PCI for Bifurcations: What You Need To Know

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Associate Director, Cardiac Catheterization Laboratory
Columbia University Medical Center
Financial Disclosures

• SB: Abbott Vascular, Medtronic, BSc, CSI

• Advisory Boards: Philips, Abbott Vascular, Medtronic
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

Medina et al. Rev. Esp. Cardiol 2006; 59(2): 183-4
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

<table>
<thead>
<tr>
<th></th>
<th>Patients (N)</th>
<th>Randomization</th>
<th>Primary End Point</th>
<th>Outcome (Provisional vs Systematic Unless Otherwise Specified)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NORDIC</td>
<td>413</td>
<td>Provisional vs systematic (crush, culotte, T)</td>
<td>Death, MI (nonprocedural), TVR, or stent thrombosis at 6 mo</td>
<td>2.9% vs 3.4% (P=NS)</td>
</tr>
<tr>
<td>CACTUS</td>
<td>350</td>
<td>Provisional vs systematic (crush)</td>
<td>Death, MI, TVR at 6 mo</td>
<td>15% vs 15.8% (P=NS)</td>
</tr>
<tr>
<td>BBC ONE</td>
<td>500</td>
<td>Provisional vs systematic (crush, culotte)</td>
<td>Death, MI, TVF at 9 mo</td>
<td>8.0% vs 15.2% (P&lt;0.05)</td>
</tr>
<tr>
<td>Ference et al.</td>
<td>202</td>
<td>Provisional vs systematic (T)</td>
<td>Death, MI, TVF at 9 mo</td>
<td>23.0% vs 27.7% (P=NS)</td>
</tr>
<tr>
<td>Colombo et al.</td>
<td>85</td>
<td>Provisional vs systematic (crush, T, culotte)</td>
<td>Angiographic restenosis (either branch) 9 mo</td>
<td>18.7% vs 28.0% (P=NS)</td>
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<tr>
<td>Pan et al.</td>
<td>91</td>
<td>Provisional vs systematic (T)</td>
<td>Angiographic restenosis (either branch) 6 mo</td>
<td>7% vs 25% (P=NS)</td>
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<tr>
<td>NORDIC 2</td>
<td>424</td>
<td>Systematic (crush vs culotte)</td>
<td>Death, MI (nonprocedural), TVR, or stent thrombosis at 6 mo</td>
<td>Crush 4.3% vs culotte 3.7% (P=NS)</td>
</tr>
</tbody>
</table>
**Meta-Analysis of 12 Major Studies, 6961 Patients**

*(5 RCTs and 7 observational studies)*

**Provisional Single-Stenting is Better**

### DES Thrombosis

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>DDS</th>
<th>SDS</th>
<th>DDS better</th>
<th>SDS better</th>
<th>Weight*</th>
<th>RR (random)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RANDOMIZED, CONTROLLED TRIALS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NORDIC</td>
<td>2008</td>
<td>1/196</td>
<td>2/199</td>
<td></td>
<td></td>
<td>5.37%</td>
<td>0.50 (0.04–5.55)</td>
<td></td>
</tr>
<tr>
<td>Ferenc et al.</td>
<td>2008</td>
<td>2/101</td>
<td>1/101</td>
<td></td>
<td></td>
<td>5.40%</td>
<td>2.00 (0.18–21.71)</td>
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<tr>
<td>CACTUS</td>
<td>2009</td>
<td>3/177</td>
<td>2/173</td>
<td></td>
<td></td>
<td>9.73%</td>
<td>1.46 (0.24–8.66)</td>
<td></td>
</tr>
<tr>
<td>BBC-ONE</td>
<td>2010</td>
<td>5/249</td>
<td>1/248</td>
<td></td>
<td></td>
<td>6.71%</td>
<td>4.37 (0.58–42.31)</td>
<td></td>
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<tr>
<td>DK-CRUSH-II</td>
<td>2011</td>
<td>4/185</td>
<td>1/185</td>
<td></td>
<td></td>
<td>0.45%</td>
<td>4.30 (0.45–35.44)</td>
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</tr>
<tr>
<td><strong>META-ANALYSIS</strong></td>
<td>15/908</td>
<td>7/906</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>2.01 (0.77–5.23)</strong></td>
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</table>

