Which Stent Is Best for Various Femoropopliteal Anatomy?

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PACIFIC NORTHWEST ENDOVASCULAR CONFERENCE

UCLA Health

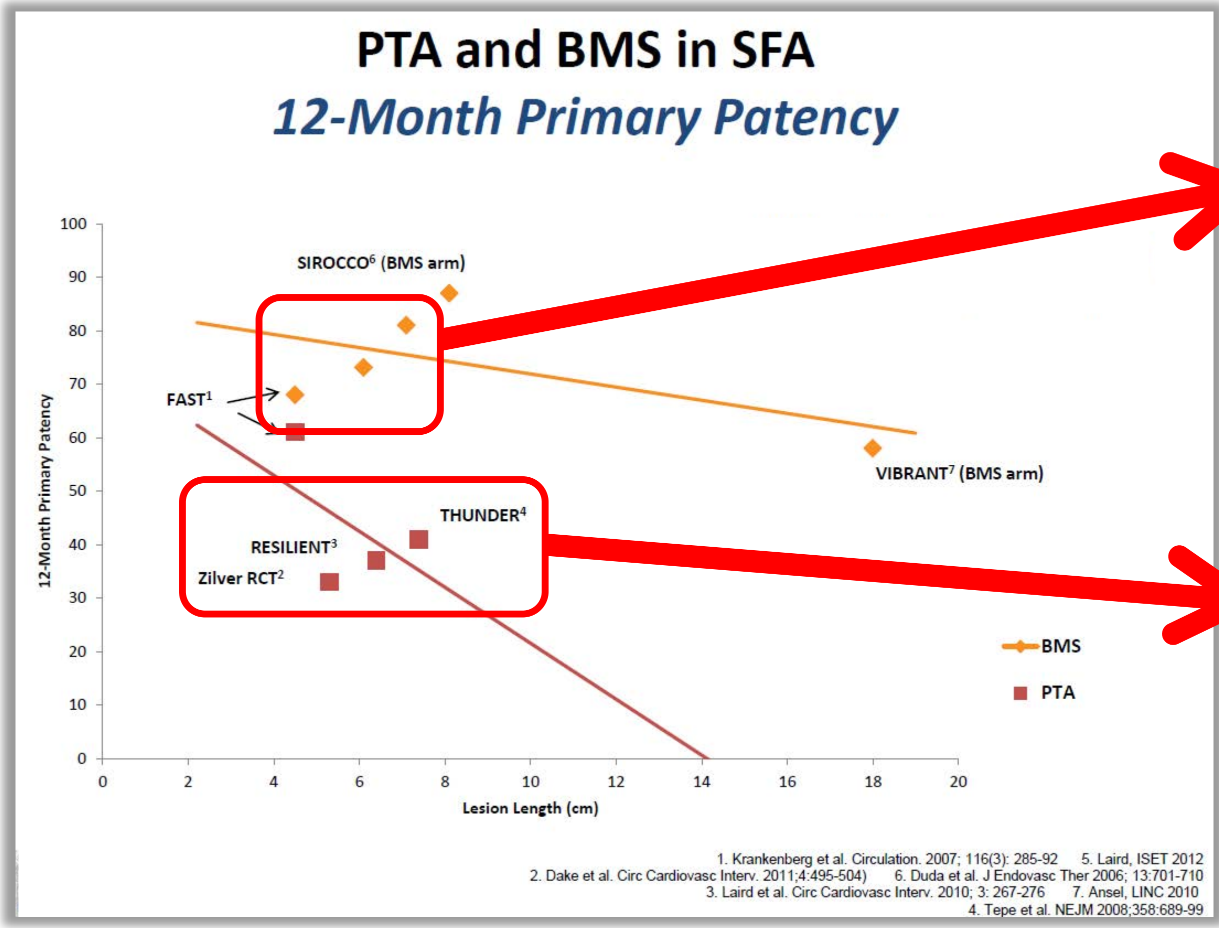
DISCLOSURE

Brian DeRubertis, MD

- **Consultant / Advisory Board:** Abbott Vascular, Medtronic, Cook, Bard
- **Speakers Bureau:** Abbott Vascular, Medtronic, Gore
- **Research Grant:** Medtronic

Which Stent is Best for Various Fempop Anatomy

Standard Laser-Cut Nitinol Stents


PTA and BMS in SFA

12-Month Primary Patency

1. Krankenberg et al. Circulation. 2007; 116(3): 285-92
2. Dake et al. Circ Cardiovasc Interv. 2011;4:495-504)
3. Laird et al. Circ Cardiovasc Interv. 2010; 3: 267-276
4. Tepe et al. NEJM 2008;358:689-99
5. Laird, ISET 2012
6. Duda et al. J Endovasc Ther 2006; 13:701-710
7. Ansel, LINC 2010

Zeller T. DES vs. DCB for long lesions. LINC 2013.

Bare Metal Laser-Cut Nitinol Stents in the SFA:

60-80% Primary Patency

- ✓ Good safety profile
- ✓ Minimal recovery

Balloon angioplasty in the SFA:

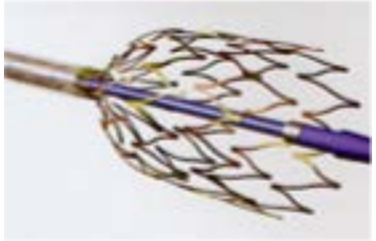
30-50% Primary Patency

* DURABILITY, STROLL, COMPLETE SE, RESILIENT

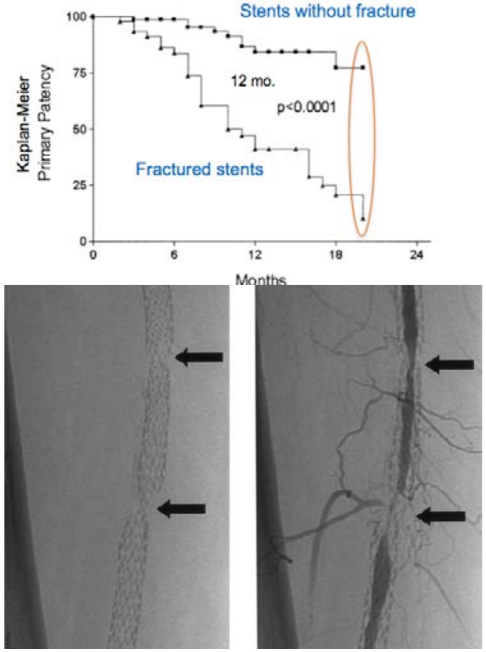
Which Stent is Best for Various Fempop Anatomy

Standard Laser-Cut Nitinol Stents

- Design of laser-cut nitinol stents limits flexibility
- This results in stent fractures and loss of patency
- Chronic outward radial force likely contributes to restenosis

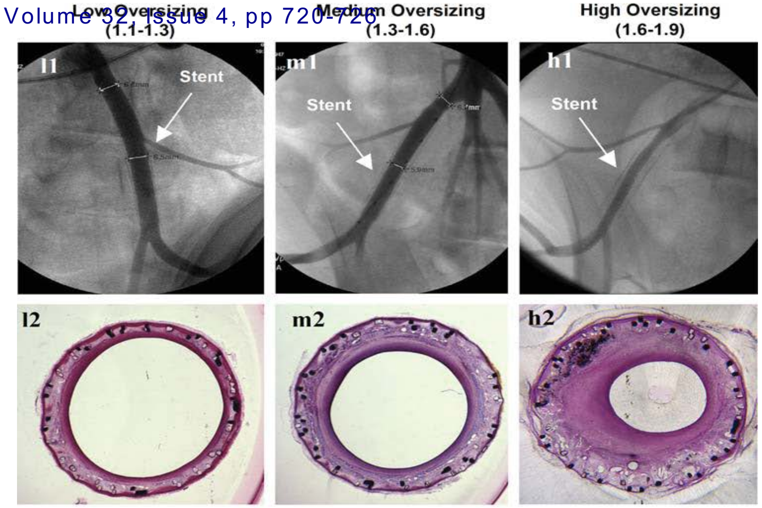


Primary stent patency rates for fractured and non-fractured stents



Late Stent Expansion and Neointimal Proliferation of Oversized Nitinol Stents in Peripheral Arteries

CardioVascular and Interventional Radiology. July 2009, Volume 32, Issue 4, pp 720-726



Which Stent is Best for Various Fempop Anatomy

Standard Laser-Cut Nitinol Stents

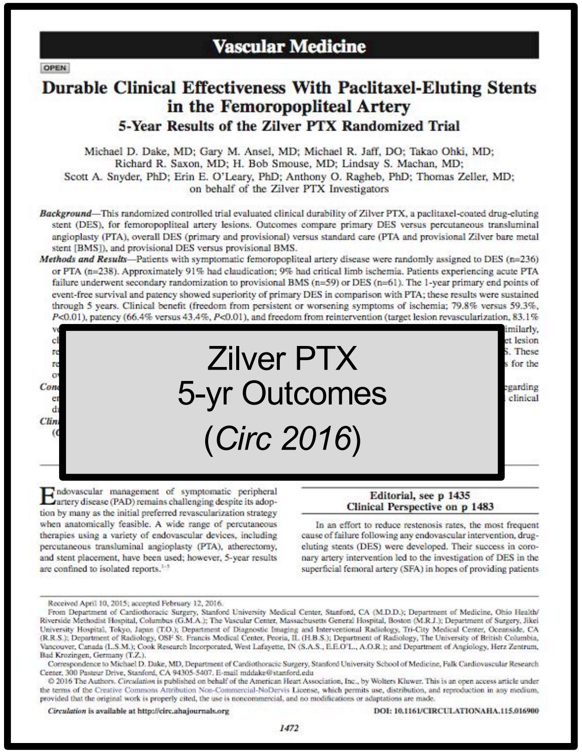
- These devices are becoming below the standard of care and probably should be retired from routine clinical practice in favor of next-generation stents

- Properties of next-generation stents:
  - Anti-restenosis therapy (drug-coated or drug-eluting)
  - Increased compression resistance
  - Increased flexibility and torsion tolerance
  - Barrier to intimal hyperplastic tissue in-growth

Which Stent is Best for Various Fempop Anatomy

Drug-Coated / Drug-Eluting Stents

Zilver PTX Randomized Controlled Trial



Vascular Medicine

OPEN

Durable Clinical Effectiveness With Paclitaxel-Eluting Stents in the Femoropopliteal Artery

5-Year Results of the Zilver PTX Randomized Trial

Michael D. Dake, MD; Gary M. Ansel, MD; Michael R. Jaff, DO; Takao Ohki, MD;
Richard R. Saxon, MD; H. Bob Smouse, MD; Lindsay S. Machan, MD;
Scott A. Snyder, PhD; Erin E. O'Leary, PhD; Anthony O. Ragheb, PhD; Thomas Zeller, MD;
on behalf of the Zilver PTX Investigators

Background—This randomized controlled trial evaluated clinical durability of Zilver PTX, a paclitaxel-coated drug-eluting stent (DES), for femoropopliteal artery lesions. Outcomes compare primary DES versus percutaneous transluminal angioplasty (PTA), overall DES (primary and provisional) versus standard care (PTA and provisional Zilver bare metal stent [BMS]), and provisional DES versus provisional BMS.

