

PCI for Bifurcations: Techniques and Outcomes

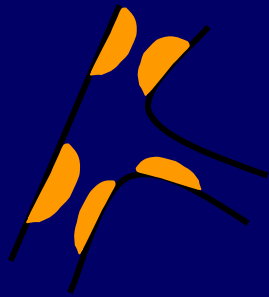
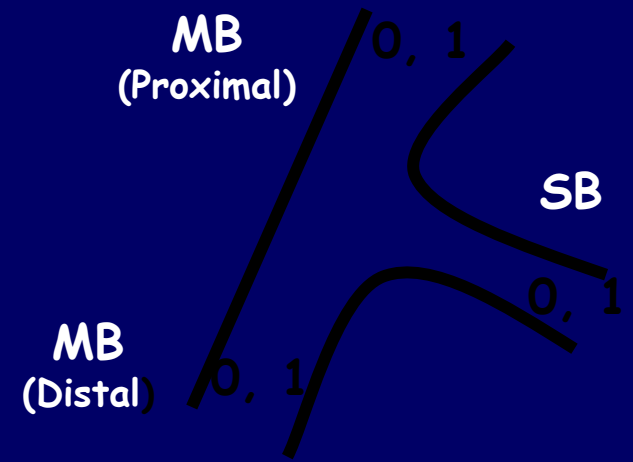
**Fellows Workshop
June 2014**

Chris Zambakides

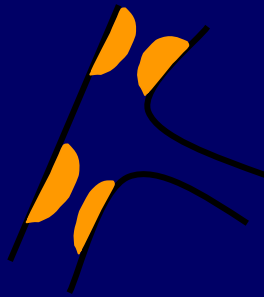
Bifurcation PCI

- **Account for 15-20% of PCI**
- **Why an individualized approach?**
 - **Variations in Anatomy**
 - Left main bifurcation disease
 - Plaque burden & location of plaque
 - Angle between MB and SB
 - **Dynamic changes in anatomy during treatment**
 - Plaque shift
 - Dissection
- **No two bifurcations are identical**
- **An appropriate strategy from the outset saves time and minimizes complication**

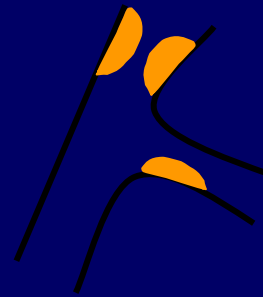
Medina Classification



1,1,1



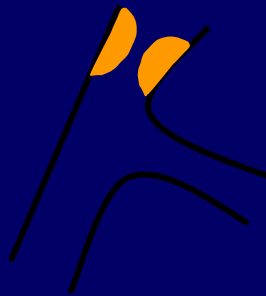
1,1,0



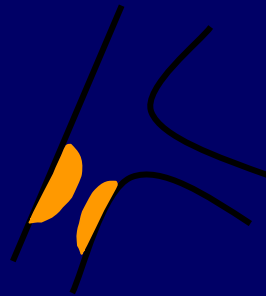
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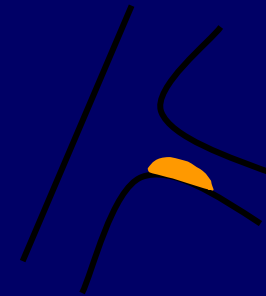
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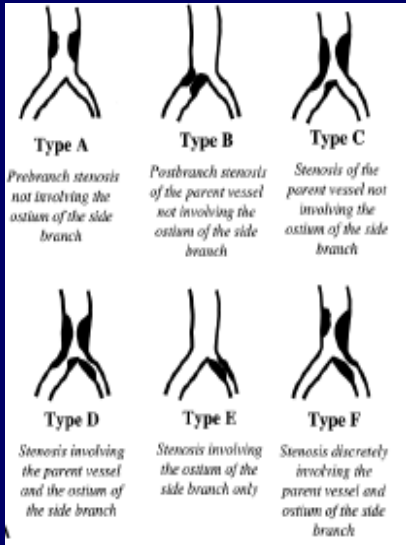


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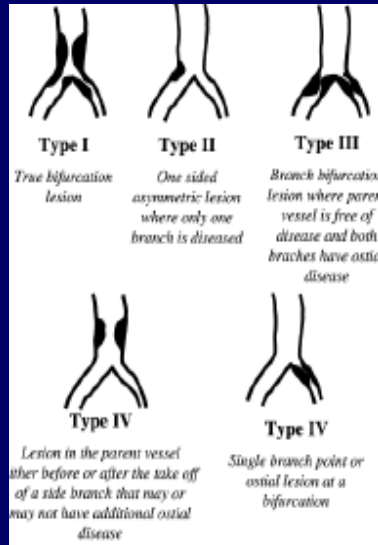


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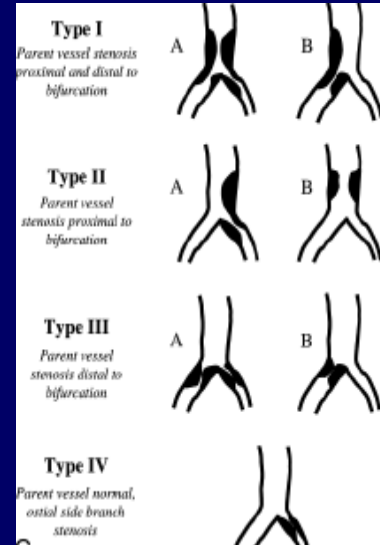
Classifications of lesions



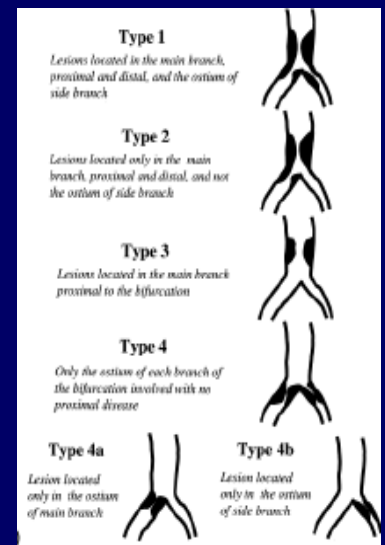
Duke



Sanborn

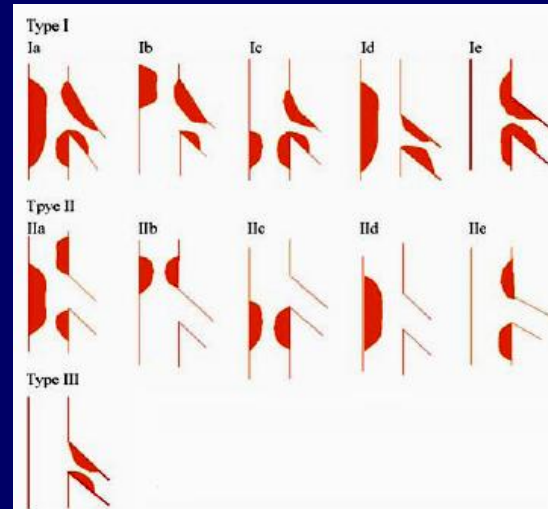
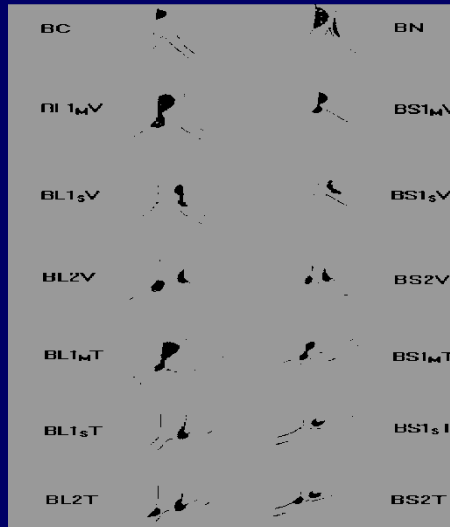


Safian



Icps-Lefevre

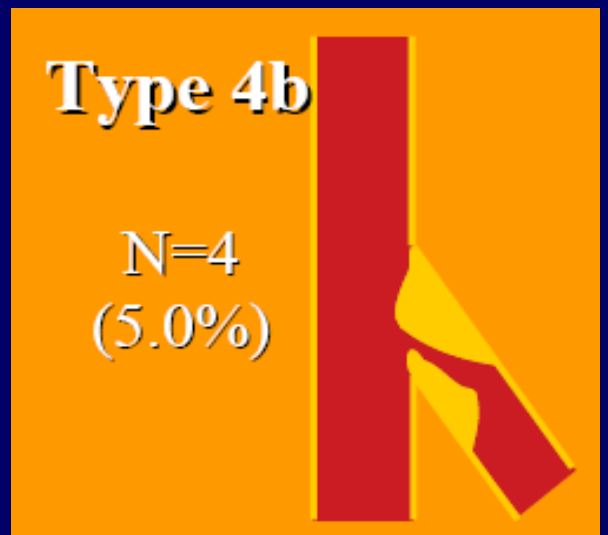
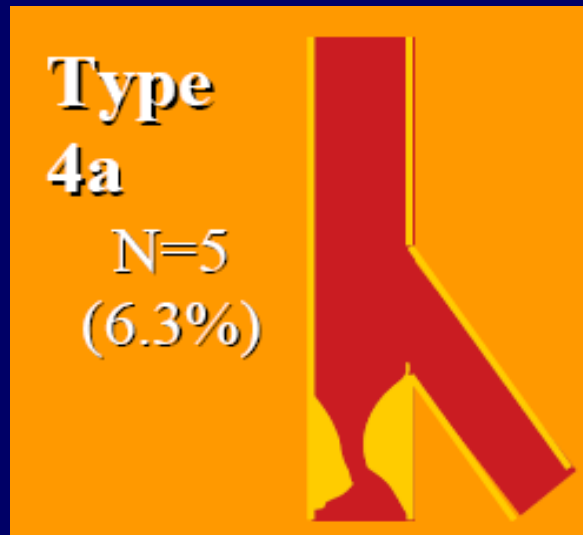
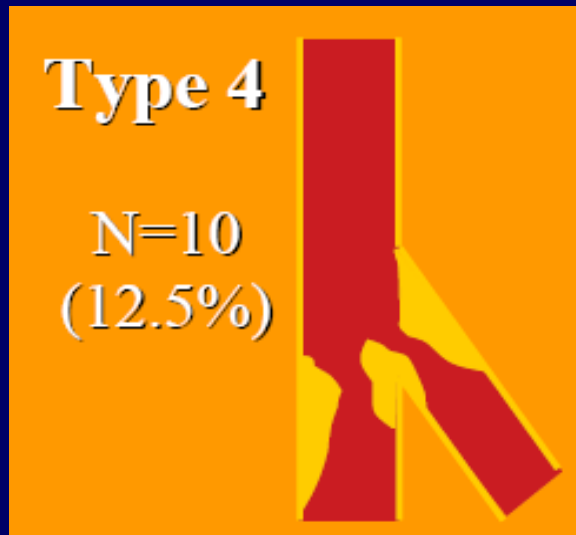
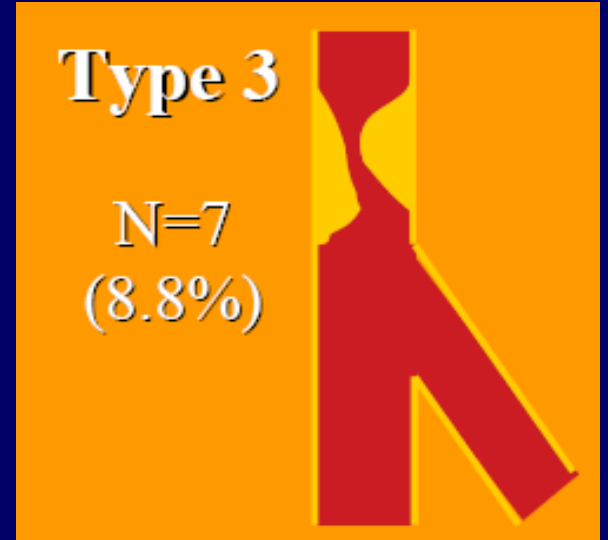
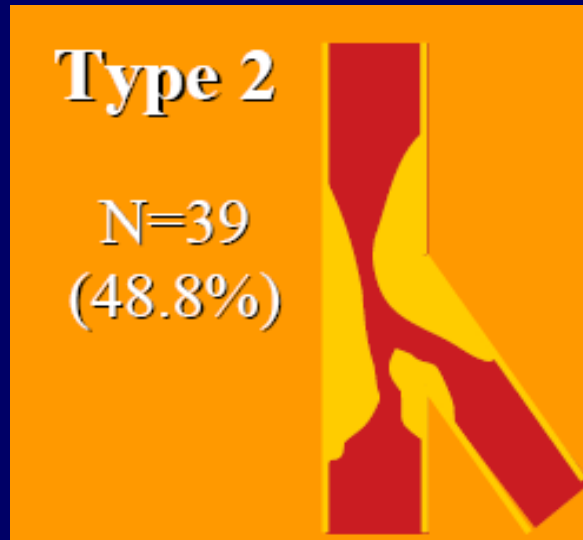
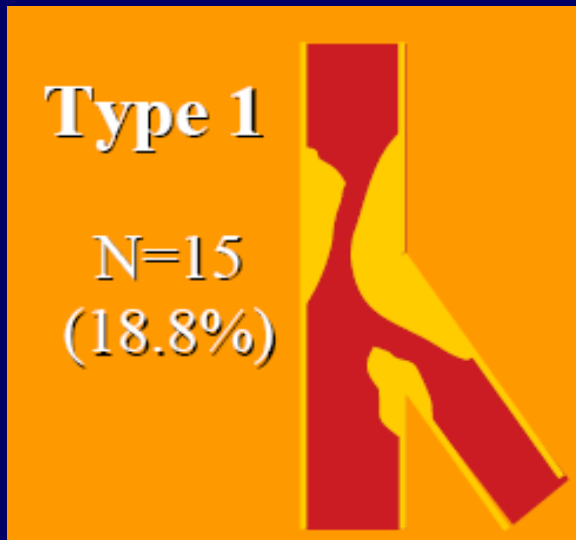
Movahed



Chen - Gao

Bifurcation Stenting: Diverse Lesion Profile

- * Type 1 and 2 most difficult to treat comprise nearly 70% of lesions
- * Only Type 3 Requires Single Stent



The Approach to Bifurcation PCI

- **The provisional approach of implanting one stent in the MB should be the default approach in most bifurcations lesions**
- **The approach is dictated by the SB:**
 - True vs. Non-true
 - Size of SB
 - Extent and distribution of disease in SB
 - How important the side branch is for that patient and for that specific anatomy
 - Angle from the main branch

Randomized Bifurcation Trials

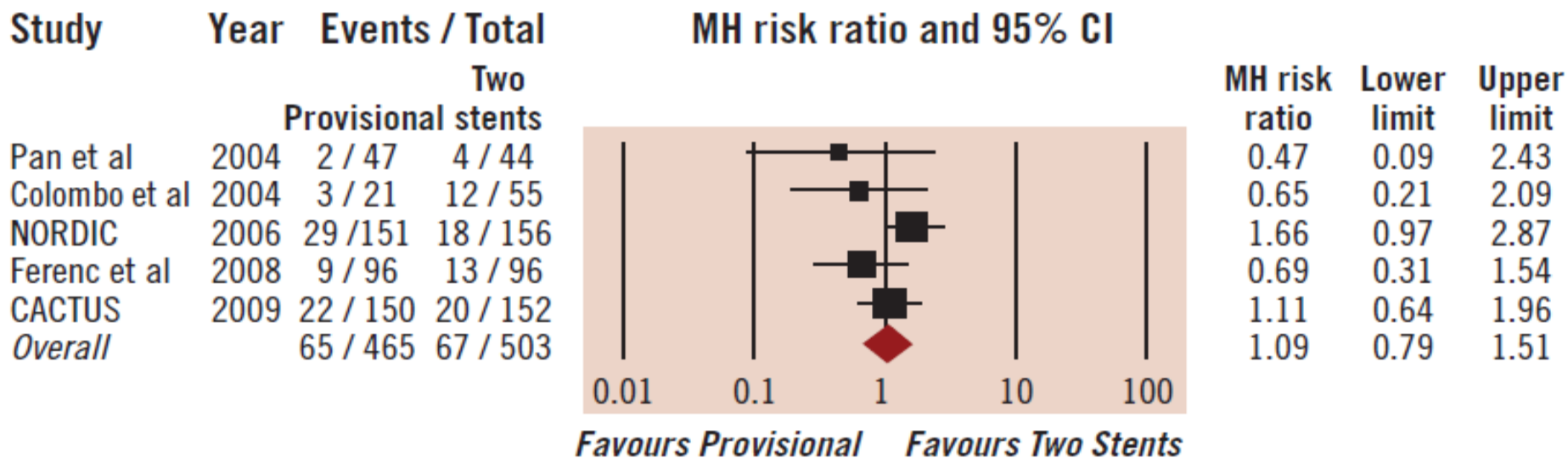
| | Patients (N) | Randomization | Primary End Point | Outcome (Provisional vs Systematic Unless Otherwise Specified) |
|----------------|--------------|---|--|--|
| NORDIC | 413 | Provisional vs systematic (crush, culotte, T) | Death, MI (nonprocedural), TVR, or stent thrombosis at 6 mo | 2.9% vs 3.4% (P=NS) |
| CACTUS | 350 | Provisional vs systematic (crush) | Death, MI, TVR at 6 mo | 15% vs 15.8% (P=NS) |
| BBC ONE | 500 | Provisional vs systematic (crush, culotte) | Death, MI, TVF at 9 mo | 8.0% vs 15.2% (P<0.05) |
| Ference et al. | 202 | Provisional vs systematic (T) | Death, MI, TVF at 9 mo Angiographic restenosis (side branch) 9 mo | 23.0% vs 27.7% (P=NS) |
| Colombo et al. | 85 | Provisional vs systematic (crush, T, culotte) | Angiographic restenosis (either branch) 6 mo | 18.7% vs 28.0% (P=NS) |
| Pan et al. | 91 | Provisional vs systematic (T) | Angiographic restenosis (either branch) 6 mo | 7% vs 25% (P=NS) |
| NORDIC 2 | 424 | Systematic (crush vs culotte) | Death, MI (nonprocedural), TVR, or stent thrombosis at 6 mo | Crush 4.3% vs culotte 3.7% (P=NS) |

Meta-Analysis - Bifurcations with DES One (Provisional) vs Two Stents

Side Branch Restenosis

Angiographic outcome -> No difference

E Side branch restenosis



Test for heterogeneity: $Q=5.3, df=4, P=0.26, I^2=25\%$
 Test for overall effect: $Z=-0.53, P=0.60$

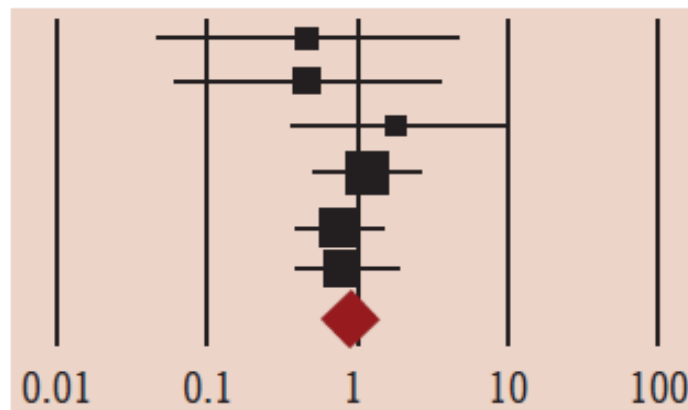
Fixed Effects Model

Meta-Analysis - Bifurcations with DES One (Provisional) vs Two Stents

TLR

Clinical outcome -> No difference

| Study | Year | Events / Total | | MH risk ratio and 95% CI | Statistics for each study | | |
|----------------|------|--------------------|----------|--------------------------|---------------------------|-------------|-------------|
| | | Provisional stents | Two | | MH risk ratio | Lower limit | Upper limit |
| Pan et al | 2004 | 1 / 47 | 2 / 44 | | 0.47 | 0.04 | 4.98 |
| Colombo et al | 2004 | 1 / 22 | 6 / 63 | | 0.48 | 0.06 | 3.75 |
| NORDIC | 2006 | 4 / 207 | 2 / 206 | | 1.99 | 0.37 | 10.75 |
| Ferenc et al | 2008 | 11 / 101 | 9 / 101 | | 1.22 | 0.53 | 2.82 |
| BBC ONE | 2008 | 14 / 250 | 18 / 250 | | 0.78 | 0.40 | 1.53 |
| CACTUS | 2009 | 11 / 173 | 13 / 177 | | 0.87 | 0.40 | 1.88 |
| <i>Overall</i> | | 42 / 800 | 50 / 841 | | 0.91 | 0.61 | 1.35 |



Favours Provisional Favours Two Stents

Test for heterogeneity: $Q=2.2$, $df=5$, $P=0.82$ $I^2=0\%$
Test for overall effect: $Z=-0.49$, $P=0.63$

Fixed Effects Model

Meta-Analysis - Bifurcations with DES One (Provisional) vs Two Stents

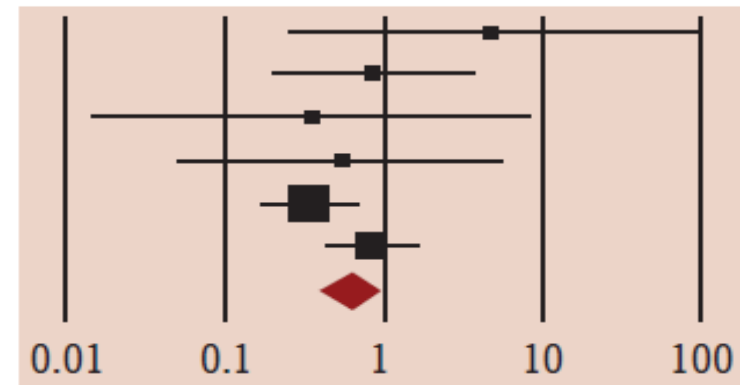
Myocardial Infarction

Provisional -> Significantly lower

Myocardial infraction

B

| Study | Year | Events / Total | | MH risk ratio and 95% CI | MH risk ratio | Lower limit | Upper limit |
|----------------|------|----------------|------------|--------------------------|---------------|-------------|-------------|
| | | Provisional | Two stents | | | | |
| Pan et al | 2004 | 2 / 47 | 0 / 44 | | 4.69 | 0.23 | 95.00 |
| Colombo et al | 2004 | 2 / 22 | 7 / 63 | | 0.82 | 0.18 | 3.65 |
| NORDIC | 2006 | 0 / 207 | 1 / 206 | | 0.33 | 0.01 | 8.10 |
| Ferenc et al | 2008 | 1 / 101 | 2 / 101 | | 0.50 | 0.05 | 5.43 |
| BBC ONE | 2008 | 9 / 250 | 28 / 250 | | 0.32 | 0.15 | 0.67 |
| CACTUS | 2009 | 15 / 173 | 19 / 177 | | 0.81 | 0.42 | 1.54 |
| <i>Overall</i> | | 29 / 800 | 57 / 841 | | 0.57 | 0.37 | 0.87 |



Favours Provisional Favours Two Stents

Test for heterogeneity: $Q=5.72, df=5, P=0.33, I^2=13\%$
 Test for overall effect: $Z=-2.58, P=0.01$

Fixed Effects Model

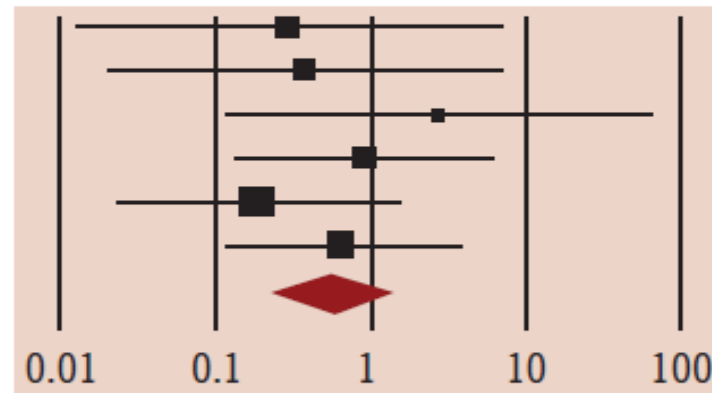
Meta-Analysis - Bifurcations with DES One (Provisional) vs Two Stents

