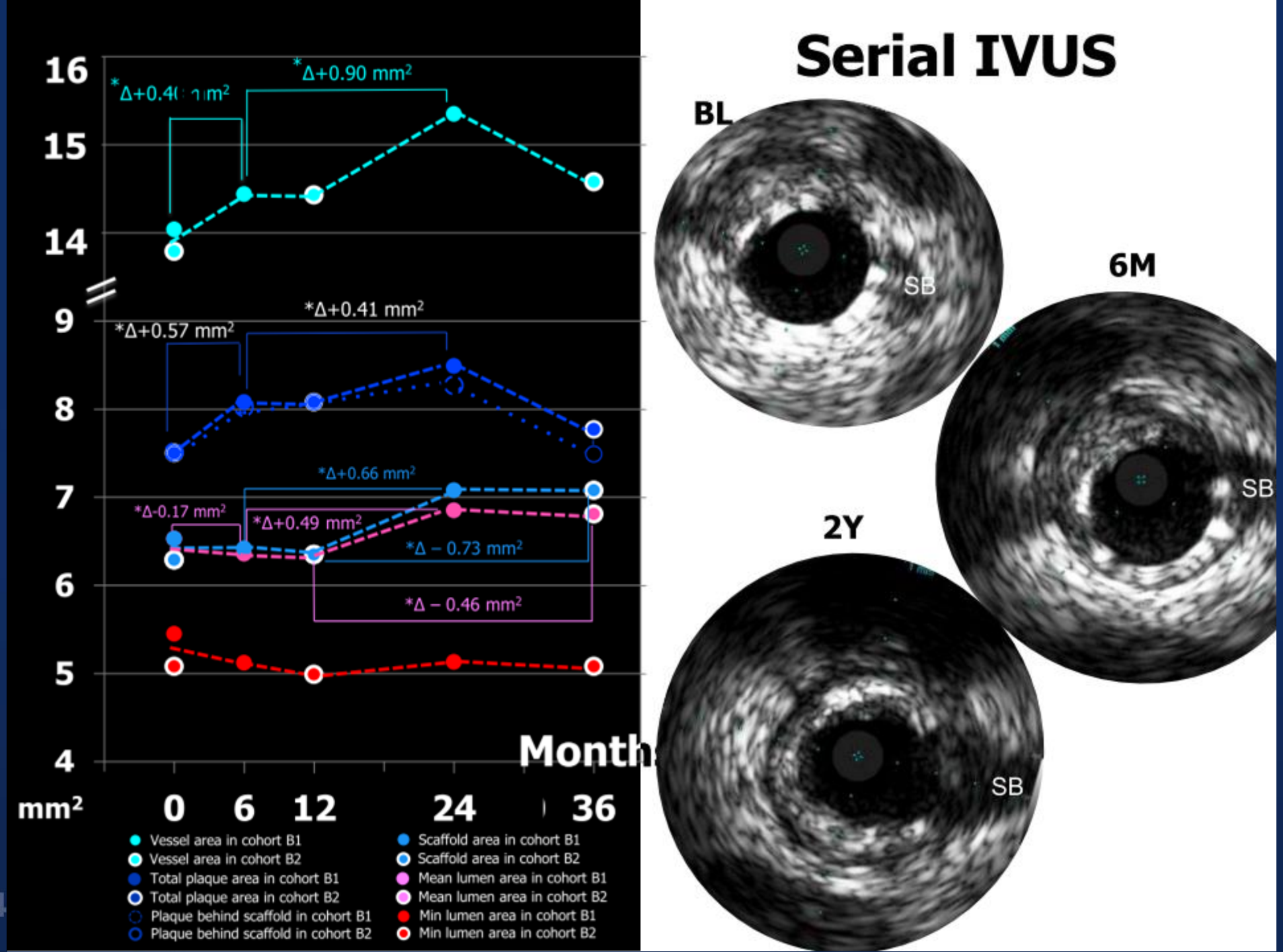
Serial QCA without TLR cases





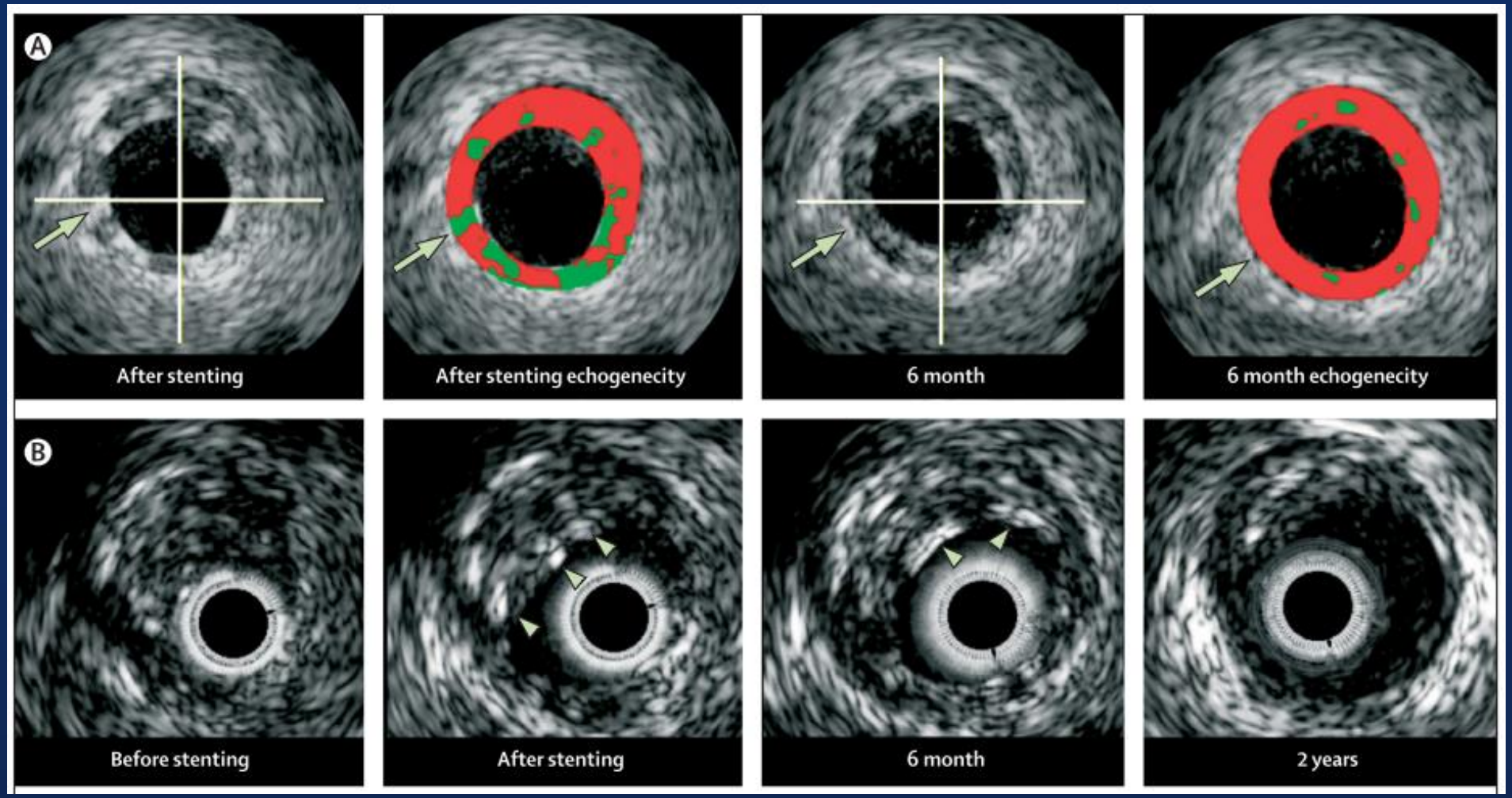


Serruys, Onuma et al. Eurointervention 2014


16
15
14
9
8
7
6
5
4
*Δ+0.90 mm²
*Δ+0.41 mm²
*Δ+0.57 mm²
*Δ+0.66 mm²
*Δ-0.17 mm²
*Δ+0.49 mm²
*Δ – 0.73 mm²
*Δ – 0.46 mm²
Month
mm²
0 6 12 24 36
Vessel area in cohort B1
Vessel area in cohort B2
Total plaque area in cohort B1
Total plaque area in cohort B2
Plaque behind scaffold in cohort B1
Plaque behind scaffold in cohort B2
Scaffold area in cohort B1
Scaffold area in cohort B2
Mean lumen area in cohort B1
Mean lumen area in cohort B2
Min lumen area in cohort B1
Min lumen area in cohort B2
Serial IVUS
BL
SB
6M
SB
2Y
SB

ABSORB Cohort B

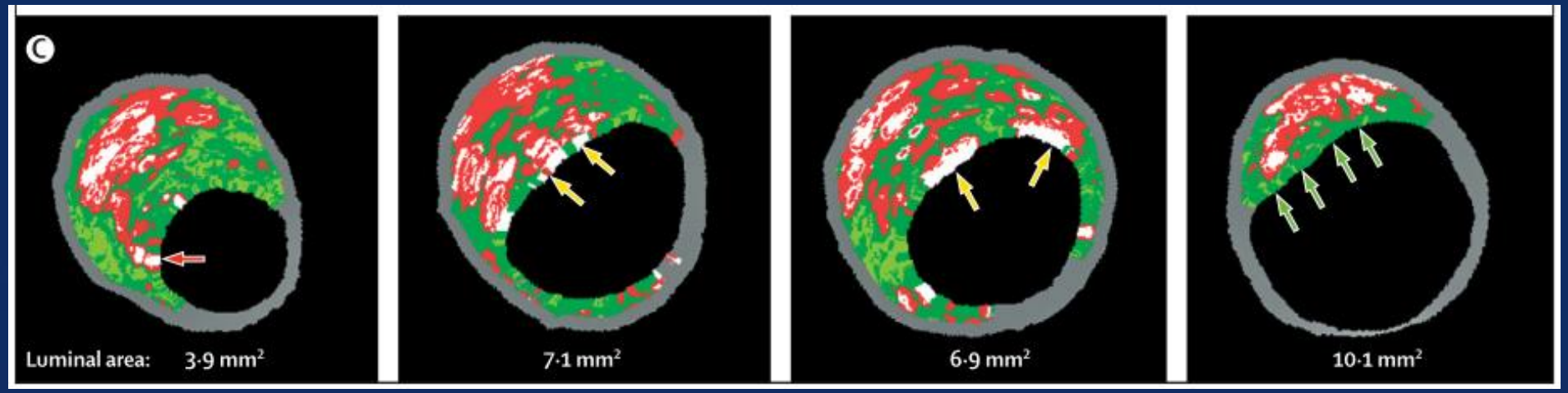
IVUS



Serruys PW et al. Lancet 2009;373:897
Serruys PW et al. EuroInt 2014 e-pub

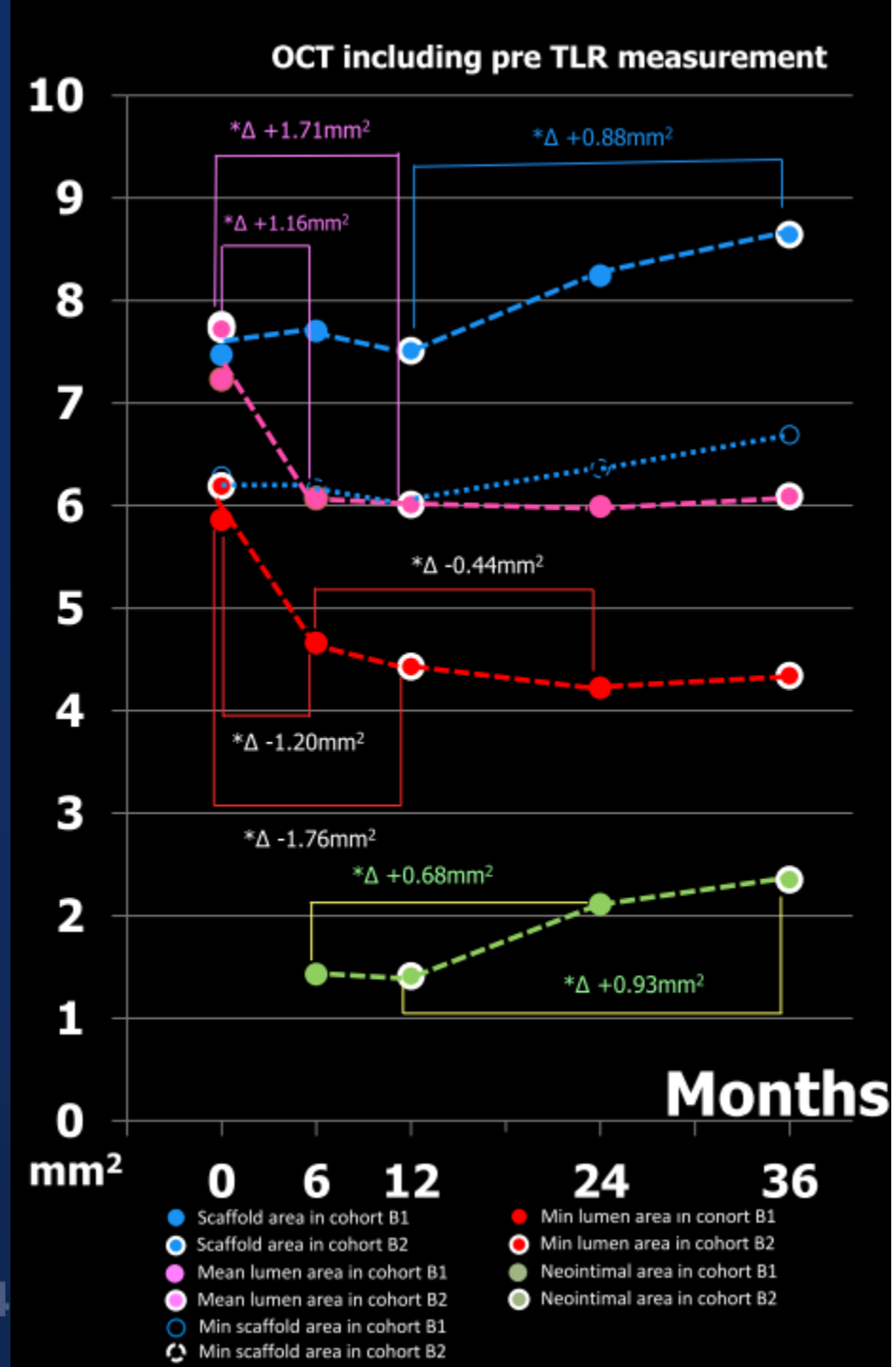
ABSORB Cohort B

VH-IVUS

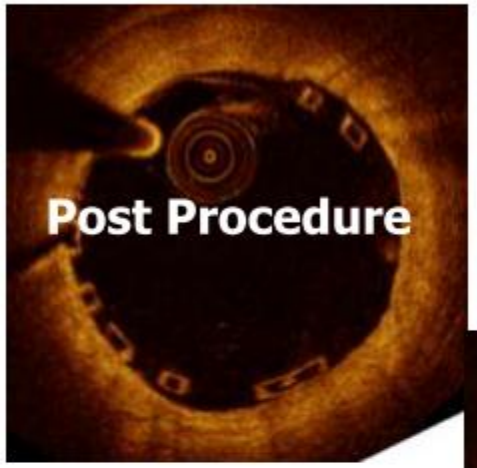


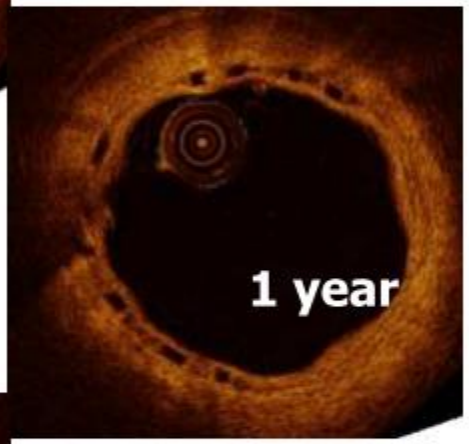
	Baseline (n=36)	1yr (n=36)	3yr (n=36)	p
Dense calcium (%)	30.74±10.11	24.95±8.28	21.84±8.41	<0.001
Necrotic Core (%)	32.10±6.62	30.01±6.29	26.11±5.99	<0.001
Fibrofatty (%)	2.94±2.43	4.23±2.29	6.87±3.66	<0.001
Fibrous (%)	34.22±10.05	40.80±9.60	45.18±9.38	<0.001

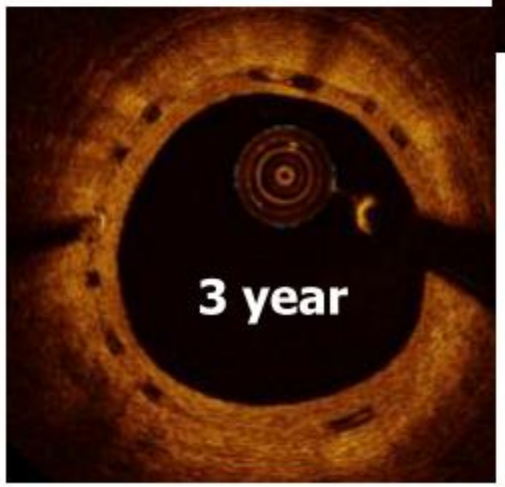
Serruys PW et al. Lancet 2009;373:897
Serruys PW et al. EuroInt 2014 e-pub

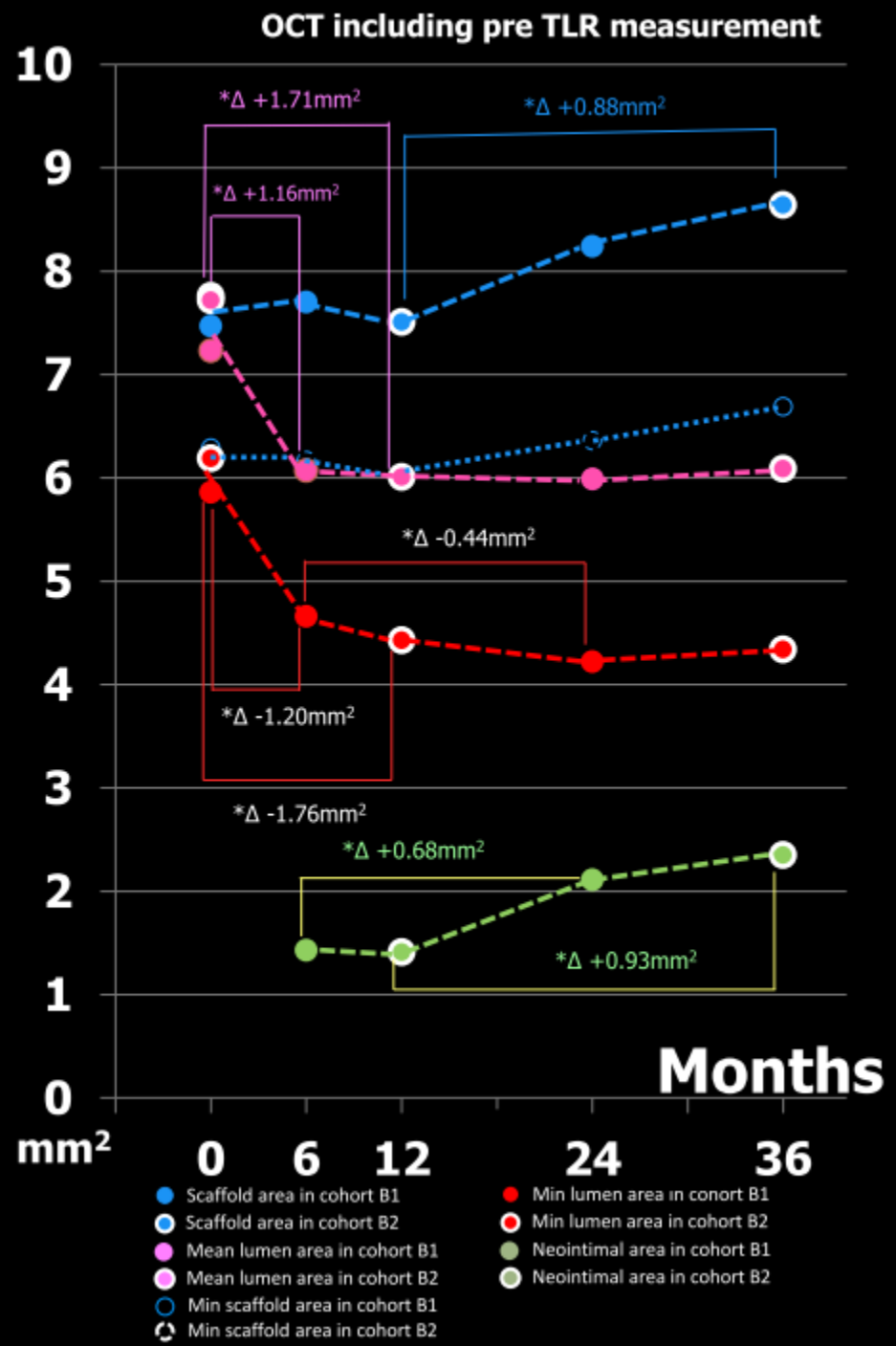

OCT including pre TLR measurement
10
9
8
7
6
5
4
3
2
1
0
mm²
*Δ +1.71mm²
*Δ +0.88mm²
*Δ +1.16mm²
*Δ -0.44mm²
*Δ -1.20mm²
*Δ -1.76mm²
*Δ +0.68mm²
*Δ +0.93mm²
Months
0
6
12
24
36
Scaffold area in cohort B1
Scaffold area in cohort B2
Mean lumen area in cohort B1
Mean lumen area in cohort B2
Min scaffold area in cohort B1
Min scaffold area in cohort B2
Min lumen area in conort B1
Min lumen area in cohort B2
Neointimal area in cohort B1
Neointimal area in cohort B2

Serial OCT


Post Procedure

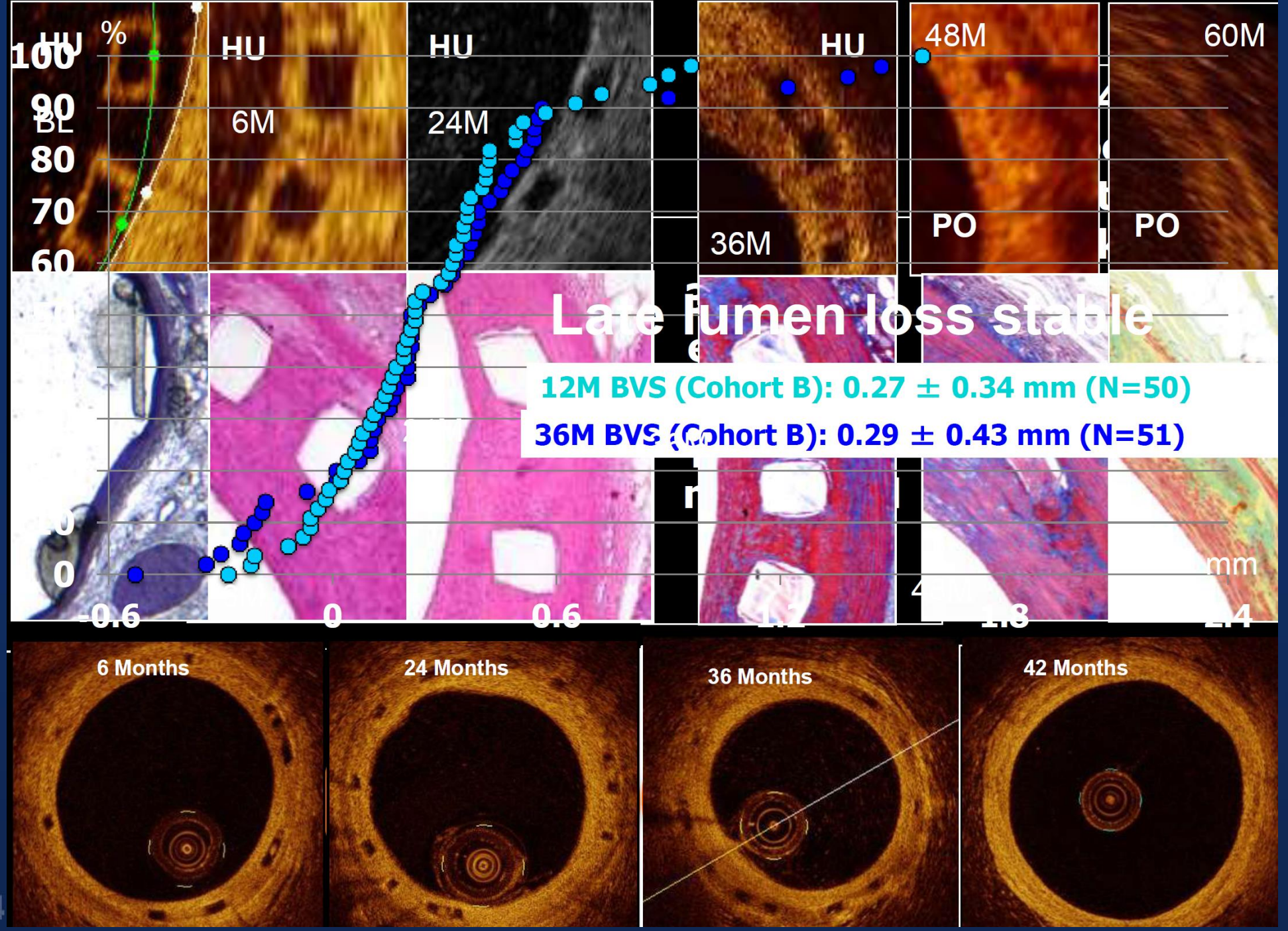

1 year


3 year



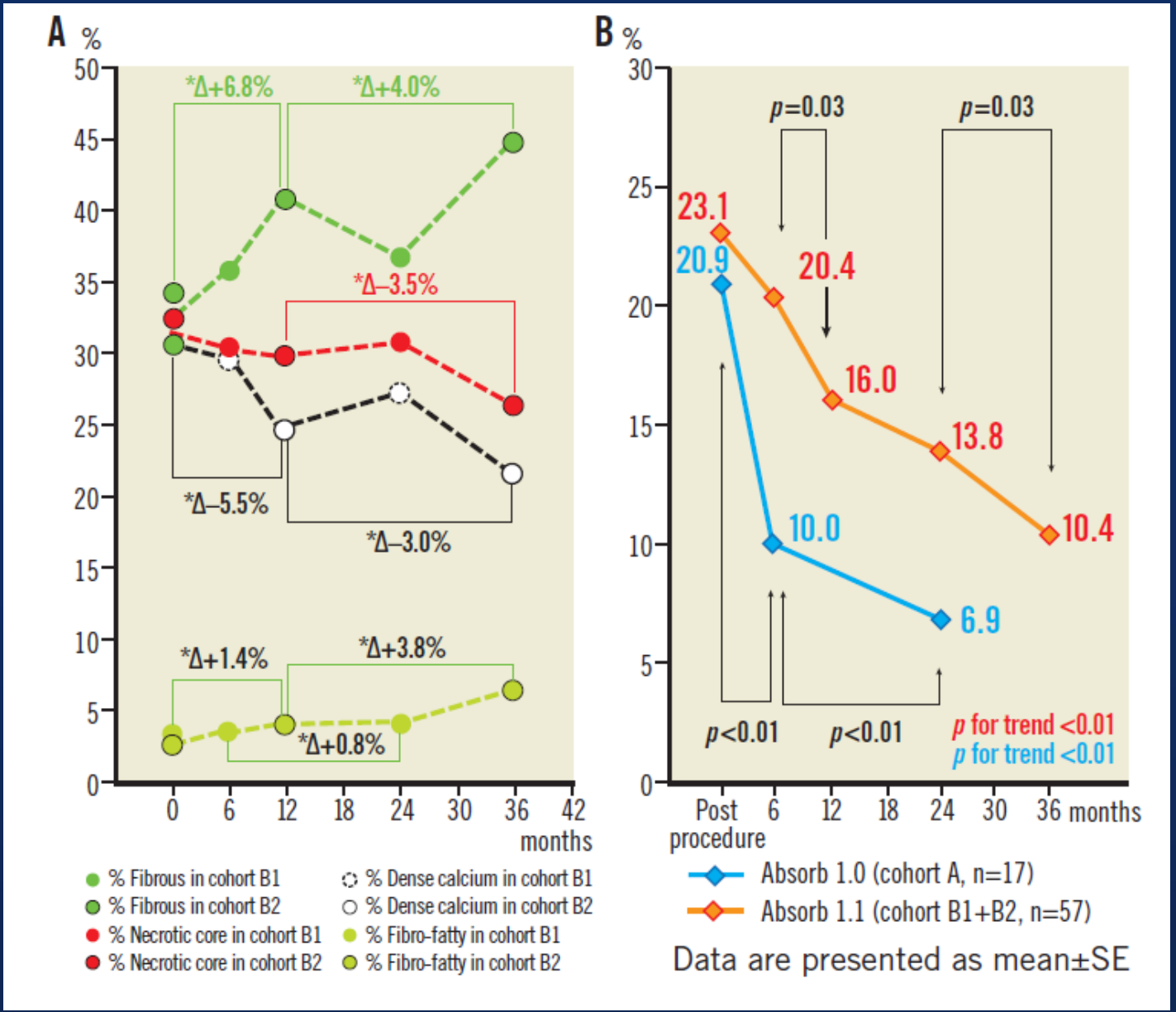
Serial OCT

- The **mean and minimum scaffold area's** significantly increase between 1 and 3 years and compensate for the increase **in neointimal hyperplasia**
- As a consequence, **mean lumen area** and **minimal lumen area** remained unchanged between 1 year to 3 years.


