Impact of Technique on Early and Late Outcomes Following Coronary Bioresorbable Scaffold Implantation: Analysis from the ABSORB trials

Gregg W. Stone, MD

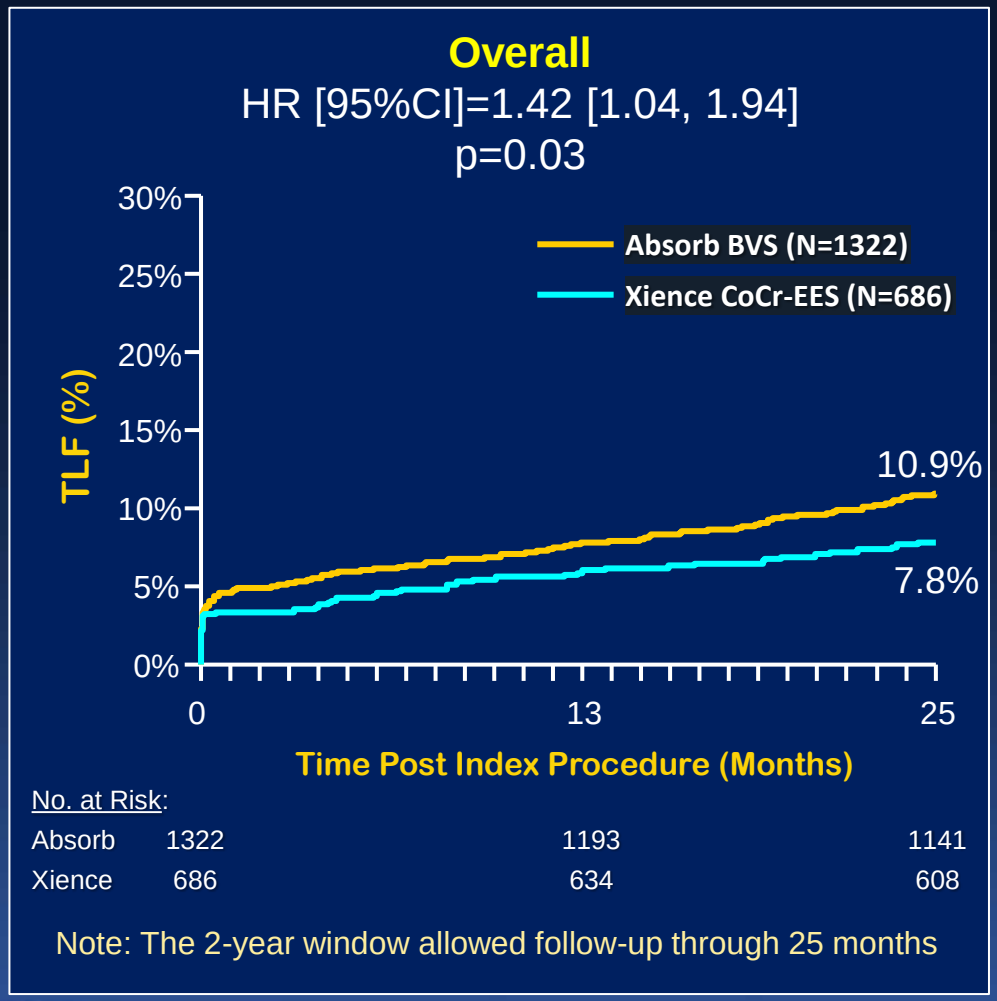
Columbia University Medical Center
NewYork-Presbyterian Hospital
Cardiovascular Research Foundation

Disclosures

- Chairman of the global Abbott Vascular ABSORB Program (uncompensated)
- Consultant to Reva

ABSORB III

TLF by 2 Years (25 Months)



Note: The 2-year window allowed follow-up through 25 months

	Overall	
	Absorb (N=1322)	XIENCE (N=686)
TLF	11.0% (143)*	7.9% (53)*
Cardiac Death	1.1% (14)	0.6% (4)
TV-MI	7.3% (95)**	4.9% (33)**
ID-TLR	5.3% (69)	4.3% (29)
ST (Def/Prob)	1.9% (24)	0.8% (5)

* P-value=0.03. ** P-value=0.04. P-value >0.05 for all other comparisons

Bioresorbable Scaffold Outcomes: Why technique may matter

- BRS are a novel first generation technology, which compared to contemporary metallic DES, have thicker struts, different expansion characteristics, possibly greater recoil, reduced visibility, and loss of structural integrity during the active bioresorption process
- The strongest predictors of thrombosis and restenosis with metallic DES are a small MSA, untreated significant edge dissections, and untreated residual disease
  - There is no reason to think these parameters would be less important with BRS
  - Acute malapposition, which may increase the likelihood of intraluminal scaffold dismantling, may be even more important to prevent with BRS than with metallic DES

Predictors of Absorb Scaffold Thrombosis (1,870 BVS in 1,305 pts)

4 German and Swiss centers, median FU 485 days

ScT developed in 42 pts (3.0%; 36 def, 4 prob, and 2 poss)

Multivariable quantitative predictors of ScT

	Thrombosis (n=42)	No thrombosis (n=84[3])	HR (95%CI) for risk	P value
Baseline RVD (mm)	2.77 ± 0.58	3.13 ± 0.66	3.70 (1.30-10)	0.01
Final RVD (mm)	2.93 ± 0.58	3.41 ± 0.52	7.69 (2.17-25)	0.002
Final MLD (mm)	2.39 ± 0.58	2.85 ± 0.49	20.0 (3.57-100)	0.001
Max footprint[1], %	43 ± 11	35 ± 6	1.20 (1.08-1.33)	0.001
Scaled residual stenosis[2], %	21 ± 18	7 ± 14	1714 (20-146,454)	0.001

1. % of the vascular circumference occupied by struts at the level of the MLD;
2. MLD divided by the nominal BVS diameter; 3. Propensity matched controls

