

Year-in-review:

*Drug-eluting stents
and
Drug-eluting balloons*

12 min

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No conflicts to disclose

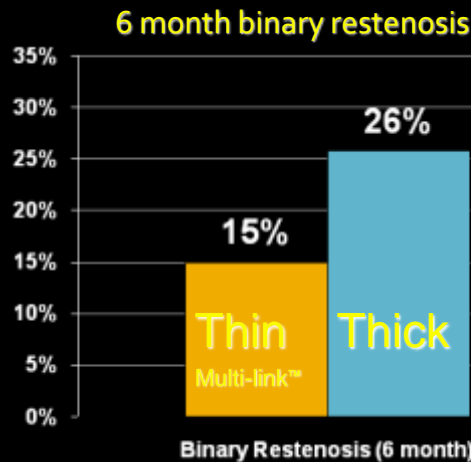
Thin Strut Impacts Clinical Outcomes

Historical Data with Bare Metal

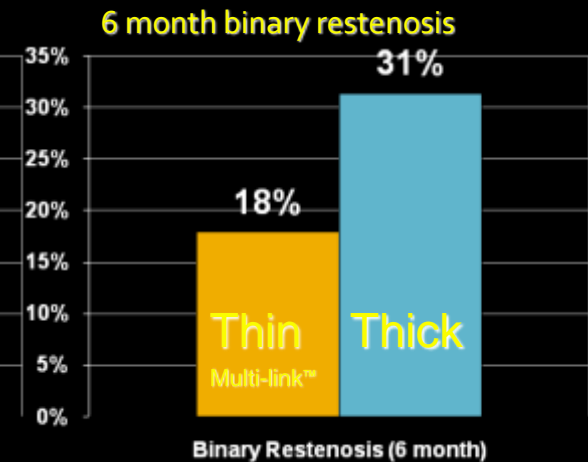
50 versus 140 micron



Multilink versus Duet
ISAR STEREO¹



Multilink versus Bx Velocity
ISAR STEREO²



Strut thickness appears to have a significant impact on long-term restenosis after stent implantation.^{1,2}

¹ISAR STEREO II JACC Vol. 41, No. 8, 2003 April 16, 2003:1283-8. ²ISAR STEREO I Circulation June 12, 2001

The same findings apply to DES

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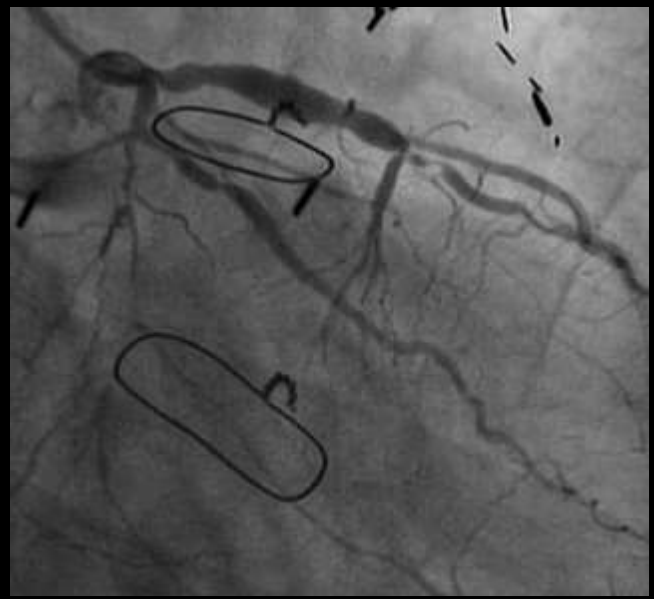
Positive Vessel Remodeling and Appearance of Pulsatile Wall Motion at Long-Term Follow-Up After Bioresorbable Scaffold Implantation in a Chronic Total Occlusion



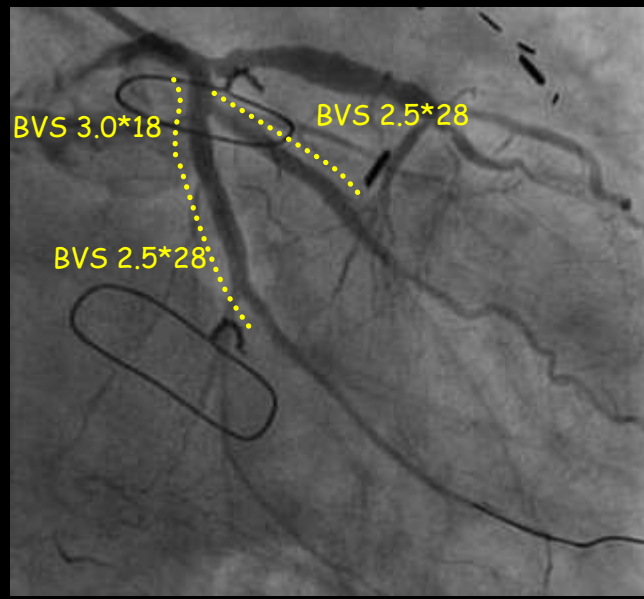
Akihito Tanaka, MD,*† Neil Ruparelia, DPhil,*†‡ Hiroyoshi Kawamoto, MD,*† Azeem Latib, MD,*†
Antonio Colombo, MD*†

