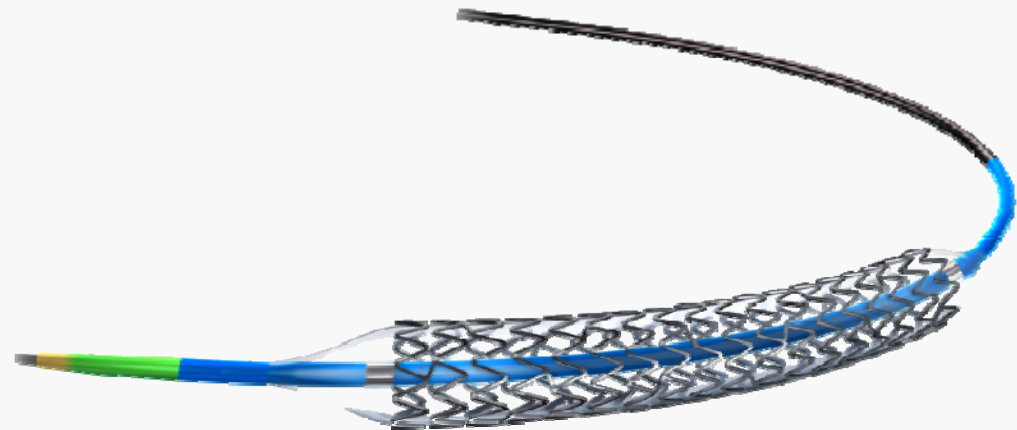
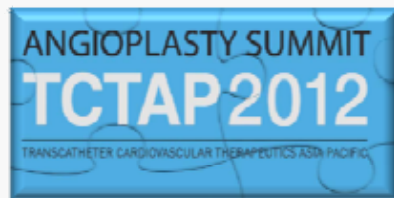


The Goal of EES Improvement: Stent Design, Alloy & Polymer

Keith Dawkins MD FRCP FACC FSCAI
Global Chief Medical Officer
Executive Vice President
Boston Scientific Corporation



Conflicts of Interest

Boston Scientific Corporation

- **Employee**
- **Stockholder**

Efficiency & Deliverability: Key Drivers of DES Choice

Reason for DES Brand Preference

Factor	Q4 '07 N=120	Q2 '08 N=132	Q1 '09 N=120	Q3 '09 N=119	Q2 '10 N=120	Q3 '11 N=119
Efficacy Data	26%	28%	27%	29%	28%	25%
Deliverability	22%	22%	20%	22%	23%	20%
Safety Data	26%	23%	20%	22%	23%	20%
Quality of Clinical Program	13%	13%	13%	14%	14%	16%
Price	9%	10%	9%	7%	9%	9%
Polymer	N/A	N/A	N/A	N/A	N/A	6%
Impression of Company/Sales Force	5%	4%	5%	5%	5%	4%

Q: When deciding on your preferred brand of drug-eluting stent, how much weight do you place on each of the following factors during your brand decision choice? (Allocate 100 points) Source: Source: US GTA Q3'11 (n=119)

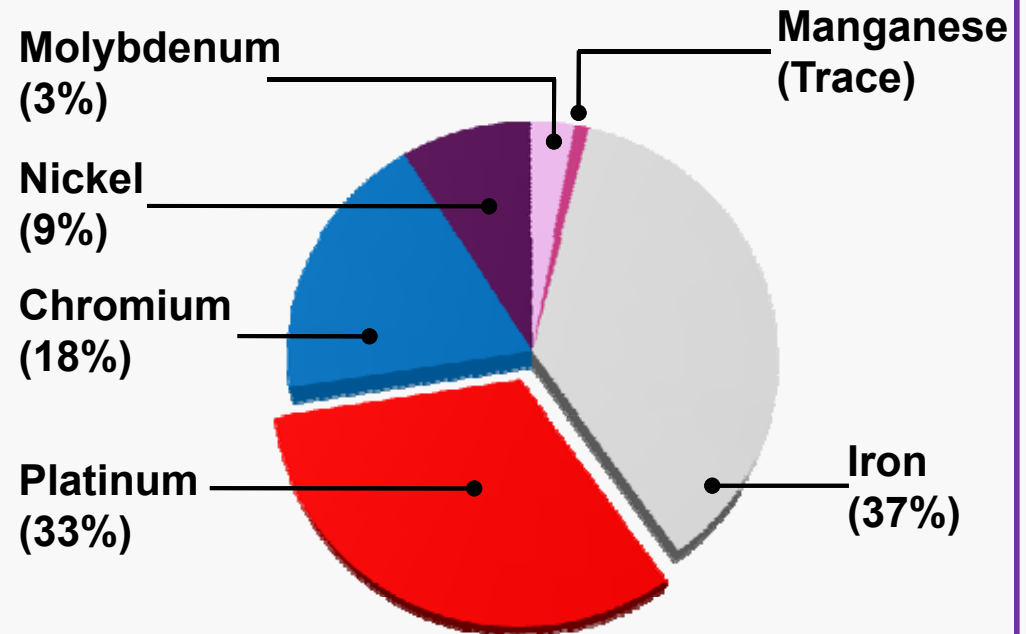
ELEMENT Stent Platform

PROMUS Element
(Everolimus)

TAXUS Element
(Paclitaxel)

OMEGA
(Bare Metal)

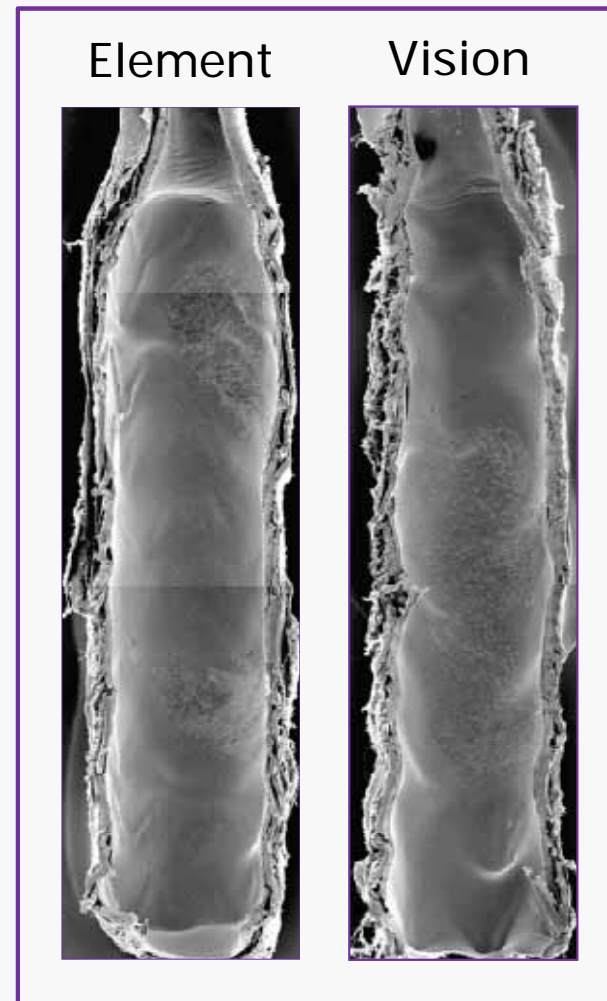
SYNERGY
(Everolimus)



Comparison of ELEMENT and VISION BMS Rabbit Endothelialization Model



14 Days

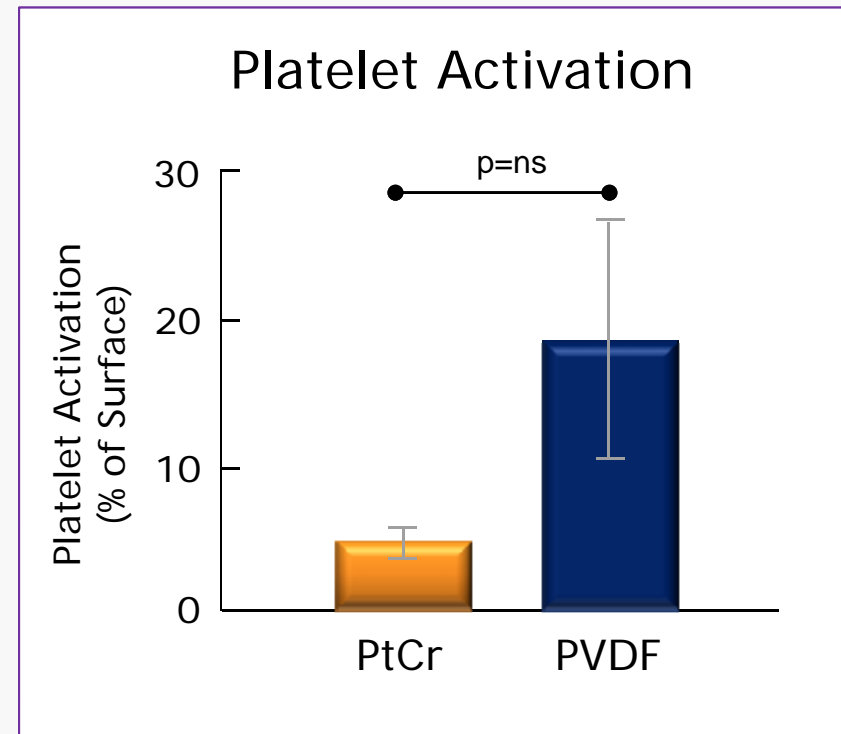
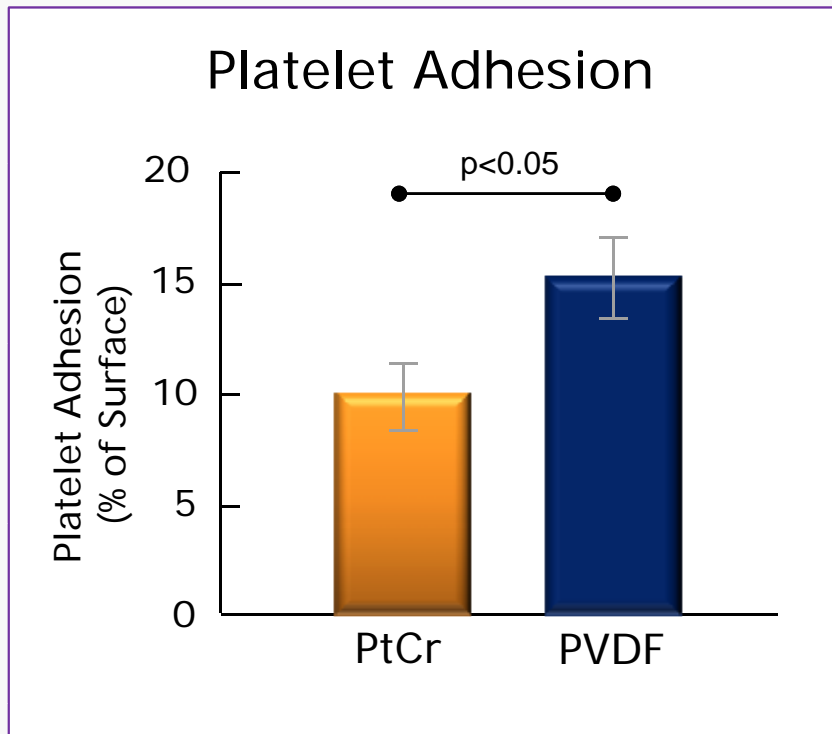


