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Comparison of neointimal coverage between ultrathin biodegradable polymer-coated sirolimus-eluting stents and durable polymer-coated everolimus-eluting stents: 6 months optical coherence tomography follow-up from the TAXCO study

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Abstract

Aim: The TAXCO study was designed to compare the degree of neointimal coverage and the prevalence of malapposition at 6 months subsequent to implantation of ultrathin biodegradable polymer-coated sirolimus-eluting stents (SES) and durable polymer-coated everolimus-eluting stents (EES) of thin strut thickness using optical coherence tomography (OCT).

Methods: The TAXCO study included a total of 42 patients who gave consent and underwent OCT examination between August 2017 and September 2017. Of 42, five patients' OCT examinations were of insufficient quality for quantitative analysis. Thus, the OCT analysis group consisted of 37 patients. Among them, 16 patients were treated with Xience (Abbott Vascular) and 21 with Tetriflex (Sahajanand Medical Technologies Pvt. Ltd., Surat, India), 6 (±1) months earlier at our institution. The OCT was performed using a C7 Dragonfly™ imaging catheter (St. Jude Medical Inc.). All OCT images were analyzed at an independent core laboratory (Cardiovascular Research Center, São Paulo, Brazil) by analysts who were blinded to patient and procedural information.

Results: A total of 763 crosssections (6,882 struts) were analyzed in Xience group, and 1,127 crosssections (9,968 struts) in Tetriflex group. At 6 months, on per-lesion basis, no significant differences were observed between Xience group and Tetriflex group in mean percentage of uncovered struts (1.87 ± 3.86 vs. 2.42 ± 3.46, p = .137) and malapposed struts (0.05 ± 0.2 vs. 0.21 ± 0.69, p = .302). Strut-level neointimal thickness also did not differ between Xience group and Tetriflex group (0.18 ± 0.12 vs. 0.14 ± 0.08 mm, p = .286).

Conclusion: This OCT study found no significant difference in strut coverage and neointimal thickness at 6 months after implantation of biodegradable polymer-coated Tetriflex, when compared with durable polymer-coated Xience.

KEYWORDS
coronary artery disease, drug-eluting stent, everolimus, percutaneous coronary intervention, sirolimus

1 | INTRODUCTION

In the era of expeditiously advancing technology, the management of coronary artery disease with percutaneous coronary intervention (PCI) has also been refined accordingly. The trend has shifted slowly but smoothly from bare metal stents to drug-eluting stents, followed by improvements in drug-eluting stents in terms of reduction in strut thickness, more efficacious drugs with better eluting profiles, more compatible polymers, and upgraded stent design with high flexibility and deliverability.[1–3] The incidences of late stent thrombosis, hypersensitivity reactions and delayed vascular healing in earlier drug-eluting stents have impelled these advancements.[4,5]

Along with advancements in management strategies, the diagnostic modalities have also progressed. A recently developed diagnostic modality, optical coherence tomography (OCT) has made it possible to analyze the endothelialization and healing after stent implantation.[6] The OCT parameters serve as surrogate marker of propensity for stent thrombosis in future, as it provides distinctive information about strut apposition and tissue endothelialization, both key factors allied with stent thrombosis.[7,8] Literature states that patients with incidence of late or very late thrombosis have higher percentage of uncovered and incompletely apposed struts.[9] More or less, the strut thickness has also been allied to strut coverage and apposition. The higher is strut thickness, longer will be the time taken to get completely covered and get healed.[10] Thus, on one hand, thin struts may provide better healing but on the other hand, there is a probability of lesser radial support and uniformity of expansion with use of thin struts. Such parameters of healing and radial strength can be studied by performing OCT. Therefore, the TAXCO study was designed to compare the healing pattern in terms of degree of neointimal coverage and the prevalence of malapposition at 6 months subsequent to implantation of ultrathin (60 μm) biodegradable polymer-coated Tetriflex sirolimus-eluting stents (SES) and durable polymer-coated Xience everolimus-eluting stents (EES) of thin strut thickness (81 μm) using OCT.

