EBC

Welcome to the 7th European Bifurcation Club 14-15 October 2011 - LISBON

How to Improve Stenting Results in Bifurcations? Platform and technique

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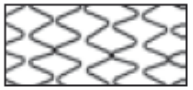
NHS Foundation Trust

Imperial College London

Stent Design and Mechanical considerations

	Specification	PROMUS Element/ TAXUS Element Stent Platform	TAXUS Liberté Stent Platform	TAXUS Express Stent Platform	PROMUS (Xience V) Stent Platform	CYPHER Stent Platform	ENDEAVOR Stent Platform
Design Elements	Pattern						
	Material	PtCr	316L SS	316 L SS	L605 CoCr	316 L SS	MP35N CoCr
	Range of Strut Width Nominal (mm/in)	0.061 / 0.0024 (SV) 0.089 / 0.0035 (LV)	Min: 0.076 / 0.0030 Max: 0.094 / 0.0037	Min: 0.071 / 0.0028 Max: 0.091 / 0.0036	0.076 / 0.0030	0.081 / 0.00321 0.132 / 0.0052	0.090 / 0.0036
	Strut Wall Thickness (mm/in)	0.081 / 0.0032[a] 0.086 / 0.0034[b]	0.097/ 0.0038	0.132 / 0.0052	0.081 / 0.0032	0.140 / 0.0055	0.090 / 0.0036
Bench testing	Surface Artery Ratio (SAR) (%)	2.5mm: 17.6 3.0mm: 16.4	2.5mm: 15.5 3.0mm: 17.6	Data not available	2.5mm: 16.8 3.0mm: 14.1	2.5mm: 18.3 3.0mm: 14.3	2.5mm: 18.1 3.0mm: 21.4
	Additional testing available in Figure 2 below.						
Stent Integrity	Fatigue Strength	Passed 400 mil cycles	Passed 400 mil cycles	Passed 400 mil cycles	Data not available for comparison	Data not available for comparison	Data not available for comparison
	Focal Bending	All designs demonstrated acceptable bending fatigue performance					
	Corrosion Resistance	All designs passed potentiodynamic, galvanic, crevice, fretting testing					
	Overexpansion	All designs passed to overexpansion diameter					

Boston Scientific, Element white paper

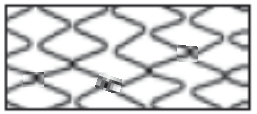
- **Different designs (crowns, cells) depending on diameters**

Small Vessel
ø 2.00, 2.25, 2.50 mm
L = 7, 10, 13, 16,20, 25, 30 mm
3 circum-ferential cells
Strut Thickness: 70 µm
Metal to Artery Ratio: 12.5% avg

Medium Vessel
ø 2.75, 3.00, 3.50 mm
L = 7, 10, 13, 16, 20, 25, 30, 35 mm
4 circum-ferential cells
Strut Thickness: 80 µm
Metal to Artery Ratio: 14.5% avg

Large Vessel
ø 4.00, 4.50, 5.00 mm
L = 10, 13, 16, 20, 25, 30, 35, 40 mm
5 circum-ferential cells
Strut Thickness: 95 µm
Metal to Artery Ratio: 14% avg

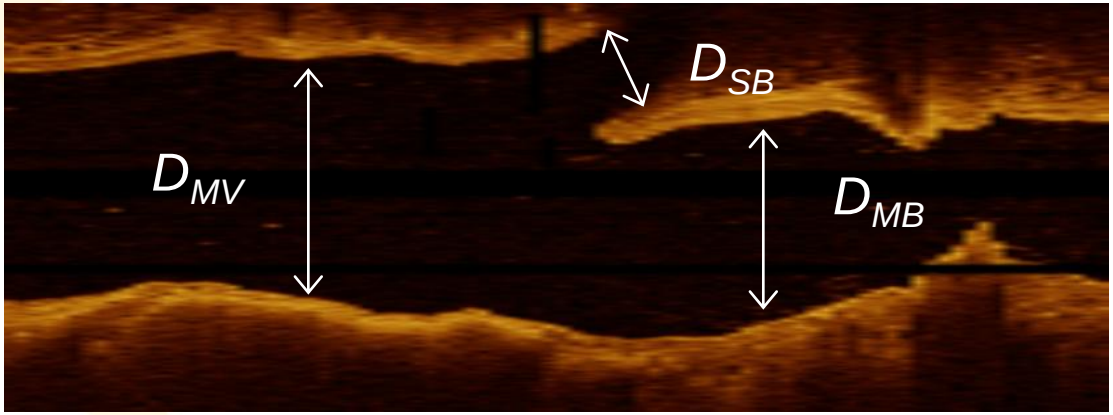
Choosing the right workhorse for provisional stenting: comparison of DES designs

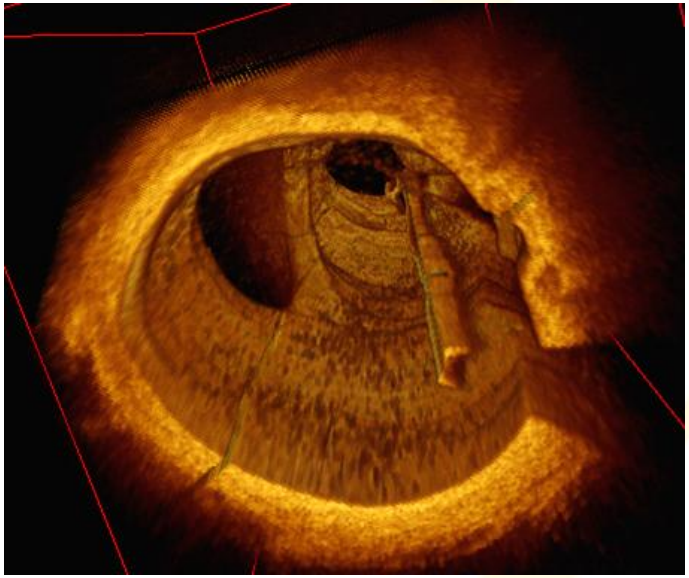


	Element	Xience V	Taxus	Integrity	Biomatrix	Cypher
2.25	Small vessel workhorse: *max exp. 2.75mm*	Medium Workhorse: (6 crowns , 3 cells) *max. expansion to 3.5mm*	Small workshorse (2 cells) : *max expansion 3.5mm*	Small workhorse (7crowns, 2 cells*) *Max expansion 3.2mm* **1 cell in resolute*	Medium workhorse (6 crowns, 2 cells design): max expansion 3.75	
2.50	Small workshorse (8 crowns, 2 cells) : *max expansion 3.5mm*					Medium workhorse (6 cells design): max expansion 3.75
2.75			Medium Workhorse (3 cells): *max expansion 4.25mm*			
3.00	Medium Workhorse (8 crowns, 2 cells) : *max expansion 4.25mm*			Medium workhorse (10 crowns, 2 cells) : *max expansion 4.4mm*		
3.50		Large workhorse: (9 crowns , 3 cells) *max expansion 4.5mm*			Large vessel workhorse (9 crowns, 3 cells) max expansion 5.0	Large vessel workhorse (7 cells design): max expansion 4.75
4.00	Large workhorse (10 crowns) *max expansion 5.75mm*		Large workhorse: (3 cells) *max expansion 4.5mm*			
4.50						

Sources: stent manufacturers

Anatomy of Bifurcations

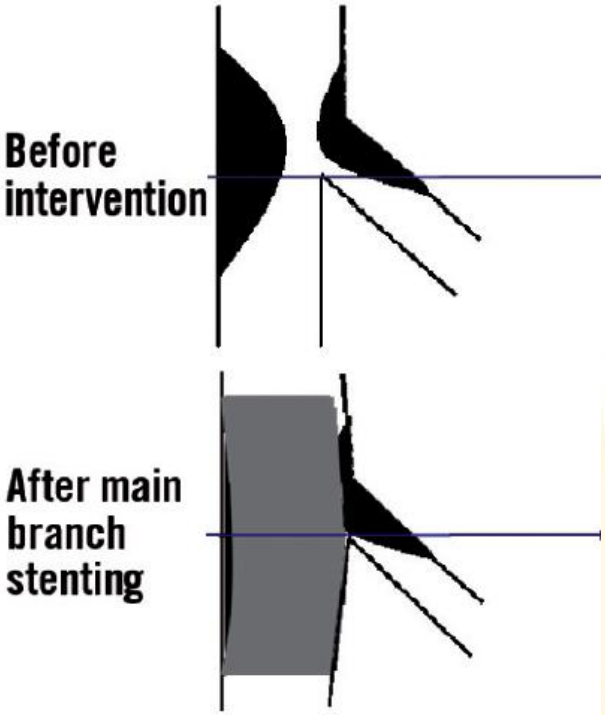


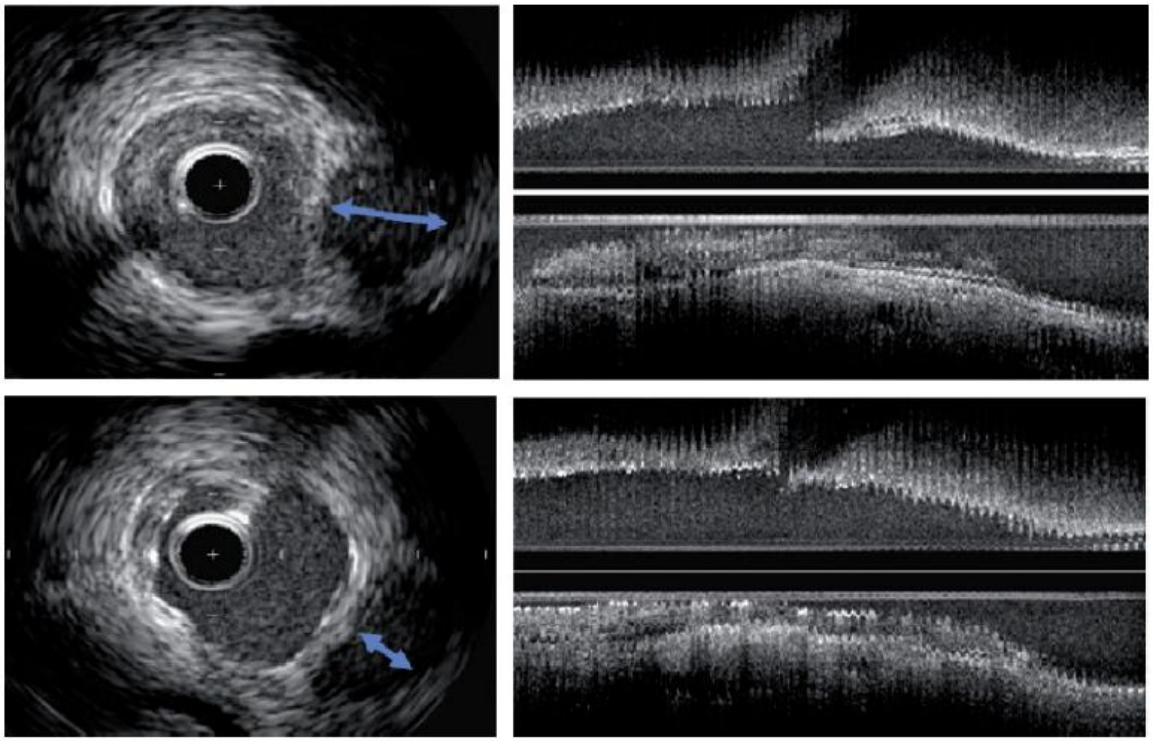


	Principle	Relation	*Ratio Dm/Dd for D_{d1}~ D_{d2}*
Murray's law	Minimum Work	$D_m3 = D_{d1}3 + D_{d2}3$	*1.26*
HK: Hong-Kassab	Minimum Energy	$D_m7/3 = D_{d1}7/3 + D_{d2}7/3$	*1.35*
Flow conservation	$Q_m = Q_{d1} + Q_{d2}$	$D_m2 = D_{d1}2 + D_{d2}2$	*1.4*
Finet	Measurement	$D_m = \underline{0.678}\ (D_{d1} + D_{d2})$	*1.36*

