

## TCT-298

**Six-month Intravascular Ultrasound Analysis of the DESolve FIM Trial with a Novel PLLA-based Fully Biodegradable Drug-eluting Scaffold**

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**Background:** The DESolve Bioresorbable Coronary Scaffold is a novel drug-eluting device combining a PLLA-based scaffold coated with a bioresorbable polylactide-based polymer and the drug Myolimus. Myolimus, a macrocyclic lactone mTOR inhibitor, has demonstrated potent anti-proliferative properties in two First-in-Man (FIM) trials using Elixir's metallic coronary stents. The drug dose is 3 mcg per mm of scaffold length. We aimed to present the IVUS results of the first-in-man evaluation of this novel scaffold.

**Methods:** The DESolve FIM trial enrolled 15 patients, treated with a single 3.0x14 mm DESolve at 3 centers. IVUS was performed at the end of the procedure and repeated at six-month invasive follow-up. Complete and adequate IVUS images at baseline and follow-up were obtained for 11 cases. Serial changes in vessel volume, scaffold area and the degree of NIH formation were assessed. All analyses were performed by an independent core laboratory.

**Results:** From baseline to 6 months, IVUS showed a small increase in scaffold mean area (from 5.35 ± 0.78 mm<sup>2</sup> to 5.61 ± 0.81 mm<sup>2</sup>). Additionally, there was no significant change in vessel volume (from 148.0 ± 37.0 mm<sup>3</sup> to 150.03 ± 35.38 mm<sup>3</sup>) or area, demonstrating the absence of constrictive or expansive remodelling. There was very low neointimal volume (5.6 ± 2.8 mm<sup>3</sup>) and % scaffold obstruction (7.18 ± 3.37%), and no cases of incomplete strut apposition.

**Conclusions:** The DESolve scaffold demonstrated a unique property of expansion and no chronic recoil from baseline to follow-up. Results at 6 months showed effective neointimal suppression and no late strut malapposition thus suggesting a very efficacious and novel bioresorbable scaffold.

## TCT-299

**Impact of Baseline Peri-Stent Plaque Volume on Positive Vessel Remodeling after Implantation of Paclitaxel Eluting Stents: A Pooled Volumetric Intravascular Ultrasound Analysis**

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**Background:** Positive vessel remodeling, caused by an increase in peri-stent plaque volume during follow-up, has frequently been demonstrated in clinical studies of paclitaxel-eluting stents (PES). Histopathologic studies have also shown an association of positive remodeling with vessel inflammation, possibly related to the occurrence of very late stent thrombosis. This study aimed to investigate the determinants of vessel remodeling in patients treated with PES as assessed by IVUS.

**Methods:** Serial (post-procedure and 8-9 months follow-up) volumetric IVUS data were analyzed in 227 de novo coronary lesions electively treated with PES. Volume index (VI) was defined as volume/length (mm<sup>3</sup>/mm). Peri-stent plaque VI was standardized by stent VI (%PVI). Vessel remodeling during follow-up was assessed as a change of peri-stent plaque VI per stent VI. Morphologic properties with a p-value<0.10 on univariate analysis were inserted into multivariate models.

**Results:** Overall, the change of vessel VI during follow-up was 5.0±8.1% (range: -21.7% to +36.1%), resulted from a significant increase of %PVI (95.9±29.9% to 103.9±28.9%, p<0.0001). Among IVUS parameters at post-procedure, vessel VI and %PVI had significant inverse correlations with positive vessel remodeling (p=0.002, p=0.0002, respectively). In multivariate analysis, less %PVI at post-procedure was independently associated with positive vessel remodeling during follow-up (p=0.02).

**Conclusions:** This pooled IVUS analysis identified thinner peri-stent plaque surrounding PES at baseline as a predictor of larger positive vessel remodeling during follow-up. This may reflect the differential mechanical compliance and/or increased drug infiltration into the deep vessel wall structure in the setting of less underlying plaque behind the stent.

Variable	Positive Vessel Remodeling					
	Univariate Analysis			Multivariate Analysis		
	Regression Coefficient (β)	95% CI	p	Regression Coefficient (β)	95% CI	p
IVUS Parameter at Post Procedure						
Stent Length (mm)	-0.051	-0.003 -0.002	0.446			
Stent VI (mm <sup>3</sup> /mm)	-0.087	-0.013 -0.003	0.191			
Vessel VI (mm <sup>3</sup> /mm)	-0.209	-0.010 -0.002	0.002	0.083	-0.013 -0.018	0.751
%PVI (%)	-0.242	-0.168 -0.052	0.0002	-0.297	-0.248 -0.021	0.020
Minimum Lumen Area(mm <sup>2</sup> )	-0.122	-0.017 -0.001	0.067	-0.233	-0.049 -0.018	0.358

## TCT-300

**Differential Prognostic Impact of Intravascular Ultrasound Utilization According to Implanted Stent Length**

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**Background:** It is unknown whether IVUS utilization during percutaneous coronary intervention (PCI) may modify the stent length effect on clinical outcomes. We sought to find differential prognostic impact of intravascular ultrasound (IVUS) utilization according to the implanted stent length.

