Spring 2019 Symposium: New Perspectives in Diabetic Limb Preservation

Session Summaries

Opening

Mariam Botros, Wounds Canada’s chief executive officer, set the tone of the May 31, 2019, symposium by expressing that nothing is more disheartening than seeing a patient lose a limb due to a poorly managed wound.

Robin Martins, staff assistant of Christine Elliott, minister of Health and Long-term Care for the Government of Ontario, recognized the efforts of individuals in the room in education, research, advocacy and awareness in wound care and noted the difference these efforts are making. She said this symposium is another example of the leadership in this area; diabetes is a prevalent problem in Canada, and sharing information and best practice ensures patients receive the best possible care. She thanked attendees for their willingness to learn and share with colleagues, emphasizing that the symposium is part of a conversation that can improve health care for Canadians.

Green Party of Ontario deputy leader Abhjeet Manay thanked attendees for the invitation to be among those who “care, nurture and heal.” Manay noted that the health-care system places too great an emphasis on treatments and cures rather than on prevention. He went on to express frustration that politics can impede early interventions and cost millions of dollars.

Morty Eisenberg, president of the board of directors of Wounds Canada, welcomed attendees to this first event in the new symposium series. He provided an overview of the day, which would feature a panel of experts discussing important topics in the care of patients with diabetic foot ulcers, with a special focus on preventing amputation. He thanked the Canadian Podiatric Medical Association (CPMA) for its collaboration in this event.

Ahmed Kayssi, from the Department of Vascular Surgery at Sunnybrook Health Sciences Centre and the symposium’s chair, and James Hill, president of the CPMA, welcomed attendees and thanked the partnering and endorsing associations.

Get More!

The written session summaries highlight the key points presented by each speaker. For a deeper dive into the information, please view the full session videos. Just click on any video window to launch.
Keynote Address:
Multidisciplinary Approach to Limb Preservation: Past, Present, Future

Richard F. Neville, MD FACS DMSVS

Session Summary
Throughout global health systems, there is a constant need for multidisciplinary limb teams. Looking into the future, health-care professionals must have a better understanding of successful approaches to limb preservation. After this session, participants were expected to be able to understand the structure of a successful limb preservation team, explain the options for revascularization in a limb preservation program and outline research and educational opportunities associated with limb preservation teams.

There is a worldwide need for limb preservation; over seven million chronic wounds are treated annually, costing about $20 million. In addition to the physical and psychological effects of amputation, few disease processes have a higher mortality rate, which reaches 30% to 50% after two years.

Diabetic foot ulceration is a complex process caused by many co-existing factors, including trauma, neuropathy, infection and arterial insufficiency (see Figure 1). The goals of a limb preservation clinic are equally complex and might include...
increasing awareness of the program and the success rate of limb preservation, streamlining care, acting as a referral source for the community, providing patient and caregiver education, and acting as a forum for research and education.

**Figure 1:** Cofactors in Diabetic Foot Ulcer Development

<table>
<thead>
<tr>
<th>Neuropathy</th>
<th>Arterial Insufficiency</th>
<th>Infection</th>
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<tr>
<td>• Sensory</td>
<td>• Tibial disease</td>
<td>• Increased risk</td>
</tr>
<tr>
<td>• Motor</td>
<td>• Medical calcinosis</td>
<td>• Defective host defence</td>
</tr>
<tr>
<td>• Autonomic</td>
<td></td>
<td></td>
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<tr>
<td>• Decubitus</td>
<td></td>
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<tr>
<td>Minor Trauma</td>
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To meet these objectives, limb preservation clinics include the following:

- A team: vascular surgeons, cardiologists, radiologists, podiatrists, plastic surgeons, infectious disease specialists, nephrologists, endocrinologists, nurse practitioners, wound care nurses, case managers and administrators.
- A physical space, including a central core and an outpatient space
- Diagnostic imaging capabilities
- An operating room
- Vascular therapy
- Soft tissue therapy
- Patient education and support resources
- Research

- Marketing
- Financial analysis

The success of such limb preservation clinics has been seen in other countries, including the United States (82% reduction in amputation), Sweden (78% reduction), the United Kingdom (62% reduction) and Italy (from 10 to 6 amputations per 100,000 patients). We are on the cusp of truly making a difference through multidisciplinary teams to reduce both amputation and mortality.

“All politics is local; every situation is a little different. Find people who are truly interested in this topic, and just get started.”
—Richard F. Neville
The Impact of Diabetic Foot Complications: National and Global Trends

Session Summary
This session discussed the prevalence and incidence of diabetes, diabetic foot ulceration, amputations related to diabetes, and mortality post-amputation related to diabetes provincially/territorially, nationally and internationally. Speakers described the impact of diabetes and diabetic foot complications on people living with the disease and the financial impact of these complications on health-care systems. The session explored government funding approaches to diabetic foot complication prevention and management. Finally, it explored limitations to statistical data collection and reporting.

National Trends
Charles de Mestral, MD PhD FRCSC

While the number of Canadian publications on this topic has steadily increased over the past 20 years, more data are needed on diabetic foot complications. Despite the best clinical efforts, there’s an overall increase in amputation numbers due to the increasing population of persons with diabetes. Unlike cancer care centres and traumatic injury clinics, which have integrated models of care, there are few integrated amputation-prevention facilities. Limb-preservation centres exist mainly in urban areas, where amputation rates are already lowest. Individuals in lower-income communities need access to this specialized care, but often don’t have it. Funding is also an issue: diabetic foot ulcers (DFUs) cost $500 million annually across Canada (2011 data), and the cost of a patient’s care following an amputation does not return to the lower cost of their care before the amputation; it continues to rise.

Even though the community is making gains through new research, increases in the diabetic population mean more amputations overall. National and global trends emphasize the importance of diabetic foot research and preventative care.

Key Presentation Points
- The medical community needs more data on diabetic foot complications.
- Location matters in diabetic foot care. There are regional differences in amputation rates. Rates can be two or three times higher in the North, where health services are fewer and less accessible.

Global Trends
Samantha D. Minc, MD MPH FSVS FACS

Amputations are an unfortunately common complication of diabetic foot disease. This is a preventable issue, as 85% of lower-limb amputations are preceded by a diabetic foot ulcer or vascular disease. Common barriers to care include race and
socio-economic status (those with public insurance are five times more likely to have an amputation than those with private insurance). The five-year mortality rate for above-knee amputations is higher than that of breast, prostate and colon cancer, with a 50% comorbidity at one year. The health-care cost of an amputation is about $200,000 higher than lifetime health-care costs for patients without an amputation.

There are many barriers to amputation prevention, including lack of awareness and education, patient “apoplexy,” poor access to care, poor adherence to recommendations, poor co-ordination of care, social and cultural barriers, inability to cease smoking, lack of access to adequate offloading devices and, in Ontario, the cap on the number of podiatrists.

Practitioners also face organizational and institutionalized barriers such as lack of time, high costs of care, lack of research and resources, and culture (outdated practices or lack of education). These barriers can be dismantled, however, through care co-ordination, a focus on preventative care and public health, as well as comprehensive education for both practitioners and patients.

Amputation rates are a quality marker for diabetes care in the United States, an approach that should be widely spread across the globe. Preventable foot ulcers can be taken care of for a lower cost than amputation, while also improving quality of life and patient survival.

Key Presentation Points
- Amputations are devastating but preventable complications of diabetes and vascular disease, making them a marker for diabetes care quality.
- There are significant disparities in amputation rates related to socio-economic status and race. Geographic variation in amputation is likely a marker for significant variation in access to supports for positive social determinants of health.

Limb Preservation Clinics

Session Summary
This session defined the components of a successful limb preservation clinic and described the role of limb preservation clinics in preventing amputations. Speakers explored the collective knowledge and clinical skills required to run an effective limb preservation clinic. Discussions focused on successful and sustainable approaches to the development, implementation and evaluation of basic, intermediate and advanced limb preservation clinics in Canada and internationally. Speakers also discussed related national and international research initiatives.
Limb Preservation Clinics

Karim Manji, MD FACFAS

Major amputations, compared with minor, are associated with lower quality of life, significantly lower survival rates and higher costs to society. Successful limb preservation clinics are multidisciplinary centres that facilitate collaboration and close communication among specialists dedicated to limb preservation. These centres focus on the reduction of major amputations and can reduce major amputations by up to 72% by implementing the “toe and flow” model (Lee Rogers).