Reduction in Absorb Scaffold Thrombosis with Improved Technique

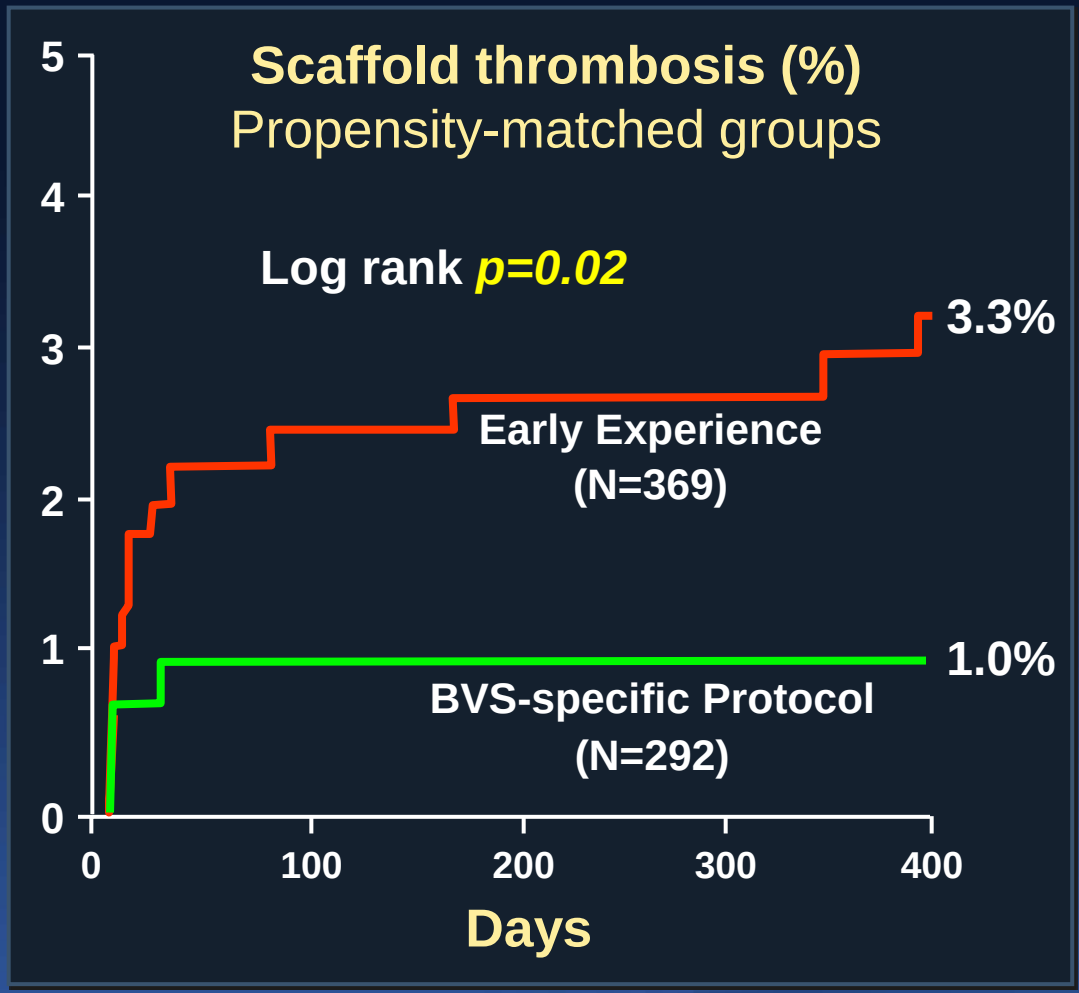
At 4 German and Swiss centers

BVS specific protocol

- Nitrates
- Sizing with balloon (1:1:1) 2 angiographic planes
- Low threshold for OCT
- Implant following IFU
- NC postdilation (+0.5mm)

Do not accept MLD <2.5/2.9mm*
MLA <4.9/6.6mm^2*

*For a 2.5-3.0 mm and 3.5 mm scaffold respectively



Puricel S et al. JACC 2016;67:921–31

Hypothetical Keys to Absorb Success: "P-S-P"

P: Prepare the Lesion (aggressively)

- Pre-dilate with balloon:RVD ~1:1
- For calcified lesions or those that won't fully pre-dilate: cutting/scoring balloons or atherectomy
- Don't implant scaffold unless full balloon expansion is achieved

