Leave the Right Thing Behind
Patterns of Symptomatic Restenosis

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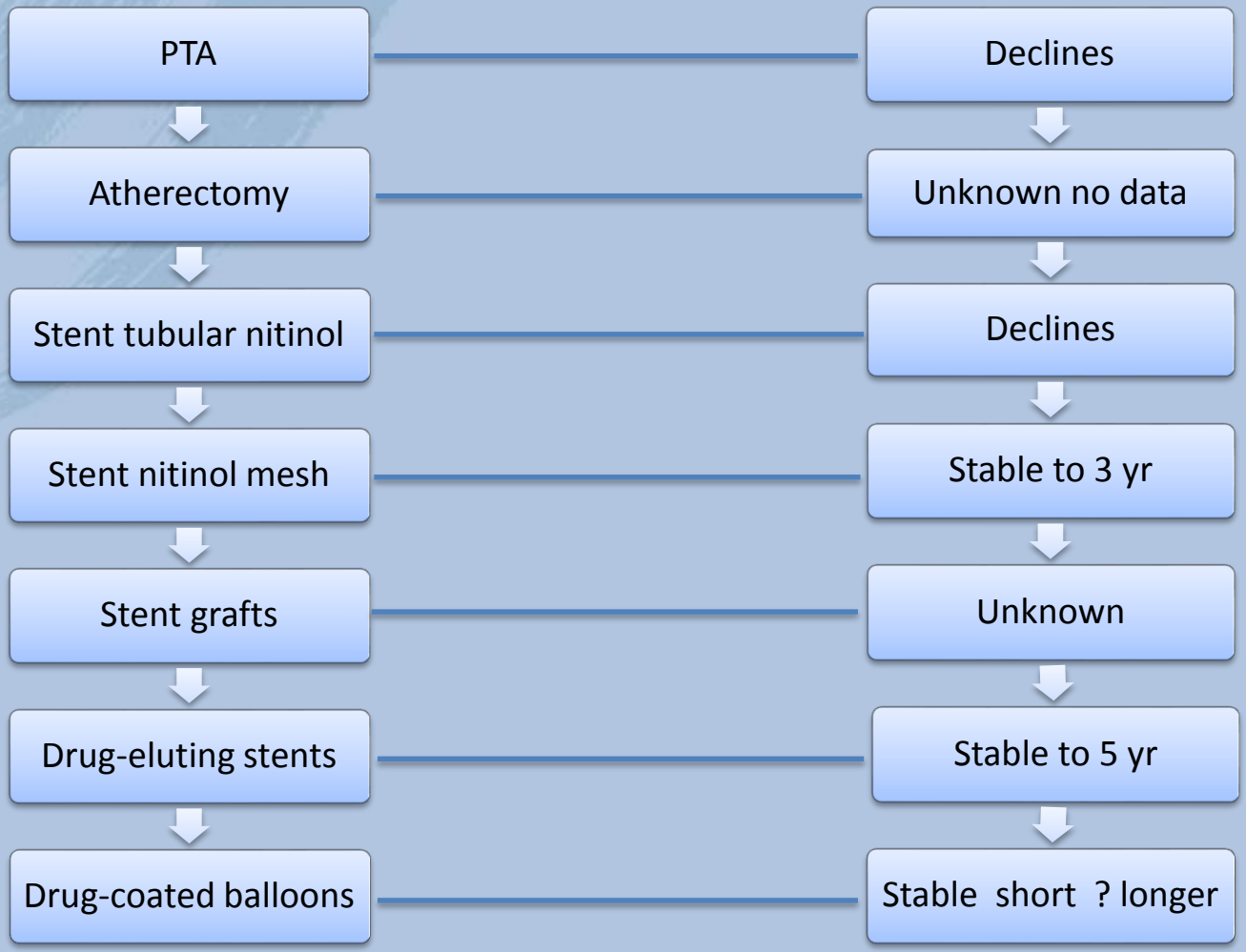
Disclosure Statement of Financial Interest