- **The larger the SB, the larger the change in MV diameter throughout the bifurcation**

Oversized Stent: risk of carina shift

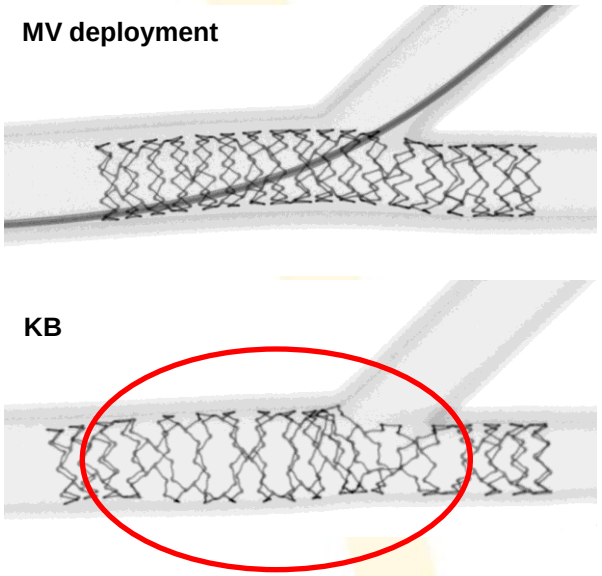


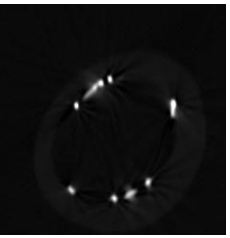


BK Koo. Eurointervention 2011

Examples

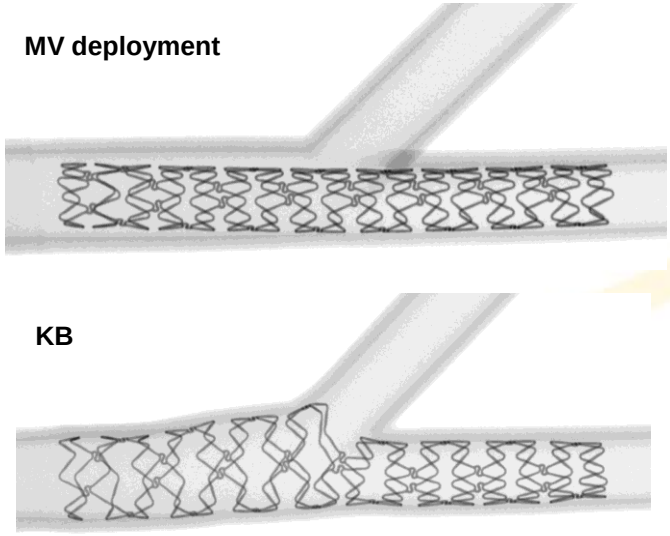
Element 2.75

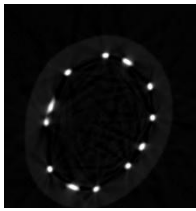




MSA proximal
8.2 mm2

Biomatrix 2.75

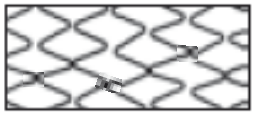




MSA proximal
11.0 mm2

- ✓ **In presence of a large diameter mismatch, we should look at workhorse maximal expansion capacity**
- ✓ **Or upscale to a larger diameter (at low pressure)**

Choosing the right workhorse for provisional stenting: comparison of DES designs



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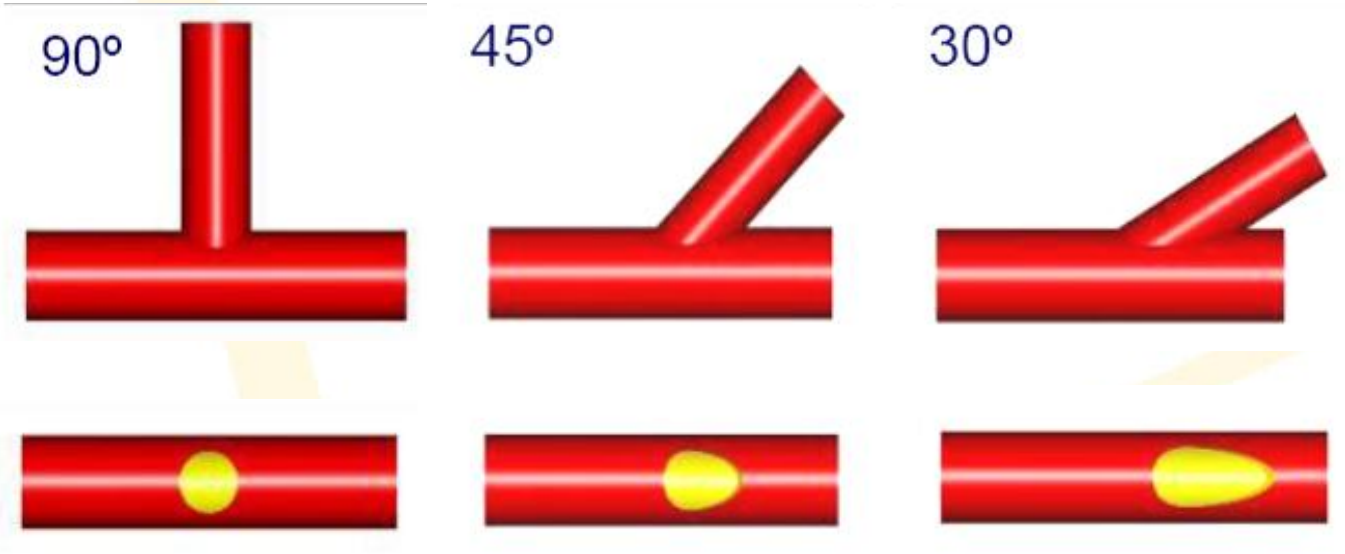
4.50						

Sources: stent manufacturers

Bifurcation ostium: angle matters !



