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Comparison of a Novel Biodegradable Polymer Sirolimus-Eluting Stent With a Durable Polymer Everolimus-Eluting Stent

5-Year Outcomes of the Randomized BIOFLOW-II Trial

Thierry Lefèvre, MD,[a] Michael Haude, MD,[b] Franz-Josef Neumann, MD,[c] Karl Stangl, MD,[d] Carsten Skurk, MD,[e] Ton Slagboom, MD,[f] Manel Sabaté, MD,[g] Javier Goicolea, MD,[h] Paul Barragan, MD,[i] Stéphane Cook, MD,[j] Jean-Christophe Macia, MD,[k] Stephan Windecker, MD[l]

ABSTRACT

OBJECTIVES The authors aimed to compare long-term data of an ultrathin cobalt-chromium stent with passive silicon carbide coating and an active biodegradable polymer that releases sirolimus (O-SES) (Orsiro, BIOTRONIK, Bülach, Switzerland) with the durable polymer-based Xience Prime everolimus-eluting stent (X-EES) (Abbott Vascular, Santa Clara, California).

BACKGROUND Biodegradable polymer stents have been developed aiming to overcome long-term detrimental effects of durable polymer stents, ultimately leaving a bare-metal stent in the vessel.

METHODS This multicenter, assessor-blinded trial randomized 452 patients with 505 lesions to either O-SES or X-EES in a 2:1 fashion. Endpoints at 5 years were target lesion failure (TLF), its components, and stent thrombosis.

RESULTS TLF occurred in 10.4% (n = 30) of O-SES patients versus 12.7% (n = 19) of X-EES patients (p = 0.473), overall stent thrombosis occurred in 0.7% (n = 2) versus 2.8% (n = 4) (p = 0.088), and definite stent thrombosis in 0% versus 0.7% (n = 1) (p = 0.341). Post hoc analysis was performed in diabetic patients (n = 128) and vessels ≤2.75 mm (n = 259). In diabetic patients, the O-SES group had numerically more target lesion revascularizations (13.5% vs. 4.5%; p = 0.138), but fewer cardiac deaths (1.3% vs. 6.9%; p = 0.089) and stent thrombosis (0% vs. 6.9%; p = 0.039). In small vessels, the O-SES group had a significantly lower 5-year mortality (3.7% vs. 11.3%; p = 0.022).

CONCLUSIONS At 5 years, the biodegradable polymer O-SES demonstrated low TLF rates comparable to the durable polymer X-EES, confirming its long-term safety and performance. Particularly encouraging is the absence of definite stent thrombosis. (J Am Coll Cardiol Intv 2018;11:995–1002) © 2018 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

From the [a]Department of Interventional Cardiology, Hopital Jacques Cartier, Massy, France; [b]Medical Clinic I, Städtische Kliniken Neuss, Lukaskrankenhaus, Neuss, Germany; [c]Department of Cardiology and Angiology, Universitäts-Herzzentrum Freiburg-Bad Krozingen, Bad Krozingen, Germany; [d]Department of Cardiology, Campus Charité Mitte, Charité - Universitätsmedizin Berlin, Berlin, Germany; [e]Department of Cardiology, Charité Campus Benjamin Franklin, Berlin, Germany; [f]Department of Cardiology, Onze Lieve Vrouwe Gasthuis, Amsterdam, the Netherlands; [g]Department of Cardiology, Hospital Clínic, Thorax Institute, Barcelona, IDIBAPS, University of Barcelona, Barcelona, Spain; [h]Department of Cardiology, Hospital Puerta de Hierro, Madrid, Spain; [i]Department of Cardiology, Polyclinique les Fleurs, Ollioules, France; [j]Department of Cardiology, Hospital and University Fribourg, Switzerland; [k]Department of Cardiology, University of Montpellier, Montpellier, France; and the [l]Department of Cardiology, Bern University Hospital, Bern, Switzerland. The study was funded by BIOTRONIK AG, Buelach, Switzerland. Dr. Lefèvre has been a proctor for Edwards Lifesciences, Abbott Vascular, and Terumo. Dr. Haude has received study grants and lecture fees from Biotronik, Abbott Vascular, Cardiac Dimensions, Medtronic, Volcano, and Daiichi Sankyo; and has served on an advisory board and speakers bureau for Biotronik. Dr. Neumann has received research support from Biotronik. Dr. Stangl has been a consultant for Abbott Vascular. Dr. Slagboom has been a consultant to Biotronik. Dr. Sabaté has been a consultant for Abbott Vascular. Dr. Windecker has received research grants to the institution from Abbott, Biotronik, Boston Scientific, Biosensors, Medtronic, Edwards Lifesciences, and St. Jude Medical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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ABBREVIATIONS AND ACRONYMS

ASA = acetylsalicylic acid

CI = confidence interval

DAPT = dual antiplatelet therapy

DES = drug-eluting stent(s)

HR = hazard ratio

IQR = interquartile range

O-SES = Orsiro sirolimus-eluting stent(s)

ST = stent thrombosis

TLF = target lesion failure

TLR = target lesion revascularization

X-EES = Xience Prime everolimus-eluting stent(s)

Continued efforts to improve outcomes after percutaneous coronary interventions using drug-eluting stents (DES) led to the design of DES with biodegradable polymers. Because durable polymers have been associated with local vascular inflammatory reactions and stent thrombosis (ST), the concept of a biodegradable polymer is appealing, eluting the drug over an appropriate amount of time, ultimately leaving the bare-metal stent in the vessel (1).

