Peripheral Artery Disease

Surgical Technique and Peripheral Artery Disease

David Paul Slovut, MD, PhD; Evan C. Lipsitz, MD

Invasive treatment for patients with peripheral artery disease (PAD) has changed dramatically. Medicare claims data from 1996 to 2006 reveal an almost doubling of lower-extremity vascular procedures: The use of endovascular repair increased >3-fold, bypass surgery decreased 42%, and the amputation rate decreased by 29%. For patients admitted to hospital for PAD between 1996 and 2005, the likelihood of undergoing surgery decreased from 34.5% to 26.3%. Although the rate of bypass is decreasing, surgery remains an important component in the armamentarium for treating patients with advanced vascular disease. Surgical revascularization is indicated in patients with acceptable surgical risk who require a more durable repair, in those with lesions technically unsuitable for endovascular repair, and in patients who experienced failure of endovascular repair.

Despite significant increases in patient morbidity, surgical bypass has become safer over the past 2 decades. Nationally, mortality after surgical bypass decreased from 7% to 4% from the 1980s to mid-1990s. From 1998 to 2003, mortality for open and combined procedures stabilized at 3% to 4%. Data from the National Inpatient Survey comparing outcomes in 1998 and 2007 show significant reductions in complication rates across all categories except infection. Several factors may account for improved outcomes: a shift to endovascular therapy or “limited” open surgery to achieve revascularization in high-risk patients; better patient selection; more effective medication regimens consisting of a statin, an antiplatelet agent, and β-blocker; and improved intraoperative care and postoperative management.

This review examines the risk of adverse events after vascular surgery, identifies strategies for determining and decreasing cardiac risk, and describes contemporary surgical approaches to treating patients with PAD.

Adverse Events and Outcomes After Vascular Surgery

Patients with symptomatic PAD frequently have concomitant cerebrovascular or coronary artery disease (CAD) that places them at high risk for adverse cardiovascular outcomes after surgery. Direct reconstruction for aortoiliofemoral disease is associated with 2.8% perioperative mortality, whereas extraanatomic bypass, which typically is performed on exceptionally high-risk patients, is associated with 8.8% mortality. Mortality after direct aortic reconstruction is increased in patients >65 years of age and in those with chronic obstructive pulmonary disease who undergo operation at a low-volume center. Surgical mortality after lower-extremity bypass for Medicare patients treated between 1994 and 1999 in high-volume hospitals was 4.1%. In the Project or Ex-Vivo Vein Graft Engineering via Transfection (PREVENT) III trial, which examined outcomes in 1404 patients who underwent infragenual bypass for limb salvage, the 30-day mortality was 2.7%, myocardial infarction (MI) rate was 4.7%, and rate of stroke/transient ischemic attack was 1.4%. Complications after surgical bypass include wound infection, necrosis, tissue loss, graft occlusion, and bleeding. Independent predictors of adverse outcomes include female sex, advanced age, diabetes mellitus, and below-knee bypass. Results from the National Surgical Quality Improvement Program (NSQIP) provide further insight into the complications associated with lower-extremity bypass. The database includes 2404 patients, of whom 47.6% had critical limb ischemia (CLI) and 37% had a nonhealing wound. As expected, the incidence of death (3.6% versus 2.0%; P<0.023) and major complications (30.1% versus 16.3%; P<0.001) was greater in patients who underwent bypass for CLI. However, the difference was greater for major operative-site complications such as graft failure, wound dehiscence, sepsis, and wound infection (23.9% versus 12.8%) than for major systemic complications (7.1% versus 4.6%) between the CLI and claudication cohorts.

The NSQIP data serve as a reminder that patients who undergo infragenual bypass for limb salvage often experience delayed wound healing, episodes of recurrent ischemia, and need for repeat operations. For example, Nicoloff and colleagues followed up 112 patients who underwent bypass for CLI and found that only 14% had an ideal surgical result, which was defined as an uncomplicated operation with long-term symptom relief, maintenance of functional status, uncomplicated wound healing, and no recurrence or repeat operations regardless of postoperative survival time.

Preoperative functional status profoundly influences outcome. Functional outcome, which includes survival, maintenance of ambulation, and maintenance of independent living status, was assessed in a cohort of 841 patients who underwent 1000 revascularization procedures for CLI. The most important predictors of poor functional outcome were impaired ambulatory status at the time of presentation and dementia. In

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the NSQIP database, patients were classified as independent or dependent, defined as someone who requires some or total assistance from another person for activities of daily living. Compared with their independent counterparts, dependent patients were older and had more congestive heart failure and a higher incidence of MI in the past 6 months, dialysis dependency, and American Society of Anesthesiologists class. Dependent patients fared worse in all parameters: mortality (6.1% versus 1.5%), major systemic complications, and major operative-site complications. A concern with NSQIP is that classification of dependent status is highly subjective. Moreover, there are degrees of dependence that were not accounted for by NSQIP. For example, patients who required a home health aide for 2 h/d were considered just as dependent as patients living in a skilled nursing facility. It may be reasonable and appropriate to treat patients with CLI who have impaired ambulation at presentation, are demented, or are dependent on others with a limited open procedure (endarterectomy), endovascular repair, hybrid revascularization, or primary amputation rather than open reconstruction.

