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Research Article

Malapposed Struts with Cre8, Biomatrix, and Xience Stents Assessed with OCT Immediately after Implantation and at 6-Month Follow-Up: Can the Different Biomechanical Characteristics of the Three Stents Impact on Struts Malapposition?

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Background. Although the clinical effects of stent malapposition remain controversial, several analyses of stent registries consistently have found that malapposed struts were frequently identified in patients who experienced stent thrombosis. In this study, which is a subanalysis of the previously published CREBX-OCT study, we compared optical coherence tomography (OCT) analysis at the index percutaneous coronary intervention (PCI) and at six-month follow-up in 37 patients randomly assigned to receive, by a single operator, three different second-generation drug-eluting stents (Cre8, Biomatrix, and Xience) aiming to clarify if the malapposition observed at six-month follow-up was persistent or late-acquired. Moreover, we investigated if there were some differences in the behavior of the three different kinds of stents in relation to the struts malapposition. *Material and Methods*. We analyzed 614 and 599 cross sections and 5514 and 5377 struts at the index PCI and at six-month follow-up, respectively. The qualitative analysis of the plaque composition among the three groups did not show significant differences. *Results*. The lumen area did not significantly change from the index procedure to the six-month follow-up in the three groups; on the contrary, the number of malapposed struts increased significantly in the Cre8 and Biomatrix groups but not in the Xience group: 0.58 ± 1.51 and 3.29 ± 5.33 ($p < 0.023$) in the Cre8 group, 0.55 ± 1.81 and 1.73 ± 2.28 ($p < 0.024$) in the Biomatrix group, and 0.55 ± 1.5 and 0.25 ± 0.87 ($p < 0.166$) in the Xience group, respectively. *Conclusions*. Therefore, the malapposition observed at six-month follow-up in our study population could be mainly considered as acquired and attributable to biomechanical reasons due to the structural differences among the three stents. This trial is registered with Clinical Trials.gov Identifier: NCT02850497.

1. Introduction

Optical coherence tomography (OCT) allows for high-resolution intracoronary imaging and has been validated for assessment of stent struts coverage and apposition with an accuracy resembling that of histological examination [1–3]. Using OCT to guide stent implantation, it has been found that stent deployment can be associated with stent malapposition to the vessel wall which is too subtle to be detected by angiography or even by intravascular ultrasound. Although the clinical effects of stent malapposition remain controversial, several analyses of stent registries have

consistently found that malapposed struts were frequently identified in patients who experienced stent thrombosis [4–8]. In the CREBX-OCT study [9], using OCT 6 months after stent implantation, we compared the number of uncovered, protruding, or malapposed struts among the three different second-generation drug-eluting stents (DES) in 60 patients submitted to PCI and randomly assigned to receive Cre8, Biomatrix or Xience. Our previous study showed that the three second-generation stents were similarly effective in permitting complete struts coating 6 months after implantation, but Cre8 and Biomatrix showed a greater proportion of protruding and malapposed struts. These differences did not translate into different risks of MACE over the 6-month follow-up but the study was not powered for detecting differences in the clinical outcome. Although OCT was not mandatory at the time of the index procedure, in 51/60 patients enrolled in the CREBX-OCT study, it was also performed immediately after stent implantation and, in 37 patients, the data recorded were technically suitable for comparative analysis. In this present study, we compared OCT data recorded at the index PCI with those recorded at six-month follow-up in this group of 37 patients. The aim of the study was to clarify whether the malapposition observed at six-month follow-up had persisted since the index PCI or was late-acquired. Moreover, we analyzed any differences in the behavior of the three different kinds of stents in relation to the struts malapposition at the index PCI and at 6-month follow-up.

2. Methods

The present study is a subanalysis of the data recorded in patients enrolled in the previously published CREBX-OCT study [9] in a nonprofit, single-center, prospective randomized study (Clinical Trials.gov identifier: NCT02850497). Funding for this subanalysis was provided by Abbott CV, which had no role in the data collection, management, analysis, or results of this study.

2.1. Endpoints. The primary endpoint was to verify if the malapposed struts observed at 6-month follow-up by OCT were late-acquired or were persistent since being recorded by OCT at the index procedure. The coprimary endpoint was to analyze any differences among the three kinds of stents in relation to the struts' malapposition at the index PCI and at 6-month follow-up.

