

Bifurcation Lesion Intervention

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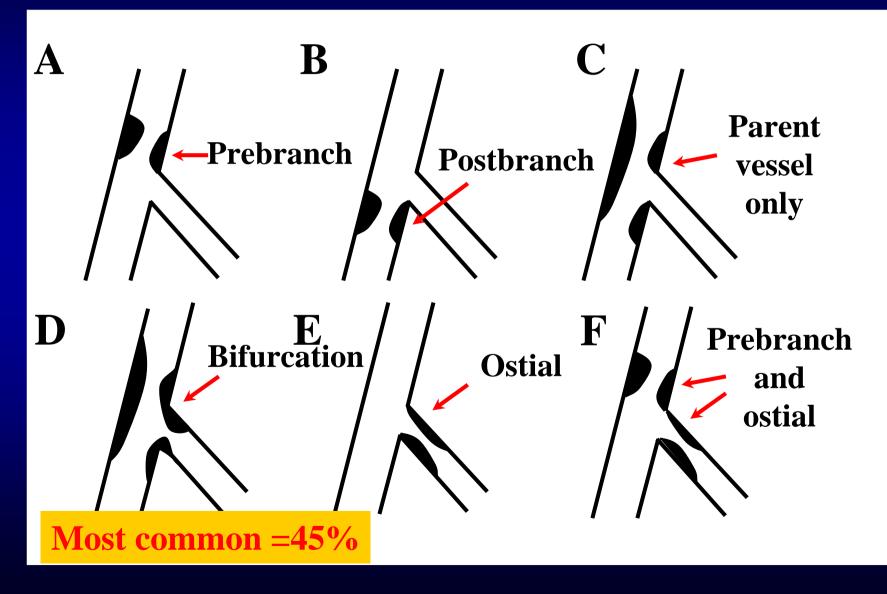
Mount Sinai Hospital, New York

I have no real or apparent conflicts of interest to report

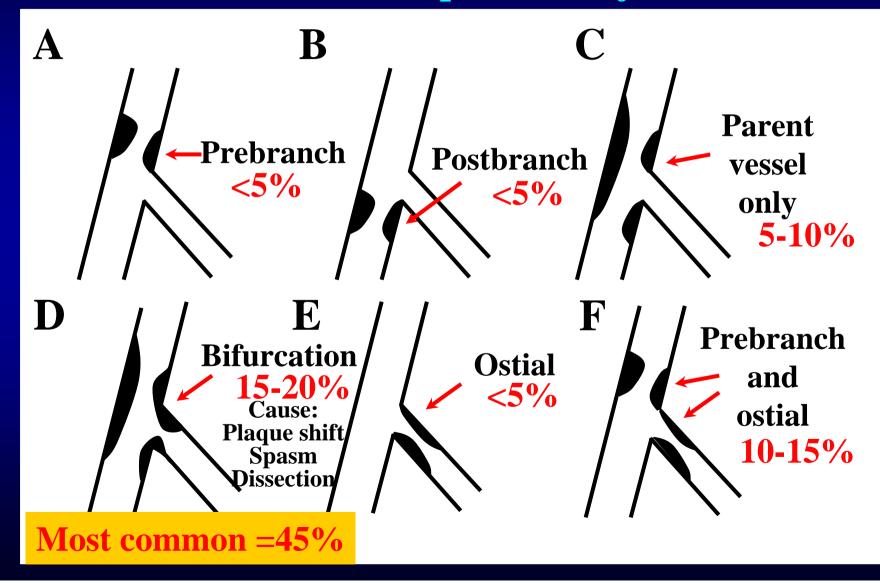
Bifurcation Lesion Intervention Scope of The Problem

- Bifurcation lesion intervention is performed in about 8-15% of PCI at most centers
- Most of these lesions are complex (type C of ACC/AHA class)
- Technically challenging with higher learning curve
- PCI of these lesions requires higher number of devices
- Higher LOS, higher MACE and higher restenosis

Bifurcation Lesion Classification Duke's



Bifurcation Lesion Classification Side-branch Compromise After PCI

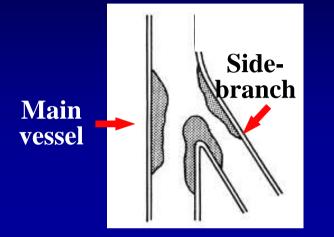


Bifurcation Lesion Intervention *Issues*

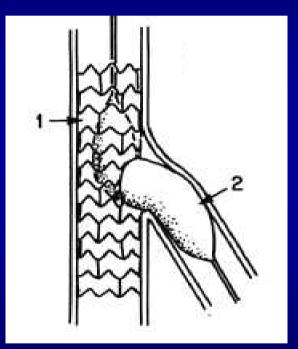
- Plaque shift / displacement
- Elastic lesion / recoil
- Disparity in the size of parent vessel with distal vessel and sidebranch
- Sidebranch angulation (T vs. Y)

Various Techniques for Stenting Bifurcation Lesions

Bifurcation Lesion



Stent the MV+ Balloon or Debulk SB



..and stent the SB only if suboptimal results

Provisional/ Conventional Stent Technique

Optimal Treatment of Bifurcation Lesions *Short & Long-term Results*

Variable	Angiographic appearance	Acute complication	Restenosis	Technical challenge
Stent of parent vessel & PTCA+provisional stent of the side-branch	Excellent for parent vessel, suboptimal for SBr	1-3%	High for SBr	+
Conventio	onal/Provision	nal Stent S	Strategy	
	is the			
Bes	t Recommend	ed Strateg	y	

Suwaidi, Holmes et al. JACC 2000;35:929 Yamashita, Colombo et al. JACC 2000;35:1145 Kobayashi, Colombo et al. CCD 1998;43:323 Pan et al. AJC 1999;83:1320 Dauerman et al. JACC 1998;32:1845 Oesterle et al. JACC 1998;32:1853

