Balloon angioplasty versus Viabahn stent graft for treatment of failing or thrombosed prosthetic hemodialysis grafts

Thomas Vesely, MD,[a] William DaVanzo, MD,[b] Terry Behrend, MD,[c] Amy Dwyer, MD,[d] and **John Aruny, MD,[e]** *Saint Louis, Mo; St. Simons Island, Ga; San Diego, Calif; Louisville, Ky; and New Haven, Conn*

Objective: **To compare the results of stent graft placement to balloon angioplasty for the treatment of stenosis at the venous anastomosis of failing and thrombosed prosthetic hemodialysis grafts.**
Methods: **This prospective, multicenter trial included 293 patients randomized (1:1) to the stent graft (n = 145) or balloon angioplasty (n = 148) group for treatment of stenosis at the venous anastomosis of dysfunctional (n = 164) or thrombosed (n = 129) hemodialysis grafts. The primary study end point was target lesion primary patency at 6 months; participants were followed for up to 24 months. Primary patency of the access circuit was a secondary end point. Statistical analysis of effectiveness was performed using both the intent-to-treat population and the effectiveness-per-protocol (EPP) populations for primary patency end points. Statistical analysis of additional effectiveness end points was performed using the EPP population.**
Results: **The 6-month target lesion primary patency was statistically greater in the stent graft group than the balloon angioplasty group (intent-to-treat, 51.6% vs 34.2% [*P* = .006]; EPP, 52.9% vs 35.5% [*P* = .008]). Compared with the angioplasty group, the stent graft group increased the median time from the index procedure to the next intervention on the target lesion by 95 days (203 vs 108 days). Patients with dysfunctional (stenotic) grafts had higher target lesion primary patency compared with patients with thrombosed grafts regardless of treatment (EPP, stent graft, 64.6% vs 36.1% and balloon angioplasty, 45.8% vs 23.5%). When compared with angioplasty, using a stent graft for treatment of a venous anastomotic stenosis of a thrombosed graft increased the 6-month target lesion primary patency by 53.6% (EPP, 36.1% vs 23.5%).**
Conclusions: **When compared with balloon angioplasty, a stent graft provided superior target lesion primary patency at 6 months for treatment of venous anastomotic stenoses of dysfunctional and thrombosed prosthetic hemodialysis grafts. (J Vasc Surg 2016;64:1400-10.)**

Balloon angioplasty is the standard percutaneous treatment for neointimal hyperplastic stenoses involving native arteries, native veins, and vascular anastomoses.[1] The ease and speed of an angioplasty procedure, for both patient and physician, contributes to the continuing popularity of the procedure. However, balloon angioplasty does not remove the neointimal tissue that causes the obstructive stenosis. Its mechanism of action is forceful intraluminal expansion creating deep fractures into the neointimal tissue thereby enlarging luminal cross-sectional area and improving blood flow.[2] Neointimal hyperplastic stenoses are dense, fibrotic lesions that are often resistant to dilatation requiring balloon inflation pressure of 15 to 20 atmospheres.[3]

The reported effectiveness of balloon angioplasty for treatment of a venous anastomotic stenoses in prosthetic hemodialysis grafts has changed over time. Older studies (1990s) have reported 6-month primary patency rates of 40% to 50%,[4,5] whereas more recent studies (2005-2010) have reported less successful results with 6-month primary patency rates of 20% to 36%.[6,7] Interestingly, this decrease in effectiveness of angioplasty occurred during a period when ultrahigh-pressure angioplasty balloons became widely available.[8]

Stent grafts are commonly used for treatment of obstructive stenoses involving native arteries, native veins, and vascular anastomoses.[9] After balloon angioplasty, a stent graft can be used to cover the damaged neointimal tissue, preventing recurrence of the stenosis.[10] Insertion of a stent graft is as easy and fast as an angioplasty procedure for both patient and physician. Recent studies using

From the Vascular Access Services, Saint Louis[a]; the Palmyra Medical Center, St. Simons Island[b]; the San Diego Vascular Access Center, San Diego[c]; the Department of Medicine, University of Louisville, Louisville[d]; and the Department of Radiology & Biomedical Imaging, Yale University School of Medicine, New Haven.[e]

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Correspondence: Thomas Vesely, MD, Vascular Access Services, LLC, 24 The Boulevard Saint Louis, #420, St. Louis, MO 63117 (e-mail: tmvesely@gmail.com).
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stent grafts for treatment of venous anastomotic stenosis have reported results that are superior to balloon angioplasty with 6-month primary patency rates of 38% to 100%.[6,10,11]

This prospective clinical trial was performed to compare two different methods for percutaneous treatment of neointimal hyperplastic stenoses; balloon angioplasty vs the Viabahn stent graft (W. L. Gore, Flagstaff, Ariz). The target lesion was the venous anastomosis of a prosthetic hemodialysis graft. The intent of this clinical trial was to compare the two treatment methods under realistic conditions. Study enrollment criteria were broad to include typical hemodialysis patients with either a dysfunctional or thrombosed prosthetic graft. After the study procedure and during the 24-month follow-up period, the hemodialysis graft was managed by the patient's local physician and the protocols at each patient's hemodialysis treatment center.

METHODS

Study design. This investigation was designed as a prospective, randomized, multicenter clinical trial to compare the safety and efficacy of balloon angioplasty vs stent graft for treatment of a venous anastomotic stenosis of an upper extremity prosthetic hemodialysis graft. The study was approved by each center's institutional review board and by the Food and Drug Administration (Supplementary Table I, online only). The trial, sponsored by W. L. Gore & Associates, is registered at ClinicalTrials.gov at: http://clinicaltrials.gov/ct2/show/NCT00737672.

Study end points. The study protocol was written in 2007 and the definitions of end points are consistent with the reporting standards of the Society for Vascular Surgery and the Society of Interventional Radiology at that time[12,13] (Supplementary Table II, online only). The primary safety end point was major device-, procedure-, and treatment site-related adverse events within 30 days. All estimates of patency were assessed using a Kaplan-Meier time-to-event model. Additional end points included patency outcomes stratified according to prior interventions at the target lesions, patency of the graft, and stent graft positioned across the antecubital fossa.

Stent graft. The investigational stent graft was a GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface, a flexible, self-expanding endoluminal endoprosthesis. It consists of two components: (i) a tubular section of expanded polytetrafluoroethylene modified with a heparin bioactive surface, and (ii) an external nitinol structure extending along the entire length of the device. The device was available in diameters of 6, 7, 8, 9, 10, 11, and 13 mm and lengths of 2.5, 5, 10, and 15 cm.