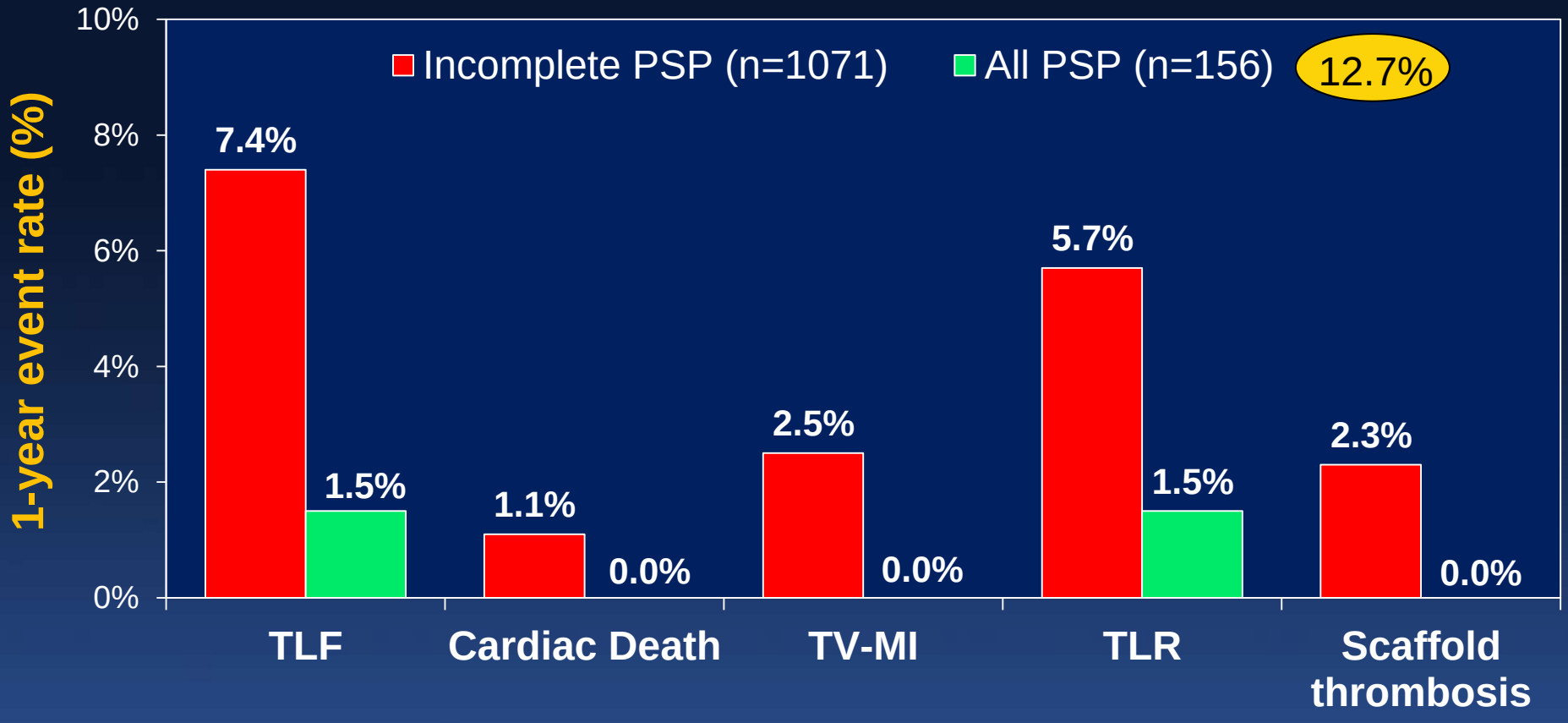
S: Size the Scaffold Correctly

- Use guide catheter, pre-dilatation balloon, on-line QCA, or intravascular imaging (IVUS, OCT). Don't undersize!
- Strongly consider IV imaging if visual RVD <3 mm or 2.5 mm BVS planned; never implant scaffold if RVD <2.5 mm!

P: Post-Dilate All Cases (unless perfect by IV imaging)

- With a NC balloon sized ≥1:1 (upsize 0.5 mm if possible, staying within the scaffold margins) to high pressure (≥18 atm)
- But never >0.5 mm larger than scaffold nominal diameter

One-Year GHOST Outcomes According to PSP (N=1227 pts)



PSP - all 3 criteria are met: 1) Pre-dilatation = yes; 2) Sizing: QCA RVD ≥2.25 mm and ≤3.5 mm;
3) Post-dilatation: Pressure >16 atm, and balloon:scaffold dia > 1:1 and balloon dia. ≤ scaffold dia. + 0.5 mm

Absorb Milan Experience

May 2012 - August 2016: 340 pts, 518 lesions

Bifurcation lesions 46%

Severely calcified lesions 23%

B2/C lesions 76%

Total BVS length 54±34 mm per patient

Use of 2.5 mm BVS/pt 45%

Technique (in 264 pts*)

Pre-dilatation	97%
- Scoring/cutting/RB	20%
Post-dilatation with NC balloon	99%
- Pressure, atm mean	20.8±4.5
- Balloon/scaffold diameter ratio	1.04 ± 0.08
- Balloon dia. = scaffold dia. + 0.5 mm	22%
- Balloon dia. > scaffold dia. + 0.5 mm	0%
IVUS or OCT	86%
- Further interventions based on imaging	25%

*Tanaka A et al. EuroInt 2017;12:1730-1737

Absorb Milan Experience

May 2012 - August 2016: 340 pts, 518 lesions

FU 98.5% of pts at median 706 days (IQR 355 - 1088)

Scaffold thrombosis (def/prob):

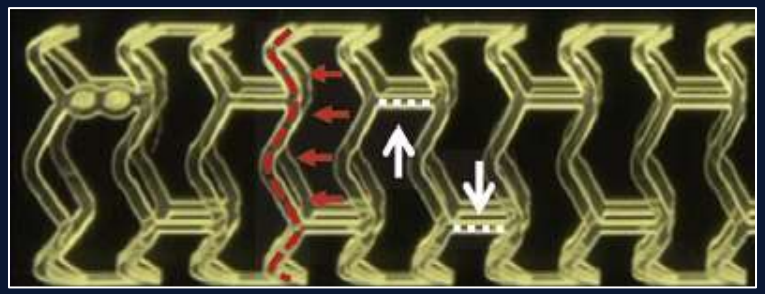
4 cases (1.2%)

