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ORIGINAL CONTRIBUTION

Procedural Performance of Ultrathin, Biodegradable Polymer-Coated Stents Versus Durable Polymer-Coated Stents Based on Intracoronary Imaging

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Abstract

Objective. Thinner stent struts might lead to a higher risk of recoil and subsequently a smaller minimal stent area (MSA), which is known to be the strongest predictor of stent failure. We compared procedural performance between an ultrathin-strut biodegradable-polymer sirolimus-eluting stent (BP-SES) and a durable-polymer zotarolimus-eluting stent (DP-ZES) using intracoronary imaging. **Methods.** A consecutive cohort of patients underwent percutaneous coronary intervention (PCI) with either BP-SES or DP-ZES in a pseudorandomized fashion between July 2018 and October 2019. In the present subanalysis, we included cases in which post-PCI imaging with intravascular ultrasound (IVUS) or optical coherence tomography (OCT) was performed. The primary endpoint of the study was MSA. Secondary endpoints included percentage stent expansion and presence of residual edge disease, malapposition, tissue protrusion, submedial edge dissections, or edge hematoma. **Results.** A total of 141 treated lesions (78 BP-SES and 63 DP-ZES) in 127 patients were analyzed. Median age was 69.3 years (interquartile range [IQR], 57.3-75.6) and 74.0% of patients were male. All baseline and procedural characteristics were comparable between both groups. Median MSA was 5.80 mm² (IQR, 4.40-7.24) for BP-SES and 6.35 mm² (IQR, 4.76-8.31) for DP-ZES (*P*=.15). No significant differences in stent expansion, residual edge disease and presence of malapposition, tissue protrusion, submedial edge dissections, or edge hematomas were found. Stent diameter and stent length were found to be independent predictors of MSA. **Conclusions.** No significant differences in MSA were found between lesions treated with BP-SES vs DP-ZES. BP-SES and DP-ZES were comparable in terms of procedural performance.

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Key words: drug-eluting stents, intravascular ultrasound, optical coherence tomography, percutaneous coronary intervention

Innovations in drug-eluting stent (DES) technologies, such as thinner struts and biocompatible polymers, have contributed to the reduction in adverse events after percutaneous coronary intervention (PCI).[1-3] Among the newer-generation DES options, the ultrathin-strut, bioresorbable-polymer sirolimus-eluting stent (BP-SES) and durable-polymer zotarolimus-eluting stent (DP-ZES) are widely studied devices that have shown similar safety and efficacy profiles up to 2-year follow-up.[4,5]

In 2 recent non-patient-level meta-analyses, thinner-strut BP-SES proved to be superior to contemporary DP-DES in terms of myocardial infarction (MI) and target-lesion failure (TLF).[6,7] This conflicts with the concept that a reduction in strut thickness may affect radial strength, as observed in standardized bench tests,[8] and increase the risk of acute recoil, smaller minimal stent area (MSA), and potentially higher adverse event rates.[9-14] Moreover, the use of thinner struts has been associated

with decreased radiopacity, which may increase the risk of geographic miss and residual edge dissections, putting the patient at risk for worse outcomes, specifically related to edge restenosis and stent thrombosis.[12,15] An in vitro comparative study confirmed a higher radiopacity for the DP-ZES as compared with the BP-SES.[16,17]

The purpose of the current study is to compare post-PCI MSA and stent expansion based on intracoronary imaging in 2 stent types: the ultrathin BP-SES and DP-ZES. Intravascular ultrasound (IVUS)- and optical coherence tomography (OCT)-derived parameters indicating procedural performance of the stent types were compared and predictors of MSA were identified.

Methods

Patient population. This is a subanalysis of a prospective, pseudorandomized, 2-armed, single-center study including all patients who underwent PCI with either the DP-ZES or the BP-SES for the treatment of significant coronary artery disease from July 2018 to October 2019 at Erasmus University Medical Centre in Rotterdam, the Netherlands. According to local institutional practice, the use of either DP-ZES or BP-SES device was pseudorandomized based on the day of the week. As such, the DP-ZES was used on even days and BP-SES on odd days. Exclusion criteria for the Orsiro vs Onyx registry were restricted to the concomitant use of other stents, the use of both study devices in the same patient, or the use of drug-coated balloons for the treatment of 1 or more segments. In patients included in this registry, intravascular imaging was performed at the discretion of the operator.

