5 6 7 JUIN 2019

Bifurcation Basic & BIOSS Concept

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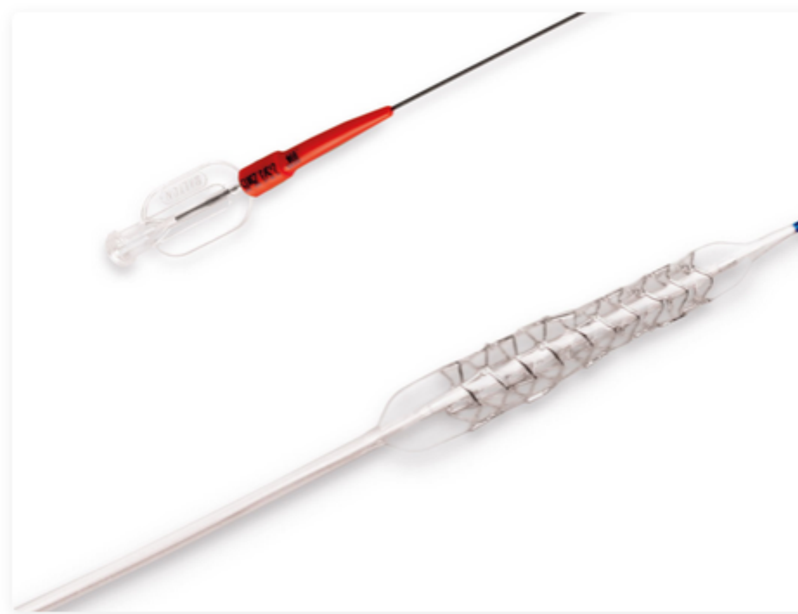
BIOSS LIM C - COBALT CHROMIUM SIROLIMUS ELUTING CORONARY BIFURCATION STENT

WITH RX DELIVERY SYSTEM

BIOSS LIM C

Innovative bifurcation stent system:

- One profiled balloon with diameters corresponding to dimensions of the coronary bifurcation vessels
- Unique configuration of the delivery system ensuring safety and efficacy during the stent implantation procedure
- Delivery system minimizes the negative effects of procedure, protecting the carina tip from being crushed or damaged
- Large cell of the stent in place of side branch entrance gives possibility to enter the SB with any standard size conventional stent
- Precision of implantation procedure thanks to three radiopaque markers



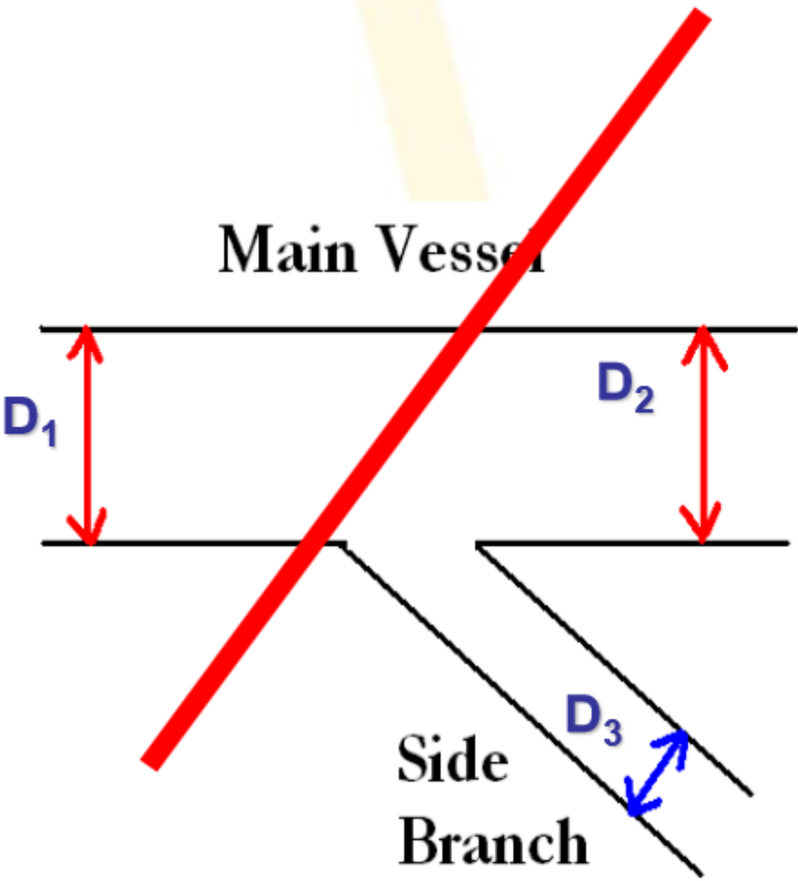
Bifurcation branching laws
The 3 Diameters

