

Angioplasty Summit TCT Asia Pacific Seoul, April 26-28, 2006

Protection of side branch is essential in treating bifurcation lesions: overview

Alfredo R Galassi, MD, FACC, FSCAI, FESC

Head of the Catetherization Interventional Laboratory Clinical Division of Cardiology, Ferrarotto Hospital University of Catania, Italy



Coronary Bifurcation Lesions

- >20% of all existing coronary lesions
- ~10% of routinely treated coronary lesions
- Frequently observed in high risk patients (UA or AMI)
- Poor outcome compared to non-bifurcated lesions (high incidence of TVR, high restenosis rate)
- DES fatigue to provide as great results as in standard stenting
- One of the few remaining areas where patients may be referred to CABG



Bifurcation Stenting NHLBI Dynamic Registry

PCI TREATMENT	Bifurcation	No-bifurcation	P-value
	N = 321	N = 2115	
РТСА	23.1%	26.5%	NS
PTCA+DCA	6.9%	4.4%	NS
PTCA+Stent	55.8%	59.9%	NS
PTCA+DCA+Stent	10.3%	7.0%	NS
OUTCOME			
Angiographic success	86%	93.5%	<0.001
Side branch occlusion	7.3%	2.3%	<0.001
In-hospital MACE	7.2%	5.0%	<0.001
1-year MACE	32.1%	25.7%	<0.05

Al Suwaidi et al, Am J Cardiol 2001

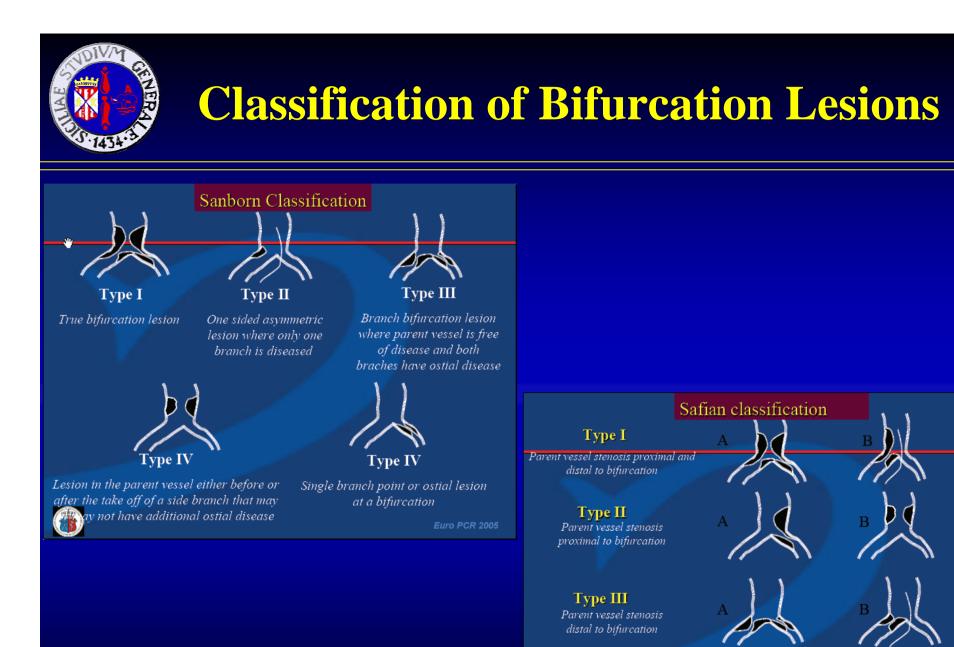


PRESTO Trial: MACE @ 9 Months According to Bifurcation or Nonbifurcation Lesions

Variable/Event	Nonbifurcation Lesions $(n = 10,068)$	One or More Bifurcation Lesion ($n = 1,412$)	p Value
Death, MI, or TVR	1,499 (15)	256 (18)	0.002
Death or MI	247 (2)	29 (2)	0.36
Death	119 (1)	13 (1)	0.39
MI	141 (1)	17 (1)	0.55
MI	141 (1)	17.(1)	0.55
Numbers in parentheses are CABG = coronary arts angioplasty: TVR = target	ery bypass grafting; MI = myocard	lial infarction; PTCA = percutaneous translum	ninal coronary

angioplasty; IVR = target vessel revascularization.