Study population. Adult patients undergoing chronic hemodialysis treatment using an upper extremity prosthetic hemodialysis graft presenting with clinical or hemodynamic evidence of graft thrombosis or dysfunction were eligible for study participation. A failing hemodialysis graft was defined by the clinical and hemodynamic criteria described in Guideline 6 of the National Kidney Foundation's 2006 Clinical Practice Guidelines for Vascular Access.[14] Patients meeting all clinical eligibility requirements (Table I) signed informed consent before the procedure. Angiographic evaluation of the entire access circuit was performed at the time of the procedure to assess characteristics of the target lesion and its relationship to the hemodialysis graft, and any secondary lesion. Only patients who met all of the clinical and angiographic inclusion and none of the exclusion criteria were enrolled (Tables I and II).

Pre-enrollment angioplasty procedure and study randomization. The first step was angioplasty of a qualifying secondary stenosis, if present, before any treatment of the target lesion. A successful angioplasty (<30% residual stenosis) of a secondary stenosis was required for patient enrollment. Patients with a thrombosed graft underwent percutaneous thrombectomy or thrombolysis so that accurate measurements of the target lesion could be obtained before angioplasty. Full inflation of the angioplasty balloon at the target lesion was the final criterion for patient enrollment before randomization. Anatomic success after initial balloon angioplasty of the target lesion was not a requirement for enrollment. Patient randomization was based on an equal assignment ratio (1:1) to treatment using balloon angioplasty or treatment using a Viabahn stent graft. A block randomization scheme was used, with six patients per block, to ensure that each clinical site enrolled approximately the same number of patients in each study group.

Study treatment and postprocedure assessments. All study patients underwent initial angioplasty of the target lesion, the venous anastomosis, as a requirement for study enrollment. Patients randomized to the balloon angioplasty group could undergo, at the discretion of the investigator, additional balloon angioplasty to achieve an optimal result at the target lesion. Angioplasty balloon size(s), number of inflations, and percent residual stenosis at the target lesion were documented. Patients randomized to undergo placement of a Viabahn stent graft were treated in accordance with the Instructions for Use document.[15] Selection of Viabahn stent graft diameter was based on the maximal diameter of the hemodialysis graft adjacent to the target lesion.

At completion of the procedure, all study subjects were assessed for the presence of a palpable, continuous thrill as a measure of procedure success. Clinical success was defined as the patient's ability to undergo at least one hemodialysis treatment at the prescribed blood flow rate for the prescribed treatment duration. Procedural complications and adverse events were classified according to criteria established by the Society of Interventional Radiology Standards of Practice Committee and all events were adjudicated by the study's data safety monitoring board.[16]

Patient follow-up. Management of each patient's hemodialysis graft was determined by the patient's nephrologist and local protocols at the hemodialysis treatment center. Each patient's hemodialysis records were reviewed and all hemodialysis graft-related events were documented. Follow-up information for each patient was

Table I. Clinical criteria for patient enrollment

Clinical inclusion criteria
1. Hemodialysis patient with a dysfunctional or thrombosed forearm or upper arm prosthetic vascular access graft.
2. The patient is ≥18 years of age.
3. The patient has a reasonable expectation of remaining on hemodialysis for 24 months.
4. The patient or his or her legal guardian understands the study and is willing and able to comply with follow-up requirements.
5. The patient or his or her legal guardian is willing to provide informed consent.
Clinical exclusion criteria
1. The age of the hemodialysis access graft is ≤30 days old from the date of the study procedure.
2. The patient has undergone an intervention (surgical or percutaneous) of the vascular access circuit ≤30 days from the date of the study procedure.
3. The patient has a native arteriovenous fistula currently used for hemodialysis.
4. The patient has an existing stent or stent graft anywhere within the current vascular access circuit.
5. The patient has an existing hemodialysis graft that has not been used successfully for hemodialysis.
6. The patient's hemodialysis graft is located in the thigh.
7. The patient has a compound or hybrid vascular access (ie, graft-fistula hybrid).
8. The patient has steal syndrome related to the current vascular access sufficient to warrant a surgical intervention to treat hand ischemia.
9. The patient has a known or suspected systemic infection.
10. The patient has a known or suspected infection of the hemodialysis graft.
11. The patient is currently taking maintenance immunosuppressant medication such as rapamycin, mycophenolate or mycophenolic acid, prednisone >10 mg daily dose, cyclosporine, tacrolimus, or cyclophosphamide.
12. The patient has a known bleeding disorder (eg, hemophilia or Von Willebrand's disease).
13. The patient has a defined hypercoagulable disorder.
14. The patient has a known sensitivity to heparin.
15. The patient is scheduled for a live donor kidney transplant.
16. The patient is enrolled in another investigational study.
17. The patient has comorbid conditions that may limit their ability to comply with the follow-up requirements.
18. Life expectancy is ≤24 months.
19. The patient has an untreatable allergy to radiographic contrast material.
20. The patient is pregnant.

Table II. Angiographic criteria for patient enrollment

Angiographic inclusion criteria
1. The target lesion starts ≤30 mm from the venous anastomosis.
2. The target lesion has >50% stenosis as measured per protocol.
3. The patient has no secondary stenosis or has a maximum of one secondary stenosis if the following criteria are satisfied:
a. The secondary stenosis must be located in the graft or a peripheral vein.
b. The secondary stenosis must be ≤50 mm in length.
c. The secondary stenosis must be located ≥30 mm away from the edge of the target lesion.
d. The secondary lesion causes >50% stenosis.
e. The secondary lesion is treated before randomization, using a conventional angioplasty balloon.
f. Treatment of the secondary lesion with conventional angioplasty is successful with <30% residual stenosis and no complications.
Angiographic exclusion criteria
1. The secondary lesion is an occlusion.
2. The patient has central venous stenosis requiring treatment.
3. The physician is unable to fully inflate a conventional percutaneous transluminal angioplasty balloon at the target lesion (ie, focal waist remains in balloon upon inflation).
4. There is an angioplasty induced rupture that is unresponsive to balloon tamponade.
5. Diameter of prosthetic graft adjacent to target lesion is <4.8 mm.
6. The target lesion is entirely within the prosthetic graft.
7. The target lesion is in such a location that the GORE VIABAHN device, once deployed, would be positioned within the zone of cannulation in the prosthetic graft.

collected at 1, 3, 6, 12, 18, and 24 months after the randomized treatment procedure.