Toe and Flow Model of Care

According to the DRRAFT guidelines, the vascular surgeon and the podiatric surgeon constitute the irreducible minimum in the formation of a diabetic foot team. Podiatric surgeons will assess, triage and surgically manage patients with infections, and will perform advanced wound care, bone biopsies and limb preservation surgery. Vascular surgeons are crucial in revascularizing a lower extremity. Over 65% of diabetic foot ulcers have an ischemic component, making vascular surgery an essential component to limb preservation. The toe and flow model of care provides a centralized patient access point and ensures referral to appropriate specialists.

Table 1: Three Levels of Limb Preservation Clinics

<table>
<thead>
<tr>
<th>Level</th>
<th>Aims</th>
<th>Location</th>
<th>Team Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic</td>
<td>Prevention and basic curative care</td>
<td>Office, health centre</td>
<td>Podiatrist, general practitioners, nurse</td>
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<tr>
<td></td>
<td></td>
<td>small regional hospital</td>
<td></td>
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<tr>
<td>Intermediate</td>
<td>Prevention and curative care</td>
<td>Hospital</td>
<td>Podiatric surgeon, vascular surgeon, diabetologist, diabetes educator</td>
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<tr>
<td></td>
<td>Advanced assessment and diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Centre of Excellence</td>
<td>Prevention and curative care</td>
<td>University hospital</td>
<td>Podiatric surgeon, vascular surgeon, diabetes educator</td>
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<td></td>
<td>for complex cases</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Advancement of knowledge base</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Education</td>
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Karim Manji, MD FACFAS

Dr. Karim Manji is director of the Zivot Limb Preservation Centre in Calgary and president of the Association of Alberta Podiatric Surgeons. He is board certified by the American Board of Foot and Ankle Surgeons. He has an interest in diabetic foot, particularly ulcers and wound care. Dr. Manji is currently involved in research surrounding the impact of technology and its ability to improve healing times for diabetic foot ulcers and to reduce rates of re-ulceration. He is also interested in tendon releases in the foot and ankle to help treat diabetic foot ulcers.

The first toe-and-flow limb-preservation clinic in Calgary was created in 1999. Clinicians performed wound debridement in an office setting and minor amputations or limb-preservation surgeries in an operating room. This basic level of care presented many problems, as it was not sustainable and made collaboration difficult. There was also a lack
“All the members of a ball team cannot pitch the ball, and no ball team wins which tries to have each member of the nine in the pitcher’s box. It is only common sense to provide in a large general hospital for specialization in diabetic surgery.” —Elliot P. Joslin, MD, quoted by Dr. Karim Manji

of understanding of podiatric surgery at that time. Changes were made in 2006 following the formal integration of podiatric surgery into Alberta Health Services. This allowed for consultation services to be paid for, which helped to build collaboration between in-patient and out-patient care, as well as with internal medicine specialists, vascular surgeons, hospitalists and infectious disease specialists. The number of minor surgery clinics began to increase in 2006, allowing procedures to be done under local anesthesia in a single clinic to increase efficiency and reduce treatment time. In 2014, the Zivot Limb Preservation Centre (ZLPC) introduced fully integrated podiatric and vascular surgery, as well as multidisciplinary care that included practitioners in the areas of endocrinology, internal medicine, infectious diseases, orthopedics, plastic surgery and diet. This model is based on the toe-and-flow model and aims to be a centre of excellence.

Key Presentation Point
• Three factors make a limb preservation centre successful: multidisciplinary care, a central access point and collaboration among all practitioners.

Limb Preservation Clinics
Matthew Smith, MSc MD RPVI FRCSC

As Smith’s interest lies in rural care, he tries to deliver care as close to patients’ homes as possible to ease their socio-economic burden. To achieve this goal, he identifies local champions willing and able to help the cause. Some of these champions include personnel at existing wound care clinics with procedure rooms and experienced nursing staff, pedorthists, home-care companies and any other interested health professionals.

Infrastructure resources are also crucial in delivering care to rural patients. These resources include travel clinics with space, nursing and clerical support; and alternatives to traditional clinic visits, such as virtual wound care and phone follow-up appointments.

To convince administrators and policy makers that providing flexible care in rural areas makes an impact, clinicians should present their ideas as a way for the hospital to support its mission.
Clinicians should also work to find an economic advantage for the hospital, such as a tax break that not only saves them money but actually returns money to the budget. For example, clinicians might present as a benefit of mobile and non-traditional clinics the savings that can be achieved by eliminating the cost of emergency transportation between care settings.

In the future, wait times could be greatly reduced by establishing connections from a central hub (like a centre of excellence) to outreach posts that can serve rural areas.

Virtual health is another viable solution to accessible limb preservation clinics. Initial outcome measures are still required to track success and savings for administrators, but these virtual clinics will save patients and hospitals time and financial resources.

**Key Presentation Points**
- Practitioners need to let patients know they’re important.
- Stakeholders and interested health professionals should be assessed and examined in their care roles.
- Additional resources and outcome measurements are needed to advance research in limb preservation clinics.

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**Medical Management of People with Diabetic Foot Ulcers**

**Session Summary**
This session outlined the pathology of diabetes and diabetic foot disease. Speakers discussed the importance of current multidisciplinary approaches to the prevention, assessment and medical management of diabetes and diabetic foot ulcers. They provided an overview of emerging trends and research directions related to the medical management of diabetes and diabetic foot ulcers.

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**ABCD of Diabetes and Beyond**

*Robyn Evans, MD*

The presentation began with some statistics about diabetes:

- According to the new 2018 guidelines for diabetes management, the prevalence of diabetes is increasing.
- Diabetes is now the seventh leading cause of death in United States.
- In 2015, 1.5 million people were living with diabetes in Ontario. Of these, 16,000 to 27,600 had diabetic foot ulcers and nearly 2,000 had had an amputation below the knee.
- In Ontario, there is one diabetic-foot-related amputation every four hours.
- The pathway to ulceration and amputation is underpinned by vascular problems such as neuropathy, peripheral arterial disease and...
trauma. Prevention is key in these cases, as the lifetime risk of a diabetic foot ulcer is 15 to to 34%.

The Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada presented 313 recommendations, which a subcommittee distilled down to 22. From these 22, three key messages were presented:

- Reduce the risk of complications by placing more focus on patient preference.
- Ensure safety and prevent hypoglycemia.
- Address self-management goals and barriers to self-management.

Updated ABCDESSSs of Care

The ABCDESSSs of care are designed to decrease the patient’s risk of cardiovascular complication by targeting anti-inflammatory, anti-thrombotic and anti-proliferative effects.

**ABCDESSSs of Diabetes Care**

**A:** Target A1c at 7%.*
**B:** Target blood pressure at <130/80 mmHg.
**C:** Manage cholesterol.
**D:** Employ drugs (for blood pressure, cholesterol, etc.).
**E:** Exercise.
**S:** Stop smoking.
**S:** Employ self-management techniques (for stress, mental health, etc.).
**S:** Screen for complications such as neuropathy, nephropathy and retinopathy.

*Target A1c levels may differ. Generally, the target should be <6.5% to reduce risks of microvascular disease, 7% for most adults with diabetes, and 7.1 to 8.5% for the frail elderly, functionally dependent individuals or those with recurrent or severe risk for hypoglycemia.

When treating diabetes, the target HbA1c is 7% for most adults. Angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) are still required for most patients. Antiplatelet therapy is no longer recommended for primary prevention but is used in patients with multiple risk factors. Statins are used in all patients with cardiovascular disease and all patients over the age of 40. If a patient is under 40 with one other risk factor, they should also be put on statins.

**Key Presentation Points**

- Ulceration is not inevitable in diabetic patients. Practitioners need to optimize medical and lifestyle factors and encourage patient self-management.
- Prevention should be approached through a comprehensive, multifactorial strategy.
- The pathway to the prevention of diabetic foot ulcers targets neuropathy, PAD and trauma.
• Practitioners should tailor targets to the needs and preference of the patient, with the goal of reducing vascular risk.

Pathology of Diabetes and Diabetic Foot Disease

Zaina Albalawi, MD MSc FRCP

Understanding the big picture of diabetes as a disease process ensures optimal care and allows for the development of targeted interventions to alter the disease’s course.

Type 1 diabetes, about 10% of cases overall, is mediated by autoimmune genetic processes in a genetically susceptible person and results in progressive beta-cell destruction and insulin deficiency. Type 2 diabetes is mediated by genetic and environmental factors resulting in beta-cell destruction and dysfunction and insulin resistance. In type 1 diabetes, tight glycemic control reduces the risk of developing peripheral neuropathy when compared with conventional glycemic control; this is not true in type 2 diabetes.

Table 2 shows the pathogenesis of diabetic foot disease.

Key Presentation Points
• When treating diabetic foot disease, the distinct pathogeneses of types 1 and 2 diabetes need to be taken into account in research and clinical practice. This will allow practitioners to target management, thereby improving patient outcomes.