HU
%
100
90
80
70
60
BL
HU
6M
HU
24M
HU
36M
48M
PO
60M
PO
Late lumen loss stable
12M BVS (Cohort B): 0.27 ± 0.34 mm (N=50)
36M BVS (Cohort B): 0.29 ± 0.43 mm (N=51)
0
-0.6
0
0.6
mm
6 Months
24 Months
36 Months
42 Months

ABSORB Cohort B

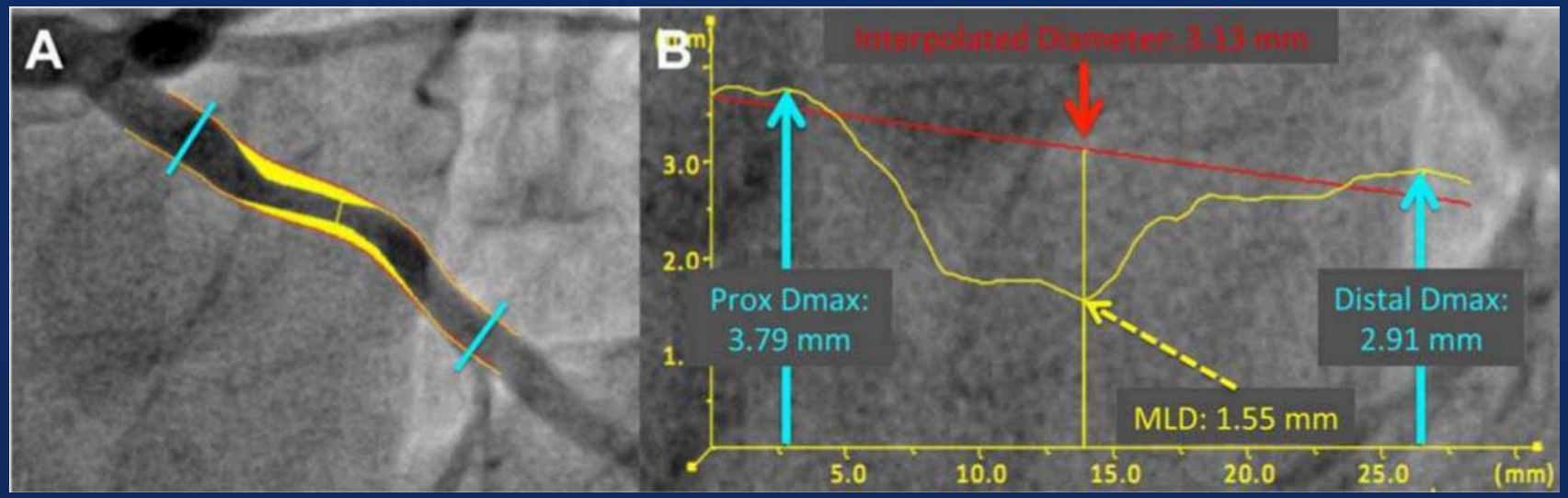
ABSORB Cohort A & B



Serruys PW et al. EuroInt 2013;9 e-pub

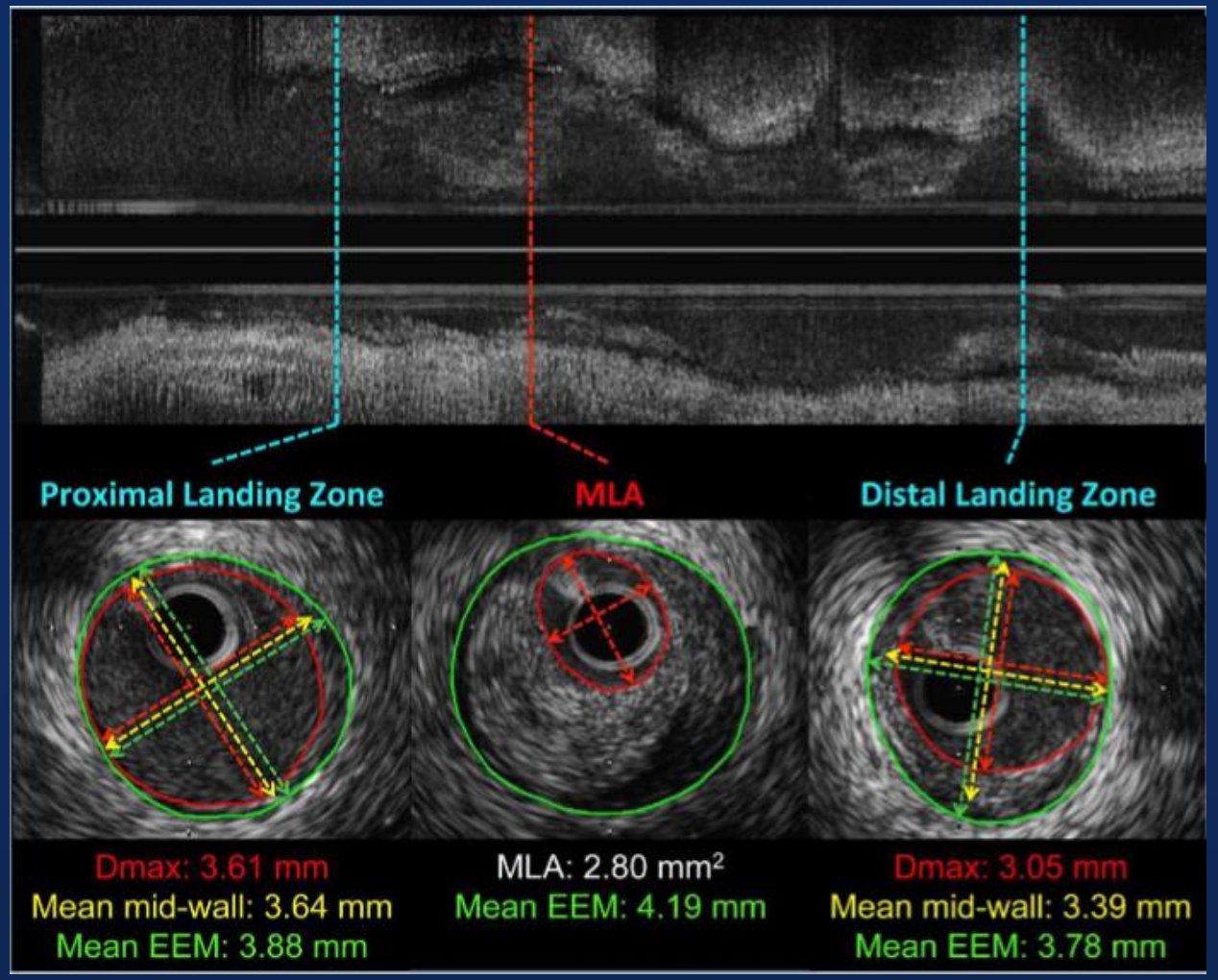
Image for BRS implantation

Vessel sizing by QCA



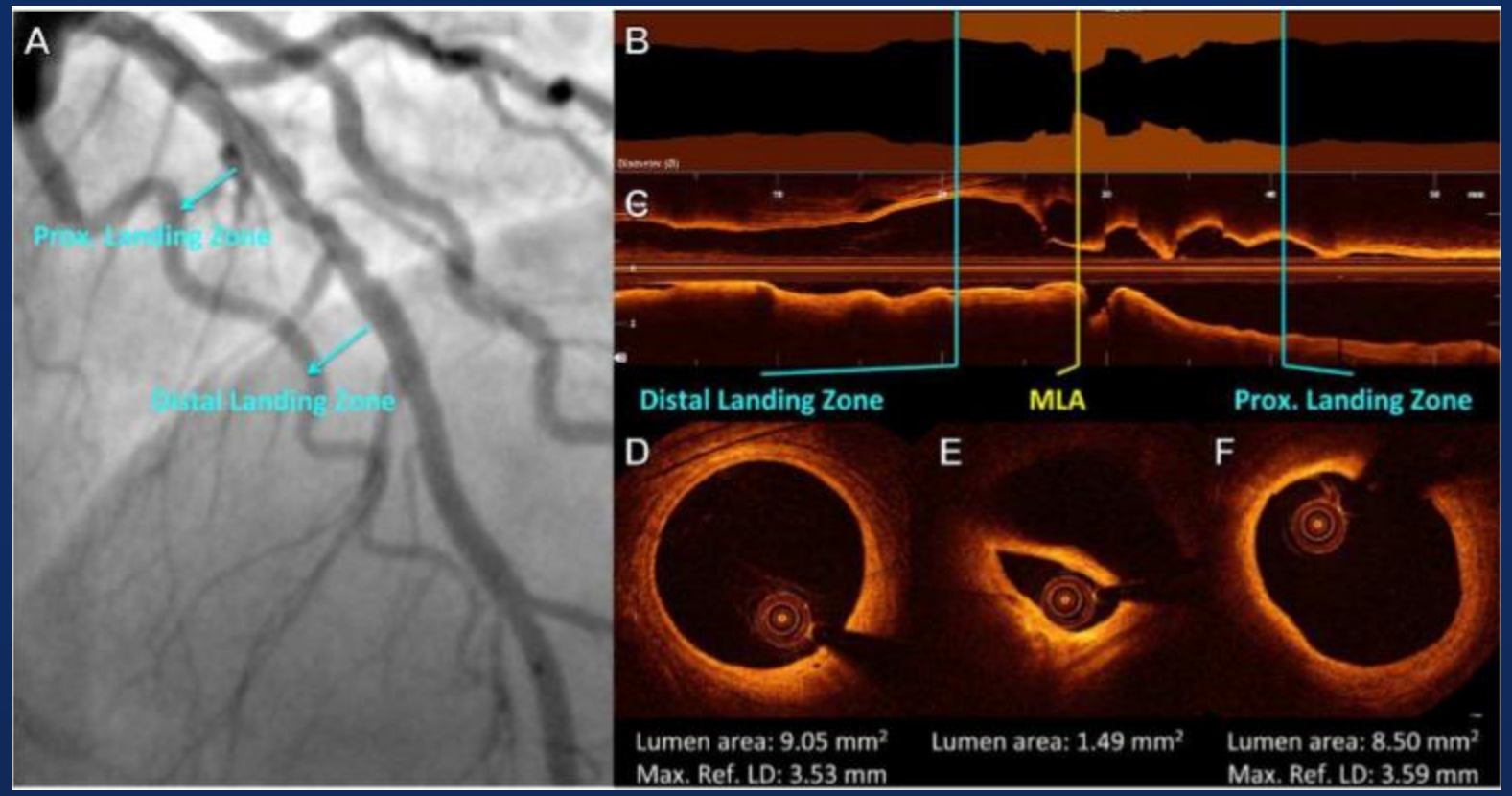
Catheterization and Cardiovascular Interventions 88:S38–S53 (2016)

Vessel sizing by IVUS



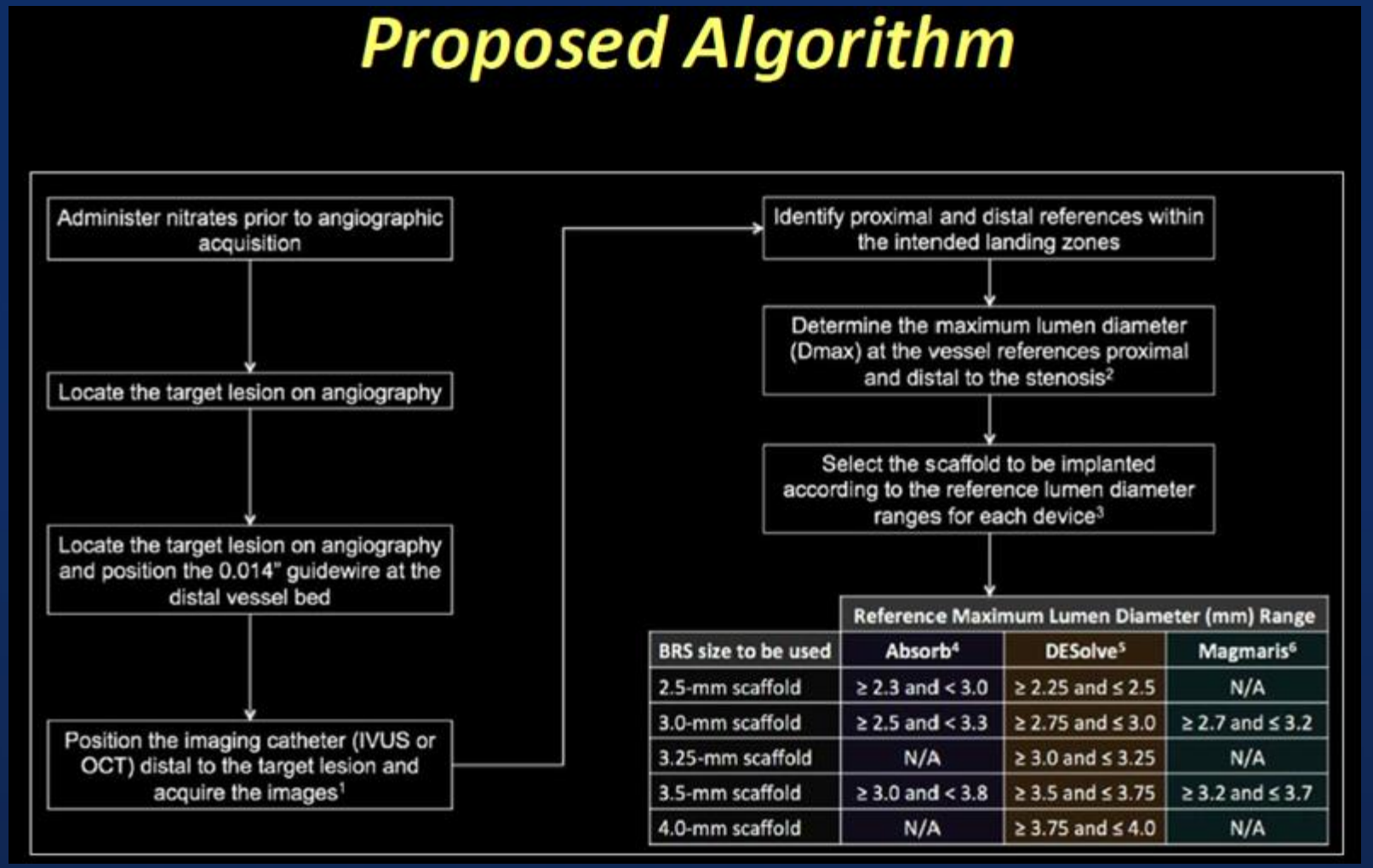
Catheterization and Cardiovascular Interventions 88:S38–S53 (2016)

Vessel sizing by OCT



Catheterization and Cardiovascular Interventions 88:S38–S53 (2016)

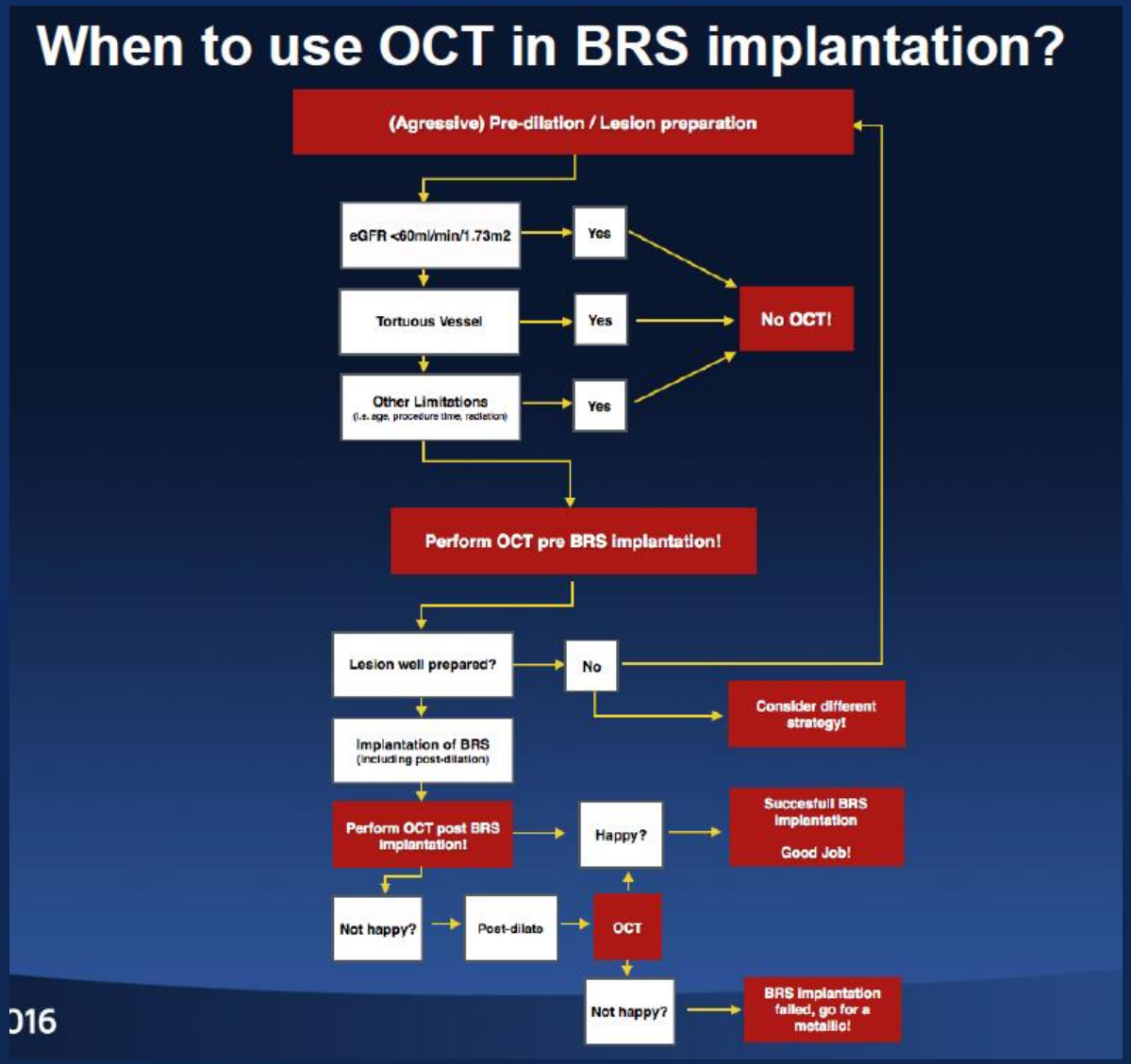
Role of invasive image



	Reference Maximum Lumen Diameter (mm) Range		
BRS size to be used	Absorb[4]	DESolve[5]	Magmaris[6]
2.5-mm scaffold	≥ 2.3 and < 3.0	≥ 2.25 and ≤ 2.5	N/A
3.0-mm scaffold	≥ 2.5 and < 3.3	≥ 2.75 and ≤ 3.0	≥ 2.7 and ≤ 3.2
3.25-mm scaffold	N/A	≥ 3.0 and ≤ 3.25	N/A
3.5-mm scaffold	≥ 3.0 and < 3.8	≥ 3.5 and ≤ 3.75	≥ 3.2 and ≤ 3.7
4.0-mm scaffold	N/A	≥ 3.75 and ≤ 4.0	N/A

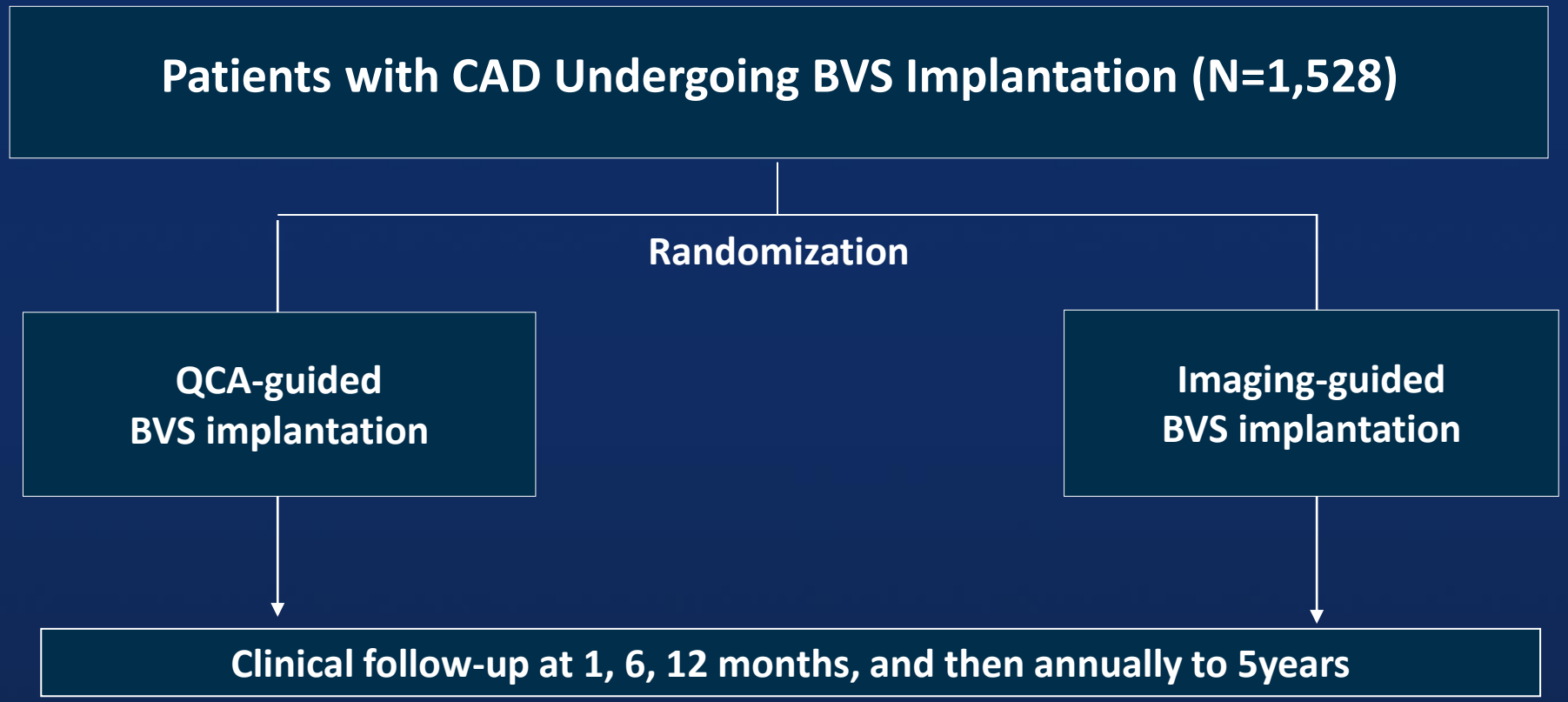
Catheterization and Caridovascular Interventions 2016;88:S38-S53

Use of OCT



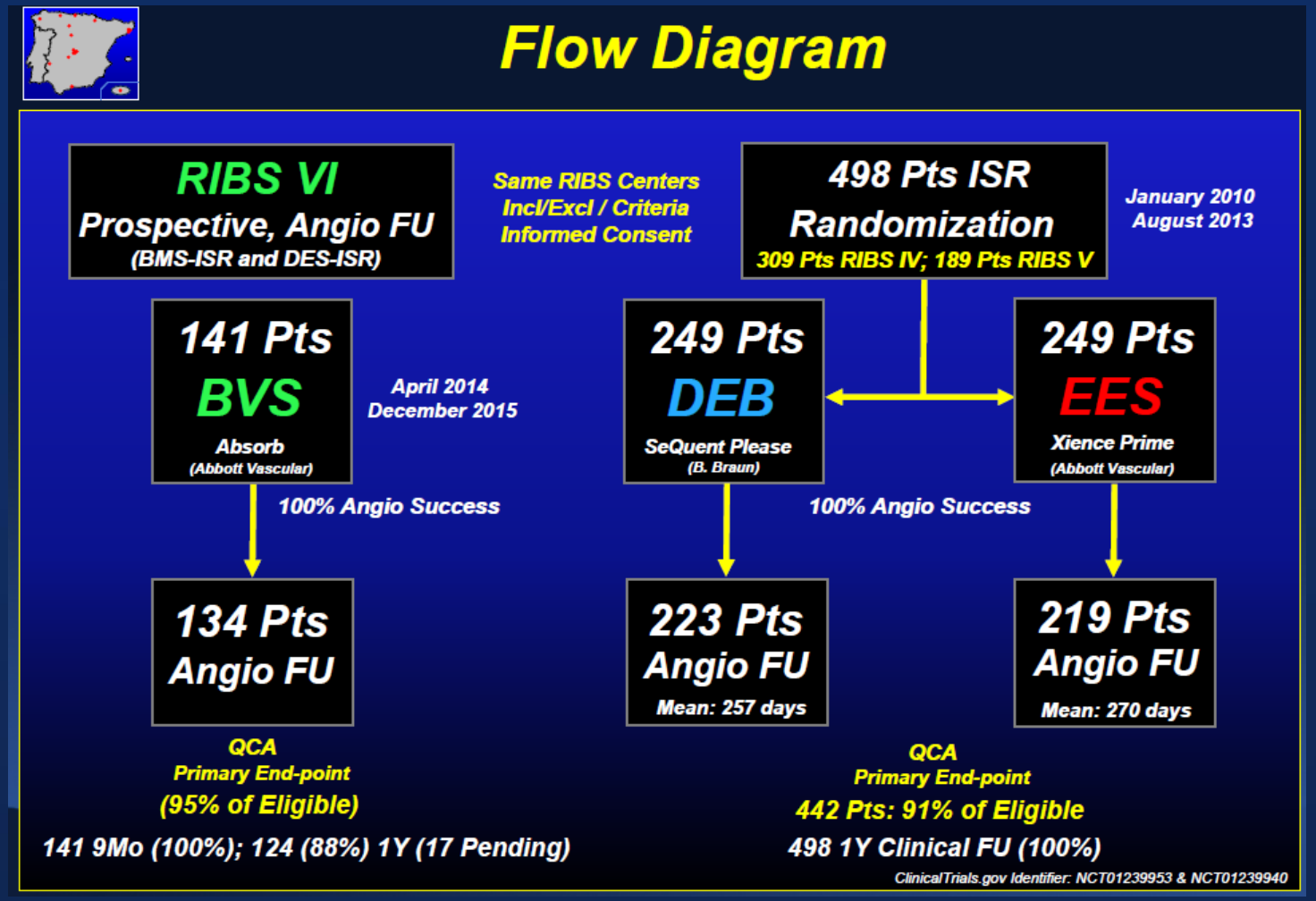
J J Wykrzykowska, TCT 2016

BRS *QCA vs. Imaging-guided*



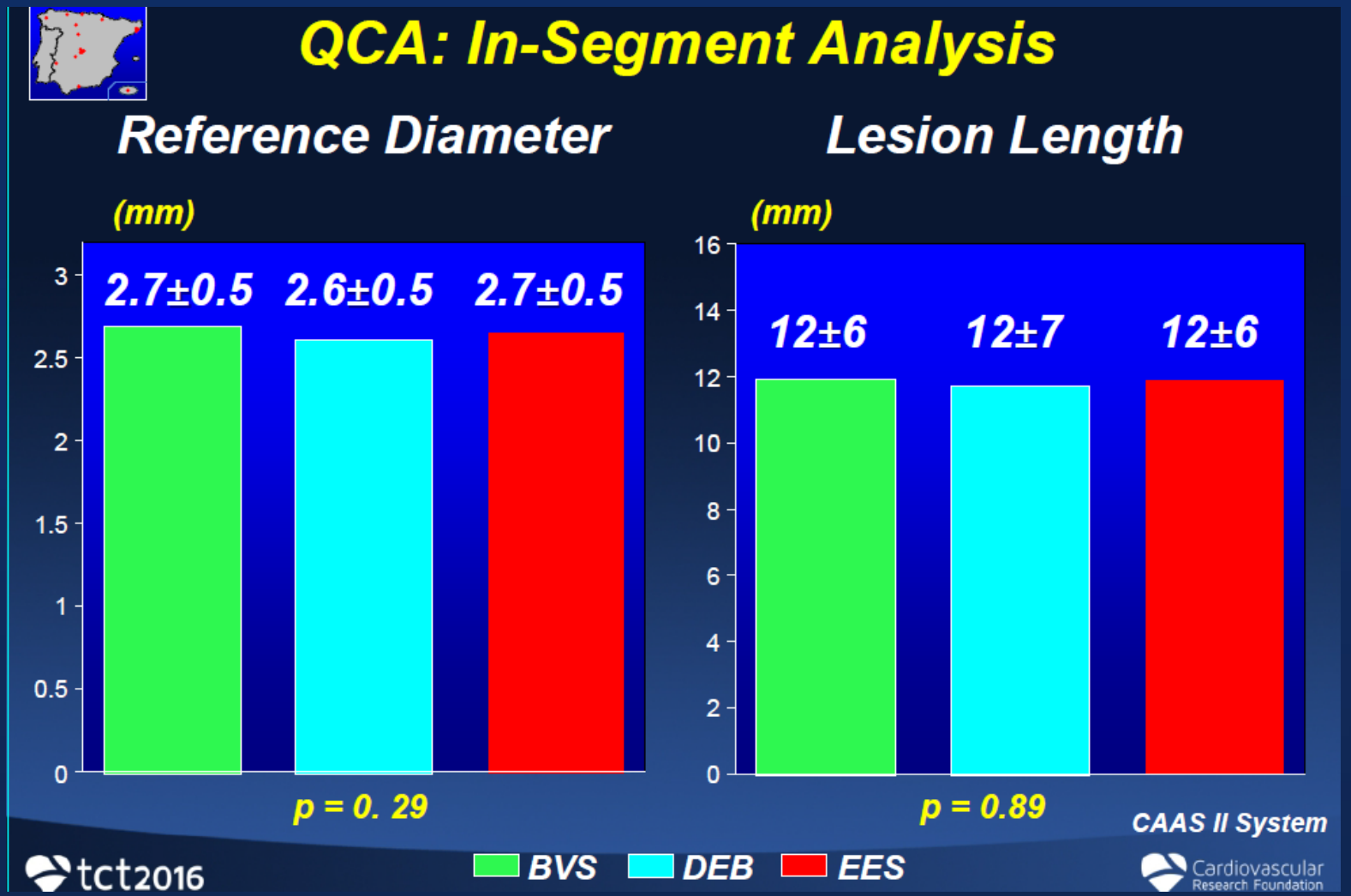
*Primary endpoint: target-lesion failure (cardiac death, TV-MI, or ID-TLR) at 1 year

