

CLI GLOBAL COMPENDIUM

THE GLOBAL VOICE OF CRITICAL LIMB ISCHEMIA

The CLI Global Society: The First Vascular Specialist Advocacy Group Focused Exclusively on CLI

CLI kills more people than many common cancers and is associated with severe outcomes if left untreated or if the presentation is too late. Yet no program exists to raise public awareness about CLI. The time has come for a call to action for better public CLI awareness, training of CLI specialists, and more data on CLI therapy outcomes.

We are proud to announce the development of the first vascular specialist advocacy group, the CLI Global Society. Join this grassroots movement and contribute to increased awareness, education, training, and development of global standards for clinical evaluation and therapy for the CLI patient. Because a multidisciplinary approach to this complex disease is critical, the Society encourages involvement of vascular specialists, primary care physicians, endocrinologists, podiatrists, and wound care specialists.

The first goal of the Society is to build public and physician awareness of CLI and its treatment options. The Society additionally will work to develop globalized standardization for clinical evaluation, noninvasive and invasive diagnostics, medical therapy, and revascularization for the CLI patient. The Society will work closely with global regulatory agencies to create an understanding of the complexity of treating a patient with CLI and recommend appropriate endpoints for CLI clinical trials.

An enthusiastic group met at the first CLI Global Society membership meeting, held in conjunction with the Amputation Prevention Symposium in Chicago on August 10, 2016. Join the CLI Global Society at www.cliglobalsociety.org and become part of the solution! ■



Members of the CLI Global Society gathered for the group's first meeting in August at the Amputation Prevention Symposium in Chicago, which hosted attendees from 22 countries.

Surgical and Endovascular Options for the CLI Patient – Thinking In and Out of the Box *Case Studies From Singapore*

Steven Kum, MBBS, FRCS, FAMS; From Changi General Hospital, Singapore.



Steven Kum, MBBS, FRCS, FAMS

Diabetes is undoubtedly the “modern plague.” Despite improvements in access to health care, we are still reeling from the daily struggle against critical limb ischemia (CLI). Patients are surviving longer, have had prior interventions, and are presenting with more complex angiograms and wounds. The CLI “animal” has now become the “beast.” Following are 3 case examples from a dedicated limb-salvage center in Changi General Hospital, Singapore.

In our hospital, limb salvage is undertaken by the vascular surgeons who deal with two of

the most pressing issues in diabetic CLI: revascularization as well as soft tissue debridement and reconstruction. We strive to attend to every diabetic CLI case referred to our service within 24 hrs. There is a hybrid operating room available 24/7. Patients undergo simultaneous endovascular and open revascularization as well as infection control, debridements, and minor amputations under regional blocks and sedation (usually an ultrasound-guided popliteal and saphenous nerve block). This is supported by a multidisciplinary team consisting of podiatrist,

wound care nurses, endocrinologist and foot and ankle orthopedic surgeons.

CASE EXAMPLES

Case 1

A 70-year-old male prior smoker with a past history of a coronary bypass surgery, diabetes, hypertension, and hyperlipidemia presented with gangrene of the left foot for 2 months, refusing intervention, and arrived in our center for a second opinion (Figure 1).

Continued on page 8



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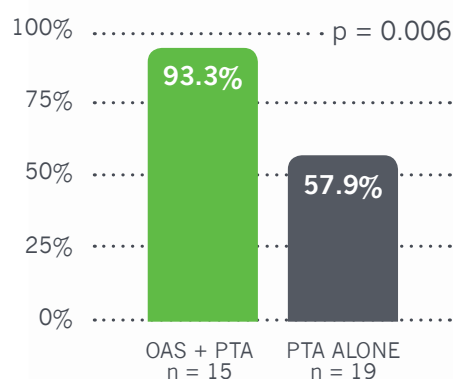
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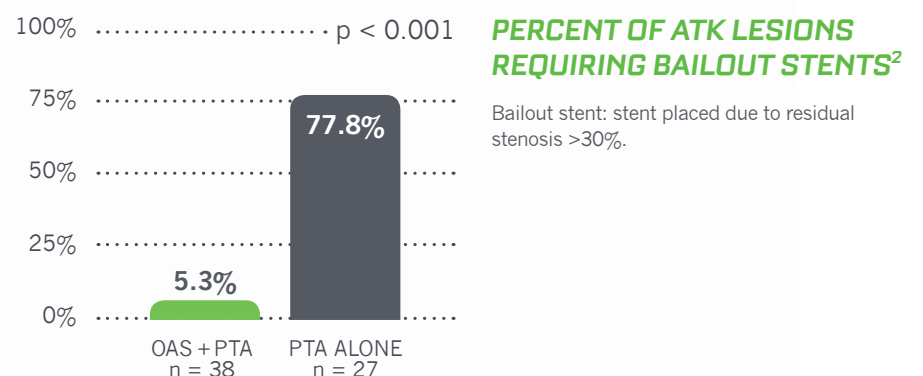
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Latest Endovascular Techniques for Complex Femoropopliteal Chronic Total Occlusion

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Andrej Schmidt, MD



Dierk Scheinert, MD

The introduction of new technologies and techniques has led to a significant increase in the success rate of endovascular procedures, which in turn has led to an increasing acceptance of endovascular therapy as a first-line approach. Dedicated chronic total occlusion (CTO) guidewires, crossing devices, re-entry systems, and new stent platforms with significantly improved crush-resistant forces are felt to have helped to push the field forward, beyond previously existing limitations. Consequently, the complexity of cases that are being offered percutaneous transluminal angioplasty (PTA) is further increasing. Highly complex lesions run the gamut from redo procedures, reocclusions after endovascular or failed surgical treatments, extreme calcification (long and circumferential), total and long occlusions of 2 and 3 tibial vessels, occluded inframalleolar arteries with need for pedal loop reconstruction, and even endovascular treatment of heavily calcified lesions in the common femoral artery, a territory that has been the last resort to be approached via endovascular means. To deal with such cases, endovascular techniques must be constantly modified and improved. Herein, the authors aim to describe some techniques and technologies that we have found to be very helpful in dealing with extremely complex CTOs.

Flush-occlusions of the superficial femoral artery (SFA) harbor significant

challenges for an endovascular treatment (Figure 1A). Especially if surgical treatment, such as bypass or thromboendarterectomy, have preceded, an antegrade guidewire access to the CTO can be impossible, due to extensive scarring. In cases of failure, a retrograde approach may be the only solution. But even then, especially after previous surgery of the femoral bifurcation, the guidewire tends to travel subintimally into the common femoral artery (CFA) and consecutive treatment steps may jeopardize the profunda femoris. For a precise re-entry of the guidewire from retrograde back into the common femoral artery (CFA), the use of a re-entry device is very helpful. They are either inserted via the popliteal artery or, as we have described previously,¹ through a retrograde approach via the distal femoral artery. However, the insertion of a re-entry device requires a 6 Fr sheath, which increases the risk for bleeding at the distal access site where closure devices might be impossible or hazardous to use.

In such situations, we seek to reduce the risk of bleeding as much as possible by trying to gain access directly into the occluded SFA (Figures 1B-1D). In cases of a typically long SFA CTO, this technique is advantageous because the access site can be chosen over the whole length of the artery (for example, into a more proximal and therefore rather

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

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How I Fit CLI Procedures Into My Busy Schedule

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Tino Pena, MD

How can we “fit in” a critical limb ischemia (CLI) procedure to a day that is already a full day in the procedure suite as well as a full schedule of patients to see the office? Can we plan for these cases? How can we include them in our already busy schedules? The ability to be an effective operator and properly treat patients with CLI requires multiple moving parts. The clock begins with a phone call or consult from the patient, referring physician, or CLI team member. The first step to a successful interaction involves the ability to quickly evaluate a patient who has been referred. Patients with CLI require prompt treatment. The initial evaluation usually provides the necessary information to properly triage the patient and establish a “pretty good” idea when the patient will need to be treated. Even though the revascularization plan is far from complete, the urgency of the procedure can usually be established after the initial evaluation.

The steps required before the patient is brought to the endovascular suite can be numerous. Understanding the complexity of treatment before the procedure is undertaken requires excellent pre-procedure evaluation. The patient is evaluated for multiple important issues including renal insufficiency, iodine allergy, and the presence of anticoagulants. Aside from a thorough history and physical examination, pre-procedural imaging is usually acquired with a complete noninvasive arterial examination that will likely include digital photoplethysmogram. Many patients will then receive an MRA or a CTA depending on the urgency of the therapy and the patient’s possible contraindications (hemodialysis, renal insufficiency, pacemaker, iodine allergy).

The challenges with preparing these patients with CLI for a procedure can be numerous. The patients will require

proper medical optimization. This will require the assessment and management of antiplatelet medications, diabetic medications, and blood pressure management. A conversation with the wound care team is important to determine the overall treatment goals to coordinate the patient’s care, including potential debridement. The planning of the eventual revascularization procedure and treatment plan for these patients will rely on the physical examination, pre-procedural imaging, and discussions with the CLI team. Many CLI teams have found great success using allied health personnel who becomes the central spoke in the communication hub.

One of the greatest challenges of being able to schedule and perform CLI procedures is that many of these procedures need to be performed urgently. There is concern in many of these patients that a long delay may lead to further tissue threat. Additionally, patients may be suffering from rest pain, further exacerbating the treatment urgency. Usually they are scheduled and performed within 1 or 2 days of being evaluated in the office. In the outpatient setting, the ability to treat a patient quickly may be limited by

CLI patient can lead to more timely and successful intervention. A case example illustrates this point nicely. A 48-year-old diabetic female presented with a non-healing wound to the emergency room. She was treated for several weeks by a podiatrist, and was sent to the emergency room when it was determined the wound was not healing. The original treating podiatrist did not have hospital privileges and there was no communication to the hospital team. Ultimately, the patient underwent a successful revascularization procedure. Aggressive diabetic control was also instituted (HbA1c was 11 on admission). Her total length of stay in the hospital was 6 days and it took several months of wound care to heal the wound. Approximately 1 year later the patient developed a new wound on the contralateral foot. However, because of her connection and ability to communicate with the CLI team, she was seen immediately as an outpatient. Following this outpatient evaluation, it was determined that the patient could be electively scheduled for an outpatient procedure. After the procedure, she went on to rapidly heal her wound (HbA1c was 7).

Fitting these procedures into a busy schedule requires communication, teamwork, proper pre-procedural evaluations, flexibility of operators in the treatment team, and a clear understanding of the treatment goal for that particular patient.

insurance authorization issues. Patients seen as inpatients usually have more advanced disease severity and can usually be evaluated more efficiently. However, an ever-increasing issue is the need to limit the overall length of hospitalization in patients with CLI.

In some cases, a well-run CLI team can provide the ultimate solution to “fitting in” a patient. The solution may be to change an urgent inpatient procedure into an elective outpatient procedure. This can be accomplished in 2 distinct ways. First, when a patient presents to the hospital with CLI some patients can be sent home to return on an elective basis. This can only happen if a detailed assessment of the degree of CLI as well as comorbidities is made in a timely manner. Moreover, the CLI team then serves as the facilitator to rapidly negotiate the system so that the patient can return as an outpatient. In addition, education of a

1 arterial access site, many require 2 or 3 accesses with subsequent treatment of both iliac, femoropopliteal, and tibial vessels. It is important to have a treatment team that can facilitate and help the primary operator so that work can be performed from multiple access sites with the aid of additional operators.

A pretreatment plan is important to improving the efficiency and success to the treatment of these patients. This plan is discussed with members of the endovascular team, usually the morning of the procedure, to create a consensus on the primary treatment approach. By discussing the treatment plan as a group, all members of the team can aid the primary operator during the procedure as needed. Additionally, when the treatment plan is clearly communicated, all of the possible treatment materials can be prepared prior to the procedure. This is important in determining the patient position in the room, preparing potential access sites, and having all necessary materials and devices in the room. We avoid scheduling these procedures at the end of the day and usually schedule them as the first case in the morning or the first case in the afternoon.

At the time of the procedure, the treatment plan is usually discussed with the team in the room so that the nurse and the technologists are aware of the treatment plan. The creation of several treatment carts that can be moved between several treatment rooms allows for the transportation of the necessary devices to be stocked in one location facilitating inventory issues and increasing efficiency. In an effort to reduce procedure times, all operators should examine their own practice pattern and make some honest assessments of their outcomes. For instance, some operators will place a set “time limit” for their attempts at antegrade tibial recanalization. If the time limit is reached and there has been no meaningful progress, then alternative routes such as pedal access are employed.

Having an idea of when to terminate the procedure is important but sometimes difficult. The pre-procedural discussions usually outline the primary goal of the procedure; however, sometimes the goal and treatment plans need to be changed or adapted. The length of the procedure is usually an important factor in determining how many tibial vessels are revascularized at the time of the initial procedure.

Fitting these procedures into a busy schedule requires communication, teamwork, proper pre-procedural evaluations, flexibility of operators in the treatment team, and a clear understanding of the treatment goal for that particular patient. These are complex procedures in patients with significant comorbidities. Proper scheduling of these patients and room preparation increase treatment success and efficiency in hopes of keeping the operators on track with all of their other responsibilities that day. ■



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Save Her Leg: My Patient Is Not Too Old or Too Sick!

Successful Peripheral Vascular Intervention in a Patient With Rutherford Category IV Critical Limb Ischemia

Guy Pupp, DPM, FACFAS¹, Patrick Alexander, MD, FACC, FSCAI¹, Mohomad Al Sawah, DPM², Meaghan Stoinski, DPM²

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A dedicated team approach using contemporary technology leads to successful limb salvage, even with significant pathology.



