Preventing Critical Limb Ischemia

Experts Discuss Podiatric and Cardiovascular Interdisciplinary Care

Supported by Cordis®
Table of Contents

Introduction: A Primer on Critical Limb Ischemia
Joseph Caporusso, DPM ................................................................. pg. 3

New Treatment Paradigm: The Angiosome Concept
Kanwar P. Singh, MD, FACC ......................................................... pg. 4

Holistic Patient Management: Working With an Interventionalist
Peter A. Soukas, MD, FACC, FSVM, FSCAI, RPVI, and Harold B. Glickman, DPM ......................................................... pg. 8

Amputation Prevention: A Multidisciplinary Approach
J. A. Mustapha, MD, FACC, FSCAI; Desmond Bell, DPM, CWS; Yazan Khatib, MD, FACC, FSCAI, FSVMB, FABVM; Fadi Saab, MD; Carmen M. Heaney, BSN, RN, CCRC, CIP ........................................ pg. 12

Diagnosing CLI: The Role of the Podiatrist
Joseph Caporusso, DPM ................................................................. pg. 18

Comprehensive Wound Care Management
Rakesh M. Shah, MD, FACS, and John Steinberg, DPM, FACFAS ................................................................. pg. 21

Authors

Desmond Bell, DPM, CWS
Executive Director, Save A Leg, Save A Life Foundation
CEO, Limb Salvage Institute
Jacksonville, FL

Joseph Caporusso, DPM
Chairman
PAD Coalition
McAllen, TX

Harold B. Glickman, DPM
Past President, American Podiatric Medical Association
Chairman Dept. Podiatric Surgery
Sibley Memorial Hospital
Washington, DC

Carmen M. Heaney, BSN, RN, CCRC, CIP
Director of Clinical Research
Metro Health Hospital
Wyoming, MI

Yazan Khatib, MD, FACC, FSCAI, FSVMB, FABVM
Co-Founder, First Coast Cardiovascular Institute
Co-Founder, Save A Leg, Save A Life Foundation
Jacksonville, FL

J. A. Mustapha, MD, FACC, FSCAI
Director of Endovascular Interventions
Director of Cardiovascular Research
Metro Health Hospital
Wyoming, MI

Fadi Saab, MD
Metro Heart & Vascular
Wyoming, MI

Rakesh M. Shah, MD, FACS
Sentara Vascular Specialists
Virginia Beach, VA

Kanwar P. Singh, MD, FACC
Assistant Professor of Medicine
Director, Vascular Medicine and Intervention
Co-Director, Interventional Cardiology
University of Connecticut Health Center
Farmington, CT

Peter A. Soukas, MD, FACC, FSVM, FSCAI, RPVI
Director, Vascular Medicine and Interventional Peripheral Vascular Lab
Director, Brown Vascular & Endovascular Medicine Fellowship Program
Assistant Professor of Medicine
Warren Alpert School of Medicine of Brown University
The Miriam and Rhode Island Hospitals
Providence, RI

John Steinberg, DPM, FACFAS
Associate Professor/Department of Plastic Surgery
Co-Director, Center for Wound Healing
Georgetown University School of Medicine
Georgetown University Hospital
Washington, DC

Disclaimer: The authors of the articles contained in this Supplement to Podiatry Today® and Vascular Disease Management® are paid consultants for Cordis Corporation. These articles contain the techniques, approaches and opinions of the individual authors. It does not constitute recommendations or medical advice of Cordis Corporation. Cordis does not provide medical advice. Cordis has no independent knowledge concerning the information contained in any of the articles, and the studies, findings and conclusions expressed are those reached by the authors. This Cordis-sponsored publication is not intended to be used as a training guide. Before using any medical device, please review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for use of the device(s).
Introduction: A Primer on Critical Limb Ischemia

Joseph Caporusso, DPM

Lower-extremity peripheral artery disease (PAD) is a major health concern worldwide. PAD prevalence has been estimated to be between 4.3% and 29%.1-5 Older populations have higher rates of PAD and, in most age groups, males have higher PAD rates than females.3

PAD natural history includes asymptomatic PAD, atypical leg pain, claudication and critical limb ischemia (CLI). CLI presents in 1–2% of the PAD population and is defined as ischemic rest pain, nonhealing wounds or gangrene.6,7 The degree and developmental chronicity of CLI determine patients’ clinical manifestations. The Rutherford and Fontaine clinical classification systems offer insight into ischemic classification and limb salvageability. CLI presents with multifocal areas of occlusion in a lower extremity’s arterial tree; the disease process is usually symmetrical.

CLI is most commonly caused by obstructive atherosclerotic arterial disease. Other causes include athereosclerotic or thromboembolic disease, trauma, and vasculitis. Disease chronicity plays a role in CLI’s formation instead of acute limb ischemia’s. Conditions such as diabetes and severe low-cardiac output reduce blood flow to the microvascular beds and can exacerbate or contribute to CLI development.

CLI is associated with very high intermediate-term morbidity and mortality. Patients with PAD are at 3 to 5 times greater risk of cardiovascular mortality than those without PAD.7 Advanced PAD and CLI greatly increase the risk of cardiovascular ischemic events. Given that this devastating disease can — and, in many cases, will — end in primary amputation, early detection and intervention are crucial.

The ischemic rest pain associated with CLI typically occurs at night and continuously in more severe cases. Patients will often present with a history of pain while asleep and waking to massage the foot and/or walk around the room to try to achieve relief. In some cases, partial relief occurs with dependency of the limb. When patients with pain have reached a point where the pain does not permit sleep in a supine position, their general physical and psychological conditions further decline.

Ischemic ulceration is an ominous sign in CLI. Ischemic ulcerations have vastly different presentations than neuropathic ulcerations. Instead of the healthy, granular base seen with neuropathic ulceration, ischemic ulceration presents with a necrotic/fibrotic base. The hyperkeratotic covering or rim is also absent and has a more “punched out” appearance.

Gangrene is the end-stage of tissue loss. This is the most feared complication of CLI due to the treatment indicated for this process. Amputation before or after revascularization is most likely needed. The literature has highlighted the downward spiral that occurs after that first pedal amputation.6 The stresses and increased pressures applied to the contralateral limb after amputation puts the remaining extremity at an increased risk for amputation. For these reasons, it’s extremely important that the length of the amputated limb be preserved as distally as possible. The energy the patient needs to ambulate greatly increases as the amputation level becomes more proximal. Patients are increasingly aware of the sequelae and are demanding limb salvage at all costs.

The devastating effects of CLI warrant a team approach to its evaluation and treatment. The podiatrist working with the vascular specialist can increase the chance of limb salvage and lessen the horrific consequences of CLI. Appropriate revascularization of the affected limb — along with appropriate wound care, debridement and/or lesser amputation — can let the patient function very close to his/her normal level.