Methods and Results—Patients with symptomatic femoropopliteal artery disease were randomly assigned to DES (n=236) or PTA (n=238). Approximately 91% had claudication; 9% had critical limb ischemia. Patients experiencing acute PTA failure underwent secondary randomization to provisional BMS (n=59) or DES (n=61). The 1-year primary end points of event-free survival and patency showed superiority of primary DES in comparison with PTA; these results were sustained through 5 years. Clinical benefit (freedom from persistent or worsening symptoms of ischemia; 79.8% versus 59.3%, *P*<0.01), patency (66.4% versus 43.4%, *P*<0.01), and freedom from reintervention (target lesion revascularization, 83.1%

Zilver PTX
5-yr Outcomes
(*Circ 2016*)

Endovascular management of symptomatic peripheral artery disease (PAD) remains challenging despite its adoption by many as the initial preferred revascularization strategy when anatomically feasible. A wide range of percutaneous therapies using a variety of endovascular devices, including percutaneous transluminal angioplasty (PTA), atherectomy, and stent placement, have been used; however, 5-year results are confined to isolated reports.[1–5]

Editorial, see p 1435
Clinical Perspective on p 1483

In an effort to reduce restenosis rates, the most frequent cause of failure following any endovascular intervention, drug-eluting stents (DES) were developed. Their success in coronary artery intervention led to the investigation of DES in the superficial femoral artery (SFA) in hopes of providing patients

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Circulation **is available at http://circ.ahajournals.org** **DOI: 10.1161/CIRCULATIONAHA.115.016900**

Baseline Lesion Characteristics		**PTA**	**Zilver PTX**	***p*-value**
Lesions		251	247	
Normal-to-normal lesion length (mm)		63 ± 41	66 ± 39	0.36
Stenosed lesion length (mm)^{1,2}		53 ± 40	55 ± 41	0.71
Diameter stenosis (%)^{1}		78 ± 17	80 ± 17	0.38
Total occlusions		27%	33%	0.20
***De novo* lesions**		94%	95%	0.68
Lesion calcification^{1}	**None**	5%	2%	< 0.01*
	Little	38%	26%	
	Moderate	22%	35%	
	Severe	35%	37%	

[1] Angiographic core lab assessment

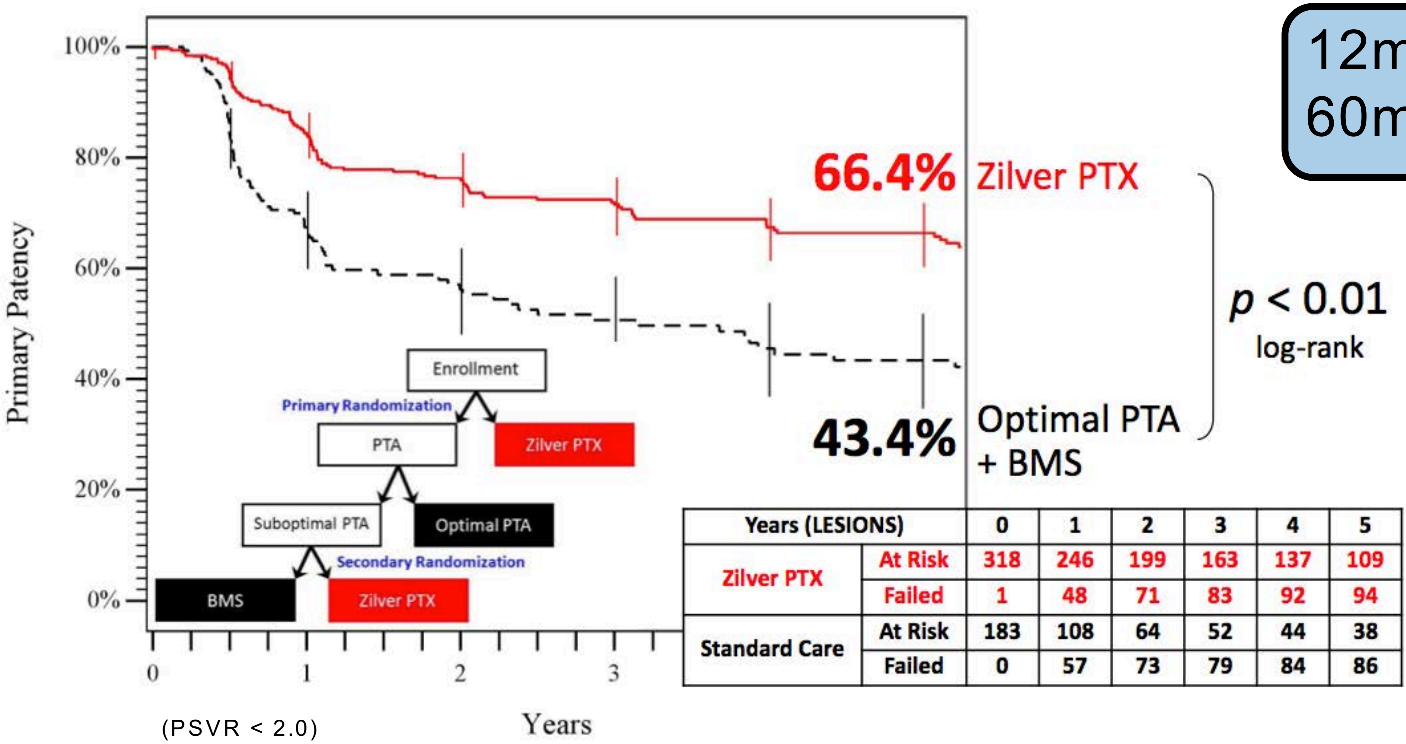
[2] Region with > 20% diameter stenosis

Which Stent is Best for Various Fempop Anatomy

Drug-Coated / Drug-Eluting Stents

Zilver PTX Randomized Controlled Trial

12mo: 67% vs 84%
60mo: 43% vs 66%



Years (LESIONS)		0	1	2	3	4	5
Zilver PTX	At Risk	318	246	199	163	137	109
	Failed	1	48	71	83	92	94
Standard Care	At Risk	183	108	64	52	44	38
	Failed	0	57	73	79	84	86

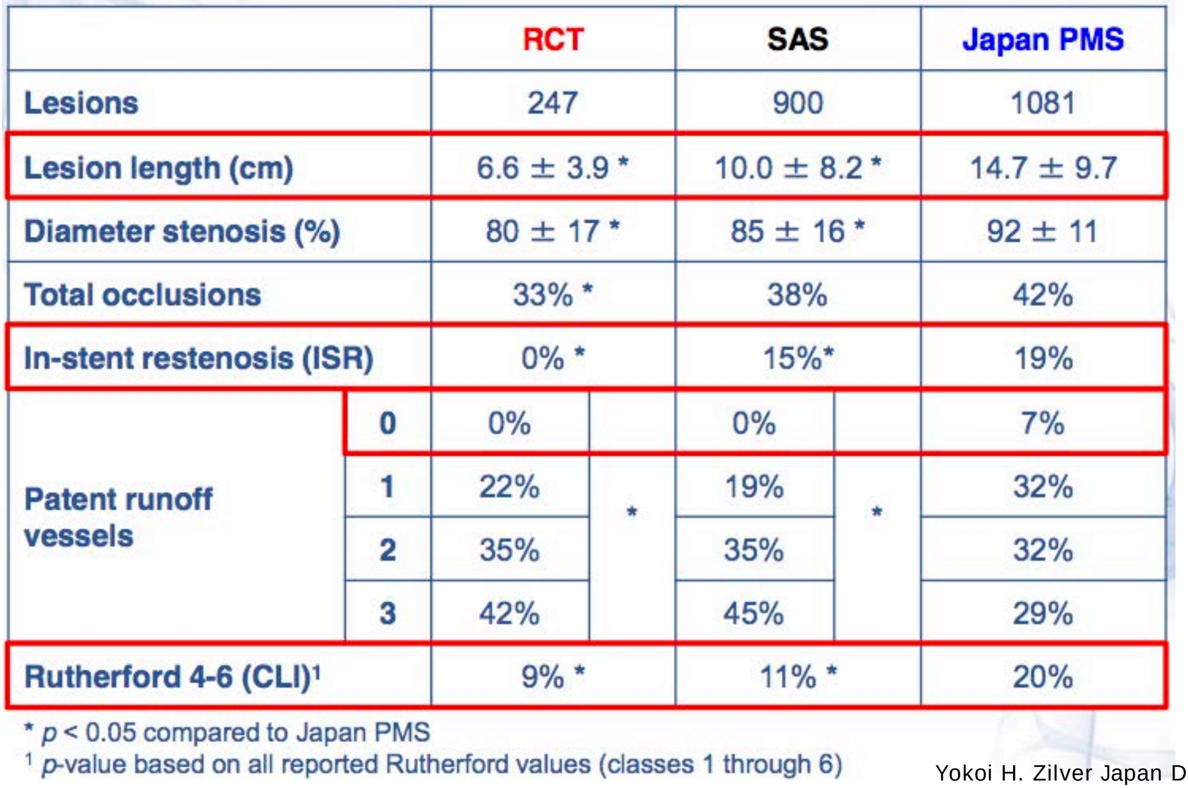
(PSVR < 2.0)

