“Real-World” Experiences of Xience V

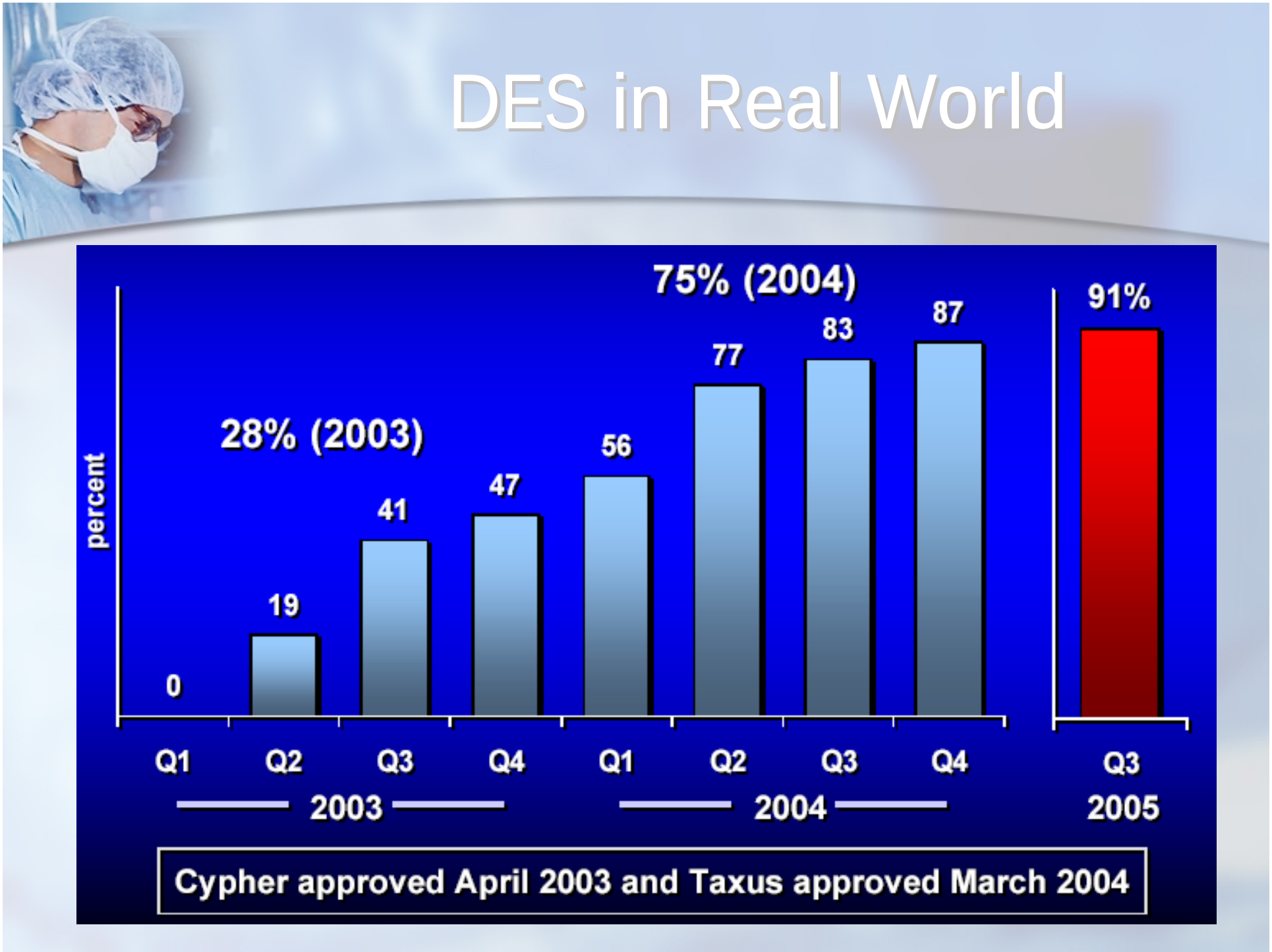
Dr. Duncan Ho

MBBS(HK),FRCP,FAHA,FSCAI

Queen Elizabeth Hospital
HONG KONG

何鴻光醫生

香港伊利莎伯醫院


DES in Real World
75% (2004)
91%
87
83
77
28% (2003)
56
47
41
19
0
percent
Q1
Q2
Q3
Q4
Q1
Q2
Q3
Q4
Q3
2003
2004
2005
Cypher approved April 2003 and Taxus approved March 2004

DES Available

CYPHER™
Cordis, Johnson & Johnson

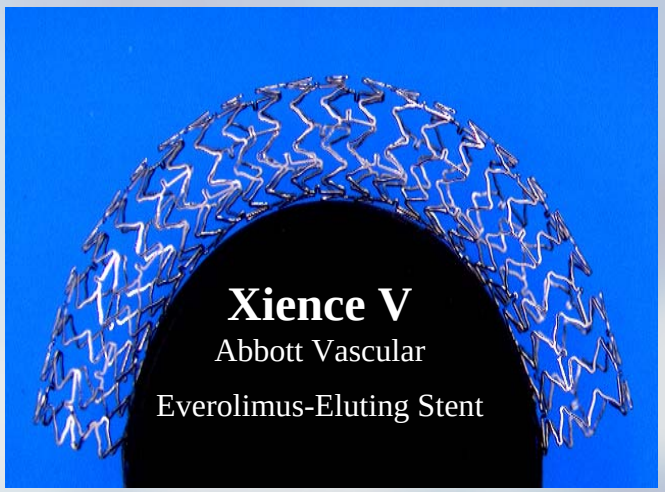
Sirolimus-Eluting Stent

TAXUS™
Boston Scientific

Paclitaxel-Eluting Stent

ENDEAVOR™
Medtronic

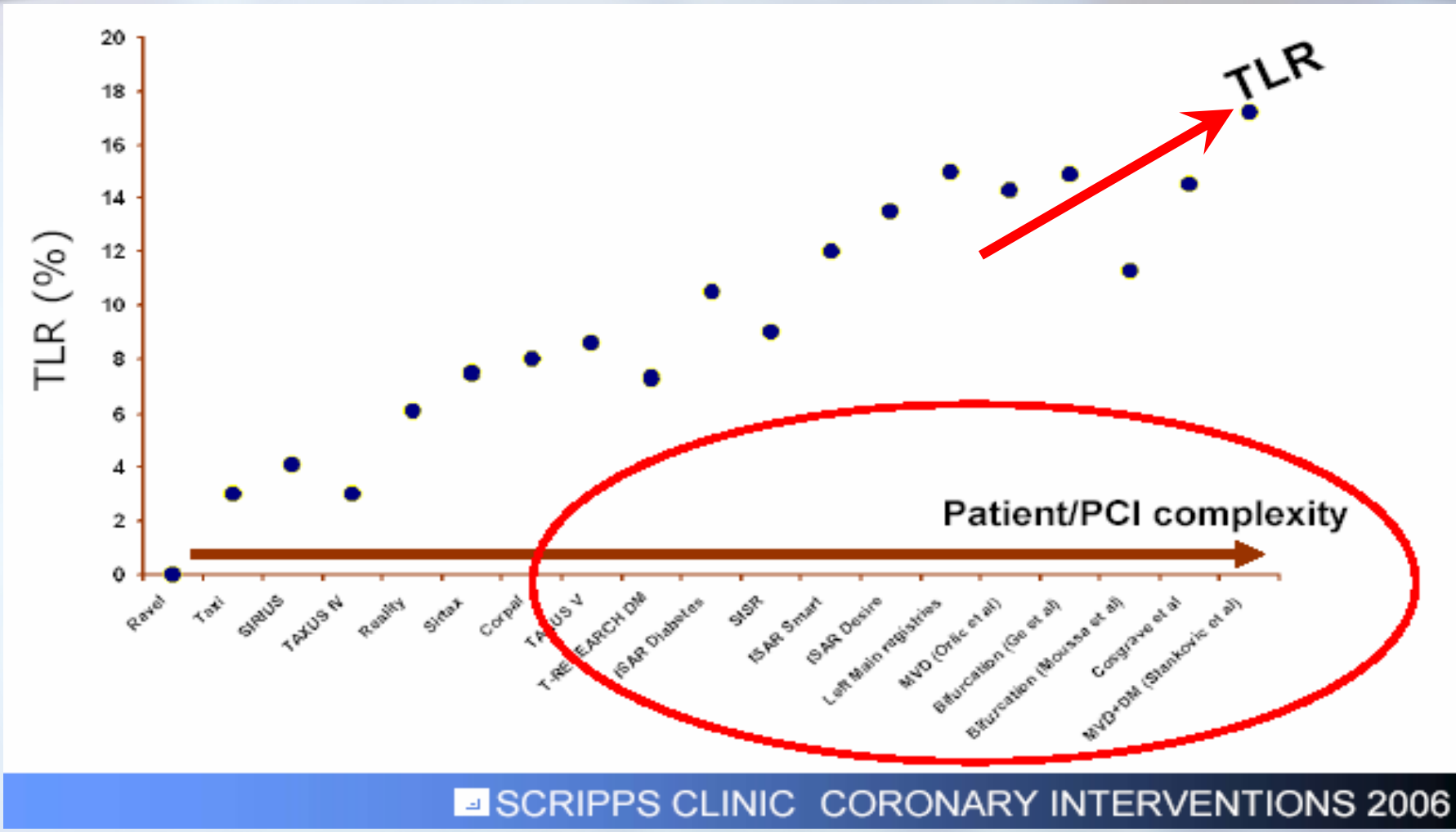
Zotarolimus-Eluting Stent



DES in Real Life for Complex Lesion

- Chronic Total Occlusion
- Multi-Vessel Disease
- Primary PCI for AMI
- Bifurcations
- Diabetics
- Long Lesion

Patient Complexity & TLR



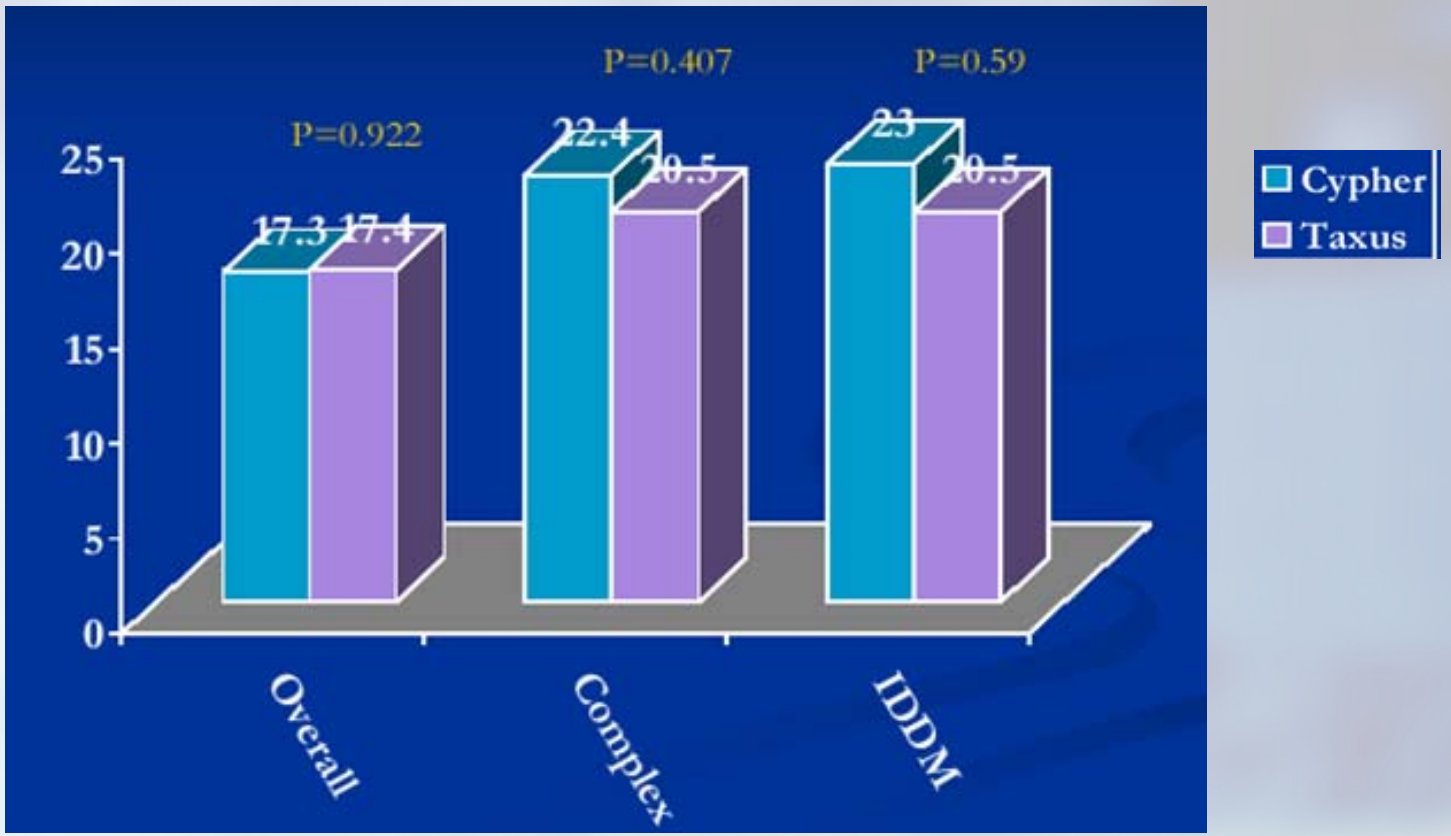
Complex Lesion in SES vs PES REWARDS Study

1) Complex Patients and Lesions defined as at least one of the following:

Osital lesion	Type C lesion	AMI
ISR	CTO	IDDM
Non-native artery lesion	2+ DESs	On Chronic Dialysis
Long lesion (>33mm)		Prior CABG