The use of biodegradable polymer stents theoretically is expected to show long-term benefits. In a first step, the novel technology had to prove its noninferiority to a contemporary first-in-class durable polymer stent. In a second step, potential long-term benefits shall be assessed (2).

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The Orsiro DES (O-SES) (BIOTRONIK, Bülach, Switzerland) is a ultrathin cobalt-chromium stent (60-μm struts) passively coated with amorphous silicon carbide. The active coating consists of a biodegradable poly-L-lactic acid polymer from which sirolimus is released. Published 1-year outcomes of the BIOFLOW-II (Study of the Orsiro Drug Eluting Stent System) study showed noninferiority to the everolimus-eluting Xience stent (X-EES) (Abbott Vascular, Santa Clara, California) (3). Those results were corroborated by several randomized controlled trials, in which Orsiro was noninferior to contemporary everolimus and zotarolimus durable polymer stents and biolimus-eluting biodegradable polymer stents (2,4–6). Moreover, in the recently published BIOFLOW-V trial, Orsiro-treated patients had significantly lower 12-month target lesion failure (TLF), target vessel myocardial infarction, and late ST rates compared with the durable polymer X-EES (7). Herein, we report 5-year outcomes of the BIOFLOW-II study.

METHODS

STUDY DESIGN. The study design has been published previously (3) and is posted on ClinicalTrials.gov (NCT01356888). In brief, the BIOFLOW-II study is a randomized, multicenter, assessor-blind, noninferiority trial comparing the biodegradable polymer-based O-SES with the durable polymer-based X-EES.

Main inclusion criteria were de novo lesions with a maximum length of 26 mm and a reference vessel diameter from 2.25 to 4.0 mm by visual estimate suitable for coronary stent implantation. Main exclusion criteria were evidence of myocardial infarction within 72 h before the procedure, unprotected left main disease of >50% diameter stenosis, 3-vessel coronary artery disease, evidence of thrombus within the target vessel, heavily calcified lesions, and ostial lesions within 5 mm of the coronary ostium.

Patients were randomly allocated to treatment with O-SES or X-EES in a 2:1 ratio. Both stent types were available in diameters from 2.25 to 4.0 mm. Dual antiplatelet therapy (DAPT) was recommended for 6 months post-procedure and acetylsalicylic acid (ASA) lifelong, according to the current European Society of Cardiology/European Association for Cardio-Thoracic Surgery guidelines on myocardial revascularization (8).

Follow-ups were scheduled at 30 days; 6, 9, and 12 months; and annually thereafter up to 5 years. All serious adverse events and adverse device effects were adjudicated by an independent clinical events committee. The study was performed in accordance with ISO14155:2011 and the Declaration of Helsinki, and was approved by all institutional ethics committees. All patients provided written informed consent.

STUDY ENDPOINTS AND DEFINITIONS. The primary endpoint was in-stent late lumen loss at 9 months after stent implantation, assessed by quantitative coronary angiography of an independent core laboratory. Secondary angiographic endpoints, intravascular and optical coherence tomography, procedure and device success, and 1-year safety outcomes have been reported previously (3). Secondary endpoints beyond 1 year were TLF, a composite of cardiac death, target vessel myocardial infarction (9), and clinically driven target lesion revascularization (TLR); target vessel failure, a composite of cardiac death, target-vessel myocardial infarction, and clinically driven target vessel revascularization; a composite of all-cause mortality and myocardial infarction; and definite ST (10).

