B vs Bench Testing

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BVS and Bifurcation

Background

- Absorb® BVS has been clinically evaluated in simple lesions
- Bifurcation management with BVS remains challenging...
- We need Bench Study!
BVS and Bifurcation

**Background**

- **Bioresorbable Vascular Scaffold Features:**
  - Radiolucent, mechanical performance of Polymer
  - BVS behaviour and result in bifurcation remain unknown
  - Clinical impact of malapposition, struts fractures, side-branch obstruction...

- **BVS Bench Bifurcation study**
  Based on our experience of Bench 2013
  & publication of John Ormiston *(Eurointervention 2014)*
Absorb®: 3.5x28mm (14 atm)
POT: NC Balloon 4.0mm (20 atm)
Kissing: NC Balloon 3.0mm & 2.5mm

Micro-CT 3D rendering
Stent distortion & fracture
BVS and Bifurcation

Absorb everolimus-eluting bioresorbable scaffolds in coronary bifurcations: a bench study of deployment, side branch dilatation and post-dilatation strategies

John A. Ormiston¹,², MBChB; Bruce Webber¹, MSc; Ben Uboh¹, BSN; Mark W.I. Webster¹,², MBChB; Jonathon White², MBChB

- Low inflation pressure
- Small Non Compliant Balloon on the side branch
- Mini Kissing: Snuggle

Ormiston JA, Eurointervention 2014

European Bifurcation Club- Bordeaux 2014
BVS and Bifurcation

Method: Bench

- BVS deployment in aqueous bath at 37°
- Dedicated Translucent silicone phantoms
- Geometric Fractal Law (Finet)
**BVS and Bifurcation**

**Bench A (LAD/Diagonal)**

**Bench B (Left Main)**

### Diameters (mm) & Inflation Pressure

<table>
<thead>
<tr>
<th>Bench</th>
<th>Prox MB</th>
<th>Dist MB</th>
<th>SB</th>
<th>10 atm</th>
<th>12 atm</th>
<th>12 atm</th>
<th>5+5 atm</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAD/Diag</td>
<td>3.5</td>
<td>3.0</td>
<td>2.5</td>
<td><strong>3.0 x 28</strong></td>
<td>3.5</td>
<td>2.5</td>
<td>3.0+2.5</td>
</tr>
<tr>
<td>Left Main</td>
<td>4.2</td>
<td>3.5</td>
<td>3.0</td>
<td><strong>3.5 x 28</strong></td>
<td>4.0</td>
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**BVS and Bifurcation**

**Method: Stenting**

- Slow BVS deployment, different strategies

| Strategy 1: BVS + POT + Side Opening + Final POT = | PSP |
| Strategy 2: BVS + POT + **Snuggle Kissing** + Final POT = | PKP |

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**One Stent**

| Strategy 3: BVS + POT + **Snuggle Kissing** + T stenting = | PKP+T |
| Strategy 4: BVS side + BVS main + POT + **Snuggle Kissing** = | MiniCrush |
| Strategy 5: BVS side + BVS Main + **Snuggle Kissing** + POT = | Culotte |

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**Two Stents**

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*European Bifurcation Club- Bordeaux 2014*
BVS and Bifurcation

Method: Stenting

16 Bifurcations Strategies
- Example of PKP in Bench A

Bench A | Bench B
---|---
PSP | 1 | 2 | 1 | 2
PKP | 1 | 2 | 1 | 2 | 3
PKP+T | 1 | 1
Crush | 1 | 2 | 1 | 2
Culotte | 1

POT
- BVS 3.0x28mm
  - 10 atm

Snuggle Kissing
- NCB 3.5mm
  - 12 atm
- NCB 2.5mm & 3.0mm
  - 5 atm

Final POT
- NCB 3.5mm
  - 12 atm

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BVS and Bifurcation

**OCT assessment**

OFDI, Lunawave TERUMO® System
Pullback speed = 10mm/s

- P (Prox)
- B (Bif)
- D (Dist)

OCT criteria: area and diameter measurements of lumen and BVS, stent deployment, stent apposition, struts fractures...

