13th Annual Angioplasty Summit TCT Asia Pacific
3rd APSIC Fellowship Convocation

Studies Investigating Optimal Bifurcation Stenting Strategy with DES

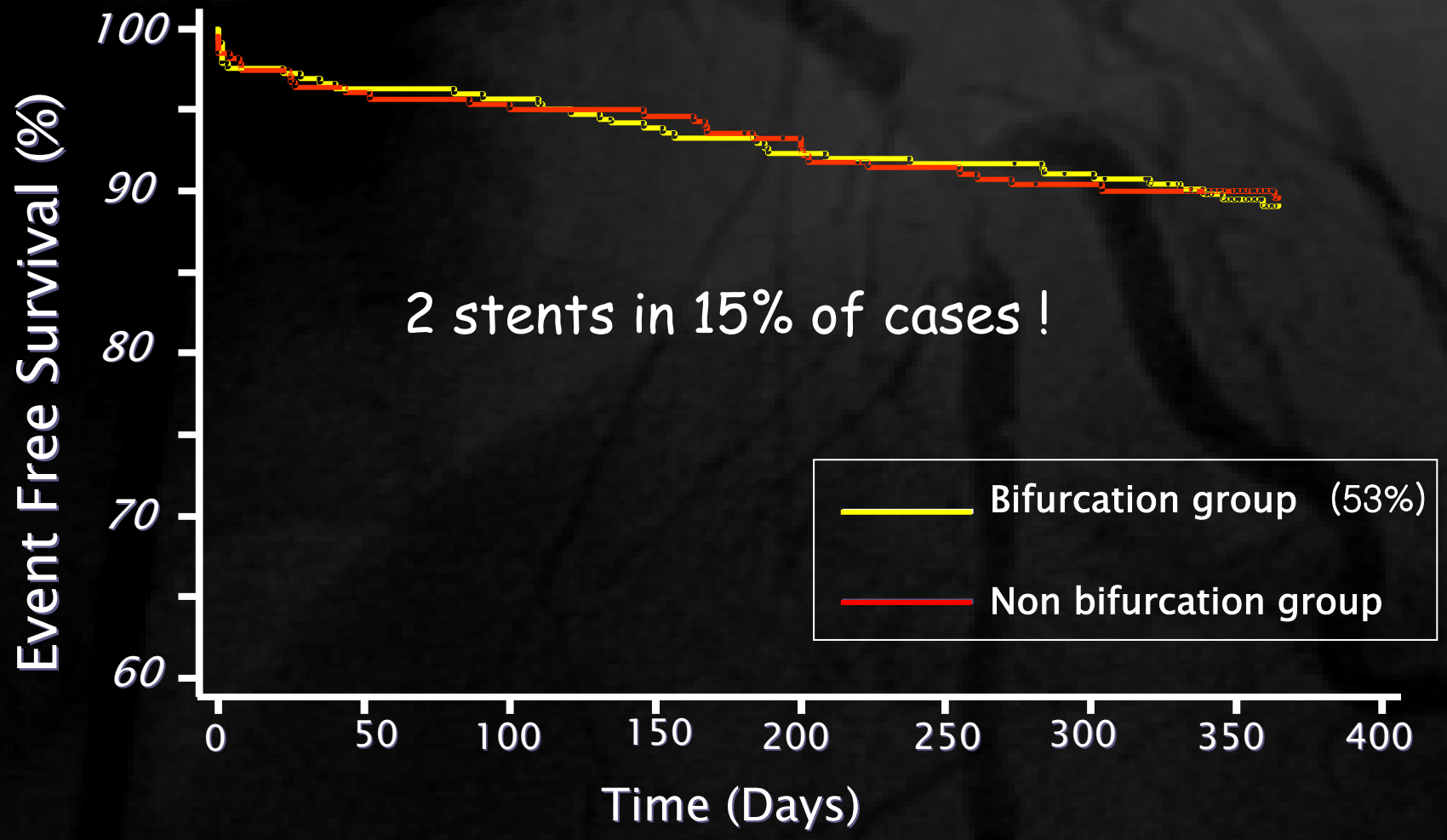
T. Lefèvre and the ICPS Team

Bifurcation Lesions:
A problem in Daily Pratice !

- ✓ Need a standardized ap ch
- ✓ Simple and safe
- ✓ High rate ess
- ✓ L of SB occlusion
- Low rate of complications
- ✓ Good long term results

