

The CLI Revolution Continues at the 8th Annual AMPutation Prevention Symposium

Chicago, August 8-11, 2018 --- The 2018 AMPutation Prevention Symposium brought together dedicated healthcare providers on a global level of all backgrounds. Over 850 attendees from 50 states and 17 countries from multiple disciplines — including vascular surgery, interventional radiology, angiology, podiatry, interventional cardiology, mid-level providers, nurses, ultrasound techs, radiology techs and other health care providers — checked their specialty at the door. This event, led by Founder and Course Director Jihad A. Mustapha, MD, demonstrated the importance of a multidisciplinary approach to limb salvage. It does not matter what your specialty is, the goal is the same: to help the patient maintain their independence and keep their limb.

The 2nd annual Alan T. Hirsch Memorial Keynote Address, “A True Multidisciplinary Approach to Limb Preservation and Why Is it Important?” was delivered by Dr. Ramon Varcoe (Figure 1). Professor Varcoe is a vascular surgeon at Sydney’s Prince of Wales and Prince of Wales Private Hospitals where he is supervisor of vascular training and director of the Vascular Institute. His busy clinical practice specializes in the minimally invasive treatment of the full gamut of occlusive arterial disease of the lower limb for which he is internationally renowned.

Dr. Mustapha and Dr. Thomas Zeller (Figure 2), Associate Professor in the Angiology Division of the Universitaets-Herzzentrum Freiburg in Bad Krozingen,

Germany, presented updates on the CLI Global Society. A recent Society publication in *JACC: Cardiovascular Interventions* titled “Disease Burden and Clinical Outcomes Following Initial Diagnosis of Critical Limb Ischemia in the Medicare Population” was highlighted. This study showed that 54% of patients diagnosed with CLI are dead within 4 years with only 42% alive and free from major amputation. The 4-year mortality rate is higher than that of most cancers.

AMP hosted more live cases this year than ever before with operators Drs. Fadi Saab, MD, from Advanced Cardiac and Vascular Amputation Prevention Centers (Figure 3); D. Chris Metzger, MD, from Wellmont CVA Heart Institute; Constantino Peña from Miami Cardiac & Vascular Institute and Lawrence Garcia from Steward St. Elizabeth’s Medical Center.

This number of fellows attending AMP this year more than tripled with a special evening program directed by Dr. Fadi Saab from Advanced Cardiac and Vascular Centers in Grand Rapids, Michigan.

The CLI Wound Summit, co-developed by The CLI Global Society and led by course directors Lee Ruotsi, MD, Vickie Driver, DPM and Dot Weir, RN, reinforced the interest and need of a multidisciplinary approach to the CLI patient, wound healing and limb salvage. Dot Weir shared “I try to make sure that attendees will have something to take home with them to use on Monday morning when they return to the clinic.

The goal is to make the information applicable to participants. Everything at AMP is about helping providers to save the limbs of their patients. As a nurse, I hope that in the future there will be more nurses coming to AMP, so they can help as part of the team, right now we are the ‘nudgers’ to remind doctors of all the real-life implications of the patient, how long a patient has been waiting, or if their pain levels are increasing.”

A valuable session on the importance of wound care post-CLI revascularization was moderated by Vickie Driver, DPM. Multiple presenters discussed the relationship between wound care and the underlying disease and how to balance these factors in approaching the treatment of the patient. Dr. Richard Neville presented on what tibiopedal level of revascularization is necessary to achieve a functional amputation. He urged, “We need better mechanisms to assess tissue perfusion. Our current methods are insufficient especially when a patient has CLI and diabetes. Desmond Bell, DPM encouraged participants “To continue to create awareness for amputation prevention and to recognize the value you bring to the team. Podiatrists and wound care specialists are the eyes and ears of the interventionist; they are the first line in recognizing ischemic changes whether pre- or post-intervention.”

The presence of CLI as a global issue was discussed in many sessions.

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Figure 1. Dr. Ramon Varcoe delivers the 2nd annual Alan T. Hirsch Memorial Keynote Address, “A True Multidisciplinary Approach to Limb Preservation and Why Is it Important?”



Figure 2. Dr. Thomas Zeller delivers an update on the CLI Global Society.



Jack Zeltzer, MD

An Interview with Dr. Jack Zeltzer from the JFK Wound Management and Limb Preservation Center

Dr. Jihad Mustapha interviews Jack Zeltzer, MD, a vascular surgeon who has more than 30 years of experience specializing exclusively in the treatment of vascular disease. Dr. Zeltzer has served as chairman of the department

of surgery at JFK Medical Center in West Palm Beach, Florida. He currently serves as president elect of the medical staff at JFK. Dr. Zeltzer treats aspects of vascular disease affecting arteries and veins, including carotid arteries in the neck,

abdominal aorta, blocked arteries in the legs, varicose veins, and ulcers.

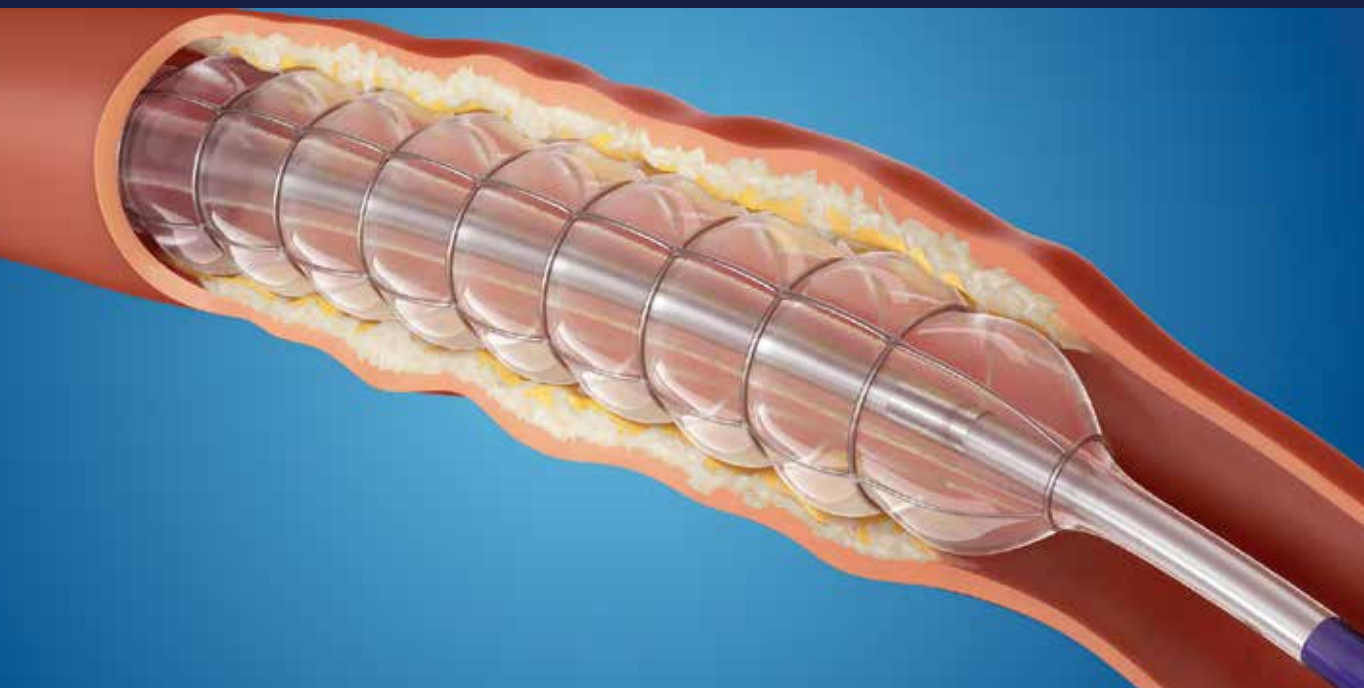
By staying abreast of the latest technology, Dr. Zeltzer has primarily replaced his classical training with less invasive surgery

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A Unique Approach to Develop a Successful Multidisciplinary Limb Salvage Program

Jihad A. Mustapha, MD, interviews Jill Sommerset, RVT, Technical Director and Registered Vascular Technologist at PeaceHealth Southwest Washington, Thoracic & Vascular Surgery, Vancouver, Washington

It is no secret that I am a supporter and believer in a multidisciplinary approach to limb salvage. I met Jill in early 2017 at a Limb Salvage Summit in Florida. She was there to learn how to create and develop a program at her own institution. Fast forward 18 months and I am thrilled to see a champion, a vascular technologist who has the drive, passion, and dedication to CLI to make a difference by developing and implementing a successful multidisciplinary limb salvage program in her own unique way.

J.A. Mustapha, MD (JM): What was your motivation to start a limb salvage program and how did you begin?

Jill Sommerset, RVT (JS): Every day working in a vascular lab I scan CLI patients, scrub in the cath lab to assist with pedal access or provide EVUS (extravascular ultrasound). I see the non-invasive and interventional process these patients go through and hear stories about providers that didn't communicate or the wound that was not addressed early on. I saw the lack of communication among specialists and wanted to do more for CLI patients. I am fortunate to work with four fantastic vascular surgeons who fully supported the idea of a limb salvage program and allowed me to be creative and collaborate on building a program.



Figure 1. A third of the team supporting the white sock campaign for the Save-a-Limb Save-a-life Foundation.

JM: Who is involved in the limb salvage team, how often do you meet, and what is the structure of your monthly meetings?

