20TH CARDIOVASCULAR SUMMIT

TCTAP2015

Limited Adoption in Selected Patients Is Possible.

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Bioresorbable scaffolds

Company	Stent	Development	Pre-clinical	Clinical trials	Post-market
Kyoto Medical	Igaki-Tamai	✔	✔	✔	
Biotronik	Dreams	✔	✔	✔	
Abbott	Absorb	✔	✔	✔	✔
Art	Art18AZ	✔	✔	✔	
Reva Medical	Resolve	✔	✔	✔	
Xenogenics	Ideal biostent	✔	✔		
Orbus Neich	Acute	✔	✔		
Elixir	DESolve	✔	✔	✔	✔
Amaranth	Amaranth PLLA	✔	✔		
Huaan Biotech	Xinsorb	✔	✔	✔	
S3V	Avatar	✔	✔		
Meril	MeRes	✔	✔		
Zorion Medical	Zorion BRS	✔	✔		
Lifetech	Lifetech Iron	✔	✔		

1st generation BVS characteristics

Potentially limiting wide adoption in "real word" scenario in complex lesions

- thickness (>150µm with more than 200µm width)
- fragility

Strut Thickness

First generation BVS thickness

- Poor deliverability in tight lesions and tortuous vessels
- limitation in treating small vessel disease, no BVS smaller than 2.5 mm
- difficulties in side-branch access
- avoiding scaffolds overlapping
- bifurcation techniques
- and, potential thrombogenicity

Strut Thickness

- 100 µm new generation BVS already CE marked > soon commercially available in Europe
- Radial force?
- Bioresorption ?

Fragility

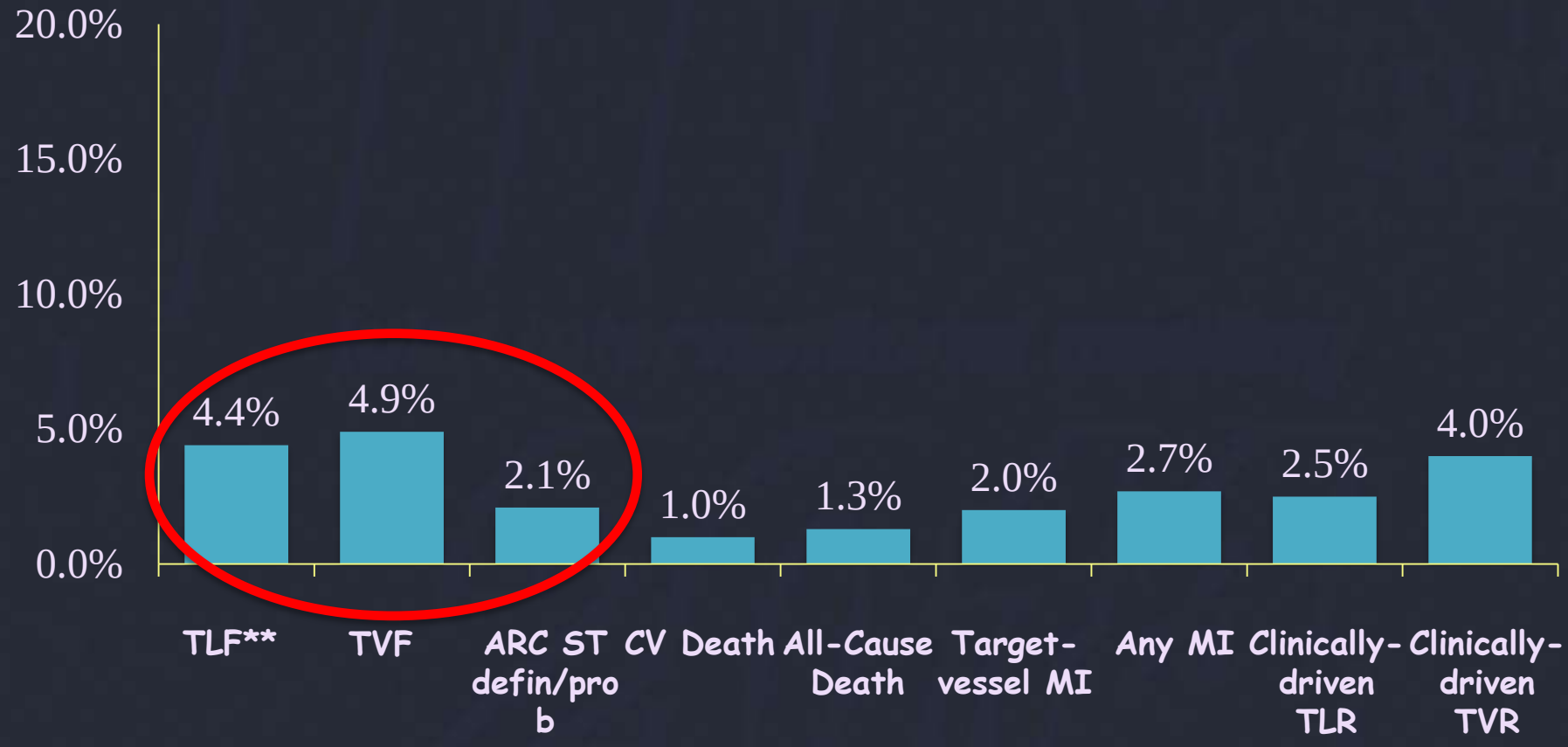
- Slow dilatation during implantation is necessary.
  - potential risk of misalignment
- Dilatation beyond limit may result in acute scaffold disruption.
  - not applicable to large vessel
  - when side-branch dilatation and kissing-balloon inflation

