DES Safety in Bifurcation Lesions

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On behalf of the ICPS Team

Angioplasty Summit TCT Asia Pacific

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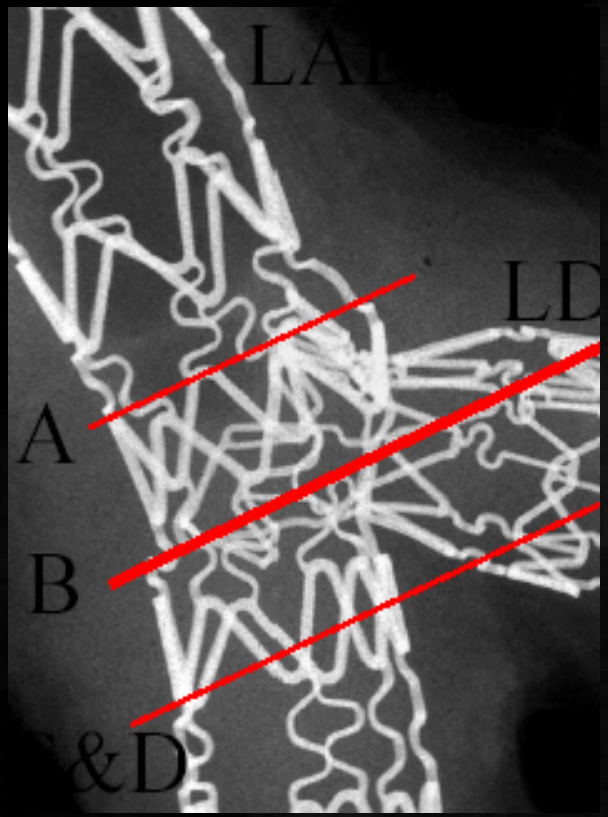
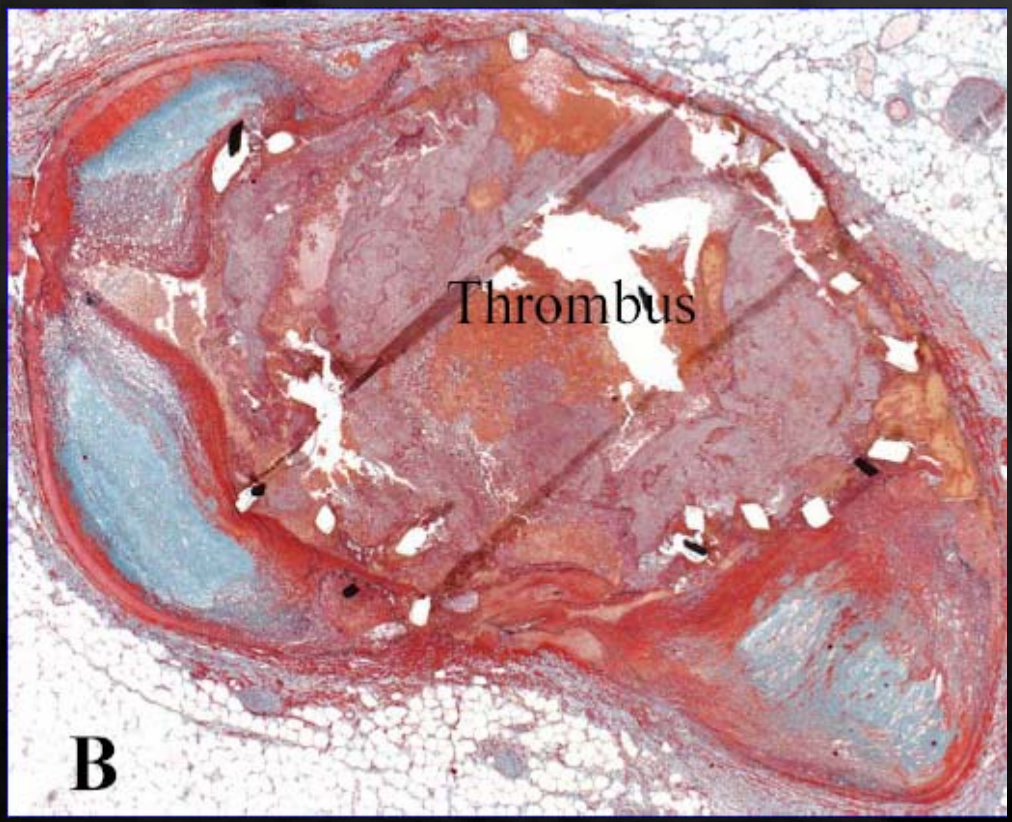
The Convention Center of Sheraton Grande Walkerhill Hotel, Seoul, Korea

Safety Issues with 2 DES





« … cause of stent thrombosis stent underexpension, crush technique … »

Renu Virmani et al, TCT 2004

Safety Issues with Bifurcation Lesions ?

Iakovou et al.	*JAMA 2005;293:2126-2130*
Ong et al.	*JACC 2005;45:947-53*
Kuchulakanti et al.	*Circulation 2006;113:1108-1113*

Incidence, Predictors, and Outcome of Thrombosis After Successful Implantation of Drug-Eluting Stents

SES (n = 1062), PES (n = 1167)

Early and Late stent thrombosis

Variables	Hazard Ratio (95% CI)	*P value*
Premature antiplatelet ther. disc.	89.78 (29.90-269.60)	.001
Renal failure	6.49 (2.60-16.15)	.001
Bifurcation lesion	6.42 (2.93-14.07)	.001
Diabetes	3.71 (1.74-7.89)	.001
LVEF per 10% decrease	1.09 (1.05-1.13)	.001

Iakovou et al. JAMA 2005;293:2126-2130

Independent Predictors of Stent Thrombosis

SES (n = 1062), PES (n = 1167)

Late stent thrombosis

Variables	Hazard Ratio (95% CI)	*P* Value
Premature antiplatelet ther.	57.13 (14.84-219.96)	.001
Bifurcation lesion	8.11 (2.50-26.26)	.001
LVEF per 10% decrease	1.06 (1.01-1.12)	.03

Iakovou et al. JAMA 2005;293:2126-2130

Thirty-Day Incidence and Six-Month Clinical Outcome of Thrombotic Stent Occlusion After Bare-Metal, Sirolimus, or Paclitaxel Stent Implantation

Multivariate analysis

Bifurcation OR 3.0, 95% CI 1.3-6.8, p< 0.01

Bifurcation + AMI OR 12.9, 95% CI 4.7-35.8, p< 0.001

Ong et al JACC 2005;45:947-53

Thirty-Day Incidence and Six-Month Clinical Outcome of Thrombotic Stent Occlusion After Bare-Metal, Sirolimus, or Paclitaxel Stent Implantation

Patient	1	2	3	4	5	6	7	8	9	10
Type of DES	SES	SES	SES	SES	SES	SES	SES	SES	SES	SES
Time to Thrombosis (days)	0.125	11	7	10	1.08	6	3	7	17	3
Baseline characteristics										
Age (yrs)	72	61	86	57	75	55	53	58	58	74
Gender	F	F	F	M	F	F	M	M	M	M
Diabetes	+	+	−	+	−	−	+	−	+	−
Current smoker	−	−	−	+	−	−	−	−	−	−
Previous MI	−	+	−	+	−	−	+	−	+	+
Previous intervention	−	−	−	+	−	+	+	−	−	−
Index procedure										
Indication for procedure	UAP	AP	UAP	AMI, ST	AP	AP, ISR	UAP post-AMI	AP	AMI	UAP post-AMI
Glycoprotein IIb/IIIa use	−	−	−	Y	−	−	−	Y	Y	−
Angiographic features of index procedure										
Culprit vessel	LAD	LAD	LAD	LAD	LAD/DIAG	LAD/DIAG	RCA	LAD	DIAG	LAD
Lesion type (AHA)	B1	C	C	C	B2	C	B2	B2	B2	B2
Bifurcation technique (where performed)	−	−	−	−	crush	t-stent	−	−	t-stent	−
Final kissing balloons in bifurcation	−	−	−	−	Y	N			N	

