



Optimal Use of DEB in Bifurcation

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What is drug eluting balloon (DEB)?

- ▶ **Old-style** balloon angioplasty married to **new** drug eluting technology



Today, we have numerous DEB studies for various indications

Treatment modality	Indications						
	All comers registries	De novo	Small vessels	STEMI	CTO	Bifurcations	ISR
DEB only	DELUX SPANISH SEQUENT PLEASE	DEAR (DM) VALENTINES II	PEPCAD I PICCOLETO BELLO Small vessel registry	PAPPA-pilot	PEPCAD-CTO	BIOLUX-I	PEPPER PACCOCATH I/II PEPCAD II PEPCAD DES PEPCAD China ISR HABARA VALENTINES I IN.PACT CORO ISR PERVIDEO I SEDUCE ISAR-DESIRE-3 Monzino RIBS V PATENT-C
DEB + BMS		PEPCAD IV (DM) PEPCAD-CTO PERFECT DE NOVO pilot OCTOPUS DEAR (DM) INDICOR		DEBAMI DEB-AMI		PEPCAD V DEBIUT	
BMS crimped on DEB		PEPCAD III					

Focus on the **ZEROs**

Trial	Devices used	Treated Lesion	Duration of DAPT	Late thrombosis at follow-up
PACCOCATH ISR I	Paccocath vs. uncoated balloon	In-stent restenosis	1 month	At 12 months: Paccocath 0%, uncoated balloon 0%
PACCOCATH ISR II	Paccocath vs. uncoated balloon	In-stent restenosis	1 month	At 12 months: Paccocath 0%, uncoated balloon 0%
PEPCAD I SVD	SeQuent™ Please	De novo, small vessels	DEB: 1 month, DEB + BMS: 3 months	At 12 months: DEB 0%, DEB + BMS: 6,3%, p=0.14
PEPCAD II ISR	SeQuent™ Please vs. Taxus™ Liberté™	In-stent restenosis	DEB: 3 months, DES: 6 months	At 12 months: DEB 0%, DES: 0%
PEPCAD III	Coroflex™ DEBlue vs. Cypher™	Complex de novo lesions	6 months	At 9 months: DEB+BMS: Definite 1.3%, probable 0.6% DES: Definite 0.3%, probable 0%
PEPCAD V	SeQuent™ Please + Coroflex™	Bifurcation	3 months	At 9 months: Definite 3.6%, probable 3.6%
PICCOLETO	Dior™ II vs. Taxus™ Liberté™	De novo, small vessels	1 month in stable angina and lone DEB use, 3 months in DEB and provisional stenting	At 9 months: DEB 0%, DES: 0%
DEBUIT	Liberté™ + Dior™ vs. Liberté™ + POBA vs. Taxus™ Liberté™ + POBA	Bifurcation	DEB: 3 months, DEB + BMS: 3 months, DES: 12 months	At 6 months: DEB: 0%, DEB + BMS: 0%, DES: 2.5%



BIOLUX-I 9-month (DEB in SB, DES in MB)

BIOLUX-I : Prospective, multicenter trial	
Patient enrolment	35
Device	Pantera Lux
Lesion type	Bifurcations (main branch DES, side branch DEB)
Primary endpoint	9 mo LLL (side branch)

9-months angio FUP	N=35
LLL (side branch)	0.10 ± 0.36 mm
12-months clinical FUP	N=35
TVR	0.0%
Target vessel MI	5.7%
Cardiac death	2.8%
TVF	8.6%

Conclusion:

Side branch treatment with the Pantera Lux DEB appears to be safe and efficacious when used with a MB DES for the planned provisional treatment of bifurcation PCI in this pilot study.



SARPEDON BIOLUX-I 12-month outcomes

SARPEDOM: Retrospective, multicenter trial	
Patient enrolment	50
Device	Pantera Lux
Lesion type	Bifurcations (main branch DES, side branch DEB)
Primary endpoint	6 mo LLL

6-months angio FUP	N=43
LLL (side branch)	0.09 ± 0.23 mm
12-months clinical FUP	N=50
TVR	6.0%
Non-fatal MI	12.0%
Any death	4.0%
MACE	22.0%

Conclusion:

By comparison with historical control, the use of DEB kissing at bifurcation may be superior to ordinary balloon kissing, a 2-arm randomized study of larger size is required to prove this theory.



The result is not optimal!!

▶ WHY ?