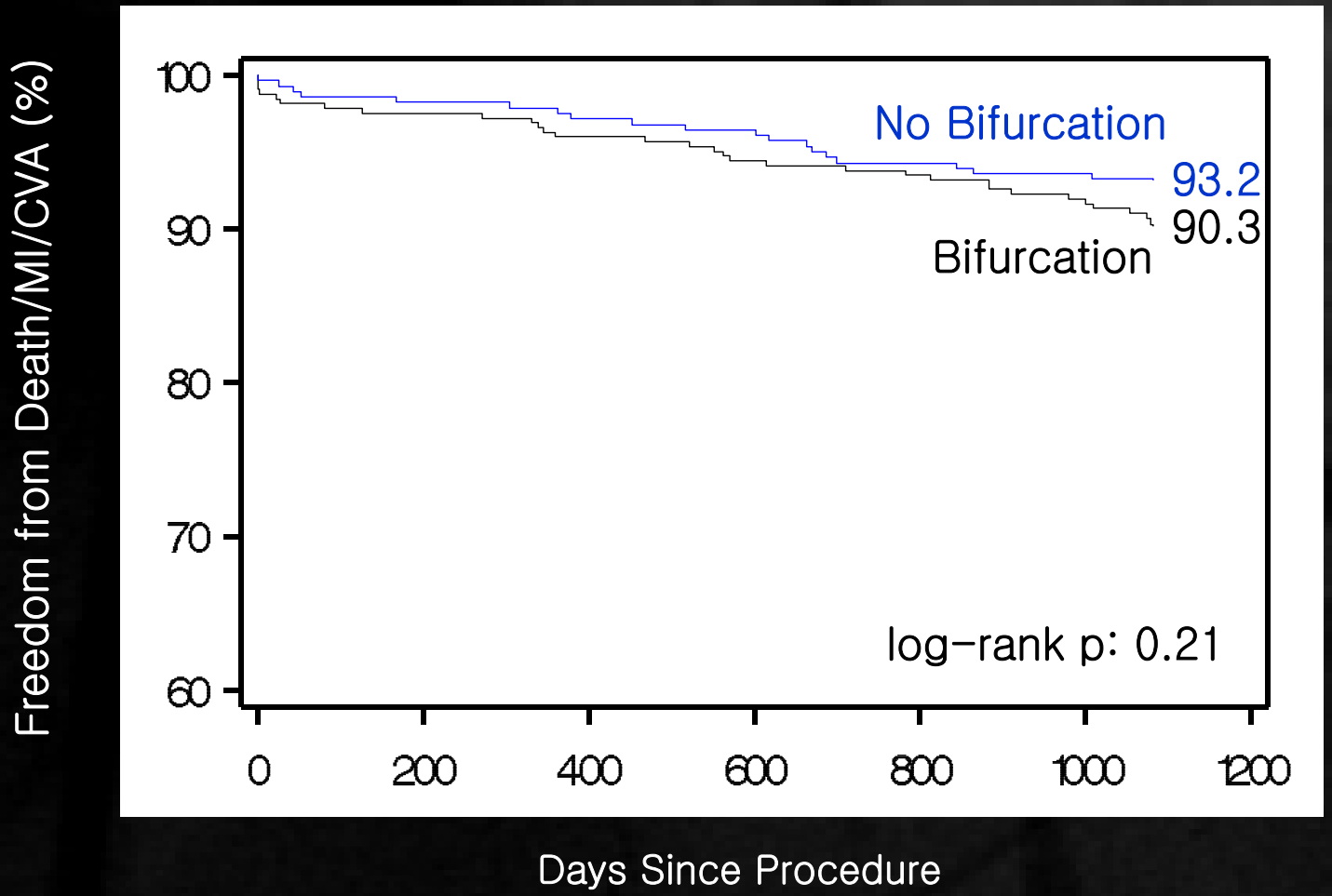
Optimal strategy

Bifurcation Lesions in ARTS II



Colombo et al. AHA 2005

Bifurcation Lesions in ARTS II

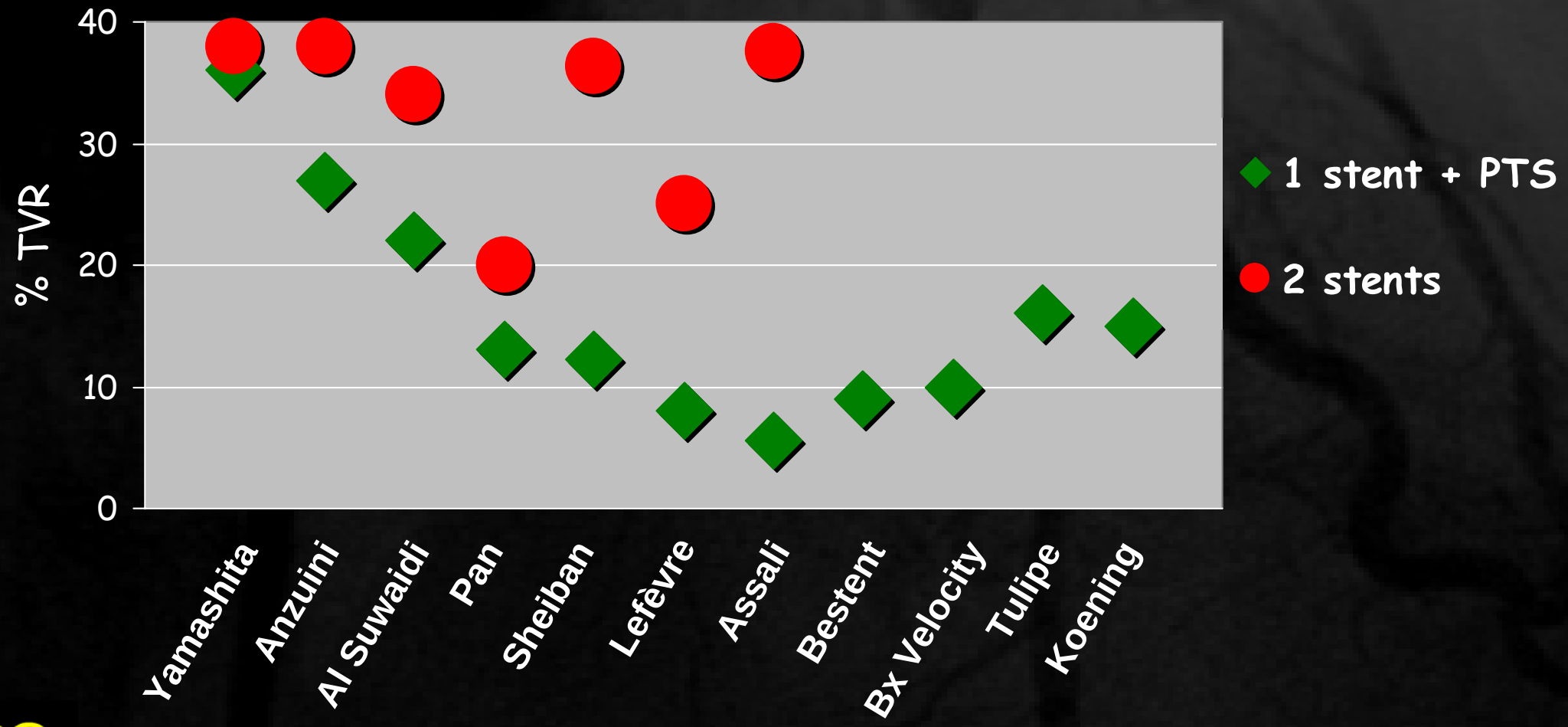


Lefèvre et al. ESC 2007

1. Efficacy: BMS vs DES

No Randomized Studies !

