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Stent expansion in calcified coronary chronic total occlusions: The impact of different stent platforms

Paola Scarparo MD  | Thom Schermers BSc | Riccardo Improta MD |
Isabella Kardys MD, PhD | Jeroen Wilschut MD | Joost Daemen MD, PhD  |
Rutger-Jan Nuis MD, PhD | Wijnand K. Den Dekker MD, PhD |
Nicolas M. Van Mieghem MD, PhD  | Roberto Diletti MD, PhD 

Department of Interventional Cardiology,
Thoraxcenter, Erasmus University Medical
Centre, Rotterdam, The Netherlands

Correspondence

Roberto Diletti, MD, PhD, Department of
Interventional Cardiology, Thoraxcenter,
Erasmus University Medical Centre, Dr.
Molewaterplein 40, Office Rg-632k,
Rotterdam 3015 GD, the Netherlands.
Email: r.diletti@erasmusmc.nl

Abstract

Objectives: To evaluate the stent expansion of the durable-polymer Zotarolimus-eluting stent (dp-ZES), the durable-polymer Everolimus-eluting stent (dp-EES), and the bioabsorbable-polymer Sirolimus-eluting stent (bp-SES) in calcified coronary chronic total occlusions (CTO).

Background: The newer generation stents with ultrathin struts might raise concerns regarding reduced radial strength and higher stent recoil (SR) when implanted in calcified CTOs.

Methods: Between January 2017 and June 2021 consecutive patients with CTO undergoing percutaneous coronary intervention with dp-ZES, dp-EES, or bp-SES were evaluated. The analysis was performed in calcific and in noncalcific CTOs. Quantitative coronary angiography analysis was used to assess diameter stenosis (DS), absolute and relative SR, absolute and relative focal SR, absolute and relative balloon deficit (BD), and absolute and relative focal BD. The primary endpoint was DS.

Results: A total of 213 CTOs were evaluated, 115 calcific CTOs (dp-ZES:25, dp-EES:29, bp-SES:61) and 98 non-calcific CTOs (dp-ZES:41, dp-EES:11, bp-SES:46). In calcific CTOs, residual DS was lower in dp-ZES than in dp-EES and bp-SES (-1.00% [$-6.50-6.50$] vs. 13.00% [$7.0-19.00$] vs. 15.00% [$5.00-20.00$]; $p < 0.001$). Dp-ZES was also an independent predictor of residual $DS \leq 10\%$ (OR 11.34, 95% CI 2.6–49.43, $p = 0.001$). Absolute and relative focal SR and absolute and relative SR were similar between dp-ZES, dp-EES, and bp-SES ($p = 0.913$, $p = 0.890$, $p = 0.518$, $p = 0.426$, respectively). In noncalcified CTOs, the residual DS was similar in the three groups ($p = 0.340$). High relative focal SR was less frequent in dp-ZES than in dp-EES and in bp-SES (19.5% vs. 54.5% vs. 37.0%; $p < 0.048$).

Conclusions: The three stent platforms demonstrated an overall low residual DS when implanted in CTOs. However, dp-ZES was associated with the lowest residual DS and identified as independent predictor of residual $DS \leq 10\%$ in patients with

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calcific CTOs. Dp-ZES was associated with a lower incidence of high relative focal stent recoil, in noncalcific CTOs. Balloon deficit might be considered as a surrogate for stent expansion in calcified CTOs.

KEYWORDS

bioabsorbable-polymer sirolimus-eluting stent, calcifications, coronary chronic total occlusions, durable-polymer everolimus-eluting stent, durable-polymer zotarolimus-eluting stent, stent expansion

1 | INTRODUCTION

Coronary calcifications are common in coronary chronic total occlusions (CTO) and moderate or severe calcifications are observed in more than half of the cases.¹ Heavy calcification has been identified as a predictor of technical failure in CTOs percutaneous coronary interventions (PCI) and might lead to suboptimal stent expansion and high residual diameter stenosis, increasing the risk of restenosis and stent thrombosis.²⁻⁴

Suboptimal stent expansion might occur in balloon undilatable lesions in which multiple high pressure inflations with noncompliant balloons fail to fully expand the stent. In CTOs, balloon undilatable lesions are relatively common and are associated with lower technical success and higher complications rate.⁵

Another potential mechanism of suboptimal stent expansion is stent recoil, that is determined by stent intrinsic forces as radial strength and by the compressive forces of the arterial wall.⁶

In calcified CTO lesions, the use of the newer generation stents with ultrathin struts might raise some concerns regarding a misbalance between the increased compressive forces of the arterial wall and the reduced radial strength of the ultrathin struts possibly leading to stent underexpansion, high residual diameter stenosis, and stent recoil.⁷

Although the ultrathin-strut durable-polymer Sirolimus-eluting stent (dp-SES) demonstrated safety and efficacy in all-comers population,⁸⁻¹² in patients with CTOs the bp-SES reported higher rates of in-segment late lumen loss and higher rates of binary restenosis compared with the thin-strut durable-polymer Everolimus-eluting stent (dp-EES) with a higher rate of target lesion revascularization at 3 years.¹³⁻¹⁵ Recently, the stent recoil of the dp-ZES and the bp-SES was evaluated in CTO lesions and the ultra-thin strut bp-SES proved to be a predictor of high absolute and high relative focal stent recoil.⁶ However, the stent expansion of the dp-ZES, the dp-EES, and the bp-SES has not yet been evaluated in the specific setting of calcific CTO lesions.

The purpose of this study is to compare the stent expansion of the thin strut dp-ZES, the thin strut dp-EES and the ultra-thin strut bp-SES in calcific and in noncalcific CTOs.

2 | METHODS

Between January 2017 and June 2021, consecutive patients with CTO undergoing PCI at the Thoraxcenter, Erasmus University Medical Center (EMC), Rotterdam, The Netherlands, were evaluated.

Only patients with CTOs treated with durable-polymer Zotarolimus-eluting stent (dp-ZES), durable-polymer Everolimus-eluting stent (dp-EES) and bioabsorbable-polymer Sirolimus-eluting stent (bp-SES) were included. Patients treated with different types of stent, mixed stent type implantation, with suboptimal angiograms, or unsuccessful procedure were excluded.

The stent selection was determined by the day of the month. Between January 3, 2017 and October 14, 2019 patients received bp-SES on odd days and dp-ZES on even days. Between October 15, 2019 and June 14, 2021 patients received bp-SES on odd days and dp-EES on even days.

The total population was divided in two groups: calcified CTOs and non-calcified CTOs. These two groups were then stratified accordingly to the stent type.

Calcified CTOs were identified by coronary angiography as apparent radiopacities within the vascular wall at the site of the stenosis. In the calcified group only lesions with moderate or severe calcifications were included. Moderate calcifications were defined as presence of radio-opacity evident only in motion during a cardiac cycle before the injection of contrast. Severe calcifications were defined as evident radio-opacity in a freeze frame usually affecting both sides of the vessel lumen.¹⁶

The Medical Ethics Committee (MEC) of the EMC provided approval for the current investigation (MEC-2022-0801) judging the study not subject to the Dutch Medical Research Involving Human Subjects Act (WMO). Therefore, the MEC waived the need for additional informed consent because of the noninterventional character of this observational study using anonymous data collection. All the patients provided consent for the use of anonymous data handling. The investigation conforms to the principles outlined in the Declaration of Helsinki.