Stent Thrombosis

Provisional -> "Trend" for lower Stent thrombosis

F

| Study | Year | Events / Total | | MH risk ratio and 95% CI | | |
|----------------|------|----------------|------------|--------------------------|-------------|-------------|
| | | Provisional | Two stents | MH risk ratio | Lower limit | Upper limit |
| Pan et al | 2004 | 0 / 47 | 1 / 44 | 0.31 | 0.01 | 7.47 |
| Colombo et al | 2004 | 0 / 22 | 3 / 63 | 0.40 | 0.02 | 7.40 |
| NORDIC | 2006 | 1 / 207 | 0 / 206 | 2.99 | 0.12 | 72.87 |
| Ferenc et al | 2008 | 2 / 101 | 2 / 101 | 1.00 | 0.14 | 6.96 |
| BBC ONE | 2008 | 1 / 250 | 5 / 250 | 0.20 | 0.02 | 1.70 |
| CACTUS | 2009 | 2 / 173 | 3 / 177 | 0.68 | 0.12 | 4.03 |
| <i>Overall</i> | | 6 / 800 | 14 / 841 | 0.56 | 0.23 | 1.35 |



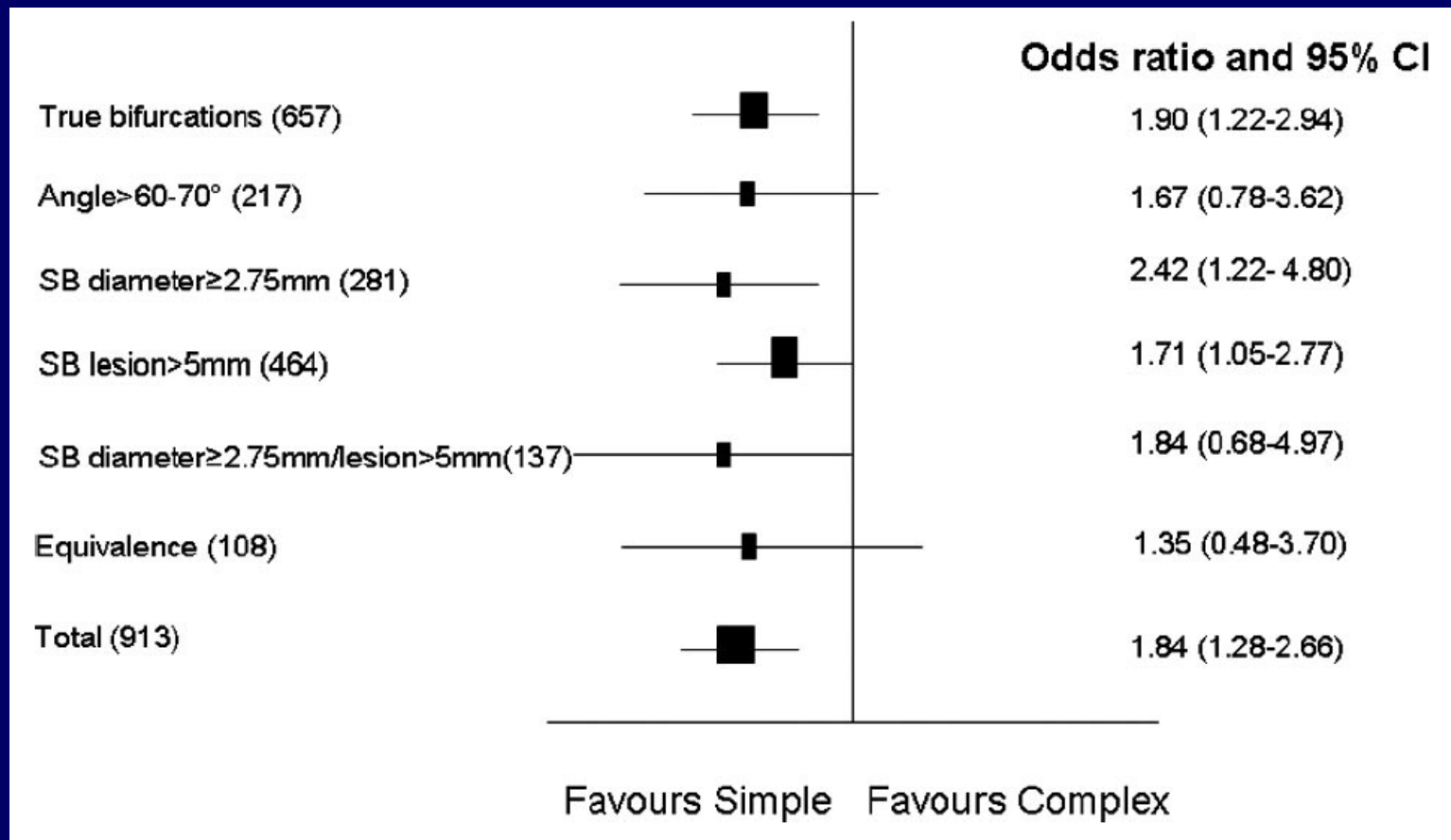
Favours Provisional Favours Two Stents

Test for heterogeneity: $Q=2.2, df=3, P=0.52, I^2=0\%$
 Test for overall effect: $Z=-0.76, P=0.45$

Fixed Effects Model

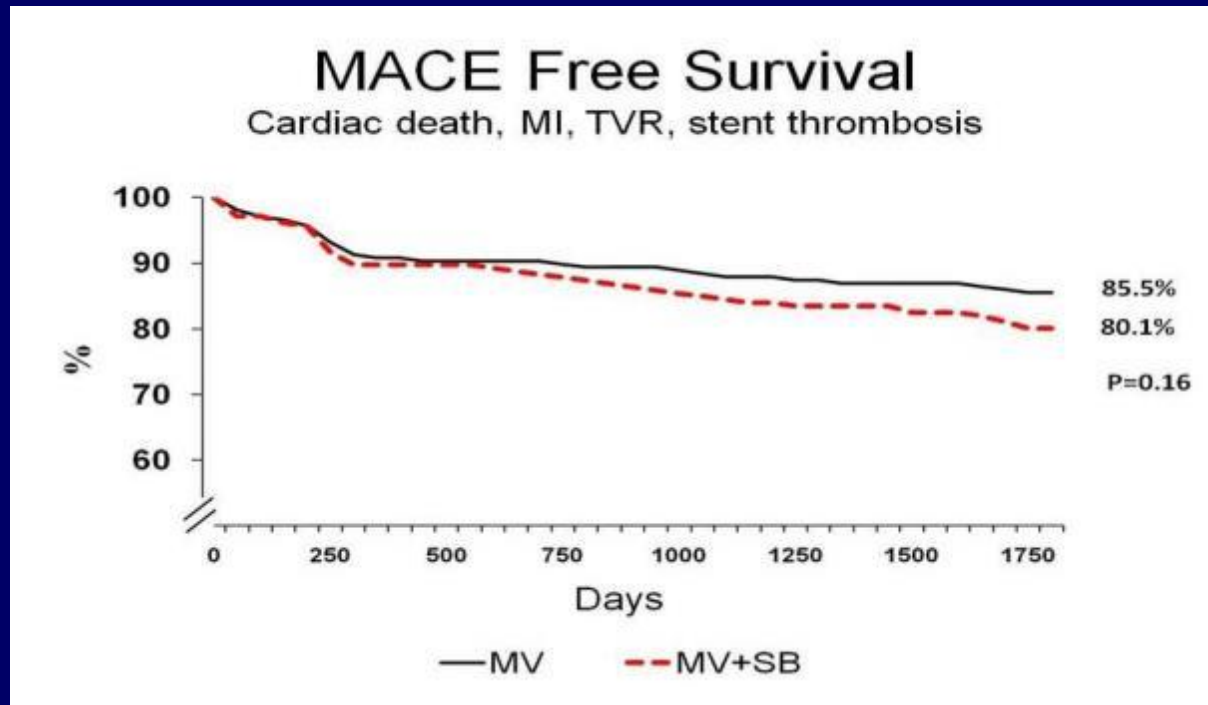
Patient-Level Pooled-Analysis of Nordic 1 and BBC

Primary outcome (death, MI, TVR) for individual subgroups



5 Year Follow-Up Nordic Bifurcation Study

Simple vs Complex Stenting Strategy in Non-LM PCI



| | MV (n=203) | MV+SB (n=202) | P-value |
|---|---------------|------------------|---------|
| MV stented (%) | 99.5 | 98.5 | 0.37 |
| SB stented (%) | 4.4 | 95.0 | <0.0001 |
| Kissing balloon (%) | 32 | 74 | <0.0001 |
| Tx successful (%) (Residual stenosis <30% of MV + TIMI flow III in SB) | 97 | 94 | 0.25 |

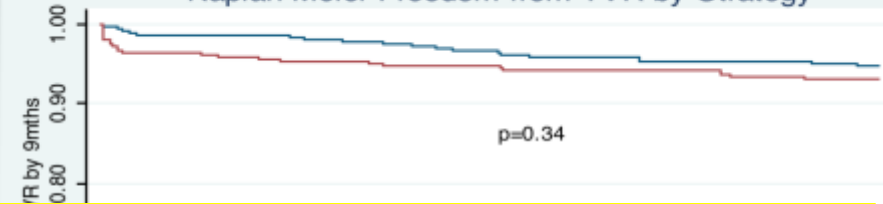
- MACE event were low and did not differ significantly in patients treated with a simple versus a complex bifurcation stenting technique.
- Stent thrombosis rate was not increased in patients treated with 2-stents.

Meta-Analysis: NORDIC I & BBC I (Non LM Bifurcations) Probability of MACE (Death/MI/TVR)

Kaplan-Meier Freedom from Event by Strategy



Kaplan-Meier Freedom from TVR by Strategy



In the Nordic-BBC meta analysis the average SB stenosis was 59% and 65% for the simple & complex strategy respectively.

In many of these trials, up to 25% of patients have no SB disease.



**In non-LM bifurcation PCI multiple studies have demonstrated the superiority of IVUS guidance over angiographic guidance.
More durable long term outcomes.**

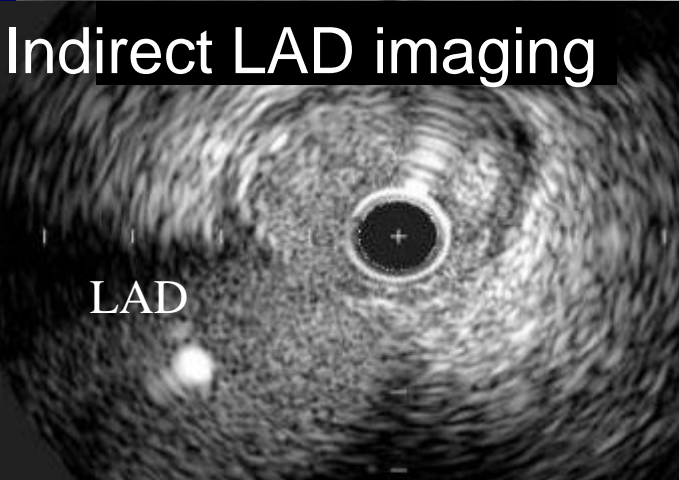
- **Kim et al. Am Heart J 2011;161:180-7**
 - **Bifurcation lesions, propensity score matching (n=487 in each group)**
- **Kim et al. Am J Cardiol 2010;106:612-8**
 - **Bifurcation lesions, propensity score matching (n=303 / n=111)**
- **Patel et al. Am J Cardiol,**
 - **Bifurcation lesions, propensity score matching (n=247 / n=202)**

An Important Principle of IVUS Imaging

Direct Imaging of Both Parent & Daughter Vessel



Indirect LAD imaging

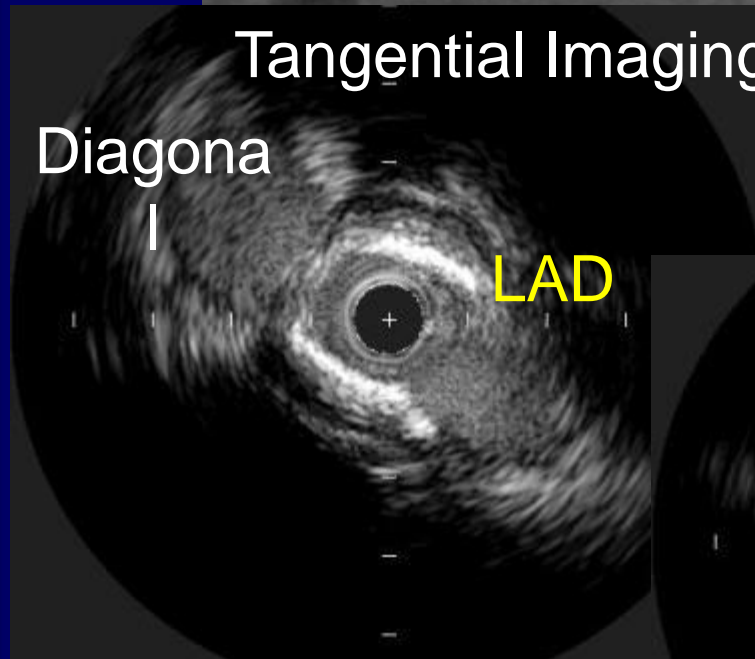


Direct LAD imaging

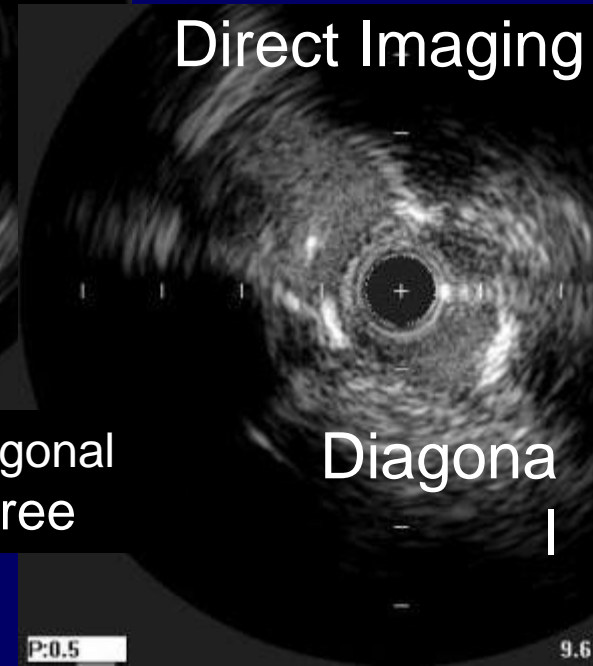


Tangential Imaging

Diagona



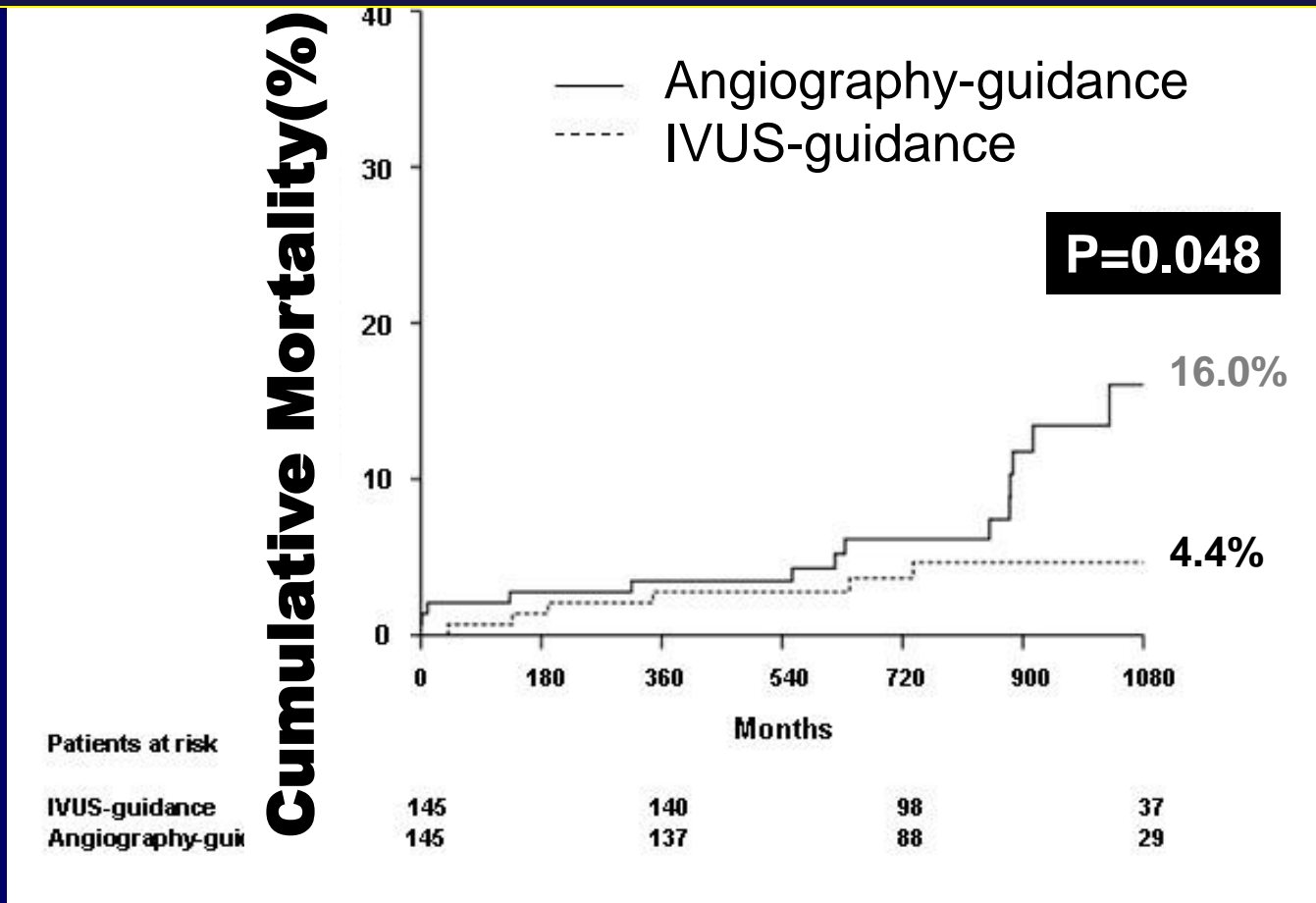
Direct Imaging



On indirect imaging the Diagonal branch appears disease free

IVUS Guidance Saves Lives in UPLM PCI

A finding yet to be convincingly demonstrated in Non-LM bifurcation PCI



DK Crush Technique

Double Kiss and Crush

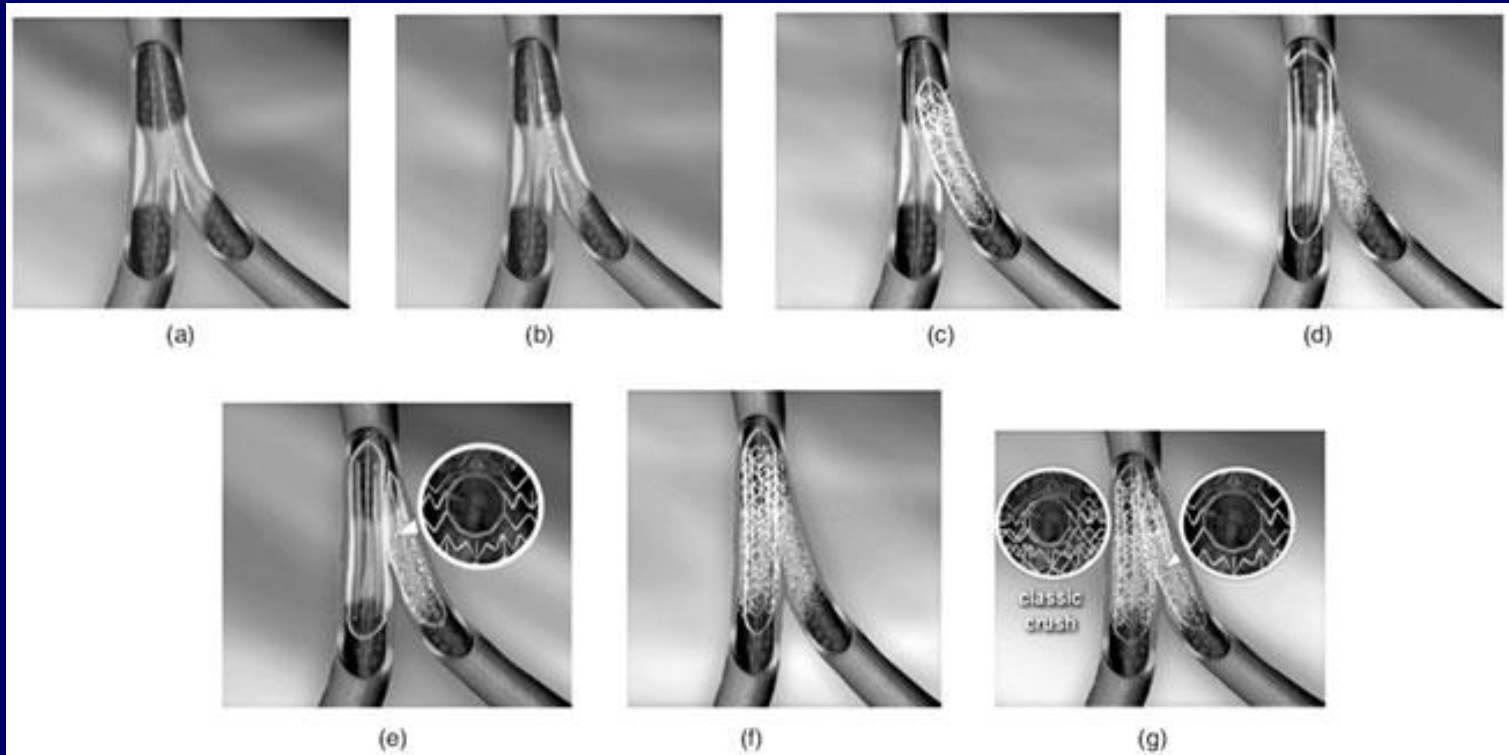


Figure 4. Double kissing (DK) crush technique. Two wires are inserted into two vessels (a). One stent and balloon are advanced into side branch and main vessel simultaneously (b). Inflated side stent firstly (c), then the balloon in the main artery is inflated after removal of stent balloon and wire from side branch (d). First kissing balloon inflation is performed after successful rewiring to side branch (e). Stenting main vessel is undertaken (f), with final kissing inflation as the final step (g). The orifice of side branch is relatively largely expanded, compared to classical crush (g).

1 Year Outcomes DK Crush Versus Provisional Stenting

↓TLR and ↓TVR favoring DK Crush
↓ in MB and SB angiographic restenosis favoring DK Crush
Trend toward reduced MACE

| Table 1. One-Year Outcomes | DK Crush in non-LM Bifurcation | | |
|-----------------------------------|---------------------------------------|-----------------------------|----------------|
| | Double Kissing Crush | Provisional Stenting | P Value |
| MACE | 10.3% | 17.3% | 0.070 |
| Cardiac Death | 1.1% | 1.1% | 1.000 |
| MI | 3.2% | 2.2% | 0.751 |
| TVR | 6.5% | 14.6% | 0.017 |
| TLR | 4.3% | 13.0% | 0.005 |
| Definite Stent Thrombosis | 2.2% | 0.5% | 0.372 |

DK CRUSH vs Cuolotte in UPLM

DK Crush in UPLM PCI

| | DK Crush (n = 176) | Culotte (n = 174) | P Value |
|------------------------|-----------------------|----------------------|---------|
| In-stent Restenosis | 6.8% | 12.6% | 0.037 |
| Diameter Stenosis | 16.39 ± 7.45% | 25.50 ± 7.36% | 0.001 |
| In-stent Late Loss, mm | 0.20 ± 0.30 | 0.39 ± 0.36 | 0.001 |

At 1 year, the primary endpoint of MACE (cardiac death, MI, and TVR) was more than halved in the DK crush group, driven mainly by a reduction in TVR. TLR was also decreased in the DK crush group (table 2).

