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Intravascular ultrasound-guided versus angiography-guided percutaneous coronary intervention with drug-eluting stents: five-year outcomes from the CREDO-Kyoto PCI/CABG registry

Hiroki Watanabe[1], MD; Takeshi Morimoto[2], MD; Hiroki Shiomi[1], MD; Yutaka Furukawa[3], MD; Yoshihisa Nakagawa[4], MD; Kenji Ando[5], MD; Kazushige Kadota[6], MD; Takeshi Kimura[1]*, MD; on behalf of the CREDO-Kyoto PCI/CABG registry investigators

H Watanabe et al AsiaIntervention 2018; 4: 26-33

What is IVUS-guided PCI ?

① No definite criteria in the guideline

② Previous observational IVUS studies findings:

Stent underexpansion/residual reference segment stenosis risk factor for ST

(Fujii et al J Am Coll Cardiol 2005;45:995-998)

Reference segment plaque burden was associated with edge restenosis

(Sakurai et al Am J Cardiol 2005;96:1251-1253)

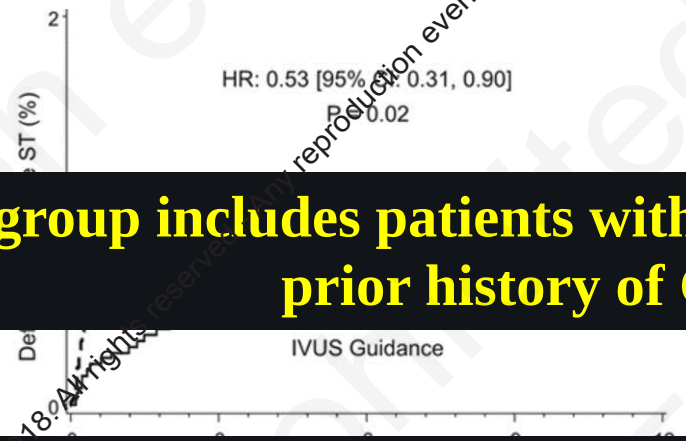
Longer stenting resulted in more stent thrombosis and restenosis

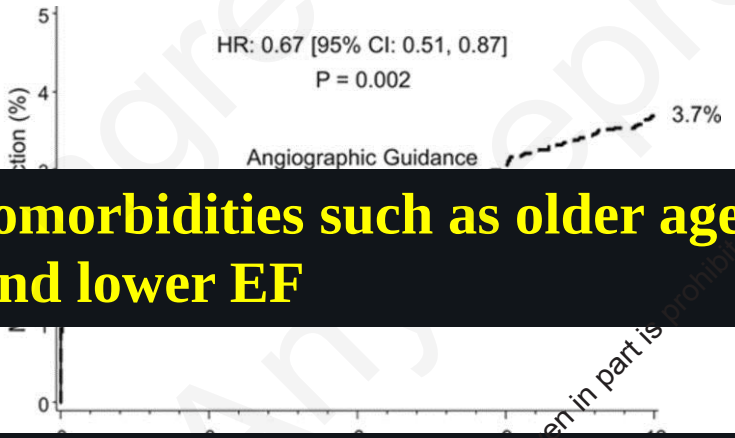
(Miura et al Am Heart J 2016;175:47-55)

③ From 'bigger is better' BMS era to 'stent optimization' DES era - the balance between less plaque burden in the landing point and shorter stent length

Relationship Between IVUS guidance and Clinical Outcomes after DES (The ADAPT-DES Study)

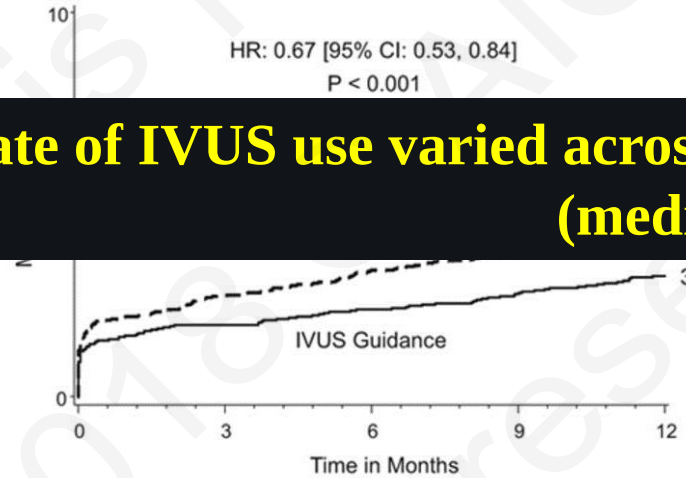
IVUS-guidance arm (n=3,361) vs angio-guidance arm (n=5,221)/largest observational study





Angio group includes patients with more comorbidities such as older age, prior history of CABG and lower EF

Study population includes both AMI and non-AMI patients (IVUS group 28%/ Angio group 22%)