Table 2: Pathogenesis of Diabetic Foot Disease: Characteristics of Comorbid Conditions

<table>
<thead>
<tr>
<th>Peripheral Neuropathy</th>
<th>Charcot Neuropathy</th>
<th>Vascular Disease</th>
<th>Peripheral Arterial Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular, metabolic and hormonal factors</td>
<td>Neurotransmitter and neurovascular components</td>
<td>Endothelial dysfunction and inflammation</td>
<td>Mismatch in supply and demand, resulting in hypoxia</td>
</tr>
<tr>
<td>Imbalance in nerve damage and nerve repair, resulting in progressive loss of sensation and structural nerve damage</td>
<td>Uncontrolled inflammation</td>
<td>Impairment of vascular repair capacities</td>
<td>Angiogenesis component</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thrombotic state (alterations of coagulation, platelet reactivity, macroparticle release)</td>
<td>High metabolic demand that isn’t met due to hypoxia and lack of angiogenesis</td>
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<td></td>
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<td>Epigenetic-driven transcription</td>
<td>Cascade of inflammation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vascular hyperglycemic memory</td>
<td></td>
</tr>
</tbody>
</table>

Zaina Albalawi, MD MSc FRCP
Dr. Zaina Albalawi is an endocrinologist. She completed her internal medicine and endocrinology fellowship at the University of Alberta, along with a Master of Science in clinical epidemiology. She co-authored the foot chapter for the 2018 Diabetes Canada Guidelines. Her clinical practice has included limb preservation at the Diabetes Foot Clinic at the Royal Alexandra Hospital, and Diabetes and General Endocrinology at the Regional Diabetes Program and Baker Clinic in Edmonton. Her research interests include limb preservation in individuals with diabetes and postoperative outcomes. She resides in St. John’s, NL.
• Diabetic foot disease pathogenesis is complex, especially given the interplay with neuropathy and vascular disease.

Emerging Trends and Research Directions

Julie Lovshin, MD PhD FRCPC

Complications and comorbidities associated with type 2 diabetes are decreasing as a result of increased awareness and attention, and new types of drugs. The presence of diabetes and cardiovascular disease in a patient reduces life expectancy and increases the risk of premature mortality by 12 years. This has driven interest in four main research areas:

• Artificial pancreas/closed-loop systems (integrated insulin pumps)
• Growth of new beta cells (stem cell research)
• Diabetes technologies (e.g., contact lenses that sense glucose, apps to monitor ECG or heart rate, retinopathy telemedicine)
• Drug research and development

Research has led to the development of two new drug classes: SGLT2 inhibitors and GLP-1R agonists. SGLT2 inhibitors are oral interventions that lower blood sugar by acting at the kidney level to pass more sugar and salt in the urine. These drugs see modest A1c-lowering effects depending on glomerular filtration rate (GFR); the less renal function a patient has, the less this effect is seen. With these inhibitors, there is also a reduction in body weight by 2 to 3 kg and lowered systolic blood pressure. According to the U.S. Food and Drug Administration (FDA), the risks posed by this drug include an increased risk of mycotic infection/urinary tract infection, especially in patients with existing risk factors.

GLP-1R agonists are injectable medications given once per week. These work by activating insulin release and decreasing glucagon in pancreatic beta cells. Results have shown a reduction in HbA1c (1–1.5%; not related to kidney function [GFR]), a decrease in body weight (3–5 kg), lowered systolic blood pressure (2–6 mmHg) and a decrease in cardiovascular/renal events in type 2 patients. The FDA notes side effects for this drug includes nausea, vomiting, diarrhea (10–20% experience this), and an increase in heart rate of 2 to 4 bpm.

Assessing the cardiovascular safety of new diabetes drugs is now a requirement in Canada. SGLT2 inhibitors seem to have a neutral effect on patients with high cardiovascular risk and type 2 diabetes. There is some research underway on

Leading Mechanisms of Cardiovascular Protection

• Oxidative stress-induced endothelial cell dysfunction
• Vascular smooth muscle cell reactive oxygen species (ROS) production and proliferation
• Thrombosis
• Inflammation and atherogenesis
• Natriuretic/diuretic effect
• Renin-angiotensin-aldosterone system effect

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Julie Lovshin, MD PhD FRCPC

Dr. Julie Lovshin is a clinician scientist and assistant professor of medicine in the Division of Endocrinology and Metabolism, Department of Medicine, at the University of Toronto. She specializes in diabetes clinical care, with an emphasis on renal and cardiovascular complications. She directs the Diabetes Complications Clinical Research Laboratory at Sunnybrook Health Sciences Research Centre in Toronto, where her research focuses on mechanistic human investigation in renal, retinal and cardiovascular disease and function.
drugs that can actually reduce the risk of heart failure and diabetic kidney disease in patients with type 2 diabetes. This includes high-cardiovascular-risk patients such as those with PAD. GLP-1R agonists are completely safe for patients with high cardiovascular risk.

Key Presentation Points
• Type 2 diabetes management changes for patients with cardiovascular disease:
  • SGLT-2 inhibitors provide cardiovascular protection and are hemodynamic.
  • GLP-1R also provides cardiovascular protection and is an anti-atherosclerotic.
• Clinical research should aim to answer the following questions:
  • Will these drugs be used for primary cardiovascular protection?
  • Will these drugs be used for cardiovascular protection in those without diabetes?
  • Do these drugs attenuate peripheral vascular disease?
  • Do these drugs improve wound healing?

Vascular Topics
Session Summary
This session explored the clinical signs and symptoms of peripheral arterial disease (PAD) and the importance of early and accurate diagnosis. Speakers described relevant non-invasive and invasive vascular diagnostic imaging options (including specificity and sensitivity) for prescribers ranging from primary care providers to vascular specialists. The indications and key components of the medical and surgical management of PAD were discussed, along with trends and research directions related to the assessment and treatment of PAD.

Diabetes and Peripheral Arterial Disease: Diagnosis and Non-operative Management
Thomas F. Lindsay, BSc MDCM MSc
The clinical criteria for diagnosing peripheral arterial disease (PAD) include classical claudication and critical limb ischemia. To determine if classical claudication is present, clinicians can take a patient history and look for reports of muscle pain while walking that is reproducible daily and relieved by rest. Risk factors for PAD include smoking, obesity, sedentary lifestyle, diabetes and family history.

The prevalence of PAD in patients with diabetes is 40% (higher in non-Caucasians) and includes more involvement of distal vessels and co-existent sensory, motor and autonomic neuropathy.

Doppler criteria for PAD are an ankle-brachial pressure index (ABPI) of <0.9 or toe brachial pressure index (TBPI) of <0.7 if vessels are calcified. An arterial duplex can be used to examine flow,
areas of stenosis and stenosis severity. This test is useful in identifying and quantifying the disease and choosing a targeted treatment. Digital waveforms are also useful in diagnosing PAD, because the test allows for the assessment of individual toe blood flow.

**Medical Management of PAD**

Patients in this population need to receive proper foot care, footwear and wound care once an ulcer is present. Patients should be encouraged to cease smoking, manage obesity and hypertension, control blood sugar, manage cholesterol and lipids, increase physical activity, engage in antiplatelet or antithrombotic therapies and alter their diet. Major cardiovascular therapy trials are now actively enrolling patients with PAD.

**Diabetes and Endovascular Interventions: Challenges and Opportunities**

*Jeffrey Siracuse, MD RPVI FACS*

In recent years, there has been an explosion of endovascular interventions for PAD; however, there is no clear evidence of efficacy, and current data do not show unified results.

In one study comparing 2,446 endovascular procedures between both individuals with diabetes and those without, diabetic patients had more comorbid conditions and major amputations, more heavily calcified lesions, more frequent multivessel disease and fewer infrapopliteal runoff vessels. Patients with diabetes were also shown to have an increased risk of mortality after 12 months when compared with non-diabetic patients. In a retrospective review of two randomized trials, however, patients with diabetes were five times more likely to have a major amputation than non-diabetics (34% vs. 20%), but there was no significant difference in mortality rate between the two groups. Another study of 73 individuals with diabetes found no significant difference in amputation rates after 36 months.

In an analysis of 598 patients with claudication (46.8% with diabetes), no difference was seen between those with diabetes and those without in terms of 12-month primary patency following a directional atherectomy. Insulin-dependent individuals were generally younger and were more likely to experience tissue loss, coronary artery disease or end-stage renal disease than non-insulin-dependent individuals and individuals without diabetes. Insulin-dependent individuals also had poorer wound healing rates and a higher risk for amputation, major amputation after three years, and re-intervention.

