LITERATURE SUMMARY

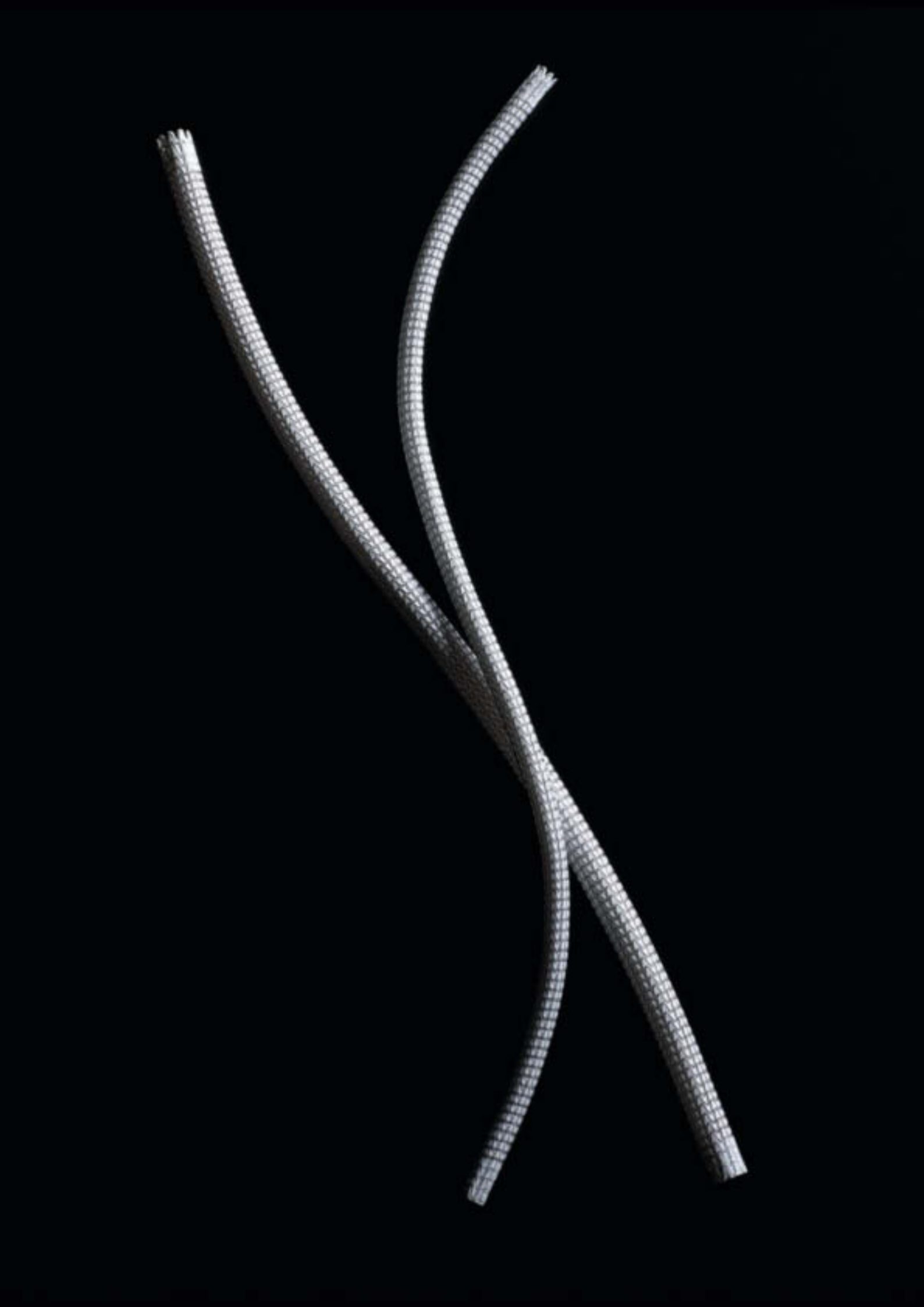
A Long-Lesion Superficial Femoral Artery Track Record