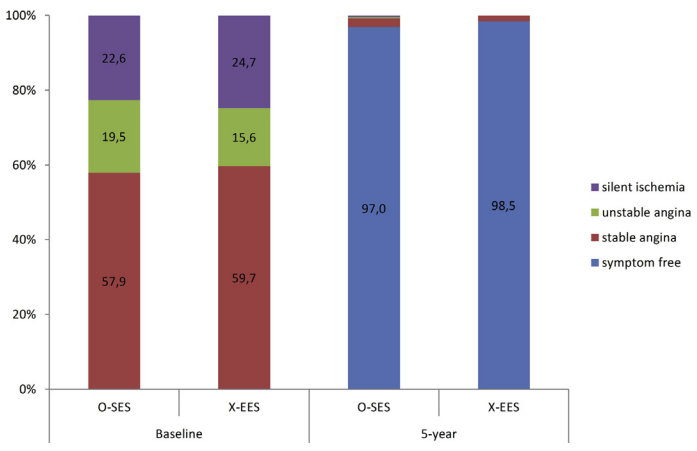
STATISTICAL ANALYSIS. This study was powered for noninferiority related to the primary endpoint, in-stent late lumen loss at 9 months (3). Patients were analyzed in the groups they were allocated to, regardless of the treatment actually received (intention to treat). Continuous variables are presented as mean ± SD or median (interquartile range [IQR]) and categorical variables as number (percent). Chi-square test was used for comparison. Clinical outcomes were presented as Kaplan-Meier estimates and groups compared using the log-rank test. The Cox proportional hazards model was used to estimate hazard ratios (HRs) and 95% confidence intervals (CIs) for between-group comparison. In a post hoc analysis,

TABLE 1 Baseline Clinical Characteristics

	O-SES (n = 298)	X-EES (n = 154)	p Value
Age, yrs	62.7 ± 10.4	64.8 ± 9.2	0.032
Male	233 (78.2)	115 (74.7)	0.400
Cardiac risk factors			
Diabetes mellitus	84 (28.2)	44 (28.6)	0.932
Insulin dependent	18 (21.4)	15 (34.1)	0.120
Hypertension	231 (77.5)	119 (77.3)	0.953
Hypercholesterolemia	202 (67.8)	113 (73.4)	0.220
History of myocardial infarction	90 (30.2)	31 (20.1)	0.022
Prior coronary intervention	128 (43.0)	55 (35.7)	0.137
Cancer	16 (5.4)	10 (6.5)	0.627

Values are mean ± SD or n (%).
O-SES = Orsiro sirolimus-eluting stent; X-EES = Xience everolimus-eluting stent.

FIGURE 1 Angina Status at Baseline and 5-Year Follow-Up



At 5-year follow-up, 97.0% of Orsiro sirolimus-eluting stent (O-SES) patients were symptom-free, 2.2% had stable angina, 0.4% had unstable angina, and 0.4% documented silent ischemia; and 98.5% of Xience everolimus-eluting stent (X-EES) patients were symptom free and 1.5% had stable angina.

the subgroups of diabetic patients and small lesions ≤2.75 mm were assessed. The statistical analyses were carried out using SAS 9.4 (SAS Institute, Cary, North Carolina).

RESULTS

Between July 2011 and March 2012, 452 patients were randomized in 24 centers in 8 European countries. Of those, 298 patients with 332 lesions were allocated to treatment with the O-SES and 154 patients with 173 lesions to the X-EES. At 5 years, 8 patients (2.7%) in the O-SES group had withdrawn consent, and another 8 (2.7%) were lost to follow-up, whereas 6 patients (3.9%) of the X-EES group withdrew consent, and 2 (1.3%) were lost to follow-up.

Baseline data are provided in Table 1. By core laboratory assessment, mean reference vessel diameter was 2.78 ± 0.49 mm for O-SES and 2.75 ± 0.49 mm for X-EES, mean lesion length was 13.36 ± 6.82 mm and 13.65 ± 5.58 mm, and type B2/C lesions presented in 28.2% and 22.2% of lesions, respectively. All subjects received the allocated study stent (100% device success). At 9-month follow-up, in-stent late lumen loss was 0.10 ± 0.32 for O-SES versus 0.11 ± 0.29 mm for X-EES ($p_{noninferiority}$ <0.0001).

At 5-year follow-up, 24.7% (66 of 267) of patients in the O-SES group received dual or triple antiplatelet therapy versus 14.4% (19 of 132) in the X-EES group (p = 0.018). Of the overall 85 patients, 75.3% (n = 64) received ASA plus clopidogrel, 11.8% (n = 10) received ASA plus prasugrel, 7.1% (n = 6) received ASA plus ticagrelor, and 5.9% (n = 5) received triple therapy with ASA, clopidogrel, and prasugrel (n = 4) or ticagrelor (n = 1) without a difference among the groups. On single-use ASA only were 65.5% (175 of 267) in the O-SES group versus 73.5% (97 of 132) in the X-EES group (p = 0.109), and a few patients received single-dose clopidogrel (n = 12), prasugrel (n = 4), or ticagrelor (n = 2).

The angina status was similar among the groups, and nearly all patients were free of ischemic symptoms at 5 years (Figure 1).