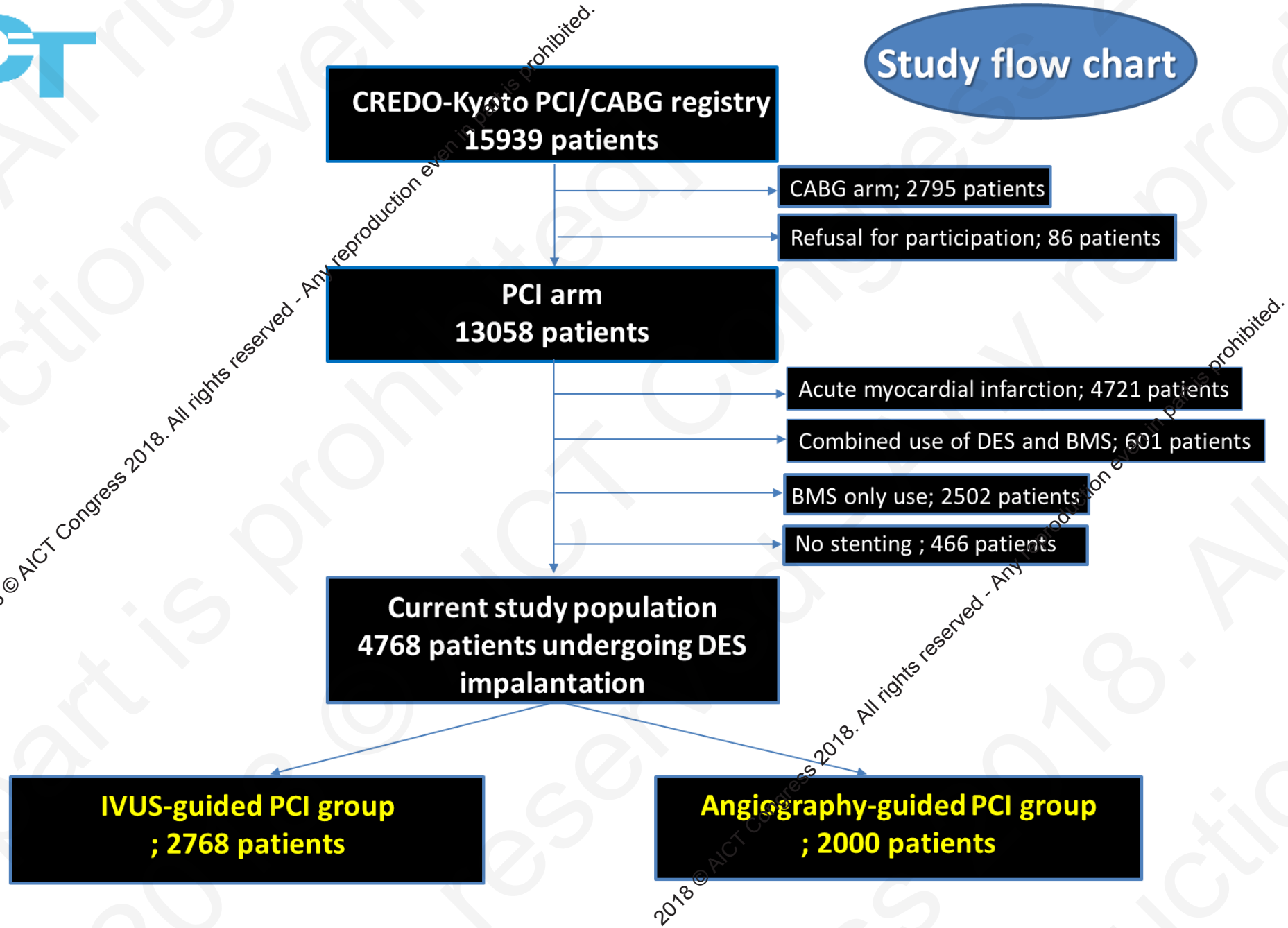


Predictors of MACE	(95% CI)	χ^2	*P* Value
IVUS guidance	0.70 (0.55–0.88)	7.56	0.002
artery disease			
Prior myocardial infarction	1.40 (1.12–1.76)	8.18	0.004
Acute coronary syndrome presentation	1.36 (1.10–1.69)	7.92	0.005

The rate of IVUS use varied across the 11 sites from 1% to 90% of cases (median; 33%)

Bernhard Witzenbichler et al Circulation 2014; 129: 463-470

Study flow chart



Results

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Baseline Patient Characteristics

Variables	IVUS-guided PCI group N=2768	Angio-guided PCI group N=2000	p value
Clinical characteristics			
Age	68.5±9.8	68.5±10.2	0.91
*>75years	845(30.5%)	602(30.1%)	0.75
*Male gender	1979(71.5%)	1433(71.7%)	0.91
Body mass index	**23.7±3.4**	**23.9±3.5**	**0.03**
*<25.0kg/m2	1855(67.0%)	1308(65.4%)	0.24
*Hypertension	2347(84.8%)	1664(83.2%)	0.14
Diabetes mellitus	1148(41.5%)	861(43.1%)	0.28
*requiring insulin therapy	286(10.3%)	241(12.1%)	0.06
*Current smoking	672(24.3%)	530(26.5%)	0.08
*Heart failure(current and prior)	404(14.6%)	310(15.5%)	0.39
*Multivessel disease	1669(60.0%)	1188(59.4%)	0.53
***Mitral regurgitation3-4/4**	**82(3.0%)**	**88(4.4%)**	**0.009**
***Previous myocardial infarction**	**378(13.7%)**	**348(17.4%)**	**0.0004**
*Previous stroke	342(12.4%)	226(11.3%)	0.27
*Peripheral vascular disease	236(8.5%)	196(9.8%)	0.13
Left ventricle ejection fraction	**61.5±12.5**	**60.0±13.1**	**0.0003**
LVEF <= 40%	**173/2556(6.8%)**	**154/1658(9.3%)**	**0.003**
*eGFR<30, without hemodialysis	99(3.6%)	80(4.0%)	0.45
*Hemodialysis	139(5.0%)	104(5.2%)	0.78
*Atrial fibrillation	225(8.1%)	160(8.0%)	0.87
*Anemia(hemoglobin<11.0g/dl)	322(11.6%)	246(12.3%)	0.48
*Thrombocytopenia(Platelet < 100*109/L)	37(1.3%)	27(1.4%)	0.97
*COPD	87(3.1%)	83(4.2%)	0.07
*Liver cirrhosis	64(2.3%)	49(2.5%)	0.76
*Malignancy	243(8.8%)	186(9.3%)	0.54

Baseline Patient Characteristics

Variables	IVUS-guided PCI group N=2768	Angio-guided PCI group N=2000	p value
Lesion and procedural characteristics			
Target lesion			
*Unprotected LMCA	117(4.2%)	62(3.1%)	0.04
***Proximal LAD**	**1827(66.0%)**	**1167(58.4%)**	**＜0.001**
LAD	**1892(68.4%)**	**1218(60.9%)**	**＜0.001**
LCX	**799(28.9%)**	**659(33.0%)**	**0.003**
RCA	**993(35.9%)**	**789(39.5%)**	**0.01**
***Bifurcated lesion**	**1208(43.6%)**	**770(38.5%)**	**0.0004**
***Chronic total occlusion**	**353(12.8%)**	**383(19.2%)**	**<.0001**
*Side-branch stenting	142(5.1%)	128(6.4%)	0.06
SES only use	2459(88.8%)	1799(90.0%)	0.22
TAXUS only use	**207(7.5%)**	**84(4.2%)**	**<.0001**
Implanted stents	2(1-2)	2(1-2)	0.26
Total stent length(mm)	36(23-56)	33(18-56)	0.14
***>28mm**	**1570(56.7%)**	**1053(52.7%)**	**0.005**
MSD(mm)	**2.75(2.5-3.0)**	**2.5(2.5-3.0)**	**0.004**
*< 3.0mm	1425(51.5%)	1082(54.1%)	0.07

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Baseline Patient Characteristics