The FRONTIER Stent Registry QCA Analysis

	Main Branch	Side Branch	Any branch	
	(n = 96)	(n = 96)	(n = 96)	
Baseline			40	[°]] 35.9 31.3
Reference diameter (mm)	2.77±0.51	2.10±0.67	- 30	
MLD (mm)	1.07 ± 0.35	1.23 ± 0.45	- %	
Post-procedure			20	13.3
MLD (mm)	2.43 ± 0.41	1.47 ± 0.40	- 10	D -
Diameter stenosis (%)	15±10	25±13	n	
6-mo FU			v	StentedBalloonNontreatedAnySBSBSBTLR
MLD (mm)	1.59±0.56	1.13 ± 0.47		
In-segment binary restenosis (%)	29.9	29.1	44.8 🧹	
Late lumen loss (mm)	0.48±0.55	0.34±0.45	-	

Lefèvre et al, J Am Coll Cardiol 2005;46:592

Bifurcation Lesion Stenting

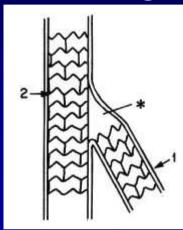
What about 2 vs 1 Drug Eluting Stents?

Various Techniques for Stenting Bifurcation Lesions

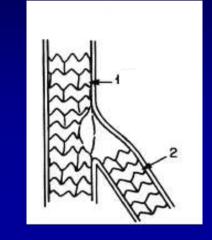
Bifurcation Lesion

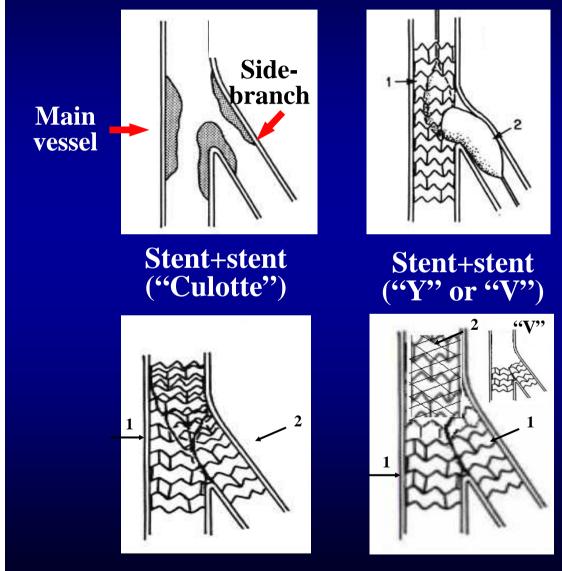
Stent+PTCA

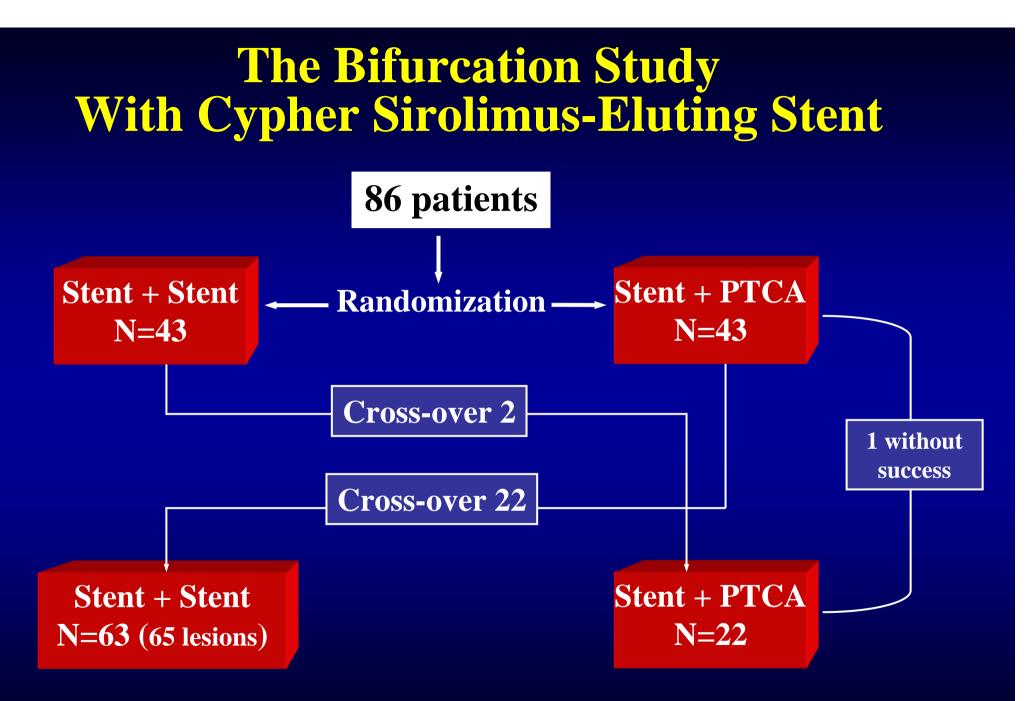
Stent+stent ("T stenting")



Stent+stent ("reverse-T")



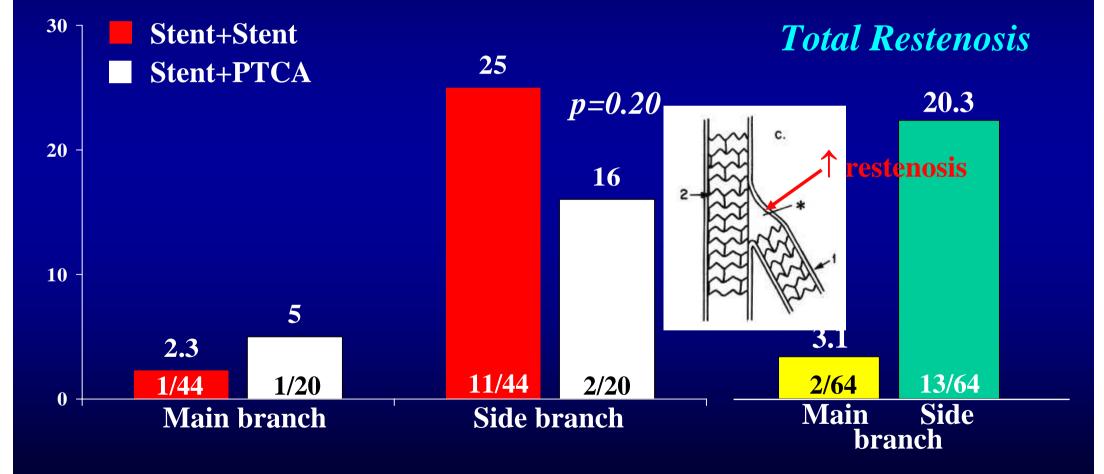




Colombo et al. Circulation 2004;109:1244.