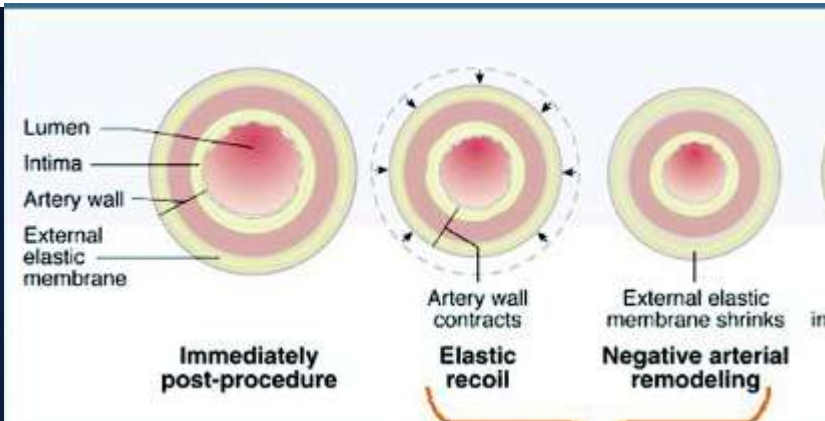
Two Mechanisms for Re stenosis

Neointimal Hyperplasia



Re-stenosis

Negative Remodeling



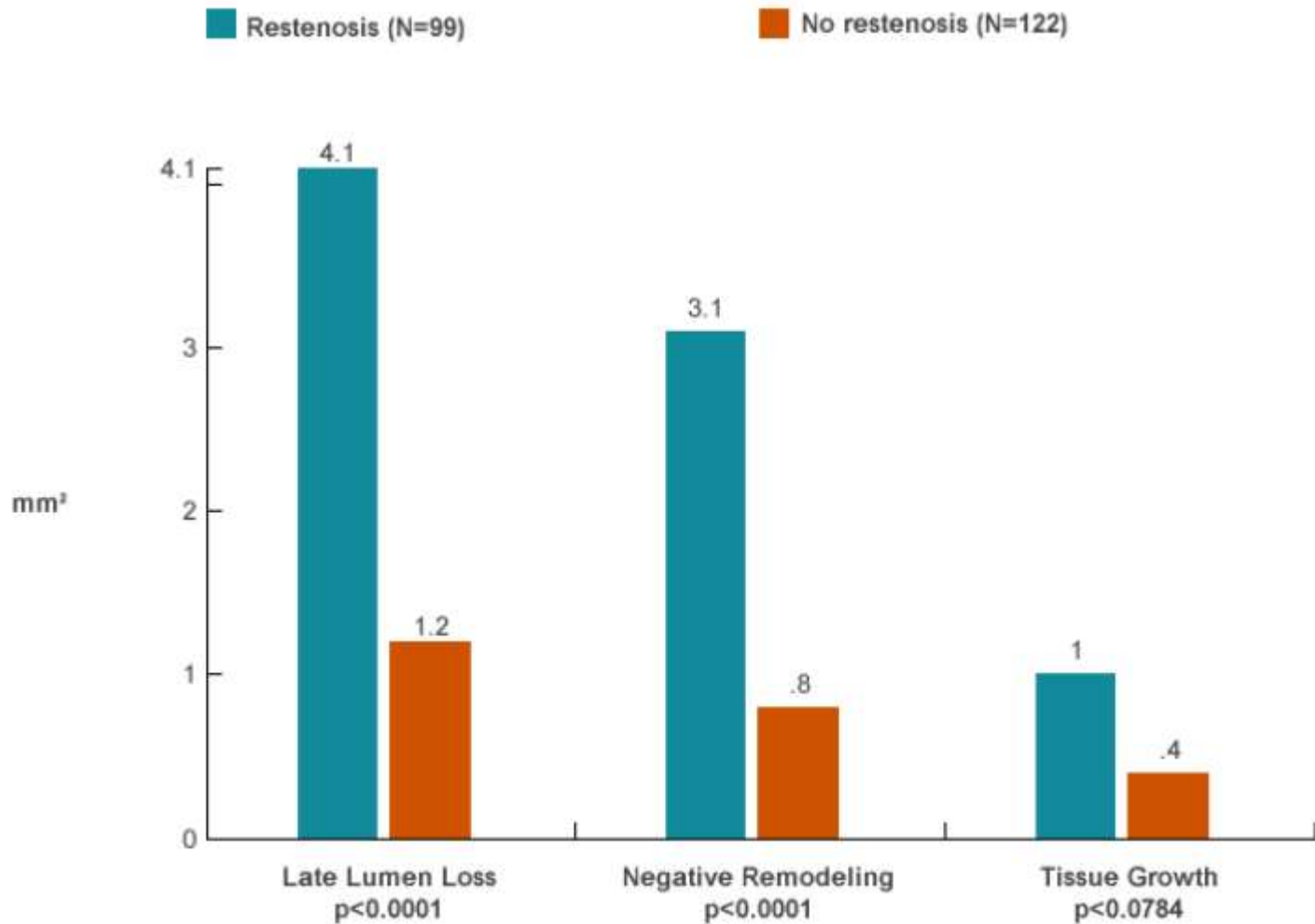
DEB



DEB



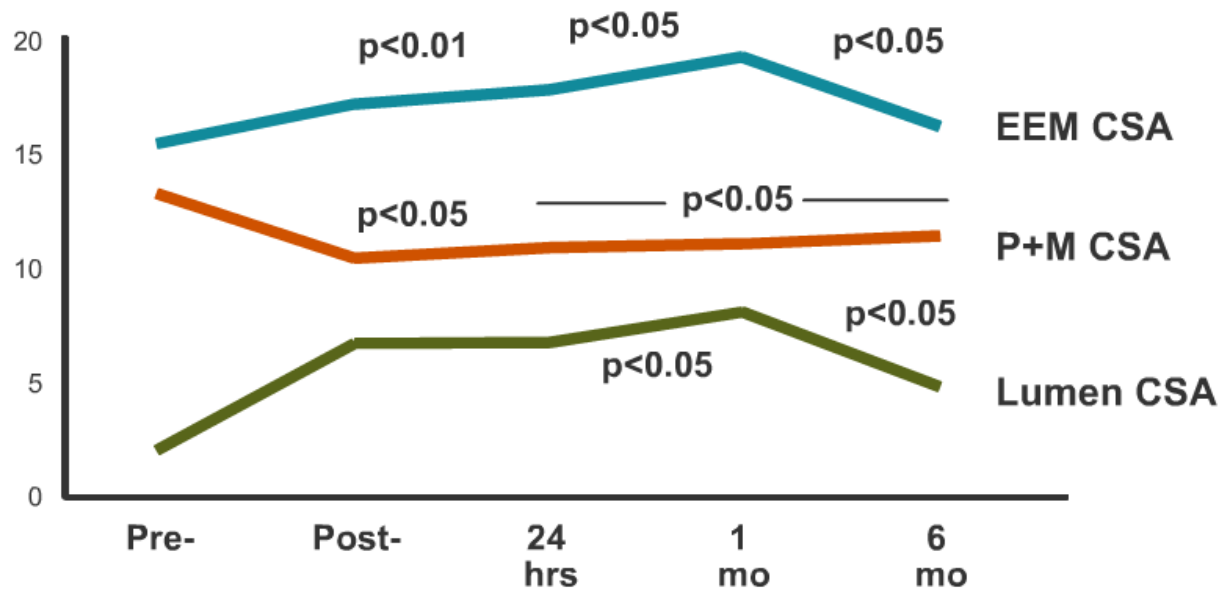
For restenosis in **Non-stented** lesion, **negative remodeling** is common



SURE Trial

SURE Trial:

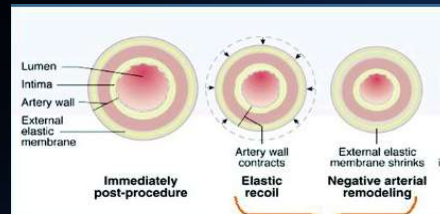
Negative Remodeling Is a Late Event and Follows Earlier Positive Remodeling



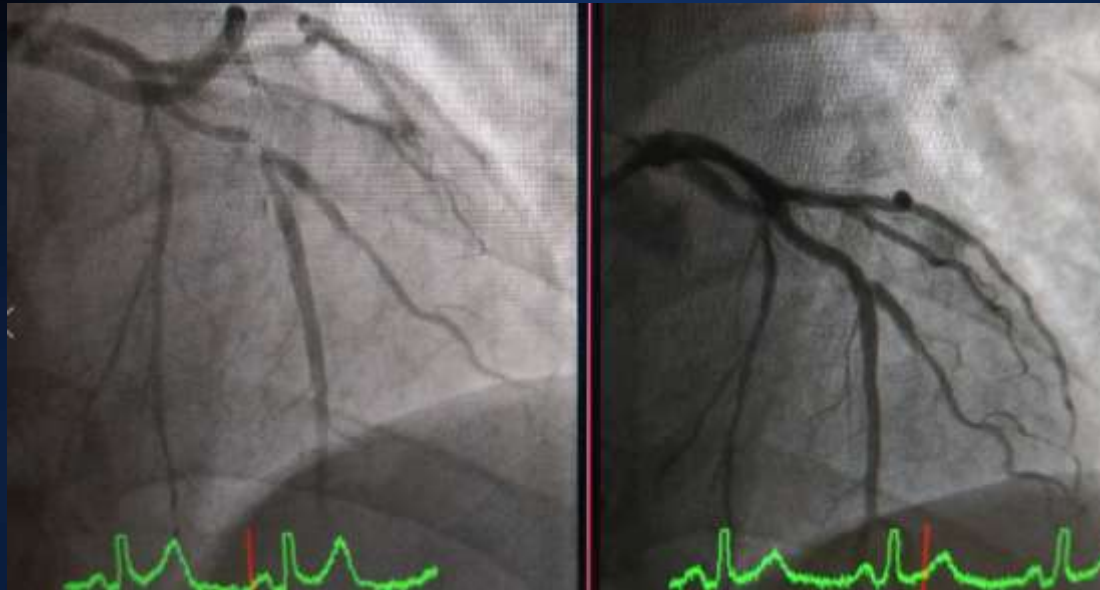
