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Duplex Ultrasound Surveillance Can Be Worthwhile After Arterial Intervention

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A surveillance program based on duplex ultrasound testing after peripheral arterial intervention can increase long-term patency by identifying and by repairing clinical significant lesions. Its successful application requires numerous conditions regarding pathobiology of arterial repair failure and its consequences, arterial testing expertise, and durability of secondary procedures used to repair duplex-detected lesions. The methodology of surveillance should be tailored to the type of arterial intervention. Clinical reports on the efficacy of duplex ultrasound surveillance have supported its routine use, but controversy of cost-effectiveness remains. Duplex surveillance will decrease procedural primary patency, but when successful, the primary-assisted and secondary patency rates should be significantly higher than the rates when no surveillance was performed. An examination of the primary, primary-assisted, and secondary patency rates of an arterial procedure will indicate the benefit (or lack of benefit) of a surveillance program and the appropriateness of the threshold criteria used for secondary interventions

Keywords: duplex ultrasound; surveillance

The rationale for the application of duplex ultrasound surveillance after peripheral arterial intervention is straightforward—to assess residual technical error and to identify developing lesions for repair prior to failure. The failure of arterial reconstructive procedures whether performed by open repair, arterial bypass, or endovascular intervention (balloon, stent, stent graft, atherectomy) is an important clinical problem. The likelihood of failure varies with procedure type, patient characteristics, and disease severity; when arterial repair thrombosis occurs, patient morbidity and health care costs increase. The most common mechanisms of arterial repair failure are technical error, stenosis caused by myointimal hyperplasia, and atherosclerotic disease progression. These vascular conditions are readily identified by duplex ultrasound imaging, and their severity can classified as mild, moderate, or severe, that is, a critical lesion that should be repaired. It has been our experience that the use of duplex ultrasound testing at operation and in the postoperative period can result in more favorable outcomes.[1-3]

Several essential elements must exist for a surveillance program to be worthwhile. Vascular testing should be noninvasive, inexpensive, and should have diagnostic accuracy with high sensitivity to ensure that clinically significant lesions are not missed. It is also necessary that mechanisms of arterial repair failure have a pathology and natural history appropriate for detection by a surveillance protocol. Lesion severity, that is, degree of stenosis, should correlate with risk of failure, and testing should be capable of detecting stenosis progression from mild to severe categories. The incidence of lesion development should be sufficiently common (incidence = 5%-10% or greater) to be cost-effective. Finally, but vitally important, there must be safe and effective procedures to repair identified lesions. Many, if not all, open and endovascular interventions performed for peripheral atherosclerotic disease in the carotid or lower limb arterial circulations satisfy these conditions for surveillance to be of clinical benefit. Certainly, if the primary failure mode of arterial repair is the result of myointimal hyperplasia, surveillance and timely repair of lesions that progress to a severe stenosis should enhance long-term patency. Another important measure of a surveillance program

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is the incidence of arterial repair failure when testing is normal, that is, no anatomic or hemodynamic abnormality is identified. When duplex testing is interpreted as showing no stenosis or other anatomic abnormality (aneurysm, mural thrombus), repair failure should be uncommon; if it occurs, the cause should be from a condition, which testing would not have detected such as a cardiac embolus or an acquired hypercoagulable state. It has been our observation that when arterial surveillance is properly performed and interpreted, the incidence of unexpected repair failure should in the range of 1% to 5%/year—depending on the arterial repair type.[1-3]

