New Devices in Bifurcation Lesions: Do We Really Need One?

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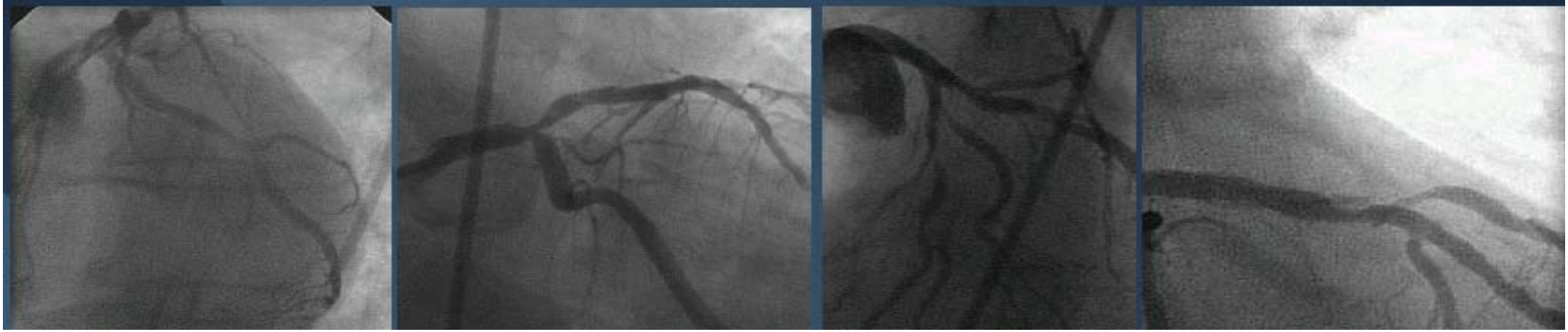
Conflict of Interest

Scientific Advisory Board to

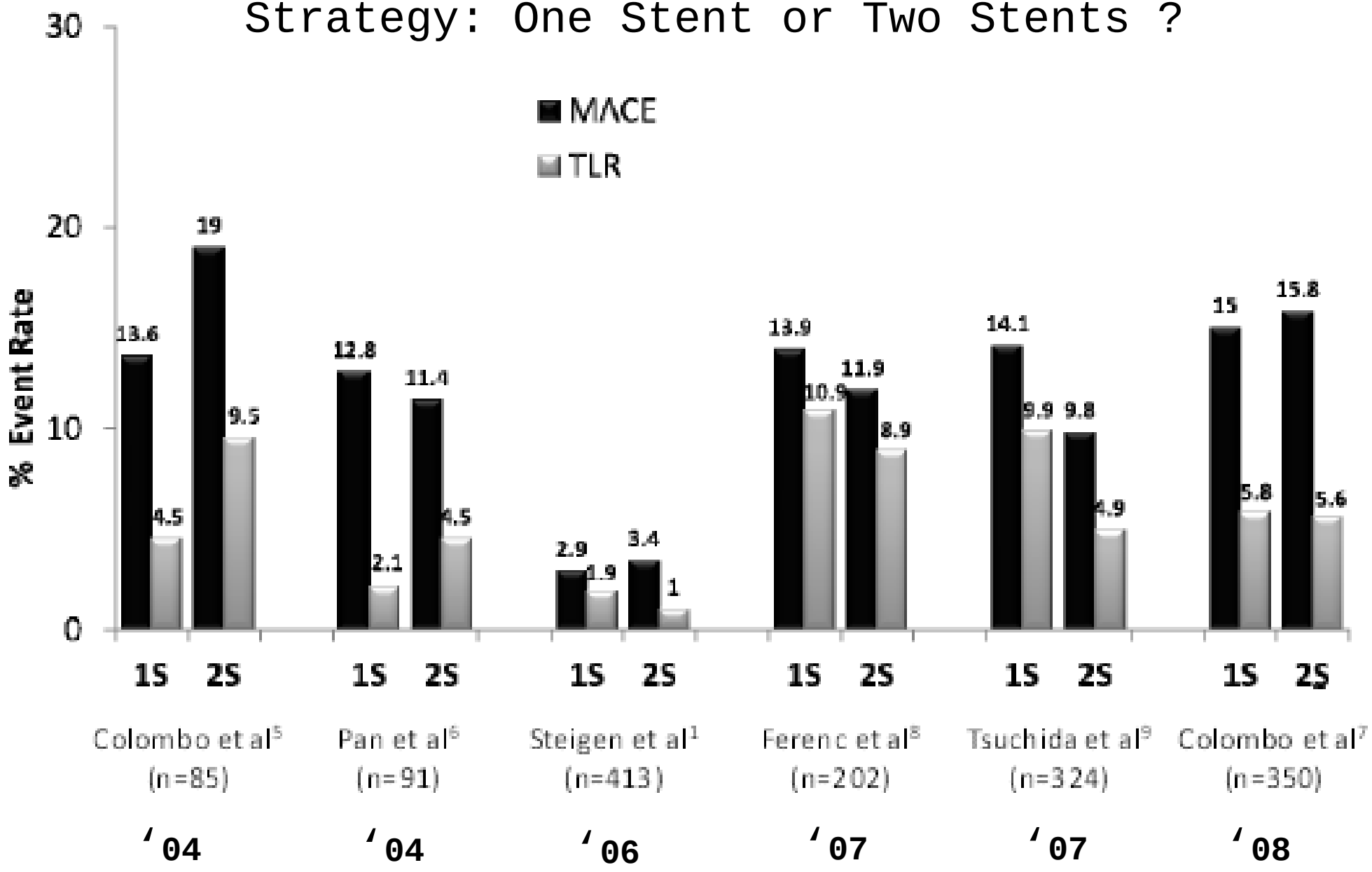
- **Abbott Vascular**
- **Boston Scientific Corpoaration**
- **Cordis**
- **Medtronic**

The challenge of bifurcations

- Risk of peri-procedural infarction
- Relatively high rate of restenosis
- Not all lesions are the same
  - Size of vessels
  - Variable plaque distribution
  - Extent of side branch disease
  - Variable angulation



Strategy: One Stent or Two Stents ?