Table 2. One-year Outcomes

| | DK Crush (n = 210) | Culotte (n = 209) | P Value |
|---------------|-----------------------|----------------------|---------|
| MACE | 6.2% | 16.3% | 0.001 |
| Cardiac Death | 1.0% | 1.0% | 1.0 |
| MI | 3.3% | 5.3% | 0.377 |

The DKCRUSH studies: An Overview

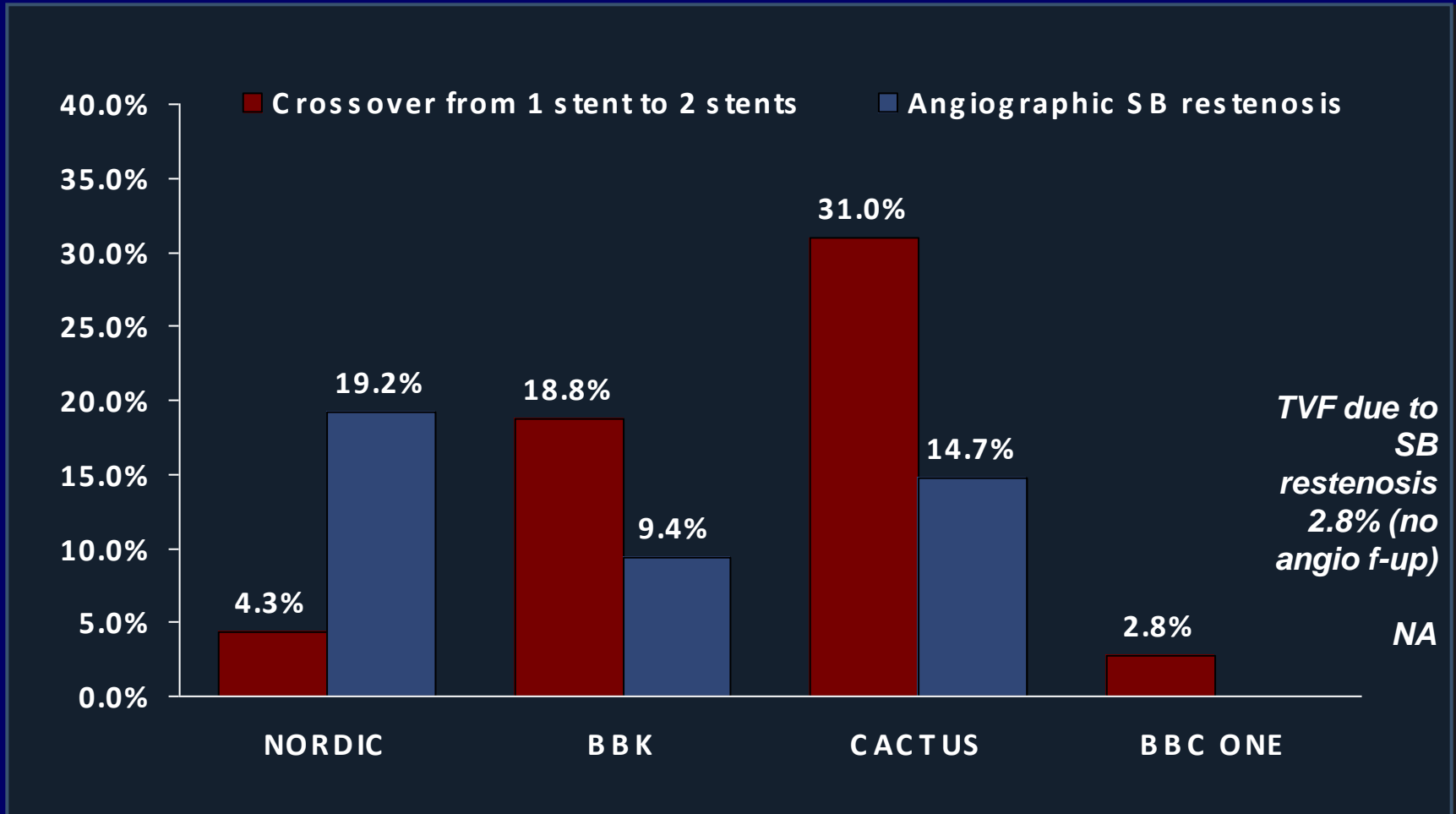
| | DKCRUSH-1 | DKCRUSH-II | DKCRUSH-III |
|----------------|-------------|----------------|-------------|
| Lesion types | 111/011/101 | 111/011 | 111/011 |
| Techniques | DK/crush | DK/provisional | DK/culotte |
| DES | PES | SES | SES |
| Locations | all | all | LM |
| SB diameter | 2.0 mm | >2.5 mm | LCX |
| lesion length | 10.2 mm | 11.3 mm | 16.9 mm |
| MI (not acute) | ✓ | ✓ | ✓ |
| CTO | ✓ | ✓ | ✓ |
| No. patients | 312 | 370 | 420 |
| Endpoint | MACE 8-m | MACE 12-m | MACE 12-m |

DKCRUSH studies: Angiographic/Procedural Characteristics

| | DKCRUSH-1 Crush vs DK | DKCRUSH-II PT vs DK | DKCRUSH-III Culotte vs DK |
|------------------|--------------------------|------------------------|------------------------------|
| RVD-MV,mm | 2.6±0.41 | 2.8±0.50 | 3.20±0.52 |
| RVD-SB,mm | 2.30±0.33 | 2.32±0.45 | 2.83±0.46 |
| DS-SB, % | 61.7±5.1 | 63.2±9.4 | 64.6±7.9 |
| No. stent in SB | 1.15±0.2 | 1.24±0.31 | 1.29±0.30 |
| FKBI, % | 76 vs 100 | 79.5* vs 100 | 99.5 vs. 99.5 |
| Proc. Time (min) | 35 vs 47 | 37 vs 38 | 55 vs 57 |

How Often We Need 2nd Stent after MV Stent?

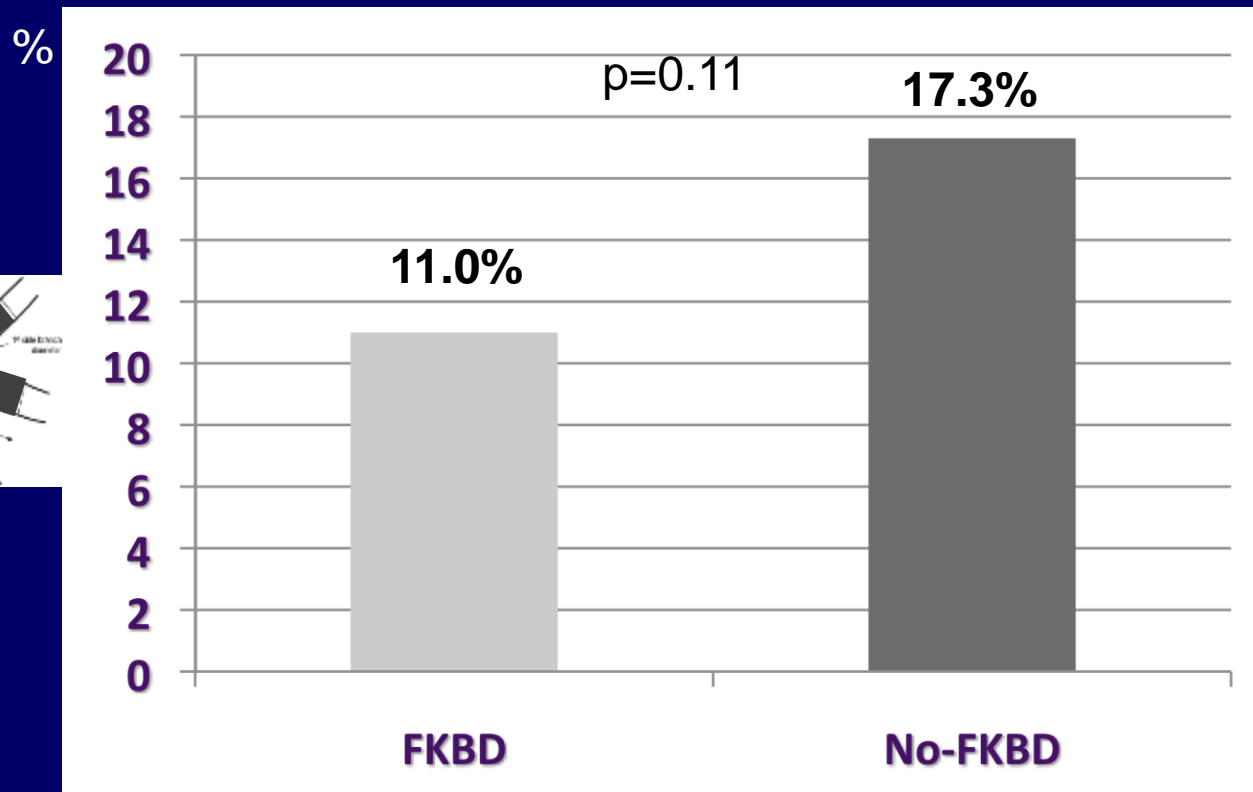
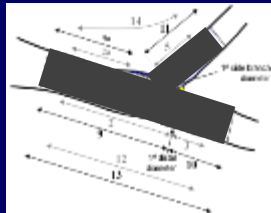
Crossover from 1 Stent to 2 Stents



Steigen TK et al. *Circulation*. 2006;114:1955-1961 Ferenc M et al. *Eur Heart J* 2008; 29: 2859–2867 Colombo A et al. *Circulation*. 2009;119:71–78 Hildick-Smith D et al. *Circulation*. 2010;121:1235-1243

Nordic-Baltic Bifurcation Study III

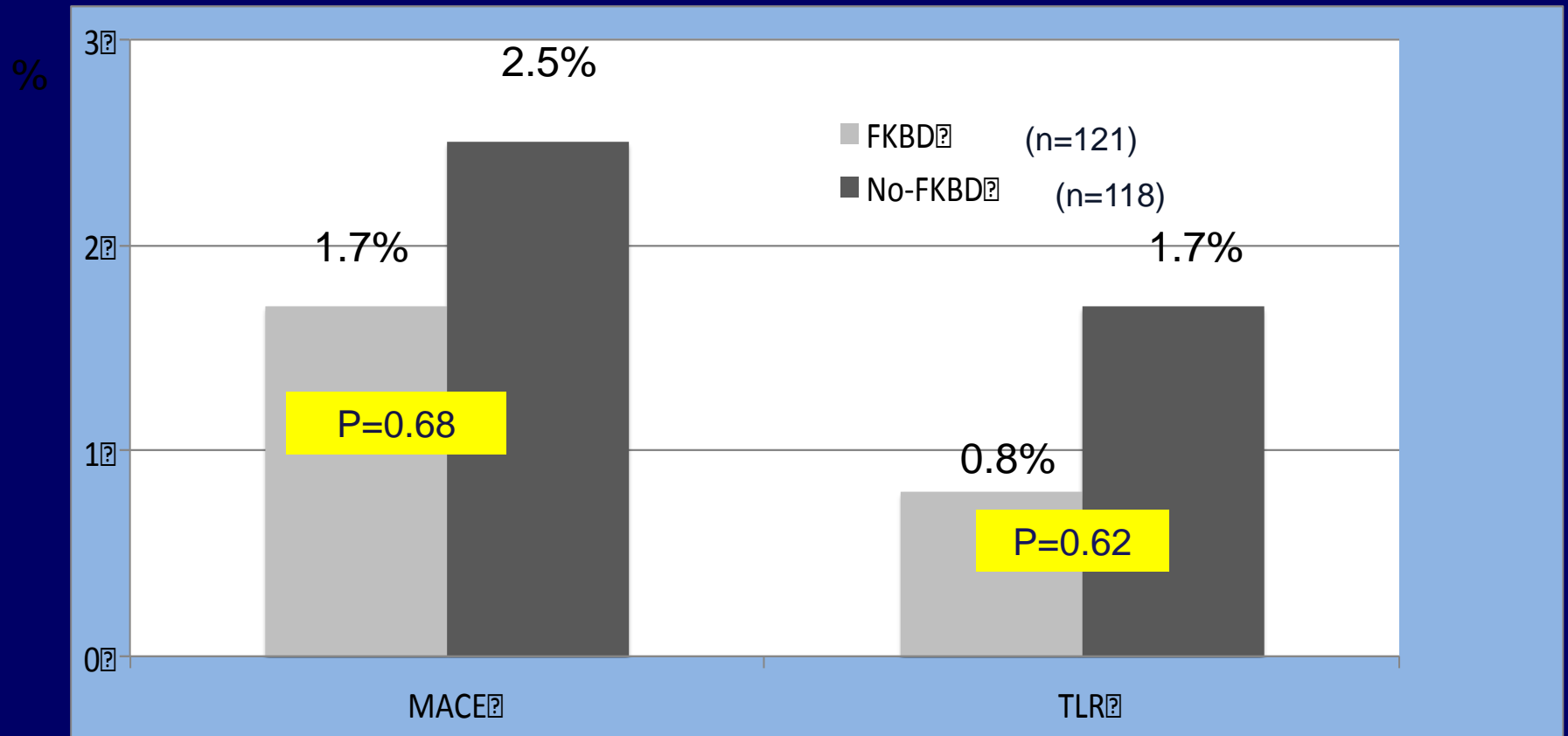
(Re)stenosis at 8-months QCA: Entire bifurcation lesion



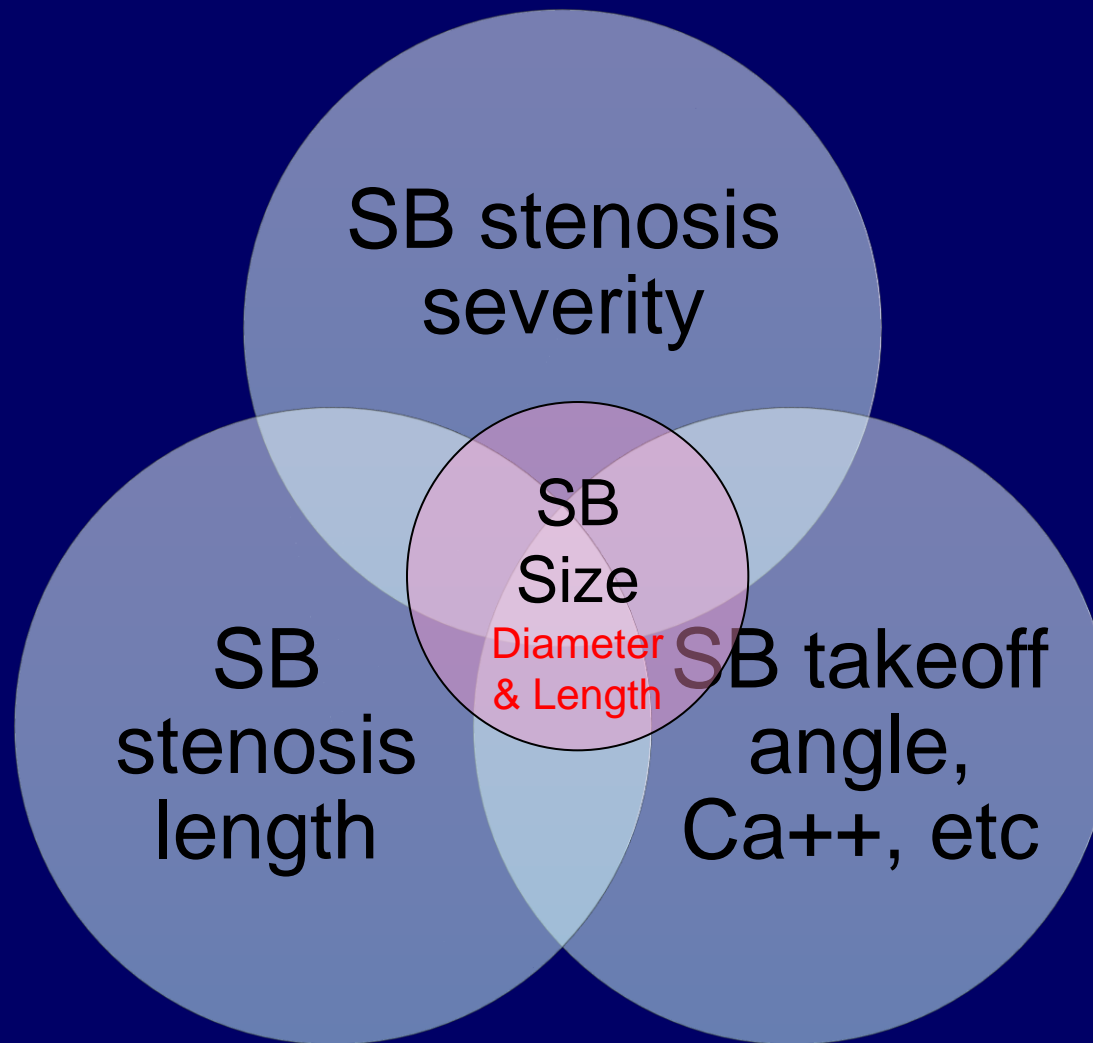
Binary Restenosis: $\geq 50\%$ diameter stenosis at follow-up

True bifurcation subgroup

MACE and TLR at 6 month clinical FU



What is a “Complex Bifurcation”?



Provisional Stenting Technique

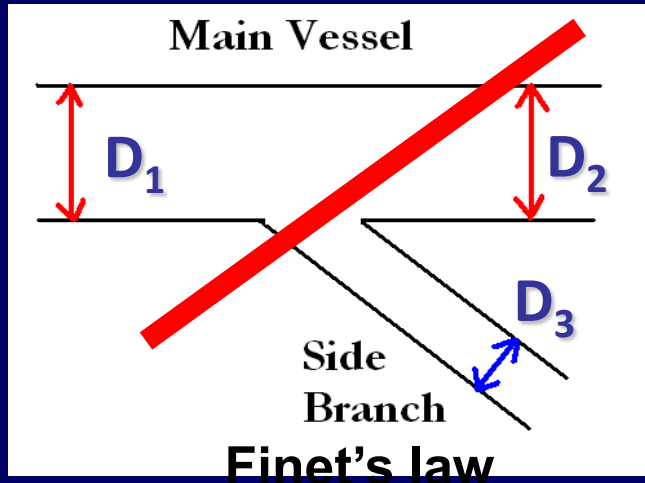
Why wire both branches in Provisional Stenting

- Protects SB from closure due to plaque shift and/or stent struts during MB stenting
- Jailed SB wire facilitates re-wiring of the SB:
 - widening the angle between the MB and SB
 - by acting as a marker for the SB ostium if SB occludes
 - changing the angle of SB take-off
- In the Tulipe multicenter study, absence of this jailed wire was associated with a higher rate of re-interventions (OR:4.26; 1.27–14.35) during follow-up
- **CAUTION WHEN REMOVING JAILED WIRES!**

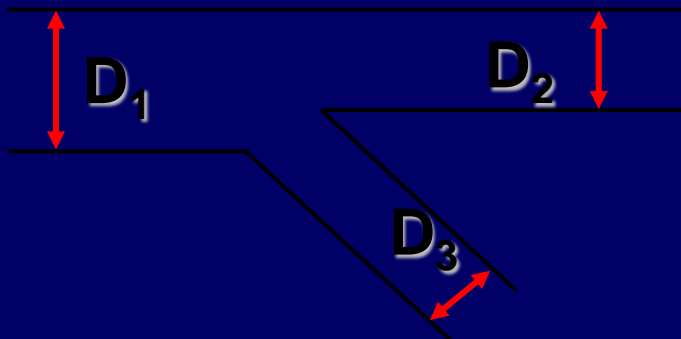
Why Protect SB's from Closure?

- **Occlusion of SB's >1mm associated with 14% incidence of myocardial infarction**
 - Arora RR et al. *Cathet Cardiovasc Diagn* 1989;18:210-2
- **SB closure associated with large periprocedural MI**
 - Chaudhry EC et al. *J Thromb Thrombolysis* 2007

Murray's law



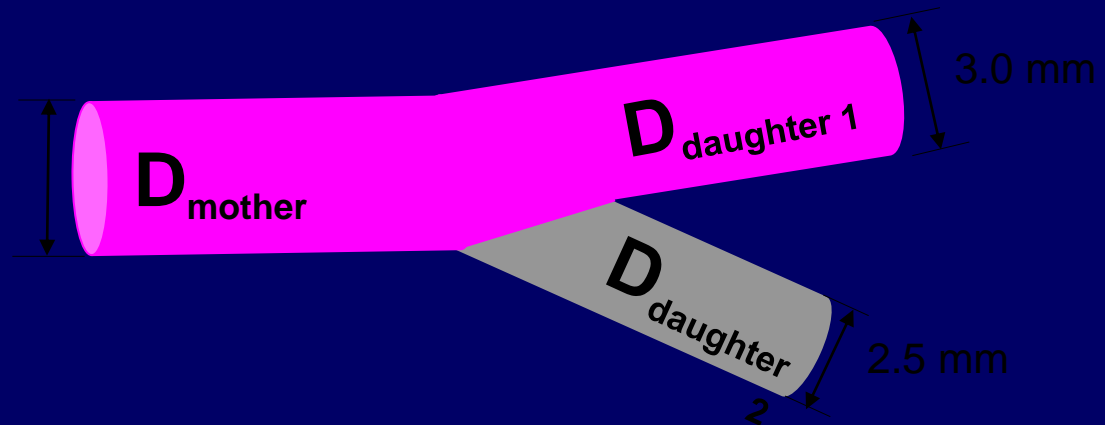
$$D_1 = 0.678 (D_2 + D_3)$$



$$D_1^3 = D_2^3 + D_3^3$$

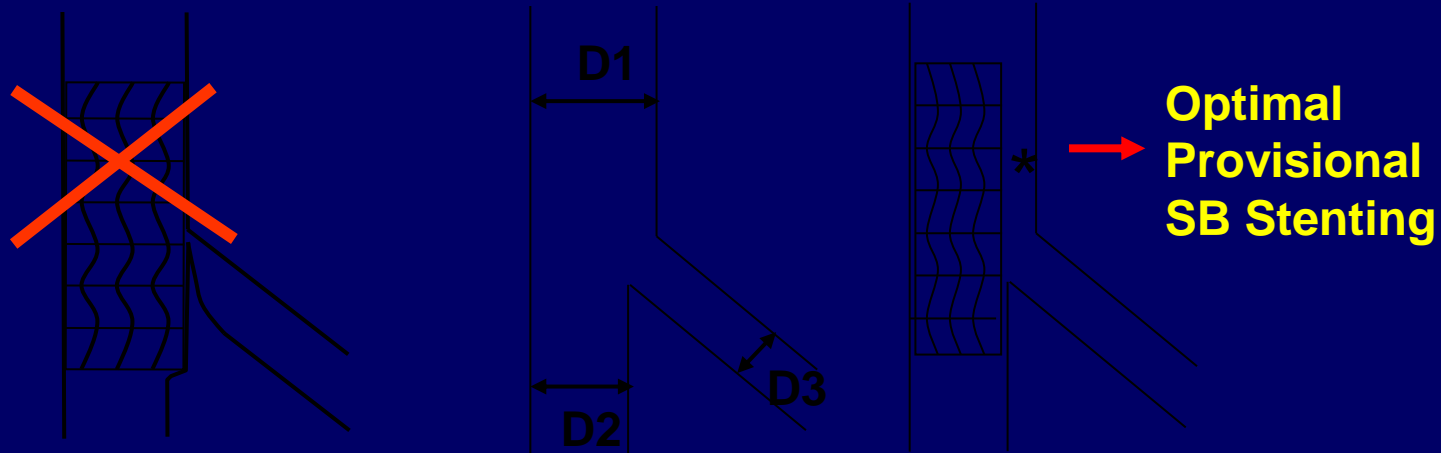
(Murray's law)

$$3.68 = 0.67 * (3.0 + 2.5)$$



$$D_{\text{mother}} = 0.67 * (D_{\text{daughter 1}} + D_{\text{daughter 2}})$$

The 3 Diameter Rule



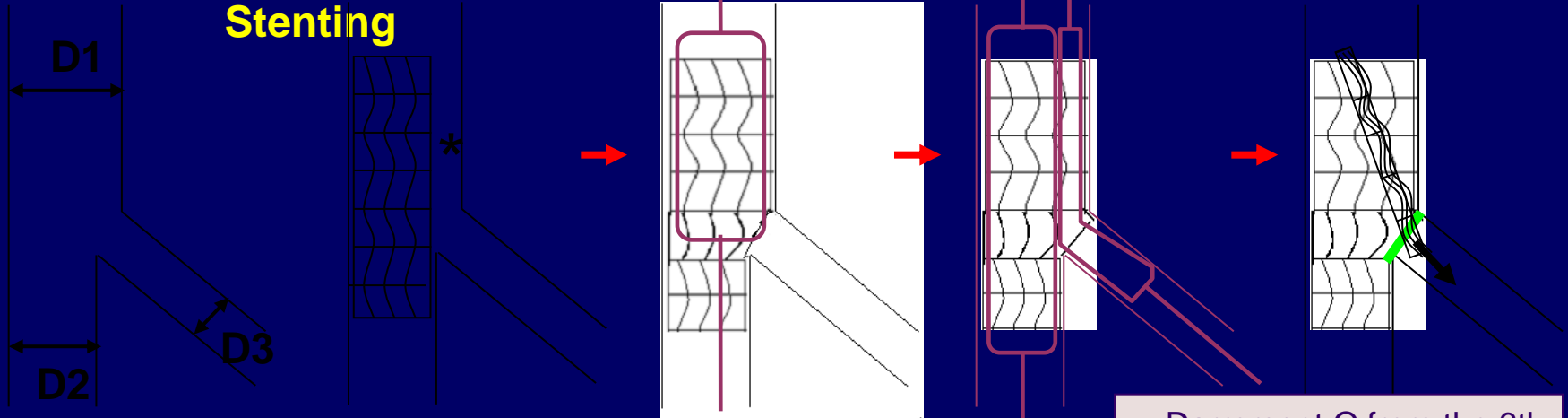
$$D1 = 0.67 * (D2 + D3)$$

Recommendations:

- In single stent techniques, the primary stent should be sized according to the distal main vessel diameter
- Postdilatation (POT), or kissing balloon inflations (FKB), are required to optimise the proximal main vessel stent diameter

Proximal Optimisation Technique (POT)

Optimal Provisional SB Stenting



$$D1 = 0.67 * (D2 + D3)$$

POT

FKB

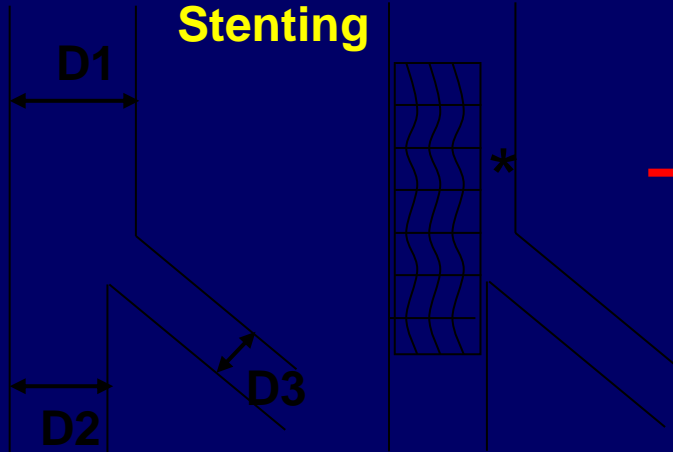
Darremont, O from the 6th
EBC meeting 2010

- Expansion of the stent at the carina, using a short oversized balloon
- Produces curved expansion of the stent into the bifurcation point and facilitates recrossing, distal recrossing, kissing inflations and ostial stent coverage of the side branch

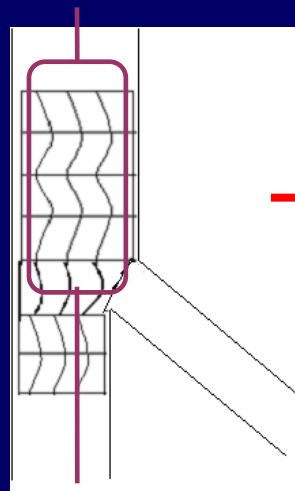
First Recommendation: the POT technique should be used in any case of difficulty recrossing into a side branch

Proximal Optimisation Technique (POT)

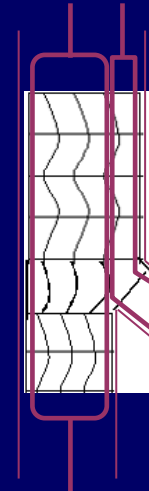
Optimal
Provisional SB
Stenting



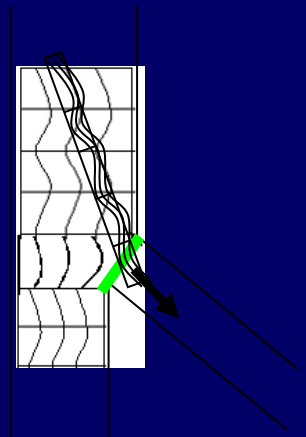
$$D1 = 0.67 * (D2 + D3)$$



POT



FKB

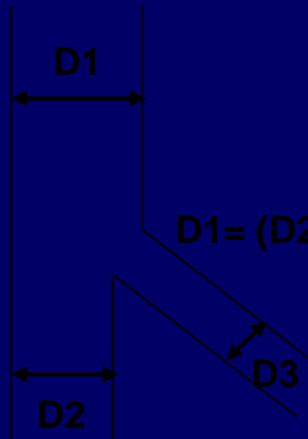


Darremont, O from the 6th
EBC meeting 2010

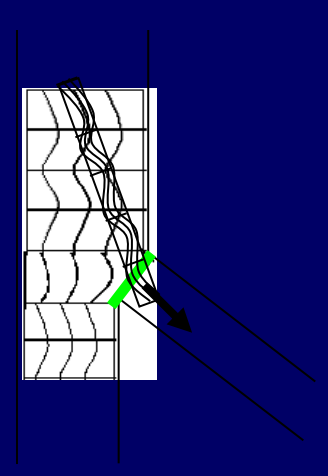
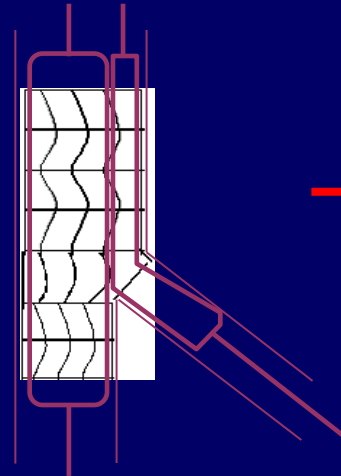
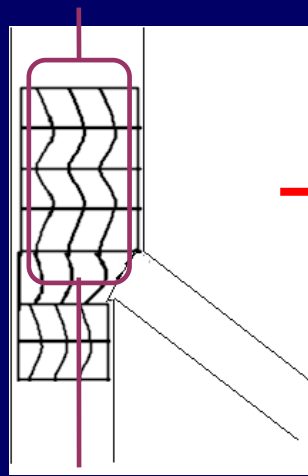
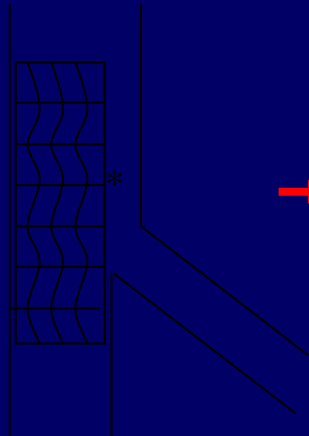
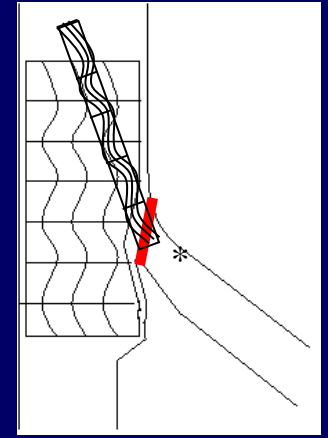
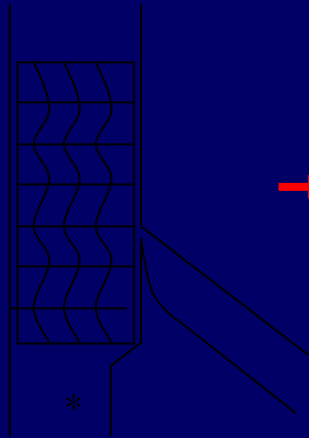
Second Recommendation:

- When using a single stent technique (in the absence of kissing balloon inflations) the proximal main vessel stent should be postdilated (POT) to an appropriate **diameter**

Stent diameter = PM diameter



Stent diameter = DM diameter

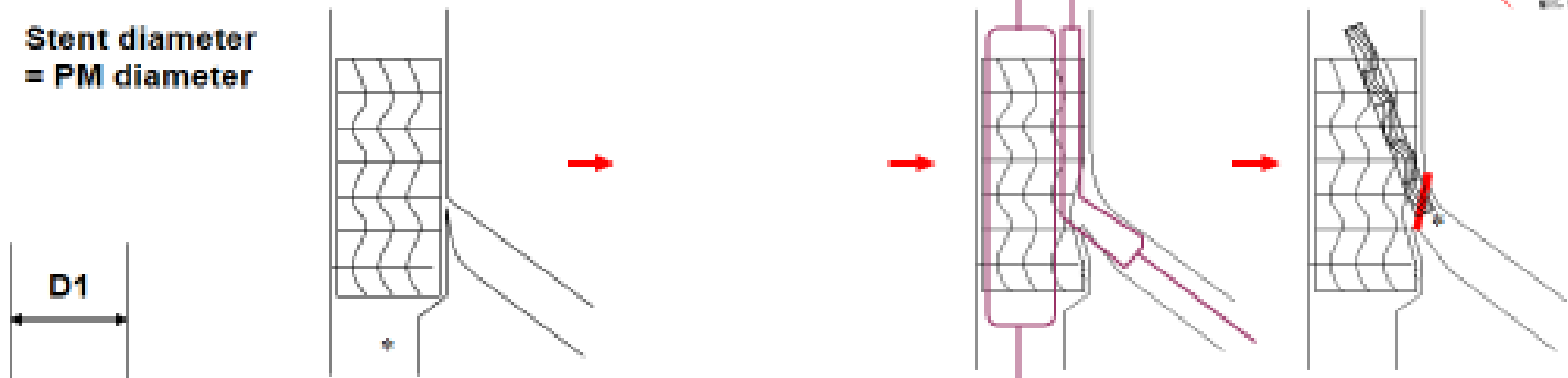


POT

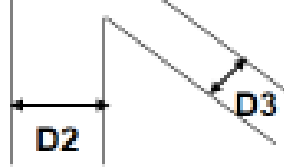
After MV stenting, cross into the SB through the distal strut

In the provisional technique, wire cross following MV stenting should be done through the distal strut, because it creates better SB scaffolding than a proximal crossing

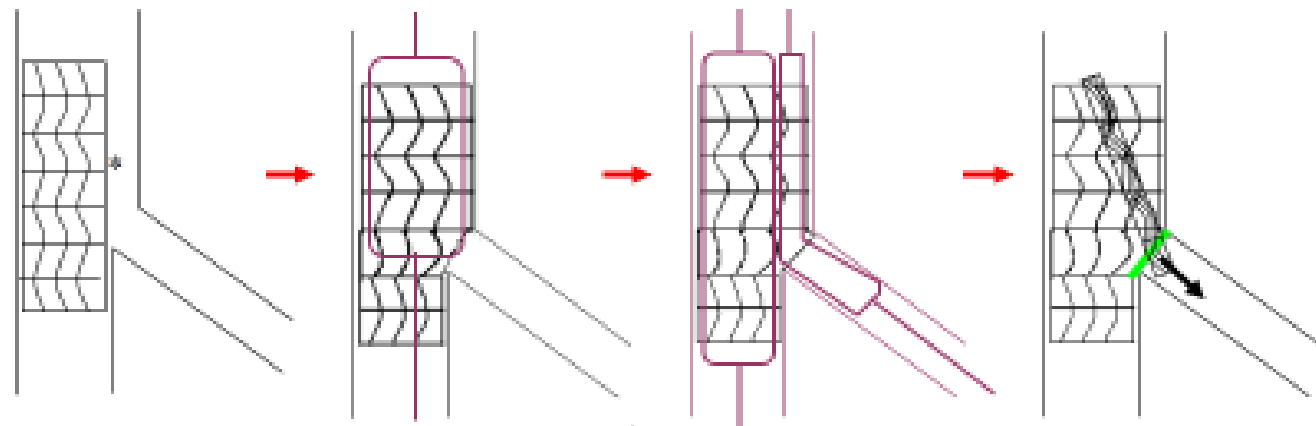
Stent diameter = PM diameter



$$D1 = (D2 + D3) \cdot 2/3$$

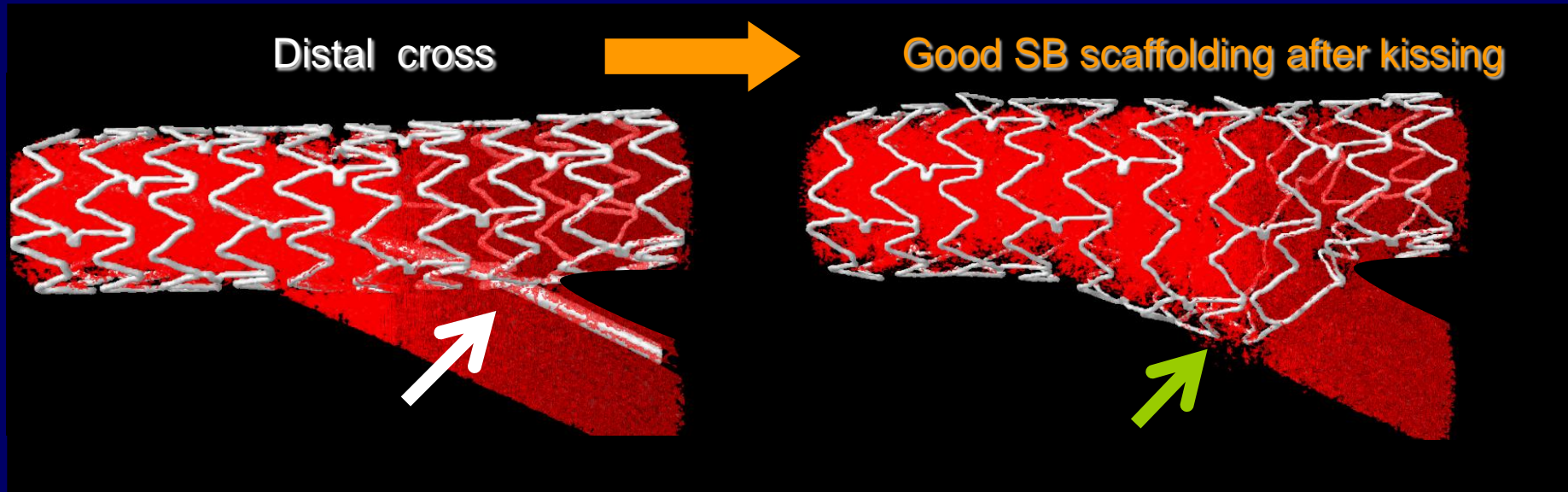


Stent diameter = DM diameter



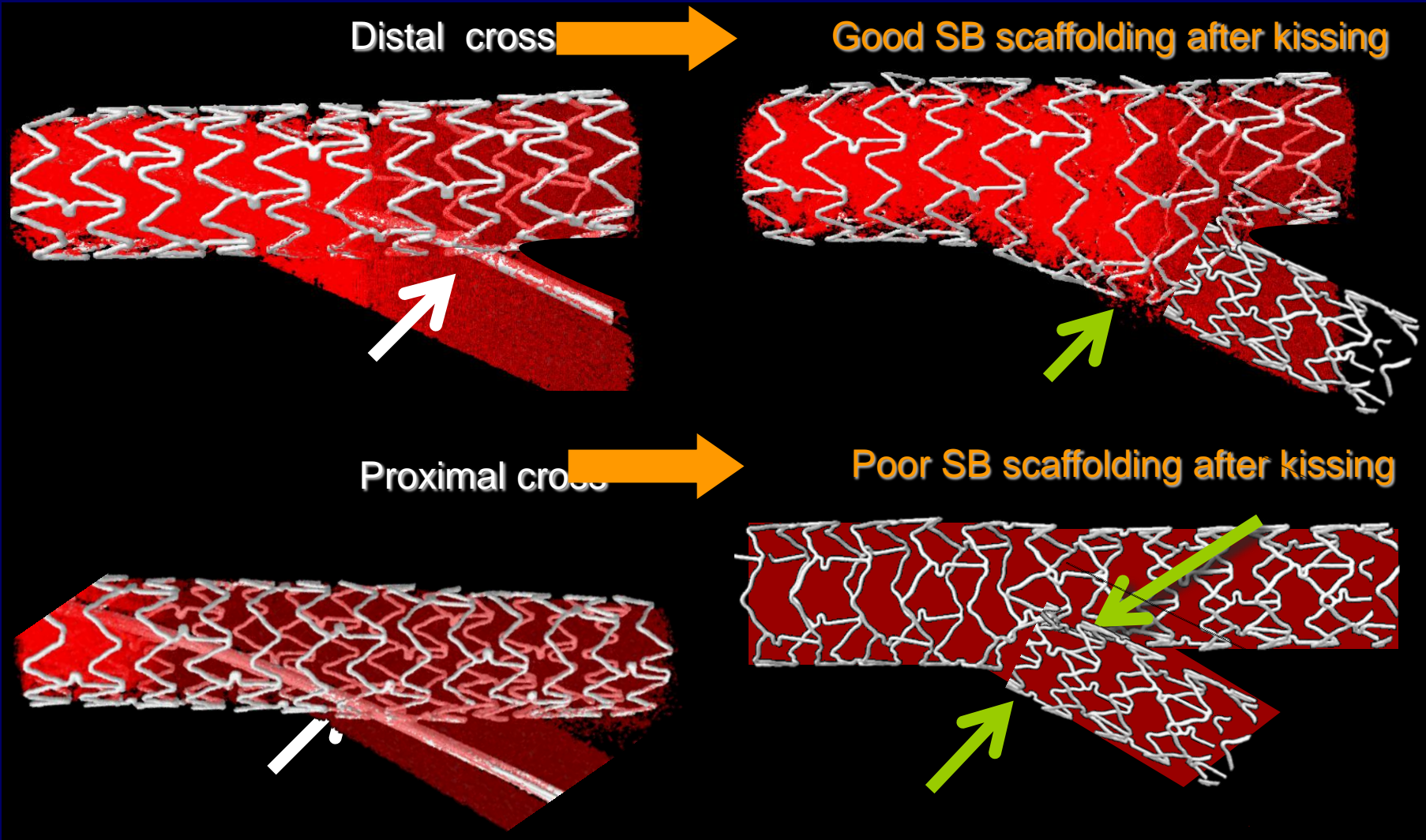
POT

Wire should cross the MV into the SB through the distal strut



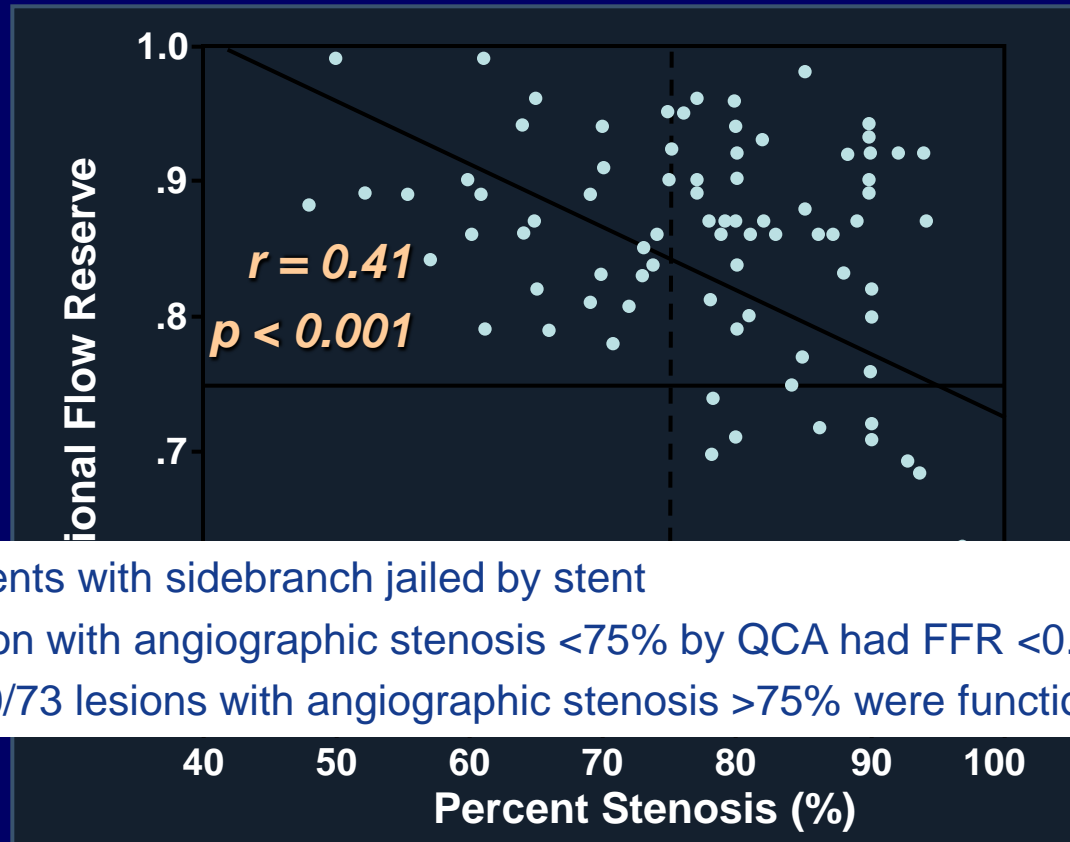
- **Recommendation: When rewiring a side branch, efforts should be made to cross the main vessel stent distally, thereby ensuring stent coverage of the ostium of the side branch**

MV Stent Distortion after FKBD



Side-Branch Stenosis Functional Significance – FFR

Correlation between FFR and % Stenosis



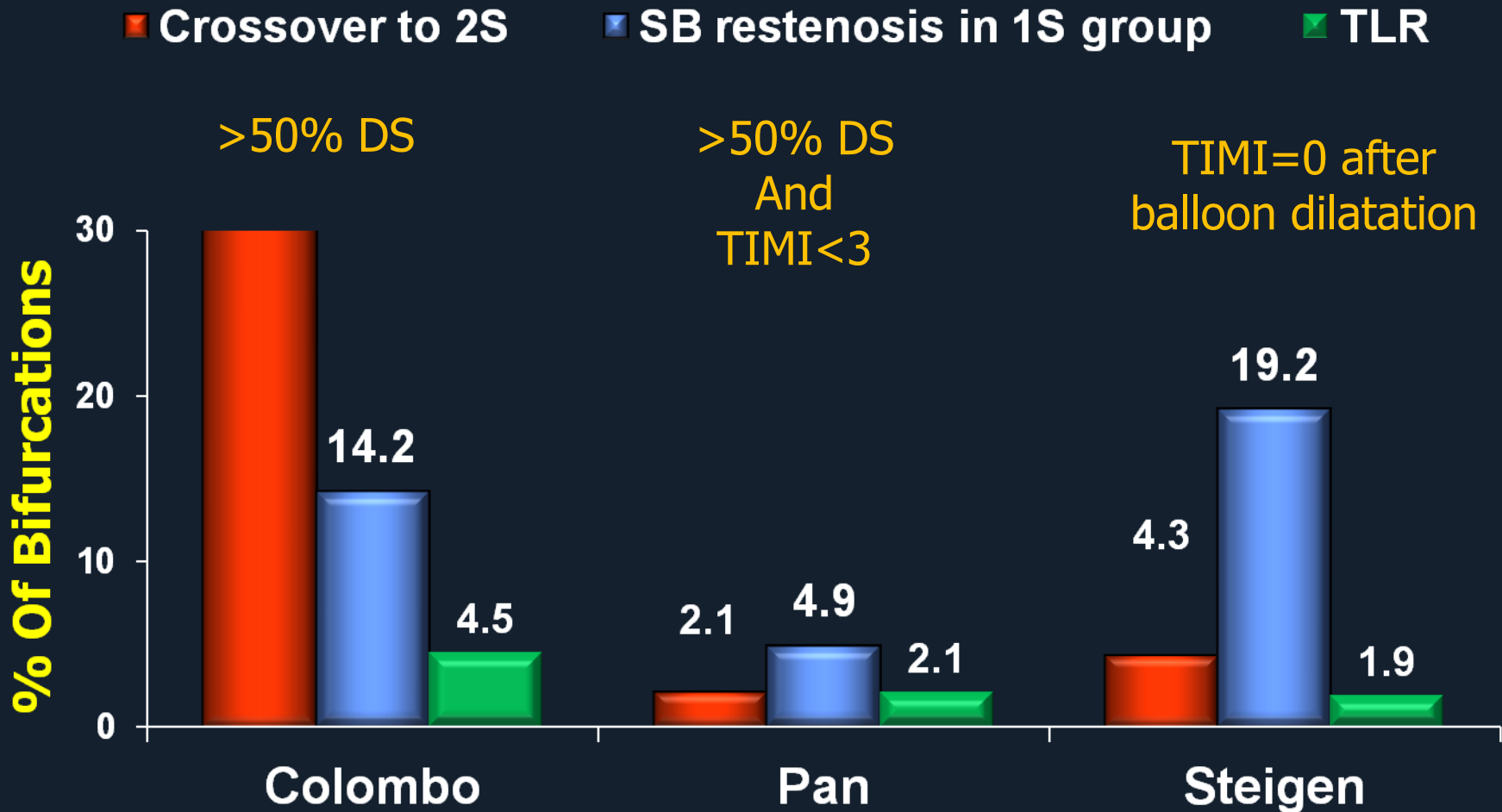
97 patients with sidebranch jailed by stent

No lesion with angiographic stenosis <75% by QCA had FFR <0.75

Only 20/73 lesions with angiographic stenosis >75% were functionally significant

Almost All Side Branch Lesions <70% DS Are Not Functionally Significant

How often do we need a second stent when using the Provisional approach?