28 Days

Courtesy: Renu Virmani MD

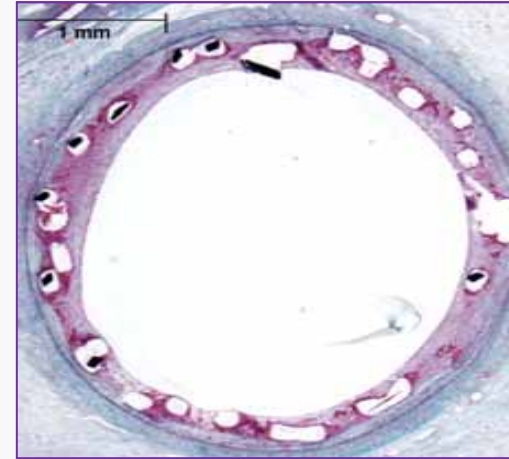
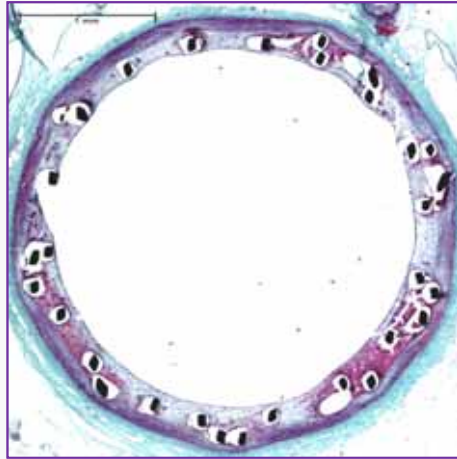
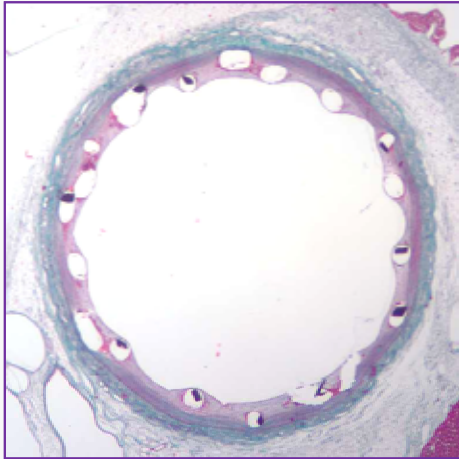
Platelet Responses to Stent Materials

Platinum Chrome (PtCr) vs. Stent Polymer(PVDF)



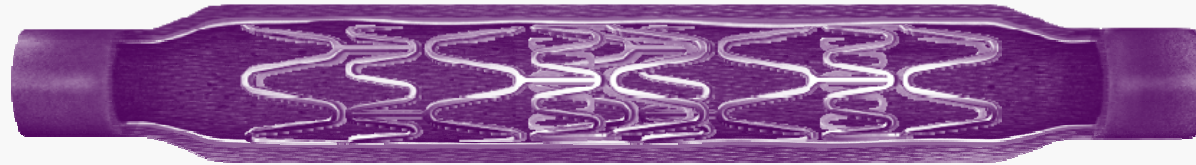
PtCr demonstrated greater thrombo-resistance than PVDF

Consistent Results across Stent Platforms

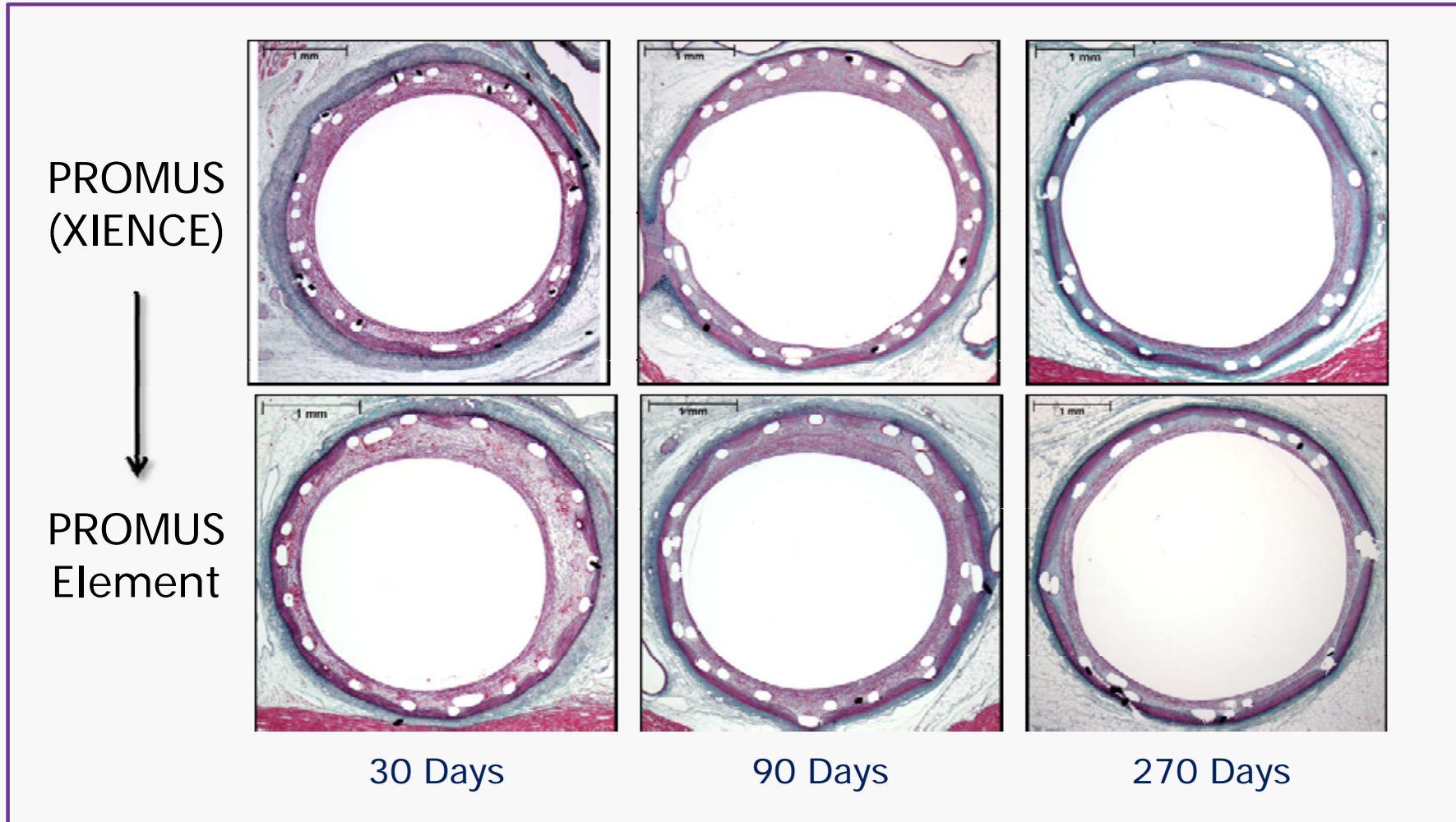


TAXUS Express → TAXUS Liberté → TAXUS Element

Porcine Overlap Model (30 days)



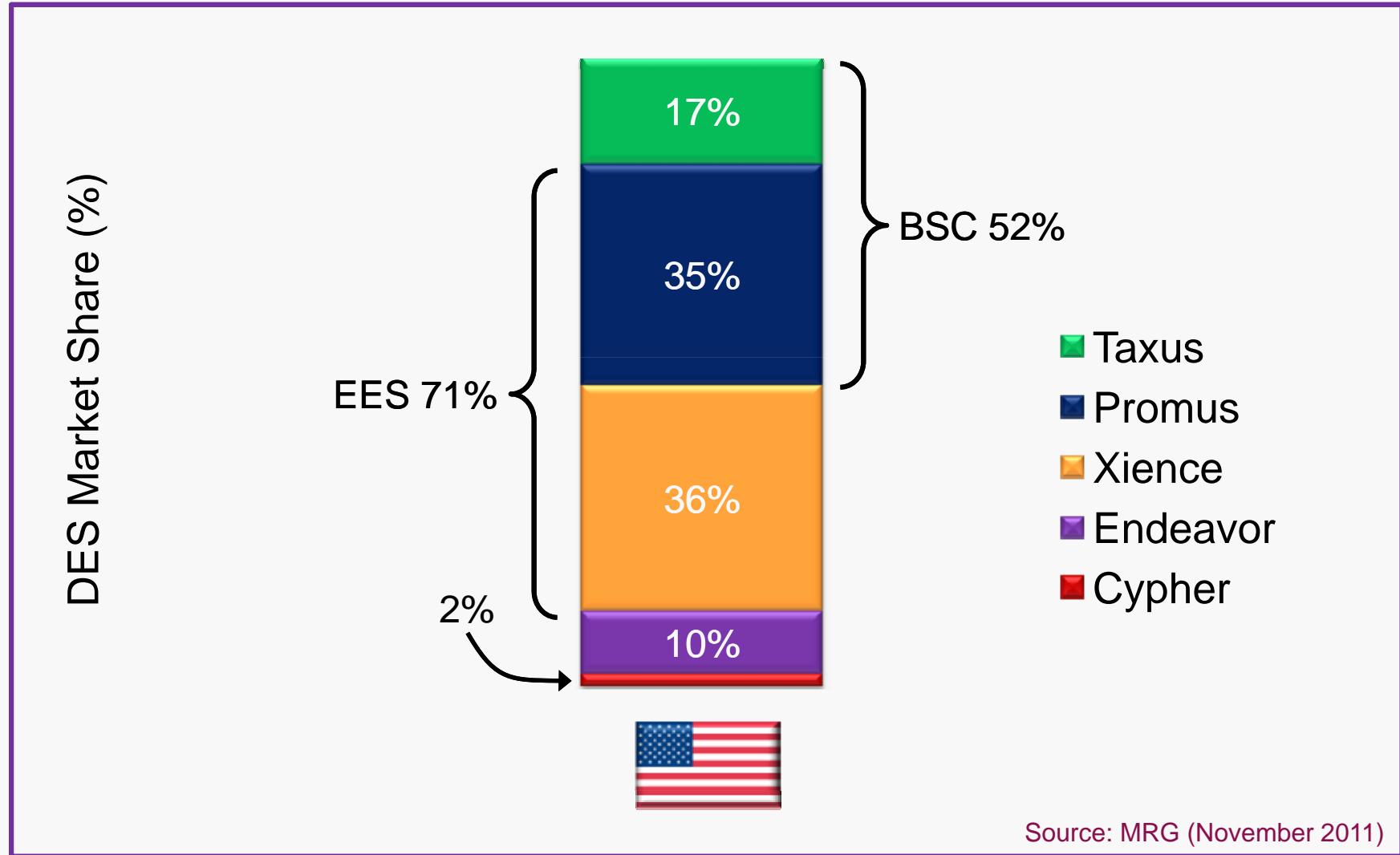
Consistent Results across Stent Platforms



