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Clinical outcomes of the BioMime™ morph coronary stent system for long (30 to ≤56 mm length) coronary lesions: Three-year follow-up of the Morpheus Global Registry

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ABSTRACT

Background: Percutaneous coronary intervention (PCI) of long coronary artery lesions (CAL) presents a puzzle, often requiring multiple stents. As the arteries twist and narrow, this becomes even more challenging with issues like potential distal overexpansion and proximal under expansion, and edge dissections. The study aims to assess the safety and performance of BioMime™ Morph sirolimus-eluting stent (SES) in individuals with long CAL.

Methods: This prospective, single-arm, multi-center, observational, real-world registry, included 565 patients with long CAL (length 30 to ≤56 mm) in native coronary arteries (reference vessel diameters: 2.25 mm to 3.50 mm). Based on lesion length, patients were implanted with 30 mm, 40 mm, 50 mm, or 60 mm BioMime™ Morph SES. Primary endpoint was freedom of target lesion failure (TLF) at 6-month and up to 36-month.

Results: Over 65 % of patients had lesions requiring 50 mm and 60 mm stents. The follow-up length was up to 24-month for the whole cohort and up to 36-month only for 211 patients from seven selected centers. The freedom from TLF rate was 97.86 %, 97.26 %, 96.27 %, and 95.15 % at 6-, 12-, 24-, and 36-month follow-ups, respectively.

Abbreviations: ADP, adenosine-diphosphate; AHA, American Heart Association; ARC, Academic Research Consortium; CAL, coronary artery lesion; CTO, chronic total occlusion; EC, Ethics Committee; DES, drug-eluting stent; ICH, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; ID-TLR, ischemia-driven target lesion revascularization; IEC, Independent Ethics Committee; IRB, institutional review board; ITT, Intention-To-Treat; LOCF, Last Observation Carried Forward; MACEs, major adverse cardiac events; MI, myocardial infarction; NSTEMI, Non-ST-Elevation Myocardial Infarction; PCI, percutaneous coronary intervention; PTCA, percutaneous transluminal coronary angioplasty; SD, standard deviation; SES, sirolimus-eluting stent; ST, stent thrombosis; TCAL, tapered coronary artery lesions; TIMI, Thrombolysis in Myocardial Infarction; TLF, target lesion failure; TLR, target lesion revascularization; TVF, target vessel failure; TVR, target vessel revascularization.

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The cumulative rates of major adverse cardiac events (MACE) were 2.74 % at 12-month, 3.73 % at 24-month and 4.85 % at 36-month. Additionally, the rates of ischemia-driven target lesion revascularization were 2.01 % at 12-month, 2.16 % at 24-month, and 3.88 % at 36-month. Lastly, stent thrombosis (ST) was reported in only 2 cases (0.97 %) at 36-month.

Conclusion: The lower incidences of MACE and ST up to three-year follow-up indicate BioMime™ Morph SES is an effective and safe option for PCI in long CAL.

1. Introduction

Long tapered coronary artery lesions (CALs) are common in real-life clinical situations [1]. Tapering refers to the ratio of change in the vessel area to the vessel length [2,3]. A tapered artery has unequal diameters at the proximal and distal ends [3,4]. Natural tapering can make it challenging to choose an ideal stent size for percutaneous coronary intervention (PCI) [3,5]. Conventional balloons are cylindrical, with a uniform diameter [4]. Selecting stent and balloon sizes based on the larger proximal reference diameter in tapered CALs (TCALs) may result in over-dilatation of the distal segment and increase the risk of artery injury [4,6]. On the other hand, using smaller distal reference diameter for sizing can result in inadequate dilatation of the proximal segment, which may increase residual malapposition and under-expansion [4]. To address this challenge multiple post-dilations with different balloon sizes are usually performed in clinical practice. Nevertheless, post-dilation with oversized balloons can cause deformation or structural damage of implanted stents [1,4]. Angiographic data have shown, right coronary artery and left anterior descending artery exhibit a tapering of roughly 9 % and 14 %, respectively, over their lengths [4,7]. Employing a tapered balloon during PCIs in tapered CALs might ensure effective dilation of the stenosis and preserve native anatomy of the arteries [4].

Long lesions in tapering arteries make it further difficult to select the appropriate interventional strategy [4]. In such cases, some clinicians may opt for placing multiple overlapping stents rather than one single long stent [1,3]. However, the impact of stent overlap on clinical outcomes remains uncertain, with some studies suggesting a potential increase in the likelihood of major adverse cardiac events (MACEs), while others report comparable outcomes [8–10]. It can cause increased neointimal proliferation and lumen loss due to delayed healing and increased inflammation [8,11], but also wide variations in drug concentration along the vessel wall with areas of low and high concentration [12]. Moreover, overlapped portions of the stents cause vessel rigidity due to the excess metal, leading to higher risk of stent fracture and restenosis [13]. In addition to unfavorable short-term outcomes, overlapping stents are also linked to adverse outcomes, which include death or myocardial infarction (MI) [3,8]. Nevertheless, stent overlap has been reported in as many as 30 % of patients undergoing PCI [8]. Currently available options for treating long tapered CALs include multiple overlapping stents, single long tubular stent, or single stent with a tapered end [1,9]. Data suggest that full lesion coverage is essential to prevent restenosis at stent edge [11] and one long stent may be preferable option compared to multiple overlapping stents for treating long lesions or tapered CALs. Additionally, long, tapered stents can be more appropriate for addressing extended TCALs [1].

In summary, currently available balloon-expandable stents in the treatment of long tapered CALs have limitations possibly leading to stent malapposition, overexpansion, under expansion, edge dissection, and immediate vascular injury. BioMime™ Morph Sirolimus-Eluting Coronary Stent System (Meril Life Sciences Pvt. Ltd., India) is a tapered sirolimus-eluting stent (SES), available up to sizes of 60 mm in length [3,14]. BioMime™ Morph SES system is suitable for tapering native coronaries with long lesions [3,15]. Previous studies have reported the safety and performance of BioMime™ Morph at 12 months in long tapered CALs. The objective of this investigation is to assess the safety and performance of the BioMime™ Morph SES system through 36 months follow-up in patients with long TCALs.

