

a significant higher rates of malapposed strut, particularly toward the SB ostium ($40.6 \pm 6.0\%$ versus $26.0 \pm 5.7\%$, $p=0.0005$), as well as a higher SB lumen residual stenosis than after mid-distal recrossing ($39.7 \pm 7.1\%$ versus $18.9 \pm 8.0\%$, $p < 0.0001$). In-vivo Optical Coherence Tomography (OCT) analysis on 52 patients undergoing elective treatment of bifurcation lesions using provisional stenting showed that using OCT to guide cell recrossing is feasible and can reduce significantly strut malapposition in bifurcation. Patients who were treated using OCT-guided distal recrossing had a significantly lower number of malapposed stent struts, especially in the quadrants towards the SB ostium than in the angiography-guided group (9.5% vs 42.3% , $p < 0.0001$).

Conclusions: Optimal distal cell recrossing of the guidewire is critical to ensure a successful stent optimization in bifurcation PCI.

TCT-596

Early Vascular Restoration following treatment of single de-novo coronary artery lesions with the DESolve Nx Novolimus Eluting Bioresorbable Coronary Scaffold System (NEBCSS) at 6 months: Insights from the Serial IVUS analysis of the pivotal, prospective, multicentre, DESolve NX Trial

Jose D. Costa Jr¹, Joachim Schofer², Stefan Verhey³, Sara Toyloy⁴, Daniel Chamié⁵, Vinayak Bbhar⁶, Ricardo A. Costa⁶, Bernhard Witzendichler⁷, Lynn Morrison⁸, John Yan⁹, Amanda Sousa⁵, J. Eduardo Sousa¹⁰, Alexandre Abizaid¹¹

¹Instituto Dante Pazzanese de Cardiologia, São Paulo, Brazil, ²Medicare center Prof Mathey, Prof Schofer, Hamburg University Cardiovascular Center, Hamburg, Germany, ³Antwerp Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium, Antwerp, Belgium, ⁴Elixir Medical Corporation, Sunnyvale, CA, ⁵Dante Pazzanese, São Paulo, Brazil, ⁶Instituto Dante Pazzanese De Cardiologia, Sao Paulo, Brazil, ⁷Charité Campus Benjamin Franklin, Berlin, Germany, ⁸Elixir Medical Corporation, Sunnyvale, CA, ⁹Elixir Medical Corp, Sunnyvale, CA, ¹⁰Instituto Dante Pazzanese de Cardiologia, São Paulo, CA, ¹¹Instituto Dante Pazzanese de Cardiologia, São Paulo, São Paulo

Background: The DESolve Bioresorbable Scaffold is a novel drug-eluting device combining a PLLA-based scaffold coated with a bioresorbable polylactide-based polymer and a potent anti-proliferative sirolimus metabolite, Novolimus. The drug dose is 5 mcg per mm of scaffold length. An early benefit with regard to vessel restoration is a potential feature of this unique technology. The aim of this study is to assess the serial changes in the vessel treated with the DESolve scaffold using IVUS technology.

Methods: The DESolve NX is a pivotal, prospective and multicentre clinical trial, which enrolled 126 patients with de novo coronary lesions treated with a single scaffold available in three diameters (3.0, 3.25 and 3.5) and two lengths (14 and 18 mm). The first 46 patients enrolled in this trial were part of an IVUS sub-study, which consisted of a paired analysis of the automatic pullbacks performed at the end of the baseline procedure and at six-month follow-up (an additional 24 month follow up will also be performed). All analyses are being performed by an independent IVUS core lab.

Results: The mean age of the study population was 62 years, 68% of which were men and 21% had diabetes. Pre procedure reference vessel lesion length and diameter were 11.2 ± 3.8 mm and 3.06 ± 0.31 , respectively. 40 of the 46 patients enrolled in the IVUS sub study had serial analyses available at 6 months that demonstrated a significant increase in mean lumen ($\Delta 9.0\%$, $p = <0.001$), scaffold ($\Delta 15.7\%$, $p = <0.001$) and vessel ($\Delta 16.8\%$, $p = <0.001$) areas between baseline and 6 months and low % volume obstruction (5.05%) with no case of late acquired scaffold incomplete apposition or aneurysm formation.

