BRS in Left Main PCI

Clinical Data and Experience

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Evolution of DES Technology

First Gen

Durable Polymer Stents

	Cypher	TAXUS Express	TAXUS Liberte
Strut Thickness	140 µm	132 µm	96 µm
Coat Thickness	7µm / side	16µm/side	14µm/side

Bioabsorbable Polymer Stents

	Biomatrix	Nobori
Strut Thickness	120 µm	125 µm
Coat Thickness	10 µm	20 µm

Second Gen

	Resolute Integrity	Xience Xpedition	Promus PREMIER
Strut Thickness	89 µm	81 µm	81 µm
Coat Thickness	6µm / side	8µm / side	8µm / side

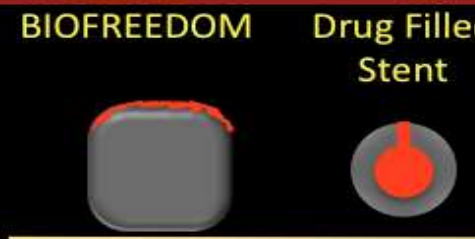
	Firehawk	Synergy	Ultimaster
Strut Thickness	86µm	74µm	80µm
Coat Thickness	10 µm	4 µm	14 µm

First Generation Future Technologies

Fully Bioresorbable Stents

	BVS	ELIXIR DESolve	DREAMS II
Strut Thickness	150 µm	150 µm	150 µm
Coat Thickness	3 µm / side	<3 µm / side	8 µm / side

Polymer Free Stents

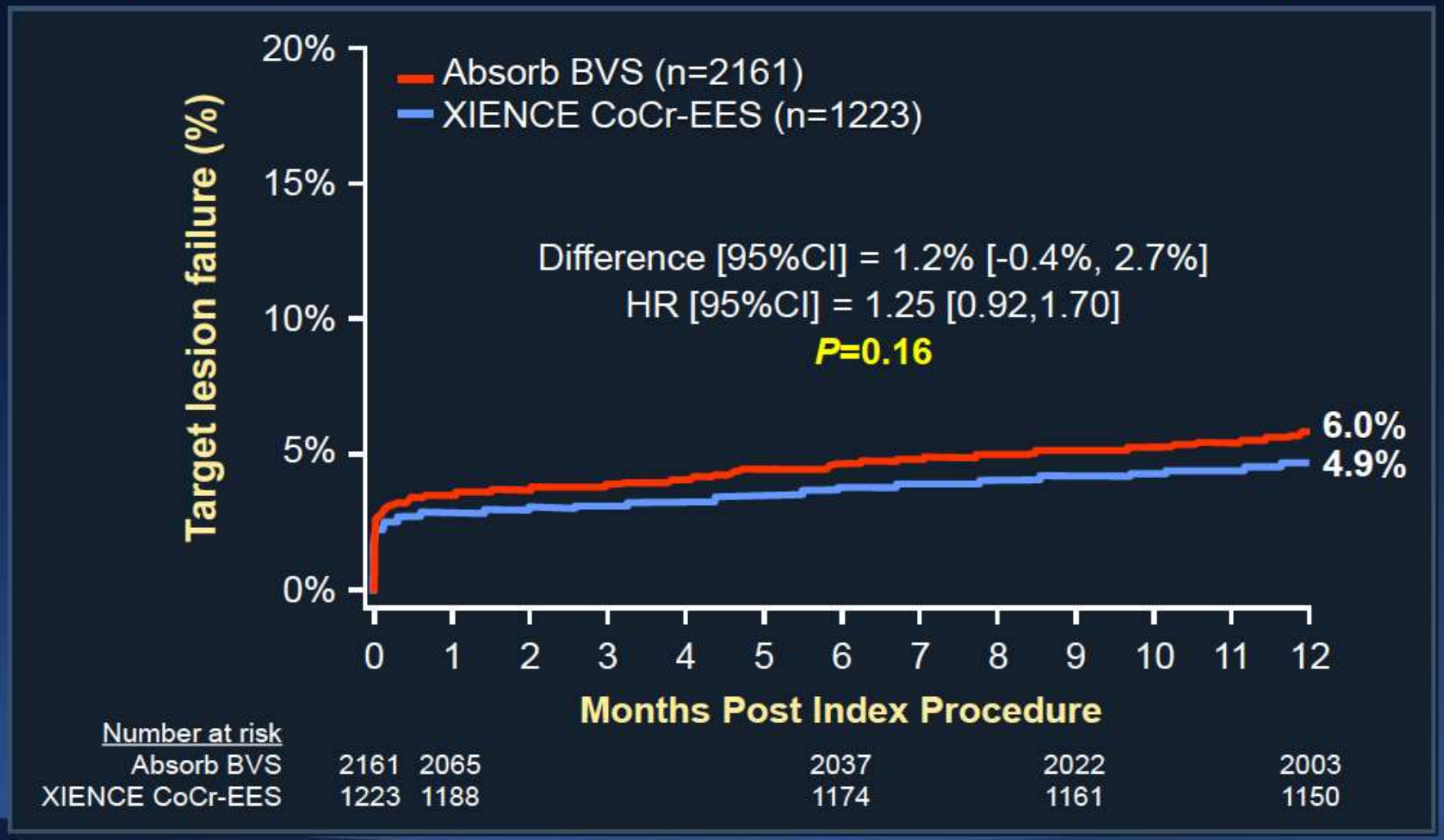


	BIOFREEDOM	Drug Filled Stent
Strut Thickness	112	86
Coat Thickness	NA	NA

ABSORB 1-Year Meta-analysis

ABSORB II, ABSORB III, ABSORB Japan, ABSORB China

DoCE (TLF): Cardiac Death, MI or ID-TLR (pooled)