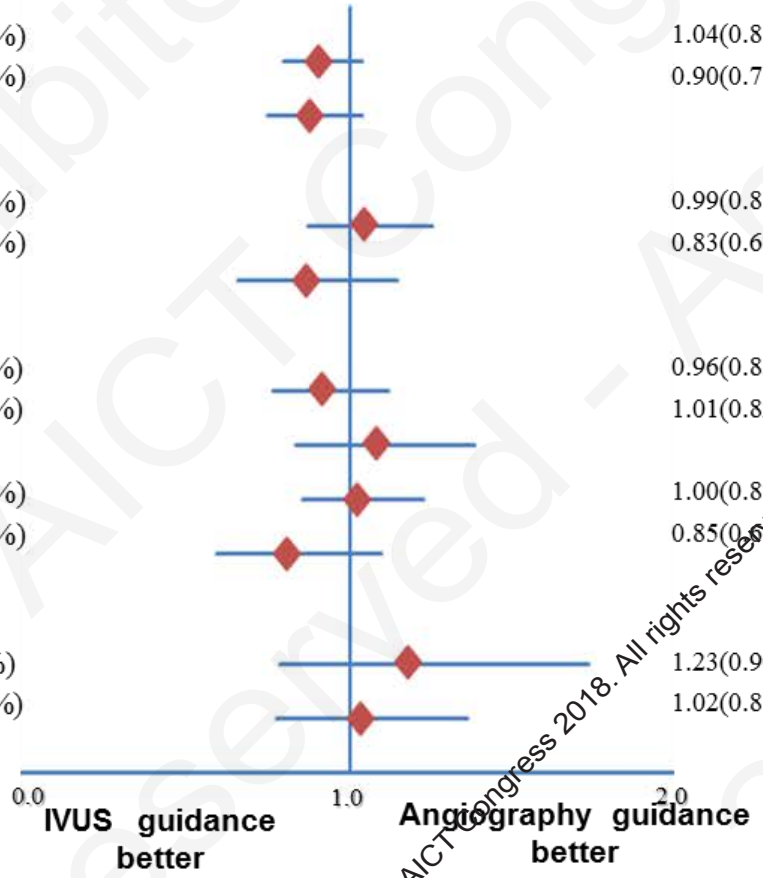
Variables	IVUS-guided PCI group N=2768	Angio-guided PCI group N=2000	p value
Medication at discharge			
Aspirin	2732(98.7%)	1971(98.6%)	0.66
Thienopyridine	2759(99.7%)	1995(99.8%)	0.63
Cilostazole	**264(9.5%)**	**138(6.9%)**	**0.001**
Statin	**1603(57.9%)**	**961(48.1%)**	**<.0001**
ACE-I/ARB	**1474(53.3%)**	**962(48.1%)**	**0.0004**
β blocker	720(26.0%)	521(26.1%)	0.98
Calcium channel blocker	1458(52.7%)	1005(50.3%)	0.10
Nitrate	**940(19.7%)**	**838(17.6%)**	**<.0001**
Nicorandil	**656(23.7%)**	**401(20.1%)**	**0.003**
PPI	**648(23.4%)**	**365(18.3%)**	**<.0001**
H2 blocker	**630(22.8%)**	**390(19.5%)**	**0.007**
Warfarin	217(7.8%)	149(7.5%)	0.62

Clinical Outcomes

Variables	IVUS group Number of patients with events (Cumulative 5-year incidence) N=2768	Angio group Number of patients with events (Cumulative 5-year incidence) N=2000	Crude HR (95%CI)	P value (log-rank)	Adjusted HR (95%CI)	P value
TVR	556(21.5%)	408(22.2%)	0.97 (0.85-1.09)	0.57	1.09 (0.90-1.32)	0.37
Clinically-driven TVR	281(11.3%)	211(11.8%)	0.94 (0.79-1.11)	0.44	1.01 (0.78-1.31)	0.93
All-cause death	368(14.1%)	303(16.0%)	0.85 (0.74-0.98)	0.02	0.82 (0.65-1.02)	0.08
Myocardial infarction	177(6.8%)	143(7.4%)	0.84 (0.68-1.04)	0.12	0.87 (0.62-1.22)	0.41
Definite stent thrombosis	31(1.2%)	20(1.1%)	1.14 (0.68-1.98)	0.62		-
MACE	905(33.9%)	699(36.2%)	0.90 (0.82-0.99)	0.02	0.96 (0.83-1.11)	0.64

Subgroup Analysis

Variable	IVUS group No. of patients with TVR (Cumulative incidence) N=2768	Angiography group No. of patients with TVR (Cumulative incidence) N=2000	Crude HR (95% CI)	Log-rank P	Adjusted HR (95% CI)	P value	Interaction P
Diabetes	291 (27.3%)	208 (26.7%)	1.04(0.88-1.24)	0.65	0.92(0.83-1.03)	0.14	0.35
Non-diabetes	265 (17.5%)	200 (18.9%)	0.90(0.75-1.07)	0.23	0.91(0.76-1.09)	0.31	
Total stent length							
>28mm	406 (27.9%)	271 (27.9%)	0.99(0.85-1.15)	0.88	1.04(0.89-1.21)	0.66	0.14
<=28mm	150 (13.7%)	137 (15.9%)	0.83(0.67-1.04)	0.11	0.89(0.71-1.12)	0.31	
Minimal stent diameter							
< 3mm	351(26.3%)	273(27.5%)	0.96(0.83-1.12)	0.61	0.93(0.80-1.10)	0.41	<.0001
>= 3mm	205(16.5%)	135(16.1%)	1.01(0.82-1.25)	0.93	1.07(0.86-1.32)	0.55	
Multi-vessel disease	420 (27.0%)	291 (27.0%)	1.00(0.87-1.16)	0.97	1.02(0.88-1.19)	0.76	0.13
Single-vessel disease	136 (13.3%)	117 (15.4%)	0.85(0.67-1.07)	0.169	0.84(0.66-1.08)	0.18	
IVUS use per centers							
Frequent use (>70%)	470(21.3%)	33(16.8%)	1.23(0.90-1.74)	0.22	1.15(0.82-1.61)	0.42	0.36
Non-frequent use (≦ 70%)	86(22.7%)	375(22.8%)	1.02(0.81-1.28)	0.84	1.03(0.81-1.30)	0.81	



Conclusion

IVUS-guided PCI as compared with Angiography-guided PCI was not associated with a lower risk for TVR in non-AMI patients treated with first-generation DES.