1 Gen BRS use in real world registries

	patients	type B2/C (%)	Follow up (months)	MACE (%)	TLR (%)	Scaffold thrombosis (%)
Costopoulos et al. 2014	92	83.9	6	3.3	3.3	0 (d)
ABSORB EXTEND Registry	512	41.0	12	4.3	1.8 (ID)	0.8 (d/p)
Liang et al. Registry	35	75.0	2	0	0	0
GHOST EU Multicentre registry	1189	51.2	6	10.1 (TLF)	2.5	2.1 (d/p)
AMC registry et al. Registry	135	67.0	6	8.5	6.3	3 (d)
Elabbassi et al. Registry	140	62.0	12	7.2	2.9 (ID)	
L'Allier P et al. Registry	339	41.0	In-hospital	2	0	1.2 (d)
ASSURE Registry	183	64.6	12	5	2.8	0
ABSORB FIRST[24] Registry	1200	46.7	1	0.8	N/A	0.42 (d/p)

GHOST-EU

6-month outcomes



*Event rates are expressed as Kaplan–Meier estimates

** Device-Oriented composite primary endpoint

EMO GVM CENTRO CUORE COLUMBUS s.r.l.

GHOST-EU

GHOST-EU

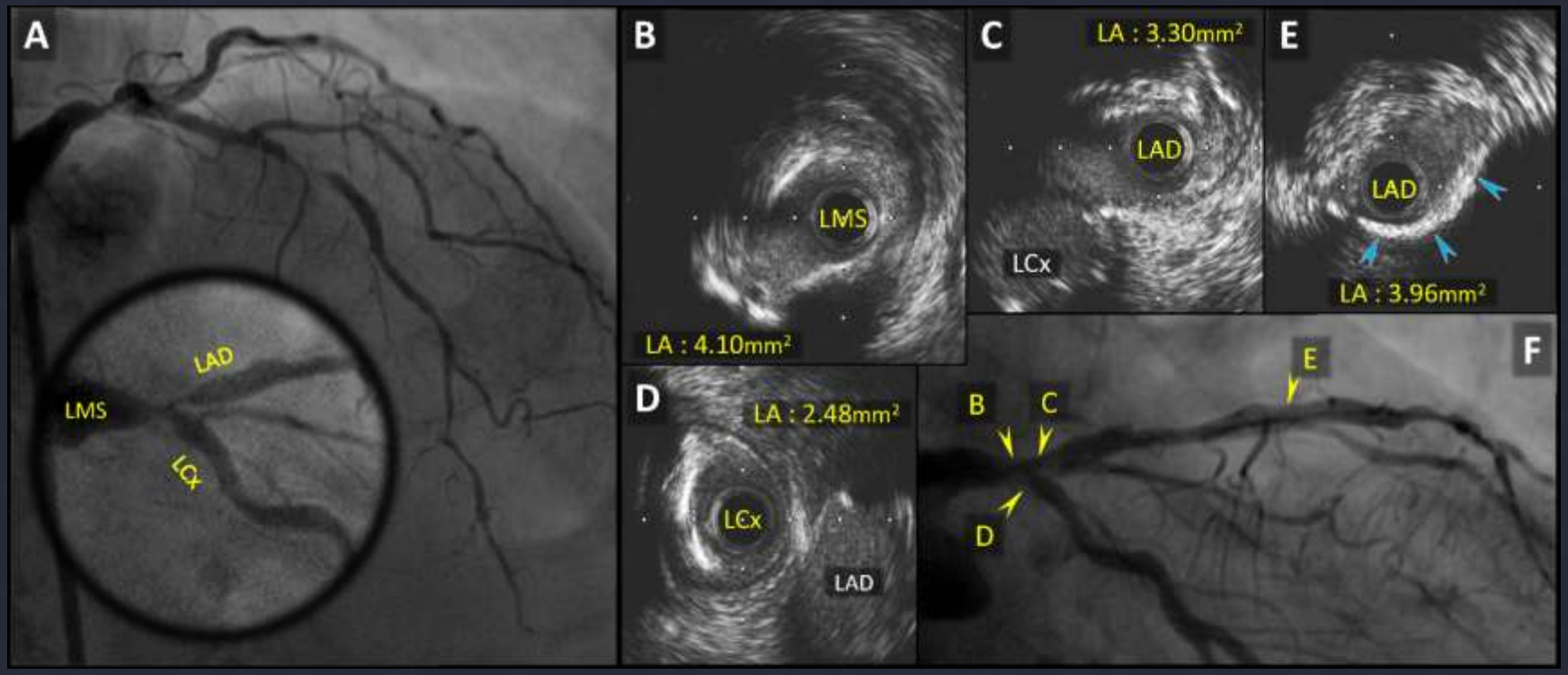
Lesion-based	
Pre-Dilatation	1,405/1,440 (98%)
Post-Dilatation	712/1,1440 (49%)
Patient-based	
No. Target Lesion/Pt	1.2±0.5
Multivessel Disease	485/1,186 (40.9%)
SYNTAX Score	11.3±7.9 (820)
Hybrid (BVS plus non-BVS)	219/1,189 (18.4%)
IVUS-guided	171/1,184 (14.4%)
OCT-guided	163/1,184 (13.8%)
Tot. Scaffold Length (mm)	32.6±23.0 (1,189)
Aver. Scaffold Diameter (mm)	3.0±0.5 (1,189)
Tot. Scaffold Implanted (n)	1731

Long Lesions and Diffuse Disease

- BVS is promising in diffuse disease taking its absorption into account
- It is currently the first indication in my practice
- No Overlap but adjacent scaffolds
  - results in further decrease in lumen area
  - increases risk of delayed endothelialisation
  - should be avoided in favor of adjacent scaffolds

