

Duplex Scanning of Expanded Polytetrafluoroethylene Dialysis Shunts: Impact on Patient Management and Graft Survival

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ABSTRACT

The steady decline with time in patency of expanded polytetrafluoroethylene (e-PTFE) dialysis shunts led to a trial protocol of postimplantation surveillance to identify those grafts at risk for thrombosis. Duplex scanning is a noninvasive, reproducible method of monitoring anatomic and hemodynamic aspects of graft function that provides the surgeon with an opportunity for early operative intervention. The data from this randomized prospective study suggest that early intervention based on surveillance findings is more successful in terms of access site salvage and morbidity reduction than intervention prompted by graft thrombosis or malfunction is. Duplex scanning appears to be the preferred modality that, together with timely reoperation, impacts favorably on functional graft survival.

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Introduction

The progress in chronic access to the circulation during the past quarter century has enabled hemodialysis to save or prolong a great many lives. The increased number of patients receiving chronic hemodialysis, estimated to be near 100,000 in the United States, coupled with a cumulative ten-year survival rate of more than 60%, challenges the ingenuity of the surgeon in maintaining vascular access.

The primary radiocephalic arteriovenous (A-V) fistula, developed by Brescia and Cimino in 1966,¹ is associated with a fairly high early failure rate of 10-15%.² Once successfully constructed, however, long-term patency is excellent, reportedly as high as 78% at three years.³ Approximately two thirds of patients referred for primary access procedures are candidates for autogenous fistulae.

When such fistulae fail, owing often to narrowed or diseased vessels, secondary reconstruction with an expanded polytetrafluoroethylene (e-PTFE) A-V shunt becomes necessary. Furthermore, in approximately one third of end-stage renal disease patients, this nonautogenous material is the only permanent primary access possible. Despite high initial patency rates, these grafts are prone to thrombosis because of venous outflow stenosis (VOS), hypotension and other causes.^{4,5} Reports show poor graft

survival: 66% at twelve months, and 50% at twenty-four months.⁶⁻⁹

The steady decline with time in patency of e-PTFE shunts led to this trial protocol of postimplantation surveillance to identify those grafts at risk for thrombosis. Duplex scanning provides a noninvasive, reproducible method of monitoring anatomic and hemodynamic aspects of graft function, providing the surgeon with an opportunity for early operative intervention.

This study is designed to validate that early intervention based on surveillance findings is more successful in terms of functional graft survival and morbidity reduction than intervention prompted by episodes of graft thrombosis or malfunction is.

Methods

Seventy consecutive patients who underwent e-PTFE A-V dialysis shunt implantation were randomized between two study arms and followed up prospectively. Thirty-five patients were assigned to the control group. The average period of follow-up was 16.9 months. There were 10 deaths, and 6 patients were lost to follow-up during the study. Nineteen patients had upper arm grafts (14 loop and 5 straight), and 16 had lower arm grafts (13 loop and 3 straight). Clinical examination was scheduled at three, six, and twelve months, and yearly thereafter. Surgical intervention was based on graft thrombosis or malfunction.

Table I
Classification of Venous Outflow Stenosis

Grade	% Diameter Reduction	Average Velocities* (cm/sec)	
		VO	ML
I Normal	0		
II Minimal	1-20	88	95
III Mild	21-49		
IV Moderate	50-79	220	88
V Severe	80-99	>400	55
VI Occluded	100	No Doppler signal	

* All data taken with 5 mHz probe and a 60° Doppler angle
VO = venous outflow, ML = midloop.

Table II
Secondary Operations

Indications	Procedures	Study Arm		
		Control		Surveillance
Graft thrombosis		42		2
	Declot, interposition		20	–
	Declot, patch		18	1
	Declot alone		4	1
Venous outflow stenosis		0		13
	Patch		–	7
	Interposition		–	6
Graft degeneration		5		3
	PA		3	1
	Seroma		2	2
Infection/erosion	Graft removal	4		2
Graft ligation		2		3
	Lack of VO at revision		2	1
	Steal syndrome		–	1
	Extremity edema		–	1
Arterial inflow stenosis	Revise arterial inflow	1		–
Combined		2		1
	Declot-seroma		1	–
	Declot, interposition & PA		1	–
	Interposition & PA		–	1
Total reoperations		56		24

PA = pseudoaneurysm, VO = venous outflow.

