Bioresorbable Scaffolds

New Data and Perspectives

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Disclosures

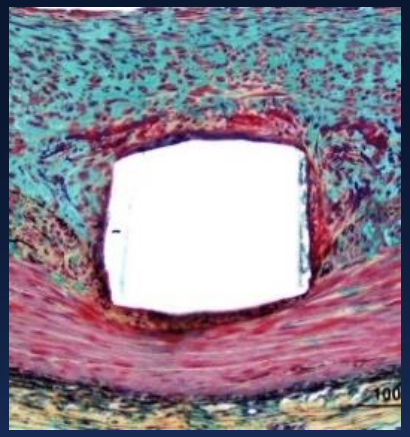
Consultant to Reva

Fully Bioresorbable Scaffolds (BVS/BRS)

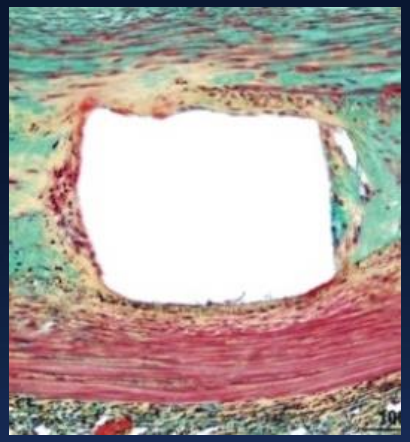
- Designed to provide the mechanical support and drug delivery functions of metallic DES within the first year, and then completely resorb within 2-4 years, removing the nidus for very late adverse events

