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

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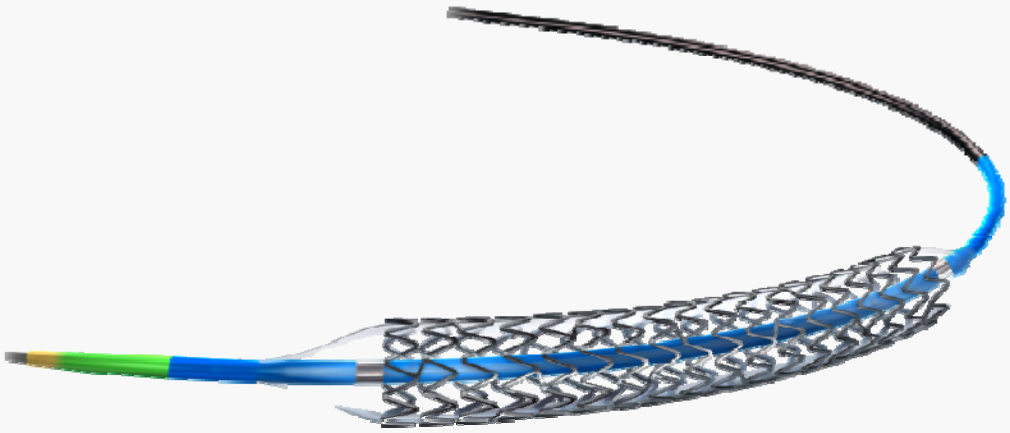
Global Chief Medical Officer
Executive Vice President
Boston Scientific Corporation

ANGIOPLASTY SUMMIT
TCTAP2012
TRANSCATHETER CARDIOVASCULAR THERAPEUTICS ASIA PACIFIC



Conflicts of Interest

Boston Scientific Corporation

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

Efficacy & 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)

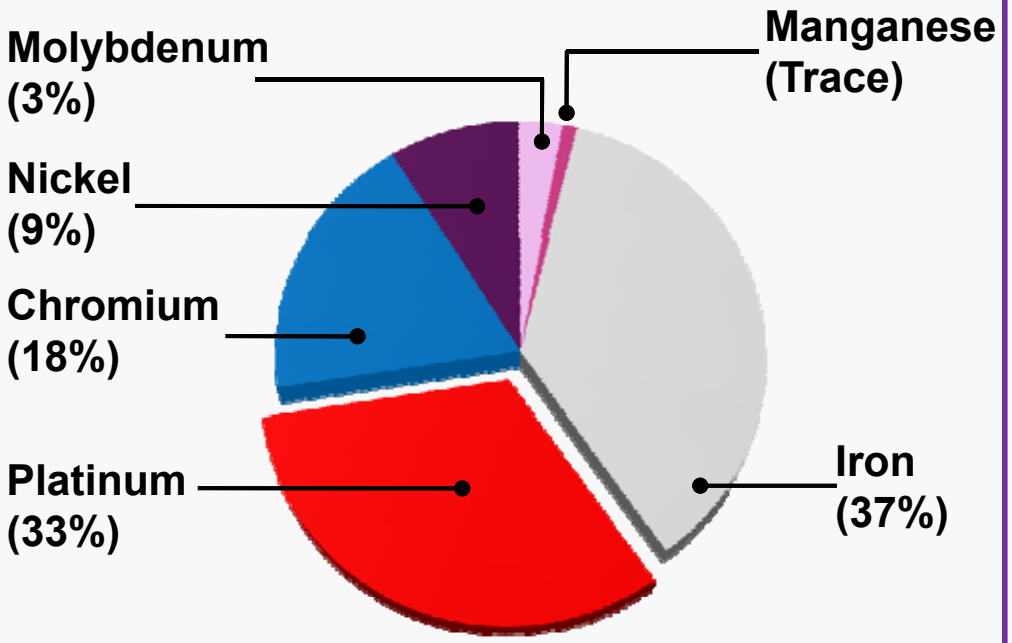
ELEMENT Stent Platform

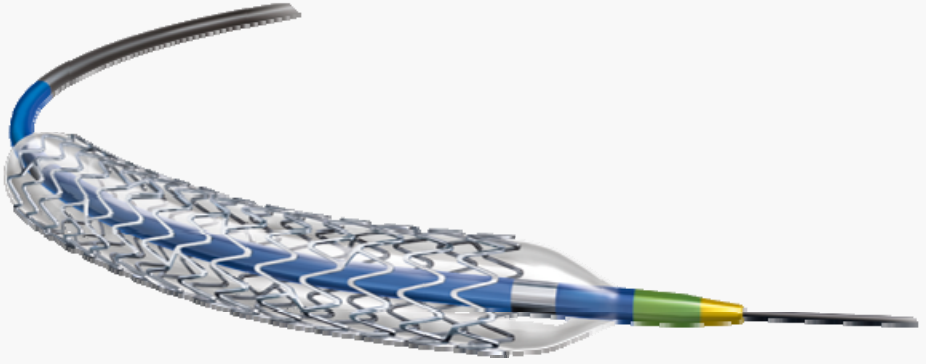
PROMUS Element
(Everolimus)

TAXUS Element
(Paclitaxel)

OMEGA
(Bare Metal)

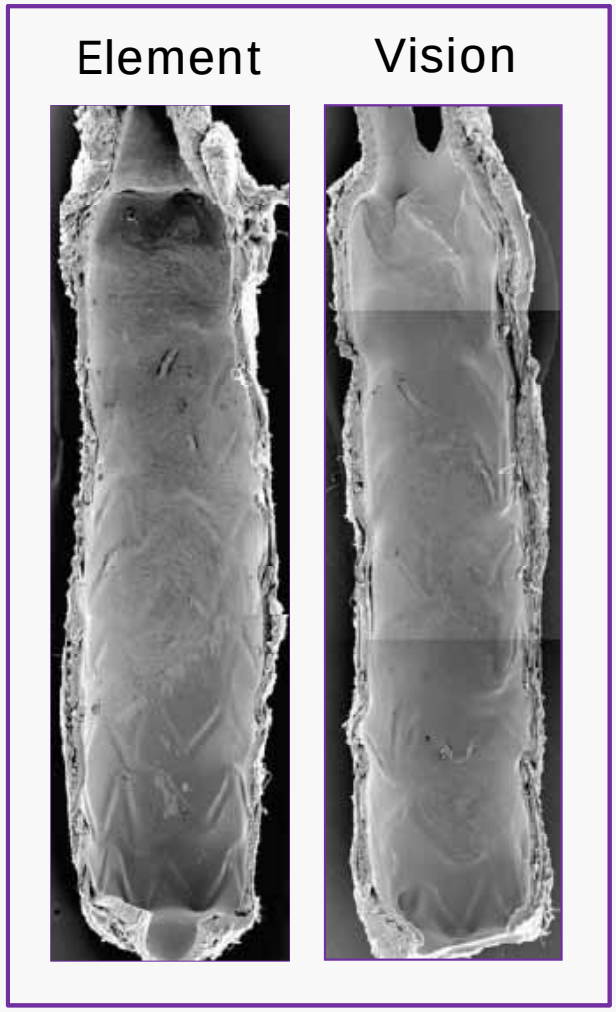
SYNERGY
(Everolimus)