Conclusions: The DESolve scaffold is the first scaffold to demonstrate lumen area enlargement with no chronic recoil at 6 month follow up with no evidence of aneurysms. Serial IVUS results at 6 months showed effective neointimal suppression and no late acquired strut malapposition suggesting the natural ability of the scaffolded vessel to remodel at 6 months.

TCT-597

Predictors of Stent Expansion After Drug-eluting Stents: An ADAPT-DES IVUS substudy

Nobuaki Kobayashi¹, Gary S. Mintz², Bernhard Witzendichler³, D. Christopher Metzger⁴, Michael Rinaldi⁵, Ernest L. Mazzaferri⁶, Peter L. Duffy⁷, Giora Weisz⁸, Thomas Stuckey⁹, Bruce R. Brodie¹⁰, Ke Xu¹¹, Gregg Stone¹², Akiko Maehara¹³

¹Cardiovascular Research Foundation and Columbia University Medical Center, New York, NY, ²Cardiovascular Research Foundation, Washington, DC, ³Charité Campus Benjamin Franklin, Berlin, Germany, ⁴Wellmont CVA Heart Institute, Kingsport, TN, ⁵Associate Professor of Medicine, UNC Chapel Hill, Charlotte, NC, ⁶Ohio State University, Dublin, OH, ⁷Pinehurst Cardiology, Pinehurst, NC, ⁸Columbia University, New York, United States, ⁹LeBauer Cardiovascular Research Foundation, Greensboro, NC, ¹⁰LeBauer CV Research Foundation, Greensboro, NC, ¹¹Cardiovascular Research Foundation, New York, NY, ¹²Columbia University Medical Center and the Cardiovascular Research Foundation, New York, United States, ¹³Cardiovascular Research Foundation and Columbia University Medical Center, New York, United States

Background: While a smaller minimum stent cross-sectional area (MSA) predicts adverse events (stent restenosis and thrombosis), predictors of stent underexpansion have not been fully investigated.

Methods: ADAPT-DES was a prospective, multicenter, registry of 8,583 consecutive pts with undergoing PCI with DES. Among 2064 pts enrolled in a pre-specified intravascular ultrasound (IVUS) substudy, 769 pts with 889 lesions were examined by both pre and post-PCI IVUS. Stent expansion (ST-Exp) was calculated as MSA divided by average of proximal and distal stent edge lumen area; %ST-Exp was divided into (1) $\geq 70\%$ (adequate expansion), (2) 60-70% (moderate underexpansion), and (3) $< 60\%$ (severe underexpansion).

Results: Lesion length was longer and maximum arc of superficial calcium was greater in the severe underexpansion group than in the other 2 groups (Table). These findings were independent of vessel size and were also similar when stent expansion was divided into tertiles: highest tertile of stent expansion (ST-exp $> 83\%$), middle tertile (73%-83%), and lowest tertiles (ST-exp $< 73\%$). Multiple logistic regression analysis revealed that lesion length [OR 1.80 per 10 mm (1.54, 2.09), $p < 0.0001$] and maximum arc of superficial calcium [OR 1.13 per 90° (1.30, 2.00), $p = 0.006$] were independently associated with severe stent underexpansion (ST-Exp $< 60\%$). ROC curve analysis showed that cut-off values of lesion length and maximum arc of superficial calcium that best predicted stent expansion $< 60\%$ (severe underexpansion) were 42.0 mm and 127°. Conversely, plaque burden was unrelated to stent expansion.

Conclusions: Lesion length and the extent of superficial calcium are the strongest determinants of stent underexpansion.