2. Materials and methods

Morpheus Global Registry (NCT02901353) was a prospective, single-arm, multicenter, observational, real-world registry to assess the safety and performance of the BioMime™ Morph SES System for very long CALs. Nineteen sites from eleven countries participated in the study. The study followed the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) standards for clinical research including ICH-E6 (Good Clinical Practice) and ICH E3 (Study Reporting). Approval of the study was granted by EC/IRB/IEC of each site and informed consent was obtained from study participants.

2.1. Study population

Patients with very long lesions defined as lengths from 30 to 56 mm in native coronary arteries and with reference vessel diameters of 2.25 to 3.50 mm were included in this registry. Patients were implanted with a 30, 40, 50, or 60 mm BioMime™ Morph SES, based on the size of the lesion.

2.2. Study device description (Fig. 1)

BioMime™ Morph SES system was described in detail in the earlier publications [3]. In brief, BioMime Morph is a long-tapered, ultrathin (65 μm) SES system for treating long CALs. It uses cobalt-chromium platform (L605) with unique hybrid cell design, including open cells in the mid-segment and closed cells at the tapered end [3]. BioMime™ Morph is available with a choice of two delivery systems:

a) A long and tapered PTCA balloon catheter
b) A long and tapered PTCA balloon catheter with a hydrophilic coated distal shaft except for balloon and soft tip.

2.3. Eligibility criteria

Study included patients aged 18 years and older with significant native coronary artery stenosis (>50 % by visual assessment) and lesions ranging from 30 to 56 mm in length. Patients with contraindications to medications like aspirin, heparin, clopidogrel, cobalt-chromium, contrast agents, and sirolimus; those requiring elective surgery necessitating interruption of antiplatelet therapy within first 6 months post enrolment; and individuals actively participating in another drug or device investigational study were excluded from the study.

2.4. Endpoints

2.4.1. Primary endpoints

Freedom from target lesion failure (TLF) at 6 months and up to 36 months.

2.4.2. Secondary endpoints

Major adverse cardiovascular events (MACE), target vessel failure (TVF), and Academic Research Consortium (ARC)-defined stent thrombosis (ST) at 1-, 6-, 12-, 24- and 36 months; procedural success and device success.

2.4.2.1. Definitions. TLF: composite of cardiac death, myocardial infarction, and target lesion revascularization (TLR). MACE: composite of cardiac death and MI attributed to the target vessel or ischemia-driven target lesion revascularization (ID-TLR). TVF: cardiac death, MI attributed to the target vessel, or target vessel revascularization. ST was categorized as definite, probable, and possible ST during the acute, subacute, late and very late phase. Procedure success was defined as angiographic evidence of <30 % final residual stenosis of the target lesion after stent placement and no occurrence of a procedure-related MACE prior to hospital discharge (for subjects with more than one stented lesion, the worst outcome was considered). Device success was defined as angiographic evidence of <30 % final

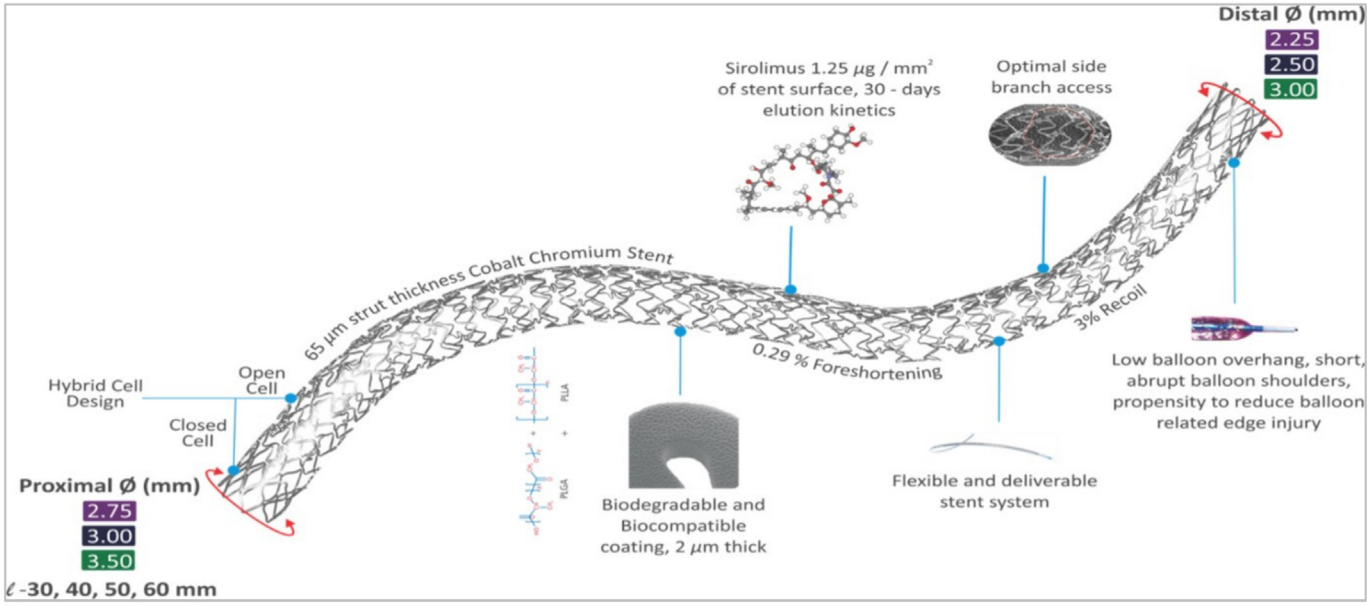

Fig. 1. Study device: BioMime™ Morph.

residual stenosis of the target lesion using only the assigned device [3]. Procedure success was defined as angiographic evidence of <30 % final residual stenosis of the target lesion after stent placement and no occurrence of a procedure-related MACE prior to hospital discharge (for subjects with more than one stented lesion, the worse case was counted). Peri-procedural MI was defined according to the Third Universal definition of MI [16].

2.5. Follow-up schedule

The clinical follow-up assessments were performed at 1-, 6-, and 12 months; with further clinical/telephonic follow-up at 24 months, and telephonic follow-up at 36 months.