Median follow-up time was 1,825 days (IQR: 1,815 to 1,831 days) for O-SES and 1,823 days (IQR: 1,813 to 1,830 days) for X-EES. At 1 year, TLF estimates were 6.5% (95% CI: 4.2% to 10.0%) in the O-SES group versus 7.9% (95% CI: 4.6% to 13.5%) in the X-EES group, and at 5 years, rates were 10.4% (95% CI: 7.4% to 14.5%) versus 12.7% (95% CI: 8.3% to 19.3%; p = 0.473). Five-year mortality was numerically lower in the O-SES group (4.9% [95% CI: 2.9% to 8.1%] vs. 9.5% [95% CI: 5.8% to 15.6%]; HR: 0.51 [95% CI: 0.24 to 1.07]; p = 0.069), as was the rate of overall ST (0.7% [95% CI: 0.2% to 2.8%] vs. 2.8% [95% CI: 1.1% to 7.4%]; HR: 0.25 [95% CI: 0.05 to 1.39]; p = 0.088, thereof 0% and 0.7% [95% CI: 0.1% to 5.0%]; p = 0.341, were definite ST) (Table 2, Figure 2).

DIABETIC AND SMALL VESSEL SUBGROUPS. For both, diabetes (n = 128) and small vessels (n = 259), groups were well balanced. The only significant difference in the diabetic subgroup was less frequent baseline congestive heart failure in O-SES compared with X-EES patients (13.1% vs. 27.3%; p = 0.047). The small vessel (≤2.75 mm in diameter) group had fewer left circumflex lesions (22.7% vs. 37.6%; p = 0.005) and longer stents implanted (19.3 ± 6.1 mm vs. 17.4 ± 5.9 mm; p = 0.005) in the O-SES group.

TABLE 2 Kaplan-Meier Estimates of Clinical Outcomes at 5 Years

	O-SES	X-EES	Hazard Ratio (95% CI)	p Value
Overall, n	298	154		
Death	14 (4.9)	14 (9.5)	0.51 (0.24–1.07)	0.069
Cardiac death	5 (1.7)	4 (2.8)	0.64 (0.17–2.39)	0.504
MI, univ. def.	13 (4.5)	9 (6.2)	0.74 (0.32–1.73)	0.487
TV MI, univ. def.	10 (3.4)	5 (3.3)	1.03 (0.35–3.02)	0.953
Clinically indicated TLR	18 (6.3)	10 (6.7)	0.93 (0.43–2.01)	0.850
Clinically indicated TVR	36 (12.6)	15 (10.1)	1.25 (0.68–2.28)	0.465
Coronary artery bypass graft	0 (0.0)	0 (0.0)	1.00 (1.00–1.00)	–
Target lesion failure, univ. def.	30 (10.4)	19 (12.7)	0.81 (0.46–1.44)	0.473
Target vessel failure, univ. def.	45 (15.6)	19 (12.7)	0.97 (0.59–1.58)	0.891
Mortality or MI, univ. def.	26 (9.0)	20 (13.4)	0.66 (0.37–1.19)	0.166
Stent thrombosis	2 (0.7)	4 (2.8)	0.25 (0.05–1.39)	0.088
Definite	0 (0.0)	1 (0.7)	–	0.341
Probable	0 (0.0)	0 (0.0)	–	–
Diabetic subgroup, n	88	44		
Death	6 (7.3)	4 (9.1)	0.78 (0.22–2.78)	0.707
Cardiac death	1 (1.3)	3 (6.9)	0.18 (0.02–1.69)	0.089
MI, univ. def.	4 (4.9)	1 (2.4)	2.15 (0.24–19.26)	0.482
TV MI, univ. def.	2 (2.5)	0 (0.0)	–	0.545
Clinically indicated TLR	11 (13.5)	19 (4.5)	2.96 (0.66–13.37)	0.138
Clinically indicated TVR	17 (20.8)	4 (9.3)	2.33 (0.79–6.94)	0.116
Target lesion failure, univ. def.	13 (15.9)	5 (11.5)	1.43 (0.51–4.00)	0.498
Target vessel failure, univ. def.	19 (23.3)	7 (16.0)	1.52 (0.64–3.60)	0.344
Mortality or MI, univ. def.	8 (12.1)	4 (9.1)	1.34 (0.42–4.28)	0.617
Stent thrombosis	0 (0.0)	3 (6.9)	–	0.039
Definite	0 (0.0)	0 (0.0)	–	–
Probable	0 (0.0)	0 (0.0)	–	–
Small vessels subgroup, n	168	91		
Death	6 (3.7)	10 (11.3)	0.33 (0.12–0.90)	0.022
Cardiac death	1 (0.6)	2 (2.2)	0.28 (0.03–3.08)	0.265
MI, univ. def.	8 (4.9)	5 (5.6)	0.86 (0.28–2.63)	0.791
TV MI, univ. def.	6 (3.7)	4 (4.4)	0.81 (0.23–2.86)	0.738
Clinically indicated TLR	14 (8.7)	8 (8.9)	0.97 (0.41–2.32)	0.948
Clinically indicated TVR	25 (15.6)	12 (13.3)	1.16 (0.58–2.31)	0.676
Target lesion failure, univ. def.	18 (11.1)	14 (15.5)	0.69 (0.35–1.40)	0.303
Target vessel failure, univ. def.	27 (16.8)	18 (19.9)	0.80 (0.44–1.46)	0.475
Death or MI, univ. def.	13 (8.0)	14 (15.6)	0.50 (0.23–2.86)	0.066
Stent thrombosis	1 (0.6)	1 (1.1)	0.55 (0.03–8.84)	0.671
Definite	0 (0.0)	0 (0.0)	–	–
Probable	0 (0.0)	0 (0.0)	–	–

Values are n (%) unless otherwise indicated.