2.1 | Resolute Onyx

The durable polymer Zotarolimus-eluting stent (Resolute ONYX; Medtronic Vascular) consists of a cobalt-chromium stent platform with a denser platinum-iridium metal alloy core. The strut thickness is 81 μm in stent diameter ≤ 4.0 mm and 91 μm in stent diameter ≥ 4.5 mm. The strut width is 91 μm in stent diameter ≤ 4.0 mm. The stent platform is shaped in a continuous sinusoid pattern from a single-strand, swaged shape corewire.

Resolute ONYX elutes Zotarolimus ($1.6 \mu\text{g}/\text{mm}^2$) from its circumferential durable Biolinx polymer coating ($5.6 \mu\text{m}$). Resolute Onyx is manufactured in four model designs for small vessels (diameter 2.25–2.50 mm) with 6.5 crowns and two connectors, for medium vessels (diameter 2.75–3.0 mm) with 8.5 crowns and two connectors, for large vessels (diameter 3.25–4.0 mm) with 9.5 crowns and 2.5 connectors, and for extra-large vessels (diameter 4.5–5.0 mm) with 10.5 crowns and 2.5 connectors.¹⁷ The radial resistance is $233 \pm 5 \text{ mN}/\text{mm}$ for stent diameter 3 mm.¹⁸

2.2 | Xience

The durable polymer Everolimus-eluting stent (Xience; Abbott Vascular) consists of a cobalt-chromium alloy platform with $81 \mu\text{m}$ strut thickness coated ($5.3 \mu\text{m}$) with a permanent fluoropolymer (vinylidene-fluoride hexafluoropropylene polymer–PVDF-HFP) releasing Everolimus (average concentration of $100 \mu\text{g}/\text{cm}^2$) a synthetic derivative of Sirolimus. Xience family stents are manufactured in two model designs dedicated for small vessels (diameter 2.25–3.0 mm) with six crowns and three connectors and for large vessels (diameter 3.5–4.0 mm) with nine crowns and three connectors.¹⁷ The radial resistance is $222 \pm 14 \text{ mN}/\text{mm}$ for the 3 mm diameter.¹⁸

2.3 | Orsiro

The biodegradable polymer Sirolimus-eluting stent (ORSIRO; Biotronik) is an ultra-thin strut, of either $60 \mu\text{m}$ for stent diameter up to 3.0 mm or $80 \mu\text{m}$ for stent diameter $>3.0 \text{ mm}$, cobalt-chromium metal alloy platform with an ultra-thin ($4 \mu\text{mol}/\text{L}$) biodegradable BIO-lute active coating composed of poly-L-lactic acid (PLLA) polymer located mainly on the abluminal side ($7.4 \mu\text{m}$ vs. $3.5 \mu\text{m}$ vessel side) which releases Sirolimus (drug density $1.4 \mu\text{g}/\text{mm}^2$). Orsiro stent is manufactured in two model designs for small vessels (diameter 2.25–3.0 mm) with six crowns and three connectors and for large vessels (diameter 3.5–4.0 mm) with six crowns and three connectors.¹⁷ The radial resistance is $167 \pm 14 \text{ mN}/\text{mm}$ for the 3 mm diameter.¹⁸

2.4 | Definitions and angiographic evaluation

CTO was defined as 100% stenosis with Thrombolysis in Myocardial Infarction (TIMI) grade 0 flow for more than 3 months.¹⁹ The duration of the occlusions was estimated based on clinical history and/or prior angiograms.

A successful CTO-PCI was defined as recanalisation with an angiographic residual diameter stenosis less than 30% and a TIMI flow grade 3.²⁰

Complexity of the lesions was assessed by J-CTO score, lesions were considered difficult when J-CTO was greater or equal than 2.²

CTO-PCIs were performed according to the hybrid algorithm. Stent sizing was determined by online QCA and the stents were deployed at minimum nominal pressure and balloon inflation duration of at least 20 s.

Postdilation was performed at the discretion of the operator. The final balloon diameter was considered equal to the stent delivery balloon if the stent was just released or postdilated with the stent balloon. If multiple postdilations were performed, the last at the highest pressure was considered for the angiographic analysis.

Nominal diameter of stents and balloons was obtained from the manufacturer device chart and balloon pressure was collected from the hospital database.

The use of intracoronary imaging was performed at the discretion of the operator.

2.5 | Quantitative coronary angiography analysis (QCA) and derived parameters

QCA analysis was performed using Coronary Angiography Analysis System (CAAS; Pie Medical Imaging). All the angiograms were evaluated by two analysts blinded to the stent type.

Before and after stenting, the same angiographic views with minimal foreshortening of the lesion and minimal overlap with other vessels were selected for the analysis.⁶ For each lesion only the in-stent part was analyzed.

Measurements included lesion length, reference vessel diameter (RDV), minimal luminal diameter (MLD), residual diameter stenosis, and maximum balloon diameter.

Lesion length was measured from the proximal cap to the distal filling either by ipsilateral or contralateral retrograde collateral, during simultaneous bilateral contrast injections.

Maximum balloon diameter was measured at the peak pressure of the largest balloon used for postdilation. If no postdilation balloons were used, the diameter of stent delivery balloon was calculated.

High balloon pressure was defined as a pressure greater or equal than 18 atmosphere (atm).

Stent recoil was assessed from two frames in the same angiographic projection: (1) frame during complete stent expansion at the highest pressure of the balloon (either the stent delivery balloon or the postdilation balloon), (2) frame with contrast injection and acquisition of the stented segment immediately after the deflation of the balloon (Figures 1 and 2).⁶

All the following measurements were analyzed on the stent segment:

Absolute stent recoil was defined as the mean diameter of the last inflated balloon at the peak pressure minus the mean diameter immediately after the stent release or postdilation (Figures 1 and 2).

Relative stent recoil was defined as the ratio between absolute stent recoil and the mean diameter of the last inflated balloon at the peak pressure, and expressed as a percentage (Figures 1 and 2).

