**TCTAP A-077**

Two-year Imaging Results of the Absorb Bioresorbable Everolimus Eluting Vascular Scaffold with Planned Overlapping from the ABSORB EXTEND Optical Coherence Tomography Subgroup

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**BACKGROUND**

ABSORB EXTEND is a global continued access study that followed the First-In-Man ABSORB trial. It is aimed at expanding experience with Absorb bioresorbable everolimus eluting vascular scaffold (Absorb BVS, Abbott Vascular, Santa Clara, CA, US) to more geographies and to a larger population of patients, including patients treated for longer lesions using planned overlapping of scaffolds. Interim analyses from ABSORB EXTEND have shown the safety and efficacy of Absorb BVS for the first 450 subjects up to 2 years with low target lesion failure and scaffold thrombosis rates (6.5% and 1.1%, respectively). The Optical Coherence Tomography (OCT) imaging sub-study is being conducted within this trial to assess the outcomes associated with planned overlapping of Absorb BVS.

**METHODS**

A total of 812 patients were enrolled from 56 global sites in this prospective, single-arm, open-label clinical study. Patients with lesions ≤ 28 mm in length and reference vessel diameter of 2.0 - 3.8 mm were included with treatment of a maximum of two de novo native coronary artery lesions, each in a different epicardial vessel. A subset of 14 patients (designated as the OCT subgroup) who received planned overlapping of Absorb BVS at designated OCT sites will be assessed using OCT, angiography and intravascular ultrasound imaging post-procedure and at 2 years.

**RESULTS**

The mean age of this OCT subgroup was 62.01 years and 85.7% were male. 14.3% of patients had a history of previous MI and 14.3% had a prior cardiac intervention. The mean lesion length was 15.22 mm. About 25% of the lesions were longer than 20 mm. Despite the use of planned overlapping of Absorb BVS, clinical device and procedure success rates were both 100%. OCT and other imaging outcomes from post-procedure and at 2-year follow-up will be reported.

**CONCLUSION**

The treatment with planned overlapping of Absorb BVS was highly successful in this small cohort of OCT subgroup patients. The 2-year imaging results will provide further information on the feasibility and long term outcomes of longer lesion treatment using planned overlapping of Absorb BVS.

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**TCTAP A-078**

Intravascular Ultrasound Guidance Could Improve Outcomes in Proximal Left Anterior Descending Artery Interventions

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**BACKGROUND**

The relative failure of PCI in proximal LAD compared to CABG remains an important challenge for interventional cardiologists. Numerous trials comparing CABG to PCI in proximal LAD from the balloon angioplasty to BMS to DES era, demonstrated that CABG has less TVF rates compared to PCI driven by less repeat revascularizations in the CABG arm. IVUS-guided PCI trials clearly suggest that patients in the IVUS - guided arm consistently had stents which were larger in diameter. This led us to think that the possible cause of failure in the proximal LAD could be because of under-sizing of the proximal LAD by Quantitative Coronary Angiography. We set out to test this fact by doing simultaneous IVUS and QCA measurements of the proximal LAD in a series of 50 patients undergoing PCI to LAD. We present illustrative QCA and IVUS images of a patient to demonstrate our contention.

**METHODS**

The proximal LAD was defined as the segment of LAD between the ostium and the first diagonal artery. Simultaneous QCA and motorized IVUS-pullback studies using ATLANTIS PRO 40Mhz IVUS probe were done in all patients undergoing PCI to LAD. We measured the LAD diameter at the ostium, and prior to its bifurcation with the first diagonal by IVUS. Two cross-sectional measurements of the LAD were done at each point. We took an average of these four values to arrive at the diameter of the proximal LAD. These values were then compared to the maximum QCA value obtained along the length of the proximal LAD.
**RESULTS** Our findings in this study clearly demonstrate that IVUS measurements of the proximal LAD diameters (media to media) of our subjects were consistently 3.5 mm or above irrespective of the height, weight, age, sex, body surface area and presence or absence of diabetes or hypertension. We also demonstrated that QCA consistently underestimates the diameter in the proximal LAD when compared to IVUS measurements by 0.74 mm on average.

**CONCLUSION** Our findings have led us to change our practice significantly in the direction of aggressive proximal optimization of LAD with 3.5 mm diameter balloons or greater as suggested by IVUS measurements. We conclude that IVUS could add significant value in intervention in proximal LAD and further reduce TVF rates in proximal LAD.
We propose a multi-center, randomized trial for proximal LAD lesions comparing QCA and IVUS-guided angioplasty to ascertain whether application of IVUS improves outcomes in this subset of patients.

**TCTAP A-079**  
**Vascular Edge Response After Percutaneous Coronary Intervention Using Serial Optical Coherence Tomography**  
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**BACKGROUND** The purpose of this study was to investigate the vascular response at the proximal and distal edges of the drug-eluting stent (DES) using optical coherence tomography (OCT).

**METHODS** A total of 40 patients with 45 lesions were examined by OCT immediately post-implantation and at follow-up. Quantitative and qualitative measurement was performed at the adjacent proximal as well as distal vessel segments to the implanted DES less than 1mm interval.