Porcine Overlap Model

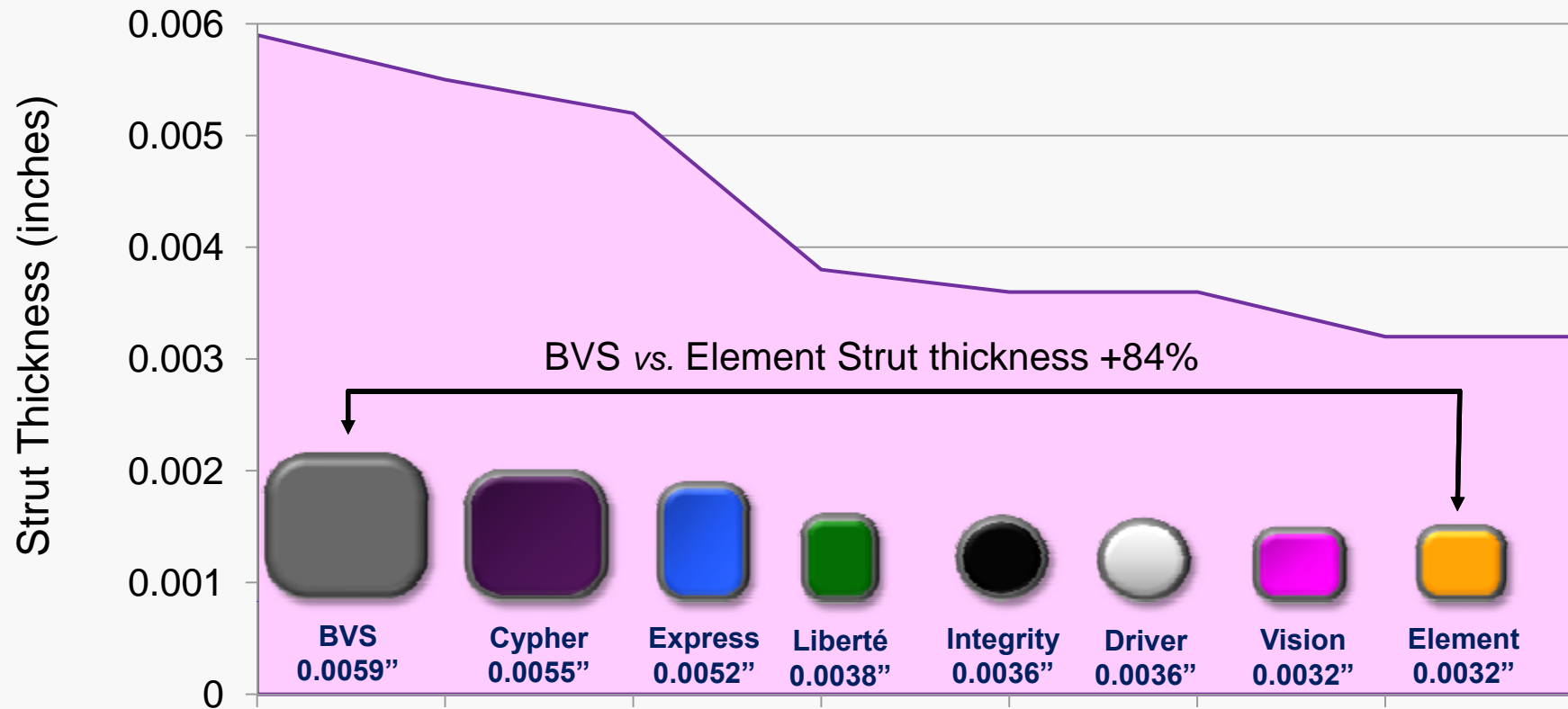
BSC Internal Data

Everolimus is the DES Drug of Choice

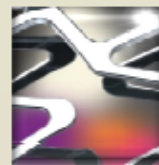




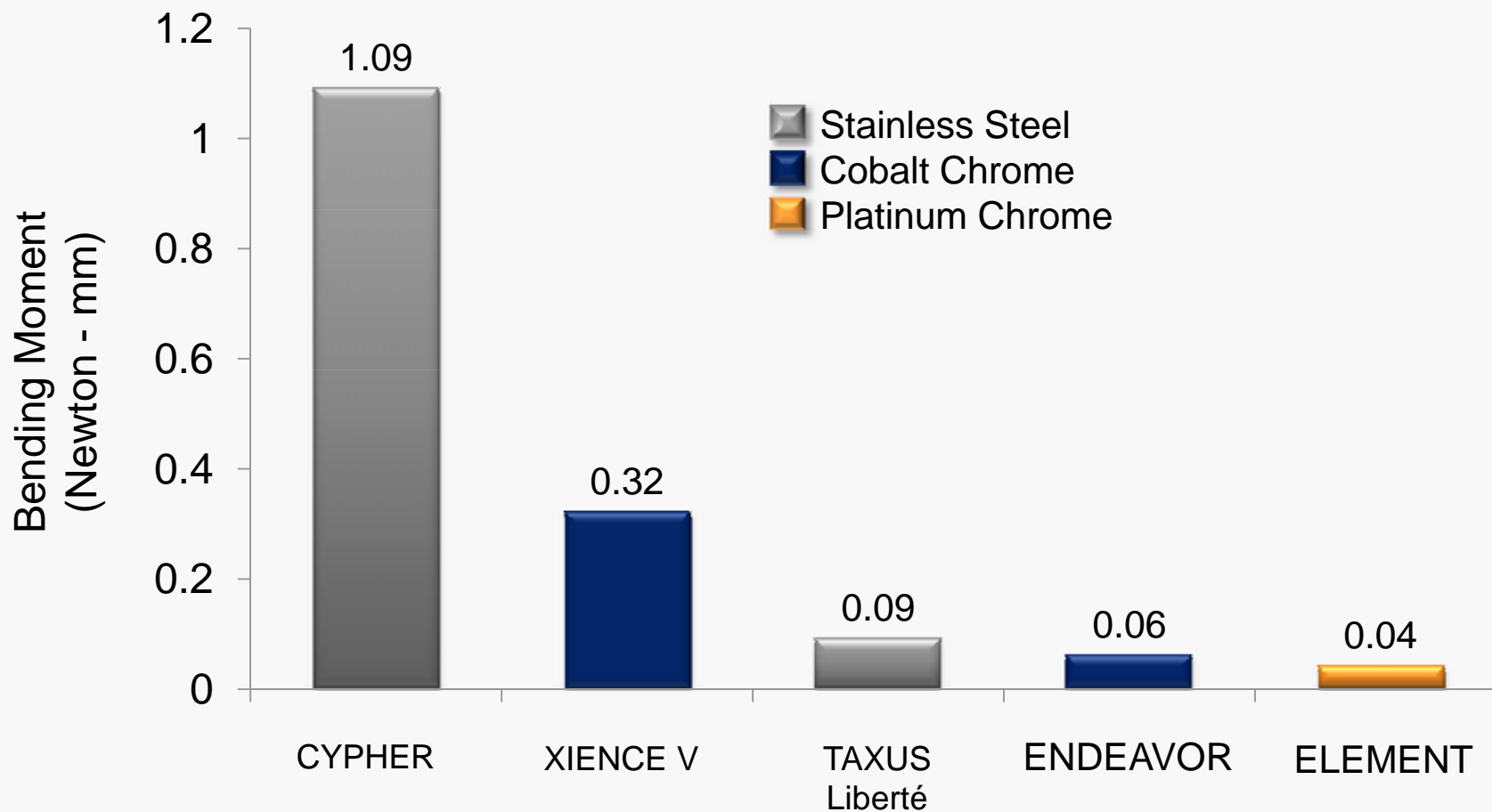
Stent Strut Thickness



Thinner struts are associated with more rapid healing

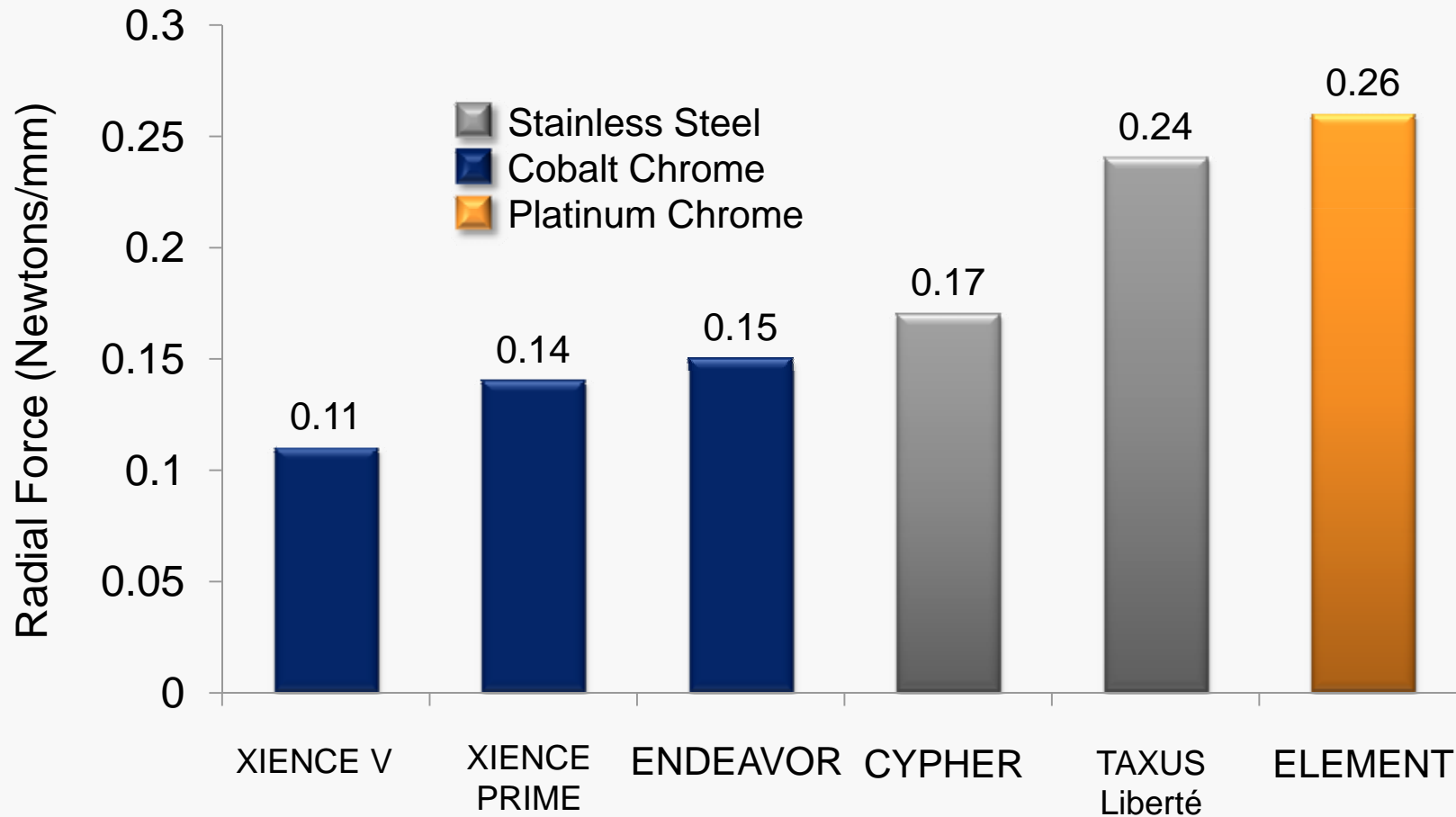


Stent Conformability





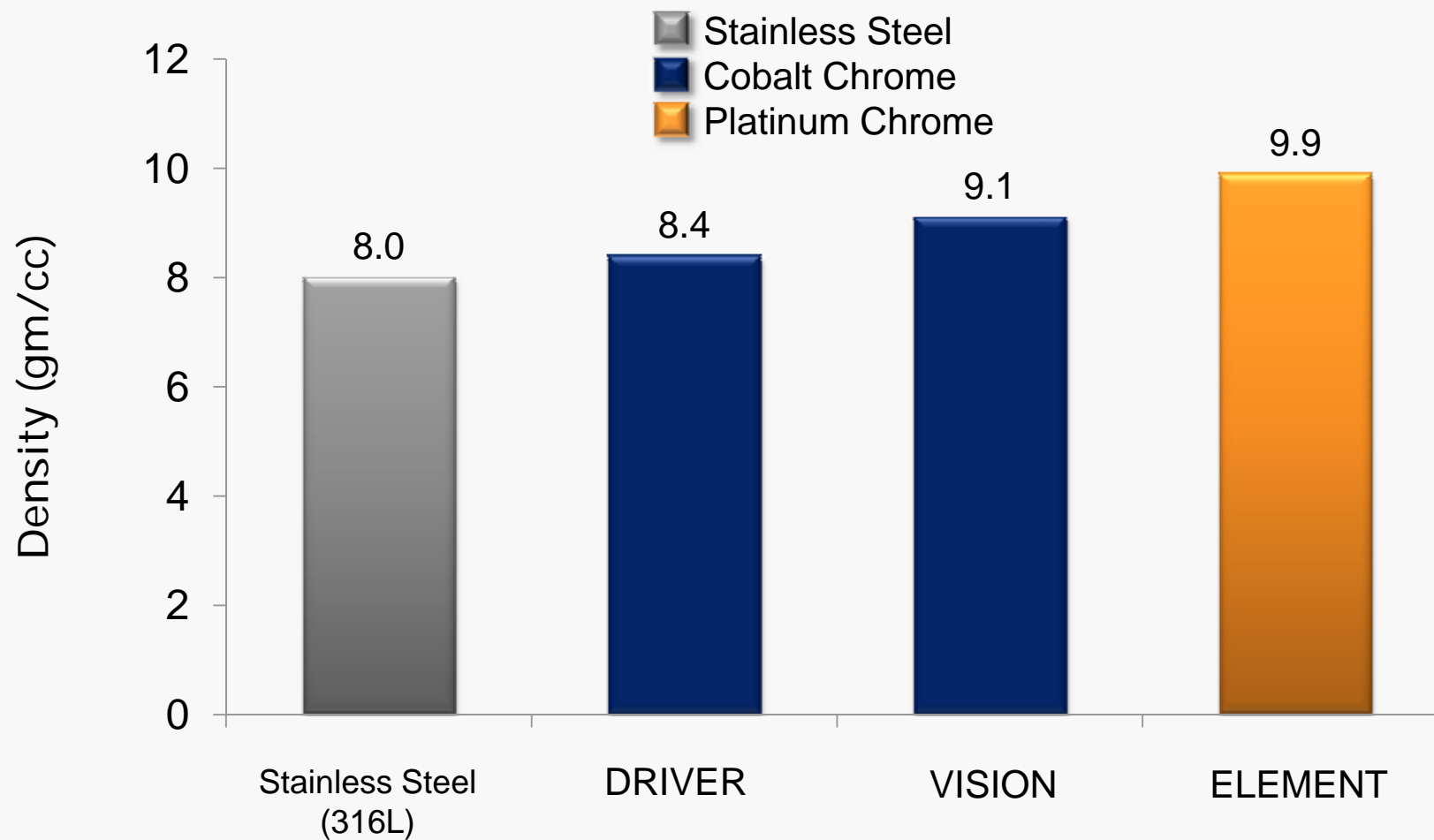
Stent Radial Strength



Platinum Chrome has 70% more Radial Strength than Cobalt Chrome

