

TCT Asia 2006

**Drug Eluting Stents:
Bifurcation and Left Main Approach**

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FACC, FSCAI

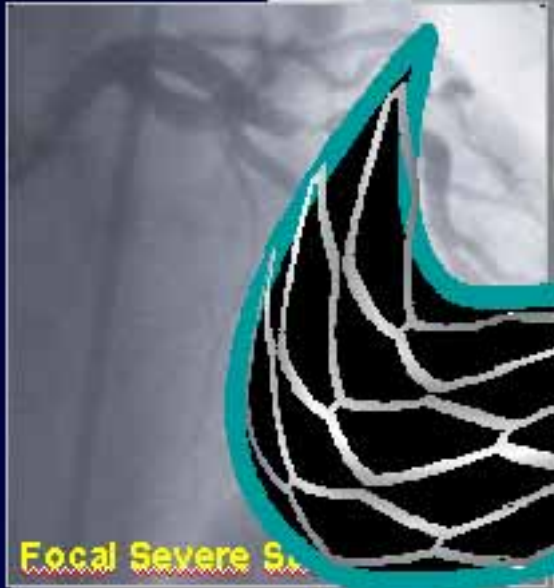
Heart Center Siegburg, Siegburg, Germany
Stanford University, School of Medicine, CA, USA



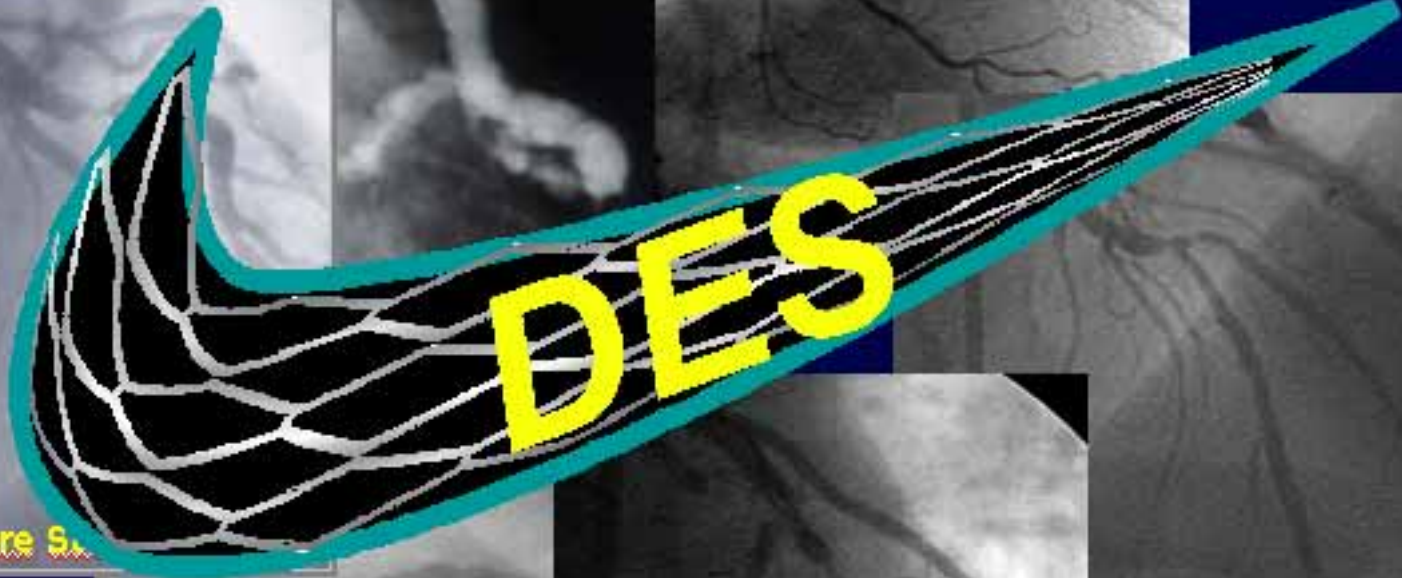
SVG



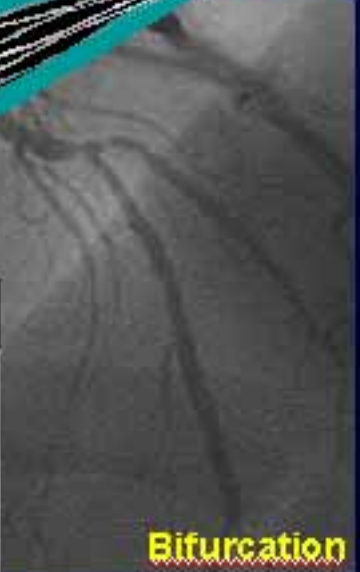
In-stent



Focal Severe Stenosis



DES



Bifurcation

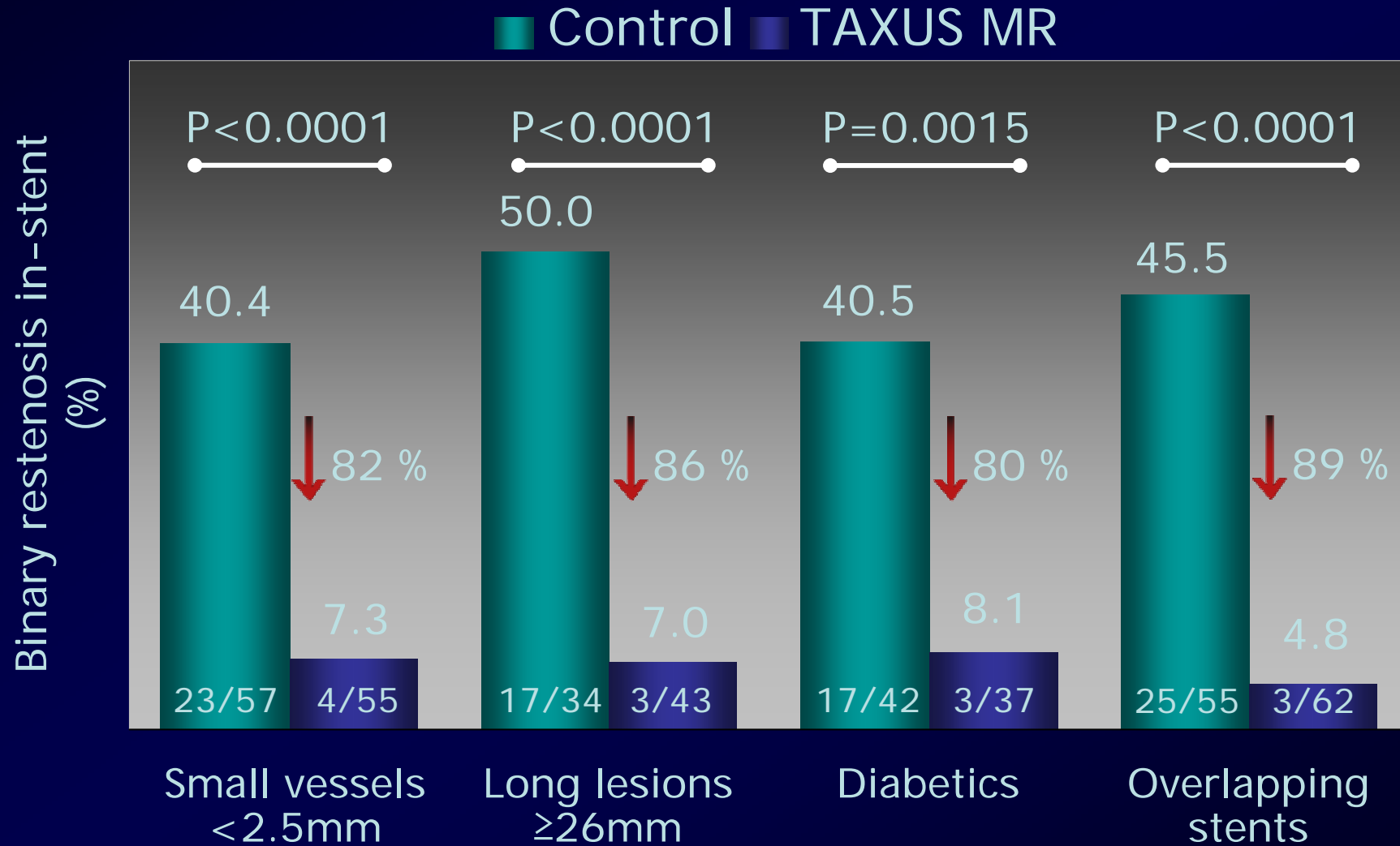


Focal Mild Stenosis



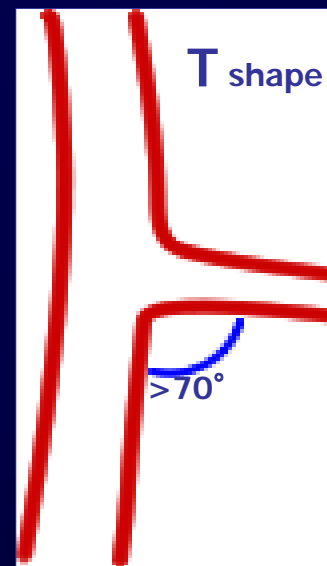
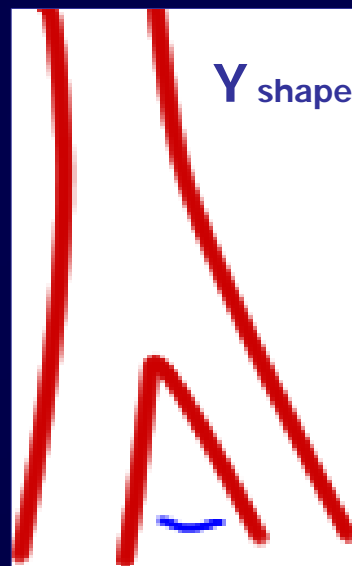
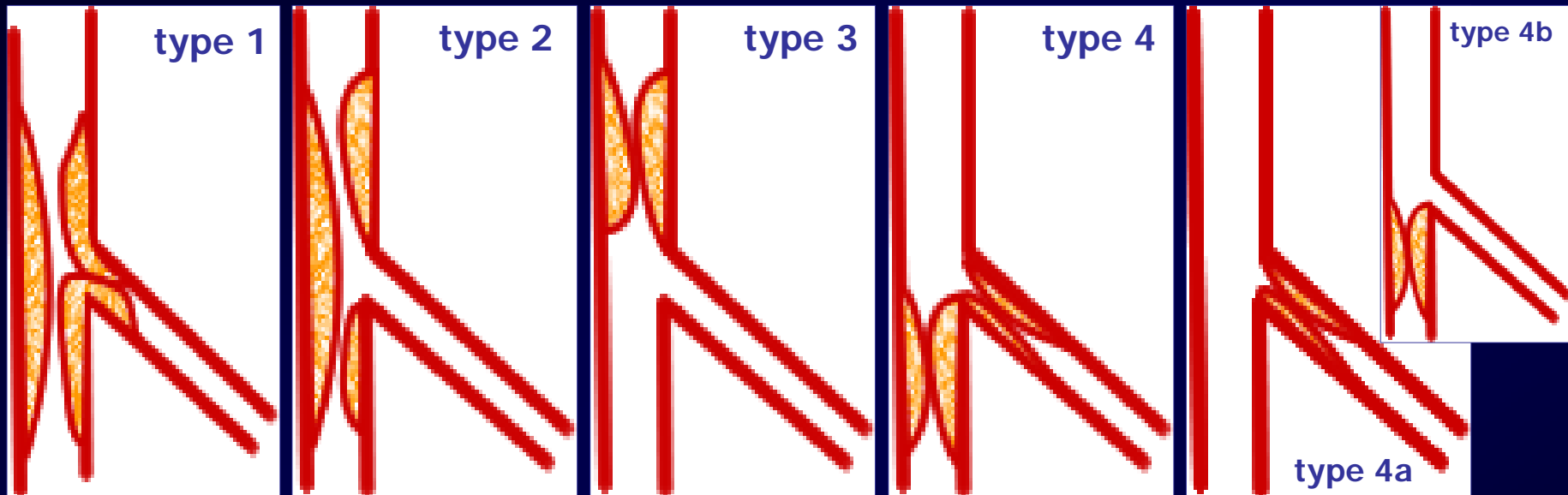
Diffuse

