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First report of the use of long-tapered sirolimus-eluting coronary stent for the treatment of chronic total occlusions with the hybrid algorithm

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Abstract

Background: Coronary chronic total occlusions (CTO) usually coexist with diffusely diseased coronary segments proximal and/or distal to the CTO segment. During percutaneous treatment of CTO, multiple overlapping stents are often needed to treat these long lesions.

Objectives: Aim of this study is to report the first use of long, tapered coronary sirolimus-eluting stents (SES) in this setting.

Methods and results: This is a retrospective analysis of 100 consecutive patients undergoing CTO recanalization following the hybrid algorithm. Procedural success rate was 89% (11 failures). Among the successful cases, "conventional" drug-eluting stents(DES) were used in 40(44.9%) patients, while in 49(55%) patients long-tapered SES were attempted with a success rate of 98% (1 cross-over to regular stents). Total stent length in the long-tapered DES group was higher compared to the "conventional" stenting group (76 ± 28 mm vs 46 ± 22 mm, $P < .001$), with a similar total number of stent (1.6 ± 0.8 vs 1.9 ± 0.8). At quantitative coronary analysis, proximal and distal segment involvement was more extended in patients undergoing long-tapered stenting, with longer overall lesion length. No differences in periprocedural complications and clinical outcomes at a mean follow-up of 303 ± 179 days were observed.

Conclusions: The use of long tapered coronary DES is technically feasible and safe for the percutaneous treatment of CTOs, especially for patients presenting with long lesions.

KEYWORDS
chronic coronary total occlusion, drug eluting stent, stable angina

*Both authors equally contributed to the current manuscript.

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All other authors have no conflict of interest to declare.

1 | INTRODUCTION

Coronary chronic total occlusions (CTOs) prevalence ranges from 18 to 52% among patients undergoing coronary angiography in daily practice [1–4]. Some reports from observational studies have suggested improved cardiovascular outcome and better quality of life after successful CTO revascularisation [5–7]. Percutaneous coronary intervention (PCI) of CTOs remains challenging but, thanks to relevant developments in tools and techniques, the success rate has increased to more than 80% [8,9].

Further improvements in outcome may be achieved by optimization of balloons and stents. After successful recanalization of the CTO segment, multiple overlapping stents are frequently needed to properly treat the occluded segment and the diseased coronary bed commonly found upstream and/or downstream. Overlapping stents are known to have increased risk for in-stent restenosis and stent thrombosis [10–12]. In addition, most branching coronary arteries show a reduction in diameter of about 0.25 mm over 10–20 mm segment length [13]. A novel dedicated long-tapered DES may overcome these challenges, with a recent report by Valero et al. describing a positive experience with this device in the settings of general PCI [14].

This is the first report on the use of such a long-tapered DES, specifically designed to tackle length and tapering issues typical of long and diffusely diseased segments related to CTO lesions.

2 | MATERIAL AND METHODS

2.1 | Study population

In this observational, retrospective and independent study, we describe the performance of long-tapered sirolimus-eluting coronary stent (Biomime Morph, Meril Lifescience, Vapi, India) for the treatment of CTOs. The main objective was to evaluate the clinical applicability of these stents in long diffused lesions, which are a common finding in CTO treatment.

The study population comprised consecutive patients that were percutaneously treated for a CTO lesion between March 2016 and October 2017 in our institution by one operator (PA) applying the hybrid algorithm. Chronic total occlusions were defined as an occluded coronary segment with TIMI flow 0 for ≥3 months duration [15]. CTOs were treated according to the appropriate use criteria that have previously been developed [16]. In short, all patients were aged >18 years, had symptoms of angina and/or evidence of ischemia on functional testing.

2.2 | Study procedure and devices

The Japanese CTO (J-CTO) score and PROGRESS (Prospective Global Registry for the Study of Chronic Total Occlusion Intervention) score were calculated by independent analyzers and used to describe the complexity of the CTO lesion [17,18].

