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Technical Tips of BVS in Bifurcation

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Background

- TVF due to the permanent presence of the metallic stents is more than 2% per year
- BVS were developed to eliminate this and and other potential limitations of a permanent metallic stent .
- Currently, the use of BRS for the treatment of Bifurcation lesions is based on case reports or small observational studies which support feasibility and good clinical short term outcome and should be considered investigational.

Limitations

- Limited expansion
- Reduced radial strength
- Possible fracture
- Strut thickness

Rev Esp Cardiol. 2016;69(6):554–562

Original article

Bioresorbable Vascular Scaffold for the Treatment of Coronary Bifurcation Lesions: Immediate Results and 1-year Follow-up

Javier Suárez de Lezo,[a,*] Pedro Martín,[b] Manuel Pan,[a] Soledad Ojeda,[a] José Nóvoa,[b] José Segura,[a] Francisco Mazuelos,[a] Miguel Romero,[a] Alfonso Medina,[b] and José Suárez de Lezo[a]

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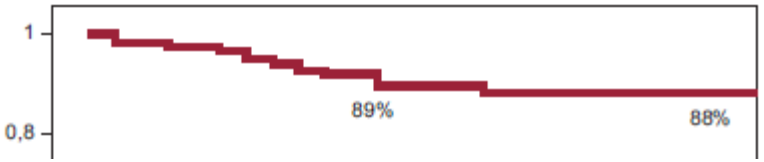
Table 3
Procedural Data

Diameter BVS, mm	3.16 ± 0.33
Length BVS, mm	23.25 ± 9.59
Direct implantation of BVS in MV	129 (56)
Inflation pressure, atmospheres	14.8 ± 2.4
Duration of inflation, s	59 ± 15
Postdilatation of BVS	114 (49)
Diameter postdilatation balloon, mm	3.11 ± 0.46
Postdilatation of SB	90 (40)



CONCLUSIONS

The treatment of coronary bifurcation lesions with BVS, using a provisional strategy, is safe and effective. The degree of initial success was high and the rate of major adverse cardiovascular events at 1 year was 8.7%. Longer-term studies are needed to confirm these findings, as are randomized studies comparing these devices with bare metal stents.

Catheterization and Cardiovascular Interventions 88:854–862 (2016)

Clinical Outcomes Following Bifurcation Double-Stenting With Bioresorbable Scaffolds

Akihito Tanaka,[1,2] MD, Azeem Latib,[1,2] MD, Hiroyoshi Kawamoto,[1,2] MD, Richard J. Jabbour,[1,2,3] MD, Antonio Mangieri,[2] MD, Matteo Pagnesi,[2] MD, Claudio Montalto,[2] MD, Damiano Regazzoli,[2] MD, Marco Ancona,[2] MD, Alaide Chieffo,[2] MD, Mauro Carlino,[2] MD, Matteo Montorfano,[2] MD, and Antonio Colombo,[1,2]* MD

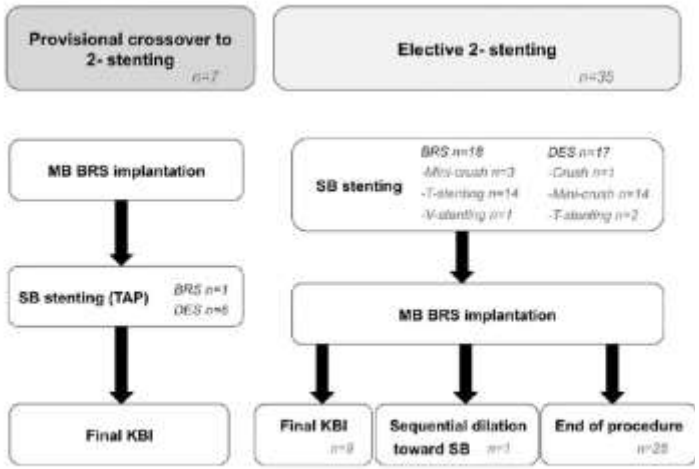


Fig. 1. Flow chart of procedural process. KBI, kissing balloon inflation.

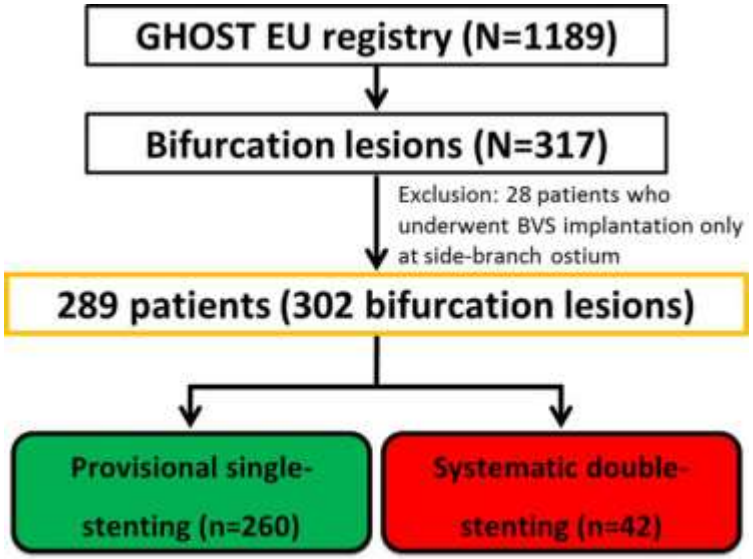
TABLE III. Clinical Outcomes at 1- and 2-Years

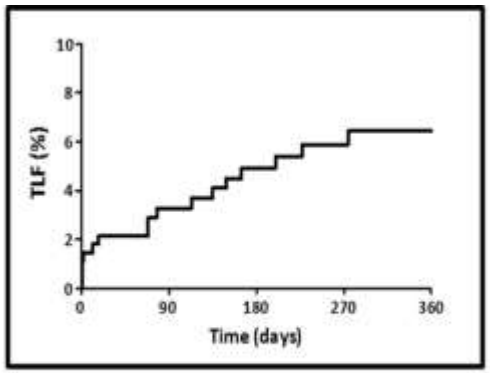
		Overall	SB BRS	SB DES	*P*-value (2 years)
Lesions		*N* = 42	*N* = 19	*N* = 23	
TLR per bifurcation	at 1 year	3 (9.7%)	2 (12.9%)	1 (5.6%)	
	at 2 years	4 (14.0%)	3 (19.6%)	1 (5.6%)	0.42
	in MB at 1 year	2 (6.9%)	2 (12.9%)	0 (0%)	
	at 2 years	3 (11.1%)	3 (19.6%)	0 (0%)	0.11
	in SB at 1 year	3 (9.7%)	2 (12.9%)	1 (5.6%)	
	at 2 years	4 (14.0%)	3 (19.6%)	1 (5.6%)	0.42
Patients		*N* = 41	*N* = 19	*N* = 22	
All-cause death	at 1 year	1 (2.5%)	0 (0%)	1 (4.5%)	
	at 2 years	1 (2.5%)	0 (0%)	1 (4.5%)	0.37
Cardiac death	at 1 year	1 (2.5%)	0 (0%)	1 (4.5%)	
	at 2 years	1 (2.5%)	0 (0%)	1 (4.5%)	0.37
Follow-up MI	at 1 year	0 (0%)	0 (0%)	0 (0%)	
	at 2 years	0 (0%)	0 (0%)	0 (0%)	–
TVR	at 1 year	3 (9.9%)	2 (12.9%)	1 (5.9%)	
	at 2 years	5 (18.4%)	3 (19.6%)	2 (17.6%)	0.91
Definite ST	at 1 year	0 (0%)	0 (0%)	0 (0%)	
	at 2 years	0 (0%)	0 (0%)	0 (0%)	–

TLR, target lesion revascularization; MB, main branch; SB, side branch; MI, myocardial infarction; TVR, target vessel revascularization; ST, scaffold/stent thrombosis (%), Event rates are estimated using Kaplan–Meier analysis.

