

# Efficacy of duplex ultrasound surveillance after infrainguinal vein bypass may be enhanced by identification of characteristics predictive of graft stenosis development

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**Objective:** Controversy regarding the efficacy of duplex ultrasound surveillance after infrainguinal vein bypass led to an analysis of patient and bypass graft characteristics predictive for development of graft stenosis and a decision of secondary intervention.

**Methods:** Retrospective analysis of a contemporary, consecutive series of 353 clinically successful infrainguinal vein bypasses performed in 329 patients for critical (n = 284; 80%) or noncritical (n = 69; 20%) limb ischemia enrolled in a surveillance program to identify and repair duplex-detected graft stenosis. Variables correlated with graft stenosis and bypass repair included: procedure indication, conduit type (saphenous vs nonsaphenous vein; reversed vs nonreversed orientation), prior bypass graft failure, postoperative ankle-brachial index (ABI) < 0.85, and interpretation of the first duplex surveillance study as “normal” or “abnormal” based on peak systolic velocity (PSV) and velocity ratio (Vr) criteria. **Results:** Overall, 126 (36%) of the 353 infrainguinal bypasses had 174 secondary interventions (endovascular, 100; surgery, 74) based on duplex surveillance; resulting in 3-year Kaplan-Meier primary (46%), assisted-primary (80%), and secondary (81%) patency rates. Characteristics predictive of duplex-detected stenosis leading to intervention (PSV:  $443 \pm 94$  cm/s; Vr:  $8.6 \pm 9$ ) were: “abnormal” initial duplex testing indicating moderate (PSV: 180-300 cm/s, Vr: 2-3.5) stenosis ( $P < .0001$ ), non-single segment saphenous vein conduit ( $P < .01$ ), warfarin drug therapy ( $P < .01$ ), and redo bypass grafting ( $P < .001$ ). Procedure indication, postoperative ABI level, statin drug therapy, and vein conduit orientation were not predictive of graft revision. The natural history of 141 (40%) bypasses with an abnormal first duplex scan differed from “normal” grafts by more frequent (51% vs 24%,  $P < .001$ ) and earlier (7 months vs 11 months) graft revision for severe stenosis and a lower 3-year assisted primary patency (68% vs 87%;  $P < .001$ ). In 52 (15%) limbs, the bypass graft failed and 20 (6%) limbs required amputation.

**Conclusions:** The efficacy of duplex surveillance after infrainguinal vein bypass may be enhanced by modifying testing protocols, eg, rigorous surveillance for “higher risk” bypasses, based on the initial duplex scan results and other characteristics (warfarin therapy, non- single segment saphenous vein conduit, redo bypass) predictive for stenosis development. (J Vasc Surg 2008;48:613-8.)

The purpose of a surveillance program after infrainguinal bypass grafting is to identify stenotic or aneurysmal lesions as they develop and repair them to prevent graft thrombosis. When successful, functional bypass graft patency as measured by assisted primary patency rate is increased, the need for redo bypass grafting reduced, and limb salvage in the critical limb ischemia (CLI) population prolonged. How to best perform graft surveillance remains an unresolved issue. Duplex ultrasound imaging after infrainguinal vein bypass was not recommended in the recent 2007 Inter-Society Consensus for the Management of Pe-

ripheral Arterial Disease (TASC II) document based primarily on the results of a European multicenter randomized clinical trial.<sup>1,2</sup> Instead a clinical surveillance program (palpation of limb pulses, measurement of ankle-brachial systolic pressure index) was proposed beginning in the postoperative period and conducted every 6 months for a least 2 years. Our vascular group have been proponents of routine duplex ultrasound surveillance based on outcome data demonstrating asymptomatic development of duplex-detected graft stenosis in one-quarter of patients, graft failure when stenotic lesions were not repaired, and assisted primary patency rates >80% at 3 to 5 years.<sup>3-5</sup> It was our intent in this report to address this discrepancy in clinical practice guidelines for surveillance after infrainguinal vein bypass.