**Myocardial Infarction**

<table>
<thead>
<tr>
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<tr>
<td><strong>META-ANALYSIS</strong></td>
<td>94/908</td>
<td>49/906</td>
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<td></td>
<td><strong>1.88 (1.35–2.62)</strong></td>
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</tbody>
</table>

**Non-randomized, observational studies**

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<td><strong>NON-RANDOMIZED, OBSERVATIONAL STUDIES</strong></td>
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<td>0/38</td>
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<td>3.66%</td>
<td>3.19 (0.17–57.92)</td>
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<tr>
<td>ARTS II</td>
<td>2007</td>
<td>1/81</td>
<td>4/263</td>
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<td>6.50%</td>
<td>1.37 (0.12–9.47)</td>
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<td>COBIS</td>
<td>2010</td>
<td>2/292</td>
<td>9/1376</td>
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<td></td>
<td>13.17%</td>
<td>1.34 (0.22–4.82)</td>
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<td>J-CYPHER</td>
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<td>3/203</td>
<td>10/1870</td>
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<td>2/263</td>
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<td></td>
<td>11.12%</td>
<td>14.21 (2.69–74.92)</td>
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<tr>
<td>Assali et al.</td>
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<tr>
<td><strong>META-ANALYSIS</strong></td>
<td>19/960</td>
<td>27/4187</td>
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<td><strong>2.55 (1.13–5.78)</strong></td>
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<td><strong>META-ANALYSIS</strong></td>
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<td>93/4187</td>
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<td><strong>1.85 (1.03–3.32)</strong></td>
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**Meta-analysis**

<table>
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<tr>
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<tr>
<td><strong>META-ANALYSIS</strong></td>
<td>100%</td>
<td>1.86 (1.34–2.60)</td>
<td></td>
</tr>
</tbody>
</table>

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Zimarino et al. J Am Coll Cardiol Intv 2013;6:687–95
Another Meta-Analysis of 9 RCT, 2569 Patients

2 Stent Techniques Are Also Good!

**Main vessel Restenosis**

**SB Restenosis**

**TLR**

**TVR**
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.
Nordic Bifurcation Study- 10 Year RESULTS

413 patients randomized

207 patients
Stenting main vessel
MV

206 patients
Stenting main vessel and side branch
MV+SB

6/8/60 months clinical/angiographic follow-up

120 months clinical follow-up
405 patients (98%)

MV
203 patients
MORTALITY 16.3 %

MV+SB
202 patients
MORTALITY 21.3 %

P=0.19
An Important Principle of IVUS Imaging
Direct Imaging of Both Parent & Daughter Vessel

Indirect LAD imaging

Direct LAD imaging

Tangential Imaging
Diagonal
LAD

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

Cumulative Mortality (%)

Angiography-guidance

IVUS-guidance

$P = 0.048$

16.0%

4.4%

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!
When the SB has ostial or diffuse disease AND when the SB is *not suitable* (too small) for stenting or clinically not relevant

- 6 Fr guiding catheter
  1. Wire both branches
  2. Dilate MB if needed
  3. Stent MB and leave wire in the SB
  4. Post-dilatation of MB with jailed wire in SB

Do not re-wire SB or post or predilate SB
When SB has minimal disease or only at the ostium AND when SB is suitable for stenting

- **6 Fr guiding catheter**
  1. Wire both branches
  2. Dilate MB and SB if needed
  3. Stent MB leaving a wire in the SB
  4. Re-wire SB and then remove jailed wire
  5. Kissing balloon inflation – *very important* to ensure optimal MB stent morphology at SB ostium
  6. Stent SB only if suboptimal result (TAP, reverse crush, culotte)
Murray’s law

\[ 3.68 = 0.67 \times (3.0 + 2.5) \]

Finet’s law

\[ D_1 = 0.678 \times (D_2 + D_3) \]

\[ D_1^3 = D_2^3 + D_3^3 \]

(Murray’s law)

Insights from the 2nd meeting of the EBC. EuroIntervention 2007; 3(4): 44.

