12-Month and preliminary 24-month outcomes of combining a DCB with a modern generation of nitinol stent in fem-pop lesions

BIOLUX 4EVER study

Dr. Lieven Maene
OLV Aalst, Belgium
Disclosure slide

Speaker name: Lieven Maene

☐ I have the following potential conflicts of interest to report:

☒ Consulting: Biotronik
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
The reality of BMS anno 2018

By introducing PTX

Source: graphic courtesy of Paul Ransom, Biotronik AG
## “PTX effect” by DES

### Without Polymer...

<table>
<thead>
<tr>
<th>Zilver PTX³ – 12m</th>
<th>Zilver FLEX* arm</th>
<th>Zilver PTX* arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>---</td>
<td>474</td>
</tr>
<tr>
<td>Av.Lesion Length (cm)</td>
<td>6.6</td>
<td>6.6</td>
</tr>
<tr>
<td>ABI</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Diabetic (%)</td>
<td>42.0</td>
<td>49.6</td>
</tr>
<tr>
<td>CLI (%)</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Occlusion (%)</td>
<td>25.0</td>
<td>30.0</td>
</tr>
<tr>
<td>Calcification (%)</td>
<td>57.0</td>
<td>72.6</td>
</tr>
<tr>
<td>Primary Patency (%)</td>
<td>73.0</td>
<td>83.1</td>
</tr>
<tr>
<td>fTLR (%)</td>
<td>85.8</td>
<td></td>
</tr>
</tbody>
</table>

### With Polymer...

<table>
<thead>
<tr>
<th>superNOVA/MAJESTIC 12m</th>
<th>superNOVA (Innova**)</th>
<th>MAJESTIC² (Eluvia**)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>299</td>
<td>57</td>
</tr>
<tr>
<td>Av.Lesion Length (cm)</td>
<td>9.3</td>
<td>7.1</td>
</tr>
<tr>
<td>ABI</td>
<td>---</td>
<td>0.73–1.02</td>
</tr>
<tr>
<td>Diabetic (%)</td>
<td>40.5</td>
<td>35.1</td>
</tr>
<tr>
<td>CLI (%)</td>
<td>---</td>
<td>1.8</td>
</tr>
<tr>
<td>Occlusion (%)</td>
<td>---</td>
<td>46.0</td>
</tr>
<tr>
<td>Calcification (%)</td>
<td>70.2</td>
<td>78.9</td>
</tr>
<tr>
<td>Primary Patency (%)</td>
<td>66.4</td>
<td>96.1</td>
</tr>
<tr>
<td>fTLR (%)</td>
<td>85.8</td>
<td>96.2</td>
</tr>
</tbody>
</table>

PTX effect + 10% @ 1 year

PTX effect + 30% PPR @ 1 year

PTX effect + 10% fTLR @ 1 year

1. COOK Zilver PTX clinical data guide 2010-11
“PTX effect” by DCB

Evidence supports use in simple & complex lesions

Performance of DCBs seems to be lesion complexity

INDEPENDENT
“PTX effect” by DCB
Evidence also shows increasing use of scaffolds in more complex lesions:
Bail-out stenting is lesion complexity DEPENDENT


With the courtesy of Azah Tabah, Medtronic

Lesion length (cm)  DCB rate  Bail-out stent rate
...Evidence is reflecting the reality of daily angiosuite experiences...

<table>
<thead>
<tr>
<th>Procedure Details SFA (N= 145 Lesions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vessel preparation</td>
</tr>
<tr>
<td>Pre-dilation</td>
</tr>
<tr>
<td>Cutting/scoring balloon</td>
</tr>
<tr>
<td>Rotational thrombectomy</td>
</tr>
<tr>
<td>Atherectomy</td>
</tr>
<tr>
<td>Technical success¹</td>
</tr>
<tr>
<td>Bailout Stenting</td>
</tr>
<tr>
<td>Stent only</td>
</tr>
<tr>
<td>Stent plus DCB</td>
</tr>
<tr>
<td>Stent plus rotational thrombectomy</td>
</tr>
<tr>
<td>Stent plus atherectomy</td>
</tr>
<tr>
<td>Stent plus scoring balloon</td>
</tr>
<tr>
<td>Stent plus cutting balloon</td>
</tr>
</tbody>
</table>

Stent >1/3 + DCB

DCB >1/7 + Stent
Let’s evaluate this daily practice in a prospective multicentric way...

