CLI GLOBAL
THE OFFICIAL PUBLICATION OF THE CRITICAL LIMB ISCHEMIA GLOBAL SOCIETY

CLI Global Society Spreading Awareness Among Physicians of All Disciplines

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Critical limb ischemia (CLI) snuck up on us over the years until rising to its current major epidemic status in the United States and around the globe. How did that happen, especially in a country that is known for tackling deadly diseases with vim and vigor? Examples are awareness campaigns for lung cancer, colon cancer, stroke, heart failure, and prostate cancer. And yet, when you stop to think, CLI is actually deadlier than all of the afore-mentioned diseases. With the knowledge that a CLI diagnosis is associated with impending death, what is it going to take for us as physicians, for all the societies, and our government to take this disease seriously, to a point where we actually start to see a change in behavior from current status quo to taking action? Now is the time to stop doing nothing and JUST DO SOMETHING!

The CLI Global Society is proud to announce it is involved in data mining and analysis to create a wealth of knowledge based on peer-reviewed, published data. The CLI Global Society is involved in putting these data together to help guide those that are involved in the therapy of CLI on a daily basis. The CLI Global Society has a multidisciplinary, patient-centric approach to awareness.

Most recently, the CLI Global Society co-developed a session at the International Symposium on Endovascular Therapy (ISET) 2018 in Miami, Florida, titled "Wound Care for the Interventionalist." The session was moderated by CLI Global Society Board Members Richard Neville, MD, FACS, and Vickie Driver, DPM, MS, FACVAS (Figure 1). The multidisciplinary panel represented podiatry, vascular surgery, wound care and nursing (Figure 2). This Deep Dive session started with a comprehensive talk on the physiology of wound healing by Gary Gibbons, MD, who emphasized, "A multidisciplinary approach to the patient with vascular compromise and a wound is crucial. The revascularization specialist must have clear knowledge of progression and regression of wound status." Dr. Gibbons also provided a primer for the revascularization specialist on bacteria, biofilm and antibiotics.

Steven Dean, DO, did a deep dive on how to identify typical and atypical ischemic wounds, which are not created equal. He also shared a comprehensive talk on imaging in wound care,

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Figure 1. Vickie R. Driver, DPM, MS, FACFAS, co-moderated the Deep Dive Session on "Wound Care for the Interventionalist" at ISET 2018 in Miami, Florida.

Sabeen Dhand, MD

Beyond the Pedal Loop: Superselective Direct Angiosome Recanalization

Sabeen Dhand, MD, Lambert Radiology Medical Group at PIH Health, Whittier, CA

A 54-year-old female presented to our institution for evaluation of a poorly healing, shallow ulcer involving the great toe of her right foot (Figure 1). In addition to multiple medical problems, including Type 2 diabetes mellitus, coronary artery disease, and chronic kidney disease (Stage III), among others, the patient suffered from severe peripheral arterial disease resulting in below-the-knee amputation of her left leg, performed for a similar ulcer over 8 years ago in Mexico. No vascular workup was performed at that time.

Given the patient's desire to avoid a second amputation, she was referred by her cardiologist to our institution's wound care center and underwent a multidisciplinary work-up, including evaluation by podiatry, vascular surgery,

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AN HMP PUBLICATION

Pedal Loop and Its Critical Importance in Complex CLI Interventions

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Kumar Madassery, MD

Over the years, the pace of advancements in limb salvage interventions for patients with critical limb ischemia (CLI) has been fascinating, as new techniques, equipment, and imaginative interventions continue to evolve. Limb salvage has come to the forefront for the endovascular experts in multiple specialties, and the expectations of angiographic and clinical outcomes have never been more important. We have seen the evolution from above-the-knee interventions hoping to provide "adequate" flow to the foot, to working with the tibial vessels in an "angiosome" concept, to the present-day goal of pedal loop reconstruction. The necessity of having as much perfusion as possible in the distribution of the wound, and not necessarily just to the presumed angiosome, is what many of us aspire to achieve, due to the understanding that wounds have watershed arterial distributions.

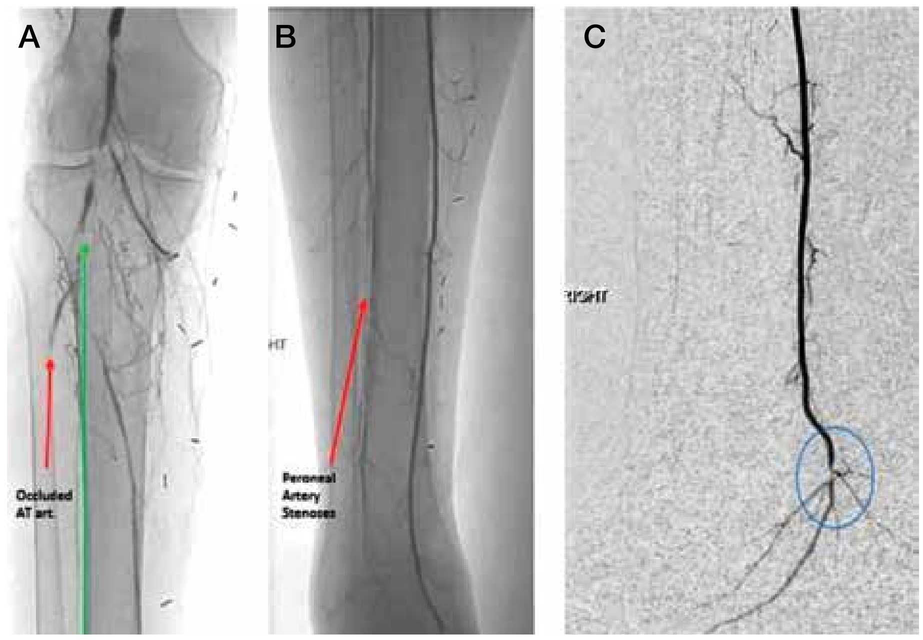

Figure 1A-C. A) Multifocal stenosis in a previously stented popliteal artery and chronically occluded anterior tibial artery. Tibioperoneal trunk disease is also present. B) A diseased peroneal artery. Primary posterior tibial artery inflow. C) Posterior tibial artery inflow, with focal stenosis at bifurcation into plantar arteries.

Due to our endovascular pioneers, pushing the previous limits of how distal we can intervene, we have reached a point where it is not uncommon to perform angioplasty of a proper digital artery. With this in mind, reconstruction of the pedal loop, with the caution that this type of intervention requires an advanced level of operator experience, is of immense benefit to the patient, so that maximum blood flow is achieved to heal their wounds.

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Editor's note: Articles in this supplement to *Cath Lab Digest* did not undergo peer review.

#CLIFighters: Turning Passion Into Action

Paul Michael, MD, FSCAI, Cardiology Partners, JFK Medical Center, Atlantis, Florida

Paul Michael, MD, FSCAI

Figure 1. Toe prosthesis of a female burial from the Theban tomb TT95, early first millennium BC. Egyptian Museum Cairo, JE100016a. © University of Basel, LHTT. Image: Matjaž Kačičnik. Reprinted with permission.

The discovery of a 3,000-year-old wooden toe prosthesis found in the necropolis of Sheikh Abd el-Qurna near Luxor, Egypt by Egyptologists almost two decades ago may mark the first-ever documented case of critical limb ischemia (CLI) (Figure 1). The wooden toe, which may represent the oldest discovered prosthetic device in human history, was recently reexamined using modern imaging by Egyptologists from the University of Basel. The recent reexamination of the toe using modern imaging by the Swiss team revealed details of its meticulous construction. It was designed with a lace-up leather strap, engineered to be worn with open-toe sandals, and showed evidence of multiple refittings, displaying exquisite attention to human foot mechanics.[1] Anthropological investigation revealed the mummy to be a 50- to 60-year-old woman.[2] Paleopathological examination revealed the toe was removed during her lifetime, given the intact layer of soft tissue. Further analysis using computed tomography (CT) of the mummified soft tissues revealed a peripheral arterial calcification pattern consistent with the multilevel and multivessel disease described later[3] with focal severe calcification of the aorta and tibio-pedal vessels.[2] This lifelike prosthesis was able to maintain aesthetics, mobility, and a way of life for a patient who may have suffered from ischemic gangrene. The same appreciation for the functional consequences of limb salvage drives many of us to dedicate our practices to amputation prevention and saving lives; this passion, however, is not enough and more collaborative action is needed against CLI.

The multi-billion-dollar burden known as CLI is responsible for 5-year

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Figure 3. 8 Fr access via posterior tibial vein (Terumo) for iliofemoral DVT using 8 Fr Boston Scientific Zelante (A). Ambulatory thrombolysis via posterior tibial vein for iliofemoral DVT (B).

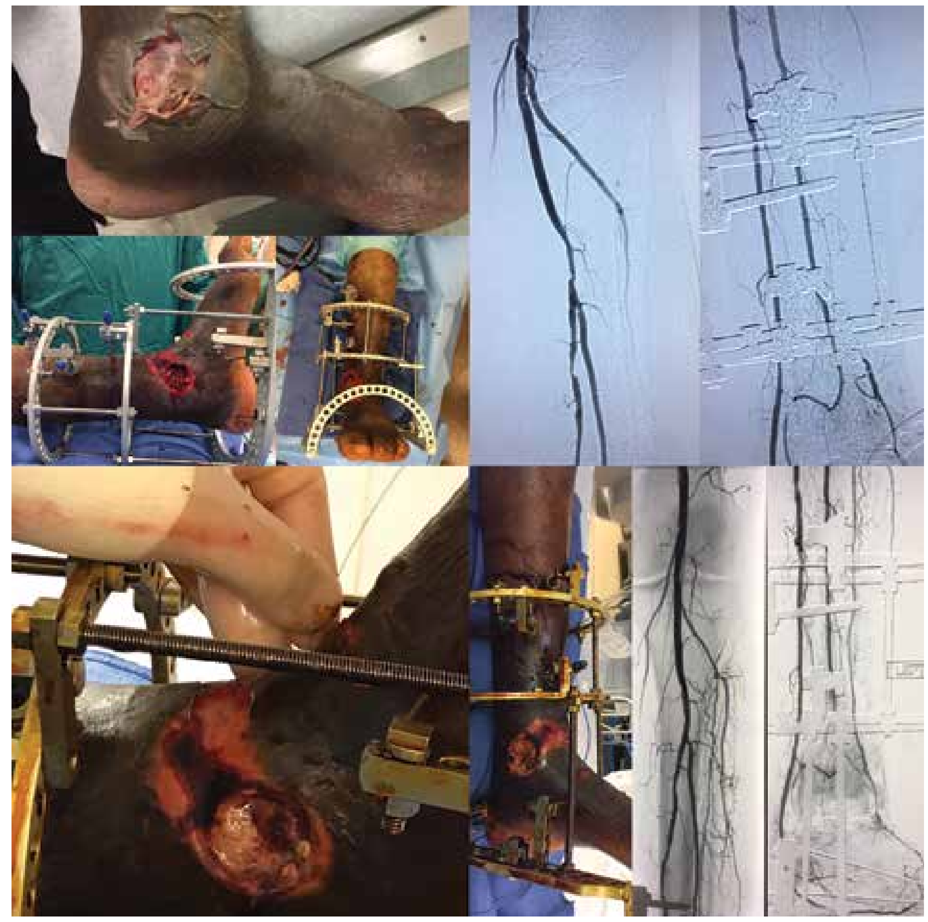

Figure 2. Infrapopliteal and inframalleolar reconstruction of a traumatic wound (A) leading to CLI with TP trunk disease and an AT artery CTO, (B) highlighting dorsalis pedis access through an external fixation frame (C), with restoration of in-line flow (D).

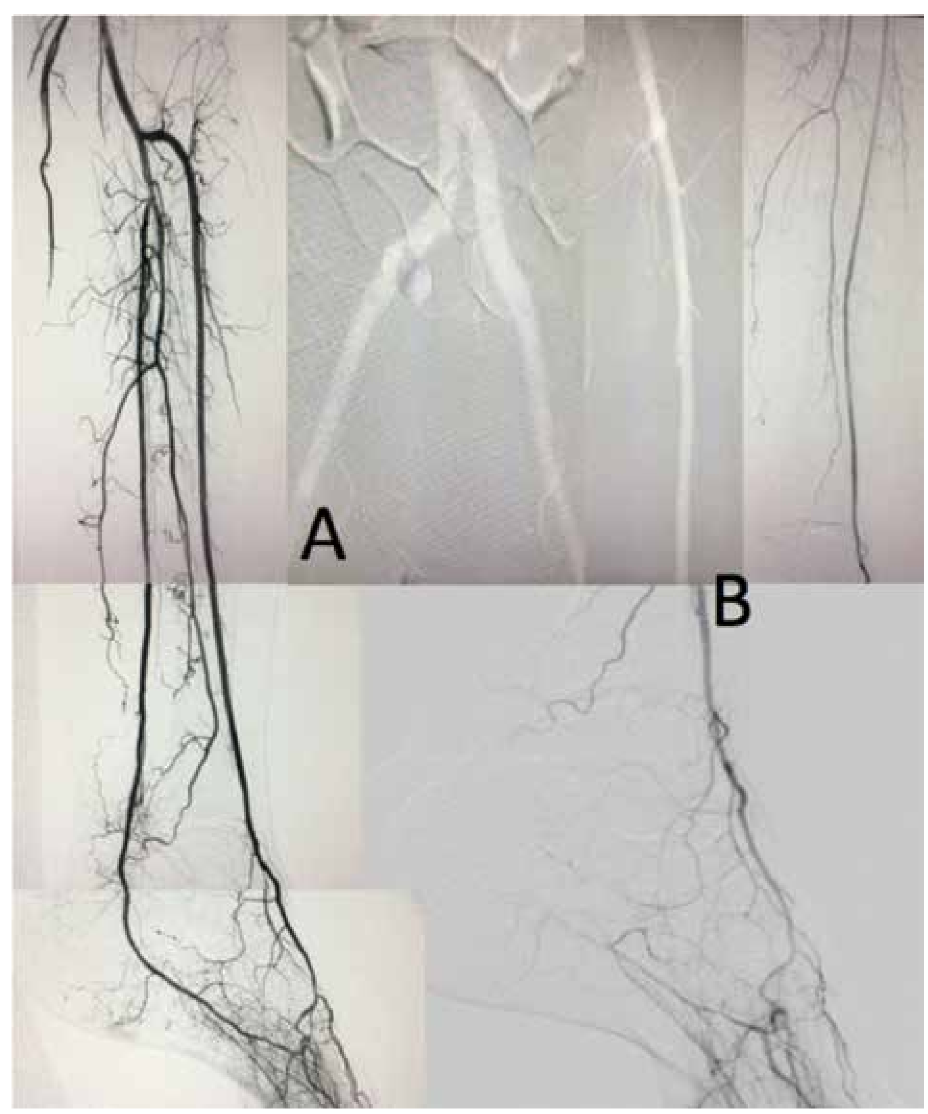

Figure 4. CO_2 angiography (A) followed by super-low contrast for CLI PTA planning in a chronic kidney disease stage IV patient (B). Final angiography after "Near Zero" intervention with 3-vessel in-line flow and a complete pedal loop for wound-directed therapy (C).

Contemporary Adjuncts to Flow and Lesion Assessment

Steve Henao, MD, FACS, FACC, Vascular Surgery and Vascular Interventional Radiology, New Mexico Heart Institute, Albuquerque, NM

Steve Henao, MD, FACS, FACC

A 69-year-old gentleman presented to our critical limb ischemia (CLI) service with debilitating rest pain and gangrene affecting the right first and second toes of the foot. His past medical history was notable for poorly controlled diabetes mellitus, coronary artery disease, chronic obstructive pulmonary disease, hypertension and end-stage renal disease (on dialysis Monday, Wednesday, and Friday). He had suffered a below-knee amputation eight years prior secondary to ischemic gangrenous degeneration of his forefoot with resultant osteomyelitis. Unfortunately, no angiography or intervention was offered to the patient at that time. Now, the patient presents to our service as a second opinion for an above-knee amputation.

His preoperative evaluation at our clinic demonstrated a right ankle-brachial index of 0.46. An arterial duplex was performed that showed reasonable, biphasic flow at the femoropopliteal segments, with monophasic flow consistent with occlusive disease of the peroneal, anterior, and posterior tibial arteries of the remaining leg. The patient was consented for right lower extremity angiography and possible intervention within 72 hours.

On angiography, the aortoiliac and femoropopliteal segments demonstrated diffuse, calcific disease. There was no evidence of critical stenotic disease, however. The tibial circulation demonstrated severe occlusive disease, as suspected on the preoperative duplex imaging. There was a chronic total occlusion of the tibioperoneal trunk. The proximal two-thirds of the posterior tibial artery were also chronically occluded. The anterior tibial artery was chronically occluded 6 centimeters after its take-off. There was reconstitution of the all three vessels ultimately at the level of the ankle. An on-table ultrasound of the leg was performed that demonstrated an absent right great saphenous vein (secondary to coronary artery bypass graft vein harvest).

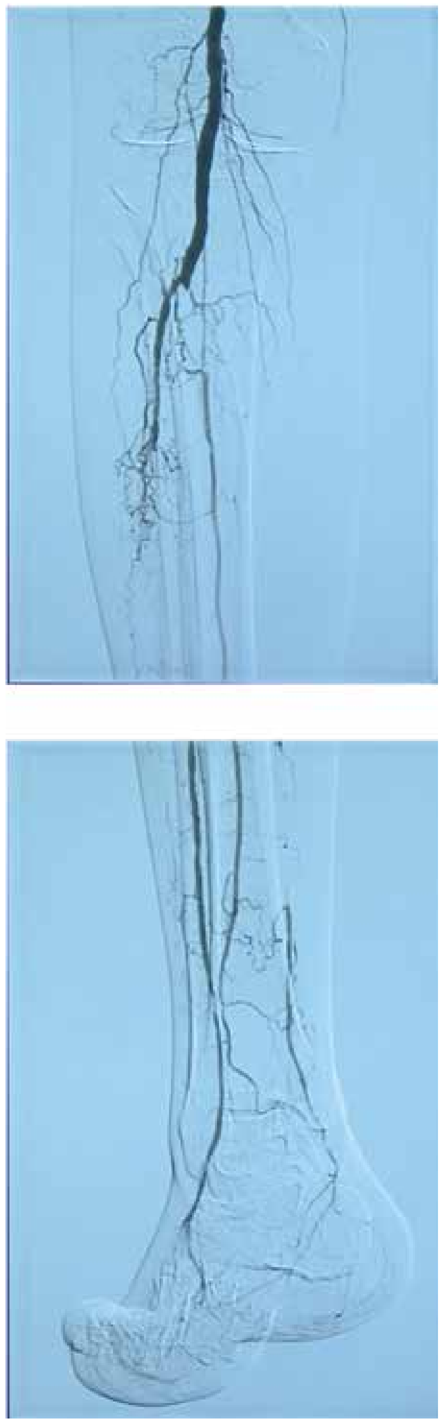

Figure 2. Chronic total occlusion (CTO) of the proximal tibioperoneal trunk, anterior and posterior tibial arteries with reconstitution at the ankle.

Figure 1. Right 1st and 2nd digit gangrene. The foot and ankle are prepped in anticipation for possible retrograde access.

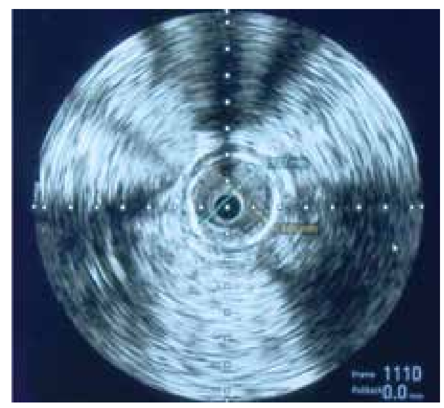

Figure 3. Intravascular ultrasound (IVUS) of the anterior tibial artery demonstrating a larger than expected 3.7 x 3.8 mm vessel.

Figure 4. IVUS of the anterior tibial artery after CTO crossing demonstrates a short segment subintimal wire position not recognized on angiography.

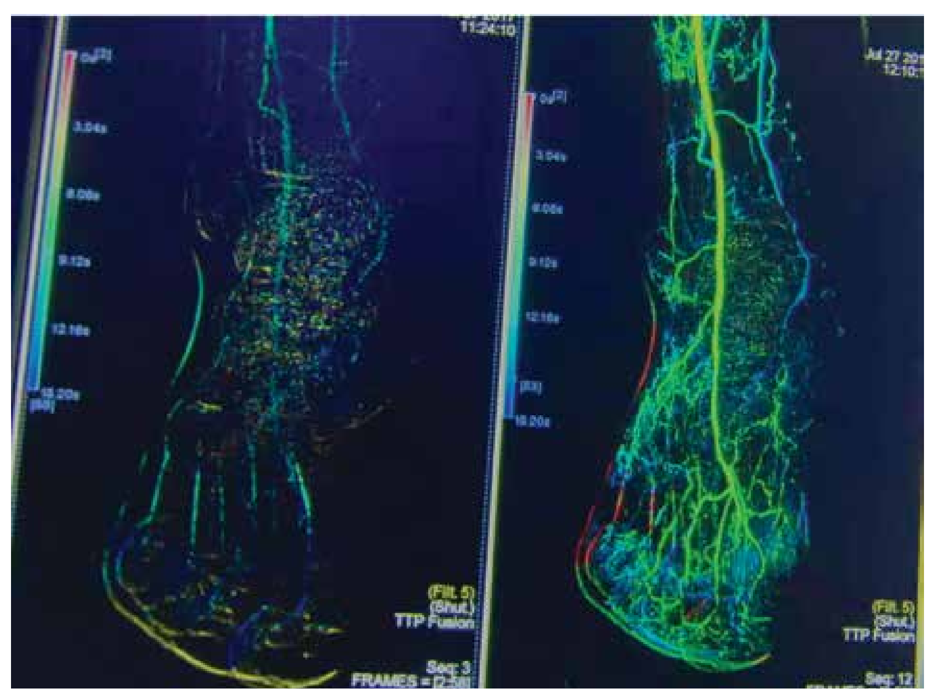

Figure 5. Before and after assessment of peak flow after single vessel (anterior tibial artery) revascularization.

A 6 French, 90 centimeter (cm) sheath was placed up and over the bifurcation, and positioned in the popliteal artery after heparin was administered. Activated clotting times were performed every twenty minutes to ensure a value of at least 250 seconds. An 0.014-inch chronic total occlusion (CTO) wire and support catheter were carefully advanced into the proximal stump of the anterior tibial artery. Tactile interrogation of the vessel was consistent with a convex fibrous cap. After several conservative attempts at antegrade CTO crossing, ultrasound-guided pedal access

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Primary Patency					
Overall	**87.9**	**79.4**	**68.1**	**53.7**	**50.3**
TASC IIA/B	**92.3**	**84.9**	**76.5**	**64.7**	**62.0**
TASC IIC/D	**80.0**	**70.4**	**58.9**	**34.4**	**NA**
Run-Off ≥ 2	**91.2**	**83.7**	**69.8**	**59.6**	**59.6**
Run-Off ≤ 2	**85.0**	**76.2**	**67.0**	**48.9**	**42.5**
Secondary Patency	**96.5**	**91.7**	**85.0**	**73.8**	**67.7**

- 319 limbs in 269 patients
- Critical Limb Ischemia (CLI) observed in 14.1% of limbs
- Mean target lesion length was 118.5±81.0 mm
- 57.7% of lesions had poor distal runoff
- 37.3% classified as TASC IIC/D
- 41.1% CTO

IMPORTANT INFORMATION: Prior to use, refer to the "Instructions for Use" supplied with these devices for indications, contraindications, side effects, suggested procedures, warnings and precautions.

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Reference: 1. Matsumi J, Tobita K, Shishido K, et al. Long-term outcomes of SMART stent implantation in patients with femoro-popliteal disease. *Catheter Cardiovasc Interv*. 2016 Nov; 88(5): 832-841. doi: 10.1002/ ccd.26718.

Extreme Wound Healing: Acute Limb Ischemia Superimposed on Chronic Limb Ischemia

Srini Tummala, MD, Limb Preservation; Chief Vascular Interventional Services, Department of Vascular & Interventional Radiology, University of Miami Health System & Clinics,University of Miami Miller School of Medicine, Miami, FL

Srini Tummala, MD

CASE REPORT

A 78-year-old female presented to the emergency department with a 2-week history of worsening, intractable, left lower extremity pain. For the past several months, the patient had been undergoing treatment for a large non-healing wound after a left great toe amputation. Her past medial history was significant for severe peripheral arterial disease with chronic lower extremity pain/rest pain, insulin-dependent diabetes mellitus, hypertension, hyperlipidemia, and previously treated osteomyelitis of the left foot.

Her past endovascular and surgical history revealed prior left superficial femoral artery (SFA), left popliteal artery, and proximal left anterior tibial artery stents placed at an outside hospital. She had no prior bypass surgery. The patient has never used tobacco and was a non-bypass candidate. Her labs: CBC, BMP, PT/PTT/INR, and fibrinogen, were all within normal limits. Her medications were as follows:

Xarelto 15 mg po;
Lipitor 80 mg at bedtime;
Zyrtec 10 mg daily;
Dakin's Solution 1/4 strength daily topically to affected area;
Glimepiride 4 mg po daily;
Cozaar 100 mg po daily;
Metoprolol 100 mg every 12 hours;
Bactroban 2% ointment daily to affected area;
Nifedipine XL 60 mg po daily;
Protonix 40 mg po daily;
Insulin sliding scale;
Percocet 1 tab q 6h prn po for severe pain.

On exam, the patient had a large non-healing wound at the site of prior left great toe amputation (Figure 1). The left lower leg and left foot were cool with decreased sensation, but intact motor/strength. Her left common femoral artery (CFA) pulse was 1+ with non-Doppler and non-palpable left popliteal artery and pedal pulses.

Non-invasive arterial study showed flattening of the waveforms in the left thigh and below the knee, compatible with left femoral-popliteal disease and left tibial-peroneal artery occlusive disease (Figure 2).

Given the patient's presentation, acute limb ischemia (ALI) superimposed on chronic limb ischemia (CLI) was suspected. The patient was taken to the angio suite for pelvic and left leg angiography with intervention.

Right CFA access was obtained with placement of a 6 French (Fr) sheath (Terumo). A 5 Fr Omni Flush catheter (AngioDynamics) was advanced into the distal abdominal aorta. A pelvic angiogram was performed in the anterior-posterior (AP) and bilateral 30-degree oblique projections (Figure 3). A 4 Fr Cobra catheter (AngioDynamics) was then used to selectively catheterize the distal left CFA with an .035-inch Glidewire (Terumo). A left leg angiogram was performed, showing sluggish flow in the left SFA suggestive of distal occlusion (Figure 4). Additional imaging confirmed an occluded left popliteal artery at the knee joint with no significant below-knee runoff, except for reconstitution of an isolated distal left peroneal artery without opacification of the pedal arch (Figure 5).

Since ALI superimposed on CLI was suspected given the patient's presentation, the 4 Fr Cobra catheter was exchanged for an .035-inch Amplatz guidewire (Boston Scientific) and the 6 Fr sheath at the right groin was exchanged for a 6 Fr, 45 cm Destination sheath (Terumo), which was advanced into the left external iliac artery. A 5 Fr Cragg-McNamara catheter (30 cm infusion length) (Medtronic) was advanced over the guidewire so that its proximal marker was in the proximal SFA and its distal marker was in the proximal left anterior tibial artery. Thrombolysis

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Figure 1. Large non-healing wound status post left great amputation.

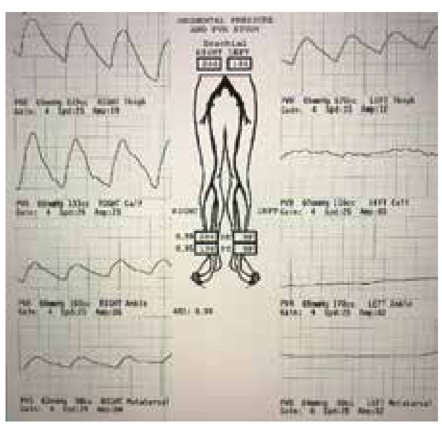

Figure 2. Non-invasive arterial study shows flattening of the waveforms in the left thigh and below the knee, compatible with left femoral-popliteal disease and left tibial-peroneal occlusive disease.

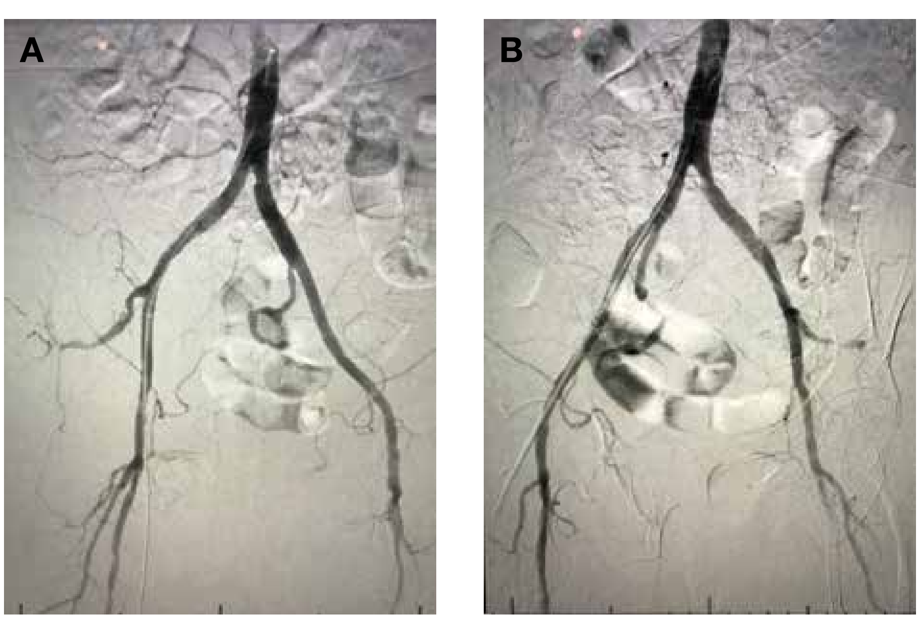

Figure 3. Pelvic angiogram shows no hemodynamically significant inflow stenosis.

Figure 4. Left leg angiogram shows sluggish flow in the left SFA, suggestive of distal occlusion.

Critical Ischemia in a Morbidly Obese Female: Revascularization Complicated by Stent Fracture and Particle Catheter Tip Dislodgement, With Successful Treatment by the CrossLock LP Device

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Richard R. Heuser, MD, FACC, FACP, FESC, FSCAI

Peripheral arterial disease affects nearly 9 million Americans over 40 years of age. The manifestation of PAD ranges from asymptomatic to intermittent claudication to critical limb ischemia with tissue loss. Critical limb ischemia "is characterized by chronic ischemic rest pain, non-healing wound or ulcers, gangrene in at least one leg attributable to objectively proven arterial disease".[1] In general, an interventionist will attempt to improve the blood volume to the ischemic territory. Davies et al documented in 2008 that the number of runoff vessels was directly related to the patency, and clinical outcomes and interventions performed in the femoral popliteal segment in patients with critical limb ischemia.[2] Iida et al reported in 2010 that patients treated with establishment of direct in-line flow to the angiosome where the wound was located had better limb salvage rates at 4 years, than those where indirect flow was obtained.[3]

Many of our critical limb ischemic patients have had multiple interventions. In the case described below, this morbidly obese female had multiple previous complications from previous procedures. In addition to a small piece of a nitinol wire in her access site in the left groin, she also had a self-expanding stent placed in her superficial femoral artery (SFA) that had fractured, restenosed, and occluded. We also managed, with this difficult patient,

Figure 1. A contralateral injection reveals the occluded SFA at its origin. The occlusion has a very small bud. Note the hydrophilic tip previously sheared off.

to break off the tip of a otherwise very effective self-expanding stent, leading to our own complication. With the patient's difficult anatomy and fracture of a previously placed stent, it was imperative that we stay in the intraluminal position in order to safely cross this previously placed stent. We have long felt that the CrossLock (Radius Medical) device, the first centering device for coronary and peripheral intervention, would be ideal when you want to make sure you stay in the lumen. In this difficult case, we felt it was essential.

CASE DESCRIPTION

A 63-year-old African American female presented for critical limb ischemia of her left foot. She had a non-healing ulcer on the dorsum of her left foot that had been present for the last 3 months. She has had previous placement of a self-expanding stent in her SFA territory by another operator. A previous angiogram confirmed that this stent was not only restenosed, but was fractured and occluded. Because of her obesity, perhaps,

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Figure 2. The CrossLock LP at the origin of the CTO with a Miracle 3 wire (Asahi Intecc) across the SFA occlusion.

Figure 3. The proximal SFA after recanalization. We now have 2-vessel infrapopliteal filling.

Figure 4. Mid SFA after stenting.

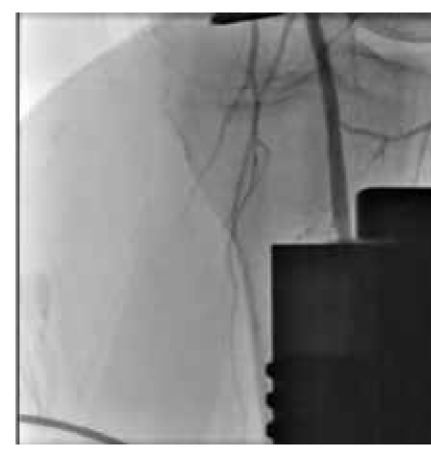
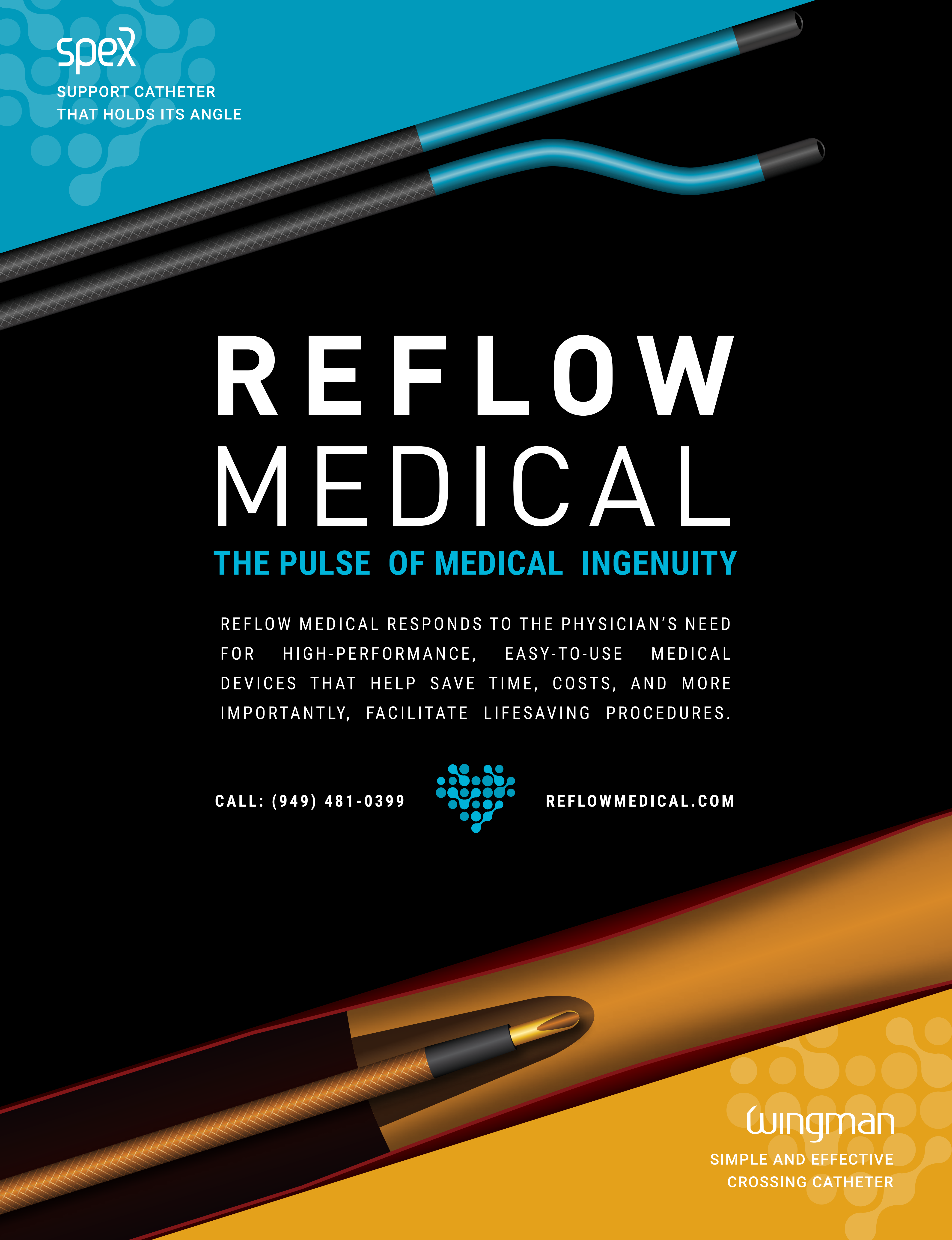


Figure 5. Proximal popliteal vessel.

Figure 6. Distal popliteal vessel after recanalization.

Figure 7. The EXPRO Elite snare removing the nosecone of the Supera that had embolized.



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I. Surgical Wound Dehiscence
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Timothy E. Yates, MD, Mount Sinai Medical Center,
Miami Beach, Florida

CASE #1: A 68-YEAR-OLD MALE WITH SURGICAL WOUND DEHISCENCE

History: This is a 68-year-old male with diabetes mellitus II (last HgA1c was 11), prior smoking, hypertension, hyperlipidemia, and known peripheral vascular disease. We treated his left anterior tibial (AT) previously with orbital atherectomy (CSI) and angioplasty prior to a left 5th ray resection for dry gangrene and osteomyelitis. One month later, his wound dehisced and he had continued osteomyelitis of the left 5th metatarsal head.

CLINICAL PRESENTATION

Figure 1. The operative site has reopened laterally over the 5th metatarsal head.

Figure 2. Lateral and anterior-posterior (AP) views of the left foot demonstrate patent anterior tibial/dorsalis pedis, peroneal, and common/medial plantar arteries.

Figure 3. Lateral and AP views of the left foot demonstrate occlusion of the lateral plantar artery.

INTERVENTION

Figure 4. Completion angiography now demonstrates patent superficial femoral artery, popliteal, and single vessel runoff to the left foot via the posterior tibial artery. The anterior tibial and peroneal arteries are occluded.

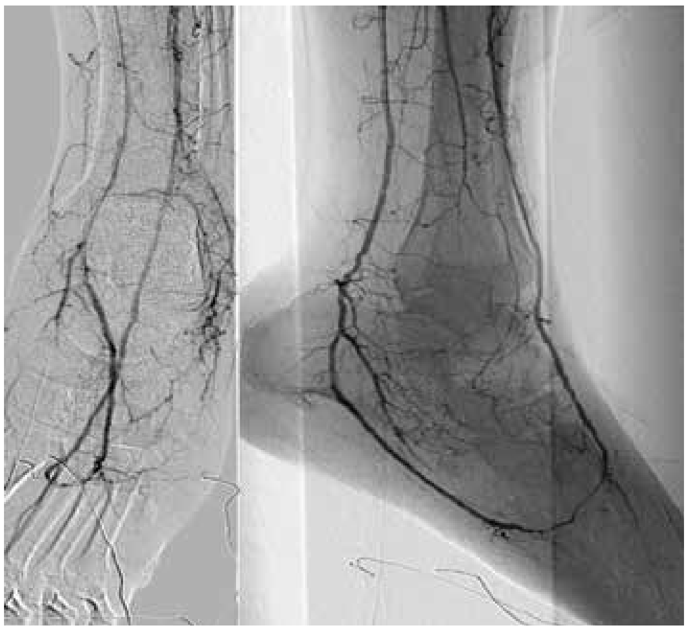

Figure 5. Complete patency of the pedal plantar loop with TIMI-3 flow and lateral foot perfusion, in addition to preservation of the medial plantar artery.

INTERVENTION

Figure 6. Complete healing of the lateral foot wound at 3 weeks post intervention. With thanks to John Houseworth, DPM.

CASE #2: A 67-YEAR-OLD MALE WITH LEFT FOOT REST PAIN

History: This is a 67-year-old male with hypertension, coronary artery disease, peripheral arterial disease, and a prior left femoral-popliteal (fem-pop) bypass in 2013 at our institution. He initially presented with bypass occlusion, which was treated with thrombolysis and complicated by compartment syndrome. After fasciotomies, the bypass reoccluded. The patient was told he needed an amputation by his bypass surgeon, because "there is nothing left to do."

INITIAL INTERVENTION

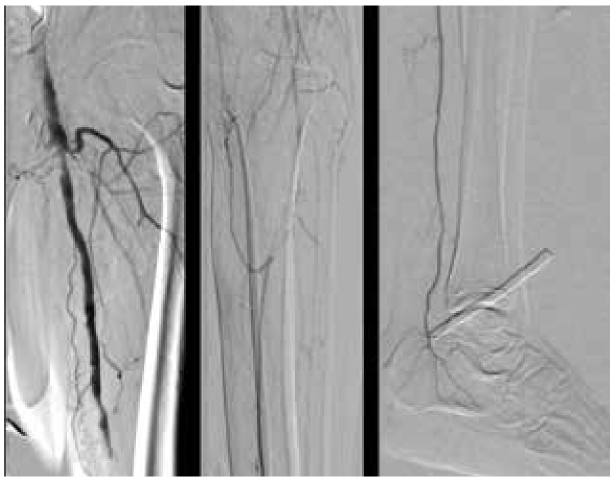

Figure 1. Initial angiogram demonstrated occlusion of the bypass. There is a distal superficial femoral artery (SFA) occlusion with reconstitution of the P1/P2 popliteal artery, but this reoccludes below the knee (P3). The posterior tibial is reconstituted and continuous below this level to the plantar arteries.

Figure 2. The bypass was abandoned. The left profunda was recanalized for a TASC II type A occlusion (blue arrow), using plain and drug-eluting angioplasty. The second image demonstrates profunda recanalization.

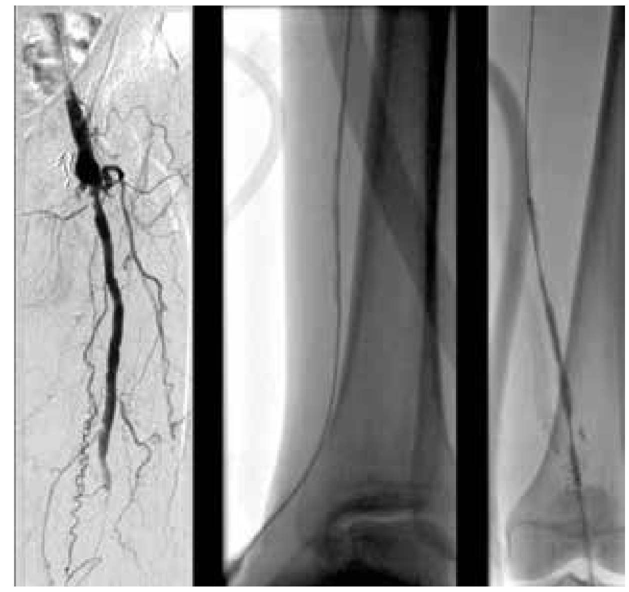

Figure 3. The left superficial femoral artery occlusion was crossed with retrograde access from the posterior tibial, with an .018-inch system. Body flossing was performed. The SFA was then treated with plain and drug-eluting angioplasty.

ONE-MONTH FOLLOW-UP

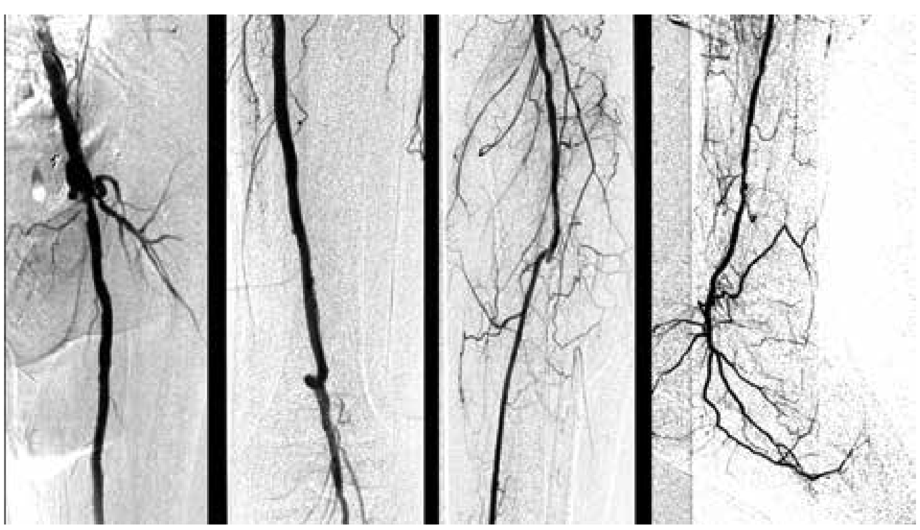

Figure 4. Completion angiography now demonstrates patent superficial femoral artery, popliteal, and single vessel runoff to the left foot via the posterior tibial artery. The anterior tibial and peroneal arteries are occluded.

INTERVAL HISTORY

Figure 5. One-month follow-up demonstrates breakdown of the fasciotomy sites, with exposed fibula.

ONE-MONTH FOLLOW-UP INTERVENTION

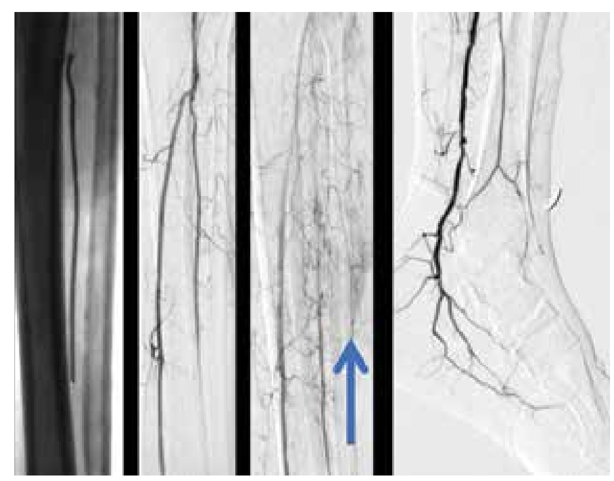

Figure 6. Peroneal artery recanalization was performed with plain angioplasty. The third image demonstrates blush around the borders of the wound not present prior to intervention. Free bleeding was seen at the wound site after intervention. The anterior tibial remains occluded on the completion image.

FOLLOW-UP

Figure 7. Aggressive wound care and debridement was performed, followed by fibulectomy (both performed by Dr. Jennifer Davies). Finally, skin grafting was performed to cover the defect.

Figure 8 The patient with "no options" is now ambulatory with complete closure of his surgical wounds. Without aggressive multidisciplinary care, this patient would have lost his leg.

MADASSERY *from page 3*

CASE REPORT

A 66-year-old woman presented to our clinic with history of surgeries and interventions at an outside institution. She had a pertinent past medical history of diabetes mellitus type 1 and end-stage renal disease, along with peripheral arterial disease. Her surgical/interventional history included a prior left lower extremity below-the-knee amputation as well as right popliteal artery stenting approximately 4 months prior for rest pain and non-healing wounds, complicated by loss of pulses on that same day, necessitating thrombolysis/thrombectomy and additional superficial femoral artery/popliteal artery stenting, per the outside reports. She reported experiencing continued, intermittently progressive right foot rest pain, worse when weight bearing and also had developed non-healing ulcers on the second and third digits of the right foot. The patient was subjectively, increasingly "cooler" in the right foot.

On physical exam, she had 2+ femoral pulses, a 1+ right popliteal artery pulse, and a well-healed left lower extremity amputation stump. No right dorsalis pedis tones were present. There was a monophasic right posterior tibial (PT) tone. There were noticeable necrotic wounds along the plantar surfaces of the right second and third digits. Non-invasive exam demonstrated an ankle-brachial index of 0.4 on the right. Due to her exam and findings, patient was brought to an outpatient interventional radiology platform for arteriogram and intervention.

Initial access was obtained in the left common femoral artery in order to evaluate the aorto-iliac vessel inflow to the right lower extremity. In our practice, we rely on non-invasive studies and clinical exam for most patients, and do not routinely obtain cross-sectional computed tomography (CT) angiography or magnetic resonance imaging (MRI) unless there is complex surgical history or concerns on the physical exam, such as very weak/non-palpable femoral pulses. A diagnostic reverse curve flush catheter is used to obtain the anterior posterior (AP) infra-renal aortogram and bilateral oblique iliac angiograms. No significant disease in the infra-renal abdominal aorta or iliac arteries was noted. The same catheter was used to obtain up-and-over access into the right distal external iliac artery. A diagnostic sequential angiogram of the right lower extremity was performed, which showed scattered areas of mild atherosclerotic disease with no significant stenosis in the common femoral, profunda femoris, and superficial femoral arteries. There was focal moderate stenosis of the P1 segment of the popliteal artery which had been previously stented at an outside institution. Additionally, there was complete occlusion of the P3 segment of the popliteal artery. There was occlusion of the proximal anterior tibial artery beyond a few centimeters of its origin. The peroneal and posterior tibial arteries were patent, but had multifocal areas of moderate stenosis, particularly moderate to severe stenosis in the distal posterior tibial artery at its bifurcation into the medial and lateral plantar branches.

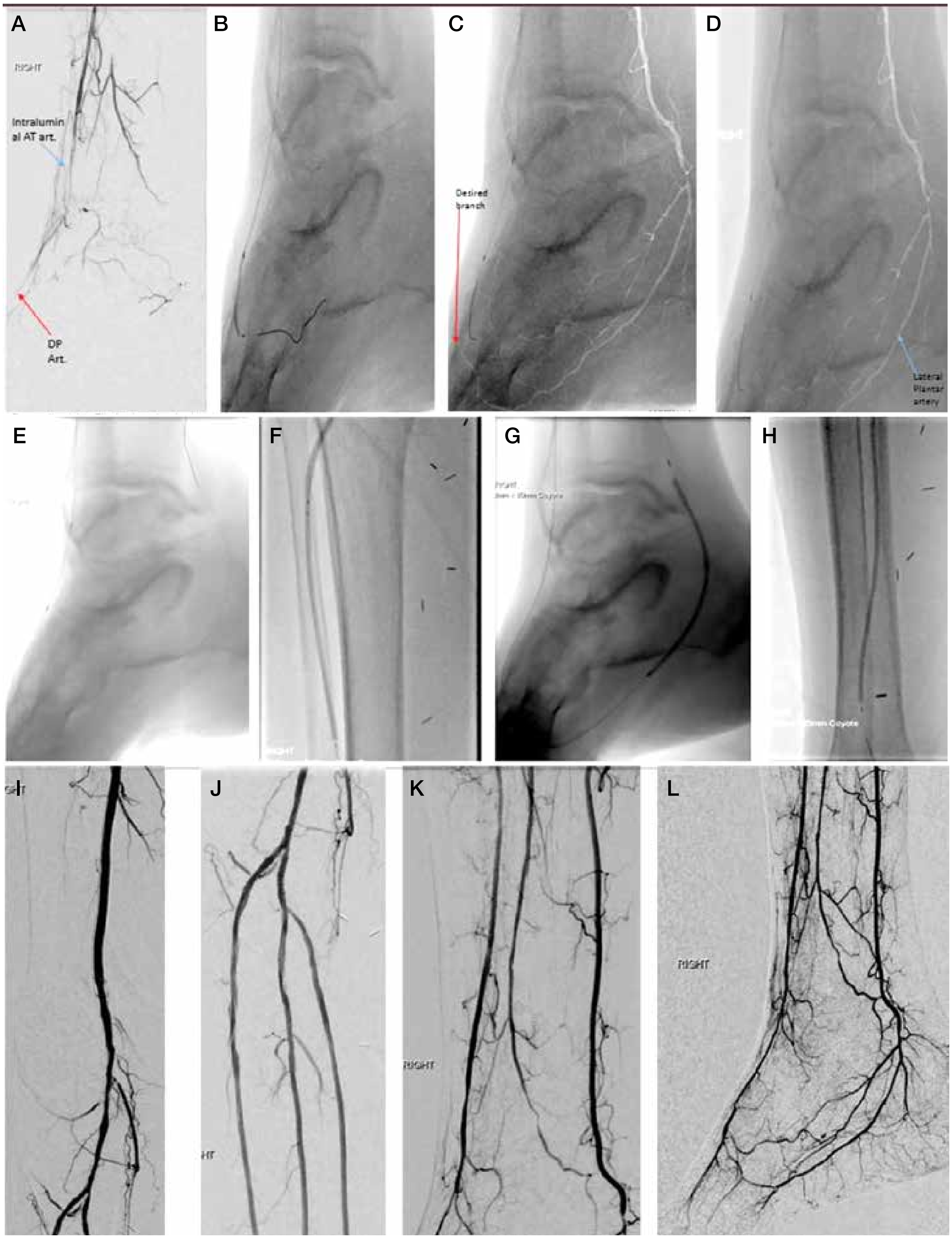

Figure 1A-L. A) Recanalized anterior tibial artery intraluminal confirmation injection shows a wisp of a dorsalis pedis artery. B) Initial difficulty traversing the pedal loop into the lateral plantar artery. C) DSA roadmap from groin sheath injection shows that wire was in lateral tarsal branch (lesson learned: always repeat angiogram if not having success). D) Wire advanced into desired branch to traverse lateral plantar artery. E) 0.014-inch guidewire forming complete pedal loop from anterior tibial artery to the posterior tibial artery. F) Balloon angioplasty of proximal and mid anterior tibial artery. G) Balloon angioplasty of distal posterior tibial artery and lateral plantar artery. H) The peroneal artery was recanalized and angioplasty performed. I) Post plain and drug-coated balloon angioplasty of popliteal artery stenosis. J) 3-vessel proximal runoff. K) Distal 3-vessel runoff. L) Completion foot angiogram showing 3-vessel inflow and now intact pedal loop.

A long 6 French Flexor (Cook Medical) sheath was advanced into the distal superficial femoral artery. Initially, plain and drug-coated balloon angioplasty was performed across the stenoses of the popliteal artery. Once post angioplasty angiograms showed restored patency, the 0.035-inch system was exchanged for a 0.014-inch Hydra ST guidewire (Cook Medical) and Quick-Cross (Philips) catheter, used to recanalize the occluded anterior tibial artery, with contrast injection in the dorsalis pedis artery confirming intraluminal location of the catheter and also providing a view of the tarsal arch. For navigational assistance, a digital subtraction angiography (DSA) roadmap of the plantar arteries from injection through the sheath was of significant help. Using this roadmap, along with a 0.014-inch Glidewire Advantage (Terumo) and a Seeker catheter (Bard Peripheral Vascular), the catheter was advanced around

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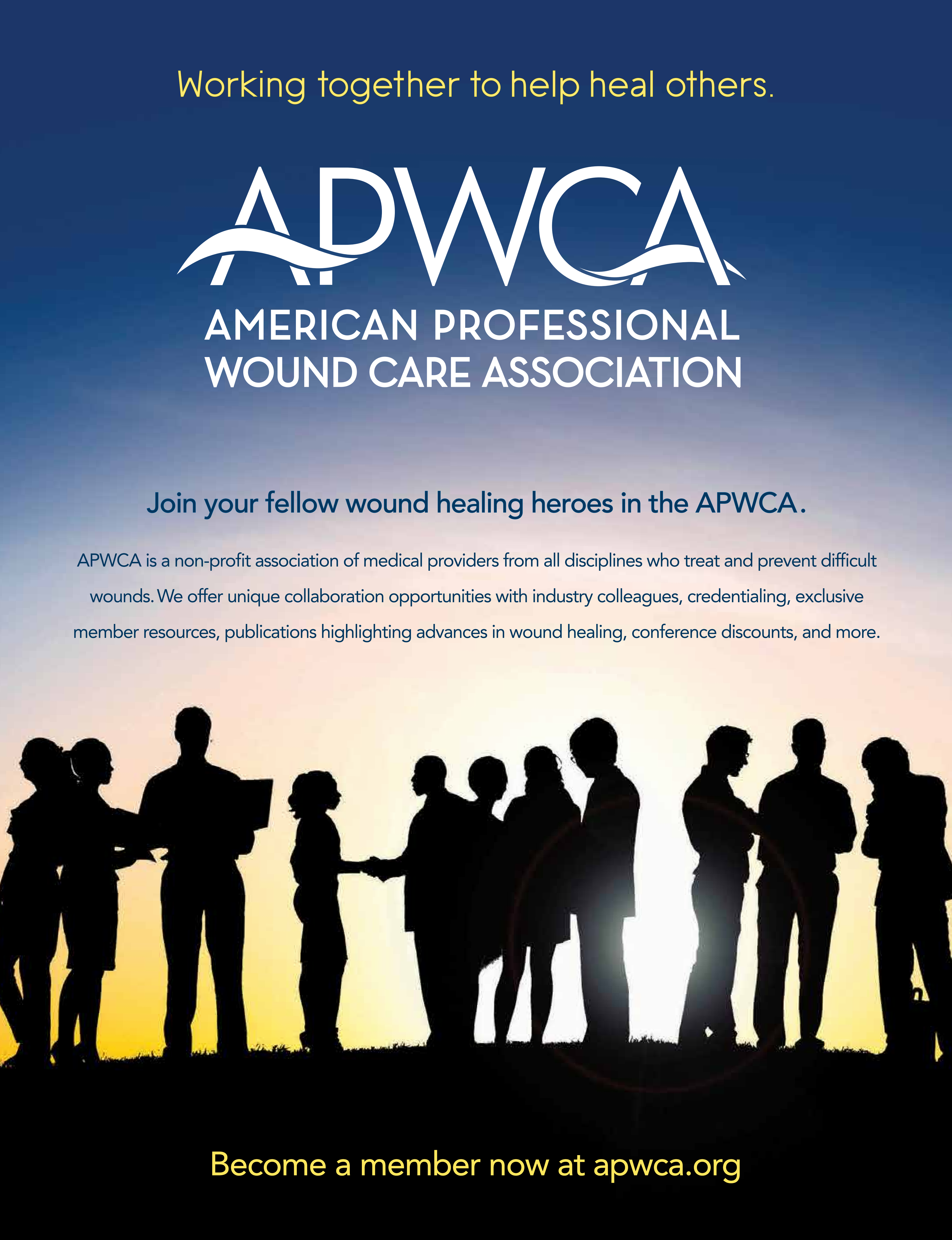
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Figure 1. Photograph of the patient's right foot demonstrating a shallow ulcer at the tip of the great toe. All toes show nail and skin changes, including hair loss. No gangrene is present and no additional ulcers are identified. A strong, palpable posterior tibial pulse is present, but the dorsalis pedis artery pulse is very weak and absent in the forefoot.

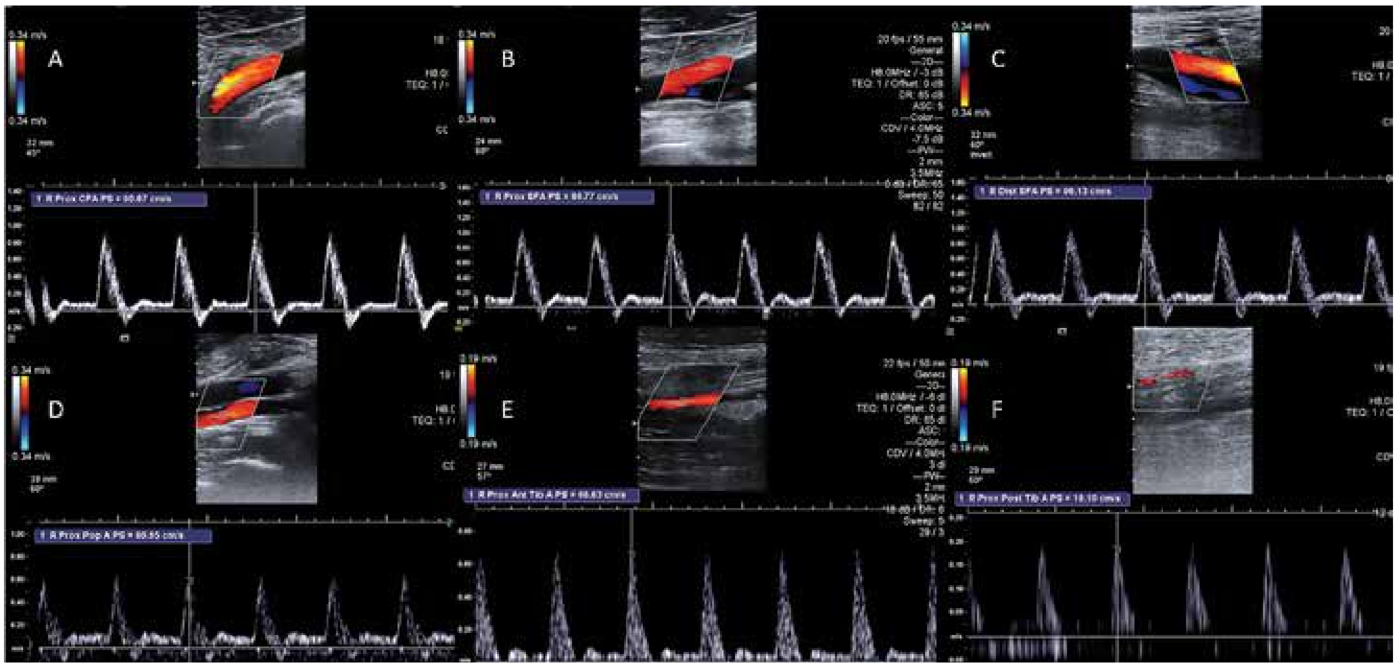

Figure 2. Arterial duplex study of the right lower extremity. Triphasic waveforms are identified in the (A) common femoral artery, (B-C) superficial femoral artery, (D) popliteal artery, (E) anterior tibial artery, and (F) posterior tibial artery. Of note, increased spectral broadening identified on the waveform on the posterior tibial artery is assumed to be related to artifact. Toe photoplethysmography (PPG) and transcutaneous oximetry ($TCPO_2$) were not performed.

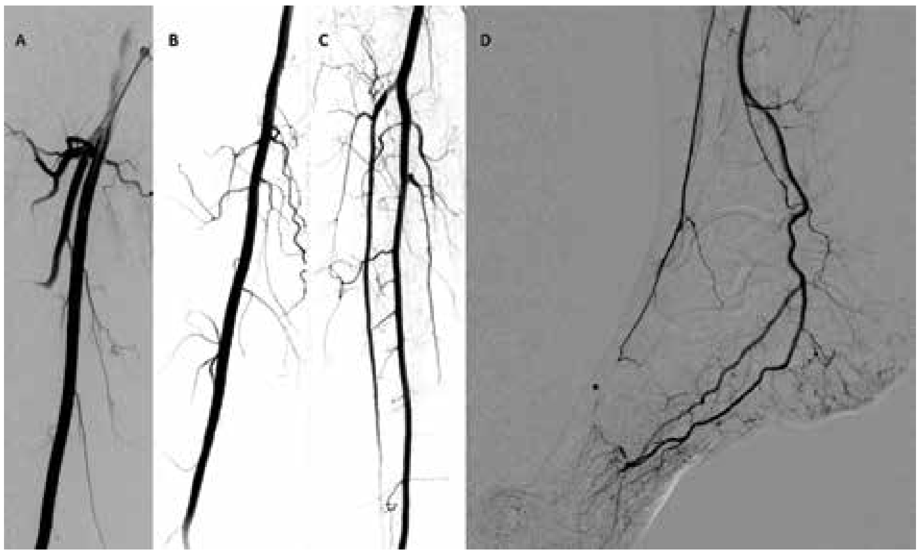

Figure 3. Right lower extremity angiography via antegrade access. (A) Patent right common femoral artery, deep femoral artery, and superficial femoral artery; (B) patent right superficial femoral artery and popliteal artery; (C) common right posterior tibial and peroneal artery, which is dominant, as well as patent anterior tibial artery; (D) patent, dominant in-line flow to the medial and lateral plantar arteries. Although the proximal dorsalis pedis artery is patent, it is occluded distally (*).

Figure 4. Selective angiography of the dorsalis pedis artery shown in (A) digital subtraction and (B) native views. A near-complete occlusion is now visualized of the distal dorsalis pedis artery (small arrows), supplying a diminutive dorsal metatarsal artery (arrowheads), with trace perfusion to the digital artery (*).

DHAND *from page 1*

and interventional radiology. In addition to conservative, topical management of the wound, the patient underwent a lower extremity arterial duplex study to evaluate flow to the foot. The exam demonstrated widely patent arteries of the right leg with a patent tibial runoff to the foot (Figure 2). On physical exam, however, the patient had a faintly palpable dorsalis pedis (DP) pulse and a strongly palpable posterior tibial pulse. Thus, the patient was referred for lower extremity angiogram for further evaluation and potential revascularization.

A right lower extremity angiogram utilizing an antegrade approach was performed under moderate conscious sedation by interventional radiology. Access was performed under ultrasound guidance to minimize complications, and dilute contrast was utilized to decrease contrast load due to the patient's renal disease (glomerular filtration rate [GFR] = 37). Diagnostic angiogram was congruent with the duplex results, demonstrating patent infra-inguinal arteries to the level of the ankle (Figure 3). The patient had variant anatomy with common posterior tibial and peroneal arteries. This variant branch demonstrated dominant, in-line flow to the foot into the medial and lateral plantar arteries. However, consistent with the physical exam, the DP artery was nearly completely occluded at the level of the midfoot (Figure 3D). At this time, 5000 units of heparin was administered intravenously.

Through a 6 French sheath at the groin, an 0.014-inch Quick-Cross support catheter (Philips) and Command 0.014-inch wire (Abbott Vascular) were advanced coaxially to select the patent proximal DP artery. Selective angiography was performed in both lateral and anteroposterior views, confirming near total occlusion of the distal DP artery, with near lack of perfusion to the first digit (Figure 4). Utilizing road-mapping techniques, the 0.014-inch wire was advanced into the first dorsal digital artery. The support catheter was removed, and plain old balloon angioplasty of the first dorsal digital artery (not shown), dorsal metatarsal artery (not shown), and distal DP artery was performed with a 1.5 x 40 mm Ultraverse balloon (Bard PV) (Figure 5). Post angioplasty arteriography demonstrated improved caliber of the treated arteries with in-line flow and perfusion to the great toe via the dorsal digital artery. Arteriography was also performed from the level of the sheath located above the knee, confirming flow in the distal DP artery and metatarsal artery (Figure 6). Although still faint, physical exam demonstrated improved

Figure 5. Single fluoroscopically saved image during 1.5 mm balloon angioplasty. In this station, angioplasty of the distal dorsalis pedis artery. Not shown are angioplasty of multiple overlapping stations along the course of the wire, extending to the dorsal digital artery.

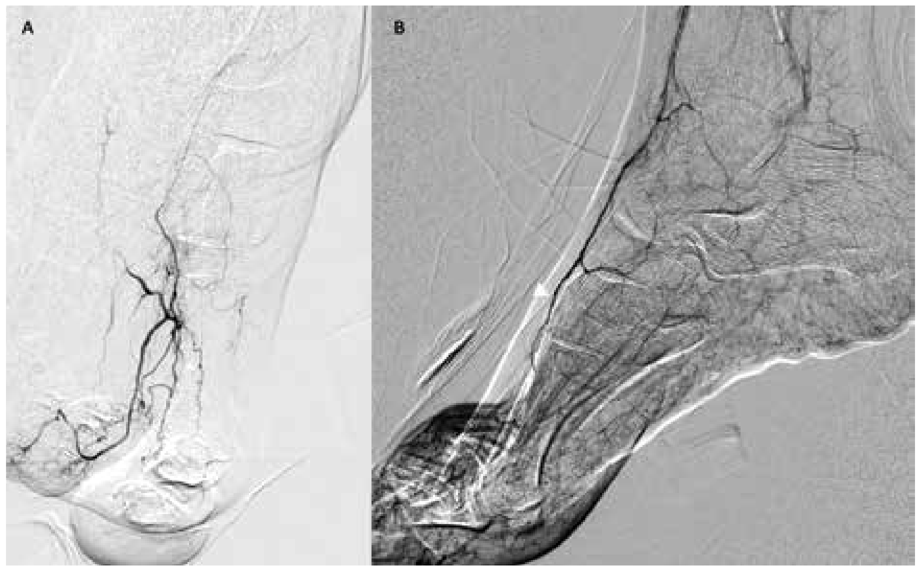

Figure 6. Post angioplasty arteriography of the (A) dorsalis pedis artery in the anteroposterior view demonstrated significant improved caliber of the distal dorsalis pedis artery (small arrows) and dorsal metatarsal arteries (*). Improved perfusion of the digital artery is not seen in this phase, but is present. (B) Post angioplasty arteriography performed from the level of the groin sheath demonstrated an improved appearance of the distal dorsalis pedis artery (white arrowhead) and proximal metatarsal artery. The dorsalis pedis artery still opacifies later than the dominant posterior tibial/plantar runoff, which is in near venous phase in this image.

Figure 7. Photograph of the patient's right foot performed at two months after intervention demonstrates complete healing of the first toe ulcer. Skin and nail changes are still present, but there are no new wounds. The dorsalis pedis artery remains palpable, but faint.

palpability of the DP pulse at the end of the exam.

The patient's ulcer completely healed within two months after the procedure (Figure 7). At 8 months from the initial encounter, no new ulcers have developed on her right extremity.

As noted previously, peripheral arterial disease is treated utilizing a multidisciplinary approach at our institution, which is streamlined with an established wound healing center.[1] Comprehensive wound care, including dressings, debridement, skin substitutes, oxygen therapy, etc., is vital to optimize healing after any endovascular or surgical intervention. Regarding endovascular approach, the concept of direct and indirect angiosome revascularization has been well described in the past.[2-4] Although studies suggest that direct angiosome revascularization results in faster wound healing, indirect angiosome revascularization also provides excellent wound healing due to extensive intra-pedal collaterals.[3,4] Therefore, the lack of a direct angiosome approach should not prevent an operator from performing below-the-knee intervention, a concept that is sometimes misunderstood amongst physicians. More recently, pedal loop, also known as plantar arch, reconstruction has been described, which involves revascularizing the primary intra-pedal collateral in the foot, supplying numerous metatarsal arteries to the toes.[5] Unfortunately, pedal loop reconstruction requires a combination of high operator skill, specific devices, time, and adequate target vasculature, which is not present in all patients and/or practices.

This case demonstrates the importance of direct angiosome revascularization, with recognition of arteries beyond the pedal loop, supplying the target tissue. Anatomic knowledge of the forefoot and appropriate radiologic views are vital for intervention beyond the ankle. For example, if the direct DP artery approach was not feasible or successful, evaluation of the superficial branch of the medial plantar artery can be performed, which also supplies the great toe. Finally, the metatarsal and digital arteries are small and thin walled, and thus, prone to complication, such as rupture.[6] As with any intervention, any operator must be prepared to treat an iatrogenic complication.

Other than toe photoplethysmography (PPG) and transcutaneous oximetry ($TCPO_2$), evaluation of these digital and forefoot arteries can only be seen on invasive, and potentially therapeutic, angiography. Fortunately, the patient underwent angiography despite a limited, unremarkable duplex study, and with combination of established multidisciplinary wound care, amputation of the toe(s) was successfully prevented (#StopTheChop). The patient will continue to follow-up routinely with her primary physician and interventional radiology for maintenance and early prevention. ■

Disclosure: Dr. Dhand reports that he has been a consultant for Abbott.

Dr. Dhand can be reached on Twitter: @SDhandMD

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MADASSERY *from page 14*

the pedal loop and retrograde into the distal PT artery.

The guidewire was exchanged for a Spartacore wire (Abbott Vascular), used for more support during balloon angioplasty:

- A 2 mm coronary balloon was used in the distal posterior tibial artery across the above-noted focal moderate to severe stenosis;
- A 1.5 mm coronary balloon was used across the pedal loop and dorsalis pedis;
- 2 mm and 2.5 mm coronary balloon were used along the mid and distal anterior tibial and peroneal arteries; and
- A 3 mm coronary balloon was utilized in the proximal anterior tibial and peroneal arteries.

Completion angiogram now showed 3-vessel runoff to the foot with reconstructed pedal loop. Marked flow to the digital arteries, particularly to the second and third digits, was now visible. There was non-flow-limiting dissection of the proximal recanalized anterior tibial artery, which improved with prolonged balloon dilation and was expected to improve with remodeling over time.

Upon completion of the case, there was a palpable dorsalis pedis pulse. The patient was followed subsequent to the intervention, and within the initial visits reported resolving pain, and following debridements of her ulcers by podiatry, the wounds showed progressive healing, thus avoiding an amputation.

DISCUSSION

As #CLIfighters, we have all come to appreciate that we need to continually push the boundaries of endovascular interventions in CLI. The ultimate desire in present-day complex CLI interventions is to aim for reconstruction of the pedal loop in order to give patients every chance of healing, so we can #StopTheChop. These patients are very complex from a vascular disease and co-morbidity standpoint, and require a team approach. In our practice, we put a premium on a multidisciplinary management for patients with peripheral arterial disease, and specifically with CLI, an approach which we hope and expect everyone practicing limb salvage to utilize. This includes working hand-in-hand with our podiatrists and vascular surgeons, as well as nutritionists and other supportive staff. All the interventional radiologists in our practice performing peripheral artery disease interventions are wound care-certified, with the understanding that we must not simply perform endovascular management of this complex disease; rather, we must actively participate in the longitudinal care of the patients we treat. The more we advance limb salvage together, the more lives can be saved from this critical disease, a growing concern globally. ■

Disclosures: Dr. Madassery reports he speakers' bureau member for Cook Medical, Abbott Vascular, and Penumbra. He is a consultant for Bard Peripheral Vascular and Cardiva.

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Please follow #CLIfighters and #stopthechop on Twitter, and add to the discussion of relevant CLI treatment issues and strategies.

Figure 5. Rotating a Turnpike catheter to displace friction with an .014-inch Victory wire (A). Orbital atherectomy using a 1.25 micro crown (B) followed by an .014-inch Opticross IVUS (C). PTA (D). IVUS pullback from distal pedal vessels to TP trunk confirming intraluminal revascularization (E).

Figure 6. Extensive tissue loss in a 62-year-old diabetic patient presenting with CLI, with photographic follow-up of wound healing over 4 months following revascularization.

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mortality rates ≥50%, 6-month mortality rates as high as 20%, and 6-month amputation rates as high as 40%.[4] Thanks to advancements in technology, better disease awareness, and the passion of trailblazing pioneers, we have been able to turn the tide and improve CLI prognosis. With more endovascular procedures and less major amputation being performed, limb salvage and survival rates are improving.[5] Despite the full-blown assault on CLI, led by fearless leaders in conjunction with an arsenal of weapons and established data, we are still falling short in this mission for various reasons. In many institutions, there is a lack of access to CLI therapy and significant disparities exist in CLI care delivery across the nation.[6] Despite focused guidelines on infrapopliteal arterial interventions,[7] the endovascular-first approach remains controversial, transpedal access is still seen as last resort only, infra-malleolar pedal reconstruction is not part of the wound-healing strategy, interdisciplinary CLI evaluation before amputation fails to occur, and time to wound healing and wound healing rates are ignored.

TEAMWORK MAKES THE D.R.E.A.M. WORK

Unable to ignore the burden any longer and in an effort to do more in our community, we began the previously described D.R.E.A.M. movement (Docs Revascularizing Extremities Against Major amputation) (CLI Global, December 2017). It is a reproducible, multidisciplinary action plan inspired by the great CLI mentors of our era. D.R.E.A.M. is practiced in a "real-world" setting amongst community practices, wound care centers, and hospitals. Building on the success and familiarity of guideline-driven, multi-specialty, collaborative structural heart and coronary artery disease programs, we employed a similar model to jump-start a real effort on limb salvage. Since hospital administrations, cardiovascular providers, and healthcare payers are all familiar with the "heart team approach", we decided not to reinvent the wheel and to start with proven, successful model. In addition, the incorporation of a CLI planning sheet and use of dedicated wound care electronic medical record (EMR) data (WoundExpert®) has allowed us to better provide the necessary revascularization and prove wound-directed therapy with objective results. This real-time communication facilitates the multidisciplinary "buy-in" and drastically improves our CLI outcomes. Regardless of the station from which the patient enters the limb salvage "train", the track of treatment makes a multidisciplinary circuit to complete the wound healing process.

FAIL TO PREPARE OR PREPARE TO FAIL

Given the lack of preparation to combat CLI in our communities and hospitals,

Figure 7. Diagnostic angiography with no in-line flow to the wound-affected foot (A), followed by staged revascularization and establishment of 2-vessel in-line flow to the foot (B).

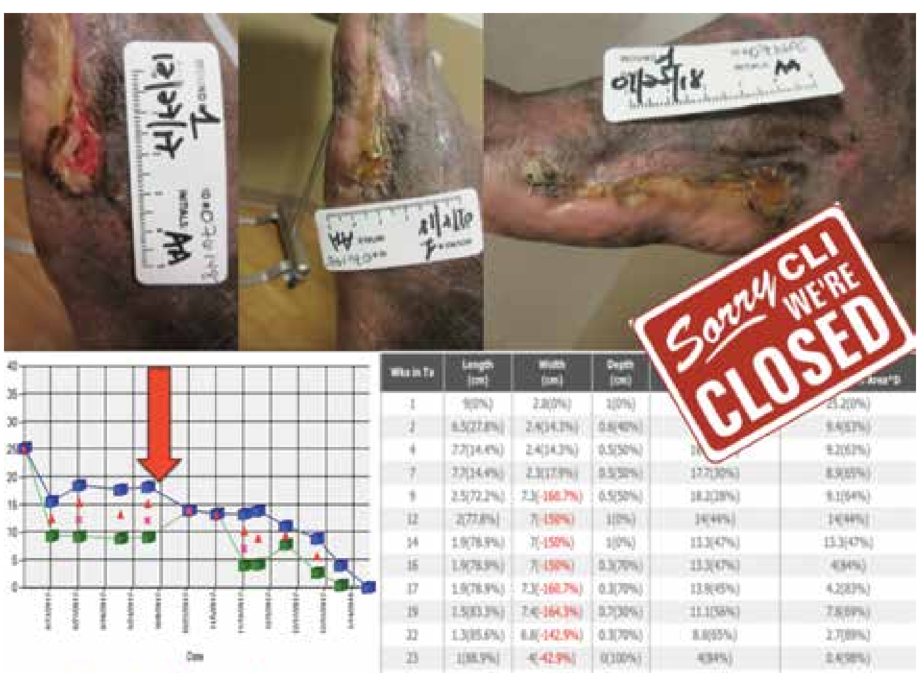

Figure 8. Graphical and geometric wound analysis confirming wound closure.

we are faced with predictable challenges that should not discourage us from doing more. These challenges provide opportunities for fighters to emerge and lead the movement on amputation prevention. Armed with data now supporting endovascular interventions in the most complex CLI, including Rutherford-VI disease,[8] providers, payers, and hospitals should think twice before supporting amputations in patients without a CLI workup. Although plenty of data are available supporting the cost efficiency of amputation prevention, CLI therapy is still underutilized in many communities.[9] By putting together focused outpatient and inpatient CLI teams, it does not take long to prove the data. By fortifying outpatient facilities and hospital labs with the necessary personnel and equipment required to successfully perform these procedures, success against CLI soon follows. We commend our outpatient partners and hospital administration for adopting these changes in such a quick time frame, despite the logistical challenges that come with starting a CLI program.

Our institution, JFK Medical Center, in Atlantis, Florida, agreed with their community partners that more needed to be done to support limb salvage. Given the lack of budgeting and resources, the growing volume of CLI cases, and the persistent challenges to starting a program, an interdisciplinary meeting was held to tackle the issue. This community collaboration with hospital administration, led by passionate physicians, is what drove us to collectively think outside the box to do more now, instead of later. The support of radiology, surgery, and cardiology leaders in conjunction with open-minded administration resulted in the almost overnight development of a dedicated space for operators to perform CLI-focused revascularization procedures. In order to do this quickly and take a no-compromise attitude in quality, we focused on portable equipment, used undesignated operating room space, and pooled passionate technologists and nursing staff from interventional cardiology, interventional radiology, and the hybrid OR with complex vascular experience. What was once referred to as "alternative access" is now routine for this motivated CLI team, with significant experience in dealing with complex access and multilevel chronic total occlusions (CTOs) (Figure 2). Making tibio-pedal arterial access routine has also made our team comfortable with tibial venous access for deep vein thrombosis (DVT) therapy (Figure 3). The following routine cases highlight this collaborative effort to provide early therapy against CLI necessary for complete wound healing.

CASE #1: "NEAR ZERO"

Using a combination of super low contrast, extravascular ultrasound (EVUS), intravascular ultrasound (IVUS), and CO_2 angiography, we have been successful in performing CLI interventions in infrapopliteal and inframalleolar CTOs for advanced chronic kidney disease patients with great success. Our goal for these tibio-pedal reconstruction cases, which we refer to as "Near Zero", is to provide a diagnostic angiogram as well as a staged intervention with minimal contrast. CO_2, IVUS, and hemodynamics are used to exclude inflow disease, and 3-6 cc of contrast are used to identify the inframalleolar disease if necessary. Once a good setup picture is obtained, "0" contrast is used for the interventional work and a final angiogram with 3-6 cc of contrast, if necessary, is used.

One such case was performed for a 55-year-old diabetic construction worker who sustained a disabling plantar heel injury from a large nail puncture on the job. His podiatrist referred him after debridement and wound evaluation were indicative of CLI. Diagnostic angiography via radial access protocol using CO_2 angiography was performed starting with a 5 French (Fr), 130 cm pigtail catheter (Angiodynamics) positioned in the terminal aorta (Figure 4A). A 150 cm Navicross catheter (Terumo) was placed in the left common femoral artery (L-CFA) for selective CO_2 runoff of the wound-affected extremity. Once a better definition of the tibio-pedal vessels was required, we used low contrast to finish the diagnostic angiogram. Angiography revealed complete occlusion of the left posterior tibial artery with no collateral flow to the plantar heel wound, as well as occlusions of the medial and lateral plantar arteries below the ankle (Figure 4B). Staged intervention began with antegrade L-CFA access and using landmarks from the previous angiogram to spare contrast, a 6 Fr Destination sheath (Terumo) was positioned in the popliteal artery. Modified Schmidt access was obtained of the posterior tibial (PT) artery using our workhorse pedal access Command-18 ES .018-inch wire (Abbott Vascular). In order to perform the case with zero contrast usage, the retrograde .018-inch wire was advanced as close as possible to the proximal PT CTO cap at the tibioperoneal (TP) trunk in order to find the true ostium of the PT artery. Once the ostium was found and confirmed with EVUS, we took an antegrade wire escalation strategy to ensure remaining in the lumen and avoid dealing with dissection, and removed the pedal sheath. Although tibial dissection is easily dealt with and even used as a regular strategy, we try to avoid it if possible during near-zero cases to prevent test injections. We began with a combination of telescoped .035-inch x 90cm and .014-inch x 150 cm CXI support catheters (Cook Medical). After seeing how the calcified vessel handled a Fielder XT and Pilot 200 wire (both Abbott Vascular) we went straight to a Victory 18 wire (Boston Scientific) in order to drive through calcium. Once the wire penetrated the most distal CTO cap at the level of the plantar bifurcation, pushability of the .014-inch catheter was lost. We switched to a 135 cm Turnpike catheter (Vascular Solutions) and a less traumatic, workhorse Marvel wire (Boston Scientific) to advance the Turnpike to the arcuate artery and complete a pedal loop (Figure 5). In order to avoid contrast as well as confirm wire position and sizing, a .014-inch Opticross IVUS catheter with a 1 mm crossing profile (Boston Scientific) was advanced down to the distal medial plantar artery, confirming intraluminal placement. After removing the catheter, we performed prolonged inflations with a 1.5 mm x 40 mm Armada balloon (Abbott Vascular) from the distal plantar back to the PT artery to facilitate passage of equipment. The CXI .014-inch catheter was then easily advanced to the distal plantar artery and a Flex Tip ViperWire (CSI) was positioned in the distal plantar artery. Orbital atherectomy using a 1.25 micro crown was used to prep the PT from the TP trunk to the distal medial plantar artery. Balloon angioplasty was performed, finishing with a 2.0 sizing in the distal plantar, 2.5 at the proximal plantar and distal PT, 3.0 for the entire PT body, and 4.0 for the proximal PT and TP trunk, all guided by IVUS with no test injections (Figure 5). Final angiography with 2 injections using 10 cc of diluted contrast revealed excellent results, with 3-vessel in-line flow to the foot and a reconstructed pedal loop (Figure 4C). A

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HENAO from page 6

was performed. An .018-inch wire and support catheter were advanced from this retrograde position to successfully navigate through the occluded anterior tibial artery, back into the true lumen of the popliteal artery. The wire was externalized through the femoral sheath, where an intravascular ultrasound (IVUS) catheter was loaded for definitive evaluation of the lesion.

The preliminary evaluation by angiography suggested a strategy that supported atherectomy, as there appeared to be significant calcification. This would likely be followed by angioplasty, typically using a 3 millimeter (mm) balloon as determined by visual estimation of the vessels via angiography. Using IVUS, however, allowed for precise sizing of the vessel, which was significantly larger than anticipated. In addition, there was a dissection at the proximal anterior tibial artery that would make atherectomy potentially treacherous. A 4 mm balloon was ultimately selected on the basis of these IVUS findings and inflated for 3 minutes. Following percutaneous transluminal angioplasty, angiography demonstrated robust anterior tibial artery flow into the dorsalis pedis. As an adjunct to evaluate flow assessment, time to peak and peak opacification software were utilized to help judge the improvement of flow. This demonstrated a dramatic improvement in the area of interest in the forefoot.

Figure 6. IVUS of the tibioperoneal (TP) trunk demonstrating a much larger than expected 6.3 x 6.4 mm vessel.

Following this confirmatory step to assess perfusion, the tibioperoneal trunk was accessed using an .014-inch CTO wire and support catheter, where the fibrous cap appeared to be a more favorable concave morphology, allowing for relatively easy passage into the true lumen of the peroneal artery. IVUS was re-loaded onto the wire and used when passed across the tibioperoneal trunk, demonstrating a 6 mm vessel, significantly larger than what had been estimated by angiography alone. This guided the selection of a 6 mm balloon, where angioplasty was performed for a 3-minute inflation time at nominal pressure.

This was then followed by digital subtraction angiography, as well as peak flow evaluation on the workstation, which demonstrated further optimization of flow to

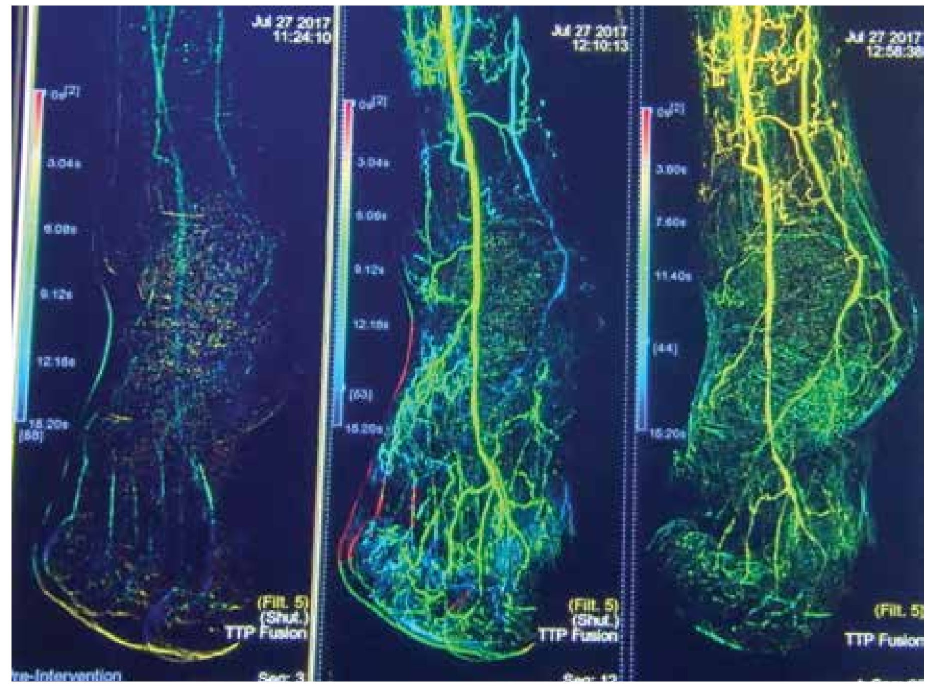

Figure 7. Before and after assessment of peak flow after revascularization of the TP trunk, demonstrating optimal restoration of flow to the entire foot.

the peroneal distribution of the ankle and hind foot. The procedure was completed and the patient discharged uneventfully, where outpatient follow-up was arranged with his podiatrist for definitive management of his gangrenous foot. Within 3 weeks, the patient went on to have an uneventful first and second toe amputation, with complete healing of the surgical site.

This case demonstrates a contemporary utilization of imaging modalities that assist in the decision-making required for optimal outcomes of the challenging CLI patient. Utilizing IVUS, a better understanding of plaque morphology, vessel size, and wire position within the lumen is achieved. This should be considered among the best practices for those physicians routinely faced with managing CTOs in the peripheral vasculature. Newer adjuncts for flow assessment, as demonstrated here, should be considered to help determine the adequacy of flow following the complex interventions. ■

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Perclose closure device (Abbott) was used for antegrade access hemostasis.

CASE #2: "SORRY, CLI, WE'RE CLOSING FOR BUSINESS"

Objective evidence of wound-directed therapy is best achieved as a team, working in a multidisciplinary fashion. The goal of CLI therapy, according to guidelines, is pain relief, healing ulceration, and closing wounds. In addition to advanced revascularization, including below-the-knee and below-the-ankle reconstruction using various CTO techniques, meticulous wound care and follow-up is practiced at our limb salvage program. One recent closure patient is a 62-year-old diabetic who presented with a Rutherford class VI wound with extensive tissue loss (Figure 6) Referred by his podiatrist after a previous revascularization attempt worsened his wound, diagnostic angiography revealed a subtotal occlusion of the left popliteal artery with CTOs of all 3 tibial vessels (Figure 7). Staged intervention began with antegrade access and a 6 Fr Destination sheath placed in the popliteal artery. The peroneal artery was initially treated using antegrade wire escalation followed by orbital atherectomy and percutaneous transluminal angioplasty (PTA), finished with a 4.0 IN.PACT Admiral drug-coated balloon (Medtronic). Revascularization of the anterior tibial artery began with antegrade wire escalation and was unsuccessful. Retrograde dorsalis pedis access was obtained using an .018-inch Command wire. A "double-Navi" technique was then used to successfully gain antegrade and retrograde control of the anterior tibial artery. This was followed by access reversal, pedal sheath removal, and antegrade crossing into the dorsalis pedis using an .014-inch Command wire. The wire was switched for a Flex Tip ViperWire and orbital atherectomy was performed using a 1.25 crown. PTA was then performed starting with a 2.5 mm x 200 mm Armada balloon, then a 3.0 mm x 200 mm balloon, and finishing with a 4.0 mm x 80 mm IN.PACT drug-coated balloon. The patient now had 2-vessel inline flow to the foot and antegrade hemostasis was obtained with a Perclose device (Figure 7). Following revascularization, the patient's large wound closed within 3 months, giving him back his mobility. Using software for photographic, graphical, and geometric wound analysis has allowed us to objectify wound-directed therapy and prove what multidisciplinary collaboration can accomplish (Figure 8).

Using software for photographic, graphical, and geometric wound analysis has allowed us to objectify wound-directed therapy and prove what multi-disciplinary collaboration can accomplish (Figure 8).

DISCUSSION

We are currently experiencing a renaissance in end-stage peripheral arterial disease treatment, fueled by advancements in technology and multidisciplinary motivation. Passionate collaboration has created breakthroughs in techniques, algorithms, and gained knowledge in battling CLI. Despite this explosion of growth in wound-directed therapy, including advanced below-the-knee and ankle revascularization, there is significant work to be done on the CLI battlefield. Community physicians, hospital systems, payers, and the government need to give amputation prevention the attention it deserves, given its mortality and cost burden. Saving limbs saves lives, so let's join together in fighting CLI. ■

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MUSTAPHA *from Cover*

Figure 2. (left to right) Panelists Mary Kathleen Wood, MSN, RN, Steven Dean, DO, Gary Gibbons, MD, Richard Neville, MD, and Vickie Driver, DPM, at the Deep Dive Session on "Wound Care for the Interventionalists" at ISET 2018.

Figure 3. #CLIfighters at the CLI Global Society Member Reception at ISET 2018. (Left to right) Drs. Srini Tummala, Bret Wiechmann, Barry Katzen, Jihad Mustapha, Richard Neville, and Thomas Zeller.

describing when to intervene and how to measure success.

Jason Hanft, DPM, discussed the importance of removing the wound dressing to evaluate the wound. With more than 3,000 types of wound dressings available on the market today, he noted it is easy to become overwhelmed by the options. "Just like every intervention is unique, every wound is unique and there are different approaches. Explore the wound before you intervene and not afterward. The high likelihood of infection in the non-healing wound should prompt an infectious disease referral even without visual evidence of infection. Wounds resulting in exposed bone, tendon, and ligaments don't heal with revascularization alone. A multidisciplinary team is required. Not one of us can save legs by ourselves and not one of us can save lives by ourselves."

Dr. Neville reinforced the necessity of a comprehensive interdisciplinary approach to manage complicated CLI patients. He issued a call to action to encourage all attendees to join the multidisciplinary, patient-centric CLI Global Society. He described the role that angiosome-directed therapy plays in wound healing. "This is a controversial topic and not the whole answer to arterialization of the foot, but it is an important component to wound healing in real-world practice, possibly even more importantly so for endovascular revascularization. Angiosome should be considered whenever possible; it should be factored into the overall plan."

Dr. Gibbons discussed situations when amputation is not always a defeat. "Ensuring the highest level of limb preservation ensures functional status of the patient. It is important to take into consideration patient and family goals and expectations."

Dr. Driver described the components of good podiatric care as a key member of the multidisciplinary team — pressure control, surgery, infection management, and wound care. Dr. Driver also gave an overview of future directions in wound care. "The future is allowing us to bioengineer tissue, add cells, add biomaterial, add growth factors, and the list goes on. These therapies need to be studied in order to ensure the right therapy is used on the right wound at the right time. We need to develop treatments that are worth their price and truly improve the patient's life. The most expensive therapy is the one that doesn't work."

Mary Kathleen Wood, MSN, RN, from the Wound Center at South Miami Hospital, shared the benefits of an interdisciplinary wound team. She described their comprehensive wound team which includes over 20 different categories. "A successful wound center is like an orchestra. Each member provides a valuable contribution, but no single member is successful alone."

Also at ISET this year were several members of a group of young, skilled, passionate, high-volume operators who connected over social media to share approaches to CLI success, failures, tips and tricks, and to receive feedback and mentorship (Figures 3 and 4). They call themselves #CLIfighters. Although the number of #CLIfighters is <50, when you look at the scale of CLI prevalence, I believe we are at least 1,000 physicians short to accommodate the complexity of this disease.

The treatment of CLI is not only the technical aspect of the procedure/revascularization, but also provision of excellent care for the wound associated with the CLI, aggressive medical therapy, close follow-up and engagement in the well-being of the CLI patient. Each of the current #CLIfighters saw the need and were able to create a multidisciplinary approach around a patient-centric modality which is unique to this group. Our hope is to see more physicians doing the same. This issue includes cases from several of the CLI Fighters who have decided to JUST DO SOMETHING! ■

Figure 4. CLI Global Society Board President Barry T. Katzen, MD (left), and Founder and Secretary/Treasurer Jihad A. Mustapha, MD, welcomed guests at the CLI Global Society Member Reception at ISET 2018 in Miami, Florida.


HANDS-ON.
HIGH IMPACT.

TUMMALA *from page 8*

Figure 5. Left leg angiogram confirms an occluded left popliteal artery at the knee joint, with no significant below-knee runoff and reconstitution of the distal left peroneal artery without opacification of the pedal arch.

Figure 6. Catheter-directed thrombolysis with tPA was initiated through the sheath in the left external iliac artery (0.5 mg/hr), with the thrombolytic catheter spanning the distal left SFA and ending in previously stented left anterior tibial artery (0.5 mg/hr).

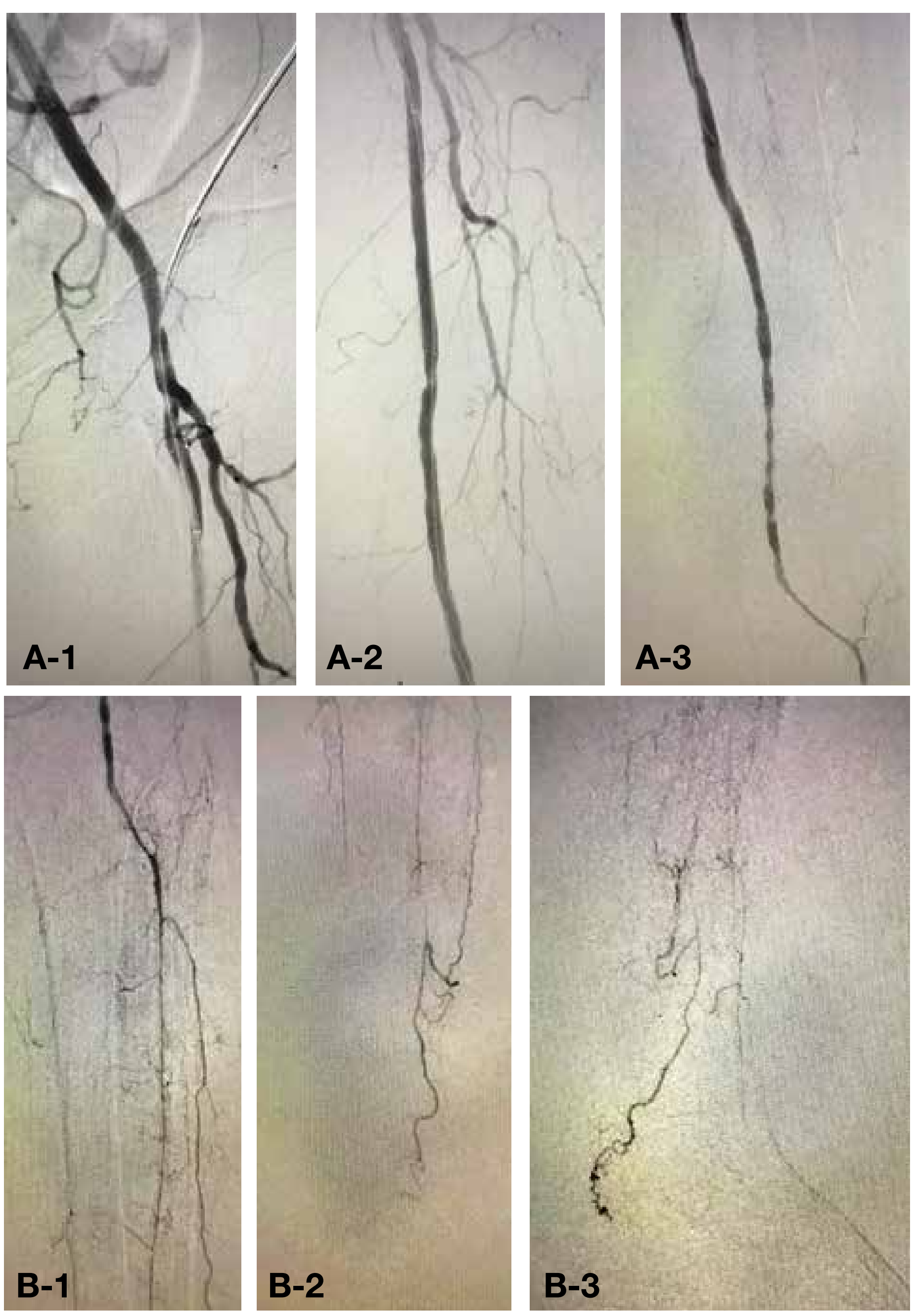

Figure 7A-B. Left leg angiogram after overnight tPA thrombolysis (total of 10 mg) shows a patent but diseased left popliteal artery, and visualization of previously unseen collaterals with poor runoff and no significant pedal arch.

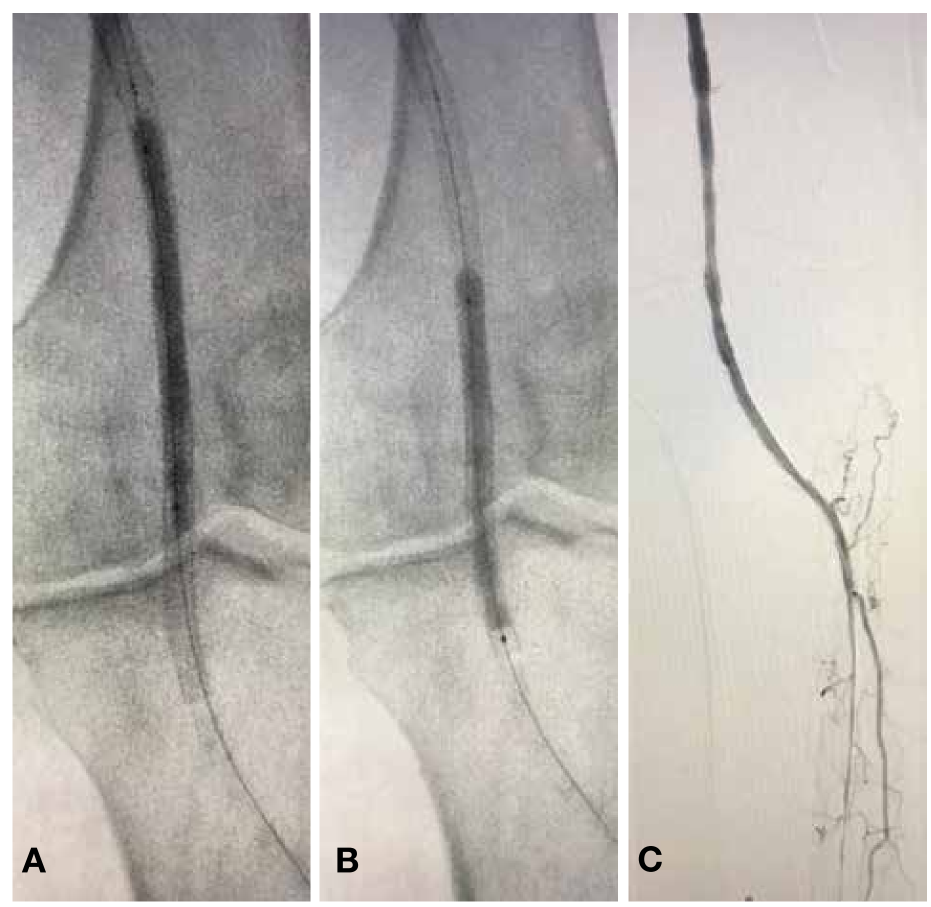

Figure 8. Excellent angiographic result after 6mm plain old balloon angioplasty (Ultraverse, Bard Peripheral Vascular) followed by a 6 mm AV Lutonix drug-coated balloon (2-minute inflation for both) (Bard Peripheral Vascular).

(tPA) was initiated through both the Destination sheath in the left external iliac artery (0.5 mg/hr), and the thrombolytic catheter in the distal SFA and left anterior tibial artery (0.5 mg/hr) (Figure 6). After overnight thrombolysis with 10 mg tPA, a repeat left leg angiogram showed a patent but diseased left popliteal artery and visualization of previously unseen collaterals, with poor runoff and no significant pedal arch (Figure 7A-B). The stenoses in the previously stented left popliteal artery were treated with 6 mm plain balloon angioplasty (POBA) followed by a 6 mm AV Lutonix drug-coated balloon (Bard Peripheral Vascular) (2 minute inflation for both) with an excellent angiographic result (Figure 8). This was followed by recanalization and 3 mm POBA of the anterior tibial artery chronic total occlusion (CTO) and 2 mm POBA of the dorsalis pedis artery (3 minute inflation at each

Figure 9. Recanalization and 3 mm plain old balloon angioplasty of anterior tibial artery CTO and 2 mm plain old balloon angioplasty of dorsalis pedis artery (3 minute inflation at each site).

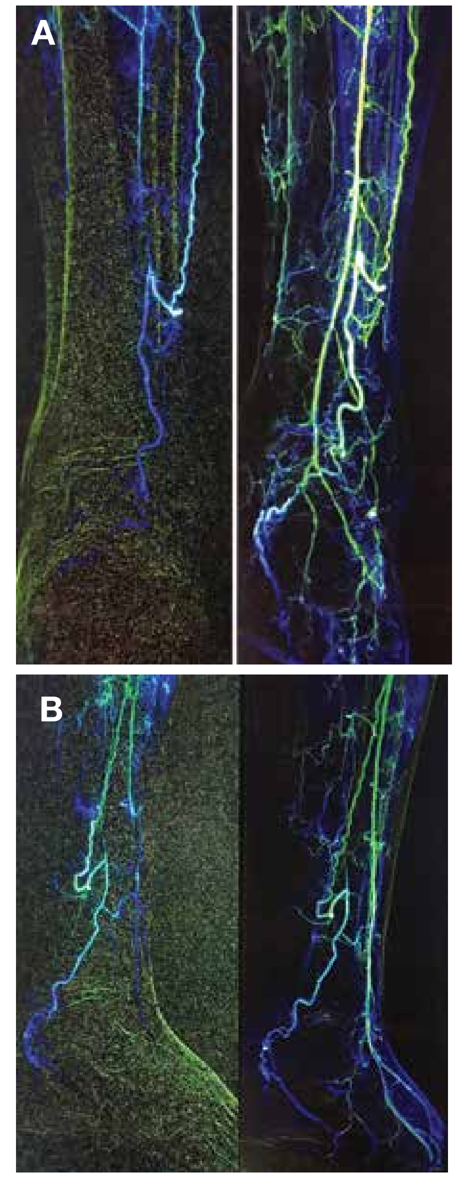

Figure 11. Pre and post intervention AP and lateral 2-dimensional perfusion images confirmed improvement of the runoff to the foot and amputation site.

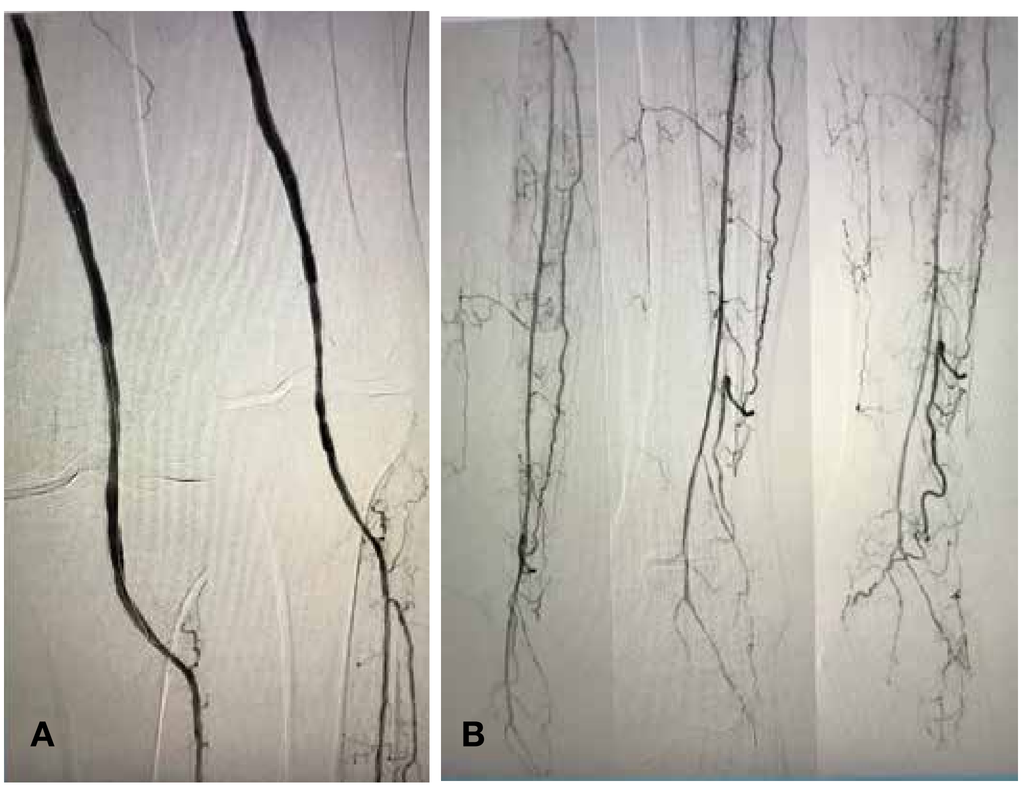

Figure 10. In-line flow re-established to the foot via the left anterior tibial artery and dorsalis pedis artery.

Post intervention images confirmed in-line flow to the foot via the left anterior tibial artery and dorsalis pedis artery.

site) (Figure 9). Post intervention, there was an excellent angiographic result, with in-line flow re-established to the foot via the left anterior tibial artery and dorsalis pedis artery (Figure 10). Pre and post intervention AP and lateral 2-dimensional perfusion images (Siemens Healthineers) confirmed improvement of the runoff to the left foot and amputation site (Figure 11A-B). The next morning, the patient underwent non-invasive arterial imaging that showed physiologic improvement of blood flow in the left leg and foot post intervention (Figure 12). The patient was followed closely by interventional radiology doctors in our outpatient vascular clinic every 3 months and by our wound care center doctors. One year post intervention, the large non-healing wound at the prior amputation site was healed (Figure 13), preventing further amputation. ■

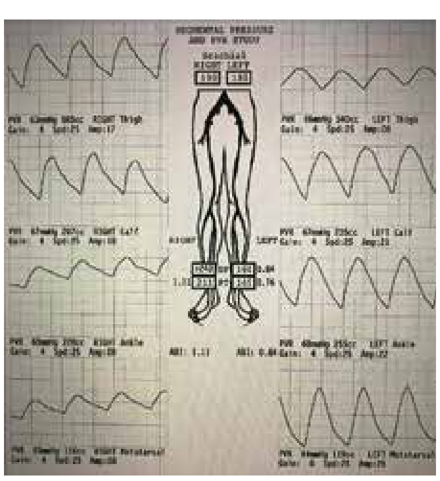

Figure 12. Post intervention non-invasive arterial study shows physiologic improvement of blood flow to the left leg post intervention.

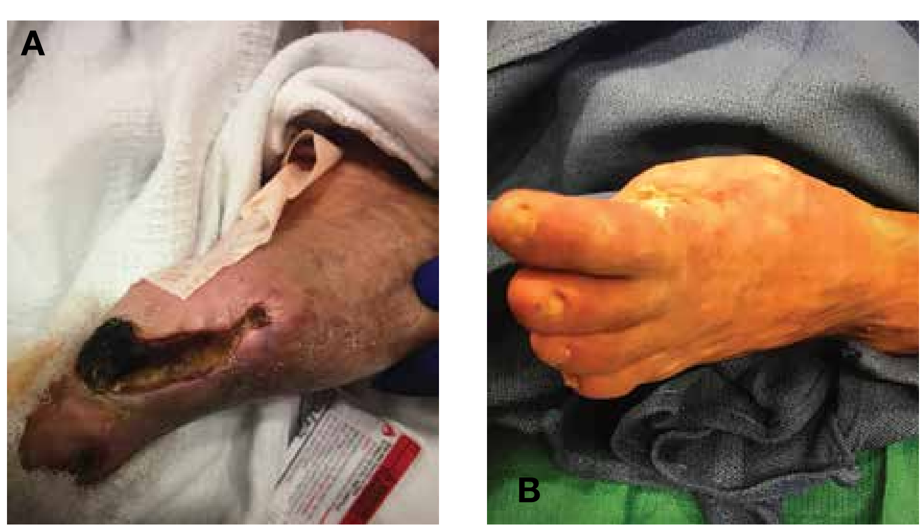

Figure 13. One year post intervention, the large non-healing wound at the prior amputation site is healed, preventing further amputation.

Disclosure: Dr. Tummala reports he is a speaker for BD Peripheral Vascular.

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HEUSER *from page 10*

there had also been a previously sheared nitinol wire present in what appears to be subcuticular tissue in the left groin. This previous smoking, diabetic female is 200 pounds above her ideal weight.

PATIENT ANATOMY

A contralateral approach was used and the previously sheared-off hydrophilic tip was visualized. This was of no relevance, but the SFA was noted to be occluded at its origin. The small origin of the total occlusion appeared large enough for placement of the CrossLock LP. The original CrossLock device has a elastomeric balloon that can dilate up to 8 mm in diameter. The CrossLock LP is smaller, with the inflated diameter as large as 3 mm.

REVASCULARIZATION APPROACH

With the previous fracture of the SFA stent, we felt it was imperative to stay in the intraluminal position to cross this occluded stent, the benefit of the CrossLock technology as a centering balloon (Figure 2). With the CrossLock LP in place, we maintained an intraluminal position to cross the area of the occlusion and stent fracture. After recanalization, there was 2-vessel infrapopliteal filling (Figures 3-6).

In order to reduce the likelihood of restenosis because of the previous stent fracture, we performed inflation with a drug-eluting balloon (Lutonix, Bard Peripheral Vascular). We also deployed the Supera stent (Abbott Vascular) at the site of the previous stent fracture. Perhaps because of the patient's weight, the previously placed stents, or our contralateral approach, the nosecone of the Supera stent broke off. We attempted to remove the nosecone with the ENSnare (Merit Medical) and the GooseNeck snare (Medtronic), but only the EXPRO Elite snare (Vascular Solutions) was able to remove the embolized nosecone. The 150 cm EXPRO Elite snare was the only snare long enough to get to the embolized piece of the previously placed stent (Figure 7). The patient is doing well and has improved healing of the wound since the procedure.

DISCUSSION

Self-expanding stents, particularly long stents or some of the earlier designs, not infrequently undergo fracture. Fracture can lead to restenosis and/or occlusion, as it did in this case. In order to cross a fractured stent, it is important to maintain an intraluminal position. The CrossLock LP was successful in navigating the occlusion (Figure 8). The device is similar to the CrossLock in that it has a 6 French outer diameter and is compatible with the 6 French sheath. The inner lumen is large enough to fit in its lumen the following devices: FrontRunner (Cordis, A Cardinal Health company), Crosser (Bard Peripheral Vascular), Viance (Medtronic), CrossBoss (Boston Scientific), and laser. It has a 3 mm in diameter elastomeric balloon at the tip that effectively centers the device, allowing for very enhanced support. ■

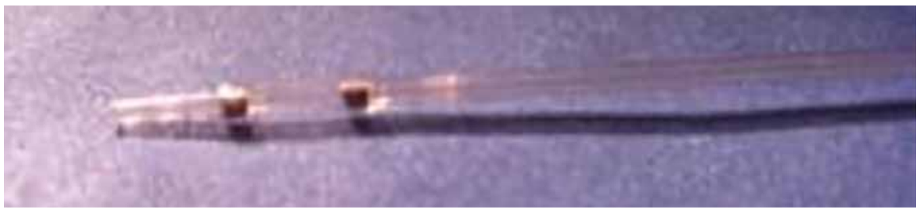

Figure 8. The CrossLock LP, which has a 3 mm in diameter elastomeric balloon at the tip.

Disclosure: Dr. Heuser reports that he owns patents on the CrossLock™ and Elite® snare and has equity in Radius Medical.

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Upcoming Meetings and Events

March 10–12, 2018
American College of Cardiology Scientific Sessions (ACC)
Location: Orlando, Florida
Website: http://acc2018.com/

March 17-22, 2018
Society of Interventional Radiology (SIR) Annual Scientific Meeting
Location: Los Angeles, California
Website: www.sirmeeting.org

April 5-7, 2018
9th Diabetic Limb Salvage Conference (DLS 2018)
Location: Washington, DC / Venue: JW Marriott
Website: www.dlsconference.com

April 24-27, 2018
Charing Cross International Symposium (CX 2018)
Location: London, UK / Venue: Olympia London
Website: www.cxsymposium.com

April 25-28, 2018
Society of Cardiovascular Angiography & Intervention (SCAI)
Location: San Diego, California
Website: www.SCAI.org

May 22-25, 2018
EuroPCR
Location: Paris, France
Website: www.europcr.com

May 30-June 1, 2018
New Cardiovascular Horizons (NCVH)
Location: New Orleans, Louisiana
Website: www.ncvh.org

June 17-20, 2018
Complex Cardiovascular Catheter Therapeutics (C3)
Location: Orlando, Florida / Venue: Rosen Shingle Creek
Website: www.c3conference.net

June 20-23, 2018
Society for Vascular Surgery (SVS) Annual Meeting
Location: Boston, Massachusetts
Website: https://vascular.org

August 8-11, 2018
Amputation Prevention Symposium (AMP)
Location: Chicago, IL / Venue: Hilton Chicago / #AMP2018
www.amptheclimeeting.com

September 21-25, 2018
Transcatheter Cardiovascular Therapeutics (TCT)
Location: San Diego, California
Website: www.tctconference.com

November 5-8, 2018
Vascular Interventional Advances (VIVA)
Location: Las Vegas, NV
Website: www.vivaphysicians.org

November 13-17, 2018
VEITH Symposium
Location: New York, New York
Website: www.veithsymposium.org

January 26-30, 2019
International Symposium on Endovascular Therapy (ISET)
Location: Hollywood, Florida / Venue: The Diplomat Hotel
Hashtag: #ISET2019
Website: www.iset.org

DATAPOINTS

REVEALING REAL-WORLD GLOBAL DATA

LUTONIX® 035 DCB had the **highest reported freedom from TLR rate** at 2 years among real world patients in two separately-conducted registry studies.[1]

In.Pact Global Study

83.3%

FREEDOM FROM CD-TLR At 24 Months[2]

In.Pact™
Drug Coated Balloon

Lutonix Global SFA Real-World Registry

90.3%

FREEDOM FROM TLR At 24 Months[3]

LUTONIX® 035
Drug Coated Balloon PTA Catheter

[1] Data are not from head-to-head clinical studies and are provided for background and educational purposes only. Different trials have varying patient profiles, protocol structures and other criteria that may affect reported outcomes.
[2] In.Pact™ Global Study, n=1,406. Medtronic reported data, VIVA 17, 2-Year Results from the In.Pact™ Global Study, Thomas Zeller, MD, PhD. Primary endpoint defined as freedom from clinically driven (CD) target lesion revascularization (TLR) within 12 months. Freedom from TLR was 92.6% through 1 year. Freedom from CD-TLR was 83.3% through 2 years.
[3] LUTONIX Global SFA Real World Registry, n=691. Primary efficacy endpoint is defined as freedom from TLR at 12 months. TLR Free rate by subject counts at 12 months was 93.4% (605/648). The Kaplan-Meier TLR-Free survival estimate was 94.1% at 12 months and 90.3% at 24 months. In the LEVANT 2 IDE Clinical Trial, treatment with LUTONIX® 035 DCB resulted in freedom from TLR rate of 87.7% at 12 months (250/285) and a freedom from TLR rate of 82.0% at 24 months. Data on file, Bard Peripheral Vascular, Inc.

BARD has joined BD