The present intravascular imaging analysis included all patients who underwent post-PCI intravascular imaging with either IVUS or OCT. Multiple vessels per patient could be included and inclusion of multiple lesions per vessel was allowed if treated with non-overlapping stents. Exclusion criteria included treatment of in-stent restenosis and inadequate quality of the IVUS or OCT pullback.

The local ethical committee provided approval for the current study (MEC-2021-0080).

Study stents and procedures. The Resolute Onyx DP-ZES (Medtronic) is a newer-generation permanent-polymer-coated DES with thin struts (uncoated 81-91 μm), high radial strength, and improved visibility due to its high-density platinum iridium core.[17] Its durable BioLinx polymer elutes zotarolimus during a period of 180 days.[18] The Orsiro BP-SES (Biotronik) is a biodegradable-polymer-coated cobalt-chromium stent. The stent has a strut thickness of 60 μm for stents 3.0 mm and smaller and 80 μm for larger stents. The biodegradable polymer elutes sirolimus for a period of 100-120 days and is reabsorbed over a period of 1-2 years.[18]

Stent implantation was performed according to standard techniques. The decision to perform thrombus aspiration, atherectomy, predilation or postdilation, or additional stenting after imaging was left to the discretion of the operator.

IVUS/OCT acquisition and analyses. IVUS images were acquired using the Opticross (Boston Scientific Corporation) or Kodama HD-IVUS (ACIST Medical Systems) catheters. OCT images were obtained using the Dragonfly Optis OCT catheter (Abbott Vascular). IVUS and OCT pullbacks were stored in a local database and were analyzed offline.

IVUS and OCT analyses were performed using QCU-CMS image analysis software, version 4.69 (Leiden University Medical Center). In case multiple post-PCI pullbacks were available, the first IVUS or OCT pullback performed after stent implantation was analyzed. Quantitative measurements of vessel, stent, and luminal areas were performed at 2 frames/mm, including the stented segment and 5 mm proximal and distal reference segments. *Stent expansion* was subsequently defined as (MSA/average of proximal and distal reference lumen) x 100% and as (MSA/distal reference lumen) x 100%. In IVUS pullbacks, at the stent edges and at 5-mm reference points, *plaque burden* was defined as ([external elastic lamina (EEL) area – lumen area]/EEL area) x 100%. In OCT pullbacks, *residual edge disease* was defined as a minimal lumen area (MLA) smaller than 4.5 mm^2 within the 5-mm reference segment either proximal or distal to the stent. Each pullback was inspected in order to identify malapposed struts, tissue protrusion, and submedial edge dissections. *Malapposition* was defined as presence of malapposition of at least 2 struts, with a malapposition distance of at least 2 strut thicknesses. *Tissue protrusion* was defined as any tissue protruding through the stent. Furthermore, the presence of submedial edge dissections with a length of at least 3 mm was assessed.

Study endpoints. The *primary endpoint* of this study was MSA. *Secondary outcomes* were stent expansion, residual disease at the stent edges, and presence of stent edge dissections, tissue protrusion, and malapposition.

Statistical analysis. For continuous variables, normality was evaluated using Shapiro-Wilk tests. Normally distributed continuous data are presented as mean ± standard deviation and non-normally distributed continuous data as median ± interquartile range (IQR). Categorical data are presented as numbers and percentages. Comparisons of patient characteristics between the group treated with BP-SES and the group treated with DP-ZES were performed using independent-samples *t* tests or Mann-Whitney tests for continuous data, and using χ^2 or Fisher's exact tests for categorical data.