BRS for ISR lesions: *RIBS VI*



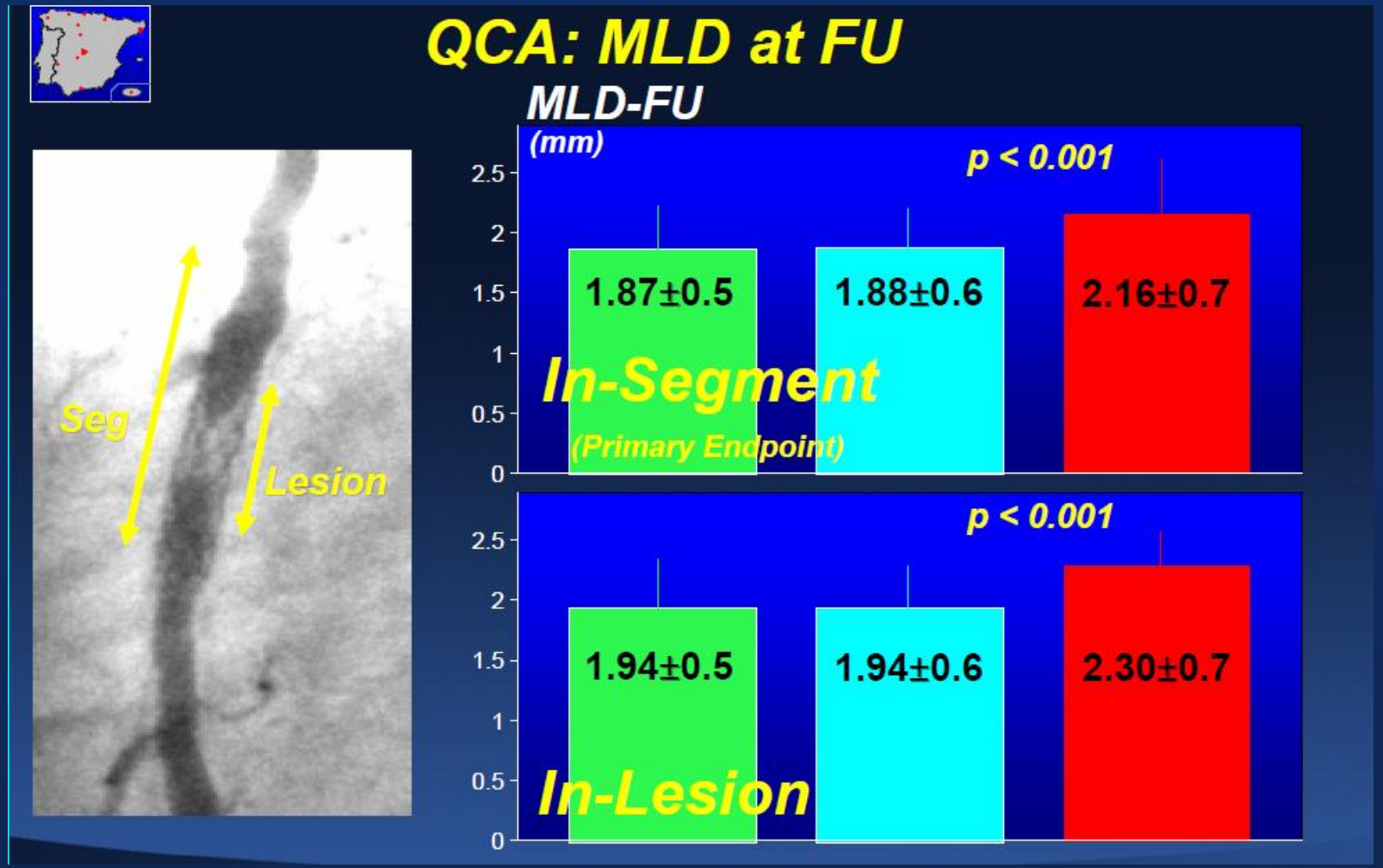
F Alfonso, TCT 2016

RIBS VI



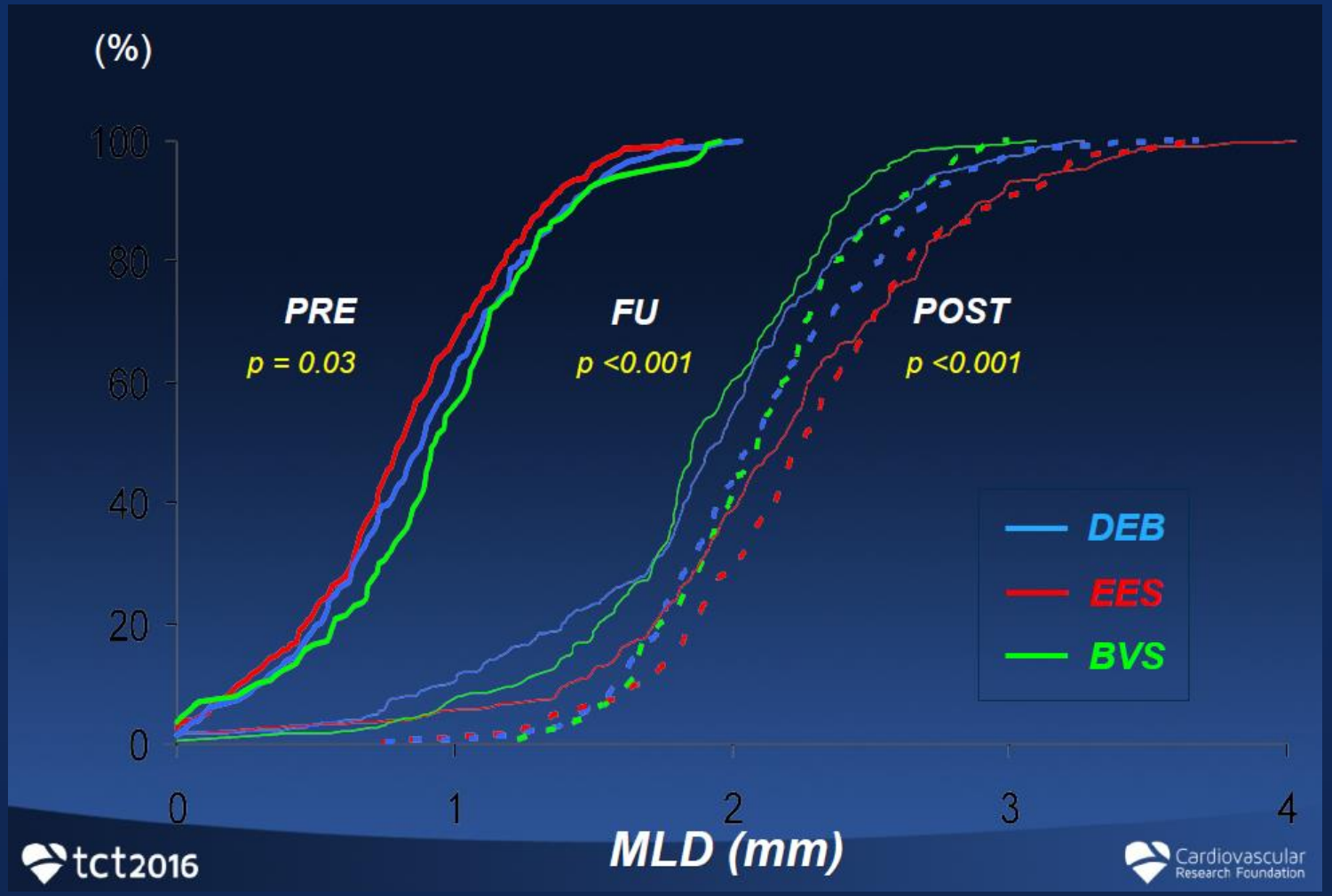
F Alfonso, TCT 2016

RIBS VI



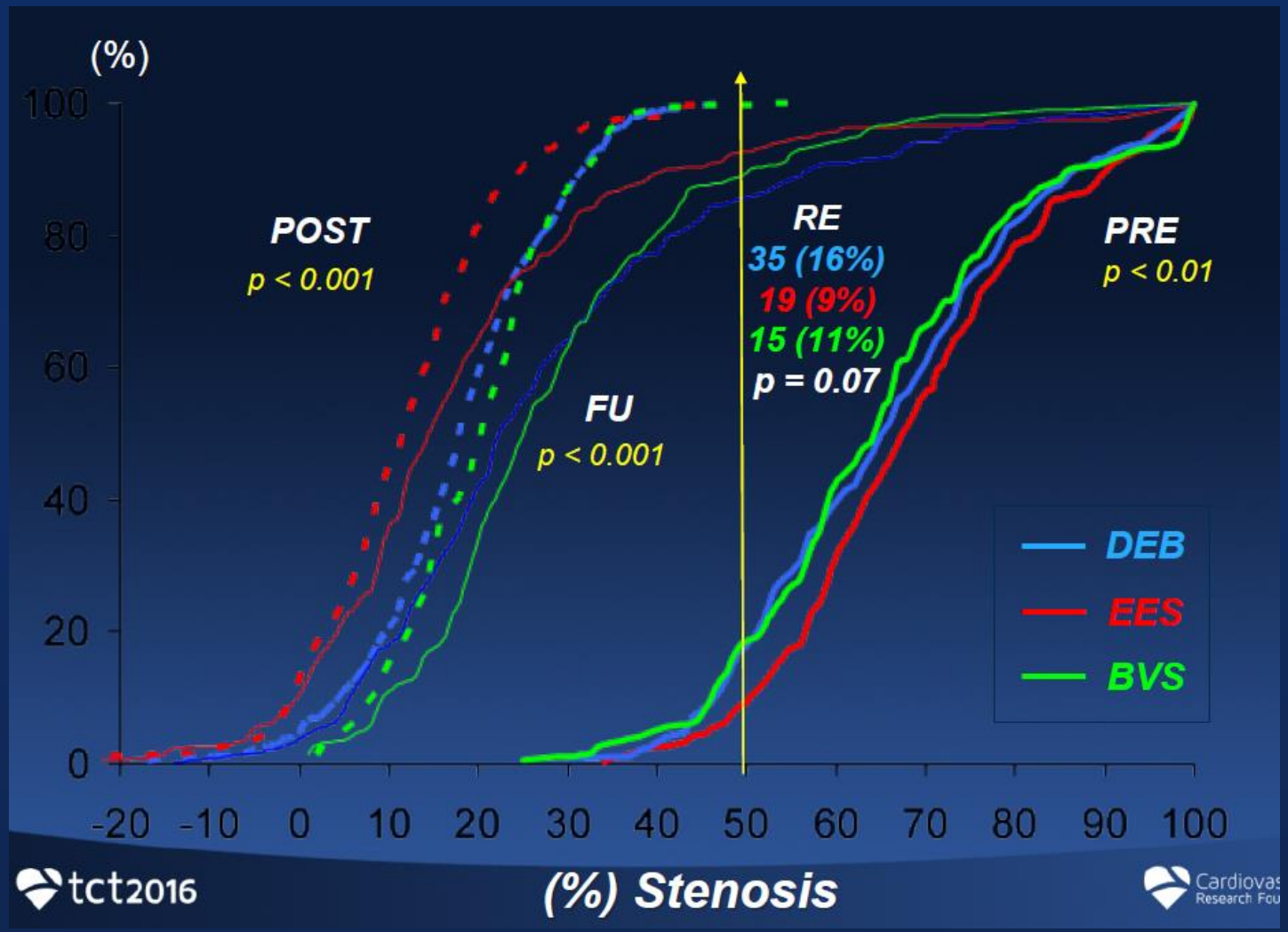
F Alfonso, TCT 2016

RIBS VI



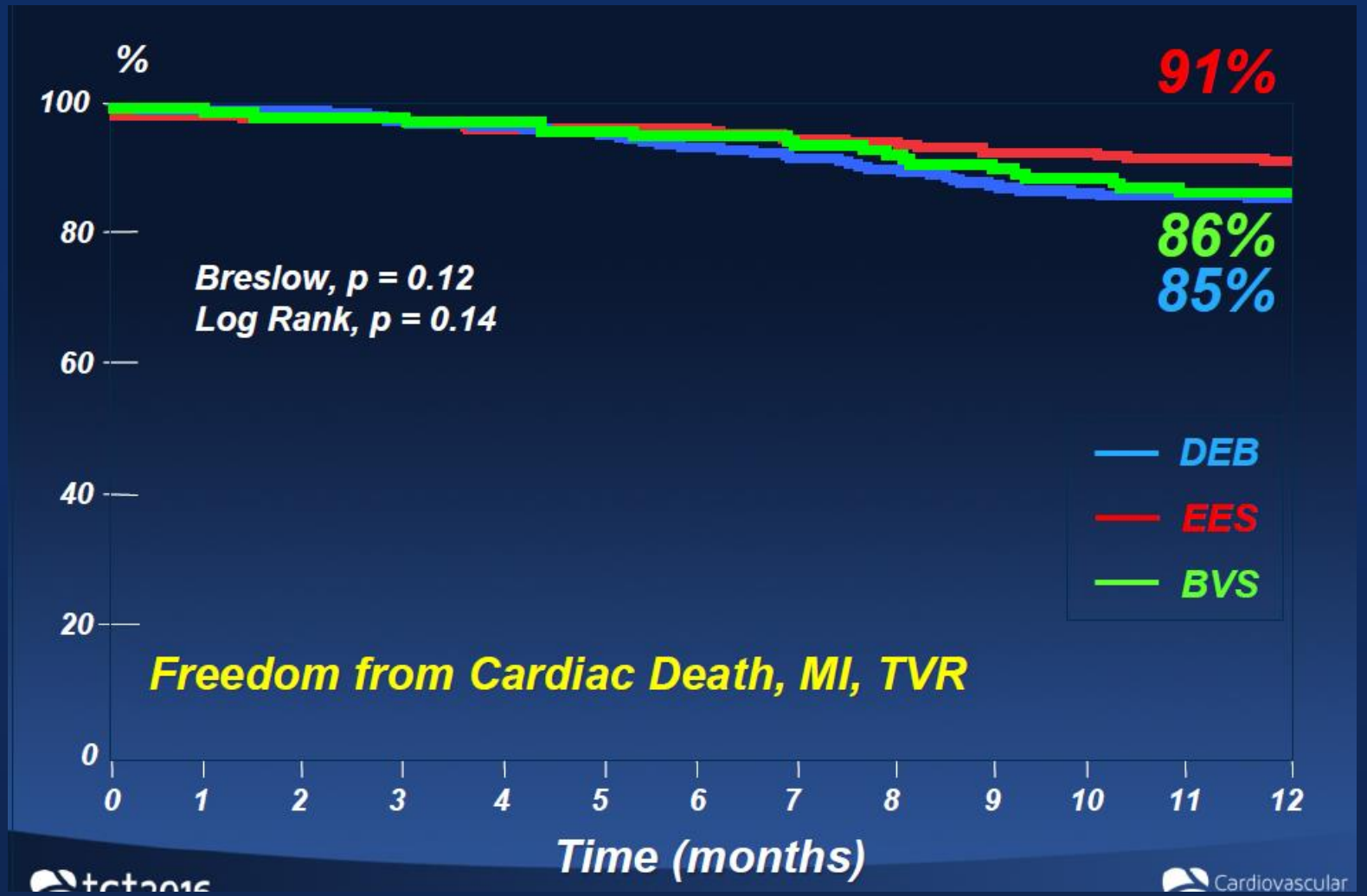
F Alfonso, TCT 2016

RIBS VI



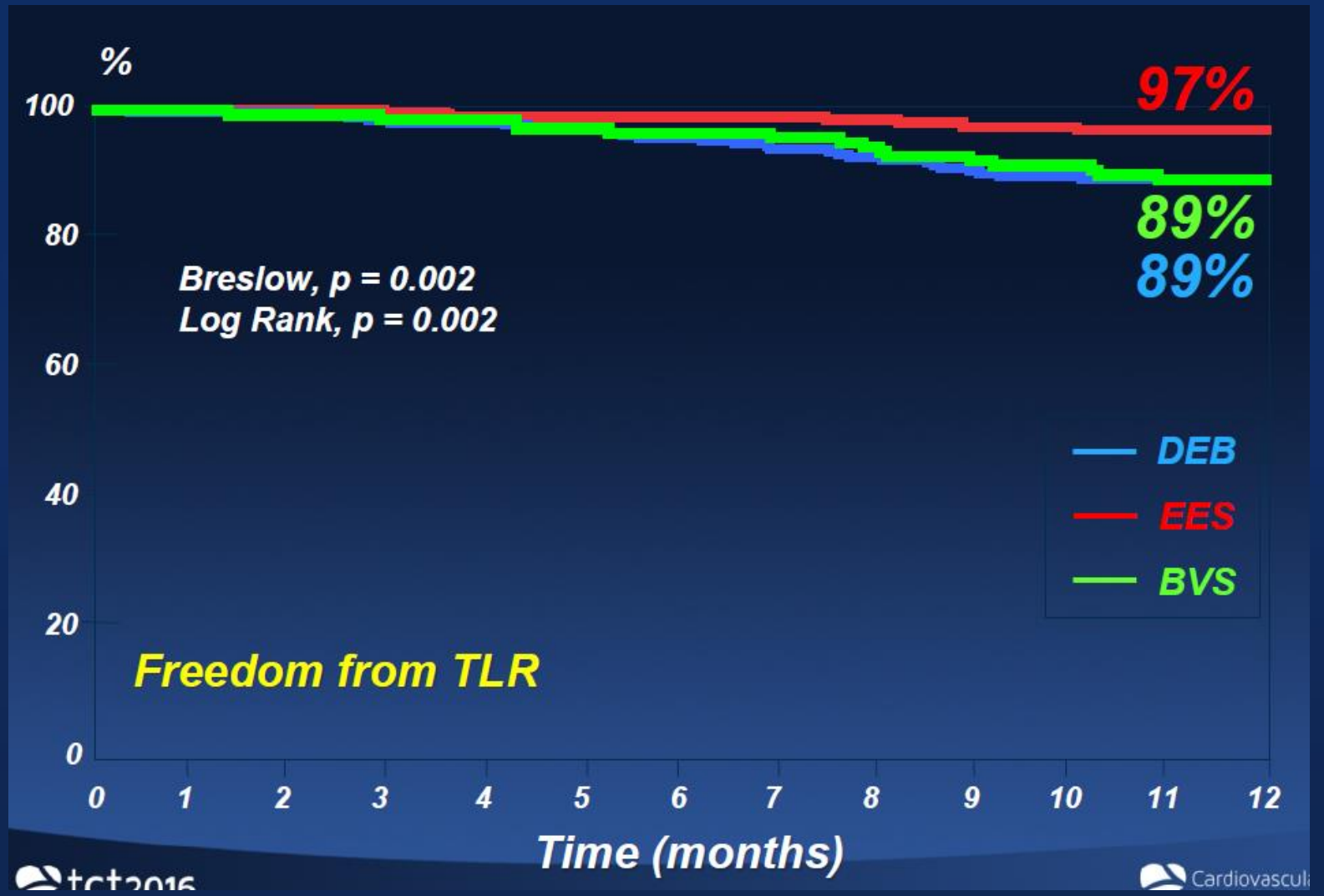
F Alfonso, TCT 2016

RIBS VI



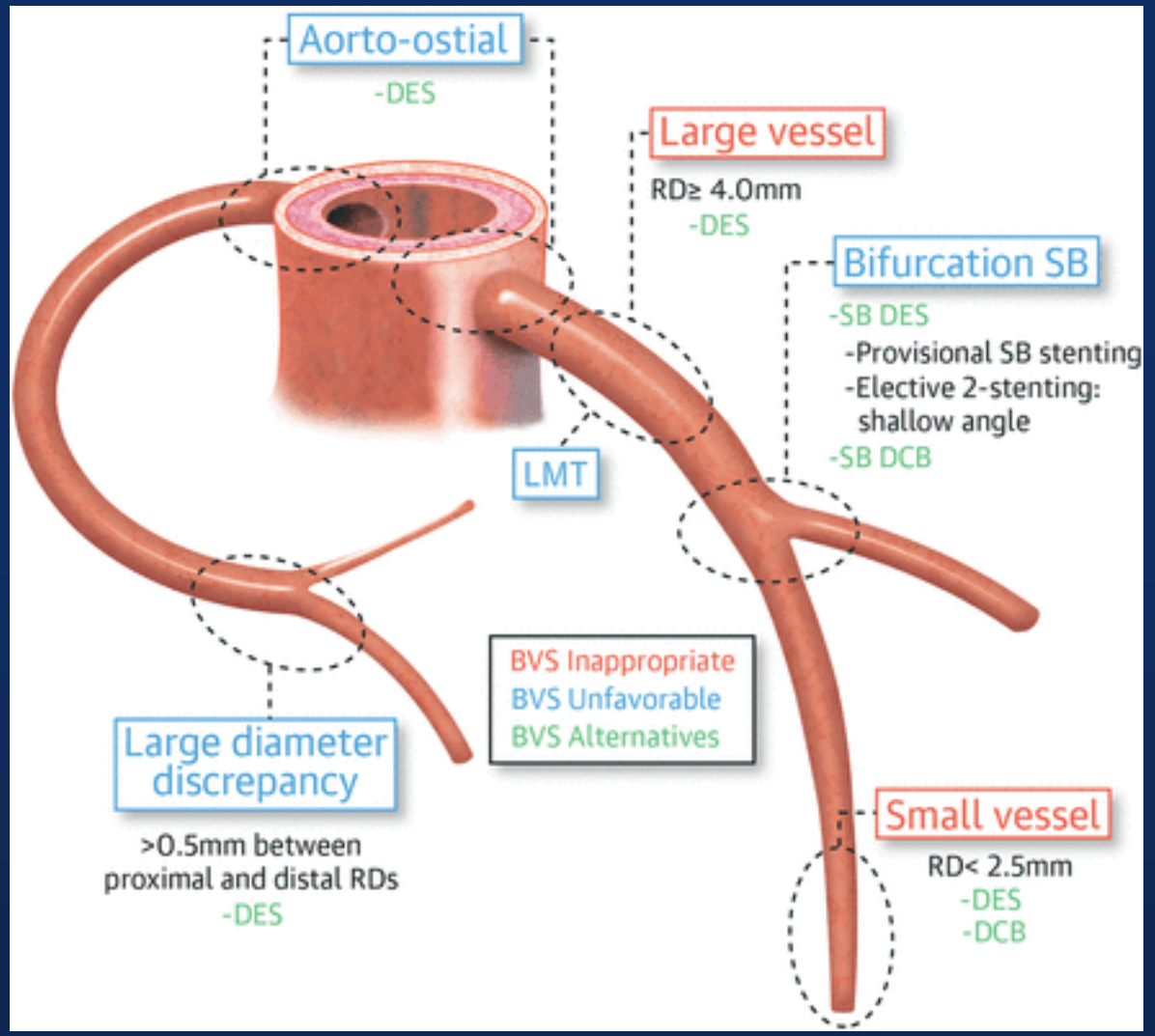
F Alfonso, TCT 2016

RIBS VI



F Alfonso, TCT 2016

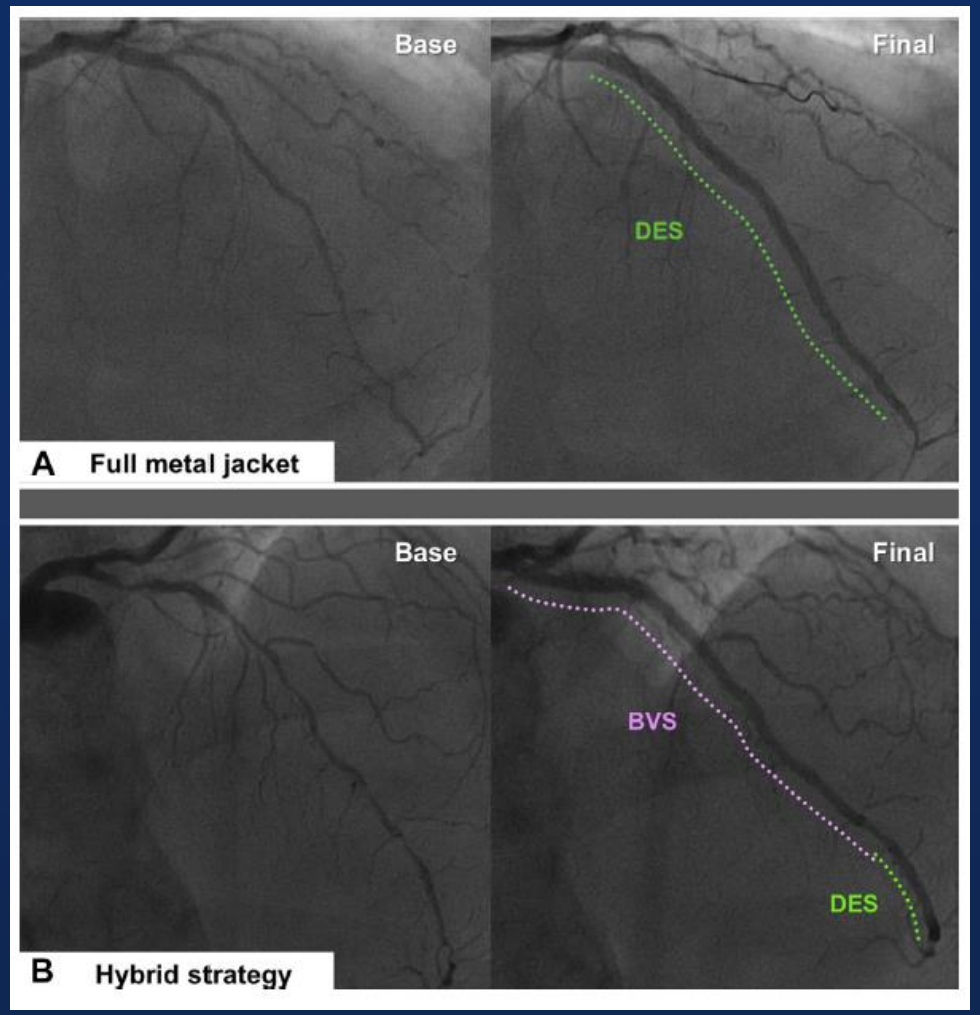
BRS Hybrid technique



J Am Coll Cardiol Intv 2017;10:539–47

BVS Hybrid technique

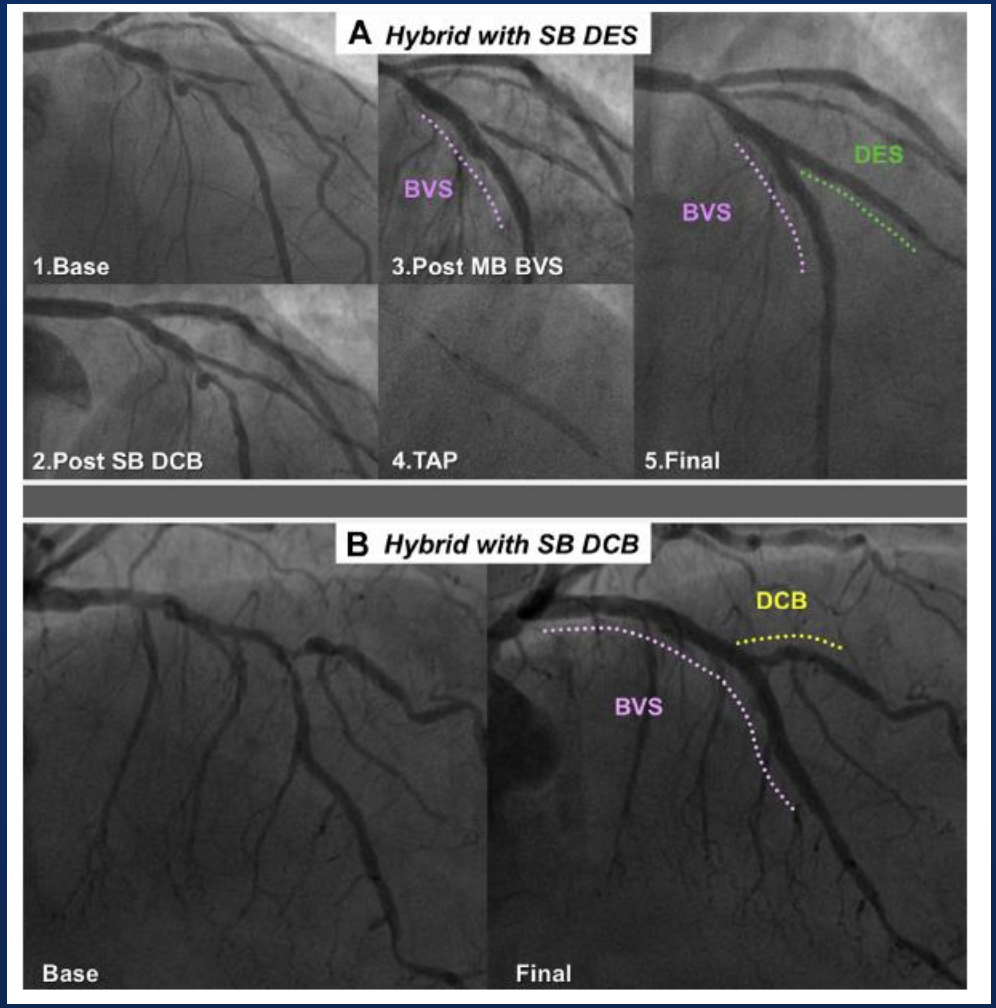
Involving long lesion



J Am Coll Cardiol Intv 2017;10:539–47

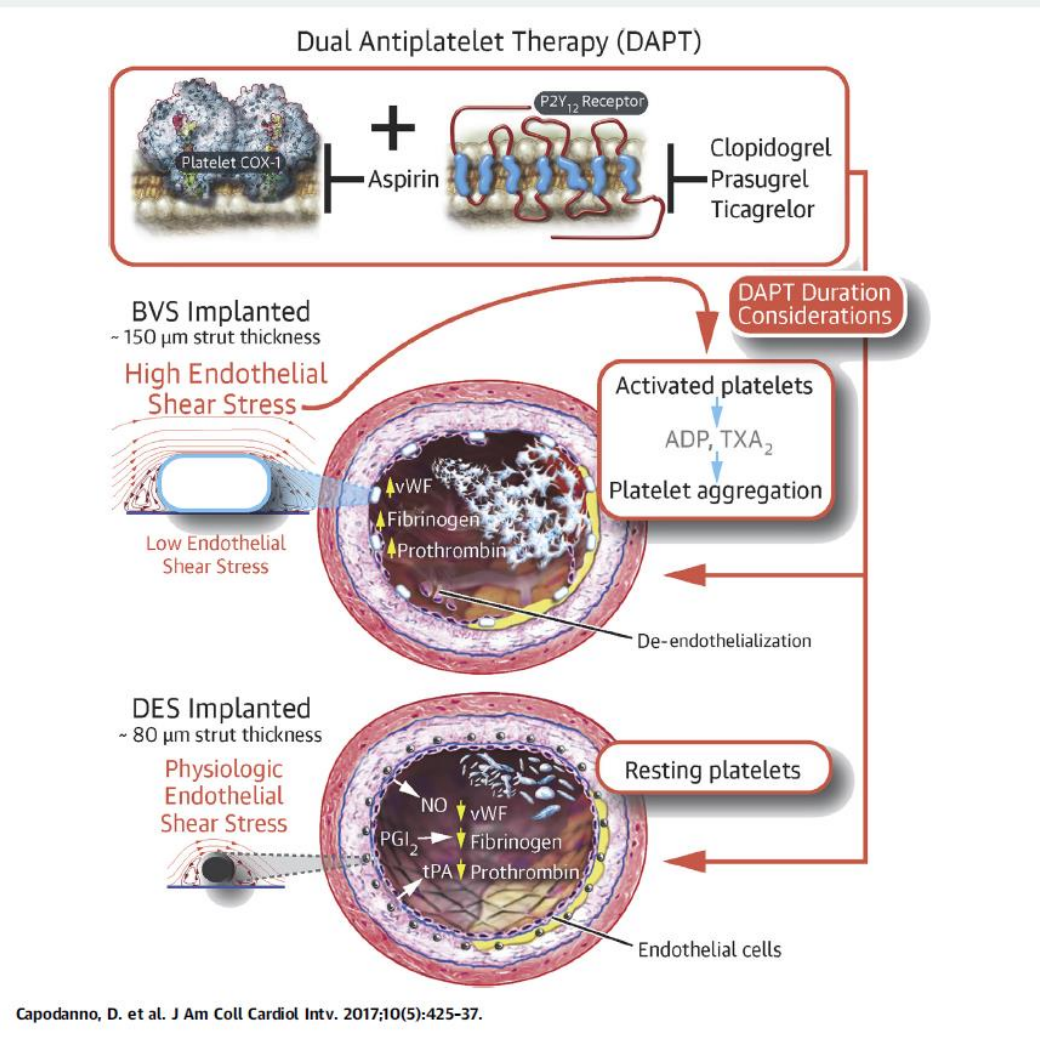
BVS Hybrid technique

Bifurcation Lesion



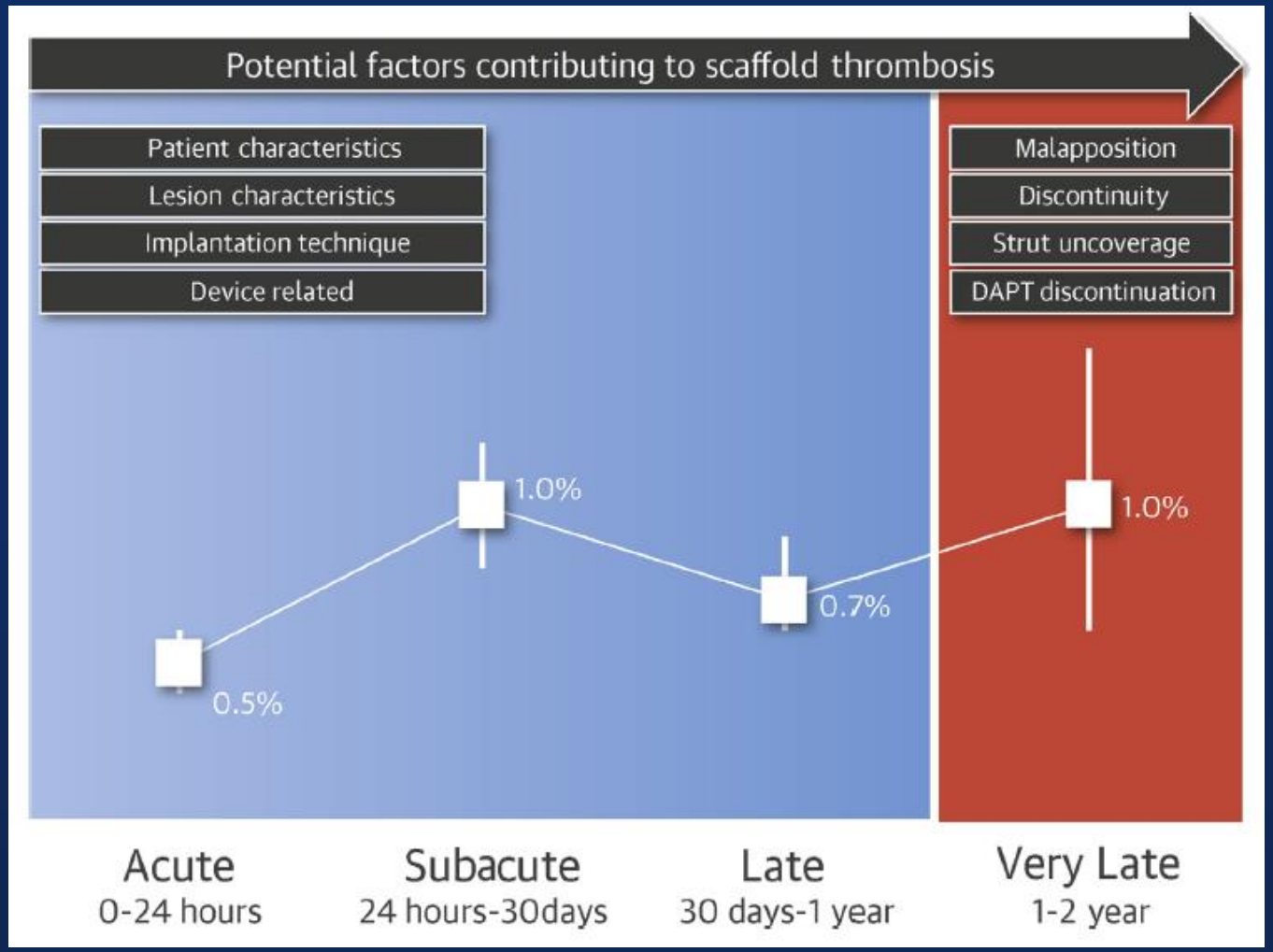
J Am Coll Cardiol Intv 2017;10:539–47

Antiplatelet therapy for BVS



J Am Coll Cardiol Intv 2017;10:425–37

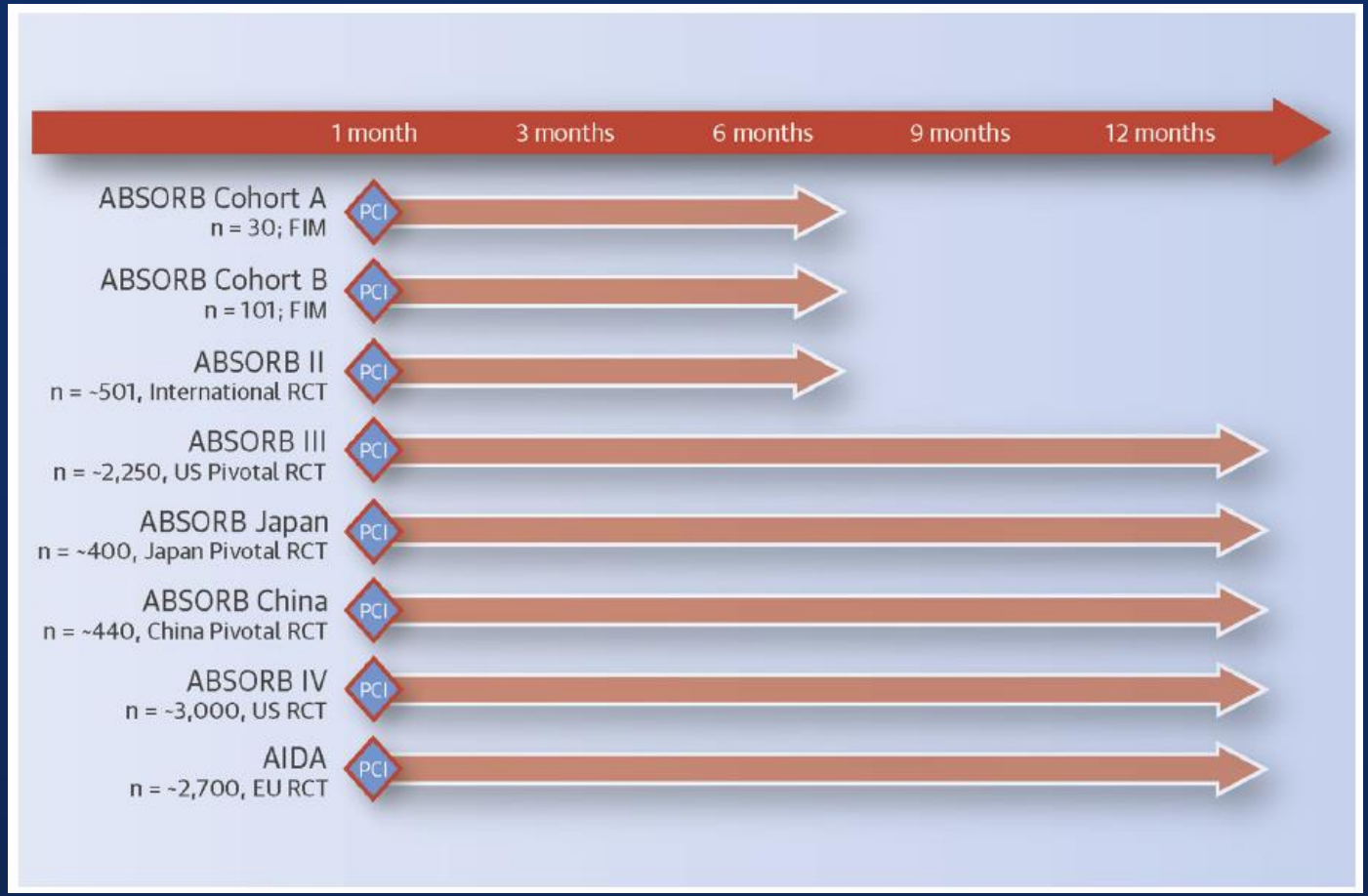
Antiplatelet therapy for BVS



J Am Coll Cardiol Intv 2017;10:425–37

Antiplatelet therapy for BVS

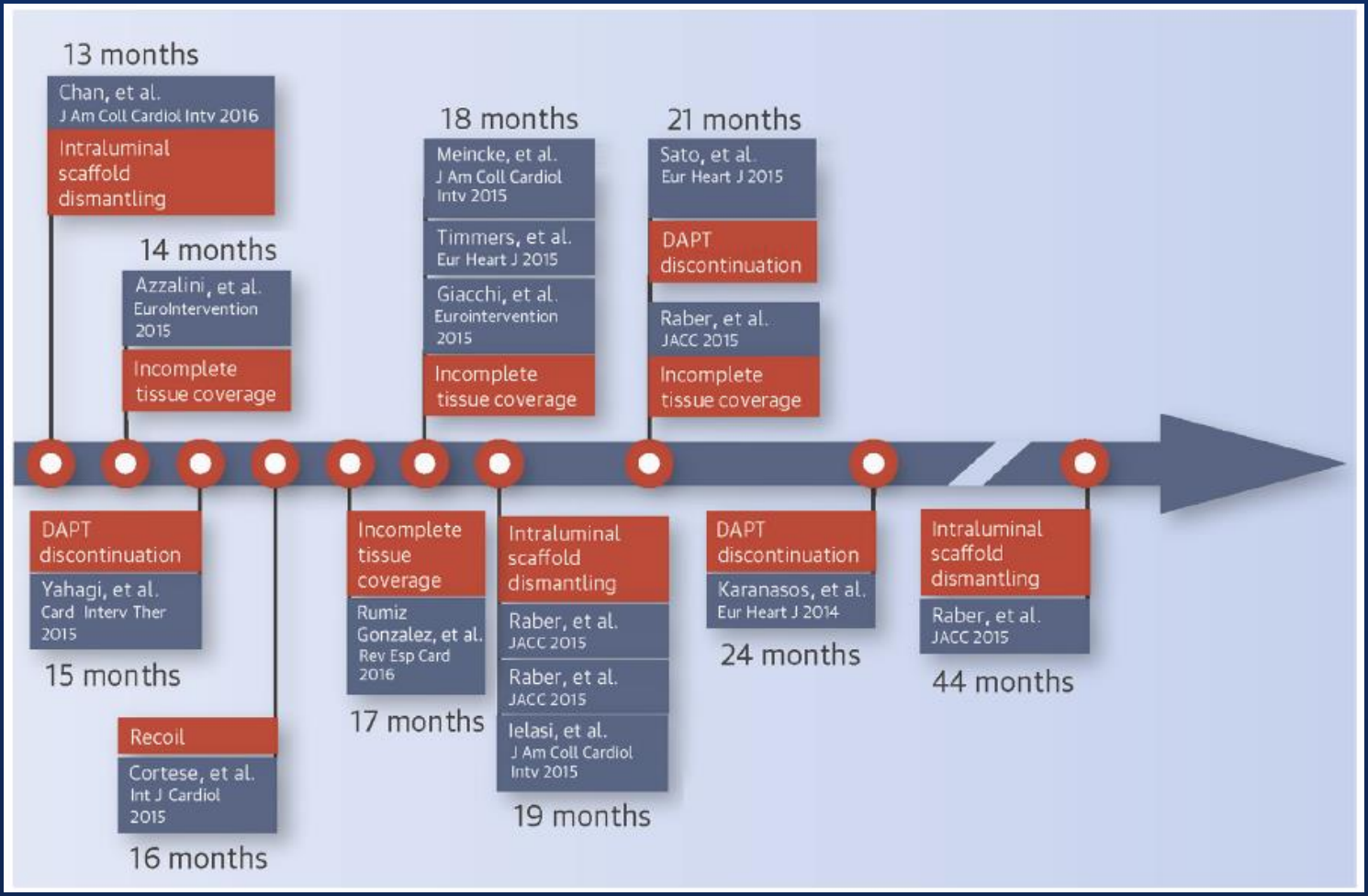
Minimum Dual-Antiplatelet Therapy duration



J Am Coll Cardiol Intv 2017;10:425–37

Antiplatelet therapy for BVS

Very late Scaffold thrombosis



J Am Coll Cardiol Intv 2017;10:425–37

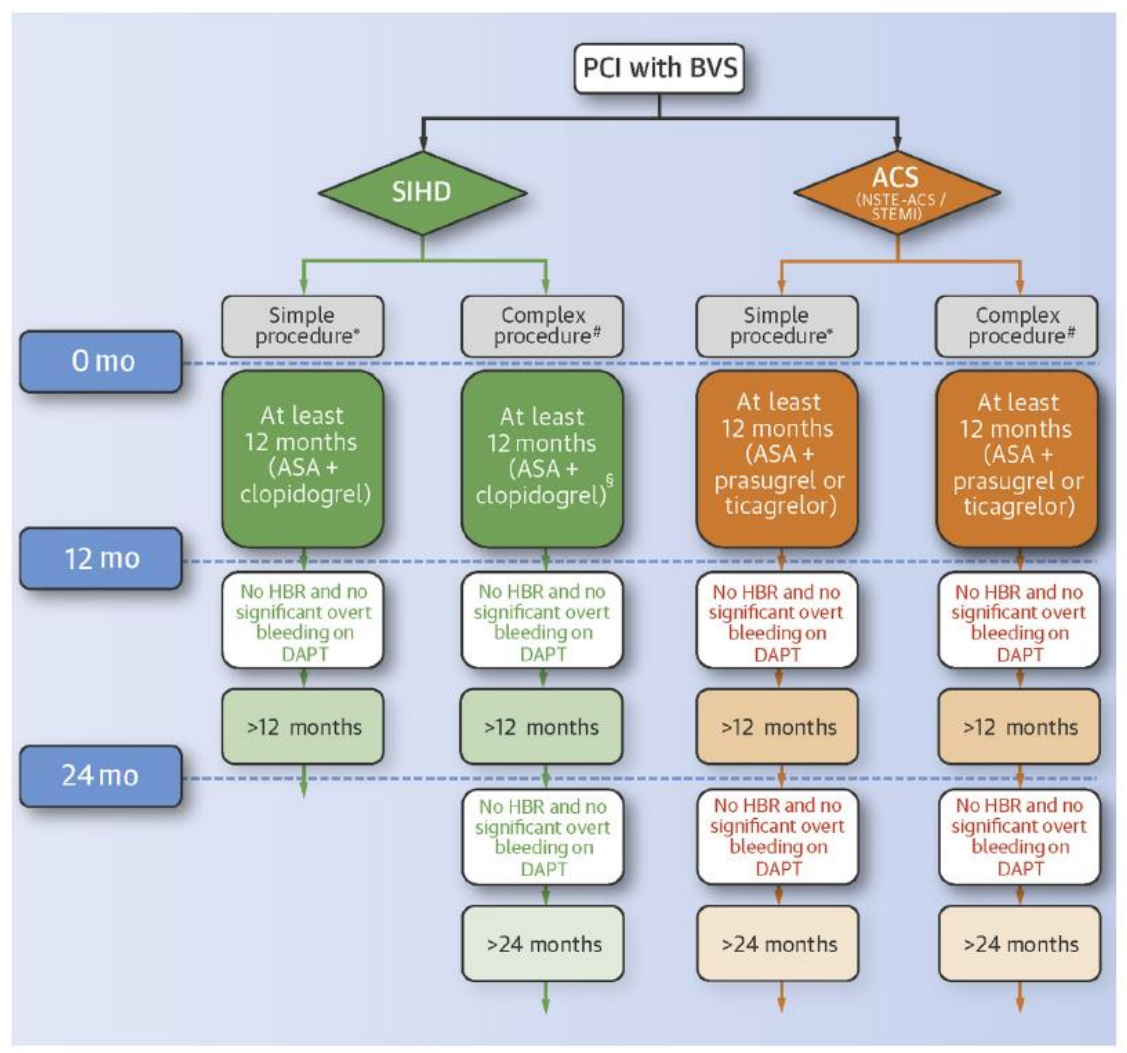
Antiplatelet therapy for BVS

Event rates and Adherence to DAPT

	ABSORB II (23,25,43)		ABSORB CHINA (14)		ABSORB JAPAN (13,24)		ABSORB III (15)	
	BVS	EES	BVS	EES	BVS	EES	BVS	EES
Patients	335	166	241	239	266	134	1322	686
On $P2Y_{12}$ inhibitors								
1-yr follow-up	83.0%	83.0%	98.7%	99.2%	97.0%	97.3%	94.4%	95.0%