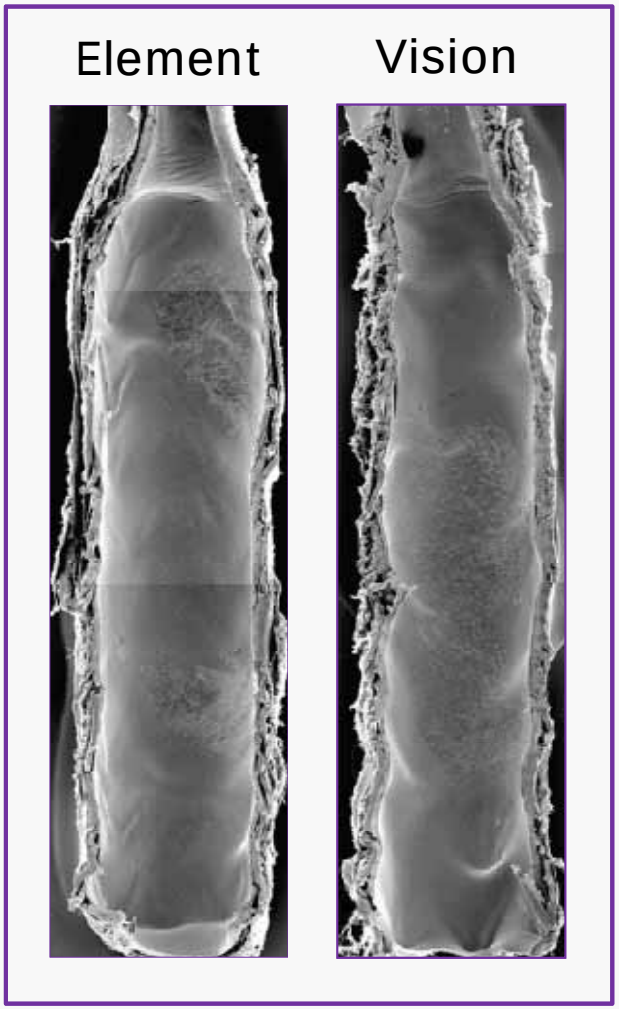


Comparison of ELEMENT and VISION BMS

Rabbit Endothelialization Model



14 Days

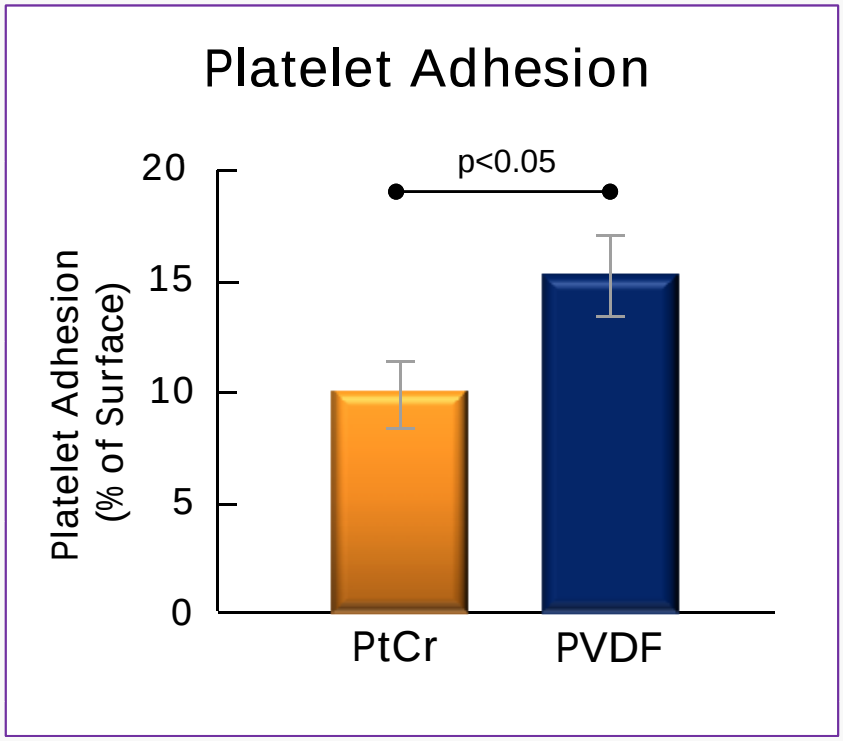


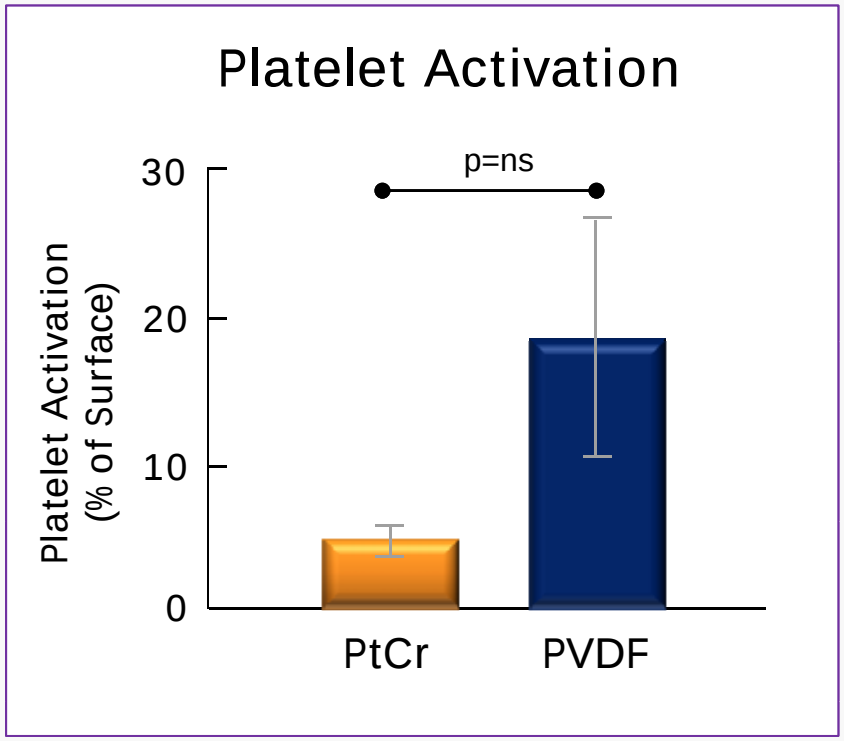
28 Days

Courtesy: Renu Virmani MD

Platelet Responses to Stent Materials

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

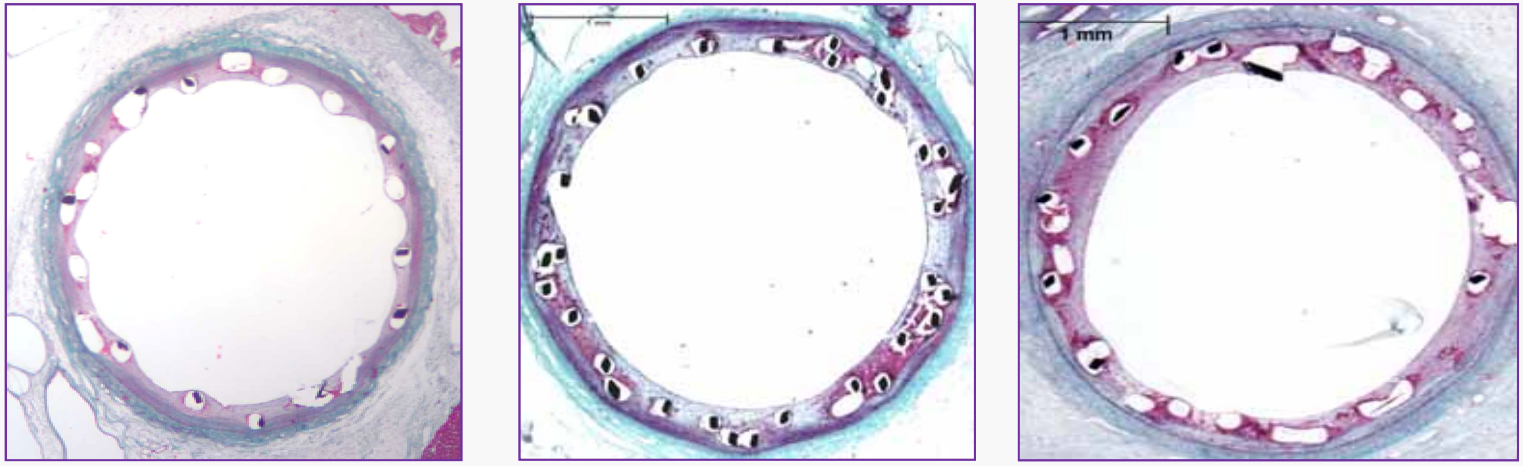




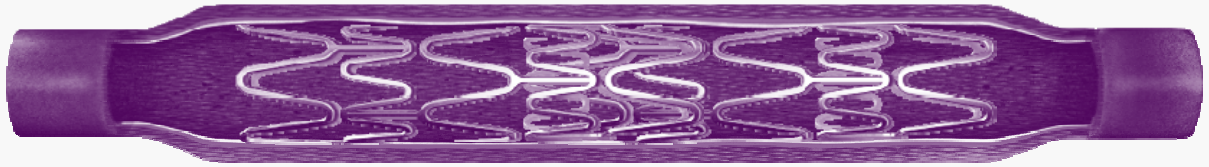
PtCr demonstrated greater thrombo-resistance than PVDF

Garanich JS: J Am Coll Cardiol 2011;58:B126

Consistent Results across Stent Platforms



Porcine Overlap Model (30 days)

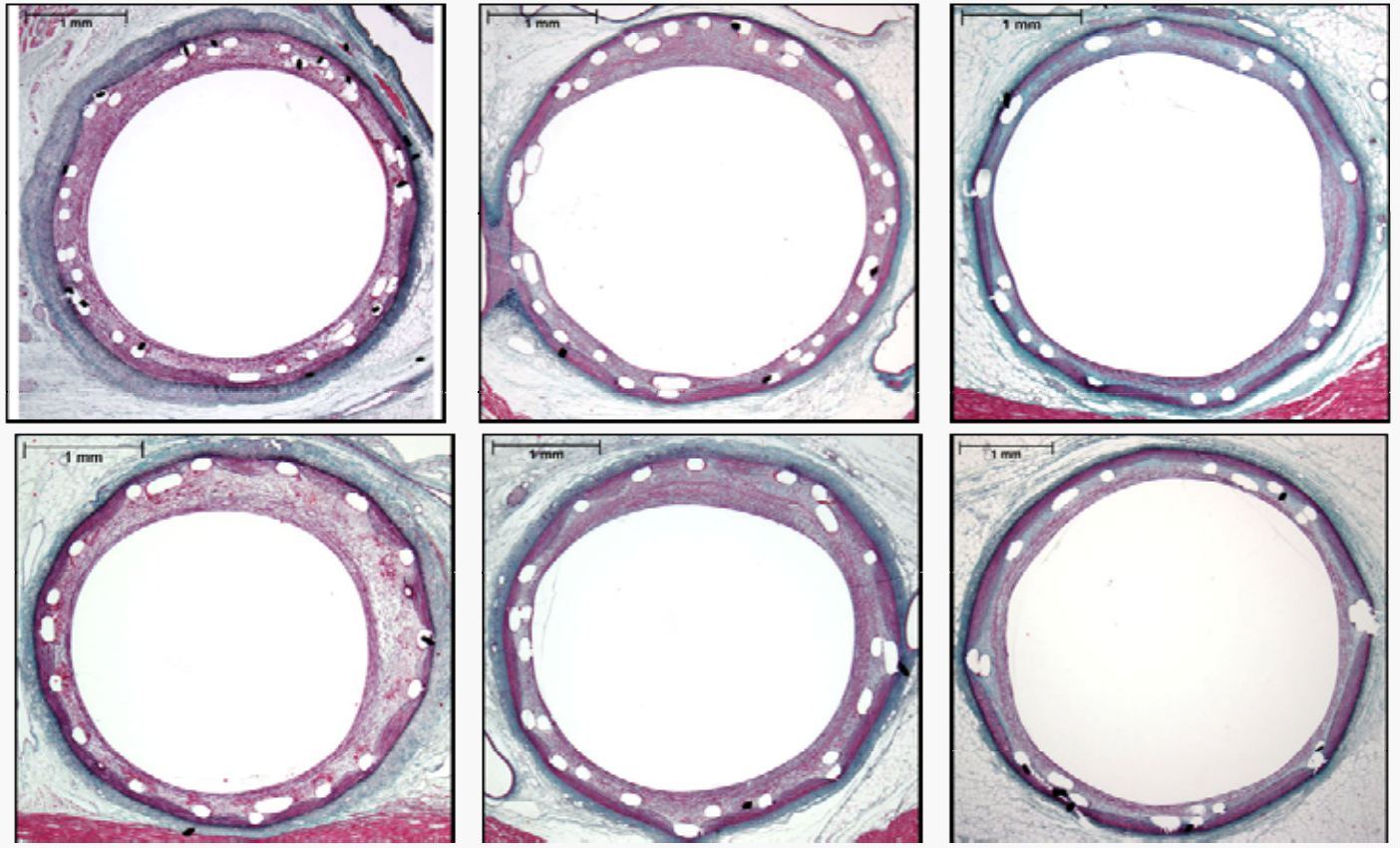


BSC Internal Data

Consistent Results across Stent Platforms

PROMUS (XIENCE)