Dake, M. Zilver 5yr Data Presented at LINC 2015

Which Stent is Best for Various Fempop Anatomy

Drug-Coated / Drug-Eluting Stents

Zilver PTX Global Clinical Program



		RCT		SAS		Japan PMS
Lesions		247		900		1081
Lesion length (cm)		6.6 ± 3.9 *		10.0 ± 8.2 *		14.7 ± 9.7
Diameter stenosis (%)		80 ± 17 *		85 ± 16 *		92 ± 11
Total occlusions		33% *		38%		42%
In-stent restenosis (ISR)		0% *		15%*		19%
Patent runoff vessels	**0**	0%		0%		7%
	1	22%	*	19%	*	32%
	2	35%		35%		32%
	3	42%		45%		29%
Rutherford 4-6 (CLI)[1]		9% *		11% *		20%

* $p < 0.05$ compared to Japan PMS

[1] *p*-value based on all reported Rutherford values (classes 1 through 6)

Yokoi H. Zilver Japan Data Presented at VIVA 2014

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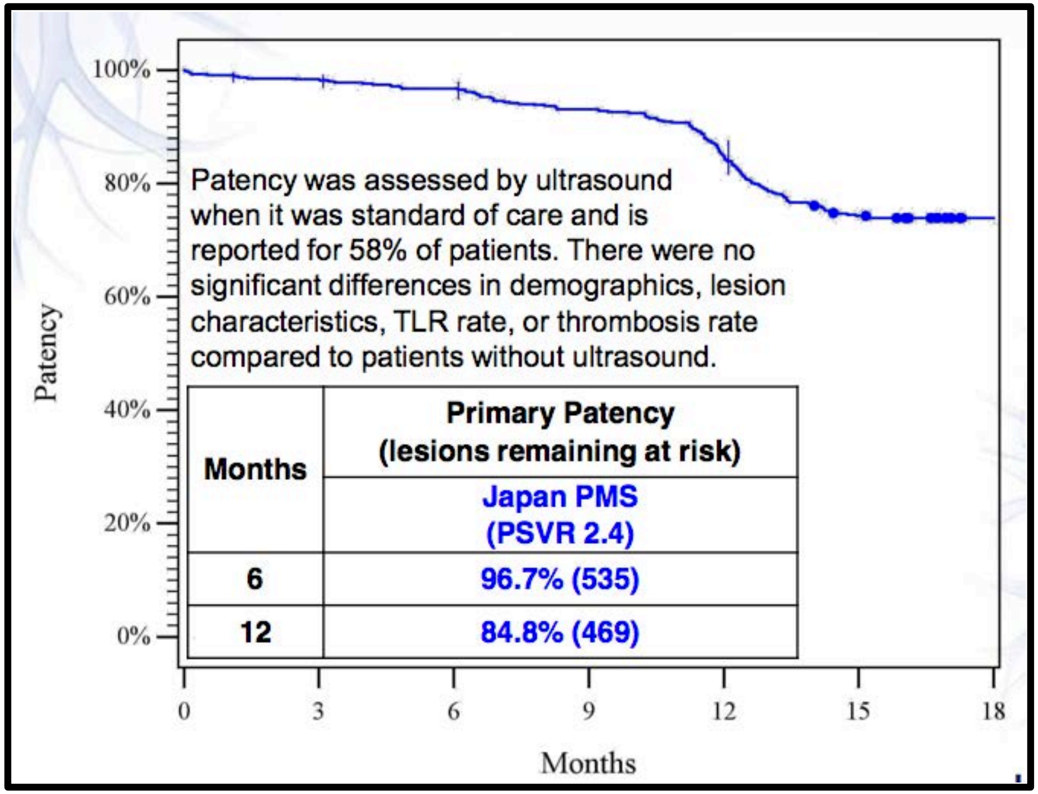
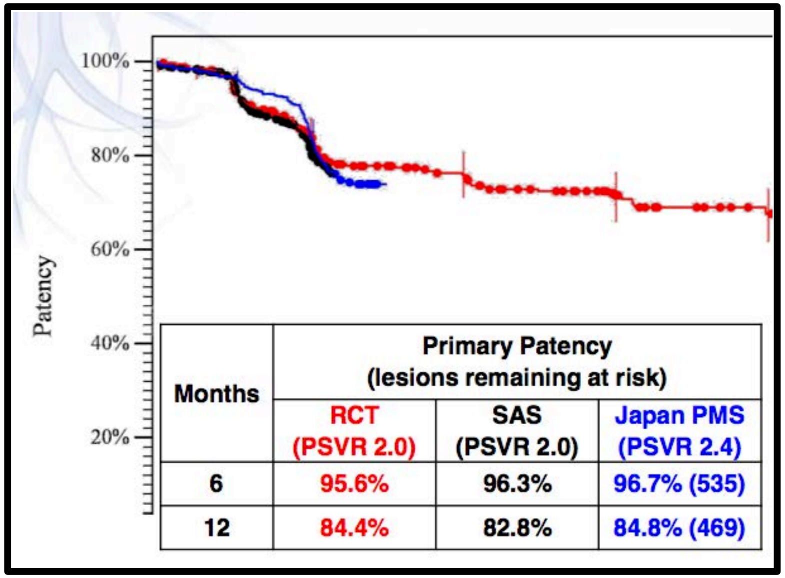
Zilver PTX Global Clinical Program



Patency was assessed by ultrasound when it was standard of care and is reported for 58% of patients. There were no significant differences in demographics, lesion characteristics, TLR rate, or thrombosis rate compared to patients without ultrasound.

Months	**Primary Patency (lesions remaining at risk)**
	Japan PMS (PSVR 2.4)
6	**96.7% (535)**
12	**84.8% (469)**

Yokoi H. Zilver Japan Data Presented at VIVA 2014



Months	**Primary Patency (lesions remaining at risk)**		
	RCT (PSVR 2.0)	**SAS (PSVR 2.0)**	**Japan PMS (PSVR 2.4)**
6	**95.6%**	**96.3%**	**96.7% (535)**
12	**84.4%**	**82.8%**	**84.8% (469)**

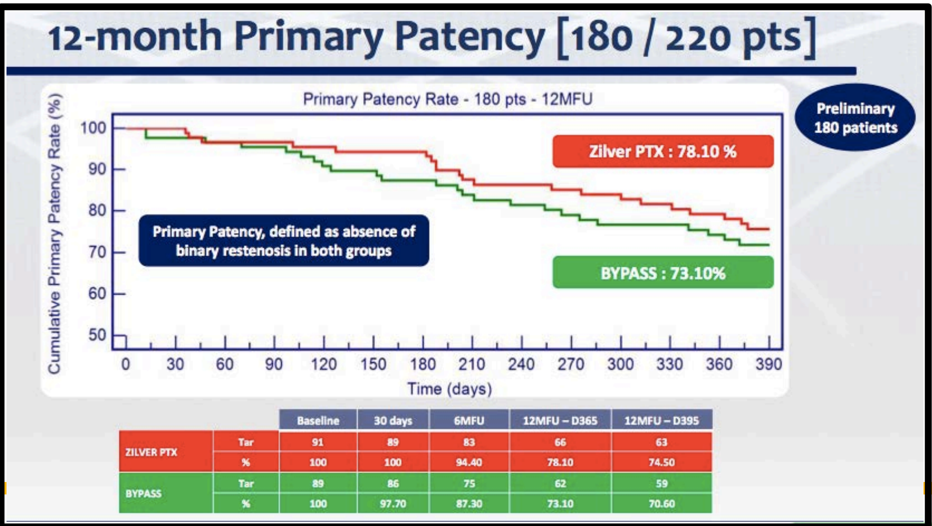
Japanese results superimposable on RCT results

Which Stent is Best for Various Fempop Anatomy

Drug-Coated / Drug-Eluting Stents

ZILVERPASS Trial:
ZilverPTX vs Prosthetic BPG in TASC C & D Lesions

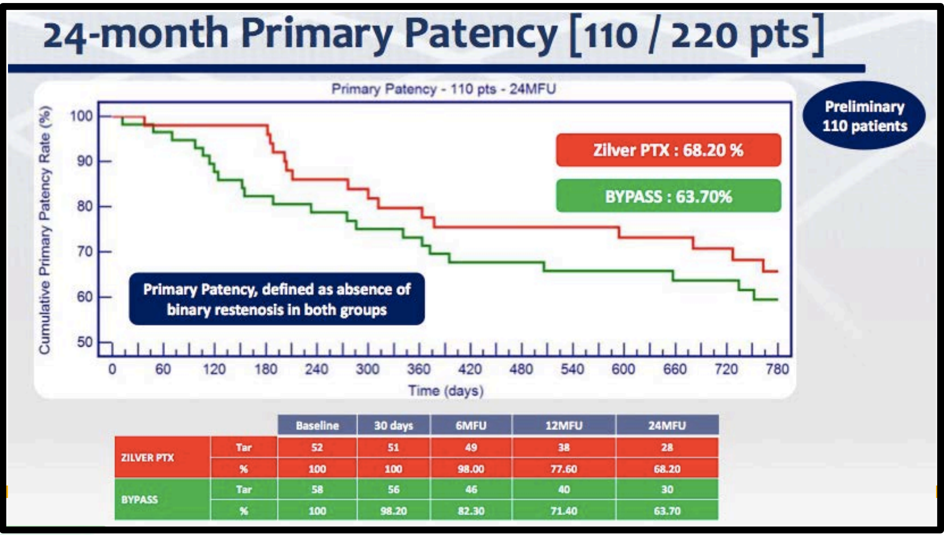
- Multicenter RCT in Belgium, Germany Italy, Brazil
- 220 patients randomized 1:1 to ZilverPTX vs prosthetic bypass graft
- Enrollment complete (LINC 2018, M Bosiers)
- Same outcome assessment (PSVR < 2.4 lesion or in bypass)
- Mean lesion length 24.7cm, 95% occlusions



12-month Primary Patency [180 / 220 pts]

Primary Patency, defined as absence of binary restenosis in both groups

		Baseline	30 days	6MFU	12MFU – D365	12MFU – D395
ZILVER PTX	Tar	91	89	83	66	63
	%	100	100	94.40	78.10	74.50
BYPASS	Tar	89	86	75	62	59
	%	100	97.70	87.30	73.10	70.60



24-month Primary Patency [110 / 220 pts]

