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Original Article

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Long-Term Safety and Performance of BioMime™ Morph Sirolimus-Eluting Coronary Stent System for Very Long Coronary Lesions

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Abstract

Background: The use of multiple overlapping stents for long lesions in tapered coronary arteries has been associated with poor outcomes. This study was conducted to evaluate the 3-year safety and performance of the BioMime™ Morph sirolimus-eluting stent (SES) in very long (length 30 to ≤ 56 mm) coronary lesions in native coronary arteries with a reference vessel diameter of 2.25 to 3.50 mm.

Methods: This was a prospective, single-center, observational, real-world, post-marketing surveillance study. Eligible patients were implanted with BioMime™ Morph SES. Patients were followed up at 6, 12, 24, and 36 months.

Results: A total of 88 patients were enrolled in the study. The mean age was 58.72 ± 10.10 years and 82.95% were male. Most patients had angina (81.82%) and ischemic heart disease (78.41%), and there was a high prevalence of comorbidities like diabetes mellitus (59.09%), and hypertension (54.55%). A total of 92 long coronary *de novo* lesions were treated with BioMime™ Morph SES with an average stent length of 45.54 ± 10.20 mm. Device and procedural success rates were 100%. One patient died at 30 days and one case of myocardial infarction was recorded. The cumulative rates of major adverse cardiovascular events (MACEs) at 6, 12, 24, and 36 months were 3.41%, 6.82%, 7.95%, and 7.95%, respectively. There were no cases of stent thrombosis (ST), ischemia-driven target vessel revascularization, or ischemia-driven target lesion revascularization until 36 months of follow-up.

Conclusion: BioMime™ Morph SES showed favorable outcomes up to 3 years in treating very long coronary lesions in native coronary arteries, as demonstrated by an acceptable rate of MACEs and absence of ST, based on clinical outcomes up to 3 years.

Keywords: BioMime Morph; *De novo* lesions; Drug-eluting stent; Stent thrombosis; Tapered stent; Target vessel failure; Long coronary lesions; Tapering coronary vessels

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Introduction

Long coronary vessels are prone to natural tapering. Stenosis or occlusions in major parts of a long coronary vessel can pose a challenge in selecting the optimal stent size during percutaneous coronary intervention (PCI) [1]. Tapering is defined as the ratio of the area change to the vessel length [2]. Studies have shown that tapering of coronary arteries is common. Banka et al assessed the degree of taper between 1 cm proximal and distal to the stenosis. They found that 23% of arteries showed > 1 mm taper, 19% of arteries showed 0.5 - 0.99 mm taper, and reverse tapering was seen in 8% of arteries [3]. Similarly, Zhang et al showed that in Asians, the left anterior descending (LAD) artery had an average diameter of 3.92 mm at the origin and 2.10 mm at the distal end, with a 7.7% decrease in the ratio. The average diameter of the left circumflex artery (LCx) was 3.57 mm at the origin and 2.10 mm at the distal end, with a 9.7% decrease in the ratio, and the average diameter of the right coronary artery (RCA) was 3.97 mm at the origin and 2.15 mm at the distal end, with a 5.1% decrease in the ratio [4]. Angiographic data have shown that LAD and RCA taper approximately 14% and 9%, respectively, along their lengths [5].

Contemporary drug-eluting stents (DESs) are commonly used for PCI in long-tapered segments. However, in such cases, there are often considerable discrepancies between the proximal and distal parts of the targeted lesion. Hence, the optimal stent size must be selected according to the distal diameter of the treated segment. However, this leads to a mismatch between the stent size and the proximal diameter of the vessel, which requires post-dilatation using larger balloons to ensure optimal strut apposition [6]. Different stent model designs can have a critical impact on overexpansion results [7]. Incomplete stent apposition is known to increase the risk of in-stent restenosis and stent thrombosis (ST) [8].

Malapposition of stents due to incomplete stent expansion is a predictor of adverse outcomes. On the contrary, extensive overexpansion approaching the physical limits of the stent might affect the mechanical stiffness of the stent and the drug delivery process, limiting the performance of the device [9-11]. In the overexpanded regions, the increased cell diameter can cause a reduction in drug elution per mm, which can lead to a higher risk of excessive neointimal proliferation [6]. Further, there is an increased risk of damage to the drug-coating or the detachment of debris leading to higher rates of thrombosis and

inflammation, with neointimal reactions, after overexpansion of the stent [12]. Hence, some clinicians deploy multiple overlapping stents instead of a single long stent. However, studies have shown that stent overlapping is associated with delayed healing and increased inflammation at the site of deployment, which ultimately results in impaired angiographic and long-term clinical outcomes, including death or myocardial infarction (MI) [13].