A study looking at 539 critical limb ischemia patients receiving either direct (63.4%) or indirect (36.6%) angiosome-directed revascularization found that complete wound healing rates were higher at 12 months among the direct revascularization patients, but that freedom from major adverse limb events (MALE) and amputation-free survival were not significantly different at up to 24
months. In this study, indirect angiosome-directed revascularization was seen to have an independent negative impact on wound healing.

In a retrospective analysis of 137 endovascular interventions on diabetic chronic limb-threatening ischemia (CLTI) patients with foot wounds, three groups of pedal arch statuses were examined: complete pedal arch, incomplete pedal arch and absent pedal arch. Healing, one-year limb preservation and one-year survival rates were significantly higher for the complete pedal arch group than for the other groups.

In a study of 93 diabetic patients with foot wounds and below-knee endovascular interventions, direct angiosome-directed revascularization was not found to affect healing time after three months or limb preservation rates after one year. Pedal arch procedures, on the other hand, were shown to have a positive impact on both factors.

**Key Presentation Points**

- Poor evidence has driven practice, causing an increase in endovascular interventions.
- Individuals with diabetes tend to have more advanced presentation and more severe disease.
- Diabetes itself is not likely the cause of higher amputation risk.
- Further investigations into angiosome and pedal arch procedures are needed.

Patients with PAD may be asymptomatic or may present with claudication, critical limb ischemia, rest pain and/or ulceration or gangrene. Revascularization is indicated in patients with peripheral arterial disease and ABPI <0.90.

Endovascular interventions are now performed much more commonly than bypass surgery in the treatment of lower extremity PAD (LEAD). Out of 2.5 million inpatient diabetic foot ulcer cases, 16.5% require amputation and 8.5% require revascularization. Of those 8.5%, 43.5% receive open surgery and 51.1% receive endovascular intervention. Some 5.4% receive both.

Currently, there are no randomized controlled trials (RCTs) directly comparing open surgery and endovascular intervention for diabetic foot ulcers. Major outcomes are similar across all studies (including two meta-analyses where revascularization of the foot was successful). The results of both open surgery and endovascular procedures depend, however, on the expertise in a given centre. In one RCT, balloon angioplasty was associated with a significantly higher early failure rate than bypass surgery. In the BASIL trials, it was concluded that physicians should consider endovascular treatment first for a patient with a life expectancy of fewer than two years and vein bypass surgery first for patients with a life expectancy of more than two years. Patients who cannot have vein bypass are
probably better served by an attempt at endovascular intervention as opposed to a prosthetic bypass. Endovascular treatment as a first approach, however, is not necessarily a “free shot,” as the success of subsequent bypasses may be compromised if the endovascular procedure fails.

The 2016 American Heart Association (AHA) Guidelines for Revascularization Surgery provide the following recommendations:

- In patients with DFU who have PAD, revascularize by either surgical bypass or endovascular therapy.
- In functional patients with long-segment occlusive disease and a good autologous conduit, bypass is likely to be preferable.
- The choice of intervention depends on the degree of ischemia, the extent of arterial disease, the extent of the wound, the presence or absence of infection and the available expertise.

**Key Presentation Points**

- Be aware of the current role of open revascularization.
- Understand the current guidelines regarding the role of open revascularization.
- Appreciate the importance of a multidisciplinary team for limb preservation.

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**Vascular: Emerging Trends and Research Directions**

Samantha Minc, MD

See Dr. Minc’s bio, page 20.

The WIfI (wound, ischemia and foot infection) classification system was created to provide a comprehensive understanding of the threatened limb in order to guide management and expectations. This system looks at the wound, ischemia and infection to create a predictive model to guide care. Practitioners can use an interactive practice guideline app with patients to provide a calculation based on this classification system, which can then guide a conversation around treatment options.

Multidisciplinary teams have demonstrated significant improvement in amputation rates with simple, preventative care and co-ordination of specialists. The Preservation-Amputation Care and Treatment Program (PACT) from the Veterans Health Administration in the United States showed an 80% risk reduction (2005), the Lower Extremity Amputation Program (LEAP) study showed a 79% risk reduction in Louisiana (2000), and the Multidisciplinary/Toe and Flow teams (podiatrist and vascular surgeon) showed a 36 to 86% risk reduction (2010). These results extend to Indigenous communities, as the LEAP plus Staged Diabetes Management (SDM) study showed a 50% risk reduction in a Chippewa First Nation community (2001).

Amputation is a contextual issue; in other words, where you live matters. By definition, patients who
live in rural areas and have rarer diseases are few in number, making statistical analysis difficult. This does not mean, however, that these patients should not be provided with equal access to high-quality wound care. Bayesian methods allow for a more granular statistical picture and a more effective allocation of resources. The problem is that the current literature focuses on descriptive data rather than inferential information.

Some other barriers to practice change include lack of education, poor availability of protocols, lack of specialists, poor access to care at all levels and lack of time. Some solutions to overcome these barriers include implementing incentives and payment models, implementing standardized protocols and encouraging improved communication between patients and practitioners.

Key Presentation Points
- Vascular surgeons employ strategies at multiple levels to reduce amputation risk. These include societal guidelines, algorithmic protocols and multidisciplinary teams.
- At all levels, co-ordination and access to care is key. Practitioners need to understand the issue of vascular surgery and related diseases at a broad social level.

Infection

Session Summary
This session outlined the risk factors associated with developing a diabetic foot infection and the incidence and impact of this condition. Speakers described the role of biofilm and latent infection in diabetic foot ulcers and discussed strategies used to reliably diagnose osteomyelitis in the diabetic foot. Speakers compared medical and surgical management strategies for people with diabetes, infection, osteomyelitis and peripheral arterial disease. This session also explored emerging trends and research directions related to the diagnosis and management of infection and osteomyelitis in the diabetic foot.

Diagnosing Infections in the Diabetic Foot
Zain Chagla, MD FRCPc

Diabetic foot ulcers are a massive burden on Canada’s health-care systems, resulting in approximately 16,000 hospitalizations, 31,000 emergency room visits and 11,000 operating room visits per year. The financial cost of these cases is $547 million annually ($21,000–$50,000 per clinical case), not including secondary costs associated with disability.

The most important parts of an examination for possible infection are the patient history and the physical exam. Clinicians should assess for calor (warmth), dolor (pain), tumor (swelling) and rubor (redness). Note that vascular disease may affect rubor and calor, and neuropathic disease can mask pain. Other signs of infection include purulence, concomitant ischemia, foul odour, surrounding cellulitis and long duration of the wound. While examining the wound, clinicians should debride the overlying membrane to get a thorough examination of the wound characteristics. They should expose any tracts or tunnels. It is important to identify any abscesses or contiguous tracts.

Zain Chagla, MD FRCPc
Dr. Zain Chagla completed his MD at Queen’s University, Internal Medicine at Western University, and Infectious Diseases at McMaster University. He also has an MSc and Diploma in Tropical Medicine from the London School of Hygiene and Tropical Medicine. He currently practises as an infectious diseases physician. He is an assistant professor of medicine at McMaster University, and the medical director for Infection Control at St. Joseph’s Healthcare and Niagara Health System. Dr. Chagla has interests in medical education, health-care technology, global health and transplant infectious diseases.
When considering microbiologic testing, clinicians should swab wounds using the Levine method: cleanse the wound, debride non-viable tissue, and swab the cleanest, deepest area of the wound possible. There is often mixed growth of varying bacteria, but clinicians should look for staph, strep, pseudomonas and/or coliforms.

When ruling out osteomyelitis, clinicians should determine a pre-test probability in order to save resources by avoiding expensive, time-consuming tests for patients who are unlikely to have this complication. If the wound is superficial and unlikely to probe to bone, further diagnostic testing should not be initiated. Similarly, if the wound is deep and very likely to probe to bone, further testing should not be initiated. However, if the wound is in the “sweet spot” and difficult to stage, diagnostic radiology for an accurate diagnosis should be considered.

Table 3 explains characteristics of the different types of diagnostic testing.

