BVS: aktuální data

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KLINIKA KARDIOLOGIE

BVS ABSORB (PLLA)

ABSORB III

2,250 pts with up to 2 de novo lesions in different epicardial vessels enrolled, with follow-up for at least 5 years, at up to 122 US and non-US sites

2,000 pts randomized 2:1 ABSORB vs. XIENCE

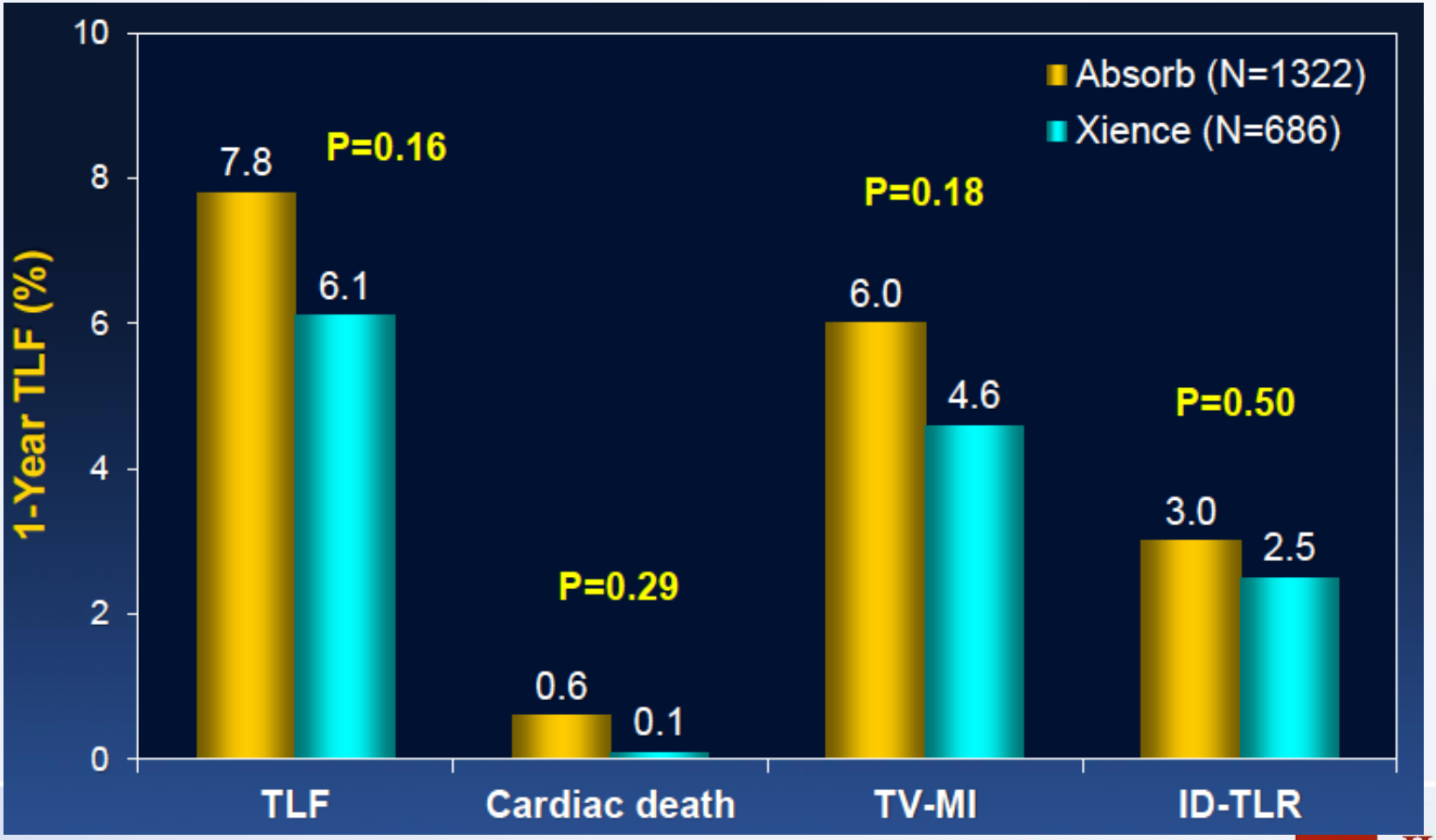
(+50 lead-in pts and 200 pt non-randomized angio/IVUS/OCT/VM FU cohort)

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

Primary endpoint (n=2,000):

