

# Real-World Use Of Ultrathin-Strut Biodegradable Polymer-Coated Sirolimus-Eluting Stents In Patients With Coronary Artery Disease: 6-Month Clinical Outcomes

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**Background:** Although a number of drug-eluting stents have been developed with different design, composition, and polymers, the search for an ideal drug-eluting stent is ongoing. The Tetriflex (Sahajanand Medical Technology, Surat, India) is a newer-generation, ultrathin (60 µm) biodegradable polymer-coated sirolimus-eluting stent (SES) designed with a unique long dual Z-link on a cobalt-chromium alloy. The present registry aimed to evaluate the safety and clinical outcomes of the Tetriflex SES at 6-month post-implantation.

**Methods:** This was an investigator-initiated, retrospective, multicenter, single-arm, observational registry conducted at five tertiary-care centers in India. A total of 1,269 consecutive patients with coronary artery disease who underwent implantation of at least one Tetriflex SES between March 2017 and March 2018 were included. The primary outcome was considered a composite of cardiac death, myocardial infarction and target-lesion revascularization (TLR) at 6-month follow-up. Stent thrombosis was evaluated as a safety outcome at 6-month follow-up.

**Results:** The mean age of patients was 54.99±10.80 years. Among 1,515 lesions treated with 1,682 Tetriflex SES, 58.3% were type C lesions. Six-month follow-up was done for 1,245 (98.1%) patients. At 6 months, composite events had occurred in 31 (2.5%) patients, consisting of ten (0.8%) cardiac deaths, 16 (1.3%) myocardial infarctions, and five (0.4%) TLRs. Stent thrombosis was observed in seven (0.56%) cases at 6 months. A subgroup analysis between diabetic and nondiabetic patients did not reveal any statistically significant difference for clinical outcomes at 6-month follow-up.

**Conclusion:** The results of the current registry outline the safety and effectiveness of the Tetriflex SES in real-world patients, as it displayed favorable clinical outcomes at 6-month follow-up, with low incidence of TLR and stent thrombosis.

**Keywords:** biodegradable polymer, drug-eluting stents, sirolimus, ultrathin strut

## Introduction

With the beginning of the 21st century, the era of drug-eluting stents (DESs) was instigated as a novel discovery in the world of interventional cardiology. Favorably, DESs to a certain extent have overcome the complications of bare-metal stents, as they reduce the restenosis rate and need for revascularization.<sup>1-4</sup> However, incidents of restenosis were still noted, in addition to the higher rate of late stent thrombosis with DESs.<sup>5,6</sup> It has been well established that not only patient and lesion characteristics but also stent platform, drugs, polymers, strut thickness, type

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of coating, and stent design play a key role in deciding the safety and effectiveness of coronary stents.<sup>7–10</sup> Therefore, the development of DESs has evolved from durable polymers to biodegradable polymers for controlled drug-release kinetics, from stainless steel to cobalt–chromium (Co-Cr) and a platinum–chromium stent platform, and from thick to ultrathin struts with better stent designs. Although newer-generation DESs with biodegradable polymer coating and ultrathin struts have been developed with different design and composition, the search for an ideal newer-generation biodegradable polymer-coated DES is ongoing.

The Tetriflex (Sahajanand Medical Technology, Surat, India), a latest-generation ultrathin (60 µm) biodegradable polymer-coated sirolimus-eluting stent (SES), uses Co-Cr as the stent platform. The stent was designed with a unique long dual Z-link (LDZ-link) and in-phase struts. The surface of the stent has multilayered conformal coating comprised of hydrophilic and hydrophobic polymers in combination for controlled and sustained release of sirolimus. The clinical performance of the Tetriflex SES has not been published anywhere yet. Therefore, the present registry aimed to evaluate the safety and clinical outcomes of the Tetriflex SES in unselected, real-world patients with coronary artery disease (CAD).

## Methods

### Study Design And Participants

This was an investigator-initiated, retrospective, multi-center, single-arm, observational registry carried out at five tertiary-care centers in India. A total of 1,269 consecutive CAD patients (aged ≥18 years) who underwent implantation of at least one Tetriflex SES between March 2017, and March 2018 were included in this registry. The registry strictly obeyed the principles of good clinical practice and Declaration of Helsinki, and was approved by the Institutional Ethics Committee, Dr Ramesh Cardiac and Multispecialty Hospital (ECR/81/INST/AP/2013/RR/2016). At the time of the index procedure, written informed consent for percutaneous coronary intervention and use of properly anonymized clinical data was obtained from patients or from patient designees.