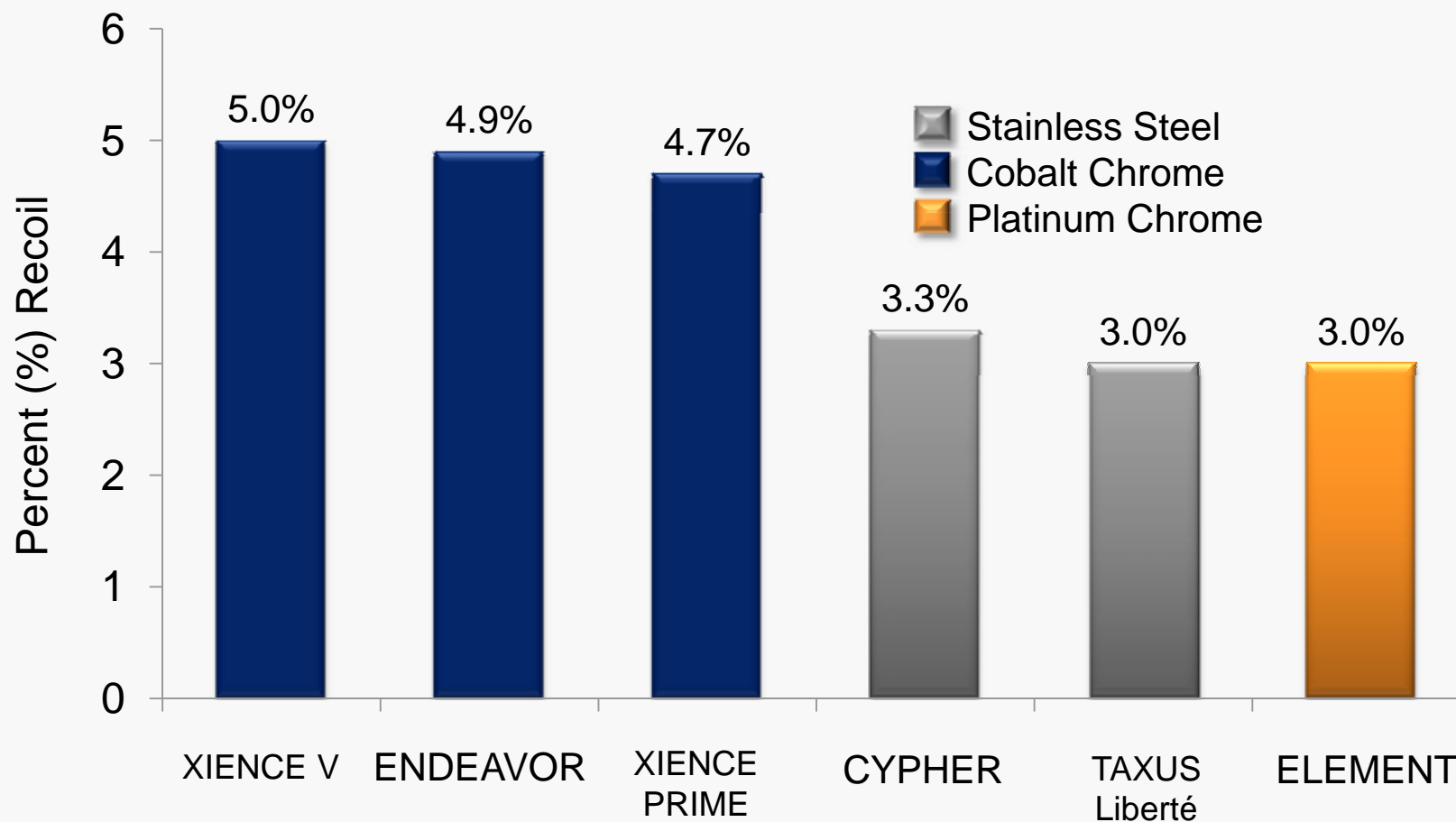


Comparative Density




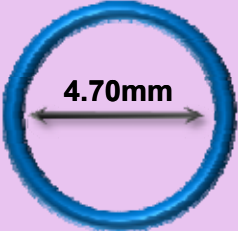
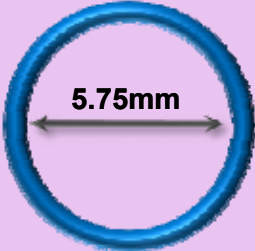
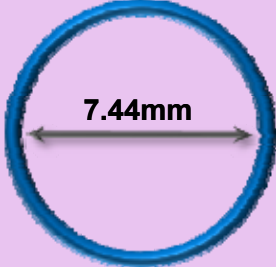


Stent Recoil

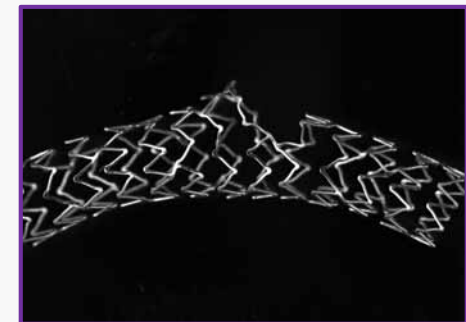


Platinum Chrome has 36% less Recoil than Cobalt Chrome

ELEMENT Stent: Side-Branch Access

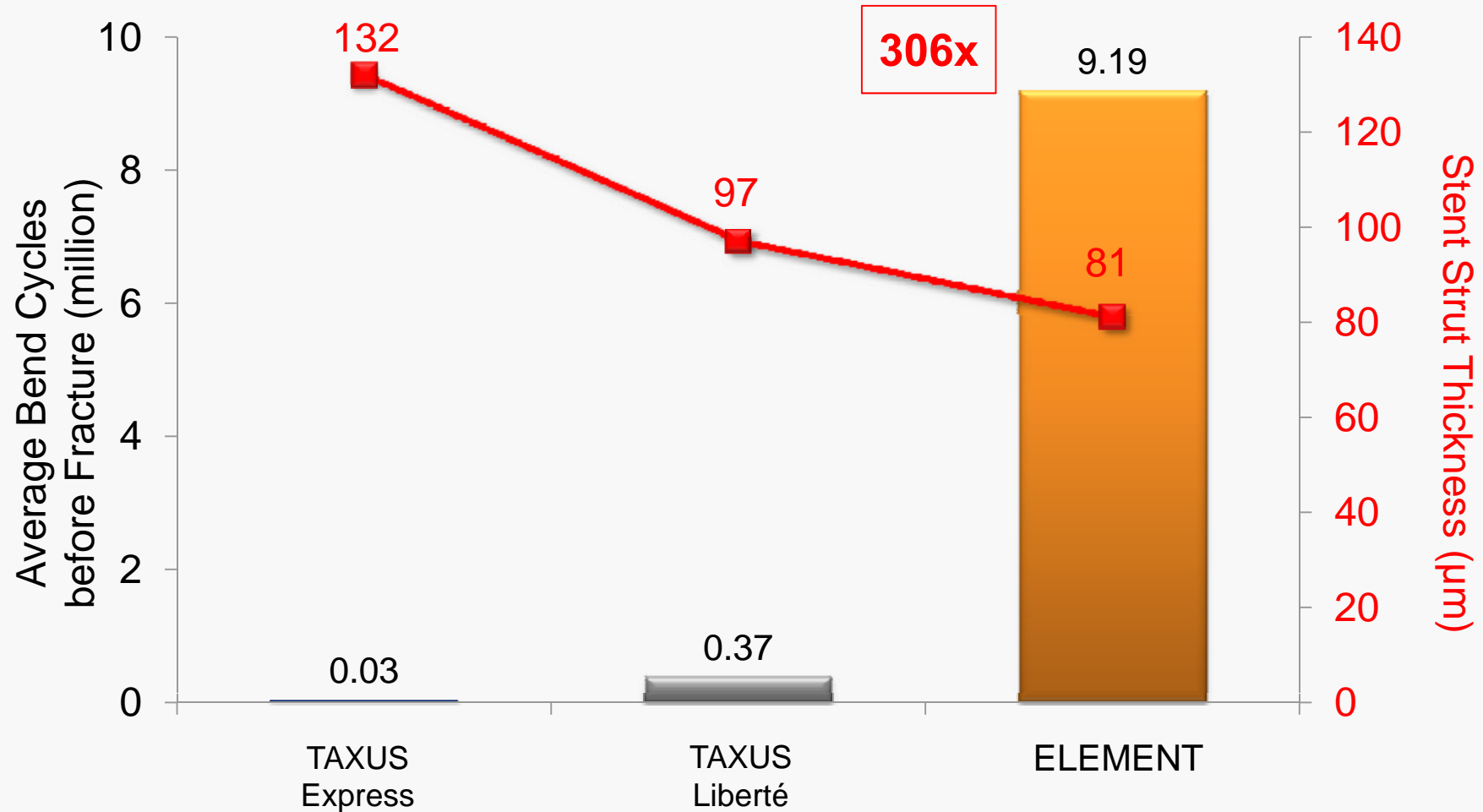
2.25mm	2.50-2.75mm	3.00-3.50mm	4.00-5.00mm
 <p>4.18mm</p>	 <p>4.70mm</p>	 <p>5.75mm</p>	 <p>7.44mm</p>

