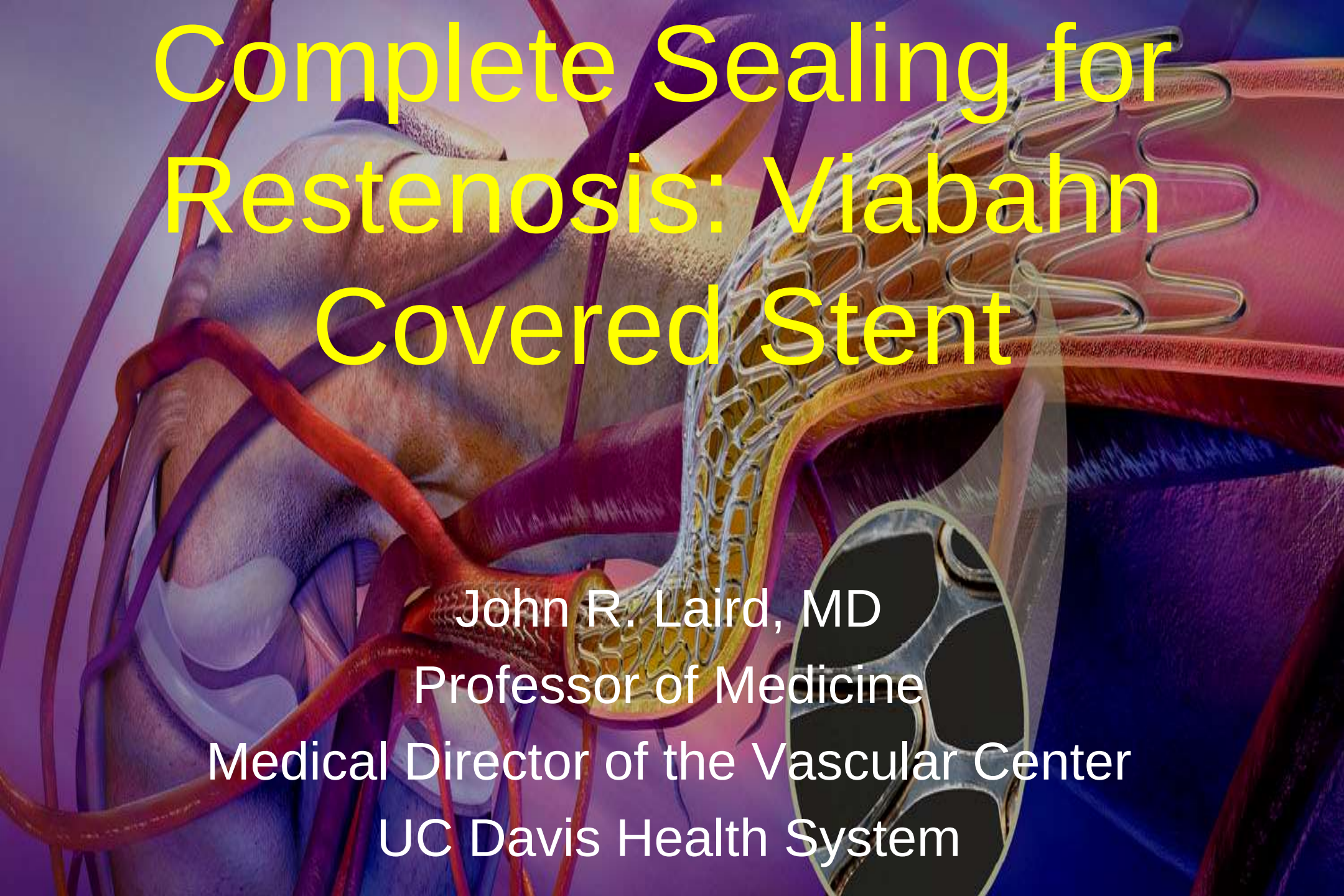


Complete Sealing for Restenosis: Viabahn Covered Stent

John R. Laird, MD
Professor of Medicine
Medical Director of the Vascular Center
UC Davis Health System

GORE VIABAHN® Endoprosthesis

GORE VIABAHN® Endoprosthesis

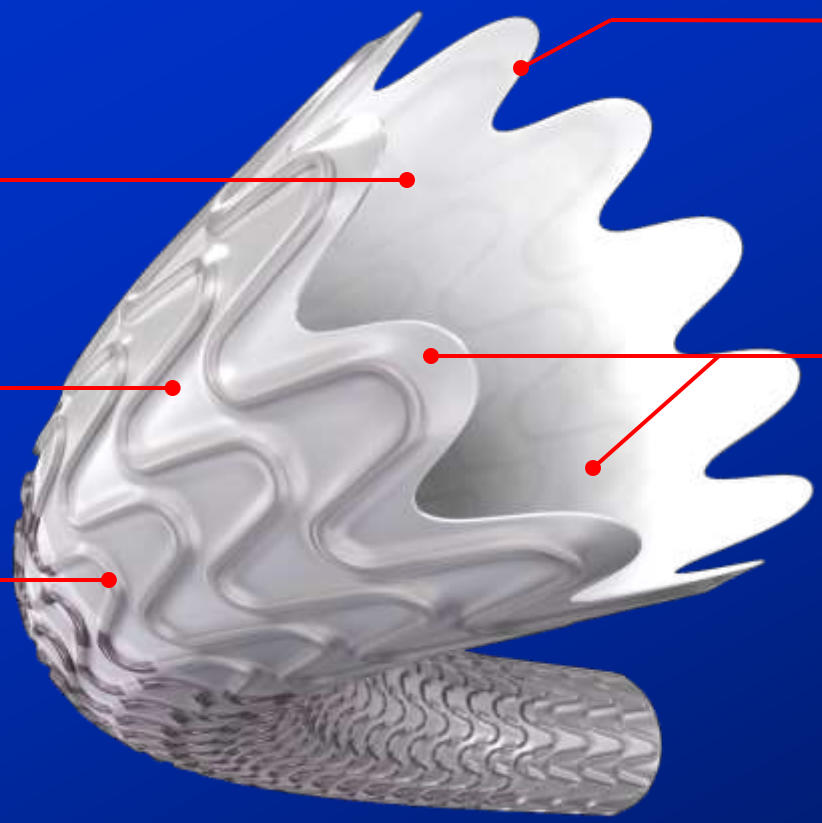
- Approved by the FDA for iliac and femoral use
- Incremental improvements:
  - Lower profile
  - Longer lengths
  - Proximal contoured edge to reduce the risk of proximal edge restenosis
  - Heparin Bioactive Surface