Index PCI

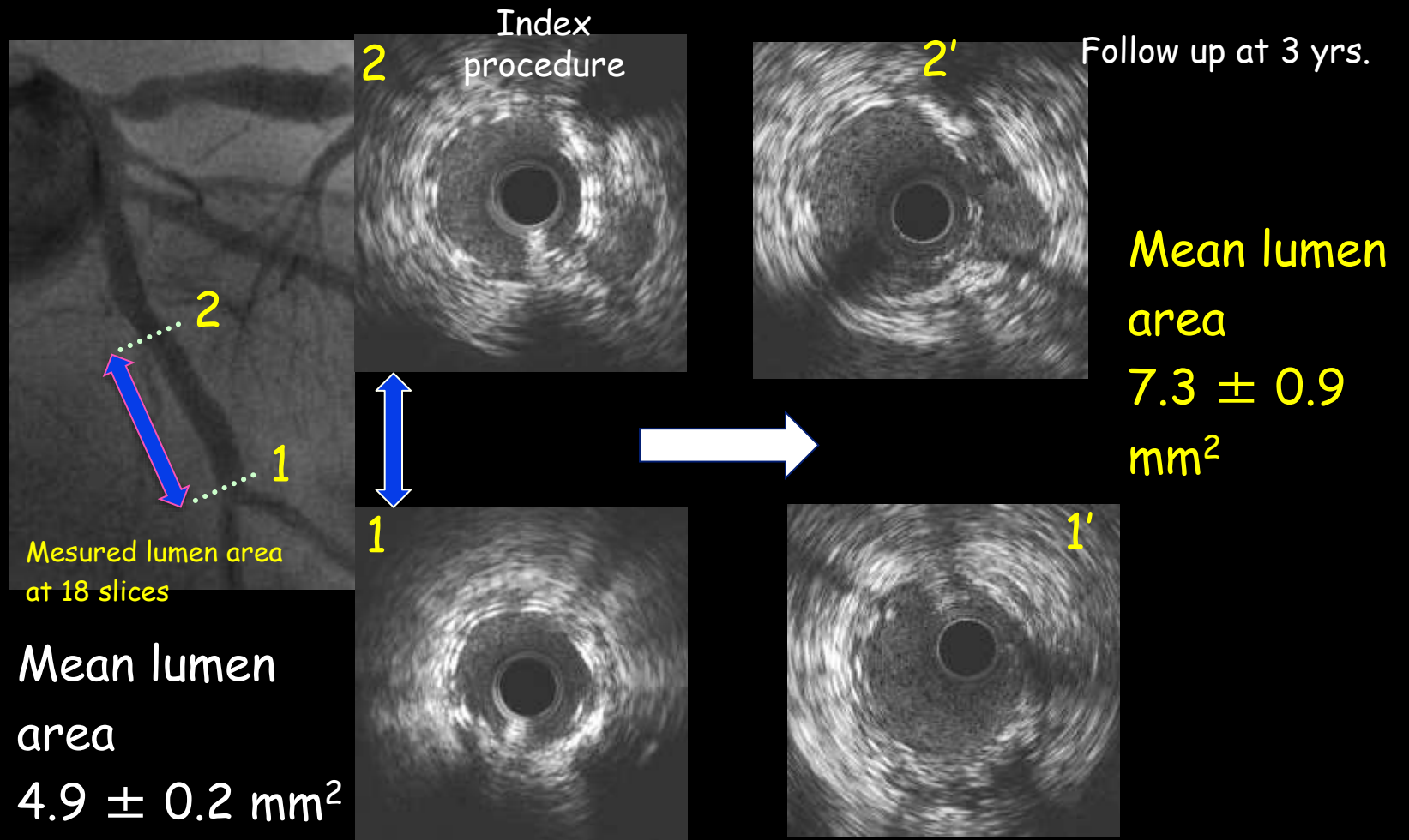
Pre



Post



Lumen enlargement at CTO site



DynamX Coronary Bioadaptor System

DESIGNED TO DELIVER SUPERIOR OUTCOMES



UNCAGING ELEMENT

KEY FEATURES

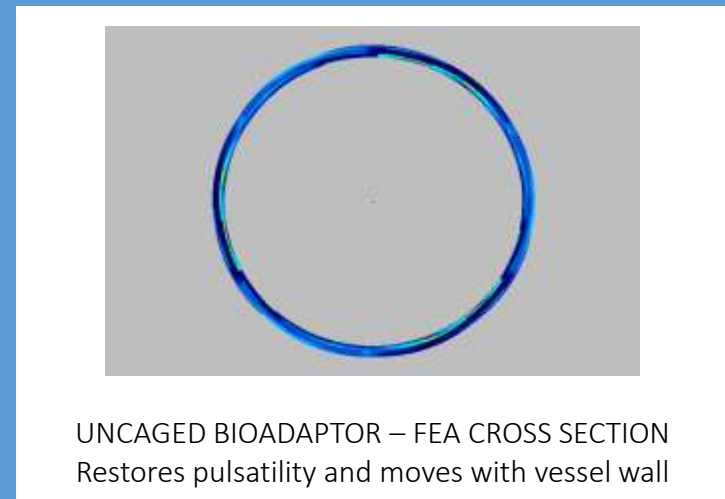
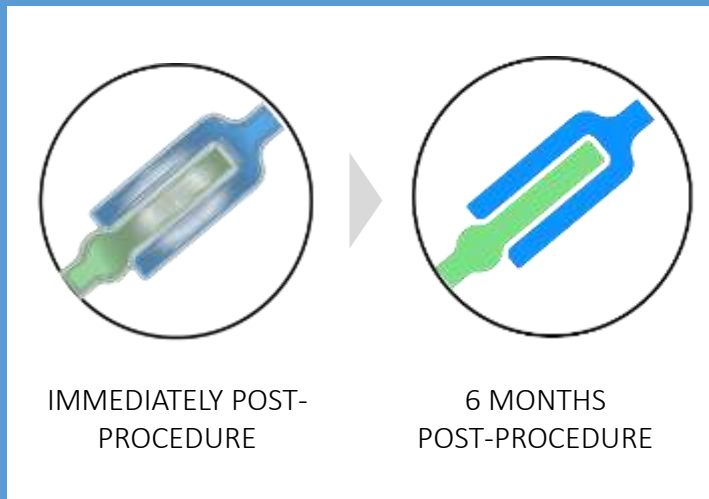
- » Novel uncaging elements
- » Bioresorbable polymer coating
- » Elutes low-dose olimus drug over 3 months
- » Thin cobalt chromium 71 μ m strut¹
- » Excellent deliverability²

1) 2.25mm – 3.0mm are 71 μ m thick, Data on file at Elixir Medical

2) Verheye, et al. Twelve-month clinical and imaging outcomes of the uncaging coronary DynamX Bioadaptor System. EuroIntervention 2020;16:e974-e981

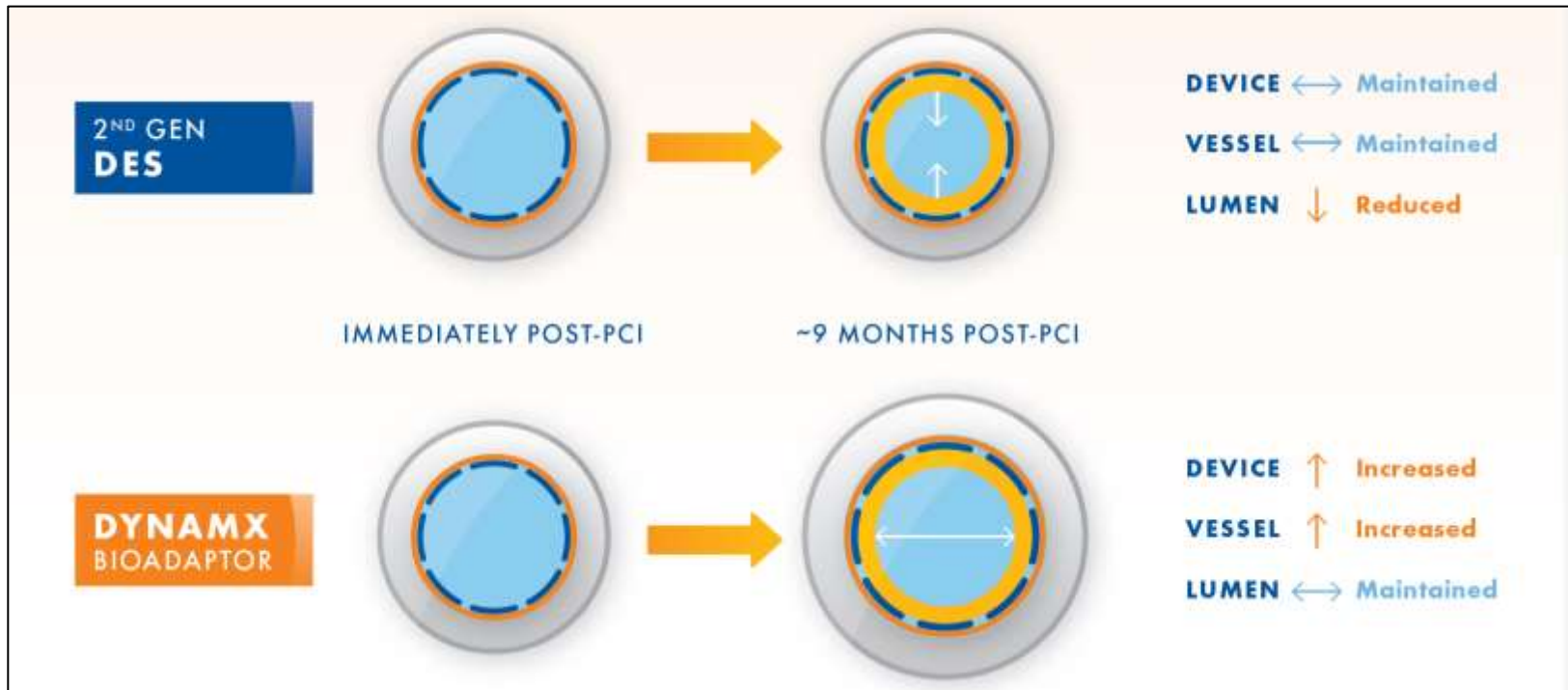
Advancing Implant Design through Novel Uncaging Elements

- » Polymer coating resorbs over 6 months to safely disengage the uncaging elements and allow the bioadaptor to move with the vessel wall