- Colombo A, et al. *Circulation* 2004;109:1244-9
- Pan M, et al. *Am Heart J* 2004;148:857-64.
- Steigen TK, et al. *Circulation* 2006;114:1955-61.

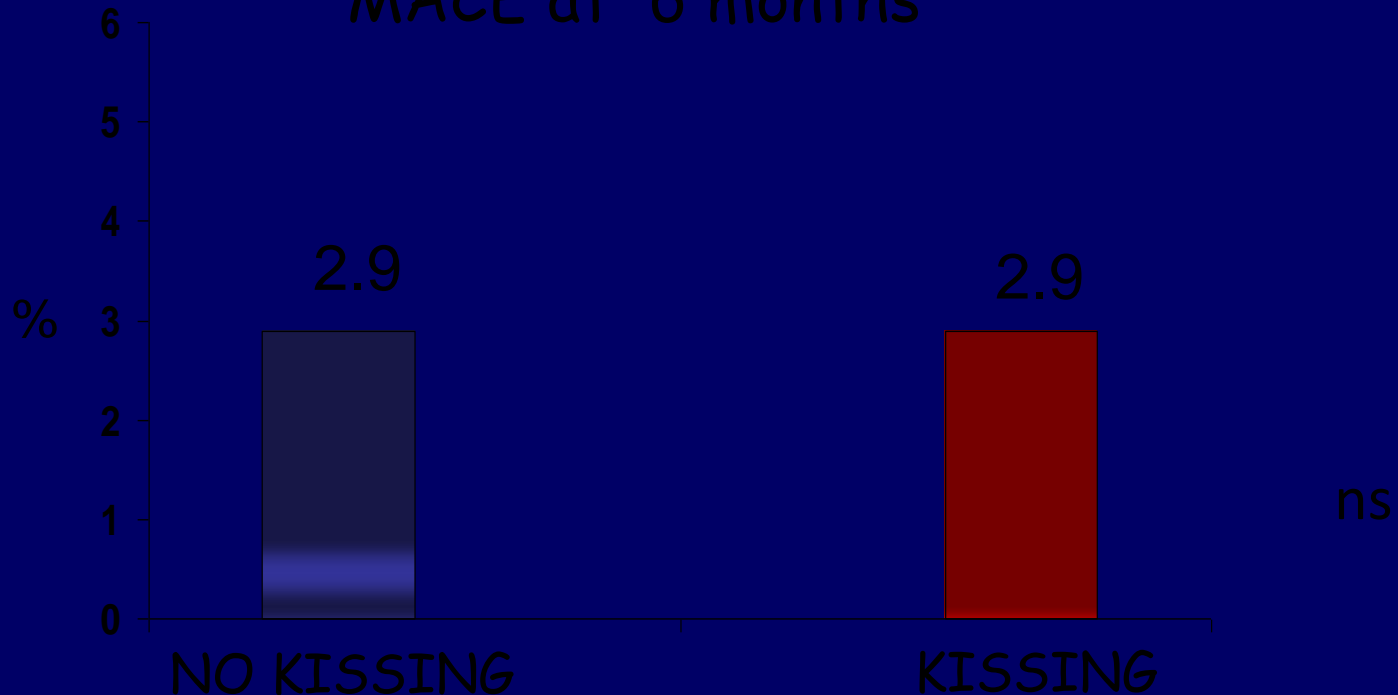
NORDIC 3

RCT on FKB vs no FKB in All Bifurcations

Only 50 % of the cases had a True Bifurcation Lesion!!

Primary end point

MACE at 6 months

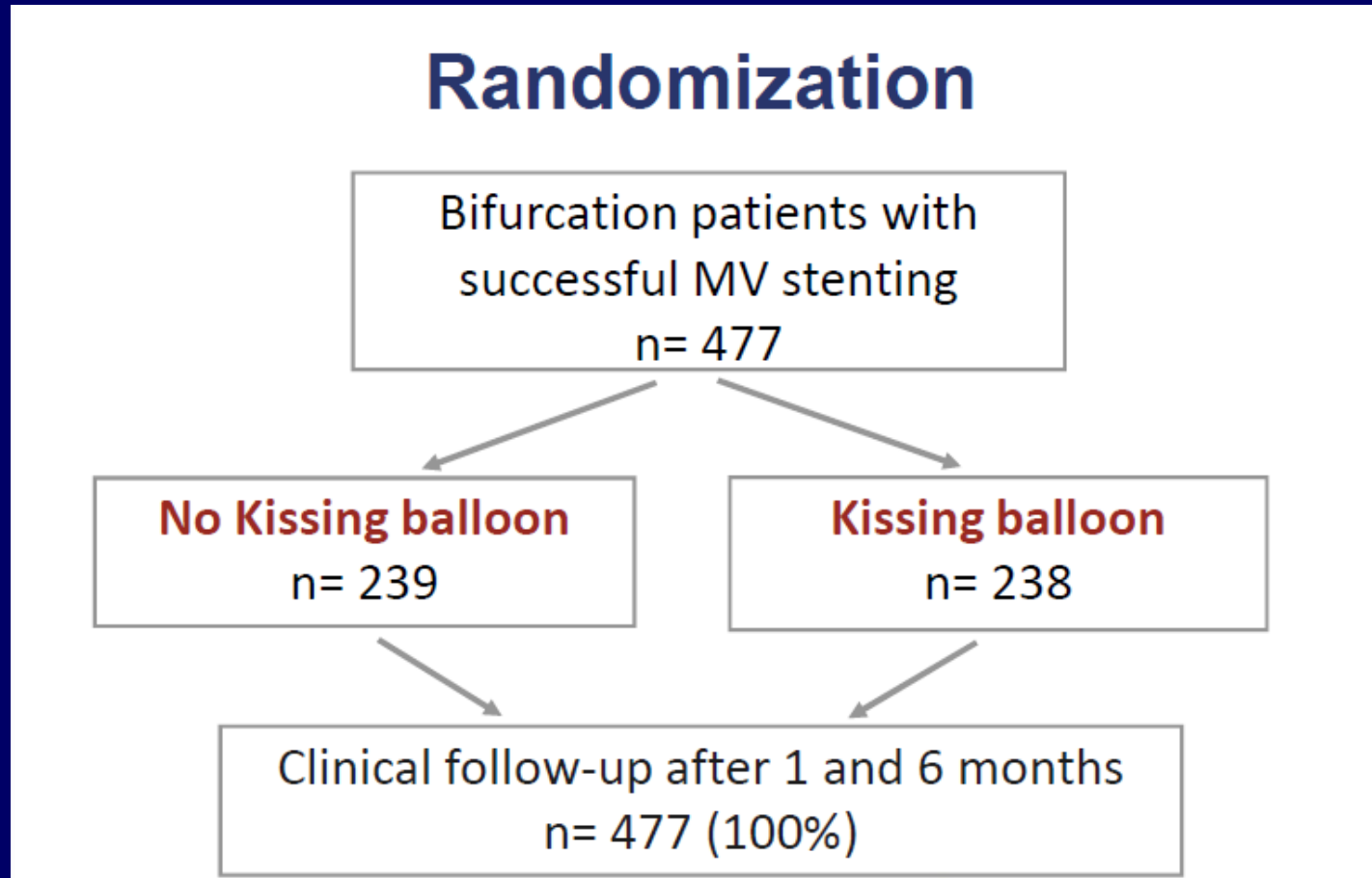


Niemela et al *Circulation* 2011 (123): 79-86

NORDIC III

RCT on FKB or No FKB on all Bifurcations

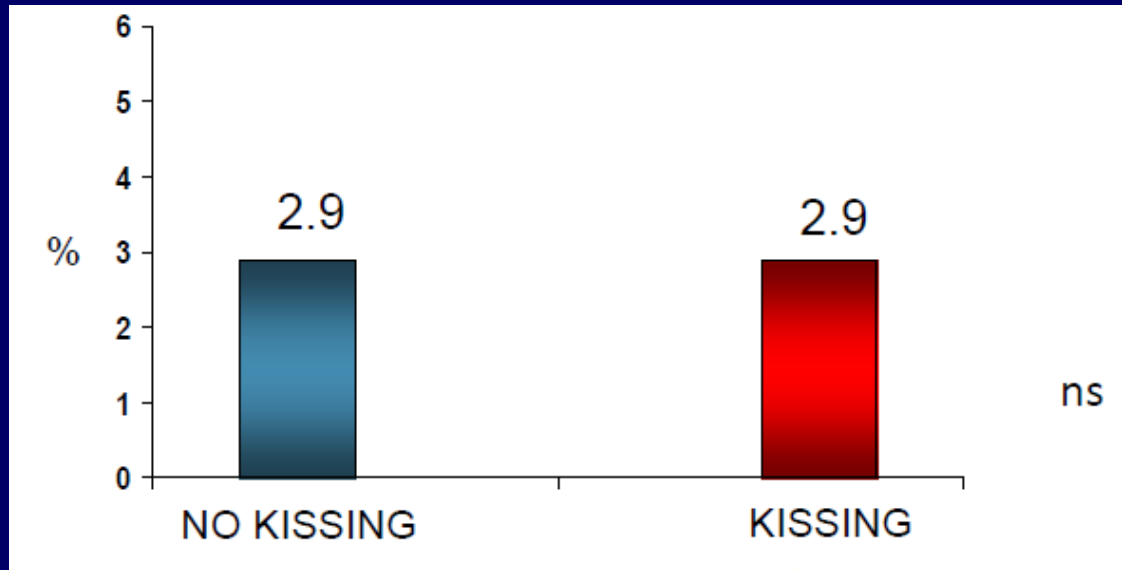
Only 50 % of the cases had a True Bifurcation Lesion



NORDIC III

Primary end point

MACE (cardiac death, index lesion MI, TLR, stent thrombosis) after 6 months

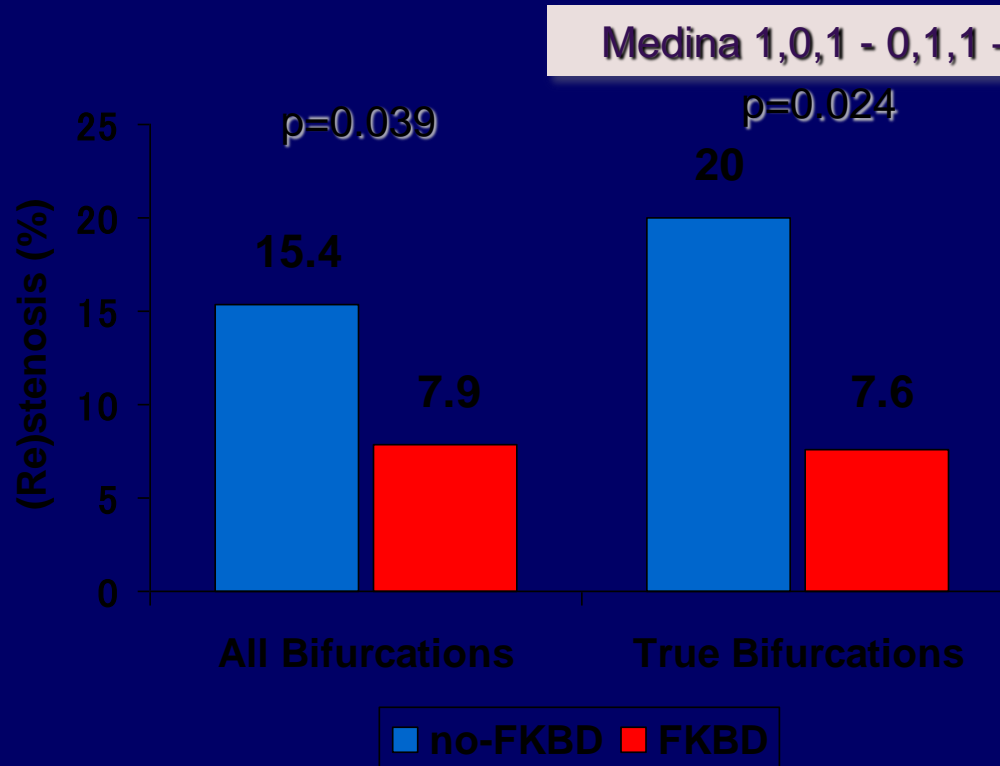
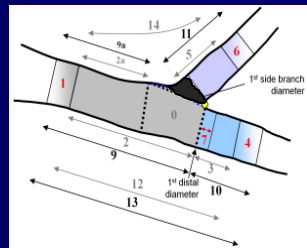


- **Conclusion:** Routine use of Final Kissing Balloon (FKB) did not improve clinical outcome, but there was not a penalty for undertaking FKB

NORDIC III

Secondary end point

Side Branch (SB) Binary (Re)stenosis after 8 months

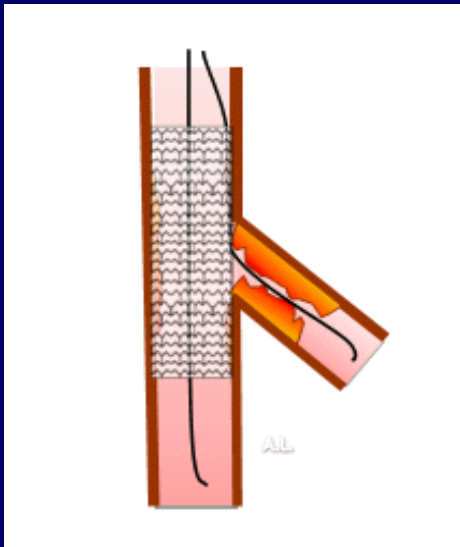


In the MV was
2.5% vs 3.1%
($P=0.68$)

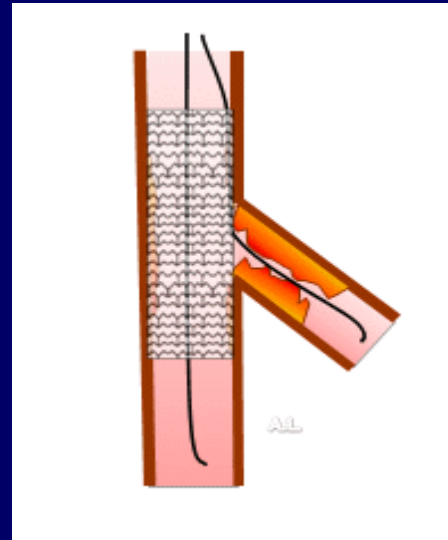
- **Conclusion: FKBD reduced angiographic side branch (re)stenosis, especially in patients with true bifurcation lesions**

Provisional Approach -requiring a 2nd stent in the SB

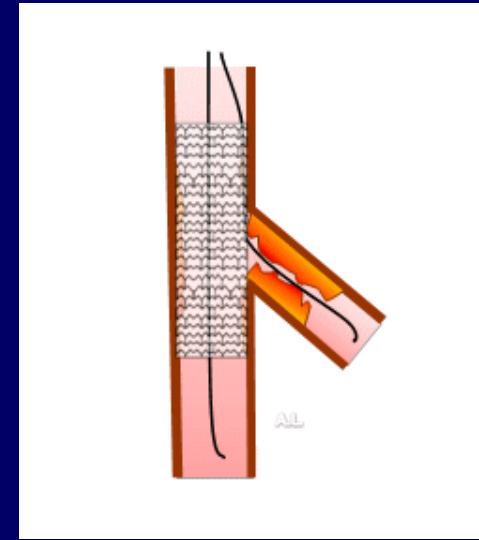
TAP



Reverse Crush



Culotte



Advantages

Easy to perform
No recrossing

Disadvantages

Struts protruding
into MB

Complete coverage of
ostium
Any anatomy

Recrossing into SB
3 layers of struts

Complete coverage of
ostium

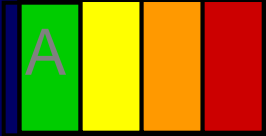
More labourious
Rewiring both branches
Double stent layer

Courtesy Dr. Chieffo

The Guidelines

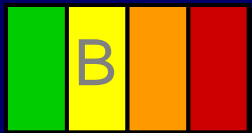
Provisional versus Elective SB stenting

I IIa IIb III



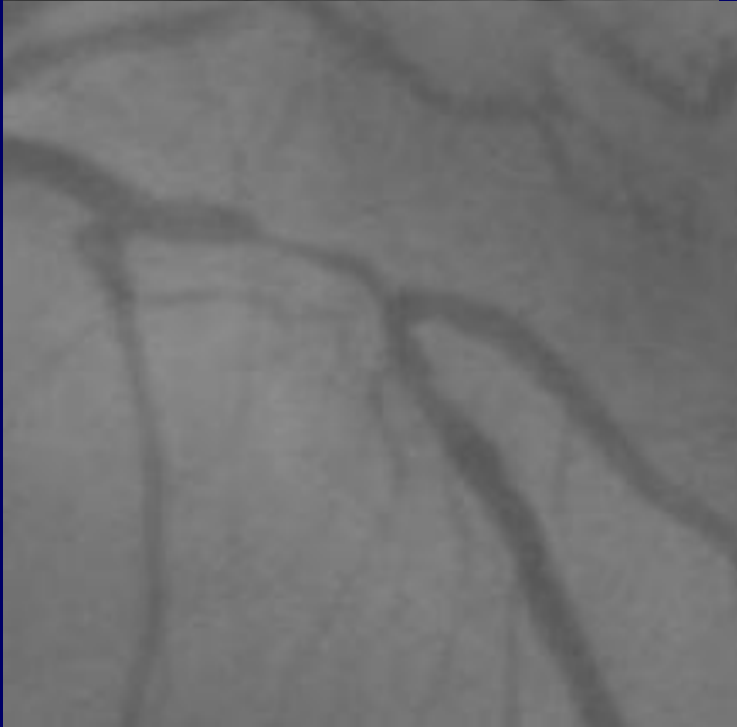
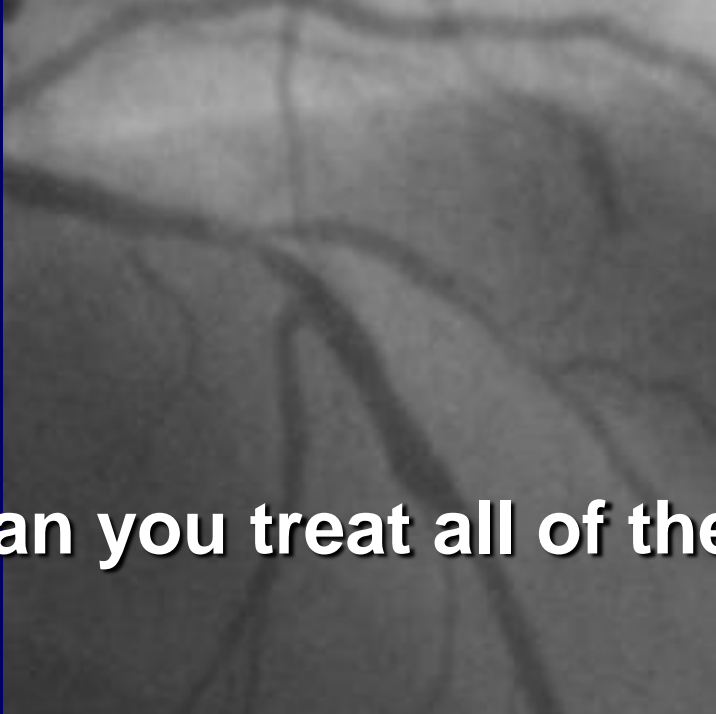
Provisional side-branch stenting should be the initial approach in patients with bifurcation lesions when the side branch is not large and has only mild or moderate foal disease at the ostium

I IIa IIb III



It is reasonable to use elective double stenting in patients with complex bifurcation morphology involving a large side branch where the risk of side-branch occlusion is high and the likelihood of successful side branch re access is low

Can you treat all of these bifurcations in the same way?



Two Stent Bifurcation Techniques

True Bifurcation

(significant stenosis on the main and side branches)

No

Yes

Provisional SB stenting

Is SB suitable for stenting?

No

Yes

Stent on MB
"Keep It Open" for SB

SB disease is diffuse &/or not localized
to within 5 mm from the ostium?