CTO-PCIs were performed according to the hybrid algorithm, leaving the operator free in choice of strategies. Strategies included antegrade wire escalation (AWE), antegrade dissection re-entry (ADR), retrograde wire escalation, and reverse controlled antegrade and retrograde subintimal tracking (R-CART).

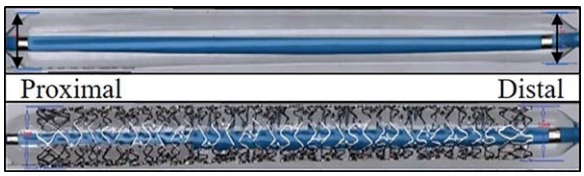

FIGURE 1 Picture of a 60 mm long-tapered 3.5 to 3.0 mm stent. Panel above, tapering of the balloon. Panel below, tapering of the stent mounted on the balloon during inflation at nominal pressure [Color figure can be viewed at wileyonlinelibrary.com]

After recanalization of the diseased segments and subsequent predilatation, stent implantation was performed at the discretion of the operator, using either conventionally available 2nd generation drug-eluting stents, or the novel Biomime Morph stent. The Biomime Morph stent is a sirolimus-eluting tapered coronary stent specifically designed to treat long diffused lesions, thus avoiding multiple stent implantation with overlapping segments. Indeed, the operator choice of adopting this stent was mainly based on major lesion length and vessel tapering as disclosed by angiography after predilation of the CTO lesion. This device consists of a Cobalt Chromium (L605) platform with 65 μm strut thickness, whose cell design structure is hybrid, with open cells in the body of the stent and close cells at the edges. In addition, it maintains a high radial strength without compromising flexibility. The stents are coated with 1.25 ug/mm^2 Sirolimus formulated with biodegradable polymer mix of PLLA + PLGA and mounted on a newly created extra support balloon catheter with ½ sized tapered diameters. For the present study, we used the currently available proximal-to-distal diameters of 3.5-3.0, 3.0–2.5, 2.75-2.25 mm, and lengths of 30, 40, 50, and 60 mm (see Figure 1). The device has Conformité Europeen (CE) mark from October 2015.

2.3 | Outcome parameters

Procedural success was defined as the achievement of <30% residual diameter stenosis within the stent segment and antegrade TIMI flow grade 3. Device success was defined as the ability of the study device (Biomime Morph) to reach and cross the CTO lesion, with a final residual stenosis <30%, absence of more than type B coronary dissection postangioplasty and a final TIMI 3 flow in the culprit vessel [19].

In-hospital major adverse cardiac events included peri-procedural myocardial infarction, dissection of the donor coronary artery requiring intervention, perforation (with need for percutaneous or surgical drainage), tamponade, cerebrovascular accident, cardiogenic shock, target vessel failure requiring urgent repeat vessel revascularization with PCI or coronary artery bypass grafting, and death. Myocardial infarction was defined as ongoing chest pain, electrocardiogram changes and positive cardiac enzymes measured ad hoc, requiring prolonged hospital stay. Clinical follow-up was obtained by means of clinical evaluation or telephone contact when clinical visit was not possible.

TABLE 1 Baseline characteristics

	Regular stenting ($n = 40$)	Biomime Morph ($n = 49$)	P value
Demographics			
Male gender	34 (87.2%)	37 (75.5%)	.18
Age, mean ± SD	66 ± 10.3	63.1 ± 9.6	.18
BMI, mean ± SD	28.9 ± 4.8	27.8 ± 3.8	.21
CV risk factors			
Smoking	18 (45%)	22 (44.9%)	.99
Diabetes Mellitus	10 (25%)	6 (12.2%)	.17
Hypertension	31 (77.5%)	31 (63.3%)	.17
Dyslipidemia	32 (80%)	39 (79.6%)	.99
Positive family history	25 (62.5%)	30 (61.2%)	.99
Medical history			
Myocardial infarction	13 (32.5%)	22 (44.9%)	.28
PCI	15 (37.5%)	29 (59.2%)	.06
CABG	2 (5%)	7 (14.3%)	.18
Preprocedural			
Proven ischemia	34 (85%)	40 (81.6%)	.78
Modality			.64
Ergometry	10 (29.4%)	7 (17.5%)	
MRI	8 (23.5%)	13 (32.5%)	
SPECT	16 (47%)	20 (50%)	
LVEF, mean ± SD (%)	52.8 ± 12	51.6 ± 12.8	.64
LVEF<40%	5 (12.5%)	7 (14.3%)	.99