A dedicated long-tapered DES could overcome the challenges of stenting tapered coronary arteries. It has been reported that a single long-tapered BioMime™ Morph SES system is often adequate for treating a long, diffuse lesion in tapered arteries thereby avoiding the risks associated with multiple stenting and stent overlapping [14]. This stent system is designed to be deployed across single long lesions in a tapering coronary artery. It can be used for *de novo* lesions with lengths 30 to ≤ 56 mm in coronary arteries like the LAD and RCA. Several previous studies have reported the procedural success rates and 1-year safety and efficacy outcomes of this stent system for long coronary lesions [14-22].

This study was conducted to evaluate the 3-year safety and performance of the aforementioned BioMime™ Morph SES in very long (length 30 to ≤ 56 mm) coronary lesions in native coronary arteries with reference vessel diameters of 2.25 to 3.50 mm.

Materials and Methods

Study design and patient population

This was a prospective, single-arm, single-center, observational, post-marketing surveillance study to evaluate the safety and performance of the BioMime™ Morph SES in very long (length 30 to ≤ 56 mm) coronary lesions in native coronary arteries with reference vessel diameter of 2.25 to 3.50 mm in real-world settings.

Eligibility criteria

The inclusion criteria were age ≥ 18 years, significant native coronary artery stenosis (> 50% by visual estimate) with lesion length of 30 to ≤ 56 mm. Patients with contraindication to any of the medications including aspirin, heparin, clopidogrel, cobalt chromium, contrast agents, or sirolimus, those participating in any other drug or device investigational study, or females with ongoing pregnancy or lactation were excluded from the study.

Ethics statement

This study was conducted according to the ICH standards for clinical research including ICH-E6 (Good Clinical Practice) and ICH E3 (Study Reporting); ISO 14155 standards for the conduct of the study. The Institutional Review Board and Independent Ethics Committee provided approval for the study (Ref: KLEU/EC/2016-17/D-3896, dated: January 10, 2017). The study was registered on the National Institute of Medical Statistics portal of the Indian Council of Medical Research, Clinical Trials Registry - India (CTRI) (CTRI number: CTRI/2017/03/008167).

Study device

BioMime™ Morph SES is a novel, ultra-thin (65 µm) balloon expandable sirolimus-eluting long-tapered stent for the treatment of long coronary lesions. It consists of an L605 cobalt-chromium alloy platform coated with biodegradable polymers poly (L-lactide) (PLLA), 50/50 poly (D,L-lactide-co-glycoside) (PLGA). This L605 cobalt-chromium long stent mounted on a long and tapered rapid-exchange percutaneous transluminal coronary angioplasty (PTCA) balloon catheter (Xpedient™/Mozec™) between two platinum-iridium radiopaque marker bands placed on the inner lumen within the balloon segment. Long and tapered sizes of the PTCA balloon catheters are specially designed to suit the anatomically tapering arteries. The balloon tapers from the proximal to the distal end with approximately 0.5 mm taper and the stent remains expanded after deflation of the balloon. BioMime Morph device is depicted in Figure 1.

Procedure

PCI was performed according to the standard practices. The choice of access site, pre-dilatation or direct stenting, the use of glycoprotein IIb/IIIa inhibitors, deployment of a pressure wire, approach for treating branching or completely blocked artery segments, and stent selection including type, length, and diameter were at the operator's discretion. A staged procedure was allowed if necessary, and such cases were not considered as instances of revascularization. During the index procedure, anticoagulation was maintained using unfractionated heparin. Following PCI, patients were prescribed antiplatelet therapy (aspirin + ticagrelor/clopidogrel/prasugrel) as per the investigator's discretion and in accordance with the standard guidelines of the American College of Cardiology/American Heart Association/European Society of Cardiology (ACC/AHA/ESC). Procedural success, device success, freedom of target lesion failure (TLF), and target vessel failure (TVF) were recorded to evaluate the performance of BioMime™ Morph SES.

Endpoints and follow-up

Safety endpoints

The safety endpoints were major adverse cardiovascular events (MACEs), cardiac death, MI, ischemia-driven target lesion revascularization (ID-TLR), ischemia-driven target vessel revascularization (ID-TVR), and ST at each follow-up till 36 months.