Ong et al JACC 2005;45:947-53

Thirty-Day Incidence and Six-Month Clinical Outcome of Thrombotic Stent Occlusion After Bare-Metal, Sirolimus, or Paclitaxel Stent Implantation

Patient	11	12	13	14	15	16	17	18	19	20	Mean ± SD, %
Type of DES	PES	PES	PES	PES	PES	PES	PES	PES	PES	PES	
Time to Thrombosis (days)	0.04	4	7	6	3	4	24	5	5	3	6.3 ± 5.7
Baseline characteristics											
Age (yrs)	59	50	67	47	61	52	60	54	65	31	59.7 ± 11.9
Gender	M	M	M	F	M	F	M	M	M	M	13 M:7 F
Diabetes	–	–	–	–	+	–	–	–	–	–	30%
Current smoker	–	–	–	+	+	+	–	+	–	+	30%
Previous MI	–	–	+	–	+	–	+	–	+	–	45%
Previous intervention	–	–	+	–	–	–	–	–	–	+	25%
Index procedure											
Indication for procedure	AMI	AMI	AP	AMI	AP	AMI	AP	AMI	AP	AP	
Glycoprotein IIb/IIIa use	–	–	–	Y	–	–	–	Y	Y	–	30%
Angiographic features of index procedure											
Culprit vessel	RCA	LAD	OMCX	LAD/DIAG	LCx	LCx/OMCx	LCx	LAD/Diag	LAD/IM/LCx	LAD	
Lesion type (AHA)	B2	B2	C	C	B2	C	C	C	C	B2	
Bifurcation technique (where performed)	–	–	crush	crush	–	t-stent	–	crush	culotte crush	–	40%
Final kissing balloons in bifurcation	–	–	N	N	–	N	–	N	Y	–	

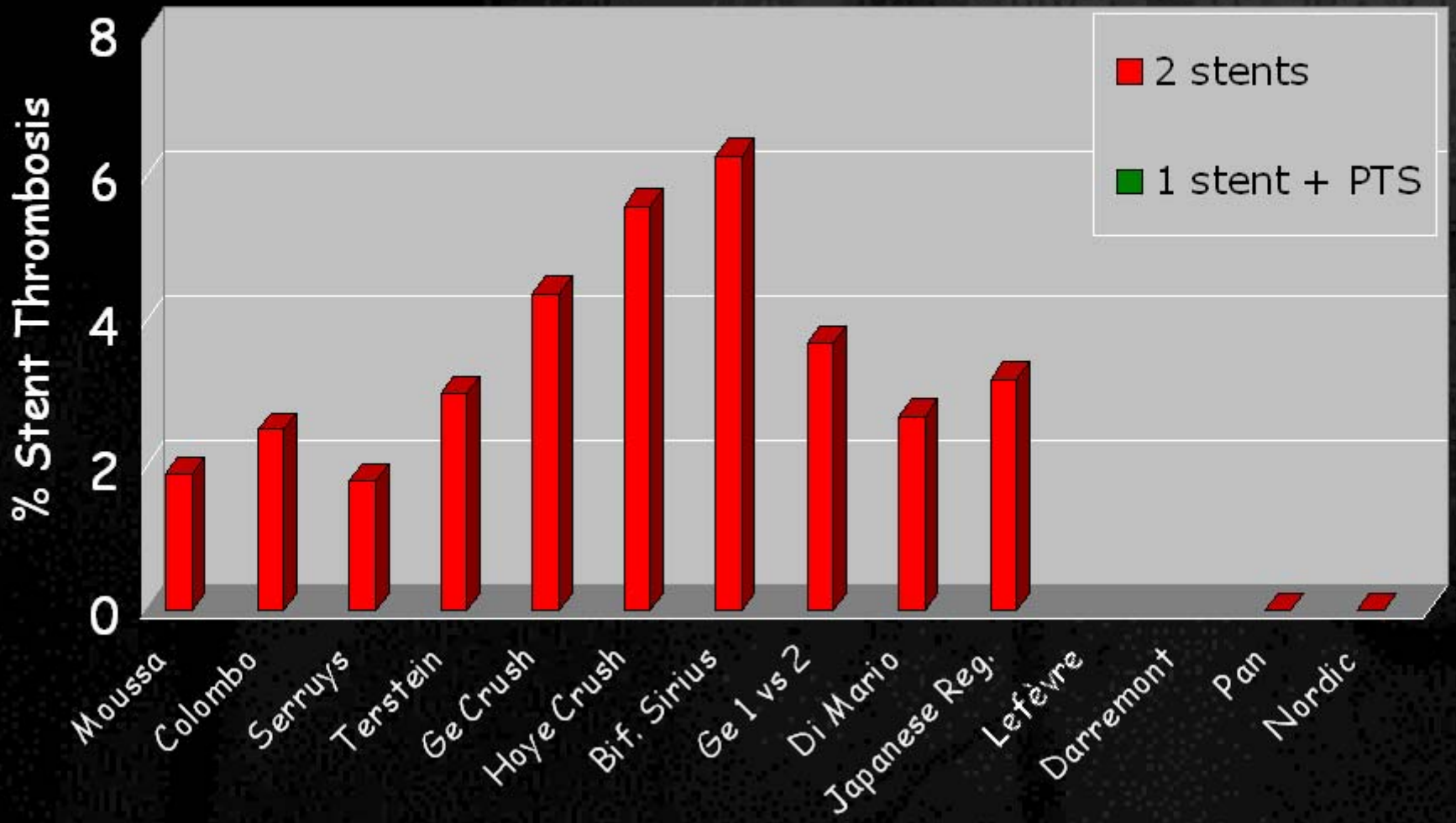
Ong et al JACC 2005;45:947-53

Correlates and Long-Term Outcomes of Angiographically Proven Stent Thrombosis With Sirolimus- and Paclitaxel-Eluting Stents

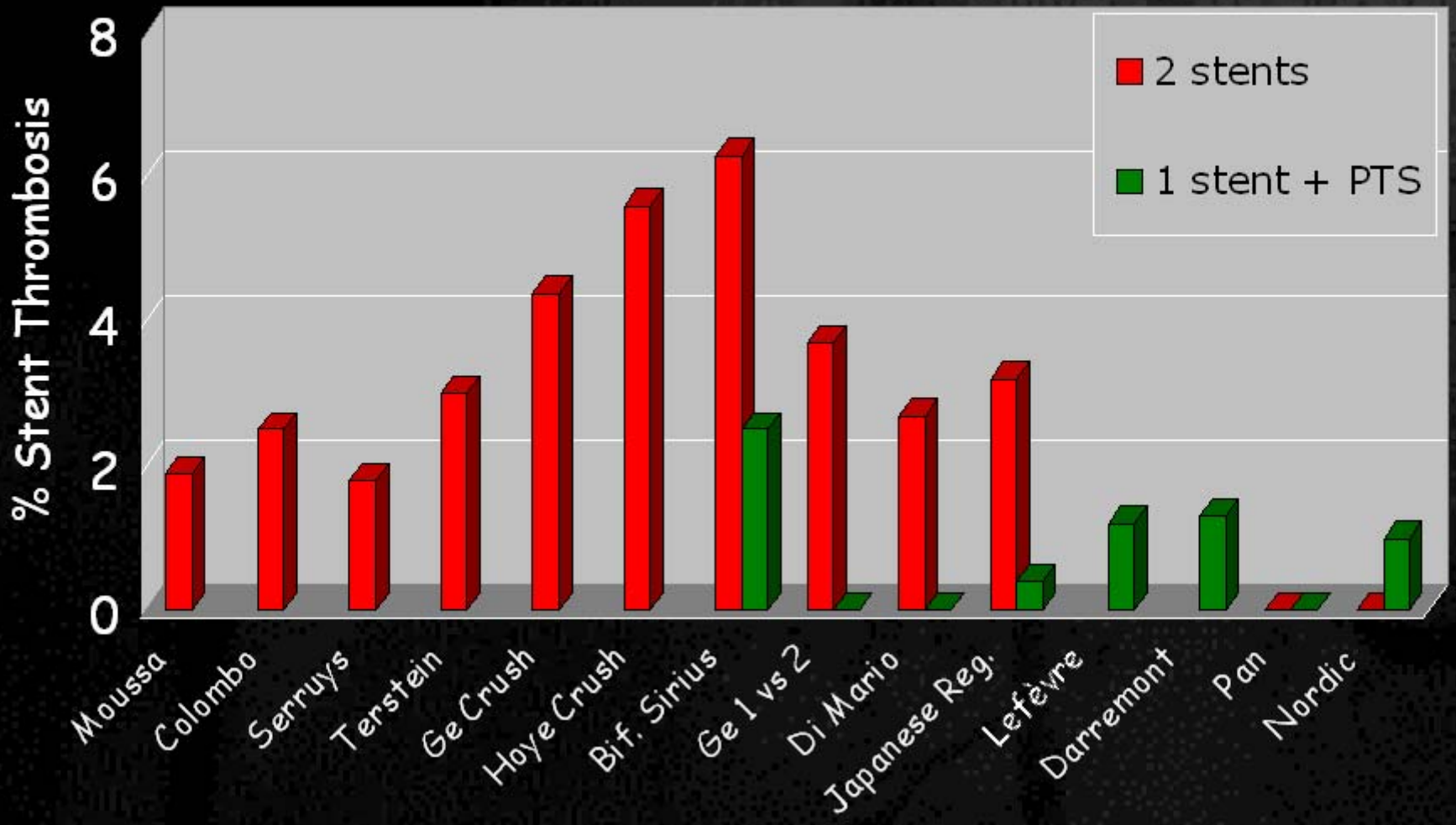
Multivariate predictors			
Age	0.97	0.94–1.0	0.06
Male	0.66	0.31–10.4	0.27
History of CABG	0.15	0.01–1.2	0.07
In hospital Renal failure	3.75	1.2–11.3	0.0183
IDDM	2.0	0.84–4.9	0.12
Bifurcation lesion	4.4	1.96–10.0	0.0004
In-stent restenosis	4.5	1.8–11.4	0.0013
Lack of clopidogrel therapy	0.21	0.09–0.49	0.0003

