Results: Analysis of coverage revealed an important impact of baseline strut-wall ISA distance on the risk of incomplete strut coverage at follow-up. Malapposed segments with an ISA detachment < 100 µm at baseline showed complete strut coverage at follow-up whereas segments with a maximal ISA detachment distance of 100-300 µm and >300 µm had 6.1 % and 15.7% of their struts still uncovered at follow-up respectively ($p < 0.001$).
Conclusions: Flow disturbances and risk of delayed strut coverage both increase with ISA detachment distance. Insights from this study are important for understanding malapposition as a quantitative, rather than binary phenomenon (present or absent), and to define the threshold of ISA detachment that might benefit from optimization during stent implantation.

TCT-366

Thrombus Downstream From Plaque Rupture Site in Acute Myocardial Infarction Identified On Optical Coherence Tomography

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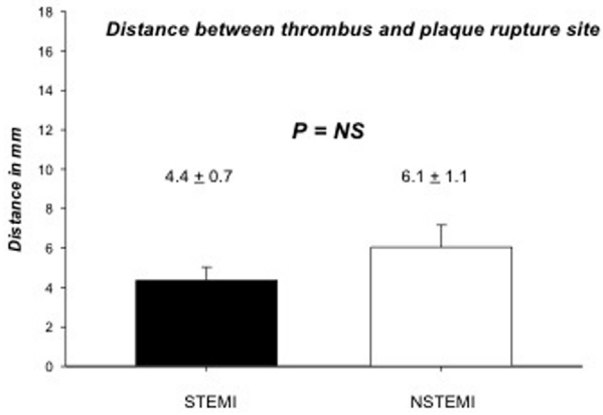
Background: Rupture of atherosclerotic plaque and resulting thrombosis is the basis for acute coronary syndrome (ACS). Standard arteriography is commonly used to guide percutaneous treatment of ACS but it has limited ability to detect thrombus or plaque rupture site. Intravascular ultrasound (IVUS) has improved capabilities to detect these lesions. However, optical coherence tomography (OCT) is more sensitive than IVUS in detecting thrombus and plaque rupture site which can potentially improve stent positioning.
Methods: Retrospective review of OCT images in 46 patients who presented with ST-elevation myocardial infarction (STEMI) and non-ST elevation myocardial infarction (NSTEMI) was performed. The plaque rupture site and thrombus were identified and the distance from the two were measured.
Results: Plaque rupture site was identified in 80% of cases. Thrombus was identified in 89% of STEMI cases and 67% of NSTEMI cases (n=0.09). One patient had the thrombus upstream, one patient had it at the rupture site, and the remaining 44 patients had it downstream to the plaque rupture site. Mean distance between the thrombus and plaque rupture site is shown in graph.



Conclusions: OCT has good sensitivity in identifying plaque rupture site and thrombus in patients with STEMI and NSTEMI. The mean distance between the plaque rupture site and the thrombus was 5.1 mm suggesting that using standard arteriography to guide stenting may lead to suboptimal treatment since the stent can cover the thrombotic site but miss the plaque rupture site that remains thrombogenic.

TCT-367

2-Year Sequential OCT Follow-up Findings and 3-Year Clinical Outcomes of the New Dual Therapy Endothelial Progenitor Cell Capturing Sirolimus-eluting COMBO Stent: The EGO-COMBO Study

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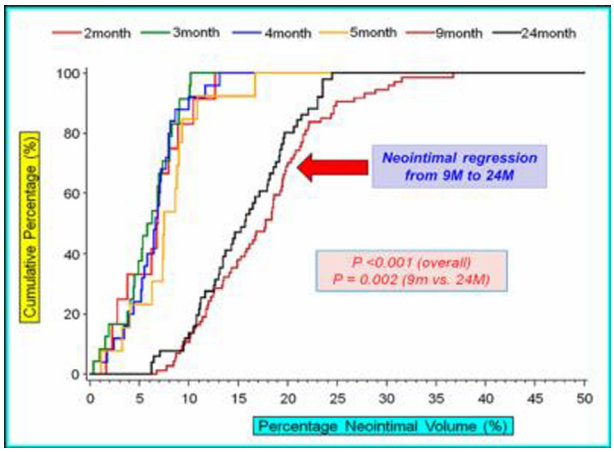
Background: The benefits of the first available "dual" therapy approach endothelial-progenitor-cell capturing sirolimus-eluting stent (COMBO Stent, OrbusNeich Medical, FL, USA) were studied.
Methods: Using 4 longitudinal sequential OCTs in this prospective, single center study, 61 patients treated by COMBO Stent had baseline OCT (for optimal stent apposition), at early FUs (4 monthly groups in 1:2:2:1 ratio from 2nd to 5th month for healing profile [% strut coverage] using 6 Categories), at 9M (for neointima), and a final 24M OCT (for late loss outcomes). Clinical event adjudication, angiographic and OCT analyses were performed by CRF core laboratory.
Results: 61 patients (33% DM) with 74 lesions received 88 COMBO stents. Early strut coverage (OCT Cat. D to F) increased from 77, 86.9, 90.7, to 92.5%; interpolated 100% coverage at 150 days. 9M OCT FU Rate was 100% & TLR at 1.64%. 24M OCT FU Rate was 68.3%; at 38M (Clinical FU Rate 98.3%) MACE Rate was 3.28%. From 9 to 24 months, neointima regression by OCT was observed:- (Mixed Model, Median, IQR) neointimal thickness (mm) 0.14 [0.08, 0.21] vs 0.12 [0.07, 0.19], p< 0.001; neointimal volume (mm3) 29.91 [22.13-43.22] vs 26.17 [19.94-35.81], p=0.003; & in-stent % plaque volume (%) 17.76 [12.21-21.22] vs 15.65 [11.17-19.35], p=0.011. No neoatherosclerosis or ARC definite or probable LST recorded.
Conclusions: This OCT Study demonstrates the benefits of the "dual" therapy DES approach, with excellent pro-healing profile established translating into durable outcomes of neointimal suppression (even 24M regression, for the first time in a DES) without late stent failure.



