

## **Bifurcation Summit**

# **One Stent or Two Stents in Coronary Bifurcations: Evidence-Based Medicine Review**

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**No conflict of interest to  
disclose**

# 1 vs 2 stent for bifurcation lesions: 8 randomized studies

1. Colombo. Randomized study to evaluate sirolimus-eluting stents implanted at coronary bifurcation lesions. *Circulation*. 2004;109:1244-1249.
2. Pan. Rapamycin-eluting stents for the treatment of bifurcated coronary lesions: a randomized comparison of a simple versus complex strategy. *Am Heart J* 2004;148(5):857-64.
3. Steigen. Randomized study on simple versus complex stenting of coronary artery bifurcation lesions: the Nordic bifurcation study. Nordic PCI Study Group. *Circulation* 2006;114(18):1955-61.
4. Ferenc. Randomized trial on routine vs. provisional T-stenting in the treatment of de novo coronary bifurcation lesions. *Eur Heart J* 2008;29(23):2859-67.
5. Colombo. Randomized study of the crush technique versus provisional side-branch stenting in true coronary bifurcations: the CACTUS Study. *Circulation* 2009;119(1):71-8.
6. Hildick-Smith. Randomized Trial of Simple Versus Complex Drug-Eluting Stenting for Bifurcation Lesions: The British Bifurcation Coronary Study: Old, New, and Evolving Strategies. *Circulation* 2010;121:1235-43.
7. Cheng. Randomized study on T stenting and small protrusion technique versus simple stenting for patients with coronary artery bifurcation lesions and with big size side branch. *Zhonghua Xin Xue Guan Bing Za Zhi*. 2010 Feb;38(2):131-4.
8. Chen. A Randomized Clinical Study Comparing Double Kissing Crush With Provisional Stenting for Treatment of Coronary Bifurcation Lesions Results From the DKCRUSH-II Trial. *J Am Coll Cardiol*. 2011 Feb 22;57(8):914-20

# 1 vs 2 stent for bifurcation lesions: 9 meta-analysis

1. **Biondi-Zoccai. Superiority of A Simple Stenting Strategy For Coronary Bifurcation Lesions In The DES Era (Meta-Analysis Of 1141 Patients). ESC 2008**
2. **Brar. Bifurcation stenting with drug-eluting stents: a systematic review and meta-analysis of randomised trials. EuroIntervention. 2009 Sep;5(4):475-84.**
3. **Katritsis. Double versus single stenting for coronary bifurcation lesions: a meta-analysis. Circ Cardiovasc Interv. 2009 Oct;2(5):409-15.**
4. **Zhang. Simple versus complex stenting strategy for coronary artery bifurcation lesions in the drug-eluting stent era: a meta-analysis of randomised trials. Heart. 2009 Oct;95(20):1676-81.**
5. **Hakeem. Provisional vs complex stenting strategy for coronary bifurcation lesions: meta-analysis of randomized trials. J Invasive Cardiol. 2009 Nov;21(11):589-95.**
6. **Niccoli. Coronary bifurcation lesions: to stent one branch or both? A meta-analysis of patients treated with drug eluting stents. Int J Cardiol. 2010 Feb 18;139(1):80-91.**
7. **Athappan. True coronary bifurcation lesions: meta-analysis and review of literature. J Cardiovasc Med (Hagerstown). 2010 Feb;11(2):103-10.**
8. **Zamani. Long-term risk of clinical events from stenting side-branches of coronary bifurcation lesions with drug-eluting and bare-metal stents: An observational meta-analysis. Catheter Cardiovasc Interv. 2010 Sep 7.**
9. **Behan. Simple or Complex Stenting for Bifurcation Coronary Lesions: A Patient-Level Pooled-Analysis of the Nordic Bifurcation Study and the British Bifurcation Coronary Study. Circ Cardiovasc Interv. 2011 Jan 4.**

**Provisional SB strategy is the gold standard**

# Long-term risk of clinical events from stenting SB of coronary bifurcation lesions with DES / BMS: meta-analysis

**DES Main Branch Only**

Hildick Smith 2008  
Pan 2004  
Assali 2006  
Vigna 2007  
Ge 2005  
Pan 2007  
Ferenc 2008  
Colombo 2004  
Pan 2007  
Palmerini 2008  
Galassi 2009  
DiMario 2007  
Valgimigli 2006  
VA MB DES No SB Stent  
Pooled Estimate

**DES With Side Branch Stent**

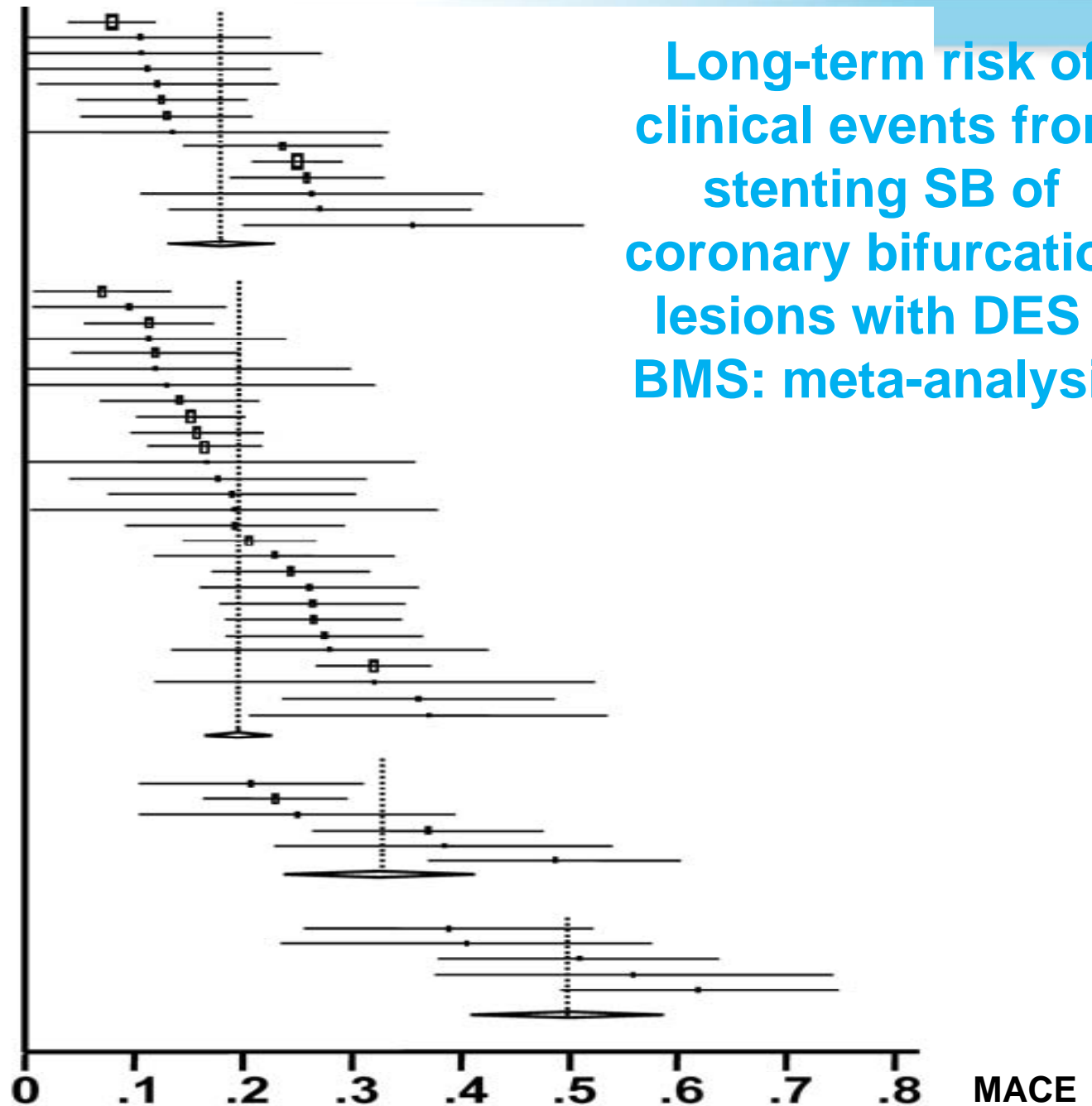
Chen 2007  
Burzotta 2007  
Chen 2008  
Pan 2004  
Ferenc 2008  
Assali 2006  
Hoye 2005  
Moussa 2006  
Hildick Smith 2008  
Colombo 2009  
Hoye 2006  
Prasan 2004  
Kaplan 2007  
Colombo 2004  
Rizik 2006  
Diaz de la Liera 2006  
Galassi 2009  
Ge 2007  
Chen 2008  
Galassi 2009  
Ge 2006  
Adriaenssens 2008  
DiMario 2007  
Valgimigli 2006  
Palmerini 2008  
VA MB DES and SB Stent  
Ge 2006  
Kaplan 2007  
Pooled Estimate

**BMS Main Branch Only**

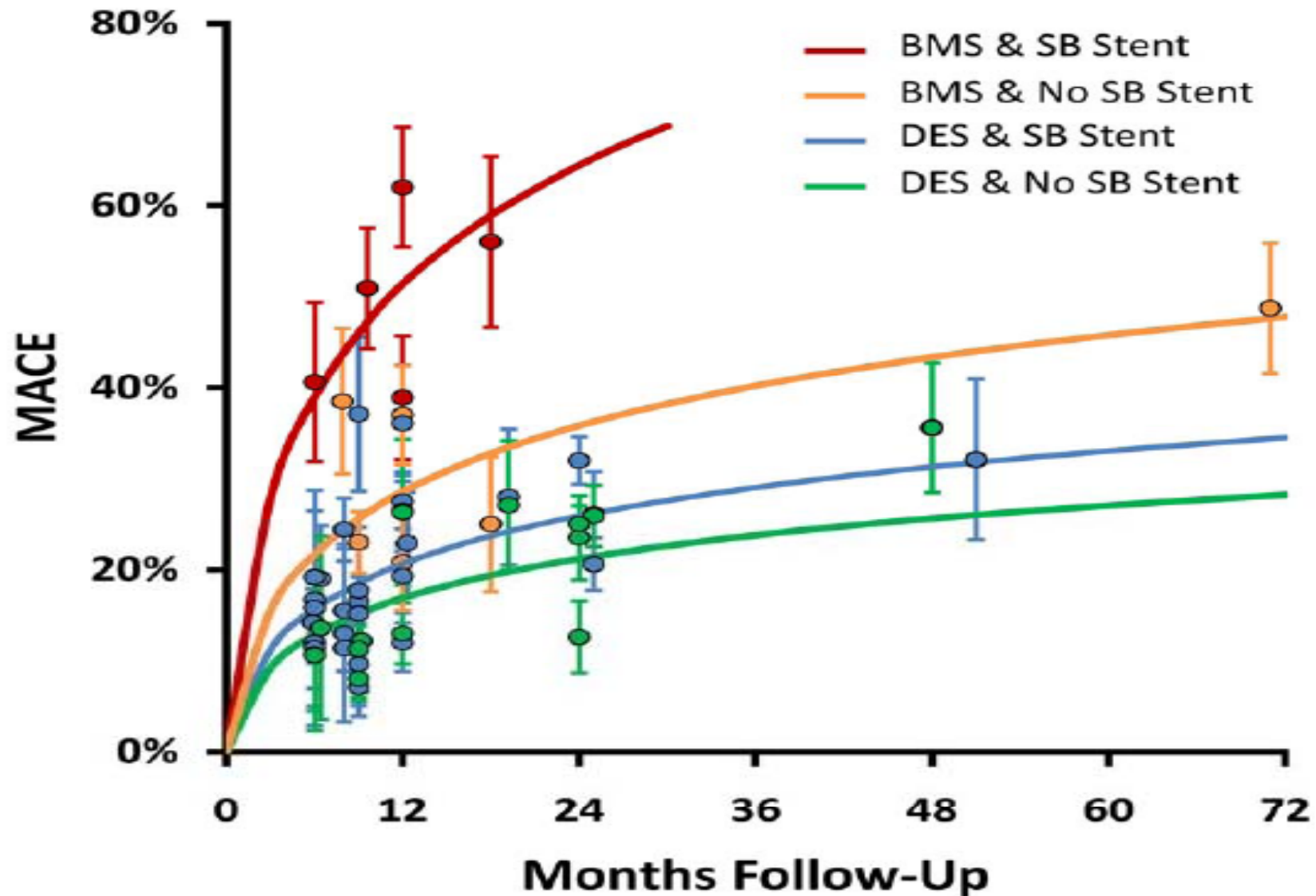
Al Suwaidi 2000  
Aliabadi 1997  
Pan 1999  
Finci 2000  
Yamashita 2000  
VA MB BMS No SB Stent  
Pooled Estimate

**BMS With Side Branch Stent**

Al Suwaidi 2000  
Assali 2004  
Yamashita 2000  
Pan 1999  
Finci 2000  
Pooled Estimate