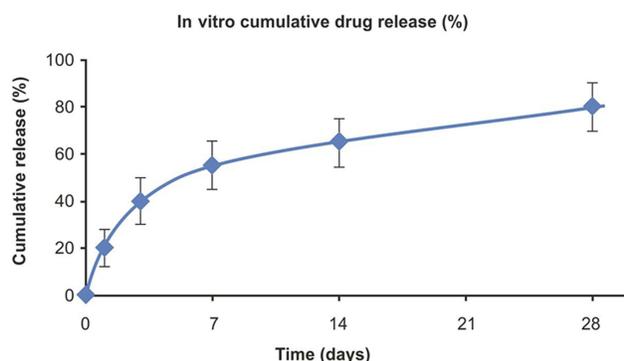
### Description Of Study Stent

The Tetriflex SES (Tetrinium L605) is a latest-generation ultrathin (60 µm) biodegradable polymer-coated, Co-Cr

coronary stent designed with unique LDZ-link and in-phase struts. Detailed characteristics of the Tetriflex SES are given in Table 1. The multilayer conformal coating on surface of the Tetriflex stent contains a blend of sirolimus and biodegradable polymeric matrix comprising a combination of hydrophilic and hydrophobic polymers containing poly-L-lactide, 50/50 poly(D,L-lactide-co-glycolide), and polyvinyl pyrrolidone. These polymers give an elastomeric property to the coating in line with the metal-expansion mechanism and control drug elution from the stent coating. The coating matrix offers good coating adhesion with the stent surface. The multilayer coating technology offers controlled drug release to accommodate arterial drug requirements post-stent implantation. Further, the unique blend of biodegradable polymers in each layer aids in achieving controlled drug release and offers unmatched coating integrity. Figure 1 displays the release profile of drug from the Tetriflex SES. In addition, the drug-free top layer composed of hydrophilic polymers with antioxidants tends to improve product shelf life and protect coating layers during implantation. Scanning

**Table 1** Characteristics Of Tetriflex Drug-Eluting Stent

Characteristic	Tetriflex Stent
Available stent lengths (mm)	8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48
Available stent diameters (mm)	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50
Stent material	L605 Co-Cr alloy
Stent design	Laser cut from seamless tubing in a serpentine pattern
Stent platform	Tetrinium
Stent-strut dimension	Thickness 60 µm
Drug	Sirolimus (1.4 µg/mm <sup>2</sup> )
Polymer type	Biodegradable polymer Combination of hydrophilic and hydrophobic polymers: <ul style="list-style-type: none"> <li>• poly-L-lactide</li> <li>• 50/50 poly(D,L-lactide-co-glycolide)</li> <li>• polyvinyl pyrrolidone</li> </ul>
Drug-release profile	80% sirolimus release in 1 month Remaining releases slowly within 3 months
Average coating thickness	4–6 µm
Guiding catheter	5F-compatible (minimum)

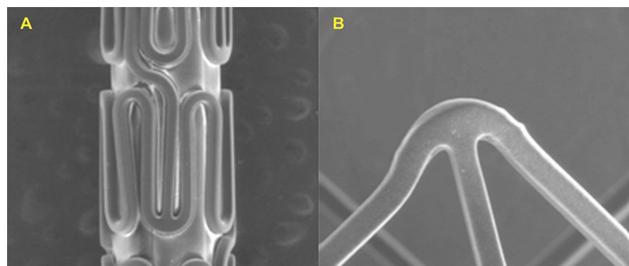


**Figure 1** In vitro sirolimus-release profile of Tetriflex stent.

electron microscopy of the sterile crimped stent and expanded stent are depicted in [Figure 2](#), showing a smooth and uniform coating surface without any coating anomalies or defects, such as webbing, bridging, or strut-to-strut contact, even after expansion of the stent.