References

As discussed throughout this supplement, critical limb ischemia (CLI) is the most severe form of peripheral arterial disease (PAD). It occurs when the resting metabolic need of tissue is not met by the arterial supply. The anatomic substrate of CLI typically consists of severe, multi-level occlusive or stenotic atherosclerotic disease, including combinations of aorto-iliac, femoral, popliteal and tibial vessels. The conditions of patients with CLI are typically complicated by medically significant comorbidities including advanced age, diabetes, renal insufficiency, coronary artery disease, and cerebrovascular disease, among others. Such patients are at increased risk of surgical revascularization complications, rendering percutaneous options more attractive. However, these same medical issues may complicate percutaneous revascularization.

Taylor and Palmer published the angiosome concept in 1987, describing a three-dimensional model of human anatomy segregated into 40 blocks of tissue fed by source arteries. Its initial clinical application was centered on healing surgical graft sites for operative wounds and plastic surgery reconstructions. More recently, the angiosome concept has been shown to help successfully guide tibial vessel selection in optimizing revascularization strategies for surgical and endovascular CLI therapies.

The angiosome concept is part of a new paradigm in the treatment of CLI that aims to simplify these complex cases and gives the vascular specialist a framework to guide therapies.

Traditional Approach to CLI

The first issue in treating CLI is determining the acuity of the clinical scenario. In truly acute presentations, it’s urgent that patency of the affected vessels be restored. With subacute or more chronic presentations, the traditional approach has been to consider staged or sequential revascularizations, focusing first on inflow and subsequently on infrainguinal and infrapopliteal lesions.

Indeed, the 2011 American College of Cardiology/American Heart Association update to the guidelines for managing patients with PAD suggests that patients with CLI should undergo outflow interventions only after an incomplete response to inflow therapy, a recommendation carried over from the 2005 document. This recommendation is afforded Class I status despite having the lowest caliber of evidence (Level C, expert opinion).

However, staged vascular procedures carry additional risks: vascular access, sedation, contrast, radiation, healthcare costs, and disruption of patient’s lives. Additionally, patients are (appropriately) often reluctant to accept a wait-and-see approach and wish for definitive procedures. So in many cases, I choose to optimize the endovascular treatment with a single procedure to re-establish inflow and the key tibial vessel. The angiosome model drives the choice of tibial runoff target.

The Angiosome Model

The human body has been divided into 40 discrete angiosomes. With regard to foot ulcerations, six territories are described according to the anterior tibial (ATA), posterior tibial (PTA) and peroneal (PA) arteries (see Figure 1 on page 5).

The ATA arises from the popliteal artery and courses anterolaterally in the anterior compartment, then crosses the dorsal aspect of the shin and over the ankle joint, where it becomes the familiar dorsalis pedis (DP) pulse. With this anatomic path in mind, it becomes easy to identify the anterior tibial angiosome.

The popliteal artery continues after the ATA separates and becomes the tibioperoneal trunk (TPT). From here, the TPT divides into the PTA and peroneal (PA) arteries. The PTA travels in the deep posterior compartment and follows the medial aspect of the tibia. It tucks behind the medial malleolus, where it’s typically identified on exam, and wraps along the plantar surface of the heel. Under the heel, it gives off medial calcaneal branches, and then divides into a medial plantar and lateral plantar arteries. These two arteries feed the plantar aspect of the foot (Figure 1).

The PA is the other branch of the TPT, running along the posterior side of the fibula in the superficial posterior compartment. As it terminates at the ankle, it gives off lateral calcaneal branches for its own angiosome distribution, as well as named collaterals that perfuse the AT and PTA. One of the PA’s key aspects is that it’s the most in-line continuation of the popliteal artery. When the popliteal artery is occluded and there are no visible tibial targets, crossing catheters and wires will most commonly enter the PA, allowing revascularization. PA collaterals can at times be used.
to perform retrograde revascularization of occluded tibials via antegrade femoral or retrograde pedal access.

**Selected Data Supporting Angiosome-based Revascularization**

Surgical bypass and endovascular revascularizations are accepted options for treating patients with CLI and promoting healing. Retrospective analyses of both approaches show that direct revascularization (DR) — in which the target artery for reperfusion is the one associated with the ischemic angiosome — is associated with higher limb-salvage rates than indirect revascularization (IR), in which a non-angiosome-based vessel is targeted.

Neville et al reported on 48 consecutive patients with 52 non-healing ulcerations who underwent tibial bypass over a 2-year period. In a retrospective analysis, DR was associated with a fourfold lower rate of amputation rate when compared with IR (9.1% vs. 38%, $P = 0.03$) (Figure 2). Similarly, Iida et al reported on 329 consecutive patients with 369 ischemic limbs managed with endovascular therapy, and found freedom from major amputations at 4 years, and overall amputation-free survival was significantly higher among patients treated with DR versus IR (Figure 3).

These analyses are limited by their retrospective nature and, therefore, cannot control for decisions made by individual treating physicians in choosing the revascularization targets. Not all DR targets will be suitable for grafting, nor will all DR targets be crossable or revascularizable from the endovascular perspective. Nonetheless, these and other data suggest that, whenever possible, an angiosome-based direct approach may be preferable to an indirect one. Ideally, a randomized, blinded clinical trial would be performed to determine if DR is superior to IR, but this type of trial would be challenging to populate, as providers familiar with the angiosome concept are unlikely to feel satisfactory clinical equipoise for such an investigation.

**The Angiosome in Context of the BASIL Trial**

Perhaps the most significant change regarding CLI in the updated guidelines statement was the statement that a patient’s overall prognosis should be considered when determining whether to use surgical or endovascular revascularization. The new statement indicates that, in patients likely to survive longer than 2 years, a surgical approach is preferable to an endovascular one. This is based on two key observations of the large Bypass Versus Angioplasty in Severe Ischemia of the Leg (BASIL) Trial. Patients first treated with bypass enjoyed improved overall survival and amputation-free survival. Furthermore, among patients who first underwent endovascular therapy and failed, outcomes were significantly worse than for patients who underwent primary bypass.
Preventing Critical Limb Ischemia

Supplement to Podiatry Today® and Vascular Disease Management®

On the surface, these findings might suggest endovascular therapy’s role in CLI should be limited. However, it’s worth noting many limitations on the general applicability of these findings relative to real-world practice.

First, the trial suffers immediate obsolescence when published relative to modern endovascular care. Indeed, patients currently treated endovascularly for CLI have the options of treatment with many devices that might increase salvage and patency rates, including atherectomy and covered, self-expanding stents (including the use of coronary drug-eluting stents for tibial vessels, albeit off-label). Patients in the BASIL Trial were treated with balloon angioplasty; a minority underwent endovascular stenting. Anatomic analysis of the angioplasty treatments suggested that few patients underwent tibial reconstruction, and no data describe the thoroughness of endovascular reconstruction. Therefore, it’s unclear if an optimal strategy was pursued, although the suggestion is that it wasn’t.

Second, only 10% of patients with CLI at the participating centers were enrolled in the study. This leaves the remaining 90% of patients (the “real world” patients) out of the analysis.

Third, there is no subgroup analysis that guides us regarding the anatomic patterns that may be better suited to bypass than the endovascular approach — a key factor in clinical practice.