Murray's law

$$D_1^{3*} = D_2^{3*} + D_3^{3*}$$

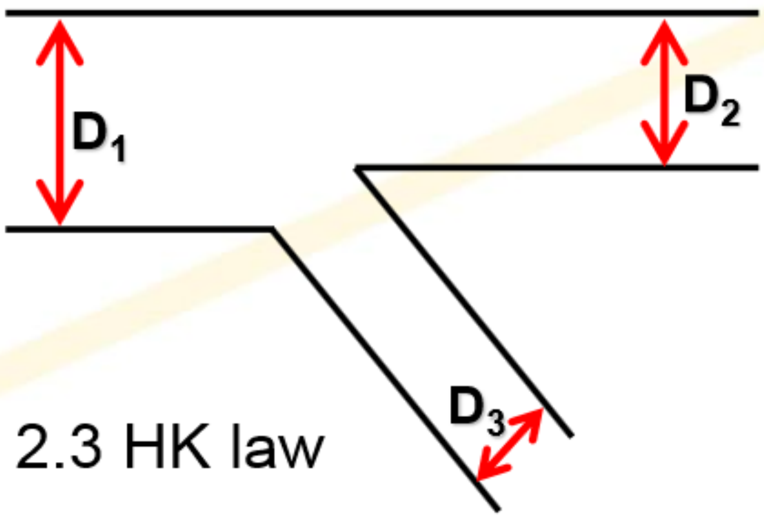
Finet's law

$$D_1 = 0.67(D_2 + D3)$$



MV diameter preserved before and after SB origin

* 2.3 HK law

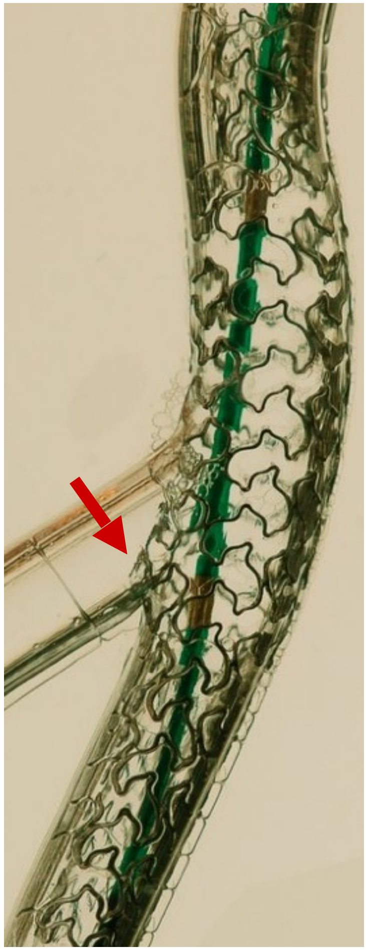


Self replicating

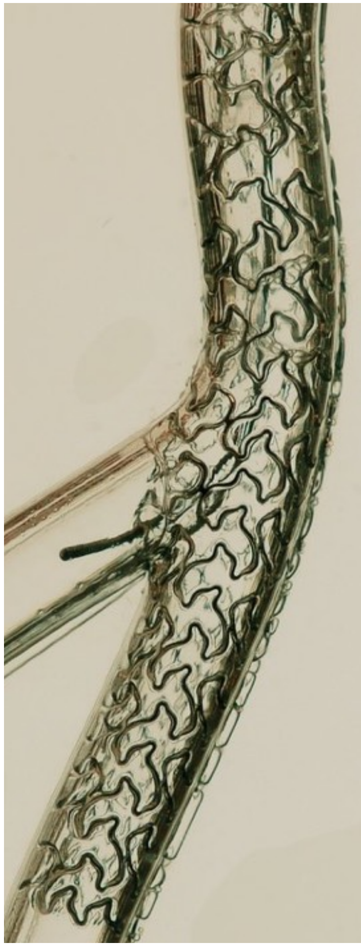
From Koo, EBC, 2008

Proximal Optimisation Technique

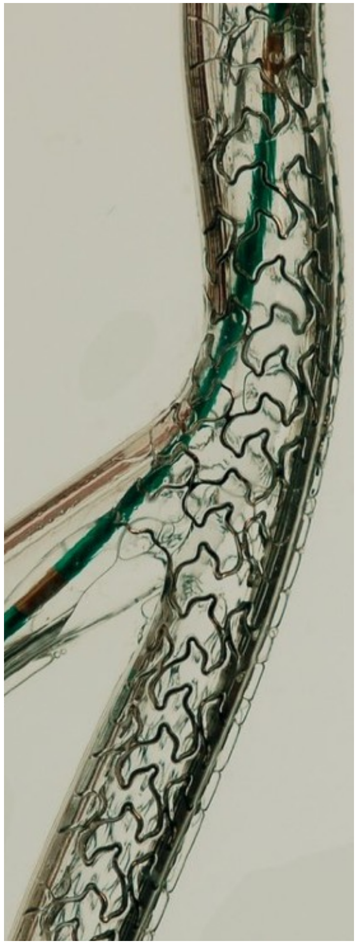
3.0 x 20mm



Balloon
3.5 x 8mm



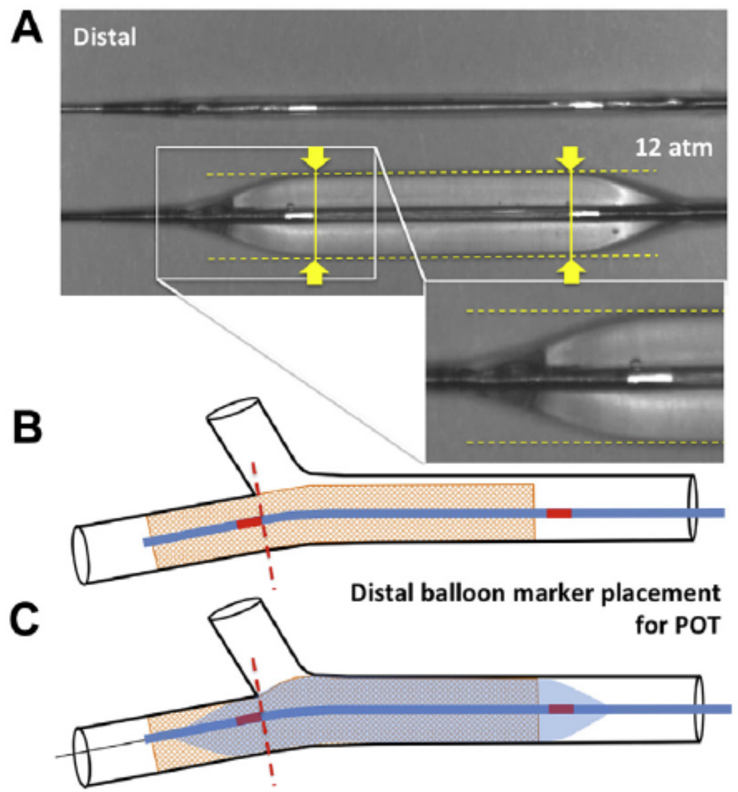
Carenal cell
entry



Post kissing

Courtesy of O. Darremont

FIGURE 2 **Balloon Positioning for the POT**

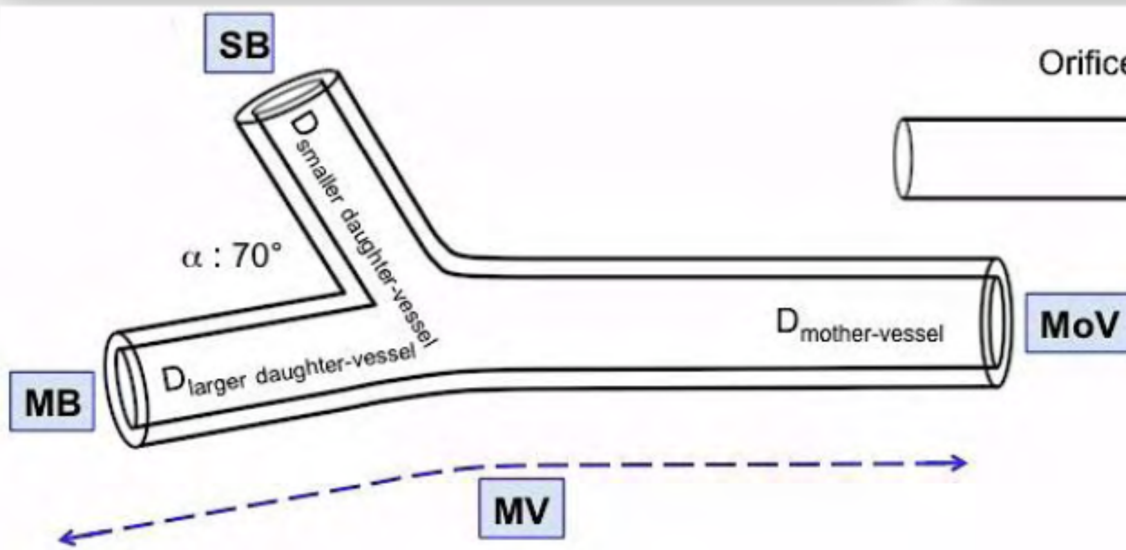


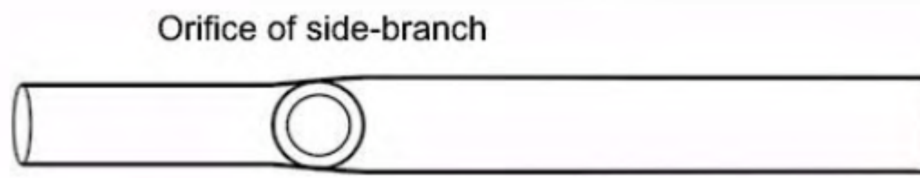
(A) Compliant balloon before and after inflation to 16 atm: parallelism ceases at the inner edge of the radio-opaque marker. **(B and C)** Balloon positioning for proximal optimizing technique (POT): the inner edge of the distal radio-opaque marker is positioned in the cross section of the main-branch ostium just under the carina.

Fractal coronary bifurcation test bench *(G. Finet)*

55 shA crystal PVC with the rheology of a 1-mm thick coronary artery (Young's modulus: 500 kPa

SEGULA technologies Sud, St-Priest, France





Linear law of coronary artery bifucation geometry and self-similarity

$D_{mother\text{-}vessel} = 0.678\ (D_{daughter\text{-}vessel1} + D_{daughter\text{-}vessel2})$

Relations between vessel diameters in healthy bifurcations

This relation is particularly useful when the reference diameters of only two vessels are known: the third is given by the relation.

Diameter of smaller daughter vessel	Diameter of larger daughter vessel (in terms of the main stent sizes in use)							
(mm)	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
2.25	3.03	3.20	3.39	3.58	3.78	3.99	4.20	4.42
	Δ=0.78	Δ=0.70	Δ=0.64	Δ=0.58	Δ=0.53	Δ=0.49	Δ=0.45	Δ=0.42
2.50		3.36	3.54	3.72	3.91	4.11	4.32	4.53
		Δ=0.86	Δ=0.79	Δ=0.72	Δ=0.66	Δ=0.61	Δ=0.57	Δ=0.53
2.75			3.70	3.87	4.06	4.25	4.44	4.64
			Δ=0.95	Δ=0.87	Δ=0.81	Δ=0.75	Δ=0.69	Δ=0.64
3.00				4.04	4.21	4.39	4.58	4.77
				Δ=1.04	Δ=0.96	Δ=0.89	Δ=0.83	Δ=0.77
3.25					4.37	4.55	4.73	4.91
					Δ=1.12	Δ=1.05	Δ=0.98	Δ=0.91
3.50						4.71	4.88	5.06
						Δ=1.21	Δ=1.13	Δ=1.06
3.75							5.05	5.22
							Δ=1.30	Δ=1.22
4.00								5.38
								Δ=1.38

The red and blue colours represent the diameter of mother segment and stepwise difference, respectively.

Huo, Finet, et al. EuroIntervention 2012;7:1310-1316.

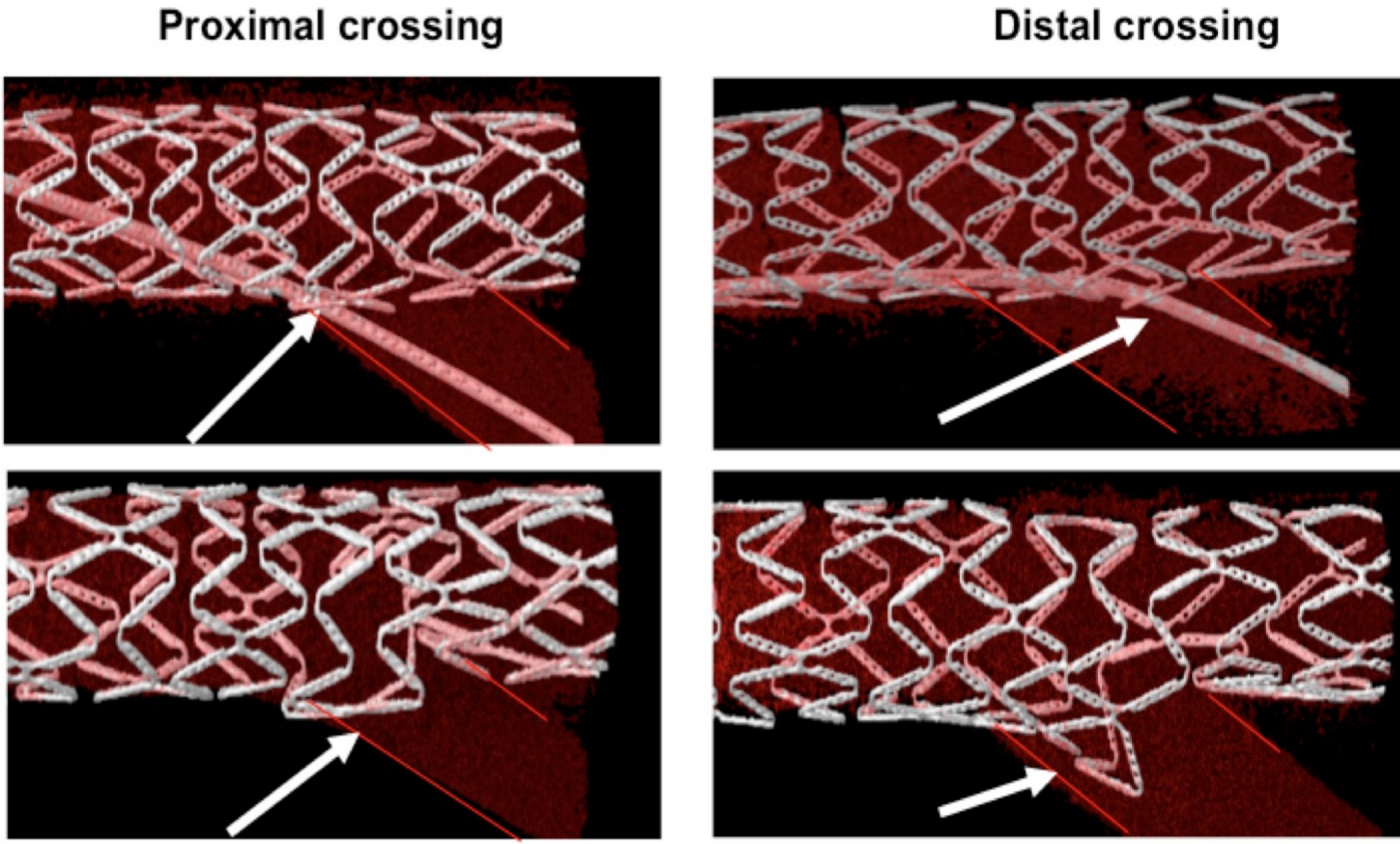
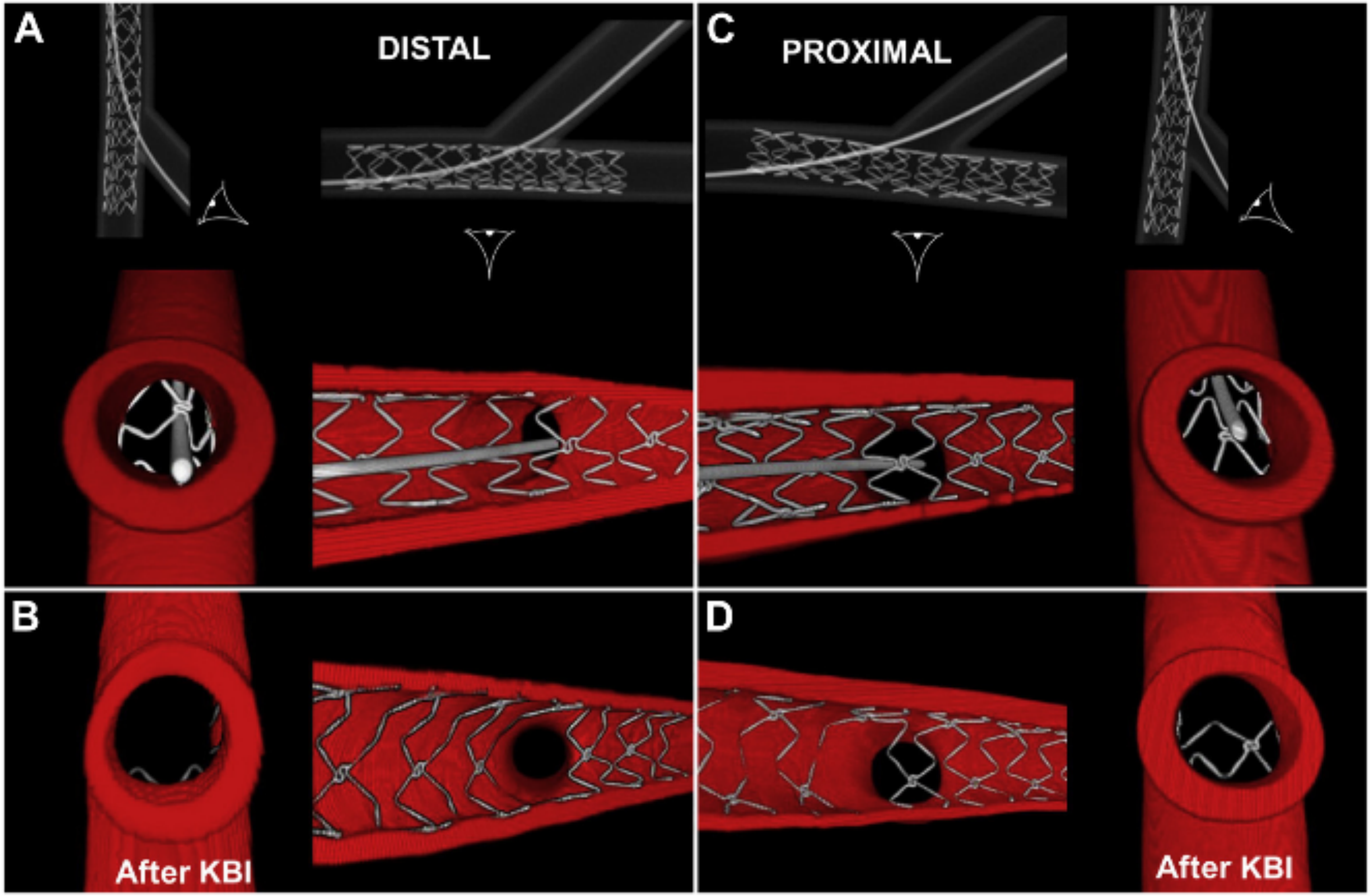
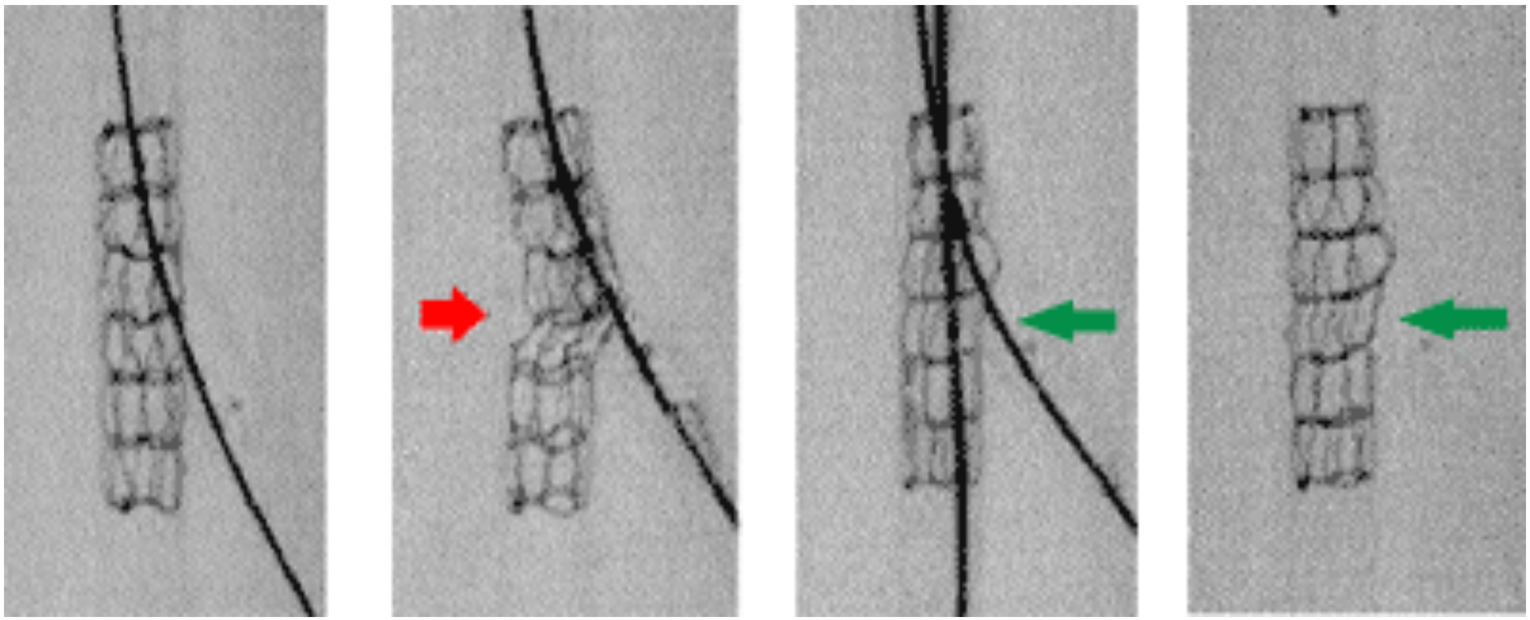