Overall Weighted Average† Patency Rates for the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface* as Reported in the Literature	
Total Number of Limbs	241
Mean Lesion Length (cm)	19
Study Limb Amputation	0
Primary Patency at One Year	75%
Secondary Patency at One Year	91%

GORE VIABAHN® ENDOPROSTHESIS

PROPATEN BIOACTIVE SURFACE

PERFORMANCE
through data



Endoluminal bypass for the treatment of long occlusive disease of the Superficial Femoral Artery

Michel M. P. J. Reijnen, MD, PhD, Department of Surgery, Rijnstate Hospital, Arnhem, The Netherlands

Peripheral arterial occlusive disease affects over 10% of the general population and the prevalence increases with age to 15–20% over the age of 70 years. The frail condition of these patients, often with a high cardiovascular risk, justifies the search for minimally invasive treatment alternatives. Nitinol stents have improved the outcome of endovascular treatment of superficial femoral artery (SFA) occlusive disease in lesions with an intermediate length up to 10 cm. The performance of bare metal stents decreases in longer lesions due to the occurrence of in-stent restenosis (ISR).

The GORE® VIABAHN® Endoprosthesis was specifically designed to treat SFA occlusive disease. The ePTFE attached to the nitinol stent prevents the development of ISR by acting as a physical barrier to neointimal proliferation, and thus the outcome will not depend on lesion length. Moreover, the endoprosthesis has a high flexibility, an adequate radial strength and a low fracture rate. During the last decade various improvements to the device have been made. One of the latest improvements to the endoprosthesis was the incorporation of the CBAS Heparin Surface (heparin bonding technology), which has been shown to significantly improve the patency rates of surgical vascular grafts. Moreover, the proximal edge of the GORE® VIABAHN® Device now has a contoured shaped edge instead of a straight edge. This adjustment reduces infolding and may improve hemodynamics at the leading edge of the device.

Endoprosthesis Treating SFA Occlusive Lesions in Published Studies (Updated June 2013)

Author (Study)	Journal	Year	No. of Limbs	Lesion Length (cm)	Follow Up (yr)	% of Occlusion	% of TASCII C and D	Primary Patency	Secondary Patency
Lammer (VIASTAR)	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.	2013	66	19.4	1	79%	72%	78%	90%
Saxon (VIPER)	Saxon RR, Chervu A, Jones PA, *et al.* Heparin-bonded, expanded polytetrafluoroethylene-lined stent graft in the treatment of femoropopliteal artery disease: 1-year results of the VIPER (Viabahn Endoprosthesis with Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease) Trial. *Journal of Vascular & Interventional Radiology* 2013;24(2):165-173.	2013	119	19	1	56%	60%	73%	92%
Lensvelt	Lensvelt MM, Fritschy WM, van Oostayen JA, Holewijn S, Zeebregts CJ, Reijnen MM. Results of heparin-bonded ePTFE-covered stents for chronic occlusive superficial femoral artery disease. *Journal of Vascular Surgery* 2012;56(1):118-125.	2012	56	18.5	1		84%	76%	89%
12 month TOTAL weighted results			241	19.4		71%	72%	75%	91%

Patency rates for the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface as reported in the literature. Selection Criteria: Published papers evaluating the treatment of long segment peripheral arterial disease in the superficial femoral artery (SFA) with the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface only (not a mixture of device types). Studies must include ≥ 30 subjects and at least one year of follow-up.

The recently published VIASTAR study has shown higher primary patency of heparin-bonded GORE® VIABAHN® Endoprosthesis compared to bare metal stents at 12-months. With a pooled primary patency rate of 75% and a secondary patency rate of 91%, in lesions with a mean length of 19 cm, the performance results of the heparin-bonded GORE® VIABAHN® Endoprosthesis are in the same range of open surgery, the current gold standard for long lesions.

VIASTAR TRIAL

Level one Clinical Evidence for the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface

Significant clinical and patency benefits for the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface vs. Bare Metal Stents (BMS)

Heparin-bonded covered stents versus bare metal stents for complex femoropopliteal artery lesions: the randomized VIASTAR trial.
J. Lammer , T. Zeller , K. Hausegger, P. J. Schaefer, M. Gschwendtner, S. Mueller-Huelsbeck, T. Rand, M. Funovics, F. Wolf, A. Rastan, M. Gschwandtner, S. Puchner, R. Ristl, M. Schoder.

