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

Healthcare Disparities and CLI Treatment

The CLI Global Society Recent Webinar "Racial and Ethnic Disparities in CLI Diagnosis and Treatment: The Ugly Truth and What We Must All Do About This"

Moderator: Paul Michael, MD
Guest Speaker: Wayne Batchelor, MD
Panelists: Barry Katzen, MD; Jihad Mustapha, MD; Richard Neville, MD; Michael R. Jaff, DO; and Michael Parker, MD

"What we see changes what we know. What we know changes what we see."
- Jean Piaget

BACKGROUND

Healthcare disparities are the inequalities experienced by different groups as they interact with the healthcare system. These groups can be divided by race, sex, geographic location, education level, and a variety of other factors. As early as 1840, reports have demonstrated mortality differences between social classes.[1] In the United States, the US Department of Health and Human Services released "Health, United States, 1983," detailing an increased "burden of death and illness experienced by blacks and other minority Americans…"[2] It has been almost 40 years since that report was published and racial healthcare disparities remain a well-documented and troubling issue.

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The CLI Global Society Announces the *Journal of Critical Limb Ischemia*

The First Peer-Reviewed Journal Dedicated to CLI

Jihad A. Mustapha, MD

The first issue of CLI Global launched in November 2014 to help meet an unmet educational need in CLI. Over the years, the issue has provided data, tips and tricks, and case studies to CLI enthusiasts internationally. The CLI Global Society came into existence in January of 2016 adopting CLI Global as its official publication. Over the years, the Society worked to

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CLI Global Society Recommendation: An Amputation Should Never Occur Without Proper DSA

Despite recent guideline updates on peripheral artery disease (PAD) and critical limb ischemia (CLI) treatment, the optimal treatment for CLI is still debated resulting in inconsistent care. With evolving diagnostic technology, operators can generate clarity when imaging of target vessels. The CLI Global Society recently published an interdisciplinary expert recommendation for superselective digital subtraction angiography (DSA) that includes the ankle and foot in properly indicated CLI patients to optimize limb salvage.

The CLI Global Society believes the following recommendations may help reduce the incidence of primary amputation in the CLI population, resulting in better outcomes and lower burden on society[1]:

1. Primary amputation should not be the first line of treatment for CLI unless there are mitigating circumstances.
2. An interdisciplinary specialty care team should determine if a CLI limb is salvageable.
3. A superselective DSA (including the ankle and foot) should be utilized to delineate a salvageable limb prior to amputation.

The Society's DSA algorithm in conjunction with an interdisciplinary specialty team evaluation can prevent unnecessary amputations or minimize the amputation level in CLI patients.[1]

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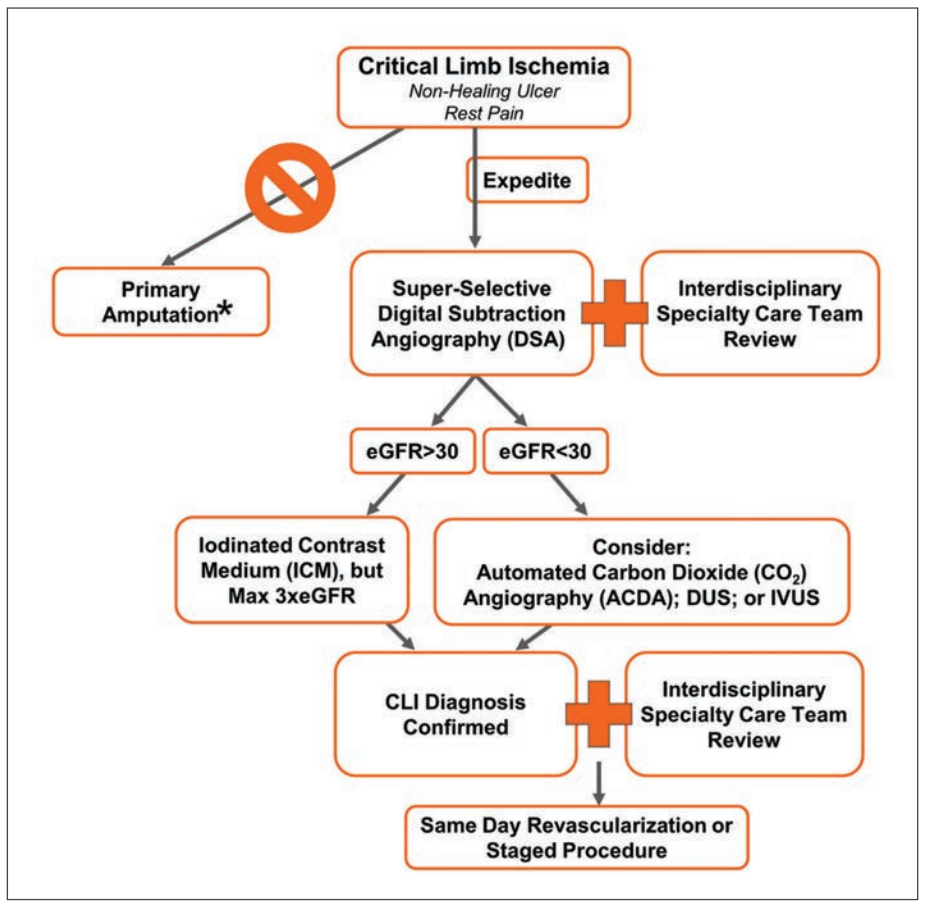

DSA Algorithm. Digital subtraction angiography algorithm for critical limb ischemia (CLI) patients is shown. *From Mustapha JA, et al. J Endovasc Ther*[1] used with permission. *Primary amputation should not be the first line of treatment for CLI unless there are mitigating circumstances (eg, life-threatening sepsis, intractable infection, extensive gas gangrene, bedridden status, severe dementia, or tissue loss/necrosis beyond salvage). *DUS = duplex ultrasonography; eGFR = estimated glomerular filtration rate; IVUS = intravascular ultrasound*[1]

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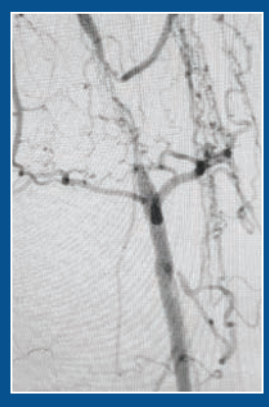

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Multi-Modality Approach to Successful Intervention of CTO SFA After Failed Bypass Surgery

Iyad K. Azzam, MD, FACC, FSCAI; Sandra Hansen, PA; Samantha Keihl, RCIS; Heather Dehnert, RN; Krystina McMillen, RN; and Sarah Krause, RCIS, MS
Aurora St. Luke's Cardiac Care Center, Summit, Wisconsin

Iyad K. Azzam, MD, FACC, FSCAI

Figure 1. CTA was done in order to better plan the percutaneous intervention of the right SFA. The CTA revealed 100% occlusion of the right common iliac with reconstitution at the popliteal artery.

Due to the growing need for peripheral intervention in CLI patients, strategic planning and alternative access methods is key to successful intervention. In CLI patients with suspected common femoral disease or known anatomical challenges, CTA is useful in guiding peripheral intervention.[1] Alternate access via radial and pedal arteries for complex CLI patients allows for higher success rates in treating CTO arteries and complex peripheral disease.[2-4]

CASE STUDY

A 66-year-old male presented with severe bilateral lifestyle limiting claudication. The patient had significant pain and numbness at rest and with any exertion. He has a significant history of peripheral vascular disease including multiple

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A Discussion of Racial Disparities

Healthcare Inequity Illustrates the Need for Health Justice for the Most Vulnerable Americans

Joel Rainwater, MD
CMO Comprehensive Integrated Care, Phoenix, Arizona

Joel Rainwater, MD

As our country faces numerous ongoing challenges related to the coronavirus pandemic and, more recently, as our citizens reel from turmoil centered around racial inequities, such unrest strikes many of us in the healthcare sector as a cruel irony. U.S. healthcare providers have long witnessed different races suffering a disproportionate increase in disease prevalence and worse, unequal access to care. To echo the expressed outrage over disparate treatment of various ethnic groups in our nation, or our frustration over the seemingly menacing way a virus targets the elderly and infirm, it is timely for the medical community to not only remind ourselves that healthcare injustice exists, but also to rededicate ourselves to erasing it from the practice of medicine altogether.

For those of us fighting to preserve lives and limbs in our communities, such as the readers of the CLI Global Society Newsletter, our shared experience offers a unique glimpse into the reality of disparities in healthcare delivery. As the CMO of Comprehensive Integrated Care (CiC), a multispecialty group based in Phoenix, Arizona, which is adjacent to the largest reservation lands in the country, I have spent my entire career amid the largest population concentration of Native Americans. Hence, I have witnessed, and continue to experience, Native patients suffering a disproportionate increase in the incidence of various lethal diseases and their complications. Much work has gone into understanding the epidemiology of this phenomenon, but research has also uncovered a somewhat more troubling fact, that, there remain overwhelming barriers to Native patient access to the diagnosis and treatment of disease. In addition, this population also suffers from obstacles that delay medical treatment and lead to measurably worse outcomes. This is the central concept of health injustice.

Allow me to explain. Native Americans (and Alaska Natives) suffer from diabetes on average 4 times that of the general population (CDC, Summary Health Statistics for U.S. Adults: National Health Interview Survey 2012). Some tribes are hit particularly hard. Our neighboring Pima Indians of Arizona and their ethnic relatives are found to have a prevalence of diabetes which is a staggering 19 times greater than a comparable white majority cohort (Knowler, et al.). Worse, they are 90% more likely to die from diabetes than their Caucasian counterparts (CDC, Deaths, Final Data 2010). Natives are 60% more likely to suffer from end-stage renal disease (USRDS Annual Data Report: Atlas of Chronic Kidney Disease and End Stage Renal Disease in the United States 2013). These conditions have the strongest correlation to atherosclerotic cardiovascular disease and peripheral arterial disease known. Hence is it of little surprise that Native populations are ravaged by CLI, and lower extremity amputation is a growing concern. (Ziegler Graham K 2008).

"I have spent my entire career amid the largest population concentration of Native Americans. Hence, I have witnessed, and continue to experience, Native patients suffering a disproportionate increase in the incidence of various lethal diseases and their complications."

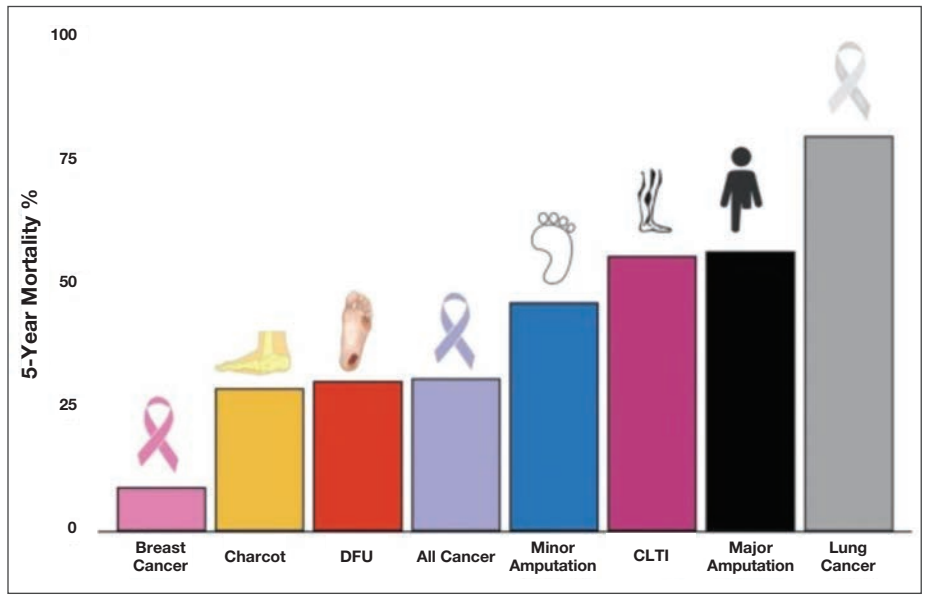

Figure 1. Five-Year Mortality of Diabetic Foot Complications and Cancer. Diabetic foot complications, mortality at 5 years, compared to cancer.
DFU = diabetic foot ulcers = 30.5%. Charcot = Charcot neuroarthropathy of the foot. All Cancer = pooled 5-year survival of all cancers. CLTI = chronic limb threatening ischemia. Major Amputation = above foot amputation. Minor Amputation = foot level amputation

Incredibly, while this population is in the most need of endovascular revascularization, preventative care, and chronic disease management, these non-surgical treatments, are, in fact, LESS LIKELY to be employed. Sadly, the major amputation rate among Native patients is 3-4 times that of the general population (Burrows, et al. 2000). Researchers have identified the frightening correlation between overall mortality and diabetic foot ulcer, CLI, and major amputation, placing them among the most deadly of diseases. (David G. Armstrong★ 2020) See Figure 1.