Proximal crossing
Distal crossing

FIGURE 2 In Vitro Bench Testing of Bifurcation Stenting



This figure highlights the importance of crossing the side branch through a distal cell of the main vessel stent to achieve good side branch ostial opening after final kissing balloon inflation (KBI). Crossing the guidewire through a distal stent cell **(A)** optimizes the side branch ostial area **(B)**, whereas crossing through a proximal stent cell **(C)** leaves malapposed struts near the carina **(D)**. Adapted with permission from Foin et al. (65).

Why using «kissing balloon» technique ?



Courtesy of T. LEFEVRE

DES Designs Overexpansion

Balloon Max Size		Synergy	Xpedition	Res. Onyx	Ultimaster	BioMatrix A	Orsiro
4.0	2.25	Small vessel (8 crowns, 2-4 connectors) *Expansion: 3.6mm*	Small vessel (6 crowns, 3 connectors) *Expansion: 4.1mm*	Small vessel workhorse (6.5 crowns, 2 connectors) *Expan: 3.3mm*	Small vessel (8 crowns, 2 connectors) *Expansion: 4.3mm*	Small vessel (6 crowns, 2 connectors) *Expansion: 4.1mm*	Small vessel (6 crowns, 3 connectors) *Expansion: 4.0mm*
	2.50						
5.0	2.75			Medium vessel workhorse (8.5 crowns, 2 connectors) *Expansion: 4.4mm*			
	3.00	Workhorse (8 crowns, 2-4 connectors) *Expansion: 4.2mm*					
	3.50		Large vessel (9 crowns, 3 connectors) *Expansion: 5.6mm*	Large vessel (9.5 crowns, 2.5 connectors) *Expansion: 5.6mm*	Large vessel (8 crowns, 2 connectors) *Expansion: 5.8mm*	Large vessel (9 crowns, 3 connectors) *Expansion: 5.9mm*	Large vessel (6 crowns, 3 connectors) *Expansion: 5.3mm*
6.0	4.00	Large vessel (10 crowns, 2-5 connectors) *Exp: 5.7mm*					
	4.50			Extra-Large vessel (10.5 crowns, 2.5 connectors) *Expansion: 6.0mm*			
	5.00						

- *Expansion : inner stent MLD excluding struts*
- *Max balloon size : Maverick 6.0mm at 14 ATM*

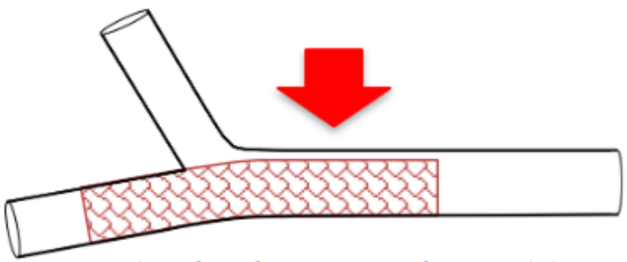
Int J Cardiol. 2016 Oct 15;221:171-9. doi: 10.1016/j.ijcard.2016.06.097. Epub 2016 Jun 24.

Over-expansion capacity and stent design model: An update with contemporary DES platforms. Ng J[1], Foin N[2]

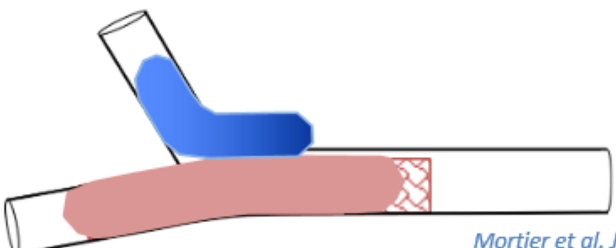
Kissing balloon inflation fails to improve the rate of MACE compared with non-KBI treatment

Niemela Met al. Circulation 2011;123(1):79-86.
Gwon HC et al. Heart 2012;98(3):225-31.
Yamawaki Y et al. Circ J 2014;78(1):110-2.
Korn HV et al. Circ Cardiovasc Interv 2009;2/535-42.

The detrimental effects of KB caused by the juxtaposition of the two balloons

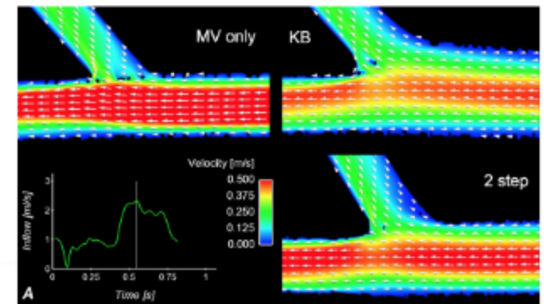


proximal unknown malapposition

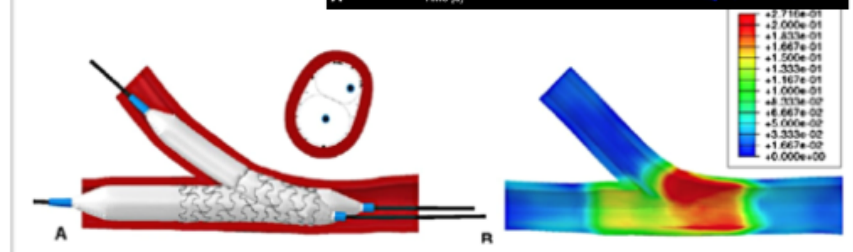


arterial overstretch

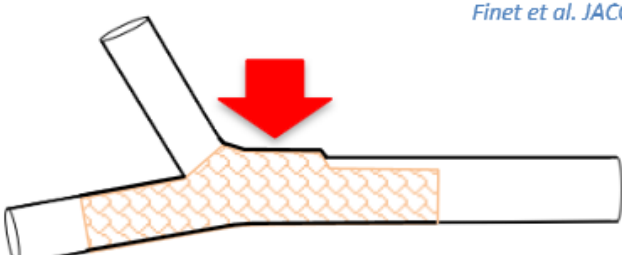
Mortier et al. JACC:CI 2014
Foin et al. EuroIntervention 2011
Finet et al. JACC:CI 2015



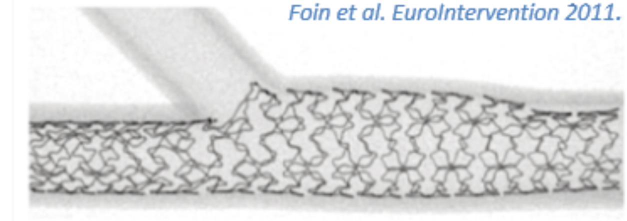
Foin et al. JACC CI 2012.



deleterious mechanobiological impacts



"bottle neck" effect



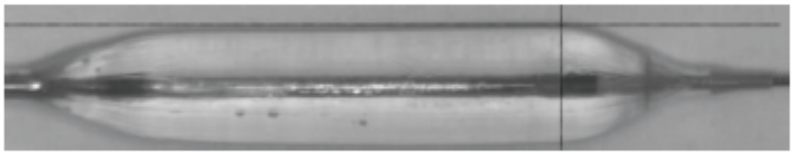
Foin et al. EuroIntervention 2011.

"bottle neck" effect

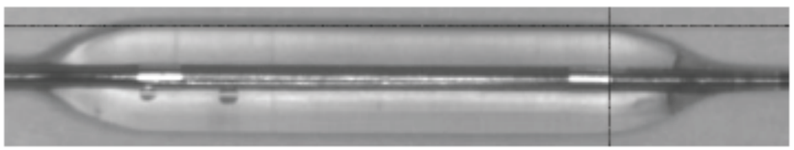
The rePOT sequence

Balloon positioning for the POT

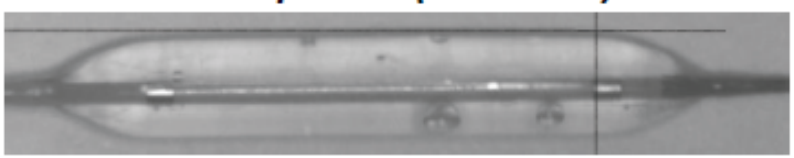
3.0 x 15 mm TREK™ (Abbott)



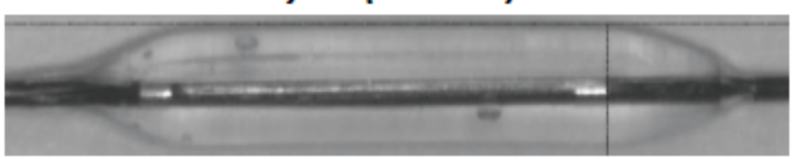
3.0 x 15 mm Maverick™ (Boston)