JS: Our multidisciplinary team is made up of vascular surgery, interventional specialists, wound healing, infectious disease, podiatry, orthopedics, cardiology, care management, ostomy nurses and hospitalists (Figures 1 and 2). We meet face-to-face once a month for 1-hour over lunch. The face-to-face meeting, with consistently

25-30 care providers engaged in a roundtable discussion, is what makes this program unique. A "specialty talk" takes place first where a specialist presents a 5-10 minute overview on the latest information as it relates to CLI. Next, I present a formal PowerPoint presentation reviewing 3-4 CLI patients from our registry. The presentation includes a comprehensive history, current wound care, photos, labs, surgical history, etc. Every specialist is encouraged to weigh in, provide recommendations,

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

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Figure 2. Jill Sommerset (right) scrubbed into a limb salvage case.

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and hear other specialists' perspective. A plan is created and a discussion takes place about lessons learned or where we can improve. Patient updates are also presented that were previously reviewed. We celebrate the successes and discuss the losses. Lunch is always provided, which seems to boost attendance.

JM: How do you motivate specialists to take an hour out of their day to attend?

JS: Creating buy-in, sharing excitement, and commitment to decreasing the rate of unnecessary amputation is what drives the program. Showing up face-to-face in their office, calling, and/or sending email reminders about the meeting is also helpful. Prior to the meeting a preview of the cases with

photos is provided, which helps to retain interest. Every provider involved in the case weighs in on his or her case prior to it being presented, which drives the desire for the specialist to be present at the meeting. Over the last 18 months our team started to truly look forward to these monthly meetings and each member has become invested in the limb salvage program. We have administrative support staff members who also attend the meetings. We have already seen a decrease in amputations and we are collecting data for future publication.

JM: Can you share a patient story where the limb salvage team really made a difference?

JS: There are many; however, the following story stands out. A 70-year-old male presented with a long history of uncontrolled diabetes. He had gangrene

“Direct benefit to each patient helps to drive the limb salvage program. Additional benefits ... (are) communication, collaboration, and unity across specialties to ultimately increase patient care and outcomes.”

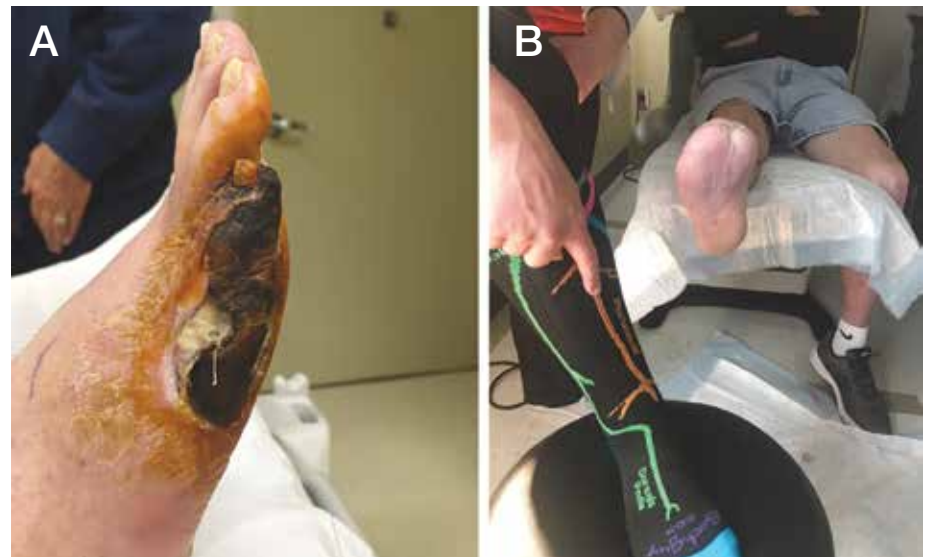


Figure 3. CLI patient pre (A – left) and post intervention, demonstrating his anatomy to him via our vascular sock (B – right).

“The face-to-face (monthly) meeting, with consistently 25-30 care providers engaged in a round table discussion, is what makes this program unique.”

on his 4th and 5th digits with osteomyelitis. He had good inflow and outflow; however, his tibio-peroneal artery had a tight lesion with single vessel runoff via the diffusely diseased peroneal artery. There was lengthy discussion among the group about options, including the option to simply resort to a BKA, or, given the extent of his situation, to take the time needed to heal a transmetatarsal amputation. The decision to revascularize and perform a minor amputation (transmetatarsal) was made by the team. The vascular surgery team performed atherectomy with balloon angioplasty of his tibio-peroneal trunk and peroneal arteries. His anterior and posterior communicating arteries were widely patent with adequate flow in the plantar arteries, documented by duplex ultrasound in real time during the case. He then underwent a transmetatarsal amputation, and the amputation site was treated with biologics and a wound VAC. His amputation site successfully healed (Figure 3A and 3B). We were so pleased to save him from experiencing a higher-level amputation because driving cars is his passion. Direct benefit to each patient helps to drive the limb salvage program. An additional benefit of the program is communication, collaboration, and unity across specialties to ultimately increase patient care and outcomes.

JM: Tell me about the socks your team is wearing (figure 1, page 3).

JS: Yes, the socks! These are so fun! Our limb salvage program (Joint Interdisciplinary Lower Limb Saving Program) had our one-year anniversary celebration last February. To show gratitude and team unity to all the care providers invested in the program, I designed an arterial limb salvage compression sock for everyone to wear. I also have non-compression socks that we give to our CLI patients. We use this sock to bring awareness to CLI as well as educate patients with arterial disease (www.flow-socks.com).

JM: Can you share any advice for other care providers who may be thinking about starting a limb salvage program?

JS: Just do it! You don't have to be a physician to lead a program. All you need is passion, dedication, and enthusiasm to get a program started. Find a physician champion to get behind you and support your endeavor. The momentum will increase and excitement will spread over time. I believe we all have a common goal to decrease the rate of unnecessary amputations and bring awareness to CLI. A limb salvage program not only shines a spotlight on that common goal but also helps facilitate better provider collaboration and communication, which ultimately increases patient care. Together we are better. ■

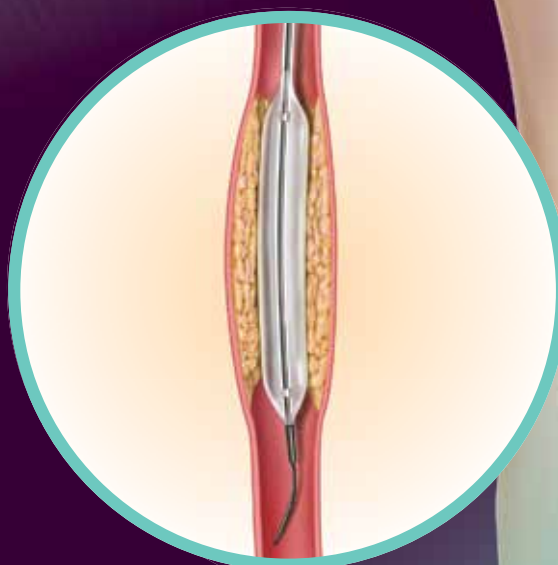
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Recanalization of Popliteal Artery CTO Using Fluoroscopic and EVUS Guidance With Successful Management of Tibial Perforation

Joseph Campbell, MD¹; Fadi Saab, MD²; Jihad A. Mustapha, MD²



Joseph Campbell, MD

An 80-year-old male patient was referred to our facility at Advanced Cardiac & Vascular Amputation Prevention Centers for further management of Rutherford class 4 critical limb ischemia (CLI) affecting his right leg. His medical history was notable for hypertension, hyperlipidemia, type 2 Diabetes Mellitus complicated by peripheral neuropathy, coronary artery disease with prior coronary artery bypass surgery, chronic venous insufficiency (CEAP class 3), infrarenal abdominal aortic aneurysm (AAA) (5.7 cm), and remote tobacco use.

The patient had a known history of peripheral arterial disease (PAD) and one month prior to the current presentation underwent revascularization of his left posterior tibial artery with resolution of his left-sided symptoms. Diagnostic right lower extremity runoff done at this time was notable for occlusion of P3 segment of popliteal artery (Figure 1). Duplex ultrasound (US) demonstrated similar findings with distal

reconstitution of the posterior tibial artery via collateral flow.

At the conclusion of the previous procedure, staged intervention to his right lower extremity was planned. As such, he presented for the current procedure with ongoing Rutherford class 4 symptoms involving his right leg.

On physical examination, he had a well-healed right groin access site with 1+ right femoral pulse and weak monophasic Doppler signal in the dorsalis pedis and posterior tibial arteries. He had trace edema with cool skin and elevation pallor/dependent rubor in his right lower extremity. There were no ulcers or gangrene present.

Pertinent medications included aspirin 325 mg daily, clopidogrel 75 mg daily, and atorvastatin 80 mg daily. He reported being compliant with this regimen. Laboratory studies including CBC, basic metabolic panel, and INR were all within normal limits.

Review of the prior diagnostic angiogram suggested a CTO type 3 CTO with a complex calcified proximal cap including several side branches emanating from this location (Figure 2). Given this, we planned on dual access from the outset of the procedure with both antegrade femoral and retrograde posterior tibial approaches.