MACE was defined as a composite of cardiac death, MI attributed to the target vessel or ID-TLR. Cardiac death was defined as any death resulting from an acute MI, sudden car-

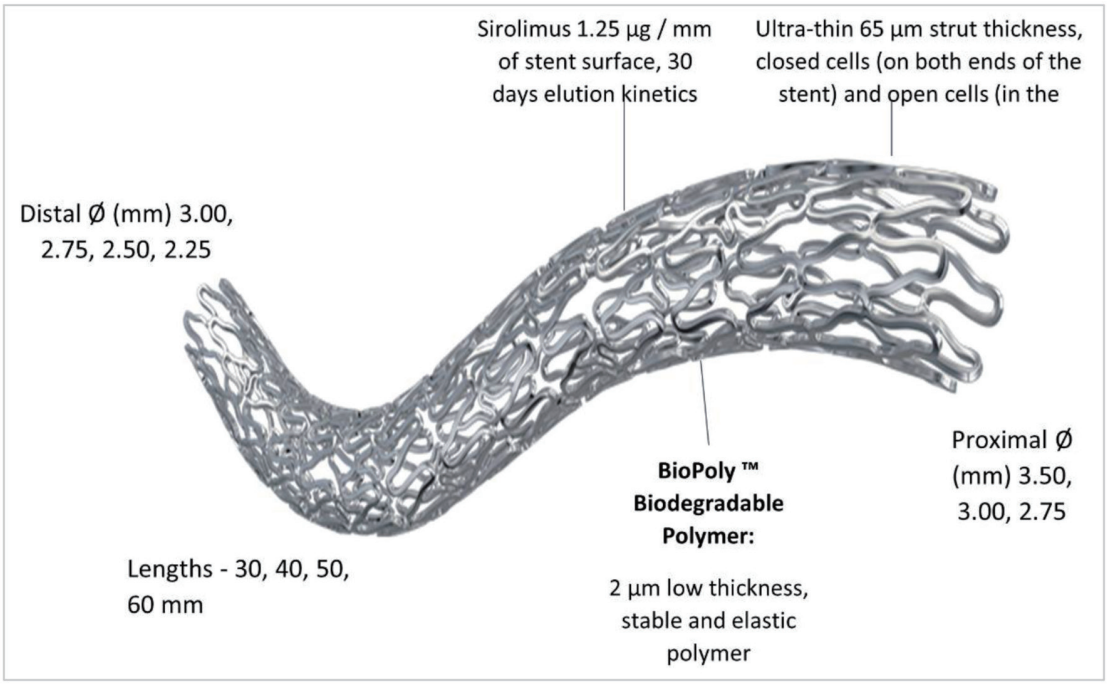

Figure 1. Design and features of BioMime™ Morph SES. SES: sirolimus-eluting stent.

diac death, death due to heart failure, or death due to stroke. MI was defined as the development of new, pathological Q waves on electrocardiogram, or elevation of creatinine kinase (CK) ≥ 2-fold the upper limit of normal with elevated CK-MB in the absence of new pathological Q waves. ID-TLR included any repeat PCI of the target lesion or bypass surgery of the target vessel performed for restenosis or other complications of the target lesion. ID-TVR included any repeat percutaneous intervention or surgical bypass for any segment in the target vessel. ST was defined as the presence of a thrombus that originates in the stent or in the segment of 5 mm proximal or distal to the stent and the presence of at least one of the following criteria within a 48-h time frame: 1) acute onset of ischemic symptoms at rest; 2) new ischemic electrocardiogram (ECG) changes that suggest acute ischemia; and 3) typical rise and fall in cardiac biomarkers.

Performance endpoints

The performance endpoints were TVF and freedom from TLF at each follow-up till 36 months. Additional performance endpoints included procedural success 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 (subjects implanted with stents for more than 1 lesion, the worse outcome was considered) and device success defined as angiographic evidence of < 30% final residual stenosis of the target lesion using only the assigned device. Freedom from TLF was defined as a composite of cardiac death, MI attributed to the target vessel, and TLR. TVF was defined as the composite of cardiac death, MI attributed to the target vessel, or TVR.

The patients were followed up at 1, 6, 12, 24, and 36 months post-procedure. During the follow-up, the occurrence of MACE, cardiac death, MI, ID-TLR, ID-TVR, and ST was recorded.

Statistical analysis

The data were analyzed based on the assessment of outcome measures for the study population on an intention-to-treat basis. Continuous variables are summarized as means ± standard deviations, while categorical data are presented as numbers/frequency with percentages. The safety analysis was performed after excluding the dropouts and subjects lost to follow-up. The statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) version 21 (IBM Corporation, Chicago, IL, USA). The Kaplan-Meier estimate was used for the presentation of MACEs.

