

Limb Preservation IN CANADA

**The Impacts of COVID-19 on
Diabetic Foot Care**

**A Foot Health Pathway for
People Living with Diabetes**

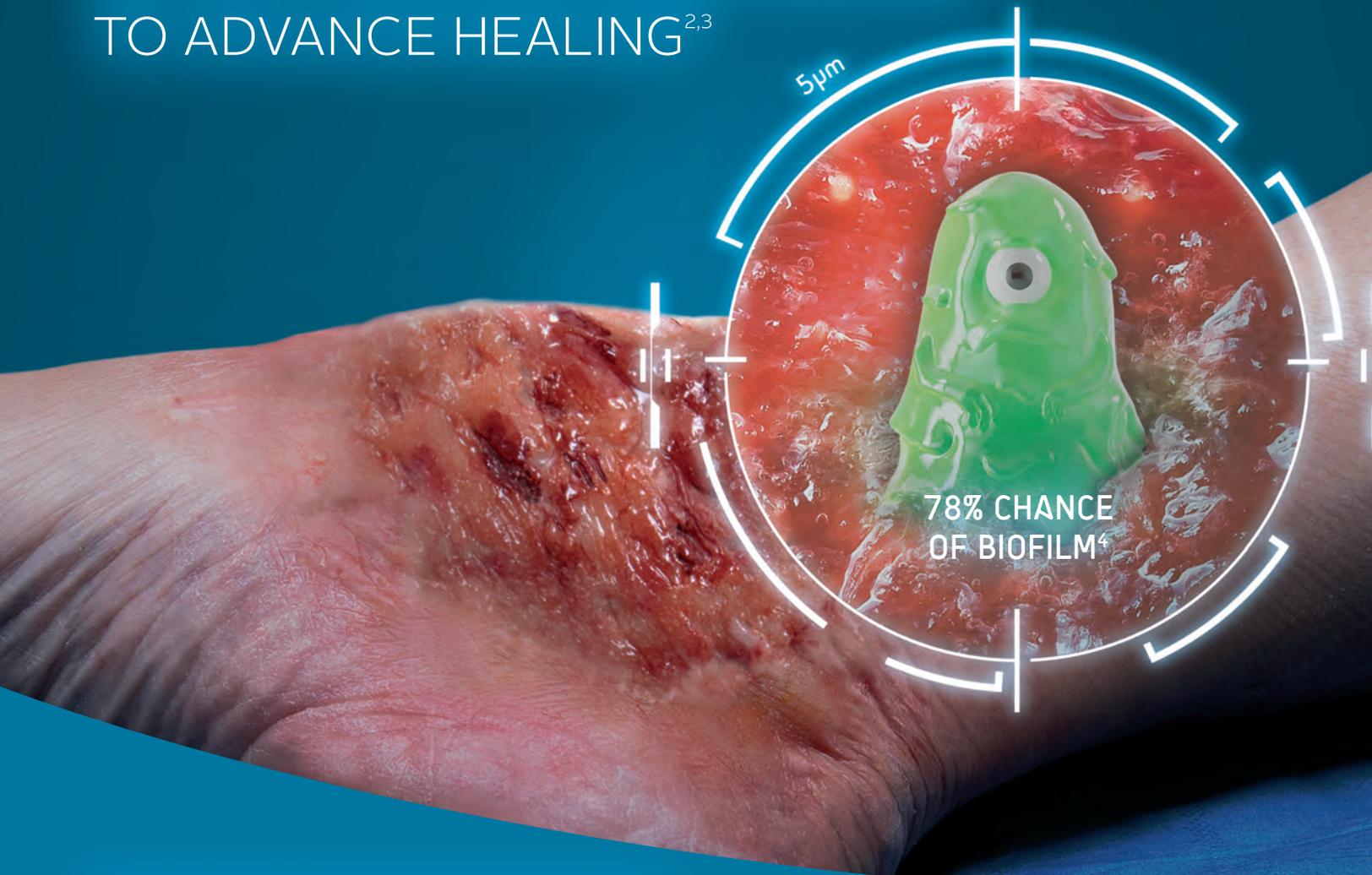
**Saving Limbs and Lives: Building
Out an Ontario Lower-Limb
Preservation Strategy**

**Sex, Gender, Race and Ethnicity
Matter in Limb Preservation in
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**Current and Emerging Treatments
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1. Bowler PG, et al. Parsons, Wound Medicine 14 (2016) 6–11. 2. Metcalf DG et al. J. Wound Care 2016; Vol25, No3. 3. Metcalf DG, et al. Int Wound J 2017; 14: 203-213. 4. Malone M et al. 2017. JWC; 20-25.
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1. Tiscar-Gonzalez V, Rodriguez MJM, Rabadan Sainz C, et al. Clinical and economic impact of wound care using a polyurethane foam multi-layer dressing versus standard dressings on delayed healing ulcers. Adv Skin Wound Care. 2021;34(1):23-30

From the Editor- in-Chief

Dear colleagues,
Welcome to another
issue of *Limb
Preservation in Canada*. Our
goal with this publication is to
create a forum for Canadian
health-care professionals who
are interested in amputation
prevention to learn, share experiences and, most
importantly, better serve our patients.



The past few years have been very difficult. Beyond the significant obstacles to providing timely and appropriate care to our patients during the COVID-19 pandemic, many health-care professionals have faced serious challenges to their safety and mental health. As always, we have rallied to grow, learn and come together as a community to address these challenges.

The 2021 Canadian Limb Preservation Symposium was, in many ways, reflective of the tremendous diversity that makes amputation prevention work so unique. Vascular surgeon Dr. Neil Hopper spoke passionately and very candidly about his personal experience with limb loss. His story, however, is about hope rather than tragedy, and perseverance rather than self-pity. His journey highlights the vigilance with which we need to

approach this work in order to help the many individuals in our communities who are living with an amputation or who are at risk of losing their limbs.

We learned about the many advances in amputation prevention work in the fields of wound care, foot and ankle and plastic surgery, vascular surgery and physiatry. We heard about the importance of adequate data gathering to help track patient outcomes and guide conversations with policy makers around the country. Finally, we heard from Indigenous health-care professionals about the challenges and opportunities with limb preservation work in Indigenous communities.

Reading the many excellent articles contained in this issue, I am very encouraged by the quality of work being done in amputation prevention across Canada and beyond. I am hopeful that every year will find us taking greater strides toward our goal of improving the amputation prevention services that are available for all Canadians.

Respectfully,

A handwritten signature in blue ink that reads "Ahmed Kayssi". The signature is fluid and cursive.

Ahmed Kayssi, MD MSc MPH FRCSC

The Impacts of COVID-19 on Diabetic Foot Care

An interview with Devon Jahnke and Iris Noland

In early 2022, Janet Kubnke, RN, BScN, MS, NSWOC, DrPsych, interviewed Devon Jahnke, DCh, IIWCC, CDE, MClSc (Wound Healing), and Iris Noland, BSc (Biochem), MD, MClSc (Wound Healing), to ask them about their experiences in treating patients with diabetes-related foot complications in the age of COVID.

Q: From your provider perspective can you tell me about your role and the impact COVID has had on care and services for patients with diabetes and foot complications?

Devon Jahnke (DJ): My role as a chiropodist is to provide wound care to people with diabetes and advanced comorbid conditions. Since the pandemic started, I've noticed there has been limitation in services to our people with diabetes and foot wounds. This may be due to several reasons, including:

- Having to limit access to services as per medical directives, both institutionally and provincially
- Redeploying staff to provide services in different ways to provide care for the acute inpatients
- Triaging many patients to the sickest of patients and therefore, not being able to put our efforts toward more preventative means of care

- Experiencing limitations in diagnostic testing such as X-rays and C&S—everything's delayed

What we've noticed over the years of pandemic is that, unfortunately, our patients' wounds have become worse. We are seeing more frequent infections, increased need for antibiotics, more emergency room visits and higher rates of inpatient hospitalizations due to septicemia bacteremia. We've even had complications from infections such as cardiac arrest, higher limb amputations and death.

Interestingly we've also seen an increase in people having more than one type of wound on their feet, and instead of just treating a single wound, we're often treating multiple wounds.

When patients come in, they're scared to be here. They are scared they may become infected with COVID-19 by coming to their appointment and worried about being in a waiting area with other people. They are also scared of what they are going to hear from their medical provider.

Patients can also be very angry due to the circumstances, or very depressed, and that actually

creates a barrier for them to adhere to treatment goals.

We've had to stop all patient education classes for diabetic foot care unless it is through direct contact with a clinician during a scheduled in-person appointment.

Even access to proper footwear or offloading devices has been affected. Supplies of footwear and trying to get people to be fitted with footwear have been limited.

Basic hygiene to keep skin and wounds clean and timely dressing changes have all been impacted and limited. In fact, many times scheduled home care visits have not actually occurred due to an overwhelmed system and lack of personnel or skilled providers.

Iris Noland (IN): I provide both consultant and primary care for patients with diabetes and foot complications in an underserved rural area. Referrals are sent to me from emergency physicians and primary care providers for persons with diabetes and diabetic foot ulcers.

I have seen a lot of what Devon describes. The access that persons with diabetes and foot complications have to medical services has often been delayed due to lack of primary care provider in-person assessments, avoidance of emergency departments because of fear of contracting COVID-19 and fear of being admitted to hospital with the COVID-19 restrictions of visitors.

I consider all DFU referrals as urgent and try to see them within one week. My initial assessment focuses on assessment of vascular status, infection management, pressure redistribution and wound care, including debridement of callus.

The pandemic has resulted in later presentation of complicated wounds and extreme reluctance of patients and families to attend emergency and urgent care clinics as well as specialty clinics and diagnostics. The wait times for CTs, MRIs, vascular Dopplers, interventional radiology and vascular surgery have increased for those with critical ischemia but not immediately limb-threatening wounds. Pressure redistribution/offloading was difficult to obtain before the pandemic and remains extremely challenging, with bottlenecks to access

Devon Jahnke is a chiroprapist, wound consultant and certified diabetes educator with 20 years of experience in wound care. She is employed by Health Sciences North/Horizon Santé-Nord in Sudbury, Ontario. She is an advisory committee member for Health Quality Ontario (HQO) Wound Care Standards and an Ontario Health Technology Committee member for offloading devices. She is a faculty member for Wounds Canada and the Wounds Canada Institute.



Iris Noland is a former medical director of emergency and primary care at Quinte Health, in Ontario, overseeing four emergency departments and three primary care sites (2010–2017), and medical director of primary care (2017–2019). She worked as a hospitalist on the inpatient unit at Trenton Memorial Hospital (1984–2019) and has a primary care practice as a part of the Brighton-Quinte West FHT. In addition, she is the medical director of a long-term care facility and has a consulting practice in wound care with an interest in chronic wounds and lymphedema.



to funded programs through home-care-supported services.

Diabetes education programs have been moved to virtual and online since the pandemic for many patients and, as a result, foot examinations are more often not completed and opportunities for focused education and prevention are missed.

Q: In terms of care delivery, is there anything that has improved? What is not going well?

IN: I can talk about a couple of areas where I've seen improvements. For example, a diabetic foot program was launched in the region through home care, and more home care nurses are doing APBIs, so vascular disease is being identified earlier.

In addition to the things Devon and I mentioned earlier, some of the negative impacts include a shortage of wound care nurses, resulting in inconsistent care and service delays. The rollout

of many diabetic foot programs has not been well communicated, and access has been limited by the need for referrals and nursing availability.

I have also observed shortages in dressing and wound care supplies, which has led to missed dressing changes and substitutions to “whatever is available” to cover the wound.

The already limited and delayed access to pressure redistribution (chronic) has worsened, with bottlenecks at both the referrer and provider points in the process.

There continues to be limited access to funded high-risk foot care in community, and even those who can self-pay or have third-party insurance have found it difficult to access these services due to pandemic restrictions.

Tertiary care interventions for those with vascular compromise are often delayed and subject to multiple cancellations and rebooking due to limited operating room availability and high demand for interventional radiology services.

DJ: We are being more thorough when investigating patients if they’re feeling sick with flu-like symptoms. Infection control and prevention awareness and practices have reduced spread of viral infections prior to entering and mixing with other patients in small spaces. If patients are feeling unwell, we can suspect that these illnesses will impact blood glucose levels and we can correlate the time of illness with blood glucoses changes and possible wound deterioration.

