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Early Healing After Treatment Of Coronary Lesions By Everolimus, Or Biolimus Eluting Bioresorbable Polymer Stents. One-month Results In The SORT-OUT VIII Optical Coherence Tomography Study

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Background: Improved early healing may reduce the risk of early stent thrombosis in patients treated with drug eluting stents. Incomplete healing is found more frequently after treatment for acute myocardial infarction, in patients with acute stent strut malapposition and after treatment by specific stent types. Dual antiplatelet therapy is used to balance the risk of incomplete healing but early discontinuation is rather common and hard to predict at the primary intervention. We aim to evaluate and compare early healing of an everolimus-eluting biodegradable polymer stent (Synergy, Boston Scientific, USA) having potential advantages in early healing with a biolimus-eluting biodegradable polymer stent (BioMatrix NeoFlex, Biosensors, Switzerland).
Methods: The study is a prospective, randomized dual center trial with one month follow-up (Cohort A) or three months follow-up (Cohort B). Patients are randomized 1:1 to Synergy or Biomatrix Neoflex. A total of 160 patients are scheduled, 80 in each cohort. Inclusion criteria are stable angina pectoris, non-ST, or ST-elevation myocardial infarction. Exclusion criteria are impaired renal function, severe vessel tortuosity or severe systemic disease. Optical frequency domain imaging (OFDI, Lunawave, Terumo, Jp) will be acquired at baseline and at follow-up or earlier in case of a target vessel event. The primary endpoint is the Coronary Stent healing Index, a combination of uncovered apposed and malapposed struts, excess neointimal hyperplasia, acquired and persistent malapposition and size of the extra-stent lumen. Frame level matching is performed for baseline adjusted analysis by experienced observers using semi-automated software analysis (QCU-CMS Research, Leiden University Medical Center, The Netherlands). Clinical follow-up will be continued up to 5 years.
Results: One-month OFDI follow-up (Cohort A) will be presented at TCT2014.
Conclusions: The study is designed to compare early healing in two different stents. A potential difference may indicate improved early safety after stent implantation.

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Clinical Outcomes of Patients With High Risk Acute Coronary Syndrome Treated With a New Generation Drug-Eluting Stent, Ultimaster compared with Xience – Results from CENTURY II trial

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Background: PCI with use of DES has been increasingly used in patients with high risk acute coronary syndromes (STEMI/NSTEMI). However, controversies related to their long-term safety in this complex patient population are still present. Therefore safety and efficacy of new, sirolimus-eluting stent coated with bioresorbable polymer, Ultimaster DES(Terumo Corporation, Tokyo, Japan), in high risk acute coronary syndrome (ACS) patients was assessed.
Methods: In the frame of a single-blind, randomized, multicentre CENTURY II study, out of 1123 patients enrolled, 264 have been diagnosed with high risk ACS and assigned randomly to treatment with Ultimaster (126) or Xience (138) DES. Primary endpoint of the study was TLF at 9 months. All data were 100% monitored and adverse events were adjudicated by an independent clinical event committee.
Results: Baseline patient characteristics such as age, gender, presence of diabetes, hypertension, dyslipidemia, family history of CAD, smoking, previous MI and previous PCI were similar in both study arms. Also, there were no differences noted in thrombus presence (10.1% vs 11.8%, p=0.61) or bifurcation lesions (10.2% vs 9.8%, p=0.88). LAD was the most frequent target vessel and radial access was used in >70% of cases, without difference between treatment arms. Clinical outcomes at 4-months are shown in the table below. No significant differences were observed between the two stent arms. There were 2 patients with subacute stent thrombosis in Ultimaster and 1 patient with 3 vessels of stent thrombosis in Xience arm, resulting in low and similar ST rates (1.6% vs 0.7%, p=0.51).

%	Cardiac death, %	MI,%	TLR, %	non TL-TVR	TLF, %	TVF, %
Ultimaster	0.0	1.6	1.6	0.0	3.2	3.2
Xience	0.0	3.6	0.7	2.2	3.6	5.1

Conclusions: Short term safety and efficacy of new Ultimaster DES was very similar to the Xience DES in patients with high risk ACS. Follow up of patients is ongoing and 1-year data will be available at the time of presentation.

