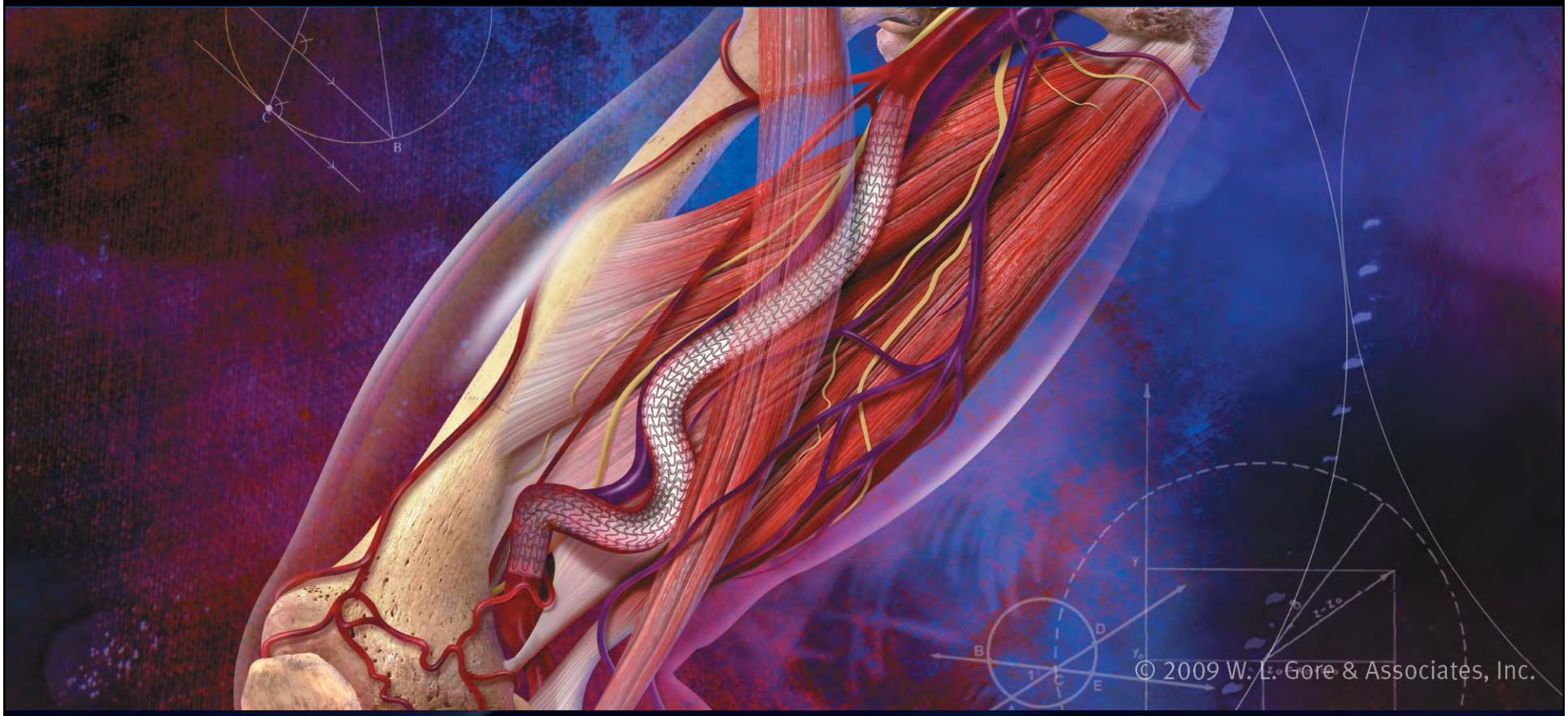


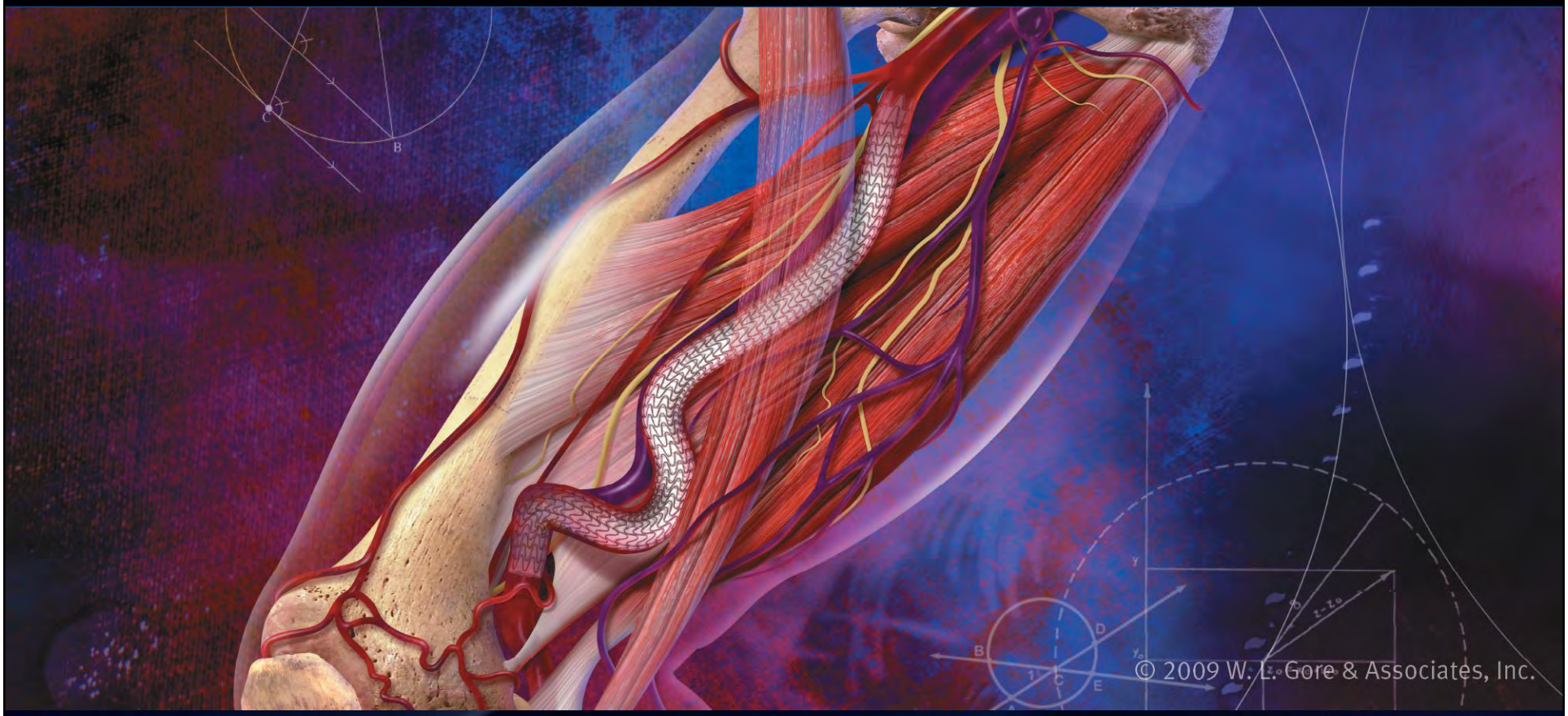
Speaker's Presentation

GORE
VIABAHN
ENDOPROSTHESIS

Table of Contents

- Product Overview
- Mechanical Properties
- Clinical Performance
- Recent Key Papers
- Latest Device Revisions
- Current US Clinical Study
- Selected Bibliography
- Image Materials