2 | METHODS

2.1 | Study design and population

The TAXCO study was a single-center, observational, investigator-initiated OCT follow-up study. Xience (Abbott Vascular) and Tetriflex (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) are the most frequently used stents at our institute. This provided us a unique opportunity to compare consecutive, contemporaneous patients implanted with either of the stents in the same time frame. The stents were selected on operators' discretion or majorly on availability of nearest size and length. A total of 65 patients underwent implantation of either Tetriflex or Xience; of which, 42 patients who gave consent and underwent OCT examination between August 2017 and September 2017 were included in the study. Group A included patients who were treated with Xience and group B included patients who were treated with Tetriflex, 6 (±1) months earlier at our institution. At that time, all PCI were performed under angiographic guidance alone. All patients underwent follow-up 6 months after the index procedure with OCT evaluation of all study stents. The study protocol was approved by Institutional Ethics Committee (Reg. no.—ECR/8550/Inst./GJ/2016) and all patients had provided the informed consent.

Inclusion criteria were: patients 18 years of age or older, both genders; underwent PCI with Tetriflex (alone) or Xience (alone); patient who understood and agreed to comply with all specified study requirements and provided written informed consent. Patients were excluded if: underwent PCI with a non-Tetriflex or non-Xience during the same index procedure; received both Tetriflex and Xience during the same index procedure.

2.2 | Technical specifications of study devices

The Tetriflex SES has the Tetrinium (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) L-605 cobalt chromium (Co–Cr) alloy coronary stent with a strut thickness of 60 μm as its stent platform. The multilayer coating on conformal surface of the Tetriflex stent contains 1.4 $\mu g/mm^2$ of sirolimus drug blended together with biodegradable polymeric matrix comprising a combination of hydrophilic and hydrophobic polymers, containing of poly L-lactide, 50/50 poly DL-lactide-co-glycolide, and polyvinyl pyrrolidone. Nearly 80% of drug is released within 1 month in biological media. Remaining drug is programmed to get released at a sustained rate for about 3 months. After releasing the drug, biodegradable polymers undergo hydrolysis and then gradually degrade into biologically acceptable molecules that are metabolized and removed from the body via normal metabolic pathways. The average coating thickness of Tetriflex stent is between 4 and 6 μm.

On the other hand, Xience EES is composed of a Multilink Co–Cr stent platform with thin strut having thickness of 81 μm and an open cell non-linear link design. It is coated with a formulation containing the anti-restenotic drug everolimus, embedded in a durable polymer. The drug load is 100 $\mu g/cm^2$ for all stent sizes, for a nominal everolimus content of 37–181 μg depending on the stent size. The co-polymer elutes everolimus in a controlled fashion, 80% in 1 month and the remainder within 4 months.

2.3 | OCT analysis methods

The OCT images were acquired with a frequency-domain OCT system (C7 XR™, St. Jude Medical, St. Paul, MN), which acquires 100 frames per second along a maximum pullback length of 54 mm. A 20 mm/s pullback speed was applied in all pullbacks. All OCT analyses were performed on the raw images with commercially validated software for offline analysis (QIVUS version 3.0, Medis Medical Imaging, Leiden, The Netherlands). The analyses of the OCT images were performed at an independent core laboratory (Cardiovascular Research Center, São Paulo, Brazil) by analysts who were blinded to patient and procedural information. Basic concepts and definitions that form the basis for the current analysis were based on the consensus standards for acquisition, measurement, and reporting of intravascular OCT studies and previously published methodologies.[11,12]