Garot P, et al; JACC 2005;46:606-612

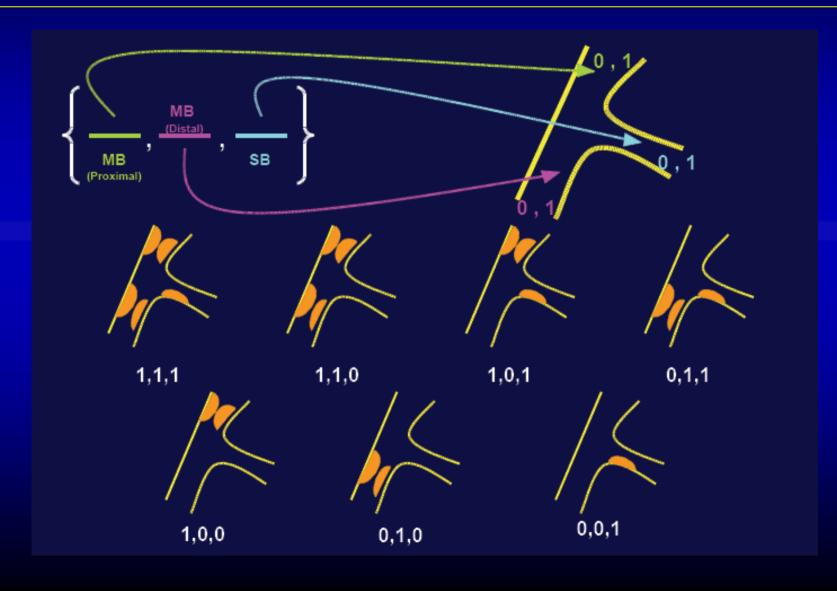


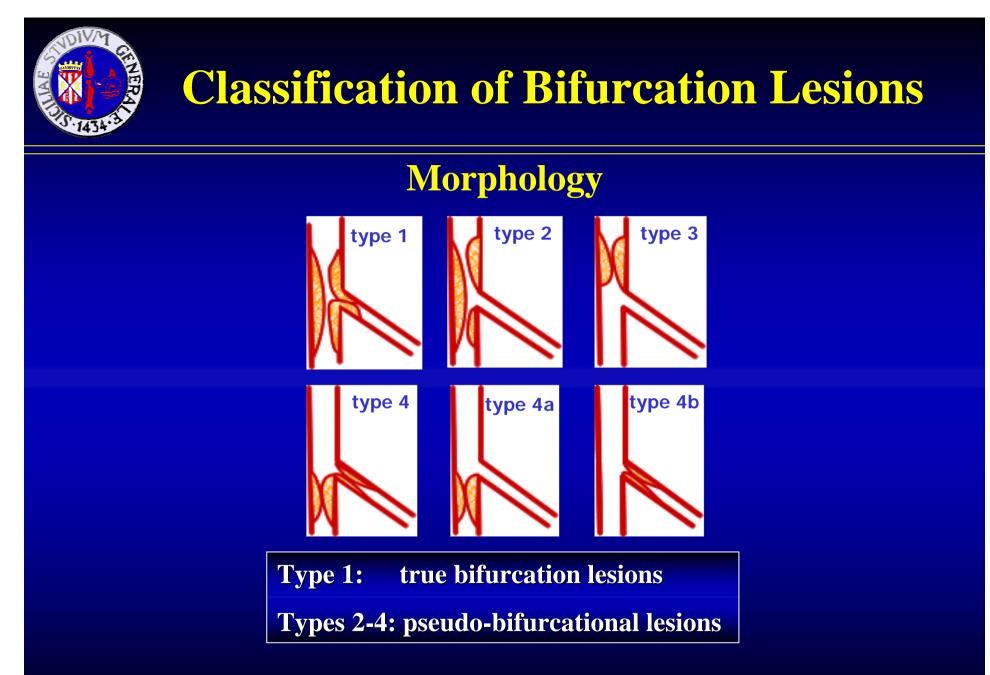
Type IV Parent vessel normal, ostial side branch stenosis

Euro PCR 2005



Medina Classification

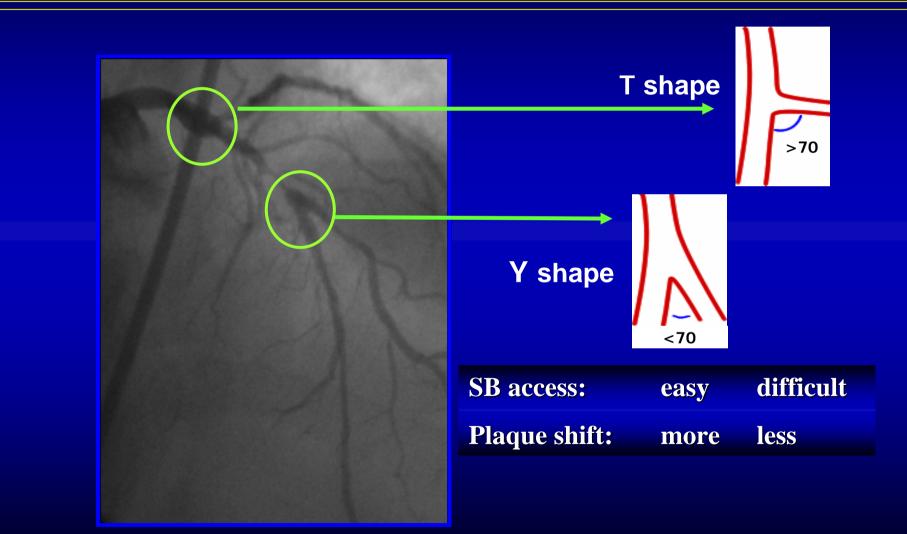


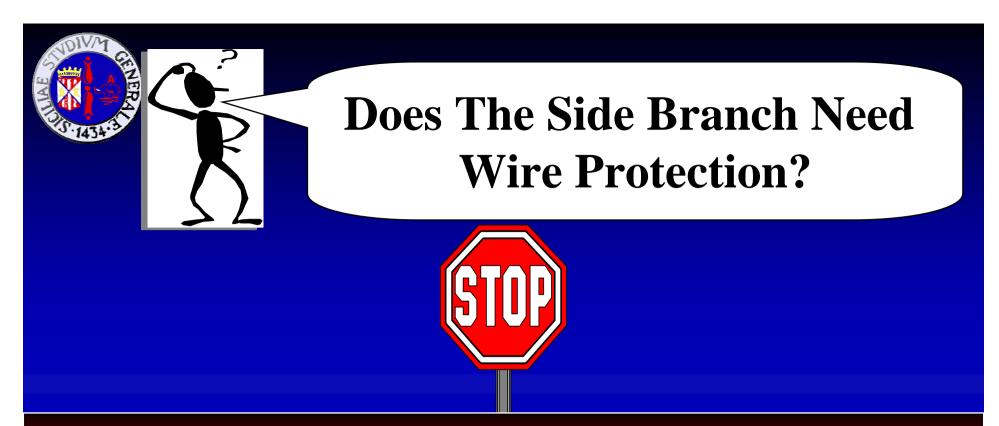


Lefevre T et al, Catheter Cardiovasc Interv 2000



Classification by the Angle of Bifurcation Lesions between MB and SB





Which is the risk of closure while treating the main branch (severity of ostial involvement and angle of origin)? What is the size of the side branch?