Kuchulakanti et al. Circulation 2006;113:1108-1113

DES in Bifurcation Lesions: Safety

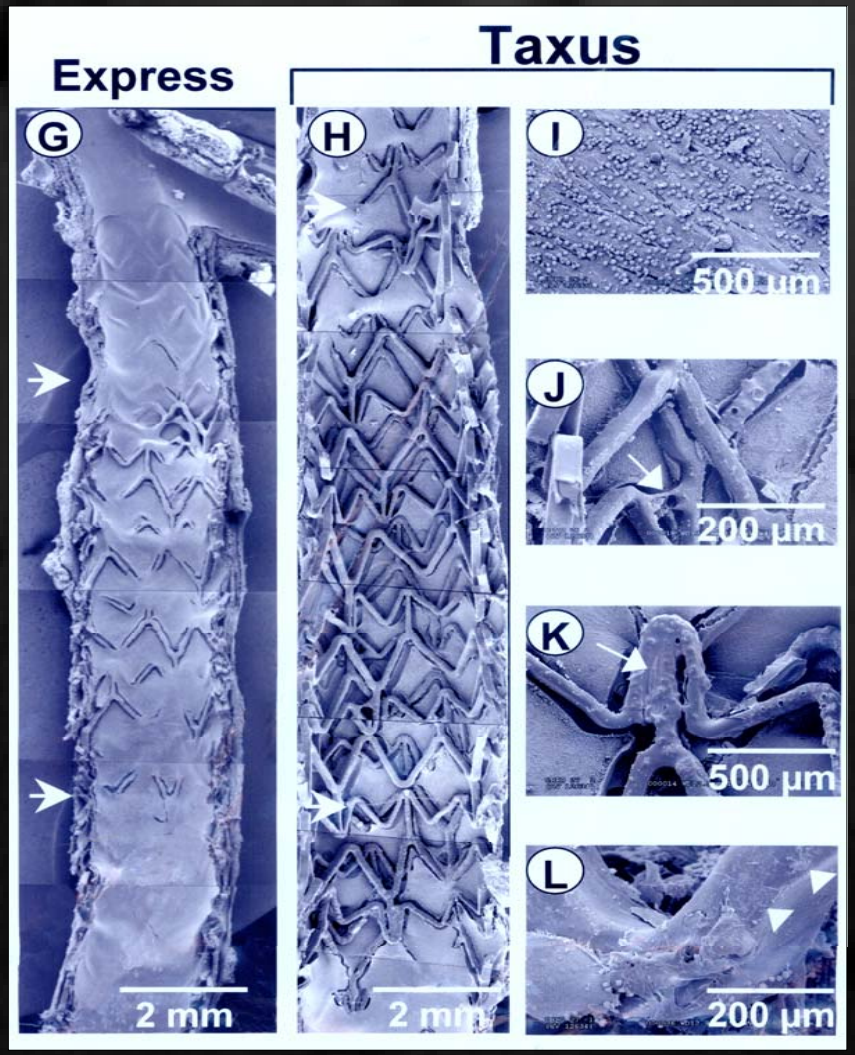


DES in Bifurcation Lesions: Safety



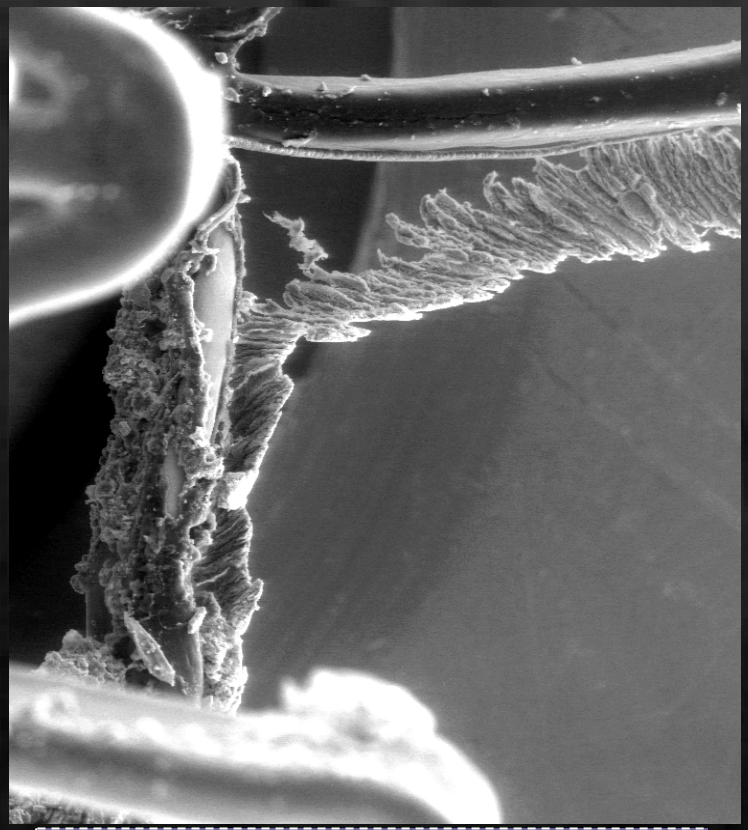
Can we Explain Safety Issues In Bifurcation Lesions ?

