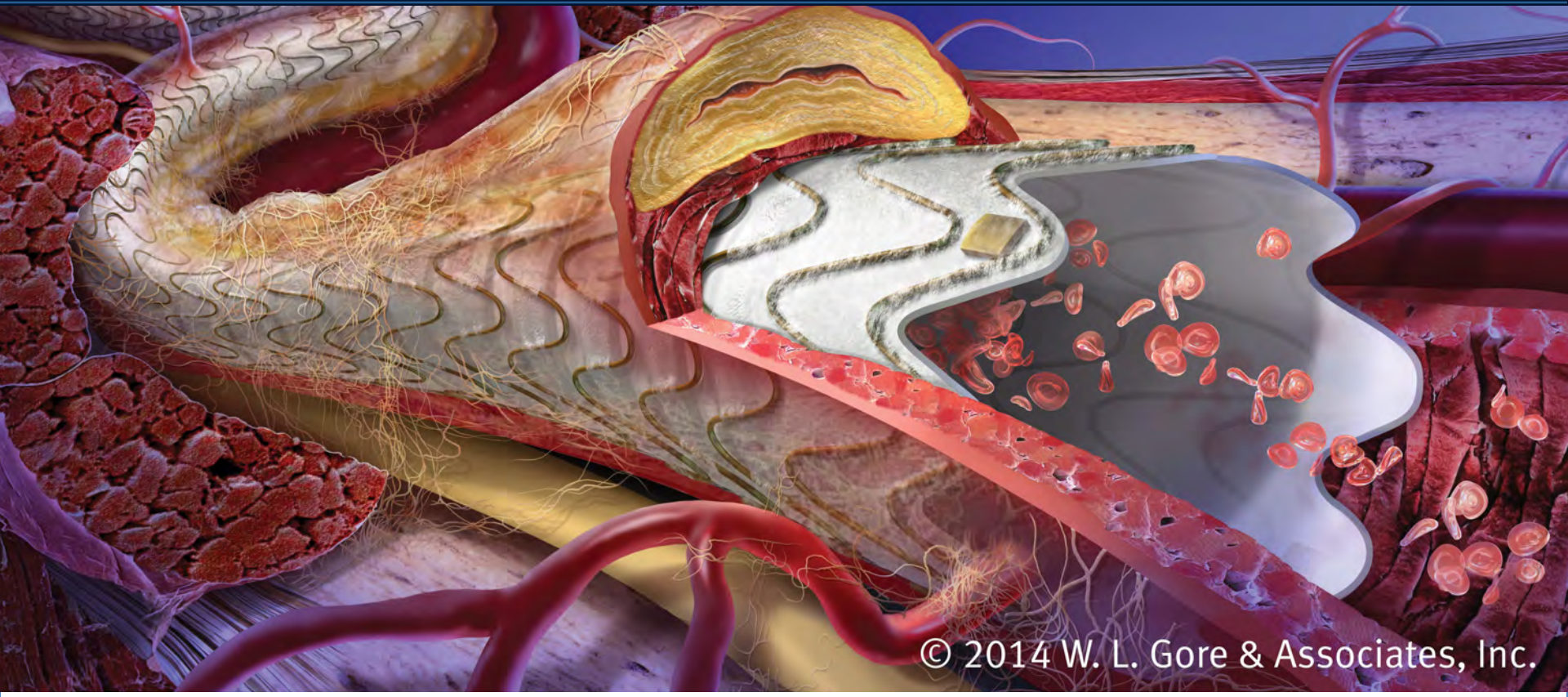
Gore VIPER Clinical Study
One-Year Results



GORE VIABAHN ENDOPROSTHESIS
PROPATEN BIOACTIVE SURFACE

Product with radiopaque markers planned for European availability in 2016.