For comparison of procedural characteristics and IVUS and OCT parameters, 3-level linear mixed models and generalized linear mixed models with nested random intercepts were used to account for clustering of vessels within patients and clustering of stents within vessels. MSA and stent expansion were compared in the total cohort and in a subgroup of stents with a stent diameter ≤3.0. In addition, IVUS and OCT measurements were compared within subgroups of calcified lesions, vessels, and stent diameters. *P*-values for between-group differences were obtained using Mann-Whitney tests and 3-level mixed models.

We performed uni- and multivariable linear regression analyses using a linear mixed-effect model to identify predictors of MSA. Patient and procedural characteristics with a *P*-value <.20 in univariable analysis were included in the multivariable model. Possible interaction terms and non-linear effects were tested and included in the model if the *P*-value from the likelihood ratio test was <.05.

IVUS- and OCT-measured values of MSA and mean stent diameter were pooled for analysis of the primary outcome, for the multivariate analysis of predictors of MSA, and for subgroup analyses.

All statistical tests were 2 sided. *P*-values <.05 were considered statistically significant. Statistical analyses were performed with IBM SPSS Statistics for Windows, version 25.0 (IBM Corp) and R, version 4.1.1 (R core team 2021; packages: lme4, lmerTest, numDeriv, ggplot2, ggpubr, foreign, plyr, gridExtra, cowplot, and rprintf).

Results

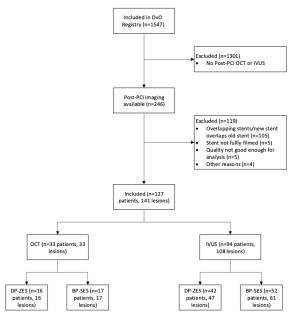

Figure 1. Flow chart of patient inclusion and exclusion criteria.

Table 1. Patient baseline characteristics.

Variable	Total (n = 127)	BP-SES (n = 69)	DP-ZES (n = 58)	*P*-Value
Age (years)	69.3 (57.3–75.6)	69.5 (58.2–75.2)	68.7 (56.7–75.8)	.94
Gender (male)	94 (74.0%)	49 (71.0%)	45 (77.6%)	.40
Body mass index (kg/m²)	26.5 (24.0–28.6)	26.9 (23.9–28.9)	26.3 (24.5–27.8)	.59
Hypertension	81 (63.8%)	44 (66.7%)	35 (60.3%)	.46
Dyslipidemia	77 (60.6%)	45 (65.2%)	32 (55.2%)	.25
eGFR (mL/min/1.73m²)	75.0 (61.5–88.5)	78.5 (64.5–88.5)	74.0 (59.0–87.0)	.43
Diabetes	29 (22.8%)	16 (23.2%)	13 (22.4%)	.92
Chronic obstructive pulmonary disease	8 (6.3%)	3 (4.3%)	5 (8.6%)	.47
Heart failure	15 (11.8%)	8 (11.6%)	7 (12.1%)	.93
Atrial fibrillation	16 (12.6%)	7 (10.1%)	9 (15.5%)	.36
Former or current smoker	35 (27.6%)	20 (29.0%)	15 (25.9%)	.70
Myocardial infarction in medical history	22 (17.3%)	15 (21.7%)	7 (12.1%)	.15
PCI in medical history	29 (22.8%)	18 (26.1%)	11 (18.0%)	.34
CABG in medical history	7 (5.5%)	3 (4.3%)	4 (6.9%)	.70
PCI indication				.81
Stable angina pectoris	57 (44.9%)	31 (44.9%)	26 (44.8%)	
Unstable angina pectoris	12 (9.4%)	7 (10.2%)	5 (8.6%)	
NSTEMI	40 (31.5%)	23 (33.3%)	17 (29.3%)	
STEMI	18 (14.2%)	8 (11.6%)	10 (17.2%)	

Data presented as median (interquartile range) or number (%).
BP-SES = biodegradable-polymer sirolimus-eluting stent; CABG = coronary artery bypass grafting; DP-ZES = durable-polymer zotarolimus-eluting stent; eGFR = estimated glomerular filtration rate; NSTEMI = non-ST segment elevation myocardial infarction; PCI = percutaneous coronary intervention; STEMI = ST segment elevation myocardial infarction.