CI = confidence interval; MI = myocardial infarction; TLR = target lesion revascularization; TVR = target vessel revascularization; univ. def. = universal definition.

For diabetic patients, 5-year TLF rates were 15.9% for O-SES versus 11.5% for X-SES (p = 0.498), caused by a numerical difference in clinically driven TLR (13.5% vs. 4.5%; p = 0.138), whereas cardiac death was numerically lower in the O-SES group (1.3% vs. 6.9%; p = 0.089) as well as ST (0% vs. 6.9%; p = 0.039). In patients with small vessels ≤2.75 mm, 5-year TLF rates were 11.1% versus 15.5% (p = 0.303). This difference was mainly due to a lower overall death rate in the O-SES group (3.7% vs. 11.3%; p = 0.022).

DISCUSSION

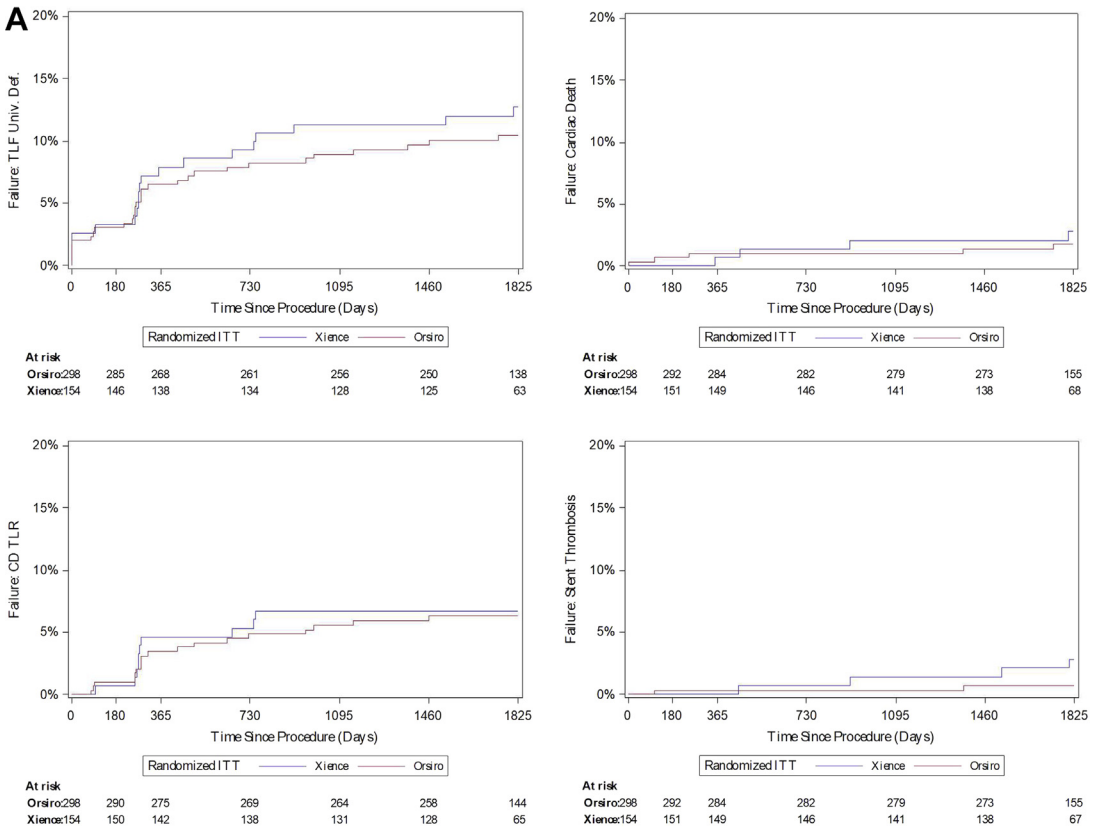
To our knowledge, this is the first report of the Orsiro biodegradable polymer stent at 5 years. The main findings of this randomized trial are the excellent 5-year outcomes for both the biodegradable polymer O-SES and the durable polymer X-EES. Further, even though the trial was not powered for clinical outcomes, there was a trend toward less ST in the O-SES group (0.7% vs. 2.8%; p = 0.088%), which was significant in the diabetics subgroup (0% vs. 6.9%; p = 0.039).