Endoprosthesis Description

Ultra-thin wall ePTFE tube

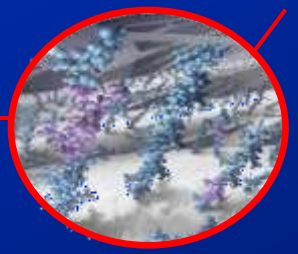
Unique, durable bonding film

Polished nitinol support



Contoured proximal edge

Heparin Bioactive Surface



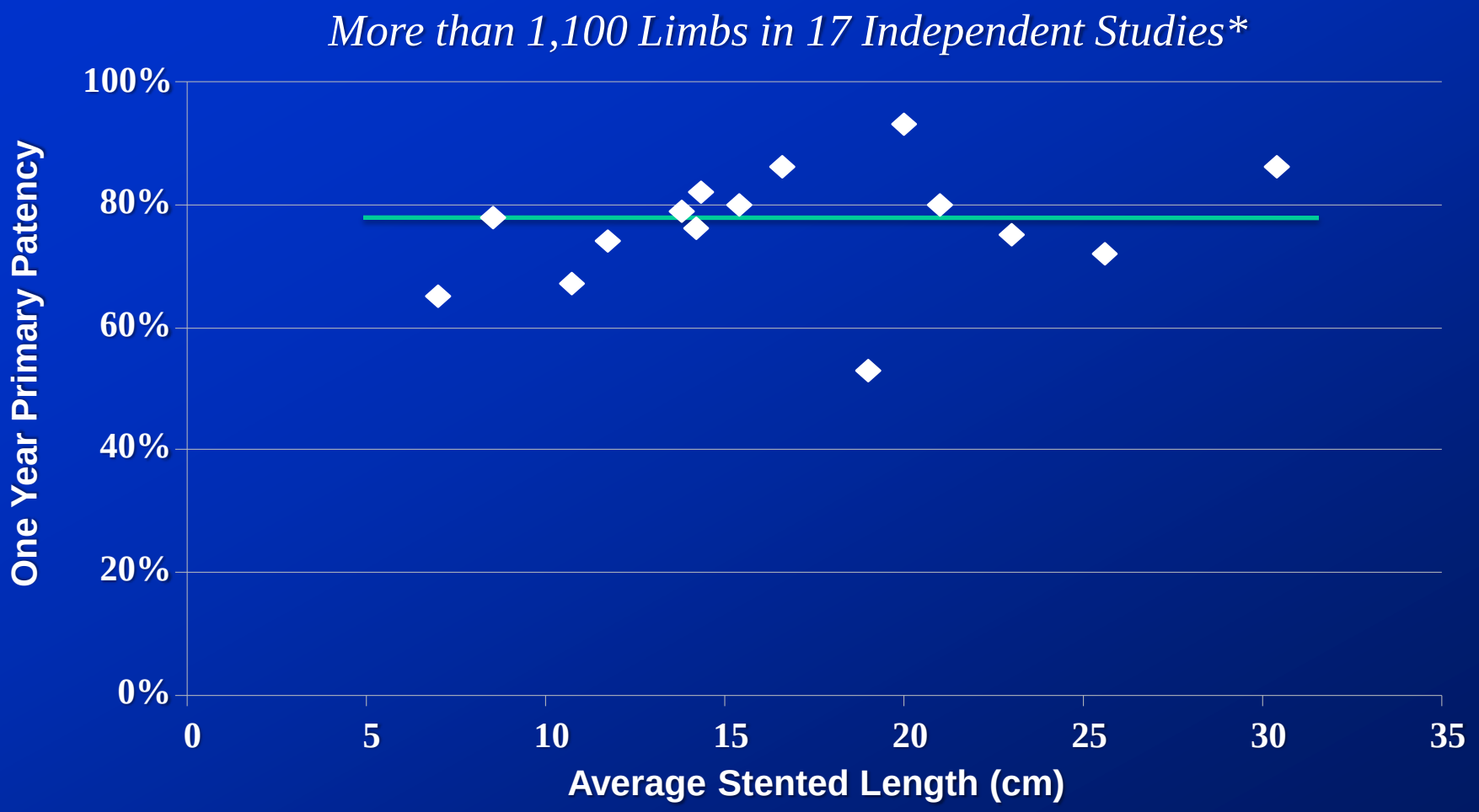
Lengths: 2.5, 5, 10, 15, 25 cm

Diameters: 5–8 mm

Key Advantages

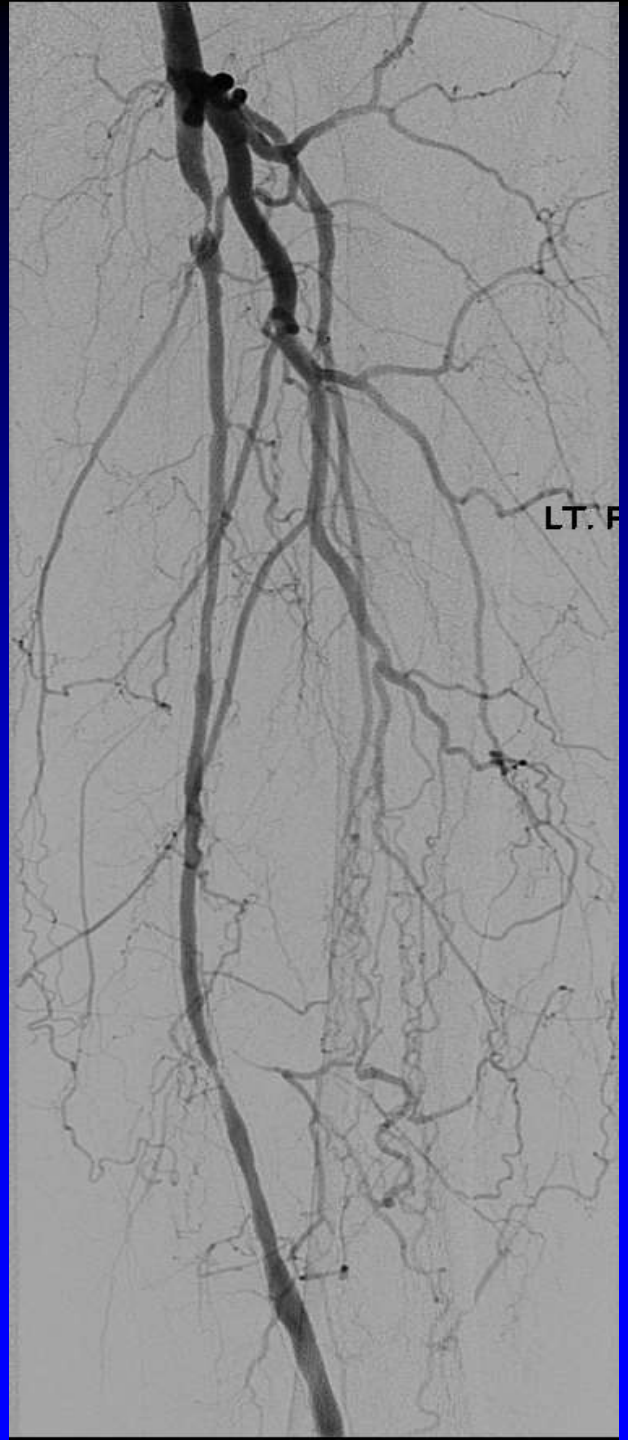
- Patency rate independent of lesion length
- Good results for long occlusions/stenoses
- When restenosis occurs, it is usually focal, edge restenosis
- Effective for instent restenosis

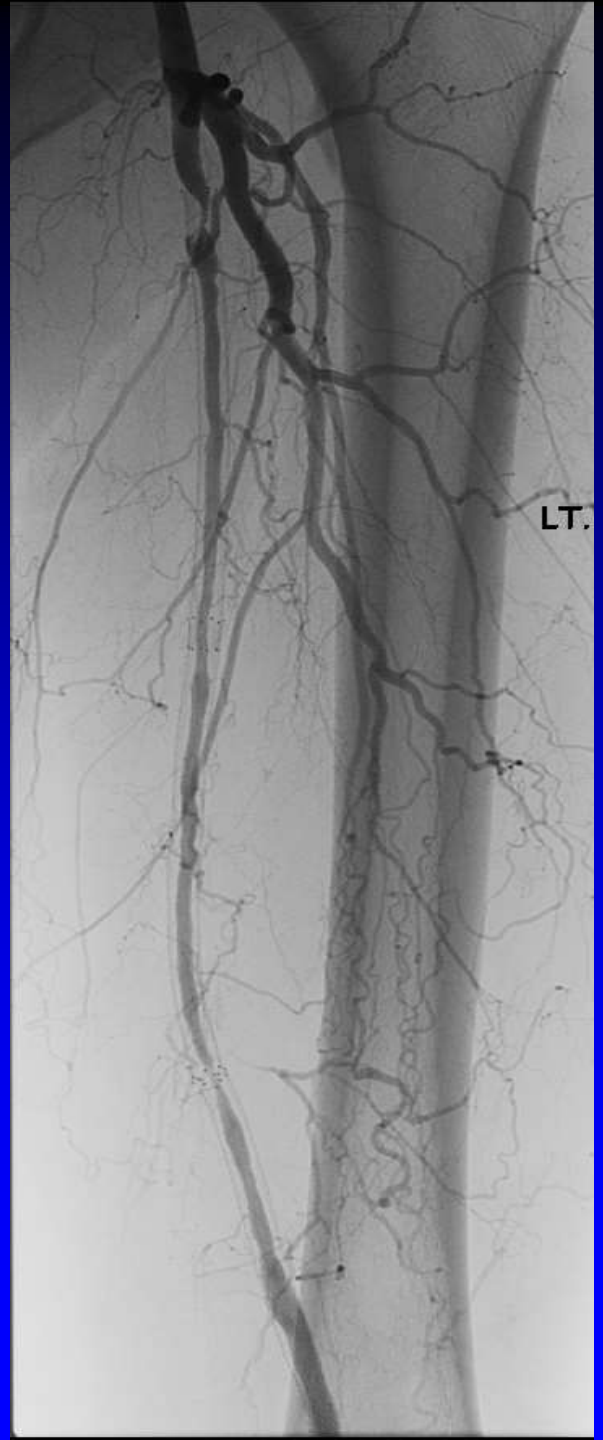
GORE® VIABAHN® Device One Year Primary Patency in the SFA Based on Lesion Length



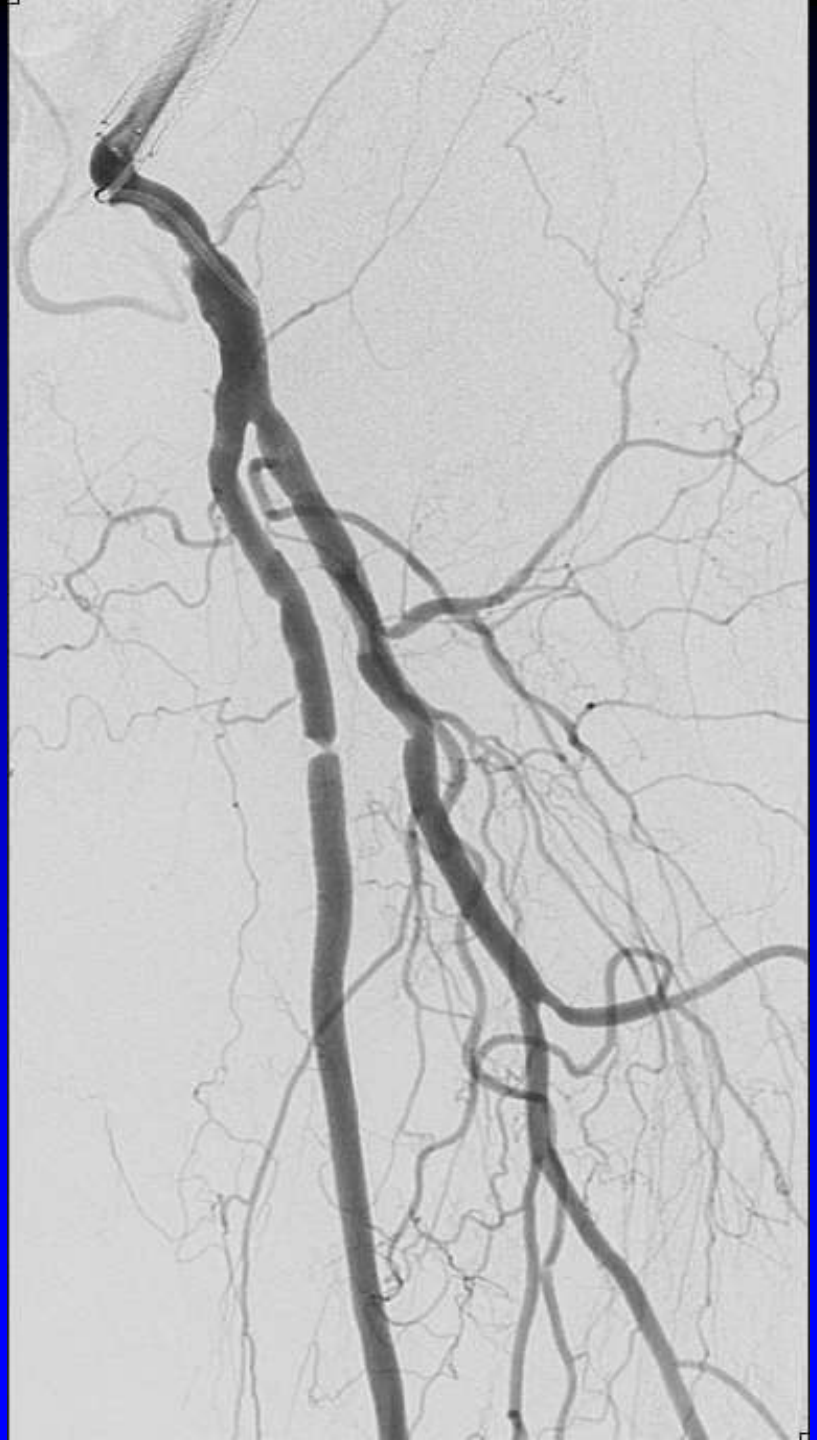
* Patient demographics, lesion characterization, and patency definitions may differ among studies. Studies include at least 30 limbs. Coats, et al., and Rabellino, et al., did not report lesion length

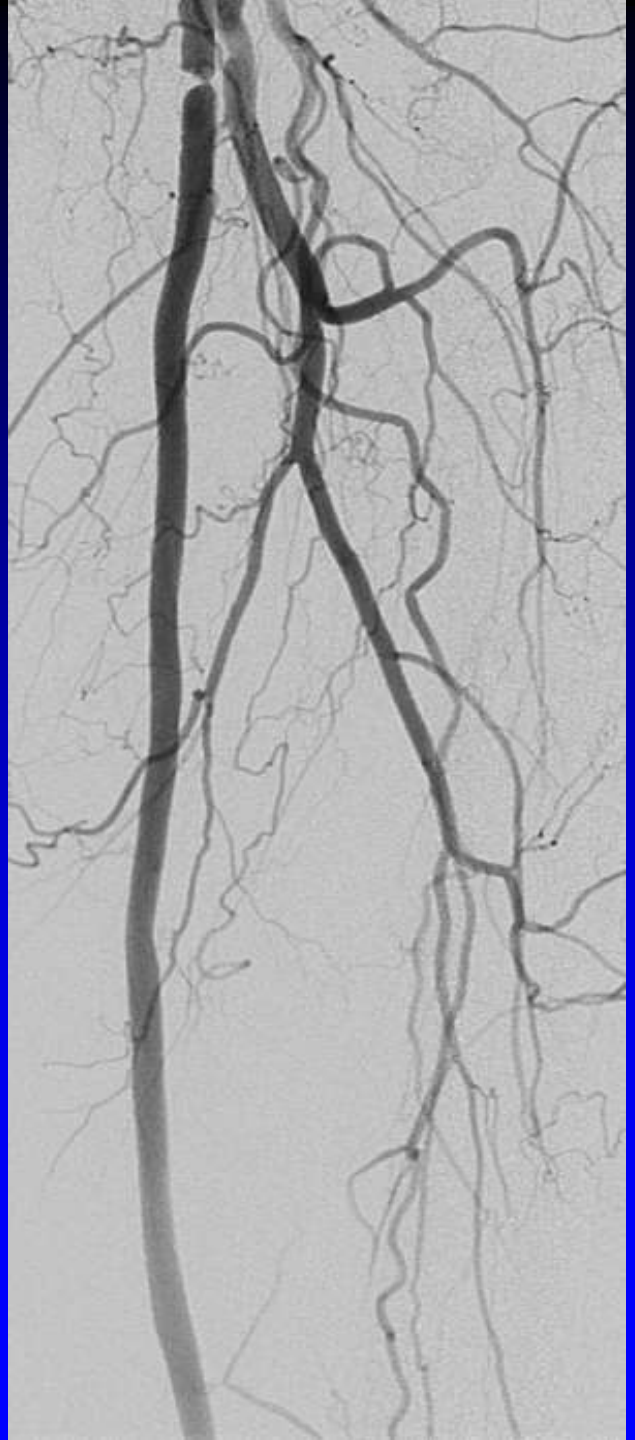
Restenosis Following Bare Metal Stent





Restenosis Following Stent Graft





Viabahn vs Fem-Pop Bypass

	GORE VIABHAN® Endoprosthesis (n = 50)		ePTFE or Dacron® Bypass (n = 50)	
Diameter	5.7 mm		7.4 mm	
Length	25.6 cm		--	
TASC II A and B	n = 39		n = 35	
TASC II C and D	n = 11 (22%)		n = 15 (30%)	
	Primary	Secondary	Primary	Secondary
1 Year Patency	72%	83%	76%	86%
2 Year Patency	63%	74%	63%	76%
3 Year Patency	63%	74%	63%	76%
4 Year Patency	59%	74%	58%	71%