Not only is major amputation a marker for high mortality, analysis shows that it results in a tremendous cost waste, as amputation is a more expensive treatment for CLI than revascularization. In fact, the estimated lifetime cost of major amputation is $509,272, without even considering any treatment which preceded amputation (Hopkins 2020).

Such racial disparity is not limited to diabetes, renal insufficiency, and atherosclerotic disease. In fact, Native patients are 40% more likely to have tuberculosis, and 30% more likely to be diagnosed with HIV/AIDS (CDC, National Center for HIV/AID, Viral Hepatitis, STD and TB Prevention; 2011). The list goes on. Confounding this is a significant underreporting of the data for healthcare statistics in the American Indian and Alaska Native (AI/AN) population overall (Ernest Moy 2006). Thus, some inequities are yet unknown.

Unfortunately, barriers to diagnosis and preventative care for these highly prevalent diseases are rampant, particularly in the Western United States. The Kaiser Family Foundation research gives us insight into some of the causative factors. The lack of population density, with its inherently reduced infrastructure, the remote locations of much of Reservation territory, and the economic struggles of the Native patients all factor into a regrettable result: little to no diagnosis, education, or preventative care (Foundation 2013). See Figure 2.

Furthermore, the Native patients perceive that they themselves cannot utilize nor tolerate the overburdened existing mechanism for delivery of care in their communities, even when motivated to do so. Care-seeking behavior is consequently frustrated. (Foundation 2013) See Figure 3.

How does healthcare address this? Calls for more Native American physicians and other healthcare workers in Native communities are certainly welcome (Marcinko 2016), as are demands for an increase in those facilities which can both accommodate the needs of the underserved and do so near the geography of the reservation. Nevertheless,

"And by no means is healthcare inequity limited to the Native Americans. It is also well-documented in Black, Latino, and Asian populations across all age groups. Some of these data are illustrated at FamiliesUSA.org."

such solutions are several years and likely billions of dollars away. Immediate results are critical to move us from what now constitutes "disaster care," or the management of the end-stages of disease, to the type of preventative and minimally invasive care that non-Native populations enjoy.

And by no means is healthcare inequity limited to the Native Americans. It is also well-documented in Black, Latino, and Asian populations across all age groups. Some of these data are illustrated at FamiliesUSA.org.

Our experience at CiC led us to develop a multipronged approach to address these challenges. We began by offering state-of-the art care and facility access to Native Americans in the Phoenix area through fully engaging the state's Medicaid (AHCCCS) system coupled with the assignment of benefits administered through tribal reimbursement mechanisms. This allowed virtually all Native patients to have access to our facilities within their existing benefits. We then located our facilities in proximity to those in need, such as our endovascular center in Flagstaff, Arizona, which serves the Native communities of Northern Arizona, New Mexico, and the Colorado Plateau, where there is a high concentration of Reservation land. These allowed us to service a sizeable catchment area of the Native community, where we accomplished a quantifiable decrease in major amputation rates.

More recently, we founded a non-profit organization dedicated to removing healthcare barriers wherever they exist. The Foundation to Improve Care Access for Native Americans (FICANA) began in 2017 to overcome any hurdle, no matter how small, which prevented our Native patients from accessing care, Figure 4.

FICANA was subsequently granted 501 (c) (3) status and has since been able to provide funding for over 1700 micro-grants to assist Native American patients in obtaining access to transportation, lodging, Native language translation, and education. These grants help keep patients in their care plan, yielding tremendous results in amputation prevention, as well as improved outcomes for the many other conditions plaguing some of the most vulnerable patients in our country. More information about tax deductible donations can be found at https://myficana.org/

The foundation, along with the other tools mentioned above, allows us to dramatically impact Native American lives in so many ways, and to eliminate at least some of the disparities that these patients face on a continual basis. It is my belief that similar methods can be deployed anywhere populations are suffering from unequal care. Health Justice, indeed. ■

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Disclosures: Physician trainer for Abbott, Medtronic & Philips.

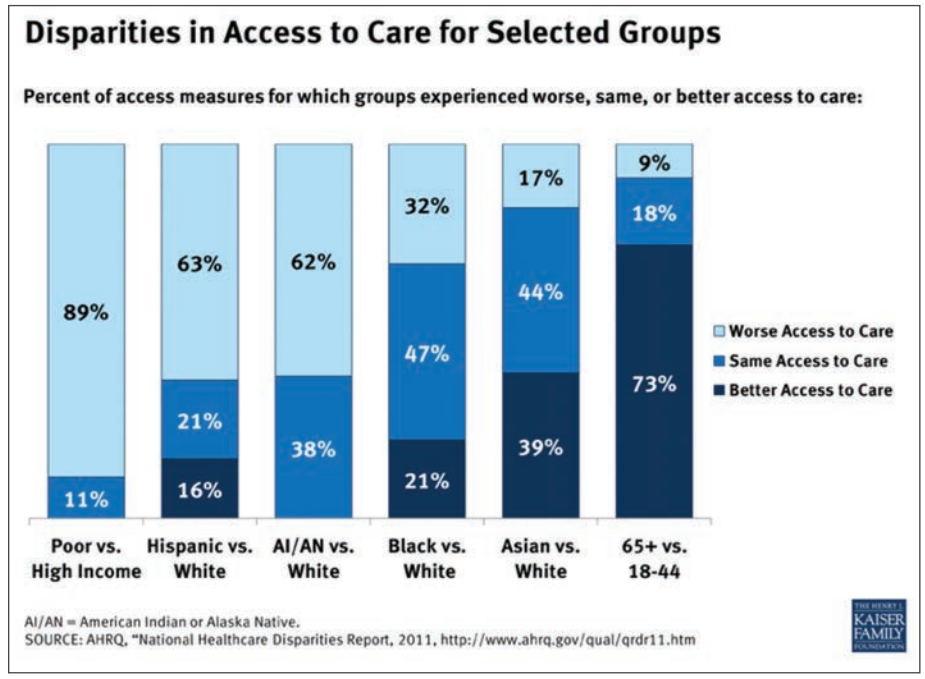

Figure 2. Disparities in access for selected groups.

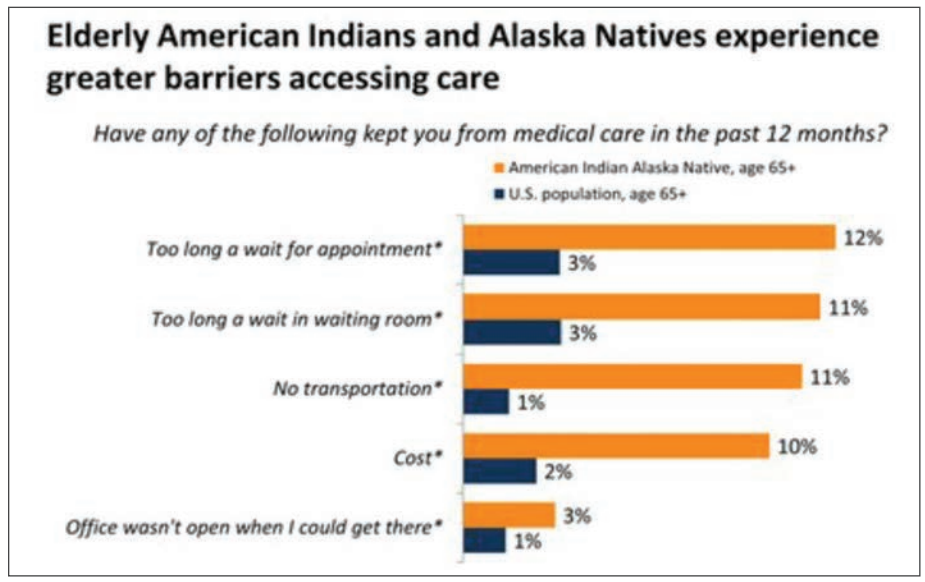

Figure 3. Elderly American Indians and Alaska Natives experience greater barriers accessing care.

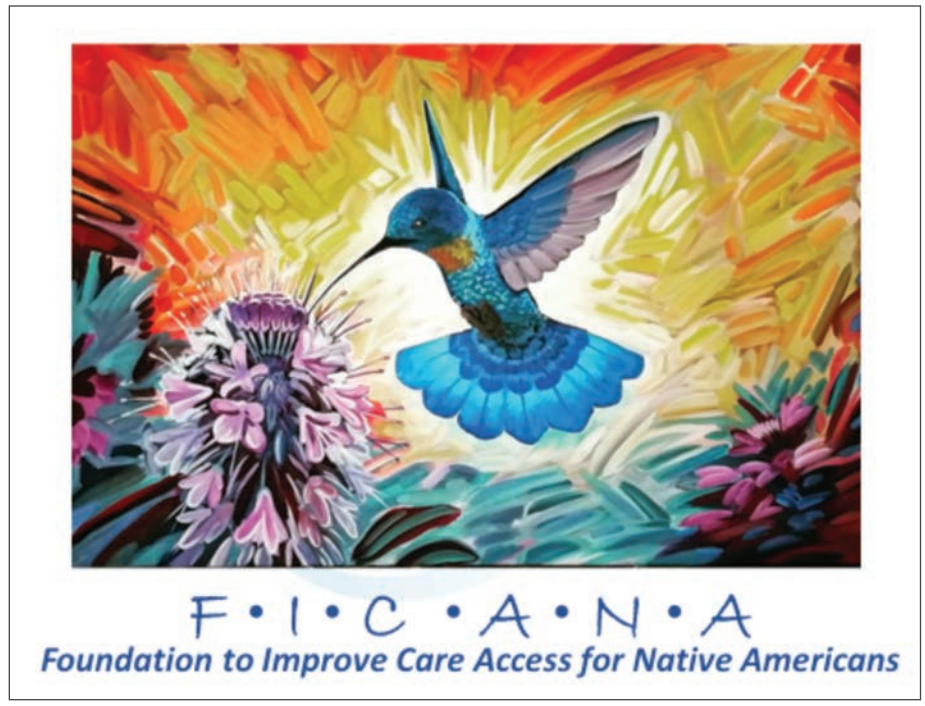

Figure 4. FICANA, a non-profit foundation to remove healthcare barriers for Native Americans, was created in 2017.

Stories in CLI: Dr. Lee Sanders and The Storyteller's Tale

Paul Michael, MD

Paul Michael, MD

Lee Sanders, MD

Tyrion Lanister in *Game of Thrones* said, *"What unites people? Armies? Gold? Flags? Stories. There's nothing in the world more powerful than a good story. Nothing can stop it. No enemy can defeat it."* The stories of medicine help us remember and unite us in common goals. Our medical specialties began with creative stories, shaped by ideas, and driven by courageous personalities wanting to find truths to serve unmet needs. Studying the individuals who contributed to forging our medical cultures gives contemporary thinkers the opportunity to appreciate the struggles our foundational medical architects wrestled with as they worked together to improve quality of life of individuals and the community around them. Revisiting their stories provides an exciting opportunity to rediscover the excitement which their solutions and discoveries still give us today. Telling the stories and keeping them alive unites our medical fields with a common purpose, serving the greater good of our patients in a better way. These stories often come by our memorable mentors and living legends, helping us understand where we are going by knowing where we came from and better understanding where we still need to go.

One great storyteller who brings much joy and understanding to the culture of limb salvage and amputation prevention is a special friend, Dr. Lee J. Sanders. Many of us may find ourselves at crossroads between career and purpose, often driven by wants. The motivation and passion to preserve limbs can easily burn out without the discipline and dedication Dr. Sanders practiced with. Despite the common struggles and persistent disparities in care today, the available paths we have and opportunities to take them were not always available in the practice of limb salvage, amputation prevention, and critical limb ischemia. Dr. Sanders is someone we need to know and remember not only for his original research and literature, his dedication to reviving the significant methods and accomplishments of our historical mentors' accomplishments, but also for his story in shaping and elevating the role of the podiatric team in the multidisciplinary league of limb salvage united against preventable amputation.

It is, of course, impossible to summarize Dr. Sanders in one short interview. His humility, curiosity, and dedication to excellence in serving the needs of patients facing amputation brought him to places all over the world. His story and his writings help us focus on the type of patient-centered care that is much needed in today's culture. It also motivates us to try harder because *"You can't always get what you want, but if you try sometime you find, you get what you need." – The Rolling Stones*

Dr. Michael: Hi Lee, thanks for taking the time to share your incredible stories with us. As serendipity would have it, I came across your work hunting for information on my favorite medical hero Dr. Elliott P. Joslin when preparing for an AMP presentation on multidisciplinary teams, and I just knew I had to meet you one day. Thanks to a common friend, Dr. Vickie Driver, that meeting actually happened and we met up in South Florida where our schedules luckily aligned. Over some Stella Artois, you shared some unbelievable stories, and the rest is history. We have common passions which you effortlessly weave into your medical publications which I think many find interesting. You are a serious bibliophile, philatelist, medical historian, world traveler, and lover of multidisciplinary team care for patients. Can we start with how you landed in podiatry?