The Bifurcation Study With Cypher Sirolimus-Eluting Stent Segment Restenosis

%



Colombo et al. Circulation 2004;109:1244.

Various Techniques for Stenting Bifurcation Lesions

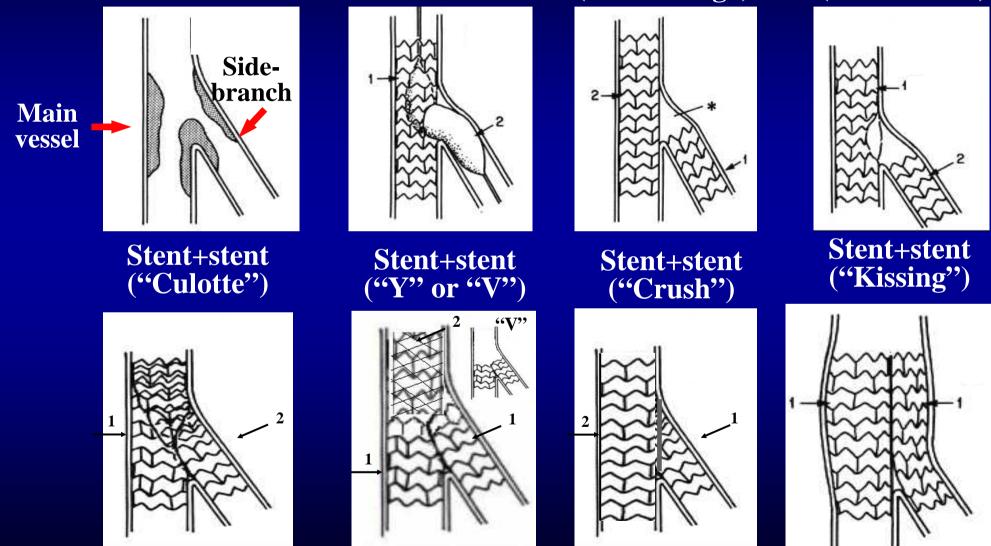
Bifurcation Lesion

Stent+PTCA

Stent+stent ("T stenting")

Stent+stent

("reverse-T")



Bifurcation Lesion Intervention Using DES *"Stent Crush" Technique*





Long-Term Outcome of "Crush" Stenting Technique Clinical Outcomes

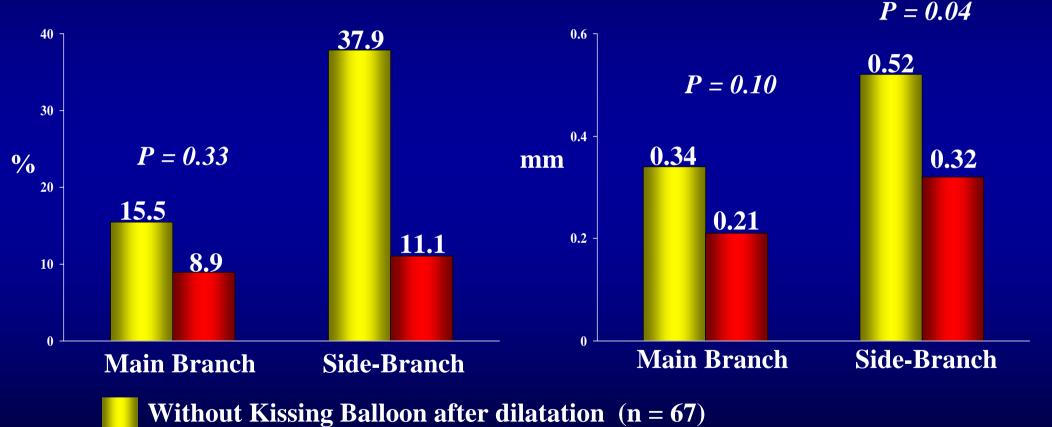
	Entire Cohort	FKB Group	Non-FKB Group	P Value
	(n = 181 pts)	(n = 116 pts)	(n = 65 pts)	
9-months MACE (%)	26.5	19.8	38.5	0.008
Cardiac death	1.1	1.7	0	0.54
Q-wave MI	3.3	1.7	6.2	0.28
Non Q-wave MI	8.3	8.6	7.7	0.95
TLR	14.9	9.5	24. 6	0.008
TVR	17.1	10.3	29.2	0.002
Stent thrombosis	2.8	2.6	3.1	0.78
Subacute	0.6	0	1.5	0.77
Late	2.2	2.6	1.5	0.95

FKB = final kissing balloon after dilation

Ge et al, J Am Coll Cardiol 2005;46:613

Long-Term Outcome of "Crush" Stenting TechniqueRestenosis RateLate Lumen Loss

P <0.001



Kissing Balloon after dilatation (n = 118)

