Stents - Drug-eluting: Novel Metallic DES
Washington Convention Center, Lower Level, Hall A Saturday, September 13, 2014, 5:00 PM–7:00 PM
Abstract nos: 599-609

TCT-599
Final procedural, 30-day and 6-month angiographic, clinical and OCT outcomes from the DIRECT II Trial using the Svelte Integrated Delivery System with Ezymatic Bioabsorbable Sirolimus Coating
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Background: The Svelte (New Providence, NJ) sirolimus-eluting coronary stent utilizing a bioresorbable acid-based (PEA) drug carrier is mounted on a novel Integrated Delivery System (IDS) consisting of a low-compliant balloon with balloon control bands (BCBs) affixed to a 0.014-inch wire with shapeable tip. The IDS is low-profile and specifically designed for use with the trans-radial approach (TRI). 'slender' PCI and direct stenting. The DIRECT I First-In-Man study (n = 30) reports 2.7% stent volume obstruction (via IVUS) at 6-months with 0% clinically-driven MACE through 24-months. All events and imaging were reviewed and adjudicated by an independent core lab and DSMB.

Methods: 159 patients with symptomatic ischemic heart disease due to de novo stenotic lesions in arteries with RVD 2.5mm – 3.5mm and lesion length < 20 mm were prospectively randomized (2:1 Svelte IDS : Medtronic Resolute Integrity) at 18 sites in Europe. Clinical and angiographic follow-up was scheduled at 6-months to assess TVF and LL as well as multiple secondary endpoints, with clinical follow-up continuing through 5-years. Stent evaluation post-procedure and at 6-months via OCT evidenced a lower incidence of late loss. Study enrollment completed November 2013 (n = 106 Svelte IDS arm, n = 51 Medtronic Resolute Integrity); 6-month data on all available patients is expected May 2014. Procedural, 30-day and 6-month clinical and angiographic data on all patients, along with OCT image analysis (n = 30), will be presented. Comparative data for time and cost savings, including TRI vs. femoral approach, device time, adjunctive product and contrast use, and radiation exposure, will be reported.

Conclusions: A review of the Svelte DES platform and available procedural, 30-day and 6-month angiographic, clinical and OCT outcomes from the study will be reported. These data provide first insights into the safety, efficacy and procedural efficiencies, as well as time and cost savings, of this unique DES IDS system compared with a prospective, matched control group utilizing a conventional DES system.

TCT-600
Distinct Vascular Response between Vulnerable and Stable Coronary Plaques after the Second Generation Drug-eluting Stents Implantation: One-year Angioscopic Comparison
Kenji Kawai1, Minoru Ichikawa2, Takashi Takagi3, Mitsutoshi Asai4, Yoshiyuki Takei5, Kenji Fukuda5, Shohei Yoshima5, Takeshi Oshita5, Yoshiyuki Kijima5, 1Higashi-osaka City General Hospital, Higashi-osaka, Osaka

Background: The second generation drug-eluting stents (G2-DES) have been implanted safely at culprit lesions not only of stable angina pectoris but also of acute coronary syndrome. The aim of this study was to angioscopically characterize vascular response after implantation of various G2-DES and to compare healing processes between stable and vulnerable plaques.

Methods: 64 patients were consecutively enrolled who were successfully implanted with various G2-DES. Five patients were withdrawn from further analysis because of death or stroke. Coronary angiography at one year after stenting detected in-stent restenosis in 6 patients, who were excluded from further analysis. Subsequently, coronary angioscopy was performed in 63 lesions (32 vulnerable and 31 stable plaques) of 53 patients, revealing the in-stent appearance of each G2-DES, that is, [1] neointimal stent coverage (NSC, good/poor), [2] presence of thrombus (presence/absence), and [3] presence of yellow plaques (YP, presence/absence).

Results: In-stent thrombus was detected at only 1 vulnerable plaque implanted with BMS. As shown in table, in both vulnerable and stable plaques, E-ZES was better covered with neointima than other G2-DES. In stable plaques, no significant differences were found in YP prevalence among G2-DES. In vulnerable plaques, however, prevalence of YP was significantly higher in BMS than in another G2-DES.

