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

Riccardo Improta MD | Paola Scarparo MD | Jeroen Wilschut MD | Quinten Wolff BSc | Joost Daemen MD, PhD | Wijnand K Den Dekker MD, PhD | Felix Zijlstra 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, Interventional Cardiology, Thoraxcenter, Erasmus MC, Dr. Molewaterplein 40, 3015 GD Rotterdam, The Netherlands. Email: r.diletti@erasmusmc.nl

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.
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 endothelialization and arterial healing.\(^4\)\(^-\)\(^9\) Additionally, stents with bioabsorbable-polymer were introduced to overcome the sustained inflammatory response induced by permanent-polymer.

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 depend 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.

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.

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 μg/mm²). 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 connectors.\(^18\) The radial resistance is 167 ± 14 mN/mm² for the 3 mm diameter.\(^19\)

The durable polymer Zotarolimus-eluting stent (Resolute ONLYX, 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/mm²) 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 lesion 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 release 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).

**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 (74.5%)      | .517    |
| Diabetes             | 43 (35.0%)      | 20 (30.8%)      | 23 (39.7%)      | .302    |
| Hypertension         | 81 (65.9%)      | 44 (67.7%)      | 37 (57.7%)      | .649    |
| Hypercholesterolemia | 83 (67.5%)      | 42 (64.4%)      | 41 (62.7%)      | .473    |
| Smoking history      | 30 (24.4%)      | 15 (23.1%)      | 15 (25.9%)      | .720    |
| Family history of CAD| 54 (43.9%)      | 30 (46.2%)      | 24 (39.6%)      | .594    |
| Previous myocardial infarction | 51 (41.5%) | 23 (35.4%) | 28 (43.3%) | .147    |
| Previous PCI         | 66 (53.7%)      | 32 (49.2%)      | 34 (50.6%)      | .297    |
| Previous CABG        | 14 (11.4%)      | 5 (7.5%)        | 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.
| CTO vessel                       | Total (N = 128) | dp-ZES (N = 67) | bp-SES (N = 61) | p value |
|---------------------------------|-----------------|----------------|----------------|---------|
| Right coronary artery           | 61 (47.7%)      | 28 (41.8%)     | 33 (54.1%)     | .371    |
| 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                   |                 |                |                |         |
| 0                               | 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       |
| Percardiocentesis               | 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.
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 release 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 minimal 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 mean 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.

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).

### 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 |
| 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 |
| High balloon pressure (≥18 atm) | 1.59 | 0.74–3.41 | .230 |
| Bioabsorbable polymer SES | 3.21       | 1.48–6.97 | .003 |

| Univariate analysis | Multivariate analysis |
|---------------------|----------------------|
| 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 |
| Bioabsorbable polymer SES | 2.53       | 1.19–5.39 | .016 |

### TABLE 5 Predictors of high relative focal elastic recoil

| Univariate analysis | Multivariate analysis |
|---------------------|----------------------|
| 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 |
| Bioabsorbable polymer SES | 2.53       | 1.19–5.39 | .016 |

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 2.22, 95% CI 1.01–4.46, p = .047; and OR 2.74, 95% CI 1.24–6.02, p = .012, respectively) (Table 3). 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. 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.

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

The stents evaluated in this study have both a cobalt-chromium alloy platform that provides high resistance to the elastic deformation and tensile strength. 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.

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.

In experimental studies, SR was observed more often in overexpanded stents relative to that detected in stents implanted under nominal pressure.

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.

