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Twelve-month clinical and imaging outcomes of the uncaging coronary DynamX bioadaptor system

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KEYWORDS

- clinical research
- miscellaneous
- other technique
- stable angina

Abstract

Aims: We aimed to assess the safety and efficacy of the DynamX Novolimus-Eluting Coronary Bioadaptor System, a novel device that initially acts as a second-generation drug-eluting stent, but after six months frees the vessel through uncaging elements.

Methods and results: This multicentre study enrolled 50 patients with single *de novo* lesions. In-device acute lumen gain was 1.61±0.34 mm, and device and procedure success was 100%. Up to 12 months, two target lesion failures occurred: both were cardiac deaths (day 255 and day 267 post procedure). No definite or probable device thrombosis was observed. Mean late lumen loss was 0.12±0.18 mm in-device and 0.11±0.16 mm in-segment. Per intravascular ultrasound, the mean device area and mean vessel area increased significantly by 5% and 3%, respectively, while the mean lumen area was maintained. Stationary optical coherence tomography in seven patients demonstrated restoration of cyclic pulsatility, with an approximate lumen area variance of 11% between systole and diastole.

Conclusions: The DynamX bioadaptor showed drug-eluting stent-like acute performance and safety and efficacy up to one year. Positive remodelling with an increase of vessel and device area while maintaining the mean lumen area was demonstrated. Long-term follow-up and randomised trials are required to assess the benefit of this device on events beyond one year.

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Abbreviations

DES drug-eluting stent
IVUS intravascular ultrasound
NIH neointimal hyperplasia
OCT optical coherence tomography
TLF target lesion failure
TLR target lesion revascularisation
TV-MI target vessel myocardial infarction
TVR target vessel revascularisation

Introduction

Improvements in device technology have reduced early event rates after drug-eluting stent (DES) implantation but, beyond one year, a persistent 2-4% annual incidence of major adverse events or target lesion failure (TLF) without plateau is observed[1,2]. Device-related factors contributing to these events are that conventional DES "cage" the coronary artery, causing mechanical distortion, preventing positive adaptive remodelling and pulsatility, as well as serving as a nidus for chronic inflammation and strut fractures[2]. Although bioresorbable scaffolds attempted to address these issues by providing structural support to the vessel early on, followed by resorption, randomised trials showed that, prior to their resorption, they were less safe and effective than contemporary DES[3,4].

The DynamX™ Novolimus-Eluting Coronary Bioadaptor System (Elixir Medical Corporation, Milpitas, CA, USA) is a novel device with a series of unique characteristics that gained CE mark in September 2019. It is a thin (71 µm) cobalt-chromium platform that offers a fundamental innovation in stent design, incorporating uncaging elements in the sinusoidal rings. The thin polymer coating on the uncaging elements resorbs over six months, allowing the device to accommodate vessel expansion. In this context, the DynamX bioadaptor combines the acute performance of contemporary DES with the unique benefit of arterial "uncaging" to permit a return towards cyclic pulsatility and compensatory positive adaptive remodelling, which may result in fewer clinical events beyond one year. We report the first clinical experience from the DynamX study.

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Methods

STUDY DESIGN

DynamX is a prospective, single-arm feasibility study to assess the safety and performance of the novolimus-eluting DynamX Bioadaptor System. Patients were enrolled at six centres in Belgium and Italy from November 2017 to September 2018. Follow-up assessments were scheduled at 30 days, 6, 12, 24 and 36 months, and angiographic and intravascular ultrasound (IVUS) follow-up at 9-12 months. Optical coherence tomography (OCT) was performed at two centres.

The full list of inclusion and exclusion criteria is provided in **Supplementary Table 1** and at ClinicalTrials.gov (NCT03429894). In brief, patients with a single *de novo* target lesion were included. The concomitant treatment of a single, non-target lesion in a separate major epicardial vessel prior to target lesion treatment was allowed.

The study was conducted according to the Declaration of Helsinki, ISO14155 and local regulations, and was approved by the respective ethics committees. Each patient provided written informed consent. Monitoring included source document verification, and an independent clinical events committee adjudicated all events. A list of study centres and study committees is provided in **Supplementary Table 2**.

STUDY DEVICE

The DynamX bioadaptor is composed of 71 µm cobalt-chromium sinusoidal rings connected to each other axially by three S-links which remain intact after uncaging. Each ring contains three uncaging elements that are positioned at equal distance in low-stress regions of struts oriented in a helical configuration along the length of the bioadaptor **(Figure 1)**. The uncaging elements consist of three separable junctions per ring held together by a 6 µm polymer coating that is resorbed over six months, allowing uncaging of the vessel and adaptive remodelling **(Supplementary Figure 1)**. The bioadaptor is circumferentially coated with a thin conformal, bi-layer biodegradable polymer, similar to that used on the DESolve scaffold and DESyne® BD DES (Elixir Medical)[5,6]. The inner bioresorbable coating is poly-l-lactide acid-based and the outer coating is poly-lactic-co-glycolic acid-based and releases the sirolimus metabolite novolimus over three months. The study device was available in diameters of 2.5, 3.0 and 3.5 mm and lengths of 14, 18 and 28 mm.

PROCEDURE

Predilatation of the target lesion was recommended with a balloon size approximately 0.25-0.5 mm smaller than the mean vessel reference diameter. A residual stenosis of <35%, Thrombolysis In Myocardial Infarction (TIMI) flow of ≥2 and no greater than a Grade B dissection able to be covered by a single device were prerequisites for implantation of the bioadaptor that is implanted in a similar way to a traditional DES. All patients received a loading dose of acetylsalicylic acid and a $P2Y_{12}$ inhibitor pre-procedure followed by dual antiplatelet therapy for 12 months; statin therapy was recommended.

IMAGING ANALYSIS

All imaging analyses were performed at an independent core laboratory (Cardiovascular Research Center [CRC], São Paulo, Brazil) by experienced operators blinded to procedural data and clinical outcomes. Further information is provided in **Supplementary Table 3** and **Supplementary Table 4**.

ENDPOINTS

The primary safety endpoint was target lesion failure (TLF) at six months, a composite of cardiac death, target vessel myocardial infarction (TV-MI), and clinically driven target lesion revascularisation (CD-TLR). The primary imaging/efficacy endpoint was change in mean in-device and mean lumen area from post procedure to 9-12 months by IVUS. Secondary endpoints were TLF at