Dr. Sanders: In my senior year of college, as a pre-med student, I applied for admission to several medical schools in the United States. I remember that in 1969, Richard Nixon had just been elected President and this was at the height of the Vietnam War. The number of applicants to medical schools had increased exponentially. I was waitlisted at two medical schools in the United States and was in a holding pattern while waiting to learn my fate. At the same time, I had a one-way plane ticket to Europe. I ended up being accepted to medical school at the Université Libre de Bruxelles and was enrolled in the French section of the University. My acceptance was contingent upon completion of an undergraduate pre-med degree (with degree in hand), passing a written examination in French, and having an interview in French with members of the medical school faculty. This was a real challenge for me having had only two years of college French. I sat at a huge conference table across from the faculty. It was an intimidating experience, however, I managed to survive the interview. This was in July 1969, American Astronauts Neil Armstrong and Edwin "Buzz" Aldrin had just landed on the moon. I watched this on television and was so very proud to be an American.

In 1970, I reapplied to medical schools in the United States, as well as to schools of podiatric medicine. Podiatry was my back-up plan. I was accepted at the Pennsylvania College of Podiatric Medicine (PCPM) in Philadelphia. This was the very beginning of my career path to diabetic foot care, amputation prevention, limb salvage, health care, and education. I had no idea how far it would take me. This choice set my career in motion and has been tremendously rewarding. I have never looked back or regretted this decision. On a personal note, I met an amazing young woman, a student nurse at the Pennsylvania Hospital in Philadelphia. She has been at my side for nearly 50 years, supporting me, encouraging me, and proofreading all of my publications.

Following graduation from PCPM and completion of residency training at Saint Luke's & Children's Medical Center in Philadelphia, I became a commissioned officer in the United States Air Force. I served on active duty for two years at Clark Air Force Base, Philippines, and was assigned to the hospital's orthopedic service as chief of Podiatry. This opportunity furthered my medical and surgical skills. I enjoyed working in a hospital and being a part of a team. It was during this time that I began to focus my attention on diabetes and diabetic foot care. One of the textbooks that I brought along with me to the Philippines was a first edition (1973) of Levin and O'Neal's The Diabetic Foot. This was a comprehensive textbook dedicated to all aspects of the evaluation and

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Figure 1. A) Reinier de Graaf demonstrating to two others the pancreas of a dissected corpse; in the foreground, the retriever which Reinier de Graaf used for his experiments on pancreatic juice.
B) Illustration of the pancreas

Credit: R. de Graaf, Demonstration of pancreas. Credit: Wellcome Collection. Attribution 4.0 International (CC BY 4.0)

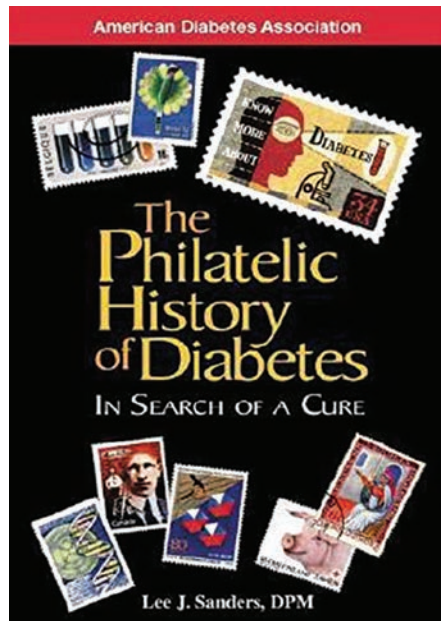

Figure 2. In this book, Dr. Sanders included what he believes is the first illustration of the human pancreas.

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MICHAEL *from page 6*

management of the diabetic foot and its complications. I read this book cover to cover and would daydream about contributing a chapter to this book one day. That day would come for me in 1993, with a chapter on the *Charcot Foot, in the 5th Edition of The Diabetic Foot*.[1] This was the beginning of a lasting friendship with Dr. Marvin Levin.

When I completed my obligation to the Air Force I returned to Pennsylvania. After a year in private practice, I chose to apply for a position at a VA Hospital. I was granted an interview at the VA Central Office in Washington D.C. A week later I was offered a position at the VA Medical Center in Lebanon, Pennsylvania. Once there, I was given marching orders by the National Director of the VA Podiatry Service to accomplish several goals: to become board certified, to obtain a podiatry school faculty appointment, to start a formal podiatry externship and residency program, to do research, and to publish. This was a tall order to fill. However, over time I completed all of these objectives.

Dr. Michael: Without your struggles and your try try-again attitude, your journey would obviously never have been the same. Seeing how history rhymes, what strategies facilitated eliminating barriers between the developing culture of podiatry and other medical specialties leading to the acceptance of the groundbreaking lower extremity work you were doing that eventually led many medical and organizational interdisciplinary teams?

Dr. Sanders: My early years at the VA Medical Center were frustrating to say the least, since, as a podiatrist I did not rank very high on the medical staff hierarchy. Initially, my request for surgical privileges was denied, in spite of a glowing letter of recommendation from the Chief of Orthopedics at Clark Air Force Base. My boss at the VA, the chief of surgery, made it abundantly clear that he would not support me. His exact words were "Sanders, I don't want to be a pioneer." He then went on to say that I had only 30 minutes for lunch and that I did not need to attend monthly medical staff meetings. I was speechless. Fortunately, once he retired, things improved significantly. I received surgical privileges, started a residency program, began to conduct clinical research, and to publish. My status as a podiatrist was significantly elevated, as I became accepted by the medical and surgical staff. In fact, I was elected President of the Medical Staff from1988-1990. I persevered, and this set me on a path to the team approach to diabetic foot care. I worked closely with a diabetologist, a diabetes nurse educator, an infectious disease specialist, and a general surgeon. What really made a big difference for me was the support and encouragement of my Medical Center Director, Leonard Washington, one of the finest gentlemen that I have ever met.

Dr. Michael: Your career is marked with many accomplishments, one that particularly stands out for its multidisciplinary magnitude is becoming the first podiatrist to lead the American Diabetes Association. Tell us how you became involved and which accomplishments with the institution you cherish the most.

Dr. Sanders: It was during the years 1988 to 2002 that I was a volunteer for the American Diabetes Association. At first on a state level, serving on the Board of Directors and Research Committee of the Mid Pennsylvania and Pennsylvania Affiliates of the ADA and then on a National Level. On the National level I served as Chair of the Council on Foot Care and on numerous committees and task forces. I was elected to the National Board of Directors (1996-2002) and to the Executive Committee (1998-2001). Eventually I became ADA's President for Health Care and Education (2000-2001), the first and only podiatrist to achieve this position. This was clearly the highlight of my career. My role with the ADA took me to the halls of congress and to other federal agencies to advocate for federal funding for diabetes research and health care. This included a landmark Medicare Coverage Policy Decision in 2001 that provided coverage for foot examinations for Medicare beneficiaries with diabetic peripheral neuropathy and loss of protective sensation. In 2001, I traveled to Beijing with ADA Vice President Dr. Christopher Saudek, Professor of Endocrinology at Johns Hopkins University, to meet with representatives of the Chinese Medical Association. The purpose of this visit was to discuss collaborative educational opportunities for Chinese physicians to learn more about Western medicine for the management of diabetes. On April 4, 2001, I had the opportunity to represent the American Diabetes Association at a Research to Prevention Congressional Briefing that addressed the burden, costs, and prevention opportunities associated with chronic diseases. Together with representatives from other voluntary health organizations, we addressed critical health issues and emphasized the importance of focusing our attention on populations disproportionately affected by these diseases. I cherish all of these accomplishments as well as the shared knowledge that I received and the friends that I made along the way.

Dr. Michael: Critical Limb Ischemia, Amputation Prevention, and Wound Management would never be what they are today without the groundbreaking work of the amazing British physician Dr. Paul Brand. Through his service, spirit, and surgical work, discovering novel therapies for Hansen's disease, and treating leprosy, he found his calling back in India where he was born and raised to missionary parents. Dr. Brand essentially discovered that loss of protective sensation, which he termed "The Gift of Pain," was the root issue in limb loss. Just as you connected with so many people interested in amputation prevention, Dr. Brand translated the peripheral sensory neuropathy he studied in leprosy patients to the "diabetic ulcers" American diabetologists were observing. After proving that leprosy related tissue loss could be prevented, he observed striking commonalities between diabetes and leprosy and helped clear the misconception that amputation was the only option for diabetic foot ulcers. Lee, you made many of the same conclusions with your groundbreaking work in tissue preservation and partial amputations. How did this critical work lead you to meet Dr Paul Brand?

Figure 3. (A) This is Jean-Martin Charcot's Library, which was originally in his home. His son J-B Charcot donated the library to the (B) Salpetriere. Deb and I visited the Library by appointment in 2007. I presented my translation of Charcot's 1868 paper to the librarian, who thanked me and said "Professor Sanders I already have your paper." (C) Charcot's home, as mentioned in the article.

Dr. Sanders: I first met Dr. Paul Brand, a world-renowned orthopedic surgeon, at the US Public Health Service Hospital, National Hansen's Disease Center, on the banks of the Mississippi, in Carville, Louisiana in 1983. I attended a course there on the assessment and management of patients with neuropathic foot ulcers. Paul shared the lessons he had learned treating neuropathic ulcers in patients with leprosy and transferred these findings to patients with diabetes and neuropathic foot ulcers. Dr. Brand discussed the pathomechanics of soft tissue including the effects of repetitive mechanical stress on the skin. He demonstrated this with experiments on the footpads of rats. Paul also discussed surgical management of the diabetic foot with transmetatarsal amputation and lengthening of the Achilles tendon. Paul Brand served as a consultant to me and to Dr. Peter Cavanagh, in the 1980s, for a VA/Penn State University Study "The Role of Pressure Distribution Measurement in Diabetic Foot Care."[2,3] I corresponded with Paul for several years and was privileged to honor him for his lifetime contributions in 1995 at ADA's 55th Annual Meeting and Scientific Sessions, in Atlanta, Georgia.

Dr. Michael: Describe how you became interested in perfecting the practice of TMAs and tissue preservation.

Dr. Sanders: My concerns regarding foot structure and function following ablative forefoot and midfoot procedures called into question some of the digital and ray amputations that had been performed on patients who were then referred to me for treatment. These feet were often difficult to fit in a shoe, they were deformed, foot function was impaired, and they repeatedly ulcerated. Leland McKittrick, MD, Chief of Surgery at the New England Deaconess Hospital (1931-1966) introduced the transmetatarsal amputation in 1944.[4,5] He recognized that amputation of a toe, in particular the great toe, with its metatarsal

Continued on page 10

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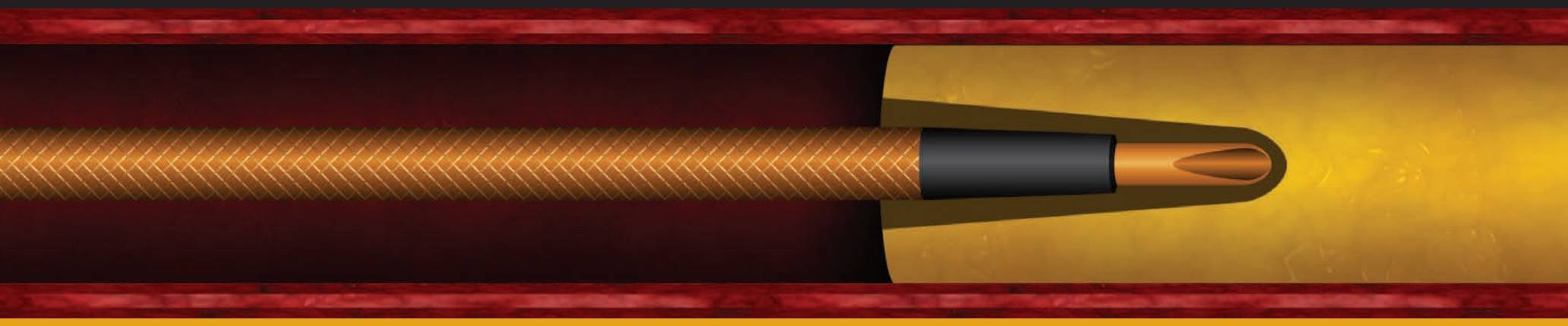

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J Hist Neurosci (1992): 1, 75–87. 75

On some arthropathies apparently related to a lesion of the brain or spinal cord, by Dr J.-M. Charcot, January 1868

Translated and Edited by Georges Hoché and Lee J. Sanders*

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Among the diverse conditions that may develop in the extremities as a result of certain traumatic or spontaneous lesions of the peripheral nerves, some as we know, have a predilection for the joints. This group of arthropathies has for a long time attracted the attention of observers and is frequently discussed today as an example of various nutritional disturbances that sometimes affect the distribution of nerve trunks affected by some alteration of a greater or lesser degree. Such conditions have been the subject of many important studies and I do not believe that at this time one can add much to the interesting work recently published by one of my old students Dr J.B.A. Mougeot[1]. Some features, less well known but no less remarkable, do exist that tend to establish the fact that joints can also be affected more or less directly as a result of lesions, not of the peripheral nerves, but of the central nervous system, ie of the brain or the spinal cord.