2-yr follow-up	36.2%	34.3%	NR	NR	52.3%	50.7%	–	–
3-yr follow-up	31.0%	30.0%	–	–	–	–	–	–
Definite or probable device thrombosis								
1-yr follow-up	0.9%	0.0%	0.4%	0.0%	1.5%	1.5%	1.5%	0.7%
2-yr follow-up	1.5%	0.0%	0.8%	0.0%	3.1%	1.5%	–	–
3-yr follow-up	2.8%	0.0%	–	–	–	–	–	–
ARR 1-2 yr follow-up	+0.6%	0.0%	+0.4%	0.0%	+1.6%	0.0%	–	–
ARR 2-3 yr follow-up	+1.3%	0.0%	–	–	–	–	–	–

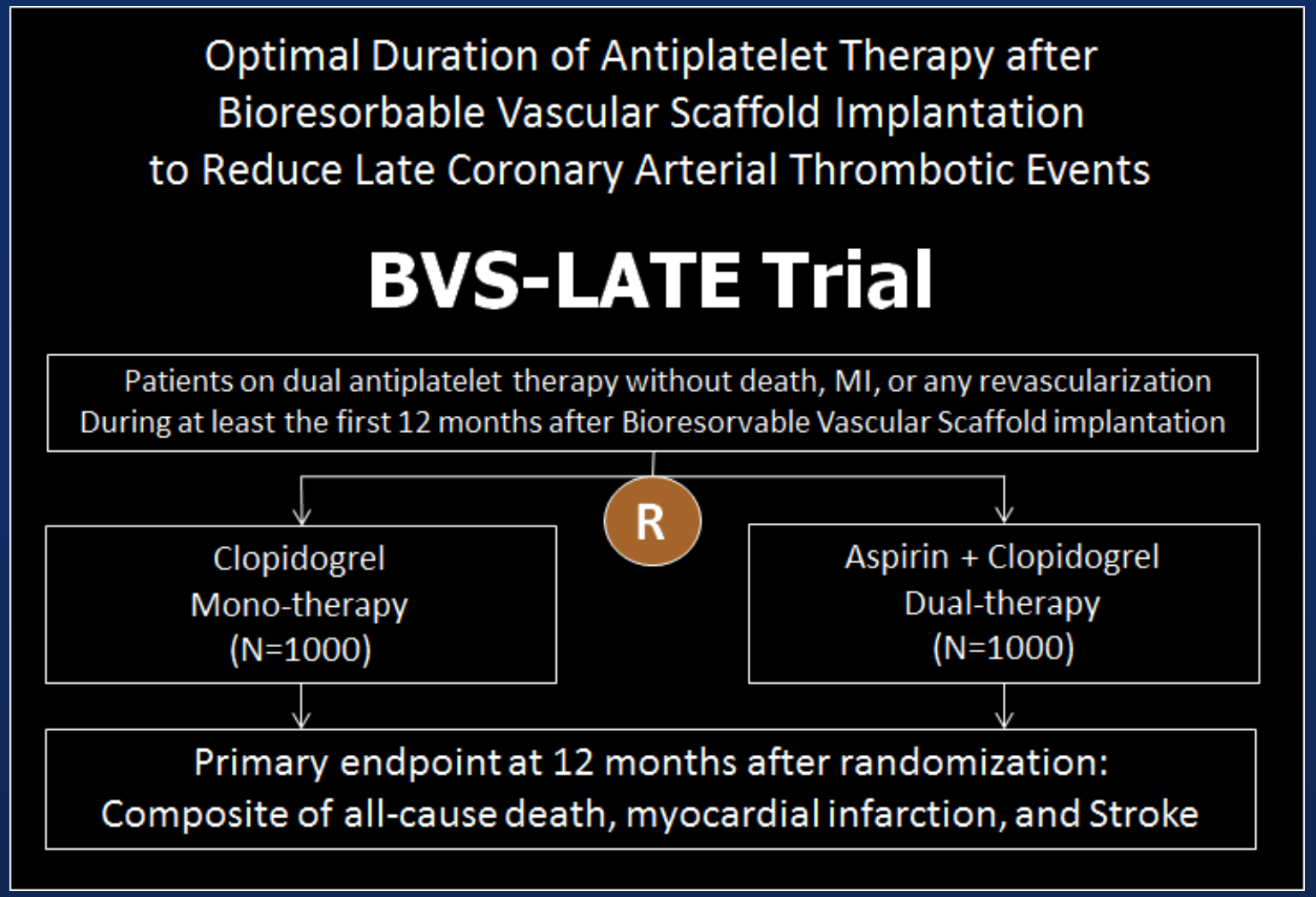
J Am Coll Cardiol Intv 2017;10:425–37

Antiplatelet therapy for BVS



J Am Coll Cardiol Intv 2017;10:425–37

BVS *How Long DAPT?*



Unresolved Mechanical Issues of BVS

- Complex lesions; calcified or tortuous, long lesion, bifurcation, left main
- Stretchability and fracture
- Overlapping
- Side branch
- Relatively high late loss

Appropriate Use of Absorb in Current Practice

Appropriate

Big Vessel >2.5 mm
Young Age <70 years
Diabetes
STEMI
Multi-vessel Disease
Long Lesion
Bifurcation (Provisional)
CTO

Not Yet

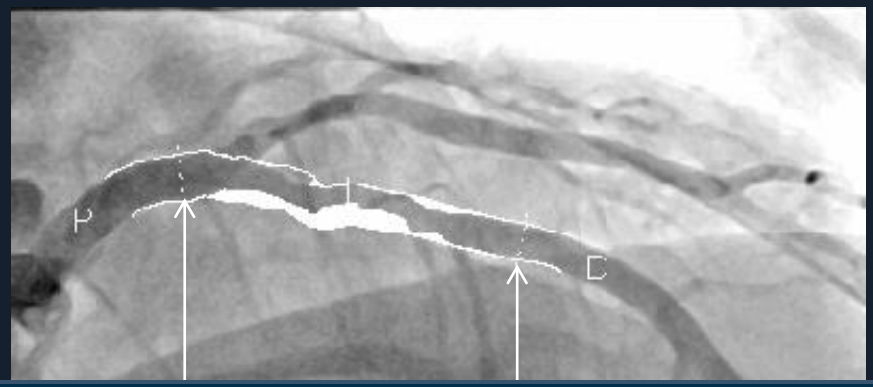
Bifurcation (2 stents)
Severe Calcification
ISR

What do I need to Know to Use the Absorb Scaffold Appropriately?

1. Is Imaging guided BRS implantation mandatory ?
2. What are the early results in complex lesions compared to those of 2nd Generation DES ?
3. Is one year DAPT enough ?
4. Are the long term results really better with Absorb ?

How to Do *QCA guided Absorb* ?

QCA
Proximal RD
3.7 mm



QCA
Distal RD
3.0 mm

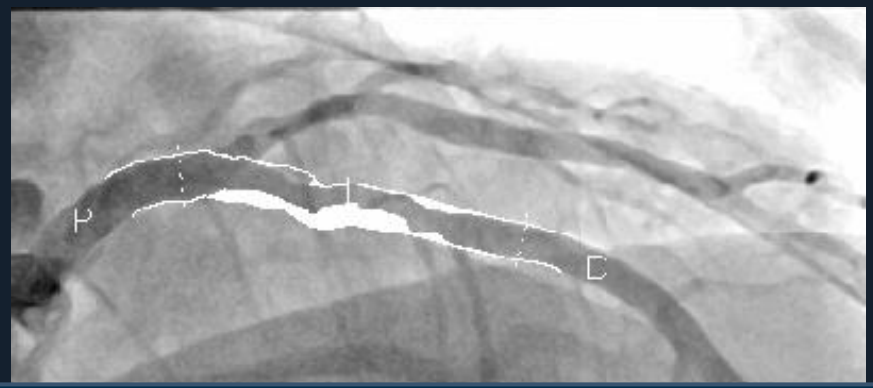
- **P** 3.0x 20 mm NC balloon pre-dilation
- **S** 3.5x 28 mm Absorb deployed
- **P** 3.5 mm NC balloon post-dilation for distal part and 4.0x 15 mm NC balloon post-dilation for proximal part

How to Do *IVUS guided Absorb* ?

Exactly Same Procedure !

