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Bioresorbable Vascular Sccafold For The Treatment Of Chronic Total Occlusion Lesions - Clinical Outcomes And Intracoronary Imaging Follow-Up

Jarosław Wójcik,[1] Marek Jankiewicz,[1] Andrzej Madejczyk,[2] Krzysztof Wiórkowski[1]
[1]Department of Cardiology Medical University of Lublin, Lublin, Poland; [2]Departament of Cardiology Medical University of Lublin, Lublin, Poland

BACKGROUND For the treatment of chronic total occlusion (CTO), the efficacy and safety of the bioresorbable vascular scaffold is still considered limited. The aim of this study was to assess the feasibility of BVS for the CTO percutaneous treatment, analyze clinical outcomes and intracoronary imaging at one year follow-up. The reabsorption of the BVS could provide some advantages at long-term follow-up as compared with metallic drug-eluting stents.

METHODS Between October 2013 and January 2015, percutaneous treatment of CTO with BVS implantation were performed in 66 patients (66 lesions). The mean patient age was 62±11 years and 63% patients were male, 45.1% suffered from hypertension and 30.3% from diabetes. The decision of an antegrade or retrograde approach was taken by the operator after a thorough study of the CTO anatomy. An antegrade approach was the strategy used to cross 42% CTO, 33% a retrograde approach, while in 25% antegrade and dissection technique was needed. The most frequently treated vessel was the LAD (45%). Estimate the size of the BVS was made on the basis of the IVUS examination just after first balloon predilatation. The total scaffold length implanted per lesion was 55.8±18.9 mm. Post-dilatation was undertaken in 93%. All scaffolds were successfully delivered and deployed. Optical coherence tomography (OCT) was performed after BVS implantation. Primary endpoints were procedural success of deployment of the BVS at the target lesion and absence of in-hospital major adverse events (death, Q-wave myocardial infarction, stroke or any repeat target lesion revascularization). After 6 month of BVS implantation clinical evaluation was made, all included patients will have control angiography with OCT in 12 months follow-up.

RESULTS All scaffolds were delivered and deployed successfully. The final OCT analysis not revealed any significant scaffold malapposition. 9.1% patients presented significant troponin elevations in the range associated with a non-Q periprocedural myocardial infarction. No other in-hospital adverse clinical events were recorded. After 12±1 months of follow-up, the events rate was 6.0% due to 4 repeat revascularization (3 PCI and 1 CABG). Re-evaluation by angiography with OCT will be obtained in next 12 months follow-up after procedure.

CONCLUSIONS In this study we demonstrated midterm safety and efficacy BVS implantation in percutaneous treatment of chronic total occlusion.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

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Clinical follow-up after implantation of bioresorbable drug-eluting scaffolds - a prospective single center experience up to 3 years

Julia Seeger,[1] Sinisa Marcovic,[1] Birgid Gonska,[1] Daniel Walcher,[1] Wolfgang Rottbauer,[1] Jochen Wöhrle[1]
[1]University of Ulm, Ulm, Germany

BACKGROUND In the Absorb II study the use of the scaffold was associated with similar results compared with the everolimus eluting stent. Lesion complexity in Absorb II as well as follow-up (12 months) was limited. We evaluated clinical results in our prospective registry including a real world population with dual antiplatelet therapy for 6 months (stable angina) or 12 months (acute coronary syndrome).

METHODS In this prospective registry (clinicaltrials.gov NCT01583608) 236 patients were enrolled and treated with the bioresorbable scaffold (Absorb). Patients had stable or unstable coronary artery disease. Pre-dilation was mandatory and post-dilation with a high-pressure balloon was performed in patients with a scaffold length >12mm. Quantitative coronary angiography pre and post scaffold implantation was done. Patients received dual antiplatelet therapy for 6 months (aspirin and clopidogrel) for stable angina pectoris and 12 months for acute coronary syndrome. Mean follow-up was 382 days. Primary outcome measure was a device oriented composite endpoint defined as cardiac death, myocardial infarction not clearly related to a non-target vessel and target lesion revascularization. Scaffold thrombosis were defined according to the ARC criteria.