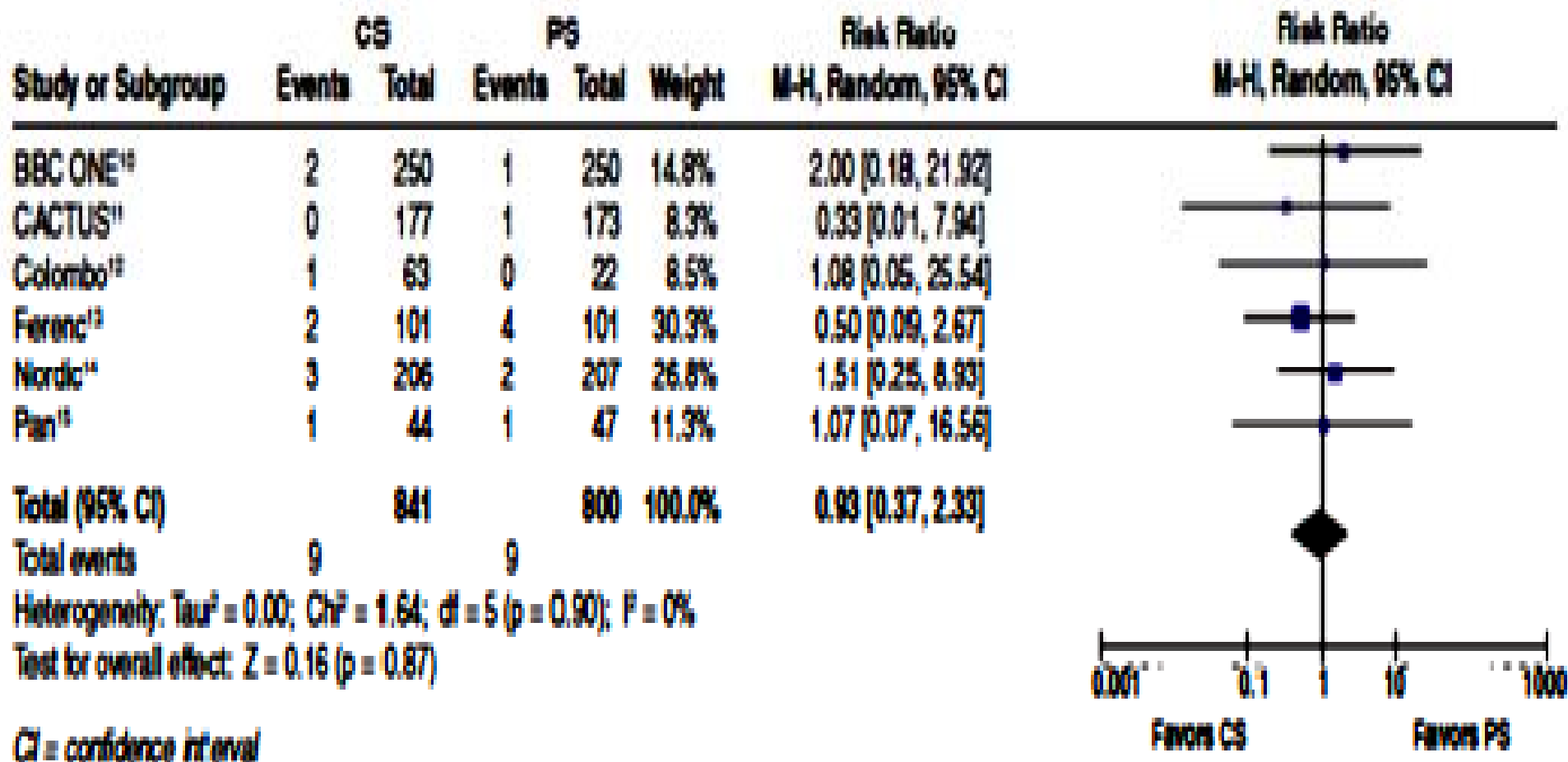


## Long-term risk of clinical events from stenting SB of coronary bifurcation lesions with DES / BMS: meta-analysis



# Provisional vs. complex stenting strategy for coronary bifurcation lesions: meta-analysis of randomized trials

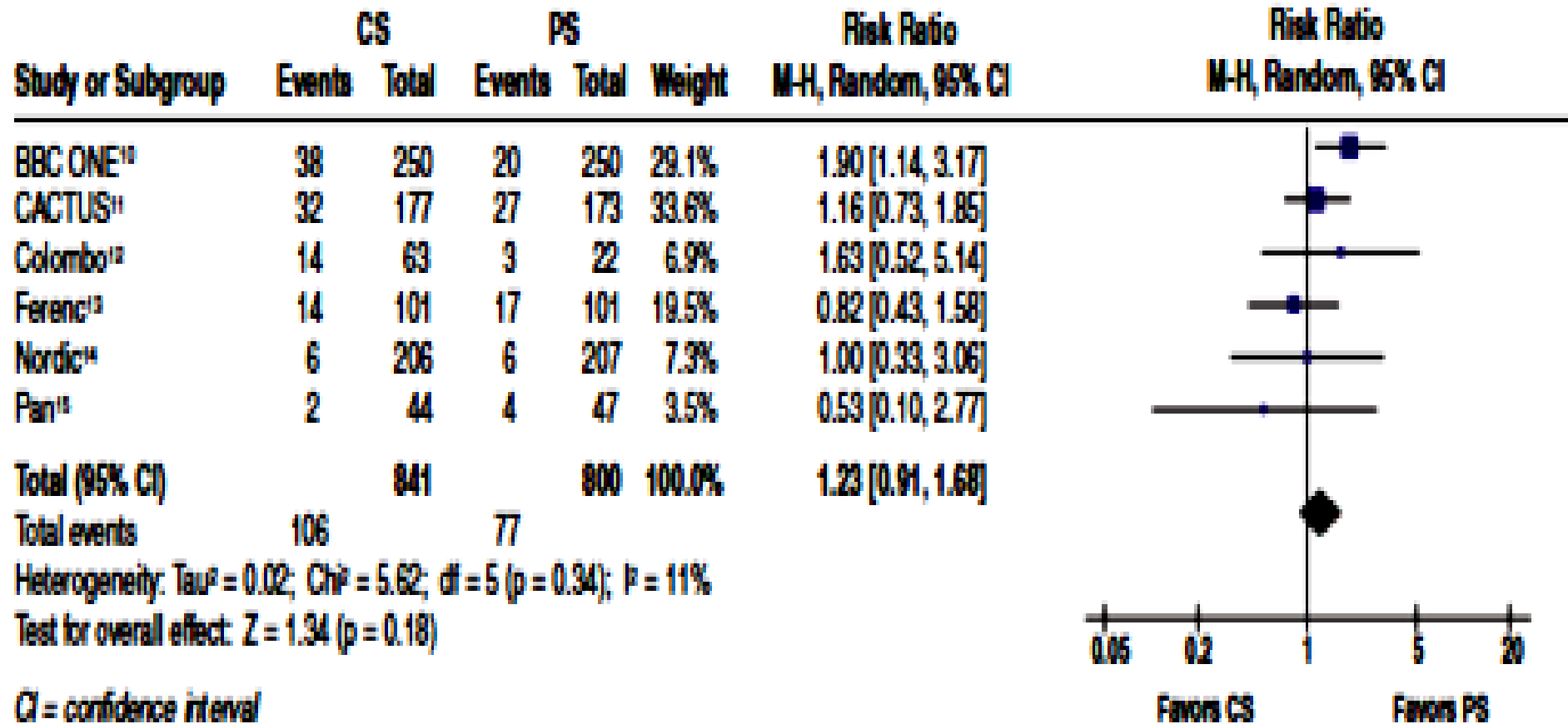
## DEATH





# Provisional vs. complex stenting strategy for coronary bifurcation lesions: meta-analysis of randomized trials

## MACE



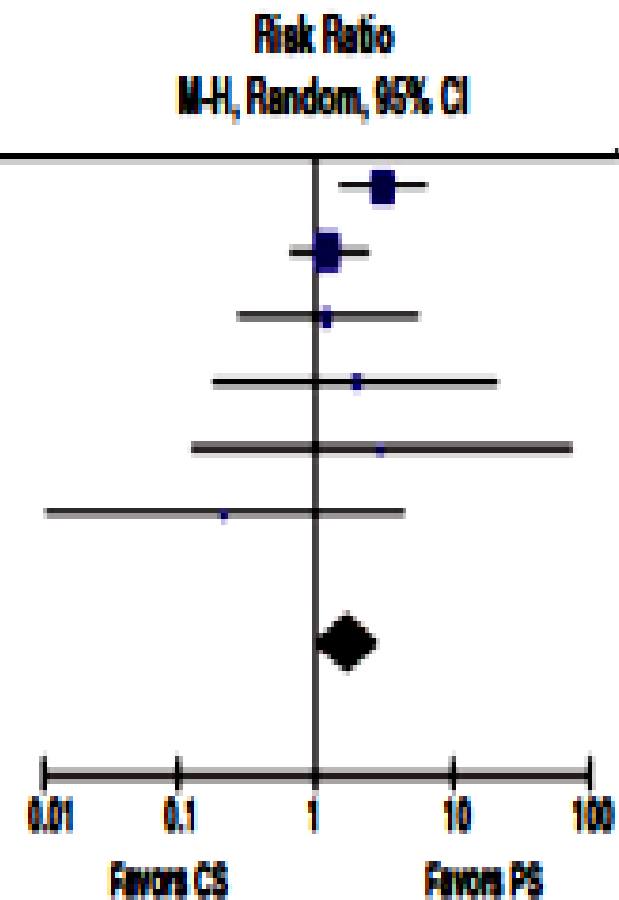
# Provisional vs. complex stenting strategy for coronary bifurcation lesions: meta-analysis of randomized trials

## MI

Study or Subgroup	CS		PS		Weight	Risk Ratio
	Events	Total	Events	Total		M-H, Random, 95% CI
BBC ONE <sup>10</sup>	28	250	9	250	36.0%	3.11 [1.50, 6.46]
CACTUS <sup>11</sup>	19	177	15	173	42.8%	1.24 [0.65, 2.36]
Colombo <sup>12</sup>	7	63	2	22	11.1%	1.22 [0.27, 5.45]
Ferenc <sup>13</sup>	2	101	1	101	4.6%	2.00 [0.18, 21.71]
Nordic <sup>14</sup>	1	206	0	207	2.6%	3.01 [0.12, 73.57]
Pan <sup>15</sup>	0	44	2	47	2.9%	0.21 [0.01, 4.32]
<b>Total (95% CI)</b>		<b>841</b>		<b>800</b>	<b>100.0%</b>	<b>1.71 [1.02, 2.88]</b>

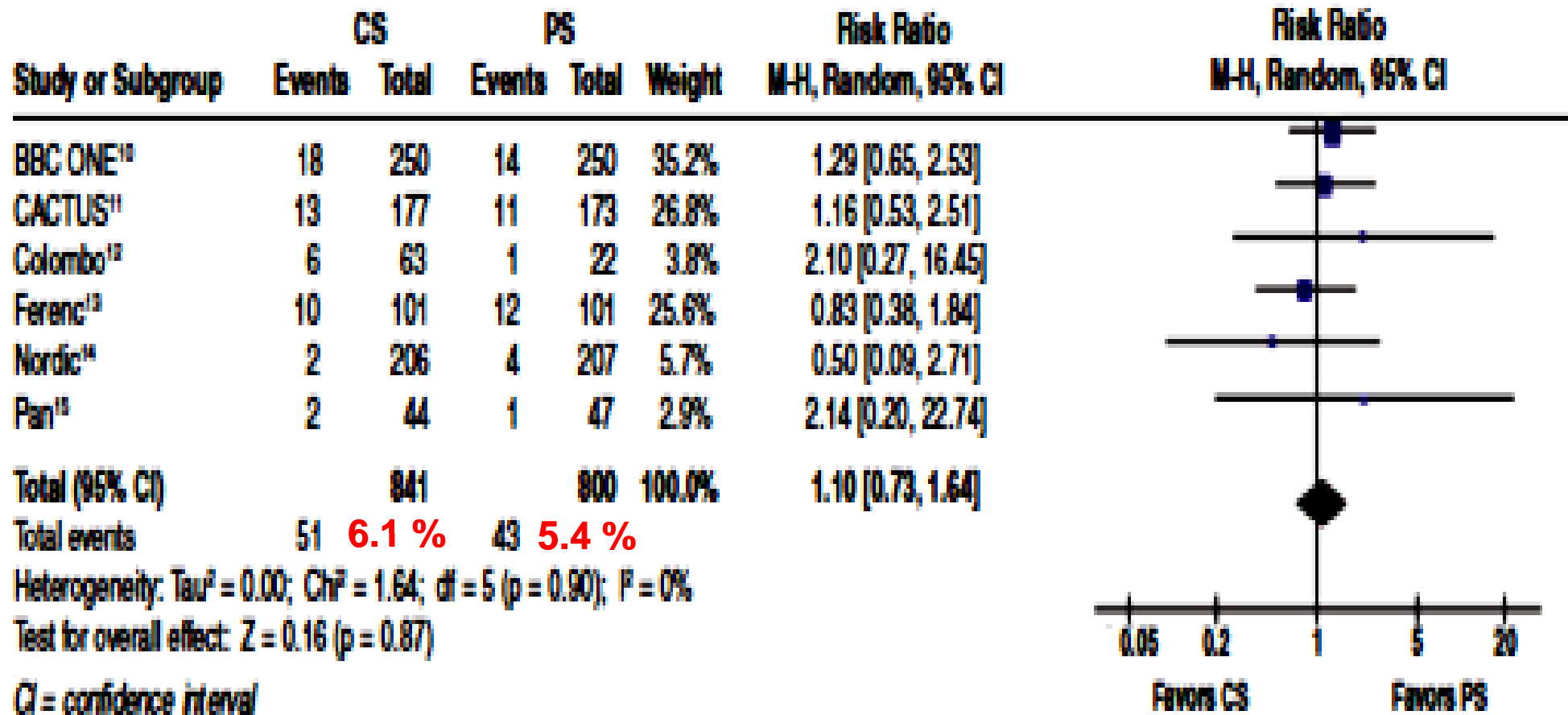
Total events 57 29  
 Heterogeneity:  $I^2 = 0.06$ ;  $Chi^2 = 5.72$ ;  $df = 5$  ( $p = 0.33$ );  $I = 13\%$   
 Test for overall effect:  $Z = 2.02$  ( $p = 0.04$ )

CI = confidence interval



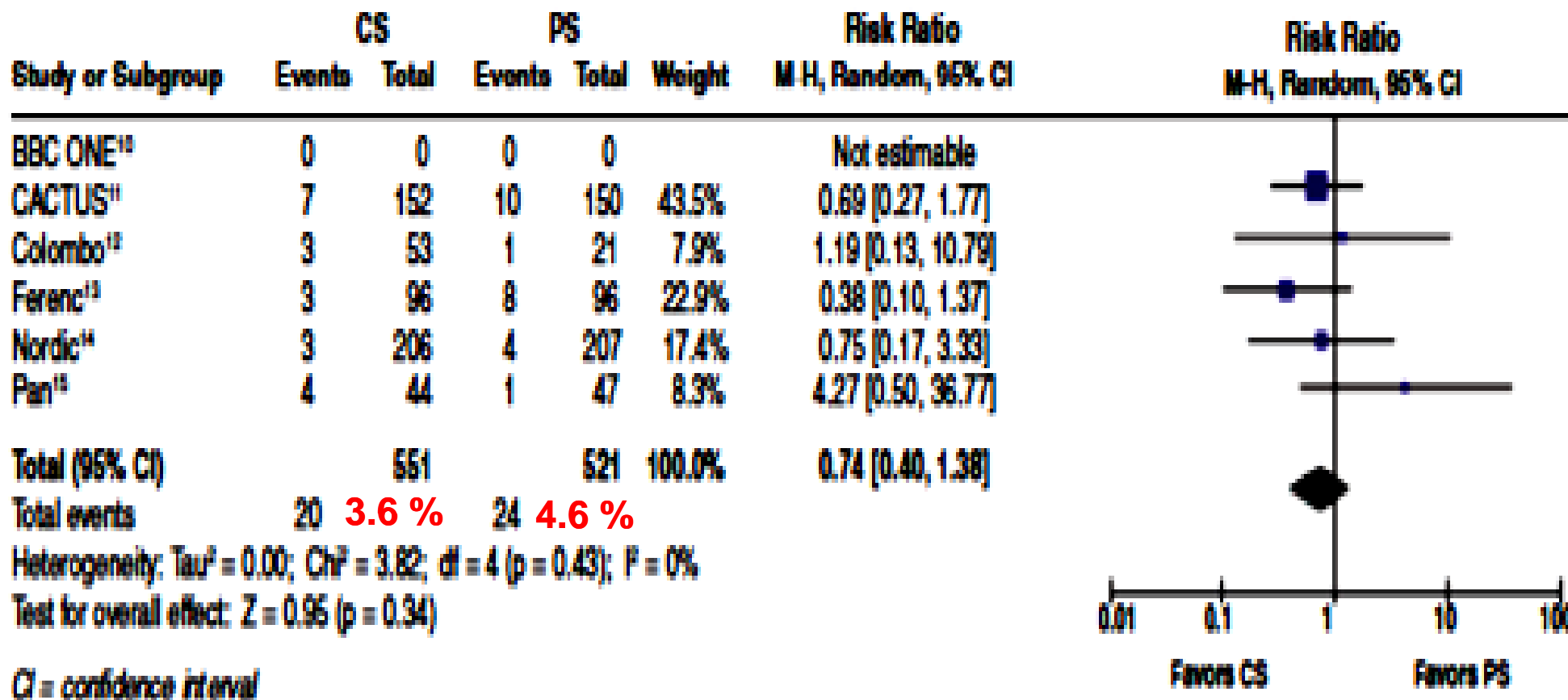
# Provisional vs. complex stenting strategy for coronary bifurcation lesions: meta-analysis of randomized trials