Table. Angioscopic findings in G2-DES

<table>
<thead>
<tr>
<th>Stable plaque</th>
<th>BES (n=8)</th>
<th>EES (n=11)</th>
<th>E-ZES (n=7)</th>
<th>R-ZES (n=7)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good NSC (%)</td>
<td>16.7</td>
<td>45.5</td>
<td>100.0</td>
<td>28.6</td>
<td>0.01</td>
</tr>
<tr>
<td>Prevalence of YP (%)</td>
<td>16.7</td>
<td>18.2</td>
<td>0.0</td>
<td>0.0</td>
<td>0.43</td>
</tr>
</tbody>
</table>

Vulnerable plaque

<table>
<thead>
<tr>
<th>Stable plaque</th>
<th>BES (n=8)</th>
<th>EES (n=8)</th>
<th>E-ZES (n=5)</th>
<th>R-ZES (n=11)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good NSC (%)</td>
<td>25.0</td>
<td>12.5</td>
<td>100.0</td>
<td>54.5</td>
<td>0.01</td>
</tr>
<tr>
<td>Prevalence of YP (%)</td>
<td>85.7</td>
<td>0.0</td>
<td>0.0</td>
<td>9.1</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Conclusions: Vulnerable plaques implanted with BES remained yellowish and thrombogenic even at one year after stenting, suggesting the distinct vascular response after BES implantation at vulnerable plaques.

TCT-601
Comparison of sirolimus-eluting stents with biodegradable polymer versus sirolimus-eluting stents with durable polymer assessed by optical coherence tomography: The ALSTER-OCT registry
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Background: Nevertheless the promising results of 2nd generation DES, recent findings suggest hypersensitivity reactions caused by the durable polymer coatings leading to chronic inflammation and possibly to late stent strut malapposition. Therefore new DES generations with improved biocompatibility and biodegradable polymers were introduced.

Methods: The registry aims to compare optical coherence tomography (OCT) based stent coverage at three, six and nine-months follow-up after PCI by 3rd generation Orsiero Hybrid sirolimus-eluting stents with biodegradable polymer (O-SES, Biotronik) and widely used 2nd generation zotarolimus-eluting stents with durable polymer (EES, EndeavorTM ResoluteTM and ResolveTM IntegrityTM, Medtronic Vascular). A total of 80 patients received implantation of O-SES (n = 34) and ZES (n = 46). Clinical driven OCT-analysis was performed at three, six or nine-months follow-up.

TCT Abstracts/Stents - Drug-eluting: Novel Metallic DES
B175
Results: Strut tissue coverage was classified according to published criteria (O-SES vs. ZES, mean±SD): Apposed uncovered struts, three-months: 6.1±4.4% vs. 17.1±18.7% (n=8 vs. n=31, p=0.631), six-months: 4.6±5.9% vs. 10.3±12.0% (n=21 vs. n=7, p=0.068), nine-months: 1.5±1.8% vs. 6.5±8.9% (n=5 vs. n=8, p=0.190). Malapposed uncovered struts three-months: 6.2±12.8% vs. 5.0±7.5% (p=0.982), six-months: 4.3±5.5% vs. 3.3±4.5% (p=0.629), nine-months: 1.3±2.1% vs. 1.1±1.2% (p=0.748). The intra-group analysis found no statistical differences between the observed time-points. Neointimal thickness was: three-months: 94.8±33.5 vs. 96.3±35.7 (p=0.760), six-months: 102.9±29.0 vs. 92.2±34.6 mm (p=0.264), nine-months: 98.6±34.8 vs. 161.3±82.0 mm (p=0.070). To discriminate mature and immature tissue coverage OCT based grey scale signal intensity (GSI) analysis was assessed. We found no statistical differences either for intra-group and the inter-group comparison. Concerning 12-months follow-up patients no statistical differences were found for clinical follow-up.