We have improved our awareness of sanitation, hand hygiene, cleaning our rooms, floors and garbage, as well as the need for proper equipment and PPE to keep everyone safe.

We are looking into how to deliver services in different ways, whether it’s virtually, digitally or through telephone conferences. Providing joint appointments with other specialists to reduce the number of appointments the patient may have in the day is something that is showing promise.

However, direct patient care remains limited, including the amount of time provided. Also, some services have been limited or cancelled, such as non-urgent surgeries. This has resulted in more major amputations instead of minor amputations

and an increase in patient hospitalization due to sepsis.

Q: Can you discuss the COVID-related barriers and strengths when it comes to patient and family self-management?

DJ: Well, what we’re witnessing right now due to limited access to clinicians, providers and specialists is patients relying on their family members to provide care. In many instances, their family members have had to advocate for the patient’s needs through telephone conversations or virtual programs. This has given us some insight into what the patient’s home life is like, what their true living conditions are or what their overall environment is. For example, knowing how many stairs a patient may have in their home or how able they are to use the washroom readily when wearing an offloading device is valuable. Family members have had to take blood glucose readings and provide foot inspections and dressing changes. So, in that respect, it has allowed us to address the needs of the patients in a different way.

Patients have had to develop new self-management skills to achieve health-care goals for their diabetes and diabetic foot wounds. This responsibility has been laid at the feet of the patient’s family and immediate social circle. We have identified a care gap. This care gap means we must provide a lot more education to the patient—and their families. This educational approach to care may strengthen the family bonds and support prevention strategies.

However, when the service or treatment of the patient requires hands-on care, that’s when it is truly important for that visit to be in person. It can’t be through the telephone or online.

I have seen more patients want to bring in an additional care provider or support person to their appointments. Therefore, it is not just the patient in the appointment you are educating but the support person as well, and the appointment may take more time to address the concerns of both the patient and the additional caregiver. I think there is an appreciation or better understanding by the family member or support person regarding

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Reference: 1. West, D. (written communication-letter) December 2013

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wound and diabetes management when both parties attend.

IN: The need for self-management has increased due to lack of access to in-person services. For those with education and confidence to manage their diabetes this has worked well, but for those with complications and difficult-to-manage disease there has been inadequate support.

The pandemic has allowed those with skills, access and motivation to become more confident in their ability to manage their diabetes. Patients who have been able to engage family members to support them have benefited from both physical and emotional supports.

Q: Can you describe your experience regarding access to care—both positive and negative—that your patients with diabetes have had to navigate?

IN: With the move to more virtual and telephone education, those without computer skills or access have had limited assessment and education opportunities for management of their diabetes. On the other hand, patients and families with good computer skills, access and motivation have been able to connect with educators/endocrinologists virtually, which has increased their access and improved their diabetes control.

DJ: Well, basically I haven't been able to see as many patients or provide a virtual program to address the needs of our people with diabetes and wounds. People with diabetes haven't been able to access in-person classes. Specialists haven't been able to take on more referrals, and triaging is backed up, leaving our people not being seen in a timely manner.

We've tried to provide services virtually but, as Iris says, not everybody has the technology, good internet connections or skills to manage it.

We have had to rely on telephone conversations, but this limits people with hearing issues who have had difficulty not being able to read lips—especially our elderly population with diabetes.

However, if a patient has had a family member or caregiver to assist them with these things, I think it's helped to build a relationship and an understanding of what the patient needs for self-management of their diabetes. I also think it's allowed us to discover new ways to deliver care using technology. It's shed a light on the gaps in services for people with diabetes. It has exposed the need of advancing wearable technology.

Not having access to in-person care or infrequent patient visits also makes it harder for clinicians to determine if the mental health of the person with diabetes is getting worse. We know that people with diabetes and chronic illness have a higher risk of depression and anxiety. COVID-19 has compounded this. As clinicians we see this reflected in how patients adhere to treatment.

Q: What additional information do you want readers of *Limb Preservation in Canada* to know?

IN: The socioeconomic divide in diabetes care has widened during the pandemic.

The pandemic has resulted in far fewer in-person diabetic assessments, which, for many, has resulted in worsened diabetic management and delayed diagnosis of complications, including DFUs and critical ischemia.

The pandemic has resulted in patients avoiding emergency services due to fear of contracting disease AND fear of being admitted to hospital and separated from family supports. This has led to late diagnosis of severe infection and ischemia with increased major amputations and death.

Diagnostic delays related to access to DI, interventional radiology and vascular surgery have adversely affected outcomes of those with DFU.

DJ: I think it's important that we understand that the impact of COVID-19 will last for years.

Additional Reading

- Carro GV, Carlucci EM, Torterola I, Breppe P, Ticona Ortiz MÁ, Palomino Pallarez JE. Diabetic foot and COVID-19. Medical consultation and severity of lesions compared to 2019. *Medicina*. 2020;80 Suppl 6:30–4.
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- Schuivens PM, Buijs M, Boonman-de Winter L, Veen EJ, de Groot HG, Buimer TG, et al. Impact of the COVID-19 lockdown strategy on vascular surgery practice: More major amputations than usual. *Annals of Vascular Surgery*. 2020;69:74–9.

The impact of chronic wound care on health-care providers—though not studied well—has led to compassion fatigue. COVID-19 has amplified this, leading to loss of experienced professionals to early retirement and an exodus into other fields.

Patients coming to see us are afraid of getting an infection or losing a leg. Now, there's an additional fear that patients are not going to get care or enough care. We know they've lost faith in our health-care system. It's up to us to make sure that faith is returned in a caring and compassionate way. We must inform our patients that services may not be delivered in the same ways as before, but that this creates opportunities for us to advocate and intervene through technological means. Maybe some of our own fears with technology will also be overcome.

I think it has really led to an understanding that we are treating and educating more than just the person with diabetes with the diabetic foot ulcer. We're also treating and educating the surrounding caregivers, family members, partners, neighbours, friends, nieces, nephews and grandchildren. We used to say it takes a village to raise a child. Maybe it should also be said that it takes a village to save a limb. ■

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A Foot Health Pathway for People Living with Diabetes: Integrating a Population Health Approach

By Robyn Evans, BSc MD CCFP FCFP; Janet L. Kuhnke, RN BScN MS NSWOC DrPsych; Virginie Blanchette, BSc MSc DPM PhD; Mariam Botros, DCh DE IIWCC Med; Sue Rosenthal, BA MA; Joel Alleyne, BSc MA MIST; Idevania Costa, RN NSWOC PhD

Current Issues with Diabetic Foot Disease: The Disease Model

Complications from diabetes result in significant challenges for individuals, families and health-care systems.^{1,2} Those living with diabetes are more likely to be hospitalized, live with cardiovascular and renal complications and experience diabetic foot ulcers (DFUs), the leading cause of non-traumatic lower limb amputation.³ People at risk for or living with diabetic foot disease report that the fear of amputation is more significant to them than the fear of death.⁴ The lifetime risk of a diabetic foot ulcer is 19–34%, with a recurrence rate of 40% within a year.⁵ The good news is there are successful evidence-based solutions to prevent four out of five amputations.⁶ The Foot Health Pathway presented here—which is based on an approach that has been successfully implemented in other countries—provides a framework that could be used for optimized care delivery in Canada.

The development of pre-ulcerative lesions and DFUs is a result of well-defined pathophysiologic changes that involve one or more of the following (see Figure 1):

- Neuropathy (loss of protective sensation, leading to injury)
- Foot deformity (as a result of neuropathy, leading to pressure points)
- Peripheral arterial disease (PAD) (compromised blood supply, leading to poor healing outcomes and increased risk for ulcers)

Major foot amputations are on the increase. A recent Canadian study demonstrated the overall rate of any (major or minor) amputation initially declined from a quarterly rate of 9.88 per 100,000 individuals to 8.62 between 2005 and 2010 but increased to 10 per 100,000 individuals by 2016.⁷

Diabetes foot health services in Canada are fragmented—a costly problem that deserves more attention.^{7,8} Funding is inconsistent and is based on treating problems, not preventing them. Funding is split between public and private payers

Figure 1: The pathophysiological conditions required for the development of diabetic foot complications

The Foot Complications Equation



Note: The development of ulcerative DFU or pre-ulcerative lesions (e.g., callus) results from sequelae related to neuropathy. The three types of neuropathy are: **motor**, causing weakness of the small muscles, with resultant foot deformities and biomechanical imbalance; **autonomic**, leading to overly dry skin prone to breakdown; and **sensory**, causing loss of protective sensation. Foot deformities, along with minor trauma related to footwear or other mechanical causes, can precipitate injury to the tissues. Approximately 50% of patients with diabetes also have underlying arterial insufficiency.⁹ This will impact DFU formation and impair wound healing. Metabolic abnormalities related to diabetes will also impact wound healing and the risk for infection. This road to ulceration is also the path to prevention, as many of these issues can be recognized early and managed in the community.

with no co-ordination between the two. What is often missing for persons with diabetes in Canada is timely access to:

- Preventative foot care and screening programs as a part of a national strategy
- Early interventions based on risk
- Proper footwear and offloading devices funded by provincial/territorial health plans
- Access to and/or co-ordination among care providers and payors

In addition, people at risk may not receive enough education about how to care for their feet to prevent or manage foot complications.¹⁰ Such deficits can lead to complications that result in patient suffering and significant social and health-system costs.^{11,12}

Research has shown there is a significant economic burden associated with poor foot health, diabetic foot issues and amputations. Hopkins and colleagues reported that “the annual cost associated with DFU-related care was \$547.0 M, or \$21,371 annual cost per prevalent case.”¹³ This is viewed as a fraction of the total impact to society and the economy—which also would include: intangibles such as pain and suffering, care provided by non-

paid care partners, loss of employment and related costs and impacts on family units.¹³ “Canada is not listed among the top 10 countries for the number of people with diabetes, but it is among the top 10 for diabetes-related health expenditures, with the cost estimated to be \$23 billion. This cost is projected to rise to almost \$30 billion in 2040.”¹³

Diabetic foot hospitalization = A costly intervention

Did you know? A Toronto-based study found the cost for treating foot ulcers related to diabetes was almost \$23,000 per patient, compared to the cost of a stroke at about \$10,000 per patient.¹⁴

The Foot Health Pathway and the Population Health Model

The Foot Health Pathway takes a risk-based approach focused on patient outcomes, experiences and value-based care consistent with the population health principles outlined by the Institute for Healthcare Improvement (IHI).¹⁵ The aim of

this approach is to prevent foot ulcerations, the devastation of amputations, and amputation-related deaths.

To develop the Foot Health Pathway for People Living with Diabetes, a group of Canadian stakeholders (experts and organizations) associated with Wounds Canada came together to develop a system-based guide based on the principles of the IHI's Quadruple Aim framework¹⁵ (see Figure 2). The aims are to:

- Enhance the patient experience
- Improve health outcomes
- Improve value to the health-care system
- Enhance the provider experience

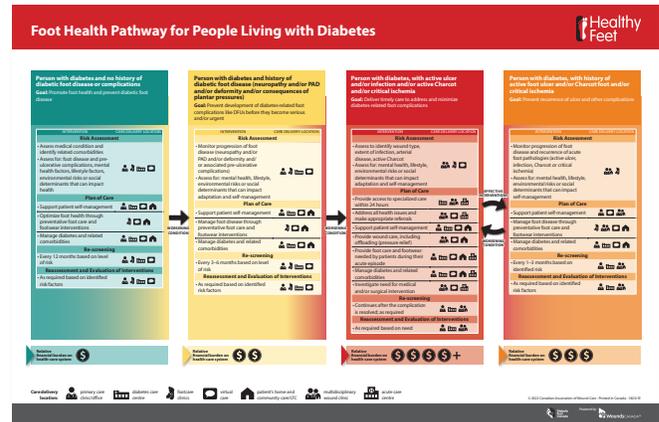
Figure 2: The four components of the Institute for Healthcare Improvement's Quadruple Aim framework¹⁵



The resulting Foot Health Pathway outlines a prevention-based, holistic approach for people living with diabetes, *whether or not they have already developed diabetes-related foot complications* (see Figure 3). The Pathway consists of four domains, each organized around interventions that drive the most desirable outcomes for patients at different levels of risk.