Fourth, a practitioner’s ability to reliably discern patients most likely to survive to 2 years (and hence be most likely to derive benefit from surgical revascularization) is suspect at best. A subsequent analysis attempted to develop a predictive model of survival, but the model requires prospective validation and cannot predict outcomes for individual patients.6

Additional limitations of the BASIL Trial have been expertly described by Conte.7 As a result, while the study’s findings are thought-provoking, they require additional validation and support before the conclusions can carry the weight of evidence beyond opinion. Regardless, angiosome-based revascularization is associated with improved limb-salvage rates using endovascular and surgical approaches, so the type of revascularization is less important than re-establishing flow to the correct territory to promote wound healing.

Conclusion

CLI is the most severe form of PAD and carries a significant risk of amputation, morbidity and mortality. Revascularization in this setting is complex, as CLI is typically a function of multi-segmental disease, and patients generally have significant comorbid conditions. The optimal strategy for revascularization — endovascular or via surgical bypass — remains an area of active research and debate, but ultimately is a combination of lesion, patient, operator and local resource characteristics. However, the angiosome concept provides an important framework that guides the vascular caregiver to choose the optimal target for re-establishing inline flow to the ischemic distribution. A definitive randomized clinical trial would provide an interesting challenge to this hypothesis but is unlikely to be performed.

References


Figure 3. Long-term outcomes in patients with CLI treated with direct versus indirect revascularization.
Critical limb ischemia (CLI) results from severe compromise of blood flow to the affected extremity and manifests as rest pain, ulceration or gangrene. It’s usually caused by multi-segmental obstructive atherosclerosis, but may be caused by atheroembolic, thromboembolic or vasculitic disease (Table 1). With the staggering increase in the number of CLI cases, primarily due to smoking and the diabetes pandemic, it’s vital that a dedicated multidisciplinary team treat patients to save limbs and lives. A successful team should feature a strong partnership between the podiatrist and the interventionalist.

Scope of the Problem

In 2003, more than 2.5 million Americans had CLI, and there were more than 240,000 amputations in the United States and Europe.¹ Primary amputation was the initial treatment in 67% of these patients and, surprisingly, 50% were performed without angiography or even an ABI.¹

Risk factors for developing CLI include age (older than 65), hypertension, hyperlipidemia and abnormal ABI. The most lethal risk factors for CLI are smoking and diabetes. The number of cases of diabetes mellitus (DM) has swelled from 30 million to 230 million in the last 20 years. Diabetes increases CLI risk fourfold; smoking triples the risk.² Diabetic patients with CLI are 10 times more likely to require amputation than non-diabetics.³ Worldwide, a limb is lost every 30 seconds to diabetes.⁴

Fate of the CLI Patient

The CLI patient faces a poor prognosis, principally due to death from cardiovascular and cerebrovascular disease. As depicted in Figure 1, 25% will die within 1 year, and 50% will die within 5 years. A year after initial presentation, 30% are alive with amputation and, after 2 years, 15% will require above-knee amputation, and 15% will undergo contralateral amputation (Figures 2 and 3).⁵

How Podiatrists and Interventionalists Can Improve CLI Outcomes

Primary care providers often don’t ask patients at risk for CLI to remove their shoes and socks, nor do they perform thorough pulse examinations or detailed vascular histories. As such, podiatrists are frequently the first healthcare professionals to actually see CLI manifest.

Table 1. Critical Limb Ischemia Definition

<table>
<thead>
<tr>
<th>Persistent recurring ischemic rest pain</th>
<th>Requiring opiate analgesics for at least 14 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ulceration or gangrene of the foot or toes</td>
<td>ABI &lt; 0.40</td>
</tr>
<tr>
<td>Toe pressure &lt; 30 mmHg</td>
<td>Systolic ankle pressure &lt; 50 mmHg</td>
</tr>
<tr>
<td>Flat pulse volume waveform</td>
<td>Absent pedal pulses</td>
</tr>
</tbody>
</table>

Adapted from Norgren L, Hiatt WR, Dormandy JA, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). Eur J Vasc Endovasc Surg. 2007;33 Suppl 1:S1–75.

Figure 1. Survival of patients with peripheral arterial disease. Adapted from Norgren L, Hiatt WR, Dormandy JA, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). Eur J Vasc Endovasc Surg. 2007;33 Suppl 1:S1–75.

Patients should be asked about their atherosclerosis risk factors and symptoms of claudication, and should fill out a walking impairment questionnaire, (e.g., the WHO/Rose or Edinburgh Claudication Questionnaire).⁶ In the physical exam, document blood pressure in both arms, assess cardiac murmurs, palpate for abdominal aortic and popliteal aneurysms, perform a thorough pulse exam, and listen for bruits. CLI patients often present with ischemic ulcers or gangrene. Ulcers above the ankle are frequently venous; foot ulcers may be neurotrophic due to DM or underlying ischemia. Document ulcer size, location and type. Promptly refer CLI patients to the interventionalist for diagnostic evaluation and candidacy for revascularization.
Diagnostic Evaluation

Diagnostic evaluation usually begins with an ankle-brachial index (ABI). Evaluate toe pressure or transcutaneous oxygen tension in patients for whom ABI may be unreliable (e.g., those with medial calcinosis, DM or renal failure). Reduced ABI has been shown to be a powerful predictor of future cardiovascular events; the lower the ABI, the higher the risk.\(^8\) Duplex ultrasound and pulse volume recordings are useful for defining the severity and level of disease, and to plan intervention. CT and magnetic resonance angiographies can better evaluate aorto-iliac and distal infrapopliteal diseases, respectively. If the patient is deemed a candidate for revascularization, angiography can be used to confirm the diagnosis and define treatment options.

Treatment of CLI

The primary goals of CLI treatment are to relieve ischemic pain, heal ulcers, prevent limb loss, and improve function and quality of life for the patient. CLI patients who develop cellulitis or spreading infection require systemic antibiotic therapy. Figure 4 presents a general treatment algorithm for the CLI patient. Podiatrists are vital to implementing limb-loss prevention strategies including: education about self-care of the feet; provision of conforming orthotics and shoes; and aggressive wound care, such as debridement, dressings and skin grafting.

Before revascularization, all patients should undergo risk-factor modification, such as smoking cessation, statin therapy to reduce LDL cholesterol to < 100 mg/dl, glucose control to achieve HgA1c < 7.0%, BP < 140/90 mmHg, BP < 130/80 if diabetic or renal disease, and antiplatelet therapy with aspirin or clopidogrel. Given the high prevalence of coronary artery disease (CAD) in patients with CLI, evaluate for evidence of CAD. Manage patients with clinical evidence of heart disease — as manifested by angina, congestive heart failure or symptomatic arrhythmias — according to current guidelines.\(^9\)
Routine coronary revascularization in preparation for vascular surgery or endovascular intervention isn’t recommended, except for individuals found to be at very high risk.¹⁰

**Revascularization Strategies**

Multi-level disease is common in CLI. As such, general principles subscribe to first correcting inflow, and then outflow with the goal of establishing in-line flow to the foot. More recent guidelines call for providing direct flow to the ischemic angiosome, the composite anatomic vascular territories of skin and underlying muscles, tendons, nerves and bones, based on segmental or distributing arteries.¹¹ Successful wound healing, whether accomplished by open bypass or endovascular therapy, is accomplished in 91% and 87% of patients, respectively, if the proper angiosome is revascularized.¹²,¹³

The risk of the intervention and expected degree and durability of improvement determine the revascularization method. CLI patients are often elderly with multiple comorbidities, and the goal is not primary patency of the intervention, but limb salvage. Endovascular techniques are therefore preferred for most patients. Surgery is reserved for patients with failed endovascular procedures, long occlusive disease or recurrent restenosis, who are healthy enough to undergo open repair or bypass. Primary amputation may be appropriate in cases of unreconstructable arterial disease, persistent infection, sepsis or in the presence of paresis with an uncorrectable flexion contracture.