61 native vessel lesions (26 DCA, 35 PTCA) with complete serial IVUS studies (out of 79 lesions enrolled in the study)

Why result of DEB use in bifurcation is not optimal ?

- ▶ 1. Side Branch is essentially an **Ostial Lesion**.



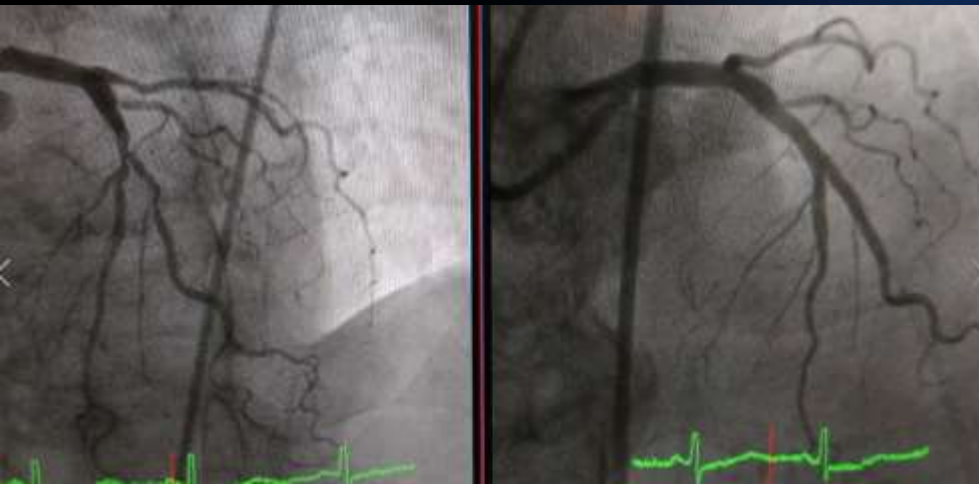
- ▶ 2. Simple bifurcation-> Keep it simple!





Why result of DEB use in bifurcation is not optimal ?

- ▶ 3. Two stent techniques can be very good now with new stents and method.



DK Crush 44ml Contrast

Is it Comfortable to use DEB?



DK Crush 63ml Contrast

Is it possible to use DEB?

Why am I here ?