The purpose of this article is to reveal a broad outline of some clinical and autopsy observations which, if I am not mistaken, deal with this latter category of arthropathies. It seemed to us that the study of these observations might yield some information about the influence of the nervous system on the process of nutrition, and this is what stimulated our observations. However, for the time being we plan to limit ourselves to stating the facts while eventually developing the physiological events that these observations suggest.

We shall observe two main groups: The first group will involve a specific condition of the joints which sometimes manifests itself in the course of progressive locomotor ataxia; the other group will include several examples of a type of arthritis, which affects, under certain circumstances, the

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[1]J.B.A. Mougeot, Research on some nutritional disturbances subsequent to affections of the nerves, pp 32, 79, Paris, 1867.

Figure 4. On some arthropathies apparently related to a lesion of the brain or spinal cord, by Dr J.-M. Charcot, January 1868

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MICHAEL *from page 8*

head, increased the susceptibility of the foot (toes and metatarsals) to further injury. As a result, he preferred "the relative security" of a transmetatarsal amputation (TMA). In 1992, I published an outcomes study on 42 consecutive transmetatarsal and midfoot amputations that were performed by me over a six-year period at the Lebanon VA Medical Center. The purpose of this study was to characterize the veteran patient population having transmetatarsal amputations, to identify the indications for surgical intervention and to determine the effectiveness of this conservative approach. Results of the study demonstrated that TMA under regional ankle block anesthesia is a safe and successful approach to limb salvage. 72% of the amputations performed in this study were on diabetics. Peripheral neuropathy and chronic ulceration were significant factors in the pathway to lower extremity amputation in our patients with diabetes. 30 of the 34 TMAs (88%) healed successfully. Two of these patients returned to the operating room for debridement of necrotic tissue and in one case for revascularization.[6]

In 1997, I published an article on indications and technique for Transmetatarsal and Midfoot Amputations.[7] Several years later I was invited to speak on this topic at a surgical meeting in Italy. Among the notable faculty at this meeting was the eminent vascular surgeon Frank LoGerfo, MD. Following our lectures Frank and I had dinner together, accompanied by our wives. Frank complemented me on my lecture and was surprised at how much thought went into my surgical approach to transmetatarsal amputation. I thanked Dr. LoGerfo and explained my concerns for residual foot function, how the foot would fit in a shoe, how durable the stump would be, and, of course, the cosmetic result. Frank subsequently invited me to write a chapter on Ray and Transmetatarsal Amputations for the Fifth Edition of Josef E. Fischer's Mastery of Surgery.[8] I gladly agreed.

Dr. Michael: Your admiration for French physician Jean-Martin Charcot is not just a historical novelty but an inspiration to much of your work, as your work has also been inspirational to the field of limb preservation. Can you tell us a bit about your fascination with Charcot?

Dr. Sanders: My fascination with the Charcot foot and with Professor Jean-Martin Charcot began in the 1980s. I saw my first acute case of diabetic neuropathic osteoarthropathy in 1982 and totally missed the diagnosis. The patient was a 63-year man with a history of poorly controlled type 2 diabetes, peripheral sensory neuropathy and a left below-knee amputation (BKA). He arrived at the Emergency Department on his motorcycle. The patient reported no history of trauma, only mild discomfort, acute swelling, redness and mild deformity of his right foot. I admitted the patient to the hospital, attempted a closed reduction of his tarsometatarsal dislocation in the operating room, and put him in a non-weight bearing total contact cast. Sadly, because of his left BKA we couldn't keep him off of his right foot. The end result was further collapse of his foot with chronic non-healing ulcers over the medial cuneiform and at the apex of his collapsed foot. This ended badly with a BKA amputation of his right leg. Lesson learned, you see what you look for and recognize what you know. I hadn't recognized the problem.

During the time frame of 1982-1989 I treated 28 confirmed cases of diabetic neuropathic osteoarthropathy with 39 affected extremities. Together with my podiatry resident, Dr. Donald Mrdjenovich, we gathered all of the x-rays, detailed medical records and photographs for these patients and performed a retrospective analysis. We looked at age, sex, duration and type of diabetes, sites of bone and joint involvement, presence of plantar ulceration and their association with anatomic patterns of involvement. We also looked at clinical laboratory data, including erythrocyte sedimentation rate and white blood cell counts. An abstract of the results of the study was presented at the International Diabetes Federation Congress (IDF) in Washington, D.C. in June 1991, and published in the textbook The High Risk Foot in Diabetes Mellitus.9,10 The classification of these anatomic patterns of bone and joint destruction in the Charcot foot has since been referenced around the globe.

Dr. Michael: Is it true that you really had dinner in Charcot's house? Do tell.

Dr. Sanders: Yes, I had dinner at J-M Charcot's house twice in 2010 and again in 2011. The first time was serendipitous. I was in Paris for a diabetes advisory board meeting, after which I was taken to dinner at the Maison de l'Amérique Latine, 217 Boulevard Saint-Germain. The Restaurant's address was familiar but I couldn't connect it until I arrived there. What I saw was a stately home with an inscribed plaque just to the left of the front door. The inscription, in French, read "Professor Jean-Martin Charcot born in Paris on 29 November 1825, Founder of the Salpêtrière School, lived in this hotel from 1884 until his death on 16 August 1893. His son Commander J-B Charcot lived here during his youth." I asked someone to take a picture of me standing in front of the plaque. This immediately piqued curiosity. Who was this man they asked? For the rest of the evening Jean-Martin Charcot was the topic of conversation.[11,12,13] In 2011 I returned to Paris for an international task force of experts meeting, convened at the Salpêtrière Hospital, by the American Diabetes Association and the American Podiatric Medical Association. The purpose of the meeting was to summarize available evidence on the pathophysiology, natural history, presentations, and treatment recommendations for the diabetic Charcot foot.[14] Yes, this time I arranged for the task force to dine at the Maison de l'Amérique Latine. A very special treat for everyone.

Dr. Michael: Were you always so interested in history? How did your love for history start, what's your favorite piece in your collection, and what advice can you share about the importance of history in practicing medicine?

Dr. Sanders: Although I had a general interest in world history as a youth, it was not until I became a podiatrist that I developed a focused interest on the history of medicine, specifically as it relates to medical conditions that are relevant to my work. This was the case with diabetes and its complications. I firmly believe that knowledge of the history of medicine gives us a better understanding of contemporary issues and a clearer vision as we look to the future. I have been fortunate to have had access to the library resources of the VA and the New York Academy of Medicine Malloch Rare Book Room,

which enabled me to locate original source materials for manuscripts that I have written. I recall the thrill to see and handle, with white gloves, Andreas Vesalius' Masterpiece *De Humani Corporis Fabrica (On the Fabric of the Human Body)*, first edition 1543. This is one of the most beautiful scientific books ever written. I was looking to see if Vesalius illustrated the human pancreas. He did not, however, the librarian recognized my disappointment, and pointed to a pile of books that she had set aside for me. In that pile I found what I believe to be the first illustration of the human pancreas, by Renier de Graaf in 1641. I included a photo of the engraved plate of the pancreas in a book that I wrote on the history of diabetes for the American Diabetes Association.[15] This was a unique project directed at health care professionals, as well as to people with diabetes and their families.

I've written about Jean-Martin Charcot, one of the most celebrated French physicians of the 19th century. He created the foundations of neurology as an independent discipline. His name is attached to the distinct pathologic entity, Charcot's joint disease. Together with Dr. George Hoché, a general surgeon, we translated Charcot's 1868 classic paper, Sur quelques arthropathies qui paraissent dépendre d'une lésion du cerveau ou de de la moelle épinière, On some arthropathies related to a lesion of the brain or spinal cord published in the *Journal of the History of the Neurosciences*.[16]

Dr. Michael: How was the field of podiatry and foot & ankle surgery different then vs now? What major changes have you observed allowing the field and its culture to be so well integrated in the interdisciplinary approach to amputation prevention?

Dr. Sanders: Then: When I graduated from podiatry school there were not enough residency positions for all graduates. It was extremely competitive, and most positions were for just one year. There were just a handful of second year positions. Some programs didn't pay their residents, as was the case for me. I was told to be thankful that I had a position, and I was. Fortunately, I had two additional years of military hospital experience in a multidisciplinary noncompetitive setting. The scope of surgical practice in those early years was largely forefoot surgery (hammer toes, bunions, interdigital neuromas), soft tissue and some midfoot & rearfoot procedures. Hospital privileges were limited, and most orthopedic surgeons looked down their noses at podiatrists.

Growth of postgraduate training programs and research were critical to the advancement of podiatric medicine in the 1980s, 1990s and the first two decades of the 21st century.

Now: The scope of podiatric education, post graduate residency training (3 years) and specialized fellowship training have advanced significantly. Fellowships in limb salvage, wound care and diabetic foot research have added additional opportunities for multispecialty integration. Podiatrists are now included with orthopedic surgery groups across the country.

We have made significant contributions in the areas of diabetic foot care, wound care, prevention of amputation, foot & ankle surgery, limb salvage, sports medicine and clinical research. Comprehensive standardized training has helped clarify any ambiguity in the medical community regarding the scope and quality of podiatric medical education.

Dr. Michael: If you could design the ideal multidisciplinary team, who would you bring on and how would it be run?

Dr. Sanders: Diabetic foot patients are among the most complex and vulnerable of all diabetes patients, with high morbidity and mortality. Specialized diabetic foot clinics should be equipped to coordinate revascularization procedures, to aggressively treat infections, and to manage medical comorbidities within a multidisciplinary setting. Optimal management of diabetic foot complications is best provided in a comprehensive diabetic foot clinic. The clinic must be available to manage emergencies and to initiate immediate parenteral antibiotic therapy. It must also be able to obtain rapid vascular, podiatric, and orthopedic opinions and to arrange for emergency admissions to the hospital.[17]

I would design a Diabetic Foot Rapid Response Team, following the Toe and Flow model, with emphasis on early revascularization, treatment of infection, and soft tissue reconstruction. My team would consist of a diabetologist, podiatrist, vascular interventionalist/surgeon, infectious disease specialist, general surgeon, orthopedic surgeon, plastic surgeon, pedorthist/prosthetist, and a social worker.

The gatekeeper would be the podiatrist, the vascular interventionalist/surgeon, or the diabetologist, depending on where the patient enters the system of care.

Dr. Michael: Is there anything else you would like to share with our readers?

Dr. Sanders: I am very fortunate to have enjoyed a very successful and rewarding career, that has taken me around the world. Along the way I've had the privilege to meet and work with some amazing people: patients and their families, residents, colleagues, collaborators, librarians and ADA staff. In my retirement I have the pleasure of spending more time with my wife, my children and grandchildren. My wife and I continue to travel, especially to places that remain on our bucket list. Just prior to the COVID-19 Pandemic we visited Alaska and Israel. As an amateur wildlife photographer, there are many opportunities to head out with my camera. I have always had a camera close by, especially during my years working for the VA, capturing clinical photos for case reports, journal articles and chapters in textbooks. My clinical photos were definitely not for sharing at social gatherings. Fortunately, now I am only too happy to share my photos, especially those of my grandchildren.

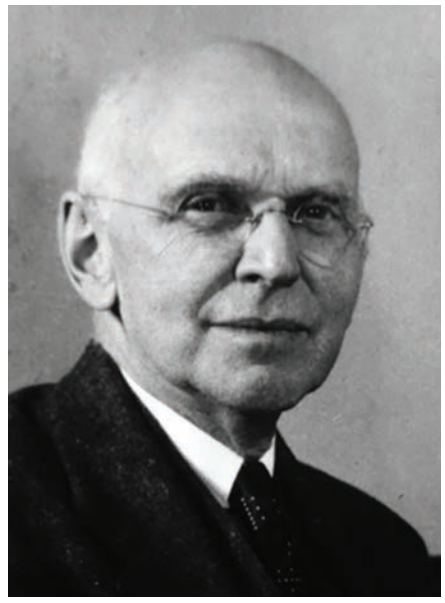

Figure 5. Elliott Proctor Joslin, MD (1869-1962), Director of George F. Baker Clinic, Internal Medicine, New England Deaconess Hospital, Boston, Massachusetts. Courtesy of the National Library of Medicine.