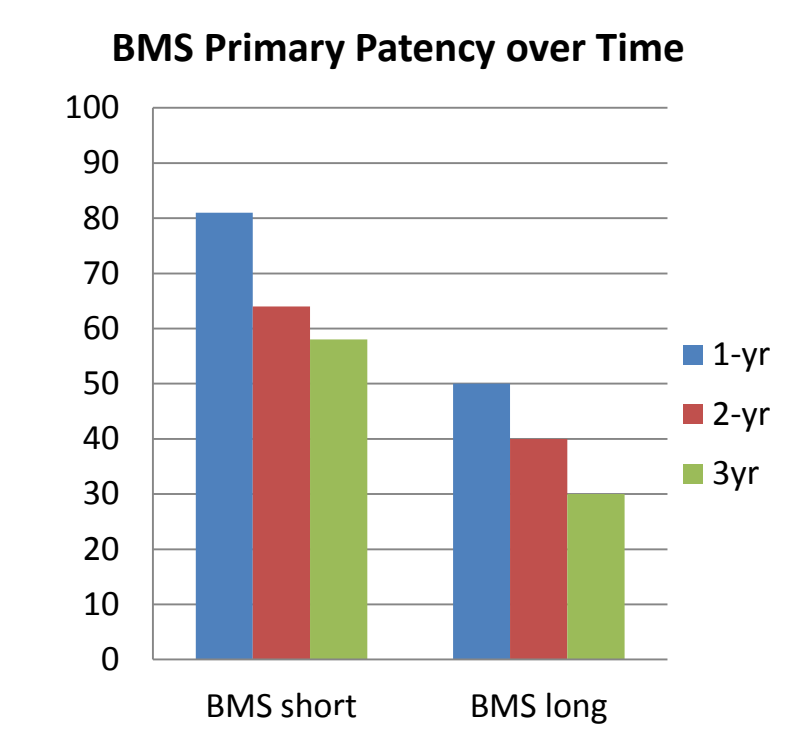
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

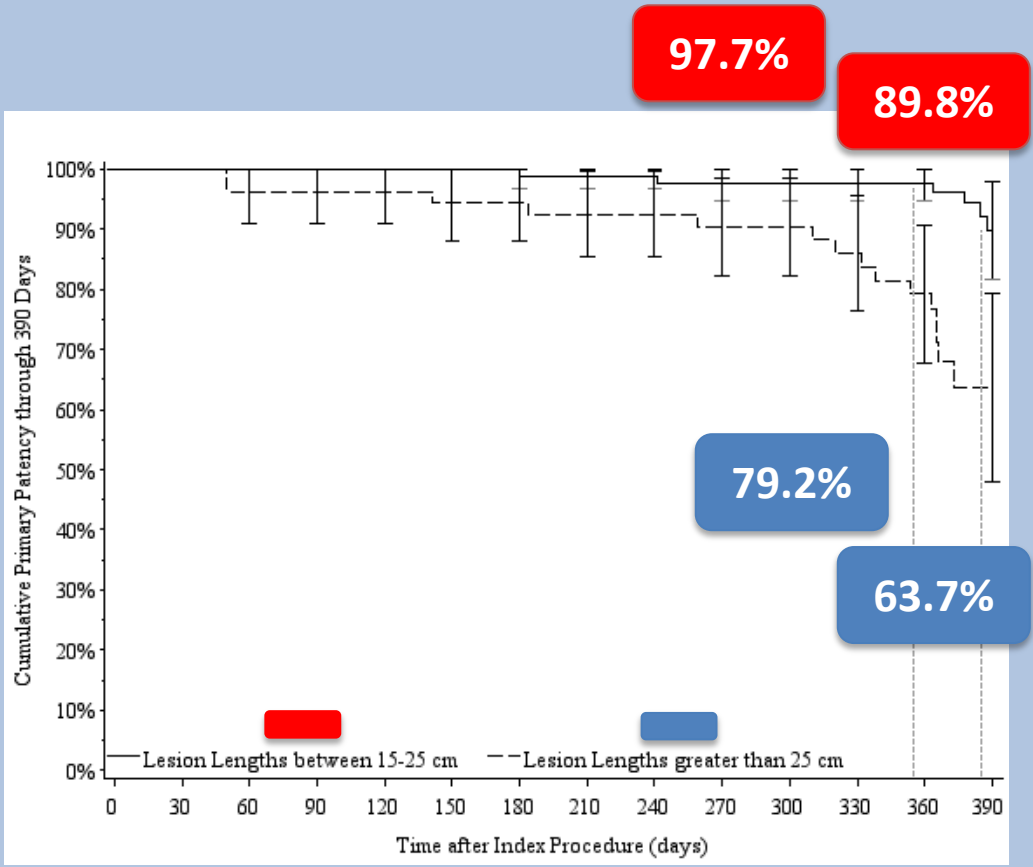
Affiliation/Financial Relationship	Company
• Consulting Fees/Honoraria	• Abbott Vascular • Medtronic • Boston Scientific • CR Bard • WL Gore • Cordis Endovascular • Cardinal Health • CSI • Novate • Reflow Medical
• Major Stock Shareholder/Equity	• Endologix • Veryan/Novate
• Royalty Income • Ownership/Founder	• Cook Medical • Embolitech