Product Overview



GORE® VIABAHN® ENDOPROSTHESIS

Product Overview

THE *GORE*® *VIABAHN*® ENDOPROSTHESIS IS THE ONLY STENT-GRAFT WITH AN SFA INDICATION

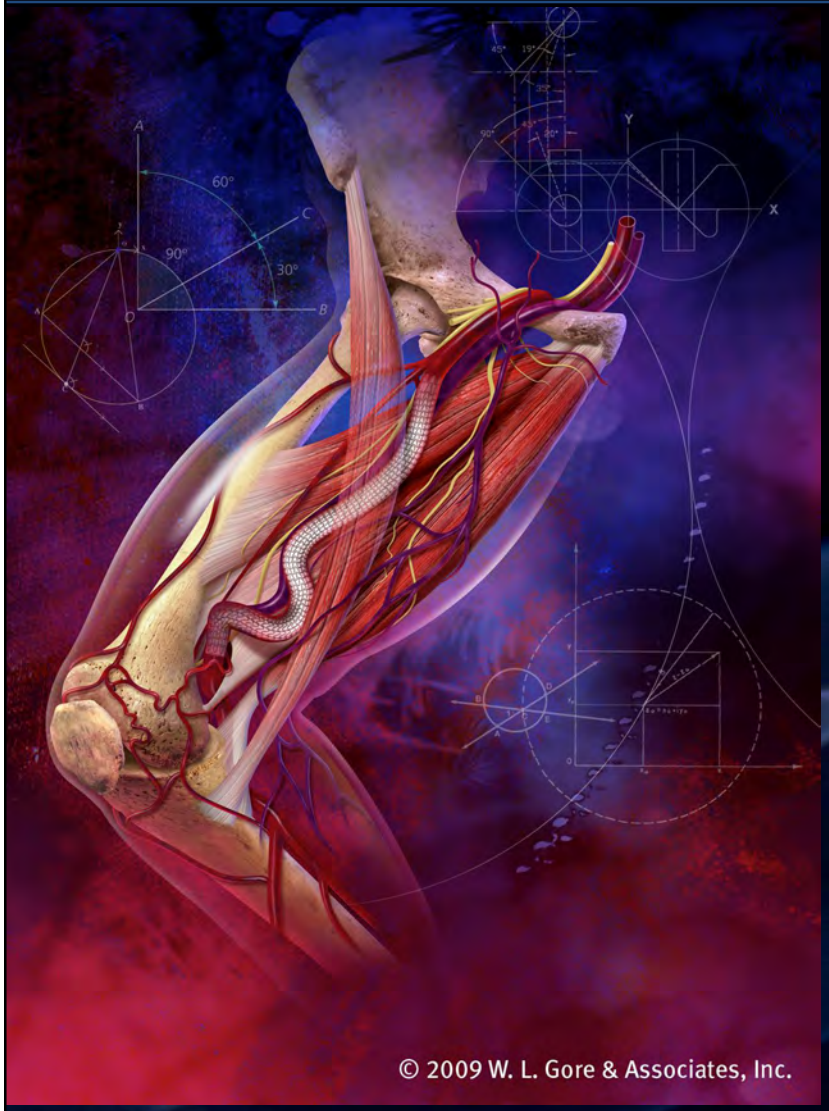
Product Overview

CONTRAINDICATIONS

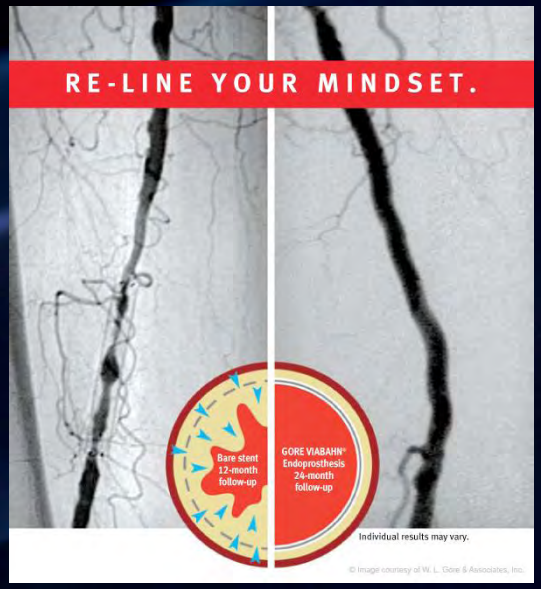
Non-compliant lesions where full expansion of a balloon dilatation catheter cannot be achieved during pre-dilatation, or where obstructions cannot be dilated sufficiently to allow passage of the delivery system.

Refer to the *Instructions for Use* at goremedical.com for contraindications, warnings and precautions. ℞ Only

Total Endoluminal SFA Bypass:
Preventing Trans-Mural Tissue Prolapse



The GORE® VIABAHN® Endoprosthesis covers and seals off the diseased and irregular tissue of the arterial wall. In contrast, a bare nitinol stent covers only a small portion of the diseased arterial lumen.



Individual results may vary.

Features and Benefits

ePTFE + NITINOL = CONFIDENCE

ePTFE Lining

- Limits in-stent restenosis

Nitinol Stent

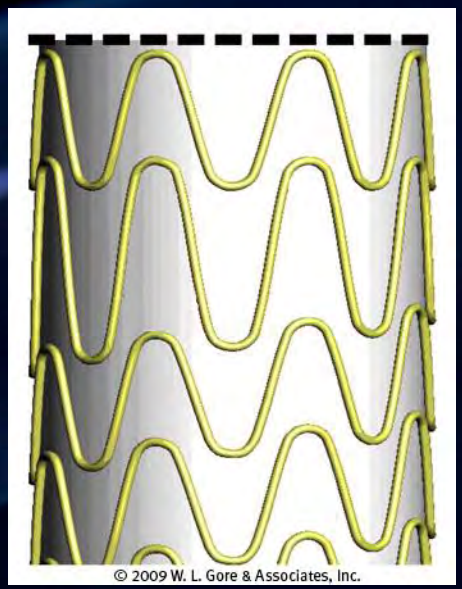
- Conformable yet durable

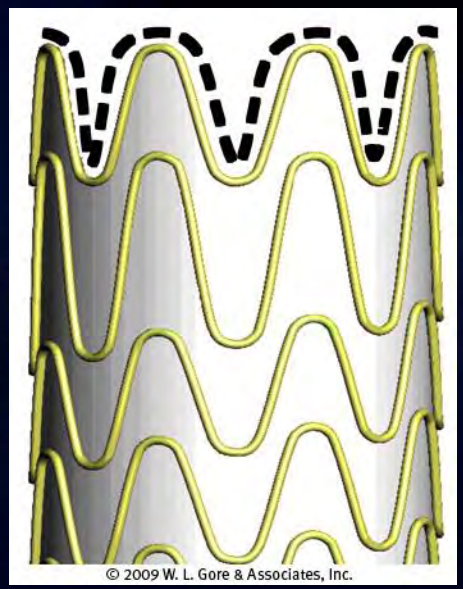
Contoured Proximal Edge

- May improve flow dynamics as blood enters endoprosthesis

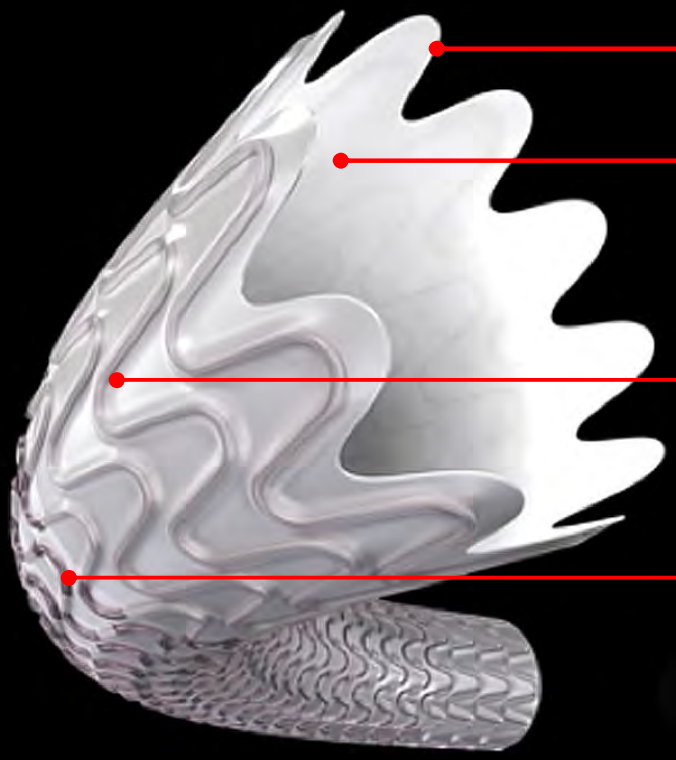
Contoured Edge

- Precision laser trimming technology enables manufacturing change
- Excess graft material is removed
- Contoured trim is on **proximal** edge only





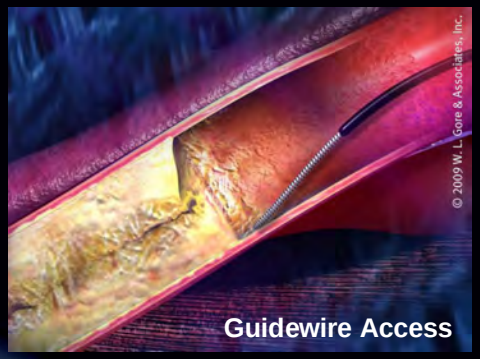
Endoprosthesis Description



- Contoured proximal edge
- Ultra-thin wall ePTFE tube
- Unique, durable bonding film
- Polished nitinol support

Lengths: 2.5, 5, 10, 15 cm
Diameters: 5–13 mm

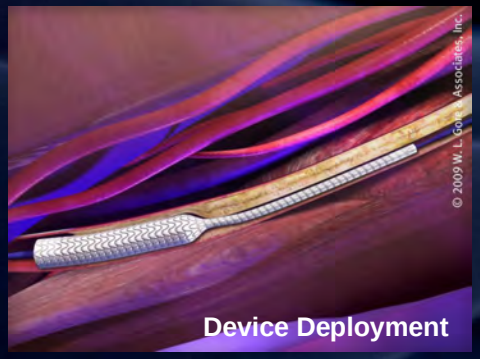
TIP to HUB Deployment



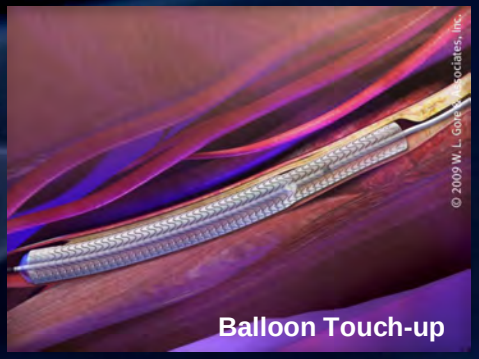
1. Gain access to appropriate lesion with the guidewire.

2. Pre-dilate with appropriately sized balloon.

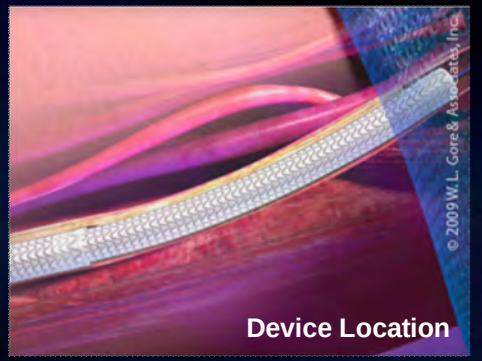
3. Confirm initial landing zone before deployment.