BMI, body mass index; CABG, coronary artery bypass grafting; CV, cardio-vascular; LVEF, left ventricular ejection fraction; MRI, magnetic resonance imaging; PCI, percutaneous coronary intervention; SD, standard deviation; SPECT, Single-photon emission computed tomography.

2.4 | Quantitative coronary analysis

Quantitative coronary analysis (QCA) was performed offline by an independent operator (CZ) using the software QAngio® XA 7.1 (Medis Medical Imaging, Leiden, The Netherlands). Angiograms were chosen in the projections allowing the best possible visualization of the stenosis. The contrast-filled catheter was used for calibration. From an end-diastolic still-frame, CTO's reference diameter (RD, mm) and lesion length (LL, mm) were calculated, taking advantage of dual catheter injections when necessary. Regarding proximal and/or distal diseased segments, LL (mm), minimum luminal diameter (MLD, mm) and percent diameter stenosis (DS,%) were obtained after successful recanalization and predilation. Finally, postprocedural result was analyzed by means of in-stent and in-segment MLD, RD, and DS.

2.5 | Statistical analysis

Baseline and outcome data were analyzed using descriptive statistics. Numerical values were expressed as mean ± standard deviation(SD) or median(interquartile range, IQR) as appropriate. Categorical variables were expressed as percentages. Comparisons between groups were performed using Pearson chi-square test for categorical variables and student t-test for continuous variables. A two tailed probability value of $P < .05$ was considered statistically significant. All statistical analyzes were performed using SPSS version 22.0(SPSS, Inc., Chicago, Illinois).

3 | RESULTS

During the study period, 100 consecutive patients underwent an attempt to percutaneous CTO recanalization. Procedural success was obtained in 89 of these (89%) and the unsuccessful cases were excluded from the subsequent analysis, since no stent was implanted. Among successful cases, conventional stent implantation was performed in 40 cases (44.9%), while a Biomime Morph stent was adopted in the remaining 49 (55%). No significant differences were observed in baseline demographic and preprocedural parameters (see Table 1).

3.1 | Procedural results

Angiographic and procedural characteristics are shown in Tables 2 and 3. From an angiographic standpoint, CTOs were mostly located in the RCA, while retrograde collaterals were the most frequent in both stenting groups, with predominant septal course. The preferred access site was radial or bi-radial and was not significantly different in the two groups (Regular stenting 85% vs Biomime Morph 73.5%, $P = .09$).

Of note, significantly more difficult CTO lesions were observed in the Biomime Morph group, as indicated by an average higher J-CTO score (1.33 ± 1.05 in the regular stenting group vs 2.16 ± 0.5 in the Biomime Morph group), mainly driven by a higher rate of lesion length > 20 mm in the same group (22.8% vs 57.1%, $P = .001$). However, the PROGRESS score resulted substantially equal in the two groups.

Consistently with the differences in lesion difficulty, revascularization techniques adopted in the Biomime Morph group were also more frequently complex and advanced. In fact, AWE was the preferred technique in the Regular stenting group (77.4% vs 44.9% in the Biomime Morph), while a significantly higher adoption of R-CART technique was observed in the Biomime group (12.5% vs 40.8%, respectively, $P = .006$).