Representative bioadaptor Images generated by Elixir Medial

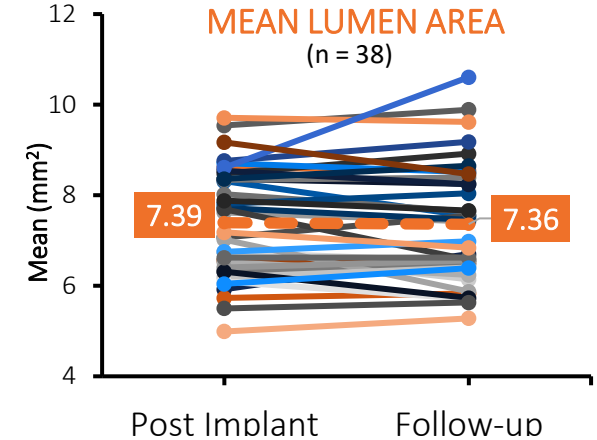
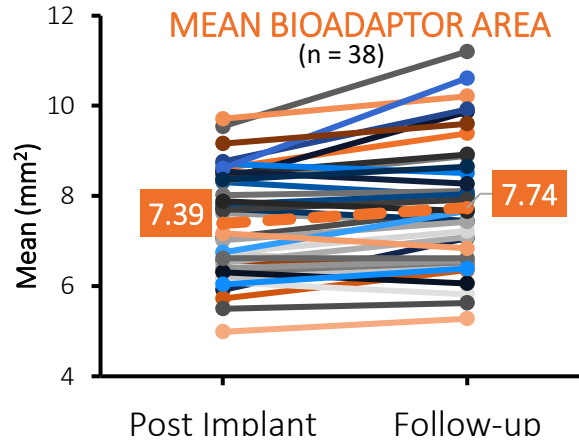
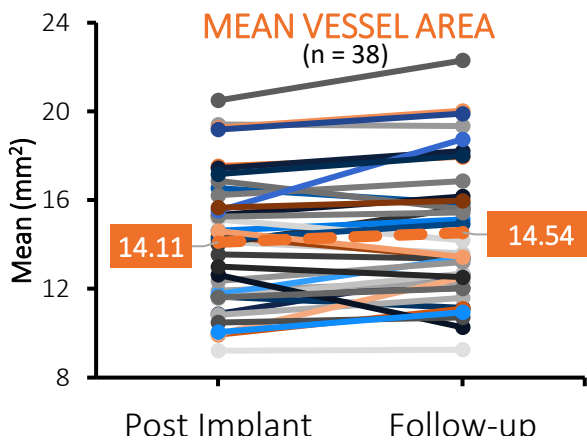
DynamX Bioadaptor Preserves Positive Adaptive (Glagov) Vessel Remodeling



Vessel and device increase in area, allowing the vessel to maintain lumen diameter and preserve good blood flow over time

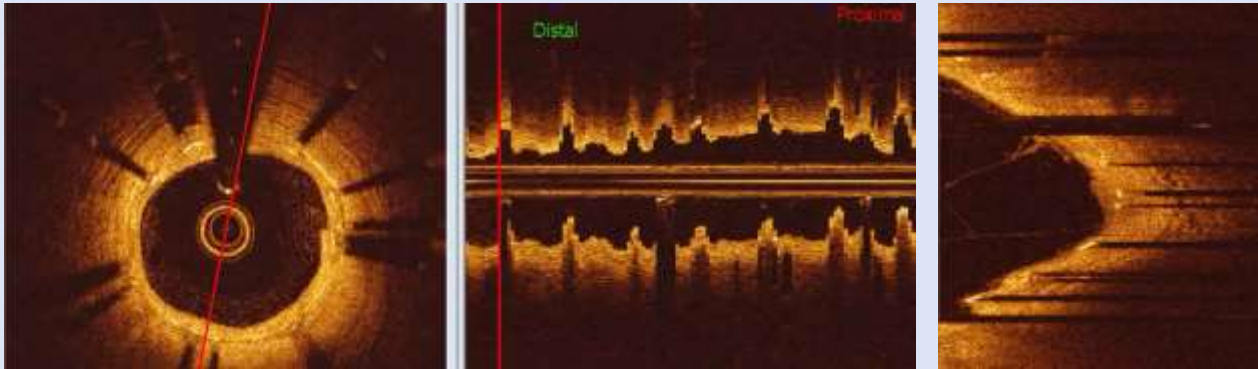
Positive Adaptive Remodeling Accommodates Disease Progression to Maintain Lumen Area (Paired IVUS Analysis)

IVUS Parameter	9 + 12 Months (n=38)			
	Post-Procedure	9 + 12 Month Follow-up	Change from Post-Procedure	p= (p<0.05 = significant)
Mean Vessel Area (mm ²)	14.10 ± 2.99	14.54 ± 3.12	3%	0.0170
Mean Bioadaptor Area (mm ²)	7.39 ± 1.20	7.74 ± 1.46	5%	0.0005
Mean Lumen Area (mm ²)	7.39 ± 1.20	7.36 ± 1.31	0%	0.5940

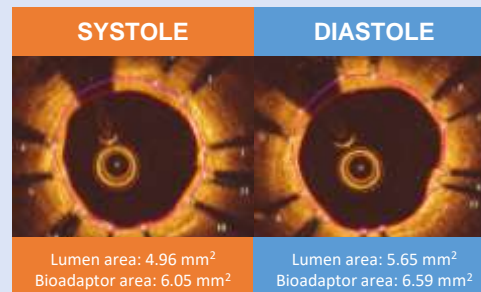
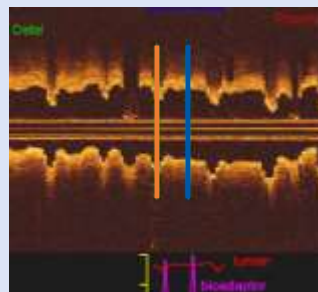


Restores Vessel Function: Allows for Normal Vessel Pulsatility

Allows arteries to expand & contract each heart beat (cyclical strain)



Stationary OCT of case example from DynamX Mechanistic Clinical Study demonstrates how **Bioadaptor** allows for vessel pulsatility

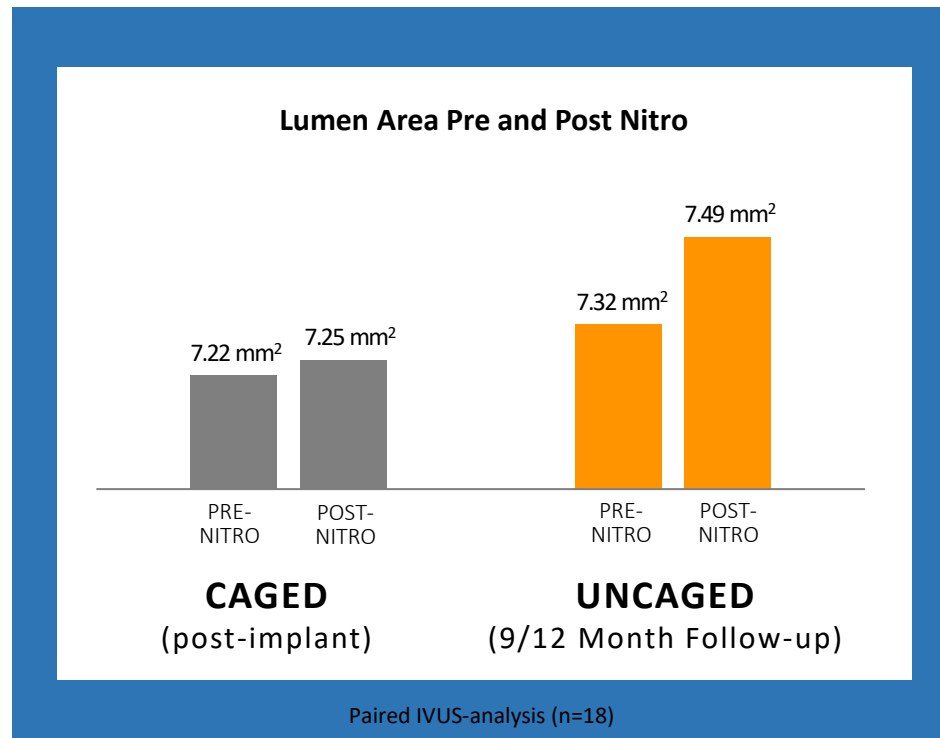


14%
increase in
lumen area

9%
increase in
bioadaptor area

Restores Vessel Function: Allows for Normal Vessel Response to Stimuli

Uncaging allows artery to respond to nitro



Another option to maintain vessel physiology

PCI with DCB, rather than standard stent implantation

Why implanting a DES if after lesion predilatation you have an optimal result even a small dissection, when you can effectively deliver an antiproliferative medication?