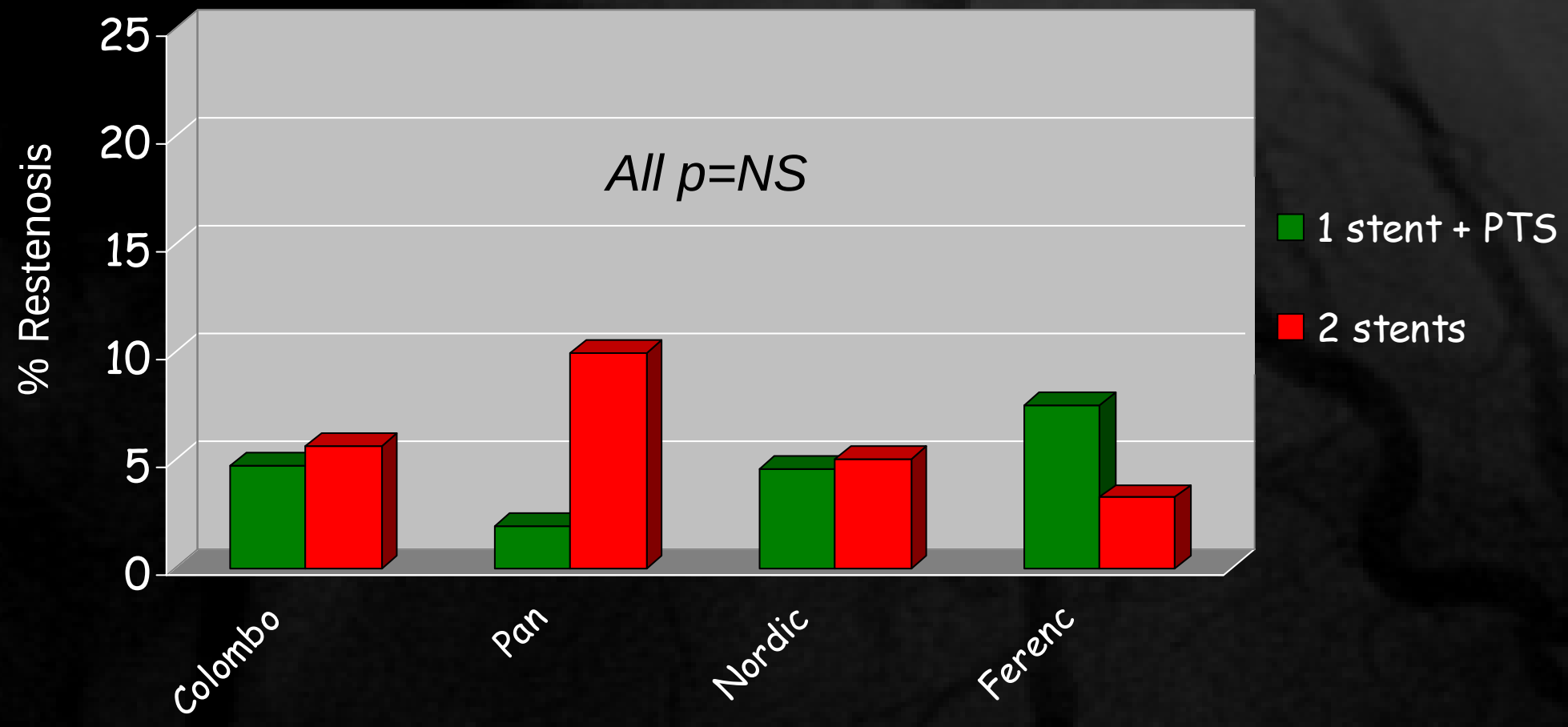
TVR After BMS in Bifurcation lesions



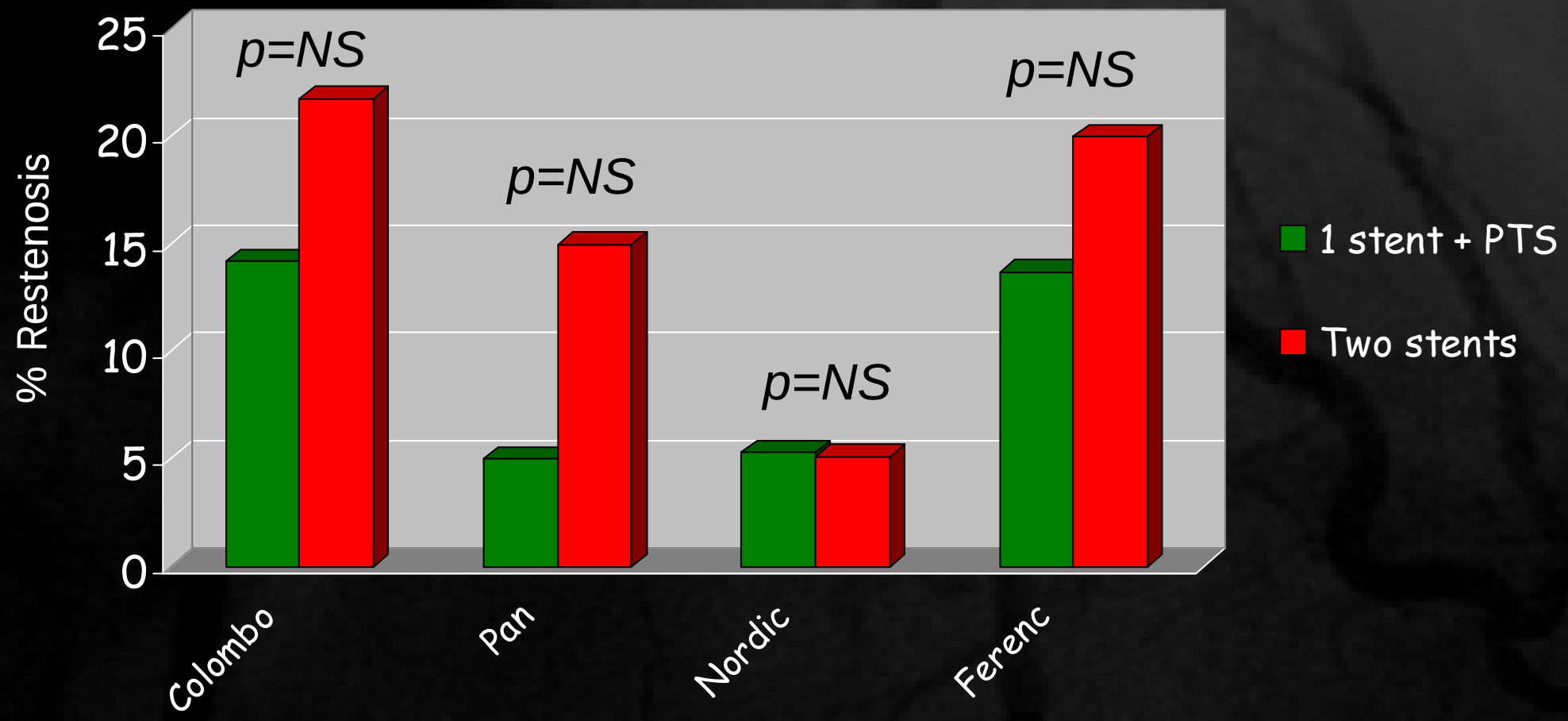
2. Efficacy: 1 vs 2 Stents

4 Randomized Studies !

Low Rate of MB Restenosis

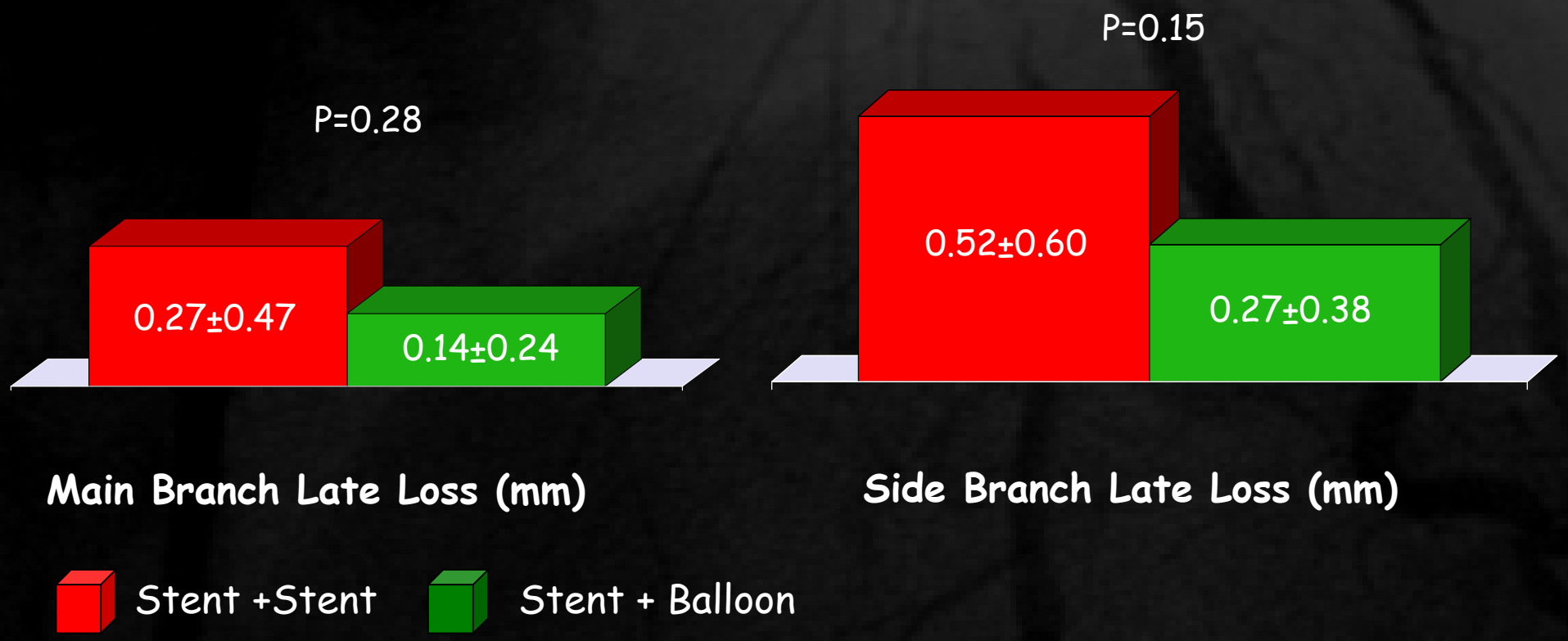


Low Rate of SB Restenosis



Late Loss after Bifurcation stenting

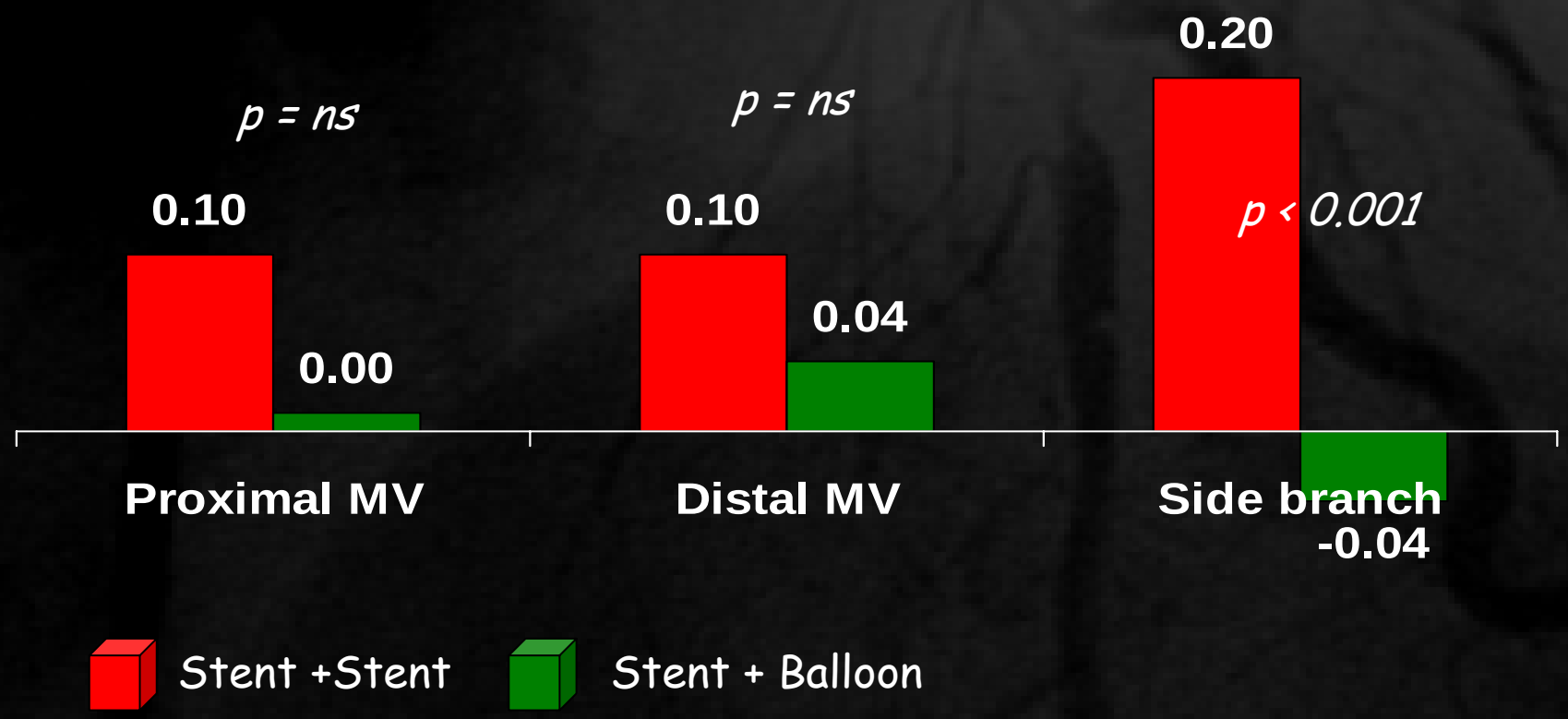
Bifurcation Sirolimus Study



Colombo et al. Circulation 2004; 109: 1244-49

Late Loss after Bifurcation stenting

Nordic 1 Study



Terje K Steigen. Circulation 2006;114;1955-1961

1 vs 2 stents:

Limitations of randomized studies

Randomized Study to Evaluate Sirolimus-Eluting Stents Implanted at Coronary Bifurcation Lesions

Antonio Colombo, MD; Jeffrey W. Moses, MD; Marie Claude Morice, MD; Josef Ludwig, MD; David R. Holmes, Jr, MD; Vassilis Spanos, MD; Yves Louvard, MD; Benny Desmedt; Carlo Di Mario, MD; Martin B. Leon, MD

	In-Hospital		6 Months	
	Stent/Stent (63 Patients)	Stent/PTCA (22 Patients)	Stent/Stent (63 Patients)	Stent/PTCA (22 Patients)
Death	0	0	1 (1.6)	0
Q-wave MI	0	1 (4.5)	1 (1.6)	1 (4.5)
Non–Q-wave MI	[illegible]	[illegible]	6 ([illegible])	1 (4.5)
MB restenosis*	...	...	3/53 (5.7)	1/21 (4.8)
SB restenosis*	...	...	12/55 (21.8)	3/21 (14.2)
Re-PTCA, TLR	1 (1.6)	0	6 (9.5)	1 (4.5)
Bypass	0	0	1 (1.6)	0
Re-PTCA, TVR	0	1 (4.3)	7 (11.1)	2 (9.0)
TVF	6 (9.5)	2 (9.1)	12 (19.0)	3 (13.6)

Cross-over 51%

Circulation 2004; 109:1244-1249