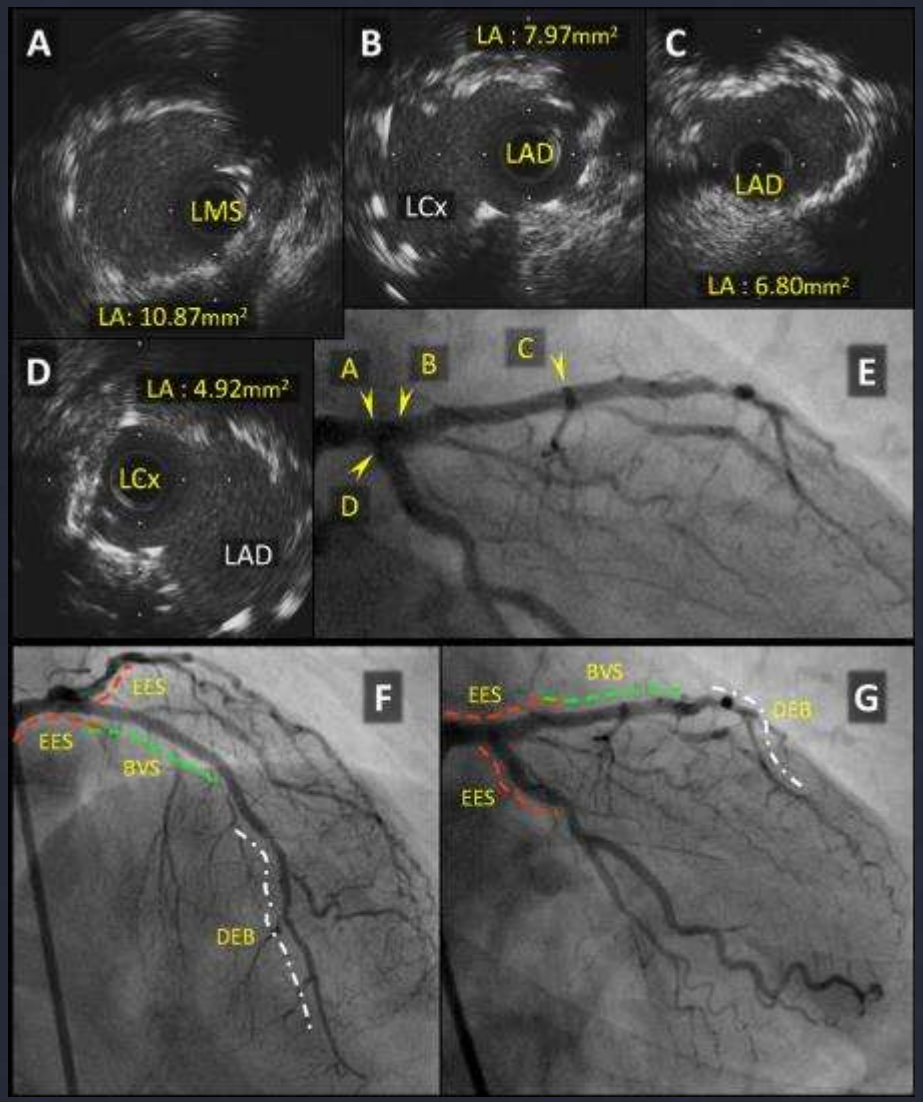
Farooq, V., et al. (2011). "Optical coherence tomography (OCT) of overlapping bioresorbable scaffolds: from benchwork to clinical application." EuroIntervention 7(3): 386-399.

Long Lesions and Diffuse Disease



Hybrid revascularization with DES in LMS and BVS and DEB for diffuse LAD disease

Long Lesions and Diffuse Disease



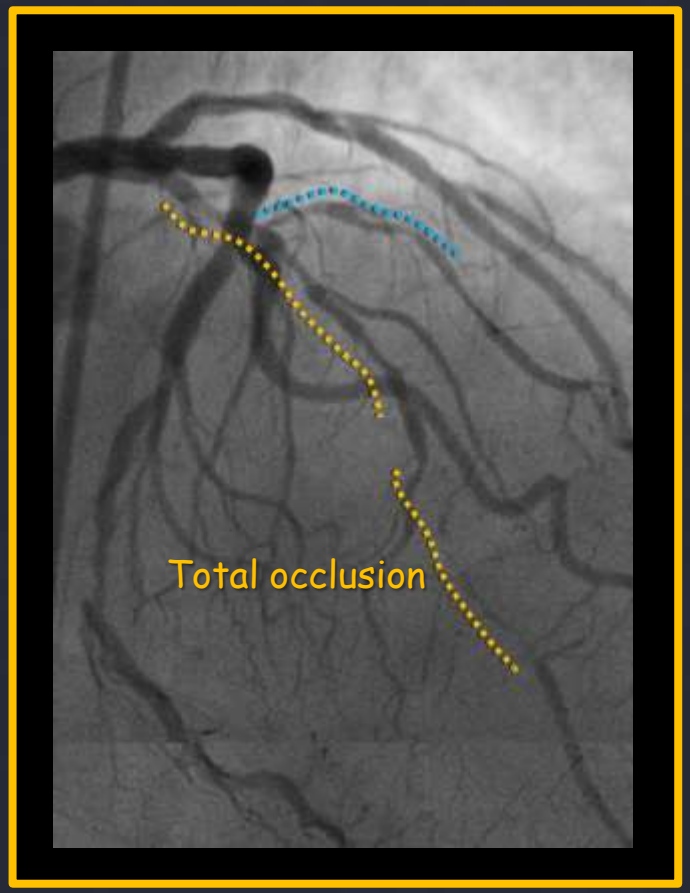
Panoulas VF Miyazaki T et al. Hybrid percutaneous coronary revascularisation for a patient with left main bifurcation and extensive, diffuse coronary artery disease Int J Cardiol 2014

