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ORIGINAL STUDIES

Imaging and 2-year clinical outcomes of thin strut sirolimus-eluting bioresorbable vascular scaffold: The MeRes-1 extend trial

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Abstract

Objectives: This study explores the safety and efficacy of thin strut MeRes100 sirolimus-eluting bioresorbable vascular scaffold (BRS) in patients with de novo coronary artery lesions.

Background: In interventional cardiology, the emergence of BRS technology is catalyzing the next paradigm shift.

Methods: The MeRes-1 Extend was a multicenter, prospective, single-arm, open-label study enrolling 64 patients in Spain, Macedonia, Brazil, South Africa, Malaysia, and Indonesia. The safety endpoint was major adverse cardiac events (MACE) which composed of cardiac death, myocardial infarction (MI), and ischemia-driven target lesion revascularization (ID-TLR). The imaging efficacy endpoint was mean in-scaffold late lumen loss (LLL) evaluated by quantitative coronary angiography (QCA). Optical coherence tomography (OCT) imaging was performed at baseline and 6-month follow-up.

Results: A total of 69 target lesions were identified in 64 enrolled patients (mean age 58.30 ± 9.02 years). Of the treated lesions, 49 (71.01%) lesions were of type B2/C. Procedural and device success was achieved in 64 and 62 patients, respectively. At 2-year follow-up, MACE was reported in one patient (1.61%) in the form of

ID-TLR. There was no case of MI, cardiac death or scaffold thrombosis through 2-year. In a subset of 32 patients, paired QCA showed mean in-scaffold LLL of 0.18 ± 0.31 mm at 6-month follow-up. In a subset of 21 patients, OCT revealed 97.95 ± 3.69% strut coverage with mean scaffold area of 7.56 ± 1.79 mm^2 and no evidence of strut malapposition.

Conclusions: The clinical and imaging outcomes of MeRes-1 Extend trial demonstrated favorable safety and efficacy of MeRes100 sirolimus-eluting BRS in patients with de novo coronary artery lesions.

KEYWORDS

coronary artery disease, optical coherence tomography, percutaneous coronary intervention, quantitative coronary angiography, thin-strut scaffold

1 | INTRODUCTION

Bioresorbable vascular scaffold (BRS) has been touted as the next paradigm shift in percutaneous coronary intervention (PCI) technology.[1] BRS, in the short-term, aims to provide adequate mechanical support to prevent vessel recoil, release an anti-proliferative drug to prevent restenosis, while leaving nothing behind over the long-term as the scaffold is resorbed, thereby preventing very late scaffold events and preserving options for future revascularization.[1,2]

Previously published trials with the early generation BRS (Absorb scaffold, Abbott Vascular, Santa Clara, CA, USA) showed promising performance in simple and complex coronary anatomy when proper implantation technique was employed.[3,4] However, concerns have been raised about the safety and efficacy of such device due to increased rates of myocardial infarction (MI) and device thrombosis over longer-term follow-up when compared with contemporary drug-eluting stents (DES).[1,3,5-7] Several studies have shown that greater strut thickness (156 μm) and higher crossing profile of Absorb BRS restricts its deliverability, creates laminar flow disruptions and delays endothelialization thereby increasing the rate of MI and scaffold thrombosis (ST).[1,8]

The newly designed MeRes100™ sirolimus-eluting BRS (Meril Life Sciences Pvt. Ltd., India) is a fully bioresorbable polymeric scaffold with strut thickness of 100 μm which provides improved deliverability. This device is based on a balloon-expandable semi-crystalline poly-L-lactic acid (PLLA) polymer backbone scaffold which is coated with more rapidly absorbed poly-D, L-lactide (PDLLA) amorphous matrix mixed in 1:1 ratio with anti-proliferative drug, 1.25 μg/mm^2 of sirolimus. The MeRes100 BRS was first evaluated in de novo coronary artery lesions in the MeRes-1 trial with promising initial results of safety and effectiveness of the device.[9]

Hence, to confirm the applicability of MeRes100 BRS, the MeRes-1 Extend trial was initiated with the aim to continue assessing the safety and efficacy of the MeRes100 BRS in a more diverse subject pool in the Spain, Macedonia, Brazil, South Africa, Malaysia and Indonesia.