PROMUS Element

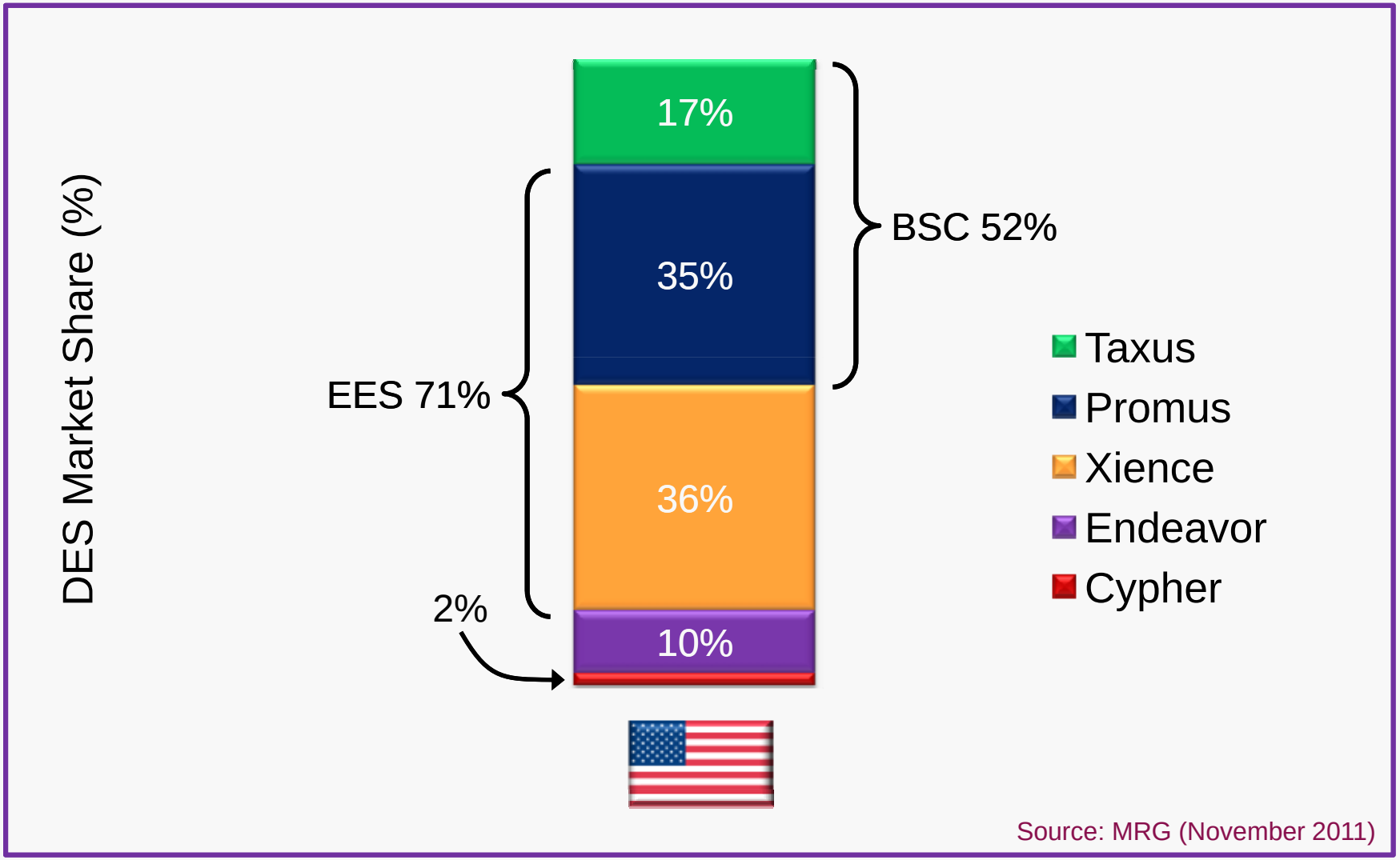


30 Days | 90 Days | 270 Days

Porcine Overlap Model

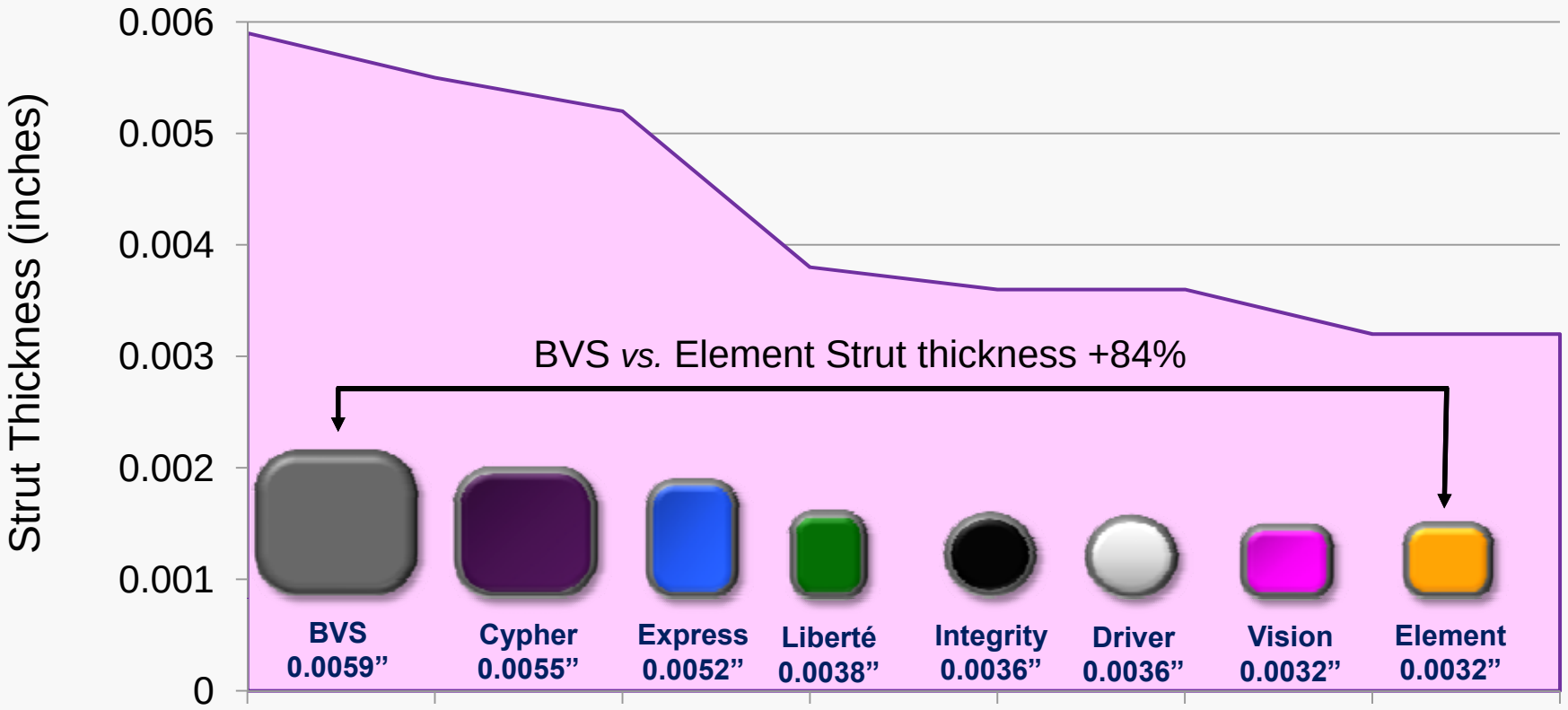
BSC Internal Data

Everolimus is the DES Drug of Choice



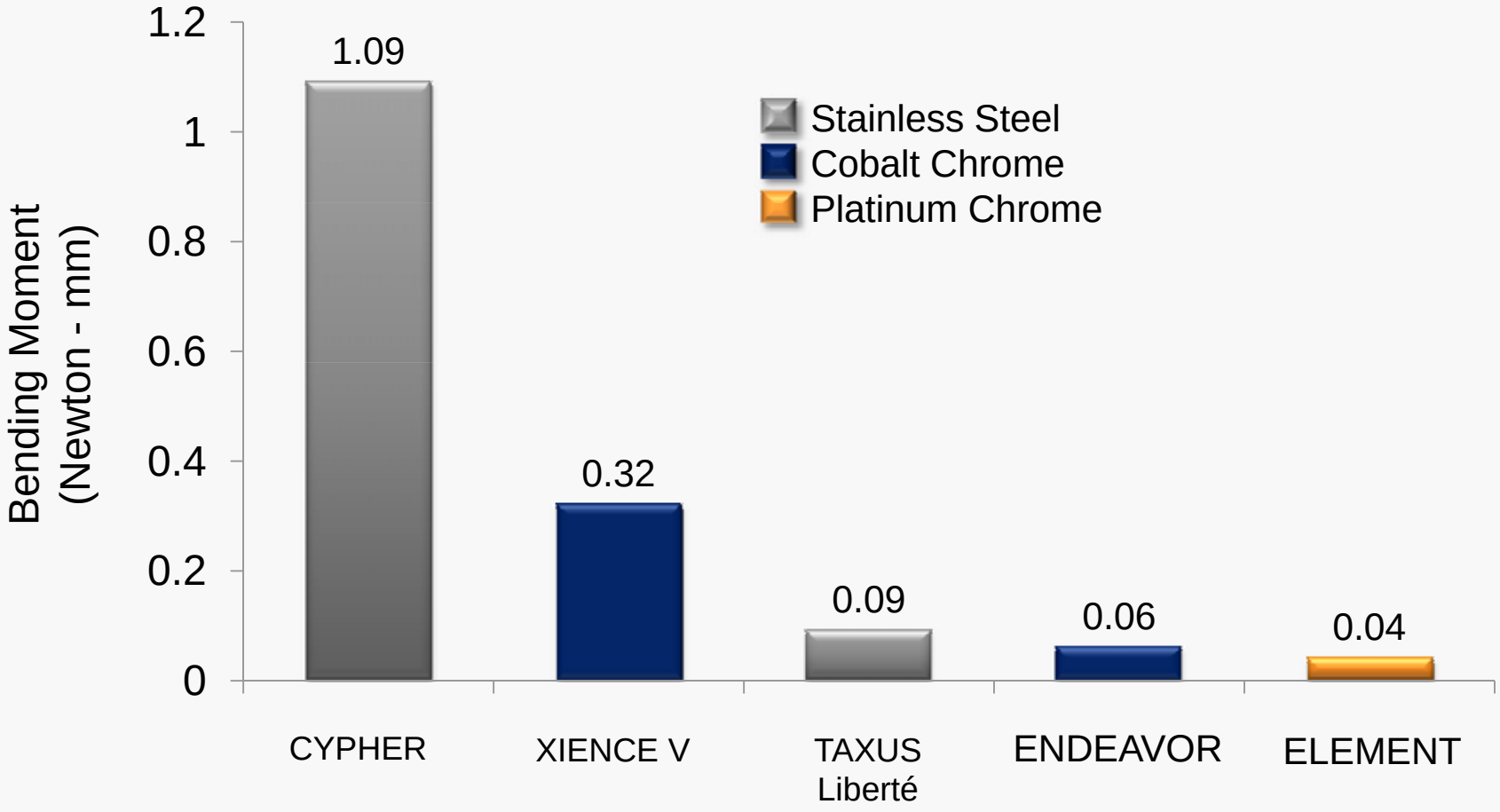
Source: MRG (November 2011)