## TLR



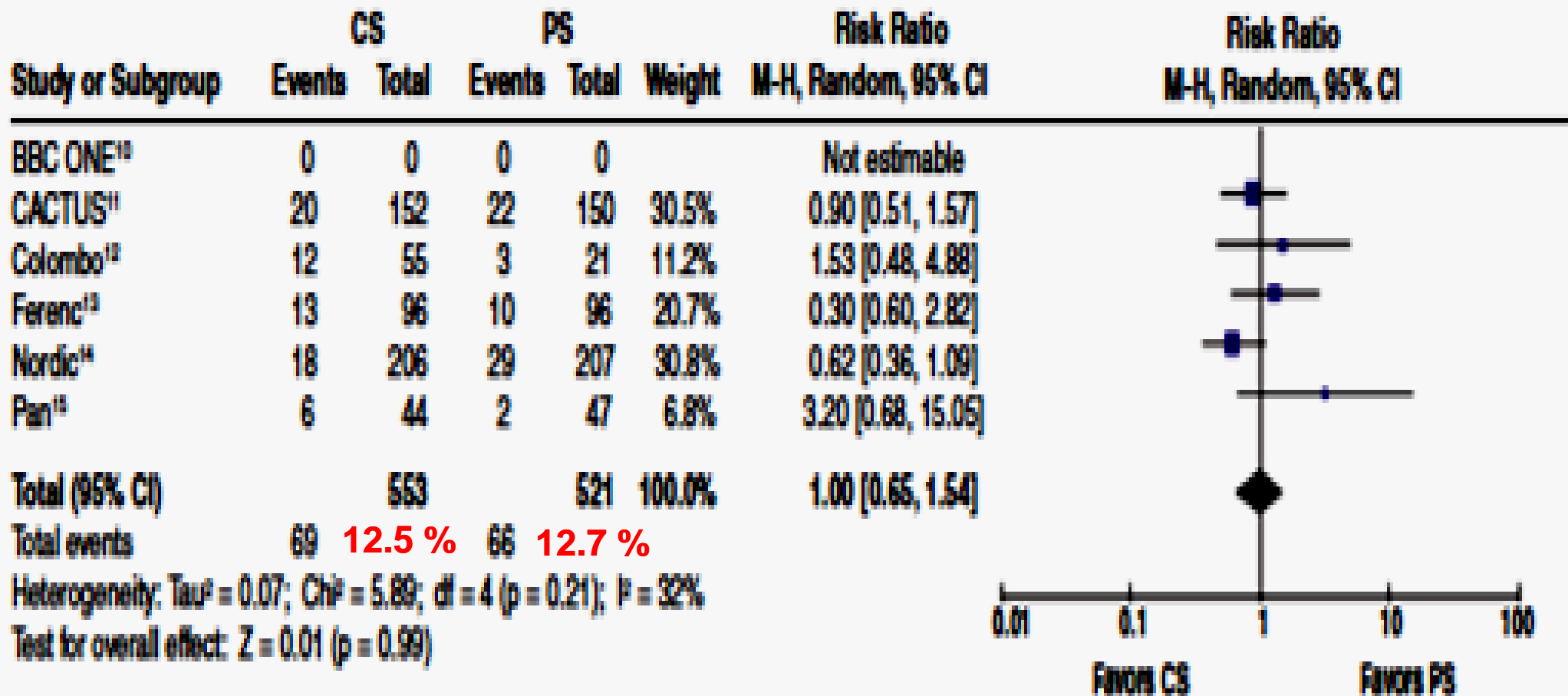
# Provisional vs. complex stenting strategy for coronary bifurcation lesions: meta-analysis of randomized trials

## Main Branch Restenosis



# Provisional vs. complex stenting strategy for coronary bifurcation lesions: meta-analysis of randomized trials

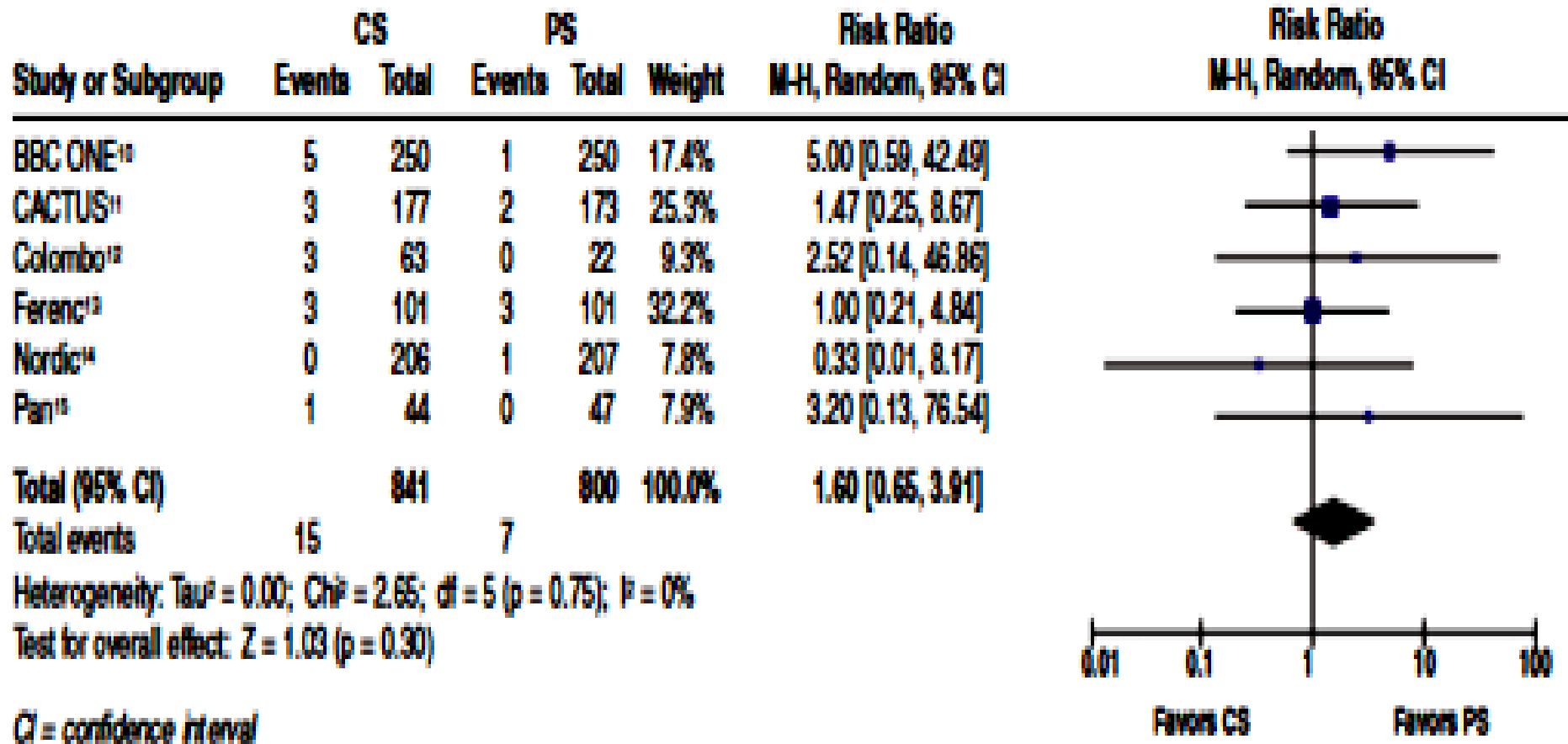
## Side Branch Restenosis



CI = confidence interval

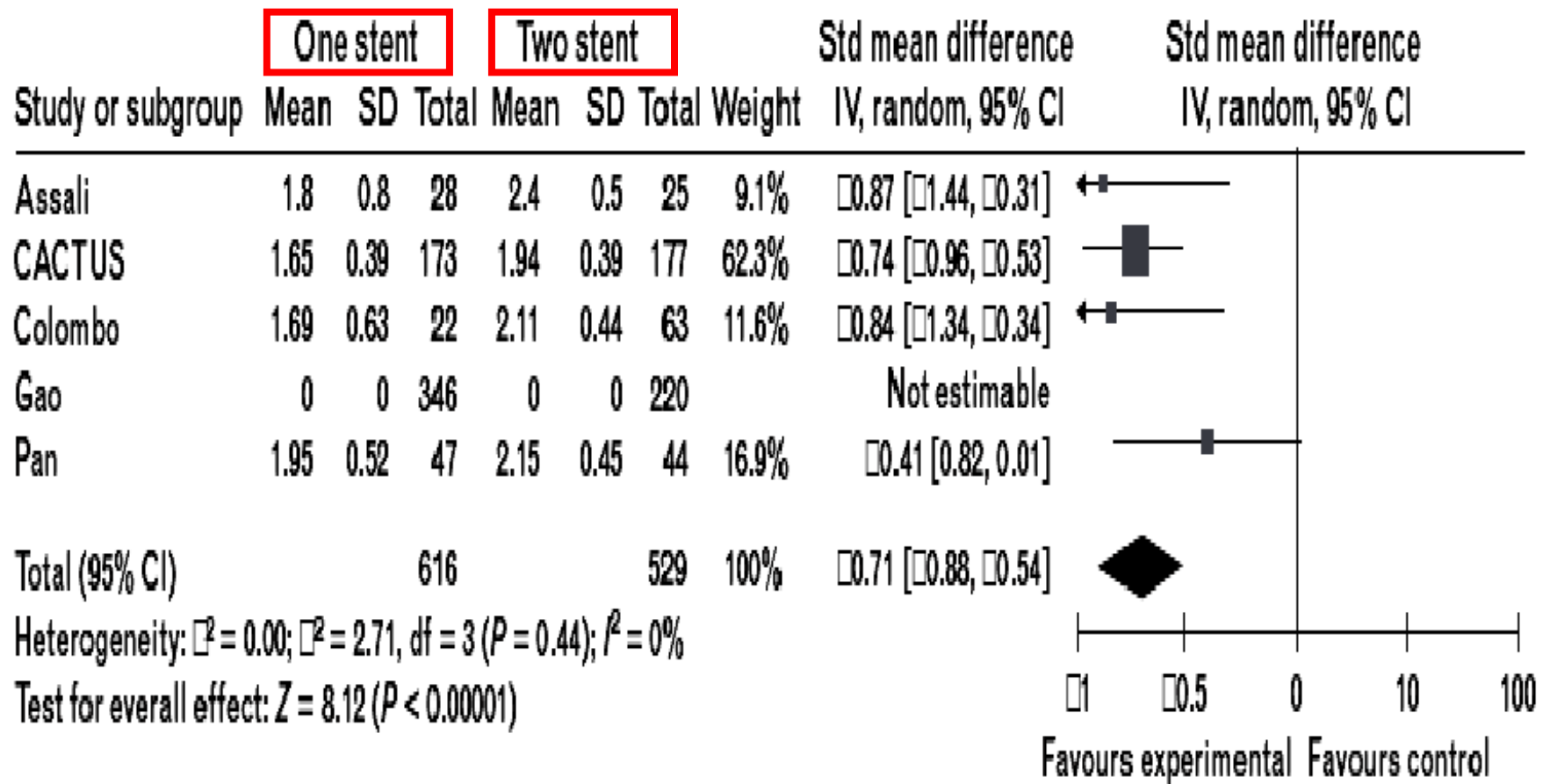
# Provisional vs. complex stenting strategy for coronary bifurcation lesions: meta-analysis of randomized trials

## Stent Thrombosis



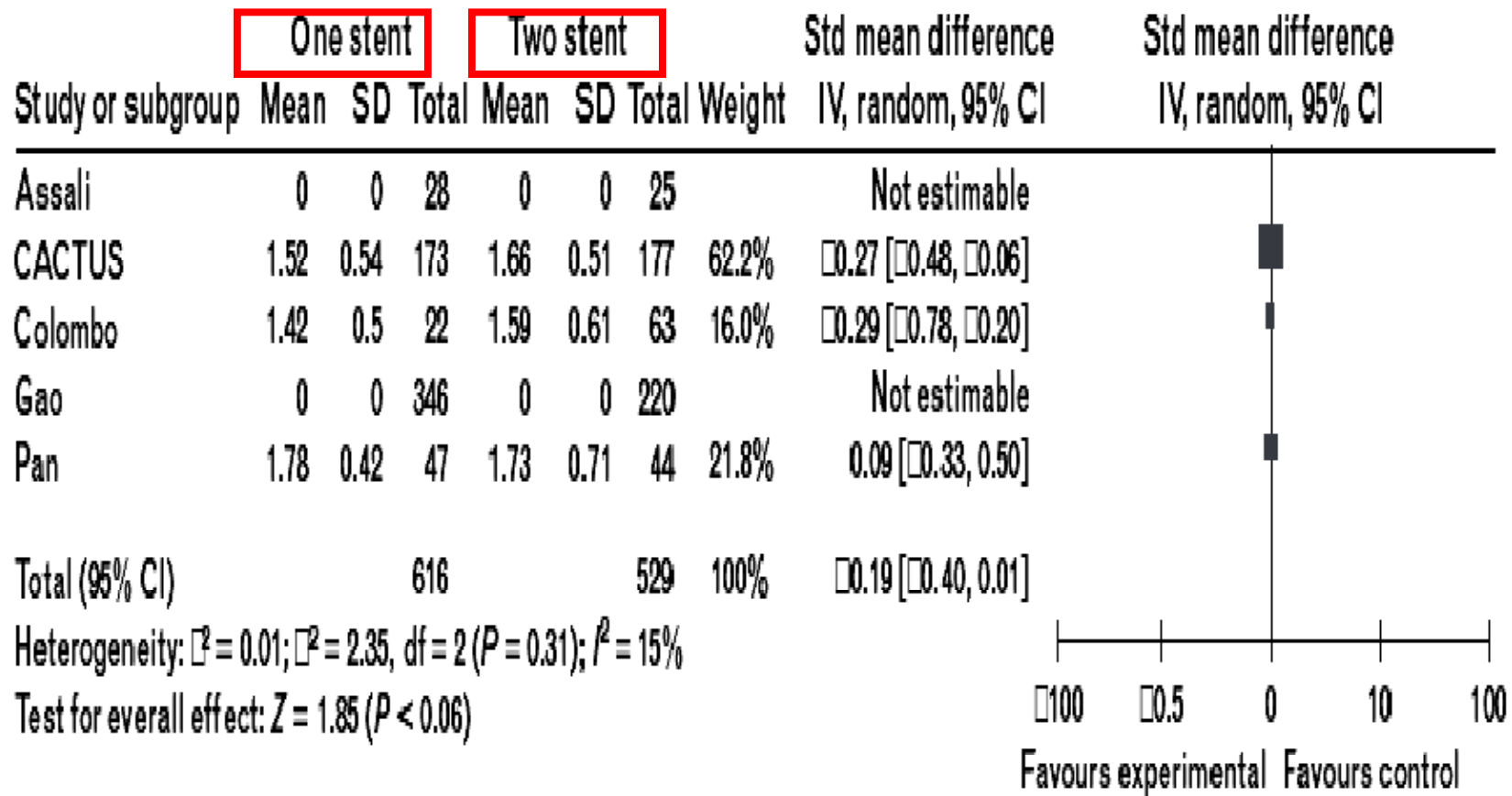
# True coronary bifurcation lesions: meta-analysis and review of literature