Table 1. Patient baseline characteristics.

Table 2. Procedural and angiographic characteristics per treated lesion.

Variable	Total (n = 141)	BP-SES (n = 78)	DP-ZES (n = 63)	*P*-Value
Analyzed vessel				.11
Right coronary artery	30 (21.3%)	17 (21.8%)	13 (20.6%)	
Left anterior descending coronary artery	78 (55.3%)	43 (55.1%)	35 (55.6%)	
Left circumflex coronary artery	21 (14.9%)	15 (19.2%)	6 (9.5%)	
Left main coronary artery	11 (7.8%)	3 (3.8%)	8 (12.7%)	
Left internal mammary artery	1 (0.7%)	0 (0.0%)	1 (1.6%)	
Lesion type B2/C	107 (75.9%)	63 (80.8%)	44 (69.8%)	.13
Chronic total occlusion	3 (2.1%)	1 (1.3%)	2 (3.2%)	.89
Calcification (moderate to severe)	64 (45.4%)	36 (46.8%)	28 (46.8%)	.84
Thrombus	25 (17.7%)	17 (21.8%)	8 (12.7%)	.79
Bifurcation				
1-stent bifurcation	3 (2.1%)	0 (0.0%)	3 (4.76%)	.1
Provisional stenting	31 (22.0%)	18 (23.1%)	13 (20.6%)	.73
Pre-PCI imaging performed	61 (43.3%)	28 (35.9%)	33 (99.2%)	.11
Predilation	93 (65.2%)	51 (65.4%)	41 (65.1%)	.97
Postdilation before imaging	67 (47.5%)	39 (50.0%)	28 (44.4%)	.51
Postdilation after imaging	64 (45.4%)	36 (46.2%)	28 (44.4%)	.94
Lesion preparation (Shockwave or RA)	10 (7.1%)	2 (2.6%)	8 (12.7%)	.69
Additional over-kapping stent after study IVUS/OCT	43 (30.5%)	29 (37.2%)	14 (22.2%)	.07
Stent length (mm)				.43
Median length	22 [15–30]	22 [15–30]	18 [15–26]	
Mean length	22.35 ± 9.20	22.88 ± 9.26	21.65 ± 9.15	
Stent diameter (mm)				.88
Median diameter	3.0 [3.0–3.5]	3.0 [3.0–3.5]	3.5 [3.0–3.5]	
Mean diameter	3.30 ± 0.51	3.23 ± 0.46	3.39 ± 0.56	
Stent diameter ≤3.5 mm	15 (10.6%)	8 (10.3%)	7 (11.1%)	.87

Data presented as mean ± standard deviation, median (interquartile range), or number (%).
BP-SES = biodegradable-polymer sirolimus-eluting stent; DP-ZES = durable-polymer zotarolimus-eluting stent; IVUS = intravascular ultrasound; OCT = optical coherence tomography.

Table 2. Procedural and angiographic characteristics per treated lesion.

Table 3. Pooled IVUS and OCT quantitative parameters in the total cohort and in stents with diameter ≤3.0 mm.

Variable	Total Cohort			Stent Diameter ≤3.0 mm		
	BP-SES (n = 78)	DP-ZES (n = 63)	*P*-Value	BP-SES (n = 45)	DP-ZES (n = 26)	*P*-Value
Minimal stent area (mm²)						
Median stent area	5.80 (4.40-7.24)	6.35 (4.76-8.31)	.15	4.78 (4.01-5.42)	4.70 (4.30-4.78)	.96
Mean stent area	6.20 ± 2.39	6.90 ± 2.77		4.77 ± 1.22	4.78 ± 1.01	
MSA <5 mm²	28 (35.9%)	17 (27.0%)	.27	27 (60.0%)	16 (61.5%)	.90
Stent expansion (%)						
Based on distal reference	98.09 (81.46-113.25)	93.38 (77.58-113.12)	.30	98.87 (90.64-107.60)	98.49 (78.78-118.67)	.44
Based on distal and proximal reference	81.36 (65.85-93.06)	79.94 (67.31-93.96)	.63	78.91 (63.42-91.32)	80.34 (63.51-90.94)	.78
Stent expansion <90% (of distal reference)	28 (35.9%)	28 (44.4%)	.31	11 (24.4%)	12 (46.2%)	.06