Parameter	ST-Exp $\geq 70\%$ (n=672)	ST-Exp 60-70% (n=159)	ST-Exp $< 60\%$ (n=58)	p-value
ST-Exp (%)	82.1 [76.7, 86.7]	65.8 [63.7, 68.0]	55.0 [51.4, 57.4]	< 0.0001
MSA (mm ²)	6.5 [5.0, 8.2]	5.2 [4.1, 6.5]	4.1 [3.2, 4.9]	< 0.0001
Lesion length (mm)	21.0 [15.4, 30.2]	32.1 [22.2, 46.7]	47.5 [32.8, 62.0]	< 0.0001
Plaque burden at MLA (%)	77.6 [69.2, 83.7]	77.7 [69.5, 83.9]	80.3 [75.2, 85.2]	0.18
Superficial arc of calcium (°)	87 [47, 145]	100 [68, 171]	159 [90, 230]	< 0.0001

TCT-598

Mechanisms of Incomplete Stent Apposition After Implantation of Drug-eluting Stents in patients with ST-segment Elevation Myocardial Infarction

Lisbeth Antonsen¹, Evald H. Christiansen², Michael Maeng², Anne Kalfoti², Per Thyssen¹, Hans-Henrik Tilsted³, Leif Thuesen², Jan Ravkilde³, Lars Krusell², Mikkel Hougaard¹, Jens F. Lassen², Lisette Okkels Jensen¹

¹Odense University Hospital, Odense, Denmark, ²Aarhus University Hospital, Skejby, Aarhus, Denmark, ³Aalborg University Hospital, Aalborg, Denmark

Background: Incomplete stent apposition (ISA) is a potential factor in the subsequent development of later adverse events, including stent thrombosis, in patients treated with drug-eluting stents (DES). We assessed the incidence and mechanisms of ISA in patients with ST-segment Elevation Myocardial Infarction (STEMI) treated with a biolimus-eluting Nobori stent (BES) or a sirolimus-eluting Cypher stent (SES).

Methods: In the Randomized Comparison of Biolimus-Eluting Biodegradable Polymer Coated Stent and Durable Polymer Sirolimus-Eluting Stent in Unselected Patients (SORT OUT V) trial, a prespecified intravascular ultrasound (IVUS) substudy enrolled 116 STEMI patients (57 BESs and 59 SESs) treated with PPCI where post-procedure and 12-month follow-up imaging data were available. The vascular response and influence of remodeling (changes in external elastic membrane (EEM) cross sectional area (CSA)) in "acute", "resolved", and "late acquired" ISA was evaluated.

Results: Post-intervention ISA occurred in 22 (19.0%) stented lesions (15.8% BES and 22.0% SES, $p=ns$). Of these, 7 (31.8%) resolved at follow-up without significant remodeling (post-intervention EEM CSA 19.7 mm² (interquartile range (IQR) 17.0 to 23.5 mm²) vs. follow-up EEM CSA 20.9 mm² (IQR 17.8 to 23.5 mm²), $p=ns$. Plaque CSA increased from post-intervention 6.7 mm² (IQR 5.5 to 8.9 mm²) to follow-up plaque CSA 10.0 mm² (IQR 9.2 to 12.4 mm²), $p=0.018$. At follow-up late acquired ISA was seen in 19 (16.4%) stented lesions (14.0% BES and 18.6% SES, $p=ns$). In patients with late acquired ISA, the mechanism was positive remodeling in 73.7% of the stented lesions (post-intervention EEM CSA 21.0 mm² (IQR 13.5 to 26.9 mm²) vs. follow-up EEM CSA 27.4 mm² (IQR 18.6 to 31.3 mm²), $p=0.001$, and maximum ISA CSA was 3.5 mm² (IQR 1.3 to 5.8 mm²). In 26.3% of the patients with late acquired ISA, negative remodeling and plaque/thrombus resolution was seen.

Conclusions: In STEMI patients "acute" ISA resolved in one third of the stented lesions, mainly due to plaque progression. "Late acquired" ISA was predominantly due to positive remodeling.