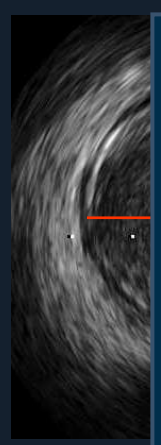
QCA
Proximal RD
3.7 mm

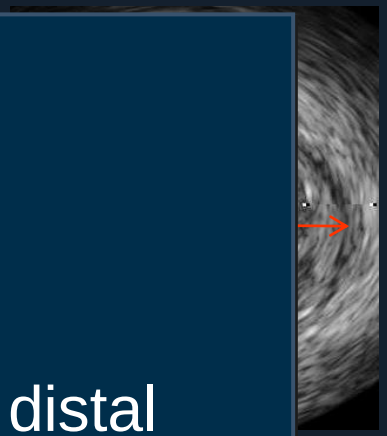
IVUS RD
4.2 mm



QCA
Distal RD
3.0 mm

IVUS RD
3.5 mm



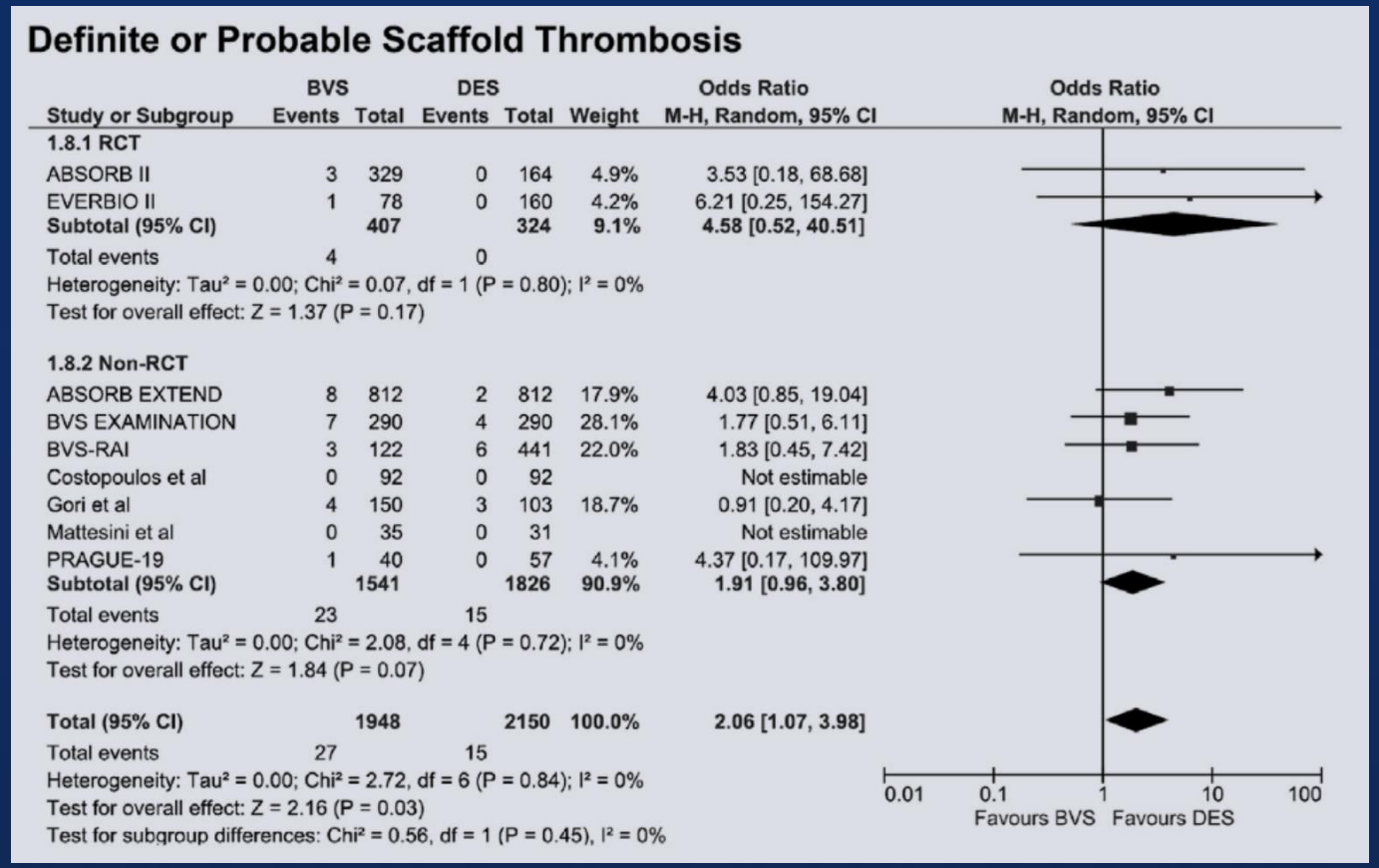


P 3.0x 20 mm NC balloon pre-dilation

S 3.5x 28 mm Absorb deployed

P 3.5 mm NC balloon post-dilation for distal part and 4.0x 15 mm NC balloon post-dilation for proximal part

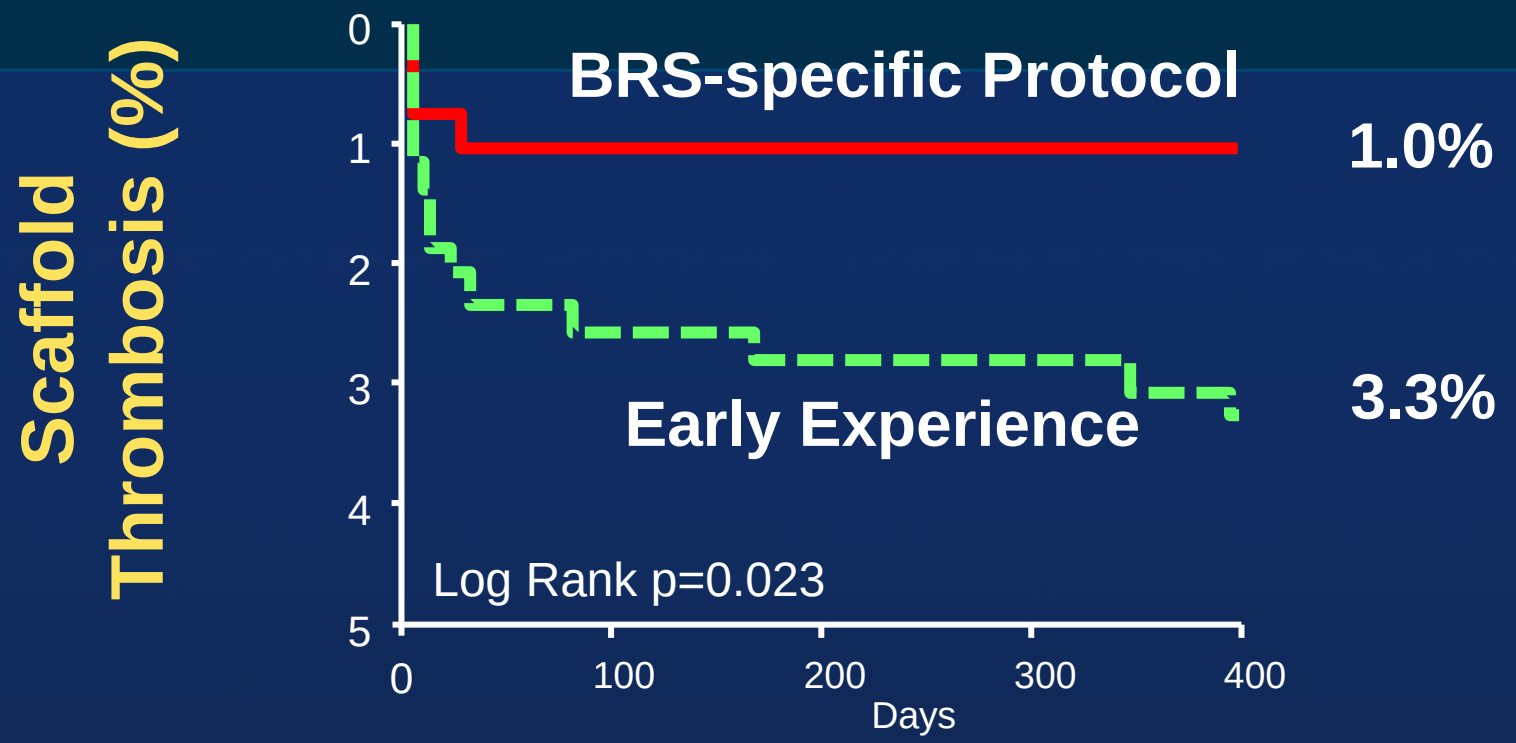
Increased Risk of ST



Lipinski et al. JACC CardiovascInterv2016;9(1):12-24

Concept of PSP

BVS Thrombosis Reduced with Improved Technique !



Patients					
Early Experience	369	369	369	369	369
Absorb-specific	292	292	281	217	155

Puricel, S. et l. J Am Coll Cardiol. 2016; 67(8):921–31

Recommended Technique
BVS Specific Protocol

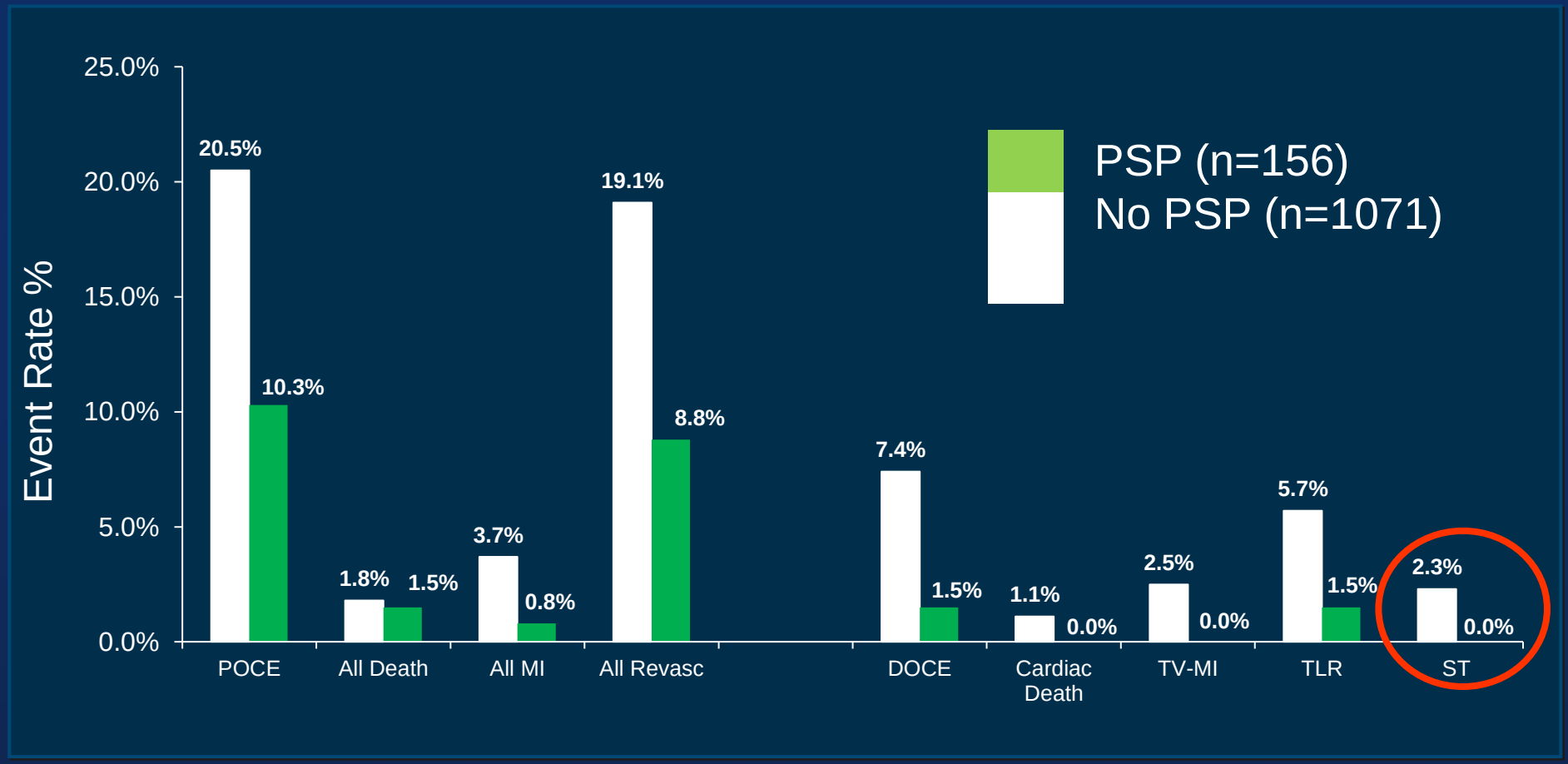
P ***Pre-Dilation***	Pre-dilation with noncompliant balloon, 1:1 with the RVD.
S ***Sizing Appropriately***	BVS of the same size as the RVD at 10 to 12 atm.
P ***Post-Dilation***	Post-dilation with noncompliant balloon with a maximum of 0.5mm larger at 14 to 16 atm.

Puricel, S. et l. J Am Coll Cardiol. 2016; 67(8):921–31

PSP Use by Trial (As-Treated Population)

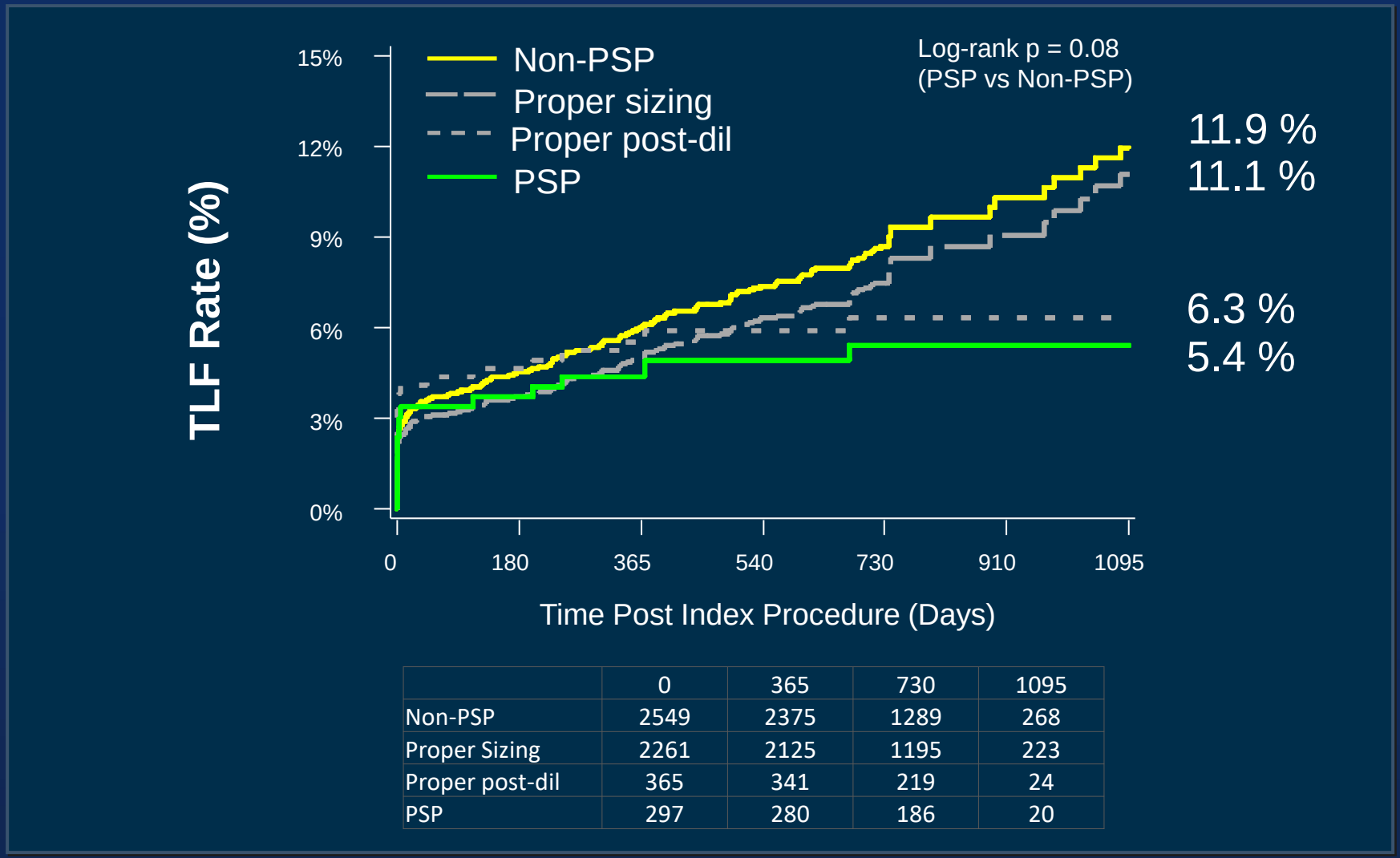
EXTEND	108/772	(14.0%)
ABSORB-II	21/324	(6.5%)
ABSORB-Japan	35/258	(13.6%)
ABSORB-China	32/237	(13.5%)
ABSORB-III	96/1224	(7.8%)

Significant Improvement of Outcomes
In GHOST-EU At 1 Year *With Completed PSP*



Brugaletta, S., GHOST-EU PSP Analysis, TCT 2016.

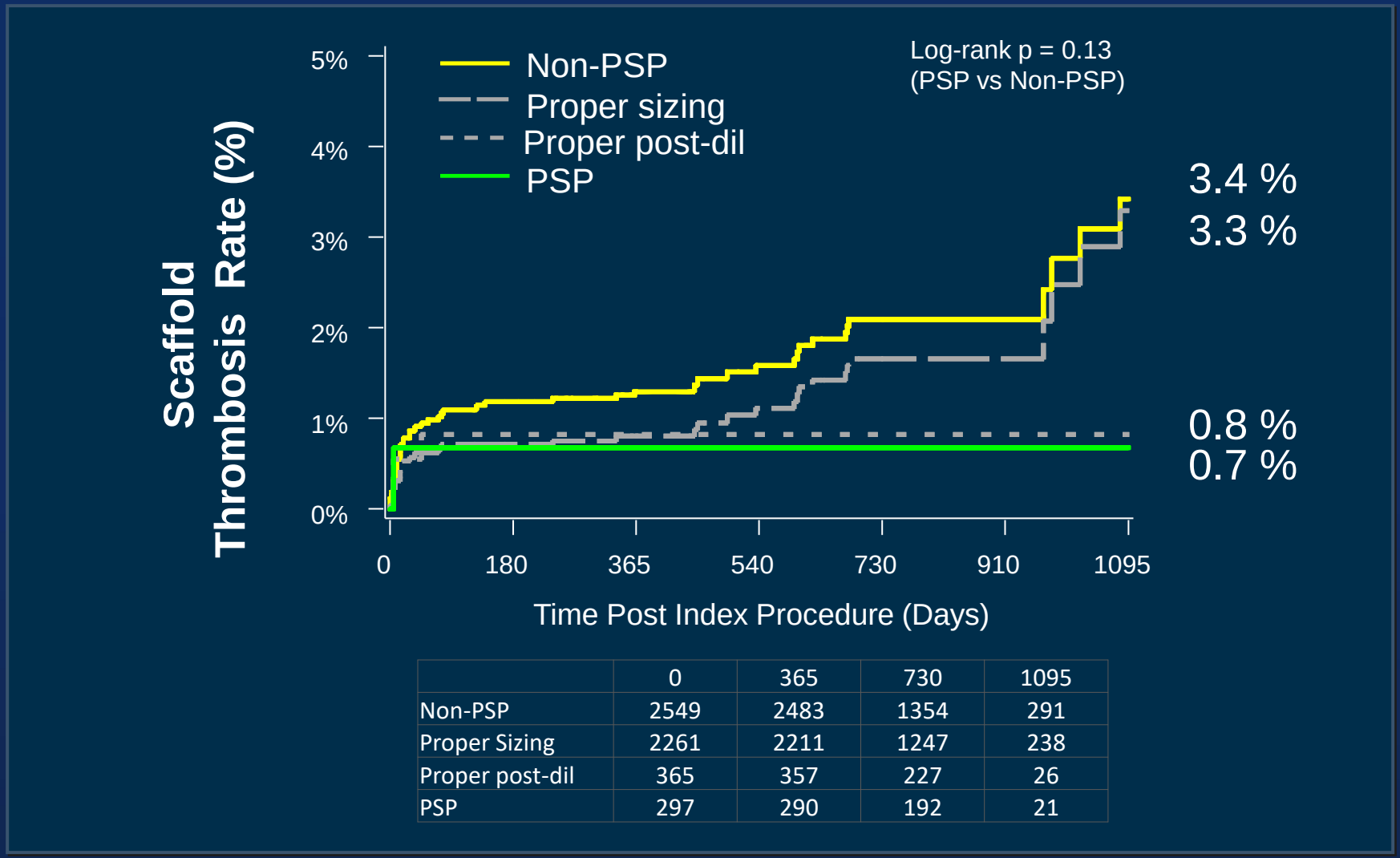
PSP Analysis - *TLF At 3-Years*
(Absorb Patients, As-Treated Population)



	0	365	730	1095
Non-PSP	2549	2375	1289	268
Proper Sizing	2261	2125	1195	223
Proper post-dil	365	341	219	24
PSP	297	280	186	20

0-365 days population: A-EXTEND, A-II, A-Japan, A-China, A-III
366-730 days population: A-EXTEND, A-II, A-Japan, A-China
731-1095 days population: A-II

PSP Analysis – *Def/Prob ST At 3-Years*
(Absorb Patients, As-Treated Population)

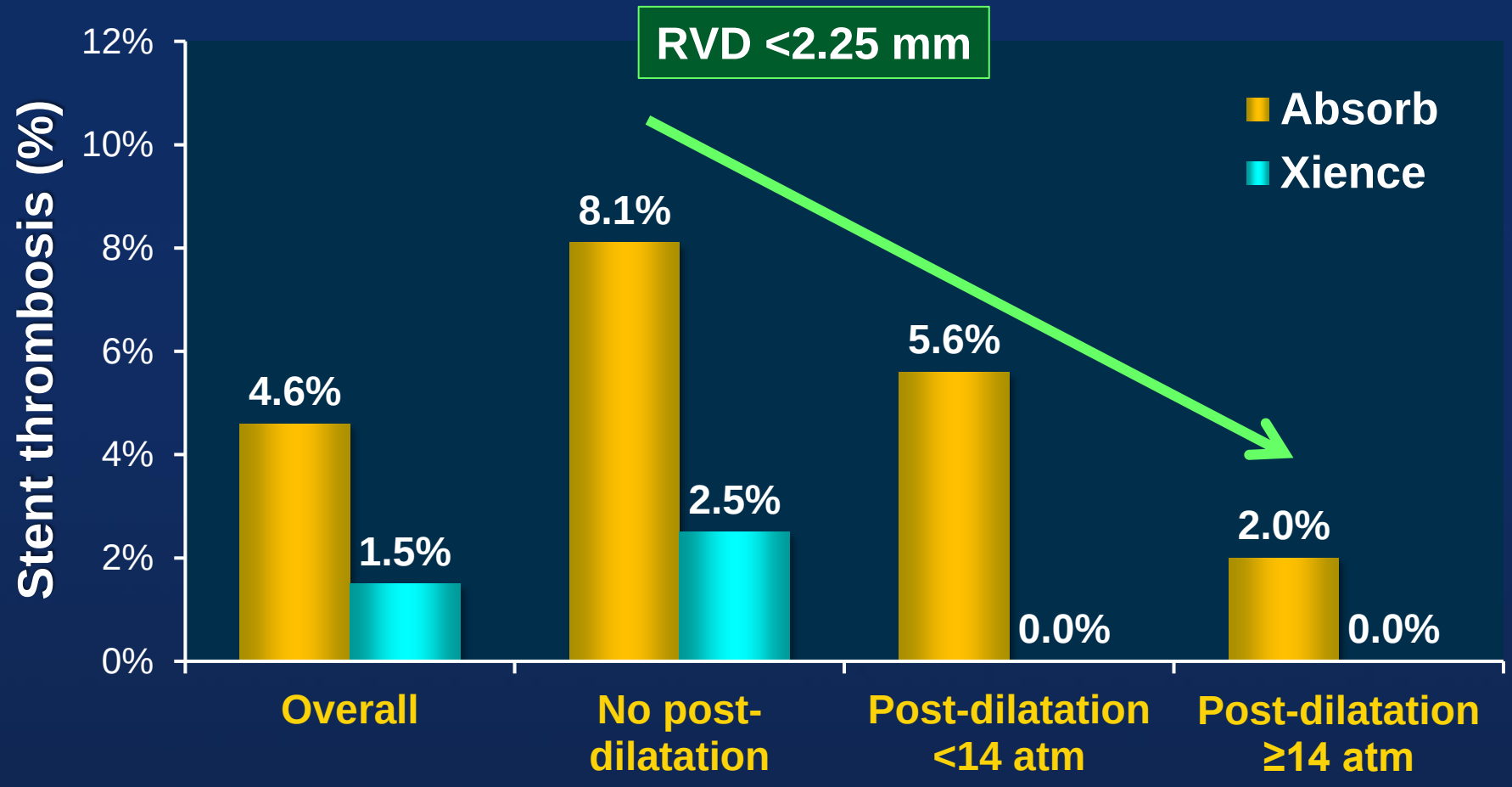


	0	365	730	1095
Non-PSP	2549	2483	1354	291
Proper Sizing	2261	2211	1247	238
Proper post-dil	365	357	227	26
PSP	297	290	192	21

0-365 days population: A-EXTEND, A-II, A-Japan, A-China, A-III
366-730 days population: A-EXTEND, A-II, A-Japan, A-China
731-1095 days population: A-II

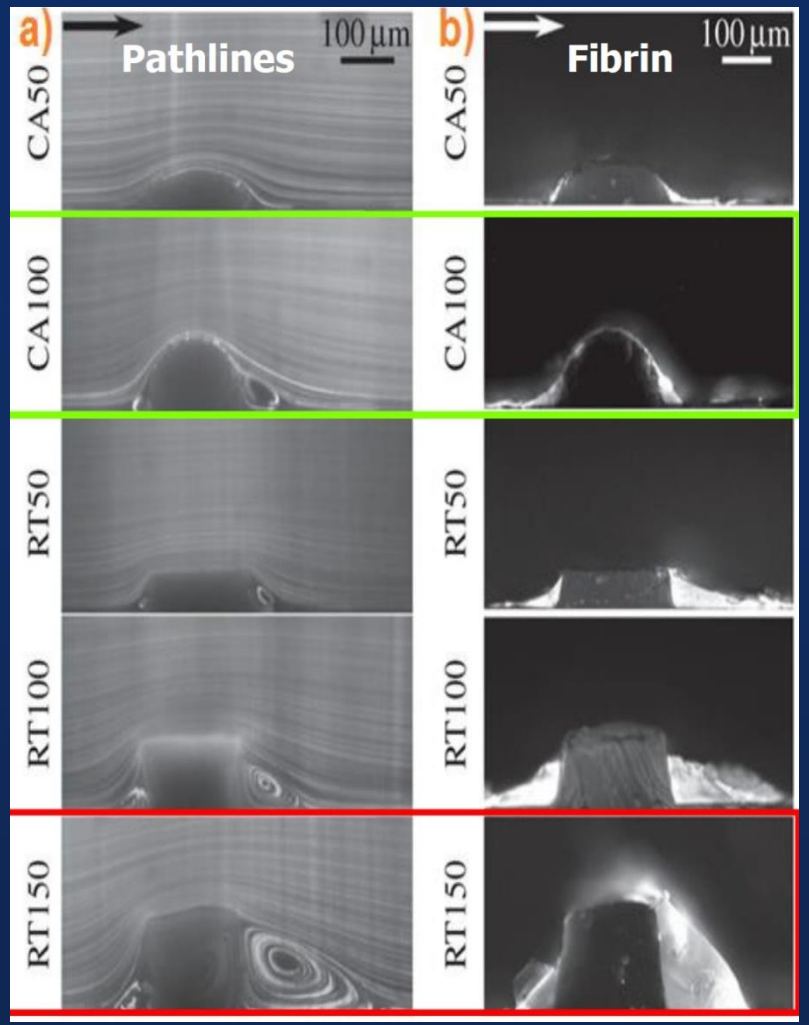
1-Year ST in Very Small Vessels, ABSORB 3

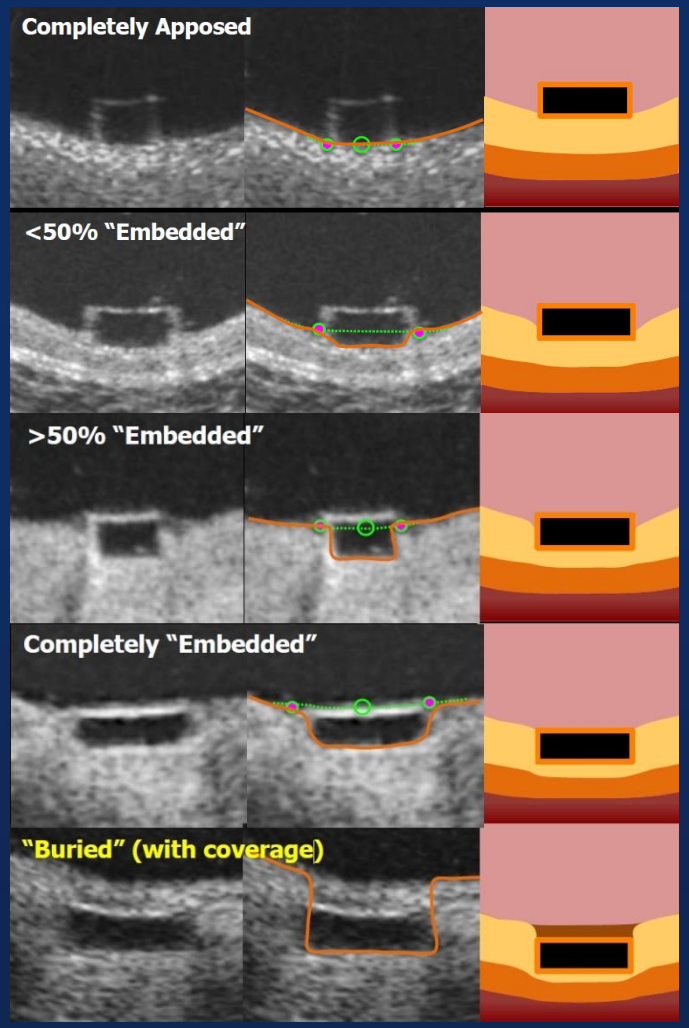
Impact of Post-Dilatation and Pressure



Stone GW. TCT 2015

Why is the high pressure post-dilatation so important? Embedding of struts?