## Postprocedural MLD of the side branch



# True coronary bifurcation lesions: meta-analysis and review of literature

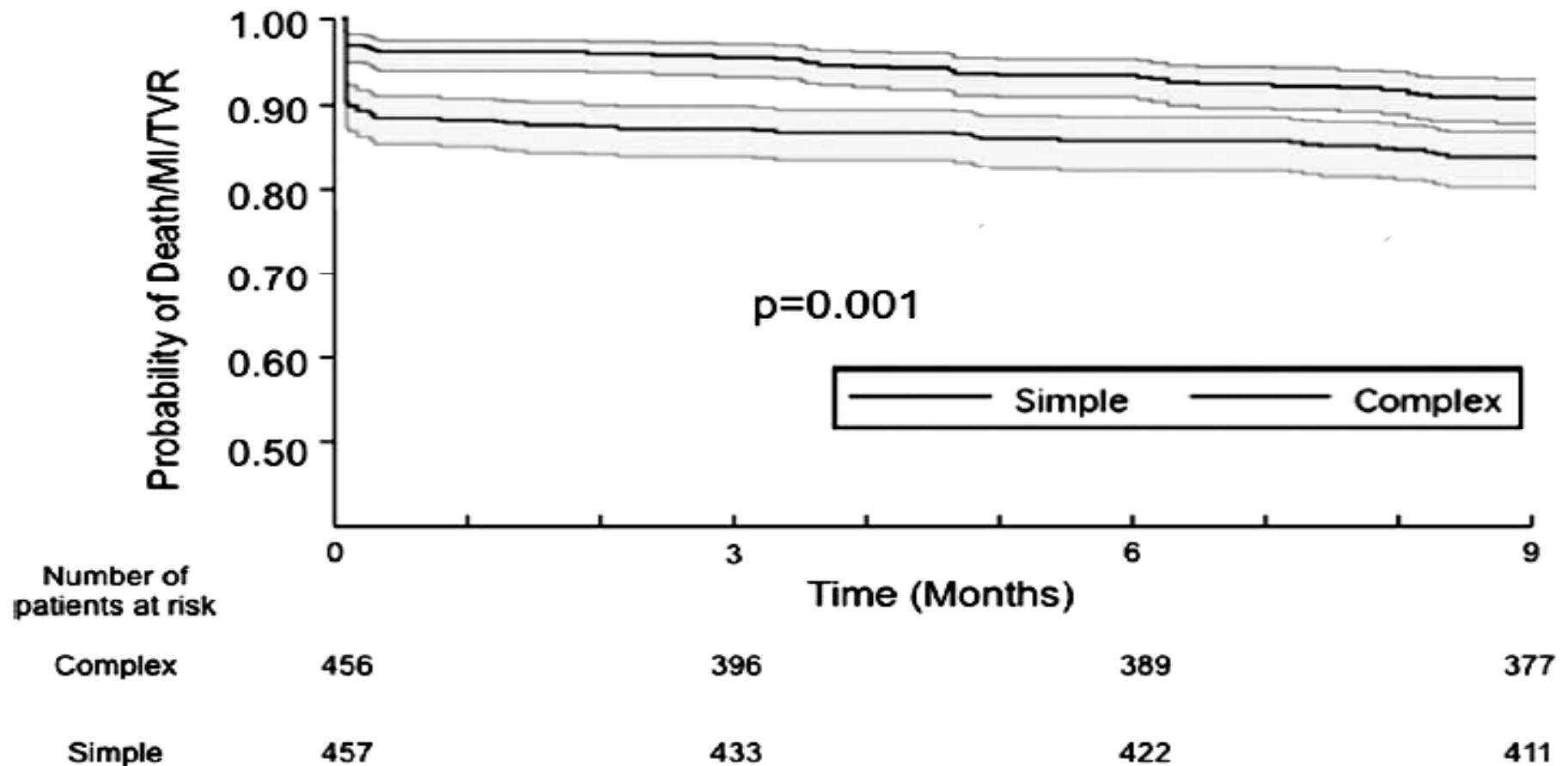
## Follow-up MLD of the side branch





# Simple or Complex Stenting for Bifurcation Coronary Lesions : A Patient-Level Pooled-Analysis of Nordic 1 and BBC

Kaplan-Meier freedom from the composite event



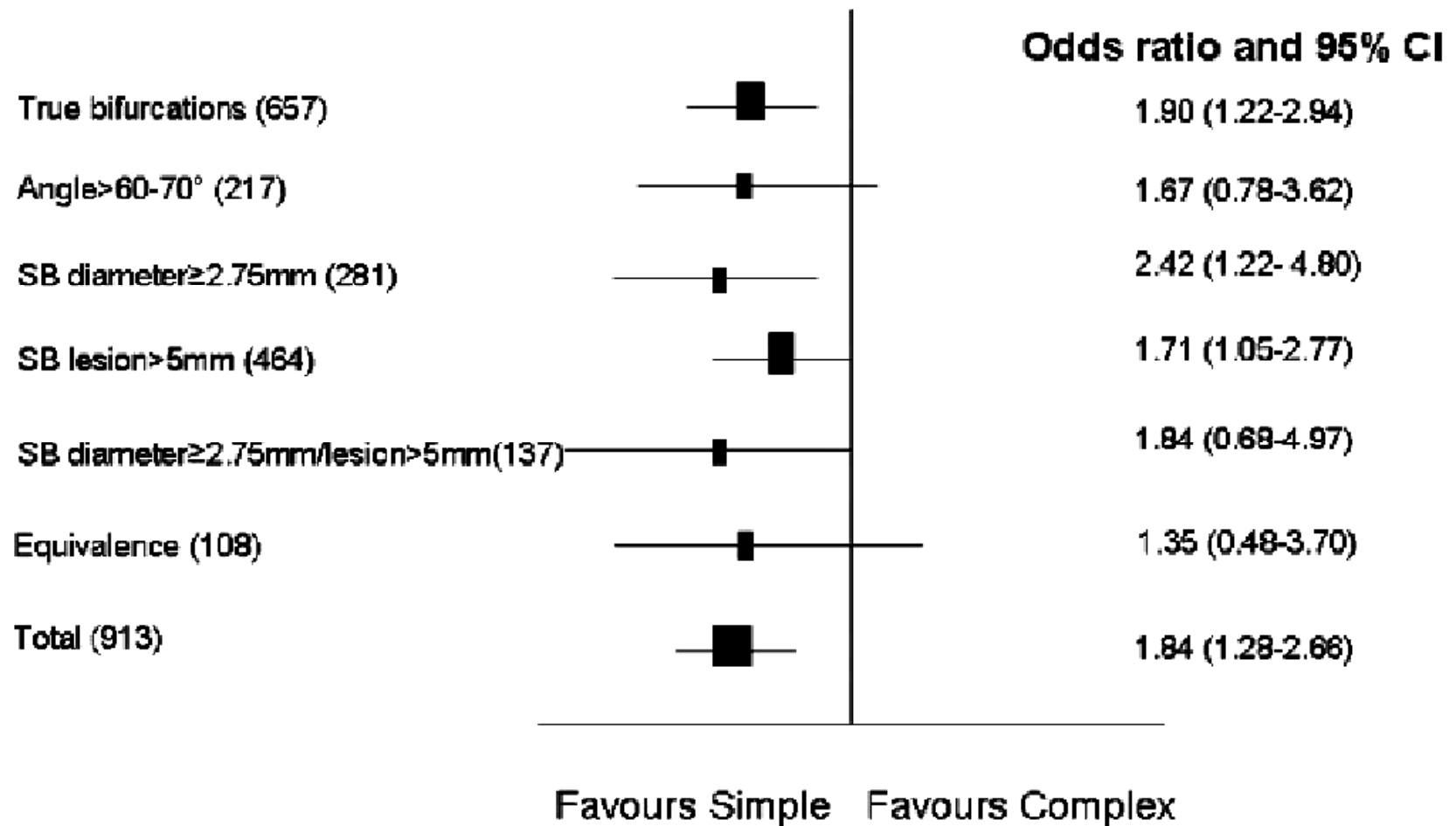
## Simple or Complex Stenting for Bifurcation Coronary Lesions : A Patient-Level Pooled-Analysis of Nordic 1 and BBC

### Procedure Characteristics

	Simple (n=457)	Complex (n=456)	P Value
Side branch stented, n (%)	16 (3.5%)	421 (92.3%)	<0.001
Crush technique, n (%)	...	272 (59.6%)	
Culotte technique, n (%)	...	118 (25.9%)	
Other complex technique n (%)	16 (3.5%)	59 (12.9%)	
Final kissing balloons, n (%)	129 (28.3%)	342 (75.3%)	<0.001
Procedural success, n (%)	435 (95.4%)	429 (94.5%)	0.430
Procedural time (min, SD)	59.1 (39.1)	77.4 (34.4)	0.001
Fluoroscopy time (min, SD)	15.1 (11.1)	21.5 (11.4)	<0.001
Contrast volume (mL, SD)	243.2 (108.1)	297.9 (129.3)	<0.001

# Simple or Complex Stenting for Bifurcation Coronary Lesions : A Patient-Level Pooled-Analysis of Nordic 1 and BBC

## Primary outcome for individual subgroups



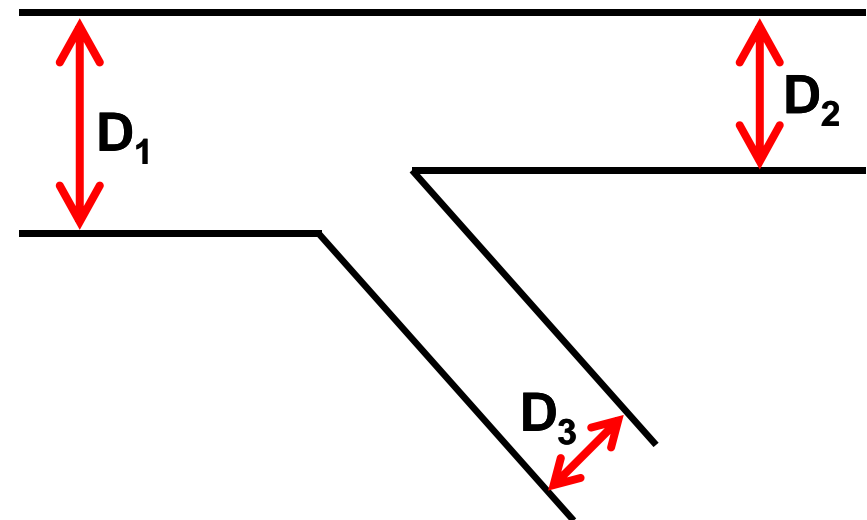
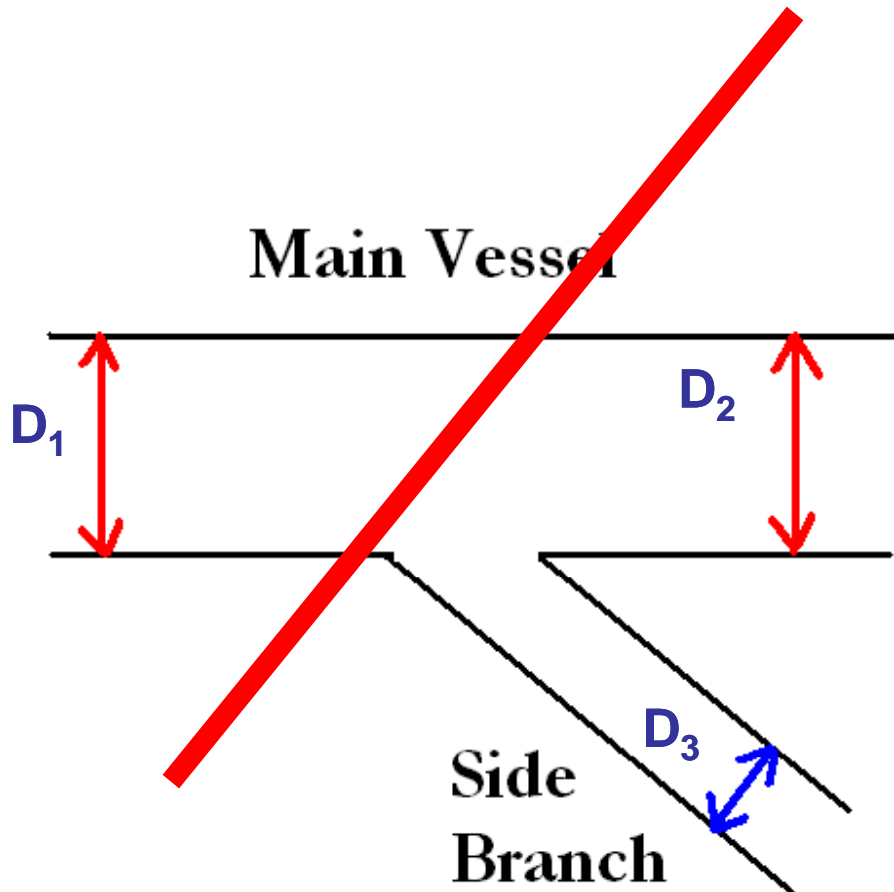
# Bifurcation branching laws