**Micro-CT assessment**

3D rendering, qualitative assessment
BVS and Bifurcation

Results:
Distal Segment

- Final results: excellent
- Perfect apposition
- No stent distortion
- No strut fracture

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<td>PSP</td>
<td>1 2 1</td>
<td>1 2</td>
</tr>
<tr>
<td>PKP</td>
<td>1 2 1</td>
<td>1 2 3</td>
</tr>
<tr>
<td>PKP+T</td>
<td>1 1</td>
<td></td>
</tr>
<tr>
<td>Crush</td>
<td>1 2 1</td>
<td>1 2</td>
</tr>
<tr>
<td>Culotte</td>
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BVS and Bifurcation

**Results:**

- Final results: excellent
- No stent distortion
- No strut fracture
- POT is safe & mandatory

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**BVS and Bifurcation**

**Results:** Bifurcation Segment

« Heterogeneous Results »

- Apposition
- Side Opening
- Protrusion
- Lumen Obstruction
- Strut Fracture

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**One stent**

**Two stents**

*European Bifurcation Club- Bordeaux 2014*
**PSP (POT, Side opening, final POT)**

- Simplest strategy
- Soft strategy: no fracture (small NCB Ø: 2.5mm, low pressure: 5atm)
- Good result on Main Branch

*Micro-CT, P. Pilet, P. Guérin*
Excellent correlation Micro-CT/OFDI
OFDI provides BVS assessment Step by Step.

- **Distortion**
- **Malapposition**

**BVS distortion after Side Opening**
PSP (POT, Side opening, final POT)

- Final POT is mandatory to correct BVS distorsion induced by Side opening

Impact of Final POT on BVS distorsion
**PSP (POT, Side opening, final POT)**

- Sub-optimal Side ostium scaffolding

bench defect? inelasticity of BVS? low angle?

Bench A  

Bench B
PKP (POT, Kissing, final POT)

- Final result very similar to PSP
- Good result on Main branch
PKP (POT, Kissing, final POT)

- Soft distorsion of BVS without fracture
- Sub-optimal Side ostium scaffolding

malapposition
PKP (POT, Kissing, final POT)

- Final POT is not essential

Snuggle

Final-POT

OFDI frame registration
Culotte or Minicrush

Even if appearances are flattering....

Culotte or Minicrush should be avoided with BVS

- Complex strategy with BVS (*recrossing*)
- Culotte inapplicable in Left Main Bench
- Bad OCT and Micro-CT results:
  *Struts fracture, Side branch Obstruction, Protrusion in main branch*....
Culotte

Lumen and Side Branch Obstruction

2 layers > 600μm
Minicrush

Lumen and Side Branch Obstruction
PKP+ T (POT, Kissing, final POT + T stenting)

- If two stents are required, the least worst strategy is...
- Good result especially in Left Main Bench
PKP+ T (POT, Kissing, final POT + T stenting)

- If two stents are required, the least worst strategy is...
- Good result especially in Left Main Bench
BVS and Bifurcation

Conclusion

- Stenting Bifurcation with BVS is possible but we must stay cautious
- Bench study is useful to assess the behaviour of BVS in bifurcation

- **OCT gives information very similar to those provided by micro-CT:**
  - Small NCB and low pressure prevent strut fractures
  - One Stent rather than Two
  - Simplest is better:

  POT + Side & Final POT or POT + Snuggle
BVS Bench Testing

Appearances are Sometimes Deceptive
Low angulation

BVS Bench Bifurcation Study

Ormiston JA, Eurointervention 2014
PSP (POT, Side opening, final POT)

View from distal SB

View in direction of SB
PKP (POT, Snuggle Kissing, final POT)
**PSP** (*POT, Side opening, final POT*)

View from distal SB