1. Excess of Metal



Finn et al ACC 2005

2. Fracture of the Polymer



High Pressure (20 atm. 5x)
Repeated “Kissing”

Courtesy of J. Ormiston

3. Rheology not Optimal

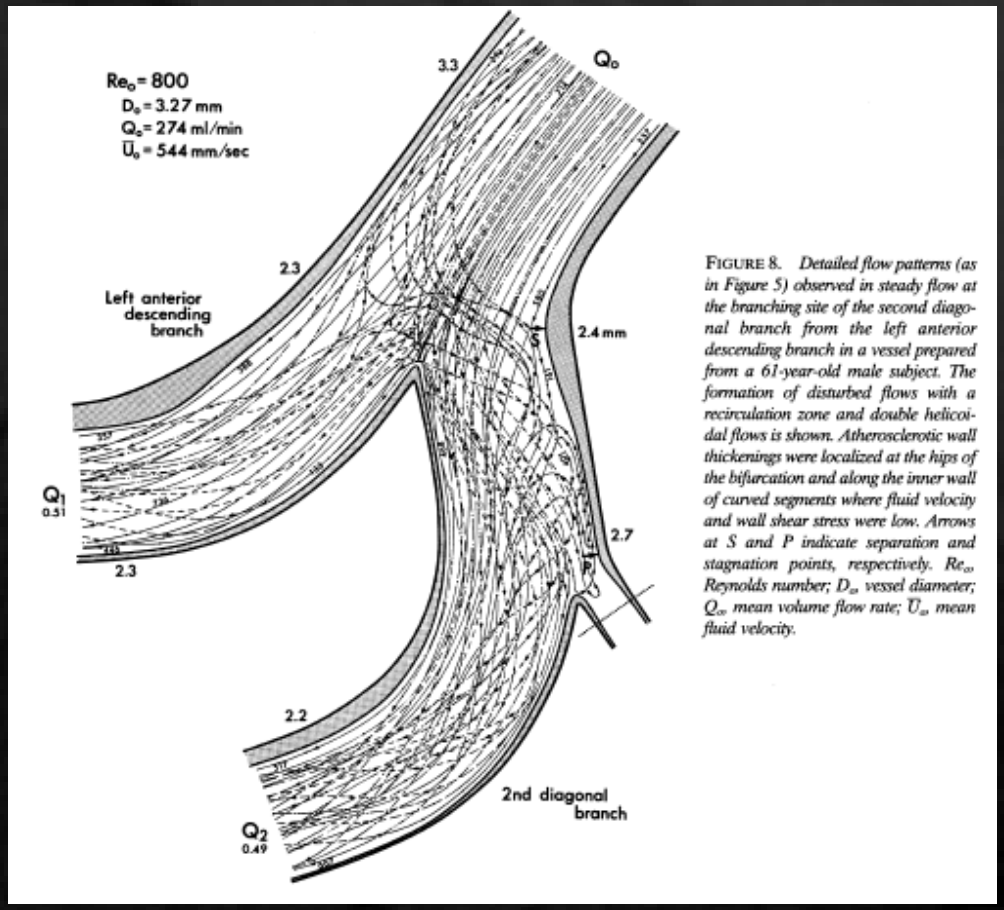
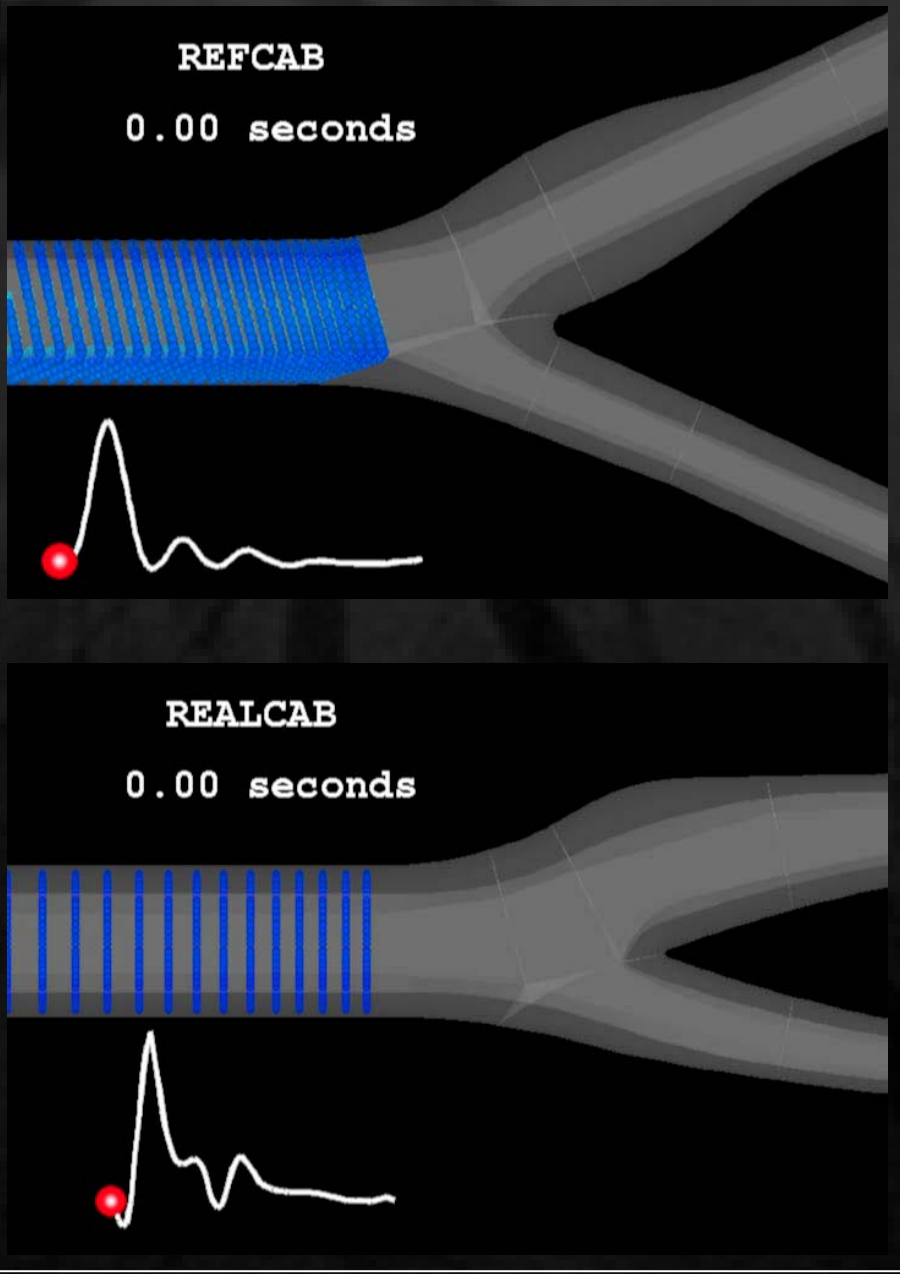


FIGURE 8. *Detailed flow patterns (as in Figure 5) observed in steady flow at the branching site of the second diagonal branch from the left anterior descending branch in a vessel prepared from a 61-year-old male subject. The formation of disturbed flows with a recirculation zone and double helicoidal flows is shown. Atherosclerotic wall thickenings were localized at the hips of the bifurcation and along the inner wall of curved segments where fluid velocity and wall shear stress were low. Arrows at S and P indicate separation and stagnation points, respectively. Re_o, Reynolds number; D_o, vessel diameter; Q_o, mean volume flow rate; $\bar{U}_o$, mean fluid velocity.*

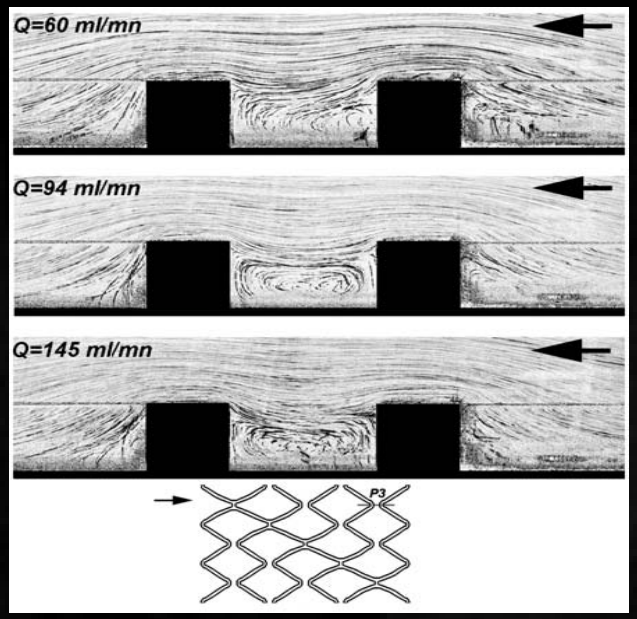
Asakura and Karino, Circulation Research 1990;66:1045-1