2.2. Patients. Inclusion and exclusion criteria in the study, randomization method to Cre8, Biomatrix, and Xience implantation, stenting, and OCT technique of our study population were previously published in the CREBX-OCT study [9]. Briefly, patients above 18 years of age planned to be treated with PCI for stable angina (SA) or non-ST segment elevation acute coronary syndrome (N-STE ACS) at the catheterization laboratory of the University of Florence from September 2015 to July 2017 were considered eligible for the study. Exclusion criteria were the following: ST segment elevation myocardial infarction, contraindication to dual antiplatelet therapy, surgical intervention planned <6 months, indication to anticoagulant therapy, expected survival <6 months, cardiogenic shock, unwillingness to sign informed consent or to undergo 6-month coronary angiography.

Randomization to Cre8, Biomatrix, or Xience was performed in computer-generated sequences after coronary angiography resulting in indication to DES implantation. In case of multivessel coronary disease, only one vessel (vessel reference diameter ≥2 5 mm and without stents previously implanted) was chosen for the study. The study population included 37 out of 60 patients enrolled in the CREBX-OCT study in whom OCT analysis was performed not only at 6-month follow-up but also at the index PCI, immediately after stent implantation at operator's discretion. Figure 1 shows flow chart of patients enrolled in the study.

28 patients (75%) were males; 14 (37%) were randomized to receive Cre8, 11 (29%) were randomized to receive Biomatrix, and 12 (32%) were randomized to receive Xience.

2.3. Stents and OCT Analysis. The three types of stents implanted were structurally different.

The polymer-free Cre8™ (CID S.p.A, Saluggia, Italy) has a cobalt-chromium platform, coated with "*Carbofilm*," eluting Amphilimus™ which is composed of Sirolimus and a mixture of long chain fatty acid, contained in grooves on the stent's outer surface (strut thickness: 80 μm).

The Biomatrix *Flex*™ (Biosensor Europe SA, Morges, Switzerland) has a steel platform, eluting Biolimus A9^{TM} which is a semisynthetic Sirolimus derivate with improved pharmacokinetic properties. Its poly-lactic acid polymer is biodegradable: the drug and the polymer are present only on the abluminal surface (strut thickness: 112 μm, polymer thickness: 11 μm).

The Xience™ V (Abbott Vascular, Santa Clara, California, USA) has a cobalt-chromium platform, eluting Everolimus, with a nonbiodegradable polymer: the drug and the polymer are present on intraluminal as well as on the abluminal stent's surface (strut thickness: 81 μm; polymer thickness: 3,9 μm × 2).

In all three arms, DES were deployed by a single operator (C.G.) at a pressure selected at its discretion according to the characteristics of the lesion, and eventual optimization with noncompliant balloon was based on qualitative assessment of postdeployment angiographic images.

OCT was performed with ILLUMIENTM PCI Optimization System-St. Jude Medical (resolution power 20 μm) after completion of index PCI and at 6-month follow-up coronary angiography as previously described [9]. The offline analysis of OCT data was performed by ILLUMIENTM OPTISTM St. Jude Medical workstation by two different investigators (C.F. and E.C.) who were blinded to each other's assessment and to the type of implanted stent as previously described [9]. To obtain identical analysis of segments at baseline and at follow-up OCT, we displayed the baseline and follow-up images side by side and performed serial OCT analysis using information about the motorized pullback speed and landmarks as the presence of calcium