Specific endovascular techniques and devices are beyond the scope of this paper. Generally, aortoiliac inflow disease is treated with stenting because stents are more durable over balloon angioplasty/percutaneous transluminal angioplasty (PTA). Common femoral and ostial profunda femoris lesions are best treated with local endarterectomy and patch angioplasty in patients who are good surgical candidates. Infrainguinal lesions may require plaque-debulking technologies. For heavily calcified lesions, orbital atherectomy and rotational atherectomy may be used alone or with PTA and stenting. A plaque-excision atherectomy device may be used to remove obstructive atheroma, particularly in arterial segments where stents are to be avoided, such as the common femoral, profunda femoris, behind-the-knee popliteal and tibial vessels. Laser atherectomy may be used to photoablate plaque and is preferred for treating in-stent restenosis.

Infrainguinal vessels are often occluded in patients with CLI. The development of dedicated chronic total occlusion (CTO) devices has significantly increased the success rates of CTO traversal, up to 90%, in our practice. They include controlled micrdissection, ultrasound-energy-emitting and spiral-wedge-turning devices. When these devices result in subintimal passage, specialty-needle lumen-re-entry devices allow wire access to the reconstituted true lumen.

PTA is reserved for short, focal lesions due to vessel recoil, a high risk of restenosis and the risk of arterial dissections in long, calcified lesions. Self-expanding nitinol stents provide intravascular scaffolding and seal dissections after PTA, and have proven to provide good short- and mid-term patency in lesions up to 10 cm long. Covered stents efficaciously seal perforations and treat longer segment lesions. This nitinol stent is covered with a PTFE and has heparin covalently bonded to the endoluminal surface.

Anatomic factors that limit patency include severity of disease in the run-off vessels, length of the stenosis/occlusion, small vessel diameters and number of lesions treated. Adverse clinical variables include DM, renal failure and ischemia severity. All patients undergoing endovascular treatment require anti-platelet therapy with aspirin; clopidogrel is additionally used in patients undergoing stent implantation.

---

[Figure 4. Adapted from Norgren L, Hiatt WR, Dormandy JA, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). *Eur J Vasc Endovasc Surg*. 2007;33 Suppl 1:S1–75. Cannot be reprinted without permission of HMP Communications]
Post-Revascularization Management

After revascularization, the interventionalist must communicate with his/her podiatric colleague to review the angiographic findings and revascularization procedures. The new medical regimen is reviewed, and the timing of any additional procedures is discussed. Coordination of wound care and adjunctive therapies — such as hyperbaric oxygen treatment, systemic antibiotics and possible need for amputation — are discussed and agreed upon.

The podiatrist again assumes the primary role in successful limb salvage. Pre- and post-revascularization, the podiatrist treats the ulcer patient with offloading, achieved by several methods, including shoe modifications, orthotics and casting techniques. Although discussing each ulcer product in depth is beyond the scope of this article, the principles of wound care should be faithfully followed. Chief among them is removing infected/necrotic tissue from the ulcer, treating infection, and maintaining a moist environment to promote ulcer healing.

The interventionalist must routinely follow the CLI patient with ABI and duplex ultrasound surveillance to assess the patentcy of the endovascular or surgical bypass site. Return of claudication or rest pain, drop in ABI or elevated Doppler velocities at the treated segment likely represents restenosis, mandating prompt angiography and repeat revascularization to avoid vessel re-occlusion.

The podiatrist can frequently recognize impending treatment site failure by noting slowed wound healing, worsening pulse exam, elevation pallor and dependent rubor, ulcer growth, or new areas of ischemia on the toes and foot. In such a case, the interventionalist should be contacted to assess vessel patency.

Both the podiatrist and interventionalist should use every office visit to reinforce risk factor reduction strategies, medication compliance, and engage patients in playing active roles in their care. By partnering, the interventionalist and podiatrist can save both limbs and lives.

Partnering for Interdisciplinary Care

When the podiatrist recognizes and diagnoses CLI and PAD, and there’s a lesion such as a wound on one or both feet, the podiatrist should properly treat and debride the wound, then refer the patient to the vascular specialist for examination and treatment of the PAD. Similarly, the vascular interventionalist should refer the patient back to the podiatric physician for continued treatment of the lower-extremity wound. This is the ideal path for overcoming the patient’s disease state.

To that end, it’s critical that the podiatric physician who has diagnosed CLI and PAD maintain a working relationship with the vascular interventionalist. This relationship should be based on competency, knowledge, trust and friendship. Face-to-face contact between the podiatrist and interventionalist is the easiest and best way to start a working relationship.

In our experience, podiatric and vascular interventionalist practices complement one another. They not only can refer patients back and forth, but prevent lower-extremity amputations in many diabetic and non-diabetic patients.

In the large urban area where we practice, it’s very easy to find this type of approach to CLI. It might not be that way in smaller communities. Either the podiatrist or interventionalist must take the initiative to start such a relationship. Don’t hesitate to pick up the phone to discuss referring patients to one another. This team approach is critical to preventing lower-extremity amputations, and patients’ lives may depend on it.

References
A mputation is no longer an acceptable first option for patients with critical limb ischemia (CLI). This is primarily because rapidly evolving technology, including less-invasive endovascular and hybrid (combined surgical and endovascular) procedures, and clinical follow-up with podiatry and wound care specialists are more likely to lead to amputation prevention. Due to post-amputation consequences, immediate revascularization should be the first step in treating patients with CLI to prevent the comorbidity associated with limb loss.

Unfortunately, this primary goal is achieved in only a minority of patients. In a recent series, only 40% of patients with CLI received prompt revascularization. This low rate is explained partly by late referrals and the fact there’s no agreed upon definition of a non-salvageable limb.

With currently available, swift vascular therapeutic options, the issue remains how to identify and refer CLI patients early to ensure the complete benefit of early revascularization in conjunction with podiatric, wound care and diabetic specialists. The answer lies in a multidisciplinary team approach, which we believe has been shown to lower amputation rates.

**Evolution of Centralized Care**

The term “wound care center” was not part of the specialty’s vocabulary as recently as approximately 20 years ago. The concept of a central location where individuals with chronic or non-healing wounds could receive intensive care and advanced treatment has gone from a novel medical concept to a well-established service and has become a common term in the process. By taking the team approach found in other areas of medicine (stroke teams, burn teams) and applying it to wound care, we have not only improved outcomes for many suffering patients, but raised the bar by creating a demand for greater research, clinical practice, standardization and improved outcomes.