Guy Pupp, DPM, FACFAS

Salvaging an ischemic limb necessitates wide resection of all affected, nonfunctional tissue.¹ Rutherford Category VI classification for vascular disease manifestations is graded clinically as major tissue loss behind transmetatarsal level with unrecoverable foot functionality.² Time is tissue loss for patients with critical limb ischemia (CLI); without perfusion, our tissue dies and becomes a magnet for

infection.¹ In addition, morbidity and mortality rates are astonishingly high after major lower extremity amputations, which often become the treatment for patients with CLI.^{1,3} We report successful limb salvage in a patient with CLI after undergoing extensive peripheral vascular intervention followed by podiatric surgical revision. In a multidisciplinary setting with skilled providers, limb salvage is possible, even in the most challenging cases.

CASE REPORT

An 89-year-old black female was referred to the first author for a second opinion on her ischemic left transmetatarsal amputation site. Past medical history for the patient included peripheral vascular disease (PVD) with claudication status post multiple peripheral vascular interventions, anemia, atrial fibrillation, and 40 pack-year history of tobacco use with 10 years since cessation. Risk factors for PVD included age and tobacco use.⁴

The pathological course began 3 years ago, when a nonhealing wound on the patient's left third toe resulted in toe

amputation following her first left lower extremity peripheral vascular intervention at an external facility. Despite the initial peripheral intervention, gangrene progressed to all remaining toes of the left foot. She then underwent a series of endovascular interventions at an external facility. The patient's final angiogram at the external facility 6 months ago revealed 100% left superficial femoral artery (SFA) in-stent restenosis, as well as posterior tibial artery, peroneal artery, and tibiopedal (TP) trunk occlusions. Peripheral intervention was performed including balloon angioplasty x3 of the left SFA, peroneal and TP trunk followed by subsequent left transmetatarsal amputation 1 week later. The procedures failed, and the patient's lower extremity was deemed nonsalvageable. Her physicians recommended a below-the-knee amputation.

Upon refusal of the amputation, the patient was treated with local wound care and hyperbaric oxygen therapy for 3 months. The patient sought out opinions from providers at external facilities, all of whom recommended the below-knee

amputation. Her limb ischemia progressed and she became completely bed-bound due to unbearable pain.¹ She was referred to our limb salvage team at Providence Hospital. At initial evaluation, the patient was found to have anemia, leukocytosis, and acute infectious components including osteomyelitis to her ischemic amputation site. She was evaluated and referred to our interventional cardiologist who performed an angiogram with extensive peripheral vascular intervention (PVI) to the left lower extremity (Figure 1). Interventions included drug-eluting stents to the popliteal, tibio-peroneal trunk (TPT) and peroneal arteries, resulting in 0% stenosis from 100% at the beginning of the procedure; 3 lesions in the vascular tree underwent angioplasty as well. The intervention was followed 3 days later by a left revisional Chopart amputation, removing all nonviable soft tissue and osteomyelitic bone by the podiatry team. The patient still had a small soft-tissue defect at the amputation site. Two months later, the podiatry team applied an amniotic stem cell membrane biologic dressing to the residual small

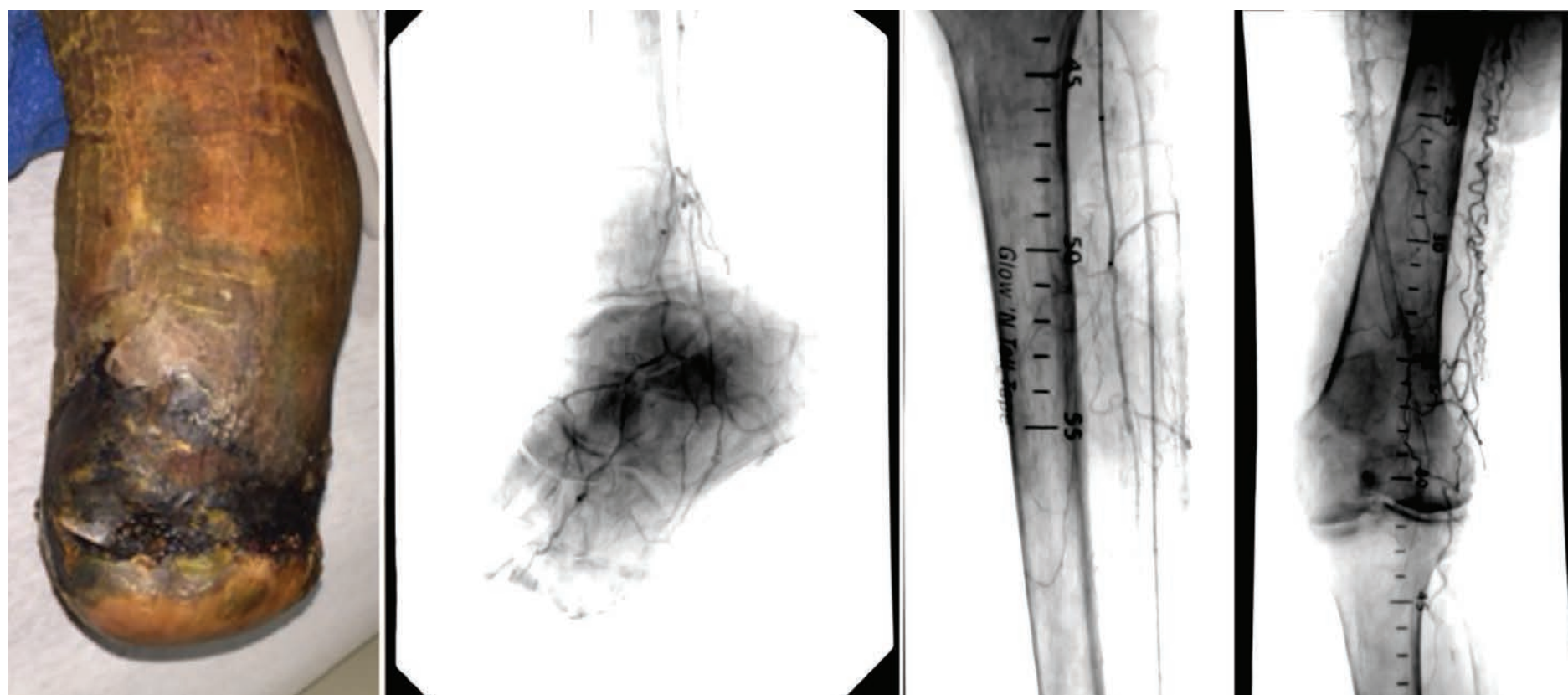


Figure 1. Initial presentation.

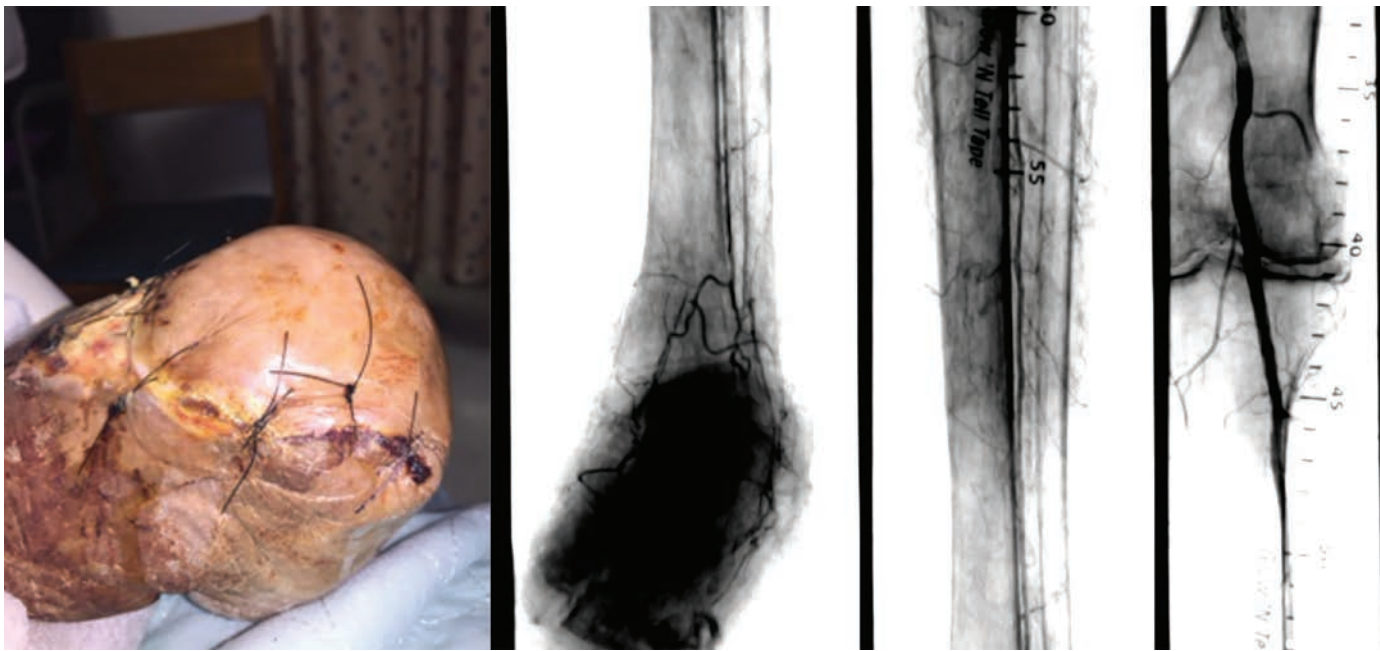


Figure 2. Post revascularization and revisional amputation.

soft-tissue defect. Close follow-up was maintained with no weight-bearing activity until the left Chopart amputation site was healed completely, as noted three months post PVI.

DISCUSSION

This case describes a geriatric female with a past history of nicotine use who developed gangrene and CLI. She presented to another institution and after multiple unsuccessful vascular interventions and partial foot amputations, she was referred for a below-the-knee

amputation.¹ She sought another opinion at our institution, where successful limb preservation was attained. Utilizing aggressive contemporary technology, successful limb salvage can be achieved in most cases.

Understanding the epidemiology of CLI patients with a major amputation, she would be wheelchair bound for the remainder of her life, which would also be shortened.³ Her inability to ambulate independently would also affect her quality of life. There is also significant mortality and morbidity in

patients undergoing a major amputation such as above- or below-knee amputation.³ The cost of a lower-extremity prosthetic ranges from \$5,000 to \$30,000 per prosthetic device without replacement or maintenance costs, which are significant.^{5,6}

In the case of this 89-year-old female patient who had undergone multiple revascularizations and failed prior partial foot amputations, successful peripheral vascular intervention followed by a revised partial foot amputation avoided a below-the-knee major amputation.

By utilizing a multidisciplinary skilled team to achieve limb salvage, we can prolong life and functional status of patients suffering from severe peripheral vascular disease and critical limb ischemia.³ This case demonstrates the fact that a dedicated team approach using contemporary technology leads to successful limb salvage,⁷ even with significant pathology. We feel major amputations can many times be avoided, and that there are no patients too old or too sick. ■

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KUM from page 1

Examination reveals signs of congestive heart failure with lower-limb edema and orthopnea. In the work-up, a cardiac echocardiography revealed an ejection fraction of 50% and normal

renal function. Preprocedure duplex ultrasound reveals multivessel, multilevel disease typical of diabetics who smoke. There was a superficial femoral artery (SFA) and popliteal artery chronic total occlusion (CTO) and a posterior tibial artery (PTA) stenosis. He was optimized

with diuresis for 72 hours and underwent a left lower limb angioplasty via the right femoral approach and a simultaneous transmetatarsal amputation. This was done under intravenous sedation and a popliteal nerve regional block (Figure 2).

The vessels were heavily calcified and re-entry with a stiff 0.035" Terumo wire failed. A retrograde puncture of the posterior tibial artery was performed under ultrasound guidance. After snaring the retrograde 0.018" wire with an angled catheter and reversal of the wire, predilatation and lesion preparation was done with a high-pressure 6 mm Conquest Balloon (Bard Peripheral Vascular). In view of the severe recoil seen and the need to optimize the inflow, the SFA and popliteal artery were stented with a 5 mm Supera stent (Abbott Vascular) with good results. Supplementary balloon angioplasty of the posterior tibial artery was done with a 3 mm Armada 14 PTA Catheter (Abbott Vascular). A transmetatarsal amputation of the toes was performed simultaneously. Post procedure, the patient required 1 week stay for optimization of fluid status and wound care and was started on life-long dual antiplatelet therapy (DAPT) in view of the advanced nature of arterial disease and stents. Negative pressure wound therapy was started (VAC therapy). The patient achieved complete wound healing in 9 months. He was given insoles with a toe filler and he remains wound free and free of cardiovascular events (Figure 3). On 3-year follow-up, he is ambulating without a walking aid.

Case 2

The second patient presented with a history of diabetes, hypertension, and hyperlipidemia and extensive gangrene over the left heel. On examination she had lower-limb edema and absent pulses over the foot. Dry gangrene of the left heel almost extended to, but did not involve, the calcaneal bone (Figure 4).