Gore VIPER Clinical Study Centers and Principal Investigators

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Mercy Hospital, Chicago, Illinois	Paul Jones, MD
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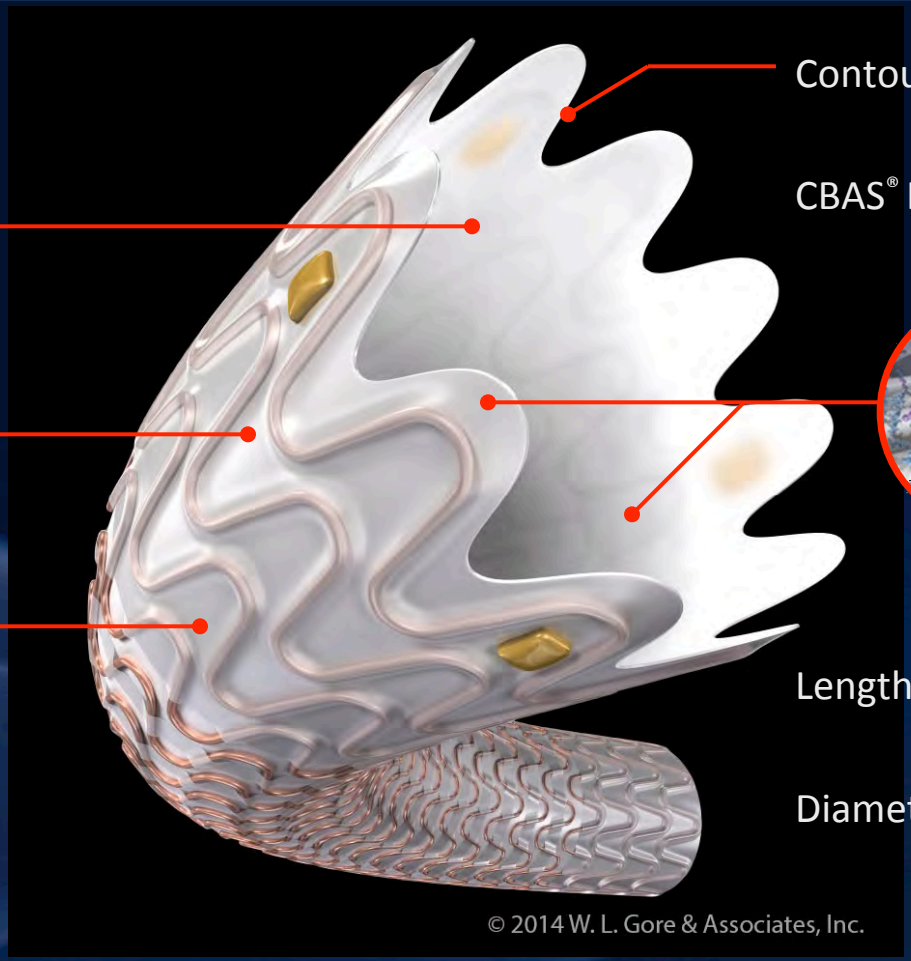
Gore VIPER Clinical Study Overview

GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface for treatment of long SFA disease

Objective	**Evaluate the performance of GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface (W. L. Gore & Associates, Inc.) in treating long-segment SFA disease (> 5 cm in length)**
Design	**Single-arm, prospective, 12 sites, 120 limbs**
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 uninterpretable or unavailable** **Proportion of subjects experiencing major procedure related adverse events within 30 days of procedure**
Secondary Endpoints	**Primary assisted patency** **Secondary patency** **Device-related major adverse events at 12 months**