Using extra vascular ultrasound (EVUS) guidance, antegrade saphenous femoral artery access was obtained using a 5 Fr Precision sheath (Terumo Medical). Angiography obtained at this time demonstrated stable findings compared to previous images. Systemic heparin was given. At this point, retrograde posterior tibial access was obtained using EVUS guidance, micropuncture needle, and a 0.018" Command wire,

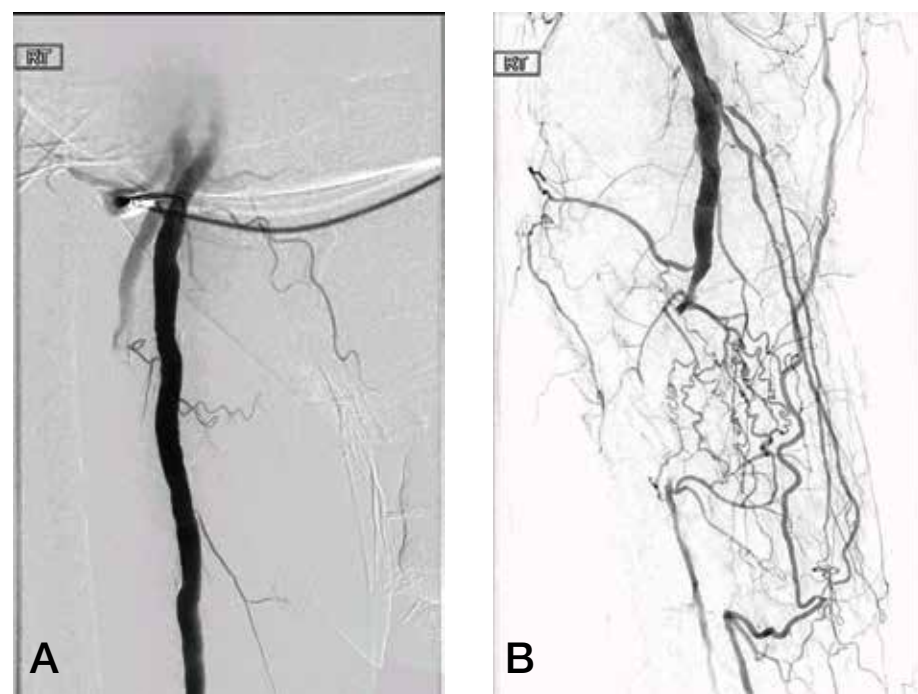


Figure 1. Diagnostic angiogram (A) SFA; and (B) Popliteal occlusion.

with subsequent insertion of a 2.9 Fr Cook pedal sheath (Cook Medical). Serial doses of 100–200 micrograms of intra-arterial nitroglycerin were administered throughout the duration of the procedure via the pedal sheath to counteract distal vessel vasospasm.

Using fluoroscopic guidance, we initially attempted to wire antegrade with a 0.018" Command wire (Abbott Vascular) over a 0.035" angled Navicross catheter (Terumo). As expected, the Command wire was unable to penetrate the proximal cap likely due to the heavy calcification and multiple side branches present. We subsequently attempted to break the proximal cap using the tip of the Navicross catheter but were unable to do



Figure 2. CTO type 3 chronic total occlusion.

¹Department of Cardiovascular Medicine, Cleveland Clinic, Cleveland, Ohio; and ²Advanced Cardiac & Vascular Amputation Prevention Centers, Grand Rapids, Michigan

Disclosures: Dr. Campbell has no disclosures. Drs. Mustapha and Saab report consulting agreements with Terumo Medical.

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“Familiarity with the CTO classification and recognition of the proximal cap hostility resulted in our selection of a dual-access strategy from the outset.”

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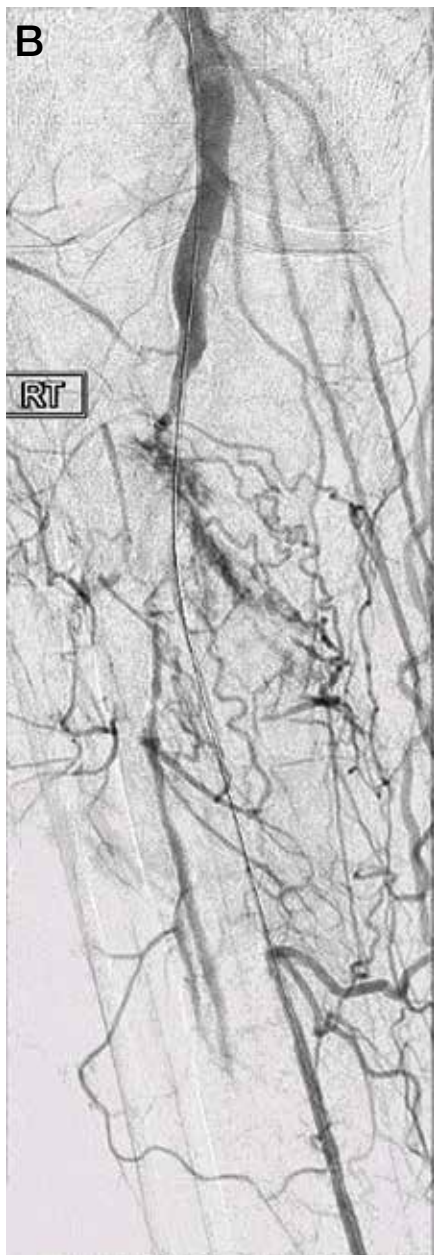


Figure 3. Serial angiography demonstrating side-branch perforation of collateral vessel at proximal cap. (A) Initial angiogram; (B) Subsequent angiogram noting stability after successful CTO crossing and before balloon inflation.



Figure 4. EVUS-guided CTO crossing. Note position of Navicross catheter within true lumen of vessel prior to proximal cap. Careful manipulation allowed for traversal of proximal cap beyond side branches into subintimal channel.

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so, instead noting that this was too direct—ed laterally toward a side branch.

Given the lateral deflection of both the wire and microcatheter, angiography was performed via contrast injection through the Navicross catheter, which had been retracted to the P2 segment of the popliteal artery. This showed contrast extravasation through a small side branch at the proximal cap of the CTO (Figures 3 A and B). Immediately we proceeded with evaluation of the calf compartments using EVUS. US is more sensitive in detecting bleeding. At this point, there was no hematoma and his compartments were

soft without any tenderness. However, as a precautionary measure, we placed an external blood pressure (BP) cuff. The BP cuff was inflated to 2/3 of the systemic BP. The BP was deflated every 5 minutes with an angiogram to evaluate any extravasation. In addition, EVUS was used to evaluate if there is a hematoma forming within the calf compartments.

We then began to work from the retrograde tibial access point while closely monitoring the popliteal fossa and posterior and leg compartments. A 0.018" Command wire was advanced via the true lumen of the PT to the distal cap, and using a 0.018" CXI microcatheter (Cook) for additional support we were

able to successfully knuckle the wire to the P3 segment of the popliteal artery adjacent to the Navicross catheter. At its distal end, the retrograde wire appeared to be in a subintimal plane adjacent to the proximal cap.

Using EVUS guidance, the Navicross catheter was re-advanced and ultimately able to penetrate the proximal cap staying within the true lumen (Figure 4). The catheter was guided using EVUS to determine the right direction into the popliteal artery. After serial manipulations of both the antegrade and retrograde systems, the subintimal planes were successfully connected. Using the tunneling technique, the retrograde wire and 0.018" CXI were advanced into the Navicross catheter and subsequently exchanged for a 0.014" Command wire which was externalized through the pedal sheath. Repeat angiography was stable and there remained no clinical concern for evolving compartment syndrome. At this point, additional heparin was administered to ensure that a therapeutic activated clotting time was maintained.

IVUS was then performed and demonstrated the wire to be in the true lumen for the length of its course aside from a very small segment in the distal portion of the CTO. Being careful to avoid the subintimal portion and area of perforation, laser atherectomy was done throughout the length of the lesion in the distal popliteal artery, TP trunk, and posterior tibial artery using the 0.9 mm device at a fluence of 45 and rate of 25.

This was followed by angioplasty of the tibioperoneal trunk and posterior tibial artery using a 3.5 mm balloon. The 0.014" Command wire was directed around the pedal loop and balloon occlusion of the posterior tibial access site was successfully employed to obtain hemostasis. We proceeded with advancing