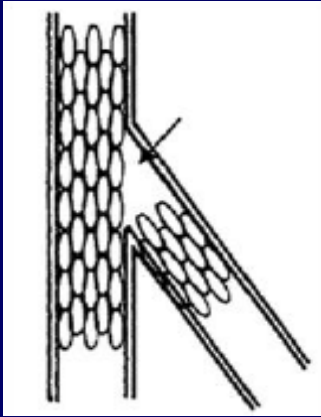
No

Yes

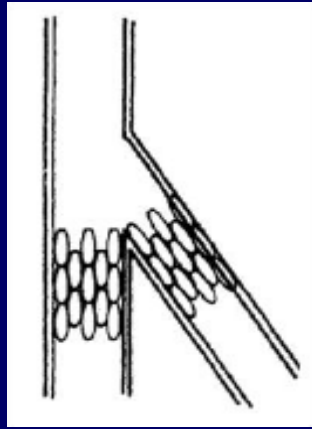
Provisional SB
stenting

Elective implantation of two stents
(MB and SB)

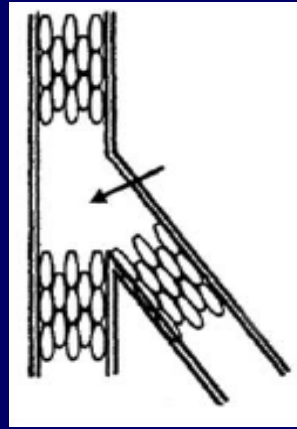
Bifurcation Stenting Techniques with Workhorse Stents



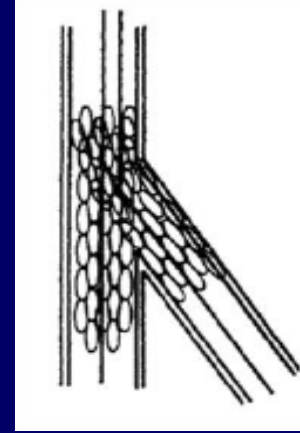
T Stenting



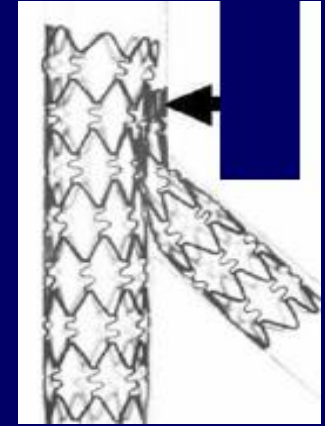
V Stenting



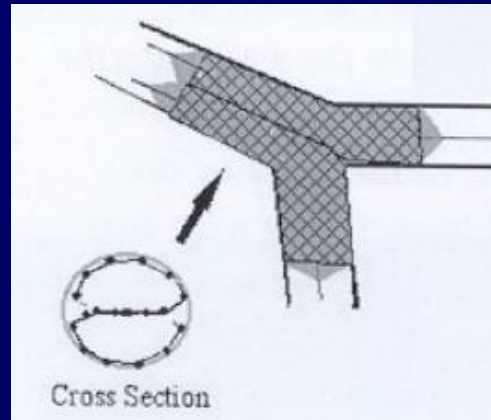
Y Stenting



Culotte



Crush

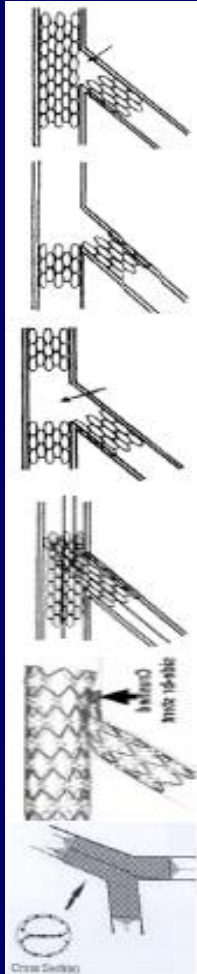


Kissing Stent

Workhorse Stents, a Suboptimal Solution

A = Best

C = Worst



| | Coverage | Amount of metal | Branch jailing | Number of stents |
|------------------|----------------|-----------------|----------------|------------------|
| T stenting | B C | A | B | B |
| V stenting | C | A | A | B |
| Y stenting | C | A | A | C |
| Culotte stenting | A | C | C | B |
| Crush stenting | A | C | C | B |
| Kissing Stent | A | C | A | B |

Bifurcation PCI

Provisional and Dedicated 2-Stent Techniques

Performed with 6 Fr Guide

Performed with a 7F Guide

Provisional Single Stent

Crush and Mini-Crush

T- and modified T

V-stent

T and Protrusion (TAP)

Simultaneous Kissing Stents
(SKS)

Step and Double Kiss Crush

Culotte




Reverse Crush

Double Stenting Techniques for Bifurcations

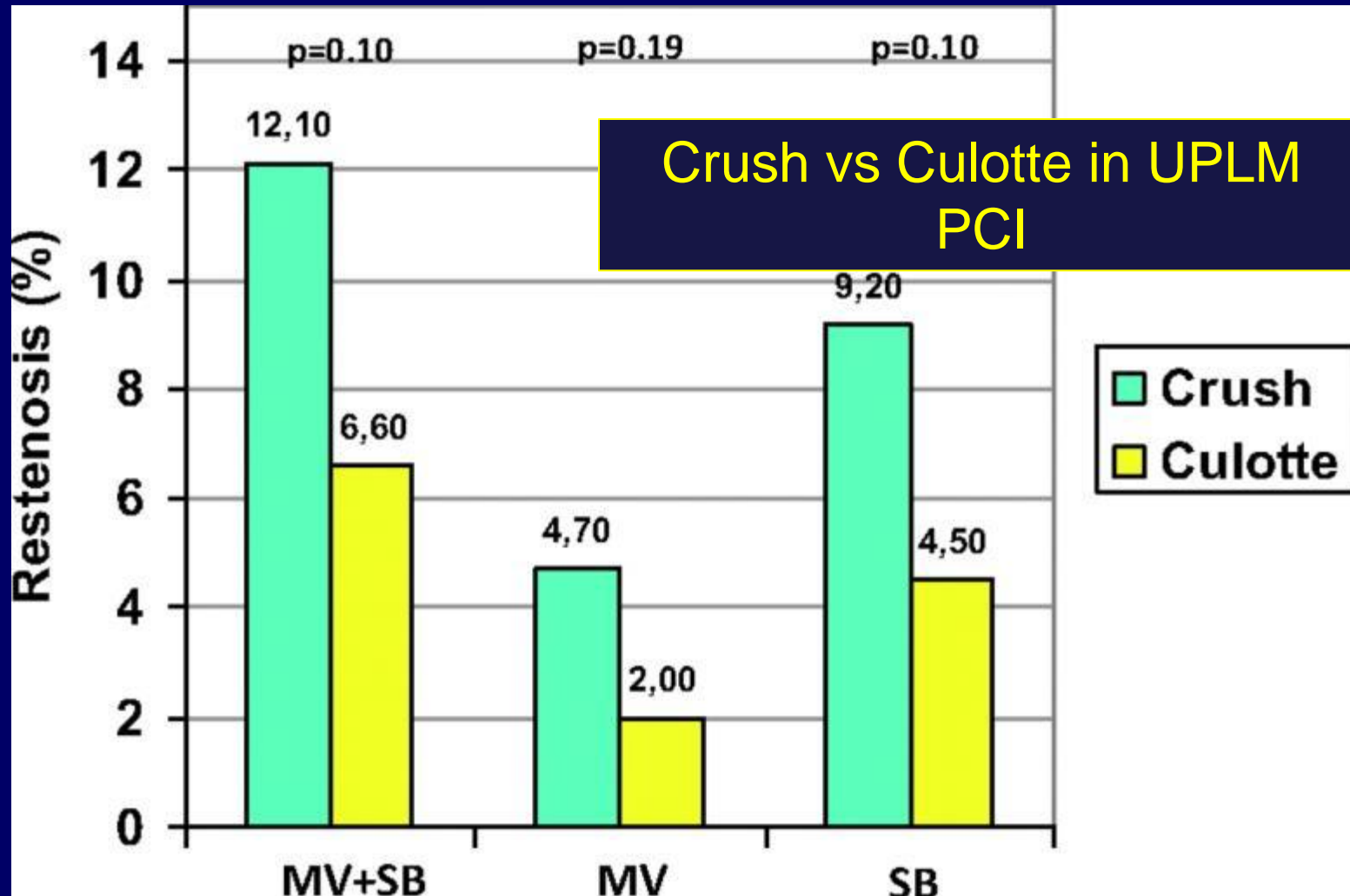
Step-by-Step Handbook

Crush, Culotte, SKS : What Do They Have in Common?

In Theory, Full Coverage of the Entire Bifurcation

| |  Crush |  Culotte |  SKS |
|------------|---|--|---|
| Guiding | 7 | 6 | 7 |
| MV Access | +++ | - | +++ |
| SB Access | - | - | +++ |
| Complexity | ++ | +++ | - |
| SB Cover | Mandatory | Provisional | Mandatory |

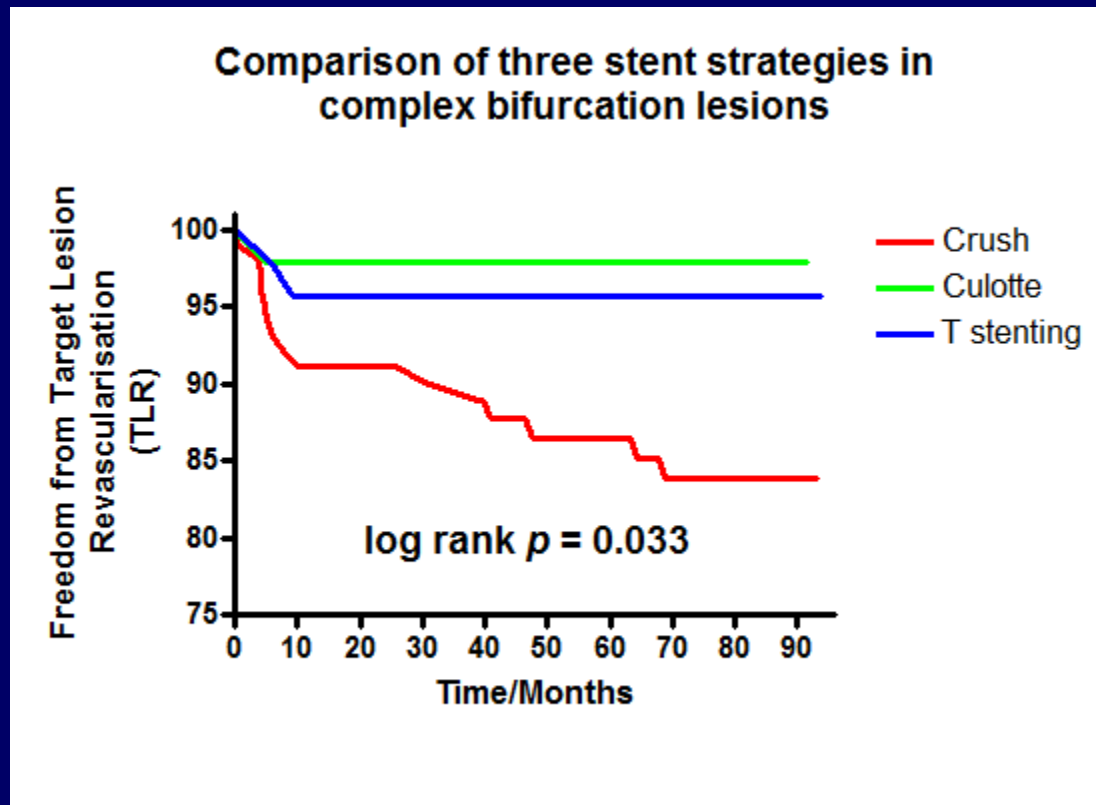
Rates of in-segment restenosis in crush vs culotte-treated bifurcation lesions.



Erglis A et al. *Circ Cardiovasc Interv.* 2009;2:27-34

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Results



DK Crush Technique

Double Kiss and Crush

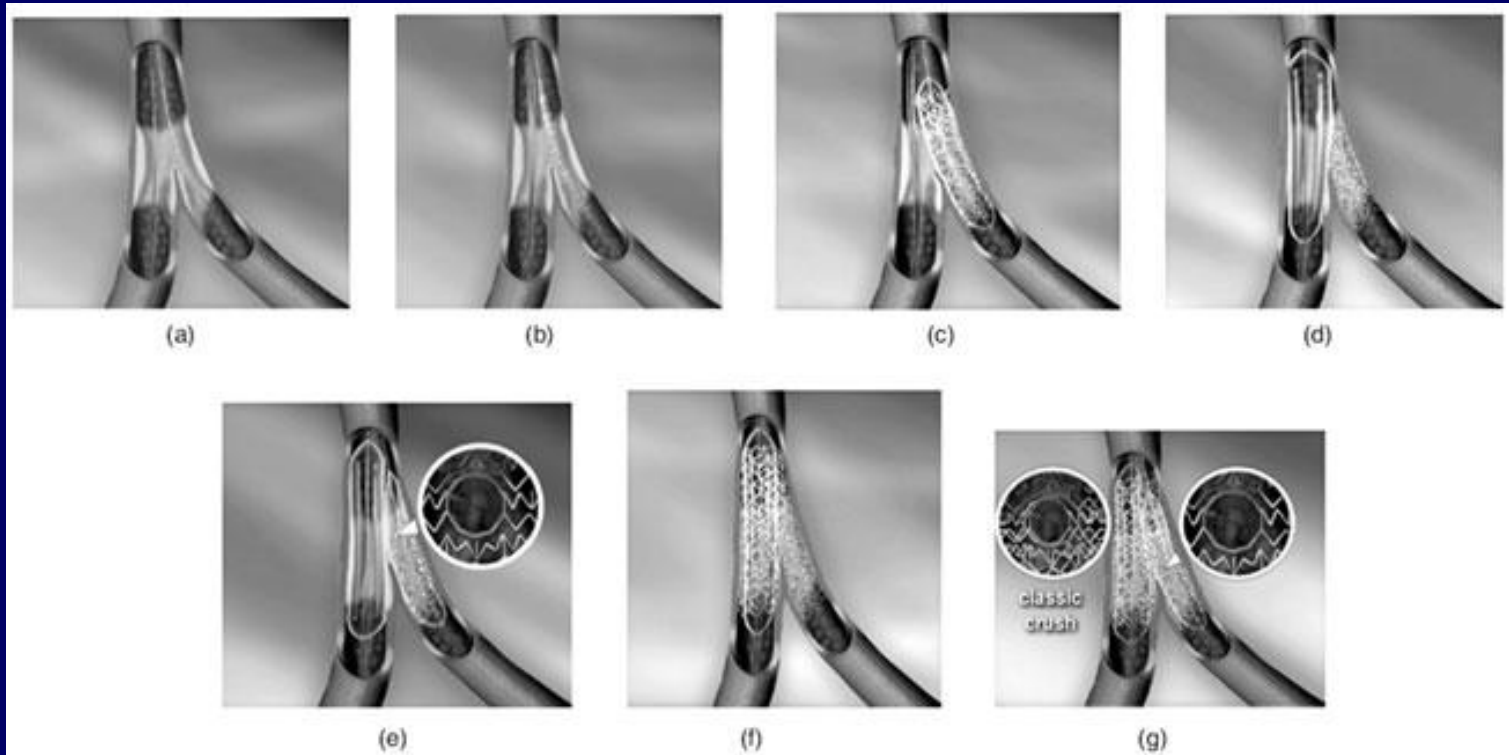


Figure 4. Double kissing (DK) crush technique. Two wires are inserted into two vessels (a). One stent and balloon are advanced into side branch and main vessel simultaneously (b). Inflated side stent firstly (c), then the balloon in the main artery is inflated after removal of stent balloon and wire from side branch (d). First kissing balloon inflation is performed after successful rewiring to side branch (e). Stenting main vessel is underwent (f), with final kissing inflation as the final step (g). The orifice of side branch is relatively largely expanded, compared to classical crush (g).

DKCRUSH studies

Completed

DKCRUSH-I

DKCRUSH-II

DKCRUSH-III

Ongoing

DKCRUSH-V: DK/PT for LMCA

DKCRUSH-VI: FFR-/Angio-SB

DKCRUSH-VII: registry, Post-DES FFR predicts MACE

DKCRUSH-IV: dynamic change of FFR after DK/PT

DKCRUSH studies: Outcomes

| | DKCRUSH-1 Crush vs DK | DKCRUSH-II PT vs DK | DKCRUSH-III Culotte vs DK |
|--------|--------------------------|------------------------|------------------------------|
| MACE,% | 24.4 vs 11.4 | 17.3 vs 10.3 | 16.3 vs 6.2 |
| TLR,% | 18.9 vs 9.0 | 13.0 vs 4.3 | 6.7 vs 2.4 |
| TVR,% | 26.5 vs 10.3 | 14.6 vs 6.5 | 11.0 vs 4.3 |
| CD,% | 1.7 vs 0.6 | 1.1 vs 1.1 | 1.0 vs 1.0 |
| QMI,% | 3.5 vs 1.2 | 2.2 vs 3.2 | 5.3 vs 3.3 |
| ST*, % | 3.0 vs 1.1 | 0.6 vs 2.2 | 1.0 vs 0.5 |

1 or 2 stents?

- A) If the side branch is significantly diseased at its ostium or nearby or if it is sufficiently large to be stented or safety and duration of the PCI are an issue: use 2 stents**
- B) In all other conditions 1 stents and then evaluate**

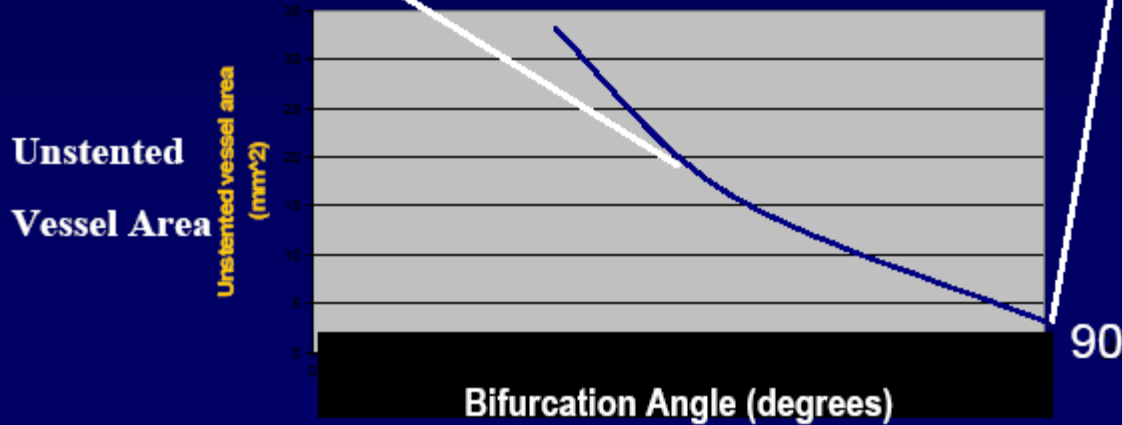
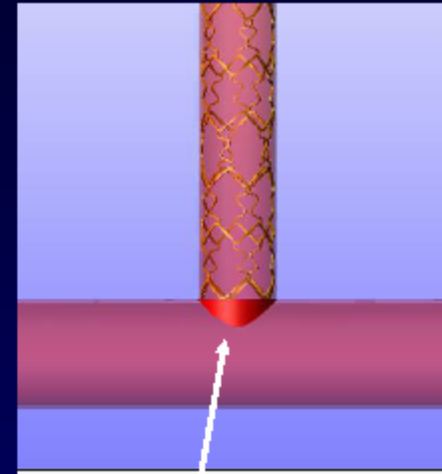
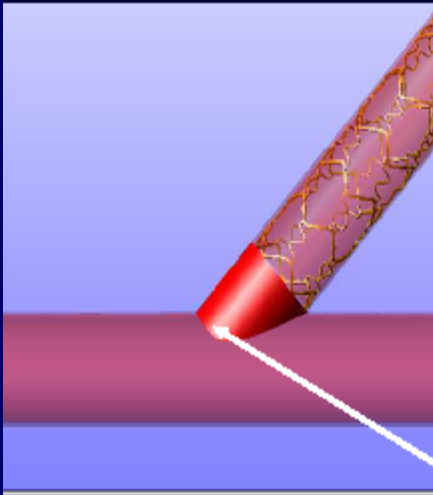
If you are not certain:

In many conditions such as A), you will get an optimal result following 1 stent in the main branch a wire in the side branch will guarantee safety and then you can make your final decision

Suboptimal coverage & Drug delivery

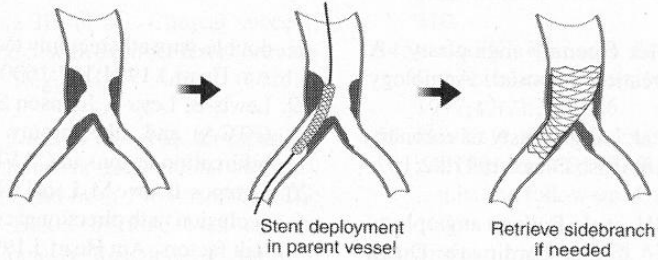
- As bifurcation angle changes from 90°, unstented vessel area increases rapidly with “workhorse stents” unless stents overlap or workhorse struts engage the ostium of side branch

Unstented Vessel area versus Bifurcation angle

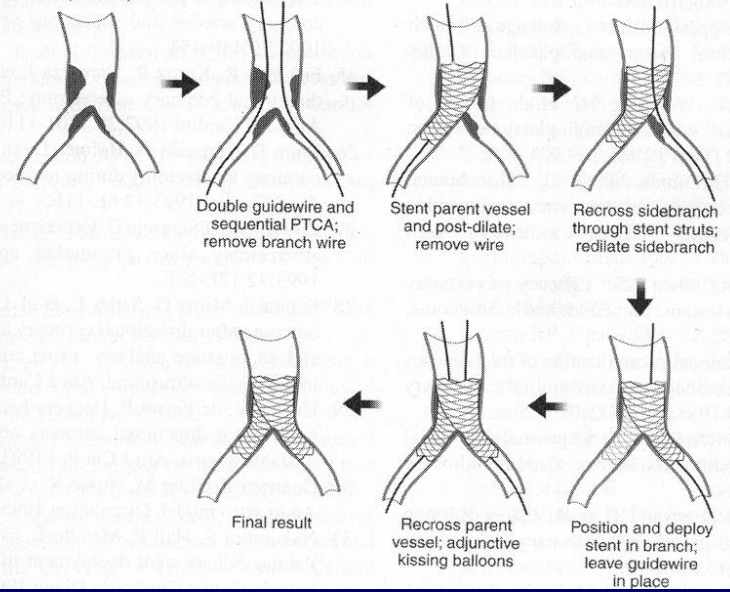


Bifurcation Techniques

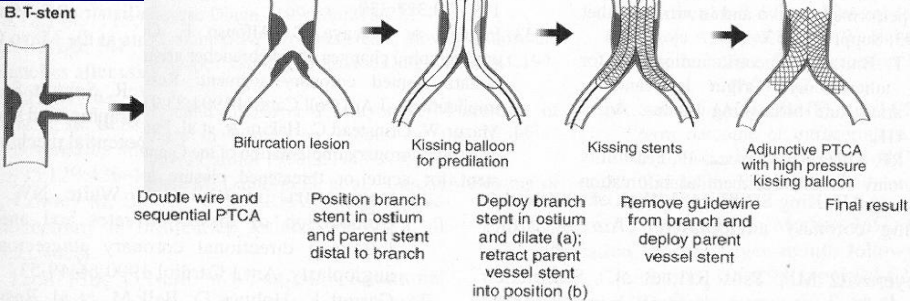
A. Stent-and-Retrieve



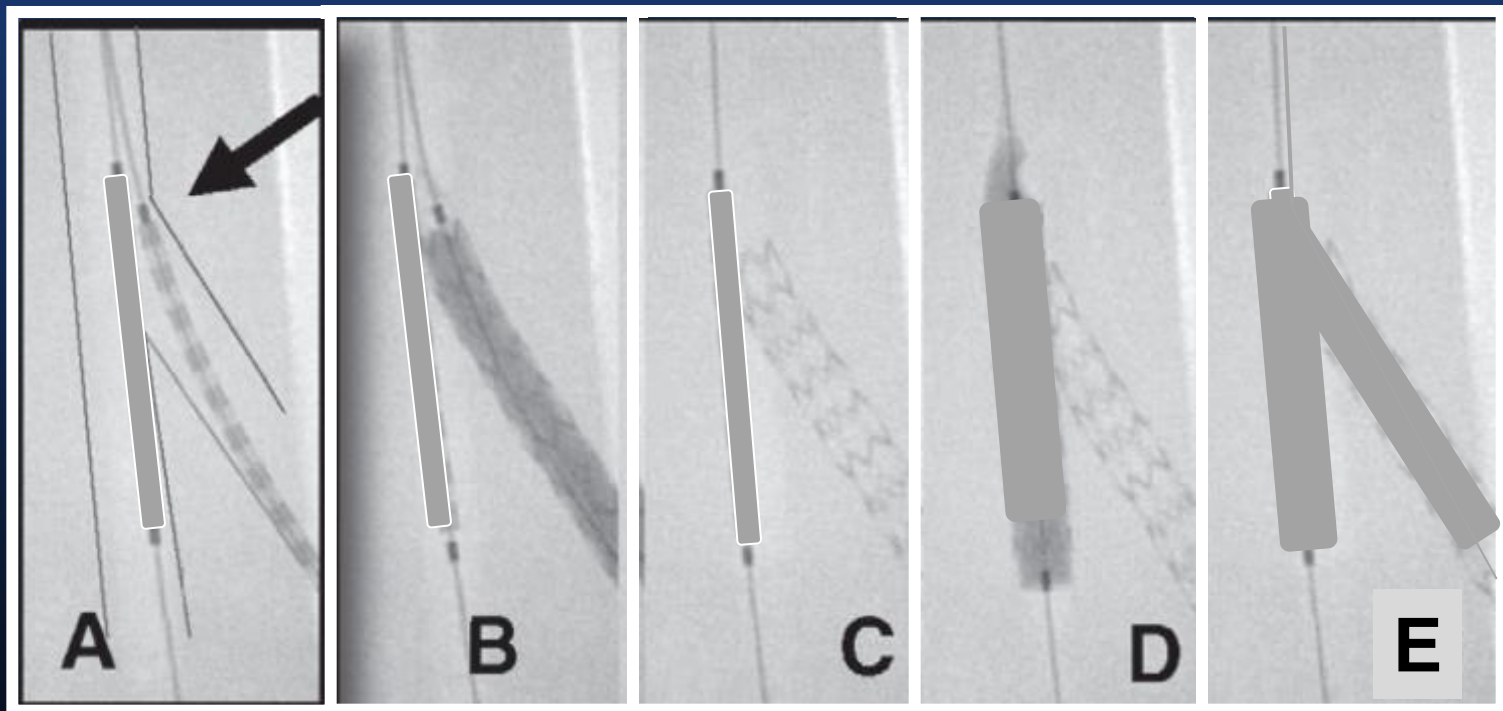
C. Culotte Stent (Y-stent)