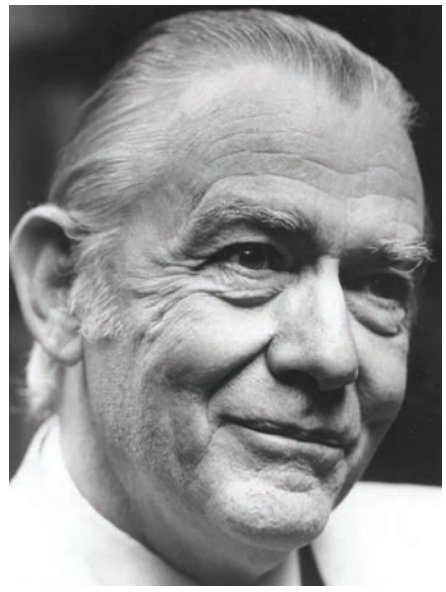

Figure 6. Paul Wilson Brand, MD (1914-2003), renowned orthopedic hand surgeon and leprosy specialist. Brand spent years re- searching the cause and effect of the neuropathic limb. Photo courtesy of John H. Bowker, MD.

My years as a volunteer for the American Diabetes Association are among the highlights of my career. I have looked forward to attending the ADA Scientific Sessions each year. This provided a great opportunity to meet with other professionals (podiatrists, orthopedists, vascular surgeons, cardiologists, general practitioners, nurses, pedorthists and psychologists) who share a common interest in management of the diabetic foot, including wound care, limb salvage and amputation prevention. In June 2020, I was honored by the American Diabetes Association as the recipient of the 2020 Roger Pecoraro Award, in recognition of outstanding contributions to the knowledge and treatment of the diabetic foot. My virtual presentation at this year's Scientific Sessions was titled Collaboration for the Advancement of Diabetic Foot Research and Education. I have been fortunate to have outstanding collaborators.

Dr. Michael: The only way to fully experience the passion and stories of the great tellers is to listen to and read them ourselves. I hope this brief exposure to Dr. Sanders and his stories may motivate others to read his works and the history Dr. Sanders so thoroughly has collected and presented for us to cherish. The spirit of amputation prevention has definitely been strengthened through his works and by the personalities he brings to life which hopefully unifies us all in saying no to preventable amputation. ■

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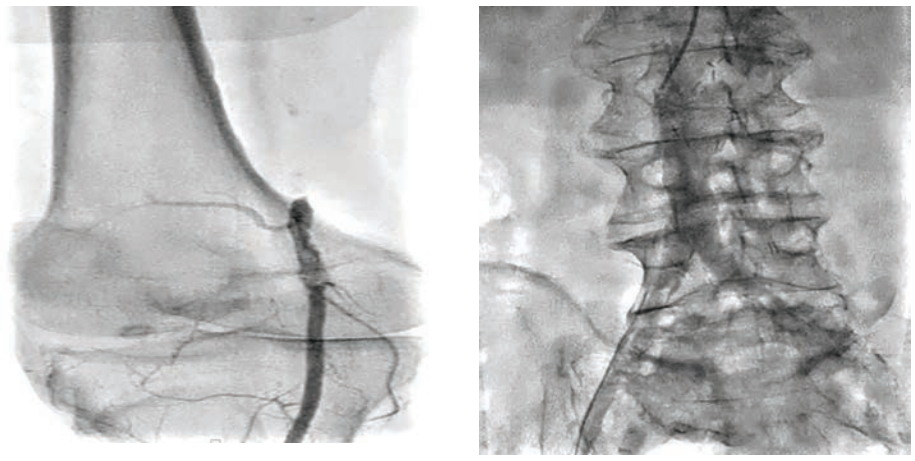

Figure 2. Angiography revealed significant stenosis in bilateral common iliac arteries with 100% occlusion of the external iliac arteries, internal iliac arteries have moderate to severe stenosis. The right common femoral and SFA are 100% occluded with distal reconstitution of the right popliteal artery.

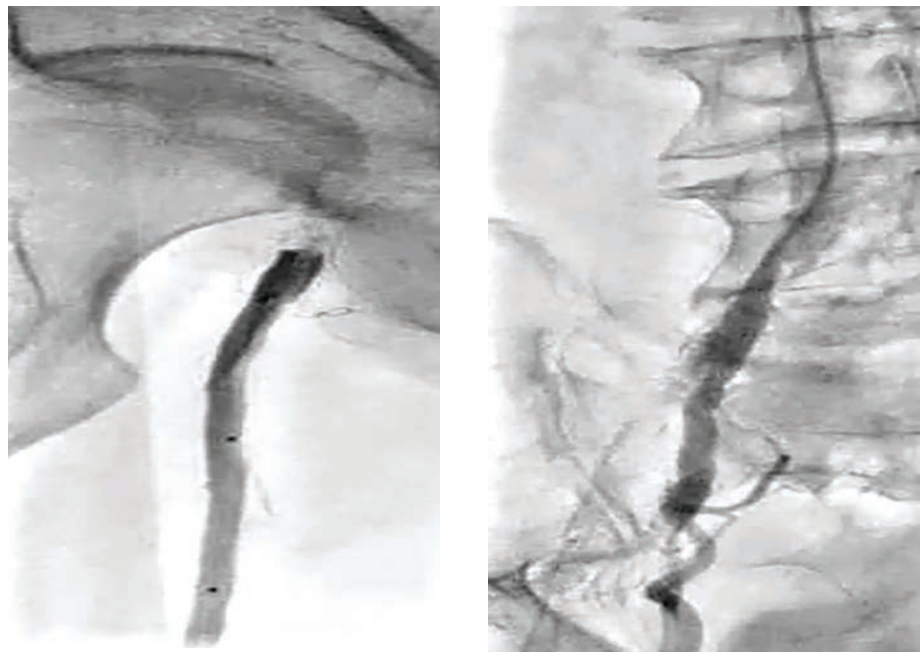

Figure 3. Intervention of the right SFA retrogradely from the anterior tibial artery using A 0.035˝ Navicross catheter (Terumo) and 0.035˝ Glidewire advantage (Terumo). The Navicross was exchanged for a 0.035˝ Trailblazer (Medtronic) and still would not cross the cap. A multipurpose catheter was used to guide retrograde intervention.

AZZAM *from page 3*

bypasses and attempted percutaneous interventions. In 2009 the patient underwent an unsuccessful attempt at intervention of his right superficial femoral artery (SFA). Then, in 2010 a right fem-pop and right to left fem-fem bypass was performed. In 2011 the patient underwent a bilateral aorto-profunda bypass surgery. Despite attempted intervention and multiple bypass surgeries, the patient continued to have severe peripheral vascular disease and associated CLI symptoms.

Arterial duplex was performed and revealed occluded fem-pop, fem-fem graft and bilateral SFA occlusion with reconstituted flow in the peroneal and anterior tibial arteries and the bilateral aorto-profunda bypass graft is widely patient. Due to the complexity of the bypass grafts and the arterial duplex results computed tomographic angiography (CTA) was done in order to better plan the percutaneous intervention of the right SFA. The CTA reveled 100% occlusion of the right common iliac with reconstitution at the popliteal artery (Figure 1). From the CTA images we were able to plan for right pedal and right radial access for the SFA intervention.

The patient was brought to the cath lab, and under ultrasound guidance right dorsalis pedis arterial access was obtained and a 4 Fr x 45 cm Fortress sheath (Biotronic) was placed. A right radial access was obtained during the procedure and a 5/6 Fr Slender sheath (Terumo) was placed. Selective angiography of the right anterior tibial artery revealed an occluded popliteal artery with patent anterior and posterior tibial arteries. Using a 125 cm multipurpose guiding catheter, selective abdominal angiography revealed significant stenosis in bilateral common iliac arteries with 100% occlusion of the external iliac arteries. Internal iliac arteries have moderate to severe stenosis. The right common femoral and SFA are 100% occluded with distal reconstitution at the distal right popliteal artery (Figure 2).

We proceeded with intervention of the right SFA retrogradely from the anterior tibial artery with a 0.035-inch Navicross catheter (Terumo) and 0.035-inch Glidewire Advantage (Terumo). This was able to cross the distal cap of the SFA up to the proximal SFA where it would not cross the proximal CTO cap. The Navicross (Terumo) was exchanged for a 0.035-inch Trailblazer (Medtronic) for better support, but crossing was unsuccessful. We then exchanged for a Gaia 3rd 0.014-inch wire (Asahi), which, with the Navicross (Terumo), made some progress but would not cross into the true lumen of the external iliac artery (Figure 3). Using the right radial access, we exchanged the 5/6 Fr Glidesheath Slender (Terumo) over Glidewire Advantage (Terumo) for 7Fr

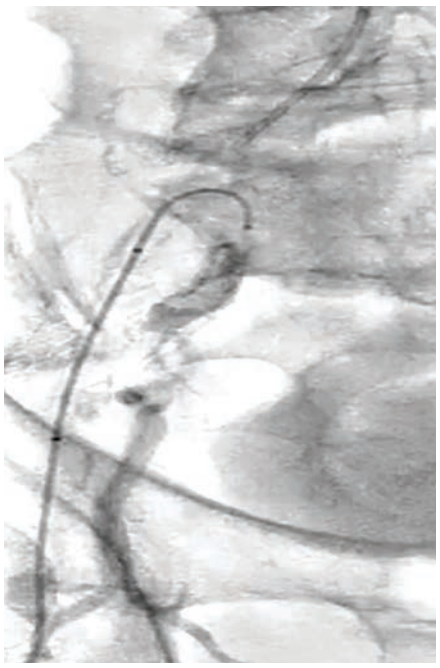

Figure 4. A Navicross catheter (Terumo) and Gaia 3rd wire (Asahi) were advanced into the right internal iliac artery, and used to enter the true lumen of the external iliac artery. purpose catheter was used to guide retrograde intervention.

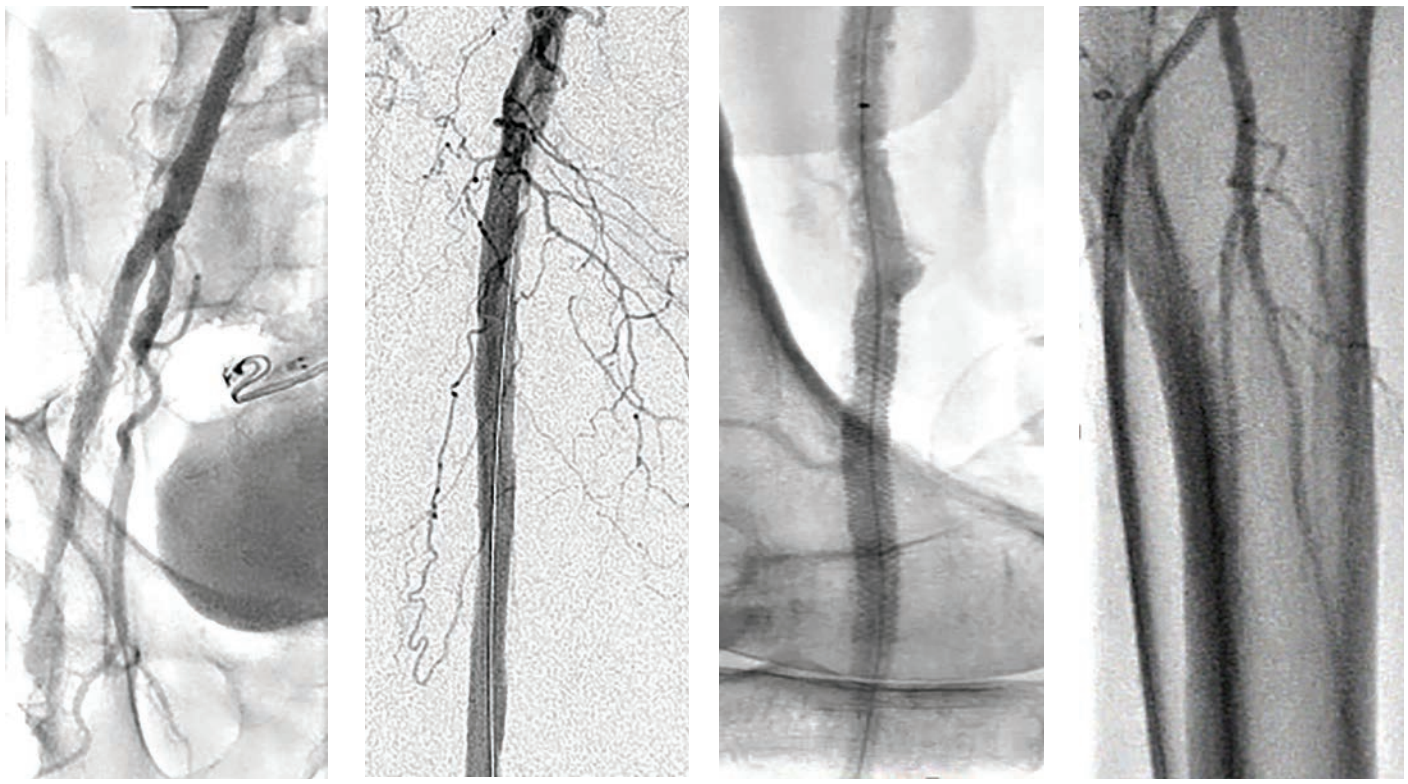

Figure 5. The distal SFA was stented with a 6.0 mm x 150mm Pulsar self-expanding stent (Biotronic) and a 6.5 mm x 60 mm Supera self-expanding stent (Abbott). Final angiography revealed less than 10% residual stenosis at the stented segments and three vessel run-off.