## Coronary Intervention And Adjuvant Medications

The interventional procedure was performed according to the manufacturer's instructions for use provided with the Tetriflex SES and institutional standard practice. Before the interventional procedure, all patients received a loading dose of aspirin (150–300 mg) and clopidogrel (600 mg), or prasugrel (60 mg), or ticagrelor (two tablets of 90 mg each). During the procedure, all patients received heparin or bivalirudin, whereas use of glycoprotein IIb/IIIa inhibitors was done as per investigator preference. After the procedure, dual-antiplatelet therapy was recommended for at least 12 months (aspirin 75–100 mg and clopidogrel 75 mg daily, or prasugrel 10 mg daily, or ticagrelor 90 mg twice daily), followed by aspirin monotherapy ad infinitum.



**Figure 2** Scanning electron microscopy: (A) crimped Tetriflex SES; (B) expanded Tetriflex SES.

## Data Collection And Follow-Up

Baseline clinical data, lesion and procedural characteristics, and in-hospital clinical outcomes were consecutively extracted from individual hospital medical records. Follow-up at 30 days and 6 months of the index coronary intervention was received via clinical follow-up or telephone contact.

## Study Outcomes And Definitions

The primary outcome of the registry was a composite event rate of cardiac death, myocardial infarction (MI), and target-lesion revascularization (TLR) at 6 months. Any death due to a cardiac cause (such as MI, low-output failure, lethal arrhythmia), unwitnessed death, death of unknown reason, and all procedure-related deaths linked to concomitant treatment was stated as cardiac death, whereby noncardiac death included any death where a noncardiac cause was well established. MI was defined according to the third universal definition by the European Society of Cardiology and American College of Cardiology Foundation.<sup>11</sup> TLR was defined as repeat revascularization percutaneously or surgically to the lesion anywhere within the stent or subsequent 5 mm of distal or proximal segment to the stent. A non-target lesion target-vessel revascularization was considered when there was stenosis in any segment of the treated vessel other than a treated lesion. During follow-up, stent thrombosis, defined as per the Academic Research Consortium, was evaluated as a safety outcome.<sup>12</sup>

## Statistical Analysis

All data were analyzed using statistical software SPSS 20. Means  $\pm$  SD were used to present continuous variables. Categorical variables were presented as frequencies and percentages, and were compared using  $\chi^2$  or Fisher's exact test.  $P < 0.05$  was considered statistically significant. A Kaplan Meier method was used to estimate cumulative composite event-free survival at 6-month follow-up.

## Results

### Baseline Demographic And Clinical Characteristics

The mean age of the patients was  $54.99 \pm 10.80$  years, with 910 (71.7%) male patients, 622 (49.0%) hypertensive, 465 (36.6%) diabetic, 370 (29.2%) with hypercholesterolemia, and 218 (17.2%) smokers. Forty (3.2%) patients were presented with cardiogenic shock. Demographic details and clinical presentation of all patients are given in [Table 2](#).

## Lesion Characteristics And Procedure Details

Lesion characteristics are delineated in Table 3. In sum, 613 (48.3%) patients were diagnosed with single-vessel disease, 536 (42.2%) double-vessel disease, and 120 (9.5%) triple-vessel disease. The most common diseased vessel was the left anterior descending artery (47.7%). Among 1,515 lesions, 222 (14.7%) were totally occluded, of which 131 (8.6%) were chronic total occlusions. Of the lesions, 58.3% (n=883) were type C. Among all patients, 1,095 (86.3%) were accessed via the femoral artery and 174 (13.7%) via the radial artery. A total of 1,682 stents of different dimensions were implanted to treat the 1,515 lesions. Mean stent length and stent diameter were 25.15 ±8.83 mm and 2.89±0.32 mm, respectively. Table 4 highlights the procedural and stent details. Procedural success was achieved in 98.7% of patients. During the procedure, no incidence of bleeding or coronary artery dissection was observed.

## Clinical Outcomes

At 6-month, the primary outcome had occurred in 31 patients (2.49%): ten (0.8%) cardiac death, 16 (1.29%)

**Table 2** Baseline Characteristics For 1,269 Patients Implanted With the Tetriflex SES

Characteristics	Number Of Patients (n = 1269)
<b>Age (years), mean ± SD</b>	54.99±10.80
<b>Male, n (%)</b>	910 (71.7%)
<b>Cardiovascular risk</b>	
Hypertension, n (%)	622 (49.0%)
Diabetes mellitus, n (%)	465 (36.6%)
Hypercholesterolemia, n (%)	370(29.2%)
Smoking, n (%)	218 (17.2%)
Previous MI, n (%)	136 (10.7%)
Previous PCI, n (%)	89 (7.0%)
Previous CABG, n (%)	23 (1.8%)
Previous stroke, n (%)	26 (2.0%)
Renal insufficiency, n (%)	17 (1.3%)
Family history of CAD, n (%)	32 (2.5%)
Cardiogenic shock, n (%)	40 (3.2%)
<b>Clinical presentation</b>	
Stable angina, n (%)	336 (26.5%)
Unstable angina, n (%)	364 (28.7%)
ST-elevation MI, n (%)	398 (31.4%)
Non-ST-elevation MI, n (%)	171 (13.5%)