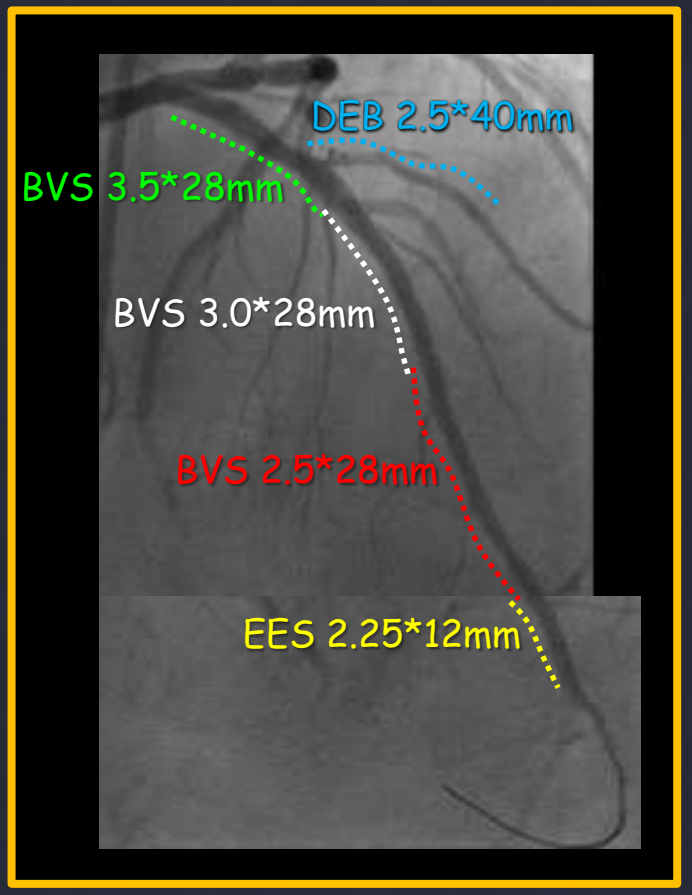
Chronic Total Occlusion

- As in diffuse disease, BVS can be promising also in CTO lesions.
- Lesion crossability and distensibility could be a matter of concern.
- Evidence stems from just a small number of case reports

Gori T, Guagliumi G, Munzel T. Absorb bioresorbable scaffold implantation for the treatment of an ostial chronic total occlusion. Int J Cardiol 2014;172:e377-8.