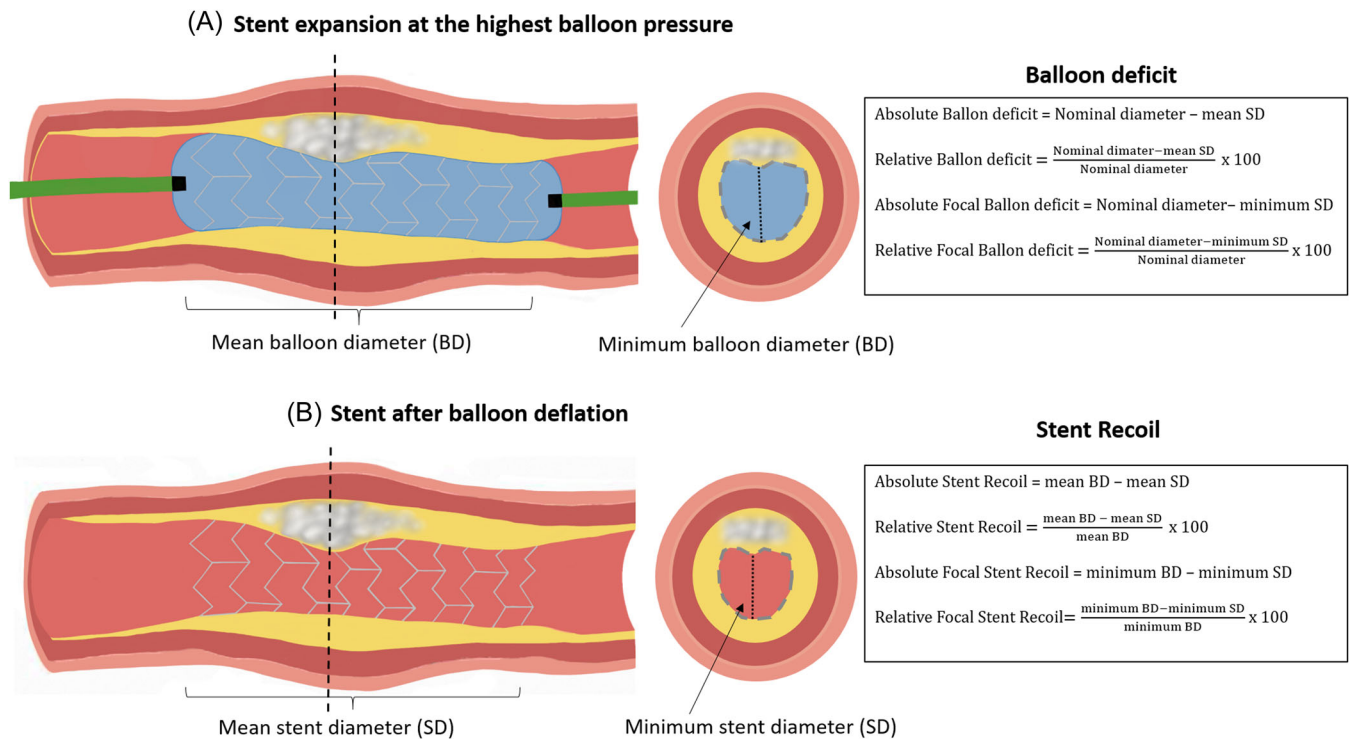


FIGURE 1 Schematic representation of balloon deficit and stent recoil. (A) Complete stent expansion at the highest balloon pressure. (B) Stent immediately after balloon deflation. Nominal diameter of the balloon is obtained from the manufacturer device charts. BD, balloon diameter; SD, stent diameter; SR, stent recoil. [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.wiley.com)]

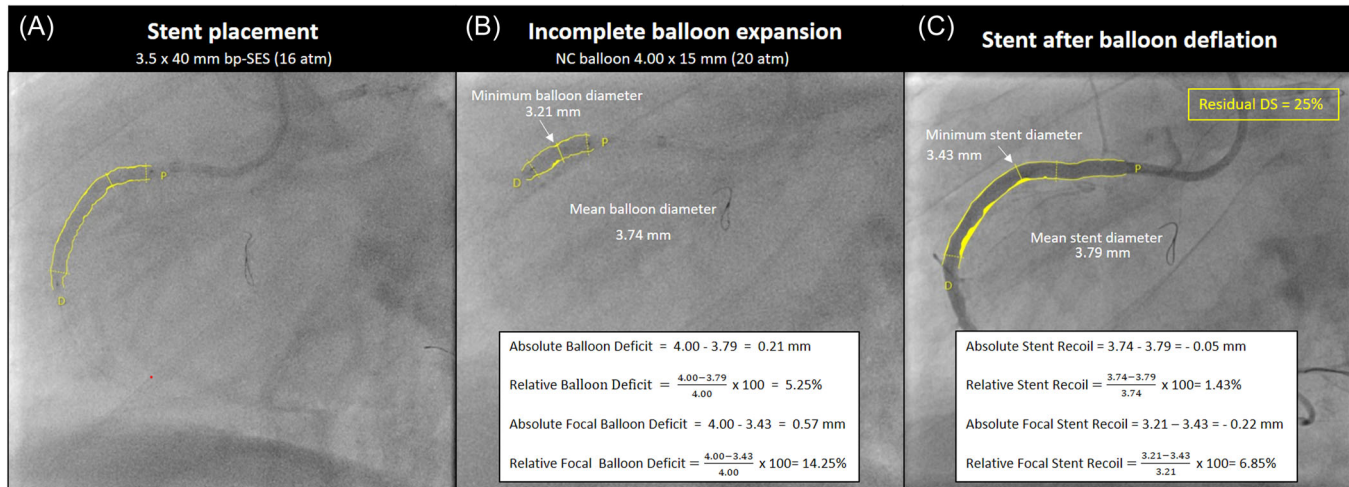


FIGURE 2 (A) Stent placement. (B) Postdilation with a 4.0 × 15 mm noncompliant balloon inflated at the highest pressure (20 atm). (C) Stent immediately after the balloon deflation. In this case a 3.5 × 40 mm bp-SES was implanted, the stent was placed at 16 atmospheres (atm). The analysis was performed between the balloon markers (dotted yellow lines). The white arrows indicate in (B) the minimum diameter of the balloon at the highest pressure and in (C) the minimum diameter of the stent immediately after balloon deflation. The mean diameter of the balloon was 3.74 mm and the mean stent diameter 3.79 mm that correspond to absolute stent recoil -0.05 mm and relative stent recoil 1.43%. The minimal diameter of the balloon is 3.21 mm and the minimum stent diameter 3.43 mm, this corresponds to absolute focal stent recoil -0.22 mm. [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.wiley.com)]

Focal absolute stent recoil was defined as the minimal diameter of the last inflated balloon at the peak pressure minus the minimal diameter immediately after the stent release or postdilation (Figures 1 and 2).

Focal relative stent recoil was defined as the ratio between focal absolute stent recoil and the minimal diameter of the last inflated balloon at the peak pressure, and expressed as a percentage (Figures 1 and 2).

High absolute and high relative focal stent recoil and high absolute and high relative stent recoil were defined as higher than the second tertile of the value distribution.

Absolute balloon deficit was defined as the nominal balloon diameter (either the postdilatation balloon or the stent delivery balloon) minus the mean luminal diameter after stent deployment²¹ (Figures 1 and 2).

Relative balloon deficit was computed by dividing absolute balloon deficit with the nominal balloon diameter (either the postdilatation balloon or the stent delivery balloon) and expressed as a percentage (Figures 1 and 2).

Absolute focal balloon deficit was defined as the nominal balloon diameter (either the postdilatation balloon or the stent delivery balloon) minus the minimum luminal diameter after stent deployment (Figures 1 and 2).

Relative focal final balloon deficit was computed by dividing absolute balloon deficit with the nominal balloon diameter (either the postdilatation balloon or the stent delivery balloon) and expressed as a percentage (Figures 1 and 2).

2.6 | Statistical analysis

Continuous variables are presented as median and interquartile range (IQR, 25th–75th percentile), and were compared with the Kruskal–Wallis test. Categorical variables are presented as counts and percentages, and were compared with the Pearson's χ^2 test.

Univariable logistic regression was performed to assess the predictors of residual diameter stenosis $\leq 10\%$ in calcific CTOs and variables with p values of ≤ 0.10 were considered in a multivariable logistic regression. Results are presented as odds ratios (ORs) with

95% confidence intervals (CIs). Two-tailed $p < 0.05$ were considered statistically significant. Statistical analyses were performed by using IBM SPSS Statistics for Windows, version 25.0 (IBM Corp).

3 | RESULTS

Between January 2017 and June 2021, 213 consecutive patients with CTOs treated with PCI were included in this analysis. Among them 115 had calcific CTOs and 98 had noncalcific CTOs.