Primary Patency, defined as absence of binary restenosis in both groups

		Baseline	30 days	6MFU	12MFU	24MFU
ZILVER PTX	Tar	52	51	49	38	28
	%	100	100	98.00	77.60	68.20
BYPASS	Tar	58	56	46	40	30
	%	100	98.20	82.30	71.40	63.70

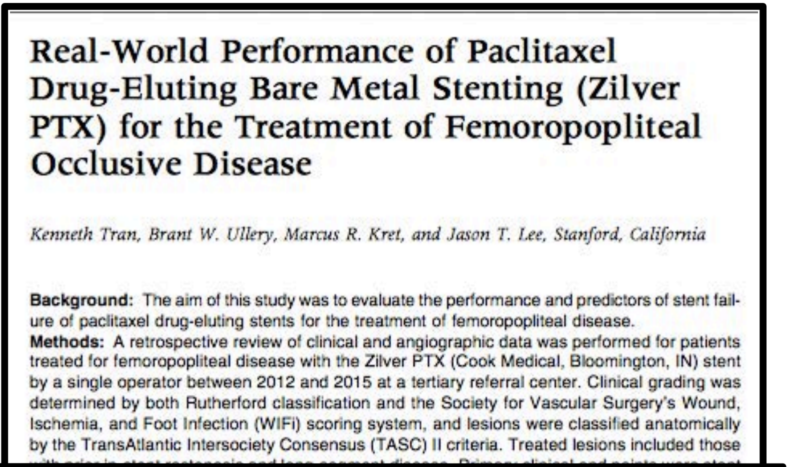
Interim results show numerically higher patency with ZilverPTX and non-inferiority compared to prosthetic bypass

Which Stent is Best for Various Fempop Anatomy

Drug-Coated / Drug-Eluting Stents

Stanford Real World ZilverPTX

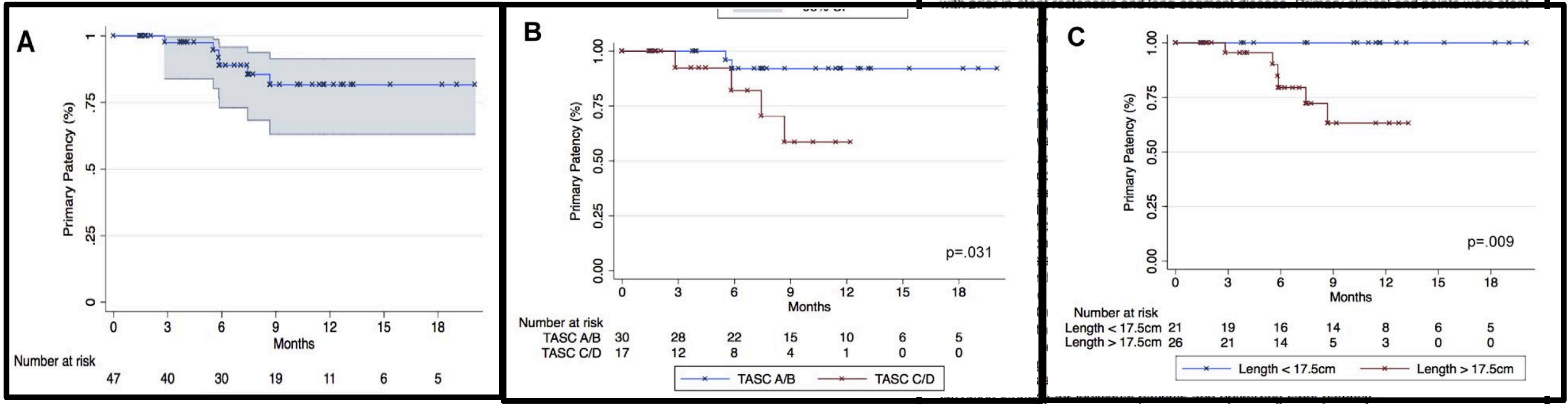
- Retrospective single center
  - 52 limbs (11mo mean f/u)
  - Claudicants 77%, CLI 23%
  - TASC C&D only 40.4%



Real-World Performance of Paclitaxel Drug-Eluting Bare Metal Stenting (Zilver PTX) for the Treatment of Femoropopliteal Occlusive Disease

Kenneth Tran, Brant W. Ullery, Marcus R. Kret, and Jason T. Lee, Stanford, California

Background: The aim of this study was to evaluate the performance and predictors of stent failure of paclitaxel drug-eluting stents for the treatment of femoropopliteal disease.
Methods: A retrospective review of clinical and angiographic data was performed for patients treated for femoropopliteal disease with the Zilver PTX (Cook Medical, Bloomington, IN) stent by a single operator between 2012 and 2015 at a tertiary referral center. Clinical grading was determined by both Rutherford classification and the Society for Vascular Surgery's Wound, Ischemia, and Foot Infection (WIFi) scoring system, and lesions were classified anatomically by the TransAtlantic Intersociety Consensus (TASC) II criteria. Treated lesions included those



d at the Vascular
eting, February 4–
res: None.
of Vascular Surgery, Stanford University Medical Center,
A.

Manuscript received: February 26, 2016; manuscript accepte
2016; published online: 20 August 2016

Tran K, et al. Ann Vasc Surg 2017

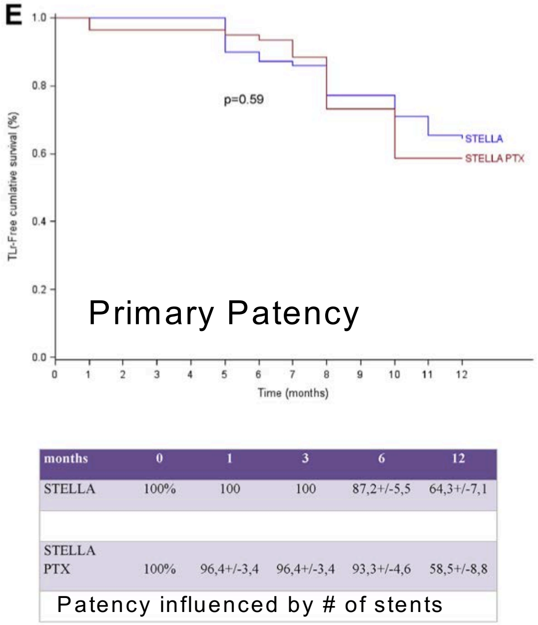
Primary Patency (12mo)		
	All patients	82%
	TASC C&D	~62%
	Lesion > 17.5cm	~59%

Which Stent is Best for Various Fempop Anatomy

Drug-Coated / Drug-Eluting Stents

French Propensity Matched Study

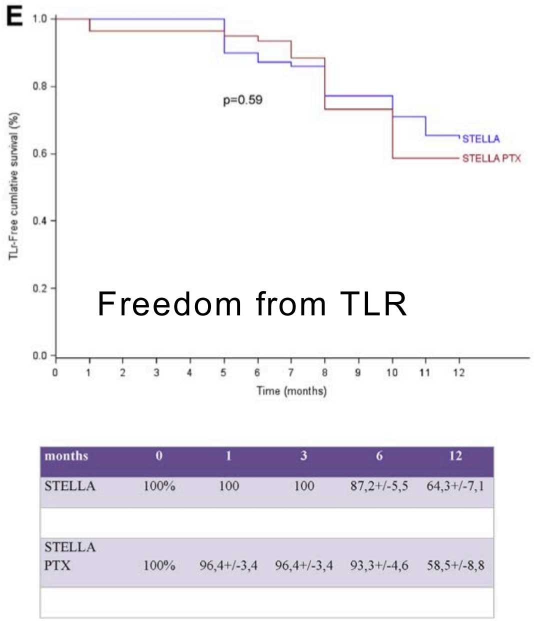
- Retrospective propensity matched analysis
  - 110 limbs (62 BMS, 48 ZilverPTX)
  - CLI 55%, Claudicants 45%
  - 100% TASC C&D
  - Mean LL 22cm BMS vs 25cm PTX (ns)



Primary Patency

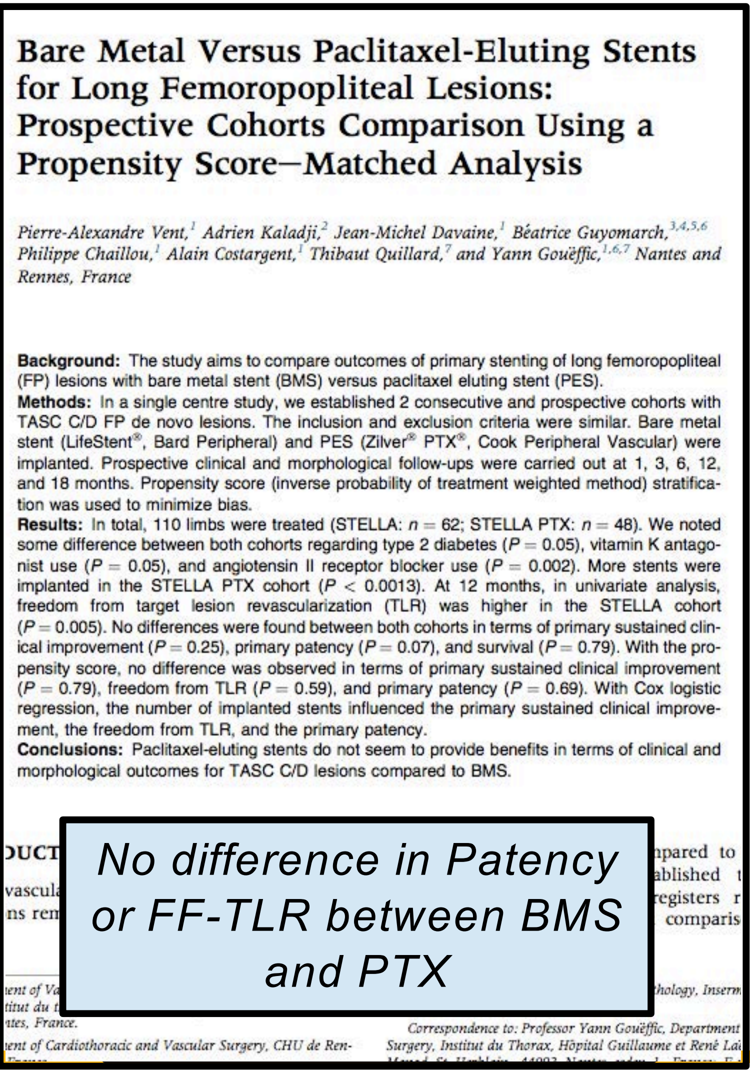
months	0	1	3	6	12
STELLA	100%	100	100	87,2+/-5,5	64,3+/-7,1
STELLA PTX	100%	96,4+/-3,4	96,4+/-3,4	93,3+/-4,6	58,5+/-8,8