Type of Study

- Prospective, randomized, single-blind, multicenter study (seven centers)
- Physician initiated
- CoreLab: Bad Krozingen
- March 2009 to March 2011

Objective

Evaluate the performance of the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface (5–8 mm diameters) and bare metal stents* in treating long SFA disease (lesions 10–35 cm).

Journal

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.

Lesion Characteristics

Baseline demographics were similar for both treatment groups.

Lesion Characteristics	GORE® VIABAHN® Endoprosthesis N = 72	Bare Metal Stents N = 69	P-value
Lesion Length (mm)	190 ± 63	173 ± 66	0.13
Target Vessel Reference Diameter (mm)	6.1 ± 0.6	6.3 ± 0.7	0.88
Occlusions — no. (%)	56 (79)	46 (70)	0.21
TASC Classification — no. (%)			0.09
TASC II A	0	2 (3)	
TASC II B › 10 cm	20 (28)	29 (42)	
TASC II C	18 (25)	16 (23)	
TASC II D	34 (47)	22 (32)	
Number of Crural Runoff Vessels — no. (%)			0.96
3	32 (44)	29 (42)	
2	28 (39)	27 (40)	
1	10 (14)	10 (14)	
0	2 (3)	3 (4)	

Therapy

After treatment, patients were set on 100 mg aspirin daily for life and 75 mg clopidogrel daily for at least six months.

* Bare metal stent devices used in this study were the BARD® LIFESTENT® device, the Covidien PROTÉGÉ® EVERFLEX® Stent, and the CORDIS® S.M.A.R.T.® Control Vascular Stent.

Results

Treatment per protocol Analysis One-Year results	GORE® VIABAHN® Endoprosthesis N = 57 / N = 66*	Bare Metal Stents N = 52 / N = 63*	P-value
Restenosis	9	22	0.003
Reocclusion	6	4	0.74
Primary Patency (all)	78%	54%	0.009
Primary Patency (lesion ≥ 20 cm)	73%	33%	0.004
Freedom from TLR	85%	77%	0.37

* 12 / 141 patients had major protocol violation (six each arm) and are not included in this analysis.

Safety Endpoints

Treatment per protocol Analysis — One-Year results	GORE® VIABAHN® Endoprosthesis N = 57 / N = 66	Bare Metal Stents N = 52 / N = 63	P-value
Adverse Events — no. (%)	11 (15)	9 (13)	0.77
Hematoma	2	2	
Pseudoaneurysm	1	0	
Dissection	1	4	
Peripheral Embolization	4	1	
Death	0	0	
Study Limb Amputation	0	0	
Severe Adverse Events	1 (1.4)	1 (1.4)	1

Clinical success

- ABI at one year: 0.94 ± 0.23 (GORE® VIABAHN® Endoprosthesis) versus 0.85 ± 0.23 (bare metal stents) ($p < 0.05$ — significant).
- Walking distance at one year (assessed by WIQ: walking impairment questionnaire) was 1,000 meters for > 70% of patients in the GORE® VIABAHN® Endoprosthesis arm and < 50% of patients in the bare metal stent arm.

Conclusion

- This randomized trial in symptomatic PAD patients who underwent endovascular treatment for long femoro-popliteal lesions demonstrated significant clinical and patency benefits for heparin-bonded GORE® VIABAHN® Endoprostheses across all lesions in the treatment per protocol analysis. The risk of binary restenosis at one year was 2.23 times higher in the bare metal stent arm.
- In lesions ≥ 20 cm in length, the performance improvement for GORE® VIABAHN® Endoprosthesis over bare metal stent was even greater.
- Only edge stenosis was observed in the GORE® VIABAHN® Endoprosthesis arm. In the bare metal stent arm, both edge stenosis and diffuse in-stent restenosis were observed, but diffuse in-stent stenosis was “seen most commonly.”