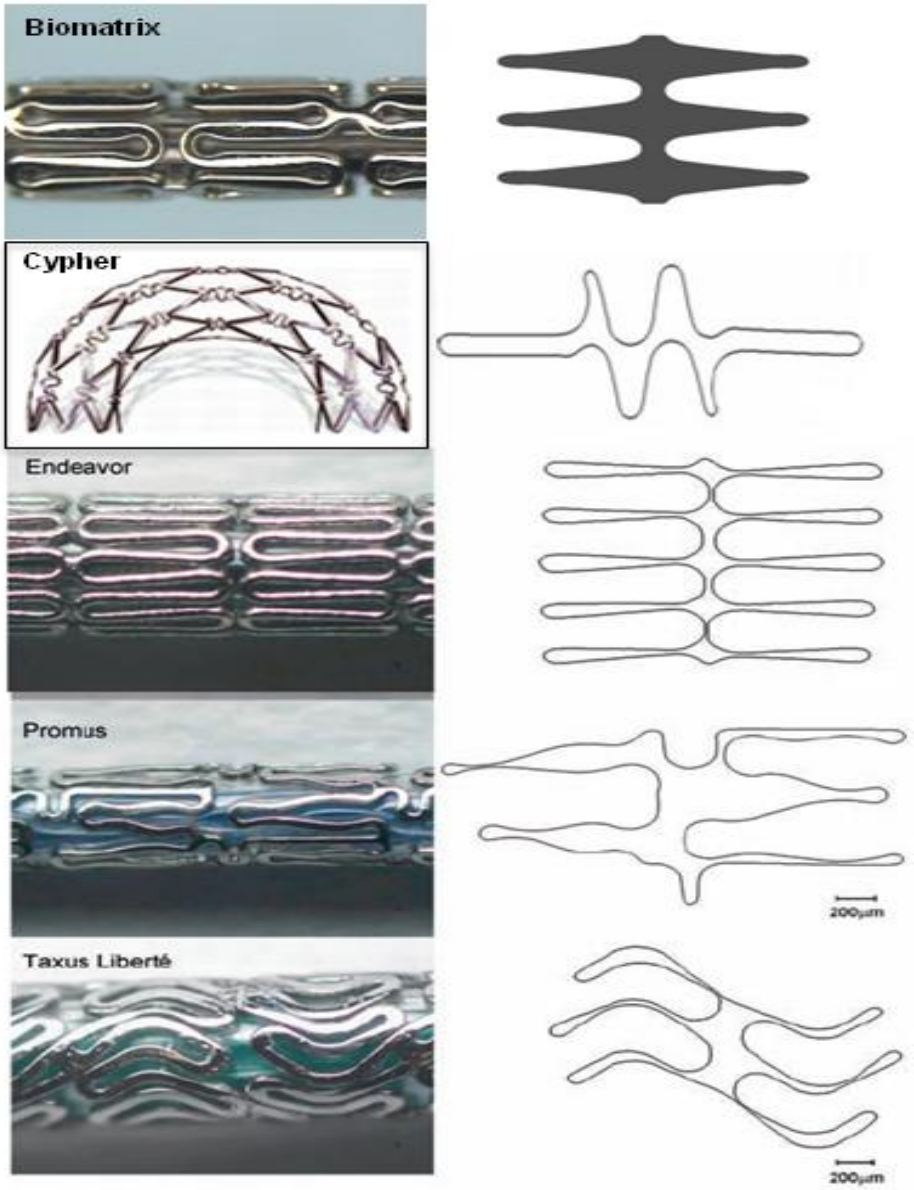
Mortier et al. EBC IV, Prague 2008

- ✓ **Acute angle produce larger ostium area**

Stent Cell Size

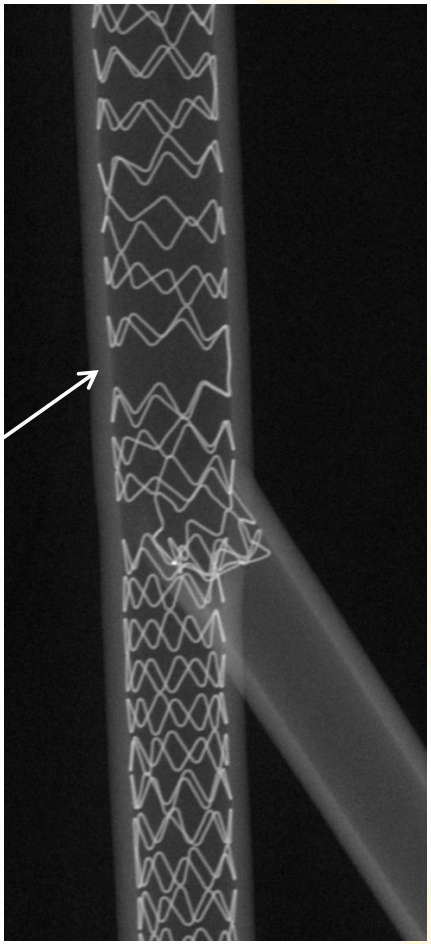
*Based on 3mm stent

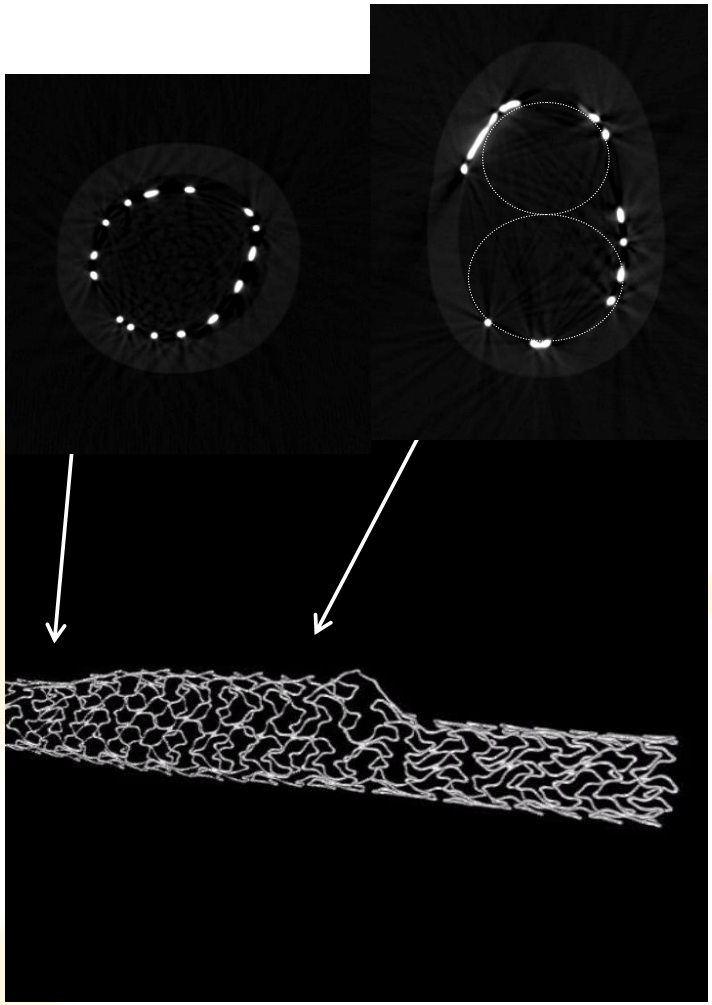
	Maximum cell circumference* (mm)	Maximum cell diameter* (mm)
Biomatrix	10.8	3.7
Cypher	9.5	3.0
Endeavor	19.8	6.3
Promus	12.6	4.0
Taxus Liberté	12.6	4.0



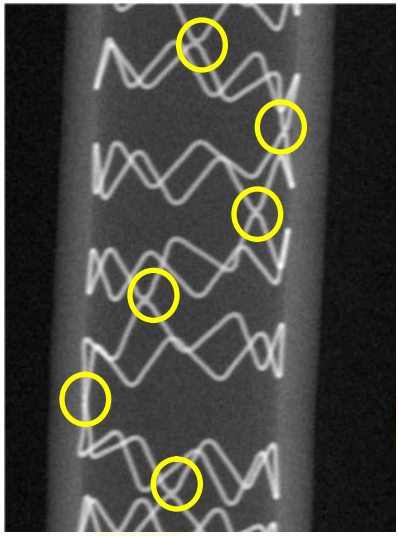
P. Mortier and manufacturer data

Stent Cell Size: the larger the better ?

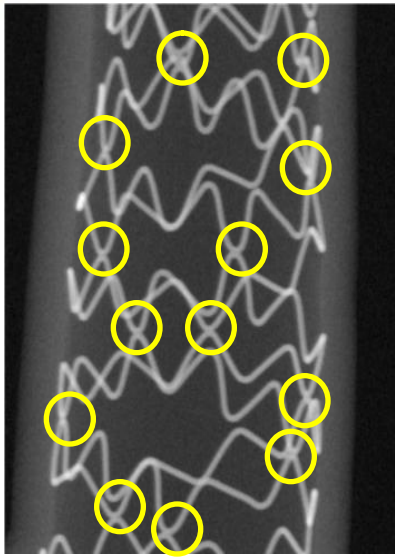




Endeavor 2.75mm
after KB with 2.5/2.75

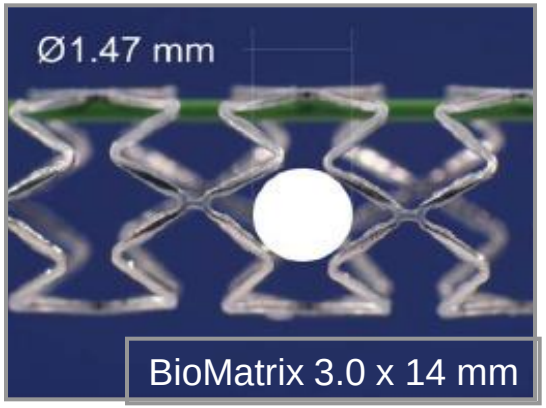


Endeavor/Resolute



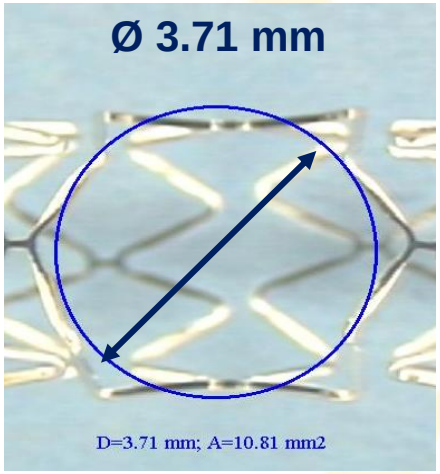
Integrity

Cell opening capacity with Biomatrix

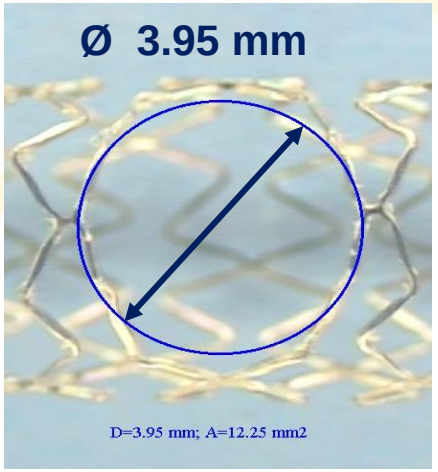


With a 6 crown BioMatrix (2.5 – 3.25 mm) dilation of a cell is possible with balloons up to 3.5 mm

With a 9 crown BioMatrix (3.5 – 4.0 mm) dilatation of a cell is possible with balloons up to 3.75 mm

