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ORIGINAL STUDIES

WILEY

Elastic stent recoil in coronary total occlusions: Comparison of durable-polymer zotarolimus eluting stent and ultrathin strut bioabsorbable-polymer sirolimus eluting stent

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Abstract

Objectives: To compare stent recoil (SR) of the thin-strut durable-polymer Zotarolimus-eluting stent (dp-ZES) and the ultrathin-strut bioabsorbable-polymer Sirolimus-eluting stent (bp-SES) in chronic total occlusions (CTOs) and to investigate the predictors of high SR in CTOs.

Background: Newer ultrathin drug eluting stent might be associated with lower radial force and higher elastic recoil due to the thinner strut design, possibly impacting on the rate of in-stent restenosis and thrombosis.

Methods: Between January 2017 and November 2019, consecutive patients with CTOs undergoing percutaneous coronary intervention were evaluated. Only patients treated with dp-ZES or bp-SES were included and stratified accordingly. Quantitative coronary angiography analysis was used to assess absolute SR, relative SR, absolute focal SR, relative focal SR, high absolute, and high relative focal SR.

Results: A total of 128 lesions (67 treated with dp-ZES and 61 with bp-SES) in 123 patients were analyzed. Between bp-SES and dp-ZES no differences were found in absolute SR ($p = .188$), relative SR ($p = .138$), absolute focal SR ($p = .069$), and relative focal SR ($p = .064$). High absolute and high relative focal SR occurred more frequently in bp-SES than in dp-ZES ($p = .004$ and $p = .015$). Bp-SES was a predictor of high absolute focal SR (Odds ratio [OR] 3.29, 95% confidence interval [CI] 1.50–7.22, $p = .003$]. High-pressure postdilation and bp-SES were predictors of high relative focal SR (OR 2.22, 95% CI 1.01–4.86, $p = .047$; OR 2.74, 95% CI 1.24–6.02, $p = .012$, respectively).

Conclusions: Both stents showed an overall low SR. However, ultra-thin strut bp-SES was a predictor of high absolute and high relative focal SR.

Riccardo Improta and Paola Scarparo contributed equally to this article.

KEYWORDS
percutaneous coronary intervention, CTO, quantitative coronary angiography, stent design/structure/coatings, stent, drug eluting

1 | INTRODUCTION

Second generation drug eluting stents (DES) are currently recommended for chronic total occlusion (CTO) interventions as they have superior efficacy and safety compared with the first generation.[1-3]

Recently, thinner strut devices have been developed to reduce the risk of in-stent restenosis and thrombosis, facilitating early strut endothelization and arterial healing.[4-9] Additionally, stents with bioabsorbable-polymer were introduced to overcome the sustained inflammatory response induced by permanent-polymers.

Newer generation stents namely the thin-strut durable-polymer Zotarolimus-eluting stent (dp-ZES) and the ultrathin-strut bioabsorbable-polymer Sirolimus-eluting stent (bp-SES) demonstrated safety and efficacy in all-comers population that included only 3.5% CTOs.[10] Conversely in the PRISON (Primary Stenting of Occluded Native Coronary Arteries) IV Trial, bp-SES showed higher rates of in-segment late lumen loss and higher rates of binary restenosis compared with a thin-strut Everolimus-eluting stent (EES).[11]

CTO lesions are characterized by a higher rate of restenosis and re-interventions compared with standard procedures.[12] The increased risk of restenosis, reocclusion, and reinterventions is often caused by incomplete stent expansion, which is influenced by several factors including extensive calcification, subintimal stenting, vessel resistance, stent dimensions, delivery pressure inflations, and stent recoil (SR).

The stretching of the vessel wall during balloon dilation is followed by an elastic recoil of the vessel immediately after balloon deflation, showing in some cases nearly a 50% loss in acute lumen gain area.[13] Multiple compressive forces dependent on characteristics of the vessel wall such as elasticity, plaque composition, fibrosis, and calcification contribute to the elastic recoil. In this scenario, stent implantation has proved to remarkably reduce the elastic focal recoil compared with balloon angioplasty.[14-17]

However, in heavily calcified and tortuous lesions, the reduction of strut thickness could raise some concerns regarding a loss of radial strength possibly leading to higher SR. SR of the dp-ZES and the bp-SES has not yet been evaluated in the setting of CTOs.

Therefore, our aims were to compare the recoil of thin strut dp-ZES and ultra-thin strut bioabsorbable Sirolimus-eluting stent (bp-SES) in CTO lesions and investigate the potential predictors of high SR in CTOs.

2 | METHODS

Between January 2017 and November 2019, consecutive patients with CTO undergoing PCI at the Thoraxcenter, Erasmus University Medical Center (EMC), Rotterdam, The Netherlands, were evaluated, retrospectively.

