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REVIEW

The Platinum Chromium Element Stent Platform: from Alloy, to Design, to Clinical Practice

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ABSTRACT

Despite advances in polymer and drug technology, the underlying stent platform remains a key determinant of clinical outcome. A clear understanding of stent design and the differences between various stent platforms are of increasing importance for the interventional cardiologist. Reduction in stent strut thickness has been associated with improved stent deliverability, improved procedural outcome, and lower rates of subsequent restenosis. Newer-generation 316L-SS stent designs have enabled reduced strut thickness while retaining radial strength and minimizing recoil, but with significant loss of radiopacity, leading to reduced visibility. Cobalt chromium alloys have enabled a reduction in stent strut thickness to around 80-90 mm while retaining modest radiopacity, but due to higher elastic properties, have been associated with greater stent recoil. Development of a novel 33% platinum chromium alloy with high radial strength and high radiopacity has enabled design of a new, thin-strut, flexible, easily visualized, and highly trackable stent platform, the use of which is further illustrated in several clinical case descriptions.

Keywords: cobalt chromium stent; coronary stent; platinum chromium stent; radial strength; radiopacity; stainless steel stent; strut thickness

INTRODUCTION

While advances in polymer-based antiproliferative drug delivery have significantly improved cardiovascular outcome for patients undergoing coronary stent implantation (primarily due to a marked reduction in target lesion revascularization), key developments in design, structure, and composition of the stent platform per se have also been associated with important practical and clinical benefits.

The ideal stent is typically considered as one that is highly deliverable with a thin-strut, low-profile, flexible design but with high radiopacity,

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high radial strength, and minimal recoil. Close collaboration is necessary between engineer and interventional cardiologist to advance this goal. In the following paper, we describe development of a novel platinum chromium (PtCr) alloy, and how the properties of this alloy have enabled design and development of a new stent platform—the Element stent (Boston Scientific, MN, USA). Potential clinical advantages of this new platform from an interventional cardiology perspective are discussed and illustrated by patient examples from our initial clinical experience.

PLATINUM CHROMIUM ALLOY AND THE ELEMENT STENT PLATFORM: KEY ENGINEERING DATA FOR THE INTERVENTIONAL CARDIOLOGIST

Reduction in stent strut thickness has been associated with improved stent deliverability, improved procedural outcome, and decreased rates of subsequent restenosis (the latter likely due to less vascular injury and therefore less subsequent neointima growth).[1-6] A randomized comparison of two 316L stainless steel (316L-SS) multilink stent designs (originally Advanced Cardiovascular Systems; now Abbott Laboratories, IL, USA), which were similar apart from differences in strut height thickness,[1] found that the thinner-strut stent was associated with a lower incidence of angiographic binary restenosis at 6 months (15.0% vs. 25.8%; $P<0.003$) despite a slightly smaller initial post-stent luminal diameter. Subsequent research suggested that thin-strut design was particularly advantageous in clinical scenarios most suited to drug-eluting stents, such as small vessel diameter[2] or complex (B2/C) lesion anatomy.[3]

Newer-generation 316L-SS stent designs have enabled reduced strut thickness, while retaining radial strength and minimizing recoil, but with significant loss of radiopacity, leading to reduced visibility. However, given the relatively moderate yield strength of 316L-SS, further opportunity for reduction of 316L-SS strut thickness is limited due to compromise of stent compression strength.

The conflicting requirements of reducing strut thickness while maintaining or improving device radiopacity were initially addressed by addition of highly radiopaque material surface coatings. Various gold-coated devices were explored but several studies demonstrated higher restenosis rates compared with uncoated 316L-SS devices.[7,8]

Development of cobalt chromium (CoCr) alloys enabled a reduction in stent strut thickness to around 80-90 mm (compared with 316L-SS devices of 100-140 mm) while retaining adequate radiopacity.[9] However, the improvement in radiopacity with CoCr is relatively modest (for example the CoCr alloys L605 [Vision stent; Abbott Laboratories] and MP35N [Driver stent, Medtronic Inc., MN, USA) have densities of 9.1 g/cm^3 and 8.4 g/cm^3, respectively, compared with 8.0 g/cm^3 for 316L-SS). Also, the CoCr alloy, due to its higher elastic properties, is associated with greater stent recoil than 316L-SS, which may be clinically disadvantageous, as discussed later. As part of the Element stent development program, testing of alternative additional materials to 316L-SS and CoCr was undertaken, including tantalum, tungsten, and platinum; each selected due to their high radiopacity (to improve visibility) and known solubility in iron-chromium-nickel systems. Unlike surface-coating techniques, which have been employed in earlier stents such as the NIR Royal gold plated stent (Medinol Ltd., Jerusalem, Israel), here the material was homogeneously alloyed into the 316L-SS base.

Initial work showed that addition of tantalum and tungsten to 316L-SS resulted in the formation of unfavorable brittle phases and ferrite structures, respectively, even at low levels providing only minor improvements in radiopacity.[10,11] In contrast, addition of low levels of platinum (10%) resulted in a stable alloy with a moderate increase in yield strength (355 vs. 274 MPa for 316L-SS) and a moderate increase in radiopacity.[12] Platinum is an attractive material given its known biocompatibility, chemical stability, and corrosion resistance, and has already been successfully incorporated into a variety of implantable devices including platinum-coated coronary stents such as the ProPass stent (Vascular Concepts, Essex, UK) and Valecor Platinum stent (CorNova Inc., MA, USA), aortic and intravascular stents and stent markers and electrodes.[13-15]