Ge et al, J Am Coll Cardiol 2005;46:613

Various Techniques for Stenting Bifurcation Lesions

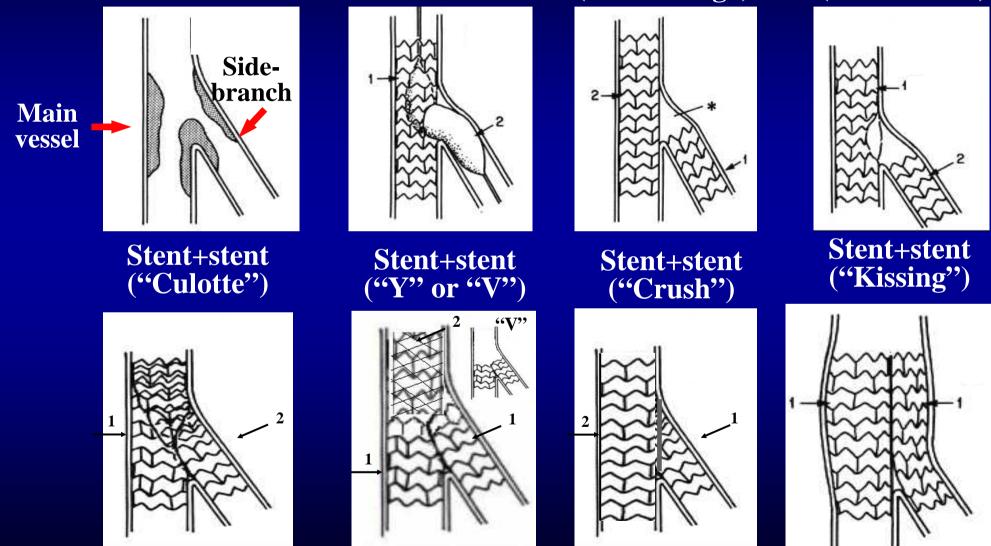
Bifurcation Lesion

Stent+PTCA

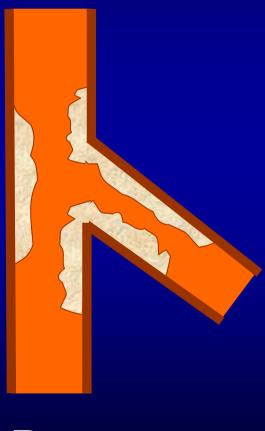
Stent+stent ("T stenting")

Stent+stent

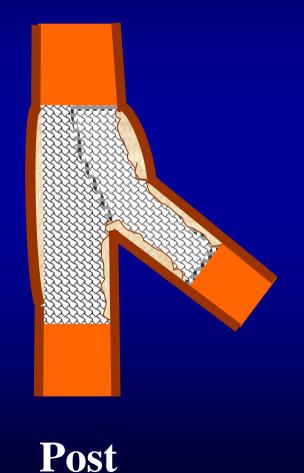
("reverse-T")



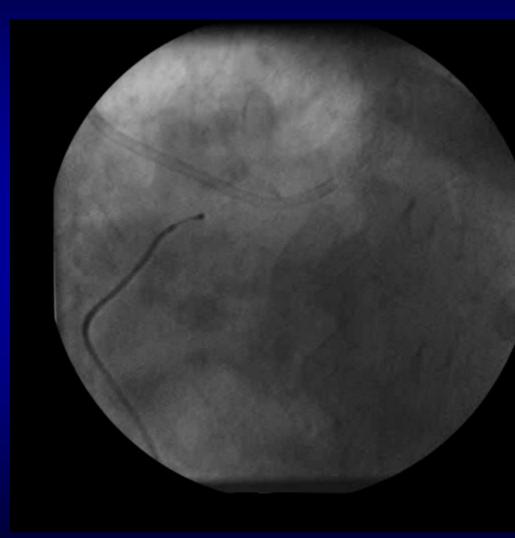
Bifurcation Lesion Intervention Using DES *"Simultaneous Kissing Stent" (SKS) Technique*



Pre



"Simultaneous Kissing Stent" Technique of Complex Unprotected LMCA / LAD & LCX Lesion



- 74-yr old woman presenting with non-Q wave MI, CHF, chronic type A dissection
- Risk factors: HTN, hyperlipidemia CRF on dialysis, smoker
 ECG: LBBB
- Med: ASA, atorvastatin, β-blocker, captopril, amlodipine, clonidine
- Pre: 70-80% LMCA
 - 90% prox LAD
 - 60-70% prox LCX
- PCI: "kissing" stent technique
- 3.5/18 mm Cypher in LMCA/LAD
 & 3.5/13 mm Cypher in LMCA / LCX
- Post: -10% LMCA, LAD, LCX

SKS Technique Bifurcation lesion involving LAD and Diagonal



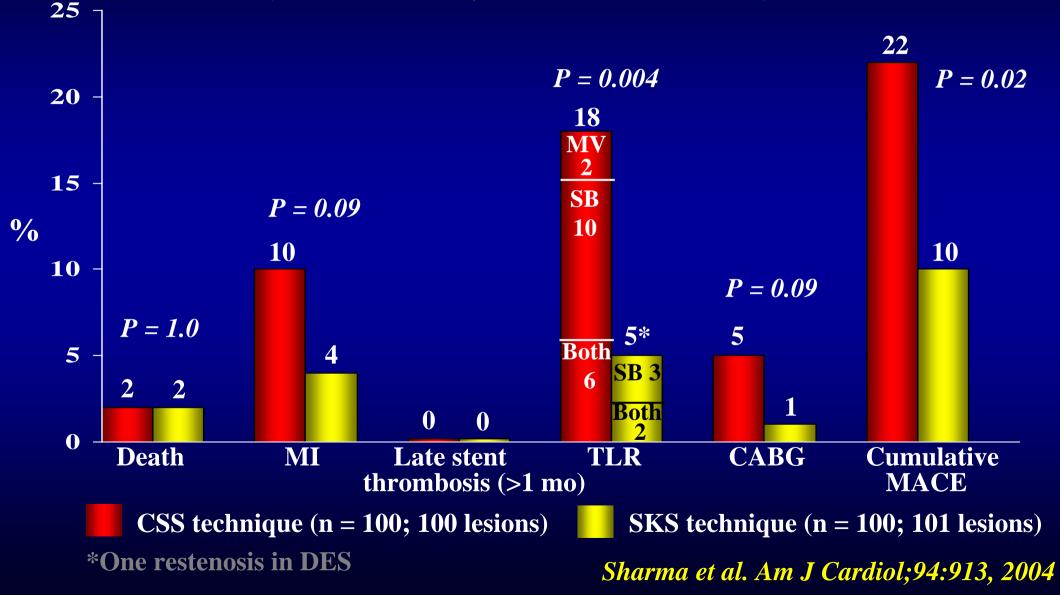
LAD

Diagonal

IVUS images revealing double lumen and carina

SKS Technique

Mid-Term (Min >6 mo; Mean 8 ± 4 mo) FU Results



Simultaneous kissing drug-eluting stent (SKS) technique for bifurcation lesions in large-size vessels Baseline Clinical and Angiographic Characteristics (May 03 - June 04)