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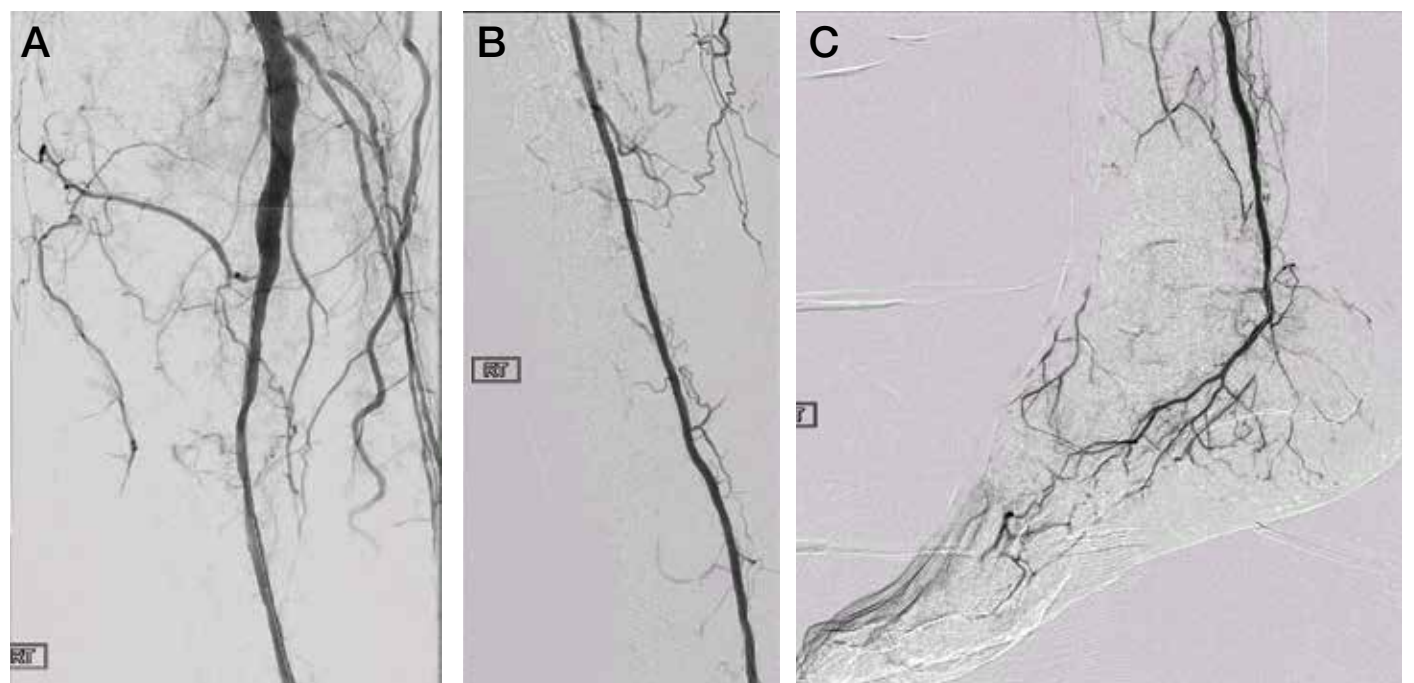


Figure 4. Final angiography (A) popliteal; (B) PT; and (C) foot.

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a 5.0 mm balloon for further treatment of the popliteal artery

Following angioplasty of the popliteal artery and proximal tibioperoneal trunk with a 5 mm balloon, repeat angiography showed no further angiographic evidence of contrast extravasation. The blood pressure cuff was deflated and after several minutes of observation, there was no change in physical examination. Final angiography demonstrated widely patent popliteal artery, TP trunk, and PT artery with in-line flow to the plantar branches (Figures 5A-C). The femoral sheath was removed with manual compression hemostasis. After an uneventful recovery, the patient was discharged home several hours following the procedure.

This case highlights several important points pertinent to physicians treating patients with CLI. Heavy calcification and CTOP type 2 or 3 lesions were shown to predict need for conversion to a dual-access strategy for successful CTO crossing.¹ Familiarity with the CTOP classification and recognition of the proximal cap hostility resulted in our selection of a dual-access strategy from the outset. This, in addition to EVUS-guided

proximal cap penetration, likely were critical aspects that resulted in successful lesion crossing and furthermore limited the length of dissection to a small portion of vessel abutting the proximal cap.

By employing adjunctive IVUS use, we were able to confirm our wire position throughout the lesion length and thereby confidently employ laser atherectomy in what was a very fibrocalcific vessel. In long-segment tibial CTOs, atherectomy devices are underutilized often owing to concern about subintimal wire position. Use of IVUS obviates this concern and allows for plaque modification and yielding of lesions at lower balloon inflation pressures, thereby further limiting the risk of further dissection or vessel recoil.

Lastly, it goes without saying that an integral aspect of a CLI operator must include strategies for dealing with a multitude of complications that might result either during or after the procedure. During this case, we noted a side branch perforation likely related to a wire perforation. In these situations, prompt attention is necessary to evaluate for expanding hematoma and early signs of compartment syndrome. If this were to occur, we were prepared for heparin reversal and coil embolization of the involved branch. In

“It goes without saying that an integral aspect of a CLI operator must include strategies for dealing with a multitude of complications that might result either during or after the procedure.”

addition to coil embolization, additional strategies that one must be familiar with in the case of a tibial vessel perforation are appropriate use of covered stents (especially in the case of severe main branch perforations) and prompt surgical consultation with any evidence of evolving compartment syndrome. Thankfully, in this case, a combination of external compression via a BP cuff and balloon tamponade allowed for successful management and completion of the procedure.

Although recent years have noted improvement in the outcomes of patients with CLI, the morbidity and mortality associated with this diagnosis remains unacceptably high. Recognition of this within the vascular community has led to a multidisciplinary movement focused on

improving lives and saving limbs through promoting clinical research, patient advocacy, innovation, and education among all who treat this complex disease process. As a group who identify as CLI fighters, we are poised to be front and center in this effort and by continued collaboration stand to make a big difference in the lives of those who live with CLI. ■

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

REFERENCE

Saab F, Jaff MR, Diaz-Sandoval LJ, Engen GD, McGoff TN, Adams G, Al-Dadah A, Goodney PP, Khawaja F, Mustapha JA. Chronic total occlusion crossing approach based on plaque cap morphology: The CTOP classification. *J Endovasc Ther*. 2018 Jun;25(3):284-291. doi: 10.1177/1526602818759333. Epub 2018 Feb 27.

AMP NEWS from cover

Dr. Miguel Montero-Baker, Director of the HENDOLAT meeting, shared the “Current State of CLI in Latin America: Available Technologies and Unmet Needs.” A CLI update in the Asia-Pacific session including Drs. Varcoe (Australia), Hiroshi Ando, Tatsuya Nakama, Makoto Utsunomiya

(Japan) and Steven Kum (Singapore), highlighted interesting cases and intervention coming from Asia-Pacific.

Course co-director, Craig Walker, MD, Clinical Professor of Medicine, Tulane Medical School, Cardiovascular Institute of the South, led a stimulating discussion on “Data Driven vs Policy Driven Decisions for DCB Therapy.” Dr. Zeller moderated a session on “Complex CLI

Revascularization: Experts Share Cases and Discuss Strategies.” Dr. Marianne Brodmann from Medical University Graz, Austria, updated the attendees on the Lutonix BTK Global Registry and Randomized Trial of DCB vs PTA: 2-Year Results of In.PACT Japan Trial.

CLI Global Society members were present in full force including a growing subset of the Society membership

“(AMP) is hands down the best meeting to learn about preventing amputation and its impact on patients.”

who identify as #CLIFighters. These are high volume CLI specialists connected over social media with a mutual passion to fight this disease. Dr. Paul Michael commented, “The CLI Fighters movement is a group of multi-specialty physicians united under the CLI Global Society to combat CLI and prevent amputation.” He continued that the beauty of the AMP Symposium is that it is “where the best of the best discuss the latest and greatest on CLI, hands down the best meeting to learn about preventing amputation and its impact on patients.”

Dr. Bret Wiechmann provided a few reasons that AMP is unique: “This meeting is focused on one aspect of PAD, specifically on CLI. This makes it different from other vascular meetings. It is very important to acknowledge the different specialties that treat CLI and PAD because we all have a common goal. The meeting reinvigorates you. It helps get the passion going as well. Learning technical tidbits helps to motivate you to get patients in the treatment pipeline sooner. The passion is contagious.” ■

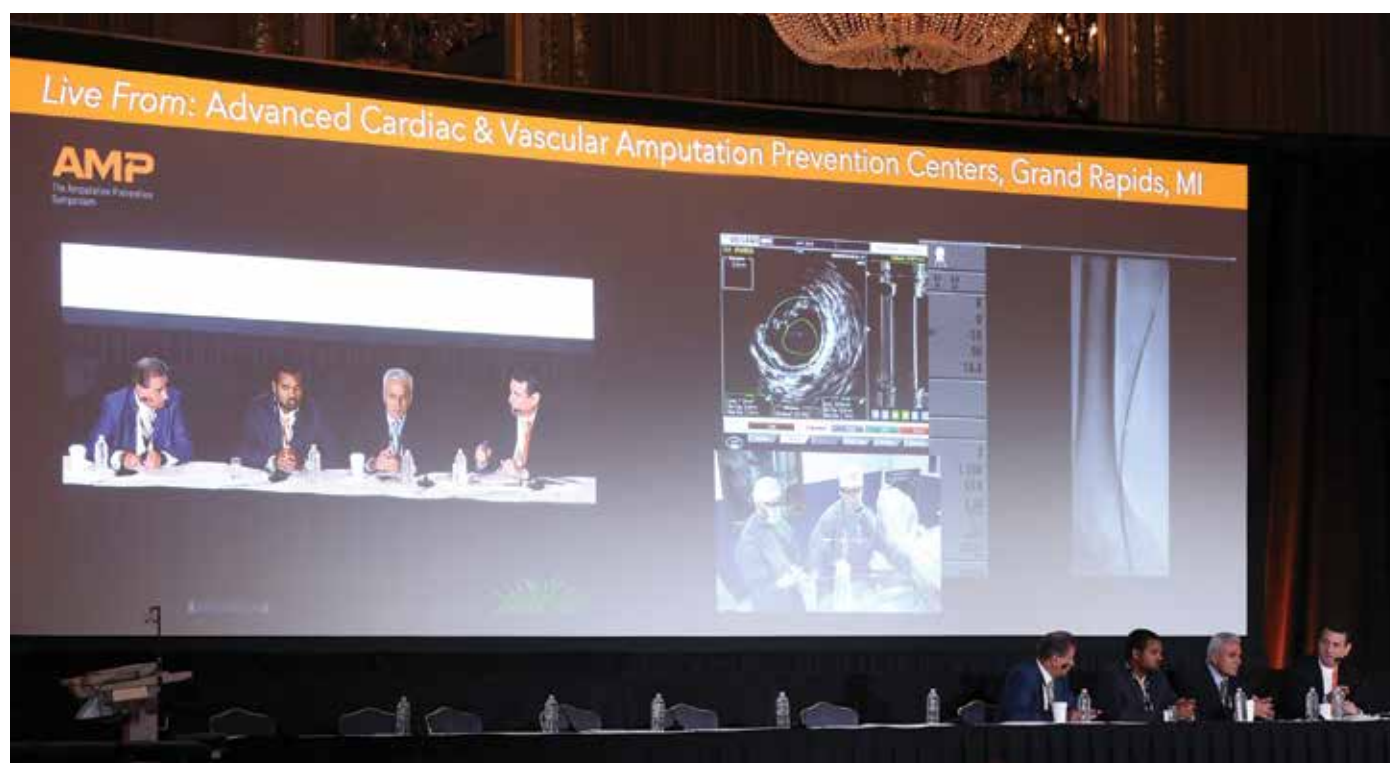


Figure 3. Course Director Dr. Jihad Mustapha and panelists Drs. Laiq Raja, Bryan Fisher and George Pliagas (right to left) discuss live complex CLI case presented by operator Dr. Fadi Saab during the broadcast from an outpatient CLI center in Grand Rapids, Michigan (Advanced Cardiac & Vascular Amputation Prevention Center).