**First Stent, then DCB**

**DEBAS STUDY**
- Direct scaffolding
- No DCB only possibility
- Loosing PTX-wall contact

**Single center, single arm prospective study**
65 lesions
Pulsar 18 + Passeo-18 Lux (Biotronik)
Mean lesion length: 18.7 cm

**First DCB, then Stent**

**BIOLUX 4EVER**
- Maximum contact PTX
- DCB only possibility
- Distal embolization?

**Multicenter, single arm prospective study**
120 lesions
Passeo-18 Lux + Pulsar 18 (Biotronik)
Mean lesion length: 8.3 cm
Is there a “PTX effect”...

... if we “prepare” the vessel with a DCB & scaffold with a stent afterwards???

BIOLUX 4EVER

5 PARTICIPATING CENTERS

• Sint-Blasius Hospital, Dendermonde (K. Deloose, M. Bosiers, J. Callaert)
• Imelda Hospital, Bonheiden (P. Peeters, J. Verbist, W. Van den Eynde)
  • OLV Hospital, Aalst (L. Maene, R. Beelen)
  • RZ Heilig Hart, Tienen (K. Keirse, B. Joos)
• University Hospital Antwerp (J. Hendriks, P. Lauwers)
## Patient demographics

<table>
<thead>
<tr>
<th>Condition</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (%)</td>
<td>79</td>
<td>65.83%</td>
</tr>
<tr>
<td>Age (min – max; ±SD)</td>
<td>70.87 years</td>
<td>43.73 – 92.41; ±10.52</td>
</tr>
<tr>
<td>Nicotine abuse (%)</td>
<td>73</td>
<td>60.83%</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>76</td>
<td>63.33%</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>23</td>
<td>19.17%</td>
</tr>
<tr>
<td>Renal insufficiency (%)</td>
<td>15</td>
<td>12.50%</td>
</tr>
<tr>
<td>Hypercholesterolemia (%)</td>
<td>66</td>
<td>55.00%</td>
</tr>
<tr>
<td>Obesity (%)</td>
<td>28</td>
<td>23.33%</td>
</tr>
</tbody>
</table>

*N = 120 out of 120

*missing data for 1 patient
### Indications & Procedural characteristics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length ((\text{min} - \text{max}; \pm \text{SD}))</td>
<td>(83.33\ \text{mm} \ (6.0 - 190.0; \pm 49.49))</td>
</tr>
<tr>
<td>Reference Vessel Diameter</td>
<td>(5.26\ \text{mm} \ (4.0 - 6.0; \pm 0.59))</td>
</tr>
<tr>
<td>DCB</td>
<td>N = 151</td>
</tr>
<tr>
<td>STENT</td>
<td>N = 131</td>
</tr>
<tr>
<td>Mean DCB diameter ((\text{min} - \text{max}; \pm \text{SD}))</td>
<td>(5.15\ \text{mm} \ (4.0 - 6.0; \pm 0.57))</td>
</tr>
<tr>
<td>Mean STENT diameter ((\text{min} - \text{max}; \pm \text{SD}))</td>
<td>(5.78\ \text{mm} \ (5.0 - 7.0; \pm 0.53))</td>
</tr>
<tr>
<td>Occlusion (%)</td>
<td>40 \ (33.33%)</td>
</tr>
<tr>
<td>Calcified lesion (%)</td>
<td>60 \ (50.00%)</td>
</tr>
</tbody>
</table>

*Minimal oversizing for lowest possible COF (ca. 0.5mm)*
12 Month Primary Patency (120pts)

Primary Patency at 12 months

<table>
<thead>
<tr>
<th>time</th>
<th>baseline</th>
<th>1MFU</th>
<th>6MFU</th>
<th>12MFU (D365)</th>
<th>12MFU (D395)</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>100</td>
<td>100</td>
<td>94.7</td>
<td>89.9</td>
<td>86.9</td>
</tr>
</tbody>
</table>
12 Month freedom from TLR (120 pts)

<table>
<thead>
<tr>
<th>time</th>
<th>baseline</th>
<th>1MFU</th>
<th>6MFU</th>
<th>12MFU (D365)</th>
<th>12MFU (D395)</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>100</td>
<td>100</td>
<td>97.4</td>
<td>93.6</td>
<td>91.6</td>
</tr>
</tbody>
</table>
24 month primary patency (105/120 pts)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>1M</th>
<th>6M</th>
<th>12M</th>
<th>24M – D730</th>
<th>24M – D760</th>
</tr>
</thead>
<tbody>
<tr>
<td>% PP</td>
<td>100</td>
<td>100</td>
<td>95.20</td>
<td>90.00</td>
<td>83.30</td>
<td>82.10</td>
</tr>
</tbody>
</table>

83.3 %
24 month freedom from TLR (105/120 pts)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>1M</th>
<th>6M</th>
<th>12M</th>
<th>24M – D730</th>
<th>24M – D760</th>
</tr>
</thead>
<tbody>
<tr>
<td>% PP</td>
<td>100</td>
<td>100</td>
<td>98.10</td>
<td>94.00</td>
<td>86.20</td>
<td>86.20</td>
</tr>
</tbody>
</table>

86.2 %
Is there a “PTX effect”...