Preoperative Cardiac Risk Stratification

Cardiac Risk Assessment

Cardiac risk may be determined by procedure timing (elective versus emergent), extent of surgery, and patient-specific factors. The American College of Cardiology Foundation/American Heart Association (ACCF/AHA) guidelines provide a framework for evaluating cardiac risk in patients slated for vascular surgery (Figure 1). According to the guidelines, “… one of the ultimate objectives of the preoperative cardiac assessment is to exclude the presence of such serious CAD that some form of direct cardiac intervention is warranted even if no noncardiac operation was necessary.”

Patients with unstable coronary syndromes (severe angina or MI within 30 days), decompensated heart failure, arrhythmias (third-degree atrioventricular block, symptomatic ventricular arrhythmias), and severe aortic or mitral stenosis should be evaluated and treated before noncardiac surgery. Symptomatic heart failure also is associated with postoperative cardiac complications.

The importance of asymptomatic disease is less certain. Recent data on 1005 patients who underwent elective vascular surgery demonstrated that isolated asymptomatic diastolic left ventricular dysfunction (odds ratio, 1.8), asymptomatic left ventricular systolic dysfunction (odds ratio, 2.3), and symptomatic heart failure (odds ratio, 6.8) were associated with increased 30-day cardiovascular events and reduced long-term survival. Biochemical markers such as N-terminal pro-B-type natriuretic peptide may improve our ability to detect heart failure and to determine cardiac risk.

Patients with reasonable exercise tolerance—those able to walk on level ground at 4 mph or to run a short distance—may not require further cardiac evaluation. Oftentimes, however, functional ability is difficult to evaluate in patients with PAD because their lower-extremity symptoms limit their ability to walk. Various indexes have been devised that attempt to predict the cardiac risk of undergoing surgery.

The Revised (Lee) Cardiac Risk Index assigns a value of 1 to each of the following: high-risk surgery, ischemic heart disease, congestive heart failure, cerebrovascular disease, insulin-dependent diabetes mellitus, and preoperative serum creatinine >2 mg/dL. Surgical procedures are classified as low risk (eg, creation of arterial-venous fistula, toe amputation), intermediate risk (eg, carotid endarterectomy, endovascular aneurysm repair), or high risk (eg, open aortic surgery, infrainguinal bypass). Cardiac complications were defined as MI, significant dysrhythmia, or congestive heart failure. Mortality was not included. Rates of major cardiac complications with 0, 1, 2, or ≥3 risk factors were 0.4%, 0.9%, 7%, and 11%, respectively, among patients in the validation cohort. Adjusting the Lee index with age and hypertension may improve its predictive value. The Revised Cardiac Risk

Figure 1. Suggested approach to cardiac risk stratification. HR indicates heart rate. Adapted from Fleisher et al. *Active cardiac conditions include unstable coronary syndromes, new or decompensated congestive heart failure, significant arrhythmias, and severe valvular disease. †4 metabolic equivalents (METS) entails performing light work around the house. ‡Clinical risk factors include ischemic heart disease, compensated or prior heart failure, diabetes mellitus, renal insufficiency, and cerebrovascular disease.
The VSGNE risk score may provide a more accurate respecti
cally, for patients undergoing lower-extremity by-
vascualr procedures, the cardiac complication rates with 0, 1,
and invasiv stress test if it will alter their management.14 Because
/ Abbreviations:
CAD indicates coronary artery disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; CABG, coronary artery bypass graft surgery; and PCI, percutaneous coronary intervention. Reprinted from Bertges et al18 with permission from the publisher. © 2010, Elsevier Inc.

Index, which was published in 1999, appears to underestimate cardiac risk in contemporary surgical practice. In the Vascular Study Group of New England (VSGNE) cohort, comprising >10 000 patients who underwent nonemergent vascular procedures, the cardiac complication rates with 0, 1, 2, or ≥3 risk factors were 4.6%, 7.1%, 13.1%, and 17.8%, respectively, for patients undergoing lower-extremity bypass.18 The VSGNE risk score may provide a more accurate means than the Lee index of identifying patients at risk for cardiac complications (Table 1).

Patients with ≥3 clinical risk factors and poor functional capacity (<4 metabolic equivalents) should undergo a non-invasive stress test if it will alter their management.14 Because most patients with severe PAD are unable to exercise, image-based, pharmacological stress testing is often performed.

Risk Reduction Strategies

β-Blockers

The role of β-blockade has been reevaluated over the past 15 years. Early studies suggested that β-blockade was associated with decreased mortality and cardiac complications in patients undergoing noncardiac surgery.19,20 A retrospective study of 560 patients who underwent open vascular surgery showed a reduced rate of perioperative MI and death among patients receiving a β-blocker.21 In PREVENT III, among patients not receiving a β-blocker before undergoing infrain
guinal bypass for CLI, the adjusted odds ratio of a perioperative MI was 3.9 times higher in those with a history of advanced CAD compared with those with no such history.8 Data from Perioperative Ischemic Evaluation (POISE), a randomized, controlled trial of fixed, high-dose metoprolol in >8000 patients undergoing noncardiac surgery, raised concerns about the safety of β-blockade.22 Although cardiovascular death, MI, and cardiac arrest were reduced in patients receiving β-blockade, the rate of stroke and total mortality increased. The adverse outcomes likely related to hypotension and bradycardia associated with high doses of meto

### Table 1. Vascular Surgery Group Cardiac Risk Index

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Points</th>
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<tbody>
<tr>
<td>Age ≥80 y</td>
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</tr>
<tr>
<td>Age 70–79 y</td>
<td>3</td>
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<tr>
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<td>2</td>
</tr>
<tr>
<td>CAD</td>
<td>2</td>
</tr>
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</tr>
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<td>2</td>
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</tr>
<tr>
<td>Smoking</td>
<td>1</td>
</tr>
<tr>
<td>Insulin-dependent DM</td>
<td>1</td>
</tr>
<tr>
<td>Long-term β-blockade</td>
<td>1</td>
</tr>
<tr>
<td>CABG or PCI</td>
<td>–1</td>
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CAD indicates coronary artery disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; CABG, coronary artery bypass graft surgery; and PCI, percutaneous coronary intervention.