DES in High Risk Lesions TAXUS VI



Bifurcation Lesions

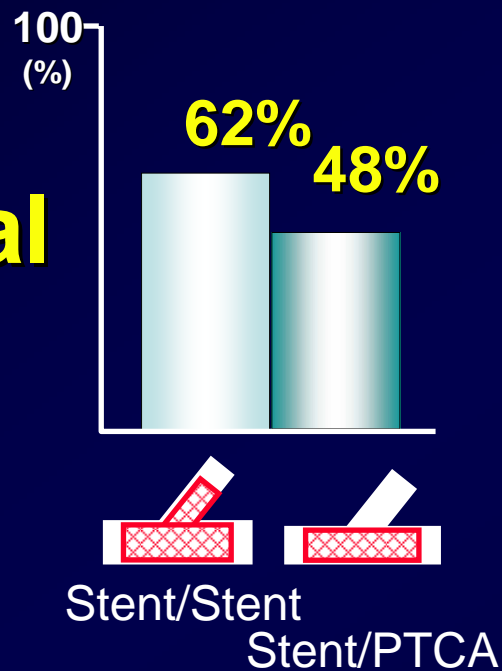
One term – Many variations



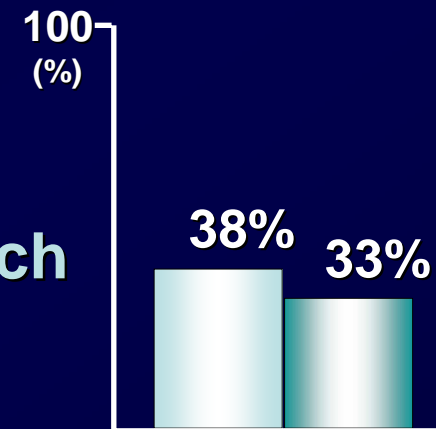
Bifurcation Lesions

Restenosis Rates BMS

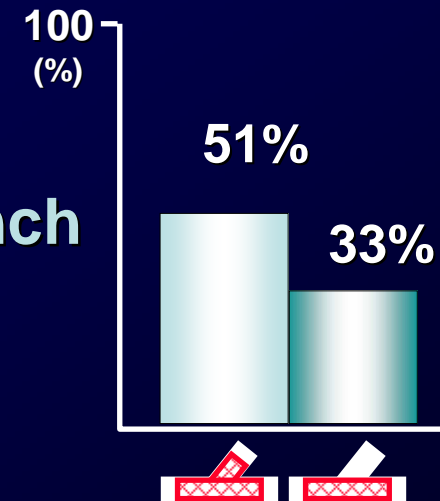
Global



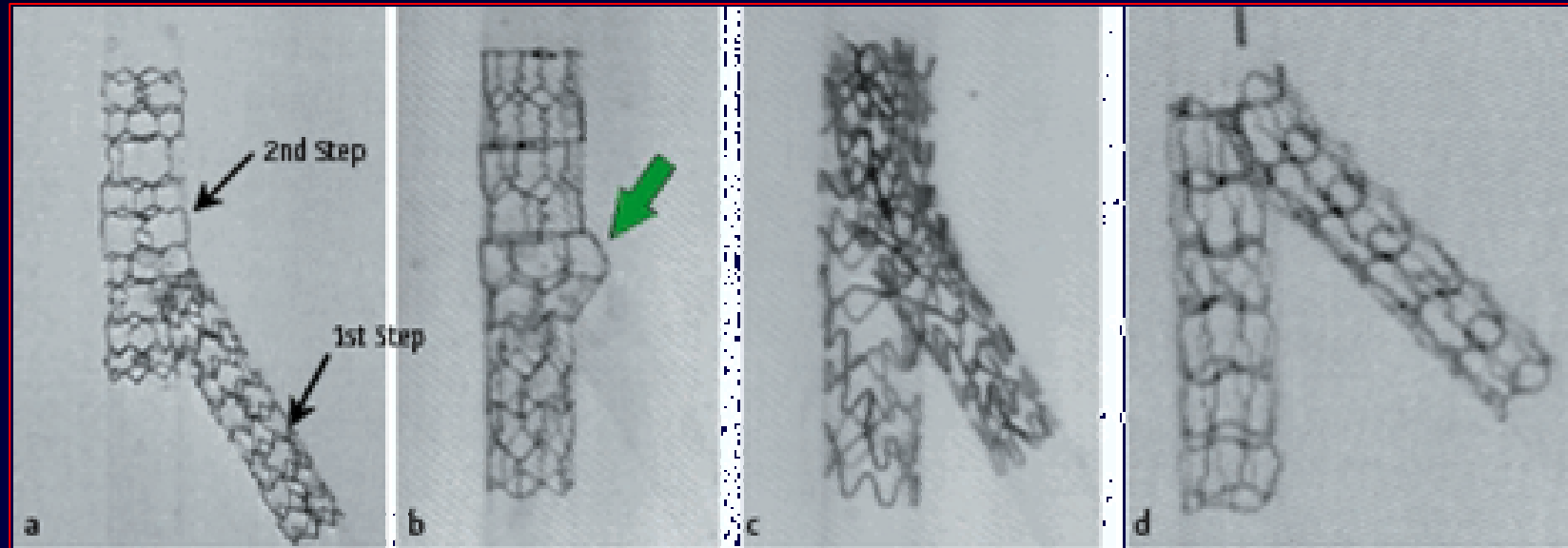
Main Branch



Side Branch



Bifurcation Lesions Specific Techniques

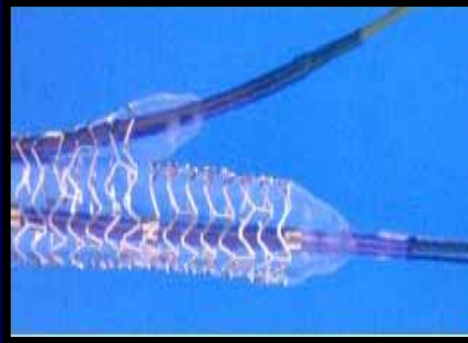


T, V
Provisional T
Coulotte
Kissing
Crush
Reverse/Inverse Crush
Mini-Crush
etc.

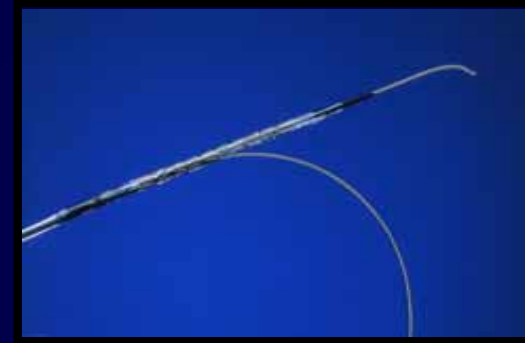
Dedicated Bifurcation Bare Metal Stents



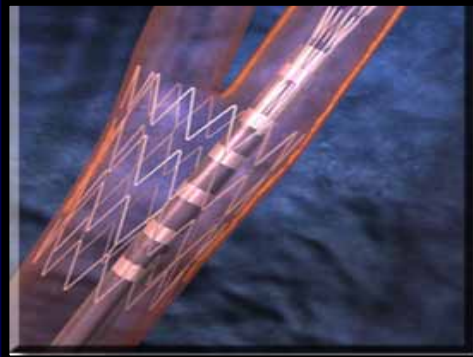
AST petal



Guidant frontier



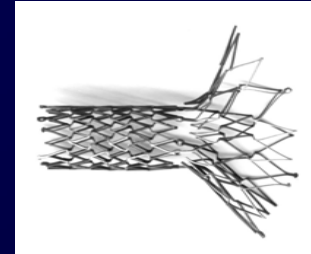
YMed sidekick



Devax



"true" bifurcation designs



sidebranch designs

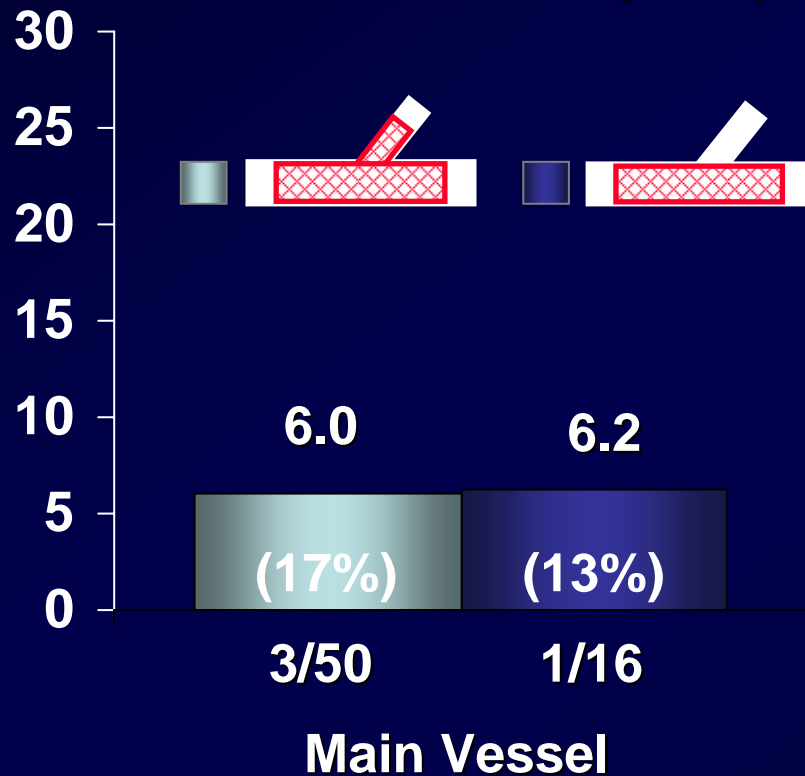


SIRIUS Bifurcation Study

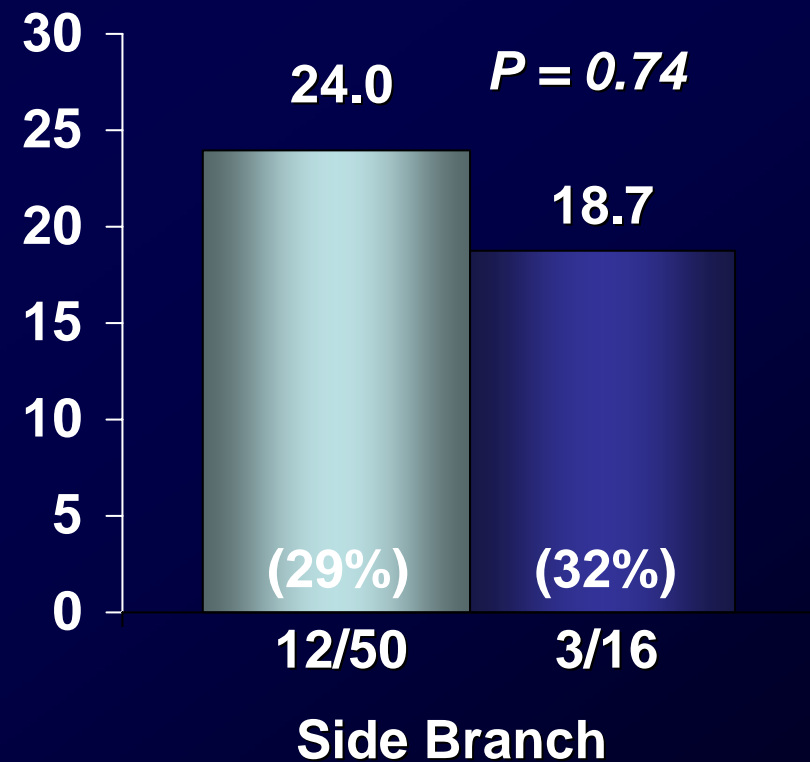
In-lesion Restenosis (treatment received); 78% FU