Data presented as mean ± standard deviation, median (interquartile range), or number (%).
BP-SES = biodegradable-polymer sirolimus-eluting stent; DP-ZES = durable-polymer zotarolimus-eluting stent; IVUS = intravascular ultrasound; MSA = minimal stent area; OCT = optical coherence tomography.

Table 3. Pooled IVUS and OCT quantitative parameters in the total cohort and in stents with diameter ≤3.0 mm.

Study population and patient and lesion characteristics. Between July 1, 2018 and October 31, 2019, a total of 1547 patients were enrolled in the Orsiro vs Onyx Registry. Of these, 127 patients (141 vessels) met the inclusion criteria and were included in the present analysis (**Figure 1**).

Patient characteristics are presented in **Table 1**. A total of 94 patients underwent IVUS-guided stenting and 33 patients underwent OCT-guided stenting. In total, 69 patients were treated with the BP-SES and 58 patients were treated with the DP-ZES. There were no significant differences in baseline characteristics between both groups.

Procedural and angiographic characteristics per treated lesion are presented in **Table 2**. A total of 141 treated lesions (78 BP-SES and 63 DP-ZES) were analyzed. No significant differences in angiographic characteristics and procedural strategies were found.

IVUS and OCT measurements. Median MSA was 5.80 mm² (IQR, 4.40-7.24) for BP-SES and 6.35 mm² (IQR, 4.76-8.31) for DP-ZES (*P*=.15) (**Table 3**). In the subgroup of stents with a stent diameter ≤3.0 mm, median MSA was 4.78 mm² (IQR, 4.01-5.42) for BP-SES and 4.70 mm² (IQR, 4.30-4.78) for DP-ZES (*P*=.96). No significant differences in MSA or stent expansion were found between the 2 groups.

No significant differences in IVUS-measured parameters were found between both devices (**Table 4**). IVUS-measured median MSA was 5.86 mm² (IQR, 4.37-7.19) in lesions treated with the BP-SES stent and 5.64 mm² (IQR, 4.70-8.10) in lesions treated with the DP-ZES (*P*=.27). Similarly, all OCT-derived

Variable	BP-SES (n = 41)	DP-ZES (n = 47)	P-Value
MSA (mm²)			.27
Median	5.86 [4.37-7.19]	5.64 [4.73-8.10]	
Mean	6.09 ± 2.32	6.71 ± 2.72	
MSA <5 mm²	22 (56.2%)	19 (51.9%)	.66
Stent expansion (%)			
Based on distal reference only	99.4 [77.5-105.3]	89.3 [75.8-118.3]	.62
Based on distal and proximal reference	78.8 [65.1-93.5]	78.0 [62.6-91.4]	.57
Stent expansion <90% (of distal reference)	25 (61.0%)	24 [51.1%]	.31
Mean plaque burden at stent edge (%)	39.79 ± 8.38	39.10 ± 9.45	.72
Distal edge	39.78 ± 11.81	39.12 ± 13.80	.44
Proximal edge	43.69 ± 11.21	43.08 ± 12.62	.85
Plaque burden at distal or proximal edge >50% (on 3 consecutive analyzed frames)	22 (56.2%)	18 (38.3%)	.81
MLA distal or proximal reference <4.5 mm²	29 (47.1%)	18 (38.3%)	.34
Stent malapposition	16 (26.2%)	21 (44.7%)	.07
Tissue protrusion	5 (8.2%)	4 (8.5%)	.84
Submedial edge dissection (>3 mm)	4 (6.6%)	3 (6.4%)	.99
Hematoma at stent edges	9 (14.8%)	7 (14.9%)	.98

Data presented as mean ± standard deviation, median [interquartile range], or number (%).
BP-SES = biodegradable-polymer sirolimus-eluting stent; DP-ZES = durable-polymer zotarolimus-eluting stent; MSA = minimal stent area; MLA = minimal lumen area.

