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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Changes In Bioabsorbable Scaffold Geometry After Kissing Balloon Intervention

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One-year Clinical Outcomes of Diabetic Patients Treated With Everolimus-Eluting Bioabsorbable Vascular Scaffolds: A Pooled Analysis From the ABSORB Cohort B and the ABSORB EXTEND Trials

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Background: Everolimus-eluting ABSORB Bioresorbable vascular scaffolds consisted of poly-lactide are programmed to bioresorb 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 bioresorbable scaffold decreased up to 2 years due to growing tissue between the struts, but late ostium area enlargement was observed at 3 years.

Changes In Bioabsorbable Scaffold Geometry After Kissing Balloon Inflation In Bufurcated 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 provisional BVS strategy. In 21 out of 80 lesions, we performed final KB inflation after BVS implantation. The reason for side branch (SB) 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 nor distorted. The table summarizes the findings.

TCT-34
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<table>
<thead>
<tr>
<th>Procedure</th>
<th>After BVS</th>
<th>After KB inflation</th>
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<tr>
<td>Proximal BVS area</td>
<td>7.48±1.73</td>
<td>7.95±1.19</td>
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<tr>
<td>At proximal stent</td>
<td>0.85±0.06</td>
<td>0.86±0.05</td>
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<td>Before SB origin area</td>
<td>6.70±1.99</td>
<td>7.53±2.04</td>
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<tr>
<td>After SB origin</td>
<td>0.81±0.08</td>
<td>0.80±0.07</td>
<td>0.88</td>
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<tr>
<td>After SB origin area</td>
<td>6.03±1.76</td>
<td>5.89±1.67</td>
<td>0.77</td>
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<tr>
<td>At distal stent</td>
<td>0.85±0.06</td>
<td>0.82±0.07</td>
<td>0.04</td>
</tr>
<tr>
<td>Distal BVS area</td>
<td>6.99±2.03</td>
<td>7.01±1.72</td>
<td>0.98</td>
</tr>
<tr>
<td>At distal BVS</td>
<td>0.84±0.06</td>
<td>0.84±0.05</td>
<td>0.75</td>
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</tbody>
</table>
Background: Bioresorbable vascular scaffolds represent an exciting advance in percutaneous coronary intervention (PCI), providing an initial coronary scaffold which are eventually resorbed by the body. The DESolve® Nx Bioresorbable Coronary Scaffold System (BCSS) is a novel drug eluting bioresorbable scaffold that utilises a PLLA-based scaffold coated with a biodegradable polylactide-based polymer and the drug Novelimus, a macrocyclic lactone mTOR inhibitor which has demonstrated potent anti-proliferative properties in previous clinical trials using Elixis® metallic Novolimus-Eluting (NE) coronary stents. The DESolve NX study is a prospective, multicenter evaluation of the safety and efficacy of the DESolve Nx BCSS in patients with single de novo native coronary artery lesions through clinical endpoints and multiple imaging modalities.

Methods: 126 patients with single, de novo coronary artery lesions were enrolled in this prospective, multi-centre, single-arm study. Those patients receiving the study device are being analysed for multiple clinical endpoints including: Major Adverse Cardiac Events (MACE), a composite endpoint of cardiac death, target vessel MI, or device are being analysed for multiple clinical endpoints including: Major Adverse Cardiac Events (MACE), a composite endpoint of cardiac death, target vessel MI, or cardiac death or scaffold thrombosis. 36-month clinical data of the DESolve Nx BCSS will be presented. The primary study endpoint was freedom from ischemic-driven target lesion revascularization (CI-TLR); Clinically-indicated Cardiac Events (MACE), a composite endpoint of cardiac death, target vessel MI, or device are being analysed for multiple clinical endpoints including: Major Adverse Cardiac Events (MACE), a composite endpoint of cardiac death, target vessel MI, or cardiac death or scaffold thrombosis. 36-month clinical data of the DESolve Nx BCSS will be presented.

Results: At baseline, the patient population had a mean age 62 years, 32% were diabetic patients. The DESolve NX study is a prospective, multicenter evaluation of the safety and efficacy of the DESolve Nx BCSS in patients with single de novo native coronary artery lesions through clinical endpoints and multiple imaging modalities.

Conclusion: The DESolve Nx BCSS demonstrated safety and efficacy in treating de novo coronary artery lesions with low clinical event rate and evidence of low late lumen loss at 6 months. A first report of results through 12 months will be presented.