McQuade, JVS, 2010

VIPER Overview

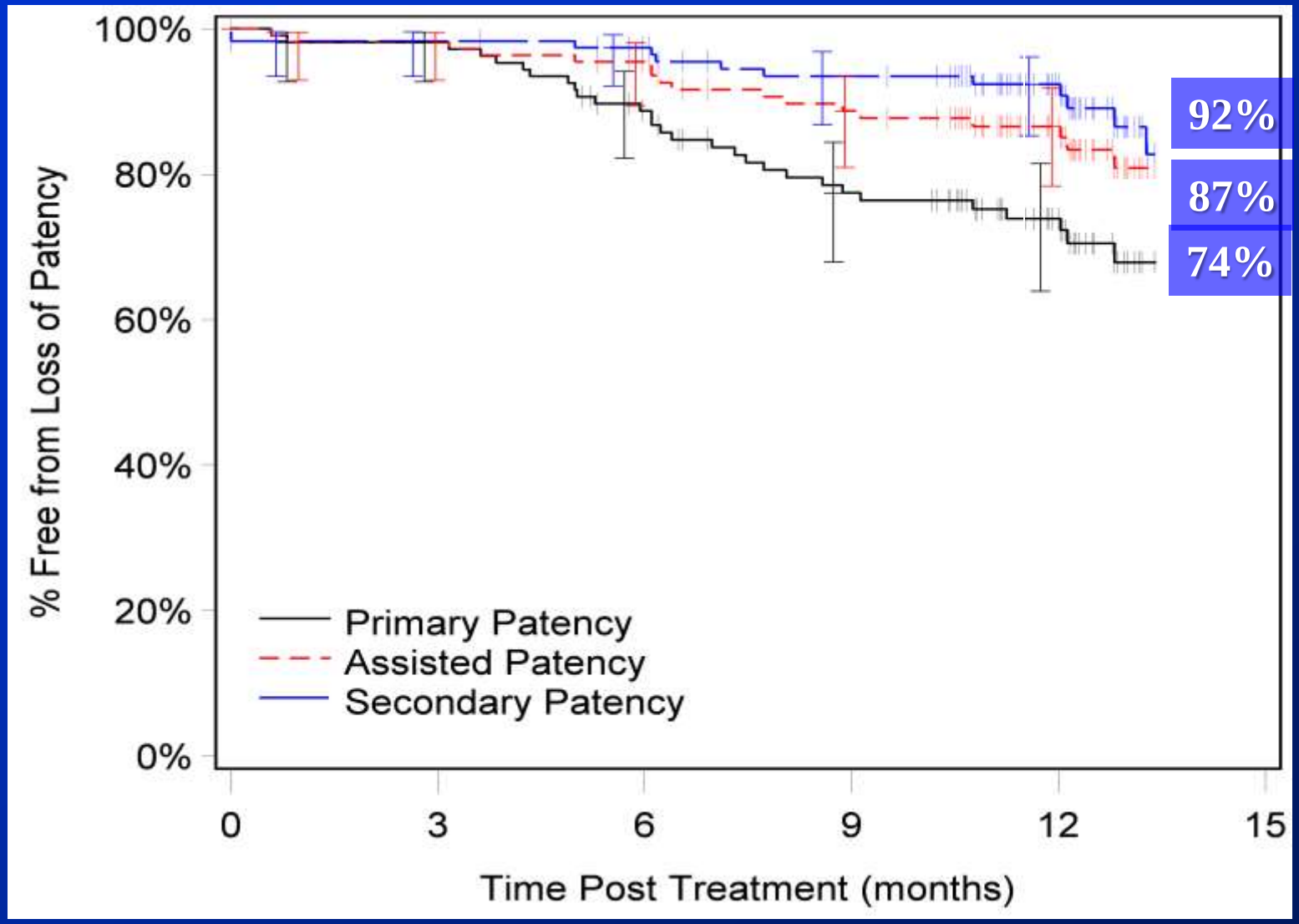
VIABAHN Endoprosthesis for treatment of long SFA disease

Objective	**Evaluate the performance of VIABAHN Endoprosthesis with Heparin Bioactive Surface (W.L. Gore, Inc.) in treating long-segment SFA disease (> 5 cm in length)**
Design	**Single-arm, Prospective, 12 sites, 120 patients**
Primary Endpoints	**Primary patency at 12 months** • **No evidence of restenosis or occlusion within the originally treated lesion based on CDUS; PSVR <2.5;** • **No angiographic evidence of stenosis >50% if CDUS is uninterruptable or unavailable or TVR performed**
Secondary Endpoints	**Primary assisted patency** **Secondary patency** **Device related major adverse events at 12 months**

Lesion Characteristics

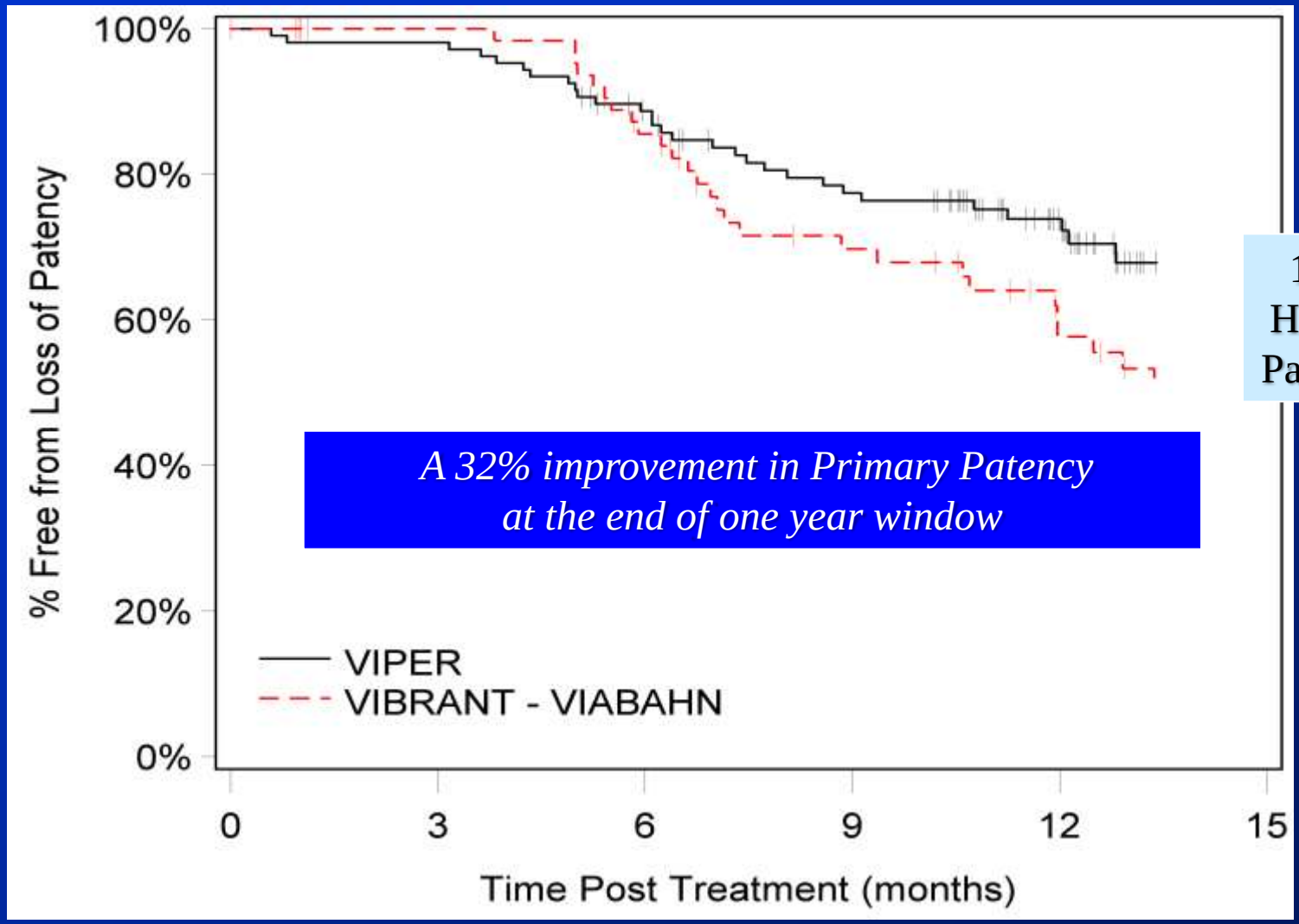
	VIPER
Treated Occlusions	56%
Lesion Length	19 cm
Lesion Calcification	
none-mild	39%
moderate-severe	61%
Tibial Runoff	
1 vessel	21%
2 vessel	33%
3 vessel	46%