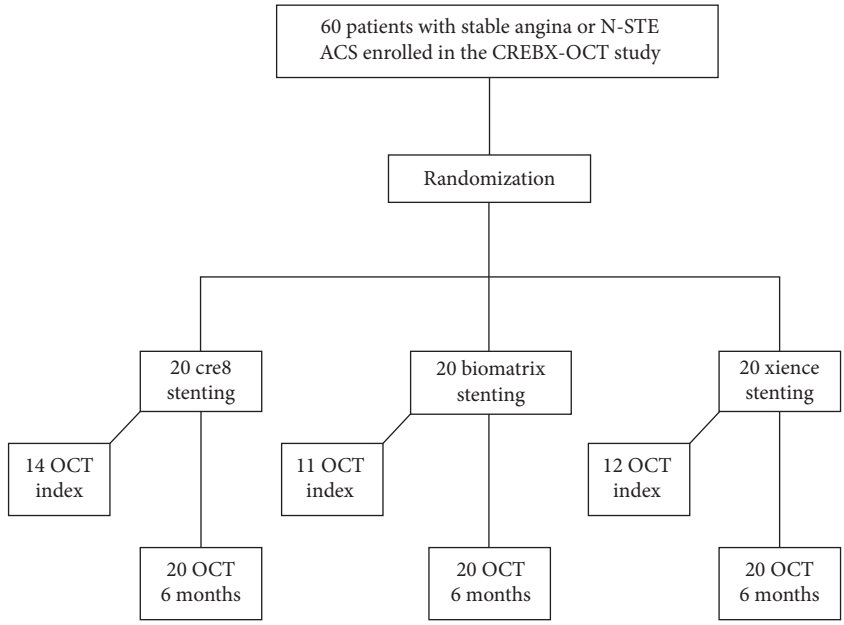

Figure 1: Study's flow chart. PCI: percutaneous coronary intervention; N-STE ACS: non-ST segment elevation acute coronary syndrome; OCT: optical coherence tomography.

deposits, side branches, and plaque shape [10]. For qualitative analysis, we evaluated the presence of stent malapposition, thrombus, tissue prolapsed and stent edge dissection, homogeneous struts distribution, and plaque composition.

Struts were classified as apposed or malapposed in relation to their adherence to the vessel wall [11, 12]. The thickness of struts was different in the three types of stents in relation to the different structural characteristics and to the polymer presence: malapposition was determined by adding the actual strut thickness and polymer thickness to OCT resolution limit as mentioned above. On the basis of this definition, the cutoff to consider a strut as malapposed is different in the three types of stents.

Malapposition identified at the index PCI but absent at follow-up was defined as resolved; otherwise, it was classified as persistent. Late-acquired malapposition was defined as that not present immediately after the index PCI but observed at the follow-up. Tissue prolapsed was defined as a protrusion of tissue between stent struts, extending inside a circular arc connecting adjacent struts. Stent edge dissection was defined as disruption of the luminal vessel surface in the edge segment [10]. Representative serial OCT images of these figures are shown in Figure 2.

2.4. Pharmacological Treatment. Patients treated for SA received a loading dose of 600 mg of Clopidogrel before PCI and patients treated for NST-ACS received a loading dose of 180 mg of Ticagrelor or 60 mg of Prasugrel. All patients received 325 mg of ASA orally or 250 mg intravenously before the procedure and heparin was given as an initial bolus of 70 UI/kg. After the procedure, all patients were treated with ASA 100 mg indefinitely and with Clopidogrel 75 mg daily for six months in patients treated for SA or with Ticagrelor 180 mg daily or Prasugrel 10 mg daily for almost 12 months in patients with NST-ACS. 34/37 (92%) patients were taking statins (12, 11, and 11 patients, respectively in Cre8, Biomatrix, and Xience groups). Other drugs such as beta-blockers and angiotensin-converting enzyme inhibitors were used in accordance with international guidelines. Response to the dual antiplatelet therapy was evaluated by light transmittance aggregometry (LTA) using 10 μM/L adenosine-diphosphate (ADP) and 1 mM arachidonic acid (AA) as agonists. Patients with high on-treatment platelet reactivity (HPR) by ADP ≥70% were switched to another P2Y12 antagonist [13].

2.5. Statistical Analysis. The statistical software was SPSS (version 20.0; SPSS Inc., Chicago, IL). Normally distributed data were expressed as mean ± SD, nonnormally distributed data were expressed as median (25^{th}–75^{th} percentile, i.e., interquartile range, IQR), and categorical data were presented as the frequency (percentage). Sometimes, to better highlight differences, values were reported as both means ± SD and medians (IQR). Comparisons of variables across the 3 groups were made using one-way analysis of variance (ANOVA) for normal distribution variables, Kruskal-Wallis test for nonnormal distribution variables, and Chi-square test for categorical variables. For intragroup comparisons (i.e., values at follow-up versus index), the parametric paired-samples t-test and the nonparametric Wilcoxon test were used. All tests were two-sided. A p value < 0.05 was considered statistically significant.