90cm Destination sheath (Terumo). We then advanced a 125 cm multipurpose guiding catheter to guide the retrograde intervention. The system was upgraded to be ready for covered stents if needed. Using the Navicross catheter and Gaia 3rd wire, we were able to advance the system into the right internal iliac artery (Figure 4). We then were able to use the angle of the Navicross catheter and Gaia 3rd to cross back into the lumen of the external iliac and advance the wire into the Multipurpose guide and externalized the wire. The pedal sheath was then upgraded for a 6/7 Fr Glidesheath Slender (Terumo). Multiple balloons were inflated for the intervention including 5.0 mm, 7.0 mm and 8.0 mm balloons.

The next step was to place stents in the right common and external iliac arteries. We used an 8.0 mm x 59 mm Omnilink Elite balloon expandable stent (Abbott) that covered the ostium of the right common iliac artery. An 8.0 mm x 80 mm Absolute Pro self-expanding stent (Abbott) was deployed in the right external iliac artery.

The distal SFA was then stented retrogradely with a 6.0 mm x 150 mm Pulsar self-expanding stent (Biotronic). After deployment there was significant residual stenosis distally, multiple balloons were inflated, including Angiosculpt (Spectranetics), with a suboptimal result. Therefore, a 6.5 mm x 60 mm Supera self-expanding stent (Abbott) was deployed in the distal SFA and popliteal artery and a 6 mm balloon was inflated across these self-expanding stents.

Final angiography revealed less than 10% residual stenosis at the stented segments and three vessel run-off to the right foot (Figure 5). The right common femoral artery has moderate stenosis that will be left for endarterectomy in the future. On follow-up visit, his symptoms were shown to have dramatically improved with no pain at rest, and only minimal pain after walking several blocks.

CONCLUSION

This case demonstrates the need for CTA in CLI patients to plan access and peripheral intervention. Unsuccessful interventions in CLI patients are reduced through the use of various modalities for diagnostic and interventional treatment. The use of radial and pedal access in CLI patients is a key for successful intervention. ■

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COVID-19 *from cover*

Race is one of the most consistently demonstrated factors leading to healthcare disparities. Black patients are more likely to undergo amputation, less likely to have a procedure prior to amputation, more likely to have an above knee amputation, and more likely to have open vascular intervention than white patients.[3,4] These trends are disturbing. The majority of the aforementioned studies attempted to find confounding reasons for these inequalities. While some portion of these disparities can be explained as race being a surrogate for socioeconomic status or access to healthcare,[5] after logistic regression and independent of all other variables, being black, alone, increased the odds of receiving an amputation by 78%.[6] These very real inequalities exist, and we need to do more than describe them if we hope to change practice patterns.

In addition to racial disparities, the intensity of vascular care and the amputation rate vary significantly across different regions.[7,8,9] For instance, patient in regions of high intensity care in a 2012 study were shown to be 2.4 times more likely to undergo a revascularization attempt the year prior to amputation. Other factors are intrinsic such as sex and race. Women are less likely to receive an open bypass and more likely to die from CLI or have an amputation than men.[10]

These trends have been clear for several decades, the real question is what do we do next?

The field of Amputation Prevention provides a unique arena to examine the thought provoking, often avoided, and uncomfortable topic of racial and ethnic disparities in healthcare due to the contribution of complex social determinants of health. Critical Limb Ischemia (CLI) represents end-stage peripheral arterial disease (PAD) and is created by a perfect storm of multiple out of control chronic disease states, primarily diabetes and foot infection which become the leading cause of preventable amputation in the United States. Worldwide, a diabetic related amputation occurs every thirty seconds. The staggering mortality numbers fueled by preventable amputations due to CLI have been well established in the medical literature. The higher mortality numbers of minorities have also been examined and documented, with African American and Hispanic patients in the US having twice the preventable amputation rates of non-minority patients. Even the mainstream media has picked up this story (CNN: Black, Latino Patients Much More Likely Than Whites to Undergo Amputations Related to Diabetes).

Despite the necessary modern awareness for this monumental medical problem, our healthcare delivery system persists in struggling to contain preventable amputations. Over one hundred years ago in Boston, a medical prophet named Elliott P. Joslin established the world's first multidisciplinary foot clinic. Joslin had the foresight to establish a multidisciplinary infrastructure, starting with seeing patients in his own home. This concept spread out into his community and eventually the entire world. He understood the pandemic proportion of a problem he called "the menace of diabetic gangrene." He described what it would become and fought a great fight for his fellow man by preaching awareness, prevention, discipline, and love. This same message is being disseminated by the Amputation Prevention Symposium (AMP) and embodied by the CLI Global Society which understand that the beginning of limb salvage is the fear of amputation.

Why then, with such amazing progress and light being shed on an old problem, do we persist in contributing to a state of preventable amputation marked by drastic disparities in all aspects of healthcare, spanning from awareness to access to delivery? Why does the modern medical culture and political system allow itself to fall short in serving those intended for it to protect? Perhaps the reason for this is that we have individually and systemically allowed ourselves to remain in a collective self-state of thinking even when attempting to comprehend others' problems. This global pandemic has proven to be a great equalizer, sparing no one and affecting anyone. Equalizing times allow us to open our peripheral vision for contemplation to focus on things that matter, and people matter, minorities matter. If people matter, then racial and ethnic disparities in amputation prevention, CLI, and all healthcare matter. We must begin to invest in who we are treating instead of what we are treating.

"While some portion of these disparities can be explained as race being a surrogate for socioeconomic status or access to healthcare,[5] after logistic regression and independent of all other variables, being black, alone, increased the odds of receiving an amputation by 78%.[6]"

The opportunity to have a respectful conversation about who and what matters was provided by the CLI Global Society on June, 24th, 2020 through a dynamic webinar "Racial and Ethnic Disparities in CLI Diagnosis and Treatment: The Ugly Truth and What We Must All Do About This." The discussion was moderated by Dr. Paul Michael, Medical Director of the JFK Wound Management & Limb Preservation Center at JFK Medical Center and hosted by The CLI Global Society Board members, Drs. Katzen, Jaff, Mustapha, and Neville, with guests Dr. Wayne Batchelor and Dr. Michael Parker.

The CLI Global Society Board members are passionate physicians who have devoted their careers to the advancement of care for patients with advanced PAD and CLI. Dr. Barry Katzen, is an interventional radiologist and Chief Medical Innovation Officer for Baptist Health South Florida and Miami Innovation Institute. Dr. Michael R. Jaff, is a vascular medicine specialist and Chief Medical Officer and Vice President, Clinical Affairs, Innovation & Technology, Peripheral Interventions for Boston Scientific. Dr. Jihad Mustapha is an interventional cardiologist, practicing at Advanced Cardiac & Vascular Centers for amputation prevention. He is the founding board member of the CLI Global Society and founder & director of the Amputation Prevention Symposium. Dr. Richard Neville is a vascular surgeon who is the Associate Director of Inova Heart and Vascular Institute and Vice Chairman of the Department of Surgery at Inova Health System. The guest speaker is Dr. Wayne Batchelor who serves as the Director of Interventional Cardiology, Director of Interventional Cardiology Research, Innovation and education, and Associate Director of the Innova Heart and Vascular Institute. Dr. Batchelor has lectured and published extensively on topics related to disparities in cardiovascular medicine.

To begin the conversation, Dr. Batchelor was asked about his thoughts on the staggering morbidity and mortality numbers associated with CLI alone. His initial impression was that health care disparities in amputation prevention further exacerbate these data in CLI. When examined closely, the amount of lives that could be saved by not only raising awareness but actually paving a pathway for a solution to addressing these differences could save millions. One solution to addressing the problem would be to design better clinical trials, inclusive of minorities, women, and older adults, taking into consideration the demographic makeup of the United States. Because minorities are largely underrepresented in trials, a huge data gap persists in outcomes research. Dr. Batchelor cited the Platinum Diversity Trial, which enrolled 1501 women and minorities across 52 centers, where coronary stent outcomes were followed to in an attempt to help provide a better understanding of treatment effects in a more diverse patient population.

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Although selecting minority populations improves detection, unknown biases also contribute to the disparities in minority outcomes as evidenced by a landmark 1999 *New England Journal of Medicine* paper. In this study, actors representing different cardiovascular disease presentations were interviewed by over 700 cardiologists. Despite the same objective test results, fewer black women were selected for cardiac catheterization. Dr. Batchelor mentioned the importance of recognizing implicit bias, the conscious and unconscious. He stated that the only way to overcome this hurdle is to recognize it and train ourselves to avoid it from the very beginning, starting in medical school. Being trustworthy, empathetic, and compassionate contributes to patient compliance, and has major implications in how we manage public health across the country.

If the data shock in regard to CLI is real, then the lack of awareness must begin somewhere. When Dr. Michael Parker, senior surgical resident, was asked "how many times did you hear the word critical limb ischemia in medical school?" The answer was "zero," despite being a well-established problem for over 100 years.

When Dr. Mustapha was asked why the CLI data are currently so poor, he stated there is a consensus for the need for meaningful data. This stems from the fact that patients facing amputation are not in trials, and this task needs to be better handled by dedicated facilities practicing CLI therapy and amputation prevention. Meaningful data feeding better therapy would reduce regional variances in care and prevent the amputation lottery which occurs on a daily basis in this country.

Recognizing our own biases in order to more effectively communicate is something physicians feel they are good at, but Dr. Michael Jaff carefully pointed out that we are not so good at recognizing what we don't know or understand. The opportunity to prove this was offered by allowing the audience to visit www.implicit.harvard.edu to test themselves in regards to self-bias and prepare to potentially be enlightened by the degree of bias we actually carry before even walking into a patient's room.

One of the issues plaguing CLI data is operator variability, Dr. Batchelor pointed out that in his data analysis the same level of respect for CAD and Structural Heart Disease operator skill is not demanded of the community when it comes to CLI. He stated it must become the responsibility of those working in the CLI space to build expert teams.

When Dr. Richard Neville was asked how we can make a dent in amputation disparities in regard to minorities, the answer was simple: fix our broken training system. He stressed that we need to increase the diversity in outreach training programs. Well established in PAD outcomes disparities, Dr. Neville stressed the importance of having the tough conversations and making a multidisciplinary plan of action to tackle these real problems, not to be afraid of them.

Dr. Katzen was asked about a unique program addressing a major need at the medical school level. He elaborated on a Florida International University Medical School's initiative to implant medical students at the community level in patients' homes from a healthcare delivery standpoint allowing each to follow a family throughout their training. By identifying underserved communities and placing students among those who are experiencing socioeconomic healthcare disparities, a sense of responsibility and empathy can begin.

Through numerous trials and studies, two of the most important predictors of outcomes after one year of cardiovascular therapy were found to be social determinants of health and bereavement. Losing loved ones dramatically affects overall mortality and myocardial infarction outcomes. Dr. Batchelor then highlighted what the implications of losing a limb would be and why it is crucial to collect these data to better understand the overall impact of untreated CLI.

Dr. Jaff pointed out that although we are in pandemic times fueling further disparities in access to care, by opening the discussion with a call to action, we are doing much better than we imagine. We now have a dedicated society, culture, and CLI specialists who are committed to moving beyond the status quo. Dr. Neville echoed this sentiment by stating that the time for talk is over, and the time for action and prevention is at hand. Integrating societies and using the platform of the CLI Global Society's dedication to amputation prevention will lead to a solution and reduce the number of people at home who face mortality accelerated by limb loss.

In his closing remarks, Dr. Neville challenged the CLI Global Society to survey patients as a new starting point to really understand the roots of their psychosocial problems and avoid the ivory tower approach to data collection. The solution to a better understanding is through the providers and patients who are suffering the most. This was also the main take-away point of Dr. Jihad Mustapha, who described in detail why the current CLI data is so poor and how a CLI focused approach benefits CLI patients. Dr. Mustapha stressed the importance of having a CLI specific code diagnoses to actually identify these patients in the healthcare system and allow them to be heard and felt in the healthcare system for the disease burden they are bearing. Without the code to identify CLI patients, Dr. Katzen acknowledged that the costs associated with this critical illness are hidden within numerous avenues of healthcare, making them difficult to measure.