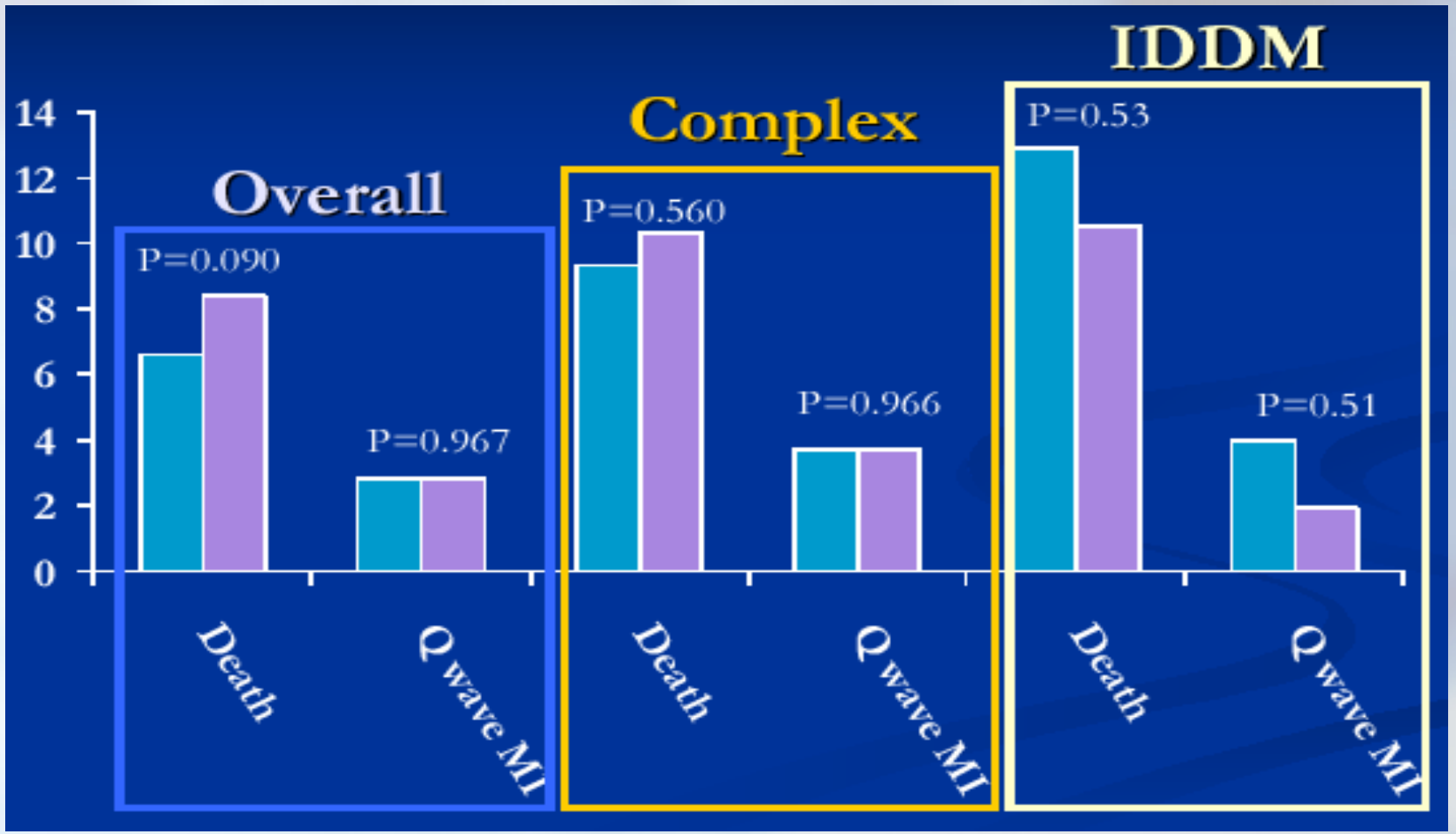
2) Insulin Dependent Diabetes Mellitus

REWARDS 12 Month MACE



Include TVR

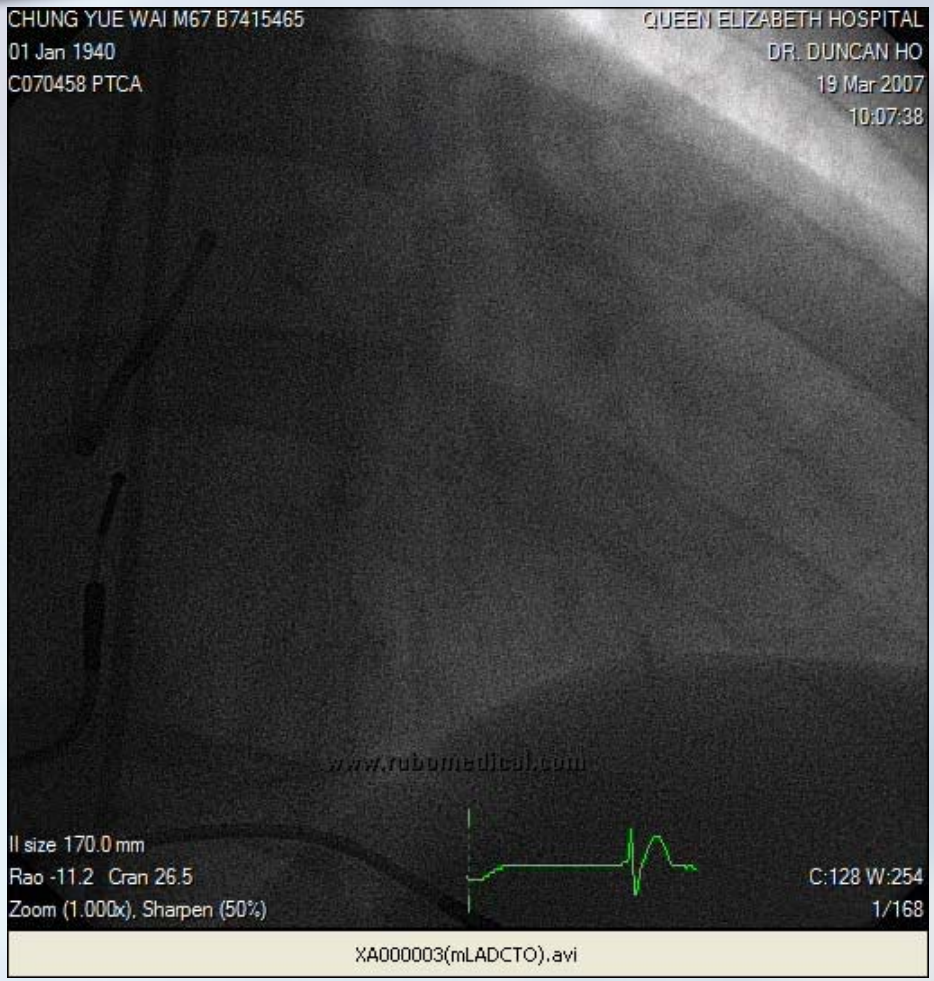
REWARDS 12 Month Clinical Outcome



CTO case

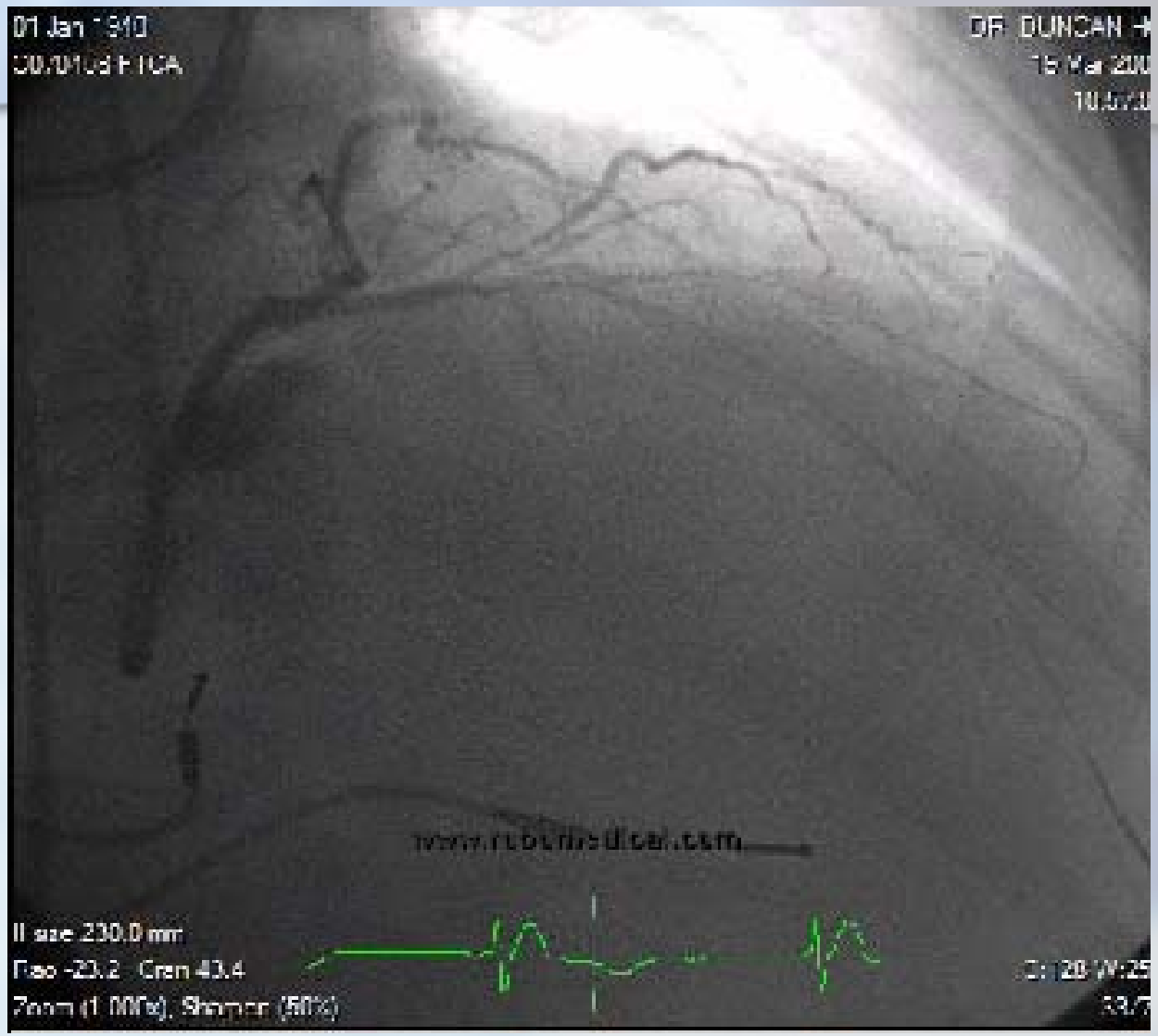
- M/67
- Patient History: ex-smoker, HT, impaired fasting glucose
- NSTEMI in 1/07
- Ejection Fraction: <35%

Coro



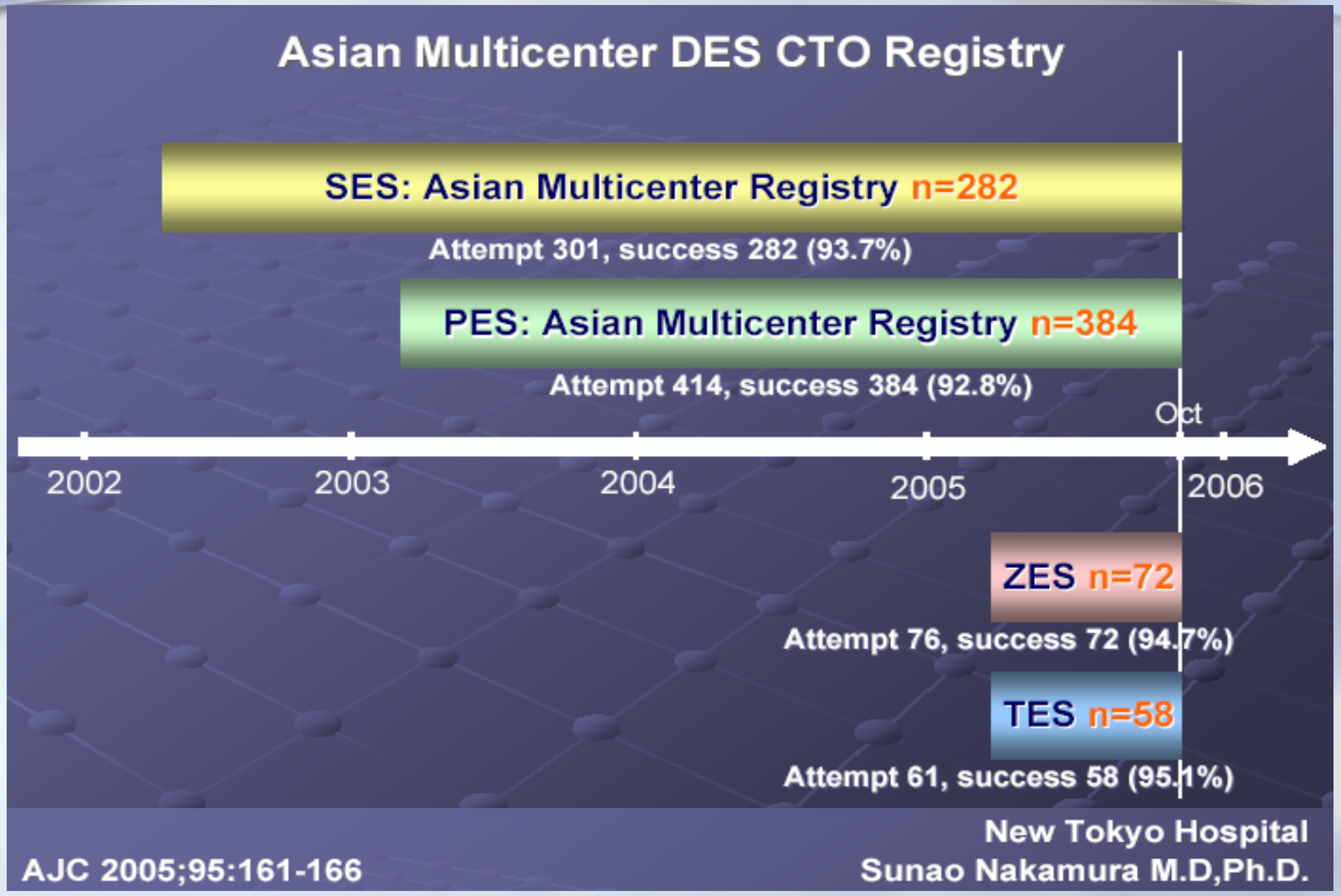
D1 70%, mLAD CTO with very faint antegrade flow

CTO



PIC: GW to LAD & D2

Asian Multi-centers CTO Registry



12 Months Angiographic FU

	SES 12 mo (n=282)	PES 12 mo (n=384)	ZES 12 mo (n=72)	TES 12 mo (n=58)
Clinical f/u (n)	282 / 282	384 / 384	72 / 72	58 / 58
Angiographic f/u (n)	213 / 282	291 / 384	66 / 72	49 / 58
Ref. diameter (mm:mean)	2.9	2.8	2.7	2.8
MLD (mm:mean)	2.6	2.5	2.0	2.2
Late loss (mm:mean)	0.1	0.2	0.5*	0.4*
Loss index (%:mean)	3.7	7.4	20.4*	17.7*
Restenosis rate (%)	4.2	6.9	12.5*	12.1*
Re-occulusion rate (%)	0	0.5	2.8	1.7
TVR (%)	5.2	7.9	12.5*	12.1*
TLR (%)	4.2	6.9	11.1*	10.3*

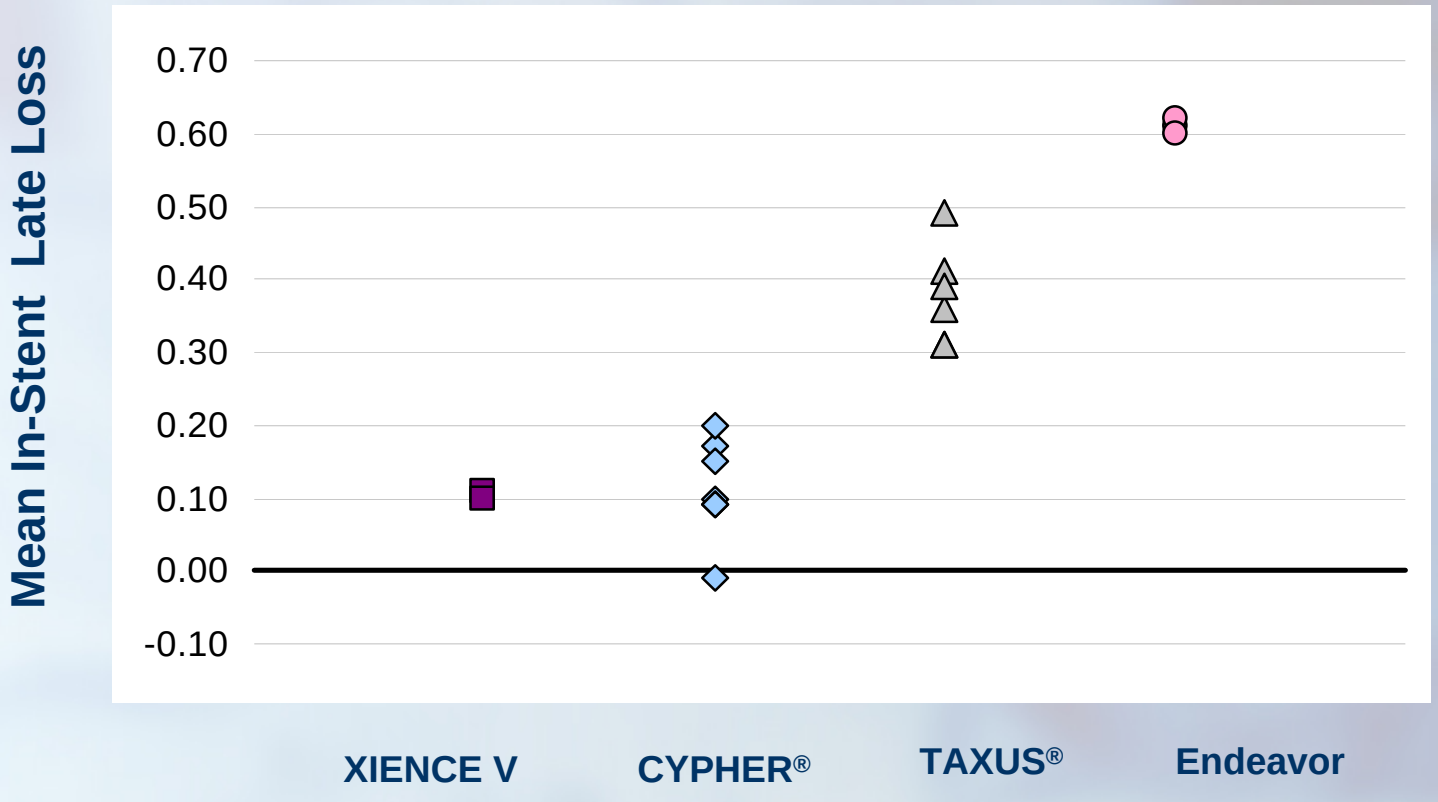
12 Months Clinical FU

	SES 12 mo (n=282)	PES 12 mo (n=384)	ZES 12 mo (n=72)	TES 12 mo (n=58)
MACE (%)				
Death	0	0	0	0
MI	0.7	0.8	1.4	1.7
CABG	0	0	0	0
Re-PCI	5.6	8.6	12.5*	12.1*
Any events (%)	6.0	9.1	13.9*	13.8*

LST 0.5%

*p<0.05 vs SES.

Late loss as shown by IVUS: to determine DES effectiveness



Source: In-Stent LL Endpoints for SPIRIT FIRST 6M, SPIRIT II, FIM, RAVEL, SIRIUS, C-SIRIUS, E-SIRIUS, TAXUS I, TAXUS II SR, TAXUS IV, TAXUS V, ATLAS, REALITY, ENDEAVOR I, ENDEAVOR II, ENDEAVOR III.

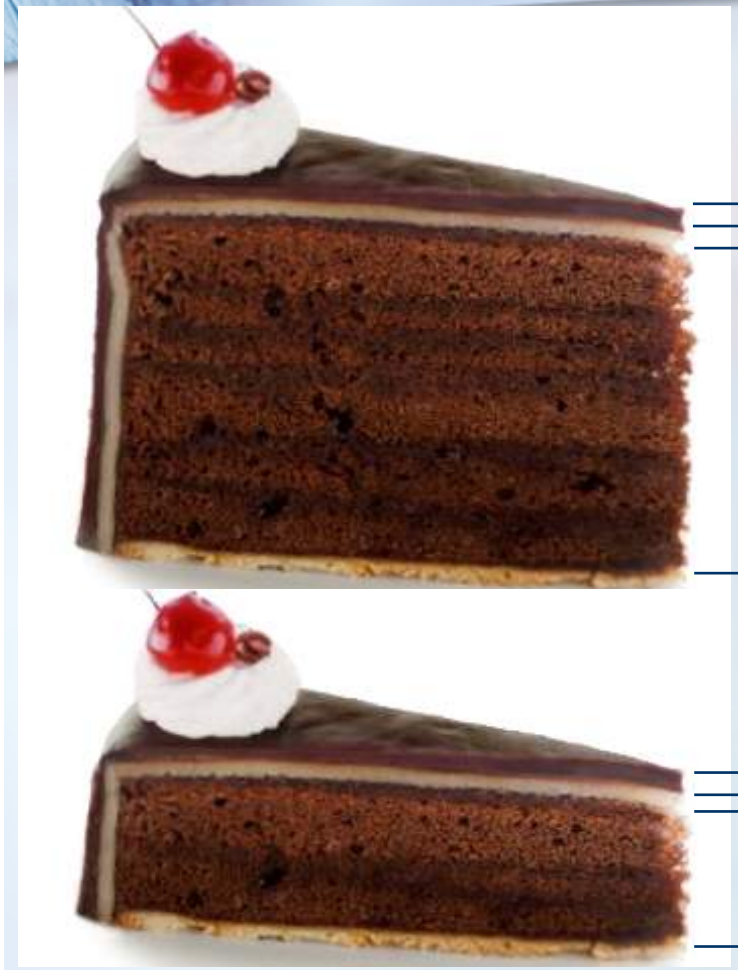
Note: Results from different clinical trials are not directly comparable. Information provided for educational purposes only.

Consistent Power in Late Loss

	6-month follow-up		8-month follow-up
	SPIRIT First 30/30	SPIRIT II 225/75	Spirit III 669/333
Late Loss in stent (mm)	**.10**	**.11 / 0.37***	.16 **/ .31***
Late Loss in segment (mm)	**.09**	**.07/0.15**	.14/.28*
Binary Restenosis in stent	**0%**	**1.3%/3.5%**	2.3% /5.7%
Binary Restenosis in segment	**<5%**	**3.4%/5.8%**	4.7%/8.9%
MACE	**7.7%**	**2.7%/ 6.5%** 2.7%/ 9.2%* **12-month FU**	4.6%/8.1%* **9-month follow-up**
Comparator	**Xience V vs Vision**	**Xience V vs Taxus**	Xience V vs Taxus

*Statistically Significant Difference p<0.05

Healing is characterized by re-endotheliazation



Re-endothelialization: Single layer of cells necessary for smooth,non-thrombogenic surface. Not seen angiographically.

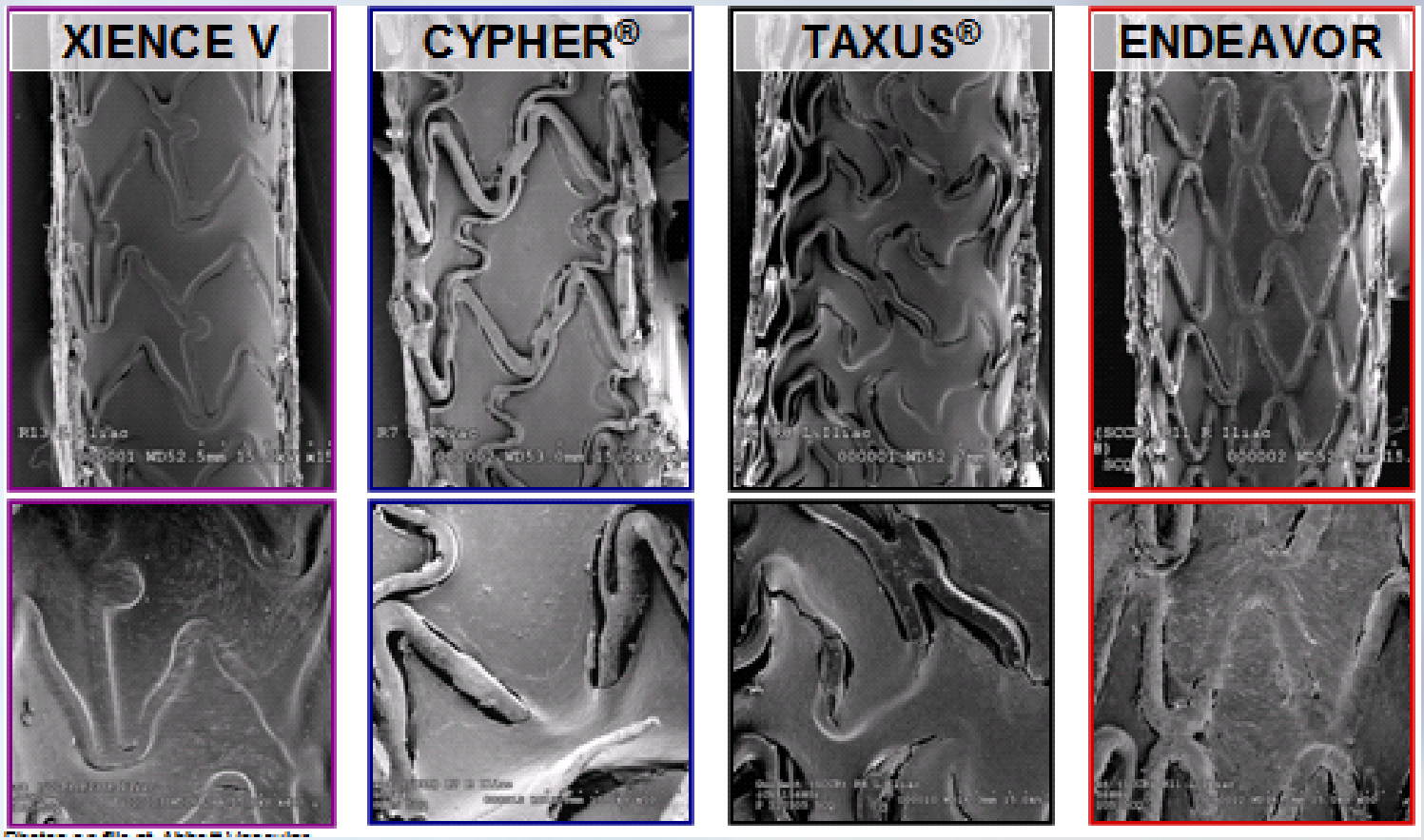
Late Loss

Re-endothelialization is Delayed with DES

Late Loss is Reduced with DES

[1]Finn et al JACC 2005;112:270-278

Rapid Re-endothelialization
14-Day Rabbit Iliac Study

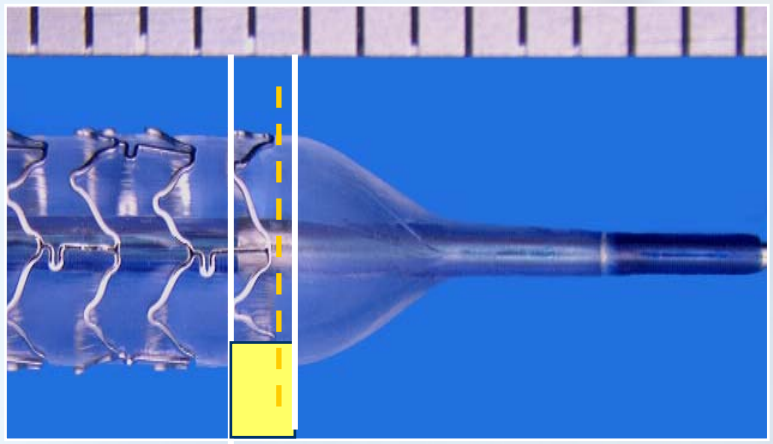


Courtesy of Dr. R Virmani

Accurate Placement & Marker

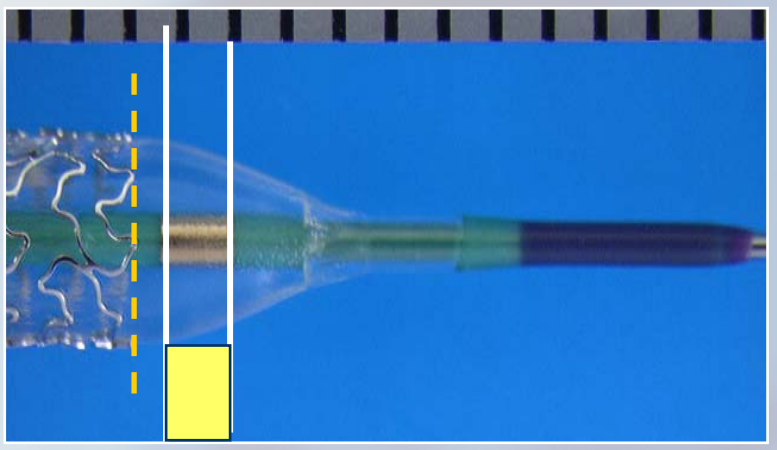
Marker position is critical to accurate placement

