

Novel Drug-Eluting Coronary Stents Nearing Approval in the United States

New stent platforms may offer enhanced performance, safety, and efficacy characteristics.

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The advent of drug-eluting stents (DES) has resulted in significant reductions in both angiographic as well as clinical restenosis rates compared with bare-metal stents (BMS). In multiple randomized, controlled clinical trials, clinical registries, and meta-analyses, the relative benefit of DES (vs BMS) in terms of reduced restenosis rates has been demonstrated for both on- and off-label indications.^{1,2} Nevertheless, specific safety considerations related to DES have emerged and have limited the more universal adoption of DES (vs BMS) for percutaneous coronary interventions (PCI). These concerns have largely been focused on issues related to late (30 days and 1 year) and very late (> 1 year) stent thrombosis, the need for extended-duration dual-antiplatelet therapy (DAPT), and the relative safety of discontinuing DAPT late after DES deployment.³

First-generation DES employ metal alloy scaffolds and durable, nonerodible polymer from which an antiproliferative medication is eluted. The intracoronary presence of these permanent mechanical prostheses may provide a nidus for inflammatory and/or hypersensitivity reactions, as well as a platform for accelerated neoatherosclerosis.⁴

In an attempt to improve safety as well as efficacy of first-generation DES, new-generation DES have been developed that incorporate specific design iterations directed toward improving stent healing and endothelial

coverage, as well as recovery of endothelial and microvascular function. Because many of these next-generation devices are already available outside of the United States, it is appropriate at this time to review select platforms that are nearing approval in the United States.

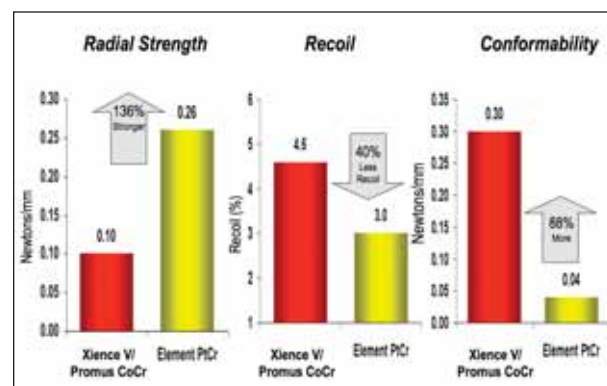


Figure 1. Bench comparisons between the Xience V (Abbott Vascular, Santa Clara, CA)/Promus (Boston Scientific Corporation, Natick, MA) cobalt chromium and Element platinum chromium (PtCr; Boston Scientific Corporation) stent platforms (2.5-mm-diameter stents). Ion stent [Boston Scientific Corporation], n = 15; Xience V/Promus stent, n = 10. Adapted from Menown et al. *Adv Ther.* 2010;27:129–141.⁵

ION (TAXUS ELEMENT)

The Ion paclitaxel-eluting stent (marketed outside the United States as Taxus Element) incorporates a novel, thin-strut (81 μm) PtCr metal alloy platform designed to enhance radiopacity, radial strength, and conformability.⁶ The PtCr metal platform has increased bend fatigue resistance, as well as reduced recoil when compared with either 316L stainless steel or cobalt chromium platforms (Figure 1).⁵ Both the polymer (styrene-*b*-isobutylene-*b*-styrene [Translute, Boston Scientific Corporation]) and the drug (paclitaxel 1 $\mu\text{g}/\text{mm}^2$ polymer) are similar to those of previous Taxus paclitaxel-eluting stent platforms.

The TAXUS PERSEUS trial was designed to evaluate the safety and efficacy of the Ion compared with the Taxus Express stent (Boston Scientific Corporation) in single, de novo coronary stenoses.⁷ In PERSEUS, eligible subjects (single, native vessel, de novo target lesions $\geq 50\%$ diameter stenosis with length ≤ 28 mm and reference vessel diameter ≥ 2.75 to ≤ 4 mm) were randomly assigned (3:1) single-blind to treatment with either the Ion or Taxus Express DES platforms. Randomization was stratified for the presence or absence of medically treated diabetes and additional subjects ($n = 330$) were randomly assigned to undergo quantitative coronary angiography (QCA) at 9-month follow-up throughout the course of trial enrollment.