The panel ended by reinforcing the need to develop a new comfort level with the uncomfortable, and recognition of how during a time of social distancing we can come together to find new meaning in providing inclusive amputation prevention therapy. The conversation took on an often-avoided topic of minority morbidity and mortality associated healthcare disparities and agree that something must be done, and something will be done. Minorities matter. ■

"It must become the responsibility of those working in the CLI space to build expert teams."

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JOURNAL *from cover*

bring together a multidisciplinary group of healthcare providers around the globe to discuss contributing factors that create challenges for CLI. Over the past six years we have seen increased awareness for CLI, development of more research in the field and an increase in the number of dedicated CLI specialists.

We have seen interest and growth in CLI educational opportunities such as the Amputation Prevention Symposium, which has more than doubled in attendance since the first issue of CLI Global was published.

We have seen expansion of CLI care into the outpatient arena. I ponder why highly performing physicians who specialize in CLI leave large institutions to focus exclusively on CLI. I believe my story is like many. When we truly look at the CLI patient and the challenges they encounter, we realize the limitations in their care. It takes a very dedicated and passionate provider to work with the patient to coordinate care with their PCP, podiatrist, cardiologist, revascularization specialist, infectious disease physician, nephrologist, and wound clinic. There is a cascade of care for the CLI patient that can start with entry into any one of the specialists listed. CLI is a chronically managed illness that is managed for the lifetime of the patient. And we know that the CLI patient's prognosis is grimmer than most aggressive cancers. I find great reward in the complex care of CLI patients that require an intricate diagnostic workup, revascularization, and post-revascularization surveillance. Starting an outpatient CLI center of excellence that focuses on leadership, best practices, research, and training all dedicated to CLI has been one of the most rewarding steps in my career.

However, despite advances in care for CLI patients, we know there is still a long row to hoe. More attention to awareness, research, guidelines, and education must occur. The CLI Global Society Board Members and members of the Society recognize this. With this last issue of CLI Global, the Society is taking the next step forward to continue its mission. The Society strives to improve quality of life by preventing amputations and death due to CLI by collaborating with like-minded organizations that share an interest in CLI to address treatment, outcomes, coding, and reimbursement to globally improve care.

I am honored to report the launch of a new peer-reviewed journal in 2021 that will focus exclusively on CLI. The *Journal of Critical Limb Ischemia* will bring to light original research from global experts on CLI in a format that will be available internationally. We encourage you to consider submission of your work where it will be reviewed by CLI experts who understand the complex nature of critical limb ischemia. ■

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CLI Global Society Represented at AMP Virtual 2020

The need for CLI awareness and education is higher now than ever. The Amputation Prevention Symposium held their annual meeting via a virtual format this year. Over 75 expert faculty led stimulating discussion on the latest CLI data, tips & tricks, case studies and live cases from 3 U.S. centers. Nearly 800 attendees logged in from 40 states and 40 countries. The AMP meeting has always embraced the multispecialty approach to CLI. Faculty and attendees represented specialties of Interventional Cardiology, Interventional Radiology, Vascular Surgery, Podiatry, Wound Care and more.

"The CLI Global Society was well represented by the Board of Directors and Members as faculty and attendees of the meeting. CLI is not taking a rest during the COVID-19 Pandemic and neither are the #CLIFighters," said course founder and director, Dr. Jihad Mustapha.

AMP Virtual 2020 On-Demand live cases and meeting content will be available until August 13, 2021. Next year's AMP meeting will take place August 11-14, 2021 in person in Chicago, IL, USA. CLI Global Society members enjoy a $150.00 discount to the AMP meeting. Register now for both opportunities at https://www.amp-theclimeeting.com/registration. ■

AMP Virtual 2020 On-Demand live cases and meeting content will be available until August 13, 2021. Next year's AMP meeting will take place August 11–14, 2021 in person in Chicago, IL, USA

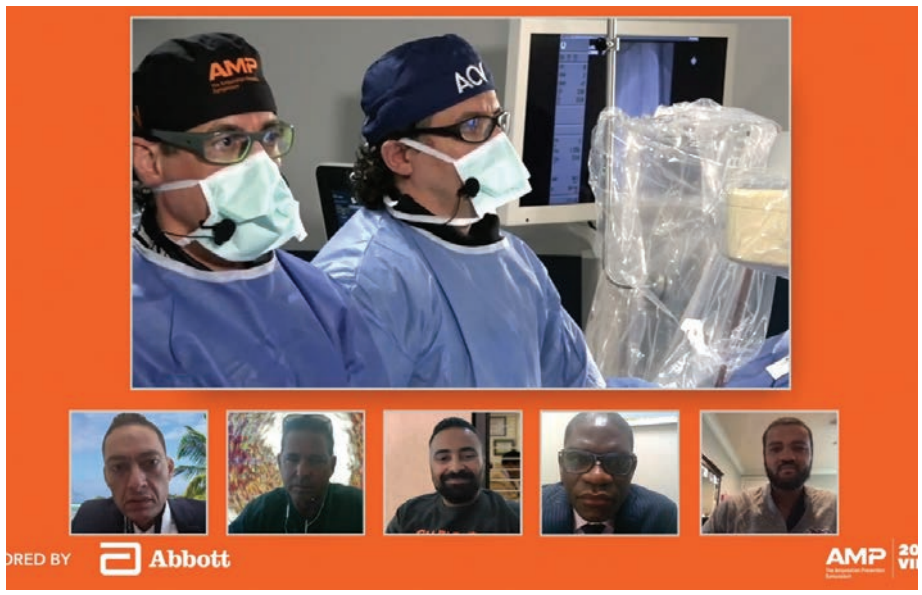

Figure 1. Drs. Jihad Mustapha (top left) and Fadi Saab (top right) performed 3 live CLI cases from their outpatient dedicated CLI Center in Grand Rapids, MI, Advanced Cardiac and Vascular Centers for Amputation Prevention. Dr. Paul Michael (moderator) and panelists Drs. John Rundback, Kumar Madassery, Zola N'Dandu, and Bryan Fisher (left to right).

Figure 2. Drs. Jihad Mustapha (top left) and Fadi Saab (top right) performed CME approved live case supported by an education grant from Philips IGTD, with some behind the scenes photos. It takes a village to perform and transmit a complex CLI case!

Figure 3. Panelists Drs. Barry Katzen, Michael Jaff, Richard Neville and Mariano Palena (clockwise from top left).

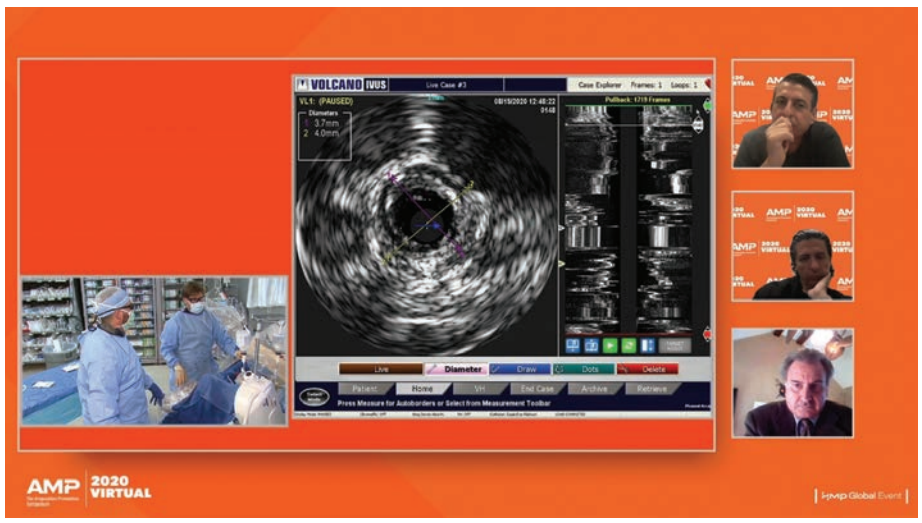

Figure 4. Dr. Chris Metzger performing a live case utilizing intravascular ultrasound (IVUS) with moderator Dr. Jihad Mustapha (top right) and panelists Drs. Fadi Saab (right center) and George Pliagas (bottom right).

Figure 5. Drs. Craig Walker, Barry Katzen, Jihad Mustapha, Thomas Zeller and Keynote Speaker, William Lombardi (clockwise from top left).

AMP 2020: Selected Abstracts from the Amputation Prevention Symposium

Outcomes of Drug-Coated vs Non-Drug-Coated Balloon Revascularization Strategy in Chronic Limb Threatening Ischemia

Stefanos Giannopoulos, MD[1]; Ehrin J Armstrong, MD, MSC[1,2]; Subhash Banerjee, MD[3]; Amutha Baskar, MBBS[3]; Haekyung Jeon-Slaughter, MD3; Ravi S. Kahlon, MD[1]; Ishita Tejani, BDS[1]
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PURPOSE: Endovascular therapy is often the preferred first treatment option for chronic limb threatening ischemia (CLTI) patients. Drug-coated balloons (DCB) reduce restenosis rates compared to percutaneous transluminal angioplasty (PTA); however, DCB use has not been studied systematically in patients with CLTI. Thus, the optimal treatment option for these complex lesions remains controversial.
MATERIAL AND METHODS: We report on 327 patients with CLTI treated either with DCB (n=105) or non-DCB (n=222) for femoropopliteal disease. Data were retrieved from the Excellence in Peripheral Artery Disease (XLPAD) registry (NCT01904851). Two DCB types were used at the discretion of the operator: Lutonix® (BARD Peripheral Vascular, Inc., Tempe, Arizona) and IN.PACT Admiral™ (Medtronic, Santa Rosa, California). Odds ratios and the respective 95% confidence interval were synthesized to examine the association between the two groups in terms of all-cause mortality, target limb repeat endovascular or surgical revascularization, target vessel revascularization (TVR), major and minor amputation at 12 months of follow up.
RESULTS: The mean lesion length was 150.0 mm (SD:123.2) and 151.2 mm (SD:108.3) for the DCB and non-DCB group respectively. No difference between the two groups was detected in terms of all-cause mortality (2.86% vs 2.7%, *P*=0.94), target limb repeat endovascular or surgical revascularization (16.19% vs 12.61%, *P*=0.25), TVR (16.19% vs 11.71%, *P*=0.26) or minor amputation (15.24% vs 10.81%, *P*=0.25) at 12 months of follow up. Although a higher incidence of 12 months major amputation was observed in the DCB group (11% vs 4%, *P*=0.01), after adjusting for several risk factors the odds of major amputation were not statistically different between the DCB and non-DCB groups (OR:1.54; 95%CI:0.53-4.51; *P*=0.43).
CONCLUSIONS: Both DCB and non-DCB strategies are effective modalities for revascularization of patients with CLTI. No differences were identified between the DCB and non-DCB group in terms of late outcomes during 12 months of follow-up.

Outcomes of Endovascular Interventions for Peripheral Arterial Disease Stratified by Rutherford Classification

Stefanos Giannopoulos, MD[1]; Ehrin J Armstrong, MD, MSC[1,2]; George Adams, MD[3]; Gary Ansel, MD[4]; William A. Gray, MD[5]; Jihad Mustapha, MD[6]; Eric A. Secemsky, MD[7]
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PURPOSE: The 12-month results of the LIBERTY 360 (NCT01855412) study have been previously published and supported endovascular therapy as a viable treatment option for Rutherford classes (RC) 2-3, RC 4-5, and even RC 6 patients. Thus, the scope of this study was to report the 3-year results of the LIBERTY 360 study, investigating endovascular outcomes of the treatment of all symptomatic RC from RC 2-6.
MATERIAL AND METHODS: Hazard ratios and respective 95% confidence intervals were synthesized to examine the association between Rutherford category (RC) at baseline and late-term outcomes over a 3-year follow up period.
RESULTS: Data from 1,189 (RC 2-3:500; RC 4-5:589; RC 6:100) patients were analyzed. The 36-month Kaplan Meier (KM) survival rates were respectively 86.0% in RC 2-3, 79.8% in RC 4-5 and 62.0% in RC 6 groups, with significant differences among all groups. The KM estimates of freedom from major amputation at 36-months were 98.5% in RC 2-3; 94.0% in RC 4-5; and 79.9% in RC 6. The 36-month KM estimates for freedom from target vessel/lesion revascularization were 71.1% in RC 2-3, 64.7% in RC 4-5 and 61.9% in RC 6 groups. Patients with claudication at baseline were at lower risk for MAE, all-cause death, major amputation, and major amputation/death compared to RC 4-5 and RC 6 patients during 36-month follow up. Vascular quality of life as measured by VascuQoL improved from baseline and was maintained at 12-, 24- and 36-months among all patients.
CONCLUSIONS: Endovascular therapy is a viable treatment option for patients with symptomatic PAD, with acceptable three-year freedom from major amputation rates and sustained improved quality of life in both claudication and chronic limb threatening ischemia. These results provide important point estimates for long-term outcomes after modern endovascular interventions for PAD.