2 | MATERIALS AND METHODS

2.1 | Trial design

The MeRes-1 Extend (ClinicalTrial.gov no. NCT02663323) is a prospective, multicenter, single-arm, open-label clinical trial which included patients from different geographic population. A total of 64 patients were included between February 2016 and June 2017. The major inclusion criteria were patients with up to two de novo native coronary artery lesions (maximum one per target vessel), visually assessed reference vessel diameter (RVD) of 2.75–3.5 mm and lesion ≤20 mm and having pre-treatment diameter stenosis between >50 and <100% with a thrombolysis in myocardial infarction (TIMI) flow grade of ≥1. However, patients with acute MI, prior coronary revascularization and left ventricular dysfunction <30% were ineligible for participation in the study. The clinical follow-up was planned at one and 6-month, as well as at one, two and 3-year after the index procedure. In addition, imaging follow-up was performed at post-procedure and 6- month. Institutional review board at each investigational site approved the clinical trial protocol prior to initiation of the study. The data was managed by an independent contract research organization (JSS Medical Research India Pvt. Ltd., Faridabad, India) and all clinical endpoints events were validated by an Independent Adjudication Committee.

The trial was conducted in accordance with the ICH-GCP guidelines, Declaration of Helsinki, ISO 14155 and ethics committee requirements. All patients provided written informed consent for participation in the trial prior to the index procedure.

2.2 | Study device

The MeRes100 BRS has a hybrid cell design with close cells at the edges and open cells in the mid segment, which ensures conformability and scaffolding. Additionally, the design incorporates strut-width variability; thus, the scaffold maintains high radial strength without loss in flexibility despite low strut thickness (100 μm). It has a crossing profile of 1.20 mm for the 3.0 mm diameter scaffold.

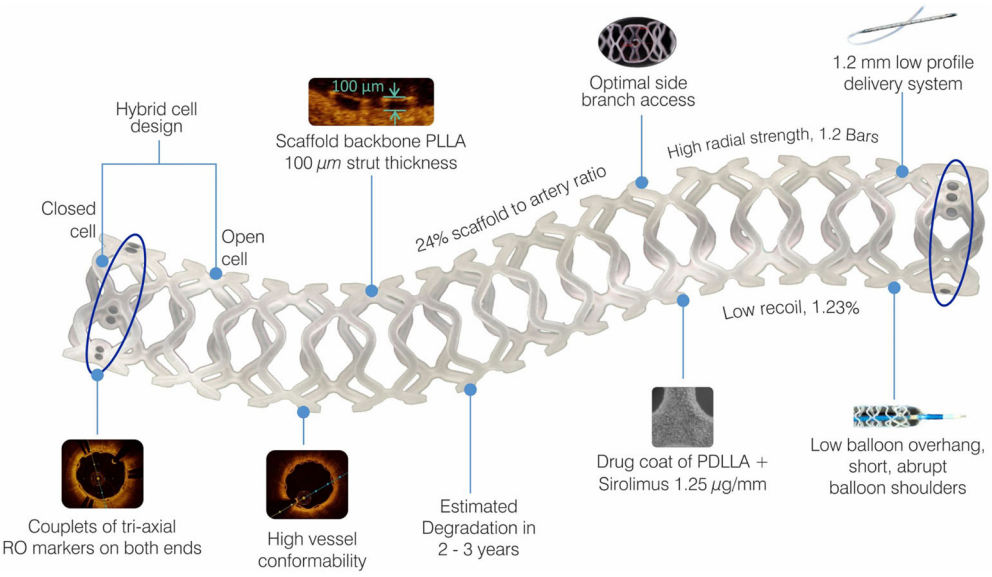

FIGURE 1 MeRes100 BRS design. Adapted from: EuroIntervention 13 (4), Seth et al, First-in-human evaluation of a novel poly-L-lactide based sirolimus-eluting bioresorbable vascular scaffold for the treatment of de novo native coronary artery lesions: MeRes-1 trial. 415–23, Copyright (2017), with permission from Europa Digital & Publishing. PDLLA, poly-D; L, lactide; PLLA, poly-L-lactic acid; RO, radiopaque [Color figure can be viewed at wileyonlinelibrary.com]

The MeRes100 BRS is a balloon expandable PLLA polymer backbone scaffold. Coating of this scaffold consists of a blend of sirolimus as an anti-proliferative drug and amorphous PDLLA polymer as a reservoir with a coating-to-drug ratio of 1:1 (Figure 1). The degradation of the scaffold is expected to occur within 2–3 years of implantation (Data on file). The presence of couplets of tri-axial platinum radiopaque markers that are 120° apart from each other are fixed on the cross-linking struts at the end of scaffold which allow clear viewing of its position. The MeRes100 BRS of diameters 2.75, 3.00, and 3.50 mm, and lengths of 19 and 24 mm were used for the MeRes-1 Extend trial.