The algorithm for arterial repair surveillance should begin with an intraprocedural study to assess technical error, followed by enrollment in a surveillance protocol with an initial testing several weeks after the procedure (Figure 1). When an intraoperative duplex scan is performed, and the findings confirm a normal, that is, no imaged defect and normal hemodynamics, arterial repair, or bypass graft, the likelihood of initial surveillance study will demonstrate a severe stenosis is low (<2%-4%). This has been our experience following carotid endarterectomy and lower limb bypass grafting and to a lesser extent after peripheral angioplasty.[1-3] Documenting normal duplex ultrasound findings after arterial intervention is clinically useful. It confirms absence of technical error, predicts early clinical success, and establishes a baseline for subsequent surveillance testing to detect stenosis development. The use of clinical assessment alone, which relies on patient recognition of the symptoms associated with procedure failure, or the use of indirect physiologic testing methods, such as ankle brachial systolic pressure index after lower limb arterial interventions, is not sufficiently sensitive to detect developing myointimal hyperplasia and is completely insensitive to aneurysmal degeneration. Myointimal stenosis capable of producing arterial repair failure can develop without symptoms until a high-grade stenosis forms or a thrombosis occurs.

It is essential to use objective interpretation criteria to grade the lesion severity in a surveillance program. This allows for the application of threshold criteria for reintervention or for a decision for additional arterial imaging. Establishing 2 or 3 disease categories is sufficient to characterize an arterial repair as normal or abnormal and to further grade the abnormality as one that be followed for progression, that is, intermediate lesion, or the one that should be considered for repair (Table 1, Figure 1). We

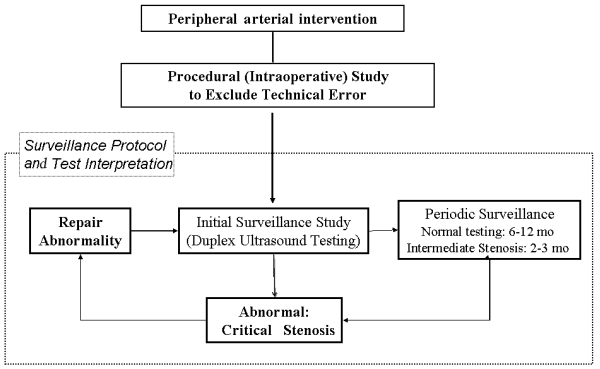

Figure 1. Schematic of a duplex ultrasound surveillance protocol following peripheral arterial intervention. Components included a procedural study to exclude technical error, initial surveillance using duplex surveillance to identify residual repair abnormality, and then periodic surveillance testing to detect and repair acquired stenotic lesions that meet criteria for severe critical stenosis.

recommend using combined peak systolic velocity (PSV) and velocity ratio thresholds to define the severe (>70%-75% diameter reduction) stenosis category. A duplex-detected stenosis with a PSV >300 cm/s and associated turbulent velocity spectra at the lesion is associated with a resting systolic pressure gradient of >20 mm Hg; thus, it meets the criteria for hemodynamically significant stenosis.[1,2] The use of duplex testing for screening or intervention decisions depends on the surveillance application. Following visceral (mesenteric, renal) artery angioplasty, the application of duplex testing is a primary screening method to identify stent or angioplasty stenosis. An abnormal study should prompt additional confirmatory angiographic imaging and/or pressure gradient measurement to assess lesion severity and clinical significance. After peripheral interventions, duplex testing may be used for management decisions including reintervention. The finding of >75% duplex-detected stenosis is sufficient anatomic or hemodynamic information, if used in conjunction with limb blood pressure measurements or treadmill exercise testing, to recommend and to proceed with a secondary intervention (endovascular or open surgical repair). Typically, the stenotic lesions detected during surveillance are focal in nature and thus amenable to endovascular therapy. At the time of angioplasty, lesion severity will be confirmed, and other anatomic features that correlate with technical success and durability can be assessed.