2.6. Anticoagulation during and after the procedure

A loading dose of aspirin and an adenosine-diphosphate (ADP) receptor antagonist (clopidogrel, prasugrel, or ticagrelor) was administered within 24 h, but no later than one-hour prior to the index procedure as per current clinical practice guidelines. Following the procedure, 75 mg clopidogrel or 5 to 10 mg prasugrel once daily or 90 mg ticagrelor twice daily was administered for a minimum period of 12 months. Additionally, ≥75 to ≤100 mg aspirin was administered daily through the 12-month follow-up during the study and was continued indefinitely [17].

2.7. Sample size calculation

The objective of this study was to assess the safety and performance of the BioMime™ Morph SES system (30, 40, 50, or 60 mm) over a three-year period in individuals with extended and narrowing coronary artery lesions.

Based on previous literature showing a 96.8 % rate of freedom from TLF [18], a sample of 360 subjects gives a 95 % confidence interval of 2.1 % (Wilson) margin of error. Considering a 10 % dropout rate, a total of 400 subjects needed to be recruited for this study.

2.8. Statistical analysis

Descriptive statistics including mean ± standard deviations (SD) for continuous variables and frequencies with percentages for categorical

Table 1
Baseline characteristics of patients.

Baseline characteristics	Patients (n = 565)	50 mm length stent (n = 165)	60 mm length stent (n = 210)
Age, years, mean ± SD	65.53 ± 10.37	66.05 ± 10.47	65.20 ± 10.23
Sex, n (%)			
Male	432 (76.46)	120 (72.73)	171 (81.43)
Female	133 (23.54)	45 (27.27)	39 (18.57)
Medical history, n (%)			
Diabetes	176 (31.15)	48 (29.09)	66 (31.43)
Hypertension	397 (70.27)	115 (69.70)	147 (70.00)
Hyperlipidemia	374 (66.19)	109 (66.06)	152 (72.38)
Renal insufficiency	41 (7.26)	6 (3.64)	18 (8.57)
Previous myocardial infarction	161 (28.50)	39 (23.64)	75 (35.71)
Previous percutaneous coronary intervention	209 (36.99)	55 (33.33)	96 (45.71)
Previous coronary artery bypass surgery	44 (7.79)	72 (43.64)	102 (48.57)
Family history of coronary artery disease	256 (45.31)	10 (6.06)	26 (12.38)
Clinical presentation, n (%)			
Stable angina	227 (40.18)	58 (35.15)	112 (53.33)
Unstable angina	98 (17.35)	35 (21.21)	30 (14.29)
ST-elevation myocardial infarction (STEMI)	96 (16.99)	32 (19.39)	27 (12.86)
Non-STEMI	101 (17.88)	29 (17.58)	21 (10.00)
Silent ischemia	20 (3.54)	6 (3.64)	9 (4.29)
Asymptomatic	23 (4.07)	5 (3.03)	11 (5.24)

Table 2
Lesion characteristics.

Lesion characteristics	Overall patients n = 565 patients/605 lesions	50 mm length n = 165 patients/168 lesions	60 mm length n = 210 patients/226 lesions
Total number of lesions treated with the study stent	605	168	226
Total study device implanted	606	168	227
Stenosis, n (%)			
De novo	568 (93.88)	157 (93.45)	215 (95.13)
In-stent	25 (4.13)	7 (4.17)	9 (3.98)
Bifurcation	10 (1.65)	4 (2.38)	2 (0.88)
Trifurcation	2 (0.33)		
Procedure access site, n (%)			
Radial	421 (74.51)	146 (88.48)	115 (54.76)
Femoral	141 (24.96)	19 (11.52)	93 (44.29)
Others	3 (0.53)	0	2 (0.95)
Ulnar	2(0.35)	0	1(0.48)
Radial + femoral	1 (0.18)	0	1(0.48)
Pre-dilatation, n (%)	553 (91.40)	149 (88.69)	223 (98.67)
Post-dilatation, n (%)	449 (74.21)	131 (77.98)	175 (77.43)
Lesion location, n (%)			
RCA	228 (37.69)	60 (35.71)	126 (55.75)
LAD	302 (49.92)	92 (54.76)	81 (35.84)
LCx	69 (11.40)	14 (8.33)	19 (8.41)
Left main	2(0.33)	1 (0.59)	0
Others	4 (0.66)	1(0.59)	0
Obtuse marginal I	1(0.17)	–	–
Diagonal II	1(0.17)	1(0.59)	0
First diagonal	1(0.17)	–	–
Obtuse marginal III	1(0.17)	–	–
Lesion type, n (%)	n = 1038	n = 305	n = 380
Calcified	119 (11.46)	40 (13.11)	36 (9.47)
CTO	171 (16.47)	24 (7.87)	118 (31.05)
Diffused	234 (22.54)	76 (24.92)	73 (19.21)
Thrombus	63 (6.07)	21 (6.89)	22 (5.79)
Lesion class (ACC/AHA classification), n (%)			
Type A	23 (3.80)	4 (2.38)	7 (3.10)
Type B1	121 (20.00)	32 (19.05)	24 (10.62)
Type B2	64 (10.58)	19 (11.31)	16 (7.08)
Type C	397 (65.62)	113 (67.26)	179 (79.20)
Mean lesion length, mm, mean ± SD	47.91 ± 9.37	–	–
Stent length, mm, n (%)			
Average stent length, mm, mean ± SD	49.21 ± 10.17	–	–
30	64 (10.56)	–	–
40	147 (24.26)	–	–
50	168 (27.72)	168	–
60	227 (37.46)	–	227
Stent diameter, mm, n (%)			
Average stent diameter, mm, mean ± SD	2.98 ± 0.30	2.99 ± 0.30	3.00 ± 0.29
2.75–2.25	81 (13.37)	24 (14.29)	27 (11.89)
3.00–2.50	209 (34.49)	52 (30.95)	71 (31.28)
3.50–2.75	0	92 (54.76)	129 (56.83)
3.50–3.00	316 (52.14)	0	0
Procedure success	565 (100.00)	165 (100)	210 (100)
Device success	565 (100.00)	165 (100)	210 (100)

ACC, American College of Cardiology; AHA, American Heart Association; CTO, chronic total occlusion; LAD, left anterior descending artery; LCx, left circumflex artery; RCA, right coronary artery; SD, standard deviation.

variables were used to present the data. All endpoints were primarily analyzed on the Intention-To-Treat (ITT) evaluable population. All subjects lost to follow-up with a clinical endpoint after 6 months were considered for effectiveness evaluation based on Last Observation Carried Forward (LOCF) population. Statistical analysis was performed with Statistical Package for Social Sciences (SPSS) v22.0 (IBM Corp., Somers, NY, USA).