## Murray's law

$$D_1^{3^*} = D_2^{3^*} + D_3^{3^*}$$

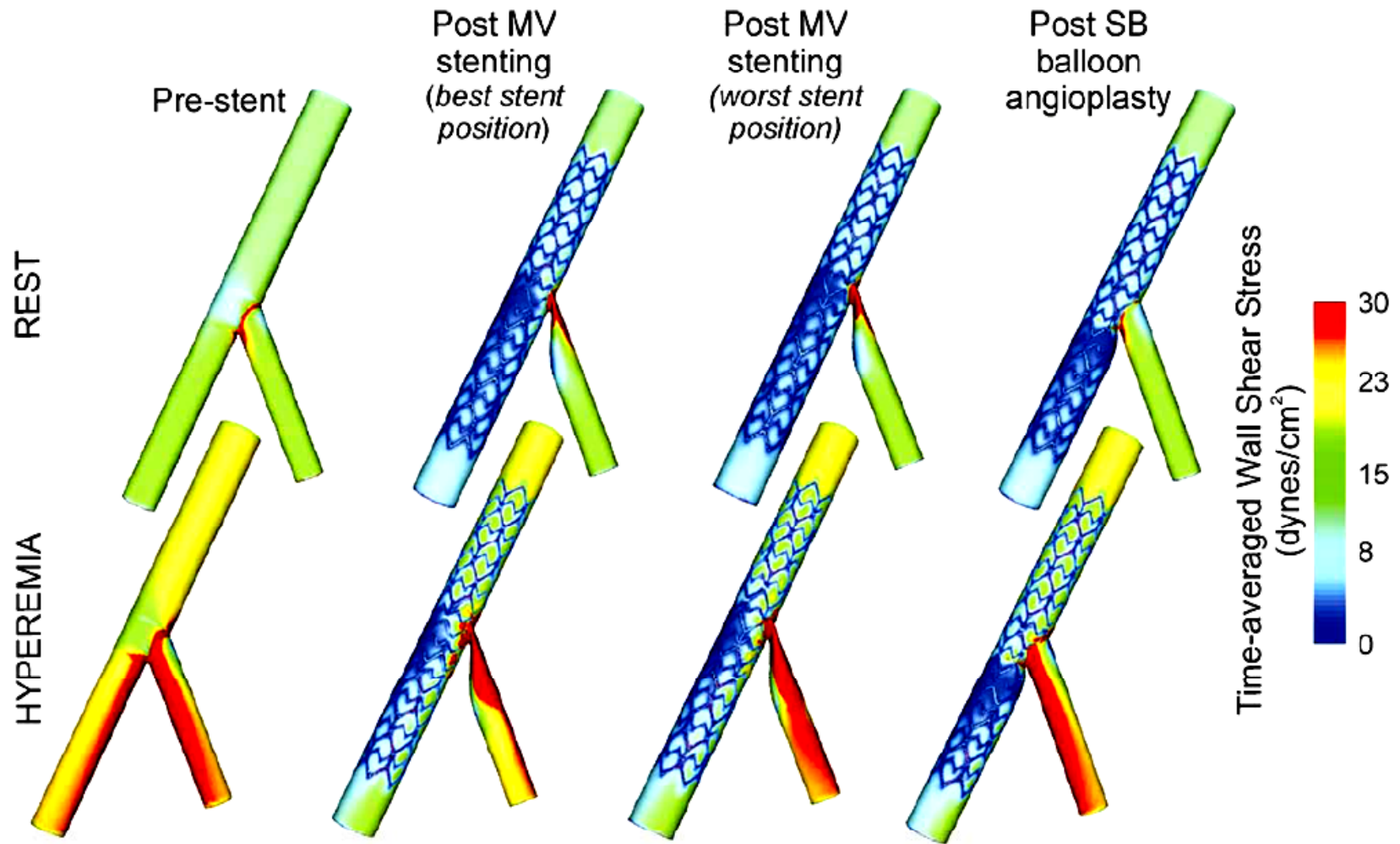
## Finet's law

$$D_1 = 0.67(D_2 + D_3)$$



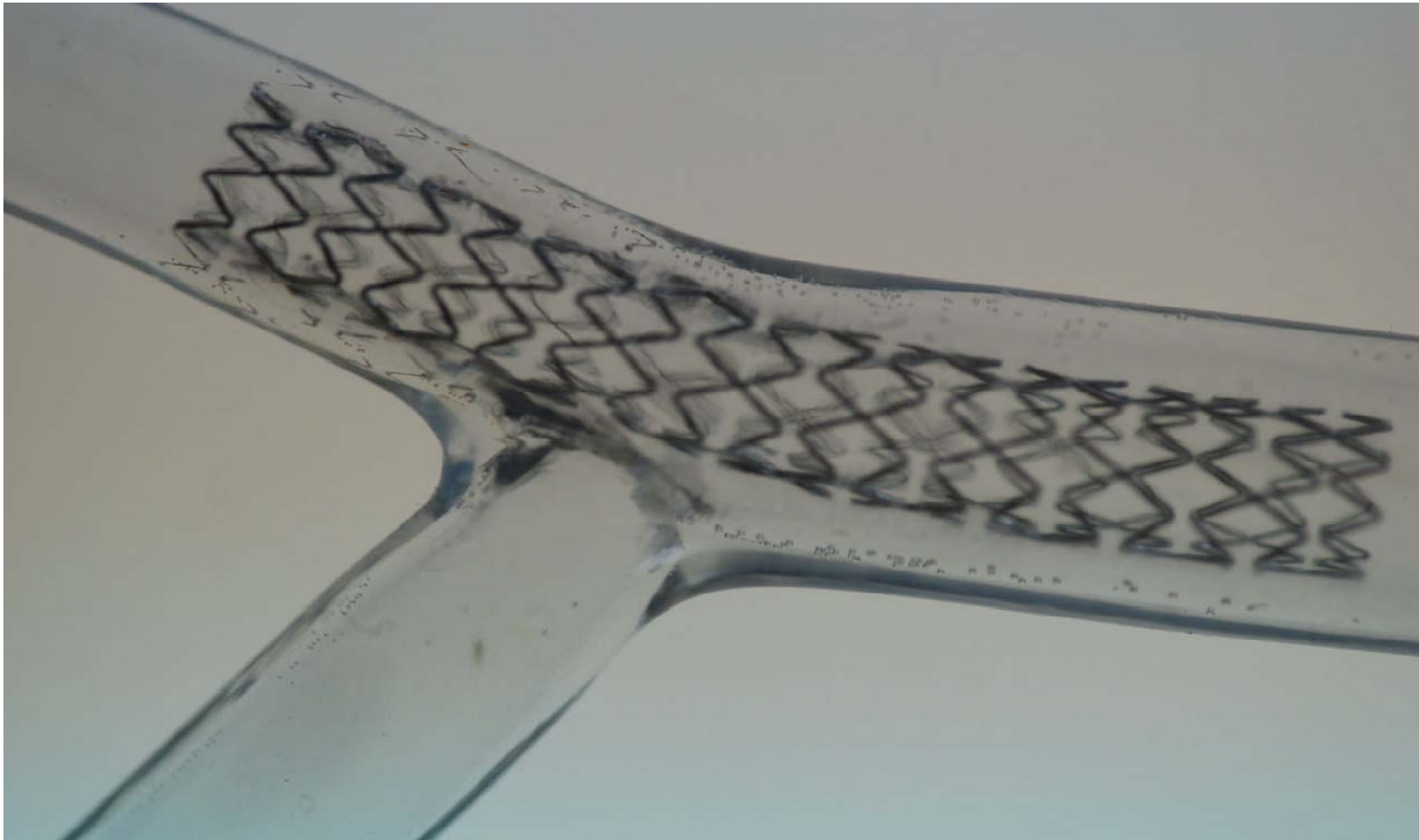
\* 2.3  
From Koo, EBC, 2008

# Hemodynamic changes after MB stenting and subsequent SB balloon angioplasty in a representative coronary bifurcation



Changes in time-averaged wall shear stress introduced by bifurcation stenting

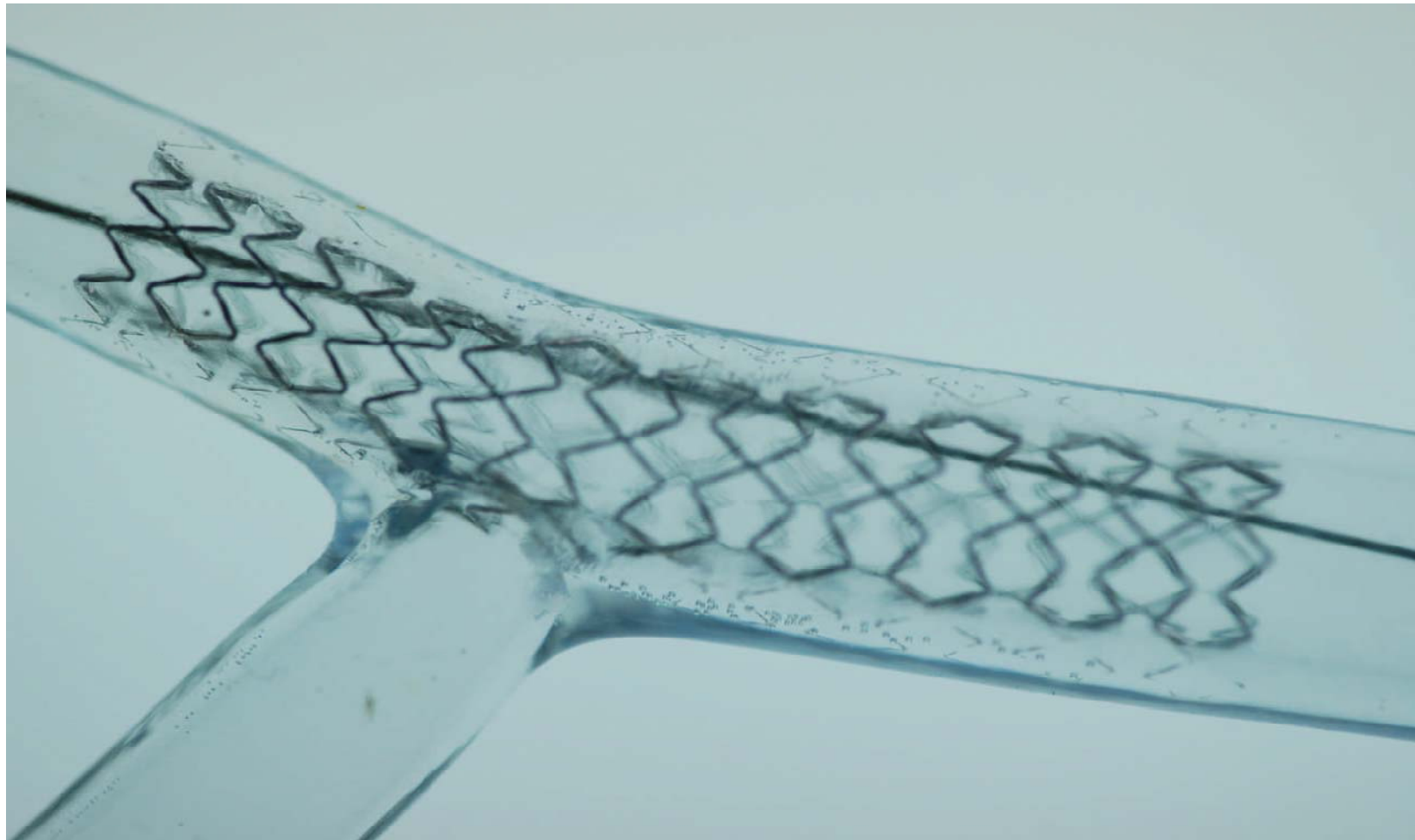
3.5 x 24 at 12 ATM  
Proximal vessel 4.5 mm, distal 3.5 mm



3.5 x 24 at 12 ATM

Proximal vessel 4.5 mm, distal 3.5 mm

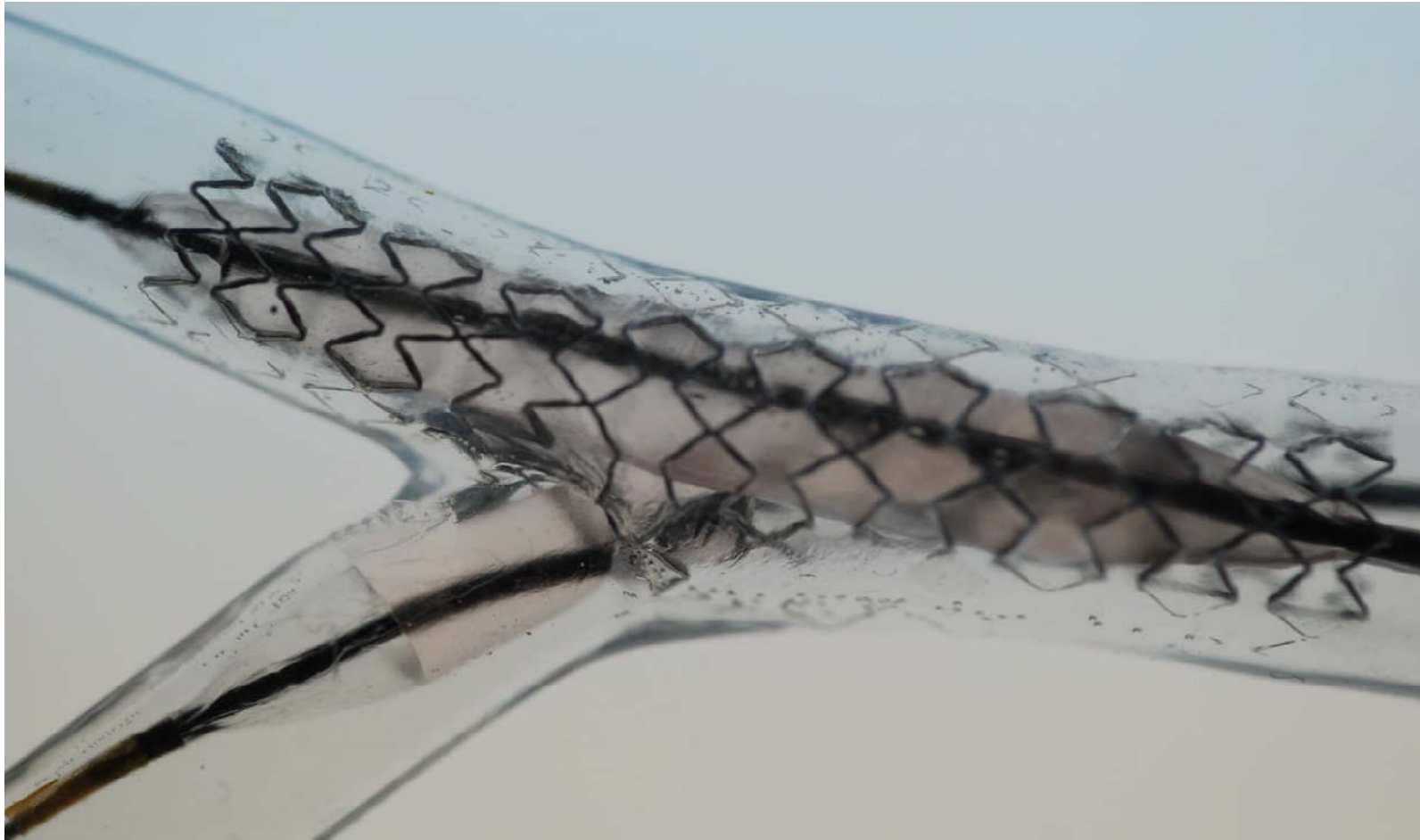
After POT technique using NC balloon 4.5 x 10