Current SFA Endovascular Intervention Options and Stability of Patency



Lesion Length Affects Patency Outcomes

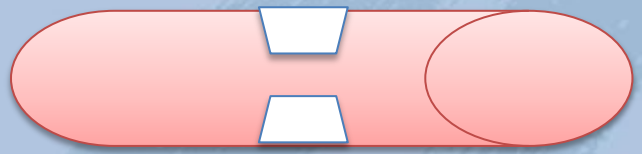
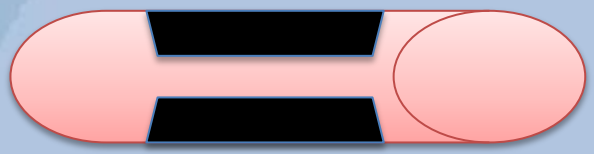




Data from Superb, Durability II, Complete SE, Zilver BMS, and Vibrant Trials

IN.PACT Global Long Lesion Imaging Cohort: Primary Patency by Lesion Length Subgroup

BMS Patterns of Restenosis

	Class I (29%) Focal ISR Group (≤ 50 mm length)	Class II (38%) Diffuse ISR Group (> 50 mm length)	Class III (33%) Totally Occluded Group
			
2-yr Restenosis after PTA*	**49.9%**	**43.3%**	**84.8%**
Using adjunctive tech**	39.0%	67.0%	72.0%
Occluded after PTA*	***15.9%***	***18.9%***	***64.6%***
Occluded using adjunctive	**8.0%**	**11.0%**	**52.0%**

***N = 133 pts Japan avg lesion**
****N = 75 pts in US**

Tosaka, et al. *J Am Coll Cardiol* 2012;59:16–23
Armstrong, et al. *Cath Card Interv* 2013;82:1168-74

Variable Symptomatology Leads to Changes in Outcomes

- Variable Outcomes of Venous Bypass Restenosis (2 yr)

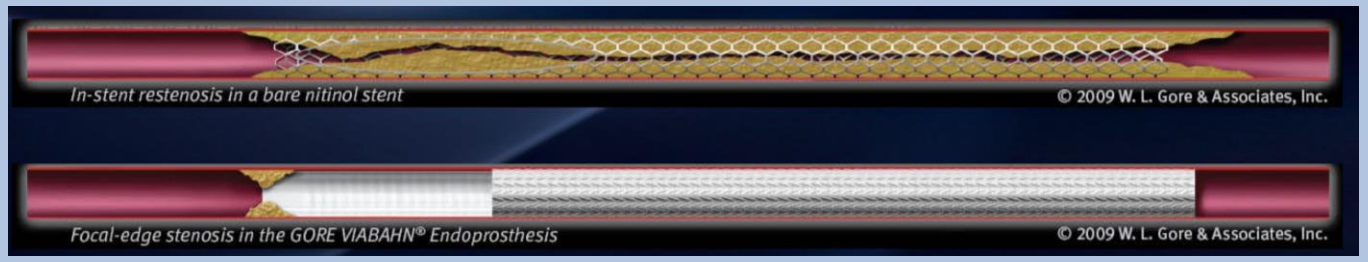
Recurrent restenosis (non-occlusion)	43.0 – 61.2%
Recurrent restenosis (occlusion)	78.8 – 84.5 %

(Surgical revision and PTA included)

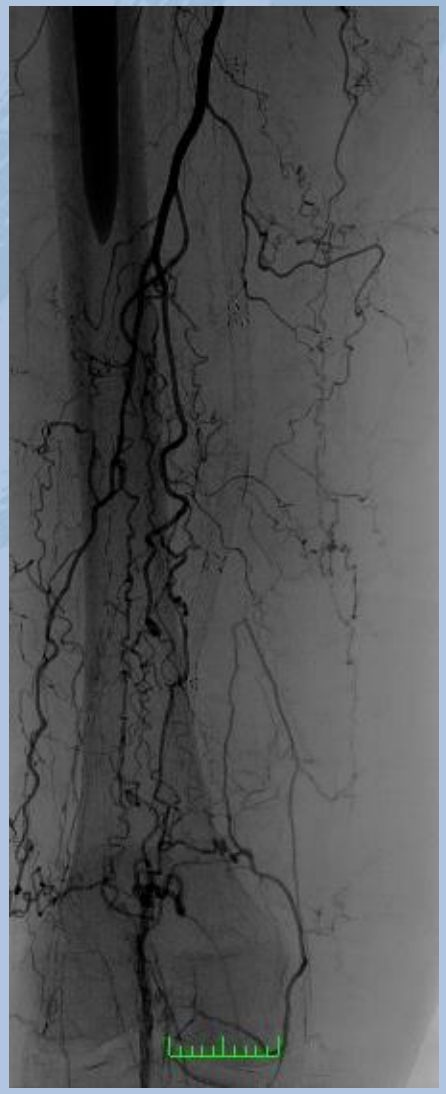
Nguyen LL, Conte MS, Menard MT, et al. *J Vasc Surg* 2004;40:916 –23.

