VIASTAR Trial

Randomized, multi-center data supporting the use of GORE® VIABAHN® Endoprosthesis in complex SFA lesions.

VIASTAR Trial Design [1]

Objective: Evaluate the performance of GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface (5–8 mm diameters) and bare metal stents (BMS) in treating long SFA disease.

Primary Endpoints:

- Primary Patency at 12 months
- Proportion of subjects experiencing composite adverse events within 30 days of procedure

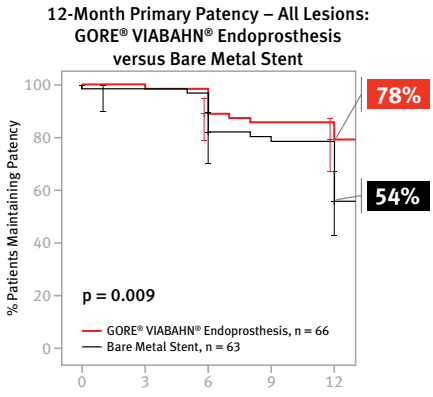
VIASTAR Trial Randomization [1]

141 PATIENTS RANDOMLY ALLOCATED TO TREATMENT [1]	
72 patients allocated to GORE® VIABAHN® Endoprosthesis (Intent-to-Treat)	69 patients allocated to Bare Metal Stent (Intent-to-Treat)
66 patients analyzed (Per-Protocol)	63 patients analyzed (Per-Protocol)

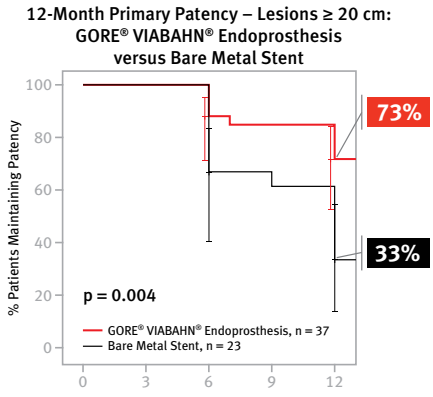
Lesion Characteristics [1]

LESION CHARACTERISTICS	GORE® VIABAHN® ENDOPROSTHESIS (n = 72)	BARE METAL STENT (n = 69)	P-VALUE
% Chronic Occlusions	79%	70%	0.21
Mean Lesion Length (mm)	190	173	0.13

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.

Statistically fewer restenosis in GORE® VIABAHN® Endoprosthesis group.
No statistical difference in occlusions or incidence of Acute Limb Ischemia (ALi) between GORE® VIABAHN® Endoprosthesis and Bare Metal Stent arms of the study.

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PERFORMANCE through data

VIASTAR Clinical Study Conclusions [1]

- "When treating PAD in patients with long diffuse femoropopliteal artery disease, [the use of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface yields] clinical and patency benefits compared with BMS." [1]
- Primary patency significantly higher for the GORE® VIABAHN® Endoprosthesis in all lesions, particularly 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.

1. Lammer J, Zeller T, Hausegger KA, *et al*. Heparin-bonded covered stents versus bare-metal stents for complex femoropopliteal artery lesions: the randomized VIASTAR trial (Viabahn endoprosthesis with PROPATEN bioactive surface [VIA] versus bare nitinol stent in the treatment of long lesions in superficial femoral artery occlusive disease). *Journal of the American College of Cardiology* 2013;62(15):1320-1327.

INTENDED USE / INDICATIONS: The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery de novo and restenotic lesions up to 270mm in length with reference vessel diameters ranging from 4.0 – 7.5 mm, in superficial femoral artery in-stent restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 6.5 mm, and in iliac artery lesions up to 80 mm in length with reference vessel diameters ranging from 4.0 – 12 mm. The GORE® VIABAHN® Endoprosthesis is also indicated for the treatment of stenosis or thrombotic occlusion at the venous anastomosis of synthetic arteriovenous (AV) access grafts. Refer to Instructions for Use at goremedical.com for a complete description of all contraindications, warnings, precautions and adverse events. ℞ Only

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