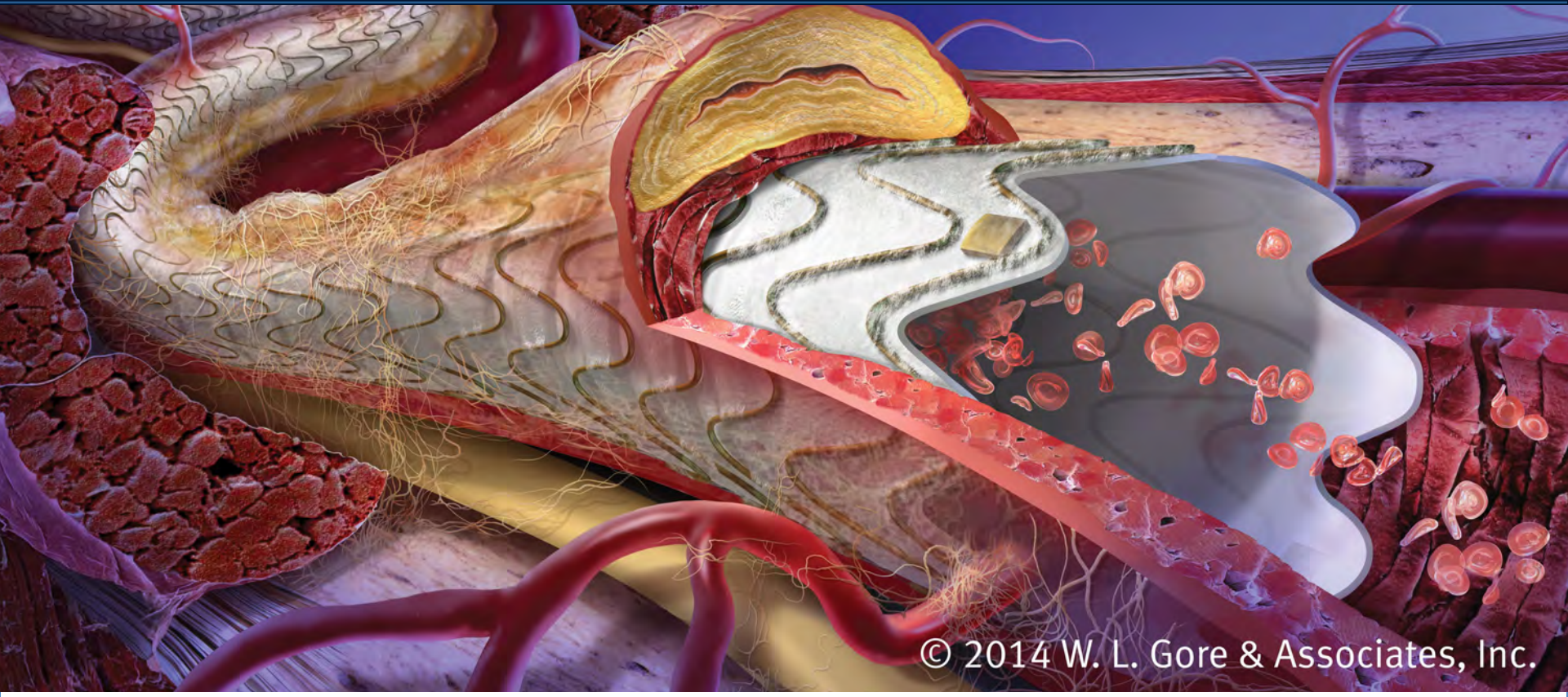
VIASTAR Trial: One-Year Results[1]



Product with radiopaque markers planned for European availability in 2016.

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VIASTAR Trial Design[1]

Physician-initiated randomized trial conducted at seven centers in Europe

GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface* versus bare-metal stent (BMS) for treatment of long SFA disease

Objective	Evaluate the performance of GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface (5–8 mm diameters) and BMS in treating long SFA disease.
Primary Endpoints	Primary Patency at 12 months • Patency loss by PSVR > 2.5 assessed by CDUS or ≥ 50% stenosis assessed by CTA / DSA Proportion of subjects experiencing composite adverse events within 30 days of procedure
Secondary Endpoints	Technical and clinical success Primary assisted and secondary patency at one and two years TVR and TLR at one and two years
BMS Used	BARD® LIFESTENT® Device, Covidien PROTÉGÉ® EVERFLEX® Stent, and the Cordis S.M.A.R.T.® CONTROL® Stent.