Total Restenosis (MV and/or SB) 25.7% (17/66)

Total MV 6.1% (4/66)



Total SB 22.7% (15/66)

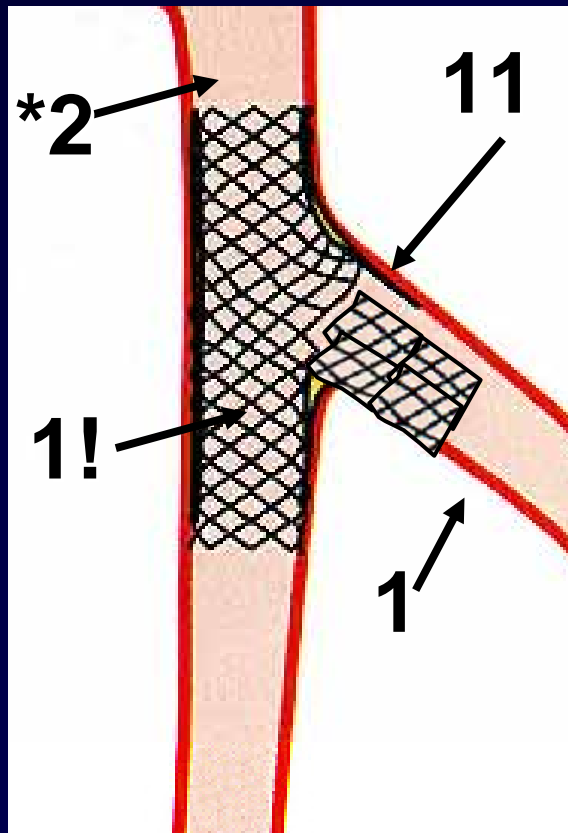


Mean DS% in parentheses

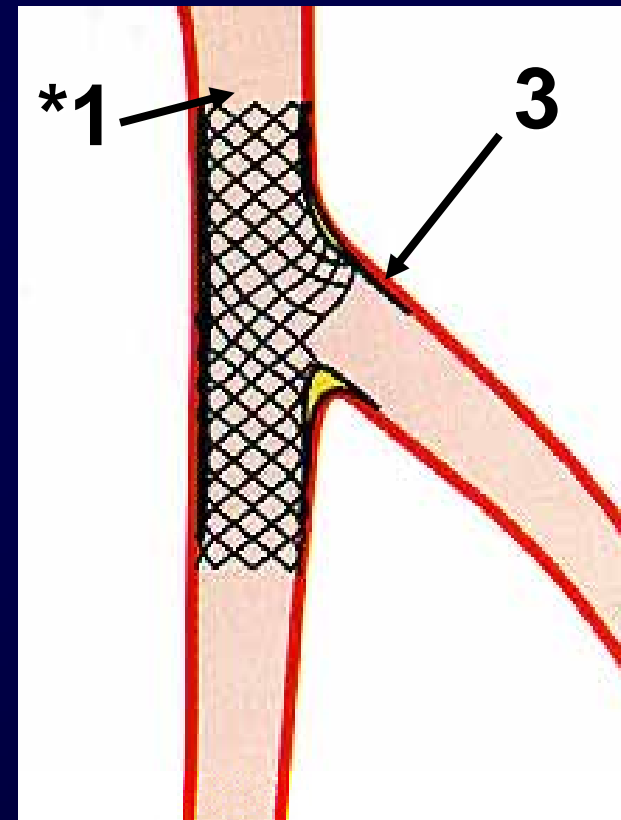
Siegburg

SIRIUS Bifurcation Study Restenosis Site (17 cases)

Stent + Stent

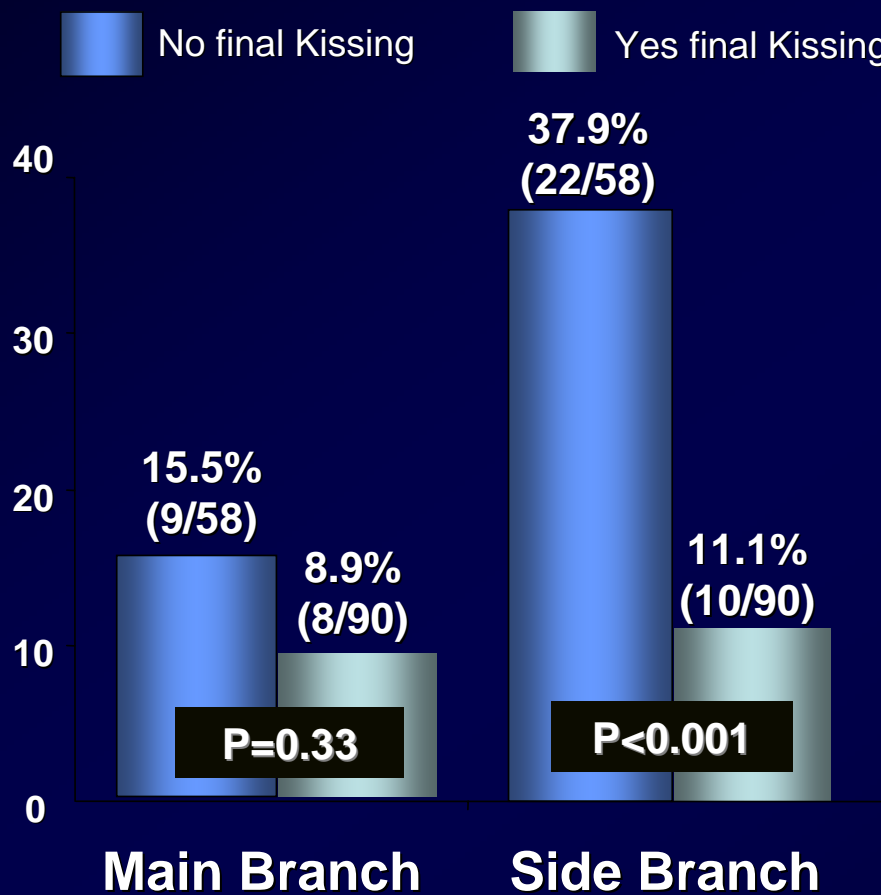


Stent + PTCA

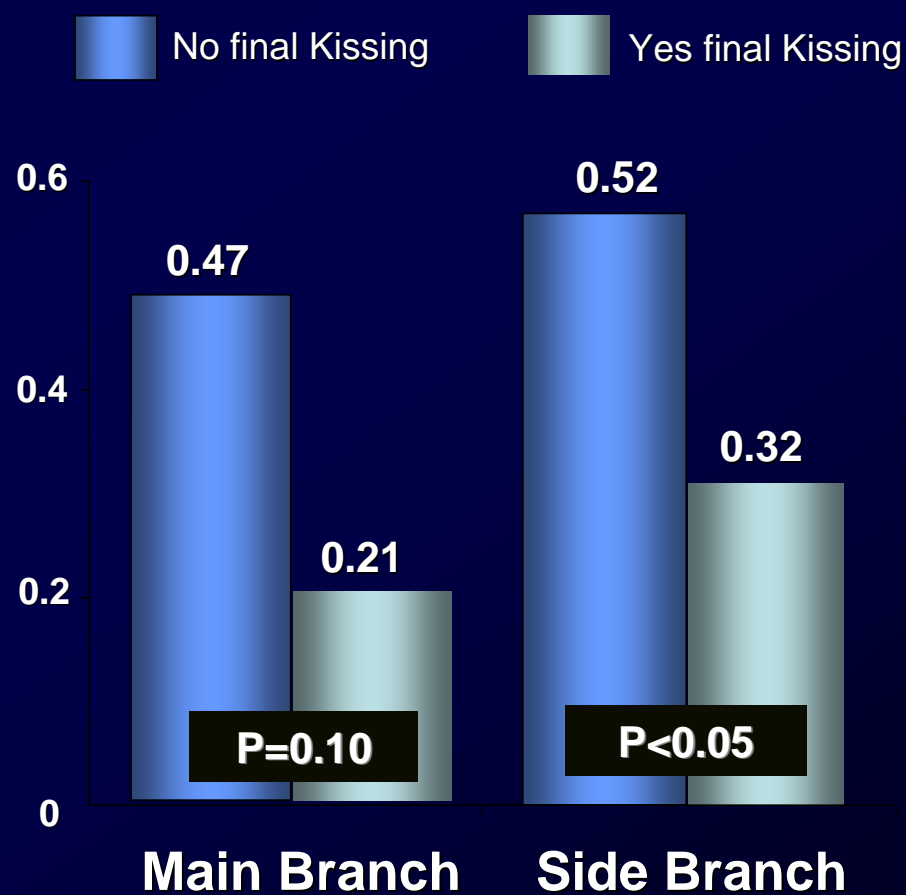


Results with Crush stenting according to performance of final kiss (n=148)

Restenosis Rate (%)



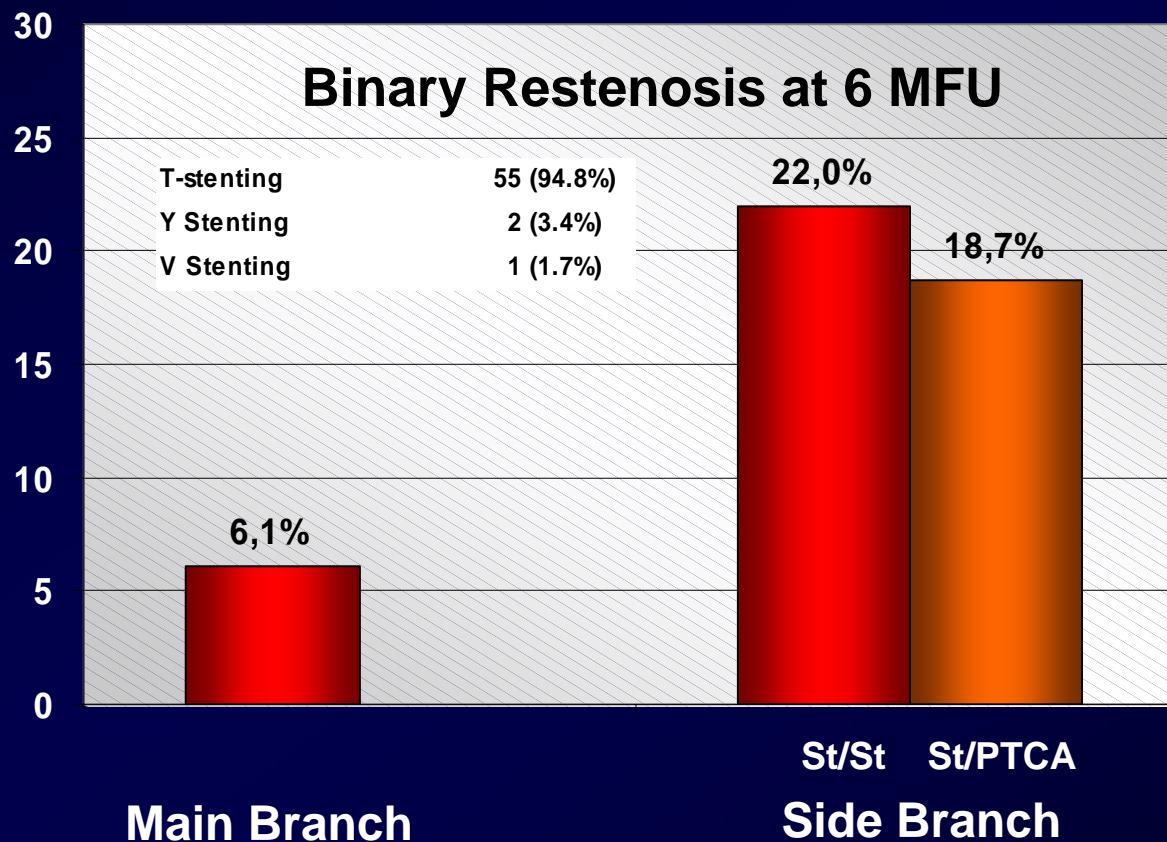
Late Lumen Loss (mm)