Maximum Expanded Cell Diameter (mm)





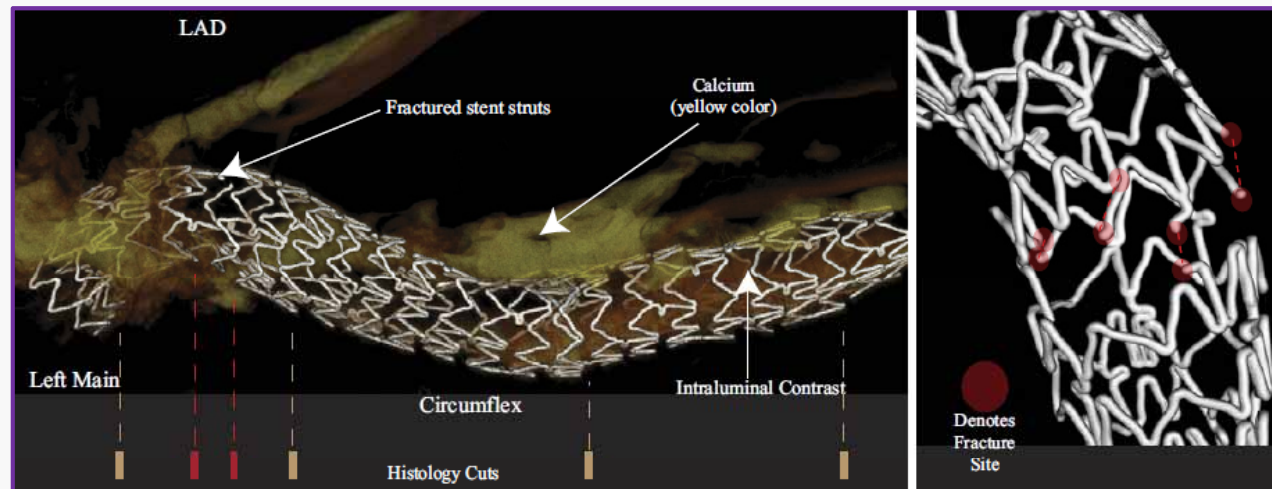
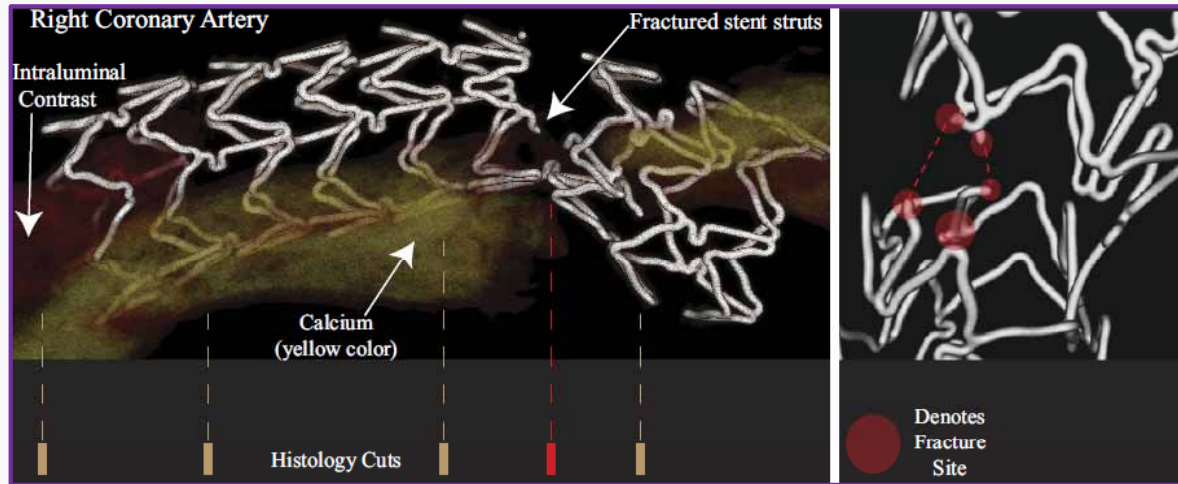
Fracture Resistance (Bend Fatigue)



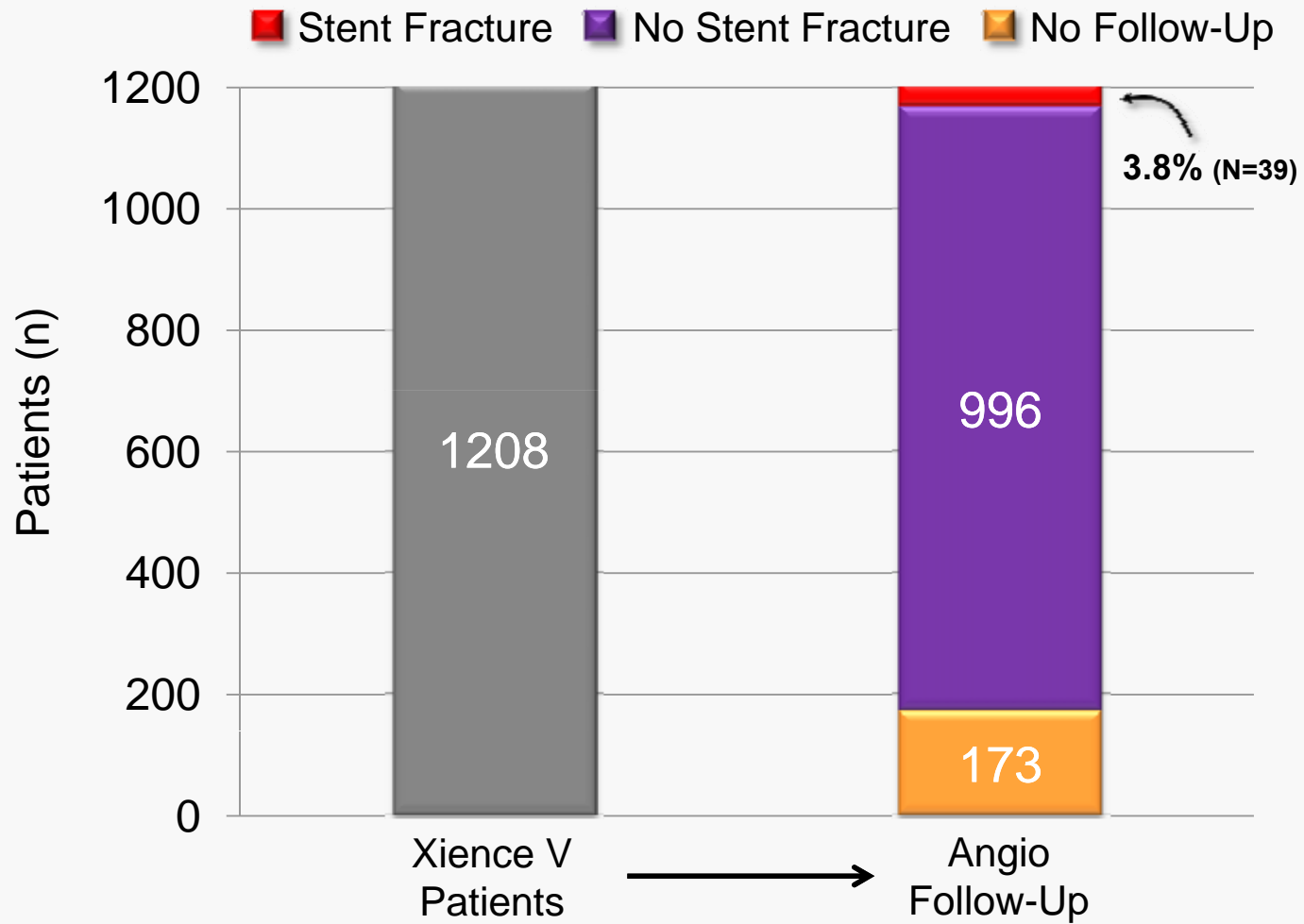
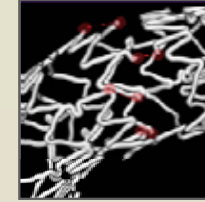
TAXUS Element (ION) has Thinner Struts *and* Higher Fracture Resistance

Late Complications

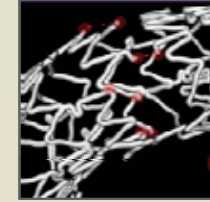
Xience V Stent Fractures with Restenosis



Incidence of XIENCE V Stent Fracture

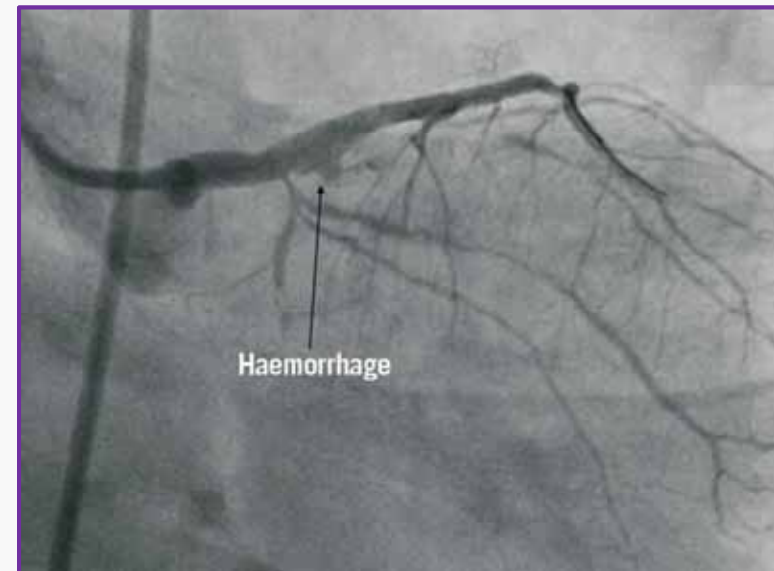
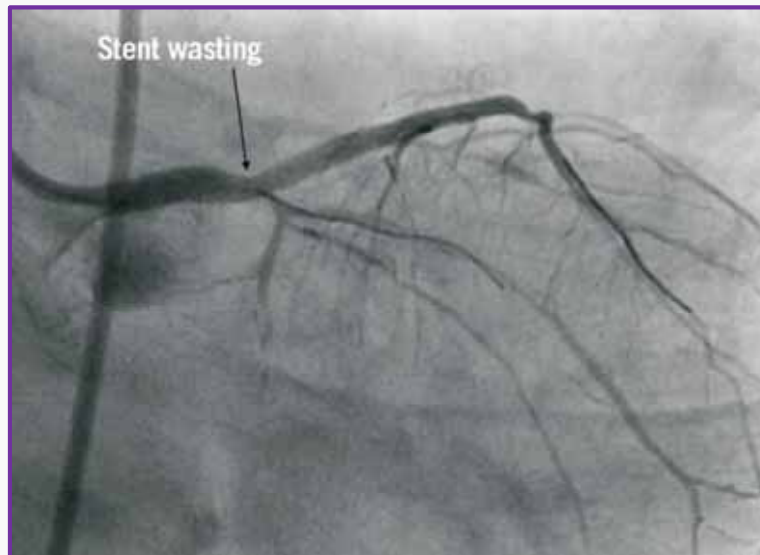