4. Slowly pull deployment knob in a smooth motion.



5. Seat balloon well inside device during touch-up.

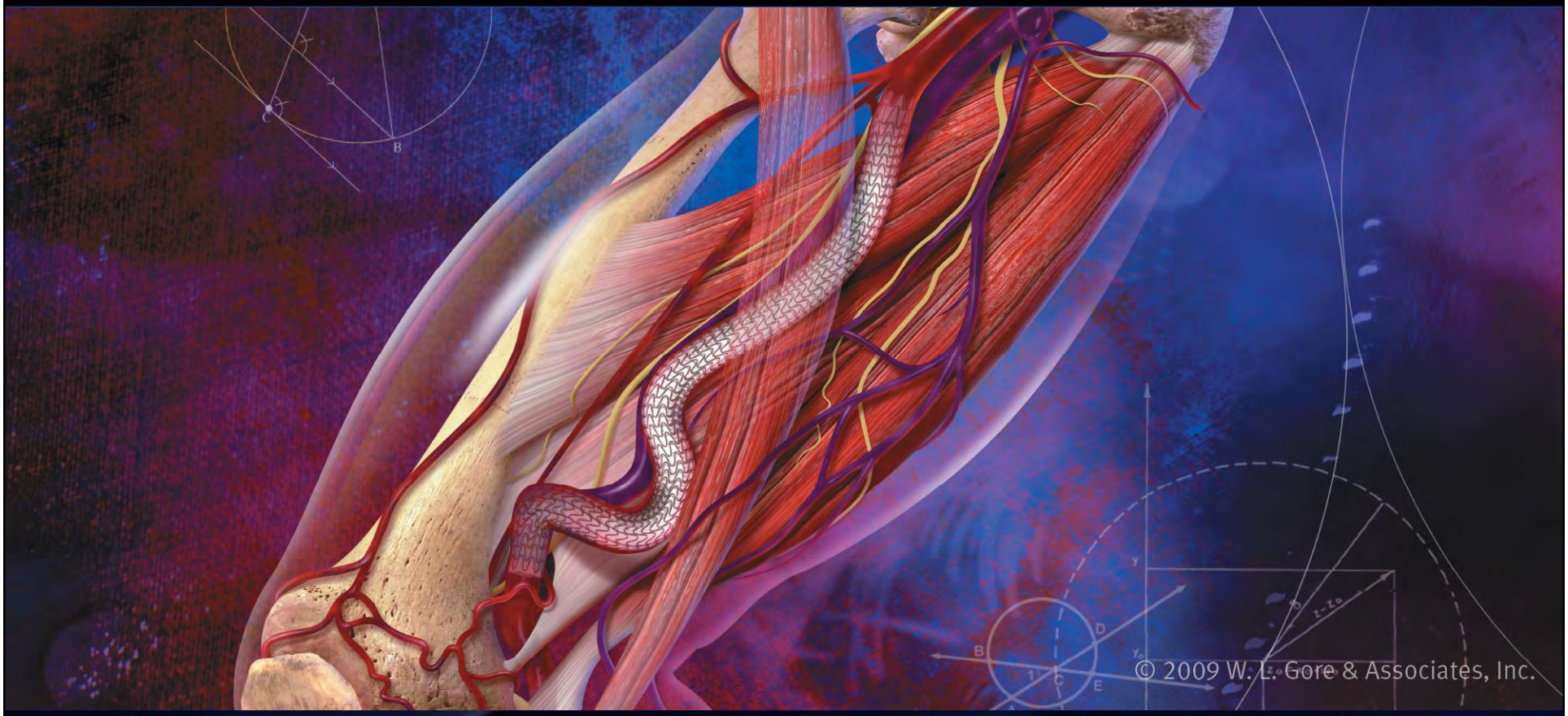


6. Land proximal edge at least 1 cm into healthy vessel.

Clinical Lessons Learned

- Avoid non-complicated lesions
- Ensure adequate inflow and outflow (i.e., at least one vessel run-off)
- Correct sizing is key
- Land device at least 1 cm into healthy vessel proximally and distally to the lesion for obstructive disease
- Every region pre-treated with PTA needs to be covered by the device
- During post dilatation, only balloon inside the region covered by the device
- Consider an antiplatelet regimen post-procedure
- Duplex ultrasound monitoring is recommended

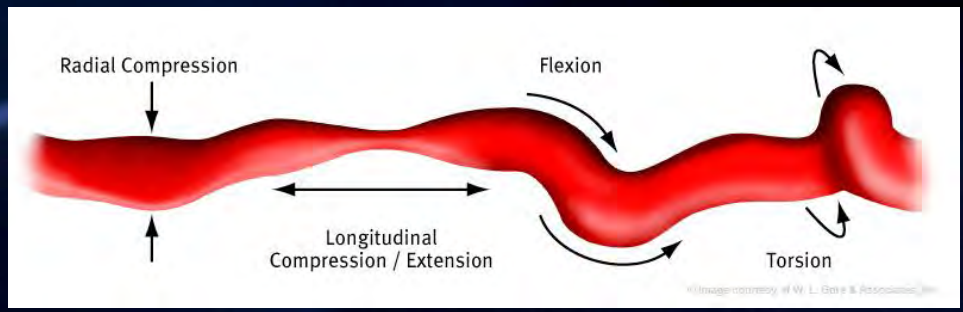
Mechanical Properties



GORE® VIABAHN® ENDOPROSTHESIS

Compliant with the Mechanical Forces of the SFA

- More than 250,000 GORE® VIABAHN® Endoprosthesis sold worldwide
- Very low incidence of reported fractures (< 0.02%)
- Capable of longitudinal compression with little residual force
- Superb flexibility



Mechanical Forces in the SFA

THE *GORE*® *VIABAHN*® ENDOPROSTHESIS IS CAPABLE OF LONGITUDINAL COMPRESSION WITH LITTLE RESIDUAL FORCE

Longitudinal Compression

- "From the supine position to the fetal position, the SFA shortened 13% ± 11% (P < .001)" [1]

[1] Cheng CP, Wilson NW, Hallett RL, Herfkens RJ, Taylor CA. In Vivo MR Angiographic Quantification of axial and twisting deformations of the superficial femoral artery resulting from maximum hip and knee flexion. *Journal of Vascular & Interventional Radiology* 2006;17(6):979-987.

Mechanical Forces in the SFA

Flexion

- "The curvature of the femoral vessels was studied and quantified in stretched and flexed positions…Three or more small curves were seen proximal to the knee joint in all volunteers" [1]

The GORE® VIABAHN® Endoprosthesis

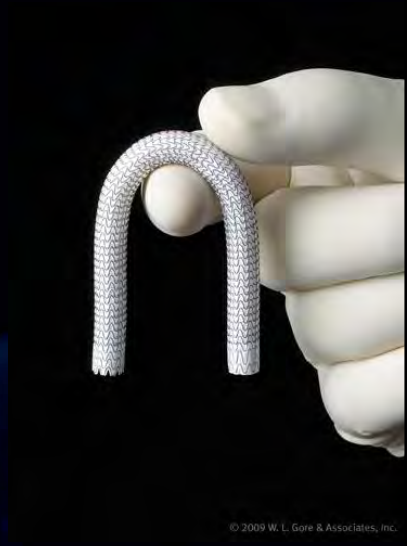
- Outstanding bending and flexibility

Durability

- "One premise is that the SFA … undergo[es] unique and severe conformational changes that can literally pull apart a metal device (stent)." [2]

The GORE® VIABAHN® Endoprosthesis

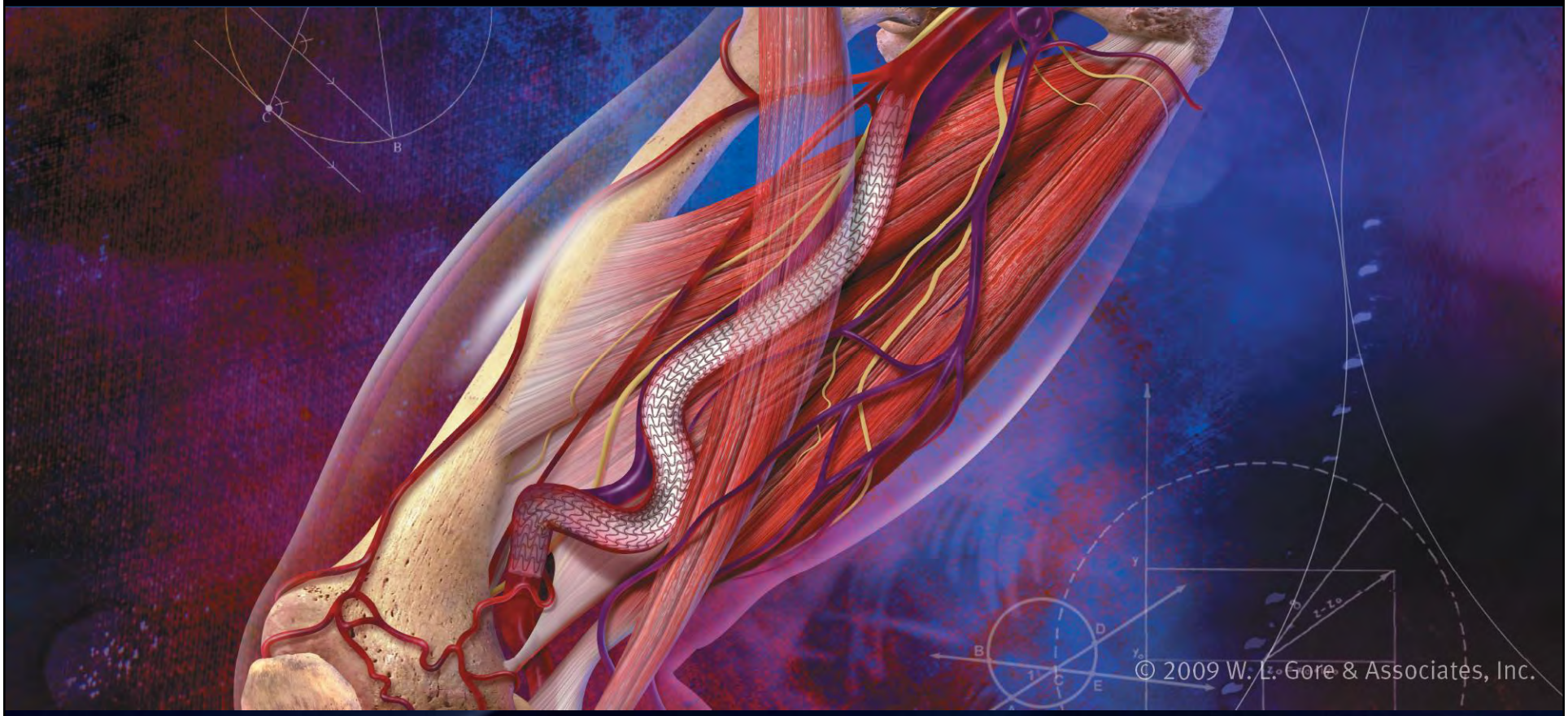
- Very low incidence of reported fractures (< 0.02%)



[1] Wensing PJ, Scholten FG, Buijs PC, Hartkamp MJ, Mali WP, Hillen B. Arterial tortuosity in the femoropopliteal region during knee flexion: a magnetic resonance angiographic study. *Journal of Anatomy* 1995;187(Pt 1):133-139.

