THE GLOBAL VOICE OF CRITICAL LIMB ISCHEMIA

Preprocedure, Intraprocedure, and Postprocedure Plans for Care of the CLI Patient

J.A. Mustapha, MD

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J.A. Mustapha, MD Clinical Editor

nterventional therapy to the critical limb ischemia (CLI) patient varies due to many factors, including the severity of the disease. Approaching treatment with a well thought out strategy, from intervention to follow-up care, reduces the risk of complications and increases the chance of successful long-term results. In preprocedural evaluation, to appropriately formulating a feasible path of therapy, the following treatment plan should be considered.

THE INTRAPROCEDURAL STAGE

At the beginning of a procedure it is important to plan a valid exit strategy. This can significantly decrease the amount of, and severity of, access-site complications. Antegrade CFA access should always be done under the guidance of extravascular ultrasound (EVUS) in order to avoid calcium in the vessel, thus allowing for an informed decision in selecting the most appropriate closure device. Intraprocedurally, there must also be constant assessment of the groin and continuous observation of sheath positioning. Many CLI patients present with plaque protrusions, which create irregular vessel lumens. If the sheath becomes dislodged or dislocated, advancing the sheath over a dilator will reduce the chance that plaque will slough off.

Considering the risk of compartment syndrome, it is essential for retrograde tibial approach to be accessed via EVUS. Both the anterior and posterior tibial arteries should be accessed in an area extending from the ankle strap above the ankle joint, to the insertion of the gastrocnemius head. The safest access for the peroneal is medially, midway between the gastrocnemius head and the medial malleolus.

After obtaining antegrade/retrograde access, different techniques for chronic total occlusion (CTO) crossing can be executed. These

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An Update on the VOYAGER PAD Trial: The Need to Study Postrevascularization Antithrombotic Therapy

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William R. Hiatt, MD Guest Editor

evascularization has become a mainstay of therapy for patients suffering from symptomatic peripheral artery disease (PAD) due to its immediate and pronounced impact on symptoms. Though PAD symptoms can be addressed with revascularization, PAD patients remain at high risk for major adverse cardiovascular events (MACE).¹ Major adverse limb events (MALE), such as need for repeat major revascularizations, acute limb ischemia (ALI) and amputations, also constitute a significant risk in PAD,² and there

is emerging evidence suggesting MALE risk is higher in patients who have previously undergone a peripheral revascularization.^{1,3,4} Therefore, treatment considerations in these patients must incorporate short-term (early graft patency and limb health) and long-term (cardiovascular morbidity/mortality) concerns.

Due to the central role of platelets in thrombosis, antiplatelet therapy has been the focus of large cardiovascular prevention studies; knowledge about cardiovascular event prevention specifically in PAD has been gleaned from these studies, but often through subgroup analyses. Both aspirin⁵ and clopidogrel⁶ have shown modest cardiovascular benefit in stable PAD, and aspirin has shown benefits in maintaining graft patency following peripheral revascularization.⁷ However, dual antiplatelet therapy (DAPT) using aspirin with a thienopyridine has failed to demonstrate benefit in a general cardiovascular risk population and in the peripheral postrevascularization setting, as discussed in this article.

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1. Shammas NW, et al. J Endovasc Ther. 2012;19(4):480-8. 2. Dattilo R, et al. J Invasive Cardiol. 2014;26(8):355-60.

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Physiological Steps and Required Elements in Wound Healing

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hronic wounds are defined as those that do not progress through the stages of healing in an organized, timely fashion and are often recalcitrant to healing via standard wound management methods.1 It has been estimated that about 1% to 2% of the general population will develop a chronic wound during their lifetime,² and more than 6.5 million patients in the United States are currently affected by chronic wounds.³ More than \$25 billion is spent annually in the United States for the treatment of chronic wounds,⁴ and this number is expected to rise due to the aging population as well

as increased prevalence of comorbidities such as diabetes mellitus and obesity. According to the US Centers for Disease Control and Prevention, an estimated 36.5% of United States adults have obesity⁵ and approximately 9.3% have diabetes mellitus.⁶ These chronic diseases have a known direct negative impact on the normal wound healing progression.

Acute wounds generally heal in a complex but predictable fashion. When patients fail to progress through these stages of healing, the health care provider must determine the etiology of the stalled wound. To combat the rise in prevalence and cost to the health care system, clinicians should have a comprehensive knowledge of the physiology of wound healing. Proper assessment and management of peripheral arterial supply, bioburden control, and wound bed management can increase the probability of progression toward wound closure.

PHYSIOLOGY OF WOUND HEALING

Following a breach in the skin, the body initiates the healing cascade that consists of four stages, namely hemostasis, inflammation, proliferation, and remodeling. The cellular activity that occurs during this process is complex but predictable. Subsequent to a break in the protective skin barrier, platelets aggregate to initiate a clot. The platelets then degranulate and release/recruit growth factors into the wound, including platelet-derived growth factor (PDGF), epidermal growth factor (EGF), insulin-like growth factor-I (IGF-I), and transforming growth factor- β (TGF- β).⁷ Growth factors are proteins produced by the body that bind to receptors on cells and initiate division, differentiation, and proliferation of cells. Following the recruitment of neutrophils and macrophages, these growth factors released from platelets are removed from the wound and the wound enters the inflammatory stage. During this inflammatory phase, neutrophils and macrophages that are present release inflammatory cytokines such as interleukin-1 (IL-1), interleukin-6 (IL-6), tumor necrosis factor alpha (TNF- α), and matrix metalloproteinases (MMPs) to enzymatically degrade damaged extracellular matrix tissue and expel bacterial contents from the wound.

Following removal of the injured tissue and bacterial debris, the inflammatory cells reduce in quantity and the wound progresses to the proliferative and remodeling stages of healing.⁹ The proliferative phase of healing is an anabolic process whereby fibroblasts produce collagen, endothelial cells produce new vessels, and the wound begins to contract through the action of myofibroblasts. Wounds that have poor tissue oxygenation, increased bioburden, or poor wound bed management have increased risk of prolonged inflammation and failure to progress to this proliferative stage of healing.

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Optical Coherence Tomography for Visualization During Peripheral Interventions

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hronic total occlusions (CTOs) are observed in approximately 40% of patients with symptomatic peripheral artery disease (PAD) and this number is increasing.1 Successfully crossing CTOs with a guidewire and/or support catheter can be challenging in the presence of a resistant fibrous cap, severe calcification, and long lesion length.² Furthermore, a failure to cross a CTO with a guidewire or to re-enter the true lumen beyond the CTO can lead to prolonged procedure time, dissections, and perforations. This is especially important in critical limb ischemia (CLI), where 50% of lesions present as CTOs, and distal flow preservation is paramount for downstream oxygenation of at-risk tissue.³

A majority of CTO crossing technologies relies solely on angiographic imaging for positioning and guidance. While several techniques, devices, and

guidewires have been developed and refined for use in CTOs, the inability of angiography to adequately visualize occluded arterial segments makes intervention in this setting technically challenging. The emergence of optical coherence tomography (OCT) for intravascular visualization allows practitioners to identify arterial structures and tissue location in real time.⁴ Optical coherence tomography technology utilizes near-infrared light to optimize intravascular visualization. This newer technology offers 10 times better spatial resolution than intravascular ultrasound (IVUS) and has been extensively researched in the coronary arteries.⁵ Ocelot (Avinger) is the first CTO crossing device to use real-time OCT technology (Figure 1). Its crossing catheter utilizes spiral wedges to corkscrew the CTO cap, while real-time OCT offers direct visualization to facilitate luminal position.6 This onboard diagnostic imaging enables direct confirmation of luminal crossing, leading to a tremendous safety and efficacy profile.^{7,8}

So, when is the use of OCT-guided crossing devices needed? What value does direct visualization offer the operator? Certainly, long superficial femoral artery (SFA) CTOs with moderate to heavy calcification remain an increasingly prevalent challenge for interventionalists. The Ocelot catheter, with OCT visualization, assures true-lumen tracking and results for safer and more efficient percutaneous interventions. Additionally, OCT guidance provides assistance in flush occlusions, quickly distinguishing catheter location at the proximal cap. Lastly, below the knee, OCT mitigates dissection and subintimal tracking, which may leave distal tissue vulnerable to ischemia. The following case report represents one of the most challenging CTOs, extending from a flush origin of the SFA, through the popliteal and trifurcation vessels, into the distal peroneal and posterior tibial branches. The Ocelot catheter successfully recanalized the complex lesion via the true lumen.

CASE REPORT

A 53-year-old male with a prior history of hypertension and tobacco use was referred with severe rest pain of the left lower extremity consistent with Rutherford category 4 classification. The left lower extremity ankle-brachial index (ABI) was 0.5 and a subsequent angiogram with runoff showed a long 800 mm total occlusion from the origin of the left superficial femoral artery to the reconstitution of the posterior tibial artery at the ankle (Figure 2A). Due to the nocontralateral approach and a flush occlusion, an antegrade approach was not feasible leading to a primary tibial approach.

Ipsilateral antegrade and pedal retrograde access were established. A 5 Fr sheath was inserted in the posterior tibial artery below the ankle, at which point a 0.014" Regalia guidewire (Asahi Intecc) and a 0.014" Quick-Cross support catheter (Spectranetics) were advanced, crossing the posterior tibial (PT) CTO up to the tibioperoneal trunk (TPT). Selective angiogram from below confirmed connection with an occluded TPT segment. The Ocelot PIXL (Avinger) was inserted over the 0.014" wire to the distal cap of the TPT CTO. The Ocelot PIXL was



Figure 1. Design of the Ocelot catheter and real-time optical coherence tomography visualization. Image reproduced with permission from Avinger.



Figure 2. Angiographic images before intervention (A) and after intervention (B).

advanced using OCT guidance to visualize arterial walls and maintain a luminal position. The Ocelot PIXL tracked into the mid SFA where significant luminal calcium was encountered, as evidenced on angiogram. At this point the Ocelot PIXL was aimed medially, away from the calcium via OCT, allowing for the wire to extend past the calcium in an intramedial position. The Ocelot PIXL was then advanced over the wire and back into the lumen all the way up to the proximal SFA, where it successfully crossed through the proximal cap into the common femoral artery via the true lumen. The Ocelot was removed and the wire externalized via the antegrade access site.

Percutaneous transluminal angioplasty (PTA) was performed with a 5.0 mm x 200 mm Evercross peripheral balloon (Covidien) and a 3.0 mm x 150 mm Nanocross balloon then stented with two 5.5 mm X 120 mm Supera peripheral stents (Abbott Vascular) (Figure 2B). Postprocedure ABI improved to 1.0 with progressive resolution of his rest pain and Rutherford category 0 (no claudication) at 1-month follow-up.

TIPS AND TRICKS FOR OPTICAL COHERENCE TOMOGRAPHY INTERVENTIONS

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Pedal Loop Reconstruction: The New Frontier A Step-by-Step Guide to Creating the Pedal Arch

Fadi Saab, MD; J.A Mustapha, MD From Metro Health Hospital, Wyoming, Michigan.



