Three-year results of the VIBRANT trial of VIABAHN endoprosthesis versus bare nitinol stent implantation for complex superficial femoral artery occlusive disease

Patrick J. Geraghty, MD,[a] Mark W. Mewissen, MD,[b] Michael R. Jaff, DO,[c] and **Gary M. Ansel, MD,[d] for the VIBRANT Investigators,** *Saint Louis, Mo; Milwaukee, Wisc; Boston, Mass; and Columbus, Ohio*

Objective: **The predominant mode of bare nitinol stent failure is diffuse in-stent restenosis, and failure rates correlate to the length and complexity of the treated lesion. Addition of an expanded polytetrafluoroethylene lining to a nitinol stent frame, as found in the VIABAHN endoprosthesis, mitigates the ingrowth of intimal hyperplasia. We compared the long-term outcomes of complex superficial femoral artery disease intervention using the VIABAHN endoprosthesis to those obtained with bare nitinol stent implantation.**

Methods: **One hundred forty-eight patients with symptomatic complex superficial femoral artery disease (TransAtlantic Inter-Society Consensus I class C and D lesions, accompanied by intermittent claudication or ischemic rest pain) were randomized to endovascular intervention using either bare nitinol stent implantation (76 patients) or nonheparin-bonded VIABAHN endoprosthesis deployment (72 patients). Patency, limb hemodynamics, and quality of life were evaluated at 1, 6, 12, 24, and 36 months following intervention.**

Results: **The average treated lesion measured 18 ± 8 cm in length, and 58.8% of lesions displayed segmental or complete occlusion. At 3 years, primary patency rates (defined by peak systolic velocity ratio ≤2.0 and no target lesion revascularization) did not significantly differ between patients treated with the VIABAHN stent graft and those who received a bare nitinol stent (24.2% vs 25.9%; $P = .392$). Stent fractures were significantly more common in bare nitinol stents (50.0%) than in the VIABAHN endoprostheses (2.6%). Primary-assisted patency rates were higher in those receiving bare nitinol stents than the VIABAHN stent graft (88.8% vs 69.8%; $P = .04$), although secondary patency rates did not differ between bare nitinol stent and stent graft recipients (89.3% vs 79.5%; $P = .304$). There were no instances of procedure-related mortality or amputation. The hemodynamic improvement and quality measures improved equally in both groups.**

Conclusions: **The long-term outcomes of complex superficial femoral artery disease intervention using the VIABAHN endograft and bare nitinol stents are similar. Although primary patency rates are low in both study arms, excellent primary-assisted and secondary patency rates were achieved, with sustained augmentation of limb perfusion and quality-of-life measures. Patency rates diminish most rapidly in the first year after device implantation. (J Vasc Surg 2013;58:386-95.)**

From the Section of Vascular Surgery, Department of Surgery, Washington University School of Medicine, Saint Louis[a]; Aurora Cardiovascular Services, St. Luke's Hospital, Milwaukee[b]; the Department of Medicine, Massachusetts General Hospital, Boston[c]; and the Department of Medicine, Riverside Methodist Hospital, Columbus.[d]

The VIBRANT trial was funded by W. L. Gore and Associates. Online database management, clinical support staff, and statistical support staff were provided by W. L. Gore and Associates. All statistical analyses were reviewed in conjunction with the authors.

Author conflict of interest: Dr Geraghty is a member of the Advisory Board, Bard/Lutonix and Bayer/Medrad. Dr Mewissen is a consultant for Bard and Medtronic. and a member of the Advisory Board, Abbott Vascular. Dr Jaff is a member of the Advisory Board (noncompensated), Abbott Vascular, Cordis, Covidien, and Medtronic. Dr Ansel is a consultant for W. L. Gore and Associates.

Registered on ClinicalTrials.gov (NCT00228384).

Additional material for this article may be found online at www.jvascsurg.org.

Reprint requests: Patrick J. Geraghty, MD, Section of Vascular Surgery, Department of Surgery, Washington University School of Medicine, 660 S. Euclid Ave, Campus Box 8109, Saint Louis, MO 63110 (e-mail: geraghtyp@wustl.edu).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214/$36.00

http://dx.doi.org/10.1016/j.jvs.2013.01.050

In 2005, the GORE VIABAHN [GORE and VIABAHN are trademarks of W. L. Gore and Associates, Inc, Flagstaff, Ariz] Endoprosthesis (W. L. Gore and Associates, Flagstaff, Ariz) received United States Food and Drug Administration (FDA) approval for treatment of symptomatic peripheral arterial disease of the superficial femoral artery (SFA). The TransAtlantic Inter-Society Consensus (TASC) I writing group had previously established a classification scheme for infrainguinal occlusive disease (Table I) and had provided recommendations regarding the choice of endovascular or surgical management for each lesion class. Endovascular intervention was favored for limited TASC A lesions, whereas surgical revascularization was recommended for extensive TASC D obstructions. No conclusive recommendations were made for the TASC B and TASC C lesions.[1]

The TASC I recommendations notwithstanding, endovascular treatment of complex SFA lesions became more frequent in the subsequent years. Thus, at the 2005 inception of the GORE VIABAHN Endoprosthesis versus Bare Nitinol Stent in the Treatment of Long Lesion (≥8 cm) Superficial Femoral Artery Occlusive Disease (VIBRANT)

Table I. Morphologic lesion stratification[a]

TASC I type A femoropopliteal lesion
Single stenosis <3 cm
TASC I type B femoropopliteal lesion
Single stenosis 3-10 cm length, not involving distal popliteal
Heavily calcified stenoses up to 3 cm in length
Multiple lesions, each less than 3 cm (stenoses or occlusions)
TASC I type C femoropopliteal lesion
Single stenosis or occlusion longer than 5 cm
Multiple stenoses or occlusions, each 3-5 cm, without heavy calcification
TASC I type D femoropopliteal lesion
Complete common femoral or SFA occlusions or complete popliteal and proximal trifurcation occlusions

SFA, Superficial femoral artery; *TASC,* TransAtlantic Inter-Society Consensus.
[a]Adapted from Dormandy JA, Rutherford RB. Management of peripheral arterial disease (PAD). TASC Working Group. TransAtlantic Inter-Society Consensus (TASC). J Vasc Surg 2000;31(1 Pt 2):S104.

trial, vascular interventionists commonly undertook endovascular treatment for TASC I class C and D SFA lesions. Although virtually all of the bare nitinol stents deployed in the femoropopliteal arteries lacked FDA-labeled indication for arterial use, these devices had gained substantial clinical adoption for the treatment of complex SFA lesions. Enthusiasm for this off-label use was somewhat tempered by substantial loss of midterm patency.[2] The primary mode of bare nitinol stent patency loss was the ingrowth of intimal hyperplasia through the stent interstices, a process that appeared to be potentiated by nitinol stent fractures in the mobile SFA territory.[3] The microporous polytetrafluoroethylene lining of the VIABAHN endoprosthesis inhibits the development of in-stent restenosis, and early clinical data suggested the potential of this device to provide better patency rates than angioplasty in this challenging territory.[4-6] A randomized, controlled trial comparing treatment with the VIABAHN endoprosthesis to bare nitinol stents was therefore conducted.

METHODS

Investigational design and study inclusion. A total of 19 medical centers in the United States were selected for trial participation. Site primary investigators included seven interventional cardiologists, six interventional radiologists, and six vascular surgeons. Participating vascular laboratories had achieved accreditation from the Intersocietal Commission for the Accreditation of Vascular Laboratories. All ultrasound and radiographic examinations underwent blinded, independent analysis by a duplex ultrasound (DUS) core laboratory (VasCore, the Vascular Ultrasound Core Laboratory, Massachusetts General Hospital, Boston, Mass). Each participating center's institutional review board approved the VIBRANT study protocol. From October 2005 to December 2007, patients undergoing evaluation for endovascular treatment of symptomatic SFA occlusive disease were screened for trial participation. The study protocol was reviewed with each potential patient, and written informed consent was obtained. The study was registered on ClinicalTrials.gov (NCT00228384).