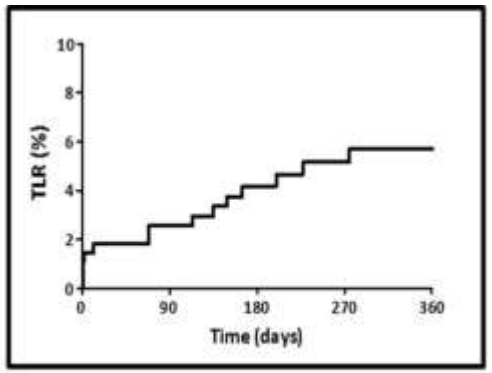
Bioresorbable Vascular Scaffold Use for Coronary Bifurcation Lesions: A Substudy from GHOST EU Registry

Toru Naganuma,[1,2] MD, Antonio Colombo,[1] MD, Maciej Lesiak,[3] MD, Davide Capodanno,[4] MD, PhD, Tommaso Gori,[5] MD, PhD, Holger Nef,[6] MD, Giuseppe Caramanno,[7] MD, Christoph Naber,[8] MD, Carlo Di Mario,[9] MD, Neil Ruparelia,[1] MD, Piera Capranzano,[4] MD, Jens Wiebe,[6] MD, Aleksander Araszkiewicz,[3] MD, Salvatore Geraci,[7] MD, Hiroyoshi Kawamoto,[1,2] MD, Stelios Pyxaras,[8] MD, Alessio Mattesini,[9] MD, Thomas Münzel,[5] MD, Corrado Tamburino,[4] MD, PhD, and Azeem Latib,[1]* MD

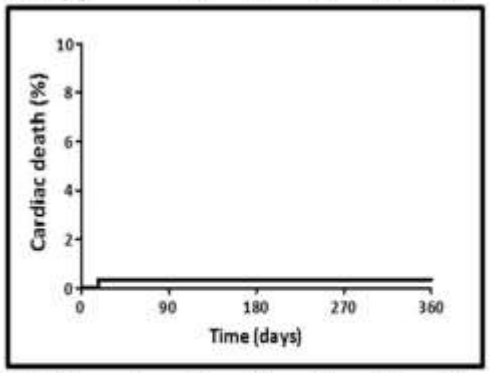




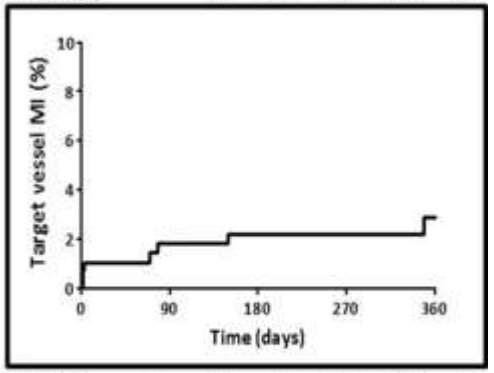
Time (days)	0	30	90	180	270	360
Number at risk	289	271	251	217	175	135
Event rate (%)		2.2	3.3	4.9	5.9	6.4



Time (days)	0	30	90	180	270	360
Number at risk	289	272	253	219	174	134
Event rate (%)		1.8	2.5	4.2	5.2	5.7



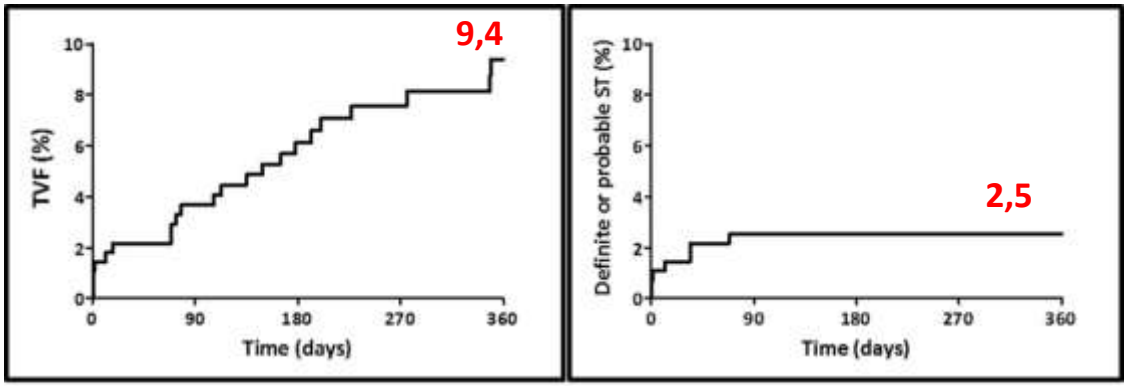
Time (days)	0	30	90	180	270	360
Number at risk	289	276	259	229	186	143
Event rate (%)		0.4	0.4	0.4	0.4	0.4



Time (days)	0	30	90	180	270	360
Number at risk	289	274	255	224	180	139
Event rate (%)		1.1	1.8	2.2	2.2	2.9

CCI 2016; 89:47-56

GHOST EU Registry : Stent Thrmbosis



Time (days)	0	30	90	180	270	360
Number at risk	289	271	250	215	173	131
Event rate (%)		2.2	3.7	6.1	7.6	9.4

Time (days)	0	30	90	180	270	360
Number at risk	289	272	252	221	181	137
Event rate (%)		1.4	2.5	2.5	2.5	2.5

TABLE VI. Independent Predictors for TLF on Cox Regression Analysis

	Univariate		Multivariate	
	HR (95%CI)	*P* value	HR (95% CI)	*P* value
Age	1.00 (0.96–1.04)	0.912		
Male	0.95 (0.32–2.84)	0.927		
Current smoker	1.42 (0.55–3.71)	0.470		
Diabetes mellitus	2.73 (1.13–6.61)	0.026	3.37 (1.38–8.26)	0.008
Hypertension	7.13 (0.95–53.2)	0.056		
Previous PCI	0.42 (0.14–1.27)	0.125		
Renal disease	0.59 (0.13–2.67)	0.490		
LVEF	1.01 (0.95–1.08)	0.739		
ACS	3.91 (1.55–9.86)	0.004	4.67 (1.78–12.3)	0.002
ISR	2.14 (0.49–9.29)	0.310		
CTO	0.62 (0.08–4.65)	0.642		
IVUS	0.59 (0.19–1.79)	0.351		
OCT	2.19 (0.86–5.60)	0.101		
Predilation on MB	0.20 (0.06–0.71)	0.012		
Postdilation on MB	0.54 (0.21–1.35)	0.186		
Prasugrel or Ticagrelor use	1.83 (0.72–4.65)	0.201		
True bifurcation	0.65 (0.26–1.63)	0.363		
Double-stenting	0.65 (0.15–2.80)	0.561	1.01 (0.23–4.53)	0.988
KBI	0.25 (0.03–1.88)	0.178		
Sequential dilation/dilate MB–BVS toward SB	1.55 (0.52–4.64)	0.435		

ACS, acute coronary syndrome; BVS, bioresorbable vascular scaffold; CTO, chronic total occlusion; ISR, in-stent restenosis; IVUS, intravascular ultrasound; KBI, kissing balloon inflation; LVEF, left ventricular ejection fraction; MB, main branch; OCT, optical coherence tomography; PCI, percutaneous coronary intervention.

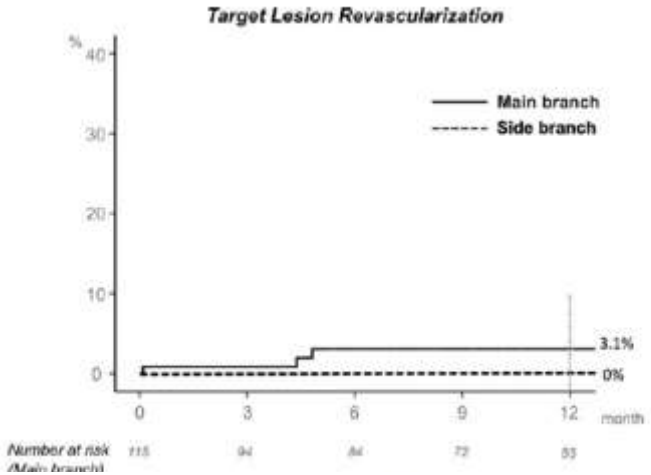
CCI 2016; 89:47-56

BVS in Bifurcations

- Data from studies on BMS and DES should guide for an appropriate use : Provisional Stenting in Bifurcation is possible and should be preferred in at least 80% of cases (Particularly true with BVS)
- BVS as compared to metallic stent is breakable : Attention should be made :
  - Maximal expansion = nominal value + 0.5mm
  - Use a non compliant balloon.
  - Maximal balloon at SB ?

Preliminary Report of Clinical Outcomes After Single Crossover Bioresorbable Scaffold Implantation Without Routine Side Branch Strut Dilation

Akihito Tanaka,[1,2] MD, Richard J. Jabbour,[1,2,3] MD, Hiroyoshi Kawamoto,[1,2] MD, Antonio Mangieri,[2] MD, Matteo Pagnesi,[2] MD, Claudio Montalto,[2] MD, Alaide Chieffo,[2] MD, Mauro Carlino,[2] MD, Matteo Montorfano,[2] MD, Azeem Latib,[1,2] MD, and Antonio Colombo,[1,2*] MD



CONCLUSION

Our results indicate that SB dilation may not be routinely necessary as long as SB compromise does not occur after single crossover BRS implantation, but further research with angiographic and longer follow-up is needed.