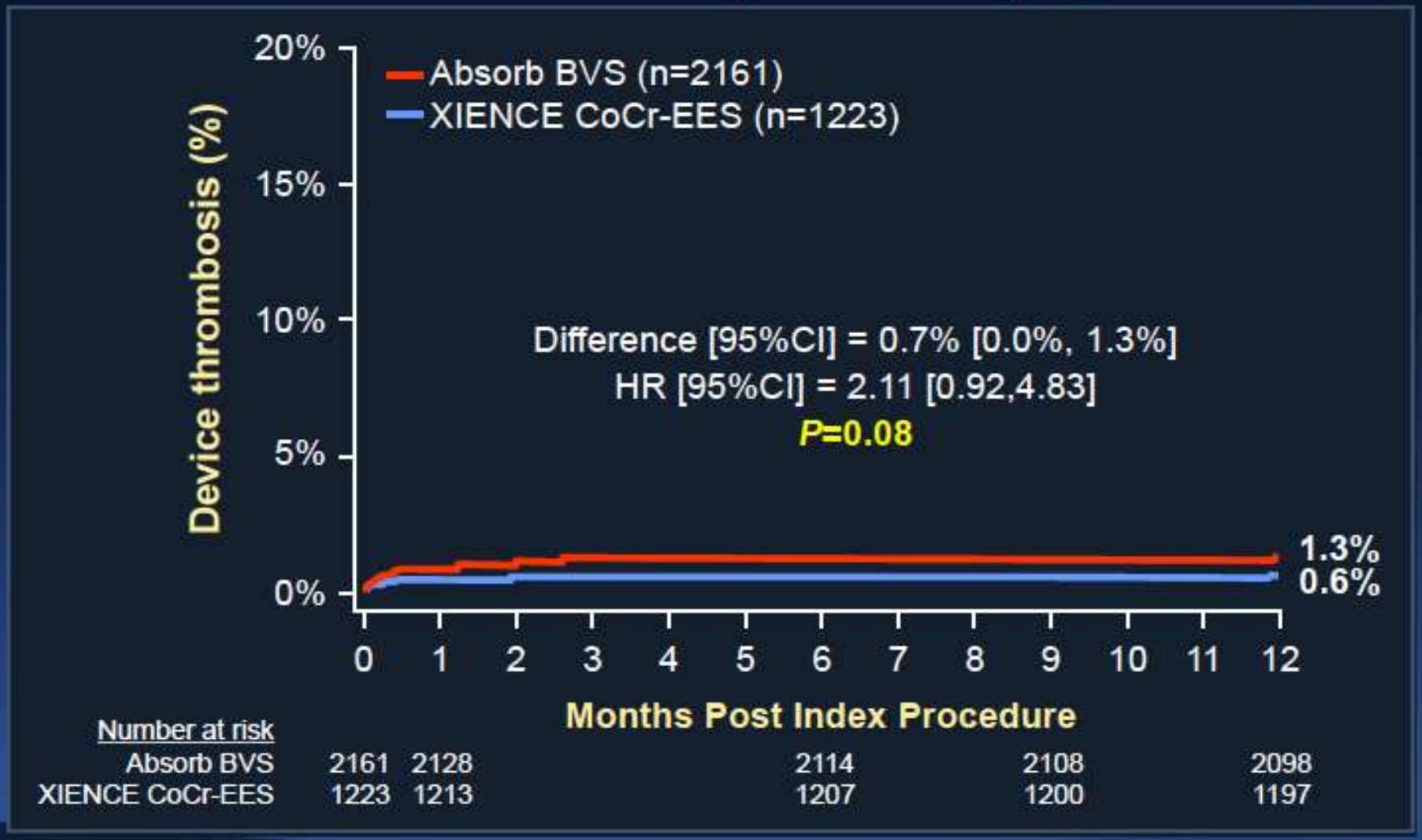


Lancet 2016;387:1277-89.

ABSORB 1-Year Meta-analysis

ABSORB II, ABSORB III, ABSORB Japan, ABSORB China

Device Thrombosis (Def/Prob) (pooled)



Lancet 2016;387:1277-89.

Study-level Meta-Analysis of 6 RCT

ABSORB Series and EVERBIO II and TROFI II

A Target lesion revascularisation

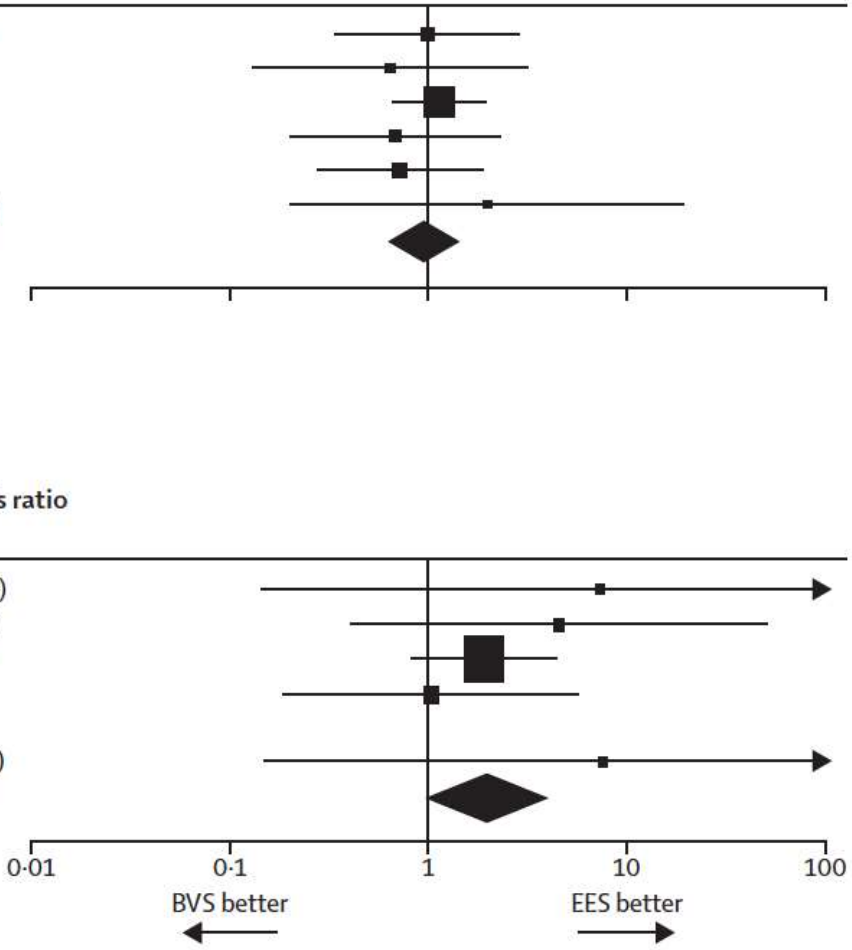
	BVS Events	BVS Total	EES Events	EES Total	Weight (%)	Fixed-effects odds ratio (95% CI)
ABSORB China	7	238	7	237	13·2	1·00 (0·34–2·88)
ABSORB II	4	335	3	166	5·9	0·64 (0·13–3·12)
ABSORB III	42	1313	19	677	51·6	1·14 (0·67–1·95)
ABSORB Japan	7	265	5	133	10·1	0·68 (0·20–2·31)
EVERBIO II	8	78	11	80	16·3	0·72 (0·28–1·87)
TROFI II	2	95	1	96	2·9	1·98 (0·20–19·29)
Overall	**70**	**2324**	**46**	**1389**	**100**	**0·97 (0·66–1·43)**