Table II. Demographics and past medical history

	VIABAHN stent graft	*Bare nitinol stent*	P *value*[a]
Number of randomized subjects	72	76	
Subject sex			.865
No. (data available)	72	76	
Male	45 (62.5%)	49 (64.5%)	
Female	27 (37.5%)	27 (35.5%)	
Subject ethnicity			.714
No. (data available)	72	76	
Hispanic or Latino	1 (1.4%)	3 (3.9%)	
Not Hispanic or Latino	70 (97.2%)	71 (93.4%)	
Unknown	1 (1.4%)	2 (2.6%)	
Subject race[b]			
No. (data available)	72	76	
American Indian or Alaska Native	0 (0.0%)	0 (0.0%)	
Asian	0 (0.0%)	2 (2.6%)	.497
Black or African American	8 (11.1%)	9 (11.8%)	1.000
Native Hawaiian or Pacific Islander	0 (0.0%)	0 (0.0%)	
White or Caucasian	63 (87.5%)	63 (82.9%)	.493
Other race	1 (1.4%)	2 (2.6%)	1.000
Unknown race	0 (0.0%)	0 (0.0%)	
Subject age, years			.012
No. (data available)	72	76	
Mean (SD)	69 (10)	64 (11)	
Median	69	63	
Range	(45-90)	(43-89)	
Smoking status			.357
Ever smoked	59 (81.9%)	67 (88.2%)	
Never smoked	13 (18.1%)	9 (11.8%)	
Diabetes			1.000
Insulin-dependent diabetic	11 (15.3%)	12 (15.8%)	
Noninsulin-dependent diabetic	20 (27.8%)	22 (28.9%)	
Not diabetic	41 (56.9%)	42 (55.3%)	
General medical history			
Myocardial infarction	17 (23.6%)	19 (25.0%)	.851
Hypertension	63 (87.5%)	58 (76.3%)	.091
Dyslipidemia	52 (72.2%)	59 (77.6%)	.456
Stroke	4 (5.6%)	7 (9.2%)	.535
Chronic obstructive pulmonary disease	9 (12.5%)	6 (7.9%)	.420
Current treatment for angina	2 (2.8%)	2 (2.6%)	1.000
Congestive heart failure	3 (4.2%)	8 (10.5%)	.211
Previous PTA on study limb >6 months ago	5 (6.9%)	4 (5.3%)	.741

PTA, Percutaneous transluminal angioplasty; *SD,* standard deviation.
[a]*P* values for continuous measures based on Wilcoxon test with pooled variances; for categorical variables on two-tailed Fisher exact test (comparing VIABAHN stent graft and bare nitinol stent).
[b]Subjects may report multiple races.

All study candidates reported claudication symptoms and/or ischemic rest pain, with or without minor ischemic tissue loss (Rutherford categories 1-5),[7] corroborated by demonstration of an ankle-brachial index (ABI) of ≤ 0.9 in the symptomatic limb. Anatomic inclusion criteria included the presence of de novo atherosclerosis or >6 months post-percutaneous transluminal angioplasty (PTA) disease of the SFA with stenosis and/or occlusion ≥8 cm in length (consistent with TASC I class C and D lesions),

Table III. Lesion and anatomic characteristics

	VIABAHN stent graft	*Bare nitinol stent*	P *value*[a]
Number of randomized subjects	72	76	
Location of lesion within the SFA			
No. (data available)	72	76	
Proximal	31 (43.1%)	33 (43.4%)	1.000
Mid	59 (81.9%)	64 (84.2%)	.827
Distal	56 (77.8%)	60 (78.9%)	1.000
Type of lesion			.619
No. (data available)	72	76	
Stenosis	28 (38.9%)	33 (43.4%)	
Occlusion	44 (61.1%)	43 (56.6%)	
Target lesion length (cm)			.867
No. (data available)	72	76	
Mean (SD)	19 (8)	18 (7)	
Median	20	16	
Range	(8-40)	(8-36)	
Lesion calcification			.009
No. (data available)	72	76	
None	14 (19.4%)	11 (14.5%)	
Mild	13 (18.1%)	33 (43.4%)	
Moderate	31 (43.1%)	24 (31.6%)	
Severe	14 (19.4%)	8 (10.5%)	
Tibial runoff			.104
No. (data available)	72	76	
1 vessel	11 (15.3%)	17 (22.4%)	
2 vessels	36 (50.0%)	25 (32.9%)	
3 vessels	25 (34.7%)	34 (44.7%)	

SD, Standard deviation; *SFA,* superficial femoral artery.
[a]*P* values for continuous measures based on Wilcoxon test with pooled variances; for categorical variables on two-tailed Fisher exact test (comparing VIABAHN stent graft and bare nitinol stent).

with patency of the aortoiliac inflow arteries, the proximal 1 cm of the SFA, and the popliteal artery beginning 5 cm above the radiographic knee joint line. Unobstructed runoff to the level of the ankle was documented, consisting of a patent popliteal artery and at least one tibial artery. Vessel reference diameters were appropriate to the use of 6-, 7-, or 8-mm diameter stents or stent grafts. Because of a lack of FDA approval at the time of the study, 5-mm-diameter and heparin-bonded VIABAHN stent grafts were not used.

Primary end points. The efficacy end point of the study was primary patency at 3 years postprocedure. Loss of primary patency was defined as the first occurrence of any of the following: ultrasound demonstrating peak systolic velocity ratio (PSVR) >2.0 or occlusion within the treated arterial segment, angiography with >50% stenosis or occlusion within the treated arterial segment, a target lesion revascularization (TLR), or a surgical bypass. DUS-derived PSVR >2.0 was indicative of >50% restenosis. Lesions occurring within 5 mm of the proximal or distal ends of the stented segment ("edge stenoses") were considered to be part of the treated arterial segment for analytic purposes. The safety end point was a composite of procedural (30-day) major adverse events, including death, myocardial infarction, acute renal insufficiency, and significant access site and procedural complications that required surgical intervention or blood transfusion.

Table IV. Technical success

	VIABAHN	*Bare nitinol stent*	P *value*[a]
Number of enrolled subjects	72	76	
Overall technical success			1.000
No. (data available)	69	69	
Yes	67 (97.1%)	66 (95.7%)	
No	2 (2.9%)	3 (4.3%)	
Maximum stenosis following stent deployment <30%			1.000
No. (data available)	72	76	
Yes	71 (98.6%)	74 (97.4%)	
No	1 (1.4%)	2 (2.6%)	
Final hemodynamic peak gradient ≤15 mm Hg			1.000
No. (data available)	69	69	
Yes	68 (98.6%)	68 (98.6%)	
No	1 (1.4%)	1 (1.4%)	
Device(s) successfully delivered to cover target lesion			1.000
No. (data available)	72	76	
Yes	72 (100.0%)	76 (100.0%)	
No	0 (0.0%)	0 (0.0%)	

[a]*P* values derived from Fisher exact test.

Secondary end points. Secondary end points of the study included additional patency measures, technical success, hemodynamics, ischemic symptom classification, generic and disease-specific quality-of-life instrument reporting, and stent fracture assessment.