Subsequent testing was undertaken across of a range of platinum addition levels (from 5% to 70%) to 316L-SS and found that alloys with very high levels of platinum (>50%) were more difficult to process due to high strength and hardness. However, a level of 33% provided the optimum balance between processability, metallurgical characteristics, magnetic susceptibility, microstructure/stability, mechanical properties, and radiopacity (increasing the density to 9.9 g/cm^3 compared with 8.0 g/cm^3 for 316L-SS) and was thus selected for ongoing development of the Element stent.[12]

Table 1 shows a comparison of the composition of PtCr alloy with current 316L-SS and CoCr alloys. Compared with standard 316L-SS, the addition of 33% platinum primarily replaces a portion of both the iron and nickel content. While nickel contributes to corrosion resistance, its reduction is well compensated by the effect of the added platinum. Reduction in nickel content may potentially reduce the risk of allergic response in some patients, although this concept remains to be proven.[16] Materials critical to corrosion resistance, such as chromium and molybdenum, have been maintained at levels comparable to 316L-SS. Also of note is the reduction of manganese to trace levels compared with ~2.0% allowed in 316L-SS. Reduction in manganese (combined with the lower sulfur content) is desirable as this leads to a lower risk of manganese sulfide inclusions, which can act as sites for corrosion pit initiation.[12] The PtCr alloy, compared with 316L-SS, has resulted in a significant increase in yield strength (480 vs. 275 MPa),[12] enabling reduction in stent

Table 1. Comparison of stent alloy compositions.

	Elemental composition by weight (%)			
Element	**Platinum chromium (Element stent)**	**316L stainless steel (Liberté stent)**	**L605 cobalt chromium (Vision stent)**	**MP35N cobalt chromium (Driver stent)**
Iron	37	64	3.0 max	1.0 max
Platinum	33	–	–	–
Cobalt	–	–	52	34
Chromium	18	18	20	20
Nickel	9	14	10	35
Tungsten	–	–	15	–
Molybdenum	2.6	2.6	–	9.75
Manganese	0.05 max	2.0 max	1.5	0.15 max
Titanium	–	–	–	1.0 max

strut width and thickness while maintaining similar radial strength.

The Element stent is laser cut from a tube of PtCr alloy, electropolished, and dipped in an acid solution that draws chromium to the surface of the stent (passivation), yielding a corrosion-resistant chromium oxide-rich surface; it is comparable to that of 316L-SS stents, which undergo the same passivation process.[17] Given the new alloy, development of custom laser-cutting techniques and methods to uniformly strip away specific surface components without damaging the structure or properties of the stent bulk material were required. A novel electropolishing process was also designed using a multicomponent chemical bath composition and voltage-controlled bi-polar waveform to simultaneously strip and polish the PtCr alloy, to yield a smooth, rounded, dimensionally uniform, chromium oxide-rich surface to help optimize biocompatibility.

The bio- and vascular-compatibility of the PtCr alloy has been evaluated extensively in the preclinical setting. Vessels implanted with three different types of bare metal stent—PtCr (Element), 316L-SS (Liberté; Boston Scientific) and L605 CoCr (Vision)—were shown to be comparable for all clinical safety parameters and histologically indistinguishable at 30, 90, and 180 days in a nondiseased swine model.[18]

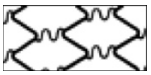
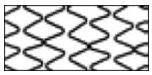
The Element stent platform has recently been introduced for clinical use in two drug-eluting versions. A bare metal version is expected at a later date. The Taxus Element comprises an Element stent with identical polymer (poly[styrene-b-isobutylene-b-styrene]), drug (paclitaxel), and drug formulation and dose density (1.0 μg/mm^2) to the Taxus Liberté stent (Boston Scientific), with a reduced polymer coat thickness (topcoat 18 vs. 20 μm). The Promus Element comprises an Element stent plus identical poly n-butyl-methacrylate primer, polyvinylidene fluoride and hexafluoropropylene copolymer, drug (everolimus), drug formulation and dose density (1.0 μg/mm^2), and polymer thickness (7 μm) to the Promus/XienceV stent (Boston Scientific/Abbott Laboratories). Clinical outcomes with these polymer/drug combinations are already well established from the large TAXUS and SPIRIT clinical trial programs. Preclinical studies have shown comparable vascular healing for the Taxus Element versus Taxus Liberté versus Taxus Express (Boston Scientific), and for the Promus Element versus Promus/XienceV stent. The PERSEUS clinical trial confirmed transferability of Taxus drug/polymer efficacy to the Element platform, showing noninferior rates of target lesion failure for Taxus Element versus Taxus Express (5.6% vs. 6.1%; P=0.78) among 1262 patients undergoing "workhorse" stenting (2.75-4.0 mm diameter, 2/3 with B2/C lesions).[19] The PERSEUS small vessel study showed a significantly lower incidence of target lesion failure among 224 patients undergoing small vessel stenting (2.25-2.5 mm) compared with 124 bare metal Express historical controls (6.6% vs. 20.5%; P=0.01).[19] Initial clinical data from the PLATINUM trial (comparing Promus Element with the Promus/XienceV stent) are expected later in 2010.[20]

The ongoing focus of this paper will thus be on the mechanical and clinical characteristics of the Element stent platform itself and the implications of its novel alloy and stent design for clinical practice, illustrated by recent case examples from the authors' experience of the device.