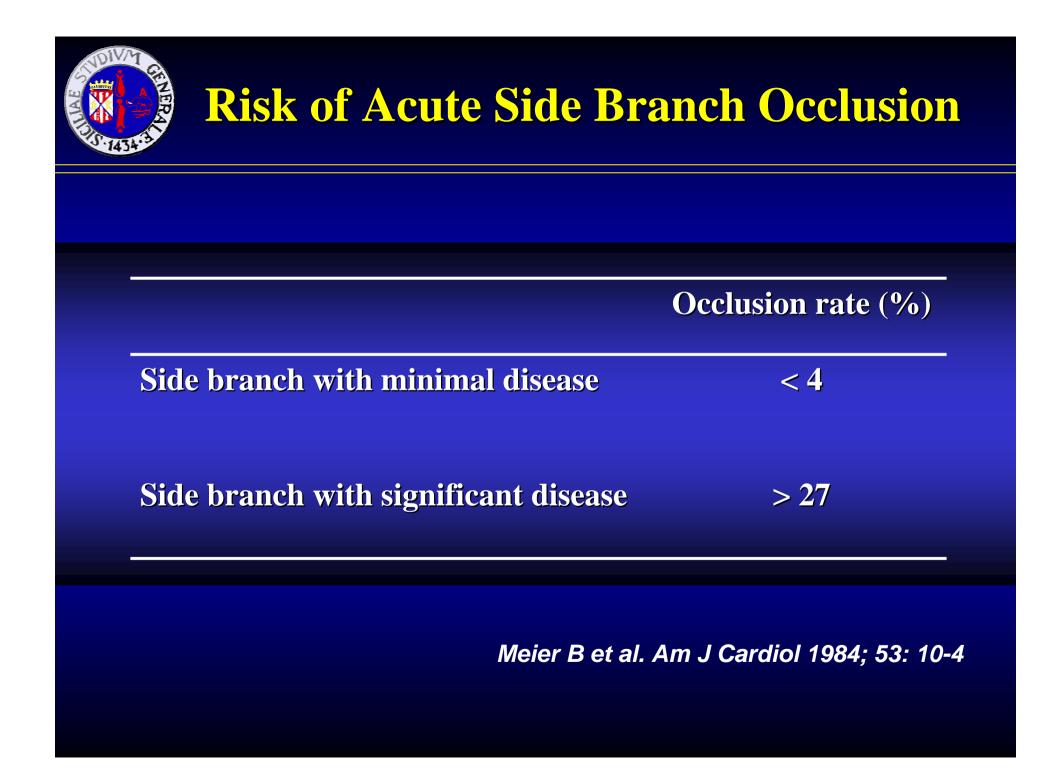


Side Branch Occlusion during PCI

• Generally clinical sequelae are transient chest pain and ST-T wave changes

• A small percentage of patients develop Q-wave infarction or require emergency surgery as long as main vessel remain patent

• Non Q-wave myocardial infarction undoubtely occurs frequently (serial systematic evaluation of enzymes not available)

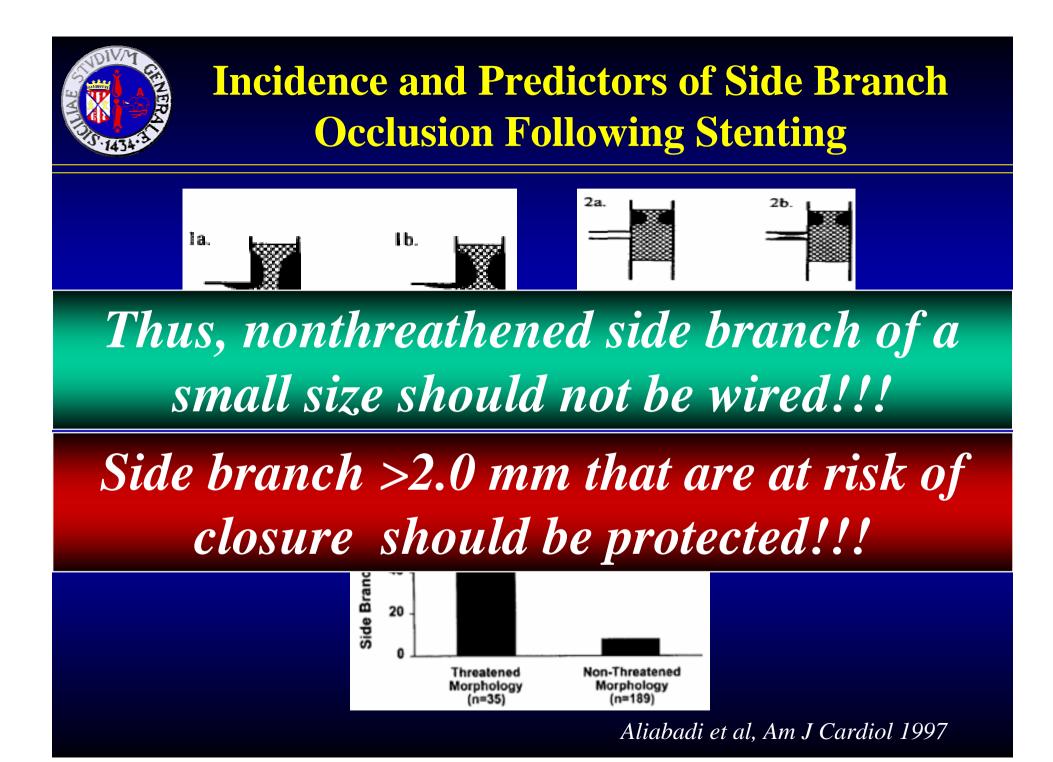




Incidence and Predictors of Side Branch Occlusion Following Stenting

	Occlusion	No occlusion	P value
Patients (n)	10	156	-
Calcifications (%)	0	16	NS
Lesion eccentricity (%)			
Concentric	Ο	12.9	
Excentric IPSI	80	49	0.143
Excentric Contro	20	38.1	
Angle >70º (T shape)	140º <u>+</u> 19º	137º <u>+</u> 26º	NS
Angle <70° (Y shape)	42° <u>+</u> 22°	60º <u>+</u> 22º	0.033
Stenosis main banch (%)	58 <u>+</u> 10	62 <u>+</u> 12	NS
side banch (%)	46 <u>+</u> 20	38 <u>+</u> 21	NS
Jailed guide wire technique (%)	80	91	NS

Y. Louvard, T. Lefèvre et al, TCT 2004

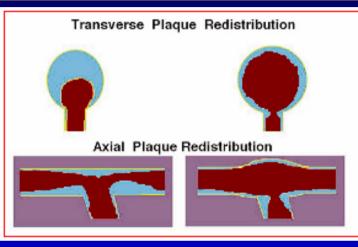




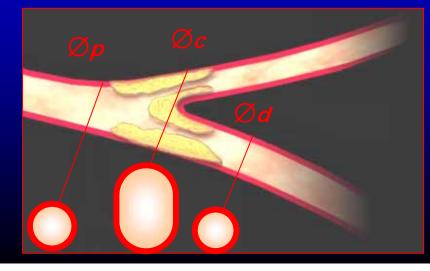
...if the side branch is ≥ 2.5 mm in diameter with ostial disease or at risk of plaque shift elective balloon dilatation with or without kissing balloon is advised... but remember no oversized balloon in the side branch to prevent dissection!!!