Patency influenced by # of stents



Freedom from TLR

months	0	1	3	6	12
STELLA	100%	100	100	87,2+/-5,5	64,3+/-7,1
STELLA PTX	100%	96,4+/-3,4	96,4+/-3,4	93,3+/-4,6	58,5+/-8,8



Bare Metal Versus Paclitaxel-Eluting Stents for Long Femoropopliteal Lesions: Prospective Cohorts Comparison Using a Propensity Score–Matched Analysis

Pierre-Alexandre Vent,[1] Adrien Kaladji,[2] Jean-Michel Davaine,[1] Béatrice Guyomarch,[3,4,5,6] Philippe Chaillou,[1] Alain Costargent,[1] Thibaut Quillard,[7] and Yann Gouëffic,[1,6,7] Nantes and Rennes, France

Background: The study aims to compare outcomes of primary stenting of long femoropopliteal (FP) lesions with bare metal stent (BMS) versus paclitaxel eluting stent (PES).
Methods: In a single centre study, we established 2 consecutive and prospective cohorts with TASC C/D FP de novo lesions. The inclusion and exclusion criteria were similar. Bare metal stent (LifeStent®, Bard Peripheral) and PES (Zilver® PTX®, Cook Peripheral Vascular) were implanted. Prospective clinical and morphological follow-ups were carried out at 1, 3, 6, 12, and 18 months. Propensity score (inverse probability of treatment weighted method) stratification was used to minimize bias.
Results: In total, 110 limbs were treated (STELLA: $n = 62$; STELLA PTX: $n = 48$). We noted some difference between both cohorts regarding type 2 diabetes ($P = 0.05$), vitamin K antagonist use ($P = 0.05$), and angiotensin II receptor blocker use ($P = 0.002$). More stents were implanted in the STELLA PTX cohort ($P < 0.0013$). At 12 months, in univariate analysis, freedom from target lesion revascularization (TLR) was higher in the STELLA cohort ($P = 0.005$). No differences were found between both cohorts in terms of primary sustained clinical improvement ($P = 0.25$), primary patency ($P = 0.07$), and survival ($P = 0.79$). With the propensity score, no difference was observed in terms of primary sustained clinical improvement ($P = 0.79$), freedom from TLR ($P = 0.59$), and primary patency ($P = 0.69$). With Cox logistic regression, the number of implanted stents influenced the primary sustained clinical improvement, the freedom from TLR, and the primary patency.
Conclusions: Paclitaxel-eluting stents do not seem to provide benefits in terms of clinical and morphological outcomes for TASC C/D lesions compared to BMS.

No difference in Patency or FF-TLR between BMS and PTX

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UCLA Health

Which Stent is Best for Various Fempop Anatomy

Drug-Coated / Drug-Eluting Stents

Paclitaxel-eluting stent loses BATTLE against bare metal stent

2nd May 2018 👁 1287

The BATTLE trial comparing a drug-eluting stent (Zilver PTX, Cook Medical) vs. a bare metal stent (Misago, Terumo) for the treatment of intermediate femoropopliteal lesions has failed to the show superiority of the paclitaxel-coated stent at one-year follow-up. The trial highlights a need for further direct comparative data between devices and strategies for treatment of femoropopliteal lesions

The BATTLE Trial

- Multicenter RCT
- Designed as superior study
- ZilverPTX vs Misago (Terumo)

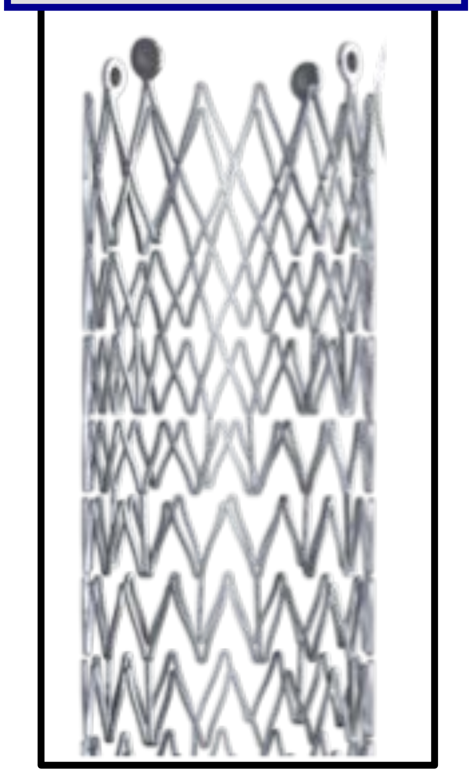
	ZilverPTX	Misago BMS	p
1° Primary	84%	82%	0.41
FF-TLR	91%	91%	0.91

Conclusion: *ZilverPTX not superior to fempop stenting with the Misago BMS*

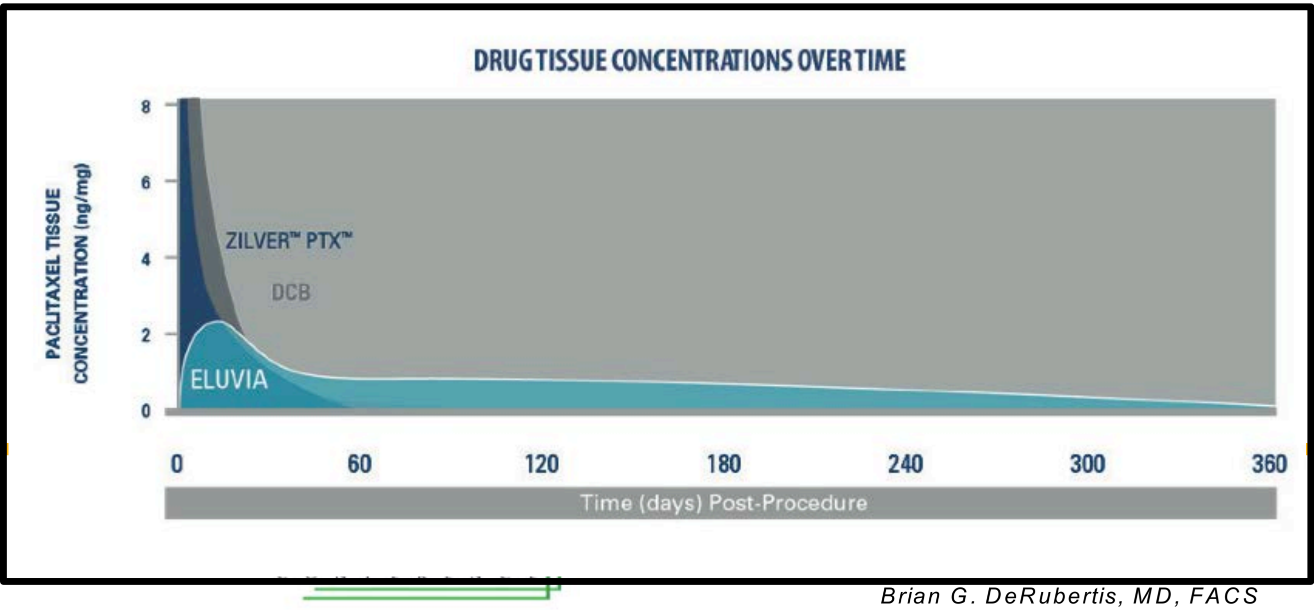
Which Stent is Best for Various Fempop Anatomy

Drug-Coated / Drug-Eluting Stents

Eluvia (Boston Scientific)



- Laser-cut nitinol stent with interconnecting bars
- Strut angles designed for optimizing radial force and flexibility
- Paclitaxel and polymer coating
- Drug-eluting (vs drug-coated)
- Improved drug kinetics vs ZilverPTX



Which Stent is Best for Various Fempop Anatomy

Drug-Coated / Drug-Eluting Stents

		Majestic Feasibility Eluvia DES (n=57)	Zilver PTX RCT DES Arm (n=241)
Lesion Length		7.1 cm	6.6 cm
CD-TLR	12mo	3.8%	9.5%
	24mo	7.5%	13.4%
	36mo	NR	16.0%
Primary Patency	12mo	96.1%	83.1%
	24mo	85.3%	74.8%
	36mo	NR	68.7%

Cardiovasc Intervent Radiol (2017) 40:1832–1838
DOI 10.1007/s00270-017-1771-5

CIRSE CrossMark

CLINICAL INVESTIGATION ARTERIAL INTERVENTIONS

Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3-Year Follow-up

Stefan Müller-Hülsbeck[1] · Koen Keirse[2] · Thomas Zeller[3] · Herman Schroë[4] · Juan Diaz-Cartelle[5]

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Abstract
Purpose To repo
first-in-human stu
Stent System for
Methods The pro
trial enrolled 57
ischemia (Rutherf
superficial femor
Mean lesion leng
lesions were oc
included primary
peak systolic velocity ratio of ≤2.5 and the absence of target lesion revascularization (TLR) or bypass. Safety monitoring through 3 years included adverse events and TLR.
Results Primary patency was estimated as 83.5% (Kaplan–Meier analysis) at 24 months, and 90.6% (48/53) of patients maintained an improvement in Rutherford class. At 36 months, the Kaplan–Meier estimate of freedom from TLR was 85.3%. No stent fractures were identified, and no major target limb amputations occurred.
Conclusion MAJESTIC results demonstrated long-term treatment durability among patients whose femoropopliteal arteries were treated with the paclitaxel-eluting Eluvia

y

tent ·
liteal artery ·

Majestic Trial
3-yr Outcomes
(*Card Int Rad 2017*)

Femoropopliteal artery disease treatment with polymer-coated drug-eluting stents was previously investigated in the SIROCCO [1] and STRIDES [2] studies of sirolimus- and everolimus-eluting stents, respectively. The prolonged elution profile enabled by a polymer coating theoretically allows the drug to protect against continued initiation of restenotic pathways caused by persistent mechanical forces on the vessel wall [3] and to inhibit downstream effectors activated weeks to months after stent implantation [4, 5]. Longer-term drug activity may be of particular importance in peripheral arteries, as restenosis follows a longer time-course than is observed following coronary interventions [6]. Results of these initial clinical studies of "-limus" eluting stents in the femoropopliteal segment were disappointing, however, as 1- and 2-year restenosis rates were similar to those of bare metal stents [1, 2]. More recently, antirestenotic potential of the alternative agent paclitaxel, applied with drug-coated balloons [7–10] or a polymer-free stent [11, 12], was confirmed in the peripheral vasculature.