D. Kissing Stents

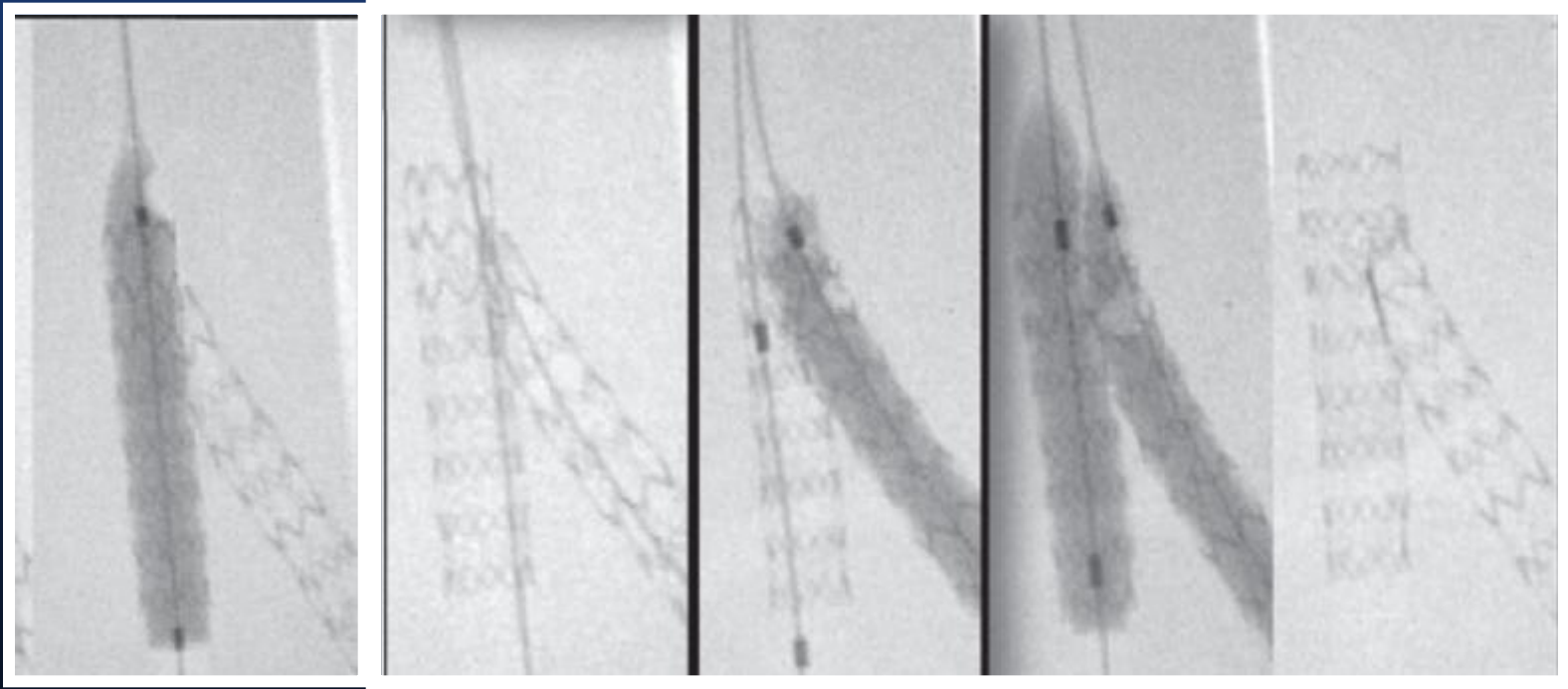


DK Crush Illustration



- **1-2 mm of SB stent positioned in MV (proximal SB stent marker on MB wire or SB just covers proximal edge of ostim)**
- **The SB stent is deployed & stent balloon withdrawn slightly with high RBP inflation (flares proximal stent) – then angiogram to make sure no distal dissection**
- **The SB is crushed by a MV balloon then rewire and kiss (extra kiss)**

DK Crush Illustration



- **Deploy Main Branch Stent**
- **Rewire SB (for 2nd kiss)**
- **SB – high pressure dilatation NC balloon (1st step of kissing balloon inflation)**
- **Final kissing balloon inflation**

Example of Double Kiss Crush

Example of Culotte

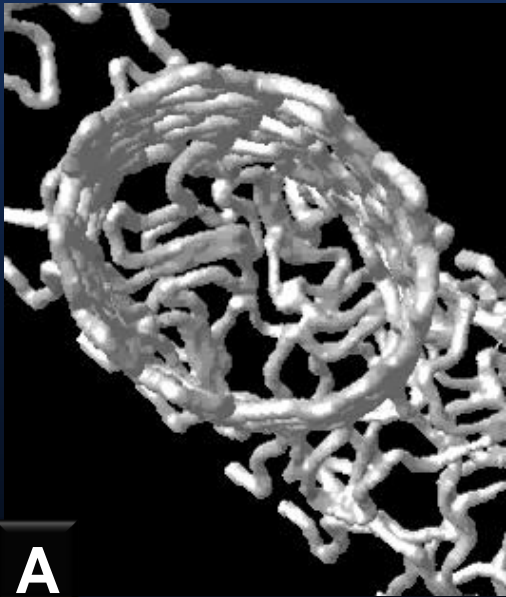
Example of Culotte and Provisional stenting

Example of Culotte with Tryton

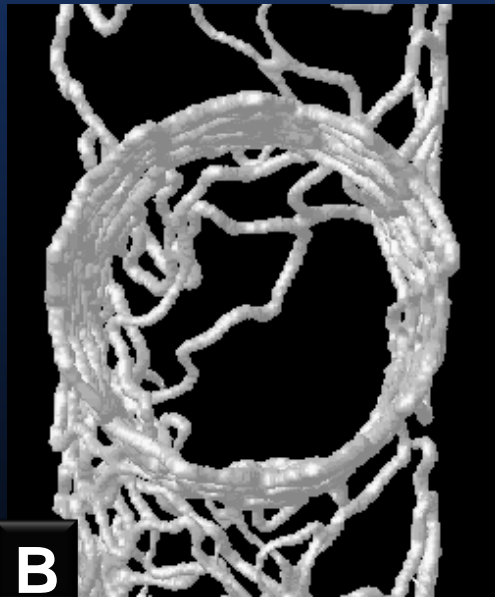
Example of Provisional Stenting

A Second Kiss: Two Step

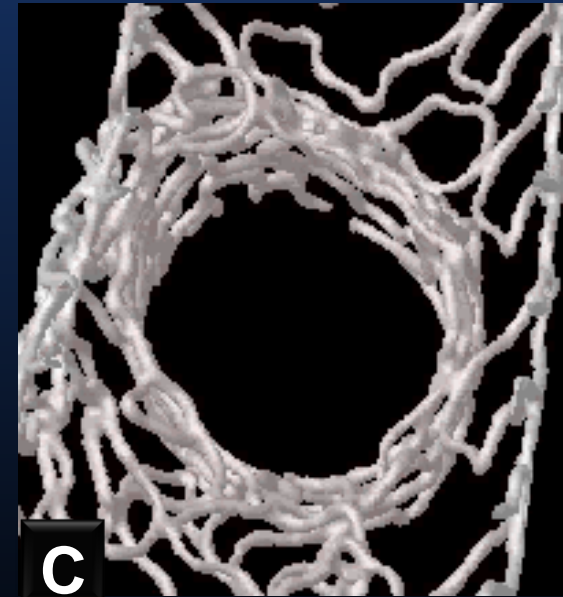
No Kiss



One-step Kiss



Two-step Kiss

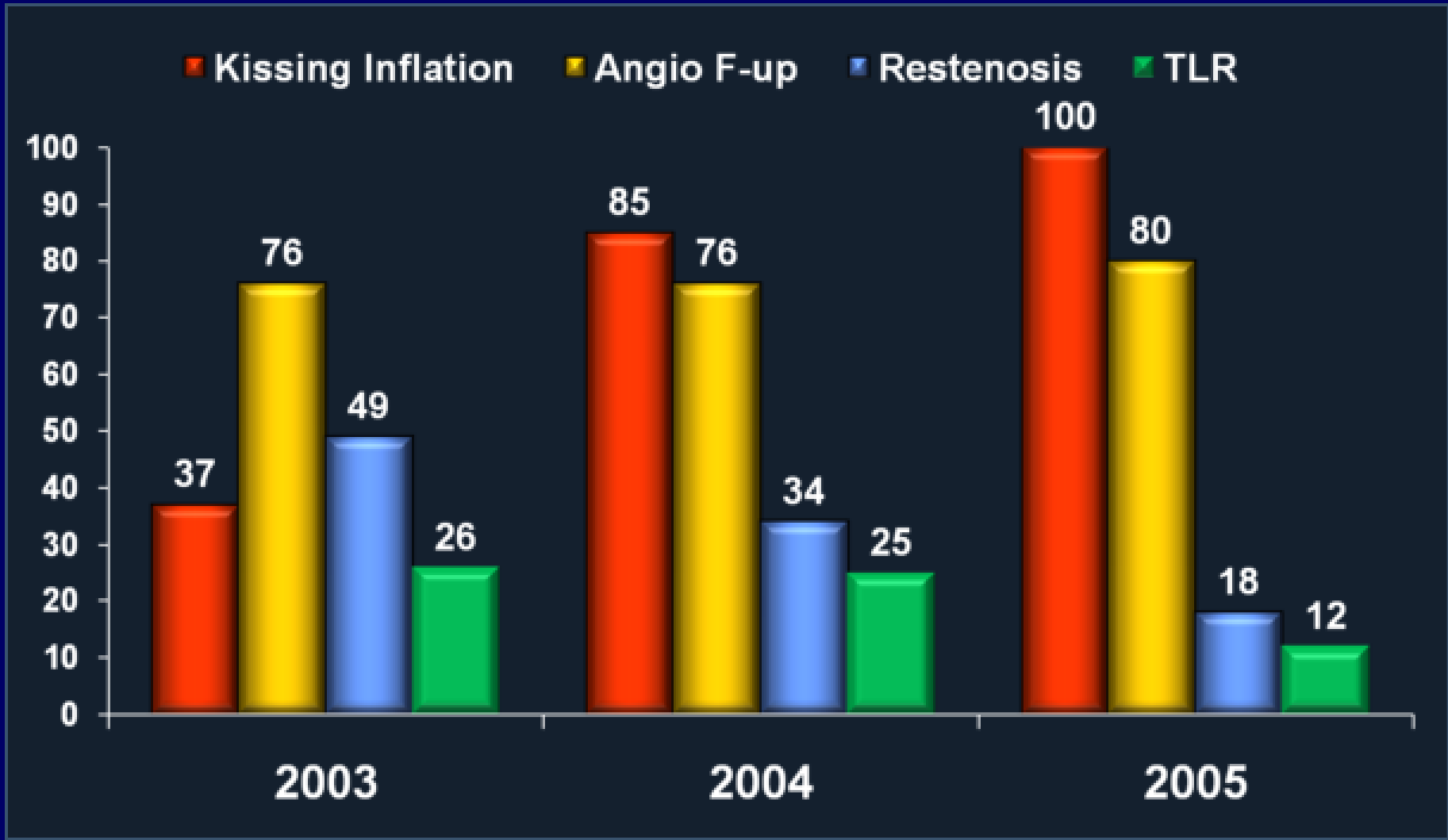


Slide courtesy of John Ormiston

Technical Factors that May be Important in Reducing Restenosis & TLR when 2 Stents Implanted in Bifurcations

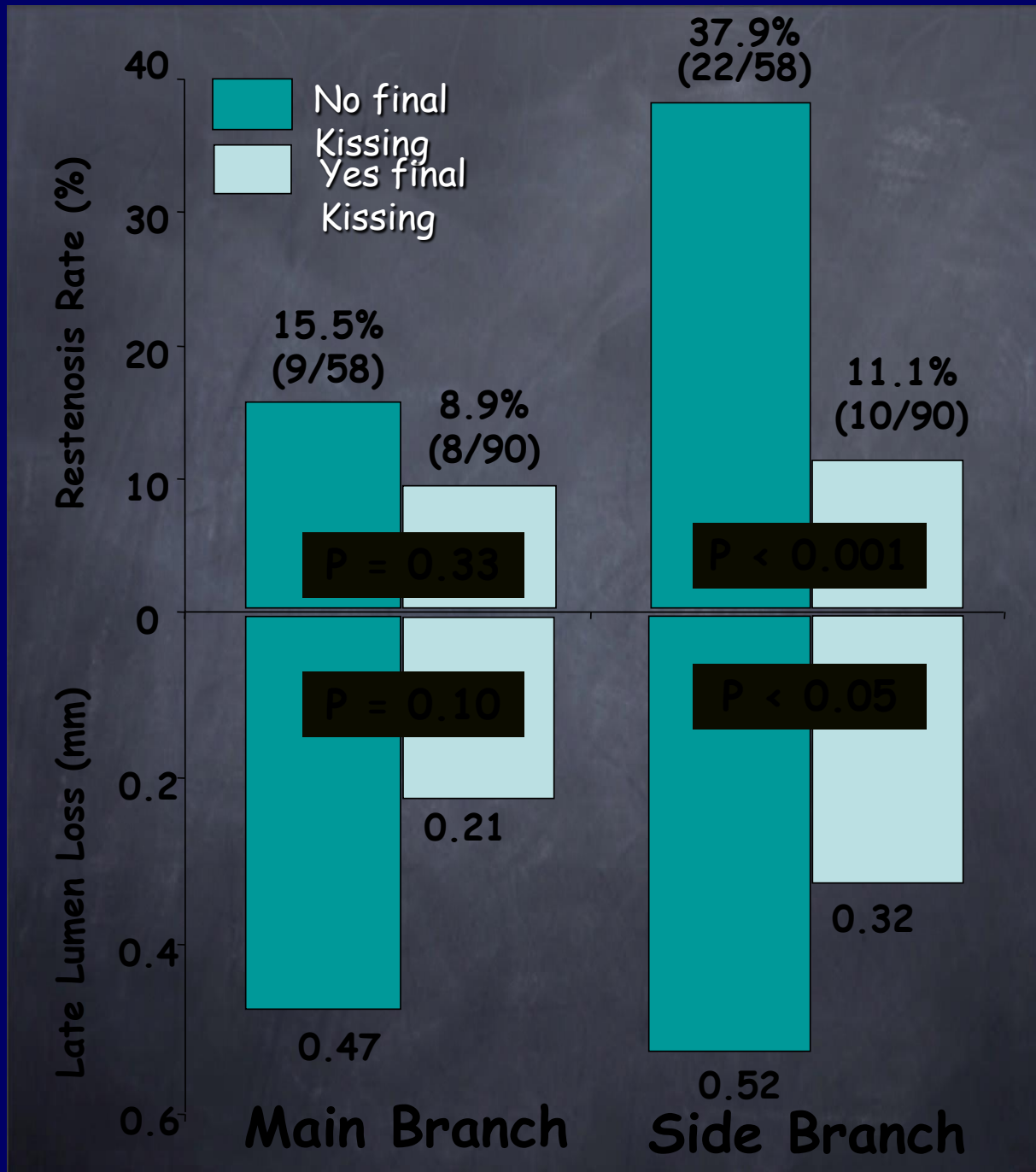
- **High pressure side branch inflation**
- **2-step Kiss: Pre-FKI side branch dilatation**
- **Use of low-compliant balloons**
- **Less protrusion of SB stent into MB (mini-crush)**
- **IVUS-guided stenting**

Optimal Performance of 2 Stent Techniques Important in Reducing Event Rates



Impact of learning curve in Technique; TCT 2006

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

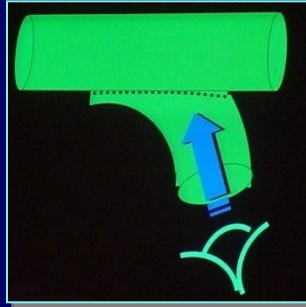


Need for high pressure side branch inflation and kissing



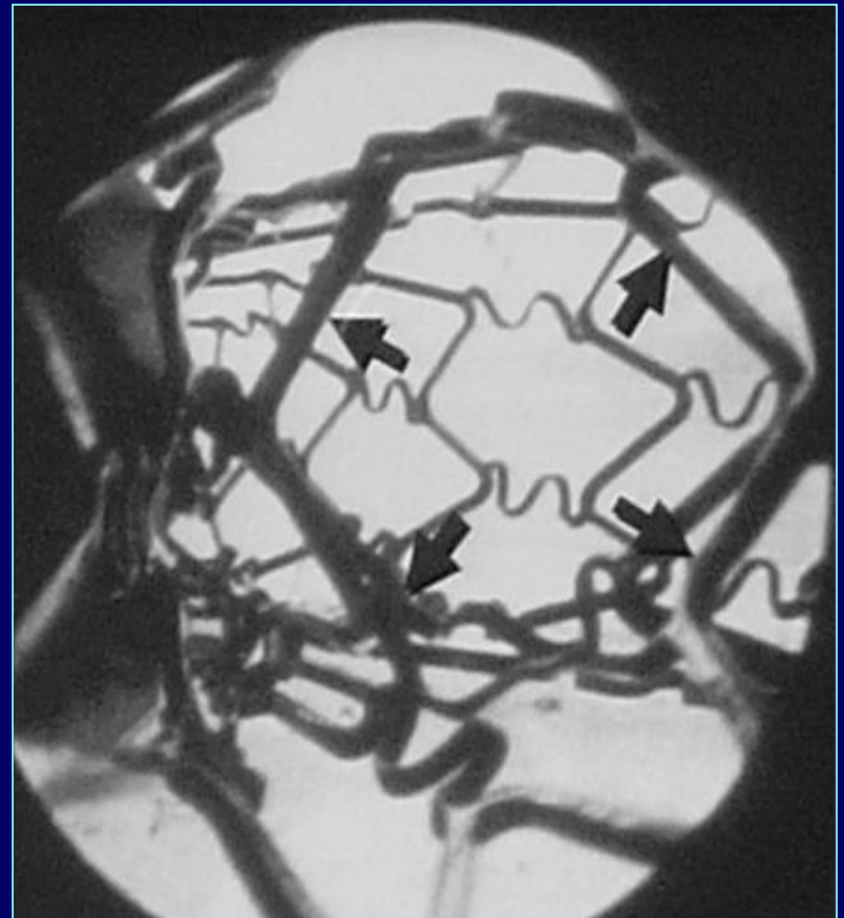
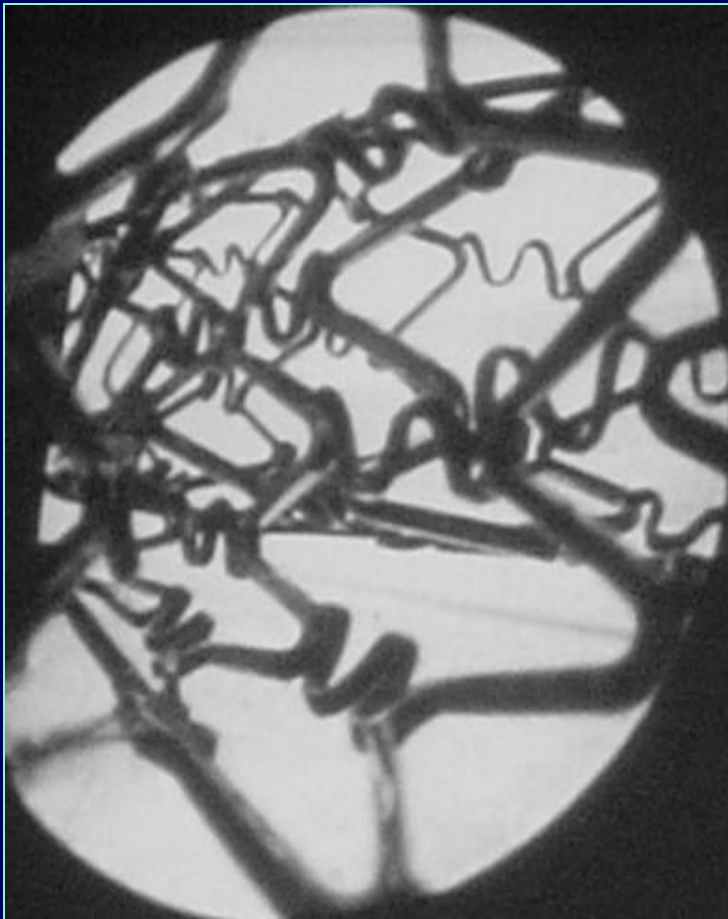
J. Ormiston (Crush)

Treatment of Bifurcational lesions



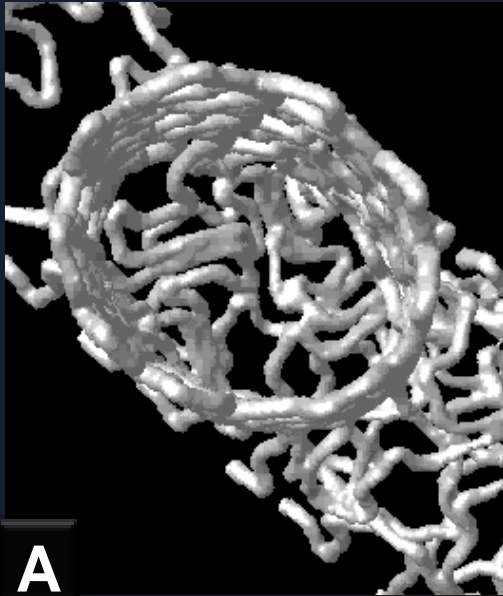
After Crush

After Kissing

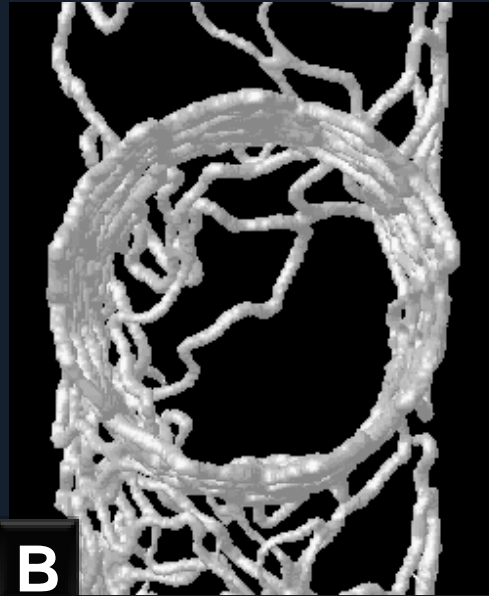


2-Step Kiss

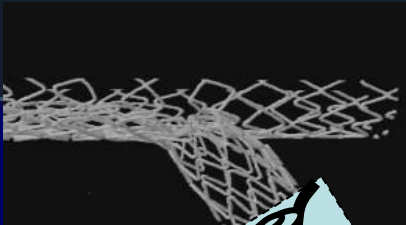
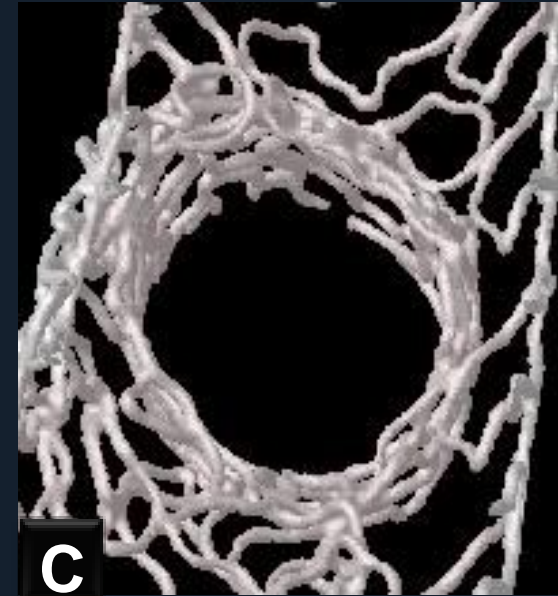
No Kiss