Repeat interventions to the vascular access circuit. The need for a repeat intervention was determined by each patient's local physician(s). Clinical indications for a repeat intervention included low intragraft blood flow, elevated venous pressures, arm swelling, prolonged time to hemostasis, and graft thrombosis. Per study protocol, nonsignificant lesions (<50% stenosis) were not treated.

For study patients receiving a stent graft, the postprocedure definition of the target lesion was expanded to include any intervention within the Viabahn device or 5 mm from the distal or proximal edges of the device. For patients treated with balloon angioplasty, the venous anastomosis continued to be the target lesion. During interventions performed during the 24-month follow-up period, if any study patient needed a stent graft, a Viabahn stent graft was recommended.

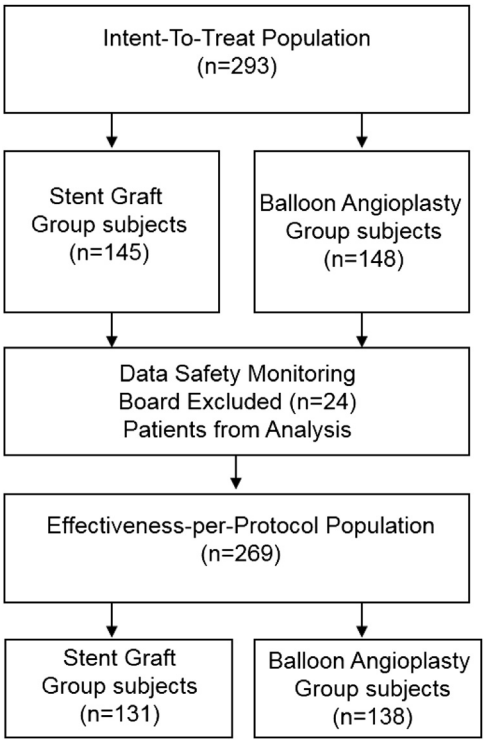

Fig 1. Distribution of patients.

Study completion or discontinuation. Participation in this study was considered complete once a patient completed the full 24 months of follow-up or was withdrawn before study completion. Reasons for study withdrawal included abandonment of the vascular access circuit, elimination of the target lesion from the vascular access circuit, death, subject or investigator choice, or loss to follow-up.

Statistical analysis. Two different patient populations were used in the analyses of the data collected as part of this trial (Fig 1). The intent-to-treat (ITT) population was comprised of all patients randomized and treated in the study. The effectiveness-per-protocol (EPP) population excluded those patients with significant violations of the protocol as determined by the study's data safety monitoring board. The sample size required to test the primary effectiveness outcome, time to loss of target lesion primary patency, was based on a one-sided log-rank test of superiority. In calculating sample size, it was estimated that the time to loss of target lesion primary patency was 54% at 6 months for the stent graft group and 40% at 6 months for the balloon angioplasty group. PASS software (Kaysville, Utah) was used to determine that a sample size of 280 subjects would be required to achieve statistical significance.

RESULTS

A total of 293 patients at 31 clinical sites who presented with dysfunctional (ITT, n = 164; EPP, n = 151) or thrombosed (ITT, n = 129; EPP, n = 118) prosthetic hemodialysis grafts from September 2008 to May 2011 were enrolled, randomized, and treated with balloon angioplasty (ITT, n = 148; EPP, n = 138) or a Viabahn stent graft (ITT, n = 145; EPP, n = 131). With the exception of ethnicity of the ITT population, there were no differences in the demographic characteristics (Table III), medical history (Table III), clinical indications for patient referral (Table IV), graft location and configuration (Table V), vascular access history (Table VI), or clinical success (Table VII) between the two treatment groups.

There was no difference in the number of subjects who completed the 24-month follow-up between the stent graft and balloon angioplasty groups (ITT, 45% vs 44%; EPP, 47% vs 45%). The most frequent reason for study withdrawal was graft abandonment (ITT, 33% vs 38% [P = .46]; EPP, 33% vs 38% [P = .37]) followed by death (ITT, 16% vs 15% [P = .87]; EPP, 15% vs 14% [P = .73]; Table VIII).

Procedural assessments. There were no differences between the two treatment groups with respect to the angiographic characteristics of the target lesion: target lesion percent stenosis (ITT, 73% vs 74% [P = .40]; EPP, 72% vs 74% [P = .41]) and the total length of the target lesion (ITT, 22 vs 24 mm [P = .39]; EPP, 23 vs 25 mm [P = .60]; Table IX). The ITT population of the balloon angioplasty group had significantly more patients with successful initial angioplasty at the target lesion, as defined by 30% or less residual stenosis, compared with the stent graft group (ITT, 68% vs 85% [P = .001]; EPP, 70% vs 84% [P = .006]; Table X). Nearly all patients in the stent graft group received a single stent graft (ITT, 97%; EPP, 987%).

The mean total procedure time was statistically longer in the stent graft group compared with the balloon angioplasty group (ITT, 51 vs 44 minutes [P = .002]; EPP, 50 vs 45 minutes [P = .015]). More patients in the stent graft group received intraprocedural antibiotics compared with the balloon angioplasty (ITT, 43% vs 26% [P = .002]; EPP, 44 vs 25% [P = .002]). A similar percentage of patients in both the stent graft and balloon angioplasty groups received heparin during the randomized treatment procedure (ITT, 53% vs 60% [P = .24]; EPP, 50% vs 60% [P = .11]).

There was no difference between the stent graft and balloon angioplasty groups in the percentage of patients with a secondary stenosis (ITT, 24% vs 21% [P = .58]; EPP, 20% vs 20% [P >.99]; Table XI). For both groups, the majority of these stenoses were located within the graft (ITT, 68.6 vs 83.9% [P = .17]; EPP, 65.4 vs 82.1% [P = .22]). The angiographic characteristics of the secondary lesions were not different between the two groups: there were no differences in length (ITT, 16 vs 14 mm [P = .64]; EPP, 17 vs 14 mm [P = .24]) or mean percent stenosis (ITT, 67% vs 68% [P = .79]; EPP, 69% vs 68% [P = .91]; Table XI).

Primary patency. Target lesion primary patency of the stent graft group was statistically superior to the balloon angioplasty group (ITT, P = .006; EPP, P = .008).