Full Bioresorption of Absorb Within ~3 Years

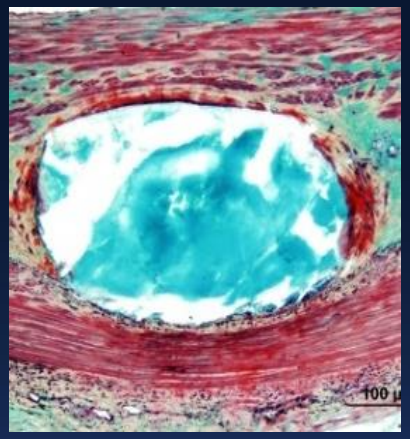
Porcine Histology



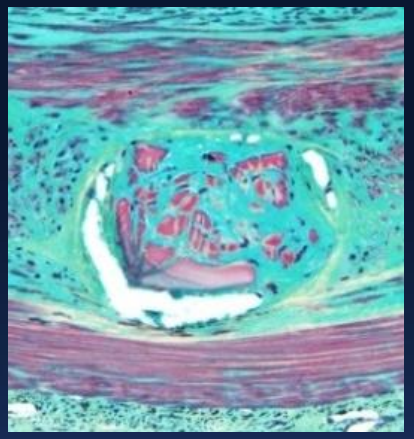
1 month



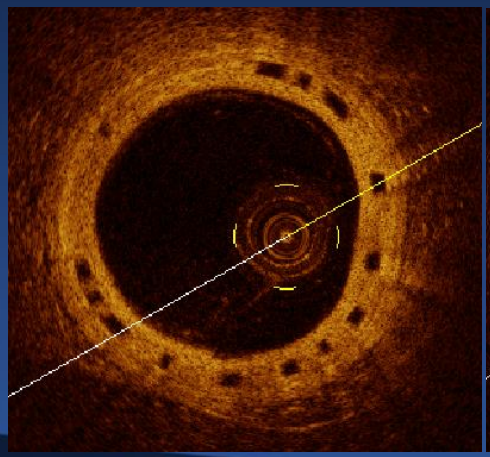
12 months

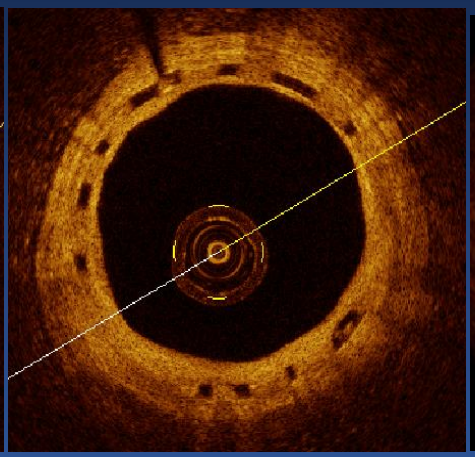


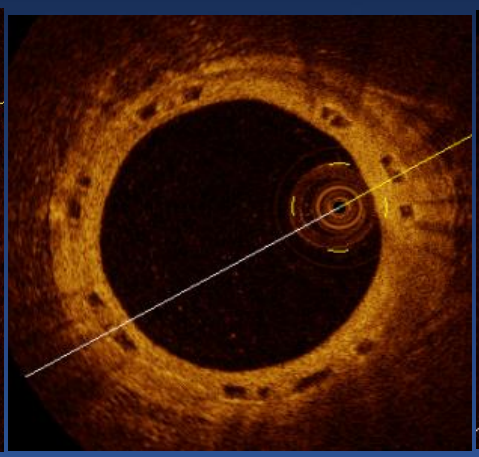
24 months

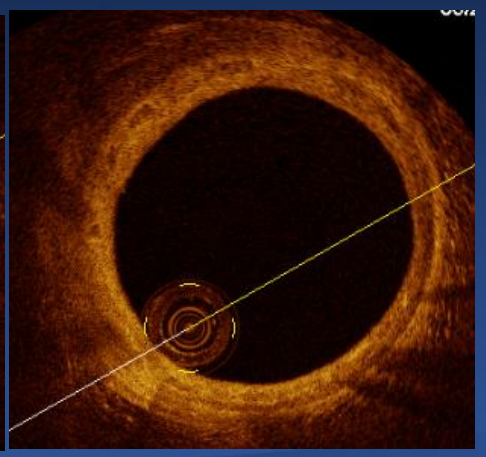


36 months









Human OCT

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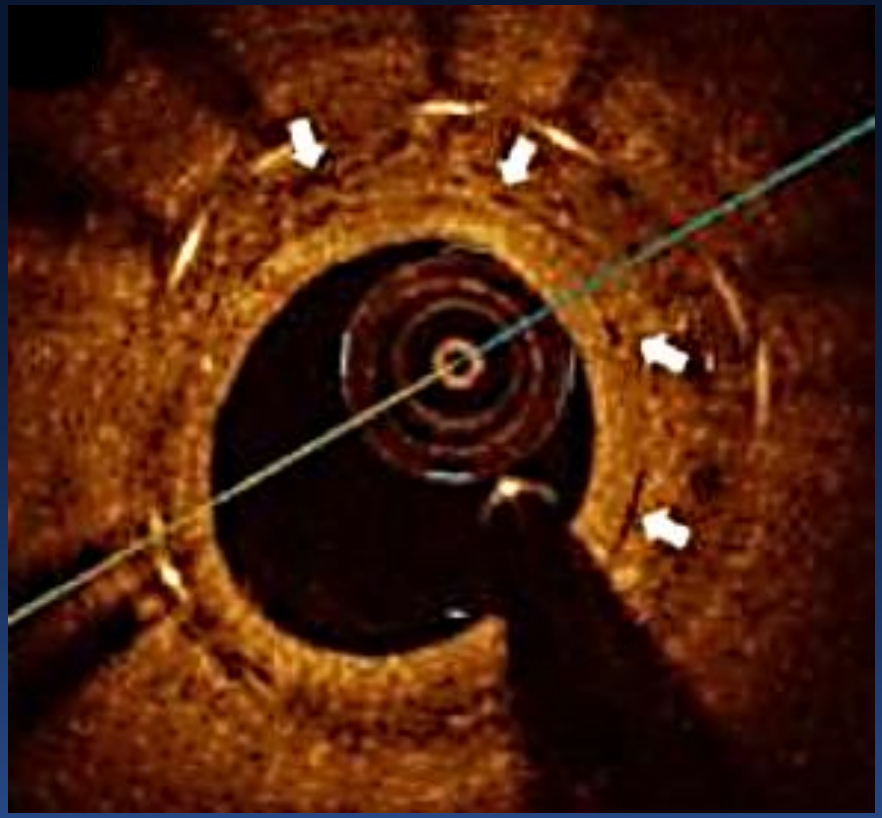
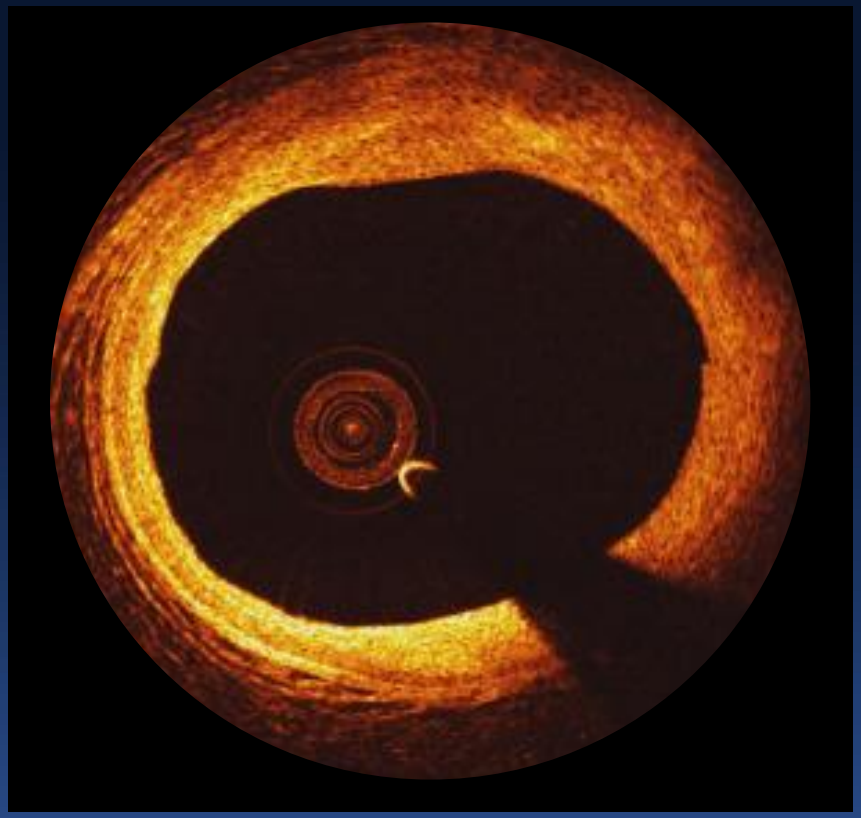
Metallic DES vs. Absorb BVS