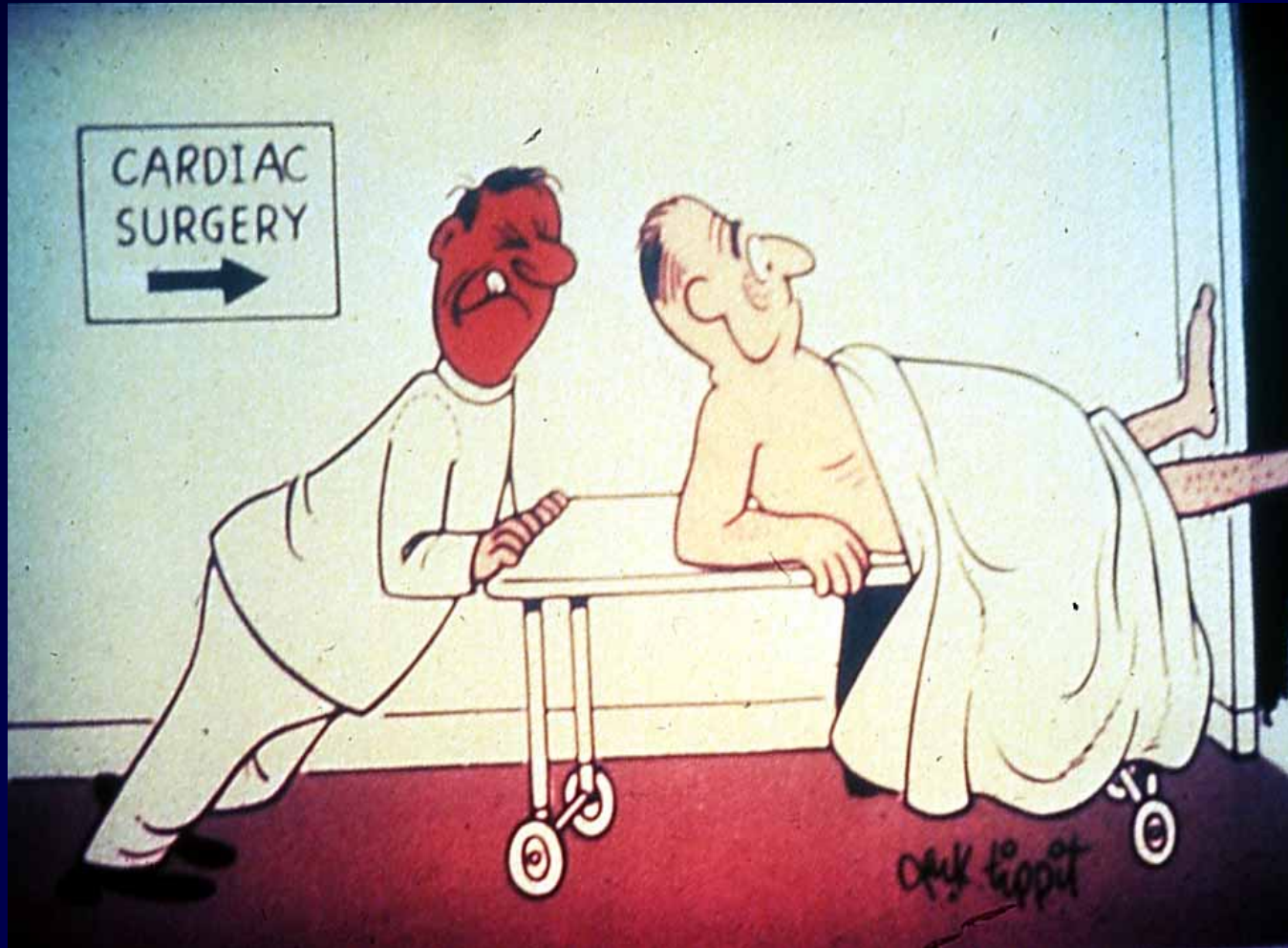
Bifurcation Lesions

Drug Eluting Stents

Colombo A et al. Circulation 2004 16;109(10):1244-9

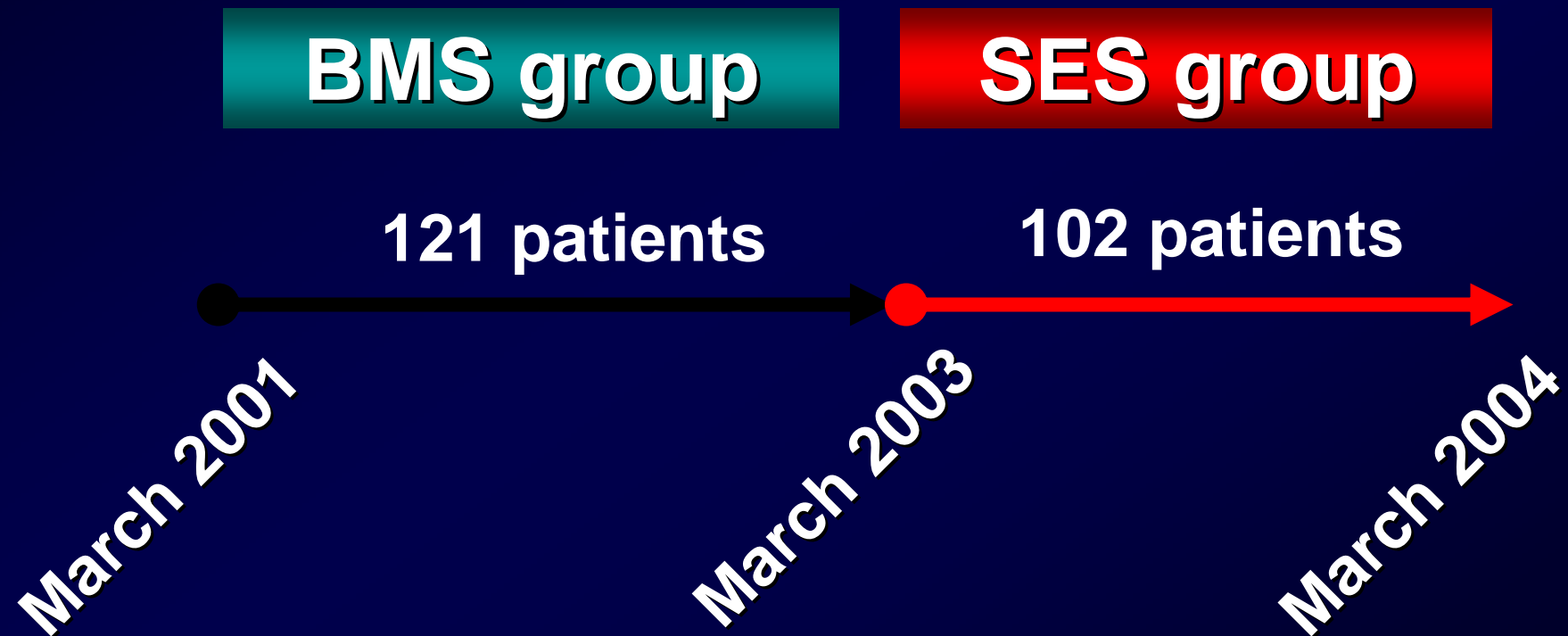


LM PCI: No one likes surgery

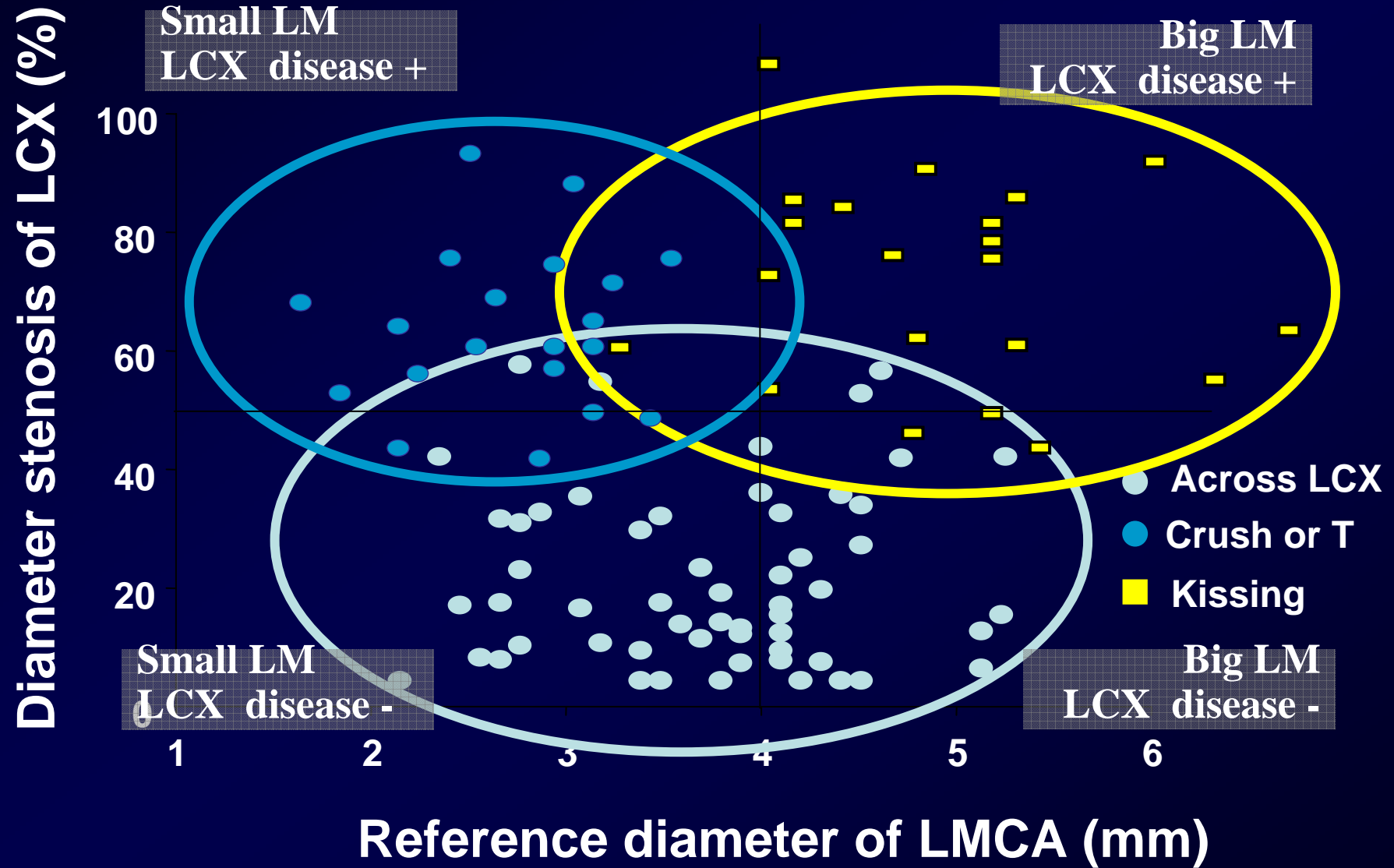


LMCA Stenting in S. Korea

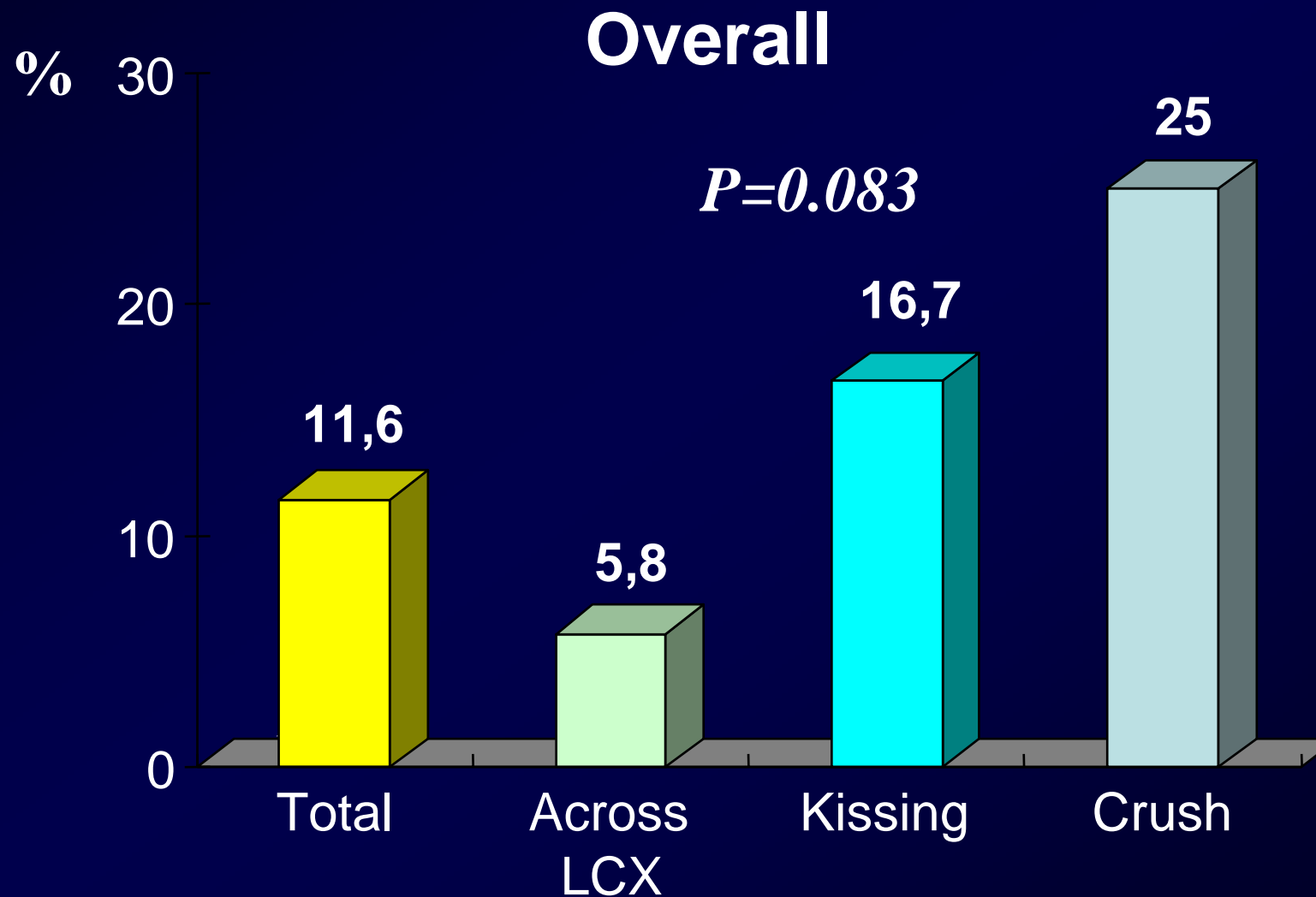
Matched Comparison with BMS



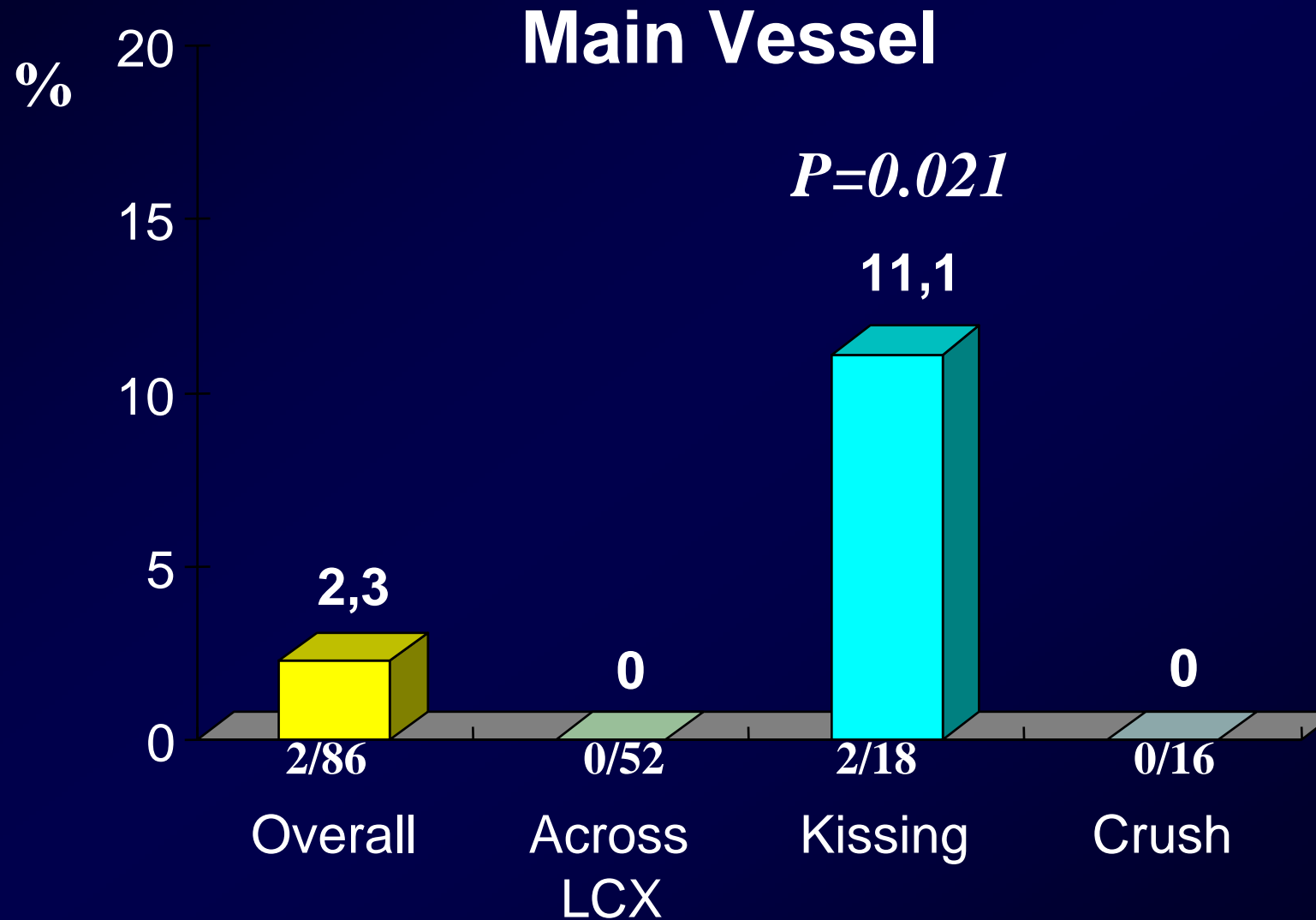
LM-Stenting Techniques



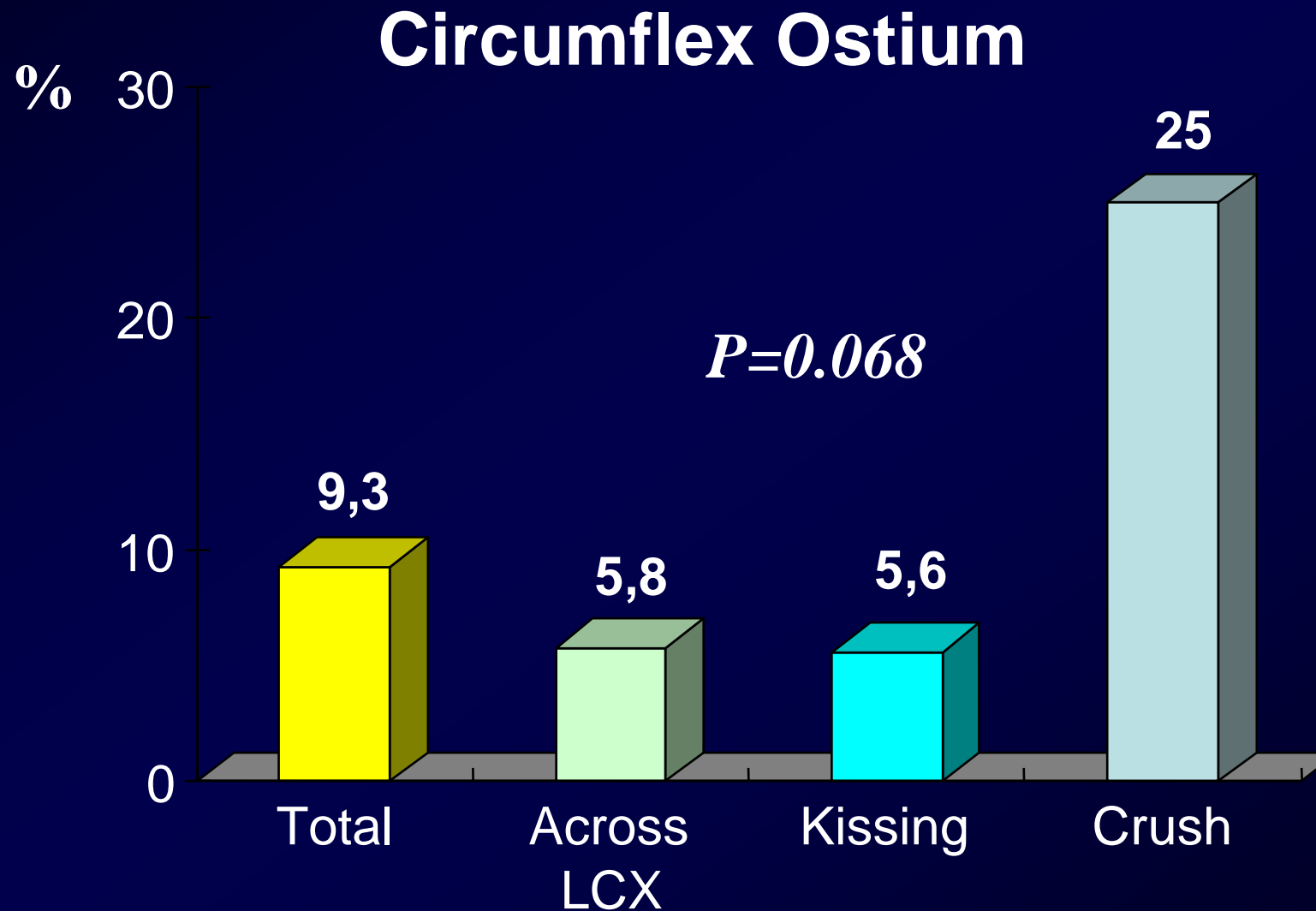
LM-Stenting Restenosis Rates



LM-Stenting Restenosis Rates

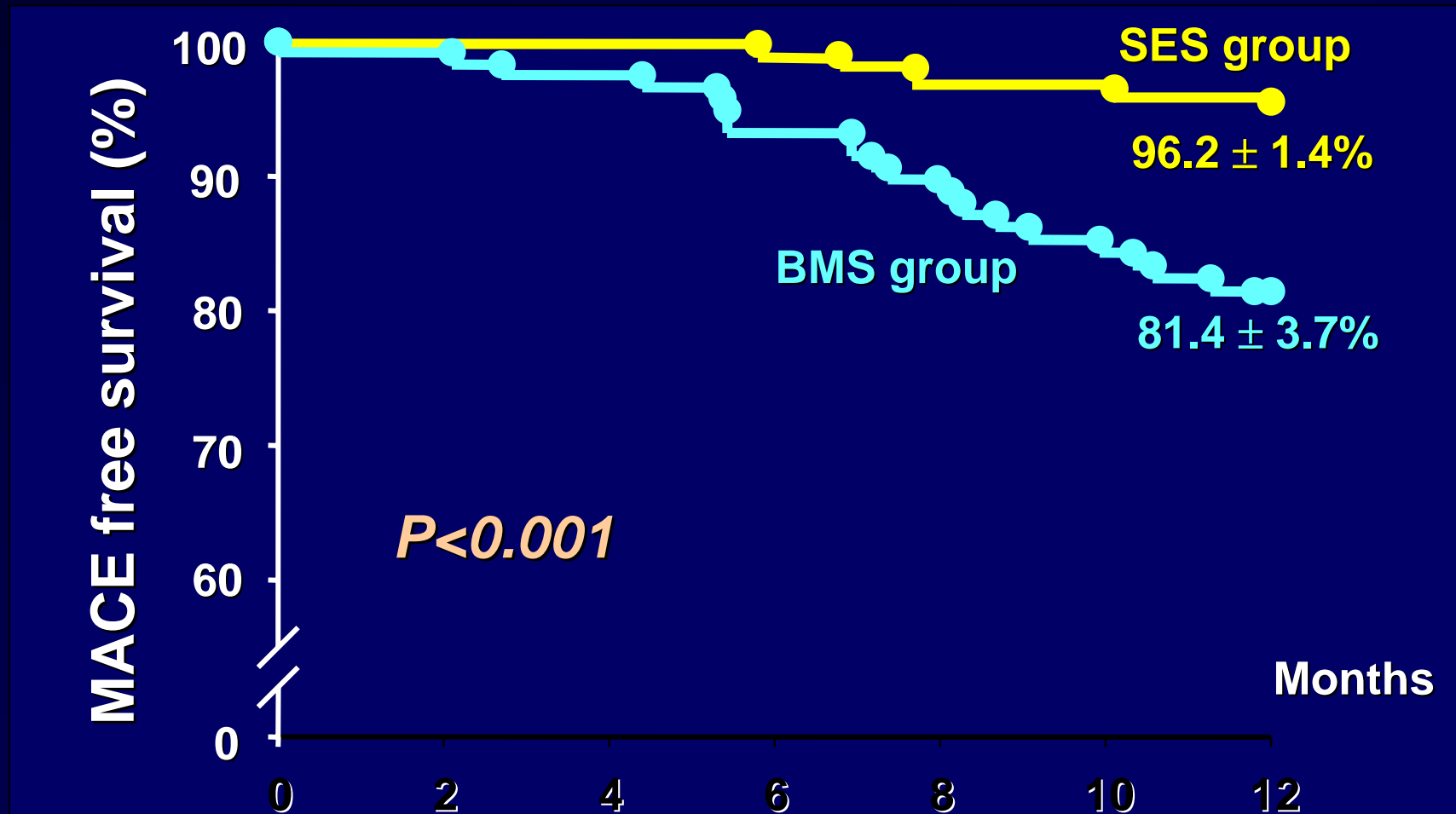