Randomized Study on Simple Versus Complex Stenting of Coronary Artery Bifurcation Lesions: The Nordic Bifurcation Study

Terje K. Steigen, Michael Maeng, Rune Wiseth, Andrejs Erglis, Indulis Kumsars, Inga Narbute, Pål Gunnes, Jan Mannsverk, Oliver Meyerdierks, Svein Rotevatn, Matti Niemelä, Kari Kervinen, Jan S. Jensen, Anders Galløe, Kjell Nikus, Saila Vikman, Jan Ravkilde, Stefan James, Jens Aarøe, Antti Ylitalo, Steffen Helqvist, Iwar Sjögren, Per Thayssen, Kari Virtanen, Mikko Puhakka, Juhani Airaksinen, Jens F. Lassen, Leif Thuesen and for the Nordic PCI Study Group

	MV (n=207)	MV+SB (n=206)	P-value
Diabetes (%)	12	13	ns
Ref. diameter (mm)	3.3±0.4	3.3±0.4	ns
SB stented (%)	4.3	95.1	<0.001
Kissing balloon (%)	32	74	<0.001

Terje K Steigen. *Circulation* 2006;114;1955-1961

SIROLIMUS ELUTING STENT (2002-2003)

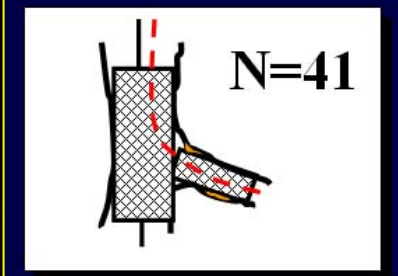
91 Bifurcated lesions

Randomization

Complex N=44

Simple N=47

Cross-over



1

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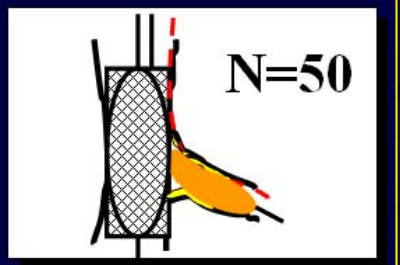


Pan et al. Am Heart J 2004; 148: 857-64.

PROSPECTIVE RANDOMIZED STUDY

April 2005 – August 2006

202 patients with de novo bifurcation lesion

Provisional T-stenting	Systematic T-stenting
n = 101	n = 101

Angiographic follow-up with QCA at 9 months

Clinical follow-up at 30 days and 1 year

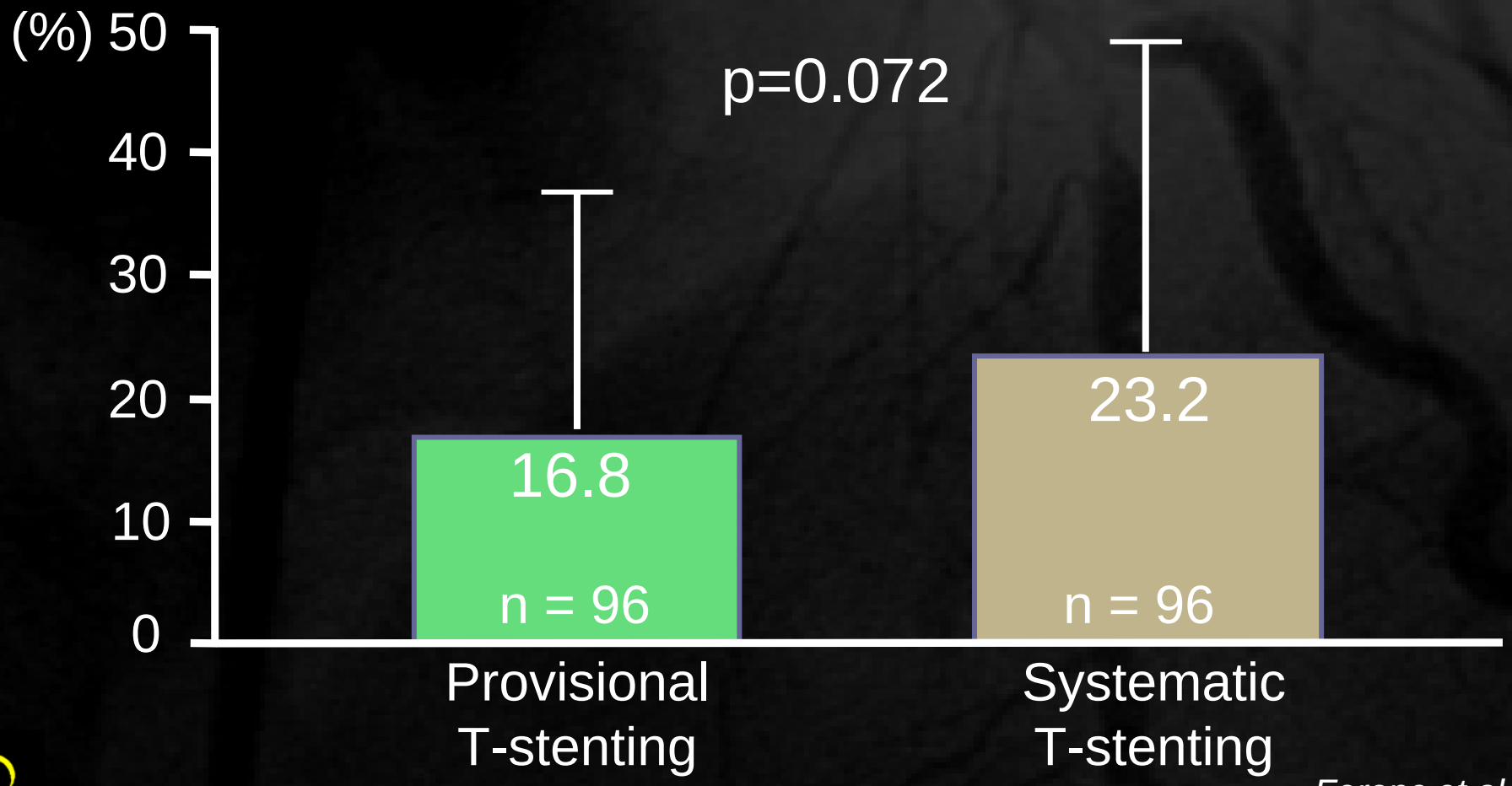
Primary endpoint

In-segment percent diameter stenosis of the side branch

Ferenc et al. TCT 2007

Primary study endpoint:

In-segment percent diameter stenosis of the side branch 9 months follow-up

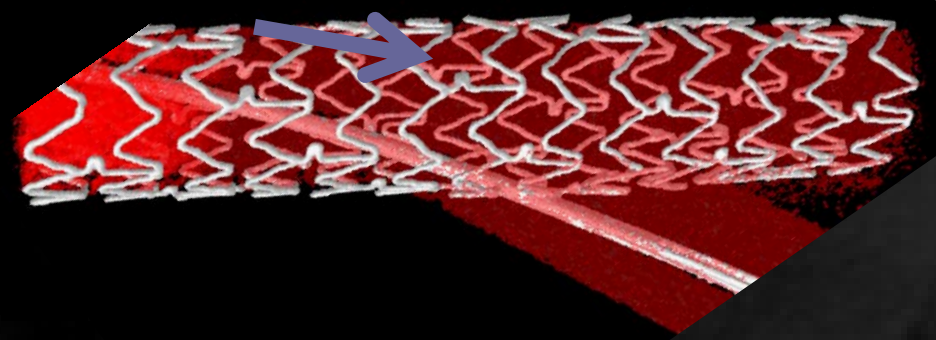


Ferenc et al. TCT 2007

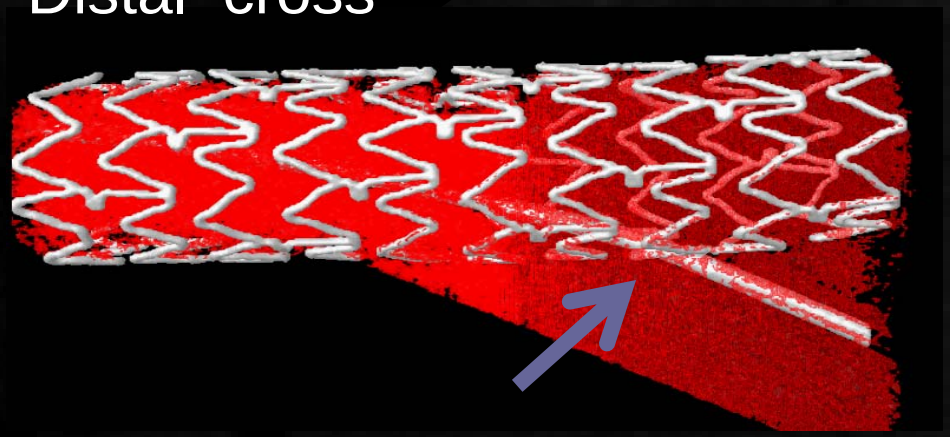
Provisional SB stenting
is now the gold standard !

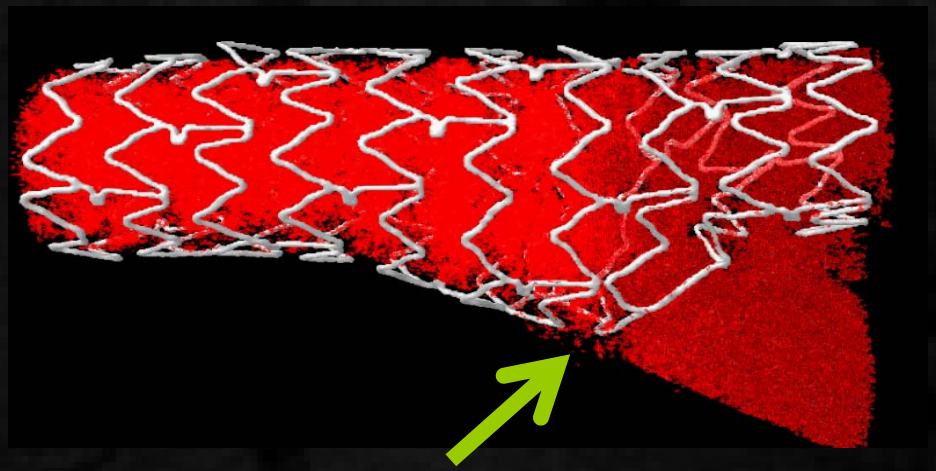
Provisional SB Stenting (Proximal vs Distal strut)

Proximal cross



Distal cross





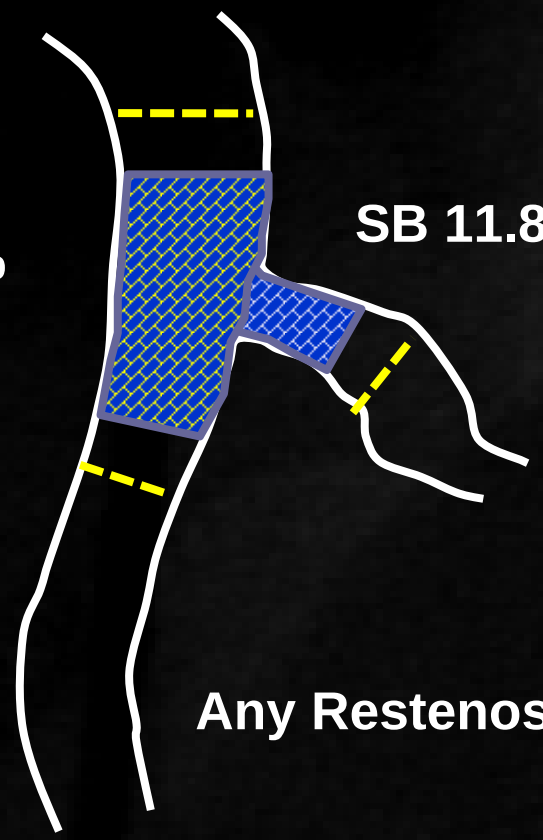
Courtsey of John Ormiston

When 2 stents are needed ?