Despite improvements in surgical technique and medical therapy for atherosclerosis, vein bypass grafts continue to fail; an outcome of severe consequence in the CLI patient. Observations from a large multicenter trial of patients with CLI who underwent lower limb bypass with excised autogenous vein found vein diameter and conduit type were dominant determinants of early and late graft failure, and suggested “aggressive postoperative graft sur-

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**Table I.** Patient demographic data

| <i>Characteristic</i>                       | <i>Percent of patients</i> |
|---|----------------------------|
| Men   | 61%                        |
| Hypertension                                | 78%                        |
| Coronary artery disease (prior CABG or PTA) | 43%                        |
| Diabetes mellitus                           | 53%                        |
| Incompressible tibial arteries              | 17%                        |
| History of smoking                          | 75%                        |
| Current tobacco smoking                     | 36%                        |
| End-stage renal disease                     | 6%                         |
| Statin drug therapy                         | 34%                        |
| Antiplatelet therapy                        | 78%                        |

CABG, coronary artery bypass grafting; PTA, percutaneous transluminal angioplasty.

veillance” for the high-risk conduits.<sup>6</sup> Since the durability of the vein bypass is limited by the development of intraluminal stenosis and failure correlates with specific risk factors, it seems reasonable that application of duplex surveillance should be individualized to the patient and graft type, ie, a more rigorous protocol for “high-risk” vein bypasses. We sought in this retrospective analysis to identify specific patient and bypass graft characteristics, which are predictive for the development of graft stenosis and the need for secondary intervention with the intent to enhance the efficacy of a graft surveillance program.

## METHODS

**Patient demographic data.** From December 1999 to August 2007, 353 consecutive infrainguinal vein bypasses were performed in 329 patients to treat critical limb ischemia (n = 284, 80%), disabling claudication (n = 52, 15%), or superficial femoral/popliteal aneurysm (n = 17, 5%), Table I. All bypasses were patent at the time of hospital discharge with clinical examination indicating a successful limb revascularization. In 114 (32%) of 353 limbs, the vein bypass was performed as a redo procedure because of a failed femorodistal arterial bypass. Measurement of ankle-brachial systolic pressure index (ABI) was not possible in 17% of limbs due to tibial artery calcific disease and ankle cuff incompressibility. Prior to bypass grafting, the patients’ medical treatment for peripheral arterial disease included antiplatelet (78%) and statin (34%) drug therapy.

**Infrainguinal vein bypass procedure.** The vein grafting technique varied with the surgeon’s preference, vein availability, and the sites selected for the proximal and distal anastomosis (Table II). Two hundred thirty-four (66%) of the infrainguinal arterial bypasses were constructed with in situ (n = 61) or nonreversed, translocated (n = 173) saphenous vein bypass techniques. Valve lysis was performed by direct valve cusp excision, Karmody scissors, or with the Mills (American V. Mueller, Chicago Ill) and Gore (W. L. Gore & Associates, Flagstaff, Ariz) valvulotome. The remaining 119 bypasses consisted of reversed great saphenous vein (n = 50), upper extremity cephalic or basilic arm veins (n = 35), or spliced arm and saphenous

**Table II.** Anatomic configuration of 353 infrainguinal vein bypasses

| <i>Bypass, configuration</i> | <i>No. of grafts</i> |
|------------------------------|----------------------|
| Femoropopliteal, above knee  | 46                   |
| Femoropopliteal, below knee  | 98                   |
| Femoral, anterior tibial     | 43                   |
| Femoral, posterior tibial    | 49                   |
| Femoral, peroneal            | 62                   |
| Femoral, tibioperoneal trunk | 11                   |
| Femoral, pedal               | 9                    |
| Popliteal, tibial artery     | 25                   |
| Popliteal, pedal             | 10                   |

vein (n = 34) conduits. Inflow artery of the infrainguinal bypass included: common femoral artery (n = 312, 89%), superficial femoral artery (n = 7), popliteal artery (n = 35, 9%), and tibio-peroneal artery trunk (n = 1).

