Optimal provisional coronary bifurcation stenting: Final kissing balloon dilatation or not?

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The problematics of final kissing balloon inflations

1) Recent and original concept has been proposed by Dr O. Darremont: **Proximal Optimizing Technique (POT)**

   But POT has not had precise quantitative analysis

2) The use in our technical practice of the fractal geometry of arterial bifurcation *(in accordance with the law of the conservation of mass)*

3) Several recent and contributive publications on **FKB optimization**
   - Final proximal post-dilatation is necessary after KB in bifurcation stenting
   - KB and sequential dilatation of the SB and MV for provisional stenting
   - FKB post-dilatation with assymmetric balloon inflation pressure
The objectives of this bifurcation model study

1) Quantify the mechanical effects of the POT

2) Quantify the differences between:
* FKB approach (with its modified protocols) after POT
* approach with no FKB but consecutive POT with single SB inflation (re-POT)

regarding:
- optimal SBO (side-branch ostium) opening,
- no strut MAP (malapposition),
- circular arterial shape,
- no excessive arterial overstretching
- respect of the final fractal geometry of the bifurcation
- simplicity of the technique
METHODS

Fractal coronary bifurcation test bench (G. Finet)
55 shA crystal PVC with the rheology of a 1-mm thick coronary artery (Young’s modulus: 500 kPa
SEGULA technologies Sud, St-Priest, France

Linear law of coronary artery bifurcation geometry and self-similarity

\[ D_{\text{mother-vessel}} = 0.678 \left( D_{\text{daughter-vessel1}} + D_{\text{daughter-vessel2}} \right) \]
In vitro bench testing protocols

FKB symmetric BIP (12/12 atm)

POT
METHODS

before POT
METHODS

after POT
## RESULTS

**Analysis of POT mechanical effects**

<table>
<thead>
<tr>
<th>Promus Premier™ (Boston)</th>
<th>Before POT n=20</th>
<th>After POT n=20</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean D MoV&lt;sub&gt;ref&lt;/sub&gt; (mm)</td>
<td>4.10±0.02</td>
<td>4.16±0.03</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Proximal mean D stent (mm)</td>
<td>3.38±0.05</td>
<td>4.16±0.03</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Expected stepwise difference diameter between MoV&lt;sub&gt;ref&lt;/sub&gt;-Mb&lt;sub&gt;ref&lt;/sub&gt; according to fractal geometry (mm)</td>
<td>0.83±0.06</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Measured diameter difference between MoV&lt;sub&gt;ref&lt;/sub&gt; &amp; stent (mm)</td>
<td>0.71±0.04</td>
<td>0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Elliptic ratio of reference MoV</td>
<td>1.04±0.02</td>
<td>1.04±0.01</td>
<td>0.88</td>
</tr>
<tr>
<td>Elliptic ratio of stent into MoV</td>
<td>1.05±0.02</td>
<td>1.04±0.01</td>
<td>0.88</td>
</tr>
<tr>
<td>Stent strut obstruction in SBO (%)</td>
<td>31.1±3.6</td>
<td>24.2±3.0</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
In vitro bench testing protocol

- FKB symmetric BIP (12/12 atm)
- FKB symmetric BIP (12/12 atm)
- FKB asymmetric BIP SB @ 12 atm to 4 atm w/ MV @ 12 atm
- FKB asymmetric BIP SB @ 12 atm w/ MV @ 4 atm
- SB inflation alone SB @ 12 atm
- SB inflation SB @ 12 atm + Final POT
METHODS

Final result

Ostial area obstruction (%)  
Ellipticity index ≥ 1.0  
Final proximal Stent/artery ratio  
Final distal Stent/artery ratio  
Final fractal ratio after stenting  
Malapposed struts (%) (A,B,C,D)
Re-POT
Re-POT
Re-POT
Re-POT
Re-POT
Quantitative analysis of the different bifurcation stenting protocols (1-stent strategy)

<table>
<thead>
<tr>
<th>Promus premier™ stent (Boston)</th>
<th>Total (n=25)</th>
<th>with FKB</th>
<th>without FKB</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>no POT</td>
<td>with POT first</td>
</tr>
<tr>
<td></td>
<td></td>
<td>symFKBi</td>
<td>assymFKBi</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n=5</td>
<td>4 atm MV</td>
</tr>
<tr>
<td>Prox area overstretch (MoV) %</td>
<td>13.7±1.41</td>
<td>7.25±4.38</td>
<td>5.73±1.92</td>
</tr>
<tr>
<td>Prox Elliptic ratio (MoV)</td>
<td>1.25±0.02</td>
<td>1.08±0.05</td>
<td>1.03±0.01</td>
</tr>
<tr>
<td>Prox ΔD max (Stent-Ref) mm</td>
<td>0.64±0.09</td>
<td>0.25±0.18</td>
<td>0.09±0.06</td>
</tr>
<tr>
<td>Prox ΔD min (Stent-Ref) mm</td>
<td>-0.12±0.08</td>
<td>0.04±0.05</td>
<td>0.15±0.05</td>
</tr>
<tr>
<td>Mid area overstretch (MoV) %</td>
<td>13.81±2.20</td>
<td>13.0±1.19</td>
<td>6.16±1.25</td>
</tr>
<tr>
<td>Mid Elliptic ratio (MoV1)</td>
<td>1.25±0.02</td>
<td>1.08±0.05</td>
<td>1.03±0.01</td>
</tr>
<tr>
<td>Mid ΔD max (Stent-Ref) mm</td>
<td>0.58±0.11</td>
<td>0.52±0.05</td>
<td>0.26±0.09</td>
</tr>
<tr>
<td>Mid ΔD min (Stent-Ref) mm</td>
<td>-0.08±0.09</td>
<td>0.04±0.16</td>
<td>-0.01±0.11</td>
</tr>
<tr>
<td>Final linear fractal geometric ratio</td>
<td>0.66±0.01</td>
<td>0.65±0.02</td>
<td>0.65±0.01</td>
</tr>
<tr>
<td>Stent strut obstruction in SBO %</td>
<td>22.7±5.7</td>
<td>9.1±5.6</td>
<td>3.7±4.5</td>
</tr>
</tbody>
</table>