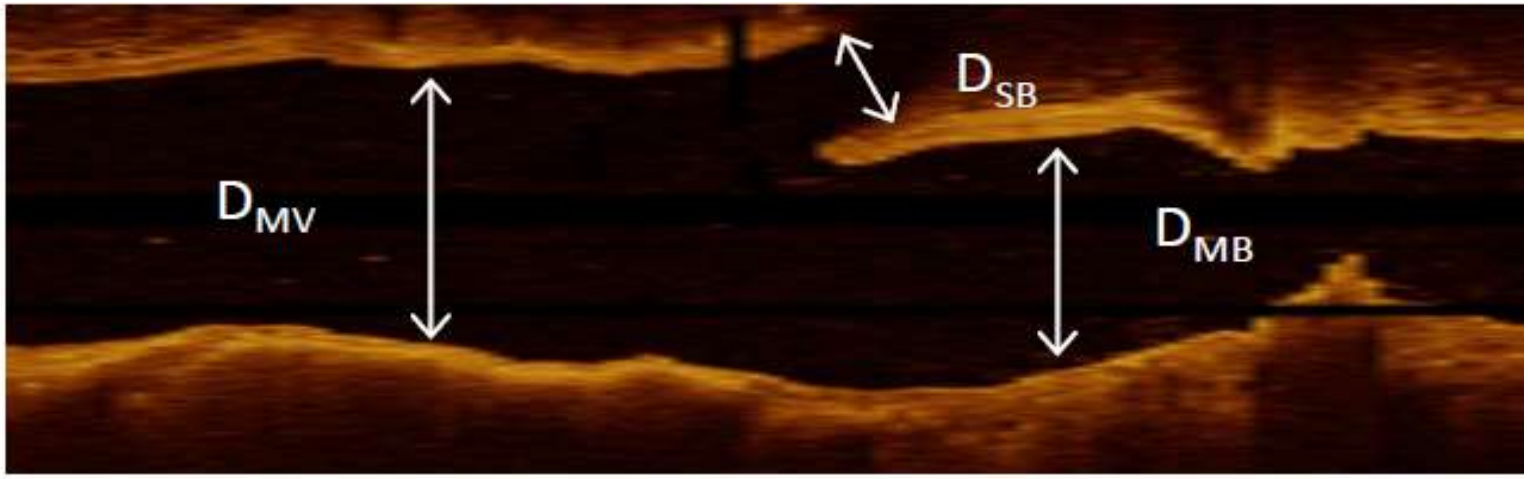
CCI 2016 ; 88:865-870

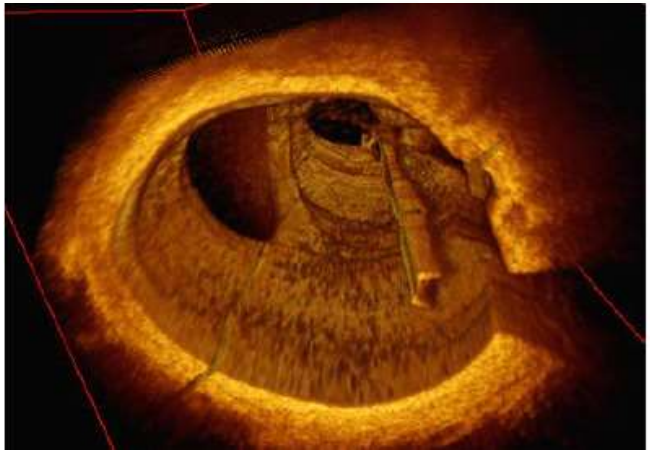
1- Provisional Approach : Keep it simple

- **Meticulous lesion preparation**
- **Appropriate BVS sizing**
- **1 BVS acrross**
  SB : not compromised & TIMI III flow - No further interventions needed

- **Predicting SB occlusion after stenting ?**
- **SB predilatation with undersized balloon**
- **keep the wire in position**
- **BVS (appropriately sized) accrossat nominal pressure**
- **POT with NC balloon**

2-Appropriate Sizing according to Bifurcation Anatomy



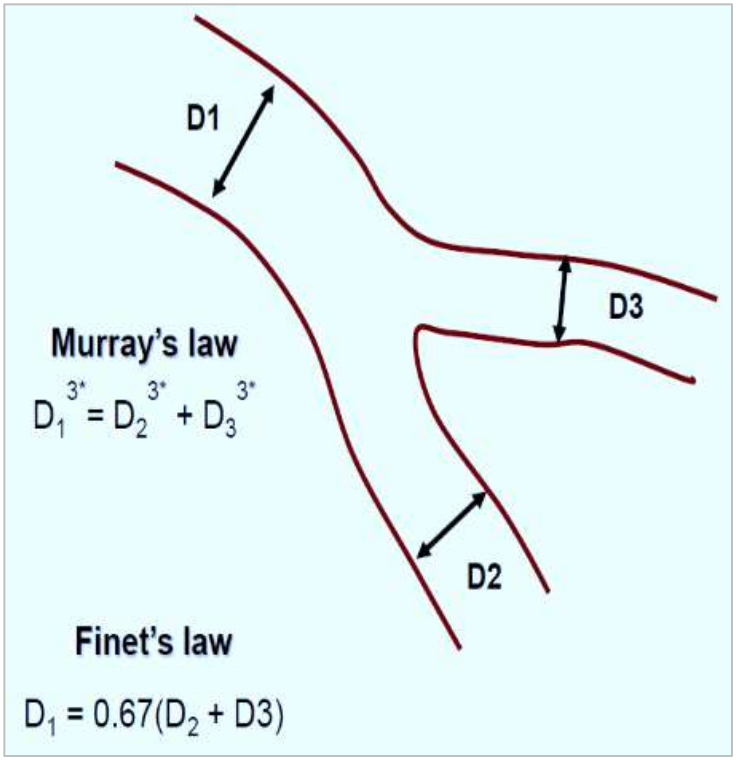


	Principle	Relation	*Ratio Dm/Dd for D_{d1}~ D_{d2}*
Murray's law	Minimum Work	$D_m3 = D_{d1}3 + D_{d2}3$	*1.26*
HK: Huo-Kassab	Minimum Energy	$D_m7/3 = D_{d1}7/3 + D_{d2}7/3$	*1.35*
Flow conservation	$Q_m = Q_{d1} + Q_{d2}$	$D_m2 = D_{d1}2 + D_{d2}2$	*1.4*
Finet	Measurement	$D_m = \underline{0.678}\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

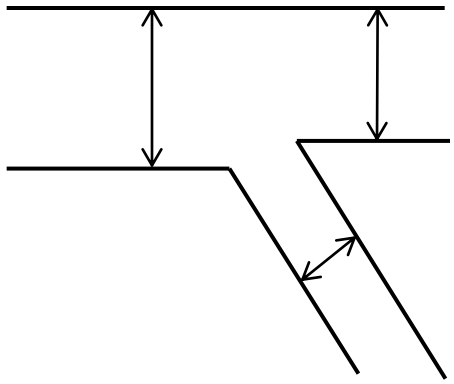
The larger the SB, the larger the change in MV diameter throughout the bifurcation