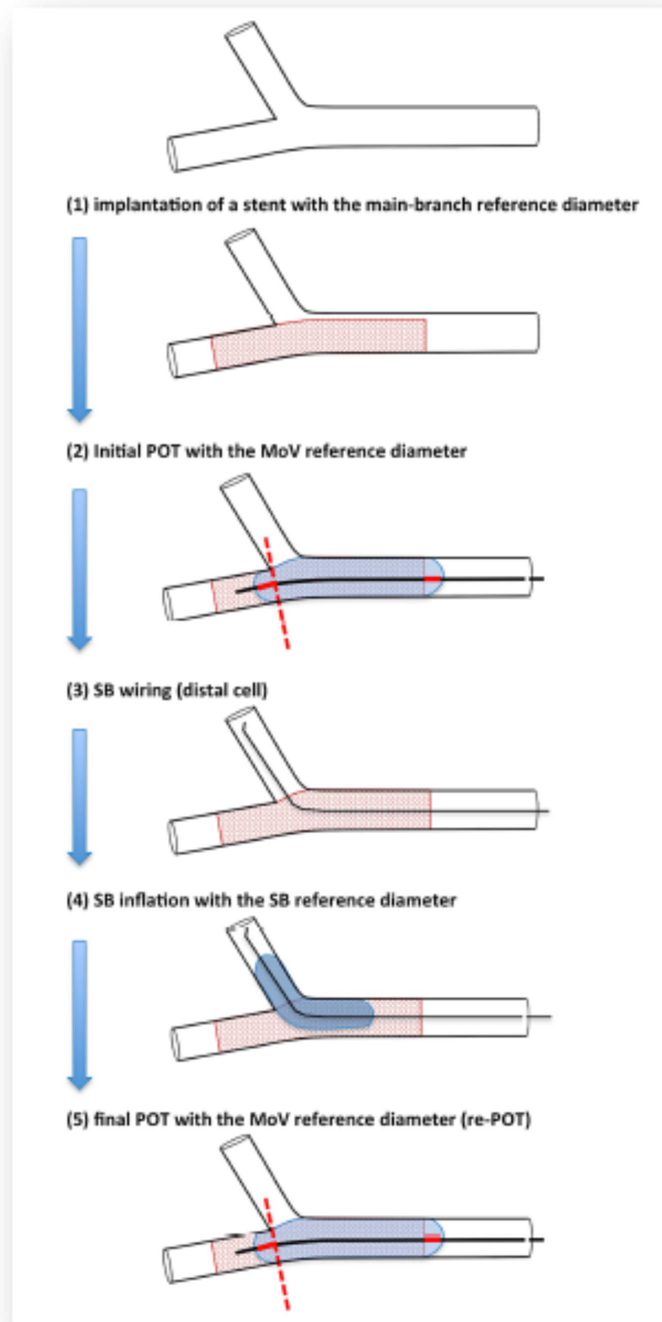


3.0 x 15 mm Euphora™ (Medtronic)



3.0 x 15 mm Hityu™ (Terumo)



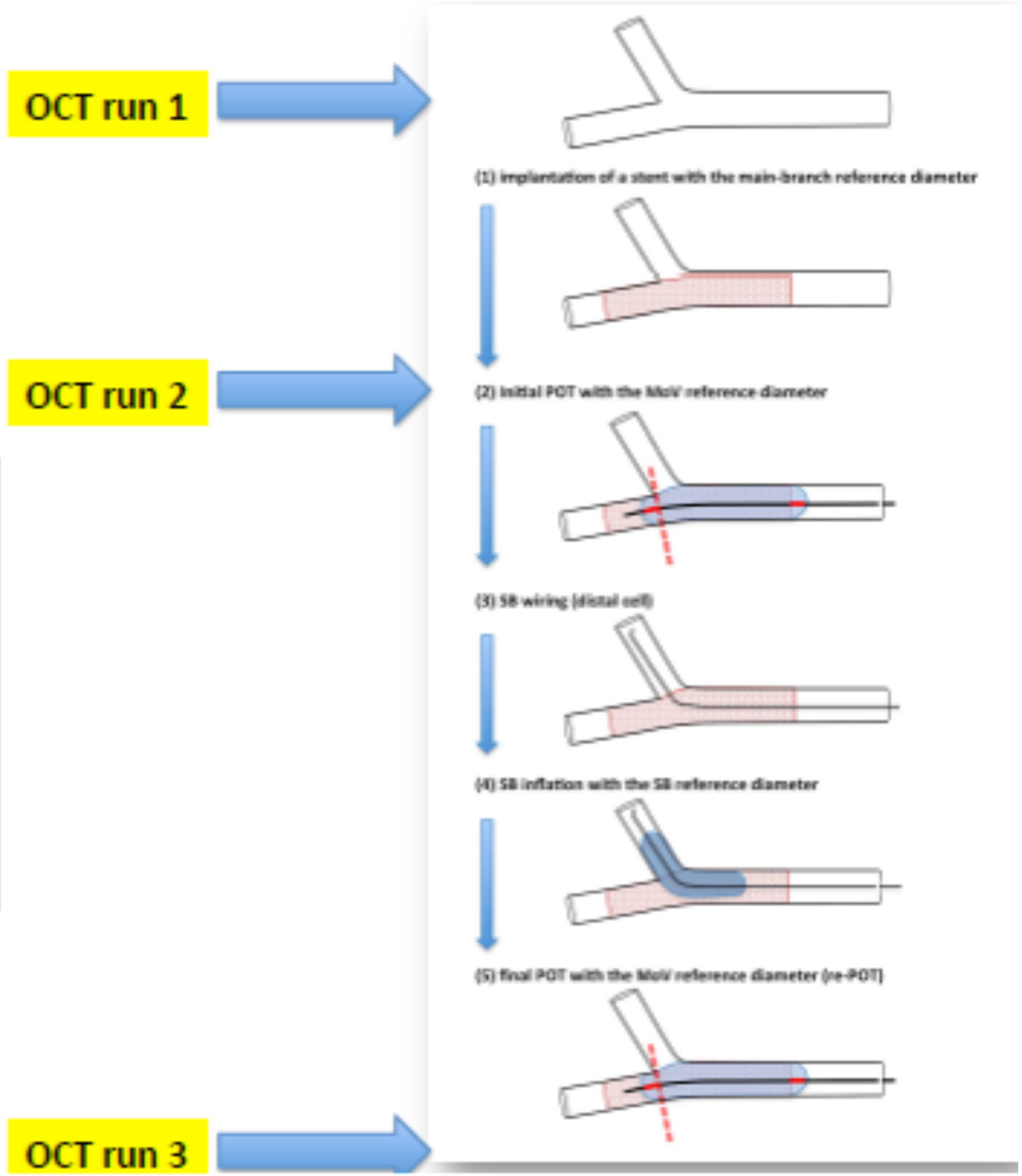


rePOT study

EuroIntervention. 2018 Mar 20. pii: EIJ-D-17-00941.
doi: 10.4244/EIJ-D-17-00941. F. Derimay

Clinical Study

Protocol flowchart



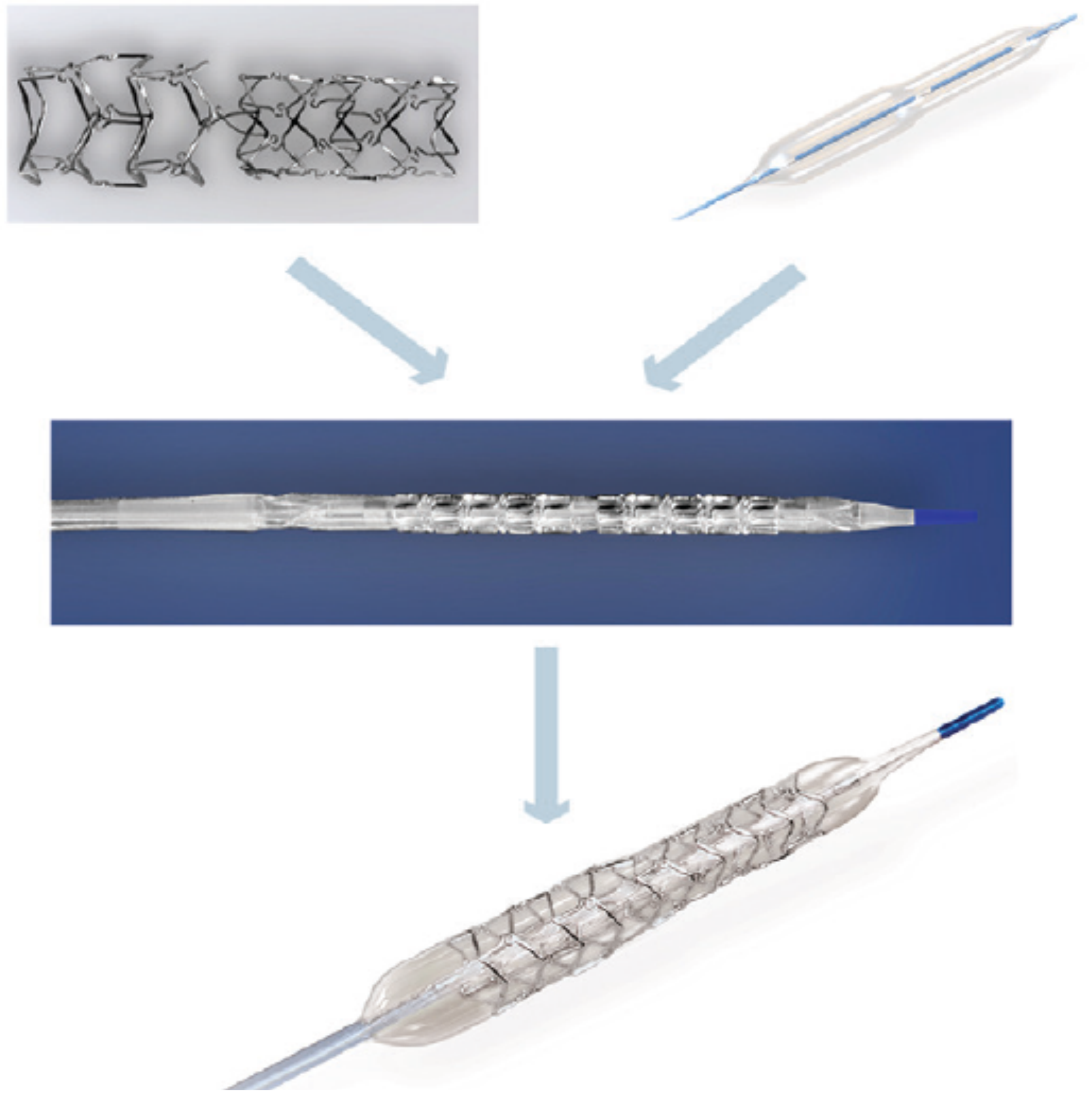
Bifurcation LM/LAD-DIAG
or others
with
MB≥2.5 mm
SB≥2.0 mm
stable lesion or ACS NSTEMI

POT with compliant balloon
adjusted to the D_{MoV}

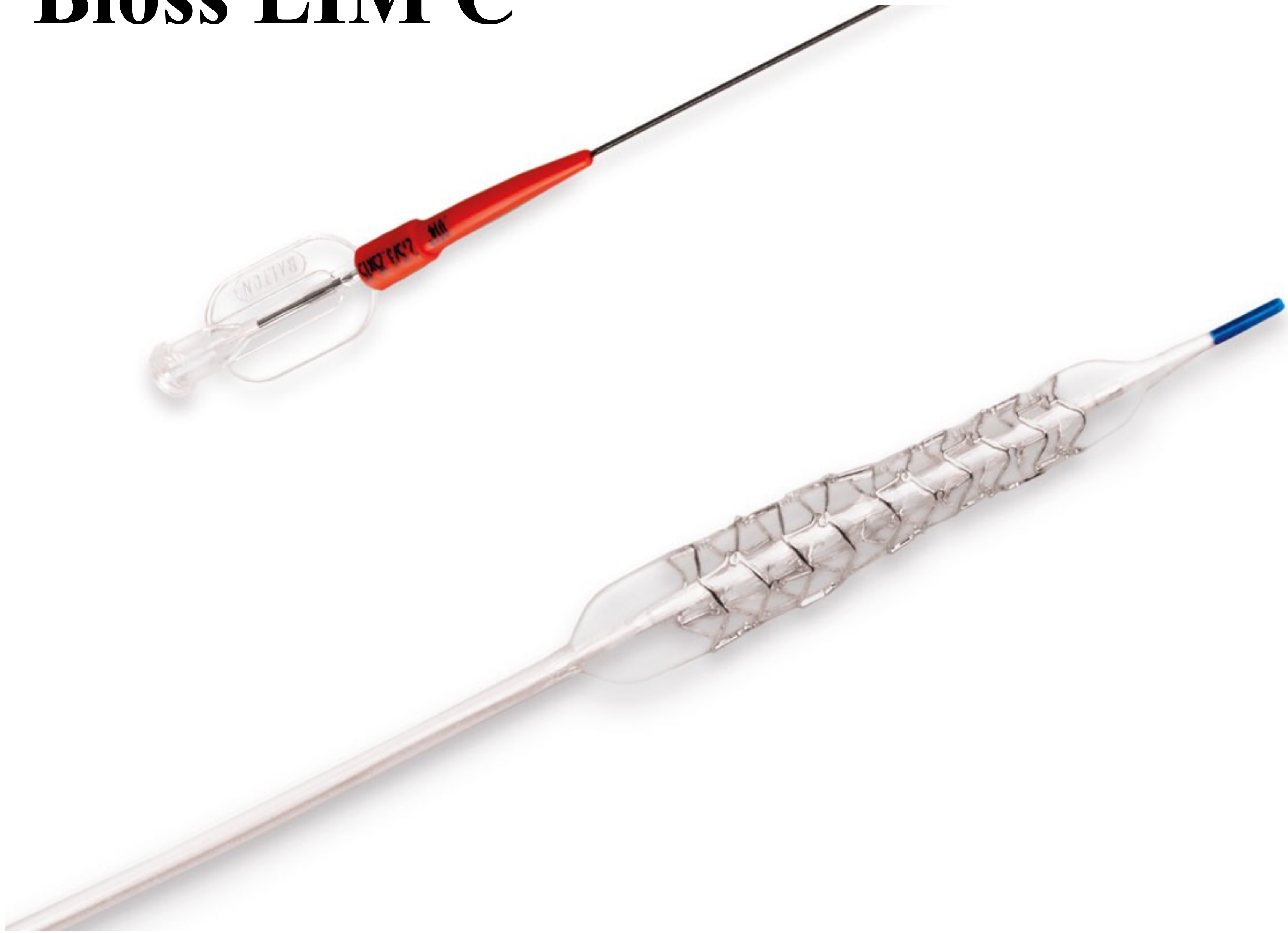
TIPS and Tricks For tubular Stents

How to size the stent?	Diameter of the distal main Except LM (Foin table)
When should I POT?	All time POT (almost)
When should I Side?	Future access Poor result at the ostia Inverted T stenting (Main Branch access)
When should I KISS?	2 Stents
When Should I RePOT?	Post Side Post Kiss