3.1 | Calcified lesions

In the calcific CTOs group 25 patients received dp-ZES, 29 dp-EES, and 61 bp-SES. Baseline and procedural characteristics did not differ between the three groups except for the tortuous lesions that were more frequent in the dp-ZES group than in the other two groups (dp-ZES: 36.0%, dp-EES: 3.4%, bp-SES: 11.5%; $p = 0.002$) (Tables 1 and 2).

Residual percentage diameter stenosis was lower in the dp-ZES group than in dp-EES and bp-SES (dp-ZES: $-1.00 [-6.50-6.50]\%$, dp-EES: 13.00 [7.00–19.00]%, bp-SES: 15.00 [5.00–22.00]%; $p < 0.001$) (Table 3) (Figure 3).

Residual diameter stenosis $\leq 10\%$ occurred in 125 (58.7%) lesions. The dp-ZES was an independent predictor of residual diameter stenosis $\leq 10\%$ (OR 11.34, 95% CI 2.6–49.43, $p = 0.001$) (Table 4).

Absolute balloon deficit, relative balloon deficit, absolute focal balloon deficit and relative focal balloon deficit were lower in dp-ZES group than in dp-EES and bp-SES group (Absolute balloon deficit: dp-ZES: 0.26 [0.13–0.43] mm, dp-EES: 0.48 [0.30–0.66] mm, bp-SES:

TABLE 1 Patients baseline characteristics in calcific lesions group.

	Calcific lesions (N = 115)	Dp-ZES (N = 25)	Dp-EES (N = 29)	Bp-SES (N = 61)	p Value
Age, years	69.00 (63.00–76.00)	68.00 (65.00–75.50)	75.00 (62.50–79.50)	67.00 (62.00–73.00)	0.093
Male	101 (87.8%)	22 (88.0%)	22 (75.9%)	57 (93.4%)	0.058
Diabetes mellitus	33 (28.7%)	6 (24.0%)	12 (41.4%)	15 (24.65)	0.217
Hypertension	75 (65.2%)	16 (64.0%)	23 (79.3%)	36 (59.0%)	0.166
Hypercholesterolemia	66 (57.4%)	18 (72.0%)	18 (62.1%)	30 (49.2%)	0.127
Smoking history	14 (12.2%)	2 (8.0%)	3 (10.3%)	9 (14.8%)	0.645
Family history of CAD	40 (34.8%)	11 (44.0%)	7 (24.1%)	22 (36.1%)	0.297
Previous myocardial infarction	42 (36.5%)	7 (28.0%)	12 (41.4%)	23 (37.7%)	0.573
Previous PCI	58 (50.4%)	12 (48.0%)	12 (41.2%)	34 (55.7%)	0.428
Previous CABG	16 (13.9%)	3 (12.0%)	5 (17.2%)	8 (13.1%)	0.828
Previous stroke	13 (11.3%)	2 (8%)	3 (10.3%)	8 (13.1%)	0.779
Peripheral artery vascular disease	10 (8.7%)	2 (8.0%)	2 (6.9%)	6 (9.8%)	0.890

Note: Values are reported as median and interquartile range or absolute numbers and percentage (%).

Abbreviations: bp-SES, bioabsorbable-polymer Sirolimus-eluting stent; CABG, coronary artery bypass graft; CAD, coronary artery disease; dp-EES, durable-polymer Everolimus-eluting stent; dp-ZES, durable-polymer Zotarolimus-eluting stent; PCI, percutaneous coronary intervention.

TABLE 2 Procedural baseline characteristics in calcific lesions group.

	Calcific lesions (N = 115)	Dp-ZES (N = 25)	Dp-EES (N = 29)	Bp-SES (N = 61)	p Value
Multivessel disease	59 (51.3%)	11 (44.0%)	17 (58.6%)	31 (50.8%)	0.560
CTO vessel					
Right coronary artery	63 (54.8%)	12 (48.0%)	17 (58.6%)	34 (55.7%)	0.719
Left coronary artery	40 (34.8%)	11 (44.0%)	9 (31.0%)	20 (32.8%)	0.543
Circumflex coronary artery	10 (8.7%)	2 (8.0%)	3 (10.3%)	5 (8.2%)	0.935
Intermediate branch	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (1.6%)	0.640
Left main	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (1.6%)	0.640
J-CTO score					
0	-	-	-	-	-
1	5 (4.3%)	1 (4.0%)	2 (6.9%)	2 (3.3%)	0.731
2	34 (29.6%)	8 (32.0%)	7 (24.1%)	19 (31.1%)	0.758
3	45 (39.1%)	11 (44.0%)	15 (51.7%)	19 (31.1%)	0.149
4	30 (26.1%)	5 (20.0%)	5 (17.2%)	20 (32.8%)	0.215
5	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (1.6%)	0.640
Blunt proximal cap	40 (34.8%)	11 (44.0%)	11 (37.9%)	18 (29.5%)	0.404
Tortuosity	17 (14.8%)	9 (36.0%)	1 (3.4%)	7 (11.5%)	0.002
Length >20 mm	72 (62.6%)	12 (48.0%)	18 (62.1%)	42 (68.9%)	0.192
Bend >45°	89 (77.4%)	19 (76.0%)	21 (72.4%)	49 (80.3%)	0.691
Second attempt	18 (15.7%)	4 (16.0%)	2 (6.9%)	12 (19.7%)	0.296
Recanalization technique					
Antegrade wire escalation	61 (53.0%)	17 (68.0%)	15 (51.7%)	29 (47.5%)	0.222
Retrograde wire escalation	24 (20.9%)	4 (16.0%)	6 (20.7%)	14 (23.0%)	0.771
Antegrade dissection re-entry	12 (10.4%)	1 (4.0%)	4 (13.8%)	7 (11.5%)	0.466
Retrograde dissection re-entry	14 (12.2%)	3 (12.0%)	2 (6.9%)	9 (14.8%)	0.567
Reverse CART	4 (3.5%)	0 (0.0%)	2 (6.9%)	2 (3.3%)	0.383
Contrast (mL) ^a	200.00 (145.00–250.00)	200.00 (150.00–237.50)	175.00 (142.50–247.50)	200.00 (135.00–262.50)	0.663
Total area dose (cGy/cm ²) ^b	6507.66 (3693.36–10573.41)	5465.44 (4494.26–7573.26)	7136.93 (3147.86–11084.09)	6632.93 (3712.72–11915.83)	0.521
Fluoroscopy time (min) ^b	41.00 (23.08–62.17)	33.22 (16.70–49.00)	41.83 (20.14–53.35)	42.01 (26.59–76.33)	0.103
Number of stents	3.00 (2.00–3.00)	2.00 (2.00–3.00)	2.00 (1.50–3.00)	3.00 (2.00–3.00)	0.064
Stent Length (mm)	38.00 (30.00–40.00)	34.00 (28.00–38.00)	38.00 (30.50–48.00)	40.00 (30.00–40.00)	0.042
Stent diameter (mm)	3.00 (3.00–3.50)	3.00 (2.75–3.50)	3.50 (3.00–3.50)	3.00 (2.75–3.50)	0.478
Postdilation	79 (68.7%)	22 (88.0%)	18 (62.1%)	39 (63.9%)	0.062
Maximum balloon size, mm	3.50 (3.00–3.50)	3.50 (3.00–3.50)	3.50 (3.00–3.50)	3.50 (3.00–3.50)	0.468
Balloon pressure, atm ^c	18.00 (16.00–20.00)	16 (14.50–19.50)	18.00 (16.00–20.00)	18.00 (16.00–20.00)	0.284
High balloon pressure (≥18 atm) ^c	46 (55.4%)	10 (41.7%)	10 (55.6%)	26 (63.4%)	0.235
Complications					
Perforation	4 (3.5%)	1 (4.0%)	0 (0.0%)	3 (4.9%)	0.486
Acute thrombosis	1 (0.9%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0.163

TABLE 2 (Continued)

	Calcific lesions (N = 115)	Dp-ZES (N = 25)	Dp-EES (N = 29)	Bp-SES (N = 61)	p Value
Pericardiocentesis	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (1.6%)	0.640
Donor artery dissection	-	-	-	-	-
Distal dissection	3 (2.6%)	0 (0.0%)	1 (3.4%)	2 (3.3%)	0.651
Distal embolization	-	-	-	-	-

Note: Data are reported as median and interquartile range. Bold value is statistically significant.