Stent Strut Thickness



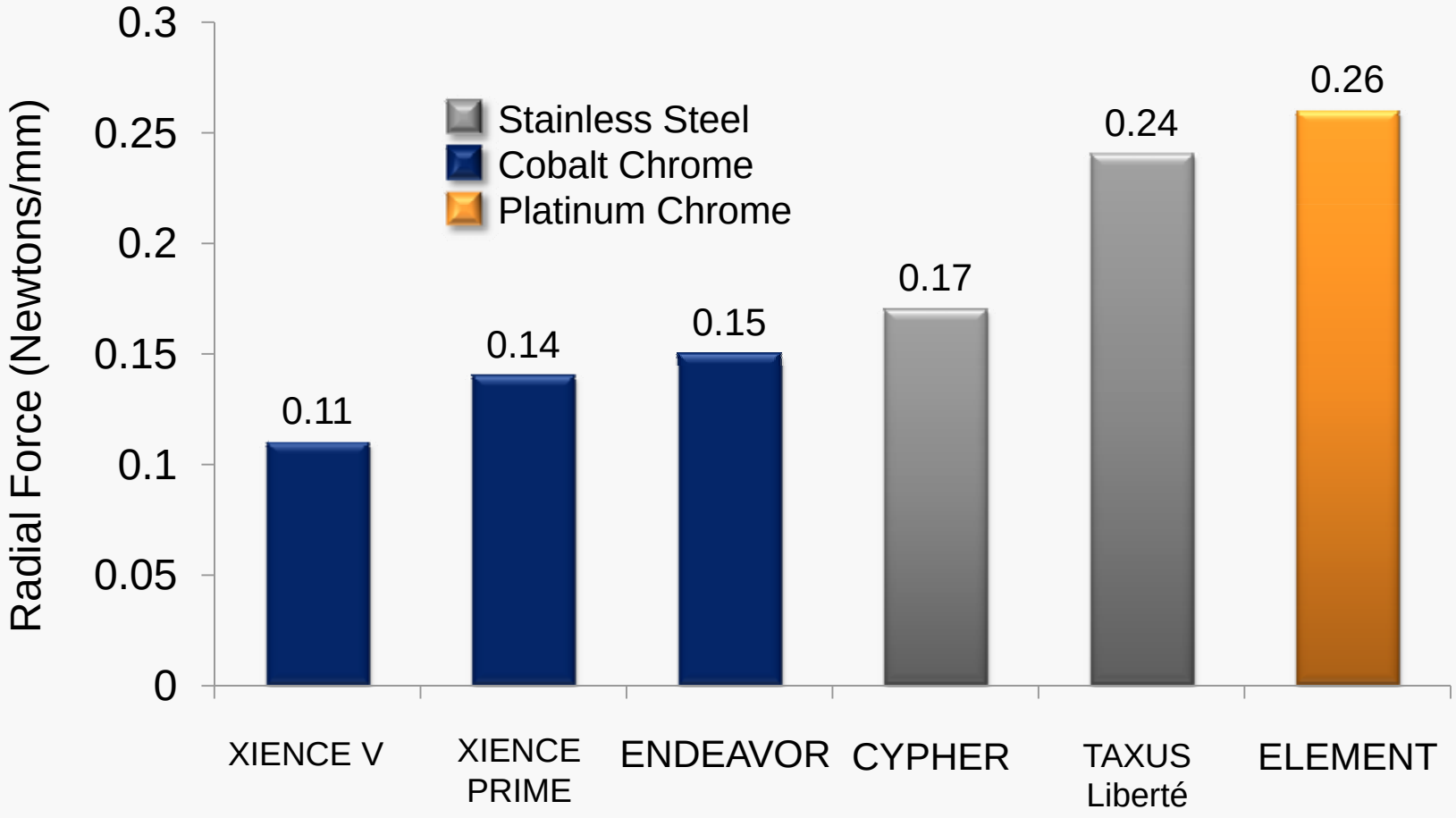
Thinner struts are associated with more rapid healing