A strut was considered suitable for analysis only if it had a well-defined bright blooming and a characteristic dorsal shadow perpendicular to the light source. Neointimal hyperplasia (NIH) area was determined in follow-up examinations by the area comprised between the stent and lumen contours. NIH volume was automatically computed by the Simpson's rule. The strut-to-lumen distance was automatically measured from the center point of the luminal surface of each individual analyzed strut to the lumen contour by a line projected through the gravitational center of the lumen. Covered struts had positive strut-to-lumen distances—a measure of the NIH thickness covering each covered strut. Uncovered and malapposed struts had negative strut-to-lumen distances. Malapposed struts were differentiated from uncovered struts when the negative value of the strut-to-lumen distance was higher than the sum of the strut thickness + polymer thickness + a compensation factor of 20 μm to correct for the strut blooming. Hence, an individualized cutoff value for determination of malapposed struts were 116 μm for Xience [i.e., 81 μm + 7.8 μm (*2) + 20 μm] and 92 μm for Tetriflex [i.e., 60 μm + 6 μm (*2) + 20 μm]. In cross-sections where any malapposed strut was identified, the area of stent malapposition was also quantified in the cross-section level. The stent eccentricity was defined as: (maximum stent diameter–minimum stent diameter)/maximum stent diameter.

The first and last frames in which stent struts could be seen occupying at least four quadrants of the cross-sectional circumference were considered the landmark to define the beginning and end of the stents, respectively. After adjusting for the pullback speed, cross-sections were analyzed at 0.6-mm longitudinal intervals throughout the treated segment. Results were presented at the frame level (e.g., stent and lumen areas and diameters, NIH area, malapposition area) and strut level (e.g., percentage of covered, uncovered, and malapposed struts, NIH thickness over each individual covered struts, malapposition distance for each malapposed strut, etc).

2.4 | Study endpoints

The primary study endpoints were proportion of covered struts, thickness of NIH over covered struts and proportion of malapposed struts. The secondary endpoints were mean malapposed strut-to-lumen distance, ratio of uncovered struts to total struts, maximum length of consecutive segments of uncovered and malapposed struts, NIH area, volume, percent volumetric stent obstruction, and incomplete stent apposition (ISA) area at 6 months OCT follow-up.

2.5 | Statistical analysis

Qualitative data are presented as frequencies, and quantitative data are shown as means *SD*s. For continuous variables, comparisons

TABLE 1 Baseline demographics and lesion characteristics

	Xience	Tetriflex	*p* Value
Number of patients	16	21	
Age, (mean ± *SD*, years)	49.56 ± 10.77	50.05 ± 11.27	.896
Male, *n* (%)	13 (81.3%)	13 (61.9%)	.285
Risk factors			
Current smoker, *n* (%)	6 (37.5%)	9 (42.9%)	.742
Hypertension, *n* (%)	6 (37.5%)	10 (47.6%)	.538
Hypercholesterolemia, *n* (%)	6 (37.5%)	15 (71.4%)	.039
Diabetes mellitus, *n* (%)	5 (31.25%)	7 (33.3%)	.893
Clinical presentation			
Stable angina, *n* (%)	3 (18.75%)	2 (9.5%)	.634
Unstable angina, *n* (%)	9 (56.25%)	14 (66.7%)	.517
ST-elevation myocardial infarction, *n* (%)	1 (6.25%)	2 (9.5%)	1.00
Non-ST-elevation myocardial infarction, *n* (%)	3 (18.75%)	4 (19%)	1.00
No. of lesions, *n*	16	21	
Target vessel location			
Left anterior descending artery, *n* (%)	6 (37.5%)	8 (38.1%)	.970
Left circumflex artery, *n* (%)	6 (37.5%)	6 (28.6%)	.565
Right coronary artery, *n* (%)	4 (25%)	7 (33.3%)	.583
Pre-dilatation performed, *n* (%)	13 (81.3%)	18 (85.7%)	1.00
Post-dilatation performed, *n* (%)	16 (100%)	20 (95.2%)	1.00
Maximum inflation pressure, atm *n* (%)	18.00 ± 1.52	17.05 ± 1.80	.292
Lesion classification (ACC/AHA score)			
Type A, *n* (%)	2 (12.5%)	1 (4.8%)	.568
Type B1, *n* (%)	3 (18.75%)	3 (14.3%)	1.00
Type B2, *n* (%)	4 (25%)	7 (33.3%)	.723
Type C, *n* (%)	7 (43.75%)	10 (47.6%)	.815
Total number of stents, *n*	17	22	
Average stent length, mm (mean ± *SD*)	25.12 ± 9.3	29.27 ± 8.5	.155
Average stent diameter, mm (mean ± *SD*)	3.015 ± 0.4	3.02 ± 0.307	.944