The team approach to wound care has been validated through retrospective analyses and the number of positively affected lives. Evidence has shown that a team approach to managing diabetes is an effective way to avoid or postpone the onset of serious complications. The Nashville, TN, Department of Veterans Affairs Medical Center used the Preservation Amputation Care and Treatment program and demonstrated a 40% decrease in the number of lower-extremity amputations over the past 5 years. The program has decreased the costs of pharmaceuticals by 48%, lab studies by 32% and inpatient bed days by 44%. Concomitant to the team approach, lower-extremity preservation and the use of limb salvage, limb preservation and amputation prevention has increased.

The acute risk of mortality and morbidity facing patients with CLI necessitates critical urgency for limb preservation, particularly given the aging population and the number of patients with diabetes increasing at an alarming rate, both in the United States and worldwide. The financial impact and the inherent issues associated with lower-extremity amputation compound the importance of lower-extremity preservation.

Patients suffering from non-healing, lower-extremity wounds and CLI often have multiple comorbidities requiring multiple specialties. Patients with CLI are among the most complicated to treat and, as a result, a specialized team is best suited for managing limb-threatening complications.

Better understanding of the need for limb preservation and development of breakthrough technologies have given rise to a concept similar to that of wound care centers — increasingly referred to as limb-salvage, limb preservation and amputation-prevention centers. This model inherently incorporates the need for a team approach. Not that the team members need work under the same roof. Rather, the concept should be community-centered — whether hospital-
based, private-practice-based or a combination — to develop processes for screening, evaluation, treatment and follow-up, with the collective goal of achieving the best outcomes.

The Multidisciplinary Team

Members of the multidisciplinary limb preservation team include those typically found in a wound care team or center. The members include primary care physicians, podiatrists, nurse practitioners, physician assistants, internists, hospitalists, cardiologists (interventional and non-interventional), vascular surgeons, radiologists (interventional and non-interventional), infectious disease specialists, DM specialists, endocrinologists, plastic surgeons, orthopedic surgeons, nephrologists, neurologists, nurses, case managers, physical therapists, certified pedorthists, patient caregivers and, most importantly, patients themselves.

The team approach can be summarized by three points: a high level of primary medical team awareness; dedicated foot clinics; and inclusion of multiple disciplines. The care provided by the disciplines should coordinate diagnosis, offloading, preventive care and revascularization procedures; aggressively treat infections; and manage medical comorbidities.

An invasive vascular specialist incorporates the necessary diagnostic modalities and endovascular/surgical therapies to provide an inside-out approach to restoring the blood flow to the affected wound. Angiography plays a vital role in the decision-making process of a vascular specialist.

The role of the podiatrist is paramount to the success of any multidisciplinary limb-preservation team. Podiatrists serve as the front line in identifying those at increased risk for amputation, and their surgical expertise often is the difference between the amputations of a toe and a higher-level amputation, such as below the knee or higher.

Communication with other members of the team often begins with the podiatrist, who must know when to make appropriate referrals, especially when moderate to severe
peripheral arterial disease (PAD) is suspected or observed. Developing a working relationship with a vascular interven-
tionalist (cardiologist, vascular surgeon or radiologist) should be mutually beneficial and ultimately benefit patients at high risk for amputation.

In a multidisciplinary therapeutic treatment flow, the cycle of therapy does not always start in the office of the same specialist (Figure 1). A patient with CLI may enter the multidisciplinary cycle via a podiatry office, primary care practitioner, wound clinic or vascular specialist. Whatever the point of entry into the cycle (Figure 2), the patient should receive the appropriate care each specialist can offer.

**Approach to Patient Evaluation**

The success of a patient’s experience (including evaluation, therapy and recovery) who presents with critical limb ischemia requires a collaborative approach to all aspects of care using the following criteria.

**Thorough Physical Exam**

The physical examination can significantly increase the diagnostic accuracy in patients evaluated for suspected PAD. A systematic approach using palpation, auscultation and inspection is quite effective. Blood pressure should be measured in both arms. The examiner should palpate the femoral, popliteal, dorsalis pedis and posterior tibial pulses, and note the amplitude and symmetry in each territory. Carefully inspect the extremities and note the color (e.g., cyanosis, pallor), temperature, distribution of hair growth, and presence of trophic skin or muscle changes.

PAD and CLI remain clinical diagnoses that should be classified for severity according to either the Rutherford or Fontaine classification. Multiple modalities can aid CLI diagnosis, particularly when examining peripheral pulses at baseline. A provider who is unable to palpate pulses should document the pulse by an arterial doppler (triphasic, biphasic, monophasic). An ankle-brachial index (ABI) is an adequate starting point to assess the significance of the disease. An ABI test can be easily performed and interpreted by the performing discipline. A transcutaneous partial pressure of oxygen (TcPO2) is another measurement that can be used in a podiatry or wound clinic setting. A TcPO2 less than 30–50 mmHg is consistent with CLI and poor healing. Currently available technology lets skin-perfusion pressure be done within 4 minutes and doesn’t require the recalibration needed with older-generation TcPO2 machinery. Skin-perfusion pressure should be routinely measured in all patients with Rutherford grades IV–VI.

**Computerized Tomography and Magnetic Resonance Angiographies**

Computerized tomography angiography (CTA) and magnetic resonance angiography (MRA) are two noninvasive modalities that can, despite their limitations, better define the vascular anatomy of patients with CLI.

Multiple studies have demonstrated that CTA of the ex-
tremities accurately detects arterial occlusions and stenosis > 50%. CTA usually requires an IV injection of 100–200 ml of iodinated contrast, and exposure to radiation. CTA is limited by poor visualization of vessels with heavy calcification, artifact from stented vessels, venous opacification, and decreased spatial resolution when compared to digital subtraction angiography.

MRA with gadolinium contrast enhancement is very effective for diagnosing the anatomic location and degree of stenosis in PAD. A recent meta-analysis demonstrated MRA’s superior accuracy compared to arterial duplex ultrasound in detecting arterial stenosis > 50%. Limitations of MRA include mainly an overestimation of the degree of stenosis due to turbulence, artifact due to metal clips, and association of gadolinium toxicity in patients with renal insufficiency.

**Arteriogram With Run-Off**

Arteriogram (or CTA, MRA) with run-off to the digital branches of the foot is done primarily to evaluate the aortoiliac and superficial femoral arteries. Arteriogram has shown to less accurately visualize the tibial arteries and their collaterals, especially, the communicating collaterals. The pedal vessels are also under-visualized in most cases. In the authors’ opinion, retrograde angiography using tibial access might highlight different vascular conduits.

**Selective Angiography**

Selective angiography with and without vasodilators must be performed. Amputation should never be recommended without having performed combined antegrade retrograde selective angiography.