Chronic Total Occlusion

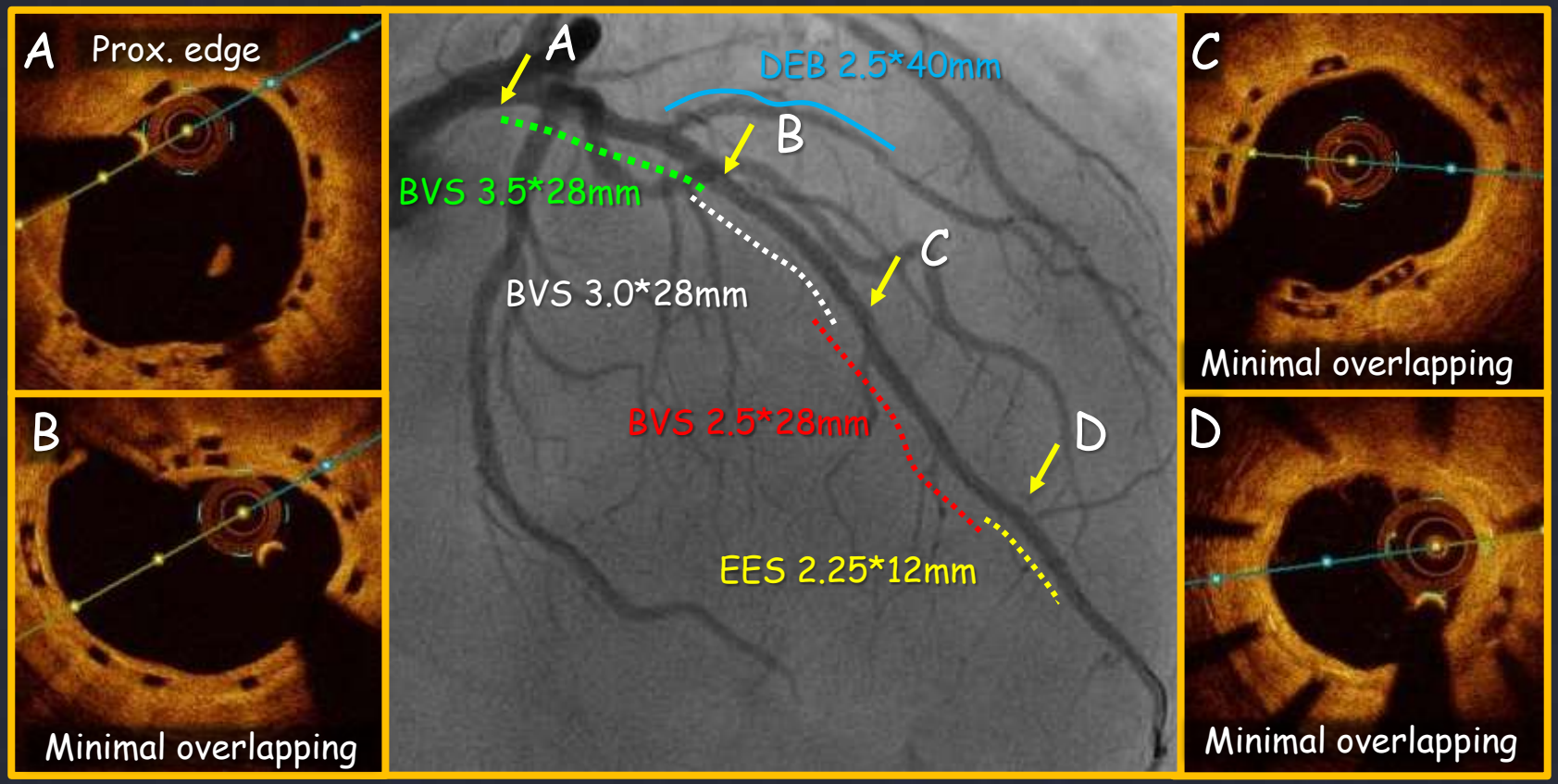




- Diffusely diseased LAD with CTO ( )
- Severe stenosis in the diagonal ( )
- All lesions were treated with 3 BVS + small EES + DEB

Chronic Total Occlusion

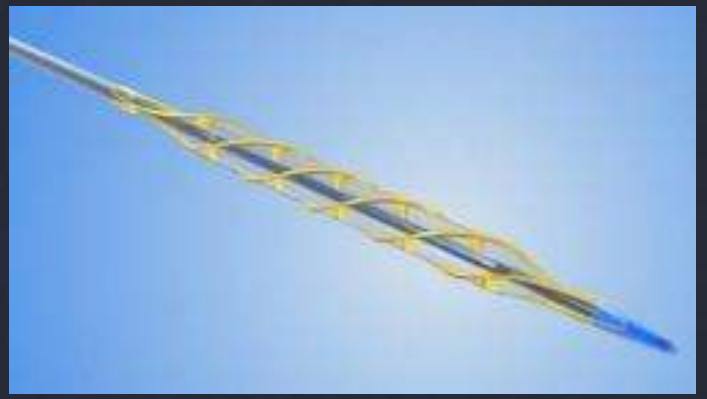
18M follow- up OCT images



Favorable neointimal coverage is apparent.
Black boxes: scaffolds (and/or tissue matrix) remain visible.