Results

A total of 88 patients were enrolled in the study. All subjects completed the 3-year follow-up after the index procedure (Fig. 2).

Baseline and demographic characteristics

The eligible study population comprised 82.95% men and 17.05% women, with a mean age of 58.72 ± 10.10 years. Most

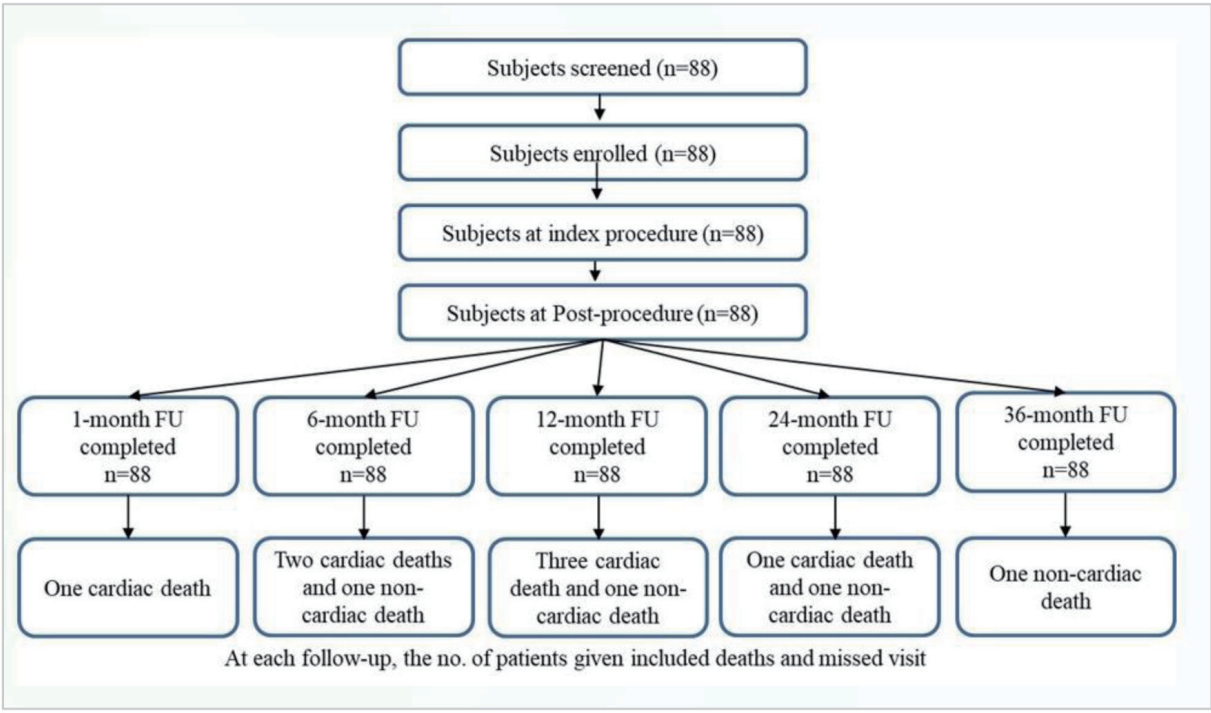

Figure 2. Study flowchart of patient enrolment and follow-up.

patients had a history of angina (81.82%) and ischemic heart disease (IHD) (78.41%). The leading risk factors for cardiovascular disease including diabetes mellitus (59.09%) and hypertension (54.55%) were also prevalent in our study population. The mean left ventricular ejection fraction (LVEF) at baseline was 50.23±9.22%. Almost 50% of patients presented with ST-elevation myocardial infarction (STEMI), followed by unstable angina in 12.50%. The baseline characteristics of the patients are shown in Table 1.

Lesion characteristics

A total of 92 *de novo* coronary lesions with an average lesion length of 43.32 ± 9.46 mm and mean diameter stenosis of 90.17 ± 9.93% were implanted with of BioMime™ Morph SESs (1.05 stents/patient). The lesion characteristics are shown in Table 2.