Table III. Comparison of demographic information and medical history

	ITT				*EPP*			
	Stent graft	*Balloon angioplasty*	*Overall*	P *value*	*Stent graft*	*Balloon angioplasty*	*Overall*	P *value*
Age								
No. (data available)	145	148	293		131	138	269	
Mean (SD)	62 ± 13	61 ± 15	62 ± 14	.55[a]	63 ± 13	61 ± 15	62 ± 14	.37[a]
Ethnicity								
No. (data available)	142	144	286		128	134	262	
Hispanic or Latino	16 (11)	30 (21)	46 (16)	.036[b]	16 (13)	28 (21)	44 (17)	.098[b]
Race								
No. (data available)	145	147	292		131	137	268	
American Indian or Alaskan Native	0 (0)	1 (1)	1 (0)	>.99[b]	0 (0)	1 (1)	1 (0)	>.99[b]
Asian	9 (6)	7 (5)	16 (6)	.62[b]	7 (5)	7 (5)	14 (5)	>.99[b]
Black or African American	74 (51)	80 (54)	154 (53)	.64[b]	66 (50)	75 (55)	141 (53)	.54[b]
Native Hawaiian or Pacific Islander	1 (1)	0 (0)	1 (0)	.50[b]	1 (1)	0 (0)	1 (0)	.49[b]
White or Caucasian	61 (42)	56 (38)	117 (40)	.55[b]	57 (44)	51 (37)	108 (40)	.32[b]
Other	0 (0)	4 (3)	4 (1)	.12[b]	0 (0)	4 (3)	4 (2)	.12[b]
Gender								
No. (data available)	145	148	29		131	138	269	
Female	76 (52)	75 (51)	151 (52)	.82[b]	70 (53)	70 (51)	140 (52)	.72[b]
Physical characteristics, mean ± SD								
No. (data available)	145	148	292		131	138	269	
Height, cm	167 ± 12	165 ± 13	166 ± 12	.17[a]	167 ± 12	166 ± 12	167 ± 12	.20[a]
Weight, kg	84 ± 29	81 ± 26	83 ± 28	.51[a]	85 ± 30	81 ± 26	83 ± 28	.38[a]
BMI	29.7 ± 9.1	29.5 ± 8.6	29.6 ± 8.8	.89[a]	30.1 ± 9.4	29.5 ± 8.7	29.8 ± 9.0	.60[a]
History of diabetes								
No. (data available)	145	148	292		131	138	269	
Yes	94 (65)	98 (66)	192 (66)	.81[a]	84 (64)	90 (65)	174 (65)	.90[a]
History of hypertension								
No. (data available)	145	148	293		131	138	269	
Yes	143 (99)	144 (97)	287 (98)	.68[a]	129 (99)	134 (97)	263 (98)	.69[a]

EPP, Effectiveness-per-protocol; *ITT,* intent-to-treat; *SD,* standard deviation.

Data are presented as number (%) unless otherwise indicated. Percentages cited are the percentage of subjects out of the data available. Subjects may select multiple races.

[a] *P* value assesses treatment differences using a two-tailed Wilcoxon rank-sum test.

[b] *P* value assesses treatment differences using a two-tailed Fisher's exact test.

Table IV. Indications for patient referral

	ITT				*EPP*			
Indication for procedure	*Stent graft*	*Balloon angioplasty*	*Overall*	P *value*[a]	*Stent graft*	*Balloon angioplasty*	*Overall*	P *value*[a]
No. (data available)	145	148	293		131	138	269	
Low blood flow	47 (32)	39 (26)	86 (29)	.31	42 (32)	35 (25)	77 (29)	.23
Elevated venous pressure	28 (19)	30 (20)	58 (20)	.88	26 (20)	26 (19)	52 (19)	.88
Arm swelling	4 (3)	8 (5)	12 (4)	.38	3 (2)	7 (5)	10 (4)	.34
Prolonged time to hemostasis	18 (12)	19 (13)	37 (13)	>.99	18 (14)	19 (14)	37 (14)	>.99
Graft thrombosis	63 (43)	66 (45)	129 (44)	.91	54 (41)	64 (46)	118 (44)	.46
Other	13 (9)	20 (14)	33 (11)	.27	13 (10)	18 (13)	31 (12)	.45

EPP, Effectiveness-per-protocol; *ITT,* intent-to-treat.

Data are presented as number (%) unless otherwise indicated. Percentages cited are the percentage of subjects out of the data available. Subjects may have multiple indications for procedure.

[a] *P* value assesses treatment differences using a two-tailed Fisher's exact test.

At 6 months, the primary patency of the target lesion was higher in the stent graft group than the balloon angioplasty group (ITT, 51.6% vs 34.2%; EPP, 52.9% vs 35.5%) and was higher at every time point of the 24-month analysis period (Fig 2, *A*). The median time to loss of target lesion primary patency increased by 88% in the stent graft group compared with the balloon angioplasty group (EPP, 203 vs 108 days). The most common intervention to end primary patency of the target lesion in both the stent graft and balloon angioplasty group was the need for an additional angioplasty procedure (EPP, 63.4% vs 76.1%; $P = .025$).

Circuit primary patency was also statistically superior in the stent graft group over the balloon angioplasty group (ITT, $P = .035$; EPP, $P = .035$). At 6 months the primary

Table V. Description of prosthetic grafts

	ITT				*EPP*			
	Stent graft	*Balloon angioplasty*	*Overall*	P *value*	*Stent graft*	*Balloon angioplasty*	*Overall*	P *value*
Arm with current prosthetic graft, No. (%)				.70[a]				.59[a]
No. (data available)	145	148	293		131	138	269	
Left	105 (72.4)	104 (70.3)	209 (71.3)		97 (74.0)	98 (71.0)	195 (72.5)	
Right	40 (27.6)	44 (29.7)	84 (28.7)		34 (26.0)	40 (29.0)	74 (27.5)	
Current prosthetic graft location, No. (%)				.80[a]				.79[a]
No. (data available)	145	148	293		131	138	269	
Forearm	46 (31.7)	49 (33.1)	95 (32.4)		41 (31.3)	46 (33.3)	87 (32.3)	
Upper arm	99 (68.3)	99 (66.9)	198 (67.6)		90 (68.7)	92 (66.7)	182 (67.7)	
Current prosthetic graft configuration, No. (%)				.82[b]				.77[b]
No. (data available)	145	148	293		131	138	269	
Loop	83 (57.2)	82 (55.4)	165 (56.3)		77 (58.8)	75 (54.3)	152 (56.5)	
Straight	27 (18.6)	32 (21.6)	59 (20.1)		25 (19.1)	29 (21.0)	54 (20.1)	

EPP, Effectiveness-per-protocol; *ITT,* intent-to-treat.
[a]*P* value assesses treatment differences using a two-tailed Fisher's exact test.
[b]*P* value assesses treatment differences using a two-tailed Wilcoxon rank-sum test.