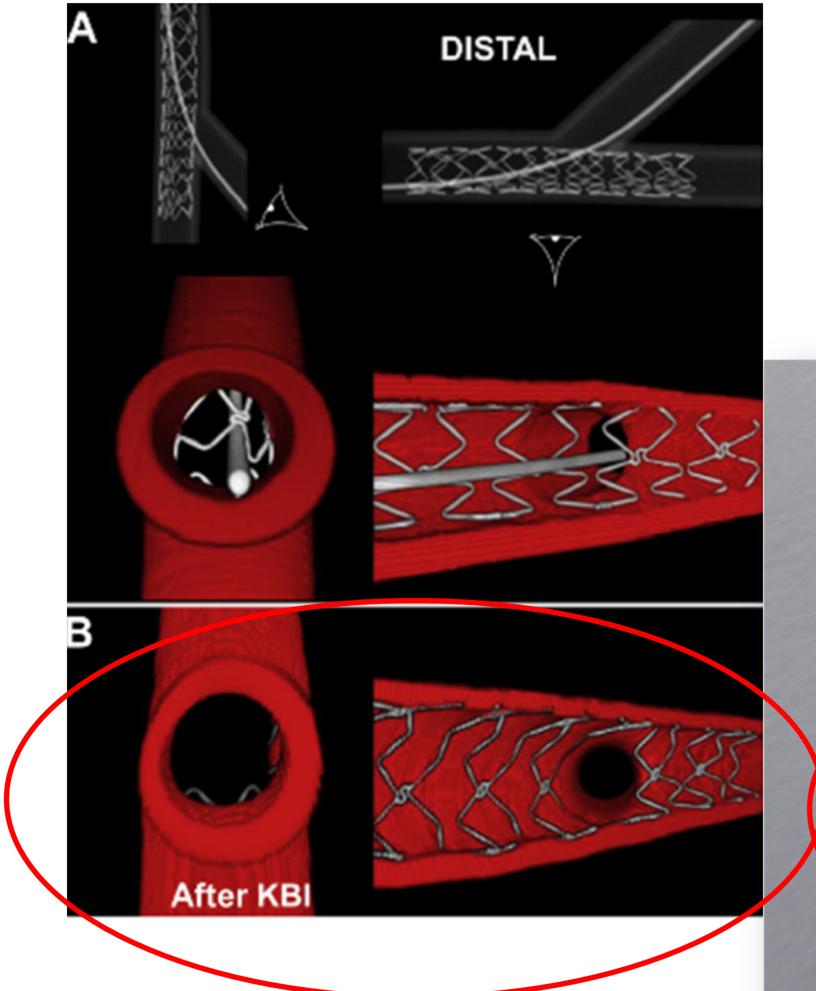
BiOSS® Stent and Bottle® Balloon Structures



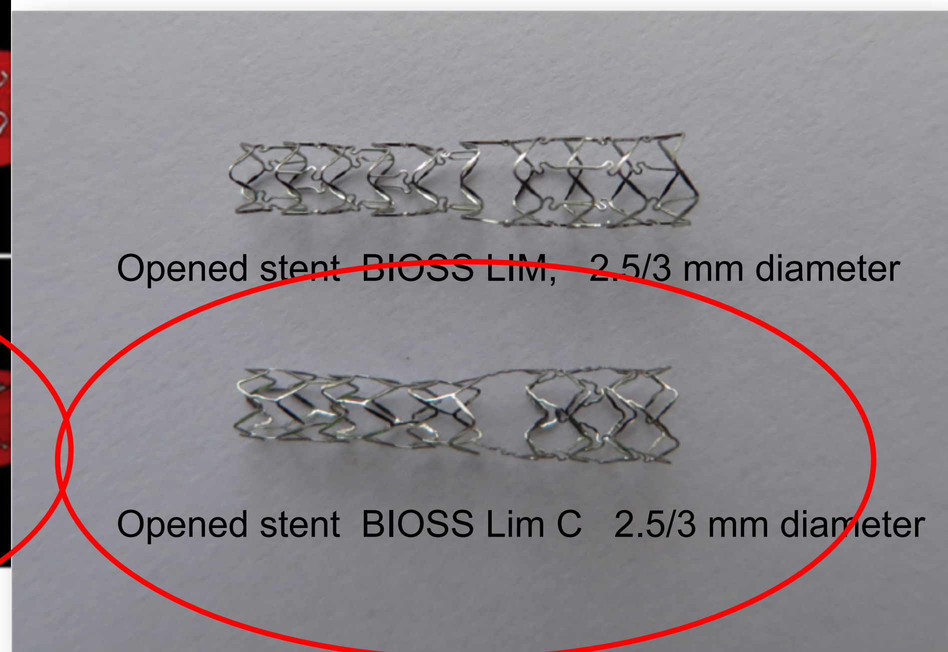
Bioss LIM C



DIFFERENCES IN STENT DESIGN



Tubular stent post Kissing



BIOSS Lim C

First Generation

BIOSS®

CORONARY BIFURCATION STENTS

BIODEGRADABLE POLYMER

Innovative bifurcation stent system:

- One profiled balloon with diameters corresponding to dimensions of the coronary bifurcation vessels
- Unique configuration of the delivery system ensuring safety and efficacy during the stent implantation procedure
- Delivery system minimizes the negative effects of procedure, protecting the carina tip from being crushed or damaged
- Large cell of the stent in place of side branch entrance gives possibility to enter the SB with any standard size conventional stent
- Precision of implantation procedure thanks to three radiopaque markers

Technical data overview:

Stent platform material	316LVM stainless steel
Catheter coating	hydrophilic
MRI	safe
Ferromagnetism	none
Radiopacity	excellent
Radial force	high
Pushability and trackability	excellent
Inflation and deflation time	very short
Proximal shaft diameter	2F (0.65 mm)
Distal shaft diameter	2.7F (0.90 mm)
Compatible guide wire	max. .014"
Compatible guiding catheter	5F (.056")
Nominal pressure	10 atm
Rated Burst Pressure	16 atm
Delivery system type	Rapid Exchange
Catheter length	140 cm

BALTON®

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e-mail:balton@balton.pl, www.balton.pl

11/2011

BIOSS®

CORONARY BIFURCATION STENTS

BIODEGRADABLE POLYMER

International patent pending

BALTON since 1980

BALTON®

CE 1023

PARAMETER'S COMPARISON

	BIOSS Lim C	BIOSS LIM
Stent material	L605	316L
Immunosuppressive drug	SIROLIMUS	SIROLIMUS
Polymer	BIODEGRADABLE	BIODEGRADABLE
Wall thickness	0,07 mm	0,12 mm
Compatible with guide wire	max. .014"	max. .014"
Compatible with guiding catheter	5F	5F
Crimped stent profile	.038" (0,96 mm)	.042" (1,06 mm)
Nominal pressure	10 atm	10 atm
RBP	16 atm	16 atm
Catheter length	140 cm	140 cm
Delivery system type	RX	RX

BALTON since 1980

First-in-Man Study of Dedicated Bifurcation Sirolimus-Eluting Stent: 12-Month Results of BiOSS LIM® Registry

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DOBRIN VASSILIEV, M.D., Ph.D.,[3] and LUIS A. IÑIGO GARCIA, M.D.[4]

From the [1]Invasive Cardiology Department, Central Clinical Hospital of the Ministry of Internal Affairs, Warsaw, Poland; [2]Institute of Experimental and Clinical Medicine, Polish Academy of Science, Warsaw, Poland; [3]National Heart Hospital, Sofia, Bulgaria; and [4]Costa del Sol Hospital, Marbella, Spain

***Objectives**: The aim was to assess the effectiveness and safety profile of a new dedicated bifurcation stent - sirolimus-eluting BiOSS LIM® (Balton, Poland) in 12-month Registry.*
***Background**: The optimal approach to coronary bifurcations treatment by percutaneous coronary intervention (PCI) has been still a subject of debate. Dedicated bifurcation stents are one of the proposed solutions.*
***Methods**: This was the international, 3-center registry, which enrolled patients with non-ST-elevation acute coronary syndrome (NSTE-ACS) and stable angina. Provisional T-stenting was the obligatory strategy of the treatment. Angiographic control was planned at 12 months. The primary endpoint was cumulative rate of death, myocardial infarction (MI) and target lesion revascularization (TLR) at 12 months.*
***Results**: A total of 60 patients with coronary bifurcations were enrolled (mean age 66.4 ± 11 years, 28.3% of female). There were 21.7% of patients with NSTE-ACS, 78.3% with hypertension, 38.3% with diabetes, 28.3% had previous MI, and 46.7% and 10% underwent prior revascularization, respectively, PCI and coronary artery bypass graft. The device success rate was 100%. Side branch was treated with an additional classical drug-eluting stent implantation in 23.3% of cases. At 12 months, the cumulative major adverse cardiovascular events rate was 11.7%. During follow-up (11 ± 1 months) there was 1 non-cardiac death (1.7%), 1 non-ST-elevated myocardial infarction (1.7%) due to restenosis and no case of stroke or in-stent thrombosis. Overall TLR was 8.3% (clinically driven TLR – 1.7%, angiographically driven – 6.6%). Mean late lumen loss was as follows: In main vessel – 0.35 ± 0.33 mm, in main branch – 0.34 ± 0.27 mm and in side branch – 0.18 ± 0.38 mm.*
***Conclusion**: Dedicated bifurcation stent BiOSS® LIM proved to be feasible device, with promising safety and long-term clinical effectiveness in the treatment of coronary bifurcation lesions, including distal left main stem stenosis.*
(J Interven Cardiol 2015;28:51–60)