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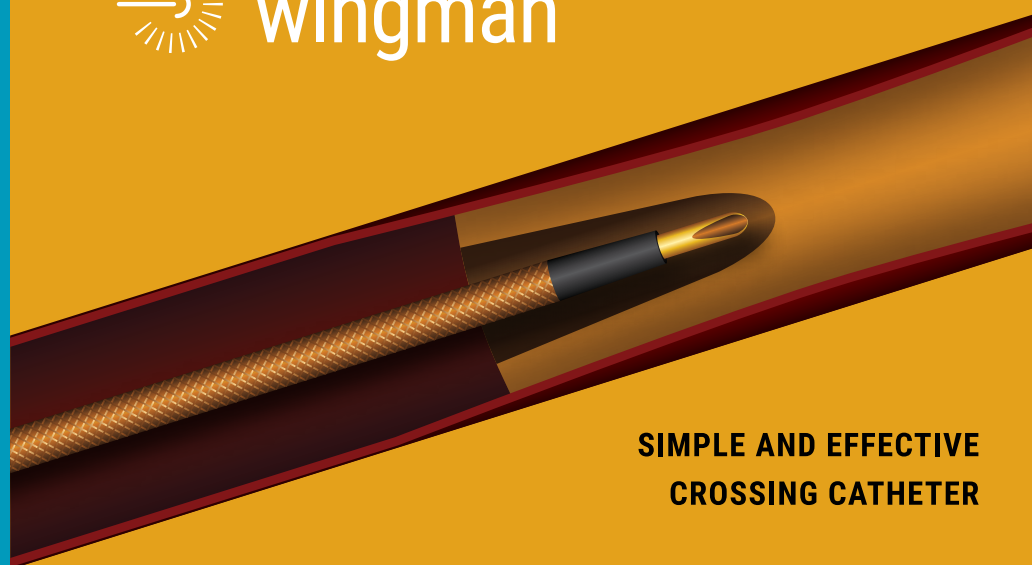
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ZELTZER *from cover*

such as balloon angioplasty, stent replacement, atherectomy, and laser therapy to treat blocked or narrowed arteries, aneurysms, and veins. He also performs bypass surgery when necessary. “Lifesaving techniques have seen phenomenal improvement since I started practicing medicine,” Dr. Zeltzer says. “Technology has brought us great advantages that offer us the right tool for the right patient. One size does not fit all.”

Dr. Zeltzer, a vascular surgeon, is part of the multi-disciplinary limb salvage team at JFK Wound Management and Limb Preservation Center.

Dr. Zeltzer jokingly says that he went into medicine because his mother wanted him to become a doctor, but as it turns out she was right. “I went into medicine because I was always interested in it and particularly in vascular surgery,” he says. Individualized patient care delivered with compassion is his philosophy. “Call me old-fashioned in everything but technology, and I won’t be offended,” he says. “I still like that ‘Norman Rockwell’ kind of doctor.”

Dr. Zeltzer shares his insight and experience in transforming the way he approaches CLI management and shares some reasons why he has been able to achieve superior CLI outcomes.

JM: Tell me about the JFK Wound Management and Limb Preservation Center.

JZ: Ours is a multidisciplinary center focused on advanced wound management using a data-driven, patient-centered holistic approach to total wound healing and amputation prevention. As director of medical staff for JFK, I am proud to be one of the founding members of the Center. Our medical director, Paul Michael, MD, is an interventional cardiologist who has advanced training in CLI revascularization. Our center is unique in that vascular surgery and interventional cardiology work side by side to determine and execute the best treatment plan for each patient.

JM: How have your views as a surgeon on CLI management changed since forming a collaborative multidisciplinary team?

JZ: As the treatment of vascular therapies has evolved, there has been an evolution in open surgery where we have realized that it is not always the answer. With the development of advanced endovascular techniques and equipment leading CLI therapy for limb preservation it was necessary to collaborate with a team that could utilize these therapies to their potential. Through team collaboration—not competition—I have been able to extend my reach down the extremity to vessels that heretofore were not accessible to me but now result in limb salvage.

JM: Describe what makes your multidisciplinary team so successful?

JZ: Given the complex nature of the CLI disease process and the severity of the inherent comorbidities, the management of these tough patients mandates we collaborate with specialized team members with a common goal. By recognizing the unique talents of each team member, we have developed an efficient algorithm which allows everyone to practice at the top of their game. The result of this synergy has been overwhelmingly successful.

JM: How has your role as a vascular surgeon changed by becoming part of a team?

JZ: Contrary to the fear that this may be a loss in terms of my practice volume, it has actually increased and enhanced my ability to extend successful therapy to more patients. By being collaborative I can offer the patient my set of skills, whether through endarterectomy, bypass surgery, or endovascular therapy and all these treatments complement my CLI colleagues’ efforts to reach further down the limb in providing wound-directed therapy to prevent amputation.

JM: You mention going further down the limb in providing CLI therapy, can you please elaborate?

JZ: The final frontier of open surgical options traditionally terminated at the level of the ankle with advanced distal bypass. Even in the hands of the most advanced surgeons, success rates for limb salvage were suboptimal. By incorporating the team approach with the expanded knowledge base of dedicated foot and ankle surgeons in conjunction with interventionalists specialized in tibio-pedal reconstruction; we have eliminated the border for limb salvage.

JM: Have you been able to quantify the results of your collaborative experience?

JZ: I can think of many people for whom I had exhausted all therapeutic options and the only thing I could offer them was amputation. With the advent of this program these people, who would have had no options in the past, now have been successfully revascularized through advanced CLI techniques and continue to walk. This has resulted in a paradigm shift in my thinking such that prior to ever considering amputation, I now consider whether the patient is a candidate for limb salvage therapy.

JM: What techniques are utilized by this team that result in your limb salvage success?

JZ: As a vascular surgeon, all forms of open vascular surgery are readily available to me, but because of the extensive medical comorbidities present in the typical CLI patient, these techniques are not recommended. Instead, we prefer an aggressive endovascular approach, which relies selectively on the talents of the team members to ensure the appropriate technique to give us the desired results of complete wound healing. These techniques include

The future of vascular therapy will emphasize the empowering of teams of experts to combat CLI in an adaptive manner that will always seek to embrace future technologies that contribute to the advancement of limb salvage.

proper diagnostic staging angiograms to define the complete tibio-pedal anatomy. After careful planning, we use all tools necessary to achieve wound-directed therapy. Specialty wires, atherectomy devices, drug-coated technologies, embolic protection, pedal access, radial equipment, stents, and much more are routinely used to provide patients all options for limb salvage. Once the goal of directed revascularization is achieved, the patients undergo aggressive wound management. If necessary, foot and ankle surgery may be used to minimize tissue loss, provide a functional foot, and prevent amputation.

JM: How have you been able to achieve such administrative support for your CLI team?

JZ: Hospital administrators must look at the economics and cost effectiveness of any program or technology and this is understandable. There are multiple papers proving the economic benefit of limb salvage as opposed to amputation. We went about proving the effectiveness of such a program by combining our resources into the team we needed and educating the necessary individuals so that they could embrace this concept prior to formalizing the entity. We were able to first prove its value within our own institution. This required collegial cooperation at the outset.

We had to dissolve the interdisciplinary competitive boundaries between the various specialties involved to understand the concept that the team is stronger than the individual.

JM: Congratulations, Dr. Zeltzer, you have had remarkable success in your 30+ years of practicing vascular surgery in South Florida. Why are you now so involved in the concept of a team approach for limb salvage?

JZ: My career focus has always been patient-centric in that whatever I choose to do is motivated by being beneficial for the patient. Having spent 30 years witnessing vascular disease, it is evident to me that the technologies have advanced, and we must embrace them. More importantly is the realization that a single individual combating this disease cannot expect to succeed on his or her own. In order to effect limb salvage, it does truly take a team of specialized experts.

JM: Where do you see the future of vascular therapy regarding CLI?