Conclusions: No statistical differences between O-SES and ZES concerning stent struts coverage as well as GSI based quality assessments were found. The data show generally comparable healing characteristics and neointimal formation of the O-SES and ZES.

TCT-603

Abstract Withdrawn

TCT-604

Novel Patient-based Finite Element Simulation Framework To Evaluate Fatigue Resistance Of Coronary Stent Design
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Background: Fatigue fracture of coronary stents is a recurring problem that may lead to an array of complications. It is important, both for stent design and selection, to better understand this phenomenon. In this study, the fatigue resistance of three coronary stent designs was qualitatively compared through means of finite element analysis in a patient-specific setting.

Methods: Finite element computer simulations were used to virtually deploy and realistically deform three stent designs within a human coronary artery. The three stent models (Element, Boston Scientific; Multi-Link 8, Abbott Vascular; Biolimus Flex, Biosensors) were generated based on micro-computed tomography scans of disease samples. The vessel geometry and deformation was modeled based on intravascular fluoroscopy images of a human right coronary artery at diastole and systole. After device deployment and recoil the fatigue safety of the stents was evaluated by imposing a cyclic deformation to the vessel model. The risk of fatigue fracture of different stents or fracture locations within a specific stent is assessed based on these computer simulations, and relative comparisons between stents can be made. Predicted fracture locations and relative fatigue resistances are put into perspective of fatigue fracture data reported in literature.

Results: For the investigated patient, the Element was the stent with the highest relative fatigue safety. Relative to the Element stent, the fatigue safety of the Multi-Link 8 and Biolimus Flex stent was 95% and 91%, respectively. Unlike the Element, both the Multi-Link 8 and Biolimus Flex showed regions of low fatigue safety in the connectors between rings. These results are in close agreement with fatigue fracture data reported in literature.

Conclusions: The proposed method for comparing the relative fatigue resistance of coronary devices in a patient-specific setting can be used to optimize device design and selection.

TCT-605

Safety and Efficacy of a Novel Abluminal Groove-Filled Biodegradable Polymer Sirolimus-Eluting Stent for the Treatment of De Novo Coronary Lesions: 2-Year Results from the Prospectively Patient-Level Pooled Analysis of the TARGET I and TARGET II Trials
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Background: Early reports revealed that a novel abluminal groove-filled biodegradable polymer sirolimus-eluting stent (named target eluting technology) FIREHAWK (MicroPort Medical, Shanghai, China) was safe and effective in 1-year follow-up in a large cohort of patients from the TARGET clinical program. We aimed to investigate the long-term clinical outcomes of this novel stent.

Methods: An objective performance criterion (OPC) study was required by the China Food and Drug Administration for new drug-eluting stent. The primary endpoint, target lesion failure (TLF), was defined as the composite of cardiac death, target vessel myocardial infarction (TV-MI), or ischemia-driven target lesion revascularization (iTLR) at 12 months. A patient-level pooled data derived from

<table>
<thead>
<tr>
<th>Proximal Average</th>
<th>Pre-PCI</th>
<th>Post-PCI</th>
<th>P Value</th>
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<tbody>
<tr>
<td>luminal diameter(ALD)</td>
<td>2.45 ± 0.65</td>
<td>2.55 ± 0.59</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Reference diameter</td>
<td>1.88 ± 0.38</td>
<td>1.99 ± 0.27</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Minimal lumen diameter (MLD)</td>
<td>0.42 ± 0.35</td>
<td>1.66 ± 0.28</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>%Diameter stenosis(DS)</td>
<td>77.0 ± 19.1</td>
<td>16.5 ± 11.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Distal ALD</td>
<td>1.35 ± 0.49</td>
<td>1.56 ± 0.31</td>
<td>&lt;0.0001</td>
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<tr>
<td>Total stented length</td>
<td>39.2 ± 19.4</td>
<td></td>
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<tr>
<td>Acute gain</td>
<td>1.90 ± 0.49</td>
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References: