CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
JANUARY 23-25 2014
MARRIOTT RIVE GAUCHE & CONFERENCE CENTER PARIS, FRANCE

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University Heart-Center
Freiburg-Bad Krozingen
Bad Krozingen
Germany

Femoro-popliteal Angioplasty: *When a stent is needed, do you choose a bare stent or a covered stent? Bare stent and I'll tell you why*

My Disclosures:

Advisory Board:

Medtronic-Invatec, Gore, Angioslide, MEDRAD, Medtronic-Ardian, Covedian-ev3

Consulting Fees/Honoraria:

Sanofi-Aventis, C.R. Bard, J&J Cordis, ev3, Boston Scientific, Straub Medical, Invatec, Biotronik, Optimed, Medrad

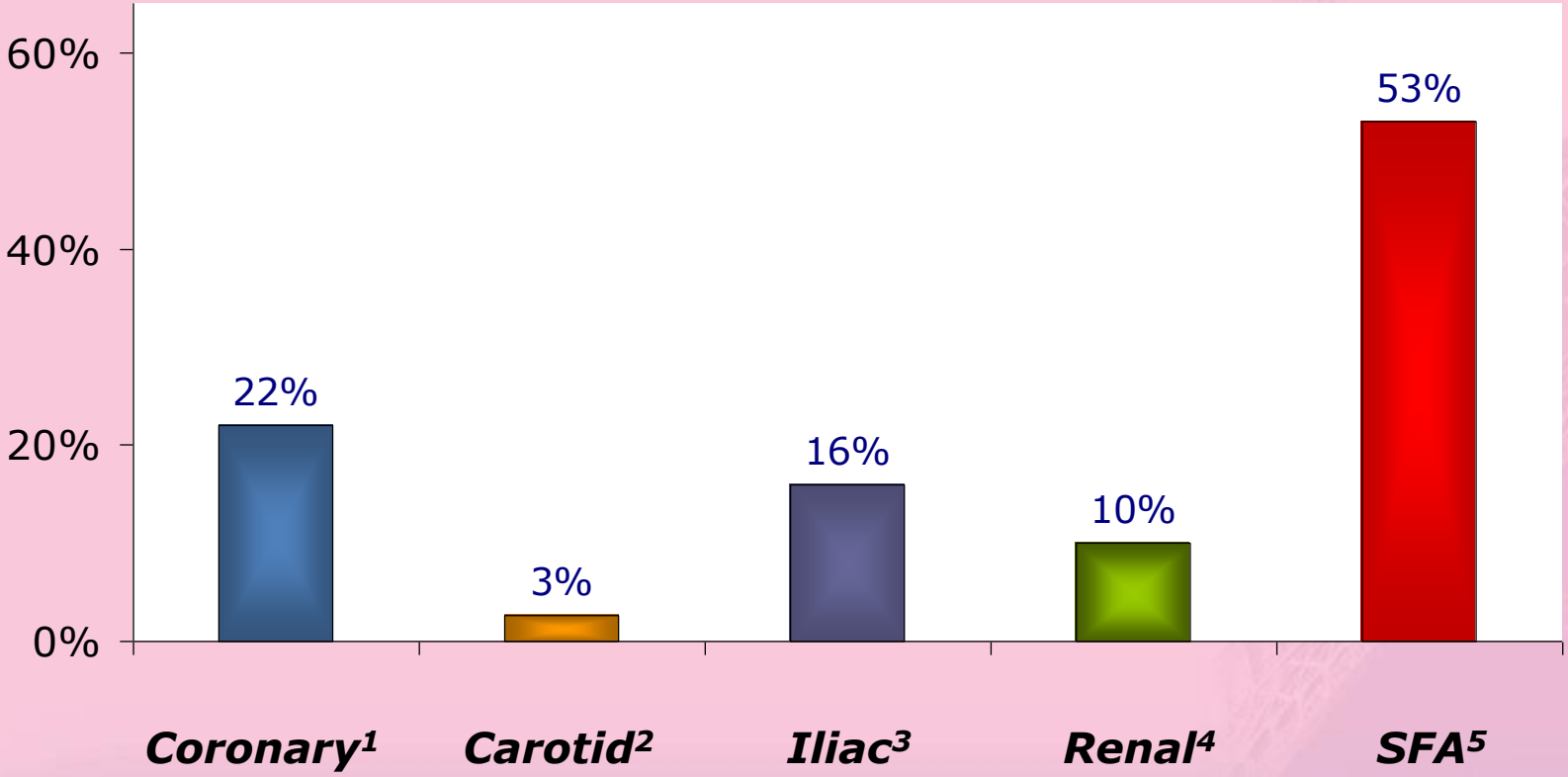
Research Grants:

Cook, Krauth Medical, Pathway Medical, Abbott Vascular, J&J Cordis, Angioslide, Ardian, Biotronik, Invatec, InnoRa

Endovascular Therapy

Durability Stratified to Lesion Location

Comparison of restenosis rates after interventional therapy in different vascular territories

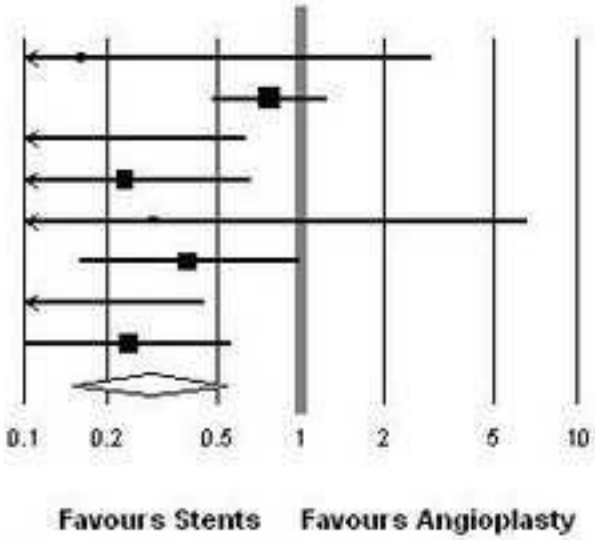


[1]Serruys PW et al. (1994); [2]Wholey MH et al. (2003); [3]Scheinert D et al. (2001); [4]Zeller T et al. (2004); [5]Conroy RM et al. (2000)

Meta-Analysis POBA vs. BMS

Immediate Failure

Study name	Stent type	Time point	Statistics for each study: Risk ratio	Lower limit	Upper limit	p-Value	Failure / Total: Stent	Angioplasty	Relative weight
Vroegindeweij	Palmaz	1997	0.16	0.01	2.95	0.218	0 / 24	3 / 27	4.2
Intra Coil	Nitinol	2001	0.77	0.48	1.25	0.291	25 / 177	32 / 175	24.1
Cejna	Palmaz	2001	0.08	0.01	0.63	0.016	1 / 77	12 / 77	7.5
Becquemin	Palmaz	2003	0.23	0.08	0.66	0.006	4 / 115	17 / 112	15.9
Saxon	Stent-graft	2003	0.29	0.01	6.60	0.439	0 / 15	1 / 13	3.7
Mabahn	Stent-graft	2005	0.39	0.16	0.95	0.038	6 / 97	16 / 100	18.1
Schillinger	Nitinol	2006	0.06	0.01	0.44	0.006	1 / 51	17 / 53	7.7
Krankenberg	Nitinol	2007	0.24	0.10	0.56	0.001	6 / 123	25 / 121	18.7
Summary risk ratio			0.28	0.15	0.54	0.000			



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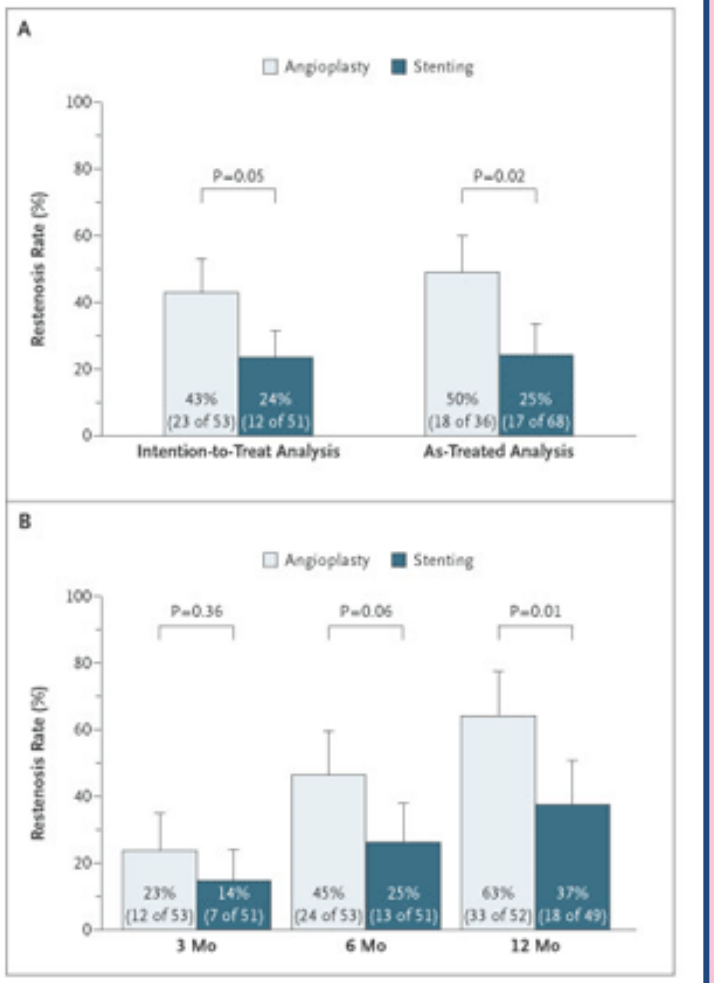
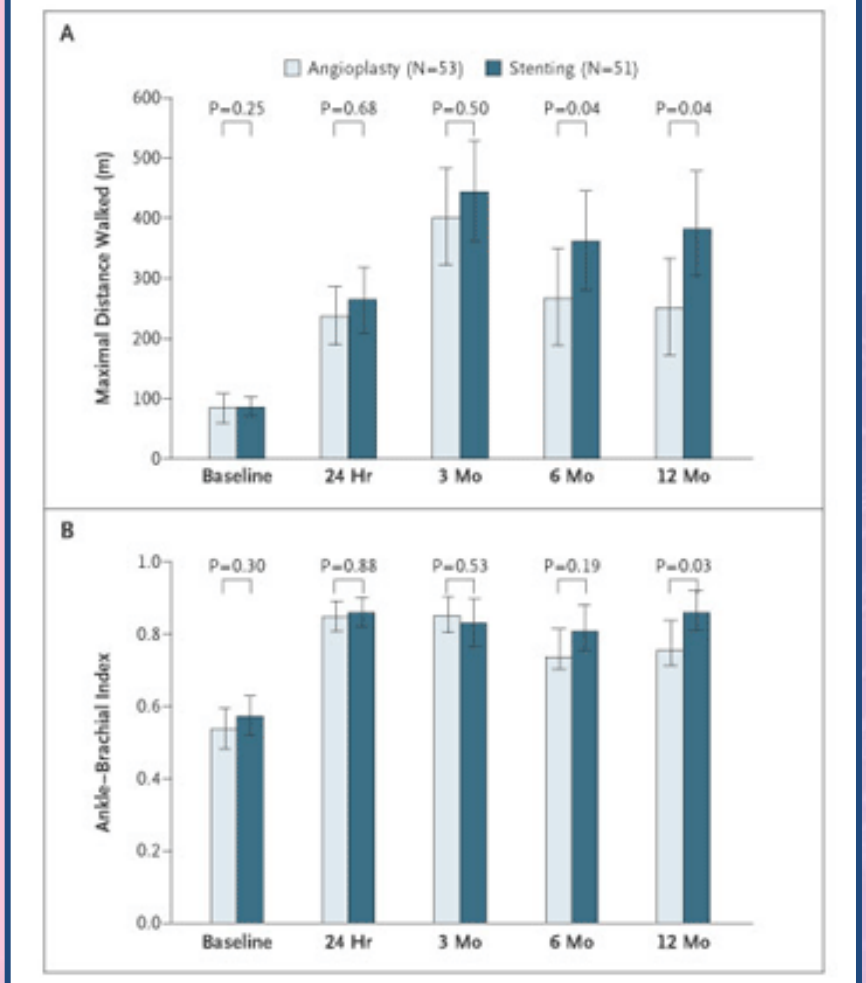
Kasapis C et al. European Heart Journal 2008

PTA and BMS in SFA

Vienna Absolute 1 Year Results

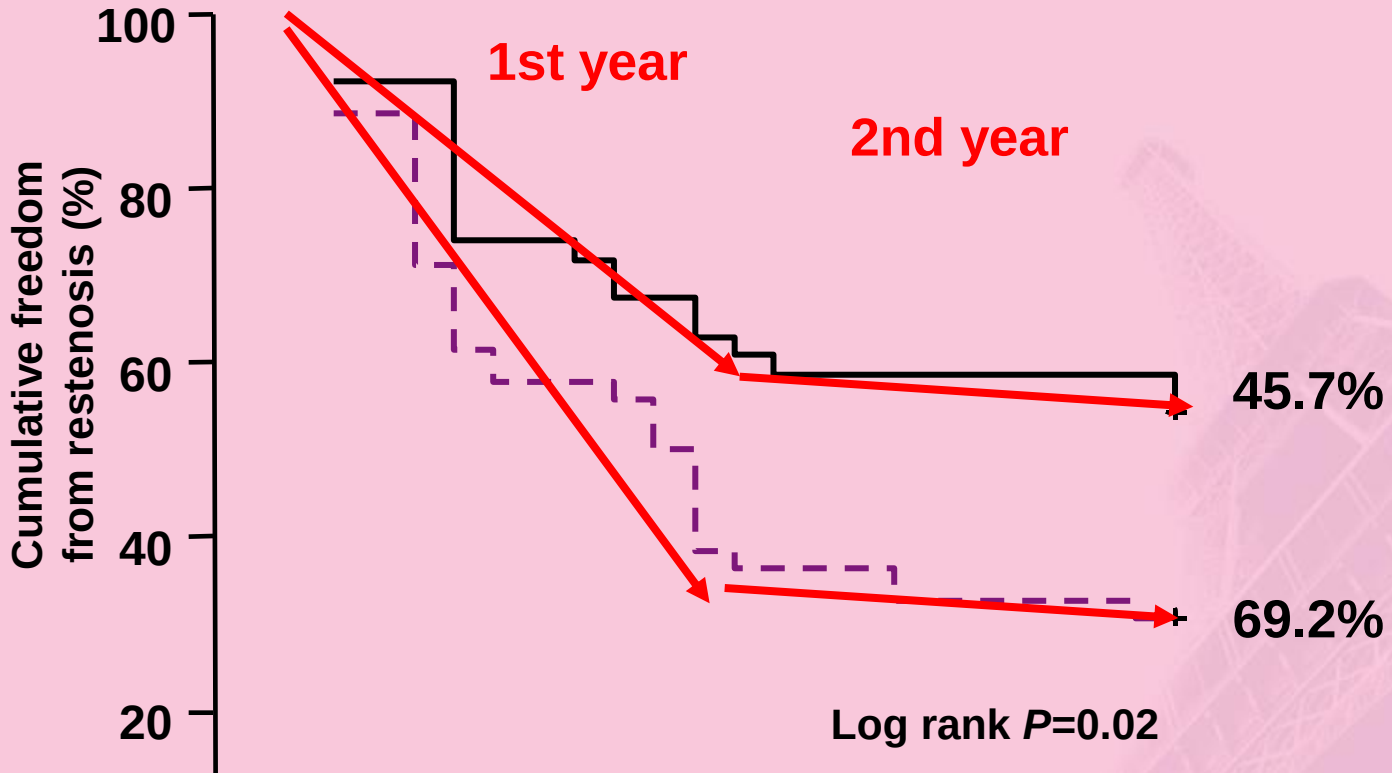




Schillinger M et al. NEJM 2006

ABSOLUTE Trial

Pattern of Restenosis until 24 months

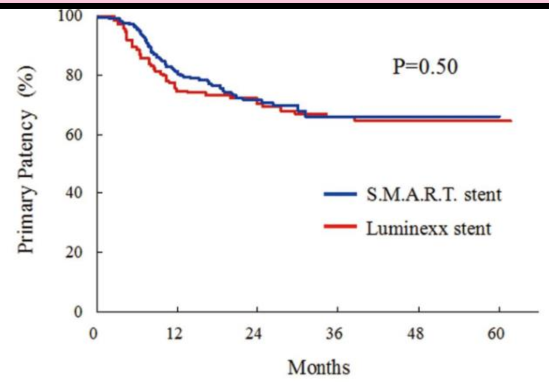


- Sustained benefit of nitinol stents @ 2-year follow-up
- No ‘catch-up’ phenomenon
- Restenosis later than 12 months was rare

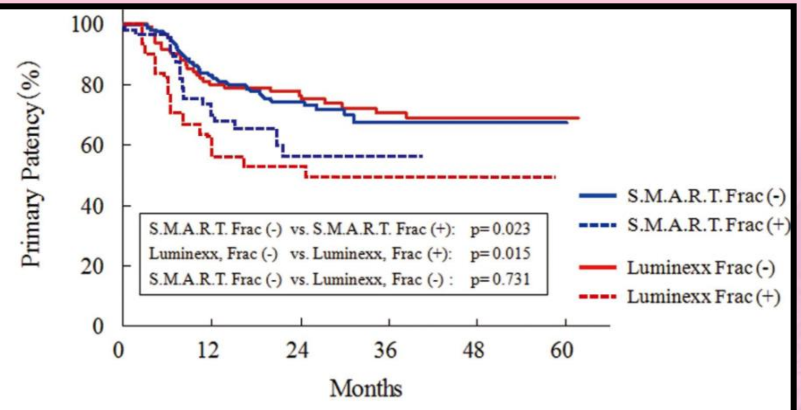
Schillinger M et al. *N Engl J Med.* 2006;354:1879-1888
Circulation. 2007;115:2745-2749

Femoro-popliteal BMS Stenting

Comparison of Different Designs



Months		0	12	24	36	48	60
at risk	– (blue)	503	291	88	13	4	3
	– (red)	135	89	71	54	23	2
Patency, %	– (blue)	100	81.3	72.0	66.4	66.4	66.4
	– (red)	100	74.6	69.9	65.7	64.3	64.3
SE	– (blue)	0.000	0.019	0.025	0.037	0.037	0.146
	– (red)	0.000	0.039	0.042	0.044	0.045	0.045
P value			0.0777	0.4158	0.5185	0.4992	0.4992

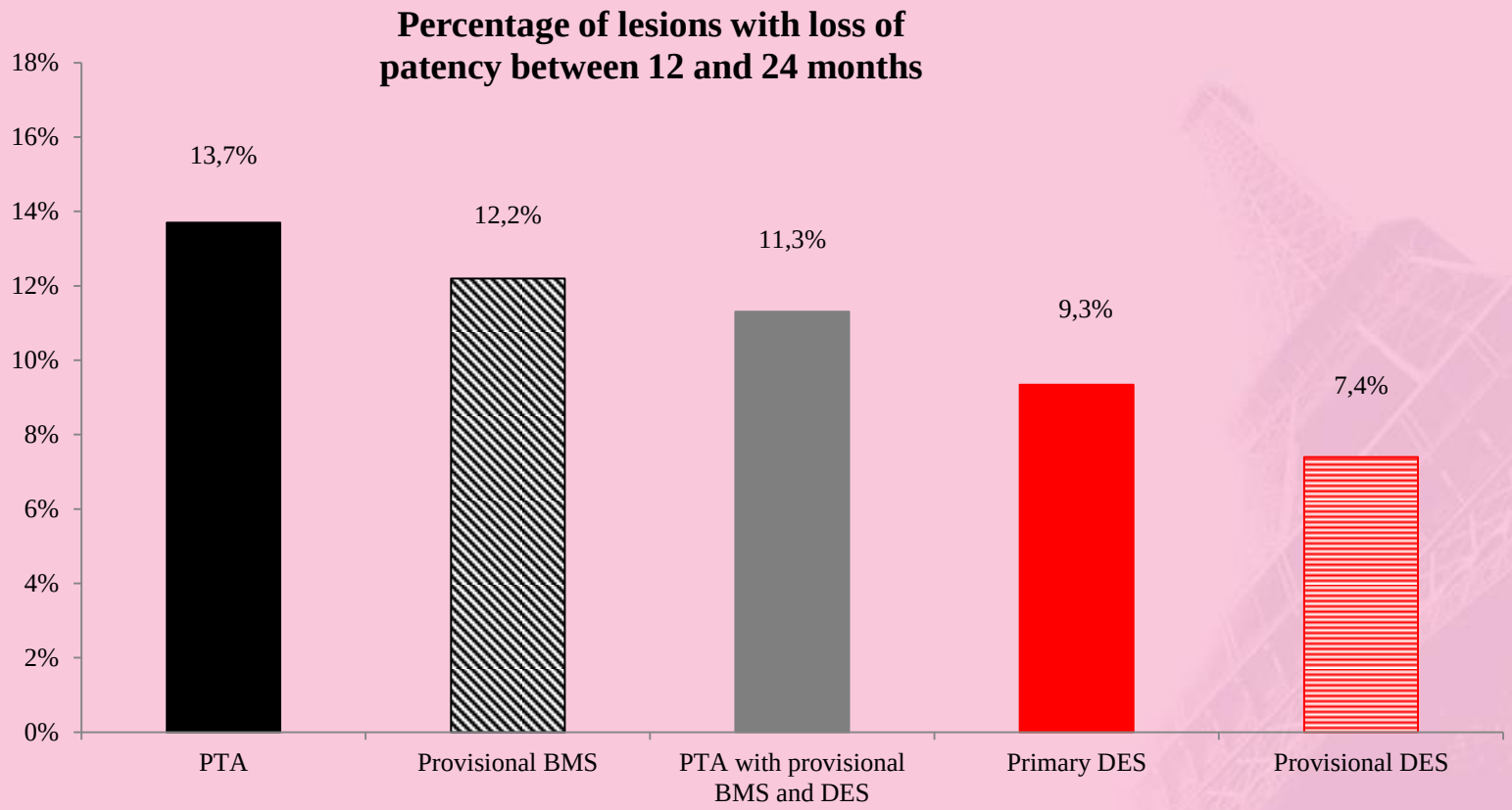


Months		0	12	24	36	48	60
at risk	S-F(-)	446	252	78	11	3	3
	S-F(+)	57	38	9	1		
	L-F(-)	104	73	57	41	13	2
	L-F(+)	31	16	14	13	10	10
Patency, %	S-F(-)	100	82.6	74.0	67.4	67.4	67.4
	S-F(+)	100	71.4	56.4	56.4		
	L-F(-)	100	80.2	75.1	70.7	68.7	68.7
	L-F(+)	100	56.5	52.9	49.1	49.1	49.1
SE	S-F(-)	0.000	0.020	0.026	0.041	0.041	0.041
	S-F(+)	0.000	0.060	0.081	0.081		
	L-F(-)	0.000	0.041	0.045	0.049	0.052	0.052
	L-F(+)	0.000	0.091	0.092	0.093	0.093	0.093

Iida O et al. Circ J 2011;76:421-426

Zilver PTX

Percentage of lesions with loss of patency between 12 and 24 months



Dake et al. Circ Cardiovasc Intervent 2012

PTA and BMS in SFA

RESILIANT

Nitinol Stent Implantation Versus Balloon Angioplasty for Lesions in the Superficial Femoral Artery and Proximal Popliteal Artery

Twelve-Month Results From the RESILIENT Randomized Trial

John R. Laird, MD; Barry T. Katzen, MD; Dierk Scheinert, MD; Johannes Lammer, MD; Jeffrey Carpenter, MD; Maurice Buchbinder, MD; Rajesh Dave, MD; Gary Ansel, MD; Alexandra Lansky, MD; Ecaterina Cristea, MD; Tyrone J. Collins, MD; Jeffrey Goldstein, MD; Michael R. Jaff, DO; for the RESILIENT Investigators

Background—Controversy still exists regarding the best endovascular treatment strategy for patients with symptomatic disease of the superficial femoral artery. There are conflicting data regarding the benefits of superficial femoral artery stenting and the role of primary stenting compared with balloon angioplasty with provisional stent implantation.

Methods and Results—A total of 206 patients from 24 centers in the United States and Europe with obstructive lesions of the superficial femoral artery and proximal popliteal artery and intermittent claudication were randomized to implantation of nitinol stents or percutaneous transluminal angioplasty. The mean total lesion length was 71 mm for the stent group and 64 mm for the angioplasty group. Acute lesion success (<30% residual stenosis) was superior for the stent group compared with the angioplasty group (95.8% versus 83.9%; $P<0.01$). Twenty-nine (40.3%) patients in the angioplasty group underwent bailout stenting because of a suboptimal angiographic result or flow-limiting dissection. Bailout stenting was treated as a target lesion revascularization and loss of primary patency in the final analysis. At 12 months, freedom from target lesion revascularization was 87.3% for the stent group compared with 45.1% for the angioplasty group ($P<0.0001$). Duplex ultrasound-derived primary patency at 12 months was better for the stent group (81.3% versus 36.7%; $P<0.0001$). Through 12 months, fractures occurred in 3.1% of stents implanted. No stent fractures resulted in loss of patency or target lesion revascularization.

Conclusions—In this multicenter trial, primary implantation of a self-expanding nitinol stent for moderate-length lesions in the superficial femoral artery and proximal popliteal artery was associated with better acute angiographic results and improved patency compared with balloon angioplasty alone.

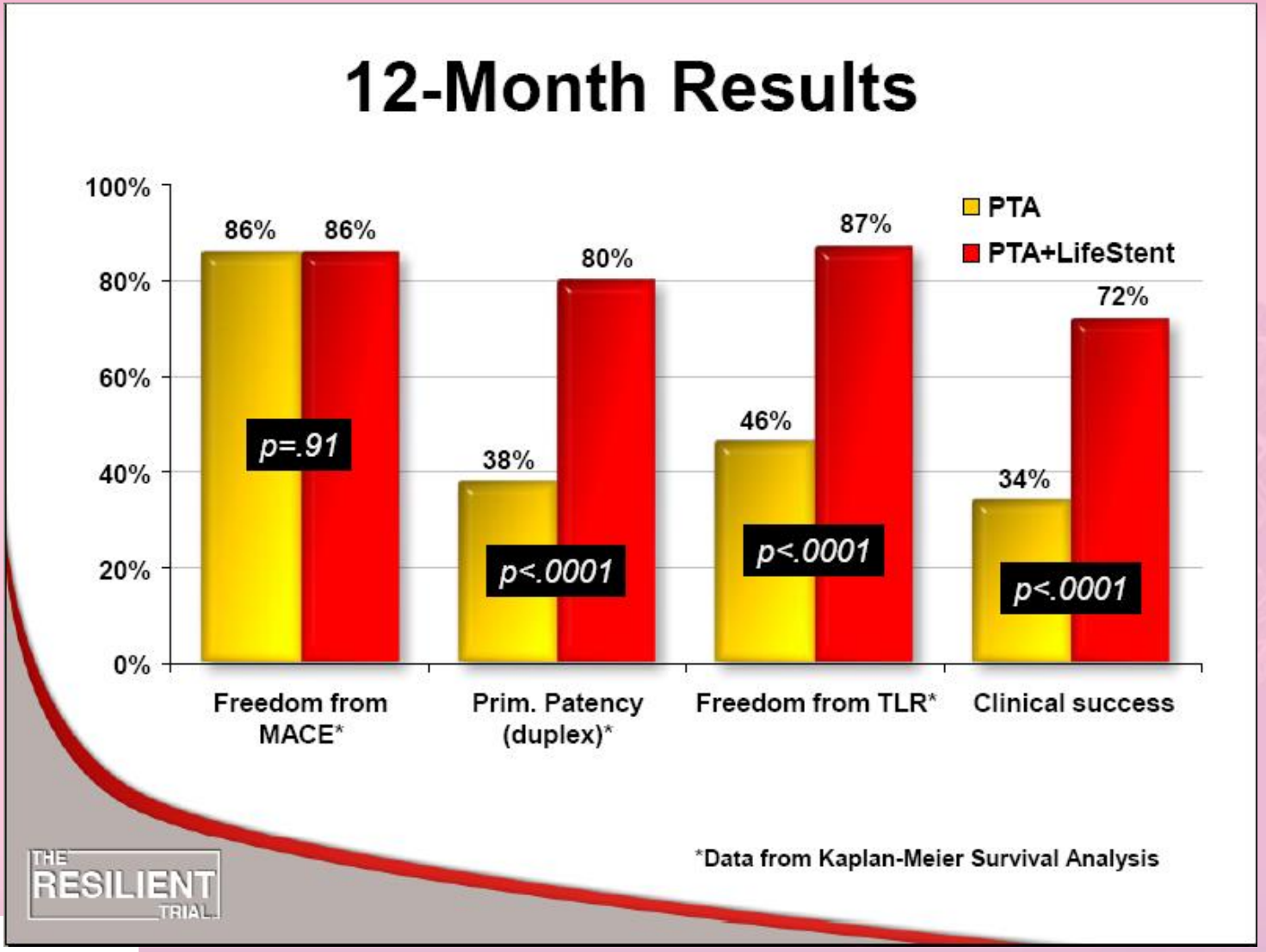
Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00673985.

(*Circ Cardiovasc Interv*. 2010;3:267-276.)

Key Words: angioplasty ■ stents ■ peripheral vascular disease

PTA and BMS in SFA

RESILIANT



Laird JR et al. Circ Cardiovasc Intervent. 2010;3:267-276

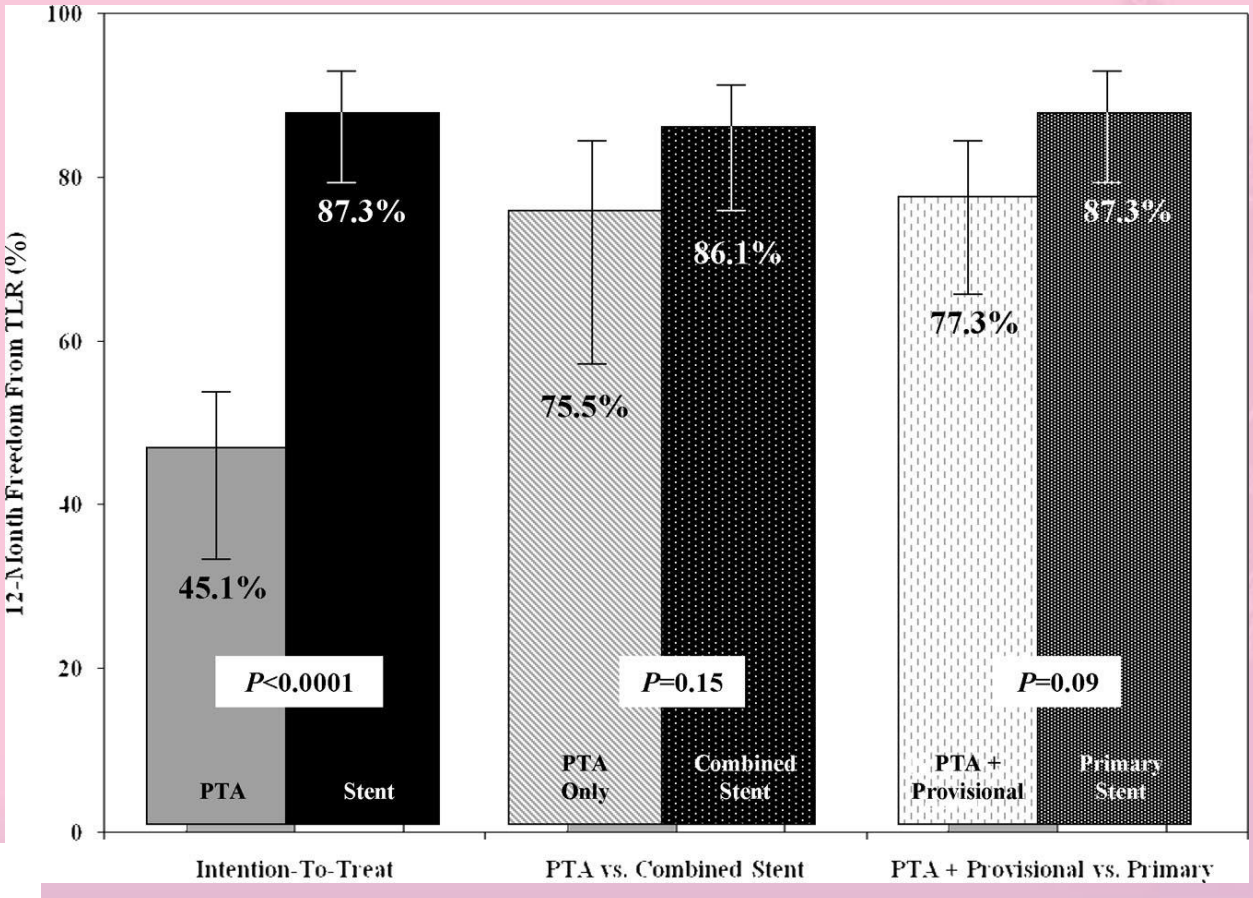
RESILIANT

Freedom from TLR at 12 months (per-protocol & post hoc analyses)

First: PTA vs. stent group ITT

Second: as-treated analysis PTA vs. combined (primary plus provisional)-stent group

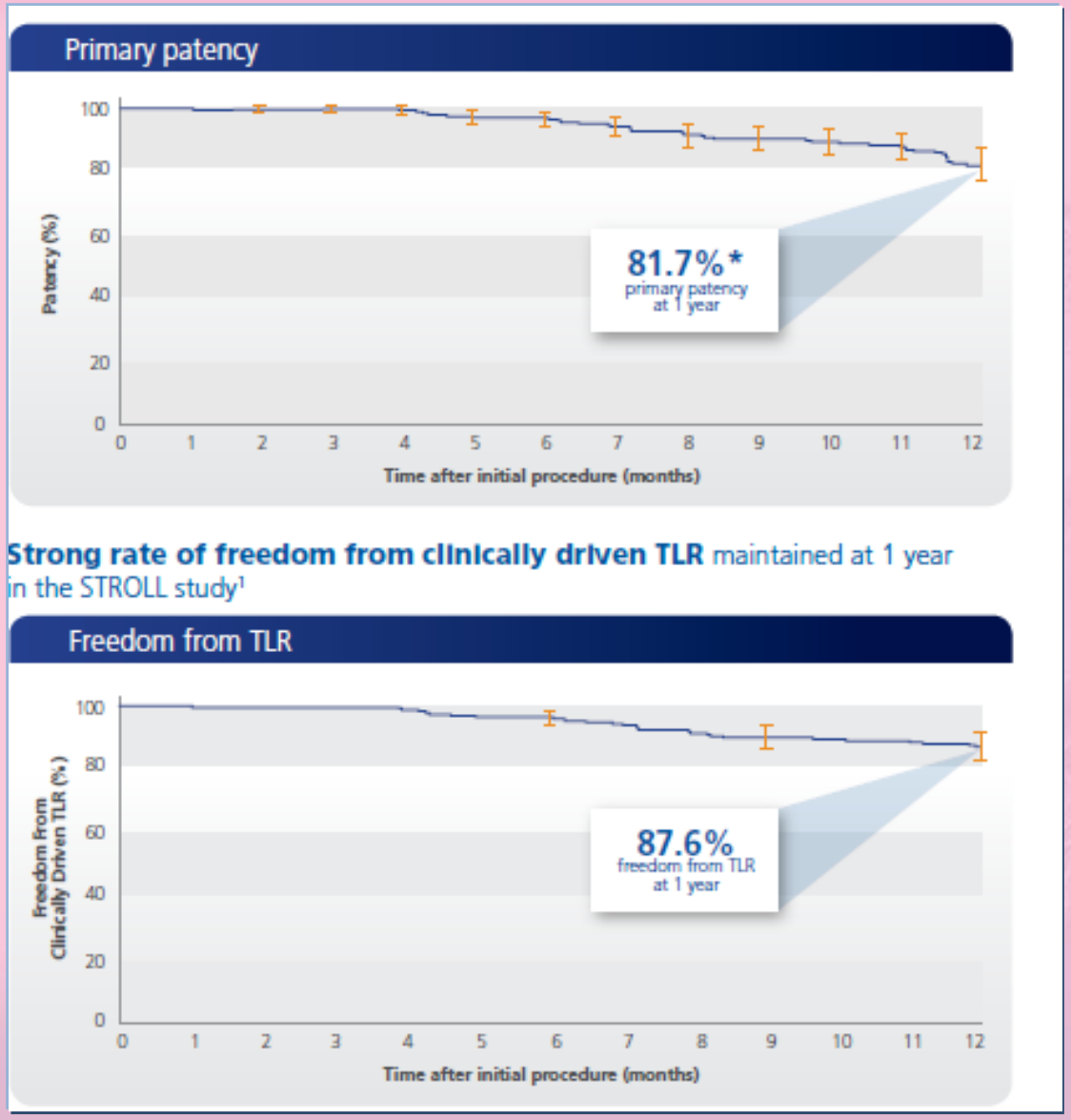
Third: PTA plus PTA with provisional stent vs. primary stent



Laird JR et al. Circ Cardiovasc Intervent. 2010;3:267-276

Femoro-popliteal BMS Stenting

STROLL Registry



Strong rate of freedom from clinically driven TLR maintained at 1 year in the STROLL study[1]

A Novel Self-Expanding Interwoven Nitinol Stent for Complex Femoropopliteal Lesions: 24-Month Results the SUPERA SFA Registry

Dierk Scheinert, MD; Lars Grummt, MD; Michael Piorkowski, MD; Jacqueline Sax; Susanne Scheinert, MD; Matthias Ulrich, MD; Martin Werner, MD; Yvonne Bausback, MD; Sven Braunlich, MD; and Andrej Schmidt, MD

Center for Vascular Medicine, Angiology, and Vascular Surgery, Park Hospital Leipzig, Germany.

Purpose: To examine the efficacy and integrity of a novel interwoven self-expanding nitinol stent system for the treatment of complex femoropopliteal lesions in a "real world" medical practice.

Methods: This retrospective analysis included 107 consecutive patients (77 men; mean age 68.9 years) with atherosclerotic femoropopliteal lesions (occlusions in 31%) who underwent implantation of 137 SUPERA stents. The patients were followed for up to 24 months by Doppler ultrasound examinations, radiography of the stent, and assessments of Rutherford-Becker class and ankle-brachial index (ABI).

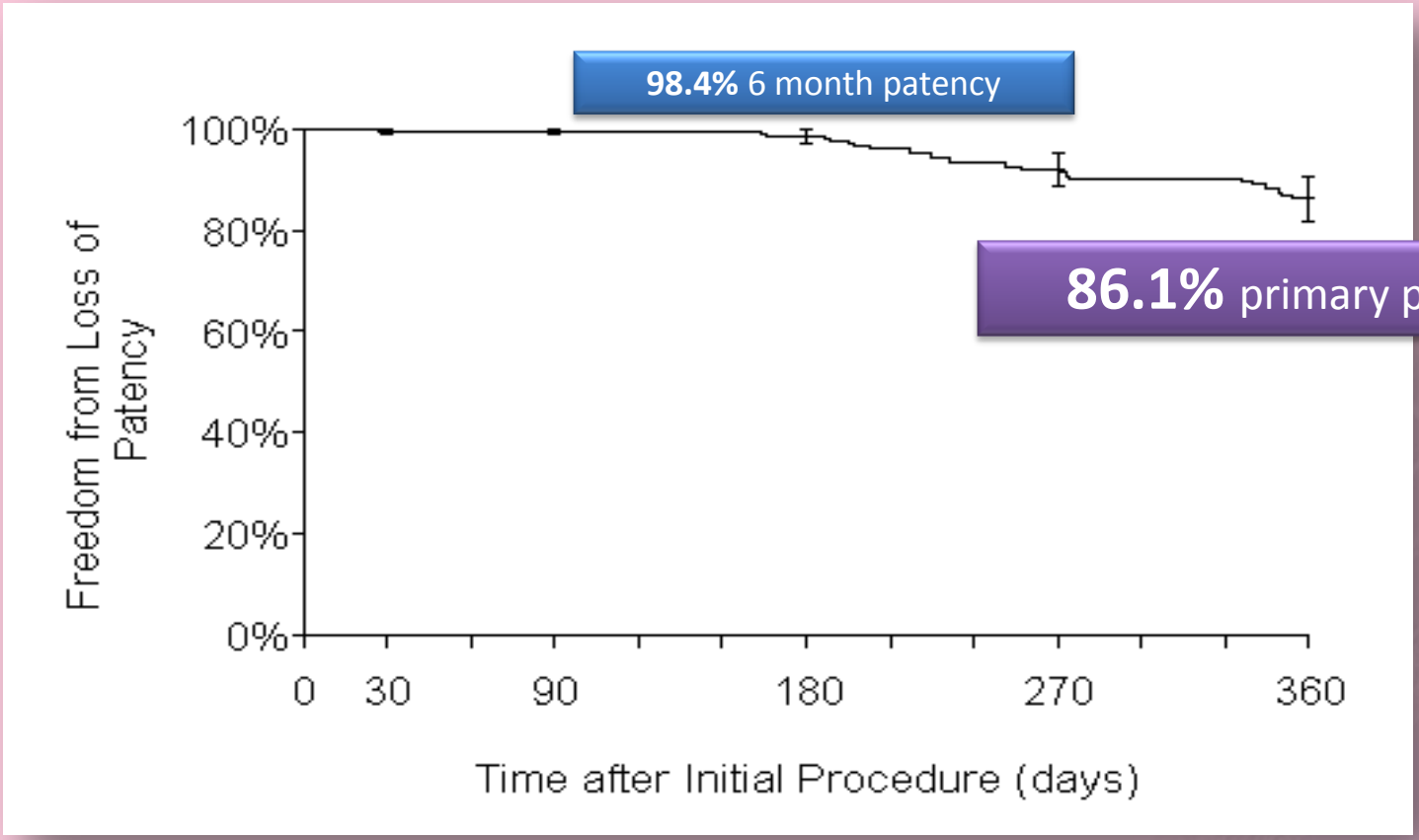
Results: The mean implanted stent length was 111±50 mm (range 40–270). Procedure success (residual stenosis <30%) was achieved in 99% of procedures. The 6-, 12-, and 24-month cumulative primary patency rates (± standard error) were 93.1%±2.5%, 84.7%±3.6%, and 76.1%±4.5%, respectively, and the secondary patency rates were 99.0%±0.1%, 94.8%±0.2% and 91.9%±0.3%, respectively. Between baseline and 24 months, mean ABI increased from 0.68±0.14 to 0.87±0.10 and the mean Rutherford-Becker class decreased from 3.3±0.7 to 2.0±1.0 ($p<0.0001$ for both). Radiographs performed in 91 patients at a mean of 16.8±7.0 months found no stent fractures.

Conclusion: Over a 2-year surveillance period, excellent durability without stent fractures was documented after implantation of the SUPERA stent in complex femoropopliteal lesions. In addition, significant improvements were observed in symptom classification and hemodynamics.

J Endovasc Ther. 2011;18:745–752

Key words: nitinol stent, superficial femoral artery, stenosis, occlusion, angioplasty, peripheral artery disease, stent fracture

Freedom from Loss of Primary Patency at 1 Year (PSVR < 2.0)



Freedom from TLR = 90%

Survival Analysis conducted by HCRI

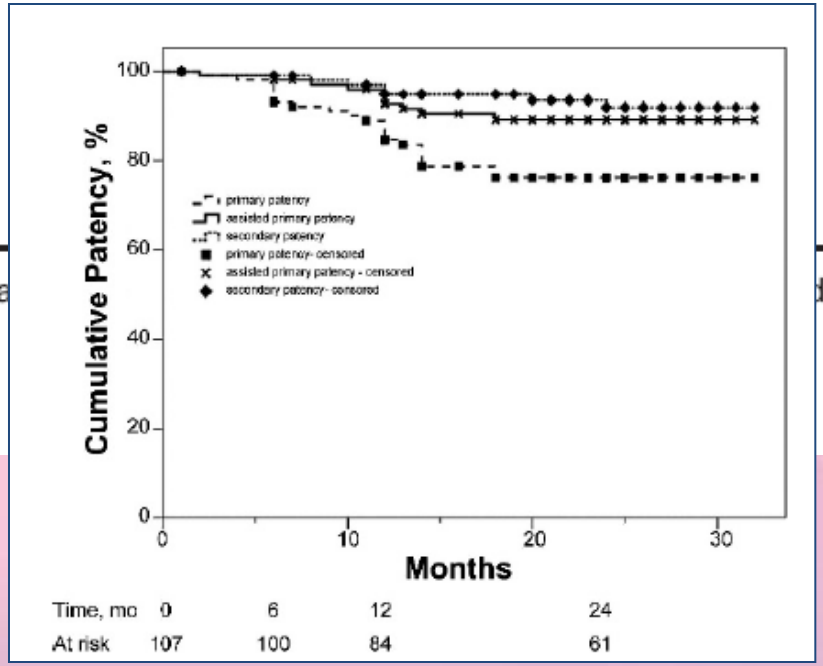
Scheinert D. et al. J Endovasc Ther 2011;18:745-752

TABLE 3

Stent Patency Rates, Clinical Outcomes, and Cumulative Adverse Events at 6, 12, and 24 Months of Follow-up

	Follow-up, mo		
	6 (n=88)	12 (n=88)	24 (n=79)
Stent patency (Kaplan-Meier estimates)			
Primary	93.1%±2.5%	84.7%±3.6%	76.1%±4.5%
Assisted primary	98.0%±0.1%	92.8%±0.3%	89.2%±0.3%
Secondary	99.0%±0.1%	94.8%±0.2%	91.9%±0.3%
Rutherford-Becker class (baseline 3.3±0.7)	2.0±1.2*	1.7±1.1*	2.0±1.0*
Ankle-brachial index (baseline 0.68±0.14)	0.85±0.14*	0.89±0.14*	0.87±0.1*
Cumulative adverse events			
Death	4		
In-stent occlusion	2		
>50% in-stent stenosis	5		
Amputation	1		
Repeat percutaneous recanalization	5		

Continuous data are presented as means ± standard devia... data are given as counts (percentages).
* p<0.0001 vs. baseline.
Patients may have suffered >1 adverse event.



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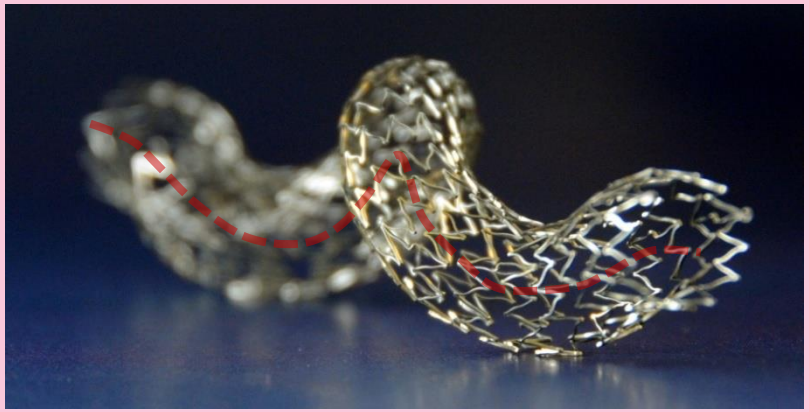
www.cacvs.org

Scheinert D. et al. J Endovasc Ther 2011;18:745-752

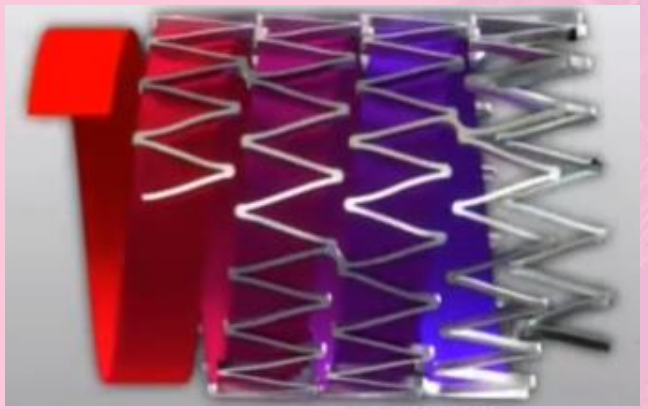
BioMimics 3D™ Stent
a true helix

Unique pattern and 3D shape memory

BioMimics 3D stent with centreline curvature



Stent with helical pattern
(e.g. LifeStent control in MIMICS study)



Veryan Medical received CE Mark approval for the BioMimics 3D stent system in November 2012

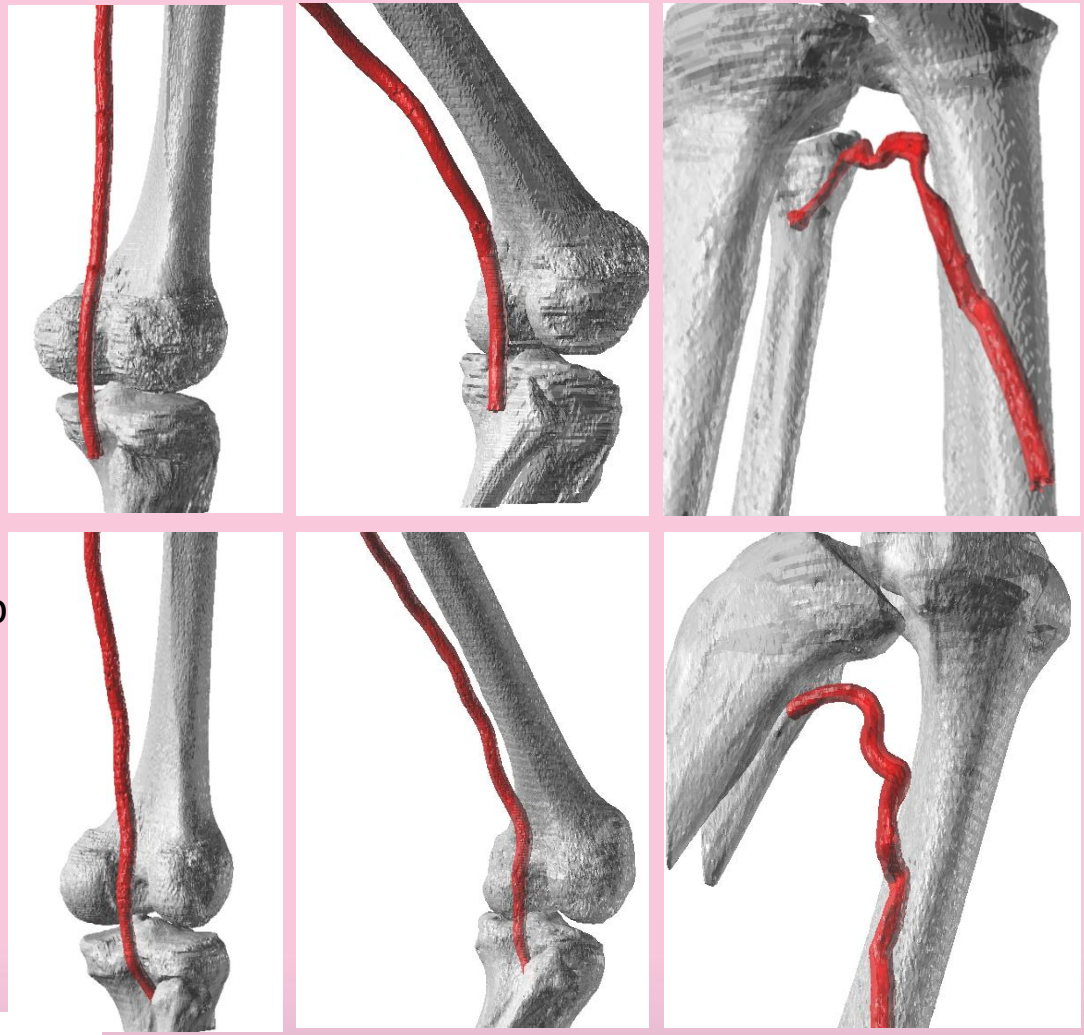
Cadaver Study

Biomechanical Proof of Principle for 3D Helical Stent

Straight Stent

Extensio

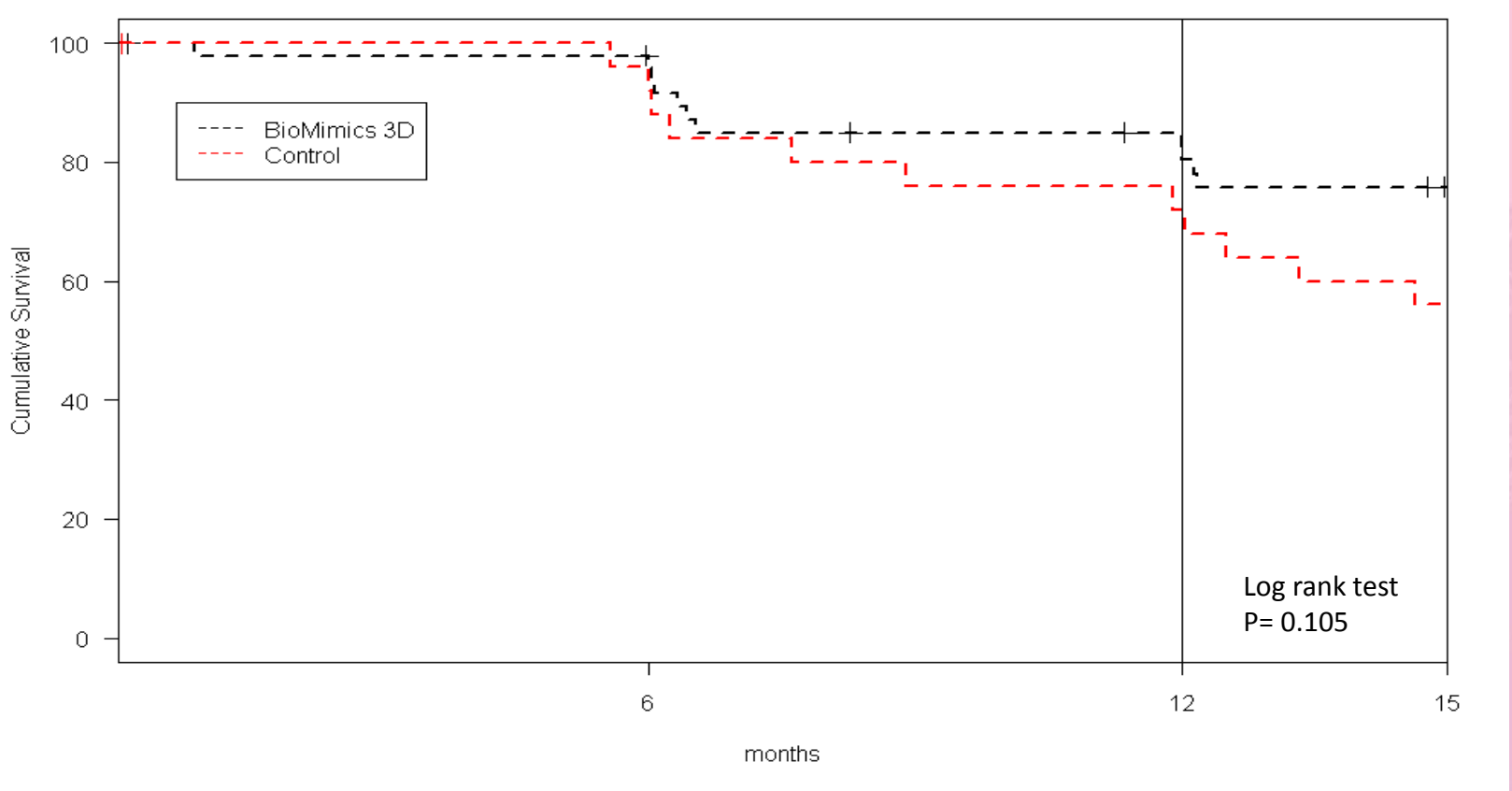
3D Helical Version of Stent



- 3D stented segment accommodates loading and enables shortening
- Vessel management reduces risk of kinking and vessel injury

Mimics Study
Primary Patency

Kaplan Meier Estimate of 12-Month Freedom From Loss of Patency*	BioMimics 3D: 80.4% Control: 72.0%



*** Loss of patency is defined as PSVR >2.0, or where angiography reveals >50% diameter stenosis; or clinically driven TLR**

Results of the Protégé EverFlex 200-mm-long nitinol stent (ev3) in TASC C and D femoropopliteal lesions

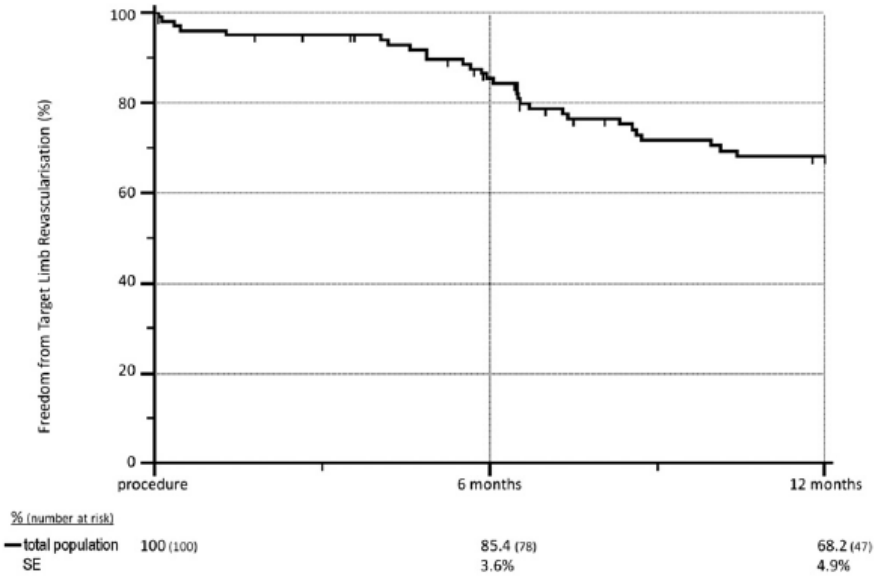
Marc Bosiers, MD,[a] Koen Deloose, MD,[a] Joren Callaert, MD,[a] Nathalie Moreels, MD,[a] Koen Keirse, MD,[b] Jürgen Verbist, MD,[b] and Patrick Peeters MD,[b] *Dendermonde and Bonheiden, Belgium*

Objectives: This study investigated the results with primary stenting using the Protégé EverFlex 200-mm-long self-expanding nitinol stent (ev3 Endovascular Inc, Plymouth, Minn) in femoropopliteal TransAtlantic Inter-Society Consensus (TASC) C and D lesions of at least 150 mm in length.

Methods: Between March 2008 and June 2009, 100 patients (66 men) presenting with 100 symptomatic TASC C and D femoropopliteal lesions were treated with at least one 200-mm-long Protégé EverFlex stent. The intention of this study was to treat all lesions with as few stents as possible. The primary study end point was primary patency at 12 months, defined as the absence of hemodynamically significant stenosis on duplex ultrasound imaging (systolic velocity ratio <2.4) at the target lesion and without target lesion revascularization (TLR) ≤12 months. Stent fracture occurrence was assessed at the 12-month follow-up by conventional x-ray imaging.

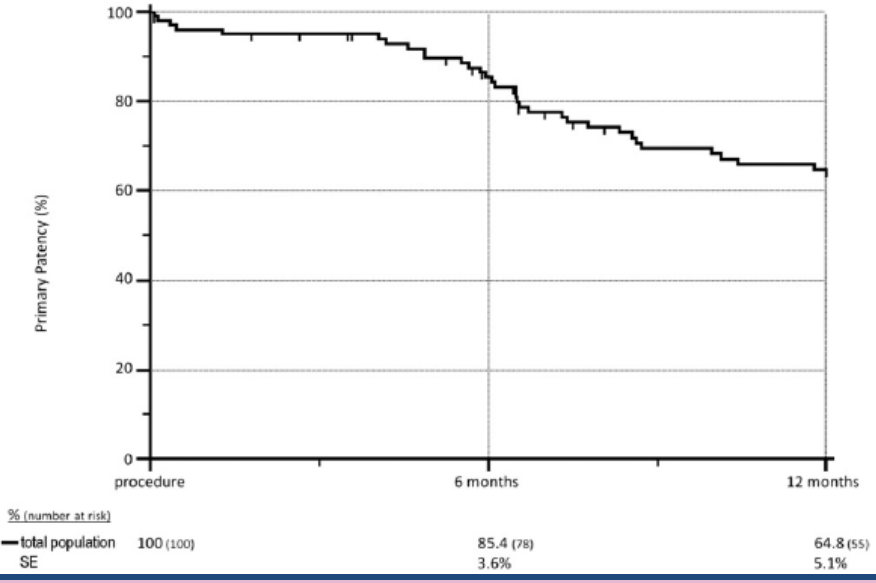
Results: Average patient age was 70 years. Preoperative symptom assessment reported 71 patients (71%) had claudication vs 29 (29%) with critical limb ischemia. Average lesion length was 242 mm (range, 160-450 mm), and 27 patients (27%) presented with popliteal involvement. A total of 158 Protégé EverFlex stents were used to treat 100 lesions. Kaplan-Meier estimation reported a 12-month freedom from target lesion revascularization of 68.2% and a primary patency rate of 64.8%. Stent fractures occurred in six patients (6.0%) when x-ray images taken immediately after the procedure were compared with those taken after 1 year.

Conclusions: The results of our Durability-200 study show an acceptable primary patency rate after 1 year was obtained in this patient cohort with TASC C and D femoropopliteal lesions. (J Vasc Surg 2011;54:1042-50.)



Freedom from TLR: 68%

Fig 1. Kaplan-Meier estimate shows freedom from target lesion revascularization at 12 months for the total population.



Primary patency: 64.8%

Bosiers M et al. J Vasc Surg 2011;54:1042-50

Femoro-popliteal BMS Stenting

Comparison of Different Designs

	1-year prim. Patency	P-value	Fracture rate
Luminexx[1]	55.8%		
Smart[1]	65.8%	ns	
Viabahn[2] (n=72)	53%		2%
Nitinol stent[2] (n=76)	58%	ns	38%