Stent Conformability



BSC Internal Data

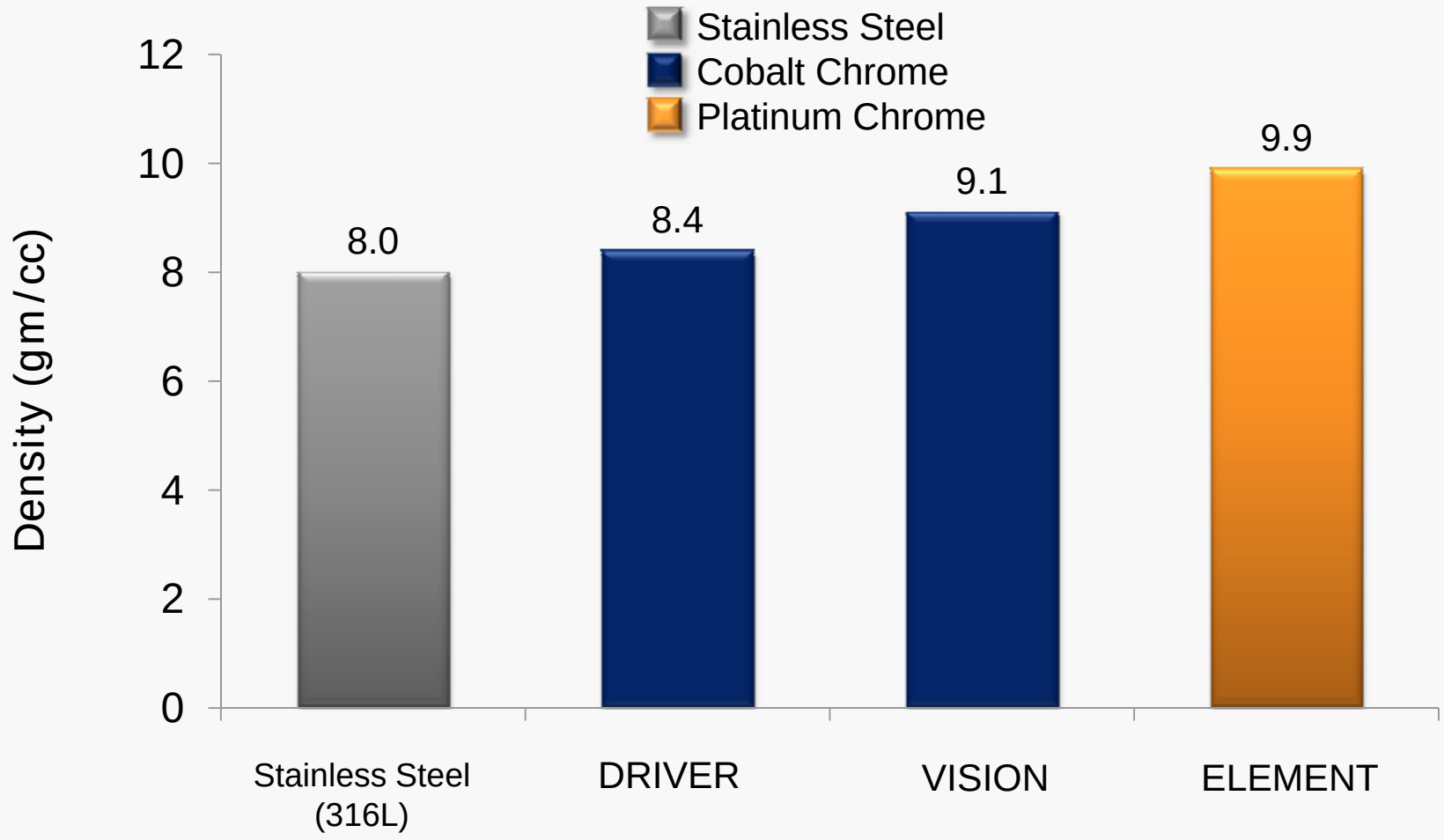
Stent Radial Strength



Platinum Chrome has 70% more Radial Strength than Cobalt Chrome

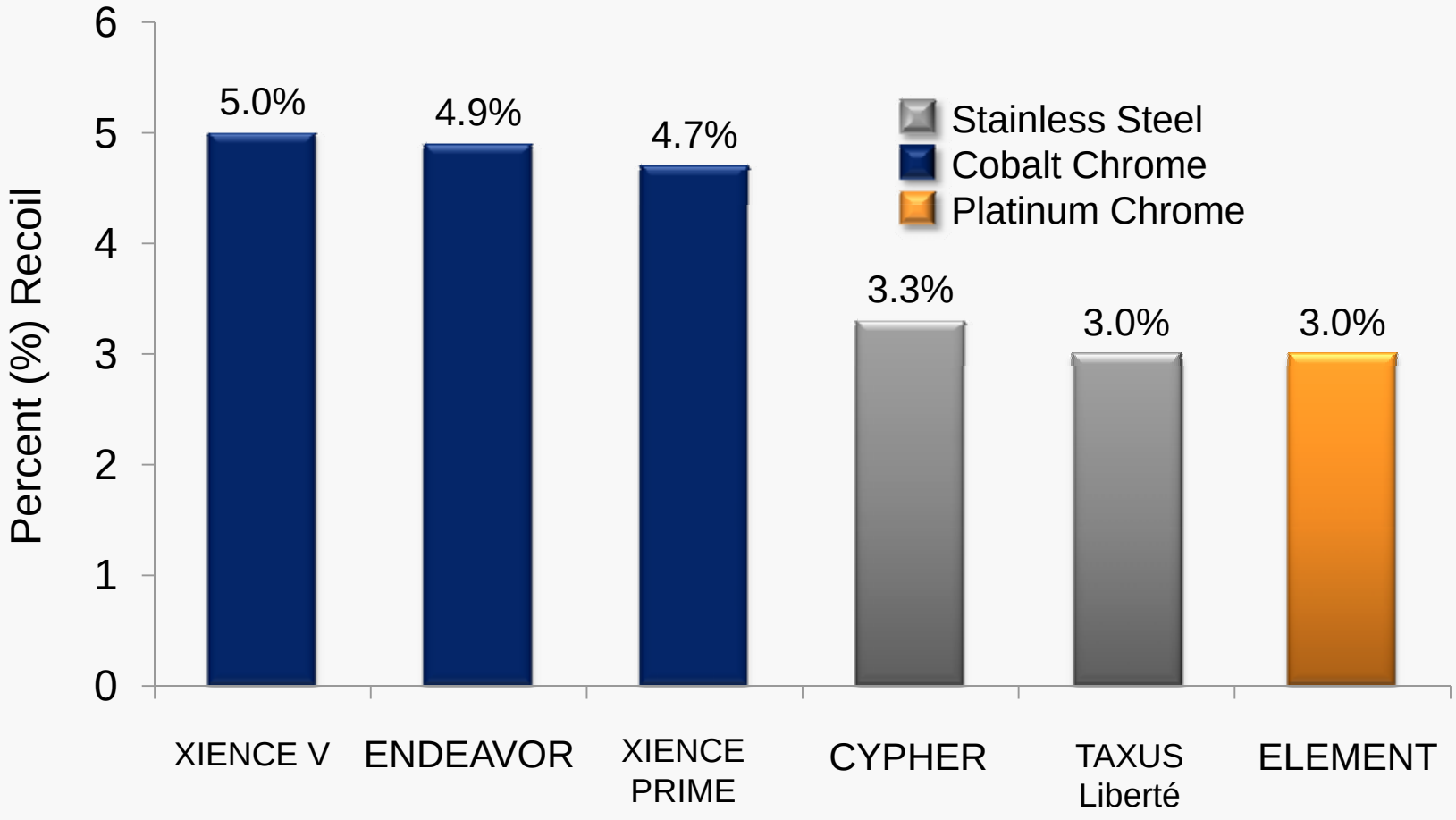
BSC Internal Data

Comparative Density



BSC Internal Data

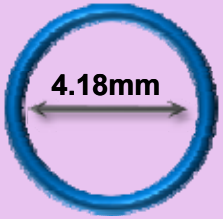
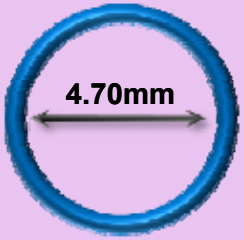
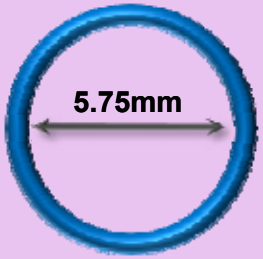
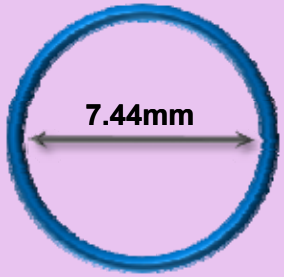
Stent Recoil

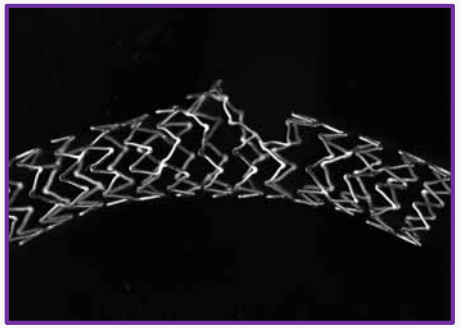


Platinum Chrome has 36% less Recoil than Cobalt Chrome

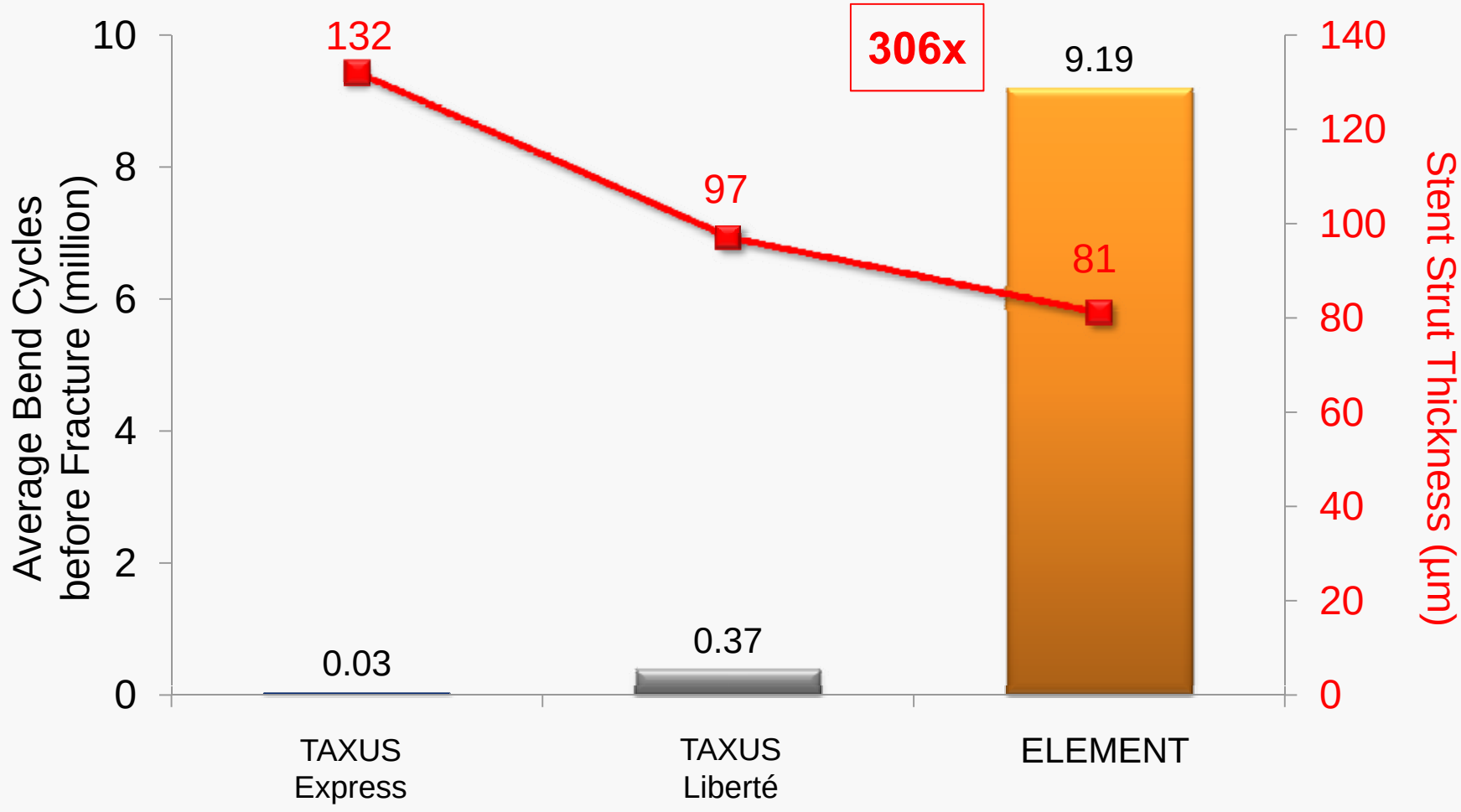
BSC Internal Data

ELEMENT Stent: Side-Branch Access

2.25mm	2.50-2.75mm	3.00-3.50mm	4.00-5.00mm
			
Maximum Expanded Cell Diameter (mm)			



Fracture Resistance (Bend Fatigue)