Table 1. Classification of Stenosis Severity Following Arterial Intervention

Duplex Ultrasound Surveillance Categories			
		Abnormal	
	Normal	Intermediate Stenosis	Severe Stenosis
	<50% DR	50%-75% DR	>75% DR[a]
Carotid repair			
CEA	PSV < 150 cm/s	PSV > 150 cm/s PSV_{ICA}/PSV_{CCA} > 2	PSV > 300 cm/s PSV_{ICA}/PSV_{CCA} > 4
Stent	PSV < 150 cm/s	PSV > 150 cm/s PSV_{ICA}/PSV_{CCA} > 2	PSV > 300 cm/s PSV_{ICA}/PSV_{CCA} > 4 End-diastolic > 125cm/s
Bypass graft	PSV < 180 cm/s Vr < 2	PSV = 180-300 cm/s Vr ≤ 3.5	PSV > 300 cm/s Vr > 3.5
Peripheral angioplasty	PSV < 180 cm/s	PSV = 180-300 cm/s Vr ≤ 3.5	PSV > 300 cm/s Vr > 3.5
	<60% DR	>60% DR[a]	
Renal stent	PSV < 200 cm/s RAR ≤ 3.5 <70% DR	PSV > 200 RAR > 3.5 >70% DR[a]	
SMA stent	PSV < 300 cm/s	PSV > 300 cm/s	

NOTE: DR = diameter reduction; PSV = peak systolic velocity; Vr = PSV ratio across stenosis; CEA = carotid endarterectomy; SMA = superior mesenteric artery; RAR = renal aortic ratio; ICA = internal carotid artery; CCA = common carotid artery.
[a]Threshold for reintervention or additional arterial imaging to confirm stenosis severity.

The goal of arterial surveillance is to prolong patency and to avoid thrombotic events as well as other procedure-specific adverse events such as stroke following carotid endarterectomy or stent angioplasty, amputation after peripheral arterial intervention, organ ischemia after visceral bypass or angioplasty. Assessment of patency, including intervention-free patency, is relatively straightforward to calculate using life-table (Kaplan-Meier) methods, which take into account duration of follow-up and death of patient. Duplex ultrasound is the preferred method to assess arterial repair patency because it is inexpensive, highly accurate, and applicable to the spectrum of carotid, visceral, and peripheral arterial interventions. The primary (freedom from intervention or thrombosis) and secondary (freedom from thrombosis despite intervention, including thrombectomy or thrombolysis) patency rates of a hypothetical procedure X estimated by life-table analysis shown in Figure 2 depict decrease in arterial repair patency with time. The treatment that can increase secondary patency thereby improving clinical outcome should be used. If surveillance is successful, secondary patency rates should be higher than with no surveillance or with an ineffective surveillance protocol that does not identify and correct the lesions producing failure. Thus, assessment of secondary patency rate is an appropriate measure of surveillance efficacy and procedure durability. The improved patency with surveillance is due to correction of identified lesions, which if left unrepaired would lead to thrombosis or failure. The term "assisted-patency" was developed to deal with the failing arterial repair or bypass and to provide a measure of patency following revision of a patent but abnormal arterial intervention. This concept is useful because in clinical vascular surgery once thrombosis of an arterial repair or bypass occurs, secondary interventions to restore patency are not considered durable. Thus, an important principle of vascular procedure surveillance is correcting lesions electively to prevent thrombosis rather than waiting until thrombosis occurs and then attempting to restore patency and salvage the repair. Peripheral arterial interventions with assisted-primary, that is, intervention-free patency, and secondary patency rates that exceed 80% at 5 years are generally considered to be clinically successful and durable.

The primary, assisted-primary, and secondary patency rates of 3 hypothetical arterial procedures

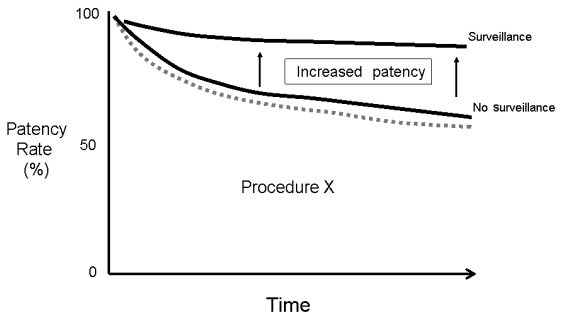

Figure 2. Primary and secondary patency rates of a hypothetical procedure X, which depict a >20% increase in secondary patency with the application of a surveillance protocol.

