The appearance of jailed side branches post-procedure, at 6, 12, 24 and 36 months following implantation of bioresorbable vascular devices – Insights from the ABSORB Cohort B trial using three-dimensional optical coherence tomography

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Background: Everolimus-eluting ABSORB Bioresorbable vascular scaffolds consisted of poly-lactide are programmed to bioabsorb approximately in three years. It is still unknown how the struts implanted in front of a side branch behave during bioresorption. The purpose of this study was to assess the fate of bioresorbable struts jailing side branch ostia at 6, 24 months (cohort B1) or at 12 and 36 months after implantation of the BVS (cohort B2), with three-dimensional (3-D) optical coherence tomography (OCT) reconstruction.

Methods: The ABSORB Cohort B trial is a multicentre single-arm trial to assess the safety and performance of the BVS. Fourier domain-OCT pullbacks were obtained at a pullback speed of 20 mm/s and 3-D rendering are computed. The area and the number of strut-free compartments at side branch ostium delineated by the BVS struts were evaluated. The endo- and abluminal coverages of the struts present at the ostium of sidebranch were quantified at 6, 12, 24 and 36 month follow-up.

Results: Serial 3D-OCT images were available in total 26 side branches (13 in cohort B1 and 13 in cohort B2). In the Cohort B1, the number of compartment and average ostium area free from jailing struts did not change from baselines to 6 months, but significantly reduced from 6 months to 2 years. In the Cohort B2, there was similarly a reduction of the number of compartments and the ostium area from baseline to one year. However, from one year to 3 years, there was late enlargement of the sidebranch ostium area (1Y: 0.47±0.64mm2, 2Y: 0.68±0.38mm2) without changing the number of compartment. The thickness of the strut coverage was greater at the abluminal surface compared to endoluminal strut side at followup.

Conclusions: The ostial area jailing by bioabsorbable scaffold decreased up to 2 years due to growing tissue between the struts, but late ostium area enlargement was observed at 3 years.

TCT-35
Changes In Bioabsorbable Scaffold Geometry After Kissing Balloon Inflation In Bifurcated Coronary Lesions

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Background: In vitro and in vivo geometry of metallic single stent implantation in coronary bifurcated lesions after kissing balloon (KB) intervention, has been well studied. The same analysis of bioabsorbable vascular scaffolding (BVS) had not yet been reported. Our own in vitro observations with BVS showed integrity and no device fracture after KB inflation when a ≤2.5 mm balloon diameter was inflated through the struts.

Methods: In our series, 80 coronary bifurcated lesions were treated with provisory BVS strategy. In 21 out of 80 lesions, we performed final KB inflation after BVS implantation. The reason for side branch (SBV) intervention was ostial angiographic stenosis (present before BVS implantation in 14 lesions, and appearing after it in 7). IVUS studies were performed in 3 conditions: before treatment, immediately after BVS and after KB inflation. Measurements were performed at the proximal scaffold segment, before SB origin, under SB origin and at the distal segment. This study analyzes the ultrasonographic (IVUS) findings after BVS implantation and after KB inflation. For KB technique, the balloon diameter inflated in the MV was always 0.5 mm minor than BVS diameter and the SB balloon diameter was 2 or 2.5 mm.

Results: BVS diameter was 3.10 ± 0.39 mm and the mean inflation pressure was 15±1 atm. The MV balloon diameter was 2.8±0.3 mm (0.5 mm minor than BVS diameter in all cases). The SB balloon diameter was 2.3±0.2 mm and the inflation pressure of both balloons was 7-8 atm. Integrity of the device was always observed after KB. Good aposition of the proximal BVS and angiographic improvement of the SB origin was always obtained. Geometry of the BVS may be modified after KB technique, but not distorted. The table summarizes the findings.

<table>
<thead>
<tr>
<th>Stent Type</th>
<th>Proximal BVS Area</th>
<th>SB-ostium Area</th>
<th>AI Before SB origin</th>
<th>AI After SB origin</th>
<th>Device Fracture</th>
</tr>
</thead>
<tbody>
<tr>
<td>BVS DES</td>
<td>7.48±1.73</td>
<td>6.03±1.76</td>
<td>0.81±0.08</td>
<td>0.84±0.06</td>
<td>None</td>
</tr>
<tr>
<td>BVS</td>
<td>7.95±1.99</td>
<td>5.89±1.67</td>
<td>0.80±0.07</td>
<td>0.84±0.06</td>
<td>0.71</td>
</tr>
<tr>
<td>DES</td>
<td>6.70±1.99</td>
<td>6.03±1.76</td>
<td>0.85±0.06</td>
<td>0.82±0.07</td>
<td>0.72</td>
</tr>
<tr>
<td>OCT</td>
<td>7.53±2.04</td>
<td>6.99±2.03</td>
<td>0.81±0.07</td>
<td>0.84±0.06</td>
<td>0.77</td>
</tr>
</tbody>
</table>

Conclusions: Final KB inflation in bifurcated coronary lesions treated with BVS is feasible, without inducing fracture or important distortion of the scaffold.

TCT-36
One-Year Clinical Outcomes of Diabetic Patients Treated With Everolimus-Eluting Bioresorbable Vascular Scaffolds: A Pooled Analysis From the ABSORB Cohort B and the ABSORB EXTEND Trials.

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Background: The aim of this study was to evaluate clinical outcomes of diabetic versus non-diabetic patients when treated with the Absorb Bioresorbable Vascular Scaffold (BVS) at 1-year follow-up.

Methods: This interim post-hoc analysis included 101 patients of the ABSORB Cohort B and the first consecutive 450 patients of the ABSORB EXTEND trial with at least 1-year follow-up. These 2 trials had similar inclusion and exclusion criteria; 136 diabetic patients were compared to 415 non-diabetic patients. Primary end point was assessed by a composite of major adverse cardiac events (MACE), including cardiac death, myocardial infarction, and target lesion revascularization.

Results: There were no significant differences in baseline patient demographics and lesion characteristics between diabetic and non-diabetic patients treated with the Absorb BVS, except for the prevalence of hypertension requiring medications (75.0% in diabetics vs. 61.4% in non-diabetics, p = 0.004). The cumulative incidence of MACE did not differ between diabetic and non-diabetic patients treated with the Absorb BVS at 1-year follow-up (3.7% vs. 5.1%, p = 0.64). One patient out of 136 diabetic patients experienced definite late scaffold thrombosis (ST), whereas four ST events (1 definite and 1 probable subacute ST, and 1 definite and 1 possible late ST) were observed in the 415 non-diabetic patients. The incidence rate of definite/probable ST was thus 0.7% in diabetic group and 0.7% in non-diabetic group (p = 1.0).