3.5 x 24 at 12 ATM

Proximal vessel 4.5 mm, distal 3.5 mm

Final double balloon kissing

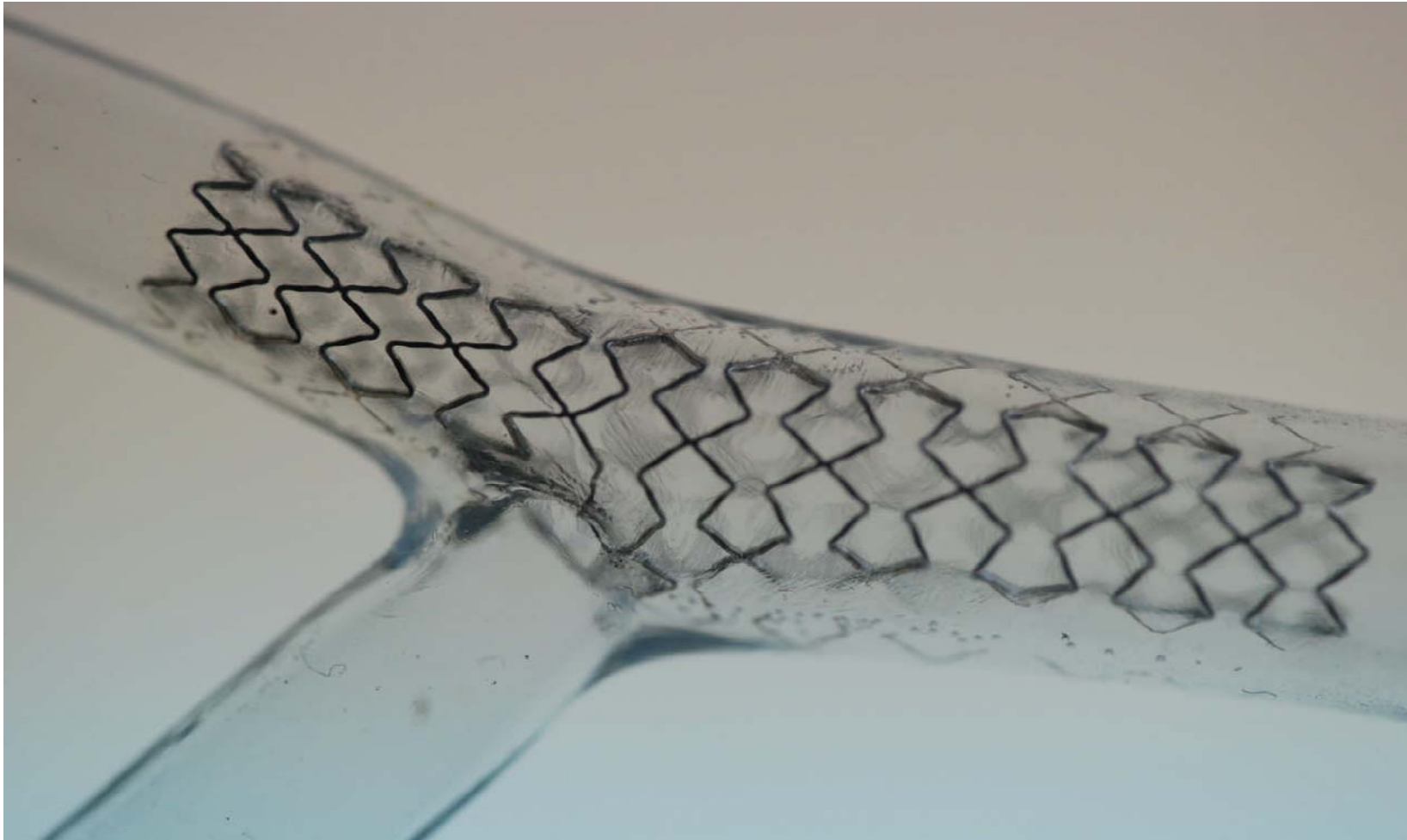




3.5 x 24 at 12 ATM

Proximal vessel 4.5 mm, distal 3.5 mm

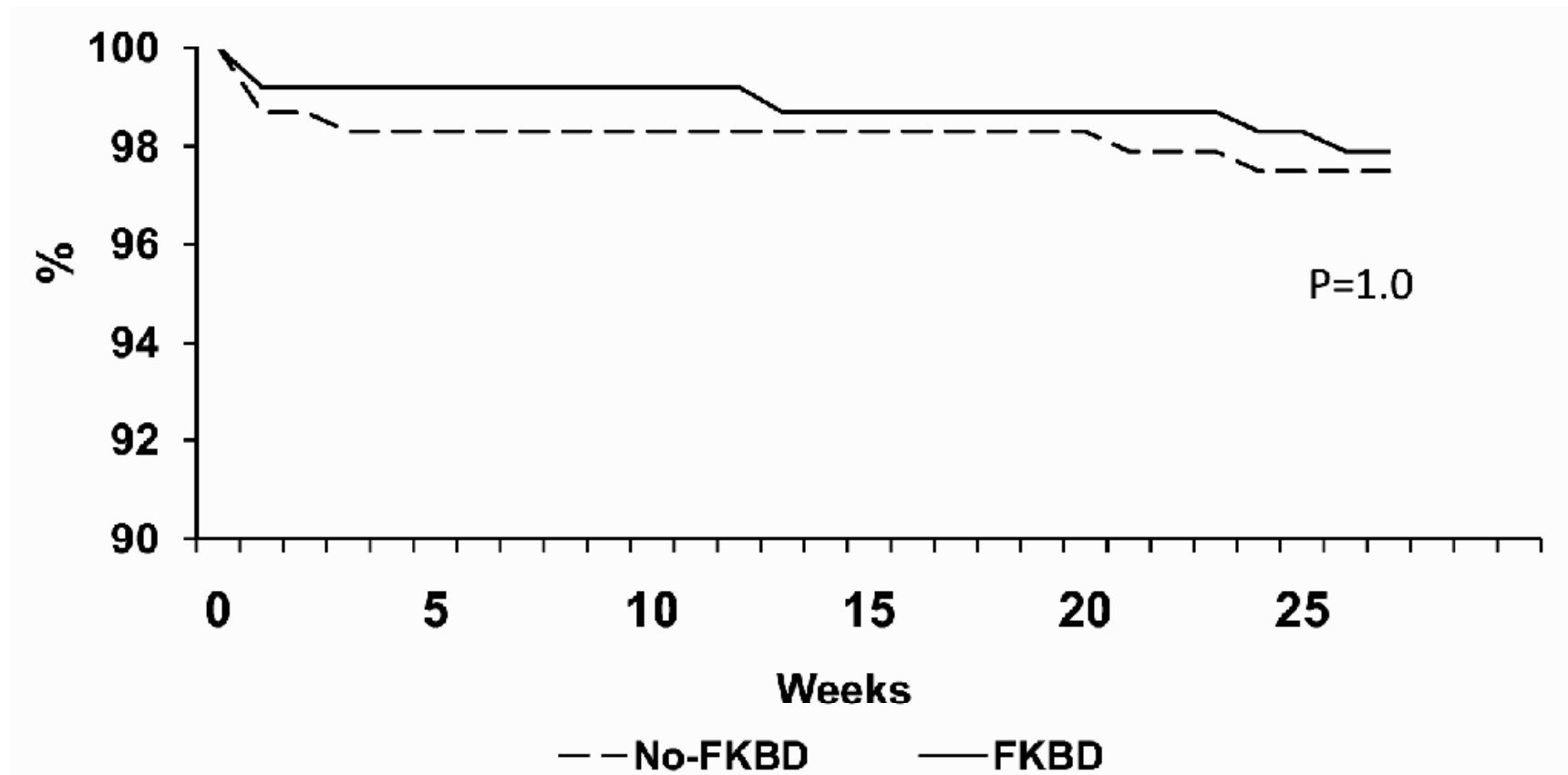
Final result after kissing



# Randomized comparison of final KB Vs no final KB in pts with coronary bifurcation lesions treated with main vessel stenting. The Nordic-Baltic Bifurcation study III

MACE-free survival

(cardiac death, non-procedure-related index lesion MI, TLR, definite stent thrombosis)



## Randomized comparison of final KB Vs no final KB in pts with coronary bifurcation lesions treated with main vessel stenting. The Nordic-Baltic Bifurcation study III

True Versus Nontrue Bifurcation Subgroup Comparison: 8-Month Angiographic Follow-Up

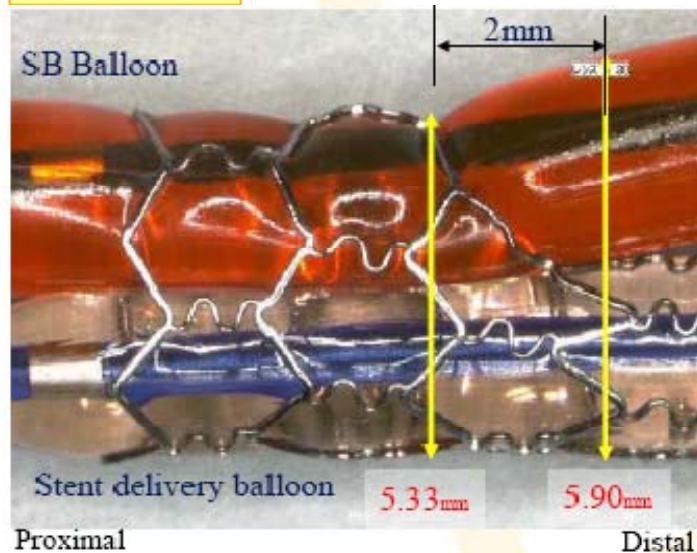
Variable	True Bifurcation Subgroup			Nontrue Bifurcation Subgroup		
	FKBD (n=92)	No FKBD (n=80)	<i>P</i>	FKBD (n=72)	No FKBD (n=82)	<i>P</i>
<b>In-segment MV</b>						
DS, %	22±15	22±15	0.85	22±14	21±12	0.90
≥50% DS, n (%)	3 (3.8)	2 (2.2)	0.67	3 (4.2)	1 (1.2)	0.34
<b>Ostial 5 mm of the SB</b>						
MLD, mm	1.71±0.42	1.50±0.53	0.005	1.79±0.54	1.77±0.61	0.79
DS, %	25±14	32±21	0.009	23±15	27±19	0.21
≥50% DS, n (%)	7 (7.6)	16 (20)	0.024	6 (8.3)	9 (11)	0.79

# Non compliant high pressure balloons for kissing

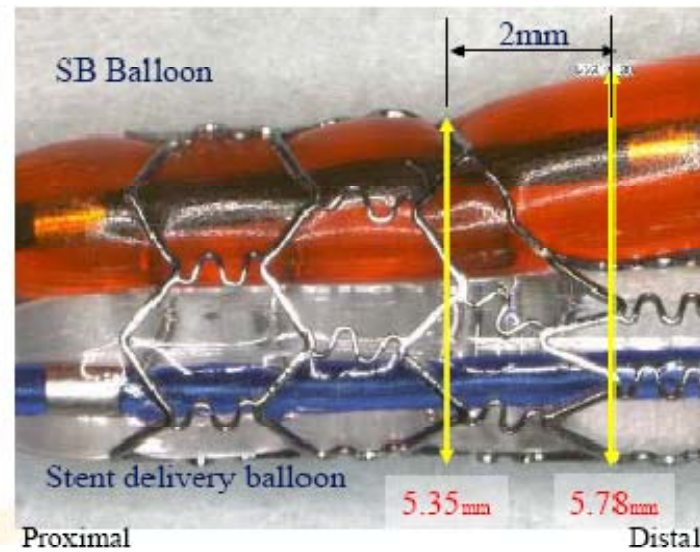


## Results

Cypher  
(J&J)



Semi-Compliant Balloon  
(Ryujin Plus, Terumo)

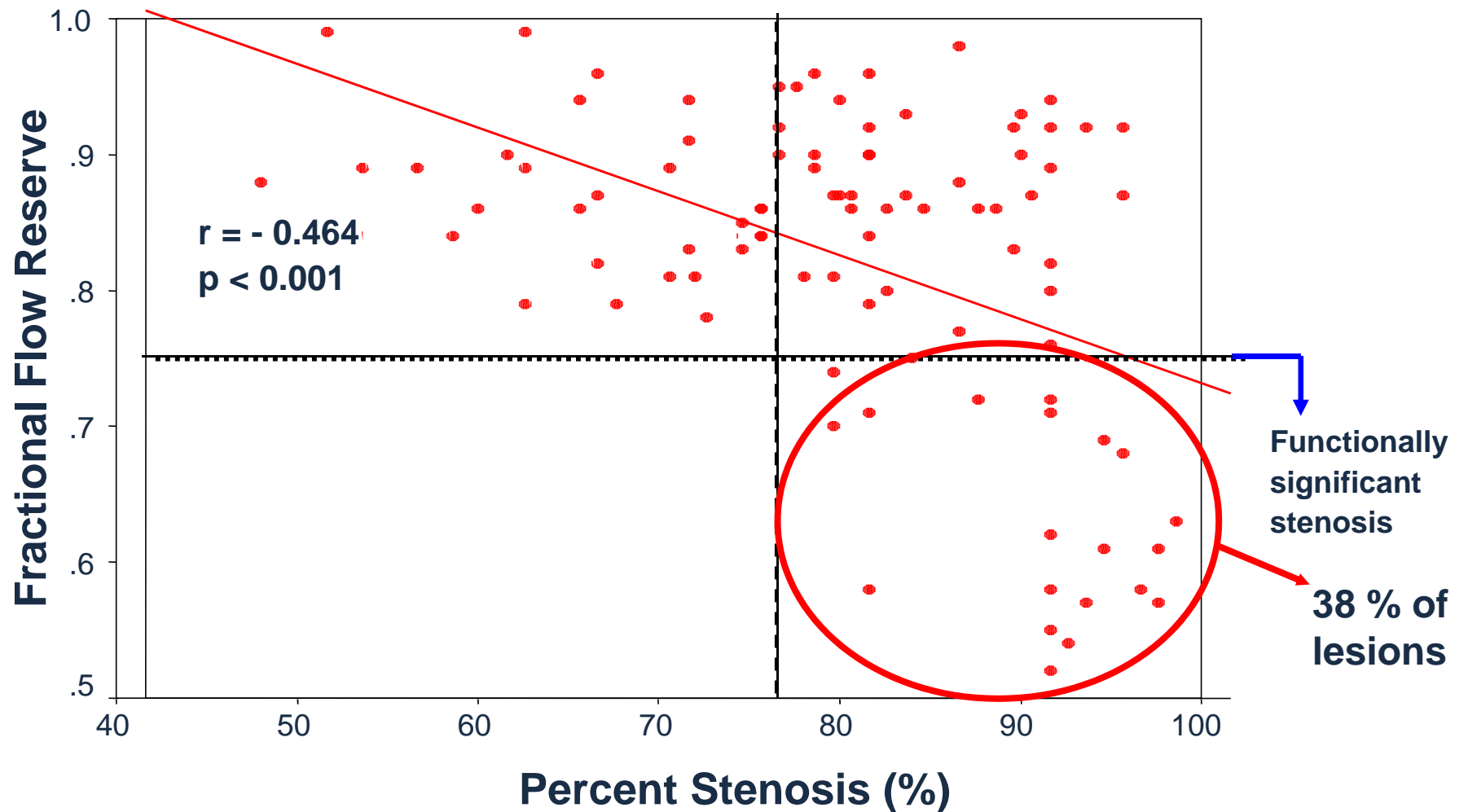


Non-Compliant Balloon  
(Hiryu, Terumo)

## Kissing With NC Balloons Toulouse (Ranguel/Massy) Pilote Study

Bifurcation lesions (n)	100
FKS success (%)	100
FKS success without SB opening (%)	97
Metal projection in SB (%)	89
Need for SB stenting (%)	7
In-hospital MACE (%)	0