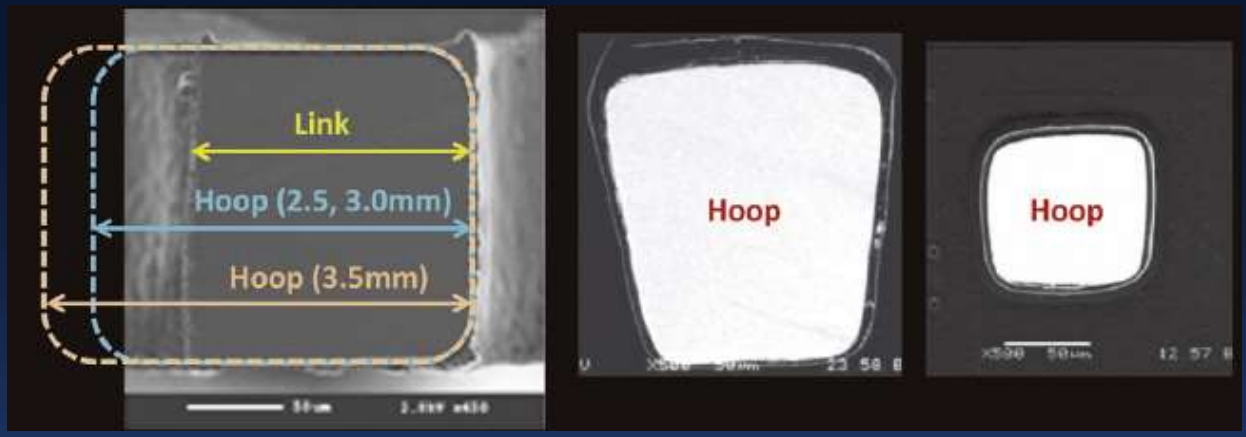
1 Acute	(day 0)
1 Subacute	(day 3)
2 Late	(day 63, day 143)
0 Very late	

All definite, no probable

How much space does the scaffold occupy?