In addition to the primary patency end point, primary-assisted patency and secondary patency were tracked for the duration of the study. Loss of primary-assisted patency was defined as the first occurrence of any of the following: ultrasound or angiography demonstrating occlusion of the treated arterial segment or surgical bypass of the treated arterial segment. Loss of secondary patency was defined as the first occurrence of any of the following: ultrasound or angiography demonstrating occlusion of the treated arterial segment *and* no subsequent intervention successfully re-established blood flow in that arterial segment, or surgical bypass of the treated arterial segment. The DUS-derived PSVR >2.0 criterion provides a noninvasive proxy for angiographic 50% restenosis of the femoropopliteal segment, but the relationship of less stringent PSVR criteria to stent, and stent graft patency was not fully understood. To explore this relationship, primary patency outcomes were additionally stratified by less stringent criteria, utilizing PSVR cutoffs of 2.5 and 3.0. Technical (procedural) success was defined as appropriate device deployment with <30% residual stenosis of the treated arterial segment and ≤15 mm Hg translesional peak pressure gradient at procedural completion. ABI values were recorded prior to intervention and at 1, 6, 12, 24, and 36 months postprocedure. Ischemic symptoms were stratified by Rutherford category, and both the generic short-form 36 (SF-36) questionnaire and disease-specific intermittent claudication questionnaire

Table V. Subject status

	VIABAHN stent graft, No. (%)	*Bare nitinol stent, No. (%)*	*Overall, No. (%)*
Subjects randomized	72	76	148
Final subject status	72 (100)	76 (100)	148 (100)
Completed study	43 (59.7)	47 (61.8)	90 (60.8)
Surgical intervention	5 (6.9)	5 (6.6)	10 (6.8)
Withdrawn	9 (12.5)	10 (13.2)	19 (12.8)
Lost to follow-up	6 (8.3)	10 (13.2)	16 (10.8)
Death	9 (12.5)	3 (3.9)	12 (8.1)
Other	0 (0.0)	1 (1.3)	1 (0.7)

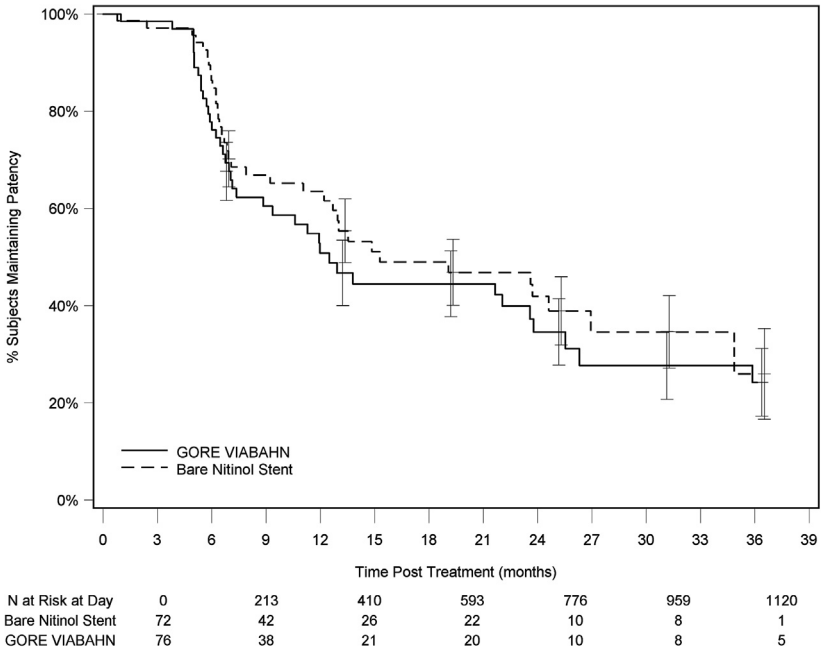


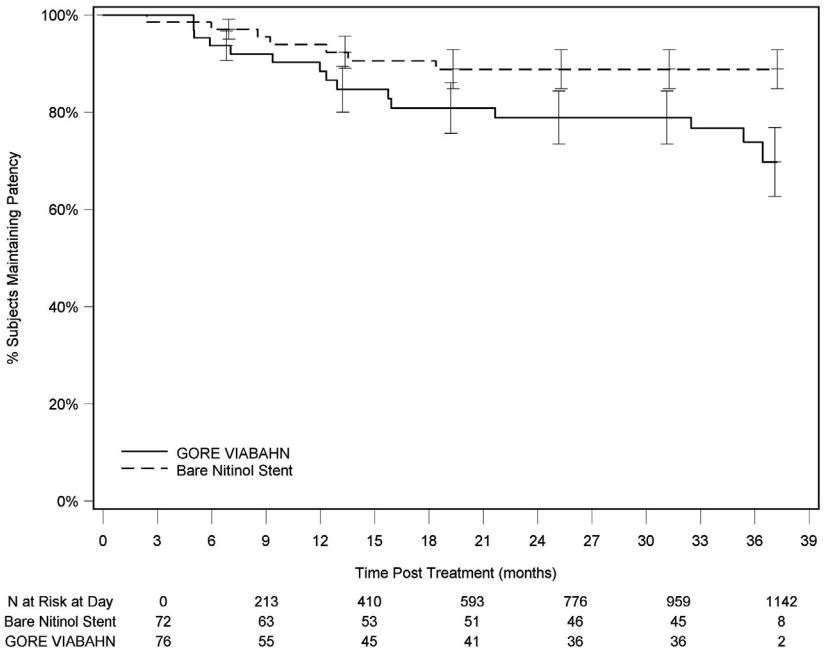
Fig 1. Primary patency (peak systolic velocity ratio [PSVR] ≤ 2.0).

(ICQ) were administered at each follow-up interval.[8-11] Device fractures were determined by independent core laboratory review of multiplanar radiographs obtained at 12, 24, and 36 months postimplantation (VasCore).

Intervention protocol. Arterial access was obtained via antegrade ipsilateral or retrograde contralateral femoral approach. Biplanar angiography of the symptomatic limb was performed and anatomic inclusion criteria were verified. On-table randomization to the VIABAHN device or bare nitinol stent implantation was undertaken after successful translesional guidewire passage. The technique and devices used for crossing total occlusions were left to the discretion of the treating physician. Systemic intraprocedural anticoagulation was mandatory. Predilation of the target lesion was accomplished using balloons of nominal diameter equal to or less than the diameter of the implanted device. Devices were deployed beginning at the most distal aspect of disease, and treatment progressed proximally. All hemodynamically significant disease within the SFA, and all predilated regions were incorporated in the stented segment. Where more than one device was required, overlap zones of 5-10 mm were recommended. Postdilation was performed using balloons of nominal diameter equal to that of the implanted devices, and extension of the postdilation balloon beyond the margins of the implanted devices was prohibited. Biplanar completion angiography and translesional catheter pressure gradient measurements were used to verify technical success. Arterial closure devices were used at the discretion of the treating physician.

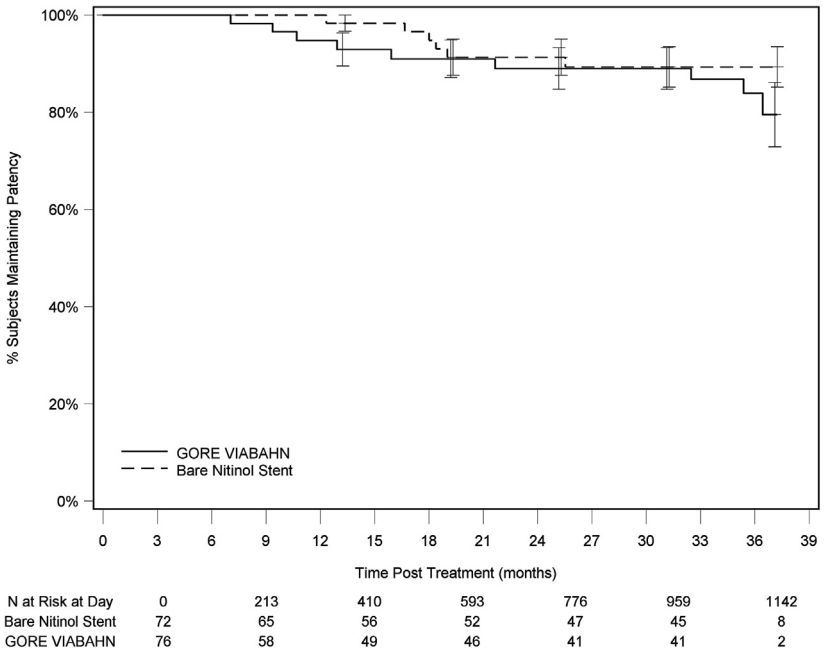
Medical therapy. Daily aspirin therapy was initiated prior to intervention. After device implantation and attainment of access site hemostasis, those patients not already receiving maintenance clopidogrel therapy were given a 600-mg loading dose. The protocol dictated that study participants received daily clopidogrel (75 mg) for at least 6 months postprocedure and aspirin (81 mg) until study completion.