LM-Stenting Restenosis Rates



LMCA Stenting in S. Korea

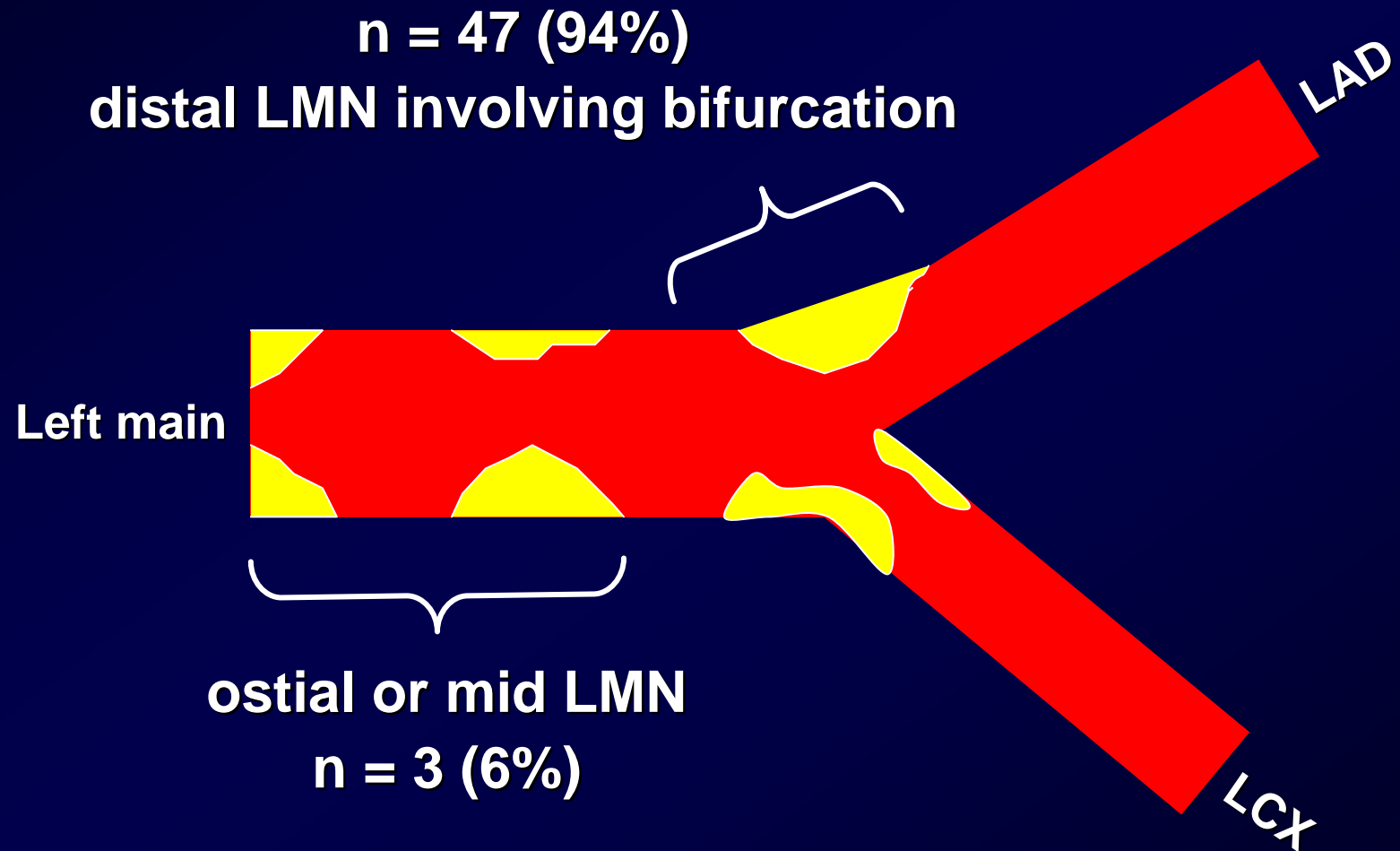
MACE-free Survival at 1 year



Park SJ et al, JACC 2005;45:351

Siegburg

Sirolimus-Eluting Stents for Unprotected Left Main The Scripps Clinic Experience (n = 50)



LM DES at SCRIPPS: Angiographic Restenosis at 9 Mos

QCA performed on 48/50 patients (96%)

Left Main Late-loss (mm) 0.49 + 0.43

Left Main Restenosis 8.3%

	LMN - LAD	Circumflex
In-lesion Late Loss (mm)	0.44 ± 0.68	0.66 ± 0.77
In-stent Late-Loss (mm)	0.48 ± 0.72	0.83 ± 0.89
In-lesion Restenosis	23%	35%

LM DES at SCRIPPS