TABLE 2 Optical coherence tomography (OCT) results at the cross-section level analysis

	Xience	Tetriflex	*p* Value
Number of analyzed lesions	**16**	**21**	
Analyzed stent length, mm	23.54 ± 9.38	27.9 ± 7.93	.135[a]
Total number of analyzed cross-sections	763	1,127	
Cross-sections analyzed per stent	47.69 ± 15.76	53.67 ± 14.32	.236[a]
Reference analysis			
Mean reference lumen area, mm^2	5.79 ± 1.54	6.65 ± 2.45	.813[c]
Mean reference lumen diameter, mm	2.68 ± 0.34	2.85 ± 0.54	.708[c]
Stent analysis			
Mean stent area, mm^2	7.48 ± 2.38	7.06 ± 2.46	.609[c]
Minimum stent area, mm^2	6.36 ± 2.21	5.68 ± 2.2	.362[a]
Mean stent diameter, mm	3.05 ± 0.46	2.95 ± 0.53	.547[c]
Mean stent eccentricity index	0.07 ± 0.03	0.1 ± 0.04	.016[c]
Stent volume, mm^3	170.77 ± 79.5	198.51 ± 100.64	.371[a]
Lumen analysis			
Mean lumen area, mm^2	6.09 ± 2.63	5.97 ± 2.31	.891[c]
Minimum lumen area, mm^2	4.68 ± 2.55	4.53 ± 2.11	.847[a]
Mean lumen diameter, mm	2.72 ± 0.56	2.70 ± 0.55	.887[c]
Mean lumen eccentricity index	0.12 ± 0.03	0.15 ± 0.04	.062[c]
Lumen volume, mm^3	137.43 ± 72.83	165.77 ± 86.91	.300[a]
Lumen area stenosis, %	0.21 ± 0.21	0.25 ± 0.12	.564[b]
Incomplete stent apposition (ISA)			
No. of lesions with ISA, *n*	1	4	
Mean ISA area, mm^2	0.4 ± NA	0.58 ± 0.45	.502[c]
NIH quantification			
Mean NIH area, mm^2	1.42 ± 1.01	1.13 ± 0.68	.299[c]
Mean NIH volume, mm^3	33.34 ± 23.62	32.74 ± 27.21	.797[b]
Percent stent obstruction, %	20.45 ± 12.99	16.76 ± 10.22	.339[c]

[a]Student *t* test.
[b]Mann–Whitney test.
[c]Linear mixed model, considering lesion as a random effect.

TABLE 3 Optical coherence tomography (OCT) results at the strut level analysis

	Xience	Tetriflex	*p* Value
Number of analyzed lesions	16	21	
Total number of analyzed struts	6,882	9,968	
Analyzed struts per lesion	430.12 ± 178.28	474.67 ± 138.14	.342[a]
Analyzed strut per cross -section	10.85 ± 3.29	10.27 ± 2.94	.347[b]
Covered struts per lesion, %	98.13 ± 3.86	97.58 ± 3.46	.137[c]
Malapposed struts per lesion, %	0.05 ± 0.2	0.21 ± 0.69	.302[c]
Mean malapposed strut-to-lumen distance, mm	0.33 ± NA	0.3 ± 0.07	.356[b]
Mean NIH thickness over covered struts, mm	0.18 ± 0.12	0.14 ± 0.08	.286[b]
Mean neointimal unevenness score	1.69 ± 0.41	1.72 ± 0.4	.967[b]
Frequency of cross-sections with any uncovered struts, %	7.78 ± 12.33	14.17 ± 14.99	.121[c]
Frequency of cross-sections with >30% uncovered struts, %	2.24 ± 5.41	1.36 ± 4.13	.686[c]
Frequency of cross-sections with any malapposed struts, %	0.6 ± 2.42	0.92 ± 2.55	.302[c]
Frequency of cross-sections with >30% malapposed struts, %	0 ± 0	0.18 ± 0.81	.413[c]
Maximum length of consecutive segments of uncovered struts, mm	0.6 ± 0.79	1.66 ± 1.71	.036[c]
Maximum length of consecutive segments of malapposed struts, mm	0.08 ± 0.3	0.11 ± 0.24	.326[c]

