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BACKGROUND Assessment of the safety and clinical performance of the Sirolimus-Eluting Bioabsorbable Magnesium Scaffold (DREAMS 2G) from the combined analysis of Biosolve-II and BIOSOLVE-III studies at 24-month.

METHODS 184 subjects have been enrolled in BIOSOLVE-II and BIOSOLVE-III studies. Clinical follow-ups are scheduled at 1, 6, 12, 24 and 36-months. Angiographic follow-ups are planned at 6-month and voluntarily at 12-month and 36-month in BIOSOLVE-II and one angiographic examination is mandatory at 12-month in BIOSOLVE-III study. Dual antiplatelet therapy is recommended for a minimum of 6 months. The angiographic results are analyzed by an independent corelab and all clinical events are adjudicated by an independent clinical events committee.

RESULTS 117 men and 67 women with 189 lesions and a mean age of 65.5 ± 10.8 years were enrolled at 18 clinical sites in Europe, Brazil and Singapore. Hypertension was present in 79.3% of the subjects and 62% of patient had hyperlipidemia. The mean lesion length was 12.6±5.1 mm with a mean reference vessel diameter of 2.70±0.43 mm. At 12-months 97 angiographic follow-up were available. There was no difference in late lumen loss between the two studies; in the overall population, it was 0.25±0.31 mm in-segment and 0.39±0.34 mm in-scaffold. The target lesion failure (TLF) rate of the combined population was 3.3%, including two cardiac deaths (1.1%), one target vessel myocardial infarction (0.6%), and three clinically driven target lesion revascularizations (1.7%). The clinical 24-month results of BIOSOLVE-II study are available. Target lesion failure occurred in seven patients (5.9%) and included two cardiac death (1.7%), one target-vessel myocardial infarction (0.9%) and four clinically driven target lesion revascularizations (3.4%). No definite or probable scaffold thrombosis was observed. The 24 month clinical data of the combined cohort will be available upon presentation.

CONCLUSION The 24-month safety and clinical performance results of DREAMS 2G are encouraging and will be presented for a larger population of subjects enrolled in BIOSOLVE-II and BIOSOLVE-III studies.

CATEGORIES **CORONARY:** Stents: Bioresorbable Vascular Scaffolds

TCT-64

Two-Year Clinical and Imaging Outcomes of Thin Strut Sirolimus-Eluting Bioresorbable Vascular Scaffolds in De Novo Coronary Artery Lesions: The MeRes-1 Trial

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BACKGROUND The development of fully bioresorbable vascular scaffolds (BRS) offers a new intervention strategy for coronary artery lesion by replacement of “full-metal jacket” into “full-plastic jacket”. The aim of the present study was to assess the long-term safety and performance of thin strut sirolimus-eluting BRS (MeRes100™, Meril Life Sciences, India) in patients with de novo coronary artery lesions.

METHODS The MeRes-1 (CTRI number: CTRI/2015/04/005706) was a prospective, multicentre, single-arm study of sirolimus-eluting BRS deployment in 108 patients at 13 clinical sites. The main safety endpoint was major adverse cardiac events (MACE) which is a composite of cardiac death, myocardial infarction, and ischemia-driven target vessel revascularization. Angiographic, intravascular ultrasound (IVUS) and optical coherence tomography (OCT) were performed in a subset of patients.

RESULTS Two-year clinical follow-up was completed in 107 (99.07%) patients with mean age of 50.13±8.82 years. Among 108 patients, 30 (27.78%) patients had diabetes mellitus and 45 (41.67%) patients had hypertension. The majority of the treated lesions were present in left anterior descending artery 70 (60.34%) and most of the target lesions were classified as type 71 (61.21%) B2/C. At 2-year follow-up, MACE occurred in 2 (1.87%) patients. None of the patient experienced incidence of stent thrombosis. At 2-year angiographic follow-up, in-scaffold late lumen loss was 0.26±0.24 mm. The strut-level OCT analysis demonstrated almost complete strut coverage (99.24%), and IVUS analysis showed low percentage of neointimal volume obstruction (7.50%) at 2-year.

CONCLUSION The MeRes-1 trial confirmed favorable safety and performance of thin strut sirolimus-eluting bioresorbable vascular scaffolds in de novo coronary artery lesions with low major adverse cardiac events rate and zero scaffold thrombosis at 2-year follow-up.

CATEGORIES **CORONARY:** Stents: Bioresorbable Vascular Scaffolds

INTRAVASCULAR IMAGING

Abstract nos: 65 - 68

TCT-65

High-Definition Micro-Optical Coherence Tomography for Endothelial Cell Visualization in the Coronary Arteries

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BACKGROUND Impairment of endothelial cells (ECs) is at the origin of coronary atherosclerosis. More recently, plaque erosion has emerged as the second most prevalent pathological finding in acute coronary syndrome (ACS). However, the study of ECs in humans remains elusive because of a lack of an imaging tool with sufficient resolution. This study aimed to utilize a novel microscopic imaging technology, termed micro-optical coherence tomography (μOCT), that offers a resolution of 1 μm for evaluating of EC morphology.

METHODS We stripped the endothelium from 36 fresh swine coronary segments with cyanoacrylate glue. Coronary segments were imaged in 3D with μOCT, and were processed for histology and scanning electron microscopy (SEM). μOCT images of stripped vs. intact sites were volume rendered in 3D and visually compared. ECs visualized by μOCT were validated with those seen by SEM. Surface roughness was calculated for both stripped and intact sites by computing root mean squared error (RMSE). Human coronary plaque was also imaged with μOCT.

RESULTS Histology showed the stripping procedure successfully removed ECs from the swine coronary arteries. 3D-μOCT allowed