	SKS technique (n=200;202 lesions)
Age (yrs)	68 ± 8
Male (%)	67
Clinical syndrome: Stable/Unstable/MI (%)	55/42/3
Diabetes mellitus (%)	35
LVEF (%)	48 ± 5
GP IIb/IIIa Inhibitor use (%)	84
Clopidogrel preloading (%)	24
Multivessel disease (%)	42
Lesion location: LAD/LCx/RCA/LMCA (%)	52/15/26/7
Additional lesion PCI (%)	8

Simultaneous kissing drug-eluting stent (SKS) technique for bifurcation lesions in large-size vessels *Procedural and Angiographic Characteristics*

	SKS technique (n=200;202 lesions)		
	MAIN VESSEL	SIDE-BRANCH	
Reference vessel size (mm)	3.46 ± 0.61	2.58 ± 0.44	
Minimum luminal diam (mm)	0.81 ± 0.42	0.71 ± 0.34	
Lesion length (mm)	19.4 ± 4.2 12.2 ± 3.2		
Debulking (%)	24	66	
Rotablator	21	4	
Cutting balloon	3	62	
Direct stenting (%)	32 12		
Maximal inflation press (atm)	18 ± 3	15 ± 2	
Average length of carina (mm)	8 ± 5		
Total stent length (mm)	42 ± 8		
Total procedure time (minutes)	36 ± 14		
	Sharman SV Catheter	Cardionasa Intorn 2005.65	

Simultaneous kissing drug-eluting stent (SKS) technique for bifurcation lesions in large-size vessels *Procedural Results*

	SKS technique (n=200;202 lesions)
Angiographic success (%)	
Main vessel	100
Side-branch	99
Dissections requiring PTCA only (%)	6
Dissections requiring stent (%)	0
Coronary perforation (%)	1*
Post-procedural residual stenosis (%)	
Main vessel – proximal	0 ± -5
Main vessel – distal	10 ± 8
Side-branch	12 ± 8

*Both type II perforations and sealed by prolonged balloon dilatation

Simultaneous kissing drug-eluting stent (SKS) technique for bifurcation lesions in large-size vessels Procedural, In-hospital and 30-day Results

	SKS technique (n=200;202 lesions)
Peri-procedure MI (%)	3
Q-wave MI	0
Non Q-wave MI	3
Clinical success (%)	97
In-hospital MACE (%)	3
30-day MACE (%)	5
Stent thrombosis at 30-day (%)	1*
Hospital stay (days)	1.8 ± 0.4

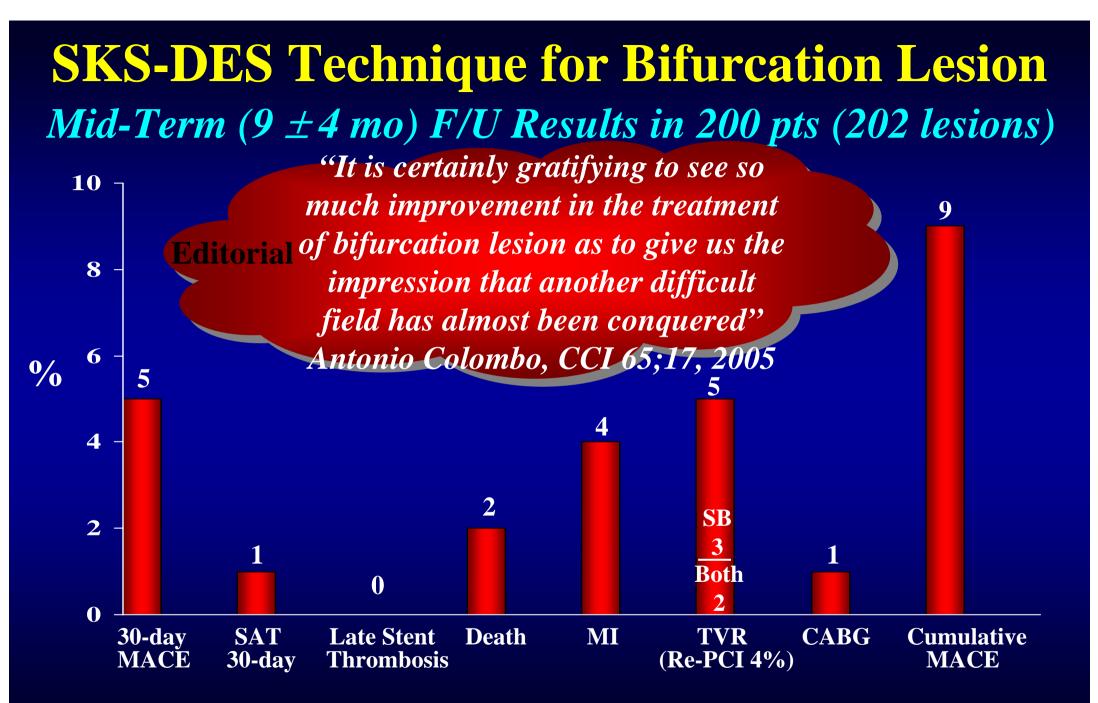
*Both proximal to the overlapping stents

