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Svelte Stent-on-a-Wire showed vascular healing and tissue response equivalent to that observed with ML Vision stents.

TCT-448
Scanning Electron Microscopic Observation of Coating Irregularities and Their Precursors in Unexpanded Durable Polymer-Based Drug-Eluting Stents
Mounir W. Z. Basalsæ1, Kenneth Tangpong1, Hamid Ser1, Theo van Westen1, Dirk W Grigioni2, Aart A van Apeldoorn3, Clemens von Bugeleisen4 1MST hospital, Department of Cardiology, Enschede, Netherlands; 2MIRA – Institute for Biomedical Technology and Technical Medicine, University of Twente; Enschede, Netherlands

Background: Previous scanning electron microscopy (SEM) studies in expanded DES revealed differences in the frequency and size of coating irregularities between DES types and specific distribution patterns, however, the origin of these irregularities is unclear. The current study quantifies coating irregularities on unexpanded and expanded durable polymer-based drug-eluting stents (DES) to gain insights into the potential origin of coating irregularities.

Methods: We assessed at bench side a total of 1200 SEM images obtained in 30 DES samples (15 expanded and 15 unexpanded) of Cypher Select, Taxus Liberté, Endeavor, Xience V, and Resolute.

Results: For most types of coating irregularities seen on expanded DES (72%; 23/32), a matching irregularity (n=18/24) and/or its precursor (n=11/24) was observed in unexpanded corresponding DES; Only a few individual coating irregularities (13%; 3/24) could not be assessed in unexpanded samples, as these irregularities were located on the (invisible) luminal side. Unexpanded Cypher Select showed (small) crater lesions and cracks together with precursors of ‘peeling of polymer’. On unexpanded Taxus Liberté, thinning of polymer, small bare metal areas, wrinkles and one type of precursor was found. Unexpanded phosphorylcholine-based Endeavor stents showed cracks, small bare metal areas, and crater lesions as well as precursors of the latter. Unexpanded Xience V and Endeavor Resolute mainly revealed crater lesions and their precursors.

Conclusion: SEM assessment demonstrated the presence of various coating irregularities and/or their precursors on unexpanded durable polymer-based DES. These findings provide evidence that coating irregularities arise during both DES manufacturing and stent expansion.

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Pre-clinical Evaluation of a Myolimus-Eluting Bioresorbable Polymeric Scaffold in the Porcine Coronary Artery Model
Gay Leclerc, MD, Louis-Georges Gay, PhD, Jean-Martin Lapointe, DVM, Martin Laflamme1, Sonida Horng1, Vinayak Bhat, PhD, Howard Huang2, Anuja Patel2, John Yan2 1AccelLab Inc, Montreal, Canada; 2Elixir Medical, Sunnyvale, CA

Background: The Polymeric Bioresorbable Myolimus-Eluting Polymeric Scaffold is a novel drug eluting device that combines a PLLA-based scaffold coated with a matrix of biodegradable poly lactide and the drug Myolimus. Myolimus is a macrocyclic lactone mTOR inhibitor similar to rapamycin (sirolimus) which has demonstrated potent anti-proliferative properties in cell culture studies and successfully used in two First-in-Man (FIM) studies on Elixir’s Myolimus eluting coronary stents. The drug dose is 3 mcg per mm of scaffold length, similar to the dose used in the prior Elixir FIM studies. Multiple radiopaque markers are located on each end of the scaffold to aid delivery and placement in vivo. The objective of this study was to evaluate the safety and efficacy of the Polymeric Bioresorbable Myolimus-Eluting Scaffold in a preclinical model.

Methods: Polymeric Bioresorbable Myolimus-Eluting Scaffolds were implanted in swine coronary arteries and evaluated over a period of 28, 90 and 180 days. Analyses by OCT and histopathology were employed to evaluate the safety and efficacy of the scaffolding systems. Pharmacokinetics (PK) of the drug from the scaffold was measured using standard analytical techniques.