3. Results

The main baseline demographic, clinical, and angiographic characteristics of the 37 patients included in the present

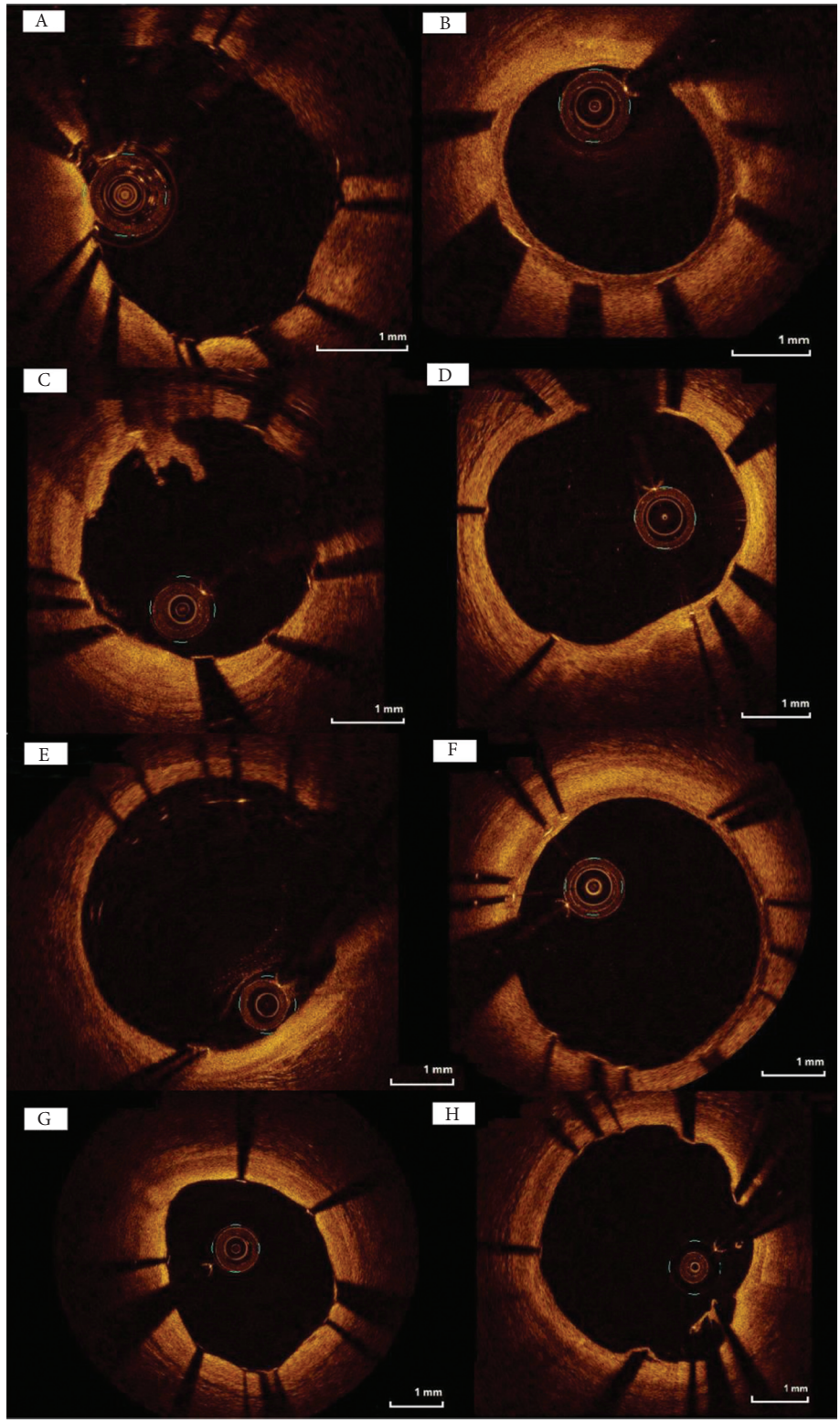

Figure 2: Examples of optical coherence tomography (OCT) cross sections obtained from our study's population: (a) OCT at index percutaneous coronary intervention (PCI); (b) OCT at follow-up. (A) Optimal stent apposition; (B) normal healing; (C) optimal stent apposition with plaque prolapse; (D) normal healing; (E) stent malapposition with incomplete stent apposition area; (F) resolved malapposition; (G) optimal stent apposition; (H) acquired stent malapposition with incomplete stent apposition area.

