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Journal

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY, 58(20)

ISSN

0735-1097

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Publication Date

2011

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Excimer Laser LEsion Modification to Expand Non-dilatable sTents (The ELLEMENT Registry)

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Background: Stent underexpansion is a risk factor for in-stent restenosis (ISR) and stent thrombosis. Existing techniques to optimize stent expansion are often ineffective and can be harmful. Implantation of a second stent within an underexpanded stent is unlikely to correct what is a primary mechanical problem, leading to recurrent presentations with ISR.

Methods: This study aimed to clarify the effectiveness and feasibility of Excimer Laser Coronary Angioplasty (ELCA) in improving stent expansion when high pressure non-compliant balloon (NCB) inflation was ineffective. ECLA ablation was performed at high energy during contrast injection and only within the under-expnaded stent. The primary endpoint of optimal stent dilatation was defined as successful stent expansion using the same NCB which had been unsuccessful prior to ECLA. Secondary endpoints were the composite of all-cause death, myocardial infarction (MI) and target lesion revascularization (TLR) at 6-months and defined as Major Adverse Cardiac Events

(MACE).
Results: Between June 2009 and March 2011, 18 consecutive patients with an under-expanded stent despite high pressure balloon inflation were included. The mean age was 70.4±10.4 years, 11 patients (61.2%) were male, and diabetes mellitus was present in 9 patients (50.0%) Target lesions included 1 (5.6%) in the distal left mainstem, 11 (61.1) in the left anterior descending artery, 3 (16.7%) in the left circumflex and 3 (16.7%) right coronary artery. The mean catheter size was 1.2±0.4 (range 0.9-2.0mm) and a mean of 3610±1824 laser pulses were required for optimal expansion. Optimal stent dilatation was achieved in 17 cases (94.4%), with an improvement in minimum lumen diameter measured by QCA (1.59mm at baseline to 2.78mm post-procedure) and minimum stent area measured by IVUS (3.80mm2 to 7.99mm2). Periprocedural MI was observed in 2 patients and transient slow flow in 1 patient following ELCA. During follow-up, MACE occurred in 1 patient (5.5%) who underwent TLR.
Conclusion: The ELLEMENT study confirms the efficacy and reproducibility of ELCA with contrast injection in improving stent underexpansion in undilatable lesions.

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Two Year Follow Up Data of Orbital Atherectomy System for the Treatment of De Novo Calcified Coronary Lesions - A Single Center Experience

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Background: Coronary Artery Disease continues to be a widespread and growing problem worldwide. Performing PCI on calcified lesions can lead to higher MACE rates and stent under expansion/malapposition. The Orbit I trial was conducted to evaluate the safety and performance of the Diamondback 360 Orbital Atherectomy System (OAS) (Cardiovascular Systems, Inc., St. Paul, MN, USA) for the treatment of calcified coronary lesions.
Methods: From May 2008 to July 2008, a single-center subset of 33 non-consecutive patients from the ORBIT I study were enrolled at CIMS Hospital Pvt. Ltd., India center based on several criteria, including a de novo, coronary lesion with stenosis ≥50% and ≤100% and at least one quadrant of calcification via IVUS. The patients were treated with OAS prior to stent placement. The safety endpoint was MACE rates, and patients were followed to two years at this center.
Results: Of the 33 patients, 90.90% (n=30/33) were male and the average age was 54.9 years. The ACC/AHA lesion class was: Type A 6.06% (n=2/33); Type B1 33.33% (n=11/33); Type B2 60.60% (n=20/33). The % diameter stenosis was 85.75%; lesion length was 15.90 mm. The procedural success was 97% (32/33) with one case where IVUS/device was not able to cross the lesion due to severe calcification. The observed MACE rate was as follows: in-hospital 6.06% (n=2/33); 30 days 9.09% (n=3/33); 6 months 12.12% (n=4/33) and 2 years 15.15% (n=5/33). MACE rate comprised of 2 patients with a non Q-wave MI in-hospital; one patient with non Q-wave MI at 30 days that led to TLR; and one patient with cardiac death at 6 months and at 2 years respectively. All stents were successfully deployed with 0.3% ± 1.8% residual stenosis.
Conclusion: This case series demonstrates that OAS safely and effectively modified calcified lesions and facilitated stent delivery in this difficult-to-treat plaque morphology, which continues up to two years post-procedure.