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My Personal Take

① Registry studies with significant difference in baseline patient characteristics

② IVUS use up to operators- selection bias; no criteria about stent optimisation

③ Lack of difference heavily influenced by operators' judgement and experience

Defining optimal stent overexpansion strategies for left main stenting: insights from bench testing

Jiang Ming Fam[1,2*], MBBS; Peter Mortier[3,4], PhD; Matthieu De Beule[3,4], MS, PhD; Tim Dezutter[3,4], MS; Nicolas Van Mieghem[1], MD, PhD; Roberto Diletti[1], MD, PhD; Bert Everaert[1,5], MD, PhD; Soo Teik Lim[2], MBBS; Felix Zijlstra[1], MD, PhD; Robert-Jan van Geuns[1], MD, PhD

1. Thoraxcenter, Erasmus University Medical Center, Rotterdam, the Netherlands; 2. National Heart Centre Singapore, Singapore; 3. FEops-bioMMeda, iMinds Medical IT, Ghent University, Ghent, Belgium; 4. FEops, Ghent, Belgium; 5. AZ Monica Hospital, Antwerp, Belgium

This paper also includes supplementary data published online at: www.asiaintervention.org

JM Fam et al AsiaIntervention 2017, 3: 111-120

Background- LM PCI

- Increasingly used as a mode of revascularization in selected cases
- Key Considerations

Large Vessel Diameter

- Beyond max diameter of delivery balloon catheter of largest stent size available.
- Frequently require post dilation with larger balloons for full apposition.
- Beyond manufacturer recommended max diameter of stent

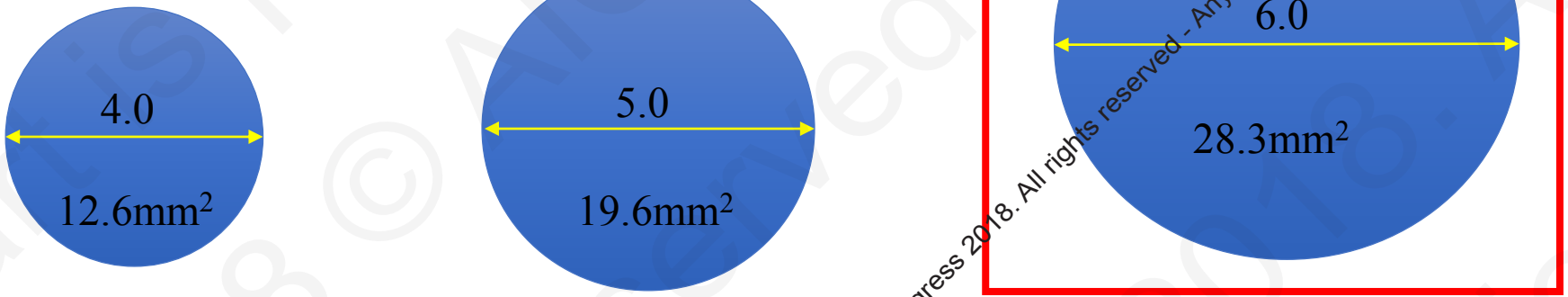
Ostial Stenting: High Radial Strength to Prevent Recoil

And/ Or Bifurcation stenting

Key Procedural Challenge: To achieve adequate expansion with minimal malapposition

Study Objectives

- To investigate if overexpansion could be achieved beyond the recommended stent expansion limit for a metallic stent platform
- To compare different expansion techniques to achieve optimal apposition



Methods

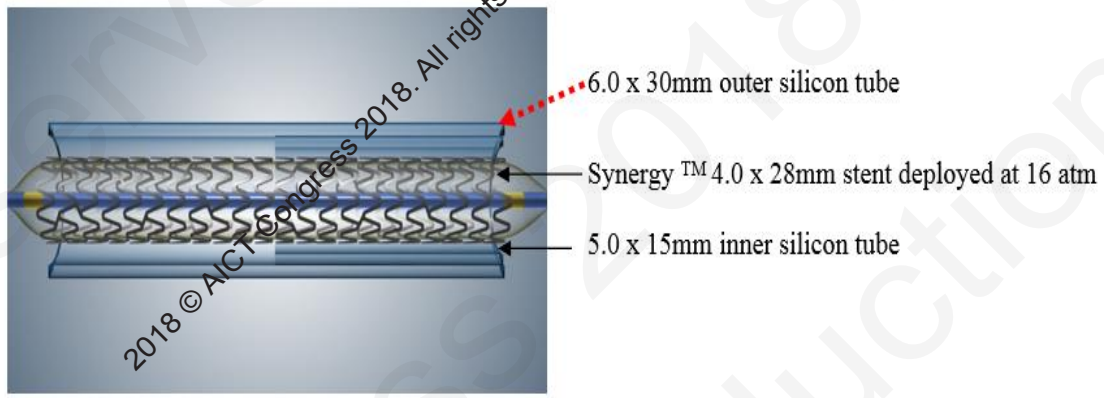
- In vivo bench testing

- SYNERGY ™ stent (Boston Scientific, MN, USA)
  - DES with large vessel design
  - Thin struts made of platinum chromium
  - 4.0 x 28mm

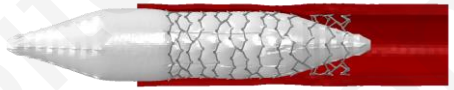
Labelled Post Dilation Limit: 5.75mm

- Stents deployed in an aqueous bath at standard temperature of 37 ±1 degree Celsius

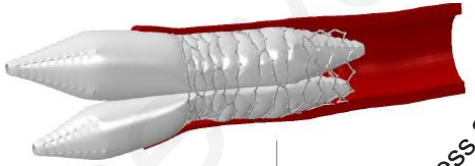
- Stent expansion and apposition were evaluated by implanting the stents in silicon tube phantom models