Table 4. Quantitative and qualitative intravascular ultrasound analysis post PCI per treated lesion.

Variable	BP-SES (n = 17)	DP-ZES (n = 16)	P-Value
MSA (mm²)			.20
Median	5.73 (4.78-7.25)	7.65 (6.48-8.56)	
Mean	6.60 ± 2.66	7.47 ± 2.91	
MSA <5 mm²	6 (35.3%)	2 (12.5%)	.22
Stent expansion			
Based on distal reference	118.15 ± 31.09	101.32 ± 26.87	.11
Based on distal and proximal reference	88.76 ± 22.16	85.05 ± 15.05	.58
Stent expansion <90% (of distal reference)	3 (17.6%)	4 (25.0%)	.69
MLA distal or proximal reference <4.5 mm²	9 (52.9%)	6 (37.5%)	.37
Stent malapposition	8 (47.1%)	11 (68.8%)	.21
Tissue protrusion	13 (76.5%)	12 (75.0%)	>.99
Submedial edge dissection (>3 mm)	2 (11.8%)	0 (0.0%)	.48
Hematoma at stent edges	2 (11.8%)	0 (0.0%)	.48

Data presented as mean ± standard deviation, median (interquartile range), or number (%).
BP-SES = biodegradable-polymer sirolimus-eluting stent; DP-ZES = durable-polymer zotarolimus-eluting stent; MSA = minimal stent area; MLA = minimal lumen area.

Table 5. Quantitative and qualitative optical coherence tomography analysis post PCI per treated lesion.

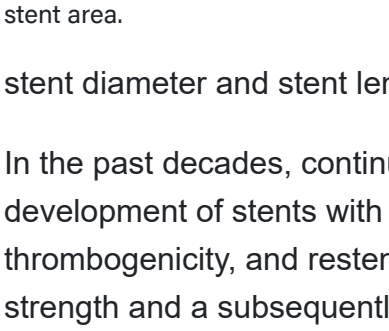

Figure 2. IVUS/OCT-measured MSA of BP-SES vs DP-ZES stratified by vessel (A), presence of calcification (B), stent diameter (C), and IVUS/OCT-measured mean stent diameter by stent diameter (D). No significant differences between DP-ZES and BP-SES were observed. Categories containing observations from 1 stent type only were excluded from the box plots. BP-SES = biodegradable-polymer sirolimus-eluting stent; DP-ZES = durable-polymer zotarolimus-eluting stent; IVUS = intravascular ultrasound; LAD = left anterior descending artery; LCX = left circumflex artery; LM = left main coronary artery; MSA = minimal stent area; OCT = optical coherence tomography; RCA = right coronary artery.

	Univariable		Multivariable	
	β (95% CI)	P-Value	β (95% CI)	P-Value
Gender, male	0.24 (-0.77 to 1.25)	.64		
eGFR (per mL/min/1.73 m²)	0.005 (-0.02 to 0.03)	.65		
Stent type, BP-SES	-0.66 (-1.54 to 0.23)	.15	-0.001 (-0.46 to 0.45)	>.99
Predilation	-0.37 (-1.25 to 0.51)	.41		
Postdilation	0.26 (-0.55 to 1.05)	.52		
Lesion modification	0.37 (-1.30 to 2.04)	.66		
Lesion type B2/C	-0.59 (-1.63 to 0.46)	.25		
2-stent bifurcation	-0.55 (-3.52 to 2.41)	.71		
Provisional stenting bifurcation	0.51 (-0.52 to 1.54)	.32		
Calcification (moderate to severe)	-0.37 (-1.26 to 0.50)	.39		
Thrombus	0.76 (-0.37 to 1.90)	.19	0.02 (-0.56 to 0.60)	.94
Stent diameter (per mm)	4.23 (3.77 to 4.69)	<.001	4.07 (3.63 to 4.51)	<.001
Stent length (per mm)	-0.08 (-0.12 to -0.04)	<.001	-0.05 (-0.08 to -0.03)	<.001
Vessel, LAD	-0.63 (-1.47 to 0.21)	.15	-0.28 (-0.73 to 0.17)	.22