- VIBRANT: Focal restenosis may lead to fewer clinical issues
- Focal restenosis may allow up to 50% higher flow rate compared to diffuse restenosis

Effect of Stenosis and Occlusion on Clinical Outcomes			
PSVR > 3.0	**VIABAHN**	**BMS**	**p-value**
ICQ	20	33	0.02
ABI	0.94	0.79	0.01
Rutherford	0.8	1.2	0.11



Stent Occlusion?



Pre-treatment

Inside stent

Does Restenosis Pattern Impact the Need for Reintervention?

RCT Provisional Zilver PTX and Provisional BMS Arms:

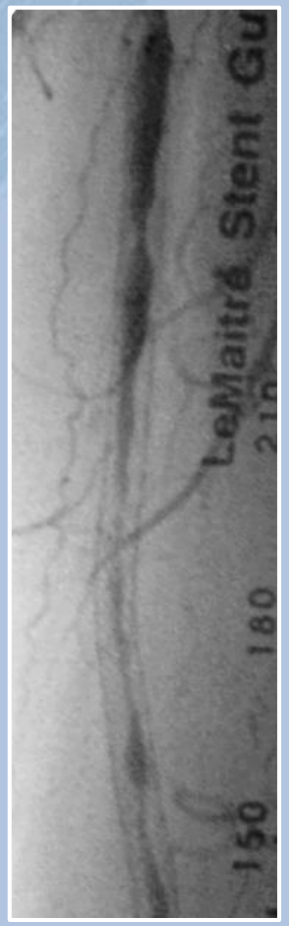
	12-mo restenosis rate	12-mo TLR rate	% of restenoses requiring TLR
Zilver PTX	9.7%	5.3%	54.6%
Zilver BMS	25.3%	17.2%	70.0%

- Significant reduction in restenosis and TLR with Zilver PTX
- For patients with restenosis, Zilver PTX further reduces the need to treat

