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ABSORB EXTEND: An Interim Report on the 36-month Clinical Outcomes from the First 250 Patients Enrolled

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Background: The safety and performance of the current Absorb Bioresorbable Vascular Scaffold (Absorb BVS) (Abbott Vascular, Santa Clara, CA) has been previously established in 101 patients from Cohort B of the First-in-Man ABSORB trial. At 48 months, the MACE rate in Cohort B was 10.1%, with no scaffold thrombosis reported. ABSORB EXTEND was initiated as a global continued access study (outside of the US) to expand experience with the Absorb BVS to different geographies. Additionally, patients were allowed to be treated for longer coronary lesions and smaller vessels than those in the Cohort B trial, using either longer scaffold lengths or planned overlap with the 2.5 and 3.0 mm Absorb BVS.

Methods: ABSORB EXTEND is a prospective, single-arm, open-label clinical study that enrolled 812 subjects at 58 sites. Included were patients with lesions ≤ 28 mm in length and reference vessel diameter of 2.0 - 3.3 mm (as assessed by on-line QCA or IVUS). Treatment of a maximum of two de novo native coronary artery lesions, each in a different epicardial vessel, was permitted. Interim 24-month data in the first 250 ABSORB EXTEND study patients has been previously presented. Patients included 33% with unstable angina, 29% with prior MI and 27% with diabetes mellitus. The mean RVD was 2.61 ± 0.35 mm and mean length was 11.61 mm. In these 250 patients, the hierarchical MACE, TVF and def/prob ST rates at 2 years were 7.3%, 8.1% and 0.8% respectively. Long-term, 36-month follow-up data will be presented for these patients and will provide substantial data on the long-term safety and performance of the Absorb BVS in a larger population of patients, including those with planned overlapping and dual vessel treatment. Furthermore, a propensity score matched comparison with Xience treated patients from the SPIRIT trials will be presented.

Conclusions: Long-term outcomes in approximately 250 patients at 36 months (the largest patient cohort reported at this time point to date) from ABSORB EXTEND will provide further insight into the safety and performance of the Absorb BVS.

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Attenuation Analysis Of The 'Sealing Effect' And Plaque Morphology 5 Years After Implantation Of The Everolimus-Eluting Bioresorbable Vascular Scaffold. An Optical Coherence Tomography Study

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Background: Bioresorbable vascular scaffold (BVS) implantation has been suggested to induce a tissue response separating potentially thrombogenic plaque components from the lumen, thus ‘sealing’ the plaque. Attenuation is an optical property of tissues that can be measured in optical coherence tomography (OCT) images. High attenuation is associated with necrotic core or macrophages, whereas lower attenuation values correspond to more benign phenotypes. We analysed the attenuation properties of a segment treated with BVS 5 years post implantation.

Methods: Eight of 14 living patients enrolled of the Thoracenter cohort of ABSORB Methods: of a segment treated with BVS 5 years post implantation.

Results: The mean attenuation value within the ‘sealing layer’ was 1.77 ± 0.32 mm-1 and the median was 1.28 ± 0.25 mm-1. This value was higher within the entire ‘neo-plaque’ (mean: 2.87 ± 0.54 mm-1, median: 2.33 ± 0.49 mm-1, p < 0.001). Spread-out attenuation maps at different depths from the luminal surface are displayed in the Figure. The surface layers (first 200µm) had low attenuation, overlying high-attenuation areas located deeper in the plaque.

Conclusions: At long-term BVS follow-up, attenuation analysis confirms the finding in most cases of a superficial homogeneous layer with low attenuation, unlikely to contain high-risk wall components such as necrotic core and macrophages.

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Short- and long-term safety evaluation of a novel bioresorbable scaffold in a miniature swine coronary artery model

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Background: Current bioresorbable scaffold technology has shown promising results in small-sized clinical studies. However, preclinical data addressing long-term vascular reactions remain limited. The aim of this study was to investigate vascular responses of a novel bioresorbable polymeric scaffold (BRS) (PLA; Arterial Remodeling Technologies, Paris, France) by histology and optical coherence tomography (OCT) compared with bare-metal stent (BMS; Vision, Abbott Vascular, Santa Clara, CA, USA) in porcine coronary arteries.

Methods: A total of 107 devices (54 BRS and 53 BMS) were implanted in miniature swine coronary arteries and examined by OCT at follow-up of 30-, 90-, 180-, 270-, 365-, 545-, and 720-days (22 BRS and 20 BMS) and all were examined by light microscopy at each time point.