With this approach the focus is on prevention, or “upstream” interventions (yellow and green domains) to prevent “downstream” complications (orange and red domains). While prevention of foot complications is key, it is also necessary to structure health-care systems for the delivery of timely care for persons who do develop a foot ulcer, Charcot deformity, acute critical ischemia or infection (red and orange domains).

Figure 3: The Foot Health Pathway for People Living with Diabetes



For a larger version, see Figure 4 on pages 22 and 23.

Upstream:

Upstream interventions are carried out by a team, including the patient and their families, that focus on the prevention of diabetes and diabetes-related foot complications in relation to social determinants of health, lifestyle engagement and self-management.¹⁶ This care takes place in the community.

Downstream:

Downstream interventions are activities that respond to existing diabetes-related foot complications.

Implementing the Foot Health Pathway

The risk-based Foot Health Pathway provides all stakeholders—including patients and families, health-care providers, administrators, policy makers and researchers—with a clear vision of how the population health approach can be delivered and evaluated at an individual, facility and systems level.

Assess risk

The first step is to identify persons with diabetes and establish their risk for foot complications. A plan of care, with interventions such as a schedule for foot screening at appropriate intervals, can then be implemented.⁹

Early intervention

A callus on a foot may seem like a minor issue; however, for a person with diabetes this represents a pre-ulcerative lesion and should have a defined path for timely evaluation and treatment. The onset of a DFU, a more serious issue, deserves immediate attention by a specialized care team to avoid complications.

Appropriate education

Education is included in all four domains, and it is incumbent on all health-care providers to engage the individual, family and others to become partners in care to identify foot and skin issues early and know where to access timely professional evaluation and intervention.

Individualized care plans

Each domain is organized to assist in identifying an individual's specific risk and then recommend

an appropriate care plan, using a holistic approach, complete with follow-up requirements. These requirements include the need to manage blood glucose and other diabetes-related targets such as cholesterol and blood pressure. Fortunately, care related to comorbidities is available through primary care, sub-specialties and patient self-management. The targets for optimal management of persons with diabetes are listed in Table 1.¹⁷

An Illogical Gap

Individuals with diabetes have ready access to preventative interventions and resources for other disease complications related to eye, cardiac and renal issues that help prevent blindness, heart disease and renal failure. It is necessary to complete their care by implementing risk-driven foot screening to prevent amputations.

Table 1: ABCDESSS of Staying Healthy with Diabetes

A	A1C targets	<ul style="list-style-type: none"> A1C \leq 7% If on insulin or insulin secretagogue, assess for hypoglycemia and ensure driving safety
B	BP targets	<ul style="list-style-type: none"> BP < 130/80 mmHg If on treatment, assess for risk of falls
C	Cholesterol targets	<ul style="list-style-type: none"> LDL-C < 2.0 mmol/L
D	Drugs for CVD risk reduction	<ul style="list-style-type: none"> ACEI/ARB (If CVD, age \geq 55 with risk factors, <i>OR</i> diabetes complications) Statin (if CVD, age \geq 40 for Type 2, <i>OR</i> diabetes complications) ASA (if CVD) SLGT2i/GLP1ra with demonstrated CV benefit (if have type 2 DM with CVD and A1C not at target)
E	Exercise goals and healthy eating	<ul style="list-style-type: none"> 150 minutes of moderate to vigorous aerobic activity per week and resistance exercises 2–3 times per week Follow healthy dietary pattern (e.g., Mediterranean diet, low glycemic index)
S	Screening for complications	<ul style="list-style-type: none"> Cardiac: ECG every 3–5 years if age > 40 <i>OR</i> diabetes complications Foot: Monofilament/Vibration yearly or more if abnormal Kidney: Test eGFR and ACR yearly, or more if abnormal Retinopathy: yearly dilated retinal exam
S	Smoking cessation	<ul style="list-style-type: none"> If smoker: Ask permission to give advice, arrange therapy and provide support
S	Self-management , stress, other barriers	<ul style="list-style-type: none"> Set personalized goals Assess for stress, mental health and financial or other concerns that might be barriers to achieving goals

Source: Diabetes Canada¹⁷

Green = Low Risk

- Person with diabetes and no history of diabetic foot disease or complications
- Goal: Promote foot health and prevent diabetic foot disease

An upstream, population health approach should be utilized to identify foot risk and then improve early detection, with the aim of preventing diabetic foot complications.¹³ To this end, appropriate health policy should be in place to provide and promote foot screening for individuals with diabetes. Patients in the green domain are low risk, and the green domain is considered a low-cost domain.



This foot health and prevention perspective requires a care approach that supports patient education and engagement in their own daily foot care activities.^{18,19} It also identifies diabetic foot problems (calluses, corns, ingrown toenails, fungal infections) and associated risk factors that can result in further complications and development of active pathologies, which would move the patient to the yellow domain, with different surveillance parameters.

Ideally, patients with diabetes who are defined as low risk (green domain) need to be screened annually as per Canadian guidelines.¹⁹

Location of care:

Care takes place at home and in the community in locations such as primary care offices/clinics and diabetes education centres. Depending on resources in communities there are many health providers that can screen and educate patients about the general principles of diabetic foot health.

Yellow = Moderate Risk

- Person with diabetes-related foot disease (neuropathy, PAD, deformity, plantar pressures)
- Goal: Prevent development of diabetes-related foot complications like DFUs before they become serious and/or urgent

Patients in the yellow domain are at higher risk for foot complications because they have identified risk factors; neuropathy and/or deformity and/or peripheral

arterial disease. Even though they may not have an ulcer, they will require more frequent screening and preventative foot care interventions to manage pathologies such as calluses, blisters and ingrown toenails. This is a critical time for preventative interventions, as the next step is a complication that moves the patient into the red domain. The screening interval in this domain is every 3–6 months depending on the identified risk.



Location of care:

Care for patients in the yellow domain remains in the community (primary care, preventative foot care clinics, diabetes education centres and pharmacies in some communities). It is essential that the screening clinician be able to manage the identified foot issue or refer to the appropriate care provider.

Note: Often, the offloading of pressure—which is key to managing calluses and other foot deformities—is required. It is a specialized skill most often provided by chiropody/podiatry and is needed at this crucial time to prevent additional, more serious, complications. Because of neuropathy, foot deformities change over time and require more frequent screening by a specialist. Footwear education, evaluation and adjustments are patient specific and must be ongoing. In Canada, funding for this specialized care would improve the system of health-care delivery so patients with diabetes could be better supported in the community.

Who and when? The Green and Yellow Domains

Patients and Care Partners

Individuals, their families and care partners are the first line of defence for preventing diabetes-related foot complications. Their individualized, risk-based plan of care should include:

- Access to education/information about their condition, risks, supports and resources
- Self-monitoring through daily foot inspections, basic foot nail and skin care
- Selection and use of appropriate footwear
- Identification of necessary contacts in the event of a concerning change

Each time individuals see their health providers, including their family physician, podiatrist, nurse practitioner or certified diabetes educator, they should ask or remind these health providers to assess and discuss their risk level for developing diabetes-related disease or complications and initiate interventions as necessary.

Screening, assessments and care planning should begin as soon as they are diagnosed with diabetes and continue throughout their lives.

The Clinical Team

According to the International Working Group on the Diabetic Foot, the health providers who should support individuals at the lower levels of risk include:⁹

- Primary care practitioners, diabetes educators, dietitians and pharmacists for Low Risk (Category 0)
- General practitioners, podiatrists, chiropodists, diabetes educators, dietitians, pedorthists and orthotists for Moderate Risk (Category 1)

Where this screening takes place is dependent on available resources across the country. Screening and primary care are the responsibility of providers such as family physicians, podiatrists/chiropractors, nurse practitioners, certified diabetes educators, dietitians and pharmacists. Some key points for them to consider include:

- At-risk patients should have foot exams scheduled according to their risk. A commonly used risk assessment tool is **Inlow's 60-second Foot Screen**
- Patients need to set realistic and practical goals to support a healthy lifestyle to reduce the risk of developing diabetes-related foot complications
- Socio-economic determinants of health that may be barriers for the patient should be investigated and addressed as part of any care plan²⁰
- Professional development for care partners/clinicians in the areas of skin and wound care should be supported, as rates of diabetes and diabetes-related foot complications are on the rise²⁴

Red Domain = Urgent Risk (Complications)

- Person with diabetes with active ulcer/infection/active Charcot/critical ischemia
- Goal: Deliver timely care to address and minimize diabetes-related foot complications

Individuals who have an active foot ulcer, infection, Charcot neuro-osteoarthropathy, or critical limb-threatening ischemia represent an urgent issue. In any of these scenarios, the goal is to eliminate or minimize complications through timely access to specialized care.⁹



Persons with limb- or life-threatening complications need to involve an interprofessional team, ideally within 24 hours.^{21,22} In a country as large as Canada, this can be a challenge for some patients, particularly for those living in remote or rural communities. A potential solution involves increased educational programs for both clinicians and patients, as well as access to virtual wound care hubs.²³ Ideally, the need for this level of care can be reduced if the Pathway is implemented in all regions.

Location of care:

Depending on the urgency of the condition and availability of wound care services, initial care may take place in a hospital emergency department or a foot care centre in which multiple disciplines specializing in diabetic foot care are assembled. The team to manage these patients varies but often includes wound care nurses and physicians, a vascular surgeon, infectious disease specialists, endocrinologists and others related to specific patient comorbidities.^{24,25}

To address current gaps, policy makers, administrators and researchers should investigate the feasibility of establishing multidisciplinary virtual or physical limb preservation clinics across Canada. This approach, which has proven successful in other countries, is a well-established method to enhance support of limb preservation efforts based on what is known as the Toe and Flow model.^{26,27} The

Table 2: Three Levels of Limb Preservation Clinics

	Aims	Location	Team Members
Basic	<ul style="list-style-type: none">• Prevention and basic curative care	<ul style="list-style-type: none">• Office, health centre, small regional hospital	<ul style="list-style-type: none">• Podiatrist, primary care practitioner, foot/wound care nurse
Intermediate	<ul style="list-style-type: none">• Prevention and management• Advanced assessment and diagnosis	<ul style="list-style-type: none">• Hospital	<ul style="list-style-type: none">• Podiatric surgeon, vascular surgeon, diabetologist, diabetes educator, wound care nurse
Advanced	<ul style="list-style-type: none">• Prevention and curative care for complex cases• Advancement of knowledge base• Education	<ul style="list-style-type: none">• University hospital	<ul style="list-style-type: none">• Podiatric surgeon, vascular surgeon, diabetes educator, orthopedic surgeon, orthotists, rehab therapist, psychologist, infectious disease specialist, diabetologist, wound care nurse

Adapted from Rogers and colleagues.²⁷

presence of more of these clinics in Canada would facilitate the engagement of all stakeholders working together in all regions and better address patient risk factors, including social determinants of health. Table 2 illustrates the aims, location and personnel generally present at the different types of limb preservation clinics.

Orange Domain = Very High Risk

- Individuals with a history of an active foot ulcer, Charcot foot or critical ischemia
- Goal: Prevent recurrence of ulcer and other complications

After a DFU is closed, there is an estimated 40% recurrence rate within one year and almost 60% within three years.⁵ Once a foot ulcer has closed, the new tissue is only 75–85% as strong as the original.²⁸ These figures remind providers to consider individuals who have achieved wound closure as “living in remission” rather than having a healed wound.²⁸

A gradual return to pre-ulcer level activities is recommended.^{29,30} Patient education should focus on sustaining engagement in diabetes and foot



self-care and implementing strategies to maintain remission. Strategies should include screening every 1–3 months, offloading devices, appropriate footwear, daily foot exams, glycemic control and healthy nutrition.

Location of care:

Care for patients in the orange domain takes place at home, in a primary care setting and/or in a specialized foot care centre.