The remaining 35 patients were assigned to the surveillance group. The average period of follow-up was 24.9 months. There were 9 deaths, and 2 patients were lost to follow-up during the study. Fifteen patients had upper arm grafts (13 loop and 2 straight), and 20 had lower arm grafts (12 loop and 8 straight). This group was followed up by postoperative duplex scanning at three, six, and twelve months and yearly thereafter if vascular hemodynamics were satisfactory. Those grafts determined to be a risk were examined more frequently. Surgical intervention in this group was based on surveillance findings.

In all, 118 examinations of implanted e-PTFE A-V grafts were performed by duplex scanner in the surveillance group during the study. The method of examination consisted of real-time B-

mode ultrasound visualization of the access, including the arterial anastomosis, the e-PTFE graft in its entirety, the venous anastomosis, and the proximal arterialized vein above. Areas of localized turbulence or accelerated velocities were recorded and checked by visual confirmation of the lesions. Stenoses were also confirmed by low flow distal to the lesions, as well as by lower overall midgraft velocities. In addition, pseudoaneurysms due to puncture site graft degeneration could be differentiated from perigraft collections. Thrombus, when present, was easily imaged.

It became apparent that examination of e-PTFE grafts with B-mode ultrasound during the first seven to ten postimplant days was suboptimal owing to perigraft edema. The grafts were also found ultrasonically opaque

Table III
Surveillance Group
Comparative Classifications of Degree of VOS

Case#	Duplex	Grade Angiography	Intraoperative	Operation
1	IV	IV	IV	Patch angioplasty
2	IV	IV	IV	Patch angioplasty
3	V	V	V	Patch angioplasty
4	V	V	V	Interposition graft and repair PA
5	V V	V V	V V	Patch angioplasty Interposition graft
6	V V	V V	V V	Patch angioplasty Interposition graft
7	V V V	V V NP	V V V	Patch angioplasty Interposition graft Interposition graft
8	V V V V	V V NP NP	V V V V	Patch angioplasty Interposition graft Interposition graft Access site abandoned—lack of VO
9	V	V	NA	Patient expired before revision possible
10	VI	NA	VI	Decлот and patch angioplasty
11	VI	NA	VI	Simple decлот

NP = not performed, NA = not applicable, VO = venous outflow.

during the first one to two days, attributed to air-filled interstices in the e-PTFE material not yet replaced with fluid.¹⁰

A scheme to classify the degree of venous outflow stenosis (VOS) was developed to allow comparison of duplex results with fistulography and intraoperative findings (Table I).

Results

Twenty-seven of 35 patients (77%) of the control group required secondary operations during the study. Of 56 reoperations, 75% were performed for e-PTFE graft thrombosis (Table II). The control group averaged 1.6 reoperations per patient. Those requiring secondary procedures

averaged 2.0 reoperations each. Thirteen grafts were lost during the study: 8 were abandoned owing to lack of venous outflow, 4 were removed for infection/erosion, and 1 was lost owing to graft degeneration.

Fifteen of 35 patients (43%) of the surveillance group required secondary operations. Of 24 reoperations, 54% were performed for venous outflow stenosis on patent e-PTFE grafts (Table II). The surveillance group averaged 0.7 reoperation per patient. Those requiring secondary procedures averaged 1.6 reoperations each. Ten grafts were lost: 5 for lack of venous outflow, 2 for infection/erosion, 1 for steal syndrome, 1 for intractable extremity edema,

and 1 for repeated thrombosis due to low cardiac output.