Fadi Saab, MD

eripheral arterial disease (PAD) is a condition that involves atherosclerosis involving major vascular beds. The prevalence of PAD has been increasing worldwide. The number of patients suffering from PAD is expected to increase by 15% in western countries and 30% in developing countries.1 This increase is a reflection of other comorbidities driving the increase in incidence. Patients with PAD suffer from higher morbidity and mortality.^{2,3} Endovascular revascularization of patients with PAD is becoming a front-line strategy. This approach has been adopted by multiple disciplines, including vascular surgery, radiology, and cardiology.

Bypass surgery is an excellent option in appropriately selected patients.^{4,5} However, many PAD patients may not be appropriate candidates for surgical bypass. Endovascular therapy has been fueled by continuous innovation in techniques and devices.⁶ This improvement allows operators to push the boundaries and tackle more distal and complex disease. This explains the migration toward an endovascular-first approach in treating many patients with PAD. Patients with critical limb ischemia (CLI) suffer from life-threatening limb loss. Patients with Rutherford class 5 and 6 CLI have tissue wounds that impact the most distal parts of limbs and ultimately increase the risk for major amputation.

As revascularization techniques improve, our ability to tackle the smallest of vessels is increasing. Pedal vessels are small and complex. However, they supply the foot, and regardless of flow in the tibial circulation, occluded plantar vessels will certainly translate into limb loss if left untreated. The term "pedal loop" refers to the vessels branching off the dorsalis pedis (DP) artery that connect with vessels branching off the posterior tibial (PT) artery within the foot. This article will serve as a road map, describing the anatomy of pedal loops and different techniques to establish revascularization.

PEDAL ANATOMY

Many different variations in pedal anatomy exist. This article will focus on the most common types. The anterior tibial (AT) artery crosses in the foot at the ankle area becoming the dorsalis pedis (DP). The DP generally runs in the medial direction of the great toe, turning laterally to supply the arcuate artery. The arcuate artery connects with the most distal portion of the lateral plantar artery, which, in turn, branches off the posterior tibial (PT) artery. The arcuate artery supplies the dorsal and pedal digital branches. The lateral tarsal branch takes off from the proximal portion of

Pedal loop reconstruction will add another dimension in achieving wound healing and limb preservation. A deep understanding of pedal anatomy, coupled with applying new revascularization techniques, will ultimately improve CLI revascularization outcomes.



Figure 1. Lateral view of the pedal loop showing the calcaneal branch of the peroneal artery (1), the calcaneal branch of the posterior tibial (2), the DP (3), medial plantar artery (4), lateral plantar artery (5), and digital branches (6).

the DP and travels laterally. Commonly, it joins back with the DP distally before supplying the arcuate artery. The peroneal artery typically terminates above the level of the ankle joint. The peroneal artery is responsible for supplying the lateral calcaneal branch of the ankle. This in turn supplies the lateral aspect of the heel. The PT passes posterior to the medial malleolus before dividing into medial and lateral plantar arteries. Before the plantar branches, the PT gives rise to the medial calcaneal branch, supplying the medial aspect of the heel. Within the foot, the plantar branches off the PT, and the DP branch of the AT create the pedal loop. The digital branches arise from this loop and provide the supply to the toes (Figure 1). There are multiple loops that can be created. The most common loop is the lateral plantar to the DP via the arcuate branch. This loop tends to be the most distal and supplies the digital branches (Figures 2A and 2B). Less common loops include a medial loop through the medial plantar artery into the DP.A proximal loop may be created through communication from the tarsal branches into the DP, or it may connect to the PT via collaterals through the metatarsal bone. These variations are important to recognize, thus allowing the operator to create loops depending on vessel patency and availability.

A STEP-BY-STEP GUIDE TO REVASCULARIZATION

1. Evaluate Disease Patterns

Noninvasive assessment in the foot region is variable and unreliable. Basic ankle brachial index (ABI) has no value in these cases, simply because ABIs assess flow at the ankle level. Toe brachial index (TBI) may also be misleading, as it is difficult to perform in patients with wounds. Selective angiography remains the gold standard to define the nature and extent of the disease in patients with tibial/plantar disease. There are two main categories of pedal disease. The first type includes those with tibial vessel involvement and hibernating plantar circulation. Those patients will have CTOs originating in the tibial vessels that reconstitute within the plantar vessels. These CTOs are typically best crossed in an antegrade fashion. The second most common type of pedal disease tends to be more challenging. The tibial vessels are relatively intact and the disease is more focused in plantar vessels. Those lesions will require retrograde crossing of the CTO via the vessel opposite to the occlusion, as described later in this article.

2. Access

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Figure 2. Anterior, posterior (A) and lateral view (B) showing an inflated tapered balloon (2.0/2.5 mm x 210 mm) from the DP through the arcuate artery into the lateral plantar artery.



Figure 4. Distal posterior tibial access in an antegrade fashion for pedal loop reconstruction from the lateral plantar artery to the dorsalis pedis.

SAAB from page 6

chronic total occlusion (CTO) or treating tibial vessels, ipsilateral common femoral artery (CFA) antegrade access should be the preferred access point. Pedal loop reconstruction is no exception. It requires multivessel, multilevel intervention, and an antegrade access will afford the operator superior pushability, trackability, and torqueability. The authors use ultrasound (US) guidance to gain access to any vascular conduit. Pedal loop reconstruction procedures start with CFA antegrade access. Start with a 5 Fr Precision Sheath (Terumo Medical) and, after gaining access, upsize to a 7 Fr, 45 cm Destination Pinnacle sheath (Terumo) (Figure 3). Preferably, reconstruct the pedal loop through the AT to the DP into the lateral plantar artery. An alternate approach is through the PT to the lateral plantar artery into the DP. However in rare cases, accessing the distal AT or PT in an antegrade fashion may be necessary (Figure 4). The vessel is usually occluded proximally, and obtaining access distally allows the operator to navigate through the

pedal circulation to meet another catheter from the other tibial vessel. Consider employing this strategy if crossing the CTO from the CFA antegrade access site is not possible.

3. Chronic Total Occlusion Crossing

Pedal circulation as described above is variable and, depending on the objective, the approach may vary. With pedal loop reconstruction, adhering to the concept of angiosome-directed therapy might offer the guidance needed. Generally, the most common type of pedal loop reconstruction depends on establishing flow from the DP into the lateral plantar artery. This is the most distal loop, and establishing flow perfuses the digital branches, thus healing the most distal wounds. The operator approach may vary depending on the location of the CTO. For example, if the DP is occluded and the distal lateral plantar is involved with the disease, the operator may choose to tackle the DP CTO in an antegrade fashion and cross into the lateral plantar artery. As mentioned above, this CTO will involve the distal tibial vessels where antegrade



Figure 3. Antegrade common femoral artery access with an 0.035" Navicross catheter (Terumo Medical) inserted through a 5 Fr antegrade Precision sheath (Terumo Medical).





Figure 5. Diamondback 360 orbital atherectomy system (Cardiovascular Systems, Inc.) (A). Orbital atherectomy through the lateral plantar artery (B).

crossing is more feasible. However, in the majority of cases retrograde crossing into the occluded segment tends to be easier. This is especially true with plantar CTOs where the distal tibial vessels are relatively preserved. The operator is more likely to be successful in crossing the DP CTO, for example, if approached from the lateral plantar artery in a retrograde fashion. This explains the need for a 7 Fr sheath, allowing catheters in both tibial vessels. Having a continuous flow from the DP to the plantar circulation and vice versa will achieve the goal of supplying the superior and inferior digital branches.

4. Revascularization

The topic of pedal loop reconstruction is relatively new among peripheral vascular endovascular operators. Most physicians are not aware that balloon angioplasty can be performed across the collaterals. Stenting within the foot is not currently a viable option. The mechanical and high stress forces within the foot deem placing a stent within that region at risk of failure. With that said, there are currently plaque-modifying atherectomy





Figure 6. Excimer Laser System (Spectranetics; image courtesy of The Spectranetics Corporation) (A). Laser Atherectomy with a 0.9 Turbo Elite catheter through the dorsalis pedis artery (B).

devices that are commercially and readily available for use in this region. The Diamondback 360 orbital atherectomy system (Cardiovascular Systems, Inc.) using a tungsten metal crown with synthetic diamonds can modify the proximal two-thirds of plantar vessels (Figure 5A). The Diamondback has been shown to be very effective in treating supra- and infrapopliteal disease. The authors typically will utilize the Diamondback 1.25 mm Solid Micro Crown to modify the DP or lateral plantar artery (Figure 5B). The device can be advanced to the arcuate artery, but operators should avoid traversing through that branch for fear of the device getting stuck.

Another option for atherectomy therapy is the Excimer Laser System (Spectranetics) (Figure 6A). The 0.9 mm Turbo-Elite catheter (Spectranetics) can be advanced through the lateral plantar and DP (Figure 6B). The basic settings in terms of frequency and fluency should be used. Again, laser should not be advanced through the tarsal branch due to the risk of dissection and perforation.

A third option is a relatively new device, the Phoenix hybrid atherectomy system (Philips Volcano), which uses the concept of an Archimedes screw with the rotational capabilities of the device

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Figure 7. Phoenix hybrid atherectomy (Philips Volcano) (A, B). Phoenix hybrid atherectomy device advanced through the distal posterior tibial artery into the lateral plantar artery (C).

removing plaque from the vessel (Figures 7A and 7B). The smallest diameter device can be advanced through the lateral plantar or DP (Figure 7C).

After atherectomy is performed, balloon angioplasty can be performed. A 1.5 mm x 2.0 mm tapered balloon is preferred when crossing from the DP to the lateral plantar or vice versa. Using a 2.0 mm x 2.5 mm balloon may also be reasonable. It is important to avoid trauma to the pedal communication. On average, the authors have discovered, the length of the pedal loop ranges from 200 mm to 250 mm. There are two distinct pedal views allowing the operator to adequately visualize the pedal loop. The medial view usually shows a straight connection between the DP and lateral plantar (Figure 2B). This is misleading, because when you evaluate the vessel in an anterior posterior projection, the operator will notice the balloon twisted in a figure eight configuration (Figure 2A).



Figure 8. Philips 2D Perfusion images before revascularization (A). Philips 2D Perfusion images after revascularization. The change in color from green to red indicates a higher concentration of contrast within the tibial and plantar vessels (B).

The plantar circulation has a tendency toward significant spasm and the operator must aggressively use vasodilators such as nitroglycerin and calcium channel blockers. The authors typically inject 200 micrograms to 600 micrograms of nitroglycerin, as the patient blood pressure allows.

5. Final Assessment

Following intervention, angiography with visual assessment remains the best modality to judge the results of therapy. Severe spasm can limit flow within the plantar circulation. Perform final images after withdrawing the wire across the pedal loop. It is worth mentioning that the authors typically prefer advancing a 0.014" catheter through the pedal loop. Avoid withdrawing the wire without the catheter for concern that the stiff portion of the wire will injure the pedal circulation. Contrast flow velocity, as observed by the operator, may offer some insight into circulation improvement. Another modality under investigation is Philips 2-D perfusion, as assessed by computergenerated software that compares contrast volume, concentration, and arrival time in the foot before and after intervention (Figures 8A and 8B). This modality is still investigational and practical aspects are still under development.