Both the primary clinical endpoint (target lesion failure [TLF]: ischemia-driven target lesion revascularization, target vessel-related myocardial infarction or cardiac death) and the key secondary angiographic endpoint (in-segment % diameter stenosis at 9 months) of the trial were met, with the Ion demonstrating noninferiority to the Taxus Express stent.⁸

Interestingly, despite a similar incidence of postdilatation (approximately 54%) and similar postdilatation pressures (16.6 atm), the postprocedural in-stent minimum lumen diameter after Ion implantation (2.68 ± 0.39 mm) was significantly larger than after Taxus Express implantation (2.54 ± 0.36 mm; $P = .01$) and was supported by a larger in-stent acute gain (1.93 ± 0.41 vs 1.83 ± 0.40 mm, respectively; $P = .09$).⁸ This observation suggests that the novel PtCr Element platform has enhanced radial strength and/or reduced elastic recoil when compared with the 316L stainless steel Express stent platform. The PERSEUS Workhorse and Small Vessel trials⁹ provided the necessary assurance of safety and efficacy for the Ion DES to allow US Food and Drug Administration approval and commercialization.

PROMUS ELEMENT

The Promus Element stent (Boston Scientific Corporation) combines the same antiproliferative agent

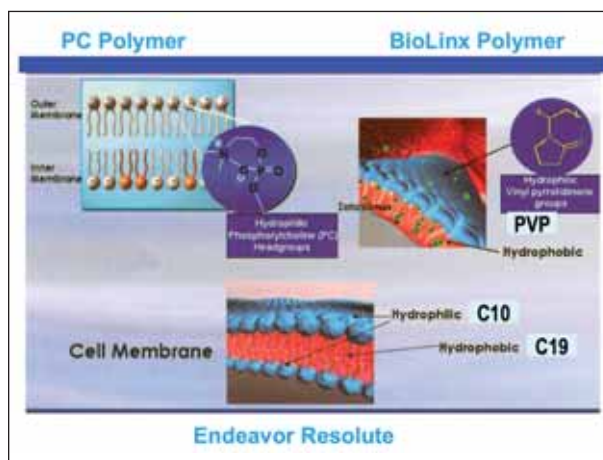


Figure 2. The evolution from phosphorylcholine to BioLinx polymers in the Endeavor and Resolute stent platforms (Medtronic, Inc., Minneapolis, MN), respectively. BioLinx was three distinct components. Reprinted from EuroIntervention, 3, Udipi K et al, The next-generation Endeavor Resolute stent: role of the BioLinx polymer system, 137-139, 2007, with permission from Europa Edition.¹⁰

(everolimus) and polymer (fluorocopolymer) present on the Xience V/Promus cobalt chromium metal alloy platform with the novel Element PtCr scaffold designed for enhanced deliverability, conformability, and side branch access (described previously).

In a prospective, randomized, multicenter trial to assess an everolimus-eluting coronary stent system (Promus Element) for the treatment of up to two de novo coronary artery lesions (PLATINUM) trial, Promus Element was not inferior to the Promus stent platform with respect to the occurrence of TLF to 12 months and was associated with similar rates of cardiac-related death, myocardial infarction, target lesion revascularization (TLR), and stent thrombosis.¹¹ The Promus Element combines the same specific distinctive attributes of the novel PtCr platform with the proven, durable safety, and efficacy of the thin nonadhesive, inert, biocompatible fluorocopolymer and everolimus elution from the Xience V/Promus platform.¹² The resistance to platelet-thrombus deposition in blood-contact applications of the fluorocopolymer may explain the relative infrequency of stent thrombosis when compared with other DES.^{13,14}

Although both technical and procedural success rates were similar for the Promus and Promus Element platforms in the PLATINUM trial, unplanned (bailout) stenting was more frequently required after Promus deployment (9.8%) versus Promus Element deployment (5.9%; $P = .004$) and was ascribed to procedural complications in 48% or inadequate lesion coverage in 35% of these