In vivo pharmacokinetic studies have reported that in pig models, the peak concentration of sirolimus in blood occurred at 1–4 hr after scaffold deployment and the average of maximum concentration was 7.38 ± 0.42 ng/ml. The sirolimus arterial tissue concentration gradually declined over time and was detectable until 186 days. Moreover, the study elucidated expansive vascular remodeling at 1-year and no vascular recoil with adequate inhibition of neointimal proliferation in the treated segments at 2-year follow-up.[10]

TABLE 1 Baseline characteristics of the intention-to-treat population

Variables	*N* = 64 patients
Age (years), mean ± SD	58.30 ± 9.02
Male, n (%)	44 (68.75)
Body mass index (kg/m^2), mean ± SD	28.6 ± 4.13
Current smokers, n (%)	23 (35.94)
Diabetes mellitus, n (%)	17 (26.56)
Dyslipidemia, n (%)	31 (48.44)
Hypertension, n (%)	49 (76.56)
Chronic lung disease, n (%)	2 (3.13)
Previous myocardial infarction, n (%)	18 (28.13)
Clinical presentation, n (%)	
Stable angina	44 (68.75)
Unstable angina	6 (9.38)
Silent ischemia	14 (21.88)
Diseased vessel, n (%)	
Single vessel	59 (92.19)
Double vessel	5 (7.81)
Left ventricular ejection fraction (%), mean ± SD	59.61 ± 8.75

2.3 | Implantation technique

The standard guidelines for PCI were applied to treat the target lesions.[11] Pre-dilatation was performed with either 0.5 mm smaller sized or 1:1 sized balloon which matches the RVD. After scaffold deployment, pressure for an additional 30 s was maintained before balloon deflation. Further, post-dilation with a non-compliant balloon (diameter at least equal to and preferably 0.5 mm larger than the implanted scaffold) was applied at ≥18 atm. If clinically indicated, optical coherence tomography (OCT) or intravascular ultrasound (IVUS) was recommended to ensure optimal deployment and apposition of struts of the scaffold. All patients were pre-treated with the loading dose of aspirin (80–300 mg/day) and clopidogrel (75–300 mg/day). Post-procedural dual anti-platelet therapy of aspirin (80–100 mg/day) and clopidogrel (75 mg/day) was prescribed for a minimum duration of 1- year.

2.4 | Endpoints and definitions

Device success was defined as successful deployment of the scaffold in the intended target lesion with a residual stenosis of <20%.

Procedural success was defined as angiographic success (residual stenosis <20% and TIMI flow grade 3) with absence of in-hospital major adverse cardiac event (MACE). MACE was defined as a composite of cardiac death, MI and ischemia-driven target lesion revascularization (ID-TLR). Cardiac death was defined as any death caused by immediate cardiac cause (e.g., MI, low-output failure, fatal arrhythmia), death from unknown cause, or an unwitnessed death, and all procedure-related deaths. Periprocedural MI was defined as elevation of cardiac biomarker values 3× greater than the 99th upper reference limit.[12] ID-TLR was defined as revascularization of the target lesion with a diameter stenosis of ≥70% without sign and symptoms, or diameter stenosis of ≥50% with ischemia or symptoms on follow-up angiography. ST was identified according to the definitions of the Academic Research Consortium.[13]

2.5 | Angiographic assessment

The quantitative coronary angiography (QCA) analysis was performed in 32 consecutive patients by the independent core laboratory at Cardiovascular Research Center, Sao Paulo, Brazil, using Medis QAngio XA 7.3 software (Medis Medical Imaging Systems, Leiden, The Netherlands). In-scaffold and in-segment (5 mm proximal and distal to the edges of the scaffold) characteristics were ascertained including RVD; minimal lumen diameter; percentage diameter stenosis and late lumen loss (LLL).

2.6 | Optical coherence tomography analysis

The OCT was analyzed by an independent core laboratory (Cardialysis BV, Rotterdam, the Netherlands) in a subset of 21 consecutive patients using LightLab Imaging workstation (St. Jude Medical, St. Paul, MN). A pullback system was incorporated inside the deployed scaffold for the image acquisition. Analysis of OCT was based on ultra-high-resolution, cross-sectional, intravascular images from back-scattered infrared signals. The quantitative parameters were determined including mean flow area, minimum lumen area, mean scaffold area, minimum scaffold area, mean strut area, mean neointimal hyperplasia area and percentage covered struts.

2.7 | Statistical analysis

This trial was designed to provide preliminary observations and generate hypothesis for future studies. Since there was no hypothesis testing in this study, a formal power and sample size calculations were not performed. However, the sample size requirement was determined by assessing the minimal number of patients required to provide reliable and non-trivial results. Baseline, lesion, and procedural analyses were performed on the intent-to-treat (ITT) patients. Clinical endpoints were analyzed in ITT or the modified-ITT (patients treated with MeRes100 BRS at the target lesion without major protocol deviations). In addition, at post-procedure and 6- month, QCA and OCT were performed in a subset of patients, respectively.