**Abbreviations:** MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery-bypass graft; CAD, coronary artery disease.

**Table 3** Lesion Characteristics For 1,269 Patients Implanted With the Tetriflex SES

Characteristics	
<b>Lesions, n</b>	1,515
<b>Vessel involvement (1,269 patients)</b>	
Single-vessel disease, n (%)	613 (48.3%)
Double-vessel disease, n (%)	536 (42.2%)
Triple-vessel disease, n (%)	120 (9.5%)
<b>Target coronary artery (1,515 lesions)</b>	
Left main, n (%)	5 (0.3%)
Left anterior descending artery, n (%)	723 (47.7%)
Left circumflex artery, n (%)	311 (20.5%)
Right coronary artery, n (%)	470 (31.0%)
Saphenous vein graft, n (%)	6 (0.4%)
<b>Lesion details (1,515 lesions)</b>	
Type A, n (%)*	206 (13.6%)
Type B1, n (%)*	200 (13.2%)
Type B2, n (%)*	226 (14.9%)
Type C, n (%)*	883 (58.3%)
Total occlusion, n (%)	222 (14.7%)
Chronic total occlusion	131 (8.6%)

**Note:** \*According to American College of Cardiology–American Heart Association lesion-morphology criteria.

MI, and five (0.4%) TLR. Non-target lesion target-vessel revascularization had occurred in two (0.16%) patients at 6 months. In Figure 3, a Kaplan–Meier curve of the event-free survival rate for the composite end point at 6 months is presented. Seven cases (0.56%) of stent thrombosis were reported at 6 months: two (0.16%) definite stent thrombosis, two (0.06%) probable stent thrombosis, and three (0.24%) possible stent thrombosis. Table 5 displays the clinical outcomes of Tetriflex SES at 30-day and 6-month follow-up. Subgroup analysis between diabetic and non-diabetic patients did not reveal any statistically significant difference for 6-month clinical outcomes (Figure 4).

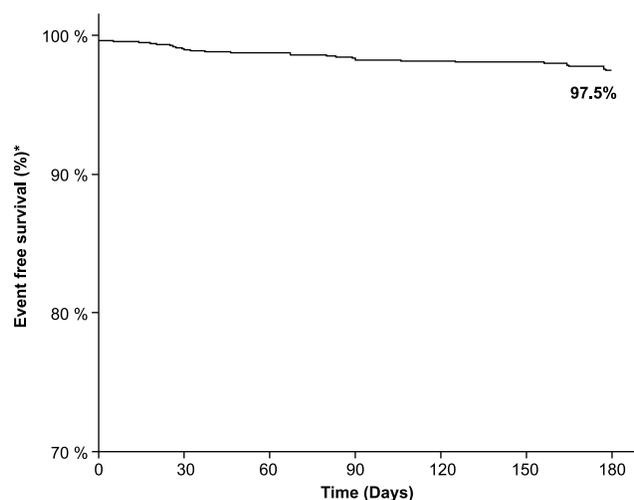
## Discussion

Since the introduction of DESs, they have been continually refined in terms of stent design and composition, strut thickness, polymers, and coating thickness in an attempt to achieve better safety and efficacy. The Tetriflex SES, used in the present registry, is a latest-generation ultrathin (60 µm) biodegradable polymer-coated DES designed with unique coating and LDZ-link on a Co-Cr alloy. This registry demonstrated positive evidence of safety and clinical performance of the Tetriflex SES in real-world patients at 6-month follow-up.

