REVA FANTOM II

Performance and healing patterns by OCT
Two-year serial follow-up

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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 BRS by 3D OCT

3D OCT by St Jude OPTIS
FANTOM OCT signature

Baseline
6 month FU
24 month FU
REVA FANTOM II – OCT analysis

PCI Research
Aarhus University Hospital, Skejby • Denmark
Customized analysis

Stent strut

Lumen

Abluminal stent

Luminal stent
REVA FANTOM II

OCT analysis optimized and validated by micro-CT

Strut thickness by micro-CT
OCT analysis optimized and validated by micro-CT
FANTOM in bifurcations

Micro-CT
Patient flow chart

FANTOM II Study Population
N = 240 Total Patients Enrolled

Cohort A - Study Population
N = 117 Patients

6 Month Follow-up
Clinical & Imaging

Angiographic
n=101

OCT
n=73

6 Month Follow-up
Clinical (n=108)

24 Month Follow-up
Clinical & Imaging

Study population
OCT + Angiography
n=35

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

Cohort B - Study Population
N = 123 Patients

9 Month Follow-up
Clinical & Imaging

Angiographic
n=103

OCT
n=79

9 Month Follow-up
Clinical

48 Month Follow-up
Clinical & Imaging

OCT + Angiography
Pending

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

24 Month Follow-up
OCT Imaging: N=35

Available for analysis
N=25

Exclusion
3 Missing baseline OCT
4 Insufficient flushing
2 Artefacts
1 DES in target segment

TLR
Mean scaffold area

Change in mean scaffold area

<table>
<thead>
<tr>
<th>Time</th>
<th>Mean scaffold area, mm²</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>7.32±1.14 mm²</td>
<td></td>
</tr>
<tr>
<td>6 Months</td>
<td>7.43±1.19 mm²</td>
<td>0.74</td>
</tr>
<tr>
<td>24 Months</td>
<td>7.45±1.28 mm²</td>
<td>0.97</td>
</tr>
</tbody>
</table>
Minimal scaffold area

Change in minimum stent area

- Baseline: 6.14±1.09 mm²
- 6 Months: 6.25±1.16 mm²
- 24 Months: 5.99±1.17 mm²

P=0.74
P=0.45
Mean lumen area

Change in mean luminal area

Mean luminal area, mm²

Baseline 6 Months 24 Months

7.09±1.38 mm² 6.01±1.32 mm² 5.87±0.19 mm²

P=0.01  P=0.47
Minimal lumen area

Change in minimum luminal area

5.58±1.09 mm²  4.65±1.10 mm²  4.10±1.21 mm²

P<0.01  P=0.10
Malapposition

p<0.001  p=0.67
0.6% [0.0;4.6]  0.0% [0.0;0.0]  0.0% [0.0;0.0]
Extra-stent lumen

<table>
<thead>
<tr>
<th>24 months follow-up cohort</th>
<th>baseline</th>
<th>6 months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extra stent lumen area (mm²)</td>
<td>0.04[0.03;0.19]</td>
<td>0.01[0.00;0.03]</td>
<td>0.00[0.00;0.01]</td>
</tr>
</tbody>
</table>

p<0.001       p=0.05
Extra-stent lumen

No evaginations or late scaffold detachment after 24 months

Example in permanent DES. Radu et al. EHJ 2017
# Neointimal area

![Image of OCT scan showing neointimal area]

## 24 months follow-up cohort

<table>
<thead>
<tr>
<th></th>
<th>6 months</th>
<th>24 months</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean neointimal area (mm²)</td>
<td>1.20±0.31</td>
<td>1.52±0.37</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Blue area: Neointimal area
# Neointimal thickness

## 24 month follow-up cohort

<table>
<thead>
<tr>
<th>Time</th>
<th>Mean neointimal thickness (µm)</th>
<th>Median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
<td>51[36;67]</td>
<td>79[53;110]</td>
</tr>
<tr>
<td>24 months</td>
<td>79[53;110]</td>
<td></td>
</tr>
</tbody>
</table>

\( p\text{-value} = 0.01 \)
Strut coverage

Strut-level results in 24m follow-up cohort

Coverage

98.6% [96.5;99.7] 100% [100;100]
Conclusion

The Fantom BRS show promising healing patterns after 24 months:

- Complete strut coverage
- Slight decrease in lumen area due to limited additional neointimal growth – mainly in cases with small acute MLA
- No stent area reduction – no late recoil
- Excellent resolution of acute malapposition and still no acquired malapposition and no evaginations detected after 24 months