The infrainguinal bypass was evaluated with color duplex ultrasound scanning after restoration of flow and verification of a functioning bypass by visual inspection and pulse palpation. The previously described technique of papavarine-augmented duplex testing was utilized to identify residual stenosis in the graft or anastomotic regions.<sup>7</sup> At the sites of duplex-detected stenosis, measurements of peak systolic velocity (PSV) were made and the peak systolic velocity ratio (Vr) was calculated, where Vr = PSV at lesion/PSV proximal to the lesion. Graft and anastomotic abnormalities with PSV > 300 cm/s were revised as were some graft sites with a PSV > 180-200 cm/s if the Vr was >2-3 and color or power Doppler imaging demonstrated >50% lumen diameter reduction.

In absence of patient-specific contraindications, perioperative administration of antiplatelet therapy (aspirin, clopidogrel), dextran-40 (25 mL/hour for 24 hours) was routinely used. Approximately one third of the patients (n = 116) were discharged with warfarin sodium therapy with an international normalization ratio target value of 1.5 to 2 unless specific indications for therapeutic anticoagulation (international normalization ratio, 2-3.5) existed, such as atrial fibrillation, mechanical heart valve, known hypercoagulable condition, repeat vein bypass, or graft velocity less than 45 cm/sec. All patients were discharged on either antiplatelet therapy alone or in combination with warfarin sodium therapy.

**Postoperative duplex ultrasound surveillance protocol.** All patients were enrolled in an outpatient surveillance program, which included clinical assessment (interval history for limb ischemia, physical examination) of arterial limb circulation, measurement of Doppler-derived ankle systolic pressure (ankle-brachial index, ABI; normal  $\geq 0.85$ ), and color duplex scanning. Testing was performed in an Intersocietal Commission for Accreditation of Vascular Laboratories-accredited vascular laboratory within 1 month of the procedure, at 3 to 4 months after the procedure, and every 6 months thereafter. The interval between duplex scans was reduced to 6 to 8 weeks in selected patients because of changes in the limb vascular status, or to

monitor an identified stenosis more frequently for progression. At each surveillance visit, the entire vein bypass graft was scanned, including adjacent inflow and distal native arteries. Criteria for “abnormal” first surveillance duplex study was based on the final test interpretation indicating presence of bypass graft lesion identified by color Doppler imaging with associated increase in PSV ( $>180$  cm/s) and Vr ( $>2$ ). When a graft stenosis was identified, measurement of PSV and Vr were recorded with lesions having PSV  $>300$  cm/sec and Vr  $>3.5$  considered for repair.<sup>5</sup> If duplex testing found recent ( $<2$  weeks) graft occlusion, or a nonstenotic graft with low (PSV  $<45$  cm/s) graft flow velocity, angiography was recommended. The arterial bypass was also evaluated (real-time B-mode, color Doppler) for aneurysmal degeneration with the criteria for vein aneurysm being a  $>2$  times focal diameter increase and the presence of mural thrombus.

**Intervention to repair duplex scan-detected graft stenosis or aneurysm.** Graft lesions with duplex criteria for repair were corrected by either open surgical or endovascular (balloon dilation) intervention. Intervention type was based on time from the original procedure, lesions length, and vessel diameter with endovascular repair for focal ( $<2$  cm) stenosis beyond 3 months of the grafting procedure.<sup>5</sup> Surgical intervention (vein patch angioplasty, interposition graft, jump graft) was performed to repair more extensive stenotic lesions, for residual stenosis after angioplasty, and for aneurysmal degeneration. Intra-procedural duplex scanning was performed after intervention to verify a technically adequate repair using criteria of a non-stenotic lumen on color Doppler imaging, PSV  $<180$  cm/s, and Vr  $<2$  at the repair site.

**Data analysis.** Outcome analysis was based on a retrospective review of patient hospital, vascular clinic, and vascular laboratory records. Patient outcomes including death, graft thrombosis, graft revision, and amputation were recorded throughout the follow-up interval that ranged from a minimum of 3 to 96 months. Ten patients were lost to follow-up beyond 6 months of the infrainguinal bypass procedure. Kaplan-Meier estimates of primary, assisted-primary, and secondary graft patency, limb salvage, and patient survival calculated according to the reporting standards committee of the Society for Vascular Surgery.<sup>8</sup> Comparisons between patency curves for different patient groups were assessed by a log-rank statistic. Potential prognostic factors associated with graft revision were evaluated for categorical variables by using contingency table ( $\chi^2$  analysis), with  $P$  value  $<.05$  considered significant. Any univariate association with a value of  $P <.1$  was included in a binary logistic regression model using a forward stepwise selection to identify variables associated with bypass graft revision followed by block entry, binary logistic regression to obtain estimates of  $P$  value. This retrospective study was approved by our institutional review board.