Absorb BVS
White arrows = links
Red arrows = hoops

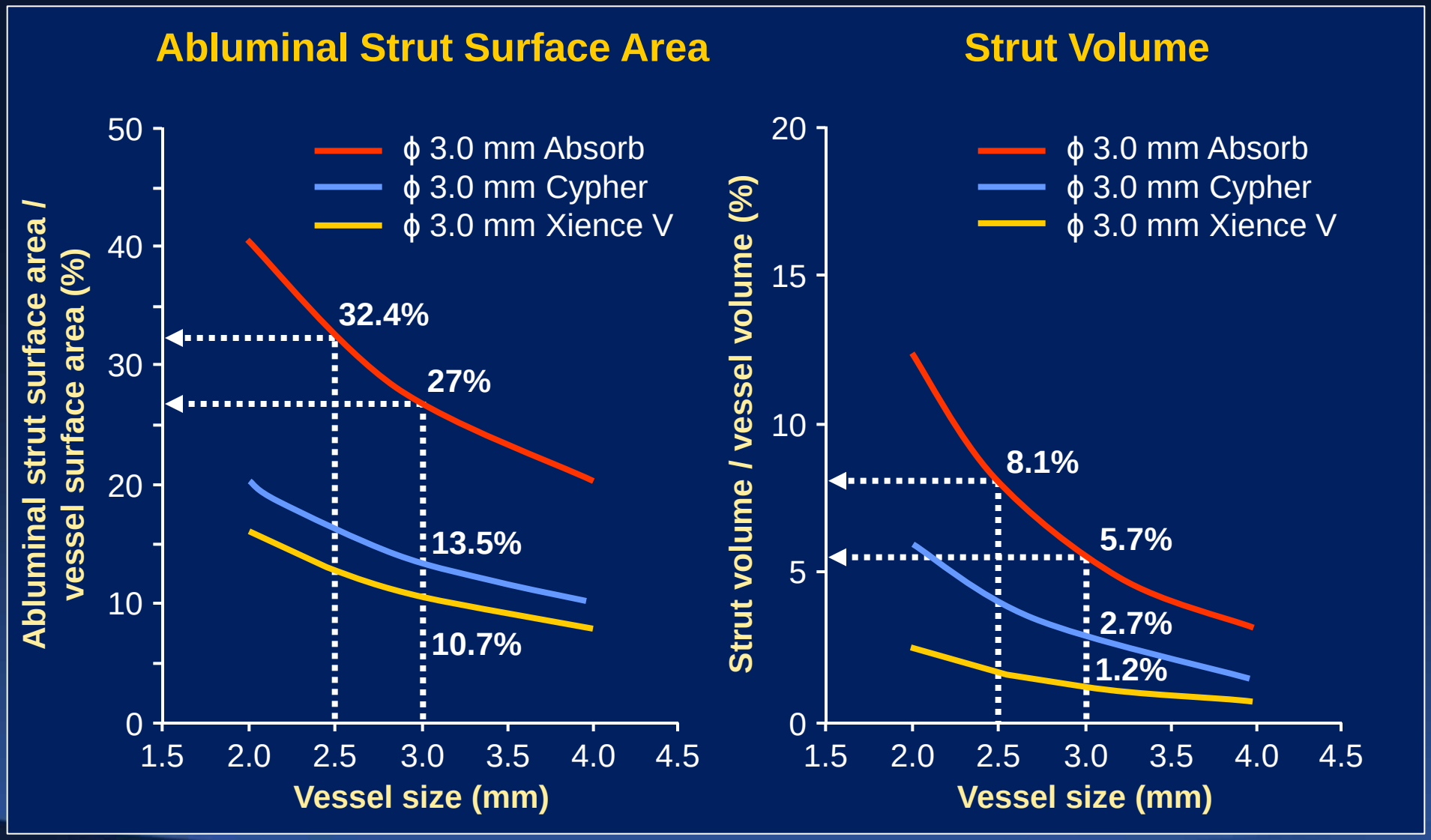




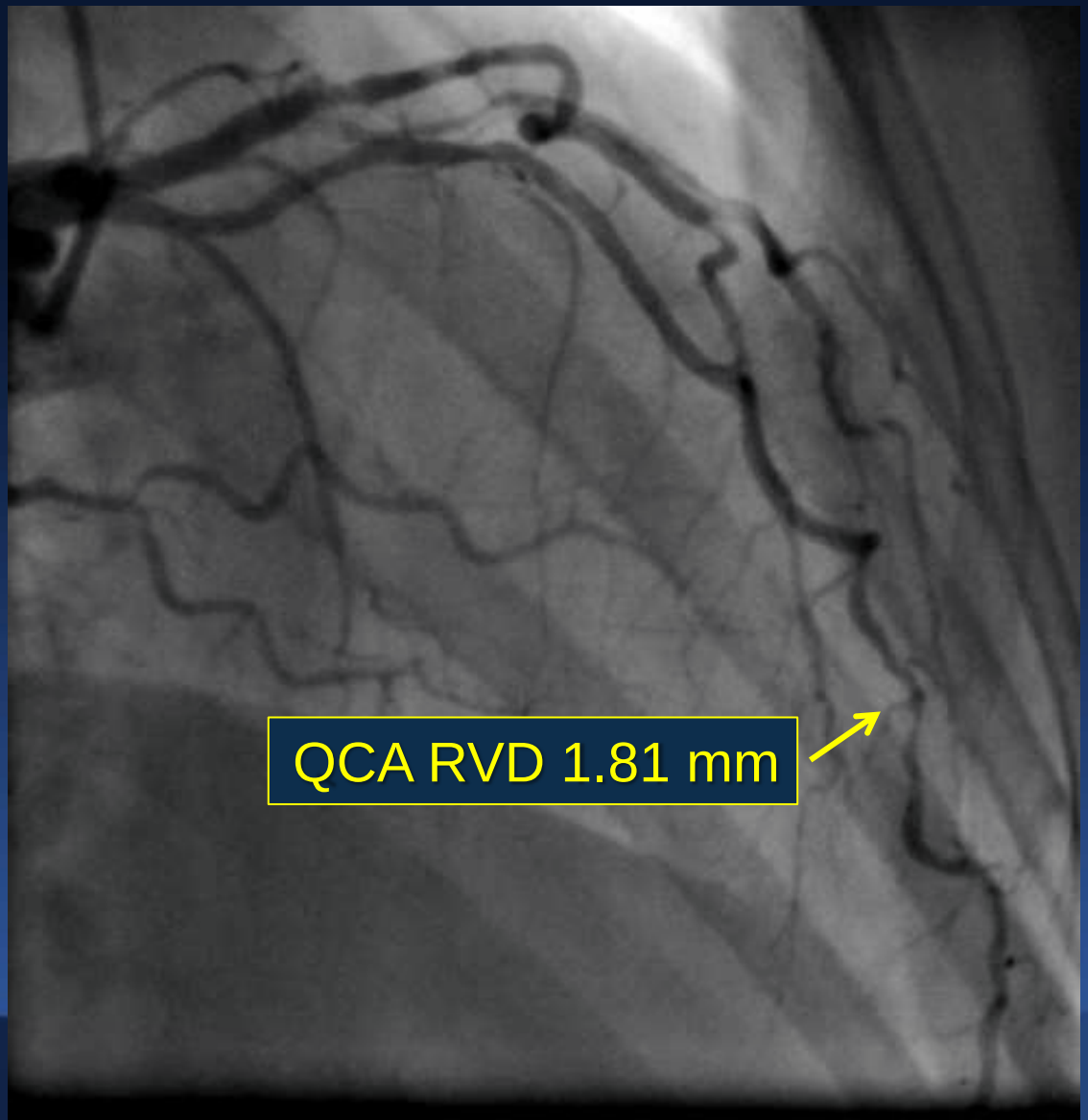
	Absorb BVS	Cypher	Xience
Strut thickness	157 um	153 um	81 um
Strut width (link)	140 um	60 um	81 um
Strut width (hoop)	2.5, 3.0 mm: 191 um 3.5 mm: 216 um	130 um	81 um
Abluminal strut to vessel surface area	2.5 mm: 32% 3.0 mm: 27% 3.5 mm: 26%	2.5, 3.0 mm: 12-15% 3.5, 4.0 mm: 12-15%	11%

Kawamoto H et al. JACC CV Int 2016;9:299–304

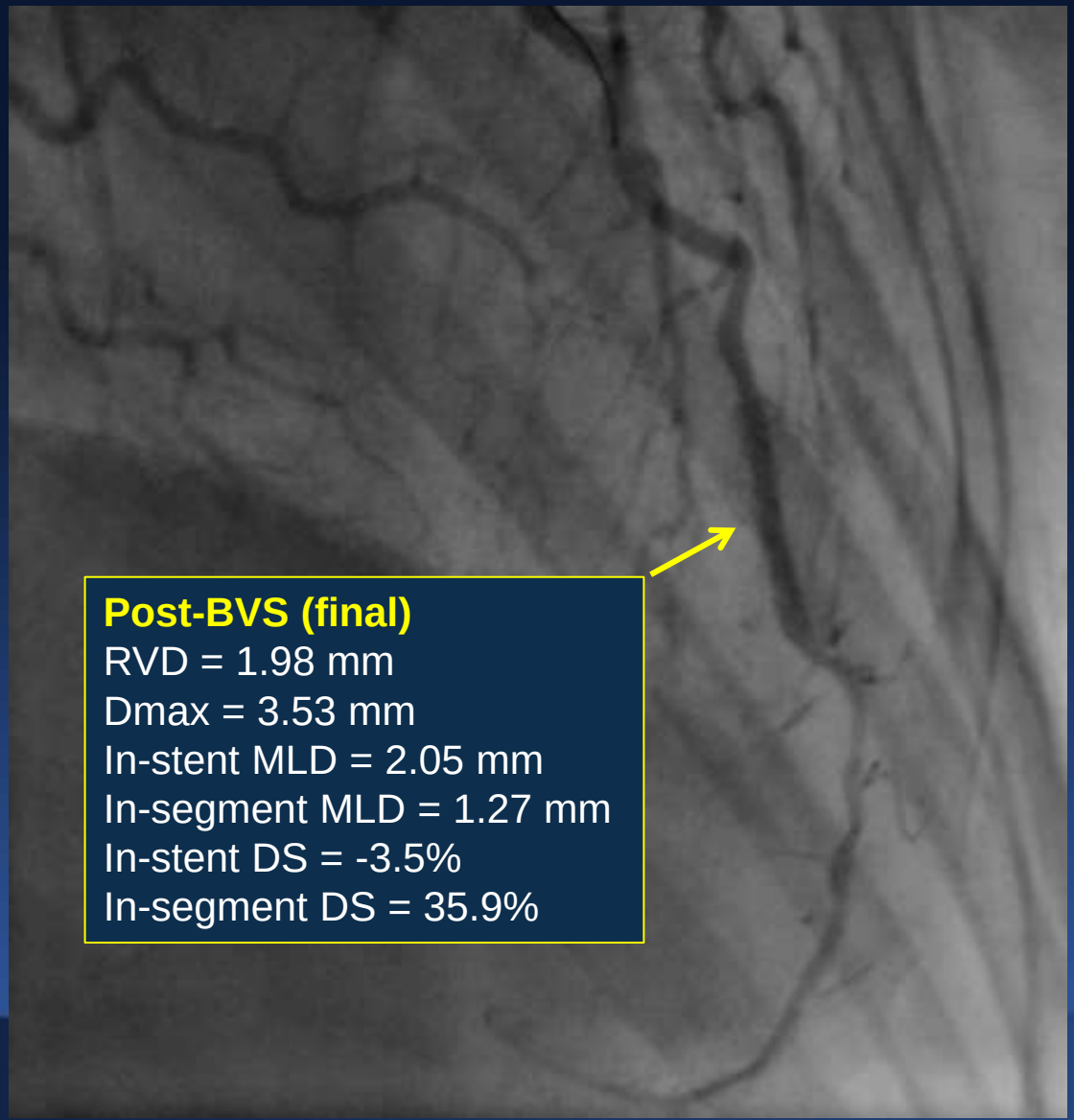
How Much Space Does the Scaffold Occupy?