ML VISION® 3.0 x 18 mm



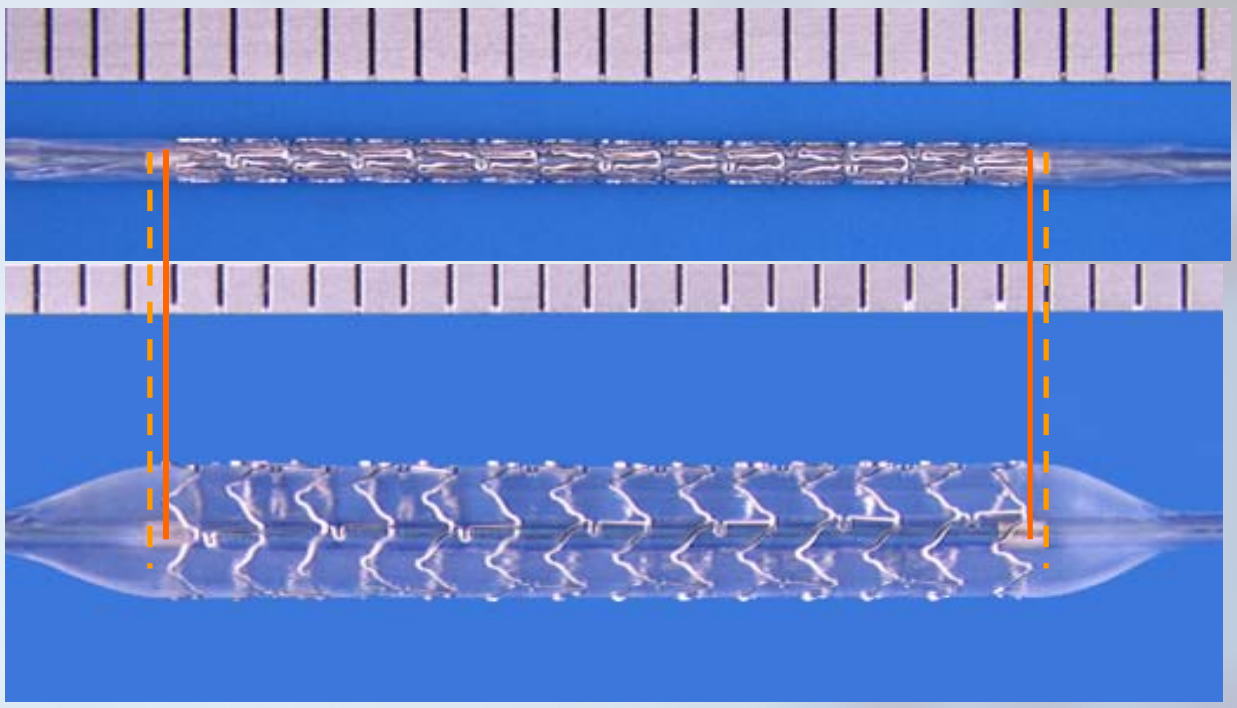
Marker Length: **1.0 mm**

Liberte™ 3.0 x 20 mm



1.30 mm

Accurate Placement

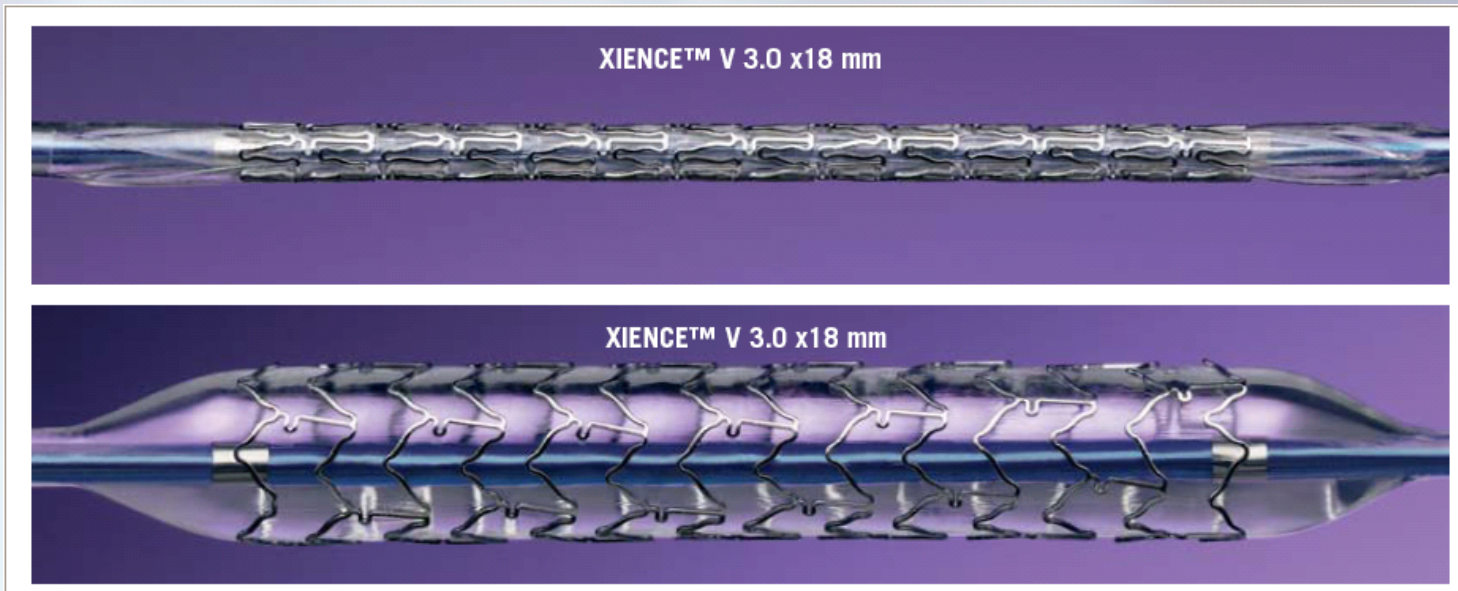


Virtually no shortening* for better placement accuracy

Thinnest Strut

	Stent Material	Strut Thickness
ML VISION®	Cobalt Chromium	.0032"
Driver™	Cobalt Nickel	.0036"
Liberté™	Stainless Steel	.0038"
Express 2™	Stainless Steel	.0052"
BX Velocity®	Stainless Steel	.0055"

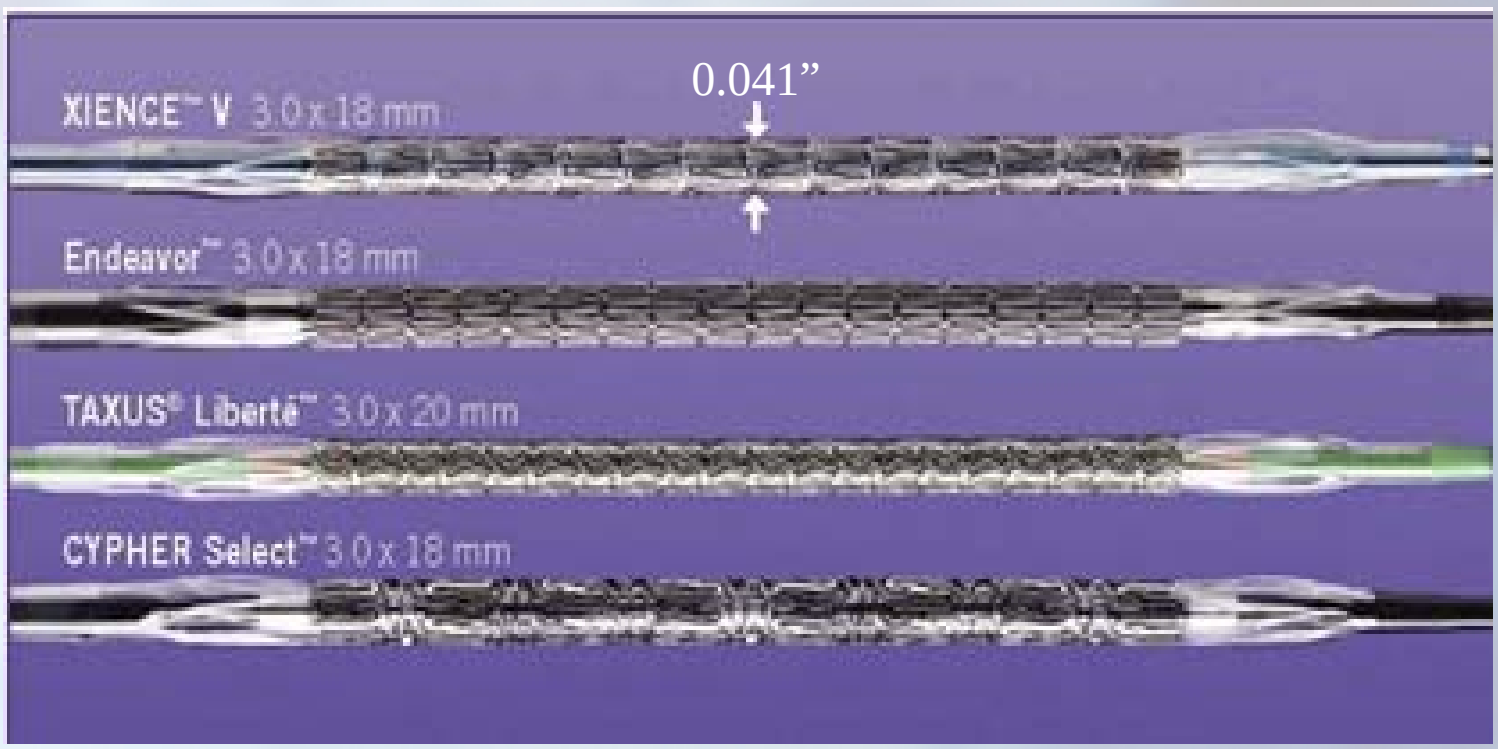
Small Crossing Profile



- Thin strut, CoCr Technology
- SDS Designed specifically for stent delivery

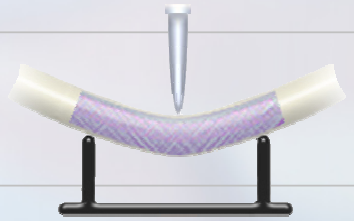
Crossing Profile	.041”

Crossing profile in different DESs



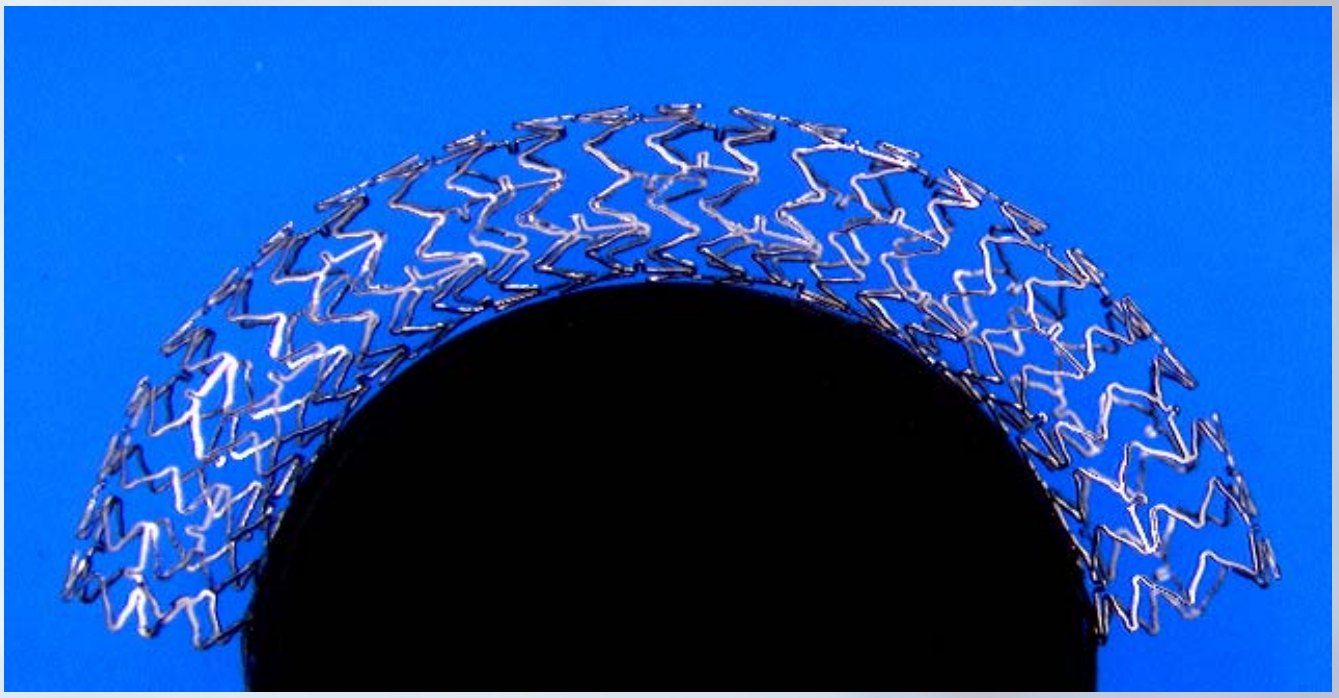
Crossing Profile 9% lower than others in average

Flexibility & Conformability of different Stent Designs



Tests performed by and data on file at Abbott Vascular.
3.5 mm x 28 mm XIENCE V , CYPHER Select, and TAXUS® Liberté. 3.5 mm x 30 mm Endeavor