Representative Human images at 5 Years



Metallic DES[1]



Absorb-Treated Artery[2]

[1]Atherosclerosis 2014;237:23e29

[2] Images courtesy of S Windecker, ABSORB Cohort B 5 Yrs

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Fully Bioresorbable Scaffolds Address Practical Limitations of Metallic Stents

- "Un-jail" covered side branches
- "Un-jacket" long treated segments (preserving late CABG options)
- "Un-layer" treated in-stent restenosis
- Eliminate artifacts with non-invasive imaging (e.g. CTA)

An Undeniable Fact

Based on cultural, religious or personal beliefs, many patients prefer not to live their lives with permanently implanted devices

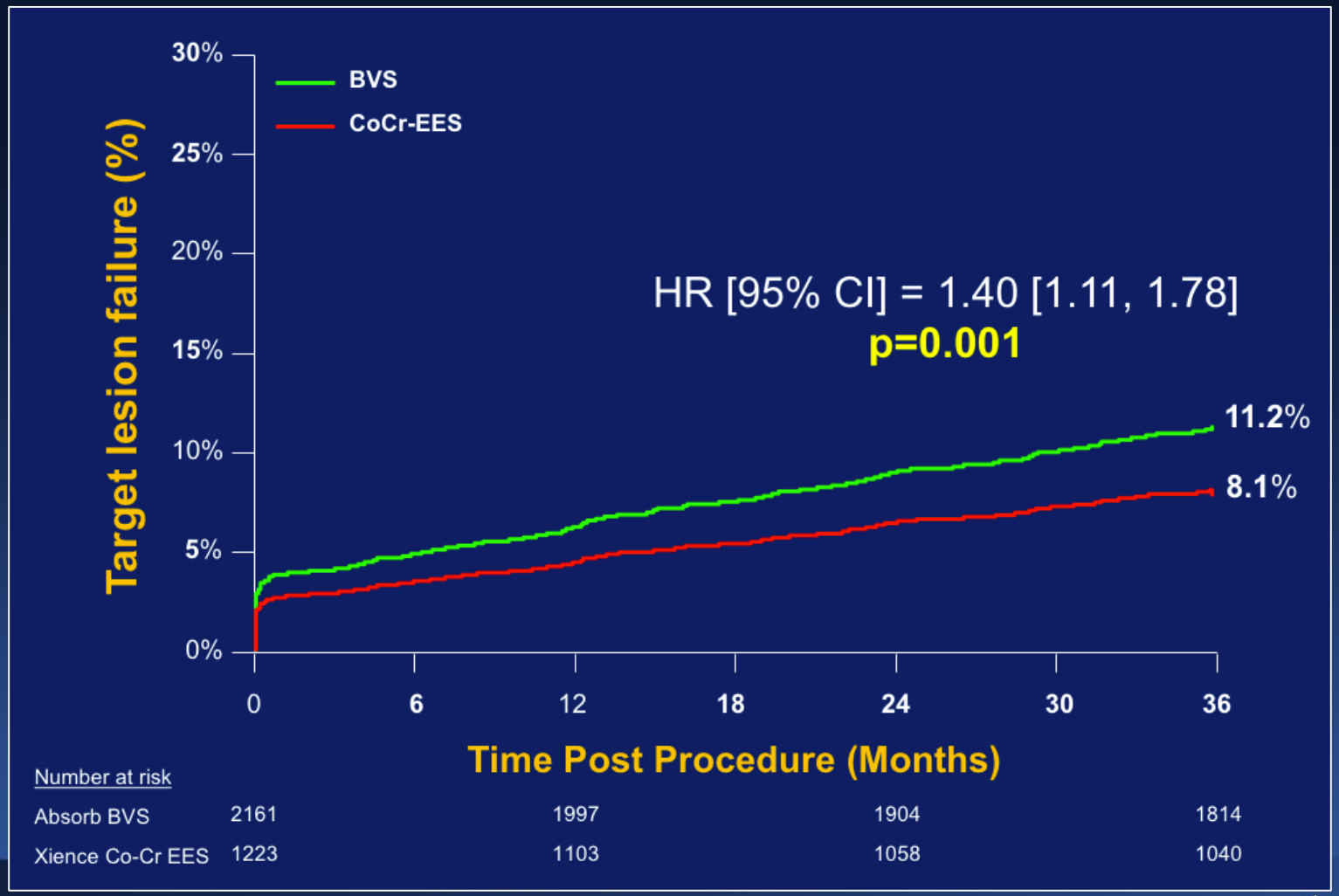
A Reliable Prediction

If BRS were as safe and effective as metallic DES within the first few years (prior to their complete bioresorption), they would ultimately replace metallic DES