The 35 patients in the surveillance group had initial duplex examinations of their e-PTFE grafts performed at three months postimplant. The occurrence of VOS at that time, based on the classification from Table I, was as follows: I [normal], 25; II [minimal], 5; III [mild], 3; IV [moderate], 1; V [severe], 1; VI [occluded], 0. Ten patients, Grades II through V, had early venous intimal hyperplasia (VIH) formation. Five of these cases (Grades III-V) represented a high-risk subgroup of rapid VOS formers characterized by frequent restenoses of their venous outflows requiring multiple reoperations. Of 3 Grade III high-risk subgroup cases on three-month scan, 1 progressed to Grade IV and 1 to Grade V on six-month scanning. Three of the 5 high-risk patients lost patency of their access sites within one year of implantation.

The 33 initial patients with nonhemodynamically significant stenoses of their venous outflows (Grades I-III) had peak Doppler flows of 88.4 ± 35.7 cm/sec at the venous ends and 95.4 ± 59.4 cm/sec at midloop recordings. The considerable range reflects 2 cases of cardiomyopathy with midloop flows of only 36 cm/sec.

The indications for operation based on surveillance findings of the venous outflows of the e-PTFE grafts were Grade IV and V stenoses, as well as Grade VI occluded shunts. During the study, 7 patients developed Grade V stenoses of their venous outflows (Figures 1-4). Peak Doppler flows across the venous ends were all > 400 cm/sec. Midloop recordings averaged 55.2 ± 19.2 cm/sec. Surgical intervention before thrombosis occurred maintained patency in 5 of the 7 cases. One patient died before the access could be repaired, and one access site was lost owing to absence of remaining venous outflow. Five patients had patch angioplasties of the VO, and 1 had an interposition graft done.

There were two restenoses within the first year post-revision, and 4 eventually required multiple reoperations. There was a total of 14 secondary procedures for these 7 patients.

There were 2 cases of Grade IV stenoses, and both had patch angioplasties resulting in long-term patency of the access sites (Figures 5, 6). The peak Doppler flows in these cases were 220 ± 20 cm/sec, with midloop recordings of 88 ± 28 cm/sec. Although it seems reasonable to assume that many of the grafts with stenotic ve-

nous outflows that were repaired "electively" would have, without intervention, gone on to eventual graft malfunction or occlusion, further study is needed to better define this natural progression, especially for Grade IV stenoses.

Duplex detected 2 Grade VI occlusions. One patient had a simple thrombectomy, while the other needed a thrombectomy and patch angioplasty of a stenotic venous outflow. Duplex also detected 2 pseudoaneurysms and differentiated them from 2 cases of perigraft seromas.

The accuracy of duplex scanning in the surveillance group was verified by comparison of the duplex grade of VOS with the grade based on angiography and on intraoperative findings (Table III). For patients with 3 or more restenoses of their grafts, angiography was limited to the first 2 occurrences for ethical reasons, for the reliability of duplex findings was apparent early on in the study.

Life-table analysis was used to demonstrate higher cumulative graft patency in the surveillance as compared with the control group (Figure 7). These differences were statistically significant ($P = 0.05$) at six months, and were significant ($P = 0.1$) at months 12, 24, and 36 after implant. The differences in morbidity between the two groups regarding reoperation (77% control versus 43% surveillance) and the number of secondary procedures per patient (1.6 versus 0.7) were also statistically significant ($P = 0.05$).

Discussion

e-PTFE graft fistulae are widely used as secondary vascular access for long-term hemodialysis. Originally developed as a conduit for peripheral arterial bypass surgery, e-PTFE has proven to be a good vascular substitute with low reactivity and thrombogenicity. Although representing an improvement over bovine carotid heterografts for angioaccess,⁶ further study is necessary to attempt to decrease the incidence of intimal proliferation, pseudoaneurysm formation, infection, and thrombosis. Increasing experience and frustration with tubular grafts has, however, led to the conclusion that the problem of secondary vascular access has not been solved by e-PTFE.⁸ While the search for a better alternative to the autogenous A-V fistula continues, the e-PTFE graft represents the closest approximation so far.