## RESULTS

Clinical patient follow-up (mean of 48 months) combined with duplex ultrasound surveillance resulted in the

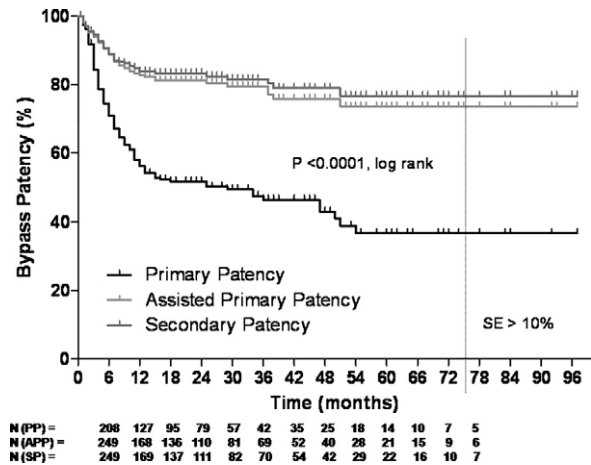


Fig 1. Kaplan-Meier estimates of primary, assisted-primary, and secondary patency rates of 353 infrainguinal vein bypasses.

revision of 126 (35%) of the 353 infrainguinal bypasses. A total of 174 secondary interventions, including multiple (two or more) revisions on 34 (10%) bypasses, were performed. The 126 first graft revisions were performed to repair duplex-detected stenosis ( $n = 96$ ), graft thrombosis ( $n = 28$ ), graft entrapment ( $n = 1$ ), or vein graft aneurysm ( $n = 1$ ). The mean ( $\pm$ SD) values of PSV and VR of repaired duplex-detected stenosis were  $443 \pm 94$  cm/s (range: 301 to 690 cm/s; median 436 cm/s) and  $8.6 \pm 9$  (range: 3 to 50; median: 6), respectively. Sites of revision included: vein conduit ( $n = 86$ ), anastomotic region ( $n = 38$ ), and inflow/outflow native artery ( $n = 2$ ). In 49 (38%) patients, symptoms/signs of limb ischemia were present on clinical examination. The majority (60%) of graft interventions were performed using endovascular therapy (balloon angioplasty,  $n = 71$ ; catheter-directed thrombolysis,  $n = 3$ ; and atherectomy,  $n = 1$ ). The first graft revision of 51 bypasses was open surgical repair by redo bypass grafting ( $n = 22$ ), ie, loss of secondary patency, vein-patch angioplasty ( $n = 13$ ), interposition/jump graft ( $n = 12$ ), thrombectomy ( $n = 2$ ), aneurysm repair ( $n = 1$ ), or graft entrapment release ( $n = 1$ ). The graft surveillance program produced 3-year (Kaplan-Meier estimates) primary, assisted-primary, and secondary graft patency rates of 46%, 80% and 81%, respectively (Fig 1). There were no significant differences at 3-year assisted-primary patency rates of bypasses performed for CLI (78%) and non-CLI arterial disease (86%); or for femoropopliteal (84%) vs infrageniculate (76%) vein bypasses. In 52 (15%) limbs, the bypass graft failed and 20 (6%) limbs required below-knee amputations (19 amputations in the CLI patient group). Overall, limb salvage at 3 years was 90% (non-CLI: 98%; CLI: 88%). Patient survival was 79% at 3 years (non-CLI, 88%; CLI, 77%,  $P = .03$ ).