study were all similar across the three randomization groups (Table 1). The main laboratory tests at baseline were also similar among the three groups (Table 2). Also, the prevalence of responder patients to ASA and P2Y12 among the three groups did not show any differences in the three groups: ASA responder patients were 13, 10, and 11; P2Y12 responder patients were 11, 9, and 10, respectively, in Cre8, Biomatrix, and Xience groups.

Table 3 shows OCT data recorded at the index procedure and the comparison with data recorded at 6-month follow-up. The qualitative analysis of the plaque composition among the three groups did not show significant differences and a homogeneous distribution of the struts was present in all groups. The lumen area had not significantly changed in the period between the index procedure and the 6-month follow-up in the three groups. On the contrary, the number of malapposed struts increased significantly in the Cre8 and Biomatrix groups but not in the Xience group. Similarly, the number of cross sections with incomplete stent apposition (ISA) increased significantly in the Cre8 and Biomatrix groups but not in the Xience group.

4. Discussion

The main findings of our analysis were the following:

(1) The number of malapposed struts increased significantly from the index procedure to the six-month follow-up. Therefore, we can state that the malapposition observed by OCT at six-month follow-up was mainly late-acquired.

(2) The three different kinds of DES showed a different behavior in relation to the struts' malapposition during the follow-up: despite a similar number of malapposed struts at the index PCI, the number of malapposed struts had increased in the Cre8 and Biomatrix groups but not in the Xience group at six-month follow-up. We hypothesized that these differences among the three groups could be ascribed to biomechanical reasons due to the different structure of the stents.

These findings deserve some consideration.

The intracoronary imaging techniques indicate that struts' malapposition is a relatively frequent phenomenon after stent implantation, observed in a portion of stents analyzed ranging from 25% to 60% [10]. There are three types of stent malapposition: acute, late-persistent, and late-acquired. Acute struts' malapposition may result from incomplete stent expansion during the index procedure, especially in the presence of calcified plaques. Late malapposition may be persistent from the index PCI or acquired due to either the presence of thrombus or dissection between stent and plaque at stent implantation, which may have disappeared at follow-up, or due to positive vessel remodeling [14, 15]. In the era of drug-eluting stents, late-acquired stent malapposition is a well-recognized problem in interventional cardiology because it may constitute a potent substrate for late stent thrombosis. The clinical role of late malapposition is somewhat controversial: several experimental and clinical studies suggested that stent malapposition has a direct impact on thrombus formation, and it is frequently identified in patients who experienced stent thrombosis [16–18]. Conversely, some long-term follow-up studies by OCT showed a favorable clinical outcome for patients with stent malapposition [4–8]. In our study's population, the number of struts malapposed and cross sections with ISA increased significantly from baseline OCT to 6-month follow-up in the Cre8 and Biomatrix groups but not in the Xience group. Although these differences did not translate into different risks of MACE over the 6-month follow-up because the study was not powered to detect differences in the clinical outcome, it could be useful for interventional cardiologists to be aware of the different behavior of the three types of stents so that they can choose the safest and most suitable type for their patients. Moreover, it could be interesting to speculate about the reasons for these differences. First of all, we can reasonably exclude the fact that the different results among the three groups were ascribable to differences in patients' characteristics (Tables 1–3) or in interventional techniques (all PCI were performed by a single operator); therefore we can suppose that the differences observed were mainly of biomechanical nature (Figure 3).