Clinical Impact of XIENCE V Stent Fracture



	Stent Fracture N=39	No Stent Fracture N=996	P Value
MACE	59.8%	6.6%	<0.001
Cardiac Death	1 (2.6%)	3 (0.3%)	0.14
AMI	2 (5.1%)	4 (0.4%)	0.02
TLR	23 (58.9%)	64 (6.6%)	<0.001
Stent Thrombosis ARC Definite/Probable	2 (5.1%)	4 (0.4%)	0.02

Acute Stent Fracture & Coronary Rupture

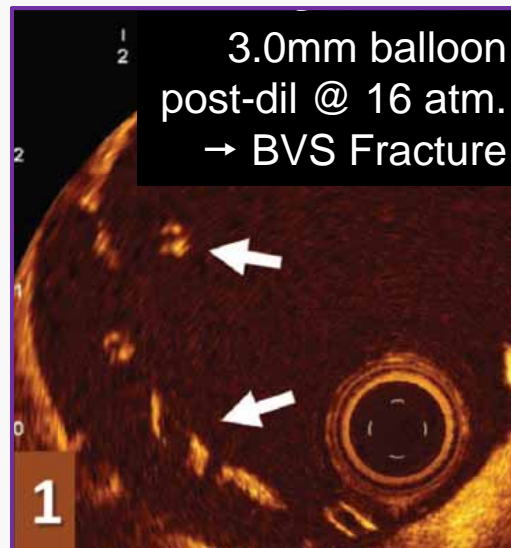
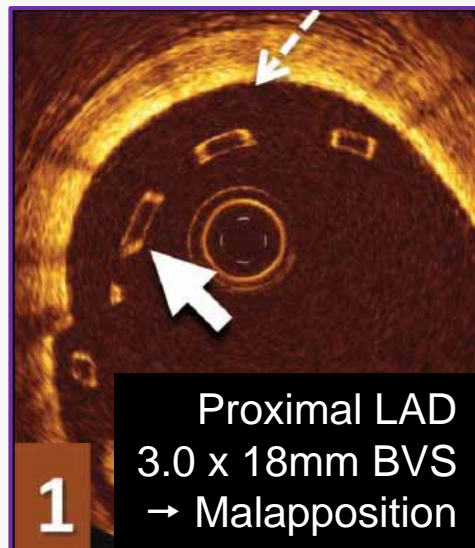


Overlapping XIENCE Prime Stents (2.5 x 38mm + 3.5 x 18mm)
Post-Dilated 4.0 x 15mm NC Balloon @ 22 atms
Stent Fracture confirmed by IVUS

BVS Malapposition & Strut Fracture

Bioresorbable Polymeric Vascular Scaffolds A Cautionary Tale

John A. Ormiston, MBChB; Frederic De Vroey, MD;
Patrick W. Serruys, MD; Mark W.I. Webster, MBChB



Stent Deformation: Initial Observations

CLINICAL RESEARCH

Major stent design changes in Endeavor Pro: a causative factor for late stent thrombosis?

Mark Pimey¹*, MD, Daniel Friedman¹, Joseph Matthews¹, David Taylor¹, MB

1. Eastern Heart Clinic, Sydney, South West

KEYWORDS

- stent designs
- angioplasty
- safety
- coronary thrombosis

SPECIAL REPORT

Longitudinal coronary stent deformation: is this a new global stent design problem?

Colin G Harrarty, MD, MRCP, Consultant Cardiologist, Belfast

Introduction

Intercoronary bare metal stent (BMS) significantly over the last three decades... (text continues)

SPECIAL REPORT

Coronary stent longitudinal deformation by compression: is this a new global stent design problem?

Gérald Finet¹, MD, PhD, Gilles Rioufol, MD, PhD

1. Department of Cardiology and Interventional Cardiology, HECU, Lyon, France

Deformation, Longitudinal Shortening

ANTWON D. ROBINSON, MD, THEODORE L. SHAW, MD

From the Division of Cardiology, Cardiovascular Institute, Wayne State University, Detroit, Michigan

Case Presentation

A 65-year-old male with a history of hypertension, hyperlipidemia, diabetes mellitus, cerebral vascular accident complicated by residual left-sided weakness, and status postcardiac artery endarterectomy presented to the cardiac catheterization lab with significant angina and positive stress test. Initial angiography revealed an infarction of 65% and the left main, left anterior descending, and left circumflex arteries all with only mild disease. The right coronary artery (RCA) was noted to be a larger caliber, dominant, tortuous, moderately calcified vessel with areas of moderate to severe stenosis (proximal 60%, proximal to mid long 80%, and distal 30-40% stenosis). At this time, we decided to instrument on the proximal to mid RCA. A hockey stick - 1 guide catheter was advanced over a wire under fluoroscopy into the ascending aorta and used to engage the RCA (Fig. 1). Subsequently, we advanced a Komet guidewire into the distal RCA. Additionally, a Force medium support wire was also used as a buddy wire into the distal RCA for additional support and to improve the characteristics of the vessel. We were able to advance a 2.5 x 15 mm Apex compliant balloon into the lesion, which was used for pre-dilatation. Due to a suboptimal balloon result and additional disease (or pseudo lesion) noted, it was decided to stent the vessel. A 2.75 x 18 mm Tera - 100 drug eluting stent was then attempted to be advanced into the lesion in the

EDITORIAL

Stent design back on longitudinal stent deformation

Peter Mortier¹*, PhD, Mortier P, PhD

1. Flippo Inba, Gent, Belgium, 2. B...

Current drug-eluting stents lead to outcomes, with small differences between them. This indicates a dominant impact of the stent design on the long-term outcome. Of course, here, like the bioabsorbable stents, which materials requires innovative stent design, stents designed to fit the coronary artery.

The paper of Hainy and Wokhlatov¹ standard metallic stents back in the sport of stent design. The stent design is a previously delivered stent. It was motivated by postulating the stent design as an additional stent if needed. The stent design as a "new" concept that more challenging lesions are best evolutions of the stent design.

There have indeed been a few years ago. The stent thickness of the stent 100 microns and the flexibility and it has been increased, often by reducing the stent length between the adjacent struts. It should be emphasized, however, that it is not the stent thickness that is the most challenging factor in stent design.

Abstract

Keywords

- percutaneous coronary intervention
- coronary stents
- prolonged stent deformation

Method

representative of the case stent design.

Conclusion

is several decades.

SPECIAL REPORT

Longitudinal stent deformation: insights on mechanisms, treatments and outcomes from the Food and Drug Administration Manufacturer and User Facility Device Experience database

John A. Ormiston, MBCR, Auckland, New Zealand

Objective Standardized methods to measure the longitudinal strength of coronary stents and deployment techniques, are needed to understand better the appearance of longitudinal stent deformation (LSD) in clinical practice.

Background The hoops of coronary stents are made of metal, which provides the balance between stent strength and flexibility. Stents are made of metal, which provides the balance between stent strength and flexibility. Stents are made of metal, which provides the balance between stent strength and flexibility.

Methods The force required to compress a stent in a phantom damaged by a balloon was measured. The force required to compress a stent in a phantom damaged by a balloon was measured. The force required to compress a stent in a phantom damaged by a balloon was measured.

Results Stents with 2 connectors (Santa Rosa, California) were elongated by 1 mm than design. Stents with 2 connectors (Santa Rosa, California) were elongated by 1 mm than design.

Conclusions Stents with 2 connectors (Santa Rosa, California) were elongated by 1 mm than design.

Keywords

- longitudinal stent deformation
- mechanisms
- treatments
- outcomes

CLINICAL RESEARCH

Longitudinal stent deformation: insights on mechanisms, treatments and outcomes from the Food and Drug Administration Manufacturer and User Facility Device Experience database

Manish A. Mehta¹*, MA, DPhil, FRAC, FRCR, Paul D. Williams², MA, BSc, DRCR, MD

1. Manchester Heart Centre, Manchester Royal Infirmary, Manchester, United Kingdom; 2. Aberdeen Academic Health Science Centre, University of Aberdeen, Aberdeen, United Kingdom

Abstract

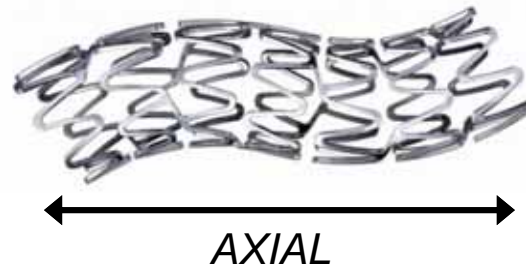
Keywords

- longitudinal stent deformation
- mechanisms
- treatments
- outcomes

Definitions

What is Stent Deformation?

- Stent deformation or axial length change (ALC) refers to the axial shortening or lengthening of a coronary stent caused by an ancillary device such as a post-dilatation balloon catheter, guide catheter or IVUS catheter

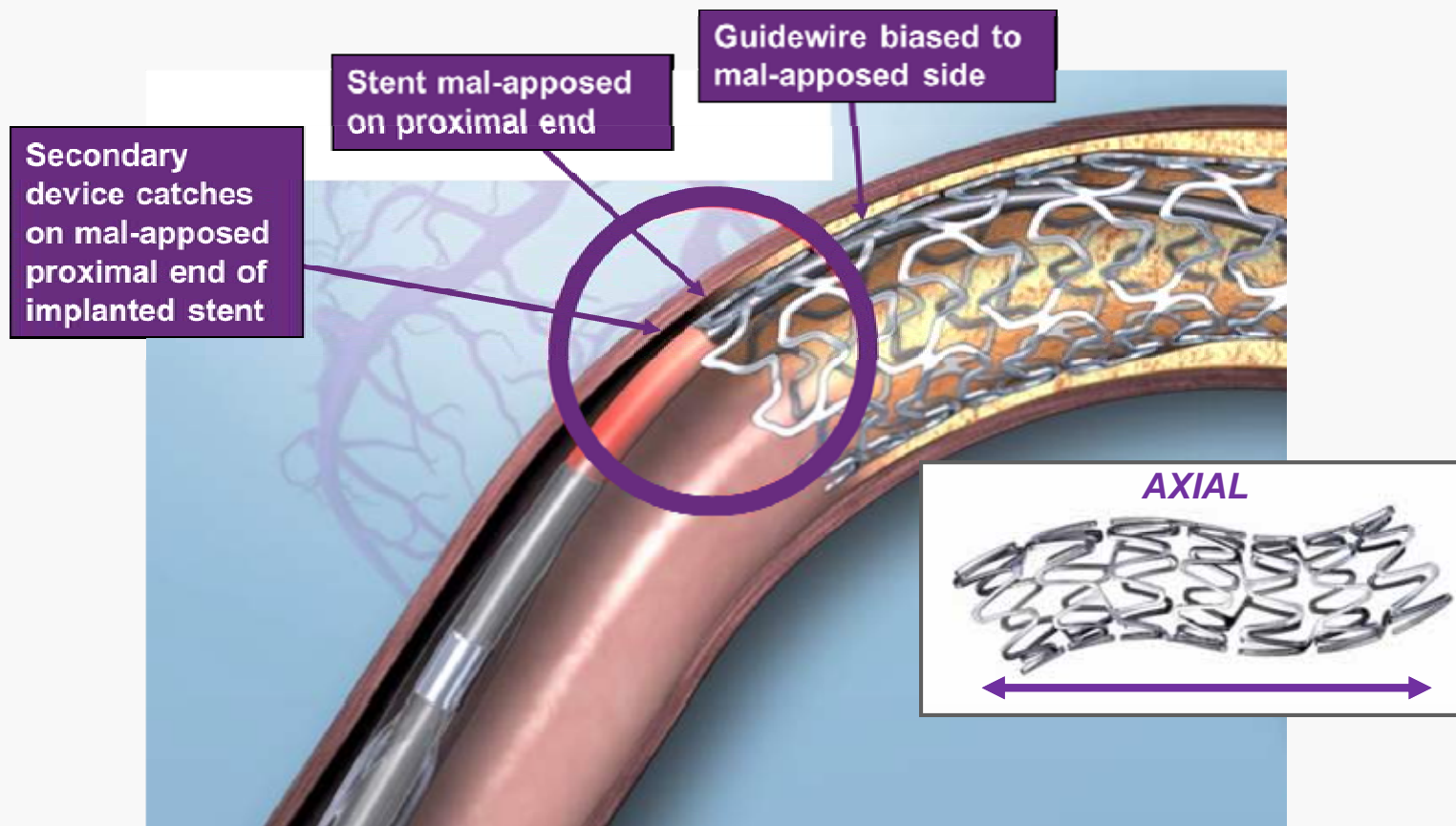


Is stent deformation the same as foreshortening?