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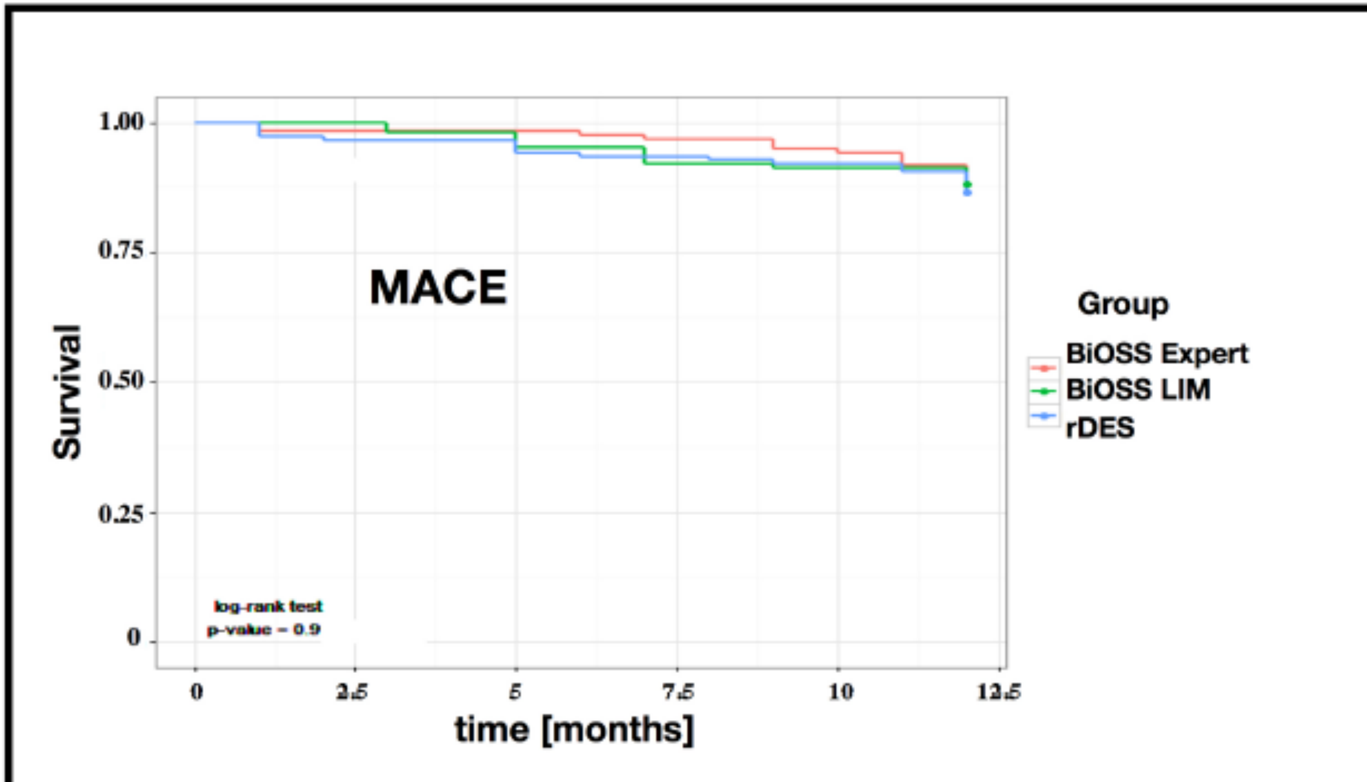
Comparison of dedicated BIOSS bifurcation stents with regular drug-eluting stents for coronary artery bifurcated lesions: Pooled analysis from two randomized studies

Authors: Robert J. Gil, Jacek Bil, Adam Kern, Luis A. Iñigo Garcia, Radosław Formuszewicz, Sławomir Dobrzycki, Dobrin Vassilev, Agnieszka Segiet



Regular drug-eluting stents versus the dedicated coronary bifurcation sirolimus-eluting BiOSS LIM® stent: the randomised, multicentre, open-label, controlled POLBOS II trial

Robert J. Gil[1,2]*, MD, PhD; Jacek Bil[1], MD, PhD; Maik J. Grundeken[3], MD; Adam Kern[4], MD, PhD; Luis A. Iñigo Garcia[5], MD; Dobrin Vassilev[6], MD, PhD; Tomasz Pawłowski[1], MD, PhD; Radoslaw Formuszewicz[7], MD; Sławomir Dobrzycki[8], MD, PhD; Joanna J. Wykrzykowska[3], MD, PhD; Patrick W. Serruys[9], MD, PhD

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GUEST EDITOR: David Hildick-Smith, MD, FRCP, FSCAI; *Sussex Cardiac Centre, Brighton and Sussex University Hospitals NHS Trust, Brighton, United Kingdom*

KEYWORDS

- BiOSS LIM®
- dedicated bifurcation stent
- sirolimus-eluting stent

Abstract

Aims: The aim of the POLBOS II randomised trial was to compare any regular drug-eluting stents (rDES) with the dedicated bifurcation sirolimus-eluting stent BiOSS LIM for the treatment of coronary bifurcation lesions. The secondary aim was to study the effect of final kissing balloon inflation (FKBI) on clinical outcomes.

Methods and results: Between December 2012 and December 2013, 202 patients with stable coronary artery disease or non-ST-segment elevation acute coronary syndrome were randomly assigned 1:1 to treatment of the coronary bifurcation lesions either with the BiOSS LIM stent (n=102) or with an rDES (n=100). Coronary re-angiography was performed at 12 months. The primary endpoint was the composite of cardiac death, myocardial infarction (MI), and target lesion revascularisation (TLR) at 12 months. The target vessel was located in the left main in one third of the cases (35.3% in BiOSS and 38% in rDES). Side branch treatment was required in 8.8% (rDES) and 7% (BiOSS). At 12 months, the cumulative MACE incidence was similar in both groups (11.8% [BiOSS] vs. 15% [rDES, p=0.08]), as was the TLR rate (9.8% vs. 9% [p=0.8]). The binary restenosis rates were significantly lower in the FKBI subgroup of the BiOSS group (5.9% vs. 11.8%, $p<0.05$).

Conclusions: MACE rates as well as TLR rates were comparable between the BiOSS LIM and rDES. At 12 months, cumulative MACE incidence was similar in both groups (11.8% vs. 15%), as was the TLR rate (9.8% vs. 9%). Significantly lower rates of restenosis were observed in the FKBI subgroup of the BiOSS group.

EuroIntervention

CORONARY INTERVENTIONS

CLINICAL RESEARCH

Long-term effectiveness and safety of the sirolimus-eluting BiOSS LIM® dedicated bifurcation stent in the treatment of distal left main stenosis: an international registry

Robert J. Gil[1,2]*, MD, PhD; Jacek Bil[1], MD, PhD; Maik J. Grundeken[3], MD; Luis A. Iñigo Garcia[4], MD; Dobrin Vassilev[5], MD, PhD; Adam Kern[6], MD, PhD; Tomasz Pawłowski[1], MD, PhD; Joanna J. Wykrzykowska[3], MD, PhD; Patrick W. Serruys[7], MD, PhD

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KEYWORDS
- BiOSS LIM®
- dedicated bifurcation stent
- left main (LM) stenosis
- sirolimus-eluting stent

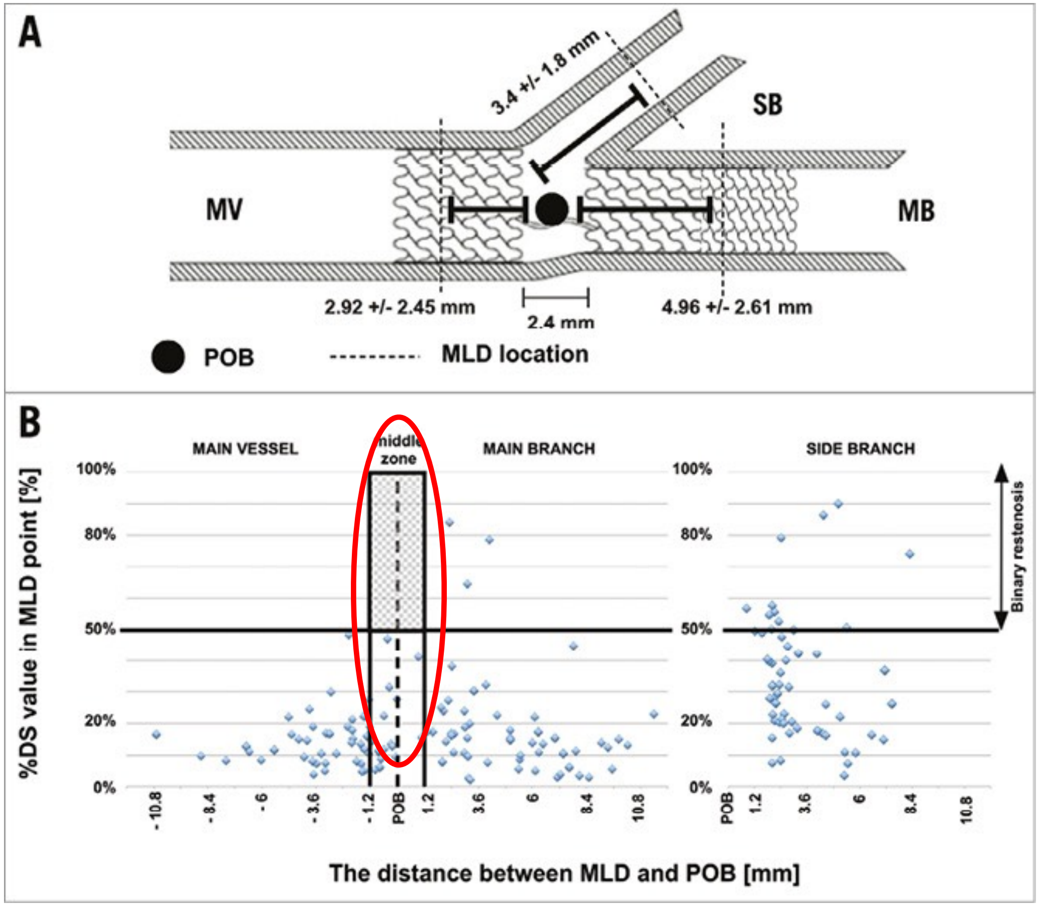
Abstract

Aims: The aim of this study was to assess prospectively the effectiveness and safety of a new version of the dedicated bifurcation BiOSS stent, the sirolimus-eluting BiOSS LIM, for the treatment of distal left main (LM) stenosis.

Methods and results: This was a prospective international registry which enrolled patients with NSTE-ACS or stable angina. Provisional T-stenting was the mandated strategy. The primary endpoint was the cumulative rate of cardiac death, myocardial infarction (MI) and target lesion revascularisation (TLR) at 12 months. Twelve-month quantitative coronary angiography endpoints included late lumen loss and percent diameter stenosis. A total of 74 patients with distal LM stenosis were enrolled. Seventy-three of the 74 patients (aged 67±9 years, 23% women, 20.3% NSTE-ACS, SYNTAX score 22.4±4.4) were successfully treated with the BiOSS LIM stent, with additional side branch placement of regular DES in 11 patients (14.9%). Periprocedural MI occurred in one (1.4%) patient. The 12-month MACE rate was 9.5% without cardiac death or definite stent thrombosis. TLR and MI rates were 6.8% (n=5) and 2.7% (n=2), respectively.

Conclusions: The use of the BiOSS LIM dedicated bifurcation stent for the treatment of distal LM stenosis was feasible and safe, with promising long-term clinical effectiveness.