Postimplantation assessments. Follow-up assessments were conducted at 1-, 6-, 12-, 24-, and 36-month intervals. Each of these evaluations included an examination



N at Risk at Day	0	213	410	593	776	959	1142
Bare Nitinol Stent	72	63	53	51	46	45	8
GORE VIABAHN	76	55	45	41	36	36	2

Fig 2. Primary-assisted patency.



N at Risk at Day	0	213	410	593	776	959	1142
Bare Nitinol Stent	72	65	56	52	47	45	8
GORE VIABAHN	76	58	49	46	41	41	2

Fig 3. Secondary patency.

by the study physician, lower extremity noninvasive studies (ABI and DUS), adverse event and Rutherford category reporting, and completion of the SF-36 and Intermittent Claudication Questionnaires under the direction of the study coordinator. Laboratory testing for serum creatinine was obtained at the 1-month visit, and radiographs for stent integrity assessment were obtained at 12, 24, and 36 months.

Statistical analyses. Patency rates/estimates were determined using Kaplan-Meier analysis. Log-rank test was used to compare patency estimates when patency end points were stratified. Discrete values were expressed as frequencies and percentages using the data available as the denominator or as noted. Continuous values were expressed as means (± standard deviation), along with the median, and range. For comparative analyses, a *P* value of

Table VI. ABI: pre- and postintervention

	VIABAHN stent graft	P *value*[a]	*Bare nitinol stent*	P *value*[a]
Number of enrolled subjects	72		76	
Preprocedure visit ABI				
No. (data available)	67		71	
Mean (SD)	0.64 (0.15)		0.67 (0.16)	
Median	0.63		0.66	
Range	(0.33-1.10)		(0.18-1.21)	
1-month visit ABI		<.001		<.001
No. (data available)	68		69	
Mean (SD)	1.01 (0.14)		1.01 (0.14)	
Median	1.01		1.00	
Range	(0.59-1.39)		(0.53-1.38)	
6-month visit ABI		<.001		<.001
No. (data available)	62		66	
Mean (SD)	0.94 (0.16)		0.94 (0.17)	
Median	0.97		0.95	
Range	(0.25-1.19)		(0.44-1.53)	
12-month visit ABI		<.001		<.001
No. (data available)	63		63	
Mean (SD)	0.92 (0.17)		0.93 (0.18)	
Median	0.97		0.96	
Range	(0.43-1.23)		(0.31-1.25)	
24-month visit ABI		<.001		<.001
No. (data available)	50		53	
Mean (SD)	0.94 (0.16)		0.94 (0.20)	
Median	0.94		0.98	
Range	(0.56-1.46)		(0.38-1.23)	
36-month visit ABI		<.001		<.001
No. (data available)	46		44	
Mean (SD)	0.95 (0.18)		0.97 (0.16)	
Median	0.97		0.99	
Range	(0.47-1.47)		(0.55-1.25)	

ABI, Ankle-brachial index; *SD,* standard deviation.
[a]*P* values obtained from two-tailed Wilcoxon test with pooled variances of the preprocedure visit and each respective visit interval.

.05 or less was considered to represent a significant difference. All statistical analyses were done with SAS software, v. 9.2 (SAS Institute, Cary, NC).

RESULTS

Demographics, medical history, and arteriographic findings. One hundred forty-eight patients elected to participate in the trial and underwent on-table randomization. Seventy-six patients were randomly assigned to bare nitinol stent implantation, and 72 were assigned to VIABAHN endoprosthesis implantation. Patient demographics and medical history (Table II) were largely similar between study arms, although patients receiving the VIABAHN device were significantly older than those receiving bare nitinol stents. Lesion and anatomic characteristics of the two study groups are displayed in Table III.

Acute procedural outcomes: procedural success and 30-day safety end point. Procedural success, defined as successful device deployment with less than 30% residual stenosis, was achieved in more than 97% of study participants (Table IV). There were no periprocedural deaths, and freedom from periprocedural safety events was achieved in 98.6% of VIABAHN recipients and 100% of bare nitinol stent recipients. The single safety event recorded was an access-site complication that occurred in the VIABAHN study arm. That event was a non-study limb thrombosis that occurred 2 days after the index procedure and required surgical intervention. Contralateral arterial access was utilized in 64/72 (88.9%) Viabahn implantations and in 72/76 (94.7%) bare nitinol stent implantations. In each study arm, a median of two devices were implanted.

Loss to follow-up. The VIBRANT trial followed patients for 3 years. Substantial participant attrition accumulated throughout follow-up, with only 60.8% of enrollees completing 3 years of postprocedural surveillance. Table V details the specific causes of subject attrition. None of the 12 late participant deaths were determined to be device or study related.

Patency rates. The primary end point of the VIBRANT trial was primary patency of the treated arterial segment at 3 years postprocedure, determined by PSVR ≤2.0, no occlusion on surveillance DUS, and no TLR. There was no significant difference between 3-year primary patency for the VIABAHN device (24.2%; 95% confidence interval [CI], 12.2%-38.5%) or bare nitinol stent (25.9%; 95% CI, 10.3%-45.0%; $P = .392$), as shown in Fig 1.

Primary-assisted patency and secondary patency were also evaluated over the course of the study. At the 3-year end point, bare nitinol stents demonstrated a statistical advantage over the VIABAHN endoprostheses with regard to

Table VII. Rutherford clinical category: pre- and postintervention

	VIABAHN stent graft	P *value*[a]	*Bare nitinol stent*	P *value*[a]
Number of enrolled subjects	72		76	
Preprocedure Rutherford category				
No. (data available)	72		75	
Mean (SD)	2.7 (0.6)		2.8 (0.8)	
Median	3		3	
Range	(2-5)		(1-5)	
1-month visit Rutherford category		<.001		<.001
No. (data available)	67		72	
Mean (SD)	0.6 (1.0)		0.4 (0.9)	
Median	0		0	
Range	(0-5)		(0-5)	
6-month visit Rutherford category		<.001		<.001
No. (data available)	62		71	
Mean (SD)	0.7 (1.0)		0.9 (1.0)	
Median	0		1	
Range	(0-4)		(0-3)	
12-month visit Rutherford category		<.001		<.001
No. (data available)	67		71	
Mean (SD)	0.8 (1.1)		0.9 (1.2)	
Median	0		0	
Range	(0-4)		(0-4)	
24-month visit Rutherford category		<.001		<.001
No. (data available)	51		59	
Mean (SD)	0.8 (1.1)		0.7 (1.1)	
Median	0		0	
Range	(0-4)		(0-4)	
36-month visit Rutherford category		<.001		<.001
No. (data available)	45		49	
Mean (SD)	0.9 (1.0)		0.6 (0.9)	
Median	1		0	
Range	(0-3)		(0-3)	

SD, Standard deviation.