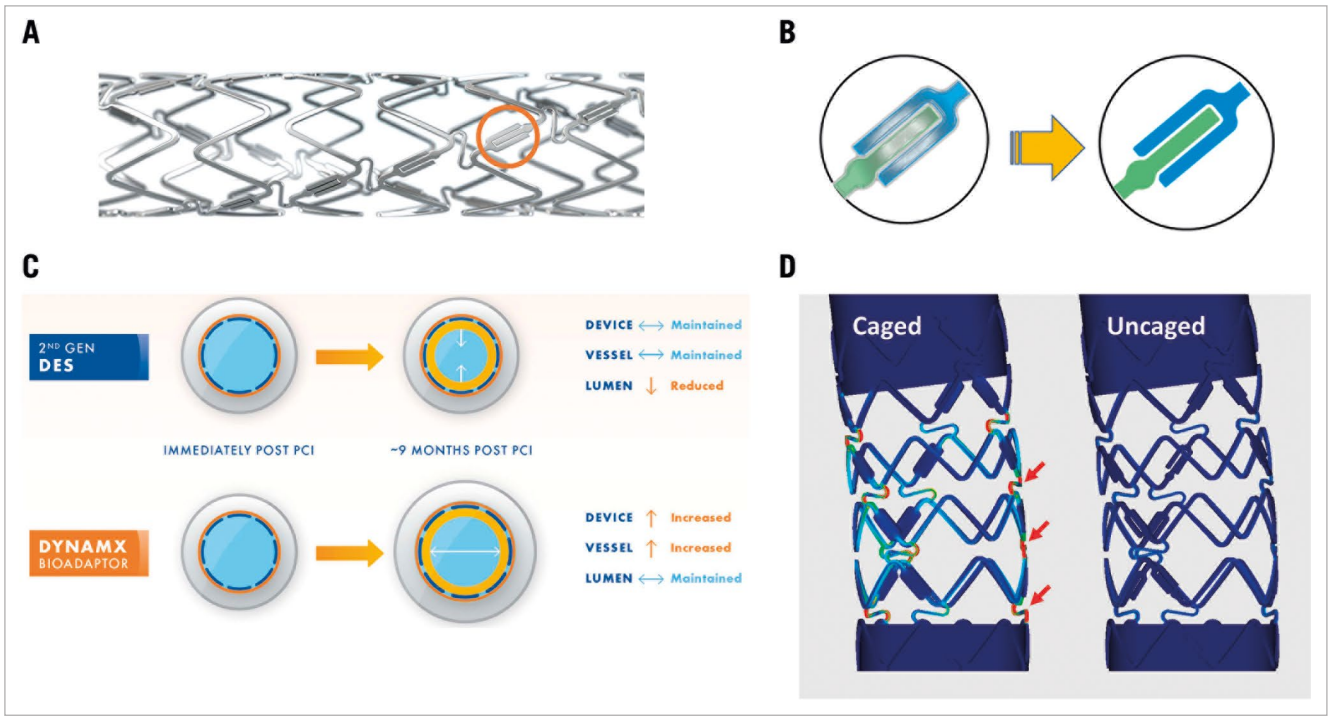

Figure 1. *DynamX bioadaptor. A) DynamX bioadaptor with three uncaging elements (orange circle) per sinusoidal device ring. B) The uncaging elements disengage after polymer resorption allowing positive adaptive remodelling. Left: the two components of the uncaging element tightly held together by the conformal biodegradable polymer coating. Right: following polymer degradation, the elements disengage thus allowing the artery to uncage circumferentially. C) The schematic illustration of Glagov remodelling[9] shows that the uncaging allows the vessel to enlarge to accommodate neointimal formation and disease progression to maintain lumen area. Blue circles reflect the device, grey circles the vessel, and yellow circles the neointimal hyperplasia. D) Reduction in tensile stress in caged versus uncaged DynamX bioadaptors loaded as in the Ormiston test[21]. The colours indicate von Mises stress in the bioadaptor segment, with cooler colours (blue) indicating lower stress, and hotter colours (red) indicating higher stress (data available at Elixir Medical).*

other time points, target vessel failure (TVF), MI, TLR, target vessel revascularisation (TVR), and device thrombosis. Device success was defined as successful delivery of the bioadaptor to the target lesion and a final residual stenosis <30% by QCA (by visual estimation if QCA was unavailable). Procedure success was defined as device success without the occurrence of in-hospital TLF. The endpoint of TVF comprised a composite of cardiac death, TV-MI, and clinically driven TVR. Cardiac death and device thrombosis were defined according to the Academic Research Consortium criteria[7]. Per protocol, MI was defined as enzyme elevation of two times the upper normal limit of CK with elevation of CK-MB.

STATISTICAL ANALYSIS

This study was designed to confirm the feasibility, performance, and safety of the DynamX bioadaptor and to generate hypotheses for future studies. The sample size was not calculated based on an endpoint hypothesis, but is in line with the current ESC-EAPCI Task Force report that recommends a sample size of 50-150 patients for feasibility studies[8]. A maximum drop-out rate of 10% for follow-up visits and 20% for angiographic assessments was expected.

Descriptive statistics of the intention-to-treat population include continuous variables expressed as mean±standard deviation and median and interquartile range as applicable, and categorical variables expressed as frequencies and percentages of the total; 95% confidence intervals (CI) were calculated as applicable. Pairwise comparisons between post procedure and follow-up were performed by the Wilcoxon signed-rank test. OCT results are presented using the generalised linear mixed model with gamma distribution and random effects by lesion to adjust for cluster distribution of continuous variables at the strut and cross-section levels. In stationary OCT analysis, vessel pulsatility was assessed with the 95% predictive interval relative to the mean for the changes observed in the lumen and bioadaptor areas. All calculations are based on the data available. The analysis was performed by an independent statistician at CRC using SAS version 9.3 (SAS Institute, Cary, NC, USA).

Results

Fifty patients were enrolled **(Figure 2)**. Per core laboratory assessment, reference vessel diameter was 2.91±0.43 mm and lesions were 11.1±5.1 mm long; 50% (n=25) were B2/C lesions **(Table 1, Table 2)**.

Predilatation was performed in 96% of lesions (n=48) and post-dilatation in 62% (n=31). One patient (2%) required an

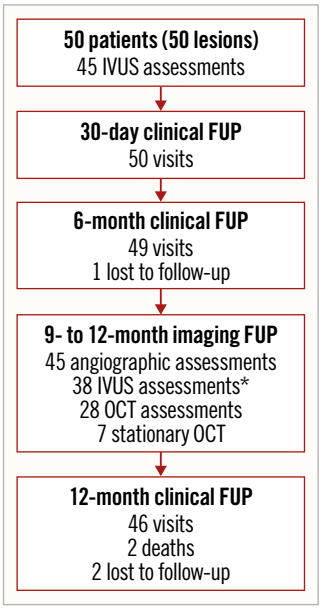

Figure 2. *Patient flow chart. Two patients were lost to follow-up with last contact on day 81 and day 304. *Out of 45 IVUS assessments, seven could not be evaluated for paired analysis as post-procedure and follow-up time points were recorded with IVUS catheters recording at different ultrasound frequencies. IVUS: intravascular ultrasound; OCT: optical coherence tomography*

additional bioadaptor to cover a vessel dissection. All devices could be implanted, and device success and procedure success were achieved in all patients. No periprocedural TV-MI was observed, but there was one non-TV-MI due to an occlusion of a side branch of a non-target vessel.

Up to 12 months, two TLFs occurred, both cardiac deaths. One patient with multiple medical comorbidities was found dead at home on day 255 post procedure. Another death on day 267 was caused by multi-organ failure following hospitalisation for heart failure (reported as not being due to ischaemic events) **(Supplementary Table 5)**. There were no TV-MI, TLR, or definite or probable device thromboses **(Table 3)**. Most patients (87.0%, 40/46) were on dual antiplatelet therapy at 12-month follow-up.