3. Results

Overall, 565 patients were recruited in this registry. Mean age of the patients was 65.53 ± 10.37 years and 76.46 % were males. Table 1 presents the baseline characteristics of overall study patients. The total number of lesions treated with the study device were 605 and a total of 606 stents were deployed. The mean lesion length was 47.91 ± 9.37 mm. Almost 94 % of patients had de novo lesions. The lesion characteristics are shown in Table 2. BioMime™ Morph stents of sizes 30 mm, 40 mm, 50 mm, and 60 mm were deployed in 64 (10.56 %), 147 (24.26 %), 168 (27.72 %), and 227 (37.46 %) patients respectively.

The baseline and lesion characteristics of patients who required 50 mm and 60 mm stents are shown in Table 1 and Table 2, respectively. Most baseline characteristics of this cohort were not different from the overall cohort, except for a lower proportion of patients with previous MI and history of previous PCI. The proportion of patients with stable angina was lower and that with unstable angina was higher compared to that in the overall cohort. Importantly, in 60 mm stent group, almost 63 % had Thrombolysis in Myocardial Infarction (TIMI) flow grade 0. Moreover, almost one-third of patients in the 60 mm subgroup had a chronic total occlusion (CTO).

The number of patients in the overall cohort, who completed the 12- and 24-month follow-ups were 548 and 510, respectively. The extension

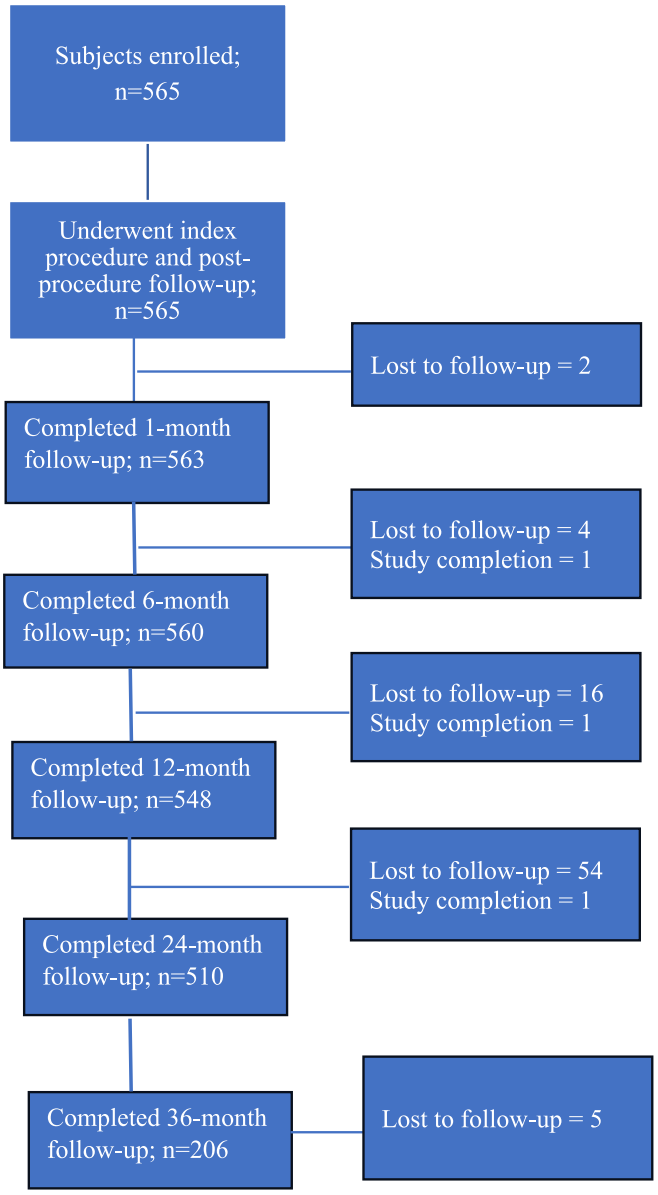

Fig. 2. Flowchart of the study participants.
At 36-month follow-up, patients from only seven sites were followed up (enrolled = 211).

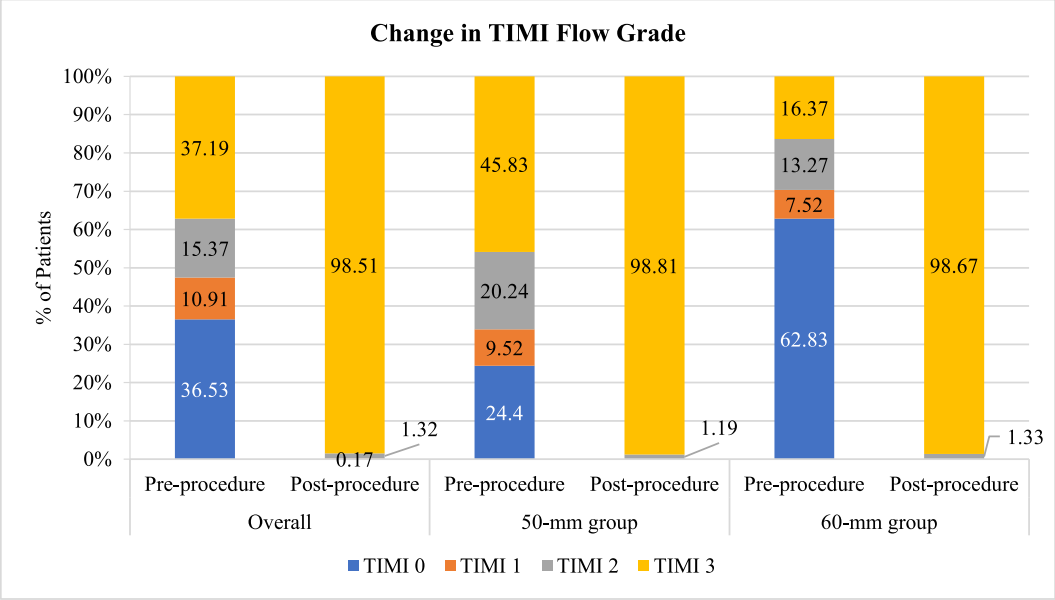

Fig. 3. Change in TIMI flow grade.
TIMI: thrombolysis in myocardial infarction.

of 36-month follow-up was conducted at seven sites with 211 enrolled patients, out of which 206 patients completed their 36-month follow-up. The disposition of the study patients is shown in Fig. 2.