Conformability

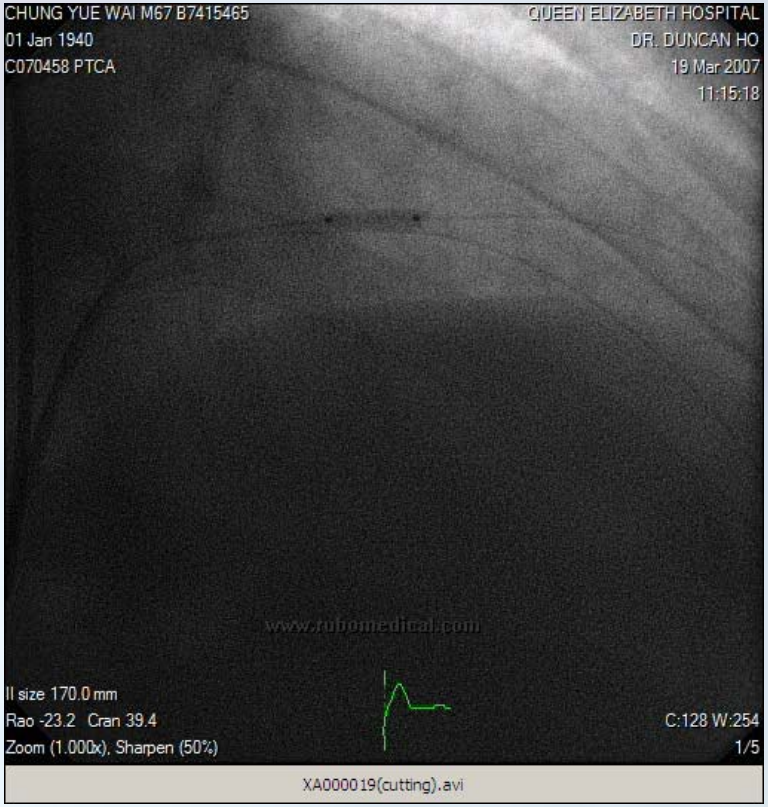


Good apposition
Good drug coverage, even in tortuous vessels

CTO

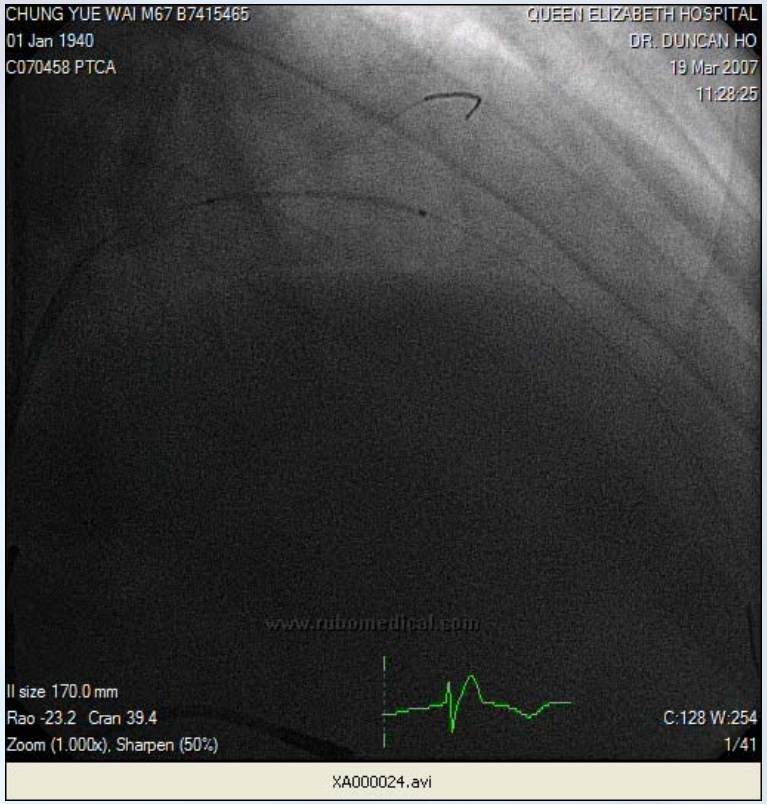
Pic: Pre-dilated mid to distal LAD & D2

CTO

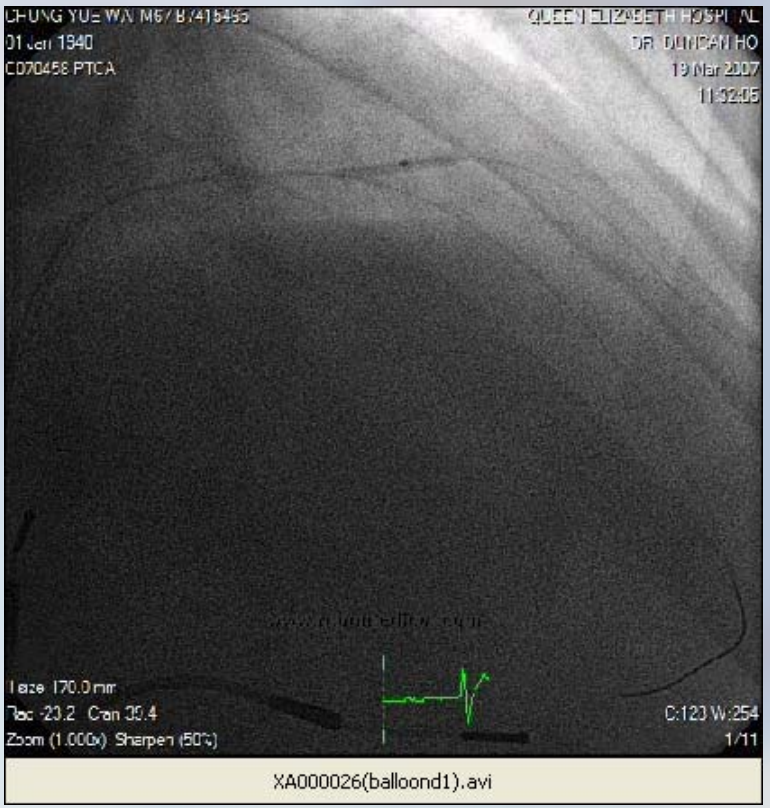


Pic: Cutting balloon on LAD & D1

CTO

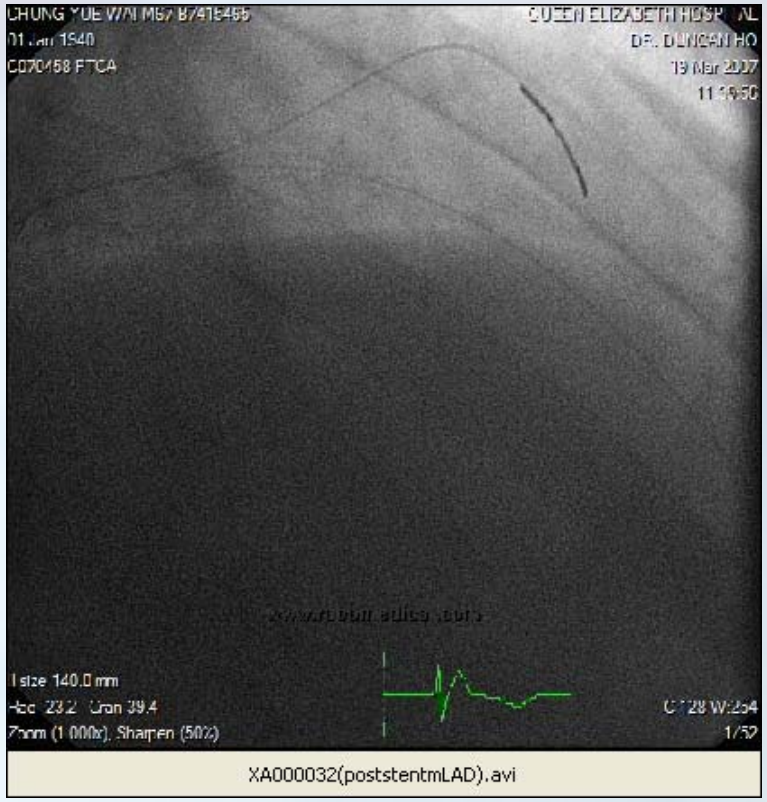


mid-LAD: Xience V

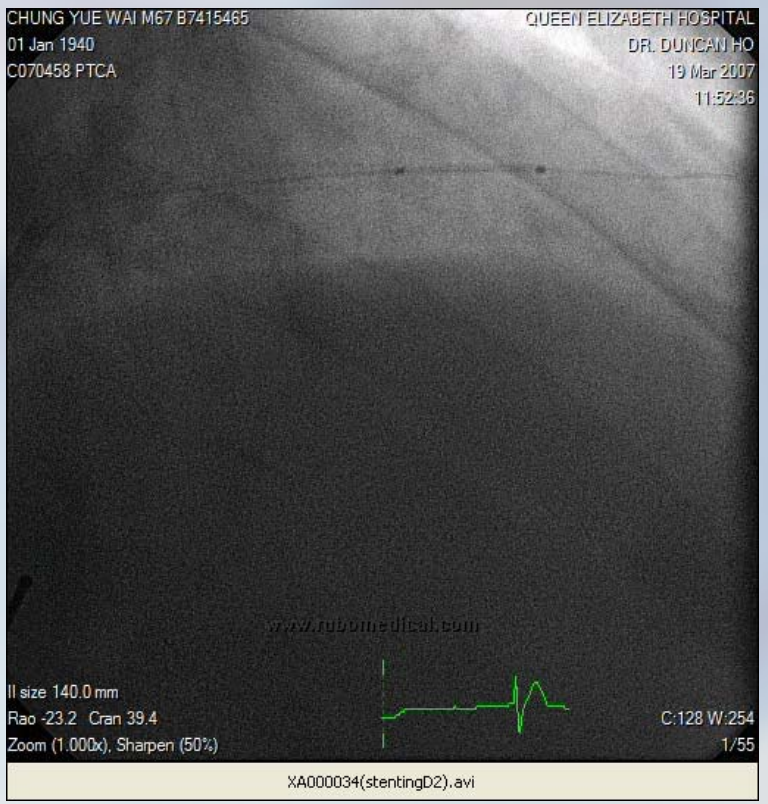


Pic: Balloon to D2 thru stent strut

CTO



post-stented LAD

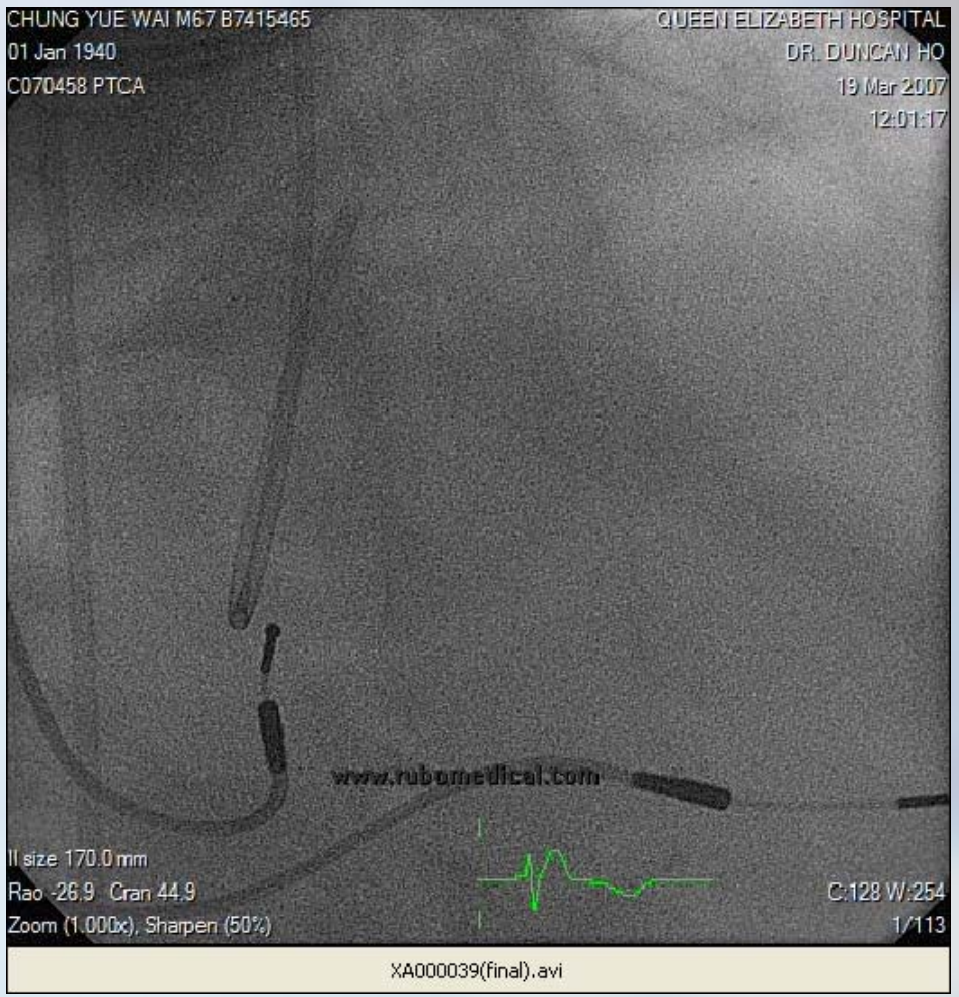


Dissection noted over D2: covered with another Xience V

Result

Successful PCI to D1, mid-LAD CTO & D2

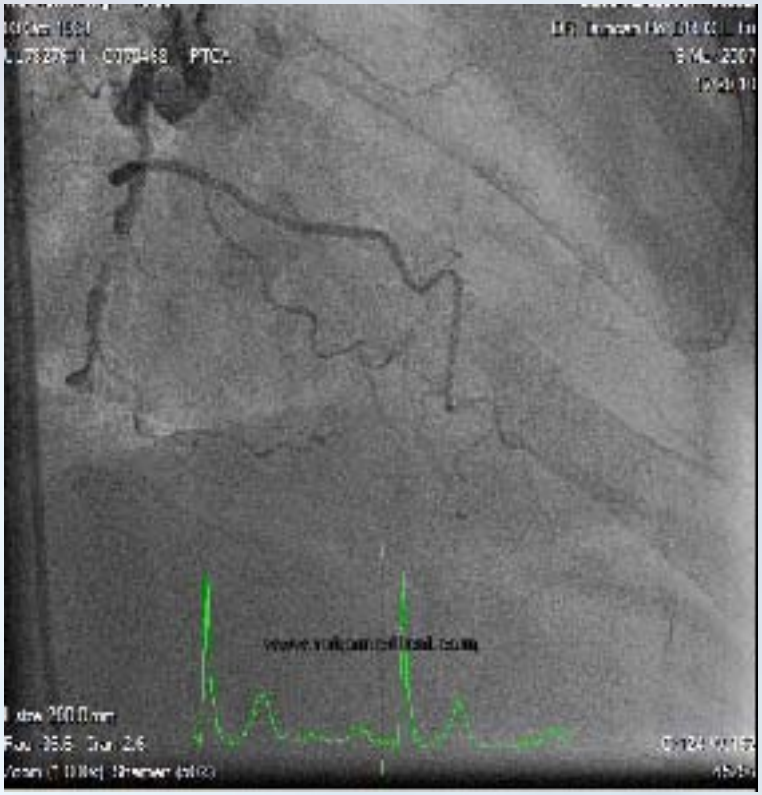
Satisfactory angiographic result



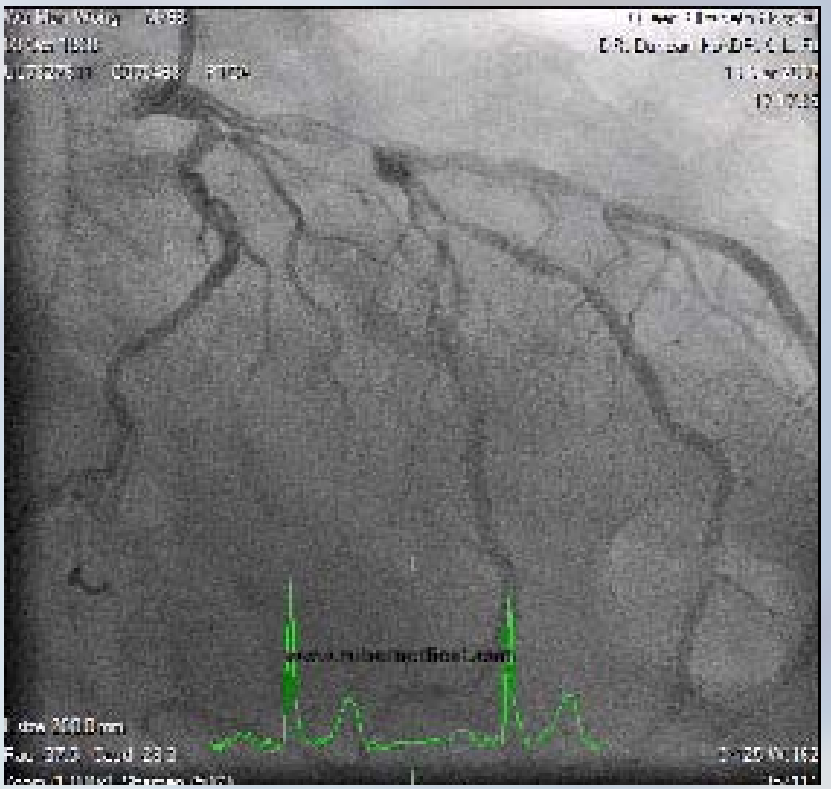
TVD

- M/68
- Patient History: stable angina, DM, HT, hyperlipidaemia
- Ejection Fraction: >55%