In contrast, the BIOFOLOW-V trial was powered for noninferiority of TLF at 12 months and included 1,334 randomized patients. It also employed a Bayesian approach incorporating data from the BIOFLOW-II and BIOFLOW-IV trials (7). The pooled analysis revealed a Bayesian posterior probability of 100% that O-SES was noninferior to X-EES, and of 96.9% that O-SES is superior to X-EES. Moreover, trial data from the BIOFLOW-V trial itself showed significantly lower TLF rates (6% vs. 10%; p = 0.0399) and target vessel myocardial infarction rates (5% vs. 8%; p = 0.0155) in the O-SES group (note: a more sensitive definition of myocardial infarction than in BIOFLOW-II and BIOSCIENCE was used). The authors postulated that O-SES establishes "a new standard for new drug-eluting stent comparison."

These superior outcomes at 12 months are surprising, as the true benefit of biodegradable polymer stents is expected to show after complete polymer dissolution at 12 to 24 months. This is the case in our series where—in the high-risk subsets of diabetics and patients with small vessels—the curves start to diverge beyond 1 year. Likely, the superior 12-month outcomes of the BIOFLOW-V study are rather related to other factors such as the ultrathin stent design (60-μm struts). In a recent State-of-the-Art paper, Orsiro had the thinnest struts of relevant contemporary stents, and thinner struts are associated with better stent delivery and are expected to be less thrombogenic. Likewise, in the BIOFLOW-V study, procedure success (defined as diameter stenosis <30%, using the assigned stent, and no in-hospital major adverse cardiac event) was significantly higher in the O-SES group than in the X-EES group (94% vs. 90%; p = 0.0191). In addition, the drug-polymer combination plays a paramount role (7,11).

Our 5-year outcomes, particularly the very low rate of 0.7% overall ST and absence of definite ST in the O-SES group at 5 years are remarkable. Aside from the biodegradable polymer, the passive coating with

FIGURE 2 Kaplan-Meier Estimates for TLF, Cardiac Death, CD TLR, and Overall Stent Thrombosis



(A) Overall population. **(B)** Diabetic patients. **(C)** Small vessels. Target lesion failure (TLF) was 10.4% for the O-SES and 12.7% for the X-EES. CD TLR = clinically driven target lesion revascularization; Univ. Def. = universal definition; other abbreviations as in Figure 1.

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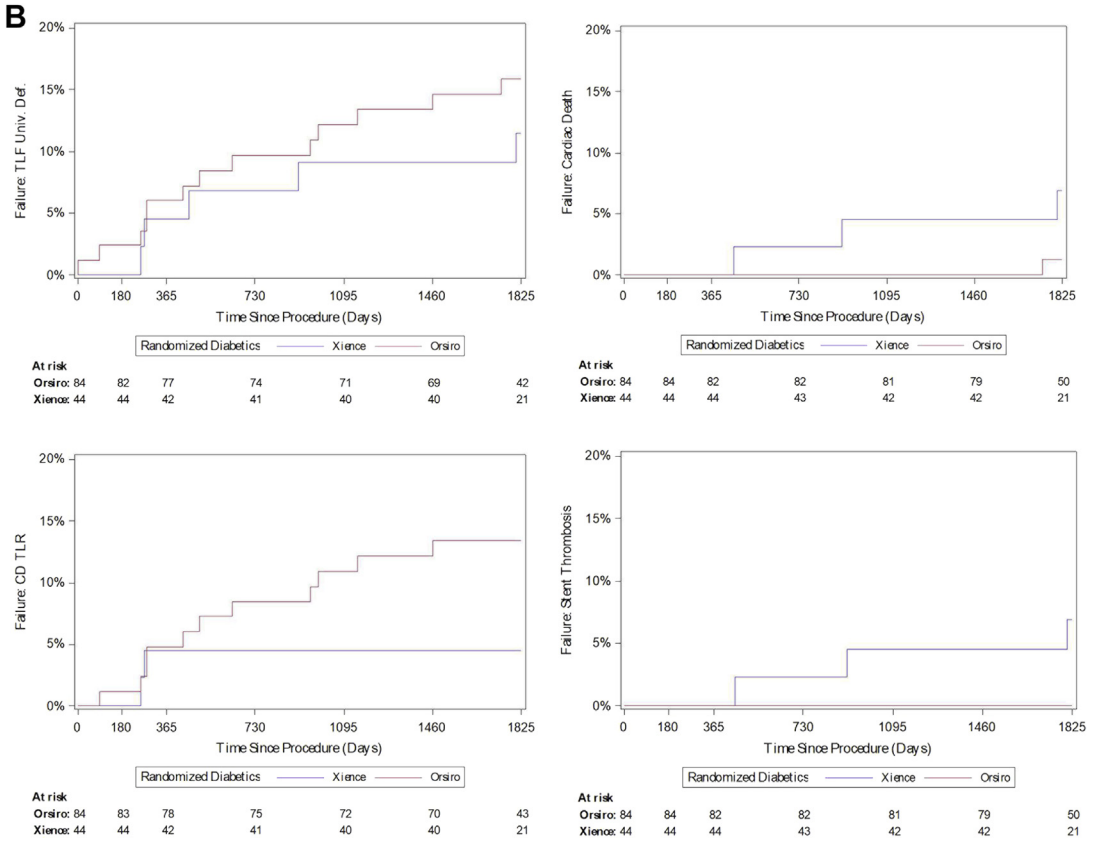
silicone carbide, which is thought to inhibit platelet adhesion, might have contributed to these outcomes. Among other things, it is thought to inhibit platelet adhesion. In more than 1,000 patients enrolled in the ENERGY (Long Term Safety Profile of the PRO-Kinetic ENERGY Coronary Stent System in Daily Clinical Practice) registry using a bare-metal stent with the same passive coating, definite ST at 2 years was only 0.6% in diabetic patients (12). Notably in our series, there were still a reasonable number—24.7% of patients in the O-SES group and 14.4% in the X-EES group ($p = 0.018$)—on DAPT at 5 years. Thereby the reason for the disparity is unclear, but it is unlikely to be associated with the device per se. Rather, it may be a by-chance finding related to differences in current comorbidities or anticoagulation regimes.