One-step Kiss



Two-step Kiss



Slide courtesy of John Ormiston

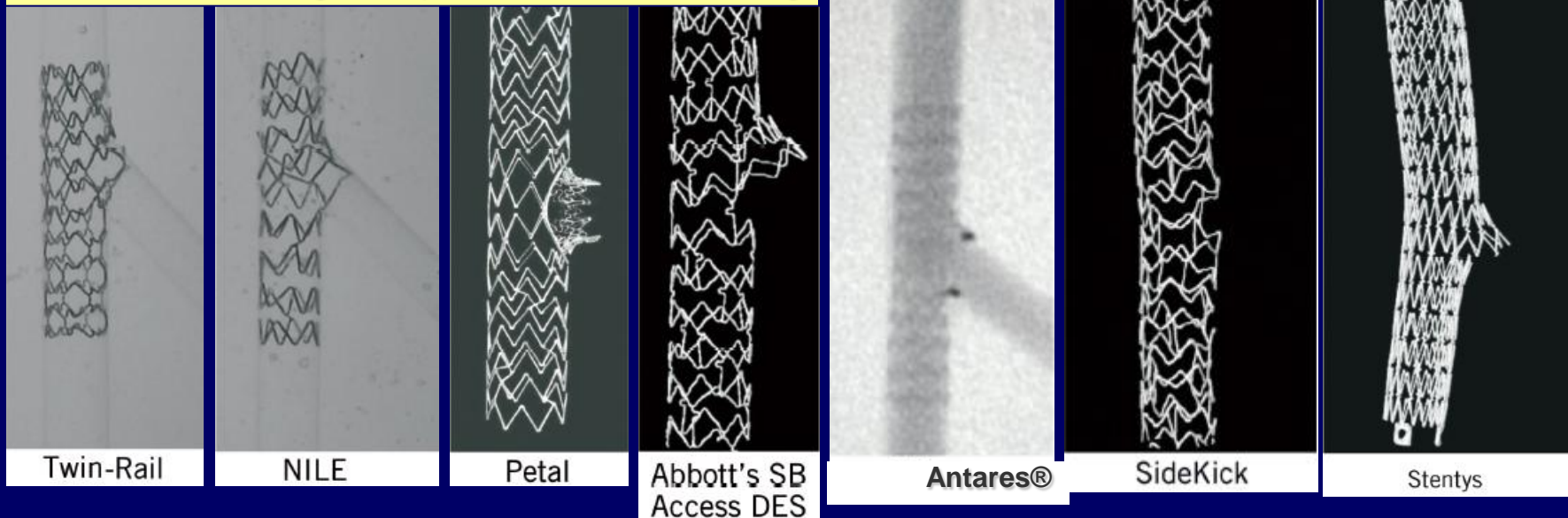
Independent risk factors for major adverse cardiac event and target lesion revascularization (1691 non LM bifurcations)

| | Hazard ratio (95% confidence interval) | <i>P</i> |
|-----------------------------------|---|----------|
| MACE | | |
| Final kissing ballooning | 2.01 (1.29-3.13) | 0.002 |
| Use of paclitaxel-eluting stent | 1.98 (1.34-2.92) | 0.001 |
| Stent length in the main vessel | 1.02 (1.001-1.03) | 0.03 |
| TLR | | |
| Final kissing ballooning | 3.09 (1.84-5.16) | <0.001 |
| Use of paclitaxel-eluting stent | 2.28 (1.45-3.59) | <0.001 |
| Stent length in the main vessel | 1.02 (1.01-1.04) | 0.01 |
| Stent diameter in the main vessel | 0.42 (0.20-0.89) | 0.02 |

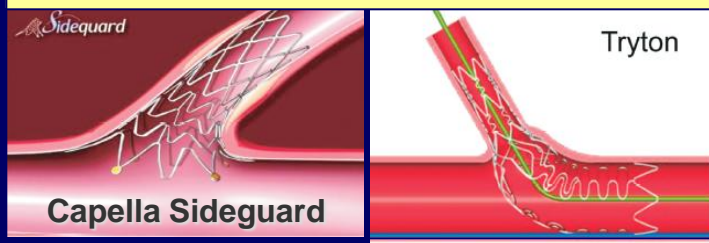
Dedicated Bifurcation Devices

- Dedicated bifurcation stent systems remain limited (EBC)
- Comparative RCTs vs. provisional stenting are lacking (ESC)

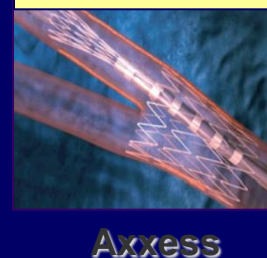
1. MB stenting with provisional SB stenting



2. Side branch stents



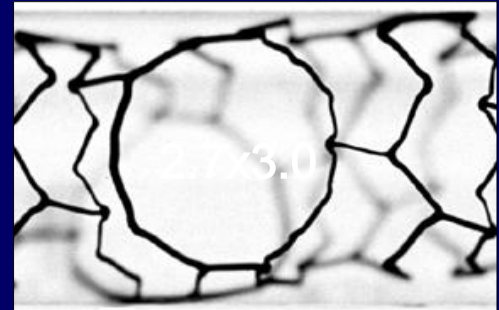
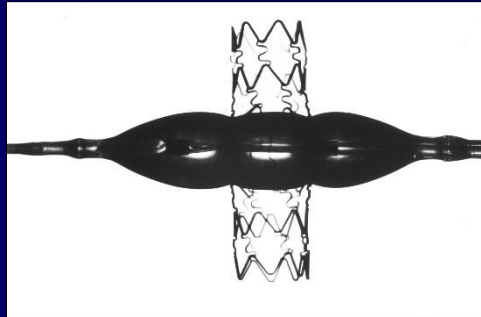
3. Proximal



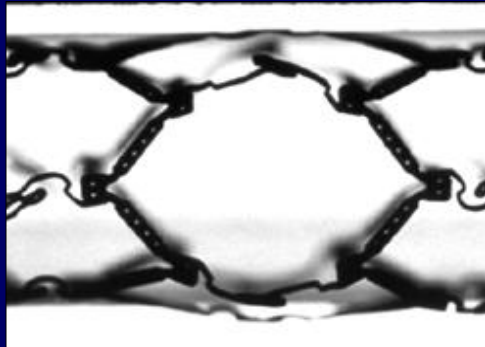
4. Bifurcated stent



Conventional photos
and Cell Size after SB
Dilatation with a 4mm
Balloon



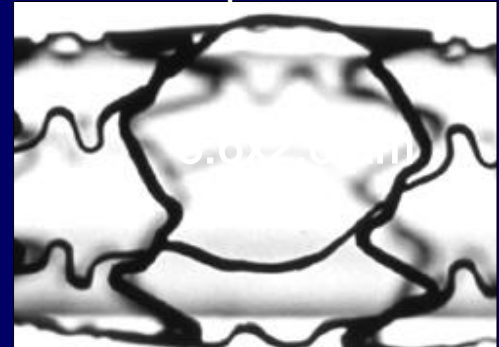
Express



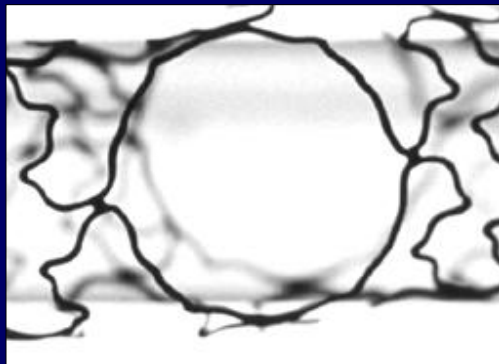
CoStar



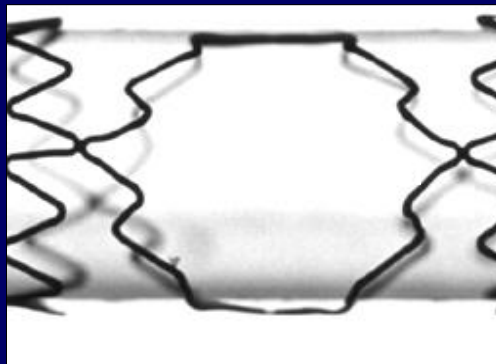
Bx Velocity



Select



Liberte



Driver



Vision

Randomized Trials using DES and Bifurcations

- **1. Compared to historical studies utilizing bare-metal stents, a remarkable improvement has been achieved in the treatment of bifurcation lesions when 1 (MB) or 2 stents (MB and SB) are implanted**
- **2. The side branch seems to be the weak link in the chain in terms of a higher risk of angiographic restenosis (~20%) and a slightly higher risk of thrombosis when 2 stents are implanted (~3.6% at 9 month f/u)**
- **3. When possible, the placement of a single stent on the MB gives a result similar to that obtained with placement of 2 stents**

Iakavou JAMA 2005;293:2126-30

Ge AJC 2005;95:757-760

Pan M AHJ 2004;148:857-864

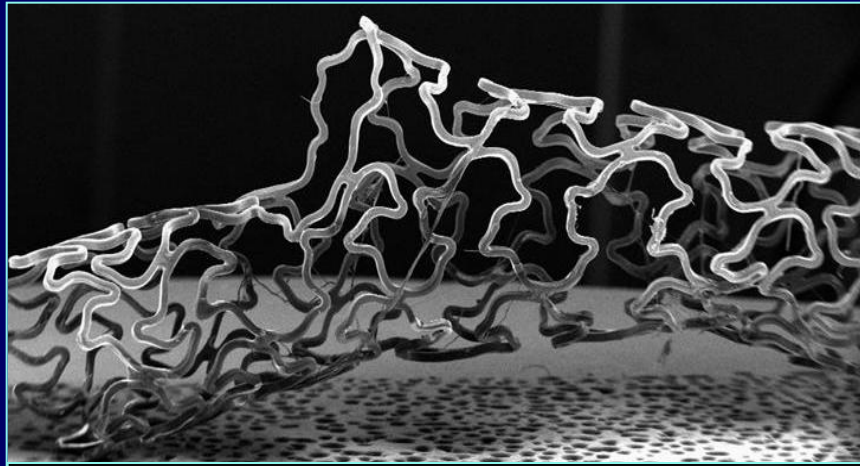
When to Favor a Planned 2 Stent Technique (and Which One)?

Summary

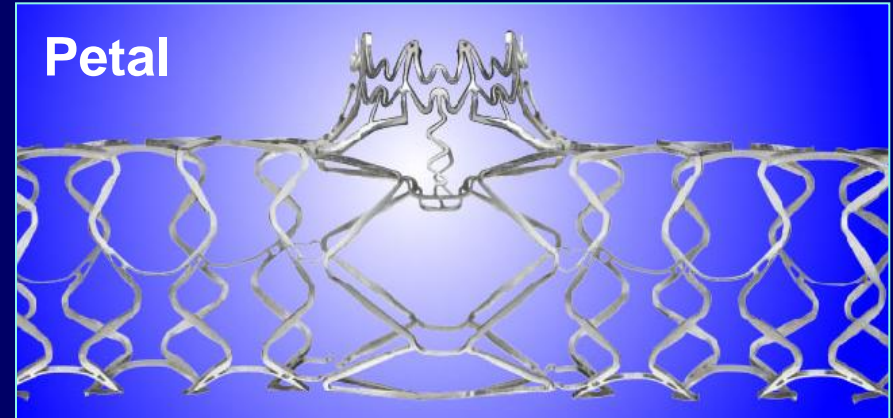
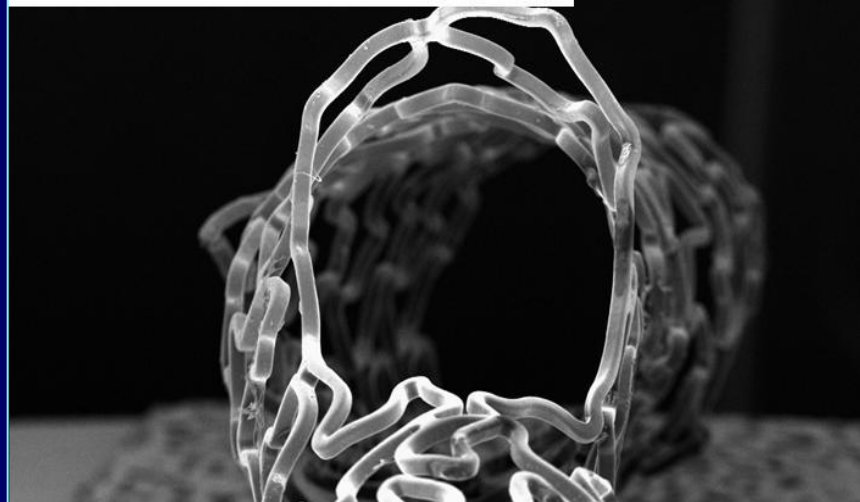
- The goal of PCI in bifurcation lesions is to attain optimal results in the MV and maintain physiologic patency of the SB. Planning of the strategy up front is critical and knowledge of all possible bailout techniques must be kept in mind.
- 4 out of 5 RCTs comparing provisional to 2-stent technique included low-risk bifurcation lesions
- While provisional SB stenting should be the default technique for “low-risk” bifurcations a 2-stent technique may be preferable for “high-risk” or true bifurcations
- Although evidence is lacking as to the superiority of one 2-stent technique versus others its unlikely that any single 2-stent technique would be superior in all bifurcation morphologies. The DK crush technique seems to be most favorable but TAP and Culotte techniques are also excellent options.
- The decision as to which 2-stent technique to use should be driven by bifurcation morphology, operator experience and randomized controlled trials.

Bifurcational Lesion Treatment: BSC Development

Step-by-Step Guide to Crushing, SKS, and More



TAXUS™ Liberté™

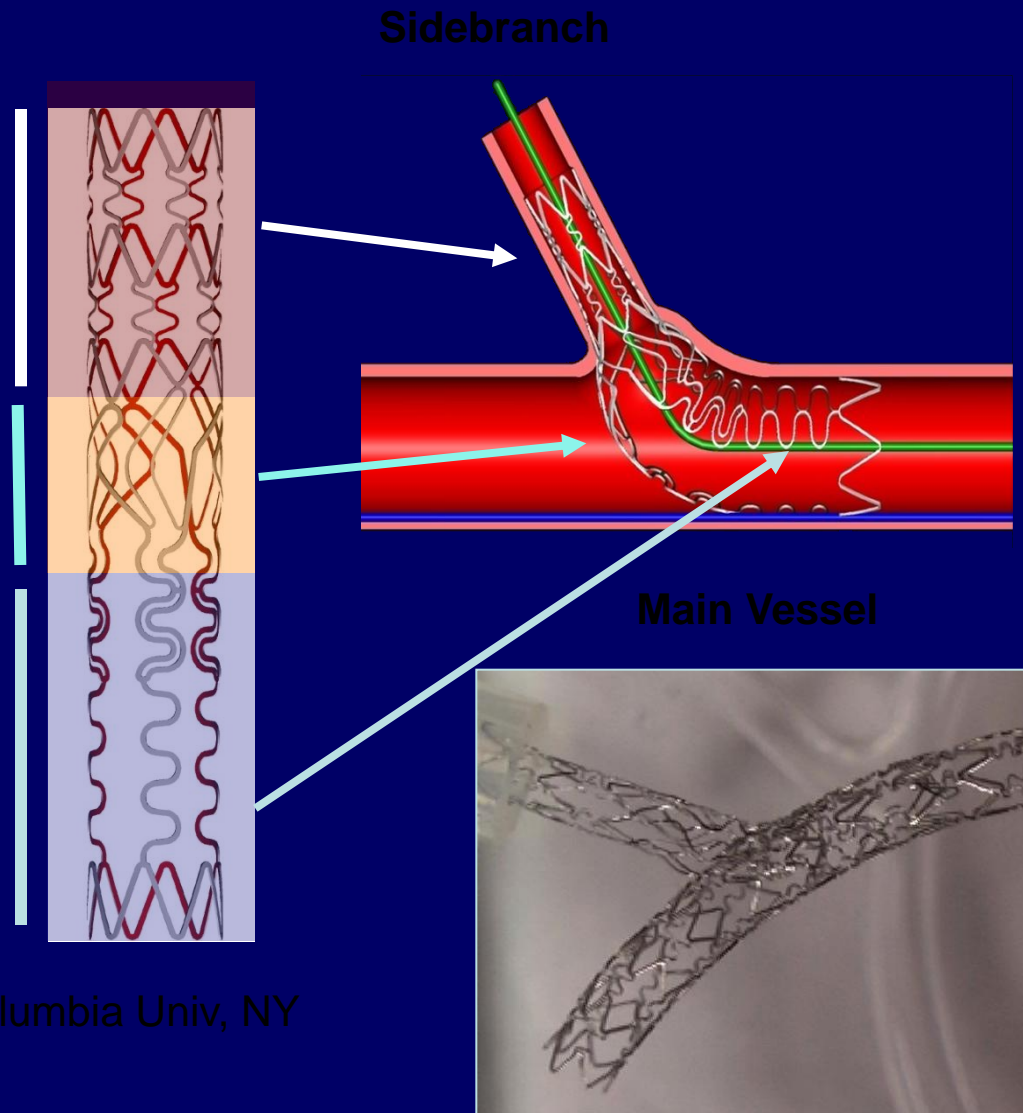


- **Stent Redesign**
 - Platinum enriched radiopaque stainless steel
 - Thinner struts – 0.0032”
 - Reduce strut spacing in mid-portion
- **Translute™ coating with paclitaxel**

Tryton Sidebranch Stent

19 mm Stent

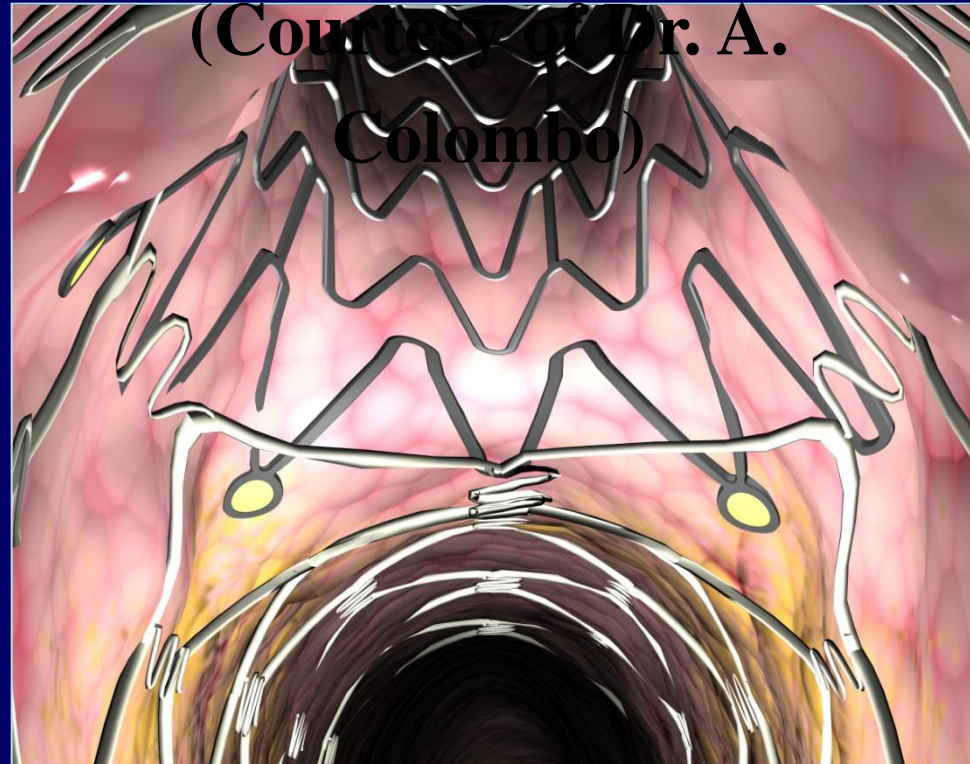
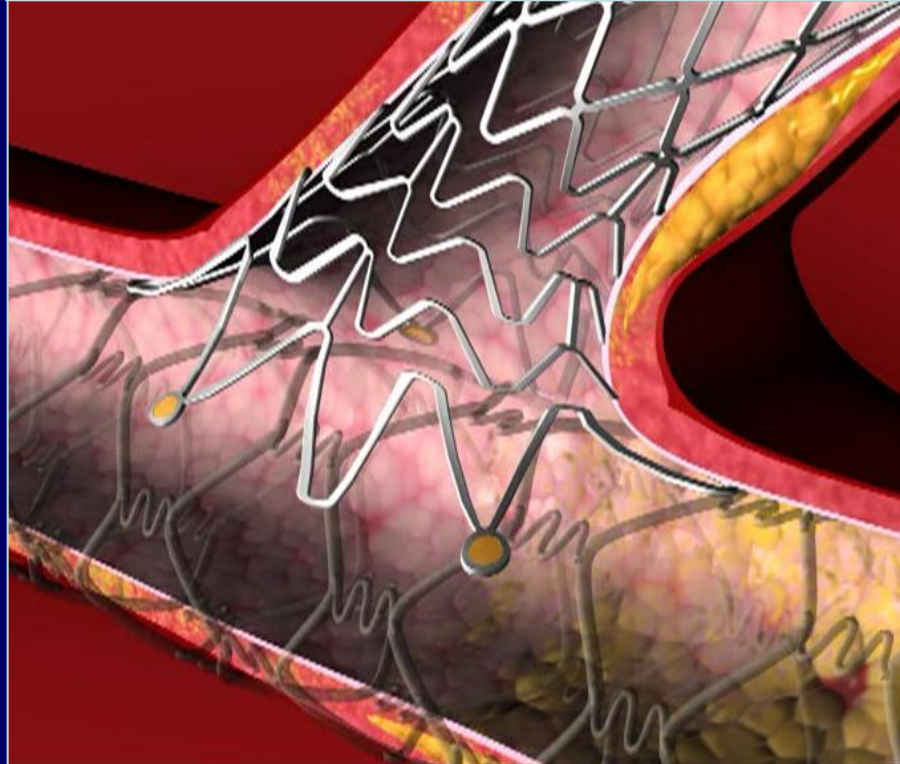
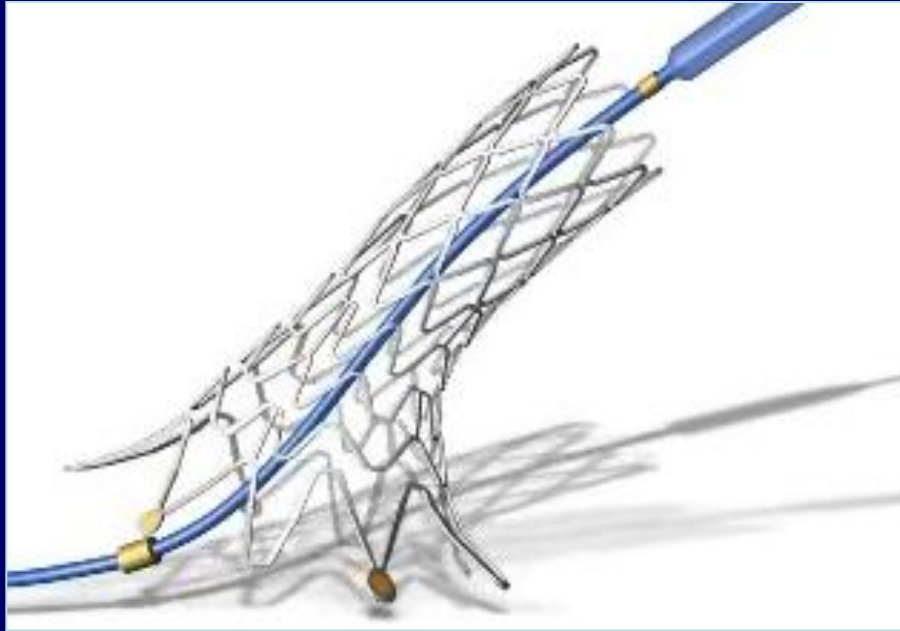
- Side Branch Region
 - Standard stent
- Transition Zone
 - Coverage
 - Hoop strength
- Main Vessel Region
 - 3 fronds
 - Minimal coverage
 - Wedding band



Courtesy of Dr. Aaron Kaplan from Columbia Univ, NY



Dedicated Self-Expanding Stent for Optimal SB Coverage



(Courtesy of Dr. A.
Colombo)

Conclusions

Treatment of bifurcation lesions using DES is feasible with very low immediate angiographic complications. One stent should be the first strategy. When 2 stents are needed, the crush stent or 'Y' stent technique with kissing balloon inflation/deflations or V/SKS stenting should be considered depending on location, size and bifurcation classification. Based on early data the "Y" stent technique seems to be a bit safer with lower TLR in the sidebranch but clearly technically it is more challenging.

In complex bifurcations 2 stents should be used as intention to treat.

Low rates of target vessel revascularization have been observed in the main branch. Thrombosis rates are low but not insignificant (larger number of patients needed to make a statement)

Problem of restenosis at the side branch is improved but not fully resolved