**Table 4** Procedural Characteristics For 1,269 Patients Implanted With the Tetriflex SES

Characteristics	
<b>Stent details</b>	
Total stents, n	1,682
Stents deployed per patient, mean $\pm$ SD	1.23 $\pm$ 0.45
Stents deployed per lesion, mean $\pm$ SD	1.11 $\pm$ 0.33
Stent length (mm), mean $\pm$ SD	25.15 $\pm$ 8.83
Stent diameter (mm), mean $\pm$ SD	2.89 $\pm$ 0.32
<b>Stent length</b>	
8 mm, n (%)	8 (0.5%)
12 mm, n (%)	134 (8.0%)
16 mm, n (%)	255 (15.2%)
20 mm, n (%)	293 (17.4%)
24 mm, n (%)	287 (17.1%)
28 mm, n (%)	234 (13.9%)
32 mm, n (%)	201 (12.0%)
36 mm, n (%)	114 (6.8%)
40 mm, n (%)	74 (4.4%)
44 mm, n (%)	47 (2.8%)
48 mm, n (%)	35 (2.1%)
<b>Stent diameter</b>	
2.25 mm, n (%)	6 (0.4%)
2.50 mm, n (%)	386 (22.9%)
2.75 mm, n (%)	463 (27.5%)
3.00 mm, n (%)	573 (34.1%)
3.50 mm, n (%)	253 (15.0%)
4.00 mm, n (%)	1 (0.1%)

Strut thickness has a great impact on stent thrombogenicity and restenosis during the early phase of stent implantation.<sup>13,14</sup>



**Figure 3** Cumulative composite event-free survival at 6-month follow-up. (\*Composite events comprise of cardiac death, myocardial infarction and target lesion revascularization).

Furthermore, the lack of complete strut coverage and optimal healing have been strongly associated with the incidence of late stent thrombosis.<sup>7,15–17</sup> However, various studies have reported that thinner struts provide rapid healing and complete endothelial coverage, which may reduce the risk of thrombus formation.<sup>14,18</sup> A recent meta-analysis also confirmed that DESs with thinner struts have significant associations with reduced risk of stent thrombosis and MI compared to thicker-strut DESs.<sup>19</sup>

It has also been found that thinner struts reduce the extent of injury to the vessel wall during stent implantation, which reduces the risk of restenosis compared to thick struts.<sup>20</sup> The ISAR-STEREO<sup>21</sup> and ISAR-STEREO-2<sup>22</sup> trials compared the association of thin-strut stents (50  $\mu$ m) and thick-strut stents (140  $\mu$ m) with restenosis. The results of both trials demonstrated that thinner-struts stent reduced the clinical and angiographic restenosis compared to thicker-strut stents.<sup>21,22</sup> The improved flexibility and deliverability, lowered crimped profile, reduced blood-flow disturbance, lowered injury to arterial wall, reduced risk of acute/chronic inflammation, faster re-endothelialization and early coverage, and quick and better healing quality offered by ultrathin struts collectively improved the clinical outcomes of the previous studies and the current registry.<sup>20,23,24</sup>

After complete drug release, permanent polymers cause chronic inflammation in the vessel wall, delay vascular healing, and trigger hypersensitivity reactions that lead to local arterial injury and ultimately result into late and very late stent thrombosis.<sup>5,25</sup> As such, there have always been safety concerns with earlier-generation permanent polymer-coated DESs. With the aim of overcoming these limitations, biodegradable polymer-coated DESs have been developed. Various studies and meta-analyses have established that biodegradable polymer-coated DESs have overcome or achieved comparable results in terms of stent thrombosis and other clinical outcomes compared to durable-polymer DESs.<sup>26–34</sup> Therefore, in addition to ultrathin struts of the Tetriflex SES, a blend of hydrophilic and hydrophobic biodegradable polymers that provide controlled-release kinetics of sirolimus also has probably contributed toward improved clinical outcomes in the present registry.

The present registry included 49% hypertensive patients, 36.6% diabetic patients, and 58% type C lesions, which displays the complexity of the patients. The Tetriflex SES is designed with a unique LDZ-link with long connectors, which provide excellent trackability and better push force through complex lesions and ease of handling the tortuous path of coronary arteries. It also has an in-phase strut design,