TABLE 2 Procedural characteristics

	Regular stenting ($n = 40$)	Biomime morph ($n = 49$)	P value
Culprit vessel			.93
RCA	23 (57.5%)	30 (61.2%)	
LAD	12 (30%)	13 (26.5%)	
RCX	5 (12.5%)	6 (12.2%)	
Collaterals			.11
Antegrade	5 (12.5%)	1 (2%)	
Retrograde	20 (50%)	33 (67.3%)	
Both	14 (35%)	15 (30.6%)	
			.21
Bypass	0	2 (4.1%)	
Septal	18 (45%)	14 (28.6%)	
Epicardial	11 (27.5%)	14 (28.6%)	
Septal+epicardial	10 (25%)	19 (38.8%)	
Access site			.09
Single Femoral	1 (2.5%)	1 (2%)	
Radial and Femoral	3 (7.5%)	8 (16.3%)	
Single Radial	26 (65%)	20 (40.8%)	
Bi-radial	8 (20%)	16 (32.7%)	
Single Ulnar	2 (5%)	0	
Bi-Ulnar	0	1 (2%)	
Radial and Ulnar	0	3 (6.1%)	
Successful technical Approach			.006
AWE	31 (77.4%)	22 (44.9%)	
ADR	1 (2.5%)	5 (10.2%)	
RWE	3 (7.5%)	2 (4.1%)	
R-CART	5 (12.5%)	20 (40.8%)	
J-CTO score			.002
Easy	8 (20%)	2 (4.1%)	
Intermediate	19 (47.5%)	12 (24.5%)	
Difficult	6 (15%)	16 (32.7%)	
Very difficult	7 (17.5%)	19 (38.8%)	
Mean ± SD	1.33 ± 1.05	2.16 ± 0.5	<.001
PROGRESS CTO score			.62
0	13 (33.3%)	18 (36.7%)	
1	19 (48.7%)	18 (36.7%)	
2	4 (10.3%)	9 (18.4%)	
3	3 (7.7%)	4 (8.2%)	
Mean ± SD	0.92 ± 0.87	0.98 ± 0.95	.77

AWE, antegrade wire escalation; ADR, antegrade dissection re-entry; J-CTO, Japanese chronic total occlusion; LAD, left anterior descending; PROGRESS, Prospective Global Registry for the Study of Chronic Total Occlusion Intervention; RCA, right coronary artery; RCX, ramus circumflexus; RWE, retrograde wire escalation; R-CART, reverse controlled antegrade and retrograde subintimal tracking.

One device failure was observed in the Biomime group, where a Biomime Morph 3.5-3.0 × 50 mm was not able to cross the CTO lesion located in the mid-segment of the left anterior descending coronary after successful AWE, even after adequate predilation. In this case, a switch to conventional stent implantation was performed, with deployment of three shorter Orsiro sirolimus eluting stents (Biotronik, AG, Berlin, Germany). In the regular stenting group 45% of the patients were treated with 1 stent, whereas in the Biomime Morph group 18 patients (36.7%) received only 1 Morph, while the remaining required additional stent implantation, which was a conventional stent in 26 cases (53.1%). Total stent length achieved in the Biomime Morph group was significantly higher than in the regular stenting group (76 ± 28 mm vs 46 ± 22 mm, $P < .001$). Finally, the use of a catheter extension (e.g., GuideLiner or Guidezilla) was required in 12 patients (24.5%) of the Biomime Morph group and in 7 patients of the conventional stents group (17.5%, $P = .45$).

3.2 | Clinical outcome

Postprocedural complication rates for both groups were low and comparable ($P = .62$). One dissection occurred in each group: one donor artery (right coronary artery) ostial dissection treated with additional stenting in the both groups during R-CART for circumflex CTO. In addition, one periprocedural MI was observed in the Biomime Morph group, due to occlusion of a large septal branch after ADR recanalization of a left anterior descending CTO, which however did not cause