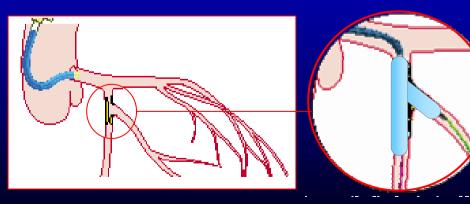


Common Approaches to Bifurcation Lesions: the Role of Kissing Balloon



Pre-dilatation *with Kissing Balloon* it avoids closure of side branch (or main vessel) by plaque shift

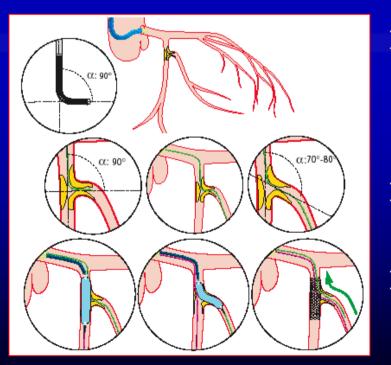






Common Approaches to Bifurcation Lesions: the Role of Jailed Wire

- Guide wire is left inside the side branch during main vessel stenting
- Side branch guide wire is jailed between main vessel stent struts and main vessel wall



- Used in T shaped Bifurcations in order to favorably modify the angle between the two vessels thus facilitating side branch re-wiring
- Helps to maintain side branch patency
- In case of side branch closure assures side branch traceability by radiopaque distal wire



Jailed Wire Effect on Proximal Main Branch/Side Branch Angle

	Baseline	Wiring	° modification	p value
Angle A > 120° (%)	77	87	-	<0.02
Angle A (°)	149 <u>+</u> 17	160 <u>+</u> 18	+ 11	<0.001
Angle A \leq 120 $^{\circ}$ (%)	23	13	-	<0.02
Angle A (°)	107 <u>+</u> 11	140 <u>+</u> 19	+ 33	<0.001

Y. Louvard, T. Lefèvre TCT 2003



Angiographic Predictors of Side Branch Success (Lesion <50% by QCA)

Age (years) Larger MB reference (mm) Larger SB reference (mm) Kissing balloon (%) "Jailed wire technique" (%)

66±11 vs 57±8	p=0.0007
3.1±0.4 vs 2.8±0.3	p=0.0085
2.5±0.5 vs 2.2±0.3	p=0.0413
98.1 vs 76.5	p=0.0019
92.9 vs 71.4	p=0.031

T. Lefèvre, Y. Louvard, unpublished

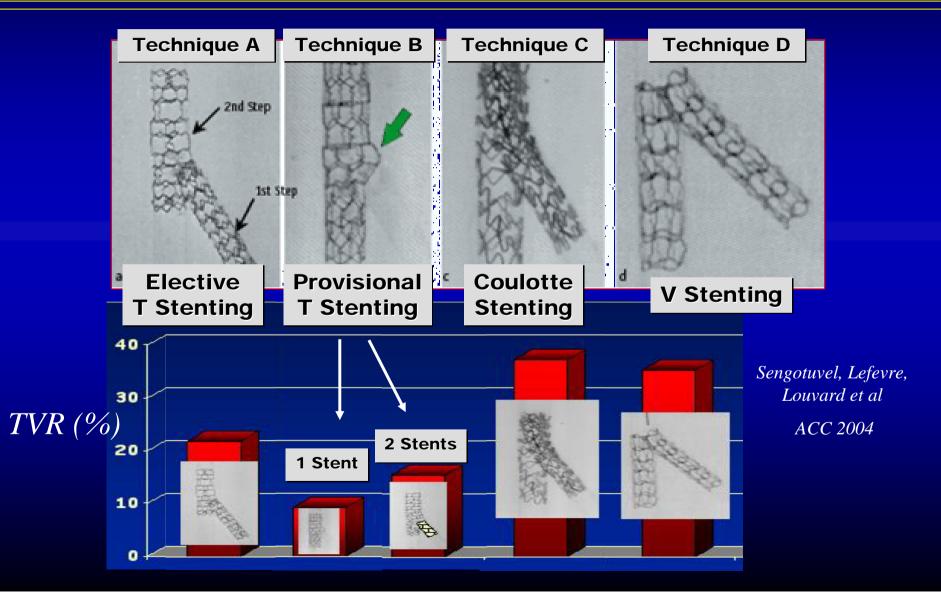


- Is the side branch a large vessel?
- Does the side branch comes out from the main with an acute angle?
- Does the ostium or the proximal segment of the side branch have a significant narrowing?
- Is the side branch very difficult to be wired?
- Is the patient a very high risk patient and the side branch appears relatively important?
- Is the main branch severely narrowed with a lot of plaque burden? If the answer is YES Antonio Colombo's suggestion is that the operator will lean more towards two stents

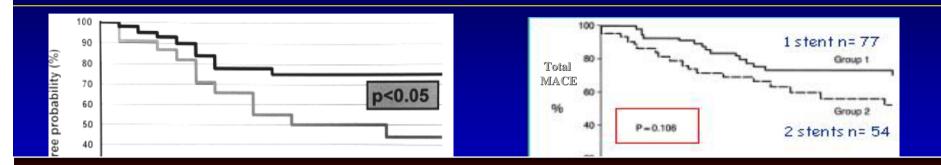
... sometimes a decision should be made only following predilatation of the main branch and of the side branch!



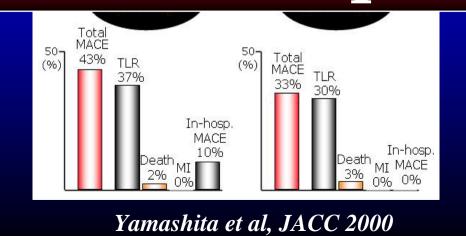
Common Approach to Bifurcation Lesions With Stents



1 Stent vs 2 Stent in the Bare Metal Stent Era (1994-2002)



No advantages of complex vs simpler strategy!