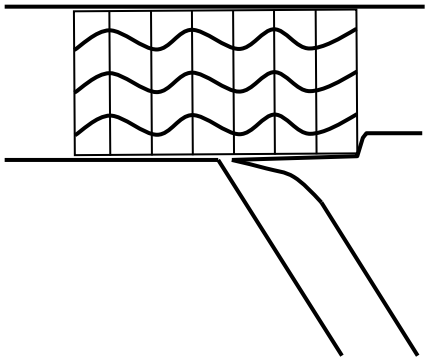
Courtesy of N Foin

2-Appropriate Sizing according to Bifurcation Anatomy

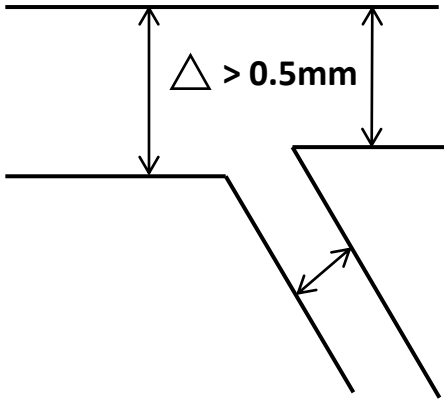


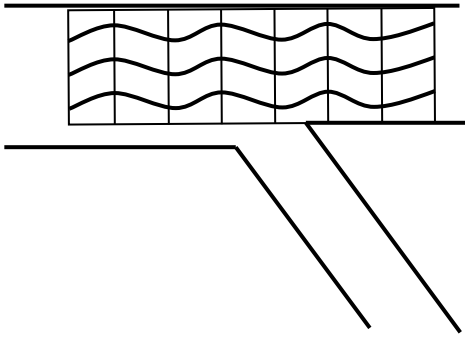
Avoid oversizing

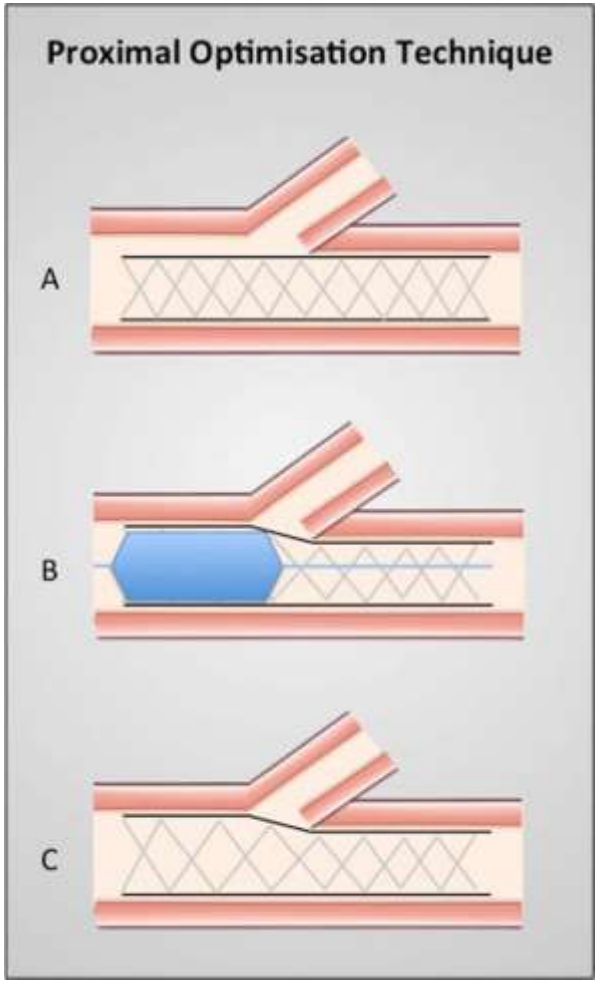




Avoid undersizing







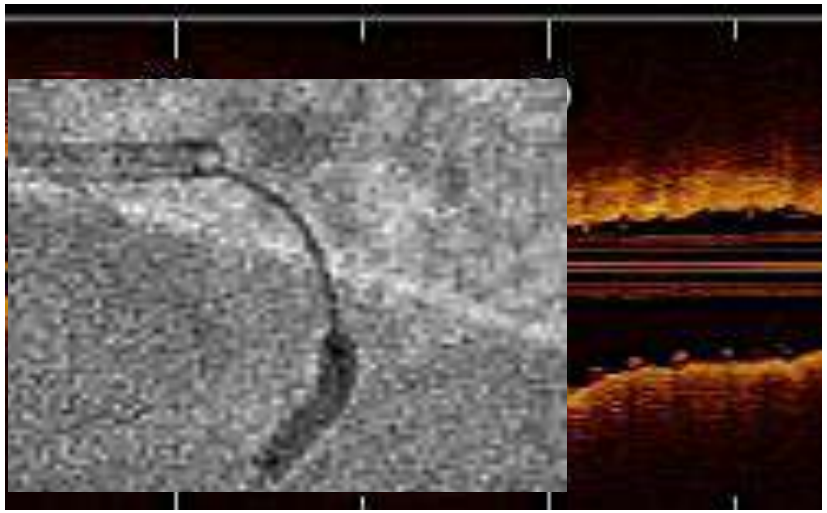
POT (before SB wiring if required) :

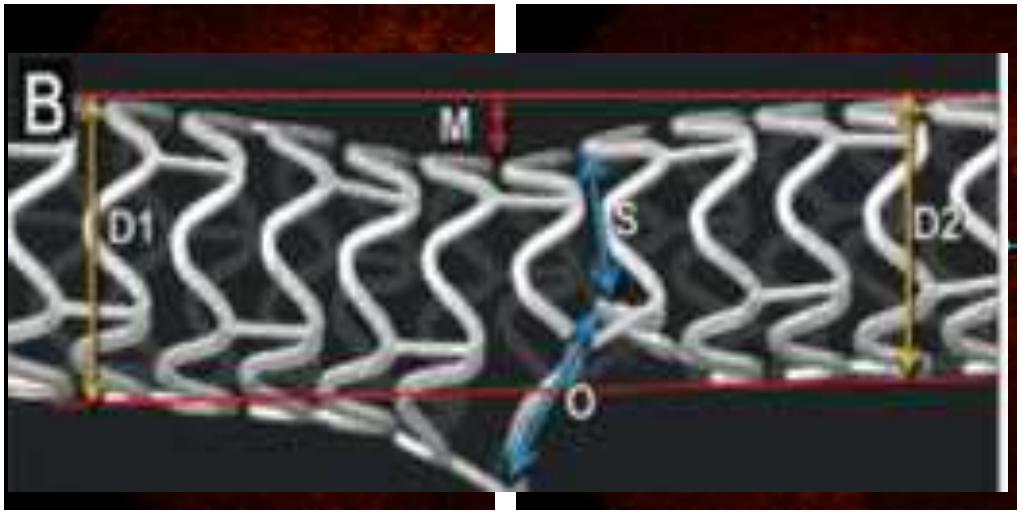
-facilitate rewiring SB accross the BVS
- good apposition of the BVS

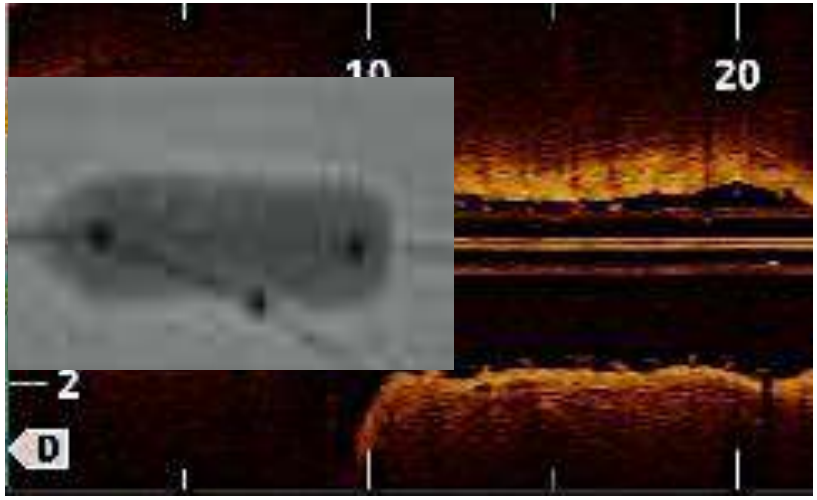
If no SB compromise : procedure finished

R Diletti et al ; CCI 2016; 88:397–406

3-Need for BVS fenestartion and SB dilatation ?
Sequential Dilataion

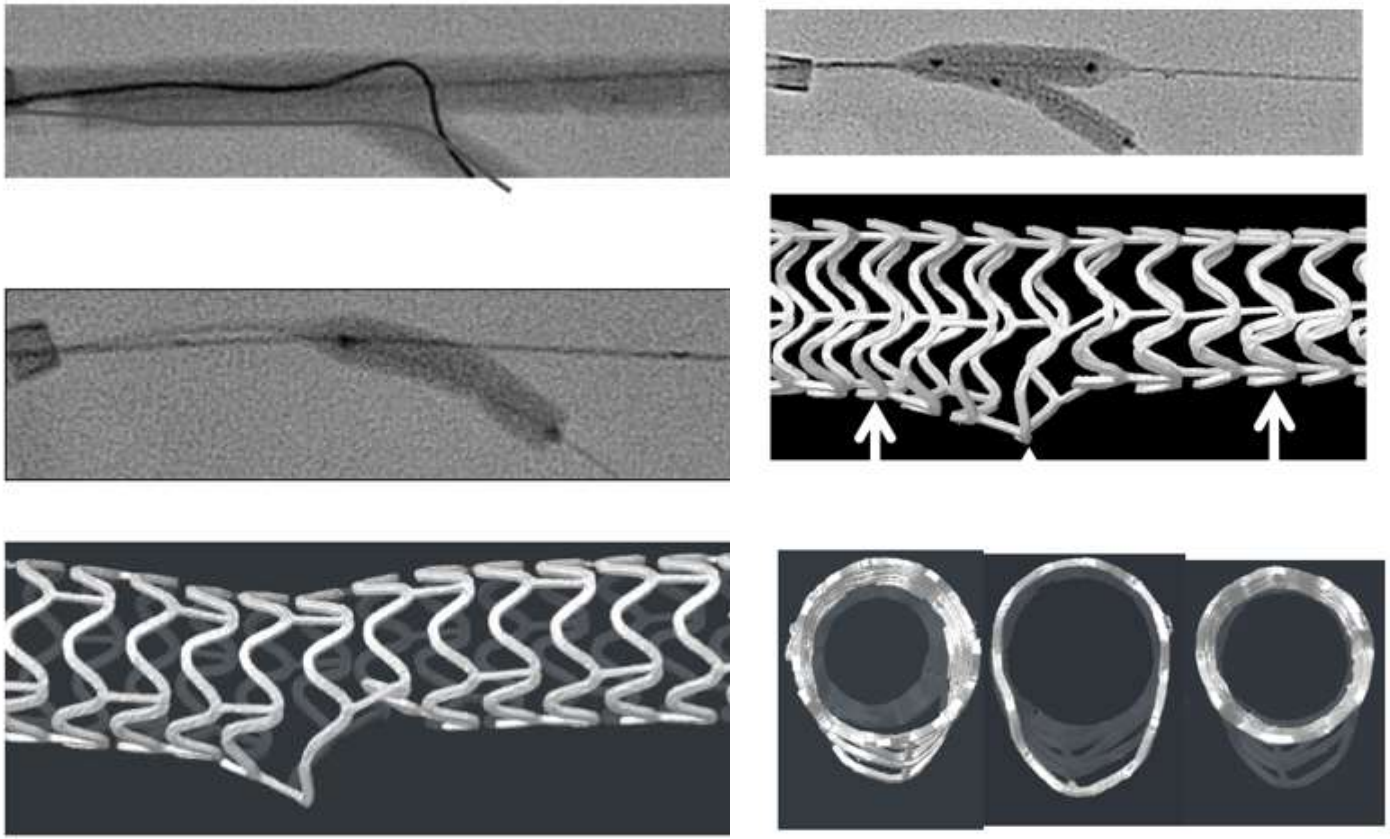






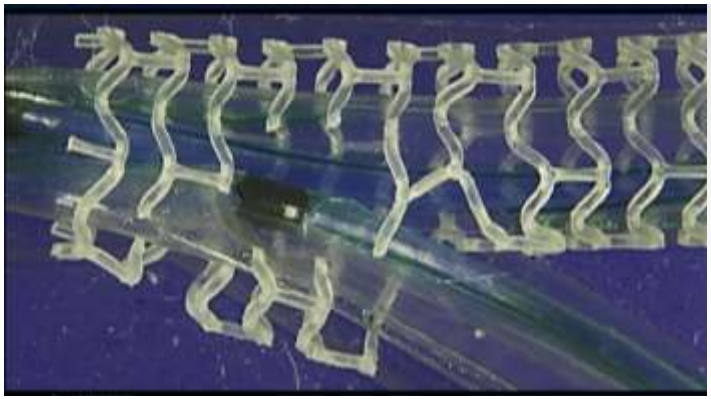
3-Need for BVS fenestartion and SB dilatation ?
Mini-KBPD or snuggle