Methods- Post Dilation Techniques



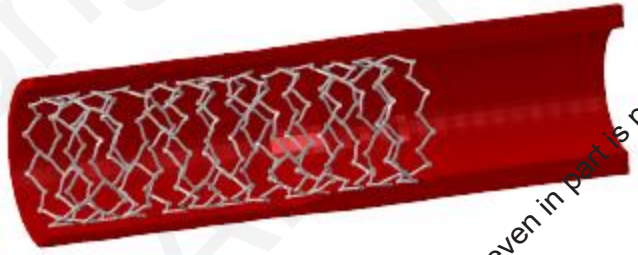
Proximal Optimisation Technique



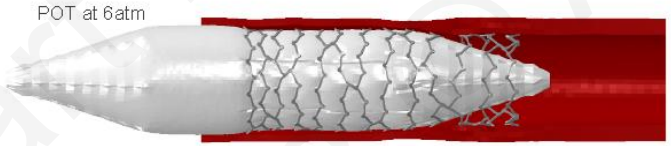
Final Kissing Balloon Dilation

POT for Overexpansion: Target for Outer SD 6mm

- Size of semi/ non-compliant balloons
  6 mm



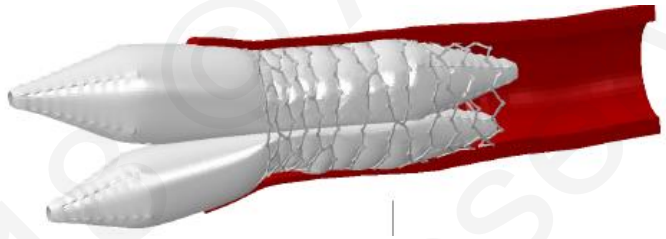
- Pressure
  6 atm (POT-SC/LP) vs 14 atm (POT-SC/SP) vs 24 atm (POT- NC/HP)



SD: Stent Diameter

FKBD for Overexpansion: Target for Outer SD 6mm

- Size of balloons
  - 3.5 + 4.0 mm at SP 12 atm (FKBD-US/SP)
  - 4.0 + 5.0 mm at LP 4 atm and SP 12 atm (FKBD-OS/LP and FKBD-OS/SP) respectively
- For optimal-sized (OS) balloons, we look at differential effects of pressure
  - 4 atm (FKBD-LP) vs 12 atm (FKBD-RBP)

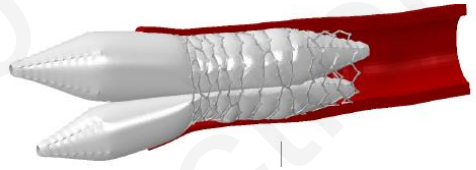


SD: Stent Diameter

Objectives

- Measure the effect of overexpansion on a 4.0 x 28mm SYNERGY stent with 6.0mm balloons [Semicompliant (SC) Maverick XL™ or Noncompliant (NC) Emerge™) using
  - Proximal Optimisation Technique (POT) at low pressure (LP) of 6 atm (Group 1 POT-SC/LP)
  - POT at standard pressure (SP) of 14 atm (Group 2 POT-SC/SP)
  - POT at high pressure (HP) of 24 atm (Group 3 POT-NC/HP)

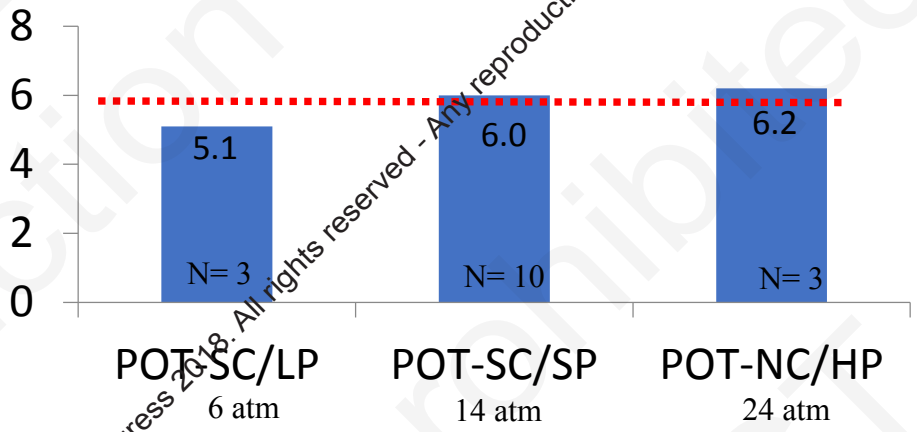
- Evaluate the effect of common clinical Final Kissing Balloon Dilation (FKBD) methods
  - Using the relative undersized (US), but commonly used 3.50mm and 4.00mm (Apex™) balloons at standard pressure (SP) of 12 atm (Group 4 FKBD-US/SP)
  - Using the optimal (according to Finet's Law*) sized (OS) 4.00mm and 5.00mm (Apex™) balloons at LP of 4 atm (Group 5 FKBD-OS/LP) and at SP of 12atm (Group 6 FKBD- OS/SP)



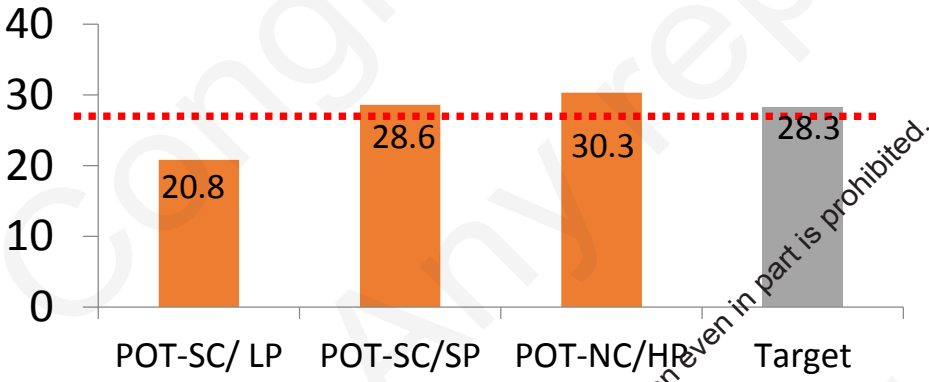
*** Finet G et al EuroIntervention 2008; 3: 490-98**

Results: POT

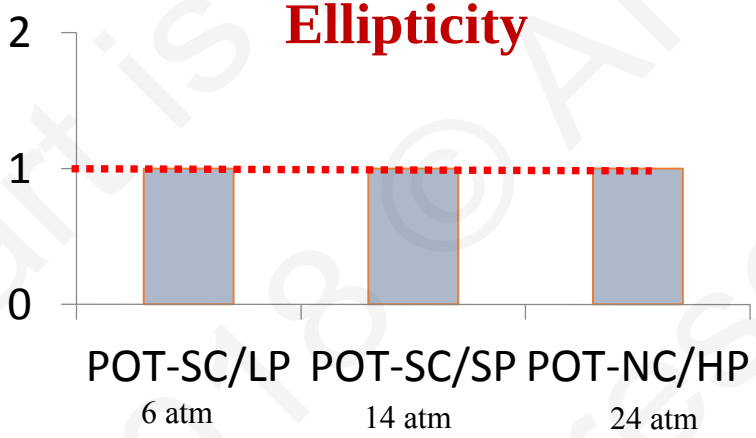
Stent Outer Diameter (mm)