3. Rheology not Optimal

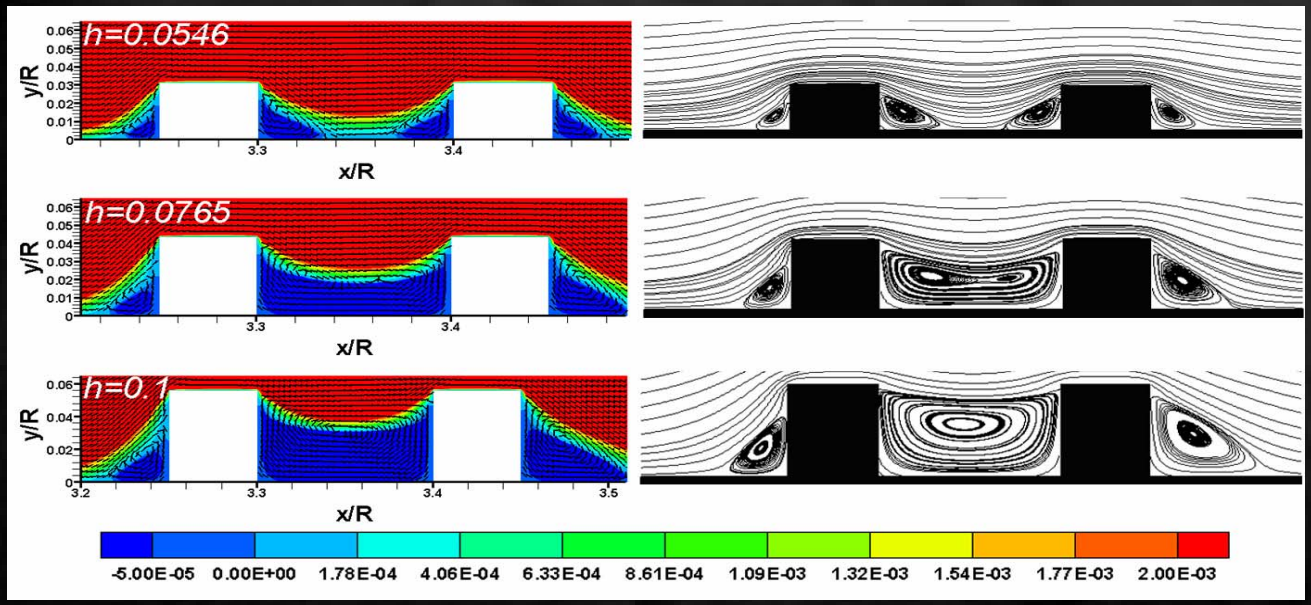


Case of a single stented coronary artery

Influence of the wire height or impact rate on 2D flow perturbations



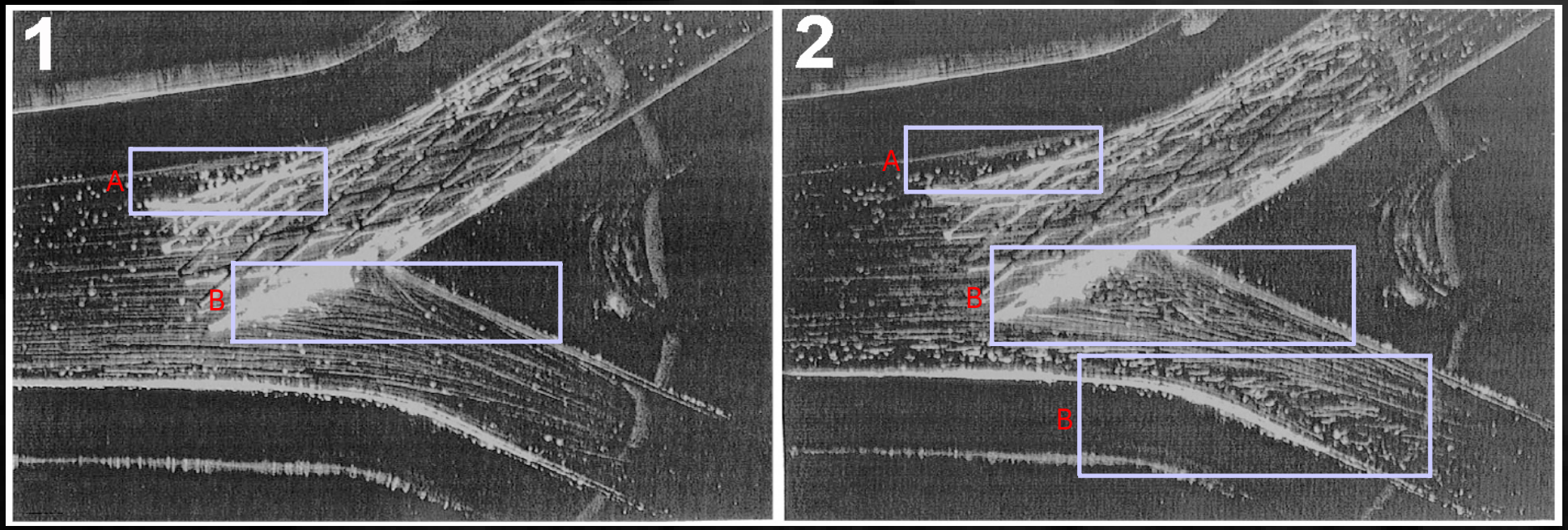
Qualitative experimental results
(Benard *et al.*)



Qualitative and quantitative numerical results (Benard *et al.*)

This study highlights that wire height is a preponderent factor of 2D flow perturbations

Macroscopic flow perturbations at stented bifurcation site

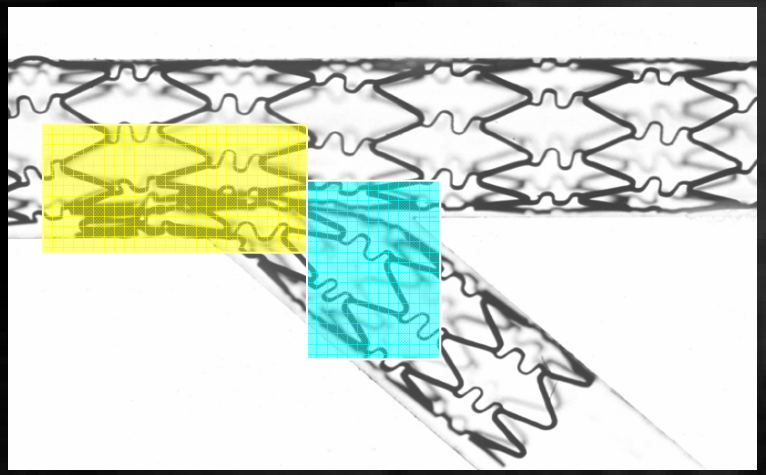


Physiological flow through a bifurcation model with palmaz stent (Fabregues, 1998, J. of Biomech.31)

A: Stagnation zone appears if the stent does not conform to the artery.

B: Stent implantation in the SB induces recirculation zones in the healthy artery branch