As specified above, the three types of stents are coated with three different biodegradable drugs with possible different biochemical effects on the vessel wall. Moreover, they differ from one another according to the presence and the type (biodegradable or not) of the polymer interposed between the metal platform and the vessel wall as well as the shape of the polymer containers on the platform surface. The Biomatrix stent, which has a biodegradable polymer on the abluminal surface of the platform, even though well-apposed to the vessel wall at the index PCI, at six-month follow-up may show an empty space between the platform and the vessel wall due to drug and polymer reabsorption. This empty space may be larger than that observed at six-month follow-up in the Xience stent, in which only the drug is reabsorbed, as the polymer is not biodegradable. Otherwise, Cre8 stents have no polymer on the platform surface and after the reabsorption of the drug they could show an empty space not larger but more heterogeneous than that of the other two stents, due to their structure with grooves on the platform surface. To sum up, at six-month follow-up, the Xience stent may show an empty space between platform and vessel wall, which is smaller than that observed in the Biomatrix stent and more homogeneous than that observed in the Cre8 stent. Therefore, the structural characteristics of the Xience stent could allow better contact with and greater homogeneous adherence to the vessel wall when compared to the other two stents. The differences in the dimensions and in the homogeneity of the empty space between the platform and the vessel wall may also be associated with differences in the shear pressure and flow disturbance between stent and vessel wall able to determine differential changes in cellular proliferation of the vessel wall among the three groups. It is known that a high shear flow disturbance is a factor of delay of neointimal growth, which may lead to a permanence of malapposition [19–21].

Table 1: Baseline clinical, angiographic, and PCI characteristics.

	Cre8	Biomatrix	Xience	*p* value
Patients (*n*)	14	11	12	
Gender M/F, *n* (%)	11/3 (78.6/21.4)	7/4 (63.6/36.4)	10/2 (83.3/16.7)	0.519
Italian, *n* (%)	14 (100)	11 (100)	11 (91.7)	0.343
Age (years), mean ± SD	66.6 ± 10.0	67.1 ± 11.1	57.9 ± 12.2	0.087
BMI (Kg/m^2), mean ± SD	26.9 ± 2.9	24.9 ± 1.6	28.2 3.0	0.036
Hypertension, *n* (%)	12 (85.7)	10 (90.9)	11 (91.7)	0.867
Diabetes, *n* (%)	4 (28.6)	3 (27.3)	3 (25)	0.979
Dyslipidemia, *n* (%)	11 (78.6)	9(81.8)	9 (75)	0.924
Ever smoker, *n* (%)	11 (78.6)	5 (45.5)	7 (58.3)	0.225
Familial history of CAD, *n* (%)	4 (28.6)	5 (45.5)	2 (16.7)	0.318
Previous CAD, *n* (%)	4 (28.6)	1 (9.1)	1 (8.3)	0.282
Previous PCI, *n* (%)	2 (14.3)	0 (0.0)	0 (0.0)	0.176
Previous CABG, *n* (%)	0 (0.0)	0 (0.0)	0 (0.0)	—
Previous TIA/stroke, *n* (%)	1 (7.1)	0 (0.0)	0 (0.0)	0.430
Chronic kidney disease, *n* (%)	1 (7.1)	0 (0.0)	0 (0.0)	0.430
COPD, *n* (%)	1 (7.1)	2 (18.2)	0 (0.0)	0.276
Sinus rhythm, *n* (%)	11 (100.0)	9 (81.8)	11 (91.7)	0.255
Atrial fibrillation, *n* (%)	0 (0.0)	1 (9.1)	0 (0.0)	0.297
Pacemaker, *n* (%)	0 (0.0)	1 (9.1)	1 (8.3)	0.524
LVEF, mean ± SD (%)	57 ± 6.4	59 ± 7.3	53 ± 8.9	0.164
Heart failure, *n* (%)	0 (0.0)	1 (9.1)	1 (8.3)	0.524
NYHA class				0.598
I°, *n* (%)	13 (92.9)	9 (81.8)	10 (83.3)	
II°, *n* (%)	0 (0.0)	0 (0.0)	1 (8.3)	
III°, *n* (%)	1 (7.1)	1 (9.1)	1 (8.3)	
IV°, *n* (%)	0 (0.0)	1 (9.1)	0 (0.0)	
Stable angina, *n* (%)	2 (14.3)	3 (27.3)	3 (25.0)	0.693
Unstable angina, *n* (%)	6 (42.9)	5 (45.5)	2 (16.7)	0.262
Silent ischemia, *n* (%)	1 (7.1)	0 (0.0)	2 (16.7)	0.338
NSTEMI, *n* (%)	3 (21.4)	3 (27.3)	3 (25.0)	0.942
STEMI, other vessels, *n* (%)	3 (21.4)	0 (0.0)	2 (16.7)	0.276
Target lesion coronary artery				
Left anterior descending	12 (85.7)	9 (81.8)	11 (91.7)	0.784
Left circumflex	7 (50.0)	4 (36.4)	7 (58.3)	0.570
Right	8 (57.1)	6 (54.5)	7 (58.3)	0.983
Left main	0 (0.0)	1 (9.1)	0 (0.0)	0.297

