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Enlargement of Distal Vessel Diameter after Percutaneous Coronary Intervention of Chronic Total Occlusion – Relationship with Collateral Flow and Intravascular Ultrasound Findings

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Background: Although the vessel diameter distal to the recanalized CTO lesion is often smaller than expected immediately after recanalization, the vessel tends to increase their diameter after one year. Therefore, we assessed how the distal segment vessel diameter would increase at 1-year follow-up.

Methods: Consecutive patients (n=88) who received successfully recanalization of CTO lesions from July 2007 to September 2011 and had 1-year follow-up catheterization were analyzed. We classified them into two groups by the Rentrop collateral flow grade: Group A, grade 0 to 2 and Group B, grade 3. We evaluated by IVUS the plaque burden and minimum lumen diameter of the distal vessel segment immediately after recanalization. Vessel diameter distal to the recanalized CTO lesions (at 10mm from distal stent edge) was compared between follow-up and immediately after recanalization (baseline) by quantitative coronary angiography.

Results: Vessel diameter increased significantly from baseline to follow-up (2.0±0.7mm vs. 2.4±0.7mm, P<0.05). Vessel diameter increased more in Group B than in Group A (76.9% vs. 94.3%mm P<0.05). There was no significant difference in IVUS findings between the patients with and without vessel diameter increase.

Conclusions: Vessel diameter in the distal segment of CTO lesion increased at 1-year follow-up especially in the patients with good collateral flow.

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Six-Month Results of the DESolve Novolimus-Eluting Bioresorbable Scaffold for the Treatment of Single, De Novo, Coronary Artery Lesions: Serial OCT Analysis from the Pivotal, Prospective Multicenter DESolve NX

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Background: DESolve is a novel PLLA-based bioresorbable scaffold (BRS), coated with a bioresorbable polylactide-based polymer that carries and delivers novolimus (5 µg/mm scaffold length). DESolve is designed to provide temporary vessel support along with neointimal suppression, followed by full bioresorption between 1-2 years. The aim of this study is to present the first morphometric changes of the DESolve BRS up to six through serial evaluation by intravascular OCT.

Methods: The DESolve NX study enrolled 126 pts with de novo coronary lesions treated with a single scaffold available in three diameters (3.0, 3.25 and 3.5 mm) and two lengths (14 and 18 mm). The first 40 enrolled pts were part of an invasive imaging sub study with IVUS and OCT, which consisted of paired analysis of automated pullbacks performed at the end of the index procedure (baseline) and at 6 months. All OCT images were analyzed by an independent core laboratory.

Results: 38/40 (95%) patients had serial images of adequate quality for analysis. Adequate scaffold expansion (96.18±11.83%) was obtained upon deployment. A significant increase in scaffold area (Δ: 16.93 ± 12.90 %, p<0.0001) compensated the small amount of NIH (0.70±0.26 mm²) that accrued on top of the struts over time, resulting in only 11.27±4.19% scaffold obstruction, and preservation of the “unobstructed” effective (excluding the inter-strut space) lumen (Δ: 4.23±14.37 %, p<0.0001). Incomplete scaffold apposition (ISA) was seen in 15 pts (39.5%) at baseline, and persisted in 5 pts (13.2%) at 6 months. There was no late acquired ISA. A total of 29,154 struts were analyzed (14,893 at baseline; 14,261 at follow-up). 6-Month rate of covered struts per patient was 98.79±1.69%. NIH thickness on top of the struts measured 100.53±30.58 µm.

Conclusions: The DESolve BRS tolerated very good expansion upon deployment. Significant scaffold expansion, along with low NIH formation, generated a very low percent scaffold obstruction and preservation of the “unobstructed” lumen,

contributing to an elevated efficacy profile. A high safety profile was additionally confirmed by the elevated rates of strut coverage and absence of late acquired ISA.

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Operator Blinded Virtual Histology Intravascular Ultrasound Observations of Usual Stenting Practice in Acute Coronary Syndromes: The OBVIOUS-ACS study

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Background: Angiographically-guided stent deployment is the conventional, albeit imperfect, approach in the setting of “real world” Percutaneous Coronary Intervention (PCI). Recently, the ADAPT-DES study and a large meta-analysis have suggested there may be a benefit to both clinical outcomes and major adverse cardiac events (MACE) with Intravascular Ultrasound (IVUS) guided PCI.

Methods: This was a single centre, operator blinded observational study. Patients with a confirmed troponin positive ACS were recruited. Pre-PCI the lesion was examined with motorized IVUS and Virtual Histology (VH) (VOLCANO CORP). The operator was blinded to the IVUS screen and carried out the procedure angiographically. Following deployment of the stent and post-dilatation, a final IVUS pullback was performed. All IVUS images were processed off-line by an independent experienced operator.

Results: The main results of the study are displayed in Table 1. 58 culprit ACS plaques underwent full examination with IVUS-VH pre and post PCI. In particular we found that the minimum stent area achieved was 6.79mm² (+/-2.43), with only 65.5% of stents achieving an MLA of >5.5mm². The maximum stent area achievable for stent used would have been 8.87mm² (+/-2.68), suggesting an under-deployment area of around 2.08mm²(+/-1.87). The average reference vessel lumen area was 10.58mm² (+/-2.51) suggesting that stents were also under-sized. Only 36% of stents met MUSIC criteria for stent symmetry (min/max lumen diameter>70%). Only 40% met a deployment criteria of (MLA/av vessel lumen area >80%).

Conclusions: We have shown that in ACS PCI, operators consistently undersize the vessel and stent. Moreover, inadequate stent deployment, under-expansion, in-apposition and geographic miss occurs frequently. This may have implications for long term event rates, in keeping with the results of ADAPT-DES. The use of up-front IVUS should be considered in PCI for ACS.

Measured Variable +/- SD	Result
Min/Max Lumen Diameter (>0.7)	0.61 (±0.13) 21/58 (>0.7) = 36%
Total Plaque Length (Pre-PCI - PB>40%)	31.63 (±12.11)
Stented Length on IVUS (mm)	20.86 (±6.15)
Residual Plaque Length (PB>40%)	14.60 (±11.56)
Minimum Stent Area Achieved (mm ²) (>5.5)	6.79 (±2.43) 38/58 (>5.5) =65.5%
Max Stent Area Achievable (mm ²)	8.87 (±2.68)
Calculated Under-deployment Area (mm ²)	2.08 (±1.87)
Average Reference Vessel Lumen Area (mm ²)	10.58 (±2.51)
MLA/Av Ref Vessel Lumen Area (should be >0.8) (mm ²)	0.66 (±0.24) 23/58 = 40%
Frequency of Longitudinal Miss	25/58 = 43%
Frequency of “unstable” VH-TCFa in residual plaque	9/58 = 15.5%
Visual Frequency of Edge Dissection	5/58 = 8.6%
Visual Frequency of Incomplete Stent Apposition	13/58 = 22.4%
Frequency of plaque prolapse/in-stent issue	3/58 =5.2%