Abbreviations: bp-SES, bioabsorbable-polymer Sirolimus-eluting stent; CART, controlled antegrade retrograde tracking; CTO, chronic total occlusion; dp-EES, durable-polymer Everolimus-eluting stent; dp-ZES, durable-polymer Zotarolimus-eluting stent; NC noncompliant; RVD, reference vessel diameter.

^aContrast volume was available in 97 (94.35%) patients.

^bTotal area dose (cGy/cm²) and fluoroscopy time (min) were available in 113 (98.26%) patients.

^cBalloon pressure and high balloon pressure were available in 83 (72.17%) lesions.

TABLE 3 QCA analysis and derived measurements in calcific lesions group.

	Calcific lesions (N = 115)	Dp-ZES (N = 25)	Dp-EES (N = 29)	Bp-SES (N = 61)	p Value
Lesion length, mm	26.79 (16.05–38.73)	18.89 (12.21–35.29)	25.56 (17.44–40.70)	28.17 (17.80–40.36)	0.139
Lesion length ≥20 mm	74 (64.3%)	12 (48.0%)	19 (65.5%)	43 (70.5%)	0.140
Minimum balloon diameter at highest pressure, mm	2.69 (2.41–2.97)	2.74 (2.35–3.08)	2.75 (2.57–3.00)	2.65 (2.35–2.96)	0.432
Mean balloon diameter at highest pressure, mm	3.12 (2.76–3.42)	3.26 (2.74–3.44)	3.11 (2.85–3.36)	3.08 (2.69–3.43)	0.771
Minimum stent diameter after balloon deflation, mm	2.43 (2.13–2.74)	2.54 (2.17–2.88)	2.43 (2.17–2.73)	2.36 (2.06–2.74)	0.386
Mean stent diameter after balloon deflation, mm	2.92 (2.64–3.24)	2.98 (2.71–3.31)	2.87 (2.65–3.24)	2.92 (2.59–3.19)	0.545
Preprocedure reference vessel diameter, mm ^a	1.90 (1.56–2.21)	2.13 (1.76–2.38)	1.84 (1.49–2.21)	1.81 (1.54–2.16)	0.243
Residual diameter stenosis, %	11.00 (1.00–19.00)	−1.00 (−6.50–6.50)	13.00 (7.00–19.00)	15.00 (5.00–22.00)	<0.001
Absolute balloon deficit, mm	0.39 (0.23–0.63)	0.26 (0.13–0.43)	0.48 (0.30–0.66)	0.45 (0.26–0.69)	0.003
Relative balloon deficit, %	12.00 (7.43–18.00)	7.71 (4.60–11.00)	14.50 (8.43–18.79)	13.14 (9.03–18.93)	0.002
Absolute focal balloon deficit, mm	0.86 (0.66–1.17)	0.66 (0.54–0.92)	0.96 (0.75–1.22)	0.95 (0.74–1.26)	0.001
Relative focal balloon deficit, %	26.00 (21.20–33.14)	21.67 (16.57–25.17)	27.71 (22.31–34.18)	29.25 (21.86–35.67)	<0.001
Absolute stent recoil, mm	0.15 (0.02–0.29)	0.10 (0.06–0.27)	0.17 (−0.04–0.28)	0.15 (0.02–0.32)	0.913
Relative stent recoil, %	5.01 (0.87–9.21)	4.26 (1.79–8.41)	5.59 (−1.26–8.89)	4.75 (0.77–9.79)	0.890
Absolute focal stent recoil, mm	0.22 (0.06–0.40)	0.14 (0.04–0.30)	0.29 (0.04–0.49)	0.24 (0.07–0.41)	0.518
Relative focal stent recoil, %	8.22 (2.39–14.29)	5.74 (1.70–10.93)	10.28 (1.79–16.64)	9.15 (2.24–14.17)	0.426
High absolute focal stent recoil, %	39 (33.9%)	5 (20.0%)	13 (44.8%)	21 (34.4%)	0.157
High relative focal stent recoil, %	40 (34.8%)	5 (20.0%)	13 (44.8%)	22 (36.1%)	0.154
High absolute stent recoil, %	39 (33.9%)	7 (28.0%)	11 (37.9%)	21 (34.4%)	0.739
High relative focal recoil, %	39 (34.2%)	7 (28.0%)	11 (37.9%)	21 (35.0%)	0.732

Note: Continuous variables are reported as median and interquartile range. Bold values are statistically significant.

Abbreviations: bp-SES, bioabsorbable-polymer Sirolimus-eluting stent; dp-EES, durable-polymer Everolimus-eluting stent; dp-ZES, durable-polymer Zotarolimus-eluting stent.

^aPreprocedure reference vessel diameter data were present in 112 (97.39%) patients.

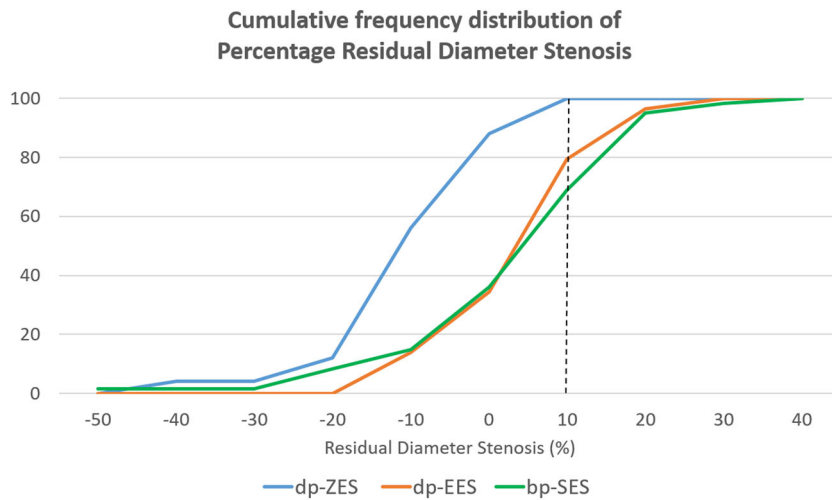


FIGURE 3 Cumulative frequencies distribution for residual diameter stenosis of dp-ZES, dp-EES, and bp-SES. The dotted black line represent the residual diameter stenosis $\geq 10\%$. Residual diameter stenosis greater or equal of 10% occurred less frequently in dp-ZES. bp-SES, bioabsorbable-polymer sirolimus-eluting stent; dp-EES, durable-polymer everolimus-eluting stent; dp-ZES, durable-polymer zotarolimus-eluting stent. [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 4 Predictors of residual diameter stenosis $\leq 10\%$ in calcific CTOs.