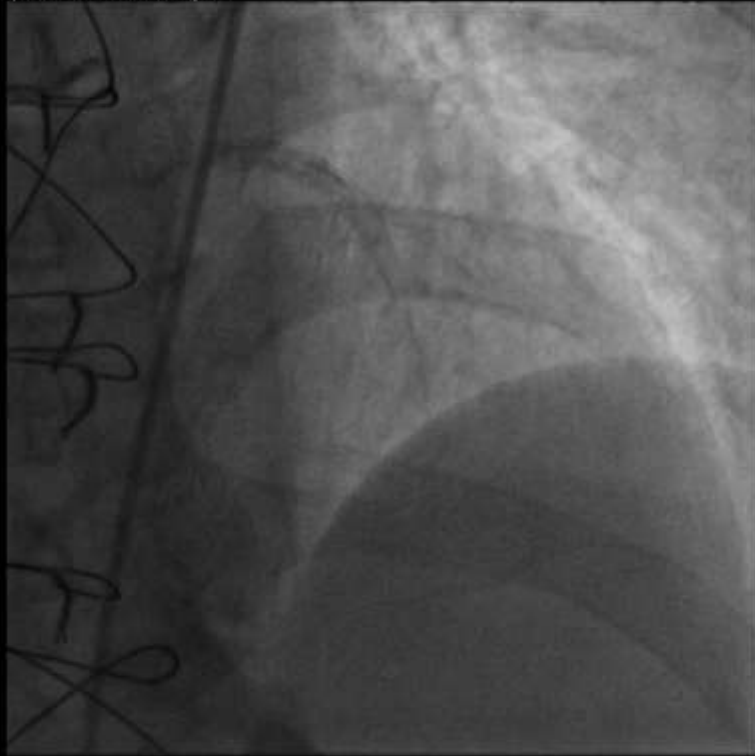


Case 1 – DEB is the best choice.

- ▶ M/ 60s with renal failure and calcified long lesion in LAD and LM
- ▶ PCI to LAD and LM 3 months ago
- ▶ Complicated with trapped IVUS
- ▶ Urgent CABG for
 - IVUS removal and SVG to LAD
- ▶ E admitted x NSTEMI
- ▶ ECG aVR ST elevation, lateral leads ST depression.

Recurrent ACS in 3 months

Lusky Compression - not intended for diagnosis



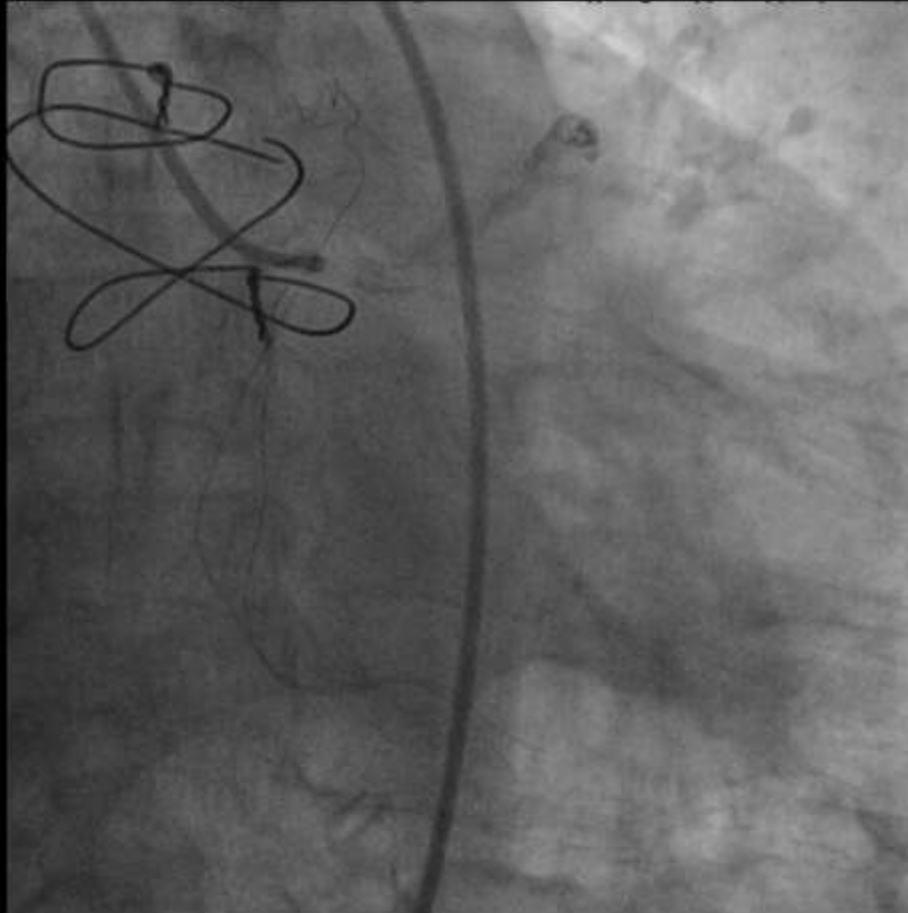
Lusky Compression - not intended for diagnosis



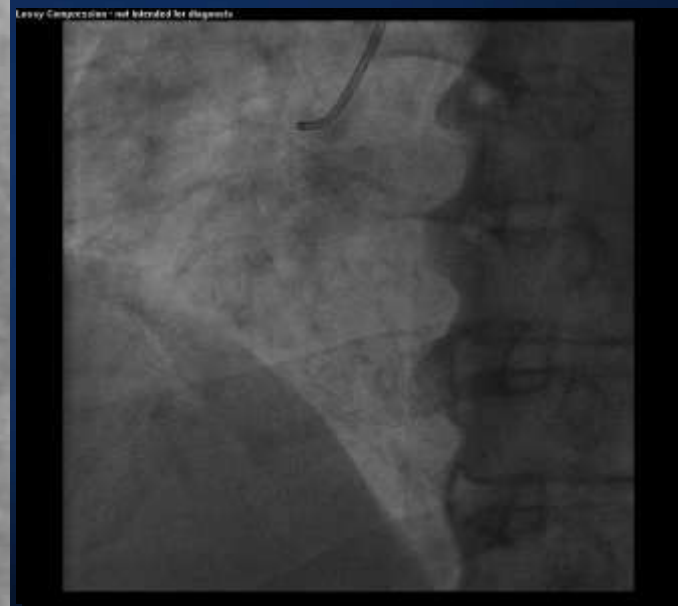
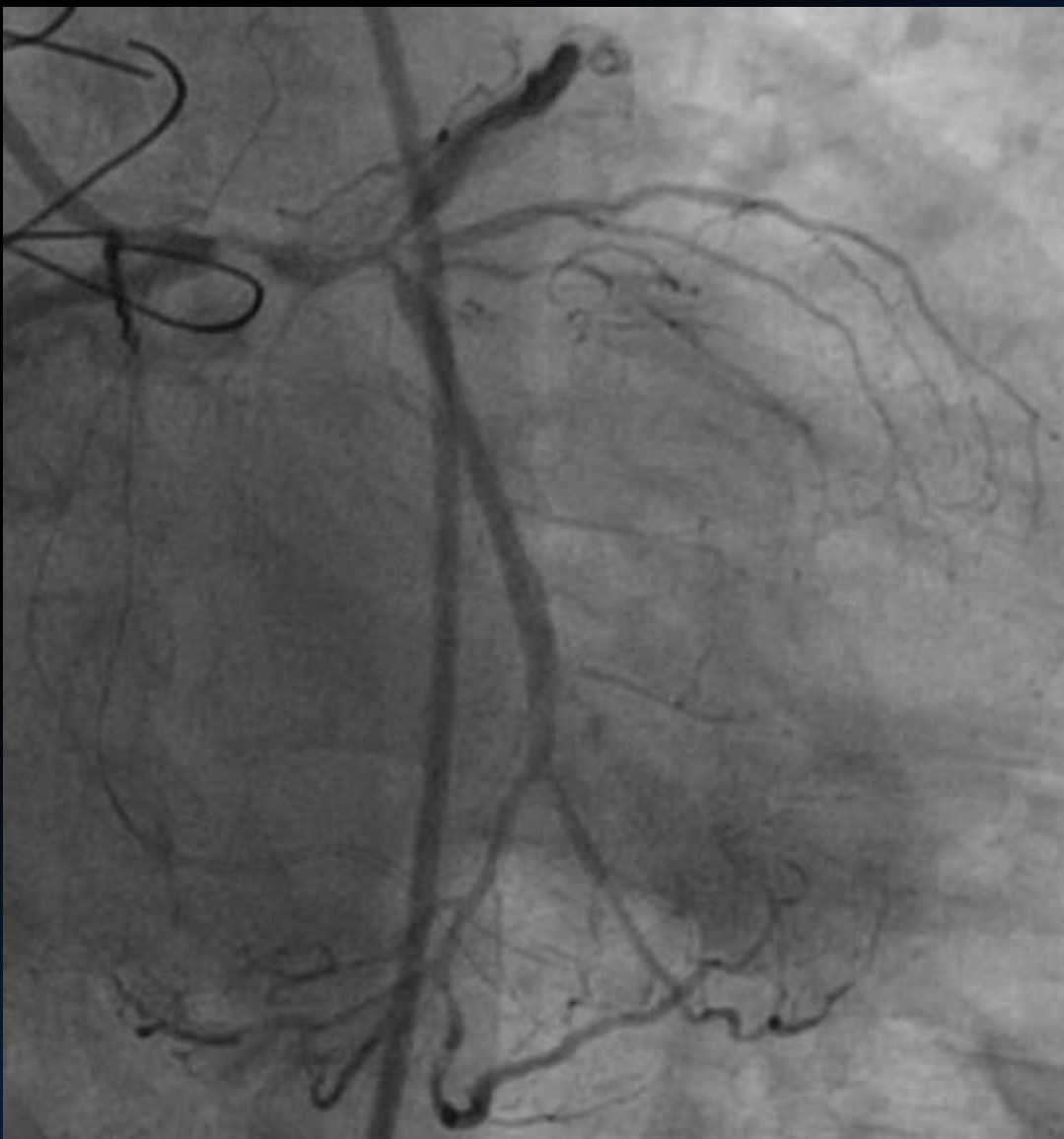
Complex dLM Bifurcation (1,1,1)