RESULTS Patients suffered from an acute coronary syndrome in 44%, diabetes mellitus in 24%. Multiple scaffold implantations were performed in 24% (N=61/74 lesions) with a mean 2.2±0.5 scaffolds (range 2-4), resulting in a total mean scaffold length of 48mm (range 28-112mm). Minimal lumen diameter (MLD) pre PCI was 1.04±0.50mm in the single scaffold and 0.89±0.49 in the multiple scaffold group. Lesion length was 13.5±5.7mm in the single versus 30.0±15.5mm in the multiple scaffold group. Reference diameter and MLD in the scaffold and total segment were significantly smaller with multiple compared with single scaffold treatment. Mean length of scaffold segment was 20mm (8-28mm) with a single scaffold and 37mm ranging from 20 to 112mm with multiple scaffolds. Pre-dilatation was performed in all cases. Acute gain in the scaffold segment was 1.37±0.47mm, leading to a final minimal luminal diameter of 2.44±0.41mm in the single scaffold and 2.27±0.37mm in the multiple scaffold group. Reference diameter post PCI was 2.94±0.77mm in the single and 2.77±0.38mm in the multiple scaffold group. With our dual antiplatelet strategy there was no definite scaffold thrombosis. Within 12 months follow-up the device oriented composite endpoint was low with 2.2% (0.8% in the single versus 6.8% in the multiple scaffold group, p=0.003).

CONCLUSIONS With careful predilation and post dilation using high pressure balloons in long scaffold segments and dual antiplatelet therapy there was no scaffold thrombosis. Device oriented composite endpoint was low with a significantly higher rate with multiple scaffold implantation. Diabetes mellitus and length of scaffold segment were significant predictors for the occurrence of a device oriented endpoint.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

KEYWORDS Bioresorbable scaffold, Coronary interventions

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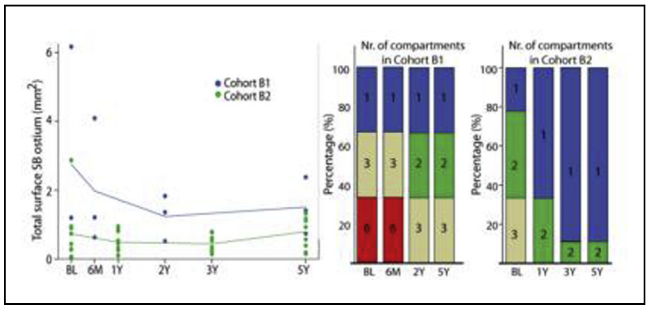
Five-year true serial evaluation of jailed side branches by Absorb bioresorbable vascular scaffolds using three-dimensional optical coherence tomography

Yoshinobu Onuma,[1] Maik J. Grundeken,[2] Shimpei Nakatani,[3] Yohei Sotomi,[4] Hector M. Garcia-Garcia,[5] Takayuki Okamura,[6] Patrick W. Serruys[7]
[1]Thorax Center, Erasmus University, Rotterdam, Netherlands; [2]Academic Medical Center - University of Amsterdam, Amsterdam, Netherlands; [3]ThoraxCenter, Erasmus Medical Center, Rotterdam, Netherlands; [4]Academic Medical Center - University of Amsterdam, Amsterdam, AK; [5]Cardialysis, Rotterdam, Zuid Holland; [6]Yamaguchi University Graduate School of Medicine, Ube, Yamaguchi; [7]Thoraxcenter, Rotterdam, Netherlands

BACKGROUND The fate of side branch (SB) ostia jailed by struts of the Absorb bioresorbable vascular scaffold (BVS, Abbott Vascular, Santa Clara, CA) has not yet been fully explored.

METHODS We performed a 3D-OCT sub-analysis of the ABSORB Cohort B trial. In this trial, 101 patients were included, all treated with a 3.0x18mm BVS. According to study protocol, the first 45 patients (cohort B1; CB1) underwent repeat angiography with invasive imaging (IVUS; OCT was optional) at 6 months and 2 years; the other 56 patients (cohort B2; CB2) were examined at 1 and 3 years. According to an additional protocol amendment all patients were consented again to return for another repeat angiography at 5 years. We present 3D-OCT assessments of jailed SB ostia from patient with true serial follow-up from baseline to 5 years, using the validated 'cut-plane'; analysis method of the new QAngioOCT 1.0 software (Medis Specials BV, Leiden, the Netherlands).