JZ: The future of vascular therapy will emphasize the empowering of teams of experts to combat CLI in an adaptive manner that will always seek to embrace future technologies that contribute to the advancement of limb salvage. ■

Upcoming Meetings and Events

September 21–25, 2018

Transcatheter Cardiovascular Therapeutics (TCT)
Location: San Diego, California
Website: www.tctconference.com

September 22–25, 2018

Cardiovascular and Interventional Radiological Society of Europe Annual Congress (CIRSE)
Location: Lisbon, Portugal
Website: www.cirse.org

November 5–8, 2018

Vascular Interventional Advances (VIVA)
Location: Las Vegas, NV
Website: www.vivaphysicians.org

November 10–12, 2018

AHA Scientific Sessions 2018
Location: Chicago, Illinois
Website: www.scientificsessions.org

November 13–17, 2018

Veith Symposium
Location: New York, New York
Website: www.veithsymposium.org

January 22–25, 2019

Leipzig Interventional Course (LINC)
Location: Leipzig, Germany
Website: www.leipzig-interventional-course.com

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- Alliance and advocacy for the prevention of unnecessary amputation.



Resources

- Subscription to *CLI Global*, the official publication of the CLI Global Society.
- Registration discounts at AMP, APWCA, ISET, NCVH, SAWC and VERVE meetings.
- Invitations to CLI Global Society networking opportunities and member events.



Advocacy

- Opportunities to get involved with a strong unified community of physician, healthcare and industry leaders with a focused goal of CLI education.
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Selected Abstracts from AMP 2018

(The Amputation Prevention Symposium, August 8-11, 2018, Chicago, Illinois)

A Retrospective Analysis of Orbital Atherectomy for Treating Calcified Iliac Artery Disease, a Single-Center Study

Siddhartha Rao, MD¹; Henisha Dhandusaria, BS²; Joseph Higgins, MS²; Brad Martinsen, PhD¹
¹WakeMed Heart and Vascular, Cary, North Carolina; ²Cardiovascular Systems Inc., Minneapolis, Minnesota

Purpose. The current standard of care for the treatment of flow limiting calcific iliac artery disease is balloon angioplasty and subsequent stent placement. However, the presence of calcified lesions may prevent adequate stent expansion or impede the delivery of large bore devices such as TAVR or EVAR implants. Plaque modification through vessel preparation with orbital atherectomy (OA) may enable stent expansion and subsequent proper large device delivery with low rates of procedural complications.

Material and Methods. A single center retrospective study of 13 subjects (14 interventions) treated with OA in iliac arteries delivery was conducted. Patients were selected for treatment based on iliac artery disease or inability to deliver devices. The procedural complication rate was defined as the composite of flow limiting dissection, perforation, slow flow, vessel closure, spasm, embolism, thrombosis. Technical success was assessed as angiographic luminal gain and subsequent successful delivery of large bore devices through the treatment area, as well as freedom from procedural complications.

Results. The cohort included 13 patients (age 72.4 ± 10.9 years; 9 males, 4 females) with 1 lesion per vessel, an average lesion length of 34.2 ± 10.8 mm, and an average reference vessel inner diameter of 9.2 ± 0.9 mm. Lesions were located in the common iliac arteries (with some extending into the common femoral arteries). The top 3 associated demographic risk factors were hypertension (92%), history of smoking (85%), and diabetes mellitus (54%). The mean total treatment time using OA per patient, per lesion site in the 14 interventions was 135.3 ± 51.9 seconds. The mean maximum balloon inflation pressure, per treated lesion site was 10.9 ± 6.3 atm. The procedural complication and technical success rates were 0% and 100%, respectively.

Conclusions. Orbital atherectomy vessel preparation of severely calcified iliac artery lesions resulted in adequate stent expansion safely and enabled delivery of rigid/large profile devices. Further studies are warranted to evaluate patient selection criteria, as well as long-term efficacy and safety rates.

Treatment of Complex Lower Extremity Wounds with Combined Urinary Bladder Matrix and Negative Pressure Therapy

Claire S. Dillingham, DO and Shawn Rayburn, PA
 Wake Forest University School of Medicine, Winston-Salem, North Carolina

Purpose. To review the essentials in wound healing and describe a new surgical treatment modality of acellular urinary bladder matrix with negative pressure wound therapy for limb salvage.

Material and Methods. A retrospective review was performed of 4 patients with complex lower extremity wounds. All patients were treated with surgical debridement of the wound and placement of acellular urinary bladder matrix (UBM) and negative pressure wound therapy. Two patients had traumatic wounds. One patient had diabetes and a previous contralateral below knee amputation. One patient had diabetes and pyoderma gangrenosum. Nutritional status and blood sugar control was addressed with each patient. Each patient was surgically debrided and the presence of infection treated if indicated. The urinary bladder matrix was applied to the wound and then covered with negative pressure therapy. The patients' wound healing was assessed weekly at the time of the dressing change. Additional UBM was applied if there was any remaining deficit in the depth of the wound.

Results. Limb salvage and wound closure was achieved in all 4 patients with the combined treatment of urinary bladder matrix and negative pressure wound therapy. Patients had substantial pain relief and positive feedback with one a week dressing changes.

Conclusions. In the treatment of complex lower extremity wounds, acellular urinary bladder matrix has shown successful coverage of complex wounds with aesthetically pleasing results. Combined therapy of UBM and negative pressure has provided significant advantages for pain control and improved convenience of once-weekly dressing changes.

Single Versus Dual Access Approach for Chronic Total Occlusion Recanalization in Peripheral Arterial Disease

Joji J. Varghese, MD, FACC, FSCAI¹; Bailey Ann Estes, RN-BC, RCIS¹; Brad J Martinsen, PhD²

¹Hendrick Medical Center, Abilene, Texas; ²Department of Scientific Affairs, Cardiovascular Systems Inc.

Purpose. Critical limb ischemia is the worst form of PAD with 20% mortality within 6 months of diagnosis and 20% of patients receiving an amputation within

one year. The biggest challenge in endovascular revascularization is multilevel chronic total occlusions (CTO), which account for 40-50% of lesions. Treatment failure occurs approximately at 20-40% due to inability to cross the lesion when utilizing single access. Few limited prior studies have shown that dual access, after failure of either antegrade or retrograde approach, can increase the success rate in superficial femoral artery CTOs. The purpose of this study is to evaluate the efficacy and safety of initial dual antegrade and retrograde access approach compared to single antegrade or retrograde approach for crossing any level of CTO.

Material and Methods. A retrospective analysis was conducted of patients who had at least one lower extremity CTO treated by a single operator at a community hospital between August 2013 and January 2018. Patient and procedural demographics were collected and analyzed. Rutherford classes III-VI were included. Chi-Square and Fisher's exact test were performed along with propensity score-matched (PSM) analysis with a confidence interval of 95%. The primary endpoint was crossing and treatment success. Patient and procedural demographics were analyzed to determine variables of treatment success and failure.

Results. 141 patients were included with 88 in the single access cohort and 53 in the dual access cohort. Crossing success in the dual access cohort was 92.5% and 73.6% in the single access cohort ($p=.010$). Average lesion length was 145.7 ± 92.1 mm and 146.4 ± 111.0 mm respectively. Dual access showed to be a very strong indicator of crossing success ($<.001$ all-subject, and $p=.001$ PSM) and going subintimal was an indicator of failure ($<.001$ all-subject, and $p=.001$ PSM). There was a low rate of complications with no statistical difference between both cohorts.

Conclusions. Our study demonstrated initial dual access approach compared to single access has shown significant success in crossing and treating peripheral CTOs. We believe this could have a major impact on successfully reducing the amputation rates.

Primary and Secondary Acoustic Pulse Thrombolysis Treatment in Acute Limb Ischemia: A Single Center Experience

Bailey Ann. Estes, RN-BC, RCIS; Alexander W. Armour, DO; Harvinder Arora, MD; Larry W. Lin, MD; Chris McClish, MD; Gorman M. Thorp, MD; Joji J. Varghese, MD, FACC, FSCAI
 Hendrick Medical Center, Abilene, Texas

Purpose. The optimal treatment strategy for acute limb ischemia (ALI) from thromboembolism remains controversial.

Catheter directed thrombolysis (CDT) and surgical thrombectomy have shown benefits, yet are associated with significant morbidity and mortality. An alternative to standard CDT, acoustic pulse thrombolysis (APT), delivers low-intensity, high frequency ultrasound waves accompanied with low dose thrombolytics. Also, the optimal timing for intervention remains unclear as PTA can aid in visualization and increase flow but it can also be a cause of distal embolization.

We evaluated the safety and efficacy of APT in the treatment of ALI. We also evaluated the treatment strategies of primary APT and delayed PTA and primary PTA with delayed APT.

Material and Methods. We retrospectively studied patients who were diagnosed with ALI at our institution (Feb. 2016–Aug 2017). Patients (pts) treated with APT using the EkoSonic Endovascular System (EKOS Corp.) and received a repeat angiogram after APT treatment were included. The severity of ischemia included Rutherford ALI class I-IIb. The primary endpoint was technical success by angiographic assessment and freedom from in-hospital amputation.

Results. A total of 19 pts (mean age 66 ± 12.4 years, 11 males) were retrospectively studied. There were 21 episodes of APT for either primary or secondary APT treatment of ALI in 34 (89%) native arteries and 4 (11%) prosthetic bypass grafts. A pre-existing diagnosis of peripheral artery disease was present in 14 (74%) pts. Average duration of symptoms was 3.45 ± 3.26 days. Mean treatment time was 21 ± 3.75 hours. Primary APT treatment was conducted in 10 (53%) pts and 9 (47%) received PTA prior to APT treatment. Technical success was achieved in 17 (89%) pts, with primary APT treatment success at 80% and secondary APT treatment at 100%. Fischer's Exact Test showed no statistical difference in primary vs secondary treatment ($p=.474$). Two (11%) major amputations and 1 (5%) major complication, fasciotomy, were documented.