[a]Student *t* test.
[b]Linear mixed model. Analyzed struts per cross-section and neointimal unevenness score were analyzed considering random effects for lesion. Malapposed strut-to-lumen distance and NIH thickness over covered struts were analyzed considering random effects of frames nested to lesions.
[c]Mann–Whitney test.

between two groups were performed using a two-tailed unpaired *t* test or Mann–Whitney test. The OCT variables have an inherent nested design. Thus, to take into account the clustered design of the data linear mixed models considering random effects for lesion, crosssections, and struts were applied as appropriate. Discrete variables are presented as percentages, and comparisons were performed using a chi-square analysis or Fisher's exact test. A probability value of <.05 was considered significant. The statistical analysis was conducted using the R software version 3.2.2. (R Core Team, 2015).

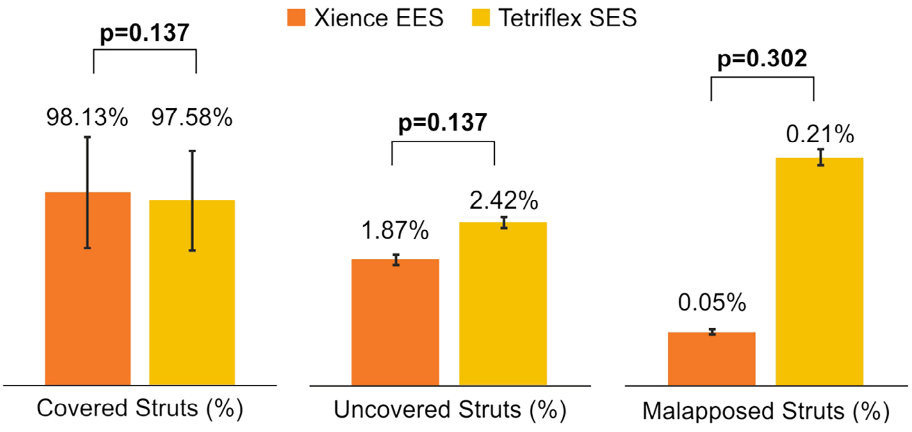

FIGURE 1 Strut-level analysis for Xience versus Tetriflex [Color figure can be viewed at wileyonlinelibrary.com]

