

	TLR (n=8)	No TLR (n=32)
Radiation failure (%)	71	54
Lesion length (mm)	41.4±33.1	25.8±14.5
Number of stents	2.8±1.9	1.6±1.0
Residual edge lesion (%)	25	19
Reference EEM area (mm ²)	9.86±6.30	9.47±4.60
Reference lumen area (mm ²)	7.31±4.14	6.54±3.44
Minimum stent area (mm ²)	4.32±1.98	4.71±1.68

1101-46 First Human Experience With the ABT-578 Eluting Phosphorylcholine Polymer Stent: A Serial Volumetric Intravascular Ultrasound Analysis From the PREFER Trial

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Background: ABT-578, an analog of rapamycin, is an anti-proliferative agent with promising preclinical study results. PREFER is a multicenter, non-randomized, single-arm, feasibility trial of the ABT-578 eluting phosphorylcholine-coated BiodivYsio® (Abbott Vascular Devices, Redwood City, CA) stent which enrolled 11 cases with de novo human coronary lesions. The aim of this substudy was to evaluate the impact of this new drug-eluting stent on both stented segment and stent edges.

Methods: Serial 3-D IVUS analysis (baseline and 3-month follow-up) was available in 9 out of 11 patients (one case was excluded due to low IVUS image quality; the other due to additional dilatation with a non-study stent). Minimum lumen area (LA) and mean areas for lumen, plaque (PA), stent (SA), vessel (VA) and neointima (NIA) were measured over the stented and the stent edge (both 5 mm proximal and distal adjacent to the stent) segments.

Results: At baseline, neither significant plaque protrusion / thrombus nor edge dissection was detected. At follow-up, no late incomplete stent apposition was observed. Mean NIA was 0.17 ± 0.32 mm², and %NIA (100*mean NIA/mean SA) was 2.11 ± 3.96%. Table shows serial changes in quantitative IVUS parameters.

Conclusion: Preliminary analysis of the initial human experience with the ABT-578 eluting phosphorylcholine-coated stent showed no apparent adverse vessel response. The amount of neointimal proliferation was minimum. Further studies will be needed to confirm these favorable observations.

	Stent	Segment		Proximal	Edge		Distal	Edge	
	Baseline	Follow-Up	P-Value	Baseline	Follow-Up	P-Value	Baseline	Follow-Up	P-Value
Minimum LA (mm ²)	6.20	6.09	NS	6.42	6.83	NS	6.48	5.96	NS
Mean LA (mm ²)	7.34	6.95	NS	8.35	8.40	NS	7.90	7.63	NS
Mean PA (mm ²)	7.41	7.30	NS	6.30	6.06	NS	5.07	4.97	NS
Mean SA (mm ²)	7.34	7.12	NS	—	—	—	—	—	—
Mean VA (mm ²)	14.75	14.42	NS	14.65	14.46	NS	12.97	12.60	NS

1101-63 Impact of Preinterventional Lesion Calcification on Neointimal Hyperplasia Following Sirolimus-Eluting Stent Implantation: An Intravascular Ultrasound Analysis

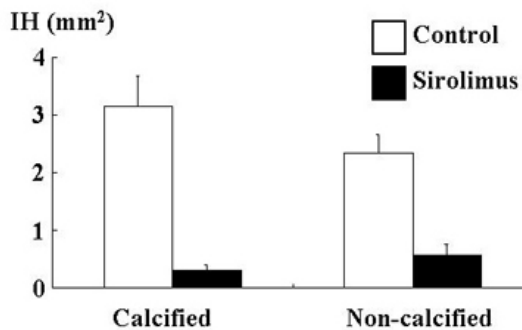
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Background: Although the negative impact of lesion calcification on stent expansion is well known, the effect of calcification on neointimal hyperplasia (IH) following sirolimus-eluting stent (SES) implantation is not well characterized.