ABSORB: 3-year Outcomes

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

3-Year TLF

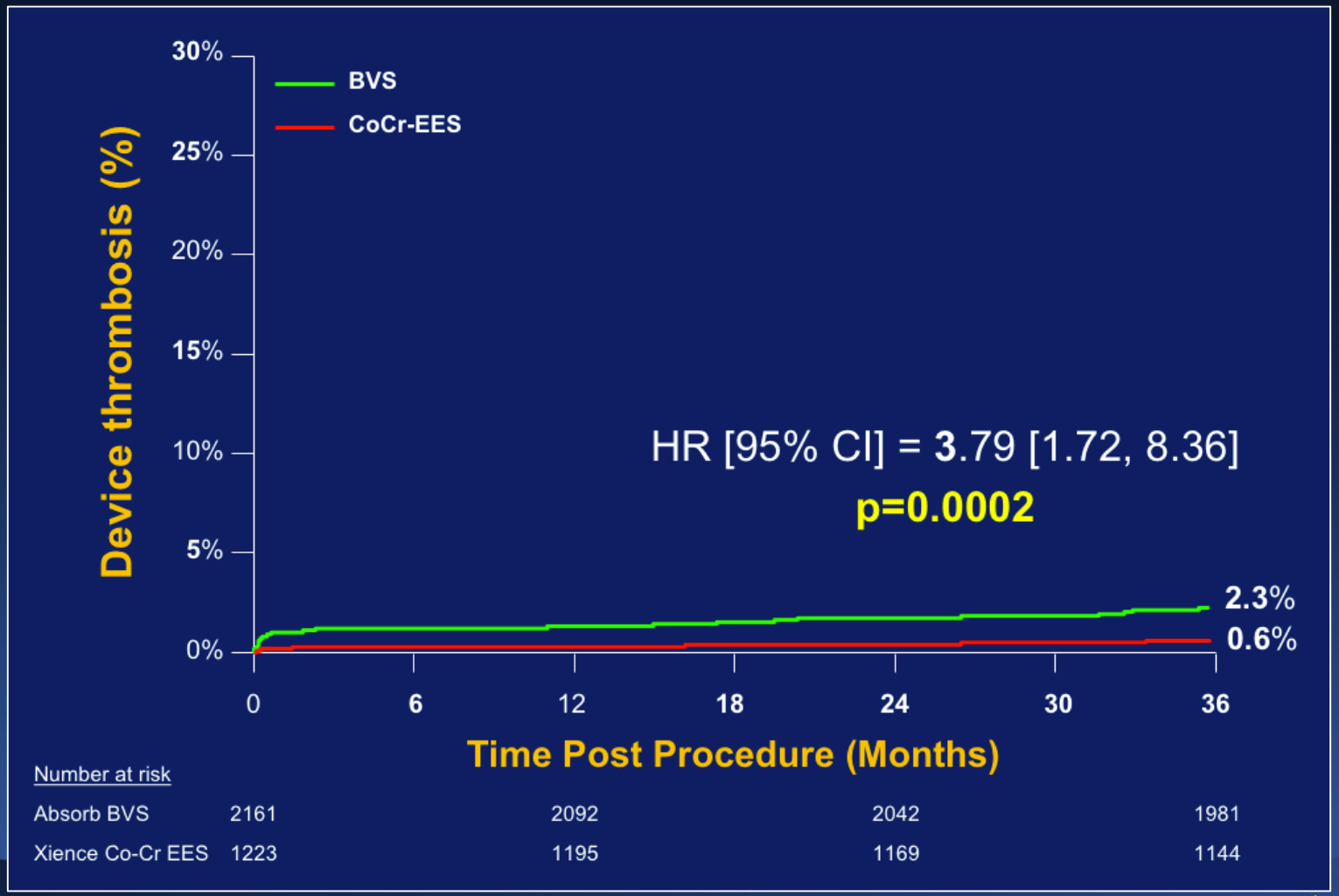


Ali Z et al. Circulation 2018;137:464-79

ABSORB: 3-year Outcomes

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

3-Year Device Thrombosis



Ali Z et al. Circulation 2018;137:464-79

Causes of Absorb BVS Failure

1. Mechanisms common to metallic DES
(but which may be more frequent with BVS)

- Under-expansion (small MSA)
- Edge issues (dissection, residual disease)
- Geographic miss
- Coverage of side-branches
- Slow and/or incomplete endothelialization
- Neoatherosclerosis