One-Year Patency



12 month duplex follow-up available for 103/120 patients

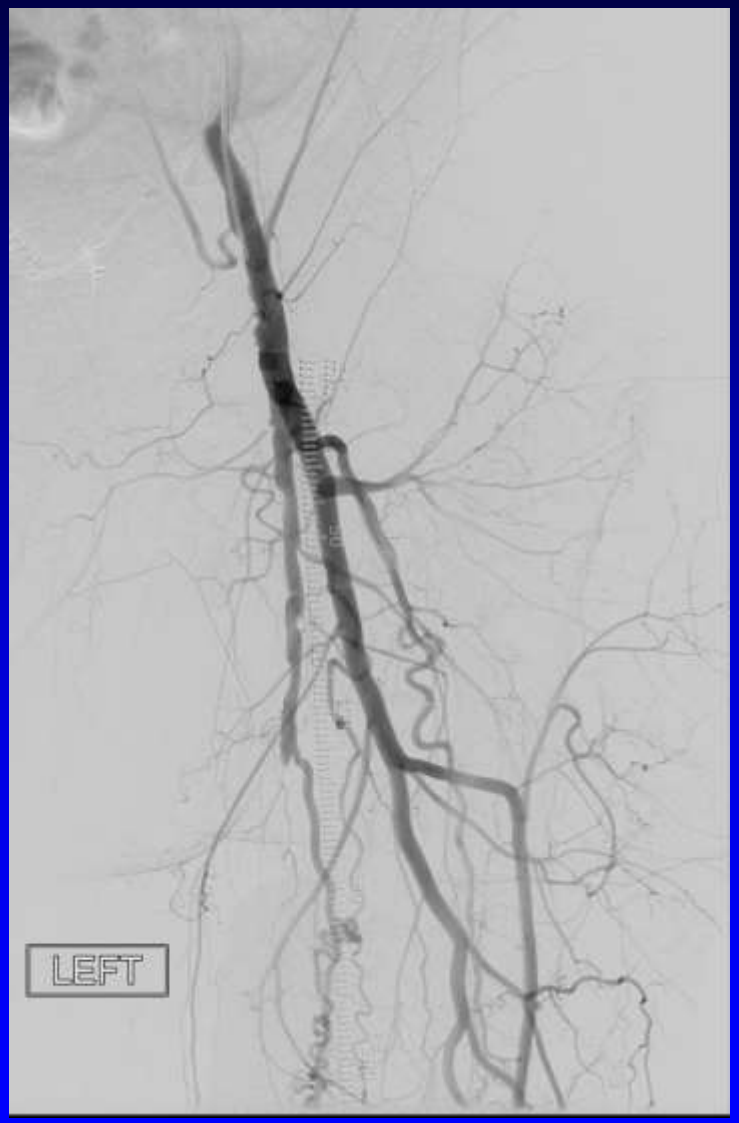
Primary Patency: VIPER vs VIBRANT

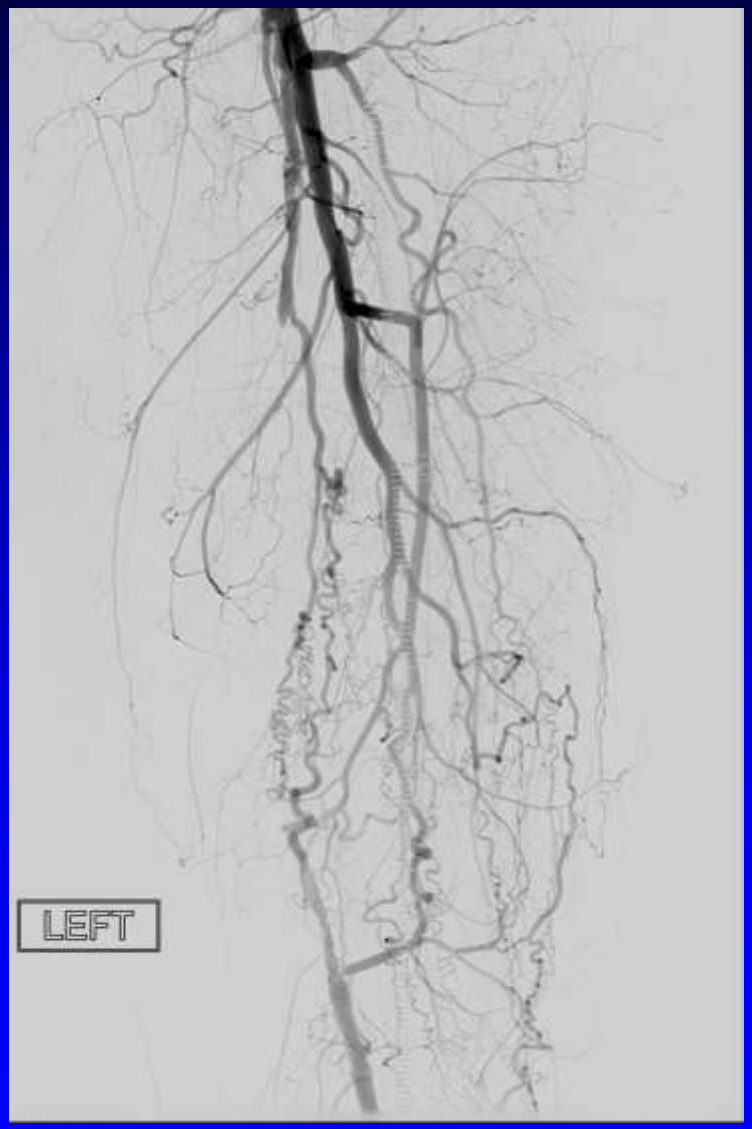


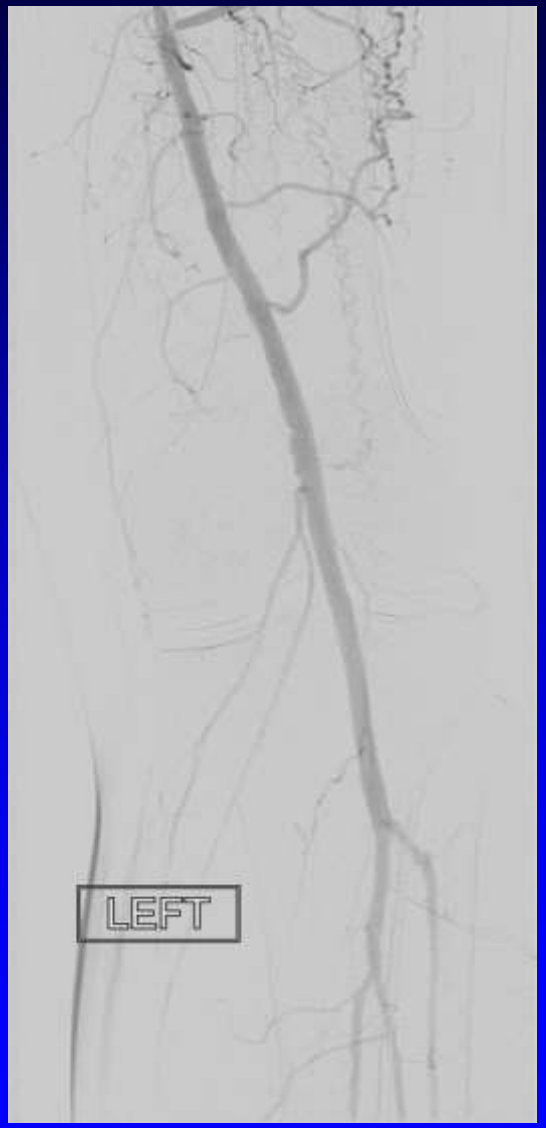
Viabahn Pitfalls and Tricks Learned from over 700,000 cases