Procedural success (%)	97.9	97.3	99.2	NS
MACE at 30 days	1 (MI)	0	0	
Angiographic restenosis	100500			
Both vessels (%)	27.8	25.8	*12.5	p<0.05
	10.0	45.3	10.0	NC
Parent vessel (%)	18.2	15.7	12.0	NS
Parent vessel (%) P<0.05 Single stenting vs Y-ster MACE: Major Adverse Cardiac E TLR: Target Lesion Revasculariz	ting and T-stent vent (death/CAB	ing	12.0	

Nakamura et al, AHA 2002



Does The Side Branch Need a Stent?

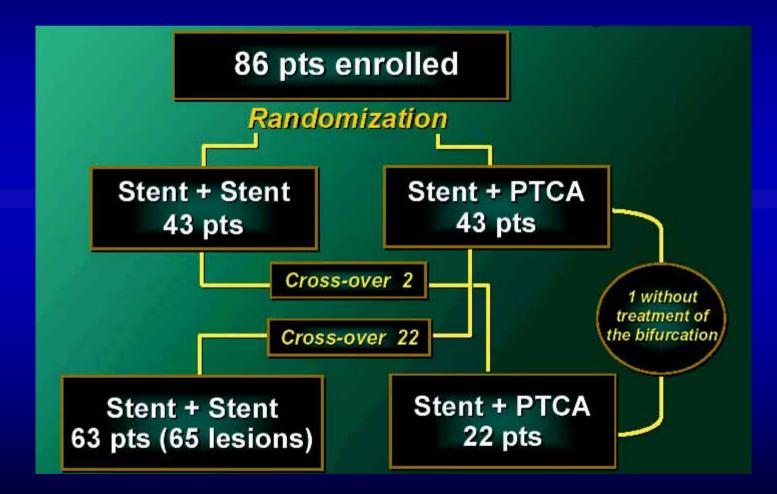


... if side branch is ≥ 2.7 mm in diameter elective stent implantation of both the main branch and the side branch should be performed!

... *if side branch is < 2.7 mm in diameter* single stent implantation of the main vessel followed by side branch dilatation may be advised!



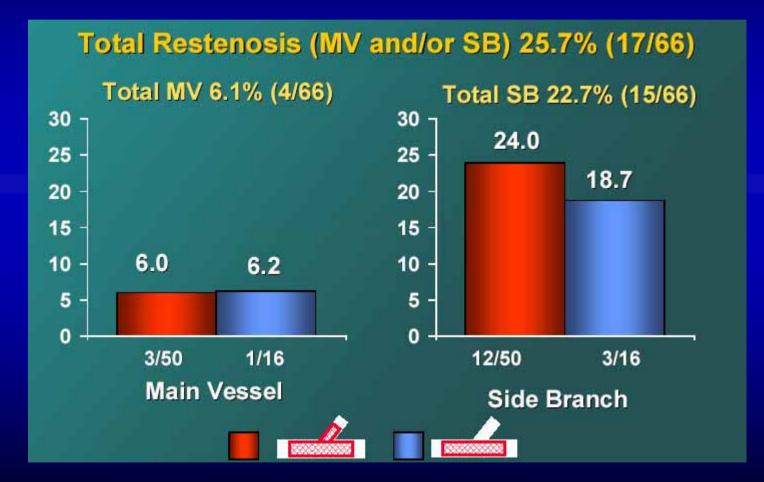
Randomized Study to Evaluate SES Implantation at Bifurcation



Colombo et al, Circulation 2004



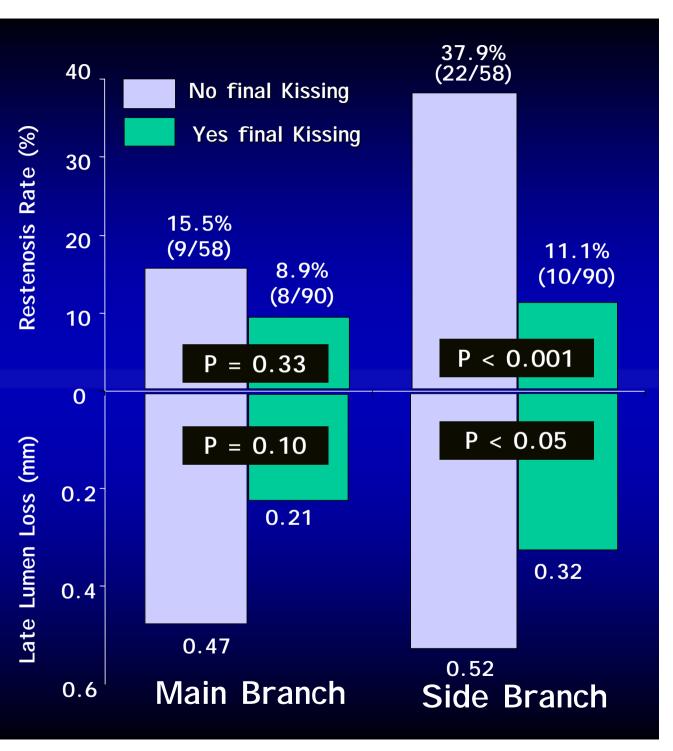
Randomized Study to Evaluate SES Implantation at Bifurcation



Colombo et al, Circulation 2004



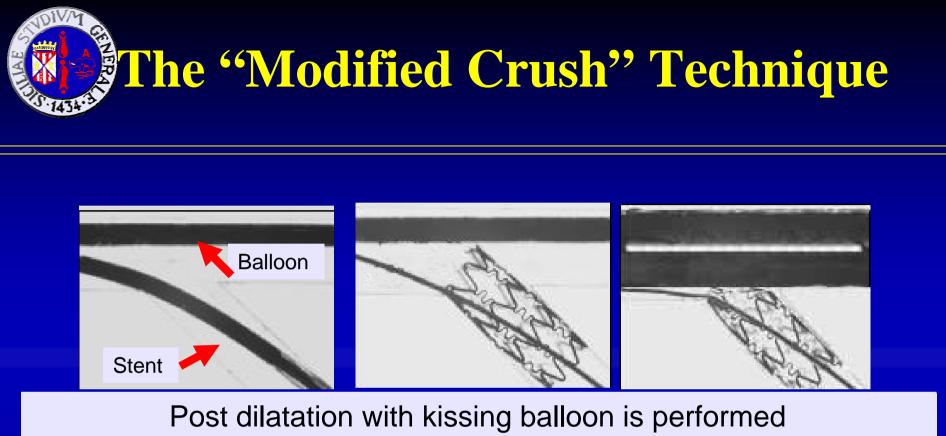
Result with Crush stenting according to performance of final kiss: restenosis and late loss are significantly reduced for the side branch Ge et al. JACC 2005