3. Efficacy: Crush vs Culotte

In lesion restenosis at 8 months follow-up

CRUSH

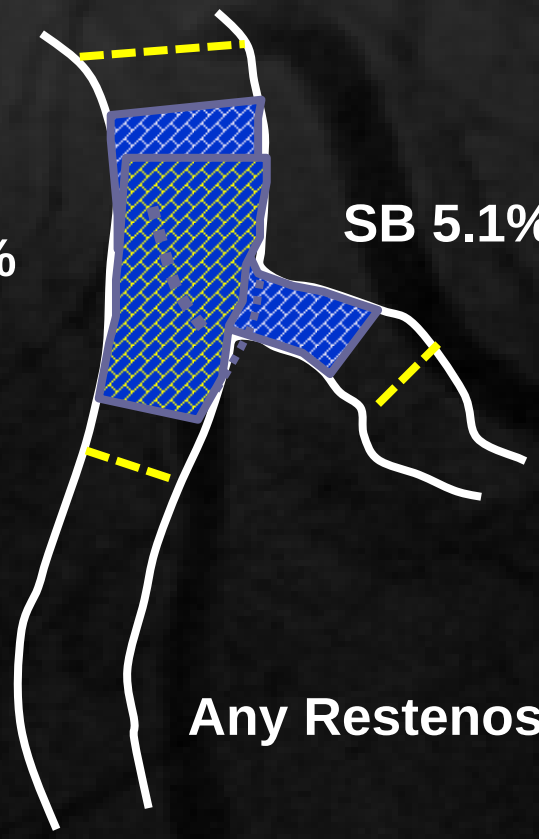


MB 4.7%

SB 11.8%

Any Restenosis 16.5%

CULOTTE



MB 1.9%

SB 5.1%*

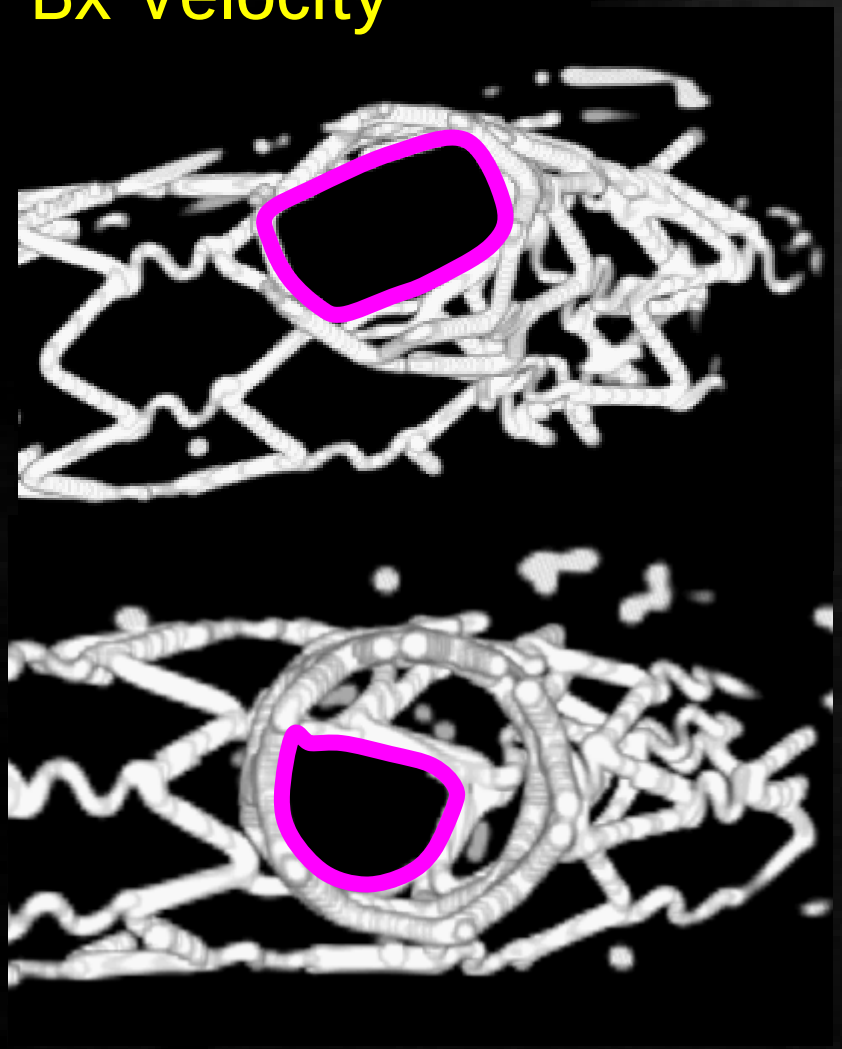
** P=0.048*

P=0.013

Any Restenosis 7.0%

Strut Configuration After Crush Technique

Bx Velocity



Express II

Courtesy of Dr. Murasato

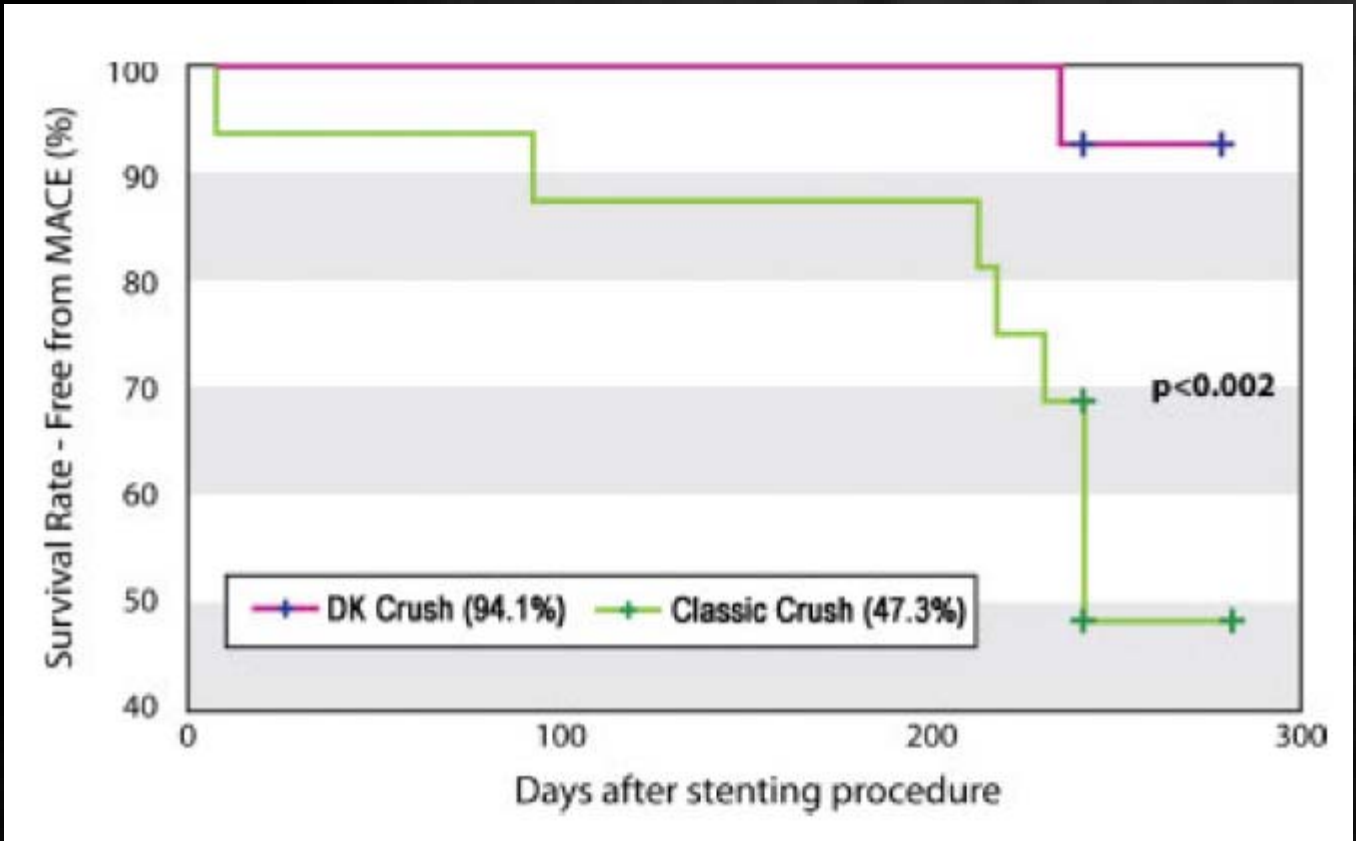
Crush vs DK Crush

Final Kissing Balloon Inflation by Classic Crush Stenting Did Not Improve the Clinical Outcomes for the Treatment of Unprotected Left Main Bifurcation Lesions: The Importance of Double-Kissing Crush Technique

	Classic crush (N = 19)	DK crush (N = 17)	P value
Age (year)	65.8 ± 8.9	64.2 ± 8.9	0.62
Male (%)	68.7	57.1	0.51
Hypertension (%)	68.7	67	0.29
Hyperlipidemia (%)	87.5	75.5	0.23
Total cholesterol (mmol/l)	4.39 ± 0.71	4.53 ± 1.02	0.68
LDL (mmol/l)	2.87 ± 0.59	2.84 ± 1.01	0.92
TG (mmol/l)	1.39 ± 0.45	1.64 ± 0.96	0.40
Diabetes Mellitus (%)	32.50	35.71	0.13
Current smoker (%)	31.25	34.29	0.26
Previous PCI (%)	12.50	9.62	0.10
Previous MI (%)	25.00	19.29	0.46
Previous CABG (%)	0	0	
Unstable angina (%)	81.25	75	0.06
AMI (%)	6.25	7.14	0.922
LVEF (%)	64.7 ± 7.9	61.9 ± 13.7	0.56

Chen et al. CCVI 2008; 77: 166-172

Final Kissing Balloon Inflation by Classic Crush Stenting Did Not Improve the Clinical Outcomes for the Treatment of Unprotected Left Main Bifurcation Lesions: The Importance of Double-Kissing Crush Technique