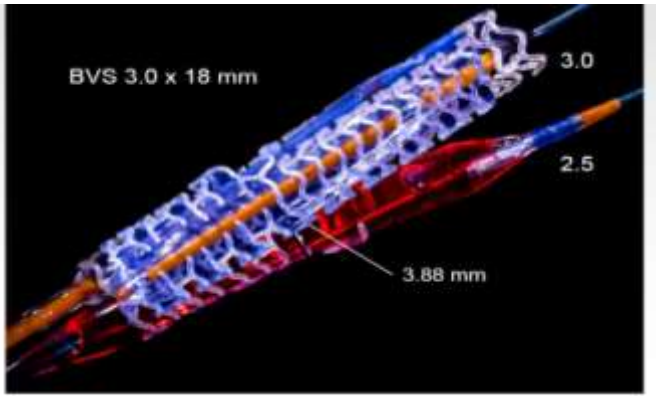
Bench test in Provisional T Stenting : deformation of the stent after stent dilatation to SB can be corrected by mini-KBPD at 5 atm

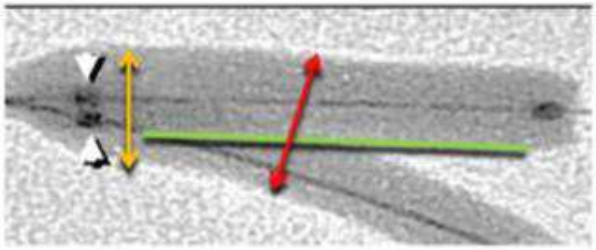


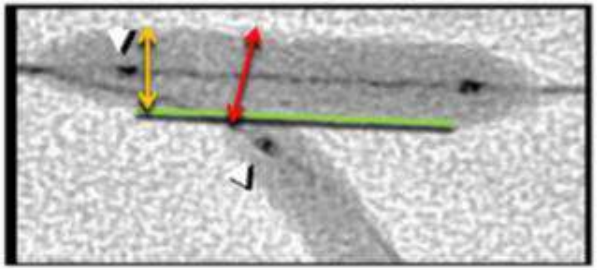
Ormiston , EuroIntervention

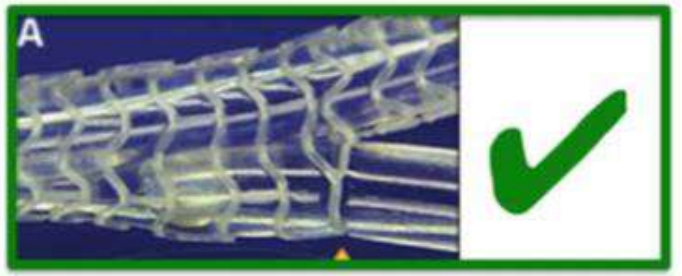
Avoid Coventional KBI











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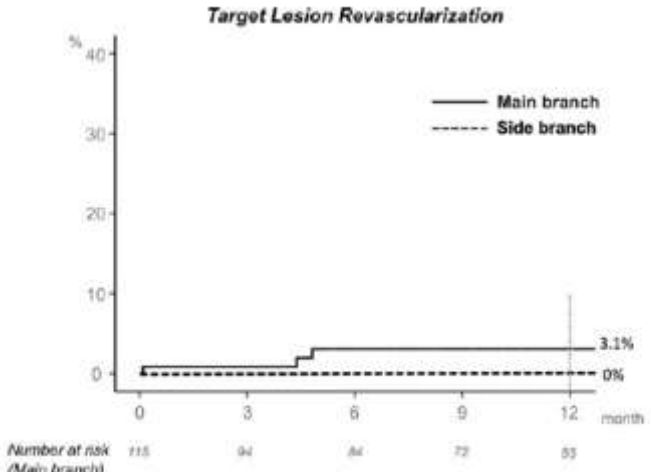


CONCLUSION

Our results indicate that SB dilation may not be routinely necessary as long as SB compromise does not occur after single crossover BRS implantation, but further research with angiographic and longer follow-up is needed.

CCI 2016 ; 88:865-870

Avoid High Pressure inflation in SB

Fracture of Bioresorbable Vascular Scaffold After Side-Branch Balloon Dilation in Bifurcation Coronary Narrowings

Manuel Pan, MD[a,*], Miguel Romero, MD[a], Soledad Ojeda, MD[a], Javier Suarez de Lezo, MD[a], Jose Segura, MD[a], Francisco Mazuelos, MD[a], Pedro Martin, MD[b], Alfonso Medina, MD[b], and Jose Suarez de Lezo, MD[a]

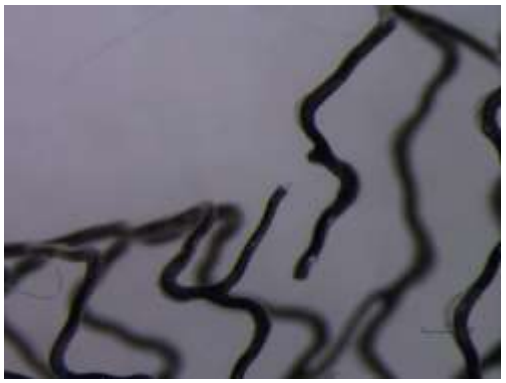
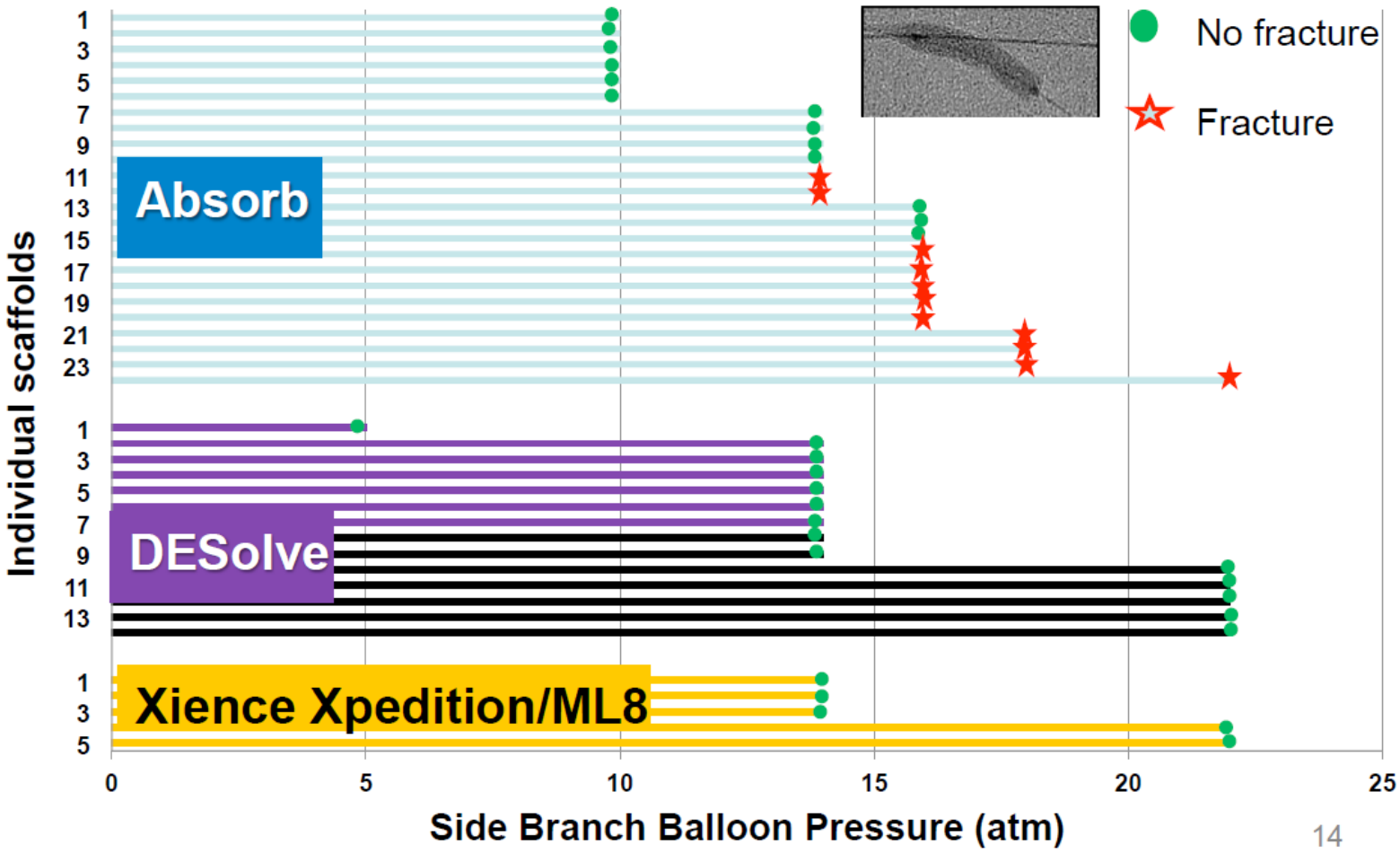