Preprocedure work-up showed a preserved cardiac ejection fraction, borderline renal function, and severe proteinuria. She was diagnosed with critical limb ischemia and nephrotic syndrome, and was treated with diuresis, DAPT, and angiotensin



Figure 4. Extensive gangrene of the heel.

receptor blockade (ARBs). She underwent a left-leg angioplasty and simultaneous debridement of the gangrene in our hybrid operating room under sedation and a popliteal nerve block. Preintervention angiogram revealed multivessel, multilevel disease and calcification typical of diabetic angiopathy. Based on the angiosome concept and the severity of the soft tissue loss, an all-out attempt was made to revascularize as many vessels as possible. Good vessel patency was also required in anticipation of prolonged wound healing. Severe recoil of the popliteal artery and dissections of the proximal tibial vessels were seen after angioplasty (Figure 5).

We decided to recruit her into a study (Drug Impregnated Bioabsorbable Stent in Asian Population Extremity Arterial Revascularization - DISAPEAR study) and proceeded with a combination of an Absorb bioabsorbable vascular scaffold (Abbott Vascular) and Supera Stent (Abbott Vascular) to reconstruct the bifurcation despite moderate calcification.

Postprocedure wound care was prolonged and the patient achieved wound healing 6 months later. Serial clinical examinations and duplex ultrasounds at 6, 12, 18, and 24 months revealed good flow

Continued on page 10



Figure 1. Case 1 presented with extensive gangrene.

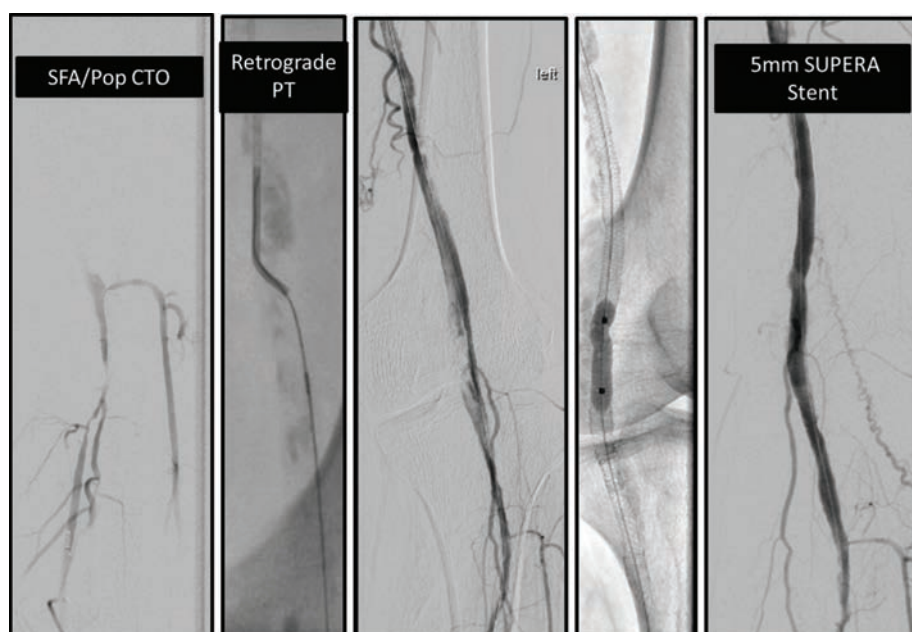


Figure 2. Intervention for case 1. Multilevel calcific disease. SFA, superficial femoral artery; pop CTO, popliteal chronic total occlusion; PT, posterior tibial artery.



Figure 3. Case 1 pre- and postprocedure follow-up.

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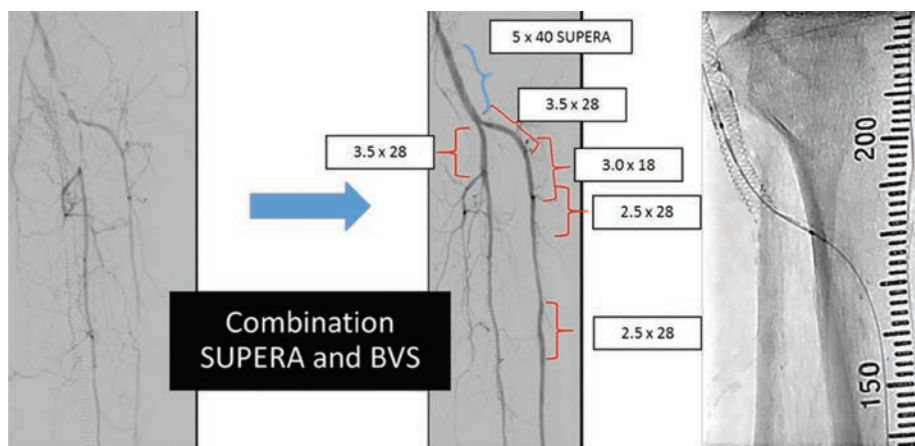


Figure 5. Case 2 pre- and postprocedure angiograms.

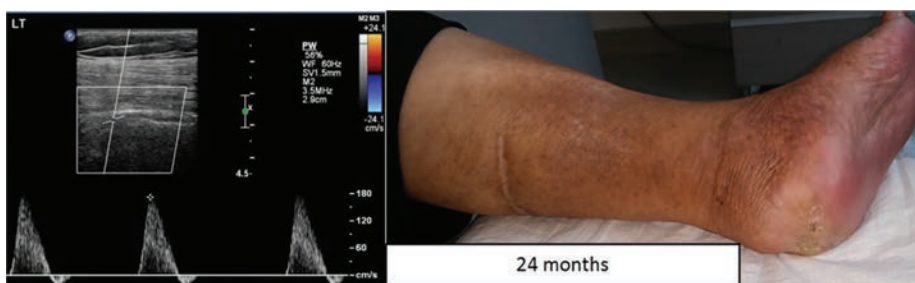


Figure 6. Two-year duplex of the anterior tibial artery and clinical follow-up for case 2.

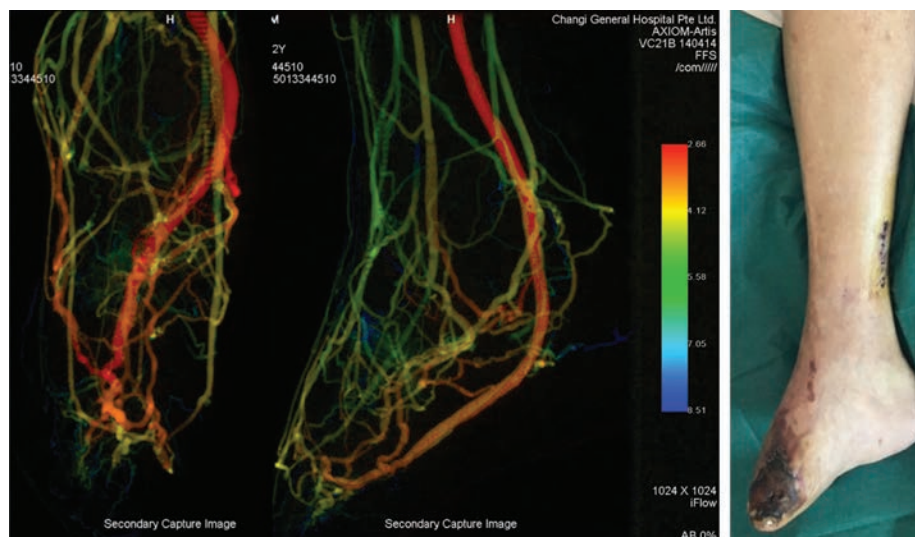


Figure 7. Case 3 iFlow perfusion angiograms post-surgical deep vein arterialization and clinical follow-up.



Figure 8. Pre and Post procedure clinical follow-up and TCPO₂ levels.

Surgical and endovascular options must be considered for revascularization.

KUM from page 8

with intact distal pulses as well as no evidence of restenosis within the Supera and bioabsorbable vascular scaffold. She remains wound free at 24 months (Figure 6).

Case 3

The last patient is also a 75-year-old female with a 20-year history of diabetes. She had previous interventions and 3 toes amputated several years ago. She returned with gangrene of her remaining first and second toes. An attempt at intervention failed due to a lack of discernible run-off, calcified SFA, and recurrent in-stent restenosis of the popliteal artery despite prior drug-coated balloon angioplasty. In view of the “desert foot” and severe in-flow lesions, a surgical bypass to the deep veins of the foot (deep vein arterialization) was performed with a hybrid approach. A 5 mm reinforced polytetrafluoroethylene graft was tunneled to above the ankle. The distal anastomosis was created percutaneously with a 5 mm Viabahn endoprosthesis (W.L. Gore) into the posterior tibial vein, for a suture-less anastomosis. Postprocedure perfusion angiogram showed brisk flow (Figure 7).

The wound was left to demarcate and was subsequently debrided. VAC therapy was started and full wound closure was possible with a split skin graft. Improvements in transcutaneous oxygen levels (TCPO₂) were also seen (Figure 8).

DISCUSSION

The first case illustrates the importance of inflow treatment in a diabetic with multilevel disease. Balloon angioplasty is often handicapped by recoil, which may not be evident on 2-view angiography. In a calcified CTO, mechanical scaffolding with a dedicated stent with high radial force is essential to give a “fem-pop bypass” equivalent for wound healing. Early results from the SUPERSUB study of the Supera stent suggest good clinical and patency outcomes for long SFA CTOs as compared to standard nitinol stents.¹ Aggressive wound care and early return to ambulation are our ultimate goals to ensure a good angiographic result is paired with a good clinical result. Risk factor modification with statins and DAPT are essential in this high-risk group.

The second case illustrates the challenges in diabetic CLI. To date, plain old balloon angioplasty (POBA) seems to be the standard of care in moderate-length to long-length lesions. Recoil after POBA is more common than many clinicians think.² In a small study, recoil of >10% was observed in 97% of a cohort of 30 consecutive patients with a mean luminal diameter (MLD) compromise of 29%

according to an angiogram taken 15 minutes after initial postangioplasty angiogram. Small-vessel diameters in addition to recoil may not only compromise the absolute blood volume for wound healing, it may also, in theory, compromise patency. Bioabsorbable stents have proven results in the coronary space and offer the promise of an antirestenotic, nonpermanent scaffold. We utilize a combination of several bioabsorbable vascular scaffolds to achieve reconstruction of the trifurcation with good patency and clinical results at 2 years for a patient with Rutherford VI heel gangrene.

The third case is an example of a patient with “no-option” CLI. A combination of inflow in-stent restenosis and the lack of any discernible run-off for conventional distal bypass or distal balloon angioplasty is a challenge. Recent publications on venous arterialization seems to hold promise.^{4,5} Conventional deep-venous bypass is technically challenging due to the small calibre of the deep veins and propensity for twisting to occur. We utilize a hybrid technique with a “suture-less distal anastomosis” with a Viabahn covered stent. In combination with aggressive wound care and skin coverage, we managed to achieve full wound healing at 8 months. A completely percutaneous approach with the Limflow device is under investigation.⁶

In summary, CLI remains a challenging disease to treat. Surgical and endovascular options must be considered for revascularization. Clinicians continue to push the envelope to find solutions to treat a disease that knows no limits. Aggressive wound care to heal wounds and return to walking should be emphasized as end-points for CLI. ■

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TRUTH
#14

I DIDN'T KNOW
MOST MECHANICAL
ATHERECTOMY
DEVICES ARE
CONTRAINDICATED
FOR ISR¹

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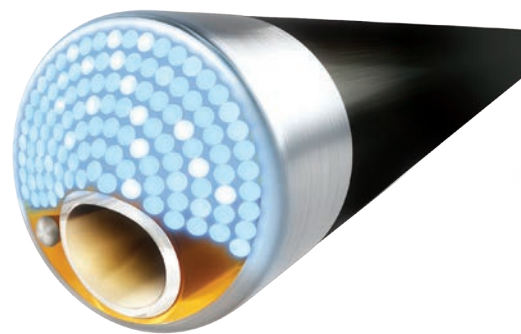
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superficial segment, or a less calcified area). The needle of choice is the standard 18-gauge, 7 cm long puncture needle together with a stiff angled 0.035" guidewire (e.g. Terumo Stiff Angled Guidewire, Terumo Medical). The authors find fluoroscopic guidance to be a very simple way to target the artery, but ultrasound-guided access is also a viable alternative. A prerequisite for fluoroscopic guidance is the visibility of calcification to direct the needle to it (Figure 1B), which is typically done using a C-arm angle, which shows adjustment of the course of the needle to the course of the artery. The C-arm angle is usually left anterior oblique 20° to 40° contralateral to the leg. Once the needle tip is touching the calcium, the C-arm is moved laterally 90° to the former position to open up the angle between the needle and the artery (Figure 1C). In this projection, the introduction of the guidewire into the occluded SFA is observed. The guidewire forming a small loop, as typically seen in an antegrade subintimal guidewire passage of SFA CTOs, signifies a successful access. If the guidewire forms a large loop, the puncture must be repeated.

Dedicated chronic total occlusion guidewires, crossing devices, re-entry systems, and new stent platforms with significantly improved crush-resistant forces are felt to have helped to push the field forward, beyond previously existing limitations.

The complexity of the flush-occlusion determines the devices to be used to successfully perform guidewire passage via the access site. In the case in which a re-entry device is felt to be necessary, a 6 Fr sheath is directly inserted into the occluded SFA from a retrograde approach. Another alternative could be the use of a newer crossing device, the Wingman Crossing Catheter (Reflow Medical), which is compatible with different guidewire sizes (0.014", 0.018", and 0.035") as seen in Figure 1E. The Wingman Crossing Catheter is an over-the-wire braided catheter with an extendable radiopaque needle-like tip that is manually controlled by a handle to engage with the lesion. A push-and-twist motion allows penetration of the tip and further advancement of the wire.