(A, B, and C) that used duplex surveillance to improve outcomes are shown in Figure 3. Each procedure has a similar primary patency rate—indicating interventions and/or thrombosis occurred with loss of intervention-free patency. Inspecting differences in the assisted-primary and secondary patency curves of each procedure, the benefit or absence of benefit from duplex surveillance can be assessed. After procedure A, surveillance produced a significant increase in both assisted-primary and secondary patency rates—indicating that surveillance and intervention for duplex-detected lesions were successful and prevented thrombosis. Contradictorily, duplex surveillance after procedure B produced only a minimal increase in assisted-primary and secondary patency rates; thus, the efficacy and cost-effectiveness of surveillance were not justified. Surveillance was also not useful after procedure C because only secondary patency was increased. The difference between the assisted-primary and secondary patency rate curves indicates the procedure C surveillance protocol did not adequately detect lesions that produced thrombosis, but secondary procedures to restore patency were successful. All the hypothetical procedures depicted demonstrated a progressive decrease in secondary patency rate, that is, failure despite medical treatment, surveillance, and intervention for stenosis or thrombosis, which is known to occur clinically. The meaning of a secondary patency curve, which is minimally increased from the assisted-primary patency curve, is that additional interventions for thrombosis to salvage the arterial procedure are of marginal benefit. Thus, efforts to enhance procedure patency should be directed at measures to avoid thrombosis, that is, repair threatening lesions while the repair, angioplasty, or bypass are patent.

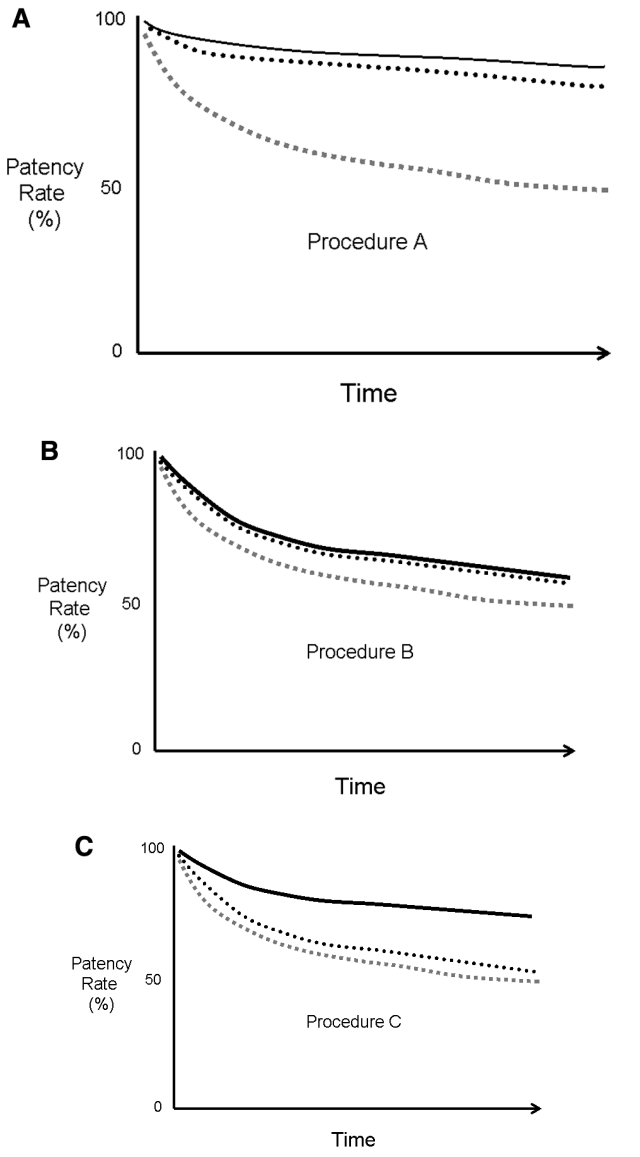

Figure 3. Primary (square box line), primary-assisted (dotted line), and secondary (solid line) patency rates of 3 hypothetical procedures (A, B, and C) managed in a duplex ultrasound surveillance program. Duplex surveillance and intervention for severe stenosis improved assisted-primary and secondary patency rates to >80% only for procedure A. Duplex surveillance was of no benefit in improving patency after procedure B (no significant increase in secondary patency) or procedure C (no significant increase in primary-assisted patency).