Simultaneous kissing drug-eluting stent (SKS) technique for bifurcation lesions in large-size vessels

Follow-Up Results (minimum >6 months post-PCI)

	SKS technique (n=200;202 lesions)
Average follow-up duration (months)	9 ± 2
Death (%)	2
Myocardial infarction (%)	4
Q-wave/Non Q-wave	1/3
Late stent thrombosis >1 month (%)	0
On dual antiplatelet therapy (%)	92
Clinical restenosis (%)	5
Main vessel only	0
Side branch only	3
Both	2
Target lesion revascularization (%)	5
CABG (%)	1
Freedom from MACE (%)	91

Sharma SK, Catheter Cardiovasc Interv 2005;65:10



Sharma S. CCI;65:10, 2005

Bifurcation Lesion Intervention *"Simultaneous Kissing Stent" (SKS) Technique*



Post

PRECISE-SKS Pilot Study

Duke's Type D Bifurcation Lesion

Conventional Technique (n=50):

One stent in the main vessel & provisional stent in the side-branch SKS Technique (n=50):

Simultaneous kissing stent deployment in the main vessel & side-branch

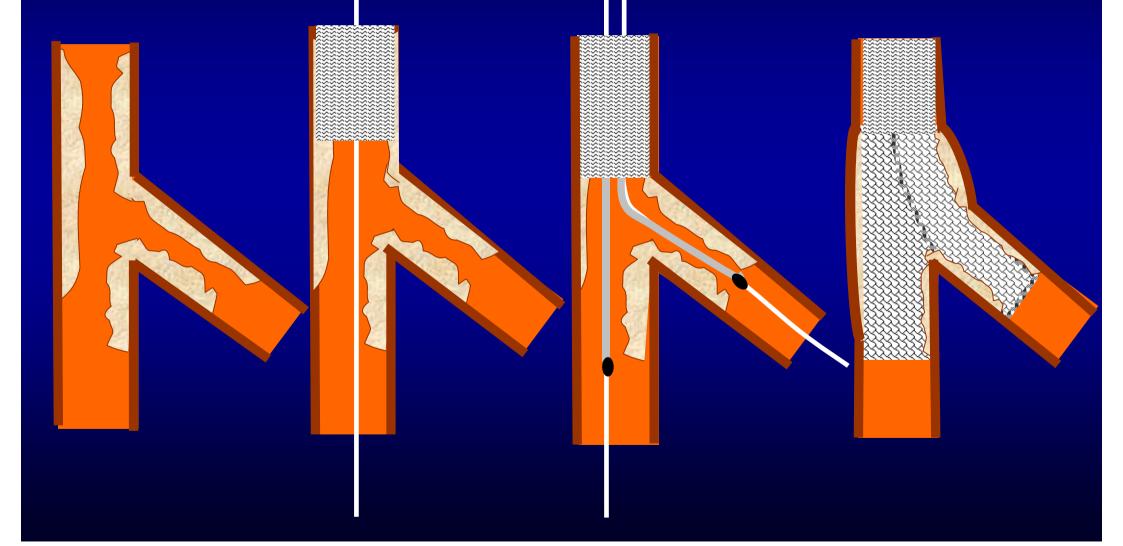
Primary endpoint: angiographic restenosis at 8-9 months

Secondary endpoints:30-day clinical MACE 9-month TLR 1-year freedom from MACE IVUS sub study of 20 pts in each arm

1-year clinical follow-up: death, TVR, MI

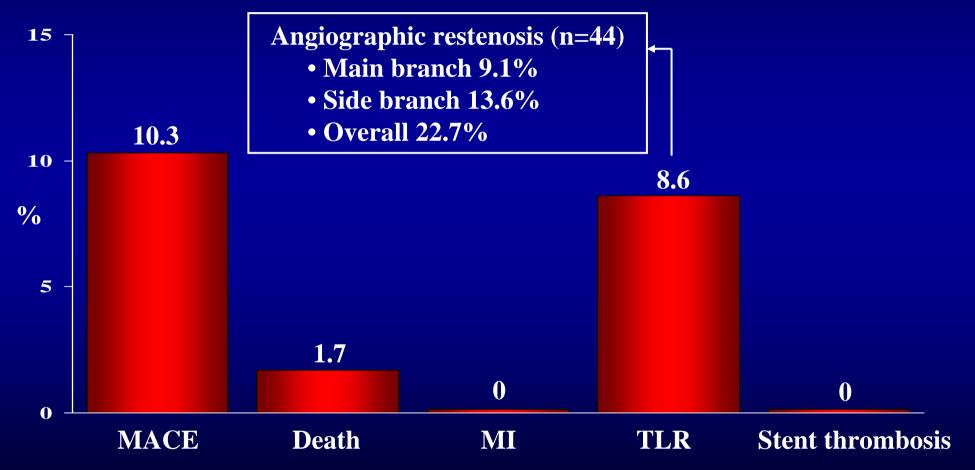
Sponsored by Cordis/JnJ

Bifurcation Lesion Intervention *Modified SKS Technique for Long Lesion Proximally to avoid New Long Carina*