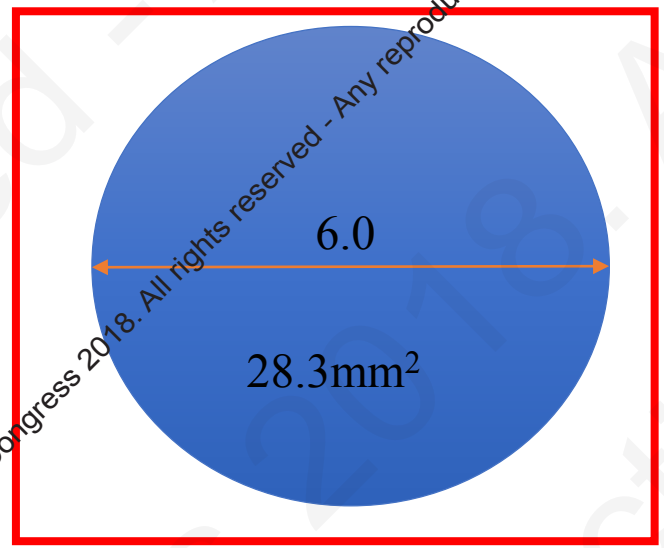


Stent Outer Area (mm^2)



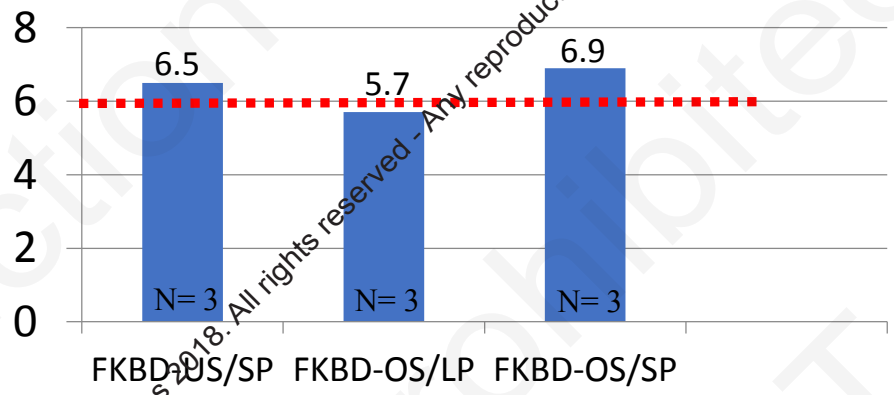
Ellipticity



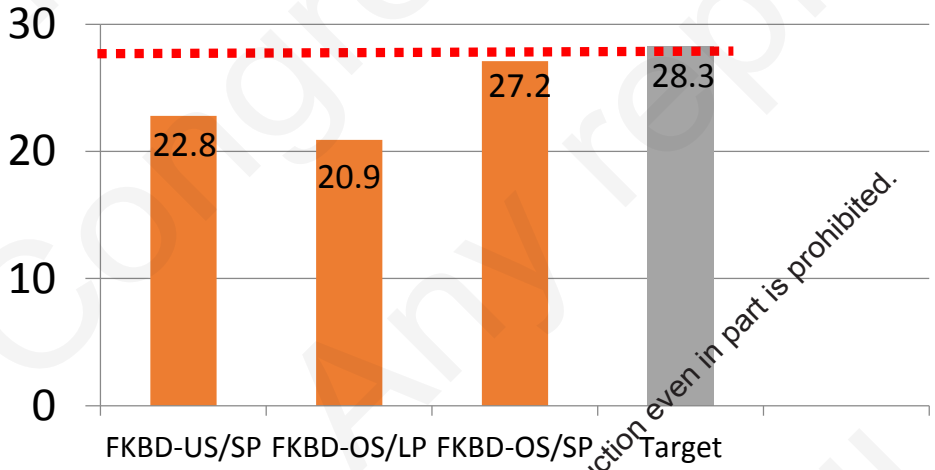


Results: FKBD

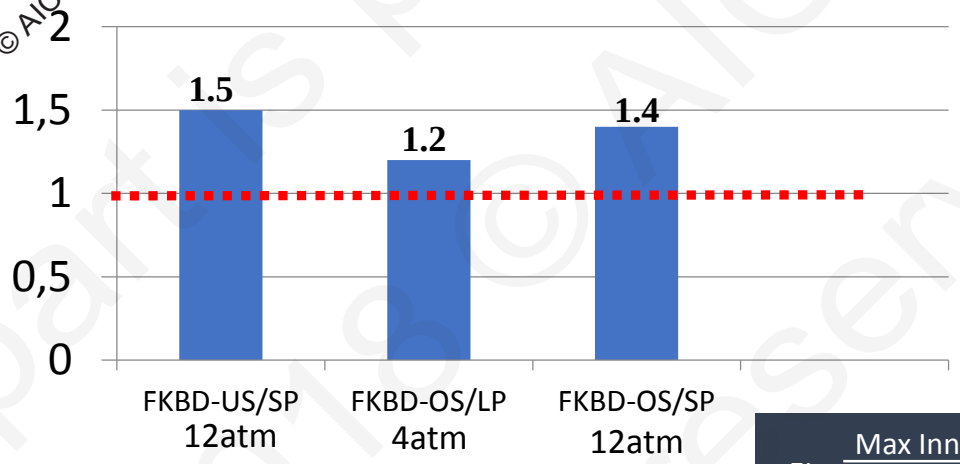
Stent Outer Diameter (mm)



Stent Outer Area (mm^2)