Barriers to care in this area include a lack of understanding of pre-test probability, resulting in the inability to refer patients to the appropriate diagnostic test. Clinicians should use judgement

<table>
<thead>
<tr>
<th>Test</th>
<th>Characteristics</th>
</tr>
</thead>
</table>
| Probe to bone             | • Useful adjunct in patients with a high pre-test probability of an infection  
• Use a metal probe to probe the deepest tract until you feel bone, which is often not obviously visible.                                                                                                                        |
| Bone biopsy               | • Gold standard test  
• Histopathologic evidence of osteomyelitis plus cultures  
• Techniques include needle puncture, image-guided, rongeur  
• Requires expertise, especially if the tract is not visible  
• Has the potential for superficial contamination of cultures; interpret with caution                                                                                                                                         |
| Plain radiography         | • Inexpensive and widely available  
• Takes time for change to occur  
• First-line test for all patients requiring diagnostic testing                                                                                                                                                                                                                      |
| MRI                       | • Use after plain radiography.  
• High sensitivity (90%) and specificity (85%)  
• Distinguishes osteomyelitis from other conditions such as Charcot foot, remodelling  
• Note: sometimes only picks up superficial cortical versus medullary infection  
• Costly                                                                                                                                                                                                                                                                               |
| Bone and WBS scan         | • An alternative to MRI; useful if the patient has contraindications for MRI  
• Burdensome on patient, particularly in outpatient settings (requires 2–3 prolonged trips to the centre)  
• Can be confounded by remodelling, Charcot foot, fractures  
• Interpret only the area involved with the wound.                                                                                                                                                                                                                                      |
| Ultrasound                | • Poor visualization of bone  
• Helps with abscesses and deep tissue structures                                                                                                                                                                                                                                                                                               |
| CT scan                   | • Limited value when compared with nuclear/MRI                                                                                                                                                                                                                                                                                                  |
| FDG and PET               | • Promising but expensive                                                                                                                                                                                                                                                                                                                                                                                   |
when ordering tests and should interpret results wisely.

**Key Presentation Points**
- Infection in the diabetic foot is a common problem requiring clinical judgement.
- Swab properly and interpret microbiology accurately.
- Generate a pre-test probability for osteomyelitis. If there are low pre-test results, don’t use testing, and skip straight to treatment. If pre-test results are high, don’t use testing; assume osteomyelitis. If the pre-test is difficult to stage, order further tests.

**Emerging Trends and Research Directions**

Christopher Kandel, MD

There is no substantial difference in the penetration of various antibiotics into the bone. Oral versus intravenous (IV) interventions were studied in an OVIVA trial: failure rates following a median treatment course of 75 weeks were 13% for oral and 15% for IV. This study should be interpreted with caution, however, since there was some heterogeneity of infections included and because the majority of patients underwent surgery.

When treating chronic osteomyelitis of the calcaneus, where surgery is not feasible, consider the pill-in-pocket approach, chronic suppression or evaluating each flare individually. There is little literature on how to most effectively treat patients with recalcitrant osteomyelitis.

Unmet research needs pose a large problem to the treatment of osteomyelitis. More research is needed in the areas of treatment success (e.g., when to cease antibiotic use), appropriate approaches to chronic osteomyelitis and standardizing the definition of effective debridement.

**Key Presentation Points**
- Oral antibiotics can be as effective as intravenous antibiotics.
- The optimal duration of antibiotic use for osteomyelitis is uncertain, but longer seems to be the rule.
- Debridement can be crucial or aggravating, depending on the situation.

**Determining the Degree of Amputation in Diabetic Foot Infections: Does Every Patient Need a BKA?**

Warren C.W. Latham, BSCH MD FRCSC MSC(C)

Between 15 and 20% of individuals with diabetes develop a foot ulcer in their lifetime. Eighty percent of amputations in individuals with diabetes are preceded by a diabetic foot ulcer (DFU), and
50% of all non-traumatic amputations are related to diabetic foot disease. Five-year mortality following an amputation ranges from 50 to 68%, increasing based on the level of amputation.

More than 50% of patients with diabetes also experience neuropathy, which leads to a seven-times increase in the risk of developing a DFU. (See Table 4 for characteristics of areas important in assessing a DFU.) The suggested follow-up window for neuropathic patients depends on wound status. If a wound is completely healed and healthy (Level 0), follow up annually; if a patient experiences sensory neuropathy (Level 1), follow-up is advised every 3 to 6 months; when sensory neuropathy, deformity and/or PAD is present (Level 2), follow-up is advised every 1 to 3 months; if a patient experiences sensory neuropathy and has previously had a DFU or amputation (Level 3), follow-up is recommended every 1 to 4 weeks.

Whether amputating or preserving a limb, the wound must heal in order to prevent future ulceration and amputations and to improve quality of life. Pinzur et al. (2011) presented essential questions to ask before making a decision to preserve a limb:

- Will it outperform a prosthetic limb?
- What is the realistic endpoint?
- What is the cost for the patient?
- How will it affect the patient’s quality of life?
- What are the risks?

It is critical to have an honest conversation about these issues with the patient prior to making a decision. Clinicians must take patient preference into account, especially when considering the desired level of functionality following treatment.

### Table 4: Assessment of Diabetic Foot Ulcers

<table>
<thead>
<tr>
<th>Assessment Area</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient history</td>
<td>Glycemic control, functional level, patient factors</td>
</tr>
<tr>
<td>Wound characteristics</td>
<td>Depth, size, location, colour, ischemia, exposed bone, deformity, callus, ulceration, infection, necrosis, drainage, pain</td>
</tr>
<tr>
<td>Examination results</td>
<td>Monofilament, neuropathy, tuning fork</td>
</tr>
<tr>
<td>Vascular assessment</td>
<td>Palpation, temperature, ABPI, TBPI, TcPO₂, Duplex vascular ultrasound</td>
</tr>
<tr>
<td>Presence of osteomyelitis</td>
<td>Cellulitis (don’t be fooled by Charcot), erysipelas, acute osteomyelitis, chronic osteomyelitis</td>
</tr>
</tbody>
</table>

**Benefits of Debridement**

- Removal of necrotic tissue
- Drainage of “pus”
- Healing stimulus
- Pressure reduction

Dr. Warren Latham is an orthopedic surgeon subspecialist in foot and ankle surgery with a focus on diabetic foot pathology and reconstruction, and minimally invasive surgical techniques in foot and ankle surgery. He is a clinical adjunct at the University of Toronto, and staff surgeon at Scarborough Health Network. Dr. Latham is currently completing a master’s in surgical science and practice at Oxford University. He is a mentor in the University of Toronto Foot and Ankle Fellowship program and is an executive member of both the Canadian Orthopaedic Association (COA) and Canadian Orthopaedic Foot and Ankle Society (COFAS).
The goals of amputation include removing all infected necrotic and painful tissue, fashioning an adequate stump for use of a prosthesis and achieving successful wound healing. When considering whether or not a patient is a good candidate for amputation, it is essential to take into account the extent of tissue loss, the anatomy of reconstruction, associated comorbidities, vascular status and sepsis. A limb may be considered unsalvageable for a number of reasons, including patient factors, clinical judgement and clinical examination (e.g., infection, poor skin quality, ischemia). In these cases, amputation should not be considered a failure in treatment.

**Key Presentation Points**

- An appropriate amputation in the face of an unsalvageable limb is not a failure of conservative management.
- Patient factors, including desired levels of function postoperatively, are critical variables when discussing amputation level.
- No matter whether preservation or amputation is selected, the end goal must be for the wound to heal.
- Understanding biomechanics is key in minimizing recurrent ulceration following amputation.

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**Practical Tips and Tricks to Prevent Major Amputations with Diabetic Foot Infections**

Karim Manji, MD
See Dr. Manji’s bio, page 21.

The WIfI classification system helps clinicians determine a patient’s risk of amputation based on three factors: wound, ischemia and foot infection. The wound score is based on the extent of tissue loss, the ischemia score depends on perfusion, and the foot infection score is based on the extent of infection. The primary goal of treatment should be to reduce a patient’s WIfI score while maintaining maximum function.

When surgically managing infection, the clinician should obtain deep cultures, evacuate infection, decompress compartments, pay attention to flexor tendons and extensor tendon tracking, and pack the wound open.

**Key Presentation Points**

- Use the WIfI score to determine the severity of a wound and seek to decrease the score through treatment.
- Drain any infection in a wound as soon as possible.

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**Wound Management**

**Session Summary**

This session explained the utility of wound debridement in the treatment of diabetic foot ulcers and presented the indications and contraindications related to the various methods of

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**VIPs of Treating DFUs**

- V: Vascular supply
- I: Infection control
- P: Pressure offloading
- S: Sharp surgical debridement

**Types of Offloading**

- Total contact cast
- Removable cast walker
- Scotch cast boot
- Surgical shoes
- Crutches, knee walker, wheelchair
- Ankle stirrup
debriding diabetic foot ulcers. Speakers discussed the evidence supporting the use of dressings and outlined the methods used to select the most appropriate dressings and advanced therapies in the treatment of diabetic foot and arterial ulcers. Also explored were emerging trends and research directions related to managing diabetic foot ulcers.