[2] Smouse HB, Nikanorov A, LaFlash D. Biomechanical forces in the femoropopliteal arterial segment. What happens during extremity movement and what is the effect on stenting? *Endovascular Today* 2005;4(6):60-66.

Clinical Performance



GORE®
VIABAHN®
ENDOPROSTHESIS

Reported Patencies of GORE® VIABAHN® Endoprosthesis in the SFA (1103 Limbs, 17 Studies)

Reported Patencies of GORE® VIABAHN® Endoprosthesis / GORE® HEMOBAHN® Endoprosthesis (5–8 mm) Treating the SFA in Studies of at Least 30 Limbs

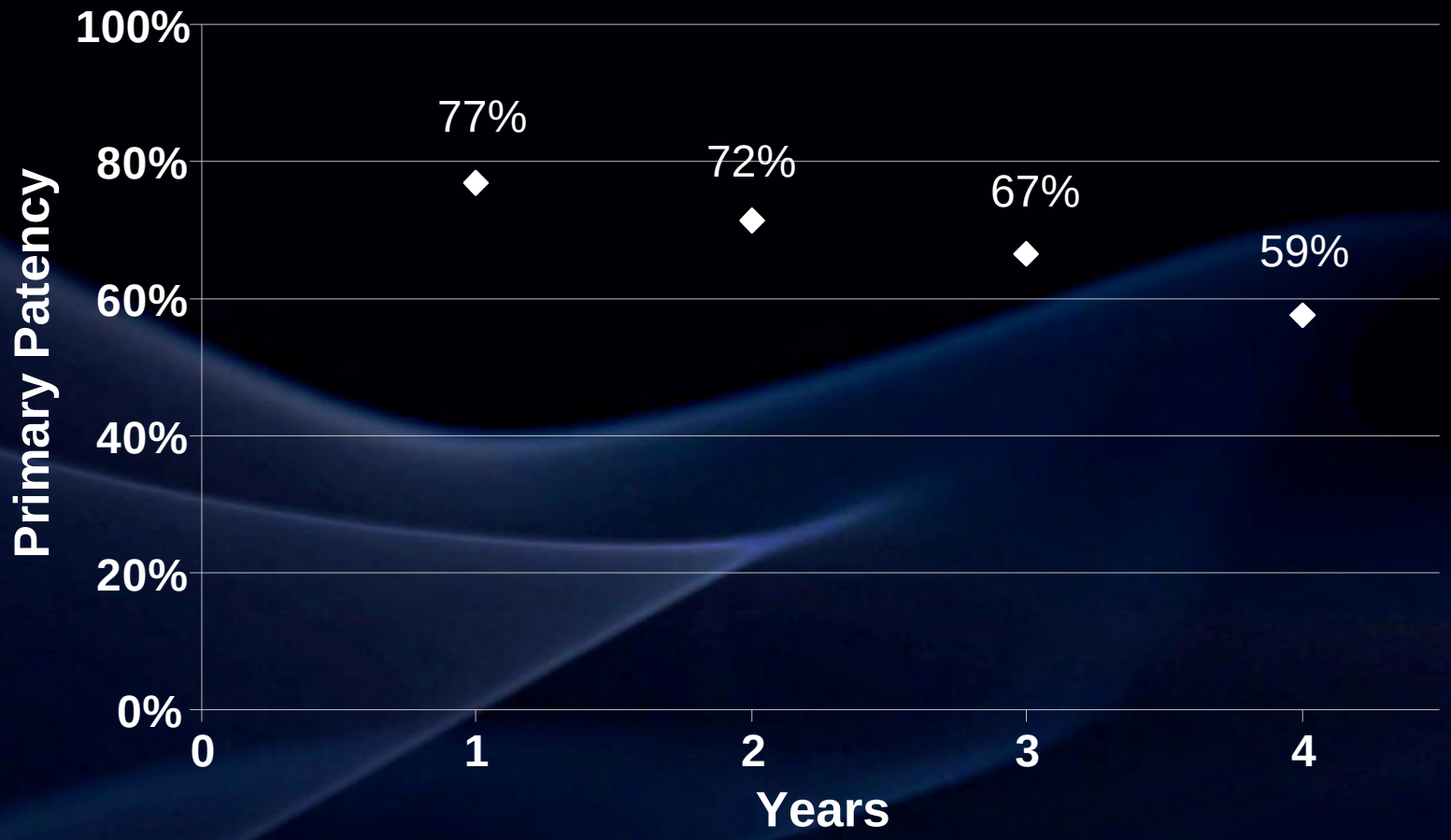
Author	Year	Journal Publication / Presentation	No. of Limbs	Lesion Length (cm)	% Occlusion	Primary Patency (years / %) 1	2	3	4
Lammer	2000	Radiology, 217:95-104	80	13.8	NR	79			
Jahnke	2003	J Vasc Interv Radiol, 14:41-51	52	8.5	83	78	74	62	
Bleyn	2004	Edizioni Minerva Medica, 14:87-91	67	14.3	100	82	73	68	54
Panetta	2005	Endovasc Today, August	41	30.4	90	86	77		
Chopra	2006	AIM Symposium, November 13 – 16	70	20	71	93	87	72	
Coats	2006	Endovasc Today, September	83	NR	47	89			
Fischer	2006	J Endovasc Ther, 13:281-290	59	10.7	87	67	58	57	52
Zander	2006	SIR Meeting, April 3	31	16.6	NR	86	78	78	78
Saxon	2007	J Vasc Interv Radiol, 18:1341-1350	87	14.2	42	76	65	60	55
Alimi	2008	Eur J Vasc Endovasc Surg, 35:346-352	102	11.7	NR	74	71	71	
Djelmami-Hami	2008	SCAI Meeting, March 29 – April 1	132	21	39	80			
Saxon	2008	J Vasc Interv Radiol, 18:823-832	97	7	21	65			
VIBRANT	2009	VIVA, September 19 – 22	72	19	60	53			
Kougias	2009	Am J Surgery, 198:645-649	31	23	100	75			
Farraj	2009	J Invasive Cardiol, 21:278-281	32	15.4	100	80			
Rabellino	2009	Cath Cardiovasc Interv, 73:701-705	32	NR	NR	82	75	75	75
McQuade	2010	J Vasc Surg, 52:584-591	50	25.6	NR	72	63	63	59
Average / Total			**1103**	**16.1**	**62**	**77**	**72**	**67**	**59**

NR = Not Reported

* Number of limbs corrected for same limbs included in both Saxon 2007 and Saxon 2008