TABLE 2 Lesion and procedure characteristics of the intention-to-treat population

Variable	*N* = 69 lesions
Lesion location, n (%)	
Left anterior descending artery	43 (62.32)
Left circumflex artery	15 (21.74)
Right coronary artery	11 (15.94)
Lesion characteristics (ACC/AHA classification), n (%)	
Type A	8 (11.59)
Type B1	12 (17.39)
Type B2	39 (56.52)
Type C	10 (14.49)
Calcification, n (%)	
Mild	12 (17.39)
Moderate	4 (5.80)
Severe	11 (15.94)
Pre-procedure TIMI flow grade, n (%)	
TIMI 2	4 (5.8)
TIMI 3	65 (94.2)
Eccentric lesion, n (%)	38 (55.07)
Tortuosity (moderate/severe), n (%)	4 (5.80)
Bifurcation lesion, n (%)	3 (4.35)
Reference vessel diameter (mm), mean ± SD	3.03 ± 0.35
Minimum lumen diameter (mm), mean ± SD	1.15 ± 0.34
Diameter stenosis, (%)	62.17 ± 10.11
Lesion length, (mm)	14.37 ± 5.89
Scaffold length (mm), mean ± SD	21.21 ± 2.56
Scaffold diameter (mm), mean ± SD	3.19 ± 0.29
Pre-dilation, n (%)	68 (98.55)
Post-dilation, n (%)	69 (100.0)
Post-dilation with balloon 0.5 mm larger than the scaffold, n (%)	18 (26.08)
Lesions treated per patient	1.08
Procedure success	64
Device success	62
Medication at discharge, n (%)	
Aspirin	64 (100.0)
Clopidogrel	57 (89.06)
Ticagrelor	02 (3.13)
Statins	62 (96.88)
β-Blocker	48 (75.00)
ACE inhibitor/angiotensin receptor blockers	37 (57.81)

Abbreviations: ACC/AHA, American College of Cardiology/American Heart Association; ACE, angiotensin-converting enzyme; TIMI, thrombolysis in myocardial infarction.

Continuous variables were expressed as the mean ± standard deviation (SD) and categorical variables were presented as frequency with percentage. Comparisons of clinical, angiographic or procedure related characteristics of patients were performed using paired *t*-test for continuous variables and McNemar's test for categorical variables. Paired comparisons between baseline and follow-up for non-normal data were performed by a Wilcoxon signed-rank test. The Shapiro–Wilk test was used to verify for normality of data distribution. A normal distribution was assumed when the *p*-value exceeded .05. All the statistical analyses were performed using SAS, version 9.3 (SAS Institute, Cary, NC).

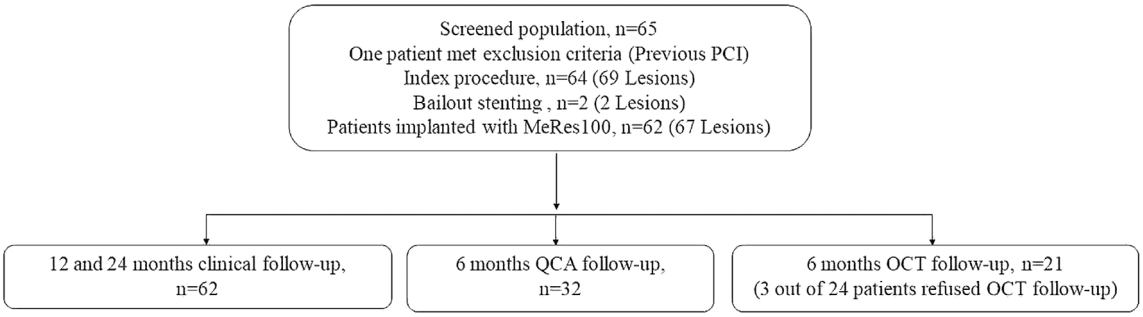

FIGURE 2 Flow diagram of MeRes-1 extend trial. OCT, optical coherence tomography; PCI, percutaneous coronary intervention; QCA, quantitative coronary angiography