[a]*P* values obtained from two-tailed Wilcoxon test with pooled variances of the preprocedure visit and each respective visit interval.

primary-assisted patency (88.8%; 95% CI, 78.0%-94.5% for bare nitinol vs 69.8%; 95% CI, 53.5%-81.3% for the VIABAHN stent graft; $P = .04$; Fig 2). No significant differences in 3-year secondary patency were observed between study arms (89.3%; 95% CI, 77.7%-95.1% for bare nitinol vs 79.5%; 95% CI, 62.6%-89.4% for the VIABAHN endograft; $P = .304$; Fig 3).

Effect of alternate PSV ratio end points. Because of inconsistencies in end point definitions in the available literature, we chose to examine the use of less stringent PSV ratios as ultrasound determinants of loss of primary patency. Selection of the alternative PSV > 2.5 and PSV > 3.0 criteria resulted in predictable stepwise increases in 3-year primary patency rates in both study arms (Figs 4 and 5, online only, respectively), without inducing significant differences between groups.

Hemodynamic and clinical status improvement. Following intervention, ankle-brachial indices (Table VI) improved significantly in both treatment arms, and this improvement was sustained throughout the duration of the study. There were no significant differences noted in mean ABI values between study groups. In similar fashion, immediate postintervention Rutherford Clinical Category scores[7] were significantly improved from baseline values, and the reduction in symptomatic status was sustained throughout the trial, with no significant differences between treatment arms (Table VII).

Quality-of-life measures. Quality-of-life data were collected using the disease-specific ICQ and the more generic SF-36 instrument. A decline in ICQ scores indicates a favorable response, whereas an increased SF-36 score indicates improvement in the relevant domain. ICQ scores improved (declined) postprocedure, and this was a durable finding at each successive surveillance interval (Table VIII, online only). A similar pattern was noted for SF-36 physical domain scores, where an immediate and durable improvement (increased score) was noted following intervention (Table IX, online only).

Medication. Clopidogrel compliance through 6 months postintervention was documented in 78.7% of VIABAHN recipients and 83.6% of bare nitinol stent recipients ($P =$ NS). At the 36-month study completion visit, all but 1/44 (2.3%) VIABAHN and 2/46 (4.3%) bare nitinol stent recipients were receiving monotherapy or some combination of aspirin, clopidogrel, or other anticoagulant.

Repeat interventions. There was no significant difference in either overall reintervention rates (Table X) or Kaplan-Meier estimates of freedom from initial reintervention (Fig 6) between study arms. Technique of reintervention was left to the discretion of the treating

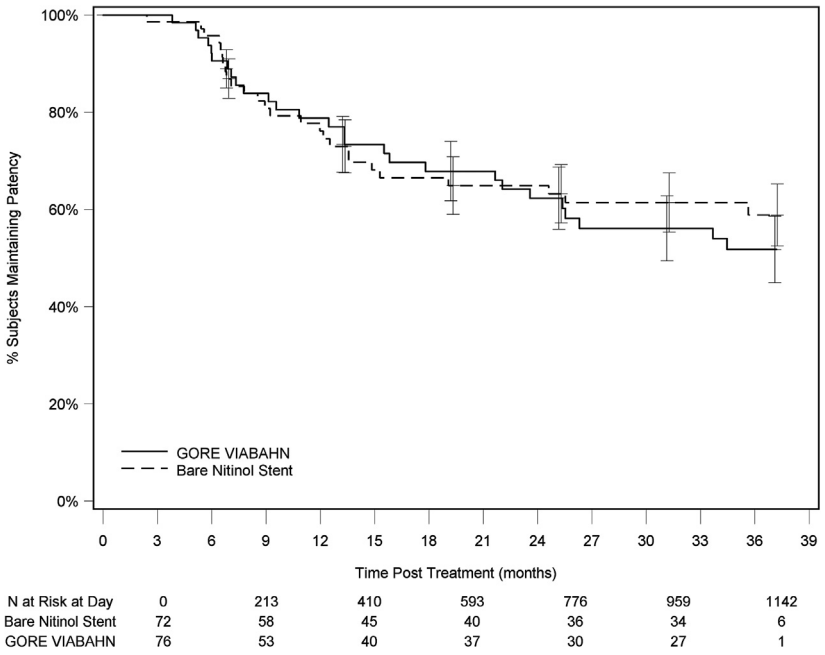


Fig 6. Freedom from first reintervention.

physician. Details of the time frame of first TLR occurrence, as well as the types of interventions employed in these TLRs, are shown in Table XI. Use of more than one technique (angioplasty, additional stent deployment, etc) to achieve successful TLR was common.

Fractures. Fractures were significantly more common in the bare nitinol stent arm, and these fractures were strongly associated with the stented lesion length (Table XII, online only). Furthermore, fracture severity was significantly greater for bare nitinol stents than for VIABAHN endoprostheses (Table XIII, online only).

Limb status. There were no instances of major amputation (transtibial or proximal) among study participants in either treatment arm.

Table X. Reinterventions (TLRs)

	VIABAHN, No. (%)	*Bare nitinol stent, No. (%)*	*Combined, No. (%)*	P *value*[a]
Subjects available	72	76	148	
Repeat interventions per subject[a]				.801
0	47 (65.3)	50 (65.8)	97 (65.5)	
1	17 (23.6)	16 (21.1)	33 (22.3)	
2	4 (5.6)	7 (9.2)	11 (7.4)	
3	3 (4.2)	1 (1.3)	4 (2.7)	
4	1 (1.4)	1 (1.3)	2 (1.4)	
5	0 (0.0)	0 (0.0)	0 (0.0)	
6	0 (0.0)	1 (1.3)	1 (0.7)	
7	0 (0.0)	0 (0.0)	0 (0.0)	
8	0 (0.0)	0 (0.0)	0 (0.0)	

TLR, Target lesion revascularization.
[a]*P* value obtained from comparison of total reinterventions for VIABAHN and bare nitinol stent groups using Fisher exact test.

DISCUSSION

The VIBRANT trial provides long-term outcomes for the endovascular treatment of complex atherosclerotic SFA lesions (TASC I class C and D).[1] The data from this multicenter, randomized trial demonstrate that expert interventionists can successfully perform percutaneous revascularization of long-segment, predominantly occluded SFA lesions with commendable procedural safety. Per the trial design, subjects were randomized after successful wire traversal of the study lesions; this departure from intent-to-treat study design precludes direct comparison of these results with surgical bypass. Although the study end point of primary patency at 3 years was disappointingly low, primary-assisted and secondary patency rates were substantially greater. Durable improvements in hemodynamic measures and clinical status were noted, and quality-of-life instruments, in particular the disease-specific Intermittent Claudication Questionnaire, displayed immediate and sustained improvement following intervention. Finally, no study patient required major amputation during the course of the trial. Thus, at 3 years, substantially equivalent safety and efficacy were demonstrated between the VIABAHN endograft and bare nitinol stent treatment arms.

