REVA FANTOM II

Performance and healing patterns by OCT

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On behalf of the FANTOM II investigators
The FANTOM BRS

- Desaminotyrosine based polycarbonate backbone
- Strut thickness 125µm
- Sirolimus eluting for 3 months
- Full resorption within 3-4 years
FANTOM angiographic signature

- Radiopacity
- Covalently bound iodine in the polycarbonate backbone
FANTOM OCT signature

Baseline 6 month FU 9 month FU
FANTOM BRS by 3D OCT

3D OCT by St Jude OPTIS
REVA FANTOM II – OCT analysis
OCT billede af baseline og FU strut
Customized analysis
OCT analysis optimized and validated by micro-CT

Strut thickness by micro-CT
REVA FANTOM II

OCT analysis optimized and validated by micro-CT
REVA FANTOM II

Baseline

FU
FANTOM in bifurcations

Micro-CT
FANTOM II Study Population
N= 240 Total Patients Enrolled

Cohort A - Study Population
N= 117 Patients

6 Month Follow-up
Clinical & Imaging

Angiographic
n=100

OCT
n=73

6 Month Follow-up
Clinical (n=108)

Long Term Follow-up
Clinical (annual through 5 years)

Cohort B - Study Population
N= 123 Patients

6 Month Follow-up
Clinical FU

Angiographic
N=105

OCT
n=80

9 Month Follow-up
Clinical & Imaging

Long Term Follow-up
Clinical (annual through 5 years)
Mean stent area

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Baseline</th>
<th>Follow-up</th>
<th>Difference</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>7.1 (1.5)</td>
<td>7.2 (1.4)</td>
<td>0.1 (-0.02;0.24)</td>
<td>0.12</td>
</tr>
<tr>
<td>B</td>
<td>7.4 (1.6)</td>
<td>7.3 (1.5)</td>
<td>-0.1 (-0.2;0.0)</td>
<td>0.16</td>
</tr>
</tbody>
</table>
Minimal stent area

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<th>Minimal stent area (mm$^2$)</th>
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<td>0.12</td>
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<tr>
<td><strong>Cohort B</strong></td>
<td>6.1 (1.4)</td>
<td>6.0 (1.3)</td>
<td>-0.1 (-0.2;0.1)</td>
<td>0.43</td>
</tr>
</tbody>
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Mean luminal area

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<tr>
<td>Cohort A</td>
<td>6.8 (1.7)</td>
<td>5.7 (1.4)</td>
<td>-1.1 (-1.3;-0.9)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Cohort B</td>
<td>7.1 (1.6)</td>
<td>5.6 (1.5)</td>
<td>-1.6 (-1.7;-1.4)</td>
<td>&lt;0.0001</td>
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Minimal lumen area

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<td>&lt;0.0001</td>
</tr>
<tr>
<td>Cohort B</td>
<td>5.7 (1.4)</td>
<td>4.0 (1.4)</td>
<td>-1.7 (-1.9; -1.4)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
Malapposition

**Cohort A**
- Baseline: 0.8% (0.0;3.5)
- 6m follow-up: 0.0% (0.0;0.0)

**Cohort B**
- Baseline: 1.6% (0.1;5.2)
- 9m follow-up: 0.0% (0.0;0.0)
### Extra-stent lumen

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<th>Baseline</th>
<th>Follow-up</th>
</tr>
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<tr>
<td>Extra stent lumen area (mm²)</td>
<td><strong>Cohort A</strong></td>
<td>0.05 (0.02;0.13)</td>
</tr>
<tr>
<td></td>
<td><strong>Cohort B</strong></td>
<td>0.08 (0.03;0.18)</td>
</tr>
</tbody>
</table>
## Neointimal area

<table>
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<tr>
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<th>6 months <strong>Cohort A</strong></th>
<th>9 months <strong>Cohort B</strong></th>
</tr>
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<tbody>
<tr>
<td>Mean neointimal area (mm²)</td>
<td>1.2 (1.0;1.4)</td>
<td>1.4 (1.2;1.7)</td>
</tr>
</tbody>
</table>
## Neointimal thickness

<table>
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<th>6 months <strong>Cohort A</strong></th>
<th>9 months <strong>Cohort B</strong></th>
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<td>Mean neointimal thickness (µm)</td>
<td>57 (40;77)</td>
<td>77 (57;105)</td>
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</table>

Median (IQR)
Strut coverage

Cohort A

6 months **Cohort A**

Covered struts

98.1% (95.9;99.4)

Cohort B

9 Months **Cohort B**

Covered struts

99.0% (98.3;100.0)
Conclusion

The Fantom BRS show promising healing patterns after 6 and 9 months

- OCT properties allows for in-procedure 3D evaluation
- Expected slight decrease in lumen area after 9 months
- No stent area reduction – no late recoil
- High completeness of strut coverage
- Limited neointimal growth
- Excellent resolution of acute extra-stent lumen and malapposition