- No. Foreshortening is the inherent change in stent length that occurs during initial balloon inflation

What is Longitudinal Stent Deformation?

Longitudinal stent deformation is the axial shortening or lengthening of a stent after implantation, resulting from interaction with an ancillary device such as a guide catheter, post-dilatation balloon, or IVUS catheter



Longitudinal Stent Deformation

Described with Ten Stent Types

Stent Name	Material	Strut Thickness	Connectors
BioMATRIX	Stainless Steel	112µm	2 or 3
Endeavor	Cobalt chromium (MP35N)	91µm	2 or 3
GR2	Stainless Steel	127µm	Coil
Micro Driver	Cobalt chromium (MP35N)	91µm	2 or 3
PROMUS Element	Platinum chromium	81µm (86µm for ≥4mm diam)	2
Resolute Integrity	Cobalt chromium (MP35N)	91µm	1, 2 or 3
TAXUS Element	Platinum chromium	81µm (86µm for ≥4mm diam)	2
TAXUS Liberté	316L Stainless Steel	97µm	3
Xience V	Cobalt chromium (L605)	81µm	3
Wiktor	Stainless Steel	127µm	Coil

First Systematic Analysis of Stent Deformation

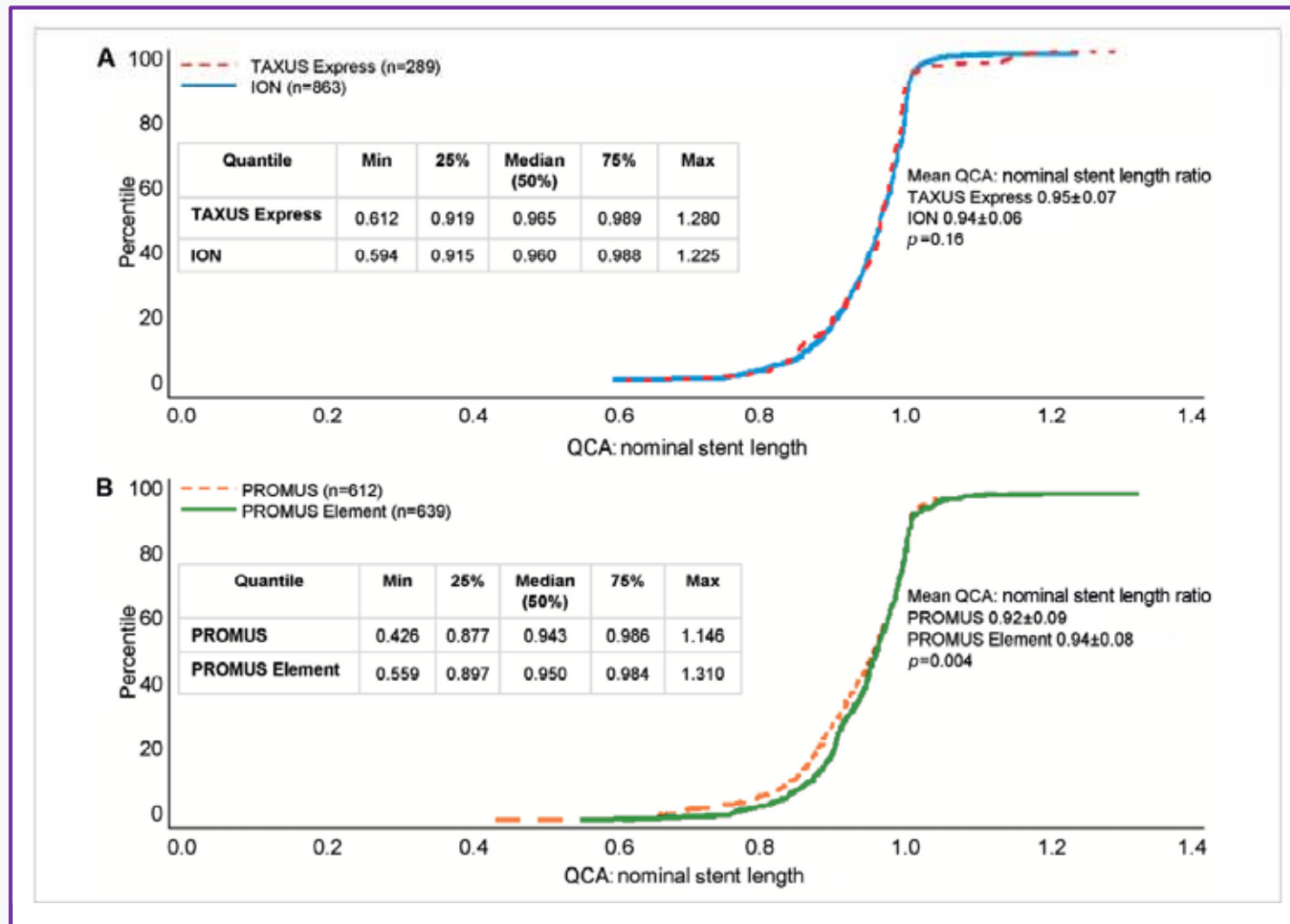


CLINICAL RESEARCH

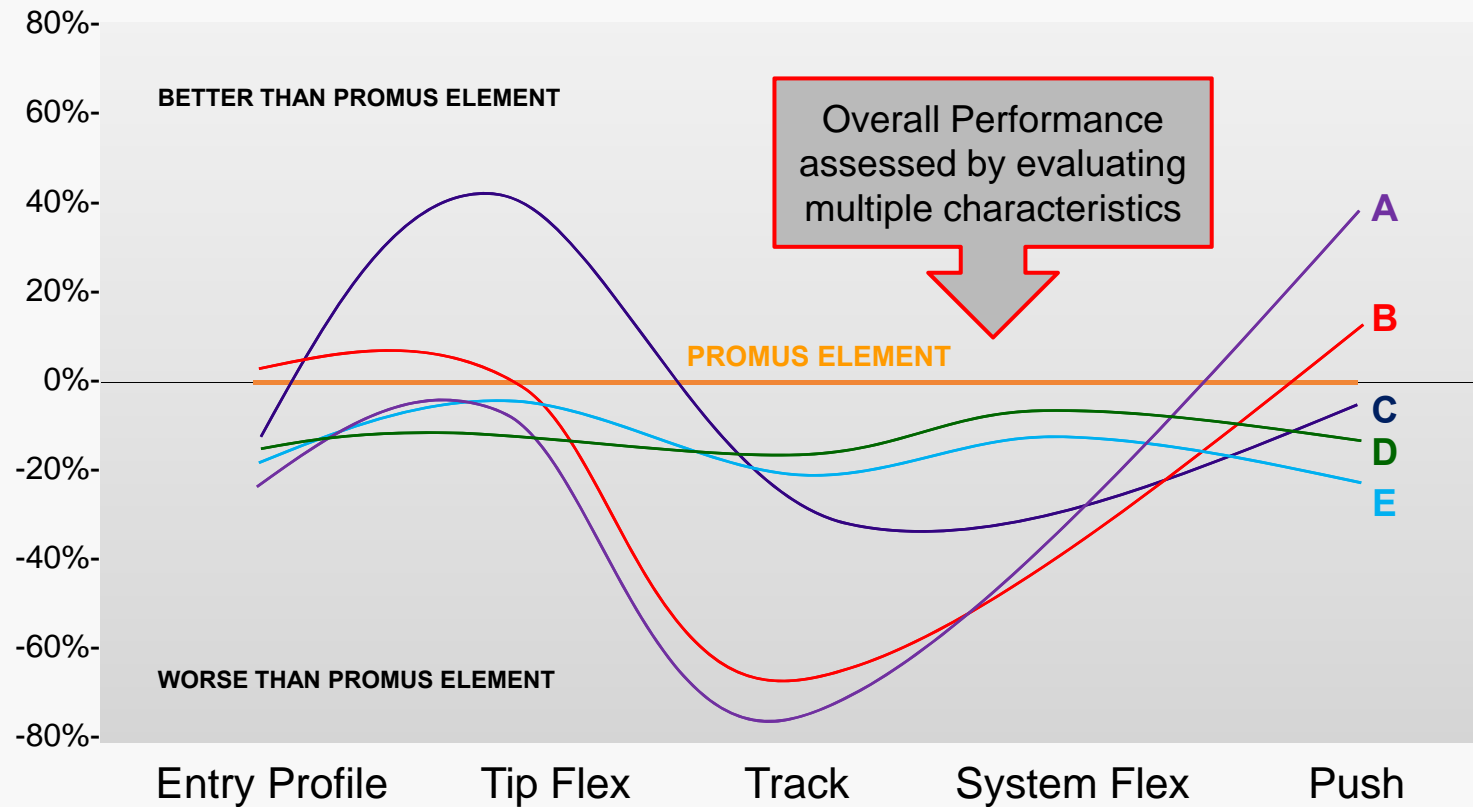
Longitudinal stent deformation: quantitative coronary angiographic analysis from the PERSEUS and PLATINUM randomised controlled clinical trials

Dean J. Kereiakes^{1*}, MD, FACC; Jeffrey J. Popma², MD, FACC; Louis A. Cannon³, MD, FACC; David E. Kandzari⁴, MD, FACC; Carey D. Kimmelstiel⁵, MD, FACC; Ian T. Meredith⁶, MBBS, PhD, FACC; Paul S. Teirstein⁷, MD, FACC; Stefan Verheye⁸, MD, PhD, FACC; Dominic J. Allocco⁹, MD, FACC; Keith D. Dawkins⁹, MD, FACC; Gregg W. Stone¹⁰, MD, FACC

Distribution of ratios of QCA Stent Length to Nominal Stent Length in the PERSEUS & PLATINUM trials (n=2,403: B2/C 63.3%)