CLINICAL IMPLICATIONS OF STENT COMPOSITION

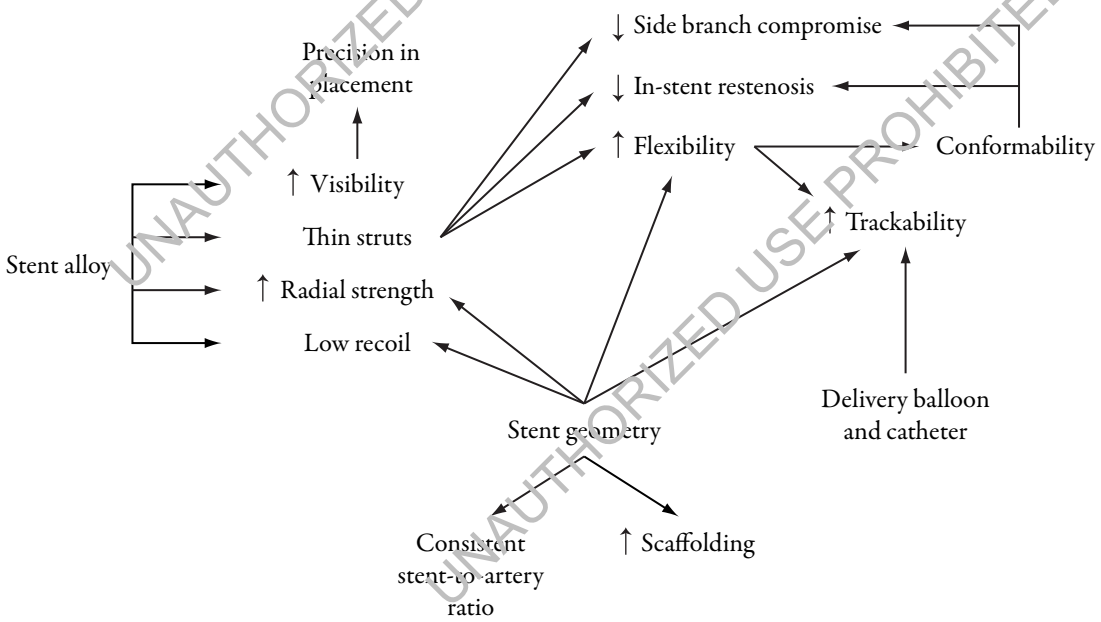
The metallurgical properties of PtCr alloy have enabled the Element stent to utilize thin struts (0.081 mm for the 2.25-3.5 mm vessel diameter

Table 2. Comparison of stent platform specifications among current drug-eluting stents.

	Specification	Promus/Taxus Element stent platform	Taxus Liberté stent platform	Promus (XienceV) stent platform	Cypher stent platform	Endeavor stent platform
Design elements	Pattern					
	Material	PtCr	316L-SS	L605 CoCr	316L-SS	MP35N CoCr
	Strut thickness (height) (mm)	0.081 (0.086 for ≥4.0 mm diameter)	0.097	0.081	0.140	0.090
	Strut width (mm)	0.061 (small vessel) 0.089 (large vessel)	Min: 0.076 Max: 0.094	0.076	Min: 0.081 Max: 0.132	0.090
Bench testing	Surface artery ratio (%)	2.5 mm: 17.6 3.0 mm: 16.4	2.5 mm: 15.5 3.0 mm: 17.6	2.5 mm: 16.8 3.0 mm: 14.1	2.5 mm: 18.3 3.0 mm: 14.3	2.5 mm: 18.1 3.0 mm: 21.4

CoCr=cobalt chromium; PtCr=platinum chromium; SS=stainless steel.

Figure 1. Inter-relationship between features of stent design, procedural outcomes, and clinical outcomes.



range) (Table 2), while achieving enhanced radiopacity (visibility) and enhanced radial strength compared with other contemporary thin-strut stents.

Thinner struts are associated with several potential advantages including a lower stent profile, which contributes to improved trackability, a lower risk of side branch occlusion/periprocedural myocardial infarction, and, as discussed earlier, a lower incidence of in-stent restenosis (likely due to reduced vascular injury) (Figure 1).

High radiopacity is also of major clinical value, particularly during complex percutaneous

coronary intervention (PCI), and can play a key role in the enhancement of procedural safety. Visualization can be difficult in many clinical scenarios, including heavily calcified vessels, overweight patients, or the need to work in extreme caudal angulation. However, adequate stent visualization is essential for example: (i) when overlapping stents to ensure full circumferential overlap (a small geographic miss can be associated with acute stent thrombosis) but avoiding excessive overlap/excessive local drug delivery; (ii) when undertaking high-pressure noncompliant postdilatation following deployment (to avoid inadvertent balloon injury beyond stent margins); and (iii) when confirming satisfactory lesion coverage following stent deployment. The Element stent due to the higher density of platinum compared with iron or cobalt, overcomes the limited visibility associated with thin-strut, stainless steel designs (Figure 2 and 3).

Radial strength (or compression resistance) is a quantitative measure of stent scaffolding strength and the ability of a stent to maintain the vessel lumen. Adequate radial strength is a key stent attribute, particularly when treating highly fibrocalcific lesions or aorto-ostial lesions (Figure 3). Radial strength for the thin-strut Promus or Taxus Element stent (0.26 N/mm) remains similar to the thicker strut 316L-SS Taxus Liberté stent, and

Figure 2. A comparison of stainless steel Liberté and platinum chromium Element visibility.