... if we “prepare” the vessel with a DCB & scaffold with a stent afterwards???

<table>
<thead>
<tr>
<th></th>
<th>4EVER^1 (Pulsar)</th>
<th>BIOLUX 4EVER (Passeo-18 Lux + Pulsar-18)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>120</td>
<td>120</td>
</tr>
<tr>
<td>LL(cm)</td>
<td>7.2</td>
<td>8.3</td>
</tr>
<tr>
<td>Diabet (%)</td>
<td>35.9</td>
<td>19.2</td>
</tr>
<tr>
<td>CLI (%)</td>
<td>16.7</td>
<td>17.0</td>
</tr>
<tr>
<td>Occl (%)</td>
<td>20.8</td>
<td>33.3</td>
</tr>
<tr>
<td>Calcium (%)</td>
<td>30.8</td>
<td>50.0</td>
</tr>
<tr>
<td>PP (%)</td>
<td>81.4</td>
<td>89.9</td>
</tr>
<tr>
<td>fTLR (%)</td>
<td>80.3</td>
<td>83.6</td>
</tr>
</tbody>
</table>

PTX effect + 8% PPR @ 1 year

<table>
<thead>
<tr>
<th></th>
<th>4EVER^1 (Pulsar)</th>
<th>BIOLUX 4EVER (Passeo-18 Lux + Pulsar-18)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24m preliminary (105/120)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>120</td>
<td>85</td>
</tr>
<tr>
<td>LL(cm)</td>
<td>7.2</td>
<td>8.3</td>
</tr>
<tr>
<td>Diabet (%)</td>
<td>35.9</td>
<td>19.2</td>
</tr>
<tr>
<td>CLI (%)</td>
<td>16.7</td>
<td>17.0</td>
</tr>
<tr>
<td>Occl (%)</td>
<td>20.8</td>
<td>33.3</td>
</tr>
<tr>
<td>Calcium (%)</td>
<td>30.8</td>
<td>50.0</td>
</tr>
<tr>
<td>PP (%)</td>
<td>72.3</td>
<td>83.3</td>
</tr>
<tr>
<td>fTLR (%)</td>
<td>82.5</td>
<td>85.2</td>
</tr>
</tbody>
</table>

PTX effect + 11% PPR @ 2 year

Is it comparable to DES data?

Benchmarking in the DES world @ 1yr

<table>
<thead>
<tr>
<th>Product</th>
<th>PPR 1yr</th>
<th>f TLR</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAJESTIC</td>
<td>96.1</td>
<td>96.1</td>
</tr>
<tr>
<td>Zilver PTX RCT</td>
<td>84.4</td>
<td>91.6</td>
</tr>
<tr>
<td>Zilver PTX Japanese PMS</td>
<td>84.8</td>
<td>91.4</td>
</tr>
<tr>
<td>BIOLUX 4EVER</td>
<td>89.9</td>
<td>93.6</td>
</tr>
<tr>
<td>DEBAS</td>
<td>94.1</td>
<td>94.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LL (cm)</th>
<th>7,0</th>
<th>5,5</th>
<th>14,7</th>
<th>8,3</th>
<th>18,7</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSVR (≤)</td>
<td>2,5</td>
<td>2,0</td>
<td>2,4</td>
<td>2,5</td>
<td>2,5</td>
</tr>
</tbody>
</table>
Adding Paclitaxel to BMS is definitely improving patency & TLR

Implanting Pulsar-18® stent, postdilated with Passeo-18 Lux® creates a win-win situation as shown in the full 12 months & 24 months data of DEBAS

Prepping with Passeo-18 Lux® & scaffolding afterwards with Pulsar-18® stent creates a win-win situation as shown in the full 12 months & preliminary 24 months data of BIOLUX 4EVER

The combination of Passeo-18 Lux® & Pulsar-18® offers similar efficacy outcomes compared to DES data
12-Month and preliminary 24-month outcomes of combining a DCB with a modern generation of nitinol stent in fem-pop lesions

BIOLUX 4EVER study

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