In the entire patient cohort, both the device success rate and procedural success rate were 100 %. More than 98 % of the patients achieved TIMI-3 flow grade after intervention with BioMime™ Morph SES (Fig. 3). There were no in-hospital deaths. There was one case of Non-ST-Elevation Myocardial Infarction (NSTEMI) during in-hospital stay. The 24-month and 36-month cumulative outcomes are shown in Table 3 and Table 4. There were no in-hospital events of all-cause mortality, ID-TLR, TVR, and ST. The cumulative ST rate remained low, at 0.36 % from 1 month to 12 months, increasing marginally to 0.39 % at 24 months and 0.97 % at 36 months. At 24 months, all-cause mortality, MACE, and TVF rates were 3.33 %, 3.73 %, and 4.12 %, respectively, and at 36 months, they were 3.40 %, 4.85 %, and 4.85 %. Freedom from TLF rate was 96.27 % and 95.15 % at 24 and 36 months, respectively, reflecting favorable long-term outcomes. The Kaplan-Meier curves for primary and secondary outcomes at 24- and 36-months are shown in Supplemental Fig. 1(A)–(D) and Supplemental Fig. 2(A)–(D), respectively.

Among the patients, who required 50 mm and 60 mm stents, >98 % of the patients achieved TIMI-3 flow grade after intervention with BioMime™ Morph SES (Fig. 3). The cumulative 24-month and 36-month outcomes of this cohort are shown in Table 5 and Table 6, respectively. The rates of cardiac death, ID-TLR, TVR, TVF, and TLF at 12 and 36 months were higher in the 60 mm group compared to the rest of the cohort. MACE rates at 36-month follow-up were 3.94 % in 50 mm group and 4.16 % in 60 mm group, respectively.

Table 3
Cumulative 24-month outcomes.

Events, n (%)	In-hospital (n = 565)	1-month (n = 563)	6-month (n = 560)	12-month (n = 548)	24-month (n = 510)
All-cause death	0	3 (0.53)	8 (1.43)	8 (1.46)	17 (3.33)
Cardiac death	0	2 (0.36)	4 (0.71)	4 (0.73)	8 (1.57)[^]
Non-cardiac death	0	1 (0.18)	4 (0.71)	4 (0.73)	8 (1.57)
Sudden death	0	0	0	0	1 (0.20)
TV-MI	1 (0.18)	2 (0.36)[*]	2 (0.36)[@]	4 (0.73)[#]	4 (0.78)[$]
Q-Wave	0	0	0	0	0
Non Q-Wave	1 (0.18)	2 (0.36)	2 (0.36)	4 (0.73)	4 (0.78)
ID-TLR	0	2 (0.36)[*]	7 (1.25)[@a]	11 (2.01)[#,a]	11 (2.16)[$,^,a]
TVR	0	2 (0.36)[*]	9 (1.61)[@a]	13 (2.37)[#,a]	13 (2.55)[$,^,a]
Stent thrombosis	0	2 (0.36)	2 (0.36)	2 (0.36)	2 (0.39)
Definite	0	1 (0.18)	1 (0.18)	1 (0.18)	1 (0.20)
Probable	0	0	0	0	0
Possible	0	1 (0.18)	1 (0.18)	1 (0.18)	1 (0.20)
TVF	1 (0.18)	5 (0.89)	14 (2.5)	17 (3.1)	21 (4.12)
MACE	1 (0.18)	5 (0.89)	12 (2.14)	15 (2.74)	19 (3.73)
TLF	1 (0.18)	5 (0.89)	12 (2.14)	15 (2.74)	19 (3.73)
Freedom of TLF	564 (99.82)	558 (99.11)	548 (97.86)	533 (97.26)	491 (96.27)

ID-TLR: ischemia-driven target lesion revascularization, MACE: major adverse cardiac events composite of cardiac death, myocardial infarction attributed to the target vessel or ischemia-driven TLR, TV-MI: target vessel-myocardial infraction, TVR: target vessel revascularization, ST: stent thrombosis, TVF: target vessel failure cardiac death, myocardial infarction attributed to the target vessel, or target vessel revascularization, TLF: target lesion failure.

[*] 1 patient had TV-MI, ID-TLR and TVR.
[@] 1 patient had TV-MI, ID-TLR and TVR.
[#] 3 patients had TV-MI, ID-TLR and TVR.
[$] 3 patients had TV-MI, ID-TLR and TVR.
[^] 1 patient had Cardiac death, ID-TLR and TVR.
[a] 1 patient underwent re-PCI with medicated balloon at 6-month and 12-month follow-up.

4. Discussion

This study evaluated the safety and performance of the BioMime™ Morph SES in patients with long TCALs over 36 months. The key findings were: a) a high device and procedure success rate (100 %) with no procedure-related deaths; (b) high freedom from TLF rates at 24 (96.27 %) and 36 months (95.15 %); (c) low rates of ST, TV-MI, and MACEs over 36 months; and (d) although the 60-mm group showed higher rates of cardiac death, ID-TLR, and TVR than overall cohort at 12 and 36 months, the cumulative rates of MACEs, ST, TVF and TLF at 12-, 24-, and 36-month follow-ups were lower in this group, despite having very long lesions.