The loss of primary patency with time during duplex surveillance deserves additional comment as it is related to several factors: criteria for intervention, thrombosis rate despite surveillance, and compliance by both the patient and physician in adhering to the surveillance protocol including agreement to a recommendation for intervention. If the threshold

Table 2. Reported Infrainguinal Arterial Repair Patency Rates Associated With Duplex Ultrasound Surveillance

	Arterial Repair Patency Surveillance			
Clinical Report/Study Design	Primary (%)	Assisted-Primary (%)	Secondary (%)	Benefit
Lundell et al[4] (1995)				
Prospective, randomized vein bypass	55	78	82	Yes, at 3 y
Prosthetic	50	55	67	No, at 1 y
Ihlberg et al[5] (1998)				
Prospective, randomized vein bypass	—	65	71	No, at 1 y
Davies et al[6] (2005)				
Prospective, randomized vein bypass	67	76	79	No, at 18 mo.
Armstrong et al[7] (2004)				
Prospective, observational arm vein	43	91	94	Yes at 3 y
Schanzer et al[8] (2007)				
Prospective, observational vein bypass	60	78	81	Yes, at 1 y
Chauvapun et al[9] (2007)				
Vein bypass	61	84	86	Yes, at 3 y
Nguyen et al[10] (2004)				
Prospective, observational revised vein bypass	49	76	80	Yes, at 5 y
Stone et al[11] (2006)				
Prospective, observational popliteal aneurysm repair	68	88	95	Yes at 3 y
Keeling et al[12] (2007)				
Retrospective, observational femoropopliteal atherectomy	62	64	76%	No, at 1 y

for intervention is too high or identified lesions are not repaired, the primary patency rate will be higher and the potential benefit of surveillance will be less evident. Thus, a significant increase in assisted-primary patency compared with primary patency should be present and is supporting evidence that there may be a benefit in repairing lesions prior to thrombosis. This is especially true when the secondary patency rate curve is similar to the assisted-primary patency curve—indicating that once thrombosis occurs, other secondary interventions are not successful. Duplex surveillance should result in an increase in the number of secondary interventions performed compared with the clinical patient follow-up alone; more abnormal but patent arterial repairs will be identified. If the primary and assisted-primary patency curves of a procedure are not significantly different (using log-rank analysis), it can be concluded that surveillance did not identify any clinically significant lesions. If secondary patency rates are also similar to the primary and assisted-primary patency curves, the clinical benefit of surveillance is lost.

Prospective, randomized clinical trial, evidence-based data proving efficacy of duplex surveillance is limited, and all the clinical trials are subject to criticism in that there was no true control group, that is, no surveillance performed. Because vascular specialists are in agreement with the concept of patient and procedure surveillance, randomized clinical trials have compared outcomes with clinical assessment versus duplex ultrasound surveillance. Criteria for intervention thus differ, but benefits of surveillance can be assessed by inspection of the assisted-primary and secondary patency rates. Published life-table patency rates of lower limb bypass and endovascular procedures enrolled in either a randomized clinical trial or prospective observational study, which utilized duplex ultrasound surveillance are shown in table 2. Clinical benefit of surveillance was reported by the authors when assisted-primary patency was significantly higher ($P < .05$) than primary patency, and secondary patency rates both exceeded primary patency by >20% and achieved levels to 80% or greater. These study data indicate that the efficacy of duplex surveillance is dependent on numerous factors—indication for procedure (critical vs noncritical limb ischemia), criteria for intervention, adherence to protocol, and study design. For a surveillance program to increase long-term patency, vascular testing must be accurate, interpreted correctly, must result in timely, successful repair of duplex-detected lesions that meet critical threshold criteria. If secondary interventions do not restore anatomy

and hemodynamics to normal, the benefit of surveillance may be lost. When a clinical report extolled the benefit of surveillance, the authors made 2 observations: unrepaired lesions resulted in thrombosis, and normal testing was associated with primary-assisted patency rates in excess of 80% at 3 to 5 years.[2,4,7-10,13]