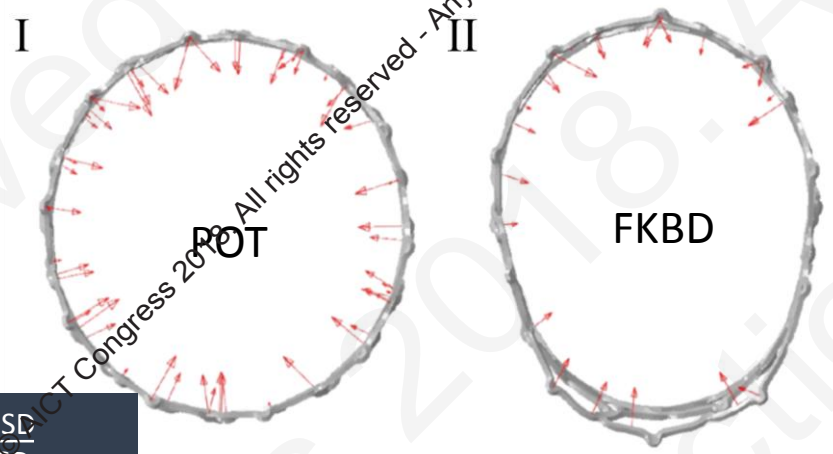


Ellipticity



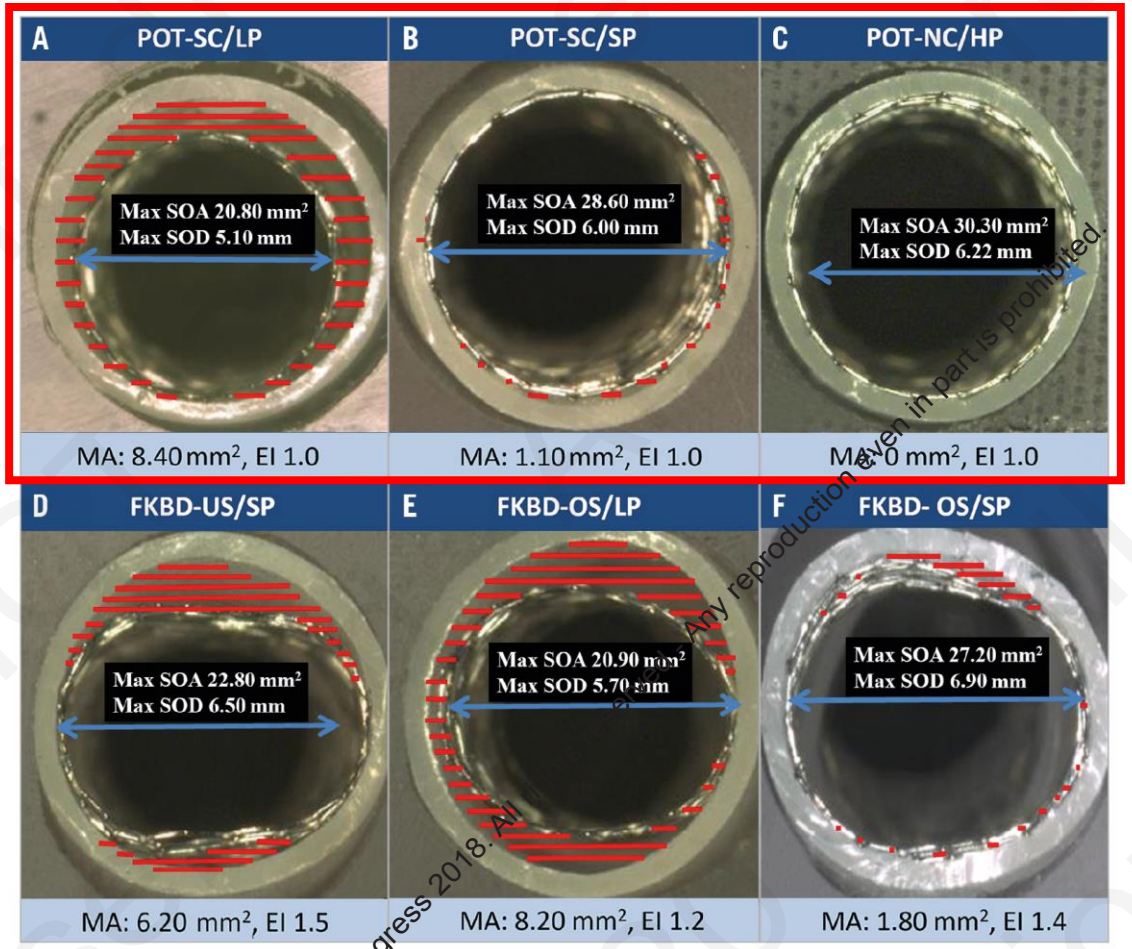
EI: $\frac{\text{Max Inner SD}}{\text{Min Inner SD}}$

Simulation models



Discussion: POT

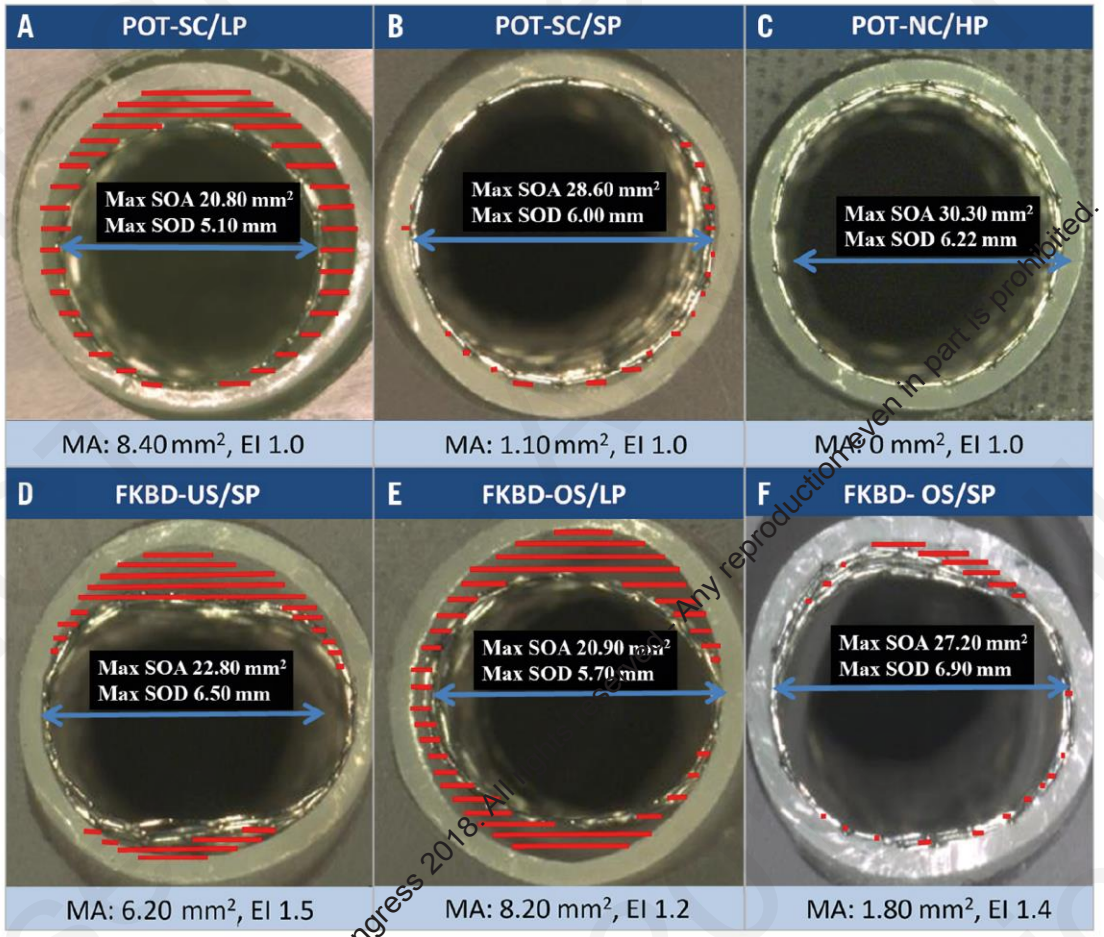
- POT-SC/LP: High Malapposed Area
- Most Optimal: POT NC/HP