Table 3
Individual characteristics of patients with BVS fractures

	Patient #1	Patient #2	Patient #3
BVS size (mm)	3.5 × 18	3.0 × 12	2.5 × 18
SB balloon diameter (mm)	2.5	2.5	2.5
SB balloon pressure (atm)	10	9	10
BVS post-dilation balloon diameter (mm)	3.5	3	3
OCT findings			
SB lateral dilation			
Protrusion	+	+	+
Overlapped	+	+	-
Not oriented	+	+	+
BVS prolonged balloon dilation			
Protrusion	-	-	-
Overlapped	+	+	-
Not oriented	-	-	-

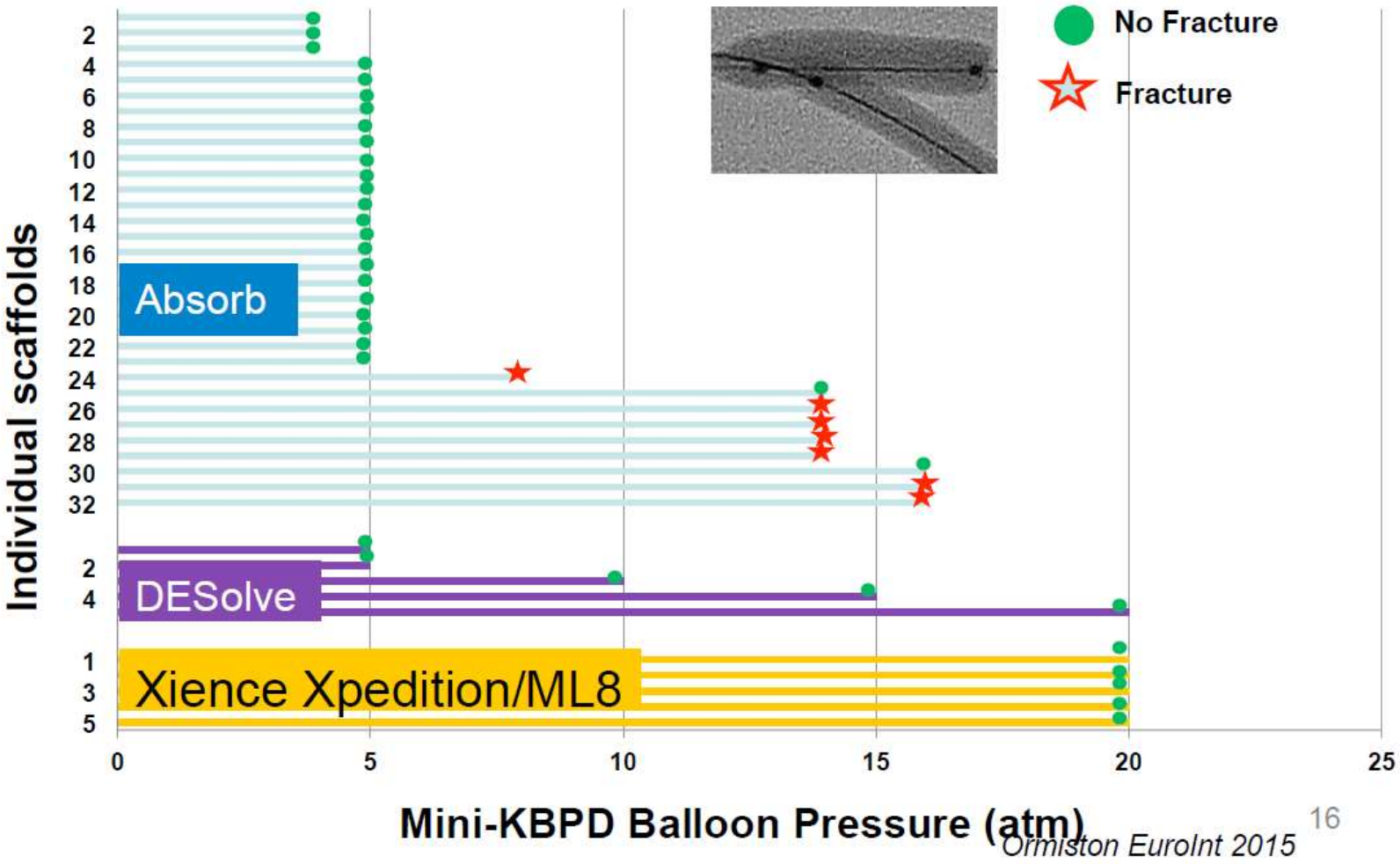
(Am J Cardiol 2015;116:1045-1049)

Bench Testing : Dilatation thru sides of 3.0 mm BVS with 3.0 mm NC balloon to inspect for strut fracture



Ormiston EuroInt 2015

Bench Testing :Mini-KBPD 0f 3.0 mm BVS with 3.0 mm NC balloons to inspect for strut fracture



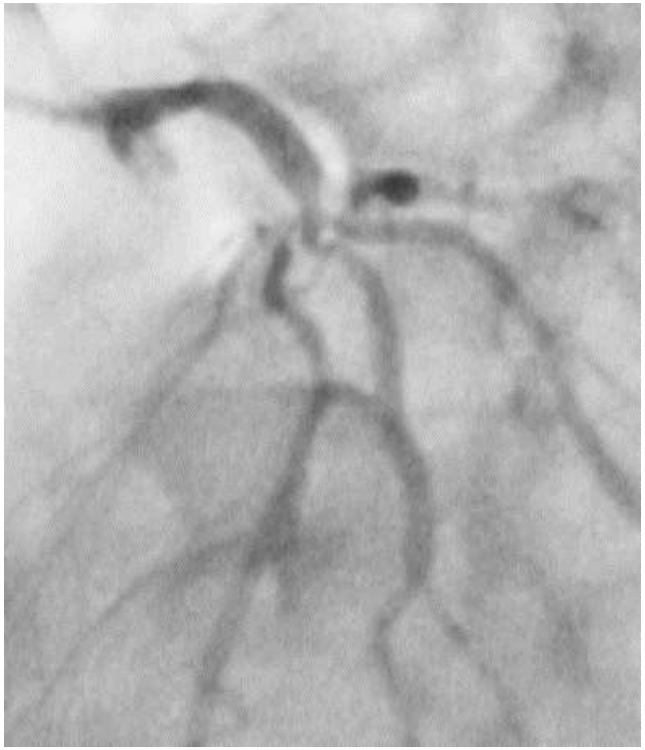
Ormiston EuroInt 2015

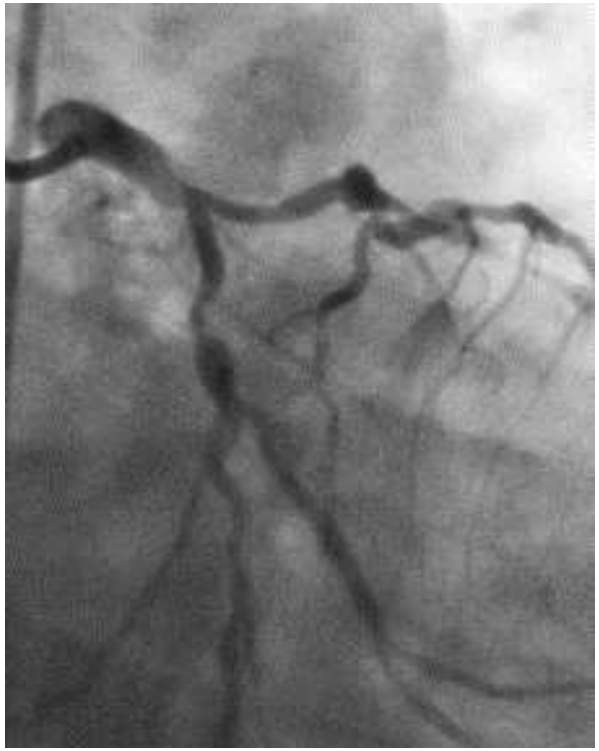
4- When 2 stent approach is planned :