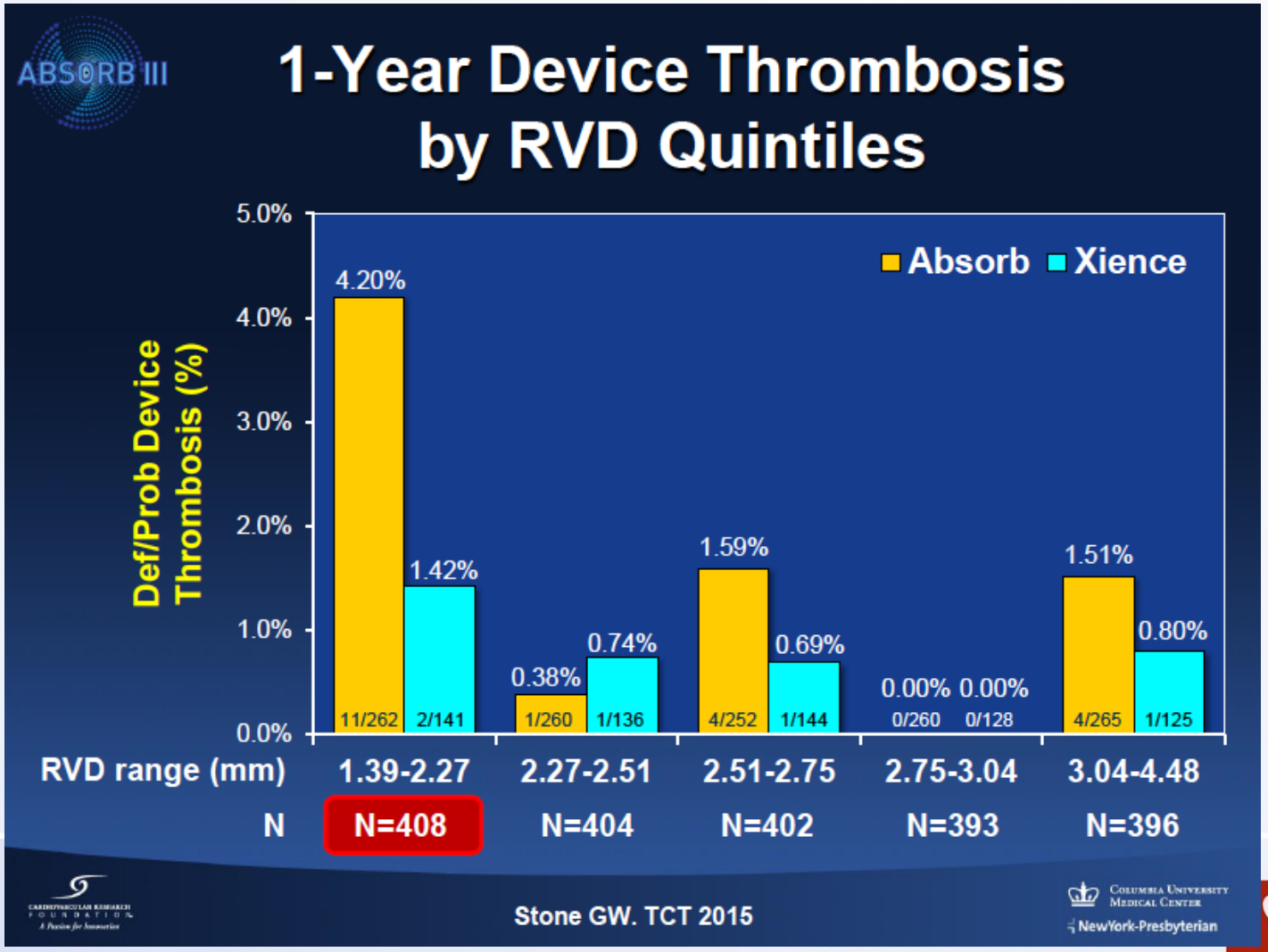
ABSORB III: 1 roční endpointy



ABSORB III:
Trombóza stentu do 1 roku

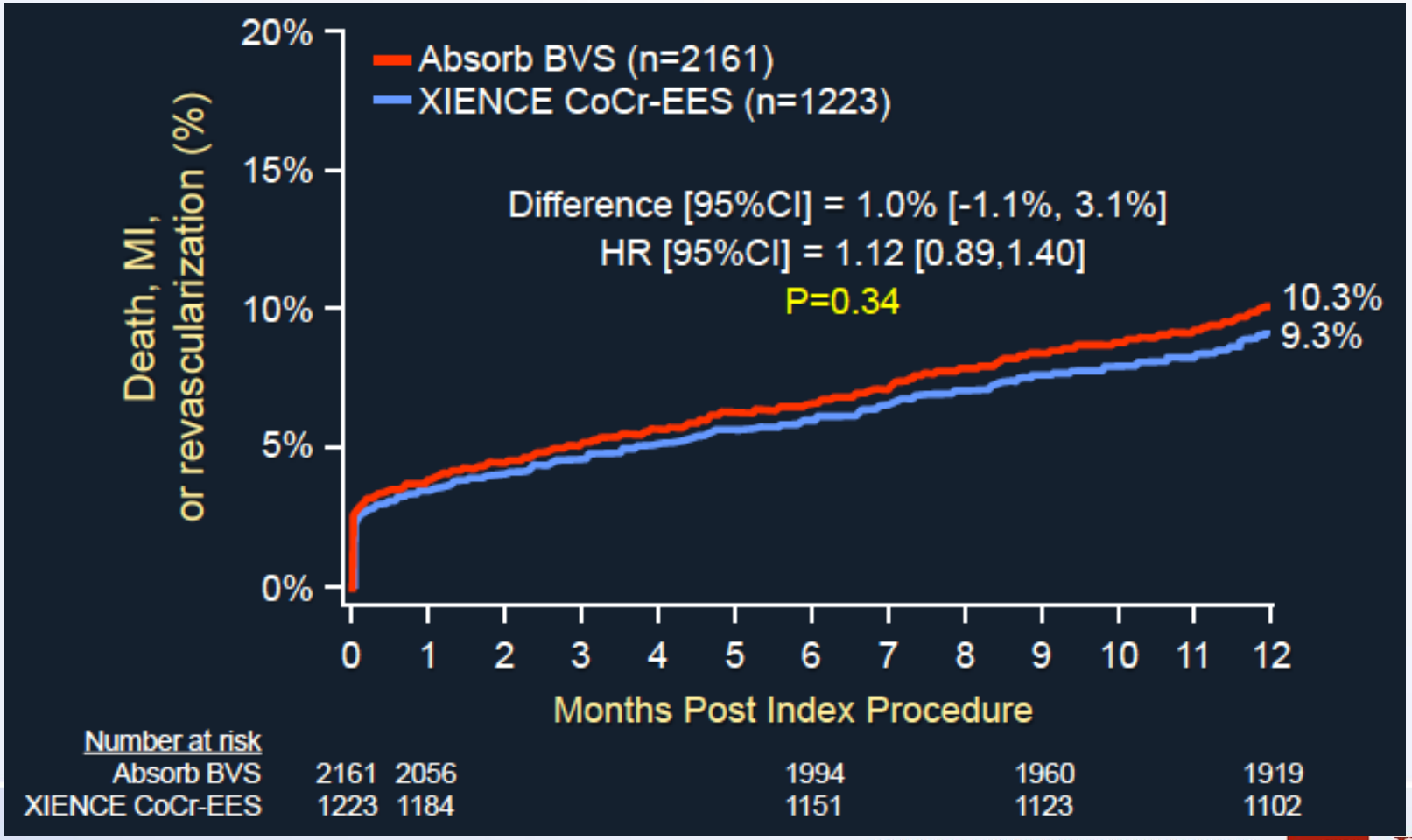
	Absorb (N=1322)	Xience (N=686)	p-value
Device Thrombosis (def*/prob)	1.54%	0.74%	0.13
- Early (0 to 30 days)	1.06%	0.73%	0.46
- Late (>30 days to 1 year)	0.46%	0.00%	0.10
- Definite* (1 year)	1.38%	0.74%	0.21
- Probable (1 year)	0.15%	0.00%	0.55