Results: Lumen area was significantly smaller in BRS than BMS at 30-, and 90-days. Although neointima area was increasing over time in BRS, lumen area also progressively increased after 90 days whereas in BMS luminal gain was not observed. Inflammation score was greater in BRS compared to BMS at 3- to 24-months. Peak degradation of stent struts was observed between 3 to 9 months. While BRS showed a significant positive correlation between lumen area and inflammation score from 1 to 9-months, a negative correlation was observed in BMS (figure).

Conclusions: This study shows positive remodeling of coronary vessels treated with BRS with increasing lumen area over time. Lumen area enlargement was associated with inflammation reaction during peak degradation.
Background: Previous ABSORB studies proved safety and efficacy of bioresorbable vascular scaffolds (BVS, Abbott Vascular Inc., Santa Clara, CA) under clinical study conditions. However, in a real world setting including patients with a worse health status, a higher proportion of complex lesions and waiving obligatory IVUS or OCT guidance, BVS treatment has not been evaluated. For this purpose, we set up the ASSURE registry over a period of 3 years.

Methods: Unselected, consecutive patients with de novo native coronary artery disease were enrolled at 6 German centers in the prospective, observational registry. Outcomes were procedural success and occurrence of cardiovascular death, myocardial infarction, ischemia driven target lesion revascularization, and target vessel failure or revascularization. Angiographic parameters including independent quantitative coronary angiography were assessed pre and post procedure. One-year experience is being reported.

Results: A total of 183 patients (198 lesions) were treated with BVS. In 128 (64.7%) lesions a complex ACC/AHA morphology (B2 or C) was present. Procedural success was achieved in all patients. Acute gain of minimal lumen diameter was 1.54 ± 0.51 mm. Through 12 months, 1 patient (0.5%) died from gastrointestinal perforation. 3 (1.7%) non-target vessel events were observed. Non-target vessel revascularization (TVR) was necessary for 2.8% of patients. TVR was performed at 12 months, angioplasty was less frequent (17.3% versus 56.8%), as was unstable angina pectoris (1.7% versus 21.3%).

Conclusions: One-year ASSURE results suggest that BVS for de novo coronary artery disease are associated with favorable clinical and functional outcomes in all day clinical practice without mandatory IVUS or OCT guidance (ClinicalTrials.gov: NCT01583608).

TCT-621

ABSORB Everolimus-Eluting Bioresorbable Scaffold In Coronary Interventions: 12-Months Results Of a Single Center Registry

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Background: There is limited outcome data on the use of the ABSORB bioresorbable vascular scaffold (BVS) in daily clinical practice, in particular in acute coronary syndrome (ACS) patients and more complex lesions. The aim of this study was to evaluate the clinical outcome after BVS implantation in both simple and complex lesions in stable patients and acute coronary syndrome patients, similar to a more “real world” population.

Methods: All patients assigned to treatment with BVS between August 2012 and August 2013 were included in this single center registry. 12-month clinical outcomes assessed were cardiac death, myocardial infarction (MI), stent thrombosis (ST), target lesion revascularization (TLR), target vessel revascularization (TVR) and target vessel failure (TVF). TVF was defined as a composite of the device oriented endpoints of all cause mortality, any MI or TVR.

Results: A total of 135 patients (59 ± 11 years, 73% male, 20% diabetic) were enrolled and 159 lesions were treated. Stable angina was the indication for PCI in 47%, and ST-segment elevation myocardial infarction (STEMI) in 13%. The majority of the lesions (67%) were lesion type B2 or C (AHA/ACC classification), including 2 left main, 13 chronic total occlusions and 24 bifurcation lesions. Median follow-up duration was 378 days [Q1-Q3: 201-435]. At 12 months the individual clinical endpoint of cardiac death occurred in one patient (12-month cumulative event rate 0.8%), MI in 5 (4.3%), TLR in 11 (9.8%) and TVR in 14 (12.0%). ST occurred in 4 patients (12-month cumulative definite ST rate of 3.0%). All cases of ST were angiographic defined as definite, including three sub-acute and one late-ST. In summary, the composite endpoint of TVF occurred in 15 patients resulting in a 12-month cumulative event rate of 13.2%.

Conclusions: Based on the results of the current study we believe that implantation of the ABSORB BVS in a “real world” patient population is applicable with associated clinical outcomes at twelve months. Complete 12-month follow-up results will be available at TCT 2014.