**Tibio-pedal Access and Angiography With and Without Vasodilators**

This is an absolute must in all CLI cases previously deemed not salvageable. The data collected from retrograde access almost always changes the therapy path from major amputation to either minor or no amputation. Another important element is determining the true lesions and lesion lengths. It lets operators accurately visualize the length of the chronic total occlusion (CTO).

A single tibial access angiogram usually opacifies most of the tibial arteries and their branches. The antegrade flow is delayed to the tibio-pedal bed due to either high-grade stenosis or CTO. This causes low-pressure states in the tibio-pedal vessels distal to the lesion, which can cause vasospasm and a low-flow state, which causes it not to fill the entire length of its patent vessel. This appears to be a long CTO when the reality is a short CTO or subtotal occlusion.

**Angiosome Mapping**

Cutaneous and arterial angiosome mapping is easy to perform. Cutaneous angiosome is straightforward and should be done on all patients with Rutherford V and VI ischemic tissue. Arterial angiosome mapping defines whether blood perfusion is reaching the target tissue via direct or indirect arterial flow. In our experience, a long tibio-pedal CTO can easily be reduced to a short-segment CTO just by adding a retrograde angiogram via tibio-pedal access.

**Treatment**

Interdisciplinary discussions and referrals, advances in pharmacological therapy and wound care treatment, and more successful foot surgery provide more options for treating complex disease. Excellent femoral, tibial and hybrid endovascular procedures provided by multiple specialties have improved revascularization success in critically ischemic limbs that otherwise would have been unsalvageable a few years ago.

**Outcomes/Follow-Up**

It’s difficult to identify objective performance goals in patients with CLI. The Society of Vascular Surgery has pro-
posed the use of major adverse limb events (MALEs) as a primary end-point to determine such goals. MALEs include amputation or any major vascular intervention with 30 days. With the rapidly evolving techniques and the significant impact of revascularization on a patient’s life, clinical trials should focus on quality of life as a primary measure to evaluate outcomes.

Podiatrists and wound clinics should closely follow up with CLI patients who undergo complex revascularization. It’s important to document treatment response and the healing process, particularly in patients with non-healing foot ulcers. There are multiple questionnaires that can help with this. By the same token, deterioration or therapy failure can be recognized by the patient’s wound care specialist or podiatrist, and triage to appropriate therapy can be initiated. Reasonable follow-up modalities include post-procedure ABIs, screening arterial Doppler ultrasound and measuring tissue oxygenation.

Successes of the Team Approach

System changes have had a major impact on management of the diabetic foot during the past decades. Comprehensive multidisciplinary foot-care programs have been shown to increase quality of care and reduce amputation rates by 36% to 86%.

Take, for example, the work of the Save a Leg, Save a Life Foundation. The foundation — originally a local, informal, lunch-and-learn/journal club — was later incorporated as a non-profit. Its primary purpose is to increase education among healthcare providers, specifically in wound care and PAD. Through a series of local meetings initially focusing on home health nurses, the message quickly spread to other providers who were similarly interested in these topics. In approximately 1 year, the group grew from 15 members to more than 100.

The regular gatherings began to form relationships within the community. In turn, these relationships positively affect-
ed quality of care. The desire to quantify this impact was the impetus for gathering data regarding lower-extremity amputation rates for the period from 2 years before and 2 years after the organization’s founding.

Data were obtained from the Agency of Health Care Administration, the Duval County Department of Health (Jacksonville, FL) and local hospitals, and amputation rates for the 4-year period were analyzed (Figure 3). The most striking data revealed some unanticipated and significant findings, centering on Memorial Hospital of Jacksonville. Among our conclusions were that the multidisciplinary approach, expedited by regular educational meetings, helped develop relationships — and the teams within a community had lowered amputation rates and increased limb-salvage rates (Figure 4).

In Singapore, the LEAP (lower extremity amputation prevention) group showed its multidisciplinary approach to amputation prevention resulted in a lower amputation rate (29% versus 76%, P = 0.00001), lower related death rate (1% versus 19%, P = 0.00001) and fewer in-hospital days per patient (17.8 days versus 23.16 days, P = 0.048) as compared to the standard clinical practice group.

The LEAP strategy also generated significant cost savings per patient during admission when compared with the pre-LEAP approach. The LEAP strategy dominated standard practice in the management of patients with DM and CLI. In essence, the implementation of this multidisciplinary approach significantly improved patient outcomes and reduced hospital stays.9

Conclusion

Approximately 30,000 to 40,000 Americans undergo amputation annually. In 2008, an estimated 1.6 million Americans were living with an amputation, and it is estimated that by 2050, 3.6 million will be living with an amputation.10 With the advancements described herein, does it make sense to perform major amputations (above- or below-knee) without fully evaluating other options? We emphatically say “No.”

In addition, we’re facing a major ethical dilemma. Many limb-salvage specialists are successfully revascularizing patients who have been told they had no options. Unfortunately, many of these patients had received gloomy recommendations without the benefit of an adequate evaluation (selective angiography, etc.). Today, no patient should undergo amputation without a full amputation-prevention assessment followed by attempted revascularization using the appropriate surgical, endovascular or hybrid approach. In short, amputation should be the treatment of last resort, used only when all other options have been exhausted, and should be described as treatment failure.11

References


Diagnosing a patient with critical limb ischemia (CLI) requires the podiatrist to perform a detailed history along with physical, vascular laboratory and possible referral angiographic examinations. Although the evaluation is not as urgent with CLI as it is in acute limb ischemia, thoroughly evaluating each of these areas in a semi-urgent manner can prevent tissue loss and a more distal amputation (should it come to that).

History and Initial Physical Evaluation

The patient’s presentation history plays an important role in the evaluation of CLI. The onset of the disease process needs to be known to help differentiate CLI from acute limb ischemia. This distinction is quite important, because the prognosis, evaluation and treatment differ between the two scenarios. An abrupt change in foot color — bluish discoloration, with an acute onset of foot pain — could very well point to an acute ischemic event of that lower limb. These events, compared to the more chronic in nature CLI changes, must be treated as an acute emergency to avoid limb loss.

The vascular history should include evaluation for arterial disease in other sites (e.g., carotid, coronary), global risk factors for atherosclerosis, and history of trauma or other incident that may have caused skin breakdown. Shoe wear can be the inciting element and should be evaluated both in the history and the exam. Patients who have exhibited CLI symptoms previously remain at risk for recurrent symptoms or signs of CLI. Prior bouts of CLI, along with their treatments and outcomes, can assist the clinician with the current episode.1

The physical examination of the lower extremity with suspected CLI begins with an overall perusal of the bilateral lower extremities. Signs of chronic ischemia include dependent rubor, lack of hair growth, pallor on elevation, atrophic shiny skin, nail dystrophy and delayed capillary refill time.1 In our experience, an ominous sign of peripheral aterial disease (PAD)/CLI is when subcutaneous tissue atrophy can be seen at the ends of the toes (Figure 1). The atrophy and the loss of elasticity of the subcutaneous tissues prevent rebounding of the subcutaneous tissues when pressure is applied to the end of the toe. We liken this sign to a baked potato that has been over-baked and lost its shape (Figure 2).