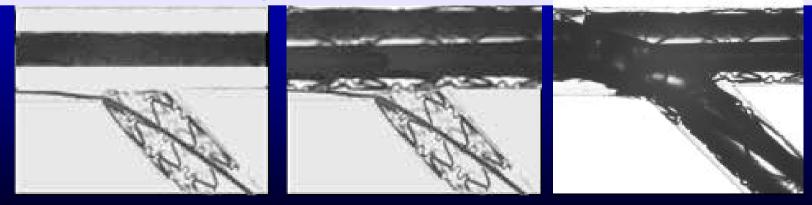


Crush Technique in the DES era

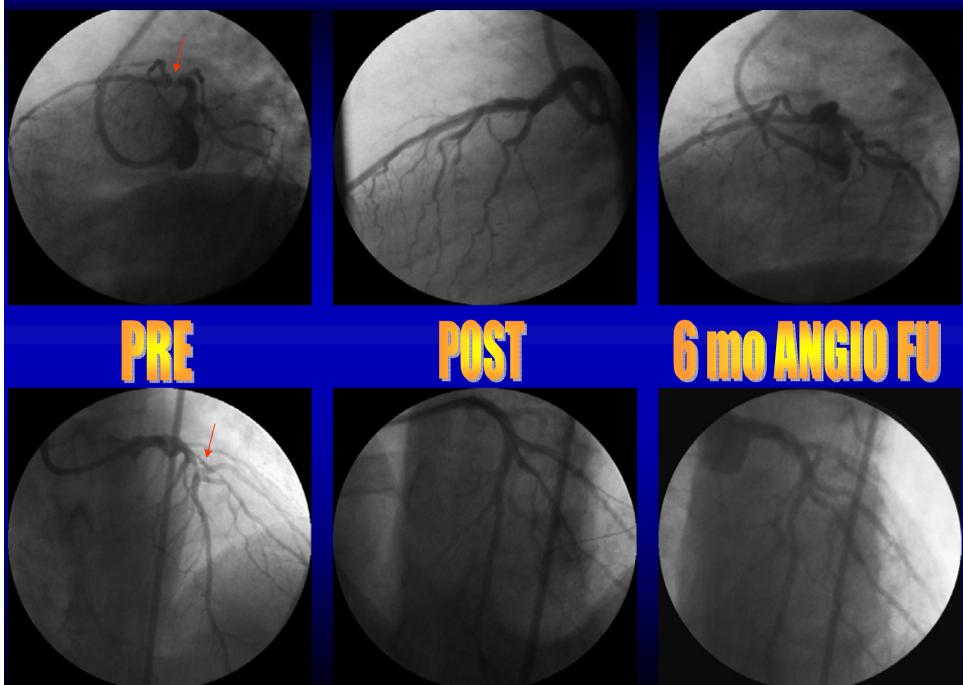
- Standard Crush (external crush): 7F, two stents in position together, side branch inflated first, main branch stent crushes side branch
- Reverse Crush (internal crush): used when provisional stenting requires another stent in the side branch: 6F, main branch stent deployed first, side branch stent is crushed against the main vessel stent with a balloon
- Inverted Crush: makes recrossing easier and improves side branch coverage: 7F similar to Standard Crush but the side branch stent is positioned more proximally than the main branch stent, the side branch stent will crush the main branch stent
- Step Crush: as standard Crush but can be done with 6F. Advance and deploy stent in side branch



(a 3rd guide wire may be employed)



Modified Crush in a Trifurcation Lesion





Procedural, in-hospital, 30-day and 8-month FU Results

Galassi AR, Buchbinder M, Colombo A et al Catheter Cardiovasc Interv 2006 (abstr)

	<i>Immediate and 30-Day pts 45/45</i>	8-month pts 45/45, lesions 52/52
Non-Q MI (%)	0	1/45 (2,2)
Q-MI (%)	0	0
Death (%)	0	0
Re-PTCA (%)	0	7/45 (15.5)
TLR (%)	0	6/45 (13.3)
TBR (%)	0	3/52 (5.7)
Acute thrombosis (%)	0	•••••
Subacute thrombosis (%)	0	•••••
Late thrombosis (%)	•••••	1/45 (2,2)
Main branch restenosis (%)	0	5/52 (9.6)
Side branch restenosis (%)	0	1/52 (1.9)
CABG (%)	0	0
Total MACE (%)	0	7/45 (15.5)



QCA Angiographic Findings (52 lesions)

Galassi AR, Buchbinder M, Colombo A et al Catheter Cardiovasc Interv 2006 (abstr)

MAIN BRANCH					
	Pre-procedure	Post-procedure	Angio follow up		
Lesion lenght (mm ± DS)	16,59 ± 9,45	$4,60 \pm 2,25$	6,00 ± 2,71		
RVD (mm ± DS)	2,69 ± 0 ,48	$2,81 \pm 0,45$	$2,79 \pm 0,50$		
MLD (mm ± DS)	$0,90 \pm 0,55$	$2,21 \pm 0,49$	$2 \pm 0,64$		
$DS (\% \pm DS)$	68 ± 17,81	22 ± 10	29,38 ± 16,74		
	SIDE BR.	ANCH			
	Pre-procedure Post-procedure Angio follow up				
Lesion lenght (mm ± DS)	7,84 ± 7,59	$2,86 \pm 1,32$	3,97 ± 3,12		
RVD (mm \pm DS)	2,29 ± 0 ,33	$2,\!30\pm0,\!47$	$2,28 \pm 0,40$		
MLD (mm ± DS)	$1,\!12 \pm 0,\!47$	$1,91 \pm 0,45$	$1,64 \pm 0,48$		
$DS (\% \pm DS)$	51,8 ± 19,26	$17,4 \pm 8,79$	$27,\!84 \pm 16,\!82$		