**Methods:** Between April 2008, and June 2010, we enrolled 3244 consecutive patients underwent single or overlapping stent implantation at 46 academic or community hospitals in Korea. The primary endpoint was a composite of death, myocardial infarction, or target vessel revascularization (MACE). Study population was divided by the tertiles of implanted stent length and IVUS utilization.

**Results:** After adjustment for significant covariates, implanted stent length was not significantly associated with the risk of MACE in IVUS group (hazard ratio [HR] 1.08, 95% confidence interval [CI] 0.97-1.20, p=0.16), whereas implanted stent length was significantly associated with the risk of MACE in no IVUS group (HR 1.13, 95% CI 1.01-1.28, p=0.042). In addition, in patients with implanted stent length of ≤22mm (N=998), the risk of MACE was not significantly different between IVUS group and no IVUS group (HR 1.06, 95% CI 0.50-2.28, p=0.88). By contrast, in patients with longer implanted stent length, the risk of MACE was significantly lower in IVUS group than in no IVUS group (HR 0.47, 95% CI 0.24-0.92, p=0.027 for 23-32mm [N=1109], HR 0.57, 95% CI 0.33-0.98, p=0.042 for ≥33mm [N=1137]).

**Conclusions:** IVUS utilization may attenuate the detrimental effect of the increase of implanted stent length, supporting the favor of IVUS utilization, particularly during PCI with the long stent implantation.

## TCT-301

**Feasibility and Results of Novel Side Branch Evaluation by Reconstructed 3-Dimensional Optical Coherence Tomography. Matched Analysis of Baseline and 12-month follow-up in Native, Jailed and Opened Side Branches**

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**Background:** Assessment of the side branch (SB) ostium by angiography and 2D optical coherence tomography (OCT) is challenging. This is the first presentation of ostial SB assessment by centerline guided 3D OCT.

**Methods:** The study was a substudy to the SORT-OUT V OCT study comparing a sirolimus eluting durable polymer stent (Cypher Select+, Cordis, US) and a biolimus eluting biodegradable polymer stent (Nobori, Terumo, JP). The SB ostium was evaluated in all SBs visible on both baseline and 12-month follow-up OCT. Each SB ostium was reconstructed in 3D by the main vessel OCT acquisition using QAngioOCT prototype (Medis medical imaging systems, NL). The minimal luminal area (MLA) was assessed up to one millimeter into the SB. The measurement plane (the cut plane), was reconstructed perpendicular to the SB centerline. In case of neointimal bridging over the SB ostium, the areas of the individual ostia of the same SB were summed.

**Results:** Matched baseline and FU OCT was available in 96 patients. At baseline 208 SBs were detected and of these were 107(51%) in-stent SBs. SBs were not analyzable due to wire shadow in 49 (23%) SBs and due to impaired image quality in 26 (12.5%) of SBs.

Total number of matched SBs for analysis was 138, 72 in-stent and 66 in native vessels. Two SBs had kissing balloon dilatation and were grouped with jailed SBs. Analysis of the entire first millimeter was possible in 58% of analyzed SBs. Mean native ostial area was increased from  $1.67 \pm 1.61 \text{ mm}^2$  at baseline to  $1.74 \pm 1.85 \text{ mm}^2$  ( $p=0.44$ ) at FU. Average in-stent ostial area was increased from  $1.30 \pm 1.42 \text{ mm}^2$  at baseline to  $1.52 \pm 1.54 \text{ mm}^2$  ( $p=0.06$ ) at FU. In-stent ostial area gain between baseline and FU for Cypher was  $0.32 \pm 1.00 \text{ mm}^2$  vs.  $0.08 \pm 0.92 \text{ mm}^2$  ( $p=0.32$ ) for Nobori. Neointimal bridging occurred in 13 (10%) of all assessed FU SBs. Intra-observer mean difference was  $0.001 \pm 0.12 \text{ mm}^2$  and inter-observer mean difference was  $0.012 \pm 0.23 \text{ mm}^2$ .

**Conclusions:** Ostial SB evaluation by 3D reconstruction of main vessel OCT acquisition is feasible when the ostium is visible and can be performed with high intra- and interobserver agreement. DES-jailed SBs tended to improve in ostial MLA at 12-month FU while mean MLA in native SB ostia remained unchanged.