Palpation of Pulses

Palpation of the lower-extremity pulses is another aspect of the physical exam necessary for diagnosing CLI. Although there are several grading systems for lower-extremity pulses — such as the four-level grading system — a simple “palpable” or “not palpable” will suffice. The literature has reported variance between clinicians when palpitating pulses.2 There may be times when one clinician believes a pedal

---

**Figure 1.** An ominous sign of peripheral aterial disease/critical limb ischemia is when subcutaneous tissue atrophy can be seen at the ends of the toes.

**Figure 2.** Atrophy and loss of subcutaneous-tissue elasticity prevent rebounding of the subcutaneous tissues when pressure is applied to end of the toe — much like an over-baked potato that has lost its shape.
pulse can be felt, while another clinician doesn’t. This subjectivity is to be considered when palpating pedal pulses. Note that both the posterior tibial and the dorsalis pedis arteries have accepted rates of anatomical absences.2

Capillary refill time is another indication of PAD/CLI. The longer it takes the capillaries to refill after the application of pressure indicates the presence of vascular disease. Less than three seconds indicates a normal capillary refill time.3

Ulceration Classification

Any ulceration that’s present should be classified as to its etiology. Distinction should be made between ischemic (arterial), neuropathic, mixed and venous ulcerations. Determining classification is extremely important to ensure appropriate treatment of the ulceration. Each type of ulceration has a unique presentation, letting the clinician differentiate one from another.

Ischemic (arterial) ulcerations occur at the ends of the digits and in the heel area. They’re usually extremely painful, although some patients who have diabetes and peripheral neuropathy may not experience the pain associated with these ulcerations. The ulcer base demonstrates an unhealthy appearance with necrosis present. A hyperkeratotic rim isn’t usually associated with an arterial ulcer. Rather, the neuropathic ulceration presents with a base that is granular and healthy in appearance, usually with a hyperkeratotic rim or covering that rules out a purely ischemic ulcer.

Calculating the Ankle Brachial Index

The calculation of an ankle brachial index (ABI) is the next step in evaluating the patient with CLI. The ABI has been reported to be 95% sensitive to and 99% specific for PAD.4 Performing the ABI helps define the at-risk population clinically and epidemiologically. An ABI index of less than or equal to 0.40 is consistent with CLI.1,4 Although a very useful test, the ABI does have limitations. First, when there are incompressible arteries, the ABI can be falsely elevated. In such cases, use the toe brachial index to provide more information regarding the PAD/CLI spectrum. The ABI also isn’t designed to define the degree of functional limitation. Segmental pressures and pulse-volume recordings in conjunction with the ABI can provide the clinician with further information.

Vascular Laboratory and Imaging

The vascular laboratory can further help the clinician evaluate the patient with suspected CLI. Arterial duplex ultrasound of the lower extremities can diagnose the anatomic location and degree of stenosis present in a peripheral artery. Duplex ultrasound can be used to provide patency information after femoral-popliteal bypass using a venous conduit (Figure 3). This examination of the extremities can also be used to select candidates for endovascular intervention, surgical bypass and selection of surgical sites for anastomosis.

More advanced and invasive tests such as computerized tomography angiogram (CTA), magnetic resonance angiogram

![Figure 3. Duplex ultrasound can be used to provide patency information after femoral-popliteal bypass using a venous conduit. Image courtesy of Joseph Caporusso, DPM](image)
(MRA) and traditional contrast angiography can be used to further detail the extent of the PAD. Each exam has its pros and cons. A complete description is beyond the scope of this work, but a cursory view will be given of each.

The angio graphic image produced by CTA is constructed by multiple cross-sectional images, and then presented in a projection similar to that of a standard arteriogram. This projection can be rotated three dimensionally to view any oblique projection, a potential diagnostic advantage when compared to catheter angiography. A possible disadvantage of CTA versus catheter angiography is the lower spatial resolution. CTA does offer patients with pacemakers, defibrillators, metal clips and prostheses an alternative to MRA. CTA also has a higher resolution than MRA, which can provide images of calcification within the vessel wall. CTA scan times are significantly faster than those of MRA.

MRA is based on imaging the arteries similar to standard arteriography, and has evolved and improved over the years. MRA accuracy depends on the technique used and the standard against which it’s compared. The MRA literature provides somewhat mixed results compared to catheter angiography.4

Contrast angiography has been considered the gold standard for defining both normal and abnormal vascular anatomy. It’s widely available and the most used technique, partly because physicians can easily interpret the images. The addition of digital subtraction techniques enhances image quality to allow better detection of abnormalities. The technological advances in angiography instrumentation have further enhanced the patient safety profile of this technique, although potential complications remain. These include bleeding, infection, vessel disruption, contrast reaction and nephrotoxicity. Less common complications could include artheroembolization, dissection, and vessel wall disruption or perforation.4

The choice of an advanced or invasive arterial angiographic technique may depend on availability on instrumentation/devices, physician experience and regional practice preferences.

Conclusion

When it comes to the treatment of foot ulceration and/or gangrene caused by CLI, the podiatric physician plays the role of both diagnostician and interventionalist. Many times, the podiatric physician is the first to discover the effects of CLI on the feet and, in doing so, sets the necessary mechanisms in motion to help the patient. Coordination of care with the vascular specialist is paramount to successful outcomes. The treatment of CLI and its pedal complications is yet another example of how the multidisciplinary team approach yields the best results. The podiatrist, working in conjunction with the vascular team, affords the patient the necessary holistic care.

References

Peripheral arterial disease (PAD) affects nearly 9 million Americans and significantly increases the risk of heart attack, stroke, and death in that population. PAD can present as leg pain that’s often mistakenly attributed to old age or arthritis. The most serious presentation of PAD is critical limb ischemia (CLI), defined as ischemic rest pain or tissue loss present for more than 2 weeks and arterial insufficiency corroborated by objective testing (see below). Approximately 300,000 patients a year present with this advanced degree of ischemia in the United States. Patients presenting with CLI face a prognosis worse than that of many cancers (Figure 1), yet CLI is often underdiagnosed and not aggressively treated.

Two demographic features suggest that the prevalence of CLI will increase over the next two decades. First, the number of persons 65 or older is expected to increase from 46 million to 80 million. Aging alone may account for a nearly 50% increase in the number of patients presenting with CLI. Second, as the incidence of diabetes mellitus continues to increase, so too will the number of patients with CLI. Optimum care of these patients needs to be multidisciplinary. These patients must have very aggressive treatment of all atherosclerotic risk factors, expeditious revascularization, and meticulous wound management to achieve the ultimate goal of limb salvage.

Restoration of inflow

The pathophysiology of CLI is quite simple. Tissue nutritive demand is greater than the supply, with arterial lesions limiting perfusion of the affected area. This typically occurs in patients with multi-level occlusive disease that affects the aortoiliac, femoral-popliteal, and tibial segments. Microcirculatory defects can also affect flow-regulatory and defense mechanisms. There’s often a combination of contributing factors, including endothelial dysfunction, altered hemorheology and activation of white blood cell count with inflammation. CLI therapy’s goals are relieving ischemic rest pain, healing the wound, preventing limb loss, and improving patient function/quality of life.