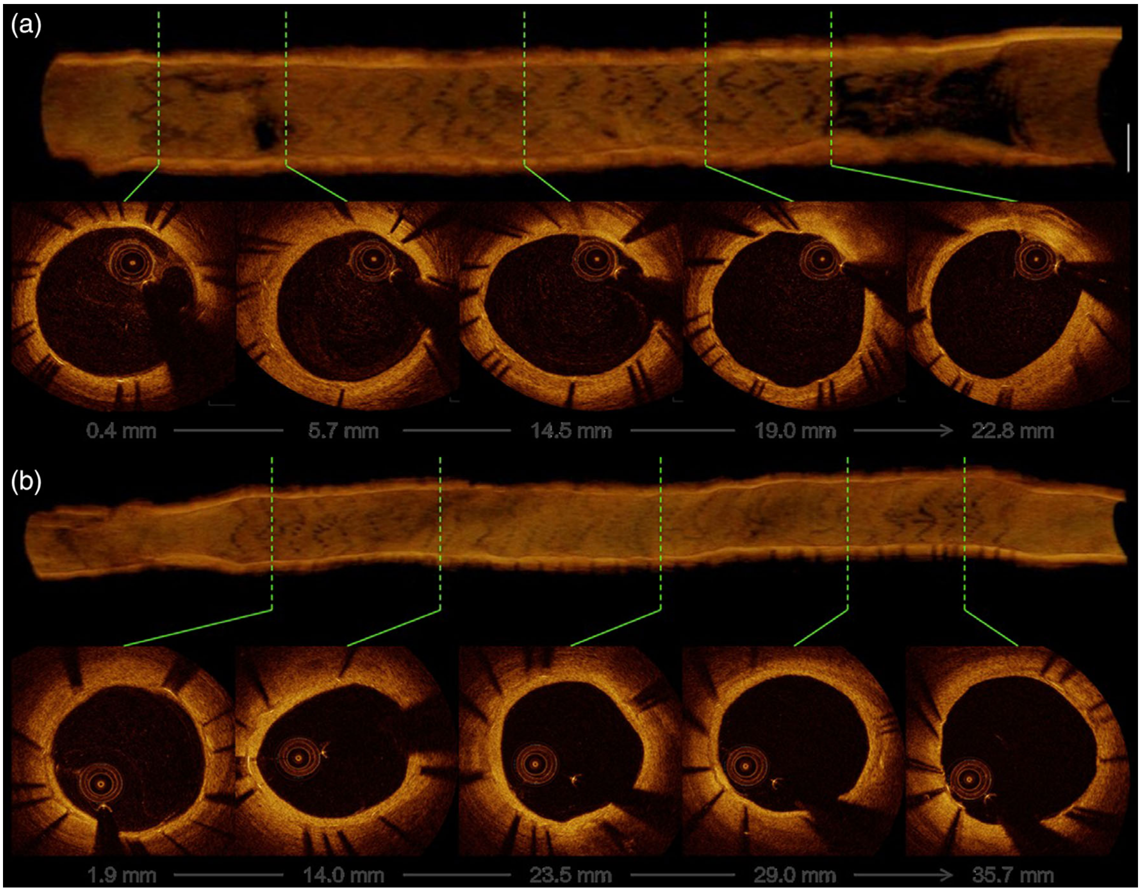

FIGURE 2 Optical coherence tomography (OCT) cross-section images show similar neointimal hyperplasia (NIH) suppression and frequency of covered struts at 6 months between group A (a: Xience) and group B (b: Tetriflex) [Color figure can be viewed at wileyonlinelibrary.com]

3 | RESULTS

A total of 44 stents were implanted for the treatment of 42 lesions in 42 vessels from 42 patients (two lesions from two patients were treated with two overlapping stents, which were also included in the analysis). Of 42, five patients' OCT examinations were of insufficient quality for quantitative analysis. Thus, the OCT analysis group consisted of 37 patients. Among them, 16 patients (group A) were treated with Xience and 21 (group B) with Tetriflex. In brief, 16 patients who had been treated with Xience and 21 patients who had been treated with Tetriflex were analyzed. Baseline clinical demographics and lesion characteristics (Table 1) were similar between the two study groups. There was no statistical difference in any of the risk factors between both the groups. Diabetes was highest prevailing risk factor in both groups. Diabetic patients were either prescribed metformin, glimepiride, or teneligliptin. All patients were on DAPT from the day of procedure till the day of follow-up. Loading dose of 150 mg aspirin and 180 mg ticagrelor was given to all patients prior to procedure, followed by 75 mg OD aspirin and 90 mg BD ticagrelor continued till the time of follow-up.

Table 2 presents the main OCT results at the cross-section level analysis. A numerically greater number of crosssections were analyzed in the Tetriflex group as compared to the Xience group (1,127 vs. 763). A mean of 47.69 crosssections per stent were analyzed in the Xience group and 53.67 crosssections per stent were analyzed in the Tetriflex group. The length of stents in Tetriflex group were numerically, but not statistically different, longer than stents in Xience group (28.33 ± 8.9 mm vs. 24.10 ± 9.31, *p* = .131). There was no significant difference in minimum lumen area of both stent groups (4.68 ± 2.55 mm^2 and 4.53 ± 2.11 mm^2, respectively [*p* = .847]), however, the eccentricity index of Xience stent group was significantly lower than the Tetriflex group (0.07 ± 0.03 vs. 0.1 ± 0.04; *p* = .016).

