Resorbable Repair Device (RRD) for Coverage of Flow Limiting Dissections after DCB angioplasty

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Disclosure

Speaker name:
Maciej Kusmierczuk

I have the following potential conflicts of interest to report:

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

☐ I do not have any potential conflict of interest
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**Background**

- After adequate vessel preparation, drug-coated balloons (DCB) allow for successful lesion treatment without stent implantation (“leaving nothing behind”)
- Current therapy in case of a flow-limiting dissection after DCB angioplasty is limited
  - implantation of “permanent cage” in the vessel (bare-metal stent (BMS) or drug-eluting stent (DES))
- Resorbable repair device (RRD) was developed to overcome implantation of permanent implant to continue stentless therapy

**Aim**

Technical feasibility, device performance and resorption of resorbable repair device was explored

**Methods**

- Resorbable repair devices were tested in vivo in twelve coronary arteries of domestic pigs
- RRD were post-dilated with POBA or DCB
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RRD: Device description

• Magnesium resorbable scaffold based on new innovative Resoloy® alloy platform
• Balloon-expandable scaffold with struts thickness of <100µm
• Available in 2.5mm, 3.0mm, 3.5mm, 4.0mm diameter and 12mm and 18mm length
• High radial strength when compared to polymer devices
• Radiopaque markers at either scaffold end
• Device without drug coating
• Complete scaffold resorption at 12 months with low local toxicity
• Dedicated for coronary and BTK lesions

Figure 1: 3D image of the tested resorbable repair device
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Results

Preclinical study
OCT: Device deployment

Device performance
- Good pushability, trackability, positioning and deployment
- No device acute recoil and no struts malapposition after device deployment

OCT: 4-week follow-up

Device performance
- Full scaffold struts coverage at 4-week follow-up
- Visible reduction of neointimal layer in the RRD + DCB group

Figure 2: A: Resorbable repair device (RRD) post-dilated with POBA; B: Resorbable repair device (RRD) post-dilated with DCB

Figure 3: A: Resorbable repair device (RRD) post-dilated with POBA at 4-week follow-up; B: Resorbable repair device (RRD) post-dilated with DCB at 4-week follow-up
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Results

Histomorphometry: 4-week follow-up

Table 1: Histomorphometric vessel parameters based on vessel diameters determined from the histological analysis

<table>
<thead>
<tr>
<th>Histomorphometry Mean ± SD</th>
<th>Resorbable repair device (RRD) + POBA</th>
<th>Resorbable repair device (RRD) + DCB</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (analyzed vessel segments)</td>
<td>6</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Vessel diameter [mm]</td>
<td>2.01 ± 0.27</td>
<td>2.29 ± 0.11</td>
<td>0.94</td>
</tr>
<tr>
<td>Lumen diameter [mm]</td>
<td>1.22 ± 0.36</td>
<td>1.61 ± 0.08</td>
<td>0.04</td>
</tr>
<tr>
<td>Max. neointimal thickness [mm]</td>
<td>0.46 ± 0.46</td>
<td>0.31 ± 0.07</td>
<td>0.06</td>
</tr>
<tr>
<td>Diameter stenosis [%]</td>
<td>39.81 ± 12.83</td>
<td>29.59 ± 2.71</td>
<td>0.12</td>
</tr>
</tbody>
</table>

Scaffold degradation: 4-week follow-up

Synchrotron X-ray μCT

Figure 4: Example of RRD post-dilated with DCB: 3D rendering with visible degraded struts (blue: MgF2 layer, green: degraded Mg, violet; strongly degraded). Scaffold degradation: ca. 11%.

Scaffold degradation in the groups

- RRD + POBA: 35%
- RRD + DCB: 18%
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Conclusions

• New concept device to repair flow-limiting dissections after DCB treatment showed promising results in the preclinical study
• Resorbable repair devices demonstrated full device expansion, no device acute recoil and no strut malapposition after device deployment
• OCT after 28 days indicated full device embedment, device recoil of about 1.7% and reduction of neointimal layer in the RRD + DCB group
• Resorbable repair devices post-dilated with DCB presented slower but more constant resorption within 28 days
• No safety issues regarding device observed up to follow-up
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