Crush Technique

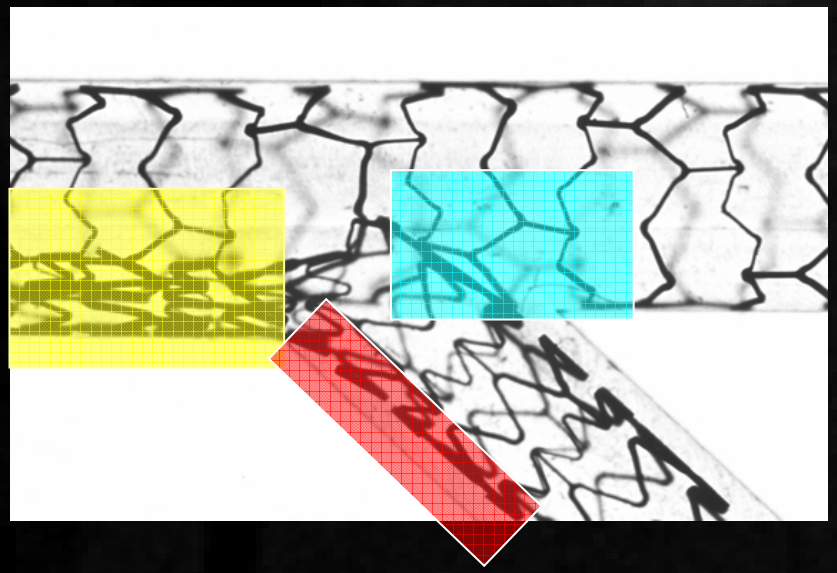


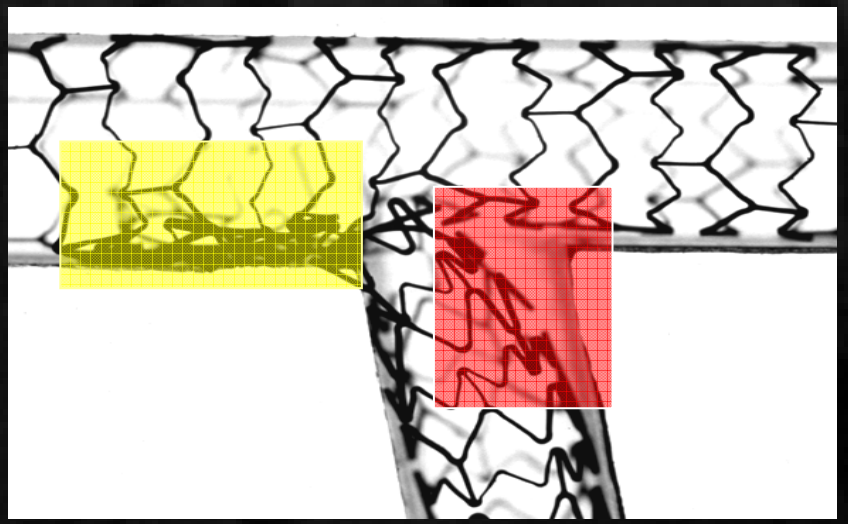
Stagnation area between the struts

Delayed endothel.