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

VIASTAR Trial Randomization[1]

141 patients randomly allocated to treatment[1]

72 patients allocated to GORE® VIABAHN® Endoprosthesis (Intent-to-Treat) 6 patients excluded from analysis 1 screening failure 3 incorrect treatment 2 study medication not received	69 patients allocated to BMS (Intent-to-Treat) 6 patients excluded from analysis 4 screening failure 1 incorrect treatment 1 consent withdrawn
66 patients analyzed (Per-Protocol) 61 patients 1 month follow-up 58 patients 6 month follow-up 57 patients 12 month follow-up 7 patients lost to follow-up 2 patients died	63 patients analyzed (Per-Protocol) 61 patients 1 month follow-up 57 patients 6 month follow-up 52 patients 12 month follow-up 8 patients lost to follow-up 3 patients died

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Patient Demographics[1]

Patient demographics similar across treatment groups.

Patient Demographics	GORE® VIABAHN® Endoprosthesis n = 72	BMS n = 69	p-value
Average Age	69	69	0.69
Male	67%	75%	0.34
Smoker	69%	70%	0.87
Hypertension	83%	84%	0.91
Diabetes	35%	36%	0.99
Hyperlipidemia	68%	68%	0.86
Rutherford Category			0.72
2	18%	17%	
3	68%	65%	
4	3%	8%	
5	11%	11%	
Baseline ABI	0.58	0.58	0.94

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Lesion Characteristics[1]

Lesion characteristics similar across treatment groups.

Lesion Characteristics	GORE® VIABAHN® Endoprosthesis n = 72	BMS n = 69	p-value
% Chronic Occlusions	79%	70%	0.21
Mean Lesion Length (mm)	190	173	0.13
TASC Classification			0.09
TASC II A	0%	3%	
TASC II B	28%	42%	
TASC II C	25%	23%	
TASC II D	47%	32%	

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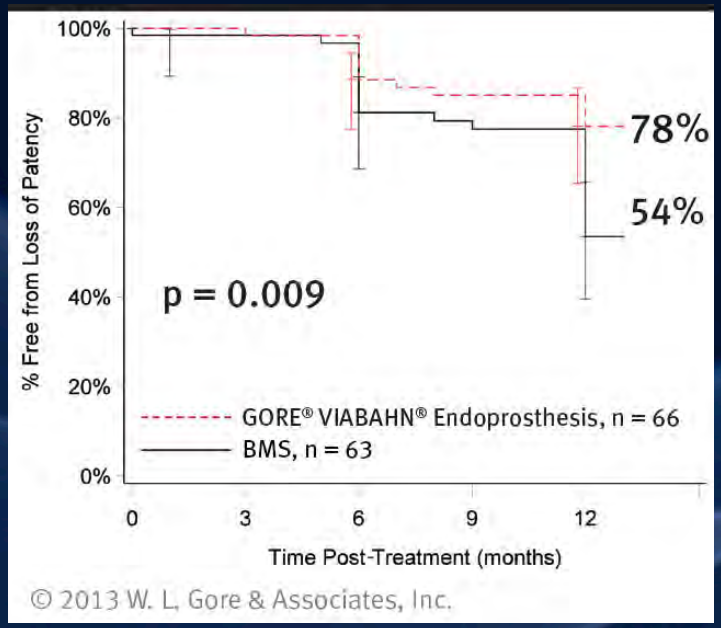
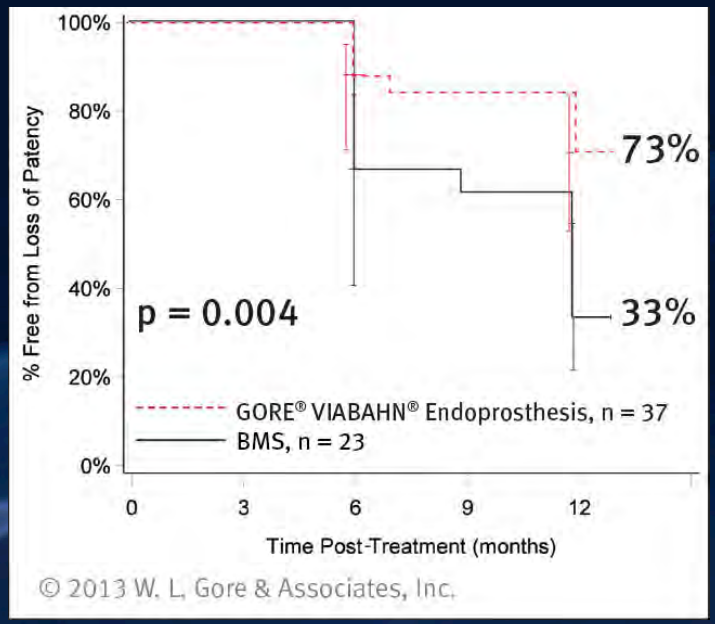
Primary Patency[1]
Per-Protocol Analysis*