REFERENCES

1. Galassi AR, Werner GS, Boukhris M, et al. Percutaneous recanalisation of chronic total occlusions: 2019 consensus document from the EuroCTO Club. EuroIntervention. 2019;15(2):198-208.
2. Moreno R, Garcia E, Teles R, et al. Randomized comparison of sirolimus-eluting and everolimus-eluting coronary stents in the treatment of total coronary occlusions: results from the chronic coronary occlusion treated by everolimus-eluting stent randomized trial. Circ Cardiovasc Interv. 2013;6(1):21-28.
3. Park HJ, Kim HY, Lee JM, et al. Randomized comparison of the efficacy and safety of zotarolimus-eluting stents vs. sirolimus-eluting stents for percutaneous coronary intervention in chronic total occlusion-Catholic Total occlusion study (CATOS) trial. Circ J. 2012;76(4):868-875.
4. Abu Sharar H, Gomes B, Chorianopoulos E, et al. Procedural advantages of a novel coronary stent design with ultra-thin struts and bio-absorbable abluminal polymer coating in an all-comers registry. Postepy Kardiol Interwencyjnej. 2018;14(3):240-246.
5. Briguori C, Sarais C, Pagnotta P, et al. In-stent restenosis in small coronary arteries: impact of strut thickness. J Am Coll Cardiol. 2002;40(3):403-409.
6. Kastrati A, Mehilli J, Dirschinger J, et al. Intracoronary stenting and angiographic results strut thickness effect on restenosis outcome (ISAR-STEREO) trial. Vestn Rentgenol Radiol. 2012;2:112-118.
7. van Bommel RJ, Lemmert ME, van Mieghem NM, van Geuns RJ, van Domburg RT, Daemen J. Occurrence and predictors of acute stent recoil-a comparison between the xience prime cobalt chromium stent and the promus premier platinum chromium stent. Catheter Cardiovasc Interv. 2018;91(3):E21-E28.
8. Ng J, Foin N, Ang HY, et al. Over-expansion capacity and stent design model: an update with contemporary DES platforms. Int J Cardiol. 2016;221:171-179.
9. Bonin M, Guerin P, Olive JM, Jordana F, Huchet F. Standardized bench test evaluation of coronary stents: biomechanical characteristics. Catheter Cardiovasc Interv. 2018;92(7):E465-E470.
10. Hamon M, Niculescu R, Deleanu D, Dorobantu M, Weissman NJ, Waksman R. Clinical and angiographic experience with a third-generation drug-eluting orsiro stent in the treatment of single de novo coronary artery lesions (BIOFLOW-IV): a prospective, first-in-man study. EuroIntervention. 2013;8(9):1006-1011.
11. von Birgelen C, Kok MM, van der Heijden LC, et al. Very thin strut biodegradable polymer everolimus-eluting and sirolimus-eluting stents versus durable polymer zotarolimus-eluting stents in allcomers with coronary artery disease (BIO-RESORT): a three-arm, randomised, non-inferiority trial. Lancet. 2016;388(10060):2607-2617.
12. Pilgrim T, Heg D, Roffi M, et al. Ultrathin strut biodegradable polymer sirolimus-eluting stent versus durable polymer everolimus-eluting stent for percutaneous coronary revascularisation (BIOSCIENCE): a randomised, single-blind, non-inferiority trial. Lancet. 2014;384(9960):2111-2122.
13. Windecker S, Haude M, Neumann FJ, et al. Comparison of a novel biodegradable polymer sirolimus-eluting stent with a durable polymer everolimus-eluting stent: results of the randomized BIOFLOW-II trial. Circ Cardiovasc Interv. 2015;8(2):e001441.
14. Price MJ, Shlomfritz RA, Spriggs DJ, et al. Safety and efficacy of the next generation resolute onyx zotarolimus-eluting stent: primary outcome of the RESOLUTE ONYX core trial. Catheter Cardiovasc Interv. 2018;92(2):253-259.
15. Izqal J, Serruys PW, Silber S, et al. Comparison of zotarolimus- and everolimus-eluting coronary stents: final 5-year report of the RESOLUTE all-comers trial. Circ Cardiovasc Interv. 2015;8(6):e002230.
26. von Birgelen C, van der Heijden LC, Basalus MW, et al. Five-year outcome after implantation of zotarolimus- and everolimus-eluting stents in randomized trial participants and nonenrolled eligible patients: a secondary analysis of a randomized clinical trial. JAMA Cardiol. 2017;2(3):268-276.

27. van der Heijden LC, Kok MM, Lowik MM, et al. Three-year safety and efficacy of treating all-comers with newer-generation resolute integrity or PROMUS element stents in the randomised DUTCH PEERS (TWENTE II) trial. EuroIntervention. 2017;12(17):2128-2131.

28. Morino Y, Abe M, Morimoto T, et al. Predicting successful guidewire crossing through chronic total occlusion of native coronary lesions within 30 minutes: the J-CTO (multicenter CTO registry in Japan) score as a difficulty grading and time assessment tool. JACC Cardiovasc Interv. 2011;4(2):213-221.

29. Madhavan MV, Tarigopula M, Mintz GS, Maehara A, Stone GW, Genereux P. Coronary artery calcification: pathogenesis and prognostic implications. J Am Coll Cardiol. 2014;63(17):1703-1714.

30. Onuma Y, Serruys PW, Gomez J, et al. Comparison of in vivo acute stent recoil between the biodegradable everolimus-eluting coronary scaffolds (revision 1.0 and 1.1) and the metallic everolimus-eluting stent. Catheter Cardiovasc Interv. 2011;78(1):3-12.

31. Zivelonghi C, Teeuwen K, Agostoni P, et al. Impact of ultra-thin struts on restenosis after chronic total occlusion recanalization: insights from the randomized PRISON IV trial. J Interv Cardiol. 2018;31(5):580-587.

32. Ota T, Ishii H, Suni T, et al. Impact of coronary stent designs on acute stent recoil. J Cardiol. 2014;64(3):347-352.

33. Watson T, Webster MWI, Ormiston JA, Ruygrok PN, Stewart JT. Long and short of optimal stent design. Open Heart. 2017;4(2):e000680.

34. Chichareon P, Katagiri Y, Asano T, et al. Mechanical properties and performances of contemporary drug-eluting stent: focus on the metallic backbone. Expert Rev Med Devices. 2019;16(3):211-228.

35. Schmidt W, Lanzer P, Behrens P, Topoleski LD, Schmitz KP. A comparison of the mechanical performance characteristics of seven drug-eluting stent systems. Catheter Cardiovasc Interv. 2009;73(3):350-360.

36. Teeuwen K, Spoormans EM, Bennett J, et al. Optical coherence tomography findings: insights from the “randomised multicentre trial investigating angiographic outcomes of hybrid sirolimus-eluting stents with biodegradable polymer compared with everolimus-eluting stents with durable polymer in chronic total occlusions” (PRISON IV) trial. EuroIntervention. 2017;13(5):e522-e530.

37. Berrocal DH, Gonzalez GE, Fernandez A, et al. Effects of over-expansion on stents’ recoil, symmetry/asymmetry, and neointimal hyperplasia in aortas of hypercholesterolemic rabbits. Cardiovasc Pathol. 2008;17(5):289-296.