TCT-590
Plaque modifications after drug eluting balloon assessed by virtual histology. The PATRIOTS trial.

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Background: The effects of paclitaxel-eluting balloon (PEB) on flow limiting intact plaques, healing processes and plaque remodeling at long term are not known. Aim of this exploratory study was to assess the long-term coronary arterial response to DEB using serial VH-IVUS.

Methods: Patients with de novo significant A/B lesion type in vessels with diameter $\geq 2.5$mm and $\geq 3.5$mm were enrolled. Major exclusion criteria were in-stent restenosis and STEMI patients. Lesion of interest was predilated and then treated with PEB (Dor, Eurocor) with a RVD/balloon diameter ratio of 1. Patients who received bail-out stenting were excluded. VH-IVUS data were acquired before the predilation and at 4-month FU. Primary objective was to assess the change in % atheroma volume (PAV) and necrotic core (NC) volume from baseline to FU in the entire lesion.

Results: A total of 23 were screened, but eventually 18 patients were enrolled in the study. Mostly, the target vessel was RCA (66.7% of cases). Mean DEB diameter and length were 2.5$\pm$0.41 and 19.3$\pm$3.9 respectively. Serial IVUS data at baseline and at 4-month FU are reported in Table 1. In the entire lesion, PAV and NC volume did not change significantly, while at the MLA site, LA increased and plaque burden at the MLA site.

4-month FU are reported in Table 1. In the entire lesion, PAV and NC volume did not change significantly, while at the MLA site, LA increased and plaque burden at the MLA site.

Conclusions: PCI with DEB was not associated with a significant change in PAV and NC volume over time. However, TCFAs changed their phenotype into a more stable looking one. This hypothesis generating study might serve as a basis for exploring further the plaque sealing concept in a larger study.

TCT-591
Stent coverage and neointimal maturity in a randomized trial of limus-eluting stents with biodegradable polymer versus permanent polymer coatings assessed by optical coherence tomography

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Background: We hypothesized that biodegradable polymer siroimus-eluting stents (BP-SES) might enhance vascular healing as compared to permanent polymer everolimus-eluting stents (PP-EES). Accordingly we compared the healing patterns of BP-SES (Osirio®) with PP-EES (Xience®) using optical coherence tomography (OCT).

Methods: A total of 60 patients undergoing coronary intervention for de novo stenoses were randomly assigned to BP-SES or PP-EES in a 1:1 allocation. Tissue coverage, stent apposition and neointimal maturity were assessed using OCT at 6-8 months.

Results: Both stents showed marked heterogeneity in vascular healing. After adjustment for strut-level clustering with a mixed linear model approach, there were no statistical differences in the rates of uncovered struts between BP-SES and PP-EES (8.3% [95%CI: 0.6-56.8%] vs. 3.9% [95%CI: 0.8-81.7%] in PP-EES, p=.41, Figure A). A total of 0.1% of struts were malapposed in BP-SES group and 0.4% of struts in PP-EES group (p=.42). In patient-level analysis, 2 patients in BP-SES group versus 3 in PP-EES group had >30% of uncovered struts, respectively (p=.52).

Conclusions: No significant differences in tissue coverage were detected by OCT between BP-SES and PP-EES. Marked heterogeneity of healing was observed in both groups.

TCT-592
Incidence, imaging and clinical outcomes of acute scaffold disruption and late structural discontinuity after implantation of the Absorb everolimus-eluting fully bioresorbable vascular scaffold: Optical coherence tomography assessment in the ABSORB Cohort B trial

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Background: Fully bioresorbable scaffolds (BRSS) are a novel approach of treatment for coronary narrowing that provides transient vessel support with drug delivery capability without the long-term limitations of metallic drug-eluting stents. However, a potential drawback of the bioresorbable scaffold is the potential for disruption of the strut network when over-expanded. Conversely, the structural discontinuity of the polymeric struts at a late stage is a biologically programmed fate of the scaffold during the course of bioresorption.

Methods: The ABSORB Cohort B trial is a multicentre single-arm trial assessing the safety and performance of the Absorb BVS (second generation, Abbott Vascular, Australia) compared with a control group of drug eluting stents (DES) during a 12-month follow-up period. The primary endpoint was strut disruption, defined as complete loss of the external scaffold strut.

Results: A total of 175 patients (average age 72 years; 83% male) were enrolled from 17 sites in five countries from April 2012 to May 2013. Baseline characteristics were comparable between the Absorb and control groups.

Conclusions: The primary endpoint of strut disruption occurred in 7.4% of the Absorb group and 2.8% of the control group (p=0.004). The rate of scaffold exposure was 3.7% vs 0.9% (p=0.3) and the rate of scaffold apposition was 96.3% vs 99.1% (p=0.003) at 6 months. The rate of scaffold thrombosis was 0.7% vs 0.4% (p=0.5). The rate of scaffold fracture was 0.7% vs 0.4% (p=0.5) at 12 months.

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Santa Clara, USA) in the treatment of 101 patients with de novo native coronary artery lesions. The current analysis included 51 patients with 143 OCT pullbacks (Baseline: 52, 6 month: 25, 1 year: 22, 2 year: 26, 3 year: 18) who underwent OCT at baseline and follow-up. The presence of acute disruption or late discontinuities was diagnosed by the presence on OCT of stacked, overhung struts or isolated intraluminal struts disconnected from the expected circularity of the device.

Results: Out of 51 patients with OCT imaging post-procedure, acute scaffold disruption was observed in 2 patients (3.9%). One patient had a target lesion revascularization presumably related to the disruption. Out of 49 patients without acute disruption, late discontinuities were observed in 21 patients. There were no major adverse cardiac events associated with this finding except for one patient who had a non-ischemia driven target lesion revascularization.