Over 65 % of our cohort had very long lesions that required stent sizes of 50 mm or 60 mm, and nearly 50 % of the cohort had pre-procedural TIMI grade 0 or 1. Moreover, 65 % of patients had lesions classified as American Heart Association (AHA) class C, which have a <60 % rate of PCI success [19]. In a recent analysis of the IRIS-DES registry, it was determined that a stent length of 43.0 mm serves as the critical threshold for predicting the risk of TVF associated with second-generation drug-eluting

Table 4
Cumulative clinical outcomes up to 36-month follow-up.*

Events, n (%)	In-hospital (n = 211)	1-month (n = 211)	6-month (n = 210)	12-month (n = 207)	24-month (n = 206)	36-month (n = 206)
All-cause death	0	2 (0.94)	4 (1.90)	4 (1.93)	7 (3.40)	7 (3.40)
Cardiac death	0	1 (0.47)	2 (0.95)	2 (0.96)	4 (1.94)[!]	4 (1.94)[!]
Non-cardiac death	0	1 (0.47)	2 (0.95)	2 (0.96)	3 (1.45)	3 (1.45)
Sudden death	0	0	0	0	0	0
TV-MI	0	0	0	2 (0.96)[#]	2(0.97)[#]	2 (0.97)[#]
Q-Wave	0	0	0	0	0	0
Q-Wave	0	0	0	2 (0.96)	2 (0.97)	2 (0.97)
ID-TLR	0	2 (0.94)	5 (2.38)[a]	8 (3.86)[#a]	8 (3.88)[#!a]	8 (3.88)[#!a]
TVR	0	2 (0.94)	5 (2.38)[a]	8 (3.86)[#a]	8 (3.88)[#!a]	8 (3.88)[#!a]
Stent thrombosis	0	2 (0.94)	2 (0.95)	2 (0.96)	2 (0.97)	2 (0.97)
Definite	0	1 (0.47)	1 (0.47)	1 (0.48)	1 (0.48)	1 (0.48)
Probable	0	0	0	0	0	0
Possible	0	1 (0.47)	1 (0.47)	1 (0.48)	1 (0.48)	1 (0.48)
TVF	0	3 (1.42)	7 (3.33)	9 (4.34)	10 (4.85)	10 (4.85)
MACE	0	3 (1.42)	7 (3.33)	9(4.34)	10 (4.85)	10 (4.85)
TLF	0	3 (1.42)	7 (3.33)	9 (4.34)	10 (4.85)	10 (4.85)
Freedom of TLF	211 (100)	208 (98.58)	203 (96.67)	198 (95.65)	196 (95.15)	196 (95.15)

ID-TLR: ischemia-driven target lesion revascularization, MACE: major adverse cardiac events composite of cardiac death, myocardial infarction attributed to the target vessel or ischemia-driven TLR, TV-MI: target vessel-myocardial infraction, TVR: target vessel revascularization, ST: stent thrombosis, TVF: target vessel failure cardiac death, myocardial infarction attributed to the target vessel, or target vessel revascularization, TLF: target lesion failure.

* Data from 7 sites is available for 36-month follow-up.

[#] 2 patients had TV-MI, ID-TLR and TVR.

[!] 1 patient had Cardiac death, ID-TLR and TVR.

[a] 1 patient underwent re-PCI with medicated balloon at 6-month and 12-month follow-up.

stent (DES) [20]. Considering these factors, the outcomes of the current registry are encouraging.

Several studies have previously examined the outcomes with BioMime™ Morph SES for lesions longer than 30 mm. However, previous studies have reported post-procedural or 12-month outcomes. Zivelonghi et al. were the first to report on the use of BioMime™ Morph SES in a specific cohort of 49 patients with CTO lesions, with a mean lesion length of 50.7 ± 25.4 mm. They achieved a success rate of 98 %, with a 10-month TVR of 4.1 %. It is important to note that these outcomes are specific to a CTO patient population, hence they may differ with results from studies involving a broader range of lesion types [21]. Valero et al. evaluated the safety and efficacy of the BioMime™ Morph in a prospective cohort of 50 consecutive patients, in whom a 60 mm long BioMime Morph implantation was attempted; 78 % of coronary lesions in the cohort were >48 mm. Optimal angiographic results were achieved in 92 % of patients with no angiographic distal vessel dissection. Over a median follow-up of 275 days, no cases of MACE were observed [13]. Matchin et al. reported satisfactory clinical outcomes in 85 patients at 12-month follow-up, the use of BioMime™ Morph stent (60 mm) resulted in a 9.4 % MACE rate with no ST [22]. In a recent publication on single-centre experience by Patted et al., BioMime Morph has shown 100 % device and procedural success. At three-year follow-up, MACE was 7.95 % without any ST, ID-TVR, and ID-TLR. Freedom from TLF was 92.05 %. In this study, >50 % of the patients were implanted with 50 mm (32.61 %) and 60 mm (20.65 %) stent lengths [3].

Table 5
Cumulative 24-month outcomes in the 50 mm and 60 mm subgroups.

Event, n (%)	In-hospital		1-month FU		6-month FU		12-month FU		24-month FU	
	50 mm (n = 165)	60 mm (n = 210)	50 mm (n = 165)	60 mm (n = 209)	50 mm (n = 165)	60 mm (n = 208)	50 mm (n = 165)	60 mm (n = 198)	50 mm (n = 165)	60 mm (n = 161)
All-cause death	0	0	1 (0.61)	0	3 (1.82)	1 (0.48)	3 (1.82)	1 (0.51)	6 (3.64)	4 (2.48)
Cardiac death	0	0	1 (0.61)	0	2 (1.21)	0	2 (1.21)	0	3 (1.82)	3 (1.86)[!]
Non-cardiac death	0	0	0	0	1 (0.61)	1 (1.48)	1 (0.61)	1 (0.51)	2 (1.21)	1 (0.62)
Sudden death	0	0	0	0	0	0	0	0	1 (0.65)	0
TV-MI	0	1 (0.48)	1 (0.61)*	1 (0.48)	1 (0.61)*	1 (0.48)	1 (0.61)*	2 (1.01)	1 (0.61)*	2 (1.24)
Q-wave	0	0	0	0	0	0	0	0	0	0
Q-wave	0	1 (0.48)	1 (0.61)	1 (0.48)	1 (0.61)	1 (0.48)	1 (0.61)	2 (1.01)	1 (0.61)	2 (1.24)
ID-TLR	0	0	1 (0.61)*	0	2 (1.21)*	3 (1.44)[#]	3 (1.82)*	5 (2.53)[$]	3 (1.82)*	5 (3.11)[@!]
TVR	0	0	1 (0.61)*	0	3 (1.82)*	3 (1.44)[#]	4 (2.42)*	5 (2.53)[$]	4 (2.42)*	5 (3.11)[@!]
Stent thrombosis	0	0	1 (0.61)	0	1 (0.61)	0	1 (0.61)	0	1 (0.61)	0
Definite	0	0	0	0	0	0	0	0	0	0
Probable	0	0	0	0	0	0	0	0	0	0
Possible	0	0	1 (0.61)	0	1 (0.61)	0	1 (0.61)	0	1 (0.61)	0
TVF	0	1 (0.48)	2 (1.21)	1 (0.48)	5 (3.03)	4 (1.92)	5 (3.03)	6 (3.03)	7 (4.24)	8 (4.97)
MACE	0	1 (0.48)	2 (1.21)	1 (0.48)	4 (2.42)	4 (1.92)	4 (2.42)	6 (3.03)	6 (3.64)	8 (4.97)
TLF	0	1 (0.48)	2 (1.21)	1 (0.48)	4 (2.42)	4 (1.92)	4 (2.42)	6 (3.03)	6 (3.64)	8 (4.97)
Freedom of TLF	165 (100)	209 (99.52)	163 (98.79)	208 (99.52)	161 (97.58)	204 (98.08)	161 (97.58)	192 (96.97)	159 (96.36)	153 (95.03)