▶ Recurrent ACS + dLM bifurcation

Lossy Compression - not intended for diagnosis



Dominant **unprotected** Lcx in critical condition



RCA

Significant lesions in mLAD



p-m septal and anteroseptal
contract well

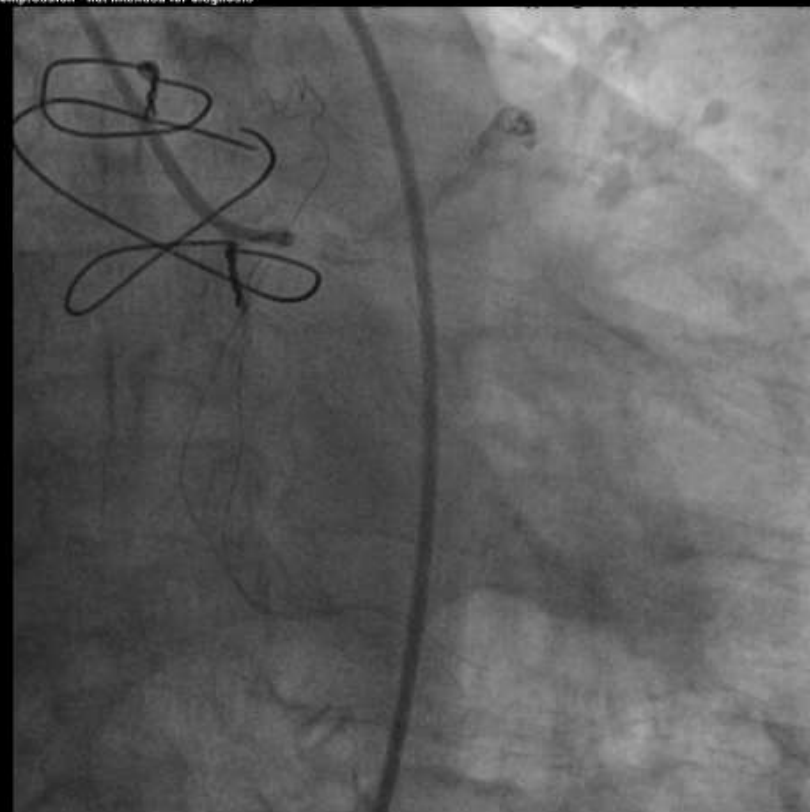




LM and ostial LAD stent strut distorted

coro 3 months ago

coro now



Stent Strut will be complex in this bifurcation



Two key points

- ▶ **Save the LCx and pLAD**
- ▶ **Avoid too much metal**



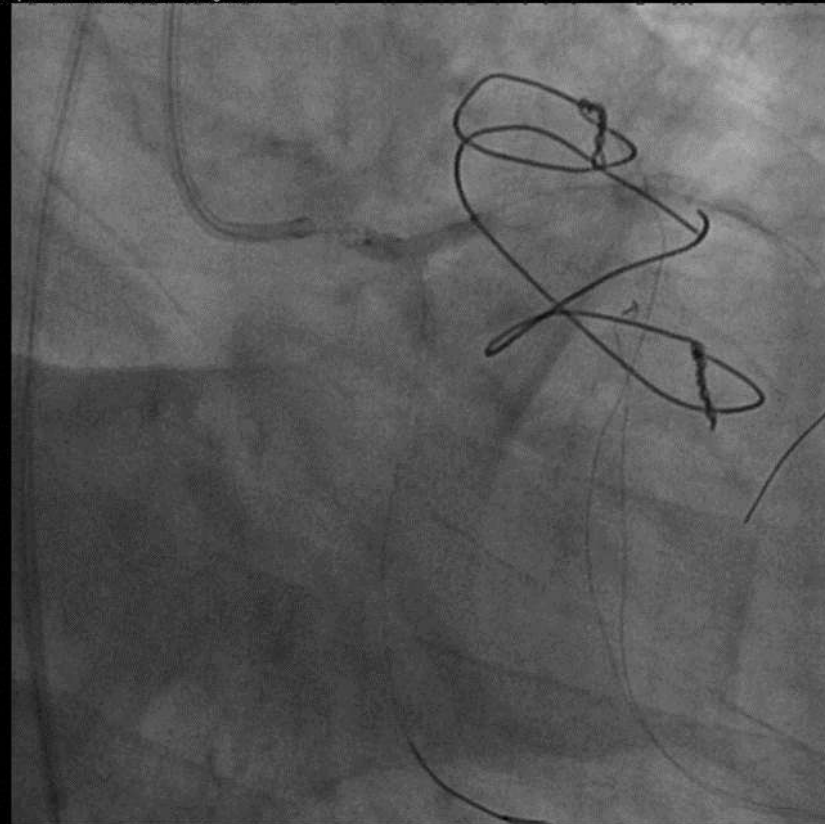
Incremental Predilatation

1.5 balloon , then 2.5 balloon, then **OPN Balloon up to 35 ATM**

Lessy Compression - not intended for diagnosis

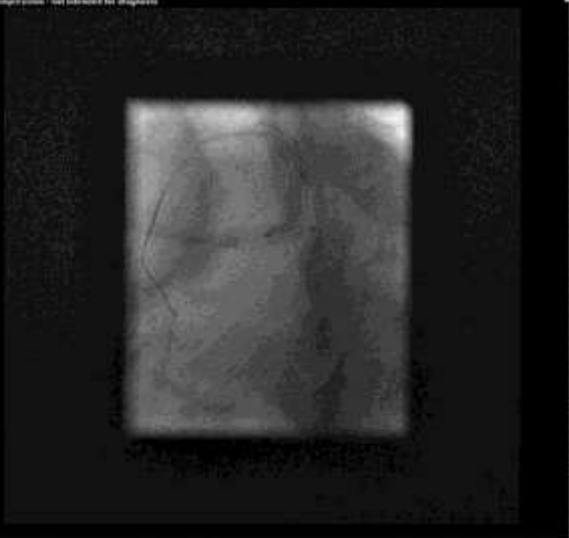


Compression - not intended for diagnosis



Use stent boost

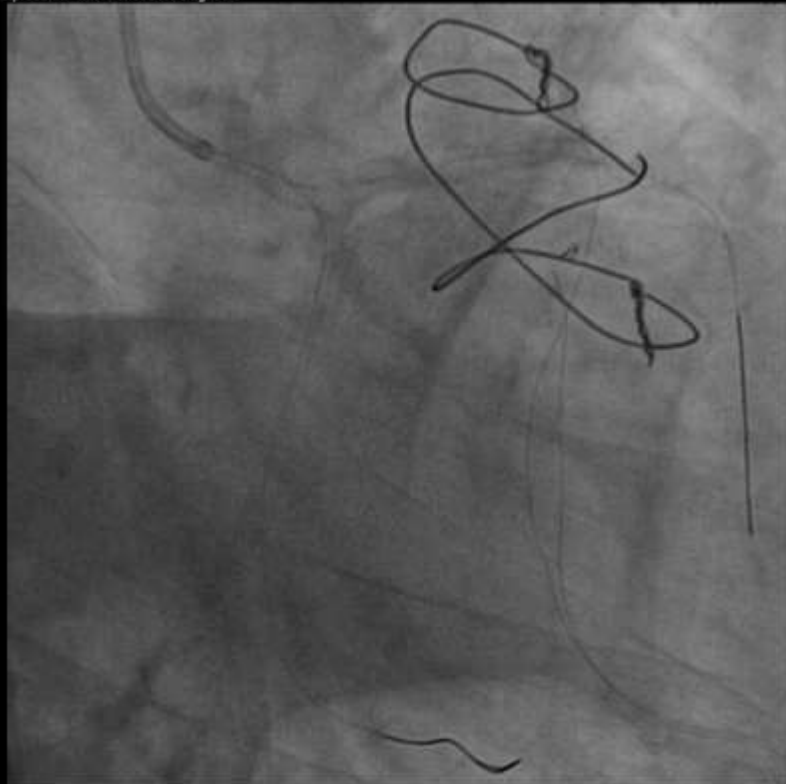
Early Compression - not inhibited by diaphragm