Patients with CTOs treated with dp-ZES and bioabsorbable Sirolimus-eluting stent were included. Myocardial viability was assessed before the treatment and the heart team consensus for percutaneous revascularization was obtained for all the patients.

CTO was defined as 100% stenosis with thrombolysis in myocardial infarction (TIMI) grade 0 flow for more than 3 months.[1] The duration of the occlusions was estimated on the clinical history or prior angiograms.

Patients treated with different types of stent, with sub-optimal angiograms, or unsuccessful procedure were excluded. A successful CTO-PCI was defined as the achievement of an angiographic residual stenosis less than 30% and final TIMI flow grade 3.

All the CTO-PCI were performed by a dedicated CTO team with consistent PCI strategies and limited procedure related variabilities.

Procedures were performed using the hybrid algorithm and under heparin 70–100 units/kg to achieve an activated clotting time > 300 s.[1] On daily alternation, patients were treated with thin strut durable polymer Zotarolimus-eluting stent or ultra-thin strut bioresorbable Sirolimus-eluting stent and the study population was stratified accordingly. The stents were deployed at nominal pressure without exceeding the rate burst pressure and successively post-dilated.

The Medical Ethics Committee of the EMC reviewed the study protocol and waived the need for additional informed consent because of the non-interventional character of this observational study using anonymous data collection.

2.1 | Description of the stents

The hybrid coating Sirolimus-eluting stent (ORSIRO, Biotronik, Bülach, Switzerland) is an ultra-thin strut, of either 60 μm for stent diameter up to 3 mm or 80 μm for stent diameter ≥ 3.5 mm, cobalt-chromium metal alloy platform with an ultra-thin (4 μmol/L) biodegradable BIO-lute coating composed of poly-L-lactic acid (PLLA) polymer located mainly on the abluminal side (7.4 μm vs. 3.5 μm vessel side), which releases Sirolimus (drug density 1.4 $\mu g/mm^2$). Orsiro stent is manufactured in two model designs dedicated for small vessels (diameter 2.25–3 mm) with six crowns and three connectors and for large vessels (diameter 3.5–4 mm) with six crowns and three connettors.[18] The radial resistance is 167 ± 14 mN/mm for the 3 mm diameter.[19]

The durable polymer Zotarolimus-eluting stent (Resolute ONYX, Medtronic Vascular, Santa Rosa, CA) consists in a thin strut (81 μm for stent diameter ≤ 4 mm or 91 μm for stent diameter ≥ 4.5 mm) platform of a denser platinum-iridium metal alloy core with increased radiographic visibility, surrounded by outer layer of cobalt-chromium, shaped in a continuous sinusoid pattern from a single-strand, swaged

shape corewire, and elutes Zotarolimus (1.6 μg/mm^2) from its circumferential durable BioLinx polymer coating (5.6 μm). 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.[18] The radial resistance is 233 ± 5 mN/mm for stent diameter 3 mm.[19]

Safety and efficacy of both stents were demonstrated in different types of lesions, included CTOs.[20-27]

2.2 | Angiographic evaluation

Complexity of the lesions was assessed by J-CTO score, lesions were considered difficult when J-CTO was greater or equal than 2.[28] Moderate calcifications were defined as presence of radio-opacity evident only in motion during a cardiac cycle before the injection of contrast and severe calcifications defined as remarkable radio-opacity evident in freeze frame usually affecting both lumen sides.[29]

Post-dilation was at operator's discretion. The final balloon diameter was considered equal to the stent delivery balloon if the stent was just released or post-dilated with the stent balloon. If multiple post-dilations 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 hospital databases.

2.3 | Quantitative coronary angiography analysis and derived parameters

Quantitative coronary angiography (QCA) analysis was performed using Coronary Angiography Analysis System (CAAS, Pie Medical Imaging, Maastricht, The Netherlands). 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. For each lession only the in-stent part was analyzed.

Measurements included lesion length, reference vessel diameter (RDV), minimal luminal diameter (MLD), residual diameter stenosis (DS %), 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 ≥ 18 atmospheres (atm).

SR 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 (Figure 1).