2. Mechanisms unique to BVS

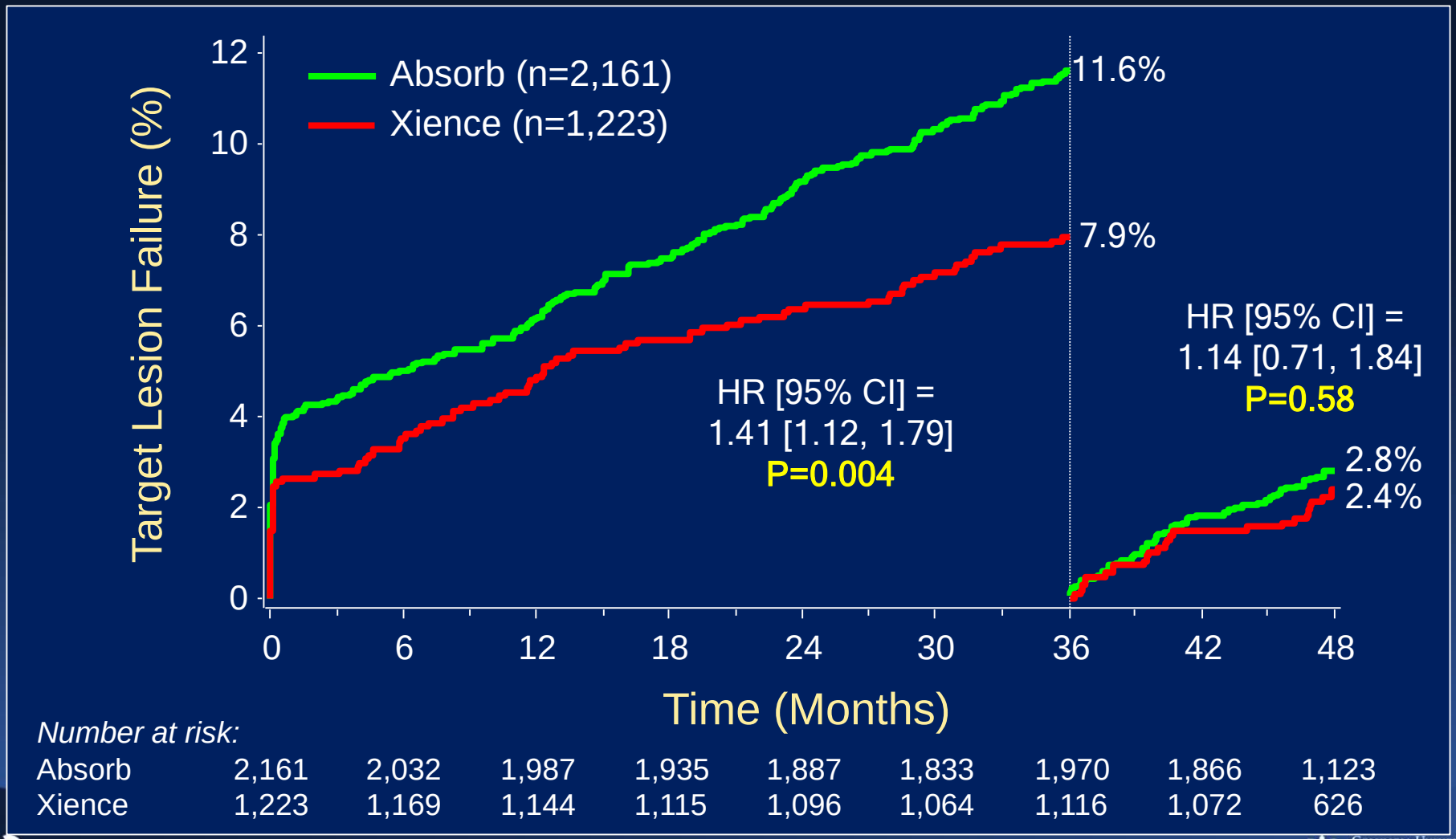
- Acute fracture
- Chronic recoil
- Late intraluminal scaffold dismantling (ILSD)
  - predisposed to by acute malapposition

Many of these may be impacted by suboptimal technique

ABSORB: 4-year Outcomes

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

4-Year TLF (Landmark)