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The combined end point of death from cardiovascular causes or nonfatal MI occurred in 4.8% of patients receiving fluvastatin versus 10.1% of those receiving placebo. This result translates into a relative risk reduction of 53% and number needed to treat of 19 to prevent 1 event.25

### Coronary Revascularization

The Coronary Artery Revascularization Prophylaxis (CARP) trial was the first randomized, controlled trial to examine the effect of coronary revascularization on vascular surgery outcome.27 Patients underwent coronary angiography followed by either percutaneous coronary intervention (PCI) or coronary artery bypass grafting before vascular surgery. Examination of a subset of patients who underwent lower-extremity bypass revealed that patients with CLI had more urgent operations, more reoperations, more limb loss, and longer hospital stays than patients with intermittent claudication. Claudicants had a higher rate of MI than CLI patients (17.1% versus 8.4%), but perioperative mortality was higher in CLI patients (3.5% versus 1.8%). For the overall CARP cohort, the risk of death and nonfatal MI increased as predicted by the Revised Cardiac Risk Index.28 However, preoperative cardiac revascularization did not decrease the rate of death or perioperative MI.27 The majority of patients in CARP had only 1- or 2-vessel CAD with preserved left ventricular systolic function.27 Subjects were excluded if they had severe left main CAD, severe left ventricular dysfunc-
tion, severe aortic stenosis, and lesions not amenable to revascularization.

In the DECREASE-V Pilot Study, dobutamine echocardiography or stress nuclear imaging was performed on 1880 patients with ≥3 risk factors who were slated for vascular surgery. A cohort of 101 subjects with extensive, stress-induced ischemia were randomized to medical therapy versus medical therapy plus coronary revascularization. All patients received β-blocker titrated to achieve a resting heart rate of 60 to 65 bpm. The composite end point of all-cause mortality or MI at 30 days was reached in 43% in the revascularization group and 33% in the nonrevascularization group (P=NS). From the pilot data, the authors estimated that a study to establish the efficacy of coronary revascularization would require screening 9000 patients to identify 600 with extensive stress-induced ischemia who would be eligible for randomization.

Another study randomized 208 patients slated for elective major vascular surgery with Revised Cardiac Risk Index ≥2 to coronary angiography if a stress test was positive (“selective strategy”) versus “mandatory” coronary angiography. A greater percentage of patients underwent coronary revascularization—PCI, off-pump coronary artery bypass, or their combination—in the mandatory group (58.1 versus 40.1; P<0.01), but perioperative mortality was similar in both groups. A greater percentage of patients in the mandatory group underwent off-pump coronary artery bypass, which may help explain the significantly improved survival and freedom from major cardiac events at the 4-year follow-up.

Coronary revascularization is recommended for patients with high-risk anatomy such as left main CAD, 3-vessel CAD with stable angina, and 2-vessel CAD with significant proximal left anterior descending artery stenosis. Coronary revascularization is particularly advantageous in patients with an ejection fraction <50%. PCI before vascular surgery is indicated in patients who present with acute ST-segment–elevation MI, non–ST-segment–elevation MI, and unstable angina. For patients who require PCI, the decision on what stent to implant depends on the willingness of the patient to comply with dual antiplatelet therapy (eg, aspirin and a thienopyridine) and the timing of vascular surgery. This is particularly pertinent because noncardiac surgery is performed on 22% of patients within 3 years of undergoing PCI with a drug-eluting stent. ACC/AHA guidelines recommend that after percutaneous balloon coronary angioplasty or bare metal or drug-eluting stent implantation, nonurgent surgery should be delayed for at least 14, 30, and 365 days, respectively. At that point, patients may proceed to the operating room on either aspirin or a thienopyridine.

Premature discontinuation of dual-antiplatelet therapy increases the risk of stent thrombosis, MI, and death after PCI. Other factors associated with coronary stent thrombosis include stenting small vessels, long stents, overlapping stents, ostial or bifurcation lesions, suboptimal stent results, and patient factors such as low ejection fraction, acute coronary syndrome, and diabetes mellitus. For patients treated with a drug-eluting stent who undergo procedures that mandate discontinuation of thienopyridine therapy, aspirin should be continued if at all possible and the thienopyridine should be restarted as soon as possible to reduce the likelihood of late stent thrombosis.

Similar recommendations have been made by a European working group. There is no controlled evidence that intravenous heparin, glycoprotein IIb/IIIa inhibitors, or warfarin decreases the risk of stent thrombosis after dual antiplatelet therapy is stopped.

Multiple studies suggest that patients undergoing coronary artery bypass grafting who are taking clopidogrel are at increased risk of major bleeding and reoperation. These risks are less defined for patients who undergo vascular surgery.