Recent Studies With DES

	RVD MainBranc	Technique	Restenosis Rate		
	h		Total	Main	Side
Colombo A et al, Circulation 2004	SideBranch 2,60 ± 0,40	Provisional Vs.	19%	4,8%	14,2 %
	2,10 ± 0,30	T-, V- stenting	27,5 %	5,7%	21,8
Tanabe K et al, Am J Cardiol 2004	2,64 ± N/A 1,99 ± N/A	and Crush Stenting Culotte V stenting Crush	22,7 %	9,1%	1%6 %
Ge L et al., JACC 2005	2,81 ± 0,58	Crush FKB Crush	20% 53,4	8,9% 15,5	11,1 %
Galassi AR, Buchbinder M, Colombo A et al Catheter Cardiovasc Interv 2006 (abstr)	2;89 ± 8;48 2,28 ±	Modified crush	13°,4 %	9,6%	2,2%
	0,22				

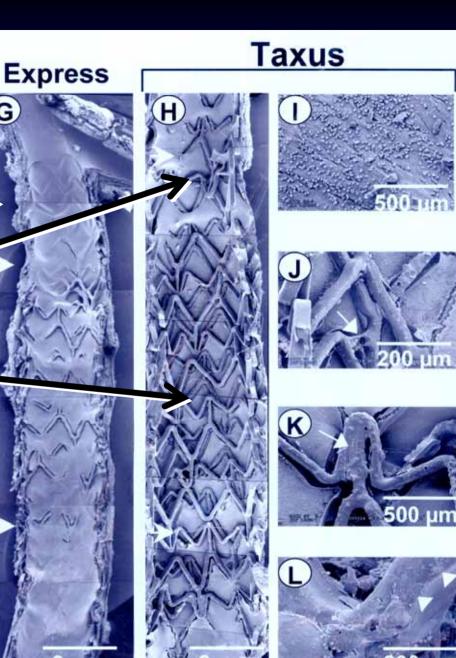
Endothelialization was complete after single or overlapping BMS

Reduced with single
layer DES

□Further reduced by
overlapping DES

Does overlapping predispose to SAT?

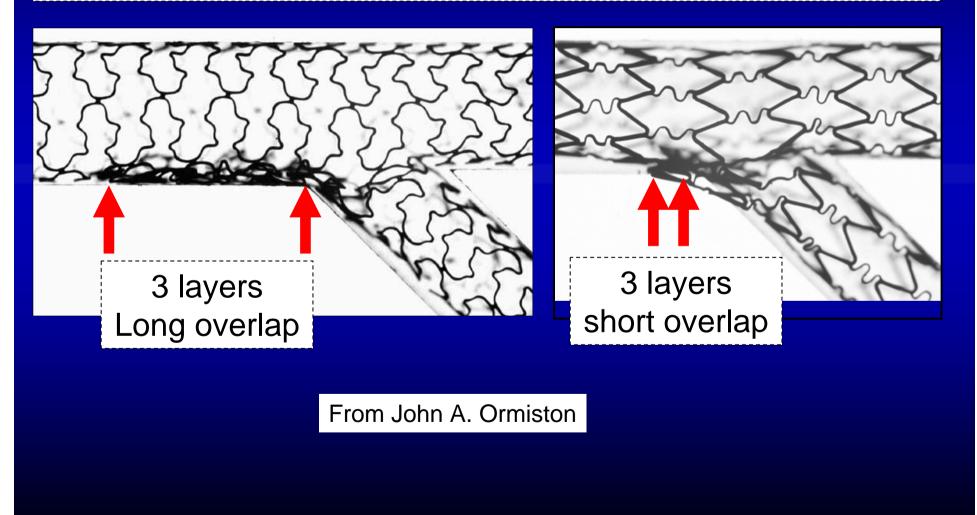






The ideal bifurcation stent or strategy should not have multiple layers with current DES

□Or overlap should be limited eg with "crush"





Appropriate Balloon Sizing for "Kissing" is Important

"If you get a crush you should kiss and if you kiss, you should do it well"

Colombo, Editorial CCVI, 2004;63

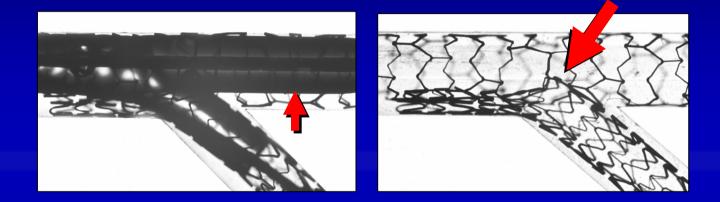


An undersized "kissing balloon" post-dilatation.....



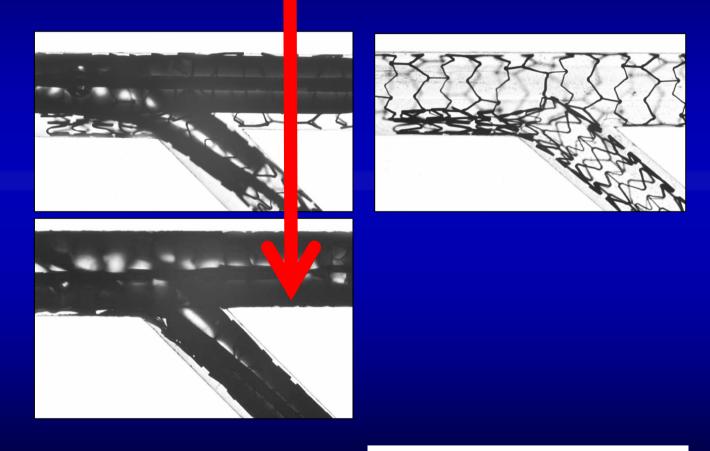


.....causes distortion after "crush"