*p*
## RESULTS

### Analysis of strut malapposition in the different bifurcation stenting protocols (1-stent strategy)

**Promus premier™ stent (Boston)**

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<tr>
<td></td>
<td></td>
<td>n=5</td>
</tr>
<tr>
<td>+SB alone</td>
<td></td>
<td>+SB and final POT</td>
</tr>
<tr>
<td>n=5</td>
<td></td>
<td>n=5</td>
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</tbody>
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### Proximal stent segment

- **number of cases with strut MAP**
  - 4/5, 5/5, 4/5, 5/5, 4/5, 1/5
- **mean max distance of strut MAP (μm)**
  - 168, 222, 164, 190, 134, 40

### Carina

- **number of cases with strut MAP**
  - 5/5, 4/5, 5/5, 5/5, 5/5, 2/5
- **mean max distance of strut MAP (μm)**
  - 622, 300, 422, 368, 330, 78

### Wall facing SBO

- **number of cases with strut MAP**
  - 3/5, 5/5, 5/5, 5/5, 3/5, 0
- **mean max distance of strut MAP (μm)**
  - 156, 262, 230, 228, 212, 0

### Global stent malapposition

- **Number of analyzed struts**
  - 761, 641, 804, 818, 834, 736
- **% of malapposed struts**
  - 15.2, 10.1, 20.1, 8.8, 10.5, 2.6

*Malapposed stent strut > 120 μm*
CONCLUSIONS

Our preliminary results with 25 fractal bifurcation models with Promus Premier® (Boston) :

- have quantitatively validated the mechanical effects of POT

- have showed by comparison with :
  - FKB alone
  - and POT + FKB with symetric or assymetric balloon inflation pressure

that with a re-POT procedure with SB dilatation provides the best mechanical results
and is the simpler technique in 1-stent bifurcation strategy.
  - SBO almost free of strut (5.4%)
  - a very low rate of global strut malappposition (2.6%)
  - a perfect morphology of the carena and the wall facing the SB ostium
  - a circular cross-sectional area of the MoV (relative elliptic ratio : 1.0)
  - the quasi respect of the linear law of coronary artery bifucation geometry (0.66)

We are completing these premilinary results with 25 other fractal bifurcation models with Ultimaster® stent (Terumo).
A total of 50 experimentions into fractal bifurcation models.

Submission in december 2014
"Re-POT" sequence

(1) Implantation du stent au diamètre de la MB

Re-POT

(2) Inflation d’un ballon compliant au diamètre du MoV
- Bord interne du marqueur distal juste au niveau de la carène
- Compléter le POT en amont si segment long
Re-POT

(3) - Mailles bombées et étirées sur la SBO
- Correction complète de la malapposition du stent dans le MoV

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<tr>
<td>Stent strut obstruction in SBO</td>
<td>34.0±7.4%</td>
<td>26.0±4.2%</td>
</tr>
<tr>
<td>Distal cell area ratio in SBO</td>
<td>22.1±15.9%</td>
<td>28.7±19.6%</td>
</tr>
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</table>

Finet G. Oral communication. EBC 2014
Re-POT

(4) - easy SBO rewiring
Re-POT

(5) - SB inflation at SB reference diameter
Ellipticity ratio : 1.03±0.01% (FKBI : 1.23±0.02%)
Stent strut obstruction in SBO (%) : 5.6±8.3% (FKBI : 23.2%)
Global stent MAP - % of malapposed struts : 2.6±1.4% (FKBI : 40.0±6.2%)

Finet G. Oral communication. EBC 2014
Thanks to the team!

Dr François DERIMAY, MD, MSc, Lyon, France (protocole, bench testing, OCT analyses)
Pr Gilles RIOUFOL, MD PhD, Lyon, France (protocole, bench testing)
Pr Pascal MOTREFF, MD PhD, Clermont-Ferrand, France (bench testing, 3D OCT)
Pr Patrice GUERIN, MD PhD, Nantes, France (micro CT)
Dr Olivier DARREMONTE, MD, Bordeaux, France (concept of the POT)

“Simplicity is the ultimate sophistication“
Leonardo da Vinci