Policy Support for the Pathway

The Foot Health Pathway highlights upstream preventative care, timely detection and immediate intervention for pathology as well as the implementation of activities to prevent wound deterioration and recurrences. The following elements must be part of any successful Pathway implementation plan:

- A vision for health goals based on risks that support wellness, early intervention and timely access to appropriate care
- Policies to ensure and guide identification, screening and risk stratification for foot complications in all individuals living with diabetes
- Policies to guide policy makers, administrators and researchers on relevant outcomes measurement and data collection, analysis and dissemination
- Policies to support the implementation of prevention strategies

- A culture where the development and implementation of individualized, patient-driven care plans are the rule, not the exception

Evaluation of this approach should be done by audits of the services that have adopted the Quadruple Aim framework³¹ to inform ongoing quality improvement.

Who and when?

The Red and Orange Domains

Patients and Care Partners

Patients in the red and orange domains should continue to perform the activities outlined for the green and yellow domains. In addition, they should receive:

- Regular updates about their health status
- Ongoing education about interventions, self-management, how to identify emergencies and what to do in an emergency
- Support and encouragement to be involved in care planning and goal setting
- Emotional and spiritual support

The Clinical Team

Specialists are required to manage the emergencies of patients described in the red domain. The types of practitioners are outlined in Table 2.

Once the person is no longer facing an emergency, primary care providers are well positioned to screen and educate these patients, who are now in the orange domain. However, primary care providers do not generally have the expertise to manage offloading and footwear recommendations, and they should be made aware of the resources available in the community so they can direct patients appropriately and avoid delay in accessing the right specialist at the right time.²² Excellence in communication between specialists and primary care providers is essential for co-managing these patients, particularly in rural and remote areas. A co-ordinated, proactive approach incorporates crucial steps to prevent poor outcomes, including:

- Ongoing foot inspection
- Early detection
- Immediate action and intervention
- Excellent communication among patients, families and health providers
- Early referrals to foot and/or wound care specialists
- Patient, family and other care partners' engagement in foot self-care

Requirements

Health systems implementing the Foot Health Pathway will be required to:

- Support preventative practices to reduce the incidence of DFUs and optimize access to preventative services
- Invest in primary care and community care to support diabetic foot screening and risk stratification
- Provide access to high-quality interprofessional wound care services
- Implement standardization in clinical practice and integrated referral protocols that are informed by the Quadruple Aim framework
- Align human resources for competency-based care delivery to optimize services
- Ensure services support timely and appropriate access to wound care services and enhance access to use of innovative health technology
- Support value-based and person-centred care delivery models
- Build mechanisms to effectively measure, monitor and evaluate processes and outcomes related to the prevention and management of foot complications
- Develop, implement and evaluate awareness strategies and campaigns informed by the best available research.¹⁶

Conclusion: The Way Forward in Canada

To match the success in limb preservation that has been reported in some European countries, Australia and Alberta^{32,33} using the holistic approach outlined in this document, we propose that the Foot Health Pathway be adopted by all health regions in the Canada. While based on international evidence and best practice standards, this pathway can be adapted to fit the needs and resources of any health jurisdiction and successfully implemented, provided the general principles are met. As a tool for communicating to individuals, families, health providers, administrators, policy makers and funders, this pathway provides a person-centred, population health model based on risk and early and appropriate interventions. It outlines a stronger focus on risk screening and secondary and tertiary prevention using an inte-

grated team approach that promotes foot health in people with diabetes. The ultimate goal is to prevent and/or reduce diabetes-related foot complications, including infection, ulcers, amputations and death. ■

Advocacy Efforts

Over the last several years, Wounds Canada and other stakeholders have advocated for research-supported policy changes.^{34–37} Among the recommendations is the need for:

- Providing universal access to preventative foot care services, including supplying preventative shoes, socks and offloading devices to those in need, free at the point of care, for all Canadians living with diabetes
- Developing policies that enable every Canadian with diabetes to have at least one foot assessment per year by a qualified health provider
- Adopting a Canada-wide interprofessional approach to diabetic foot care, with at least one multidisciplinary diabetes foot care team, with a well-defined referral pattern, in every health region
- Publishing, on an annual basis, reliable data on diabetes foot care, using internationally recognized metrics, to assist ongoing quality improvement efforts

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Useful Resources

For Clinicians

- Inlow’s 60-second Diabetic Foot Screen
- Dépistage du pied diabétique en 60 secondes
- BPR Briefs: Diabetic Foot Ulcers
- Best Practice Recommendations for the Prevention and Management of Diabetic Foot Ulcers
- Product Picker: Offloading
- Wound Dressing Selection Guide

For Patients

- Caring for Your Feet: Safe Foot Care if You Have Diabetes
- Diabetic Foot Complications: When is it an emergency?
- Wound prevention and treatment: Do it yourself (DIY) or call in a pro? Neuropathic/Diabetic Foot Ulcer
- Diabetes, Healthy Feet and You pamphlet (available in 16 languages)
- Finding the Proper Shoe Fit (available in 16 languages)
- Foot Examinations for People with Diabetes

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Dr. Virginie Blanchette is the first podiatrist PhD in Québec and has been an associate professor in the podiatric medicine program at Université du Québec at Trois-Rivières since 2014. Her research specialty is prevention and management of diabetic foot ulcers and their complications, with a limb preservation approach within patient-oriented research. She is mentored by David G. Armstrong (Keck School of Medicine, University of Southern California) and is currently a Diabetes Action Canada trainee. She joined the Diabetic Foot Canada Task Force in 2019, is a member of the scientific committee of the Limb Preservation Symposium and a member of the Wounds Canada board of directors.

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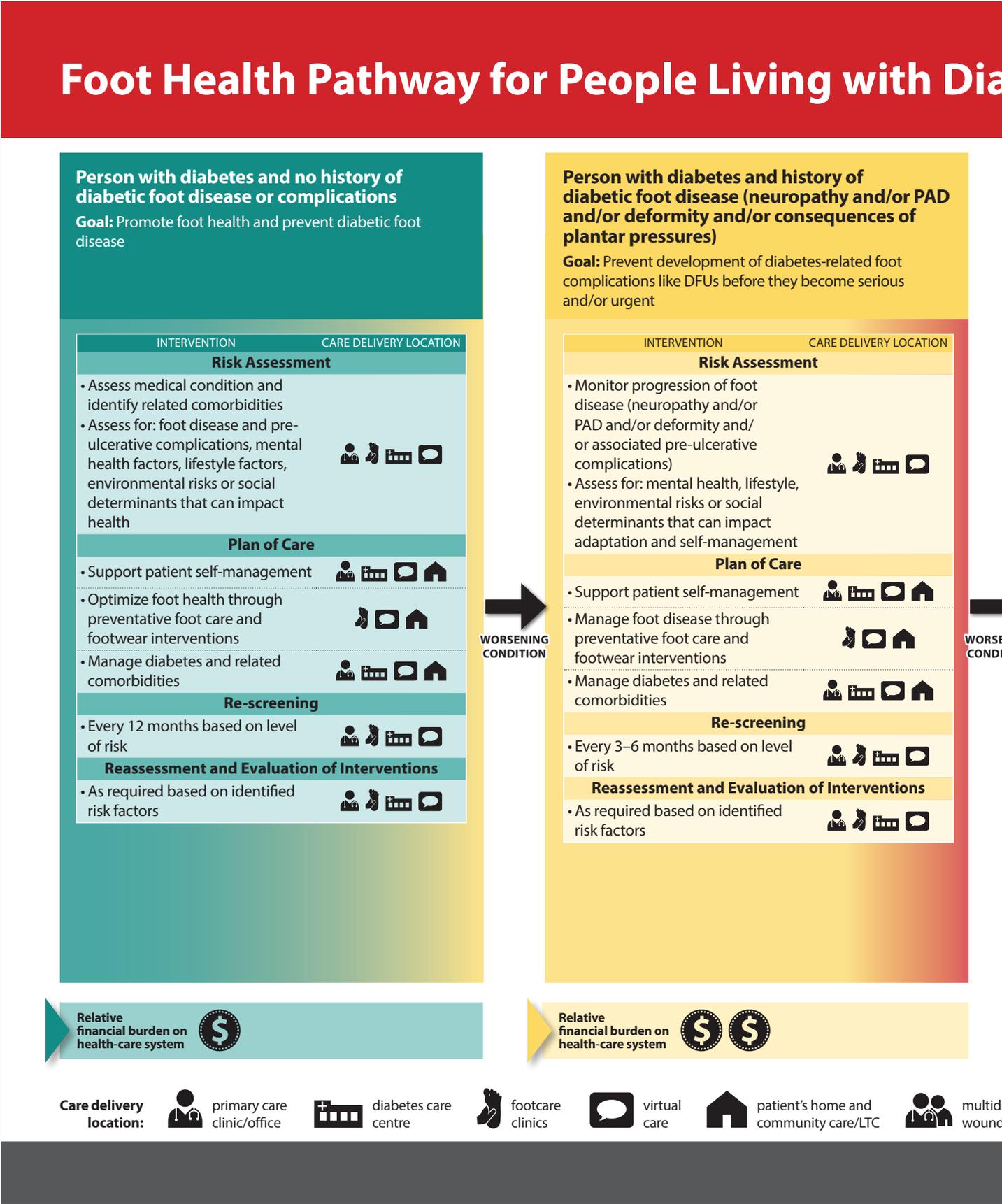
is a chiroprapist and diabetes educator by training, with a master’s degree in Educational Leadership. She has published widely, lectured extensively and supported the development, implementation and evaluation of many programs related to diabetic foot complications, wound care and amputation prevention nationally and internationally. In her various roles she has demonstrated her longstanding passion for community service, education and patient care.

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Figure 4: Foot Health Pathway for People Living with Diabetes



Person with diabetes, with active ulcer and/or infection and/or active Charcot and/or critical ischemia

Goal: Deliver timely care to address and minimize diabetes-related foot complications

INTERVENTION	CARE DELIVERY LOCATION
Risk Assessment	
<ul style="list-style-type: none"> Assess to identify wound type, extent of infection, arterial disease, active Charcot Assess for: mental health, lifestyle, environmental risks or social determinants that can impact adaptation and self-management 	
Plan of Care	
<ul style="list-style-type: none"> Provide access to specialized care within 24 hours Address all health issues and make appropriate referrals Support patient self-management Provide wound care, including offloading (pressure relief) Provide foot care and footwear: needed by patients during their acute episode Manage diabetes and related comorbidities Investigate need for medical and/or surgical intervention 	
Re-screening	
<ul style="list-style-type: none"> Continues after the complication is resolved; as required 	
Reassessment and Evaluation of Interventions	
<ul style="list-style-type: none"> As required based on need 	

EFFECTIVE INTERVENTIONS

WORSENING CONDITION

Person with diabetes, with history of active foot ulcer and/or Charcot foot and/or critical ischemia

Goal: Prevent recurrence of ulcer and other complications

INTERVENTION	CARE DELIVERY LOCATION
Risk Assessment	
<ul style="list-style-type: none"> Monitor progression of foot disease and recurrence of acute foot pathologies (active ulcer, infection, Charcot or critical ischemia) Assess for: mental health, lifestyle, environmental risks or social determinants that can impact self-management 	
Plan of Care	
<ul style="list-style-type: none"> Support patient self-management Manage foot disease through preventative foot care and footwear interventions Manage diabetes and related comorbidities 	
Re-screening	
<ul style="list-style-type: none"> Every 1–3 months based on identified risk 	
Reassessment and Evaluation of Interventions	
<ul style="list-style-type: none"> As required based on identified risk factors 	

Relative financial burden on health-care system

Relative financial burden on health-care system

Interdisciplinary clinic acute care centre

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Saving Limbs and Lives: Building Out an Ontario Lower-Limb Preservation Strategy

By Mike Setterfield, MSc; Lynn Scholey, RKin MSc

There are over 1,200 non-traumatic major lower-limb amputations every year in Ontario, the majority resulting from complications of vascular disease, diabetes or both.¹ This equates to one lower-limb amputation every 7 hours, and results in approximately \$140 million in direct amputation health-care costs annually.² Ontario amputation rates are high, particularly in Northern and Indigenous communities, compared with many other jurisdictions.^{3,4} Up to 85% of major lower-limb amputations are preventable through effective initiatives that include:^{3,5,6}

- Early identification and screening of at-risk feet and lower-limbs
- A collaborative and seamless interprofessional team approach to patient care across care settings
- Culturally safe patient education
- Continued education for health-care providers

Jurisdictions that have successfully implemented lower-limb preservation initiatives have shown tremendous reductions in amputation rates.^{7,8,9} Further, it is estimated that successful implementation will save millions in health-care dollars annually.^{6,10,11}

The Strategy

Ontario Health – CorHealth Ontario is collaborating with a provincial Advisory Committee

to develop a multi-year provincial Lower-Limb Preservation Strategy (the strategy). The Advisory Committee, chaired by Dr. Ahmed Kayssi, is composed of vascular and wound care experts, primary and community care providers, patient and family advisors and system partners. The strategy aims to facilitate a co-ordinated, integrated and patient-centred approach to lower-limb preservation care in Ontario. Strategy goals are to:

1. Reduce avoidable, non-traumatic major lower-limb amputations in Ontario
2. Improve equitable access to high-quality best-practice early screening, cardiovascular risk factor modification and integrated lower-limb wound care

To learn more about the strategy, please visit <https://www.corhealthontario.ca/llp>.