All the following measurements were analyzed on the stent segment:

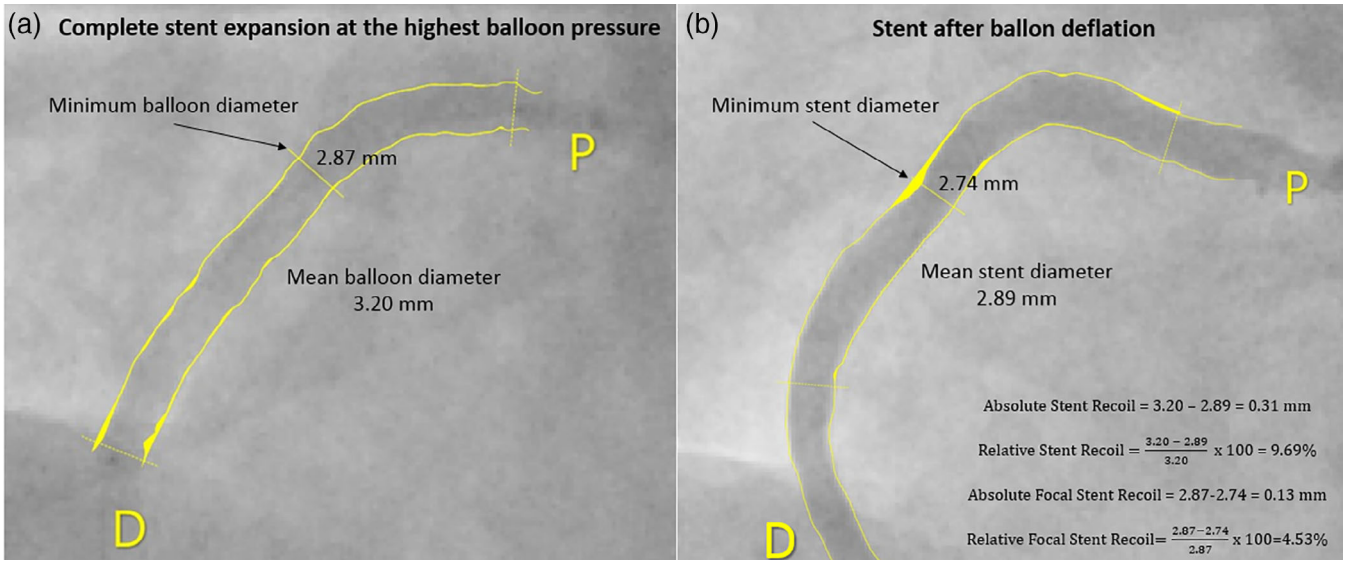

FIGURE 1 (a) Complete expansion of the stent at the highest pressure of the balloon. (b) Stent immediately after the balloon deflation. The analysis is performed between the balloon markers (dotted yellow lines). The black arrows indicate (a) the minimum diameter of the balloon at the highest pressure and (b) the minimum diameter of the stent immediately after balloon deflation. In this case, the mean diameter of the balloon is 3.20 mm and the mean stent diameter 2.89 mm that correspond to absolute stent recoil 0.31 mm and relative stent recoil 9.69%. The minimal diameter of the balloon is 2.87 mm and the minimum stent diameter 2.74 mm, this corresponds to absolute focal stent recoil 0.13 mm and relative stent recoil 4.53% [Color figure can be viewed at wileyonlinelibrary.com]

Absolute SR was defined as the mean diameter of the last inflated balloon at the peak pressure minus the mean diameter immediately after the stent releasement or post-dilation (Figure 2).