Table VI. Description of vascular access history

	ITT				*EPP*			
	Stent graft	*Balloon angioplasty*	*Overall*	P *value*[a]	*Stent graft*	*Balloon angioplasty*	*Overall*	P *value*[b]
Age of vascular access, years								
No. (data available)	144	147	291		130	137	267	
Mean ± SD	1.9 ± 1.9	2.3 ± 2.6	2.1 ± 2.3	.62	2.0 ± 2.0	2.3 ± 2.7	2.1 ± 2.4	.40
Total no. of prior interventions at the target lesion								
No. (data available)	144	145	289		130	135	265	
Mean ± SD	1.9 ± 2.2	1.8 ± 2.3	1.8 ± 2.3	.56	1.9 ± 2.3	1.8 ± 2.3	1.9 ± 2.3	.41
Total no. of prior interventions to the current prosthetic graft or circuit								
No. (data available)	144	145	289		130	135	265	
Mean ± SD	2.3 ± 2.8	2.3 ± 2.9	2.3 ± 2.8	.68	2.4 ± 2.8	2.2 ± 2.8	2.3 ± 2.8	.49

EPP, Effectiveness-per-protocol; *ITT,* intent-to-treat; *SD,* standard deviation.
[a]*P* value assesses treatment differences using a two-tailed Fisher's exact test.
[b]*P* value assesses treatment differences using a two-tailed Wilcoxon rank-sum test.

patency of the circuit was significantly greater in the stent graft group than the balloon angioplasty group (ITT, 41.5% vs 28.4%; EPP, 43.4% vs 29.4%) and was significantly greater at every time point of the 24-month analysis period (Fig 2, *B*). The median time to loss of circuit primary patency increased by 38.5% (EPP, 126 vs 91 days). More interventional procedures ending circuit primary patency were performed outside the target lesion in the stent graft group than the balloon angioplasty group (EPP, 79.6% vs 53.7% [$P \leq .001$]). Moreover, the stent graft group experienced a higher percentage of procedures ending circuit primary patency within the prosthetic graft than the balloon angioplasty group (EPP, 45.4 vs 25.2% [$P = .001$]).

Dysfunctional vs thrombosed grafts. Hemodialysis graft thrombosis was the most common indication for patient enrollment for both treatment groups (ITT, 43.4% vs 44.6% [$P = .91$]; EPP, 41.2% vs 46.4% [$P = .46$]; Table IV). Patients with thrombosed grafts had lower target lesion primary patency (EPP: stent graft, 64.6% vs 36.1% and balloon angioplasty, 45.8% vs 23.5%) and circuit primary patency (EPP: stent graft, 49.7% vs 34.2% and balloon angioplasty, 35.9 vs 21.8%) (Table XII) at the 6-month follow-up interval. Of note, patients with a thrombosed graft treated with a Viabahn stent graft had increased target lesion primary patency at 6 months when compared with treatment with balloon angioplasty (EPP, 36.1% vs 23.5%).

Prior interventions at target lesion. For patients treated with balloon angioplasty, the primary patency of both the target lesion and the circuit worsened as the number of previous interventions performed on the target lesion increased (Table XII). Patients in the angioplasty group who had at least one prior intervention at the target

Table VII. Anatomic, clinical, and procedural successes

	ITT				*EPP*			
	Stent graft	*Balloon angioplasty*	*Overall*	P *value*[a]	*Stent graft*	*Balloon angioplasty*	*Overall*	P *value*[a]
No. of subjects at index procedure	145	148	293		131	138	269	
Anatomic success				<.001				<.001
No. (data available)	145	148	293		131	138	269	
Yes	145 (100)	125 (85)	270 (92)		131 (100)	116 (84)	247 (92)	
No	0 (0)	23 (16)	23 (8)		0 (0)	22 (16)	22 (8)	
Clinical success				.72				>.99
No. (data available)	145	148	293		131	138	269	
Yes	141 (97)	145 (98)	286 (98)		128 (98)	135 (98)	263 (98)	
No	4 (3)	3 (2)	7 (2)		3 (2)	3 (2)	6 (2)	
Procedural success				<.001				<.001
No. (data available)	145	148	293		131	138	269	
Yes	141 (97)	122 (82)	263 (90)		128 (98)	113 (82)	241 (90)	
No	4 (3)	26 (18)	30 (10)		3 (2)	25 (18)	28 (10)	

EPP, Effectiveness-per-protocol; *ITT,* intent-to-treat.
Data are presented as number (%) unless otherwise indicated. Subjects may have multiple indications for procedure.
[a]*P* value assesses treatment differences using a two-tailed Fisher's exact test.

Table VIII. Disposition of patients and reason for withdrawal at 24-month follow-up

	ITT				*EPP*			
	Stent graft	*Balloon angioplasty*	*Overall*	P *value*[a]	*Stent graft*	*Balloon angioplasty*	*Overall*	P *value*[a]
No. of subjects at index procedure	145	148	293		131	138	269	
Subjects completed 24 months	65 (45)	65 (44)	130 (44)		61 (47)	62 (45)	123 (46)	
Subjects ongoing in study	0 (0)	0 (0)	0 (0)		0 (0)	0 (0)	0 (0)	
Subjects withdrawn before 24 months	80 (55)	83 (56)	163 (56)	.91	70 (53)	76 (55)	146 (54)	.81
Subject choice	1 (1)	2 (1)	3 (1)	>.99	0 (0)	2 (1)	2 (1)	.50
Investigator choice	0 (0)	2 (1)	2 (1)	.50	0 (0)	2 (1)	2 (1)	.50
Lost-to-follow-up	1 (1)	0 (0)	1 (0)	.50	1 (1)	0 (0)	1 (0)	.49
Graft abandonment	48 (33)	56 (38)	104 (36)	.46	43 (33)	53 (38)	96 (36)	.37
Death	23 (16)	22 (15)	45 (15)	.87	20 (15)	19 (14)	39 (15)	.73
Other	7 (5)	1 (1)	8 (3)	.035	6 (5)	0 (0)	6 (2)	.013

EPP, Effectiveness-per-protocol; *ITT,* intent-to-treat.
Data are presented as number (%) unless otherwise indicated. Subjects may have multiple indications for procedure.
[a]*P* value assesses treatment differences using a two-tailed Fisher's exact test.

lesion had decreased target lesion primary patency at 6 months (29.2% vs 43.9%) when compared with patients with no prior interventions. For patients in the stent graft group, the primary patency of the target lesion at 6 months was 51.1% for patients with no prior interventions compared with 53.8% for patients with at least one prior intervention at the target lesion.