- Avoid non-compliant lesions
- Ensure adequate inflow and outflow
- Full lesion coverage (healthy to healthy)
- DAPT
- Duplex ultrasound monitoring
- **Correct sizing**
  - Poor results in vessels < 4mm (VIPER)
  - Optimal results in vessels sized per IFU 5-20% oversizing (VIPER)

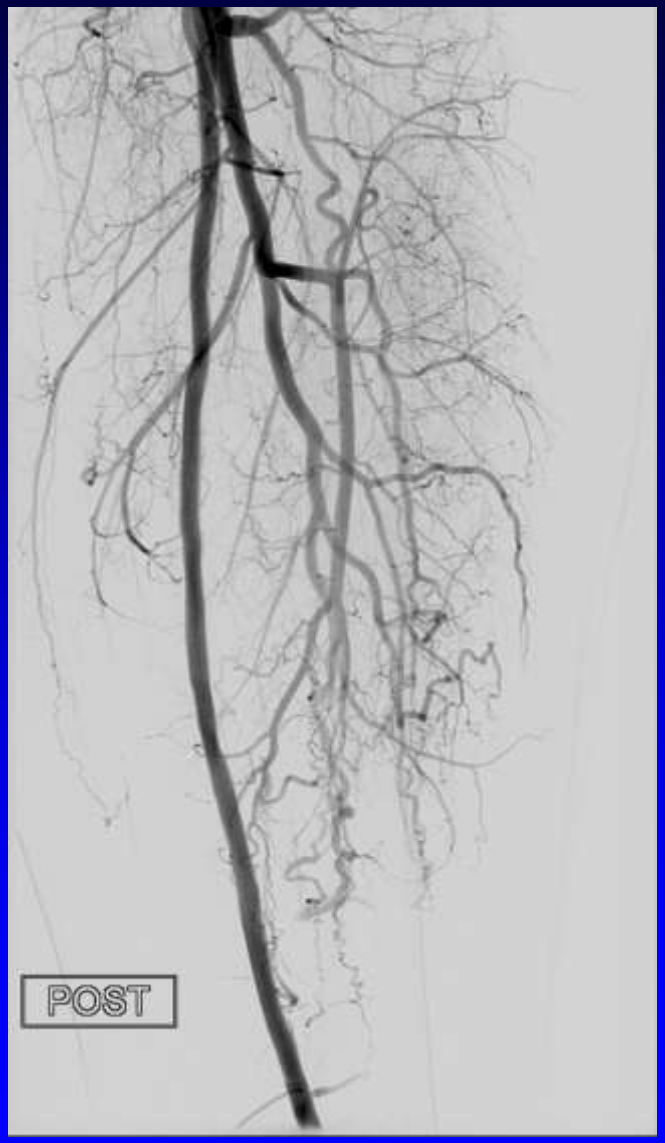
Long SFA Occlusion

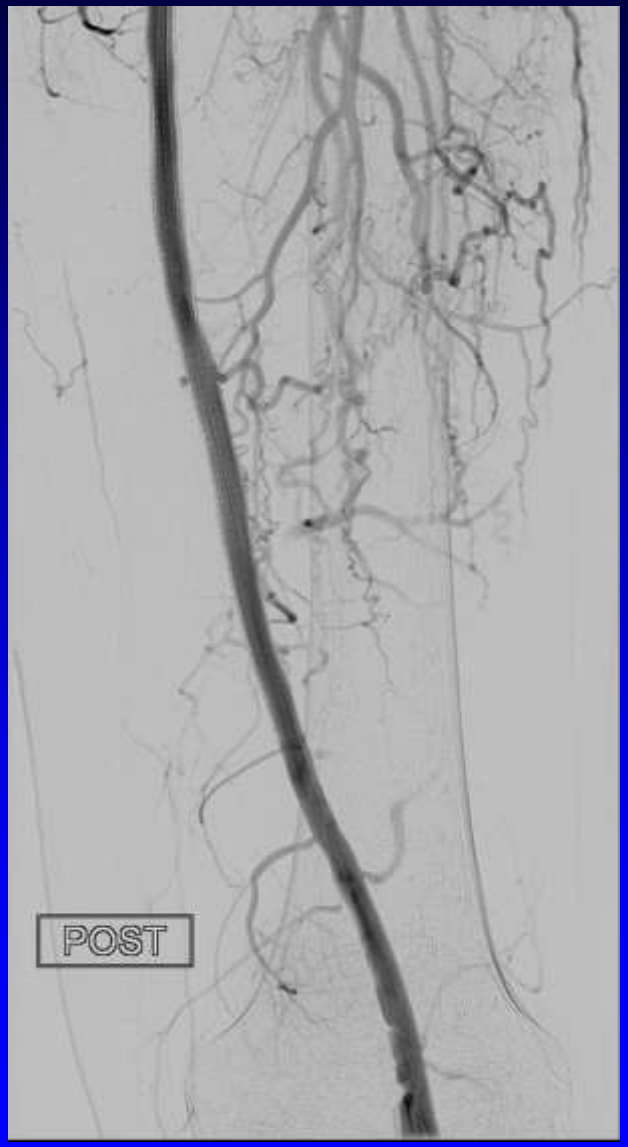


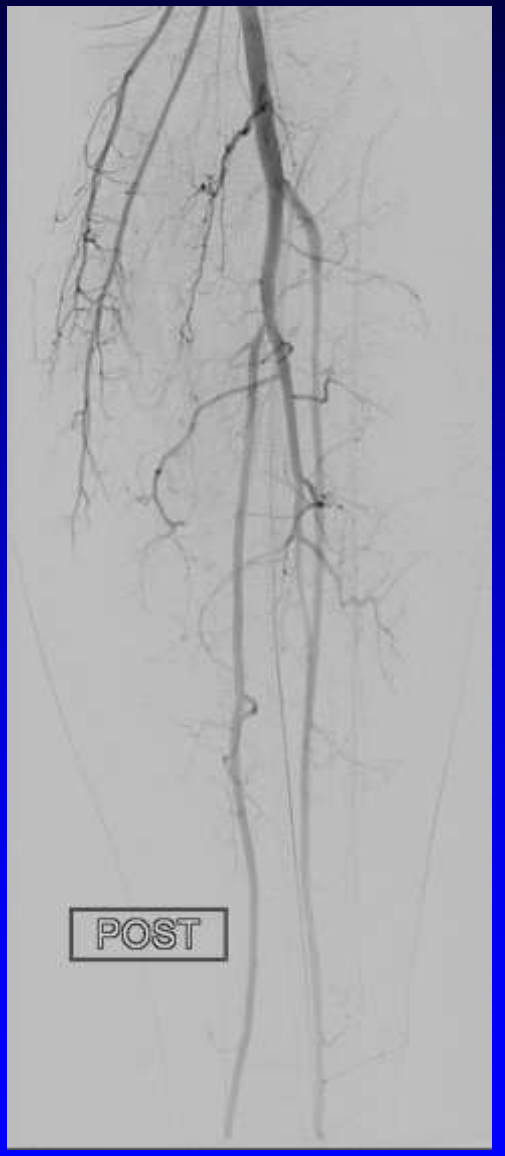




Long SFA Occlusion







VIASTAR Trial

- European randomized trial of Viabahn vs. bare nitinol stent for long SFA lesions
- Newest generation Viabahn endoprosthesis:
  - Low profile
  - Heparin bioactive surface
  - Proximal contoured edge
- 142 patients enrolled at 7 European Centers
- Rutherford category 2 - 5