ATTRIBUTES OF BIODEGRADABLE STENTS

- Removes potential “triggers” for very late stent thrombosis (polymer, uncovered struts), which may reduce the requirement for long-term DAPT
- Facilitates recovery of autoregulation and normal microcirculatory function, as well as late luminal enlargement and adaptive remodeling
- Does not interfere with future revascularization options (PCI or coronary artery bypass graft surgery)
- Eliminates issues of late side branch coverage, ostial overhang, and imaging (computed tomography) artifact
- Eliminates nidus for late development of neoatherosclerosis

cases, respectively.¹¹ Thus, the operator-user friendliness of the Promus Element stent and delivery system would appear to be associated with improved procedural results. This observation must be qualified by acknowledging the single-blind randomized design of the PLATINUM trial. The relative radial strength and reduced recoil of the PtCr metal alloy platform (vs either 316L stainless steel or the cobalt chromium Xience/Promus platform) is supported by data from both the PERSEUS and PLATINUM QCA trials.^{8,15}

In PERSEUS, as noted previously, postprocedural minimum lumen diameter by QCA was larger after using the Taxus Element (vs Taxus Express), despite a similar incidence of postdilatation and similar deployment pressures. In the PLATINUM QCA trial, the incidence of post-procedure incomplete stent apposition as determined by intravascular ultrasound (IVUS) (5.7%) was significantly less than the predetermined performance goal.¹⁵ Incomplete stent apposition was not observed in any

patient at the 9-month follow-up IVUS study. The combination of thin PtCr stent struts, fluorocopolymer, and everolimus elution were associated with a very low in-stent late (9 month) lumen loss by QCA (0.17 ± 0.25 mm; upper confidence bound, 0.22 mm).¹⁵

Finally, the Promus Element stent platform appears to be particularly well suited for small vessel application, as evidenced by the PLATINUM Small Vessel study. In PLATINUM Small Vessel, despite a baseline target vessel reference diameter of 2.08 ± 0.29 mm and a 42.6% prevalence of diabetes mellitus among participating subjects, the incidence of TLF to 12 months was 2.4% (per protocol) while neither myocardial infarction nor ischemia-driven TLR were observed.^{15,16}

RESOLUTE

The Resolute DES (Medtronic, Inc.) combines the thin (91 μ m) cobalt chromium (MP305N) metal alloy platform with the Sprint delivery system (Medtronic, Inc.), zotarolimus (ABT578) antiproliferative drug, and a tri-component BioLinx polymer.¹⁷ The most significant iteration from Endeavor to Resolute involved a change in polymer from phosphorylcholine (PC) to BioLinx, which incorporates hydrophilic overlays (C10) with a hydrophobic inner layer (C19) and hydrophilic vinyl pyrrolidinone groups (Figure 2).¹⁰ BioLinx provides more extended drug-release kinetics with more effective suppression of neointimal proliferation and subsequently, less in-stent late lumen loss as determined by QCA (Figure 3).

Although the phosphorylcholine polymer on Endeavor demonstrated complete drug elution within 14 days (burst release kinetics) and an in-stent late lumen loss of approximately 0.6 mm, zotarolimus elution from the BioLinx polymer extended beyond 30 days and was associated with an in-stent late lumen loss of approximately 0.2 mm. These characteristics of Resolute translated into

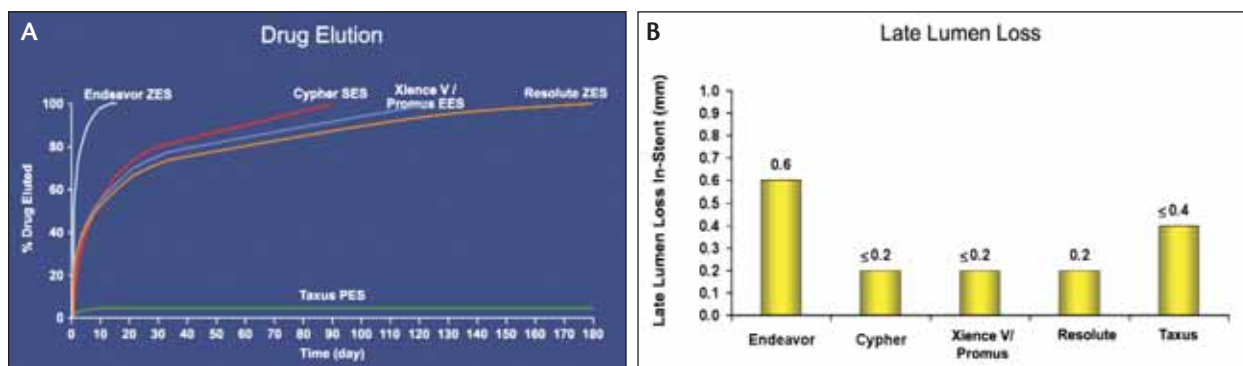


Figure 3. Drug release kinetics through 180 days for each coronary stent platform (SES, sirolimus-eluting stent; PES, paclitaxel-eluting stent) (A). Late in-stent lumen loss as determined by QCA performed at 8 to 9 months after stent deployment (B). Figure 3A use approved by Medtronic Cardiovascular Group Office of Medical Affairs.