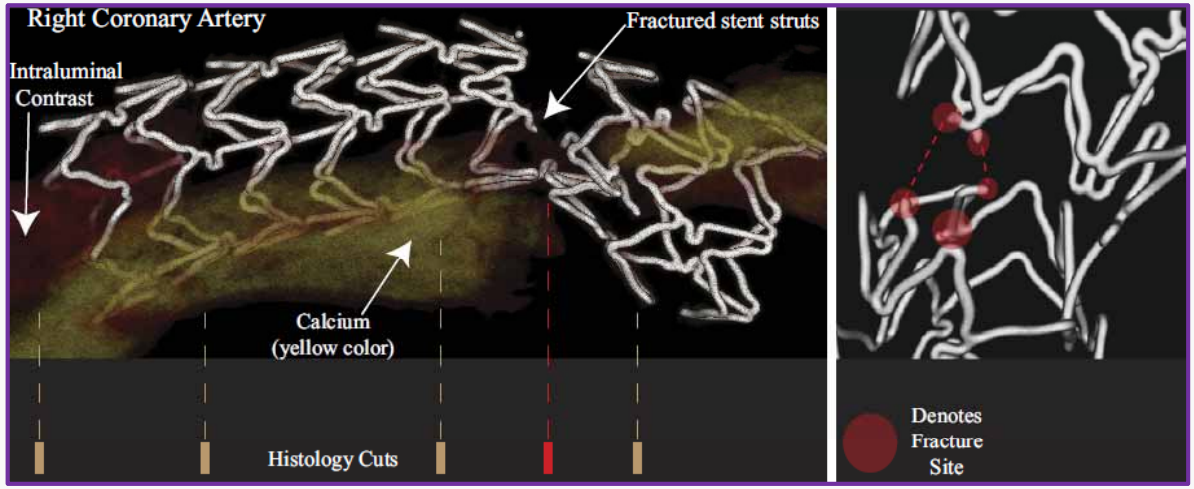


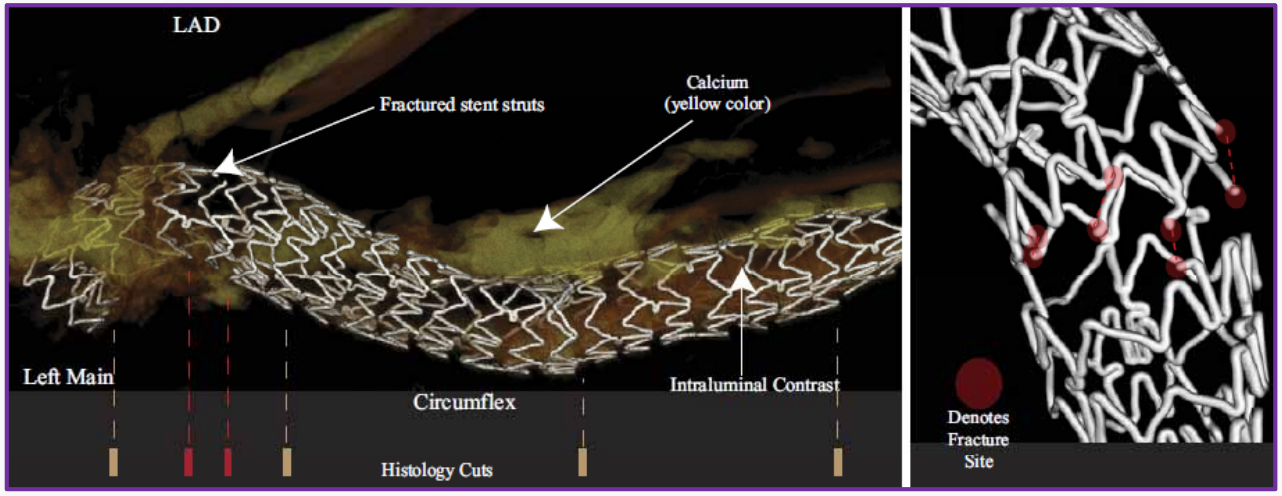
TAXUS Element (ION) has Thinner Struts *and* Higher Fracture Resistance

BSC Internal Data

Late Complications

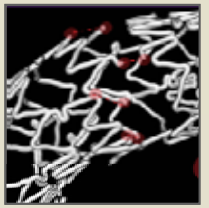
Xience V Stent Fractures with Restenosis

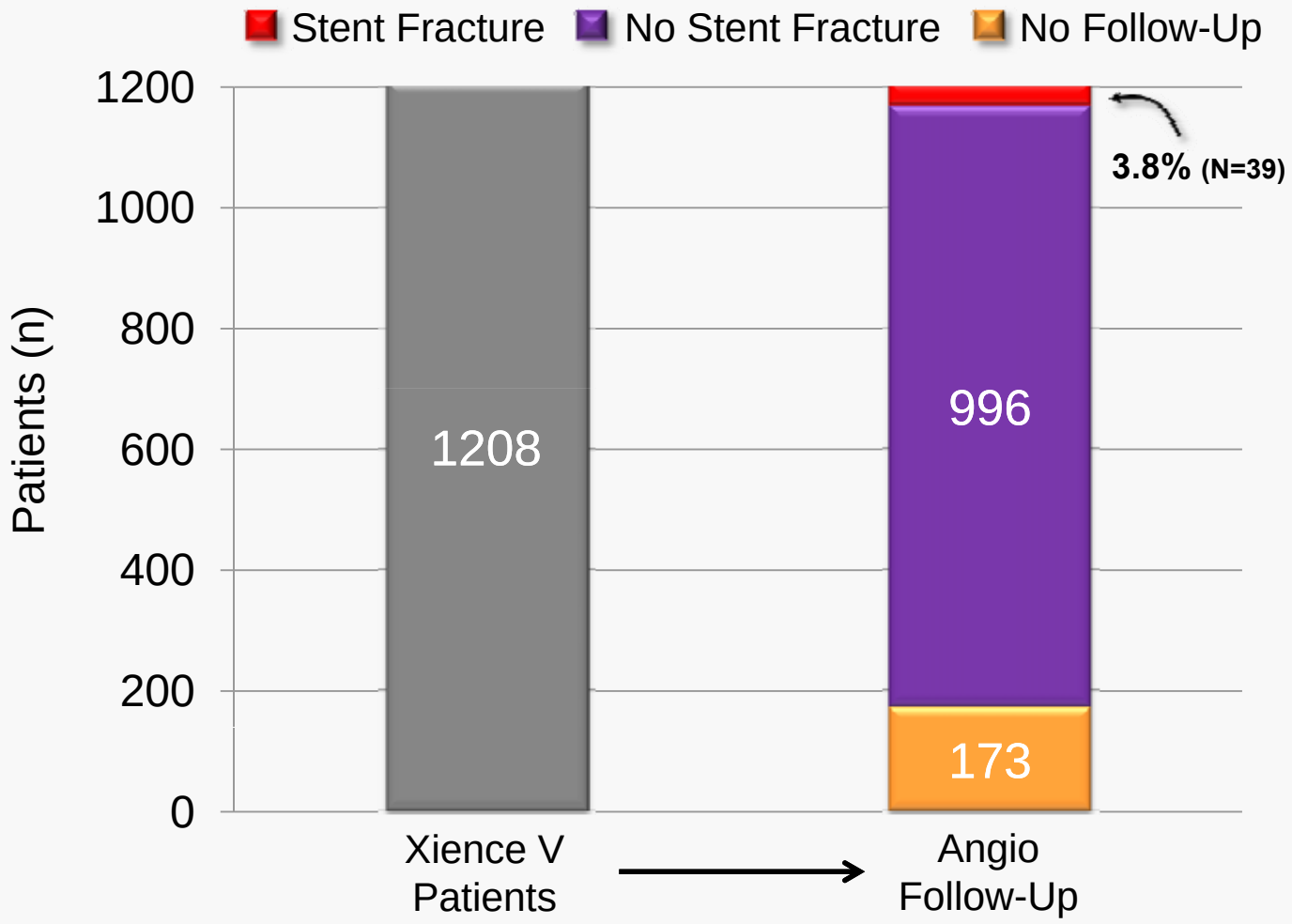




Foerst JR: JACC Intv. 2012;5;239-242

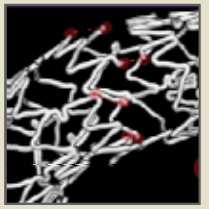
Incidence of XIENCE V Stent Fracture





Kuramitsu S: J Am Coll Cardiol 2012;59:A50

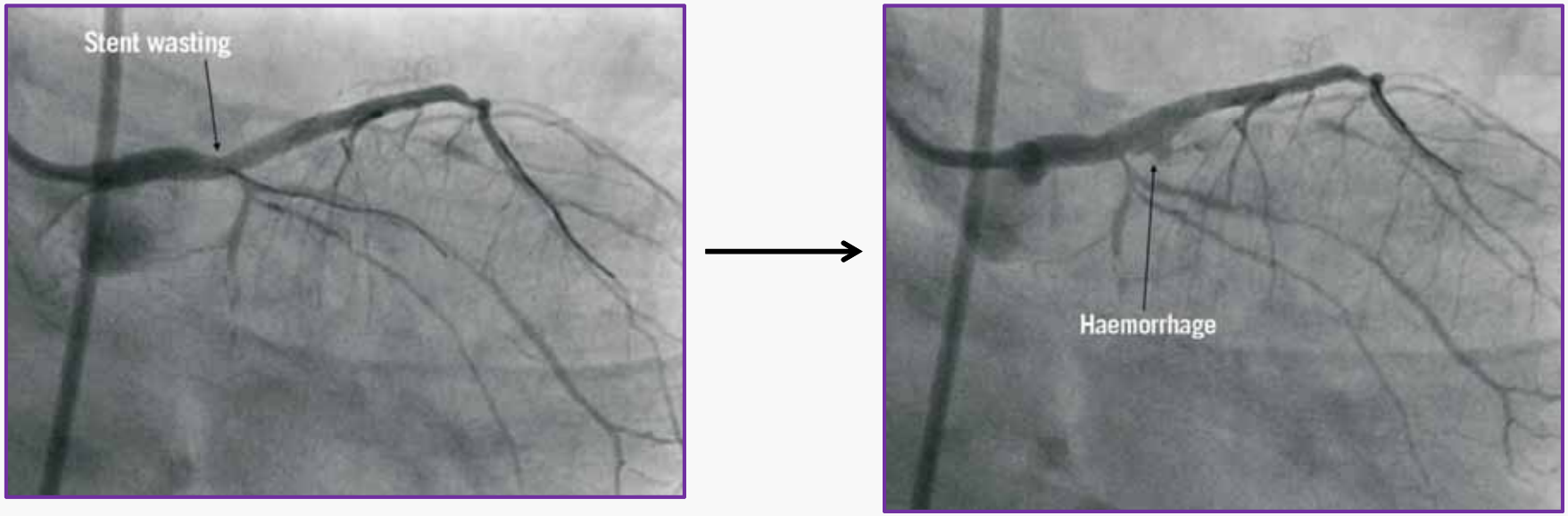
Clinical Impact of XIENCE V Stent Fracture