Per QCA core laboratory assessment, in-device acute gain was 1.61±0.34 mm and diameter stenosis was 5.4±8.4% post procedure. At a mean follow-up of 10.5±1.5 months, mean in-device late lumen loss was 0.12±0.18 mm and mean diameter stenosis 7.7±10.8% **(Supplementary Table 6)**. Fourteen patients with post-procedural change in angulation of ≥9°[9] showed a return towards

Table 1. Baseline demographics.

		N=50
Age, years		66.3±8.8
Male		37 (74%)
Diabetes mellitus		13 (26%)
Hypertension		35 (70%)
Dyslipidaemia		39 (78%)
Smoking (previous or current)		38 (76%)
Prior myocardial infarction		15 (30%)
Prior percutaneous coronary intervention		19 (38%)
Clinical presentation	Silent ischaemia	26 (52%)
	Stable angina	11 (22%)
	Unstable angina	2 (4%)
	Asymptomatic post MI	10 (20%)
	Non-ST-elevation MI	1 (2%)

Data are displayed as mean±SD or n (%). MI: myocardial infarction

Table 2. Baseline lesion characteristics.

		N=50
Target lesion	LAD	22 (44%)
	LCx	9 (18%)
	RCA	19 (38%)
Calcium (moderate/severe)		11 (22%)
Thrombus		1 (2%)
Lesion type (ACC/AHA)	A	8 (16%)
	B1	17 (34%)
	B2	20 (40%)
	C	5 (10%)
Lesion length, mm		11.1±5.1
Reference vessel diameter, mm		2.91±0.43
Minimum lumen diameter, mm		1.14±0.30
Diameter stenosis, %		60.2±9.5

Data are displayed as mean±SD or n (%). LAD: left anterior descending artery; LCx: left circumflex artery; RCA: right coronary artery; TIMI: Thrombolysis In Myocardial Infarction

Table 3. Clinical outcomes.

	30 days N=50	6 months N=49	12 months N=48
Target lesion failure	0 (0%)	0 (0%)	2 (4%)
Target vessel failure	0 (0%)	0 (0%)	2 (4%)
Overall mortality	0 (0%)	0 (0%)	2 (4%)
Cardiac death	0 (0%)	0 (0%)	2 (4%)
Non-cardiac death	0 (0%)	0 (0%)	0 (0%)
Myocardial infarction	1 (2%)	1 (2%)	1 (2%)
Target vessel MI	0 (0%)	0 (0%)	0 (0%)
Non-target vessel MI	1 (2%)	1 (2%)	1 (2%)
Target lesion revascularisation*	0 (0%)	0 (0%)	0 (0%)
Target vessel revascularisation*	0 (0%)	0 (0%)	0 (0%)
Definite/probable device thrombosis	0 (0%)	0 (0%)	0 (0%)

Data are displayed as n (%). *including clinically indicated and non-clinically indicated. MI: myocardial infarction

baseline angulation at follow-up (from a mean of 157.5±14.5° post procedure to 149.7±16.1° at follow-up **(Figure 3, Supplementary Figure 2)**.

Mean IVUS follow-up was at 10.3±1.5 months. In paired analysis of 38 patients, from post procedure to follow-up, the mean bioadaptor area increased from 7.39±1.20 mm² to 7.74±1.46 mm² (Δ=5%, p=0.0005), the mean vessel area increased from 14.11±2.99 mm² to 14.54±3.12 mm² (Δ=3%, p=0.02), while the mean lumen area was maintained (7.39±1.20 mm² to 7.36±1.31 mm², Δ=0%, p=0.59) and the minimum lumen area decreased (6.10±1.15 mm to 5.86±1.20 mm, p=0.02) **(Figure 4, Supplementary Table 7)**.

OCT pullback was performed in a subset of 28 patients at a mean follow-up of 10.9±1.5 months. Qualitative analysis confirmed disengagement of the uncaging elements in all imaged segments **(Supplementary Figure 1)**. Overall, the majority of struts (99.84±0.51%) were well apposed and fully covered by a thin, uniform neointimal layer of 140±40 µm (98.95±2.85% neointimal coverage). Complete OCT data at the cross-section and strut levels are provided in **Supplementary Table 8**. Stationary co-registered OCT performed in a subset of seven patients demonstrated pulsatility of the treated vessel segment during systole and diastole **(Figure 5, Figure 6)** with a lumen area change of 11% and a device area change of 7.3% (both are 95% predictive intervals relative to the mean).

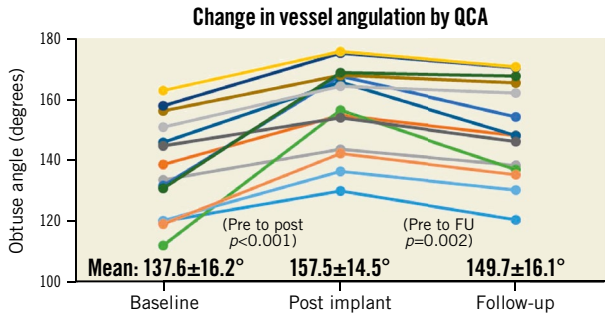

Figure 3. *Change in vessel angulation by quantitative coronary angiography. Vessel angulation in 14 patients who had a ≥9° change of vessel angulation from baseline to post implant.*

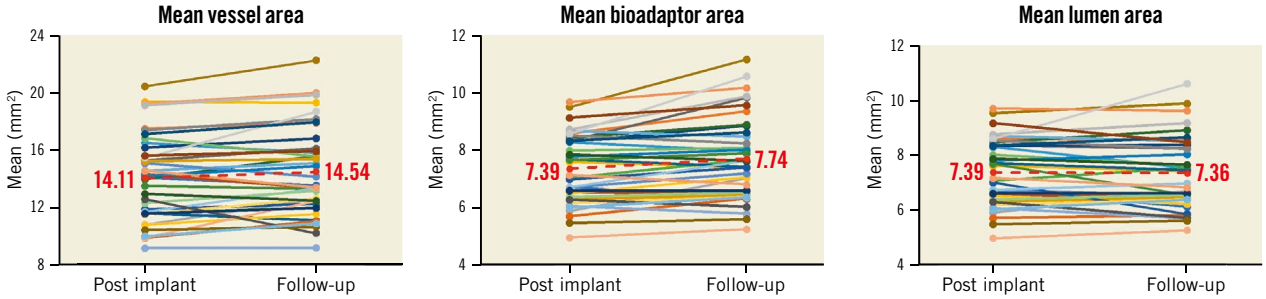

Figure 4. *Paired intravascular ultrasound outcomes at follow-up compared to post procedure. Paired data are available for 38 patients.*