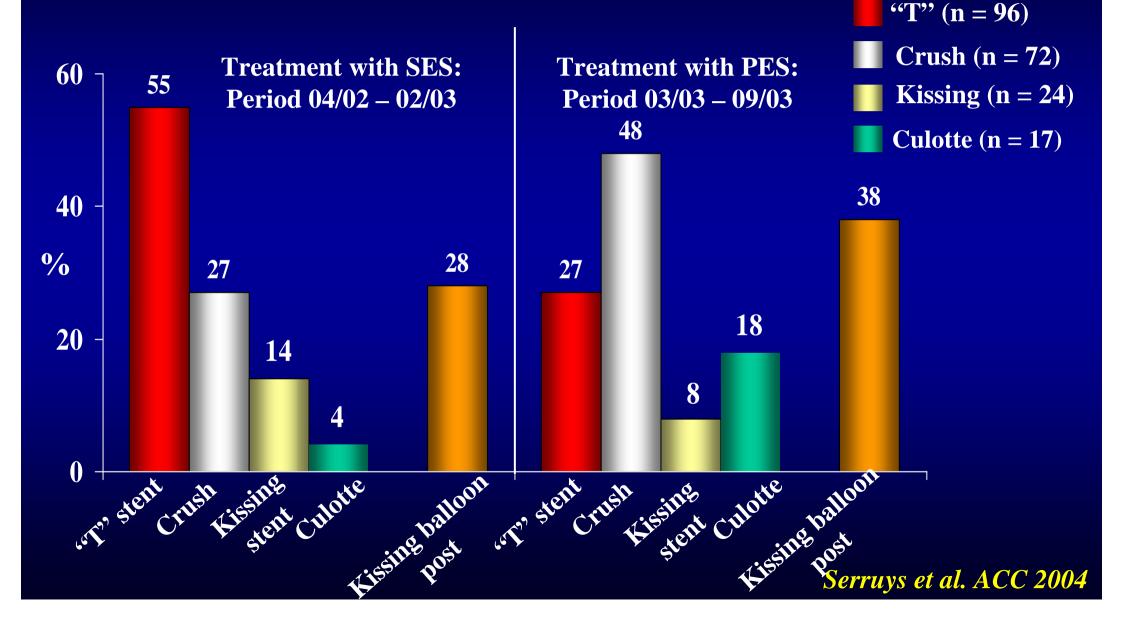
Restenosis following Bifurcation Sirolimus-Eluting Stents for De Novo Narrowings

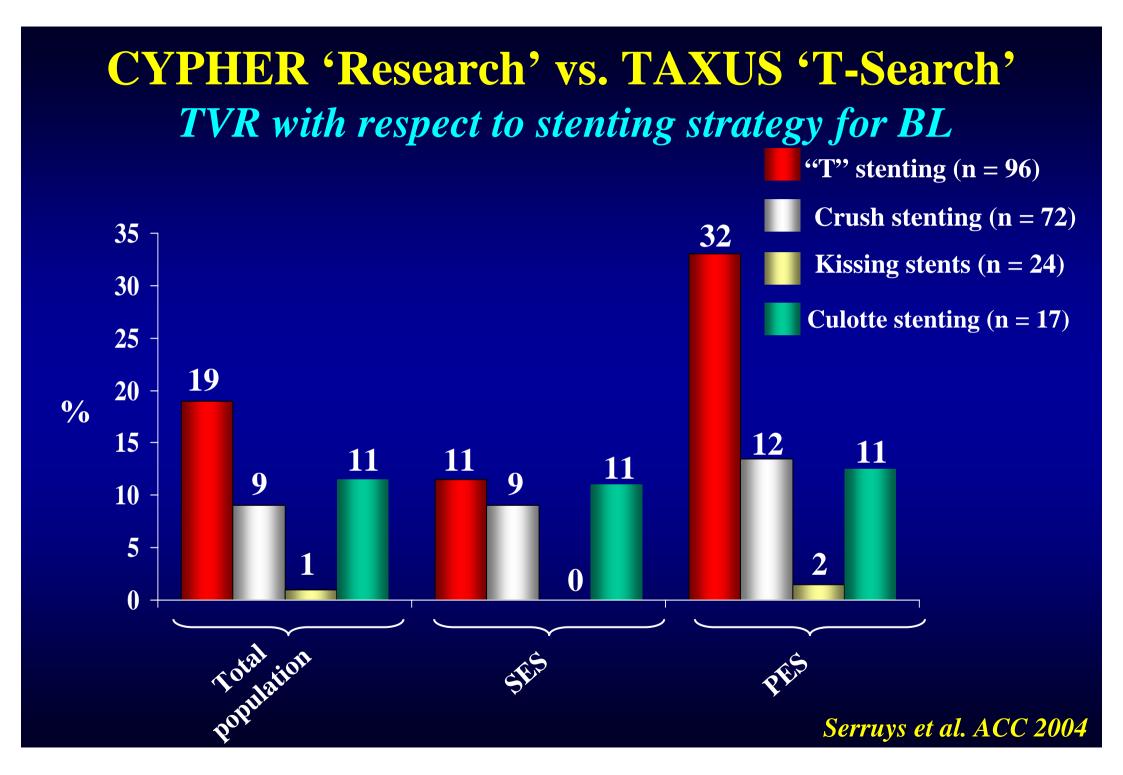
6-Months Follow-Up (N = 58; 65 Lesions)