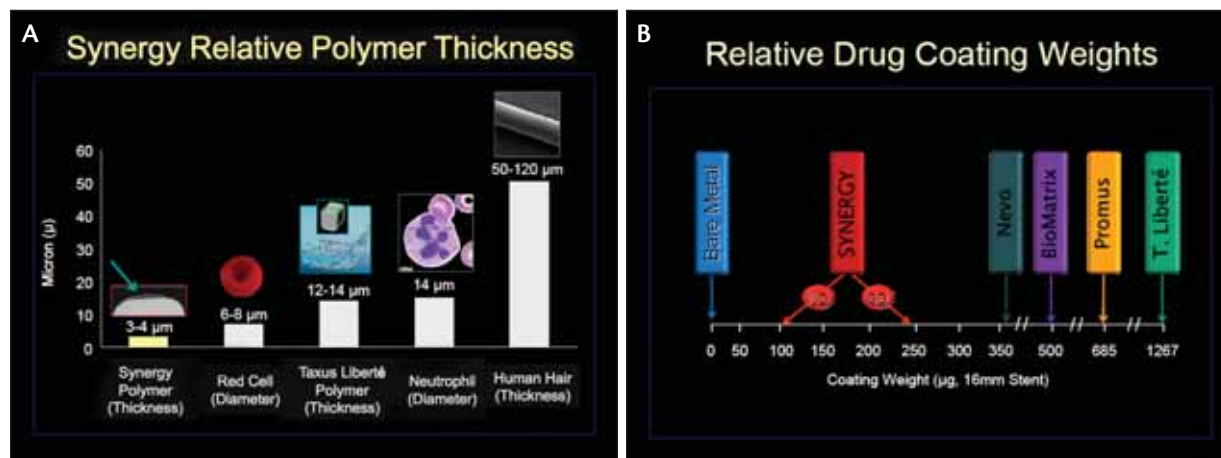


Figure 4. Relative thickness in microns compared for Synergy and Taxus Liberté polymers (Boston Scientific Corporation), red cell and human hair, as well as neutrophil (diameter) (A). Relative polymer coating weight (normalized for 16-mm-long stent) comparison across multiple DES platforms (B). Reprinted with permission from Meredith IT.¹⁸

lower rates of angiographic restenosis as well as clinically driven target lesion/vessel revascularization, which were competitive with other low late-lumen-loss-olimus DES.

The RESOLUTE global clinical program includes the first-in-human experience, the RESOLUTE All Comers randomized trial versus the Xience V everolimus-eluting stent (EES), as well as the RESOLUTE International, US, and Japan prospective observational trials involving a total of 5,130 patients treated with the Resolute zotarolimus-eluting stent (ZES). In the RESOLUTE All Comers randomized trial, the ZES (vs Xience EES) demonstrated similar rates of ischemia-driven TLR (5.7% vs 5.2% respectively), the composite occurrence of cardiac death or target vessel myocardial infarction (7% vs 6.2%, respectively), TLF (11.2% vs 10.7%, respectively) and the composite occurrence of all-cause death, all myocardial infarction, or any revascularization (20.6% vs 20.4%, respectively) through 2-year follow-up.^{19,20}

The endpoint of Academic Research Consortium definite/probable stent thrombosis was slightly higher after ZES deployment at both 1-year (1.6% vs 0.7% EES; $P = .05$) and 2-year (1.9% vs 1% EES; $P = .07$) follow-up.^{19,20} The incidence of definite stent thrombosis to 1-year follow-up was greater after ZES versus EES deployment (1.2% vs 0.3%; $P = .01$), with the majority of events with ZES occurring on or before day 5 after stent placement.¹⁸ Compliance with DAPT at both 1 and 2 years was similar between randomly assigned stent treatments (84.1% and 83.8%, respectively, at 1 year; 18.6% and 18.1%, respectively, at 2 years). The safety and efficacy of the Resolute ZES is further supported by the RESOLUTE US trial, which evaluated a wide range of ZES diameters (2.25–4 mm) and lengths (8–38 mm).²¹