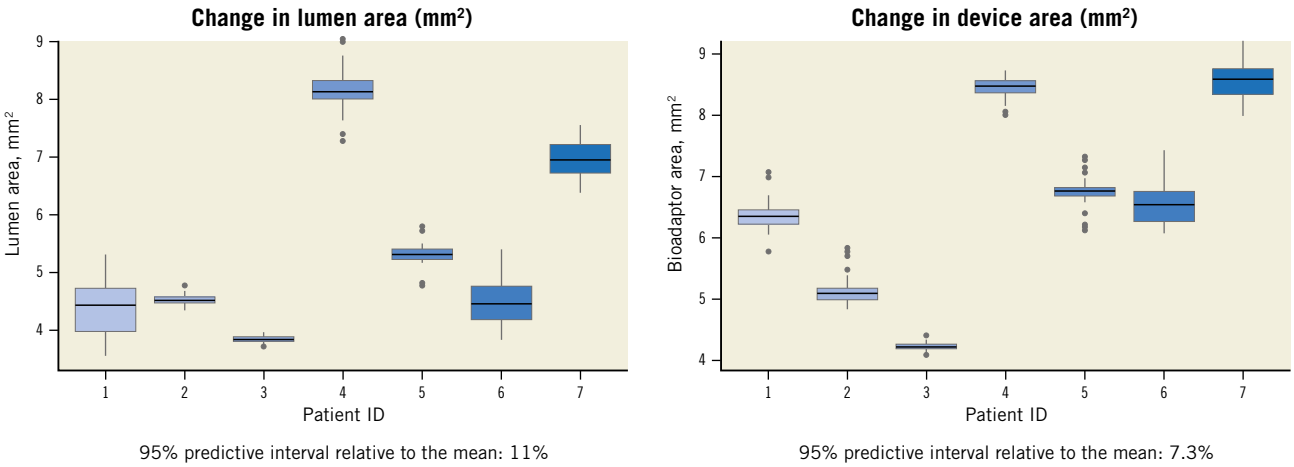

Figure 5. *Pulsatility analysis through stationary OCT recording. At follow-up, OCT recording was performed in seven patients by assessing the change during systole and diastole in the same co-registered stationary in-device spot. Each box plot represents the area changes per patient assessed during multiple cardiac cycles. The box plots themselves indicate median and interquartile ranges, and the ends of the whiskers represent maximum and minimum values excluding extreme results.*

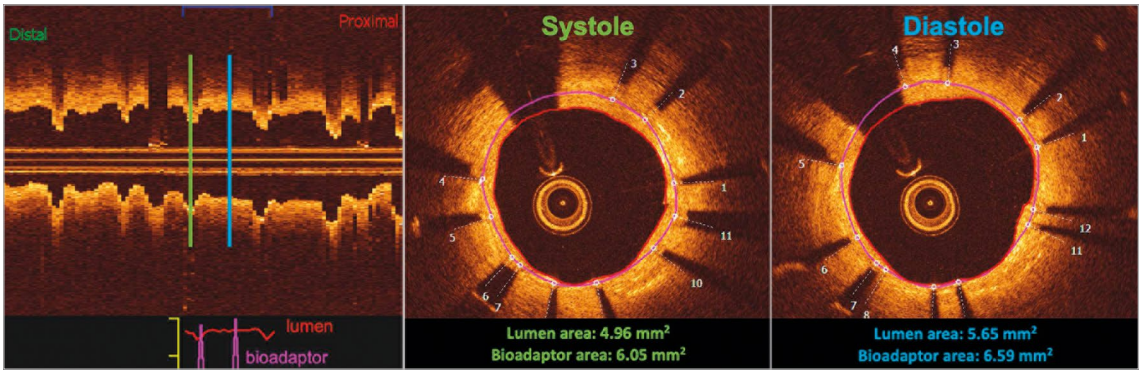

Figure 6. *Case example of stationary OCT measurement during the cardiac cycle. The case example demonstrates the uncaging of the vessel, allowing vessel motion during the cardiac cycle. The longitudinal view on the left shows the consistent area changes between systole and diastole as measured at one stationary spot (lumen area Δ14% and bioadaptor area Δ8%). The purple line represents the bioadaptor area and the red the lumen area.*

Discussion

The main findings of this study are that the novel bioadaptor demonstrated a) acute and 12-month safety and efficacy outcomes comparable to contemporary metallic DES, b) positive vascular remodelling[10], cyclic pulsatility, and less geometric vessel distortion at follow-up, and c) safe disengagement of the uncaging elements.

The DynamX bioadaptor has been developed to overcome the limitations of rigid metallic stents that alter physiologic vascular dynamics by reducing vessel wall compliance, causing mechanical distortion of the vessel, and preventing positive adaptive remodelling. The bioadaptor was designed to have comparable characteristics with regard to thin struts, thin polymer coating, "limus" drug, visibility, deliverability, radial strength, and clinical performance to contemporary metallic DES. The unique design of uncaging segments provides the circumferential rings with freedom of radial and torsional motion allowing positive adaptive remodelling which can accommodate neointimal hyperplasia and/or neoatherosclerosis. The uncaging segments are initially bound by a bioresorbable polymer that resorbs over six months, a time point beyond which radial vessel support is not required, as previously demonstrated by bioresorbable scaffolds[11].

CLINICAL EFFICACY AND SAFETY

Until the uncaging, the DynamX bioadaptor functions like a conventional stent with similar deliverability, conformability and radial strength. In particular, the acute gain (1.61±0.34 mm) and lumen diameter stenosis (5.4±8.4%) after implantation indicate a radial force comparable to other metallic stents[12]. Furthermore, the low in-device late lumen loss of 0.12±0.18 mm is comparable to latest-generation DES[13].

Clinically, there were two TLFs, both cardiac deaths unrelated to the device or procedure. No other events were observed, resulting in a low TLF rate of 4%, comparable to contemporary conventional stents in similar populations[12,13]. The absence of any revascularisation might be a chance finding, or attributed to the low neointimal growth, the ability of positive remodelling to promote lumen area maintenance, and the cyclic pulsatility that allows the vessel to adapt to increased myocardial oxygen demand, e.g., during exercise[10,14]. Finally, the absence of definite or probable device thrombosis is favoured by the thin struts of the bioadaptor, which were well apposed and covered by a thin neointima layer.

MECHANISTIC INSIGHTS

The impact on vascular structure and function was assessed by IVUS, OCT and angiography.

Positive vascular or Glagovian remodelling of the vessel[10] between implantation and follow-up was demonstrated by a vessel area increase of 3% and a device area increase of 5%. This increase enables the vessel to accommodate the neointima and maintain the lumen area unchanged, allowing the vessel to accommodate potential progression of disease. In comparison, the vessel area of contemporary stents ranged between a decrease of −2% and an increase of 1%, the device area ranged between 0% and 2%, and the lumen area decreased by −1% to −5% **(Supplementary Table 9)**[15,16]. Most importantly, the positive vascular remodelling did not come at the cost of strut malapposition.

Further, cyclic pulsatility was demonstrated by stationary co-registered OCT with a difference in cross-sectional lumen area of 11% between systole and diastole. To the best of our knowledge, no comparative OCT data are available in the literature. By IVUS, average changes in mean lumen area of 8-10% and isolated examples of up to 17% have been reported in predominantly disease-free coronary arteries, whereas segments with plaque or calcification showed smaller changes[17-19]. The observed lumen area change in DynamX-implanted vessels by OCT is thus within the range that has been reported for normal coronary arteries as measured by IVUS.

