TECHNOLOGY

Biodegradable Scaffolds

CRT-600

Malapposition, Underexpansion and Edge Dissection in Bioabsorbable Vascular Scaffolds (Absorb™) and Xience™ Stents - A Comparison Based on Optical Coherence Tomography

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Background and Aim: In addition to lesion characteristics, post-stenting.
Results: Depend on characteristics of the stent and on the inflating pressure of the stent balloon or post-dilation balloon. The biodegradable ABSORB™ scaffold has a greater flexibility (lower maximum compressive load required to deflect the device) compared to the XIENCE™ stent but due to its fragility the inflating pressure is limited and suitable lesions have to be well prepared. Aim of this study was to assess the incidence of malapposed stent-struts after ABSORB™ implantation as well as the frequency of stent-underexpansion and edge dissections compared to the XIENCE™ stent.
Methods: 23 patients after elective implantation of an ABSORB™ scaffold (n=30) were matched with 26 patients after implantation of a XIENCE™ stent (n=30) according to gender, age, stent-diameter and length. Stenting results were assessed using Optical Coherence Tomography (OCT) and compared between groups.
Results: Pre-dilation was more frequently done in the ABSORB™ group (n=28 vs. n=19, p=0.005). Inflation time was longer in ABSORB™ group (44.43±14.21 vs. 27.93± 9.42sec, p<0.001) and the inflation pressure of the stent-balloon was lower (11.43±2.85 vs. 13.57±2.84atm, p=0.005). No differences were found in frequency of NC-balloon post-dilation as well as in its inflating pressure. Post-implantation, less ABSORB™-struts were malapposed (10.83±22.75 vs. 40.93±58.50, p=0.011), incidence of underexpansion was similar and edge dissections occurred in trend more frequently in the XIENCE™ group (n=6 vs. n=12, p=0.079).
Conclusion: OCT assessment post implantation showed less adverse results concerning the ABSORB™ scaffold compared to the XIENCE™ stent.

CRT-601

"Powerful" Bioresorbable Scaffolds Have Comparable Radial Strengths - Truth or Legend?

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Background: Bioresorbable vascular scaffolds (BVS) are a novel innovation in treatment of coronary artery lesions. Initial angiographic procedure results seem to be satisfying, but data concerning optimal scaffold expansion and its radial force are rare, so our aim was to assess intravascular conformability as a hint for radial strength.
Methods: Post-implantation, Optical Coherence Tomography (OCT) images of 40 ABSORB™ scaffolds were evaluated and compared to 40 XIENCE™ stents. Procedure characteristics were collected and area, where deformation per visual assessment was most pronounced was identified and minimal-, maximal-diameter and diameter-ratio were calculated and compared between groups.
Results: Patients receiving ABSORB™ scaffolds were younger than those with XIENCE™ stents (54.0±11.2 versus 61.7±11.4, p=0.012), the remaining baseline characteristics were comparable between groups. Lesions treated with scaffolds were predilated more frequently (n=34 versus n=23, p=0.006) and inflation time was longer than in XIENCE™ stents (44.2±12.8 versus 25.6±8.4 seconds, p<0.001). Maximal inflation pressure as well as incidence of postdilation with a Non-Compliant (NC) balloon was similar in both devices. Furthermore, the extent of coronary calcification was similar and reference vessel diameters, proximal and distal, were also comparable. Diameter-ratio between maximal- and minimal-diameter was significantly higher in the ABSORB™ group (1.46±0.20 versus 1.32±0.19, p=0.004).
Conclusion: Bioresorbable scaffolds are characterized by its greater conformability than comparable Drug Eluting Stents (DES) and therefore, with the optimal inflation strategy, struts are well opposed to the vessel wall. Nevertheless, BVS show a less complete radial expansion compared to XIENCE™ stents.

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ABSTRACT WITHDRAWN

Drug Coated Balloons

CRT-603

Preclinical Evaluation of the Novel Chocolate™ Angioplasty Balloon Coated with Paclitaxel

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Background: The Chocolate™ Balloon Catheter exhibits a nitinol constraining structure covering the external aspect of the balloon that distributes radial force to the arterial surface more evenly than conventional angioplasty balloon constructs. The safety and efficacy of a paclitaxel (PTX)-coated Chocolate Balloon Catheter was investigated in a stent overstretch model.
Methods: Twenty six farm swine were studied at a 30 days. Angioplasty of coronary arteries was performed with a 16% overstretch and 60s inflation. Devices were coated with 3ug/mm^2 (for single inflation, nominal dose) or 6ug/mm^2 (two consecutive inflations, high dose) paclitaxel using a proprietary carrier. Control devices included the SeQuent™Please (3ug/mm^2 PTX, B. Braun, positive control) and a standard balloon (Maverick2™, Boston Scientific, negative control). All devices were 3.5x20mm. Following angioplasty a stent (Omega Ous, Boston Scientific, 3.5x16mm) was placed in the treatment location to stimulate neointimal response. Target arteries were evaluated angiographically pre and post treatment, by histology and histomorphometrically. Myocardial function was assessed using left ventricular ejection fractions and ECG.
Results: There were no device failures or device-related animal morbidity or mortality. No target-site thrombi or thromboemboli were observed in any of the paclitaxel treatment groups. There were no significant changes in myocardial function or histology attributable to PTX treatment. Late lumen loss was more than double for the uncoated balloon treatment group compared to the PTX treated groups. Intimal suppression was comparable between the Chocolate and SeQuentPlease treatment groups. Injury and inflammation scores were equivalent across all treatment groups; although there was a slight increase in the injury score for the high dose group likely due to the double inflations.
Conclusion: In a preclinical model of intimal thickening, the PTX-coated Chocolate Balloon Catheter demonstrated significant intimal suppression relative to uncoated balloon treatments and a favorable safety profile.