EuroIntervention



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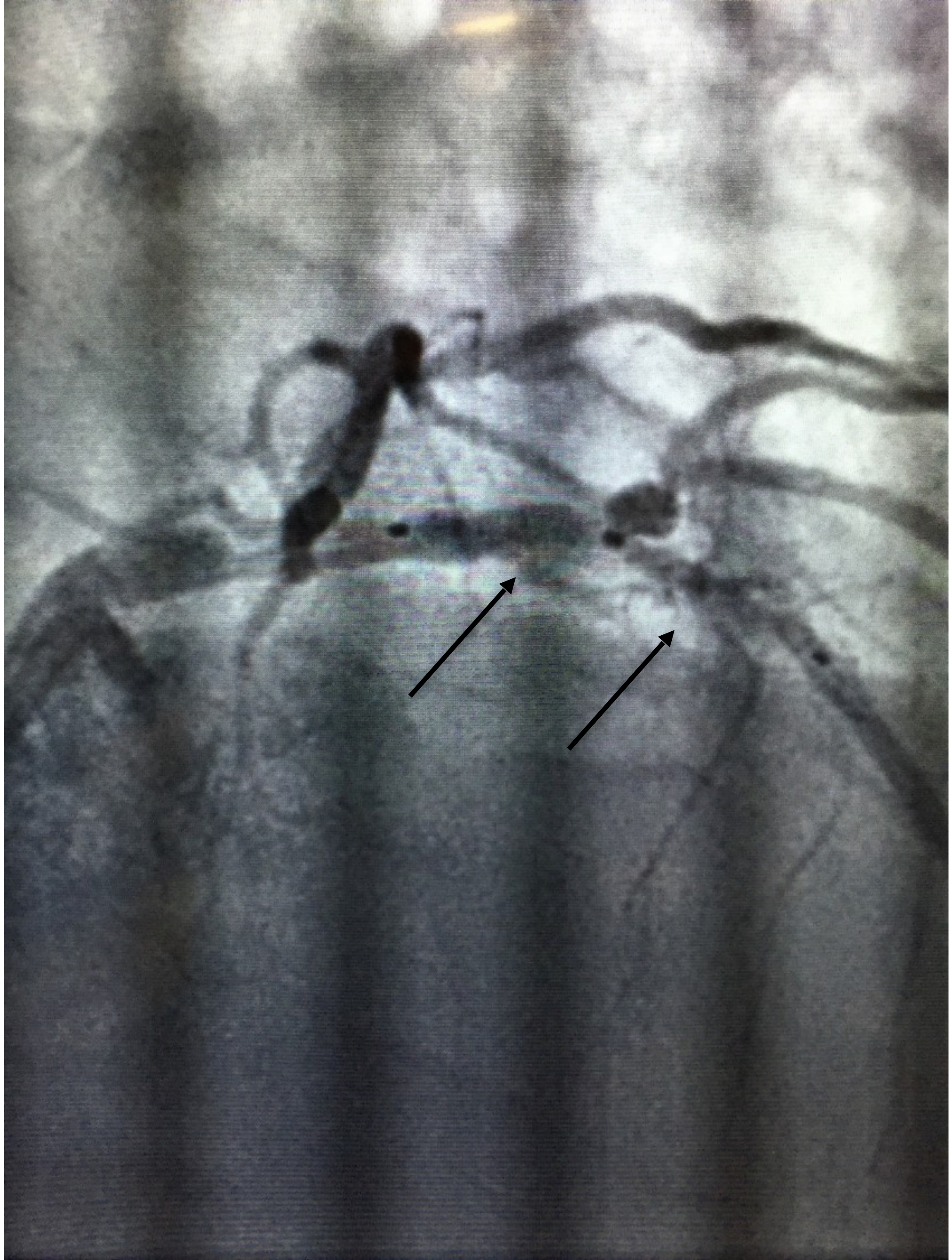
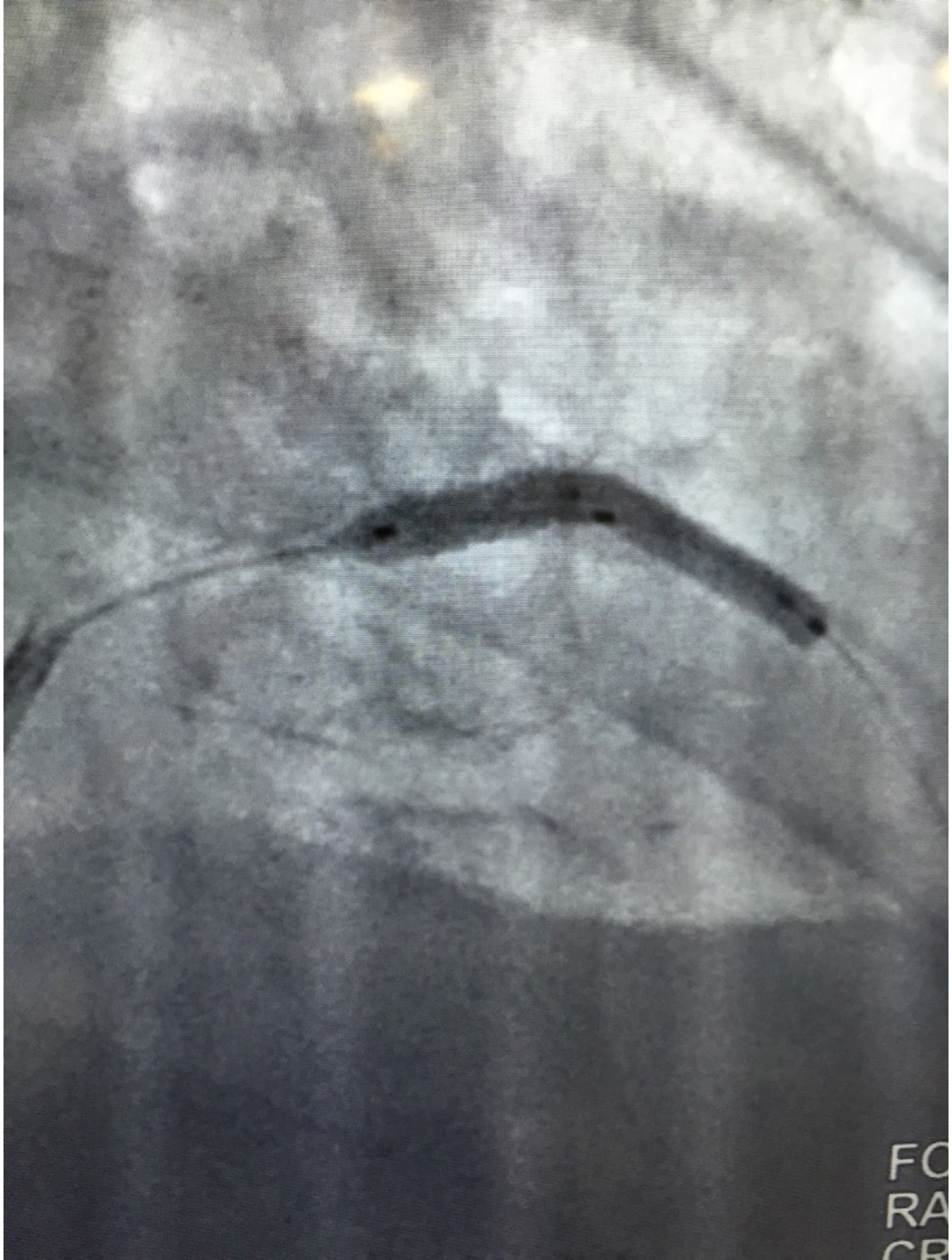
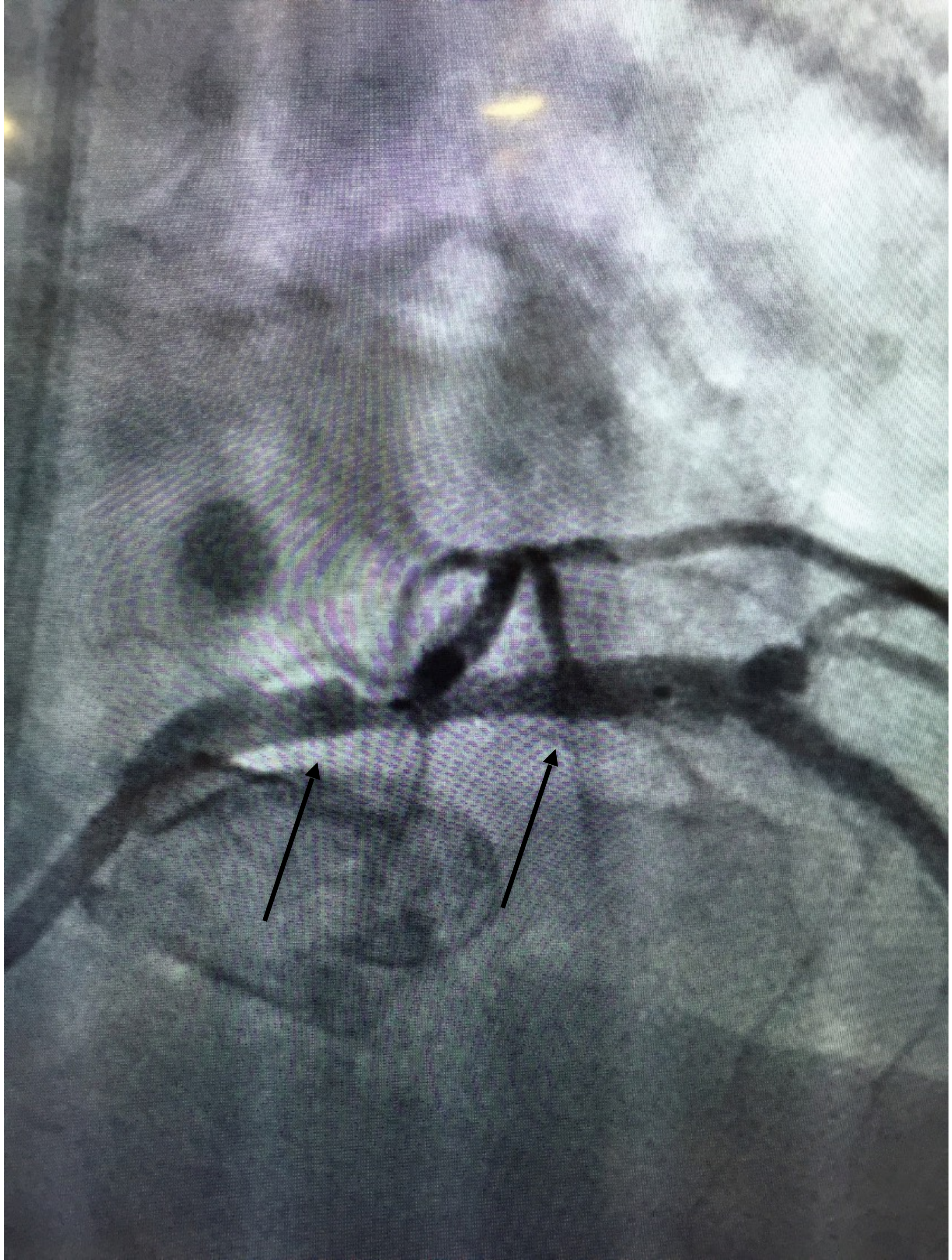
Long-term effectiveness and safety of the sirolimus-eluting BiOSS LIM® dedicated bifurcation stent in the treatment of distal left main stenosis: an international registry