All lesions were successfully implanted with a long, tapered BioMime™ Morph SES alone, with the device and procedural success rates of 100%. The average length of the implanted study device was 45.54 ± 10.20 mm and the average diameter was 2.99 ± 0.29 mm. The majority of the procedures were performed through a transfemoral approach (97.73%). The ionic contrast media were the most commonly used media in all procedures. In most patients, both pre-dilatations and post-dilatations were performed. The thrombolysis in myocardial infarction (TIMI) flow improved to grade III in all lesions, signifying the re-establishment of myocardial reperfusion. The procedural outcomes are shown in Table 3. All the patients were prescribed dual antiplatelet therapy: clopidogrel (n = 82), prasugrel (n = 1) and ticagrelor (n = 5). Antilipidemic drugs (atorvastatin (n = 6) and statin (n = 64)) were prescribed in 70 (79.54%) patients.

Outcomes at 3 years

All the patients were event-free during the hospital stay with the freedom from TLF rate of 100%. In terms of early events (1 month), one patient had MI, which led to TLF and ultimately resulted in cardiac death. At 1 month, no cases of non-cardiac death were reported and 98.86% of patients were free from TLF. During 3-year follow-up, the cumulative MACE rates were 7.95% including 7.95% of cardiac deaths due to MI. The MACE free survival rate was 92% at 36 months of follow-up as shown in Figure 3. No cases of ID-TLR, ID-TVR, and ST were reported till the final follow-up. The cumulative 3-year outcomes are shown in Table 4.

Discussion

The results of our study suggest that the BioMime™ Morph SES has favorable outcomes up to 3 years in the treatment of very long lesions, evidenced by an acceptable rate of MACEs and absence of ST. The outcomes were favorable although more than 50% of the cohort had TIMI grades 0 and 1 before the procedure and 53.26% required stent sizes of 50 and 60 mm.

More than 20% of PCI cases in modern clinical practice are associated with diffuse long lesions, which are a significant contributor to adverse clinical outcomes [23]. The IRIS-DES

Table 1. Baseline and Demographic Characteristics

Characteristics	n = 88
Age, years, mean ± SD	58.72 ± 10.10
Sex, n (%)	
Male	73 (82.95)
Female	15 (17.05)
BMI, kg/m^2, mean ± SD	25.59 ± 3.35
Systolic blood pressure, mm Hg, mean ± SD	128.91 ± 23.78
Diastolic blood pressure, mm Hg, mean ± SD	80.94 ± 10.03
Heart rate, beats per minute, mean ± SD	77.32 ± 10.81
Medical history, n (%)	
Diabetes mellitus	52 (59.09)
Hypertension	48 (54.55)
Dyslipidemia	1 (1.14)
Smoking	14 (15.91)
Alcohol consumption	6 (6.82)
COPD	2 (2.27)
Ischemic heart disease	69 (78.41)
Angina	72 (81.82)
PCI	2 (2.27)
Stroke	2 (2.27)
Other illness	1 (1.14)
Family history of CAD	4 (4.55)
LVEF, %, mean ± SD	50.23 ± 9.22
Cardiac status, n (%)	
Stable angina	2 (2.27)
Unstable angina	11 (12.50)
STEMI	44 (50.00)
NSTEMI	5 (5.68)
Asymptomatic/silent ischemia	2 (2.27)

BMI: body mass index; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; LVEF: left ventricular ejection fraction; NSTEMI: non-ST-elevation myocardial infarction; PCI: percutaneous coronary intervention; SD: standard deviation; STEMI: ST-elevation myocardial infarction.

Table 2. Lesion Characteristics

Variables	Treated lesions (n = 92)/patients (n = 88)
Diseased vessel, n (%)	
Single vessel	29 (32.95)
Double vessel	41 (46.6)
Triple vessel or more	18 (20.45)
Lesion type, n (%)	
Calcified	4 (4.35)
Diffused	1 (1.09)
CTO	5 (5.43)
Thrombus	17 (18.48)
Discrete	11 (11.96)
Tandem	1 (1.09)
Lesion location (CASS code), n (%)	
RCA	24 (26.09)
LAD	63 (68.48)
LCx	5 (5.43)
Lesion class, n (%)	
A	11 (11.96)
B1	41 (44.57)
B2	17 (18.48)
C	23 (25.00)
Stenosis type, n (%)	
de novo	92 (100)
In-stent	0
Bifurcation	0

CASS: coronary artery surgery study; CTO: chronic total occlusion; LAD: left anterior descending artery; LCx: left circumflex artery; RCA: right coronary artery.

registry that stratified patients with long lesions and/or small vessel diameters based on the cutoff points of the stent parameters, found that poor clinical outcomes were associated with a greater stent length and smaller stent diameter. This registry showed that a stent length of 43.0 mm was the differential cutoff for predicting the risk of TVF with second-generation DES [24]. Considering these factors, our outcomes are very encouraging.

