Bioresorbable Vascular Scaffolds
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TCT-421
Bioresorbable Vascular Scaffolds in Coronary Interventions: 6-Month Results From the German ASSUR-Registry
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Background: Bioresorbable vascular scaffolds have been available on the European market since November 2011. The first experience in a real-world setting is being documented in the ASSUR-registry (NCT01583608). The registry aims to investigate the safety, efficacy and performance of the everolimus-eluting, bioresorbable vascular scaffold (BVS, ABSORB™, Abbott Vascular Inc., Santa Clara, CA) over a period of 3 years.

Methods: Consecutive patients with de novo native coronary artery disease were treated with BVS at 6 German centers and included in the prospective, observational registry. Acute and 6-months outcomes of equal weight were device success, procedural success, cardiac death, myocardial infarction, ischemia driven target lesion revascularization and target vessel failure or revascularization. Angiographic parameters were assessed at baseline and post procedure.

Results: A total of 183 patients (65.3% < 93 years, 79.8% male) were enrolled from April 2012 to March 2013 and 198 lesions were treated. Eligibility criteria for ABSORB A/B would have been met in 16% and for ABSORB EXTEND in 70% of the patients. Acute device success was achieved in 194 (98%) lesions and acute procedural success in all patients. No cardiac death or myocardial infarction occurred and no target lesion revascularization was necessary during hospital stay. Median lesion length was 14.5 mm (5-84 mm) with 85 (42.9%) lesions > 20 mm. 31 (15.7%) lesions were moderately or heavily calcified, 6 (3%) lesions were tightly angulated and 6 (3%) lesions involved a side branch ≥ 2 mm in diameter. Stenosis diameter was 77.9% at baseline and 4.8% post PCI on average. In 11 (5.6%) lesions diameter of stenosis was ≥ 99%. The reference vessel diameter of 32 (16.2%) lesions was <2.5 mm. In 30 (15.2%) lesions > 1 BVS was implanted and in 11 patients > 1 larger vessel was treated. Bailout with a drug eluting stent was necessary in 3 (1.5%) lesions.

Conclusions: Acute results for safety, efficacy and performance of BVS for de novo coronary artery disease in all day clinical practice are promising. Angiographic core lab results will be obtained by June 2013 and clinical 6-months results by September 2013.

TCT-422
Malapposition is observed more frequently and to a greater degree in fibrocalcific plaques during bioresorbable vascular scaffold implantation
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Background: The bioresorbable vascular scaffold (BVS) has several advantages over existing metallic stents, including resorption and restoration of vasoreactivity. However, the mechanical properties of the BVS do not allow aggressive post-dilation, with potential for malapposition. Our aim was to assess the incidence of malapposition when malapposition was present (46.6% vs. 8.3%, p < 0.001). There was a positive correlation between %calcification and malapposition (r = 0.44, p < 0.001). The distance of malapposition in fibrocalcific plaque was increased compared to other malapposed struts (0.17±mm ± 0.10 vs. 0.14±mm ± 0.07, p = 0.01).

Conclusions: Incidence of strut malapposition with BVS is comparable to existing DES platforms. However, malapposition is more frequent and occurs to a greater degree in fibrocalcific plaques. Intracoronary imaging should be considered prior to BVS, as unrecognised calcification may lead to unnecessary malapposition.

TCT-423
Bifurcation Strategies with the Absorb BVS Everolimus-Eluting Resorbable Scaffold: A Bench Study
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Background: While bifurcation stenting techniques with metallic stents have been extensively studied on the bench and clinically, there are no data on how to treat bifurcations with Absorb everolimus-eluting bioresorbable scaffolds (BRS) which have limited post-dilatation potential without strut rupture compared with metallic scaffolds. Methods: BRS were deployed in phantoms with 30°, 60° and 90° side-branch angles in water at 37°C for testing strategies including side-branch dilatation with 2.5 and 3.0mm balloons, main branch post-dilatation, kissing post-dilatation at 4 atmospheres pressure and minimal balloon overlap, proximal optimization, “T” stenting with BRS and with metallic stents, “T” with protrusion, Crush technique, “Crush” technique, SKS technique. The deployment steps were recorded using cine-angiography and final results of each technique were recorded photographically and with micro-computed tomographic images.

Results: Dilating through the side of a BRS produced dilation similar to that with metallic stents that was worse with smaller side-branches and bigger balloons. The distortion consisted of narrowing of the scaffold beyond the side-branch and malapposition of the struts opposite the side branch. The positive effect of distal occlusion, with protrusion of struts into the side branch. The distortion could be partially repaired by pushing the struts into the lumen, but with pressure kissing post-dilatation. An unique feature of BRS use in bifurcations is the occurrence of single scaffold hoop or connector rupture. These are of uncertain significance.

Conclusions: Bench deployments of BRS provide insights into bifurcation strategies with these unique devices that behave differently from metallic scaffolds.

TCT-424
Bifurcation Bench Testing With The Bioresorbable Vascular Scaffold: Implications For Clinical Use
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Background: Little is known about bifurcation treatment with the bioresorbable vascular scaffold (BVS) from Abbott. In a bench test we investigated the mechanical properties and integrity of BVS in different bifurcation models.

Methods: In a warm water bath of 36 degrees Celsius multiple BVS were tested in 2 models. Model A: Opening towards an artificial side branch (SB) of a 3.0 mm BVS was investigated with increasing balloon sizes through a mid BVS cell under an angle of 30 and 60 degrees. Model B: With a 3D printer, 6 bifurcation models consisting of a rubber-like material (TangoPlus) with moderate stenosis (Medina 1-1-0) and 60 degree SB angle were made with the proper sizing of the proximal main branch (PMB) and distal main branch (DMB) using a validated scaling law. In these models 2.5, 3.0 and 3.5 mm BVS were implanted in the MB. Sequentially, SB opening was done using single 2.0 or 2.5 mm balloons (4 models) or using 2.0 and 3.0 mm balloons for complete (1 model) and incomplete kissing/snuggle (1 model). Opening and distorsion of the BRS struts were investigated with OCT and microCT.

Results: In model A, without surrounding structures, a cell of a 3.0 mm BVS can be expanded with 1.5 and 2.5 mm balloons at high pressure (16 atm) without disrupting struts. With a 3.0 balloon at 30 degree angle at 10 atm. and with 3.5 balloon at 60 degree angle at 8 atm. 1 or more struts ruptured. In model B, all 3D models showed no strut ruptures by OCT. By microCT only one partial strut tear was seen after incomplete kissing balloon. By OCT and microCT identical scaffold distortions of the PMB and DMB were observed, similar to what has been described with metallic stents. Distal struts adjacent to the SB were deflected into the lumen, but proximal struts adjacent to the SB were deflected towards the SB opening. Furthermore, struts opposite the SB were deflected towards causing malapposition. Increasing SB balloon size showed increased malapposition up to 270 μm. With double balloon inflation technique no malapposition was noted.

Conclusions: These results support the concept that bifurcation treatment with BVS is feasible and that similar strategies for provisional sidebranch treatment apply as to metallic stent.

TCT-425
Real-World Experience with Absorb™ Bioresorbable Scaffold Technology - Early Australian Registry Results
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Background: The safety and efficacy of the Absorb™ bioresorbable scaffold (ABS) has been documented in lower-risk lesion subsets however outcome data in more