Mean Lesion length Viabahn 19cm, stent 18cm
Focal restenosis 87% Viabahn

[1]Duda et al. SUPER SL
[2]Ansel et al. VIBRANT

Femoro-popliteal Stenting

Long Lesions - Durability

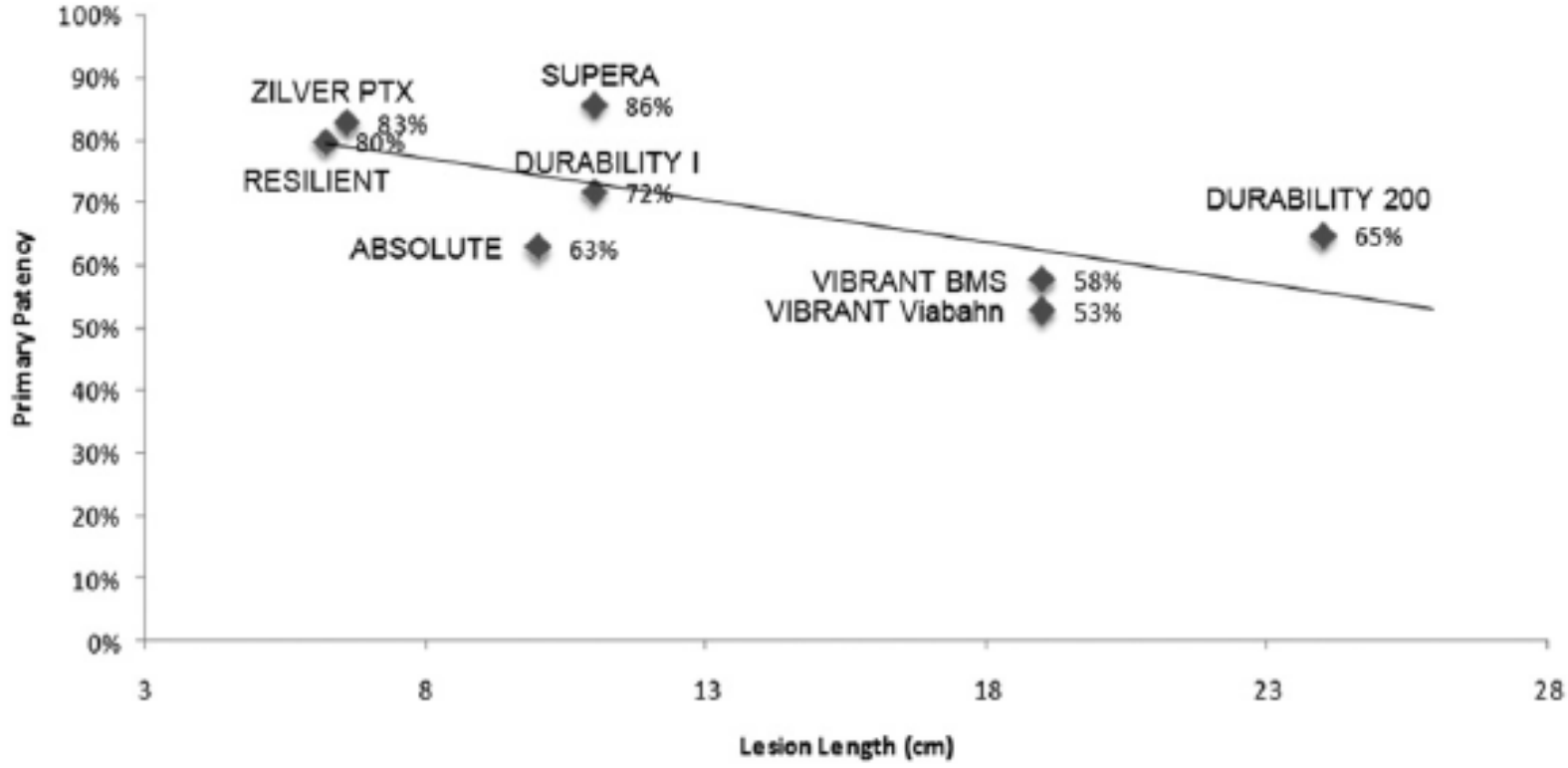
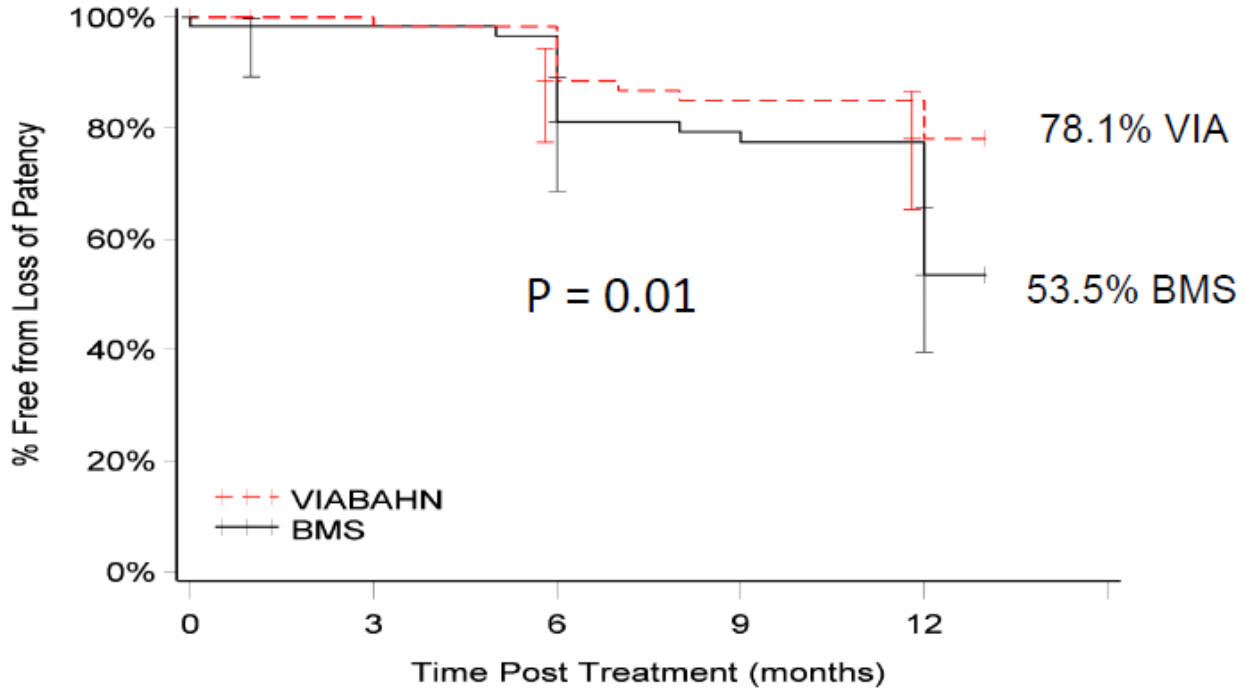


Fig 6. Positioning of the Durability-200 results compared with other studies of superficial femoral artery stenting.

Bosiers M et al. J Vasc Surg 2011;54:1042-50

VIASTAR Trial
Primary Patency



	VIABAHN	BMS	P
1 mo	96.8	96.8	
6 mo	85.3	77.8	
12mo	78.1	53.5	0.009

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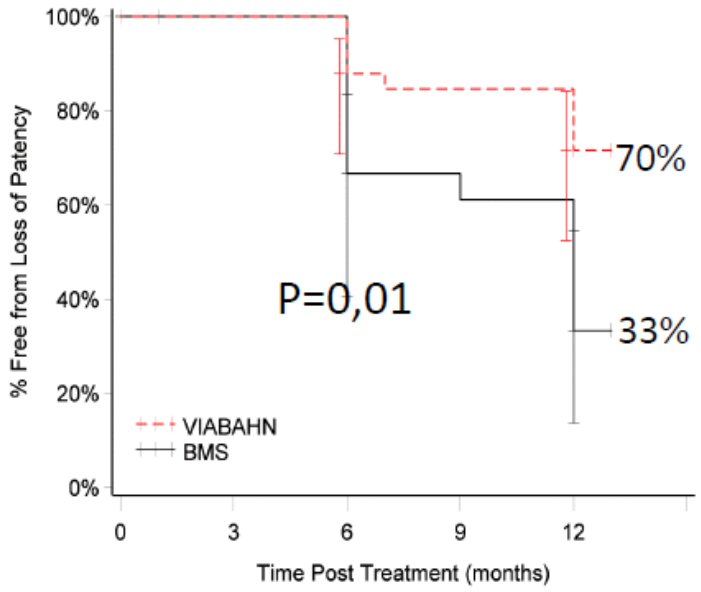
Lammer et al. JACC 2013

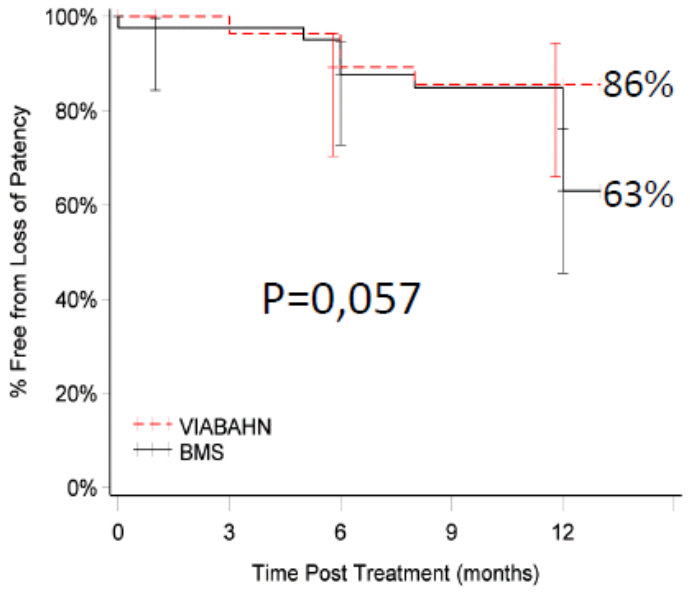
VIASTAR Trial

1-Year Primary Patency Stratified to Lesion Length

Primary patency rate >20 cm vs. ≤20 cm lesion length



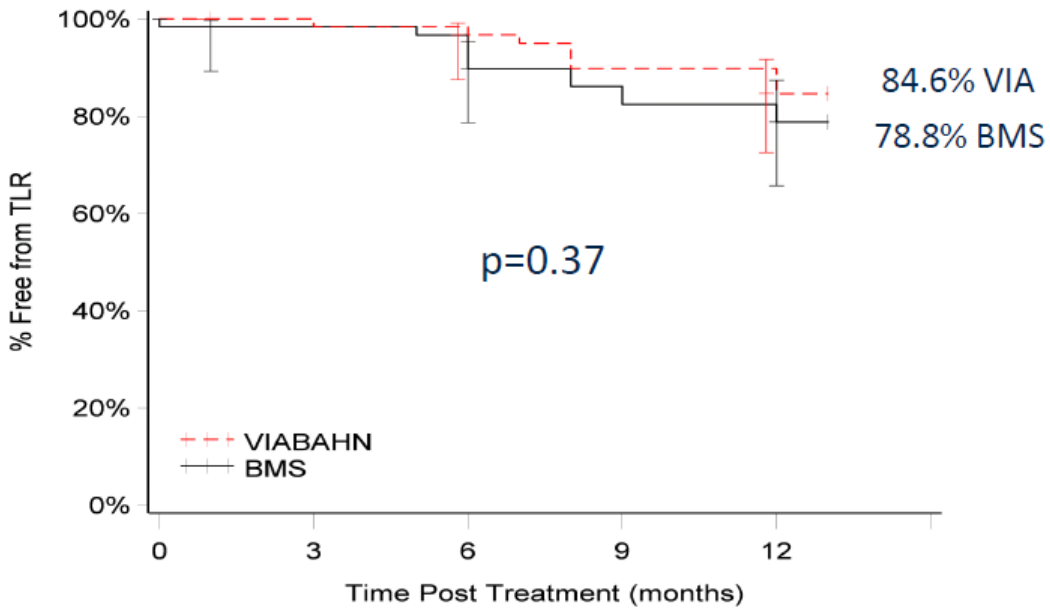
>20 cm



≤20 cm

Lammer et al. JACC 2013

VIASTAR Trial
Freedom from TLR



	VIABAHN	BMS	P
1 mo	96.8	96.8	
6 mo	90.3	81.3	
12mo	84.6	78.8	0.37

Lammer et al. JACC 2013

BMS in Femoro-popliteal Lesions

Summary

- BMS offer superior technical results over POBA due to their better acute and mid-term performance
- Dedicated stent designs such as interwoven closed cell design and 3-dimensional helical design might improve technical and clinical results of BMS (1-year patency 80+%)
- Almost no additional loss of patency after 1 year
- Viabahn endoprostheses might improve outcomes in TASC C&D lesions, however
  - Higher costs
  - Coverage of collateral vessels
  - Unknown duration of dual antiplatelet therapy