Characteristics predictive of graft stenosis (univariate analysis) requiring intervention were: “abnormal” initial duplex testing indicating moderate (PSV: 180-300 cm/s, Vr: 2-3.5) stenosis ( $P <.0001$ ), redo bypass grafting ( $P <.001$ ), non-single segment saphenous vein conduit ( $P <$

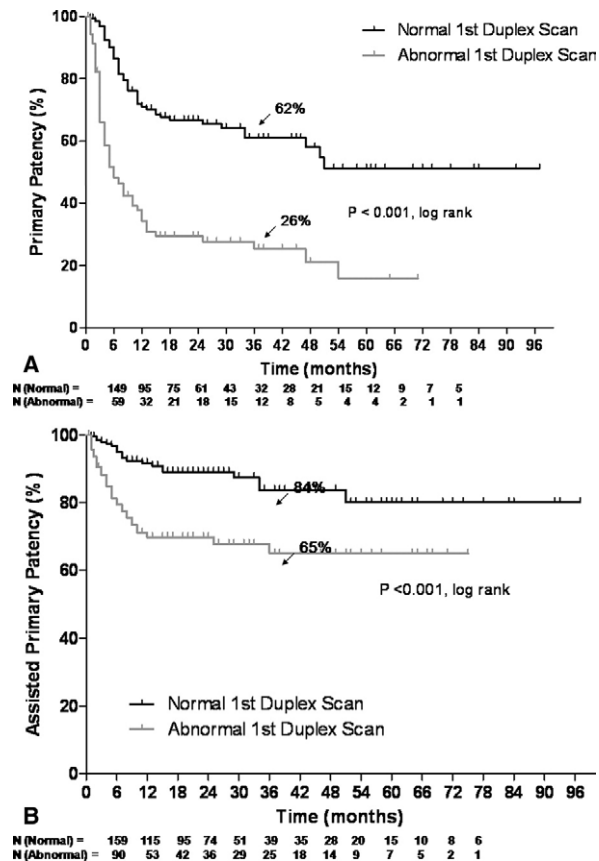
**Table III.** Univariate (contingency table) analysis of potential factors associated with infrainguinal bypass graft revision

| Variable                              | Revision<br>(n = 126) | No<br>revision<br>(n = 227) | P<br>value          |
|---------------------------------------|-----------------------|-----------------------------|---------------------|
| Gender (female)                       | 46 (37%)              | 137 (60%)                   | .57                 |
| Hypertension                          | 97 (77%)              | 177 (78%)                   | .89                 |
| Coronary artery disease               | 47 (37%)              | 80 (35%)                    | .73                 |
| Diabetes mellitus                     | 62 (49%)              | 124 (55%)                   | .37                 |
| Smoking history                       | 100 (79%)             | 165 (73%)                   | .2                  |
| Non-critical limb ischemia            | 23 (18%)              | 46 (21%)                    | .68                 |
| Critical limb ischemia                | 103 (82%)             | 181 (80%)                   | .68                 |
| Infrageniculate bypass                | 80 (63%)              | 126 (56%)                   | .18                 |
| Prior failed ipsilateral bypass       | 57 (45%)              | 57 (25%)                    | <.001 <sup>a</sup>  |
| Non single-segment saphenous vein     | 34 (27%)              | 35 (15%)                    | .01 <sup>a</sup>    |
| Nonreversed or in situ saphenous vein | 75 (60%)              | 159 (70%)                   | .61                 |
| Abnormal postoperative ABI (<0.85)    | 68 (54%)              | 105 (46%)                   | .26                 |
| Abnormal first duplex scan            | 73 (56%)              | 68 (30%)                    | <.0001 <sup>a</sup> |
| Statin drug therapy                   | 47 (37%)              | 153 (67%)                   | .41                 |
| Antiplatelet drug therapy             | 96 (76%)              | 193 (76%)                   | .37                 |
| Warfarin drug therapy                 | 54 (43%)              | 62 (27%)                    | .01 <sup>a</sup>    |

ABI, ankle-brachial index.  
<sup>a</sup>Statistical significant difference.