ABSORB BVS: tepny < 2,5 mm

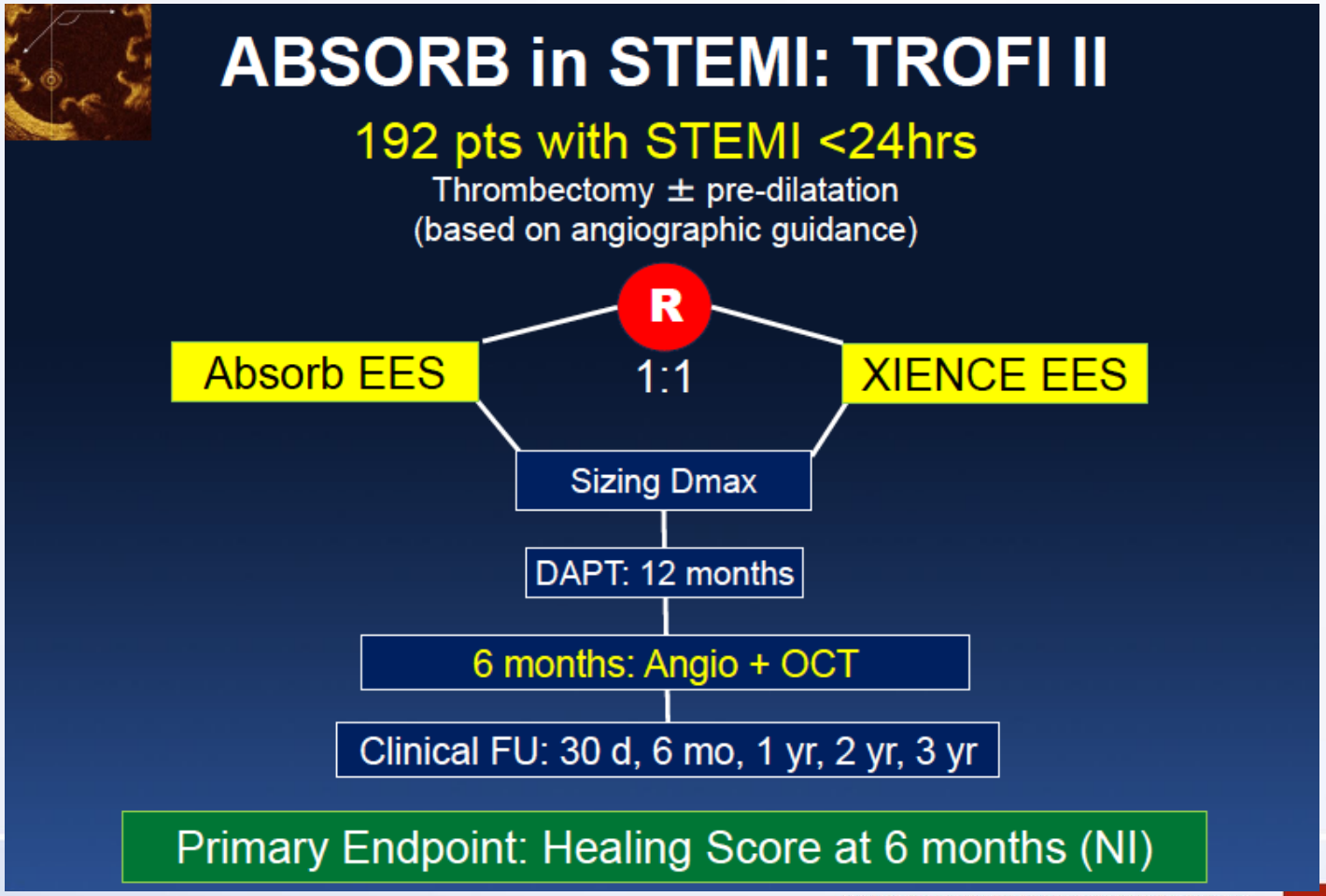


ABSORB stent: 1-roční metaanalýza

(ABSORB II, III, ABSORB Japan, ABSORB China)



BVS u AKS: Prague 19, TROFI II, BVS-EXAMINATION, POLAR ACS, GHOST-EU Registry, BVS-RAI registr, BVS STEMI



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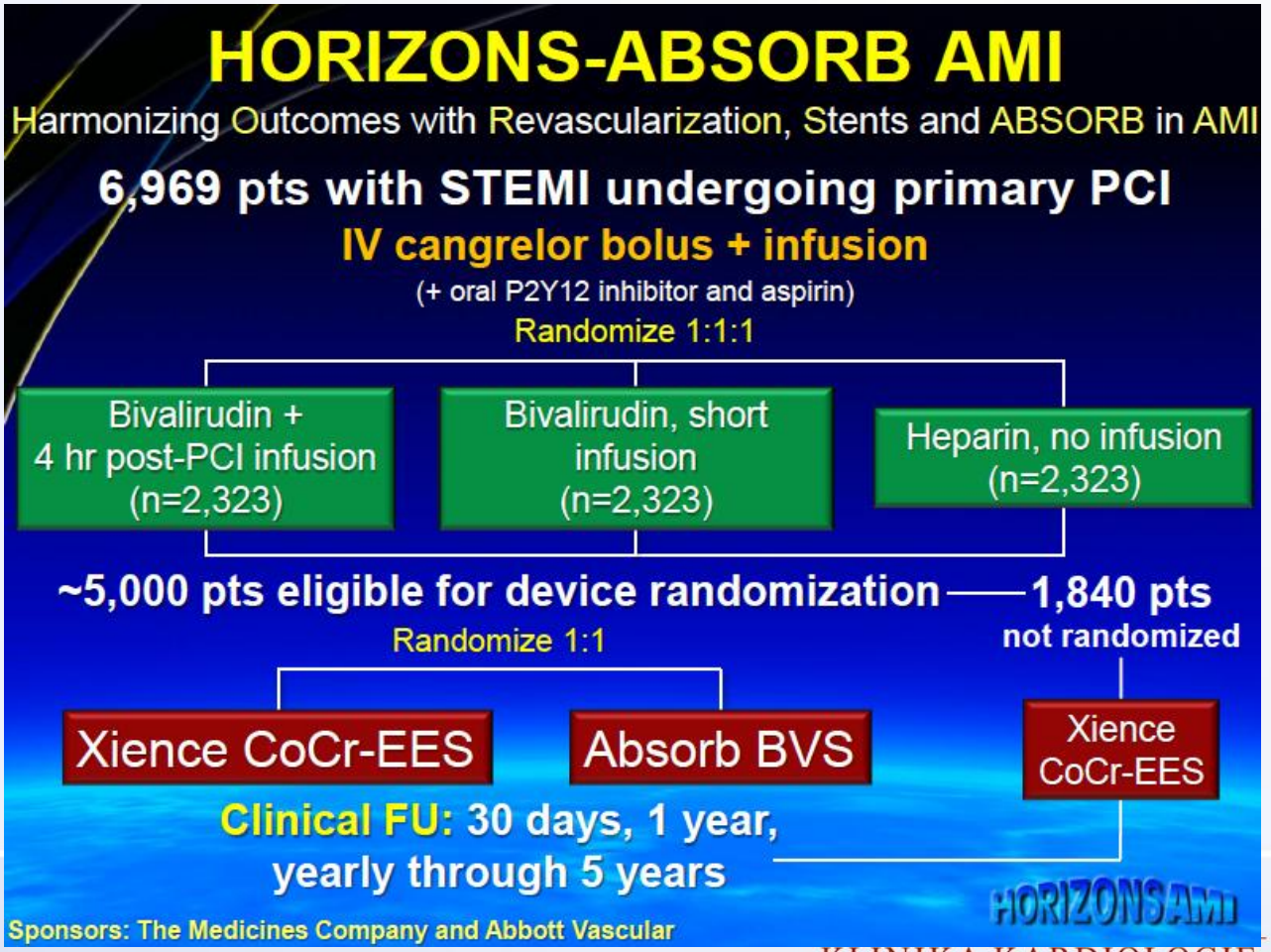