In the WORKHORSE (2.25–4 mm) study population ($n = 1,402$ patients with 1,573 lesions) of the RESOLUTE US trial, the prevalence of diabetes mellitus was 34.4%, and unstable angina clinical presentation was present in 42% of subjects. Complex American College of Cardiology/American Heart Association angiographic lesion complexity class B2/C was present in 75.2% of patients.

Despite the characteristics of the study population, TLF was observed in 4.7%, target vessel-related myocardial infarction was present in 1.4%, and clinically driven TLR was present in 2.8% of patients followed to 1 year. Compliance with DAPT was 93% at 1 year, and Academic Research Consortium definite/probable stent thrombosis was observed in only two patients (0.1%), both of whom were treated with 2.25-mm-diameter ZES devices.²¹

XIENCE PRIME

The Xience Prime DES (Abbott Vascular) combines the same antiproliferative agent (everolimus) and thin fluorocopolymer present on the Xience V/Promus and Promus Element platforms with a novel 81-μm strut thickness cobalt chromium alloy Multi-Link 8 stent backbone. The Multi-Link 8 represents a modification of the Multi-Link Vision stent design (Abbott Vascular), which incorporates a taller, nonlinear link and longer cell length that results in improved stent flexibility and better stent retention.

In addition, specific improvements in the Xience Prime stent delivery system have been made, which include (1) larger hypotube diameter with stainless steel junction support, (2) smooth, rounded tip design with improved device trackability, and (3) tapered balloon shoulders

with more rapid balloon deflation times. The Xience Prime has been designed to provide enhanced mechanical device performance while maintaining the proven safety and efficacy of the Xience V platform.

SYNERGY

Multiple biodegradable polymer DES have been developed in an attempt to obviate durable, nonerodible polymer-related inflammation and/or hypersensitivity, which have been incriminated in adverse clinical events (stent thrombosis and/or restenosis) occurring late after DES deployment.²² Various formulations of polylactide, poly-L-lactide, or polylactic-co-glycolic acid have been used.²³ In an attempt to reduce bioresorbable polymer load, the Synergy stent (Boston Scientific Corporation) employs a thin (3–4 μm) layer of polylactic-co-glycolic acid plus everolimus applied to the abluminal surface of the stent's metal platform, which results in a coating weight of < 250 $\mu\text{g}/16\text{-mm}$ stent (Figure 4).¹⁸

For first-in-human use, this polymer/drug complex has been affixed to the thin-strut (81 μm) platinum chromium Element stent platform. Everolimus-release kinetics (in vitro) appear to be similar to those of the Xience V/Promus stent. In preclinical studies after deployment in domestic swine, the Synergy stent demonstrated a similar degree of endothelial cell strut coverage and luminal thrombus formation as the bare-metal Element and/or Promus Element stent platforms, respectively.¹⁸

The Synergy monorail coronary EES system is being evaluated in a randomized controlled clinical trial (EVOLVE) using two different drug doses (either 113 or 56 $\mu\text{g}/20\text{-mm}$ stent) in comparison with the Promus Element coronary EES system. Eligible subjects with lesion length ≤ 28 mm and reference vessel diameter ≥ 2.25 to

≤ 3.5 mm, with percent diameter stenosis > 50% excluding left main (chronic total occlusion or recent/acute myocardial infarction), are being randomly assigned on a 1:1:1 basis to treatment with either the Synergy, half-dose Synergy, or Promus Element stents. The primary clinical endpoint of the trial is TLF (cardiac death, myocardial infarction, or target vessel revascularization) at 30 days, and the primary angiographic endpoint is in-stent late lumen loss at 6 months. Trial enrollment is complete, and the primary endpoint data are expected to be presented in November 2011.

BIORESORBABLE VASCULAR SCAFFOLD

There are multiple potentially attractive attributes of a biodegradable stent platform (see *Attributes of Biodegradable Stents* sidebar). The development of fully bioresorbable polymer DES offers the promise for restoration of normal coronary artery structure and function and thus, the concept of “vascular restorative” therapy, which includes stenosis relief, arterial healing, and the return to normal arterial function.