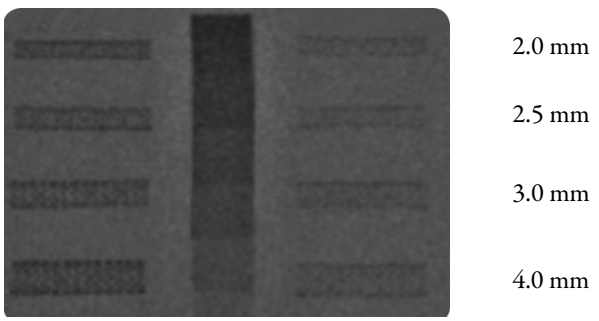
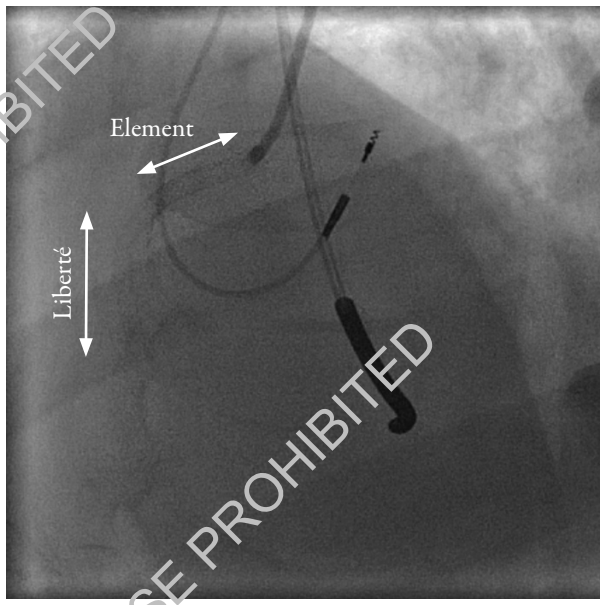


Figure 3A. Proximal/ostial right coronary artery Promus Element stent deployment in a patient with a previous stainless steel Taxus Liberté stent in the mid vessel, illustrating comparative improvement in radiopacity and preservation of radial strength at the clinically important aorto-ostial location. An implantable cardioverter defibrillator is also present. (*Case images courtesy of Dr. I. Menown.*)

(i) Pre-contrast



(ii) During contrast

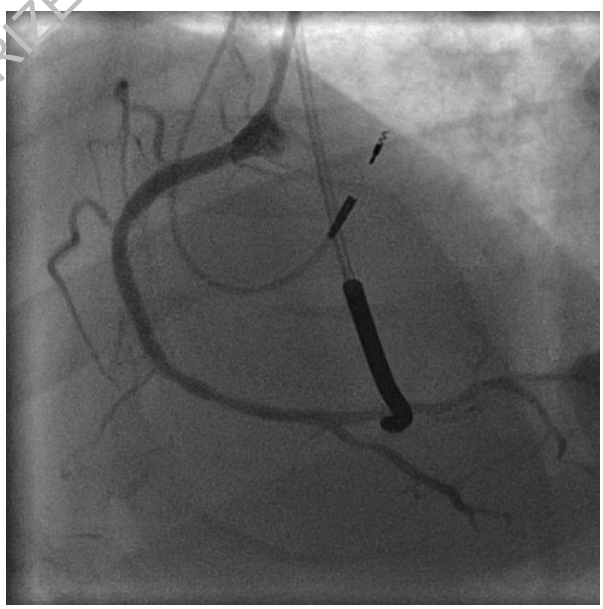
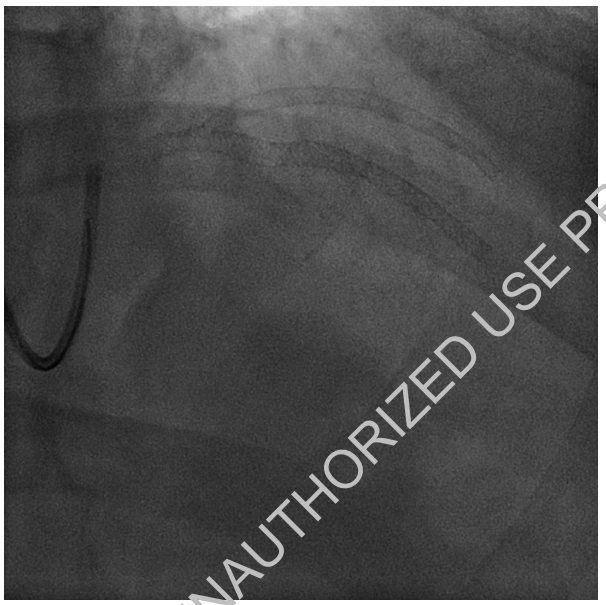


Figure 3B. Overlapping Promus Element stents in the proximal to mid left anterior descending (4.0 and 3.0 mm) and in the ostial to mid diagonal branch (2.75 and 2.5 mm) with a minicrush at the bifurcation, illustrating the value of clear visualization to enable precise stent overlap and avoidance of geographic miss/excessive crush at the bifurcation region. (*Case images courtesy of Dr. I. Menown.*)

(**i**) Pre-contrast



(**ii**) During contrast

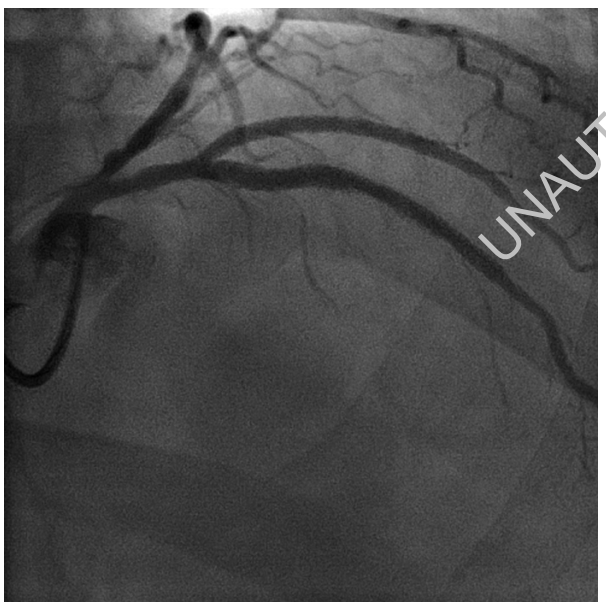
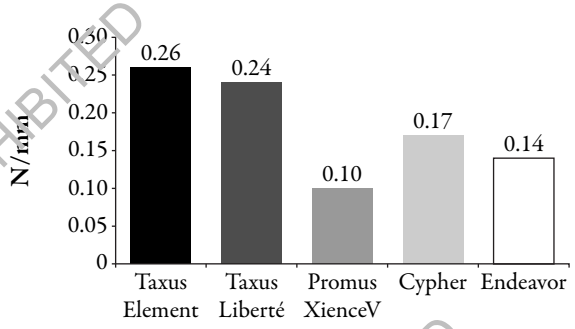
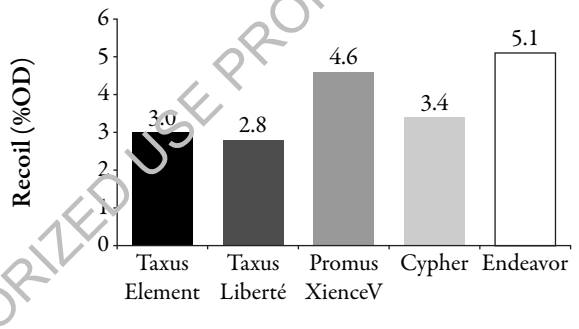