Our results for O-SES (TLF of 10.4% and absence of probable or definite ST) compare well with 5-year outcomes of other biodegradable polymer stents. In the LEADERS (Limus Eluted From A Durable Versus ERodable Stent Coating) trial, the 5-year TLF rate was 20.0% for the biodegradable polymer biolimus-eluting BioMatrix Flex stent (Biosensors, Newport Beach, California) and 23.1% for the first-generation durable polymer sirolimus-eluting Cypher SELECT stent (Cordis, Miami Lakes, Florida), whereas definite or probable ST rates were 3.6% and 5.2%, respectively (13). In the EVOLVE (Non-inferiority Trial to Assess the Safety and Performance of the Evolution Coronary Stent) study, TLF was 5.5% in 92 patients treated with the biodegradable polymer everolimus-eluting Synergy stent (Boston Scientific, Marlborough, Massachusetts) versus 7.2% in patients treated with a durable polymer everolimus-eluting stent; definite or probable stent thrombosis was absent in both groups (14). In more than 3,000 patients of the NOBORI registry using the biodegradable, polymer-coated, biolimus-eluting Nobori stent (Terumo, Tokyo,

FIGURE 2 Continued



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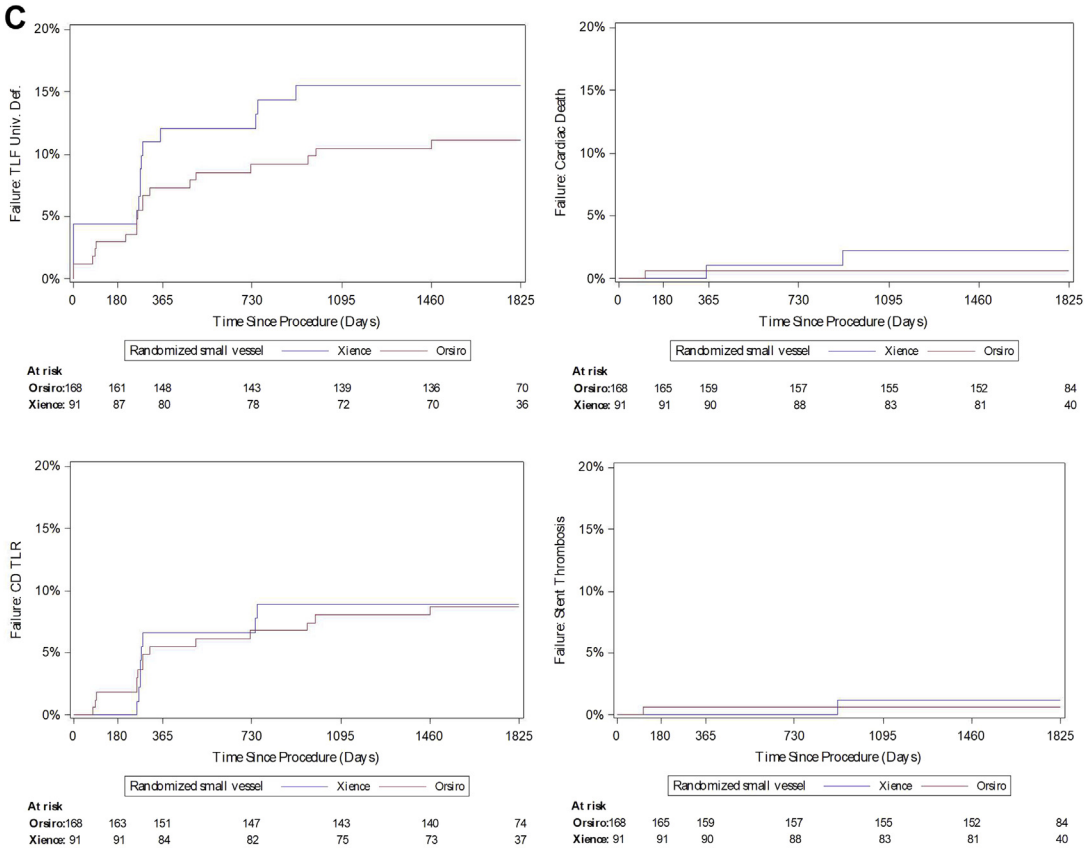
Japan), the 5-year composite of cardiac death, any myocardial infarction, and TLR was 10.0%. Definite or probable ST occurred in 1.2% (15). In the randomized COMPARE-II (Abluminal Biodegradable Polymer Biolimus-Eluting Stent Versus Durable Polymer Everolimus-Eluting Stent) trial including 2,707 patients, the 5-year TLF rate was 13.5% for the Nobori stent and 11.5% for X-EES, and the rate of definite or probable ST was 1.5% versus 0.9% (16). Although the ST rates are very low, they are still higher than in our series. Correspondingly, in the SORT-OUT VII (Scandinavian Organization for Randomized Trials With Clinical OUTcome) randomized trial comparing more than 2,500 patients, the O-SES had a significantly lower definite ST rate compared with the Nobori stent at 1 year (0.4% versus 1.2%; $p = 0.03$). The authors discussed that the slower polymer degradation (12 to 24 months compared with 6 to 9 months) and thinner struts (60 to 80 μm vs. 120 μm) may reduce inflammatory response and the risk of ST (5).