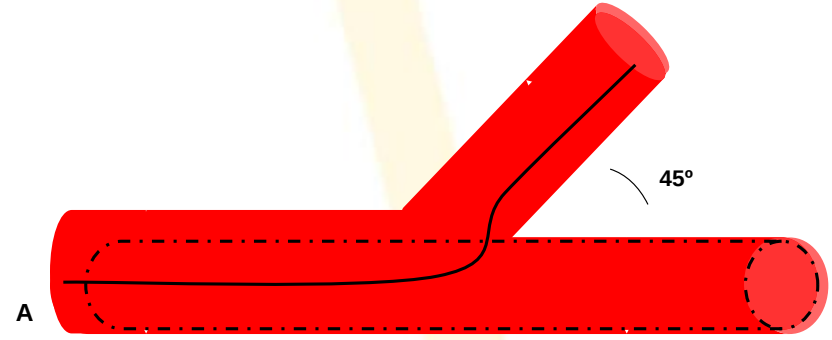


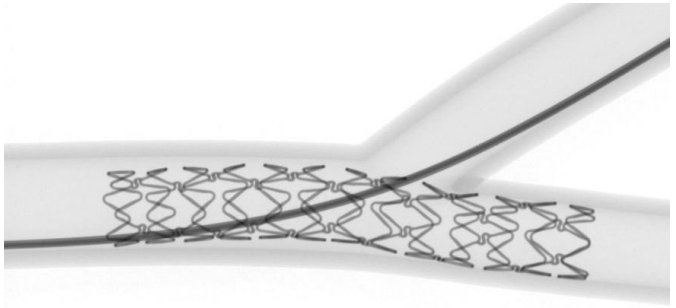
BioMatrix™ 6 crown
3.0mm expansion

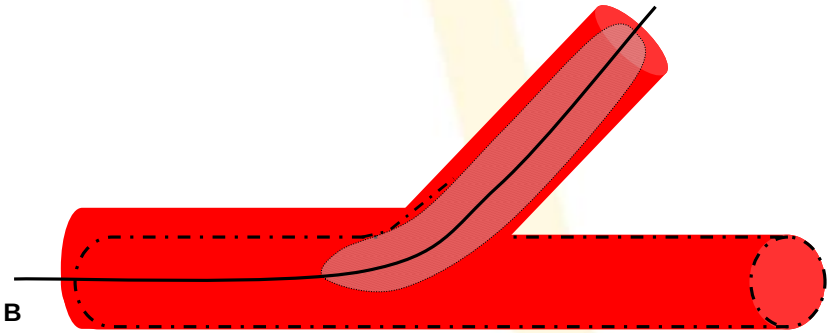


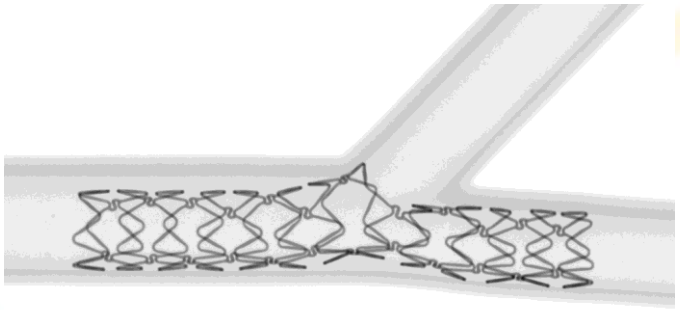
BioMatrix™ 9 crown
4.0mm expansion

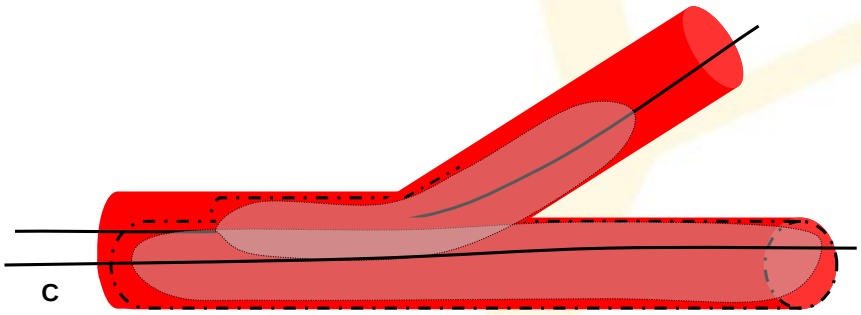
Provisional Stenting

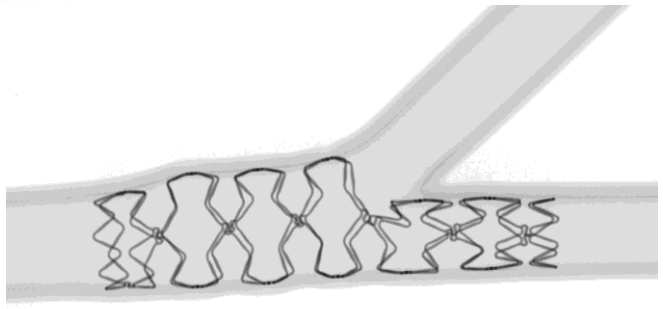




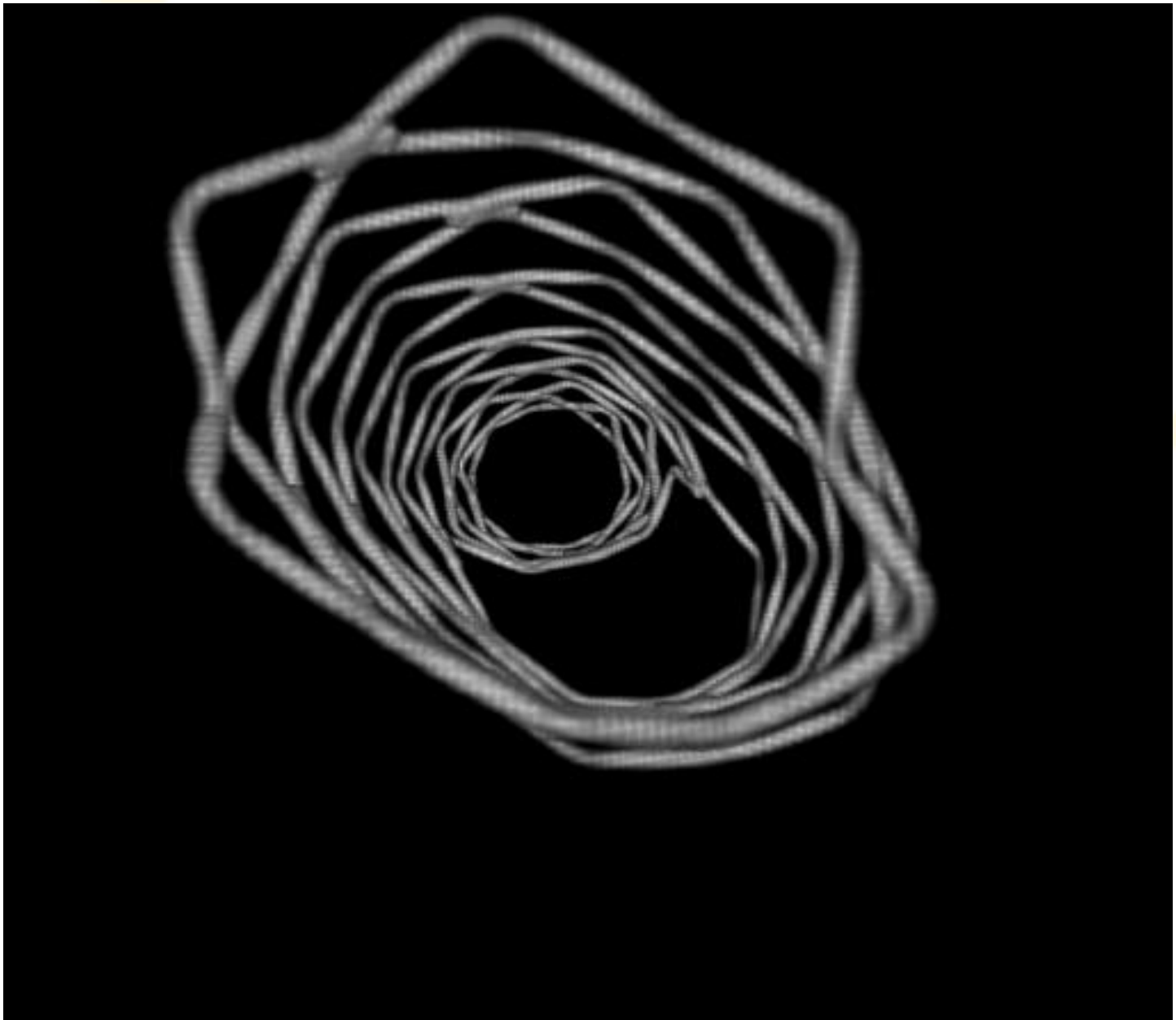








Biomatrix Flex after KB

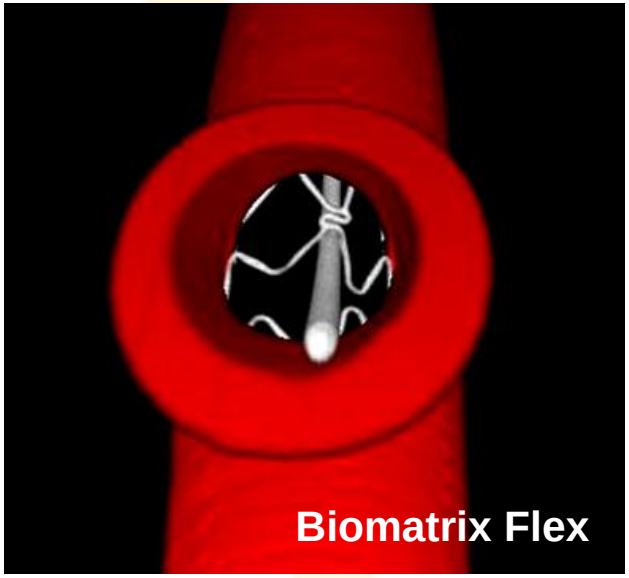


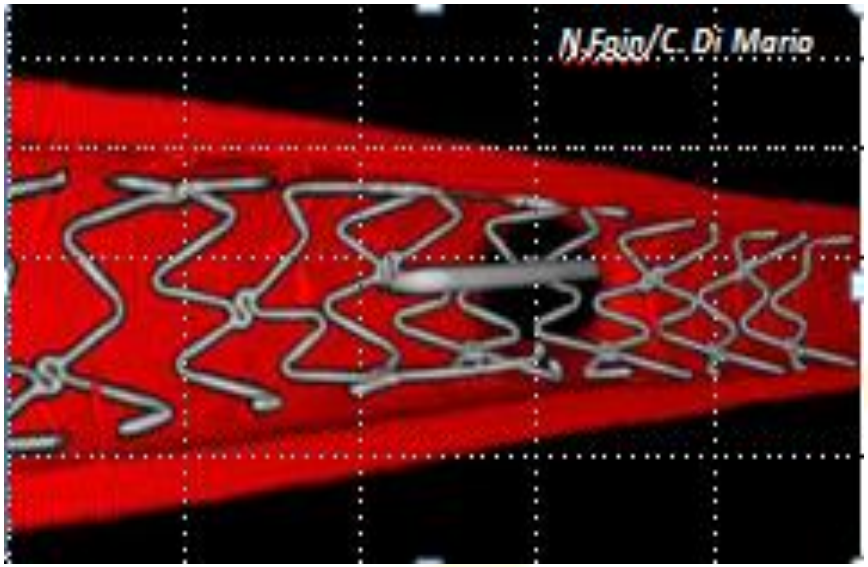
Bench Biomatrix Flex Results

3.0 MV, 2.5 SB at 12 ATM

MV

STENT

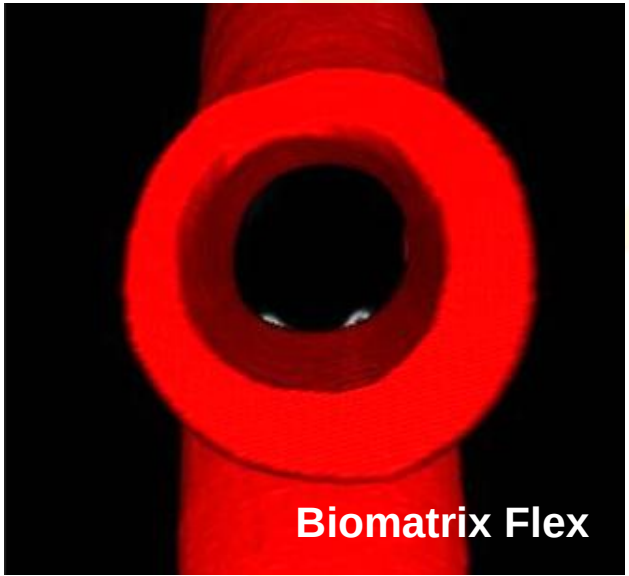


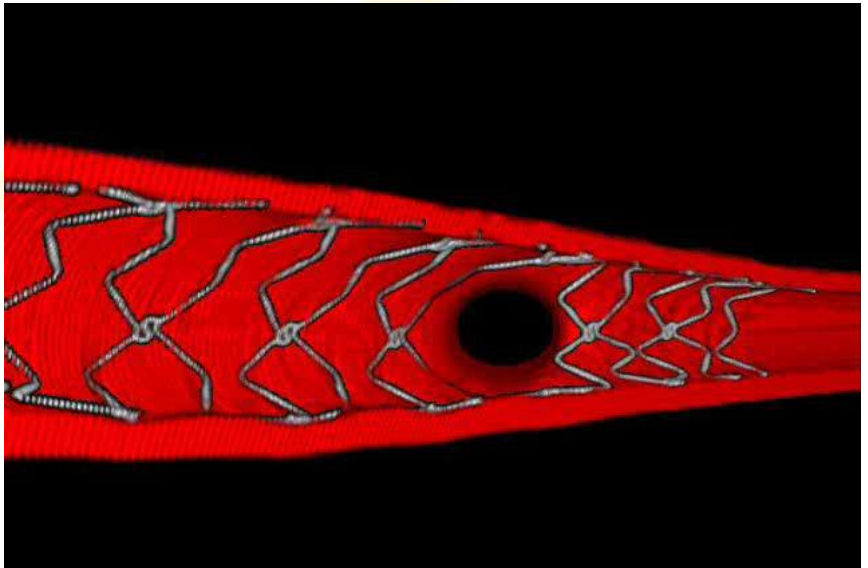


AFTER

KB

2.5/3.0 mm





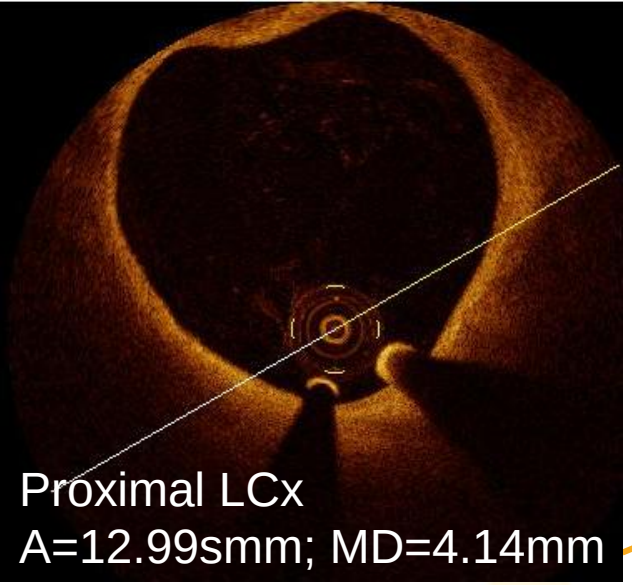
Conclusions

- ✓ **Workhorse design has a critical impact on apposition of the strut and performance when used in bifurcation settings**