Diffuse Restenosis in Bare-Metal Stents, Focal Restenosis in Zilver PTX

BMS

RCT Study



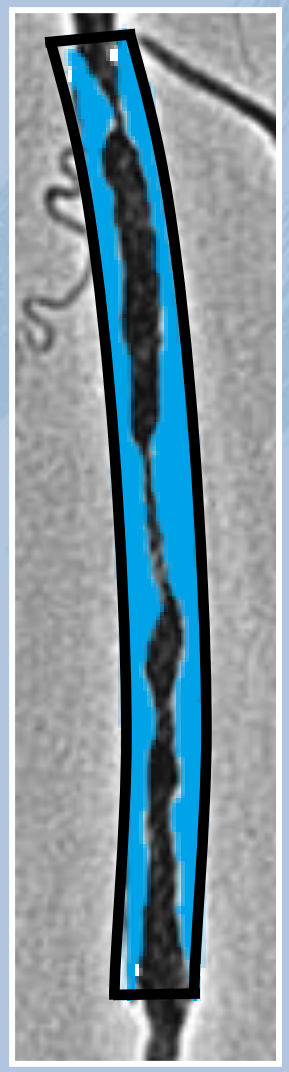
Flex EU Study

Zilver PTX

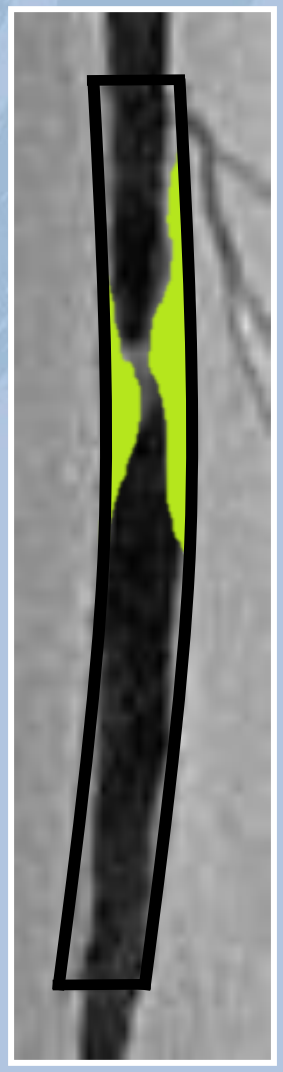
RCT Study

Japan PMS Study

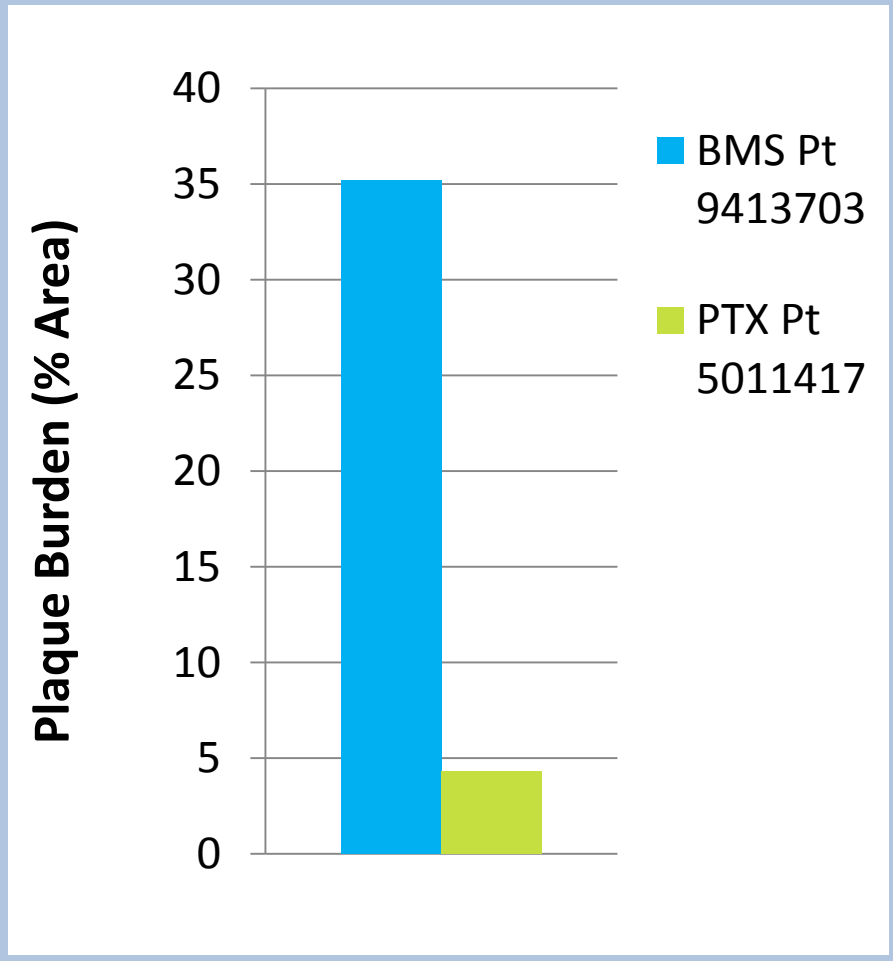
Methodology: QCA Evaluation of Plaque Burden



BMS
Pt 9413703



PTX
Pt 5011417



Sample Selection: Studies and Cases Included

- Analysis includes patients with in-stent restenosis (ISR)
- 9 BMS patients and 5 Zilver PTX patients with ISR from the Zilver PTX RCT provisional randomization group
- Due to low rate of restenosis in RCT, available post-market study data also included:
  - Zilver Flex longer length study in EU (5 BMS patients with ISR)
  - Zilver PTX Japan PMS (14 Zilver PTX patients with ISR)
- Case selection
  - Reintervention in study lesion
  - Core lab reviewed reintervention angiography
  - 50-99% diameter stenosis in study lesion
  - Within 1-year follow-up window