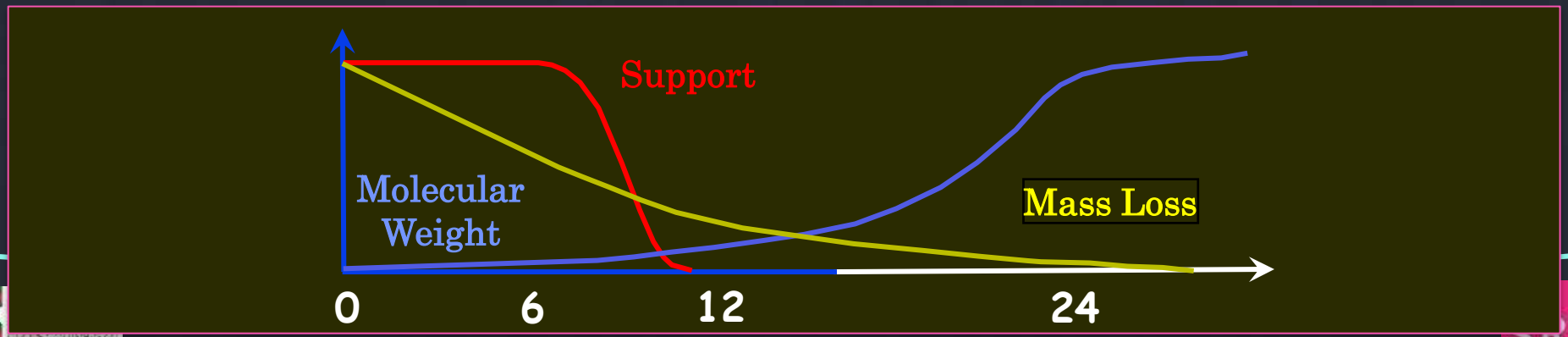
CALCIFIC LESIONS…

- remain a challenge despite the advent of
  - low-profile, non-compliant, high pressure, bladed or scoring balloons
  - Rotablation or Orbital atherectomy



BRS and calcium…

- Bulky device
- Inferior deliverability to latest generation drug eluting stents (DES)
- Radial strength which is reduced
  - With time
  - When expanding the scaffold beyond nominal size



BIFURCATION LESION

- Both the fragility and scaffold thickness make bifurcation stenting more challenging when using BVS vs. metallic DES.
- The strut thickness of main branch BVS causes side-branch occlusion.