**Surgical Reconstruction for PAD**

Potential surgical candidates include patients with acceptable surgical risk and life expectancy or >2 years, those with lesions technically unsuitable for endovascular repair, and patients who have failed endovascular repair. Because of the balance of risks and benefits and the high procedural success rates for endovascular repair, surgical reconstruction is performed more commonly on patients with CLI than on those with claudication. Outcomes after lower-extremity revascularization decline across a spectrum of preoperative indications from claudication to rest pain to tissue loss for resolution of presenting symptoms, maintenance of ambulation, amputation-free survival, limb salvage, and survival.

**Aortoiliac Reconstruction**

Aortoiliac reconstructions are classified as anatomic (eg, aortobifemoral or iliofemoral bypass) or extra-anatomic (eg, axillofemoral or femorofemoral bypass). A small number of patients may be candidates for aortic endarterectomy without bypass, which is useful in the setting of focal disease and obviates the need for prosthetic material.

Anatomic bypasses are constructed alongside the diseased anatomy using large-vessel inflow and have the highest patency. Anatomic bypass can be performed with either a transabdominal or a retroperitoneal approach. The latter approach avoids the potential complications associated with a laparotomy such as visceral injury and the late development of adhesions and obviates the need for difficult intra-abdominal dissection in patients with a hostile abdomen. Compared with the transabdominal approach, the retroperitoneal approach is associated with a lower incidence of pulmonary complications, rapid recovery of gastrointestinal function, and shorter intensive care unit and hospital stays.

Aortobifemoral bypass grafts are constructed to provide straight-line flow to the femoral arteries and to preserve flow to the internal iliac, inferior mesenteric, and lumbar arteries when patent. When the common iliac arteries are occluded, perfusion to the hypogastric arteries is supplied retrograde via the external iliacs. If the inferior mesenteric and lumbar arteries are not patent, the proximal anastomosis may be sewn to the aorta at the level of the renal arteries in an end-to-end fashion (Figure 2). If there is stenosis at the inferior mesenteric artery orifice, the inferior mesenteric artery may be bypassed or reimplanted to permit end-to-end reconstruction. When the common iliac arteries are patent and the external arteries are occluded, perfusion to the hypogastric arteries is prograde via the common iliac arteries. An end-to-side aortic anastomosis is performed in this setting and has the advantage of preserving antegrade flow to hypogastric and inferior
mesenteric arteries (Figure 2). This may be a more technically challenging anastomosis to perform than an end-to-end anastomosis, particularly if there is extensive disease in the infrarenal aorta.

Occasionally, the presence of a diseased infrarenal aortic segment, multiple previous surgeries, or severe medical comorbidities dictates the use of an alternative inflow source such as the descending thoracic aorta. In this case, the proximal anastomosis can be performed without completely cross-clamping the aorta, which reduces hemodynamic stress. The graft is tunneled posterolaterally from the thoracic cavity, through the diaphragm, and then either through the retroperitoneum or subcutaneously to the femoral vessels.

Results from direct anatomic inflow procedures are summarized in Table 2. Primary patency rates for claudicants are higher than for patients with CLI. Nationally, the mortality rate is 3.7% at lower-volume centers and 2.2% at high-volume centers.

In medically compromised patients, who typically are older and have advanced limb ischemia, a history of previous lower-extremity inflow operations, chronic kidney dysfunction, severe chronic obstructive pulmonary disease, or severe CAD, extra-anatomic bypass is a reasonable alternative to direct reconstruction. A procedure commonly used in this setting is the axillofemoral bypass in which inflow is derived from the axillary artery (Figure 3A). The graft is tunneled between the pectoralis major muscle and the chest wall, continues subcutaneously along the abdominal wall in the subcutaneous space, and is anastomosed to the femoral artery. A femorofemoral bypass may be performed to supply the contralateral lower extremity (Figure 3B). This procedure, which is usually performed under general anesthesia, is well tolerated in that there is minimal blood loss and no clamping of intra-abdominal or thoracic vessels and neither the abdominal nor thoracic cavity is entered. Patency after axillofemoral bypass is variable and depends heavily on patient characteristics. Results from femorofemoral bypass are presented in Table 3.

The construction of the distal anastomosis in both anatomic and extra-anatomic bypasses depends on the degree of disease in the femoral and infrainguinal vessels. In general, the distal anastomoses are performed to the common femoral arteries (CFA). If there is extensive CFA, superficial femoral artery (SFA), and/or deep femoral artery disease, an endarterectomy and patch angioplasty may be performed with the anastomosis constructed directly onto the patch. In the setting of CFA and SFA occlusion, the distal anastomosis may be performed directly onto the profunda femoris artery. If the indication for the procedure is tissue loss and the SFA is occluded, a femoropopliteal bypass using the distal graft limb as inflow may be performed. This adds time and complexity to the procedure but improves outflow and patency.

**Infrainguinal Reconstruction**

As with all reconstructions, long-term graft patency depends on the quality of the inflow and outflow vessels and the conduit available. In general, the patency of intervention in claudicants exceeds that of interventions performed in patients with CLI and decreases progressively with decreasing vessel diameter. Results of infrainguinal bypass from selected series are presented in Table 4.