Results: The preclinical results of the Polymeric Bioresorbable Myolimus-Eluting Scaffold implanted in the porcine coronary artery model are presented in the table below. All vessels were patent after the evaluation period with histopathology profiles expected for drug eluting stents. The PK analysis of the scaffold and tissue surrounding the scaffold showed that approximately 80% of drug is released over a 28 day period.

Conclusion: The preclinical evaluation of the Polymeric Bioresorbable Myolimus-Eluting Scaffold demonstrated safety and effectiveness in support of a First-in-Man study.

TCT-450
Insights from Network Analysis: Deficiency of Glutathione Peroxidase-1 Increases in-Stent Stenosis
Ziad A Ali, Azad Rataesdana, Xiaomei Qu, Sanjay Patel, Farshad Kesyghobadi, Amber Saced, Thomas Quernrousne, Euan Ashley Cardiovascular Medicine, Stanford University, Stanford, CA

Background: Deficiency of the glutathione peroxidase-1 (GPx1) is associated with in-stent stenosis (ISS).

Methods: We used a novel genome-wide gene expression network approach in human atherectomy samples comparing atherosclerosis to ISS (n=89) to identify signaling networks critical to the process of ISS. We found that a subnetwork with GPx1 as its hub was among the most significantly differentially regulated (Fig 1, bar thickness denotes association strength). We investigated the importance of GPx1 in ISS using knockout mice with constitutive deficiency of GPx1 crossed onto atherosclerotic ApoE-KO background using a novel model of balloon angioplasty and stenting (BAS) in mice.

Results: ApoE-KO mice had significantly decreased GPx1 expression compared to atherosclerosis. Despite equal stent expansion and injury scores, ISS was increased by 50% on histological cross-section (P<0.01) and 33% per-stented vessel longitudinally by OCT (P<0.01) in GPx1/ApoE-KO mice 28 days following BAS (Fig 2, white arrows denote neointima). In keeping with this, both proliferation (71%, P<0.01) and migration (90%, P<0.01) were significantly increased in GPx1/ApoE-KO primary aortic smooth muscle cells compared to ApoE-KO. In animals with additional targeted endothelial reporter gene expression (Tie2-Laiz) we found GPx1/ApoE-KO/Laiz mice had significantly reduced endothelial coverage (58%, P<0.03) compared with ApoE-KO/Laiz mice, suggesting impaired reendothelialization as a potential mechanism by which GPx1/ApoE-KO mice have increased ISS.

Conclusion: Using a network analysis approach we have identified an important role for GPx1 signaling in vascular wall redox processes critical to ISS.

TCT-451
Right through the Heart - Transseptal Access for Stent-Graft placement in the Ascending Aorta
Sahine Helena Wiper, Christina Lohrenz, Klaus Peymann, Eike S Debus, Tilo Köbel Department of vascular medicine, University Heart Center Hamburg, Hamburg, Germany

Background: Transseptal access is routinely used for cardiovascular procedures in the left heart, but not yet to access the aortic arch and its branches. Iliac and aortic pathology such as obstruction and tortuosity may require antegrade access to advance and deploy an endograft in the proximal parts of the thoracic aorta. The aim of the present study was to test the feasibility of antegrade transseptal access to the ascending aorta for stent-graft introduction and placement using a through-and-through guidewire technique in a porcine model.

Methods: Transseptal puncture was performed in 6 domestic pigs (51-58kgBW) from the inferior vena cava for guidewire-placement across the left heart to the descending aorta to establish transseptal through-and-through access. Custom-made endografts consisting of polyester-tube and two nitinol-stents (diameter 24mm, length of 32mm) were advanced using the transvenous antegrade access and deployed under fluoroscopy into the ascending aorta using a pull-and-push technique with moderate tension on the wire. Hemodynamic monitoring (PiCCo catheter, Swan-Ganz catheter), transit-time