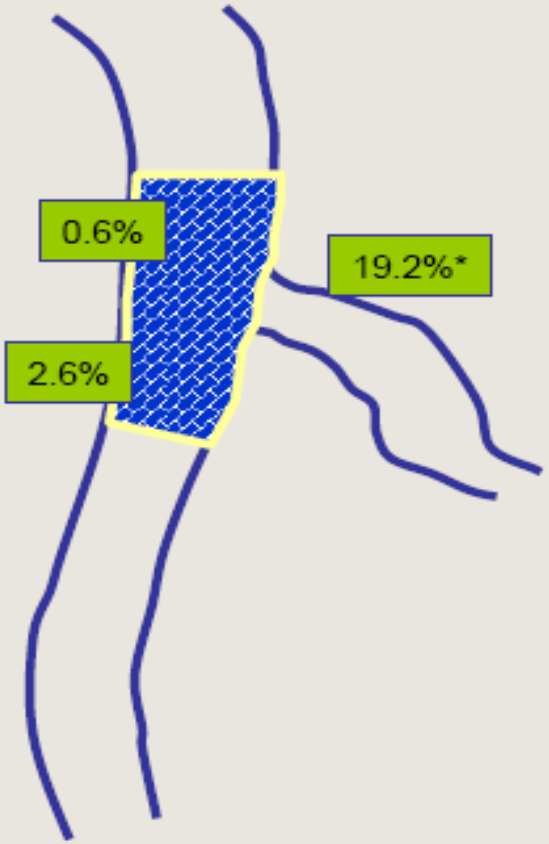
Conclusions from these studies

- Single stenting of the main branch with provisional stenting of the side branch is the strategy of choice for most bifurcations
  - There is no evidence of a significant advantage in a 2-stent strategy over one of provisional stenting
  - There is *no evidence of a significant disadvantage* in a 2-stent strategy over provisional stenting

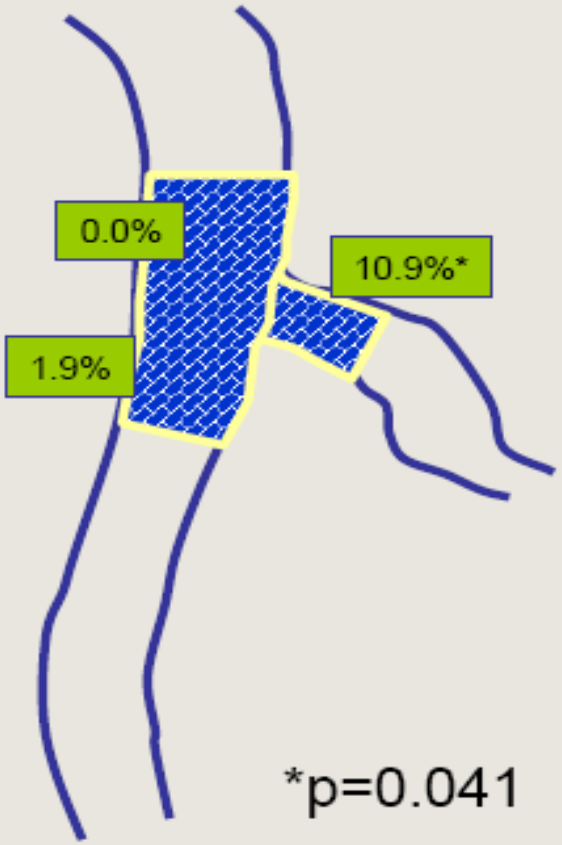
Angiographic follow-up after 8 months

Localization of >50% stenosis (in-stent and side branch)

MV



MV+SB



*p=0.041

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CACTUS trial

Coronary **B**ifurcation **A**pplication of the **C**rush **T**echnique **U**sing **S**irolimus-Eluting stents

QCA measurements

	Crush (n=177)		Prov.-T (n=173)	
	MB	**SB**	**MB**	**SB**
Reference diam. (mm)	2.85 ± 0.33	2.30 ± 0.31	2.74 ± 0.35*	2.16 ± 0.33*
Lesion length (mm)	15.8 ± 8.7	5.9 ± 4.7	14.7 ± 8.2	5.7 ± 4.2
Baseline MLD (mm)	0.90 ± 0.38	0.84 ± 0.32	0.83 ± 0.33	0.83 ± 0.30
Baseline stenosis (%)	68 ± 12	63 ± 12	69 ± 12	61 ± 13
Final MLD (mm)	2.71 ± 0.32	1.94 ± 0.39	2.58 ± 0.33*	1.65 ± 0.39*
Final stenosis (%)	12 ± 6	16 ± 11	13 ± 6	27 ± 14*
6-month MLD (mm)	2.24±0.52	1.66 ± 0.51	2.19±0.58	1.52 ± 0.54*
6-month stenosis (%)	25 ± 14	30 ± 19	25 ± 16	31 ± 22

Angiographic follow-up performed in 86% of patients in both groups

** = $p<0.05$ for comparisons between crush and prov.-T*

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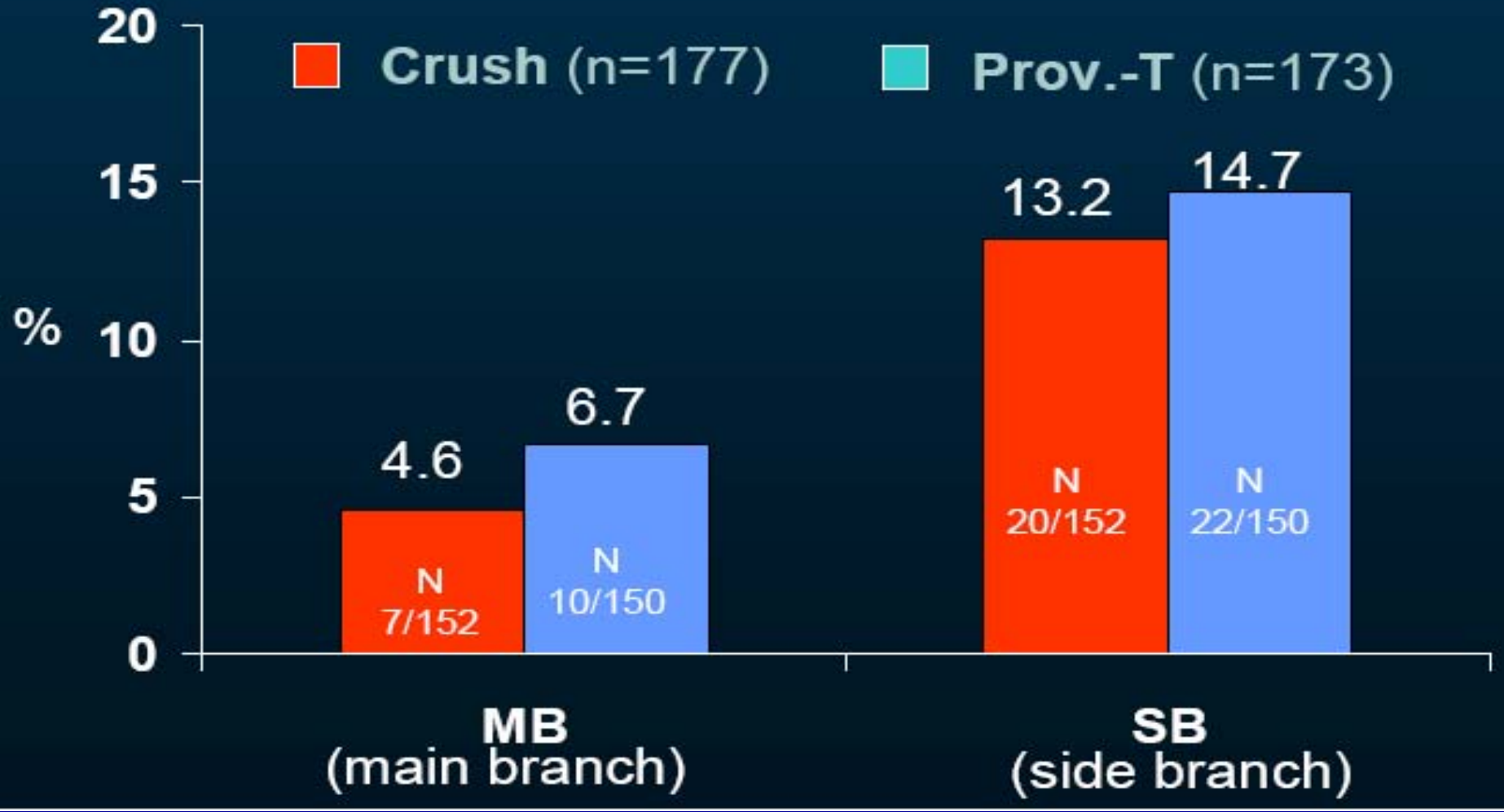
CACTUS trial

Coronary **B**ifurcation **A**pplication of the **C**rush **T**echnique **U**sing **S**irolimus-Eluting stents

6-month in-segment binary restenosis

Angiographic F.U. performed in 86% of pts in both groups



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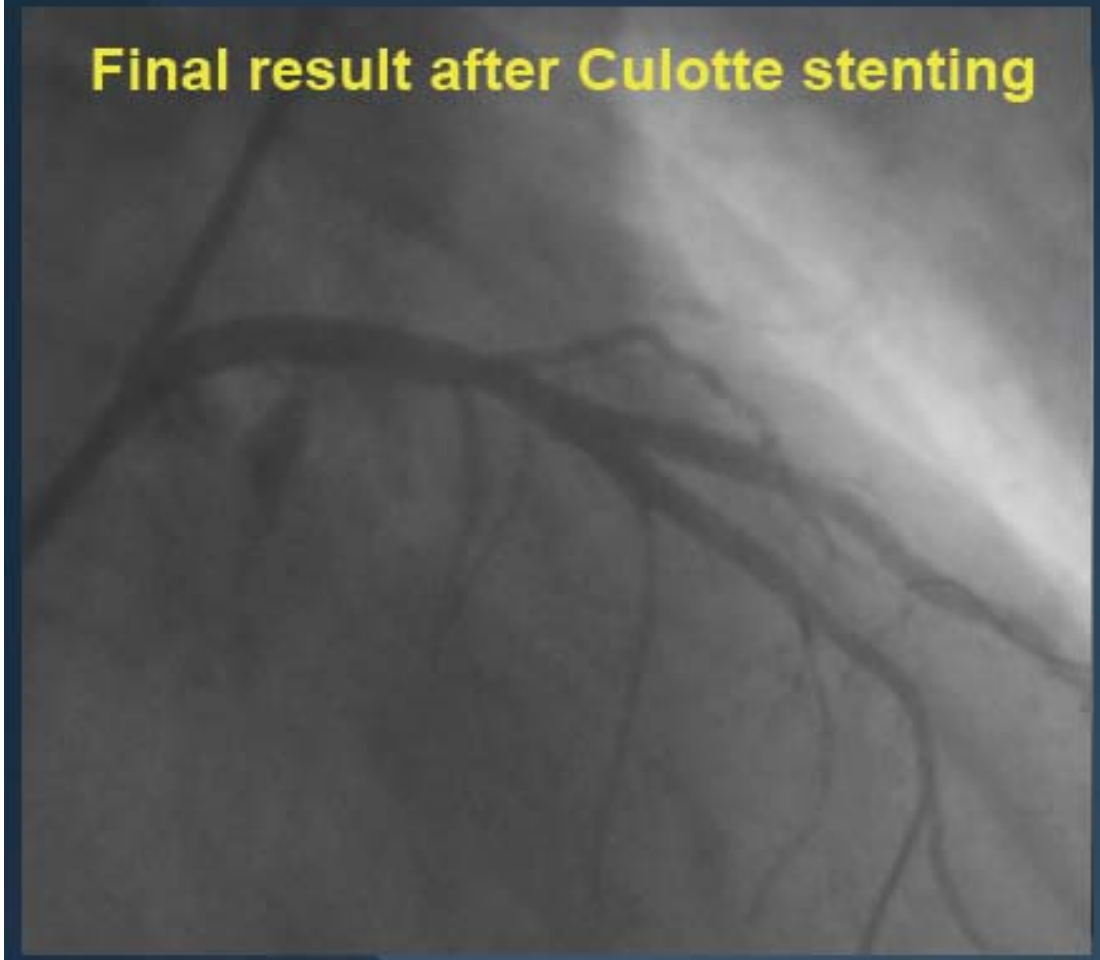
CACTUS trial

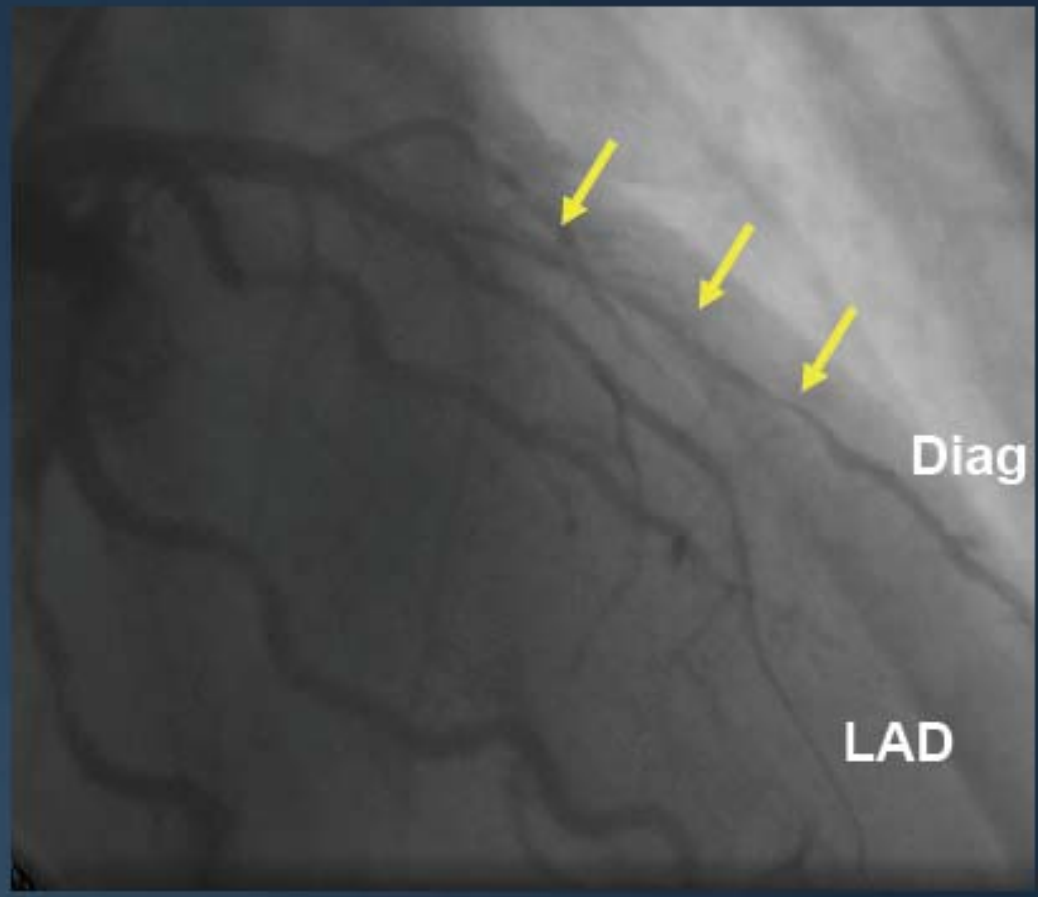
Coronary Bifurcation Application of the Crush Technique Using Sirolimus-Eluting stents

Stent thrombosis

	1	2	3	4	5
Technique	Crush	Crush	Crush	Prov.-T	Prov.-T
Days from procedure	1	7	6	7	72
Thienopyridine	Yes	Yes	No stop day 1	Yes	Yes
Number of stents	2+1	1+1	2+1	1	1+1
Total stent length (mm)	83	65	72	13	41
Final kissing	Yes	No	Yes	Yes	No
Diabetes	No	No	Yes	Yes	No
Lesion location	LAD-diag.	LAD-diag	LAD-diag	LAD-diag	RCA
Clinical consequences	Q-wave MI and TLR	Non Q-wave MI and TLR	Q-wave MI and TLR	Q-wave MI and TLR	Q-wave MI and TLR

More complex bifurcation





- *2-stent strategy is appropriate if the side branch is ≥2.5mm particularly if the SB lesion length is long*

20 YEARS OF INNOVATION TCT2008

Nordic II: Procedural charactersitics

	Crush n=209	Culotte n=215	P
Treatment according to randomization	202 (97%)	208 (97%)	1.00
Procedural success	205 (98%)	210 (98%)	1.00
Procedure time (min)	74 ± 39	72 ±28	0.70
Fluoroscopy time (min)	22 ± 15	22 ± 14	0.74
Contrast volume (ml)	276 ±104	283 ± 117	0.53

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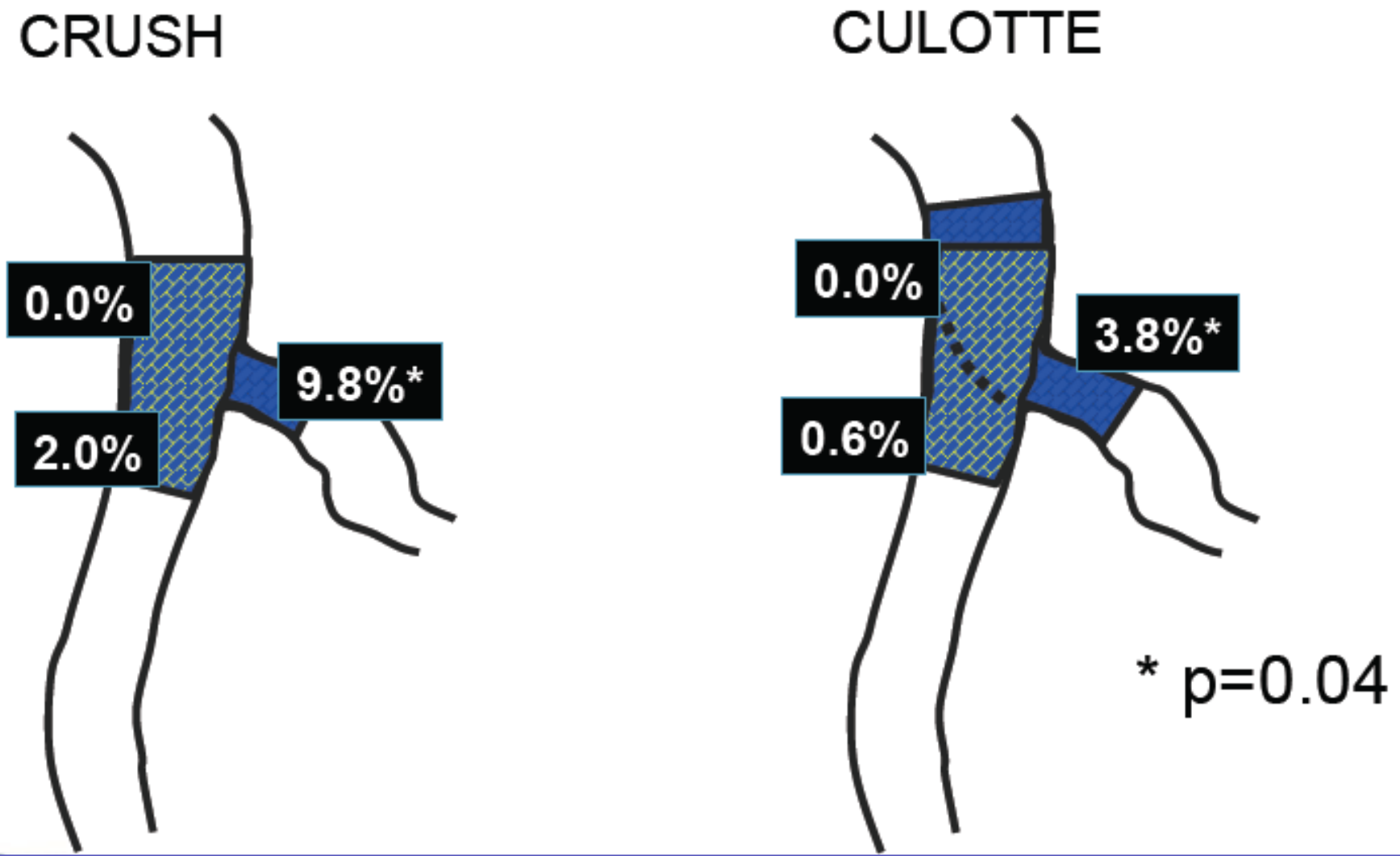
Nordic II: Localization of In-Stent Restenosis at 8 Months Follow-up



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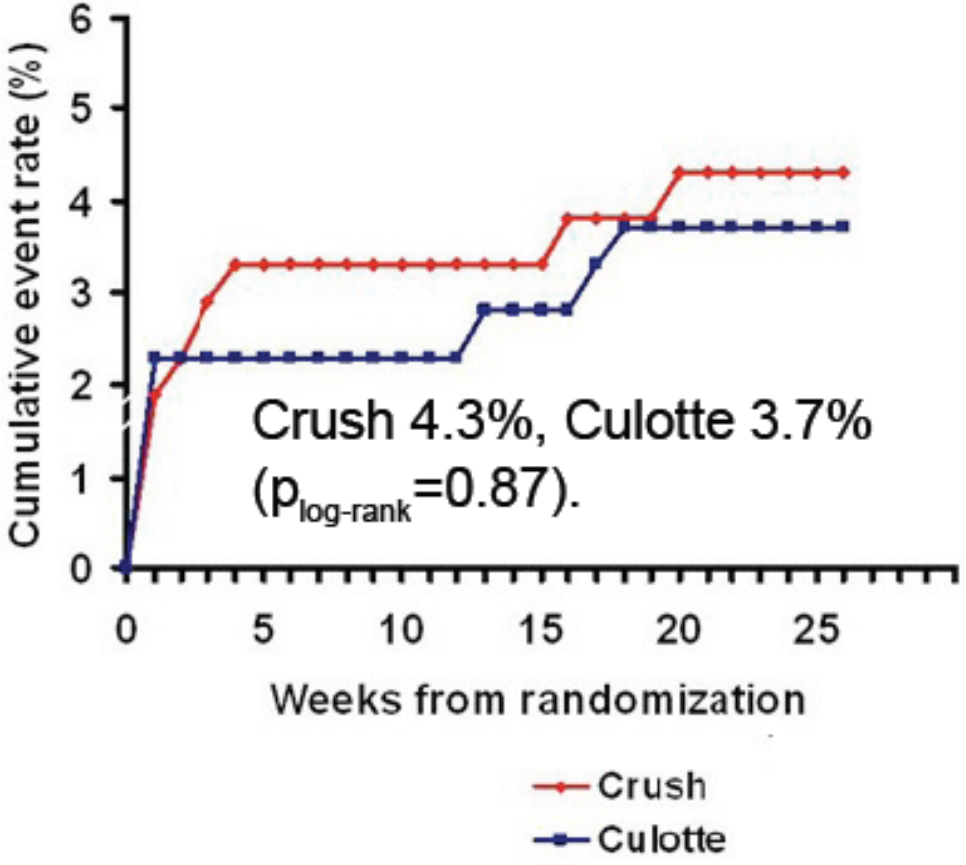
Nordic II: Major Adverse Cardiac Events at 6 Months Follow-up

Cumulated MACE rate

(cardiac death, MI, TVR, stent thrombosis)



Individual endpoints

	Crush n=209	Culotte n=215	P
Total death	2 (1.0%)	1 (0.5%)	0.62
Cardiac death	2 (1.0%)	1 (0.5%)	0.62
MI	4 (1.9%)	3 (1.4%)	0.72
ST	3 (1.4%)	4 (1.9%)	0.73
TLR	5 (2.4%)	6 (2.8%)	0.77
TVR	5 (2.4%)	6 (2.8%)	0.77

MI, myocardial infarction; ST, stent thrombosis; TLR, target lesions revascularization; TVT, target vessel revascularization

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CACTUS trial

Coronary Bifurcation Application of the Crush Technique Using Sirolimus-Eluting stents

