

The Relationship Between Post-Stent Strut Apposition and Follow-Up Strut Coverage Assessed by a Contour Plot Optical Coherence Tomography Analysis

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Objectives This study sought to evaluate the relationship between post-stent strut apposition and follow-up strut coverage using contour plot optical coherence tomographic analysis.

Background Tracking the fate of interested regions of struts at different time points has not been investigated.

Methods Post-intervention and 6-month follow-up optical coherence tomographic evaluations were performed in 82 patients treated with biolimus- (n = 37) or sirolimus-eluting stents (n = 45). Post-stent apposition was classified as embedded, apposed, or malapposed. For volumetric stent evaluation, the post-intervention strut-artery distance and the neointimal thickness at follow-up were measured as a function of the circumferential arc length and longitudinal stent length. Computer-generated contour plots of the strut-artery distance and neointimal thickness were compared.

Results The percentages of embedded and malapposed struts after intervention were 1.8% (Interquartile range [IQR]: 0.6% to 6.2%) and 2.3% (IQR: 0.5% to 5.2%), respectively. The percentages of uncovered and malapposed struts at 6 months were 16.0% (IQR: 7.4% to 33.3%) and 0% (IQR: 0% to 0.7%), respectively. The percentage of uncovered struts at 6 months varied significantly with post-stent strut apposition (0% [IQR: 0% to 11.4%] in embedded, 16.3% [IQR: 8.1% to 31.3%] in apposed, and 26.8% [IQR: 0% to 56.3%] in malapposed, $p < 0.001$ for all pairwise comparisons). In lesions without tissue prolapse, embedded struts were all covered (100% covered struts) compared with those with tissue prolapse (76.8% covered, $p < 0.001$).

Conclusions The optical coherence tomography-guided optimization of stent strut apposition enhances strut coverage at follow-up. This comprehensive method for evaluating strut apposition may provide more useful information to understanding the serial changes in strut coverage. (Neointimal Coverage After Implantation of Biolimus Eluting Stent With Biodegradable Polymer: Optical Coherence Tomographic Assessment According to the Treatment of Dyslipidemia and Hypertension and the Types of Implanted Drug-Eluting Stents; [NCT01502904](#)) (J Am Coll Cardiol Intv 2014;7:641–51)

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The drug-eluting stent (DES) is a standard modality to treat patients with symptomatic coronary artery disease. However, incomplete neointimal coverage is regarded as an important pathological parameter of late stent thrombosis in patients treated with DES implantation (1,2). In particular, it has been demonstrated that following DES implantation, there was a greater prevalence of malapposed and uncovered struts leading to increased risk of late stent thrombosis (3,4). Stent strut apposition and the serial change of neointimal formation in cross-sectional images of implanted stents have previously been evaluated by intravascular ultrasound (IVUS) (5,6). Recently, optical coherence tomography (OCT) has been used as a powerful high-resolution imaging modality that can provide more detailed information on vascular responses to DES versus IVUS (7-9). Although OCT can more accurately detect minimal neointimal coverage over the struts, it is still difficult or even impossible to compare struts between 2 time points (7,10,11). Recently, contour plot OCT reconstruction was successfully used for assessing the spatial distribution pattern of strut coverage and stent malapposition at the strut level (12). This technique is also able to visualize both

the gap between the underlying artery wall and the stent struts after intervention and the neointimal coverage at follow-up in the circumferential and longitudinal directions. The objective of this study was to investigate the relationship between post-stent strut apposition and 6-month follow-up strut coverage using contour plot OCT analysis.

Abbreviations and Acronyms

CSA = cross-sectional area(s)

DES = drug-eluting stent(s)

IVUS = intravascular ultrasound

NIH = neointimal hyperplasia

OCT = optical coherence tomography

Methods

Study design. A total of 82 stents in 82 patients (37 biolimus A9-eluting stents [Nobori, Terumo Corporation, Tokyo, Japan] and 45 sirolimus-eluting stents [Cypher, Cordis Corp., Miami Lakes, Florida]) were selected from 120 patients enrolled in a randomized trial comparing the strut coverage of the biolimus A9-eluting and sirolimus-eluting stents by an optical coherence tomography analysis (13). Thirty-eight stents were excluded for the following reasons: follow-up angiogram was not performed ($n = 7$); the OCT catheter could not be advanced through the lesion due to severe angulation ($n = 5$); poor image quality in patients ($n = 8$); reconstruction of contour plots image was not possible in patients due to severe motion artifacts ($n = 12$); and mismatch of the contour plots between post-intervention and follow-up ($n = 6$). OCT examination was performed after the procedure and at a 6-month follow-up. Inclusion

and exclusion criteria for this study were provided in a previous study (13). This study was approved by the institutional review board of our institution, and written consent was obtained from all enrolled patients.

OCT imaging and analysis. OCT imaging of the target lesion was performed after the procedure and at the 6-month follow-up using a frequency-domain OCT system (C7-XR OCT imaging system, LightLab Imaging, Inc., St. Jude Medical, St. Paul, Minnesota) developed to generate frames at much higher rates and faster pullback speeds compared with those of time-domain OCT. In this study, OCT cross-sectional images were generated at a rate of 100 frames/s, whereas the fiber was withdrawn at a speed of 20 mm/s within the stationary imaging sheath. A continuous, nonocclusive contrast-saline mixture was flushed through a guiding catheter at a rate of 4 to 5 ml/s for 3 to 4 s. During OCT image acquisition, the OCT catheter was placed as close as possible to a similar location on 6-month follow-up based on the post-intervention image to reduce the difference of the acquired OCT images between 2 time points. All OCT images were analyzed at a core laboratory (Cardiovascular Research Center, Seoul, Korea) by analysts who were blinded to patient and procedural information.

Cross-sectional OCT images were analyzed at 0.2-mm intervals. A strut was defined as an embedded strut if the endoluminal strut boundary was below the level of luminal surface (14). An apposed strut was defined as a strut completely attached to the vessel wall without any gap between itself and the wall. A malapposed strut was defined as a strut that had detached from the vessel wall by $\geq 130 \mu\text{m}$ (biolimus A9-eluting stent) or $\geq 160 \mu\text{m}$ (sirolimus-eluting stent) (15,16). Stent and luminal cross-sectional areas (CSAs) were measured; neointimal hyperplasia (NIH) CSA was calculated as the stent CSA minus the luminal CSA. NIH thickness was measured as the distance between the endoluminal surface of the neointima and the strut (17). An uncovered strut was defined as having an NIH thickness of $0 \mu\text{m}$ (17). The percentage of uncovered or malapposed struts was calculated as the ratio of uncovered or malapposed struts to total struts in all OCT cross sections. Stent malapposition was further classified into persistent, resolved, or late acquired by comparing the post-procedure and follow-up OCT images (18). To evaluate the magnitude of malapposition, the maximal extra-stent lumen CSA and the distance between the malapposed strut and the vessel wall (the strut-artery distance) were measured. In addition, tissue prolapse was defined as a mass protruding into the lumen (more than $250 \mu\text{m}$ at the thickest point).

Volumetric OCT assessment of stent strut apposition using a contour plot. Post-intervention and follow-up contour plot analyses were used to compare vascular responses as

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