### TCT-302

#### Evaluation of the Novel DESolve Myolimus-Eluting Bioresorbable Coronary Scaffold System for Treatment of De Novo Coronary Arteries: Six-Month Optical Coherence Tomography Results from the DESolve FIM Trial

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**Background:** The DESolve Bioresorbable Scaffold (BS) is a novel PLLA-based scaffold coated with a bioresorbable polylactide-based polymer and the drug Myolimus (3 mcg/mm of scaffold length). Myolimus, a macrocyclic lactone mTOR inhibitor, has shown potent anti-proliferative properties in two First-in-Man (FIM) trials using Elixir's metallic coronary stents. We aim to present the OCT results of the FIM evaluation of this novel BS.

**Methods:** 15 pts treated with a single 3.0x14 mm DESolve at 3 centers were enrolled. Serial (baseline and 6-month follow-up) OCT was available for 10 pts. All images were analyzed by an independent core laboratory at 0.6-mm interval. At baseline, scaffold malapposition and scaffold structural discontinuity (qualitatively defined as  $\geq 2$  struts overhanging each other in the same angular sector of the lumen, or by isolated struts floating inside the lumen in complete misalignment with the surrounding struts) were assessed. At follow-up, serial changes in lumen and scaffold dimensions and degree of NIH formation on top of the struts were assessed. Frequency of covered struts and NIH thickness on top of each strut were also examined. Scaffold and strut malapposition were serially assessed at the cross-section and strut levels respectively.

**Results:** At baseline, no signs of structural discontinuity were observed at the cross-section level inspection. Scaffold area was maintained over time with no evidence of scaffold recoil from baseline ( $6.57 \pm 0.68 \text{ mm}^2$ ) to follow-up ( $6.80 \pm 0.85 \text{ mm}^2$ ,  $p=0.344$ ). NIH area measured  $0.71 \pm 0.36 \text{ mm}^2$ , with  $13.16 \pm 5.59\%$  obstruction of the scaffold area. At 6 months, 2,575 struts were analyzed and 98.7% were covered with a very thin NIH ( $0.12 \pm 0.04 \text{ mm}$ ). Scaffold malapposition was observed in only 1 cross-section of 1 scaffold. Rate of malapposed struts per scaffold varied from  $2.01 \pm 2.75\%$  to  $0.04 \pm 0.12\%$  over time ( $p=0.016$ ).

**Conclusions:** The DESolve Scaffold exhibited maintenance of its structural integrity upon deployment, providing excellent mechanical support without chronic recoil. At 6 months, it demonstrated effective NIH suppression without compromising tissue coverage of the polymeric struts, with virtually complete resolution of acute scaffold malapposition.

### TCT-303

#### Predictors Of Acute And Late Persistent Stent Malapposition After Percutaneous Coronary Intervention: A Follow-up Optical Coherence Tomography Study

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**Background:** There are limited data about predictors of acute stent malapposition (ASM) and late persistent stent malapposition (LPSM) detected by optical coherence tomography (OCT).

**Methods:** A total of 252 patients (257 lesions) who underwent both post-stent and follow-up OCT were enrolled for analysis. Malapposed struts on post-stent OCT were identified and those struts were re-evaluated on follow-up OCT. Various clinical, angiographic, and OCT parameters were evaluated to identify predictors of ASM and LPSM.

**Results:** On post-stent OCT, 169 lesions (66%) showed ASM with malapposed strut % of  $5.3 \pm 6.5$ . In univariate analysis, ASM lesion was associated with calcification, B2 or C lesion complexity, intra-coronary thrombus seen on OCT, post-balloon dissection, sirolimus-eluting stent (SES), and long stent length ( $\geq 20 \text{ mm}$ ) more frequently than No-ASM lesion. However, only calcification (odds ratio [OR] = 10.9; 95% confidence interval [CI], 1.3-92.0;  $p = 0.029$ ) and long stent length ( $\geq 20 \text{ mm}$ ; OR = 2.6; 95% CI, 1.1-6.6;  $p = 0.042$ ) were independent predictors of ASM in multivariate analysis. Of 169 ASM lesions, 55(33%) showed LPSM and 114(67%) showed resolved-ASM on follow-up OCT which was performed at  $167 \pm 52$  and  $169 \pm 63$  days after the index procedure, respectively ( $p = 0.806$ ). In univariate analysis, LPSM lesion showed higher frequency of SES, older patient age, higher baseline diameter stenosis %, higher malapposed strut % on post-stent OCT, and smaller neointimal thickness on follow-up OCT than resolved-ASM lesion. Patient age ( $>60$  years) was the only independent predictor of LPSM in multivariate analysis (OR = 3.7; 95% CI, 1.2-12.7;  $p = 0.042$ ). Uncovered strut % on follow-up OCT was higher in LPSM lesion than resolved-ASM lesion (30% vs. 10%,  $p < 0.001$ ). However, there were no significant differences of major adverse cardiac events between LPSM and resolved-ASM lesion during 2-year follow-up (3.6% vs. 2.6%, respectively,  $p = 0.661$ ).