Conclusions: Acute scaffold disruption is a rare iatrogenic phenomenon that has been anecdotally associated with anginal symptoms, whereas late strut discontinuity is observed in 40% of patients and could be viewed as a serendipitous finding of a normal bioresorption process without clinical implications.

TCT-593
In Vivo Assessment of the Bioresorption process of Everolimus-eluting PLLA Scaffold: a Light Intensity Analysis of Sequential Optical Coherence Tomography Imaging post Procedure, and at 1 and 3 Years In The ABSORB Cohort B2 Trial
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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 connective tissue. Previous preclinical studies demonstrated that Optical Coherence Tomography (OCT) by visual assessment is unable to distinguish poly lactide from proteoglycan, and therefore is not sensitive enough to investigate the process of bioresorption. Light intensity assessment of strut on OCT might be a sophisticated method to quantify the phenomenon of cellularization. The aim of this study was to test this novel quantitative method on serial human OCT.

Methods: In the ABSORB Cohort B2 trial, 17 patients underwent serial frequency-domain OCT post procedure, at 1year and at 3 years. Corresponding struts in corresponding cross-sections at different times were detected by using anatomical landmarks. The region of interest (ROI) encompassing the corresponding struts was 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 and 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.

TCT-594
Acute Stent Expansion in the Latest-Generation Drug-Eluting Stent Platforms:
An Experimental Study Using Optical Coherence Tomography
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Background: Different stent material/design and post-dilatation strategies can impact on final stent expansion. The aim of this study was to evaluate the acute recoil of the latest-generation coronary stents compared with conventional stents.

Methods: Optical coherence tomography (OCT) imaging was performed on 3 latest-generation (LG) stents (Multi-Link S, Integrity and Element), 2 conventional cobalt chromium (CC) stents (Driver and Vision) and 3 conventional stainless steel (SS) stents (Select, Liberté and S-Select) ($93.0$ mm, $N=3$ each) during and after balloon inflation in a silicone-tube bench model. After nominal-pressure deployment (15 sec), a single long (30 sec) vs. multiple short (10 sec x 3 times) post-dilatations were performed using a non-compliant balloon ($3.25$ mm, $20$ atm).

Results: Stent areas during deployment significantly varied among 3 groups (LG 6.5, CC 7.1, SS 6.1 mm², p<0.001). Recoil after deflation in LG was similar to SS, but smaller than CC ($8.1\%$, $8.2\%$, $12.1\%$, p<0.001). Significant recoil was also observed after post-dilatation, regardless of stent types and inflation strategies. Overall, multiple short inflations achieved greater final stent areas than single long inflation (Figure). Final stent area in LG was similar to CC, but smaller than SS ($7.5\%$, $7.5\%$, $7.9\%$, p<0.001). In the LG group, these results were not different among 3 stent types.

Conclusions: Real-time OCT revealed significant acute recoil in the latest-generation stents as well as conventional stents. For post-dilatation, multiple short inflations may be better than single long inflation in optimizing the final stent expansion.

TCT-595
Location of Side Branch Access Critically Affects Results in Bifurcation Stenting: Insights From In-vitro Modeling and Optical Coherence Tomography
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Background: The aim of this study was to evaluate the impact of stent design and side branch access on final stent apposition during bifurcation stenting.

Methods: 42 samples of 6 different commercially available Drug Eluting Stents (DES) were deployed in an identical in vitro coronary bifurcation model. The platform tested were 16mm to 28mm in length and included the Everolimus eluting Xience V (n=9, Abbott Vascular, Santa Clara, CA), Promus Element (n=9, Boston Scientific, Natick, MA), the Paclitaxel eluting Taxus Liberté (n=8, Boston Scientific, Natick, MA), the Biolimus eluting Biomatrix Flex (n=7, Biosensors International, Morges, Switzerland), the Sirolimus eluting Cypher Select (n=4, Cordis, Warren, NJ) and the Zotarolimus eluting Resolute stent (n=5), Medtronic, Santa Rosa, CA). Kissing Balloon (KB) optimization was performed after either a proximal or a distal recrossing toward the side branch produced

Results: The provisional matrix becomes cellularized by smooth muscle cell or connective tissue. Different stent material/design and post-dilatation strategies can impact on final stent expansion. The aim of this study was to evaluate the acute recoil of the latest-generation coronary stents compared with conventional stents.

Methods: Optical coherence tomography (OCT) imaging was performed on 3 latest-generation (LG) stents (Multi-Link S, Integrity and Element), 2 conventional cobalt chromium (CC) stents (Driver and Vision) and 3 conventional stainless steel (SS) stents (Select, Liberté and S-Select) ($93.0$ mm, $N=3$ each) during and after balloon inflation in a silicone-tube bench model. After nominal-pressure deployment (15 sec), a single long (30 sec) vs. multiple short (10 sec x 3 times) post-dilatations were performed using a non-compliant balloon ($3.25$ mm, $20$ atm).

Results: Stent areas during deployment significantly varied among 3 groups (LG 6.5, CC 7.1, SS 6.1 mm², p<0.001). Recoil after deflation in LG was similar to SS, but smaller than CC ($8.1\%$, $8.2\%$, $12.1\%$, p<0.001). Significant recoil was also observed after post-dilatation, regardless of stent types and inflation strategies. Overall, multiple short inflations achieved greater final stent areas than single long inflation (Figure). Final stent area in LG was similar to CC, but smaller than SS ($7.5\%$, $7.5\%$, $7.9\%$, p<0.001). In the LG group, these results were not different among 3 stent types.

Conclusions: Real-time OCT revealed significant acute recoil in the latest-generation stents as well as conventional stents. For post-dilatation, multiple short inflations may be better than single long inflation in optimizing the final stent expansion.