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

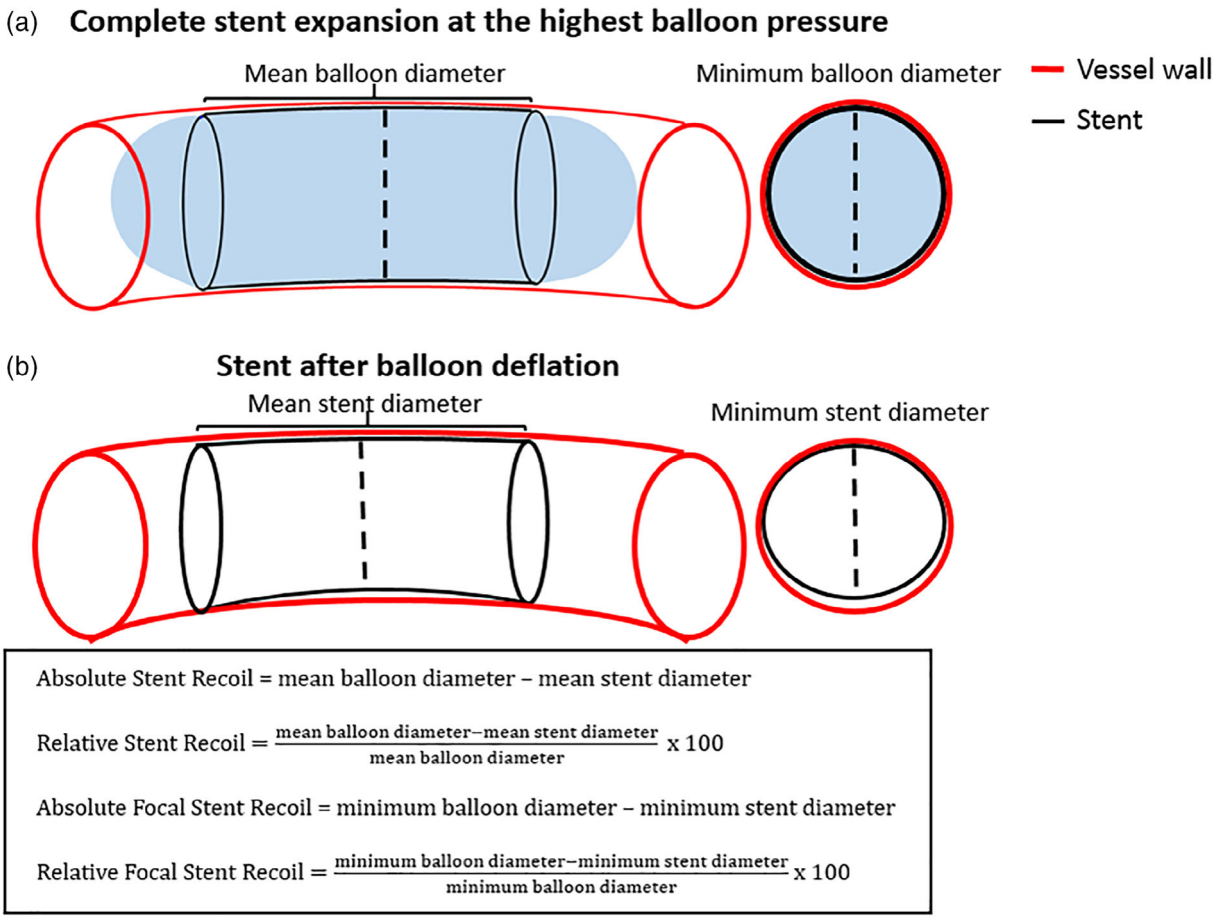

FIGURE 2 Schematic representation of stent recoil. (a) Complete stent expansion at the highest balloon pressure. (b) Stent immediately after balloon deflation [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 1 Patients baseline characteristics

	Total (N = 123)	dp-ZES (N = 58)	bP-SES (N = 65)	*p* value
Age (years)	63.85 ± 9.71	65.17 ± 9.20	62.66 ± 10.06	.515
Male	101 (82.1%)	52 (80.0%)	49 (84.5%)	.517
Diabetes	43 (35.0%)	20 (30.8%)	23 (39.7%)	.302
Hypertension	81 (65.9%)	44 (67.7%)	37 (63.8%)	.649
Hypercholesterolemia	83 (67.5%)	42 (64.%)	41 (70.7%)	.473
Smoking history	30 (24.4%)	15 (23.1%)	15 (25.9%)	.720
Family history of CAD	54 (43.9%)	30 (46.2%)	24 (41.4%)	.594
Previous myocardial infarction	51 (41.5%)	23 (35.4%)	28 (48.3%)	.147
Previous PCI	66 (53.7%)	32 (49.2%)	34 (58.6%)	.297
Previous CABG	14 (11.4%)	5 (7.7%)	9 (15.5%)	.173
Previous stroke	4 (3.3%)	2 (3.1%)	2 (3.4%)	1
Peripheral artery vascular disease	4 (3.3%)	1 (1.5%)	3 (5.2%)	.342