**RESULTS** Mean follow-up duration was 320.6±95.5 days. Distal edge showed trend of decreased mean lumen area (from 6.56±2.30 mm² to 6.25±2.16 mm², p=0.031). At proximal edge, mean lumen area was significantly decreased at follow-up compared with post-procedure (from 9.57±3.04 mm² to 8.77±3.38 mm², p=0.001). Compared with proximal edge, distal edge showed trend of lesser degree of lumen loss (-0.31±0.95 mm² vs.-0.80±1.54 mm², p=0.058). Thin-cap fibroatheroma (TCFA) was observed in 13.3% of enrolled stents (6/45) immediately after stenting, and in 8.9% (4/45) at the follow-up (3: persistent, 1: new-onset). And edge dissection was observed in 20% (9/45) immediately after stenting, and 2.2% (1/45) at the follow-up.

**CONCLUSION** The OCT-based assessment of the edge response in showed lumen loss at proximal edge. While half of TCFA was remained, almost of edge dissection was healed. However, larger cohorts study will be needed to validate these preliminary results.

**TCTAP A-080**  
**Neointimal Response After Second-Generation Drug-Eluting Stent Implantation in the Left Main Trunk – The Evaluation by Optical Coherence Tomography**  
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**BACKGROUND** Recently, percutaneous coronary intervention (PCI) of the unprotected left main trunk (LMT) with a second-generation drug-eluting stent (DES) is increasingly performed. The objective of this study is to examine the neointimal response after LMT-PCI with a second-generation DES by FD-OCT and to evaluate the safety of the procedure.

**METHODS** Fifty patients who underwent PCI for LMT with a second-generation DES and were analyzed by FD-OCT 6-8 months after PCI were included in this study.

**RESULTS** Single stenting was performed in 39 patients (Bilimus-Eluting Stent (BES) =16, Everolimus-Eluting Stent (EES) =23), and double stenting (Culotte stenting) in 11. 1) Single-stenting group: The struts were well covered irrespective of the stent (93.2% with BES, 94.2% with EES). The rate of malapposed struts was extremely low (2.9% with BES, 1.0% with EES). The neointima on the strut was thicker with EES than BES (87.7±33 μm vs. 72.5±59 μm, p=0.0001). 2) Double-stenting group: Contrary to expectations, the percentage of uncovered struts was significantly lower at over-lapping sites than non-overlapping sites (4.9% vs. 7.7%, p=0.04), and the frequency of malapposed struts and the neointimal thickness were similar at both sites.

**CONCLUSION** At 6-8 months after PCI with the second-generation DES, stents were well covered by the neointima, even at the over-lapping site of culotte stenting. Satisfactory neointimal healing after LMT-PCI with a second-generation DES was observed in our study.

**TCTAP A-081**  
**Acetycholine Provocation Test May Estimate the Intimal Coverage in Drug Eluting Stent Implanted Site**  
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**BACKGROUND** Prior studies showed the impairment of intimal function after drug eluting stent (DES) implantation caused restenosis, yet the detailed morphology of this phenomenon is still uncertain.

**METHODS** Optical coherence tomography (OCT) were performed in 16 stenting sites and divided into two groups based on positive and negative spasm provocation using acetycholine. We analyze the intimal coverage, the consistency of intima including presence of peri-strut low-intensity area and hollow formation between the struts. These evaluations were performed at every slice of stent implanted site.

**RESULTS** The interval from index procedure to OCT analysis is not significant between the groups, 342 days in provocation positive group and 329 days in negative group (P=0.64). We examined 11 lesions (1290 slices, 9828 struts) and 5 lesions (636 slices, 4792 struts) in provocation positive and provocation negative groups respectively. The number of stent coverage was significantly lower in the provocation positive compared to the negative group (5702 versus 2162 struts, P<0.001). Peri-strut low-intensity areas were more frequently observed in the provocation positive group than the other group (440 versus 239 struts, P<0.001). The hollow formation also were observed more frequently in the positive group (181 versus 55 slices, P=0.001).

**CONCLUSION** The morphological characteristics of intima in the positive group were different from those in negative group. In chronic period after DES implantation, acetycholine provocation test may estimate the intimal coverage and the delay of the fibrin absorption process around the struts.

**TCTAP A-082**  
**Impact of Lipid Rich Plaque at the Stent Edge Assessed by Optical Coherence Tomography on Edge Restenosis After EES implantation**  
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**BACKGROUND** Stent edge restenosis due to incomplete lesion coverage is one of major risk factors for stent failure after drug-eluting stent implantation. An association between plaque type at stent edge and edge restenosis has not been evaluated yet. The aim of the present study was to assess whether there is an association between plaque type assessed by optical coherence tomography (OCT) and edge restenosis after EES implantation.

**METHODS** In this study, 278 patients with 331 lesions who underwent OCT-guided EES implantation and 9-12 months scheduled follow-up angiography were enrolled. By using OCT, plaque type at stent edge was classified into the following 4 types: lipid rich plaque, fibrotic plaque, fibrocalcific plaque, and normal segment.

**RESULTS** Distal and proximal edges were visible by post stenting OCT in 323 and 318 edge segments, respectively. The proportion of plaque type at stent edge was the following, lipid rich; 21%, fibrotic; 45%, fibrocalcific; 19% and normal segment; 15%. The incidence of edge restenosis was 4.7% (Q of 641 edge segments, 17 in proximal edge, 11 in distal edge, 1 in both edge): 12.8% in lipid rich plaque, 2.8% in fibrocalcific plaque, 4.0% in fibrocalcific plaque, and 0% in normal segment, respectively (p<0.001).

**CONCLUSION** The present OCT study demonstrated that lipid rich plaque at the stent edge has impact on edge restenosis after EES implantation. The selection of residual plaque except for lipid rich plaque assessed by OCT as landing zone of the stent may allow us to avoid unnecessarily longer stents without increasing the incidence of edge restenosis.