SYSTEMATIC REVIEW AND META-ANALYSIS

Clinical and Angiographic Outcomes
With Drug-Coated Balloons for De Novo
Coronary Lesions: A Meta-Analysis of
Randomized Clinical Trials

Islam Y. Elgendy, MD; Mohamed M. Gad, MD; Akram Y. Elgendy, MD; Ahmad Mahmoud, MD;
Ahmed N. Mahmoud, MD; Javier Cuesta, MD; Fernando Rivero, MD; Fernando Alfonso, MD, PhD

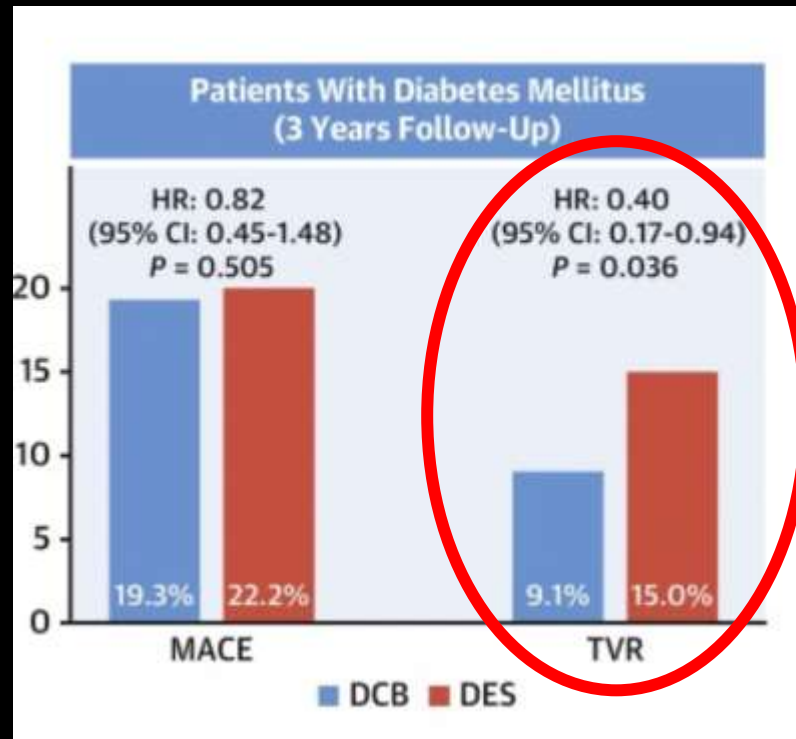
Reference vessel size <3mm

In this meta-analysis of 14 randomized trials including 2483 patients with de novo coronary lesions undergoing PCI irrespective of indication, we documented that DCBs were associated with similar MLD, diameter stenosis, binary restenosis, and lower late lumen loss compared with control on routine angiographic follow up at a mean of 7 months

Drug-coated balloons for small coronary artery disease (BASKET-SMALL 2): an open-label randomised non-inferiority trial

Raban V Jeger, MD et al.

LANCET 2018



3 years results in 242 diabetics

Wohrle, J et al. JACC Intv. 2021

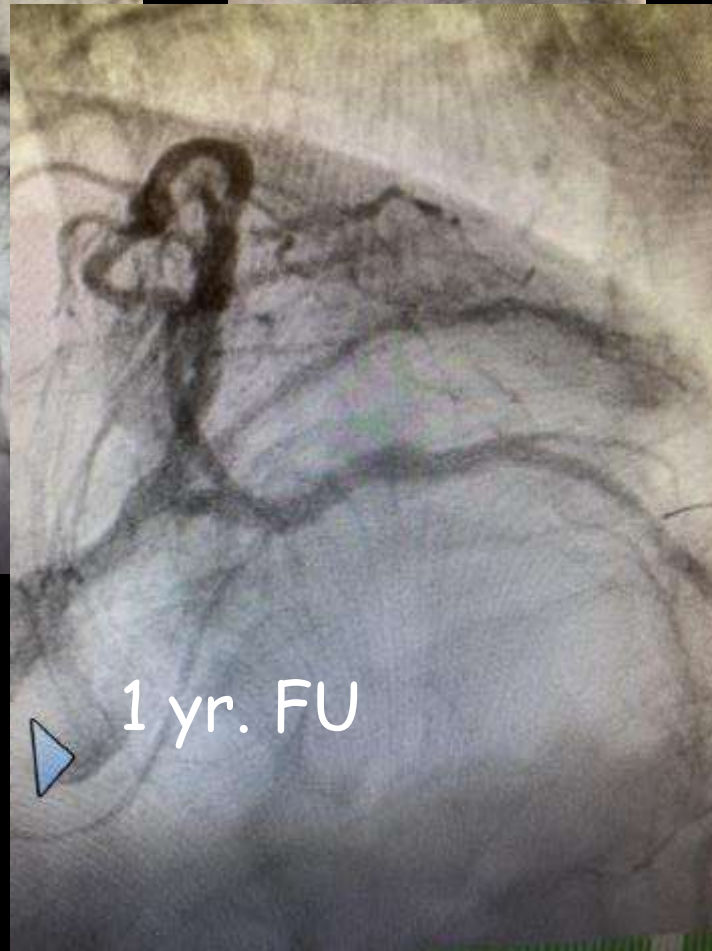
I see the need for a dedicated DCB study in diabetics even large vessels

Why most operators stent every lesion to be treated?