GORE® VIABAHN® Endoprosthesis SFA Average Primary Patency

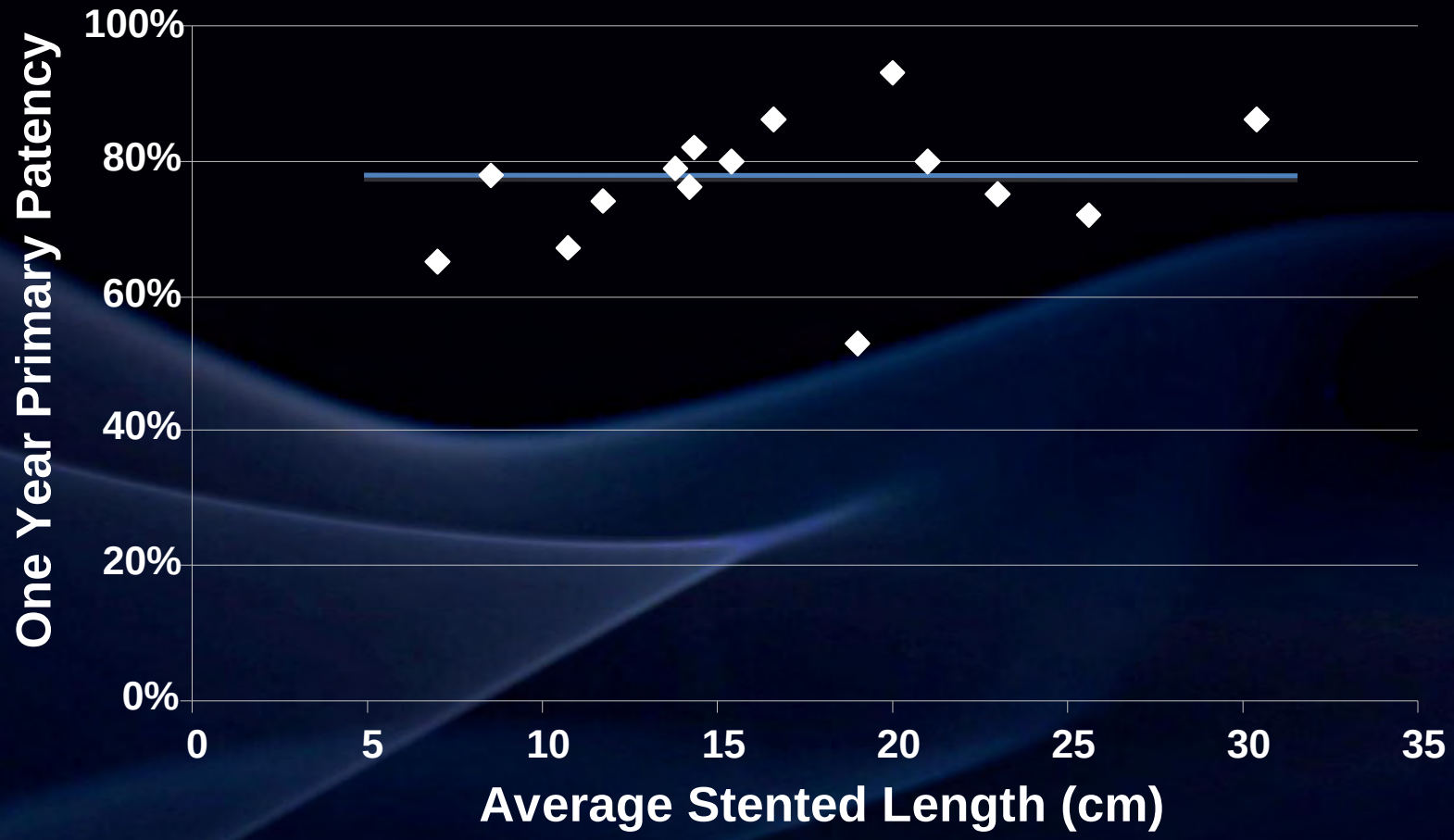
*More than 1,100 Limbs in 17 Independent Studies**



* 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

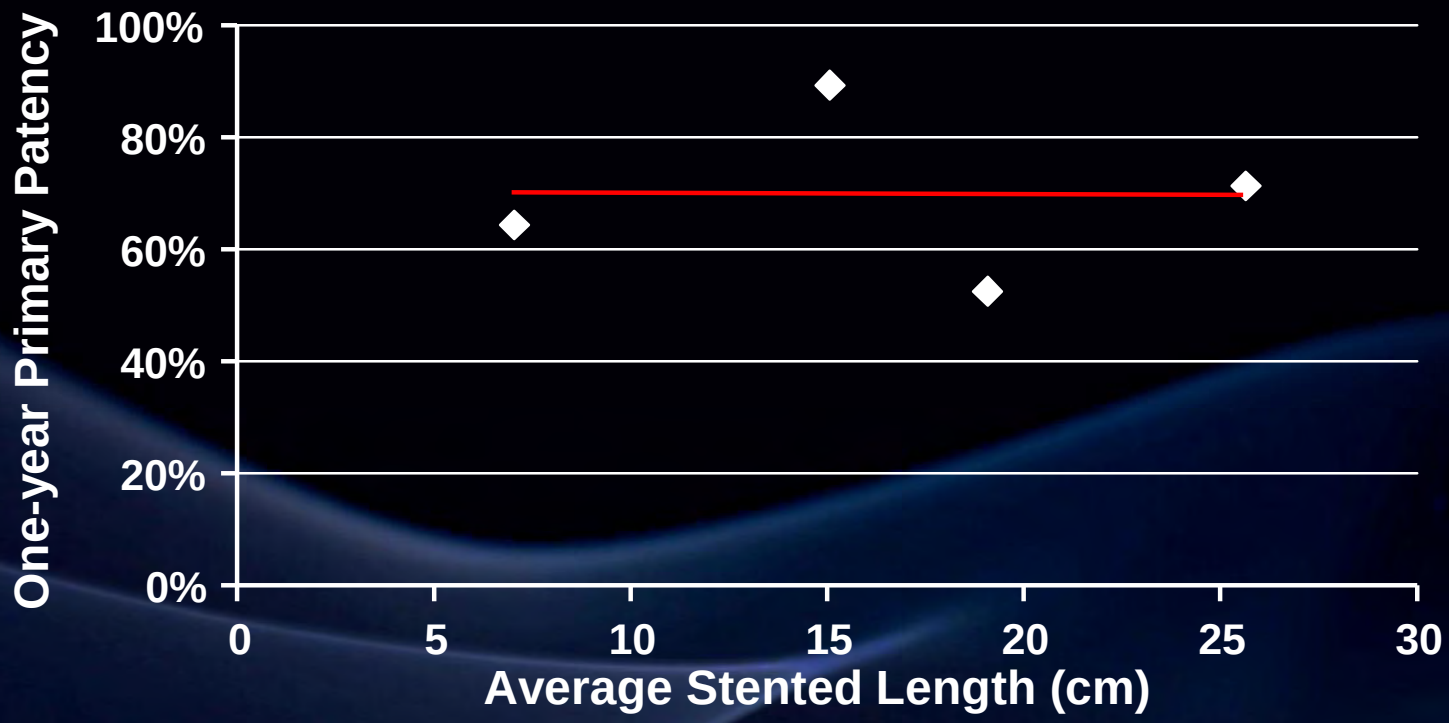
GORE® VIABAHN® Device One Year Primary Patency in the SFA Based on Lesion Length

*More than 1,100 Limbs in 17 Independent Studies**



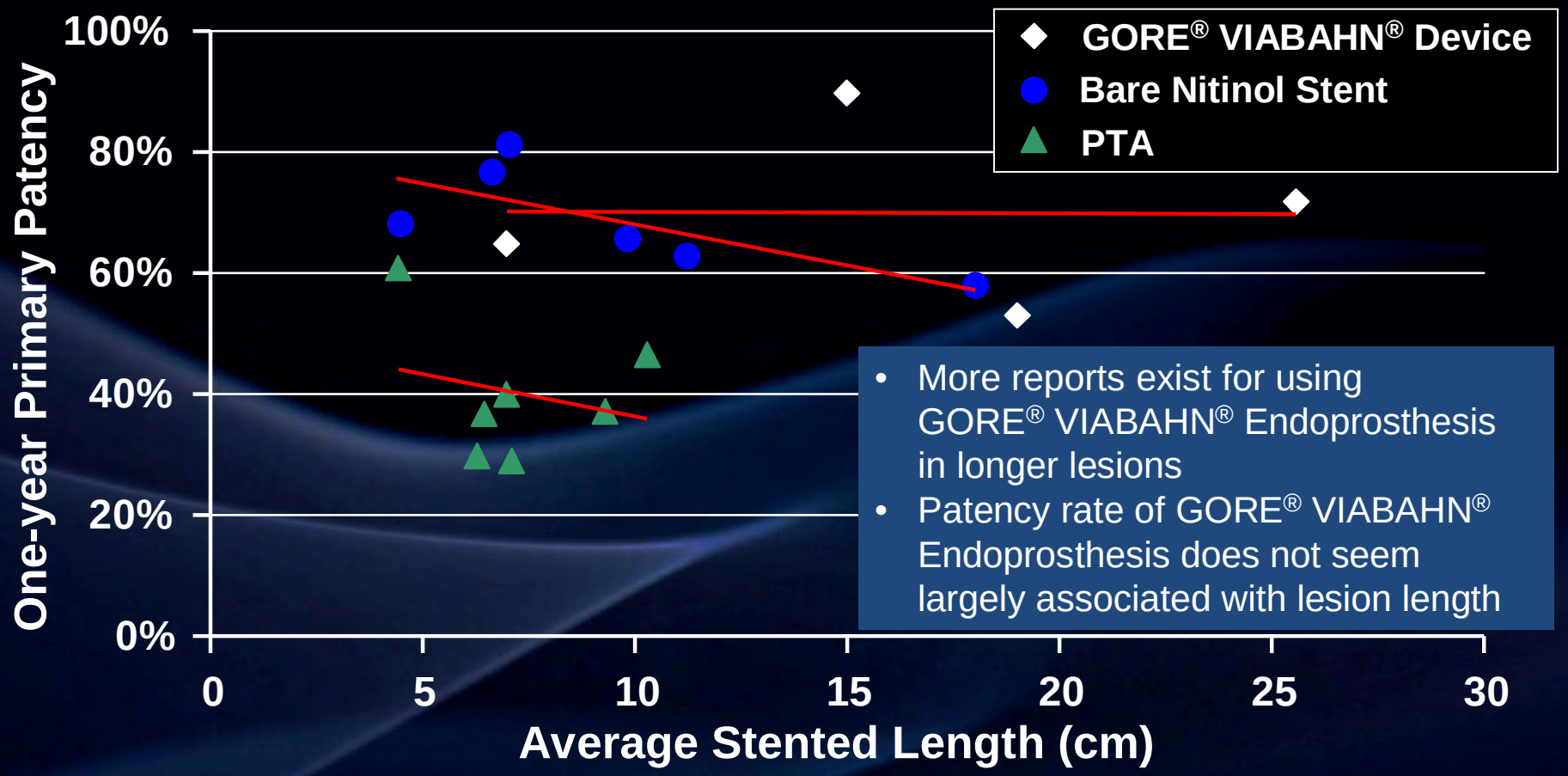
* Patient demographics, lesion characterization, and patency definitions may differ among studies. Studies include at least 30 limbs. Coats, et al., and Rabellino, et al., did not report lesion length