ID-TLR: ischemia-driven target lesion revascularization; MACE: major adverse cardiac events composed of myocardial infarction attributed to the target vessel or ischemia-driven TLR; TV-MI: target vessel myocardial infraction; TVR: target vessel revascularization; ST: stent thrombosis; TVF: target vessel failure; TLF: target lesion failure.

* 1 patient had TV-MI, ID-TLR and TVR.

[#] 3 patients had ID-TLR and TVR.

[$] 5 patients had ID-TLR and TVR.

[@] 5 patients had ID-TLR and TVR.

[!] 1 patient had cardiac death ID-TLR and TVR.

Table 6
Cumulative 36-month* outcomes in the 50 mm and 60 mm subgroups.

Event, n (%)	In-hospital		1-month FU		6-month FU		12-month FU		24-month FU		36-month FU	
	50 mm (n = 76)	60 mm (n = 74)	50 mm (n = 76)	60 mm (n = 74)	50 mm (n = 76)	60 mm (n = 74)	50 mm (n = 76)	60 mm (n = 72)	50 mm (n = 76)	60 mm (n = 72)	50 mm (n = 76)	60 mm (n = 72)
All-cause death	0	0	0	0	2 (2.63)	0	2 (2.63)	0	2 (2.63)	2 (2.77)	2 (2.63)	2 (2.77)
Cardiac death	0	0	0	0	1 (1.31)	0	1 (1.31)	0	1 (1.31)	2 (2.77)^	1 (1.31)	2 (2.77)^
Non-cardiac death	0	0	0	0	1 (1.31)	0	1 (1.31)	0	1 (1.31)	0	1 (1.31)	0
Sudden death	0	0	0	0	0	0	0	0	0	0	0	0
TV-MI	0	0	1 (1.31)!	0	1 (1.31)!	0	1 (1.31)!	0	1 (1.31)!	0	1 (1.31)!	0
Q-Wave	0	0	0	0	0	0	0	0	0	0	0	0
Non-Q-Wave	0	0	1 (1.31)	0	1 (1.31)	0	1 (1.31)	0	1 (1.31)	0	1 (1.31)	0
ID-TLR	0	0	1 (1.31)!	0	2 (2.63)!	2 (2.70)@	3 (3.94)!	3 (4.16)#	3 (3.94)!	3 (4.16)$^	3 (3.94)!	3 (4.16)$^
TVR	0	0	1 (1.31)!	0	2 (2.63)!	2 (2.70)@	3 (3.94)!	3 (4.16)#	3 (3.94)!	3 (4.16)$^	3 (3.94)!	3 (4.16)$^
Stent thrombosis	0	0	1 (1.31)	0	1 (1.31)	0	1 (1.31)	0	1 (1.31)	0	1 (1.31)	0
Definite	0	0	0	0	0	0	0	0	0	0	0	0
Probable	0	0	0	0	0	0	0	0	0	0	0	0
0		0	1 (1.31)	0	1 (1.31)	0	1 (1.31)	0	1 (1.31)	0	1 (1.31)	0
TVF	0	0	1 (1.31)	0	3 (3.94)	2 (2.70)	3 (3.94)	3 (4.16)	3 (3.94)	3 (4.16)	3 (3.94)	3 (4.16)
MACE	0	0	1 (1.31)	0	3 (3.94)	2 (2.70)	3 (3.94)	3 (4.16)	3 (3.94)	3 (4.16)	3 (3.94)	3 (4.16)
TLF	0	0	1 (1.31)	0	3 (3.94)	2 (2.70)	3 (3.94)	3 (4.16)	3 (3.94)	3 (4.16)	3 (3.94)	3 (4.16)
Freedom of TLF	76 (100)	74 (100)	75 (98.69)	74 (100)	73 (96.06)	72 (97.30)	73 (96.06)	69 (95.84)	73 (96.06)	69 (95.84)	73 (96.06)	69 (95.84)

ID-TLR: ischemia-driven target lesion revascularization, MACE: major adverse cardiac events composed of myocardial infarction attributed to the target vessel or ischemia-driven TLR. TV-MI: target vessel myocardial infraction, TVR: target vessel revascularization, ST: stent thrombosis, TVF: target vessel failure composed of cardiac death, myocardial infarction attributed to the target vessel, or target vessel revascularization, TLF: target lesion failure.

! 1 patient had TV-MI, ID-TLR and TVR.

@ 2 patients had ID-TLR and TV.

3 patients had ID-TLR and TV.

$ 3 patients had cardiac death, ID-TLR and TVR.

^ 1 patient had cardiac death, ID-TLR and TVR.

* 7 sites data available till 36 months follow-up.