# Significant Post Stenting SB Stenosis: QCA vs FFR (jailed side branch lesions, n=94)

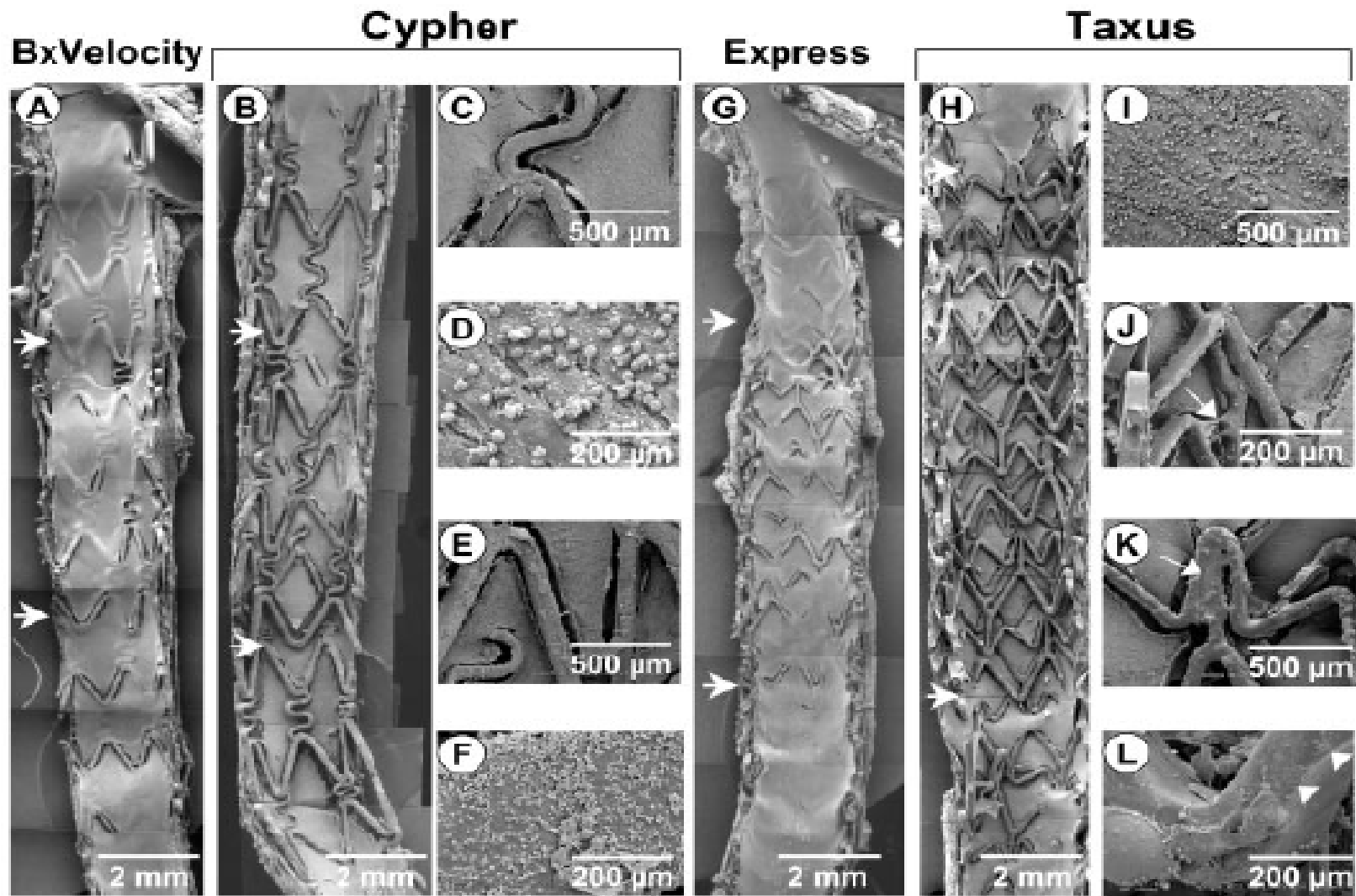


**Double stenting = Complex strategies ?**

	<b>M</b> Main prox. first	<b>A</b> Main Accross side first	<b>D</b> Double	<b>S</b> Side branch first							
<b>1<sup>st</sup> stent</b>	 PM stenting	 MB stenting across SB	 DM stenting	 Provisional SKS	 SB ostial stenting						
<b>After balloon</b>	 Skirt	 MB stenting + SB balloon	 MB stenting + kissing		 SB minicrush	 SB crush					
<b>2 stents</b>	 Skirt + DM	 Skirt + SB	 Elective T stenting	 Internal crush	 Culotte	 TAP	 V stenting	 SKS	 Syst. T Stenting	 Minicrush	 Crush
<b>3 stents</b>	 Extended V		 Trouser legs and seat								



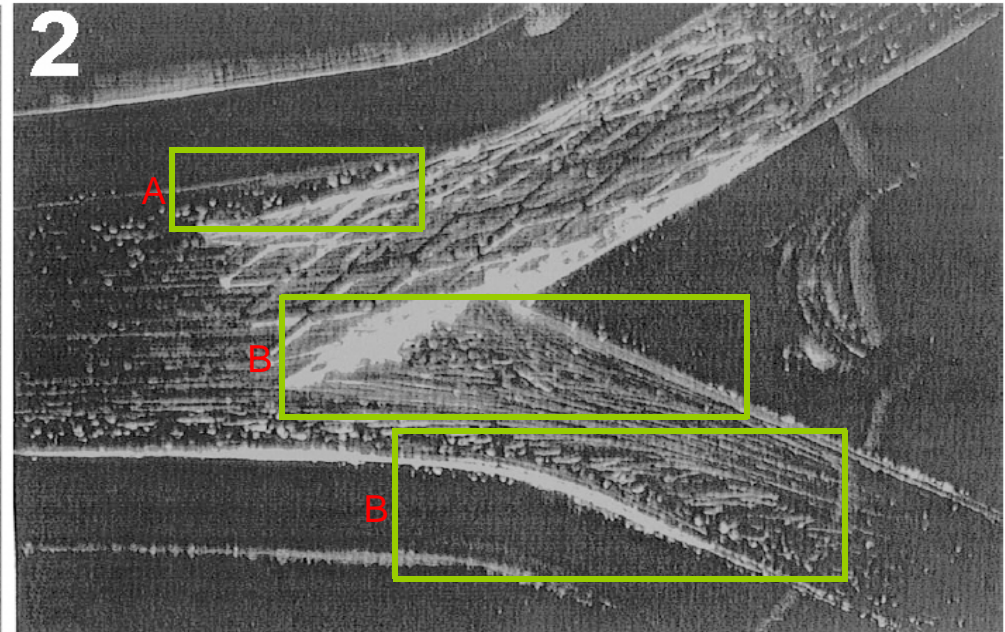
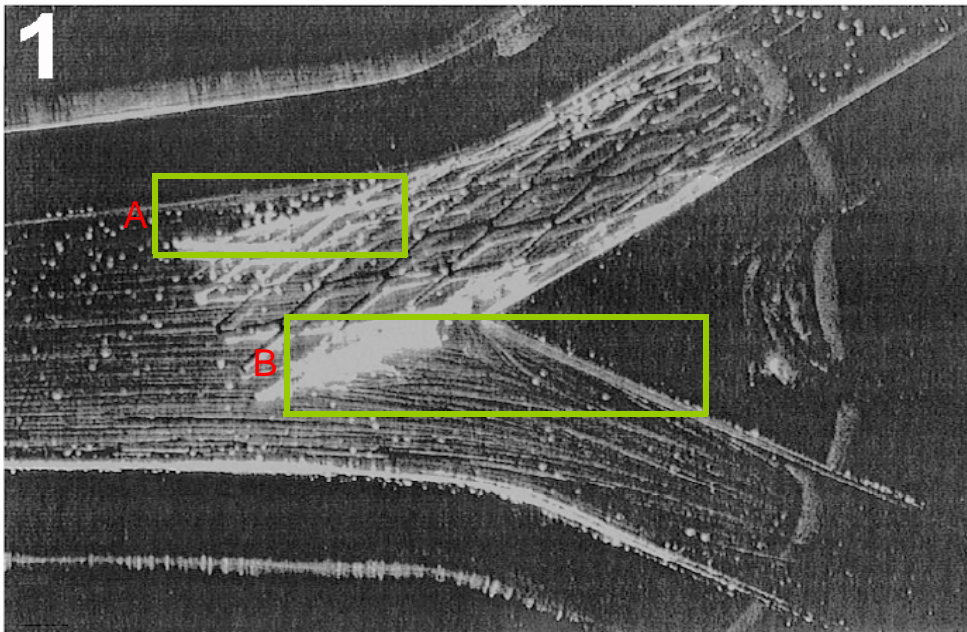
# Excess of Metal



# Bifurcations stenting

Application of fluid dynamics analysis:

Macroscopic flow perturbations at stented bifurcation site



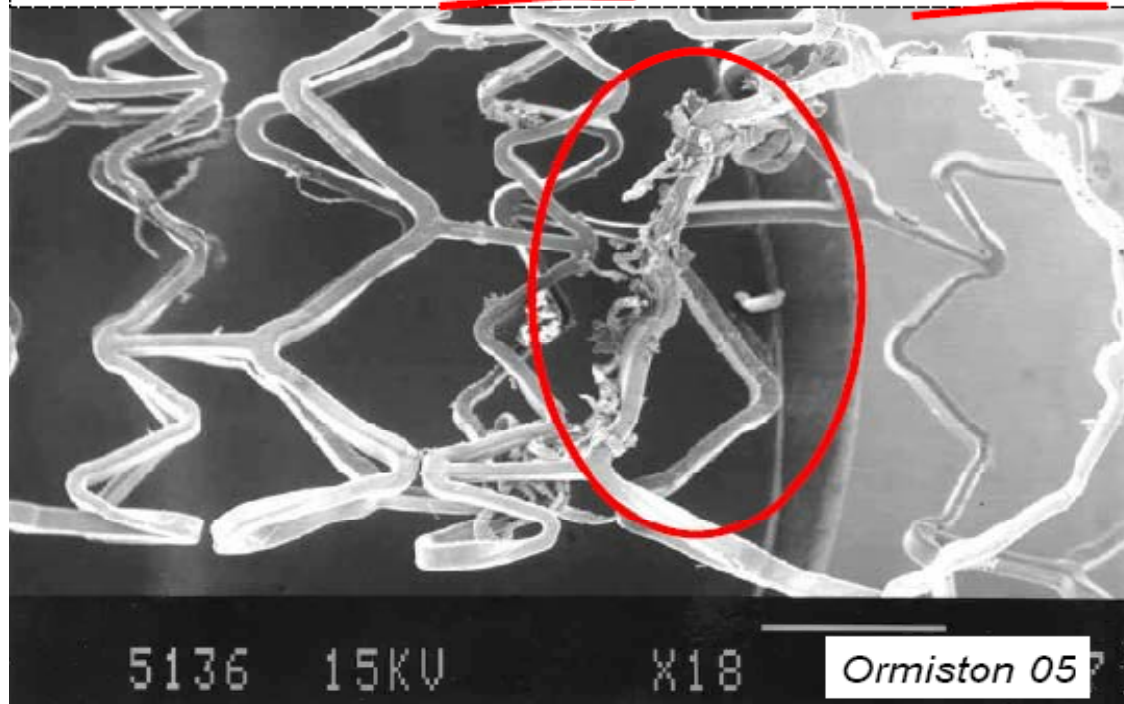
Physiological flow through a bifurcation model with palmaz stent

A stagnation zone (A) appear if the stent does not conform to the artery.

The stent implantation in a daughter branch induces recirculation zones in the healthy artery branch (B) due to the protruding part of the stent.

## Polymer damage

Side-branch ostium after "crush" + "kiss" with large balloons and multiple inflations at 20 atmos



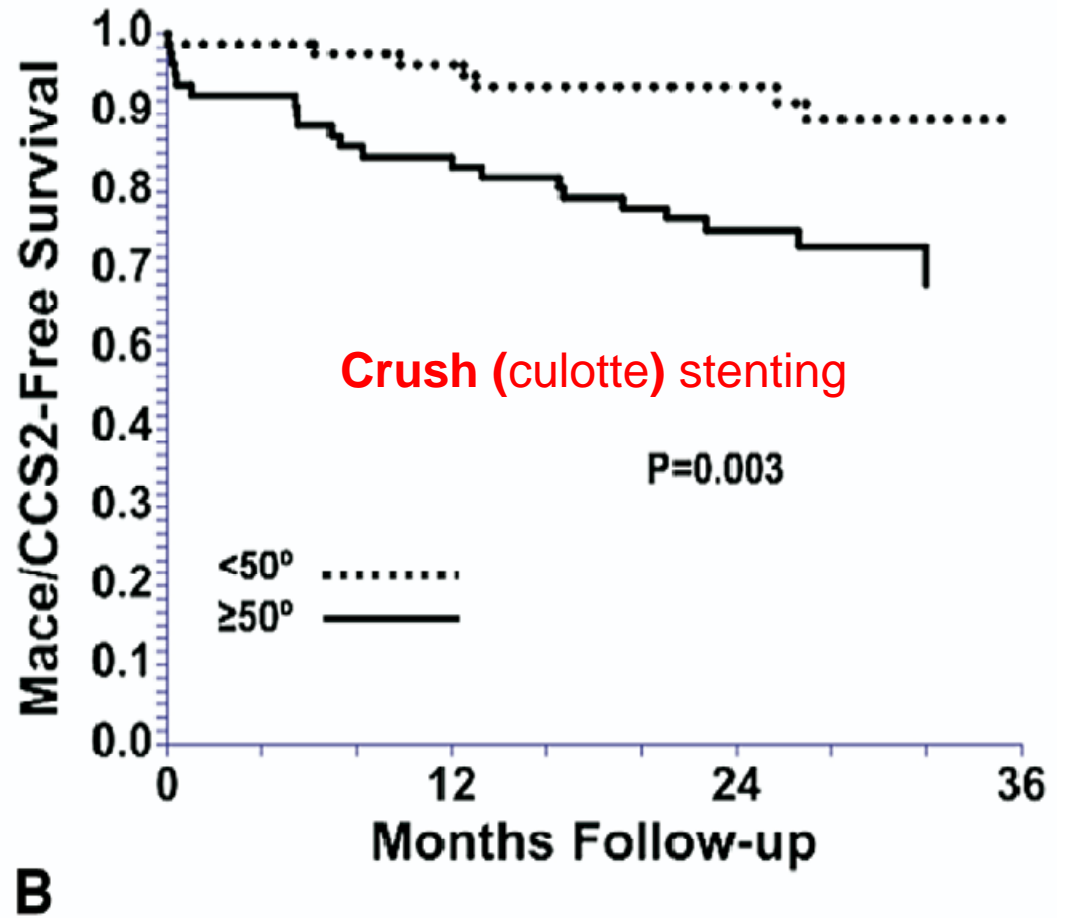
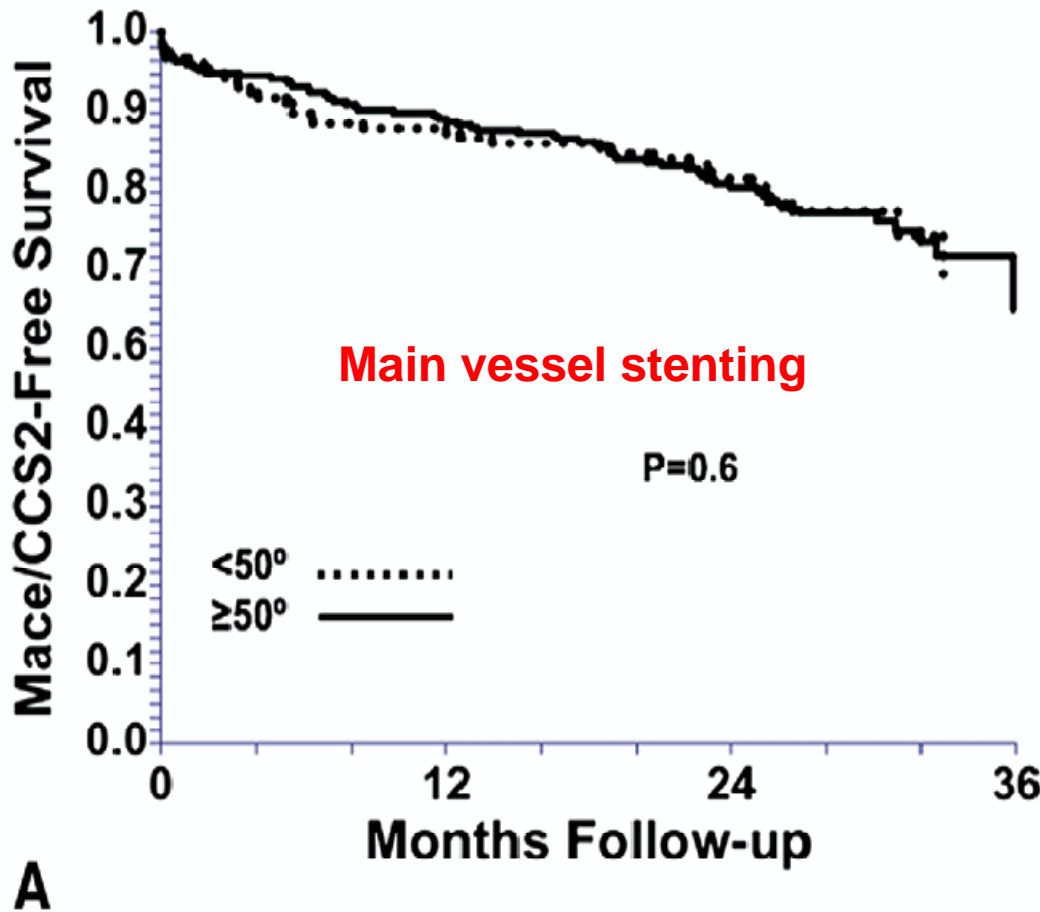
# Angio / IVUS predictors of SB failure during PCI with provisional SB stenting in complex bifurcation lesions