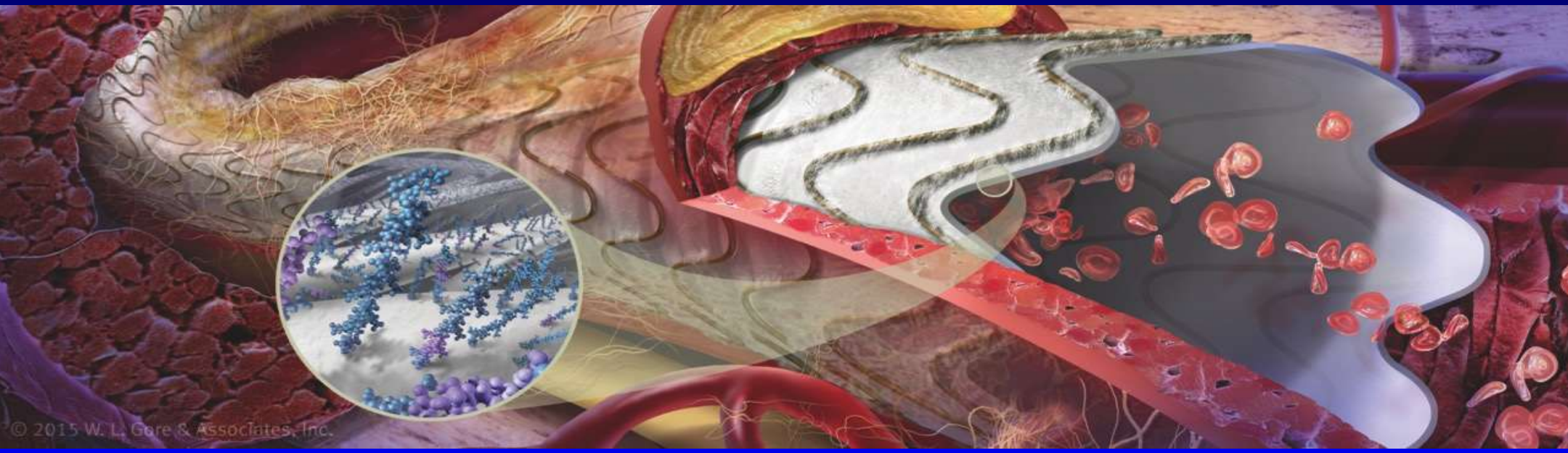
VIASTAR Outcomes

	VIABAHN™	BMS	P Value
Lesion length (cm)	19.0 ± 6.3	17.3 ± 6.6	P = 0.13
Occlusion	79%	70%	P = 0.21
12-month Primary Patency (all)	78.1%	53.5%	P = 0.009
12- month Primary Patency (> 20 cm)	73.3%	33.3%	P = 0.004
12-month Freedom from TLR	84.6%	77.0%	P = 0.37
Ankle-Brachial Index	0.94 ± 0.23	0.85 ± 0.23	P < 0.05

12-month Data from Multiple studies of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface*

Author	Journal	Year	No. of Limbs	Lesion Length (cm)	CTOs (%)	Primary Patency	Secondary Patency
LENSVELT	Journal of Vascular Surgery, Vol 56, Iss 1, July 2012, P 118-125	**2012**	**56**	**18.5**	**NR**	**76%**	**89%**
VIPER	Journal of Vascular Interventional Radiology; 24: 165-173	**2013**	**119**	**19**	**56%**	**73%**	**92%**
VIASTAR	Journal of the American College of Cardiology	**2013**	**66**	**19.0**	**79%**	**78%**	**90%**
25 cm Study	Journal of Endovascular Therapy 2014;21:765-774	**2014**	**71**	**26.5**	**93%**	**67%**	**97%**
TOTAL weighted results			**312**	**20.6**	**72%**	**73%**	**92%**

Late-Breaking clinical data: GORE VIABAHN® Endoprosthesis: 12 Month results of the Japanese IDE Trial



National Principal Investigator:
Professor Takao Ohki, MD, PhD
Jikei University, Tokyo, Japan

GORE VIABAHN ENDOPROSTHESIS

Evaluated in Long, Complex Lesions Generally Suitable for Bypass[5]

Population enrolled generally suitable for bypass: 84.5% TASC II C or D

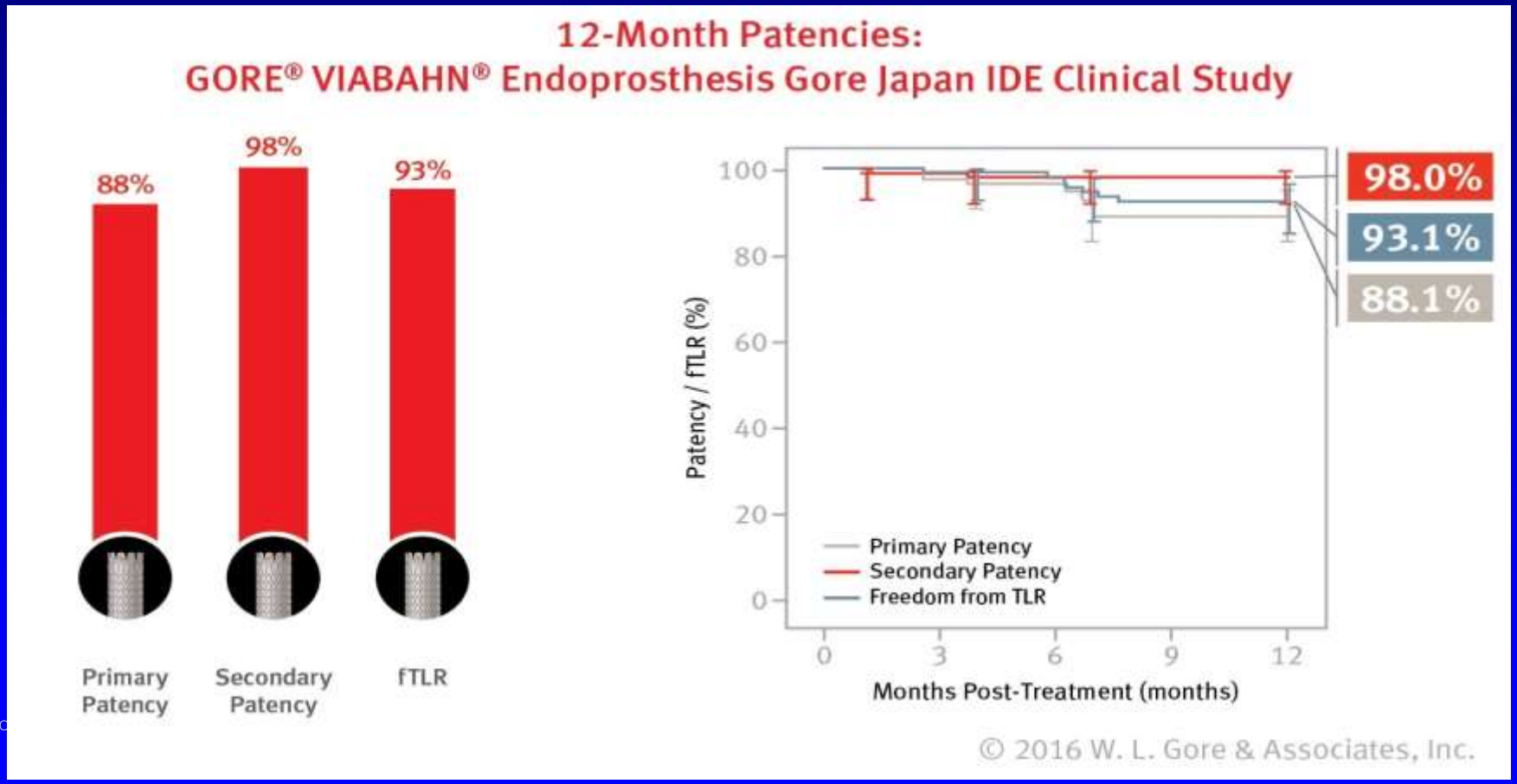
Mean Target Lesions Length (cm) ± SD	21.8 ± 5.8
Total Occlusions	67 (65.7%)