The Eluvia Drug-Eluting Vascular Stent System (Boston Scientific, Marlborough, MA) combines paclitaxel with a biocompatible fluoropolymer coating on a stent scaffold and was designed to provide sustained drug release over time [13]. The first-in-human MAJESTIC clinical study

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[4] Ziekenhuis Oost-Limburg, Genk, Belgium

[5] Boston Scientific Corporation, Marlborough, MA, USA

Springer

IMPERIAL Trial

- 2:1 Randomization vs ZilverPTX
- 485 patients at up to 70 sites
- Single-blind non-inferiority
- 12mo results due at TCT 2018

Which Stent is Best for Various Fempop Anatomy

Drug-Coated / Drug-Eluting Stents

- Paclitaxol coating improves patency
- Current drug-coated technology
    - Performs well in TASC A&B
    - Does not appear to overcome the challenges of TASC C&D disease compared to BMS
- Will drug-eluting, rather than drug-coated, stents with newer laser-cut designs will have broader applicability?

Optimal Use:

Proximal SFA / SFA origin
Soft, non-calcified disease
TASC A & B Lesions

Which Stent is Best for Various Fempop Anatomy

PTFE-Coated Nitinol Scaffolds

Tigris Stent
(WL Gore)

	Tigris	Lifestent	P-value
Lesion Length	10.7 cm	11.8 cm	0.29
Stented Length	12.9 cm	14.9 cm	0.06
Occlusions	42%	37%	
2-yr Primary Patency (KM)	63%	67%	NS
2-yr Freedom from TLR	77%	81%	NS
Stent Fractures	0%	29%	<0.001

- Tigris Stent with nitinol wire scaffold and heparin-bonded PTFE coating
- RCT 3:1 Tigris (Gore) vs Lifestent (Bard)
- 274 patients randomized

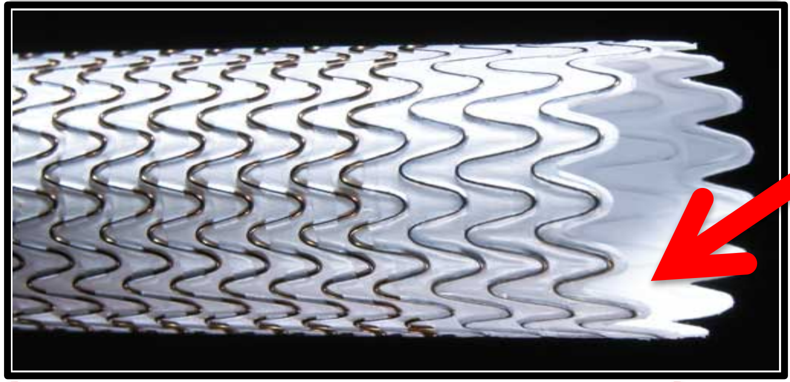
[1] Data from Tigris IDE Trial, Presented by John Laird, MD at VIVA 2016

Which Stent is Best for Various Fempop Anatomy

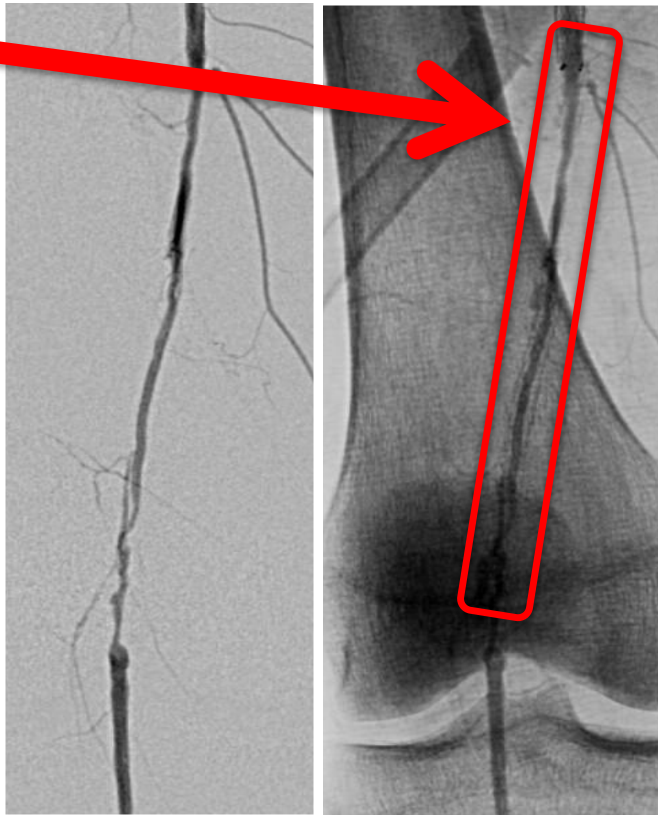
Covered Stents / Stent Grafts

PTFE covering prevents tissue ingrowth

Contoured edges designed to reduce edge stenosis



Heparin bonding to prevent thrombosis



Brian G. DeRubertis, MD, FACS

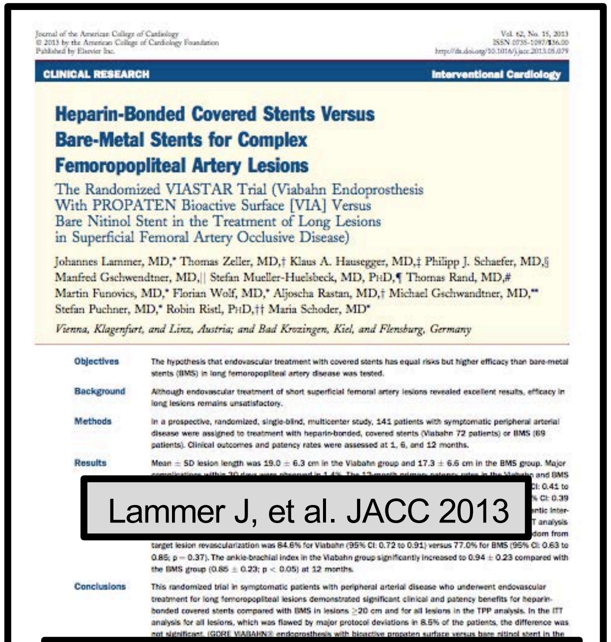
Which Stent is Best for Various Fempop Anatomy

Covered Stents / Stent Grafts

- 141 patients randomized to Viabahn vs BMS
- Lesion length: 19.0cm VIA, 17.3cm BMS
- Patency rates (12mo, intention to treat analysis):

	VIA	BMS
All	70.9%	55.1% (NS)
Lesion>20cm	71.3%	36.8% (p=0.01)

- Significant difference in PP for all-comers when analyzed by per protocol basis (78.1% vs 53.5%, p=0.009)



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CLINICAL RESEARCH — Interventional Cardiology

Heparin-Bonded Covered Stents Versus Bare-Metal Stents for Complex Femoropopliteal Artery Lesions

The Randomized VIASTAR Trial (Viabahn Endoprosthesis With PROPATEN Bioactive Surface [VIA] Versus Bare Nitinol Stent in the Treatment of Long Lesions in Superficial Femoral Artery Occlusive Disease)

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Vienna, Klagenfurt, and Linz, Austria; and Bad Krozingen, Kiel, and Flensburg, Germany

Objectives The hypothesis that endovascular treatment with covered stents has equal risks but higher efficacy than bare-metal stents (BMS) in long femoropopliteal artery disease was tested.

Background Although endovascular treatment of short superficial femoral artery lesions revealed excellent results, efficacy in long lesions remains unsatisfactory.

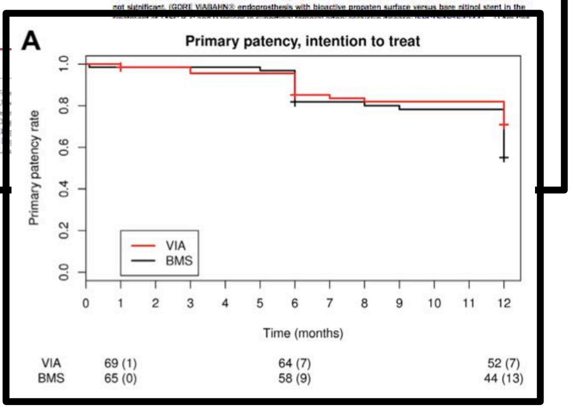
Methods In a prospective, randomized, single-blind, multicenter study, 141 patients with symptomatic peripheral arterial disease were assigned to treatment with heparin-bonded, covered stents (Viabahn 72 patients) or BMS (69 patients). Clinical outcomes and patency rates were assessed at 1, 6, and 12 months.

Results Mean ± SD lesion length was 19.0 ± 6.3 cm in the Viabahn group and 17.3 ± 6.6 cm in the BMS group. Major

target lesion revascularization was 84.6% for Viabahn (95% CI: 0.72 to 0.91) versus 77.0% for BMS (95% CI: 0.63 to 0.85; p = 0.37). The ankle-brachial index in the Viabahn group significantly increased to 0.94 ± 0.23 compared with the BMS group (0.85 ± 0.23; p < 0.05) at 12 months.