TVD - CORO

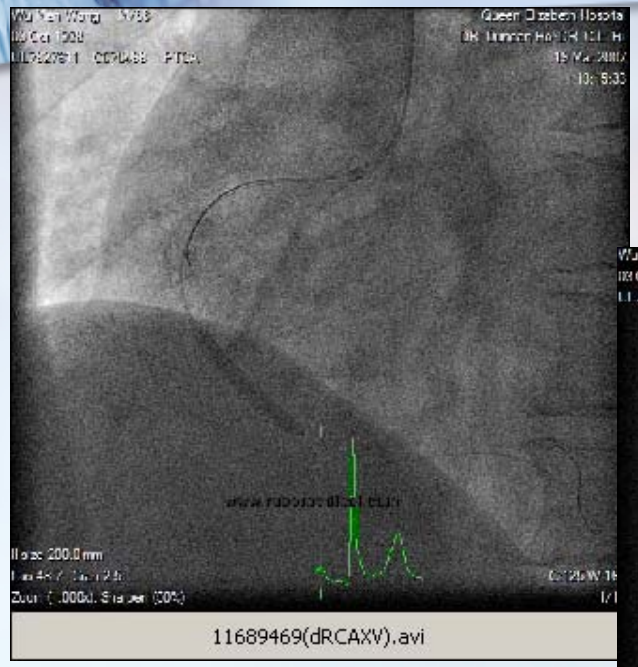


Pic: Mid-RCA total occlusion

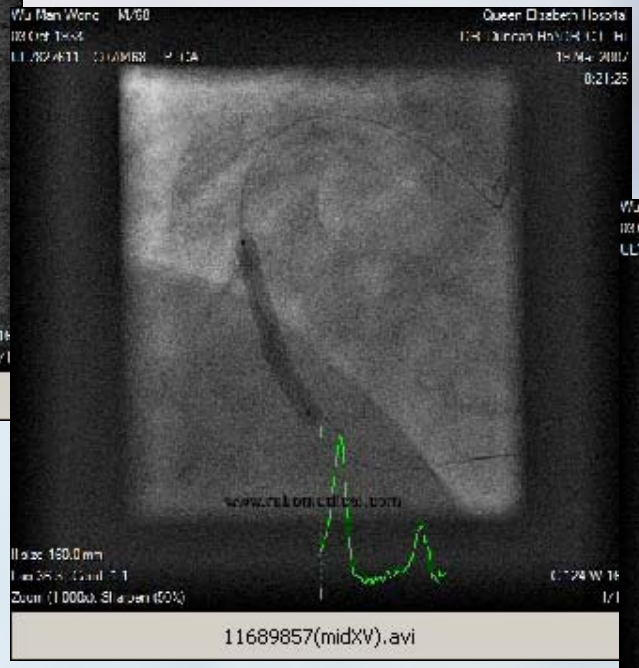


prox-mid-distal LAD 80 % stenosis
D1 80 % stenosis
LCX mild stenosis ~30 %

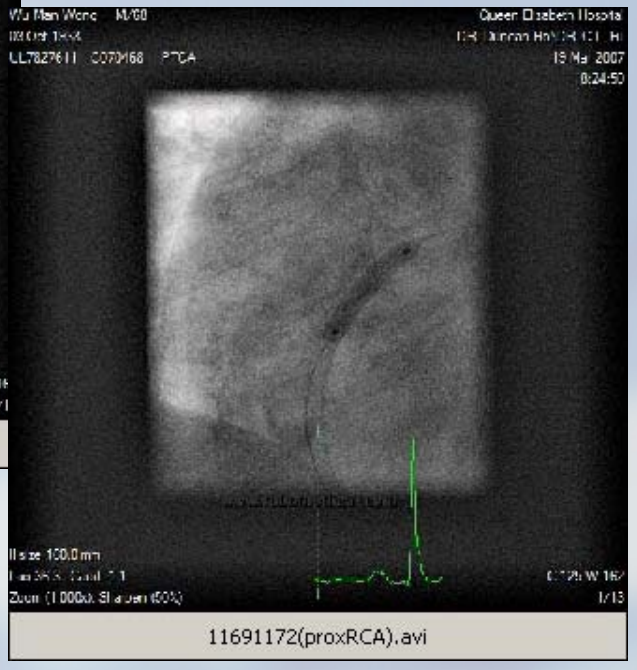
TVD



11689469(dRCAXV).avi



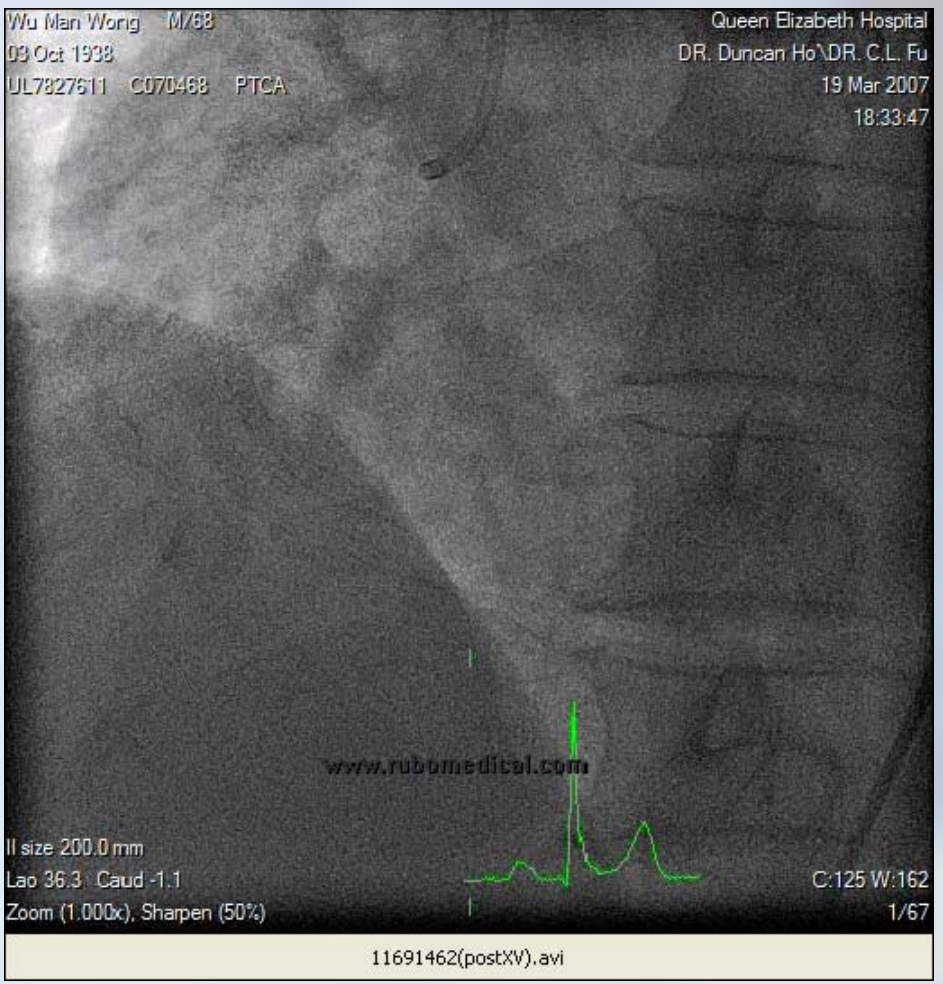
11689857(midXV).avi



11691172(proxRCA).avi

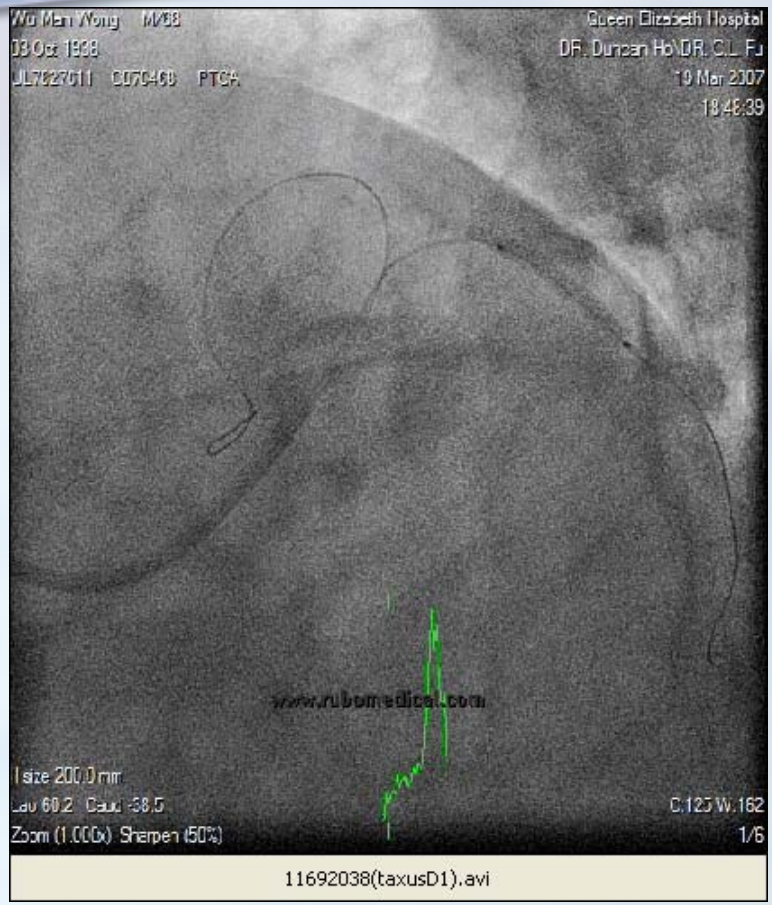
Pic: RCA – 3 Xience V implanted

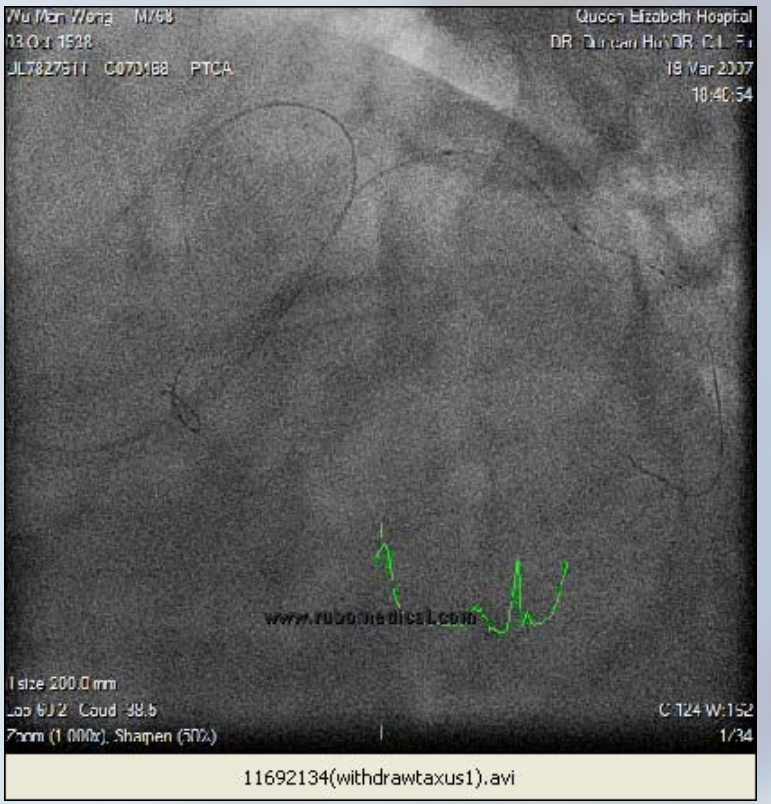
TVD



post stent RCA

TVD

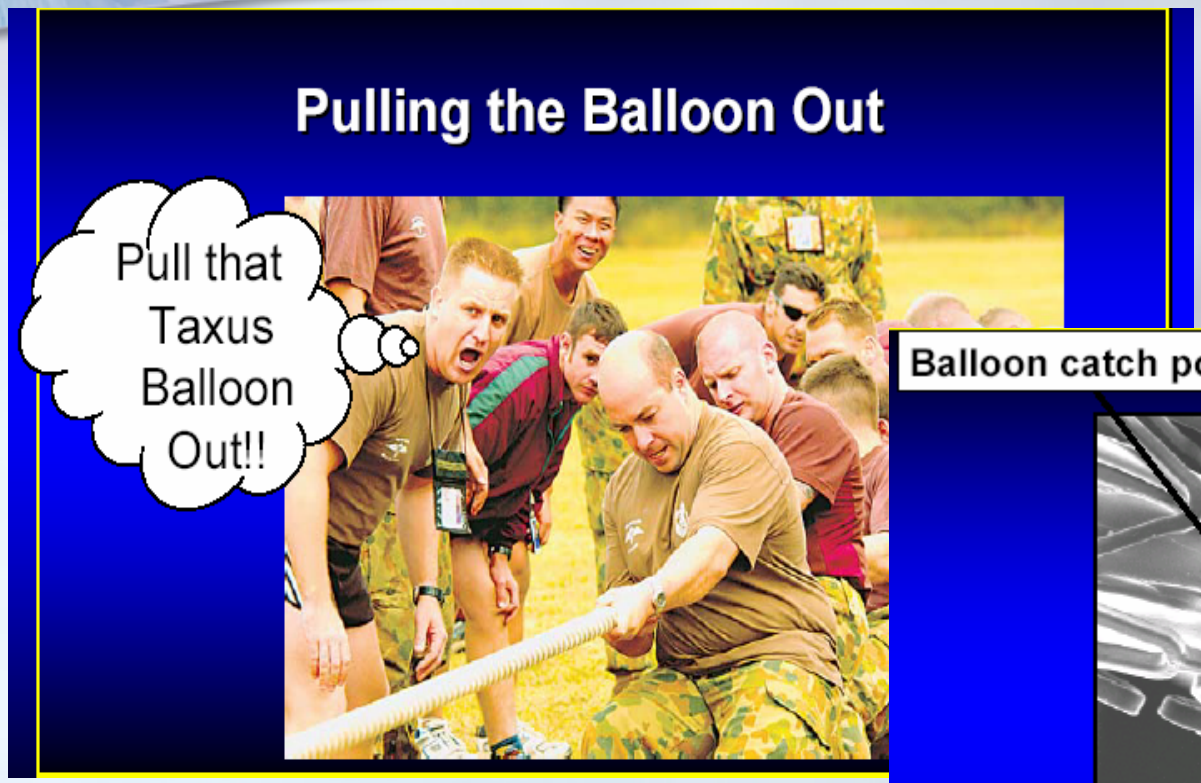


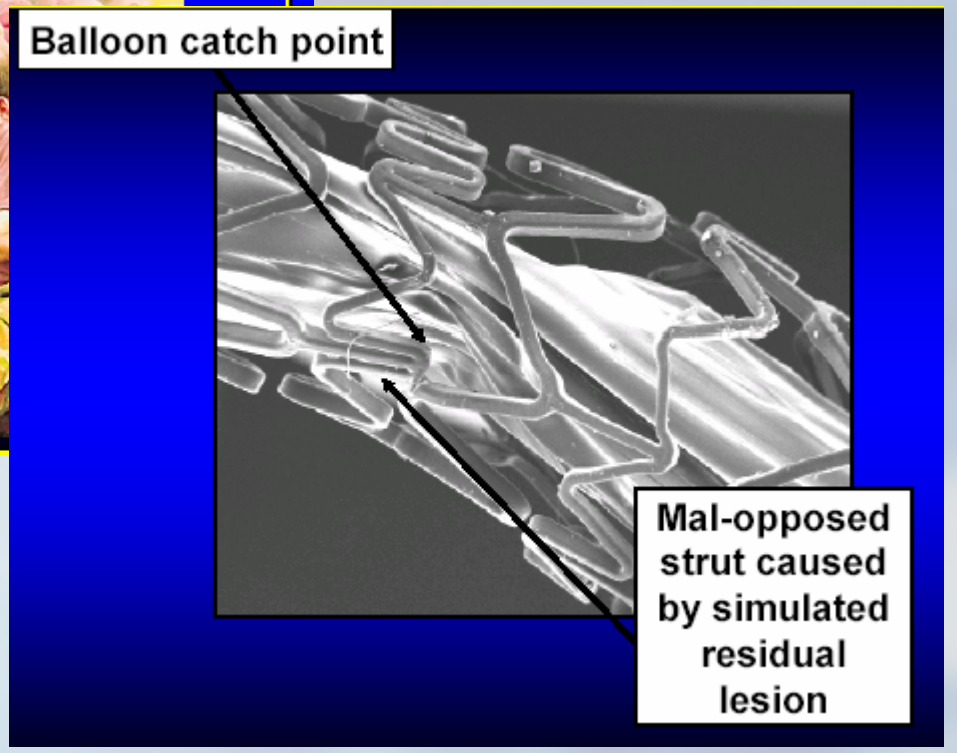


Pic: 2.25/24 another "DES" implanted at D1

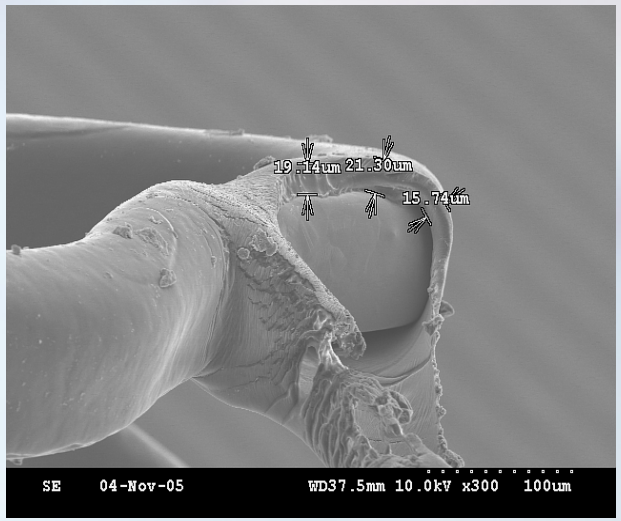
Withdrawn stent balloon

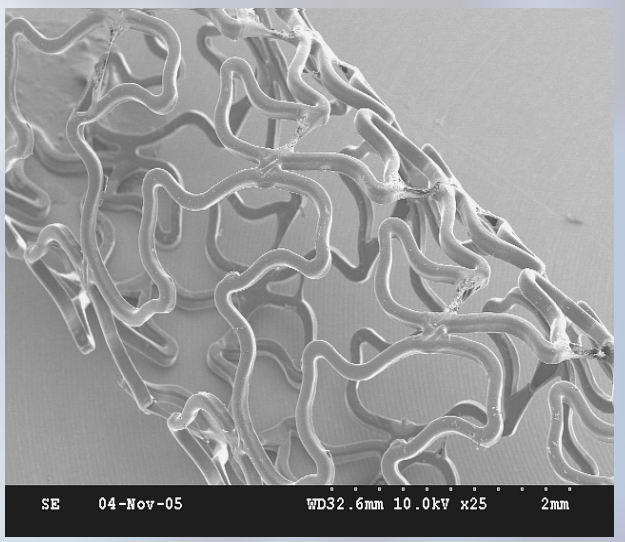
Sticky issue





Polymer Integrity

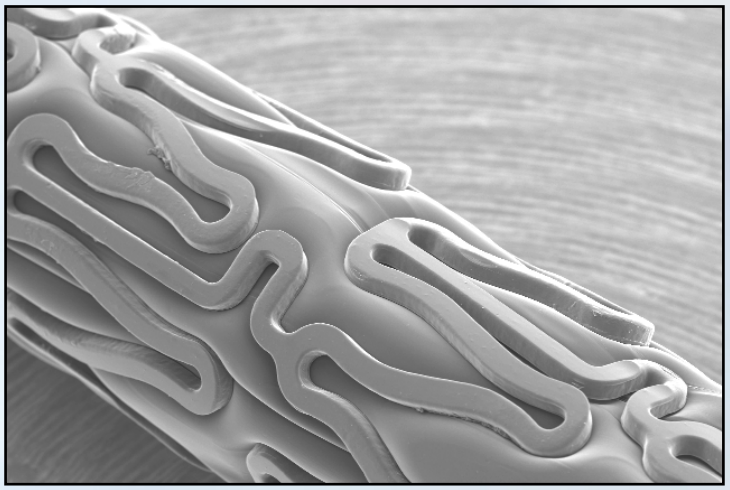




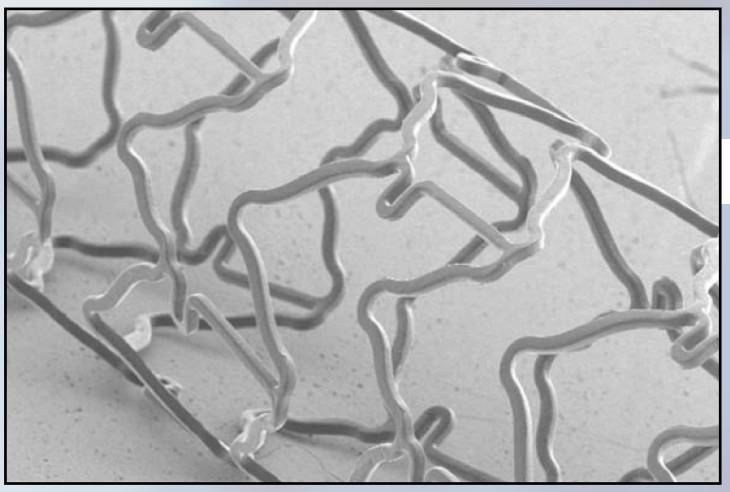
- Intense webbing of polymer
- Touch points led to webbing of polymer

What is the best Polymer?