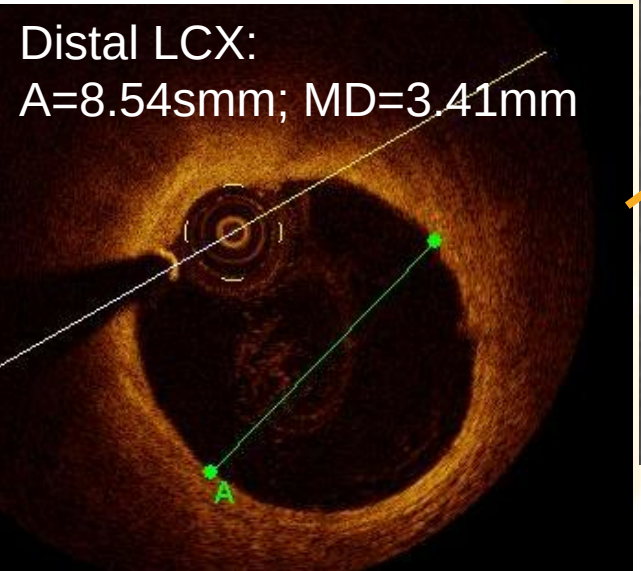
- ✓ **The Flex design offers good post-dilatation capacity and a large opening when dilated through the struts, sufficient to fit almost all coronary bifurcation anatomies**

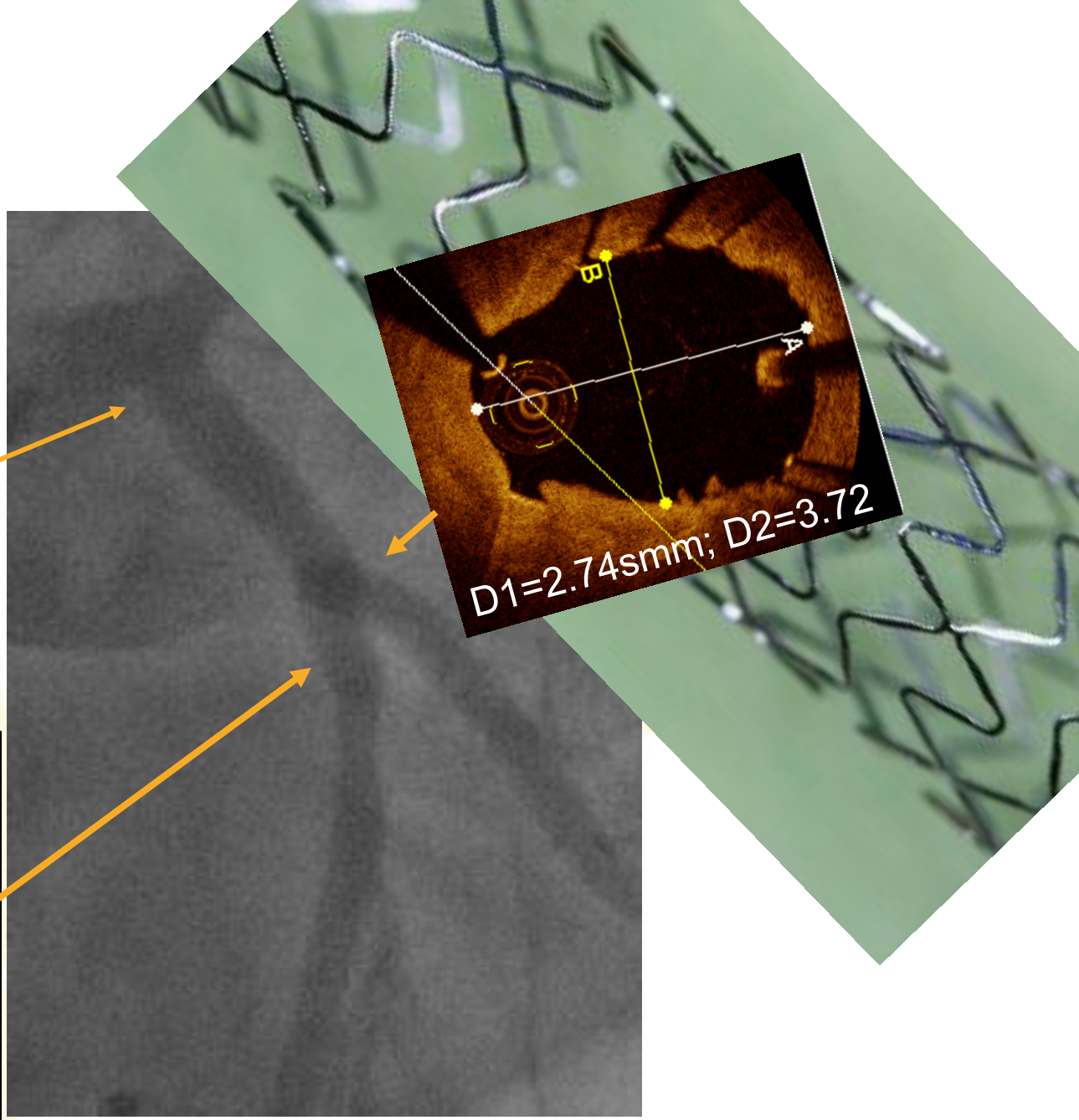
Biolimus in Bifurcations: OCT case examples and clinical results

Carlo Di Mario, Nicolas Foin



StJude FD-OCT from Dist LCx @ 2 cm/sec





3.0x28 & 4.0x8 Biomatrix Flex + KB 3.0/3.0

- 70 years-old caucasian male. HTN, Hypercholesterolemia, Positive FH.
- Severe multivessel CAD with multiple complex PCI (RCA, LAD, Cx).
- Increasing angina in the previous month

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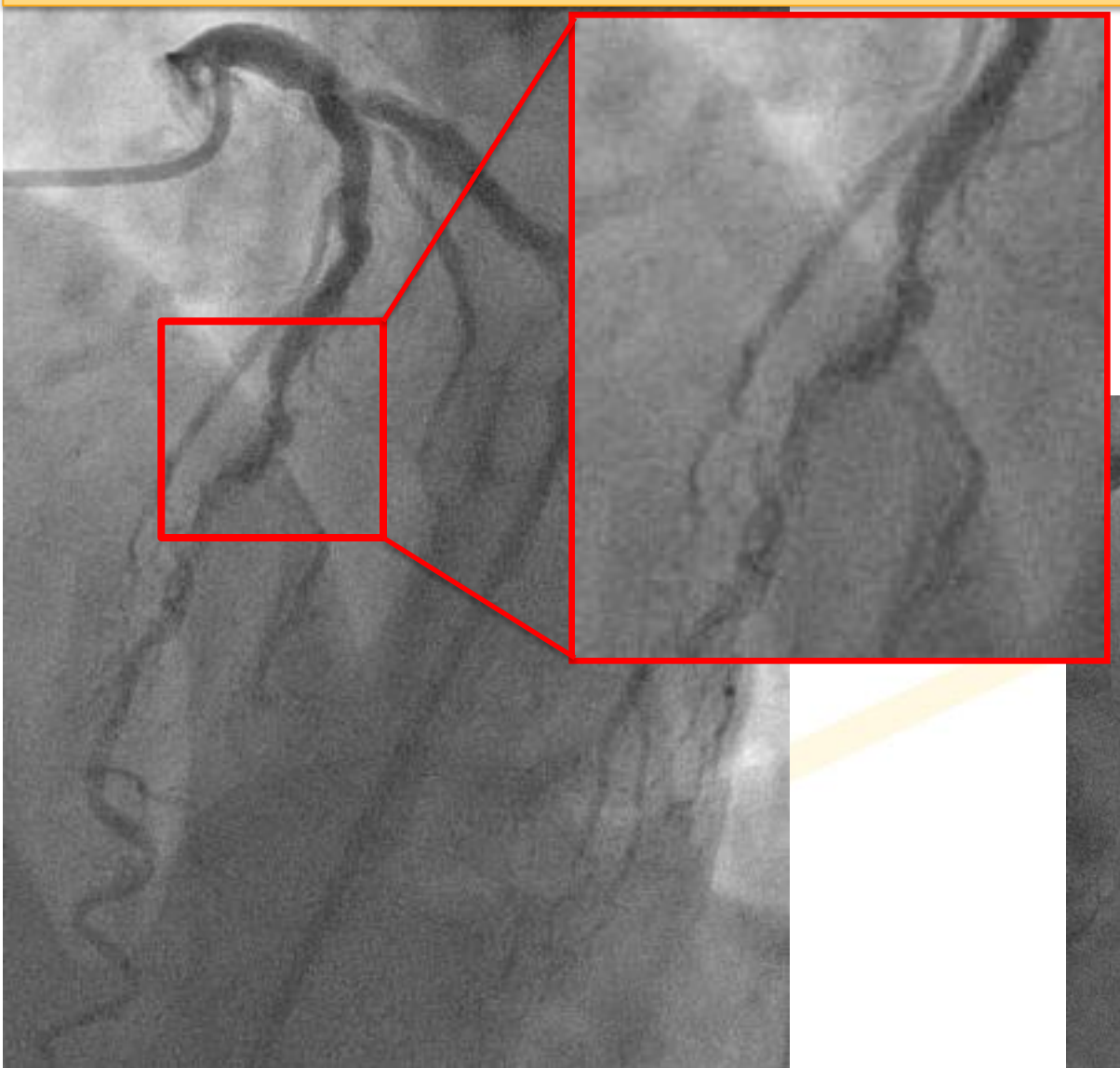
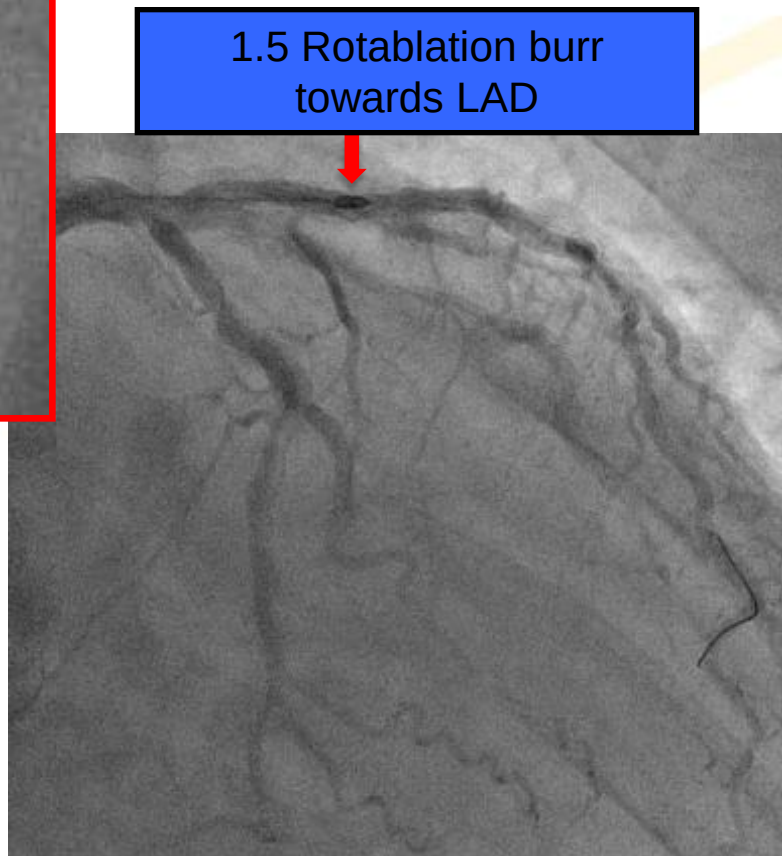
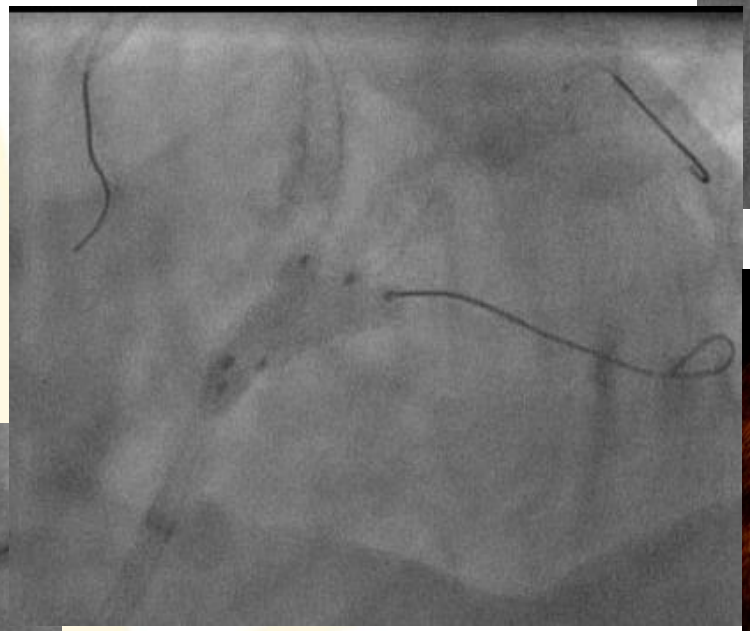