TASC Classification	
TASC II A	0 (0.0%)
TASC II B	16 (15.5%)
TASC II C	75 (72.8%)
TASC II D	12 (11.7%)

SFA Lesion Location (lesion may cross over)	
Proximal	72 (69.9%)
Mid	99 (96.1%)
Distal	77 (74.8%)

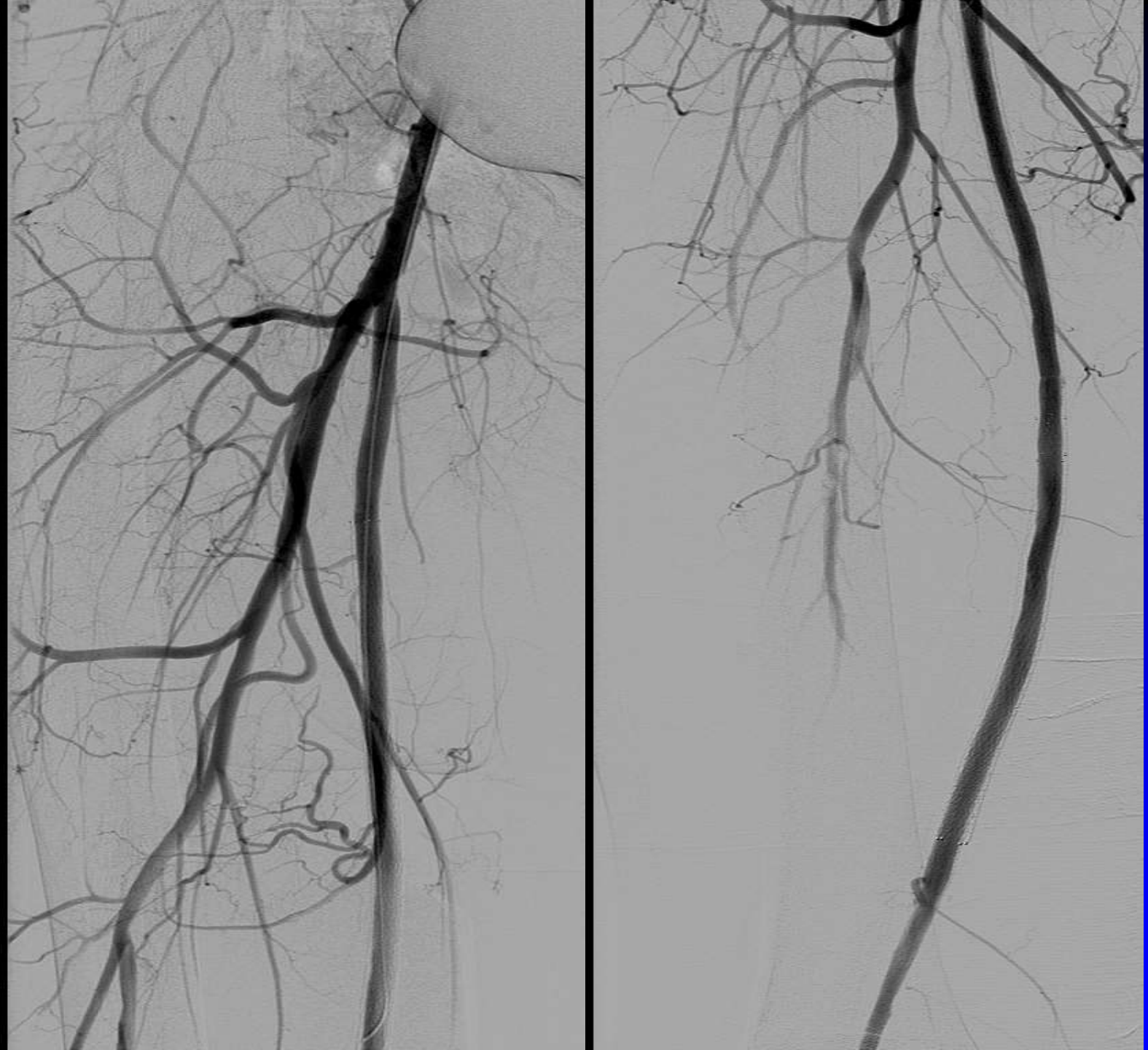
88% 1-Year Primary Patency in 21.8 cm Average Length Lesions[5]

- In the Gore Japan IDE Clinical Study, the GORE® VIABAHN® Endoprosthesis demonstrated 88% 12-month I-primary patency*
  - Average Lesion Length 21.8 cm



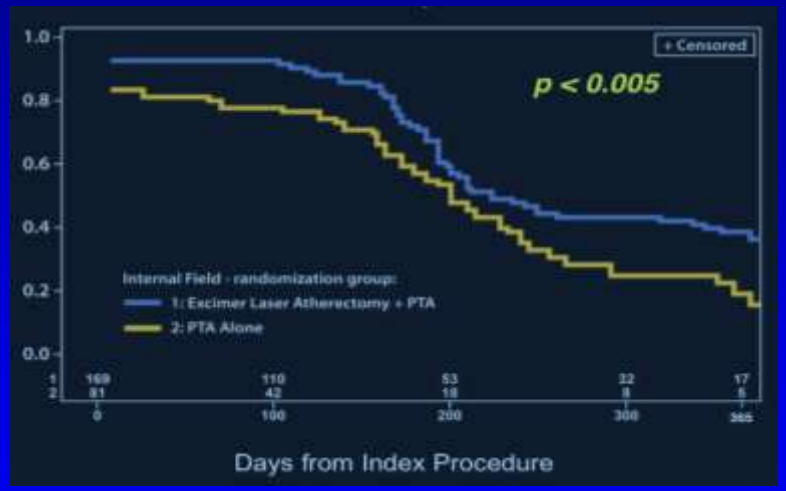
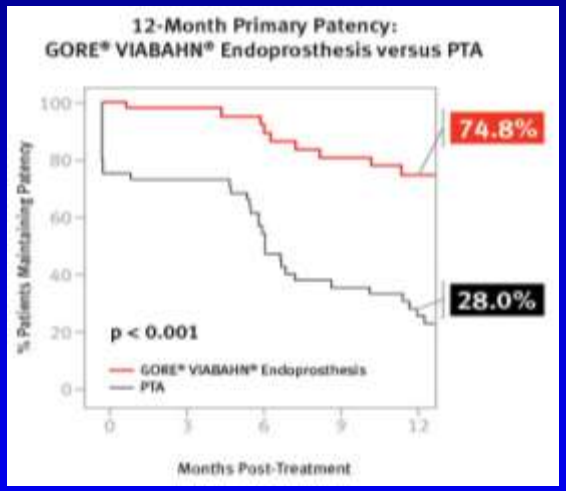
* GC

Instent Restenosis



TASC II C ISR Lesions

Randomized Trials

Laser	DCB	Viabahn
		
EXCITE ISR Trial	FAIR Trial	RELINE Trial
1-yr PP 40.0%	1-yr PP 70.5%	1-yr PP 74.8%
Ave LL 19.6 cm	Ave LL 8.2 cm	Ave LL 17.3 cm

GORE® VIABAHN® Endoprosthesis in Complex SFA Lesions

- Good option for long segment SFA disease and fem-pop occlusions
- Equivalent to prosthetic fem-pop bypass
- Better results than bare-metal nitinol stents
- Consistent patency independent of lesion length
- Effective for fem-pop ISR