TABLE 3 Stenting characteristics

		Regular stenting ($n = 40$)	Biomime morph ($n = 49$)	*P* value
Stent numbers				
Patients with *N* Stents Implanted (%)				.44
1		18 (45%)	18 (36.7%)	
2		18 (45%)	20 (40.8%)	
3		3 (7.5%)	9 (18.4%)	
4		1 (2.5%)	2 (4.1%)	
Number of stents per patient[a]		1.6 (± 0.8)	1.9 (± 0.8)	.13
Total number of stents per cohort		65	93	
Regular stents			37	
Biomime morph stents		-	56	
Patients receiving regular stent		40 (100%)	26 (53.1%)	
Total stent length, mm		46 ± 22	76 ± 28	<.001
Max post dilatation pressure		18 (± 5)	19 (± 3)	.12
Use of catheter extension		7 (17.5%)	12 (24.5%)	.45
Stent type				
Patients with specific stent implanted				<.001
Biomatrix		3 (7.5%)	0	
Orsiro		4 (10%)	15 (30.6%)	
Resolute		7 (17.5%)	1 (2%)	
Synergy		11 (27.5%)	3 (6.1%)	
Xience		10 (25%)	1 (2%)	
Promus Premier		1 (2.5%)	0	
Fire Hawk		3 (7.5%)	3 (6.1%)	
Coroflex Neo		1 (2.5%)	3 (6.1%)	
Direct RX		0	1 (2%)	
Biomime morph				
Diameter (mm)	Length (mm)			
2.75-2.25	30	NA	1 (2%)	
	40	NA	2 (4%)	
	50	NA	1 (2%)	
	60	NA	1 (2%)	
3.00–2.50	30	NA	4 (8.1%)	
	40	NA	5 (10.2%)	
	50	NA	7 (14.3%)	
	60	NA	9 (18.4%)	
3.50-3.00	40	NA	5 (10.2%)	
	50	NA	2 (4%)	
	60	NA	21 (42.8%)	

[a]Mean (SD).

relevant clinical consequences. Finally, one wire-caused perforation of distal right posterior descending artery was observed in the Biomime Morph group after a successful ADR technique (with CrossBoss-Singray system), which leaded to pericardial hematoma requiring pericardiocentesis few hours after the procedure.

3.3 | Clinical follow-up

Clinical follow-up was available in all patients, with an average duration of 303 ± 179 days. We observed no all-cause deaths in the conventional stent group and two (4.1%) in the Biomime group ($P = .49$), one of which was due to noncardiac causes (lung cancer) 6 months after CTO PCI, the other was due to terminal heart failure in a patient with very poor left ventricular function after percutaneous edge-to-edge mitral valve repair, 13 months after CTO PCI. The incidences of myocardial infarction and target vessel revascularizations were similar in the two groups (see Table 4). Finally, there was a trend towards higher nontarget vessel revascularization in the conventional stent group, which however was almost entirely due to staged procedures after the CTO recanalization (see Table 4).

TABLE 4 Clinical events at follow-up

	Regular stenting ($n = 40$)	Biomime morph ($n = 49$)	*P* value
All cause death	0	2 (4.1%)	.49
Non cardiac death	0	1 (2%)	.99
Cardiac death	0	1 (2%)	.99
Myocardial Infarction	1 (2.5%)	0	.99
Target vessel revascularization	1 (2.5%)	2 (4.1%)	.99
Nontarget vessel revascularization			
Total number	5 (12.5%)	1 (2%)	.09
Planned-nTVR	5 (12.5%)	0	.02

nTVR: nontarget vessel revascularization.

3.4 | QCA results

At QCA, preprocedural CTO-reference diameter showed a mild trend to higher values in patients treated with conventional stents than in the Biomime Morph group (2.96 ± 0.646 mm vs 2.76 ± 0.48 mm respectively, $P = .10$). After the procedure, however, this value was not significantly different in the two groups. A possible explanation for this phenomenon is the more common presence of ostial location of CTO lesions in the Biomime group, together with a different pattern of segment disease involvement herein described. Besides CTO lesion length appeared pronouncedly higher in the Biomime Morph group (14.4 ± 9.5 mm vs 24.6 ± 14.3 mm, $P < .001$), the two groups showed also significant differences regarding the overall diseased segment proximally and distally to the CTO lesions itself. In particular, a proximal-segment involvement was, although not statistically significant, more frequent in the Biomime group (36.8% vs 55.6%, $P = .12$), which however appeared significantly more diffuse than in the conventional stenting group (12.2 ± 5.9 mm vs 22 ± 15.1 mm, $P = .02$). Similarly, the distal segment involvement was equally common in both groups (69.2% vs 82.2% respectively, $P = .20$) but with significantly longer segments in the Biomime group (19.9 ± 9.8 mm vs 25.6 ± 10.2 mm respectively, $P = .04$). Consistently with these findings, the total length of the diseased segment (including CTO) was significantly higher in Biomime Morph group (32.4 ± 19.7 mm vs 50.6 ± 25.4 mm, $P < .001$). Postprocedural analysis showed good and comparable results in both groups (see Table 5).

