Background: During the first 3 years after implantation of an everolimus-eluting poly-l-lactic-acid (PLLA) scaffold (Absorb BVS, Abbott Vascular), the polymeric struts are progressively hydrolyzed and subsequently replaced by proteoglycan. Eventually, the provisional matrix becomes cellularized by smooth muscle cell or matrix metalloproteinase. Previous preclinical studies demonstrated that Optical Coherence Tomography (OCT) by visual assessment is unable to distinguish polylactide from proteoglycan, and therefore is not sensitive enough to investigate the process of cellularization. The aim of this study was to validate this novel quantitative method on serial human OCT images.

Methods: In the ABSORB Cohort B2 trial, 17 patients underwent serial frequency-domain OCT post procedure, at 1 and 3 years. Corresponding struts in consecutive OCT slices were selected visually; two different intensity assessments were performed: one was “Area assessment” for measuring the mean intensity value of the strut area line and the other was “Line assessment” for measuring the peak intensity value along a single scan line. Results: A total of 172 corresponding struts were sequentially analyzed. The results are shown in the table. (Figure)

Conclusions: The mean peak light intensity of corresponding struts increased steadily from baseline to 3 years, suggesting that this quantitative method of OCT assessment might be valuable for monitoring the resorption process of polymeric bioresorbable scaffolds.

Conclusions: Real-time OCT revealed significant acute recoil in the latest-generation stents as well as conventional stents. For post-dilation, multiple short inflations may be better than single long inflation in optimizing the final stent expansion.
a significant higher rates of malapposed strut, particularly toward the SB ostium (40.6 ± 6.0% versus 26.0 ± 5.7%, p < 0.0005), as well as a higher SB lumen residual stenosis than after mid-distal recrossing (39.7 ± 7.1% versus 18.9 ± 8.0%, p < 0.0001). In-vivo Optical Coherence Tomography (OCT) analysis on 52 patients undergoing elective treatment of bifurcation lesions using provisional stenting showed that using OCT to guide cell recrossing is feasible and can reduce significantly strut malapposition in bifurcation. Patients who were treated using OCT guided distal recrossing had a significantly lower number of malapposed strut stents, especially in the quadrants towards the SB ostium than in the angiography-guided group (9.5% vs 42.3%, p < 0.0001). Conclusions: Optimal distal cell recrossing of the guidewire is critical to ensure a successful stent optimization in bifurcation PCI.

TCT-596

Early Vascular Restoration following treatment of single de-novo coronary artery lesions with the DESolve Nx Novolimus Eluting Bioresorbable Coronary Scaffold System (NEBCSS) at 6 months: Insights from the Serial IVUS analysis of the pivotal, prospective, multicentre, DESolve NX Trial

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Background: The DESolve Bioresorbable Scaffold is a novel drug-eluting device combining a PLLA-based scaffold coated with a bioresorbable polylactide-based polymer and a potent anti-proliferative sirolimus metabolite, Novolimus. The drug dose is 5 mcg per mm of scaffold length. An early benefit with regard to vessel restoration is a potential feature of this unique technology. The aim of this study is to assess the serial changes in the vessel treated with the DESolve scaffold using IVUS technology.

Methods: The DESolve NX is a pivotal, prospective and multicentre clinical trial, which enrolled 126 patients with de novo coronary lesions treated with a single scaffold available in three diameters (3.0, 3.25 and 3.5) and two lengths (14 and 18 mm). The first 46 patients enrolled in this trial were part of an IVUS sub-study, which consisted of a paired analysis of the automatic pullbacks performed at the end of the baseline procedure and at six-month follow-up (an additional 24 month follow-up will also be performed). All analyses are being performed by an independent IVUS core lab.

Results: The mean age of the study population was 62 years, 68% of which were men and 21% had diabetes. Pre procedure reference vessel lesion length and diameter were 11.2 ± 3.8mm and 3.06 ± 0.31, respectively. 40 of the 46 patients enrolled in the IVUS sub-study had serial analyses available at 6 months that demonstrated a significant increase in mean lumen (Δ 9.0%, p < 0.0001), scaffold (Δ 15.7%, p < 0.0001) and vessel (Δ 16.8%, p < 0.0001) areas between baseline and 6 months and low % volume obstruction (5.05%) with no case of late acquired scaffold incomplete apposition or aneurysm formation.

Conclusions: The DESolve scaffold is the first scaffold to demonstrate lumen area expansion without the need for rescue balloon deployed at 6 months follow up with no evidence of aneurysms. Serial IVUS results at 6 months showed effective neointimal suppression and the natural ability of the scaffolded vessel to remodel at 6 months.

TCT-597

Predictors of Stent Expansion After Drug-eluting Stents: An ADAPT-DES IVUS substudy

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Background: While a smaller minimum stent cross-sectional area (MSA) predicts adverse events (sten ostent stenosis and thrombosis), predictors of stent underexpansion have not been fully investigated.

Methods: ADAPT-DIS was a prospective, multicenter, registry of 8,583 consecutive pts with undergoing PCI with DES. Among 2064 pts enrolled in a pre-specified intravascular ultrasound (IVUS) substudy, 769 pts with 889 lesions were examined by both pre and post-PCI IVUS. Stent expansion (ST-Exp) was calculated as MSA divided by average of proximal and distal stent edge lumen area; %ST-Exp was divided into (1) ≥70% (adequate expansion), (2) 60-70% (moderate underexpansion), and (3) <60% (severe underexpansion). ROC curve analysis showed that cut-off values of lesion length and maximum arc of superficial calcium that best predicted stent expansion <60% (severe underexpansion) were 42.0 mm and 127°. Conversely, plaque burden was unrelated to stent expansion.

Conclusions: Lesion length and the extent of superficial calcium are the strongest determinants of stent underexpansion.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>ST-Exp (&gt;70%)(n=672)</th>
<th>ST-Exp 60-70% (n=159)</th>
<th>ST-Exp &lt;60% (n=58)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST-Exp (%)</td>
<td>82.1 [76.7, 86.7]</td>
<td>65.8 [63.7, 68.0]</td>
<td>55.0 [51.4, 57.4]</td>
<td>&lt;0.0001</td>
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<tr>
<td>MSA (mm²)</td>
<td>6.5 [5.0, 8.2]</td>
<td>5.2 [4.1, 6.5]</td>
<td>4.1 [3.2, 4.9]</td>
<td>&lt;0.0001</td>
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<tr>
<td>Lesion length (mm)</td>
<td>21.0 [15.4, 30.2]</td>
<td>32.1 [22.2, 46.7]</td>
<td>47.5 [32.8, 62.0]</td>
<td>&lt;0.0001</td>
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<tr>
<td>Plaque burden at MLA (%)</td>
<td>77.6 [69.2, 83.7]</td>
<td>77.7 [69.5, 83.9]</td>
<td>80.3 [75.2, 85.2]</td>
<td>0.18</td>
</tr>
<tr>
<td>Superficial arc of calcium (°)</td>
<td>87 [47, 145]</td>
<td>100 [68, 171]</td>
<td>159 [90, 230]</td>
<td>&lt;0.0001</td>
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