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

TABLE 2 Procedural baseline characteristics per treated lesion

	Total (N = 128)	dp-ZES (N = 67)	bp-SES (N = 61)	*p* value
CTO vessel				.371
Right coronary artery	61 (47.7%)	28 (41.8%)	33 (54.1%)	
Left coronary artery	44 (34.4%)	24 (35.8%)	20 (32.8%)	
Circumflex coronary artery	22 (17.2%)	14 (20.9%)	8 (13.1%)	
Intermediate branch	1 (0.8%)	1 (1.5%)	0 (0%)	
J-CTO score				.591
0	16 (12.5%)	9 (13.4%)	7 (11.5%)	
1	36 (28.1%)	20 (29.9%)	16 (26.2%)	
2	38 (29.7%)	21 (31.3%)	17 (27.9%)	
3	25 (19.5%)	13 (19.4%)	12 (19.7%)	
4	13 (10.2%)	4 (6.0%)	9 (14.8%)	
Blunt proximal cap	72 (56.3%)	39 (58.2%)	33 (54.1%)	.764
Calcification	46 (35.9%)	21 (31.3%)	25 (41.0%)	.256
Moderate	14 (10.9%)	9 (13.4%)	5 (8.2%)	.129
Severe	32 (25.0%)	12 (17.9%)	20 (32.8%)	
Tortuosity	31 (24.2%)	16 (23.9%)	16 (24.6%)	.925
Second attempt	22 (17.2%)	12 (17.9%)	10 (16.4%)	.820
Collateral filling				.660
Retrograde	79 (61.7%)	38 (56.7%)	41 (67.2%)	
Bridging	19 (14.8%)	11 (16.4%)	8 (13.1%)	
Both	14 (10.9%)	8 (11.9%)	6 (9.8%)	
None	16 (12.5%)	10 (14.9%)	6 (9.8%)	
Recanalization technique				.244
Antegrade wire escalation	85 (66.4%)	48 (71.6%)	37 (60.7%)	
Retrograde wire escalation	17 (13.3%)	7 (10.4%)	10 (16.4%)	
Antegrade dissection re-entry	11 (8.6%)	7 (10.4%)	4 (6.6%)	
Reverse CART	15 (11.7%)	5 (7.5%)	10 (16.4%)	
Number of stents	2 (2–3)	2 (2–3)	2 (2–3)	.321
Stent length (mm)	35 (30–38)	34 (26–38)	35 (30–40)	.003
Stent diameter (mm)	3 (2.75–3.5)	3 (2.5–3.5)	3 (2.88–3.5)	.501
Post-dilation NC balloon	94 (73.4%)	50 (74.6%)	44 (72.1%)	.842
Maximum balloon size, mm	3.5 (3–3.5)	3 (2.75–3.5)	3.5 (3–3.5)	.308
Balloon pressure, atm[a]	16.0 (14.0–18.0)	16.0 (12.75–18.0)	16 (16–20)	.055
High-balloon pressure (≥18 atm)[a]	52 (42.3%)	25 (37.9%)	27 (47.4%)	.288
Complications				
Perforation	6 (4.7%)	2 (3.0%)	4 (6.6%)	.423
Acute thrombosis	1 (0.8%)	1 (1.5%)	0 (0%)	1
Pericardiocentesis	1 (0.8%)	1 (1.5%)	0 (0%)	1
Proximal dissection	2 (1.6%)	1 (1.5%)	1 (1.6%)	1
Distal dissection	5 (3.9%)	2 (3.0%)	3 (4.9%)	.669
Distal embolization	1 (0.8%)	0 (0%)	1 (1.6%)	.477

Note: Data are reported as median and interquartile range. Bold values denote statistical significance at the $p < .05$ level.

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

[a]Balloon pressure and high-balloon pressure were available in 123 lesions.

TABLE 3 QCA analysis and derived measurements

	Total (N = 128)	dp-ZES (N = 67)	bp-SES (N = 61)	*p* value
Lesion length, mm	20.37 (11.43–32.59)	16.62 (9.67–27.24)	25.95 (15.16–36.04)	.002
Lesion length ≥ 20 mm	66 (51.6%)	28 (41.8%)	38 (62.3%)	.020
Minimum balloon diameter at highest pressure, mm	2.67 (2.27–3.02)	2.71 (2.23–3.04)	2.63 (2.28–3.01)	.644
Mean balloon diameter at highest pressure, mm	3.11 (2.74–3.45)	3.16 (2.65–3.45)	3.10 (2.79–3.46)	.937
Minimum stent diameter after balloon deflation, mm	2.47 (2.14–2.76)	2.54 (2.13–2.86)	2.45 (2.14–2.73)	.180
Mean stent diameter after balloon deflation, mm	2.99 (2.62–2.76)	2.99 (2.60–3.26)	2.96 (2.62–3.12)	.370
Pre-procedure reference vessel diameter, mm	2.08 (1.70–2.31)	2.09 (1.67–2.29)	2.08 (1.73–2.35)	.654
Residual diameter stenosis, %	4.00 (−5.00–14.00)	−1.00 (−7.00–10.00)	9.00 (−2.50–16.00)	.001
Absolute balloon deficit, mm	0.32 (0.17–0.46)	0.25 (0.11–0.43)	0.38 (0.25–0.49)	.001
Relative balloon deficit, %	10.00 (5.30–13.14)	7.71 (3.60–12.00)	11.71(8.37–14.33)	<.001
Absolute focal balloon deficit, mm	0.76 (0.55–0.96)	0.66 (0.47–0.89)	0.83 (0.72–1.06)	<.001
Relative focal balloon deficit, %	23.43 (18.30–28.31)	21.67 (16.57–26.67)	24.86 (21.29–31.55)	<.001
Absolute stent recoil, mm	0.14 (0.06–0.28)	0.13 (0.05–0.27)	0.15 (0.09–0.29)	.188
Relative stent recoil, %	4.32 (2.28–8.85)	3.93 (1.40–8.00)	4.55 (2.85–9.57)	.138
Absolute focal stent recoil, mm	0.22 (0.05–0.36)	0.15 (0.04–0.29)	0.26 (0.07–0.39)	.069
Relative focal stent recoil, %	7.17 (1.94–13.32)	6.41 (1.69–11.01)	9.92 (2.17–14.51)	.064
High absolute focal stent recoil, mm	42 (32.8%)	14 (20.9%)	28 (45.9%)	.004
High relative focal stent recoil, %	43 (33.6%)	16 (23.9%)	27 (44.3%)	.015

Note: Data are reported as median and interquartile range.
Abbreviations: bp-SES, bioabsorbable-polymer Sirolimus-eluting stent; dp-ZES, durable-polymer Zotarolimus-eluting stent.