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**Table 2. Meta-Analysis of Direct Anatomic Aortoiliac Reconstruction**

<table>
<thead>
<tr>
<th>Inflow Procedure</th>
<th>Studies, n</th>
<th>n</th>
<th>Operative Mortality, %</th>
<th>Systemic Morbidity, %</th>
<th>Local Morbidity, %</th>
<th>5-Year Primary Patency, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortobifemoral bypass</td>
<td>29</td>
<td>5738</td>
<td>4.1</td>
<td>16.0</td>
<td>6.3</td>
<td>86.3</td>
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<tr>
<td>Iliofemoral bypass</td>
<td>11</td>
<td>778</td>
<td>2.7</td>
<td>18.9</td>
<td>5.7</td>
<td>85.3</td>
</tr>
<tr>
<td>Aortoiliac endarterectomy</td>
<td>11</td>
<td>1490</td>
<td>2.7</td>
<td>12.5</td>
<td>3.4</td>
<td>88.3</td>
</tr>
</tbody>
</table>

Systemic morbidity was defined as a dysfunction of ≥1 major organ systems within 30 days of the index procedure. Local morbidity was defined as a nonfatal complication limited to the site of the operation and occurring within 30 days of the index procedure.
A long-segment, continuous, good-quality, autogenous greater saphenous vein represents the optimum conduit. The degree of this advantage over nonautogenous conduits becomes greater with increasingly distal outflow targets. Autogenous vein may be used in 1 of 3 primary configurations: reversed greater saphenous vein, nonreversed translocated greater saphenous vein, and in situ. In the reversed greater saphenous vein configuration, the vein is completely removed from its anatomic position after ligation and division of its tributaries and anastomosed to the proximal and distal targets in a reversed position. In the nonreversed translocated greater saphenous vein configuration, the vein is removed as in reversed greater saphenous vein but is not reversed. This necessitates lysis of the venous valves to permit prograde flow. A valvulotome is used for this purpose. In the in situ configuration, the vein is left in its anatomic position and the valves are lysed. Tributaries along the majority of the graft need to be only ligated, not divided. Only the tributaries located near the anastomotic sites are divided so that the proximal and distal ends of the vein can be mobilized sufficiently to reach their targets. A major advantage of reversed greater saphenous vein is that they do not require valve lysis, which avoids valvulotome trauma to the intima. Nonreversed translocated greater saphenous vein and in situ grafts offer the advantage of a better size match between vein and native artery at the anastomotic sites. In situ grafts also have the theoretical advantage of reduced ischemia to the conduit itself because many of the feeding vasa vasorum are preserved. In addition, the graft lies in a superficial position, which can facilitate surveillance and reintervention, particularly if an open procedure is required. All configurations provide excellent results, and randomized, controlled trials do not favor 1 configuration over another. Although the decision to use a given graft configuration is based largely on operator preference, certain anatomic considerations such as a small distal target vessel or a bypass to the posterior tibial artery, which lies in close proximity to the greater saphenous vein, are favorable for an in situ graft. Bypasses to the anterior tibial or peroneal artery, performed via a lateral approach, are more suitable for reversed greater saphenous vein or nonreversed translocated greater saphenous vein. In these cases, a shorter length of vein is required.

Prosthetic grafts and other substitutes may be used for bypass when suitable autogenous conduit is absent or of poor quality. The most frequently used prosthetic conduits are made of polytetrafluoroethylene or Dacron. The recently

Table 3. Results of Femorofemoral Bypass Procedures

<table>
<thead>
<tr>
<th>Author</th>
<th>Trial</th>
<th>Subjects, n</th>
<th>Operative Mortality, %</th>
<th>Primary Patency, %</th>
<th>Secondary Patency, %</th>
<th>Comment</th>
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</thead>
<tbody>
<tr>
<td>Ricco et al43</td>
<td>RCT</td>
<td>74</td>
<td>0</td>
<td>71.8</td>
<td>89.8</td>
<td>Patency significantly higher after direct bypass than after crossover bypass</td>
</tr>
<tr>
<td>Eiberg et al44</td>
<td>RCT</td>
<td>198</td>
<td>0.5</td>
<td>87–93 (2 y)</td>
<td>NR</td>
<td>Dacron and PTFE</td>
</tr>
<tr>
<td>Johnson et al45</td>
<td>RCT</td>
<td>340</td>
<td>Dacron, 1.5; PTFE, 2.0</td>
<td>46.4–49.4</td>
<td>NR</td>
<td>Mortality and patency for fem-fem and ax-fem bypass grafts</td>
</tr>
<tr>
<td>Kim et al46</td>
<td>Single center</td>
<td>216</td>
<td>0.5</td>
<td>65.0</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Hertzer et al47</td>
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<td>98</td>
<td>5.6</td>
<td>80.0</td>
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<td>Thuijls et al47</td>
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<td>95</td>
<td>7.6</td>
<td>57.3</td>
<td>68.1</td>
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</table>

RCT indicates randomized controlled trial; PTFE, polytetrafluoroethylene; fem-fem, femorofemoral; ax-fem, axillofemoral; and NR, not reported. Patency rates are at 5 years unless otherwise specified.
introduced heparin-bonded expanded polytetrafluoroethylene grafts provide reasonable short- and medium-term patency compared with autologous vein.\textsuperscript{49,56} For reconstructions that cross the knee joint, grafts with removable external rings are available to help prevent graft compression and/or kinking. Meticulous construction of the distal anastomosis is crucial to avoiding short- and long-term graft failure. Some authors have advocated the use of vein patches or cuffs, the creation of a distal arteriovenous fistula, or the use of precuffed polytetrafluoroethylene grafts to reduce compliance mismatch and intimal hyperplasia at the distal anastomosis. There is no high-quality evidence favoring any of these approaches.