Strategy Resources

A foundational strategy resource is An Ontario Framework for Lower-Limb Preservation (the framework). The framework includes:

- System-level care pathways that highlight key care activities for the prevention and management of lower-limb wounds
- Minimum care requirements to standardize lower-limb preservation care

- Key considerations for a model of care to guide the organization and integration of lower-limb preservation services



The framework provides a roadmap for lower-limb preservation providers, organizations and champions to optimize the delivery of integrated, best-practice lower-limb preservation care aimed at positively impacting patient outcomes while reducing health-care costs.

Of note is the new Pathway for Preventing and Managing Vascular Wounds (the pathway). This pathway is a practical system-level pathway developed in collaboration with Wounds Canada. The pathway is aligned with the Wounds Canada “Best Practice Recommendations for the Prevention and Management of Peripheral Arterial Ulcers”¹² and highlights key care activities for evidence-informed best-practice vascular wound prevention and management in a practical one-page infographic. It defines a vascular wound and strongly recommends that every lower-limb wound should be considered a vascular wound until proven otherwise.

A Change Package has also been developed to accompany the framework. It is a working document that provides actionable change ideas, tools and resources from which lower-limb preservation providers, organizations and champions can adopt and/or adapt, based on local/regional needs and opportunities, to improve lower-limb preservation

care delivery, services and outcomes, and to measure and evaluate change success.

Included in the change package is a Patient Toolkit of provincial, national and international tools and resources on lower-limb, foot and wound prevention and management for providers to share with patients and families to support their education and self-management.



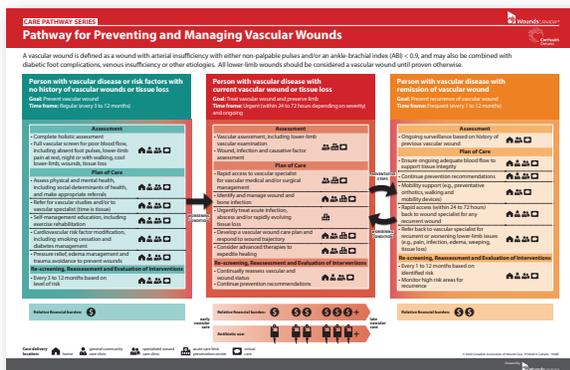
Building Out the Strategy

To begin implementation of the strategy, Ontario Health – CorHealth Ontario is partnering with demonstration programs from across diverse regions of the province.

Demonstration programs will consist of a local/regional collaboration table of interested lower-limb preservation champions and stakeholders from across the care continuum, along with patient and family advisors with lived experience. With guidance from Ontario Health – CorHealth Ontario, utilizing the framework and change package, demonstration programs will be tasked with:

- mapping current-state patient care journeys
- identifying local/regional needs
- prioritizing change opportunities
- developing, implementing and evaluating change action plans

Knowledge sharing and dialogue among demonstration programs will be facilitated through a provincial community of practice. Through the demonstration phase, key barriers and critical success factors for implementation will be identified, as well as opportunities to better align current policy to support best practice. Demonstration programs will share with Ontario Health – CorHealth Ontario an evaluation of their change



A demonstration program

is a regional, interprofessional group of primary, home, community and specialized health-care providers who are formally committed to collaborate and implement changes to improve outcomes for individuals at risk for non-traumatic major lower-limb amputation.

action plans as well as lessons learned to support the co-development of a plan for provincial implementation and adoption of the strategy.

Lower-limb preservation providers, organizations and champions are encouraged to use the framework to guide the planning, development and implementation of lower-limb preservation services. Working together, we will continue to improve access to high-quality, best-practice early screening, cardiovascular risk-factor modification and integrated lower-limb wound care, and reduce avoidable, non-traumatic major lower-limb amputations.

To learn more about the strategy and demonstration program engagement, please visit <https://www.corhealthontario.ca/llp> or contact Mike Setterfield at mike.setterfield@ontariohealth.ca. ■

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Sex, Gender, Race and Ethnicity Matter in Limb Preservation in North America

By Virginie Blanchette, BSc MSc DPM PhD; Ahmed Kayssi, MD MSc MPH FRCSC CWSP

A session summary from Wounds Canada's 2021 National Fall Conference

Sex as a biological attribute and *gender* as a social construct are crucial considerations in relation to health care. Sex and gender issues affect, among other things, patients' incomes, resource availability, access to health services, commitment to their health, and relationships with health and social services providers and caregivers.¹ Similarly, *race*, a social construct based on shared physical traits, and *ethnicity*, a cultural expression of identification, also have impacts. The causes of sex, gender, racial and ethnic disparities in health care are multifactorial and reflect differences in biological vulnerability to disease as well as differences in social resources, environmental conditions and health-care interventions.²

These factors are well known to influence the fate of people with diabetes-related foot complications such as diabetic foot ulcer, infection and amputation, and are important considerations for health-care professionals, especially with the diversity of Canada's population.³ In this paper we discuss the important concepts of health equity, equality and disparity in relation to the impact of sex, gender, race and ethnicity on limb preservation.

Health Equity

The difference in health status between populations is closely linked to social and demographic factors such as socioeconomic status, health insurance status, literacy level, sexual orientation and disability. Health equity applies the concept of social justice to the realm of health care to ensure social and environmental factors do not limit a person's access to high-quality health care.⁴ Further, health equity aims to ensure no person is denied the possibility of good health as the result of belonging to a group that has historically been economically or socially disadvantaged.

Health inequity is therefore defined as difference in health status that is avoidable, unfair and unjust.⁵ Some examples of health inequity include racial and ethnic discrimination, lack of access to high-quality education, income and/or wealth gaps, inadequate or absent housing, or an unsafe environment.

Health Disparity

Health disparities are the differences in health care—including access, patient factors and clinical outcomes—between populations related to

social or demographic factors.⁶ Health disparity is a metric used to measure progress toward achieving health equity. These disparities are modifiable factors that systematically and negatively impact less advantaged groups and compromise health-care systems. Health disparities are preventable and signal gaps in the quality of care.

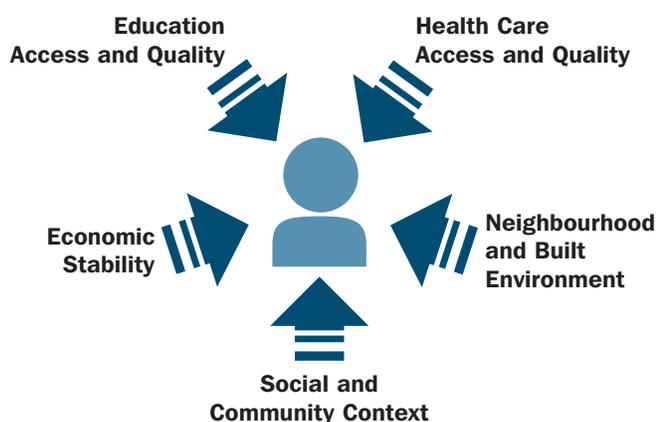
Equality in Health

Equality in health care refers to what is fair and equitable. It means that everyone receives the same standard of care, regardless of their specific needs and contexts.⁷ The patient-centred care and holistic approaches can therefore be compromised with a very rigid application of health equality. However, patient-centred care can result in a higher degree of equality in health when there is an equal patient-provider relationship.⁸

Social Determinants of Health and Limb Preservation

The World Health Organization (WHO) defines social determinants of health as conditions or circumstances in which people are born, grow, live, work, and age (see Figure 1). These conditions are shaped by political, social, and economic forces.⁹

Figure 1: Social Determinants of Health



Diabetes leads to 65% of all non-traumatic lower-extremity amputations (LEA) in Canada.¹⁰ The precursor event is the diabetic foot ulcer (DFU), with an incidence of 2–4% per annum. The prognosis of DFU is poor, especially with concomitant infection and peripheral arterial disease (PAD).^{10–12}

Dr. Virginie Blanchette is the first podiatrist PhD in Québec and has been an associate professor in the podiatric medicine program at Université du Québec at Trois-Rivières since 2014. Her research specialty is prevention and management of diabetic foot ulcers and their complications, with a limb preservation approach within patient-oriented research. She is mentored by David G. Armstrong (Keck School of Medicine, University of Southern California) and is currently a Diabetes Action Canada trainee. She joined the Diabetic Foot Canada Task Force in 2019, is a member of the scientific committee of the Limb Preservation Symposium and a member of the Wounds Canada board of directors.

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. He is a graduate of the Harvard School of Public Health, where he obtained a master of Public Health degree, focusing on quantitative methods, and is currently pursuing a doctorate of Public Health in Health Policy and Management from the Johns Hopkins Bloomberg School of Public Health.

Indeed, PAD is another leading cause of LEA in Canada.^{12–14} A recent study from Ontario showed that 94% of those who had an LEA had also PAD.¹² As a result, over 80% of LEAs in Canada are attributable to the presence of both conditions. In high-income countries like Canada and the United States, diabetes and PAD prevalence have been rising over the past two decades.^{12–14} Therefore, to support limb preservation, it is relevant to closely examine the effect of sex, gender, race and ethnicity on individuals with those comorbidities because of the impact they have on health care disparity.

Sex and Gender Differences Related to Diabetes and PAD

There is a higher prevalence of diabetes-related foot disease (DRFD) in men than in women, as well as

a higher prevalence of comorbidities and risk factors such as previous history of DFU and revascularization procedures.^{15,16} Because there is a higher risk of neuropathy for men, they are at higher risk of DFU recurrence.¹⁷ Women are associated with a higher cardiovascular risk profile.¹⁸ However, there is a higher prevalence of smokers or with a history of smoking, hypercholesterolemia, obesity, ischemic heart disease and cerebrovascular diseases in men that is associated with DRFD.¹⁵ DRFD also affects men at a younger age than women.

Further, a study has demonstrated that the rate of DFU healing is higher for men than for woman (85% vs 63%, $p < 0.001$) and also slower (124 days vs 87 days, $p = 0.02$).¹⁵ While there is no difference in major LEA rate between men and women, the mortality risk is higher for men (25% vs. 16%, $p = 0.02$), as is the risk of recurrence.¹⁵ There is evidence that women are less likely to be screened for DRFD.¹⁶ Despite our universal access to care in Canada, there are disparities in the risk of LEA among patients with diabetes related to socio-economic status and gender. Men living in low-income neighbourhoods are at greatest risk.¹⁹

PAD is more frequent in high-income countries in woman (3–29% among women aged 45–93

years). However, due to the protective effect of estrogen, women tend to present with PAD 10–20 years later than men. Moreover, women have higher rates of subclinical, asymptomatic and atypical PAD due to the more diffuse involvement of microcirculation and a pro-inflammatory profile. Women are less likely to undergo minor LEA and arterial bypass surgery. Men, however, have been found to experience a greater overall burden of PAD; their arterial tree is more severely involved, with a morphological configuration of characteristics typical of diabetic PAD.^{15,16,20–24}

In general, men are less compliant in health habits and follow-up than women are. Men also tend to have lower adoption rates of self-protective habits such as selection of appropriate footwear and regular foot care. Women, however, are less likely to be monitored for foot complications as a regular part of treatment. For these reasons, it is important for clinicians to ensure access to sex/gender-focused care and to support the empowerment of their patients while considering their differences. Targeted education can help with this disparity.^{15,25}

Table 1 provides a summary of the primary sex and gender differences in therapeutic approaches to diabetes and PAD.