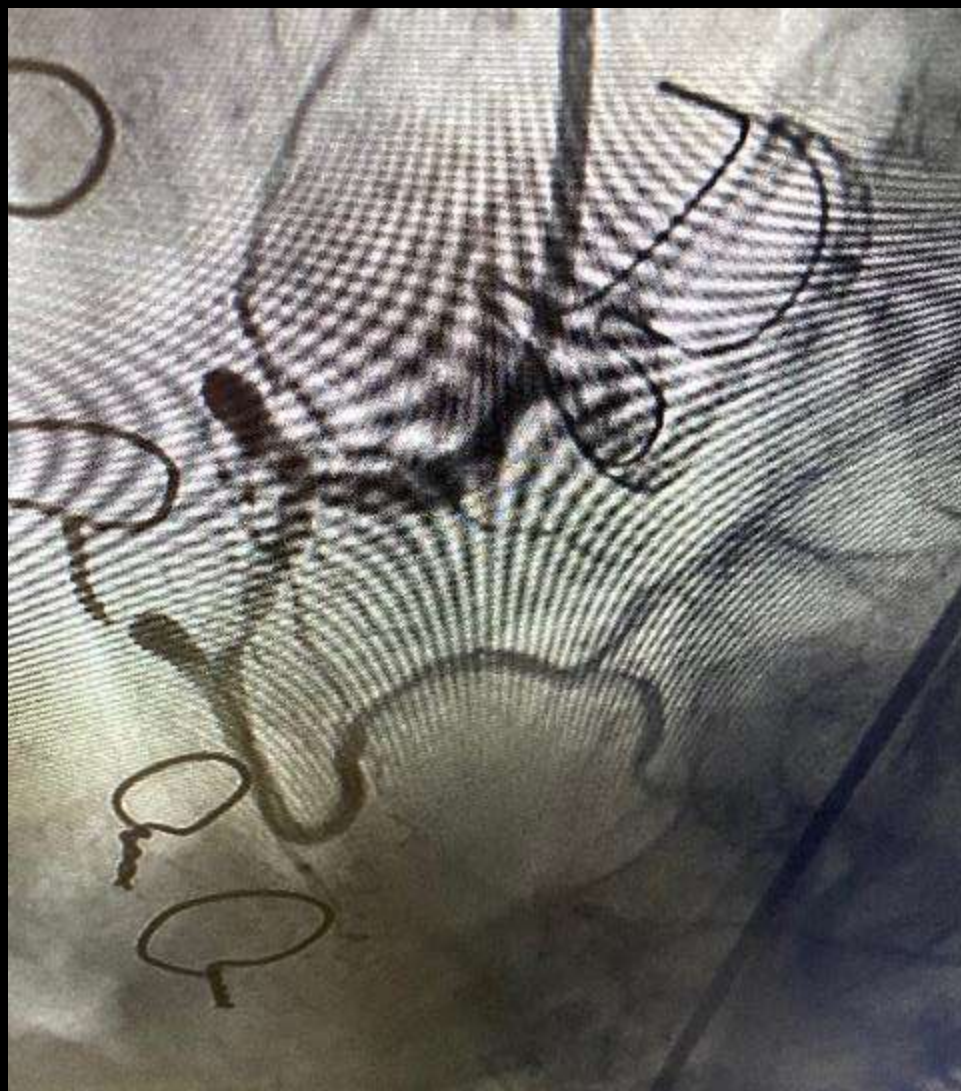
Among many reasons, the most important is to prevent sudden closure when the result is not "stent like"

I would like to reintroduce the concept of measuring Pd/Pa after predilatation to give security about the risk of sudden closure

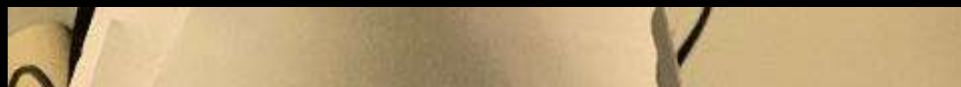
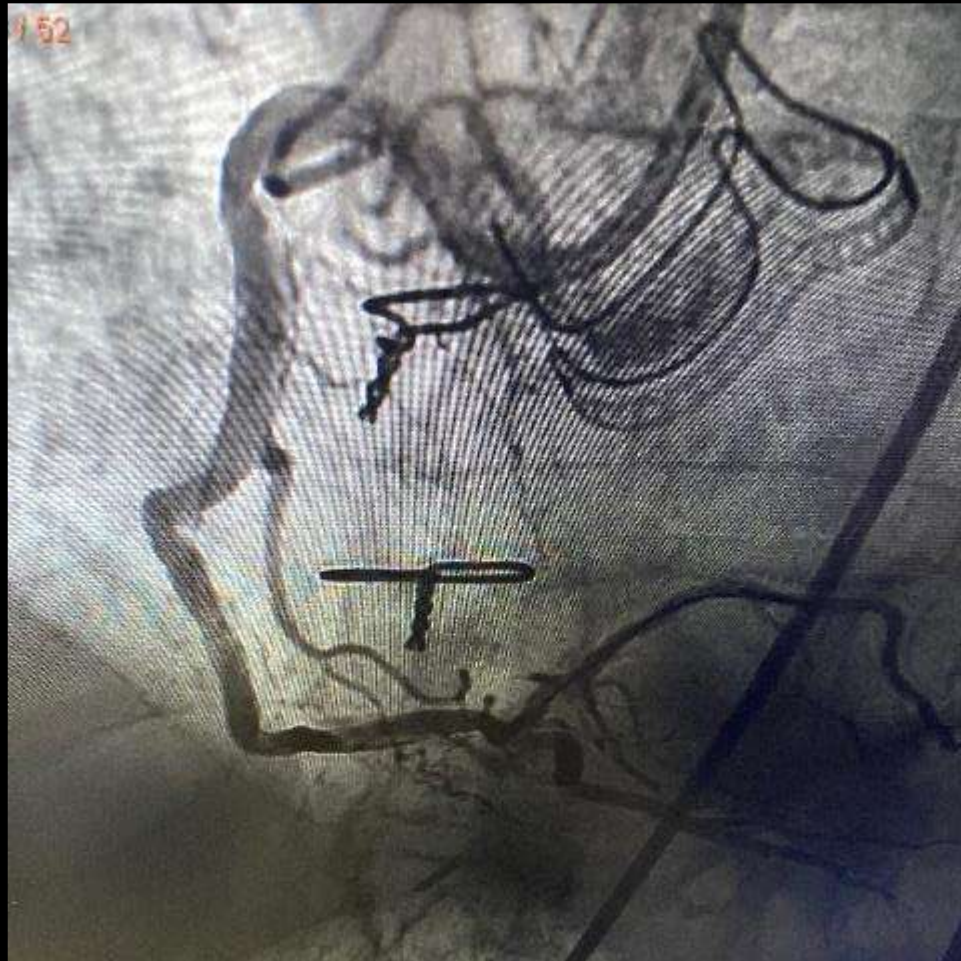
Pd/Pa interrogates the lesion treated with limited impact for the distal bed