**Conclusions:** In this OCT study, calcification and long stent length were the independent predictors of ASM. The predictor of LPSM was patient age. LPSM was not associated with increased risk of clinical events.

### TCT-304

#### Neoatherosclerosis And Impaired Vascular Healing Are Associated With Clinical Presentation Late After Coronary Stent Implantation. An Optical Coherence Tomography Study

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**Background:** Both impaired vascular healing and proliferative tissue response, including neoatherosclerosis, play a role in the pathogenesis of late stent failure, presenting either as restenosis or stent thrombosis. We investigated the association of neoatherosclerosis and neointimal rupture with clinical presentation in patients late after coronary stent implantation by optical coherence tomography (OCT).

**Methods:** From 1/1/2007 to 31/1/2012, 74 patients from two institutions underwent OCT assessment of a coronary stent implanted at least 18 months prior to examination. In 39 of the patients the studied stent was the culprit of acute coronary syndrome (ACS) (myocardial infarction  $n=34$ ; unstable angina  $n=5$ ), in 13 patients the culprit of stable angina (SA), whereas 22 patients had no symptoms attributed to the studied stent (asymptomatic). Stents containing  $>5$  frames (1mm) with  $>30\%$  uncovered struts were considered uncovered, while stents with  $>5\%$  malapposed struts were considered malapposed.

**Results:** Intervals since implantation were similar among the different clinical presentations [ACS: median 65 months (range 22-201), SA: 76.5 months (31-168), asymptomatic: 53.5 (21-168);  $p=0.19$ ]. The incidence of neoatherosclerosis within the stent ( $n=44$  stents) was higher in symptomatic than in asymptomatic patients (66.7% in ACS, 84.6% in SA and 31.8% in the asymptomatic group [ $p < 0.01$ ]). The incidence of neointimal rupture was higher in the ACS group (41%) vs. SA (15.4%) and asymptomatic (4.5%;  $p < 0.01$ ). Thrombus was evident in 97.4% of patients with ACS vs. 23.1% SA and 9.1% asymptomatic ( $p < 0.01$ ). Incomplete coverage was similar between SA (22.7%) and asymptomatic (23.1%) but more frequently in the ACS group (65.8%;  $p < 0.01$ ), whereas the incidence of malapposition was comparable among the three groups (ACS: 33.3%, SA: 15.4%, asymptomatic: 22.7%;  $p=0.39$ ).

**Conclusions:** Not only impaired vascular healing, but neoatherosclerosis and neointimal rupture as well, seem to contribute significantly in the pathogenesis of late stent failure, being associated with symptomatic presentation late after coronary stent implantation.

### TCT-305

#### Correlation Between Predicted to Observed Coronary Drug-Eluting Stent (DES) Expansion as Determined by Intravascular Ultrasound (IVUS): Variance Between Stent Platforms and Impact of Lesion Characteristics

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**Background:** Manufacturer-predicted stent expansion is based on in-vitro testing. Actual expansion is related to stent architecture, lesion characteristics, etc. We evaluated the relationships between these variables on coronary DES expansion via IVUS.

**Methods:** 1,652 IVUS frames were acquired and blindly analyzed in 56 lesions post-DES via Volcano EagleEye Platinum 20 MHz IVUS. DES studied were Medtronic Endeavor ( $n=32$ , 666 mm) and Resolute ( $n=12$ , 266 mm), and Abbott Xience V ( $n=12$ , 215 mm) deployed at 16-22 ATM after nominal balloon pre-dilatation. Expansion deficit (ED, %) was the ratio of observed to predicted average stented diameter.

**Results:** DES were less expanded than predicted (ED = -10.5%,  $p < 0.001$ ) but none evidenced malapposition after high-pressure deployment. Mean ED was highest in Endeavor vs. Xience or Resolute (-11.8% vs. -6.0% vs. -10.6%,  $p < 0.001$ , Fig 1). 98.4% of Resolute frames were under-expanded vs. 93.7% Endeavor frames and 80.4% Xience ( $p < .001$ ). ED was greater in ACS vs. non-ACS (-11.2% vs. -10.2%,  $p < .002$ ) and LAD