However, despite this armamentarium, with severe scarring or even transection of the SFA during surgery, or if the proximal SFA has been utilized as a patch for the profunda artery, guidewire passage into the CFA from a retrograde approach

might seem impossible. In these cases, we found the use of a metallic needle device like the Brockenbrough needle (Figures 1F-1H) to be a solution. The Brockenbrough needles is used in cardiology to traverse the atrial septum. It comes with a stable metallic tube, which requires a 6 Fr sheath. However, the needle itself offers enough stability if used without it and requires only a 4 Fr sheath. Any 0.018" or 0.014" guidewire can be used through this needle. Its use is not approved for peripheral arteries, but successful passage of a severely calcified SFA lesion using this device has been described in the literature.² Once guidewire passage has been accomplished, scarring from surgery might hinder further steps (Figure 1I) and might require the use of high-pressure noncompliant balloons, laser atherectomy, or other atherectomy devices before treatment can continue (Figures 1J-1L). Bleeding from the retrograde 6 Fr access through the occluded SFA is easily controlled by balloon angioplasty and stenting, and potentially implantation of a Viabahn endoprosthesis (W.L. Gore), during treatment. In a series of 56 patients at our center, the retrograde puncture of an occluded SFA segment was feasible

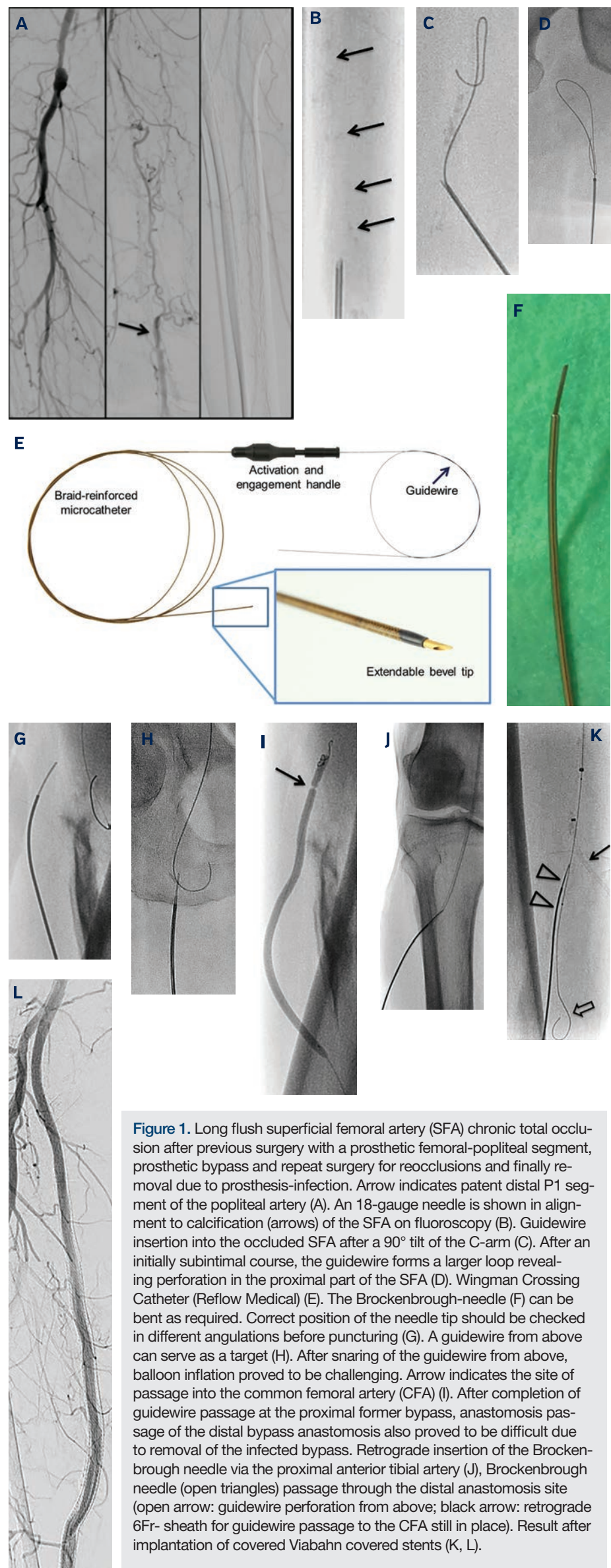


Figure 1. Long flush superficial femoral artery (SFA) chronic total occlusion after previous surgery with a prosthetic femoral-popliteal segment, prosthetic bypass and repeat surgery for reocclusions and finally removal due to prosthesis-infection. Arrow indicates patent distal P1 segment of the popliteal artery (A). An 18-gauge needle is shown in alignment to calcification (arrows) of the SFA on fluoroscopy (B). Guidewire insertion into the occluded SFA after a 90° tilt of the C-arm (C). After an initially subintimal course, the guidewire forms a larger loop revealing perforation in the proximal part of the SFA (D). Wingman Crossing Catheter (Reflow Medical) (E). The Brockenbrough-needle (F) can be bent as required. Correct position of the needle tip should be checked in different angulations before puncturing (G). A guidewire from above can serve as a target (H). After snaring of the guidewire from above, balloon inflation proved to be challenging. Arrow indicates the site of passage into the common femoral artery (CFA) (I). After completion of guidewire passage at the proximal former bypass, anastomosis passage of the distal bypass anastomosis also proved to be difficult due to removal of the infected bypass. Retrograde insertion of the Brockenbrough needle via the proximal anterior tibial artery (J), Brockenbrough needle (open triangles) passage through the distal anastomosis site (open arrow: guidewire perforation from above; black arrow: retrograde 6Fr- sheath for guidewire passage to the CFA still in place). Result after implantation of covered Viabahn covered stents (K, L).

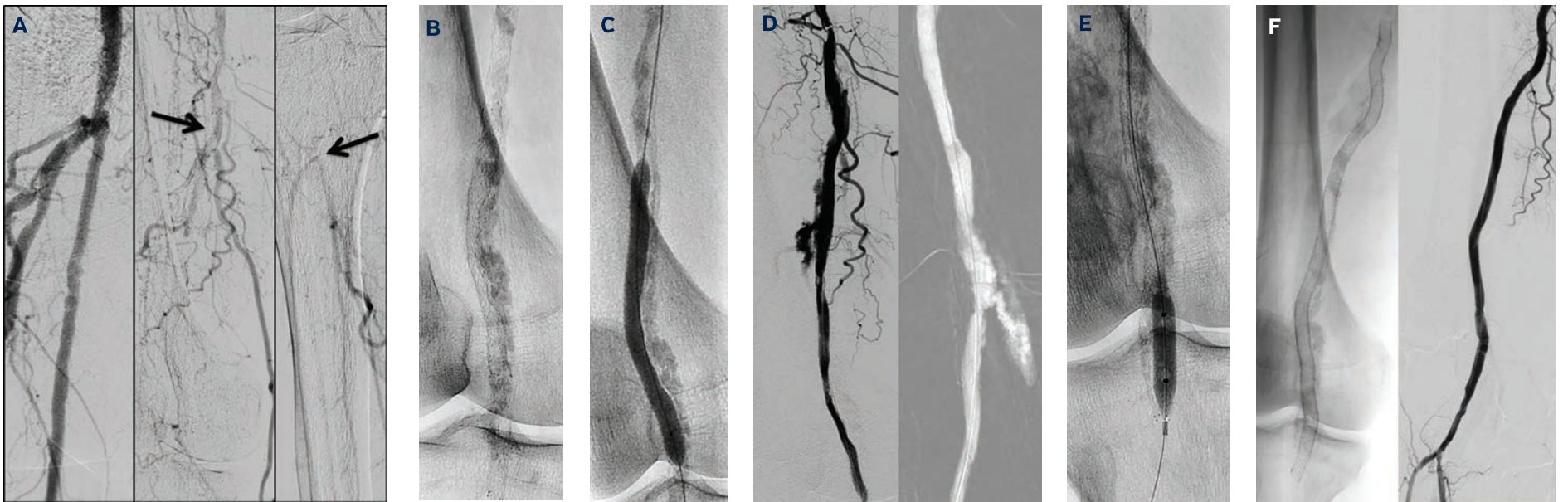


Figure 2. Severely calcified distal superficial femoral artery (SFA) and popliteal occlusion. Reocclusion 1 month after implantation of a standard nitinol stent (A). Standard nitinol stent failed to overcome the recoil forces of the calcification (B). Repeat percutaneous transluminal angioplasty (PTA) with a 5.0 mm semi-compliant balloon with insufficient performance (C). Rupture of the artery after PTA using a high-pressure balloon to prepare for the implantation of a Supera stent (Abbott Vascular) (D). Implantation of 7.0 mm diameter Viabahn covered stent and PTA with a 7.0/20mm high-pressure balloon (E). Result after relining of the Viabahn covered stents with 6.5 mm diameter Supera stents to avoid collapse of the Viabahns as seen in the previous standard stent. Angiogram image at 6-month follow-up visit (F).

implant the stent. In such situations, we implant a Viabahn endoprosthesis to seal the intended rupture and reinforce it with a Supera stent to overcome the recoil forces of the calcified plaque. This facilitates treatment without significant residual stenosis. Aggressive percutaneous transluminal angioplasty of the artery can be painful, therefore we administer local anesthetic percutaneously to the most severely calcified segments of the artery (for this purpose, a 9 cm

21-gauge needle is helpful), or we perform the procedure under general anesthesia (Figure 2).

The two techniques described here may enable interventionalists to offer an endovascular approach to some of the most severe forms of peripheral arterial occlusive disease if surgery is felt to be problematic for these patients.

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Disclosures: Andrej Schmidt, MD, is a consultant for Abbott Vascular, Boston Scientific, C.R. Bard, Cook Medical, Cordis, Intactvascular, Medtronic, ReFlow Medical, Spectranetics, Upstream Peripheral and is a former stockholder of IDEV Technologies. Dierk Scheinert, MD, is a consultant for Abbott Vascular, Boston Scientific, C.R. Bard, Cook Medical, Cordis, Gardia

Medical, Medtronic, ReFlow Medical, TriReme Medical, Upstream Peripheral and is a former stockholder of IDEV Technologies. ■

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Why CLI Patient Awareness Is Important – You Don't Know What You Don't Know

Desmond Bell, DPM, CWS

From First Coast Cardiovascular Institute, Jacksonville, Florida.



Desmond Bell, DPM, CWS

Screenings for cancer are part of a comprehensive physical examination, with the benefits of early detection indisputable. The idea that physicians, nurse practitioners, and patients would rather wait for a suspicious lesion to metastasize rather than seek proactive intervention seems outrageous, yet this is the mindset that is still pervasive when it comes to peripheral arterial disease (PAD) as it converts to critical limb ischemia (CLI).

By this time, most of us who have dedicated our professional careers to lower-extremity preservation and unnecessary amputation prevention comprehend all that PAD and CLI entails. The 5-year mortality rates when compared to various cancers,¹ the odds of amputation of the contralateral limb,² the bleak likelihood of ever ambulating with a prosthesis,³ not to mention the undignified downward spiral this group of patients experiences before departing this life. We know what these patients face and it motivates us to prevent such tragedy on a daily basis.

The emergence of technologies engineered to open occluded coronary as well as peripheral arteries has undoubtedly been responsible for extending and improving the quality of life for countless patients, many of them suffering from severe PAD and CLI. Amputation rates are apparently on the decline, which speaks to the acceptance of the team approach to limb preservation, breakthroughs in devices, and the positive impact team and technology share in this perceived improvement.

Perceived improvement is the key, because perception often intersects with reality, and no matter how much the statistics lead us to think positively, the sobering reality remains that diabetes continues to rise (and is becoming pandemic), our population is aging, and access to care is being impacted by

never-ending insurance coverage battles and a decreasing number of future providers in the proverbial pipeline.

So where does this leave our patients? How do we prepare them for what we already know? How do we convey to them the importance of what they don't know?

Certainly, if patients collectively knew what we as lower extremity preservation specialists know, there would be a public outcry and demand that we do better. Considering that we are still at a point where nearly half of all lower-extremity amputations are performed without even a simple noninvasive vascular test and where primary amputation is often the initial treatment for CLI patients,⁴ this means that lower-extremity amputations are performed often based on opinion vs fact, attitude vs objective finding.

Amputation rates are apparently on the decline, which speaks to the acceptance of the team approach to limb preservation, breakthroughs in devices, and the positive impact team and technology share in this perceived improvement.

Accompanying this outcry would be a call to action with patient education and public awareness as key components to successful intervention in preventing those unaware they have PAD from deteriorating into those with CLI.

The number of educational conferences and publications speaks to the ever-increasing awareness of CLI among specialized healthcare providers and industry. That being stated, most primary care providers “do not have the time” to look for PAD or CLI unless symptoms are conveyed by patients. Routine inspection of the feet to palpate pulses or inspect the quality of skin is just not generally performed in providers' offices.

Calling on the effectiveness of the “pink ribbon” and all it has come to symbolize, breast cancer awareness has captured the imagination of the public in countless campaigns and events that have

directly and positively impacted society. Yet PAD and CLI affect far more individuals than does breast cancer, with a 5-year mortality rate greater than breast cancer and prostate cancer combined.