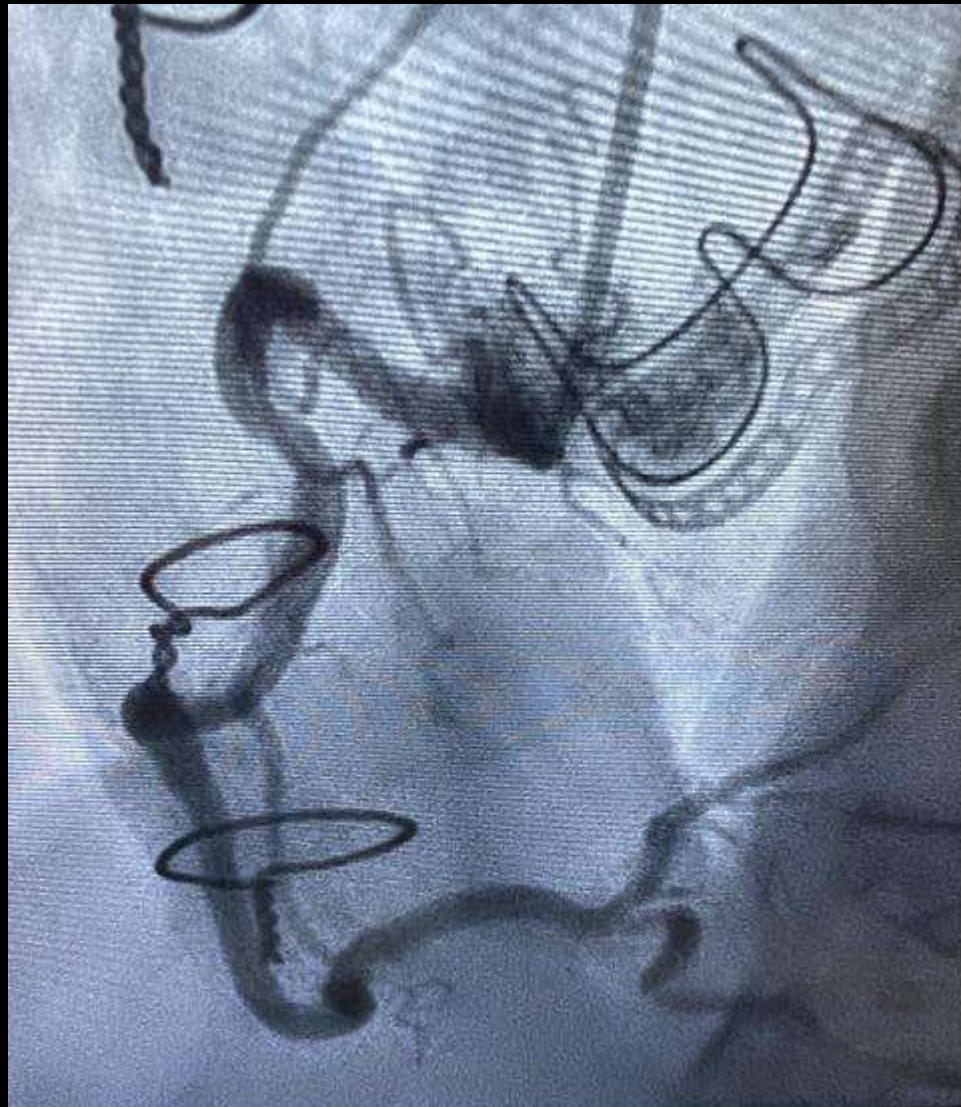
Baseline



Immediat
e result



1 month
follow-up



Baseline



Final post DCB



1 year FU



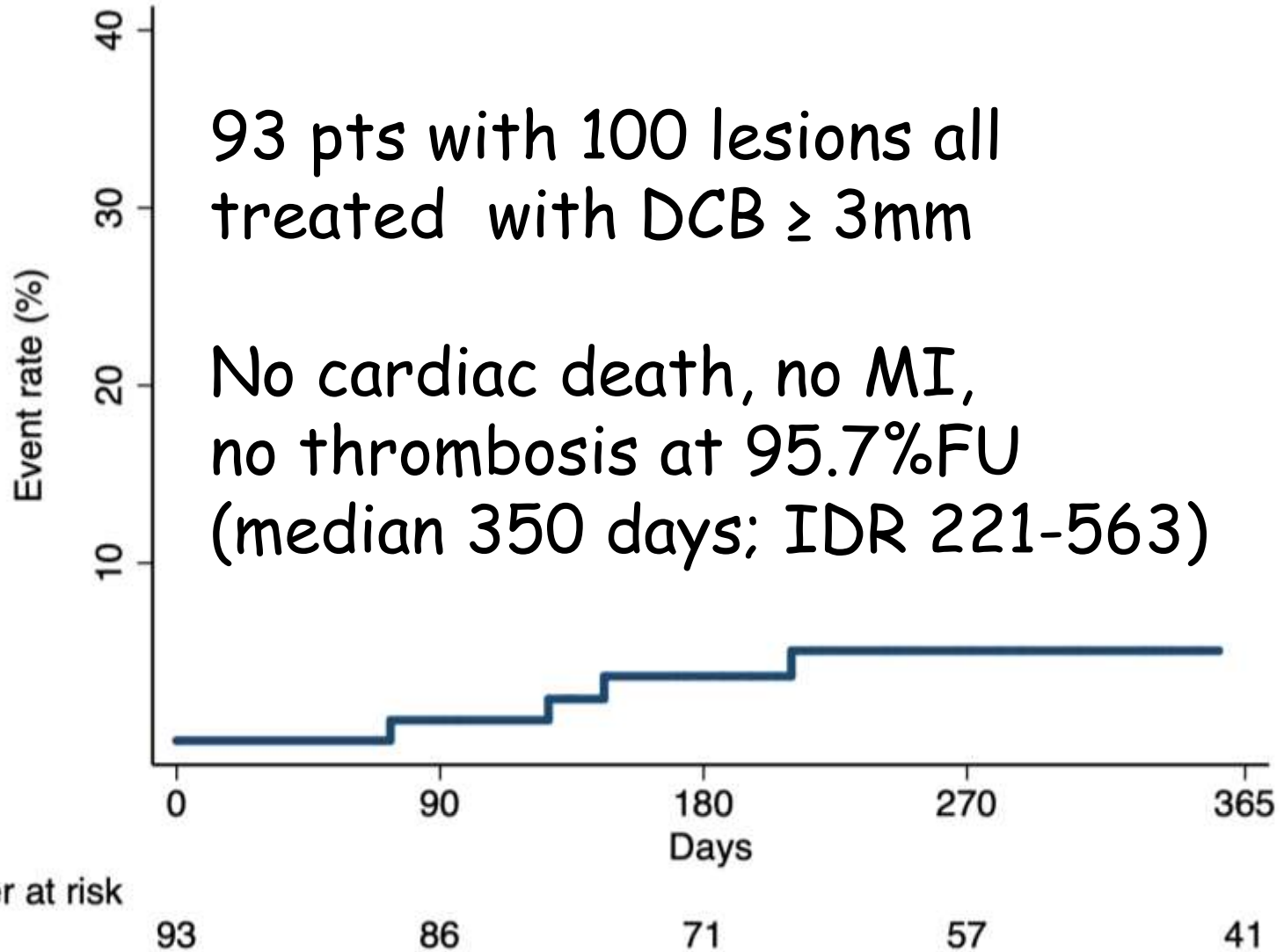
1 year FU



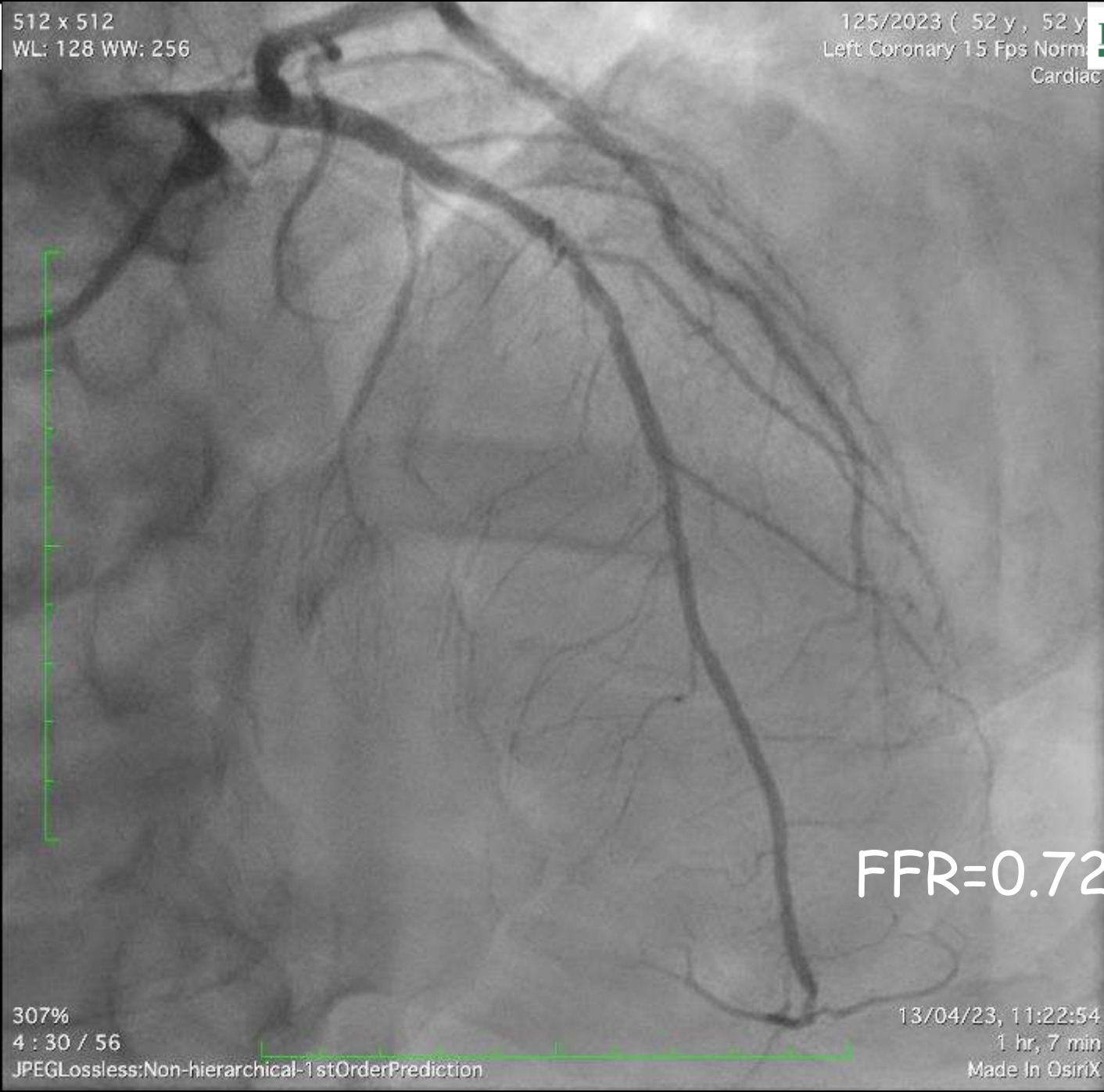
TLR/TLF