Figure 4. Radial strength (**A**), recoil (**B**), and conformability (**C**) comparisons across current stent platforms. Note: Data represent 2.5 mm diameter comparison [data on file]. Testing completed by Boston Scientific.[18,21] Taxus Element: *n*=15; Taxus Liberté: *n*=8; Promus XienceV: *n*=10; Cypher: *n*=3; and Endeavor: *n*=3. N/mm=Newtons per millimeter; %OD=percent observed decrease; Nmm=Newton millimeters.

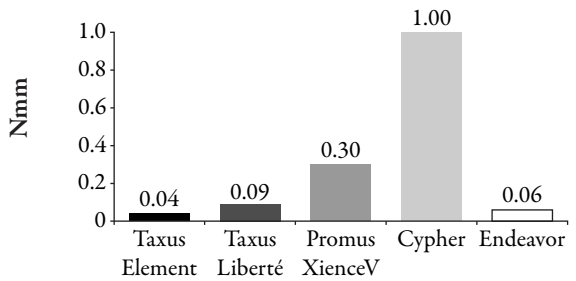
(A) Radial strength.[18]



(B) Recoil.[18]



(C) Conformability.[21]



compares favorably with Promus/XienceV, Cypher (Cordis Corporation, NJ, USA), and Endeavor (Medtronic Inc.) stents (Figure 4A).[18]

Low recoil (the ability of a stent to maintain its initial expansion diameter) is clinically desirable to reduce the risk of subsequent malapposition or restenosis. Malapposition may increase risk of subsequent late stent thrombosis. Postdeployment recoil for Promus/Taxus Element (1.74% to 3.64% across all stent diameters) is well within the typical range for contemporary stents (Figure 4B).

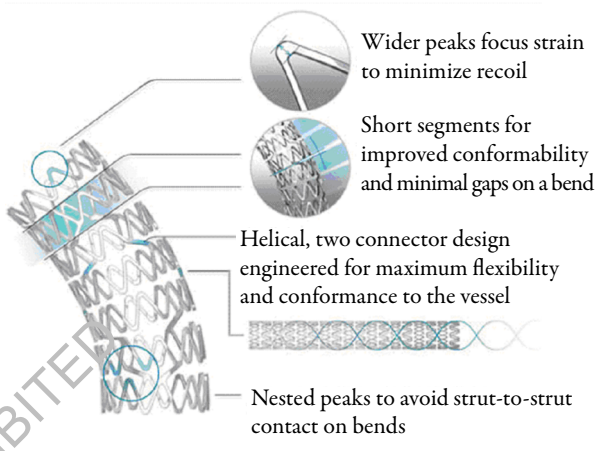
CLINICAL IMPLICATIONS OF STENT DESIGN

Key design objectives for the Element stent were improved flexibility and conformability (Figure 4C).[21] Flexibility is quantified by the force required to bend a stent to a desired radius (with a lower required force indicating higher flexibility). High flexibility contributes to improved stent trackability. In contrast, low flexibility may impair trackability, particularly along tortuous vessels, and may be a factor in vascular trauma along the delivery pathway distal to the guide catheter.

Conformability, a related concept to flexibility, describes the ability of a stent to take up the natural curvature of a vessel without inducing vessel straightening or hinge points. The ability of a deployed stent to flex with a vessel may also improve clinical outcome. Increased stent rigidity limits the use of stents in both tortuous segments and at bends, which may result in a hinge effect that has been associated with an increase in restenosis.[22]

To enhance flexibility and conformability, the Element stent has been designed as a series of serpentine segments each joined to the next by two connectors, with connector

Figure 5. Element stent geometry.



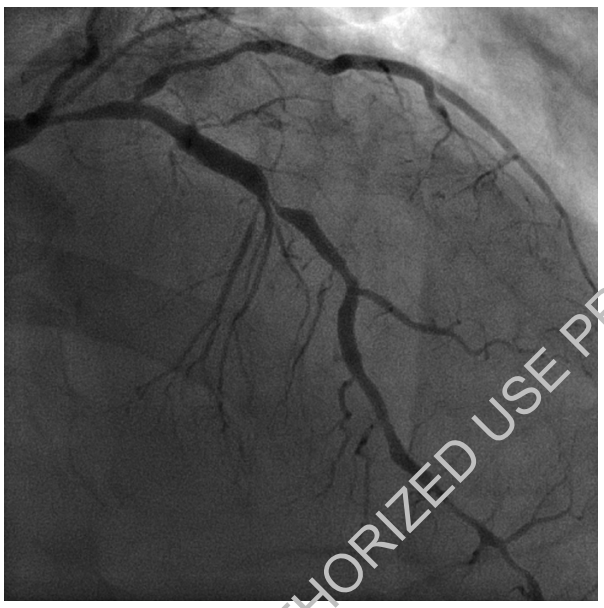
geometry arranged in a three-dimensional "double helix"-type configuration, thereby balancing forces along the stent and allowing each segment to operate almost independently of the other (Figure 5).