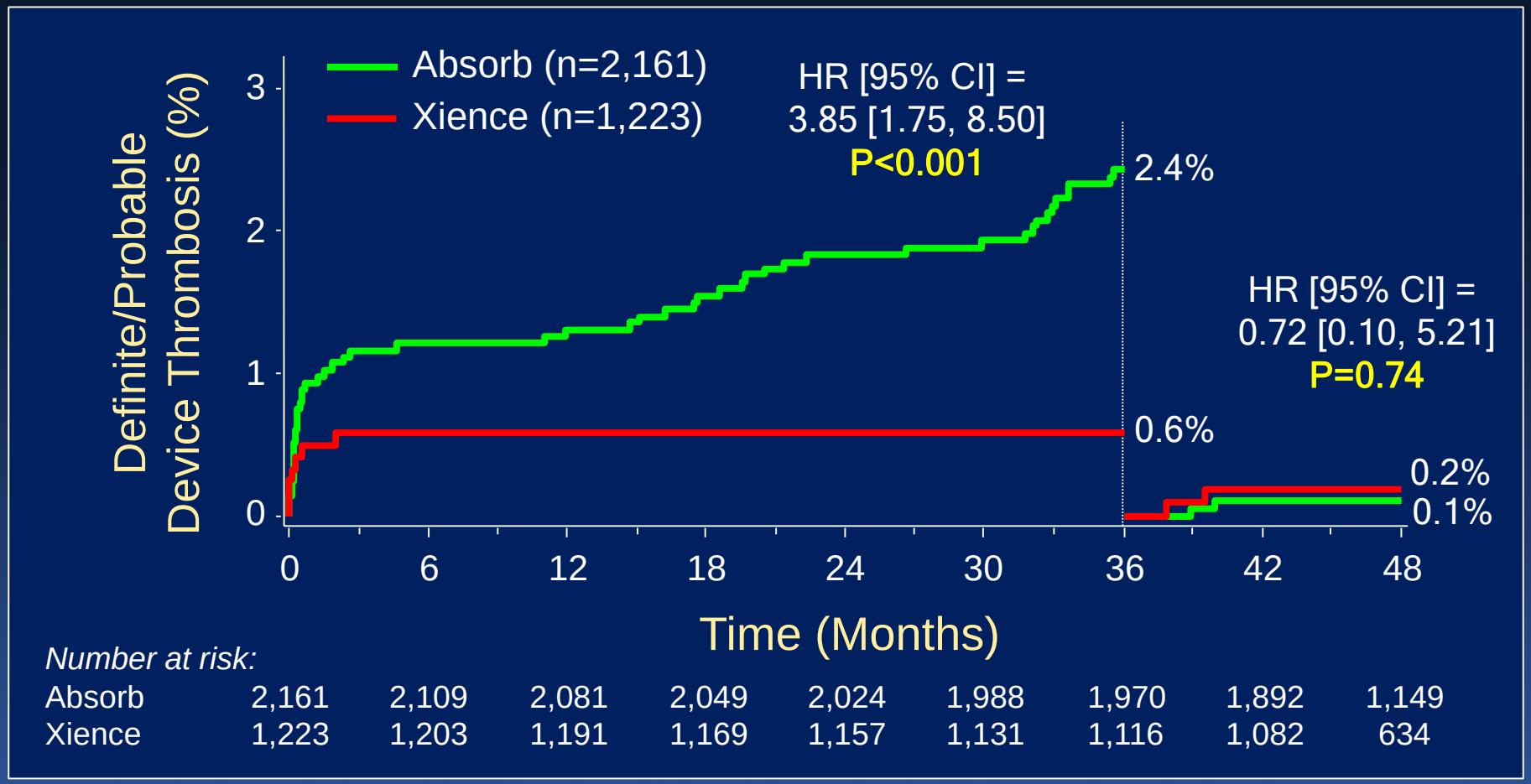
Number at risk:

Absorb	2,161	2,032	1,987	1,935	1,887	1,833	1,970	1,866	1,123
Xience	1,223	1,169	1,144	1,115	1,096	1,064	1,116	1,072	626