Proximal Optimisation Technique (POT)

D1 = 0.67 * (D2 + D3)

- 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

Consensus from 5th EBC meeting. EuroIntervention 2010;6(1):34-8
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.

Consensus from 5th EBC meeting. EuroIntervention 2010;6(1):34-8
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.
Optimising SB results in Provisional: Importance of cell recrossing location

Foin et al., Int J. Card. 2013; 168(4):3623-8
Medina Classification

1,0,0  1,1,0  0,1,0  Lesions
Case

75 year-old female presented to the E.R. with increasing dyspnea over two weeks and is admitted with a NSTEMI and pulmonary edema.
MEDINA 1,1,0
Jailed Side Branches

Angiographic severity ≠ Functional significance

FFR > 0.80

Severe stenosis, but no perfusion defect!
Side-Branch Stenosis Functional Significance – FFR

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

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

Koo et al, JACC 2005;46:633-7
Conclusion: FKBD reduced angiographic side branch (re)stenosis, especially in patients with true bifurcation lesions.

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

Provisional Side-Branch Strategies Requiring a Bailout Two Stent Strategy

Proximal cross Culotte

Reverse crush

T

TAP

Courtesy: T. Lefevre, R. Albiero
Provisional Approach - requiring a 2nd stent in the SB

TAP
- Easy to perform
- No recrossing
- Struts protruding into MB

Reverse Crush
- Complete coverage of ostium
- Any anatomy
- Recrossing into SB
- 3 layers of struts

Culotte
- Complete coverage of ostium
- More labourious
- Rewiring both branches
- Double stent layer

Courtesy Dr. Chieffo
Geographic Miss of Side Branch Ostium

Post-Procedure

8 mo F-Up

Real world = GAP

Ideal

Courtesy R. Albiero
The Guidelines
Provisional versus Elective SB stenting

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.

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 reaccess is low.
Can you treat all of these bifurcations in the same way?
True Bifurcation
(significant stenosis on the main and side branches)

- **No**
  - Provisional SB stenting
    - **No**
      - Stent on MB
        - "Keep It Open" for SB
          - **No**
            - Provisional SB stenting
    - **Yes**
      - Is SB suitable for stenting?
        - **No**
          - SB disease is diffuse &/or not localized to within 5 mm from the ostium?
            - **Yes**
              - Elective implantation of two stents (MB and SB)
            - **No**
              - Provisional SB stenting
    - **Yes**
      - Provisional SB stenting
Factors Influencing 2-Stent Approaches

- **Size of SB @ to MB**
  - Important discrepancy: Avoid Culotte
    - T-Stenting
    - Crush/DK-Crush
- **Bifurcation Angle**
  - $>70^\circ$: T-stent, or T and Protrusion (TAP)
  - $<70^\circ$: Culotte, Crush, DK Crush
- **Operator experience and expertise**
- **Life-threatening / Shock presentation**
An approach for bifurcation lesions when using 2 stents as intention to treat

- V-Stent
  - Bifurcation lesion with no disease proximal to the bifurcation or very short left main
  - Pre
  - Post

- T/TAP-Stent
  - Bifurcation lesion with main branch disease extending proximal to the bifurcation and side branch which has origin with about 90° angle
  - Pre
  - Post

- DK-Crush/Culotte
  - Bifurcation lesion with main branch disease extending proximal to the bifurcation and side branch which has origin with < 70° angle
  - Pre
  - Post

Courtesy of A. Colombo
### Table 1. Comparison of 2-stent strategies for complex bifurcation lesion treatment