	Univariable analysis			Multivariable analysis		
	OR	CI 95%	p Value	OR	CI 95%	p Value
Diabetes	0.77	0.34–1.75	0.537			
Complex CTO (J-CTO ≥ 2)	1.27	0.57–2.82	0.560			
Length ≥ 20 mm	0.76	0.36–1.63	0.485			
RVD	1.02	0.48–2.17	0.951			
Postdilation	2.31	0.97–5.49	0.058	1.71	0.67–4.39	0.265
Tortuosity	3.20	1.05–9.78	0.041	1.57	0.43–5.76	0.500
High balloon pressure (≥ 18 atm)	0.52	0.21–1.26	0.150			
Dp-ZES	13.29	3.69–47.86	<0.001	11.34	2.60–49.43	0.001
Dp-EES	0.50	0.21–1.21	0.123			
Bp-SES	0.39	0.18–0.82	0.014	1.03	0.40–2.65	0.945

Note: Results of the univariable logistic regression analysis investigating 10 variables as potential predictors of residual diameter stenosis $\leq 10\%$ and of the multivariable analysis using the four variables significant at $p \leq 0.10$ in the univariable analysis. Bold value is statistically significant.

Abbreviations: bp-SES, bioabsorbable-polymer Sirolimus-eluting stent; CTO, chronic total occlusion; dp-EES, durable-polymer Everolimus-eluting stent; dp-ZES, durable-polymer Zotarolimus-eluting stent; RVD, reference vessel diameter.

0.45 [0.26–0.69] mm; $p = 0.003$; relative balloon deficit: dp-ZES: 7.71 [4.60–11.00] %, dp-EES: 14.50 [8.43–18.79] %, bp-SES: 13.14 [9.03–18.93] %; $p = 0.002$; absolute focal balloon deficit: dp-ZES: 0.66 [0.54–0.92] mm, dp-EES: 0.96 [0.75–1.22] mm, bp-SES: 0.95 [0.74–1.26] mm; $p = 0.001$; relative focal balloon deficit: dp-ZES: 21.67 [16.57–25.17] %, dp-EES: 27.71 [22.31–34.18] %, bp-SES: 29.25 [21.86–35.67] %; $p < 0.001$ (Table 3).

Absolute and relative focal stent recoil and absolute and relative stent recoil were similar between dp-ZES, dp-EES, and bp-SES ($p = 0.913$, $p = 0.890$, $p = 0.518$, $p = 0.426$, respectively) (Table 3).

High absolute and high relative focal stent recoil and high absolute and high relative stent recoil were similar between the three groups ($p = 0.157$, $p = 0.154$, $p = 0.739$, and $p = 0.732$, respectively) (Table 3).

3.2 | Noncalcified lesions

In the noncalcific CTOs group 41 patients were treated with dp-ZES, 11 with dp-EES and 46 with bp-SES. Baseline and procedural characteristics are displayed in Tables 5 and 6.

In noncalcific CTOs, the residual diameter stenosis was similar in the three groups (dp-ZES: 1.00 [–13.00–10.00] %, dp-EES: 5.00 [–2.00–9.00] %, bp-SES: 5.00 [–4.00–14.00] %; $p = 0.340$) (Table 7). Absolute balloon deficit, relative balloon deficit, absolute focal balloon deficit and relative focal balloon deficit were lower in dp-ZES group than in dp-EES and bp-SES group (Absolute balloon deficit: dp-ZES: 0.29 [0.11–0.45] mm, dp-EES: 0.51 [0.19–0.80] mm, bp-SES: 0.39 [0.23–0.52] mm; $p = 0.032$; relative balloon deficit: dp-ZES: 8.89 [3.37–12.52] %, dp-EES: 17.00 [7.60–20.00] %, bp-SES: 11.57

TABLE 5 Patients baseline characteristics in noncalcific lesions group.

	Noncalcific lesions (N = 98)	Dp-ZES (N = 41)	Dp-EES (N = 11)	Bp-SES (N = 46)	p Value
Age (years)	68.00 (58.00–73.00)	67.00 (54.00–71.00)	65.00 (55.00–69.00)	69.50 (61.75–76.25)	0.131
Male	79 (80.6%)	31 (75.6%)	11 (100%)	37 (80.4%)	0.192
Diabetes mellitus	27 (27.6%)	10 (24.4%)	3 (27.3%)	14 (30.4%)	0.820
Hypertension	62 (63.3%)	25 (61.0%)	5 (45.5%)	32 (69.6%)	0.304
Hypercholesterolemia	54 (55.1%)	24 (58.5%)	7 (63.6%)	23 (50.0%)	0.606
Smoking history	25 (25.5%)	15 (36.6%)	3 (27.3%)	7 (15.2%)	0.073
Family history of CAD	31 (31.6%)	14 (34.1%)	2 (18.2%)	15 (32.6%)	0.589
Previous myocardial infarction	32 (32.7%)	9 (22.0%)	1 (9.1%)	22 (47.8%)	0.008
Previous PCI	42 (42.9%)	17 (41.5%)	4 (36.6%)	21 (45.7%)	0.832
Previous CABG	9 (9.2%)	3 (7.3%)	1 (9.1%)	5 (10.9%)	0.849
Previous stroke	7 (7.1%)	4 (9.8%)	0 (0.0%)	3 (6.5%)	0.523
Peripheral artery vascular disease	6 (6.1%)	1 (2.4%)	1 (9.1%)	4 (8.7%)	0.435

Note: Bold value is statistically significant.

Abbreviations: bp-SES, bioabsorbable-polymer Sirolimus-eluting stent; CABG, coronary artery bypass graft; CAD, coronary artery disease; dp-EES, durable-polymer Everolimus-eluting stent; dp-ZES, durable-polymer Zotarolimus-eluting stent; PCI, percutaneous coronary intervention.

[7.44–15.65] %; $p = 0.016$; absolute focal balloon deficit: dp-ZES: 0.67 [0.49–0.92] mm, dp-EES: 0.98 [0.73–1.38] mm, bp-SES: 0.84 [0.68–1.03] mm; $p = 0.004$; relative focal balloon deficit: dp-ZES: 22.00 [17.23–27.17] %, dp-EES: 29.20 [26.25–39.43] %, bp-SES: 24.86 [21.11–31.84] %; $p = 0.002$) (Table 7).

Absolute and relative focal stent recoil and absolute and relative stent recoil were similar between dp-ZES, dp-EES, and bp-SES ($p = 0.784$, $p = 0.769$, $p = 0.383$, $p = 0.303$, respectively) (Table 7).

High relative focal stent recoil was observed less frequently in the dp-ZES group than in the dp-EES and bp-SES group (19.5% vs. 54.5% vs. 37.0%; $p < 0.048$) (Table 7).

4 | DISCUSSION

This is the first study evaluating the stent expansion of three widely used last generation DES, namely dp-ZES, dp-EES, and bp-SES implanted in patients with calcific and noncalcific CTO lesions. The main findings of the present analysis can be summarized as follow: (1) in the calcific CTOs group, dp-ZES showed a lower residual percentage diameter stenosis compared with dp-EES and bp-SES, and it was also an independent predictor of residual diameter stenosis $\leq 10\%$. (2) Stent recoil and focal stent recoil were overall low and similar in calcific and noncalcific CTOs. In noncalcific CTOs high relative focal stent recoil was observed less frequently in the dp-ZES group than in the dp-EES and bp-SES group. (3) Absolute balloon deficit, relative balloon deficit, absolute focal balloon deficit, and relative focal balloon deficit were lower in dp-ZES group compared with dp-EES and bp-SES groups in calcific and in noncalcific CTOs.