Patency advantage with GORE® VIABAHN® Endoprosthesis amplified in lesions ≥ 20 cm.



All Lesions



Lesions ≥ 20 cm

When treating lesions at the same TASC II level, BMS were 2.71 times more likely to lose patency.

* Kaplan-Meier patency calculated at the end of the follow-up window

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Clinical Improvement[1]

ABI significantly higher in the GORE® VIABAHN® Endoprosthesis group at 12-month followup.

ABI	GORE® VIABAHN® Endoprosthesis	BMS	p-value
Baseline	0.58	0.58	0.94
Discharge	0.93	0.96	0.24
12-month follow-up	0.94	0.85	0.048

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Safety Endpoints[1]

Total number of events similar across treatment groups.

30-Day Adverse Events	GORE® VIABAHN® Endoprosthesis n = 72	BMS n = 69	p-value
Total Adverse Events – no. (%)	11 (15%)	9 (13%)	0.77
Peripheral embolization	4	1	
Hematoma	2	2	
Pseudoaneurysm	1	0	
Dissection	1	4	
Other	3	2	
Death or Study Limb Amputation	0	0	
Severe Adverse Events *	1 (1.4%)	1 (1.4%)	

* GORE® VIABAHN® Endoprosthesis group: pseudoaneurysm / hematoma requiring surgery.
* BMS group: device malposition requiring surgical retrieval and bypass.

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Restenosis and Occlusions[1]

Per-Protocol Analysis: 12-month follow-up

Statistically fewer restenoses in GORE® VIABAHN® Endoprosthesis group.

No statistical difference in occlusions or incidence of ALI.

Number with 12-month follow-up	GORE® VIABAHN® Endoprosthesis n = 57	BMS n = 52	p-value
Restenoses * (>50%)	9 (16%)	22 (42%)	0.003
Occlusions	6 (11%)	4 (8%)	0.74
Acute Limb Ischemia (ALI)	1 (1.5%)	0	1.0

* GORE® VIABAHN® Endoprosthesis group: only edge stenoses observed.
* BMS group: diffuse in-stent restenosis observed most commonly.

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VIASTAR Clinical Study Conclusions[1]

- “When treating PAD in patients with long diffuse femoropopliteal artery disease, [the use of the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface yields] clinical and patency benefits compared with BMS.”[1]
- Superior primary patency at one year in the GORE® VIABAHN® Endoprosthesis group in the per-protocol analysis.
- Patency advantage with GORE® VIABAHN® Endoprosthesis amplified in lesions ≥ 20 cm.
- When treating lesions at the same TASC II level, BMS were 2.71 times more likely to lose patency.
- Significantly higher ABI in patients treated with GORE® VIABAHN® Endoprosthesis than with BMS at one year.
- No statistical difference in occlusions or incidence of ALI.

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References

1. Lammer J, Zeller T, Hausegger KA, *et al*. Heparin-bonded covered stents versus bare metal stents for complex femoro-popliteal artery lesions: the randomized VIASTAR trial. Journal of the American College of Cardiology 2013;62(15):1320-1327.

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Note: 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.