Segment peaks are offset (nested), which reduces potential strut-to-strut contact when delivering around a bend or deploying the stent on a bend. In addition, peaks are widened to help to redirect expansion strain longitudinally further contributing to radial strength and reducing (radial) recoil. The length of each segment has been shortened, further improving conformability. Bench testing of Promus/Taxus Element stents has demonstrated improved conformability (0.04 Nmm) compared with other platforms (Figure 4C).[21] Clinical cases illustrating conformability with the Element stent are shown in Figure 6.

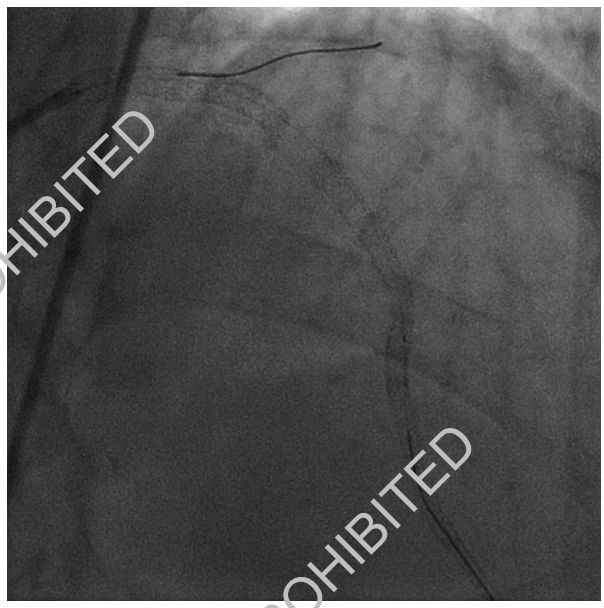
Shorter stent segments also help to minimize inter-segment gaps on greater curvatures, thus improving scaffolding and reducing plaque prolapse (which, if marked, may be associated with risk of stent thrombosis). Enhanced consistency of scaffolding and of the surface-to-artery ratio (which relates to uniformity of drug delivery)

Figure 6A. Continuous left main, proximal, mid, and distal left anterior descending (LAD) stenting with overlapping Promus Element stents (2.5 to >4.0 mm diameter) illustrating the high conformability of the stent platform. The patient had non-ST elevation myocardial infarction, not suitable for coronary artery bypass surgery due to distal LAD disease. The procedure was well tolerated with no post-PCI biomarker elevation despite the long stent length. (*Case images courtesy of Dr. I. Menown*.)

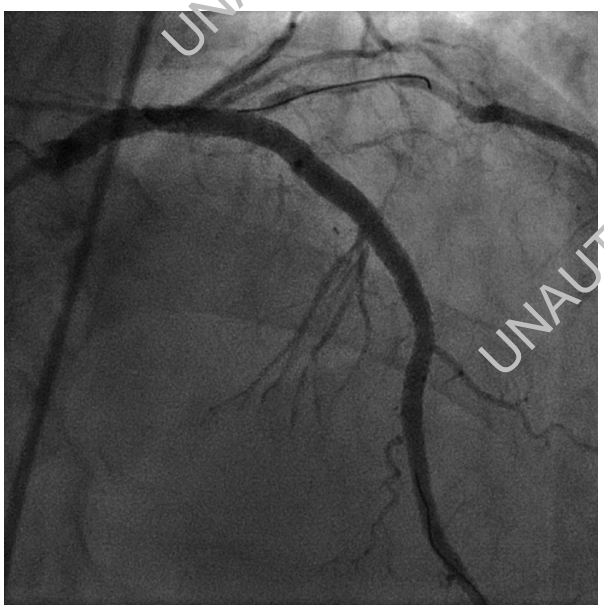
(i) Pre-stenting.



(ii) Post-stenting without contrast.



(iii) Post-stenting with contrast.



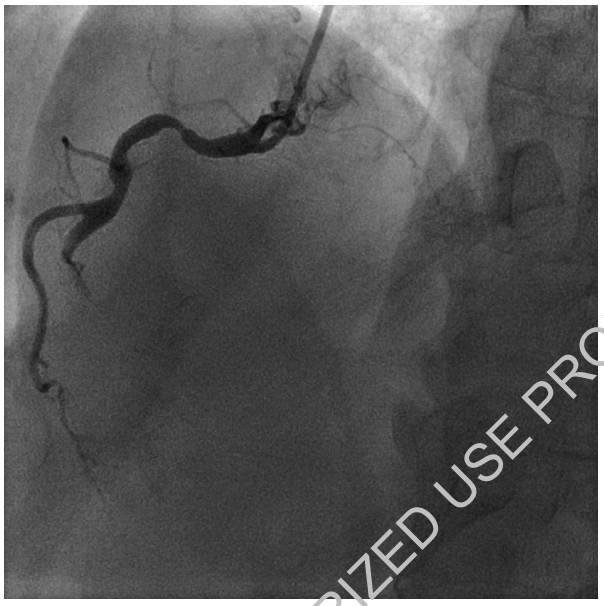
is achieved by use of four separate Element stent models, including a specific 2.25 mm diameter model with shorter segments (and therefore more) per stent than larger models, thereby improving deliverability and conformability in more tortuous, complex, and smaller vessels. In contrast, most other contemporary stents are based on two stent models mounted on different sized stent delivery balloons.