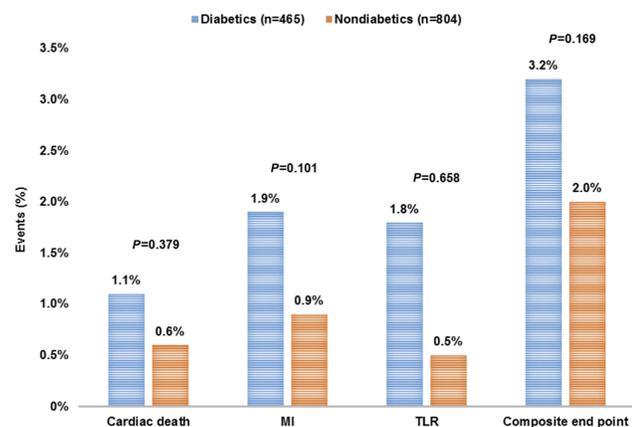
**Table 5** In-Hospital, 30-Day, And 6-Month Clinical Outcomes Of Patients Implanted With the Tetriflex SES

Clinical Outcomes	In-Hospital (n=1269)	At 30-Day Follow-Up (n=1269)	At 6-Month Follow-Up (n=1245, 98.1%)
Death from any cause, n (%)	2 (0.16%)	6 (0.47%)	15 (1.20%)
Cardiac death, n (%)	2 (0.16%)	4 (0.32%)	10 (0.80%)
Noncardiac death, n (%)	0	2 (0.16%)	5 (0.40%)
MI, n (%)	2 (0.16%)	10 (0.79%)	16 (1.30%)
TLR, n (%)	0	1 (0.08%)	5 (0.40%)
Non-TL-TVR, n (%)	0	1 (0.08%)	2 (0.16%)
Overall stent thrombosis, n (%)*	2 (0.16%)	4 (0.32%)	7 (0.56%)
Definite stent thrombosis, n (%)	2 (0.16%)	2 (0.16%)	2 (0.16%)
Probable stent thrombosis, n (%)	0	2 (0.16%)	2 (0.16%)
Possible stent thrombosis, n (%)	0	0	3 (0.24%)
Composite events (cardiac death, MI, and TLR), n (%)	4 (0.32%)	15 (1.18%)	31 (2.50%)

**Note:** \*According to Academic Research Consortium.

**Abbreviations:** MI, myocardial infarction; TLR, target-lesion revascularization; non-TL-TVR, non-target lesion target-vessel revascularization.

which aids flexibility and provides better structural support. Along with ultrathin struts, these stent characteristics enhance overall stent integrity and radial strength and resist longitudinal stent compression, ultimately making the Tetriflex SES a suitable stent to handle complex coronary lesions.<sup>6,23</sup> Another positive practical advantage of the Tetriflex SES is its availability in a wide range of sizes (diameter 2.0–4.5 mm and length 8–48 mm). This avoids the use of undersized/oversized stents, need of stent overlapping for long lesions and related technical/procedural challenges, underexpansion/overexpansion of stents, and offers the best immediate result with the lowest-possible complication rate. A case depicting successful deployment of the Tetriflex SES in a tortuous vessel, ie, right coronary artery–posterior descending artery, is displayed in [Supplementary Videos 1,2, 3](#).



**Figure 4** Comparison of 6-month clinical outcomes between diabetic and nondiabetic patients. (MI: myocardial infarction and TLR: target lesion revascularization).

At 6 months, the present registry demonstrated 2.5% composite events, comprising 0.8% cardiac death, 1.3% MI, and 0.4% TLR. Similarly, in the FLEX registry Lemos et al reported 2.2% major adverse cardiac events at 6-month follow-up with Supraflex SES.<sup>17</sup> Furthermore, the CREDIT-III trials on the Excel 2 biodegradable polymer-coated, thin-struts (88  $\mu$ m) DES reported 5% target-lesion failure and 0.1% TLR at 6 months.<sup>35</sup> All these observations are comparable with the findings of the present registry ([Table 6](#)). Further, the X-SEARCH registry reported 9.2% major adverse cardiac events for the Xience everolimus-eluting stent at 6 months.<sup>36</sup> In addition, a registry on the Synergy everolimus-eluting stent also demonstrated 4.2% target-lesion failure at 6 months.<sup>37</sup> Furthermore, in line with previous studies, the present registry also reported similar incidence of stent thrombosis, even though it comprised a complex population ([Table 6](#)). Post hoc analysis of the present registry found no significant differences in clinical outcomes between diabetic and nondiabetic patients. However, a large-scale study should be conducted to prove this, as the results may be considered exploratory.