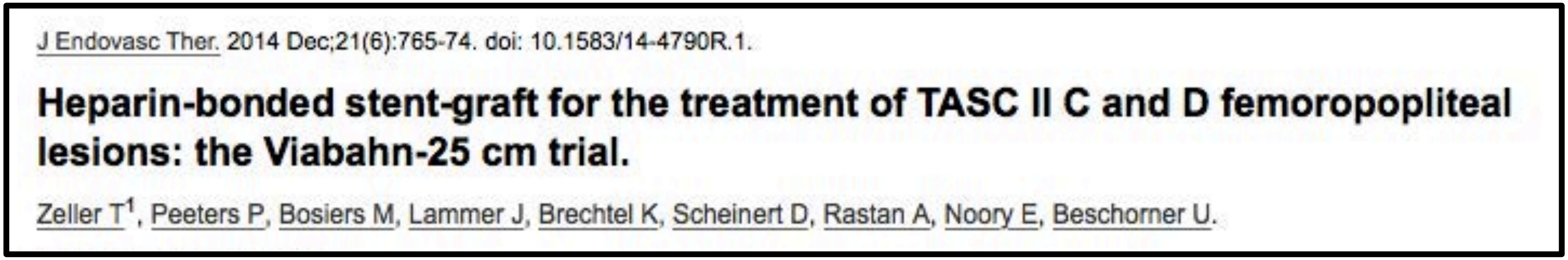
Conclusions This randomized trial in symptomatic patients with peripheral arterial disease who underwent endovascular treatment for long femoropopliteal lesions demonstrated significant clinical and patency benefits for heparin-bonded covered stents compared with BMS in lesions ≥20 cm and for all lesions in the TPP analysis. In the ITT analysis for all lesions, which was flawed by major protocol deviations in 8.5% of the patients, the difference was not significant. (GORE VIABAHN® endoprosthesis with bioactive propaten surface versus bare nitinol stent in the

Lammer J, et al. JACC 2013



Which Stent is Best for Various Fempop Anatomy

Covered Stents / Stent Grafts



J Endovasc Ther. 2014 Dec;21(6):765-74. doi: 10.1583/14-4790R.1.

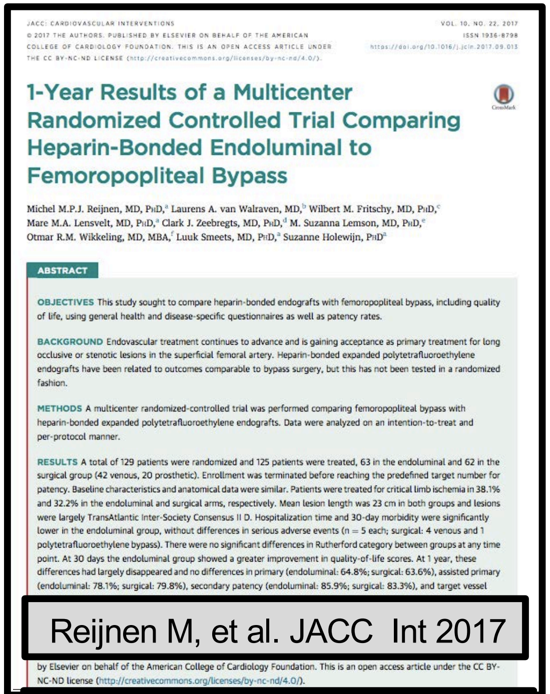
Heparin-bonded stent-graft for the treatment of TASC II C and D femoropopliteal lesions: the Viabahn-25 cm trial.

Zeller T[1], Peeters P, Bosiers M, Lammer J, Brechtel K, Scheinert D, Rastan A, Noory E, Beschorner U.

- Single-arm registry of 71 claudicants
- Mean lesion length: 26.5cm; 93% CTOs
- Patency rates @ 12 months
  - Primary 67.0%
  - Secondary 96.9%
- Device-related adverse event rate of 2.8%

Which Stent is Best for Various Fempop Anatomy

Covered Stents / Stent Grafts



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1-Year Results of a Multicenter Randomized Controlled Trial Comparing Heparin-Bonded Endoluminal to Femoropopliteal Bypass

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ABSTRACT

OBJECTIVES This study sought to compare heparin-bonded endografts with femoropopliteal bypass, including quality of life, using general health and disease-specific questionnaires as well as patency rates.

BACKGROUND Endovascular treatment continues to advance and is gaining acceptance as primary treatment for long occlusive or stenotic lesions in the superficial femoral artery. Heparin-bonded expanded polytetrafluoroethylene endografts have been related to outcomes comparable to bypass surgery, but this has not been tested in a randomized fashion.

METHODS A multicenter randomized-controlled trial was performed comparing femoropopliteal bypass with heparin-bonded expanded polytetrafluoroethylene endografts. Data were analyzed on an intention-to-treat and per-protocol manner.

RESULTS A total of 129 patients were randomized and 125 patients were treated, 63 in the endoluminal and 62 in the surgical group (42 venous, 20 prosthetic). Enrollment was terminated before reaching the predefined target number for patency. Baseline characteristics and anatomical data were similar. Patients were treated for critical limb ischemia in 38.1% and 32.2% in the endoluminal and surgical arms, respectively. Mean lesion length was 23 cm in both groups and lesions were largely TransAtlantic Inter-Society Consensus II D. Hospitalization time and 30-day morbidity were significantly lower in the endoluminal group, without differences in serious adverse events (n = 5 each; surgical: 4 venous and 1 polytetrafluoroethylene bypass). There were no significant differences in Rutherford category between groups at any time point. At 30 days the endoluminal group showed a greater improvement in quality-of-life scores. At 1 year, these differences had largely disappeared and no differences in primary (endoluminal: 64.8%; surgical: 63.6%), assisted primary (endoluminal: 78.1%; surgical: 79.8%), secondary patency (endoluminal: 85.9%; surgical: 83.3%), and target vessel

Reijnen M, et al. JACC Int 2017

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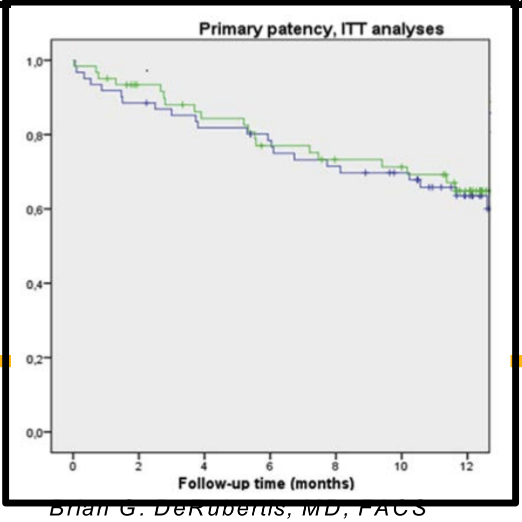
SuperB Study

- 125 patients randomized to covered stent vs vein (n=42) or PTFE (n=20) bypass
- Mean lesion length 23cm
- Patency rates at 12 months:

	VIA	Bypass
Primary	64.8%	63.6% (ns)
Secondary	85.9%	83.3% (ns)
FF-TLR	72.1%	71.05 (ns)



Primary patency, ITT analyses

Which Stent is Best for Various Fempop Anatomy

Covered Stents / Stent Grafts

- No difference from BMS for short segment disease
- Covered stents appear to have a patency advantage compared to BMS in long (>20cm) segment disease
- Remaining concerns
  - Loss of collaterals / acute ischemia with failure
  - Limited compression resistance

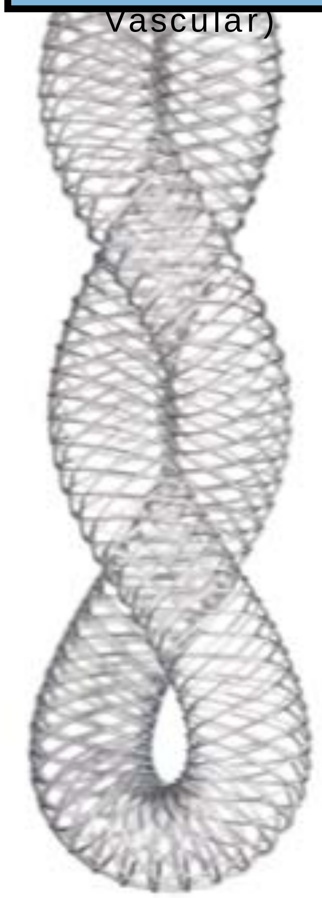
Optimal Use:

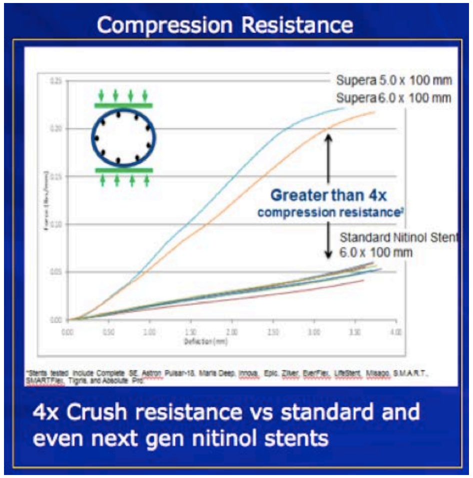
Long lesions (>20cm)
Recurrent long-segment stenosis
Long-segment ISR

Which Stent is Best for Various Fempop Anatomy

Woven Nitinol Stents

Supera Stent (Abbott Vascular)



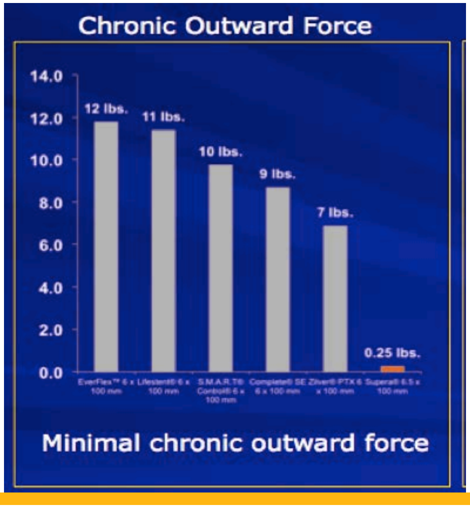


Compression Resistance

*Stents tested include Complete SE, Astron Pulsar-18, Maris Deep, Innova, Epic, Zilver, EverFlex, LifeStent, Misago, S.M.A.R.T., SMARTFlex, Tigris, and Absolute Pro.