In our analysis, the overall residual percentage diameter stenosis was 11% in calcified CTOs and 4% in noncalcified CTOs, those values might be considered low for CTO-PCI in which the angiographic success is defined as a post-PCI residual diameter stenosis $< 30\%$.²⁰ However, a post-PCI residual diameter stenosis $> 10\%$ has been reported to be associated with a higher binary restenosis rate in patients with CTOs suggesting that a target $< 10\%$ should be pursued to decrease the risks of stent restenosis and thrombosis.²²

Our findings show that the residual percentage diameter stenosis measured by QCA was lower in the dp-ZES compared with other platforms in the calcific CTOs group, further dp-ZES was an independent predictor of residual diameter stenosis $\leq 10\%$.

An improved stent expansion of the dp-ZES could be partially explained by the tridimensional design of the stents and by the difference in stent materials and structure. Dp-ZES has a swaged shape and a larger strut width-to-thickness ratio that might provide a higher radial resistance compared with dp-EES and bp-SES. These three stents consist of a cobalt-chromium alloy platform, but only the dp-ZES has a dense inner core composed of platinum-iridium that might add radial strength to the device.

These characteristics might be the mechanistic substrate at the basis of the high radial resistance showed by dp-ZES in bench tests, translating into an optimal expansion in the clinical scenario.¹⁸

In our study, the stent recoil calculated focally and in the total length of the stent was overall low, similar in the calcific and noncalcific CTOs, and further comparable with data reported for non-CTO lesions underlying the good performance of dp-ZES, dp-EES, and bp-SES also in patients with CTOs.^{21,23}

In noncalcific CTOs, high relative focal stent recoil was observed less frequently in the dp-ZES group (19.5%) than in the bp-SES

TABLE 6 Procedural baseline characteristics in noncalcific lesions group.

	Noncalcific lesions (N = 98)	Dp-ZES (N = 41)	Dp-EES (N = 11)	Bp-SES (N = 46)	p Value
Multivessel disease	58 (59.2%)	22 (53.7%)	7 (63.6%)	29 (63.0%)	0.640
CTO vessel					
Right coronary artery	40 (40.8%)	17 (41.5%)	4 (36.4%)	19 (41.3%)	0.950
Left coronary artery	32 (32.7%)	12 (29.3%)	4 (36.4%)	16 (34.8%)	0.828
Circumflex coronary artery	23 (23.5%)	11 (26.8%)	1 (9.1%)	11 (23.9%)	0.466
Intermediate branch	2 (2.0%)	1 (2.4%)	1 (9.1%)	0 (0.0%)	0.155
Left main	1 (1.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0.018
J-CTO score					
0	5 (5.1%)	2 (4.9%)	0 (0.0%)	3 (6.5%)	0.675
1	30 (30.6%)	14 (34.1%)	3 (27.3%)	13 (28.3%)	0.811
2	36 (36.7%)	15 (36.6%)	4 (36.4%)	17 (37.0%)	0.999
3	25 (25.5%)	10 (24.4%)	4 (36.4%)	11 (23.9%)	0.680
4	2 (2.0%)	0 (0.0%)	0 (0.0%)	2 (4.3%)	0.315
5	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
Blunt proximal cap	51 (52.0%)	22 (53.7%)	7 (63.6%)	22 (47.8%)	0.618
Tortuosity	13 (13.3%)	6 (14.6%)	0 (0.0%)	7 (15.2%)	0.386
Length >20 mm	49 (50.0%)	16 (39.0%)	6 (54.5%)	27 (58.7%)	0.177
Bend >45°	66 (67.3%)	27 (65.9%)	7 (63.6%)	32 (69.6%)	0.899
Second attempt	12 (12.2%)	9 (22.0%)	0 (0.0%)	3 (6.5%)	0.038
Recanalization technique					
Antegrade wire escalation	75 (76.5%)	30 (73.2%)	10 (90.9%)	35 (76.1%)	0.466
Retrograde wire escalation	8 (8.2%)	3 (7.3%)	1 (9.1%)	4 (8.7%)	0.966
Antegrade dissection re-entry	8 (8.2%)	6 (14.6%)	0 (0.0%)	2 (4.3%)	0.125
Retrograde dissection re-entry	5 (5.1%)	1 (2.4%)	0 (0.0%)	4 (8.7%)	0.298
Reverse CART	2 (2.0%)	1 (2.4%)	0 (0.0%)	1 (2.2%)	0.876
Contrast (mL) ^a	200.00 (150.00–250.00)	200.00 (172.50–250.00)	180.00 (120.00–210.00)	195.00 (135.00–250.00)	0.320
Total area dose (cGy/cm ²) ^b	6603.71 (3963.94–10104.43)	6631.13 (3373.90–10104.43)	4631.98 (2636.85–8140.12)	6991.84 (4051.77–12138.94)	0.282
Fluoroscopy time (min) ^b	32.58 (22.15–46.66)	29.03 (18.74–44.52)	25.92 (17.05–36.64)	33.58 (24.34–51.66)	0.236
Number of stents	2.00 (2.00–3.00)	2.00 (2.00–3.00)	2.00 (1.00–3.00)	2.00 (1.00–3.00)	0.128
Stent length (mm)	35 (26–38)	34 (26–38)	28 (23–33)	35 (29–40)	0.015
Stent diameter (mm)	3.00 (2.50–3.50)	3.00 (2.50–3.50)	3.00 (2.50–3.50)	3.00 (2.75–3.50)	0.619
Postdilatation	80 (81.6%)	37 (90.2%)	9 (81.8%)	34 (73.9%)	0.145
Maximum balloon size, mm	3.50 (3.00–3.50)	3.50 (3.00–3.50)	3.50 (3.00–3.50)	3.50 (3.00–3.50)	0.468
Balloon pressure, atm ^c	16 (12–18)	16 (12–18)	16 (14–19)	16 (12–18)	0.525
High balloon pressure (≥18 atm) ^c	30 (33.3%)	14 (34.1%)	4 (44.4%)	12 (30.0%)	0.700
Complications					
Perforation	4 (4.1%)	1 (2.4%)	0 (0.0%)	3 (6.5%)	0.484
Acute thrombosis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-

TABLE 6 (Continued)

	Noncalcific lesions (N = 98)	Dp-ZES (N = 41)	Dp-EES (N = 11)	Bp-SES (N = 46)	p Value
Pericardiocentesis	1 (1.0%)	1 (2.4%)	0 (0.0%)	0 (0.0%)	0.495
Donor artery dissection	1 (1.0%)	1 (2.4%)	0 (0.0%)	0 (0.0%)	0.495
Distal dissection	4 (4.1%)	2 (4.9%)	0 (0.0%)	2 (4.3%)	0.762
Distal embolization	1 (1.0%)	0 (0.0%)	0 (0.0%)	1 (2.2%)	0.565

Note: Continuous variables are reported as median and interquartile range. Bold values are statistically significant.

Abbreviations: bp-SES, bioabsorbable-polymer Sirolimus-eluting stent; CART, controlled antegrade retrograde tracking; CTO, chronic total occlusion; dp-EES, durable-polymer Everolimus-eluting stent; dp-ZES, durable-polymer Zotarolimus-eluting stent; NC noncompliant; RVD, reference vessel diameter.