The challenge clearly remains to improve functional survival of implanted e-PTFE shunts. Although abandonment of access sites will in-

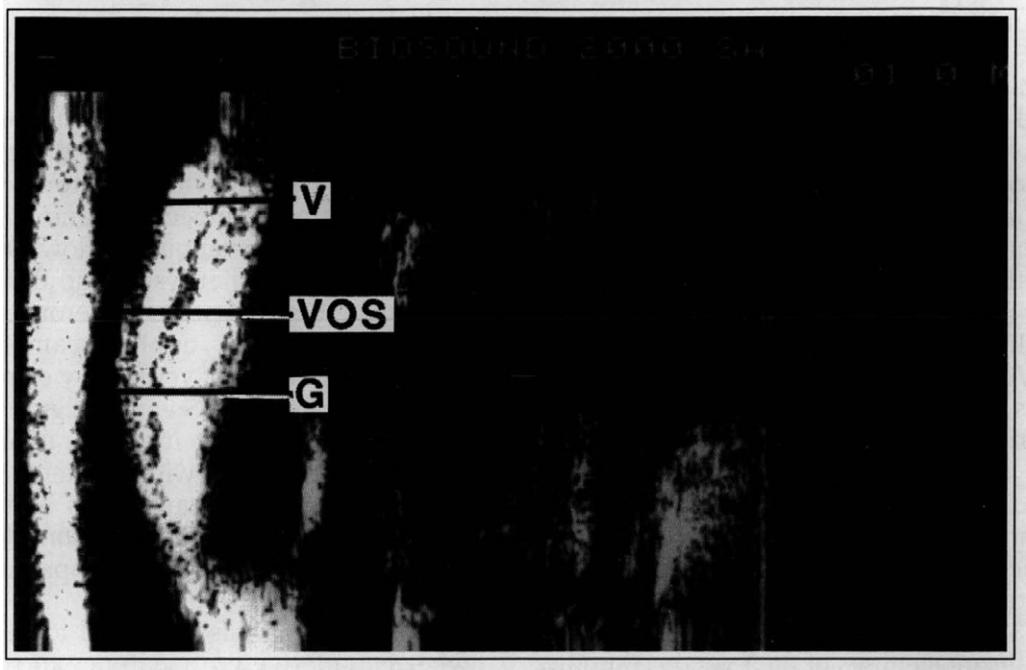
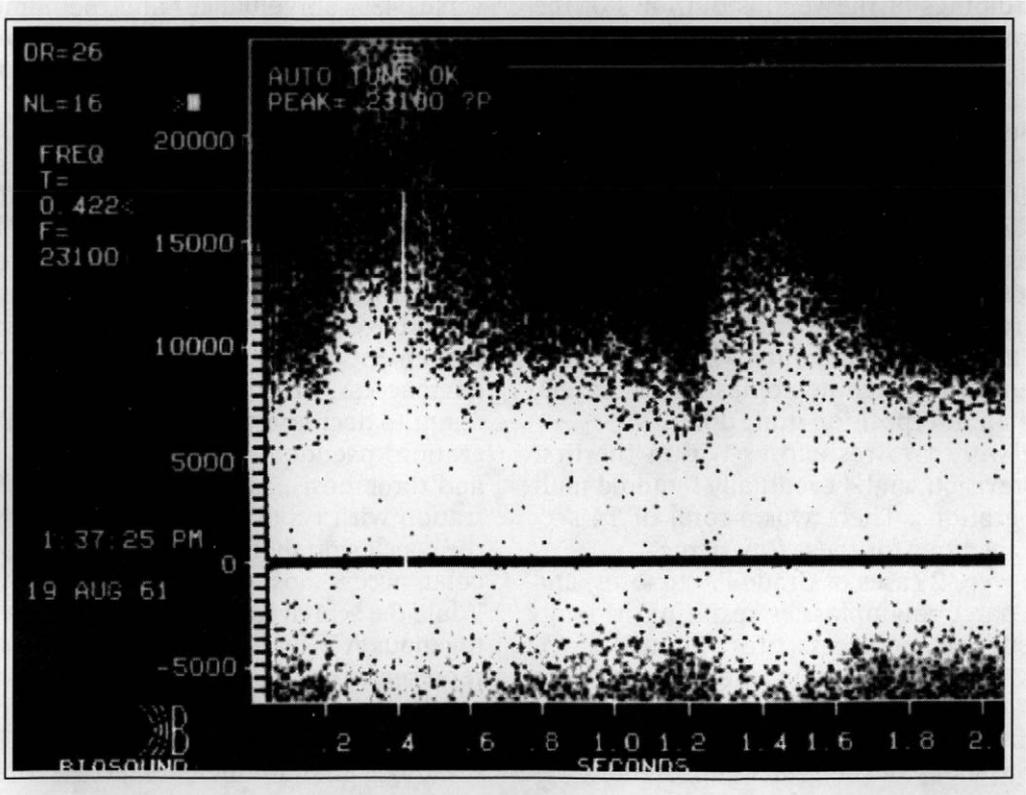