CI = confidence interval; eGFR = estimated glomerular filtration rate; LAD = left anterior descending artery.

Table 6. Univariable and multivariable predictors of minimal stent area.

qualitative and quantitative parameters were comparable between the 2 groups (**Table 5**). In vessels evaluated through OCT, median MSA was 5.73 mm² (IQR, 4.78-7.25) in the BP-SES group and 7.65 mm² (IQR, 6.48-8.56) in the DP-ZES group (*P*=.20). In addition, no significant differences in (pooled) IVUS- and OCT-measured MSA were found when stratified for vessel, calcification, or stent diameter (**Figure 2**). IVUS- and OCT-measured mean stent diameter was similar for both stents across the 2.5-mm, 3.0-mm, 3.5-mm, and 4.0-mm stents.

Analysis of predictors of post-stent MSA. Univariable and multivariable analyses were performed to identify predictors of MSA based on IVUS and OCT (**Table 6**). In the multivariable analysis, stent diameter and stent length were found to be independent predictors of MSA. A larger stent diameter was associated with a larger MSA (β = 4.07 per mm; *P*<.001), while MSA was smaller in longer stents (β = -0.05 per mm; *P*<.001).

Discussion

To the best of our knowledge, this is the first intravascular imaging evaluation of BP-SES vs DP-ZES in a registry of all-comers. The main findings of this study are the following: (1) MSA and predefined procedural performance parameters were comparable between the DP-ZES and BP-SES groups; (2) MSA was comparable between both groups for all stent diameters, vessels, and in calcified lesions; (3) IVUS-measured and OCT-measured mean stent diameter was comparable between DP-ZES and BP-SES groups across all stent diameters; and (4) stent diameter and stent length were independent predictors of post-PCI MSA.

In the past decades, continuous efforts have been made to improve DES designs, leading to the development of stents with thin or ultrathin struts to optimize shear stress profiles, strut thrombogenicity, and restenosis. On the other hand, thinner struts may be associated with lower radial strength and a subsequently higher risk of acute recoil. The latter might lead to stent underexpansion and smaller MSA, which has been correlated with a higher risk of stent failure.[9-14] Standardized bench tests indeed showed a lower radial resistance for the 3.0-mm ultrathin-strut BP-SES compared with the 3.0-mm DP-ZES.[8] By means of the present intravascular imaging evaluation, we therefore aimed to investigate whether the thinner struts and reduced radial resistance of the BP-SES impacted its risk of acute recoil and stent underexpansion.

The ISAR-STEREO trial was the first randomized trial showing a significant reduction in angiographic and clinical restenosis in vessels treated with thin as compared with thicker bare-metal stents.[2] The pivotal observation of ISAR-STEREO was subsequently confirmed in several recent meta-analyses, showing a reduced risk of TLF, target-vessel failure (TVF), or myocardial infarction in patients treated with an ultrathin-strut (BP-)DES as compared with other 2nd-generation DESs.[6,7,19] It should, however, be noted that these meta-analyses were not based on patient-level data, had relatively short follow-up times (mean follow-up, 1-2.8 years), and lacked detailed information on potential heterogeneity in the treatment effect in complex anatomy. Complex lesions such as chronic total occlusions or heavily calcified lesions may require greater radial strength to prevent recoil. As such, the PRISON IV trial failed to demonstrate non-inferiority of the BP-SES in terms of in-segment late lumen loss in chronic total occlusions and showed a higher incidence of binary restenosis as compared with patients treated with a DP-DES.[20] Moreover, in a direct comparison of BP-SES and DP-ZES in chronic total occlusions, the BP-SES was a predictor of high absolute and high relative focal stent recoil.[21] Also, in a pooled analysis of moderate to severely calcified lesions derived from

the BIOFLOW II, IV, and V trials, the hypothesized superiority of BP-SES as compared with DP-DES could not be demonstrated as no statistically significant differences in the 1-year rate of TLF were found.[22]