Conclusions. APT is a safe and effective treatment strategy for ALI with a low rate of complications and amputations. Further, large randomized control trials are needed to evaluate the timing and duration of APT with optimal timing of angioplasty.

The FLEX Dynamic Scoring Catheter as Vessel Preparation in Below the Knee Lesions

Fadi Saab, MD; Jihad Mustapha, MD; Miguel Montero-Baker, MD
 Advanced Cardiac and Vascular Amputation Prevention Centers, Grand Rapids, Michigan; and Baylor College of Medicine, Houston, Texas

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Purpose. Below the knee (BTK) lesions continue to be a challenge for interventionalists. Refinements in vessel preparation are required to improve the overall procedural and patient outcomes.

Material and Methods. The FLEX Dynamic Scoring Catheter, a non-balloon-based scoring device, creates continuous, controlled-depth, longitudinal micro-incisions regardless of lesion length. A retrospective review was conducted on 33 real-world BTK lesions (11 physicians, 12 institutions) that had been prepped prior to angioplasty with the FLEX by physician's discretion. This review focused on the luminal gain achieved, balloon opening pressures (the lowest pressure required to fully efface the lesion), and dissections rates.

Results. The average lesion length treated was 129 mm (4–315 mm). Moderate to severe calcification was present in 63.6% of the lesions. The average baseline stenosis was 92.6%, with 42.4% of the cases presenting with a chronic total occlusion. At the physician's discretion a FLEX Catheter was deployed to prepare the lesion for angioplasty. Luminal gain was evaluated after vessel prep, noting an average luminal gain of 32.6% by the FLEX alone. The lesions were subsequently treated with angioplasty, 63.6% plain old balloon angioplasty (POBA), 15.2% drug-coated balloon (DCB), and 21.2% had both. The average balloon opening pressures observed were 4 atm (2–8 atm), with an average maximal pressure at 7.6 atm (3–18 atm). Average residual stenosis post treatment was 9.4% (0–30%). In 97% of the cases no dissections occurred, 1 minor type A dissection was noted. Zero flow-limiting dissections, perforations, or embolization were reported.

Conclusions. The results obtained in this subset of BTK lesions suggests vessel prep by the FLEX can impact overall angioplasty (POBA and DCB) outcomes safely and efficiently. The FLEX created improvement in luminal gain, allowing for vessel expansion without adverse events. Further studies are warranted.

Efficacy of Indirect Endovascular Revascularization in Patients With Diabetic Ischemic Foot

Karina Soledad Garzon, MD; Fernanda Escobar, MD; Sabina Tipantaxi, MD; Paulina Cisneros, MD; Favio Carrera, MD Hospital Enrique Garcés, Quito, Ecuador

Purpose. To determine if the indirect revascularization of the compromised angiosomes allows wound healing and pain relief, if any artery is affected more frequently; to determine the time of complete healing, and the percentage of amputation and mortality.

Material and Methods. This is a prospective, observational, cross-sectional, descriptive study in which 42 patients (pts) were received in the Diabetic Foot Unit were included, which is attached to the Vascular and Endovascular Surgery

Service of the Enrique Garcés Hospital in the city of Quito, Ecuador.

Ulcerative lesion of the lower limb submitted to successful endovascular procedures in the infrapopliteal sector and that the collateral nutrient vessel was revascularized and not that of the direct line to the angiosome between January 2015 and July 2017. The follow-up was done in the Unit of Diabetic foot ambulatory. These parameters were collected in a base template.

Results. Of 41 pts undergoing indirect revascularization, we obtained follow-up, median age was 71 years, 56% were male. 100% were diabetic and hypertensive. Smoking was more frequent in men (12vs2). Chronic renal failure and dyslipidemia were more frequent in women, men had more ischemic heart disease. The angiosoma most frequently involved is that corresponding to the tibialis anterior. The peroneal artery was most frequently revascularized. The median of time of wound healing was 15 weeks. No complications were determined at 3 months, 6 months or 12 months of follow-up. Mortality represented 2.4% (1/41 pts).

Conclusions. Indirect revascularization is a feasible therapeutic option in patients with ischemic diabetic foot presenting high rates of salvage of the lower limb, clinical improvement and with minimal cardiovascular complications, mainly when it is not possible to revascularize the artery responsible for the ischemic site as long as there is a development of collateral enough to obtain an adequate plantar arch.

Percutaneous Angioplasty with Drug-Eluting Balloon for Infringuinal Venous Bypass Stenosis

Arnaud Kerzmann, MD; Evelyne Boesmans, MD; Hendrik Van Damme, MD, PhD; Vlad Alexandrescu, MD; Jean-Olivier Defraigne, MD, PhD, Department of Cardiovascular and Thoracic Surgery, CHU Liège, Belgium

Purpose. Open surgical repair has better results than percutaneous transluminal angioplasty in treating infringuinal venous bypass stenosis. The endovascular treatment has significant risk of restenosis, whichs need new intervention. The use of drug-eluting balloon in peripheral artery disease is proved. We report our experience with such balloons for treatment of infringuinal venous graft stenosis.

Material and Methods. From Nov. 2012 to April 2018, 10 pts (6 were women) with 12 infringuinal venous bypass stenosis had 14 percutaneous transluminal angioplasties with drug-eluting balloons. They were reviewed prospectively. Six had femoropopliteal bypass above the knee, 3 had femoropopliteal bypass below the knee, and 3 had femorotibial bypass. Four were treated at least one time before with simple balloon angioplasty and had early restenosis.

Results. 6 lesions were at the distal anastomosis, 2 at the proximal anastomosis,

and 4 were far from the anastomosis. The immediate angiographic results were always good. One patient died of acute myocardial infarction on the first post-operative day. Two patients developed restenosis after 15 and 29 months' follow-up and had new balloon angioplasty with coated balloons. One of those bypasses was thrombosed one year after the second intervention. Another bypass was thrombosed after 33 months' follow-up. All the other patients didn't develop restenosis. Follow-up is ongoing.

Conclusions. The use of drug-eluting balloon to treat infringuinal venous bypass stenosis is minimally invasive and safe. Randomized studies are mandatory to compare drug-eluting balloon angioplasty with simple balloon angioplasty and with open surgical repair.

XableCath - a Novel Metallic Tip Catheter Facilitating Crossing of Obstructive Lower Extremity Arterial Lesions

Johannes B. Dahm, MD, PhD¹; James F. Benenati, MD²; Charles B. Moomey, Jr.³; Stephen Lauterbach, MD⁴

¹Professor of Angiology and Cardiology, Department of Angiology-Cardiology, Heart and Vascular Center Neu, Bethlehem, Gottingen, Germany; ²Interventional Radiologist – Medical Director Vascular Lab, Miami Cardiac and Vascular Institute; ³Vascular surgeon, Longstreet Clinic; and ⁴Medical Director/ Vascular surgeon – Medical Director, XableCath, Inc.

Purpose. To investigate the efficacy and safety of a metallic tip recanalization catheter in modifying arterial obstructive lesions in the lower extremity to facilitate endovascular therapy.

Material and Methods. Between 10/2010 and 04/2018, 49 patients (21 female, mean age 72, 51% diabetic, 59% Rutherford class 3–4, 41% Rutherford class 5–6) with 53 separate arterial lesions of the lower extremity were treated with XableCath [.014, .018, .035 blunt (31) and abrasion tip (21)] catheters (XableCath, Inc. Salt Lake City, Utah) in 3 medical units (Germany, Miami, Atlanta). The lesions (8 iliac, 36 femoro-popliteal, 2 below knee popliteal, 7 tibial) were 79% moderately or severely calcified; 53% total occlusion; 72% balloon impassible; 15% wire impassible and an average length of 5.6cm. Access was done via the radial, brachial, femoral, tibial, and pedal arteries using 4–7F sheaths. The primary endpoint was successful Xablecath passage through the target lesion enabling subsequent therapy (angioplasty and/or stenting). Secondary endpoints were the absence of major adverse events attributable to XableCath use: perforation, dissection, thrombosis, or distal embolization. All patients were seen post procedure at a mean 5.9 weeks.

Results. Clinical success was achieved in 98% of cases: XableCath successfully passed through 52/53 occluding lesions enabling subsequent angioplasty and/or stenting. In 2 cases, an abrasion tip

catheter was used after failed passage of a blunt tip. The solitary failure was a blunt tip attempt; an abrasion tip catheter was not available for that case. All 19 pts with critical ischemia had successful limb salvage. There were no cases of arterial dissection, rupture, thrombosis, or distal embolization attributable to XableCath. After balloon angioplasty, 2 minor dissections occurred and were successfully stented, 1 access site femoral pseudoaneurysm was noted post-operatively and treated surgically.

Conclusions. The metallic tip XableCath is easy to use, effective, and safe in modifying severe arterial obstructive lesions in the lower extremity facilitating subsequent endoluminal therapy to be performed successfully.

Percutaneous Deep Vein Arterial-ization for Treatment of Late Stage Critical Limb Ischemia, Early Feasibility Results

Jihad Mustapha, MD, Advanced Cardiac and Vascular Amputation Prevention Center, Grand Rapids, MI

Purpose. Within critical limb ischemia (CLI) there is a broad spectrum of severity, from milder degrees of vascular insufficiency to no-option situations where occlusive lesions are so complex that current available surgical and endovascular techniques are not sufficient and amputation is considered the only solution. We report the interim results of the multicenter PROMISE Early Feasibility Trial using the LimFlow Stent Graft System (LimFlow Inc.,) for percutaneous deep vein arterialization (pDVA) in these no option patients.