Heterogeneity: χ^2=1·69, df=5; p=0·89; I^2=0%
Test for overall effect: Z=0·16; p=0·87
Random-effects odds ratio 0·97 (95% CI 0·66–1·43)

B Definite or probable stent thrombosis

	BVS Events	BVS Total	EES Events	EES Total	Weight (%)	Fixed-effects odds ratio (95% CI)
ABSORB China	1	238	0	232	3·1	7·21 (0·14–363·23)
ABSORB II	3	335	0	166	8·2	4·49 (0·04–49·92)
ABSORB III	20	1301	5	675	69·1	1·89 (0·82–4·34)
ABSORB Japan	4	262	2	133	16·5	1·02 (0·18–5·58)
EVERBIO II	0	78	0	80		Not estimable
TROFI II	1	95	0	96	3·1	7·47 (0·15–376·35)
Overall	**29**	**2309**	**7**	**1382**	**100**	**1·99 (1·00–3·98)**

Heterogeneity: χ^2=1·90, df=4; p=0·75; I^2=0%
Test for overall effect: Z=1·96; p=0·05
Random-effects odds ratio 1·99 (95% CI 1·00–3·98)



Lancet 2016; 387: 537–44

BVS Registry

A Propensity-Matched Cohort (N=1,810) of the GHOST-EU and XIENCE V USA

	BVS (%)	EES (%)	HR (95% CI)	P
Device-oriented composite outcome	5.8	7.6	0.75 (0.52 to 1.08)	0.12
CV death	0.7	1.9	0.36 (0.14 to 0.92)	0.025
MI	2.4	4.0	0.61 (0.36 to 1.05)	0.07
TLR	4.6	3.5	1.35 (0.84 to 2.17)	0.22
Definite or probable ST	1.8	1.1	1.62 (0.73 to 3.57)	0.23

J Am Coll Cardiol Intv 2016;9:440–9

General Concept for LM PCI

- Mostly high-risk PCI
- Large caliber; 4~6 mm diameter
- Frequent distal main involvement; stent cross-over or complex 2-stent techniques are commonly required

General Concept for BRS

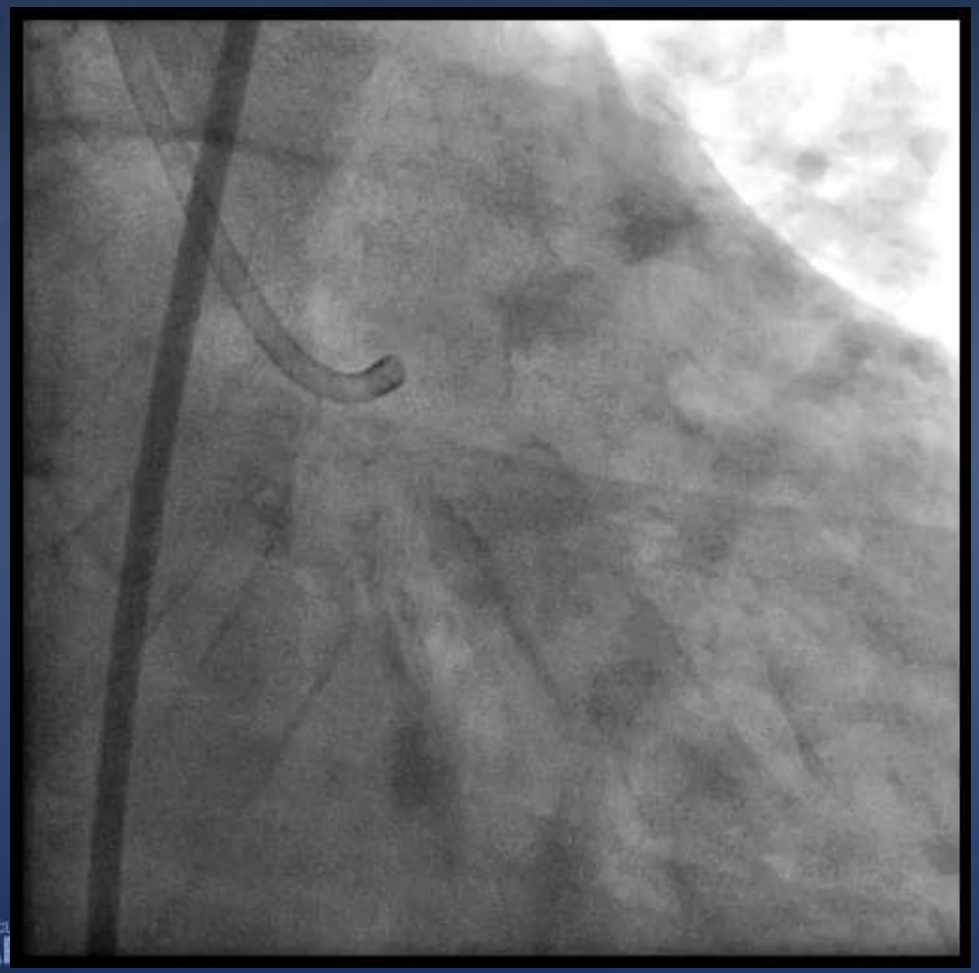
- Over-dilation is not recommended.
- Concerns regarding a lower radial force.
- Risk of fracture or crackdown.
- Higher risk of side-branch jail
- Two-stent techniques with BRS is not yet recommended.