^aContrast volume was available in 79 (80.61%) patients.

^bTotal area dose (cGy/cm²) and fluoroscopy time (min) were available in 97 (98.98%) patients.

^cBalloon pressure and high balloon pressure were available in 83 (72.17%) lesions.

TABLE 7 QCA analysis and derived measurements in noncalcific lesions group.

	Noncalcific lesions (N = 98)	Dp-ZES (N = 41)	Dp-EES (N = 11)	Bp-SES (N = 46)	p Value
Lesion length, mm	19.95 (10.95–27.38)	15.55 (9.55–26.93)	20.56 (12.08–24.61)	21.00 (12.86–31.05)	0.119
Minimum balloon diameter at highest pressure, mm	2.71 (2.21–3.02)	2.78 (2.18–3.08)	2.74 (2.53–2.99)	2.64 (2.20–3.01)	0.827
Mean balloon diameter at highest pressure, mm	3.05 (2.64–3.40)	3.16 (2.57–3.48)	3.03 (3.03–3.15)	3.05 (2.66–3.42)	0.710
Minimum stent diameter after balloon deflation, mm	2.46 (2.04–2.76)	2.50 (2.06–2.89)	2.04 (1.95–2.56) ²	2.43 (2.12–2.72)	0.250
Mean stent diameter after balloon deflation, mm	2.97 (2.51–3.18)	2.99 (2.48–3.24)	2.69 (2.49–3.20)	2.98 (2.56–3.11)	0.704
Preprocedure reference vessel diameter, mm ^a	2.03 (1.60–2.32)	1.90 (1.60–1.90)	2.04 (1.45–2.63)	2.05 (1.63–2.35)	0.519
Residual diameter stenosis, %	4.00 (–5.00–12.25)	1 (–13.00–10.00)	5 (–2.00–9.00)	5 (–4.00–14.00)	0.340
Absolute balloon deficit, mm	0.34 (0.17–0.51)	0.29 (0.11–0.45)	0.51 (0.19–0.80)	0.39 (0.23–0.52)	0.032
Relative balloon deficit, %	11.00 (5.49–14.79)	8.89 (3.37–12.52)	17.00 (7.60–20.00)	11.57 (7.44–15.65)	0.016
Absolute focal balloon deficit, mm	0.79 (0.56–1.00)	0.67 (0.49–0.92)	0.98 (0.73–1.38)	0.84 (0.68–1.03)	0.004
Relative focal balloon deficit, %	24.75 (19.12–29.38)	22.00 (17.23–27.17)	29.20 (26.25–39.43)	24.86 (21.11–31.84)	0.002
Absolute stent recoil, mm	0.15 (0.02–0.27)	0.14 (0.01–0.31)	0.08 (–0.15–0.51)	0.16 (0.09–0.25)	0.784
Relative stent recoil, %	5.05 (0.83–8.68)	3.97 (0.41–9.09)	3.35 (–4.92–16.83)	5.50 (2.52–8.27)	0.769
Absolute focal stent recoil, mm	0.23 (0.06–0.39)	0.18 (0.06–0.32)	0.47 (–0.14–0.82)	0.27 (0.08–0.39)	0.383
Relative focal stent recoil, %	8.45 (1.97–14.50)	6.56 (1.91–11.42)	15.51 (–5.22–30.04)	9.78 (3.28–14.77)	0.303
High absolute focal stent recoil, %	32 (32.7%)	9 (22.0%)	6 (54.5%)	17 (37.0%)	0.085
High relative focal stent recoil, %	31 (31.6%)	8 (19.5%)	6 (54.5%)	17 (37.0%)	0.048
High absolute stent recoil, %	33 (33.7%)	15 (36.6%)	4 (36.4%)	14 (30.4%)	0.816
High relative stent recoil, %	32 (32.7%)	13 (31.7%)	4 (36.4%)	15 (32.6%)	0.958

Note: Continuous variables are reported as median and interquartile range. Bold values are statistically significant.

Abbreviations: bp-SES, bioabsorbable-polymer Sirolimus-eluting stent; dp-EES, durable-polymer Everolimus-eluting stent; dp-ZES, durable-polymer Zotarolimus-eluting stent.

^aPreprocedure reference vessel diameter data were present in 96 (97.96%) patients.

(37.0%) and in the dp-EES group (54.5%). The focal stent recoil might be due to the presence of small eccentric calcifications or calcified noduli. In these cases the stent delivery balloon (or the postdilatation balloon) expands mainly the noncalcified part of the vessel wall while the calcific parts might remain unmodified.²³

On the other hand in heavily calcified undilatable lesions the stent recoil might be underestimated due to the fact that the balloon might fail to fully expand the stent, resulting in reduced observed recoil. This concept is supported by the recently published study by Sato and colleagues demonstrating with intravascular ultrasound (IVUS) that plaque characteristics such as plaque burden and plaque eccentricity index were predictors of bp-SES stent recoil >5% in non-CTOs, while calcifications were not associated with relevant stent recoil.²³

For this reason, in the present study we also evaluated the balloon deficit that measures the difference between the nominal balloon diameter and the luminal diameter after stent deployment, as a surrogate for stent underexpansion. The manufacturers' charts provide the relative compliance of balloons and stent delivery balloons, but they cannot accurately predict the stent dimension achieved during deployment at the site of the lesion, a parameter largely dependent from the vessel compliance.²⁴ Dp-ZES showed an overall lower balloon deficit both in the entire stent segment and focally, suggesting a tendency to achieve a better expansion compared with dp-EES and bp-SES, in both calcific and non-calcific CTOs.

Given our results, in patients with calcified CTO lesions the use of stent platforms with high radial resistance and thin struts as the dp-ZES could be considered to achieve a low final diameter stenosis possibly reducing the risk of in-stent restenosis and stent thrombosis.

4.1 | Study limitations

This is a single center observational study with its inherent limitations of selection bias and missing data. Although in our study the stents platforms were not randomly allocated, stent platform selection was determined in a pseudorandomized way which basically precludes selection bias. The stent selection was determined by daily alternation (bp-SES on odd days and dp-ZES on even days from January 3, 2017 to October 14, 2019 and bp-SES on odd days and bp-EES on even days, from October 15, 2019 to June 14, 2021),

In our analysis calcified lesions might have been underestimated by the angiographic assessment only.²⁵ Coronary angiography has a high sensitivity but a low specificity. However, angiographically visible calcium has been demonstrated a good marker to predict stent underexpansion.²⁶

Finally, the present study did not include intravascular imaging analysis, since it was not available for every patient. Vessel size, stent expansion and calcium assessment could have been quantified more precisely through intracoronary imaging.

5 | CONCLUSIONS

Dp-ZES, dp-EES, and bp-SES demonstrated an overall low residual diameter stenosis and low stent recoil when are implanted in calcific and not calcific CTO lesions. In calcific CTO lesions, dp-ZES was associated with the lowest residual diameter stenosis and identified as independent predictor of residual diameter stenosis $\leq 10\%$, while in non-calcific CTOs, dp-ZES was associated with a lower incidence of high relative focal stent recoil.

CONFLICT OF INTEREST STATEMENT

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Paola Scarparo  <http://orcid.org/0000-0001-6812-3814>

Joost Daemen  <http://orcid.org/0000-0001-9081-5518>

Nicolas M. Van Mieghem  <http://orcid.org/0000-0002-2732-1205>

Roberto Diletti  <http://orcid.org/0000-0002-2344-6705>

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