FKBD: final kissing balloon dilation; HP: high pressure; LP: low pressure; OS: optimally sized; POT: proximal optimisation technique; SC: semi-compliant; SP: standard pressure; US: undersized; MA-Malapposed area; *SOD: stent outer diameter; SOA Stent Outer Area*

Discussion: FKBD

- Serious ellipticity; Highest EI asymmetry with “US” balloons
- Adequate size and pressure necessary to achieve high stent outer diameter
  - EI and MA still higher compared to POT
  - Stent Outer Area still less than POT



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Conclusion

- PtCr EES 4.0mm can be expanded to an OD of 5.1mm by using POT (6.0 mm balloon at 6 atm). Further post dilatation with higher pressures (14 atm) resulted in an OD of **6.0mm**.

- With FKBD using usual balloon sizes for bifurcation stenting, malapposition in the LM shaft is significant when large diameters are present. FKBD with either undersized or adequately sized balloons resulted in higher ellipticity.

- Besides avoiding eccentricity seen in FKBD, POT will result in full apposition in large LM shaft and ostial segments.

OD- Outer Diameter

My Personal Take

- Important bench research for better understanding of extreme stent overexpansion in left main PCI

- Proximal optimization (POT) using adequately sized balloons **and** pressure should be the technique of first choice to achieve optimal stent expansion

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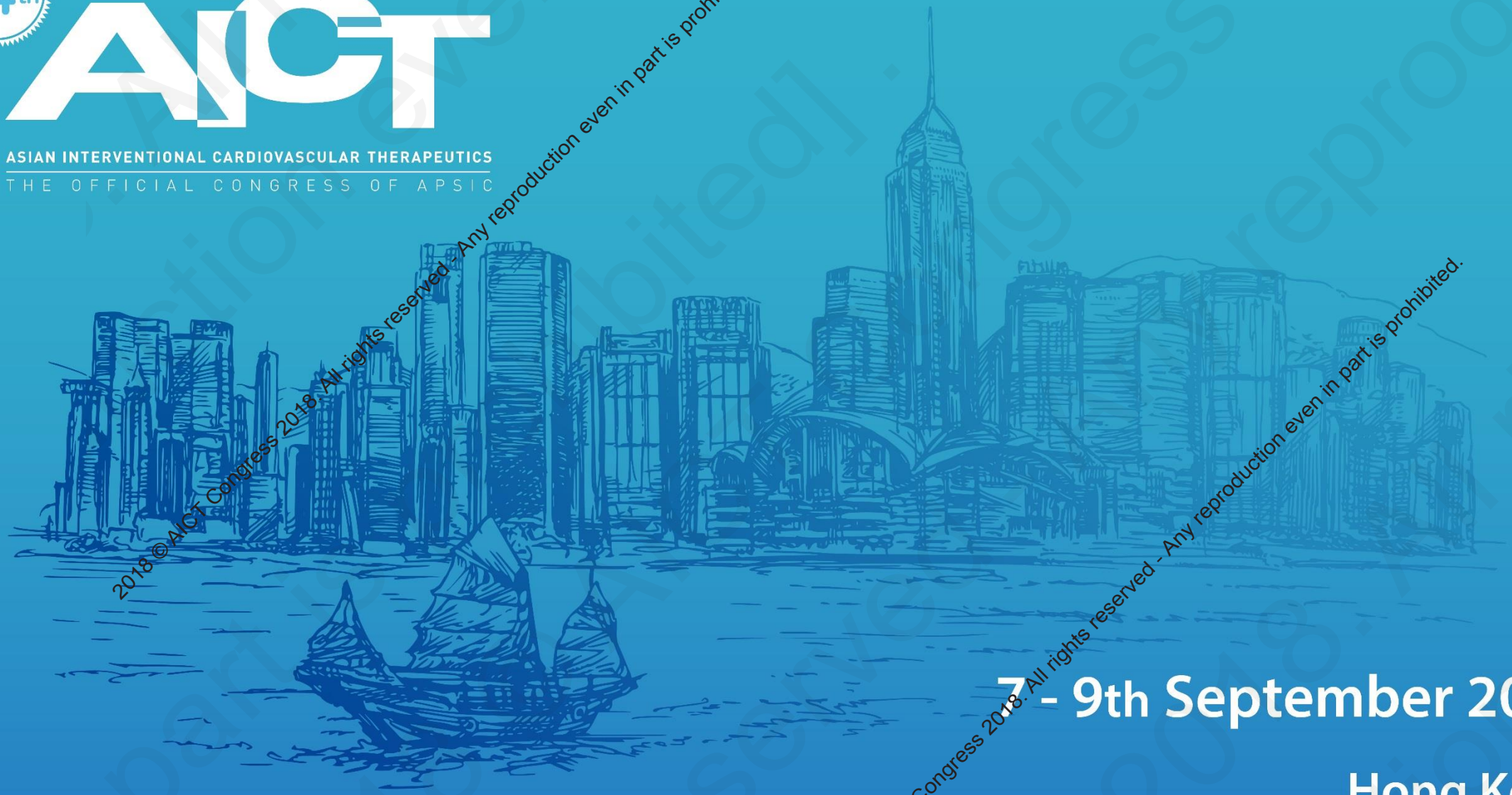

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