Distribution of angiographic in-stent restenosis

- Overall, restenosis occurred in 21 patients (44%)
- Only 4 pts (8%) had restenosis within the LMCA itself
- Restenosis was focal (Mehran class I) in 85%

Site	N = 21
LMCA (N, %)	4 (19%)
LAD ostium only	2 (9.5%)
LCX ostium only	10 (48%)
Both LAD, LCX ostia	5 (24%)

LM DES at SCRIPPS

In-hospital Outcomes

	(N=50)
Death	0
MI	4 (8%)
Non-Q-Wave	3 (6%)
Q-Wave	1 (2%)
Acute thrombosis	2 (4%)
TLR	3 (6%)
Death, any MI, TLR, or thrombosis	5 (10%)

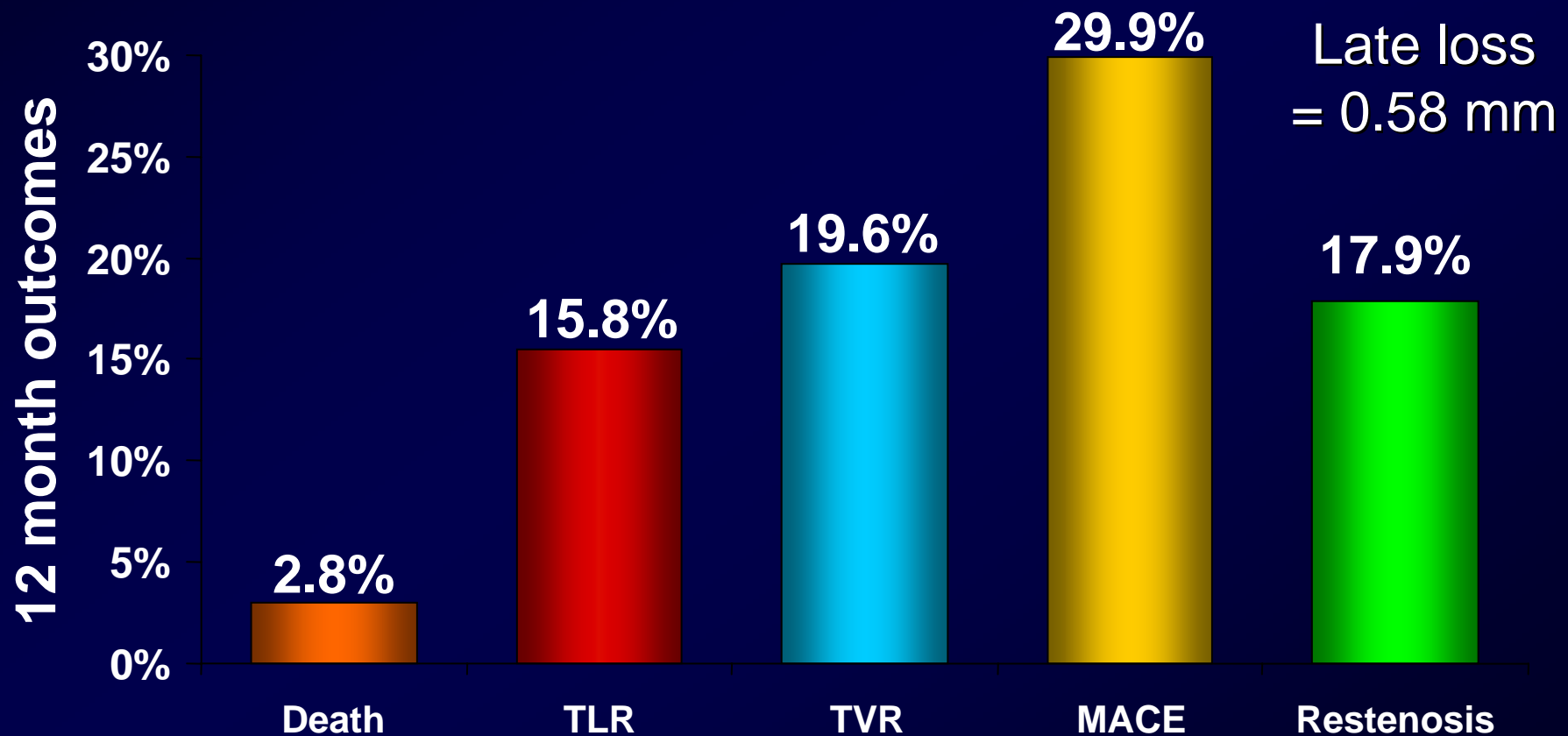
LM DES at SCRIPPS: Clinical Outcomes at 9 mos