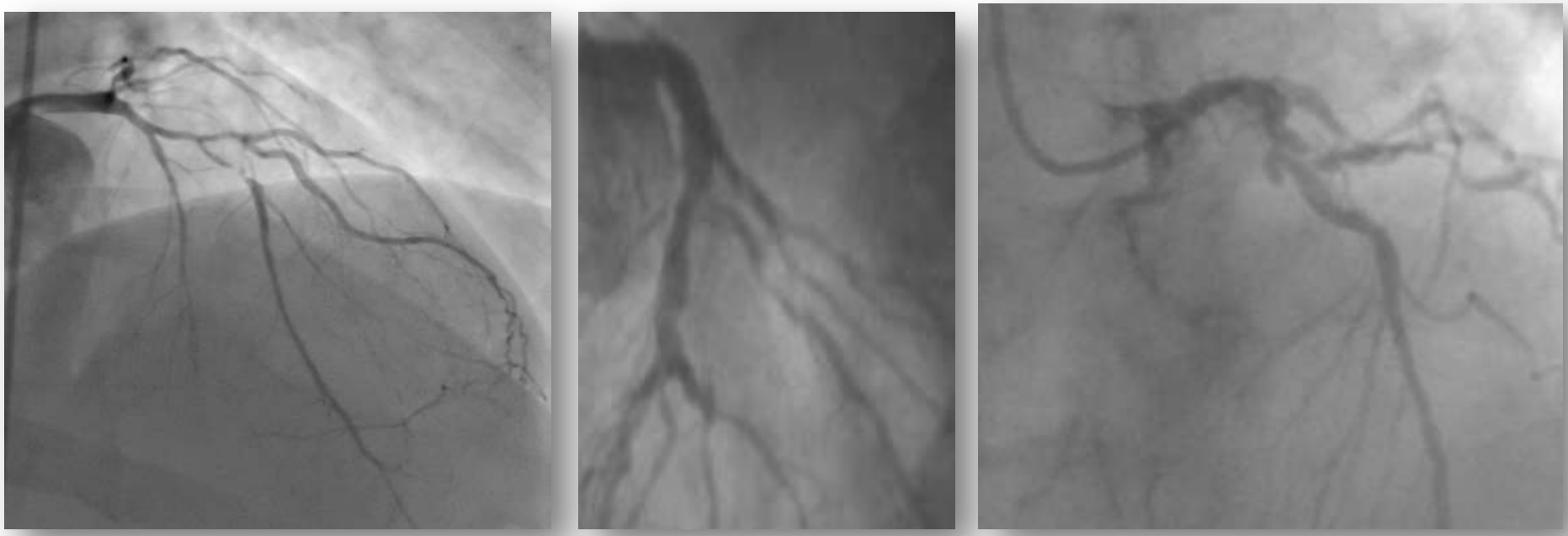
- Cpmplex BIFURCATIONS (2 STENTS)
- SEVERE CALCIFICATIONS
- Complex anatomy
- Etc….

At the present time BVS is not the appropriate choice

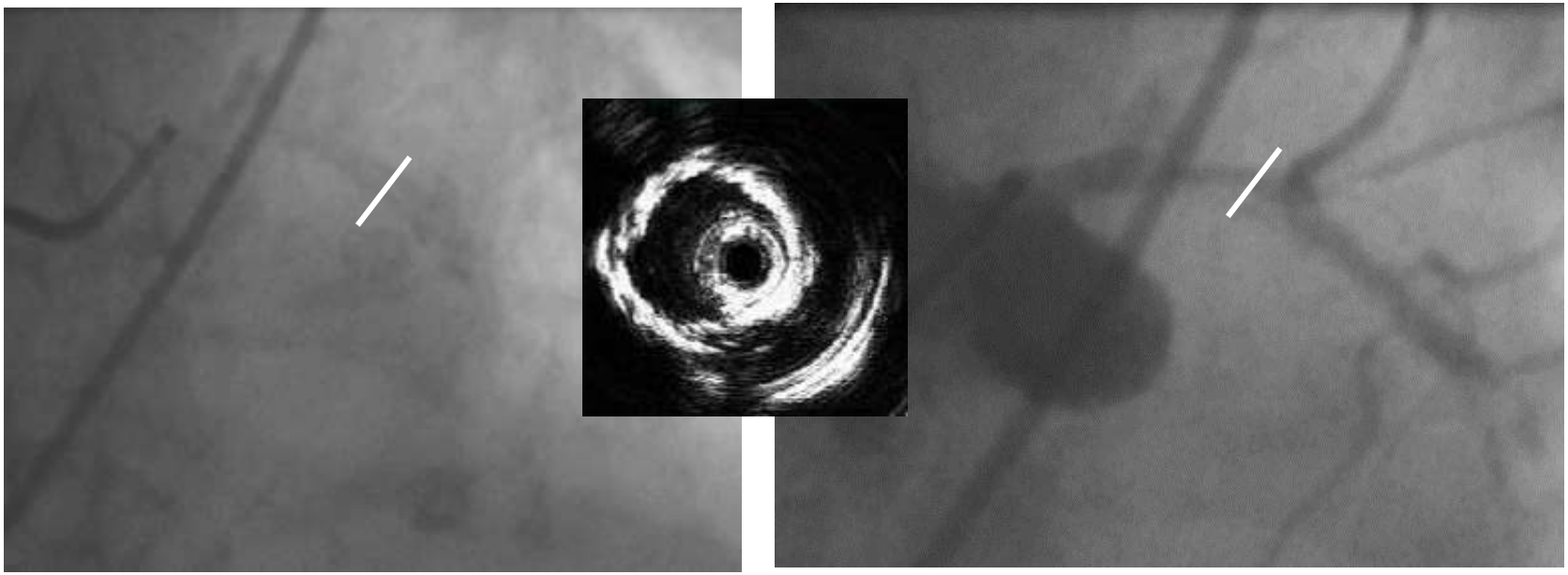
BVS & Big Mismatch in Diameter : not a good condition for BVS use – Avoid





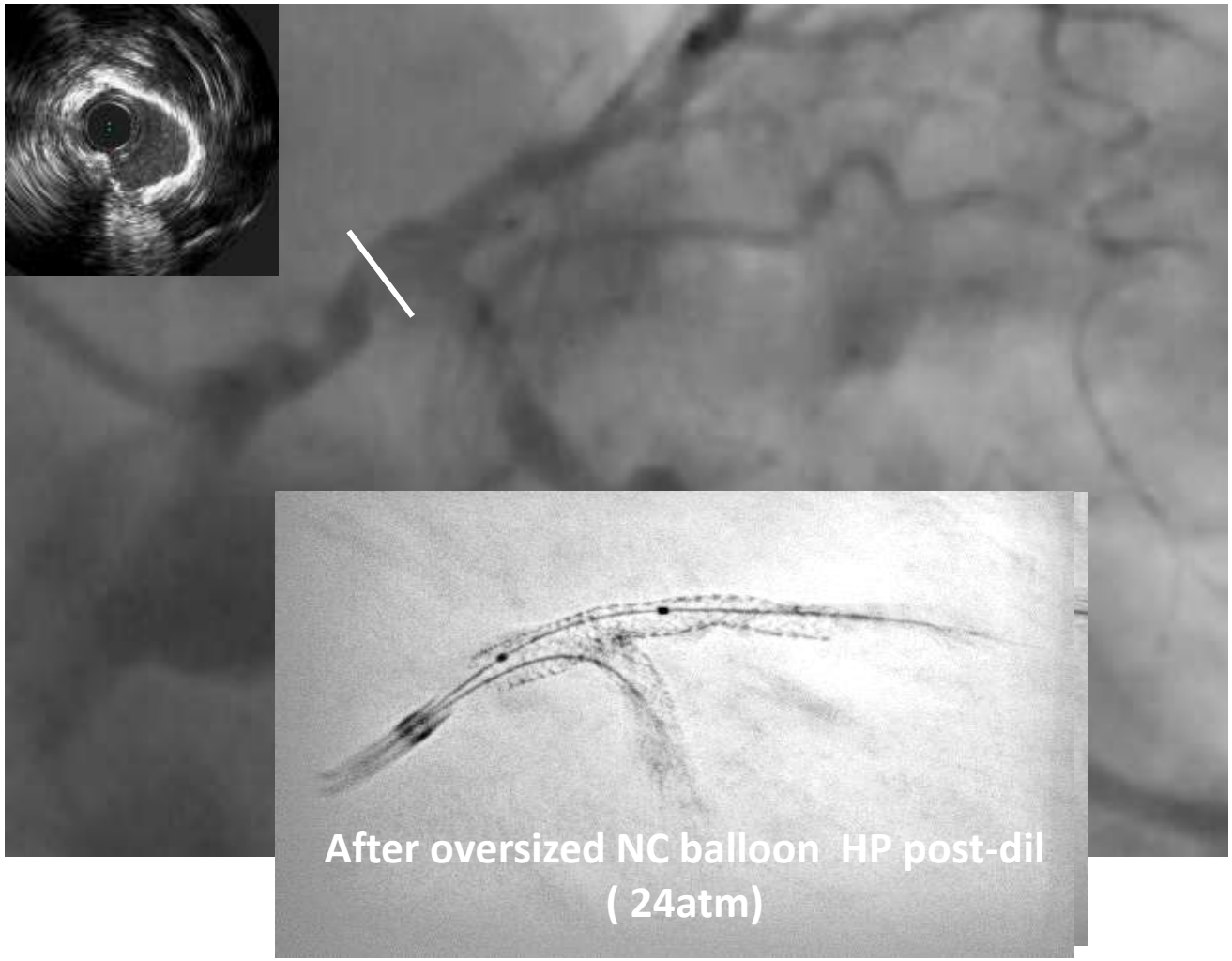


Complex Bifurcation Lesions



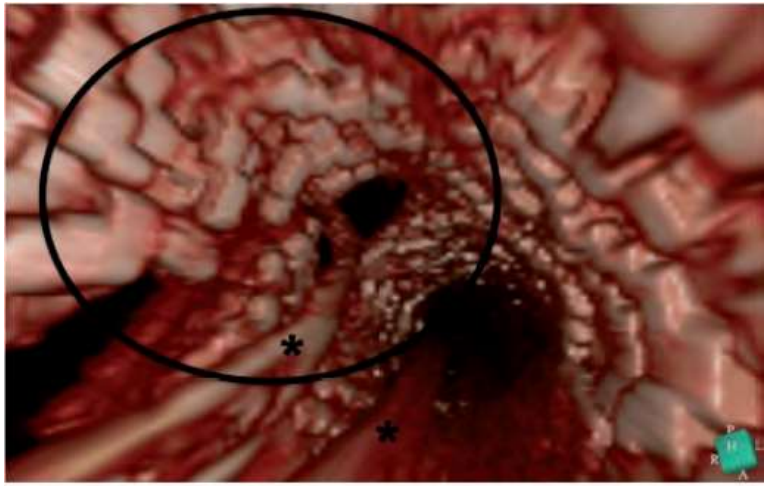
Severe Calcification

Stent underexpansion in calcified lesion despite good lesion preparation !