Endoprosthesis Description



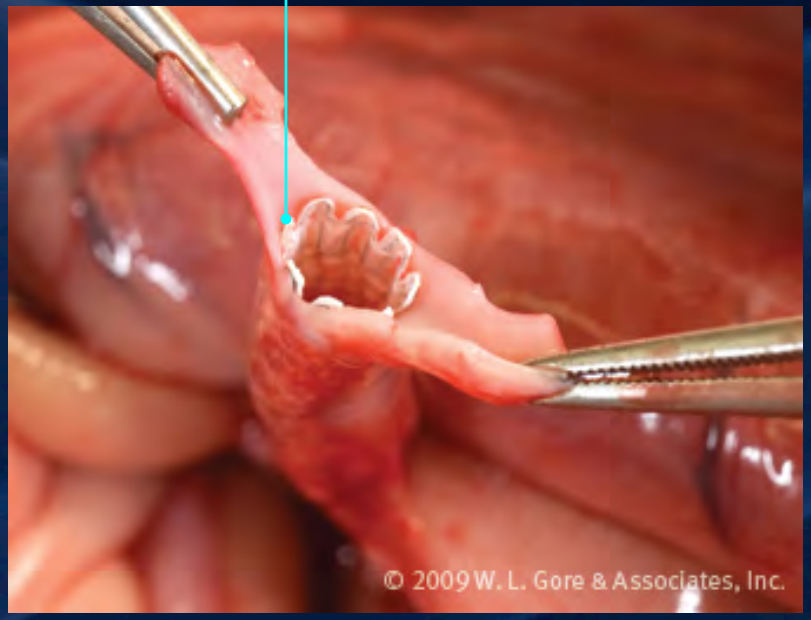
Product with radiopaque markers planned for European availability in 2016.

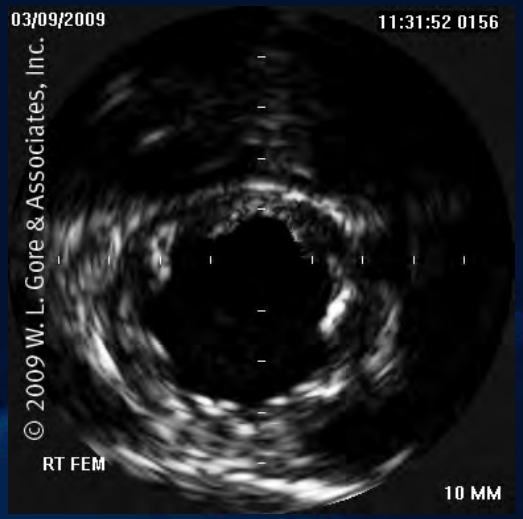
Contoured Proximal Edge

Manufacturing change during study

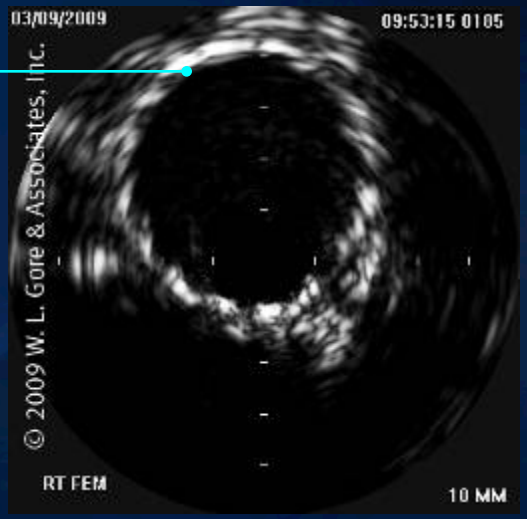
IVUS demonstrates device apposition to artery in canine model