Recirculation

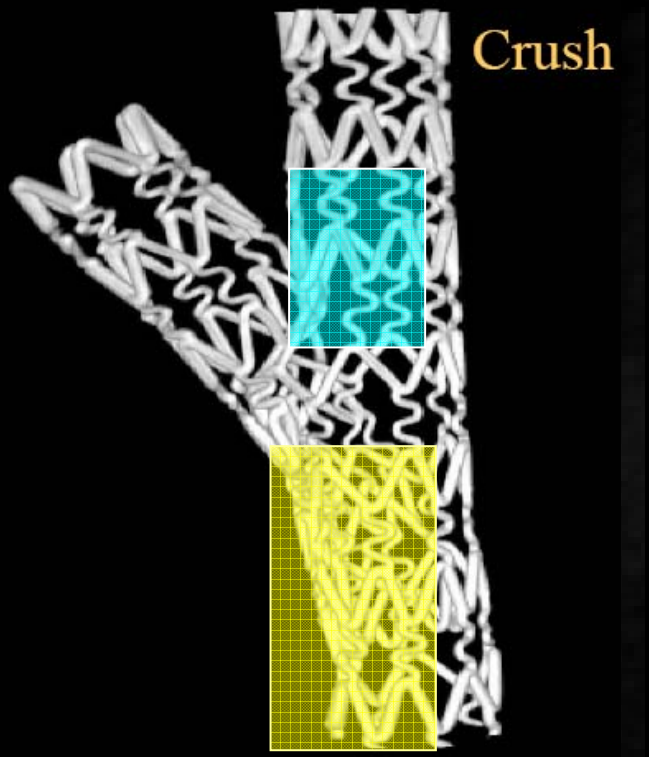
Stent not apposed

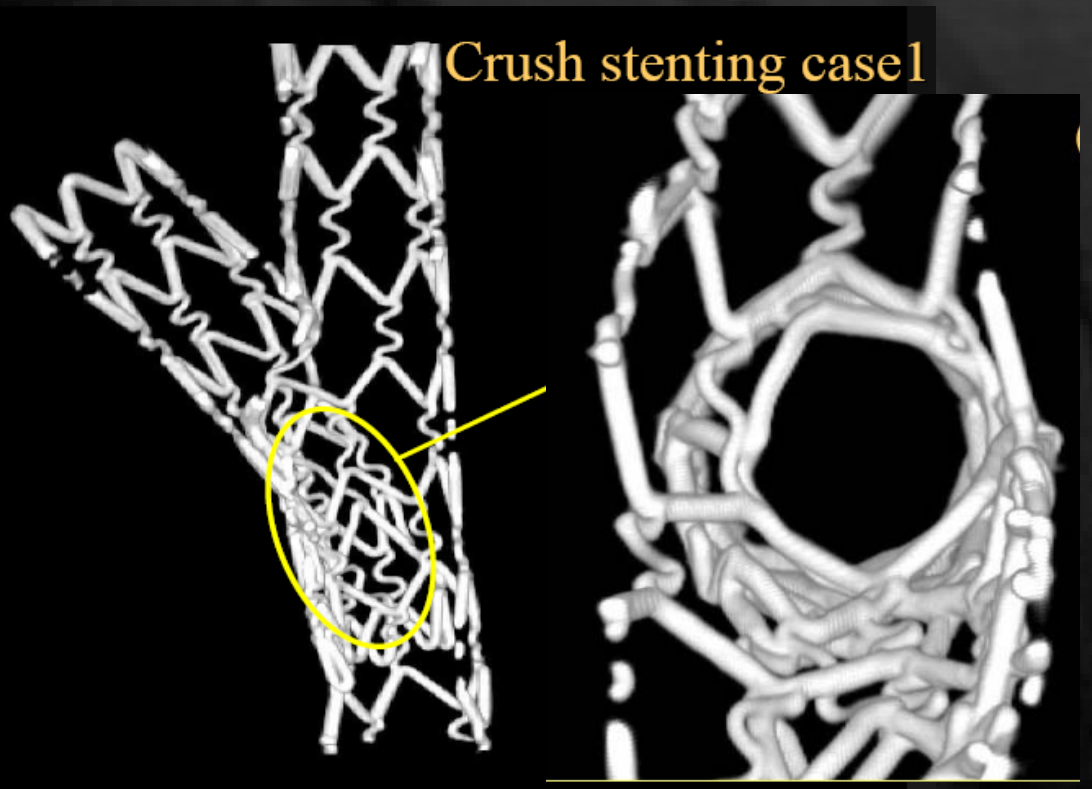




Courtesy of John Ormiston

Optimal Crush





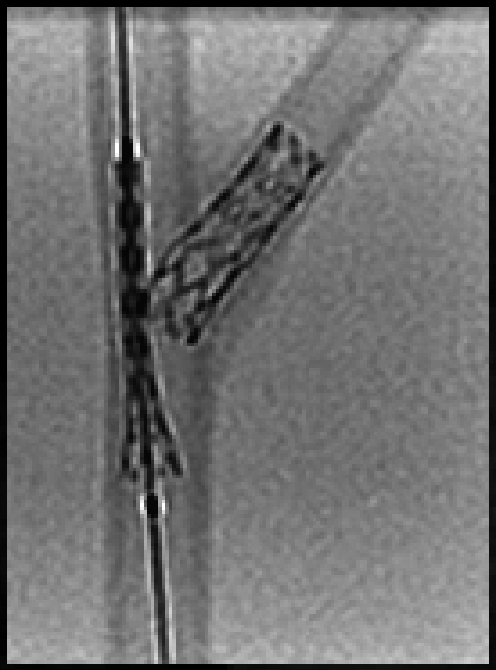
Stagnation area between the struts

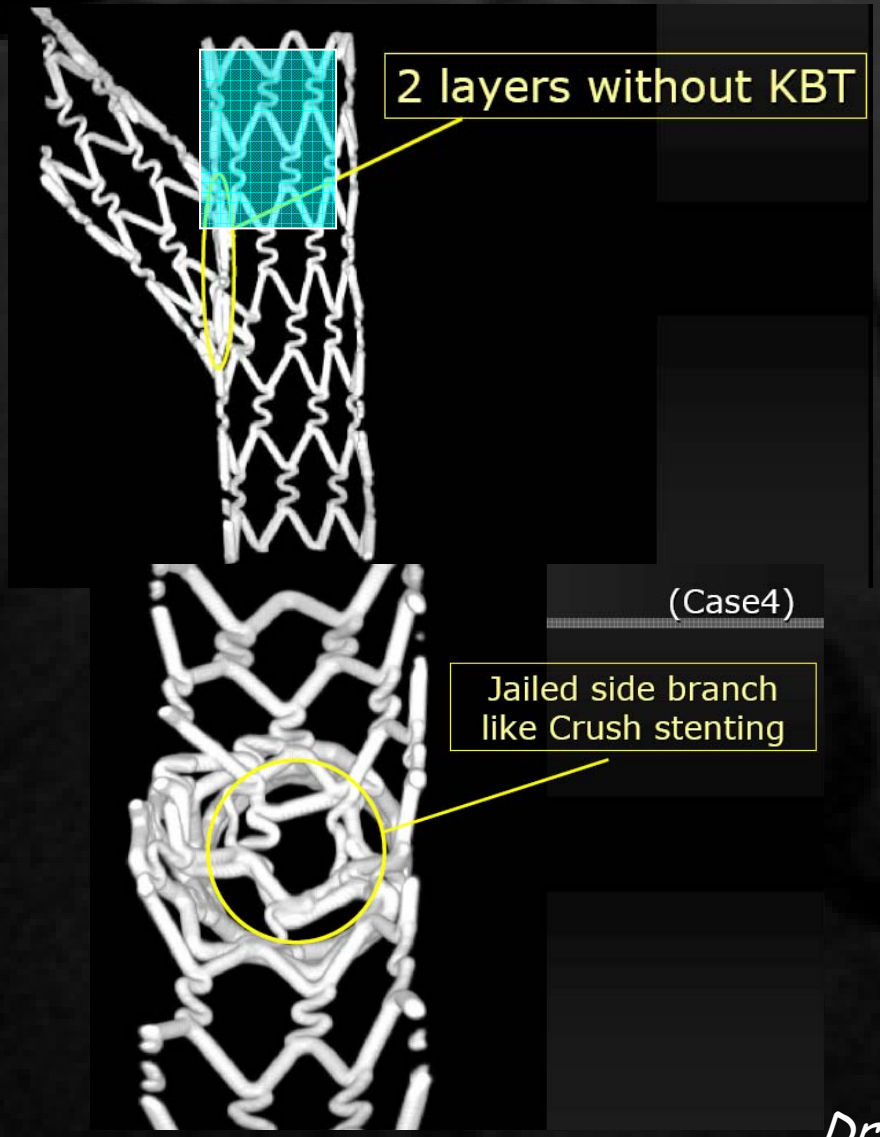
Delayed endothel.

Recirculation

Dr Hichiki

« Mini » Crush

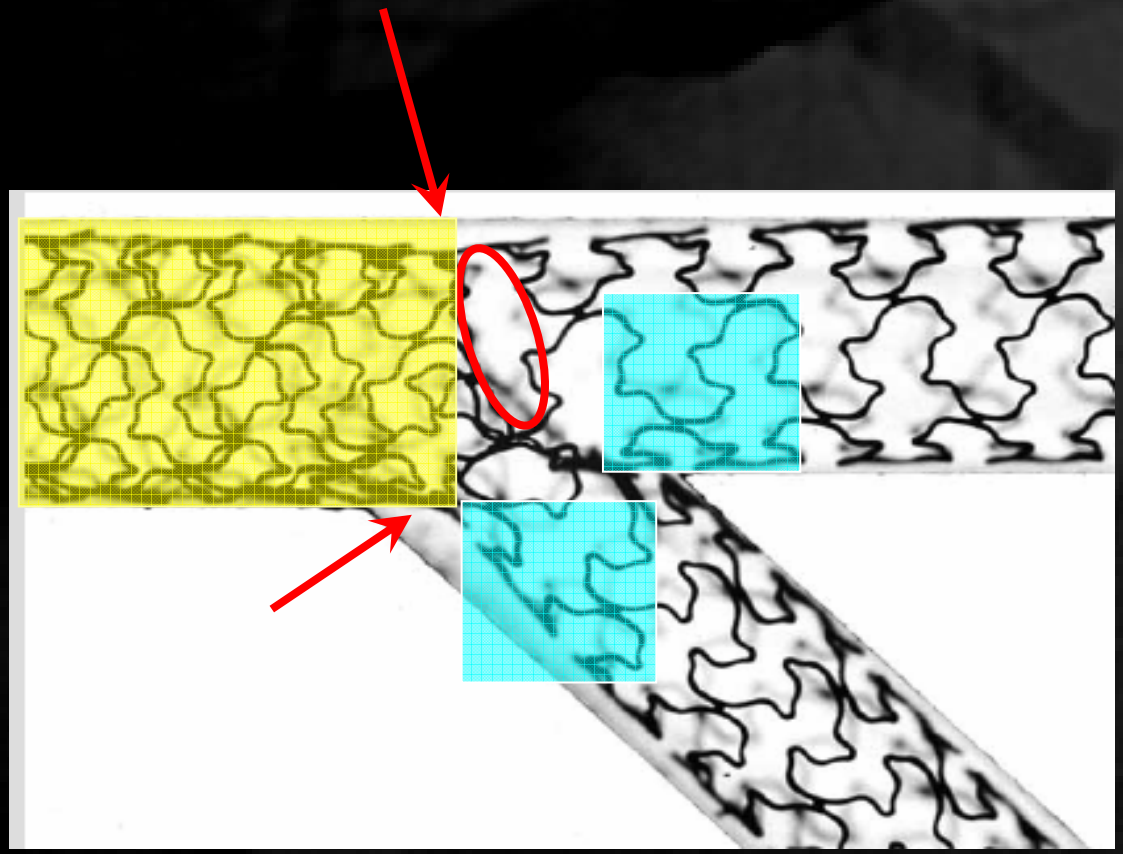




Recirculation

Dr Hichiki

Culotte Technique



Stent not apposed

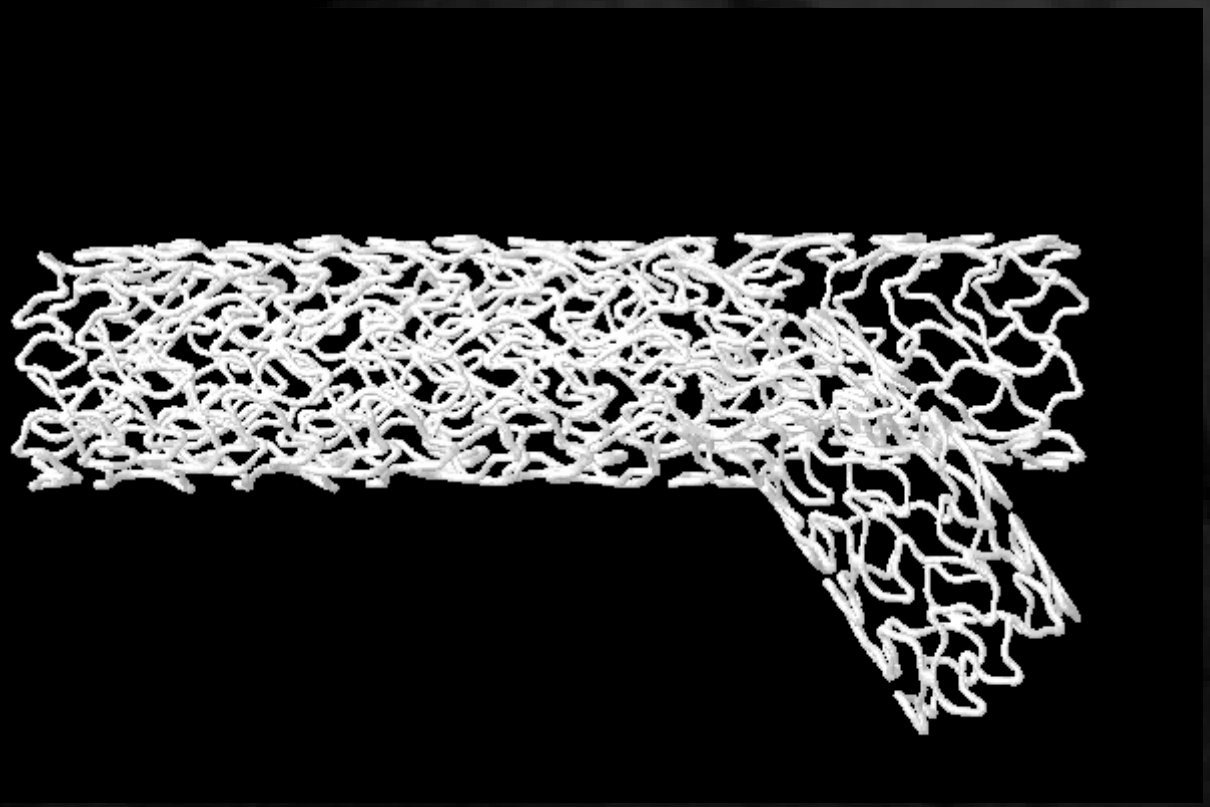
Stagnation area between the struts

Delayed endothel.