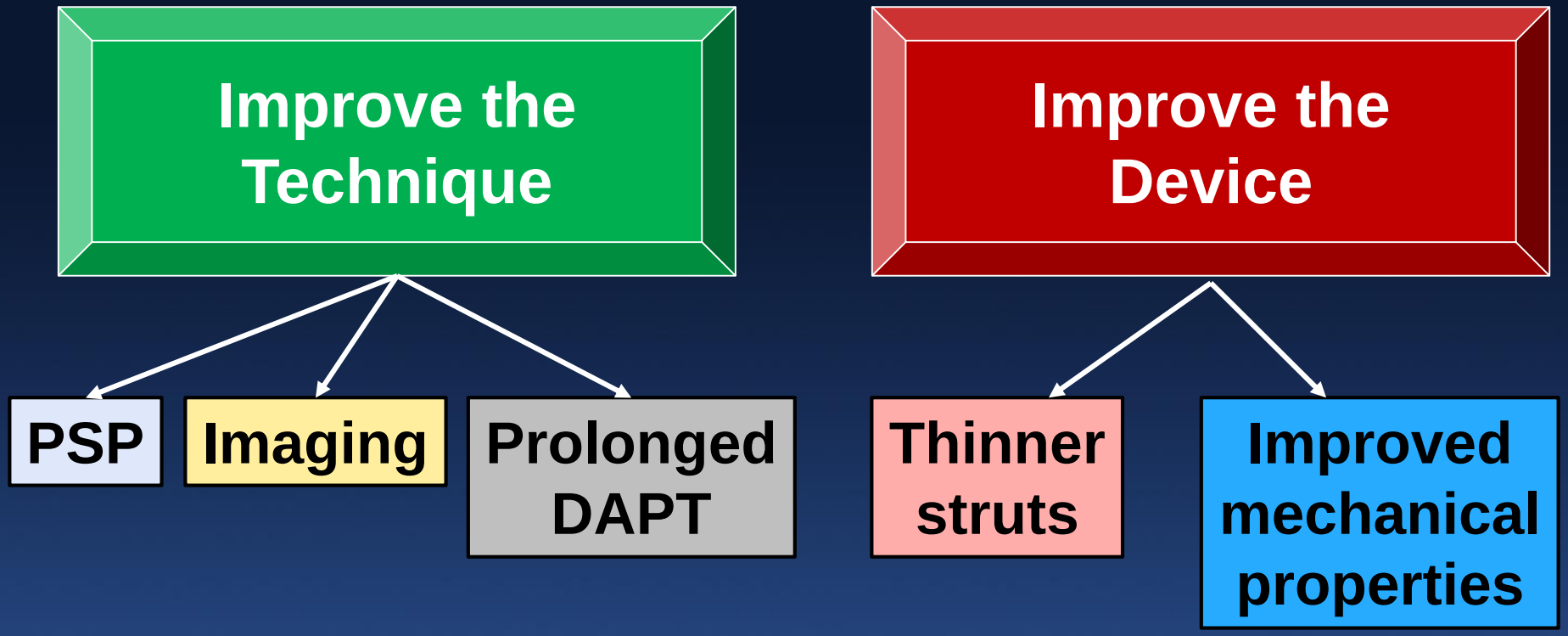
ABSORB: 4-year Outcomes

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

4-Year Device Thrombosis (Landmark)



How to Improve BRS Outcomes Prior to Their Complete Bioresorption



Hypothetical Keys to BRS 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

Performance of Optimal PSP Technique in 5 ABSORB studies

	Lesions (n=3,149)	Patients (n=2,973)
• Pre-dilatation:[1]	60.1%	59.2%
• Sizing:[2]	82.3%	81.6%
• Post-dilatation:[3]	12.7%	12.4%
• All PSP	5.0%	4.9%

[1]Performed in all lesions with a balloon to QCA-RVD ratio ≥1:1; [2]QCA-RVD ≥2.25 mm - ≤3.75 mm for all treated lesions; [3]Performed with a non-compliant balloon at ≥18 atm. and with nominal diameter larger than the nominal scaffold diameter, but not >0.5 mm larger

Trial Design (Blinded FU)

NCT01751906

~2,600 pts with SIHD or ACS
1 - 3 target lesions w/RVD
2.5-3.75 mm and LL ≤24 mm

Randomize 1:1
Stratified by diabetes and ABSORB III-like vs. not

Absorb BVS
N=1,300

Xience EES
N=1,300

BVS technique:
Pre-dil: 1:1; NC balloon recommended
Sizing: IV TNG; QCA/IVUS/OCT strongly recommended if visually estimated RVD ≤2.75 mm and 2.5 mm device intended; <2.5 mm ineligible!
Post-dil: 1:1, NC balloon, ≥16 atm strongly recommended

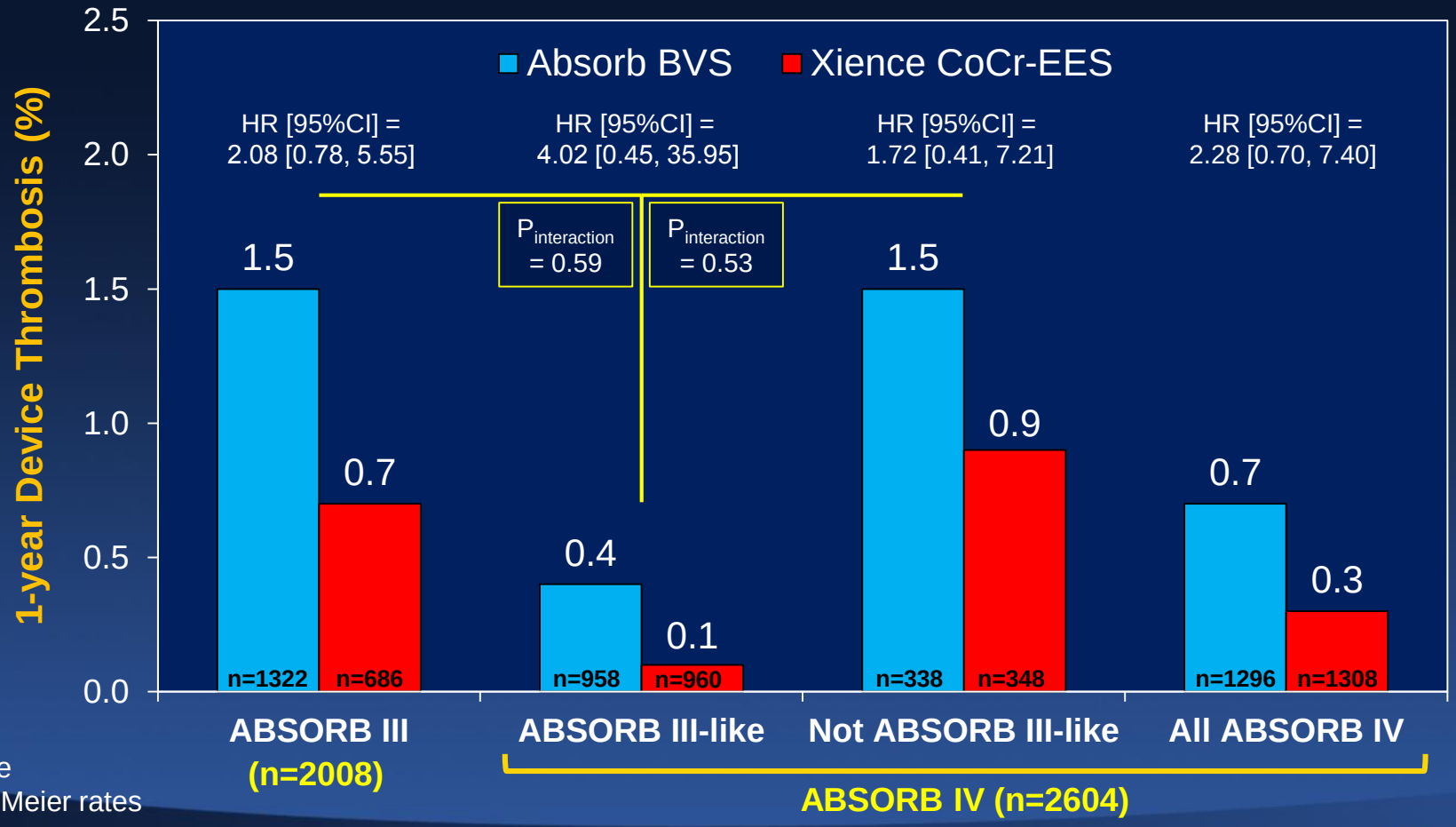
DAPT for ≥12 months
Clinical/angina follow-up: 1, 3, 6, 9, 12 months, yearly through 7-10 years
SAQ-7 and EQ-5D: 1, 6, 12 months and 3 and 5 years
Cost-effectiveness: 1, 2, and 3 years