Coro after ballooning



Lazy Compression - not intended for diagnosis



Lazy Compression - not intended for diagnosis



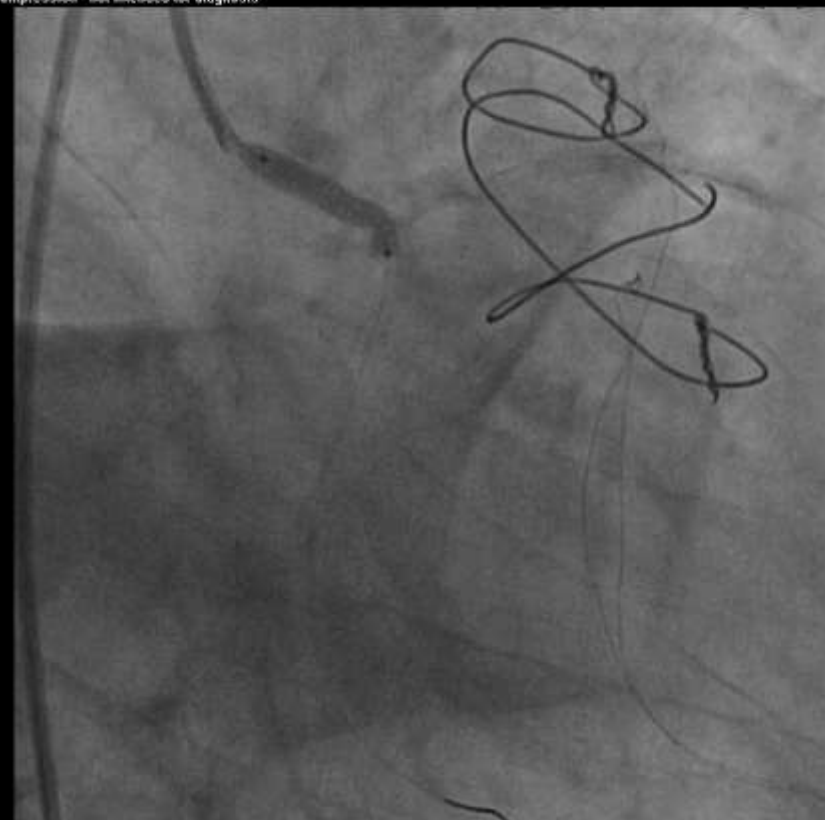


LM to LCx stenting

Lesly Compression - not intended for diagnosis

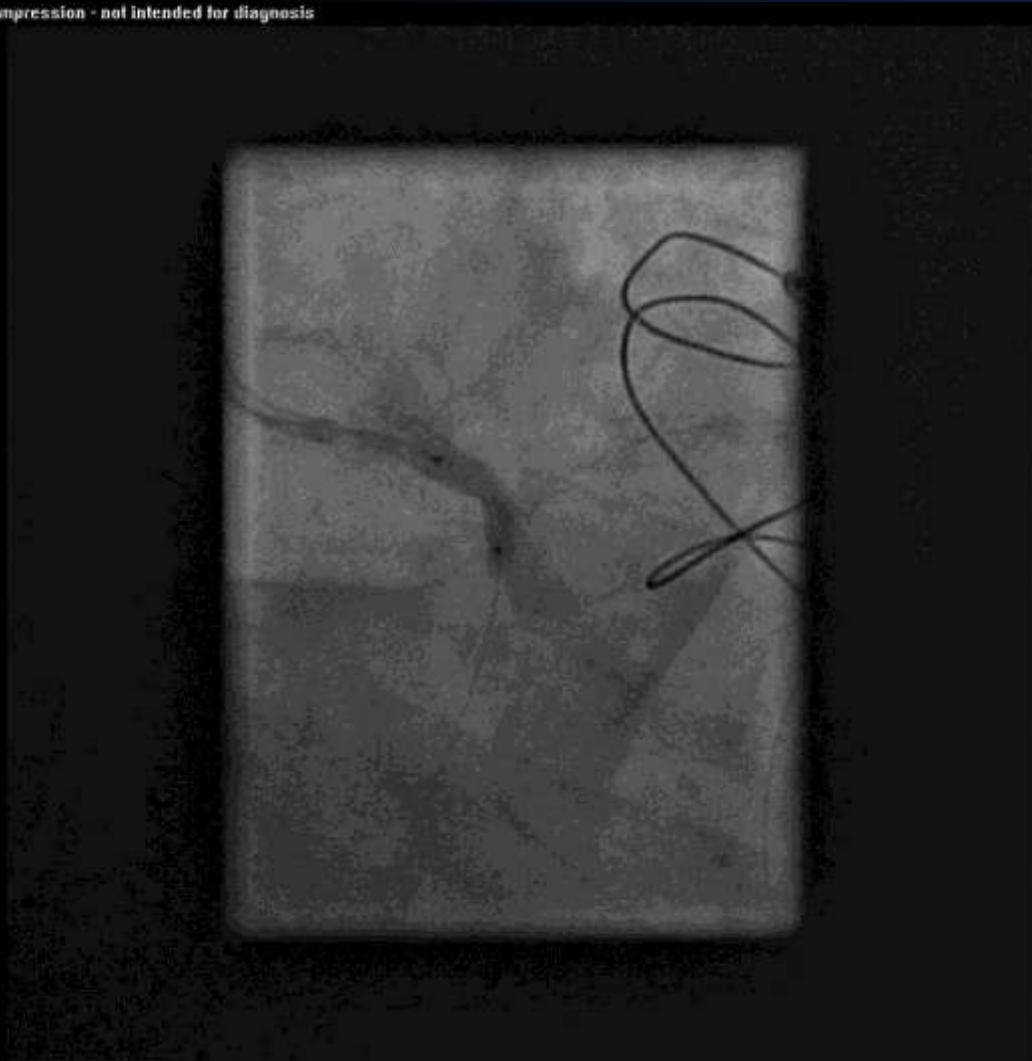


Lesly Compression - not intended for diagnosis



PSHP by fortis up to 26 ATM

Lossy Compression - not intended for diagnosis



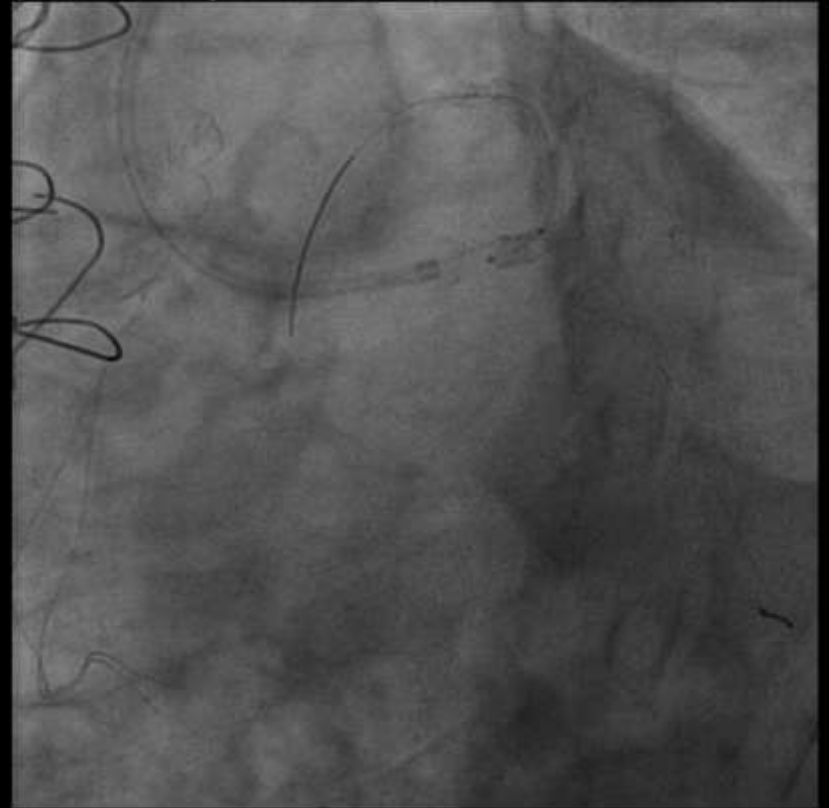


POT and 2 steps kissing

Lassy Compression - not intended for diagnosis



Lassy Compression - not intended for diagnosis





DEB to LAD (low pressure)

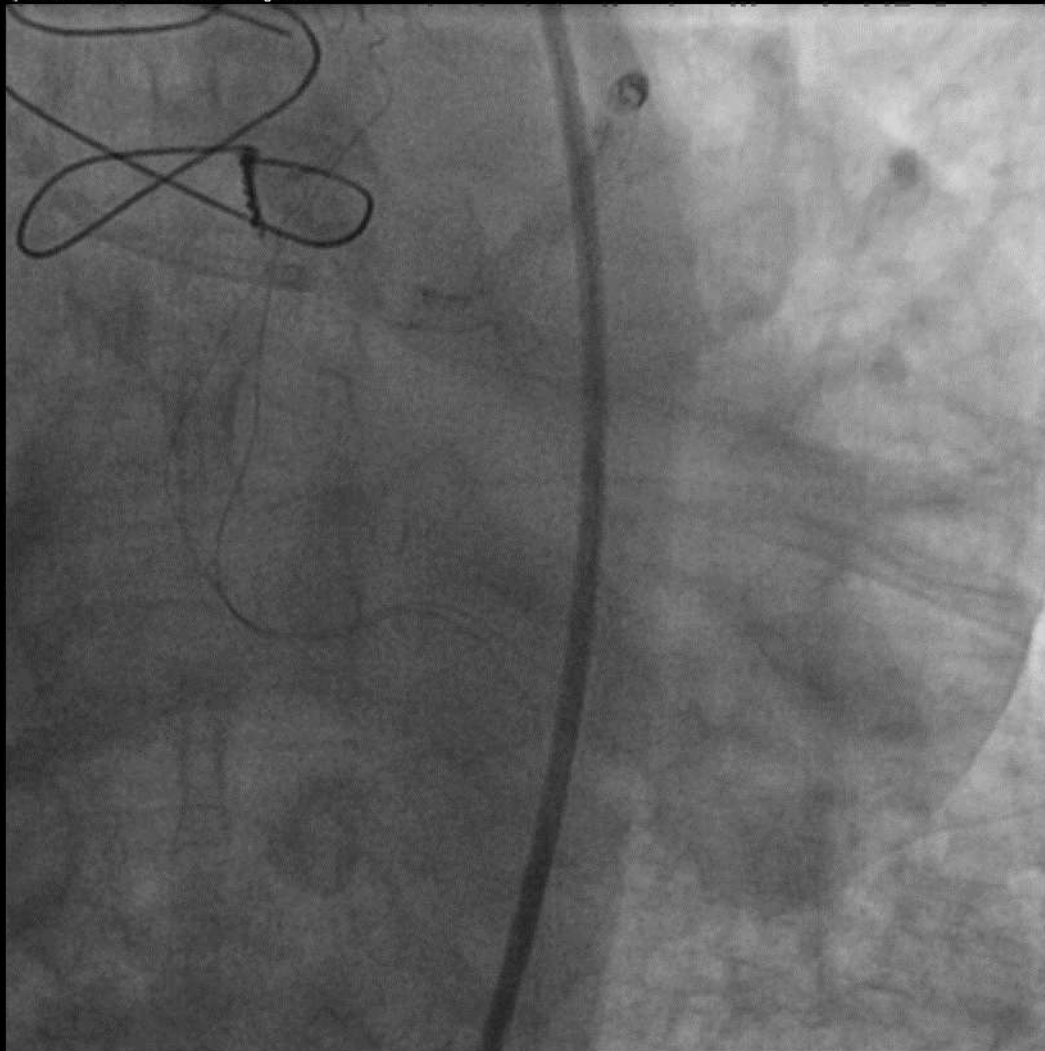
Lossy Compression - not intended for diagnosis