Good Polymer Coating should have the right balance of soft & hard domains

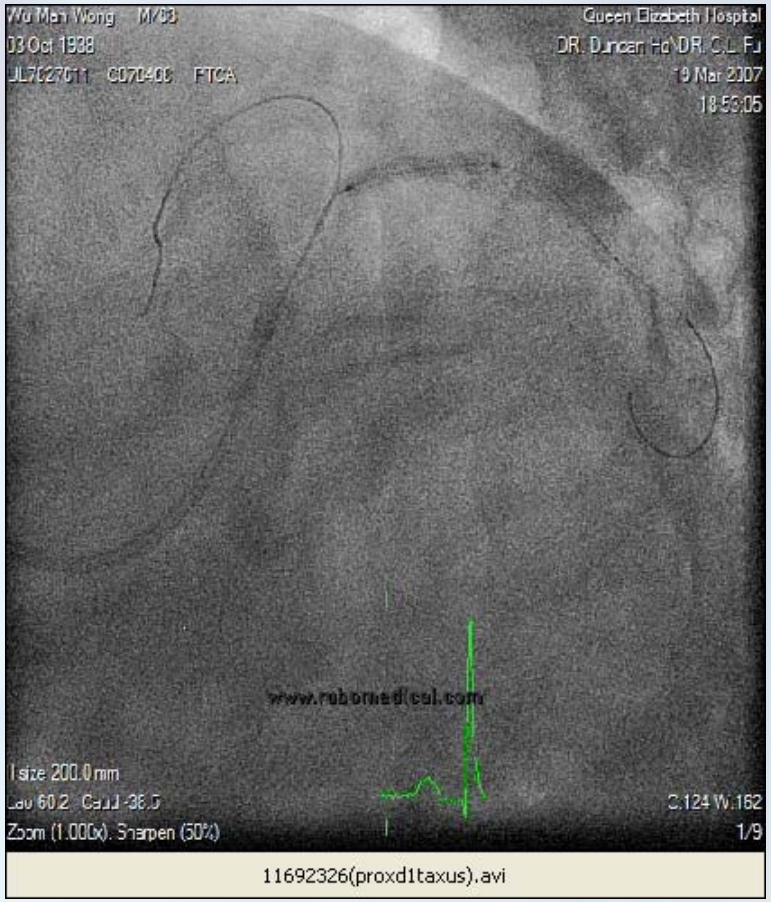


good adhesion to stent



Non-sticky matrix prevents “unwanted” adhesions

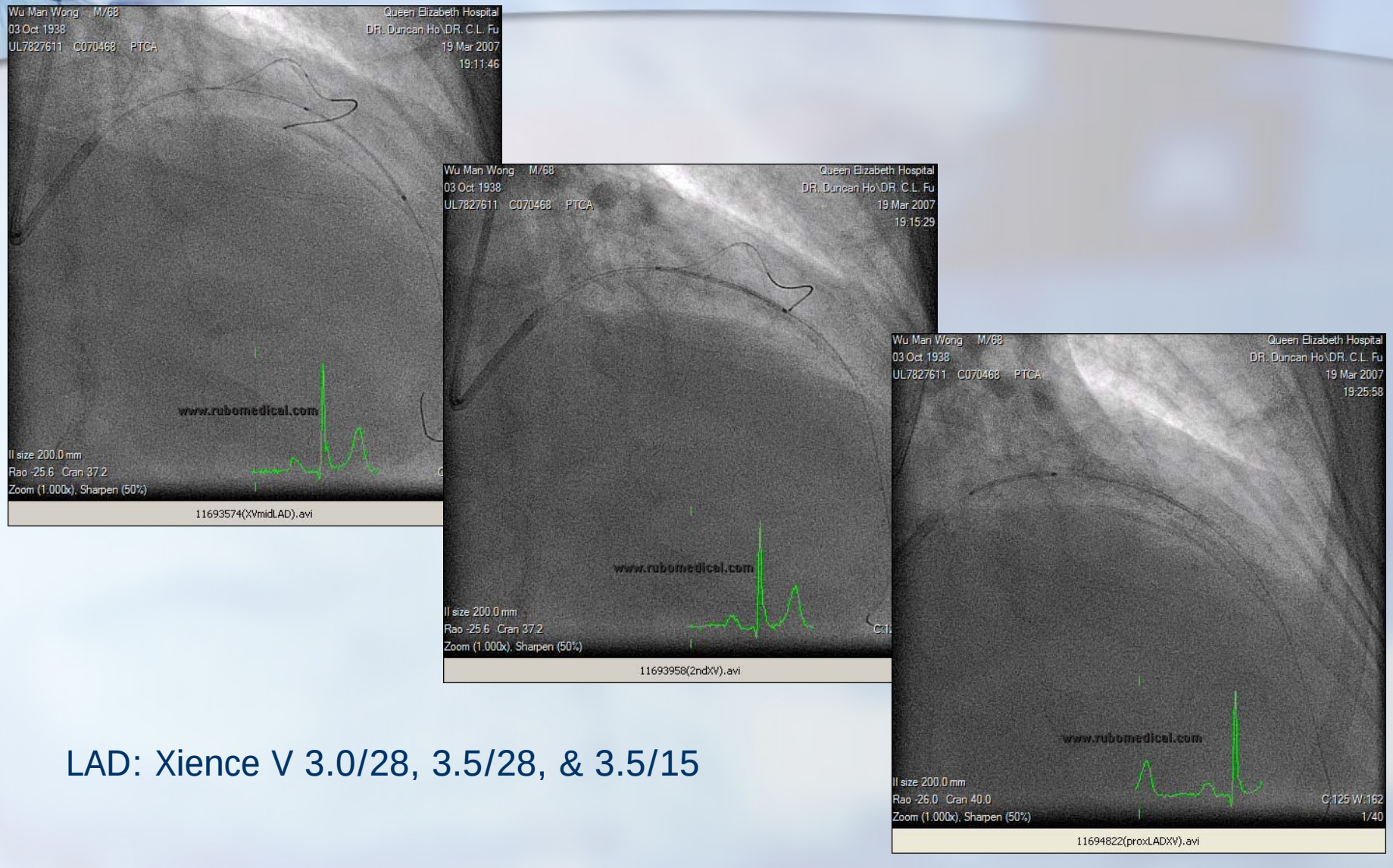
TVD



Pic: prox-LCx: Taxus

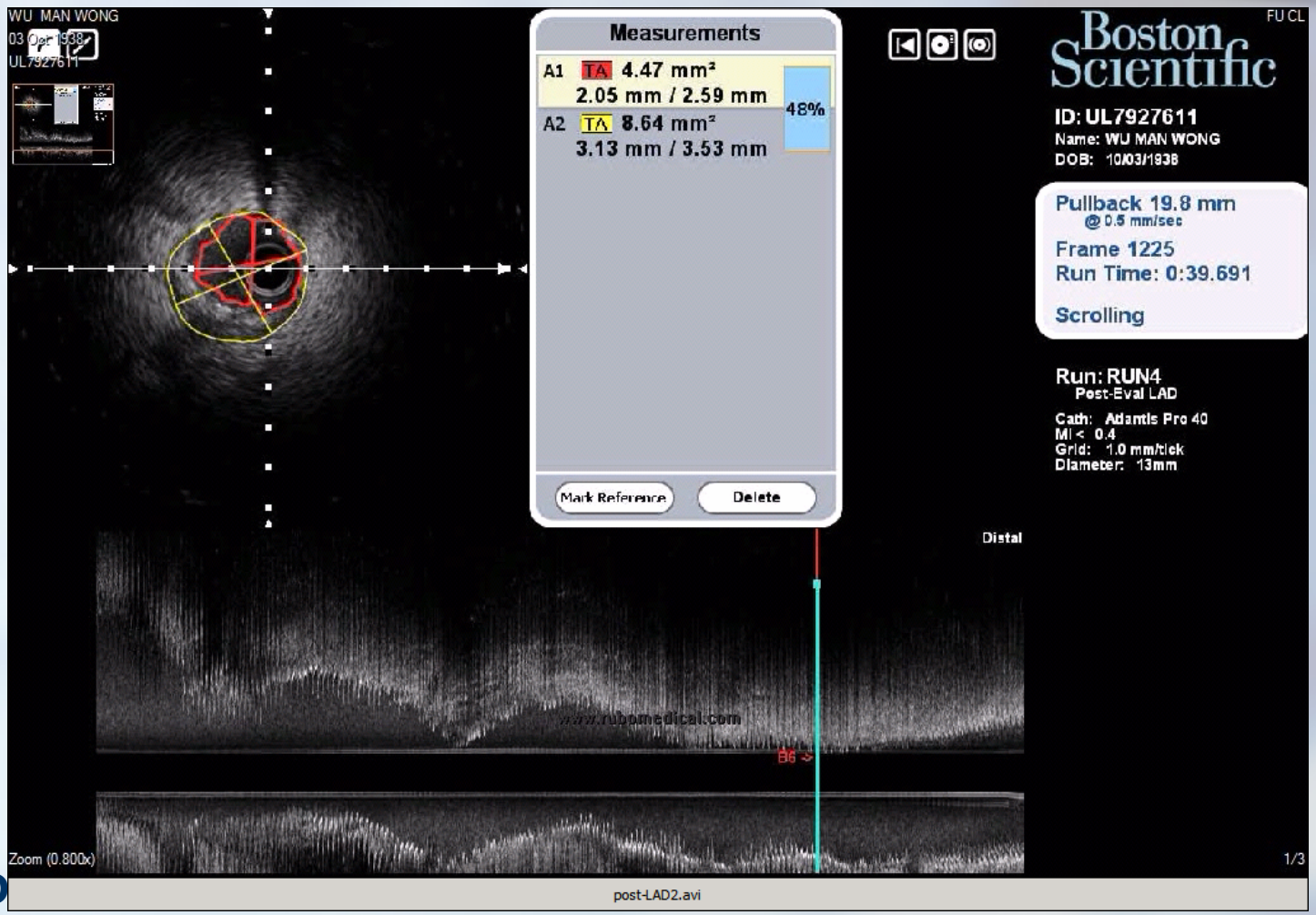
Pic: post stent: D1

TVD



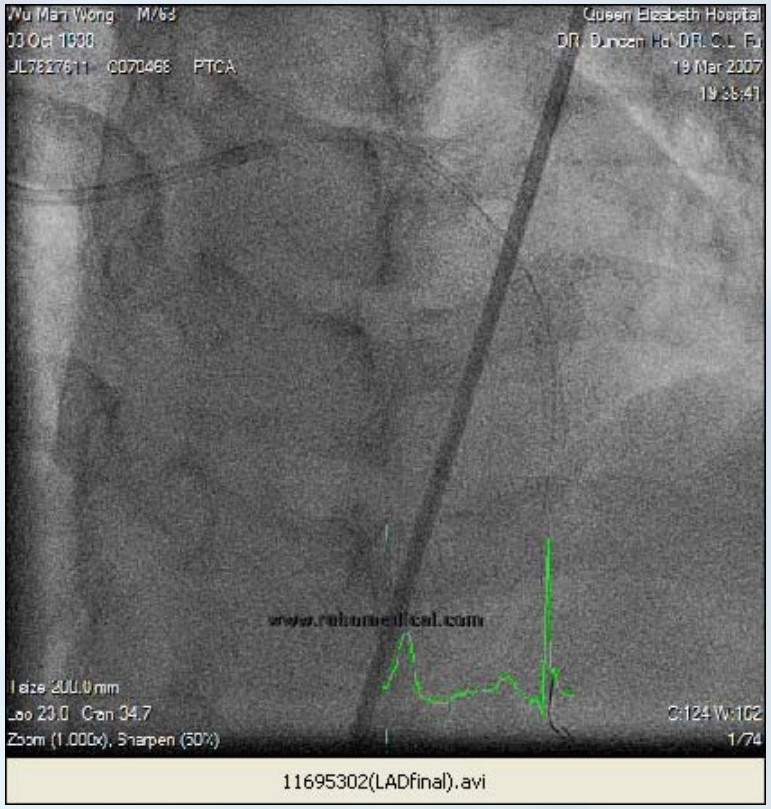
LAD: Xience V 3.0/28, 3.5/28, & 3.5/15

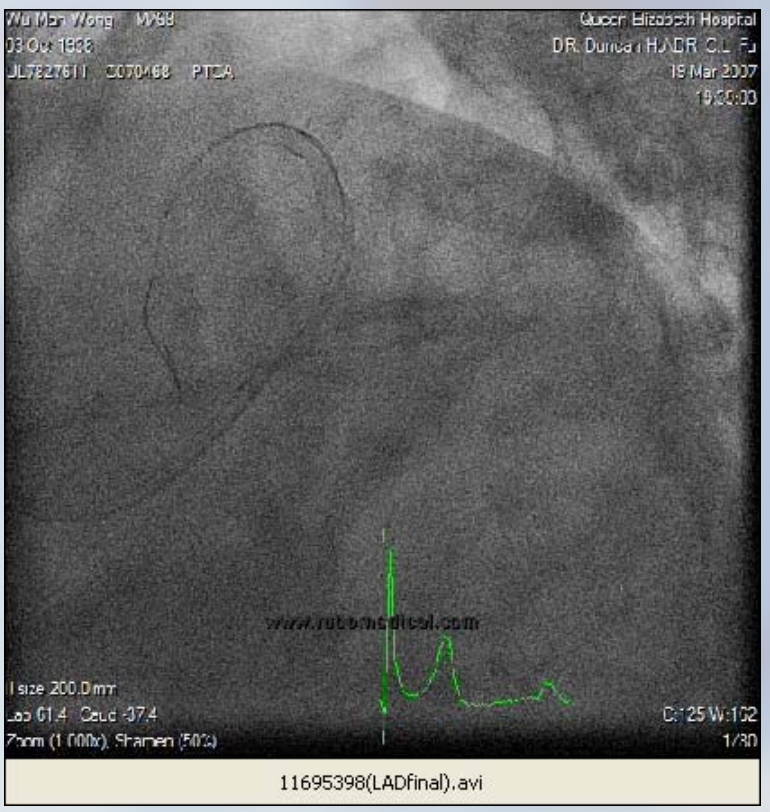
TVD


WU MAN WONG
03 Oct 1938
UL7927611
Measurements
A1 TA 4.47 mm²
2.05 mm / 2.59 mm
A2 TA 8.64 mm²
3.13 mm / 3.53 mm
48%
Mark Reference
Delete
Boston Scientific
FU CL
ID: UL7927611
Name: WU MAN WONG
DOB: 10/03/1938
Pullback 19.8 mm
@ 0.5 mm/sec
Frame 1225
Run Time: 0:39.691
Scrolling
Run: RUN4
Post-Eval LAD
Cath: Atlantis Pro 40
MI < 0.4
Grid: 1.0 mm/tick
Diameter: 13mm
Distal
www.rubomedical.com
Zoom (0.800x)
1/3
post-LAD2.avi

Post - LAD

TVD





Final post-stenting LAD

STENT Group Real World Registry for Multi-Vessel DES in the US

Strategic Transcatheter Evaluation of New Therapies

Methods (3)

- **Definition of Multivessel Study Population:**

  All patients who underwent DES PCI in 2 or more vessel distributions defined as:

  (1) Left Main
  (2) Left anterior descending territory
  (3) Left circumflex territory
  (4) Right coronary territory
  (5) Ramus (optional diagonal) territory

- Each vessel territory was inclusive of all branches arising from that major vessel
- **Example:** Separate LAD and diagonal lesions treated would be a multi-lesion case but **not** multivessel

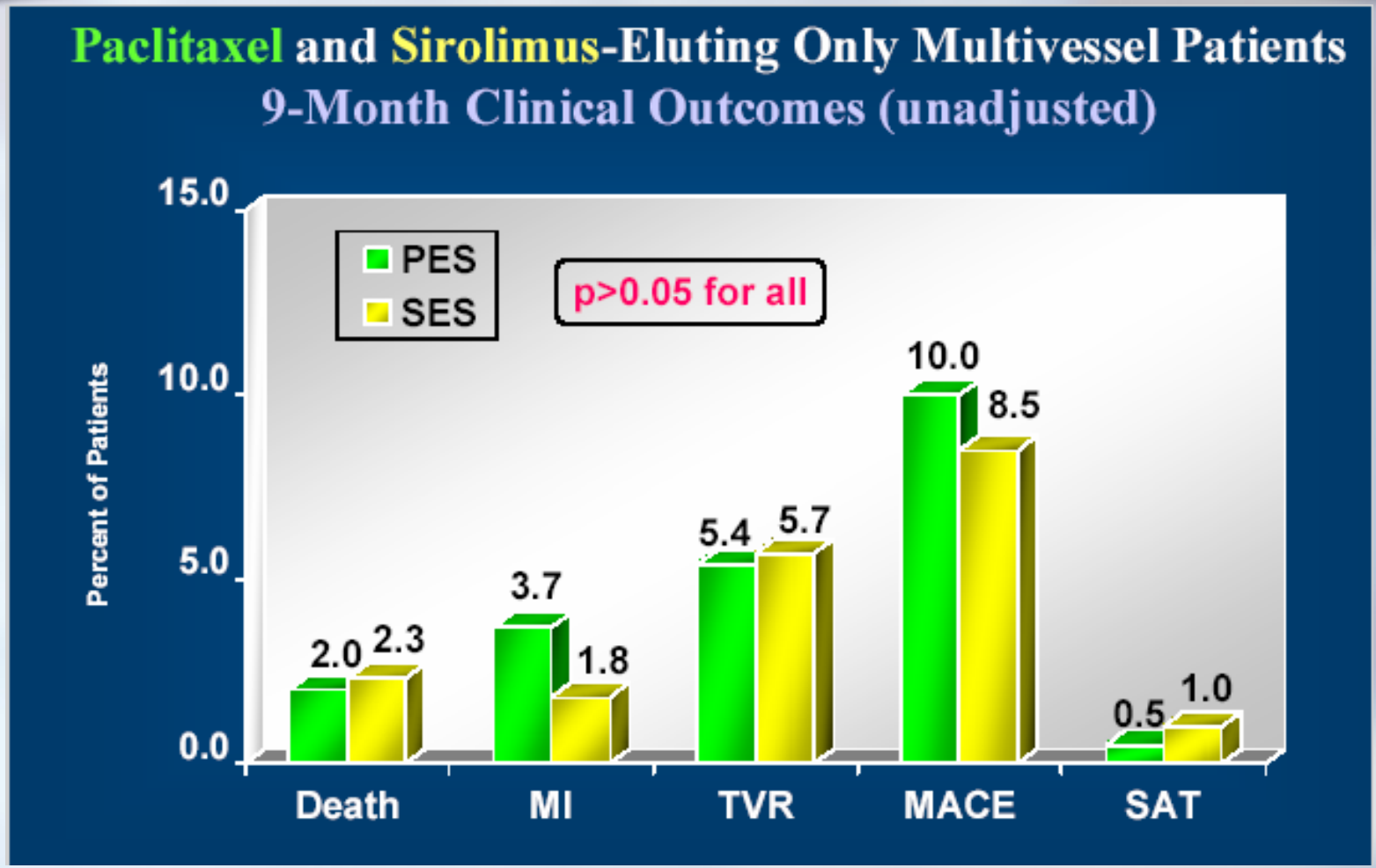
Real World Registry for Multi-Vessel DES in the US

Paclitaxel and Sirolimus-Eluting Only Multivessel Patients

Lesion Characteristics

	PES (n=939 lesions)	SES (n=883 lesions)	
Vessel Diameter<3.0mm	41.6%	33.1%	p=0.0002
Avg Lesion Length	15.1	15.7	p=0.75
Avg Stent Length/Lesion	20.8	21.8	p=0.02
Avg Stent:Lesion Ratio	1.38	1.39	---
Avg Total Stent Length	47.3	48.8	p=0.30

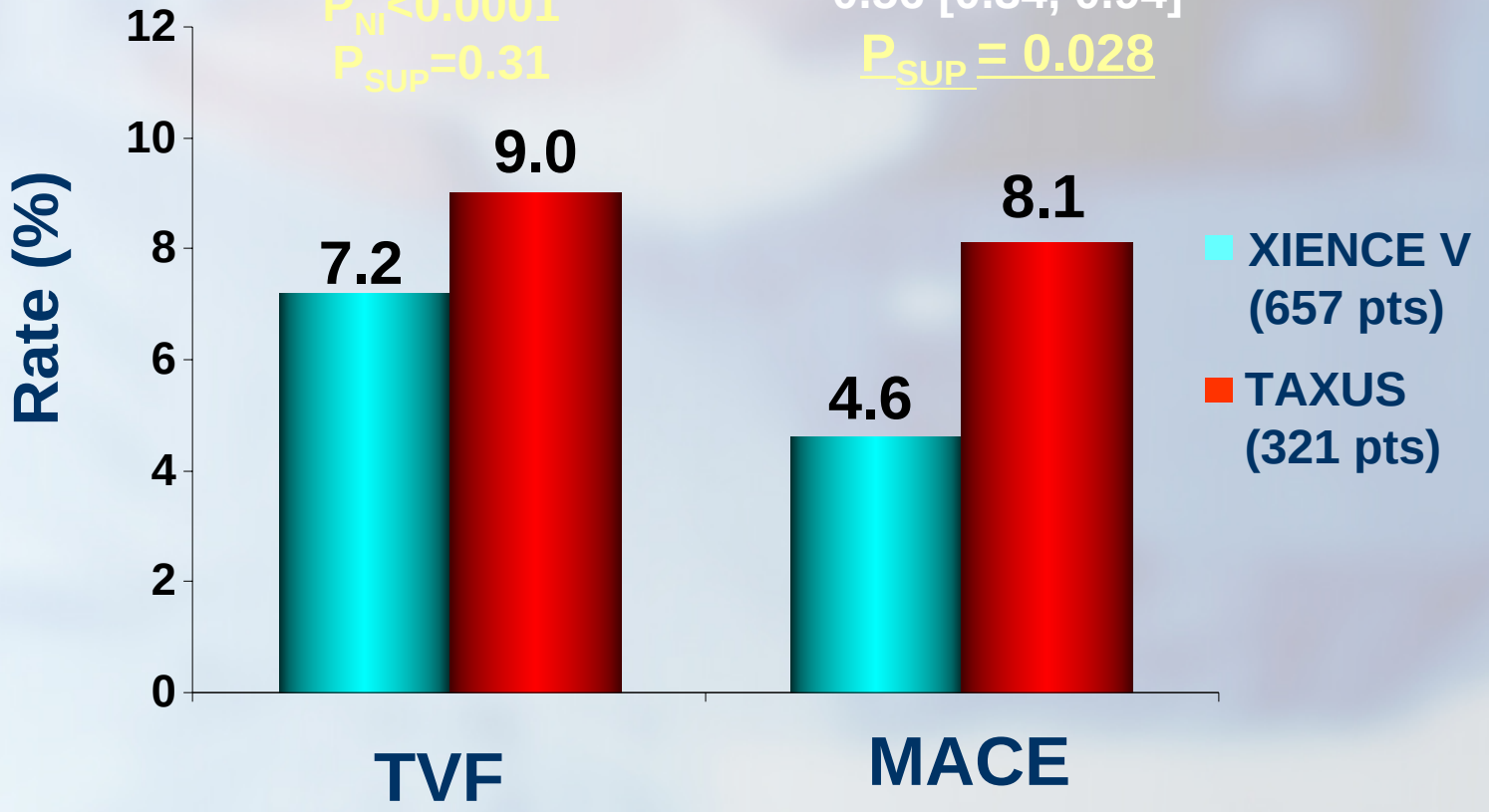
9-Month Clinical Outcomes



Spirit III :TVF & MACE at 270 days

RR [95% CI] = 0.79 [0.51, 1.23]
P_{NI}<0.0001
P_{SUP}=0.31

RR [95% CI] = 0.56 [0.34, 0.94]
P_{SUP} = 0.028

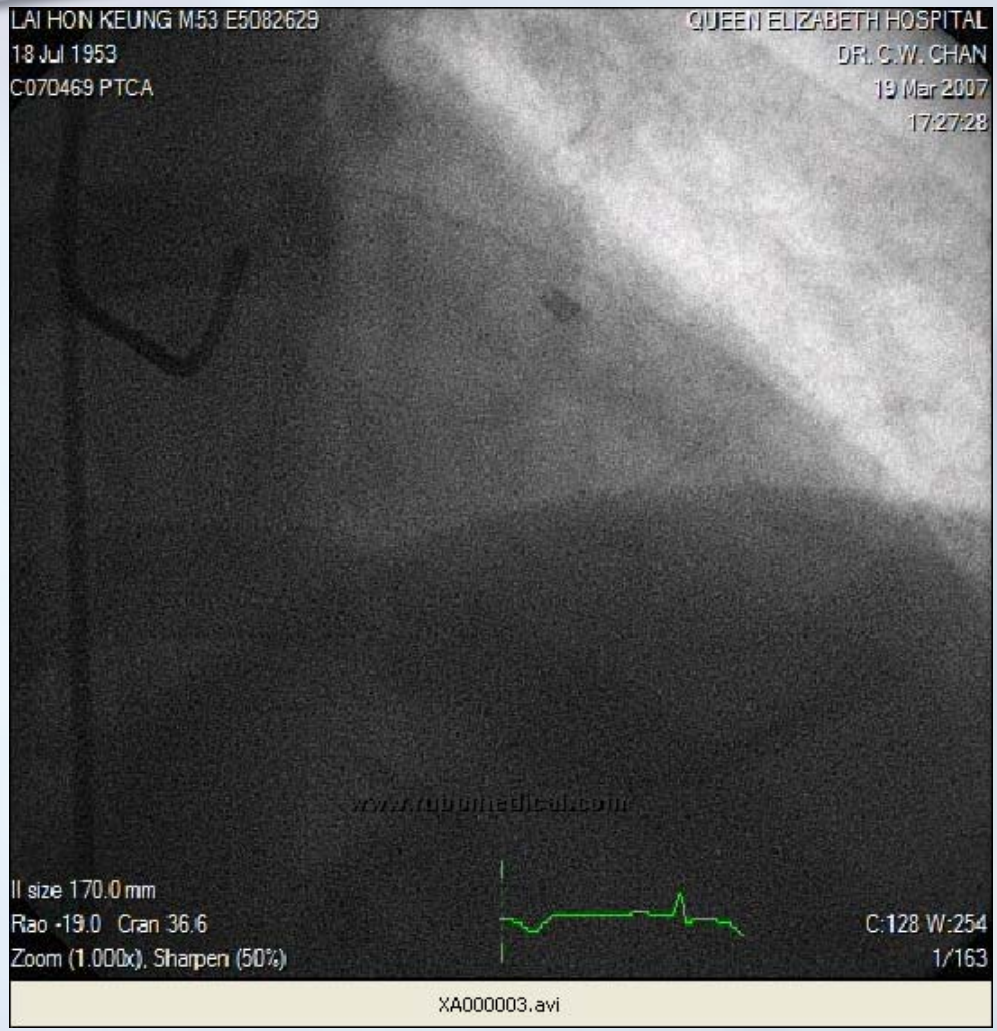


*F/U window ±14 days. TVF = Cardiac death, MI, ischemia-driven TVR.
MACE = Cardiac death, MI, ischemia-driven TLR.

AMI

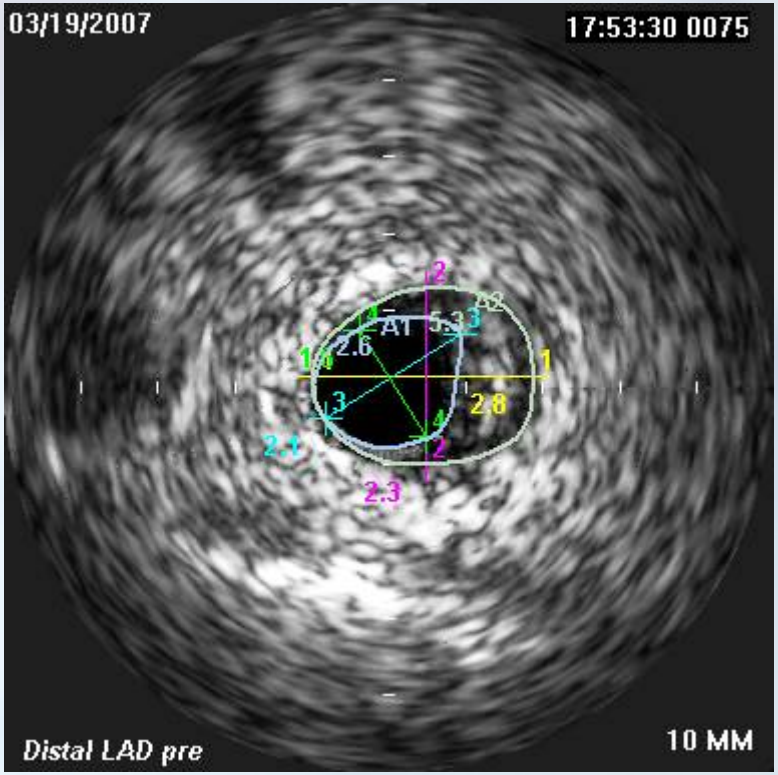
- M/53
- Patient History: HT, Recent ant. MI
- Indication: Post-MI angina
- Unstable angina
- Ejection Fraction: >55%