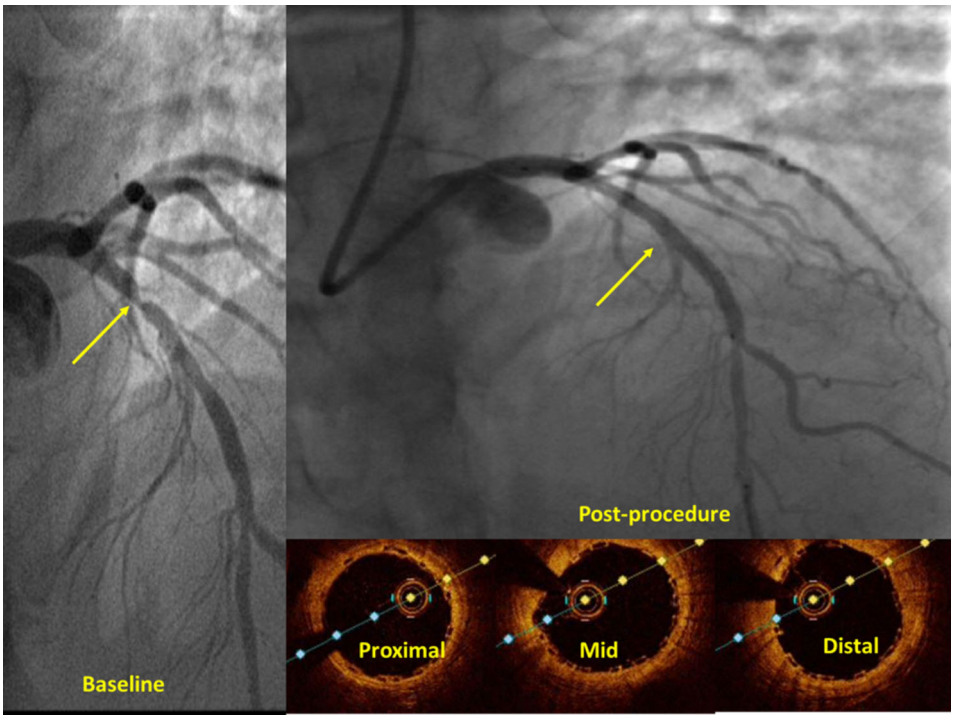

FIGURE 3 Index procedure of the TLR case. The MeRes100 (3.5 × 24 mm) was successfully implanted in the proximal left anterior descending (LAD) coronary artery under OCT guidance. TLR, target lesion revascularisation [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 3 Paired quantitative coronary angiography analysis at 6-month follow-up (*n* = 32 patients)

	In-scaffold			In-segment		
Characteristic	**Post-procedure**	**6-month**	***p* value**	**Post-procedure**	**6-month**	***p* value**
Mean reference vessel diameter (mm), mean ± SD	3.11 ± 0.41	3.06 ± 0.42	.04	3.08 ± 0.45	3.04 ± 0.44	.14
Minimal lumen diameter (mm), mean ± SD	2.74 ± 0.35	2.56 ± 0.42	.001	2.63 ± 0.45	2.46 ± 0.46	.01
Diameter stenosis (%), mean ± SD	11.70 ± 7.70	16.10 ± 10.90	.01	14.7 ± 7.90	18.50 ± 11.44	.02
Acute gain (mm), mean ± SD	1.69 ± 0.40	-	-	1.58 ± 0.43	-	-
Late lumen loss (mm), mean ± SD	-	0.18 ± 0.31	-	-	0.16 ± 0.32	-

3 | RESULTS

3.1 | Baseline and procedural characteristics

A total of 64 patients (with 69 lesions) were enrolled in the trial. Among them, a total of 67 lesions in 62 patients were treated with MeRes100 BRS at five clinical sites in Spain, Macedonia, Brazil, South Africa, Malaysia and Indonesia. This is a 2-year analysis of patients enrolled in the trial. Baseline characteristics of all patients are shown in Table 1. Overall, the mean age was 58.30 ± 9.02 years, 44 (68.75%) were male, and 17 (26.56%) had diabetes mellitus. Stable angina was the clinical presentation in 44 (68.75%) patients.

Lesion and procedural characteristics are summarized in Table 2. Out of 69 lesions, 49 (71.01%) were type B2/C according to the American College of Cardiology lesion classification. Average lesion length was 14.37 ± 5.89 mm, and mean RVD was 3.03 ± 0.35 mm.