GORE® VIABAHN® Device One Year Primary Patency in SFA Randomized Studies



Study	Year	No. of Limbs	Lesion Length (cm)	Primary Patency			
				1	2	3	4
Saxon	2008	97	7.0	65			
VIBRANT	2009	72	19	53			
McQuade	2010	50	25.6	72	63	63	59
Kazemi	2006	29	15.0	90			

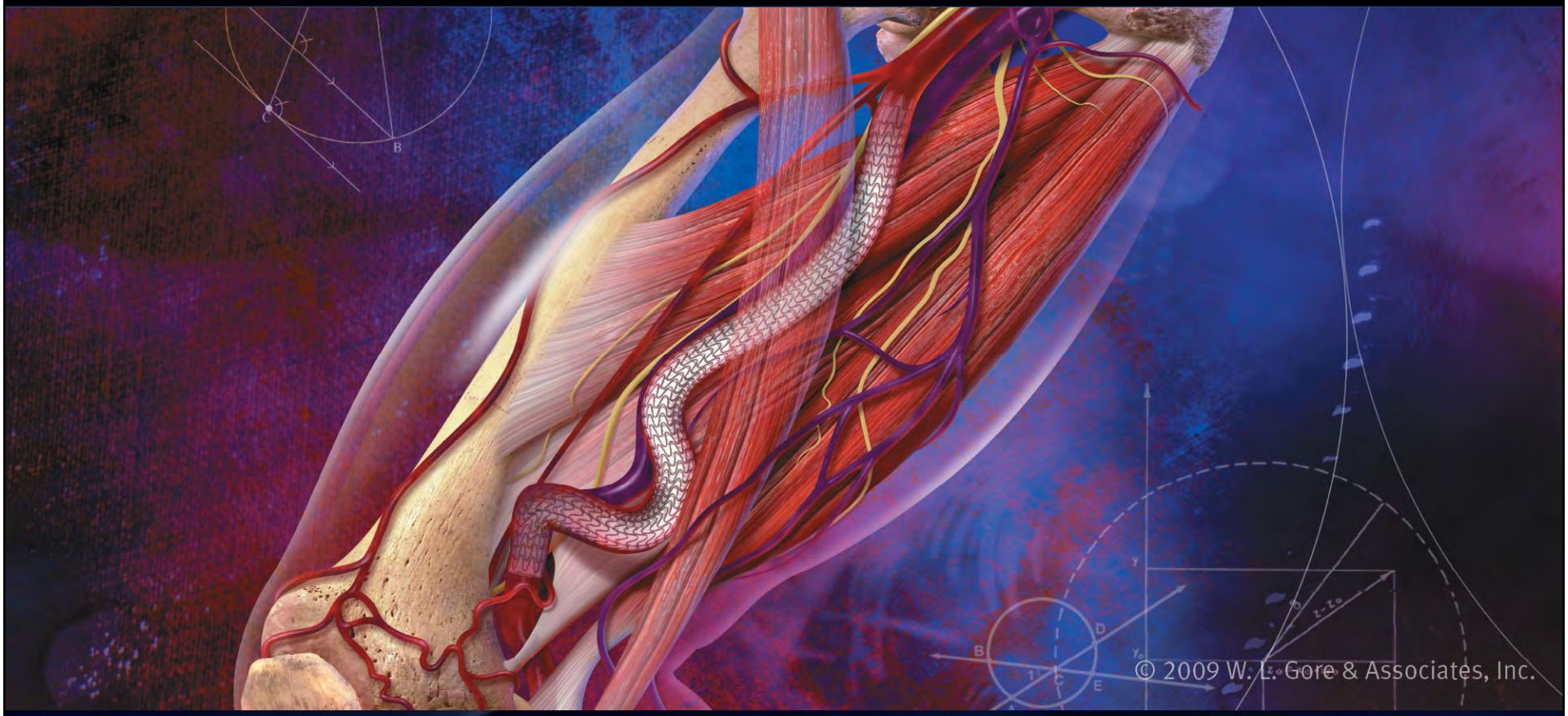
GORE® VIABAHN® Device, Bare Nitinol Stent, and PTA Patency in SFA Randomized Studies



- More reports exist for using GORE® VIABAHN® Endoprosthesis in longer lesions
- Patency rate of GORE® VIABAHN® Endoprosthesis does not seem largely associated with lesion length

* Patient demographics, lesion characterization, and patency definitions may differ among studies. World-wide published randomized studies included. Device approvals may vary by country.

Recent Key Papers



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Recent Key Papers: McQuade 2010

Randomized comparison of percutaneous GORE® VIABAHN® Endoprosthesis Stent-Grafts versus prosthetic femoral-popliteal bypass in the treatment of superficial femoral arterial occlusive disease

	GORE® VIABAHN® 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 K, et. Al. Four-year randomized prospective comparison of percutaneous ePTFE/nitinol self-expanding stent graft versus prosthetic femoral-popliteal bypass in the treatment of superficial femoral artery occlusive disease. *Journal of Vascular Surgery* 2010;52(3):584-591.

Recent Key Papers: Kougias 2009

Value of the GORE® HEMOBAHN® / VIABAHN® Endoprosthesis in the subintimal treatment of long lesions of the superficial femoral artery

	GORE® VIABAHN® Endoprosthesis (n = 31)	Angioplasty (n = 57)
Length (cm)	**23**	**19**
Occlusions	**100**	
Patency Definition	**Flow by duplex, ABI > 0.15 above baseline, pulse, no symptoms**	
Primary Patency	**75%**	**28%**
Secondary Patency	**84%**	**37%**

Kougias P, Chen A, Cagiannos C, Bechara CF, Huynh TT, Lin PH. Subintimal placement of covered stent versus subintimal balloon angioplasty in the treatment of long-segment superficial femoral artery occlusion. *American Journal of Surgery* 2009;198(5): 645-649.

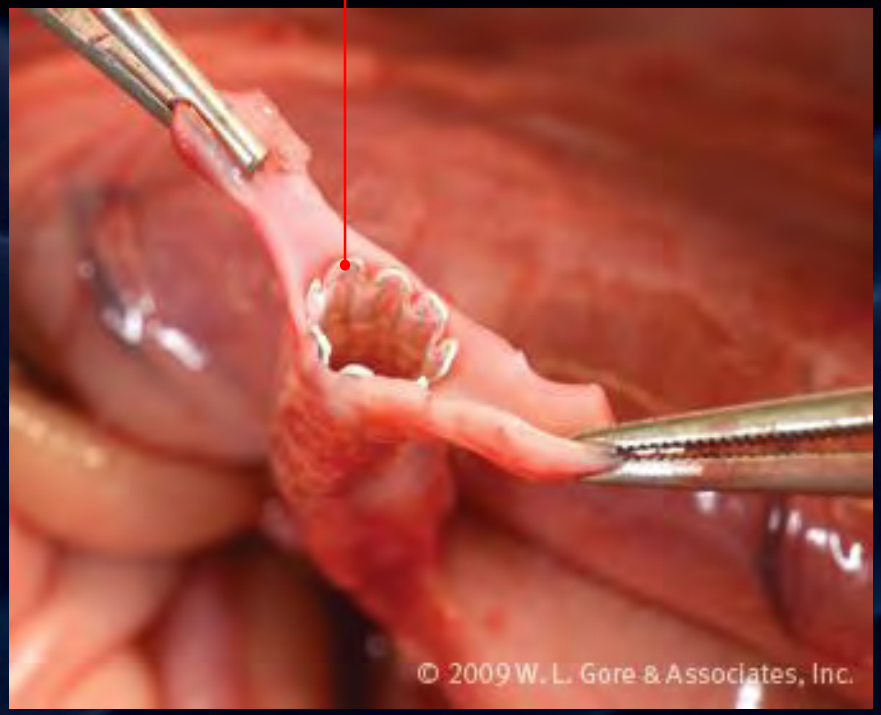
Reason for Modification

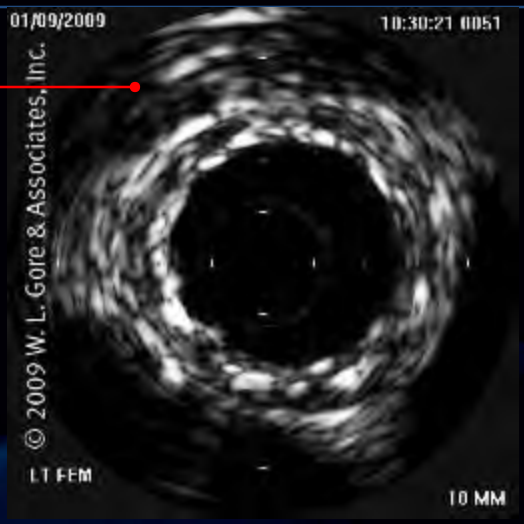
- Manufacturing process change enables excess graft material removal at proximal margin of device
- Contoured edge may improve flow dynamics at proximal edge

Contoured Edge: Canine Model

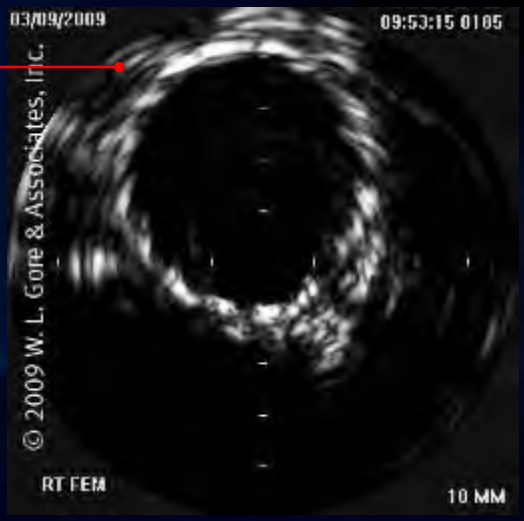
IVUS demonstrates device apposition to artery.