The 14 patients with ≥9° angulation change after a bioadaptor implantation, a threshold that has been associated with increased major adverse cardiac events and restenosis rates[9], showed a return towards baseline angulation by ~50% at follow-up, demonstrating

enhanced conformability and increased compliance of the uncaged bioadaptor device. In contrast, Gyöngyösi et al[9] reported further straightening at follow-up compared to post procedure for conventional stents.

Indeed, the bioadaptor appears to provide the "promise" of what bioresorbable scaffolds once held without the hazards of previous bioresorbable scaffolds including limited radial strength, large profile and thick struts, cumbersome implantation technique, and bulk degradation with the potential for intraluminal scaffold dismantling over a prolonged period. Furthermore, pulsatility and positive remodelling appear to have been achieved after the uncaging process at six months, sooner than most bioresorbable scaffolds[3,4,20].

UNCAGING

The safe disengagement of the uncaging elements was confirmed by a thin, uniform neointima layer with no evidence of struts protruding inside the vessel lumen by either IVUS or OCT, and absence of thrombotic events up to 12 months. Notably, finite element analysis of the bioadaptor has demonstrated reduced peak stress upon uncaging compared to a caged bioadaptor, suggesting a higher resistance to fracture after uncaging.

Limitations

Limitations include the small sample of patients with mainly stable angina and non-complex lesions. Data on less than 80% of patients were available for the primary imaging endpoint, and OCT was only performed at follow-up. Due to the absence of ECG gating, changes in the position of the OCT probe may have affected the pulsatility analysis. However, due to the high resolution of the OCT images, fiduciary landmarks to adjust for longitudinal movement of OCT catheters were used. Though perfect matching of the systolic and diastolic frames was not possible, any longitudinal mismatch that might have occurred is expected to be minimal and not of clinical relevance. Myocardial infarction was not determined according to current definitions, but as enzyme elevation of two times the upper normal limit of CK with elevation of CK-MB. Larger, randomised studies in more complex lesions are needed to compare the bioadaptor to contemporary DES and to verify whether the impact on vessel function results in a meaningful long-term clinical benefit.

Conclusions

Our study reports positive adaptive remodelling, cyclic pulsatility and return towards baseline vessel angulation after the implantation of the cobalt-chromium DynamX bioadaptor. The bioadaptor demonstrated acute performance and angiographic parameters similar to contemporary metallic DES with absence of TV-MI, TLR, and definite or probable device thrombosis to one year. Longer-term follow-up in comparative studies will show to what extent the bioadaptor may mitigate the annualised 2-4% device-oriented events that have been observed following the implantation of conventional metallic coronary stent prostheses.

Impact on daily practice

This first clinical study provides data on the DynamX bioadaptor, a novel concept with uncaging elements that are released beyond six months after implantation, allowing a more physiological vascular response and thus potentially avoiding complications beyond one year attributed to caging of permanent stents. The present study confirmed the safety and feasibility of this novel concept with positive remodelling, cyclic pulsatility, low late lumen loss and low clinical event rates at 12-month follow-up.

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Conflict of interest statement

S. Verheye reports personal fees from Neovasc and Biotronik outside the submitted work and speaker fees from Elixir Medical. B. De Bruyne reports that the Cardiovascular Center Aalst receives grant support from Abbott, Boston Scientific, and Biotronik AG and receives consulting fees on behalf of B. De Bruyne from Abbott and Boston Scientific outside the submitted work. B. De Bruyne is a shareholder in Philips, Siemens, GE, Bayer, HeartFlow, Edwards Lifesciences, and Celyad. D. Kereiakes reports other fees from Sino Medical Sciences Technology, Inc., Boston Scientific Corporation, Abbott Vascular, Svelte Medical Systems, Inc., Orchestra BioMed, Inc., Shockwave, and Elixir Medical Corporation, and personal and other fees from Ablative Solutions, Inc., during the conduct of the study. The other authors have no conflicts of interest to declare.

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Supplementary data

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Supplementary Table 9. Comparison of DynamX outcomes with contemporary drug-eluting stents.

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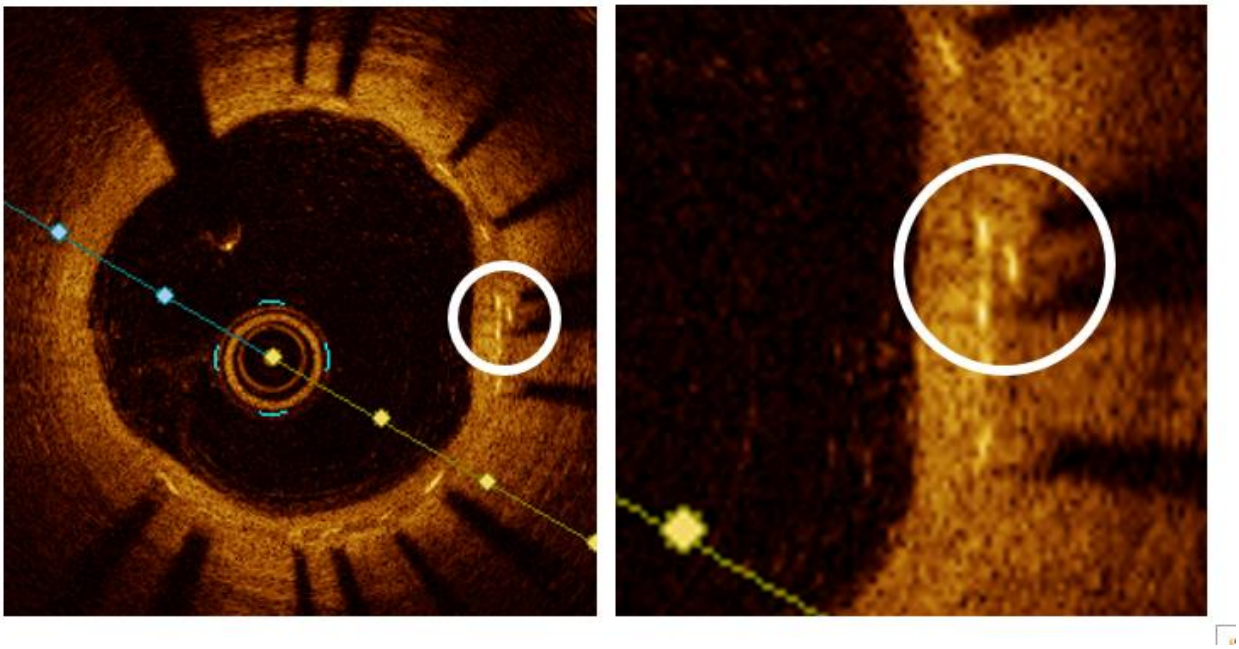
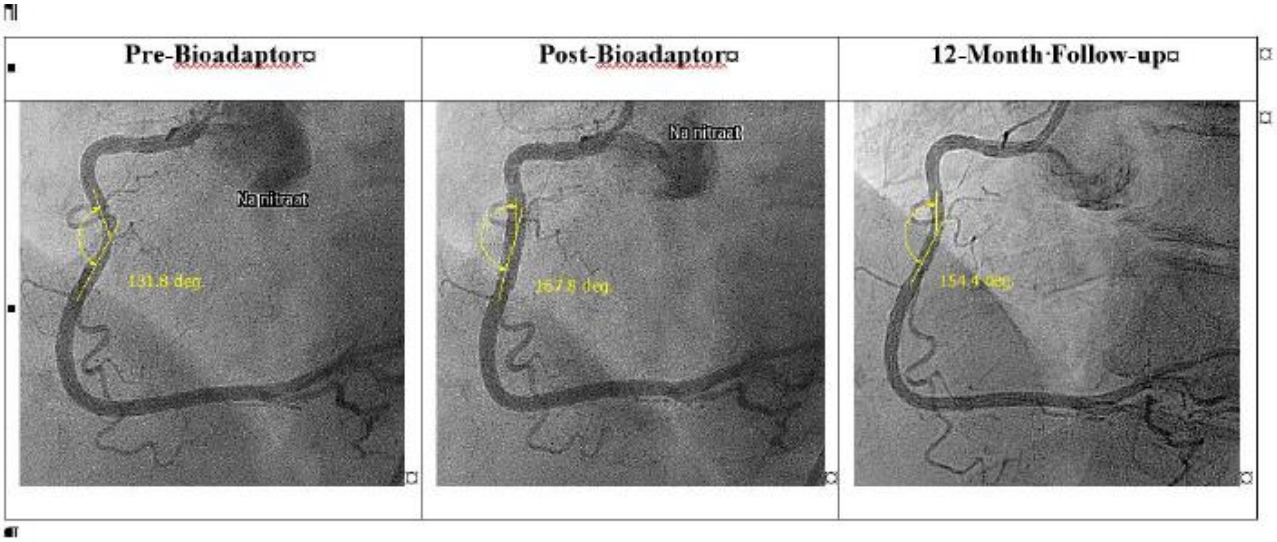
Supplementary data