Events	(n=50)
Death	5 (10%)
Cardiac death	1 (2%)
Non-cardiac death	4 (8%)
Sub-acute Thrombosis	0
MI	1 (2%)
TLR	19 (38%)
TLR – ischemia driven	7 (14%)
Death, any MI, any TLR	22 (44%)

→ 12/19 pts with TLR (63%) were asymptomatic

Unprotected Left Main Milan DES Experience at 1 Year (n=107)

Distal bifurcation 73%; 51% Cypher, 48% TAXUS; 39% crush,
19% V stent; 73% sidebranch Rx; 70% final kiss

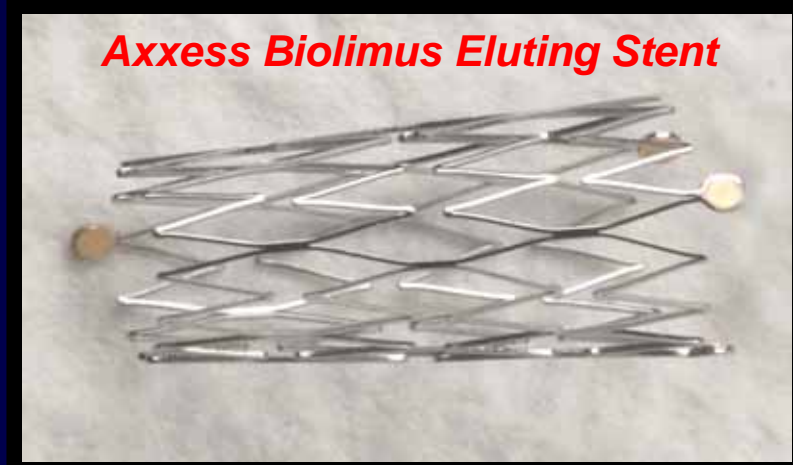


Lesion Specific DES Concept

Axxess Bifurcation Stent System

- Stent: Self expanding nickel-titanium (Nitinol) alloy
- Drug: *Biolimus A9™*
- Dose: 22 ug/mm stent length
- Drug carrier: Bioabsorbable PLA polymer
- Delivery: covered sheath RX delivery catheter

Axxess Biolimus Eluting Stent



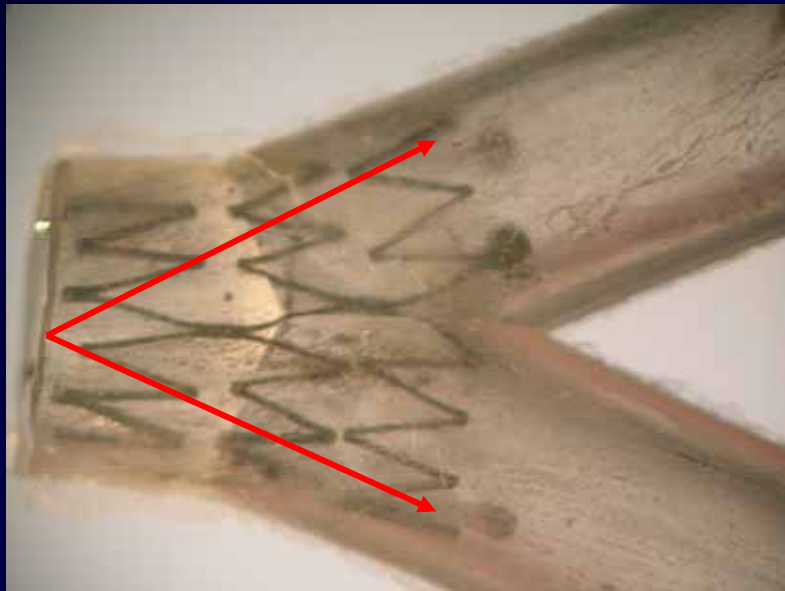
Rapid Exchange Delivery System



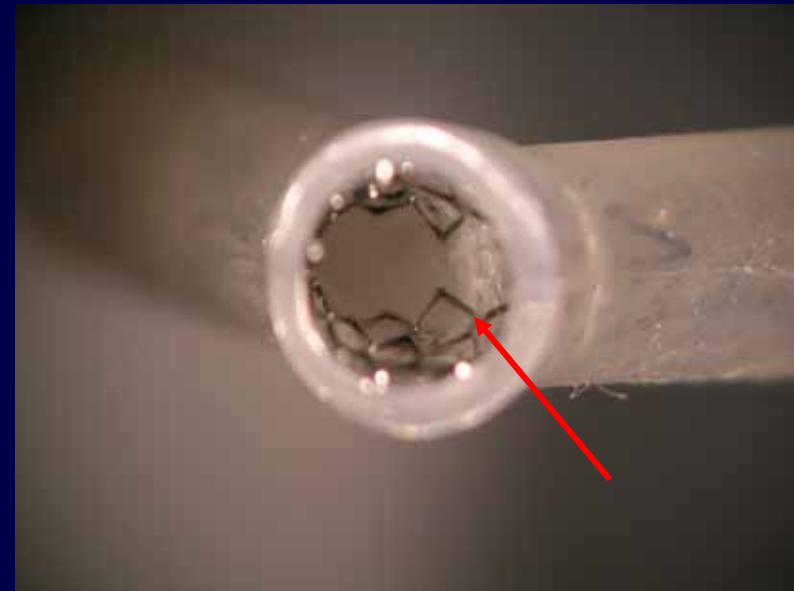
 **DEVAX** INC.

Siegburg

Complete Ostial Coverage

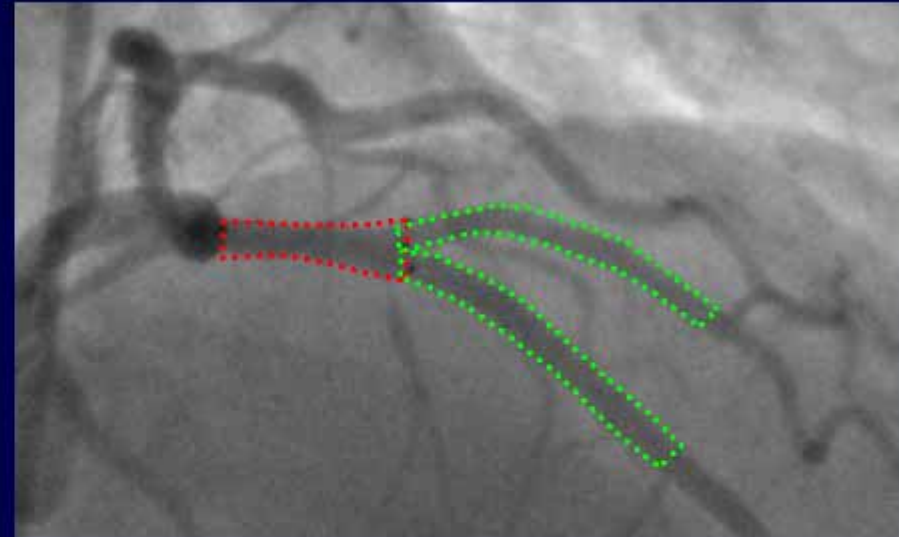
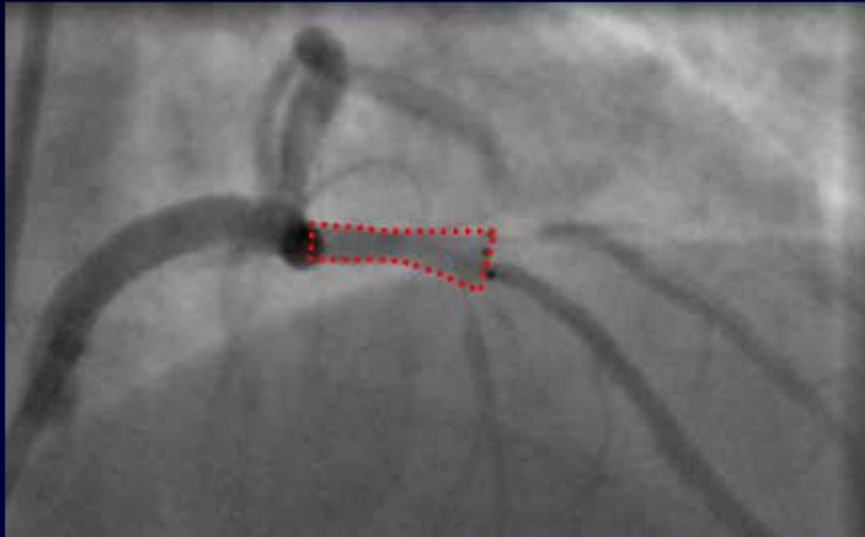


Stent flares to cover ostia of
Both branching vessels



Carina area is covered
By stent struts

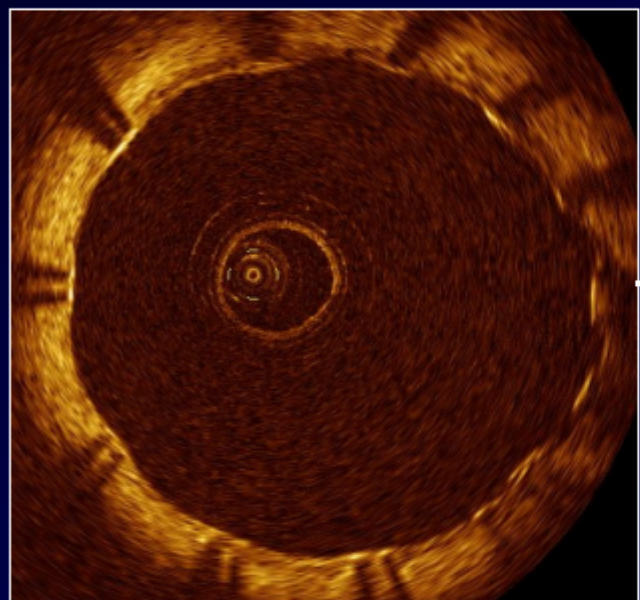
Therapeutic Concept



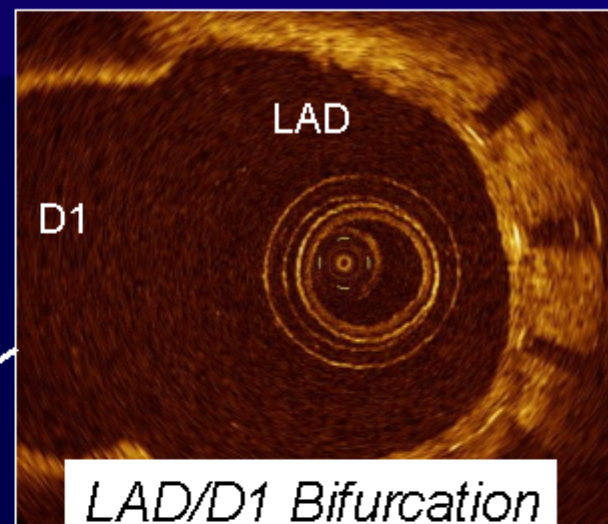
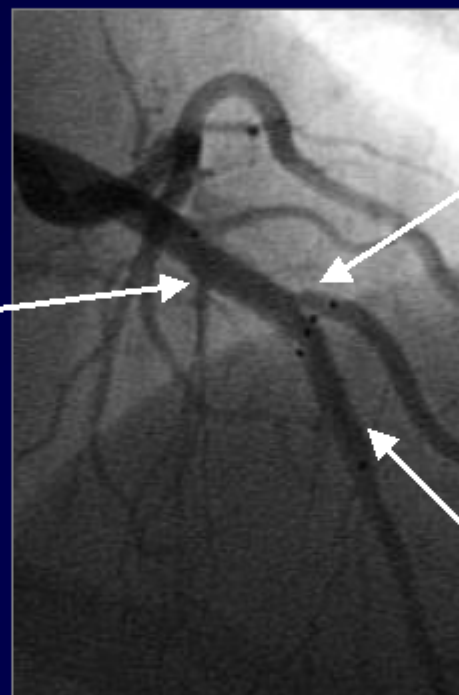
The concept of the Axxess Plus system:

- Implant a stent with the appropriate shape to treat the troublesome anatomy of the bifurcation, then
- Provisionally add subsequent stents to cover the lesion as needed stent “end to end”, rather than “through the side”

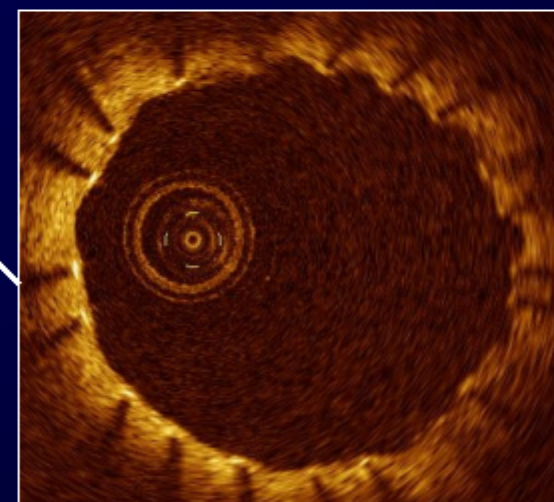
ACCESS Plus Follow-up with Optical Coherence Tomography



Bifurc Devax in prox LAD



LAD/D1 Bifurcation



'Straight' Devax in mid LAD

6 mths follow-up

Grube E, Buellesfeld L et al.