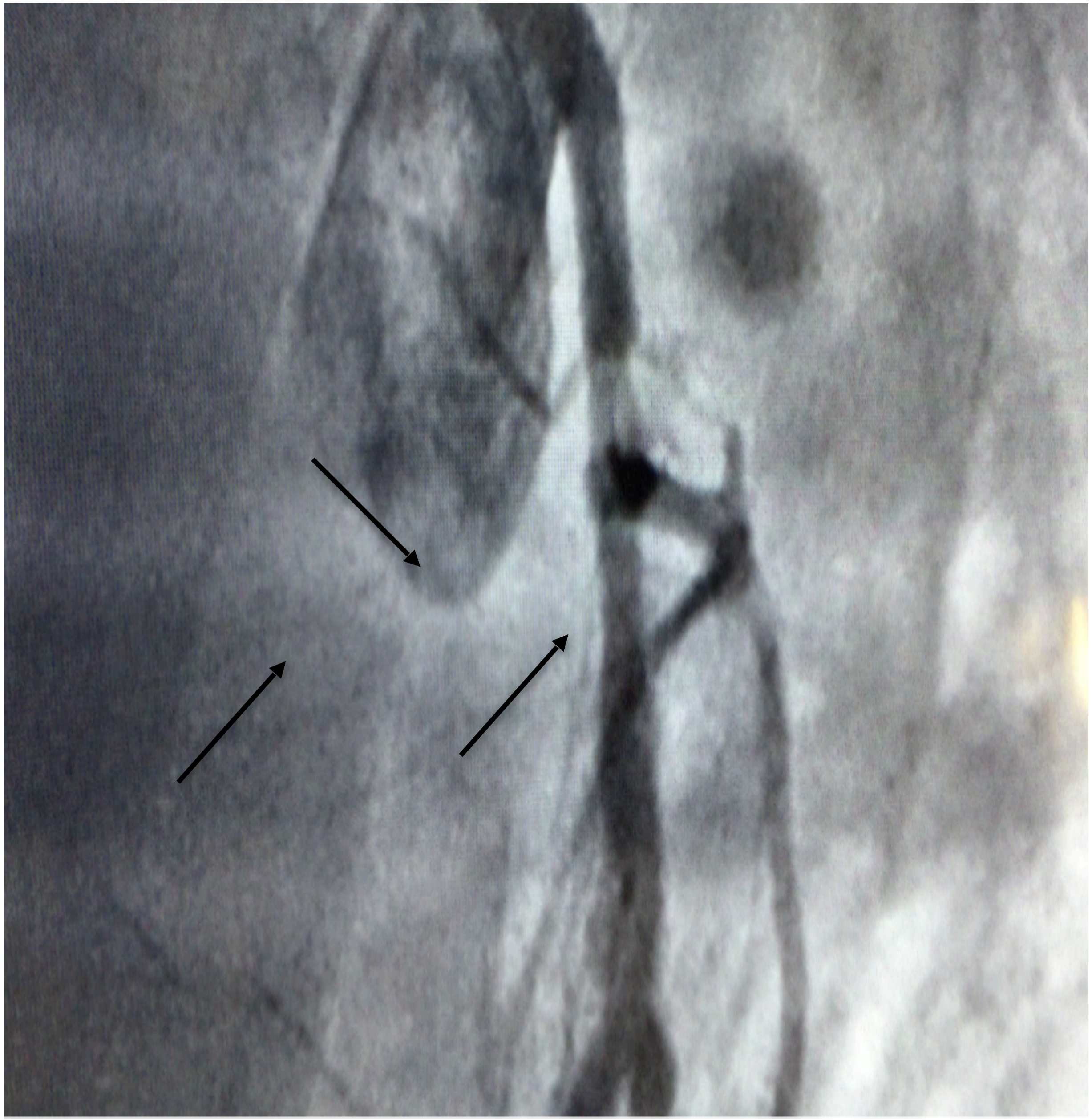
Bioss Lim C
3.5 -3.0 x 24




FO
RA

Bioss Lim C
4.25 -3.5 x 24



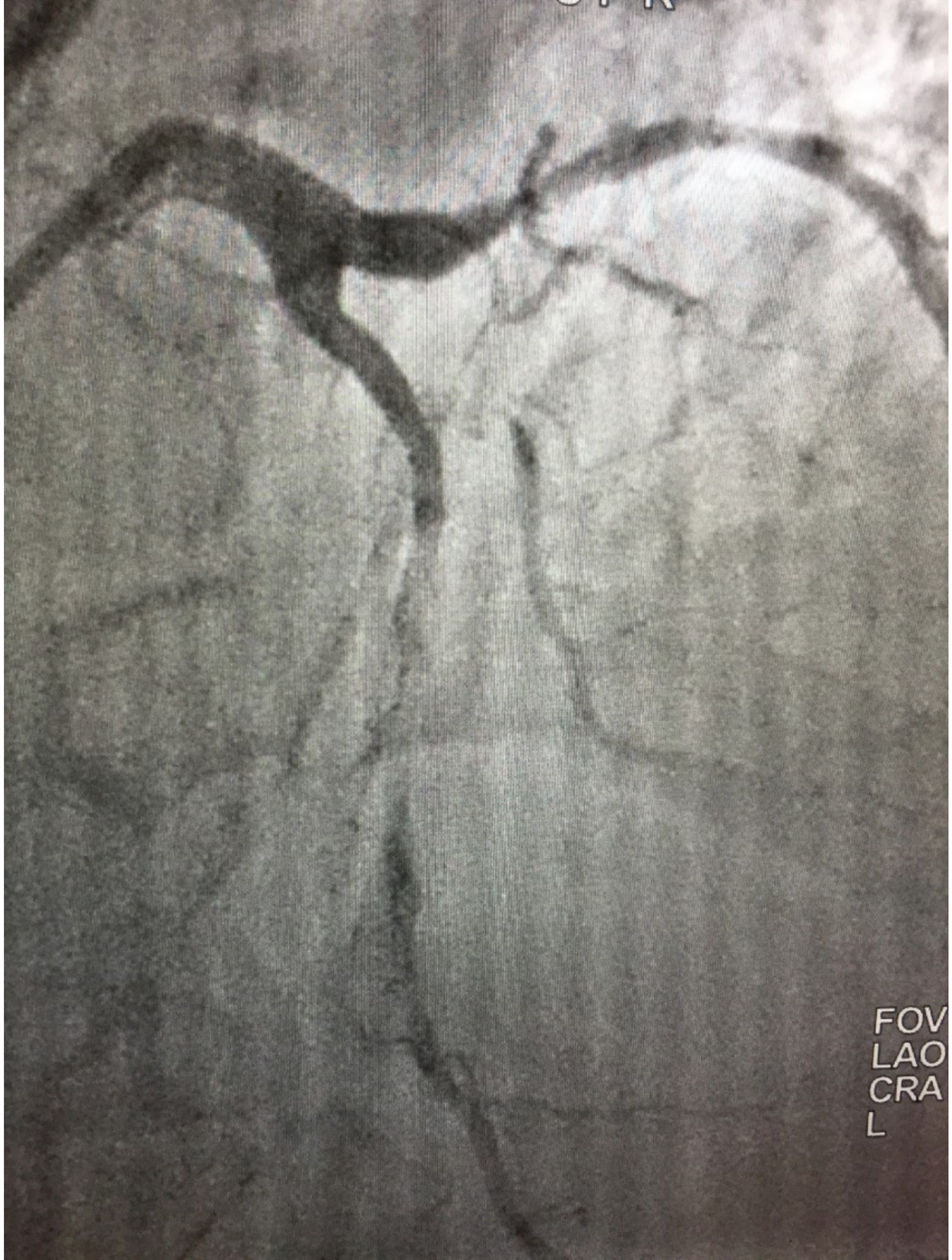


ACS
STEMI

Ost DG

Inverted T
Stenting

Bioss Lim C
3.0 -2.5 x 19



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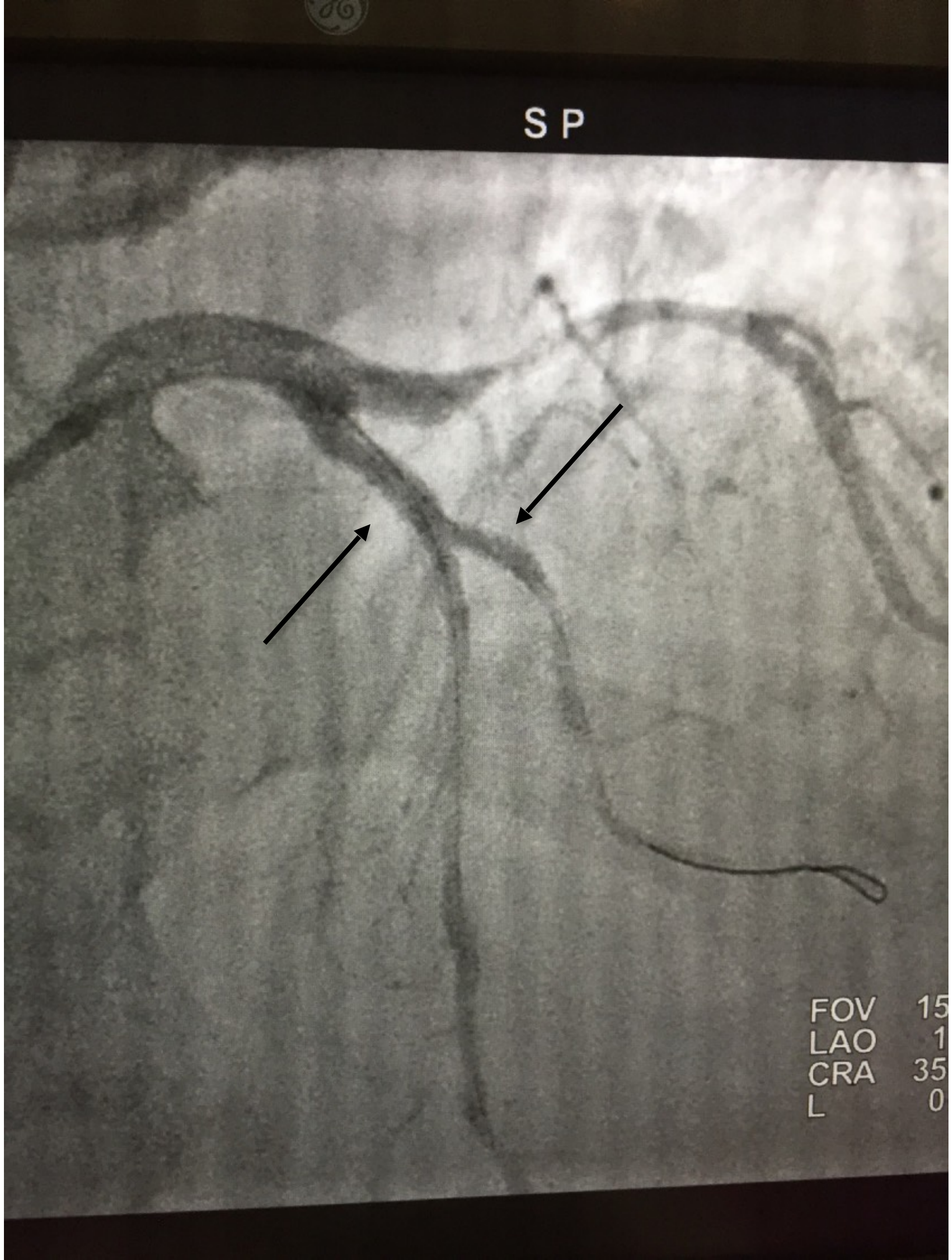

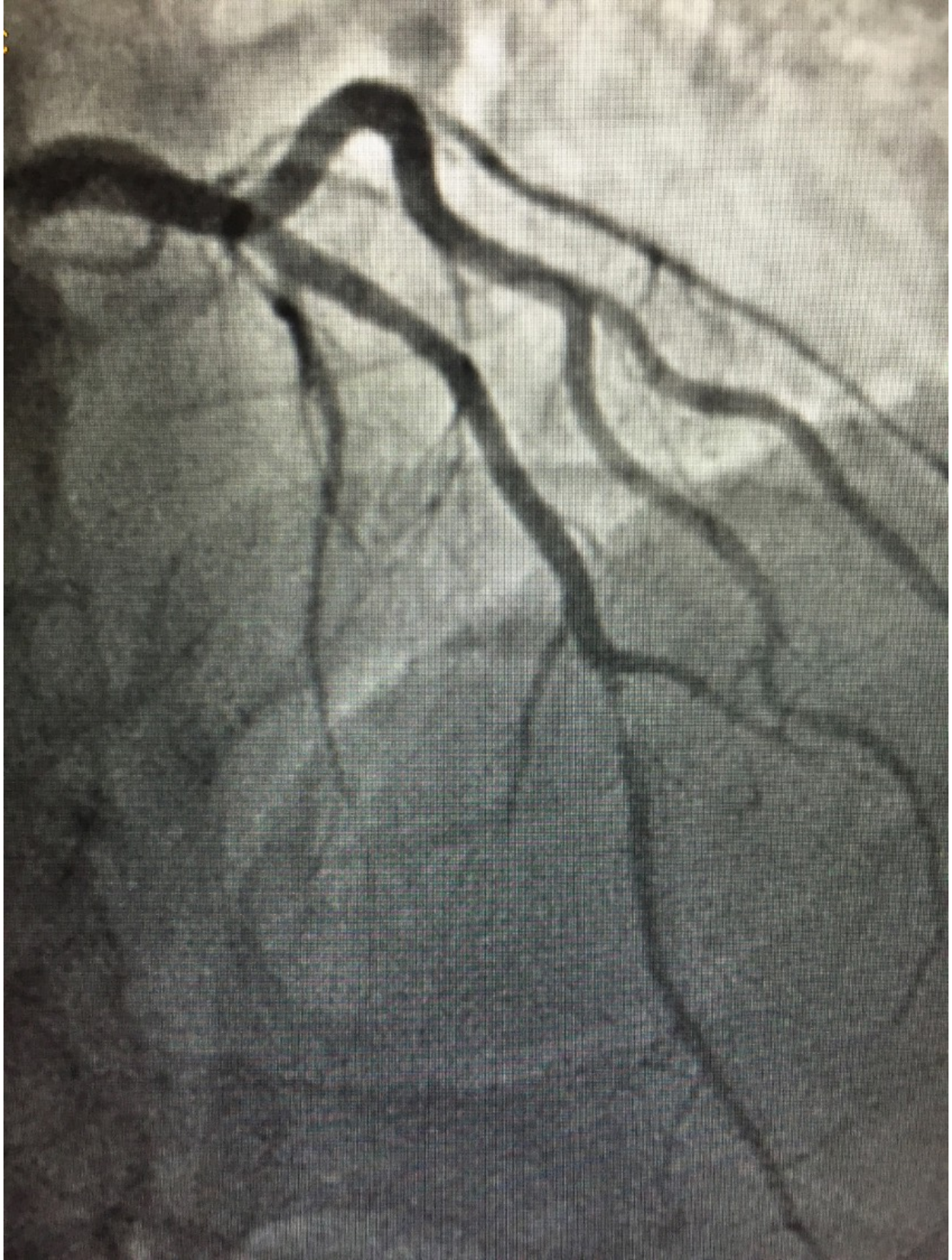

Bioss Lim C
3.0 -2.5 x 19

TIPS and Tricks for Bioss

- Pre dilatation +++
- No direct stenting with calcified lesions
- Direct stenting for ACS is feasible
- Low pressure delivery (12 Atm)
- Only one wire for majority of cases
- No need to side for <2,5 mm diameter
- Optimisation if needed

- Should we Kiss?
- Should we RePOT
- POT Side RePOT with the same device?
- Still incertitude with open angle in large vessel (LM CX)
- Still incertitude with MEDINA X-X-1