93 pts with 100 lesions all treated with DCB ≥ 3 mm

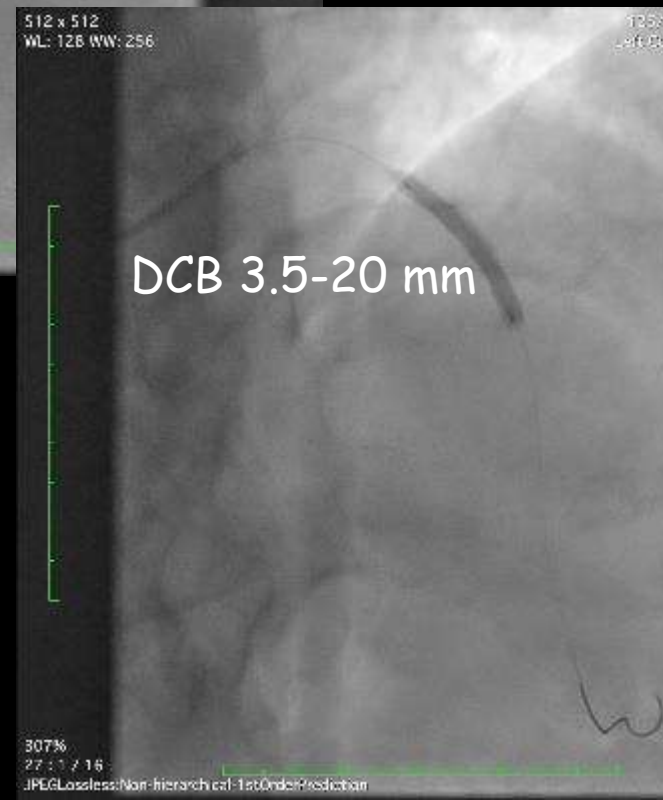
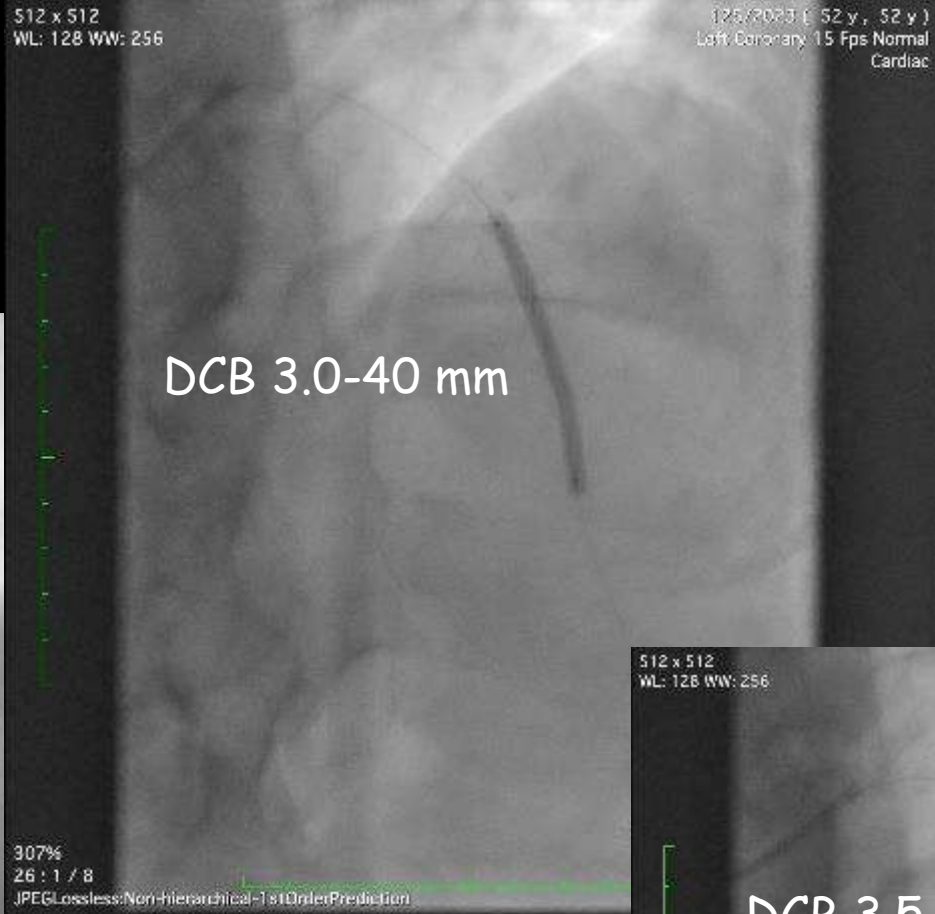
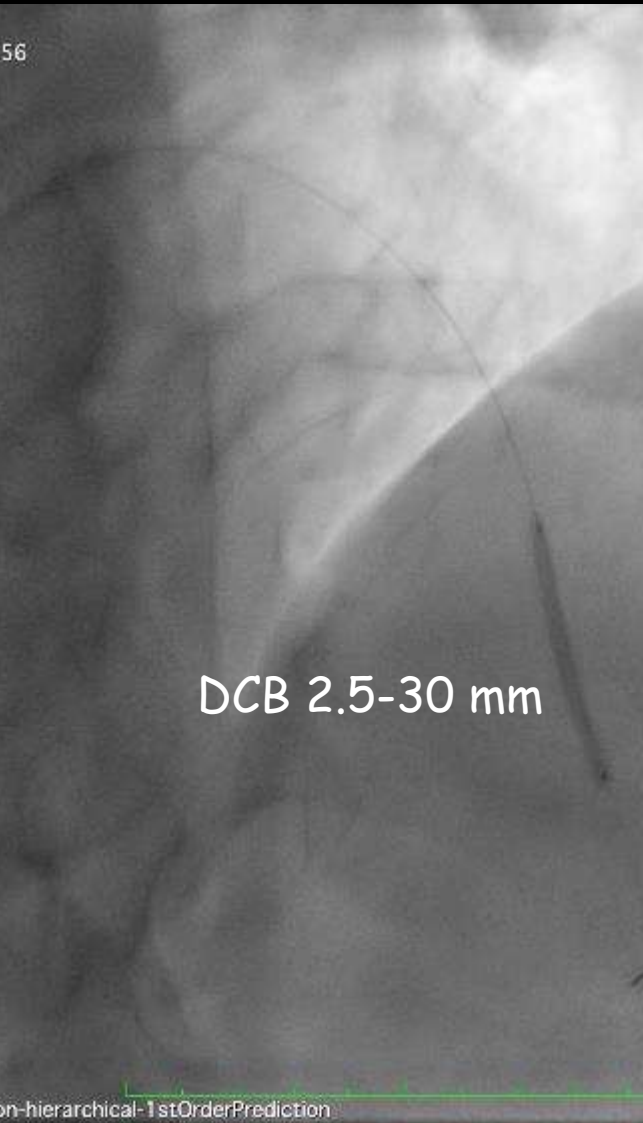
No cardiac death, no MI, no thrombosis at 95.7%FU (median 350 days; IDR 221-563)