Stent graft across the antecubital fossa. Twenty-two patients had a Viabahn stent graft deployed across the antecubital fossa and these patients had better patency of the target lesion and the entire circuit when compared with patients with stent grafts that did not cross the elbow joint (Table XII). Target lesion primary patency was higher (EPP, 72.4% vs 49.2%) and circuit primary patency was higher (EPP, 67.3% vs 39.0%) when the stent graft crossed the elbow joint.

Adverse events. There were no differences in the proportion of patients who experienced any device, procedure, and treatment site-related adverse event, either major or minor, between the two treatment groups ($P = .98$). Four patients in the stent graft treatment group and two patients in the angioplasty treatment group had a minor adverse event during the 30-day postprocedure period. Two major adverse events occurred in patients treated with angioplasty. Twenty days after treatment, one patient had significant infiltration along the hemodialysis graft that led to abandonment of the graft. The second patient developed a significant hematoma at the venous anastomosis 30 days after treatment that led to abandonment of the hemodialysis graft. There were no major procedure-related or stent graft-related adverse events in patients treated with a Viabahn stent graft during the 24-month study period.

Table IX. Description of target lesions

	ITT				*EPP*			
	Stent graft	*Balloon angioplasty*	*Overall*	P *value*[a]	*Stent graft*	*Balloon angioplasty*	*Overall*	P *value*[a]
No. of subjects	145	148	293		131	138	269	
Target lesion stenosis percentage	73 ± 13	74 ± 13	73 ± 13	.40	72 ± 13	74 ± 13	73 ± 13	.41
Distance from the venous anastomosis to the proximal edge of the target lesion, mm	4.4 ± 7.3	2.8 ± 5.3	3.6 ± 6.4	.19	4.2 ± 7.1	2.7 ± 5.4	3.5 ± 6.3	.31
Total length of the target lesion, mm	22 ± 21	24 ± 22	23 ± 21	.39	23 ± 21	25 ± 23	24 ± 22	.60

EPP, Effectiveness-per-protocol; *ITT*, intent-to-treat.
Values are presented as mean values ± standard deviation.
[a]*P* value assesses treatment differences using a two-tailed Wilcoxon rank-sum test.

Table X. Description of the initial angioplasty procedure

	ITT				*EPP*			
	Stent graft	*Balloon angioplasty*	*Overall*	P *value*	*Stent graft*	*Balloon angioplasty*	*Overall*	P *value*
No. of subjects	145	148	293		131	138	269	
No. of balloons used	1.22 ± 0.48	1.15 ± 0.43	1.18 ± 0.45	.13[a]	1.21 ± 0.48	1.15 ± 0.43	1.18 ± 0.46	.23[a]
Largest diameter balloon used	7.41 ± 0.85	7.40 ± 0.77	7.40 ± 0.81	.67[a]	7.40 ± 0.87	7.38 ± 0.78	7.39 ± 0.82	.55[a]
Highest inflation pressure	17.2 ± 5.6	16.6 ± 5.0	16.9 ± 5.3	.38[a]	17.4 ± 5.7	16.6 ± 5.0	17.0 ± 5.3	.33[a]
Total No. of balloon inflations	2.2 ± 2.1	2.0 ± 1.5	2.1 ± 1.8	.94[a]	2.3 ± 2.2	2.0 ± 1.6	2.1 ± 1.9	.98[a]
Percent residual stenosis after balloon angioplasty	99 ± 68%	125 ± 85%	224 ±77%	.001[b]	91 ± 70%	116 ± 84%	207 ± 77%	.001[b]

EPP, Effectiveness-per-protocol; *ITT*, intent-to-treat.
Values are presented as mean ± standard deviation.
[a]*P* value assesses treatment differences using a two-tailed Wilcoxon rank-sum test.
[b]*P* value assesses treatment differences using a two-tailed Fisher's exact test.

Table XI. Description of secondary stenoses

	ITT				*EPP*			
	Stent graft	*Balloon angioplasty*	*Overall*	P *value*	*Stent graft*	*Balloon angioplasty*	*Overall*	P *value*
No. of subjects	145	148	293		131	138	269	
Presence of secondary lesion	35 (24)	31 (21)	66 (23)	.58[a]	26 (20)	28 (20)	54 (20)	>.99[a]
Location of secondary lesion				.17[a]				.22[a]
No. (data available)	35	31	66		26	28	54	
Intragraft	24 (68.6)	26 (83.9)	50 (75.8)		17 (65.4)	23 (82.1)	40 (74.1)	
Peripheral vein	11 (31.4)	5 (16.1)	16 (24.2)		9 (34.6)	5 (17.9)	14 (25.9)	
Secondary lesion stenosis percentage				.79[b]				.91[b]
No. (data available)	34	31	65		26	28	54	
Mean ± SD	67 ± 15	68 ± 10.	67 ± 13		69 ± 13	68 ± 10.	68 ± 11	
Total length of the secondary lesion, mm				.64[b]				.24[b]
No. (data available)	35	31	66		26	28	54	
Mean ± SD	16 ± 14	14 ± 11	15 ± 13		17 ± 11	14 ± 11	15 ± 11	

ITT, Intent-to-treat; *SD*, standard deviation.
Data are presented as number (%) unless otherwise indicated. Percentages cited are the percentage of subjects out of the data available.
[a]*P* value assesses treatment differences using a two-tailed Wilcoxon rank-sum test.
[b]*P* value assesses treatment differences using a two-tailed Fisher's exact test.

Patient outcomes. Forty-five patients died during the 24-month follow-up period; 23 patients in the stent graft group and 22 patients in the balloon angioplasty group (Table VIII). The majority of patients died of cardiovascular disease followed by complications of end-stage kidney disease, including withdrawal from hemodialysis. Estimates of patient survival demonstrated no difference between the stent graft group and the balloon angioplasty group ($P = .87$).