In a single-center, non-randomized, comparative study by Im et al, the 3-year outcomes of two groups including patients with long lesions (> 30 mm) treated with zotarolimus-eluting stent and SES were compared. The results of the SES arm (n = 265) showed an ID-TLR rate of 4.6% and a 2.4% rate of definite ST, which were higher than those in our study. However, the cardiac death and MI rates in their study were lower due to a greater utilization rate of intravascular ultrasound (IVUS) (62% lesions in the SES group) leading to better stent expansion in complex lesions. Despite the lack of IVUS, our study showed 0% TLR and no ST events [25].

Kang et al previously compared the 12-month outcomes of three randomized clinical trials of the LONG-DES (LONG-DES III, IV, and V trials) in percutaneous treatment of LONG native coronary lesions with DES. The comparison of their findings with those of our study is shown in Table 5 [23, 26-32]. Our MACE outcomes are superior to all studies compared by Kang et al [23]. Importantly, despite the average stent length used in our study being 45.54 ± 10.20 mm, there were no cases of ST, ID-TLR, and ID-TVR up to 3 years of follow-up. Among other studies on long stents, the SPIRIT 48 trial evaluated the safety and efficacy of the XIENCE Skypoint 48 mm DES in 107 subjects with coronary artery disease having long *de novo* native coronary le-

Table 3. Procedural Outcomes

Characteristics	Treated lesions (n = 92)/patients (n = 88)
Total number of lesions treated with study device	92
Total number of study device deployed	92
Study stents per patient	1.05
Totally occluded	23 (25.00)
Diameter stenosis (%), mean ± SD	90.17 ± 9.93
Average lesion length, mm, mean ± SD	43.32 ± 9.46
Procedure access site location, n (%)	
Femoral right	86 (97.73)
Radial right	2 (2.27)
Contrast media used, n (%)	
Ionic	60 (68.18)
Non-ionic	28 (31.82)
TIMI flow pre-procedure, n (%)	
0	21 (22.83)
1	28 (30.43)
2	43 (46.74)
3	0
TIMI flow post-procedure, n (%)	
0	0
1	0
2	0
3	92 (100)
Pre-dilatation, n (%)	83 (90.22)
Post-dilatation, n (%)	72 (78.26)
Average stent length, mm, mean ± SD	45.54 ± 10.20
Average stent diameter, mm, mean ± SD	2.99 ± 0.29
Stent length (mm), n (%)	
30	17 (18.48)
40	26 (28.26)
50	30 (32.61)
60	19 (20.65)
Stent diameter (mm), n (%)	
3.00 - 2.50	34 (36.96)
3.50 - 3.00	49 (53.26)
2.75 - 2.25	9 (9.78)
3.50 - 2.75	0
Procedure success, n (%)	88 (100)
Device success, n (%)	88 (100)

SD: standard deviation; TIMI: thrombolysis in myocardial infarction.

sions. Though the device success rate was 97.2%, the rate of cardiac death/all MI at 1 year was 5.8% and the TLF rate was 5.7%, which were much higher than the rates with BioMime™ Morph SES [33].

Previous studies have reported outcomes with BioMime™ Morph SES in long coronary lesions. Among the initial studies was one by Matchin et al, who reported a 98.8% clinical success rate. Restenosis was seen in 10.4% of patients

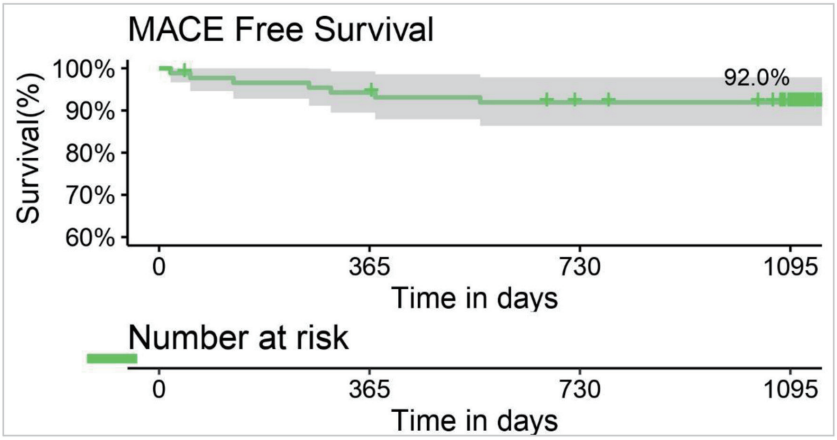

Figure 3. Kaplan-Meier curve for MACE free survival at 36 months. MACE: major adverse cardiovascular event.