.01), and warfarin drug therapy ( $P < .01$ ), Table III. Gender, procedure indication (CLI or non-CLI disease), presence of diabetes, postoperative ABI level, statin drug therapy, saphenous vein conduit orientation (reversed vs nonreversed or in situ), or bypass to an infrageniculate target artery were not predictive of graft revision. After successful bypass grafting, the initial ABI was  $\geq 0.85$  in 51% of the revascularized limbs with compressible tibial arteries, and was associated with similar graft revision rate as limbs with an ABI  $< 0.85$  or incompressible arteries. Multivariate analysis confirmed a significant association between graft revision and an abnormal first postoperative duplex scan ( $P < .001$ ; odds-ratio: 3.2, 2.02-5.1) and warfarin therapy ( $P < .03$ ; odds-ratio: 1.8, 1.08-2.89), but the variable of “redo” bypass grafting did not predict revision status ( $P = .07$ ).

The natural history of the 141 (40%) bypasses with an “abnormal” first duplex scan differed from grafts with normal duplex ultrasound imaging by more frequent (52% vs 25%,  $P < .001$ ) and earlier (7 months vs 11 months) graft revision, primarily for duplex-detected graft stenosis, and lower 3-year primary patency (28% vs 62%,  $P < .0001$ ), Fig 2, A. This bypass cohort required a total of 101 secondary interventions (47 open repairs, 54 endovascular); two times the intervention rate compared with bypasses with normal first duplex testing (0.7 vs 0.3 interventions per graft). Time to first secondary intervention was less for bypasses with abnormal first duplex scan (66% within 6 months) compared with normal duplex scan bypasses (28% within 6 months), Fig 3. Despite secondary intervention(s) and similar duplex surveillance, the graft characteristic of an

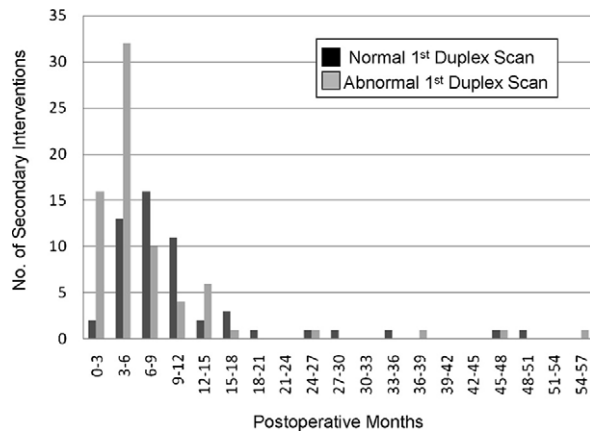


**Fig 2.** Kaplan-Meier estimates of primary (A) and assisted-primary (B) patency of 141 bypasses with abnormal first duplex scan and 212 bypasses with normal first duplex scan.

abnormal first duplex scan was associated with a lower 3-year assisted-primary patency (65% vs 84%; log-rank,  $P < .001$ ), Fig 2, A. The likelihood of graft failure was also higher ( $P < .0001$ ) in grafts with abnormal (35 [25%] of 141) compared with normal (17 [8%] of 212) first duplex scans; 3-year secondary graft patency: 68% vs 86%, respectively.

The use of single-segment great saphenous vein conduit was associated with a higher 3-year primary patency (49% vs 34%,  $P = .02$ ), but assisted primary (82% vs 72%,  $P = .24$ ) and secondary (83% vs 75%,  $P = .35$ ) patency rates were similar to non-single segment saphenous vein (arm vein, spliced vein) bypasses. Warfarin drug therapy was more frequently prescribed to patients with CLI (36%), prior failed bypass (45%), and nonsaphenous vein conduits (50%), and correlated with a higher graft revision rate and equally important a lower assisted primary (68% vs 86%,  $P < .001$ ) and secondary (72% vs 87%) graft patency. The patient cohort with the “best” outcome after infrainguinal bypass were the 178 patients, ie, approximately one-half of the study population, who underwent single-segment saphenous vein bypass and their initial duplex surveillance documented no graft abnormality: 24% graft revision rate, 88% assisted primary graft patency, and 91% secondary patency at 3 years.