<table>
<thead>
<tr>
<th></th>
<th>Prov. T</th>
<th>TAP</th>
<th>Culotte</th>
<th>V-SKS</th>
<th>Mini-Crush</th>
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<tr>
<td><strong>Guiding Catheter</strong></td>
<td>5-6</td>
<td>6</td>
<td>6</td>
<td>7</td>
<td>7</td>
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<tr>
<td><strong>Provisional</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Possible</td>
<td>No</td>
<td>No</td>
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<tr>
<td><strong>Access MV</strong></td>
<td>Yes</td>
<td>Protrusion</td>
<td>No</td>
<td>Yes</td>
<td>Protrusion</td>
</tr>
<tr>
<td><strong>Full coverage</strong></td>
<td>Possible</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td><strong>Rewiring</strong></td>
<td>only if needed</td>
<td>Yes</td>
<td>Yes (multiple)</td>
<td>No</td>
<td>Yes (multiple layers)</td>
</tr>
<tr>
<td><strong>Nb Steps</strong></td>
<td>1-5</td>
<td>5</td>
<td>7</td>
<td>1</td>
<td>3 (6 if DKC)</td>
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<tr>
<td><strong>Shallow Angle</strong></td>
<td>Suitable</td>
<td>Not ideal</td>
<td>Suitable</td>
<td>Suitable</td>
<td>Suitable</td>
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<tr>
<td><strong>Wide Angle</strong></td>
<td>Ideal</td>
<td>Suitable</td>
<td>Not ideal</td>
<td>Not ideal</td>
<td>Not above 60°</td>
</tr>
<tr>
<td><strong>Small SB</strong></td>
<td>Ideal</td>
<td>Suitable</td>
<td>Not ideal</td>
<td>Not ideal</td>
<td>Suitable</td>
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<tr>
<td><strong>Limitations</strong></td>
<td>Gap in scaffolding</td>
<td>Protrusion</td>
<td>Multiple rewiring</td>
<td>Neo-carina</td>
<td>Crushed stent layer</td>
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Culotte Technique
Culotte Technique: Step-by-Step

1. Wiring of both MV and SB.

2. Pre-dilatation of MV and/or SB (optional but recommended).

3. Stenting of the MV.

4. Rewiring SB through MV stent and removal of jailed wire.

5. Dilatation of SB through MV stent.

6. Stenting proximal MV and SB through MV stent.

7. Rewiring MV through SB stent.

8. Final kissing balloon inflation.

Typically, the first stent should be placed in the branch with the most angulated entry, whether the MB or SB.

Should not be used if a large difference (≥1.5 mm) in vessel diameter between the MV and SB exists.
2-Step Kiss

No Kiss

One-step Kiss

Two-step Kiss

Slide courtesy of John Ormiston
Culotte Bifurcation Technique

Advantages and limitations

• Full coverage of the bifurcation area (especially the carina and SB ostium)

• 2 layers of metal in the proximal MV

• Multiples steps with necessity of re-wiring SBs twice
1. Wiring of both MV and SB.
2. Pre-dilatation of MV and/or SB (optional but recommended).
3. Stenting of the SB first, with an un-inflated stent (or balloon) positioned in the MV. The proximal end of the SB stent should be several mm in the MV, but the proximal edge of the un-inflated MV stent (or balloon) must be proximal to the proximal edge of the SB stent.
4. SB wire and stent balloon are removed.

5. *Crushing the SB stent with MV stent or balloon inflation* (followed by MV stent).

6. Rewiring the SB through MV stent.

7. High-pressure inflation of SB (optional).

The Many Variations of the Crush Procedure

- **Mini-Crush:** Minimizing the length of SB stent (2-3 mm) in the MB
- **Inverted Crush:** MB stent deployed first and then crushed by the SB stent
- **Reverse Crush:** SB stent stent crushed within the MB stent
- **Modified or Sequential crush:** First stent crushed by a balloon and not by a stent (avoid the need for 2 stents in the guiding at the same time). Allowed 6 Fr radial PCI
- **DK-Crush:** 2-step kissing
Crush Stenting for Bifurcation Lesions

Costa et al.  
JACC 2005;46:599
DK-Crush Technique
Potential Issues with “Classical Crush”

FKBI = 70-80%
KUS (kissing unsatisfactory),
SB wire under the SB stent

Costa et al. JACC 2006
Chen et al. CCI 2011
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)
• 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

c/o J. Hermiller, adapted from Ormiston JACC Intv 2008
What the DK is the Difference?