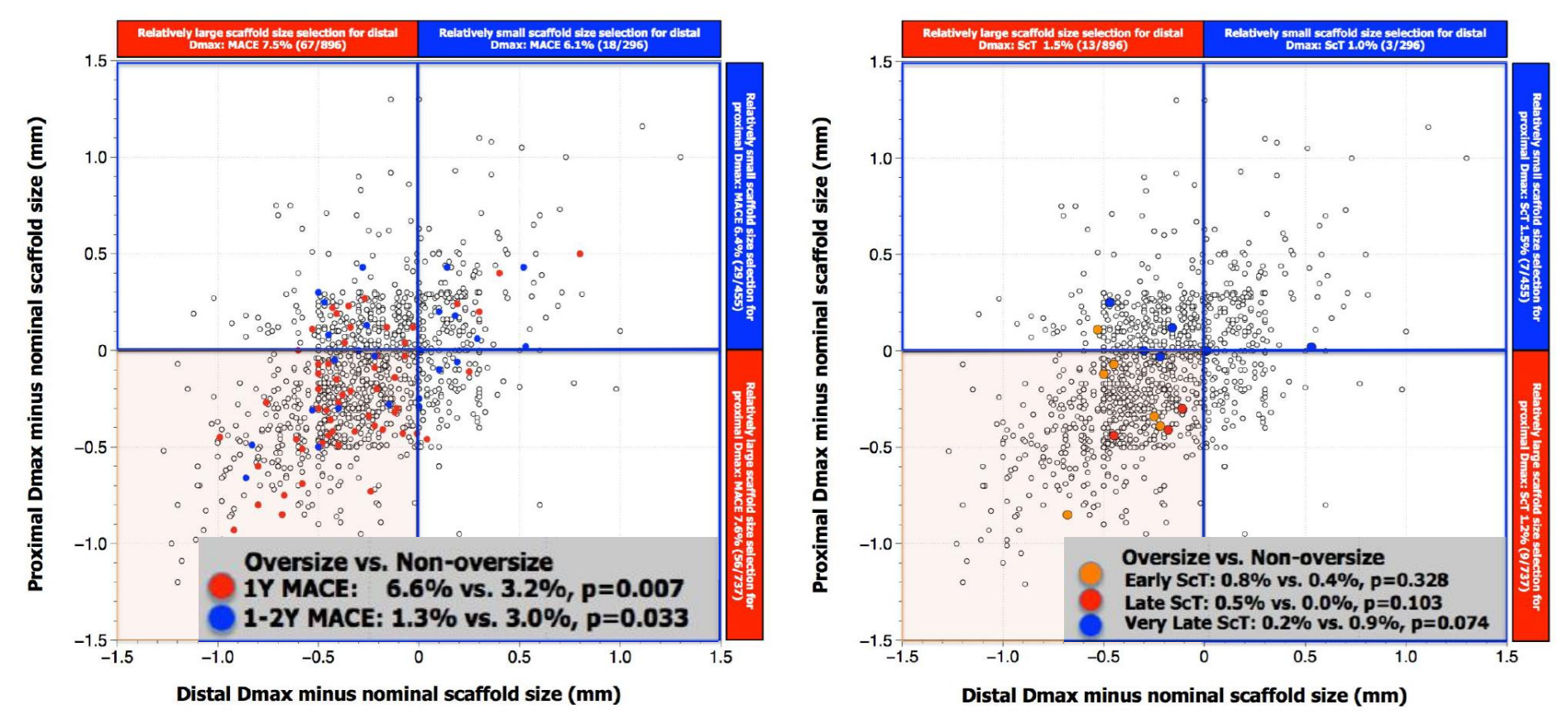




Jiménez JM, J R Soc Interface 2014, Serruys P, JIM 2016

Small vessel size issue

- A total of 1248 patients received Absorb scaffolds in the ABSORB Cohort B study (n=101), ABSORB EXTEND study (n=812), and ABSORB II trial (n=335)

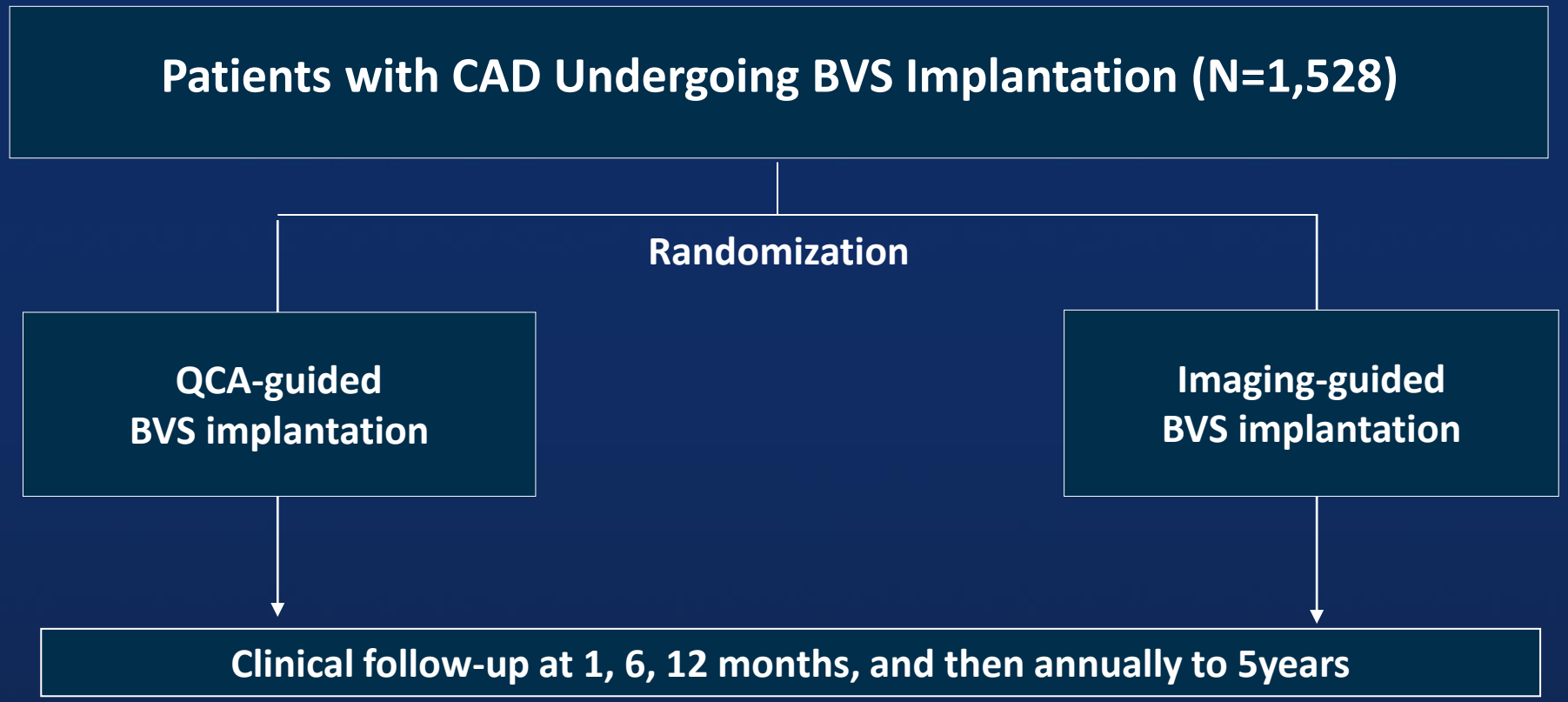


Serruys P, TCT 2016

AMC PSP

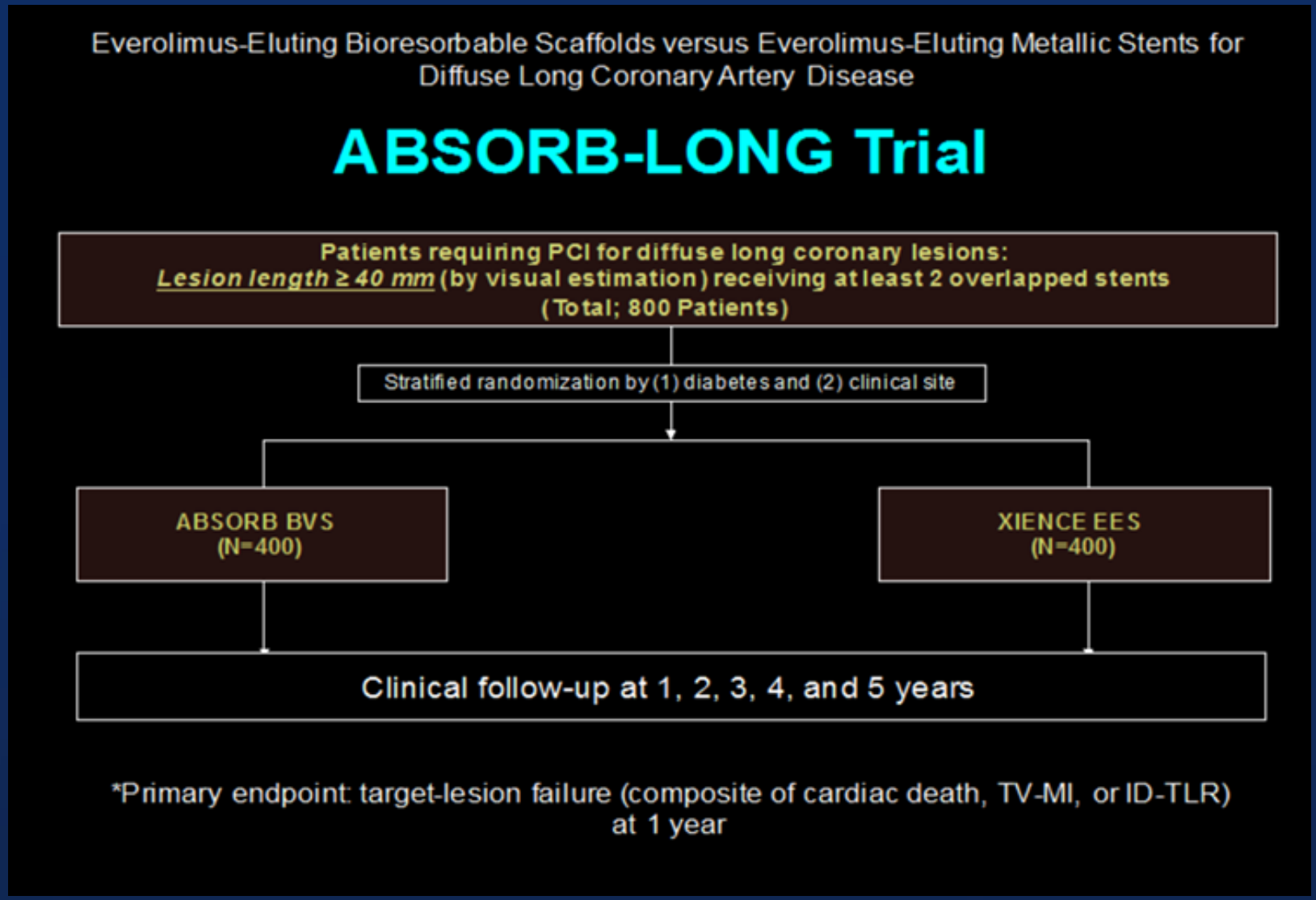
	QCA Guided	IVUS Guided
P ***Pre-Dilation***	*Pre-dilation* with NC balloon, 1:1 matched QCA RVD	*Pre-dilation* with NC balloon, 1:1 matched distal RVD
S ***Sizing***	*Absorb*, 1:1 matched proximal QCA RVD	*Absorb*, 1:1 matched distal RVD
P ***Post-Dilatation***	*Post-dilation* with NC balloon, 0.5 mm larger size (but ≤ +0.5mm, >14atm).	*IVUS guided Post-dilation* with NC balloon

BVS QCA vs. Imaging-guided

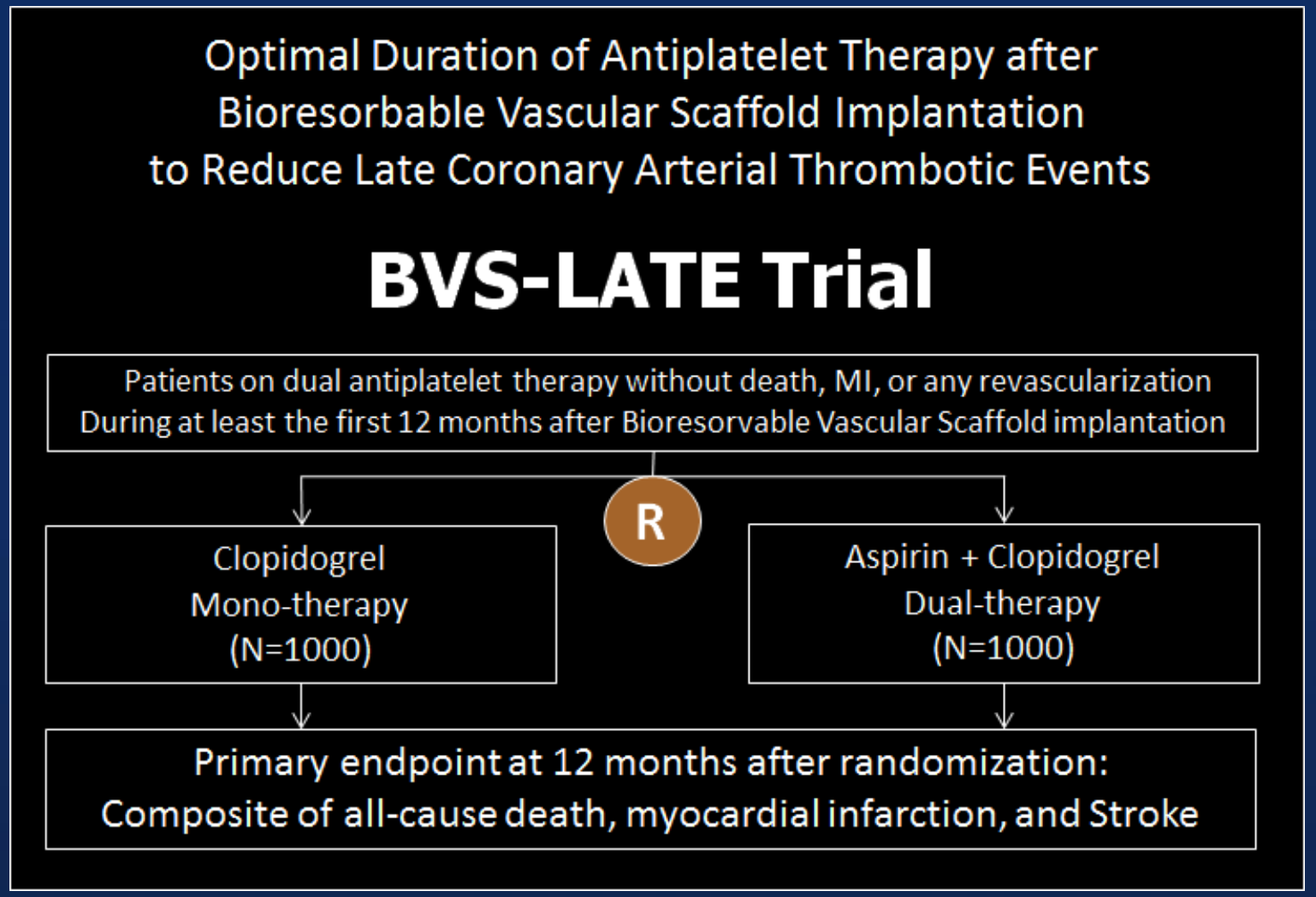


*Primary endpoint: target-lesion failure (cardiac death, TV-MI, or ID-TLR) at 1 year

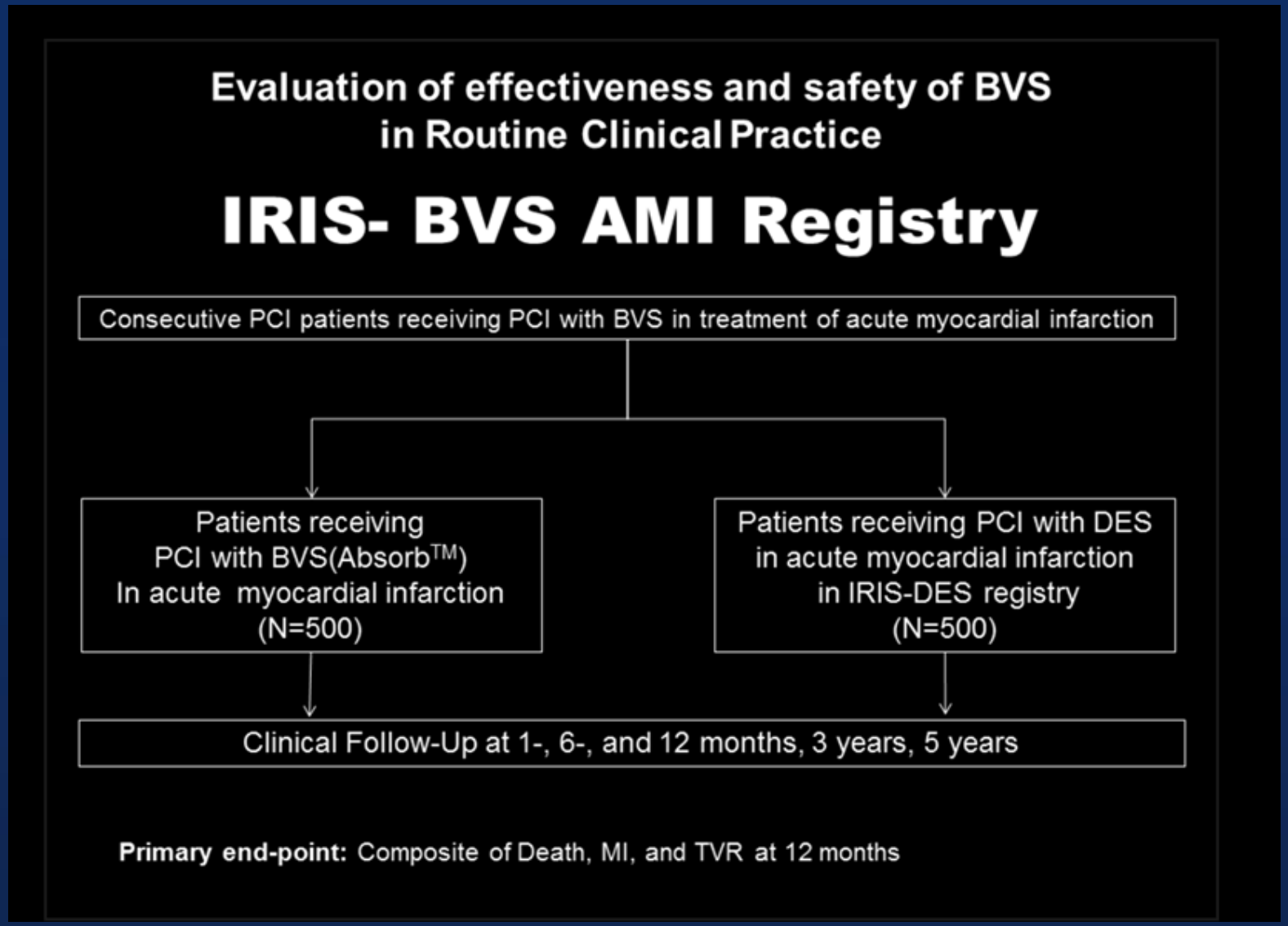
BVS *For Long Lesion (≥40mm)*



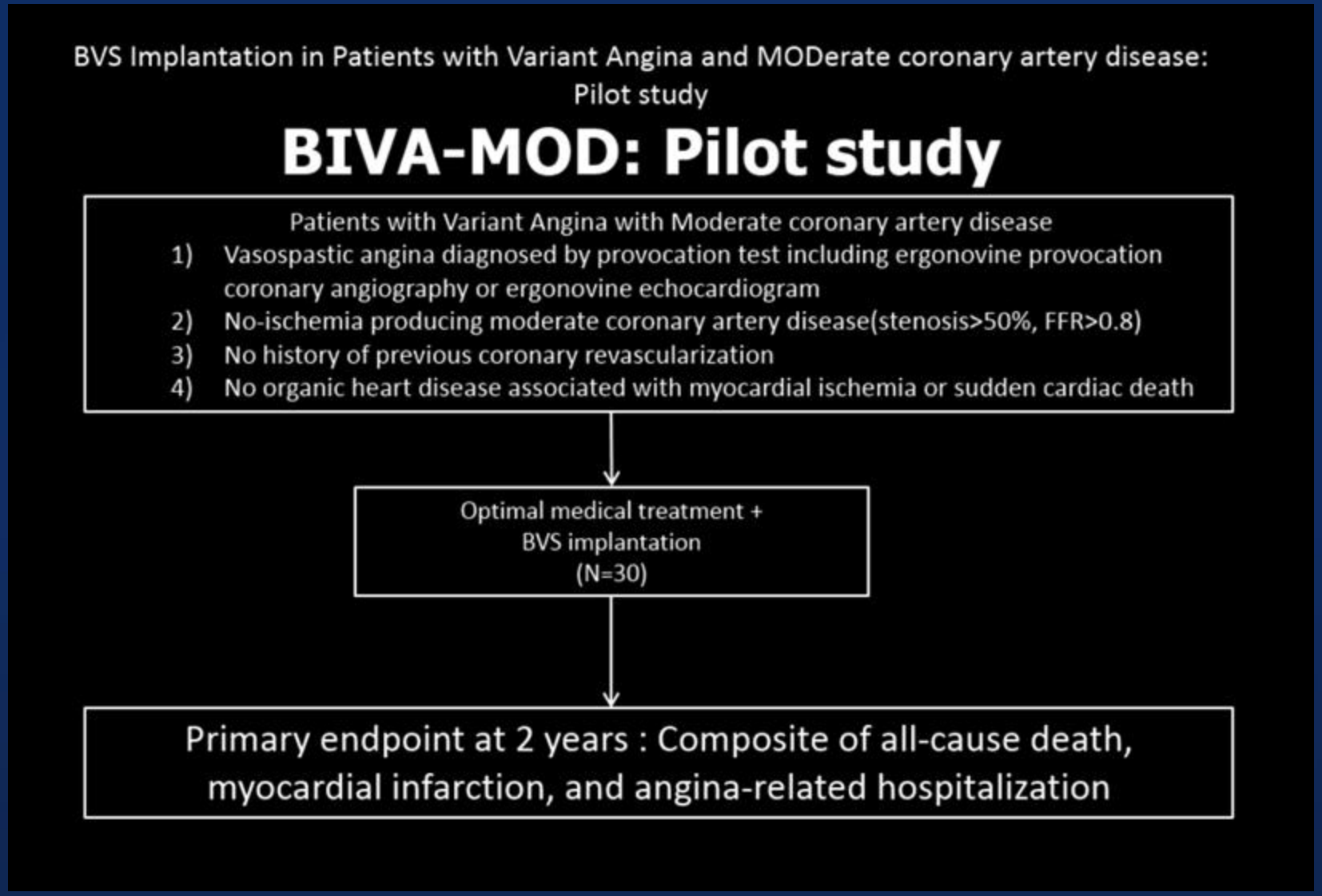
BVS *How Long DAPT?*



BVS for AMI patients



BVS for Variant Angina

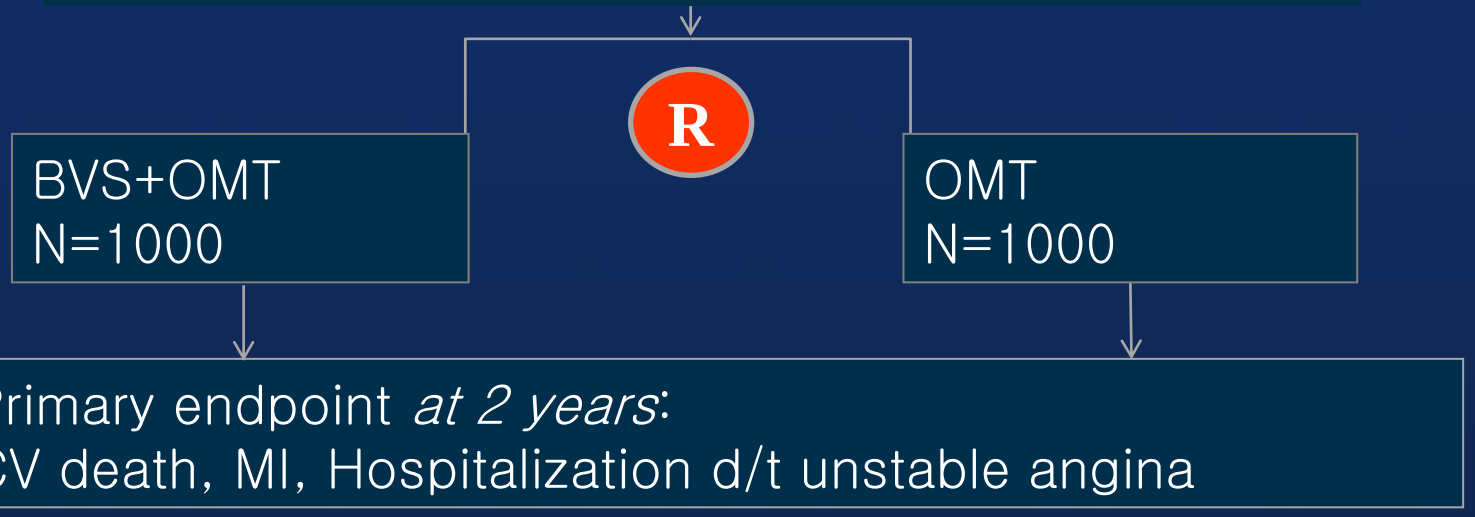


BVS for Vulnerable Plaque

PREVENT Trial

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

1. IVUS MLA ≤4.0mm^2
2. IVUS Plaque Burden >70%
3. Lipid-Rich Plaque on NIRS ($_{max}$LCBI$_{4mm}$>315)
4. TCFA defined by OCT or VH-IVUS



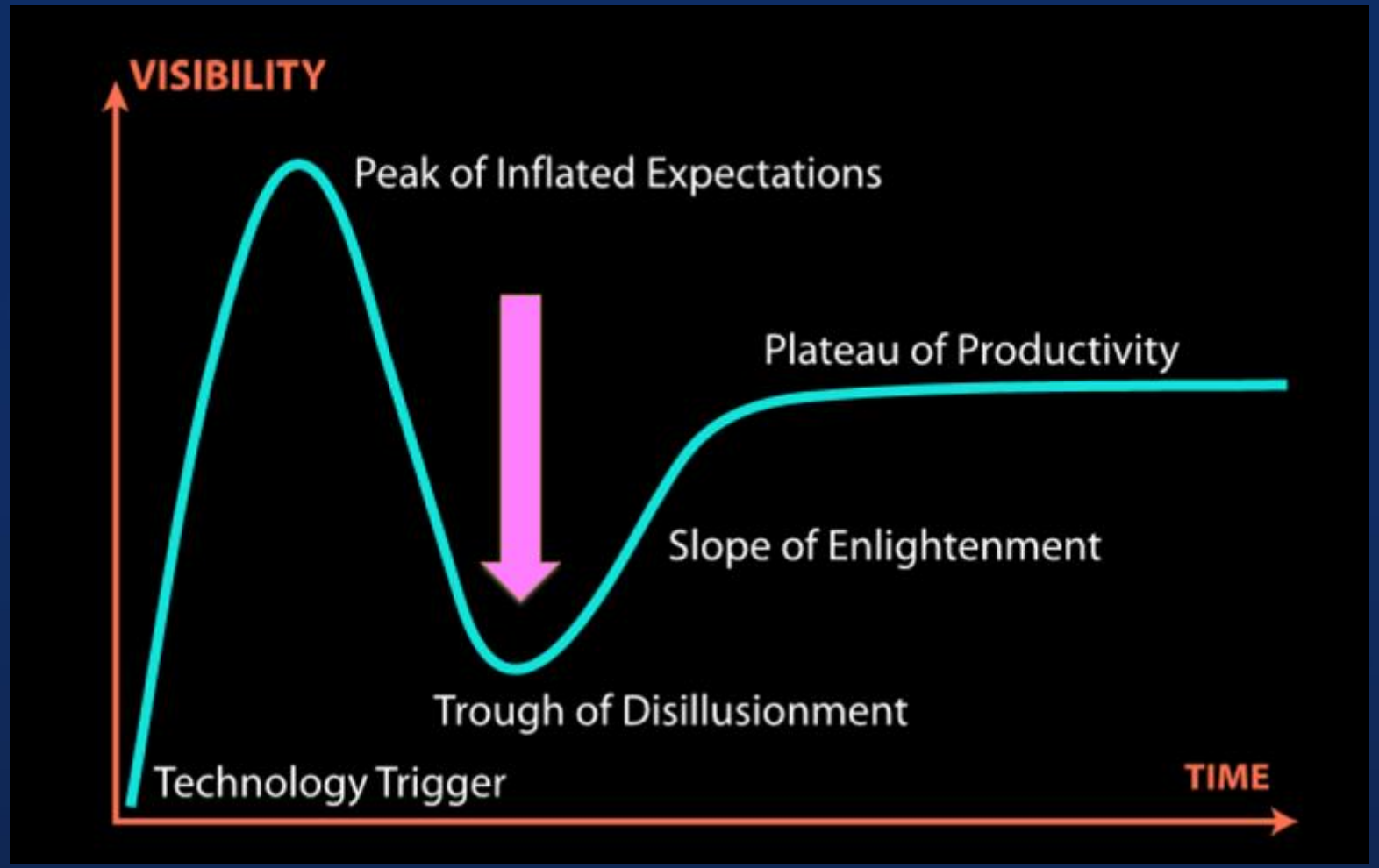
OCT sub-study/ NIRS sub-study, (300 patients in each arm at 2 years)