**Fig 3.** The number of secondary interventions performed during each postoperative time interval on bypasses with normal (n = 212) or abnormal (n = 141) first duplex surveillance scan. During the follow-up period, 53 (25%) of 212 “normal” bypasses and 73 (52%) of 141 “abnormal” bypasses based on the first duplex scan were revised.

## DISCUSSION

Infringuinal vein bypass, a technically demanding procedure especially in the CLI population, requires a revascularization strategy with regard to conduit selection and bypass configuration coupled with postoperative surveillance to achieve long-term patency. Recent large-scale clinical trials have confirmed myointimal graft stenosis is the primary failure mode of this procedure but its detection by duplex ultrasound surveillance and repair may not guarantee success.<sup>2,6</sup> In fact the value of duplex surveillance has been questioned, deemed not to be cost-effective or “worth the effort”, and with “limb loss likely to occur irrespective of the surveillance strategy”.<sup>1-3</sup> Our study addressed this clinical pessimism by identifying several characteristics (initial duplex scan findings, prior failed ipsilateral bypass, non-single segment saphenous vein conduit) that were highly predictive of graft stenosis development. The majority of duplex-detected lesions identified during surveillance were asymptomatic, progressed in severity on serial scans permitting timely repair, and were amenable to endovascular repair. Our surveillance strategy yielded assisted primary graft patency rates at 3 years of 78% for CLI (limb salvage rate of 88%) and 86% for non-CLI (claudication, aneurysm) arterial disease, but at the cost of revising 35% of the bypasses. The majority of graft revisions occurred within 12 months of the bypass grafting procedure. Our data clearly demonstrates there is a role for duplex surveillance, but also an opportunity to stratify grafts based on their risk for stenosis development and applying more rigorous duplex surveillance to only the “higher-risk” bypasses. Of note, characteristics such as female gender, presence of diabetes, saphenous vein grafting technique, or bypass to an infrageniculate target artery did not predict a higher graft revision rate. We did not address small vein diameter or bypass length as these characteristics have been previously shown to correlate with infringuinal vein bypass failure.<sup>6</sup>

The correlation of early graft flow disturbances identified by duplex scanning with subsequent development of graft stenosis requiring repair has been previously reported.<sup>9-11</sup> These “residual” graft abnormalities have a different natural history from “de novo” stenosis with higher likelihood to progress to a severe stenosis, and graft thrombosis rate.<sup>12</sup> Our review demonstrated 40% of the bypasses had an abnormality identified on the first duplex surveillance scan consisting primarily of a region of elevated PSV and lumen reduction. This characteristic was highly predictive of subsequent graft revision at 3 years primary patency of 64% if normal vs 28% if abnormal; and was identified more frequently than clinical series composed primarily of single-segment reversed saphenous vein bypass (25% incidence using similar duplex criteria).<sup>11</sup> Despite intraoperative assessment with color duplex ultrasound, graft abnormalities consistent with a moderate stenosis were identified during the early postoperative period, especially in the arm/spliced vein bypass group. Using defined, objective “threshold” duplex criteria (PSV > 300 cm/s, Vr > 3.5) for recommending and performing graft stenosis repair, the revision rate of bypasses with abnormal first duplex scan was two times higher, typically required within 6 months of the grafting procedure (66% of revisions), and resulted in a lower assisted primary patency at 3 years (65% vs 84%). Bypasses that failed typically required open surgical repairs and multiple re-interventions. These data indicate existence of infringuinal vein bypass cohort that exhibits a different biologic behavior by a propensity toward myointimal stenosis. Since at present, there is no effective medical therapy to prevent myointimal graft stenosis, we believe the duplex surveillance remains the best strategy to maximize long-term graft patency. The patient cohort on oral warfarin anticoagulation therapy required more graft revisions due to increased characteristics of prior failed bypass grafts, CLI indication, and non-single segment saphenous vein conduit usage.