CLI CASE STUDY

A 56-year-old Hispanic female presented in 2015 with a new onset of a “bruised left leg” 3 days earlier. The patient is diabetic and had an extensive tobacco history, but declared smoking cessation 5 days earlier. She had a history of type 2 diabetes, essential hypertension, hypercholesterolemia, congestive heart failure, deep venous thrombosis, and PAD.

Surgical history included coronary artery bypass graft, back and carpal tunnel, and prior amputation of her left great toe nearly 20 years prior.

The patient underwent transmetatarsal amputation by a podiatrist because digits were beyond salvage. The plantar aspect of the foot remained viable while areas of slough along the dorsum of the foot and anterior ankle progressed to eschar in subsequent weeks following procedures.

The patient was managed for wound care by podiatry as an outpatient on a weekly basis, with home nursing providing dressing changes as directed by podiatry. Regular debridement of the wound was performed, including excision of eschar upon demarcation contrasting presence of underlying viable tissue, as well as 5 applications of living skin substitute.

The patient remains on dual antiplatelet therapy and is seen for regular arterial ultrasound every 3 months. Podiatry has continued following the patient weekly to biweekly with regular handheld Doppler evaluation during wound-care visits. The patient is now weight bearing and has begun gait training with anticipation of full weight bearing in diabetic shoes and inserts in the near future.

CONCLUSION

Critical limb ischemia needs a public awareness and education campaign that will impact those afflicted with PAD in the same manner that breast cancer has been impacted by its incredibly successful public relations efforts. Early detection through screenings and education of the public can prevent countless legs from future amputation and prevent individuals and families from avoidable pain and suffering, not to mention reduce the economic impact on our healthcare system.

The Save A Leg, Save A Life Foundation is poised to begin such a campaign. An immediate goal of SALSAL is to raise awareness of the public regarding PAD and CLI through the “White Sock Campaign,” a grassroots social media effort that will occur this and every September. Anyone can participate and all it requires is a single white sock worn either outside a pants leg or solely on an exposed leg. Photos can be taken and posted on social media. White socks worn in public will certainly create stares and questions from those inquisitive enough to ask, “What's with the white sock?” This creates teaching moments and opportunities to engage the public in dialogue that can easily be converted to action in the form of an individual asking their doctor to be screened for PAD. ■

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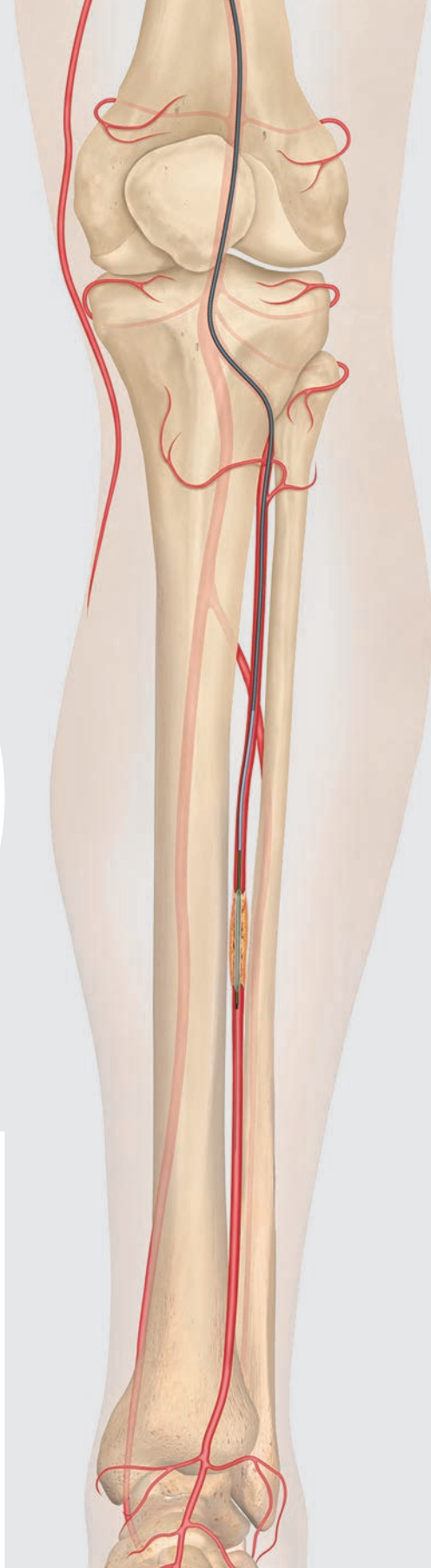
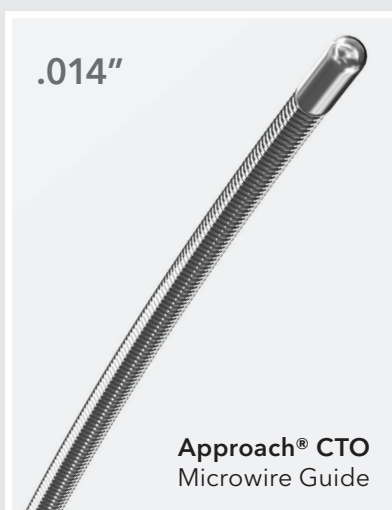
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Healing Wounds and Preventing Amputations With a Team-Based Approach

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From Metro Health Hospital, Wyoming, Michigan



A.E. Foster, FNP-BC



H.L. Volkema, FNP-BC

Communication, collaboration, and multidisciplinary approach are terms heard in healthcare on a daily basis. All are necessary to provide optimal patient care. A large number of patients requiring the use of endovascular, wound, and infectious disease (ID) specialties are treated at our institution. Due to a steady increase in patients who have peripheral vascular disease and wounds, these specialists recognized the need to enhance communication and collaboration across specialties. These efforts improved patient outcomes, including reducing amputation rates and lowering median days for wound healing. This paper describes components of a highly effective multidisciplinary approach that matured over time at a single institution.

other. These relationships were then deeply rooted in mutual respect, with a greater comprehensive understanding of how each individual service uniquely contributes to the healing process. This, in turn, led to more efficient working relationships.

Frequent face-to-face interaction evolved and is now a routine aspect of the multidisciplinary team approach. All disciplines practice on the same hospital campus, and cell phone numbers, pager numbers, and inbox messaging systems are shared amongst the team members. It is expected that the lines of communication are always open when needed. Despite different call and clinic schedules, providers save the more personal methods of communication for emergent situations.

“It takes a wise man to learn from his mistakes, but an even wiser man to learn from others.”
— Zen Proverb

DEVELOPING A TEAM APPROACH

The development of a cohesive team approach begins at the provider level (including physicians, nurse practitioners, and physician assistants). Endovascular, wound, and ID specialties had long excelled in each of their respective areas. Over time at our institution, the development of professional relationships brought about awareness of the differences and respect for the strengths within each specialty. Through genuine concern for achieving the absolute best patient outcomes, the focus shifted to learning from each

The providers quickly recognized that ancillary staff members are also important components of the multidisciplinary team. Nursing staff members who worked on endovascular cases were trained in wound care and spent time shadowing the wound staff, observing clinic flow, patient care, and different approaches to established goals. Nursing staff from wound care also had the opportunity to shadow endovascular staff to meet the same objectives. Nurse practitioners and physician assistants in both specialties also participated in this shadowing experience, gaining a greater understanding of

each discipline's preferred diagnostic testing and treatment modalities.

Leadership worked to develop changes in the scheduling process and assigned a liaison from each specialty as an initial point of contact for any urgent referrals, testing, or communication. This allows patients to be seen by wound and endovascular providers in a more timely manner, often being seen by each specialist within the same day. Infectious disease became part of this standard too, allowing for closer outpatient follow-up with the already meticulously managed inpatient cases.

To continue development of this interdisciplinary team, quarterly meetings were instituted that are open to all who work in the specialties of wound, endovascular, and ID. Leadership, quality, and research also have representation. The meetings serve as a forum for open communication in a positive setting. The face-to-face interaction allows time for stimulating discussion regarding what is working well and where the challenges exist. Time is provided to brainstorm and share ideas for improvement, and workgroups are assigned for those tasks that cannot be accomplished during the scheduled meeting time. Also, time in the meeting is reserved for a provider from one of the specialties to educate the group on a topic particularly useful or pertinent in their respective area of expertise. Recent presentation topics include education on endovascular procedures, hyperbaric oxygen therapy guidelines, and new updates on the treatment

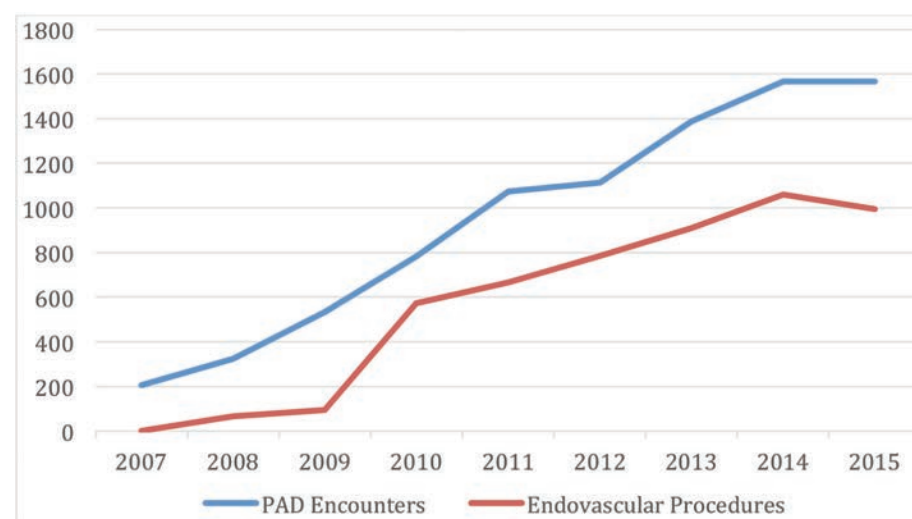


Figure 1. As the institution's multidisciplinary limb salvage program has grown, so have the number of endovascular procedures performed annually at the institution.

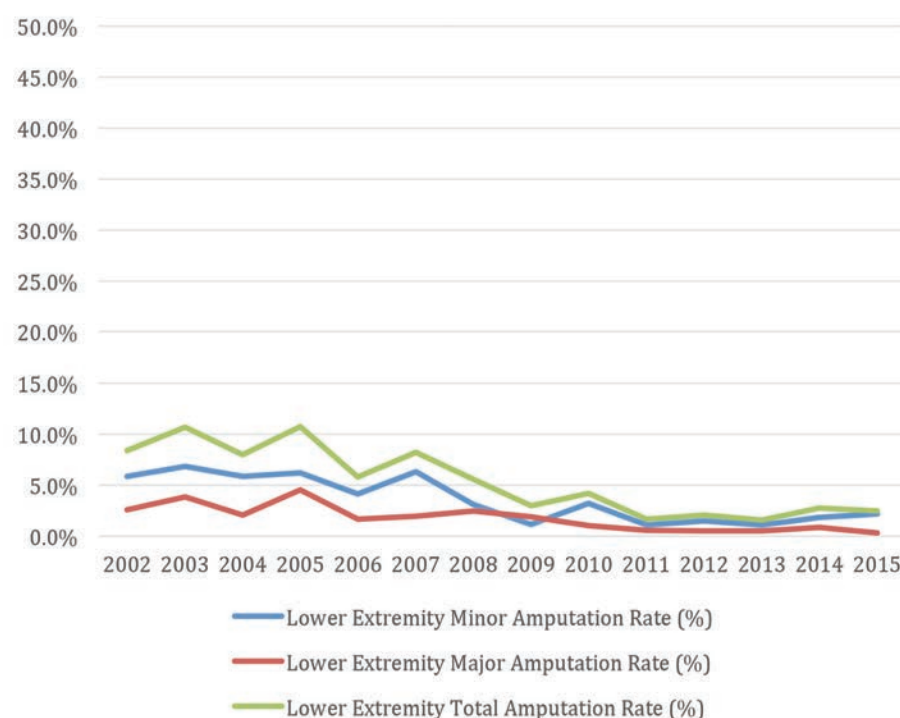


Figure 2. Institutional decline in amputation rate, despite a significant increase in number of patients seen annually with peripheral artery disease (see Figure 1).

of osteomyelitis in patients with wounds and peripheral artery disease (PAD).

With these teamwork modalities in place, our institution is much better positioned to provide the best patient outcomes, patient experiences, and staff experiences. Figure 1 highlights the institution's rapid growth in referrals of patients with PAD along with significant increase in annual endovascular revascularization procedures. Figure 2 demonstrates that with a significant influx of patients with PAD undergoing endovascular revascularization, the rate of amputation has dropped significantly.

The following 2 examples show how incorporating a multidisciplinary approach results in the positive outcomes.