Limitation of first generation BRS

- Larger catheter profile, reduced deliverability
- Thicker and wider struts than metallic DES
- Narrow expansion limits with risk of acute fracture
- Issues with scaffold visibility, overlap
- Greater recoil in some lesion
- Active bioresorption with risk of very late intraluminal scaffold dismantling

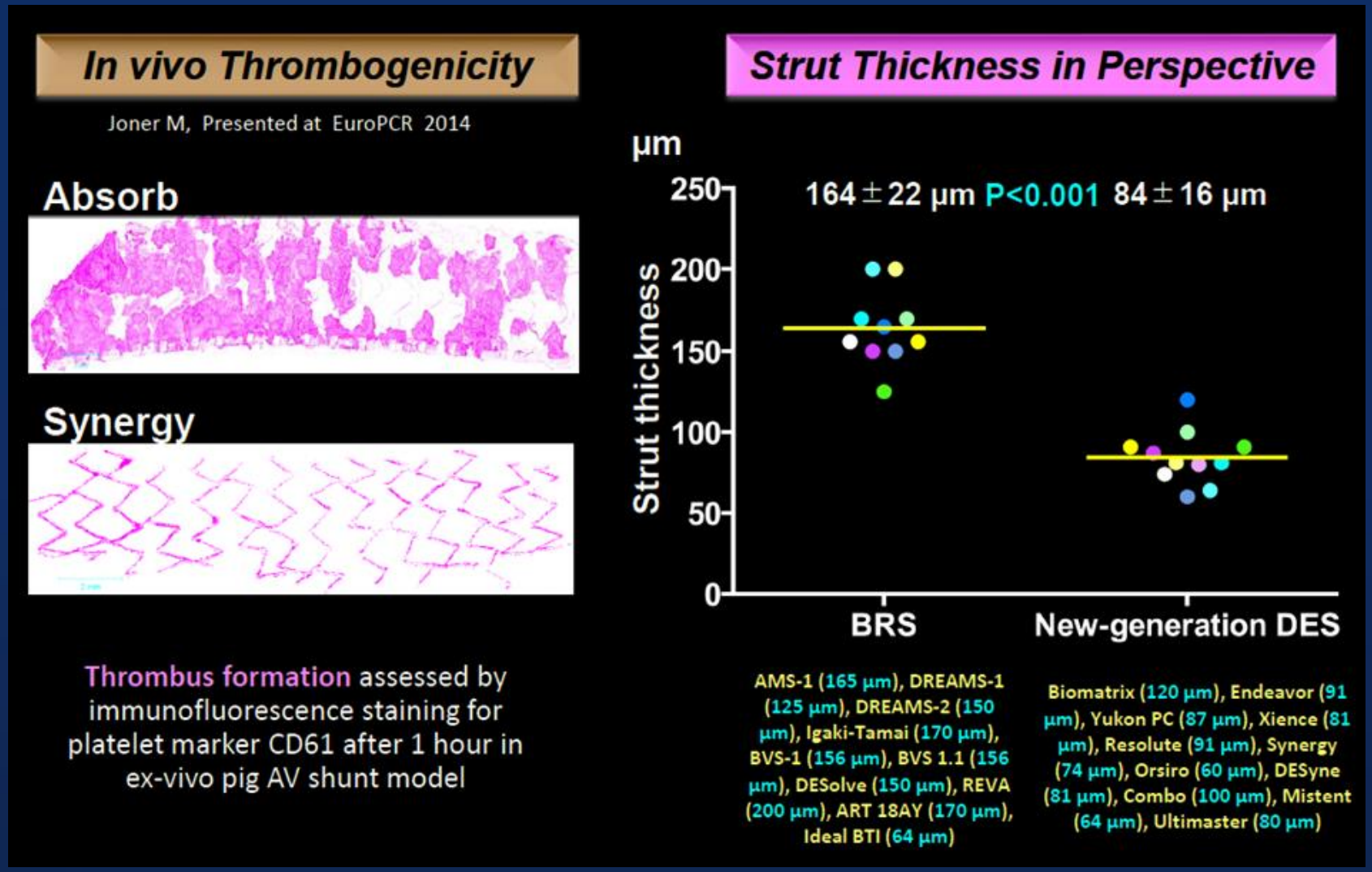
Jochen Wohrle, TCT2017

Hype Cycle for Emerging Technologies



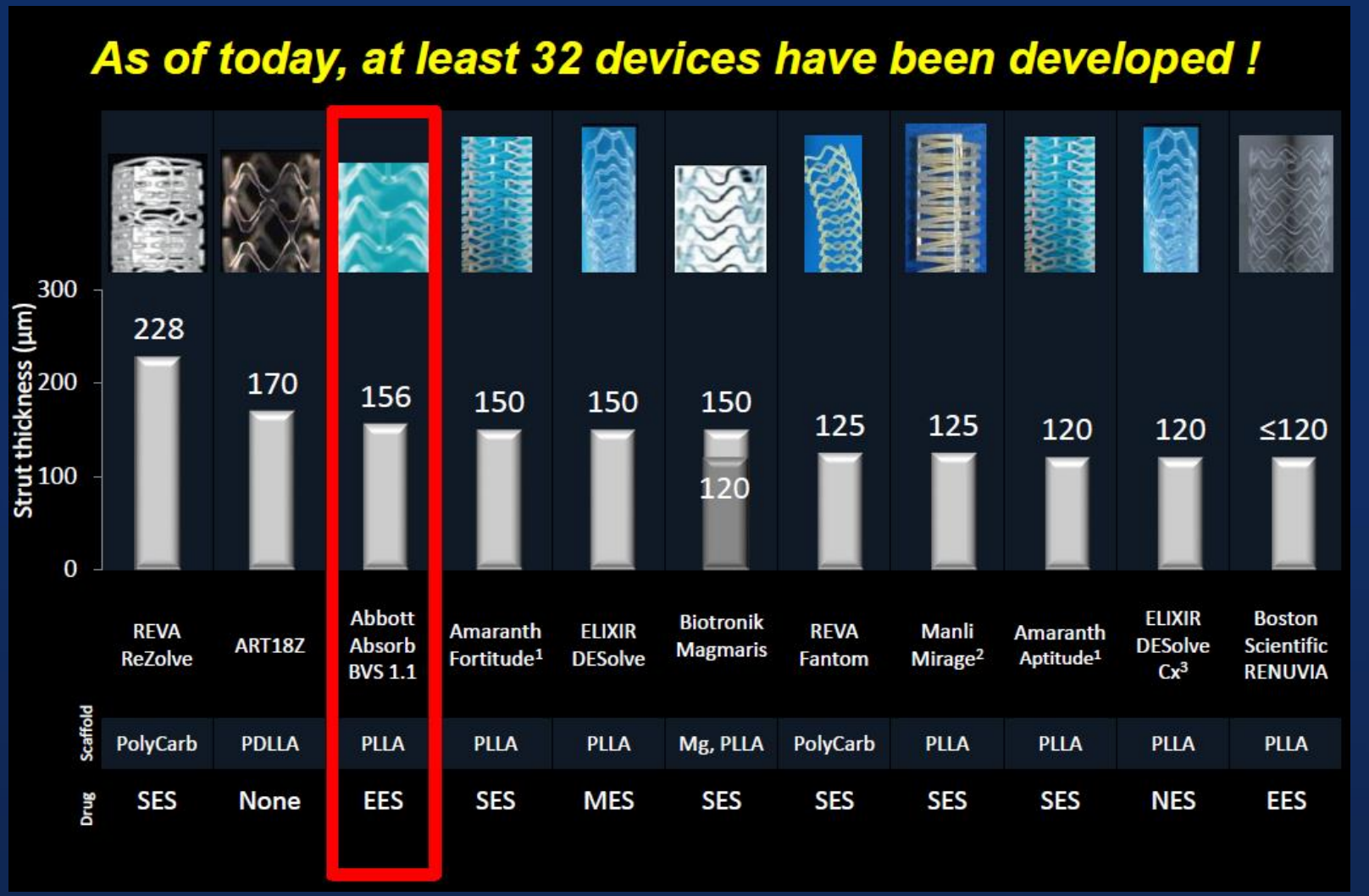
Jochen Wohrle, TCT2017

Strut Thickness in Perspective



Jochen Wohrle, TCT2017

Structure Summary

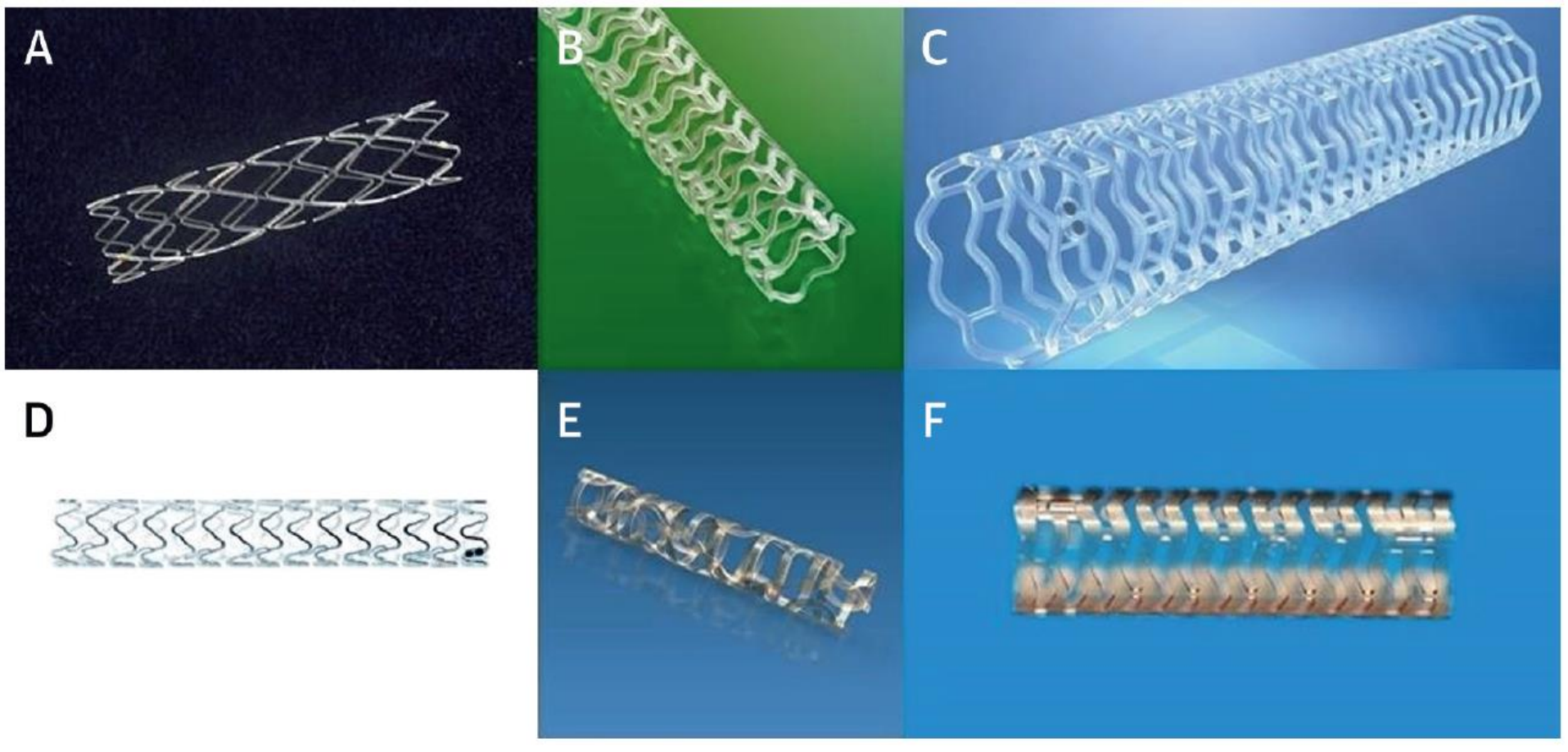


Jochen Wohrle, TCT2017

New BRSs

Basic material	MAGNESIUM			OTHER		
Scaffold name	AMS	DREAMS 1.0	DREAMS 2.0	REVA BRS	REVA ReZolve	Ideal BioStent
Manufacturer	Biotronik, Berlin, Germany	Biotronik, Berlin, Germany	Biotronik, Berlin, Germany	Reva Medical Inc., San Diego, CA, USA	Reva Medical Inc., San Diego, CA, USA	Xenogenics Corp., Canton, MA, USA
Composition	Magnesium and rare earth metals	Magnesium and rare earth metals	Magnesium and rare earth metals	Desaminotyrosine polycarbonate	Desaminotyrosine polycarbonate	Poly-lactic anhydride containing 2 salicylic acid molecules linked to 1 sebacic acid molecule
Design of the latest generation	4-crown design	6-crown design	6-crown design	Slide-and-lock ("ratchet")	Slide-and-lock ("ratchet")	Tube with laser-cut voids
Thickness of strut, µm	165	120	150	204	122	200
Visualization	Latest generation with radiopaque markers			Fully radiopaque	Fully radiopaque	--
Special feature	Electronegative charge that emerges during degradation process has an antithrombotic function			--	--	Polymer causes less inflammation
Anti-proliferative drug elution	No	Paclitaxel	Sirolimus	Paclitaxel	Sirolimus	Sirolimus
Resorption time	2 mos	9–12 mos	--	2–3 yrs	2–3 yrs	15 mos
Status	Clinical evaluation	Clinical evaluation	Clinical evaluation	Clinical evaluation; CE trial ongoing	Clinical evaluation; CE trial ongoing	Clinical evaluation, pre-clinical evaluation of the thinner 2nd generation
Trials (no. in cohort and duration)	PROGRESS AMS 63 patients up to 28 mos	BIOSOLVE-I 46 patients up to 3 yrs	BIOSOLVE-II -- --	FiM -- 15 mos	RESTORE 26 patients 12 mos	FiM 11 patients 1.5 yrs

J Am Coll Cardiol 2014;64:2541–51



(A) The Igaki-Tamai stent (Kyoto Medical Planning Co., Ltd., Kyoto, Japan)
(B) The ABSORB Bioresorbable Vascular Scaffold (Abbott Vascular, Santa Clara, California)
(C) The DESolve bioresorbable scaffold (Elixir Medical Corporation, Sunnyvale, California)
(D) The DREAMS magnesium alloy (Biotronik, Berlin, Germany)
(E) The ReZolve 2 BRS (Reva Medical Inc., San Diego, California)
(F) The Ideal BioStent (Xenogenics Corp., Canton, Massachusetts)

J Am Coll Cardiol 2014;64:2541–51

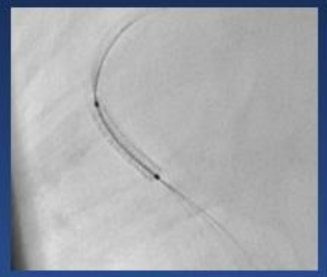
FANTOM II

Fantom Bioresorbable Scaffold

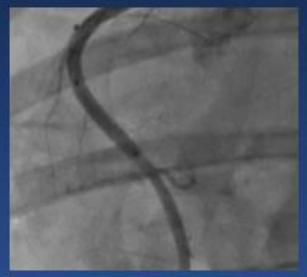
***Fantom*® (REVA Medical)**
Sirolimus-Eluting Bioresorbable Scaffold
Desaminotyrosine Polycarbonate

Key Scaffold Features

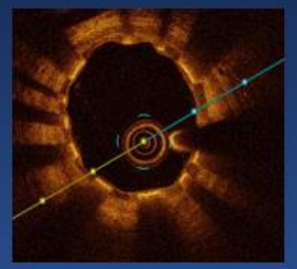
- **Complete scaffold visibility under x-ray**
- **Single-step continuous inflation**
- **Clinically significant expansion range**
- **Good radial strength at 125 µm thickness**
- **Vasomotion restoration ~1 year (Preclinical)**
- **No special storage or handling**



Visibility



Deliverability



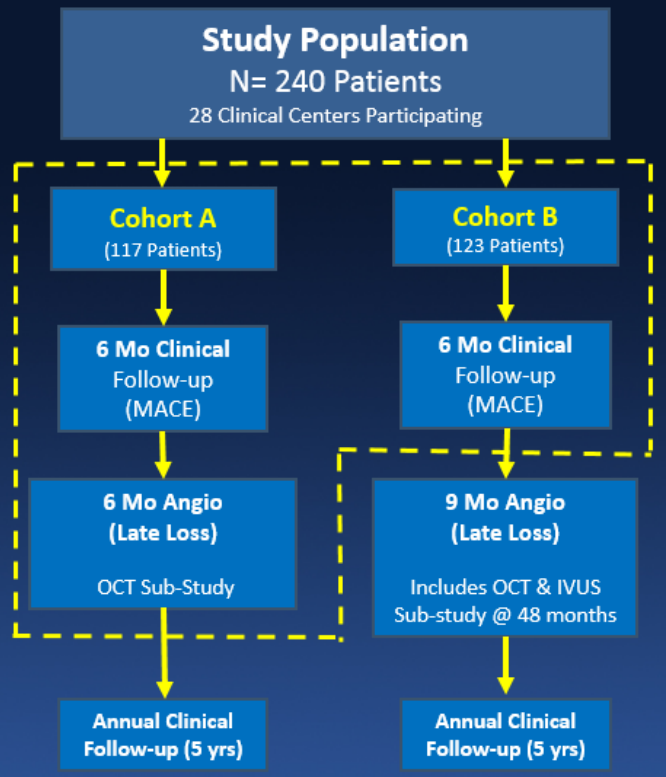
Vessel Patency

A Abizaid TCT 2016

FANTOM II

FANTOM II
Study Design and Endpoints

- **Study Design**
  - Safety and Performance Trial
  - 2.5mm to 3.5mm vessels
  - Lesion length ≤ 20mm
  - Primary Endpoint
    - MACE & Late Loss at 6 Months
  - Secondary Endpoints
    - MACE all time points
    - Late Loss at 9 Months
    - Serial imaging sub-studies
      - Cohort A: 24 months
      - Cohort B: 48 months

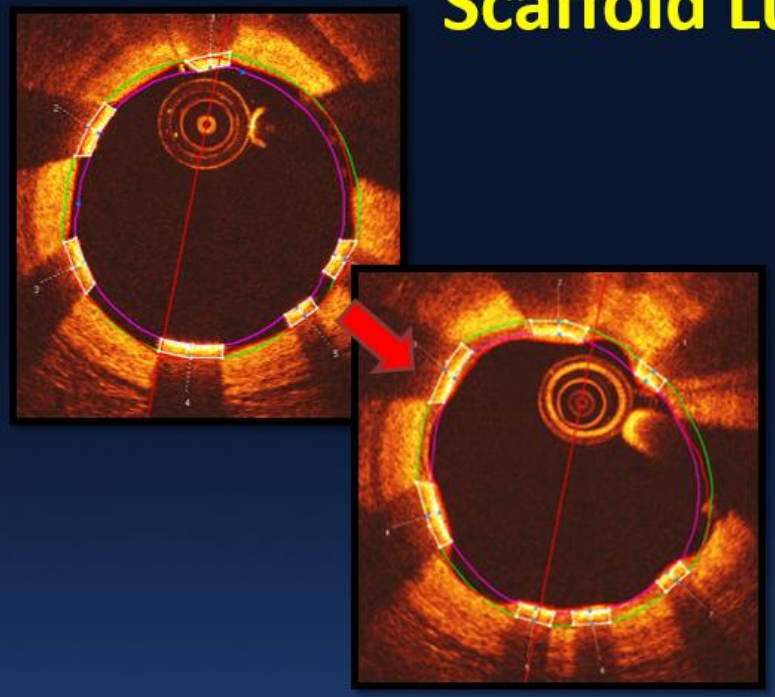


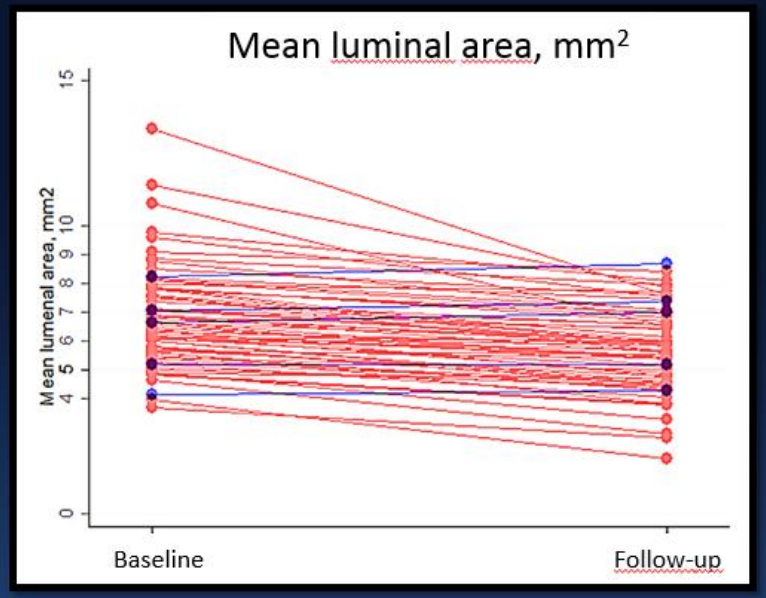
A Abizaid TCT 2016

FANTOM II

Scaffold Lumen Area

PCI Research
Aarhus University Hospital





	Baseline	Follow-up	Difference	p-value
Mean lumen area (mm²)	6.8 (1.7)	5.7 (1.4)	-1.1 (-1.3;-0.9)	<0.0001
Minimal lumen area (mm²)	5.3 (1.4)	4.4 (1.4)	-1.0 (-1.3;-0.7)	<0.0001

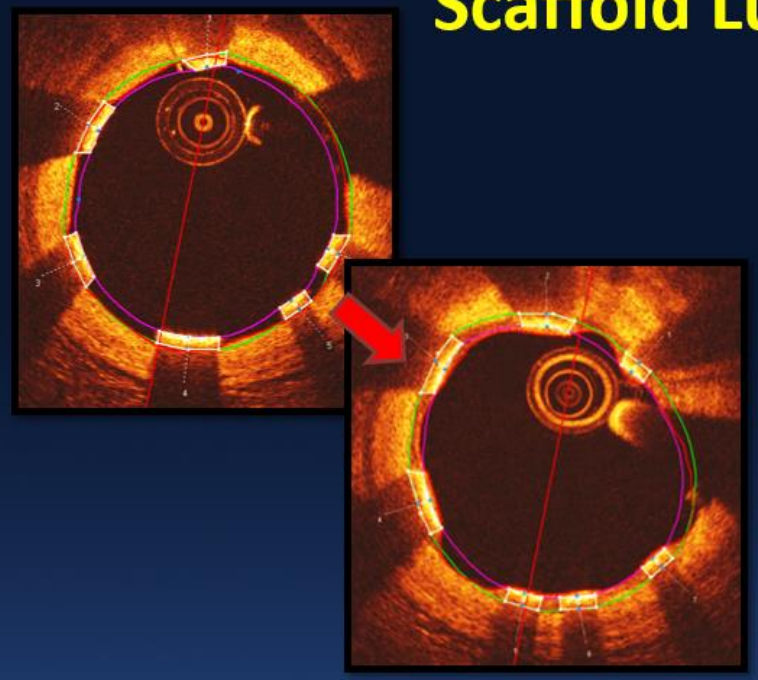
Mean(SD)

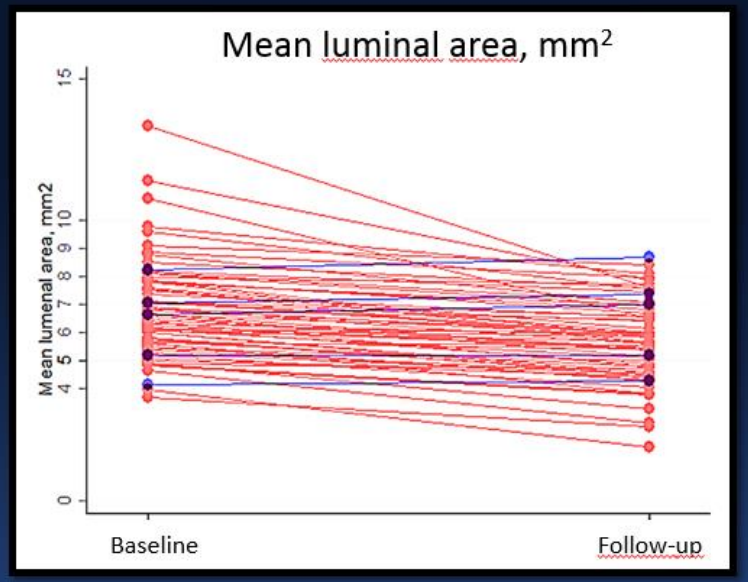
A Abizaid TCT 2016

FANTOM II

Scaffold Lumen Area

PCI Research
Aarhus University Hospital





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Minimal lumen area (mm²)	5.3 (1.4)	4.4 (1.4)	-1.0 (-1.3;-0.7)	<0.0001

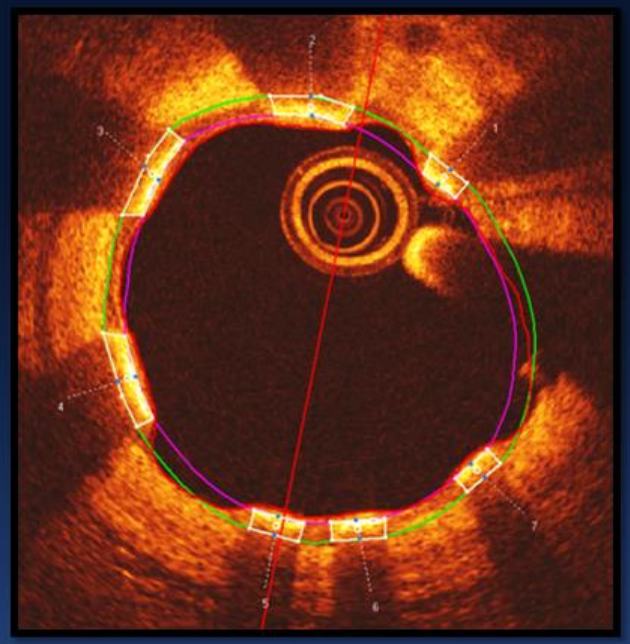
Mean(SD)

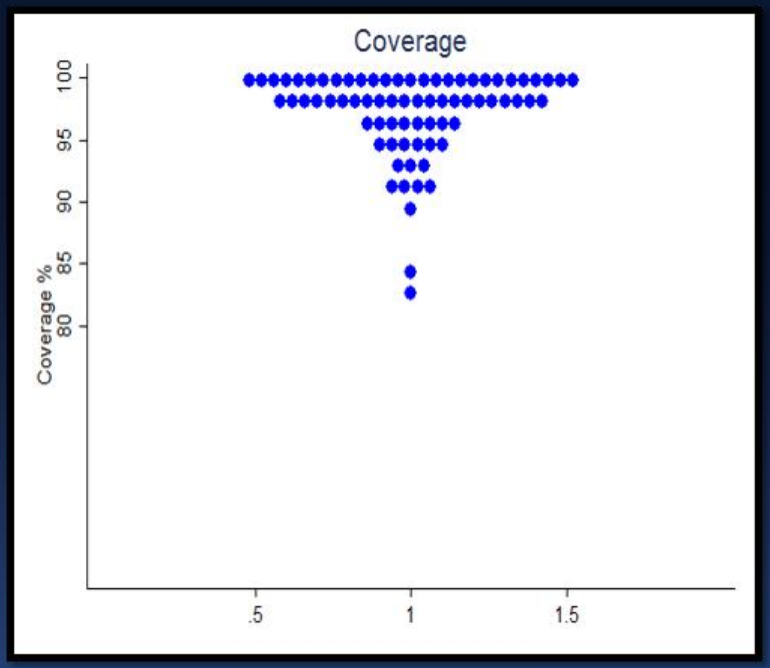
A Abizaid TCT 2016

FANTOM II

PCI Research
Aarhus University Hospital

Strut Coverage



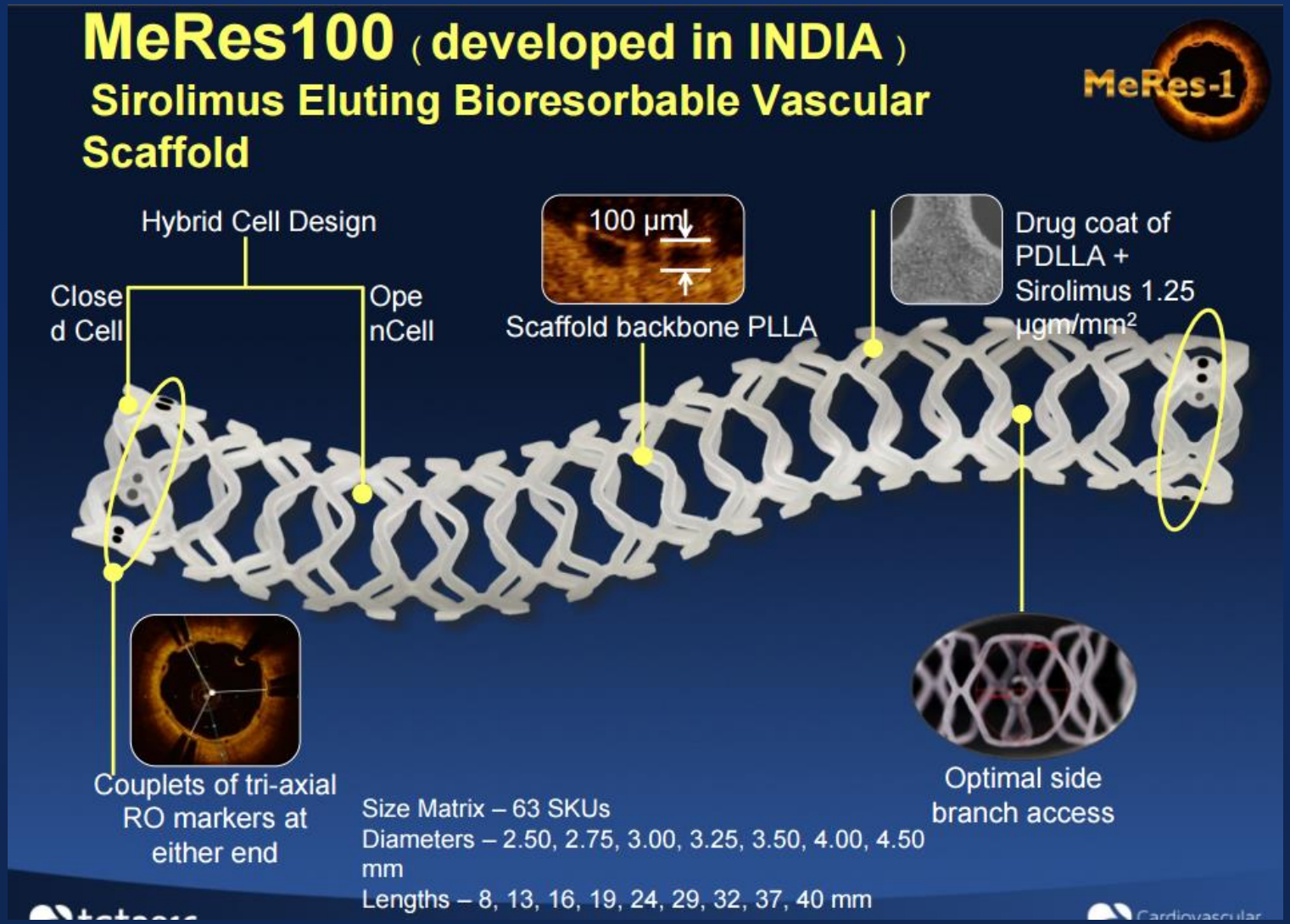


	Follow-up
Covered struts	98.1% (95.9;99.4)