Patient Demographics and History

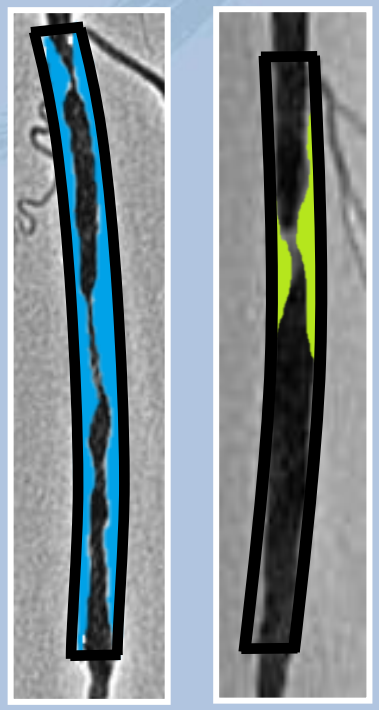
		Zilver BMS	Zilver PTX
Patients		14	19
Age (years)		70.6	71.5
Male		64.3%	57.9%
Diabetes		28.6%	57.9%
Hypertension		57.1%	78.9%
Renal disease		0%	36.8%
Rutherford Classification	**1**	**0%**	**5.3%**
	2	**50%**	**26.3%**
	3	**28.6%**	**63.2%**
	4	7.1%	0%
	5	7.1%	5.3%

Baseline Lesion Characteristics

	Zilver BMS	Zilver PTX
Lesions	14	20
Lesion length (cm)	**12.2**	**15.7**
Proximal RVD (mm)	5.0	5.2
Diameter stenosis	89.7%	90.6%
Total occlusions	**64.3%**	**50.0%**

Results

	Zilver BMS	Zilver PTX
Average days to TLR	260	262
Average stented length (cm)	15.8	19.1
Plaque burden (% area)*	28%	17%
	*p=0.03, statistically significant	



BMS
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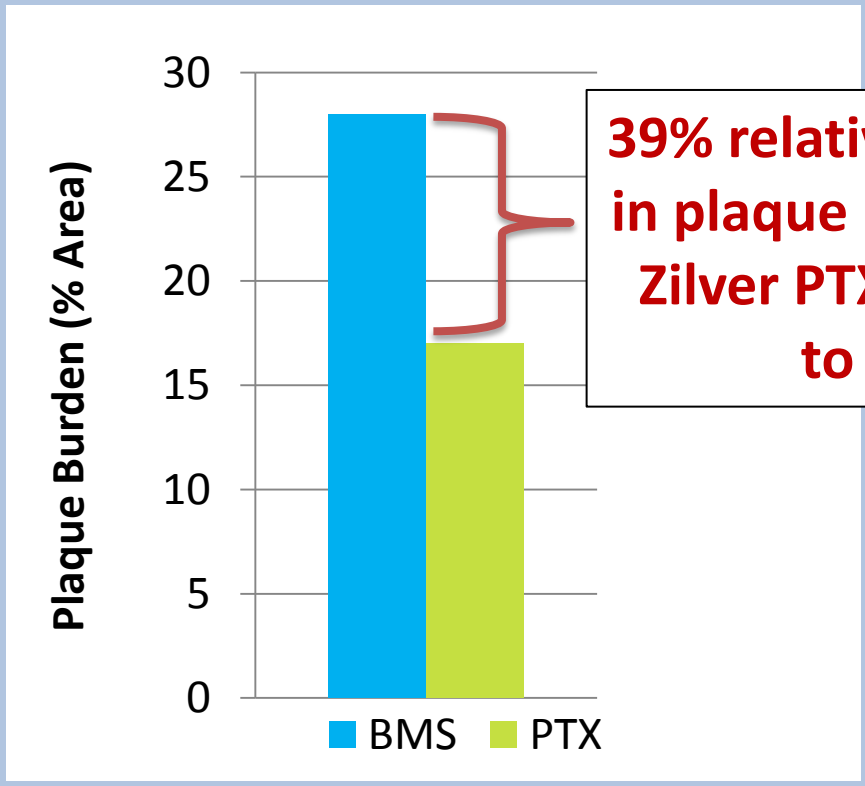

39% relative reduction in plaque burden with Zilver PTX compared to BMS

Summary

- Prior data indicate that restenosis patterns affect long-term outcomes following re-treatment
- When in-stent restenosis occurs, it is more often focal with Zilver PTX, whereas it is more often diffuse with BMS
- Zilver PTX:
  - reduces the rate of restenosis by 41% relative to BMS
  - reduces the rate of reintervention by 47% relative to BMS
  - **reduces plaque burden by 39% relative to BMS**
- Focal restenoses: Easier, faster, and cheaper to retreat than diffuse restenoses?

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