4x Crush resistance vs standard and even next gen nitinol stents

Flexibility and crush resistance required to withstand mechanical forces of residual plaque burden and dynamic forces across joints



Chronic Outward Force

Minimal chronic outward force

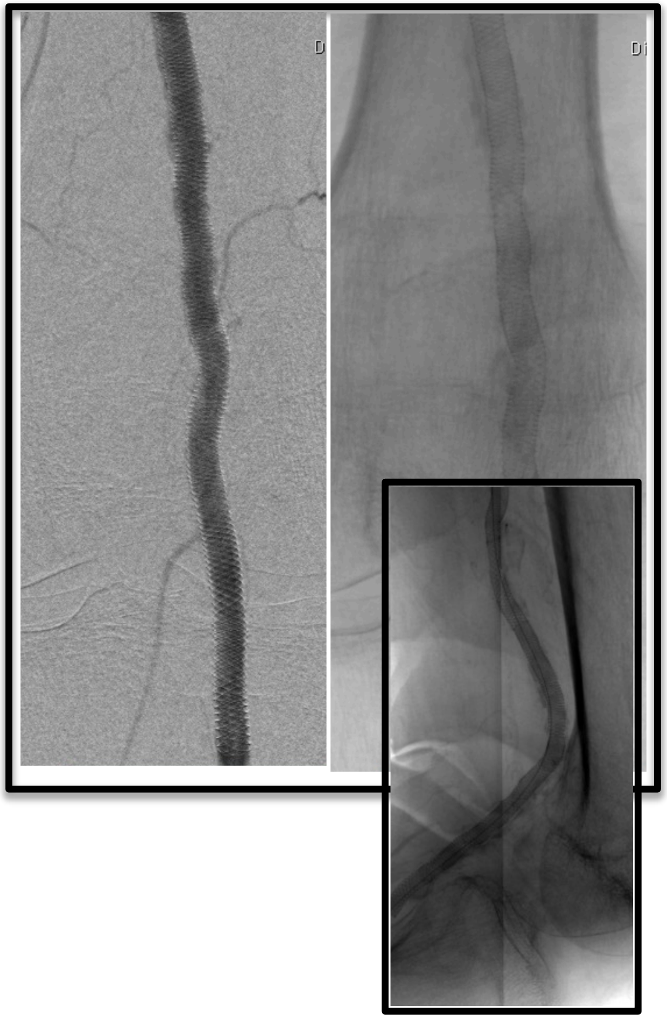
While it cannot exclude tissue as a covered stent, it appears to have less tendency to trigger intimal hyperplasia due to lack of chronic outward radial force

Which Stent is Best for Various Fempop Anatomy

Woven Nitinol Stents

Which Stent is Best for Various Fempop Anatomy

Woven Nitinol Stents

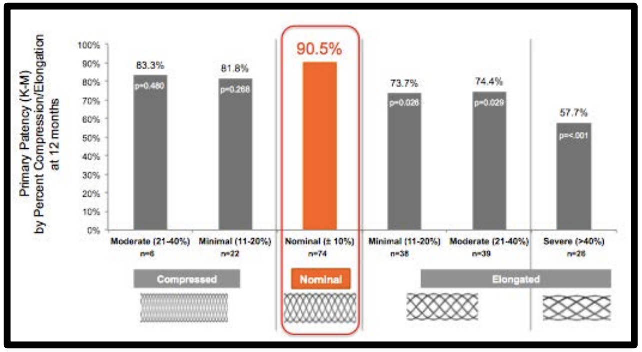


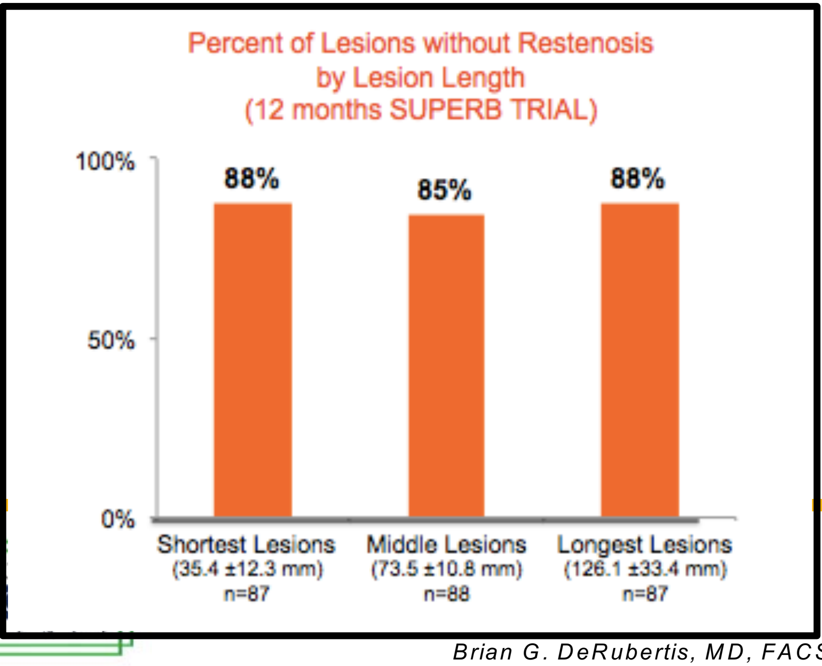
Which Stent is Best for Various Fempop Anatomy

Woven Nitinol Stents

SUPERB Trial (Supera IDE Study)

- Prospective core lab adjudicated registry and IDE trial for FDA approval
- 264 patients, mean lesion length of 7.8cm, 73% moderate/severe Ca++
- Primary patency at 12 mo – 86.3% overall, 90.5% when deployed to nominal length
- Zero fractures at 1 year
- Results in SUPERB trial were equivalent over different lesion lengths

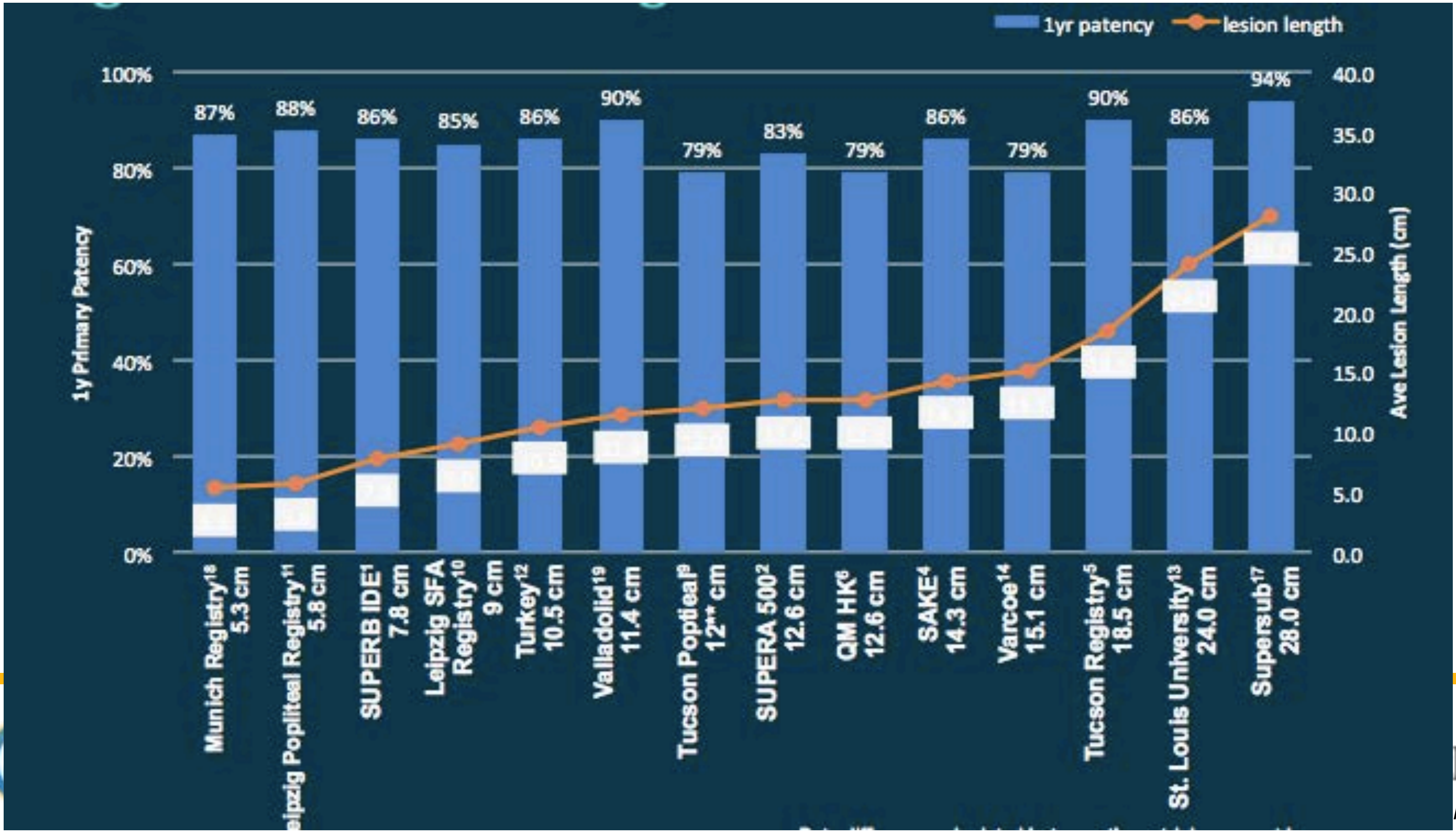




Which Stent is Best for Various Fempop Anatomy

Woven Nitinol Stents

- Consistent data from multiple centers demonstrating 12mo patency rates 80-95% independent of lesion length or implant length



Which Stent is Best for Various Fempop Anatomy

Woven Nitinol Stents

- Consistently high patency rates across multiple reports supports use across multiple lesion types
- Results unaffected by calcium burden & lesion length
- No level I data or comparator arms limits our ability to objectively evaluate the device
- Deployment accuracy remains difficult (proximal SFA)

Optimal Use:

Long segment disease
Heavily calcified disease
Distal SFA, Hunter's canal, popliteal

Which Stent is Best for Various Fempop Anatomy

Conclusions

- Stents will continue to be necessary in complex disease
- BMS is becoming below the standard of care, particularly in complex disease
- Next-generation stents should be matched to the particular disease and lesion characteristics in which they best perform

Stent Type	Best Use
Drug-coated stents	Proximal SFA Soft, non-calcified TASC A&B
Covered stents	Long-segment disease Diffuse restenosis
Interwoven nitinol	Long-segment disease Distal SFA, Hunter’s canal, popliteal Heavily calcified disease

Which Stent Is Best for Various Femoropopliteal Anatomy?

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