Example: Very small vessel enrolled in ABSORB III



Example: Very small vessel enrolled in ABSORB III



Device Thrombosis by Vessel Size

Any QCA RVD <2.25 mm vs. all RVD ≥2.25 mm

Any QCA RVD <2.25 mm

1-year results Absorb vs. Xience

4.6% vs. 1.5% respectively

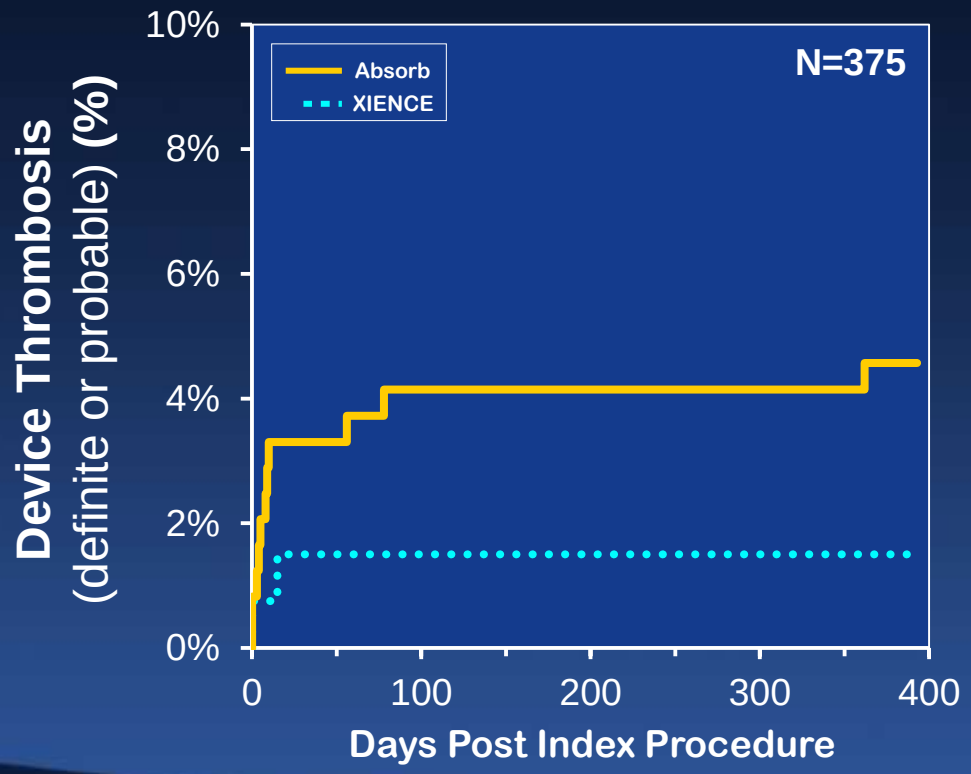
Diff [95%CI] = 3.1 [-0.3, 6.4]