PCI to ostial LCx & final tri-kissing ballooon

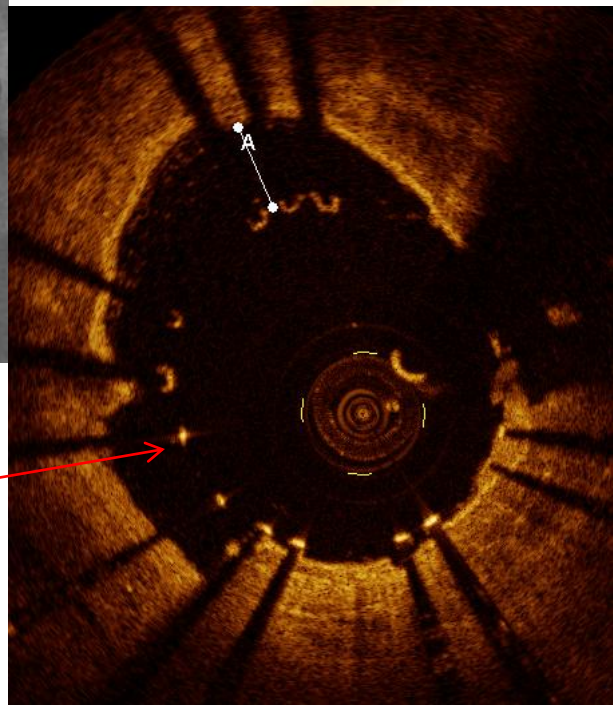
Post-Dilatatation with NCB 3.5 mm

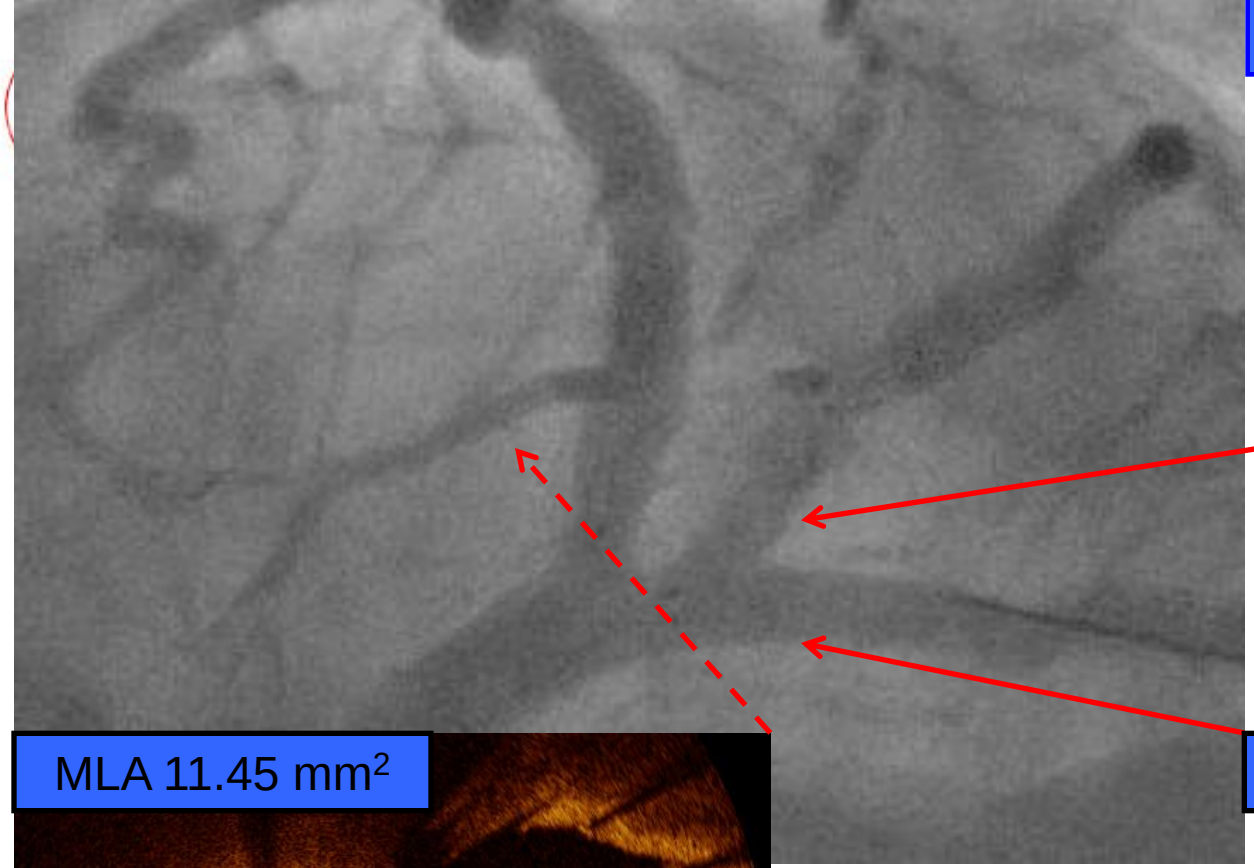
Additional 2.50 x 11 Biomatrix early OM1; Final triple -3.5, 3.0, 2.5- balloon dilatation in LAD, OM1 and LCx



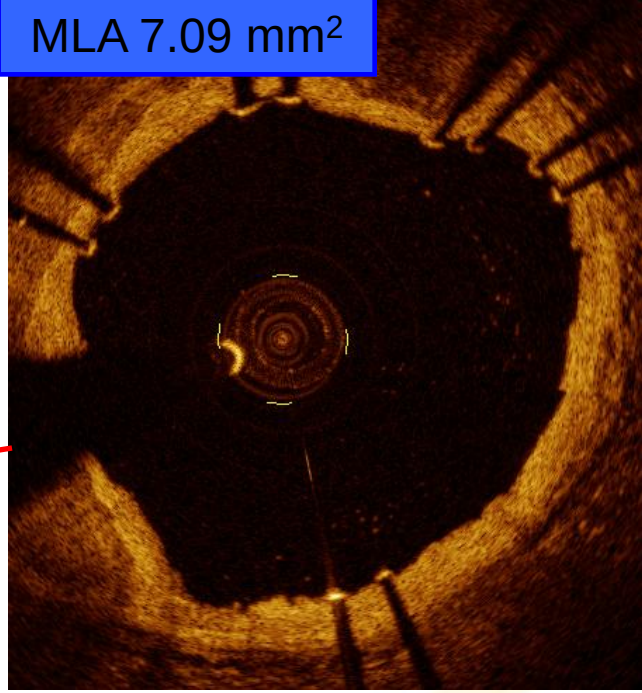
3.0 x 11 mm Biomatrix stent in the proximal LCx