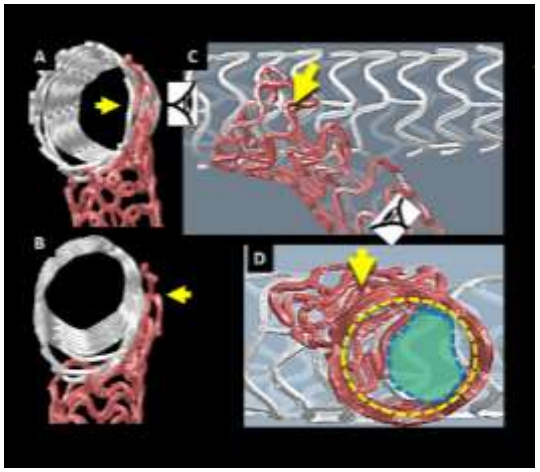


5- Shifting to two stent strategy for SB compromise

- **Hybrid approach seems to be a reasonable strategy**
- **A second BVS should be avoided : few cases reported and the mechanical characteritics of the present BVS generation is still limiting for an appropriate complex stenting procedure (cruch , culotte …)**
- **T or TAP are the most recommended in this situation**

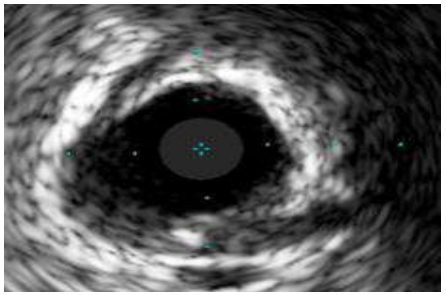


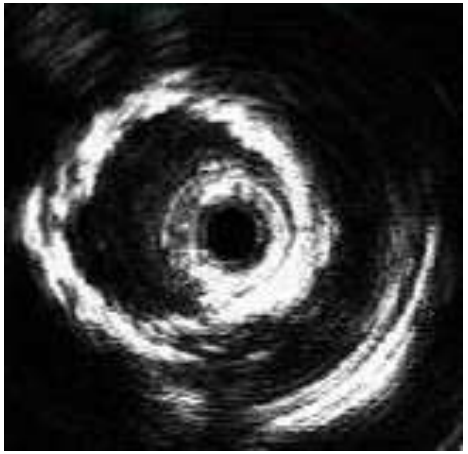
Culotte Technique with 2 BVS

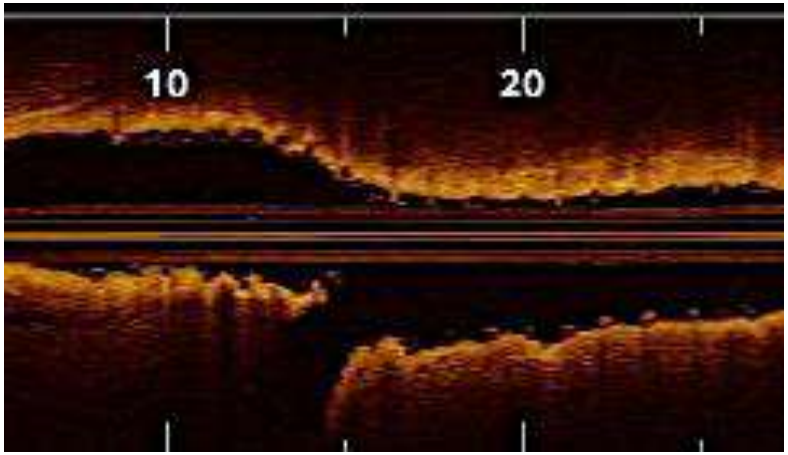


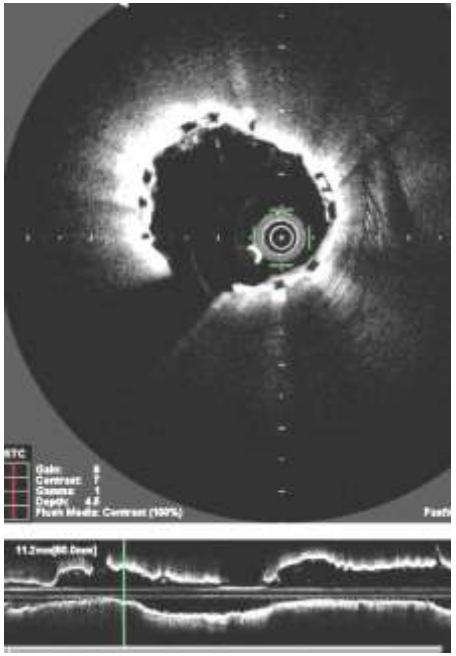
Crush Technique with 2 BVS

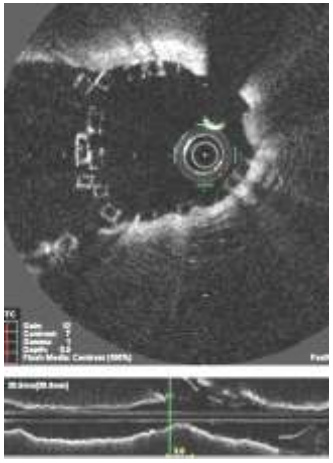
6- Use Intravasular Imaging for planning , sizing and optimization (post-dilataion)

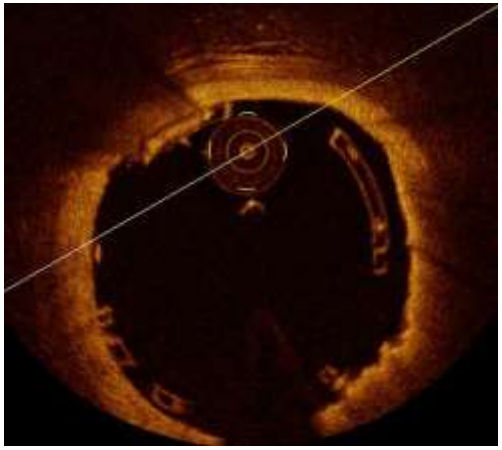


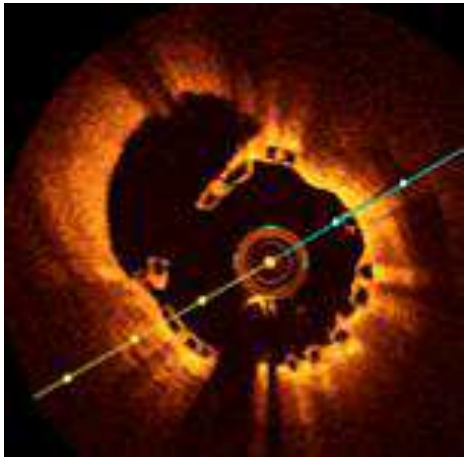












EBC Consensus on BVS in Bifurcations

Recommendations today:

1. Select the stent according to proximal reference in suitable anatomy (otherwise distal reference);
2. POT 0.5 mm bigger balloon than the reference;
3. If no SB compromise, procedure is finished;
4. If SB compromise, dilate with adequately sized balloon (≤12-14atm) and final POT;
5. Routine Final kissing balloon not recommended, Mini-final kissing balloon inflation if needed, 5atm;
6. If second stent needed: T/TAP; Metallic DES for SB;
7. Recommendations apply to current generation BRS and may need to be revised with new stent designs

Closing Remarks

Putting togother the available data :

- **Simple approach to BL with BVS seems to be feasable and safe , when performed meticolously**
- **At the present time we can not state the same for complex bifurcation procedures with 2 stents (2 BVS or hybrid approach BVS +DES)**
- **However; hybrid procedures (Metallic+BRS) maybe suggested as a reasonable strategy when needed: SB compromise , dissection , occlussion …..**
- **Bifurcations with excessive mismatch between the MV proximal and distal reference segment should be avoided .**
- **Use of Intravascular imaging (IVUS/OCT) guidance is highly recommended**