MAGNESIUM BVS PROGRAM

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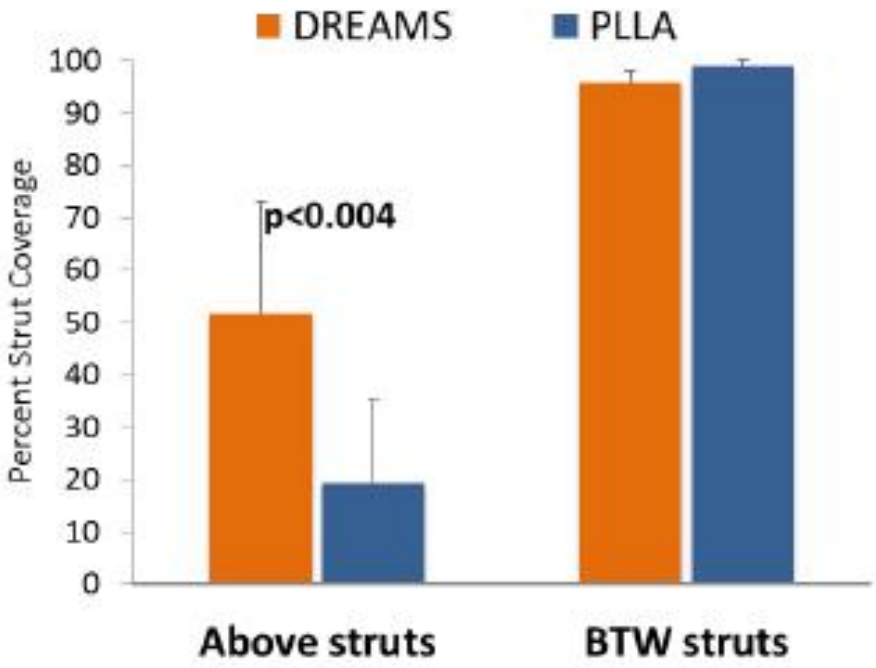
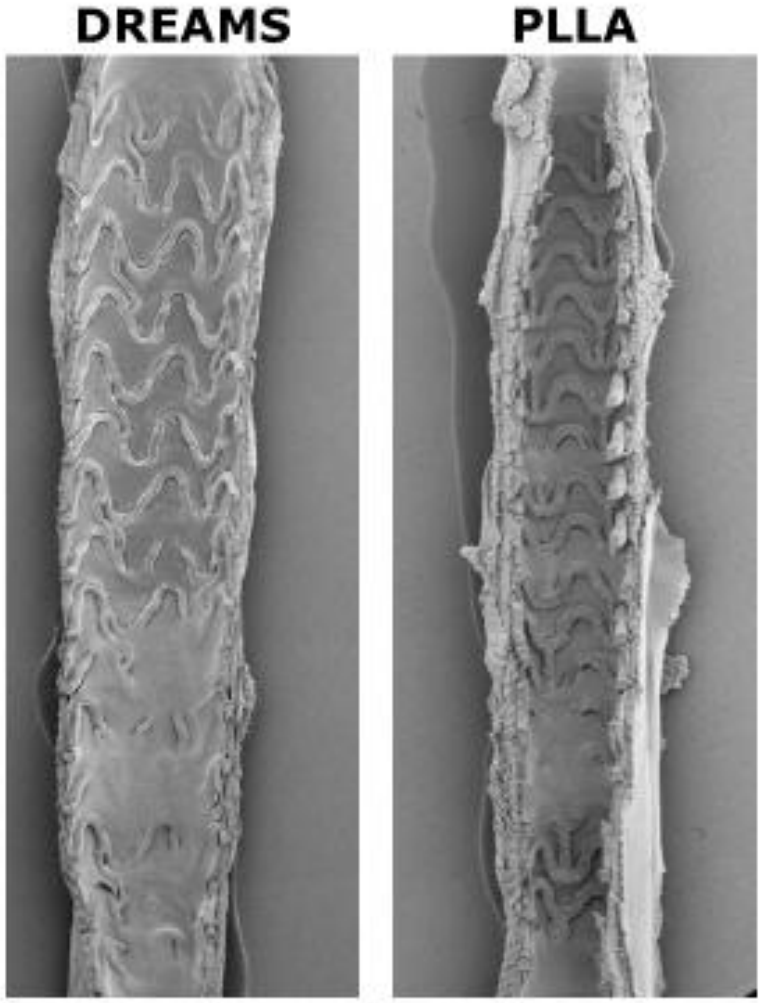
Evolution of the BIOTRONIK Magnesium Scaffold

	Device generation	AMS	DREAMS 1G	DREAMS 2G
Design	Sizes (mm)	Ø 3.0 & 3.5 Length: 15, 20	Ø3.25 & 3.5 Length: 15	Ø 2.5, 3.0 & 3.5 Length: 15, 20, 25
	Backbone	Mg alloy	Refined Mg alloy	Refined Mg alloy
	Strut thickness/width	165/80 µm	120/130 µm	120/120 µm (Ø 2.5) 150/150 µm (Ø 3.0 & 3.5)
	Markers	none	none	Ta-composite
	Coating - drug	none	PLGA/PTX	PLLA/SIR
	Crossing profile in mm	1.6	1.5	1.75
Kinetics	Drug elution kinetics	n.a.	like Taxus	like Orsiro
	Absorption period in month	1-2	3-4 (Mg)	≈12 (Mg)
Results	In-segment Late Lumen Loss (mm)	0.83±0.51	0.52±0.48	?
	In-scaffold Late Lumen Loss (mm)	1.08±0.49	0.65±0.50	?
	TLF* (%)	23.8	4.3	?
	Definite or Probable Scaffold	0.0	0.0	?

DREAMS 2G vs Absorb BVS:
Endothelialization in New Zealand white rabbits at 28 days





Source: Adapted from M. Joner, oral presentation, CRT 2015.

BIOSOLVE-II Comparison of clinical results in PROGRESS, BIOSOLVE-I and BIOSOLVE-II

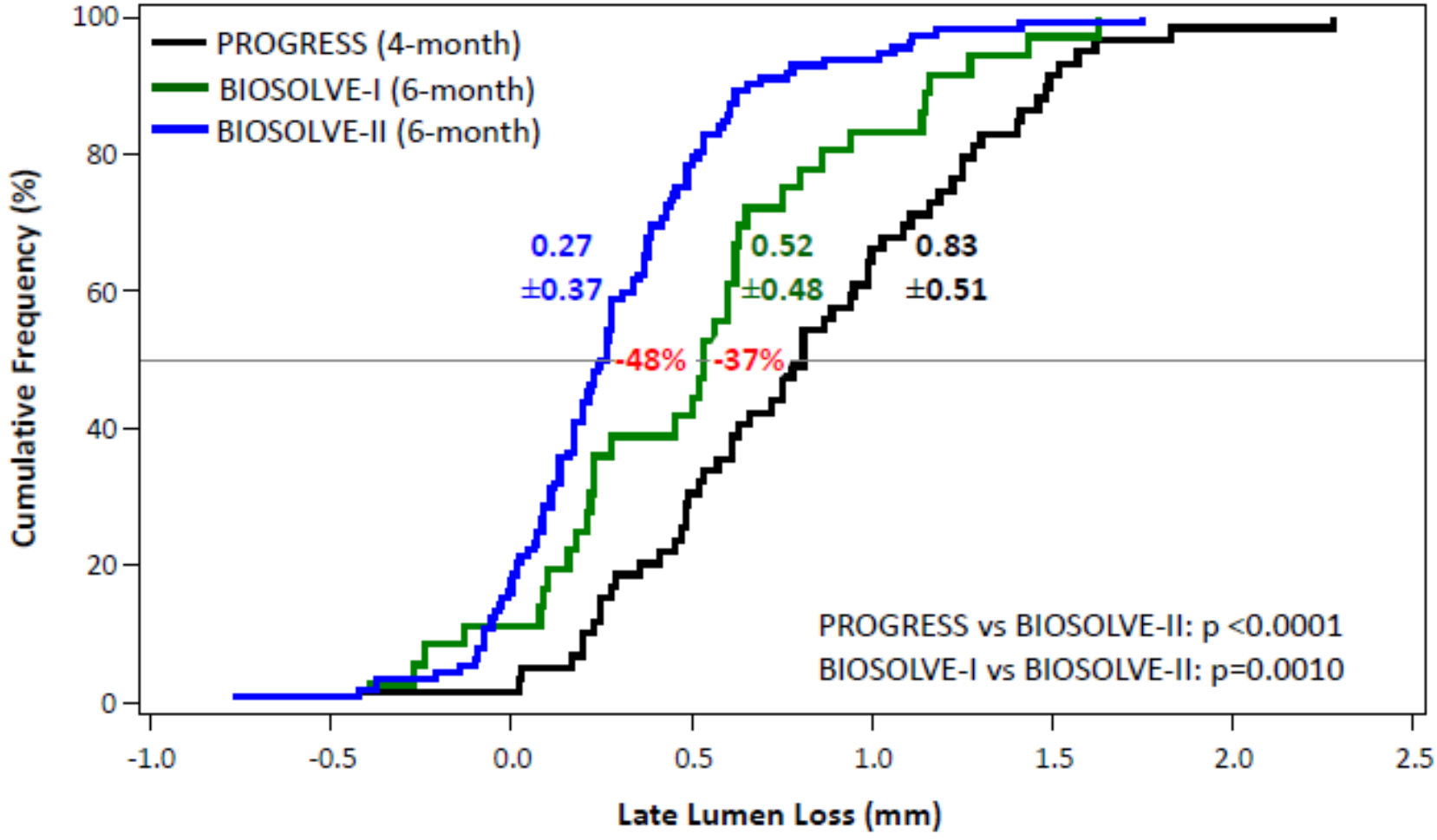
Clinical results at 6-month (4-month for PROGRESS)