at 12 months [15]. Subsequently, Patted et al reported a cumulative MACE incidence of 2.0% and ST of 0.3% at 12-month follow-up with the same stent [14]. Podolec et al reported an MACE rate of 0% at 3, 6, and 12 months in a small cohort of 32 patients [16]. Jurado-Roman et al reported an MACE rate of 6.2% and an ST rate of 0% at 20 months [18], while Sharma et al reported a 1-year MACE rate of 4.7% [21]. We compared our results with some additional studies on long coronary lesions as shown in Table 5. The incidences of ST were 0% in our study, which was noted in very few studies like Karmpaliotis et al [28] and PtCr-EES, Re-ZES groups of Kang et al [23]. It is also worth noting that in almost all previous publications, the TLR and TVR rates were higher than our study (0%).

All previous studies of BioMime™ Morph SES reported only immediate post-procedure or 1-year outcomes, except one that reported 20-month outcomes. Ours is the first study to report 3-year outcomes with the BioMime™ Morph SES in real-world settings.

Nevertheless, there are some limitations to our study. The first is the lack of a comparator arm with another long stent or multiple stents. Further, the study lacks follow-up angiographic data; hence, we could not confirm the outcomes objectively. Further long-term studies with comparator arms comprising multiple stents for long lesions are necessary to validate these outcomes. The relatively small sample size might have limited the ability to assess rare clinical adverse outcomes.

Conclusion

The BioMime™ Morph SES appears to have favorable outcomes up to 3 years in the treatment of very long coronary lesions in native coronary arteries, as demonstrated by an acceptable rate of MACEs and absence of stent thrombosis, over 3 years.

Table 4. Cumulative Clinical Events up to 36 Months Follow-Up

Events, n (%)	In-hospital (n = 88)	Follow-up				
		1 month (n = 88)	6 months (n = 88)	12 months (n = 88)	24 months (n = 88)	36 months (n = 88)
All-cause death	0	1 (1.14)	4 (4.55)	8 (9.09)	10 (11.36)	11 (12.50)
Cardiac death[a]	0	1 (1.14)	3 (3.41)	6 (6.82)	7 (7.95)	7 (7.95)
Non-cardiac death	0	0	1 (1.14)	2 (2.27)	3 (3.41)	4 (4.55)
MI[a]	0	1 (1.14)	3 (3.41)	6 (6.82)	7 (7.95)	7 (7.95)
ID-TLR	0	0	0	0	0	0
ID-TVR	0	0	0	0	0	0
ST	0	0	0	0	0	0
TVF	0	1 (1.14)	3 (3.41)	6 (6.82)	7 (7.95)	7 (7.95)
TLF	0	1 (1.14)	3 (3.41)	6 (6.82)	7 (7.95)	7 (7.95)
MACE	0	1 (1.14)	3 (3.41)	6 (6.82)	7 (7.95)	7 (7.95)
Freedom from TLF	88 (100.0)	87 (98.86)	85 (96.59)	82 (93.18)	81 (92.05)	81 (92.05)

[a]Seven patients suffered from MI and cardiac death. ID-TLR: ischemia-driven target lesion revascularization; ID-TVR: ischemia-driven target vessel revascularization; MACE: major adverse cardiovascular event; MI: myocardial infarction; ST: stent thrombosis; TLF: target lesion failure; TVF: target vessel failure.

Table 5. Comparison of Clinical Outcomes Involving Contemporary DES in Long Lesion Trials

Variables/stents	BioMime™ Morph (current study)		Kang et al, 2022 [23]					Gautier et al, 2022 [26]
			CoCr-EES	PtCr-EES	Re-ZES	BP-BES	SES	EES
Number of patients	88		224	255	250	245	476	268
Average length of stent, mm	45.54 ± 10.20		46.5 ± 16.9	44.5 ± 16.8	45.9 ± 17.1	40.2 ± 13.4	45.6 ± 17.1	66 ± 22
Polymer type	Biodegradable		Biodegradable/ permanent	Biodegradable/ permanent	Biodegradable	Biodegradable	Permanent	Permanent
Drug	Sirolimus		Everolimus	Everolimus	Zotarolimus	Biolimus	Sirolimus	Everolimus
Clinical follow-up	12-month	36-month	12-month	12-month	12-month	12-month	12-month	12-month
Clinical outcomes, n (%)								
Cardiac death	6 (6.82)	7 (7.95)	0	1 (0.4)	1 (0.4)	2 (0.8)	2 (0.4)	2 (0.7)
MI	6 (6.82)	7 (7.95)	22 (9.8)	40 (15.7)	29 (11.6)	34 (13.9)	51 (10.7)	1.2[i]
ST	0	0	1 (0.4)	0	0	3 (1.2)	2 (0.4)	2 (0.7)[a]
MACE	6 (6.82)	7 (7.95)	32 (14.3)	42 (16.5)	35 (14.0)	41 (16.7)	62 (13.0)	NA
TLR	0[c]	0[c]	7 (3.1)	5 (2.0)	4 (1.6)	8 (3.3)	9 (1.9)	4.1[i]
TVR	0[c]	0[c]	9 (4.0)	5 (2.0)	5 (2.0)	9 (3.7)	10 (2.1)	NA