Supplementary Figure 1. Optical coherence tomography image at nine months with disengagement of the uncaging elements.

The OCT image on the right shows a cross-section of the treated vessel through the uncaging elements (circled) at follow-up post uncaging, The two components of the uncaging element have the ability to move out of plane which is observed as two struts in one plane and another out of plane. The elements are covered with thin uniform neointima.



Supplementary Figure 2. Case example of restoration of vessel angulation with return towards baseline values.

Supplementary Table 1. Inclusion and exclusion criteria.

General inclusion criteria	• Patient must be at least 18 years of age • Patient is able to verbally confirm understanding of risks, benefits and treatment alternatives of receiving the DynamX Novolimus-Eluting Bioadaptor and he/she provides written informed consent, as approved by the appropriate Ethics Committee of the respective clinical site, prior to any clinical study-related procedure • Patient must have evidence of myocardial ischaemia (e.g., stable or unstable angina, silent ischaemia, positive functional study or electrocardiogram changes consistent with ischaemia) • Patient must be an acceptable candidate for coronary artery bypass graft surgery • Patient must agree to undergo all clinical study required follow-up visits, angiograms, and intravascular ultrasound testing • Patient must agree not to participate in any other clinical study for a period of one year following the index procedure
Angiographic inclusion criteria – target lesion/vessel	• Target lesion must be located in a native coronary artery with a nominal vessel diameter of between 2.5 and 3.5 mm assessed visually or by online quantitative coronary angiography • Target lesion must measure ≤24 mm in length • Target lesion must be in a major artery or branch with a visually estimated stenosis of ≥50% with a Thrombolysis In Myocardial Infarction (TIMI) flow of ≥2 • The lesion must be successfully predilated (less than 35% diameter stenosis) prior to enrolment

Angiographic inclusion criteria – non-target lesion/vessel treatment	• Treatment of a single, non-target lesion located in a separate major epicardial vessel (defined as left anterior descending artery (LAD) with septal and diagonal branches, left circumflex artery (LCX) with obtuse marginal and/or ramus intermedius branches and right coronary artery and any of its branches) attempted during the index procedure must be completed first using an approved "limus" drug-eluting stent. The segment must be located such that any injury that might occur during intervention can be clearly attributable to the treated non-target vessel. If the procedure is deemed uncomplicated and optimal, treatment of the target lesion with the DynamX stent can be considered.
	• Optimal lesion/vessel treatment defined as:
	  ○ <10% but no more than 15% residual diameter stenosis by visual assessment
	  ○ No evidence of dissection
	  ○ No evidence of thrombus in the treated lesion or vessel
	  ○ TIMI 3 flow
	  ○ Stent completely covers lesion and extends to healthy vessel on both sides (healthy to healthy)

General exclusion criteria	• Patient has a known diagnosis of acute myocardial infarction (AMI) within 72 hours preceding the index procedure and CK and CK-MB have not returned within normal limits at the time of procedure • Patient is currently experiencing clinical symptoms consistent with AMI • Patient requires the use of any rotablator intervention during the index procedure • Patient has current unstable arrhythmias • Patient presenting with heart failure, chronic arrhythmia, chronic obstructive pulmonary disease or lung function impairment • Patient has a known left ventricular ejection fraction <30% • Patient has received a heart transplant or any other organ transplant or is on a waiting list for any organ transplant • Patient is receiving or scheduled to receive chemotherapy for malignancy within 30 days prior to or after the procedure • Patient is receiving immunosuppression therapy and has known immunosuppressive or autoimmune disease (e.g., human immunodeficiency virus, systemic lupus erythematosus, etc.) • Patient is receiving chronic anticoagulation therapy (e.g., heparin, coumadin) that cannot be stopped and restarted according to local hospital standard procedures. • Patient has a known hypersensitivity or contraindication to aspirin, both heparin and bivalirudin, clopidogrel, prasugrel or ticagrelor, Novolimus, CoCr alloys, PLLA polymers or contrast sensitivity that cannot be adequately pre-medicated • Elective surgery is planned within the first 6 months after the procedure that will require discontinuing either aspirin or clopidogrel or other $P2Y_{12}$ inhibitors. • Patient has a platelet count <100,000 cells/mm^3 or >700,000 cells/mm^3, a WBC of <3,000 cells/mm^3, or documented or suspected liver disease • Patient has known renal insufficiency (e.g., serum creatinine level of more than 2.5 mg/dL, or patient on dialysis) • Patient has a history of bleeding diathesis or coagulopathy or will refuse blood transfusions