Does a rigorous postintervention program of clinical and DUS surveillance, as employed in the VIBRANT trial, favorably affect outcomes of percutaneous SFA intervention? The question cannot be answered definitively herein, as all study participants were assigned to mandatory follow-

Table XI. TLR time frame and techniques

	VIABAHN, No. (%)	*Bare nitinol stent, No. (%)*	P *value*
Subjects randomized	72	76	
Subjects having a TLR[a]	25 (34.7)	26 (34.2)	1.000
Time frame of earliest TLR[b]			
0-45 days postimplant	0 (0.0)	0 (0.0)	
>45-90 days postimplant	0 (0.0)	1 (3.8)	
>90-180 days postimplant	4 (16.0)	2 (7.7)	
>180-365 days postimplant	8 (32.0)	12 (46.2)	
>365-730 days postimplant	8 (32.0)	8 (30.8)	
>730-1096 days postimplant	5 (20.0)	3 (11.5)	
>1096 days postimplant	0 (0.0)	0 (0.0)	
TLRs performed[b]			
Total TLRs	38	43	
Balloon angioplasty	31 (81.6)	37 (86.0)	
Thrombolysis	8 (21.1)	11 (25.6)	
Mechanical thrombectomy (Angiojet)	14 (36.8)	13 (30.2)	
Deployment of an additional stent/stent graft	22 (57.9)	21 (48.8)	
Bare nitinol stent[c]	10 (45.5)	4 (19.0)	
Stent graft[c]	11 (50.0)	17 (81.0)	
Other	6 (15.8)	5 (11.6)	

TLR, Target lesion revascularization.
[a] *P* value obtained from two-tailed Fisher exact test of VIABAHN and bare nitinol stent.
[b] *P* values are not provided due to the limited observations per group and the lack of statistical power to detect a true difference between treatment groups.
[c] Percentage out of the number of subjects with additional devices deployed.

up. As shown in Table X, a substantial number of study participants underwent reintervention during the 3 years of postimplant surveillance, and multiple reinterventions were required in some instances. These secondary procedures are most easily undertaken prior to complete thrombosis of the treated arterial segment. While the optimal interval between surveillance examinations has not been defined, detection and timely treatment of restenosis likely contributed to the admirable assisted patency rates, durable clinical benefit, and complete limb preservation experienced by VIBRANT participants.

The VIBRANT trial design differed substantially from the majority of endovascular femoropopliteal intervention studies. At the outset of this study, planned trial duration of 3 years exceeded current norms, and treatment of lesion lengths with no upper limit remained to be attempted. In addition, rigorous comparison of two nonangioplasty modalities in infrainguinal trials remains a rarity. Comparison to PTA was (and remains) the de facto standard for establishing clinical safety and efficacy of newer modalities for SFA treatment. Yet the FDA's imprimatur for clinical trials that utilize the Vascular InterVentional Advances (VIVA) Physicians Objective Performance Criteria for SFA stents[12] indicates acceptance of the premise that bare nitinol stents deliver 1-year patency rates far in excess of those achieved with PTA, consistent with data derived from trials by Schillinger and others.[13-15] While PTA provides a static, if inferior, comparator for device approval purposes, robust comparisons between nonangioplasty-based strategies provide vital information for practitioners addressing complex SFA disease.

Several weaknesses of the current study deserve mention. In retrospect, VIBRANT would have been strengthened by the incorporation of a physical functioning end point.[16,17] Future trials would benefit from addition of a supervised-exercise rehabilitation comparison arm.[18] Over 3 years of surveillance, attrition rates were substantial, albeit similar between treatment groups. Device iterations progress as clinical trials are conducted, but the pace of innovation should not deter physicians from engaging in careful evaluation of each generation of devices.

Since the study completion, there have been multiple manufacturing changes to the VIABAHN device, including addition of a heparin bioactive surface, a contoured proximal edge, and an SFA treatment indication for the 5-mm-diameter device. In addition, bare nitinol stents with improved flexibility have been released to market, which may reduce the incidence of stent fracture, although these new devices await evaluation in complex lesions comparable to the VIBRANT trial.

In conclusion, the VIBRANT trial evaluated the comparative effectiveness of bare nitinol stents vs VIABAHN stent grafts for the treatment of complex SFA atherosclerosis. Primary patency rates for the two study arms were similarly low at the 3-year trial end point, but scheduled surveillance and judicious reintervention resulted in sustained hemodynamic and symptomatic improvement in both treatment groups.

AUTHOR CONTRIBUTIONS

Conception and design: PG, MM, MJ, GA
Analysis and interpretation: PG, MM, MJ, GA
Data collection: PG, MM, MJ, GA
Writing the article: PG, MJ
Critical revision of the article: PG, MM, MJ, GA
Final approval of the article: PG, MM, MJ, GA
Statistical analysis: PG, MM, MJ, GA
Obtained funding: PG, MM, MJ, GA
Overall responsibility: PG

REFERENCES

1. Dormandy JA, Rutherford RB. Management of peripheral arterial disease (PAD). TASC Working Group. TransAtlantic InterSociety Concensus (TASC). J Vasc Surg 2000;31:S1-296.
2. Mewissen MW. Self-expanding nitinol stents in the femoropopliteal segment: technique and mid-term results. Tech Vasc Interv Radiol 2004;7:2-5.
3. Scheinert D, Scheinert S, Sax J, Piorkowski C, Braunlich S, Ulrich M, et al. Prevalence and clinical impact of stent fractures after femoropopliteal stenting. J Am Coll Cardiol 2005;45:312-5.
4. Jahnke T, Andresen R, Muller-Hulsbeck S, Schafer FK, Voshage G, Heller M, et al. Hemobahn stent-grafts for treatment of femoropopliteal arterial obstructions: midterm results of a prospective trial. J Vasc Interv Radiol 2003;14:41-51.
5. Saxon RR, Coffman JM, Gooding JM, Natuzzi E, Ponec DJ. Long-term results of ePTFE stent-graft versus angioplasty in the femoropopliteal

artery: single center experience from a prospective, randomized trial. J Vasc Interv Radiol 2003;14:303-11.
6. Saxon RR, Dake MD, Volgelzang RL, Katzen BT, Becker GJ. Randomized, multicenter study comparing expanded polytetrafluoroethylene-covered endoprosthesis placement with percutaneous transluminal angioplasty in the treatment of superficial femoral artery occlusive disease. J Vasc Interv Radiol 2008;19:823-32.
7. Rutherford RB, Baker JD, Ernst C, Johnston KW, Porter JM, Ahn S, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. J Vasc Surg 1997;26:517-38.
8. McHorney CA, Ware JE Jr, Lu JF, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. Med Care 1994;32:40-66.
9. McHorney CA, Ware JE Jr, Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. Med Care 1993;31:247-63.
10. Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473-83.
11. Chong PF, Garratt AM, Golledge J, Greenhalgh RM, Davies AH. The intermittent claudication questionnaire: a patient-assessed condition-specific health outcome measure. J Vasc Surg 2002;36:764-71. discussion: 863-4.
12. Rocha-Singh KJ, Jaff MR, Crabtree TR, Bloch DA, Ansel G. Performance goals and endpoint assessments for clinical trials of femoropopliteal bare nitinol stents in patients with symptomatic peripheral arterial disease. Catheter Cardiovasc Interv 2007;69:910-9.
13. Schillinger M, Sabeti S, Loewe C, Dick P, Amighi J, Mlekusch W, et al. Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. N Engl J Med 2006;354:1879-88.
14. Laird JR, Katzen BT, Scheinert D, Lammer J, Carpenter J, Buchbinder M, et al. Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: twelve-month results from the RESILIENT randomized trial. Circ Cardiovasc Interv 2010;3:267-76.
15. Dick P, Wallner H, Sabeti S, Loewe C, Mlekusch W, Lammer J, et al. Balloon angioplasty versus stenting with nitinol stents in intermediate length superficial femoral artery lesions. Catheter Cardiovasc Interv 2009;74:1090-5.
16. Hiatt WR, Cox L, Greenwalt M, Griffin A, Schechter C. Quality of the assessment of primary and secondary endpoints in claudication and critical leg ischemia trials. Vasc Med 2005;10:207-13.
17. Brass EP, Jiao J, Hiatt W. Optimal assessment of baseline treadmill walking performance in claudication clinical trials. Vasc Med 2007;12:97-103.
18. Murphy TP, Cutlip DE, Regensteiner JG, Mohler ER, Cohen DJ, Reynolds MR, et al. Supervised exercise versus primary stenting for claudication resulting from aortoiliac peripheral artery disease: six-month outcomes from the claudication: exercise versus endoluminal revascularization (CLEVER) study. Circulation 2012;125:130-9.