CASE STUDY 1

A 70-year-old male with uncontrolled type 1 diabetes mellitus (hemoglobin A1c 7.2) first presented to the endovascular practice 4 years ago. A diagnostic angiogram at that time showed mild disease with 10% to 30% stenosis of the posterior tibial (PT) artery bilaterally. This patient did not return for scheduled follow-up visits. One year ago his primary care physician (PCP) referred him to the wound clinic for a Grade 2 diabetic foot ulcer of the right plantar aspect (Figure 3), complicated by Charcot joint and prior fractures with hardware previously treated for infection. Initial x-ray and laboratory assessments were negative for osteomyelitis. He was examined by a wound podiatrist within a week and an endovascular specialist within 5 weeks. Diagnostic angiogram at this time showed 90% occlusion of the PT, much more severe than a repeat duplex ultrasound 2 weeks prior had indicated. An endovascular peripheral vascular intervention (PVI) was performed five weeks later for Rutherford grade V, after which he also started dual antiplatelet therapy. Two weeks post revascularization he began 49 treatments of hyperbaric oxygen therapy (HBO). Three weeks after starting HBO, he was evaluated by an ID specialist who ordered 6 weeks of intravenous (IV) antibiotic therapy for possible infection at the location of his hardware. The following month, he underwent exostectomy of the fifth metatarsal base with the wound podiatrist to correct the structural pressure on the wound bed. After continued

offloading, regular follow-up with the endovascular clinic, and biweekly wound visits, his ulcer healed within 12 weeks of his exostectomy. His original ulcer reopened the following month as result of wearing his old diabetic shoes and inserts but healed within 5 weeks, again with heavy offloading. He continues with monthly podiatry follow-ups and graduated to routine surveillance with the endovascular specialist. He remains healed 4 months later (Figure 4).

This case exemplifies the multifaceted approach necessary to heal a wound and preserve a limb in a patient at high risk for amputation. The patient saw many providers in four specialties (endovascular, wound, ID and endocrine). His treatment plan was aggressive and comprehensive, including PVI, HBO, exostectomy, IV antibiotics, and strict offloading by a knee walker.

CASE STUDY 2

This second case study involves a 71-year-old female with history of uncontrolled type 2 diabetes mellitus (hemoglobin A1c of 8.6) with severe PAD and several prior PVIs in years past. She was referred to wound care by her PCP with a pulseless right foot, which included dry gangrene of the lateral foot and heel. During the wound visit, a nurse practitioner from endovascular came to the wound office to assess the patient, then worked with her collaborating physician to have the patient directly admitted. The next day the patient underwent PVI for a 100% occluded in-stent restenosis of the right mid superficial femoral artery (SFA) extending through the P3 segment of the popliteal artery. The proximal anterior tibial (AT) artery also presented with 100% occlusion in an underexpanded, previously placed stent. Treatment included an unsuccessful attempt at laser atherectomy followed by pretreatment with balloon angioplasty and final treatment with drug-coated balloons. The SFA chronic total occlusion went from 100% stenosis to <10% and AT revascularization resulted in 0% stenosis. Three weeks later, she received bilateral iliac stents and began collagenase ointment instead of betadine to the wounds. Despite refusing HBO therapy secondary to claustrophobia, this patient demonstrated complete healing within 2 months of presentation and 14 months

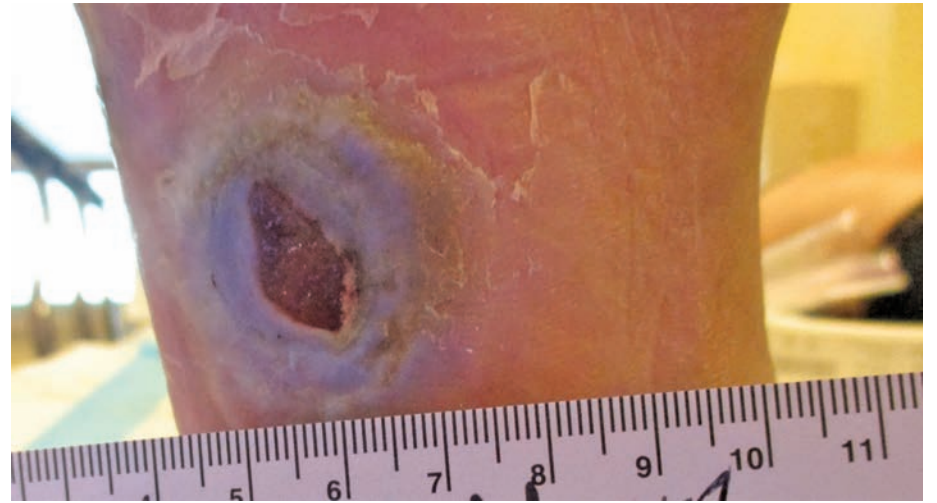


Figure 3. Patient presented with right lateral plantar foot ulcer.



Figure 4. Complete healing of right lateral plantar foot ulcer post revascularization and advanced wound care.

later remains healed. She continues follow-up visits every 1 month to 3 months with the endovascular clinic and her PCP.

This case underlines the importance of interdisciplinary communication and teamwork. A simple call from a wound nurse practitioner to an endovascular nurse practitioner resulted in the patient being admitted and revascularized within 24 hours, without involving the emergency department. Following revascularization, wound care staff provided debridement and advanced dressings, in addition to offloading and diet and diabetes recommendations. Again, the continuation of her excellent outcome was upheld through close follow-up.

CONCLUSION

These case studies highlight 2 successes of multidisciplinary collaboration. They demonstrate that providing timely, evidence-based, cooperative care gives the patient the best outcome. Many developments are in place to continue improving upon this collaborative relationship, including ongoing shadow experiences between the specialty groups, quarterly forums for discussion, and research collaboration. While this multidisciplinary relationship is relatively new and constantly evolving, a strong foundation is established. This foundation paves the way for further improvements, which will result in even better patient outcomes. ■

With these teamwork modalities in place, our institution is much better positioned to provide the best patient outcomes, patient experiences, and staff experiences.

LIBERTY 360 Study of Peripheral Endovascular Device Interventions in 1,200 Patients With Symptomatic Lower Extremity Peripheral Artery Disease: Late-Breaking Results Presented at AMP 2016

George L. Adams, MHS, MD
From Rex Healthcare, Raleigh, North Carolina.

Many peripheral artery disease (PAD) clinical device trials are supported by commercial manufacturers and designed for regulatory device approval, with extensive inclusion/exclusion criteria to support homogeneous, nonconfounded patient populations. High-risk patients with advanced PAD, including critical limb ischemia (CLI), are often excluded to reduce the risk of adverse outcomes, leading to difficulty in translating trial results into real-world clinical practice. As a result, physicians have no direct guidance regarding the use of endovascular devices in these difficult but common scenarios. There is a need for objectively

assessed studies to evaluate clinical, functional, and economic outcomes in a broader PAD patient population.

The LIBERTY 360 study aim is to fill that void. This study is a prospective, observational, multicenter clinical study to evaluate acute and long-term clinical and economic outcomes of peripheral endovascular device intervention (PVI) in patients with distal outflow peripheral artery disease (PAD) [ClinicalTrials.gov NCT01855412]. This all-comers device study has liberal inclusion criteria and few exclusions. The LIBERTY 360 study enrolled 1,204 subjects in the following classifications: 502 patients in the “Claudicant Rutherford 2-3” arm; 602 in the “CLI Rutherford 4-5” arm;

and 100 in the “CLI Rutherford 6” arm. The study will follow the subjects up to 5 years. In addition, the study utilizes 4 core laboratories for independent analysis. The LIBERTY 360 study will evaluate the following: procedural and lesion success, rates of major adverse events, duplex ultrasound interpretation of patency, wound status, quality of life, 6-minute walk test, and economic analysis. The LIBERTY patient risk score(s) will also be developed as a clinical predictor of outcomes to provide guidance for interventions in this patient population.

Procedural and 30-day results for all LIBERTY subjects were presented for the first time at the 2016 Amputation

Prevention Symposium in Chicago. LIBERTY 360 investigated real-world PAD patients with rigorous study guidelines and independent oversight of outcomes. This study provides clinically relevant data to guide future PVI. ■



First Randomized Trial of the Stellarex Drug-Coated Balloon Demonstrates Superior Patency Rate and a Significantly Lower Rate of Reinterventions Over PTA

Henrik Schröder, MD
From the Center for Diagnostic Radiology and Minimally Invasive Therapy, Jewish Hospital, Berlin, Germany.

Twelve-month results from the ILLUMENATE European Randomized Clinical Trial (EU RCT) were recently presented for the first time at the Amputation Prevention Symposium in Chicago by Prof. Dr. Marianne Brodmann of Medical University in Graz, Austria.

ILLUMENATE EU RCT was a prospective, randomized, multicenter, single-blinded trial. Patients were randomized (3:1 ratio) to treatment with the Stellarex Drug-coated Angioplasty Balloon or an uncoated angioplasty balloon. The Stellarex DCB is a low-dose (2 µg/mm² surface concentration of paclitaxel) next-generation DCB. The 12-month data showed a significantly higher primary patency rate of 89.0% in the cohort treated with Stellarex compared to 65.0% in the cohort treated with an uncoated angioplasty balloon (per Kaplan Meier estimates, $P < .001$ by log-rank test). Importantly, the higher patency rate led to a significantly lower rate of clinically driven target lesion revascularization

in the Stellarex group (5.9% vs 16.7%, $P = .014$).

The enrolled population consists of patients with symptomatic occlusion and/or >70% stenosis in the superficial femoral and/or popliteal arteries. The trial design included rigorous controls to ensure data were unbiased and accurate. Oversight included an independent Clinical Events Committee and a data safety monitoring board; additionally, blinded angiographic and duplex ultrasound core laboratories (SynvaCore and VasCore, respectively) analyzed procedural and diagnostic images. Hemodynamic, clinical, and functional outcomes will be evaluated annually for 3 years. Adverse events will be assessed through 5 years.

In total, 328 patients were enrolled at 18 centers in Austria and Germany; 294 patients were randomized to treatment with the Stellarex DCB (N=222) or an uncoated PTA balloon (N=72) following successful predilatation. The majority of patients suffered from severe claudication (82.8% in the Stellarex arm and 77.5% in

the PTA arm). Risk factors were similar between the Stellarex and PTA groups including: hypertension (77.9% and 83.3%), hyperlipidemia (61.7% and 68.1%) and diabetes (37.4% and 36.1%). Baseline angiographic data per core lab assessment were also similar between groups. The mean lesion length was 7.2 cm and 7.1 cm and 19.2% and 19.0% of lesions were total occlusions in the Stellarex group and PTA group, respectively.

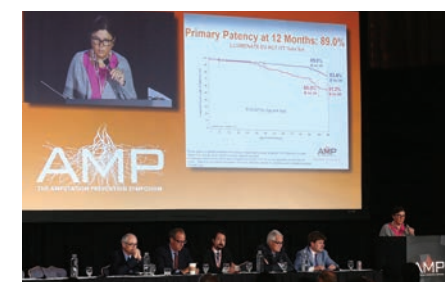
The 12-month primary patency rate observed in the Stellarex arm of this trial (89.0%) validates the early and promising patency rate demonstrated in the ILLUMENATE first-in-human study (89.5%)¹ and is comparable with the highest published 12-month DCB patency rate (89.8%).² The unique attribute of Stellarex is the ability to obtain these results with a low-dose drug coating. As a reference point, the comparable low-dose DCB has a reported 12-month patency rate of 73.5%.³

Final 12-month data from two additional trials, ILLUMENATE Global and

ILLUMENATE Pivotal, the US IDE randomized trial, are expected to be released within the next 6 months. ■

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Jihad A. Mustapha, MD, FACC, FSCAI, is an internationally acclaimed interventional cardiologist who is well known for his groundbreaking work in critical limb ischemia (CLI). As a passionate advocate for CLI education, therapy and amputation prevention, he has been instrumental in advancing CLI therapy on a global level. In this book, he has successfully assembled an expert team of authors from the world's leading centers to summarize the current best practices for the diagnosis and treatment of CLI.

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Selected Abstracts From the 6th Annual Amputation Prevention Symposium

The PRIME Registry: Interim Analysis of the First 506 Subjects

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Introduction: Subjects with advanced peripheral arterial disease (PAD) and critical limb ischemia (CLI) have high 1-year amputation and mortality rates. PRIME is an ongoing prospective clinical registry that intends to document the clinical presentation, diagnostic evaluation, endovascular treatment modalities, invasive and noninvasive follow-up, and long-term outcomes of these subjects. **Objectives:** This study aims to characterize the clinical profile and 30-day and 12-month outcomes of the first 506 PRIME subjects. **Methods:** From January 2013 to November 2015, 506 subjects with advanced PAD (Rutherford 3) and CLI (Rutherford 4-6) were enrolled. Eligible patients were over the age of 18, receiving a lower-extremity endovascular intervention, Rutherford Classification 3-6, willing and able to provide consent, and able to follow up at the enrolling site. **Results:** Most subjects were white (91.5%) males (64%) with a mean age of 69.2 years, covered by Medicare (73.5%). The most common symptoms were claudication and rest pain. Most subjects had dyslipidemia (92.1%), hypertension (89.1%), a smoking history (78.4%), and diabetes (55.8%). The number of target lesions treated was 1,182 (average 1.5 per procedure). Most lesions were severely stenosed (>90%) and 43.5% were chronic total occlusions. Balloon angioplasty (91.7%), atherectomy (47.6%), and stenting (37.5%) were the most commonly used treatments. Major amputation rates at 30 days and 12 months were 0.5% and 1.2% respectively, and mortality rates at 30 days and 12 months were 4.2% and 14.2% respectively. **Conclusions:** Observations from PRIME showed that advanced PAD and CLI most frequently affect white males who are Medicare beneficiaries. Most patients have multiple lesions involving multiple anatomic levels. Angioplasty, atherectomy, and stenting are the most commonly used endovascular therapeutic modalities.

Clinical Topography Correlates With Angiographic Severity Grade in Diabetic Wagner 2-4 Neuroischemic Foot Ulcers

François Triffaux, MD; Romain Lacrosse, LPN; Vlad A. Alexandrescu, MD
From Princess Paola Hospital, Luxembourg, Belgium.