### Wound Debridement in the Diabetic Foot

**Alan Rogers, MBChB FC Plast Surg (SA) MMed**

The impact of research in the area of diabetic foot ulcers is limited by a lack of high-quality studies, bias caused by industry sponsorship and difficulties in standardization.

Debridement is a key component of care when treating patients with diabetic foot ulcers. Debridement removes revitalized or infected tissue until surrounding healthy tissue is exposed. This allows for assessment of the capacity to heal and identification of the most appropriate closure method. There are various types of debridement, including mechanical debridement, autolytic debridement, maggot therapy, ultrasound, enzymatic debridement and negative pressure wound therapy (see Table 5). Surgical debridement is preferred for patients with significant necrosis and infection, especially if the wound is moist or stagnant.

### Table 5: Characteristics of Debridement

<table>
<thead>
<tr>
<th>Type of Debridement</th>
<th>Characteristics</th>
</tr>
</thead>
</table>
| Mechanical (wet-to-dry approach)         | • High nursing cost; low product cost  
• Can be painful                        |
| Autolytic                               | • Moist wound environment  
• Hydrogels are preferred  
• Minimal pain  
• Fairly selective                     |
| Maggot therapy                          | • Discriminates between necrosis and granulation  
• Rapid  
• Note: bagged therapies are typically more acceptable to patients |
| Ultrasound                              | • Considered less painful than sharp debridement                                |
| Negative pressure wound therapy         | • Drains exudate  
• Reduces edema  
• Contracts wound edge  
• Alters blood flow                     |
Key Presentation Points

- Evidence does not favour one method of debridement over any other.

Dressings and Advanced Therapies in Diabetic Foot Ulcers

Afsaneh Alavi, MD MSC FRCPC

When choosing a dressing, consider healing status, patient preference, cost and cost-effectiveness, wound shape, wound location, exudate, dressing availability, bioburden, periwound skin and edema. Clinicians should remember the generic name and category of each dressing, so they are able to adapt to what is available in individual clinics and areas.

There are three basic types of dressings. When using absorptive dressings, thinner is typically better, as it adds pressure to the area. Adhesive dressings such as films and hydrocolloids are not used as often with diabetic foot ulcers. The third category is the contact layer or mesh dressings, which can contain antiseptics. Other products, such as collagen-based dressings, which stimulate healing and decrease matrix metalloproteinases; smart dressings, which can detect pH; bio-engineered skin; skin substitutes; and negative pressure wound therapy are also available in some areas.

More research is needed to substantiate the role of available dressings and products on a day-to-day basis. Products must be assessed not only for clinical effectiveness, but also for cost-effectiveness.

Key Presentation Points

- Improving the clinical outcome of diabetic foot ulcers remains a challenge.
- More head-to-head studies are needed to show the effect of dressings.
- Clinical effectiveness and cost-effectiveness are both important factors in dressing selection.
- Expensive dressings do not necessarily offer healing advantages when compared with more basic, inexpensive products.
Emerging Trends and Future Directions for the Diabetic Foot

Lee C. Rogers, DPM

Around the world, a limb is lost every 30 seconds due to diabetes. Key risk factors for developing a diabetic foot ulcer include peripheral neuropathy, peripheral arterial disease, foot deformity and history of ulceration or amputation. Up to 25% of those with diabetes will develop a foot ulcer in their lifetime.

A patient’s risk for lower-extremity amputation (LEA) increases with ulceration (84%), infection (59%) and gangrene (55%). In the U.S., a patient’s risk also increases if they are older, male, from an ethnic minority, or have public insurance rather than private. LEAs often follow a pathway of the disease process (see Figure 2). The five-year mortality rate following an LEA is 70%.

Figure 2: Pathway to Lower-extremity Amputation

In 2007, $147 billion was spent on diabetes in the U.S., $116 billion of which went to direct costs. One-third of these costs can be attributed to lower-extremity complications. Amputation is the sixth most costly type of surgery; mean cost per surgery in the U.S. in 2007 was $20,200. The average hospital stay for a diabetic foot ulcer is 7.6 days; the average for LEA is 9.6 days. Following healing, 50% of patients with a diabetic foot ulcer re-ulcerate within one year.

The rationale for primary amputation assumes that patients will ambulate successfully with a prosthesis. In reality, barely one-third of patients (47% below-knee and 15% above-knee) are successfully fitted for a prosthesis; thus many are not able to walk.

New thermometry technologies are being developed to help clinicians predict and thus prevent amputation in at-risk patients. Automated home temperature monitoring systems calculate

“I marvel that society would pay a surgeon a large sum of money to remove a person’s leg . . . but nothing to save it.” —Bernard Shaw, quoted by Dr. Lee Rogers

Lee C. Rogers, DPM

Dr. Lee Rogers is the founder and medical director of the Amputation Prevention Centers of America, a company that manages 225 wound centres in 35 states. He has published more than 150 articles or book chapters on the diabetic foot and systems of care. His work has been featured in the Wall Street Journal, US News and World Report, NBC News, and he’s been a guest on ABC’s The Doctor’s Show.
trends over a set period of time based on daily measurements. To use these systems, patients stand on a mat for 20 seconds once per day, and the temperatures are updated to a server that forecasts based on pre-set thresholds. The temperature trends identified can help clinicians predict ulceration up to a month before occurrence.

**Key Presentation Points**

- Preventing ulcers is key to preventing amputations. Watch for these signs of inflammation: dolor, rubor, tumor and calor.
- Thermometry is one way of predicting ulceration in at-risk patients.

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### Offloading

#### Session Summary

This session presented evidence supporting offloading as a treatment for diabetic foot complications and explored common non-surgical and surgical approaches to offloading the diabetic foot and Charcot foot, including indications, contra-indications and effectiveness. Speakers described strategies for offloading the diabetic foot in resource-limited settings and how to identify patients with diabetic foot complications or Charcot foot who are surgical candidates. This session also discussed emerging trends and research directions related to the non-surgical and surgical management of diabetic foot and Charcot deformity.

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#### Surgical and Non-Surgical Approaches to Managing the Charcot Foot

**Lee C. Rogers, DPM**

See Dr. Lee’s bio, page 38.

Charcot foot can be treated medically or surgically. Medical treatments for patients with active inflammation and increased temperature include offloading, bisphosphonates, intranasal calcitonin, and bone stimulators. Offloading and immobilization are the most important initial treatments; there is little evidence to support the effectiveness of available pharmacological therapies to promote healing. Patients with inactive inflammation and no increases in temperature should be treated with accommodative footwear.

Surgical treatments for Charcot foot include exostectomy and reconstruction. Exostectomy can be useful for patients with a plantar prominence that is not amenable to offloading. Reconstruction is indicated for non-healing foot ulcers or those with impending ulceration, osteomyelitis or a non-functional extremity. The goal of this surgery is a stable, plantigrade foot.

When offloading, removable options result in lower patient compliance. In one United Kingdom-based study of 288 patients with Charcot foot, the use of nonremovable offloading (TCC) led to quicker resolution than removable offloading (9 vs. 12 months).

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**Given the high rates of recurrence, patients with Charcot foot require routine follow-up.**

**When you see severe inflammation, consider it Charcot foot until proven otherwise; it is a medical emergency.**
Surgical and Non-Surgical Approaches to Offloading the Diabetic Foot

James Hill, DPM FACFAS

Non-surgical Approaches to Offloading

In 2019, the International Working Group on the Diabetic Foot issued recommendations for the use of offloading in patients with diabetic foot ulcers. These recommendations are summarized in Table 6 below.