The Bioresorbable Vascular Scaffold (BVS) platform (Abbott Vascular) includes a poly-L-lactide backbone that is coated with a microlayer mixture of poly-D-L-lactide and everolimus, which enables controlled drug release with a kinetic profile similar to that of the Xience V stent platform.²³ Although BVS has a strut thickness of 150 μm , both device deliverability and radial strength are similar to those of the Xience V.

The initial clinical experience in humans showed no stent thromboses and only one major adverse cardiovascular event in 30 subjects followed through 4 years.²⁴⁻²⁶ Complete bioresorption of the implant was confirmed by serial IVUS and optical coherence tomography evaluations, and a return to normal vessel reactivity in response to methergine or acetylcholine was demonstrated.²⁴ Serial follow-up through 2 years using intravascular imaging techniques shows late lumen loss at 6 months, predominantly due to reduction in scaffold area with subsequent lumen area enlargement (approximately 17%) between 6 months and 2 years (Figure 5).²⁴

After changes in the platform design to provide more uniform strut distribution and support of the arterial wall, as well as lower late scaffold area loss, subsequent evaluation of the BVS version 1.1 in 101 patients (ABSORB cohort B) demonstrated a low rate of major adverse cardiovascular events (cardiovascular death, myocardial infarction, or ischemia-driven TLR) of 6.9% at 1 year coupled with a low in-stent late lumen loss at 6 months of 0.19 ± 0.18 mm in a prospectively defined ($n = 42$) angiographic cohort.^{27,28} In fact, in-stent late lumen loss at 1-year follow-up (0.27 ± 0.32 mm) closely

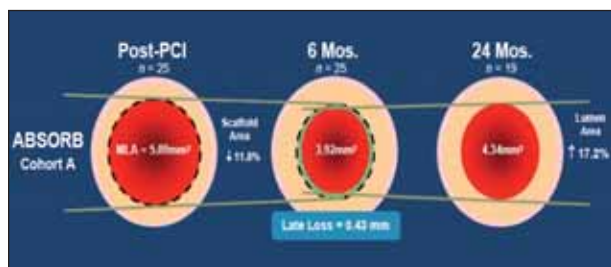


Figure 5. ABSORB cohort A lumen dimensional changes over time as determined by serial IVUS evaluation. Late lumen loss at 6 months is mainly due to reduction in scaffold area, and very late lumen enlargement is observed from 6 months to 2 years. MLA, maximum lumen area. Adapted from The Lancet, 373, Serruys PW, et al. A bioabsorbable everolimus-eluting coronary stent system (ABSORB): 2-year outcomes and results from multiple imaging methods, 897–910, 2009, with permission from Elsevier.²⁴

paralleled that of Xience V, as demonstrated in the SPIRIT FIRST study (0.23 ± 0.29 mm).²⁸

These studies provided the data required to obtain CE Mark approval for the BVS device, and further clinical evaluation is being obtained from the ABSORB EXTEND registry that will enroll approximately 1,000 subjects at up to 100 sites in Europe, Australia, New Zealand, Latin America, and Asia.

A subgroup of subjects at selected investigational sites who receive planned overlapping BVS scaffolds to treat long lesions will undergo late quantitative coronary angiography, IVUS, and optical coherence tomography follow-up evaluation. The pivotal clinical trial to obtain US Food and Drug Administration approval of the BVS platform will be the ABSORB 3 trial, which will randomly assign approximately 2,000 subjects in up to 120 North American sites to treatment with either the BVS or Xience V platforms. The primary clinical endpoint of ABSORB 3 will be noninferiority of TLF at 12 months between BVS and Xience V.

CONCLUSION

Novel DES platforms on the immediate horizon offer enhanced safety and performance characteristics in addition to efficacy at least similar to currently available second-generation DES. Biodegradable polymer DES currently available outside of the United States may avoid the late adverse events attributed to durable polymer and may obviate the requirement for extended duration of DAPT. However, the residual metal stent backbone may provide a nidus for neoatherosclerosis/thrombosis, as well as interfere with normal autoregulation and microcirculatory function. The development of fully bioresorbable polymer DES platforms offers the potential for restoration of normal coronary artery structure and function after PCI. ■

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