Introduction: Wound-targeted revascularization following the foot angiosomes was evoked to provide encouraging clinical results, particularly in diabetic, collateral depleted, neuroischemic foot ulcers. **Objectives:** The present study was conceived to assess eventual angiosome-related significance between clinical features and individual angiographic findings in diabetic patients with critical limb ischemia (CLI) foot ulcers. **Methods:** A homogeneous series of 133 Rutherford category 5 ischemic limbs having Wagner grade 2-4 diabetic neuroischemic wounds were analyzed in a prospective institutional database. Limbs with 3 or more ulcers, or showing Rutherford 6, and/or Wagner 5 ischemic irrecoverable wounds were excluded from analysis. Angiographic atherosclerotic characteristics were stratified upon specific tibial and foot arteries severity score (n=0-16). The extent of severe stenosis (>70%), the presence of chronic total occlusions, arterial calcifications, and the integrity of foot arches were detailed in specific tibial (n=0-6) and foot arteries (n=0-10) grading scales. The topography of foot ischemic ulcers was compared before and after debridement to the severity and location of related below-the-knee atherosclerotic disease. **Results:** Among all presentations, 90 cases (68%) presented 2, and 43 limbs (32%) 2 concomitant wounds, which were further studied in 2 parallel groups. In 105 cases (79%) de novo ulcers were noted, and in 28 limbs (21%) relapsing ulcers were noted. After cumulative angiographic score analysis, in the "single wound" group 61/90 wounds (68%) accurately associated specific foot angiosome to corresponding tibial and/or foot nourishing arteries at highest atherosclerotic severity scores (12/16-16/16). In the same group, 23/90 limbs (25%), including most of the forefoot lesions, fitted clinical with angiographic findings concerning two angiosomes affectation, while in 6 cases (7%) no relation was found between the severity of arterial disease and the foot ulcer's location. Among the "two wounds" group, matched clinical and angiographic correlation for one angiosome was found in 10 (23%) cases, for 2 or 3 angiosomes in 27 (63%) presentations, while in 6 cases (14%) no correspondence was noted. Global analysis showed significant clinical and angiographic angiosomal matching for the "Single wound" ($P<.0001$, $RR=7.724$, $CI=3.505-17.02$), also for the "two wounds" groups ($P<0.0001$, $RR=3.777$, $CI=1.721-8.290$), before and/or after debridement. **Conclusions:** Our registry data suggest acceptable clinical and angiographic correlation concerning foot angiosomes affectation in early CLI stages. It appears that the lesser the extent of inflammation and necrosis (duration of ischemia and concurrent factors), the clearer the clinical and iconographical angiosome orientation in diagnostic.

Endovascular Therapy of TASC-D Lesion in Critical Limb Ischemia

Ahmed Amro, MD; Alaa Gabi, MD; Mehdi Elhamdani, MD
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Introduction: CLI (Rutherford class 4-6) is a terminal stage of peripheral artery disease (PAD) and is defined by the presence of resting pain and/or tissue loss for at least 2 to 4 weeks that may require urgent revascularization to promote healing and prevent limb loss. For patients with infrarenal aortic and iliac obstructive atherosclerotic disease, the revascularization options are open surgery such as aortofemoral bypass and axillofemoral bypass or percutaneous intervention. Aortoiliac and aortofemoral bypass procedures are associated with 74% to 95% 5-year patency rates, respectively, which are comparable but not superior to percutaneous therapies. These operations may imply a significant morbidity and mortality on patients who are already at risk. **Objectives:** A 52-year-old smoker female patient presented with past medical history of hypertension, hyperlipidemia, and severe PAD with totally occluded infrarenal abdominal aorta just distal to the renal arteries and known right axillary femoral bypass with femorofemoral bypass. The patient had bilateral leg and foot pain at rest, diminished pulses, and ulceration of the legs. Ankle and toe brachial index (ABI and TBI) measurements were obtained and were abnormal (right leg ABI: 0.27; TBI: 0.12. Left leg ABI: 0.3; TBI: 0.12). Computed tomography angiography showed total occlusion of the axillo-femorofemoral bypass, totaled infrarenal aorta with reconstitution of peripheral circulation at the level of external iliac arteries bilaterally. These findings conformed 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, percutaneous transluminal angioplasty and stents to the abdominal aorta using self-expandable stent, covered stents in the right and left common iliac arteries in a kissing fashion, as well as treatment of the right and left external iliac arteries was successfully achieved. **Results:** On 3-week follow-up, the patient's symptoms of claudication resolved, and there were good pulses bilaterally, healing ulcers, and favorable ABIs (Right leg ABI: 0.84; TBI: 0.68. Left leg ABI: 0.82; TBI: 0.65). **Conclusions:** Endovascular treatment for infrarenal aortoiliac disease can be performed with lower morbidity than aortofemoral bypass and with better durability than axillofemoral bypass. Patients with TASC D lesions generally will be considered surgical candidates, but with advancement of technologies like drug-eluting balloons, drug-eluting stents, and others, endovascular therapy might be an option on a case-by-case basis.

An Impossible Meeting: Combined Radio-Pedal Access for Peripheral Intervention

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Introduction: Antegrade radial and retrograde transpedal endovascular intervention is being used as an alternative approach for peripheral angioplasty. We present a case using combined radial and pedal access for angioplasty in a patient with severe bilateral peripheral vascular disease and occluded peripheral bypass graft. **Objectives:** A 55-year-old female with history of extensive peripheral vascular disease status post right femorofemoral and left femoropopliteal bypass surgery, presented with claudication. Functional study showed evidence of multilevel severe arterial disease. Aortogram and bilateral lower extremity peripheral angiograms were performed via radial access. The right common iliac artery was patent, there was a stent across the right external iliac with total occlusion in the distal segment, and the femoral artery was occluded as well as the proximal portion of the SFA with reconstitution at the level of the mid superficial femoral artery (SFA). The popliteal artery was patent with good distal run-off. The left common, external, and internal iliac arteries were patent. The left common femoral artery had high-grade stenosis in its proximal segment, the profunda femoris was patent, and the SFA was totally occluded proximally with reconstitution distally at the proximal popliteal artery with good distal 3-vessel run-off. Femorofemoral and femoropopliteal grafts were occluded. Right-side angioplasty was planned as well as a staged angioplasty on the left side in a separate procedure. **Methods:** Right pedal access was obtained with ultrasound guidance. A balloon was inserted and inflated in the common femoral and proximal SFA at different levels. Angiography showed high-grade ostial disease in the profunda femoris. A wire was advanced through the left radial access into the profunda. A balloon was inserted to the proximal profunda and another balloon was inserted through the pedal access to the common femoral. Both balloons were inflated at the same time in the same fashion. Then, through the radial access another balloon was inserted and inflated in the right external iliac artery. Angiograms obtained afterward showed dissection in the proximal edge of the external iliac artery stent that was placed previously. A stent was then inserted and deployed in the right external iliac artery overlapping the previous stent. Angiogram imaging then showed a good outcome. **Results:** Angiograms obtained postprocedure showed a good outcome. Using

pedal and radial access in peripheral angioplasty could represent a good alternative to traditional femoral access. On the one hand, it is associated with a quicker recovery and avoidance of transfemoral access complications such as femoral pseudoaneurysm and retroperitoneal bleeding. On the other hand, the small diameter of the dorsalis pedis and radial artery enhances the control and pushability of devices during angioplasty. Studies have shown that crossing totally occluded peripheral vessels from the lower cap is usually more successful. Of importance also is that through retrograde approach there is less chance of entering unwanted branches given the caudal fashion of collateral branching in peripheral vessels. **Conclusions:** Radial and pedal access could represent a good alternative approach to the traditional femoral approach.

Long-Term Outcomes of Endovascular Treatment of Critical Limb Ischemia in Very Elderly Chinese Patients: A Single Hong Kong Center Experience

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Introduction: Primary amputation had been the predominant treatment for critical limb ischemia (CLI) in Hong Kong until the recent introduction of endovascular therapy (EVT). There is a paucity of data involving Chinese elderly patients with CLI. **Objectives:** We aim to determine long-term outcomes of EVT for CLI in elderly patients aged 75 years and older. **Methods:** Retrospective analysis of consecutive patients >75 years who underwent attempted EVT for CLI between January 2009 and December 2015 at a single tertiary referral hospital in Hong Kong. Minimum follow-up was 6 months with a maximum of 109 months. Primary endpoint was amputation-free survival (AFS) at 12 months. Secondary endpoints included 12-month freedom from major adverse limb events (MALE, consisting of major amputation and major vascular reintervention) in the index limb. **Results:** Endovascular therapy was attempted in 151 critically ischemic limbs of 128 patients (35.9% men, mean age 82.8 ± 4.8 years). Of these, 122 patients (95.3%) had significant comorbidities such as coronary artery disease (24.2%), stroke (23.4%), chronic renal failure/dialysis (10.2%), diabetes (57.0%) and hypertension (91.4%). Indication for revascularization was Rutherford class 4 (n=31, 20.5%), 5 (n=106, 70.2%) and 6 (n=14, 9.3%). The anatomical segments involved were iliac (16.2%), superficial femoral (68.9%), popliteal (27.0%) and infrapopliteal (57.4%). Technical success rate was 93.2%. Early complications occurred in 12.6% of procedures. The 30-day mortality rate was 7.8% (n=10). Median (range) in-hospital stay was 7 (1 to 84) days. There were 20 major limb amputations (13.2%) during the study period. Six-, 12-, 24-, and 36-month AFS rates were 78.9%, 73.4%, 61.7%, and 56.3% and MALE-free survival rates were 86.1%, 83.4%, 80.8%, and 80.8%, respectively. **Conclusions:** Endovascular therapy is safe and effective in preventing major amputations in very elderly patients with CLI. However, mortality rates remained high, which may reflect underlying comorbidities of this group of patients.

Ex-Vivo CTO Crossing With a Novel Shock Wave-Energized Guidewire

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Introduction: Shock waves, or short-duration high-amplitude pressure pulses, have successfully been used in various medical therapies. We use a novel generator to generate shock waves that are focused into the proximal end of a guidewire, referred to as the ShockWire. The shock waves then propagate to the distal tip of the ShockWire, which facilitate device placement into calcified and/or fibrotic chronic total occlusions (CTO). **Objectives:** In the present study, we examine the capability of this system to cross ex-vivo CTO artery segments obtained from leg amputation in a clinically representative setting. **Methods:** Below-the-knee artery trees containing CTOs are dissected from leg amputations and are incorporated into a full vascular model. CTO crossings are performed with the ShockWire device under fluoroscopy in an angiography laboratory. In particular, the procedure used a 0.018" guidewire platform along with a Rubicon 18 support catheter. CTO crossing is first attempted with a commercially available guidewire, then with the unpowered ShockWire and finally with the powered ShockWire. **Results:** The powered device was found to be able to cross stenoses and CTOs located in the popliteal, anterior tibial, and posterior tibial arteries that could not be crossed with conventional guidewires or the unpowered device. The powered device was found to be steerable by applying a slight bend near the distal tip region which allowed the device to remain intraluminal during and after crossing and also minimized risks of perforation. In some cases, it was possible to advance the support catheter over the device after a successful crossing. **Conclusions:** This novel device was found to be compatible with current guidewire-based workflow and demonstrated the ability to cross peripheral CTOs on the bench in a clinically representative setting.

Rhabdomyolysis Complicating Carbon Dioxide Angiography: A Case Report

Sinan Sarsam, MD; Patrick Alexander, MD

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Introduction: Carbon dioxide digital subtraction angiography (DSA) has been used as an alternative to iodinated contrast, both for diagnostic and therapeutic purposes in patients with advanced kidney disease and serious allergic reactions. Its safety was established in prior studies for use in the peripheral arterial system. **Methods:** A 67-year-old male with hypertension, diabetes, stage IV chronic kidney disease, coronary and peripheral vascular disease with bilateral lower extremity ulcerations (Rutherford 5), underwent a CO₂-guided DSA of the lower extremities showing severe bilateral posterior tibial artery disease. He gradually developed significant weakness with inability to stand on his legs, and presented to the emergency department 2 days after the procedure. On examination, vital signs were stable, and he was able to lift his legs while in bed. There were chronic skin changes, with evidence of diabetic neuropathy. Laboratory workup showed elevation of blood urea nitrogen and creatinine to 79 mg/dL and 5.1 mg/dL, respectively (baseline creatinine 2.8 mg/dL). Total creatine phosphokinase was 4,839 u/L. Magnetic resonance imaging of the spine ruled out spinal artery embolism. He was treated with IV fluids and his condition gradually improved. His creatinine was 2.5 mg/dL on discharge. He was seen 7 weeks later and was doing well with stable kidney function. **Results:** Carbon dioxide angiography is useful in patients with advanced kidney disease to decrease the risk of contrast-induced nephropathy. However, it is not without its own risks. Carbon dioxide should not be injected in the thoracic aorta because of risks of neurotoxicity and cardiac arrhythmias. Carbon dioxide can get trapped within the vascular space, the so-called "vapor lock," especially in patients with poor cardiac output (this patient had normal EF). Delayed clearing of CO₂ can exhibit the vasoconstrictor effect of CO₂ and cause tissue ischemia, livedo reticularis, and rhabdomyolysis. Possible air contamination may also play a role. These complications may be reduced with use of a small volume of CO₂ per imaging run (<50 cc) and allowing adequate timing between injections to help clear the CO₂ (both were followed in this case). Changing the patient's position may also help to clear CO₂. **Conclusions:** Carbon dioxide digital subtraction angiography is a good alternative to iodinated contrast in patients with renal failure. Given the increasing use of this technique in patients with advanced peripheral vascular disease, awareness of potential adverse events is crucial. This case illustrates a serious complication, rhabdomyolysis, which was likely secondary to vapor lock, which maybe decreased by using small-volume injections with adequate timing between injections.