Submitted Oct 4, 2012; accepted Jan 29, 2013.

Additional material for this article may be found online at www.jvascsurg.org.

APPENDIX. VIBRANT Site Investigators

David Lasorda, DO, Allegheny General Hospital, Pittsburgh, Pa; Michael Rush, MD, Holy Cross Hospital, Ft. Lauderdale, Fla; Jeffrey Goldstein, MD, St. Johns, Springfield, Ill; Bob Smouse, MD, St. Francis, Peoria, Ill; Manju Kalra, MD, Mayo Clinic, Rochester, Minn; Sean Lyden, MD, Cleveland Clinic, Cleveland, Ohio; R. Andrew Blum, MD, Midwest Heart Foundation, Lombard, Ill; Arun Chervu, MD, Vascular Surgical Associates, Austell, Ga; William Gray, MD, Columbia University Medical Center, New York, NY; Romi Chopra, MD, Midwest Institute, Melrose Park, Ill; Sam Money, MD, Mayo Clinic, Scottsdale, Ariz; David Mego, MD, Arkansas Heart, Little Rock, Ark; Mark Bates, MD, Charleston Medical Center, WVa; Richard Begg, MD, Heritage Valley Health System, Beaver Falls, Pa; Barry Katzen, MD, Baptist Cardiac and Vascular Institute, Miami, Fla; W. Charles Sternbergh, MD, Ochsner Clinic, New Orleans, La.

INVITED COMMENTARY

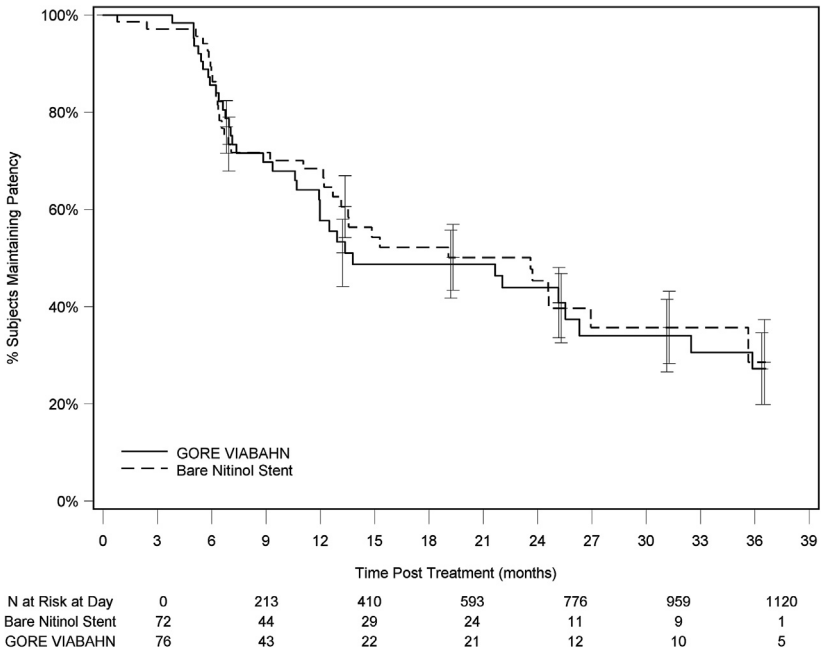
Magruder C. Donaldson, MD, *Boston, Mass*

The strengths of this multicenter prospective trial comparing bare nitinol stents to polytetrafluoroethylene stent grafts for Trans-Atlantic Inter-Society Consensus 1 C and D superficial femoral artery lesions include an uncommon effort to standardize methodology and an uncommon glimpse at 3-year outcomes. The investigators are to be commended for attempting to drive a guidepost into the riverbed and refusing to go with the flow, simply assuming that any decent study will be outdated by intercurrent innovations such as drug-eluting stents and heparin-bonded stent grafts.

The study tests the reasonable hypothesis that covered stents would eliminate in-stent restenosis, a chief cause of nitinol stent failure. Though the patency comparisons at 3 years suffer from some attrition of patients with cautionary wobble in the Kaplan-Meier curves, there was no apparent patency advantage to stent grafts. The reader remains intrigued by the lack of details regarding the ultrasound and angiographic lesions responsible for device failure, which given the surveillance protocol and high rate of reintervention, must have been available to allow distinction between intimal hyperplasia at the stent margins or within the stents and progression of disease in untreated adjacent arterial segments. Among patients followed for 36 months, the stent fracture rate was 50% for nitinol stents and only 2% for stent grafts. Acknowledging that the impact of stent fracture is controversial, if one assumes a negative impact of fracture on nitinol stent patency and a positive impact of less in-stent restenosis on stent graft patency, we might have expected an unequivocal patency advantage for stent grafts rather than the somewhat disappointing equivalency between the two groups. If indeed nitinol stents and stent grafts do have similar efficacy, device cost would assume more importance in the current penny-pinching era.

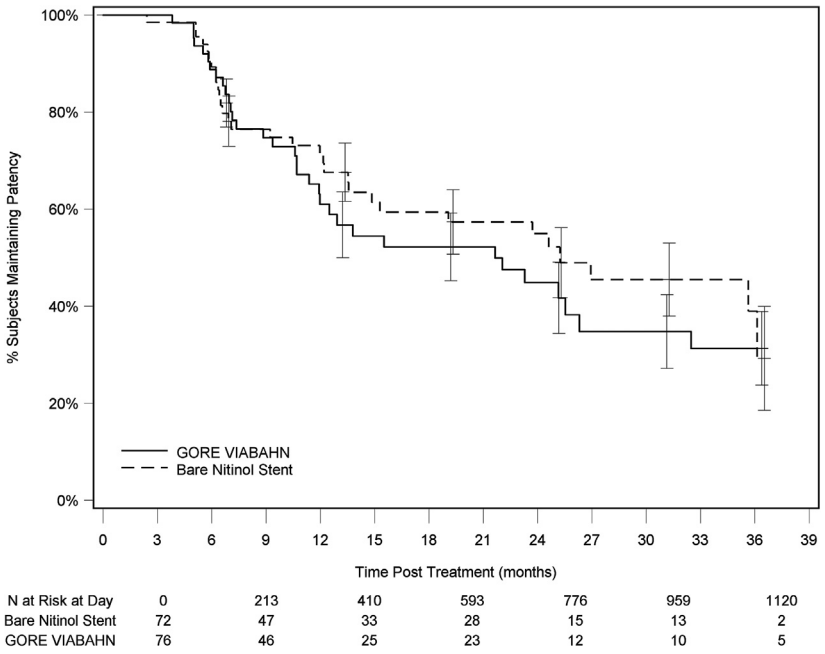
Comparison of trial results with surgical bypass is invalidated by randomization of patients only after lesions had been crossed by a guidewire. Nonetheless, optimal results at 3 years were attained only after one or more reinterventions in 40% of patients, a much higher rate than might be expected in a series of superficial femoral artery bypasses. Again, costs need consideration.

The study employed somewhat confusing patency definitions unfamiliar to most surgeons accustomed to tracking bypass grafts. Development of standards for reporting has been one of the signal contributions to vascular surgery over the years, and we must extend this effort to the endovascular arena, including our colleagues in related subspecialties. Only by adopting uniform research methodology can we build fruitfully on earnest efforts such as those of the VIBRANT trial team.



N at Risk at Day	0	213	410	593	776	959	1120
Bare Nitinol Stent	72	44	29	24	11	9	1
GORE VIABAHN	76	43	22	21	12	10	5

Fig 4 (online only). Primary patency using alternate criterion of peak systolic velocity ratio (PSVR) ≤ 2.5.