DELIVERY SYSTEM

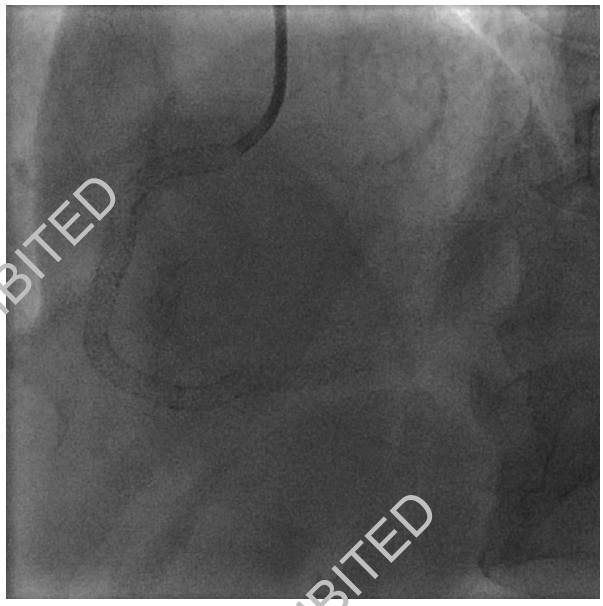
In addition to low stent profile and high stent flexibility, use of the latest balloon technology is clinically important because as stent strut thickness reduces and stent flexibility continues to improve, it is clear that the mechanical

Figure 6B. Proximal, mid, and distal overlapping Promus Element stents deployed in a tortuous right coronary artery (3.5 to 4.0 mm diameter), in a patient with an inferior ST elevation myocardial infarction, illustrating the high conformability of the stent platform. (*Case images courtesy of Dr. I. Menown.*)

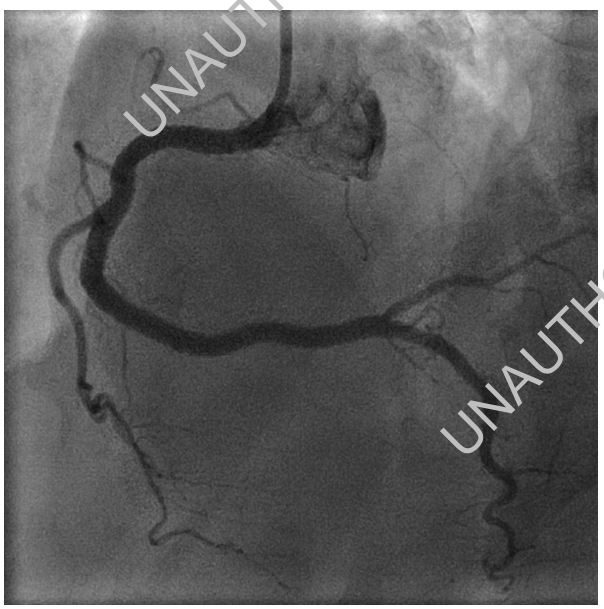
(i) Pre-stenting.



(ii) Post-stenting without contrast.



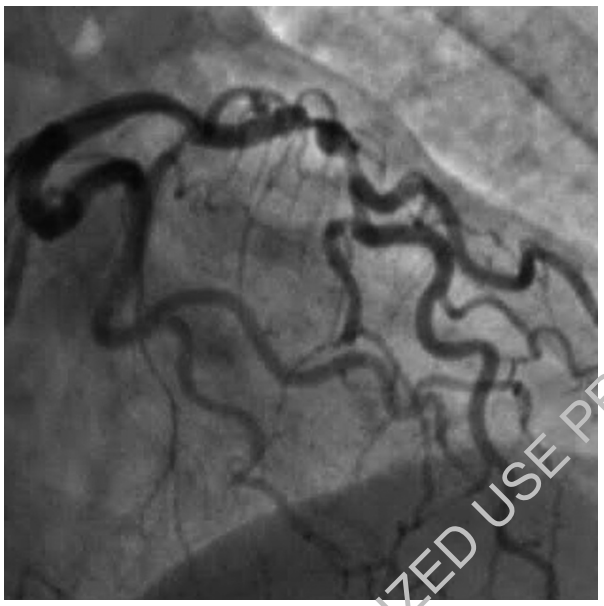
(iii) Post-stenting with contrast.



characteristics and dimensions of the balloon and delivery system play an increasing role in overall device deliverability.[16] The Element stent is mounted on a customized stent delivery system based on the Apex balloon catheter (Boston Scientific), which provides improved proximal shaft pushability and distal shaft/balloon flexibility compared with the Liberté delivery system. Overall trackability of the Element stent, as quantified by the work (Nmm) required to maneuver through a tortuous artery model, is enhanced compared with Promus/XienceV and Endeavor Resolute stents (Figure 7), reflecting a combination of low-profile struts, high flexibility, and an enhanced delivery system.[23] Improved trackability is of central clinical importance, with delivery of the stent to the lesion (followed by adequate deployment) being the primary purpose of the procedure. Availability of highly trackable

Figure 6C. Left anterior descending/diagonal bifurcation lesion in a vessel with severe tortuosity, through which a Taxus Element 3.0x28 mm passed easily and was directly deployed, illustrating high trackability and conformability. (*Case images courtesy of Dr. E. Garcia.*)

(i) Pre-stenting.



(ii) Post-stenting.