TCT-368

Preclinical validation of light intensity analysis on Optical Coherence tomography to monitor bioresorption and integration process after implantation of a bioresorbable scaffold in porcine model: a comparison between OCT and Histology

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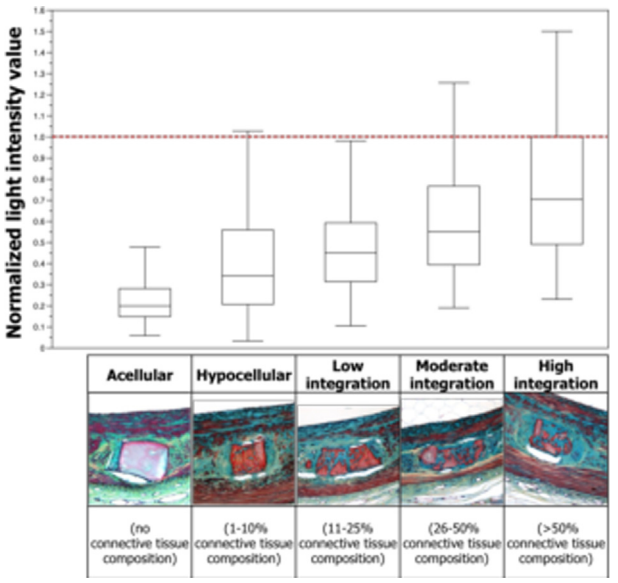
Background: After implantation of an everolimus-eluting poly-l-lactic-acid scaffold (Absorb BVS, Abbott Vascular, Santa Clara, CA), the strut is progressively hydrolyzed and integrated into the arterial wall. The quantitative light intensity analysis of the strut core on Optical Coherence Tomography (OCT) enables us to assess the light reflectivity of the resorbing polymer and its vessel wall integration. The aim of this study was to compare this quantitative method with histology in porcine model.
Methods: Seventy-six BVS were implanted in 51 pigs that underwent OCT and were then euthanized at 3, 6, 12, 18, 24, 30 and 36 months after implantation. On OCT, the median light intensity value of strut was calculated by dedicated software, which was normalized by the intensity value of inter-strut neointima. On histology, integration grade of the corresponding struts was classified into 5 groups according to the connective tissue composition.
Results: A total of 275 struts were analyzed. The normalized light intensity value (NLIV) increased steadily over time except between 12 and 18 months. (0.15 [0.12-0.20] at 6M, 0.19 [0.15-0.25] at 12M, 0.20 [0.15-0.25] at 18M, 0.23 [0.18-0.32] at 24M, 0.32 [0.24-0.44] at 30M, and 0.52 [0.35-0.76] at 36M). As the integration grade progresses in histology, NLIV increased gradually (Figure).
Conclusions: The OCT NLIV might be valuable for monitoring the integration process of polymeric bioresorbable scaffolds. Histological and imaging analysis at 42 and 48 months are ongoing. The full results will be shown at the time of the meeting.



TCT-369

Human coronary plaque characterization using a fully integrated intravascular ultrasound and optical coherence tomography (IVUS-OCT) system

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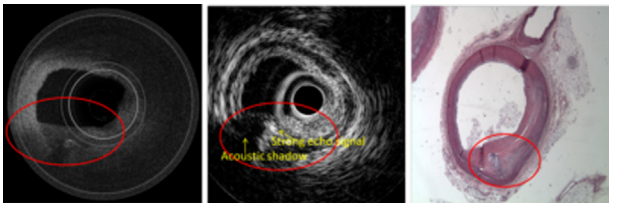
Background: The comparisons of diagnostic accuracy of OCT/IVUS have been investigated. Combined use of IVUS and OCT was proposed to increase accuracy. Fully-integrated OCT-IVUS system has also been reported. However, the diagnostic accuracy of this system for classifying different plaque types has not been studied yet.
Methods: A total of 241 coronary plaque regions from 20 cadavers were imaged by an integrated real-time OCT-IVUS system using a single fully-integrated catheter. A spatial resolution of ~8μm and a penetration depth of ~4mm were simultaneously achieved by this system at 10 frames/s and up to 2.5mm/s pull-back speed. These obtained images were randomly ordered and classified by the two cardiologists. Using histology analysis as a gold standard, we calculated the agreement between results by each imaging technique and histopathogy diagnosis by Cohen's k test. Interobserver and intraobserver variability of each imaging technique were also analyzed using Cohen's k test.
Results: IVUS-OCT had significantly higher sensitivity for characterizing lipid than IVUS (90% v.s. 63%), higher specificity for fibrosis than IVUS (98% v.s. 90%) and higher sensitivity for characterizing calcification than OCT (100% v.s. 96%). The overall agreement between IVUS-OCT and histology diagnoses was excellent (cohen's K=0.962).