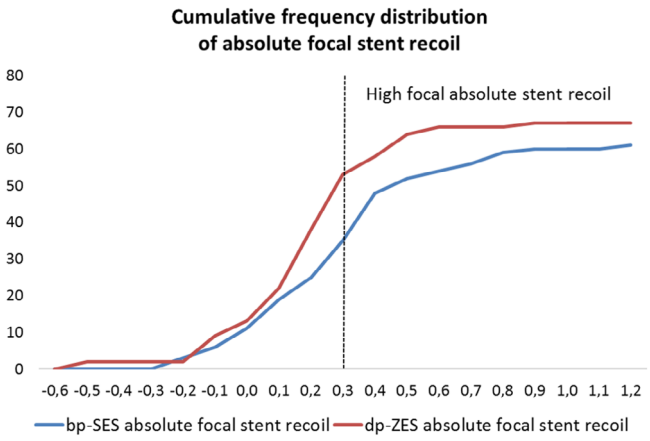

FIGURE 3 Cumulative frequencies distribution for absolute focal stent recoil of bp-SES and dp-ZES. The dotted black line represents the high absolute focal stent recoil ≥0.3. High absolute focal stent recoil occurred more frequently in bp-SES than in dp-ZES (45.9% vs. 20.9%, $p = .004$). bp-SES, bioabsorbable-polymer Sirolimus-eluting stent; dp-ZES, durable-polymer Zotarolimus-eluting stent [Color figure can be viewed at wileyonlinelibrary.com]

Focal absolute SR was defined as the minimal diameter of the last inflated balloon at the peak pressure minus the minimal diameter immediately after the stent releasement or post-dilation (Figure 2).

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

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

Absolute balloon deficit was defined as the nominal balloon diameter (either the postdilation balloon or the stent delivery balloon) minus the mean luminal diameter after stent deployment.[30]

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

Absolute focal balloon deficit was defined as the nominal balloon diameter (either the postdilation balloon or the stent delivery balloon) minus the minimum luminal diameter after stent deployment.

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

2.4 | Statistical analysis

Continuous variables presented as media and standard deviation or as median and interquartile range (IQC 25th–75th) were compared with T test or Mann–Whitney *U* test as appropriate. Categorical variables presented as counts and percentages were compared with Pearson chi-square test or Fisher exact test, as appropriate. The univariate analysis was performed using the Cox proportional hazards regression, with all the following variables: diabetes mellitus, complex CTOs (JCTO≥2), lesion length greater or equal than 20 mm, presence of

calcifications, tortuosity, high-balloon pressure greater or equal than 18 atm and bp-SES. For multivariate analysis, variables with p values < .10 were entered into the multivariate logistic regression.

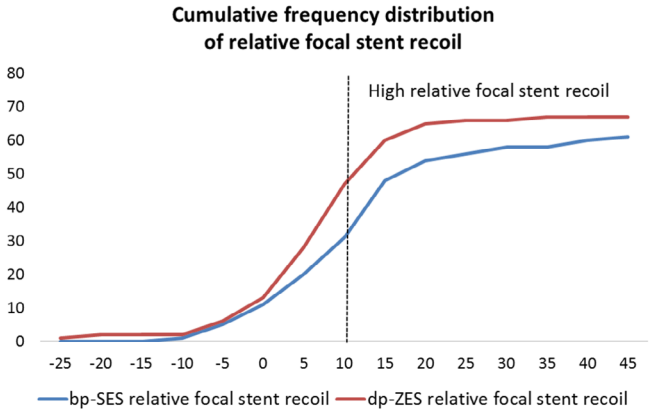

FIGURE 4 Cumulative frequencies distribution for relative focal stent recoil of bp-SES and dp-ZES. The dotted black line represents the high relative focal stent recoil ≥11%. High relative focal stent recoil occurred more frequently in bp-SES than in dp-ZES (44.3% vs. 23.9%; $p = .015$). bp-SES, bioabsorbable-polymer Sirolimus-eluting stent; dp-ZES, durable-polymer Zotarolimus-eluting stent [Color figure can be viewed at wileyonlinelibrary.com]

All statistical tests were considered significant with a two-tailed p-value <.05 and 95% confidence intervals (CI) were presented for all odds ratio (OR). Statistical analyses were performed by using IBM SPSS Statistics for Windows, version 25.0 (IBM Corp., Armonk, NY).