TCT-37
Prospective, Multi-Center Evaluation of the DESolve Nx Novolimus-Eluting Bioresorbable Coronary Scaffold: First Report of One Year Clinical and Imaging Outcomes
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Background: In order to assess the intermediate term safety, clinical performance and the bioabsorption process of the Paclitaxel-Eluting Bioabsorbable Magnesium Scaffold (DREAMS) 5-year clinical data of cohort 1 and multi-modality imaging outcomes are reported.

Methods: Forty-six subjects were enrolled in the first-in-man BIOSOLVE-I study in two different cohorts with clinical follow-up at 1, 6, 12, 24 and 36 months; angiographic and IVUS follow-up for cohort 1 at 6-month and for cohort 2 at 12-month. This primary endpoint is Target Lesion Failure (TLF) at 6-month for cohort 1 and at 12-month for cohort 2. For some patients also 18-month and 24-month imaging data are available.

Results: TLF rate at 24-month was 6.8% including 2 TLRs and 1 peri-procedural MI occurring at the 12-month follow-up angiography; no events emerged from 12- to 24-month. No cardiac death or scaffold thrombosis was observed. 36-month clinical data of Cohort 1 will be available upon presentation. Vasoconstriction after acetylcholine at 6-month (Delta=–10.04%; p<0.0008 versus baseline) followed by vasodilatation after nitroglycerine (Delta=+8.69%; p<0.0001 versus baseline) demonstrates the uncaging aspect of the absorption process with no further change at the 12-month follow-up. Six-month virtual histology (VH) data showed a significant decrease in the dense calcium by 39.5% (p<0.0015) remaining stable from 6- to 12-month follow-up. This decrease is interpreted as a surrogate assessment for the bioabsorption process of the scaffold material. Preliminary echocardiography data using the decrease in intensity of the ultrasound signal to quantify the change in strut structure demonstrate a relatively large decrease of hyperechogenicity (28.5%) in the first 6-month, followed by lower decrease (18.4%) in the 6 months thereafter, with indications that the hyperechogenicity at 18-month returns to the values seen pre-implantation.

Conclusion: TCT-37 shows excellent safety and efficacy data with no death and no scaffold thrombosis up to 3 years in the BIOSOLVE-I trial. Multi-modality imaging documented the absorption process and the uncaging aspect of this device already at 6 months.

TCT-38
12-Month Angiographic and Clinical Results of the ReZolve® Sirolimus-Eluting Bioresorbable Coronary Scaffold: The RESTORE trial
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Background: ReZolve is a novel scaffold incorporating a unique slide & lock expansion technology and a proprietary bioresorbable stent material that is a polycarbonate co-polymer of tyrosine analogs. The aim of this study was to evaluate, for the first time, the safety and performance of the ReZolve sirolimus-eluting bioresorbable coronary scaffold in non-complex human coronary lesions.

Methods: The RESTORE trial is a prospective, multi-center and multi-national trial enrolling patients with single, de novo lesions in native coronary arteries with an average reference diameter between 2.9 mm to 3.3 mm and lesion length up to 12 mm. The primary study endpoint was freedom from ischemic-driven target lesion revascularization (TLR) at 6-months and 12-month in-scaffold late loss. Serial IVUS evaluation (post procedure and at 12 months) was also performed in a subgroup of patients. All imaging analyses were performed by independent core labs.

Results: A total of 26 patients were enrolled in this trial and the device was successfully implanted in 22 cases. Most patients were male (76%) and 36% of all patients had diabetes. Mean reference vessel diameter and lesion length were 2.72 mm and 11.1 mm, respectively. Acute recoil was minimal at 3.8% ± 6.7%. Through 6 months post-implant there were 2 focal in-scaffold TLRs. The 12-month TCA evaluation was completed for the first 8 patients and resulted in a late loss of 0.20 ± 0.19 mm. Of note, the mean stent diameter at implant in this initial group of patients was 2.94mm and remained constant over the 12-month follow-up period. The QCA and safety data for the remaining patients as well as full IVUS assessment will be available at the time of the meeting.

Conclusion: In this preliminary assessment, the ReZolve scaffold showed excellent acute performance with minimal acute recoil. Complete 12-month QCA and IVUS data is required to confirm the performance of this novel device.