4 | DISCUSSION AND LIMITATIONS

This is the first report on the use of long-tapered coronary stents for the treatment of CTOs. Our preliminary results demonstrate the safety and efficacy of the study device in this setting. In fact, we observed a high device success rate (only 1 failure in delivering a 50 mm long-

TABLE 5 Quantitative coronary analysis results in the two treatment groups

	Regular Stenting	Biomime Morph	*P* value
Preprocedure			
Reference diameter[a], mm	2.96 (± 0.66)	2.76 (± 0.38)	.10
Occlusion length[a], mm	14.4 (± 9.5)	24.6 (± 14.3)	<.001
After predilation			
Proximal involvement	14 (36.8%)	25 (55.6%)	.12
Proximal LL[a], mm	12.2 (± 5.9)	22 (15.1)	.02
Proximal RD[a], mm	3.07 (± 0.85)	2.78 (0.35)	.17
Proximal MLD[a], mm	1.80 (0.67)	1.60 (0.54)	.36
Proximal DS%[a]	42% (± 14%)	43% (18%)	.92
Distal involvement	27 (69.2%)	37 (82.2%)	.20
Distal LL[a], mm	19.9 (± 9.8)	25.6 (± 10.2)	.04
Distal RD[a], mm	2.51 (± 0.49)	2.28 (0.40)	.17
Distal MLD[a], mm	1.34 (± 0.45)	0.93 (0.36)	.01
Distal DS%[a]	46% (± 15%)	58% (15%)	.02
Total diseased segment length[a], mm	32.4 (± 19.7)	50.7 (± 25.4)	<.001
Postprocedure			
In-stent RVD[a], mm	3.11 (± 0.5)	2.99 (± 0.42)	.22
In-stent MLD[a], mm	2.53 (± 0.41)	2.41 (± 0.42)	.18
In-stent DS%[a]	18% (± 8%)	19% (8%)	.55
In-segment RVD[a], mm	2.72 (± 0.62)	2.69 (± 0.47)	.17
In-segment MLD[a], mm	1.97 (± 0.68)	2.02 (± 0.54)	.85
In-segment DS%[a]	28% (16%)	24% (19%)	.37

[a]Mean (± SD). LL: lesion length; RD: reference diameter; MLD: minimal lumen diameter; DS%: percentage diameter stenosis.

TABLE 6 Maximal length for most commonly used conventional stents

Stent name (Company)	Size (mm)	Longest available (mm)	Strut thickness (μm)
Resolute Onyx™ (Medtronic Inc., Minneapolis, MN, USA)	2.25–4.00	38	89
Orsiro(BIOTRONIK AG, Berlin, Germany)	2.00–3.00	40	61
Xience PRO^{x} (Abbott Vascular, Diegem, Belgium)	3.00–4.00	40	80
	2.00–2.25	28	81
	2.50–3.50	48	81
	4.00	38	81
PtCr Synergy™ (Boston Scientific, Natick, MA, USA)	2.25	38	74
	2.50–4.00	48	74
Promus Premier (Boston Scientific, Natick, MA, USA)	2.25	32	81
	2.5–4.00	38	81
Ultimaster® (Terumo Corporation, Shibuya-ku, Tokyo, Japan)	2.25–4.00	38	80
BioMatrix NeoFlex (Biosensors Interventional Technologies, Singapore)	2.25 and 4.00	29	120
	2.50-3.50	36	120
Magmaris (BIOTRONIK AG, Berlin, Germany)	3.00–3.50	25	150