3 | RESULTS

A total of 123 patients were included in the study and 128 lesions were analyzed, 67 (52.3%) were treated with the dp-ZES and 61 (47.7%) with the bp-SES.

Clinical, angiographic, and procedural characteristics were similar between the groups, except for the stent length that was higher in bp-SES group than in dp-ZES group (35 [30–40] mm vs. 34 [26–38] mm, $p = .003$) (Tables 1 and 2) as result of higher lesion length in patients treated with bp-SES than in patients treated with dp-ZES (25.95 mm [15.16–36.04] vs. 16.62 mm [9.67–27.24], $p = .002$) (Table 3).

The fluoroscopy time was higher in bp-SES group than in dp-ZES group (38.13 [29.1–73.56] min vs. 32.02 [18.17–46.67] min, $p = .004$). High-pressure postdilation, namely balloon pressure greater or equal than 18 atm, showed no significant difference between the two groups (Table 2).

TABLE 4 Predictors of high absolute focal elastic recoil

	Univariate analysis			Multivariate analysis		
	OR	CI 95%	*p* value	OR	CI 95%	*p* value
Diabetes	1.15	0.54–2.47	.722			
Complex CTO (J-CTO≥2)	1.36	0.63–2.91	.430			
Length ≥ 20 mm	1.21	0.58–2.54	.613			
RVD	0.99	0.44–2.21	.977			
Calcifications	0.99	0.46–2.13	.971			
Tortuosity	2.03	0.88–4.67	.096	2.13	0.89–5.08	.089
High balloon pressure (≥18 atm)	1.59	0.74–3.41	.230			
Bioabsorbable polymer SES	3.21	1.48–6.97	.003	3.29	1.50–7.22	.003

Abbreviations: CI, confidence interval; CTO, chronic total occlusion; OR, odds ratio; RDV, reference vessel diameter; SES Sirolimus-eluting stent.

TABLE 5 Predictors of high relative focal elastic recoil

	Univariate analysis			Multivariate analysis		
	OR	CI 95%	*p* value	OR	CI 95%	*p* value
Diabetes	1.26	0.59–1.26	.547			
Complex CTO (J-CTO≥2)	1.44	0.67–3.08	.348			
Length ≥ 20 mm	1.29	0.62–2.70	.494			
RVD	0.90	0.40–1.99	.787			
Calcifications	0.93	0.43–2.01	.860			
Tortuosity	1.61	0.70–3.71	.261			
High-balloon pressure (≥18 atm)	2.34	1.09–5.02	.030	2.22	1.01–4.86	.047
Bioabsorbable polymer SES	2.53	1.19–5.39	.016	2.74	1.24–6.02	.012

Abbreviations: CI, confidence interval; CTO, chronic total occlusion; OR, odds ratio; RDV, reference vessel diameter, SES Sirolimus-eluting stent.

Between bp-SES and dp-ZES no differences were observed in terms of absolute SR (0.15 mm [0.09–0.29] vs. 0.13 mm [0.05–0.27], $p = .188$), relative SR (4.55% [2.85–9.57] vs. 3.93% [1.40–8.00], $p = .138$), absolute focal SR (0.26 mm [0.07–0.39] vs. 0.15 mm [0.04–0.29], $p = .069$) and relative focal SR (9.92% [2.17–14.51] vs. 6.41% [1.69–11.01], $p = .064$) (Table 3).

High absolute focal SR and high relative focal SR occurred more frequently in bp-SES than in dp-ZES (45.9% vs. 20.9%, $p = .004$; 44.3% vs. 23.9%; $p = .015$) (Table 3) (Figures 3 and 4).

To investigate whether stent type or any other clinical and angiographic variables were associated with the occurrence of high absolute focal SR and high relative focal SR, univariate and multivariate analyses were performed using a binary logistic regression model.

The bp-SES was independent predictor of high absolute focal SR (OR 3.29, 95% CI 1.50–7.22, $p = .003$) (Table 4). High-pressure postdilation (≥18 atm) and bp-SES were independent predictors of high relative focal SR (OR 2.22, 95% CI 1.01–4.86, $p = .047$; and OR 2.74, 95% CI 1.24–6.02, $p = .012$, respectively) (Table 5).

Residual DS was significantly higher in bp-SES than in dp-ZES (9% [−2.50 to 9.00] vs. −1% [−7 to 10], $p = .001$) (Table 3).