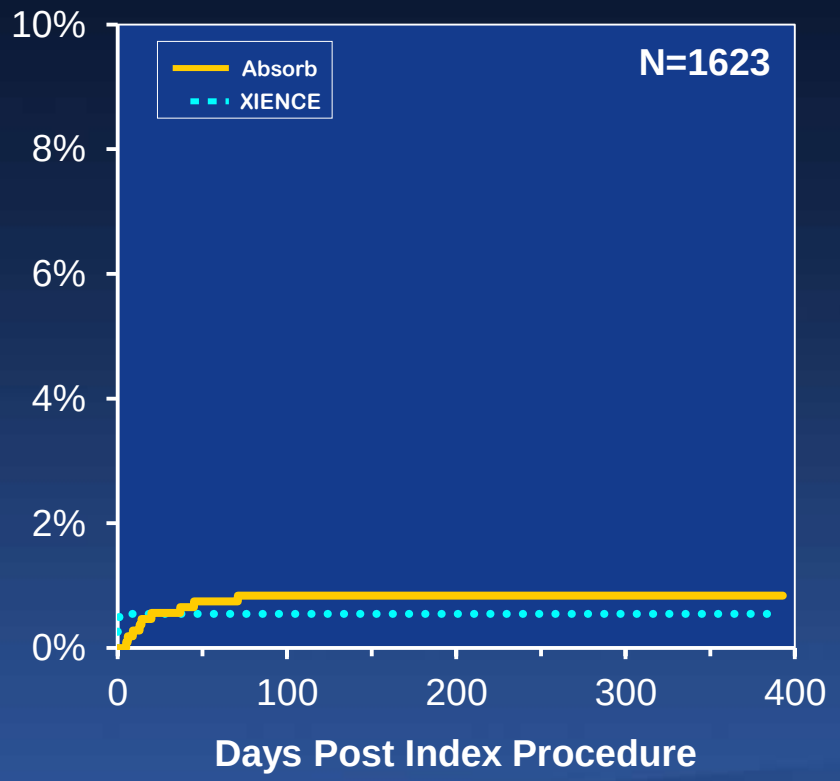
All QCA RVD ≥2.25 mm

1-year results Absorb vs. Xience

0.8% vs. 0.5% respectively

Diff [95%CI] = 0.3 [-0.5, 1.1]