Muramatsu, T., et al. (2013). "Incidence and short-term clinical outcomes of small side branch occlusion after implantation of an everolimus-eluting bioresorbable vascular scaffold: an interim report of 435 patients in the ABSORB-EXTEND single-arm trial in comparison with an everolimus-eluting metallic stent in the SPIRIT first and II trials." JACC Cardiovasc Interv **6**(3): 247-257.

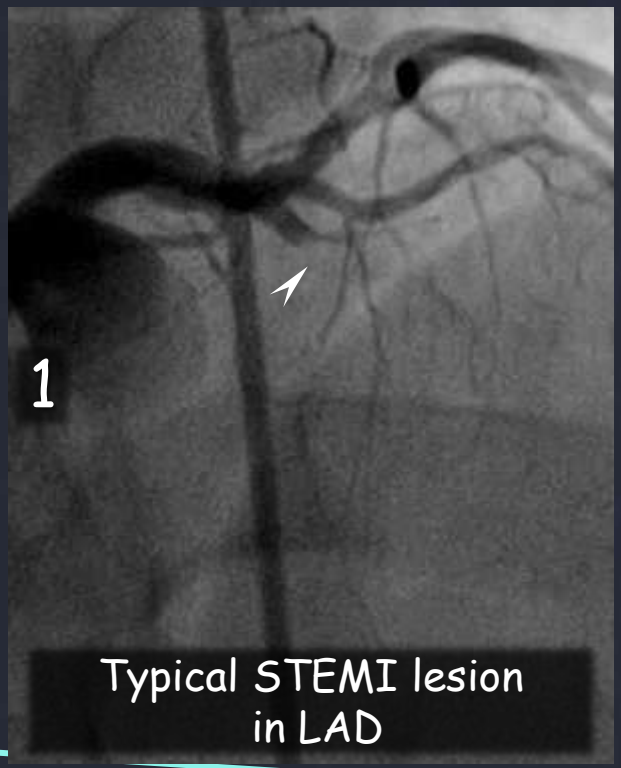
BIFURCATION LESION

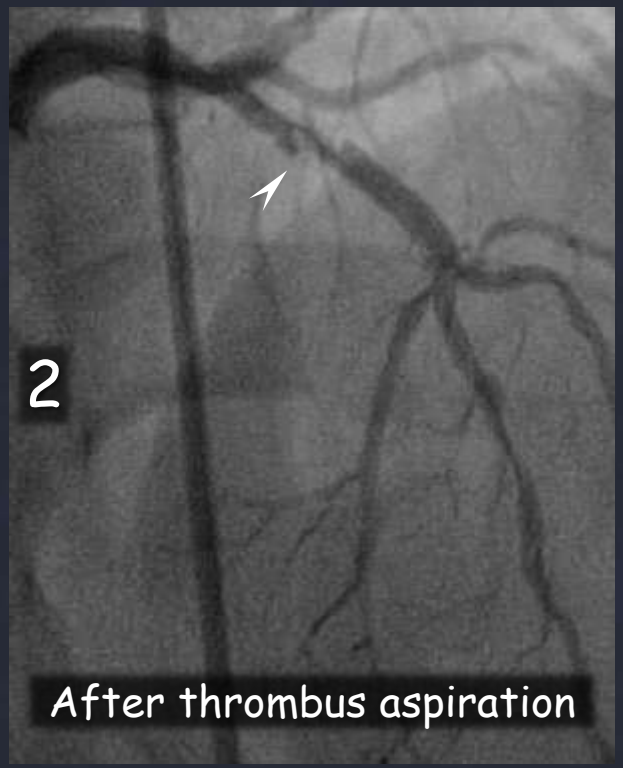
- Provisional stenting is recommended, with FKB inflation only when necessary.
- TAP with a metal DES in the side branch are preferable in case of crossover.
- Two-BVS T-stent technique can be performed in a high-angle bifurcation.