VIPER STUDY

The Long Lesion Solution

The GORE® VIABAHN® Endoprosthesis exhibits excellent performance in long, challenging SFA lesions. Primary patency is improved when IFU over-sizing is not exceeded at the proximal end of the device.

Heparin-bonded, Expanded Polytetrafluoroethylene- lined Stent Graft in the Treatment of Femoropopliteal Artery Disease: 1-Year Results of the VIPER (Viabahn Endoprosthesis with Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease) Trial

Richard R. Saxon, MD, Arun Chervu, MD, Paul A. Jones, MD, Tanvir K. Bajwa, MD, Dennis R. Gable, MD, Peter A. Soukas, MD, Richard J. Begg, MD, John G. Adams, MD, Gary M. Ansel, MD, Darren B. Schneider, MD, Charles M. Eichler, MD, and Michael J. Rush, MD

Type of Study

Prospective, single-arm, multicenter study (11 centers).

Objective

Evaluate the performance of GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface in treating long-segment SFA disease (> 5 cm in length).

Journal

Saxon RR, Chervu A, Jones PA, *et al.* Heparin-bonded, expanded polytetrafluoroethylene-lined stent graft in the treatment of femoropopliteal artery disease: 1-year results of the VIPER (Viabahn Endoprosthesis with Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease) Trial. *Journal of Vascular & Interventional Radiology* 2013;24(2):165-173.

Lesion Characteristics

Baseline demographics were similar for both treatment groups.

Lesion Characteristics	GORE® VIABAHN® Endoprosthesis N = 119
Lesion Length (mm)	190
Occlusions — no. (%)	67 (56)
Target Vessel Reference Diameter (mm)	5.5 ± 0.6
TASC Classification — no. (%)	
TASC II A	17 (14)
TASC II B	30 (25)
TASC II C	35 (29)
TASC II D	37 (31)
Number of Crural Runoff Vessels — no. (%)	
3	55 (46)
2	39 (33)
1	25 (21)
0	0

Results

Patency assessed by color-doppler ultrasound with PSVR ≤ 2.5.

Effectiveness Endpoints

Analysis — One-Year Results	GORE® VIABAHN® Endoprosthesis N = 119
Primary Patency (all)	73%
Primary Patency for Devices Oversized ‹ 20% at the Proximal Edge	88%
Primary Patency for Devices Oversized › 20% at the Proximal Edge	70%
Primary Patency for 7 mm Device Diameter	100%
Primary Patency for 6 mm Device Diameter	69%
Primary Patency for 5 mm Device Diameter	79%
Secondary Patency	92%

Safety Endpoints

Analysis — 30-day Results	GORE® VIABAHN® Endoprosthesis N = 119
Procedural Major Adverse Event Within 30 Days	1 (0.8)
Occlusion	2 (1.7)
Access Site Complication	10 (9)
Distal Embolization	4 (4)
Other	12 (10)
Unplanned Study Limb Amputation	0

Clinical Success

Of the 89 limbs that underwent a clinical follow-up evaluation at one year that included a Rutherford category assessment, 82 (92%) maintained an improvement in clinical outcome, as indicated by a Rutherford category reduction of one or more.

The mean Rutherford category had improved by 2.4 in these limbs ($p < .0001$), average ABI at rest was 0.9 ± 0.19 ($p < .0001$), and 88% had a Rutherford category of 0 or 1.

Conclusion

- The first controlled, multi-center, prospective study evaluating GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface.
- The GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface exhibits excellent patency in long SFA lesions.
  - Patency is independent of lesion length.
- Long lesions (> 20 cm) equivalent to medium lesions (5–20 cm).
- The CBAS Heparin Surface may improve patency when treating smaller vessels.
  - 5 mm device patency is equivalent to other sizes.
- Sizing is critical.
  - Primary patency is significantly better when IFU over-sizing is not exceeded at the proximal edge.
- 88% versus 70% at 12 months ($p < .05$, vessel sizing by CoreLab).