Considering the low ST rates for Orsiro, potential better re-endothelialization of ultrathin struts, improved polymer durability, and the potential that slower polymer degradation or thinner struts may reduce the risk of early ST, a shorter DAPT use may be reasonable (5,11,17,18). More insights are expected from the currently enrolling randomized HOST-IDEA (Harmonizing Optimal Strategy for Treatment of Coronary Artery Stenosis - Coronary Intervention With Next Generation Drug-Eluting Stent Platforms and Abbreviated Dual Antiplatelet Therapy) trial that compares the ultrathin Orsiro and Coroflex ISAR (B. Braun Melsungen, Berlin, Germany) stents using 3-month versus 12-month DAPT (18).

DIABETIC AND SMALL VESSEL SUBGROUPS. Orsiro performed well in patients with diabetes and small lesions. Although in 128 diabetic patients of our series, the X-EES arm had numerically less TLR (13.5% for O-SES and 4.5% for X-EES; $p = 0.138$), that came at the price of a numerically higher cardiac death rate

FIGURE 2 Continued



(1.3% for O-SES vs. 6.9% for X-EES; p = 0.089) and a significantly higher overall ST rate. Due to its low strut thickness, Orsiro may be particularly useful in small vessels. In our series, in 259 patients with small vessels, the 5-year TLF rate was numerically lower (11.1% vs. 15.5%; p = 0.303), and there were also significantly fewer deaths (3.7% vs, 11.3%; p = 0.022), but that might rather be a by-chance finding.

STUDY LIMITATIONS. The main limitation of BIOFLOW-II study is the small sample size that was powered for the primary endpoint late lumen loss, but not for clinical outcomes. As is common with early randomized trials, our series is not presenting an all-comers population, because for example, patients with acute myocardial infarction or 3-vessel disease were excluded, as were those with complex lesion morphologies such as heavy calcification, long lesion length, ostial stenosis, vein graft disease, and left main disease. Five-year outcomes of the all-comers BIOFLOW-III registry are expected to cover this knowledge gap.

CONCLUSIONS

Five-year outcomes of the randomized, assessor-blinded BIOFLOW-II study demonstrate the long-term safety and performance of the biodegradable polymer O-SES with a low TLF rates, similar to the durable polymer X-EES, and no case of definite or probable ST.

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ADDRESS FOR CORRESPONDENCE: Dr. Thierry Lefèvre, Institut Cardiovasculaire Paris Sud, Hopital Privé Jacques Cartier, 6 avenue du Noyer Lambert, 91300 Massy, France. E-mail: t.lefevre@angio-icps.com.

PERSPECTIVES

WHAT IS KNOWN? Biodegradable polymer stents have shown noninferiority to contemporary durable polymer DES, but long-term data are scarce.

WHAT IS NEW? The BIOFLOW-II study presents the first 5-year data of the biodegradable polymer O-SES and shows comparable clinical outcomes to the durable polymer X-EES with absence of definite or probable ST.

WHAT IS NEXT? The excellent outcomes of the BIOFLOW-II study should be confirmed in a larger series of patients treated under real-world conditions, and randomized trials should evaluate whether DAPT can be shortened to 3 months.

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