

Conclusions: DREAMS shows excellent safety and efficacy data with no death and no scaffold thrombosis up to 3 years in the BIOSOLVE-1 trial. Multi-modality imaging documented the absorption process and the engaging aspect of this device already at 6 months.

TCT-626

Expanding Indications of Bioresorbable Scaffolds: Single Center Procedural and In-Hospital Outcomes with the first 500 Implanted Devices in a Diversified, All-Comer Patient Population

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Background: Bioresorbable stents have not been evaluated in a wide range of clinical settings including ACS, STEMI, in-stent restenosis, SVG, and CTO. As of April 1st 2013, ABSORB BVS (BVS) became our default drug eluting device for patients at our institution. The aim of this study is to evaluate the safety and efficacy of this new technology in a real-world setting.

Methods: Detailed patient characteristics and peri-procedural data are collected for both patients receiving and not receiving a BVS and systematically entered in a registry. In-hospital outcomes include MACE and bleeding complications and are independently assessed by dedicated personnel.

Results: We will report on our first year experience with BVS. Results are compared to those in a group of patients treated concomitantly with other stent types. As of March 31st 2013, 504 BVS have been implanted in 339 patients. Unadjusted MACE (death, MI, Urgent PCI) rates were 2.0%, 2.4%, and 3.9% in patients treated with BVS, DES and BMS, respectively.

Conclusions: Conclusions will be supported by the presented data and will reflect our main findings. Preliminary results suggest comparable clinical outcomes with BVS and DES in patients without contra-indication to drug-eluting devices.

TCT-627

Comparison of Procedural Feasibility Between Bioresorbable Vascular Scaffold and New-generation Drug Eluting Stent in an All-comer Population

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Background: The strut thickness and deliverability of BVS may increase procedural time, contrast volume and fluoroscopy time, especially in complex lesions.

Methods: In this study, 205 consecutive patients treated with either BVS (n=99) or drug eluting stent (DES) (n=106) between May 2010 and May 2014 were enrolled.

Results: The number of complex lesions (ACC/AHA lesion classification type B2 and C) between BVS and DES group (84.7% vs. 90.6%, p=0.01) was similar. Pre and post-balloon dilatation were performed more frequently in the BVS group compared to the DES group (97.1% vs. 79.4%, p< 0.01; 99.2% vs. 79.4%, p< 0.01, respectively). Maximum post dilatation balloon size was larger and maximum inflation pressure was higher in the BVS compared to the DES group (3.2±0.4 mm vs. 3.0±0.1 mm, p=0.01; 21.1±5.1 atm vs. 19.2±5.0 atm, p< 0.01, respectively), despite similar quantitative coronary angiogram (QCA) results. Procedure time, amount of contrast and fluoroscopy time in BVS group were increased significantly compared to those in the DES group (Table). In multivariable analysis, after adjustment for SYNTAX score, chronic total occlusion and lesion length by QCA, BVS use was identified as an independent predictor of long procedure time (> 120 min.) (odds ratio: 4.9, 95% confidence interval: 2.67-9.36, p< 0.001).

	BVS (patient n = 99)	DES (patient n= 106)	P-value
Total procedure time, min	114.7 ± 39.2	90.4 ± 38.2	< 0.01
Total amount of contrast, ml	268.3 ± 104.2	229.2 ± 122.2	0.02
Total fluoroscopy time, min	42.4 ± 17.9	34.5 ± 19.7	< 0.01

Conclusions: Treating complex lesions with BVS requires longer procedure/fluoroscopy times and larger volumes of contrast as compared to DES implantation to achieve similar procedural success rates and results. Improvements in scaffold design may reduce the need for meticulous lesion predilatation with dedicated devices and increase the spectrum of lesions amenable to treatment with BVS.

TCT-628

Safety and Efficacy of Everolimus-Eluting Bioresorbable Vascular Scaffolds in Complex Coronary Lesions

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Background: Everolimus-eluting bioresorbable vascular scaffolds (BVS) are increasingly used in patients with complex coronary anatomies. However, data on BVS in such indications are scarce. We thus sought to evaluate the safety and efficacy of ABSORB BVS in patients with complex coronary lesions.