A real-world study conducted by Lupi et al. used the BioMime™ Morph stent to treat 272 patients with long lesions (mean length 48.8 ± 9.5 mm; AHA lesion grade B2 or C). The study population had comorbidities such as type 2 diabetes, acute coronary syndrome, and complex coronary artery disease. The procedure success rate was 96.7 %. During the hospital stay, none of the patients were reported with ST, repeat MI or revascularization of the target coronary vessel [23]. Sharma et al. reported the 12-month outcomes of the BioMime™ Morph in 172 Indian patients with long CALs with a mean target lesion length of 34.4 ± 10.4 mm and the implanted mean stent length was 53.2 ± 8.7 mm. Successful deployment of the stent was achieved in 98.2 % of cases. The rate of MACE at 1, 6, and 12 months was 2.3 %, 4.0 %, and 4.7 %, respectively [24]. The outcomes of our study are comparable with these previous reports. Thevan et al. reported the outcomes with BioMime™ Morph 60 mm in 88 patients who underwent primary PCI for acute STEMI. The procedure success rate was 96 %, with the 12-month rates of MACE, cardiac death, and TVR being 4 % each [25]. Our study is the first multi-national registry to report 36-month outcomes with the BioMime™ Morph used in long CALs (30 mm to ≤56 mm length).

Few other studies also examined other long stents, such as the SPIRIT 48 trial with XIENCE Skypoint 48 mm drug-eluting stent in which a total of 107 subjects with long de novo native CALs were studied. This trial reported 97.2 % device success rate, 5.8 % cardiac death/all MI and 5.7 % TLF at one-year. These rates were higher compared to the BioMime™ Morph in our study, where 100 % device success, and the 1-year rates for cardiac death, MI, and TLF were 0.96 %, 0.96 %, and 4.34 %, respectively were reported [26]. Furthermore, other studies have investigated the comparative performance of single long stents vs. multiple stents for long CALs. Qiao Shu Bin et al., evaluated the incidence of MACE and ST between patients who underwent single vs. multiple stenting. At 6 months, there was a significantly lower rate of cumulative incidence of MACE (composite of death, acute MI and TVR) in the single stent group compared to the multiple stenting group (3.2 % vs. 4.9 %, $p = 0.04$) [27]. Clinical and angiographic outcomes in patients implanted with single stents vs. those with overlapped stents for diffuse CALs were investigated by Mori et al., and demonstrated comparable rates of freedom from MACE and freedom from TLR at one-year follow-up between the two groups [10]. Jurado-Román et al. compared consecutive patients (n = 628) with diffuse lesions treated with either single long stent of >40 mm length or overlapping stents [9]. The reported MACE (6.2 % vs. 9.7 %) and ST rates (0.4 % vs. 0.9 %) were comparable between the two groups. In the studies by Mori et al. [10] and Jurado-Román et al. [9], it was found that there were no significant differences in the MACE rates between the groups that received a single stent and those that received multiple stents. Nonetheless, the use of overlapping stents resulted in increased contrast volume, longer procedure duration, and higher radiation dose.

5. Limitations

The limitations of our study include: first, the lack of a comparator arm due to the retrospective nature of the study design. Secondly, the absence of angiographic follow-up limited the objective confirmation of the outcomes. Lastly, 36-month follow-up data was only available from 7 sites and these outcomes do not conclusively establish the long-term efficacy. Hence, a longer follow-up duration is necessary. Further studies with long-term follow-up and comparator devices are necessary to further validate these findings.

6. Conclusion

In conclusion, our study reported low rates of MACE and ST through three years follow-up suggesting a good mid- to long-term safety and efficacy of the BioMime™ Morph SES used for PCI of long atherosclerotic lesions.

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CRediT authorship contribution statement

Pierfrancesco Agostoni: Writing – review & editing, Writing – original draft, Validation, Supervision, Project administration, Methodology,

Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Jan-Peter Van Kuijk:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Paul Knaapen:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Farhat Fouladvand:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Martin Hudec:** Writing – review & editing, Writing – original draft, Supervision, Resources, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Antonino Nicosia:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Kari Kervinen:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Salvatore Davide Tomasello:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Ramesh Singh Arjan Singh:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Girish N. Vishwanathan:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Béla Merkely:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Houng Bang Liew:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Khalid Al Faraidy:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Clive Corbett:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Saleem Dawood:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Anirban Choudhury:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Imad Abdelhafiz Alhaddad:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Azfar Zaman:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Adriaan O. Kraaijeveld:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Martino Pepe:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

Dr. Pierfrancesco Agostoni reports consulting/speaker/proctoring honoraria from Boston Scientific, CardiaWave, iVascular, Neovasc, Seven Sons, Teleflex, Terumo. Dr. Paul Knaapen reports grant support from HeartFlow. Dr. Martin Hudec received grant/ research support from Meril Life Sciences. Dr. Kari Kervinen reports consulting fees/honoraria from Medtentia and Amgen. Dr. Béla Merkely reports grants from Boston Scientific, NRDIF Hungary, National Heart Program; personal fees from Biotronik, Abbott, Astra Zeneca, Novartis, and Boehringer-Ingelheim; and grants from Medtronic. Dr. Houng Bang Liew has received speaker fees and honorarium from Medtronic and Boston Scientific; personal fees from Novartis Corporation, Bayer, Medtronic, and Boston Scientific; grants/research support from BBraun, Medtronic International Ltd., OrbusNeich Medical Co. Ltd.; honoraria or consultation fees from BBraun, and OrbusNeich Medical Co. Ltd. Dr. Anirban Choudhury have received lecture/consulting/proctor fees from Meril Lifesciences, Vascular Perspective, Teleflex, SMT, Bayer and Iroko Cardio. Dr. Azfar Zaman have received lecture/consulting fees/research support from Abbott Vascular, Boston Scientific, Cardinal Health, Medtronic Corporation, SMT, Meril, HeartFlow; speakers' fees from SMT; honoraria from SMT, Medtronic, Abbott Vascular, Meril, Boston Scientific. Dr. Adriaan O. Kraaijeveld reports research grants from Xenios AG. Lecture fees from Abiomed, Novartis and Inari; consultancy fees from Dekra, Abbott and Boston Scientific, received speakers fee from BTG, Abbott, funding from Abiomed. All the other authors declare that there is no conflict of interest regarding the publication of this article.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.carrev.2025.02.010.

Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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