Figure 1. Case 1: Duplex scan showing severe (Grade V) VOS. V = arterialized vein, VOS = venous outflow stenosis, G = e-PTFE graft.

Figure 2. Case 1: Duplex scan demonstrating extreme elevation of peak frequency, more than 400 cm/sec (20 mHz).



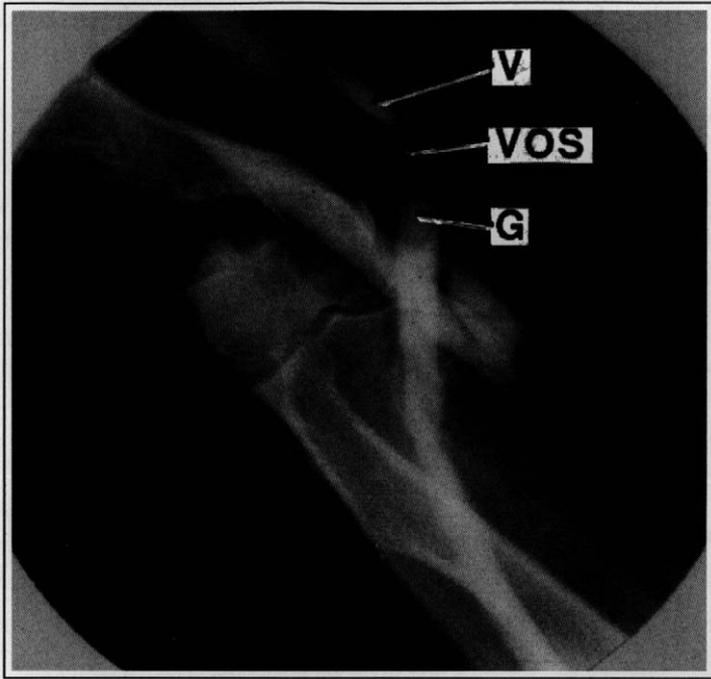


Figure 3. Case 1: Arteriogram showing severe (Grade V) VOS. V = arterialized vein, VOS = venous outflow stenosis, G = e-PTFE graft.

Figure 4. Case 1: Operative repair of venous outflow with e-PTFE patch.



evitably occur owing to graft degeneration and infection, the most common mechanical cause of graft failure is occlusion from VOS. Several theories have been advanced to explain the occurrence of intimal hyperplasia at the venous end such as: compliance mismatch between the graft and host vessel,¹¹ increased turbulence,¹² and platelet-induced subendothelial cell proliferation.¹³ Less commonly, thrombosis may be due to dehydration and hypotension after dialysis, external compression on the graft, and continuous needle trauma to the access site. A postulated consumptive deficiency of antithrombin III associated with repeated heparinization during the treatments may also be implicated.¹⁴

Although some clotted grafts will have no identifiable structural lesion, for the majority, once thrombosis occurs, thrombectomy and complex revision are usually necessary. The venous outflow must be reconstructed by e-PTFE patch angioplasty, interposition graft, or by a search for a new venous conduit. The chance for success

after each subsequent salvage operation diminishes—first, second, and third revisions reportedly achieve continued graft patency in 65%, 53%, and 44% of cases, respectively.¹⁵

Monitoring graft function at regular intervals can alert the physician to the need for early intervention prior to occlusion of the access and development of a thick fibrotic stenosis with a peel of organized thrombus. This should theoretically improve graft salvage. Waiting for the appearance of a tense, pulsatile graft on physical examination, suggestive of venous stenosis, can often lead to graft loss.¹⁶ More recent attempts at treating graft lesions and occlusions with transluminal angioplasty¹⁷ and adjunctive streptokinase infusion^{18,19} would also benefit from earlier warning of impending graft failure.