Methods: Consecutive patients (n=150) undergoing BVS implantation at a tertiary care center entered a prospective registry. All patients underwent a detailed assessment of clinical and procedural data. Clinical follow-up was performed 7±5 months following the index procedure and was completed in all patients. Major adverse cardiac events (MACE) included the occurrence of death, myocardial infarction, stent thrombosis and target lesion revascularization. Complex coronary artery disease was defined as type B2 or C lesions. Device success was defined as attainment of < 30% final residual stenosis. Procedural success was defined as device success without periprocedural complications. Clinical success was defined as procedural success and absence of MACE within follow-up.

Results: Complex coronary lesions were present in 45.3% (n=68) of patients. Baseline characteristics such as age, gender or left ventricular ejection fraction did not differ significantly between patients with type B2/C lesions versus those with type A/B1 lesions (all p>0.05). The number and length of BVS were higher in patients with complex lesions (1.4±0.6 vs. 1.1±0.3, p< 0.001 / 32±13 vs. 19±6mm, p< 0.001). Device success rate was high in both groups (97.1 vs. 97.6%, p=1.00). At a relatively low rate of periprocedural complications (edge dissection n=7, side branch occlusion n=2) procedural success did not differ significantly in patients with complex lesions in comparison to patients with non-complex lesions (91.2 vs. 95.1%, p=0.51). The majority of patients remained free of angina within follow-up (85.3 vs. 92.7%, p=0.19). MACE occurred in 1.5% (n=1) of patients with type B2/C lesions versus 7.3% (n=6) with type A/B1 lesions (p=0.13). Finally, clinical success was comparable in both groups (89.7 vs. 87.9%, p=0.80).

Conclusions: BVS in complex coronary lesions appear to be promising in terms of safety and efficacy.

TCT-629

Effect of the Absorb Bioresorbable Vascular Scaffold (BVS) on Coronary Plaque Regression in a Familial Hypercholesterolemic Swine: 1-Year Follow-Up

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Background: One of the hypothesized long-term clinical benefits of Absorb BVS is plaque regression (reduction in plaque volume) and stabilization (reduction in necrotic and lipid composition). This study evaluates the effect of Absorb BVS on plaque size and composition in a familial hypercholesterolemic (FH) swine model. We present here the IVUS results at 1-year follow-up.

Methods: Ten-month-old female FH swine were fed an atherogenic diet for 21 weeks. One week into the feeding, coronary arteries were balloon injured. Twenty weeks post injury, intervened segments were imaged by IVUS for lesion progression and randomly implanted with either Absorb BVS or metallic drug-eluting stents (DES, XIENCE™ V) at a 2:1 ratio. All animals were imaged by angiography, IVUS and OCT post implant and at an interim 1-year follow up.

Results: Plaque area (PA), %PA (as percentage of EEL area) and plaque tissue composition were statistically similar for both device groups at pre and post implant (baseline) demonstrating a good randomization of the study. At 1-year follow-up, the implanted vessel (Absorb = 23, DES = 11) sizes remained unchanged. Change in the mean PA from baseline to 1 year was -0.22±2.61mm² for BVS and 1.15±1.36mm² for DES (p = 0.05). Changes of mean %PA were 1±12% and 7±6% for BVS and DES (p=0.07), respectively. There was a significant decrease of %PA at MLD (minimal lumen diameter) in BVS (-8±12%) compared to metallic DES (4±8%) (p=0.01). Plaque tissue characterization (iMAP-IVUS, Boston Scientific) revealed that percentage changes of each plaque component were the same between the two device groups with a decrease of fibrotic and increase of lipid and necrotic components.

Conclusions: At 1 year, plaque size trended towards reduction in Absorb but not in metallic DES implanted vessels. Plaque tissue characterization suggests that plaque stabilization has not occurred at 1 year; however, plaque stabilization is hypothesized to be related to tissue replacement of polymeric struts and as such expected during later stages of resorption. This hypothesis will be examined with repeat in vivo imaging follow-up and histological evaluation in these animals at 2, 3, and 4 years.