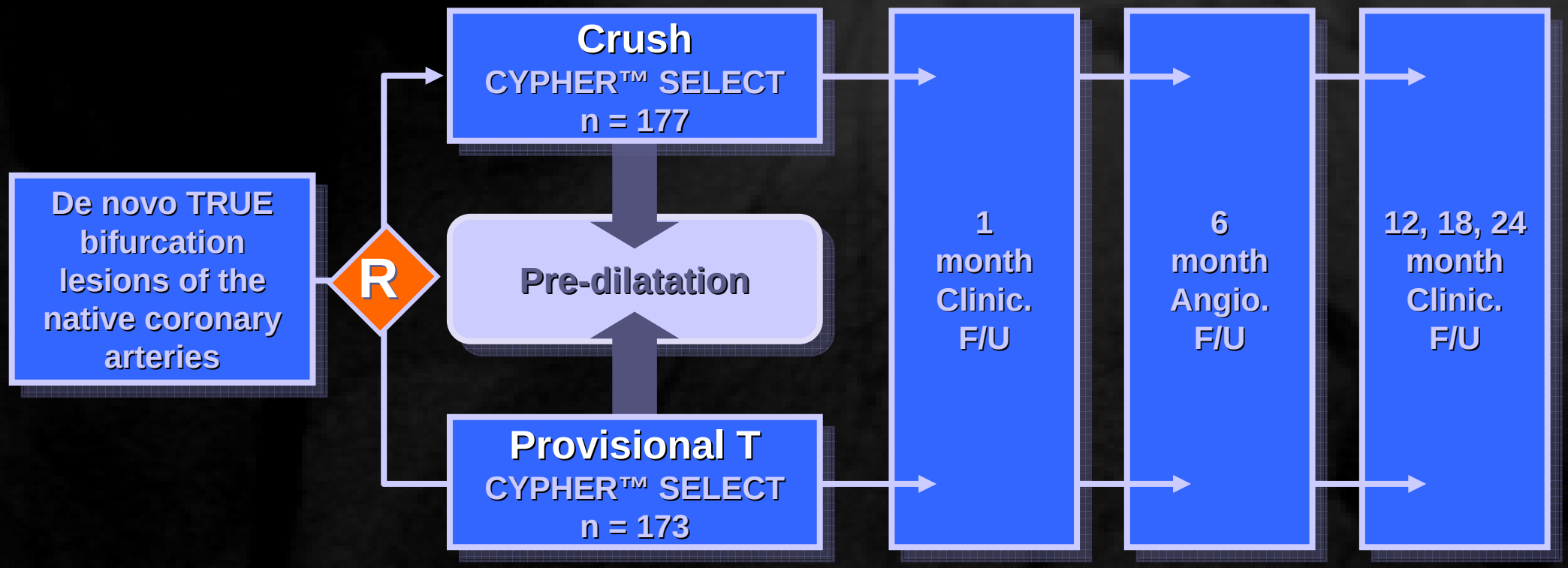


Chen et al. CCVI 2008; 77: 166-172

4. Efficacy: Crush vs PTS

CACTUS: Study Design and Time Frame

n = 350 patients



CACTUS: Conclusions

- ✓ 31% cross over from provisional to 2 stents
- ✓ Significantly larger final SB MLD with crush
- ✓ No difference in cumulative 30-day MACE
- ✓ No difference in 30-day stent thrombosis: 1.7% with crush vs 0.5% with prov.-T (p=0.62)

5. Safety

NORDIC 1: Procedural data I

	MV (n=207)	MV+SB (n=206)	P-value
Procedure time (min)	62±52	76±40	<0.001
Fluoro time (min)	18±17	21±12	<0.001
Contrast (ml)	233±93	283±117	<0.001

Terje K Steigen. *Circulation* 2006;114;1955-1961

NORDIC 1: Biomarker elevation (279 patients)

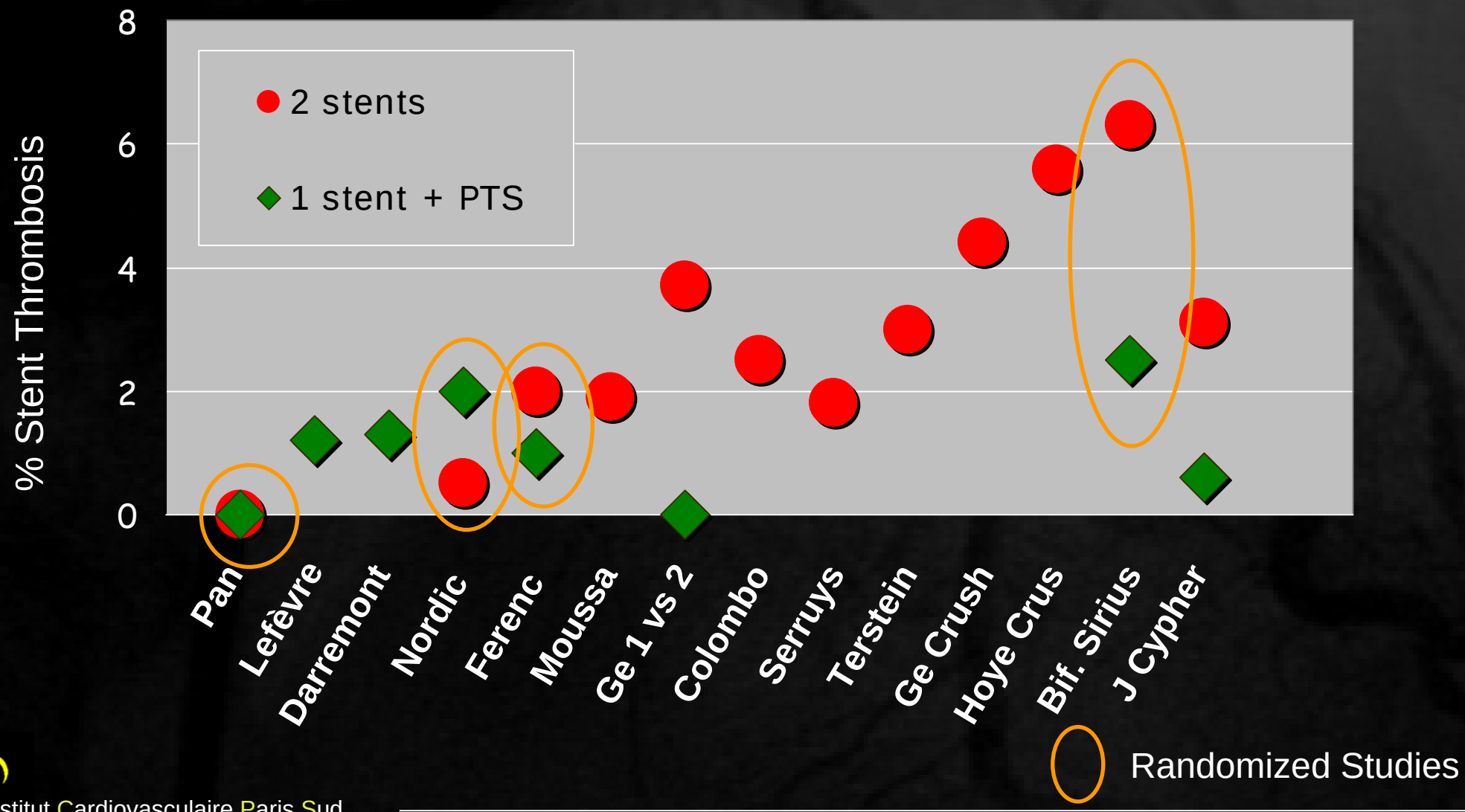
	MV (n=153)	MV+SB (n=126)	P-value
> 3 elevation (%)	8	18	0.011
> 5 elevation (%)	4	13	0.008
> 10 elevation (%)	3	5	ns

Terje K Steigen. *Circulation* 2006;114;1955-1961

Bifurcation as a potent, independent risk factor for stent thrombosis

	n	RR	95% CI	FU
Iakovou et al JAMA 2005	2229	5.96	1.90 – 18.68	Subacute
	2229	8.11	2.50 – 26.26	Late
Ong et al JACC 2005	1017	3.00	1.30 – 6.80	6 mo
Kuchulakanti et al Circulation 2006	2974	4.40	1.96 – 10.00	12 mo
Hwang + Koo TCT 2006		10.21	4.75 – 21.92	Late