tapered stent), a low incidence of peri-procedural complications (1 dissection in both groups one peri-procedural MI in the Biomime Morph group and one perforation leading to pericardial hematoma drained surgically) and a promising incidence of clinical events at a mean of 10 months of follow-up. Baseline demographic and angiographic characteristics of the present study population are in line with those described in other CTO studies, especially as far as the technical difficulty of the procedures is concerned, as reflected by the J-CTO score [4–9]. Of note, severely diffuse disease was observed in our population, requiring multiple stent implantation in nearly 60% of all patients, with subsequent need for overlapping stents segments. The clinical impact of multiple stenting in the subset of CTO-PCI is at present unknown, but previous experiences in general population have proved an adverse outcome [10–12]. From this standpoint, the use of conventional second generation DES is limited by a maximum length of 48 mm, which is even not available for all DES type (see Table 6). In our analysis, mean lesion length in the group treated with these devices was 32 ± 19 mm, which translated into a need for at least two stents implanted in more than half of the cases (total stent length 46 ± 22 mm). Similar data were reported in other recent studies on CTO-PCI [8,9].

The Biomime Morph stents have been designed to overcome limitations of conventionally used DES. The purpose of the tapered stent system is to treat long lesions in diffusely diseased coronary arteries, thus covering long segments of the culprit vessel (potentially from the proximal to the distal portions) with increased adaptability to arterial anatomy (preserving vessel conformability, providing homogenous radial force, reducing mechanical stress, and maintaining stent-arterial wall ratio along the stented segment). As shown in our study, mean lesion length in this group was 50.7 ± 25.4 mm, significantly higher than in the conventional stenting group ($P < .001$), with most of the cases (nearly 65%) requiring additional stent implantation other than the first Biomime Morph. The features of this dedicated stent allowed for covering a significantly longer diseased segment (total segment length 76 ± 28 mm in the Biomime Morph vs 46 ± 22 mm in the regular stenting group, $P < .001$) while keeping a substantially equal number of devices necessary. If treated with conventionally available DES, this group of patients would have received certainly more DES with even more overlapping segments. Similarly, if widely adopted also in the lesions treated with conventional DES, this device could have been sufficient to cover the whole lesion alone, theoretically avoiding multiple stent implantation and subsequent stent overlap in many patients. This fact was not observed in our registry, however, since the adoption of the Biomime Morph stent was limited to those patients with longest lesions length. It is also important to note the significantly more frequent adoption of advanced CTO PCI techniques (e.g., R-CART) in the Biomime group. This supports the good performance of these long-tapered DES in the technically most complex procedures, which, in the specific case of the R-CART technique may even benefit from the stable support offered by the externalized wire. Of note, the use of guiding catheter extensions (such as GuideLiner or Guidezilla), was relatively more frequent in the Biomime Morph group, observation which, however, did not result statistically significant (see Table 3).

The present study has several limitations. First, the study has a descriptive design, with the purpose to present the first results using long-tapered stents in CTO PCI, therefore no randomization was performed, thus possible bias in the device choice may have occurred. In fact, the choice of stent type was done by the operator, based on the lesion length, vessel characteristics and other angiographical feature. Third, the relatively small number of patients considered in the analysis poses limitations to eventual conclusive speculations, especially for long term comparison with conventional stents in terms of clinical events, and bigger trials are necessary for further assessment of this device's performances. Similarly, potential clinical advantages from reduction of multiple-overlapping stents thanks to application of this device were not derivable in our analysis, and require large sample

(ideally randomized) trial for further evaluation. Forth, the study device currently available does not include a stent with 4.0–3.5 mm in diameter, which limits its applicability in coronaries where this size is required. Of note, this contributed to the possible selection bias in device choice in our experience. Finally, the long term patency of these stents is still not completely known, thus long term (angiographic) follow up is required to confirm the clinical good performance of these devices.

5 | CONCLUSION

The use of long-tapered coronary stents is technically feasible and safe for the percutaneous treatment of patients with CTOs, especially for those patients with very long lesions. In addition, by limiting the need for multiple stent implantation and thus overlapping-segments, the use of these devices may have the potential to improve the long-term clinical outcome after CTO recanalization.

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