DISCUSSION

The treatment of CLI historically has been limited by the technology available. With the rapid expansion of technology and the emergence of new devices, goals of therapy are redefined. Traditionally, the goal for revascularization is to



improve blood flow to any of the vessels below the knee, ultimately achieving adequate blood supply and ultimately oxygenation to the ischemic tissue. This strategy is not adequate in CLI patients. The new endovascular specialist who is able to deliver more directed therapy is challenging the status quo. Angiosomedirected therapy is the primary strategy for the CLI patient with wounds. Critical limb ischemia patients may suffer from plantar circulation involvement with either diseased or preserved tibial vessels above the ankle. Recreating the pedal loop will serve two purposes. The first purpose is to cover the most vulnerable area within the metatarsal region or the watershed region with dual supply from the AT and PT. Secondly, recreating and opening the pedal loop will allow better outflow for blood traveling through the AT or PT. Providing better outflow will maintain patency within the plantar circulation.

Pedal loop reconstruction is a technically demanding procedure that requires the operator to have a complete understanding of the pedal anatomy and patterns of disease and occlusion. Overall, the success rate of recreating the pedal loop is reported to be as high as 80% to 85%.⁷ Currently available atherectomy technology allows delivery of therapy beyond simple balloon angioplasty. The impact on clinical outcomes, by using atherectomy followed by balloon angioplasty, is yet to be seen.

CONCLUSION

Pedal anatomy and arterial circulation is an important component of CLI therapy and wound healing. As revascularization techniques allow operators to treat these fragile and complex vessels, the understanding of pedal circulation physiology will continue to evolve. Pedal loop reconstruction will add another dimension in achieving wound healing and limb preservation. A deep understanding of pedal anatomy, coupled with applying new revascularization techniques, will ultimately improve CLI revascularization outcomes.

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Common Femoral Artery Chronic Total Occlusion: Surgical Approach Versus Endovascular Approach for Treatment

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• urgical treatment of occlusive disease in the common femoral artery (CFA) using endarterectomy with patch angioplasty closure (common femoral endarterectomy or CFE) has been regarded as the gold standard of treatment for many years. This is based on excellent safety, efficacy, and long-term results. The TASC II intersociety consensus in 2007 deemed CFA chronic total occlusions (CTOs) to be TASC D and therefore best treated surgically. Historical reports of CFE with removal of plaque from the CFA, origin of the superficial femoral artery, and profunda femoris with patch angioplasty have had excellent results. This remains a good solution for older, advanced, multilevel peripheral artery disease (PAD) or highrisk patients with comorbidities, such as chronic renal insufficiency, where a traditional endovascular approach can be challenging. These patients can present with critical limb ischemia (CLI) and can be treated with CFE and a lesser amputation, which results in limb salvage.

More contemporary CFE results include patients who have common femoral artery CTOs associated with aortoiliac occlusive and femoropopliteal disease. Wieker et al published a retrospective study evaluating 713 patients; 221 had CLI, and 434 had intermittent claudication (IC) and required CFE either alone or as a hybrid procedure to treat inflow or outflow disease¹ A 100% technical success rate was obtained, with a primary patency of 98% at 1 year, 90.3% at 3 years, and 78.5% at 7 years. No significant long-term patency difference was noted between hybrid and nonhybrid procedures during this 7-year follow-up, and the procedure-related

complication rate was 11.5%. Primary patency was 76.3% in patients with CLI vs 79.4% for intermittent claudication at 7 years. A total of 20 major amputations were performed, achieving a limb salvage rate of 92.6%. Most recent reviews mirror these results, where CFE is used either to treat isolated femoral arterial disease or in conjunction with endovascular aortoiliac occlusive disease as a hybrid procedure, or with an aortobifemoral bypass graft. Common femoral endarterectomy can enhance results for an endovascular femoropopliteal procedure or a femoropopliteal or femorotibial bypass.

COMPLICATIONS

The challenge with CFE remains a complication rate, which can vary from 6% to 20% depending on the publication. The complications are groin infection, which may be superficial or deep, groin hematoma, lymphocele, and devastating graft infections, which can occur in the future. Newer wound-closure techniques, antibiotic impregnated suture, negative pressure wound devices like Provena, and wound vac have reduced the groin infection and lymphocele rates. Common femoral endarterectomy procedures are traditionally done under general anesthesia, and patients with multiple comorbidities are subject to higher risks with general anesthesia. Many centers, including the author's, have moved to doing CFE with regional, local anesthesia with sedation and have obtained comparable results. Ballotta et al published a series of 111 patients with a mean follow-up of 4.2 years, of whom 60.3% patients had intermittent claudication (IC), and 39.7% had CLI.2 The average procedure time was 1.3 ± 0.7 hours, with a complication rate of 6.6%. The primary patency at 7 years was 96%, assistant primary patency 100%, and limb salvage 96%. Common femoral endarterectomy done with regional or local anesthesia is an excellent alternative for higher risk patients who cannot be subject to general anesthesia.

Groin access is a favorable approach for many peripheral endovascular procedures but also for aortic, thoracoabdominal, and structural heart interventions. The common femoral artery has therefore been a "no stent" zone to allow access for larger sheaths. Common femoral endarterectomy allows larger access for these procedures, and closure devices are not precluded. Closure devices can, in fact, be preferred because the artery lumen is considered noncompromised. Care must be taken using closure devices in this location where a patch is present, as it is susceptible to patch infection, and scar formation may make using closure devices difficult. Good sterile access techniques, with ultrasound guidance, correlation of landmarks with fluoroscopic guidance, and stiff micropuncture access may help alleviate some challenges.

CHOOSING AN ENDOVASCULAR APPROACH

With the increasing age and clinical complexity of patients treated, operators often must evaluate endovascular interventions in the CFA because they pose a lower risk. No large series with longterm results are available to objectively evaluate the performance of devices in this region. It is also important to identify the cause of common femoral arterial disease, be it a truly atherosclerotic CTO, access closure associated narrowing, or thromboembolic cause. Endovascular interventions done for thromboembolic causes have generally had the best results, with almost 100% technical success and excellent long-term patency.3

If interventions are evaluated based on treatment modalities, balloon angioplasty has the oldest and largest series, published by Bonvini et al, who evaluated 360 consecutive percutaneous interventions done for atherosclerotic disease of the CFA and retrospectively reviewed these to evaluate 1year patency and target lesion revascularization rates.4 Ninety-seven or 26.9% were isolated CFA interventions, 157 or 43.6% and 152 or 42.2% involved in flow and outflow vessels respectively. This retrospective review spanned 11 years, so treatment therapy included 98.6% angioplasty, angioplasty plus bail-out stenting, and a small subset (25) of SilverHawk atherectomy (Medtronic). Duplex ultrasound or clinical follow-up were available for 281 patients (87.5%) for a mean of 10.3 months. Major complication rate was 1.4% where surgical intervention was necessary and 5%minor was noted. One-year follow-up for 281 patients showed 27.6% with less than 50% restenosis, and 19.9% required target lesion revascularization. These results are obviously suboptimal but with the availability of drug-coated balloon technology, the results should improve.

STENTING

There are several small series that showed favorable results for stenting of

the common femoral artery. Paris et al published stent placement in 29 CFA lesions. Seven were CTOs, with 100% technical success, 100% amputation-free survival at 30 days, and 93% limb salvage at 23 months.4 The challenge with stenting remains long-term outcomes after 24 months, because CFA patency is important for limb salvage. Stenting of the common femoral area along with stenting of the iliac or femoropopliteal area is associated with better patency, however stent fracture was an independent predictor of poor outcomes.⁵ A strategy that was adopted was to place the stent superiorly or inferiorly. This strategy allows most of the common femoral artery to remain free for future access and spares the orifice of the profunda. The use of nitinol stents is recommended, as they are less rigid. Whenever possible, place only one stent as stent overlap can lead to stent fracture and occlusion. The author's center is evaluating the possible use of Supera stents (Abbott Vascular) in the CFA when needed for flow-limiting dissection or arterial stenosis to determine if there is an improvement in longterm patency and easier groin access for future interventions.

ATHERECTOMY

Many centers are evaluating the success of atherectomy in the CFA, especially in high-risk patients with morbid obesity, infected groin, and scar secondary to repeated interventions. We have found lesion selection is also important and is best used in focal, short, calcified segments and it is important to distinguish from thrombus. Small series anecdotal reports discuss TurboHawk (Medtronic), Diamondback (Cardiovascular Systems, Inc.), Jetstream (Boston Scientific), and Rotablator (Boston Scientific) atherectomy, with 100% technical success in each, but no large series is available to compare to device results long term. Nonatherosclerotic CFA disease caused secondary to groin access closure devices has been treated successfully with these devices.

CONCLUSION

Common femoral artery CTOs remain a challenge to treat. However, many good options are available, and treatment should be individualized according to the risks and benefits for each patient.

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This Is How I Do It: Treating a 700-mm CTO From the Groin to the Ankle

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Figure 1. Rutherford 5 great toe wound.

eripheral arterial disease (PAD) is a growing epidemic in our country. Approximately 18 million to 20 million US citizens are battling this disease, while 2 million suffer from critical limb ischemia (CLI), the most severe and deadly form of the disease. CLI represents the most severe clinical manifestation of PAD and is the major cause of ischemic amputation in the United States.¹⁻² Patients with CLI commonly present with disease that affects the inflow and outflow, with chronic total occlusion (CTOs) being prevalent in approximately 40% to 50% of patients with symptomatic PAD.³

Technological advances in the past 5 to 10 years have led to an increase in percutaneous treatment for patients with peripheral arterial disease (PAD). Endovascular treatment offers a lower



risk alternative to open surgery in many patients with multiple comorbidities.⁴⁻¹¹

THE CHALLENGES OF TREATING CHRONIC TOTAL OCCLUSIONS

Successfully crossing a CTO with a guidewire can be technically challenging due to multilevel disease, convex calcified caps, long length, and, oftentimes, subintimal wire crossing into tibial vessels. Failure to cross a CTO with a guidewire or to re-enter the true lumen beyond the CTO can lead to the need for amputation in patients with critical limb ischemia or bypass surgery.^{12,13} Multilevel CTOs are the most challenging for endovascular revascularization. The case presented below will demonstrate techniques in crossing long CTOs extending from a flush superficial femoral artery (SFA) occlusion with reconstitution in the distal posterior tibial (PT) artery.

NONINVASIVE EXAM AND TESTING

Noninvasive testing and arterial mapping enable clinicians to localize the disease and plan the treatment. If wounds are present, these tools tend to help direct the operator toward choosing the proper and most valuable target artery to open using the so-called angiosome concept. For Rutherford 5-6 patients, detailed wound assessment and documentation is a necessary baseline step to track the progress of treatment.

CROSSING AND REVASCULARIZATION

Multiple access sites and advanced techniques are often used in CLI patients with long CTOs to preserve as much native vessel and uncover any



Figure 2. Angiography revealed severe multilevel right lower-extremity disease, including flush occlusion of the superficial femoral artery (SFA) and popliteal artery as well as the tibial arteries, reconstituting at the distal posterior tibial. Occlusion at the ostial SFA (A), collaterals at Hunter's canal (B), and a hint of distal PT artery flow (C) were noted.

hibernating vessels. Wire and catheter selection for crossing may vary depending on lesion location and plaque characteristics. Techniques such as double balloon and safari are utilized to ensure successful crossing to allow for delivery of therapy.

Atherectomy, drug-coated balloon angioplasty, and stenting are considered depending on the plaque morphology, intraluminal crossing of the artery, lesion location, and patient comorbidities. Patients with multilevel disease may require staged procedures to treat both inflow and outflow disease.

CASE REPORT

The following complex case demonstrates the treatment plan for a CLI patient. An 82-year-old female with a significant past medical history of coronary artery disease, hypertension, cardiomegaly, and carotid disease presented with Rutherford class 4 rest pain. Shortly after, the patient developed a wound involving the great toe, placing her at Rutherford class 5 (Figure 1).

After physical assessment of the foot and duplex ultrasound, the patient underwent peripheral angiography, which revealed severe multilevel right lowerextremity disease, including a flush occlusion of the superficial femoral and popliteal arteries, and of the tibial arteries, reconstituting at the distal posterior tibial. This type of severe anatomical disease indicated that the patient had limited revascularization options (Figure 2).

NONINVASIVE ASSESSMENT

In our institution, we rely heavily on extravascular ultrasound for arterial mapping as well as lesion plaque morphology, length, and intraoperative crossing. These all become very important in the success of treating multilevel disease and crossing 700 mm CTOs.

The noninvasive assessment included an arterial duplex ultrasound. The patient's arterial duplex ultrasound identified a flush SFA occlusion with presence of calcification, especially intimal calcification. Only the distal PT artery showed monophasic flow, with the remainder of the tibial vessels appearing occluded.

REVASCULARIZATION

In complex disease as described in this case, access becomes extremely important for the success of the procedure. Operators should consider all access options to optimize revascularization success.

ACCESS

Choosing the proper access is a critical step in achieving adequate revascularization. At our institution, antegrade access is the preferred route for the majority of infrainguinal arterial disease. In this case, antegrade access was not an option due to the fact that the SFA had a flush occlusion and the takeoff was too high. Therefore, contralateral access





Figure 3. Contralateral femoral access (A) and retrograde pedal access of posterior tibial arteries (B).



Figure 5. Final angiograms showing flow in the superficial femoral arteries (A, B), the tibial arteries (C), and the pedal vessels (D).

was achieved to avoid an ipsilateral antegrade high stick.

Typically in long CTO crossing, multiple access sites are achieved in both antegrade and retrograde manners. The CTO in this case was from the common femoral artery (CFA) to the ankle region of the PT artery with a total CTO lesion length of 700 mm (Figure 3). The next step after access is to connect the CFA to the tibiopedal circulation. Occasionally in a long CTO segment, one can find a "hibernating lumen," defined as a patent segment between two CTO caps. A hibernating lumen was found in this case in the popliteal artery after achieving pedal retrograde access in the distal PT to find a short portion of the mid popliteal artery to patent hibernating. This concept is important to keep in mind, especially in long CTO segments and in the SFA.

PROCEDURE DETAIL

Under ultrasound guidance, the left CFA was cannulated and access was



Figure 4. Ultrasound-guided canalization of the proximal superficial femoral artery.

gained in the right common femoral artery (Figure 4). Under ultrasound guidance the origin of the SFA was engaged with the .035" angled Navicross catheter (Terumo Interventional Systems). We were then able to advance the Navicross catheter and a .018" Glidewire Advantage (Terumo Interventional Systems) under ultrasound guidance and stay intraluminal down to Hunter's canal. At this area we lost visualization with the ultrasound and under fluoroscopy we advanced our wire down into the popliteal artery. Selective angiography was performed and demonstrated that we were in a hibernating popliteal artery. At this point, distal retrograde access was obtained of the PT artery under ultrasound guidance. We advanced a .018" Treasure Floppy wire (Asahi Intecc), followed by a Treasure 12 (Asahi Intecc) with a .018" Quick-Cross catheter (Spectranetics) and were able to engage in the true lumen of the popliteal artery. At this point, we cannulated the retrograde wire from above with a Navicross catheter and reversed direction for treatment, giving us access to the entire long-segment CTO. Angioplasty was performed in the PT artery with a 3 mm x 150 mm balloon. Sequential balloon angioplasty was performed on the entire SFA with a 5 mm balloon. Sequential balloon angioplasty was performed on the popliteal artery and the SFA to its origin. Completion angiogram demonstrated in-line flow but multiple areas of dissection. With this we then placed two 6 mm x 150 mm bare metal stents and a 6 mm x 27 mm balloon-expandable stent to the origin of the SFA. Completion angiogram still demonstrated some irregularity and some recoil of the popliteal artery, so we treated this with a 5 mm x 100 mm DCB into the popliteal artery. Final completion angiogram demonstrated complete in-line flow of the SFA popliteal segment and in-line flow of the PT filling both the medial and lateral plantar arteries (Figure 5).

DISCUSSION

Peripheral artery disease is a progressive disease, and in CLI patients it is a complex process that involves multiple steps for treatment, as highlighted in the case example above. The endovascular-first approach requires advanced revascularization techniques. Having a well trained team and the latest and greatest technologies available will ensure a high rate of success in these 700 mm CTOs.

In addition, the operator's experience dictates which techniques can be performed while avoiding complication in these challenging cases.

CONCLUSION

In patients with CLI, multivessel disease is common. Chronic total occlusion revascularization is achievable with advanced modern day techniques such as multiple access sites, utilization of ultrasound-guided therapy, and newer technologies.

The case presented in this article demonstrates the importance of specialized CLI clinicians and a multidisciplinary team approach that can provide the full spectrum of care.

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Crosser Catheter Usage in Everyday Practice

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n treating peripheral arterial disease, the choice of how to cross a chronic total occlusion depends, in our experience, on how you wish to treat the vessel after you have crossed it. In our practice, methodic and optimal debulking via atherectomy and subsequent percutaneous transluminal angioplasty (PTA) with drug-coated balloons (DCBs) remains the preferred method of revascularization.

Optimal atherectomy is supported by the DEFINITIVE LE trial, which showed a 78% patency rate at 12 months,¹ while the LEVANT 2 trial showed the rate of primary patency was also significantly higher with the drug-coated balloon than with the standard angioplasty balloon at 12 months (73.5% vs 56.8%, P<0.001).² Combining directional atherectomy and antirestenosis therapy (DAART) via DCB therapy offers excellent long-term patency rates at 12 months (96.8%) in lengthy (>10 cm), non-CTO lesions and a reduced incidence of flow limiting dissections, according to the DEFINITIVE AR trial.³

CROSSER STRATEGIES

In light of this, crossing the total occlusion purely within the lumen offers key advantages over crossing the lesion using the PIER (percutaneous intentional extraluminal revascularization) method.

First, using a central-lumen crossing catheter is more reliable than a PIER



Figure 1. A: CTO of the proximal SFA which extends to hunters canal. B: Reorientation of crossing to correct deflection post-CROSSER. C: Final result post Foxhollow and DCB. D: Longitudinal IVUS of crossing. Note IEM calcification consistent with Monckeberg's pathology. E: Proximal cap of CTO. F: Mid-lesion collateral loss. G: Distal reference with collateral preservation.

crossing and offers rapid crossings and reduced usage of contrast and radiation.

Second, obtaining an intraluminal orientation offers the opportunity to optimize debulking with lowered risk of significant vessel injury. Because a PIER crossing is innately a purely eccentric crossing, the ability to debulk is hindered to a large extent, and PTA with DCB is less effective in producing an acceptable lumen gain. Injuries due to PIER crossing can also result in significant healing responses, which can lead to increased risk of restenosis and target lesion revascularization (TLR) rates.

Our extensive early experience with the Crosser catheter (Bard PV) confirmed that the crossing reliably produced an intravascular ultrasound (IVUS) confirmation of penetrating the proximal cap and traversing the total occlusion within the former luminal space, while exiting the total occlusion through the distal cap.⁴We have also found that if the patient exhibits calcification of the internal elastic lamina (IEL) consistent with Monckeberg's medial calcification, the Crosser catheter would deferentially remain intraluminal.

This is in direct contrast to intraluminal calcium, which tended to offer the most resistance to intraluminal crossing and would often deflect the catheter into the subintimal space. Differing between intraluminal calcium, intralesional calcium and Monckeberg's medial calcinosis is virtually impossible by angiography, but critical to ascertain. IVUS is very helpful in determining the depth, extent, and pathology of the calcium seen on an angiogram. With methodical and steady advancement of the catheter, the deflections associated with intraluminal or intralesional calcium can be averted or adjusted to, and if a deflection is significant and

Tape Method	TLR at 6 Months	P-Value for 2 x 2 Fisher's Exact Test (0 vs Others)	P-Value for Trend (Ordinal)	
	9/77 (11.7%)			
Tear		.03	<.001	
0	2/46 [4.4%]			
1	0/12 (0.0%)			
2	7/19 [36.8%]			
Axial		.09	.04	
0	2/39 (5.1%)			
1	2/16 [12.5%]			
2	5/22 [22.7%]			
Preservation		.15	.40	
0	2/38 [5.2%]			
1	6/26 [24.0%]			
2	1/14 (7.1%)			
Extension		.05	.02	
0	3/51 (5.9%)			
1	5/23 [21.7%]			
2	1/3 [33.3%]			
Central percent		.04	.047	
>90%	2/43 (4.7%)			
<90%	7/34 [20.6%]			
74%-89%, 75%-89%	2/9 [22.2%]			
50%-74%	2/12 (17.7%)			
<50%	3/13 (23.1%)			

Data provided as number (percentage).

Figure 2. CENTRAL study 6 month TLR rates as determined by TAPE score and Central Percent crossing.

recurrent correction of these deflections can be addressed using the Pioneer catheter (Philips Volcano) within the total occlusion using the reorientation technique (Figure 1).

The common anatomic sequelae to intraluminal or PIER crossings became evident after serial post-crossing IVUS studies, which led to our institution creating an anatomic damage scale looking at tears, axial orientation, collateral loss, and reference segment extension, which was shortened to the acronym TAPE.⁵ We score all crossings by IVUS, with a "0" score (or T0A0P0E0) being a pristine crossing and an "8" score (T2A2P2E2) being the worst score.

THE CENTRAL STUDY

To examine the hypothesis that the Crosser catheter reliably crosses intraluminally and that cleaner crossings lead to lowered TLR rates, we conducted the CENTRAL (Crosser Enters the Right

WU from page 3

VASCULAR CONSIDERATIONS

Peripheral arterial disease (PAD) is defined as a progressive stenosis or occlusion of arterial vessels of the lower extremity.¹⁰ Recently published data from the American Heart Association suggest that approximately 25% of the general population is diagnosed with this condition.¹¹ The major risk factors that directly increase risk of PAD include smoking, obesity, diabetes mellitus, hyperlipidemia, and hypertension.¹²

Adequate tissue oxygenation is critical for progression through the wound-healing cascade. Normal oxygen tension promotes fibroblast activity to produce collagen, encourages angiogenesis, facilitates keratinocyte migration to re-epithelialize the wound bed, and helps prevent wound infection through the production of reactive oxygen species (ROS).13,14 When a wound occurs acutely, there is an initial period of hypoxia that stimulates the release of growth factors and inflammatory cytokines within the wound. Patients with adequate arterial inflow will restore a normal physiologic oxygen tension in the wound, promoting fibroblast production of collagen, angiogenesis, and eventual wound contraction.14 Conversely, a wound with decreased oxygen tension will have limited ability to proliferate healthy granulation tissue and progress toward healing. Chronic wounds are often "stuck" in the inflammatory phase of healing, and local tissue hypoxia contributes to this delay.

Local tissue hypoxia helps set the stage for chronic inflammation in the wound bed. The wound environment will remain hypoxic in individuals with PAD, and this causes prolonged inflammation leading to a chronic wound.¹⁴ Without restoration of inline arterial flow, affected patients will have inadequate arterial perfusion and decreased potential of healing. Individuals with diabetes are especially vulnerable to developing arterial insufficiency of both the small and large vessels. It has been suggested that an HbA1C Arterial Lumen) study.⁶ The CENTRAL study consisted of 100 consecutive CTO crossings of the superficial femoral artery. Eight centers took part in the study, the average lesion length was greater than 132.1 mm, 74% of the lesions were moderately or severely calcified, and 81% of patients were Rutherford class 3-6.

Seventy-seven of 100 lesions were crossed by the CROSSER catheter, with 64 of the lesions exhibiting a greater than 50% intraluminal orientation. Of those lesions that were crossed, 56% (43/77) were greater than 90% intraluminal, and 68% (52/77) were greater than 75% intraluminal.

The 6-month TLR rates were impressive, if the crossing was \geq 90% intraluminal, the TLR rate was 4.7%, and if the crossing was less than 90% intraluminal, the TLR rate was 20.6% (*P*=.04). If the TAPE score (tears, axial, preservation, and extension) was measured as being acceptable (0-4), the 6-month TLR was 3.5%

and if the TAPE score was less acceptable (⁵⁻⁸), the 6-month TLR was 36.8% (P<.001). These numbers are in spite of the fact that all treatments post crossing were left to the discretion of the practitioner, with only 34% of the patients treated with stents (Figure 2). These numbers are comparable with recent non-CTO studies, such as the RESILIENT and DEBELLUM, with the average lesion length of CENTRAL also being double of either study.^{7,8}

CONCLUSION

Methodical and careful crossing of CTOs in the infrainguinal arterial tree using the Crosser catheter and documented by IVUS enables interventionalists to ensure pristine axial orientation throughout the crossing. Ensuring this allows us to utilize atherectomy and PTA in the most effective and reliable manner, which will offer advantages in TLR rates, long-term limb salvage, and symptomatic resolution.

malodor, and pale/friable granulation tissue.¹⁸ Necrotic tissue present in the wound is a medium for bacterial growth, further contributing to wound inflammation and delay in healing.²⁰ This increased bacterial count also contends for oxygen and nutrients, starving the wound of necessary resources required for healing.21 Aggressive wound bed management is critical to properly manage the bioburden. Without proper wound bed preparation, planktonic and sessile bacteria will continue to proliferate, contributing to the inflammatory status and chronicity of wounds. Successful wound bed debridement facilitates transformation of a chronic wound to an acute wound environment by reducing proteases, cytokines, and bacterial count.22 Chronic wounds often require weekly serial debridements to remove nonviable tissue and bacterial debris and to promote the development of healthy granulation tissue.

CONCLUSION

The rising prevalence and financial burden of chronic wounds presents a challenge to health care providers. Many factors, such as vascular compromise and wound bioburden, contribute to the development of chronic wounds; therefore, a comprehensive assessment by the treating provider is necessary to identify all potential roadblocks to healing. Knowledge of normal wound healing physiology provides the foundation for an understanding of the negative impact that chronic disease processes have on tissue repair.

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dividual's risk for developing PAD. Every 1% increase in HbA1C level is associated with a 26% increased risk for developing PAD.¹⁶ The initial assessment for a patient sus-

level greater than 7.0 mg/dL increases an in-

pected of vascular compromise begins with a comprehensive history and physical examination. Patients at a high risk for PAD are initially screened with noninvasive arterial studies, including ankle-brachial index (ABI) and arterial duplex studies. An ABI less than 0.9 is highly suggestive of lower-extremity arterial disease, with a diagnostic sensitivity of 95%.16 Follow-up studies to the initial screening studies include skin perfusion pressure (SPP) studies and transcutaneous oxygen measurements (TcPO₂). These two studies assist in determining the pressure of oxygen tension at the skin surface to predict probability of wound healing or determine the appropriate level of amputation. A TcPO2 greater than 40 mmHg¹⁶ and a SPP above 35 mmHg¹⁷ has been associated with a positive predictor of successful wound healing. When a wound has failed to progress through the phases of healing, and a diagnosis of limb ischemia has been obtained, further evaluation or referral to a vascular specialist is indicated.

WOUND BED PREPARATION AND BIOBURDEN

Proper wound bed preparation and management is critical to ensure physiologic progression through the wound-healing cascade. An intact stratum corneum is our body's greatest defense against the invasion of resident and transient bacteria, and following a break in the skin, these bacteria begin entering the wound bed.¹⁸ All open wounds are considered "contaminated," defined as having nonreplicating planktonic bacteria.¹⁹ Treatment with either topical or systemic antibiotics has not been recommended in contaminated wounds.

Critically colonized wounds are described as having replicating bacteria that release endo- and exotoxins to the wound bed, creating necrotic debris, increased exudate,

Frontrunner XP CTO Crossing Device for Use in CLI

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here has been a paradigm shift over the past decade from open surgical revascularization to endovascular therapies for treating symptomatic chronic total occlusions (CTOs). A number of dedicated CTO crossing devices have been developed to improve the success rate of crossing these occlusions, to allow these often fragile patients with multiple comorbidities to be treated with less invasive endovascular therapies. Advantages of these CTO devices also include less radiation to the patient and lab staff, less contrast use, and time savings.

One such device is the Frontrunner XP (Cardinal Health), designed to cross occlusions by means of controlled microdissection (Figure 1A). The proximal braided shaft offers greater pushability through calcific plaque and a flexible distal shaft that may be shaped manually, for example, to angle the device away from a large collateral. The distal tip is a 0.39" crossing profile with a 2.3 mm jaw opening. The curved, hinged jaws are advanced closed into the occlusion to allow for penetration of the proximal cap, then opened to create a microdissection plane through the plaque. It is available in shaft lengths of 90 cm for antegrade access and 140 cm for contralateral access. The Frontrunner XP often is used with an accompanying 4.5 Ff PTFEcoated microguide (Figure 1B) with a radiopaque tip, but the author prefers an inexpensive 4 Fr Aqua (Cardinal Health) support catheter. The low profile of the device allows for delivery through a 4 Fr retrograde pedal or popliteal access, a

major advantage over other more expensive and larger profile devices.

The Frontrunner XP is a versatile device that can be used for iliac, femoropopliteal, and infrapopliteal vessels. It does not require any set-up time or other capital expenditure. Indications include the following:

- Long iliac or femoropopliteal CTOs with mild to moderate calcification;
- Penetration of dense proximal caps to stay intraluminal or when wires fail;
- Occlusive in-stent restenosis (ISR) to assure true intraluminal path, thus allowing for subsequent atherectomy; and
- Straight segments of infrapopliteal occlusions to stay centered, avoid collaterals.

There have been a number of singlecenter, prospective, nonrandomized reports on the use of the Frontrunner XP after failure to cross with conventional guide wires (Table 1). In the author's experience, successful crossing is greatest when the device is used as a first-line strategy, to avoid the dissections that can be created by subintimal wire passage. This is seen on fluoroscopy as a wide loop of the wire, and will often result in the extension of the re-entry point well beyond the site of vessel reconstitution. As a result, re-entry success is reduced, and a longer segment of stenting is required, thus increasing the risk of restenosis or potentially taking away a bypass option. It is also important to keep the distance between the support catheter and the XP relatively short (3 mm to 5 mm) to maximize cap penetration and stay centered.



MICROGUIDE CATHETER

Figure 1. The Frontrunner XP (Cardinal Health).

Table 1: Studies Using the Cardinal Health Frontrunner XP										
Author, Year	# Patients (Lesions)	Mean Age in Years (Range)	Mean Lesion Length in cm (Range)	Vessels Treated	Rutherford Category and Percentage	TASC	Re-entry Device Use	Time to Cross in Minutes (Range)	Success Rate	Comments
Mossop, 2004 ¹	36 (44)	67±12 (47-89)	9.5±7 (2-45)	Aorta 2 Iliac 24 SFA 16 Popliteal 2	2: 52.2% 3: 18.2% 4&5: 13.6% 6: 15.9%	NR	35%	22±21	91%	3 of 4 failures were iliac chronic total occlusions (CTOs)
Thatipelli, 2009 ²	61 (67)	72.3±9.4	14.2±8	Aortoiliac 13% Femoro- popliteal 83% Below the knee 5%	3: 57% 4: 28% 5: 15%	B: 29% C: 20% D: 16%	12%	6.7±4 (1-15)	84%	Frontrunner-first strategy; age, chronic kidney disease, lesion length predictors of failure 55% of CTOs >10 cm
Charalambous, 2010 ³	26	68.3±8.8	17.6 (10-42)	Femoro- popliteal 100%	2: 61.5% 3: 7.7% 4: 30.8%	B: 26.9% C: 30.8% D: 42.3%	34.6%	<8 min mean 22.7 min fluoros- copy time	88.1%	73% antegrade access
Lee, 2012 ⁴	16	66.2	13.7 (6-22)	Femoro- popliteal 100%	2: 16% 3: 37.5% 4: 37.5% NR 9%	NR	45.8%	NR	100%	Frontrunner used in 5 cases, Outback (Cardi- nal Health) in 11 cases; popliteal access in 33.3%
Shetty, 2013⁵	22	58.9±11.5	18±10.1	Femoro- popliteal 100%	3: 45.5% 4: 18.2% 5: 36.4%	D: 100%	0%	<2 min	95.5%	Used microguide in all cases



Figure 2. Chronic total occlusion of proximal left superficial femoral artery (SFA) (A). Reconstitution in distal SFA/popliteal artery (B). Three-vessel run-off (C).



Figure 3. Contralateral approach and engagement of proximal cap (A). Frontrunner XP catheter crossing the chronic total occlusion (B). Complete crossing into distal superficial/femoral artery.



Figure 4. Final result after treatment.

confirmed true lumen position, so stenting was performed, which restored inline flow to the peroneal with subsequent successful ulcer healing (Figure 5).

CONCLUSION

The Frontrunner XP controlled microdissection catheter remains a versatile adjunct to the traversal of CTOs in multiple vascular beds. It can improve the chance for successful crossing, thereby saving time, contrast, and radiation exposure.

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Successful crossing is greatest when the device is used as a first-line strategy, to avoid the dissections that can be created by subintimal wire passage.

Figure 5. Below-the-knee chronic total occlusion (CTO) of the anterior tibial, posterior tibial, and peroneal arteries (A). Distal peroneal reconstitution (B). Peroneal CTO crossed with the Cardinal Health Frontrunner XP (arrows) (C). Peroneal stenting (white dots) (D). Final angiographic image after crossing, angioplasty, and 2 stents placed (E).

The distal shaft may be manually curved to avoid large collaterals and an angled support catheter may be used to allow for directionality of the device to maintain a coaxial intraluminal path. The rounded jaws make the Frontrunner an excellent choice for remaining intraluminal in the below knee vessels (by avoiding collaterals), and for the intraluminal traversal of long in-stent restenosis occlusions. This feature also greatly reduces the risk of vessel perforation, which is particularly important below the knee to avoid the risk of compartment syndrome.

If the Frontrunner XP does not traverse the distal cap in an intraluminal position, the microguide or support catheter is placed just proximal to the distal cap to allow for wire passage into the true lumen, or a re-entry device is employed to gain access to the reconstituted true lumen. Definitive therapy for the CTO (atherectomy, drug-coated balloon angioplasty, stenting, etc.) is then performed.

CASE STUDIES

Case 1: Long Superficial Femoral Artery (SFA) CTO

Contralateral femoral access obtained with a 4 Fr Aqua placed in the stump of the left SFA stump. Frontrunner XP traversed the occlusion with selective angiography confirming true lumen placement. Percutaneous transluminal angioplasty and stenting resulted in restoration of 2-vessel run-off (Figures 2-4).

Case 2: Below-the-Knee CTO in a Patient With Rest Pain and Foot Ulcer

Antegrade access obtained in the right CFA with angiography showing occluded popliteal and proximal tibial vessels with single-vessel peroneal run-off. Initial wire recanalization demonstrated extravascular position, so Frontrunner XP was delivered with the jaws closed to remain in the true lumen. Selective angiogram

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Anticoagulation using high-dose warfarin has also not provided a satisfactory solution, with a lack of both cardiovascular protection in stable PAD⁸ and graft patency benefit in postrevascularization PAD⁹ compared to antiplatelet therapy alone. The lack of benefit in these trials was further compounded by significantly increased bleeding risks in groups receiving warfarin.

A recent subgroup analysis of PAD patients from the large TRA2°P-TIMI 50 trial highlights potential MALE benefits of combining traditional antiplatelet and thrombin-directed therapies.¹ Vorapaxar, an inhibitor of PAR-1-mediated platelet activation, added to background antiplatelet therapy significantly reduced ALI due to native vessel and graft thrombosis in stable PAD patients. These results are compelling, demonstrating the ability to favorably modify the serious short-term limb risks in PAD.

Treatment of patients with advanced PAD and critical limb ischemia has advanced slowly over the past two decades. Relying on data and practice concepts derived from coronary artery disease patients is suboptimal; in many cases, these practice patterns have not been supported by larger trials that include PAD patients. Current optimal antithrombotic therapy remains unclear, and new trials that target PAD patients specifically, examining new therapeutic approaches, are needed. The VOYAGER PAD trial is a response to this critical need.

THE VOYAGER PAD TRIAL

The Vascular Outcomes studY of ASA alonG with rivaroxaban in Endovascular or surgical limb Revascularization for Peripheral Artery Disease (VOYAGER PAD; NCT02504216) was initiated in August 2015 to test a new treatment strategy to improve outcomes for PAD patients undergoing peripheral revascularization. This international, multicenter, double-blind, placebo-controlled trial will evaluate the effectiveness of the specific factor Xa inhibitor rivaroxaban plus aspirin vs aspirin alone in approximately 6,500 patients undergoing infrainguinal revascularization for symptomatic PAD.

VOYAGER PAD employs a strategy of combining very low-dose rivaroxaban (2.5 mg twice daily) with low-dose aspirin (100 mg daily) to target both platelet activation as well as intrinsic/ extrinsic coagulation pathways. This same low-dose combination strategy demonstrated significant MACE benefits in the ATLAS ACS2-TIMI 51 trial targeting patients with acute coronary syndrome.10 The majority of subjects in ATLAS ACS2-TIMI 51 had undergone recent coronary revascularization, similar to the peripheral postrevascularization population of VOYAGER PAD. The lowdose combination strategy was associated with acceptable bleeding risk profiles and therefore has the potential for clinical benefit in patients with elevated vascular risk while avoiding the limiting bleeding complications observed previously with high-dose anticoagulant therapies.^{8,9}

To be eligible for VOYAGER PAD, patients must be at least 50 years old, have moderate to severe symptomatic PAD distal to the external iliac artery, and must have completed a technically successful revascularization procedure within 10 days of randomization. There can be no planned treatment with clopidogrel for more than 30 days following the index revascularization procedure (or more than 60 days when using a device labeled for longer DAPT duration, such as a drug-coated device), and the patient must not have had a previous revascularization of the index leg within the past 10 days.

The primary outcome in VOYAGER PAD is time to first occurrence of myocardial infarction, ischemic stroke, cardiovascular death, ALI, or major amputation. This novel primary composite endpoint combines both MACE and MALE com-

study showed no significant benefit of DAPT in decreasing MACE in the overall population; there was also no MACE benefit in the PAD-specific subgroup.¹⁶ The Clopidogrel and Acetylsalicylic Acid in Bypass Surgery for Peripheral Arterial Disease (CASPAR) trial compared DAPT to aspirin alone in 851 subjects undergoing below-knee bypass graft surgery.17 Dual antiplatelet therapy failed to reduce the primary endpoint of index graft occlusion, index graft revascularization, index limb major amputation, and death. A commonly quoted subgroup analysis suggested that DAPT appeared to improve outcomes in the subgroup with prosthetic grafts; however, one cannot draw conclusions given the overall negative trial. Beyond the lack of effectiveness, DAPT was associated with increased Global Utilization of Streptokinase and t-PA for Occluded Coronary Arteries (GUSTO) scale moderate or severe bleeding compared to aspirin alone in both of these trials.^{15,17,18} It should be noted that DAPT with aspirin and the

Rather than simply trying "more," we need to investigate different approaches. Combining lowdose drugs that target distinct antithrombotic mechanisms may be a strategy that achieves additional gains without additional costs.

ponents to evaluate, for the first time as a primary outcome, the full spectrum of major irreversible harms suffered by the PAD population. Secondary outcomes will further evaluate effectiveness of the aspirin-rivaroxaban strategy on time to index leg revascularization, hospitalization for coronary or peripheral thrombotic events, venous thromboembolic events, and all-cause mortality.

DUAL ANTIPLATELET THERAPY IN PAD

Despite major international PAD treatment guidelines largely recommending either aspirin or clopidogrel monotherapy in stable and postrevascularization PAD,¹¹⁻¹⁴ we have observed diverse practice pattern patterns with respect to DAPT with clopidogrel among practitioners in the international PAD community. The derivation of these practice variations, especially those involving extended-duration clopidogrel, is not clear.

While DAPT with clopidogrel has shown some benefits in the coronary artery disease population, it has shown little benefit when studied in stable or postrevascularization PAD. The Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance (CHARISMA) trial examined DAPT vs aspirin alone in 15,603 subjects with either multiple vascular risk factors or stable cardiovascular disease.¹⁵ This P2Y12-inhibitor ticagrelor has shown benefit in reducing limb revascularization for ischemia in patients with history of PAD and myocardial infarction.⁴

Overall, in PAD there is no evidence of clinical benefit of aspirin with clopidogrel in patients with either stable disease or with vascular bypass surgery; there are also no data with endovascular procedures in PAD to support use of DAPT. Even in coronary artery disease, the use of DAPT is now coming under increased scrutiny, with the American Heart Association recently calling for a reduction in the practice due to marginal benefit-to-risk ratio in certain clinical settings.¹⁹

CONCLUSION

PAD patients represent a high-risk population in need of better treatment solutions. Practitioners struggle to improve the long-term morbidity and mortality of their PAD patients. The desire to do "more," such as by intensifying antiplatelet therapy, has not been proven beneficial and comes with undesirable risk trade-offs. Rather than simply trying "more," we need to investigate different approaches. Combining low-dose drugs that target distinct antithrombotic mechanisms may be a strategy that achieves additional gains without additional costs. With anticipated completion in January 2019, VOYAGER PAD will answer this critical question.

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include CART, reverse CART, SAFARI, RE-BACK and if needed, the Schmidt technique. Prior knowledge of the location and the type of CTO cap (type I-IV) through the use of preprocedure EVUS scanning assists in the safe and effective crossing of complex CTOs, which also leads to an increased rate of success. Due to severity and unpredictability of the disease, the CLI patient often presents with multilevel, multivessel disease. This clearly requires multiple CTO crossings in multiple vessels, which is paramount to safely accomplishing the desired results. The operator needs to be aware of appropriate locations for potential stent deployment as well as areas where placing a stent is unadvisable/inappropriate. Extra caution should be taken when utilizing atherectomy and DCB therapy in these areas in order to avoid complications such as flow-limiting deep wall dissection or perforations, as both may require bail-out stenting.

As previously discussed, a preplanned exit strategy aids in the decision-making process for whether to use a closure device or manual compression.

INPATIENT AND POSTOPERATIVE STAGES

Postprocedure nursing care is a key component in the treatment plan of the CLI patient. Obtaining hemostasis by compression is almost always successful, however, careful monitoring for bleeding or localized hematoma of the primary groin access site is essential. Post hemostasis checks every 15 minutes for the first hour, every half hour for the next 2 hours, and hourly for the next 4 hours is required. Because most CLI patients have tibial disease in combination with supragenicular disease, the calf area should also be assessed when the access site is checked due to the potential of compartment syndrome. A pre-procedure measurement of calf circumference allows for post-procedure comparison when examining the calf swelling due to any previously

undetected tibial perforation. Any issues can usually be quickly addressed by inflating a blood pressure cuff around the affected calf area. EVUS can also be used to look for any extravasation of the offending vessel with the use of color Doppler. This will also denote if there is any collection of blood in the compartment, which presents as a darkened area under ultrasound.

THE OUTPATIENT STAGE

Within 72 hours, a postdischarge follow-up phone call is recommended to reassess the patient for unexpected issues such as groin pain or swelling, thigh or calf pain, or any other unanticipated complications with the tibial or groin access sites. It also provides an opportunity for addressing patient questions or concerns.

A postoperative evaluation at the 4-week appointment includes a duplex ultrasound to measure the flow of the recently re-vascularized vessel, as well as ABIs and TBIs. If the flow is normal, the patient is seen again at 3 months. Often after revascularization, the pulses are still not palpable so the DP and PT pulses are checked with a hand-held Doppler at each visit. If in fact they are palpable, this should be documented in the patient's medical record. Presence or absence of claudication, rest pain, and/or wounds needs to be documented. If wounds are present, wound healing or lack thereof also need to be documented, and follow-up with the wound clinic suggested. The same testing is performed and the same documentation is collected at both the 6-month and 12-month followup appointments. The only exception is if a duplex ultrasound is needed at the 6-month appointment: this is not routinely ordered, and the results need to be documented. At the 12-month appointment, if the patient is asymptomatic and any previous wounds are healed, no further work-up is necessary. If any time after the first intervention the patient reports claudication symptoms or rest pain, or if the patient

presents with a wound, additional therapy is indicated and the patient may be scheduled for revascularization.

Discussion of implementing a medical therapeutic approach is necessary when providing care to patients after peripheral vascular intervention. Differing opinions on and approaches to medical therapy exist among providers. Although not much data are available to support the therapy that is currently being used, many physicians follow the atherosclerosis guidelines for treatment of the coronaries. This includes the use of dual antiplatelet therapy (DAPT) based on the type of treatment that is delivered. If a bare metal stent is deployed, DAPT is used for 4 weeks, after which only aspirin is prescribed. If a drug-eluting stent is deployed in the coronaries or below the knee, DAPT is prescribed for 12 months. For patients receiving drugeluting stents in the superficial femoral artery, DAPT is used for at least 6 months or longer if tolerated.

Statins are also included in the medical course of therapy for the CLI patient. Statins have been shown to be very effective in both atherosclerotic coronary and carotid artery disease, so one can conclude that the same benefit could be gained in the peripheral artery disease and treatment of CLI patients as well. Statins are prescribed as tolerated with the goal of keeping LDL levels below 70mg/dL. Angiotensinconverting enzyme inhibitors can also be utilized, as there may be some evidence that they contribute to possible vessel remodeling. While there are no large clinical studies to support this, coronary studies show some evidence that this would be beneficial.1

Indefinite use of beta-blockers is also suggested for CLI patients. Occasionally in CLI patients with severe distal capillary bed spasm or small vessel disease, calcium channel blockers (both dihydropyridine, i.e. Norvasc, and nondihydropyridine, i.e. cardizem or verapamil) can be used to insure that both calcium channel pathways are affected to obtain the highest level of vasodilation possible.

Finally, long-acting oral nitroglycerin is another option that can be added to the treatment of vasospastic disease or advanced CLI, although there is a lack of strong evidence to support this use. Occasionally, topical nitroglycerine is used in patients with severe foot pain to theoretically enhance subcutaneous dilation of microcirculation.

Peripheral vascular rehabilitation is a relatively new concept that should be included in the post revascularization treatment plan for CLI patients. The deconditioning of these patients due to the disease progression is a limiting factor in their healing process. Reintroducing daily activities and stressing the importance of increasing ambulation will only aid in the recovery process; however, the patient may need to be motivated to make the effort. Sending them home with a short list of attainable goals may help influence and encourage them to put in the necessary work needed to regain their independence and resume their lives.

In conclusion, treatment of CLI is multifaceted and decidedly complex. The disease itself is also particularly complex and associated with high rates of morbidity and mortality. Aggressive and urgent treatment is necessary/essential to improve quality of life, prevent amputation, and ultimately save lives. It also requires building a solid, trusting relationship with patients and their families by using an all-inclusive team approach that includes physicians, nurse practitioners, physician assistants, wound specialists, nurses, vascular techs, cath lab staff, and office personnel. In providing a solid foundation of therapy with a multistep approach and delivering a conduit of comprehensive care, patients are given the chance to avoid amputations and reclaim the lifestyle they desire.

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presented successfully crossing aortoilliac CTOs using the Ocelot, the system is indicated for SFA, popliteal, and belowthe-knee vessel disease. The Ocelot size and stiffness is designed for proximal SFA through popliteal disease. The Ocelot PIXL length and sizing is well suited for BTK disease and retrograde access.

Subintimal Location

Optical coherence tomography enables direct visualization of adventitia, external elastic laminae, media, intima, and plaque. Accordingly, if the catheter tracks into the media or adventitia, the physician can immediately recognize the location, pull back the catheter into the lumen, and readvance in a different direction.

Calcium

Optical coherence tomography is the only intravascular imaging that sees through calcium, therefore enabling its identification as luminal or medial calcification. Ocelot's flexed tip allows for navigation through medial calcification or around luminal calcium. In severely calcified locations, where the catheter is unable to pass, the wire can be aimed lateral to calcium and advanced in a subintimal track around the location, at which point the catheter can track over the wire and re-establish luminal position.

CONCLUSION

Optical coherence tomography visualization offers real-time confirmation of luminal positioning, enabling the physician to continue when in the true lumen or to stop and redirect if subintimal. Initial experience with the Ocelot catheter for the treatment of CTOs suggests a high technical success rate, best in class safety profile, and versatile use across flush occlusions, BTK lesions, and calcified vessels. Additionally, studies have shown significant reduction in both contrast volumes and radiation required for CTO crossing. Optical coherence tomography guided CTO crossing is an established technique, represents the first time diagnostic imaging is available in real time, and minimizes or eliminates the need for fluoroscopy during CTO crossing.

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Selected Abstracts From the 6th Annual Amputation Prevention Symposium

A Retrospective Analysis of the Long-Term Impact of a Comprehensive Amputation Prevention Program at a Community Hospital on Amputation Rates

Jihad A. Mustapha, MD; Larry Diaz-Sandoval, MD; Maen Karadsheh; Judy Van Dam, RN; Theresa McGoff, RN; Sara Finton, RN; Sue Rosema, RN; Carmen Heaney, RN; Fadi Saab, MD

From Metro Health Hospital, Wyoming, Michigan.

Introduction: Preventing lower-extremity amputation is critical from both a medical and economic standpoint. Annually, approximately 120,000 Americans undergo amputation and by 2050 it is estimated that 3.6 million Americans will be living with an amputation. Many of these amputations occur without prior diagnostic testing. Assessing the cost of lower extremity amputations is difficult but the direct heath care cost of major lower extremity amputation has been estimated at \$794,027 (2016 USD). This does not include socio-economic costs such as loss of productivity of patients and their family member caregivers, copays/deductibles and modifications required for living with a disability. Major amputations carry a significant risk of perioperative morbidity and mortality, including a greater risk of re-amputation, protracted surgical wound healing, loss of mobility, and poor long term survival rates of approximately 50% after 3 years. With evolving technology and multidisciplinary care, amputation is no longer an acceptable first option for critical limb ischemia (CLI) patients. **Objectives:** To analyze the long-term impact on amputation rates at Metro Health Hospital after development and implementation of an integrated researchbased amputation prevention program. Methods: A retrospective chart review was undertaken of approximately 150 patients from 2002 to 2014 with above- or belowthe-knee amputations at Metro Health Hospital due to peripheral arterial disease (PAD). Blue Cross/Blue Shield state, region, and hospital-specific data were evaluated. Analysis was performed of hospital quality data on number of PAD encounters, peripheral vascular interventions, and amputation rates before and after development of a CLI program to 2015. Results: From 2002 to 2008, prior to initiation of a CLI program, the average amputation rate was 8.2%. Metro Health Hospital's CLI program was initiated in April 2009. At the end of 2009, the amputation rate dropped to 3% for 533 PAD encounters. From 2009 to 2015, the amputation rate has averaged 2.54%. Conclusions: The number of PAD encounters has risen from 273 in 2002 to 1567 in 2015. The development and implementation of an amputation prevention program can decrease amputation rates. This decrease may be attributed to diagnostic testing, peripheral vascular interventions using the latest technology, comprehensive wound care, and management of comorbidities.

Treatment Protocol for Limb Salvage in Patients With Diabetic Foot Ulcerations

Danielle Butto, DPM; Lawrence DiDomenico, DPM; Frank Luckino, DPM From Ankle and Foot Care Centers, Youngstown, Ohio.

Introduction: The incidence of peripheral vascular disease (PVD) is 4 times higher in diabetics than in nondiabetics. Among diabetics, the patients with diabetic foot ulcers have a higher prevalence of PVD and macrovascular disease. Patients with Charcot deformity often present with a lower extremity deformity with associated ulceration and osteomyelitis. Objectives: We present our protocol for a staged reconstruction to achieve wound healing, deformity correction, and limb salvage. Methods: A retrospective chart analysis was performed on all patients that underwent a staged Charcot reconstruction and wound healing. Preoperatively, the patients underwent noninvasive vascular testing. When appropriate, patients were referred to vascular surgery for intervention before reconstruction. Reconstruction stage 1 consisted of wound debridement with bone culture and biopsy, application of wound vac, manipulation and reduction of deformity, and application of an external fixator. Infectious disease was consulted, and intravenous antibiotics were prescribed as indicated. Once wound healing was achieved, stage 2 consisted of removing the external fixator, aggressive bone resection eliminating the Charcot bone/infected bone, realignment, and correction of the deformity via arthrodesis of the deformity. All patients who underwent staged correction were included in the review. Patients were excluded if they had only a single stage reconstruction. Twenty-seven patients were identified, and 26 charts were available for review. Inclusion criteria included patients that underwent a staged Charcot reconstruction. The average age was 60 and the average BMI was 37. There were 13 females and 13 males. All of the patients had underlying diabetes mellitus. Results: Ten of the 27 patients' (37%) bone biopsies were negative for osteomyelitis. The remaining patients had a bone biopsy positive

for osteomyelitis. Six (24%) of the patients underwent removal of hardware due to infection. Regardless, 24 (92%) of the 26 patients achieved successful limb salvage. Only 2 patients (8%) went on to below-knee amputation. **Conclusions:** Successful limb salvage was achieved with proper pre-operative vascular evaluation and staged correction of the deformity. We recommend non-invasive vascular testing and referral to vascular surgery prior to reconstruction, along with an initial surgery consisting of bone debridement with biopsy and culture, wound vac application to underlying open ulcerations, and application of external fixator device. When appropriate, a referral to infectious disease is made. Once the wound is completely healed, the patient undergoes stage 2 consisting of deformity correction.

A Retrospective Analysis: The Impact of Implementation of Skin Perfusion Pressure

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Introduction: Our goal is to show increased PAD detection accuracy, improve quality of outcomes, and decrease major amputations in patients with complications related to "calcified vessel disease" through implementing skin perfusion pressure (SPP) testing within a podiatry practice setting over the past 15 months. Objectives: Twenty-nine million people in the U.S. have diabetes. Without proper management, these patients are at risk for developing a diabetic foot ulcer (DFU). Neuroischemic DFUs have dramatically increased over the past decade and now account for >50% of all DFUs with insufficient arterial supply. Traditionally, ankle-brachial index (ABI) has been used to detect disease, assess efficacy of therapy, and monitor for disease recurrence. An ABI >1.2 is classified as non-compressible vessel disease, suggesting a vascular consult. However, it is now understood that elevated ABIs are spuriously labeled normal when in the range of 0.9-1.2, and that calcification insensitive tests should be used in order to provide the best possible limb preservation outcomes. Methods: Over a 15-month period, 81 patients who had reported "normalized" arterial duplex testing with an ABI of 1.1-1.4 were retested using ABI and SPP. This study describes the podiatric wound care specialists' perspective of their "paradigm shift" when adding a noninvasive arterial SPP testing protocol for all "at-risk patients" for diabetic neuroischemic ulcers. Results: Of the 81 patients tested, 65 (80%) were identified as having PAD disease. Results ranged from ABI between 1.1-1.4 and SPP 9-50. Since implementing SPP as a routine element of our vascular assessment protocol, we have been able to improve testing accuracy and thereby better direct a plan of care, improve quality outcomes and healing rates, and decrease major amputations. This retrospective data reflects the unpredictability of an ABI for diagnosing PAD due to the calcified noncompressible vessels, and the immediate need for a "paradigm shift" in PAD evaluation and assessment quantitative beyond the ABI. Since initiating the use of SPP, there have been no major or minor amputations experienced by the primary author in his practice. Conclusions: Based on the results, 90% of the patients were referred to endovascular specialists based on the data returned from the SPP testing. These patients would not have been recognized nor treated as having PAD without the added benefit of angiosomal skin perfusion testing. Based on the results, the continued use of the ABI alone in diagnosis and management of PAD is not medically appropriate or prudent.

A Rare Cause of Critical Limb Ischemia: Previously Unknown Arteriovenous Fistulas in an Adult Patient

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Introduction: A 51-year-old male came to the emergency department referring to rest pain in his left foot. He had a previous history of diabetes, was an ex smoker, and had undergone complete hip arthroplatsy on his left hip 5 years ago, without any history of a previous accident or traumatism in his left inferior limb. He had an ankle-brachial index (ABI) of 0.35, and the angiography showed a patent aortoiliac sector, a diseased common femoral artery, an obstruction of the distal superficial femoral artery (SFA), and the presence of many arteriovenous fistulas with a rapid filling of the distal and popliteal veins, with a weak filling of the dorsalis pedis artery. **Objectives:** Following the findings of the angiography and because of the severe

pain of the patient, we attempted to revascularize the left inferior limb. A diagnostic angiogram was obtained through a 6 Fr ipsilateral sheath, showing a rapid flow of the contrast from the artery to the popliteal vein above the knee. **Methods:** A femoral endarterectomy was performed, but an initial attempt to recanalize the SFA from antegrade was not successful. After puncturing the dorsalis pedis artery, we were able to recanalize the anterior tibial artery and another angiogram was performed below the knee. After deploying a stent in the distal end of the SFA, another covered stent was left in the anterior tibial artery to seal the most important fistula. Before finishing the procedure, the peroneal artery was dilated. **Results:** The patient did well and the rest pain disappeared, still (1 year after surgery) suffering from a 200-meter claudication (ABI 0.74). Left popliteal pulse was present at discharge and 6 months after surgery. **Conclusions:** An angio-CT was done during follow-up, showing a patent common femoral artery and SFA stent. Although there was still considerable flow to the veins, the anterior tibial artery and the peroneal artery were still patent.

Endovascular Therapy of TASC D Lesion in Critical Limb Ischemia

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From ¹Cardiology, Joan C. Edwards School of Medicine, Marshall University, Huntington, West Virginia; ²Interventional Cardiology, Joan C. Edwards School of Medicine, Marshall University, Huntington, West Virginia.

Introduction: Revascularization options for patients with infrarenal aortic and iliac obstructive atherosclerotic disease are open surgery such as aortofemoral bypass and axillofemoral bypass or percutaneous intervention. Because many of these operations involve extensive abdominal incision, morbidity and mortality can become significant in at-risk patients. **Objectives:** A 52-year-old female smoker with PMH of HTN, HLP, and severe PAD with a totally occluded infrarenal abdominal aorta just distal to the renal arteries and known right axillary femoral bypass with femfem bypass, presented with bilateral leg and foot pain at rest, diminished pulses, and ulceration of the legs. ABIs were obtained and were abnormal (right leg ABI: 0.27, TBI: 0.12; left leg ABI: 0.3, TBI: 0.12). CTA showed total occlusion of the axillofem-fem bypass, and infrarenal aorta with reconstitution of peripheral circulation

at the level of external iliac arteries bilaterally. These findings were confirmed by angiogram obtained by accessing the right radial artery. Methods: Using radial access in conjunction with ultrasound-guided access to the right and left femoral arteries, respectively, successful PTA and stents to the abdominal aorta using a self-expandable stent, right and left common iliac arteries using covered stents in a kissing fashion, as well as treatment of the right and left external iliac arteries, were successfully obtained. Results: At 3-week follow-up, the patient's symptoms of claudication resolved, had good pulses bilaterally, healing ulcers and favorable ABIs (right leg ABI: 0.84, TBI: 0.68; left leg ABI: 0.82, TBI: 0.65). Discussion: Therapy of CLI must be designed to restore pulsatile flow to the distal limb with as low a procedural morbidity as possible. The Inter-Society Consensus (TASC) document described characteristic lesion morphology for ideal (type A) and unfavorable (type D) iliac lesions for endovascular therapy. The Bypass versus Angioplasty in Severe Ischemia of the Leg (BASIL) trial was a British multicenter randomized trial that compared an initial strategy of angioplasty with open surgery in 452 patients with CLI. The primary outcome was time to amputation or death (amputation-free survival). After 6 months, the 2 treatment strategies did not differ significantly in amputation-free survival. There was no difference between the groups for quality of life outcomes, but for the first year of follow-up, costs associated with a surgery-first strategy were higher than for angioplasty. For this reason, the authors concluded that a percutaneous-intervention-first strategy was the treatment of choice in patients who are candidates for either surgery or endovascular intervention. Aortofemoral bypass procedures are associated with 74% to 95% 5-year patency rates, respectively, which are comparable but not superior to percutaneous therapies. In small several series involving aortoiliac intervention, there was high success of stent placement, no major complications, symptomatic improvement, and a 2-year patency rate approaching 87%. For common iliac bifurcation lesions, kissing balloon-expandable stents have become the preferred option. In small several series involving aortoiliac intervention, there were high success rates of stent placement, no major complications, symptomatic improvement, and a 2-year patency rate approaching 87%. **Conclusions:** Patients with TASC D lesions generally will be considered surgical candidates, but with advancement of technology, endovascular therapy might be an option on a case-by-case basis.

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Use of Intravascular Ultrasound to Guide Arterial Thrombectomy in Critical Limb Ischemia John Hovorka, MD, FACS, RDMS, RDCS, RVT, RPVI, RMSK, RCIS

John Hovorka, MD, FACS, RDMS, RDCS, RVI, RPVI, RMSK, RCIS From Valley Ambulatory Surgery Center, LLC, McAllen, Texas.

Introduction: Some soft or mixed plaque has been somewhat resistant to multiple atherectomy devices, and our group has struggled to prevent early reocclusion. It was thought that suction-guided thrombectomy may help to delay reocclusion. **Objectives:** The clinics treat patients primarily by TAMI technique as the initial access if possible. There have been residual lesions seen by IVUS, not well seen on angiogram, that have led to early reocclusion. The goal is to try to increase the median reintervention rate out to 36 months. This is a pilot study to see if suction-assisted thrombectomy would be useful. Methods: We used the FDA-approved suction-assisted thrombectomy device in 5 patients. Pre and post measurements by IVUS were performed. Standard treatment has been IVUS-guided laser followed by angioplasty, and residual lesions noted by IVUS were treated with suction-assisted thrombectomy. Images of typical lesions seen by IVUS (pre and post) were presented. A commercially available aspirator was useful in 3 cases, although in 2 cases, the vessels were so small that catheters of smaller than 35 thousandths of an inch had to be used. Results: Results have been mixed, with 2 anterior tibial arteries, 2 tibioperoneal trunks, and one femoral popliteal lesion treated. All had improvement in residual stenosis by IVUS. One anterior tibial artery had complete reocclusion and one had 90% complete resolution. The best results have been in areas that are somewhat out of the reach of atherectomy devices, such as in the turn of the ATA, where our best results have been noted. Conclusions: Plaque morphology is still not fully understood. Some plaques with residual material not vaporized by laser were previously thought to be mostly calcium, although as illustrated, we have had success aspirating with thrombectomy devices and the effluent did not have hard calcific material. This is a pilot study, and in cases where aspiration thrombectomy was used, IVUS has proven to be an invaluable tool.

The Use of Arterial Testing and Intervention Prior to Lower Extremity Amputation in a Community Hospital

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Introduction: Peripheral artery disease in its most severe form, critical limb ischemia, is associated with amputation rates as high as 40% at 6 months and mortality rates approaching 25% in the first year. Despite the ever-increasing role for revascularization in critical limb ischemia, an inadequate number of patients undergo even basic arterial testing prior to amputation. Objectives: We sought to identify the frequency of arterial testing (both noninvasive and invasive) and endovascular intervention prior to lower extremity amputation at our institution. Methods: The records of 220 patients who underwent major lower-extremity amputation (above knee, below knee, and metatarsal) over a period of 24 months (April 2014 to March 2016) were retrospectively analyzed. Patient demographics included hypertension (84%), diabetes mellitus (72%), tobacco abuse (64%), and hyperlipidemia (64%). The main outcomes measured were rates of preamputation arterial testing including arterial duplex, ankle-brachial index (ABI), computed tomographic angiography (CTA), and invasive angiography. Endovascular intervention prior to amputation was also evaluated. Results: Among 220 patients undergoing nontraumatic lower extremity amputation, 181 (82%) had some form of arterial testing performed prior to amputation. Of these, 28 had ABI performed (13%), 118 had arterial duplex (54%), 86 had an angiogram performed (39%), and 58 had computed tomographic angiography prior to amputation (26%). Overall, there were 39 patients (18%) who had no arterial testing performed prior to amputation. Only 118 patients (54%) had either an angiogram or CTA performed prior to amputation. There were only 19 patients (9%) who had endovascular intervention performed prior to amputation. Our data is consistent with recent Medicare data revealing the strikingly low utilization of arterial testing and endovascular revascularization prior to lower extremity amputation. Nearly 1 out of 5 patients had no arterial testing, and less than 10% had endovascular intervention prior to amputation. Conclusions: As primary amputation is rarely the appropriate first-line therapy, this sobering retrospective analysis demonstrates the underutilization of arterial testing and potentially missed opportunities to prevent amputations. The implementation of an evidence-based multidisciplinary limb salvage program is evident.

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¹ Primary efficacy endpoint is defined as freedom from 1LH at 12 months. Iotal of 639 subjects were evaluable for the primary efficacy endpoint analysis. Ihe 12 month 1LH Free rate by subject counts at 12 months was 93.6%. Ine Kaplan-Meier estimates 1LF-Free survival was 94.2% at 12 month and 89.2% at 12 month and 89.2% at 12 months. TLR-Free survival by lesion location was 94.8% (n=483) for SFA, 94.0% (n=86) for popliteal, and 92.2% (n=121) for patients with lesion in both SFA and popliteal. Please consult package insert for more detailed safety information and instructions for use. @ Millenium Research Group, Inc. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission. Please refer to the LUTONIX® 035 IFU for complete data sets and more detailed LUTONIX® 035 DCB clinical information, including with regard to the LUTONIX® DCB Global SFA Registry and the LEVANT 2 global, prospective, randomized, pivotal study.
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