Chen et al. Chi Med J 2005
Chen et al. JIC 2006
**DKCRUSH studies: Outcomes**

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

c/o S. Chen, from EJCI, JACC, JACC
DK Crush Technique

Predilatate- 2.5/15 mm NC

Predilatate- 3.0/20 mm NC
DK Crush Technique

2.5/28 mm EES DES in D2
DK Crush Technique

3.0/30 mm NC Balloon

Re-wire the diagonal
DK Crush Technique

First of two kissing balloon inflations

Prepared to implant MV stent
3.0/38 EES DES deployed
DK Crush Technique

- Perform POT with appropriate size NC balloon
- Then re-wire the diagonal
DK Crush Technique

2nd two step kissing balloons
DK Crush Summary

• If a 2-stent strategy is needed, the DK Crush provides a viable and data-driven option

• Key Advantages:
  - 6 French compatible (though 7 French is easier)
  - More reliable final kissing inflation
  - Better SB coverage (therefore lower SB restenosis), largely independent of angle

• Remember the extra kiss!
  - For re-crossing: 1st kiss: proximal struts of crushed stent, 2nd kiss: prox/mid struts
Sequential Bifurcations
Sequential Bifurcations
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 non-compliant balloons
- Less protrusion of SB stent into MB (mini-crush)
- IVUS/OCT-guided stenting
Korean Bifurcation Pooled Cohorts
Predictors of TVF in 2-stent strategy

- Treated with 2-stent strategy: N=951

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Adjusted HR*</th>
<th>95% CI</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated bifurcation in LM</td>
<td>2.09</td>
<td>1.43 – 3.03</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>High SYNTAX score &gt;32</td>
<td>2.00</td>
<td>1.28 – 3.14</td>
<td>0.002</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1.41</td>
<td>1.00 – 1.99</td>
<td>0.05</td>
</tr>
<tr>
<td>Second-generation DES</td>
<td>0.26</td>
<td>0.12 – 0.57</td>
<td>0.001</td>
</tr>
<tr>
<td>Non-compliant balloon</td>
<td>0.53</td>
<td>0.36 – 0.79</td>
<td>0.002</td>
</tr>
<tr>
<td>Final kissing ballooning</td>
<td>0.44</td>
<td>0.29 – 0.68</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*Adjusted for age (continuous), acute coronary syndrome as presentation, preprocedural hemoglobin level, pre-procedural creatinine level, bifurcation angle (continuous), multi-vessel coronary disease, transradial approach, intravascular ultrasound, provisional approach, stenting techniques, total stent length in side branch (continuous).

Song PS, Song YB, Gwon HC, JACC CVI 2016
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
   - Twin-Rail
   - NILE
   - Petal
   - Abbott's SB Access DES
   - Antares®
   - SideKick
   - Stentys

2. Side branch stents
   - Capella Sideguard
   - Tryton

3. Proximal
   - Axxess

4. Bifurcated stent
   - Medtronic Y stent

Consensus from 5th EBC meeting. EuroIntervention 2010;6(1):34-8
TRYTON Side Branch Stent

8 mm  Main Branch Zone

4.5 mm  Transition Zone

6.5 mm  Side Branch Zone

Tryton is a Cobalt alloy bare metal stent
Tryton Deployment Sequence

1. Tryton positioned and deployed after pre-dilatation (secures and protects side branch)
2. Main vessel treated with approved DES through main vessel portion of Tryton
3. Kissing balloon post-dilatation to insure complete lesion & ostium coverage
TRYTON Pivotal RCT
Primary Non-Inferiority Endpoint
Not Met

%  
P = 0.11

TVF  Cardiac Death  Target Vessel MI  Clinically Driven TVR
17.4  0  15.1  4.7
12.8  0  10.7  3.6

P = 0.56

Non Hierarchical

Généreux et al. J Am Coll Cardiol 2015;65:533–43
Side Branch %DS (In-segment) Secondary Endpoint