Table 1: Main sex-gender differences in therapeutic approaches for diabetes and PAD^{26,27}

Procedures/Drugs	Sex and Gender Differences
• Revascularization	• Men < Women • Mortality: Men < Women
• Amputation	• Men > Women
• Statins	• Myopathy: Men < Women • Diabetes risk: Men < Women
• Hypoglycemic molecules: thiazolidinediones	• Exposure: Men < Women • Mortality: Men < Women • Risk of bone fracture: Men < Women
• Angiotensin-converting-enzyme (ACE) inhibitors	• Survival Southern Europe: Men < Women • Survival Northern Europe: Men = Women
• Hypoglycemic molecules: glucagon-like peptide-1 receptor agonists (Glp1-agonist)	• Targeted level of glycosylated hemoglobin: Men > Women
• Fibrinolytic therapy	• Benefit effect: Men < Women
• Antithrombotic	• Use: Men > Women
• Antihypertensive	• Use: Men < Women
• Pentoxifylline	• Not known
• Cilostazol	• Not known

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Race and Ethnicity Differences Related to Diabetes and PAD

In Canada, the prevalence and incidence of diabetes are greater in certain population groups such as First Nations, Métis and Inuit, along with those of African, Caribbean, East Asian, Southeast Asian, South Asian, and Latin descent.^{28–31} These groups also experience higher rates of major LEA than the non-Indigenous population (OR = 1.85, 95% CI: 1.04–3.31). The effects of rurality may be closely intertwined with ethnicity, resulting in disparate outcomes.^{32,33} However, another systematic review found no significant differences between any racial/ethnic group.³⁴ These divergent results may demonstrate the essential relationship that social determinants of health play as important cofactors for those population disparities.^{32,34–36}

In addition, in the United States, African American patients are less likely to have undergone a revascularization attempt before an LEA when compared with other patient populations. Following revascularization, the two-year LEA-free survival rate is lower for African American populations (68% vs 75%, $p < 0.001$).^{37–39} Non-white populations are associated with increased primary LEA, decreased revascularization, decreased in-hospital mortality and increased length of stay.³⁹ A recent study demonstrated that access to funded health-care resources related to limb preservation decreased lower extremity amputations among underserved racial and ethnic minority adults with DFUs in the U.S.⁴⁰

First Nations, Métis and Inuit Populations

In Canada's First Nations, Métis and Inuit populations, health disparities may be driven in part by poor access to health care, barriers to clear communication, cultural differences and discrimination.^{41,42} LEA frequency is three to five times higher in this population than in the general population. Similarly, the mortality rate following an LEA is 15% higher in First Nations populations than in non-First Nations populations (adjusted HR: 1.15, 95% CI: 1.05–1.26), and median survival is 3.5 years for First Nations versus 4.1 years for the general population. PAD is more prevalent in First Nations populations, but revascularization rates are comparable.^{43,44}

Addressing Disparities in Limb Preservation

It is critical to provide low-cost services to those living in low-income households. Preventing complications with early intervention leads to better health outcomes. Telemedicine and telehealth services that use mobile screening and management can be used effectively to support remote and rural communities and lower transportation costs for patients and organizations.^{45–47} Providing better education, screening, investigations and treatment access to those communities particularly impacted by diabetes and PAD, patient-centred care, the use of evidence-based practices and a team approach to limb preservation among all stakeholders and socio-cultural contexts can all improve outcomes.^{48,49}

Cultural Security in Care

Patients' interactions and engagement with diabetes care are influenced by personal and collective historical experiences with health-care providers and contemporary exposures to culturally unsafe health care. Minimizing or eliminating barriers to patient-provider interactions, health services and health systems is critical.^{42,51,52}

PROGRESS+PLUS Framework for Equitable Limb Preservation

PROGRESS+PLUS is a framework of considerations that can be applied to clinical practice, organizational policy and research.⁵⁰ The elements of PROGRESS+PLUS are:

- Place of residence
- Race, ethnicity, culture and language
- Occupation
- Gender and sex
- Religion
- Education
- Socioeconomic status
- Social capital

The PLUS extends the original framework to include personal characteristics associated with discrimination (e.g., disability, age), features of relationships (e.g., children of smoking parents) and time-dependent relationships (e.g., release from incarceration).

Taking Action

To improve population health and overall quality of care in the field of limb preservation, the clinical and research communities must take actions to reduce bias by being more inclusive in care settings and clinical trials. Addressing the lack of access, lack of understanding, lack of trust and lack of a common language in practice, education and research can help to reduce gender and racial gaps.

Summary

Health equality, disparity and equity are unique and important concepts that impact how limb preservation is approached. A person's ability to access limb preservation services is impacted by who they are and where they live and we, as clinicians, administrators and policy makers, have the responsibility to support care in all communities. By acknowledging barriers to health care, more effective and equitable health-care systems can be developed and better outcomes achieved. ■

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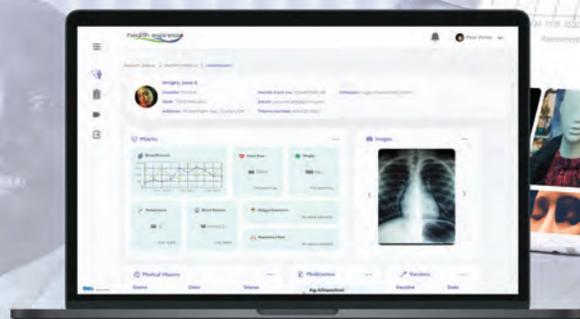
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Current and Emerging Treatments for People Living with Lower Limb Ulcers

By Robert Fitridge, MS FRACS; Deirdre O’Sullivan-Drombolis, BScPT MCISc (Wound Healing); Suzanne Stewart, RN NSWOC WOC(C)

A session summary from Wounds Canada’s 2021 National Fall Conference

Background

Lower limb ulcers (LLUs) are common, with a prevalence of 0.8 to 2.2 patients per 1000 population, doubling in incidence in people aged over 65. Only 20% of ulcers heal within three months, and 50% take longer than one year to heal. Venous ulcers are the most common LLUs and have been shown to cost 2% of the national health budget in the UK.¹ Diabetes-related foot ulcers (DFU) occur in up to 25% of individuals affected with diabetes during their lifetime and were recently found to be implicated in 79% of all minor amputations and 61% of major amputations in Australia and New Zealand.² Arterial ulcers become increasingly common with age and will be discussed below.

Management of Venous Leg Ulcers (VLU)

The basic tenets of VLU management are:

- Confirming the diagnosis: Ulcer location (generally lower third of calf) and associated features (swelling, venous skin changes, venous dermatitis)

- Excluding arterial disease (see below) and other causes of ulceration (e.g., vasculitis, malignancy)
- Utilizing compression therapy (graduated compression bandaging or compression stockings)
- Ordering early venous incompetence ultrasound (also known as a venous Duplex scan)

Early Ablation of Superficial Venous Incompetence

The Early Venous Reflex Ablation (EVRA) trial studied 450 patients who had venous ulceration for six weeks to six months, and an ankle-brachial pressure index (ABPI) less than or equal to 0.8 (i.e., no or minimal arterial disease as assessed by the clinician). Venous incompetence scanning demonstrated primary or recurrent superficial venous incompetence (great or short saphenous vein), either with or without deep vein incompetence. These patients were randomized to one of two study groups: 1) standard compression therapy or 2) compression therapy and early endovenous saphenous vein ablation with laser, radiofrequency, sclerotherapy or glue.³

The study found that ulcer healing time was quicker in the early ablation group (HR 1.38, 95% CI 1.13–1.68, $p = 0.001$). Median healing time was 56 days for the early ablation group ver-

sus 82 in the compression only group. Recurrence rate was also lower after one year, at 11.4% versus 16.5%. The two treatment arms were cost neutral, but there was a significant gain in quality adjusted life years.⁴ It is important to note that appropriate compression therapy resulted in excellent healing times in the control as well as treatment group.

Approaches to the Non-healing Venous Ulcer

If a venous ulcer is not responding to compression with or without ablation in about two months (i.e., ulcer halved in area), clinicians should consider a punch biopsy to exclude other causes. If arterial disease cannot be excluded clinically, clinicians can use toe pressure measurements to guide the level of compression the patient should receive. The presence of calf swelling and ulceration above the ankle often makes taking an ABPI reading challenging or unreliable. Doppler waveforms can be used to exclude significant arterial disease (see below). It is important to note that recurrence rates are high when there is residual venous incompetence or if there is unrepaired deep venous incompetence. Therefore, in the setting of deep vein or residual superficial vein incompetence, long-term compression (usually with class 2 or 3 knee-high compression stockings) should be worn.

Assessment of Arterial Disease in Lower Limb Ulcers

Assessing for ischemia is important for determining etiology and the likelihood of healing of lower limb ulcers. Unfortunately, clinical examination is often unreliable, particularly in patients with diabetes, renal failure and leg swelling.

Chronic Limb-threatening Ischemia (CLTI)

CLTI is a spectrum of disease that includes patients with objectively documented peripheral arterial disease (PAD) *and* any of the following:⁵

- Ischemic rest pain (ankle pressure < 50 mmHg, toe pressure < 30 mmHg)
- Diabetes-related foot ulcer
- Non-healing lower limb or foot ulceration (> 2 weeks)

- Gangrene involving any portion of the lower limb or foot

Patients with CLTI have a high risk of poor outcomes in terms of amputation-free survival. There is a three-step approach for revascularization of these patients, which can be remembered using the acronym **PLAN**:

1. Estimated **P**atient risk (procedural as well as long-term survival)
2. Severity of **L**imb threat (wound, ischemia and foot infection [WIFI]⁶)
3. **A**natomical pattern and severity of disease (using the Global Limb Anatomic Staging System [GLASS]). For revascularization, clinicians need to assess arterial disease from the aorta to the foot, including aorto-iliac, femoro-popliteal and tibial-foot occlusive disease. When tissue loss is present, clinicians plan revascularization to ensure in-line flow with a target artery path from aorta to foot to support wound healing.⁵

Revascularization Treatment Options for CLTI/Arterial Ulcers

The optimal approach to revascularization is determined by patient fitness, anatomical distribution of disease and availability of a suitable vein for bypass. Endovascular (e.g., angioplasty, stent), open surgery (e.g., bypass, endarterectomy) or combined (hybrid) procedures are equally valid. Medical management, including statin therapy, antiplatelet therapy, control of hypertension and diabetes as well as smoking cessation, are all critical components of therapy in patients with CLTI.

Adjunctive Therapies for Lower Limb Ulcers

The Role and Impact of Exercise on Lower Limb Ulcer Healing and Pain Management

In 2019, Kesterton and colleagues conducted a feasibility trial of supervised exercise training in adults with venous leg ulcers.⁷ Sixteen participants (56% male, mean age 65 years, 81% retired and 19% employed in sedentary occupation) complet-

ed face-to-face interviews about what led them to the trial and what they found beneficial in the trial.

Many patients reported living a sedentary, cautious lifestyle due to fear of injury, pain, reduced mobility, lack of education, and advice to rest and be careful. On the other hand, patients reported that support from others, individualized intervention and supervision by a specialized exercise professional were a key benefit of the trial. All participants found some benefit from the intervention, such as improved wound healing, physical benefits, improved psychological well-being, positive impact on comorbidities or improved self-management strategies for long-term health conditions.⁷

Exercise Intervention

Within the body we see arterial obstruction, endothelial dysfunction, increased blood viscosity, mitochondrial dysfunction, and ischemia and free radical creation. Overall these result in decreased oxygen delivery, decreased oxygen utilization and increased inflammation in the tissues. The outcome for the person with PAD is progressive atherosclerosis, loss of muscle mass, claudication, functional limitations and cardiovascular deconditioning. This in turn feeds back into the impairments we see in the body, creating a downward spiralling effect.⁸ When exploring the mechanisms of functional impairment in PAD, the protective and potentially reversing effect of exercise can be seen (see Figure 1).