3.2 | Clinical outcomes

The device success was achieved in 96.88% of the patients treated. In two patients, the bailout stenting was performed with DES. However, in both the cases, there was no issue with the deliverability of MeRes100 and its deployment. In one patient, bailout stenting was

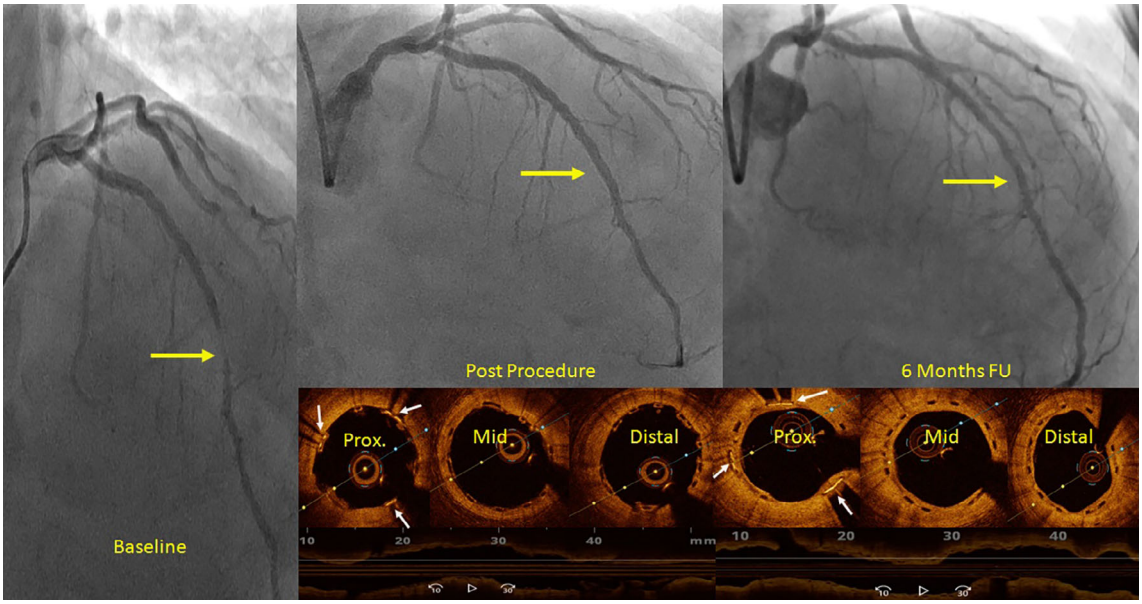

FIGURE 4 Case example from MeRes-1 extend study. The MeRes100 (3.0 × 24 mm) was implanted in the mid-left anterior descending (LAD) coronary artery and identified from angiogram at post-procedural and 6-month follow-up. Optical coherence tomography (OCT) image illustrates proximal scaffold marker (white arrow) at post-procedure and 6-month follow-up. Post-procedure cross-section view of scaffold segment represents the incomplete apposition of struts. At 6-month follow-up, scaffold struts were covered and well apposed to the vessel wall [Color figure can be viewed at wileyonlinelibrary.com]

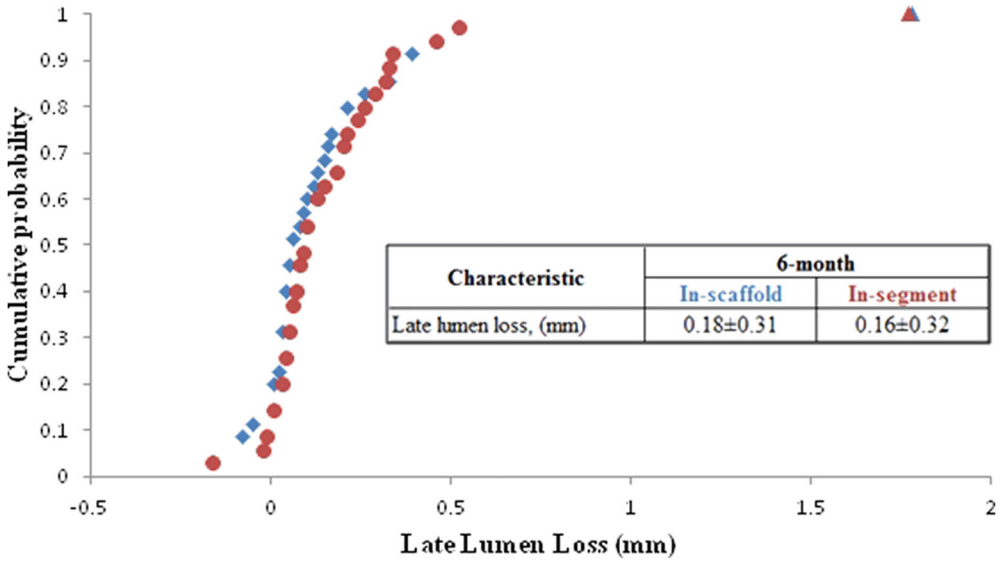

FIGURE 5 Cumulative frequency distribution curves for in-scaffold and in-segment LLL at 6-month follow-up. The triangle symbol represents the LLL values (1.77 mm in-scaffold and 1.78 mm in-segment) for the patient who underwent an ID-TLR on day 186. ID-TLR, ischemia-driven-target lesion revascularization; LLL, late lumen loss [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 4 Paired optical coherence tomography findings at 6-month follow-up (*n* = 21 patients)