<table>
<thead>
<tr>
<th>Types of Offloading Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-removable Options</strong></td>
</tr>
<tr>
<td>• Total contact cast</td>
</tr>
<tr>
<td>• Non-removable controlled ankle motion (CAM) boot—rendered immoveable by applying a layer of cast or tie wrap around the device</td>
</tr>
<tr>
<td><strong>Removable Options</strong></td>
</tr>
<tr>
<td>• Knee-high CAM boot</td>
</tr>
<tr>
<td>• Ankle-high CAM boot</td>
</tr>
<tr>
<td>• Felted foam</td>
</tr>
<tr>
<td>• Standard therapeutic footwear (e.g., diabetic shoes)</td>
</tr>
</tbody>
</table>

Table 6: Recommendations for Offloading the Diabetic Foot

<table>
<thead>
<tr>
<th>Patient Status</th>
<th>Recommended Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient with diabetes and a neuropathic plantar forefoot or midfoot ulcer</td>
<td>Non-removable knee-high offloading device (total contact cast or non-removable knee-high walker) with an appropriate foot-device interface</td>
</tr>
<tr>
<td>Patient with diabetes and a neuropathic plantar forefoot or midfoot ulcer when a non-removable knee-high offloading device is contraindicated or not tolerated</td>
<td>First choice: Removable knee-high offloading device with an appropriate foot-device interface. Encourage the patient to consistently wear the device. Second choice: Removable ankle-high offloading device</td>
</tr>
<tr>
<td>Patient with diabetes and a neuropathic plantar forefoot or midfoot ulcer when none of the above-mentioned offloading devices is available</td>
<td>Felted foam in combination with appropriately fitting conventional or standard therapeutic footwear</td>
</tr>
<tr>
<td>Patient with diabetes and a neuropathic plantar digital ulcer when non-surgical offloading treatment fails</td>
<td>Digital flexor tenotomy</td>
</tr>
<tr>
<td>Patient with diabetes and a neuropathic plantar forefoot or midfoot ulcer with either mild infection or mild ischemia</td>
<td>Non-removable knee-high offloading device</td>
</tr>
<tr>
<td>Patient with diabetes and a neuropathic plantar forefoot or midfoot ulcer with both mild infection and mild ischemia, or with either moderate infection or moderate ischemia</td>
<td>Removable knee-high offloading device</td>
</tr>
<tr>
<td>Patient with diabetes and a neuropathic plantar forefoot or midfoot ulcer with both moderate infection and moderate ischemia, or with either severe infection or severe ischemia</td>
<td>Address the infection and/or ischemia. Consider using a removable offloading intervention based on the patient’s functioning, ambulatory status and activity level.</td>
</tr>
<tr>
<td>Patient with diabetes and a neuropathic plantar heel ulcer</td>
<td>Knee-high offloading device or other offloading intervention that effectively reduces plantar pressure on the heel and is tolerated by the patient</td>
</tr>
<tr>
<td>Patient with diabetes and a non-plantar foot ulcer</td>
<td>Removable ankle-high offloading device, footwear modifications, toe spacers or orthoses, depending on the type and location of the foot ulcer</td>
</tr>
</tbody>
</table>
Surgical Approaches to Offloading
There are four classifications of diabetic foot surgery:

- Elective: reconstructive procedures on patients who do not have a loss of protective sensation (LOPS)
- Prophylactic: reconstructive procedures performed to reduce the risk of ulceration or re-ulceration in patients who have LOPS and do not have a wound at present
- Curative: procedures performed to assist in the healing of open wounds
- Emergent: procedures performed to arrest or limit the progression of infection

Some common types of reconstructive surgeries include Charcot reconstruction, minor amputation (digit, ray, metatarsal) and major amputation (below- or above-knee).

Several barriers currently impede optimal care of this patient population, including a hard cap on the number of podiatrist class registrants with the College of Chiropodists (in Ontario). In addition to this cap, the scope of practice for podiatrists in Canada is limited in all provinces and territories except Alberta and British Columbia. Limited funding for offloading devices and limited access to competent prescribers also make it difficult for patients to receive optimal care.

Key Presentation Points
- Appropriate offloading is necessary in order to heal a diabetic foot ulcer.
- Research on diabetic foot ulcers in Canada is limited.
- Both podiatrists and podiatric surgeons are key members of the multidisciplinary team evaluating and treating the diabetic foot, and access to their full range of competencies is severely limited in Canada.

Emerging Trends and Research Directions

Bijan Najafi, PhD

As the population ages, health-care providers are facing a significant change in patient demographics. More than 25% of the United States population aged 65 and over has diabetes, which trans-
lates to over 30 million adults, 12 million (40%) of whom are older adults.

Aging impacts physiology and biomechanics of lower extremities, including skin, soft tissue, joint range of motion, and causes arch collapse, foot deformity, poor gait and poor balance. Alteration in the biomechanics of the lower extremities due to aging can affect diabetic foot management because of poor adherence to offloading and the high rate of recurrence of ulcers.

Adherence to offloading is a key indicator of wound healing. Many patients report foot pain and postural instability (poor balance) as reasons they fail to use offloading devices consistently. Because of this, clinicians must work with patients to maximize their mobility with offloading devices and discuss the importance of using these devices consistently, as prescribed. Clinicians should ensure their patients understand that offloading is not just for walking; many patients stand for three times as long as they walk each day, whether or not they have an ulcer.

It is also important to consider that prolonged immobilization of the foot may lead to frailty. In frail patients with an ulcer, prolonged offloading can lead to slow muscle recovery, which can then lead to ulcer recurrence. Overall, the recurrence rate for diabetic foot ulcers is about 40% within the first year.

Lower-extremity biomechanics can be improved to reduce the risk of ulcers in three ways:
- Lower-extremity exercise: decrease the development of diabetic peripheral neuropathy (DPN), decrease DPN symptoms, increase balance, increase gait speed
- Assistive footwear/exoskeleton: decrease the risk of falling, increase balance, increase step width, increase gait speed
- Plantar stimulation: increase gait speed, increase balance, decrease DPN symptoms

There is evidence that foot and ankle exercises can address some age-related biomechanics factors, including foot strength, lower-extremity range of motion, balance, gait and frequency of falls.

**Key Presentation Point**
- As the patient population ages, there is urgent need to tailor diabetic foot management for older adults.

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**Special Topics**

**Session Summary**

This session explored the risks and challenges of treating patients with renal disease and diabetic foot ulcers. Speakers described non-surgical and surgical approaches to managing diabetic foot ulcers on the heel and discussed interdisciplinary and self-management strategies to support people with a non-healing or non-healable diabetic foot or arterial ulcer.

**Diabetic Foot Ulcers in Renal Patients: Risks, Challenges and Opportunities for Quality Improvement**

Lisa Dubrofsky, MDCM FRCP

Patients living with end-stage renal disease (ESRD) are 20 times more likely to require amputation than patients without ESRD. According to a 2016 systematic review of six studies, the prevalence of amputations among patients with both diabetes and ESRD is between 18% and 26.5%. Additional comorbidity risk factors leading to amputation in patients with ESRD include past history of a foot ulcer (70x), peripheral arterial disease (9x) and peripheral neuropathy (3x). The one-year mortality rate post-amputation in the ESRD popula-
tion is 43.6%, but this process is thought to be largely preventable through comprehensive diabetic foot ulcer care.

Recommended practices for preventing diabetic foot ulcers (DFUs) include physician education, patient and caregiver education, smoking cessation, glycemic control, custom footwear and/or orthotics, podiatry care (including callus debridement), revascularization, foot care and hygiene, and foot screening exams (if results lead to appropriate specialist referral).

When an ulcer is present, care should include proper assessment and documentation of the wound, appropriate referrals, investigation for infection, vascular assessment and the use of offloading devices. One such check, the Fresenius Monthly Foot Check, requires the following:

- Assess the patient’s shoes and socks.
- Check colour, temperature and skin integrity.
- Check pedal pulses.
- Test using monofilament.
- Refer patient to orthopedics for shoes, if necessary.
- Schedule monthly patient education.
- Refer to first available appointment with wound care clinic if new wound is present.

Patients with ESRD have complex medical issues and competing priorities. While these patients receive good care overall, nephrologists often do not have the knowledge or skills to manage DFUs or other wounds. In the presence of severe vascular disease, typical therapies might not be an option for this population. The lack of infrastructure in many care centres to manage complex wounds in a multidisciplinary fashion is also a barrier to effective care.

One of the keys to overcoming barriers is understanding the current care process and making changes to improve patient care through comprehensive foot exams for all patients. Clear algorithms for care should be put in place for nephrologists and nurse practitioners for new ulcers, chronic wounds and foot care. Finally, rapid access to wound care clinics with chiropodists, wound care specialists and vascular surgeons is essential for optimal care outcomes.

**Key Presentation Points**

- DFUs and amputations have significant morbidity and mortality in patients with end-stage renal disease.
- The management is complex in an already health-care-intensive population.
- Putting systems in place to help manage these patients should be a priority.
People with Diabetes and Heel Ulcers: Treatment Challenges

Christine Murphy, PhD RN WOCC(C)

Diabetic Heel Ulcers
Clinicians need to define ulcers not just based on type (e.g., diabetic foot ulcers [DFUs]), but also on other factors such as location and depth. Patients with diabetes, arterial disease and heel ulcers present a critical health-care problem. Some 10 to 18% of hospitalized patients have heel ulcers, and these patients are 1.5 times more expensive than those without diabetes and 2.5 times less likely to heal than those without diabetes. It is critical to include a nurse with wound credentials on any wound care team, and to take an action-oriented approach to treatment (see Table 7).

Key Takeaway Points
• Wound sub-categories influence healing time.
• Active therapies support limb preservation.
• Involve specialists early in care.
• Update chronic wound to urgent wound.