Methods: Eighty-two patients who underwent SES (n=45) or bare metal stent (n=37) implantation and preinterventional IVUS were enrolled in this substudy from the overall SIRIUS population. Lesions were divided into calcified (defined as calcific deposits at minimum lumen area cross section), or non-calcified. Stent, lumen, IH (stent-lumen) area were measured at baseline and 8 month follow-up.

Results: Overall, acute lumen area gain tended to be less in calcified lesion (5.19±2.38 vs. 6.06±2.43mm², P=0.13), resulting in smaller stent area (7.90±2.60 vs. 8.70±2.56mm², P=0.19). There was a significant interaction between calcification and stent type on IH suppression (Figure). However, multiple logistic regression analysis including stent type, stent area at baseline, and plaque type showed that stent type was the only predictor for target lesion revascularization or binary angiographic restenosis.

Conclusion: The treatment effect between sirolimus and control in reducing restenosis remained constant, irrespective of lesion characteristics. Despite less optimal acute results in calcified lesions, SES suppressed IH effectively.



1101-64 Six-Month Intracoronary Ultrasound Findings Following Sirolimus-Eluting Stents for the Treatment of Restenosis-Prone Coronary Lesions

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Background: Drug-eluting stents are promising. However, follow-up information is still limited. Intravascular ultrasound (IVUS) is a unique tool is evaluating in situ late results.

Methods: We describe the follow-up IVUS findings obtained from 102 patients with coronary lesions prone to restenosis who had been treated with sirolimus-eluting stents (SES). Lesions were considered at risk for restenosis because of the following reasons: in-stent restenosis, major bifurcation lesion, long-diffuse stenosis, or chronic total occlusion. Sixty-two patients had more than 1 risk condition for restenosis. The mean age was 60±10 years. All patients had six-month angiographic and IVUS evaluation. Motorized IVUS pull-back study of the treated segment was always performed. Proximal and distal references were interrogated at 1 cm from the stent borders. Intrastent IVUS-measurements were also performed. **Results:** Qualitatively, we observed focal non-stent apposition in 11 patients and a bulge or minor aneurysm formation in 2. Eleven patients (11%) showed focal restenosis. In the remaining 91 patients, the stent was covered with a fine lining. In addition, the intima was thicker at the edges showing compensatory vessel enlargement. The table summarizes the quantitative results.

Conclusion: These findings show that adequate healing of restenosis-prone lesions occurs in most patients. However, focal restenosis may develop. A favorable remodeling is observed at the edges.

	Intimal thickening (mm)	Intimal area (mm ²)	Lumen area (mm ²)	Stent area (mm ²)	External elastic laminae (mm ²)
Proximal reference	0.5±0.2	6±3	11±5	--	19±7
Proximal edge	0.8±0.3	8±4	9±4	--	20±7
Maximal stent diameter	--	0.8±0.9	6.9±2.2	7.7±2.5	19±5
Minimal lumen diameter	0.2±0.2	1.0±1.4	4.7±2	6±3	17±6
Distal edge	0.6±0.3	5±2	7±4	--	14±6
Distal reference	0.3±0.2	5±3	7±3	--	13±6

1101-65 Predictors of Edge Stenosis Following Sirolimus-Eluting Stent Deployment: A Quantitative Intravascular Ultrasound Analysis From the SIRIUS Trial

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Background: While sirolimus-eluting stents (SES) have substantially reduced in-stent restenosis, less efficacy at stent edges has been reported in the SIRIUS trial, a multicenter, randomized, prospective clinical trial comparing the sirolimus-eluting Bx VELOCITY™ stent to bare metal stents.

Methods: Angiographic and IVUS data were obtained from SIRIUS. To investigate possible determinants of peri-stent edge stenosis (defined as diameter stenosis greater than 50% either proximal or distal to the stent) at follow-up, baseline IVUS parameters were analyzed in 172 edges of 92 SES.

Results: Of these, 6 edges in 6 SES had edge stenosis at 8-month follow-up. Quantitative IVUS results are shown in the table.

Conclusion: The IVUS measurements of maximum stent area (SA) and edge SA compared to reference suggest that overexpansion (not detected by angio balloon / artery