Post-mortem dissection demonstrates device apposition to artery.



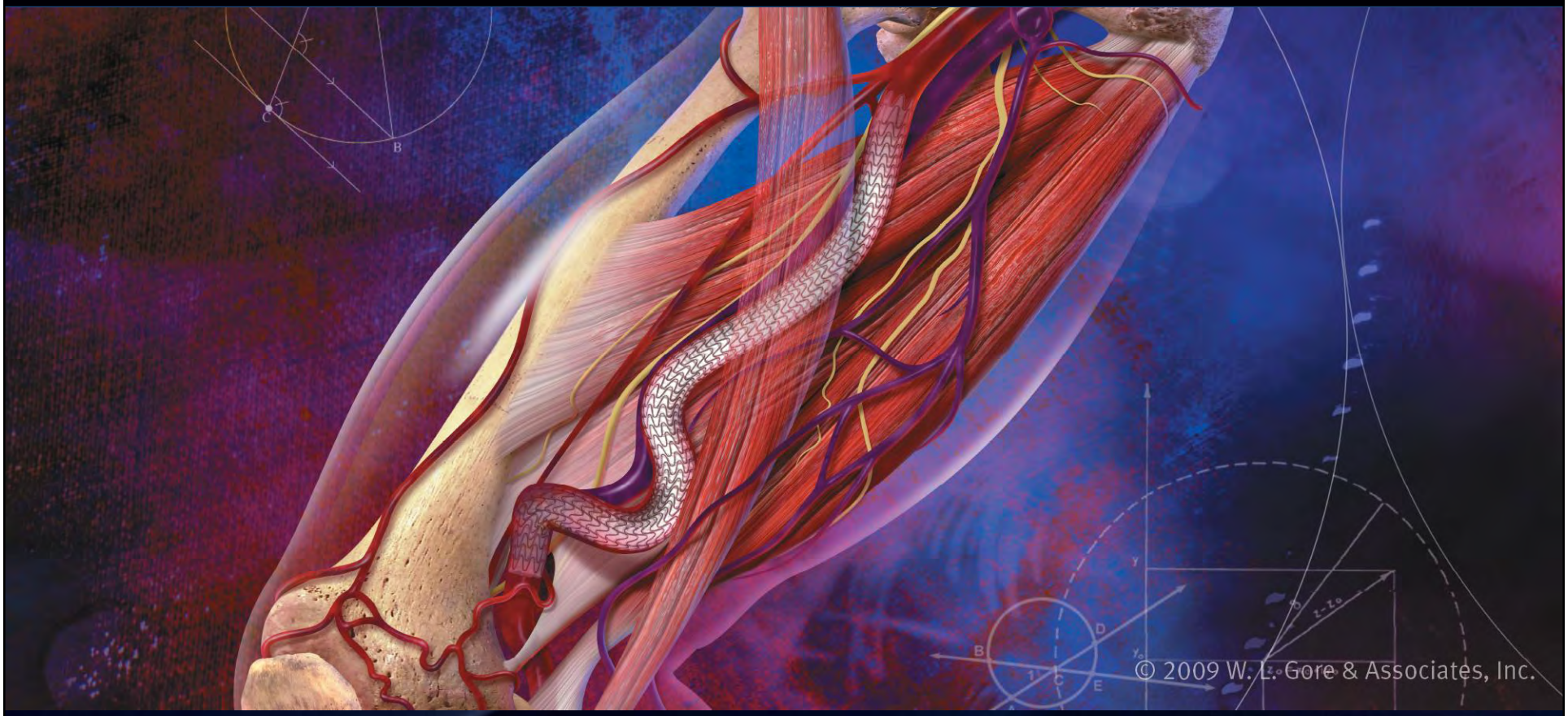


30 day



90 day

Current US Clinical Study

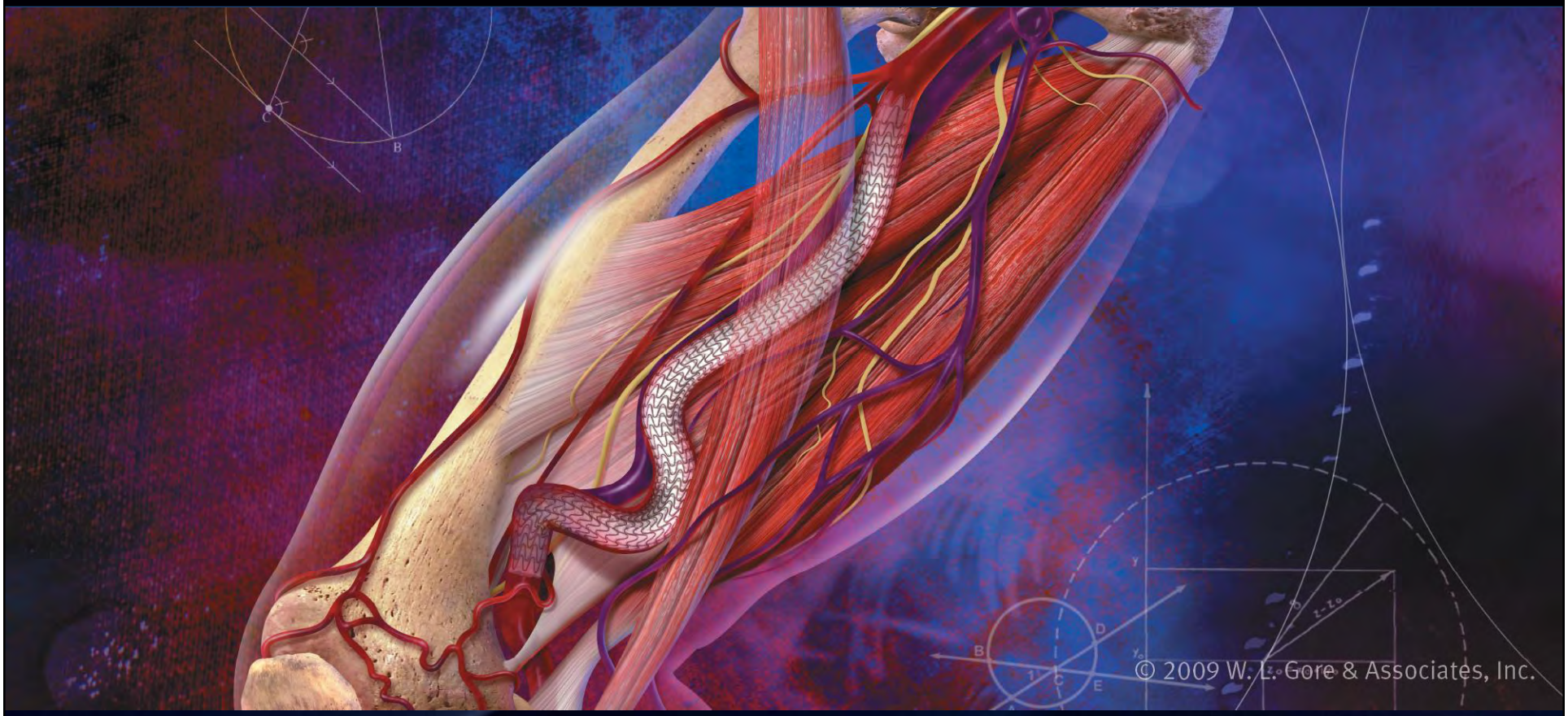


GORE®
VIABAHN®
ENDOPROSTHESIS

REVISE (US)

Sponsor	W.L. Gore & Associates
Principal Investigator	Tom Vesely, MD, Vascular Access Center, Frontenac, MO
Objective	To establish efficacy & safety of the GORE® VIABAHN® Endoprosthesis (6–13 mm) when used to revise arteriovenous prosthetic grafts at the venous anastomosis in the maintenance or re-establishment of vascular access for hemodialysis.
Design	Randomized GORE® VIABAHN® to POBA, multi-center
Primary Endpoints	Target Lesion Primary Patency at six months
Secondary Endpoints	Clinical success, technical success, access circuit primary patency, assisted primary, secondary patency and treatment area secondary patency evaluated to 24 months
Status	Currently enrolling (initiated September 2008)

Selected Bibliography



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Bare Nitinol Stenting and PTA Randomized Studies