Long lesions involving the Left Anterior Descending Artery



FFR=0.72



125/2023 (52 y , 52 y)
Left Coronary 15 Fps Normal
Cardiac

125/2023 (52 y , 52 y)
Left Coronary 15 Fps Normal
Cardiac

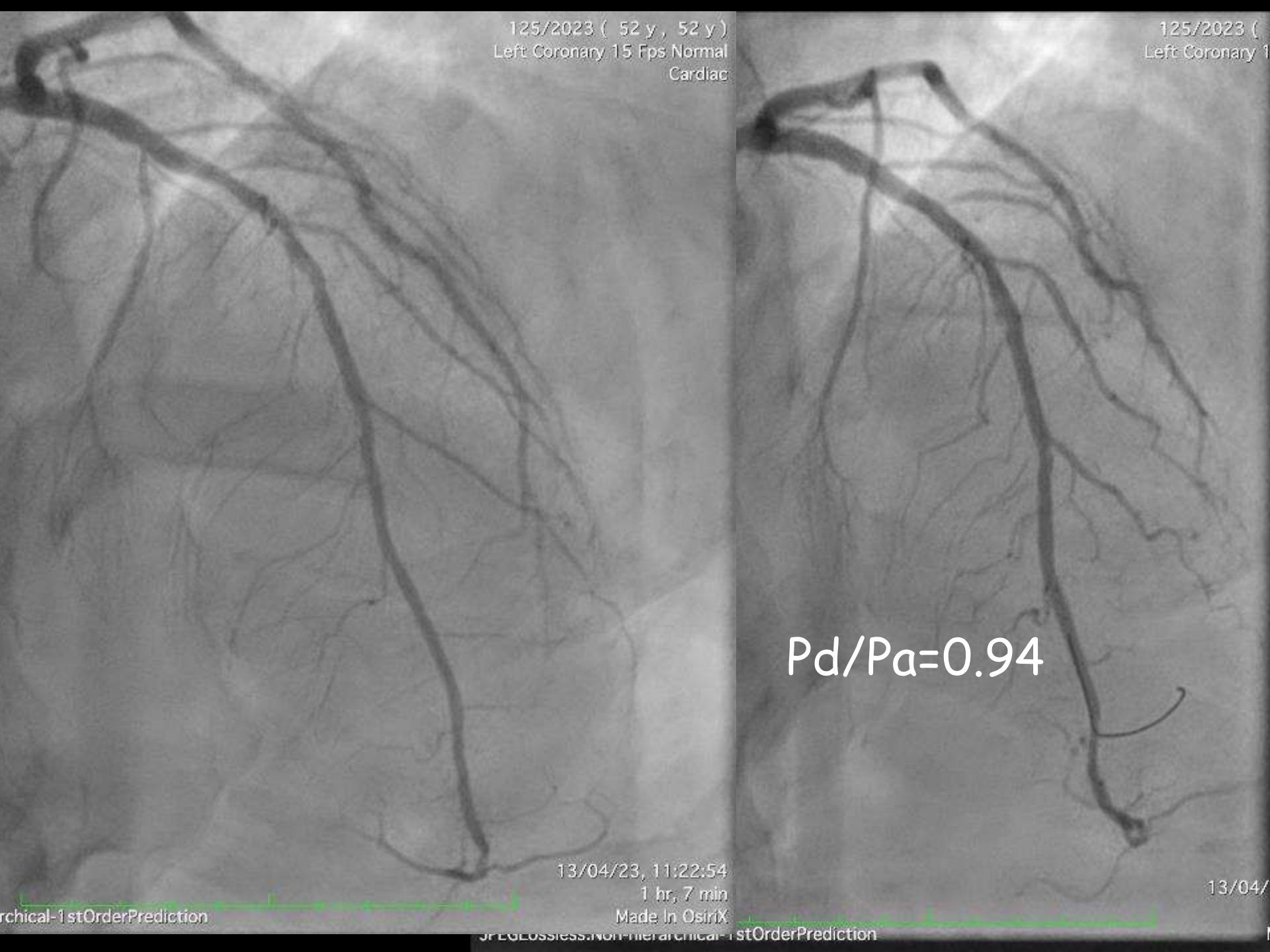
$Pd/Pa=0.94$

13/04/23, 11:22:54
1 hr, 7 min
Made In OsirX

13/04/23, 11:22:54

hierarchical-1stOrderPrediction

hierarchical-1stOrderPrediction



Baseline



6 Months FU



LONG DE NOVO LAD DISEASE

DCB-based PCI (N=147)

- Hybrid PCI in **70.8%** of pts
- DCB length > DES length in **61.9%** of patients



DES-only PCI (N=701)

- Short (<23 mm) DES excluded

1:1 PSM to account for imbalance in baseline clinical and angiographic covariates → 144 matched pairs

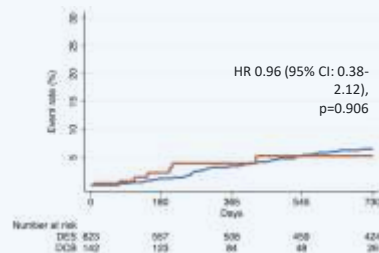
More diffuse treatment with **lower DES length** in the DCB group

	DCB	DES	P value
Treated length (mm)	65 (40-82)	53 (45-62)	<0.001
Treated length ≥60 mm (%)	60.4	34	<0.001
DES length (mm)	38 (24-62)	53 (45-62)	<0.001
Large vessel (≥3 mm) (%)	76.4	81.3	0.31

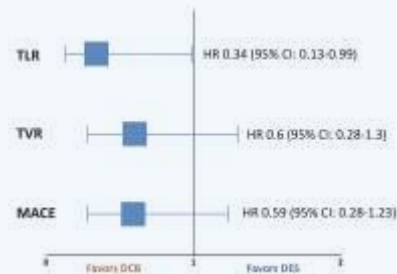
More **dissections** with DCB (non flow-limiting in 69.8%)
Higher risk of **SB closure** with DES

2-YEAR FOLLOW-UP

Similar TLR rate in the overall cohort



Lower risk of TLR with DCB after PSM



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Treatment of Coronary De Novo Lesions by a Sirolimus- or Paclitaxel-Coated Balloon



Wan Azman Wan Ahmad, MBBS,^a Amin Ariff Nuruddin, MB BCh,^b Muhamad Ali S.K. Abdul Kader, MD,^c Tiong Kiam Ong, MBBS,^d Hong Bang Liew, MB BCh,^e Rosli Mohd Ali, MD,^f Ahmad Syadi Mahmood Zuhdi, MB BCh,^g Muhammad Dzafir Ismail, MBBS,^a Ahmad K.M. Yusof, MD,^h Carsten Schwenke, PhD,^g Maren Kutschera, PhD,^h Bruno Scheller, MDⁱ

CONCLUSIONS

This first-in-human comparison of a novel Sirolimus CB with a crystalline coating showed similar angiographic outcomes in the treatment of coronary de novo disease compared with a clinically proven Paclitaxel CB.

However, late luminal enlargement was more frequently observed after Paclitaxel 60% vs, 32%) CB treatment.

JACC Card Interv;15:770–779, 2022

Open questions

Dedicated prospective studies are underway to give us specific information

DCB eluting paclitaxel or sirolimus?

Among them there are possible differences in effectiveness even with the same antiproliferative drug on the balloon