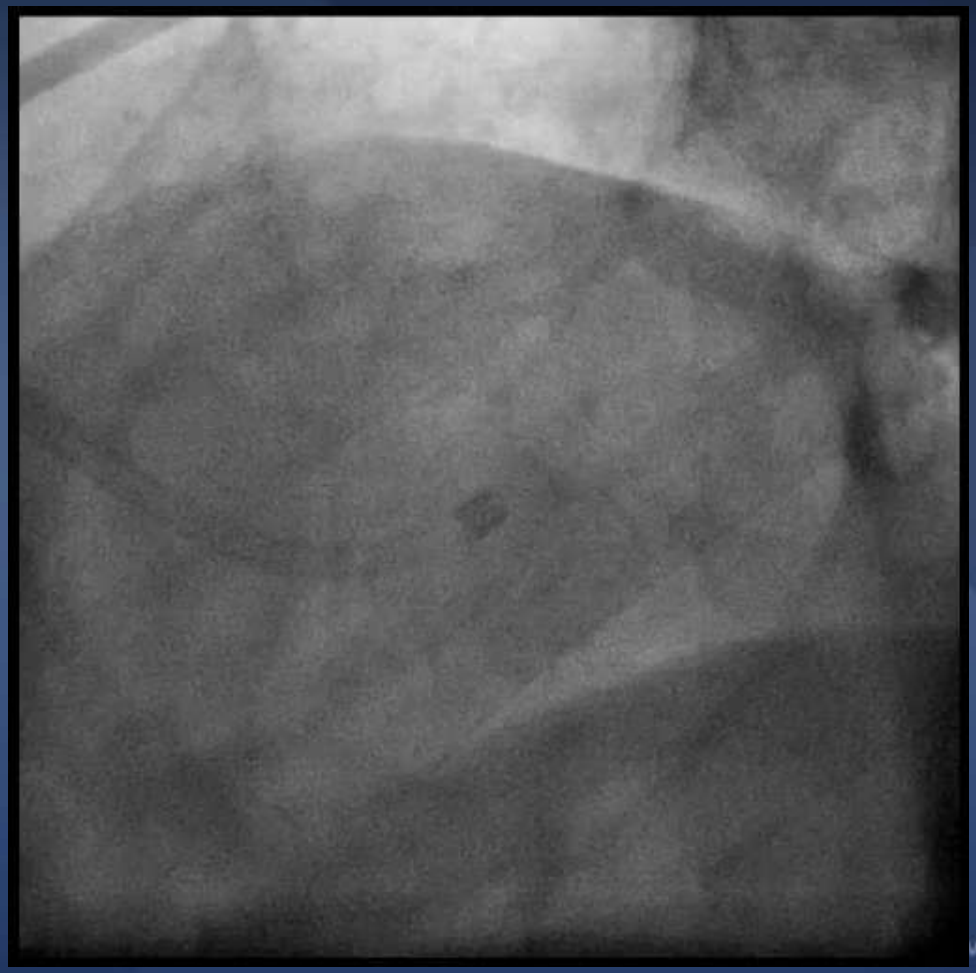
More Complex PCI Steps for BRS

- Thicker and more fragile struts
- Greater attention to procedure
  - Strut fracture with overdilation
  - Early thrombosis with underexpansion
- More techniques necessary
  - Pre: more agressive plaque modification
  - Post: routine NC ballon
  - Routine Intravascular Imaging

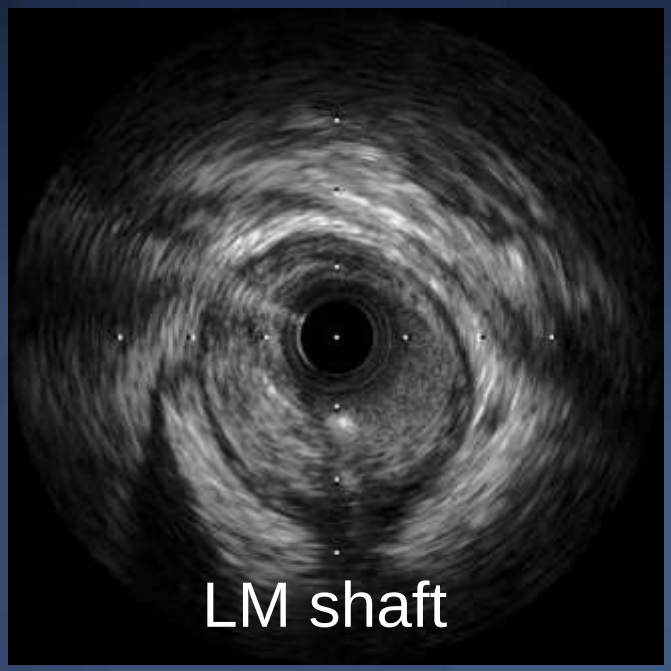
Our BRS case for LM Intervention

- 40/Male, effort chest pain 6 months ago,
- Risk factors; HTN, hyperlipidemia, smoking,
- TMT; positive at stage II, ECG; normal, Echo; normal