Primary endpoints: TLF at 30 days; TLF between 3 and 7-10 yrs (pooled with AIII)
Secondary endpoints: TLF at 1 year; angina at 1 year

1-Year Device Thrombosis

ABSORB IV (n=2604) vs. ABSORB III (n=2008)

1918/2604 pts (73.7%) enrolled in ABSORB IV were “ABSORB III-like”; 686 (26.3%) were not (23.9% troponin+ ACS, 0.5% 3 target lesions treated, 2.1% thrombus)

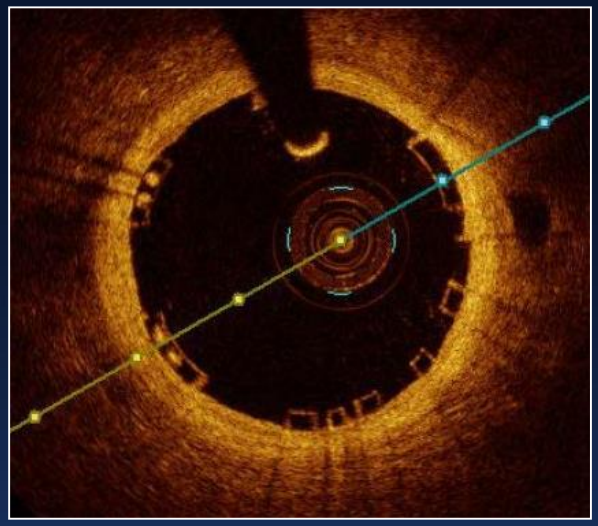


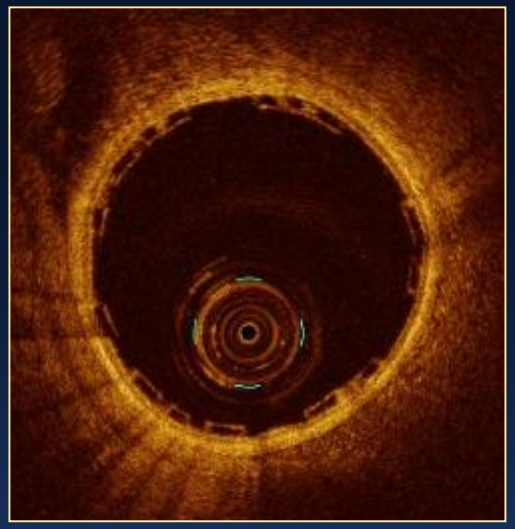
Data are Kaplan-Meier rates

Stone GW. Lancet 2018;392:1530-1540

Next Generation Absorb
"Falcon"

Absorb GT1
157 *u*m
strut
thickness





Falcon
<100 *u*m
strut
thickness

Conclusions: A Cautiously Optimistic Perspective on Bioresorbable Scaffolds

- Data have emerged that optimizing technique when implanting the thick-strut 1st gen Absorb BVS can improve mid-term results
- Improved BRS have been developed that promise to overcome many of the current limitations
- Implanted with optimized technique, improved BRS devices may be as safe as metallic DES and offer the potential to overcome metallic DES limitations and improve lifelong outcomes in pts with coronary artery disease