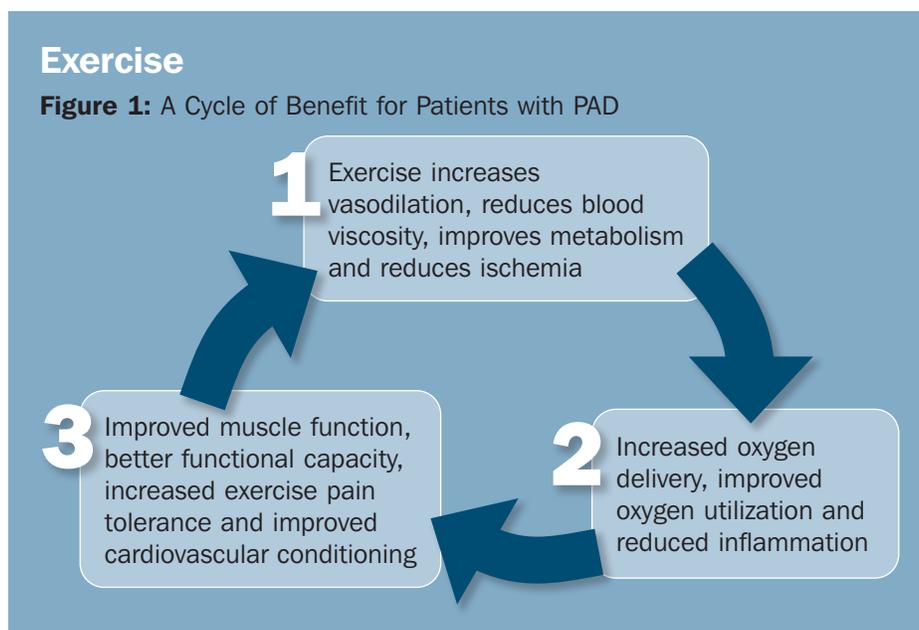
There are four main types of exercise that have been shown to be beneficial in patients with PAD.⁹

SUPERVISED EXERCISE TREADMILL TRAINING

Supervised exercise treadmill training is well established in the literature to benefit patients with

PAD.⁷ There are very specific guidelines for prescribing this training:

- **Intensity:** 40–60% maximal workload based on baseline that brings on claudication within 3–5 minutes
- **Duration:** 30–50 minutes of intermittent exercise
- **Claudication intensity:** Moderate to moderate/severe
- **Work-to-rest ratio:** 5–10 minutes to reach claudication followed by rest until pain is dissipated (usually within 2–5 minutes)
- **Frequency:** Three times per week, supervised
- **Program duration:** At least 12 weeks
- **Progression:** Every 1–2 weeks to achieve a full 50 minutes. As individuals can walk beyond 10 minutes without claudication, increase the treadmill incline or speed to keep walking bouts to 5–10 minutes
- **Maintenance:** Lifelong maintenance at least two times per week



STRUCTURED HOME-BASED TREADMILL EXERCISE

This form of exercise intervention can have a positive effect on claudication and function.¹⁰ While home-based programs are generally more access-

ible and remove the stress of constant monitoring, supervised program outcomes have been found to be superior to home-based programs. However, results are similar to those achieved in supervised programs when home-based programs include specific prescription; contact with an exercise professional or coach; specific, recorded goals; and the use of a pedometer or activity monitor.

PAIN-FREE WALKING EXERCISE TRAINING

Pain-free walking exercise training is low intensity, only bringing patients to minimal claudication. Patients should start a 0.4 km per day and increase the distance every two weeks until they reach 3.2 km. Patients should walk five days per week at $\leq 40\%$ heart rate reserve (HRR) and rating of perceived exertion (RPE) 11–13 until they feel minimal claudication. Patients should use a logbook or activity monitor to record progress.¹¹

LEG AND ARM ERGOMETRY

Both leg and arm ergometry have shown positive effects on claudication and function; however, they are not as profound as with treadmill training programs. Studies that found positive effects with this intervention were structured and involved an exercise professional.¹²

The Role of an Audible Handheld Doppler

As discussed earlier, identifying and treating the cause of a wound and its underlying physiological processes are the first steps in achieving wound healing. When looking at lower leg wounds, it is important to determine arterial blood supply using the ABPI to rule out PAD and determine that blood supply is sufficient to heal the wound.¹³ While these tests are helpful, ABPIs have several disadvantages:

- They are time-consuming
- They can cause patient discomfort and pain
- Results can be affected by calcified vessels (leading to elevated ABPI value)¹⁴
- They are not always easily accessible
- They are costly
- There is a significant chance of user error

An audible handheld Doppler (AHHD) can be used in place of a traditional ABPI to rule out arterial disease.¹⁴ An AHHD transmits a waveform that is interpreted to determine ABPI level (see Figure 2).

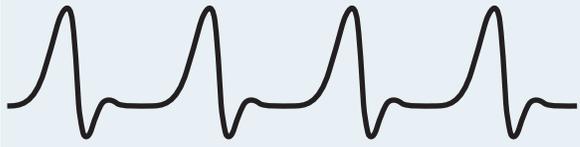
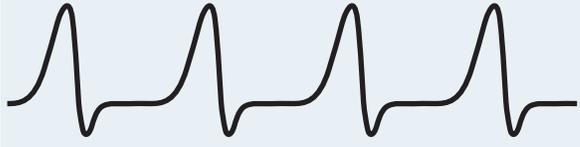
A triphasic (three distinct phases/sounds) or biphasic (two distinct phases/sounds) waveform means the patient's ABPI is 0.9 or greater and there is enough blood flow to close a wound. It also means compression can be safely initiated. If

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Deirdre O'Sullivan-Drombolis has been a physical therapist for over 20 years. In 2010 she graduated from the inaugural class of the Wound Healing program at the University of Western Ontario. Since that time she has used these skills to work with clients with chronic wounds, conduct research, participate in publications such as the Wounds Canada Best Practice Recommendations, and share knowledge by teaching numerous courses in the area of wound care for organizations like Wounds Canada and the Ontario Physiotherapy Association. As a physical therapist her passion is the promotion of safe physical activity for all and empowering patients to be able to participate in their life and maximize their independence.

Suzanne Stewart is a Registered Nurse and NSWOC currently working in Calgary, Alberta, at the Sheldon M. Chumir Wound Clinic. She completed her BScN at the University of Alberta in 2009 after which she quickly developed an interest in wounds while working on a medical teaching unit at the Foothills Medical Hospital. She briefly took a break from nursing in 2012 to pursue a lifelong dream of going to pastry school; however her love for wound care eventually brought her back to nursing. In 2018 she enrolled in the NSWOC WOC Education Program to further her ongoing passion for wound care. She has experience in providing wound education in long-term care and supportive living settings, participating in skin and wound research and providing wound care in the acute and community settings.

Figure 2: Waveforms

Type		Waveform
Triphasic	<ul style="list-style-type: none">• ABPI is 0.9 or greater	
Biphasic	<ul style="list-style-type: none">• ABPI is 0.9 or greater	
Monophasic Absent	<ul style="list-style-type: none">• arterial disease cannot be ruled out• refer to vascular lab	

there is a monophasic (only one distinct phase/sound) waveform, or the waveform is absent, further assessment is required and referral to a vascular lab for a full Duplex is needed.¹³

USING AN AHHD

This test requires an 8 MHz handheld Doppler and conductive gel. The patient does not have to lie down and can remain in a comfortable position. The clinician locates the dorsalis pedis (DP) and posterior tibial (PT) pulses, uses a generous amount of conductive gel and gently applies the Doppler at a 45-degree angle.¹³

ADVANTAGES OF AHHD

AHHD is fast (about one minute of listening), cost-effective (about half the price of an ABPI) and pain-free.¹² AHHD requires less equipment and training than an ABPI, results are not affected by calcification and it can be done at the bedside. It is important to note that while an AHHD can *rule out* vascular disease, it does not diagnose the presence and severity of vascular disease.¹⁶

Conclusion

Lower limb ulcers are common, significantly impact an affected individual's quality of life, and are costly to treat. Diagnosing the cause of the ulcer is critical to successful management. Many affected individuals have ulcers with mixed

etiology, which makes diagnosis and therapy challenging. ■

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CASE STUDY

Successful Limb Salvage Combining Revascularization Surgery with an Advanced Acellular Dermal Matrix (ADM) in Treating Multiple Non-Healing Diabetic Foot Ulcers

By Asem Saleh, MSc MD RPVI FRCSC; Idevania Costa, RN NSWOC PhD;
Paul F. Gratzner, MASc PhD PEng

Introduction

The number of people with diabetes is increasing each year and is projected to reach 439 million by 2030, approximately 10% of the world's adult population.¹ Up to 25% are expected to have non-healing foot ulcers, with the success rate for wound closure with standard of care ranging from 35 to 50% and taking an average 8–9.5 weeks.^{2,3} It is known that 85% of lower extremity amputations are preceded by a diabetic foot ulcer (DFU),^{1,2} with a limb being amputated somewhere in the world every 20 seconds.³ In Canada, the annual cost for treating non-healing DFUs is \$500 million.⁴ In addition to the economic burden of non-healing DFUs leading to amputation, few diseases have a higher mortality rate, reaching 30–50% after two years.⁵ Over 65% of DFUs have an ischemic component, making vascular surgery an essential procedure for limb preservation.⁶ Even with revascularization and best standard wound care practices, however, significant challenges remain in healing DFUs and avoiding amputations. This report features a case study of a patient with diabetes with

multiple non-healing necrotic lesions on both feet. Despite aggressive standard treatments and surgeries, the wounds remained open. After amputation of the left foot was necessary, a new approach using a combination of revascularization and an advanced acellular dermal matrix (ADM) (developed by the 3rd author) was successfully used to preserve the right foot.

Presentation

Mr. W is a 75-year-old male with diabetes. He is insulin-dependent (over 10 years), uses an insulin pump, is an ex-smoker (quit 10 years ago) and has hypothyroidism. His A1c levels indicate his sugars are well controlled. He has a history of peripheral neuropathy and loss of protective sensation. He was first seen in February 2020 due to a 3-month history of multiple necrotic lesions on both his feet.

His right foot had ulcers located at the 1st digit medial side (3 cm x 4 cm), lateral side of the foot at the base of 5th toe (3 cm x 3 cm), and a heel ulceration (2.5 cm x 3 cm), all of which displayed dry gangrene. He also had a 3rd digit amputation five

years ago that was healed. His left foot had ulcers on the 1st digit toe (2 cm x 2 cm), and two on the 4th digit toe (both 1 cm x 1 cm). He also had a 3rd digit amputation seven years ago, which was healed.

A CT (computer-aided tomography) angiogram of both feet revealed extensive vascular disease, with vessels at the lower third and below ankle chronically occluded. Initially, a bypass to the posterior tibial artery was performed on the left foot but failed after six weeks due to occlusion. A posterior pedal loop reconstruction was then performed endovascularly. The foot then developed a severe infection while on a one-week trip with his family. Unfortunately, the left foot was subsequently amputated due to the severe infection.

The right foot had an initial vascular reconstruction using a posterior pedal loop. Wounds were healing but then stopped, and surgery was performed to reopen the pedal loop. Mr. W was then sent for hyperbaric oxygen therapy (HBOT), along with aggressive serial debridement and very compliant offloading. Very slow healing and periods of regression occurred over the next eight months. Vessel re-occlusion and reopening operations occurred a total of four times. His blood vessels were very calcified and re-occluded quickly. Amputation of the leg was discussed with Mr. W, but he wanted to fight to heal. Given that the wounds on his foot seemed under control at this point and that his left foot was amputated already, aggressive standard wound care was continued. Unfortunately, even with this approach, the wounds persisted, along with recurrent superficial infections.