Recirculation

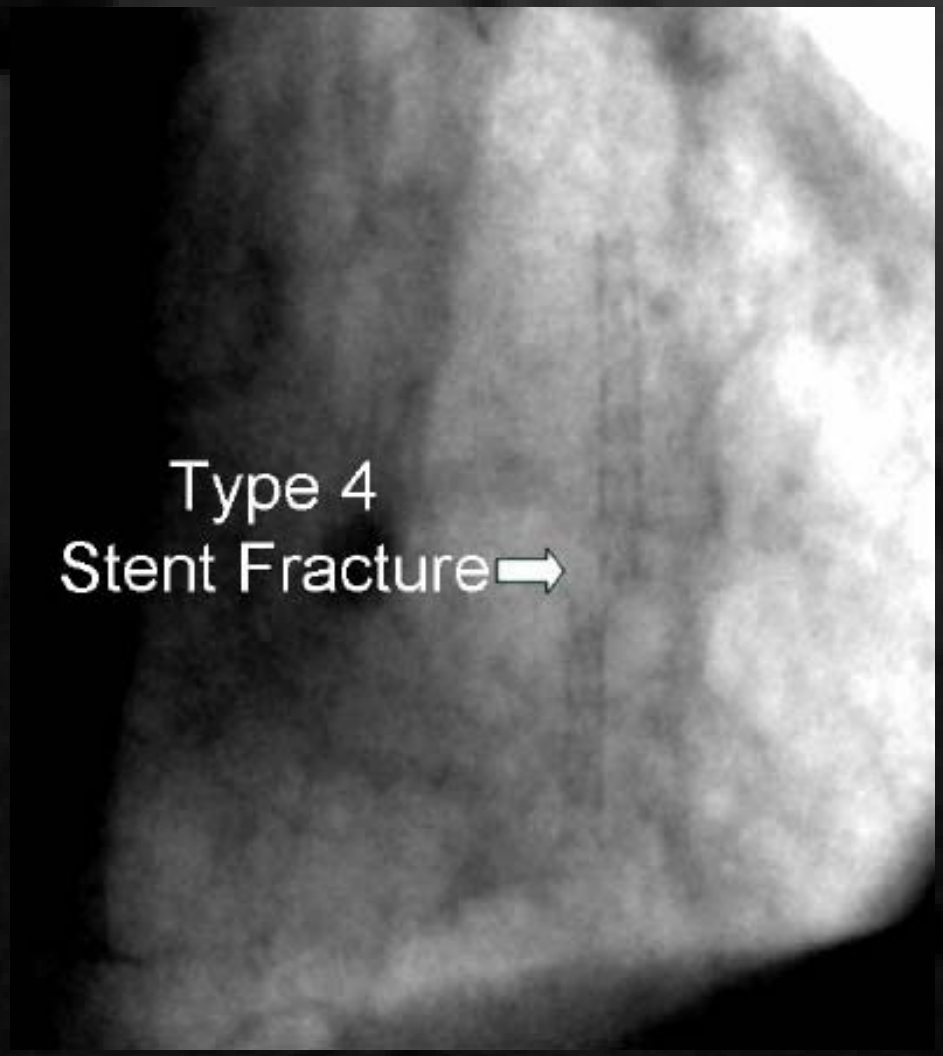
Courtesy of John Ormiston

SKS



Courtesy of John Ormiston

4. Stent Fracture



Stent Fracture: Baseline Angiographic Findings

Variable	Stent fracture	Sirius	P Value
Baseline	N = 28	N = 531	
RVD, mm	2.66±0.50	2.79±0.45	0.14
MLD, mm	0. 56±0.39	0.97±0.40	<0.001
% Stenosis	77.8±15.3	65.1±12.6	<0.001
Final	N = 28	N = 531	
Within the Segment			
Final MLD	2.06±0.48	2.38±0.42	<0.001
Final % Stenosis	24.6±11.1	16.1±9.7	<0.001
Within the Stent			
Final MLD	2.33±0.49	2.67±0.40	<0.001
Final % Stenosis	14.8±8.9	5.4±8.2	<0.001

Popma, « Enter the DES Revolution », New Orleans 2007

Stent Fracture: Baseline Angiographic Findings

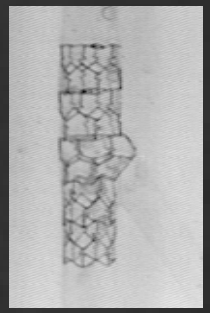
Variable	Stent fracture N = 28 (%)	Sirius N = 531 (%)	P Value
Number of Stents	1.5±0.7	1.4±0.7	0.46
Stent diameter	2.79±0.39	2.91±0.50	0.21
Maximal Balloon	2.97±0.55	3.3±0.5	<0.001
Total overlapping-stent length	35.1±16.5	21.5±6.7	<0.001
Stent-to-lesion length ratio	2.04±1.2	1.6±0.6	<0.001
Mean angle			
Systole	64.8±27.6	NA	NA
Diastole	32.5±23.1	NA	NA
Δ Systole-Diastole	32.3±15.2	NA	NA
Post-stenting	20.4±16.6	NA	NA
Δ Max Angle After Stent	44.5±21.3	NA	NA
Dissection	4 (14.3)	7 (1.3)	0.003
Perforation	2 (7.1)	0 (0.0)	0.005

Stent Fracture: Follow-up Findings

Variable	Stent fracture N = 38 (%)	Sirius N = 350 (%)	P Value
RVD, mm	2.72±0.48	2.79±0.42	0.33
Within the Segment			
Follow-up MLD	1.41±0.69	2.15±0.61	<0.001
Late Lumen Loss	0.70±0.66	0.24±0.47	<0.001
Restenosis Rate	18 (47.4)	31 (8.9)	< 0.001
Follow-up % Stenosis	48.6±23.0	23.6±16.4	<0.001
Within the Stent			
Follow-up MLD	1.52±0.82	2.50±0.58	<0.001
Late Lumen Loss	0.96±0.71	0.17±0.44	<0.001
Follow-up % Stenosis	44.1±28.5	10.4±16.5	<0.001
Restenosis Rate	18 (47.4)	11 (3.2)	<0.001
ISR Length, mm	6.53±5.08	9.1±5.8	0.01
Total occlusions	3 (7.9)	2 (0.6)	0.02
Aneurysm	5 (13.2)	2 (0.6)	<0.001

Popma, « Enter the DES Revolution », New Orleans 2007

Conclusion

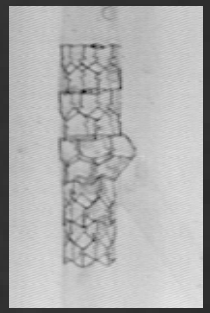


Bifurcation stenting is now a well known predictor of stent thrombosis at follow-up.

When 2 stents are used, several factors may increase the risk (fractures, uncomplete stent apposition, delayed endothelialization, distorsion, recirculation ...).

Therefore a provisional side branch stenting approach is recommended.

Conclusion



When 2 stents are needed, it is preferable to avoid long overlap of the 2 stents which is associated with a higher risk of stent or polymer fracture and poor Rheology.

And always end with final kissing balloon inflation with correct balloon size.