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Evidence of Late Neointimal Hyperplasia Formation after Five Years of Different Generations Drug-Eluting Stents

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Background: The amount of neointimal hyperplasia (IH) following drug-eluting stent (DES) implantation correlates with the potency of the anti-proliferative drug, its kinetic release as well as some individual characteristics, as the presence of diabetes mellitus (DM). Recently, some publications have suggested a continuous growth of IH following DES, which in some cases, might result in late “catch-up”. The aim of this study was to assess, by means of serial intravascular ultrasound (IVUS) the temporal course of IH formation following the implantation of two different generation of DES (durable-polymer sirolimus-eluting stent[SES] and biodegradable-polymer biolimus-eluting stent[BES])
Methods: Twenty-five pts with single de novo lesions in native coronary arteries, with reference vessel diameter between 2.5 and 3.5 mm were treated with Cypher-SES (n=12) and Biomatrix-BES (n=13), and underwent IVUS evaluation post procedure, at a mean of 9 months and 5 years.
Results: The mean age was 59 years, with 28% of DM. Baseline characteristics did not differ between the groups. Overall, percentage of IH obstruction and IH volume markedly increased from mid to long-term FU(percentage IH obstruction of 1.3% at 1st FU vs. 4.8% 2nd FU, p=0.002; mean IH volume 1.8 mm3 at 1st FU vs. 6.3 mm3 2nd FU, p=0.005). There was no significant difference in the variation (Δ) of vessel volume, lumen volume and percentage of IH obstruction between DES. In a separate analysis, sorting out patients according to diabetic status (7 diabetics and 18 non-diabetics), a more pronounced IH increase among diabetics was noticed (mean IH volume at 2nd FU 10.15 mm3 DM vs. 5.11 mm3 non-DM, p=0.02; percentage of IH obstruction at 2nd FU 8.3% DM vs. 3.5% non-DM, p=0.02).
Conclusion: The present serial IVUS assessment represents the longest serial invasive assessment of two generations DES with durable and biodegradable polymers. The findings of this study support the occurrence of continuous IH growth following the implantation of DES, these observations seem to be particularly

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Classification of Atherosclerotic Plaques using Depth Resolved Spectral Analysis of Optical Frequency Domain Imaging Datasets

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Background: Atherosclerotic plaques with thin fibrous caps, large lipid pools, and high densities of macrophages are more prone to rupture and cause acute coronary syndromes. Optical frequency domain imaging (OFDI) can identify key components related to plaque vulnerability but may suffer from artifacts and ambiguities that could prevent accurate identification of lipid rich regions.
Methods: We present a model of depth resolved spectral analysis for intracoronary plaque classification. Comprehensive pullback image datasets were acquired within 20 coronary arteries from 8 explant human hearts. Time-frequency analysis was used to generate depth resolved spectra of OFDI interferometric signals. A training set of registered OFDI-histology pairs (n=150) was used to develop a prediction model using quadratic discriminant analysis. Inputs to the model included attenuation, backscattering, and wavelength dependent attenuation. Model output is the probability for each pixel being assigned to lipid, calcium, fibrous, adventitial fat, or noise. The resultant spectroscopic diagnosis was compared to histological diagnosis.
Results: Using correlated OFDI and histology images, depth resolved spectral analysis was able to classify lipid, calcium, fibrous regions, adventitial fat, and noise with significant ($p<0.001$) areas under the receiver operator characteristic curve (0.87, 0.83, 0.97, 0.89, and 0.99 respectively). Although the backscattering and attenuation coefficients were significantly different between tissue types ($p<0.001$), the addition of spectral parameters increase the classification accuracy of lipid (AUC=0.87 with spectral parameters, AUC=0.84 without) and adventitial fat (AUC=0.89 with spectral parameters, AUC=0.87 without), $p<0.05$.
Conclusion: We have developed a method for classification of intracoronary OFDI pullbacks. This method can increase the contrast of OFDI intracoronary images and facilitate a rapid comprehensive visualization of OFDI datasets, which can potentially improve OFDI diagnosis and/or assist in guiding therapeutic procedures.

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In Vivo Tissue Characterization of Coronary Lipid Plaques: Comparison of Optical Coherence Tomography and Near-Infrared Spectroscopy

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Background: Intravascular imaging with Fourier domain optical coherence tomography produces high-resolution images (10–20 μm) of coronary atherosclerosis. The LipiScan IVUS Coronary Imaging System combines co-registered grayscale intravascular ultrasound (IVUS) with near infrared spectroscopy (NIRS) to identify lipid-rich plaques. The concordance between these 2 imaging modalities has not been studied.
Methods: 10 vessels were interrogated with both the Dragonfly OCT (pullback speed =20mm/sec) and the IVUS/Lipiscan catheter (pullback speed 0.5mm/sec). A fiduciary branch was identified for each pullback. Offline frame by frame analysis of the images was performed to identify lipid pools. By OCT, lipid-rich plaque was defined as a signal-poor region with diffuse borders.By NIRS, lipid-rich plaque was defined as a high lipid core burden index, which has been validated against histology.
Results: There was excellent correlation between the spatial lipid pool distribution as noted on OCT and NIRS, with an average 5 mm discrepancy between the two modalities (possibly due to variations in guide catheter and wire position and imaging catheter positioning). An example appears in the Figure. Small lipid pools which did not extend beyond 1-2 frames were noted on only one or the other imaging system, which might be explained by the varying distance of the light source from the small lipid pool, differences in penetration, or false positives/negatives.