Characteristic	Post-index procedure	6-month
Paired optical coherence tomography findings, n = 21 (32.81%)		
Mean scaffold area (mm^2), mean ± SD	7.41 ± 1.68	7.56 ± 1.79
Minimum scaffold area (mm^2), mean ± SD	6.12 ± 1.50	5.91 ± 1.44
Scaffold volume (mm^3), mean ± SD	155.13 ± 41.29	159.78 ± 36.33
Mean scaffold diameter (mm), mean ± SD	3.05 ± 0.35	3.08 ± 0.36
Minimum scaffold diameter (mm), mean ± SD	2.77 ± 0.35	2.72 ± 0.33
Mean lumen area (mm^2), mean ± SD	6.99 ± 1.74	6.04 ± 1.82
Minimum lumen area (mm^2), mean ± SD	5.46 ± 1.39	4.23 ± 1.19
Mean lumen diameter (mm), mean ± SD	2.96 ± 0.37	2.74 ± 0.40
Mean flow area (mm^2), mean ± SD	6.70 ± 1.67	6.04 ± 1.81
Mean neointimal hyperplasia area (mm^2), mean ± SD	-	1.47 ± 0.52
Neointimal hyperplasia volume (mm^3), mean ± SD	-	32.05 ± 13.32
Neointimal hyperplasia obstruction volume (%), mean ± SD	-	20.22 ± 6.95
Mean strut area (mm^2), mean ± SD	0.13 ± 0.03	0.11 ± 0.03
Malapposed struts (%), mean ± SD	4.68 ± 7.63	0.00 ± 0.00
Mean incomplete stent apposition area (mm^2), mean ± SD	0.06 ± 0.14	0.00 ± 0.00
Covered struts (%), mean ± SD	-	97.95 ± 3.69

done to cover the distal plaque in the same vessel (as two MeRes100 in one vessel were not allowed as per protocol); and in other patient, bailout stenting was done to treat proximal dissection. The study flow and the schedule for clinical, angiographic, and OCT follow-up are outlined in Figure 2.

Two-year clinical follow-up was completed in 62 (100%) modified-ITT patients. There was no incidence of MACE during hospital stay. However, only one MACE (1.61%) was reported, attributed to ID-TLR. Patient who experienced the event was a 49-year-old male with multiple comorbidities (diabetes, hypertension and dyslipidemia) who presented with stable angina class II. Baseline angiography revealed single vessel disease in the proximal left anterior descending artery. The MeRes100 (3.5 × 24 mm) was successfully implanted under OCT guidance (Figure 3). Post-dilatation after stent deployment was done with non-complaint balloon (3.5 × 15 mm) at maximum inflation pressure (18 atm, 20 s). At 6-month follow-up, angiography finding revealed that the patient had restenosis in the treated lesion and hence underwent PCI.

3.3 | Quantitative coronary angiography results

Results of QCA at post-procedure, and 6-month follow-up in the subset of 32 patients (excluding two patients treated with non-study device) are shown in Table 3 and Figure 4. At 6-month follow-up, mean in-scaffold LLL was 0.18 ± 0.31 mm and mean in-segment LLL was 0.16 ± 0.32 mm (Figure 5). The in-scaffold and in-segment percentage diameter stenosis were 16.10 ± 10.90% and 18.50 ± 11.44%, respectively. There was one case of in-scaffold binary restenosis.

3.4 | OCT results

OCT was carried out in the subset of 21 patients (excluding two patients treated with non-study device) (Table 4**)**. Quantitative OCT reported absolute and relative increase in mean scaffold area of 0.15 mm^2 and 2.02%, respectively. Neointimal coverage of struts was 97.95 ± 3.69% with in-scaffold neointimal hyperplasia obstruction volume of 20.22 ± 6.95%. The mean luminal area was 6.99 ± 1.74 mm^2 and the mean scaffold area was 7.41 ± 1.68 mm^2. Figure 3 shows OCT appearance of case example at post-procedure and 6-month follow-up.

4 | DISCUSSION

The key finding of this study demonstrates low MACE rate (1.61%) which was attributed to a single incidence of ID-TLR. None of the patient experienced MI, cardiac death or ST at 2-year clinical follow-up. QCA analysis confirmed one case of in-scaffold binary restenosis with relatively low in-scaffold LLL (0.18 mm). OCT sub-study showed that majority of the struts (97.95%) were covered at 6-month follow-up.

