Total number of matched SBs for analysis was 158, 72 in-stent and 66 in native vessels. There had been 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 ± 1.61 mm² at baseline to 1.74 ± 1.85 mm² (p = 0.44) at FU. Average in-stent ostial area was increased from 1.30 ± 1.42 mm² at baseline to 1.52 ± 1.54 mm² (p = 0.06) at FU. In-stent ostial area gain between baseline and FU for Cypher was 0.32 ± 0.18 mm² vs. 0.98 ± 0.92 mm² (p = 0.032) for Novolink. Neointimal bridging occurred in 13 (10%) of all assessed FU SBs. Intra-observer mean difference was 0.001 ± 0.12 mm² and inter-observer mean difference was 0.012 ± 0.23 mm².

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 DESolve Myolimus-Eluting Bioreorbable 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 Bioreorbable Scaffold (BS) is a novel PLLA-based scaffold coated with a biodegradable polydodecyl-copolymer and the drug Myolimus (3 mg/mm² of scaffold length). Myolimus, a macrocyclic lactone mTOR inhibitor, has shown potent anti-proliferative properties in two First-in-Man (FIM) trials using Elixyr’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 3.0×14 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 ≥ 2 struts overlapping 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 loss from baseline up to 6-month follow-up. NIH area measured 0.71 ± 0.36 mm², with 13.16±5.59% obstruction of the scaffold area. At 6 months, 2,405 struts were analyzed and 93.7% were covered with a very thin NIH (0.12 ± 0.04 mm). Scaffold malapposition was observed in only 1 cross-section of 1 scaffold. Rate of malapposed struts per scaffold varied from 2.01 ± 2.75% to 0.04 ± 0.12% over time (p = 0.016).

Conclusions: The DESolve Scaffold exhibited maintenance of its structural integrity upon deployment, proporing 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 % ≥ 2% and late persistent ASM 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 (≥20 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 (≥20 mm; OR = 2.6; 95% CI, 1.4-6.6; 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 ± 52 and 169 ± 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, pseudo-arsenical %, higher malapposed strut % on post-ostent 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). LPSM % on follow-up OCT was lower than pre-implantation (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 rate of late persistent malapposition was patient age. LPSM was not associated with increased risk of clinical events.

TCT-304

Neouroatherosclerosis 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 neouroatherosclerosis, play a role in the pathogenesis of late stent failure, presenting either as restenosis or stent thrombosis. We investigated the association of neouroatherosclerosis and neointimal rupture with clinical presentation in patients late after coronary stent implantation via optical coherence tomography (OCT).

Methods: From 1/1/2007 to 31/1/2012, 74 patients from two institutions underwent OCT after stent implantation of a coronary stent and were followed for 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 was 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 struts 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: 3.6 months [3-5.3]). The incidence of neouroatherosclerosis 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<0.001]). The incidence of neointimal rupture was higher in the ACS group (41% vs 15.4%) and asymptomatic (45% vs 11.95%); p = 0.01). The thrombus was evident in 97.4% of patients with ACS vs. 20.24% in SA (p<0.001). 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: 33.5%, SA: 15.4%, asymptomatic: 22.7%; p = 0.39).

Conclusions: Not only impaired vascular healing, but neouroatherosclerosis 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.