Post-mortem dissection demonstrates device apposition to artery





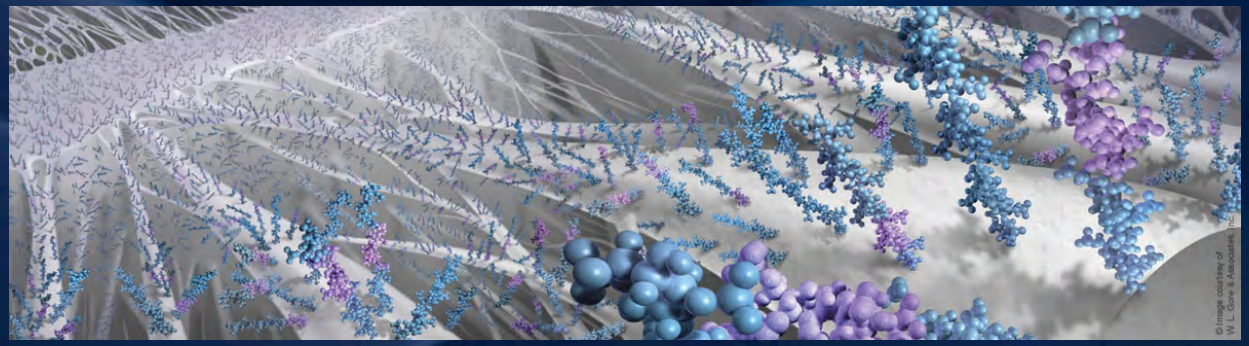
Non-Contoured



Contoured

CBAS® Heparin Surface

- End-point covalent bonding
  - CBAS® Heparin Surface technology allows for retention of bioactivity.
- Sustained bioactivity[1]
  - Active site catalytically facilitates antithrombin-thrombin complex formation and then becomes available to repeat the reaction.
- Intended to provide a thromboresistant surface
  - Clinical history: Long-term activity and safety. [2]



1. P.C. Begovac, R.C. Thomson, J.L. Fisher, A. Hughson, A. Gallhagen. Improvements in GORE-TEX® vascular graft performance by Carmeda® bioactive surface heparin immobilization. *European Journal of Vascular & Endovascular Surgery* 2003, 25(5): 432-437.

2. Lindholt JS, Gottschalksen B, Johannesen N, *et al*. The Scandinavian Propaten® Trial – 1-year patency of PTFE vascular prostheses with heparin-bonded luminal surfaces compared to ordinary pure PTFE vascular prostheses – a randomised clinical controlled multi-centre trial. *European Journal of Vascular & Endovascular Surgery* 2011;41(5):668-673.

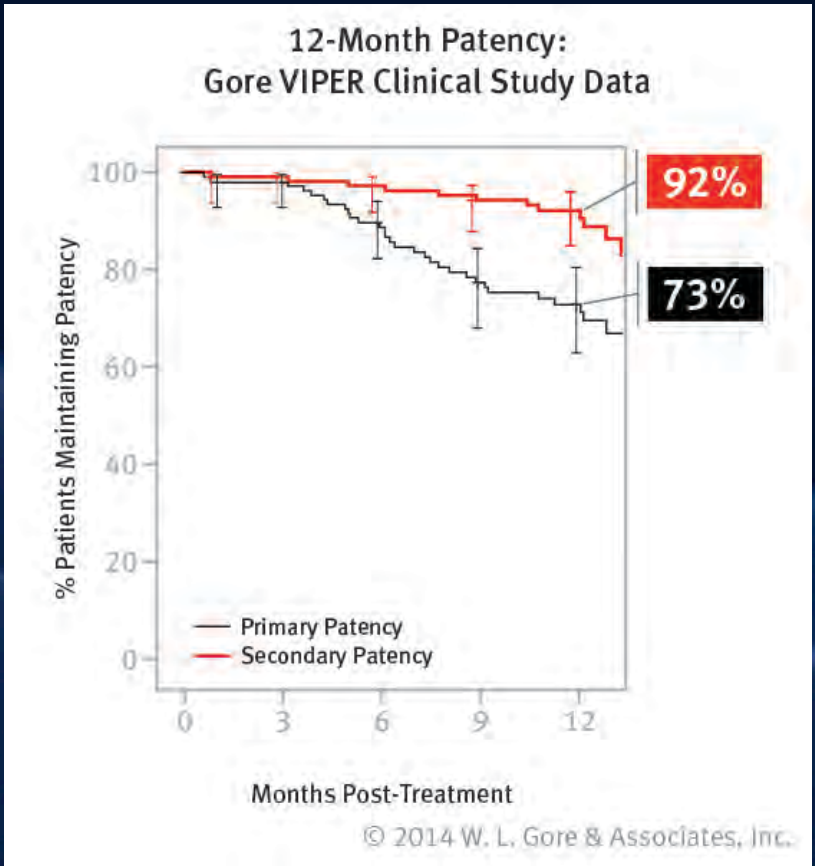
Lesion Characteristics

	Gore VIPER Clinical Study
Limbs Enrolled	**119**
Treated Occlusions	**56%**
Lesion Length	**19 cm**
Lesion Calcification	
none-mild	**39%**
moderate-severe	**61%**
Tibial Runoff	
One vessel	**21%**
Two vessel	**33%**
Three vessel	**46%**
TASC II Lesion Classification	
Type A	**14%**
Type B	**25%**
Type C	**29%**
Type D	**31%**