To date, Bypass Versus Angioplasty in Severe Ischemia of the Limb (BASIL) is the only randomized, controlled trial comparing a surgery-first and a balloon angioplasty-first revascularization approach in patients with infrainguinal disease and CLI.\textsuperscript{57} More than 450 patients were enrolled at 27 centers in the United Kingdom. To participate in the trial, patients had to be acceptable candidates for either angioplasty or bypass surgery. The periprocedural morbidity rate was higher (57\% versus 41\%) and the immediate failure rate was lower (3\% versus 20\%) in the surgery group. At 1 year, the primary end point, amputation-free survival, was not significantly different between the groups (surgery, 56\%; angioplasty, 50\%). After 2 years, a posthoc analysis found that there was a significantly greater amputation-free survival and survival in the surgery-first group. By treatment-received analysis, patients who underwent bypass after failed angioplasty had poorer amputation-free survival and somewhat poorer overall survival than patients who underwent bypass first.\textsuperscript{58} The BASIL investigators concluded that patients with CLI who are likely to live $\geq 2$ years are probably better served with a bypass-first strategy, preferably with vein. CLI patients unlikely to live 2 years and possibly those in whom vein is not available for bypass are probably better served with an angioplasty-first strategy because they are unlikely to survive to reap the longer-term benefits of surgery, because they may be more likely to suffer from surgical morbidity and mortality, and because angioplasty is less expensive than surgery in the short term.\textsuperscript{59}

The PREVENT III risk score, made up of dialysis (4 points), tissue loss (3 points), age $\geq 75$ years (2 points), and CAD (1 point), may be used to risk-stratify CLI patients under consideration for infrainguinal bypass.\textsuperscript{60} Amputation-free survival at 1 year was 87.7\% for low-risk (PREVENT III score $\leq 3$), 63.7\% for medium-risk (PREVENT III score 4–7), and 45.0\% for high-risk (PREVENT III score $\geq 8$) patients. More complex models for predicting survival based on clinical and angiographic (ie, below-knee Bollinger score) have been devised but are not used widely in practice.\textsuperscript{61}

### Postprocedural Care

Several studies have examined the effects of oral anticoagulants on bypass graft patency. The Dutch Bypass Oral Anticoagulants or Aspirin (BOA) trial examined outcomes after infrainguinal bypass surgery for patients randomized to aspirin ($n=1324$) or oral anticoagulants ($n=1326$).\textsuperscript{62} Oral anticoagulants, particularly when the target international normalized ratio ranged from 3.0 to 4.0, were beneficial in patients with vein grafts, whereas aspirin appeared to be better for nonvenous grafts. However, patients treated with oral anticoagulants had nearly twice the rate of bleeding episodes than patients taking aspirin.

The multicenter, prospective, randomized VA Cooperative Study compared long-term treatment with warfarin plus aspirin therapy versus aspirin alone in 831 patients who underwent axillofemoral, femoral-popliteal, or femoral-distal bypass.\textsuperscript{63} For patients with prosthetic grafts, the rate of bypass occlusion was higher in the warfarin plus aspirin group, with the greatest difference in patients who received a 6-mm graft (28.6\% in the warfarin plus aspirin group versus 42.1\% in the aspirin group; $P=0.022$). The graft occlusion rate for 8-mm grafts was similar in both groups (17\% in the warfarin plus aspirin group versus 24.1\% in the aspirin group; $P=0.32$). Patients with vein bypasses had no benefit from warfarin therapy. Hemorrhagic complications were higher in the warfarin plus aspirin group.

### Table 4. Results of Infrainguinal Bypass From Selected Series

<table>
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<tr>
<th>Author/Trial</th>
<th>n</th>
<th>Conduit</th>
<th>30-Day Mortality, %</th>
<th>30-Day PP, %</th>
<th>30-Day SP, %</th>
<th>Limb Salvage, %</th>
<th>Survival, %</th>
<th>Follow-Up, y</th>
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PP indicates primary patency; SP, secondary patency; PREVENT, Project or Ex-Vivo Vein Graft Engineering via Transfection; RCT, randomized controlled trial; ePTFE, expanded polytetrafluoroethylene; NR, not reported; PTFE, polytetrafluoroethylene; AK-P, above-knee prosthetic; AK-V, above-knee vein; BK-V, below-knee vein; and CLI, critical limb ischemia.
A recent Cochrane database review examined 14 trials (4970 patients) and found that vitamin K antagonists were favored for autologous grafts, whereas antiplatelet agents appeared to be more efficacious for prosthetic grafts. Most surgeons in North America use antiplatelet therapy primarily for vein bypass grafts and reserve warfarin for complicated cases, repeat procedures, or patients who have hypercoagulable disorders.