BMI: body mass index, CAD: coronary artery disease, PCI: percutaneous coronary intervention, CABG: coronary artery by-pass graft, TIA: transient ischemic attack, COPD: chronic obstructive pulmonary disease, LVEF: left ventricle ejection fraction.

Table 2: Baseline biohumoral data.

	Cre8	Biomatrix	Xience	*p* value
Pro-BNP (pg/mL), median (IQR)	661 (377–1551)	136 (87–804)	242 (78–660)	0.286
Troponin (μg/L), median (IQR)	0.60 (0.16–2.01)	1.08 (0.41–1.79)	2.06 (0.41–5.14)	0.577
Hemoglobin (g/dL)	12.3 ± 2.1	12.4 ± 1.1	13.2 ± 1.8	0.427
Leukocyte (109/L)	7.90 ± 2.70	6.50 ± 2.30	8.00 ± 1.70	0.233
Platelets (109/L)	193 ± 77	185 ± 54	201 ± 52	0.822
Creatinine (mg/dL)	0.99 ± 0.47	0.83 ± 0.25	0.96 ± 0.26	0.501
Total cholesterol (mg/dL)	165 ± 46	151 ± 27	188 ± 68	0.287
HDL cholesterol (mg/dL)	44 ± 16	39 ± 9	40 ± 17	0.739
LDL cholesterol (mg/dL)	97 ± 39	74 ± 36	113 ± 53	0.175
Triglycerides (mg/dL)	100 ± 54	139 ± 59	176 ± 88	0.090

HDL: high density lipoprotein, LDL: low density lipoprotein, pro-BNP: pro-brain natriuretic peptide.

4.1. Clinical Implications. In the choice of stents, interventional cardiologists should consider those structural characteristics, which allow a close and homogeneous contact of the stent with the vessel wall as being an important parameter. In this respect, Xience, among the three types of stents analyzed, would seem to be the best option for daily practice when considering struts' malapposition.

Table 3: OCT analysis at the index PCI and comparison with OCT analysis at 6-month follow-up.

		Cre8 ($n = 14$)	Biomatrix ($n = 11$)	Xience ($n = 12$)	p value
Stent total length (mm), mean ± SD		20 ± 7.17	28 ± 8.92	30.3 ± 11.83	0.022 (A)
Overlapping stents, n (%)		3 (21)	3 (27)	4 (33)	N.S.
Cross sections analyzed (n)					
Index PCI		221	186	207	N/A
Follow-up		217	179	203	N/A
Homogeneous distribution struts, n (%)		98.7 ± 3.3	97.5 ± 4.3	99.5 ± 1.6	0.348 (A)
Vessel wall injury, median (IQR)		0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–5.4)	0.010 (K-W)
Vessel lumen without thrombus, mean ± SD		97.9 ± 4.1	96.8 ± 4.3	96.2 ± 5.5	0.667 (A)
Protruding plaque, median (IQR)		9.1 (0.0–22.2)	0.0 (0.0–0.0)	10.5 (2.8–16.2)	0.097 (K-W)
Lipid plaque, median (IQR)		7.1 (0.0–15.8)	0.0 (0.0–6.7)	5.9 (0.0–13.6)	0.500 (K-W)
Calcified plaque, median (IQR)		0.0 (0.0–15.4)	0.0 (0.0–6.7)	0.0 (0.0–14.2)	0.579 (K-W)
Intimal dissection, median (IQR)		0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.347 (K-W)
Struts analyzed (n)					
Index PCI		2079	1615	1820	N/A
Follow-up		2041	1554	1782	N/A
Lumen area (mm^2), mean ± SD					
Index PCI		8.70 ± 2.26	8.66 ± 2.54	7.15 ± 1.40	0.138
Follow-up		8.05 ± 2.38	8.23 ± 2.87	7.77 ± 1.25	0.895
Follow-up versus Index, p (paired t-test)		0.800	0.744	0.094	
Cross section with ISA					
Index PCI, n (%)		7/220 (3.2)	3/186 (1.6)	7/207 (3.4)	0.509 $\chi 2$
Follow-up, n (%)		24/217 (11.05)	8/179 (4.5) p value = 0.017 Cre8 versus biomatrix	2/203 (0.9) p value=<0.001 Xience versus Cre8 p value = 0.033 Xience versus biomatrix	<0.001 $\chi 2$
Malapposed struts					
Index PCI	mean ± SD	0.57 ± 1.51	0.55 ± 1.81	0.58 ± 1.51	0.998 (A)
	Median (IQR)	0.00 (0.00–0.00)	0.00 (0.00–0.00)	0.00 (0.00–0.00)	0.917 (K-W)
Follow-up	mean ± SD	3.29 ± 5.33	1.73 ± 2.28	0.25 ± 0.87	0.109 (A)
	Median (IQR)	1.00 (0.00–4.00)#	1.00 (0.00–3.00)	0.00 (0.00–0.00)#	0.032 (K-W)
Follow-up versus Index	p (paired t-test)	0.023	0.024	0.166	
	p (Wilcoxon)	0.012	0.026	0.157	