Interventional ADM Product

The product utilized in this case study is an advanced human acellular dermal matrix (ADM) material (DermGEN™) that is the first to have been developed and manufactured entirely in Canada (Figure 1). The product is created from donated human skin that has been supplied by an American Association of Tissue Banks (AATB)-accredited tissue bank in Canada. The donated skin is processed using an innovative method of decellularization whereby the donor cells that cause rejection are removed while the remaining non-living protein

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Dr. Ide Costa is an advanced clinical nurse with expertise in the management of complex wounds. She was educated in both Brazil and Canada as a registered nurse, wound care specialist and researcher and has over 24 years of combined experience in clinical practice, teaching and research. Currently, she is an assistant professor in the School of Nursing and adjunct professor in the Faculty of Health Science at Lakehead University in Ontario. She practises wound care at her own clinic in Thunder Bay. She has been the recipient of multiple national and international awards in recognition of her outstanding work as a wound care nurse and researcher in Canada and Brazil. She is an advocate for improving timely access to wound care specialists for vulnerable populations and for empowering patients and families to take control of their own health.

Dr. Paul Gratzner is a licensed Professional Engineer (PEng) and an Associate Professor in the School of Biomedical Engineering at Dalhousie University in Halifax, NS, with cross-appointments in the Departments of Surgery and Process Engineering and Applied Science. He holds degrees in Chemical Engineering, Biomaterials Science and Biomedical Engineering. His research has been focused on soft tissue regeneration and decellularization technology for over 25 years. He is a co-founder and the inventor of the patented decellularization technology used by DeCell Technologies Inc. He is active as an author and on journal editorial boards, is a reviewer for many prominent biomedical journals, participates as an expert on many research funding agency committees and has been a technical advisor with Canadian Blood Services for Tissue Banking.

Figure 1: Example of the Canadian acellular dermal matrix (ADM) DermGEN™ and its application on a wound



“scaffold,” the extracellular matrix (ECM), which makes up most of the physical structure of the skin, is left intact. By removing the immune-reaction-causing cells and retaining the ECM, the ADM retains properties and characteristics of skin (proteins, growth factors and cytokines) that attract and stimulate cells within a wound to migrate into the ADM and begin the process of regenerating new tissue. In particular, for hard-to-heal wounds like DFUs, the ADM also acts as a “reset button” for inflammation, breaking the inflammatory cycle and destructive cell behaviour and pushing cells into regenerative and tissue-building activity. In short, this Canadian ADM is a scaffold that the patient’s cells recognize as the framework of skin that is incomplete and needs to be remodelled and replaced by repopulating it with appropriate cells and new ECM from the patient—thereby accelerating the healing of hard-to-heal wounds.

The ADM product is unique on the Canadian market and is the only advanced regenerative matrix technology approved by both Health Canada and the FDA. In comparison to other advanced wound care products available internationally, it is stable at room temperature, ready to use off the shelf, easy to apply, sterile and has been shown in a clinical study¹⁰ and in an increasing number of clinical cases to be highly effective in healing difficult and complex wounds in most cases with only one application.¹¹ Further, the production of this ADM uses a first-ever automated closed system that ensures quality, consistency and safety of the product. Unlike other tissue-based products that use radiation to ensure sterility, this Canadian ADM uses a validated first-ever liquid sterilization process that does not alter or degrade the product’s properties.

A recent Ontario Health Technology Assessment Committee (OHTAC) report has reviewed and recommended ADM products for the treatment of DFUs based on their health treatment economics and efficacy.¹²

Clinical Intervention with ADM

After the ADM product was supplied to our clinic (1st author), a final repair of the artery was conducted. The outcomes of that procedure are shown in the angiograms in Figure 2 and blood pressure measurements in Table 1. The ADM was placed onto each of the three wounds, with each wound prepared by debridement to provide a bleeding wound bed (a requirement to help the ADM incorporate into the wound). A piece of ADM was applied to each wound by cutting a 5 cm x 5 cm piece to approximately 2–3 mm past the margins of the ulcer, with the dermal side in contact with the wound bed. No other prep-

Figure 2: Angiogram of leg before and after revascularization procedure

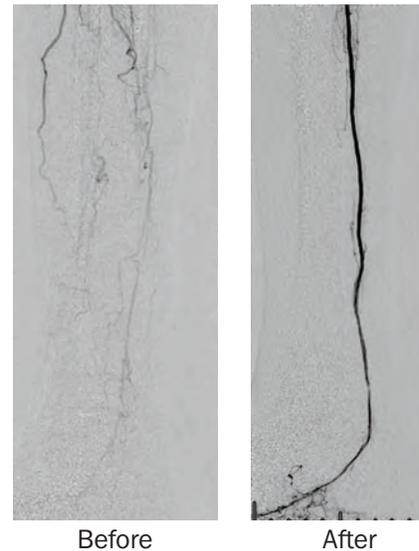


Table 1: Blood pressures and indices after revascularization procedure

Artery	Pressure (mm Hg)	Index Value	Index
Brachial	157		
Dorsalis Pedis	75	0.43	
Posterior Tibial	185	1.06	ABI
Great Toe	38	0.22	TBI

paration of the ADM was required prior to use (e.g., thawing or rehydration) as it was supplied in a sterile and hydrated form and stored at room temperature. A non-adherent dressing with moisture-controlling foam with border was used as a secondary dressing to cover the graft. No sutures or staples were needed to fix the ADM onto the wound bed. After applying the ADM graft, the patient was taught how to offload the foot and was seen weekly for follow-up and secondary wound dressing changes.

Outcomes

One week following the ADM application, all three foot ulcers had good uptake and integration of the

ADM graft into the wound bed (Figures 3, 4, 5). The heel ulcer closed after 10 days post-treatment (Figure 3), and the lateral ulcer closed after three weeks post-treatment (Figure 4). The medial ulcer slowly healed and then presented with a necrotic central area three weeks post-treatment. The medial ulcer required debridement of the necrotic area, and a second ADM graft was applied. The ulcer closed four weeks later (Figure 5).

Discussion

While the focus of most research into wound healing treatments has been on moisture and bacterial control, new approaches that target the instability

Figure 3: Progression of healing of the heel wound from treatment day with the ADM to closure



Figure 4: Progression of healing of the lateral foot wound from treatment day with the ADM to closure



Figure 5: Progression of healing of the lateral foot wound from treatment day with the ADM to closure. Note that at week 3, a necrotic centre was present in the wound. Debridement of the necrotic tissue was conducted and a second piece of ADM was placed onto the wound. The wound then went on to close four weeks later



of the extracellular matrix (ECM) in a wound is timely and much needed—particularly for hard-to-heal wounds such as DFUs. Innovative technologies that provide ECM interactions halt the chronic inflammatory cycle and stimulate cells that allow for tissue regeneration and wound healing—and have the potential to accelerate healing.^{7,8} In the clinical practice guidelines (CPG) published by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and Society for Vascular Medicine, adjuvant therapies were recommended when DFUs failed to demonstrate improvement of >50% wound area reduction after a minimum of four weeks of standard wound therapy.⁹ In this CPG, under item four entitled Wound Care for DFUs, recommendation 9 states “We suggest consideration of the use of extracellular matrix products employing acellular human dermis or porcine small intestinal submucosal tissue as an adjunctive therapy for DFUs when recalcitrant to standard therapy.”⁹

This case study illustrates that providing adequate blood flow to a lower extremity in combination with offloading, debridement and HBOT may not be enough to promote complete healing and save a limb. Patients can suffer through multiple attempts over months and even years to achieve wound healing. The multiple attempts can delay healing and may lead to infection with a devastating outcome: amputation as a final resort.

Demonstrated in a pilot study,¹⁰ and now here, is a new product and solution to accelerate the healing of hard-to-heal wounds that traditionally have challenged clinicians and raised fear of amputation among patients. This first-ever Canadian ADM

played an important role in saving Mr. W’s remaining foot and has the potential to save many others. As a vascular surgeon (1st author) and an advanced wound care nurse (2nd author) dealing with a variety of challenging, hard-to-heal wounds, we believe the use of this new ADM graft to treat non-healing ulcers may help provide the missing elements required to promote successful DFU healing and avoid amputations. ■

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Disclosure

Dr. Paul F. Gratzner is the inventor of the technology, Co-Founder and Chief Scientific Officer (CSO) for DeCell Technologies Inc. Dr. Asem Saleh and Dr. Idevania Costa have no conflicts of interest and have not received payment to write this paper.

Acknowledgments

Samples of the ADM (DermGEN™) for the study were supplied by RegenMed, Regenerative Medicine located in Thunder Bay, Ontario, Canada.

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Recommended Reading

Letter to the Editor re: Herraiz-Adillo, Á et al. The accuracy of toe brachial index and ankle brachial index in the diagnosis of lower limb peripheral arterial disease: A systematic review and meta-analysis

Read it: [https://www.atherosclerosis-journal.com/article/S0021-9150\(22\)00067-3/fulltext](https://www.atherosclerosis-journal.com/article/S0021-9150(22)00067-3/fulltext)

My colleagues and I were concerned about the results published in the article “The accuracy of toe brachial index and ankle brachial index in the diagnosis of lower limb peripheral arterial disease: A systematic review and meta-analysis.” We know the importance of vascular assessment for the detection of PAD.

We have therefore written to the Editor to obtain certain details and to highlight certain very important elements during research on the ABPI, including the instrument used and the method of calculation as well as to take into account the populations studied in order to carry out analyses of subgroups, especially for patients with diabetes and PAD. At the same time, this exercise made it possible to raise methodological biases. The editor and authors of the article, and we, are satisfied with the clarifications provided.

Original article: Herraiz-Adillo, Á. Cavero-Redondo I, Álvarez-Bueno C. Pozuelo-Carrascosa, DP, Solera-Martínez M. The accuracy of toe brachial index and ankle brachial index in the diagnosis of lower limb peripheral arterial disease: A systematic review and meta-analysis. Atherosclerosis. 2020;Dec;315:81–92.

Letter to the Editor: Patry J, Bernatchez J, Beaumier M, Blanchette V. (2022). Improving the sensitivity of the ankle brachial index using an alternative calculation method in the diagnosis of lower limb peripheral arterial disease. Atherosclerosis. 2022. S0021-9150 (0022) 00067-00063.

Response to Letter to the Editor: Herraiz-Adillo, Á. Cavero-Redondo I, Álvarez-Bueno C. Pozuelo-Carrascosa, DP, Solera-Martínez M. (2022). Reply to: “Improving the sensitivity of the ankle brachial index using an alternative calculation method in the diagnosis of lower limb peripheral arterial disease.” Atherosclerosis. 2022. S0021-9150 (0022) 00066-00061.

Reviewer: Maryse Beaumier, RN, PhD

Health service organisation impact on lower extremity amputations in people with type 2 diabetes with foot ulcers: Systematic review and meta-analysis

Read it: <https://link.springer.com/article/10.1007/s00592-020-01662-x>

This study aims to evaluate the impact of organizational aspects of care on lower extremity amputation rates among people with type 2 diabetes affected by foot ulcers. Results indicate that specific organizational arrangements, including multidisciplinary teams and care pathways, can prevent up to half of amputations in people with diabetes and foot ulcers. Further research needs to identify specific roadblocks to translating evidence into action. These may be structures and processes at the health system level, e.g., availability of professionals with the right skillset, reimbursement mechanisms and clear organizational intervention implementation guidelines.

Meza-Torres B, Carinci F, Heiss C, Joy M, de Lusignan S. Health service organisation impact on lower extremity amputations in people with type 2 diabetes with foot ulcers: Systematic review and meta-analysis. Acta Diabetologica. 2021;58:735–47.

Reviewer: Tom Weisz, BA, DCh, IIWCC

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Patient data and photos courtesy of Robert J. Klein, DPM, FACFAS, CWS; Department of Surgery, University of South Carolina – School of Medicine, Greenville, South Carolina. As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

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Foot-in-wallet disease: Tripped up by “cost-saving” reductions?

Read it: <https://diabetesjournals.org/care/article/37/9/e196/29344/Foot-in-Wallet-Disease-Tripped-Up-by-Cost-Saving>

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saved by the elimination of podiatrist reimbursement, the associated increase in hospitalization charges was \$48 (i.e., \$351,000 saved annually from podiatry vs. \$16.7 million incurred per year via increased hospitalizations).

NB: Similar results were found when a comparable loss of podiatric care occurred in the UK.

Skrepnek GH, Mills JL, Armstrong DG. Foot-in-wallet disease: Tripped up by “cost-saving” reductions? Diabetes Care. 2014;37:e196–e197.

Reviewer: Tom Weisz, BA, DCh, IIWCC



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