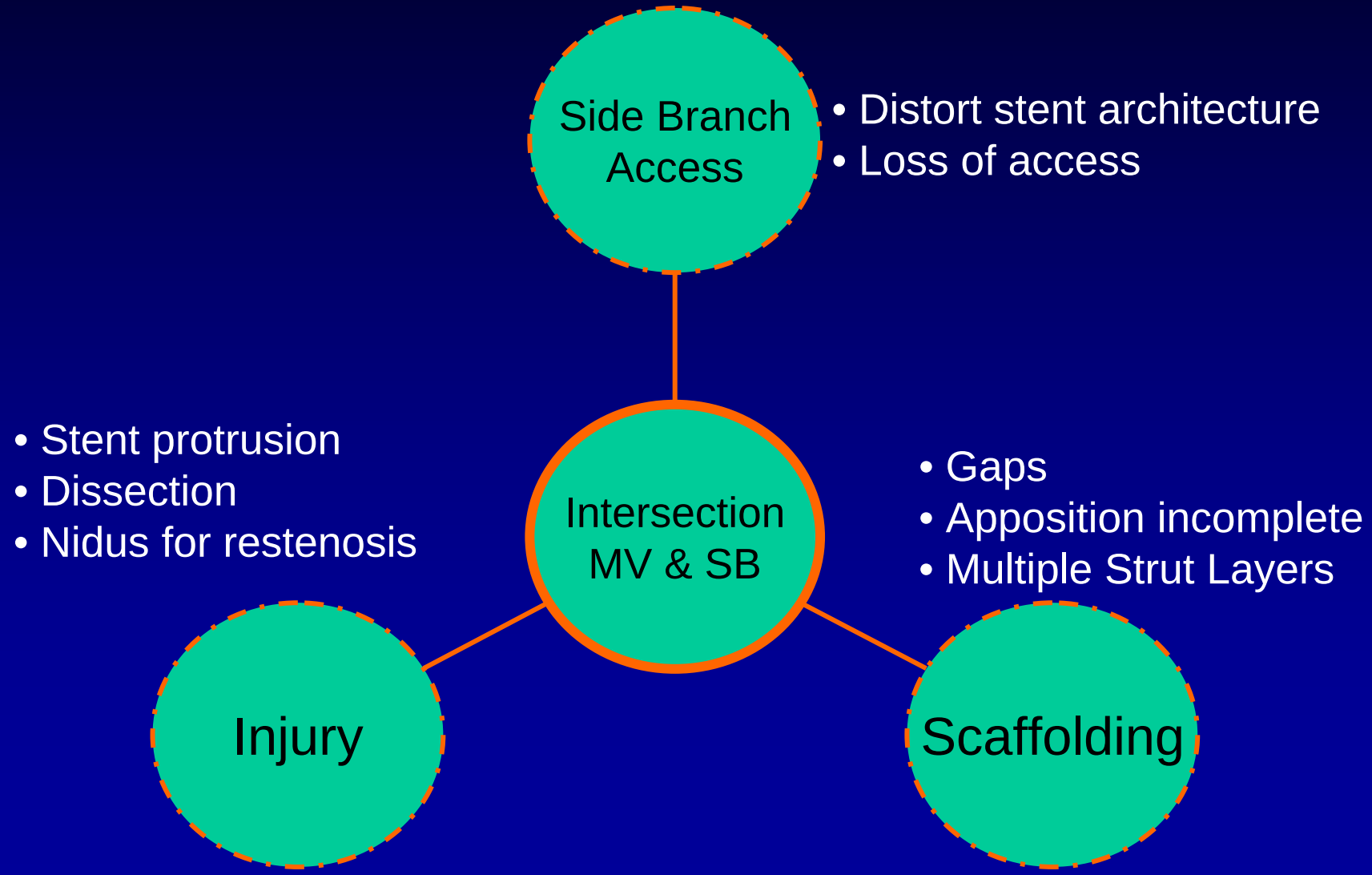
	Crush	T-Prov	
30 days MACE (days 0-30)			
Q wave MI	3 (1.7%)	2 (1.1%)	1.00
Non-Q wave MI	15 (8.5%)	12 (6.9%)	0.69
TLR	3 (1.7%)	1 (0.5%)	0.63
TVR (including TLR)	3 (1.7%)	1 (0.5%)	0.63
Death	0	0	-
6-month MACE (days 31-180)			
MI	1 (0.5%)	1 (0.5%)	1.00
TLR	10 (5.6%)	10 (5.8%)	1.00
TVR (including TLR)	11 (6.2%)	12 (6.8%)	0.83
Death	0	1* (0.5%)	0.49

*= non cardiac death (ischaemic stroke confirmed by autopsy)

Rational for Dedicated Bifurcation Stents

- 1:1:1 with large side branch distribution
- Maintain side branch access at all times
- Distortion of MB stent by SB dilatation
- Inability to cover the ostium of the SB
- Multiple layers of DES
- Time and skills
- Myocardial infarction
- Stent thrombosis

Technical Challenges with Bifurcations
Using Straight, Concentric Tubular Systems



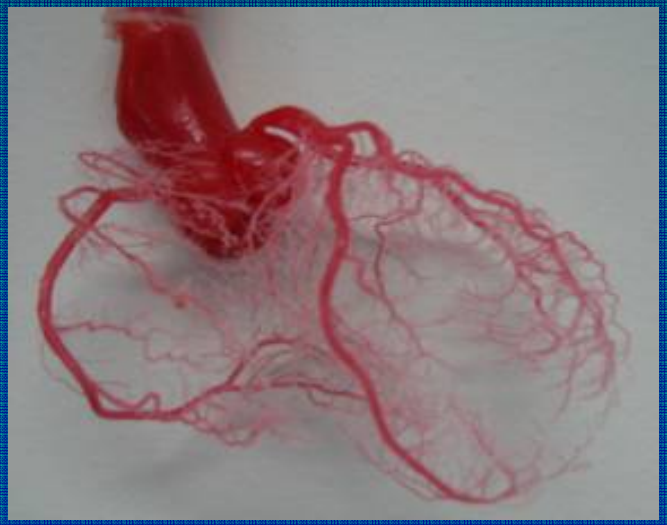
Study Objectives

Define bifurcation anatomy and geometry

- **Casts of human coronary tree to evaluate intersection between Main Vessel (MV) & Side Branch (SB)**
- **Qualitative assessments**
  - **Shapes in intersections and SB take off**
- **Quantitative measures**
  - **Specified Diameters (vessels > 1.6 mm)**
  - **Various angles**