Malapposed Struts

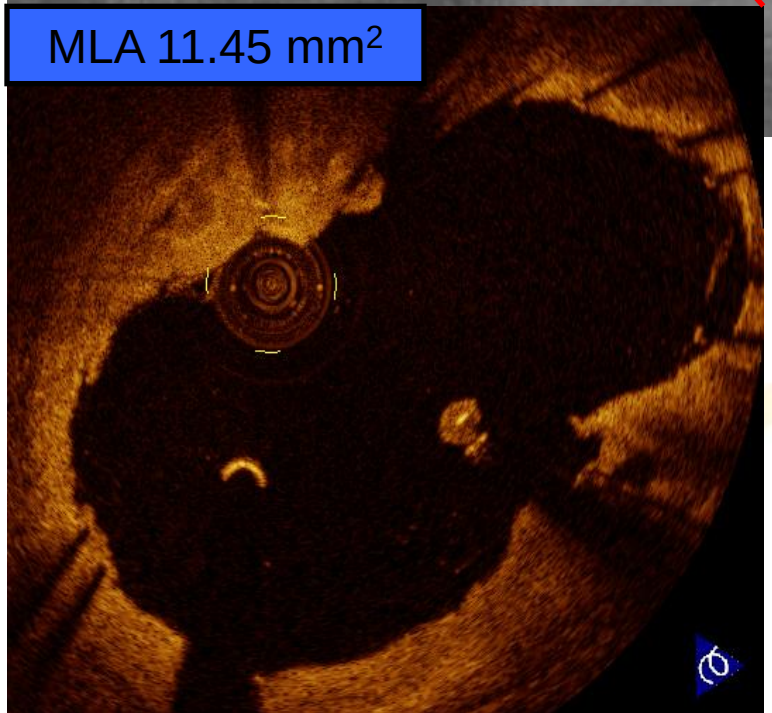




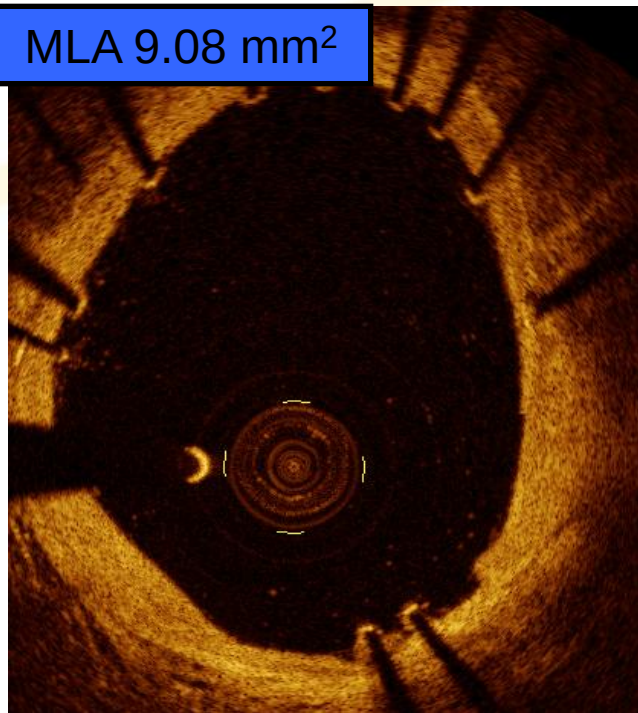
MLA 7.09 mm²



MLA 11.45 mm²

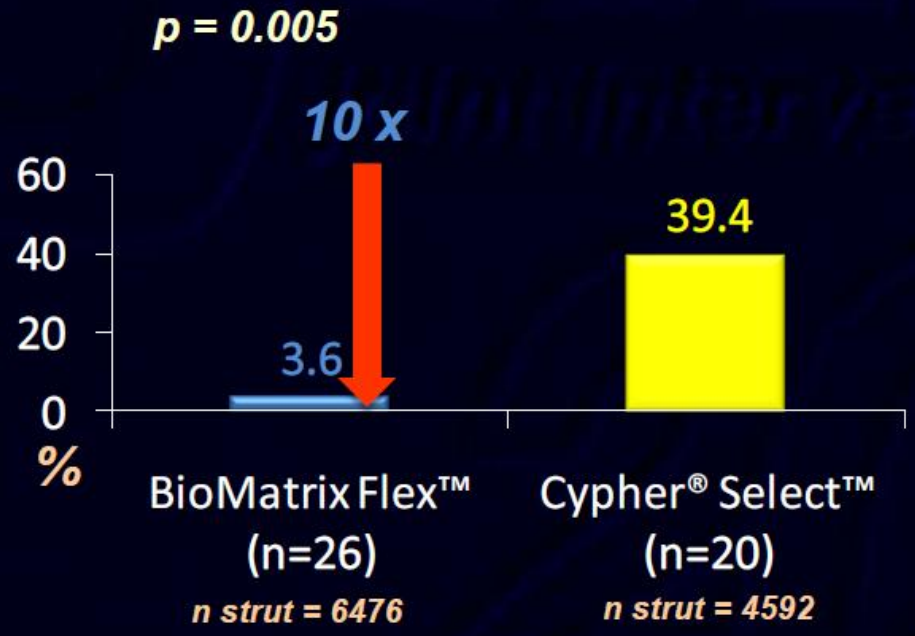


MLA 9.08 mm²

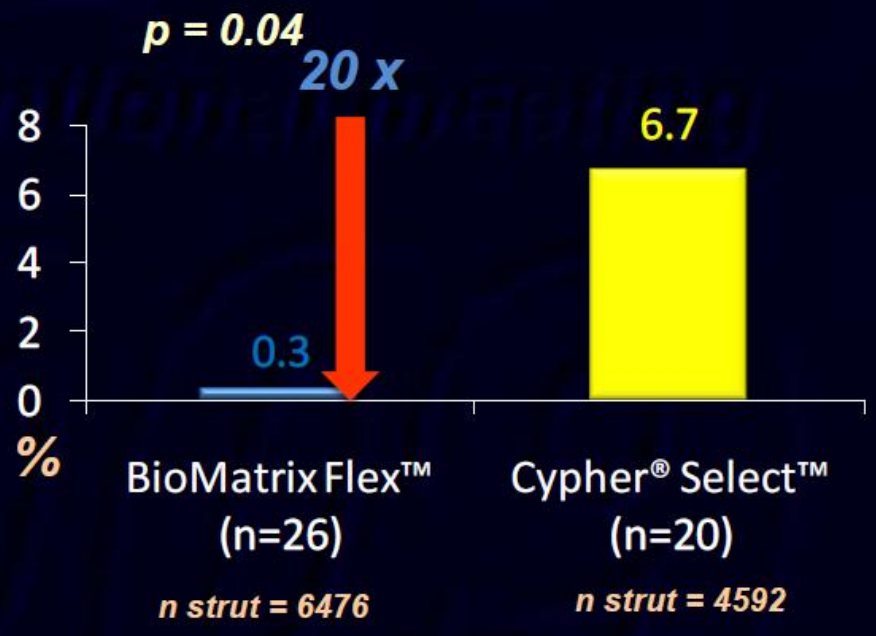


Superior Strut Coverage and Stent Apposition

Lesions with at least 5% uncovered struts



Lesions with at least 5% malapposed struts



Di Mario, C., TCT 2008

LEADERS Trial (Windecker, Serruys)

•Multicentre (n=10) • Non-inferiority • Allcomers

2,467 lesions in 1,707 patients

Randomised

SES

Patient groups 850 patients

- **No Bifurcation 611**
- **Bifurcation 239**

28.1% Pts have at least 1 Bifurc.

Lesion groups 1213 lesions

- **No Bifurcation 961**
- **Bifurcation 252**

20.1% Lesions are bifurcations

T
T
P
Partial, 2-stent technique 15

BES

Patient groups 857 patients

- **No Bifurcation 599**
- **Bifurcation 258**

30.1% Pts have at least 1 Bifurc.

Lesion groups 1254 lesions

- **No Bifurcation 972**
- **Bifurcation 282**

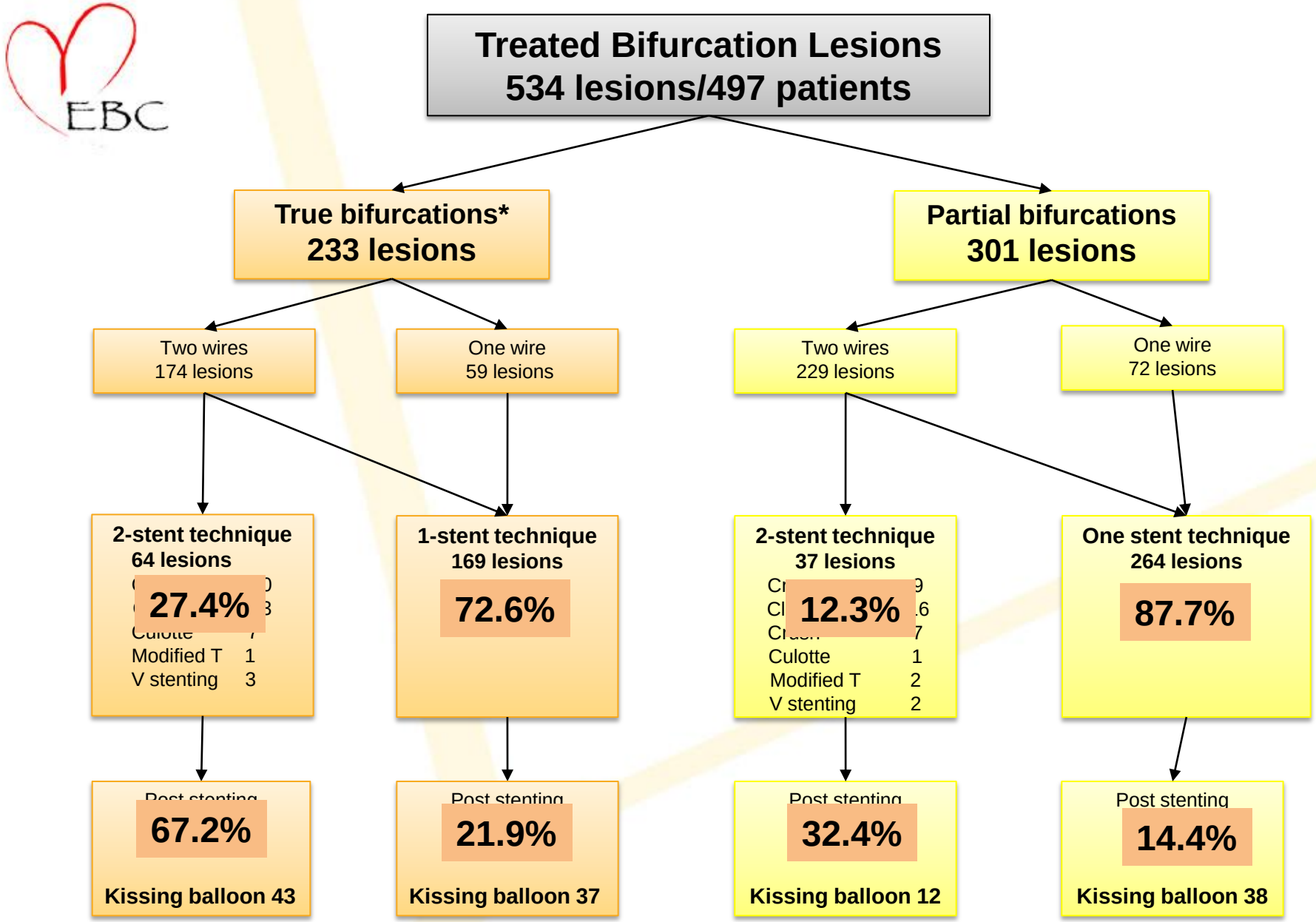
22.4% Lesions are bifurcations

True
True
Parti
Partial, 2-stent technique 22

Final Analysis
497 patients
534 lesions

- **Procedural data was collected on bifurcation technique by reviewing the angiogram of each bifurcation lesion (Dr Scot Garg)**