PREPROCEDURE VARIABLES IN THE SB	CROSS-OVER*		P value
	YES, n=6	NO, n=22	
Quantitative Coronary Angiography (QCA)			
Lesion length, mm	13.9	8.87	0.01
Reference diameter	2.47	2.51	0.83
% diameter stenosis	88.6	71.7	0.02
IVUS			
Minimum lumen area (MLA), mm <sup>2</sup>	1.73	2.33	0.005
Plaque burden	65.5	59.1	0.41
Remodeling index	0.65	0.96	0.03
Calcium (arc >90 degrees), %	83.3	29.3	0.006

\*Lesions randomized to single “provisional” stenting

56 true bifurcation lesions, SB lesion >5mm, randomized for “provisional” stenting (n=28) vs double stenting (n=28) w/ ELS. Crossover from single to double stenting: SB >70% residual stenosis, dissection >type A, and/or TIMI=0 or 1 flow, after final KB. IVUS performed in both branches at preprocedure.

## Outcome After Bifurcation PCI: role of angle



Kaplan-Meier curves for MACE or CCS class 2 angina-free survival / bifurcation angle

## Crush and ... Crush

	Entire Cohort n = 181 Patients	FKB Group n = 116 Patients	Non-FKB Group n = 65 Patients	p*
Angiographic success, n (%)	178 (98.3)	116 (100)	62 (95.4)	0.13
Procedural success, n (%)	162 (89.5)	106 (91.4)	56 (86.2)	0.40
In-hospital MACE, n (%)	16 (8.8)	10 (8.6)	6 (9.2)	1.0
Cardiac death	0	0	0	—
Q-wave MI	1 (0.6)	0	1 (1.5)	0.77
Non-Q-wave MI	15 (8.3)	10 (8.6)	5 (7.7)	0.95
TLR	0	0	0	—
TVR	0	0	0	—
Cumulative nine-month MACE, n (%)	48 (26.5)	23 (19.8)	25 (38.5)	0.008
Cardiac death	2 (1.1)	2 (1.7)	0	0.54
Q-wave MI	6 (3.3)	2 (1.7)	4 (6.2)	0.28
Non-Q-wave MI	15 (8.3)	10 (8.6)	5 (7.7)	0.95
TLR	27 (14.9)	11 (9.5)	16 (24.6)	0.008
<b>TVR</b>	<b>31 (17.1)</b>	<b>12 (10.3)</b>	<b>19 (29.2)</b>	<b>0.002</b>
Postprocedural stent thrombosis	5 (2.8)	3 (2.6)	2 (3.1)	0.78
Subacute	1 (0.6)	0	1 (1.5)	0.77
Late	4 (2.2)	3 (2.6)	1 (1.5)	0.95

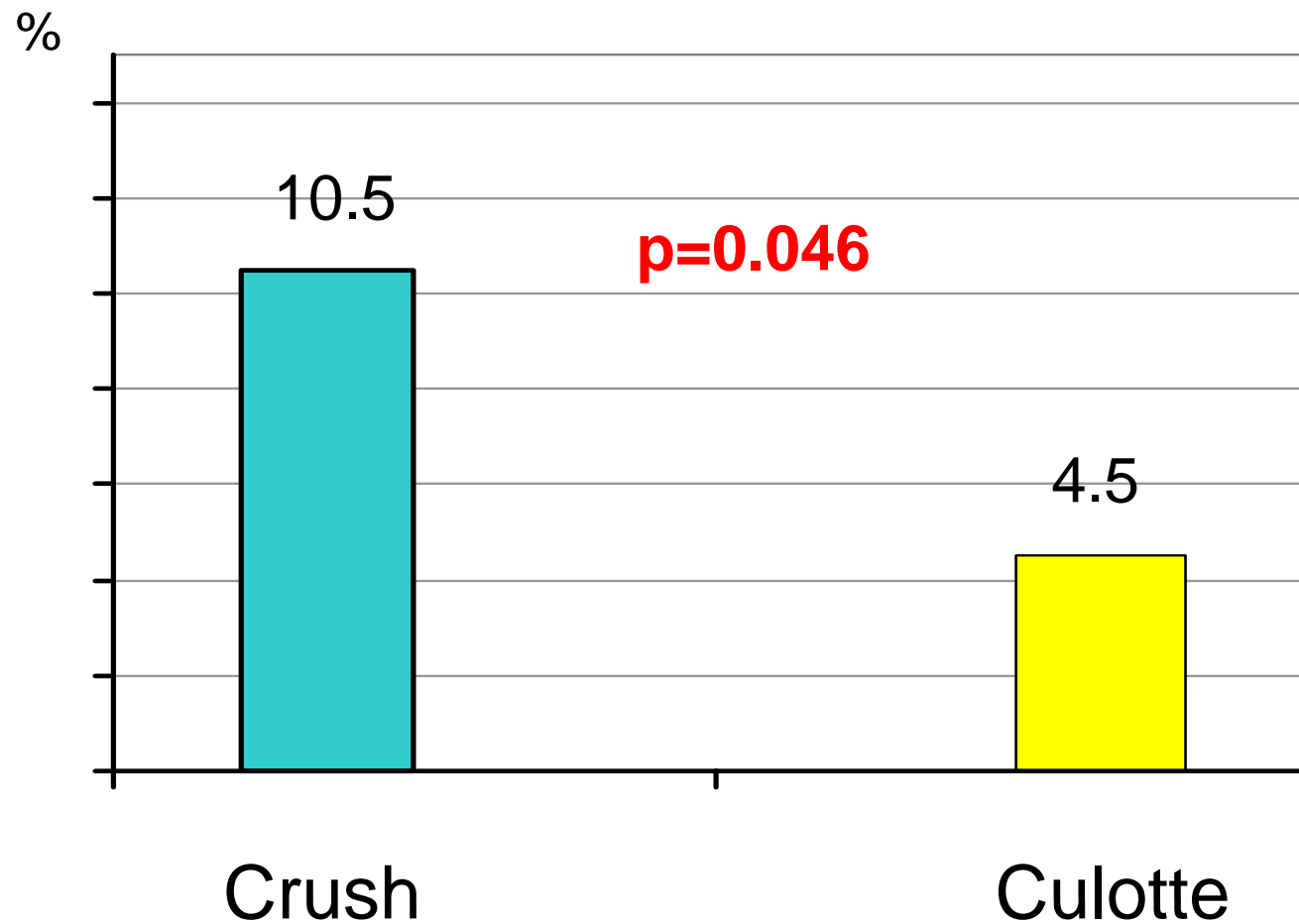


# Culotte stenting : 12m dedicated QCA and clinical outcomes

Variable	Odds ratio (95% CI)	P-value
Age increase by 10 years	2.38 (1.21–4.96)	0.01
Diabetes	3.43 (0.71–16.60)	0.13
Male sex	0.62 (0.15–2.53)	0.51
Medina classification	0.42 (0.13–1.32)	0.14
Restenotic lesion	0.52 (0.12–2.24)	0.38
<b>Bifurcation angle increase by 10°</b>	1.53 (1.04–2.23)	0.03
Calcified lesion	0.53 (0.12–2.24)	0.39
<b>Proximal main vessel</b>		
Reference vessel diameter decrease by 1 mm	4.55 (0.17–123.36)	0.37
Baseline stenosis increase by 10%	0.91 (0.67–1.23)	0.54
<b>Distal main vessel</b>		
Reference vessel diameter decrease by 1 mm	0.10 (0.00–3.17)	0.19
Baseline stenosis increase by 10%	1.47 (1.03–2.09)	0.03
<b>Side branch vessel</b>		
Reference vessel diameter decrease by 1 mm	31.83 (1.71–592.77)	0.02
Baseline stenosis increase by 10%	0.97 (0.82–1.15)	0.75
Kissing balloon post-dilatation	0.37 (0.13–1.10)	0.07

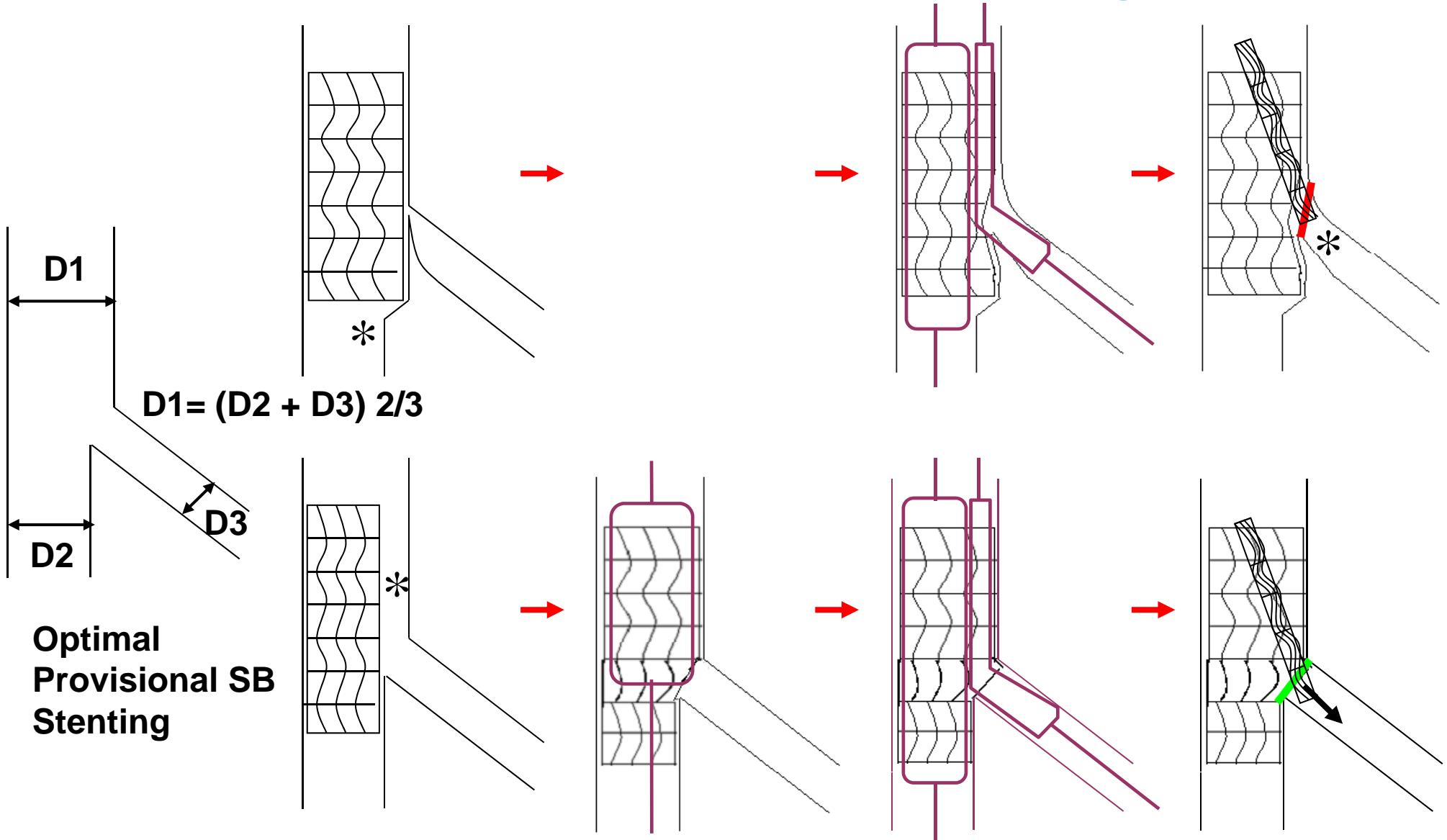
## Predictors of binary restenosis

## NORDIC II: MB and/or SB in-stent diameter stenosis >50% at 8 months FU





# Optimal Provisional SB Stenting



## Conclusions

- Provisional SB stenting is the gold standard for bifurcation stenting
- Reproducing the original anatomy seems important: POT technique
- Final kissing balloon inflation after single stenting ?: improve SB acute result, clinical impact in big bifurcations, futur access to SB
- SB stenting limited to significant important SB residual stenosis?: FFR ?, 3D angio ?
- Double systematic stenting ?: long SB stenosis, tight SB stenosis, calcium ?
- Why not begin with MB stenting ?