A : ANOVA; $\chi 2$: chi-square; N/A : not available; K-W: Kruskal–Wallis test. #: Mann–Whitney U-test; $p = 0.029$.

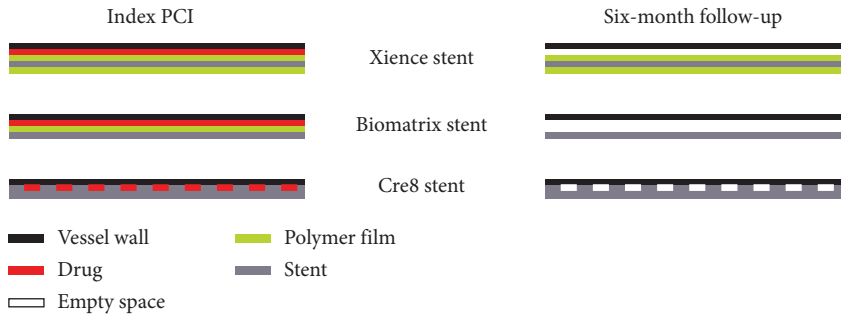

Figure 3: Schematic representation of the structural differences among the tree types of stents and their different interaction with the vessel wall during PCI and at 6-month follow-up.

4.2. Limitations. Some limitations of our study have to be acknowledged. First, the study examines only 37 patients and was therefore not powered to allow clinical considerations. Moreover, because of the small number of patients included in this study, the patients in the Xience group were 10 years younger than those in the other two groups. Consequently, we cannot exclude a possible role of aging in the speculative interpretation of the results. The younger patients might have a better long-term healing process compared to older patients.

Second, our conclusions regarding the impact of biomechanical differences on the behavior of the three types of stents are mainly based on logical hypotheses of pathophysiological nature and not on our experimental data.

4.3. Future Directions. Experimental studies or clinical studies enrolling a wider population of patients will better clarify the relation between stents' structural characteristics and their healing process.

5. Conclusions

The results of the present study suggest that the plaque composition and struts' malapposition observed with OCT at the index PCI were not significantly different among the three groups of patients. However, patients treated with Cre8 and Biomatrix showed a higher percentage of malapposed struts than those treated with Xience at six-month follow-up. Therefore, the malapposition observed at six-month follow-up in our study's population could be mainly considered as acquired and attributable to biomechanical reasons due to the structural differences among the three stents. A close and homogeneous contact of the stents' platform with the vessel wall, as we supposed for the Xience stent, could explain the lower percentage of malapposed struts observed in the group of patients treated with this kind of stent.

Data Availability

Data supporting our results are collected in a dedicated database of the AOU Careggi Hospital.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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