The Maine Amputation Prevention Initiative

Gary Degen, DPM

From Eastport Healthcare, Inc., Eastport, Maine.

Introduction: Amputation is extremely prevalent in rural and poor areas in every state in the nation. Patients in Maine with peripheral arterial disease (PAD) experience high rates of lower-extremity amputation (LEA) due to complications related to access to care, lack of comprehensive wound care programs and lack of vascular surgeons capable of performing minimally invasive lower-extremity stenting in efforts to reduce LEA in Maine. We will be compiling statewide data from the Maine Health Data Organization (MHDO) in efforts to determine the number of lower-extremity amputations, level of lower-extremity amputations and pre- and postamputation treatments in this retrospective study. We will examine trends in LEAs in Maine and associate incidences with cost per amputation. **Objectives:** We will establish that the introduction of PAD studies and earlier intervention on suspected PAD patients will reduce the LEA rate substantially in Maine. We will measure LEAs in a retrospective analysis of hospital data from the MHDO from 2013 to 2015 to determine preamputation care, level of LEA amputation (digit, ray, forefoot, midfoot, rear foot, below knee, and above knee) and limiting factors related to rural or underserved communities and proximity of patient to vascular care, along with palliative podiatry care. We will use this data to prove that the incidence of LEA in Maine is increasing and there is a need to provide greater pre-LEA PAD testing, access to vascular care, and team involvement in the prevention of amputation in the PAD patient in Maine. **Methods:** Retrospective analysis of patients admitted to hospitals in Maine from 2013 to 2015 who experienced an LEA at any level. The study includes a demographic study, evaluation of preamputation care, evaluation of presence of infection or wound/ulcer, presurgical stenting incidence, open vascular bypass incidence and postsurgical complications. Data will be evaluated by a statistician and diabetes research fellow. **Results:** Our analysis will reveal that the incidence of LEA in Maine is increasing; that lack of care, lack of continuity of care, and lack of access to care is adding to the LEA problem in Maine; and that earlier PAD and vascular evaluation is needed now to stop the issue from worsening. This study will lead to modifications in lifestyle for patients, earlier PAD testing, and earlier vascular intervention in this aging and high-risk population. **Conclusions:** Maine is experiencing a crisis for patients due to geographic inability of patients to see specialists when necessary and to have those specialists identify PAD disease in earlier stages. New methods will be initiated to provide more comprehensive vascular care for all patients who experience similar lack of care in other geographically challenged states.

Lower-Extremity Amputations Within a Veteran Population

Sarah Park, DPM; Anna Tien, DPM; Jake Ruff, DPM; Patrick Sanchez, DPM; Matthew Garoufalidis, DPM

From Jesse Brown VA Medical Center, Chicago, Illinois.

Introduction: The CDC estimated that 29.1 million adults in the United States had diabetes in 2014. An estimated 5% to 7% of this population develops diabetic foot ulcerations, and up to 85% of diabetes-related lower extremity amputations are preceded by foot ulcers. Amputation is 10 times as likely in patients with diabetes. The morbidity and mortality following a lower-extremity amputation are profound. Studies have shown 5-year mortality rates ranging from 41.4% for toe amputations to 85.7% following above-knee amputations.

Objectives: The purpose of this study was to evaluate the recent trends of distal vs proximal amputations and the significance of comorbidities on the amputations. **Methods:** IRB approval was obtained from the University of Illinois at Chicago. This is a retrospective review of 67,415 patients who underwent lower-extremity amputations between fiscal years 2000 and 2015 through the Veterans Health Administration data. The population included amputation diagnoses and procedure codes recorded within the VHA data. This included distal to proximal lower-extremity amputations. The population consisted of patients with diabetes, patients without diabetes, and combat veterans. The study included a total of 67,415 patients, representing 129,482 amputations. The patients had a range of comorbidities, defined as normal risk (diabetes, smoking history), low or moderate risk (foot deformity, peripheral neuropathy, PVD), or high risk (previous amputation, Charcot, end-stage renal disease, gangrene, nonhealing ulcer, osteomyelitis, previous PVD surgery). **Results:** The results demonstrated a clear incline in the number of digital amputations over the past 15 years. On the contrary, proximal lower-extremity amputations have remained somewhat stable despite an increasing diabetic population. Partial foot amputations and ankle disarticulations remained at a stable low number throughout the study. A t test shows that there is a statistical difference between the number of digital vs proximal amputations. **Conclusions:** Trends in lower-extremity amputations must be evaluated from a limb-salvage perspective due to the high mortality. Considering the rise in distal amputations vs proximal amputations, it is important to determine whether this is a trend that benefits patients long term. There are many factors related to the level of amputation, including vascular disease and vascular intervention, infection, and biomechanical factors. These should be compared to assess the overall function and quality of life for patients undergoing lower extremity amputations.

Final Results of the PRISM Trial for Revascularization of Peripheral and Visceral Arterial Occlusions

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Introduction: The PRISM trial was a single-arm, multicenter case review trial enrolling patients with confirmed peripheral or visceral occlusions receiving thromboaspiration therapy. Patients suffering from peripheral occlusive diseases face the risk of long-term damage, amputation, and even death. With a proven track record for success in the neurovasculature, the Penumbra System was thus adapted into the Indigo System, targeting recanalization of occlusions in the periphery. **Objectives:** The PRISM study aimed to determine the safety and technical effectiveness of the Penumbra/Indigo System in treatment of peripheral and visceral arterial occlusions. **Methods:** The PRISM trial concluded with 85 enrolled patients. Patient admission required satisfying the criterion of confirmed occlusion of the periphery (TIMI 0-1); enrolled patients included those suffering from acute limb ischemia, failed thrombolysis, and embolism of preceding intervention. The primary outcome of the study assessed the rate of successful revascularization, defined as TIMI 2-3, and procedure-related serious adverse events within 24 hours of the index procedure. **Results:** Enrolled patients yielded a median age of 69 (interquartile range, 60-78) years. Occlusion sites varied; however they can be generalized to popliteal/tibial (54.1%), femoral/superficial femoral artery (34.1%), and other (11.9%). Patients in whom Penumbra/Indigo aspiration thrombectomy was attempted as frontline (50.6%, 43/85) yielded successful thrombectomy to TIMI 2-3 in 81.4% (35/43) of cases; 6 additional patients (95.3%, 41/43) achieved TIMI 2-3 revascularization following adjunctive therapies. In 14 patients (16.5%) who received lytic therapy prior to aspiration thrombectomy, 92.9% (13/14) achieved successful recanalization from Penumbra/Indigo use alone; no change was observed after adjunctive therapies. A similar rate of success (92.9%) after thromboaspiration alone was achieved in patients with prior mechanical thrombectomy (17.6%, 15/85); post all interventions, 100% within this cohort achieved TIMI 2-3. Lastly, cohorts with combined lytic and mechanical therapies prior (15.3%, 13/85) reported 100% success immediately post aspiration thrombectomy alone. Overall, aspiration thrombectomy alone was successful in restoring vessel patency to TIMI 2-3 in 88.1% (74/84) of patients at a median procedural time of 67.5 minutes (interquartile range, 50-81) from puncture; this outcome further improved to 96.5% secondary to all interventions. The safety outcome at 24 hours included 17 serious adverse events in 10 patients; none were considered device related. **Conclusions:** Final results from the PRISM trial appear promising, exhibiting high rates of revascularization and low risk. These positive results support the broad application of the Penumbra/Indigo System both as frontline and salvage therapy. Future controlled studies are encouraged to further validate the current findings.

Occlusion Perfusion Catheter (OPC) Next Generation Treatment for Restenosis

Rex Teeslink, MD

From Wound Care 360, Olathe, Kansas.

Introduction: Advanced Catheter Therapies (ACT) has designed the Occlusion Perfusion Catheter (OPC) to function as a universal agent delivery system that will accommodate any therapeutic agent, including pharmaceuticals, biologics, and live cells. The OPC is a 5-lumen catheter designed with proximal and distal occlusion balloons, a center space occupying balloon, an inflow port, an outflow port, and a guidewire lumen compatible with standard 0.014" sizes. It is a 5 Fr catheter, compatible with a 6 Fr sheath. A fiberoptic pressure sensor is incorporated into the inflow lumen to monitor treatment region pressure. Occlusion balloons define the treatment region. **Objectives:** To demonstrate the advantages of the OPC universal drug-delivery system compared to drug-coated balloons. **Methods:** The proximal and distal occlusion balloons are inflated simultaneously to control blood flow and create a treatment chamber. In addition, they serve to prevent systemic distribution of the agent. The fourth and fifth lumens are for inflow and outflow ports located within the established treatment chamber. The trapped blood is removed from the treatment chamber by flushing with saline. The space-occupying balloon can be inflated to minimize the amount of therapeutic agent required, when indicated. This balloon never touches the vessel wall. Once the blood has been evacuated, the therapeutic agent is delivered. A sensor monitors, controls, and optimizes pressure within the chamber for penetration into the media of the vessel wall, longitudinally and circumferentially. **Results:** Preclinical results showed that confocal analysis of the vessel wall demonstrated delivery of fluorescent paclitaxel within media and adventitial layer, circumferentially and longitudinally. PK analysis demonstrated a straight line of 0.1 mcg/mL for 72 hours. According to Axel et al (*Circulation* 1997;96:636-645), the effective range of paclitaxel is 0.00085-0.85 mcg/mL to affect a 90% to 99% inhibition of human arterial SMC. Seven-day scanning electron microscopy demonstrated paclitaxel delayed healing effect. Histology at 28 days demonstrated normal endothelium. Live cell testing demonstrated that the OPC can deliver live cells with minimal mechanical damage at a wide range of pressures. **Conclusions:** The OPC delivers an agent circumferentially and longitudinally into the vessel wall. It delivers the effective range of paclitaxel for 90% to 99% inhibition of human arterial smooth muscle cells, maintaining normal intimal endothelial function by non-coating. It eliminates the need for vessel/balloon sizing, delivers multiple agents, supports multiple use in the same patient, above and below the knee, delivers live cells with minimal mechanical damage to the cell membrane, negates blood/agent admixture, minimizes systemic effect via flushing, and decreases cost.

A New Closure Device: How to Close Large-Bore Sheaths With a Single Device, Leaving Nothing Behind

Rex Teeslink, MD

From Wound Care 360, Olathe, Kansas.

Introduction: Wound Care 360 has designed a closure device, SiteSeal, which simulates external compression, but removes the associated variables. It applies invariant pressure to the vessel wall access site by utilizing internal stainless steel coils, which function as shock absorbers to dampen blood vessel pressure fluctuations. **Objectives:** To demonstrate the advantages of the Site Seal Closure Device compared to other closure devices. **Methods:** SiteSeal utilizes a number 2 Vicryl suture to make a "Z" stitch, which holds the SiteSeal device in place, and closes the arteriotomy site in a linear fashion. The Z stitch is placed by entering the soft tissue at the skin insertion site of the sheath. If the clinician is right handed, the first entrance is 1 cm east of the sheath, passing under the sheath and exits 1 cm west of the sheath. The second entrance is 1 cm above the skin insertion of the sheath and 1 cm to the east. The needle then crosses up and over the sheath and back down into the soft tissue and exits 1 cm west of the sheath. The 2 ends of the Z stitch form a double half knot, which when closed, creates an "X" over the arteriotomy site. Bioseal powder is placed around the sheath and half knot. The device is cocked by turning the cross bar horizontally and applying pressure, which loads the springs. It is then centered over the sheath at the arteriotomy site with the incline plane facing north. The dilator is removed from the sheath. The two suture ends are pulled tight against the sheath as pressure is applied to the device, closing the Z stitch into an "X" over the arteriotomy site, and the sheath is removed. The suture ends are pulled up through the designed slots and tied into the notched slot of the cross bar. The loaded springs are released by turning the cross bar back to a vertical position. Once the device is activated, the pressure created by the Z stitch continues to elevate the artery and folds in the soft tissues surrounding the arteriotomy site, closing the site in a linear fashion. The roof is placed and Tegaderm is applied for stabilization. **Results:** There have been 38 EVAR and 18 Impella procedures performed using SiteSeal without any hematoma formation at discharge and at 24-hour, 7-day, and 30-day follow-up. **Conclusions:** SiteSeal does have the ability to close large bore sheaths with a single device, leaving nothing behind. Associated advantages are that there is no limitation from sheath size, including EVAR, TEVAR, TAVR. There is no patient limitation in terms of size, anticoagulation, or calcification. Deployment is simple and rapid, the device allows immediate reaccess, it minimizes patient discomfort, allowing immediate head elevation to 30° with no restriction to leg movement. The device also enables early ambulation, with nothing left behind, and the potential of minimal risk of vessel wall injury, infection, or embolization. ■

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²Calculated based on dollar sales. MRG Moving Annual Total 2016 Data published May 2016 based on hospital sample. Includes third party vendor sales for LUTONIX®. ©2016 Millennium Research Group, Inc. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission.

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