Siegburg / Stanford

AXXESS PLUS

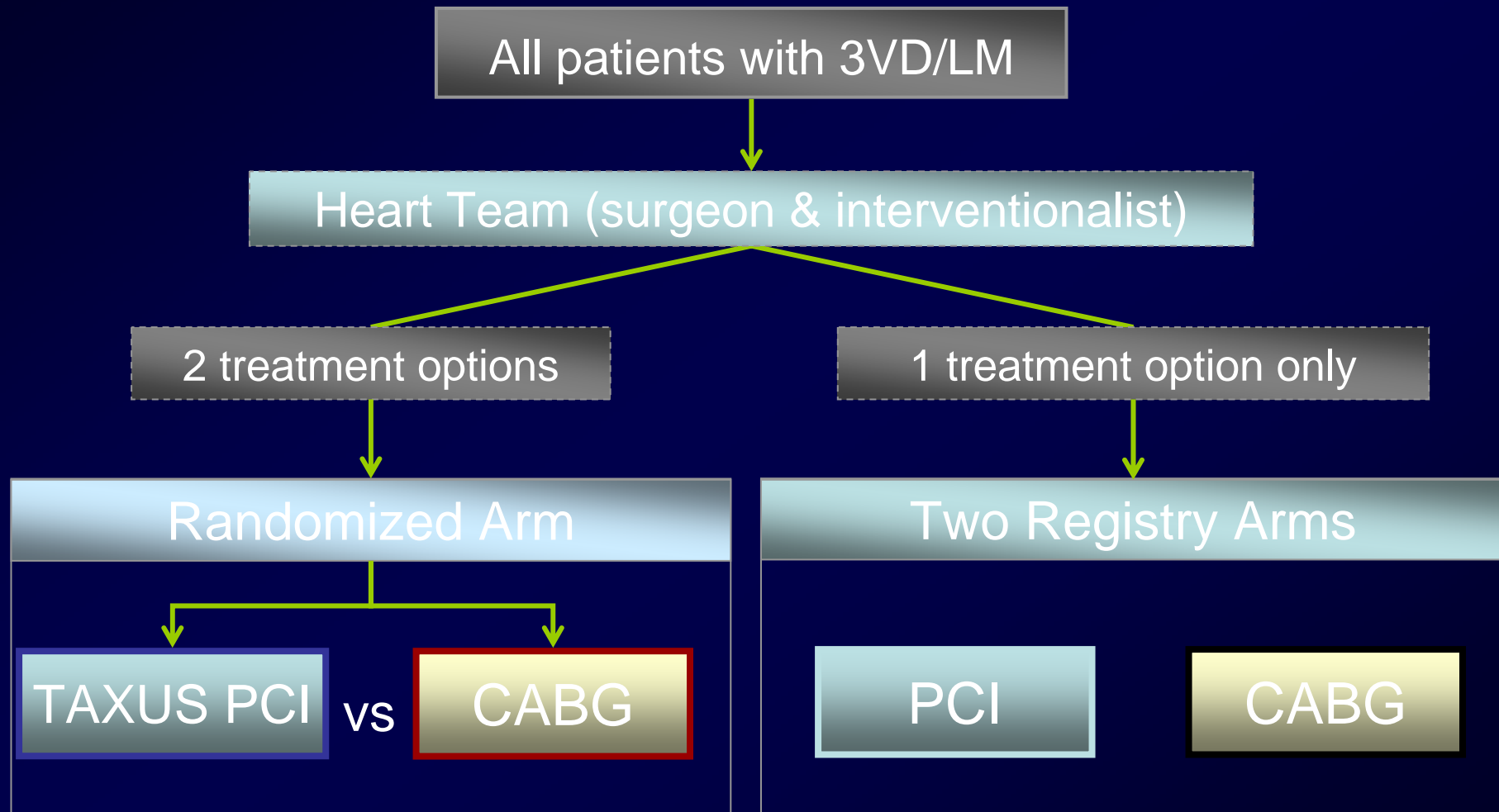
Results

Angiographic Follow Up	124/136 (91.2%)
Binary Restenosis	
- Axxess Plus only	4.0%
- All stents (Axxess + distal DES)	5.6%
- In segment	10.5%

	Axxess Plus	Control	<i>p</i>
Angiographic Late Loss	0.11 ± 0.62 mm	0.46 ± 0.51 mm	0.002

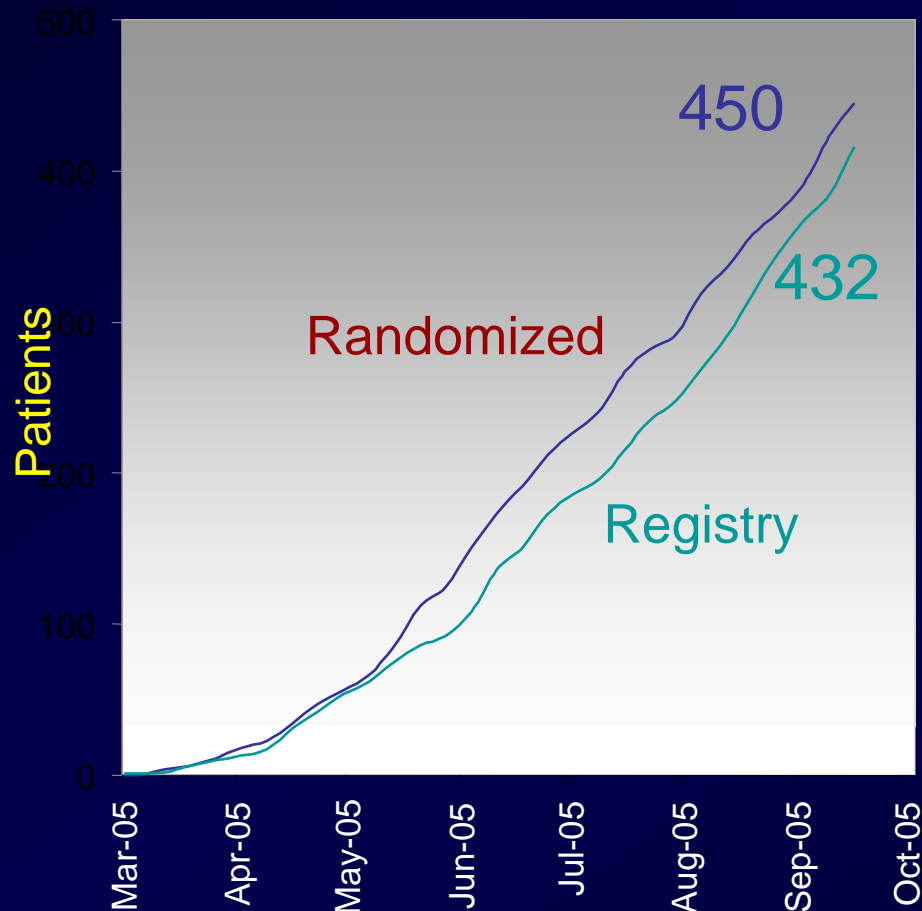
SYNTAX

TAXUS vs. CABG bei LM-Stenosen / Mehrgefäß-Erkrankung



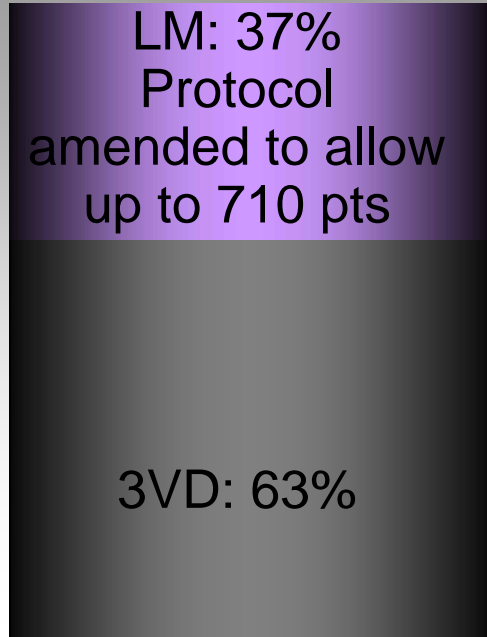
SYNTAX Study – Current Status

SYNTAX enrollment status



Left main enrollment exceeds expectations

% of Randomized

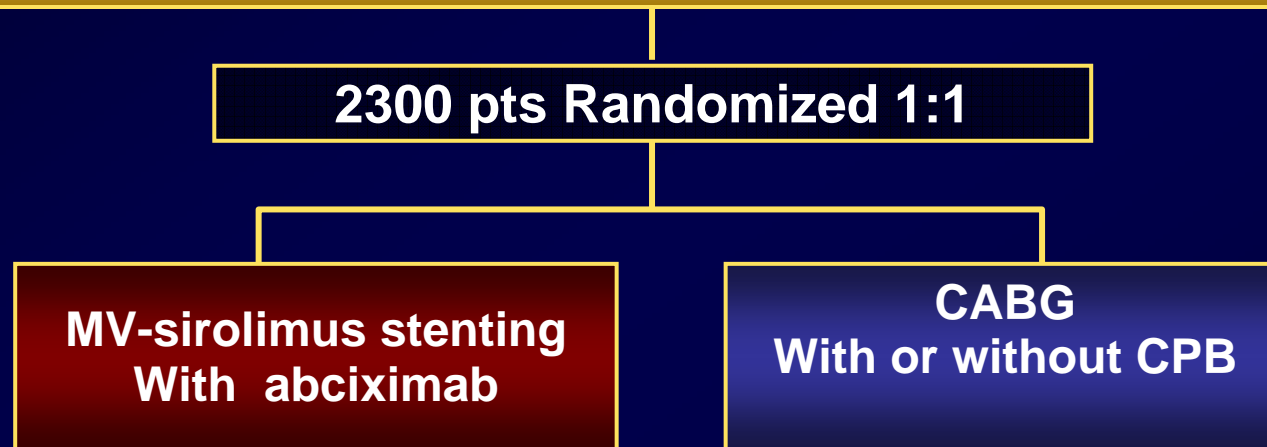


Actual

FREEDOM Trial

Multivessel Sirolimus Stenting vs. CABG in Diabetics

Eligibility: DM patients with MV-CAD eligible for stent or surgery
Exclude: Patients with acute MI and/or cardiogenic shock



*All concomitant Meds shown to be beneficial are encouraged, including:
Plavix, ACE inhibitors, b-blockers, statins, etc.*

1° Endpoint: 5-year mortality 5-year MACE
2° Endpoint : MACE/stroke at 12 months