	• Patient has had a cerebrovascular accident or transient ischaemic neurological attack within the past six months • Patient has had a significant gastrointestinal or urinary bleed within the past six months • Patient has extensive peripheral vascular disease that precludes safe 6 Fr sheath insertion • Patient has other medical illness (e.g., cancer or congestive heart failure) or known history of substance abuse (alcohol, cocaine, heroin, etc.) that may cause non-compliance with the clinical study plan, confound the data interpretation or is associated with a limited life expectancy (i.e., less than one year) • Patient is already participating in another clinical study • Women of childbearing potential who have not undergone surgical sterilisation or are not post-menopausal (defined as amenorrheic for at least one year) as well as women who are pregnant or nursing • Patient is unable to give their consent, is legally incompetent, or is institutionalised by virtue of an order issued by the courts or other authority
Angiographic exclusion criteria – target lesion/vessel	• Target lesion(s) meets any of the following criteria: o Aorto-ostial location o Left main location o Tapering within target segment of 0.5 mm or greater o Located within 10 mm of the origin of the LAD or LCX o Located within an arterial or saphenous vein graft or distal to a diseased arterial or saphenous vein graft o Lesion involving a side branch >2 mm in diameter or bifurcation o Previous placement of a stent proximal to or within 10 mm of the target lesion o Total or sub-total occlusion (TIMI flow ≤1) o Excessive tortuosity or angulation (≥45°) proximal to or within the lesion o The proximal target vessel or target lesion is moderately or severely calcified by visual assessment, or lesion prevents full predilatation balloon expansion o Previous intervention restenosis • The target vessel contains visible thrombus • Another clinically significant lesion (>40%) is located in the same major epicardial vessel as the target lesion (including side branches) • Patient has a high probability that a procedure other than predilatation and stenting and (if necessary) post-dilatation will be required at the time of index procedure for treatment of the target vessel (e.g., atherectomy, cutting balloon) • Target vessel was previously treated with any type of percutaneous coronary intervention (PCI) <6 months prior to index procedure • Non-target vessel was previously treated with any type of PCI <30 days prior to the index procedure

Supplementary Table 2. Study centres and committees.

Study centres
Stefan Verheye (Co-Coordinating Investigator), ZNA Middelheim, Antwerp, Belgium
Antonio Colombo/Matteo Montorfano (Co-Coordinating Investigator), San Raffaele Hospital, Milan, Italy
Mathias Vrolix, Ziekenhuis Oost-Limburg, Genk, Belgium
Christophe Dubois, Universitaire Ziekenhuizen Leuven, Leuven, Belgium
Francesco Bedogni, CCS Policlinico San Donato, San Donato Milanese-Milan, Italy
Bernard De Bruyne, Cardiovascular Center Aalst, Aalst, Belgium
Clinical Events Committee
Cardiovascular Research Center (CRC), São Paulo, Brazil
Core laboratory
Cardiovascular Research Center (CRC), São Paulo, Brazil
Statistical analysis
Cardiovascular Research Center (CRC), São Paulo, Brazil
Steering Committee
Stefan Verheye
Antonio Colombo
Management Elixir Medical

Supplementary Table 3. Imaging assessments.

Angiography	Repeat angiography with recording of matching, bi-directional orthogonal projections and IVUS with the same imaging sequence as at baseline were performed. Lesion morphology including target lesion calcification assessment was performed as previously reported [22]. Quantitative coronary angiographic (QCA) analysis was performed with a two-dimensional validated software - QAngio XA, version 7.3 (Medis, Leiden, the Netherlands) - after intracoronary administration of nitroglycerine (100 to 200 µg, unless contraindicated), following standard guidelines and procedures [23]. In vessels with a significant post-procedural change in angulation, defined as ≥9° [9], the measurement of vessel angulation was repeated at follow-up.
Intravascular ultrasound	IVUS imaging was performed with automated pullback at a recommended speed of 0.5 mm/second. Imaging analysis was performed with echoPlaque, version 3.0.28 (Indec Medical Systems, Santa Clara, CA, USA). Bioadaptor, vessel and lumen areas [24] obtained post procedure and at follow-up were compared to assess midterm vessel and bioadaptor remodelling.
Optical coherence tomography	OCT images were analysed using the validated OCT software, version 3.0 (Medis Medical Imaging, Leiden, the Netherlands). After adjusting for the pullback speed, cross-sections were analysed at 0.6 mm longitudinal intervals throughout the treated segment, and at 1 mm intervals 5 mm distal and proximal to the stented segment. Lumen and device areas were determined by semi-automatic algorithms in each analysed cross-section. Neointimal hyperplasia (NIH) area was determined as the area comprised between the bioadaptor and lumen contours, and the percentage of bioadaptor obstruction caused by NIH accumulation was calculated as: (NIH area/ device area) *100. Malapposed struts were differentiated from uncovered struts when the negative value of the strut-to-lumen distance was higher than 103 µm (the sum of the strut thickness + polymer thickness + a compensation factor of 20 µm to correct for the strut blooming) [25]. Qualitative assessment of disengagement of the uncaging elements was performed throughout the entire stented segment. Pulsatility was assessed by measuring the change in lumen and device areas by stationary OCT images during systole and diastole at the same in-device region.

Supplementary Table 4. Reproducibility analysis for OCT and IVUS assessments.

	Intra-observer ICC	Inter-observer ICC
OCT		
Mean lumen area, mm^2	93.3%	92.9%
Mean bioadaptor area, mm^2	99.7%	99.4%
Mean NIH area, mm^2	98.5%	97.2%
% NIH obstruction	99.3%	98.6%
Neointimal thickness, μm	99.0%	98.0%
IVUS		
Mean lumen area, mm^2	94.5%	96.4%
Mean bioadaptor area, mm^2	94.1%	96.1%
Mean vessel area, mm^2	95.8%	98.2%
% of neointimal hyperplasia	100%	100%

The variability analysis was run in 5 random patients for IVUS and OCT assessments. High reproducibility was shown for all assessed parameters. Notably, based on these parameters, cyclic pulsatility and lumen enlargement were assessed.
ICC: intraclass correlation coefficient; IVUS: intravascular ultrasound; NIH: neointimal hyperplasia; OCT: optical coherence tomography

Supplementary Table 5. Details on patients with cardiac death.

Unknown death on day 255 (patient was found dead at home on day 255 post procedure) **Baseline: 59-year-old male with arterial hypertension, smoking, hyperlipidaemia, moderately reduced left ventricular ejection fraction, 50% RCA stenosis that was not treated, alcohol abuse, Wernicke-Korsakoff syndrome, myeloid leukaemia in remission.** **Patient presented with stable angina.** **ß-blocker use.** **Procedure: Type A LAD lesion treated with a 3.5x18 mm DynamX @ 10 atm. Post-dilatation with a 3.5x12 mm balloon @ 23 atm, 0% residual diameter stenosis, no procedural event, patient was discharged the next day.** **Follow-up: day 9: itching/rash** **Day 57: dyspnoea, atypical thoracic pain that mostly disappeared spontaneously.** **Day 118: hospitalisation for alcohol abuse.** **Day 247: swollen wrist of three weeks duration. Treatment with IV clindamycin resolved the event within 5 days.** **Day 255: the subject was found dead at home on the floor. The death was determined to be natural and no autopsy was performed. The subject's wife acknowledged that the subject continued to drink.** **The site assessed the events as not device-related and not procedure-related.**
Death on day 267 due to multiorgan failure **Baseline: 78-year-old male with diabetes mellitus, arterial hypertension, arrhythmia, prior myocardial infarction, prior percutaneous coronary interventions, mildly reduced ejection fraction, peripheral vascular disease, COPD with home-based oxygen therapy, anaemia.** **Patient presented with silent ischaemia.** **ß-blocker, ACE-inhibitor, and oral anticoagulation use.** **Procedure: type A RCA lesion treated with a 3x18 mm DynamX bioadaptor @12 atm. No post-dilatation, 0% residual diameter stenosis and no procedural event, patient was discharged the same day.** **Follow-up: no adverse event up to six-month follow-up. Hospitalisation for heart failure. During hospitalisation septic shock and the patient died ultimately of multi-organ failure that was adjudicated as cardiac death.** **The site assessed the event as not device-related and not procedure-related.**

Supplementary Table 6. Overall post-procedure and paired post-procedure and follow-up quantitative coronary angiographic analysis.