	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

Kuramitsu S: J Am Coll Cardiol 2012;59:A50

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

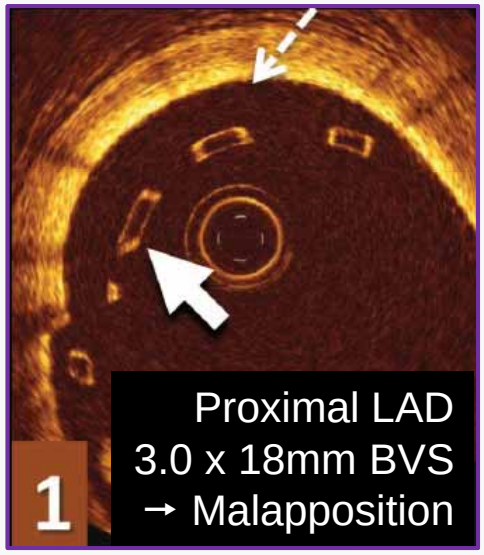
Kohli SK: EuroIntervention 2012;7:1350-1360

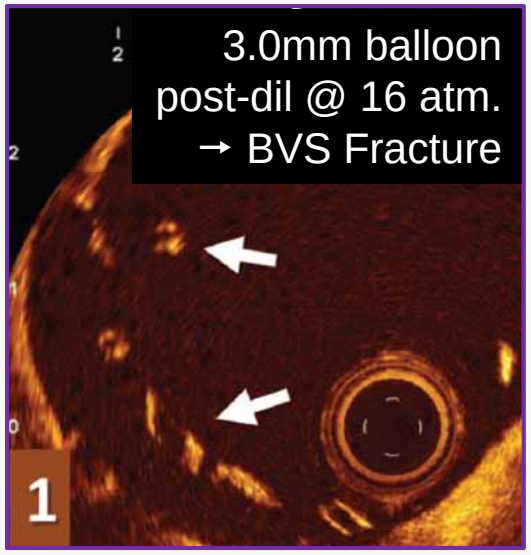
BVS Malapposition & Strut Fracture

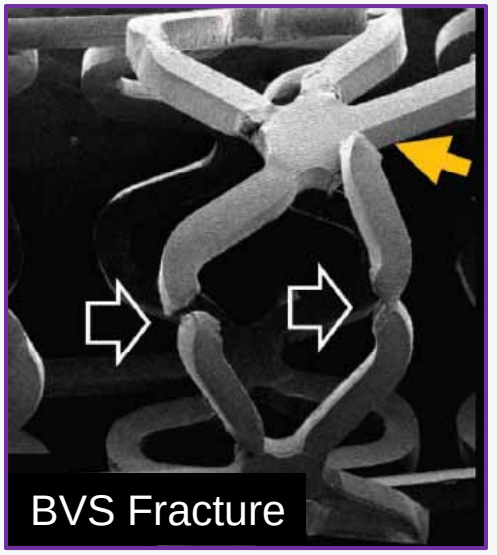
Bioresorbable Polymeric Vascular Scaffolds

A Cautionary Tale

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







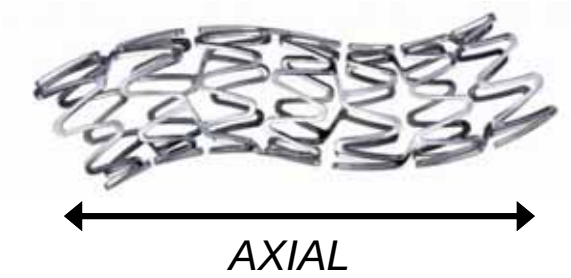
Ormiston JA: Circ Cardiovasc Interv. 2011;4:535-538

Stent Deformation: Initial Observations

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

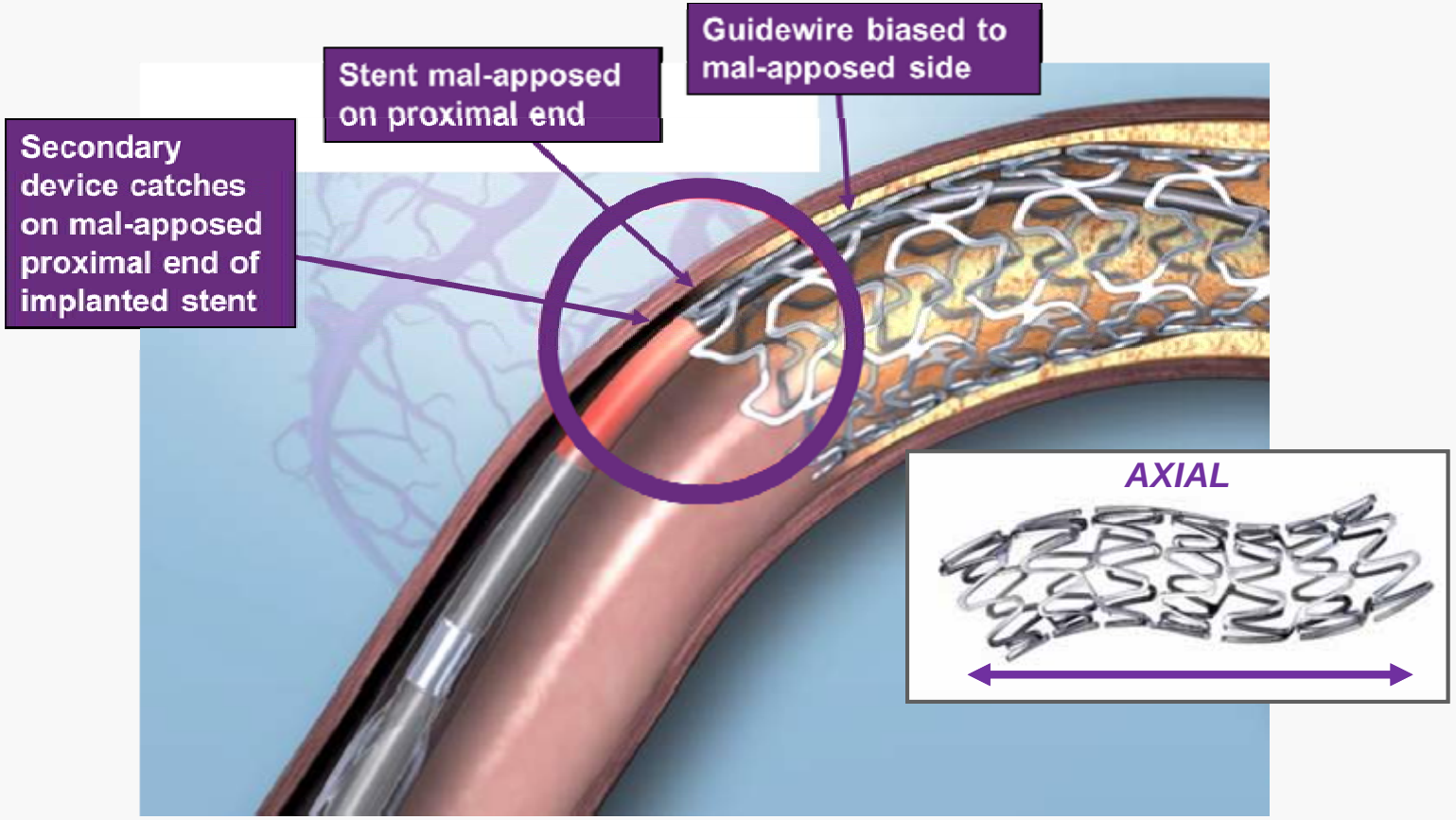


Is stent deformation the same as foreshortening?