CORO

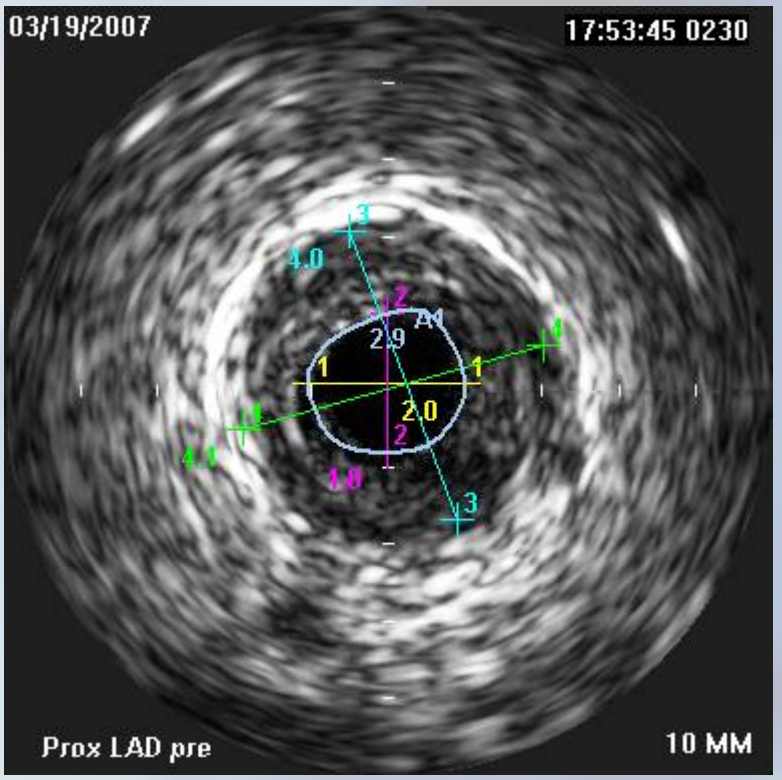


- mid-LAD 100%
- distal-LAD 50%
- Normal LCX & RCA

IVUS



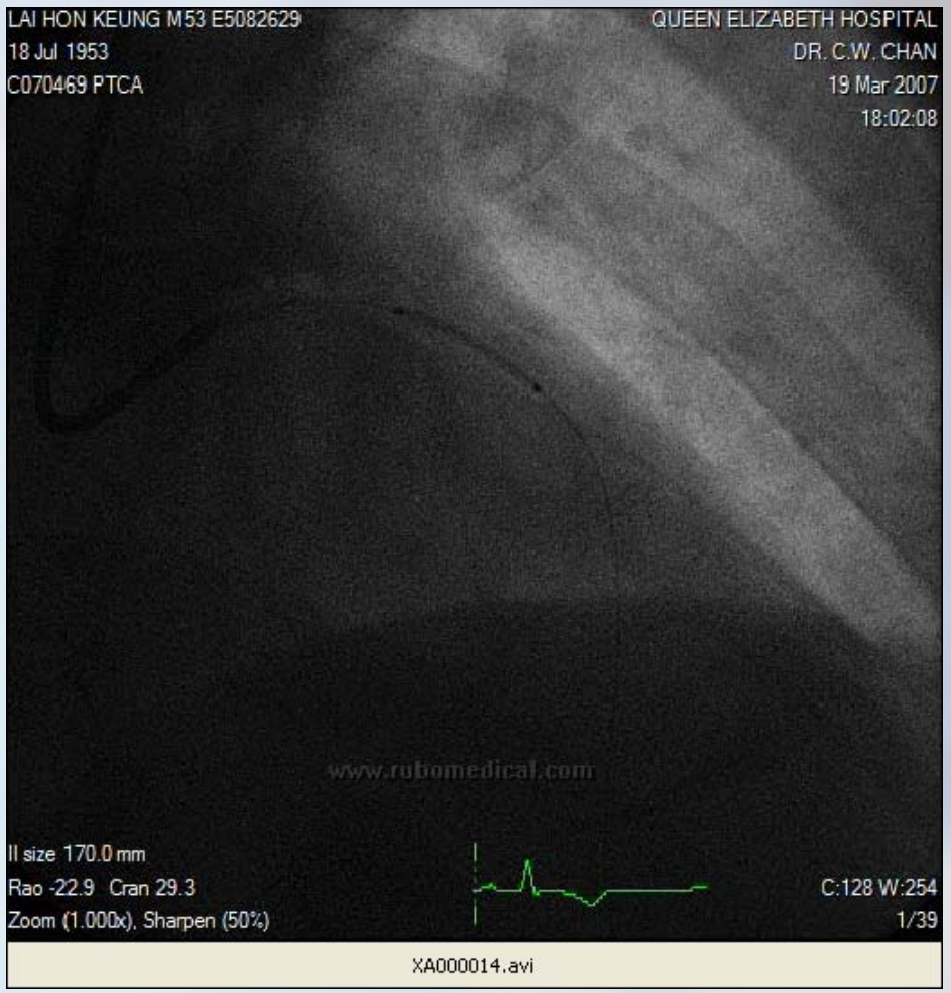
IVUS – distal LAD



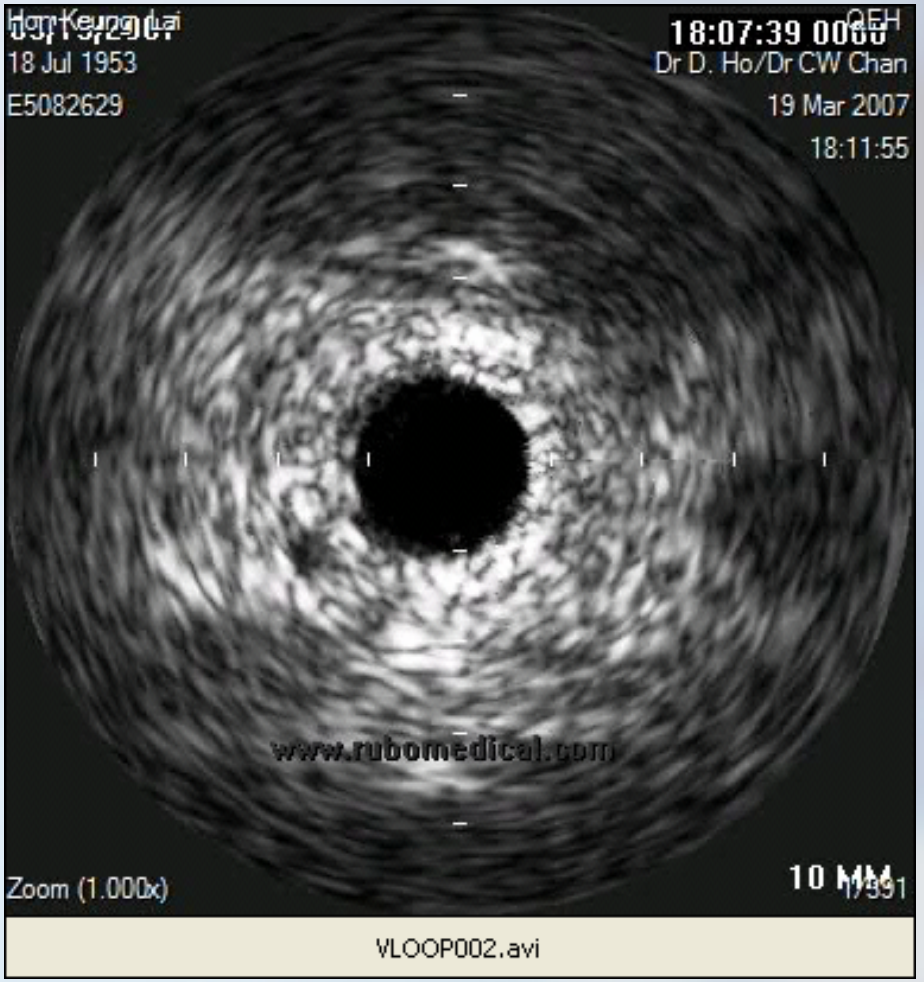
IVUS – prox LAD

AMI

Mid-LAD: Xience V



Post - IVUS

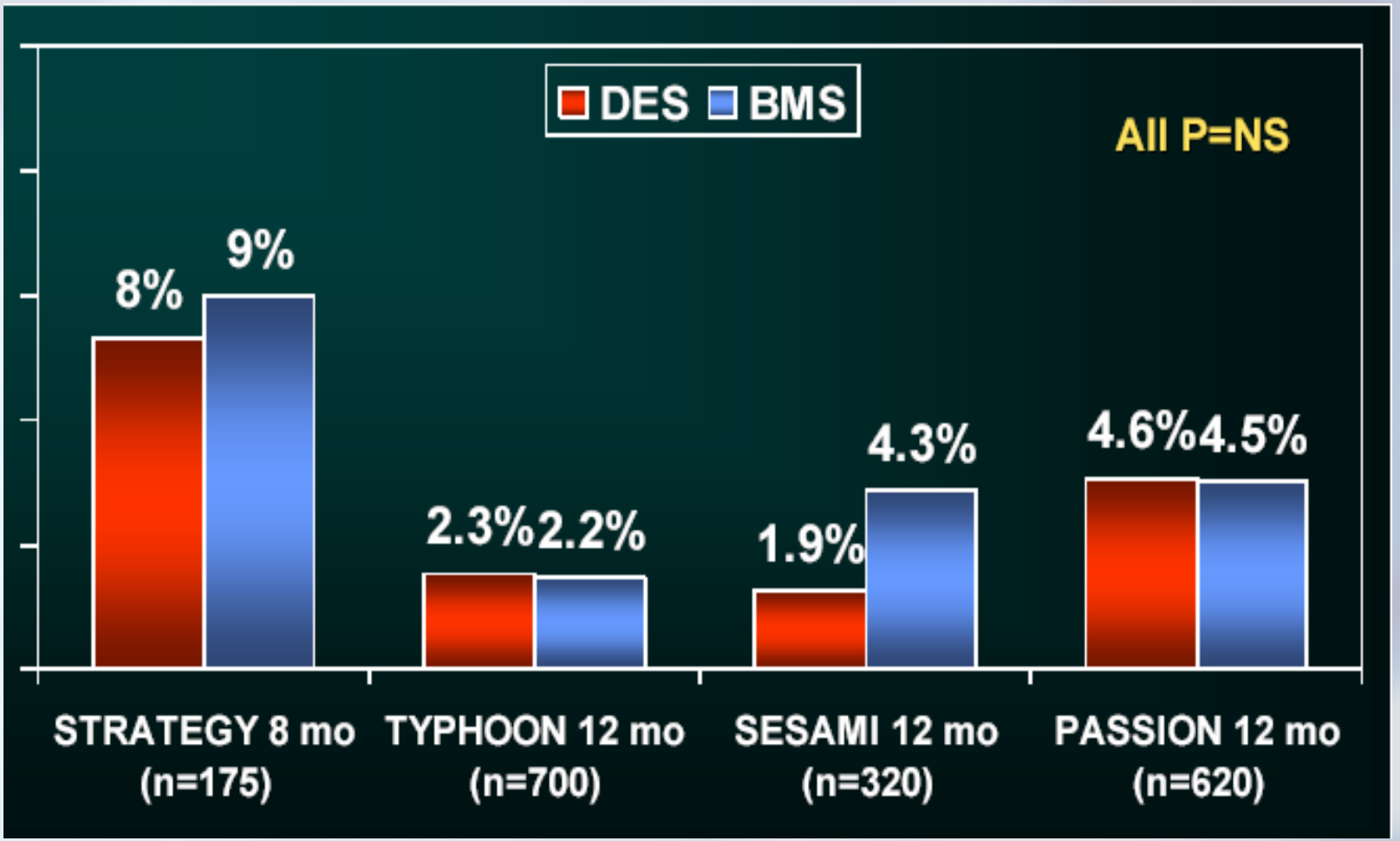

18 Jul 1953
E5082629
18:07:39 0000
Dr D. Ho/Dr CW Chan
19 Mar 2007
18:11:55
www.rubomedical.com
Zoom (1.000x)
VLOOP002.avi

DES in AMI (RCTs)

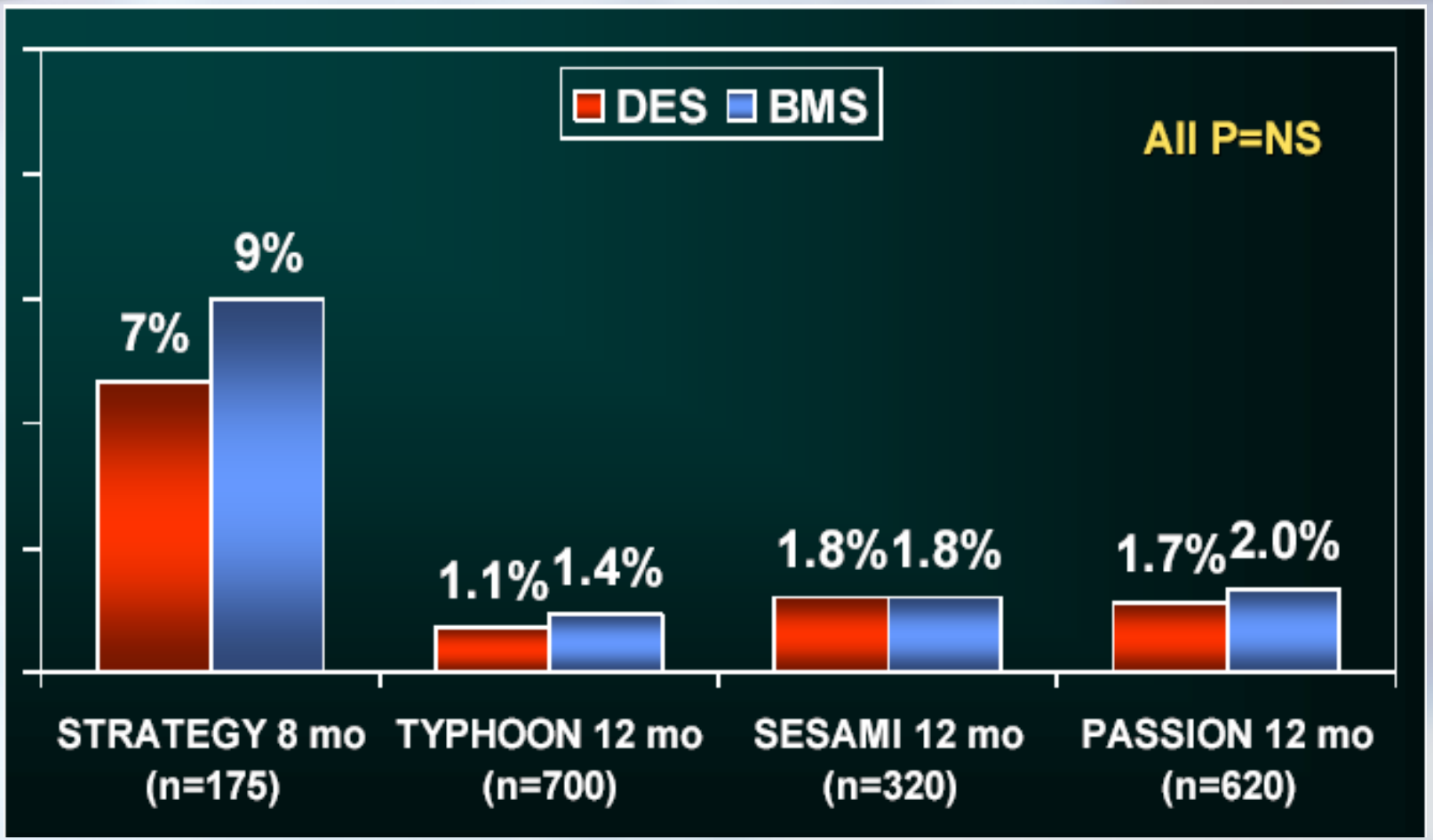
Trial	DES	BMS	N	Angio FU	1° EP
STRATEGY[1]	Cypher	Bx Vel	175	Yes	8mo D, ReMI, CVA, or TVR
TYPHOON[2]	Cypher	Any	700	Yes	12mo TVF
SESAMI[3]	Cypher	Bx Vel	320	Yes	12mo restenosis
PASSION[4]	Taxus	Exp[2]/Lib	620	No	12mo D, ReMI, TVR

1. Valgimigli M et al. JAMA 2005;293:2109-2117.
2. Spaulding C et al. NEJM 2006;355:1093-104.
3. Menichelli M. EuroPCR 2006.
4. Laarman GJ et al. NEJM 2006;355:1105-13.