In the present study, we did not observe a statistically significant difference in MSA or percentage stent expansion between both stent platforms, a finding that appeared consistent among all stent diameters and in all vessels irrespective of the presence of severe calcification. A sensitivity analysis including only stents with a diameter of 3.0 mm and smaller, in which the BP-SES has a strut thickness of 60 μm, led to similar results. In addition, stent type could not be identified as a significant predictor of MSA in multivariable analysis. This finding is consistent with the results of previous randomized trials that have shown no differences in clinical outcomes between the BP-SES and DP-ZES.[4,5] Unfortunately, the sample size of the present study precluded specific subanalyses on the performance of both devices in patients undergoing chronic total occlusion recanalization.

As compared with the DP-ZES, the BP-SES has less radiopacity,[16] potentially leading to a higher risk of geographic miss and bailout stenting. Although we observed a numerically higher incidence of additional stenting after the study imaging with IVUS or OCT following implantation of BP-SES, no significant differences were found between the 2 stent platforms in the presence of residual edge disease, plaque burden (IVUS), or small MLA at the edges (OCT). Finally, we did not observe any significant differences in the presence of stent malapposition, tissue protrusion, submedial edge dissections, or edge hematoma as indicators for procedural performance.

While stent type did not significantly predict MSA, stent length and stent diameter were found to be the sole independent predictors of MSA. In contrast to previous studies,[23-26] moderate to severe calcification did not have a significant effect on MSA. This fairly surprising result can be partly explained by the fact that in this study, the presence of moderate to severe calcification was assessed through angiography, which has a moderate sensitivity in detecting calcium compared with intravascular imaging.[27] Ideally, calcium assessment would therefore be performed on pre-PCI OCT or IVUS, which in this study unfortunately was available for only 43.3% of patients. An intravascular imaging evaluation of BP-SES compared with a DP-DES with pre-PCI imaging-based calcium assessment would be required to more accurately demonstrate the extent to which radial resistance of the ultrathin BP-SES remains sufficient for the treatment of severely calcified lesions.

Study limitations. Through this intracoronary imaging study, we were able to accurately evaluate potential differences in procedural performance between the BP-SES and DP-ZES in a pseudorandomized registry of all-comers to complement the currently available evidence on clinical outcomes based on randomized trials. However, a number of limitations of this study need to be addressed. IVUS or OCT was only performed in a small group of patients and timing of the IVUS or OCT pullback varied, potentially resulting in a limited generalizability of the results. Due to the selective use of intracoronary imaging, the study sample may consist of more complex lesions as compared with the total population.

In the Orsiro vs Onyx registry, stent selection was determined by the day of the month (BP-DES on odd days and DP-DES on even days), which basically precludes selection bias. However, since the use of invasive imaging was at the discretion of the operator, stent type was not randomly assigned within this selection of patients with post-PCI imaging. Nevertheless, we found that all baseline, angiographic, and procedural characteristics were comparable for patients treated with BP-SES and DP-ZES.

As a consequence of the small study sample size, our findings should be regarded as hypothesis generating and may need confirmation in larger randomized controlled trials.

Finally, preprocedural IVUS or OCT pullbacks were not available for every patient. If analyzed through intracoronary imaging, lesion characteristics such as calcification could have been quantified more precisely, enabling more accurate effect estimates and subgroup analyses.

Conclusion

In this population, the ultrathin-strut BP-DES and DP-DES were comparable in terms of procedural performance. No significant differences in MSA were found between lesions treated with the BP-SES and lesions treated with the DP-ZES.

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Affiliations and Disclosures

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