DES in Bifurcation Lesions: Safety



Predictors of Stent Thrombosis Through 1 Year
(ARC Definite / Probable)

Multivariate analysis

ST 30 patients (0.62%)
in 5015 patients

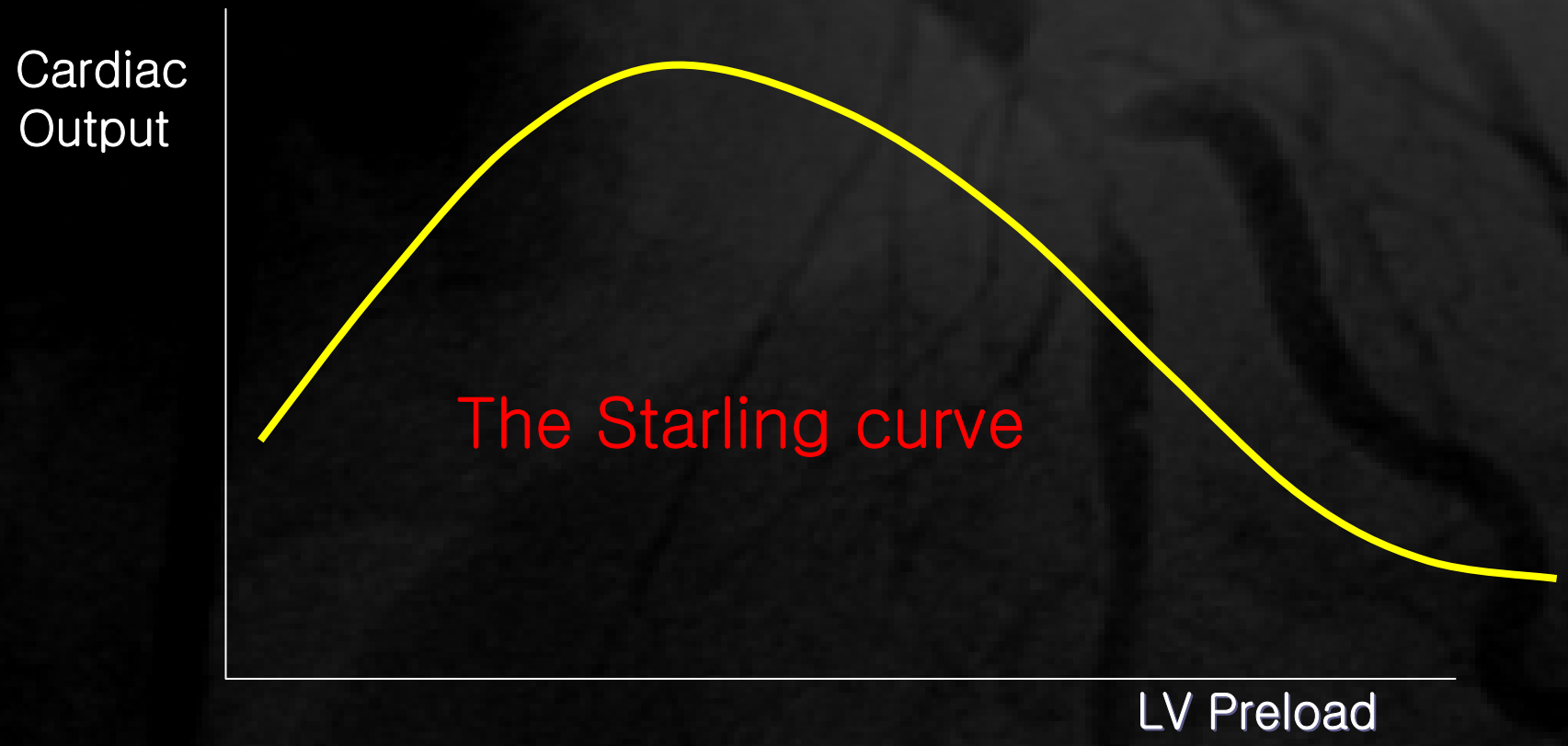
Factors	O.R.	95%C.I.	P Value
Two-stent approach for bifurcation	2.05	(1.22 - 3.3)	0.0085
Hemodialysis	2.04	(1.22 - 3.16)	0.009
Emergency procedure	1.73	(0.97 - 2.82)	0.06

Conclusion

Today the Gold standard is provisional side branch stenting.

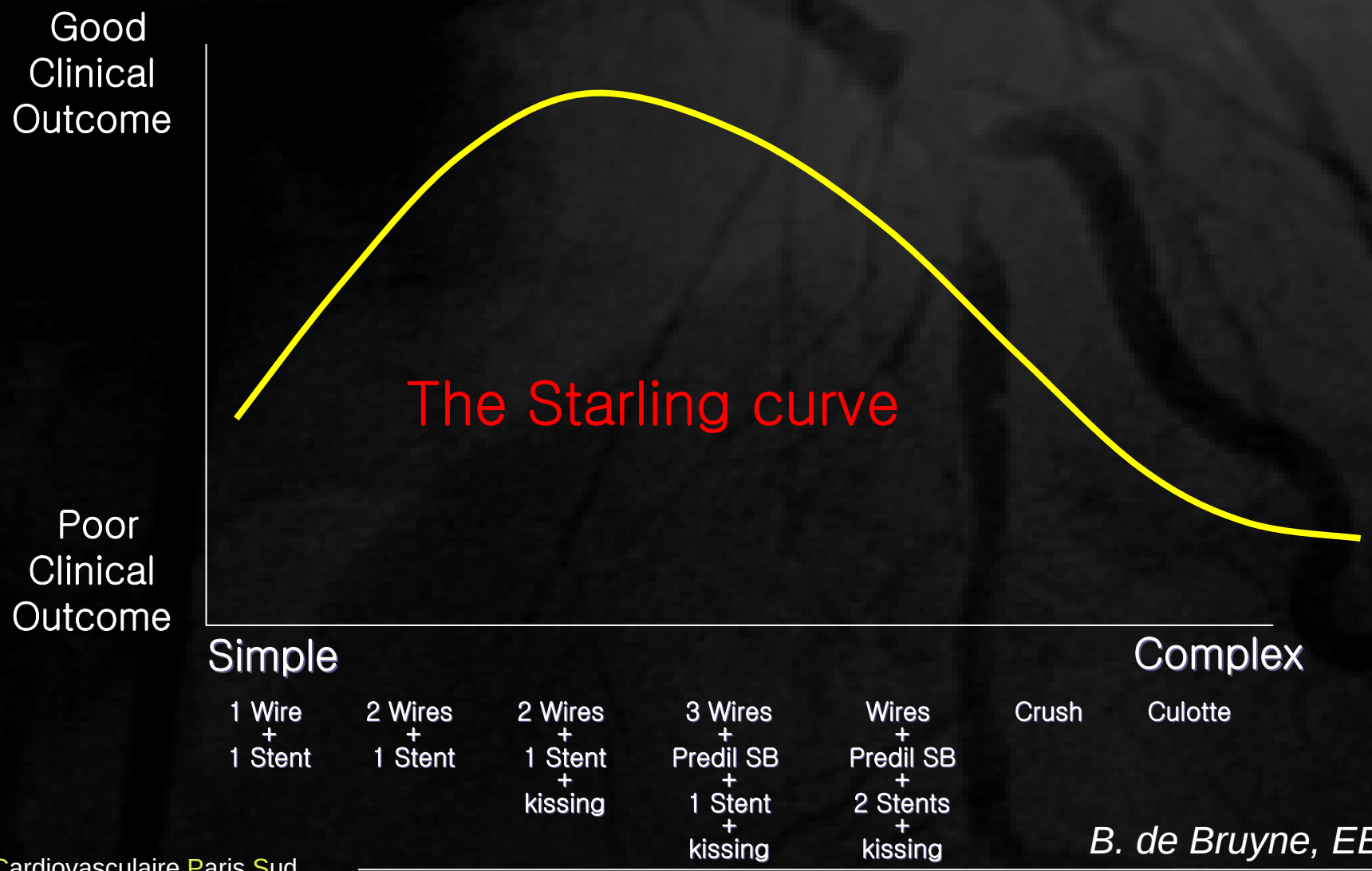
When 2 stents are needed, and when to do it is still a matter of debate.

When a 2 stents approach is used, optimal technique is crucial.



B. de Bruyne, EBC 2007

Complexity of Bifurcation Stenting



B. de Bruyne, EBC 2007