Several biodegradable polymer-coated DESs with varied strut thickness (thin to ultrathin) are available, yet the search for an ideal biodegradable polymer-coated DES goes on. With its novel design, unique three-layer biodegradable-polymer coating, and ultrathin struts (60  $\mu$ m) for all sizes, and favorable clinical outcomes at 6-month follow-up, the Tetriflex SES could be proposed as a choice of biodegradable polymer-coated DES after long-term follow-up.

Although this registry reports favorable results, it has several limitations. First, this was a retrospective and

**Table 6** Six-Month Clinical Outcomes Of Standard Biodegradable Polymer DESs And Durable Polymer DESs In Various Studies And Of the Tetriflex SES In Present Study

Stents	Polymers	Platform	Strut Thickness (µm)	Study/Database	Events At 6 Months Follow-Up			
					TLF/ MACE	TLR	MI	ST
Tetriflex	Biodegradable	Co-Cr	60	Present study	2.5% composite events	0.40%	1.30%	0.56%
Synergy <sup>37</sup>	Biodegradable	Pt-Cr	74–81	Prospective all-comers study registry (Asian population)	4.2% TLF	0.40%	0.80%	0.30%
Ultimaster <sup>38</sup>	Biodegradable	Co-Cr	80	CENTURY study	2.9% TLF	1.90%	1.90%	0.95%
Orsiro <sup>39</sup>	Biodegradable	Co-Cr	60–80	BIOFLOW-II trial	3.1% TLF	1.00%	2.35%	0
Excel 2 <sup>35</sup>	Biodegradable	Co-Cr	88	Pooled analysis of CREDIT-II and CREDIT-III trials	5.0% TLF	4.90%	0.10%	—
Firebird 2 <sup>40</sup>	Durable	Co-Cr	86	FOCUS registry	1.8% MACE	—	0.95%	0.60%
Promus	Durable	Pt-Cr	81–86	EVOLVE trial	3.1% TLF	3.10%	0	0
Element <sup>41</sup>								
Xience <sup>36</sup>	Durable	Co-Cr	81	X-SEARCH registry	9.2% MACE	—	—	0.60%

**Abbreviations:** DES, drug eluting stent; TLF, target-lesion failure; MACE, major adverse cardiac event; TLR, target-lesion revascularization; MI, myocardial infarction; ST, stent thrombosis; Co-Cr, cobalt–chromium; Pt-Cr, platinum–chromium.

observational registry. Second, there was no direct head-to-head comparison with similar or other types of stents that might have resulted in superiority or noninferiority of the Tetriflex SES. Third, the registry reported 6-month follow-up results. However, long-term follow-up should be reported in future to establish its complete safety and effectiveness. Finally, the duration of dual-antiplatelet therapy remains unknown at follow-up, which might have some clinical relevance.

## Conclusion

Altogether, the Tetriflex SES can be considered safe and effective in real-world patients, as it has displayed acceptable and positive clinical outcomes at 6-month follow-up, with low incidence of TLR and stent thrombosis. Future follow-up will further clear the picture for use of the Tetriflex SES in real-world scenarios, as polymers degrade completely within 12 months of stent implantation.

**Supplementary Video 1** Pre–stent deployment: severely tortuous right coronary artery and lesion in posterior descending artery with 80% stenosis.

**Supplementary Video 2** Stent deployment: 2.50×24 mm Tetriflex stent negotiated in right coronary artery– posterior descending artery.

**Supplementary Video 3** Post–stent deployment TIMI III flow.

## Abbreviations

ARC, Academic Research Consortium; CAD, coronary artery disease; Co-Cr, cobalt–chromium; DES, drug-eluting stent; LDZ-link, long dual Z-link; MI, myocardial infarction; SES, sirolimus eluting stent; TLR, target-lesion revascularization.

## Author Contributions

PA: conception and design of registry, data interpretation, critical revision for important intellectual content, involved in appropriate investigation of the work. RP: conception and design of the registry, critically revising it for important intellectual content, involved in appropriate investigation of the work. KC: data acquisition/data analysis and interpretation, drafting the article, involved in appropriate investigation of the work. SM: conception and design of the registry, critically revising it for important intellectual content, involved in appropriate investigation of the work. PJ: conception and design of the registry; data acquisition/data analysis and interpretation, drafting the article. VV and VV: conception and design of the registry, data acquisition/data analysis and interpretation, drafting the article, involved in appropriate investigation of the work. All authors gave final approval of the version to be published and agree to be accountable for all aspects of the work.

## Disclosure

The authors report no conflicts of interest in this work.

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