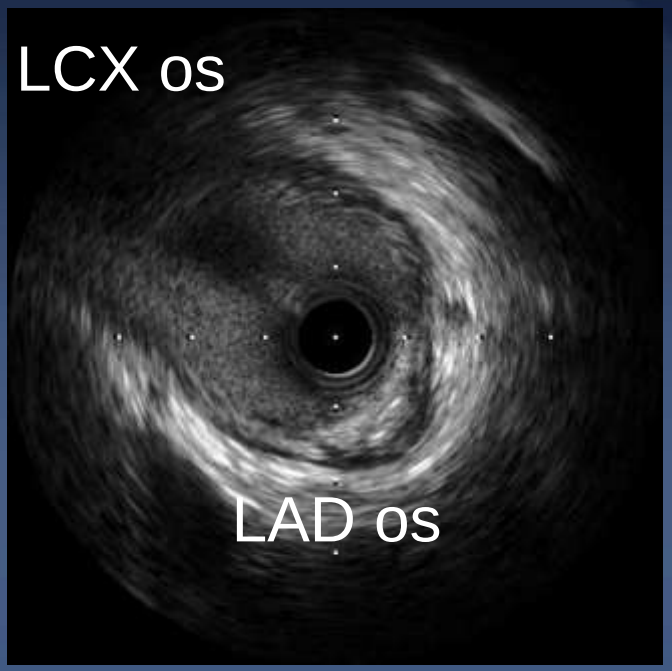




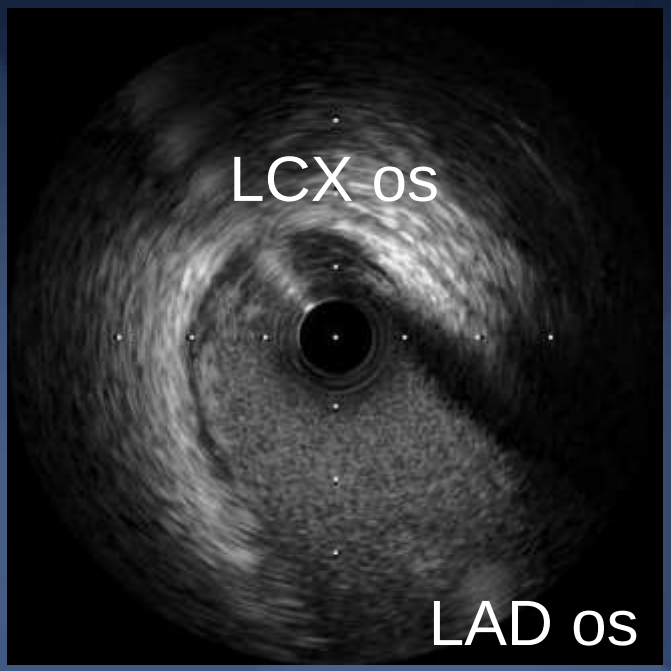
Our BRS case for LM Intervention



IVUS from LAD



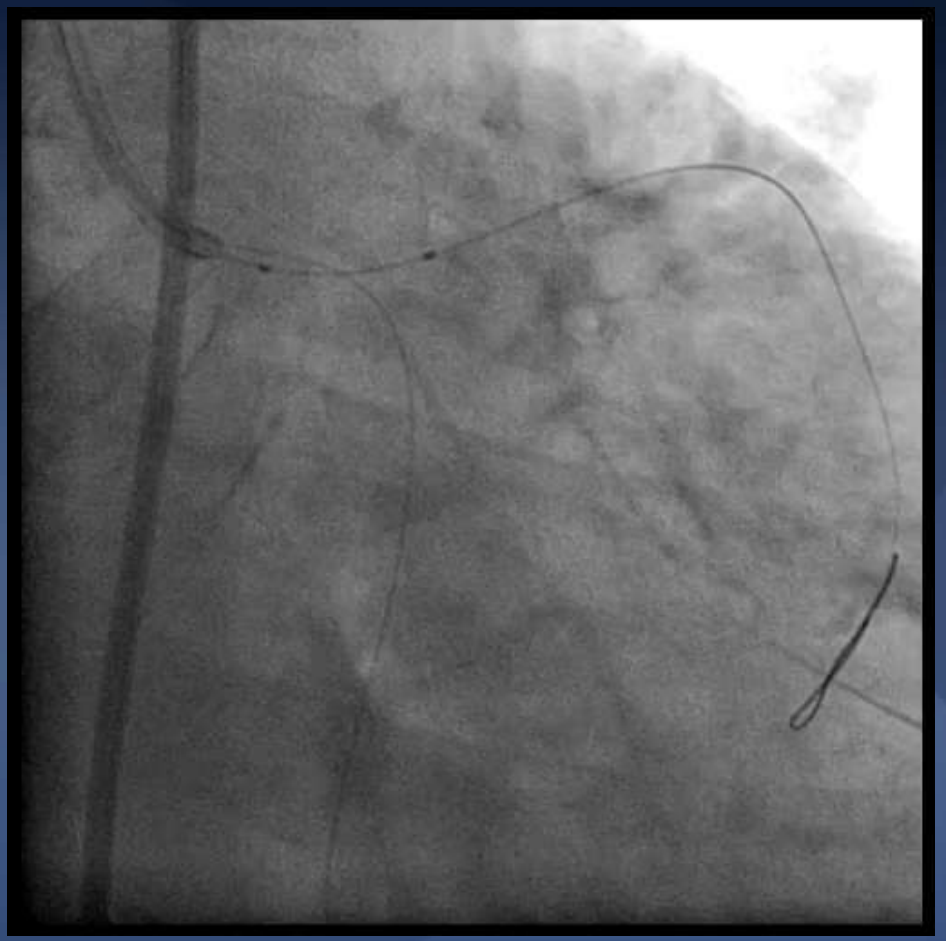
IVUS from LCX



IVUS LM Shaft-MLA = 3.3 mm^2

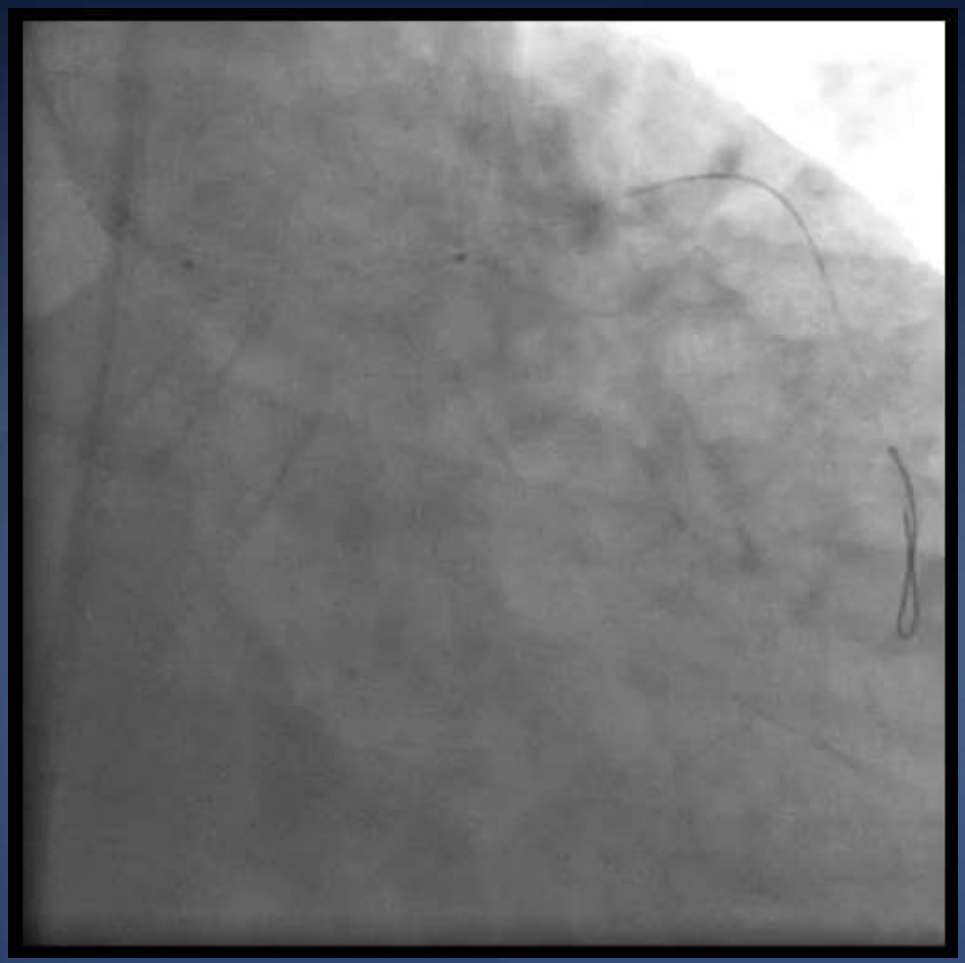
FFR = 0.64

Pre-dilation with balloon



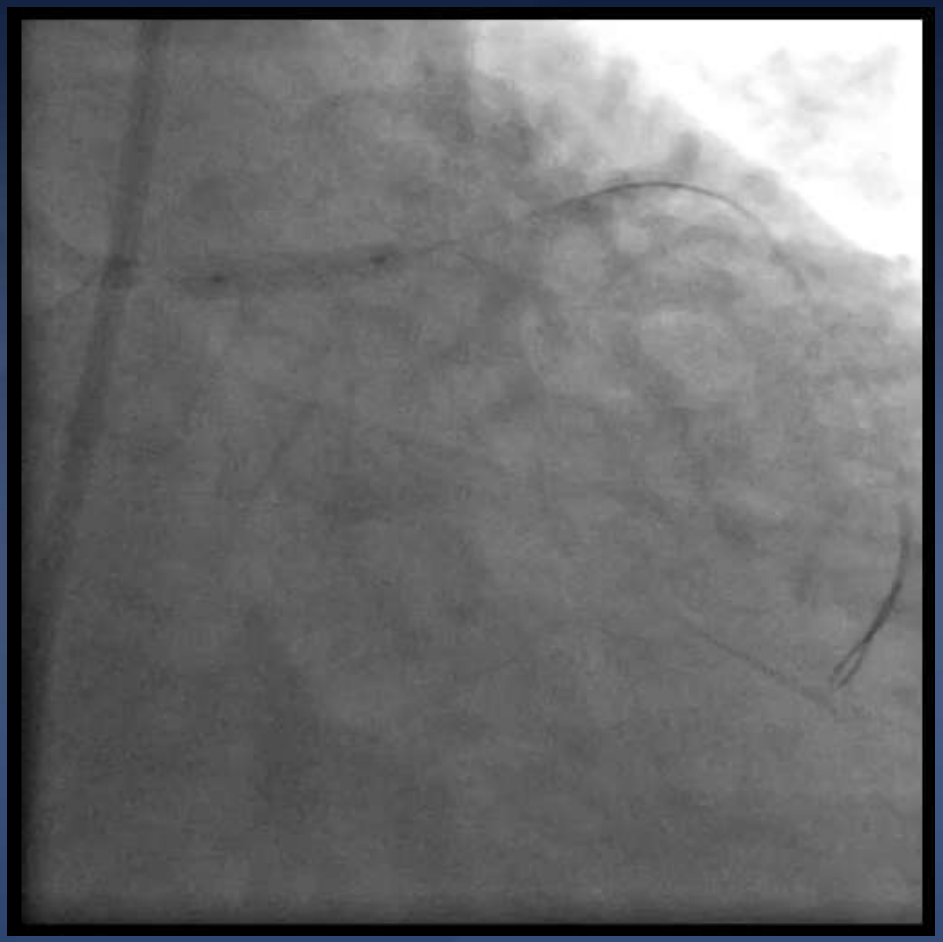
IKAZUCHI 3.0 x 15 mm

BRS Implantation



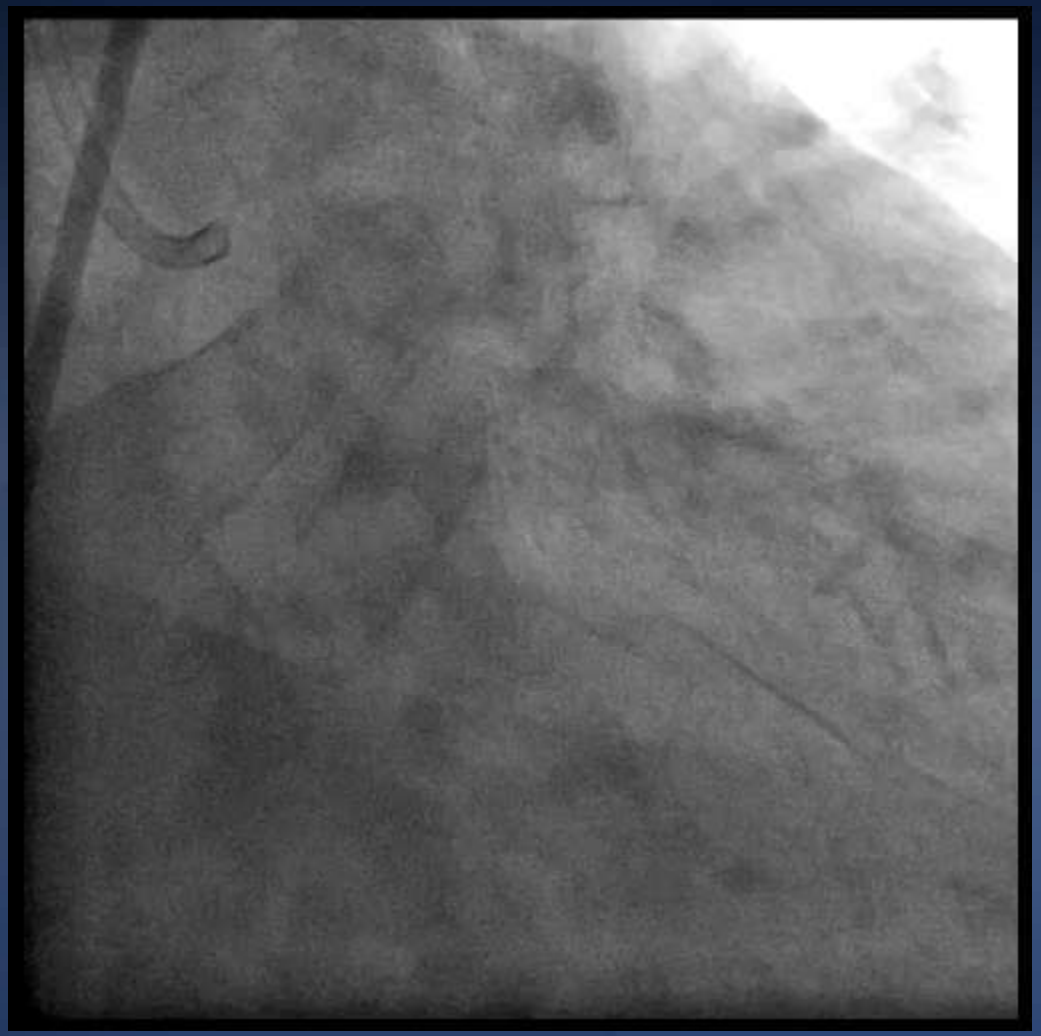
ABSORB BVS 3.5 x 23 mm