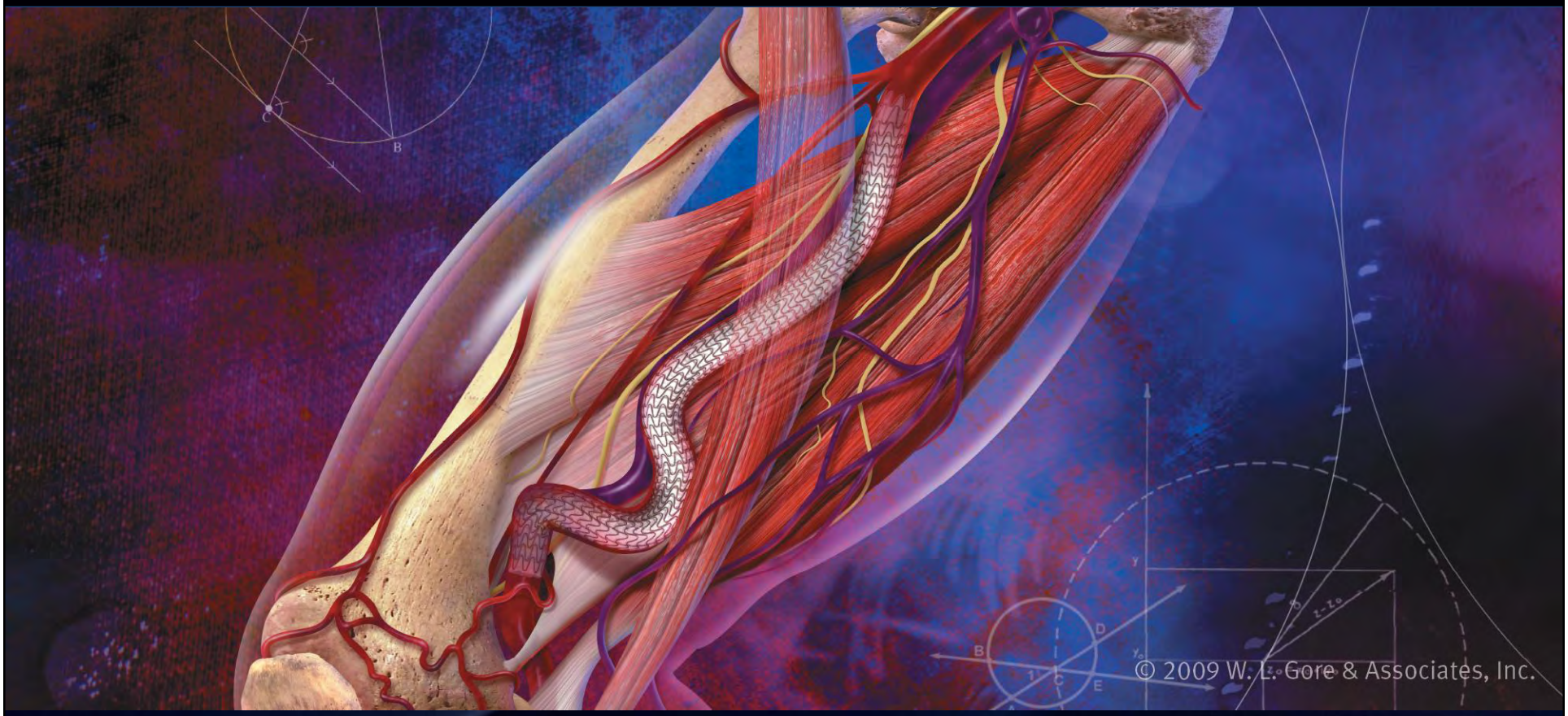
Prospective, Randomized Studies on Bare Nitinol Stenting

- RESILIENT (Edwards Lifesciences Corporation LIFESTENT Device) Pre-market approval study for US FDA
- FAST (BARD® LUMINEXX Device) European study
- Vienna (Abbott Laboratories DYNALINK / ABSOLUTE Device) European study
- ASTRON European study
- Gore VIBRANT Clinical Study US study
- Cook Medical Zilver® PTX US study

Prospective, Randomized Studies on PTA

- RESILIENT (Edwards Lifesciences Corporation LIFESTENT Device) Pre-market approval study for US FDA
- FAST (BARD® LUMINEXX Device) European study
- Vienna (Abbott Laboratories DYNALINK / ABSOLUTE Device) European study
- ASTRON European study
- GORE® VIABAHN® Device Pre-market approval study for US FDA
- VIENNA-3 brachytherapy study
- Cook Medical Zilver® PTX US study

Images



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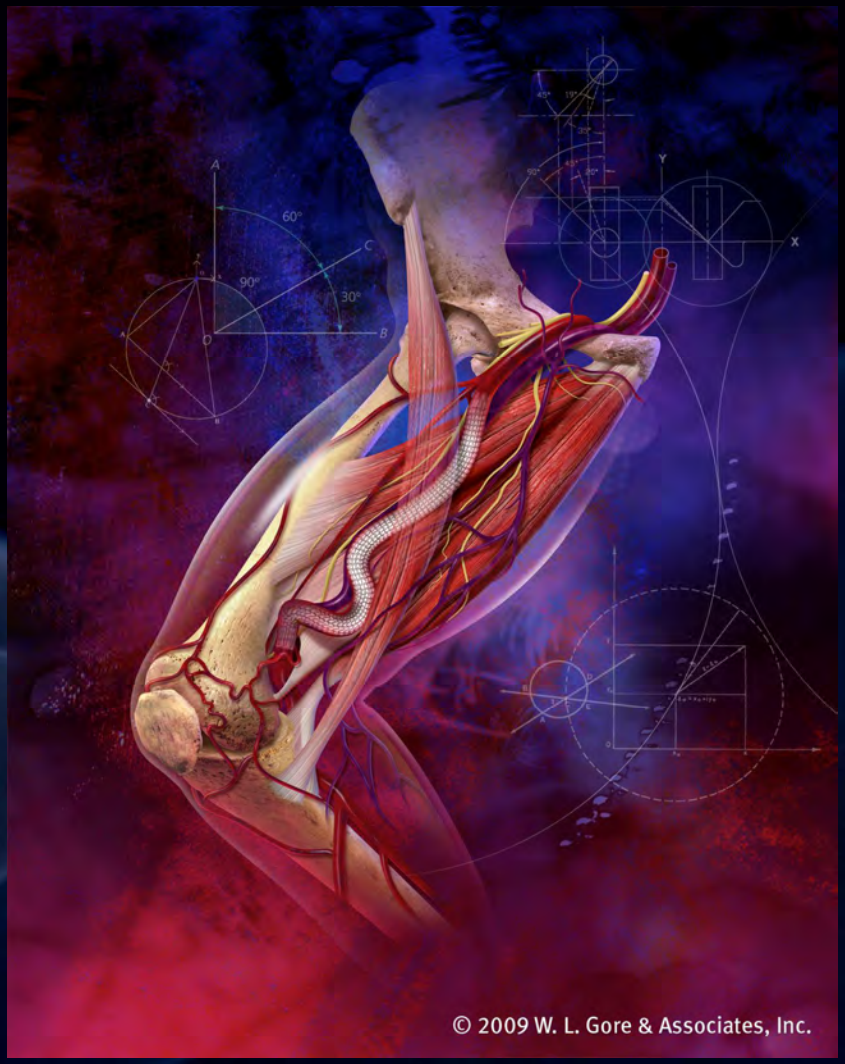
Images



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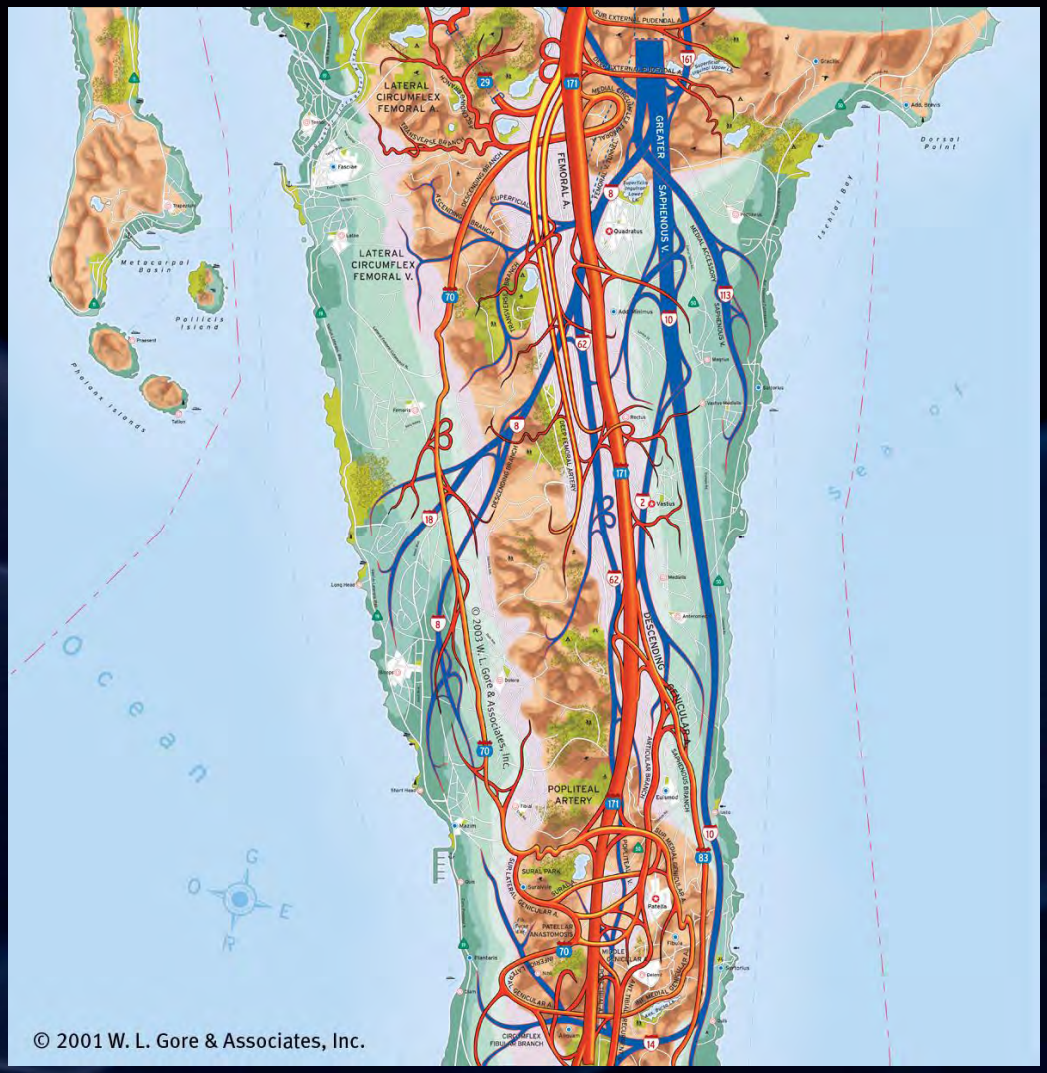

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