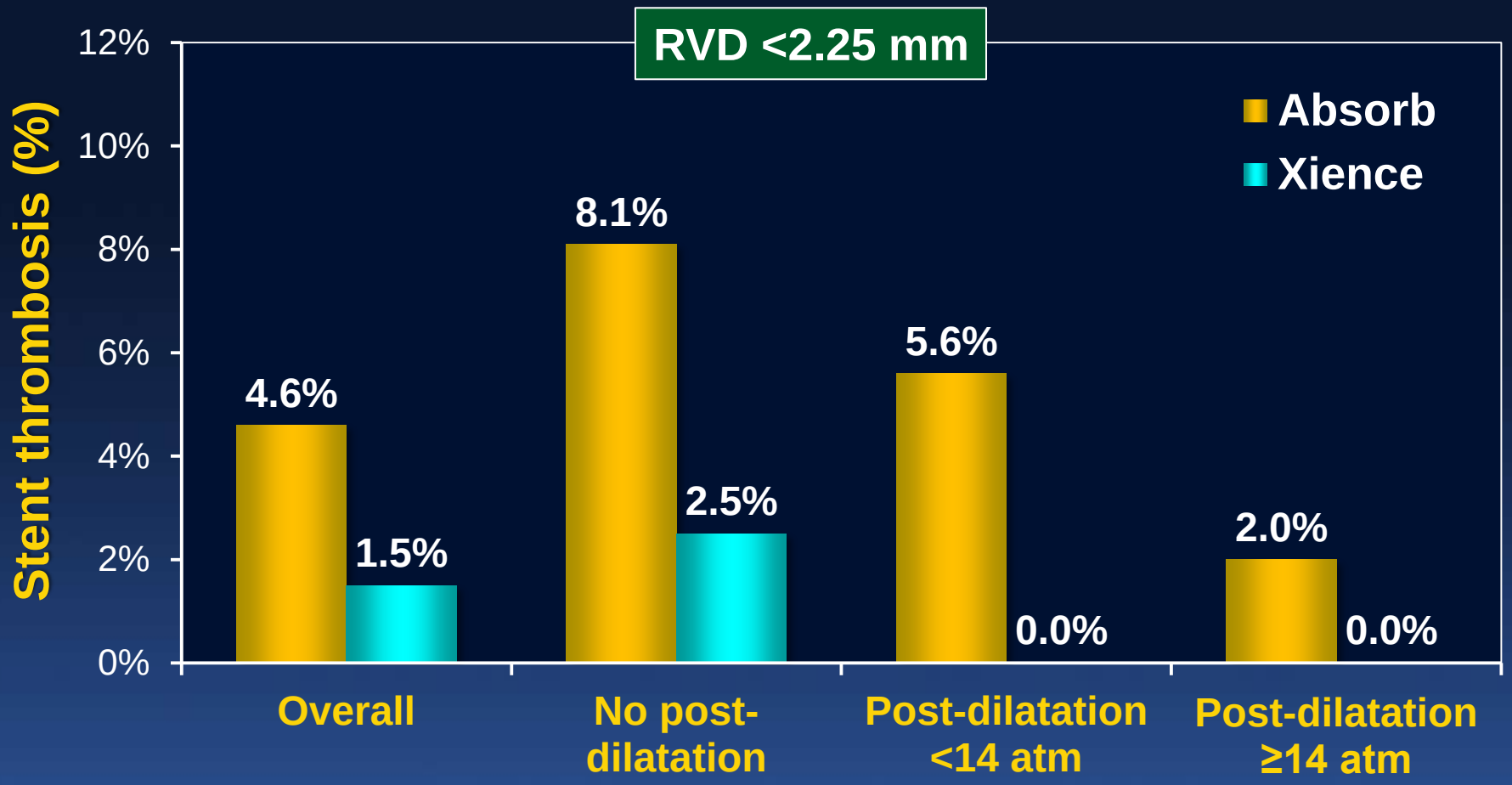
Cardiovascular Research Foundation

Stone GW et al. J Am Coll Cardiol. 2016;67(13S):35

Columbia University Medical Center
NewYork-Presbyterian

1-Year ST in Very Small Vessels

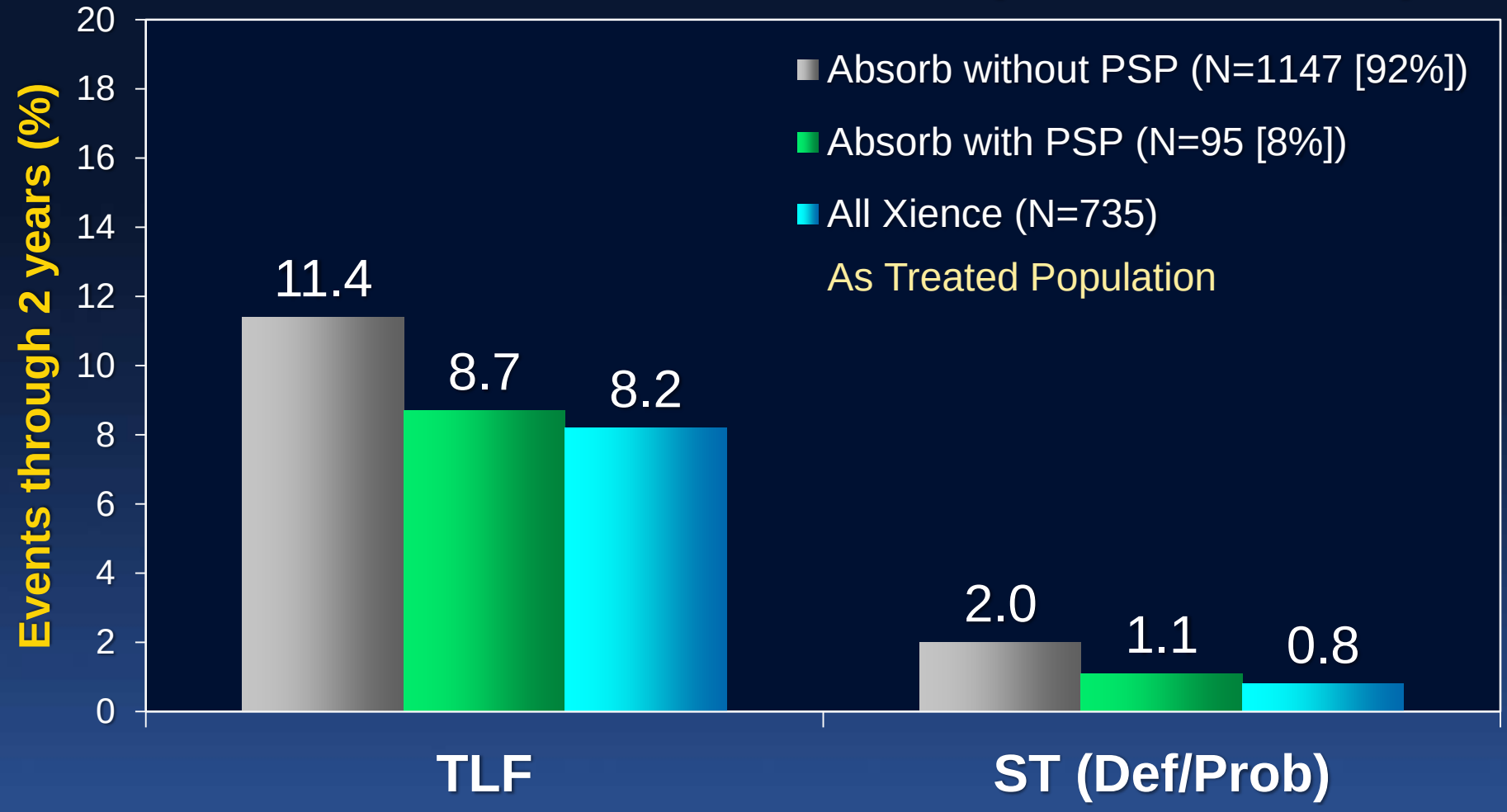
Impact of Post-Dilatation and Pressure



	Overall	No post-dilatation	Post-dilatation <14 atm	Post-dilatation ≥14 atm
Absorb:	11/238	6/74	3/54	2/101
Xience:	2/133	2/79	0/15	0/36

Stone GW. TCT 2016

ABSORRB III: Impact of PSP* on 2-Year Outcomes (25 Months)



* Defined as patients with pre-dilatation, and QCA RVD ≥2.25mm-≤3.5mm, and post-dilatation performed at ≥18 atm, with post-dilatation balloon diameter > nominal scaffold diameter but ≤ nominal scaffold diameter + 0.5mm

Blinded, Pooled, Interim ABSORB IV Outcomes: Comparison to ABSORB III

ABSORB III: 2008 pts randomized 2:1 BVS:EES (1322:686)
ABSORB IV: 2600 pts randomized 1:1 BVS:EES

	ABSORB III Pooled (N=2008)[1]	ABSORB IV Pooled (N=2546)[2,3]
QCA RVD < 2.25 mm	19%	4%
Post-dilatation (BVS)	66%	84%
	Pooled Stent/Scaffold Thrombosis	
30 days	0.9%	0.4%
1 year	1.1%	0.5%

1. Assuming the observed event rates for each arm in ABSORB III, but adjusted for the 1:1 randomization ratio in ABSORB IV. The actual observed pooled ST rates in ABSORB III were 1.0% at 30 days and 1.3% at 1 year.
2. Based on February 15, 2017 data cut (N=2397 with 30-day FU and N=1415 with 1-year FU).
3. ABSORB IV includes ~25% non A-III like subjects (troponin+ ACS, 3 lesions treated, and planned staged procedures).

Impact of Technique on Absorb Outcomes: Conclusions

- Data is emerging that optimizing technique when implanting 1st gen BRS can improve mid-term outcomes
- In particular, avoiding BRS implantation in very small vessels (QCA RVD <2.25 mm), and routinely performing high pressure (≥18 atm.) post-dilatation with a NC balloon (sized 0.5 mm larger than the scaffold, if appropriate) may reduce the 3-year rates of TLF and ScT
- Intravascular imaging is recommended to ensure optimal vessel sizing, maximal scaffold expansion, lack of acute malapposition, full lesion coverage and the absence of major edge dissections
- Although more data is needed, prolonged DAPT (3 years) may be prudent in patients not at high bleeding risk