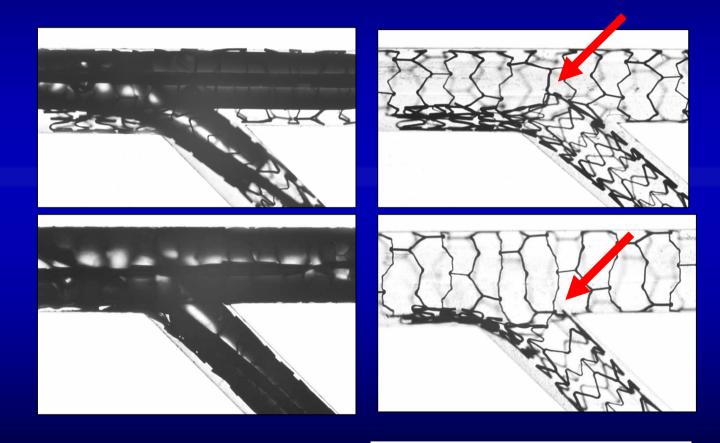


An appropriately sized main branch "kissing" balloon.....





.....repairs (or prevents) distortion



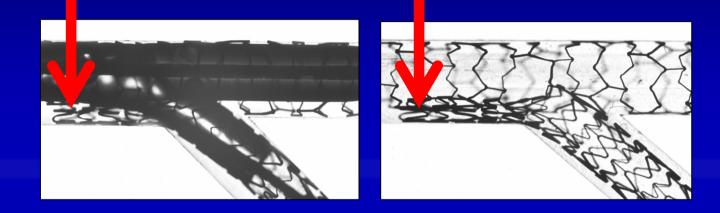


In addition, an undersized "kissing balloon" postdilatation.....



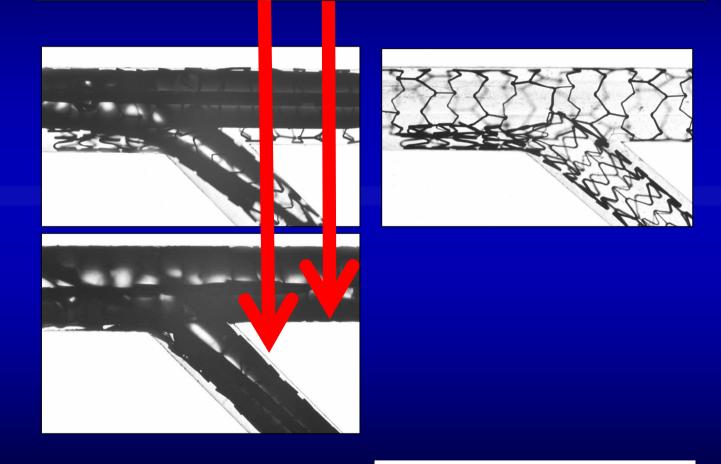


.....may incompletely crush the side-br stent in the main branch



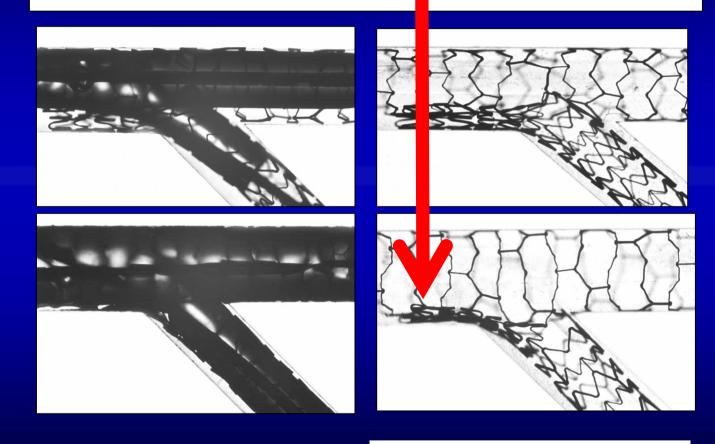


Appropriately sized main and side-branch "kissing" balloons.....



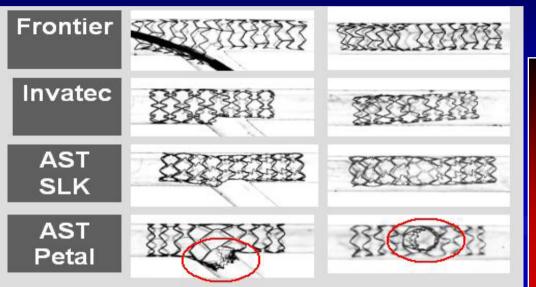


....completely crush the side-branch stent

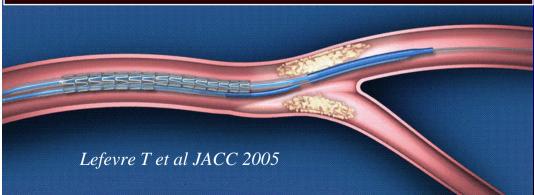




Dedicated Bifurcation Stents



FRONTIER Registry Angio @ 6-month: RR 44.8%, TLR 13.3%, MACE 17.1%



Dedicated bifurcation stents may solve problems but introduce new challenges

• more difficult to deliver (profile, flexibility, wire wrap)

- more difficult to retrieve into guide
- larger calibre guide needed.





- Nonthreathened side branch of a small size should not be wired, but side branch >2.0 mm that are at risk of closure should be protected
- If the side branch is ≥ 2.5 mm with ostial disease or at risk of plaque shift elective balloon dilatation with or without kissing balloon is advised
- If the side branch is ≤ 2.7 mm single stent implantation of the main vessel followed by side branch dilatation is advised
- If the side branch is \geq 2.7 mm elective stent implantation of both the main and the side branch should be performed



Conclusions - Before the DES Era (I)

- A single stent technique is generally preferred to the double stent technique
- Among the multiple techniques the provisional <u>T-stenting</u> is the preferred one
- Final kissing balloon is always advised



Conclusions - After the DES Era (II)

• A drug-eluting stent in the main branch can substantially lower the restenosis rate.....but Achille's heel still remain the side branch

• If a double-stent technique is used <u>crush,V stenting (SKS)</u> <u>and T-stenting</u> are the preferred ones (the "modified crush" seems a very promising approach....it need to be tested in randomized study)

• Recent introduction of <u>dedicated bifurcation stent</u> design might improve clinical outcome