Superior Short-term Patency of Stents Over Balloons in Infrapopliteal Artery Disease

Supraja Thunuguntla, MD; Obinna Echeruo, MD; Charles Mild, MD, FACC, FSCAI
University of Texas Rio Grande Valley

PURPOSE: The optimal strategy for revascularization in below-the-knee (BTK) chronic limb-threatening ischemia (CLTI) remains debatable. High restenosis rates of percutaneous transluminal angioplasty (PTA) often warrants re-intervention or amputations. Novel devices such as drug-eluting (paclitaxel) balloons (DEB), stents, and atherectomy devices- directional (HawkOne, SilverHawk, TurboHawk) or orbital (DiamondBack 360) are used infrequently as therapy when BTK. We aim to compare the rate of total re-occlusion between these interventions.
MATERIAL AND METHODS: A retrospective chart review of 97 patients who underwent BTK percutaneous intervention in 2015-2020 at our hospital. Descriptive statistics were used to assess the distribution of variables; continuous variables (time to readmissions) were summarized as mean values with standard deviations, and categorical variables were summarized as counts and percentages.
RESULTS: Out of the 97 patients, 73.4% met documented Rutherford category V-VI on initial admission, 53.6% patients were readmitted to our facility with Rutherford category IV-VI at 8 ± 8 months from initial intervention, 79.7% were diabetic and 62.5% were hypertensive. Interventions performed on the 208 arteries were plain balloon angioplasty 57.7%, DEB 2.9%, atherectomy with adjunctive PTA (A+PTA) 28.8%, stent 8.7% and atherectomy with adjunctive stent (A+S) 2.9%. Of the stents placed, 13 were bare-metal stent (BMS) and 11 drug-eluting (everolimus) stent (DES). Within 12 months from initial intervention, total re-occlusion post PTA occurred at 4 (±3) months, A+PTA 3.7 (±2) months, and stents 8 (±3) months (P= 0.015, F= 4.6). Comparing stents, restenosis was 53.8% in BMS versus 18.2% in DES (P= 0.09) at 6 (±3) months readmission. Re-occlusion rates 30 months from initial intervention were 58.1% for uncoated balloons, 33.3% A+PTA, 60% DEB, 50% stents and 50% A+S (P= 0.27). Twenty-two patients were not readmitted again for any reason. Of the 17 patients who underwent major amputation (below or above the knee), 10 had triple-vessel involvement below the knee, 4 had osteomyelitis. Restoring straight-line flow in angioplasty was unsuccessful in 10 cases.
CONCLUSIONS: These preliminary data suggest superior short term (<1-year) patency of stents over PTA and A+PTA BTK. Re-occlusion in A+PTA may be lower than PTA alone. DES seems to have better patency than BMS. Further studies needed to compare clinical outcomes.

Efficacy and Safety of MáLEI (Minimal Arterial Access Lower Extremity Intervention) Via Peripheral Orbital Atherectomy

Imraan Ansaarie, MD[1]; Rebecca F. Goldfaden, PharmD, CCRP[2]; Khyati Rana, PharmD[2]; Jessica Reid, PharmD[2]; Stephanie Niman, PharmD[2]; Rushab R. Choksi, PharmD[2]; Nicole Ansaarie, BSN, RN, MS[1]
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PURPOSE: Peripheral atherectomies are routinely performed via transfemoral access. However, due to increased risks for complications, time to discharge, and patient satisfaction, transfemoral access can be undesirable. The Cardiovascular Systems, Inc. (CSI) Diamondback 360® Peripheral Orbital Atherectomy System (OAS) has allowed transradial access for peripheral orbital atherectomies due to their compatibility with

6 French long radial sheaths. This study aimed to evaluate the efficacy and safety of MáLEI (Minimal Arterial Access Lower Extremity Intervention) using peripheral orbital atherectomy in patients with mild to severe PAD.

MATERIAL AND METHODS: A retrospective, unmatched, cohort, chart review study was conducted on patients with lower extremity PAD secondary to atherosclerosis (Rutherford Classification Category 2-6) who underwent at least one transradial peripheral atherectomy. The primary objective was to evaluate the clinical success of transradial peripheral atherectomies and the secondary objectives was to assess the acute complications. For the primary efficacy analysis, success rate was calculated as the proportion of procedures meeting the clinical success criteria (total number of successful transradial peripheral atherectomy procedures without conversion to transfemoral access). The primary safety analysis was calculated based on the incidence of acute complications overall.

RESULTS: Forty-seven patients, ages 44 to 91, underwent a transradial peripheral atherectomy. The baseline Rutherford Classification was 46.8% Grade 3, 12.8% Grade 4, 12.8% Grade 5, and 27.7% Grade 6. All procedures (n=47; 100%) resulted in clinical success. Vessels treated were the common femoral artery (n=5), anterior tibial artery (n=6), superficial femoral artery (n=27), peroneal artery (n=6), common iliac artery (n=4), popliteal artery (n=11), posterior tibial artery (n=4), and other (n=6). Average procedure time was 76.6 minutes, average fluoroscopy time was 28.3 minutes, and median time to discharge was 6.5 hours. No complications were noted.

CONCLUSIONS: For patients with severe PAD (Rutherford Grade 3-6), utilizing a MáLEI-transradial approach for peripheral atherectomies is a safe alternative to the transfemoral method. Findings from this analysis demonstrate that performing orbital atherectomies in the lower extremities is an efficacious and safe method with minimal complications.

Amputation Rates as an Indicator for Racism as a Social Determinant of Health

Donna Krawczyk, MCommH
Michener Institute, Toronto, Ontario

PURPOSE: Racism has been implicated as a social determinant of health alongside race in Canada. Taking data from the Ontario's universal health care system, it is seen that from comparing 2011 data from two completely different settings in Ontario, Canada that amputation rates are identified as an indicator of racism/race as a social determinant of Health. Racism in this sense is a defined systemic racism within healthcare and healthcare education that have implicated high amputation rates in Indigenous populations of rural Ontario. Racism can occur at different levels within the healthcare system where access to care and techniques in quality care can impact vulnerable populations.

MATERIAL AND METHODS: Based on an anonymous data collection of regional measures of diabetes burden in Ontario from 2011, data sourced from the Canadian Institute of Health Information Discharge Abstract Database compiled by the Institute for Clinical and Evaluative Sciences show that amputations that have been shown to be preventable with quality access to care have implications of a health crisis with unaddressed high amputation rates. Comparing with a 9% decrease of amputation rates in the urban setting among rich middle-aged white men from 2006 to 2014 with the addition of a dedicated Interprofessional Diabetic Foot Ulcer Team to handle the impact, the same quality care was not addressed in rural Indigenous communities that continue to have 7-times higher amputation rates.

RESULTS: Amputation rates in a previous study have been associated with populations of the highest-income quintile populations of white middle-aged men in the urban setting in the province of Ontario, Canada (Ge E, and Krawczyk D, 2019). However, with race/racism as a social determinant of health, it is now implicated that there is a health crisis represented by an ethnic disparity in health in Northern rural communities of Indigenous populations due to a continually high amputation rate, more so implicated by complications with the continuing 2019 pandemic.

CONCLUSIONS: Addressing the health crisis in amputation rates of rural parts of Ontario, Canada as an indicator for race/racism as a social determinant of health would make adequate changes to access to care as well as health practitioner education with the need for a podiatric school of medicine, a priority currently not reached in the universal health setting in place.

Fluorescence Point-of-care Imaging for Diabetic Foot Ulcers; Improving the Standard of Care

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PURPOSE: Diabetes mellitus (DM) rates and associated Diabetic Foot Ulcer (DFU) wound care costs in the United States continue to escalate despite the increased early recognition and interventions. Multiple potential associated factors contribute to this escalation including under recognition of micro and macro vascular disease, adequate consistent offloading and early recognition and appropriate intervention of wound bed biofilm and critical colonization with a high rate of progression to cellulitis. Infected wounds are both more labor and economic intensive to manage and increase recidivism rates. A recently introduced technology using 405 nm point-of-care, non-contact, no contrast, fluorescence imaging of DFU wounds has the ability to identify bacterial loads of >104 Colony Forming Units (CFU)/gram in wounds. This enables practitioners the clinical benefit of earlier detection of infection-causing bacteria. Earlier detection allows appropriate intervention of wound bed treatments that impact and diminish wound biofilm and critical colonization, improving antibacterial stewardship. The fluorescence imaging impact upon clinical cares has been validated in multiple peer reviewed studies to positively influence wound care management among experienced wound care providers. The purpose of this poster is to present 2 clinical cases (1 office based and 1 surgical based), the associated fluorescence imaging and impact on clinical management.

MATERIAL AND METHODS: Presentation of 2 DFU clinical cases (1 office based and 1 surgical based).

RESULTS: Non-contact, non-contrast 405 nm fluorescence imaging of presented DFUs positively impacted point-of-care management.

CONCLUSIONS: 405 nm fluorescence point-of-care imaging of DFU enables real-time identification of biofilm and critical colonization, allows targeted debridement of DFU and immediate confirmation of pathologic bacterial reduction, periwound bacterial load identification and management, improved antimicrobial stewardship and appropriate application (or avoidance) of cellular/decellularized tissue products. These beneficial characteristics of DFU fluorescence have the potential to improve cost effective management. More studies are indicated to determine if these characteristics may ultimately improve DFU outcomes thru more efficient and value based wound healing, decreased recidivism rates and/or decreased amputation rates. ■

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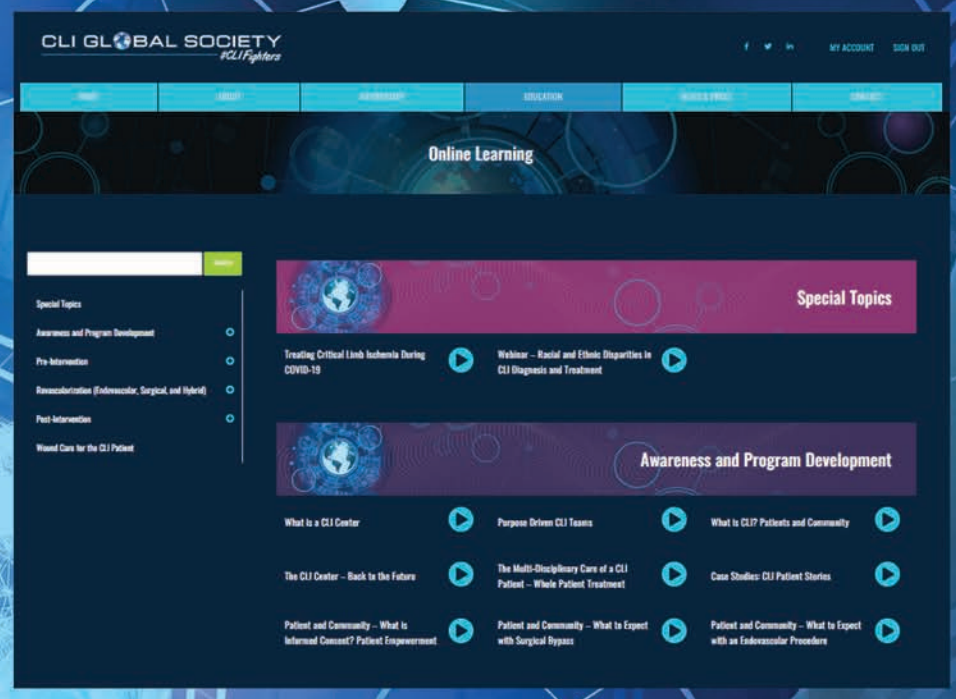

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The CLI Global Society Announces the Journal of Critical Limb Ischemia

The CLI Global Society was assembled in January of 2016, bringing together a multidisciplinary group of healthcare providers around the globe to discuss contributing factors that create challenges for critical limb ischemia (CLI). During this time, we have seen increased awareness for CLI, development of more research in the field, and an increase in the number of dedicated CLI specialists. We have seen interest and growth in CLI educational opportunities such as the Amputation Prevention Symposium (AMP), which has more than doubled in attendance since the first issue of CLI Global was published. However, despite advances in care for CLI patients, and symposia like AMP and ISET, an educational gap remains. More attention to awareness, research, guidelines, and education must occur. Because of this, the CLI Global Society Board Members are taking the next step forward to continue its mission by collaborating with HMP Global to launch a new peer-reviewed journal in 2021 that will focus exclusively on CLI. *The Journal of Critical Limb Ischemia* will bring to light original research from global experts on CLI in a format that will be available internationally.

Starting November 1st, we encourage you to submit your work where it will be reviewed by multidisciplinary CLI experts who understand the complex nature of critical limb ischemia. Visit our website for submission details: www.clijournal.com

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