No significant differences were seen in the mean reference lumen area, as well as in the mean stent area, minimum stent area, mean stent diameter, and stent volume between the groups. ISA was seen in only one lesion in the Xience group and in four lesions in the Tetriflex group. The mean NIH area was very low in both stent groups, and numerically smaller (although not significantly different) in the Tetriflex groups (1.42 ± 1.01 mm^2 vs. 1.13 ± 0.68 mm^2, *p* = .299).

Table 3 presents the main OCT results at the strut level analysis. Numerically greater number of struts were analyzed in the Tetriflex group as compared to the Xience group (9,968 vs. 6,882). The mean thickness of NIH covering each strut was very low in both groups (180 ± 120 μm in Xience group vs. 140 ± 80 μm in Tetriflex group, *p* = .286). A mean of 430.1 struts per lesion were analyzed in the Xience group and 474.7 struts per lesion were analyzed in the Tetriflex group. Importantly, the frequency of covered struts at 6 months of follow-up was similar between Xience group (98.13 ± 3.86) and Tetriflex group (97.58 ± 3.46, *p* = .137; Figure 1). The OCT images of representative cases for both the groups are depicted in Figure 2.

4 | DISCUSSION

In the present study, the frequency of uncovered struts was 1.87 ± 3.86 and 2.42 ± 3.46 for Xience group and Tetriflex group, respectively. Moreover, 2.24 ± 5.41 and 1.36 ± 4.13% of crosssections showed at least 30% uncovered stents struts in both groups. The neointimal thickness (180 ± 120 μm in Xience group vs. 140 ± 80 μm in Tetriflex group, *p* = .286), neointimal area and volume were overall low in both the groups. These results are well in line with the findings of various trials and studies which state that the elution of antiproliferative drugs in the early phases after implantation of DES have been responsible for the lower neointimal thickness over stent struts,[13–16] and in view of this, complete coverage of struts at 6 months after implantation of DES would be too impractical to be expected. However, on the downside, it is also true that excessive neointimal suppression will lead to increased probability of stent thrombosis in the future.[17] Excessive suppression of cell proliferation is allied with incomplete endothelial coverage of struts, which is a chief predictor of stent thrombosis.[4,9,18] Other than incomplete endothelialization, discontinuation of dual antiplatelet therapy, stent under expansion, incomplete stent apposition, strut fracture, and bifurcation stenting have been the different factors contributing towards stent thrombosis.[19,20] Therefore, an apt balance of neointimal thickness and amount of strut coverage becomes imperative for optimal performance of a stent.

Similar to our study, previous OCT studies have also stated that strut coverage at 6 months was comparable between various biodegradable polymer-coated DES and durable polymer-coated DES (Table 4). The number of lesions treated with the study stents in this study were similar to most of the studies. Though comparable, the degree of malapposition, coverage of struts and neointimal growth were not the same in all the studies. These differences were attributable to different stent platforms, thickness, polymeric durability and combinations, drug release kinetics, and stent design. Moreover, in a recent study, Gil et al. have stated that strut width should also be

TABLE 4 Comparison of 6 months optical coherence tomography (OCT) results with contemporary biodegradable polymer drug-eluting stents and durable polymer drug-eluting stents