Pantera Lux 3.0 x 15

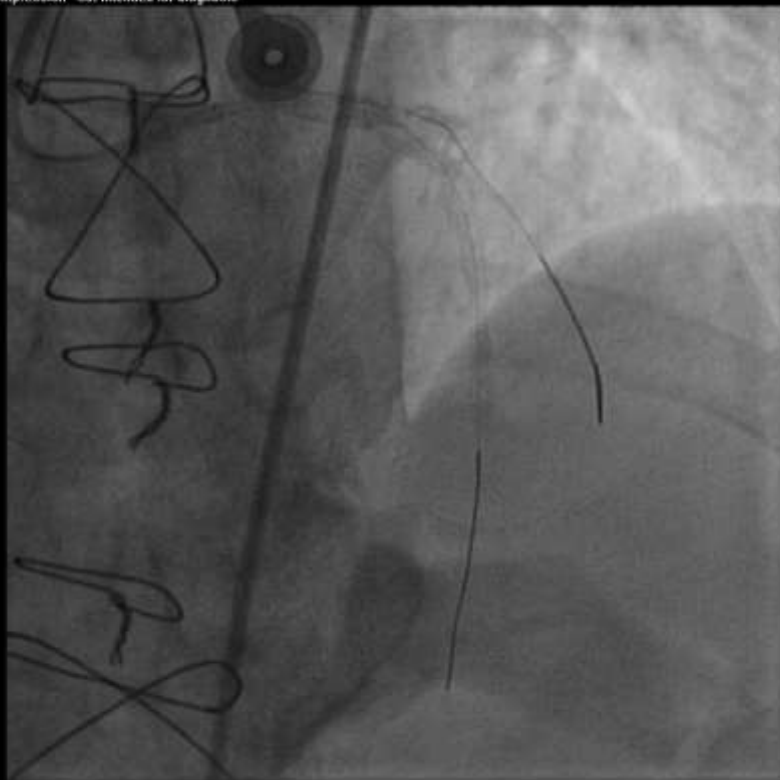
Final angiogram

Lossy Compression - not intended for diagnosis

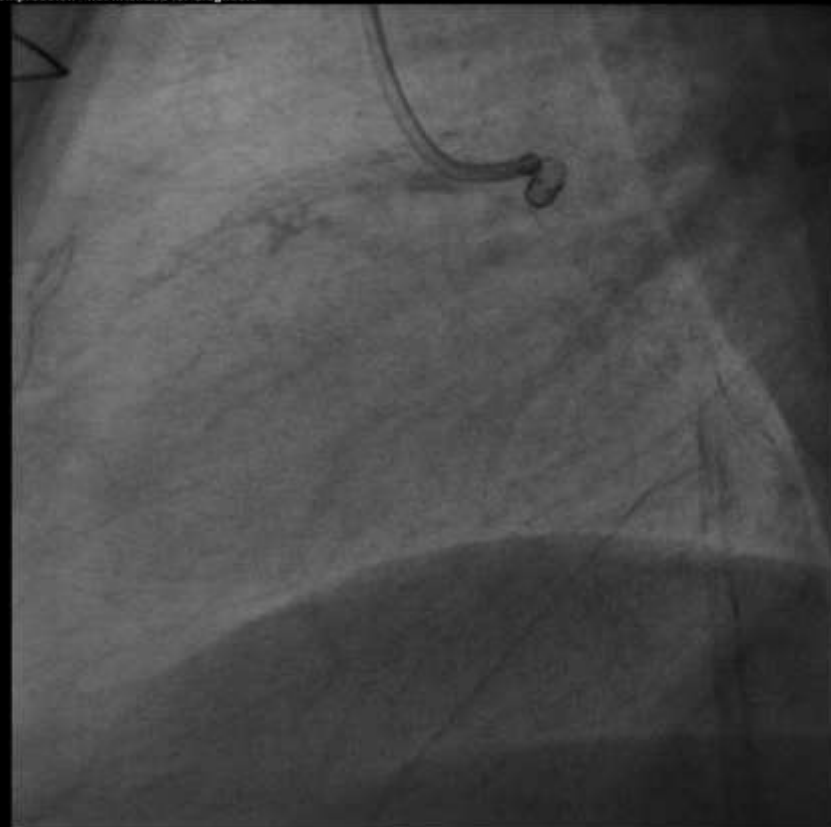


Final angiogram

Lessy Compression - not intended for diagnosis



Lessy Compression - not intended for diagnosis





- ▶ **DEB is useful in bifurcation with complex stent strut to avoid too much metal.**



Case 2

▶ M/ 75

▶ History of

1. DM, AF on warfarin

2. IHD

PCI to LCx and Diagonal (D1) with **BMS**
01/14

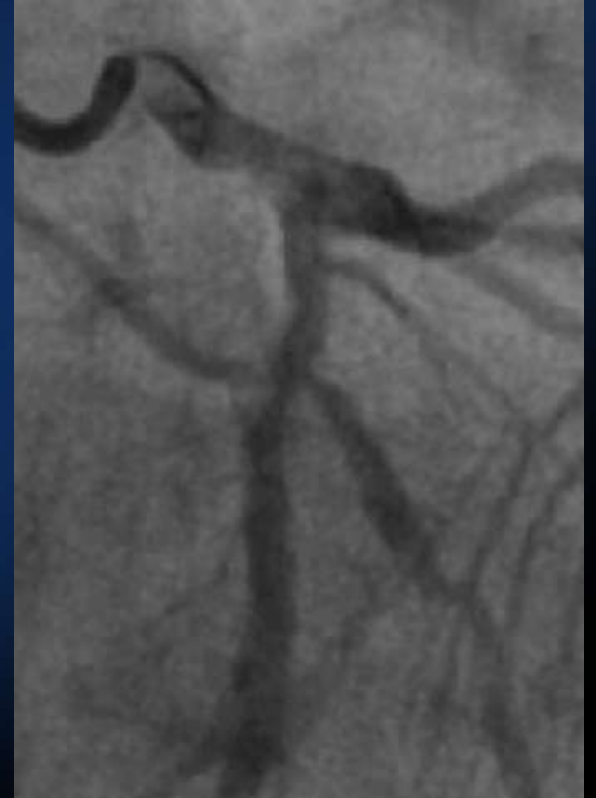
C/o recurrent angina

Coro +/- PCI 10/12/2014

Lossy Compression - not intended for diagnosis



focal ISR + side branch



**BMS 2.5 x 20
Omega
PSHP by 2.75 NC**

Larcrosse NSE 2.75 x 13

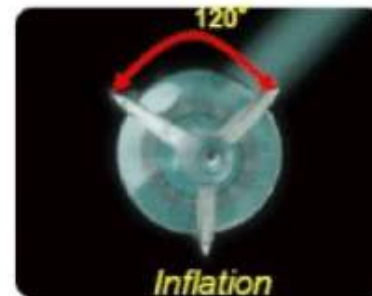
Lossy Compression - not intended for diagnosis



Good lesion preparation

Use stent boost

1. make sure in-stent
2. screening



Stent Boost for DEB



Pantera Lux **3.0** x 20

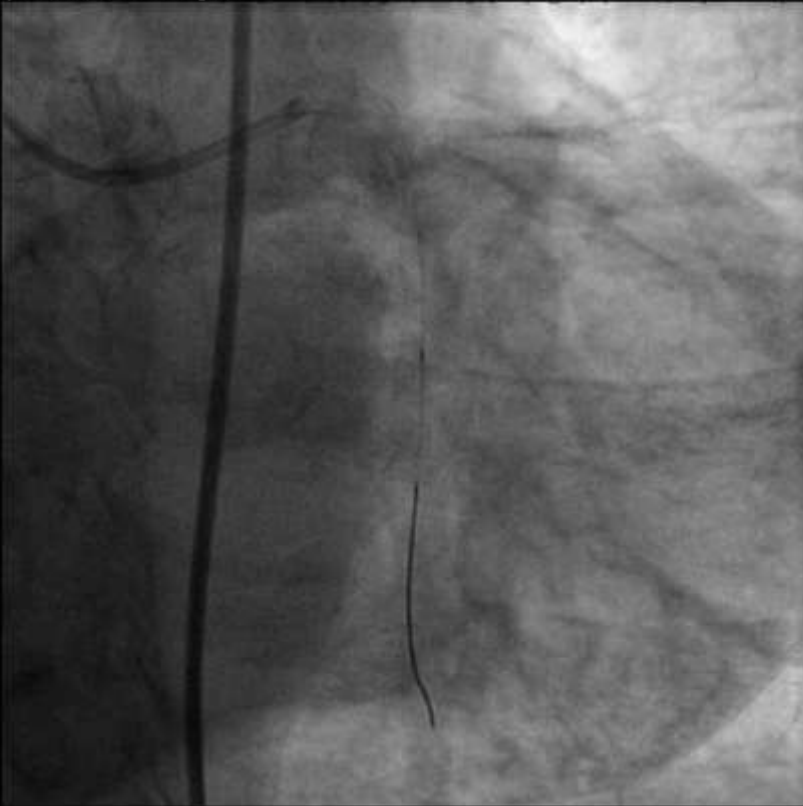
Inflation : **30s** **7ATM**

Tips:

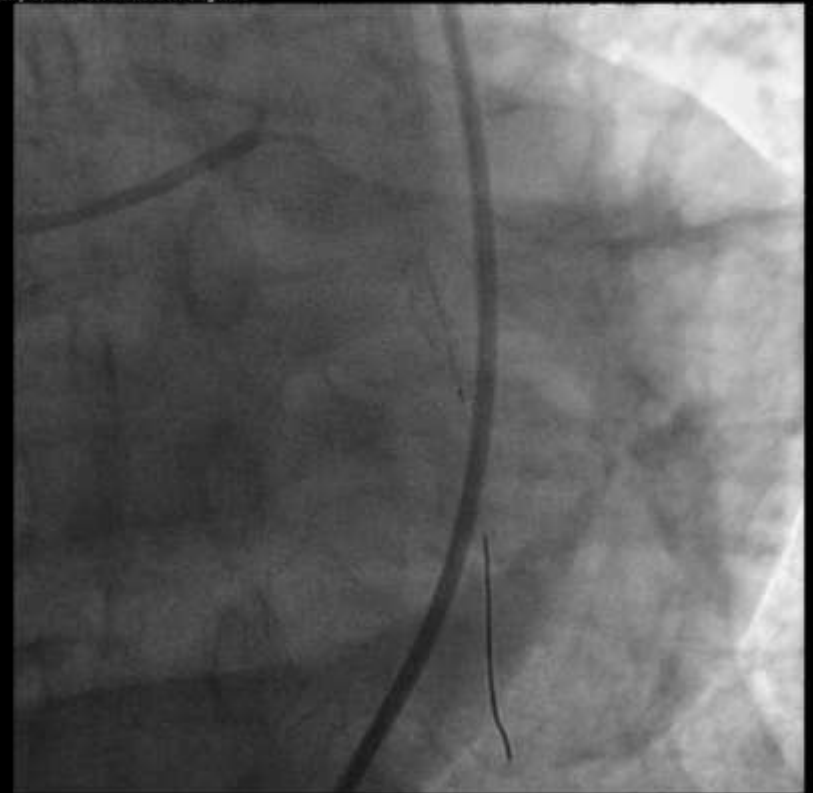
1. Use stent boost.
2. Balloon size and vessel size 1:1 ratio
3. Low pressure.
4. Duration: 30s

Final Angiogram

Lessy Compression - not intended for diagnosis



Lessy Compression - not intended for diagnosis



The side branches are still here.