Christine Murphy, PhD RN WOCC(C)
Dr. Christine Murphy is a nurse specialist in complex vascular wounds who has worked with her team to develop a multi-professional limb preservation clinic. She has been a nurse for over 30 years and completed a degree in tissue viability, Master of Clinical Science in wound healing, and a PhD investigating healing challenges in a vascular population. Her research included a randomized controlled trial on ultrasound debridement in the vascular population. Dr. Murphy is president of Nurses Specialized in Wound, Ostomy and Continence Canada (NSWOCC) and co-chair of the Registered Nurses’ Association of Ontario’s ostomy guideline update. She is a core faculty member of the Western University MCls (Wound Healing) program.

Tracking Progress
Clinicians need to aim for an endpoint when working with this population of patients. Often this endpoint is an improvement in the patient’s WIfI score.

Supporting People with Non-Healing or Non-Healable Wounds

Maryse Beaumier, MSc Inf PhD
Though there are best practices for each type of wound, some recommendations are common to all. These include determining if arterial blood supply to the wound is sufficient for healing before deciding on the treatment plan, especially for ulcers on the leg or foot, and assessing the amount of blood reaching the wound, since more oxygen to the wound equals less risk of the wound becoming infected (see Table 8). If, through comprehensive assessment, a wound is deemed unhealable, what is the best way to support the patient? Best

<table>
<thead>
<tr>
<th>Table 7: Action-oriented Treatment Approaches</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Issue</strong></td>
</tr>
<tr>
<td>Poorly perfused area</td>
</tr>
<tr>
<td>Necrosis</td>
</tr>
<tr>
<td>Exposed bone/poor tissue quality</td>
</tr>
<tr>
<td>Infection</td>
</tr>
</tbody>
</table>
The best clinical decisions are made through a combination of individual clinical experience, use of best practice recommendations, interdisciplinary teamwork and careful attention to the patient’s values and expectations.”

—Maryse Beaumier

**Dressings**
As long as ago as the 1960s, George D. Winter found that wounds with poor blood supply were predisposed to developing an infection. Most guidelines suggest a conservative dressing or appropriate treatment as soon as possible. Dressings that promote a dry wound environment and include antisepsics are preferred. Dressings should be used to limit bacterial overgrowth in the wound.

### Table 8: Non-invasive Instruments to Measure Blood Supply

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Features</th>
<th>Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABPI and macrocirculation</td>
<td>• Fast and inexpensive</td>
<td>• Dopplers are rarely accessible.</td>
</tr>
<tr>
<td></td>
<td>• Enables clinician to hear waveforms</td>
<td>• Techniques and methods are not harmonized.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 19% of results are false positives in the diabetic population (Hembling, 2007)</td>
</tr>
<tr>
<td>TPI and macrocirculation</td>
<td>• Better than the above for diabetic patients,</td>
<td>• The big toe is often amputated.</td>
</tr>
<tr>
<td></td>
<td>because the artery of the big toe has less</td>
<td>• Not performed often</td>
</tr>
<tr>
<td></td>
<td>calcification</td>
<td>• Dopplers are rarely accessible.</td>
</tr>
<tr>
<td>TcPO2 and microcirculation</td>
<td>• Only used in vascular laboratories</td>
<td>• Requires medical expertise</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Not very accessible (e.g., only three available in Quebec)</td>
</tr>
</tbody>
</table>
Clinical Decision for the Best Dressing
If the blood supply to the wound is sufficient, clinicians should consider moist wound care without antiseptics to promote wound healing. If the blood supply to the wound is insufficient, clinicians should consider dry wound care with antiseptics to prevent infection. A dry dressing with antiseptics on a non-healable wound is part of a treatment plan that fights infection, improves patient quality of life and is less expensive for the patient and the health-care system.

Overcoming Barriers
Continued research is needed in this area, and the findings of this research must be incorporated into practice, policy and education. Interdisciplinary health-care providers should be educated about current wound care practices and raise awareness of wound care among all health-care providers, organizations and governments.

Key Presentation Points
• Evaluate blood supply to the wound.
• All health-care providers must be aware that 50% of patients with PAD are asymptomatic.
• Clinical decisions should be made with the objective of limiting infections.
• If there is not sufficient blood supply, a moist wound environment can result in amputation.

What Do We Need to Succeed?

Session Summary
This session explored current and future technologies and strategies to prevent and treat diabetic foot complications and peripheral arterial disease. Speakers described select local, provincial/territorial and national preventative strategies and initiatives related to diabetic foot complications and peripheral arterial disease.

Leveraging Technology: Wound Databases, Apps and Research Directions
Bijan Najafi
See Dr. Najafi’s bio, page 41

Smart technologies to better manage diabetic foot ulcers are a large industry, but a major mistake in this area of innovation is looking for a great idea instead of a worthwhile problem to solve.

One of the major obstacles in DFU prevention is poor patient adherence to offloading. This lack of adherence is also one of the main causes of failure in wound management.

New Technologies to Monitor Offloading
The orthotimer sensor is a small tag integrated into any offloading device that can actively measure adherence, but this is not enough. Patients must be actively reinforced for adhering to offloading.

Smart sensors are new devices that measure offloading wear. They notify the patient immediately if they begin to walk without the device and give virtual badges for reaching individualized goals.

Smart shoe insoles cue offloading and prevent sustained high plantar pressure. These insoles were found to increase average wear time by eight hours when patients received repetitive alerts.

Other Technologies for Diabetic Foot Care
High-risk patients can be effectively triaged using floor mats that measure plantar temperature.
According to a 2017 study published in *Diabetes Care*, using this technology there is a 37 ± 18-day lead time in predicting ulceration with an accuracy of 97%.

Wearable technologies and smart gadgets can empower patients and caregivers to be active members of the care team. These technologies include smart socks that measure temperature or pressure and smart insoles that monitor gait.

Biosensors being developed for use on wound dressings would act as flexible electrochemical sensors to monitor pH and glucose levels. Similarly, flexible sensors placed beneath dressings can provide remote, real-time monitoring of moisture, pressure, and temperature.

A portable oxygen generator that delivers a continuous supply of oxygen to the wound bed is also available.

**Future Directions**

Researchers are exploring the use of voice-enabled speakers to manage diabetic foot ulcers. About 40 to 60% of adults in the United States already use voice search in their everyday lives, and it is estimated that 50% of all queries will be voice searches by 2020. Researchers are also looking into the possibility of using a voice-assistant application to facilitate capturing high-quality photos of plantar wounds. For more information, visit www.bcm.edu/icamp.

Dr. Ahmed Kayssi is a vascular surgeon at Sunnybrook Health Sciences Centre and a wound care physician at Women’s College Hospital. He obtained his medical degree from Queen’s University in Kingston, Ontario, before relocating to Toronto to pursue training in general and vascular surgery. He subsequently completed a fellowship in limb preservation and wound care under the supervision of Dr. Richard Neville in Fairfax, Virginia. Dr. Kayssi is a graduate of the Harvard School of Public Health, where he obtained a Master of Public Health focusing on quantitative methods and is currently pursuing a Doctor of Public Health in Health Policy and Management from the Johns Hopkins School of Public Health under the supervision of Dr. Ellen MacKenzie.

**Prevention of Diabetic Complications: Local, Provincial/Territorial and National Initiatives**

This symposium has welcomed more than 100 delegates, and attendees from as far as Thunder Bay, Ontario, and Yellowknife, Northwest Territories. Though no one thought the problems of diabetic foot ulcers and amputation would be solved in a one-day symposium, we are encouraged to have a room full of people interested and willing to stay late on a Friday evening to create a network of collaboration.

We need to keep up the momentum on common themes such as data collection and measurement, education, advocacy, public policy, leveraging technology, collaboration and protocol development in prevention and active disease. In future meetings, we will include other specialists to be even more inclusive and multidisciplinary.

The next step for this group is applying for grants to continue work on these issues and to move the agenda forward.

**Topics for Future Events**

The symposium covered a wide range of topics, but not everything could be covered in one day. A number of suggestions came up in the evaluations regarding topics attendees would like to know more about. They include:

- Care of the diabetic foot in primary care and how to prevent the need for intensive management by being proactive, earlier.
- How to access specialists when the wait times are long and unpredictable
- Practical demonstrations
- An approach to diabetic wounds, with more step-by-step instructions.
- Which wounds need a referral from family practice to a specialist
- How to diagnose Charcot neuropathic arthropathy
- A discussion with an orthopedic surgeon, a vascular surgeon and an advanced practice wound care nurse on their perspectives on the management of critical limb ischemia
- Indigenous perspectives in diabetic foot care
- A focus on tertiary care with an emphasis on vascular and podiatric surgery