	PROGRESS N=63	BIOSOLVE-I N=46	BIOSOLVE-II N=123
TLF[1] (%)	23.8	4.3	3.3
Cardiac Death (%)	0.0	0.0	0.8
Target Vessel MI (%)	0.0	0.0	0.8
Clinically driven TLR (%)	23.8	4.3	1.7
CABG	0.0	0.0	0.0
Scaffold Thrombosis Definite or probable	0.0	0.0	0.0

1. Composite of cardiac death, target vessel myocardial infarction, clinically driven target lesion revascularization and CABG

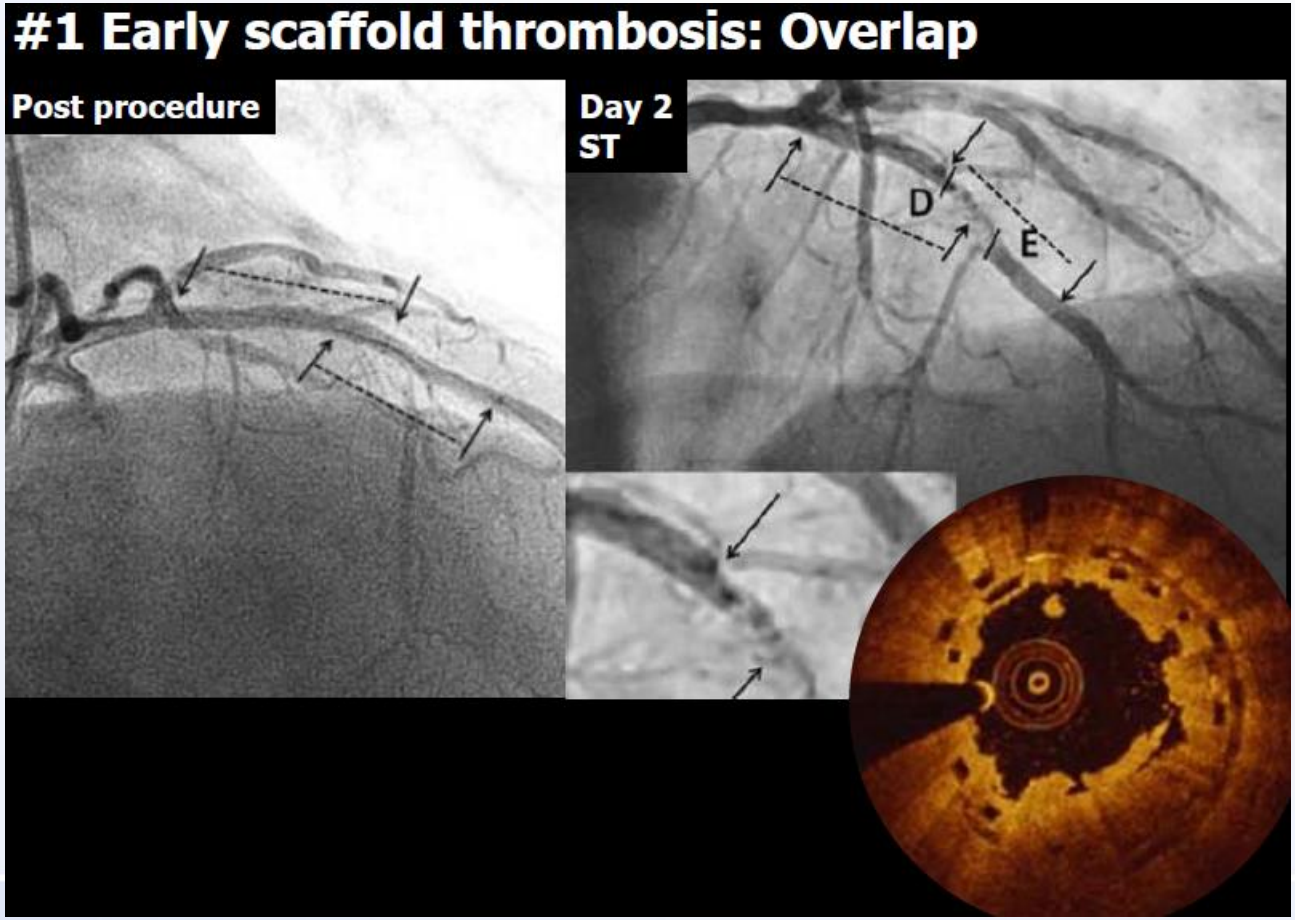
BIOSOLVE-II

Comparison of in-segment LLL in PROGRESS, BIOSOLVE-I and BIOSOLVE-II

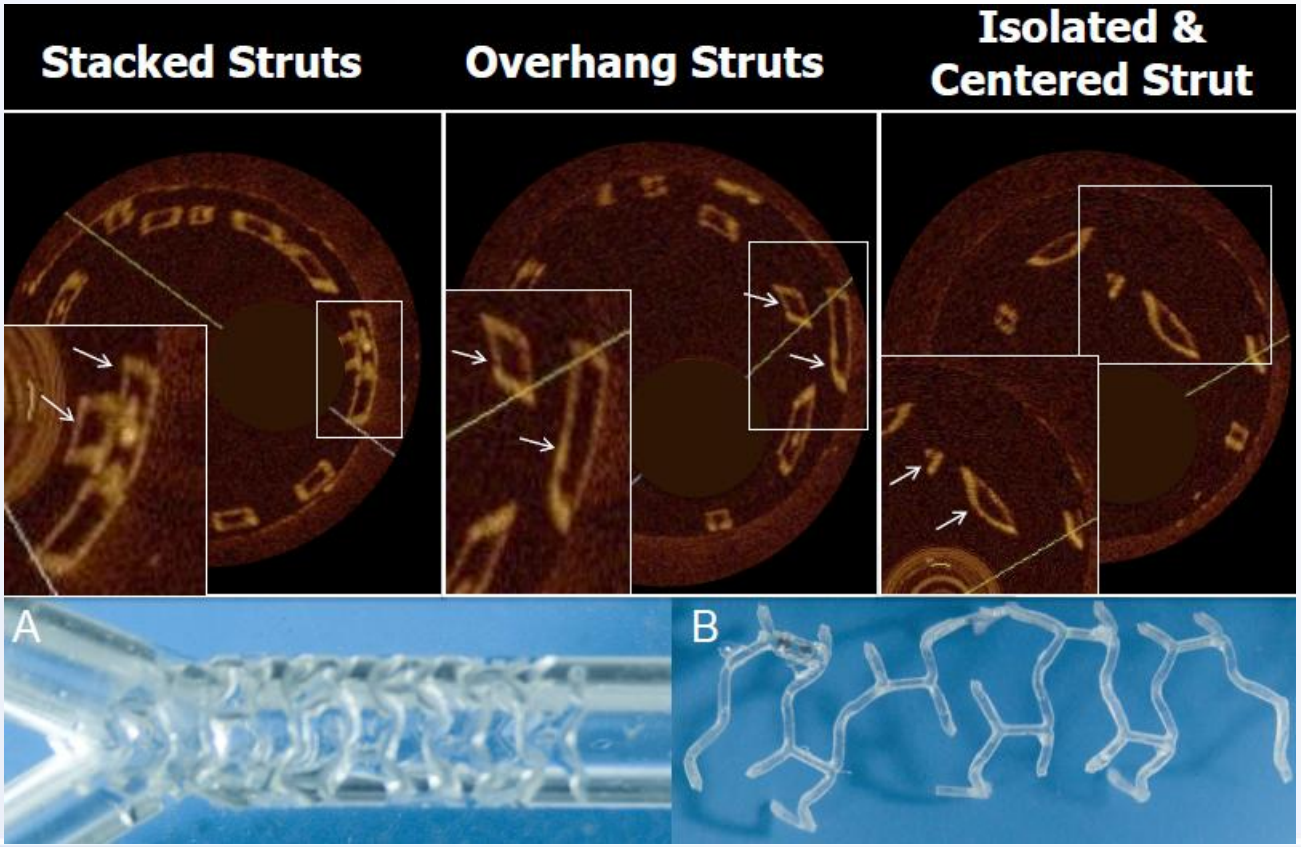


KOMPLIKACE BVS

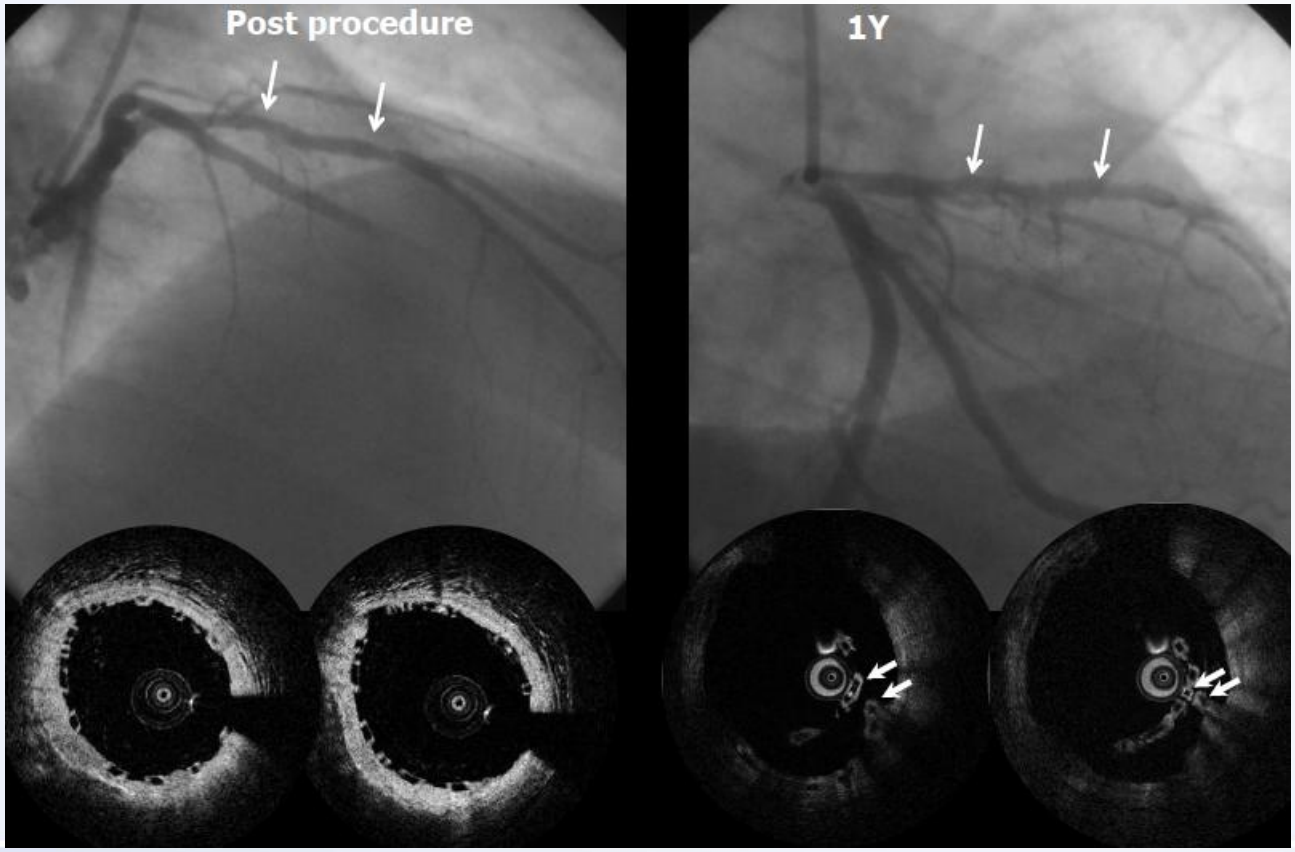
Akutní/časná trombóza BVS:
malapozice, underexpansion, překrytí strutů