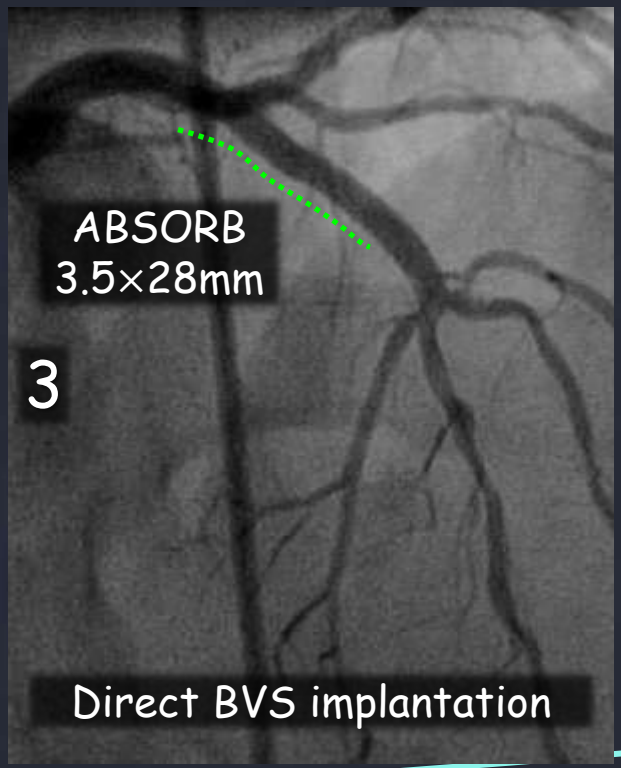
Dzavik, V. and A. Colombo (2014). "The absorb bioresorbable vascular scaffold in coronary bifurcations: insights from bench testing." JACC Cardiovasc Interv **7**(1): 81-88.

BIFURCATION LESION

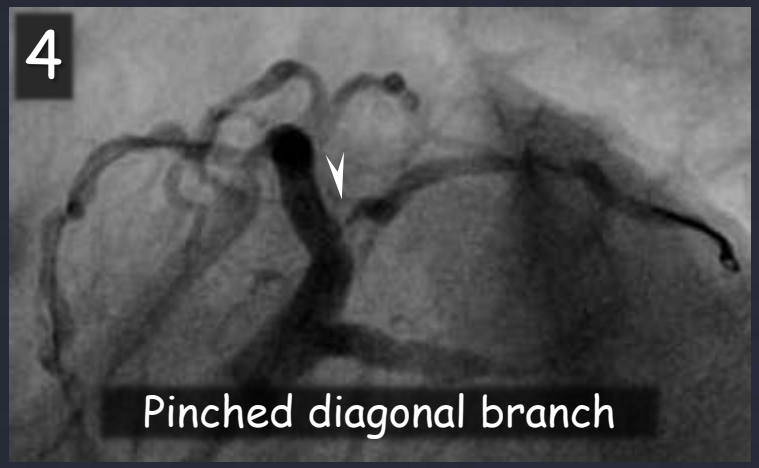
PROVISIONAL HYBRID 2 STENT TECHNIQUE (TAP)







BIFURCATION LESION



Conclusions 1

1° generation BVS should be adopted in:

- Simple lesions especially in young patients
- Long lesions and diffuse disease>> no overlapping but adjacent scaffolds
- Calcified lesion and CTO only if properly and aggressively prepared
- Non LM bifurcation lesions not involving large SB

Conclusions 2

- It is important to take into account with BVS, especially in complex lesion subsets, longer and more meticolous procedures requiring proper predilatation and if needed postdilatation IVUS/OCT guided
- Awaiting for more clinical data and technology development>> evidence coming from new gen BVS – 100µm