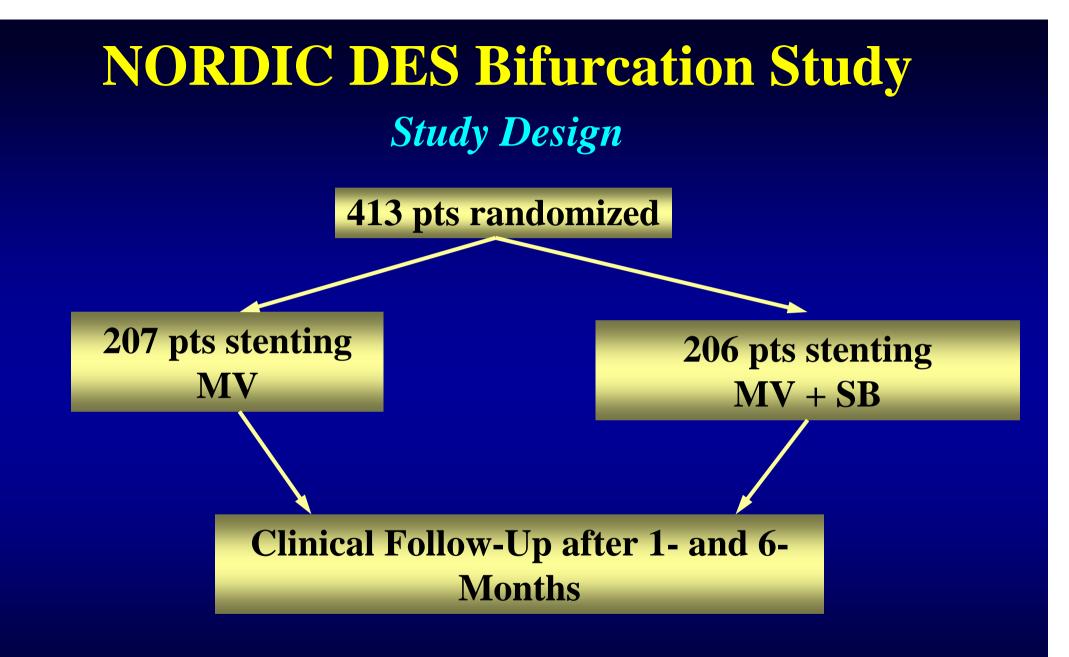


Tanabe et al, Am J Cardiol 2004;91:115

CYPHER 'Research' vs. TAXUS 'T-Search' *Stenting Technique for Bifurcation Lesions*



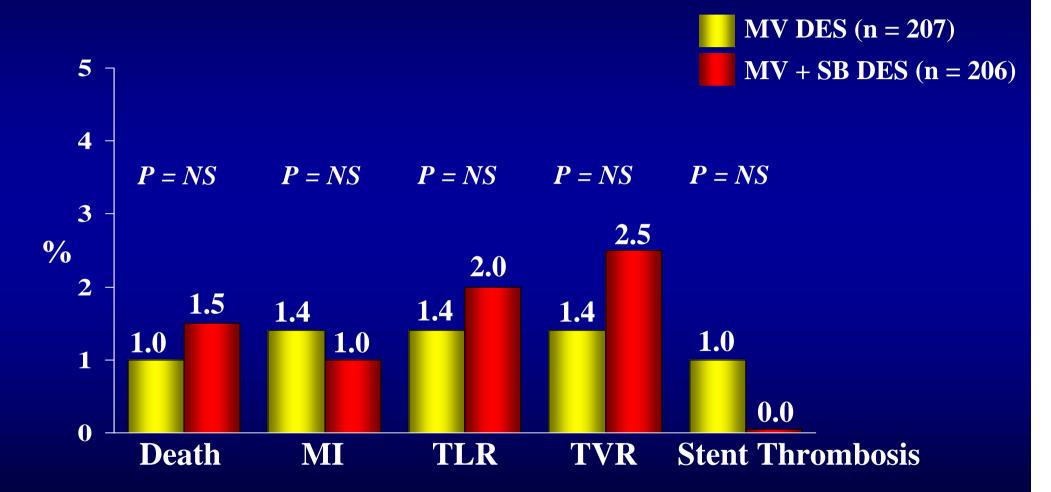




Steigen et al, ACC 2006

NORDIC DES Bifurcation Study

6-Months Follow-Up



Steigen et al, ACC 2006

NORDIC DES Bifurcation Study

Procedural Data

	MV DES	MV + SB DES	P value
	(n = 207)	(n = 206)	_
Procedure time (min)	59 ± 30	74 ± 30	<0.001
Fluoro time (min)	15 ± 9	21 ± 10	<0.001
Contrast (ml)	233 ± 93	283 ± 117	<0.001
CK-MB ↑ >3x (%)	8	18	0.011
SB stented (%)	4.3	95.1	<0.001

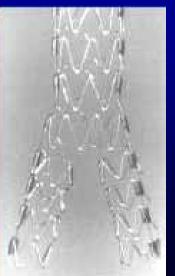
Steigen et al, ACC 2006

Bifurcated Stents

ACS stent



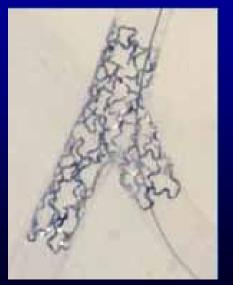
Bard stent



AVE stent



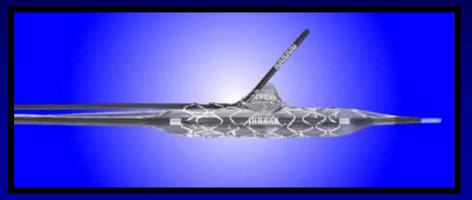
Cordis stent



Side-branch Access Stents

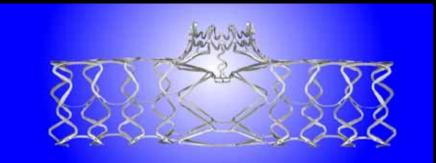
- NIRSide stent
- Jo stent
- ACS Access stent
- AST-SLK view stent

Paclitaxel Dedicated Bifurcation Stent System (AST PetalTM)*



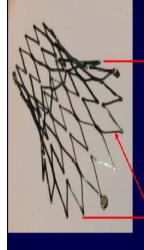
Advantages

- Special stent feature to cover ostium/proximal portion of side-branch (~ 2 mm)
- Reduces/eliminates gap
- Reduces frequency of 2nd stent
- Placing 2nd stent after provisional T stenting is intuitive



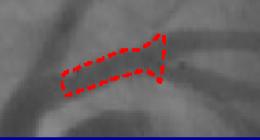
*Under development. Not currently available in the US.

A Dedicated Bifurcation DES (DEVAX)



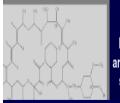
Flared Distal-End Stent Design Self Expanding Nitinol Material

8, 10, or 12 mm flare diameter



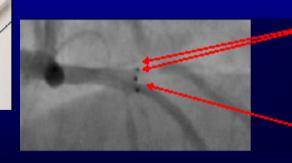
The flared shape of the AXXESS PLUS stent matches the flared geometry of a bifurcation.

4.8F Rx Delivery System





The AXXESS PLUS stent can expand into both the MB and SB providing complete vessel coverage at the level of the carina.



2 distal stent markers in D1

1 distal stent marker in LAD