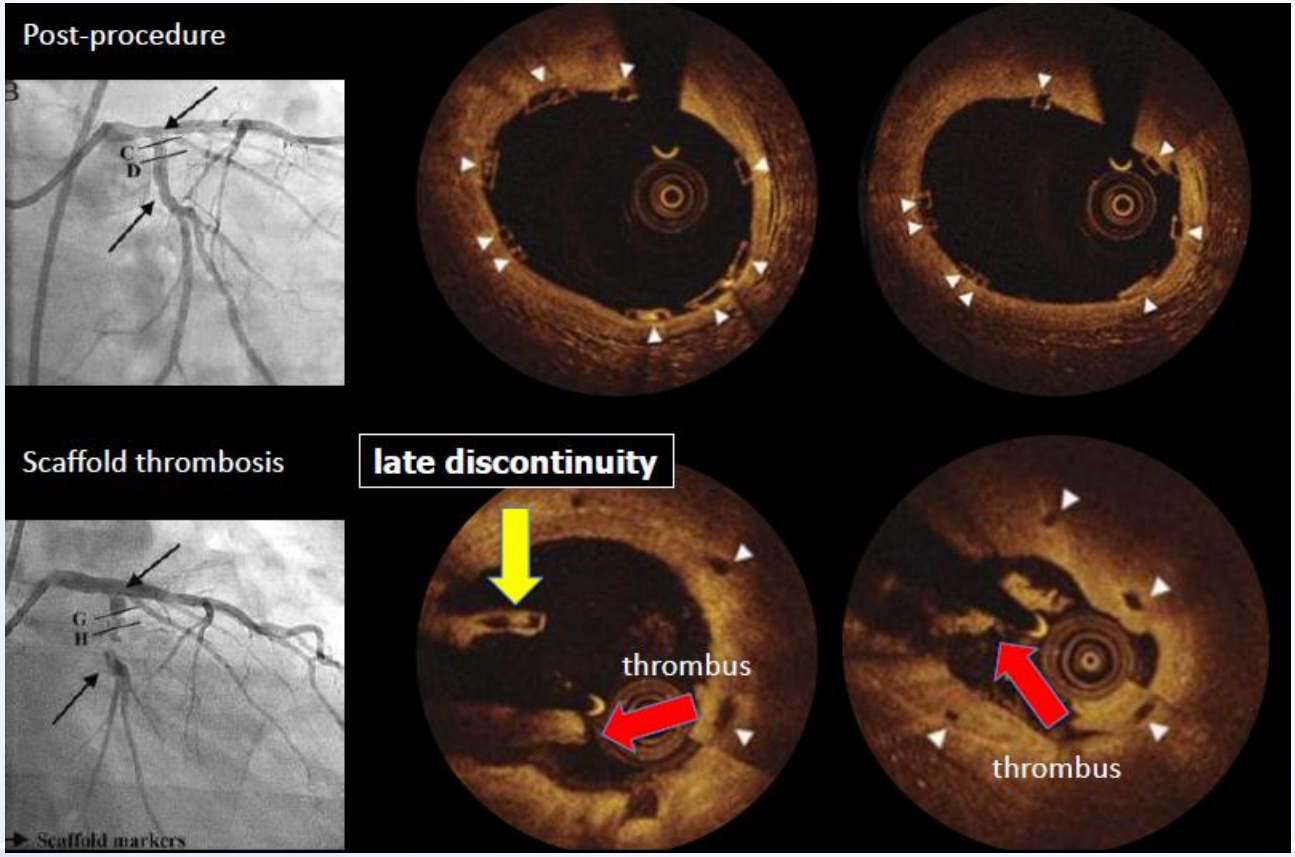
Desinetegrace BVS



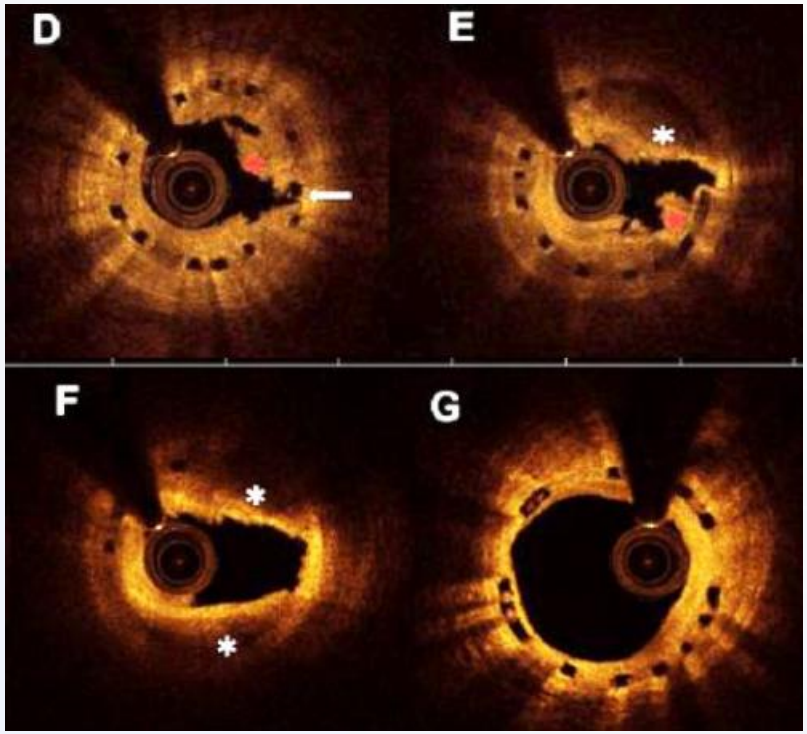
Pozdní desintegrace BVS v průběhu resorpce