HP dilation

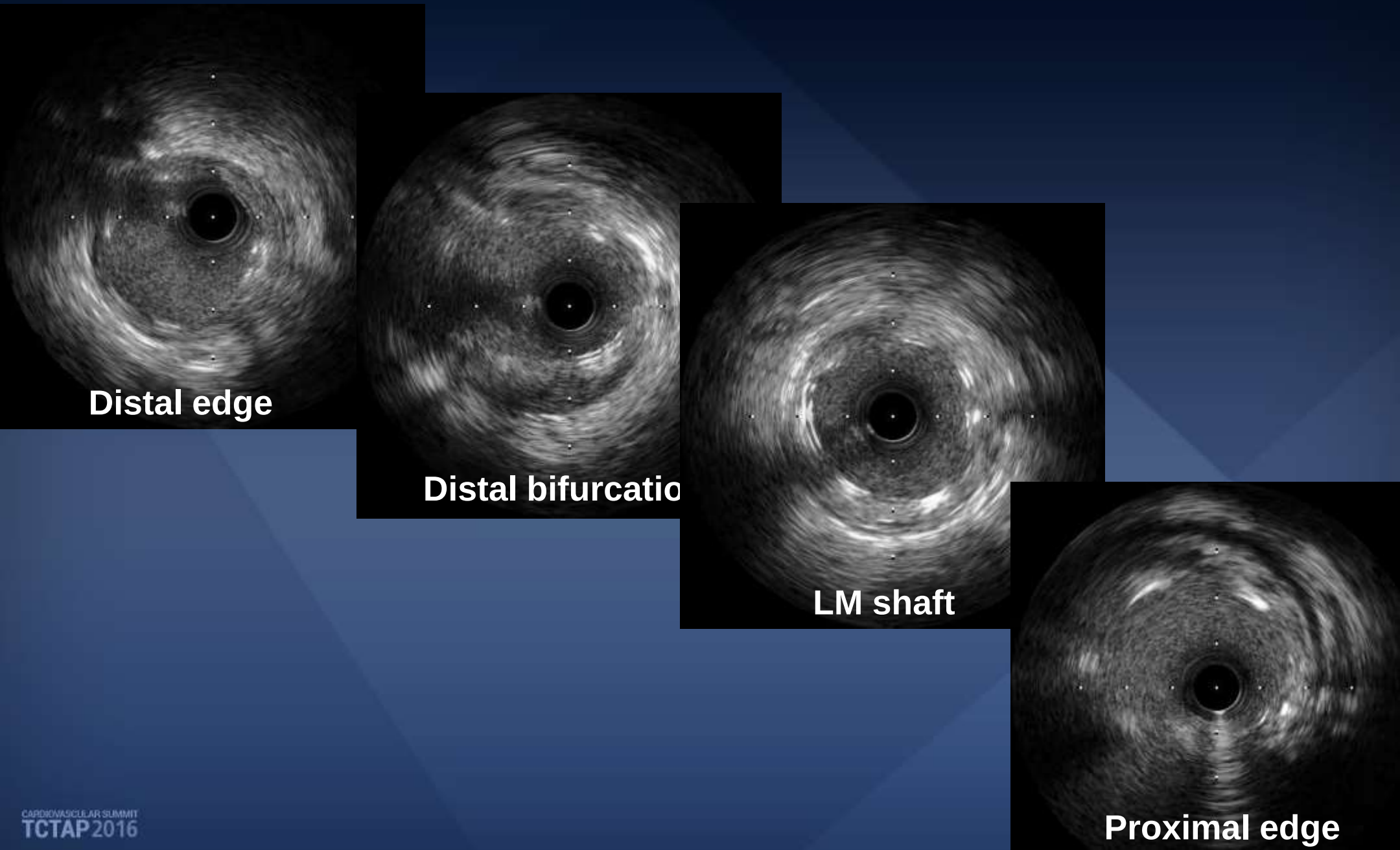


Sapphire NC 3.5 x 15 mm
NIMBUS NC 4.0 x 13 mm

Final Results



Final Results



Data of LM PCI with BRS

- Most LMCA lesions were excluded in BRS trials.
- Just case reports or expert opinions are available.

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Letter to the Editor

Bioresorbable vascular scaffolds for left main lesions; a novel strategy to overcome limitations