Prompted by concerns about increased bleeding in bypass patients maintained on warfarin plus aspirin, the Clopidogrel and Acetylsalicylic Acid in Bypass Surgery for Peripheral Arterial Disease (CASPAR) investigators conducted a randomized, controlled trial that compared aspirin plus clopidogrel and aspirin plus placebo in 851 patients who underwent femoral-to-infrapopliteal bypass grafting. The rate of primary outcome events (occlusion of bypass graft, graft revision, amputation above the ankle, or death) was similar between the 2 groups. Prespecified subgroup analysis of patients who received prosthetic grafts showed that the addition of clopidogrel was associated with improved graft patency and decreased amputation rate compared with placebo. The potential benefit of dual antiplatelet therapy awaits confirmation in a randomized trial.

Clinical follow-up after bypass should be performed in the immediate postoperative period and at regular intervals thereafter. Surveillance consists of inquiring about the recurrence of previous or the development of new lower-extremity symptoms; palpating the pulse proximal to the graft, the graft itself, and the outflow vessels; and periodically measuring the ankle brachial index.

Serial duplex ultrasound is considered the standard of care after infrainguinal bypass. Generally, examinations are performed at 1, 3, 6, 9, 12, 18, and 24 months after bypass and yearly thereafter. The rationale for this approach is to facilitate detection of intimal hyperplasia, which generally occurs within the first 2 years after bypass surgery, and to identify any stenoses within the conduit, particularly when a vein graft is used. Early detection of inflow, outflow, or conduit lesions allows treatment (usually endovascular) to maintain graft patency.

Retrospective data support using duplex ultrasound to improve long-term graft patency. The PREVENT III investigators mandated aggressive postoperative graft surveillance with ultrasound. However, the utility of this approach was called into question in the Vein Graft Surveillance Randomized Trial (VGST). In this study, 594 patients with a patent vein graft at 30 days after surgery were randomized to either clinical or duplex ultrasound follow-up at 6 weeks and then at 3, 6, 9, 12, and 18 months postoperatively. The 2 groups had similar amputation rates (7% for each group) and vascular mortality rates (3% versus 4%) over 18 months. Although more patients in the clinical group had vein graft stenosis at 18 months (19% versus 12%; P = 0.04), primary, primary-assisted, and secondary patency rates were similar in the clinical group (69%, 76%, and 80%, respectively) and the duplex group (67%, 76%, and 79%, respectively). Costs for patients followed up by duplex were substantially higher than those for patients followed up clinically.

**Combined Endovascular and Surgical Revascularization**

Hybrid revascularization combines open surgery with endovascular procedures to treat multilevel vascular disease. An example of a hybrid arterial reconstruction is shown in Figure 4. In a hybrid procedure, the endovascular portion may consist of inflow, a combination of inflow and outflow, or revision of a bypass graft. Hybrid procedures enable patients thought to be at increased risk for complete, traditional surgical reconstruction to undergo durable revascularization with a less extensive operative procedure, shorter duration of operation, and decreased risk of perioperative complications. For patients with CLI, limb salvage rates after hybrid revascularization range from 80% to 100%.

Preprocedural imaging with computed tomographic angiography, magnetic resonance angiography, or invasive angiography assists in the planning of hybrid cases. The endovascular and open portion of the procedure may be performed simultaneously or sequentially. Before the advent of modern endovascular operating suites, procedures often were performed sequentially because imaging in dedicated angiography suites was superior to the imaging in the operating room and the environment in the angiography suite was inadequate for open procedures. Now, many hospitals have a dedicated endosuite or hybrid laboratory.

Many hybrid procedures for lower-extremity arterial occlusive disease use a common femoral endarterectomy and patch angioplasty or placement of an interposition graft. In most cases, the endarterectomy and patch will extend onto the superficial and/or profunda femoris arteries. The procedure can be performed under local, spinal, or general anesthesia. After the femoral artery is exposed, loops are placed around the proximal common femoral, superficial femoral, and profunda femoris arteries. Heparin is administered before cross-clamping. Endarterectomy is performed via a longitudinal arteriotomy. In most cases, closure is achieved with a venous, bovine, or synthetic patch sutured with 5-0 or 6-0 monofilament suture. In some cases, closure is achieved without a patch (ie, primary closure) (Figure 5). No association has been found between the type of patch and surgical-site infection. Common femoral endarterectomy is associated with low morbidity and mortality. Potential complications include early failure requiring reintervention, wound infection, hematoma, and lymph leak. Typically, patients are hospitalized for 2 to 3 days. In most series, the 5-year primary and primary-assisted patency rate is >90%.

**Iliac Angioplasty With Common Femoral Artery Endarterectomy or Infrapinguinal Bypass**

Iliac artery lesions may be treated via an ipsilateral retrograde, a contralateral antegrade, a brachial approach, or a combination thereof. The femoral artery may be accessed percutaneously before femoral artery exposure or after CFA endarterectomy and patch angioplasty, in which case the arterial sheath is placed through the patch. The iliac arteries are treated with percutaneous transluminal angioplasty and provisional stenting or primary stenting (Figure 5). Covered stents may improve long-term patency. This finding requires confirmation in a larger prospective trial because...
covered stents may jeopardize important branch vessels such as the internal iliac artery.

In one of the largest series to date, 171 patients underwent CFA endarterectomy and iliac stent or stent grafting. Indications were claudication (46%), rest pain (32%), and tissue loss (22%). Forty-one percent of patients had occlusion of the common iliac or external iliac arteries. Technical success was achieved in 98% of patients. Clinical improvement was seen in 92% of patients. Thirty-day mortality was 2.3%. Five-year primary, primary-assisted, and secondary patency was 60%, 97%, and 98% respectively. Endovascular reintervention was required in 14% of patients; surgical inflow procedures were needed in 10%.