Safety – Major Adverse Events

- **Primary Endpoint: 30-day procedure-related MAE**
  - **One event, (0.8%): surgical bypass after target lesion occlusion**
- **Secondary Endpoint: One-year device-related MAE**
  - **Zero events**
- **Major Adverse Events (MAE): require significant therapy, including unplanned increase in the level of care, permanent sequelae, hospitalization, or death. Repeat interventions, stenosis, and occlusions are not adverse events.**

One-Year Patency

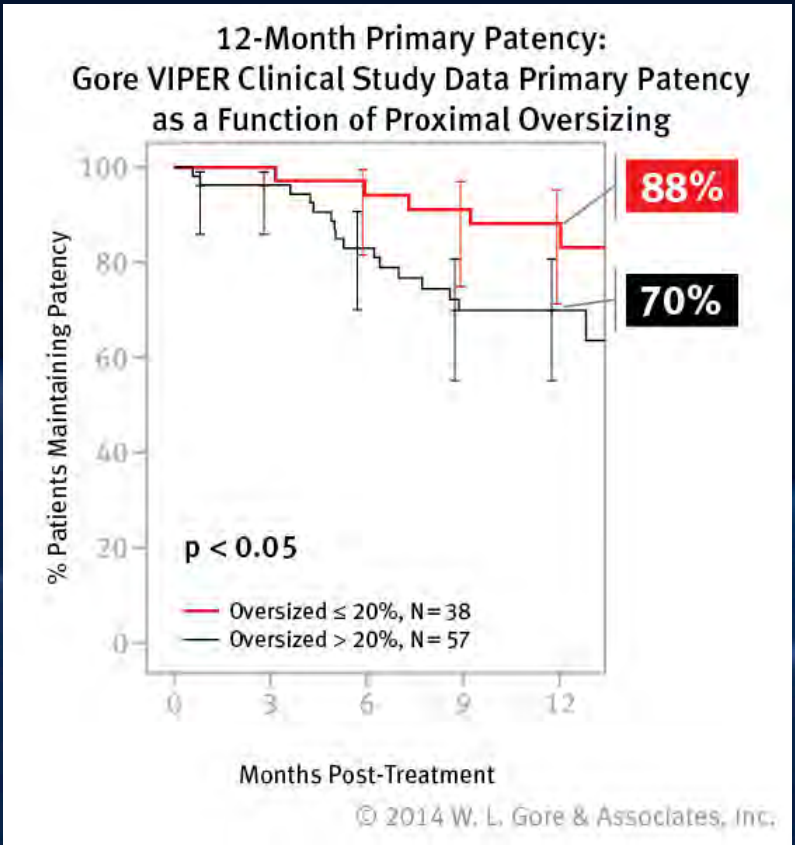


103 / 119 limbs available for follow-up at 12 months

One-Year Primary Patency by Subgroup

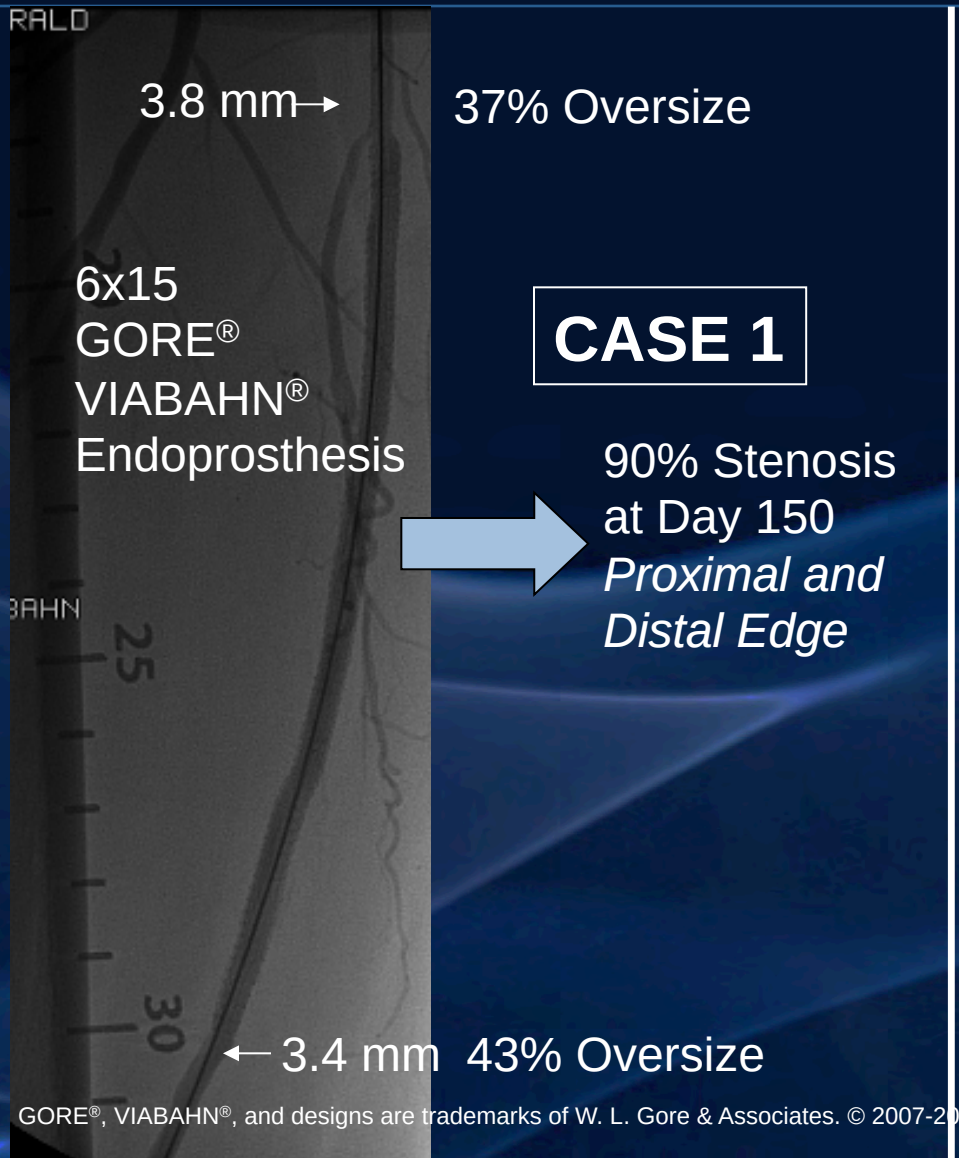
	Primary Patency
Overall	73%
Device Diameter	
5 mm (n= 23)	79%
6 mm (n= 85)	69%
7 mm (n= 8)	100%
Lesion Length	
≤ 20 cm (n= 68)	75%
> 20 cm (n= 51)	70%