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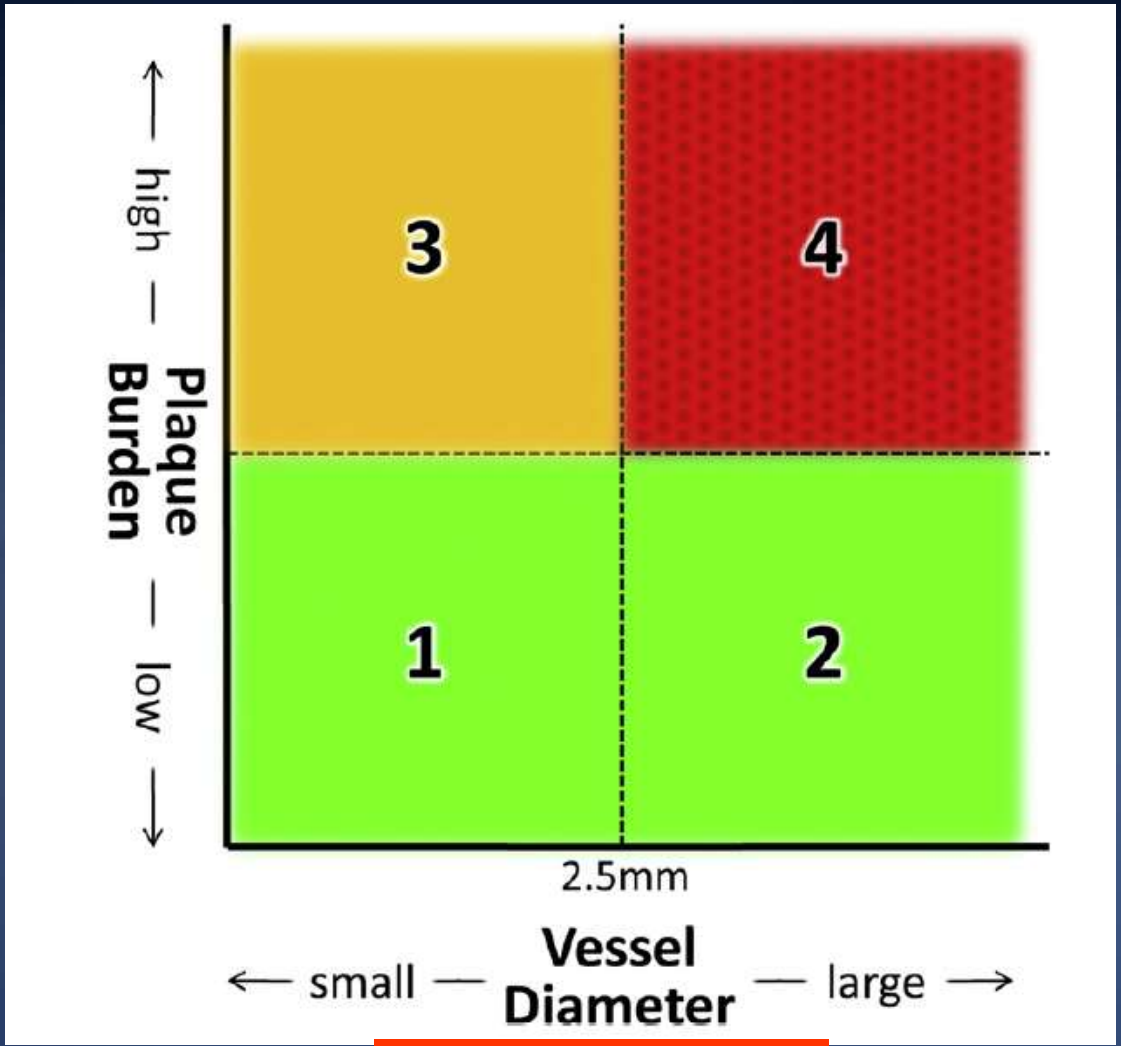
Colombo et al. Int J Cardiol. 2014;175(1):e11-3.

BRS for LM PCI



- Panel 1,2; BVS can be performed
- Panel 3; BVS should be decided on a case-by-case basis
- Panel 4; BVS should be avoided (SB big, large plaque)

Side-Branch

Colombo et al. Int J Cardiol. 2014;175(1):e11-3.

BRS in LM Intervention

- The thick struts, fragility, and limited distensibility make the use of BRS in LM lesions a challenging task.
- Simple cross-over with BRS is feasible in LM disease with intact or large side-branch ostium.
- Still, complex bifurcation stenting or FKB for LM intervention is not yet fully tested, and could be associated with risk of fractures or distortion.
- Newer generation BRS with thinner struts and more durable and less fragile platforms could be applicable for diverse LM intervention in the near future.