The Two Center Experience from the Netherlands

Consistent Performance in Long SFA Lesions with the GORE® VIABAHN® Endoprosthesis

Results of heparin-bonded ePTFE-covered stents for chronic occlusive superficial femoral artery disease

Mare M. A. Lensvelt, MD, Wilbert M. Fritschy MD, PhD, Jacques A. van Oostayen, MD, PhD, Suzanne Holewijn, PhD, Clark J. Zeebregts, MD, PhD and Michel M. P. J. Reijnen, MD, PhD, Arnhem, Zwolle, and Groningen, The Netherlands

Type of Study

- Two center.
- Data prospectively gathered in a database (all patients treated between April 2009 and October 2010) and retrospectively analyzed.
- Physician initiated.

Objective

Assess the one-year patency rates of heparin-bonded covered stents in the treatment of chronic occlusive disease of the superficial femoral artery (SFA).

Journal

Lensvelt MM, Fritschy WM, van Oostayen JA, Holewijn S, Zeebregts CJ, Reijnen MM. Results of heparin-bonded ePTFE-covered stents for chronic occlusive superficial femoral artery disease. *Journal of Vascular Surgery* 2012;56(1):118-125.

Lesion Characteristics

Lesion Characteristics	GORE® VIABAHN® Endoprosthesis N = 56
Lesion Length (mm)	185 ± 77
Target Vessel Reference Diameter (mm) — SFA	5.4 ± 1.1
Target Vessel Reference Diameter (mm) — POP	4.6 ± 0.75
TASC Classification — no. (%)	
TASC II A	0
TASC II B	9 (16)
TASC II C	14 (25)
TASC II D	33 (59)
Number of Crural Runoff Vessels — no. (%)	
3	39 (69.7)
2	11 (19.6)
1	5 (8.9)
0	1 (1.8)

Results

Patency assessed by color-doppler ultrasound with PSVR ≤ 2.5.

Safety Endpoints

Analysis — One-Year Results	GORE® VIABAHN® Endoprosthesis N = 56
Primary Patency (all)	76.2%
Primary Assisted Patency	81.7%
Secondary Patency	89%
Freedom from TLR	92.6%

Analysis	GORE® VIABAHN® Endoprosthesis N = 56
Dissection	1 (1.8)
Hematoma at the Puncture Site	1 (1.8)
Other	2 (3.5)
Study Limb Amputation	0

Clinical Success

- All but one patient were clinically improved after placement of the endograft(s). The median Rutherford category improved from category 3 (range, 3–6) preoperatively to category 0 (range, 0–4) postoperatively ($p < .001$).
- The subset of patients that were treated for critical limb ischemia (n = 18) had all improved clinically. Sixteen patients (88.9%) improved from critical ischemia to claudication (Rutherford category 1–3) and the others were asymptomatic.

Conclusion

- The GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface is associated with acceptable patency rates.
- It is related to a low morbidity and mortality rate, and does not exclude the later placement of a venous bypass if required.
- The use of three endografts showed a trend toward decreased patency. The authors comment that the use of three devices is no longer usually necessary due to the 25 cm device.

References

- 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.
- Saxon RR, Chervu A, Jones PA, *et al.* Heparin-bonded, expanded polytetrafluoroethylene-lined stent graft in the treatment of femoropopliteal artery disease: 1-year results of the VIPER (Viabahn Endoprosthesis with Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease) Trial. *Journal of Vascular & Interventional Radiology* 2013;24(2):165-173.
- Lensvelt MM, Fritschy WM, van Oostayen JA, Holewijn S, Zeebregts CJ, Reijnen MM. Results of heparin-bonded ePTFE-covered stents for chronic occlusive superficial femoral artery disease. *Journal of Vascular Surgery* 2012;56(1):118-125.

Overall Weighted Average† Patency

$$\text{† Weighted Average} = \frac{(N_1 \times \text{Primary patency}_1) + (N_2 \times PP_2) + \ldots + (N_n \times PP_n)}{N_1 + N_2 + \ldots + N_n}$$

* GORE® VIABAHN® Endoprosthesis PROPATEN Bioactive Surface is known in certain markets as GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface. PROPATEN Bioactive Surface and Heparin Bioactive Surface are synonymous with the CBAS Heparin Surface.

Consult Instructions for Use

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W. L. Gore & Associates, Inc.
Flagstaff, AZ 86004

00800.6334.4673

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