Secondary Superiority Endpoint Met

Provisional: 38.6
Tryton: 31.6

P=0.002

Angiographic Cohort n=326

Généreux et al. J Am Coll Cardiol 2015;65:533–43
Provisional

TRYTON Stent

Event Rate (%)

TVF

OR = 2.42
[1.37, 4.28]

P for interaction = 0.006

Target Vessel MI

OR = 2.34
[1.29, 4.25]

OR = 0.69
[0.35, 1.38]

P for interaction = 0.02

Clinically Driven TVR

OR = 0.81
[0.24, 2.73]

OR = 1.82
[0.66, 5.03]

P for interaction = 0.32

P for interaction = 0.02

Généreux et al. Catheter Cardiovasc Interv. 2015
TRYTON Confirmatory Study

Angiographic Inclusion Criteria: No Change

- Single de novo “true” bifurcation lesion
  - Native coronary artery
  - Medina 1.1.1, 1.0.1, or 0.1.1 by visual estimation
- Symptoms or objective evidence of ischemia
- Vessel diameter:
  - Main branch: $\geq 2.5 \text{ mm and } \leq 4.0 \text{ mm}$;
  - Side branch: $\geq 2.5 \text{ mm and } \leq 3.5 \text{ mm}$
- Lesion length:
  - Main vessel $\leq 28 \text{ mm}$; Side branch $\leq 5 \text{ mm}$
- Multi-vessel disease and staging allowed
  - Enrolment allowed after successful treatment of $\leq 2$ non-complex non-target lesions
TRYTON Confirmatory Study: *Peri-Procedural MI 3x ULN CK-MB*

**Performance Goal: 17.9%**

- **Pivotal Provisional ≥2.25mm:** 11.2%
  - 16/143

- **Confirmatory Study:** 10.5%
  - 14/133

*Primary Endpoint Met*

Error bars represent 1-sided 95% CI.
# TRYTON Confirmatory Study: Resources Utilization

## Randomized Trial

<table>
<thead>
<tr>
<th>Procedure Time (min)</th>
<th>Fluoroscopy Time (min)</th>
<th>Contrast Used (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRYTON (N=133)</td>
<td>64.6±26.2</td>
<td>248.2±85.6</td>
</tr>
<tr>
<td>NORDIC IV 2 stents (n=229)</td>
<td>92.6 min</td>
<td>238 ml</td>
</tr>
<tr>
<td></td>
<td>22.8 min</td>
<td></td>
</tr>
<tr>
<td></td>
<td>238 ml</td>
<td>~10 min more and ~30 ml more contrast</td>
</tr>
</tbody>
</table>

*p <0.001*
# TRYTON Confirmatory Study: Procedural and 30-day Follow-up

<table>
<thead>
<tr>
<th>Endpoints (%)</th>
<th>TRYTON (N=133)</th>
<th>Randomized Trial ≥2.25mm</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Death</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedural</td>
<td>0% (0)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>30 day</td>
<td>0% (0)</td>
<td>0% (0)</td>
</tr>
<tr>
<td><strong>Myocardial Infarction</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedural (3x CKMB)</td>
<td>10.5% (14/133)</td>
<td>9.2% (13/141) 12.1% (17/141)</td>
</tr>
<tr>
<td>Procedural (5x CKMB)</td>
<td>4.5% (7/133)</td>
<td>3.4% (4/118) 6.8% (7/103)</td>
</tr>
<tr>
<td>30 day</td>
<td>10.8% (14/130)*</td>
<td>8.2% (12/146) 11.9% (17/143)*</td>
</tr>
<tr>
<td><strong>Stent Thrombosis</strong></td>
<td>0% (0)</td>
<td>0.7% (1/146) 0.0% (0/143)</td>
</tr>
</tbody>
</table>

*2 patients in Confirmatory study have not completed 30 day follow-up at datalock and 1 patient withdrew at 30 days.*
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 techniques 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.
Bifurcation Stenting - Summary

- 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.