Variables/stents	BioMime™ Morph (current study)		Hsiao et al, 2022 [27]	Karmpaliotis et al, 2022 [28]	Sim et al, 2020 [29]	Paszek et al, 2019 [30]	Diaz Fernnndez et al, 2018 [31]	Rajesh et al, 2018 [32]
			EES	EES	EES	EES + ZES	EES	EES + SES
Number of patients	88		213	100	117	290	610	343
Average length of stent, mm	45.54 ± 10.20		60.1 ± 20.6[e]	50.96 ± 7.25	48.00	55.5 ± 16.8	39.83 ± 14.0	41.63 ± 2.77
Polymer type	Biodegradable		Permanent	Biodegradable	Permanent	Permanent	Permanent	NA
Drug	Sirolimus		Everolimus	Everolimus	Everolimus	Everolimus and zotarolimus	Everolimus	Everolimus and sirolimus
Clinical follow-up	12-month	36-month	12-month	12-month	12-month	831 days[h] (range: 390 - 1,373; interquartile range: 459)	12-month	12-month (n = 314)
Clinical outcomes, n (%)								
Cardiac death	6 (6.82)	7 (7.95)	3 (1.4)	1 (1.0)	1 (0.9)	21 (6.9)	1 (0.2)	5 (1.6)
MI	6 (6.82)	7 (7.95)	3 (1.4)	2 (2.0)	4 (3.4)	19 (6.6)	8 (1.3)	2 (0.6)
ST	0	0	2 (0.9)	0	1 (0.9)[f]	21 (7.2)[b]	4 (0.7)	7 (2.2)[d]
MACE	6 (6.82)	7 (7.95)	NA	NA	7 (6.0)	39 (13.4)[g]	13 (2.1)	19 (6)
TLR	0[c]	0[c]	NA	1 (1.0)	1 (0.9)	NA	4 (0.7)	3 (1)
TVR	0[c]	0[c]	7 (3.3)	1 (1.0)	1 (0.9)	18 (6.2)	NA	NA

[a]Definite ST. [b]Definite and probable ST. [c]Ischemia driven. [d]Total probable stent thrombosis. [e]Mean stent length per lesion. [f]Probable ST. [g]Device-oriented composite endpoint (DOCE) composed of cardiac death, target vessel-related MI and TLR. [h]Median follow-up. [i]Values are given as percentages. BP-BES: biodegradable polymer biolimus-eluting stents; CoCr-EES: cobalt chromium everolimus-eluting stent; DES: drug-eluting stent; MACE: major adverse cardiovascular event; MI: myocardial infarction; PtCr-EES: platinum-chromium everolimus-eluting stent; Re-ZES: Resolute (®) zotarolimus eluting stent; SES: sirolimus-eluting stent; ST: stent thrombosis; TLR: target lesion revascularization; TVR: target vessel revascularization.

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Conflict of Interest

None to declare.

Informed Consent

Written informed consent was obtained from all subjects before enrolment.

Author Contributions

Suresh Patted: conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization.

Abbreviations

CK: creatinine kinase; DES: drug-eluting stent; ID-TLR: ischemia-driven target lesion revascularization; ID-TVR: ischemia-driven target vessel revascularization; IVUS: intravascular ultrasound; LAD: left anterior descending; LCx: left circumflex; PCI: percutaneous coronary intervention; PLGA: poly (D,L-lactide-co-glycoside); MACE: major adverse cardiovascular event; MI: myocardial infarction; PLLA: poly (L-lactide); PTCA: percutaneous transluminal coronary angioplasty; RCA: right coronary artery; SES: sirolimus-eluting stent; ST: stent thrombosis; TLF: target lesion failure; TVF: target vessel failure

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