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Three Year Clinical Outcomes of a Unique Sirolimus-Eluting Stent with Fully Absorbable Polymer Coating: Long-term Results from the DESSOLVE I and the DESSOLVE II Clinical Trials

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Background: Unlike any other current bioabsorbable drug-eluting stent, the MiStent SES (Micell Technologies, Durham, NC) has a unique coating composition that allows for continued drug elution after the rapid and complete absorption of polymer. Crystalline sirolimus continues to maintain therapeutic drug tissue levels up to 9 months; 3 times longer than the presence of the polymer. The polymer coating is eliminated from a thin-strut (64µm) cobalt chromium stent in 45-60 days with complete tissue absorption within 90 days. Long-term clinical follow-up is important to confirm the continued safety of patients treated with DES in clinical practice. To date, patients from two studies have completed 3 year follow-up.
Methods: The DESSOLVE I clinical trial is a first-in-human study at 5 sites of 30 MiStent implanted patients; the DESSOLVE II clinical trial, is a 2:1 randomized study of 184 patients conducted at 26 sites in evaluating the MiStent SES as compared to the control stent, the Endeavor Sprint. In the trials, patients with discrete de novo lesions up to 27 mm in length in native coronary arteries were enrolled. In-stent late lumen loss (LLL) was evaluated in both trials and to date, patients have been followed for clinical events annually for 3-years. All MACE events, defined as all death, Q and non-Q wave myocardial infarction and all target vessel revascularization were adjudicated by an independent clinical events committee.
Results: Follow-up for DESSOLVE I was complete for all available patients at 3-years (29/29). No target lesion MACE events were reported through 3 years, however, 2 non-target vessel MIs were reported. In the DESSOLVE II trial, MACE for MiStent and Endeavor was 4.3% versus 6.7% (p=0.49) respectively at 9 months, 5.1% versus 8.3% (p=0.51) at 12 months and 6.7% versus 13.3% (p=0.167) at 2 years. Evaluation of additional 3-year clinical outcomes of the MiStent SES for DESSOLVE II will be presented.
Conclusions: The evaluation of a new DES (MiStent SES) with a distinctive coating to provide continuous drug elution in the absence of polymer reveals sustained clinical results through 3-years follow-up.

TCT-598

Randomized Comparison Between Self-Apposing Bare Metal AnD PaclitaxEl-Eluting Coronary Stents For The Treatment Of SaPhenous Vein GrafTs (SVG): Results From The ADEPT Trial

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Background: The advantages of saphenous vein are well known for CABG: it is used in 80% of these procedures. However Saphenous Vein Grafts (SVGs) get diseased over time because of thrombosis, intimal hyperplasia and atherosclerosis. PCIs of SVGs represent 10% of caseload in high volume cathlabs and carry increased risk compared to PCI in native vessels. Previous studies comparing DES with BMS showed reduced late lumen loss and target vessel revascularization, but also a higher mortality rate for DES: at the start of this study, no consensus was available. Moreover large lumen diameter and caliber change especially at the anastomosis site lead to increased risk of under- / over- sizing with balloon-expandable stents. Self-expanding stents could improve apposition after thrombus/debris resolution following PCI and their deployment from distal to proximal could limit risk of distal embolization.
Methods: The Adept study, a randomized multicenter study, compares the safety and performance of the STENTYS (STENTYS, France) coronary bare metal stent with the Paclitaxel-eluting stent in Saphenous Vein Graft lesions. Patients are followed up at 1, 6 and 12 months post-procedure. The primary endpoint is in-stent late lumen loss at 6. Secondary endpoints include MACE at 1, 6 and 12 months, binary restenosis at 6 months, and strut malapposition at 6 months (OCT substudy in 10 patients). Patients with de-novo lesion in SVG (>50%stenosis), under optimal drug regimen, and with