Material and Methods. Ten no-option CLI patients (median age 67 years; 3 women) were enrolled to determine safety, effectiveness, and feasibility of the LimFlow Stent Graft System. All patients were Rutherford Category 5 or 6. Eight were classified at high risk of amputation based on the SVS WIfI classification. The primary safety endpoint was Amputation Free Survival (AFS, freedom from mortality and freedom from above-ankle amputation of the index limb) at 30 days with a secondary safety endpoint of AFS at 6 mos. Other secondary endpoints included patency, wound healing, and technical success.

Results. The primary safety endpoint was achieved in 100%, with no deaths or above-the-ankle amputations at 30 days. Technical success rate was 100%.

Conclusions. The pDVA using the LimFlow Stent Graft System is a novel approach for treating patients with no-option CLI and may reduce amputation in this population for whom amputation would otherwise be considered inevitable. Initial findings from this early feasibility trial appear promising, and additional study via pivotal trial is warranted.



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A New Closure Device – How to Close Large Bore Sheaths

Rex Teeslink, MD, Interventional Radiologist, T-Med, Inc., InjectiMed

Access and Closure. EnSite Medical has designed a large bore closure device, SiteSeal, which simulates external compression, but removes the associated variables, leaving nothing behind. It applies invariant pressure to the vessel wall access site by utilizing internal stainless steel springs, which function as shock absorbers to dampen blood vessel pressure fluctuations.

Material and 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 right handed, the first entrance is 1cm east of the sheath, passing under the sheath and exits 1 cm west of the sheath.

The second entrance is 1cm 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 two ends of the Z stitch form a double half know, 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. Forty-five EVAR and 23 Impella procedures have been performed using SiteSeal without any hematoma formation at discharge, 24 hours, 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: not limited by sheath size, including EVAR, TEVAR, TAVAR; no patient limitation: size, anticoagulation, calcification, etc.; simple and rapid deployment; allows immediate re-access; minimizes patient discomfort, allowing immediate head elevation to 30° with no restriction to leg movement;

early ambulation; and nothing left behind the potential of minimal risk of vessel wall injury, infection, or embolization

Efficacy of XTRACT in Atrial Fibrillation Patients with Peripheral Arterial Disease - Subset Analysis from PRISM Trial

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We report clinical efficacy and safety on subset analysis of atrial fibrillation patients in the PRISM trial. This trial examined efficacy and safety of XTRACT (a power aspiration-based extraction technique) using Penumbra Indigo System as a frontline and secondary treatment for peripheral arterial occlusions.

Material and Methods. PRISM was a single-arm, multicenter, retrospective analysis of patients (pts) with acute or subacute arterial occlusions who met the inclusion criteria of peripheral arterial occlusion (TIMI 0-1) prior to attempted endovascular treatment using XTRACT. The primary endpoints were vessel patency immediately post-XTRACT and post any other subsequent endovascular procedure as measured by TIMI score, as well as the rate of procedural serious adverse events (SAE) within 24 hours of treatment. Subset analysis of 12 pts.

Results. PRISM concluded a total of 79 pts. Among these, XTRACT was the primary treatment modality for 49.4% (39/79), while 50.6% (40/79) were treated with XTRACT secondary to failure from catheter-directed thrombolysis (CDT), other endovascular therapies, and distal emboli from preceding interventions. Overall, vessel patency (TIMI 2-3) among these pts was achieved in 87.2% (68/78) immediately after XTRACT, and in 96.2% (76/79) following additional adjunctive interventions.

In this subgroup analysis, pts with atrial fibrillation (N=12), 66.7% were female. XTRACT was the primary treatment modality for 7 pts (58.3%), while the remaining 5 (41.7%) were treated with XTRACT secondary to failure from CDT and/or other endovascular therapies. Frontline XTRACT was successful in 71.4% (5/7); however as secondary therapy, 100% (5/5) of pts were successfully revascularized to TIMI 2-3. Overall, vessel patency (TIMI 2-3) was achieved in 83.3% immediately after XTRACT, and in 100% of pts following additional adjunctive interventions.

Overall, procedural SAEs were reported in 8.9% (7/79) pts, whereas in subgroup of atrial fibrillation, only 1 patient had SAE within 24 hours. None were device-related.

Conclusions. Penumbra Indigo system using XTRACT technique is a safe and effective intervention in atrial fibrillation patients with underlying peripheral arterial occlusions. XTRACT was useful both as a frontline therapy and as a salvage technique when other endovascular techniques had failed in these atrial fibrillation patients. Future prospective trials are needed.

Occurrence of Critical Limb Ischemia

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Purpose. Critical limb ischemia (CLI) is the final prognosis of peripheral arterial disease (PAD). The mortality rate for CLI patients from initial diagnosis can surge 20% at 6 mo. to 20-fold at 5 years. PAD is a slow, progressive circulation disorder, which is the leading cause of death, worldwide. PAD affects over 10 million Americans. PAD is a buildup of plaque in the arteries, causing the arteries to harden and narrow along with a reduced blood flow, which inhibits perfusion of the organs, tissue, and muscle. There are multifactorial issues that place patients with PAD at a higher prevalence, such as smoking, diabetes mellitus, hypertension, history cardiovascular disease, and chronic lung and renal disease.

History: N.F., a 45-year-old patient of Dr. Smith referred to Dr. Christopher LeSar for lower-extremity PAD. She had a previous left below-the-knee amputation (BKA). In July 2017, she was bitten on her ankle by an insect and developed cellulitis of the right foot. She was complaining of right calf claudication and rest pain with an unhealed lesion on the malleolus on the ankle. She has diabetes and blood sugar range 115-220, hypertension; hyperlipidemia; blood pressure was 138/70. She smoked for 12 years, a pack a day, and she recently stopped approximately 3 weeks before when the claudication would not subside. Physical Examination: N.F. is awake, alert, oriented, neurologically intact, in no acute distress, head is normocephalic. Abdomen is soft, round, obese, nontender. Bilateral radial pulses are +2. Grip strength is equal. Femoral and popliteal pulses unable to assess due to body hiatus. Dorsal pedal on the right is absent. Posterior tibial pulse on the right is absent. She had a 0.3 x 0.3 cm ulcer with red streaking with crusty ends and a trace of edema noted in her right ankle region. Right ankle and shin with warmth and redness. Left BKA.

Treatment: Order an arterial duplex ultrasound and ankle-brachial index (ABI) of the affected limb. The ultrasound revealed

monophasic flows with total occlusion of the superficial femoral artery with a flat toe pressure and ABI 0.32. Arteriogram of the right lower extremity per Dr. LeSar and wound care was initiated by Vascular Institute of Chattanooga Wound Center. She made a full recovery.

Conclusions. Treatment for CLI is not an easy choice; the treatment depends on the patient's age, comorbidities, severity of limb ischemia, and the vascular anatomy. The plan of care for these PAD patients is to continue improving outcomes by increasing community awareness; initiating better quality wound care, and improved medical therapy to prevent the PAD from progressing to CLI.

Treatment of Severe Diabetic Foot Ulcers with Recombinant Human Epidermal Growth Factor

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Purpose. To evaluate the results of local treatment of severe diabetic foot ulcers (Wagner 3-4) with recombinant human epidermal growth factor (Heberprot-P®) used in daily medical practice.

Material and Methods. From March 2011 to Dec. 2014, 124 patients (pts, 67% men) diagnosed with diabetic foot ulcer (42% Wagner 3 and 57% Wagner 4) who had received peri and intralesional administration of 75 g of Heberprot-P®, were included in this retrospective analysis. These were outpatients seen at the nutrition, diabetes and vascular departments of Argentine public and private hospitals.

Results. Granulation response was shown in 91% of pts. The complete granulation response rate obtained was 70.3%, with a complete ulcer closure in 69.2% of the pts. Mean wound healing time was 13 weeks. After 6 month follow up, there were 10.4% amputations and 4.2% recurrence. The treatment was well tolerated. Adverse events (AEs) were reported in 29% of pts. The most frequent were shiver, local infection, pain in the application site, fever and arterial hypotension, all with mild to moderate intensity. Three serious AEs (SAEs) were reported: 2 were pts with lower limb infections and the third a case of anaphylactic reaction, all with complete recovery. No deaths were reported.

Conclusions. In this retrospective analysis, local administration of Heberprot-P® during a brief period, was effective to induce healing of ulcers in a high percentage of patients with severe diabetic foot ulcers (Wagner 3 and 4). The recurrence rate was low, thus, further amputations were avoided and patients' quality of life improved. Local treatment with Heberprot-P® was well tolerated since since a low incidence of SAEs was observed.

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88.2%
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Lutonix Global SFA Real World Registry¹

¹ Kaplan-Meier. Lutonix Global SFA Real World Registry, N=691. Primary efficacy endpoint is defined as freedom from TLR at 12 months. TLR Free rate by subject counts at 12 months was 93.4% (605/648). The Kaplan-Meier TLR-Free survival estimate was 94.1% at 12 months and 90.3% at 24 months. Lutonix Global SFA Real-World Registry long lesion cohort was defined as lesions ≥140mm. In the LEVANT 2 IDE Clinical Trial, treatment with Lutonix® 035 DCB resulted in freedom from TLR rate of 87.7% at 12 months (250/285) and a freedom from TLR rate of 82.0% at 24 months. Data on file, Bard Peripheral Vascular, Inc.
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