DEB is more than real alternative !

▶ Side branch considerations



▶ Dual antiplatelet therapy issues

▶ M/ 75

▶ History of

1. DM, AF on warfarin

2. IHD

PCI to LCx and Diagonal (D1) with **BMS**
01/14

1 month dual antiplatelet is enough

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Conclusion

DEB should always be considered in bifurcation when there is **ISR**.

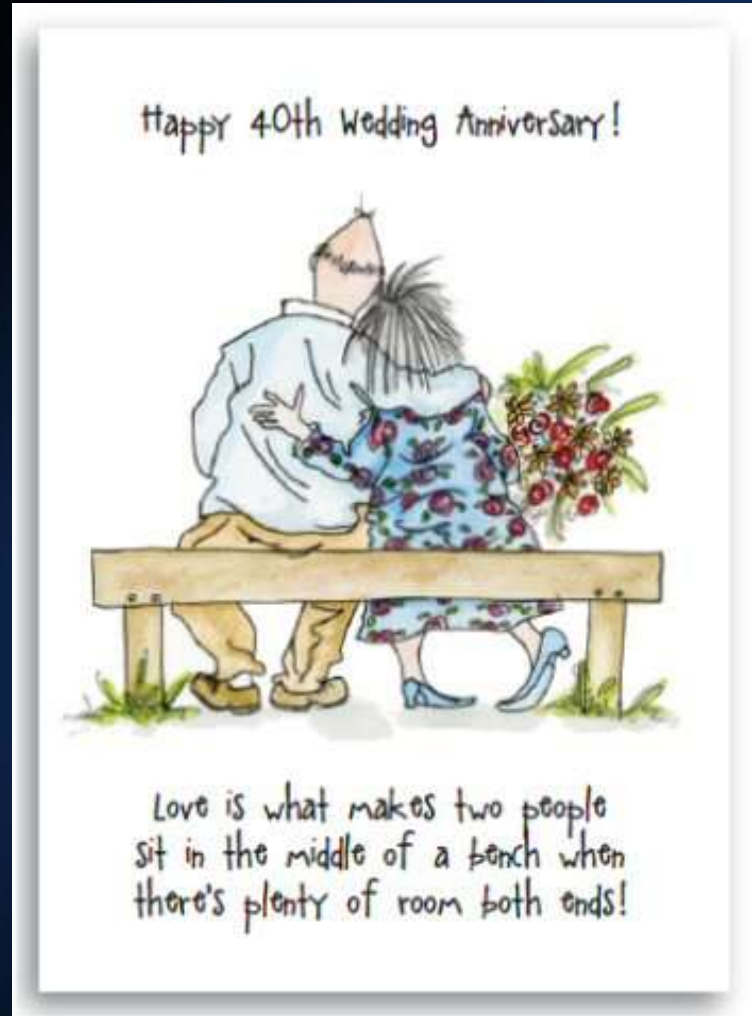
Main Advantages :

- 1. Avoid too much metal**
- 2. Shorter duration of dual antiplatelet needed.**

Second key point

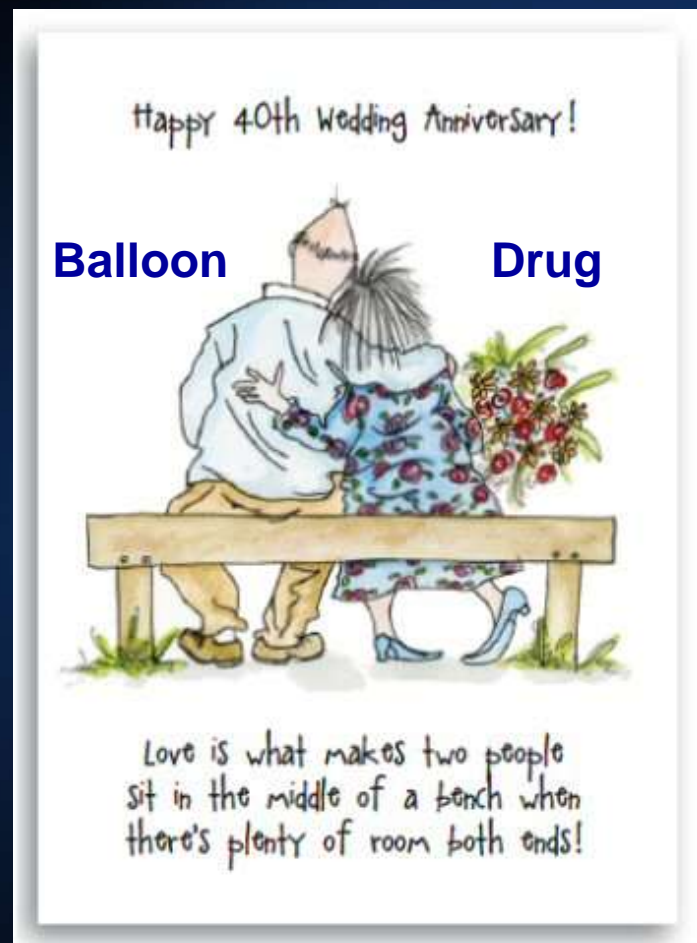
What is the key to make a successful marriage in humans?

Ans: **LOVE**

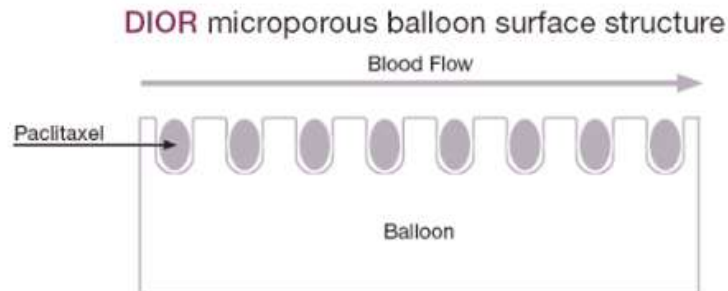


What is the key to make a successful marriage between old style balloon angioplasty and new drug eluting technology ?

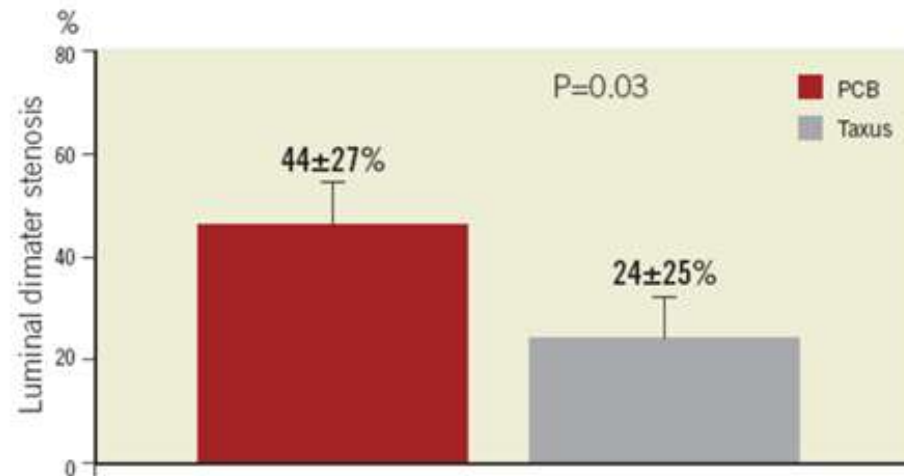
Ans: excipient



Good Excipient is essential to deliver drug



Paclitaxel-coated balloon DIOR® vs. Taxus DES in small coronary vessels (≤ 2.75 mm), n=28 + 29 patients



[Heart](#). 2010 Aug;96(16):1291-6. doi: 10.1136/hrt.2010.195057.

Paclitaxel-coated balloon versus drug-eluting stent during PCI of small coronary vessels, a prospective randomised clinical trial. The PICCOLETO study.

Cortese B¹, Micheli A, Picchi A, Coppolaro A, Bandinelli L, Severi S, Limbruno U.

Which one is the true “LOVE”?



- Pantera Lux uses BTHC excipient.
- BTHC is **highly lipophilic** and **NOT soluble in liquid**
- Loss during delivery is due to friction, not 'activation' of the coating'.

Excipient

Property

Iopromide: Paccocath/
Sequent Please

Highly hydrophilic

Urea: Medtronic In.Pact

Highly hydrophilic:

Shellac: Eurocor, DIOR

Swells in water