Conclusions: This study shows that an integrated OCT-IVUS system, with better penetration depth or higher resolution, provides a more accurate assessment of plaque components than using OCT or IVUS alone.

TCT-370

Histopathological validation of coronary plaque classification using virtual histology intravascular ultrasound and optical coherence tomography

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Background: The majority of myocardial infarctions are due to fibroatheromata (FA), advanced atherosclerotic plaques with a large necrotic lipid core and thin overlying fibrous cap. Virtual histology intravascular ultrasound (VH-IVUS) and optical coherence tomography (OCT) are invasive imaging techniques that may permit in vivo plaque classification through identification of individual plaque components. However, data validating plaque classification by these techniques are minimal.
Methods: LAD arteries were obtained at autopsy and attached to a proprietary imaging rig. The vessel was submerged and pressure-perfused with pre-warmed PBS (to 37°C) at 100mmHg, both prior to and during imaging. Both VH-IVUS (Eagle-Eye Gold, Volcano) and OCT (Dragonfly C7, St Jude Medical) imaging was performed. Regions of interest (ROI) were marked at 5mm intervals, with sections cut at ~150μm. Each ROI was meticulously matched to co-registered imaging sets offline (Indec Medical Systems, US). Hierarchical plaque classification was performed, based on previously published classification algorithms.
Results: 86 ROI were identified from five autopsied hearts, producing 372.7mm of IVUS and 358.6mm of OCT imaging. Classification was performed on a median of 15 [IQR 13-17] VH and 25 [IQR 25-26] OCT frames, for each ROI. ROI were classified as FA 12 (14.0%), fibrocalcific 29 (33.7%), pathological intimal thickening (PIT) 25 (29.1%) or non-atherosclerotic vessel 20 (23.3%) on histology. The sensitivity for VH-IVUS and OCT to identify FA was 81.8% and 80.0% (p=0.09), with sensitivities of 40.9% and 85.0% for fibrocalcific plaque (p=0.02) and 75.0% and 94.7% for PIT (p=0.12), respectively. However, the specificity for OCT was significantly higher than that of VH-IVUS (95.7% vs. 71.7% p< 0.001). Overall, the diagnostic accuracy for intra-vascular imaging to identify a FA was 73.2% for VH-IVUS and 92.9% for OCT.
Conclusions: These data suggest that both VH-IVUS and OCT can reliably identify FA in vivo. However, VH-IVUS appears to have a lower specificity and diagnostic accuracy than OCT, with consequent potential for over reporting of FA in conventional plaque classification algorithms.

TCT-371

Evaluation of Highly Automated Software for Analyzing Intravascular Optical Coherence Tomography Pullbacks of Stents

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Background: Intravascular optical coherence tomography (OCT) has been widely used to assess stent tissue coverage and malapposition in clinical evaluation trials. Typically, stent analysis is done manually with very limited software assistance, requiring 6-12 hours per pullback. Inter- and intra-observer variability is inevitable.
Methods: We developed image analysis algorithms to automate objective stent analysis. Guide wire artifact and lumen boundary were segmented using dynamic programming. Advanced machine learning algorithms were employed to detect stent struts and determine the presence of tissue coverage for each strut. Strut-level tissue coverage thickness and malapposition distance and frame-level NIH and malapposition areas were automatically determined. Algorithms were incorporated into a comprehensive software package, OCT image visualization and analysis toolkit for stent analysis (OCTivat-Stent). Convenient manual review and editing tools were included for refinement of automatic results. The software was trained on previously acquired OCT data, fixed, and used to analyze 292 stent pullbacks in the ROBUST study (NCT00888758). A cardiologist reviewed and edited automated analysis. Clinical results from our analysis of ROBUST data will be presented in other reports.
Results: The concordance correlation coefficients between automatically measured stent and lumen areas, and manual measurements were 0.97 and 0.99, respectively. 11% of struts were missed, mostly when surrounding complex plaques eliminated the telltale strut shadow. There were 1% false positive strut detections. Software mislabeled 18% of human-classified uncovered and 1% of covered struts. Compared to fully manual analysis, average inter-observer agreement for sensitivity/specificity of strut classification was improved from 62%/92% to 74%/98% using the software. Analyst time for a full stent analysis was reduced from 6-12 hours to 27+/-18 minutes.
Conclusions: Application of this software to stent trials should enable faster, larger, and more reproducible studies. There is a potential to add training examples to improve automated analysis. Online assessment is possible if algorithms are incorporated into clinical OCT platforms.