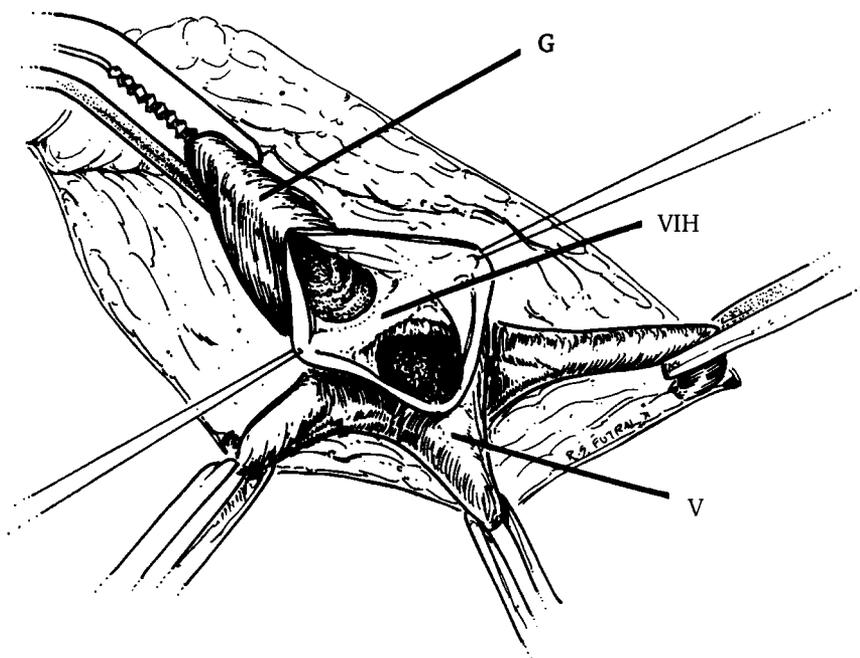
Regarding methods of graft monitoring, radiographic examinations or fistulograms fail to provide any measure of flow rate, occasionally do not visualize the entire access, and may be complicated by patient discomfort, graft infection, and

Figure 5. Case 2: Duplex scan showing moderate (Grade IV) VOS. VIH = venous intimal hyperplasia.





Figure 6. Case 2: Intraoperative findings confirming Grade IV VOS.
G = e-PTFE graft, VIH = venous intimal hyperplasia, V = vein.



thrombosis.^{4,20,21} Noninvasive detection of focal anomalies in dialysis grafts, by use of B-mode ultrasound was first described in 1980.²² Early attempts to monitor changes in Doppler shift peak frequencies were reported in 1982.^{23,24} Subsequent calculation of the volume flow rates in e-PTFE grafts from temporal average mean Doppler shift frequencies showed that those grafts with flow rates less than 500 mL/min were at risk for occlusion.²⁵

Duplex scanning, of proven accuracy in carotid and peripheral venous diagnosis,^{26,27} has advantages over either B-mode ultrasound or Doppler-derived flow measurements alone, in providing reliable reproducible data on anatomic and hemodynamic aspects of graft function.²⁸⁻³⁰