RESULTS A total of 27 patients (11 in CB1, 16 in CB2) with 100 jailed SB ostia (41 in CB1, 49 in CB2) were evaluated. A total of 12 jailed SB ostia could be truly serially assessed (3 from CB1, 9 from CB2). In CB1, the mean post-procedural ostial surface was 2.75±0.2.96mm2, which decreased to 1.98±1.85mm2 at 6 months, decreased a bit further to 1.24±0.66mm2 at 2 years, but increased to 2.83±0.82mm2 at 5 years (p-values not calculated due to low number of cases). In Cohort B2, the mean post-procedural ostial surface was 0.73±0.87mm2, which decreased to 0.49±0.32mm2 at 1 year (p=0.30), remained stable (0.44±0.24mm2) at 3 years (p=0.45), but significantly increased to 0.80±0.48mm2 at 5 years (p=0.008). The total number of compartments per jailed ostium decreased from baseline to 2 years (CB1) and 3 years (CB2), and remained similar from 2/3 years to 5 years (see figure).



CONCLUSIONS This is the first study which systematically evaluated, in a truly serial fashion, the fate of jailed BVS side branch struts up to 5 years follow-up using a validated 'cut-plane'; method. We showed that initially the total surface of the jailed ostia decreased due to closure of 1 or more compartments. However, after full bioresorption of the scaffold, the surface of the compartments which remained patent gradually increased from 2/3 years to 5 years. This information might have important implications for future bifurcation treatment using bioresorbable scaffolds.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Bifurcation, Bioabsorbable scaffolds, Optical coherence tomography

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Bioresorbable polymers and paclitaxel impair endothelial regeneration by induction of autophagy

Steven Wood,[1] Galen Hancock,[2] Belay Tesfamariam[3]
[1]Center for Devices and Radiolological Health, Silver Spring, MD; [2]Center for Devices and Radiological Health, Silver Spring, MD; [3]Center for Drug Evaluation and Research, Silver Spring, MD

BACKGROUND Bioresorbable vascular scaffolds have emerged as an alternative to permanent metallic device implants to treat vascular restenosis, because they degrade over time leaving the remodeled intimal layer with potential for full endothelial recovery. The development of a suitable bioresorbable polymer has been challenging because it must exhibit endothelial biocompatibility as the polymer degrades down and releases the antiproliferative drug such that complete vascular healing is achieved. The aims of this study were to characterize endothelial biocompatibility of bioresorbable materials and drugs using endothelial cell-based screening assays of apoptosis, oxidative stress, prothrombotic mediators and autophagic processes.

METHODS Endothelial cell line EAHy926 were cultured in chamber slides coated with poly-DL-lactide, (PDLA) 500 ug/cm2 and paclitaxel 3.125 ug/cm2 for seven days. Flow cytometric analysis was used to measure cytotoxicity, apoptosis (Annexin V and 7-amino-actinomycin D staining), expression of tissue factor, thrombomodulin, nitrotyrosine, cell adhesion molecules (CD31/PECAM-1, CD62E/E-selectin, CD162/PSGL-1), activated protein C receptor (CD201), co-stimulation modulators (CD154/CD40L, CD27/TNF receptor) and microtubule-associated protein 1A/1B-light chain 3.

RESULTS Treatment of endothelial cells with PDLA and paclitaxel induced increase in Annexin V expression, indicating enhanced apoptosis. Paclitaxel alone and in combination with PDLA upregulated tissue factor (by 37.8% vs control 12%) and down-regulated thrombomodulin (86.8% vs control 98.5%). Endothelial cells incubated in PDLA and paclitaxel showed marked increase in nitrotyrosine expression (66.2% vs control 34.2%) and exhibited an apparent cell death compared to the negative control. Paclitaxel alone or in combination with PDLA showed up-regulation of microtubule-associated protein 1A/1B-light chain 3 (44.6% vs control 13.8%), indicating activation of autophagy and impaired endothelial cell quality control. PDLA and paclitaxel had no significant effect on the expression of cell adhesion molecules, activated protein C receptor, and co-stimulation modulators.