- 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

eep
editorial expedited publication

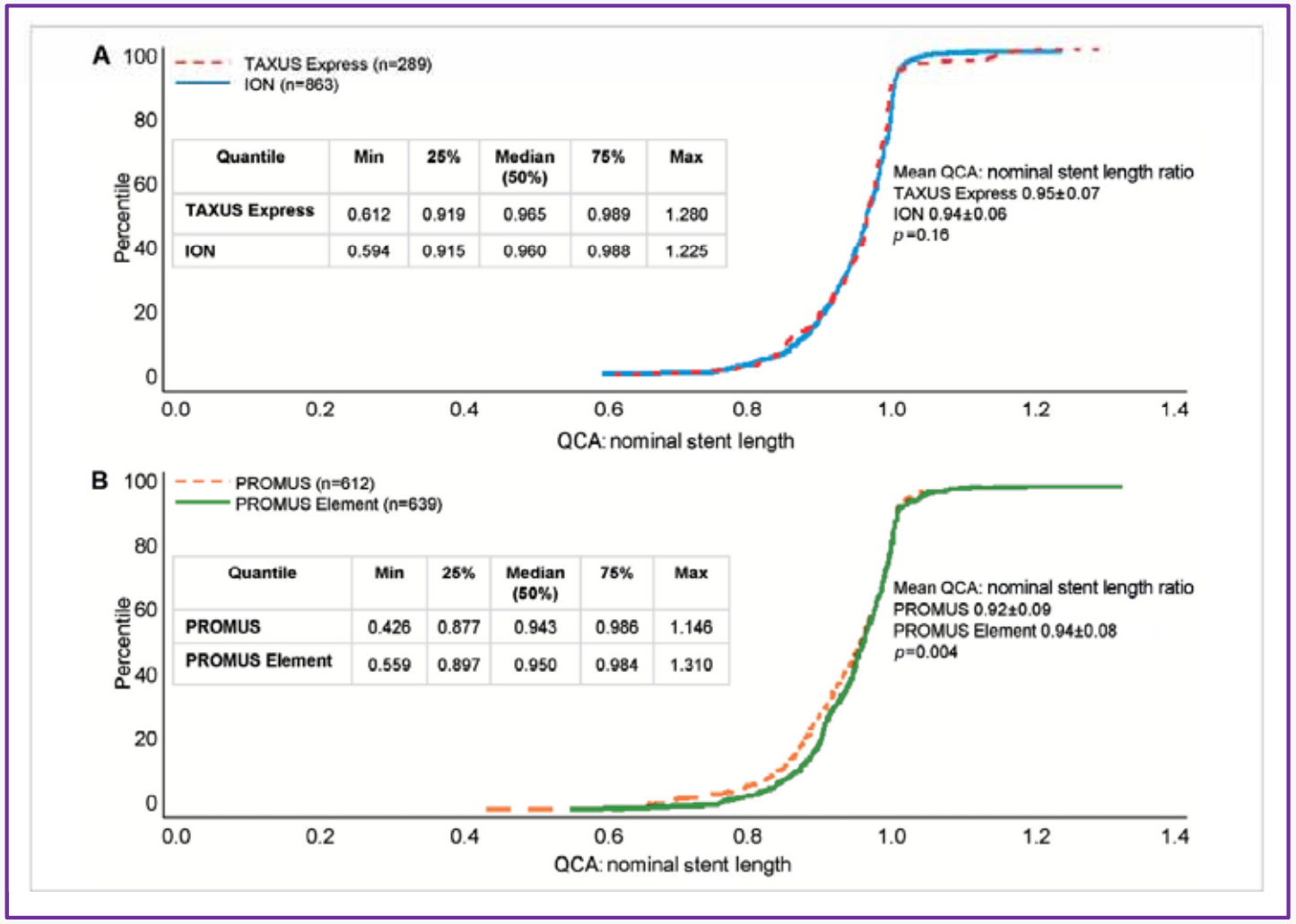
CLINICAL RESEARCH

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

Dean J. Kereiakes[1]*, MD, FACC; Jeffrey J. Popma[2], MD, FACC; Louis A. Cannon[3], MD, FACC; David E. Kandzari[4], MD, FACC; Carey D. Kimmelstiel[5], MD, FACC; Ian T. Meredith[6], MBBS, PhD, FACC; Paul S. Teirstein[7], MD, FACC; Stefan Verheye[8], MD, PhD, FACC; Dominic J. Allocco[9], MD, FACC; Keith D. Dawkins[9], MD, FACC; Gregg W. Stone[10], MD, FACC

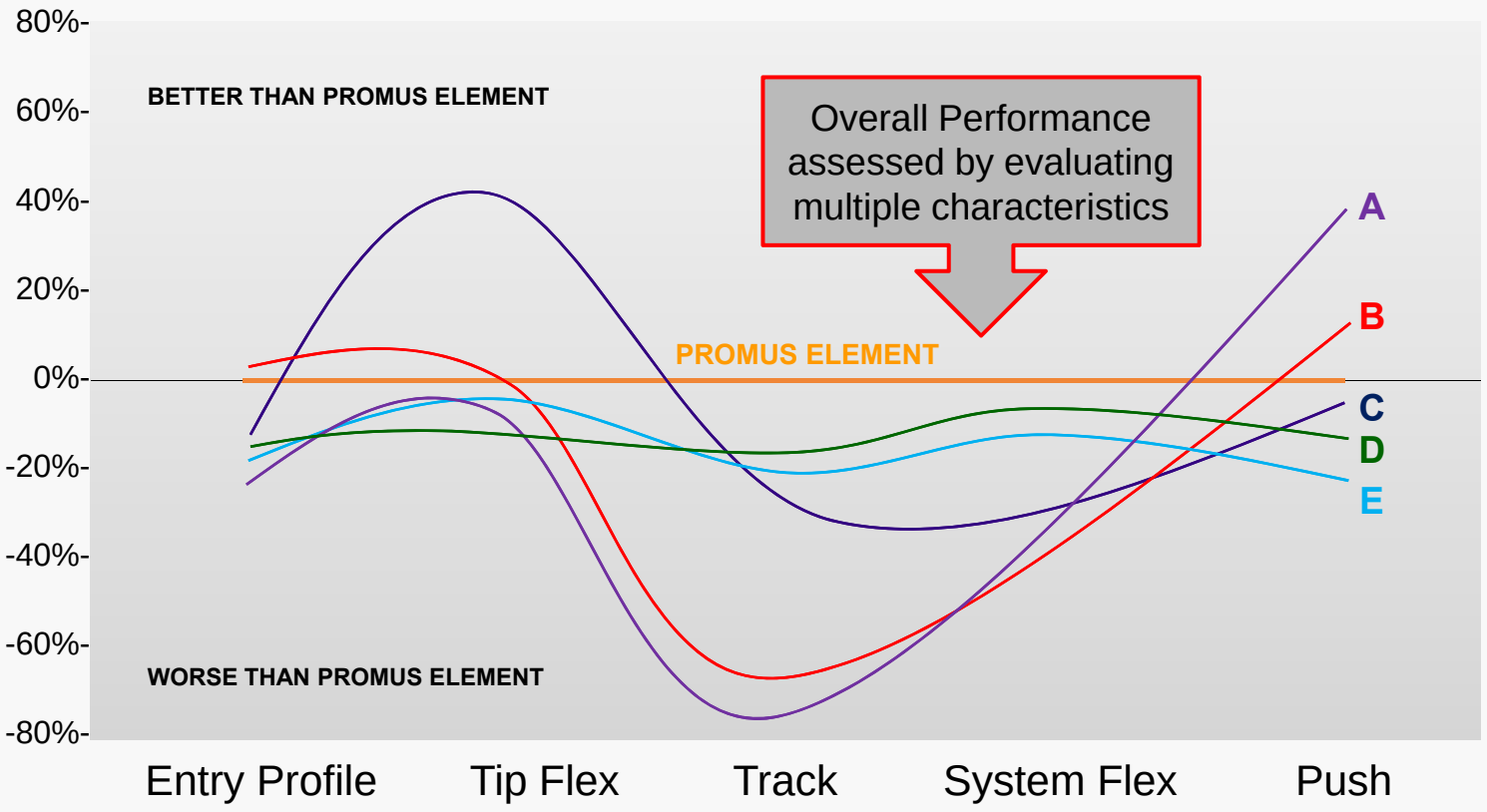
Kereiakes DJ: EuroIntervention 2012;7:EEP (March 2012)

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



Kereiakes DJ: EuroIntervention 2012;7:EEP (March 2012)

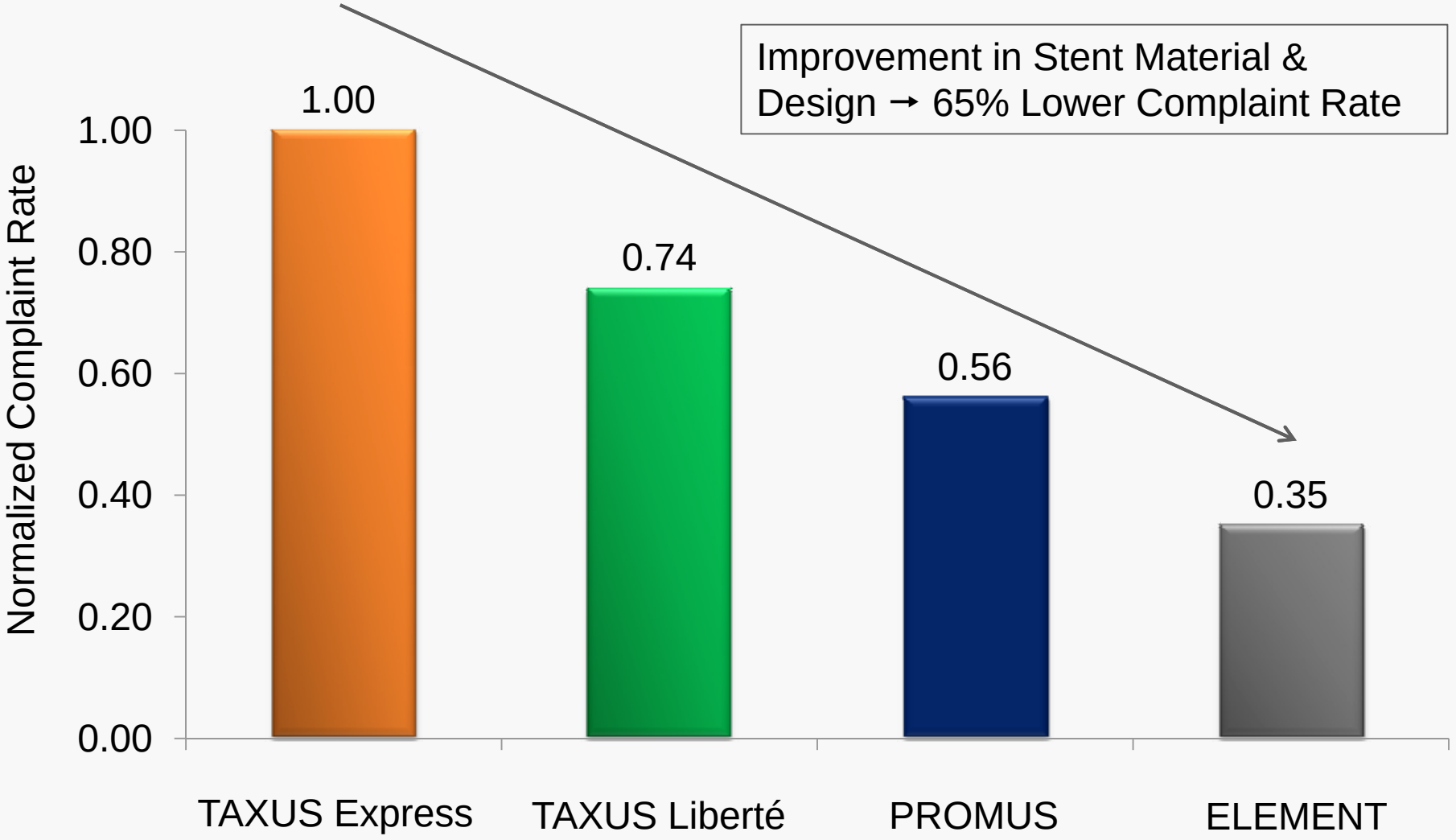
DES: Mechanical Properties Compared



Comparator Stents with Differing Characteristics (A-E)

BSC Internal Data

Platform Innovation Leads to Lower Complaint Rates



BSC: Internal Data

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