The application of duplex ultrasound surveillance after peripheral arterial intervention remains a decision of the interventionist. The patient can neither request surveillance nor perform it adequately themselves. Arterial testing and its interpretation within a surveillance protocol can be challenging. Many vascular surgeons are not convinced that routine duplex surveillance will benefit their patients or that the logistics necessary to conduct a quality surveillance program will be available to them. We are convinced that duplex surveillance should be part of patient service—a necessary component of vascular surgery care that when applied correctly should improve outcome after a variety of open and endovascular arterial procedures.

References

1. Bandyk DF. Surveillance of lower extremity reconstructions: is it worthwhile and which method should we use? *Perspect Vasc Surg Endovasc Ther*. 1995;8:20-30.
2. Back MR, Novotney M, Roth SM, et al. Utility of duplex surveillance following iliac artery angioplasty and primary stenting. *J Endovasc Ther*. 2001;8:629-637.
3. Bandyk DF. Ultrasound assessment following peripheral arterial interventions. In: Zwiebel W, Perriloto J, eds. *Introduction to Vascular Ultrasonography*. Philadelphia, PA: Elsevier Saunders; 2004:357-380.
4. Lundell A, Linblad B, Bergvist D, Hansen F. Femoropopliteal-cural graft patency is improved by an intensive surveillance program: a prospective randomized study. *J Vasc Surg*. 1995;21:26-33.
5. Ihlberg L, Luther M, Tierla E, Lepantalo M. The utility of duplex scanning in infrainguinal vein graft surveillance: results from a randomized controlled study. *Eur J Vasc Endovasc Surg*. 1998;16:19-27.
6. Davies AH, Hawdon AJ, Sydes MR, Thompson SG. Is duplex surveillance of value after leg vein bypass grafting? Principle results of the vein graft surveillance randomized trial (VGST). *Circulation*. 2005;112:1985-1991.
7. Armstrong PA, Bandyk DF, Wilson JS, et al. Optimizing infrainguinal arm vein bypass patency with duplex ultrasound surveillance and endovascular therapy. *J Vasc Surg*. 2004;40:724-731.
8. Schanzer A, Hevelone N, Owens CD, et al. Technical factors affecting autogenous vein graft failure: observations from a large multi-center trial. *J Vasc Surg*. 2007;42:104-109.
9. Chauvapun JP, Tinder C, Bandyk DF, et al. Enhanced efficacy of duplex ultrasound surveillance after infrainguinal vein bypass by identification of characteristics predictive of graft stenosis development. Abstract presented at: 2008 Southern Association for Vascular Surgery meeting. January 17, 2007; Naples, FL. Abstract 18.
10. Nguyen LL, Conte MS, Menard MT, et al. Infrainguinal vein bypass graft revision: factors affecting long-term outcome. *J Vasc Surg*. 2004;40:916-923.
11. Stone PA, Armstrong PA, Bandyk DF, et al. The value of duplex surveillance after open and endovascular popliteal aneurysm repair. *J Vasc Surg*. 2005;41:936-941.
12. Keeling WB, Shames ML, Stone PA, et al. Plaque excision with the Silverhawk catheter: Early results in patients with claudication or critical limb ischemia. *J Vasc Surg*. 2007;45:25-31.
13. Mofidi R, Kelman J, Berry O, et al. Significance of the early postoperative duplex result in infrainguinal vein bypass surveillance. *Eur J Vasc Endovasc Surg*. 2007; 34:327-332.