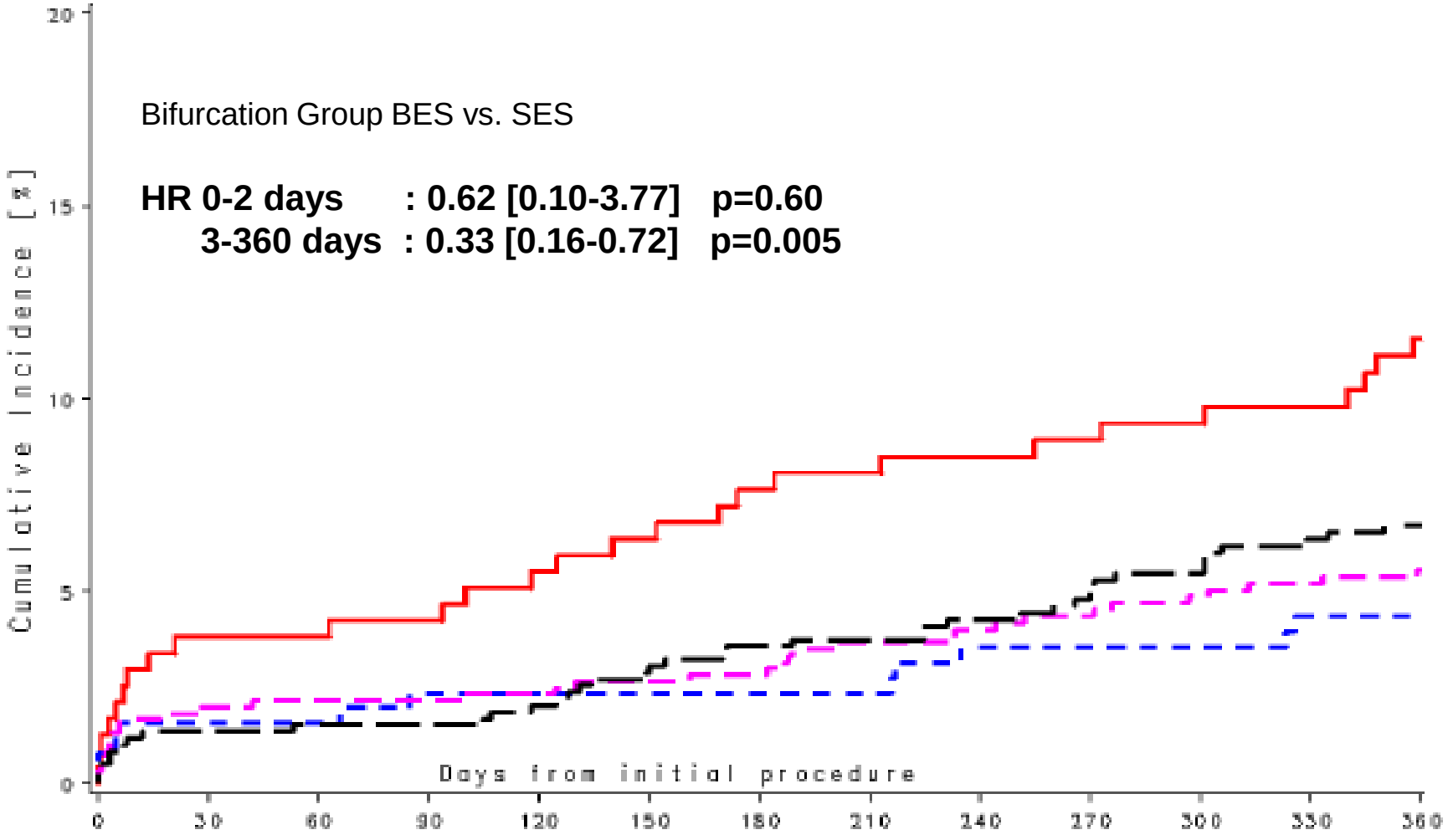
True bifurcation: Medina 1,1,1; 1,0,1; 0,1,1 Partial bifurcation: Medina 1,0,0; 1,1,0; 0,1,0; 0,0,1



*Includes 8 trifurcation lesions

True bifurcation: Medina 1,1,1; 1,0,1; 0,1,1 Partial bifurcation: Medina 1,0,0; 1,1,0; 0,1,0; 0,0,1

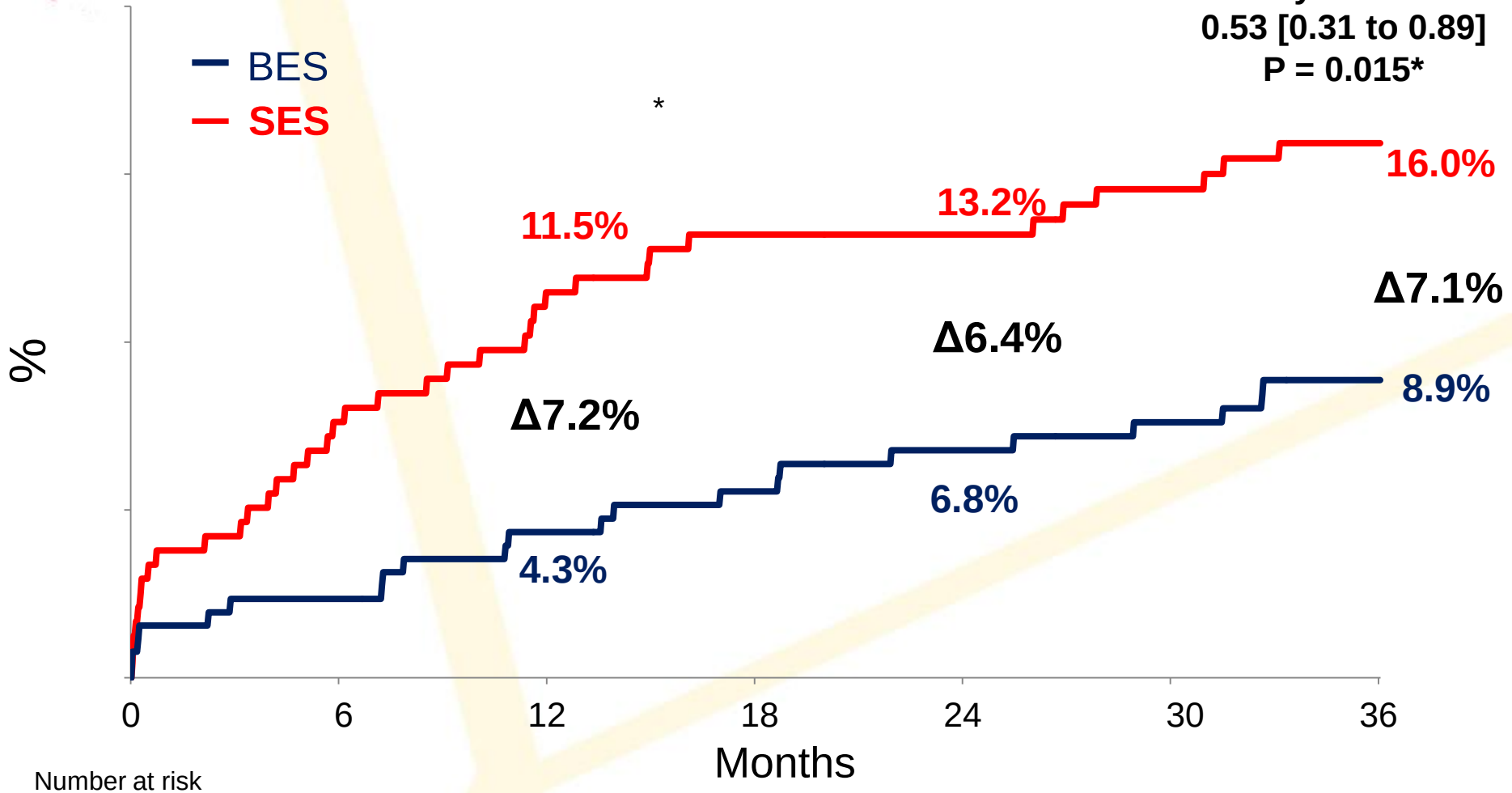
Clinically Justified TVR @ 24 Mths



Garg et, EuroIntervention 2009

Clinically-Indicated TVR @ 3 Years

Bifurcations



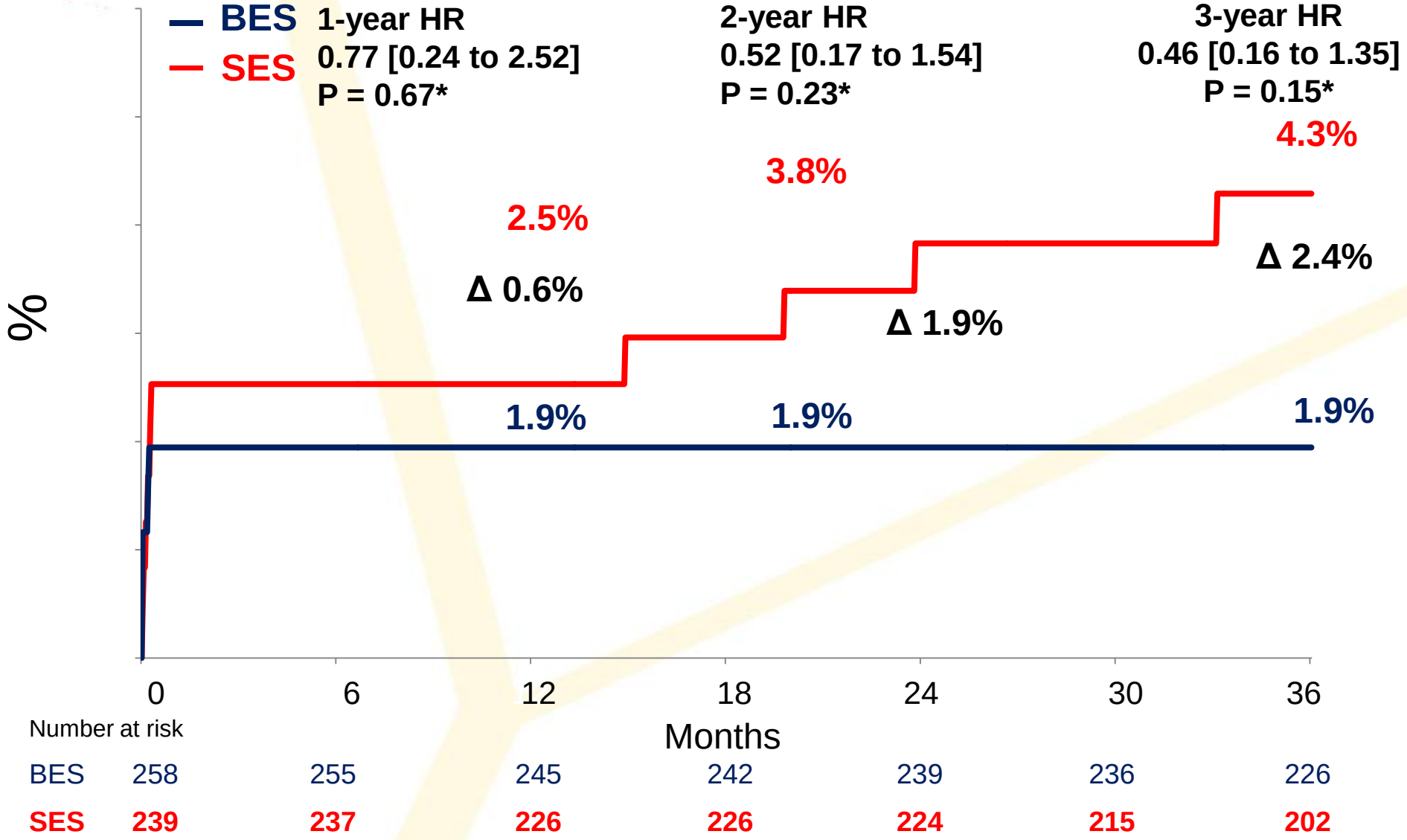
Number at risk

BES	258	255	242	237	231	225	214
SES	239	237	212	206	201	194	180

*P values for superiority

From Windecker et al, TCT 2010

Definite ST
Bifurcations



*P values for superiority

From Windecker et al, TCT 2010

Conclusions

- ✓ The Biomatrix Flex stent offers a large opening when dilated through the struts, and post-dilatation capacity of the proximal segment sufficient to fit almost all coronary anatomies
- ✓ Biolimus eluting stent appears to offer an advantage over first generation SES in treating patients with bifurcational lesions
- ✓ Comparison with other second generation platforms with biostable polymers is highly desirable