3 Dimensional Casts of Coronary Tree (Aorta to terminal branches (<1mm)

- Branching
- Curvature
- Tortuosity
- Lesions
- Intersections



High Power Views of Anatomy & Disease

Multifaceted intersection without discrete angle

No disease

Minor stenosis; minimal disease

Moderate ostial stenosis; diffuse stenosis in SB and proximal MV

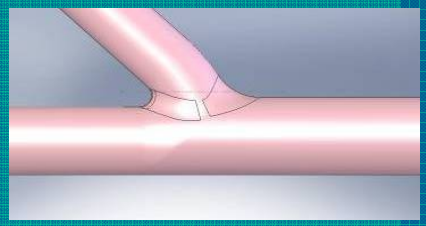
Severe stenosis and disease

Ostial Geometry:
Oval and Asymmetric Rather than Round

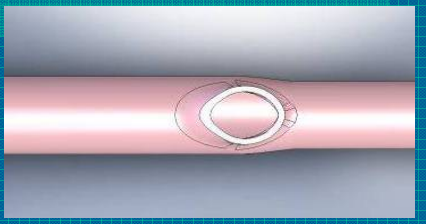
Example: Side Branch of RCA

Sketches of ostium

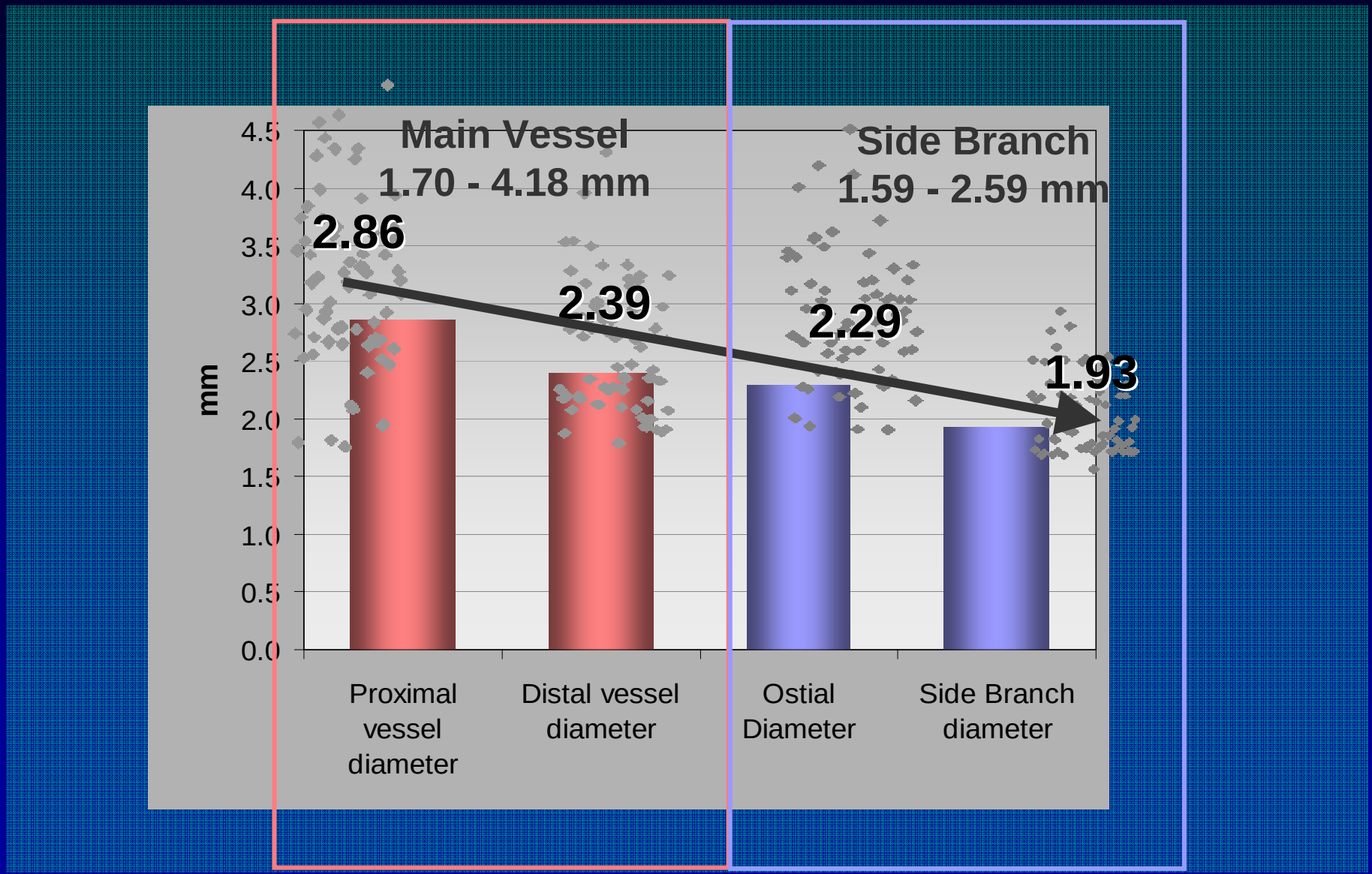
conical taper



elliptical

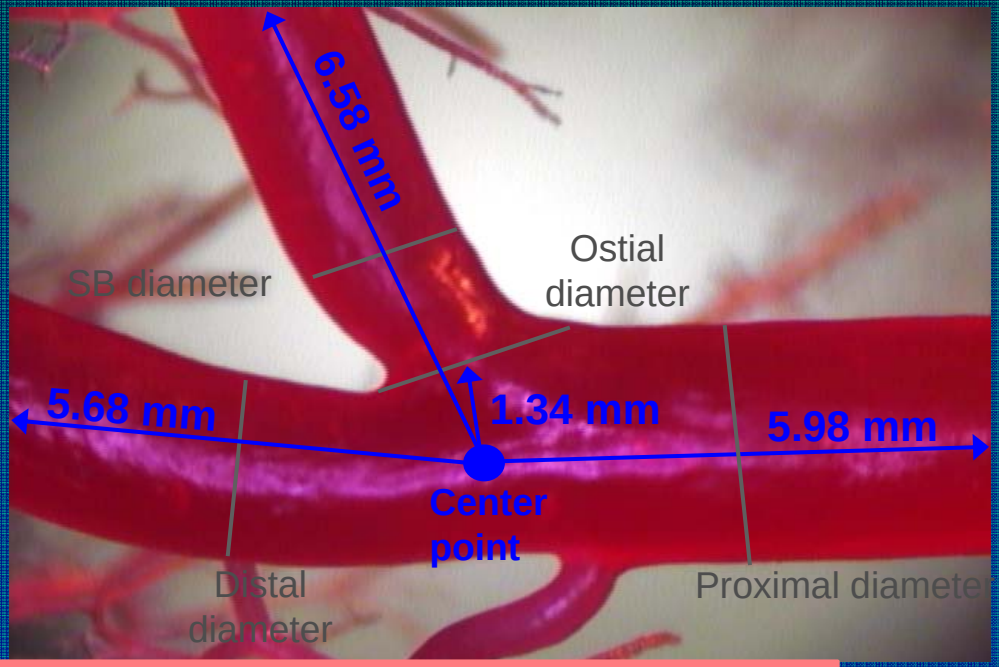


Diameters: Greater proximal to distal
Ostial SB diameter similar to distal MV



Ostial Geometry:
Transition Zone Taper Greater by 3-fold

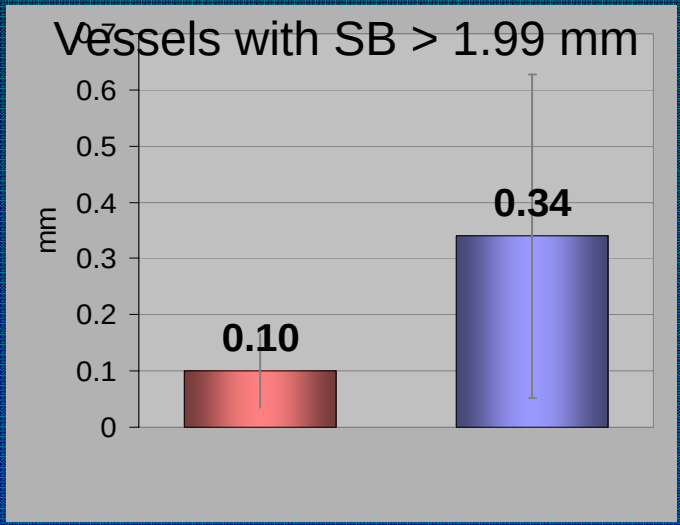
Example of Diameter Measurements



	At 3 mm	At 6 mm
Proximal diameter	**3.14**	**3.15**
Distal diameter	**2.44**	**2.56**

	At ostium	At 3 mm	At 6mm
Side branch diameter	**2.50**	**1.96**	**2.03**

Average Taper



Proximal to Distal Taper (Main Vessel)

Ostium to Side Branch Taper (Side Branch)

Main Vessel
Tapers 0.56 mm over 6.00 mm distance

Side Branch
Tapers 0.60 mm over 1.75 mm distance

Summary

Bifurcation diameters ~ to previous findings

MV: Wide Range (1.7 to 4.2),

proximal mean= 2.86

distal mean= 2.39

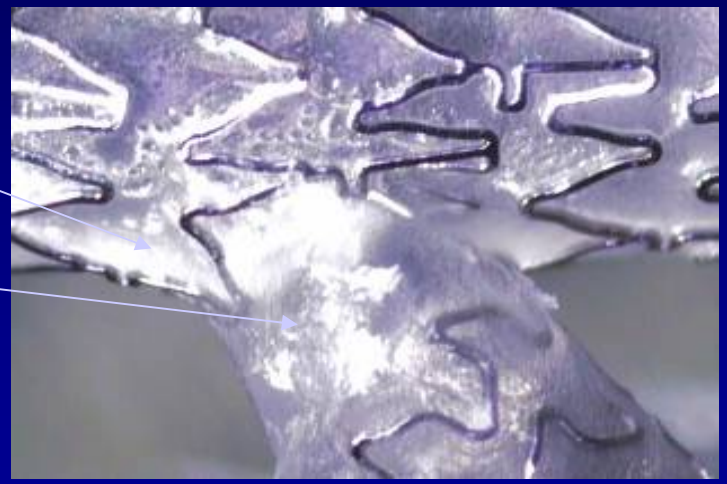
SB: Wide Range (1.6 to 2.6), mean 2.28

Four types of Asymmetric Ostial Geometry:

- **Multifaceted transition (high magnification detail)**
- **Oval rather than round ostium**
- **SB Taper 3-fold greater than MB**
- **Side branch take off angles**
  - **Proximal (obtuse)**
  - **Distal (acute)**

Conclusions
Distorted stent or Distorted anatomy

- Complex transition zone from the main vessel to the side branch with many asymmetric features
- Anatomic distortion likely with symmetric (cylindrical) designs
  - Strut protrusion/injury
  - Gaps
  - Incomplete wall apposition



- Matching design to asymmetric ostial geometry may minimize implant injury, enhance scaffolding and improve outcomes

Bifurcated Stent Companies

Twin-Rail (by Invatec)

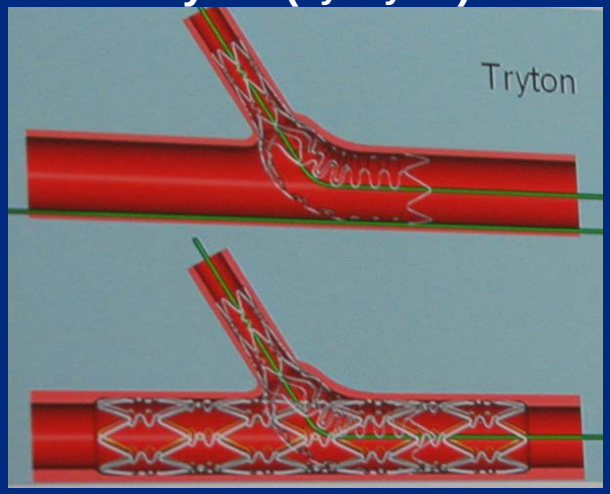
Stentys (by Stentys)

Petal (by Boston)

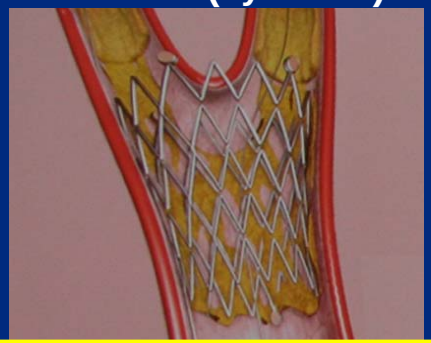
Frontier (by Abbott)

Sideguard (by Cappella)

Tryton (by Tryton)



Axxess (by Devax)



Antares™ (by TriReme)

Dedicated Bifurcation Stents

	Antares	Petal	Stentys	Frontier/ Pathfinder
DES Program	N	Y	Y	Y
FIM/Multicenter Registry	Y-11/ N	Y-13/ Y-45	Y-13/ N	N
Side Branch Angle	Dep	Indep	Dep	Indep
Overlap Struts (M/S)	Side	Side	Main	Side
New Carina	N	N	Y	N
Marker Bands Align.	Y	Y	N	N
Accuracy	Y	Y	?	Y

Dedicated Bifurcation Stents

	Axxess	Capella	Tryton
DES Program	Y	N	N
FIM/Multicenter Registry	Y-139/ Y 300	Y-20/ Y-90	Y-30/ N
Side Branch Angle	Dep	Dep	Indep
Overlap Struts (M/S)	Main	Main	Main
% 1:1:1	72%	73%	?
SB TLR/BR	1.3%/ 4.8%	5.1%/ 8.4%	?
Note	2.6 stents	IVUS Area up	