Stent	Strut thickness	No. of lesions	Uncovered struts (%)	Malapposition (%)	Mean neointimal thickness (mm)
Biodegradable polymer DES					
De la Torre Hernandez, et al. (everolimus)[21]	74–81 μm	30	3.4	3.8	0.31
Koppara, et al. (sirolimus)[22]	60–80 μm	14	15.8	1.3	0.05
FLEX registry (sirolimus)[23]	60 μm	47	1.9	0	0.13
Present study (sirolimus)	60 μm	21	2.4	0.2	0.14
Durable polymer DES					
Katoh, et al. (sirolimus)[24]	140 μm	21	10.4	1.7	0.11
Guagliumi, et al. (everolimus)[25]	81–86 μm	20	8.46	0	0.09
ANCHOR study (sirolimus)[26]	75–85 μm	51	16.7	–	0.07
Koppara, et al. (everolimus)[22]	81 μm	15	17.4	2.2	0.08
Poerner, et al. (Everolimus)[27]	81 μm	47	4.9	1.2	–
Present study (everolimus)	81 μm	16	1.9	0.1	0.18

taken into consideration as a contributing parameter. They added that strut width defined the area of stent adhering to the wall that initiate vascular response, while strut thickness was mostly responsible for the duration of neointima proliferation.[28] The strut thickness is closely allied with local inflammation at the lesion and, when the thickness is greater, it poses as an obstacle to stent strut coverage with neointima.[29] Collectively, these all have an impact on vascular healing and correlate to the safety and performance of the implanted stent.[6] But, strut thickness tends to be a prime deciding factor for the duration of strut coverage after stent implantation. In present study, group A demonstrated 98.13 ± 3.86% covered struts per lesion and group B showed 97.58 ± 3.46% covered struts per lesion (p = .137). Mean NIH area was 1.42 ± 1.01 mm^2 and 1.13 ± 0.68 mm^2 (p = .299) for group A and group B. While, mean NIH volume was 33.34 ± 23.62 mm^2 and 32.74 ± 27.21 mm^2 (p = .797), respectively for groups A and B. Mean neointimal unevenness score was 1.69 ± 0.41 and 1.72 ± 0.4 (p = .967) for groups A and B, respectively. All such parameters depict better healing of thin struts. Although, thinner struts heal better in terms of strut coverage but uniform circular expansion in thinner struts is a matter of concern. However, in this study, although minimal lumen areas were comparable between both stents, there was significant difference in eccentricity index between the stent of thin strut thickness and ultrathin strut stent (0.07 ± 0.03 vs. 0.1 ± 0.04; p = .016). The stent eccentricity index is a reflector of device expansion uniformity, depicting that the uniformity of expansion was better and healing process was uniform in Tetriflex stent. This shows that the thinner struts with advanced engineering possess good radial strength and result into uniform expansion.

Previously published long term follow-up studies that compared biodegradable polymer coated DES with durable polymer coated DES,[30,31] have reported potential benefits of biodegradable polymers over durable polymers in terms of significant reductions in late and very late incidences of stent thrombosis. Moreover, human autopsy studies have also stated that permanent polymeric coatings on earlier generation DES have been associated with late restenosis and stent thrombosis.[32,33] In addition, the durable polymer coatings on stents pose to be one of the causes for incomplete endothelialization, thus representing that the neointimal healing after implantation of durable polymer coated stent would be delayed and contribute towards increased probabilities of occurrence of late stent thrombosis. On the other side, stents with biodegradable coatings likely have better endothelialization as well as neointimal healing with passage of time, thereby, leading to lower incidences of late stent thrombosis. Thus, newer generation biodegradable polymer-coated DES tend to be safe and effective at intermediate-term follow-up; however, long-term follow-ups would further validate the performance.

4.1 | Study limitations

The study has some limitations of being a single center experience, non-randomized study, and considering difficulty to perform randomized controlled trial of such nature, this was the next best alternative to perform study in contemporaneous patients in the same period in the similar population and there was no particular operator bias and stents were largely selected on basis of nearest available diameter and length. Larger studies with higher no. of patients are required to conclusively support these results.

5 | CONCLUSION

With very effective NIH suppression, the frequency of covered struts at 6-months of follow-up was similar between Xience and Tetriflex. This highlights the very good balance between efficacy and safety profiles of both stent technologies. The OCT study found no significant difference in strut coverage and neointimal thickness at 6-months after implantation of ultrathin biodegradable polymer-coated Tetriflex, when compared with durable polymer-coated Xience.

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