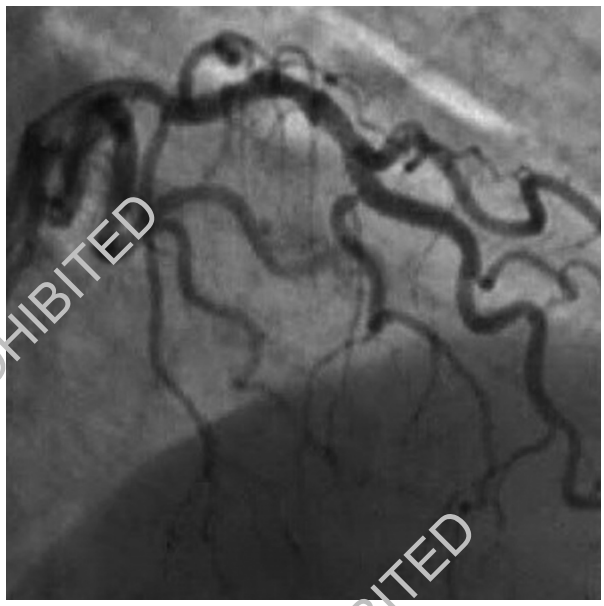
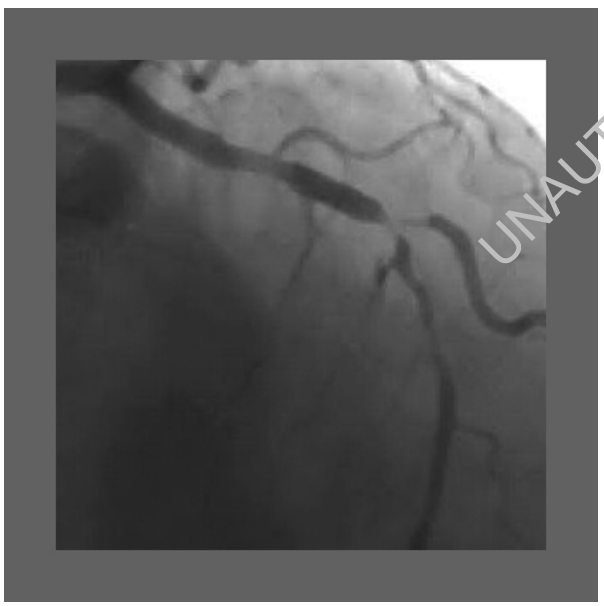
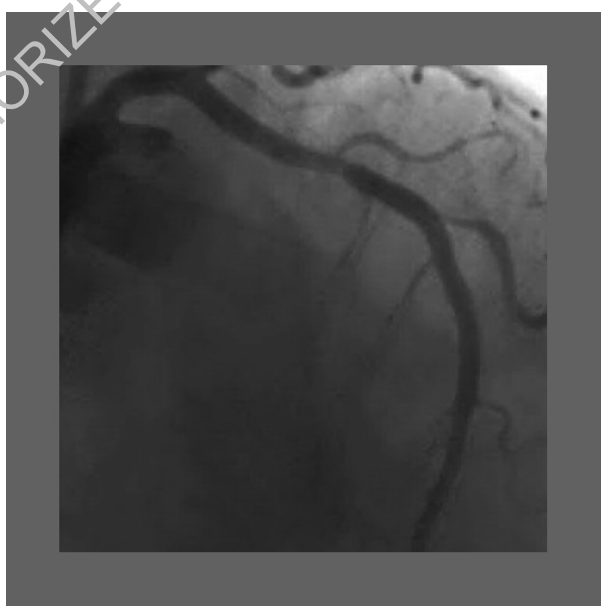


Figure 6D. Severe left anterior descending/diagonal bifurcation lesion managed by direct stenting with a Taxus Element 3.0x32 mm, illustrating good conformability and sidebranch preservation. (*Case images courtesy of Dr. E. Garcia.*)

(i) Pre-stenting.



(ii) Post-stenting



stent designs has facilitated use of long stents (at present, up to 38 mm). Use of longer stents, rather than multiple shorter stents, is likely to improve procedural safety by reducing the number of overlap zones, thereby reducing risk of side branch compromise and/or excessive local drug delivery, as well as being more cost-effective.

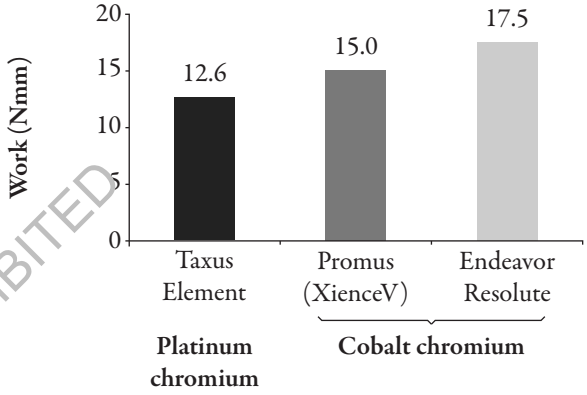
CONCLUSION

As daily interventional cardiology practice becomes ever more complex, so the interventionist's expectations and requirements of a stent platform increase. A clear understanding of differences in composition and design of various stent platforms is of increasing importance. Development of the new PtCr alloy with its high radial strength and high radiopacity has enabled design of a new, thin-strut, flexible, and highly trackable stent platform. The clinical cases illustrate the potential value of this new stent in contemporary clinical practice.

Key Messages

1. Despite advances in polymer and drug science, the underlying stent platform remains a key determinant of clinical outcome.
2. With evolving case complexity, understanding of stent design is of increasing importance for the interventional cardiologist.
3. Use of a novel PtCr alloy has enabled the design and development of a new stent platform.
4. Ideal stent characteristics to optimize clinical outcomes include high trackability, a thin-strut, low-profile, flexible design, high radiopacity, high radial strength, and minimal recoil.

Figure 7. Comparative trackability of 3.0 x 16 mm Taxus Element (n=10), 3.0 x 18 mm Promus/XienceV (n=10), and 3.0 x 18 mm Endeavor Resolute (n=3) stents. Trackability is defined as the work required to maneuver through a tortuous artery model. A lower work value indicates superior trackability.[23]



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