Velmi pozdní trombóza BVS

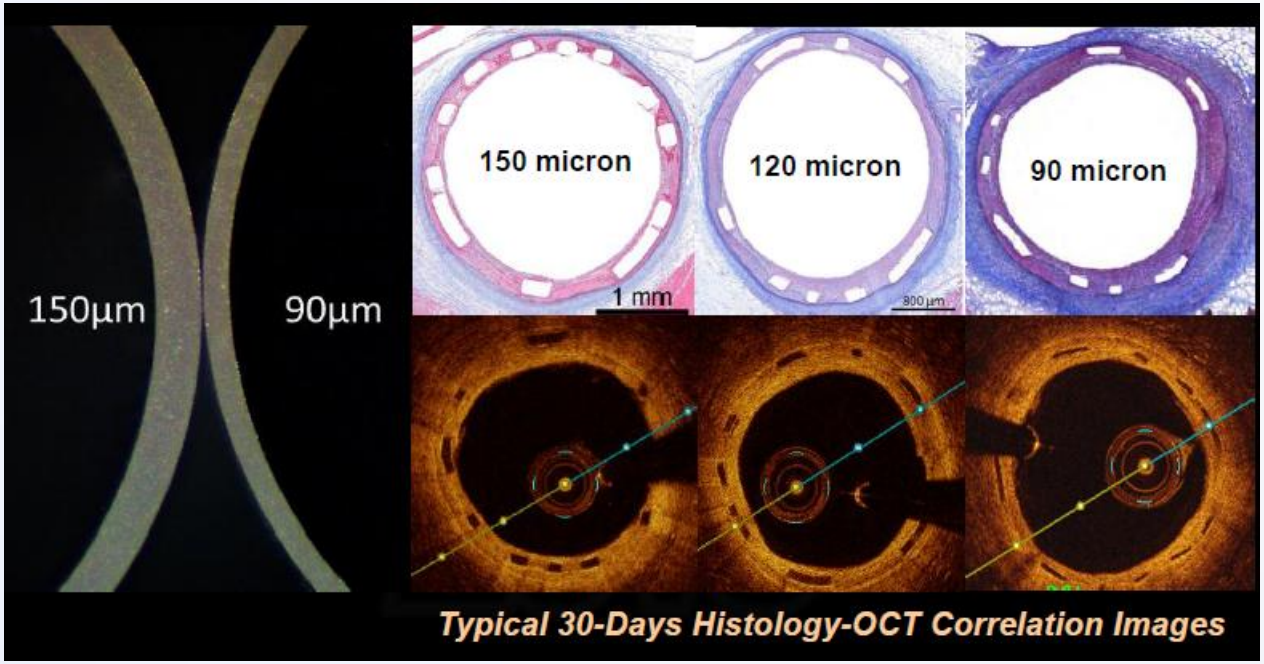


Neoateroskleróza

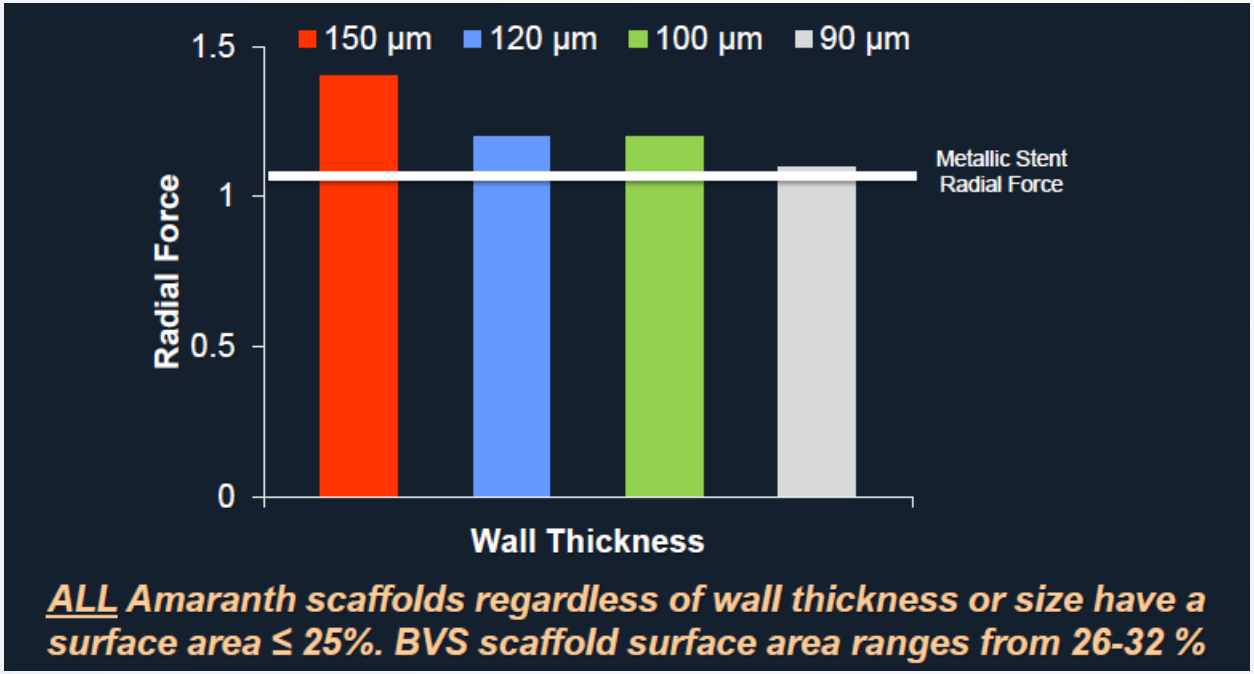


BVS: BUDOUCÍ SMĚRY VÝVOJE

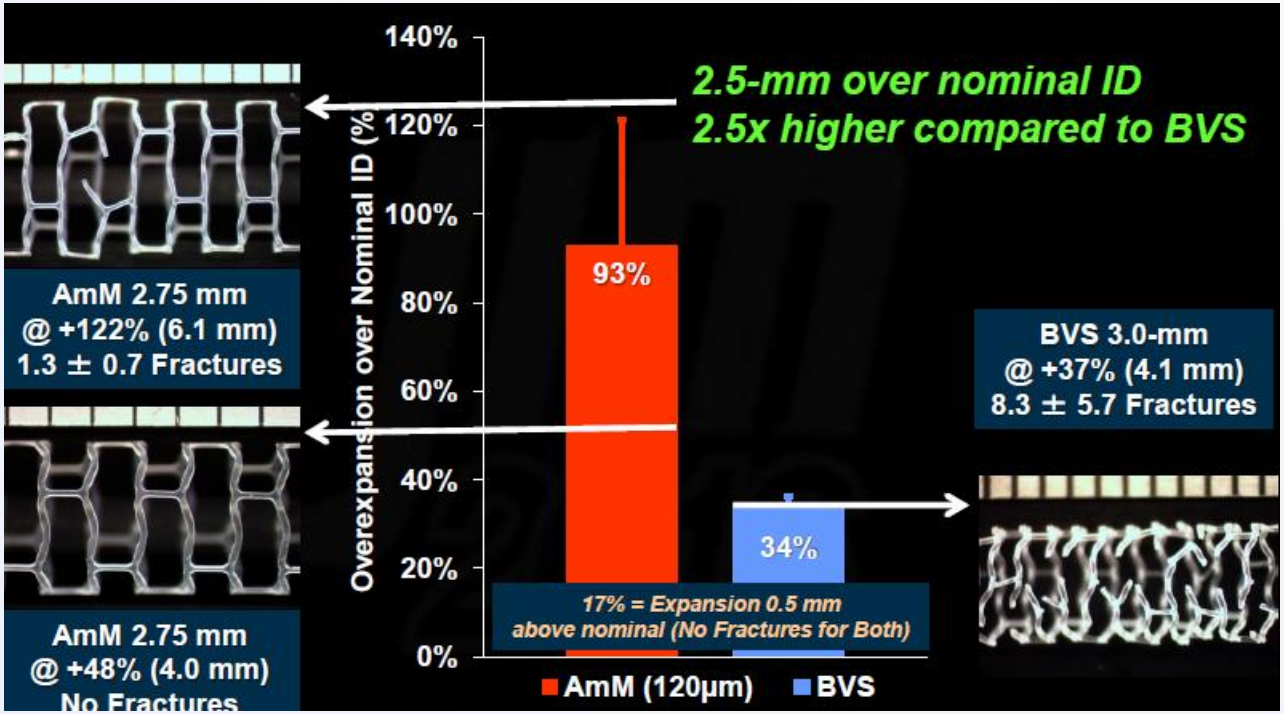
Budoucnost BVS: tenčí struty, lepší mechanické vlastnosti



Zachování radiální síly



Možnost „overexpanze“ BVS



BVS: závěry

- U nemocných s jednoduchými lézemi a stabilní ICHS má (ABSORB) BVS obdobné klinické výsledky jako DES (Xience)
- ABSORB BVS má vyšší výskyt trombózy stentu, tato je významná v malých tepnách (RVD < 2,5 mm)
- Závěry platí pro vysoce selektovanou populaci
- Technika implantace BVS vyžaduje pre I postdilataci
- Liberální užití zobrazovacích metod (OCT, IVUS)
- DAPT zřejmě déle jak 1 rok

- **Nové generace BVS jistě zlepší stávající výsledky**
- **Srovnání nutné s moderními DES**