Adequate tissue perfusion is necessary for healing ischemic ulcerations. Restoration of inflow must take priority over attempted wound healing or tissue debridement unless there is concern for deep or ascending infection with systemic signs. Objective criteria for defining ischemia include ABI < 0.50, ankle systolic pressure < 50 mm Hg, toe systolic pressure < 30 mm Hg, and transcutaneous oxygen tension <30 mm Hg. The presence of even one of these factors in a patient with a non-healing, lower-extremity wound should dictate that revascularization be achieved to ensure healing.

The natural history of ischemic wounds has been studied

**Figure 1.** Prognosis for patients with critical limb ischemia. Adapted from Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). *J Vasc Surg*. 2007;45(Suppl S):S5–S67.
extensively. Although up to 50% of wounds may actually heal with aggressive wound management, the rate of major amputation is nearly 40% at 1 year from the initiation of wound care if there is no revascularization.3 As such, amputation prevention and limb-function preservation for ambulation rely on timely revascularization.

Options for revascularization include both endovascular and open surgical bypass procedures. The decision-making depends on the anatomical distribution of arterial stenoses/occlusions, medical comorbidities of the patient, morbidity of the procedure (endovascular versus open), the likelihood of limb salvage, and the durability of the revascularization. The Transatlantic Inter-Society Guidelines provide a good framework for deciding.4 Some vascular lesions can be easily treated percutaneously, while others may be better served with an open surgical approach.

Remember, it might not be necessary to focus on achieving long-term patency of the revascularization if the immediate goal of wound healing and limb salvage are met in the short term. For example, the ultimate goal of limb salvage is still achieved if revascularization fails in the future, but the wound doesn’t recur because the entire team is managing the patient, who no longer faces the immediate danger of an open wound.

The definition of “adequate” circulation to the foot depends on the part of the foot involved. The angiosome concept divides the foot into six angiosomes based on the three tibial vessels: anterior tibial, posterior tibial and peroneal.5 Intervention directed toward revascularization of the correct tibial artery and, therefore, the correct angiosome may improve wound healing. In Figure 2, for example, in a patient with gangrene of the dorsum of the foot and toes, revascularization of the anterior tibial artery angiosome resulted in wound healing and limb salvage.

Caring for the Wound

Meticulous wound care is a must. Revascularization alone — without good wound management — has been shown to result in a 5% to 7% major amputation rate.6,7 Accordingly, we developed the following therapeutic algorithm:

1. Aggressive debridement of all devitalized tissues.
2. Culture based antibiotic therapy
3. Expeditious revascularization
4. Advanced wound care therapies as appropriate
5. Hyperbaric oxygen therapy as appropriate
6. Podiatric treatment with minor amputations and excision of osteomyelitis
7. Cessation of weight-bearing on the areas being treated
8. Resumption of weight-bearing/ambulation only with offloading and appropriate support/foot orthotics.

Fortunately, an array of advanced wound-healing technologies is widely available to help turn the tables in favor of limb salvage. These technologies include bioengineered alternative tissues, advanced surgical procedures, negative pressure wound therapy, hyperbaric oxygen therapy, topical growth factors, and advanced active dressings and topical care. In addition, our ability to offload pressure in patients with weight-bearing and decubitus ulcerations has significantly improved.

While detractors may criticize the expense of these newer technologies, we would encourage decision-makers to first review the costs of non-healing ulcerations and amputations to our healthcare system. For example, we already know that an average diabetic foot ulcer costs over $27,000.4 Foot ulcer care costs are four times higher when PAD is associated with the wound.4 And up to 84% of the cost of diabetic foot ulcer care is associated with inpatient hospital stays.4 If new technologies can heal wounds and prevent hospitalizations, they may actually present a major cost containment victory.

When confronted with a non-healing lower-extremity wound in the lower extremity, one of the first challenges is to convert the wound surface into a properly prepared wound bed for the next stage of healing. Topical and systemic means, via conservative and surgical procedures, should be used to rid the wound of biofilm, excessive drainage and non-viable tissue. (Wound bed preparation should be performed after revascularization to prevent unnecessary tissue loss from ischemia.) Once the wound has been prepared and the blood flow is suf-
icient, ultimate wound closure should be achieved via grafting, secondary intention or surgical means. “Reconstructive ladder” is a term that refers to the stepwise decision-making process that should be used to determine the most appropriate way to heal a given wound.

After revascularization comes excisional debridement of the non-healing wound. Remove all necrotic and non-viable tissue from the wound base and the wound margins so that the exudate is reduced to moderate levels, the margins are no longer undermined, and the wound is free from excessive bacterial load. Negative pressure wound therapy (NPWT) is a key technology used in combination with surgical debridement. NPWT applies sub-atmospheric pressure to the wound in the form of an active, closed-suction drain. The negative pressure is also responsible for reduced bacterial count, stimulation of angiogenesis, exercise of the cell membrane and re-approximation of the wound edges. Bioengineered alternative tissues and advanced surgical reconstruction techniques can be applied when the wound is deemed properly prepared for closure.

It’s imperative to determine the wound etiology early in the diagnostic workup. Many diabetic foot ulcers occur on the plantar aspect of the foot, primarily due to abnormal biomechanics during the gait cycle. Given that one of the key goals of limb salvage is that a patient be able to use a limb after wound healing, more than skin coverage is needed at the wound site. Unless the underlying tendon, bone or mechanical abnormality is corrected as part of the comprehensive treatment plan, the patient is almost certainly doomed to suffer wound recurrence after returning to a weight-bearing status.

Case Study

In Figure 3, the patient presents with a non-healing wound after a partial third ray amputation. This wound is fibrotic and probes deeply, but shows no evident abscess formation or ascending infection. Given the relatively stable nature of the wound, a timely vascular consultation is done before any debridement or advanced wound care attempts. The center photo shows the wound after revascularization and subsequent surgical debridement. Now the advanced wound care technologies can be safely applied in the face of restored tissue oxygenation. For this example, bioengineered alternative tissues were combined with NPWT to ultimately provide wound closure and successful amputation prevention/limb salvage.

Conclusion

Communication and teamwork are paramount to limb salvage. This is a high-stakes pathology — major morbidity and mortality are associated with even very distal amputation in the extremity. Literature reviews have repeatedly shown that comprehensive amputation prevention teams can lower the rates of proximal leg amputation significantly. While someone should direct a patient’s care process, there’s no room for ego-driven decisions or isolationism. The team approach simultaneously and rapidly tackles the problem, reassures the family and patient everything possible is being done, and helps spread the liability associated with these challenging case types. Individuals routinely involved in limb salvage include vascular specialists, podiatrists, plastic surgeons, orthopedists, nurse practitioners, physical therapists, infectious disease specialists, rheumatologists, endocrinologists, nephrologists, hospitalists and prosthetists/orthotists.

References

Access, Cross, Intervene and Close

Providing the most comprehensive portfolio to help you save limbs and enhance lives.