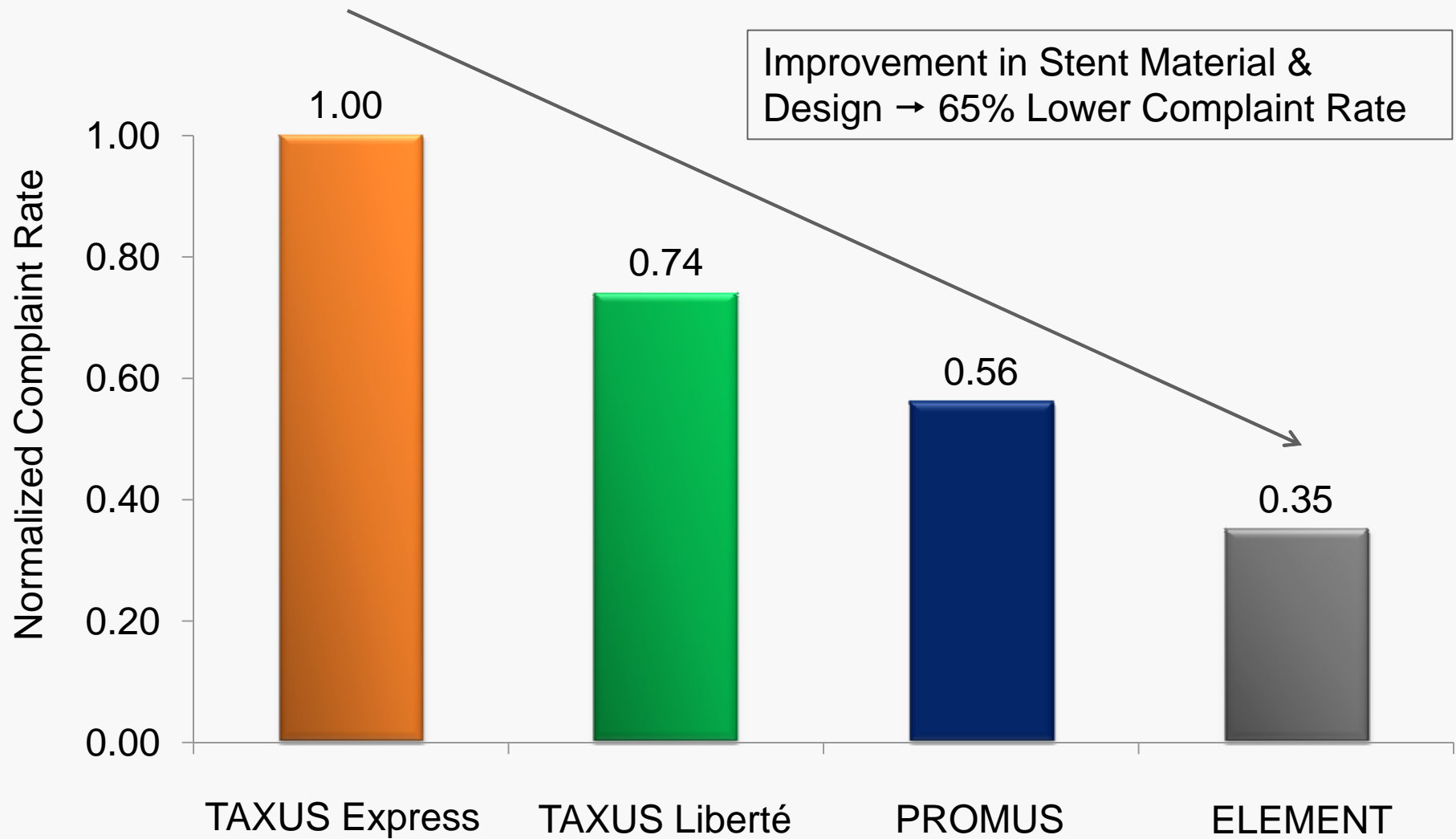


DES: Mechanical Properties Compared



Comparator Stents with Differing Characteristics (A-E)

Platform Innovation Leads to Lower Complaint Rates



ELEMENT Stent Platform: Clinical Trials

Trial	Stent	Drug	Follow-up	Patients (n)
PLATINUM WH	PROMUS Element	Everolimus	2 yrs	735
PLATINUM SV	PROMUS Element	Everolimus	1 yr	94
PLATINUM LL	PROMUS Element	Everolimus	1 yr	102
PLATINUM PK	PROMUS Element	Everolimus	6 mths	22
PLATINUM QCA	PROMUS Element	Everolimus	1 yr	100
PLATINUM China	PROMUS Element	Everolimus	9 mths	500
PE-PROVE	PROMUS Element	Everolimus	1 yr	1010
PERSEUS WH	TAXUS Element	Paclitaxel	2 yrs	933
PERSEUS SV	TAXUS Element	Paclitaxel	2 yrs	223
TE-PROVE	TAXUS Element	Paclitaxel	1 yr	1013
ION PAS	TAXUS Element	Paclitaxel	On going	1002/1115
EVOLVE FHU	SYNERGY	Everolimus	6 mths	291
OMEGA	OMEGA	None (BMS)	On going	135/328

n=6,261
(04.23.2012)

ELEMENT Stent Platform

EXPEDITED PUBLICATION

Clinical and Angiographic Outcomes After Treatment of De Novo Coronary Stenoses With a Novel Platinum Chromium Thin-Strut Stent

Primary Results of the PERSEUS (Prospective Evaluation in a Randomized Trial of the Safety and Efficacy of the Use of the TAXUS Element Everolimus-Eluting Coronary Stent System)

Dean J. Kereiakes, MD,* Louis A. Cannon, MD,† Robert L. Feldman, MD,‡§ Raymond Magidoff, MD,|| Robert Whitehouse, MBBS,¶ Ina M. Damber, MD,‡# Abram C. Rabinowitz, MD,** Michael W. Ball, MD,†† Barry Bertolozzi, MD,‡‡ Michael C. Foster, MD,||| John C. Wang, MD,††† Paul Underwood, MD,‡‡‡ Ke

Cincinnati, Columbus, and Toledo, Ohio; Princeton, Michigan; Ocala, Florida; Boston and Natick, Massachusetts; Victoria, Australia; Englewood, Colorado; San Antonio, Texas; Indianapolis, Indiana; Taipei, Mississippi; Columbia, South Carolina; and Baltimore, Maryland

Objectives The aim of this study was to evaluate the safety and efficacy of the novel platinum-chromium-thin-strut (T) stent compared with the TAXUS Express PES (Boston Scientific) in treating coronary artery stenoses.

Background The TAXUS Element is a novel thin-strut (81 μm) platinum-chromium alloy PES in its treating coronary artery stenoses.

Methods The PERSEUS (Prospective Evaluation in a Randomized Trial of the Safety and Efficacy of the Use of the TAXUS Element Everolimus-Eluting Coronary Stent System) Workgroup (PER) trial is a prospective, multicenter study of the TAXUS Element (T) stent compared with the TAXUS Express PES (Boston Scientific) in treating coronary artery stenoses. The primary end point was the 12-month rate of target lesion failure, and the secondary end point was the 12-month rate of target lesion revascularization. The study was powered to demonstrate noninferiority of the T stent compared with the Express PES.

Results The intent-to-treat analysis included 1,362 patients (500 TAXUS Element, 862 TAXUS Express PES) who were randomized to the T stent or the Express PES. The primary end point was the 12-month rate of target lesion failure, which was significantly lower in the T stent group (1.5% vs 1.9%, $p = 0.002$). The secondary end point, target lesion revascularization, was also significantly lower in the T stent group (1.5% vs 1.9%, $p = 0.002$). The study was powered to demonstrate noninferiority of the T stent compared with the Express PES.

Conclusions At 1 year, the TAXUS Element is comparable in efficacy to the TAXUS Express PES in treating coronary artery stenoses. The TAXUS Element is a novel design that offers improved safety and efficacy compared with the TAXUS Express PES.

EXPEDITED PUBLICATION

A Prospective, Randomized Evaluation of a Novel Everolimus-Eluting Coronary Stent The PLATINUM (A Prospective, Randomized, Multicenter Trial to Assess an Everolimus-Eluting Coronary Stent System [PROGRESS]) for the Treatment of up to Two De Novo Coronary Artery Lesions

Gregg W. Stone, MD,* Paul S. Teirstein, MD,† Ian T. Meredith, MD,‡§ Christopher L. Dubois, MD,¶|| Robert L. Feldman, MD,‡# Nobuhisa Higashimura, MD,** Dominic J. Alibonico, MD,†† Keith D. Drivikas, MD,‡‡§§ for the PLATINUM Trial Investigators

New York, New York; La Jolla, California; Clayton, Victoria, Australia; and Gent, Belgium; Osaka, Florida; Tokyo, Japan; and Natick, Massachusetts

Objectives We sought to evaluate the clinical outcomes with a novel polymer-coated, everolimus-eluting coronary stent compared with a previous-generation polymer-coated, everolimus-eluting coronary stent.

Background Randomized trials have demonstrated an excellent safety and efficacy profile for the novel polymer-coated, everolimus-eluting coronary stent compared with a previous-generation polymer-coated, everolimus-eluting coronary stent.

Methods A total of 1,530 patients undergoing PCI of 1 or 2 de novo coronary artery stenoses were randomized to the novel polymer-coated, everolimus-eluting coronary stent (PLATINUM) or the previous-generation polymer-coated, everolimus-eluting coronary stent (TAXUS Express PES).

Results The 12-month rate of target lesion failure was significantly lower in the PLATINUM group (1.5% vs 1.9%, $p = 0.002$). The secondary end point, target lesion revascularization, was also significantly lower in the PLATINUM group (1.5% vs 1.9%, $p = 0.002$).

Conclusions In this large-scale, prospective, single-blind, randomized trial, the PLATINUM stent demonstrated superior safety and efficacy compared with the TAXUS Express PES in treating coronary artery stenoses.

EXPEDITED PUBLICATION

Primary Endpoint Results of the EVOLVE Trial A Randomized Evaluation of a Novel Bioabsorbable Polymer-Coated, Everolimus-Eluting Coronary Stent

Ian T. Meredith, MBBS, PhD,* Stefan Verbeke, MD, PhD,† Christopher L. Dubois, MD,‡§ Joseph Deans, MD,¶ Jean Fajadet, MD,|| Didier Carrié, MD,‡# Simon Walsh, MD,‡# Keith G. Oldroyd, MD,** Olivier Varenne, MD,†† Scott E. Jackson, MD,‡‡ Raul Moreno, MD,‡‡‡ Anita A. Joshi, PhD,||| Dorazinic J. Alibonico, MD,||| Keith D. Drivikas, MD,||| Clayton, Melbourne, Australia; Amsterdam, Leuven, and Gent, Belgium; Toulouse and Paris, France; Belfast and Glasgow, United Kingdom; North Shore City, Auckland, New Zealand; Madrid, Spain; and Natick, Massachusetts

Objectives This study sought to compare the safety and efficacy of 2 drug-eluting stents: a novel bioabsorbable polymer-coated, everolimus-eluting coronary stent (EVOLVE) compared with the TAXUS Express PES.

Background Durable polymer coatings on drug-eluting stents have been associated with chronic inflammation and impaired healing. Bioabsorbable polymer-coated drug-delivery systems may reduce the risk of late adverse events, including stent thrombosis, and thus the need for prolonged dual-antiplatelet therapy.

Methods A total of 292 patients with a de novo lesion ≤ 28 mm in length, in a coronary artery of ≥ 2.25 to ≤ 3.5 mm diameter, were enrolled in the EVOLVE study, a prospective, randomized, single-blind, noninferiority trial. Patients were randomly assigned to the EVOLVE or TAXUS Express PES. The primary end point was the 12-month rate of target lesion failure, defined as cardiac death or myocardial infarction related to the target vessel, or target lesion revascularization. The primary angiographic end point was binary restenosis measured by quantitative coronary angiography.

Results The 12-month primary clinical end point of target lesion failure occurred in 0.6%, 0.5%, and 0.4% of patients in the EVOLVE, TAXUS Express PES, and SYNERGY half-dose groups, respectively. The 12-month rate for the SYNERGY half-dose group was 0.4% (95% CI, 0.0% to 0.8%). The 12-month rate for the SYNERGY half-dose group was 0.4% (95% CI, 0.0% to 0.8%). The 12-month rate for the SYNERGY half-dose group was 0.4% (95% CI, 0.0% to 0.8%).

Conclusions The EVOLVE trial confirms the effective delivery of everolimus by a novel bioabsorbable polymer-coated drug-delivery system compared with the TAXUS Express PES in treating coronary artery stenoses.