Infrainguinal Hybrid Procedures

With increasing frequency, patients who require distal bypass have insufficient or inadequate greater saphenous vein owing to prior vein stripping or use for coronary artery or peripheral bypass grafting. Endovascular treatment of inflow or outflow lesions allows a shorter length of vein to be used for revascularization. Ideally, the vein bypass is performed distally, and the proximal lesions are treated endovascularly. This approach capitalizes on the excellent outcomes after endovascular repair in proximal arteries and maximizes the benefit of the venous conduit in distal vessels. Infrainguinal hybrid procedures may include common femoral endarterectomy with SFA or popliteal artery angioplasty, distal origin bypass with ipsilateral (retrograde) SFA angioplasty, femoropopliteal bypass with infrapopliteal angioplasty, and remote endarterectomy.

Endovascular repair of the SFA may be performed percutaneously with the crossover technique from the contralateral common femoral artery, via cut-down over the ipsilateral common femoral artery, or retrograde via the popliteal artery. Subintimal angioplasty has emerged as an effective method for recanalizing long-segment occlusions. Technical success rates are high, but patients often require placement of a stent, which in infrainguinal arteries has been associated with early

Figure 4. Hybrid revascularization. The patient was a 66-year-old man with severe bilateral claudication, right greater than left. Noninvasive evaluation showed a resting ankle brachial index on the right of 0.47 and on the left of 0.73. After a 4-minute walk at 10% grade and 1.5 mph, the ABI on the right decreased to 0.33 and on the left decreased to 0.56. A, Angiography demonstrated occlusion of the right common iliac artery (arrow) with reconstitution at the right common femoral artery via collaterals from the inferior mesenteric artery. The left common and external iliac arteries featured diffuse stenosis with a resting gradient of 55 mm Hg between the aorta and left common femoral artery. The superficial femoral artery, popliteal artery, and trifurcation vessels were patent bilaterally. Hybrid revascularization was performed. B, With the use of a left brachial artery approach, the left iliac lesions were treated with angioplasty and an 8×80-mm self-expanding stent. The stent was postdilated (post dil) with a 7×40-mm balloon. The pressure gradient was eliminated. Approximately 1 month later, he underwent femoral-femoral bypass. C, The anastomosis to the left common femoral artery (arrow) is fashioned. D, The bypass graft is tunneled and an anastomosis is completed to the right common femoral artery. After revascularization, the patient’s claudication improved markedly.

Figure 5. Common femoral endarterectomy. In most cases, rather than close the arteriotomy primarily (ie, without a patch; top), the surgeon constructs a patch from vein or synthetic material to create a larger vessel lumen (bottom).
treatment failure.\textsuperscript{83,84} Reentry devices such as the Outback Reentry catheter (Cordis, Bridgewater, NJ) and Pioneer catheter (Volcano Therapeutics, Rancho Cordova, CA) improve the ability of operators to reenter the true lumen and complete the endovascular repair.\textsuperscript{85}

The use of an endovascular inflow procedure in conjunction with infragenicular bypass confers acceptable long-term patency to the downstream bypass graft.\textsuperscript{68,70} In a series of 125 patients who underwent hybrid therapy for de novo arterial reconstruction or revision of a bypass graft, the overall perioperative mortality was <1% and morbidity was 15.4%.\textsuperscript{70} Over a mean follow-up of 27.6 months, the primary patency was 39.6%, primary-assisted patency was 65.1%, and secondary patency was 73.5%. In another report, a group of diabetic patients with tissue loss underwent SFA or popliteal intervention in conjunction with popliteal-to-distal-vein bypass.\textsuperscript{75} The 1-year primary-assisted patency was 68%, and 90% of the patients had healed wounds.

### Mixed Hybrid Procedures

Dosluoglu and colleagues\textsuperscript{74} used no fewer than 10 different types of hybrid reconstruction in completing 108 hybrid procedures. In the majority of cases, common iliac or external iliac artery stenting was combined with CFA endarterectomy, CFA endarterectomy and SFA stent, femoral-femoral bypass, femoral-below knee bypass, or femoral-below knee bypass plus infraoplopalent stent. Hybrid patients had a shorter length of stay than patients who underwent open repair. Complications included deep wound infection (2.8%), major amputation (0.9%), MI (5.6%), and death (6.4%). Limb salvage rates were >90%. The remarkable heterogeneity of procedures makes it difficult to compare their outcomes with results of traditional open or endovascular reconstruction. It will be important to promulgate uniform reporting standards because these procedures are performed more commonly.

Although not a hybrid technique per se, digital fluoroscopy is used increasingly by vascular surgeons as an adjunct to open vascular operations in several ways: completion angiography after bypass to identify defects, to facilitate more controlled thrombectomy and determine the need for adjunctive procedures for patients with acute limb ischemia, and to measure pressure gradients.\textsuperscript{86}

### Conclusions

Surgical revascularization represents mainstay therapy for selected patients with severe limb ischemia. Improvements in medical risk stratification, preoperative medical optimization, and postoperative medical therapy have all contributed to advancements in surgical therapy. The use of hybrid procedures permits vascular reconstruction that is less invasive than traditional surgical repair. The optimal strategy for revascularization will continue to evolve, but surgery continues to play a significant role in managing patients with PAD.

### Disclosures

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### References