The MeRes-1 trial demonstrated safety and efficacy of the MeRes100 in 108 patients with de novo native coronary artery lesions at 1-year follow-up. The QCA finding showed in-scaffold LLL of 0.15 ± 0.23 mm at 6-month follow-up. The IVUS examinations revealed non-significant increase in mean lumen area (6.14 ± 1.28–6.25 ± 1.21 mm^2; p = .64) and mean scaffold area (6.17 ± 1.27–6.47 ± 1.25 mm^2; p = .12) between the post-procedure and 6 months. The OCT analysis demonstrated almost complete neointimal strut coverage (99.30%). Moreover, at 12-month follow-up, MACE occurred in only one patient (0.93%) in the form of ID-TLR; with no incidence of ST.[9]

The MeRes-1 Extend trial was designed to evaluate the safety and efficacy in diverse patient population with the intention to support and facilitate a more accurate estimate of the MACE and ST rates associated in the MeRes-1 first-in-man trial. The present study further confirms the findings from the MeRes-1 trial.

In the present study, the average post dilatation pressure was >18 atm. It is already known that high-pressure post dilatation after BRS implantation is associated with a good BRS expansion, reduced rate of edge dissections and strut malapposition.[14] Hence, it can be concluded that the high-pressure post-dilatation is safe in the newly designed thin strut MeRes100 BRS and is associated with the favorable outcomes as there was not a single case of strut malapposition.

Based on the LLL measure in a subset of 32 patients, MeRes100 was comparable to DESolve 150, Fantom and Magmaris scaffolds. In the MeRes-1 Extend trial, in-scaffold LLL was lower at 6 months (0.18 ± 0.31 mm) when compared to the DESolve Nx (0.20 ± 0.32 mm), FANTOM II (0.25 ± 0.40 mm) and BIOSOLVE-II (0.44 ± 0.36 mm) trials.[15-17] The results are also comparable to the current generation metallic DES where the in-stent LLL has ranged from 0.11 mm for the everolimus-eluting stents to 0.20 mm for the sirolimus-eluting stents at 6-month follow-up.[18,19] This result elucidated that the MeRes100 has established lower in-scaffold LLL which shows suppression of the "time-limited phenomenon" of restenosis between 3 and 6 months after implantation. Beyond this critical period, the active pharmacological inhibition of the neointima and mechanical support are no longer needed.[20] The OCT analysis supported the favorable efficacy profile of MeRes100, attributed to a very thin and homogenous layer of neointima covering scaffold struts (97.95%) at 6 months after deployment.

Currently, available CE marked BRS have higher rate of MACE and ST.[15,17,21] All these CE marked scaffolds are designed with thicker struts (DESolve, 150 μm; Magmaris, 150 μm; Absorb, 156 μm) as compared with the MeRes100 BRS (100 μm). The thicker strut BRS had higher TLR rates; 7.4% for DESolve, 5.9% for Magmaris, and 7.4% for Absorb when compared with the 1.61% for MeRes100 at 2-year follow-up.[15,17,22]

4.1 | Limitations

This trial was designed to provide preliminary observations and generate hypothesis for future studies. Hence, a formal power and sample size calculations were not performed. However, the sample size requirement was determined by assessing the minimal number of patients required to provide reliable and non-trivial results. Although the current analysis shows satisfactory clinical outcomes and imaging observations, the results are based on the treatment of small number of patients with simple lesions. Hence, an adequately powered randomized trial will be needed to assess the long-term efficacy and safety of MeRes100 BRS.

5 | CONCLUSIONS

In this clinical trial of patients with de novo coronary artery lesions undergoing PCI with a thin strut MeRes100 BRS, the clinical and angiographic outcomes were favorable with low rates of MACE, no ST or MI, low LLL and full strut coverage. Long-term follow-up and further well-powered comparative clinical trials are needed to confirm the safety and efficacy of MeRes100 BRS.

ACKNOWLEGEMENTS

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CONFLICT OF INTEREST

Dr. Alexandre Abizaid, Dr. Ricardo Costa and Dr. Sripal Bangalore are external scientific advisors to Meril Life Sciences Pvt. Ltd., India. Dr. Sripal Bangalore is a member of the advisory board, and has received research grants and honoraria from Abbott Vascular, USA. The other authors have no conflicts of interest to declare.

CLINICAL TRIAL REGISTRATION

https://www.clinicaltrials.gov. Unique identifier: NCT02663323.

DATA AVAILABILITY STATEMENT

Data available at request.

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