	Post-procedure N=50	Post-procedure, paired N=45	Follow-up, paired N=45
In-device			
Reference vessel diameter, mm	3.07±0.26	3.08±0.27	2.98±0.30
Minimum lumen diameter, mm	2.75±0.29	2.75±0.30	2.63±0.37
Diameter stenosis, %	5.4±8.4	5.4±8.1	7.7±10.8
Acute gain, mm	1.61±0.34	1.63±0.34	-
Late lumen loss, mm	-	-	0.12±0.18
In-segment			
Reference vessel diameter, mm	2.96±0.38	2.95±0.38	2.89±0.39
Minimum lumen diameter, mm	2.53±0.36	2.51±0.37	2.39±0.39
Diameter stenosis, %	14.0±9.1	14.7±7.8	17.0±9.5
Acute gain, mm	1.40±0.39	1.39±0.38	-
Late lumen loss, mm	-	-	0.11±0.16
Proximal edge (5 mm)			
Reference vessel diameter, mm	3.05±0.40	3.02±0.40	2.97±0.39
Mean lumen diameter, mm	2.96±0.42	2.90±0.38	2.84±0.37
Minimum lumen diameter, mm	2.79±0.43	2.75±0.40	2.68±0.41
Diameter stenosis, %	8.2±9.5	8.9±9.6	9.4±9.2
Late lumen loss, mm	-	-	0.06±0.08
Distal edge (5 mm)			
Reference vessel diameter, mm	2.80±0.45	2.80±0.46	2.74±0.46
Mean lumen diameter, mm	2.72±0.43	2.68±0.41	2.61±0.44
Minimum lumen diameter, mm	2.55±0.45	2.51±0.43	2.42±0.42
Diameter stenosis, %	8.6±9.4	10.1±8.7	11.7±7.2
Late lumen loss	-	-	0.10±0.09
Balloon-artery ratio*	1.14±0.12	1.15±0.12	-

Data are displayed as mean±SD. * Representing the largest balloon diameter used

Supplementary Table 7. IVUS assessments at post procedure and follow-up (paired data).

	Post-procedure N=38	FUP N=38	Δ post procedure vs FUP	*p*-value
Mean vessel area, mm²	14.11±2.99	14.54±3.12	0.43±1.08	0.02
Mean bioadaptor area, mm²	7.39±1.20	7.74±1.46	0.35±0.58	0.0005
Minimum bioadaptor area, mm²	2.55±0.27	2.57±0.28	0.02±0.02	0.62
Mean lumen area, mm²	7.39±1.20	7.36±1.31	-0.04±0.55	0.59
Minimum lumen area, mm²	6.10±1.15	5.86±1.20	-0.25±0.73	0.02
Neointimal obstruction, %	0	3.39±4.66	3.39±4.67	<0.0001
Malapposed volume, mm³	0.01±0.03	0.03±0.05	0.02±0.06	0.06

Data are displayed as mean±SD.

FUP: follow-up; IVUS: intravascular ultrasound

Supplementary Table 8. Optical coherence tomography results at the cross-section and strut levels.

	Overall, N=28
Cross-section level analysis	
Analysed device length, mm	19.38±5.11
Cross-sections analysed per device	48.75±11.02
Reference analysis	
Mean reference lumen area, mm^2	6.35±1.84
Mean reference lumen diameter, mm	2.81±0.41
Bioadaptor analysis	
Mean device area, mm^2	7.72±1.58
Minimum device area, mm^2	6.54±1.48
Mean device diameter, mm	3.12±0.33
In-device lumen analysis	
Mean lumen area, mm^2	6.72±1.57
Minimum lumen area, mm^2	5.33±1.6
Mean lumen diameter, mm	2.9±0.35
Lumen area stenosis, %	13.93±10.79
ISA quantification	
No. of lesions with ISA, n (%)	4 (14.3%)
Mean ISA area, mm^2	0.85±0.25
NIH quantification	
Mean NIH area, mm^2	1.07±0.44
Mean NIH obstruction, %	14.0±5.2
Strut-level analysis	
Total no. of analysed struts	11,395
Analysed struts per lesion	406.96±120.49
Analysed struts per cross-section	10.68±2.9
Covered struts per lesion, %	98.95±2.85
Uncovered struts per lesion, %	1.05±2.85
Malapposed struts per lesion, %	0.16±0.51
Malapposed strut-to-lumen distance, mm	0.38±0.07
NIH thickness over covered struts, mm	0.14±0.04
Frequency of cross-sections with >30% uncovered struts, %	0.87±4.1
Maximum length of consecutive segments of uncovered struts, mm	0.84±1.78

Data are displayed as mean±SD or n (%). ISA: incomplete stent (bioadaptor) apposition; NIH: neointimal hyperplasia

Supplementary Table 9. Comparison of DynamX outcomes with contemporary drug-eluting stents.

	BIOFLOW-II trial [15]		**SPIRIT III trial [16]***		**DynamX study**
	XIENCE Prime	**Orsiro**	**Japan - XIENCE Prime**	**USA - XIENCE Prime**	**DynamX bioadaptor**
Baseline					
No. of lesions	25	31	70	71	38
Device area, mm^2	7.28±2.17	7.50±2.50	7.0±2.4	6.3±1.7	7.39±1.20
Mean lumen area, mm^2	7.28±2.17	7.50±2.50	7.0±2.4	6.2±1.7	7.39±1.20
Vessel area, mm^2	15.95±5.06	15.73±5.5	13.0±4.5	12.4±3.8	14.11±2.99
Follow-up	**9 months**		**8 months**		**9-12 months**
Device area, mm^2	7.37±2.34	7.56±2.80	7.0±2.5	6.4±1.8	7.74±1.46
Mean lumen area, mm^2	6.95±2.34	7.40±2.79	6.8±2.4	6.0±1.9	7.36±1.31
Vessel area, mm^2	15.50±5.73	15.54±5.46	13.0±4.3	12.5±3.6	14.54±3.12
Change between baseline & follow-up					
Δ Device area, mm^2	**1%**	**1%**	**0%**	**2%**	**5%**
Δ Mean lumen area, mm^2	**-5%**	**-1%**	**-3%**	**-3%**	**0%**
Δ Vessel area, mm^2	**-2%**	**-1%**	**0%**	**1%**	**3%**

*Volume index (volume/length).