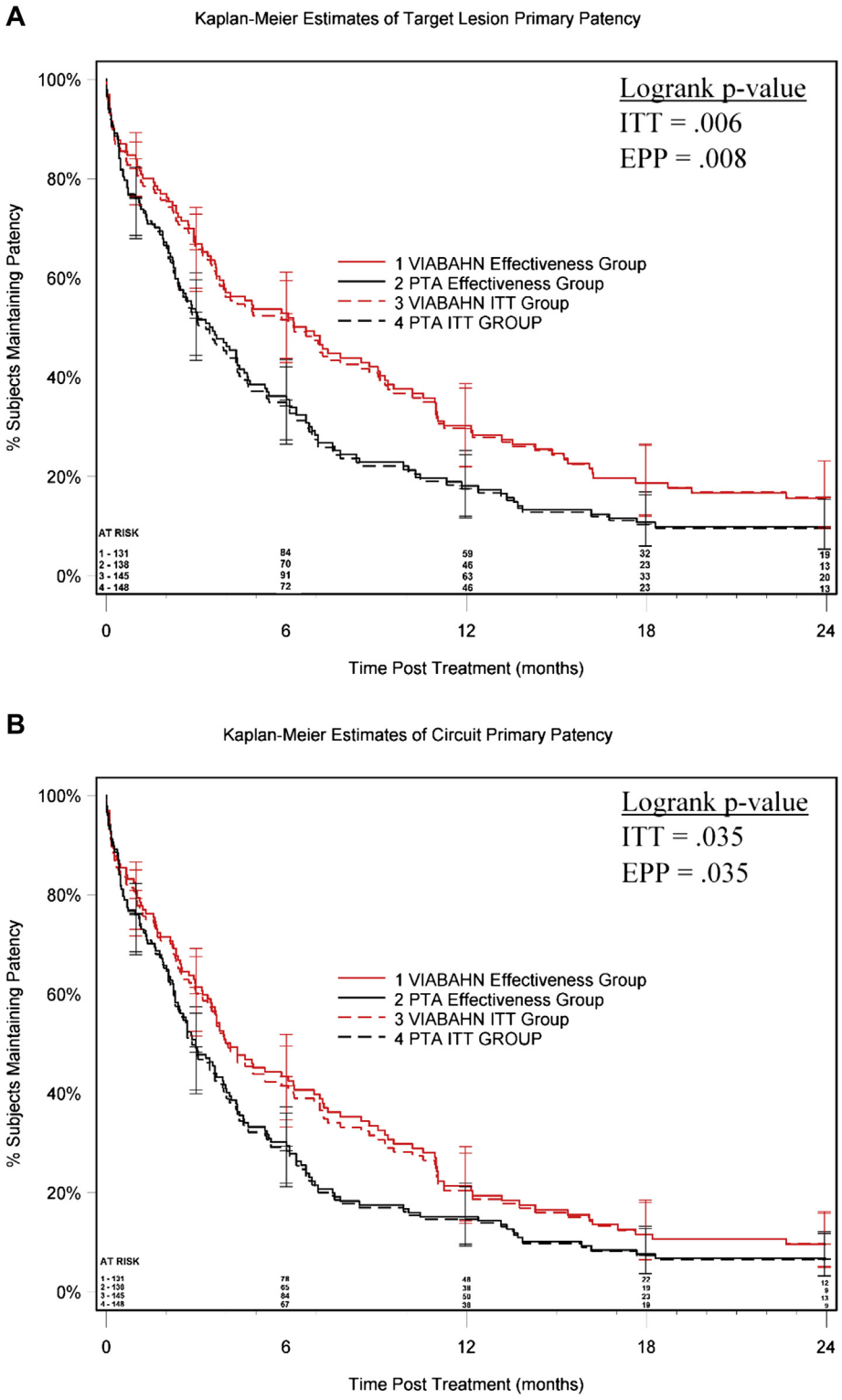

Fig 2. Stent grafts improve primary patency of target lesion and access circuit compared with balloon angioplasty. Kaplan-Meier estimates of primary patency of the target lesion **(A)** and access circuit **(B)**. In all cases, stent grafts demonstrated statistical superiority in patency compared with balloon angioplasty. (*P* values shown in each panel were calculated using the log-rank test). *EPP*, Effectiveness-per-protocol; *ITT*, intention to treat; *PTA*, percutaneous transluminal angioplasty.

Table XII. Additional measures of effectiveness at 6-months trend toward improved patency of stent grafts

	Target lesion primary patency		*Circuit primary patency*	
	Stent grafts, %	*Balloon angioplasty, %*	*Stent grafts, %*	*Balloon angioplasty, %*
Prior interventions to target lesion				
0	51.1 (36)	43.9 (45)	48.7 (36)	35.0 (45)
≥1	53.8 (64)	29.2 (59)	40.7 (64)	25.2 (59)
Stenotic vs thrombosed				
Stenotic	64.6 (61)	45.8 (64)	49.7 (61)	35.9 (64)
Thrombosed	36.1 (39)	23.5 (40)	34.2 (39)	21.8 (40)
Antecubital fossa				
Crossed	72.4 (17)	N/A	67.3 (17)	N/A
Did not	49.2 (83)	N/A	39.0 (83)	N/A

N/A, Not applicable.
Percentages cited are the percentage of subjects out of the data available. Parentheses represent number of subjects available at 6-month time point.

DISCUSSION

In the United States, nearly 75,000 patients undergo chronic hemodialysis treatment using a prosthetic hemodialysis graft.[17] The majority of these patients develop neointimal hyperplastic stenoses at the venous anastomosis and along the vascular access circuit, often within the first year after graft placement.[4] These obstructive lesions reduce intra-access blood flow, decrease the efficiency of hemodialysis treatment, and increase the risk of access thrombosis.[17] Balloon angioplasty remains a standard treatment for neointimal hyperplastic stenoses causing clinically significant problems with both prosthetic hemodialysis grafts and autogenous fistulas.[14] However, there is increasing clinical evidence that balloon angioplasty is not as effective as previously believed. The "reasonable goal" of 50% primary patency at 6 months, stated in the 2006 Kidney Disease Outcomes Quality Initiative (K/DOQI) Guidelines for Vascular Access, can be difficult to achieve using angioplasty alone.[14] The continuing popularity of balloon angioplasty may be based on the ease and speed of the procedure, not on its effectiveness for this application.