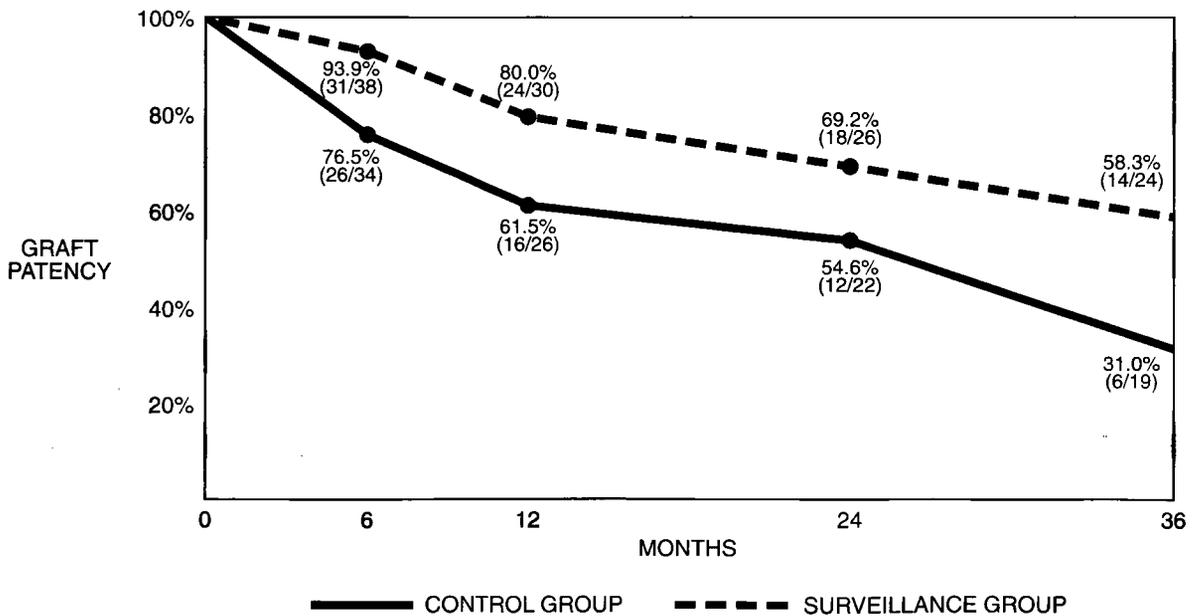
VOS was manifested by accelerated velocities across the venous outflow, lowered flows sampled at midloop, and reduction in functional diameter as visualized by B-mode ultrasound. Our data indicate that duplex scanning is accurate for the detection of VOS, as compared with fistulography, and as verified by intraoperative findings. The normal Doppler flow velocity ratio between the venous end and midloop recordings was approximately 1:1. This ratio rose

to 2.5:1 with moderate (50-79%) VOS and to 8:1 with severe (80-99%) VOS.

VIH was found in 57% of the e-PTFE grafts imaged, with hemodynamically significant stenoses being present in 29%. Rapid onset of hemodynamically significant VOS within three months following implantation was detected in 14% of patients studied. Despite multiple reoperations, graft patency could be maintained in only 40% at twelve months for this subset of cases. Early identification of this high-risk group is essential and can be accomplished noninvasively by duplex scanning.

This study suggests that early intervention based on surveillance findings is more successful in terms of access site salvage and morbidity reduction than intervention prompted by episodes of graft thrombosis or malfunction. Cumulative graft patency as assessed by life-table analysis was significantly higher at all time intervals from six to thirty-six months in the surveillance as compared with the control group. Graft patency in the surveillance group (80% at twelve months, 69.2% at twenty-four months) compares favorably with both the control group (61.5%, 54.6%) and with historical controls (66%, 50%).⁶⁻⁹ Similar differ-

Figure 7. Cumulative graft patency by life-table analysis.



ences are noted in morbidity reduction. The surveillance group averaged fewer secondary procedures per patient (0.7 versus 1.6) as well as less eventual abandonment of access sites (28.6% versus 37.1%).

Conclusion

The steady decline with time in patency of e-PTFE dialysis grafts, together with the findings from this study, provides a rationale for a protocol of postimplantation surveillance to identify those grafts at risk, allowing early intervention before thrombosis occurs. Duplex scanning appears to be the preferred modality

that, together with timely reoperation, impacts favorably on functional graft survival.

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