Median(IQR)

A Abizaid TCT 2016

MeReS-1



A Seth TCT 2016

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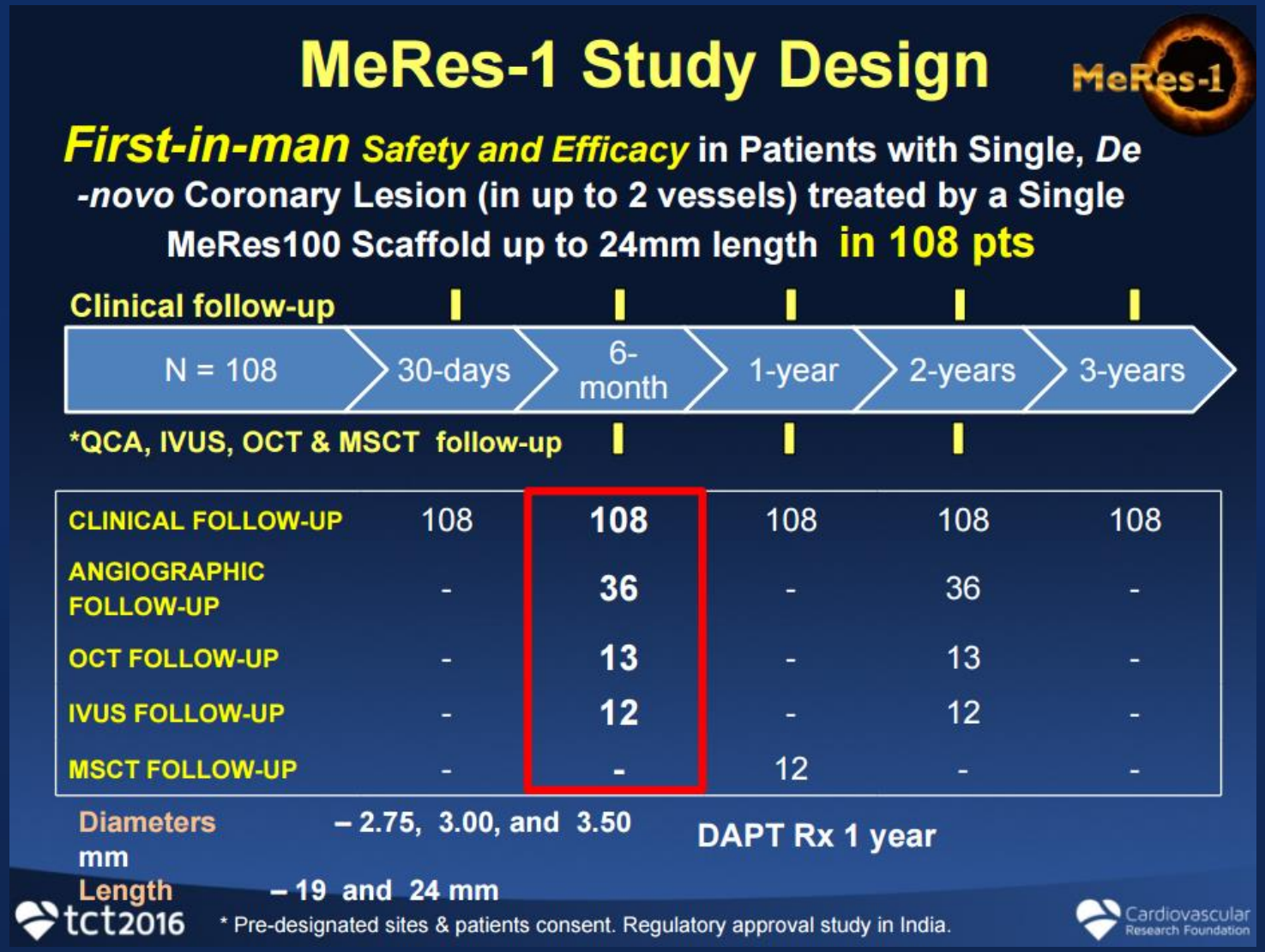

A Seth TCT 2016

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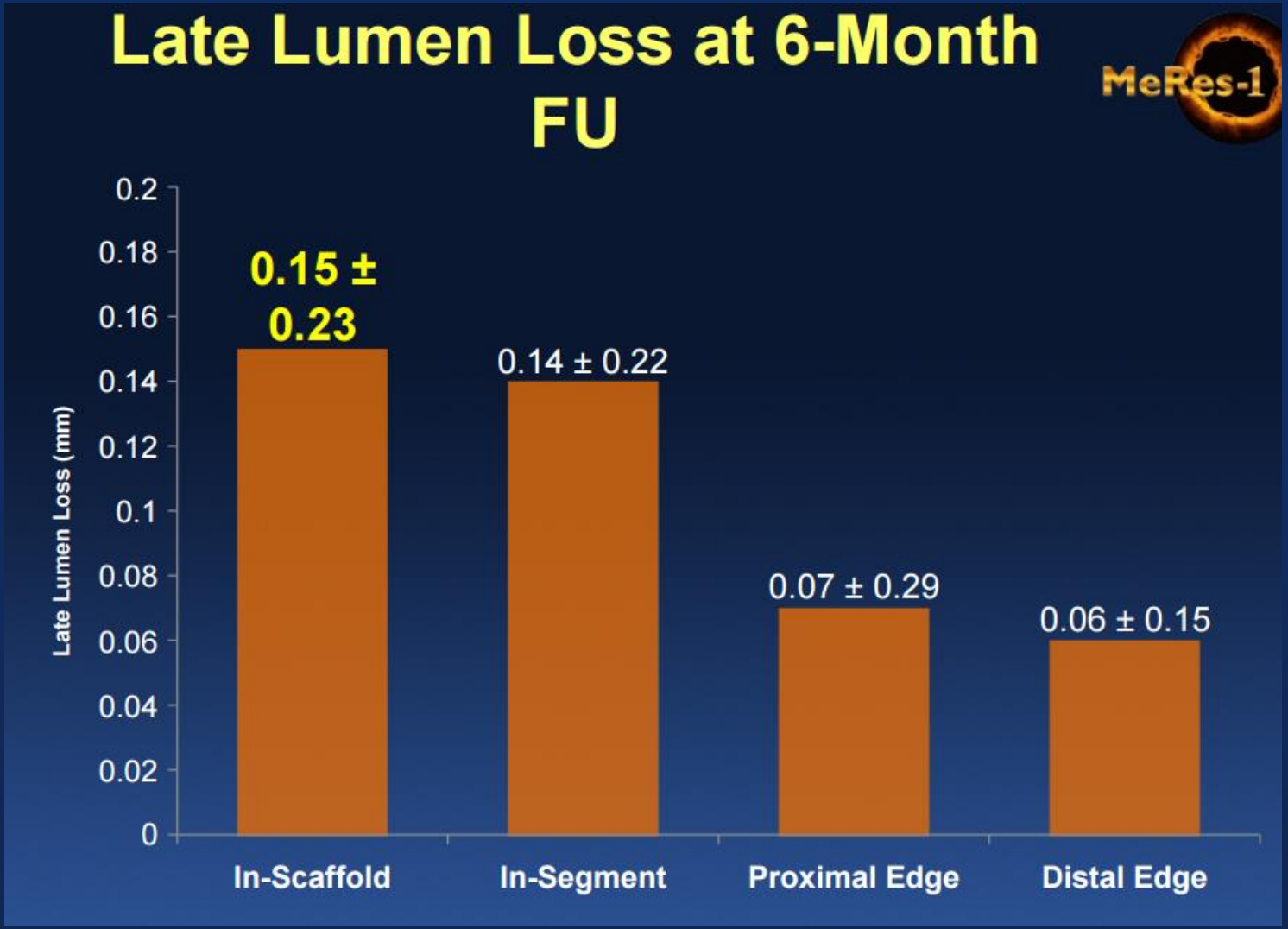

A Seth TCT 2016

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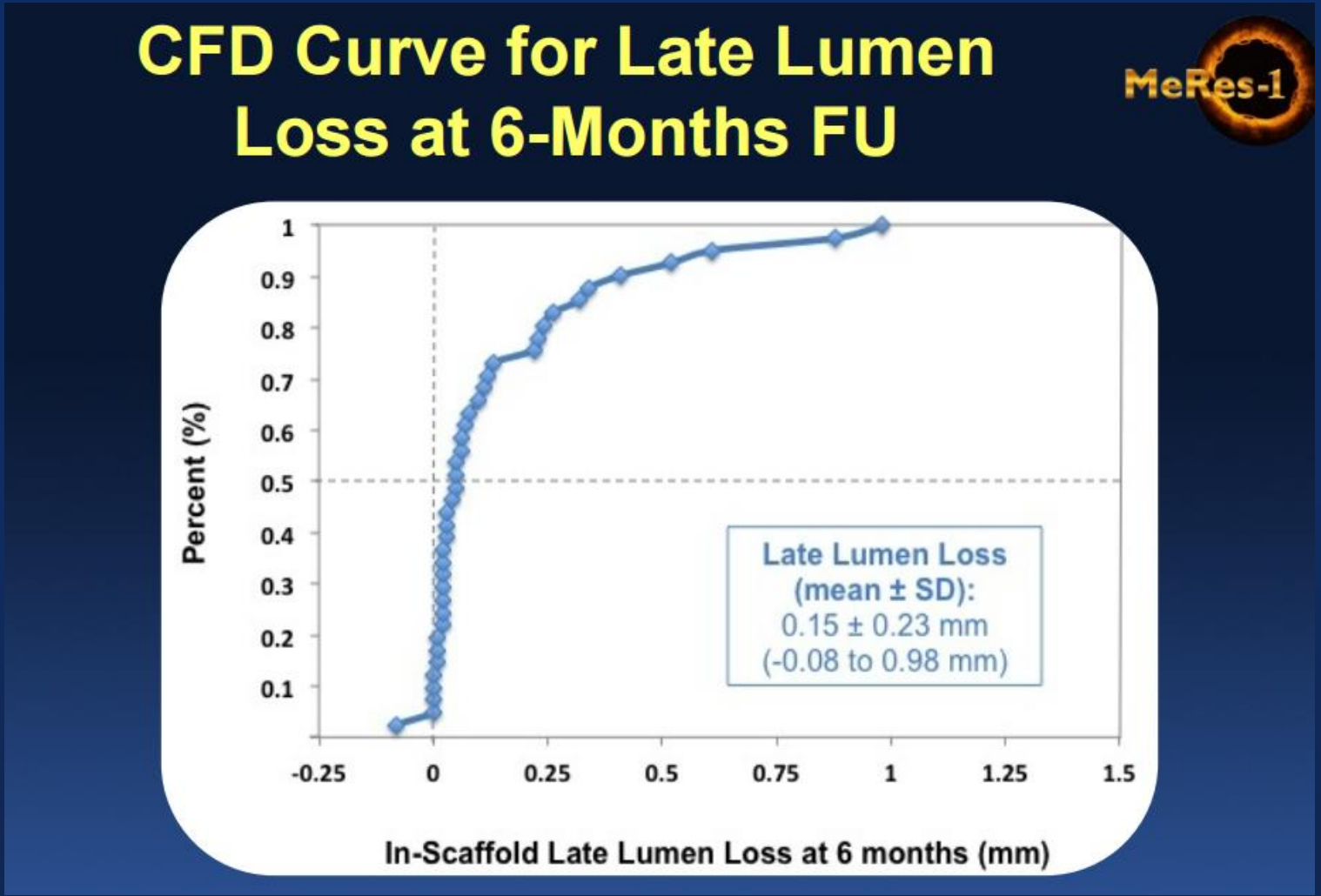
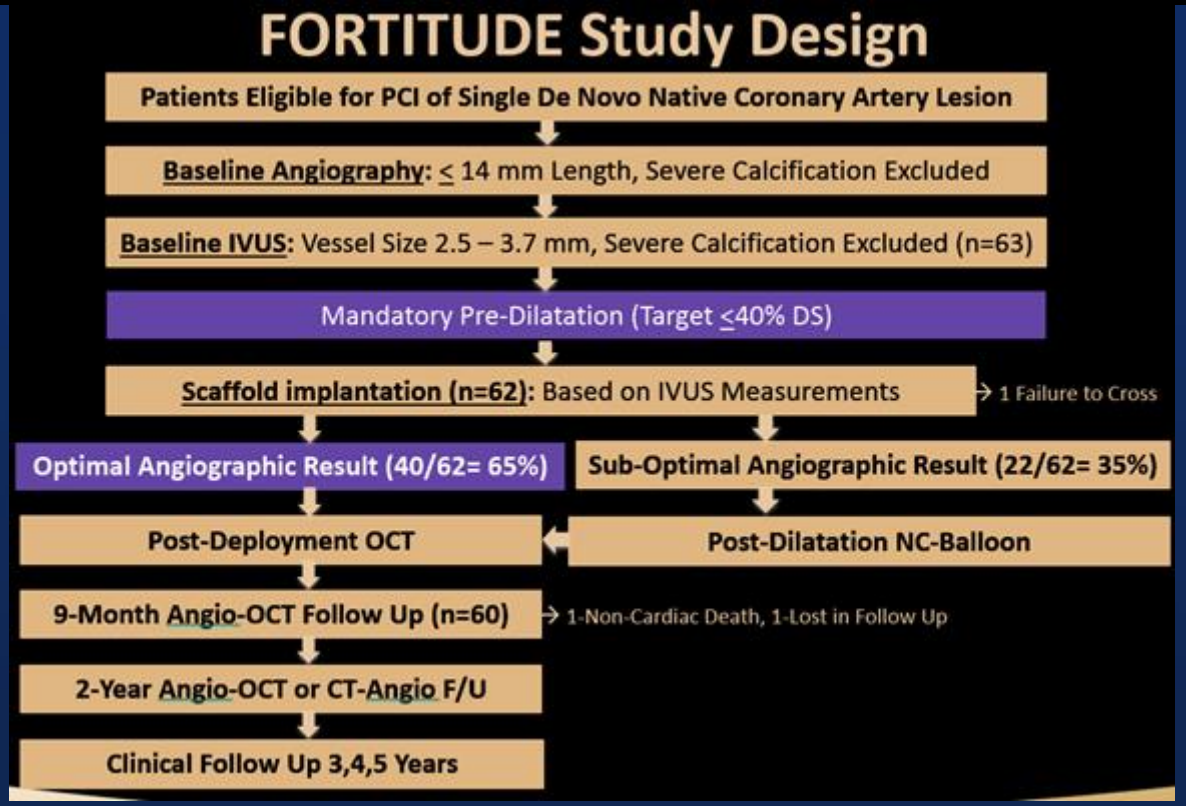


A Seth TCT 2016

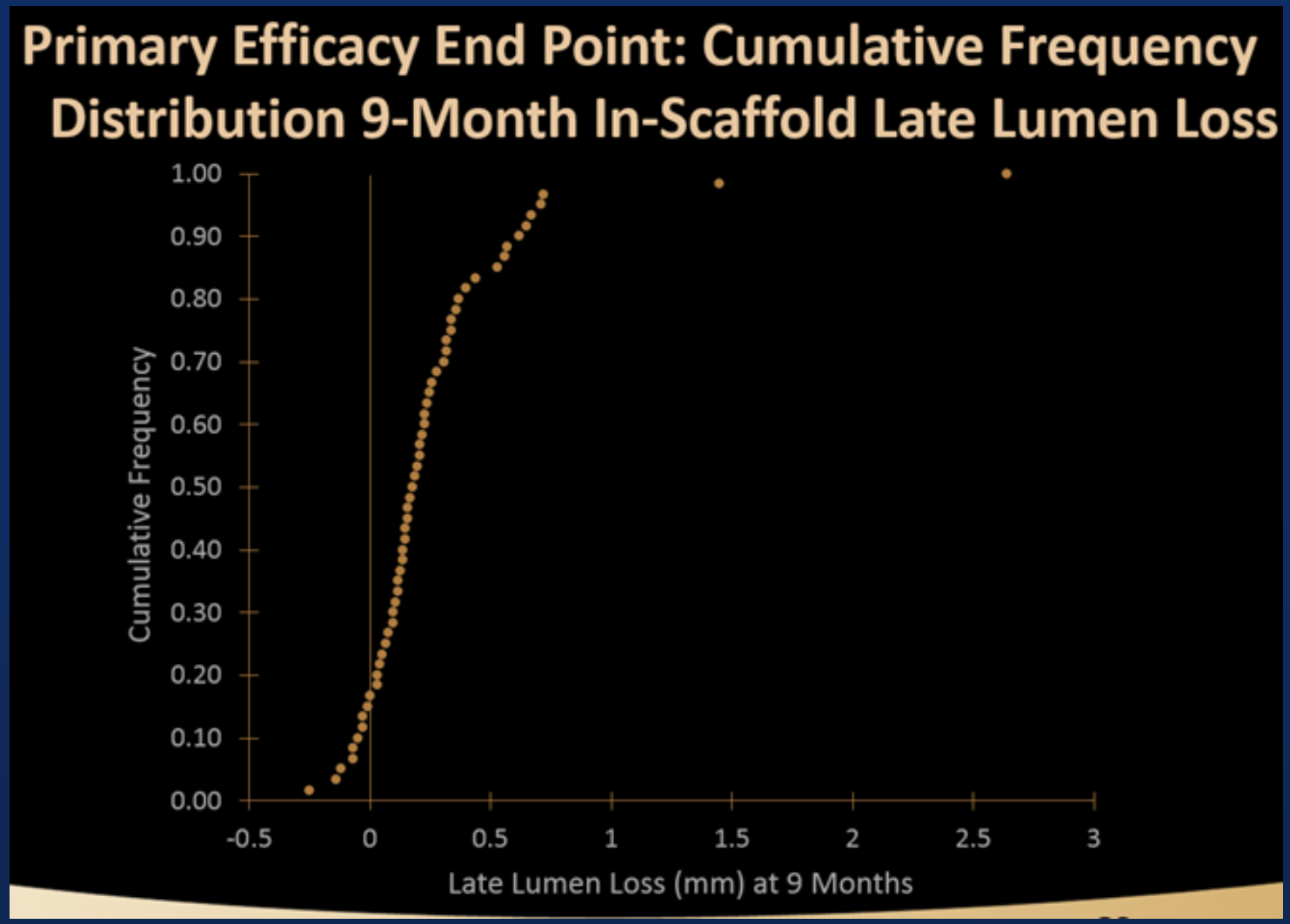
FORTITUDE

1-Year Clinical and Imaging Outcomes of a Novel Ultra High Molecular Weight PLLA Sirolimus-Eluting Coronary BRS: A Prospective Multicenter International Investigation (The FORTITUDE® Study)



A Colombo TCT 2016

FORTITUDE



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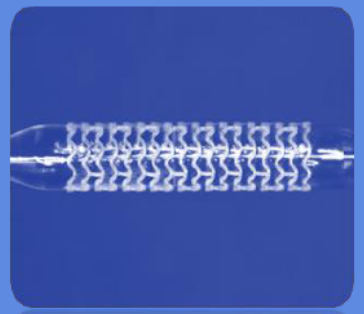
FUTURE-I

Features of the Firesorb BRS

PLLA-based BRS



- PLLA backbone
- PDLLA coating
- Balloon Expandable

Abluminal Eluting

- Abluminal coating
- Sirolimus
- Low drug dosage - 60% lower than BVS

Thin Strut

Scaffold Size	Strut Thickness
2.5 ~ 2.75 mm	100 μm
3.0 ~ 4.0 mm	125 μm

- Lower crossing profile
- Shorter resorption time
- More deliverable

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FUTURE-I

FUTURE-I (N=45)

Prospective, Single Center, First-in-Man Study

Inclusion:
- Age ≥ 18 years
- Stable and unstable angina, silent ischemia, or OMI
- Single, *de novo* lesion in native coronary artery with lesion length ≤ 25 mm (can be covered by 1 scaffold) and vessel size between 3.0~3.5 mm

Exclusion:
- AMI within 1 week
- CTO (TIMI 0), left main disease, ostial lesion, multivessel disease, bifurcation (diameter of ostial SB ≥ 2.0 mm or %DS ≥ 40%), and restenotic lesions

Device Size: Diameter: 3.0, 3.25, 3.5 mm; length: 13, 18, 23, 29 mm

Imaging and Clinical Follow-up

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FUTURE-I

Angiographic Results in Cohort 1

	Post-Procedure (N=30)	6M F/U (N=29)	Difference (95% CI)	P
Minimal Lumen Diameter, mm				
In-Scaffold	2.67 ± 0.22	2.53 ± 0.24	0.15 (0.11, 0.19)	<0.001
In-Segment	2.44 ± 0.27	2.36 ± 0.30	0.09 (0.03, 0.14)	0.003
Diameter Stenosis, %				
In-Scaffold	10.6 ± 4.7	14.1 ± 5.9	-3.5 (-5.4, -1.6)	0.001
In-Segment	15.4 ± 7.5	16.9 ± 8.7	-1.1 (-4.1, 1.9)	0.45
Acute Gain, mm				
In-Scaffold	1.67 ± 0.42	-	-	-
In-Segment	1.44 ± 0.48	-	-	-
Acute Recoil, mm	0.13 ± 0.10	-	-	-
Late Lumen Loss, mm				
In-Scaffold	-	0.15 ± 0.11	-	-
In-Segment	-	0.09 ± 0.15	-	-
Binary Restenosis, %	-	0%	-	-

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FUTURE-I

Clinical Outcomes

	30 Days			6 Months		
	Overall (N=45)	Cohort 1 (N=30)	Cohort 2 (N=15)	Overall (N=45)	Cohort 1 (N=30)	Cohort 2 (N=15)
TLF	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
PoCE	2.2% (1)	3.3% (1)	0% (0)	2.2% (1)	3.3% (1)	0% (0)
All-Cause Death	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Cardiac Death	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Non-Cardiac Death	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
All MI	2.2% (1)	3.3% (1)	0% (0)	2.2% (1)	3.3% (1)	0% (0)
Target Vessel MI	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Any Revascularization	2.2% (1)	3.3% (1)	0% (0)	2.2% (1)	3.3% (1)	0% (0)
ID-TVR	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
ID-TLR	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Def/Prob ST	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)

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FUTURE-I

IVUS Results in Cohort 1

	Post-Procedure (N=30)	6M F/U (N=29)	Difference (95% CI)	P
Cross-Section Level Analysis	1,365	1,227	-	-
Mean Vessel Area, mm^2	16.4 ± 3.49	16.2 ± 3.30	0.4 (-0.1, 1.0)	0.12
Minimal Vessel Area, mm^2	13.6 ± 3.61	13.3 ± 3.21	0.5 (0.2, 0.8)	0.003
Mean Scaffold Area, mm^2	7.87 ± 1.25	7.86 ± 1.25	0.1 (-0.1, 0.2)	0.37
Minimal Scaffold Area, mm^2	6.74 ± 1.17	6.70 ± 1.21	0.1 (-0.1, 0.3)	0.41
Mean Lumen Area, mm^2	7.68 ± 1.21	7.47 ± 1.27	0.3 (0.1, 0.5)	0.01
Minimal Lumen Area, mm^2	6.60 ± 1.15	6.30 ± 1.22	0.4 (0.1, 0.6)	0.005
Lesion Level Analysis	30	29	-	-
Mean Neointimal Hyperplasia, mm^2	-	0.18 ± 0.22	-	-
In-Scaffold Volumetric Obstruction, %	-	6.46 ± 2.57	-	-
Absolute Late Recoil, mm^2	-	0.07 ± 0.39	-	-
Late Recoil, %	-	0.76 ± 4.86	-	-

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FUTURE-I

OCT Results in Cohort 1

	Post-Procedure (N=30)	6M F/U (N=29)	Difference (95% CI)	P
Strut Level Analysis	13,843	14,945	-	-
Proportion of Covered Struts, %	-	98.4%	-	-
Incomplete Strut Apposition, %	0.85%	0.07%	0.82 (0.37, 1.27)	<0.001
Persistent Malapposition, %	-	0.07%	-	-
Late-Acquired Malapposition, %	-	0%	-	-
Mean Thickness of Strut Coverage, mm	-	0.05 ± 0.04	-	-
Cross-Section Level Analysis	1,402	1,372	-	-
Mean Black Core Area, mm^2	0.13 ± 0.02	0.14 ± 0.03	-0.01 (-0.02, 0.0)	0.01
Lesion Level Analysis	30	29	-	-
Absolute Late Recoil, mm^2	-	0.18 ± 0.44	-	-
Late Recoil, %	-	2.01 ± 5.20	-	-
Healing Score	-	3.14 ± 3.43	-	-

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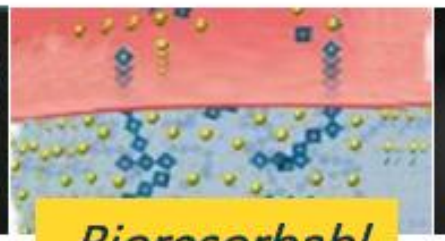
XINSORB

Balloon expanding

- Excellent deliverability

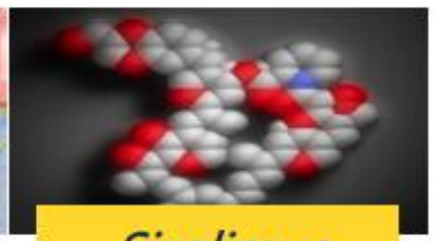
Bioresorbable Scaffold

- Polylactide (PLLA)
- Naturally resorbed, fully metabolized
- 160 µm of thickness



Bioresorbable Coating

- Polylactide (PDLLA) coating
- Fully biodegradable



Sirolimus

- 12 µg/mm
- 80% of drugs eluted in 28 days ex vivo

Junbo Ge, TCT 2017

XINSORB

1-year QCA Results (per lesion)

	XINSORB (N=169)	TIVOLI® (N=167)	P-Value
RVD (mm) prox-	3.02 ± 0.47	3.02 ± 0.56	0.99
in-device	2.88 ± 0.46	2.88 ± 0.53	0.91
distal-	2.71 ± 0.50	2.64 ± 0.52	0.22
MLD (mm) prox-	2.82 ± 0.49	2.70 ± 0.62	0.06
in-device	2.42 ± 0.46	2.35 ± 0.51	0.16
distal-	2.56 ± 0.51	2.46 ± 0.55	0.07
DS (%) prox-	6.45 ± 8.35	11.69 ± 14.4	<0.01
in-device	15.88±9.8	19.05 ± 14.8	0.02
distal-	5.13 ± 8.6	8.1 ± 13.2	0.02
In-device late luminal loss (mm)	0.23 ± 0.29	0.37 ± 0.38	<0.01
Peri-device late luminal loss (mm)	0.19 ± 0.32	0.31 ± 0.41	<0.01

Junbo Ge, TCT 201

XINSORB

1-year Clinical Outcomes (per patient)

	XINSORB (N=191)	TIVOLI® (N=187)	P-Value
PoCE	4.7% (9)	7.0% (13)	0.35
DoCE (TLF)	1.6% (3)	4.8% (9)	0.07
All-cause death	1.0% (2)	0	0.50
- Cardiac death	0.5% (1)	0	NA
All MI*	0.5% (1)	1.1% (2)	0.62
- TV-MI*	0.5% (1)	0.5% (1)	1.0
All revascularization	3.7% (7)	6.4% (12)	0.22
- ID-TLR	1.0% (2)	4.9% (9)	0.25

Junbo Ge, TCT 2017