This clinical trial confirmed results reported by previous studies; suboptimal patency after balloon angioplasty of venous anastomotic stenoses involving prosthetic hemodialysis grafts.[6,7]

The ITT population of 148 patients treated with angioplasty had a 6-month primary patency rate of 34.2%, which is well below the K/DOQI "reasonable goal" of 50%.[14] Analysis of all patients treated with angioplasty revealed subgroups with differing results. Patients who had undergone a previous intervention at the target lesion had lower primary patency at 6 months when compared with patients with no prior interventions at the target lesion (29.2% vs 43.9%). These findings are consistent with those reported by Kanterman et al[4]; patency rates diminish with each successive angioplasty procedure. Balloon angioplasty causes significant vascular damage that incites the proliferation of neointimal hyperplasia and accelerates restenosis.[18-20]

A stent graft can resist elastic recoil, optimize luminal diameter, and provide a physical barrier to prevent restenosis by the offending lesion. These characteristics of stent grafts have made these appealing devices for treatment of neointimal hyperplastic stenoses.[21] However, widespread acceptance of stent grafts has been tempered by the greater cost of the device when compared with balloon angioplasty. The use of stent grafts as first treatment of all stenosis continues to be debated.[21]

In this study, the Viabahn stent graft provided an effective barrier to prevent restenosis. When compared with balloon angioplasty, patients treated with the Viabahn stent graft had superior primary patency at the target lesion and the access circuit for every time point during the 2-year follow-up period. The intention-to-treat population of 145 patients treated with a Viabahn stent graft had a target lesion primary patency rate of 51.6% at 6 months, which exceeds the "reasonable goal" established by the K/DOQI guidelines. The subgroup of patients with dysfunctional grafts treated with a Viabahn stent graft had a target lesion primary patency rate of 64.6% at 6 months, which not only exceeds the goal of the K/DOQI guidelines, it also exceeds the patency rates reported by a similar clinical trial using a different stent graft.[6] Furthermore, the number of prior interventions at the target lesion did not negatively affect graft patency for patients treated with a Viabahn stent graft.

This study is the first to compare results after angioplasty of dysfunctional vs thrombosed grafts, revealing substantial differences in 6-month primary patency at the venous anastomosis (45.8% vs 23.5%) and the access circuit (35.9% vs 21.8%). For patients presenting with a thrombosed graft, treatment of a venous anastomotic stenosis with a Viabahn stent graft can improve primary patency at 6 months substantially (23.5% vs 45.8%). However, the best 6-month results are achieved when using a Viabahn stent graft to treat significant stenosis involving dysfunctional but still patent prosthetic hemodialysis grafts.

Previous studies have reported that it is safe to deploy a Viabahn stent graft across the inguinal ligament and the

popliteal fossa.[22,23] This study confirmed that it was safe and effective to deploy a Viabahn stent graft across the antecubital fossa. In the 22 patients who had a Viabahn stent graft placed across the elbow joint the primary patency at the venous anastomosis and along the access circuit was improved when compared with stent grafts that did not cross the joint space.

CONCLUSIONS

The results of this study support the contention that early use of a Viabahn stent graft will improve long-term patency at the venous anastomosis of a prosthetic hemodialysis graft. When compared with balloon angioplasty, treatment with a Viabahn stent graft provided superior patency at the target lesion and for the entire access circuit during the entire 24-month follow-up period.

Treatment of dysfunctional hemodialysis grafts, using either angioplasty or a stent graft, provides superior results when compared with treatment of thrombosed grafts.

AUTHOR CONTRIBUTIONS

Conception and design: TV
Analysis and interpretation: TV, WD, TB, AD, JA
Data collection: WD, TB, AD, JA
Writing the article: TV
Critical revision of the article: TV, WD, TB, AD, JA
Final approval of the article: TV, WD, TB, AD, JA
Statistical analysis: TV
Obtained funding: Not applicable
Overall responsibility: TV

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Supplementary Table I (online only). Participating principle investigators and medical facilities

Mouhamad Annous, MD	Good Samaritan Hospital, Baltimore, Md
John Aruny, MD	Yale University School of Medicine, New Haven, Conn
Terry Behrend, MD	San Diego Vascular Access Center, San Diego, Calif
William DaVanzo, MD	Palmyra Medical Center, Albany, Ga
Amy Dwyer, MD	University of Louisville, Louisville, Ky
Brian Ferris, MD	Lake Washington Vascular Surgeons, Bellevue, Wash
Preston Fox, MD	Winchester Medical Center, Winchester, Va
Frank Giese, MD	Kidney and Hypertension Center, Cincinnati, Ohio
Marc Glickman, MD	Sentara General Hospital, Norfolk, Va
Marcelo Guimaraes, MD	Medical University of South Carolina, Charleston, SC
John Hewett, MD	Los Angeles Vascular Access Center, Inglewood, Calif
Eric Hohenwalter, MD	Froedtert Memorial Lutheran Hospital, Milwaukee, Wisc
Robert Hye, MD	Kaiser Permanente, San Diego, Calif
Jeanne LaBerge, MD	University Of California, San Francisco, San Francisco, Calif
Eric Ladenheim, MD	Ladenheim Dialysis Access, Fresno, Calif
Jerry Matteo, MD	University Of Florida, Jacksonville, Fla
Andrew Nish, MD	Iowa Methodist Medical Center, Des Moines, Iowa
Yogesh Patel, MD	Nephrology Associates Access Center, Riverside, Calif
Eric Peden, MD	Methodist Hospital, Houston, Tex
Anil Pillai, MD	Rush University Medical Center, Chicago, Ill
Rodney Raabe, MD	Sacred Heart Medical Center, Spokane, Wash
Prabir Roy-Chaudhury, MD	University Of Cincinnati, Cincinnati, Ohio
Saher Sabri, MD	University of Virginia, Charlottesville, Va
Souheil Saddekni, MD	University Of Alabama, Birmingham, Ala
Richard Saxon, MD	Tri-City Medical Center, Oceanside, Calif
Scott Schultz, MD	Minneapolis Vascular Physicians, New Brighton, Minn
Earl Schuman, MD	Legacy Health System, Portland, Ore
Eugene Simoni	Good Samaritan Hospital, Dayton, Ohio
Dan Siragusa, MD	University Of Florida, Jacksonville, Fla
William Stavropoulos, MD	Hospital of the University of Pennsylvania, Philadelphia, Pa
Ben Sueoka, MD	Memorial Hermann Baptist Hospital, Beaumont, Tex
John York, MD	Greenville Medical Center, Greenville, SC

Supplementary Table II (online only). Patency definitions

Anatomic success	Less than 30% residual stenosis after study treatment (index procedure).
Clinical success	The resumption of normal hemodialysis for at least one session after study treatment (index procedure). Less than 30% residual stenosis after study treatment (Index Procedure).
Target lesion primary patency	Kaplan-Meier estimate of the time interval of uninterrupted patency from initial study treatment to the next access thrombosis or intervention performed on the target lesion. *P* value calculated from 24-month data cohort after study completion.
Access circuit primary patency	Kaplan-Meier estimate of the time interval from initial study treatment to the next access thrombosis or intervention performed within the vascular access circuit.
Access circuit secondary patency	Kaplan-Meier estimate of the time interval from initial study treatment to abandonment of the vascular access circuit.