CONCLUSIONS The results indicate that PDLA and paclitaxel promote oxidative stress, enhance apoptosis and induce excessive stimulation of autophagy, indicating that bulk hydrolysis of PDLA to lactic acid leads to cytotoxicity and may suppress endothelial regeneration.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

KEYWORDS Biodegradation polymer coating, DES, Endothelialization

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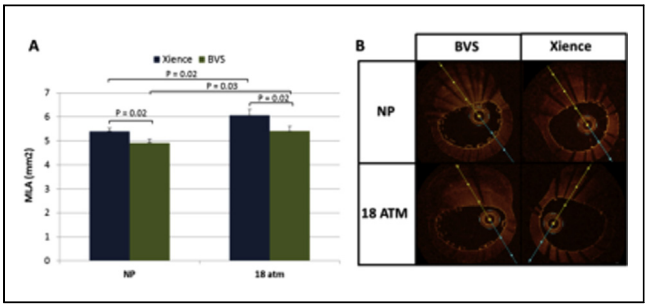
Bioabsorbable Vascular Scaffold Radial Expansion and Conformation Compared to a Metallic platform: Insights from In-vitro Expansion in a Coronary Artery Lesion Model

Nicolas Foin,[1] Renick D. Lee,[1] Christos Bourantas,[2] Alessio Mattesini,[3] Nicole Soh,[1] Ryo Torii,[2] Jie En Lim,[1] Enrico Fabris,[4] Gianluca Caiazzo,[5] Ismail D. Kilic,[6] Ricardo Petraco,[7] Sayan Sen,[8] Sukhjinder S. Nijjer,[8] Yoshinobu Onuma,[9] Justin E. Davies,[8] Carlo Di Mario,[10] Philip Wong,[1] Patrick W. Serruys[8]
[1]National Heart Centre Singapore, Singapore, Singapore; [2]University College London, London, United Kingdom; [3]Careggi Hospital, Florence, Italy; [4]BRU, Royal Bromton NHS Trust, London, United Kingdom; [5]Magna Graecia University, Catanzaro, Italy; [6]Royal Brompton NHS Trust, London, United Kingdom; [7]Imperial College, London, United Kingdom; [8]Imperial College London, London, United Kingdom; [9]Thorax Center, Erasmus University, Rotterdam, Netherlands; [10]BRU, Royal Bromton NHS Trust and Imperial College London, London, United Kingdom

BACKGROUND The aim of this study was to compare the acute expansion behavior of a polymer based Bioresorbable Scaffold and a second generation metallic DES platform in a coronary artery lesion model. Although there are significant differences in the material properties between currently available metallic stents and polymer based bioresorbable scaffolds, experimental data have shown so far little differences in their mechanical properties. Still, differences in acute results have been observed in clinical studies comparing BVS directly to metallic DES platforms.

METHODS We examined the expansion behavior of the Bioresorbable Vascular Scaffold (3.0x18mm Absorb BVS; Abbott Vascular, Santa Clara, CA) and a metallic DES (3.0x18mm Xience Prime; Abbott Vascular, Santa Clara, CA) after expansion at 37°C in an identical coronary artery stenosis model (12 different experiments were performed in total). Devices expansions were compared during balloon inflation and after deflation using microscopy to allow assessment of plaque recoil. Minimal Lumen Diameter (MLD) and Minimal Lumen Area (MLA) and Stent eccentricity were quantified from Optical Coherence Tomography (OCT) imaging at nominal diameter and after post-dilation at 18 ATM.

RESULTS The MLA in the models with BVS deployed was 4.92 ± 0.17 while in the metallic DES was 5.40 ± 0.13mm2(p=0.02) at Nominal Pressure (NP) and 5.41 ± 0.20 and 6.07 ± 0.25 mm2 (p=0.02) after expansion at 18 ATM respectively. Stent eccentricity index at the MLA was 0.71 ± 0.02 in BVS compared to 0.81 ± 0.02 in the metal stent at NP (p=0.003), and 0.73 ± 0.03 compared to 0.75 ± 0.02 at 18 ATM.



CONCLUSIONS Such in-vitro experiments provide insights to better understand the behavior of BVS scaffolds and to guide their optimal implantation in-vivo.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

KEYWORDS Bioabsorbable scaffolds, Conformability, Drug-eluting stent