N at Risk at Day	0	213	410	593	776	959	1120
Bare Nitinol Stent	72	47	33	28	15	13	2
GORE VIABAHN	76	46	25	23	12	10	5

Fig 5 (online only). Primary patency using alternate criterion of peak systolic velocity ratio (PSVR) ≤ 3.0.

Table VIII (online only). Quality of life: intermittent claudication questionnaire scores

	VIABAHN	P *value*[a]	*Bare nitinol stent*	P *value*[a]
Number of enrolled subjects	72		76	
Preprocedure visit ICQ score				
No. (data available)	72		75	
Mean (SD)	46.6 (20.1)		50.1 (18.2)	
Median	46		55	
Range	(8-91)		(8-80)	
1-month visit ICQ score		<.001		<.001
No. (data available)	66		72	
Mean (SD)	17.2 (15.7)		20.5 (18.7)	
Median	12		14	
Range	(0-58)		(0-68)	
6-month visit ICQ score		<.001		<.001
No. (data available)	57		66	
Mean (SD)	27.2 (25.8)		23.1 (20.8)	
Median	20		18	
Range	(0-91)		(0-66)	
12-month visit ICQ score		<.001		<.001
No. (data available)	53		62	
Mean (SD)	25.6 (21.3)		23.5 (20.3)	
Median	23		22	
Range	(0-72)		(0-85)	
24-month visit ICQ score		<.001		<.001
No. (data available)	44		51	
Mean (SD)	23.9 (19.3)		20.5 (18.7)	
Median	19		17	
Range	(0-66)		(0-66)	
36-month visit ICQ score		<.001		<.001
No. (data available)	40		45	
Mean (SD)	20.8 (19.6)		22.9 (21.2)	
Median	17		20	
Range	(0-71)		(0-82)	

ICQ, Intermittent claudication questionnaire; *SD,* standard deviation.
[a]*P* value obtained from two-tailed Wilcoxon test with pooled variances of the preprocedure visit and each respective visit interval.

Table IX (online only). Quality of life: SF-36 questionnaire scores (physical domain)

	VIABAHN stent graft	P *value*[a]	*Bare nitinol stent*	P *value*[a]
Number of enrolled subjects	72		76	
Preprocedure visit SF-36 physical score				
No. (data available)	71		74	
Mean (SD)	33.6 (9.9)		32.9 (8.5)	
Median	33		33	
Range	(14-59)		(14-51)	
1-month visit SF-36 physical score		<.001		<.001
No. (data available)	66		72	
Mean (SD)	42.2 (10.2)		41.4 (10.8)	
Median	43		42	
Range	(19-59)		(12-59)	
6-month visit SF-36 physical score		<.001		<.001
No. (data available)	57		66	
Mean (SD)	40.4 (11.1)		40.3 (10.4)	
Median	42		41	
Range	(22-56)		(18-58)	
12-month visit SF-36 physical score		.001		<.001
No. (data available)	52		62	
Mean (SD)	40.5 (11.7)		39.8 (10.7)	
Median	40		39	
Range	(17-60)		(19-59)	
24-month visit SF-36 physical score		.004		<.001
No. (data available)	43		48	
Mean (SD)	39.8 (11.5)		40.6 (10.9)	
Median	38		40	
Range	(15-61)		(19-62)	
36-month visit SF-36 physical score		<.001		.005
No. (data available)	39		45	
Mean (SD)	41.9 (11.7)		38.7 (10.5)	
Median	45		37	
Range	(21-61)		(16-59)	

SD, Standard deviation; *SF*, short form.
[a]*P* values obtained from two-tailed Wilcoxon test with pooled variances of the preprocedure visit and each respective visit interval.

Table XII (online only). Stent fractures by stented length

	VIABAHN stent graft	*Bare nitinol stent*	P *value*[a]
Number of enrolled subjects	72	76	
Stent fractures at 12-month visit			<.001
No. (data available)[b]	47	55	
Yes[c]	1 (2.1%)	18 (32.7%)	
Stented length 0-15 cm	1 (11.1%)/9	0 (0.0%)/10	
Stented length 16-25 cm	0 (0.0%)/16	8 (29.6%)/27	
Stented length 26+ cm	0 (0.0%)/22	10 (55.6%)/18	
No	46 (97.9%)	37 (67.3%)	
Stent fractures at 24-month visit			<.001
No. (data available)[b]	43	47	
Yes[c]	2 (4.7%)	23 (48.9%)	
Stented length 0-15 cm	2 (28.6%)/7	0 (0.0%)/11	
Stented length 16-25 cm	0 (0.0%)/16	11 (52.4%)/21	
Stented length 26+ cm	0 (0.0%)/20	12 (80.0%)/15	
No	41 (95.3%)	24 (51.1%)	
Stent fractures at 36-month visit			<.001
No. (data available)[b]	38	42	
Yes[c]	1 (2.6%)	21 (50.0%)	
Stented length 0-15 cm	1 (14.3%)/7	1 (11.1%)/9	
Stented length 16-25 cm	0 (0.0%)/14	12 (54.5%)/22	
Stented length 26+ cm	0 (0.0%)/17	8 (72.7%)/11	
No	37 (97.4%)	21 (50.0%)	

[a]Data limited to diagnostic quality x-rays. *P* value obtained from two-tailed Fisher exact test of VIABAHN stent graft and bare nitinol stent.
[b]12-, 24-, and 36-month X-rays are limited to those performed between 274-548, 549-913, and 914-1270 days since procedure, respectively.
[c]Denominator for percentages is the number of subjects available per visit window.

Table XIII (online only). Stent fracture severity classification

	VIABAHN	*Bare nitinol stent*	P *value*[a]
Number of enrolled subjects	72	76	
Stent fractures at 12-month visit			<.001
No. (data available)[b]	47	55	
Yes[c]	1 (2.1%) [1]	18 (32.7%) [24]	
Grade 1 - Single strut	1 (2.1%) [1]	7 (12.7%) [8]	
Grade 2 - Multiple struts	0 (0.0%) [0]	8 (14.5%) [10]	
Grade 3 - Fracture without separation	0 (0.0%) [0]	3 (5.5%) [3]	
Grade 4 - Fracture with separation	0 (0.0%) [0]	3 (5.5%) [3]	
No	46 (97.9%)	37 (67.3%)	
Stent fractures at 24-month visit			<.001
No. (data available)[b]	43	47	
Yes[c]	2 (4.7%) [2]	23 (48.9%) [32]	
Grade 1 - Single strut	2 (4.7%) [2]	10 (21.3%) [12]	
Grade 2 - Multiple struts	0 (0.0%) [0]	10 (21.3%) [12]	
Grade 3 - Fracture without separation	0 (0.0%) [0]	2 (4.3%) [2]	
Grade 4 - Fracture with separation	0 (0.0%) [0]	6 (12.8%) [6]	
No	41 (95.3%)	24 (51.1%)	
Stent fractures at 36-month visit			<.001
No. (data available)[b]	38	42	
Yes[c]	1 (2.6%) [1]	21 (50.0%) [25]	
Grade 1 - Single strut	1 (2.6%) [1]	8 (19.0%) [8]	
Grade 2 - Multiple struts	0 (0.0%) [0]	10 (23.8%) [12]	
Grade 3 - Fracture without separation	0 (0.0%) [0]	2 (4.8%) [2]	
Grade 4 - Fracture with separation	0 (0.0%) [0]	3 (7.1%) [3]	
No	37 (97.4%)	21 (50.0%)	

The values listed indicate the number of subjects experiencing a stent fracture, whereas the number in brackets indicates the total number of fractures, including multiple stent fractures per subject.

[a]*P* value obtained from two-tailed Fisher exact test of VIABAHN and bare nitinol stent.

[b]Availability limited to subjects with a diagnostic quality x-ray.

[c]The sum of individual grades may be greater than the number of subjects experiencing a stent fracture, for subjects can have multiple-grade stent fractures.