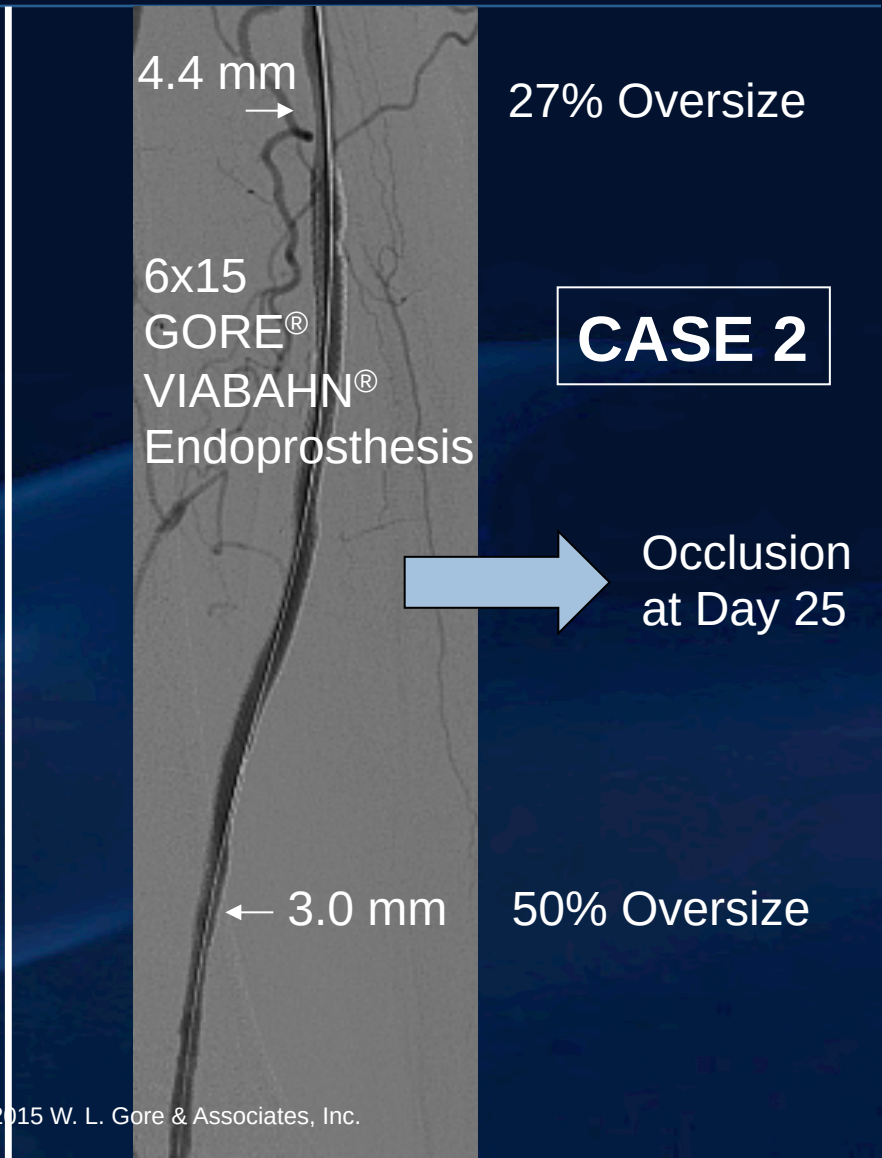
Effects of Device Sizing: Proximal



Device oversizing assessed by independent Core Lab, data on file

Oversizing



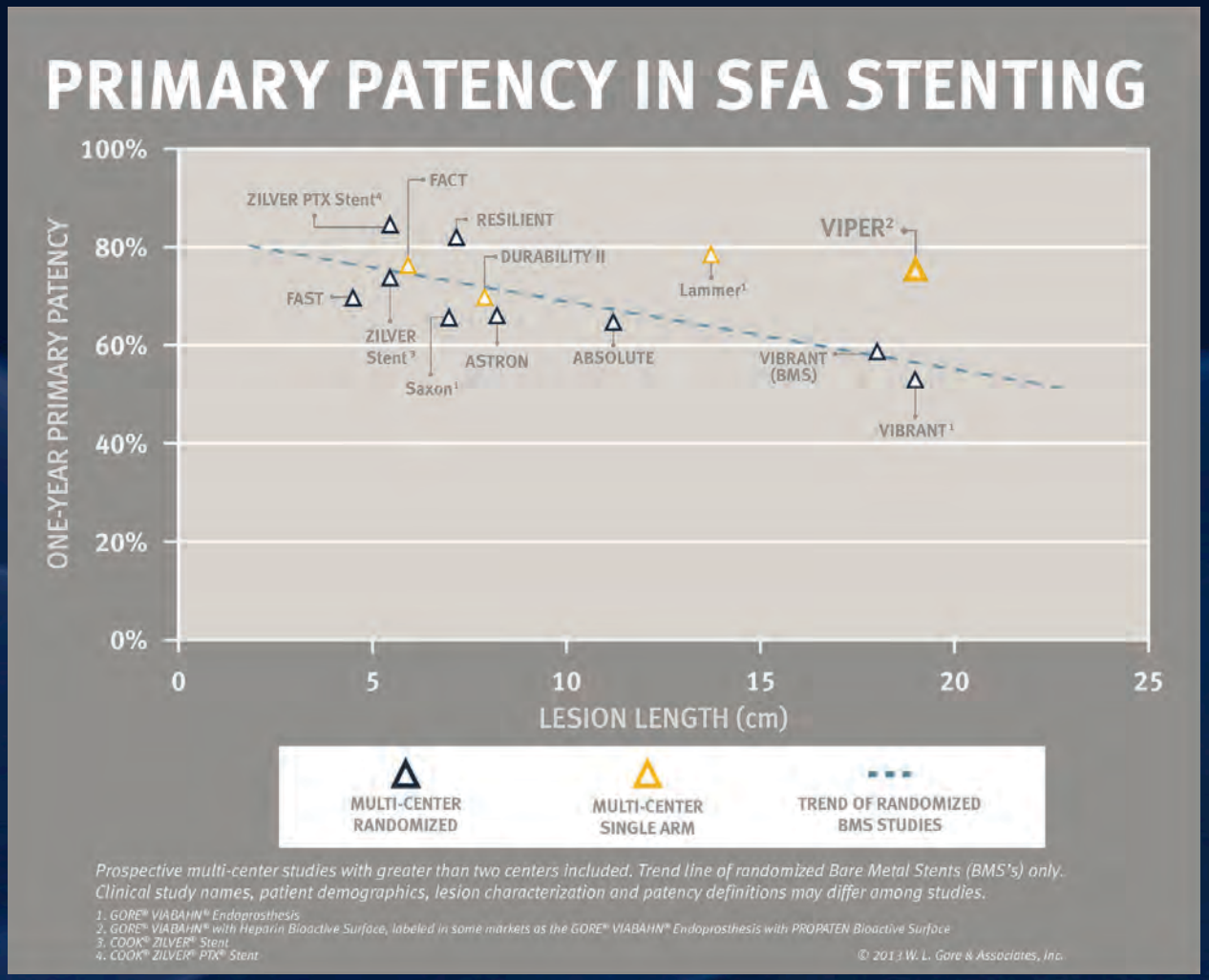


Conclusions

- **The GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface Exhibits 73% Patency in Long SFA Lesions**
  - Patency is independent of lesion length
    - Long lesions (> 20 cm) equivalent to medium lesions (5–20 cm)
  - 5 mm device patency is equivalent to other sizes
    - Appears to have no dependence on device diameter in contrast to previous experience [1]
- **Sizing is Critical**
  - Primary patency is significantly better when IFU sizing is not exceeded at the proximal edge
    - 88% versus 70% at 12 months ($p < .05$, sizing by Core Lab)
- **European VIASTAR Trial adds more Comparative Data**
  - Randomized trial of Bare Nitinol Stents versus the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface for long SFA lesions

1. Saxon RR, Coffman JM, Gooding JM, Ponec DJ. Long-term patency and clinical outcome of the Viabahn Stent-Graft for femoropopliteal artery obstructions. *Journal of Vascular & Interventional Radiology* 2007;18(11):1341-1350.

Primary Patency in SFA Stenting



Bosiers M, Deloose K, Callaert J, et al. Results of the Protégé EverFlex 200-mm-long nitinol stent (ev3) in TASC C and D femoropopliteal lesions. *Journal of Vascular Surgery* 2011;54(4):1042-1050.

GORE
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The GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface is known in some markets as the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface.

Products listed may not be available in all markets.

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