In the 2007 Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) document, a clinical surveillance program (recommendation 42) was suggested beginning in the immediate postoperative period and conducted every 6 months thereafter for at least 2 years.<sup>1</sup> Duplex ultrasound imaging was not recommended in favor of a surveillance program consisting an interval history for new limb symptoms of ischemia, palpation graft and limb pulses, and measurement of resting, and if possible, postexercise ABIs. This surveillance strategy would have not detected the majority of graft lesions repaired in our patients including: the asymptomatic duplex-detected stenosis in limbs with abnormal ABIs, limbs with incompressible tibial arteries, and inadequate secondary intervention for graft stenosis. Additionally, the use of exercise testing in the CLI patient is often not possible especially in the early (6 months) postoperative period. Our experience and that of other vascular groups with expertise in vascular laboratory testing support the routine use of duplex ultrasound after infringuinal vein bypass.<sup>4-6,11-15</sup> All patients should be evaluated using duplex ultrasound within several weeks of successful bypass grafting to identify residual graft

defects and if specific risks are present, ie, non-single segment saphenous vein bypass, redo bypass, un-controlled atherosclerotic risk factors (tobacco abuse) have repeat graft imaging 3 to 4 months later after graft arterialization and wound healing has occurred. Other clinical trials have found bypass grafting for CLI, vein diameter <3 mm, and graft lengths >50 cm to be "risk-factors" for graft failure and associated with a two-time increase in the number re-interventions within 1 year of bypass grafting.<sup>6</sup> Since graft stenosis development occurs primarily within the first 12 to 18 months after bypass grafting, duplex surveillance is most important during this time period. Beyond 18 months, the infrainguinal vein bypass with a "normal" duplex scan should have an annual evaluation of bypass function (duplex testing and ABI measurement) testing which reassures the patients and their physician(s) that arterial disease progression has not occurred. When duplex surveillance identifies a "failing" vein bypass, the information provided by high-resolution B-mode and color/power Doppler imaging is valuable to the vascular specialist because the necessary therapy (endovascular versus open surgical repair) to repair the duplex-detected stenosis, aneurysm, or graft entrapment can be based on the ultrasound findings alone.

Since the goal of infrainguinal bypass surveillance is to prolong patency and avoid thrombotic events, the measure of its success is the "assisted primary patency rate". Once graft thrombosis occurs, secondary intervention to restore patency is generally not successful or durable and this principle was reflected in this study and other publications of lower limb vein bypass outcomes by reporting a secondary patency which was not significantly higher than the assisted primary patency rate. A significant difference between assisted primary and secondary patency indicates the surveillance protocol did not adequately detect lesions that led to thrombosis, but secondary procedures were successful; outcome that has been observed in prosthetic graft surveillance.<sup>14</sup> Duplex surveillance should increase the number of secondary interventions compared with clinical assessments alone; thus primary patency will be less, and should be significantly less than assisted-primary patency if clinically significant lesions are identified and successfully repaired. These outcome measures were observed in our patients, eg, a significant (<.0001) increase in assisted primary patency compared with primary patency, but no further improvement in secondary patency. Achieving an assisted primary graft patency of 80% or greater at 3 years, and 90% or greater limb salvage are also an important measures of a successful surveillance program. When primary, assisted primary and secondary patency curves are not significant, it can be concluded that surveillance is of no benefit. This can occur because of inadequate surveillance, failure to successfully repair identified grafts lesions in a timely manner, or a result of poor compliance with the surveillance protocol. Some vascular groups have concluded duplex surveillance is too expensive or the logistics to conduct a quality surveillance program are not available. We disagree with this position. Based on duplex ultrasound surveillance studies performed in 1980s, 1990s, 2000s, and as reported herein, all of which demonstrated 80% or

greater assisted primary patency rates at 3 to 5 years, we recommend duplex surveillance as a essential component of patient care following infrainguinal vein bypass.<sup>3,5,10,13-15</sup>

## AUTHOR CONTRIBUTIONS

Conception and design: DB, JC, CT  
 Analysis and interpretation: DB, JC, CT, PA, MB, BJ, MS  
 Data collection: CT, JC, DB  
 Writing the article: DB, CT, JC  
 Critical revision of the article: DB, PA  
 Final approval of the article: DB, CT  
 Statistical analysis: DB, CT  
 Obtained funding: Not applicable  
 Overall responsibility: DB

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