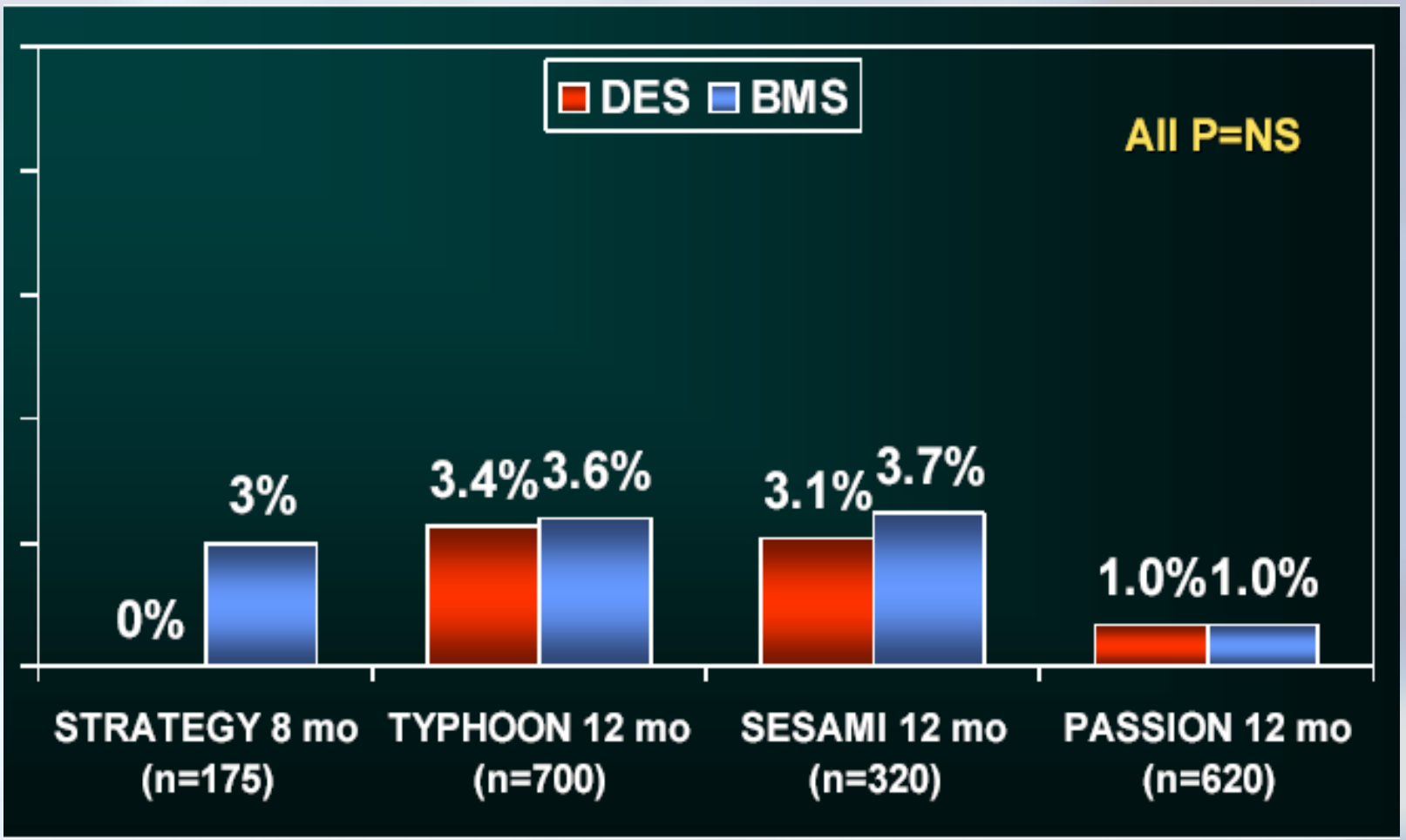
DES in AMI: Mortality



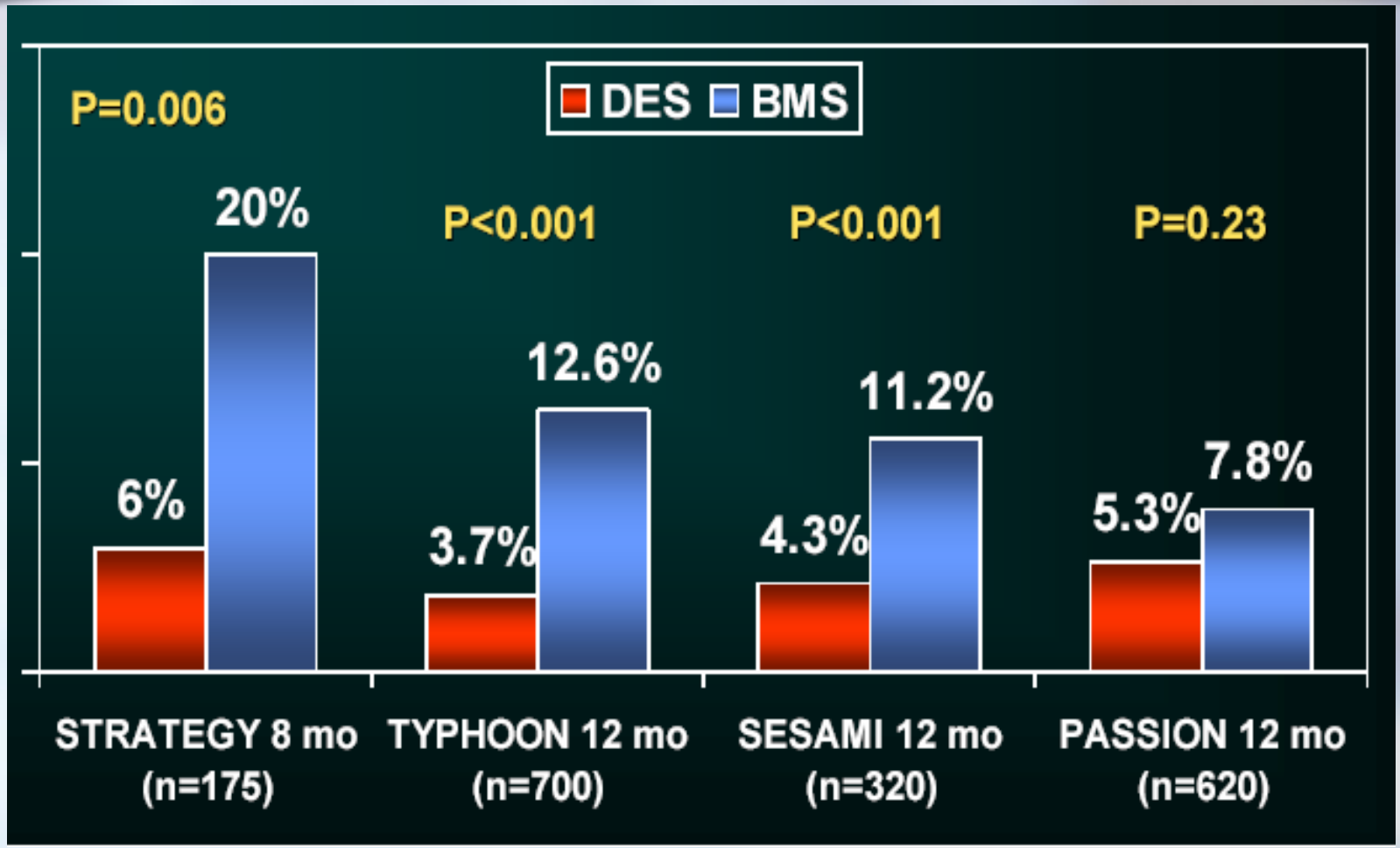
DES in AMI: Re-infarction



Stent Thrombosis



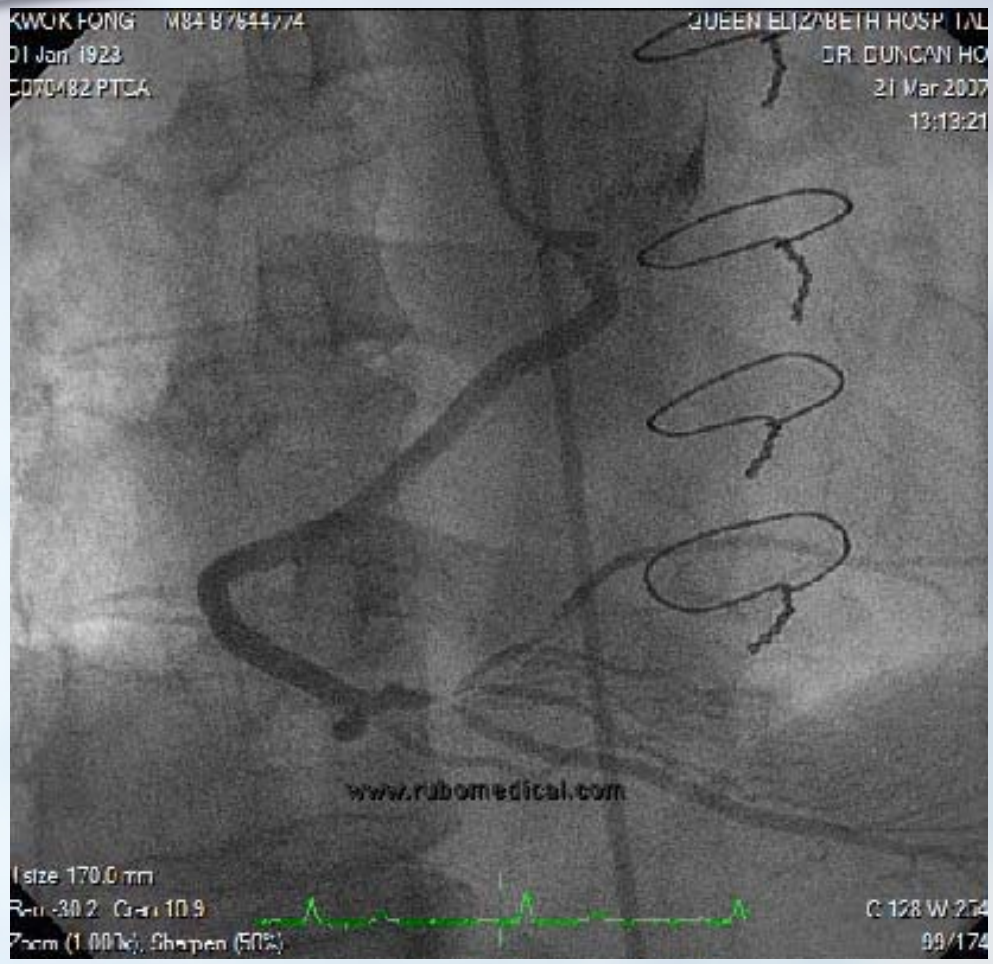
Target Lesion Revascularization



Bifurcation

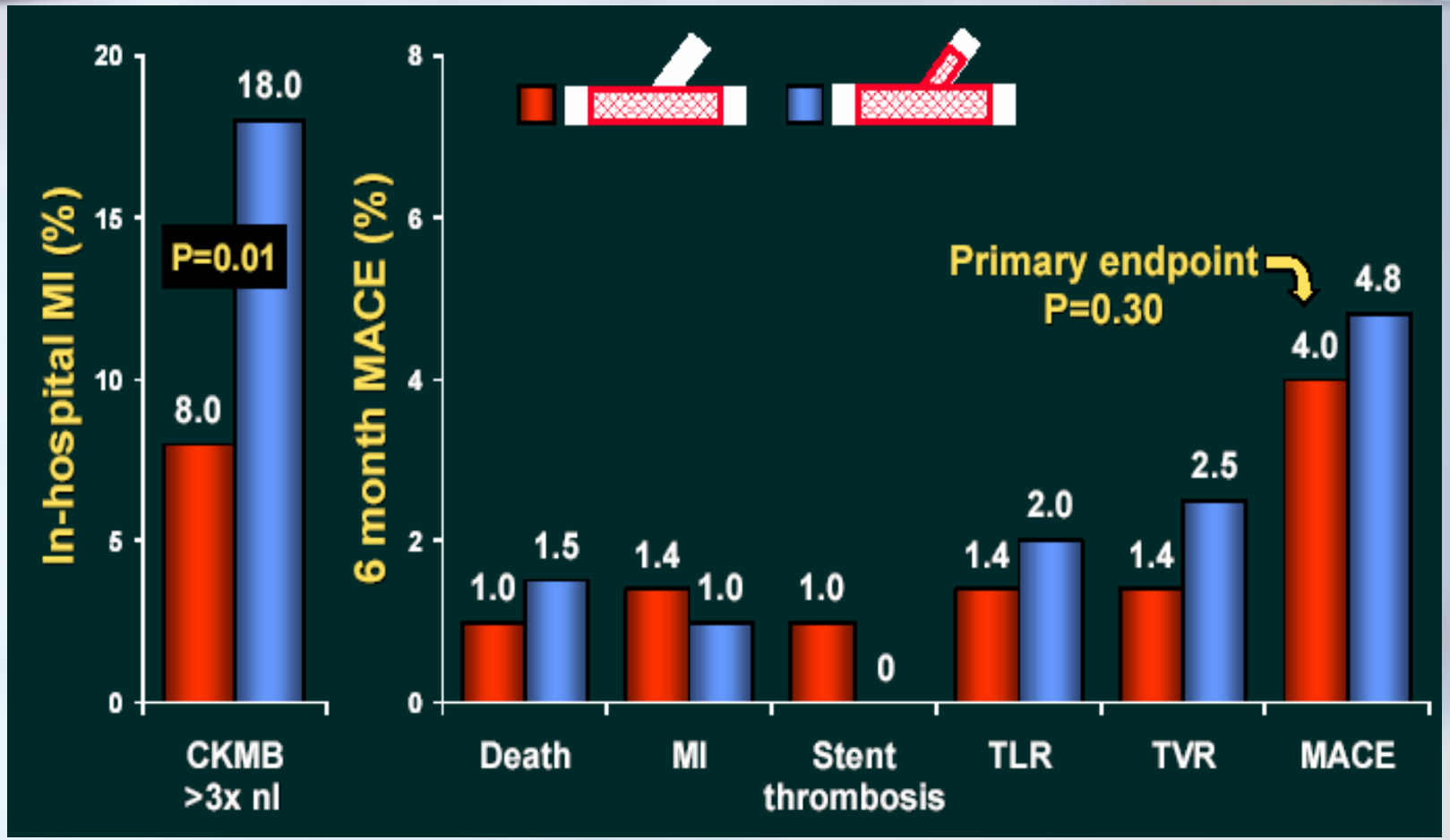
- M/84
- Ex-smoker,
- CABG in 2001
- NSTEMI recently
- EF: 35-55%

CORO



- SVG to RCA patent.
- Critical stenosis at PDA/PL bifurcation

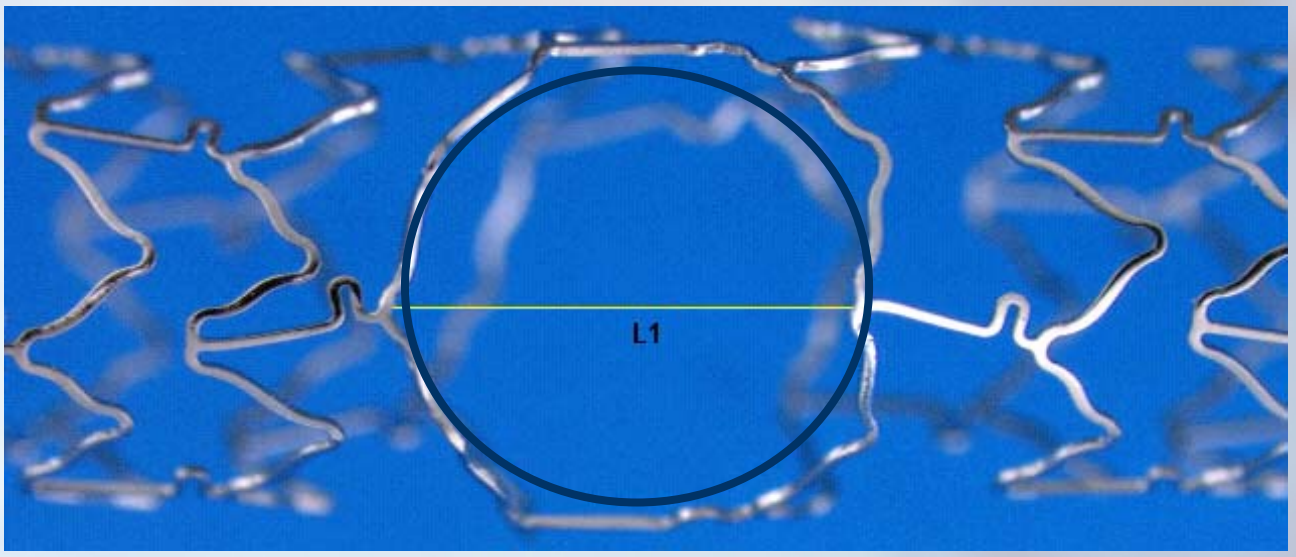
Nordic Bifurcation Study
Major Endpoints (n=413)



Steigen TC et al. ACC 2006

Bifurcation lesion

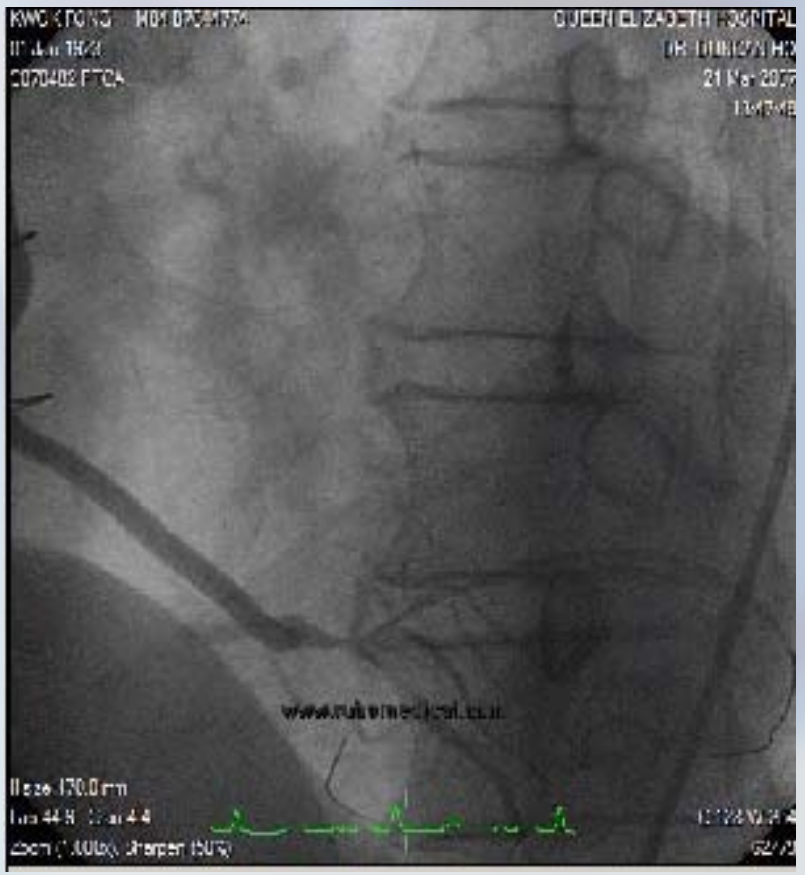
Excellent Side Branch Access



3.0 mm VISION™ with Side Branch Cell Expanded to 4.0 mm

Bifurcation

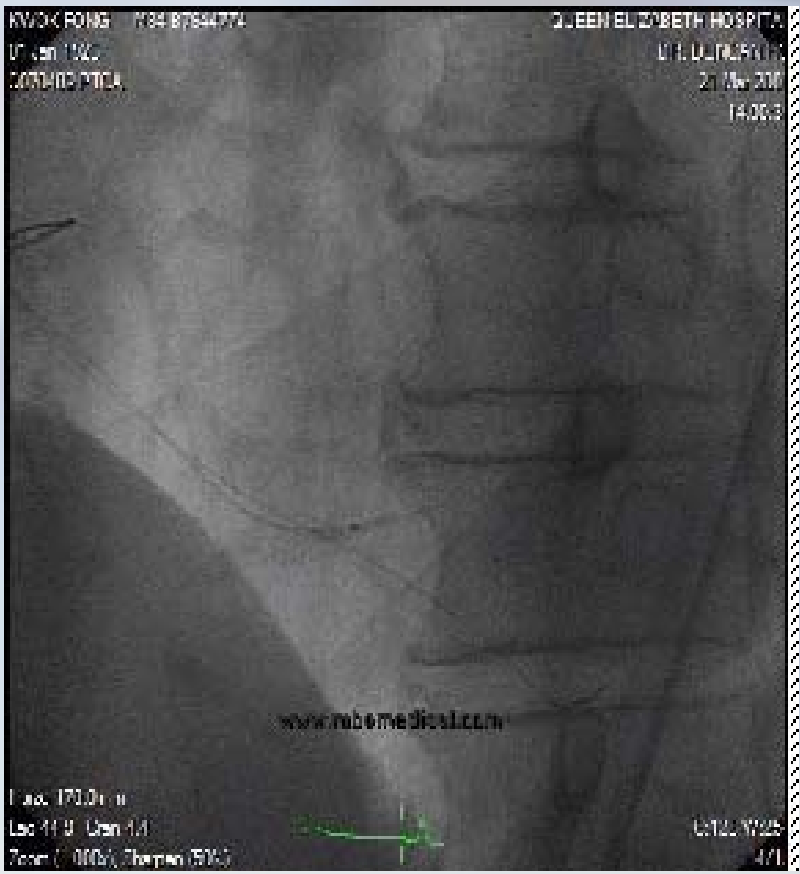
Pic: Pic: BDC to PDA & PL



Pic: Post-BDC dilation

Bifurcation

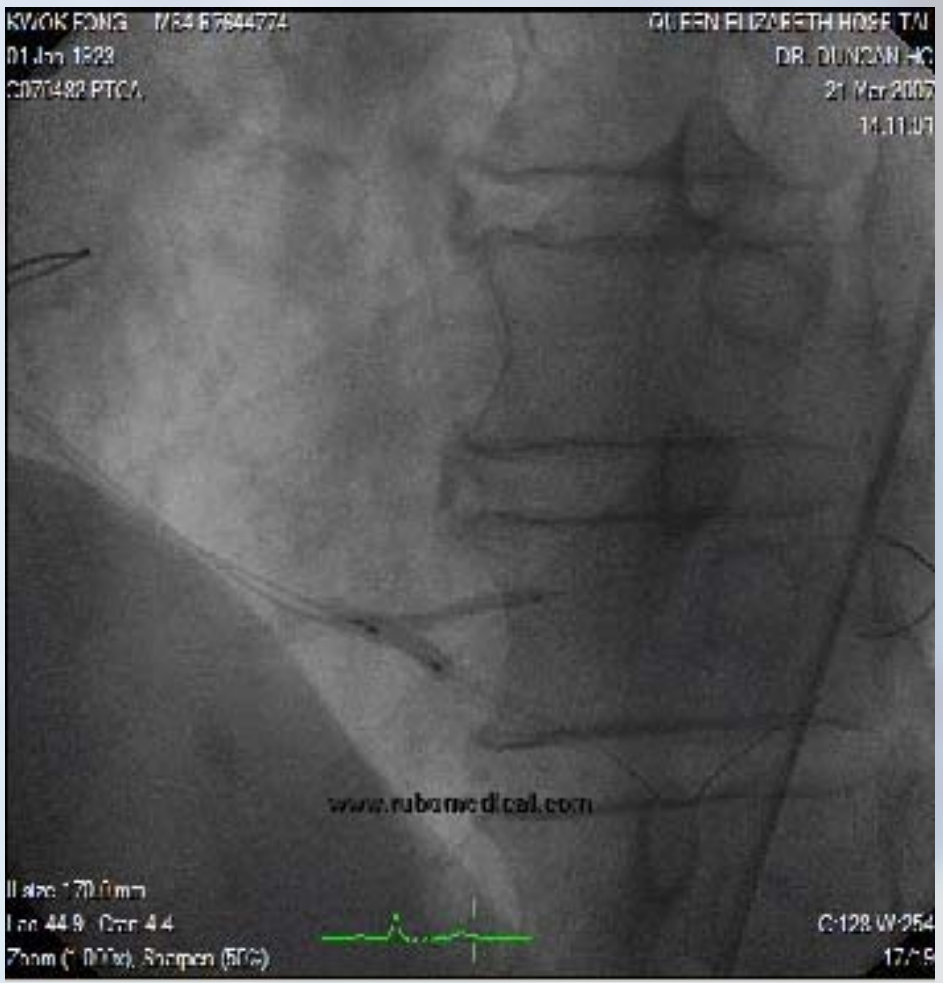
Pic: Stent from RCA to PDA: Xience V 2.5 / 18



Pic: BDC thru stent strut to PL branch

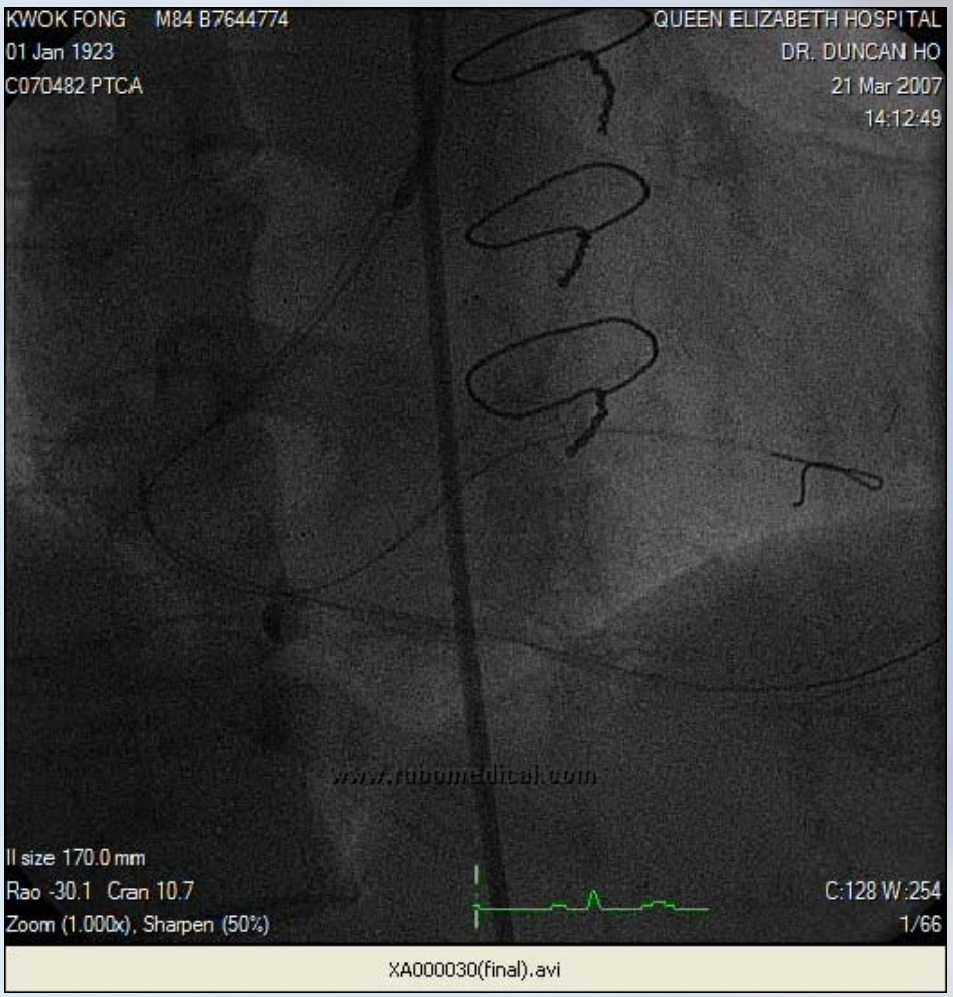
Bifurcation : PL/PDA

“Kissing balloon” technique at PL/PDA bifurcation



Result

Excellent angiographic result



CRF DES Guidelines Summary

2006

I

A - ISR of BMS (vs. PTCA or brachytherapy)

B - Chronic total occlusions

IIa

B
- Bifurcation (DES main branch, PTCA of side branch w/provisional DES)
- Aorto-ostial lesions
- Multivessel disease (mostly non complex)
- Saphenous vein grafts

C
- Planned bifurcation dual DES (for diffusely diseased side branch ≥2.5 mm diameter with ostial involvement)
- ISR of DES (?same or different DES)