Patients with bp-SES had higher absolute balloon deficit (0.38 mm [0.25–0.49] vs. 0.25 mm [0.11–0.43], $p = .001$), relative balloon deficit (11.71% [8.37–14.33] vs. 7.71% [3.6–12], $p < .001$), absolute focal balloon deficit (0.83 mm [0.72–1.06] vs. 0.66 mm [0.47–0.89], $p < .001$), and relative focal balloon deficit (24.86% [21.29–31.55] vs. 21.67% [16.57–26.67], $p < .001$) than dp-ZES (Table 3).

4 | DISCUSSION

This is the first study comparing in vivo SR of newer generation ultrathin bp-SES and dp-ZES, specifically in CTOs.

Low overall SR was observed in the two groups when considering it either in the entire stent or when analyzing it focally.

However, in the present study we also evaluated high absolute focal SR and high relative focal SR and we observed them more frequently in lesions treated with bp-SES.

The occurrence of high absolute or relative focal recoil might be associated with the presence of thick eccentric calcifications or highly fibrotic tissue limiting uniform balloon and stent expansion and such effect could be particularly relevant when implanting ultra-thin strut stents.

In the PRISON IV Trial, higher rates of binary-restenosis and in-segment lumen loss occurred in bp-SES compared with EES, and they were caused by focal in-stent restenosis.[11] Moreover, these results were driven by the group of stent with diameter ≤ 3 mm with ultra-thin struts of 60 μm and reduced radial strength.[31]

However, the radial strength of the stent is not only related to the strut thickness, but also to material and three-dimensional mesh structure.[32-34]

The stents evaluated in this study have both a cobalt-chromium alloy platform that provides high resistance to the elastic deformation and tensile strength.[35] However, differences in material and design, namely the dense platinum-iridium core wire in the Resolute Onyx and different numbers of crowns and connectors might have had a non-negligible impact on radial strength and bench-test results demonstrate that Resolute Onyx has higher radial resistance than Orsiro.[19]

In addition, the three-dimensional stent design might be altered in specific conditions, such as overexpansion.

In case of stent overexpansion, Resolute Onyx stent showed a lower increase in struts crown angle deformation compared to Orsiro, providing higher radial strength. Conversely, the Orsiro stent has relatively larger cell opening increasing the risk of plaque prolapse through the cells compared to Onyx stent of the same size.[18,36]

In experimental studies, SR was observed more often in over-expanded stents relative to that detected in stents implanted under nominal pressure.[37]

In the present study, 32% of the stents was expanded beyond nominal size, but none of them was overexpanded by >20% of the nominal size.

High postdilation balloon pressure was associated with high relative focal SR, besides the elastic return of the vessel wall, hypothetically higher balloon pressure postdilation might have been used to achieve optimal expansion in calcific and fibrotic lesions.

In addition, lesions treated with bp-SES had higher final balloon deficit than lesions treated with dp-ZES. Final balloon deficit is an indirect parameter of balloon under-expansion, mainly due to the vessel compliance. The postdilation balloon exerts a force against the stent that depends on the pressure, size of the balloon, and the severity of the lesion. The manufacturers' balloon charts provide a relative balloon compliance, but cannot predict the exact dimension of the balloon achieved in vivo, that depends on the external constrain. In CTOs, the vessel elasticity, fibrosis, and calcifications might severely limit the balloon expansion.

In our study bp-SES showed an overall higher balloon deficit both in the entire stent segment and focally, suggesting a tendency of the ultra-thin struts stent to achieve a reduced expansion compared with dp-ZES.

In conclusion, both stent types showed a low and overall similar SR when implanted in CTO lesion, on the other hand bp-SES were associated with a higher rate of high absolute and relative focal elastic recoil and a larger balloon deficit ultimately translating into an overall higher residual DS.

4.1 | Study limitations

This is a single center, observational, retrospective study with its inherent limitations of selection bias and missing data. Adjustments for differences in baseline and procedural characteristics have been performed; however, such differences might still be source of bias. Lesion characteristics such as eccentricity and plaque composition could not be analyzed by QCA and should have been investigated properly with intravascular ultrasound or optical coherence tomography; calcified lesions might have been

underestimated by the angiographic assessment only. Appropriate stent sizing might be challenging in CTO lesions, the occurrence of stent malapposition might have had an impact on SR assessment.

Treatment strategy including postdilation was per individual operator's discretion.

5 | CONCLUSIONS

Both thin strut dp-ZES and ultra-thin strut bp-SES showed an overall low elastic SR. However, bp-SES was associated with a higher rate of absolute and relative high focal recoil and balloon deficit translating into a larger residual DS.

DATA AVAILABILITY STATEMENT

Data available on request from the authors.

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