2025 · VOL.6 ISSUE 1

Limb Preservation JOURNAL

Decreasing Global Amputations Through Preventive Foot Care

The Canadian Diabetic Foot Ulcer Policy Roundtable

Mission 'Possible': Saving A Limb

Wound Assessment Across Skin Tones: An AI Model

Barriers To Adherence In Patients With DFU

WoundsCANADA.ca
30 years supporting skin health and wound care
CPMA Canadian Podiatric Medical Association / L'association médicale podiatrique canadienne
D-FOOT international
American Limb Preservation Society
CariWN

In person
Early Bird Special!
Until June 30th!!

Join the Celebration of Our 30th Anniversary

WOUNDS CANADA NATIONAL CONFERENCE

Be part of the largest wound care event in Canada as we celebrate three incredible decades of ★ innovation ★ collaboration ★ excellence

Don't miss out on early bird discounts for in person registration fees
Register at www.woundscanada2025.ca by June 30th!

Connect with leading experts, gain cutting-edge insights and make unforgettable memories.
Let's make this milestone year the best one yet!

Toronto, Ontario | The Westin Harbour Castle | October 2-4, 2025

WoundsCANADA.ca
30 years supporting skin health and wound care

For more information contact:
info@woundscanada.ca

Find us on social media: @WoundsCanada

CONTENTS

Published by:

WoundsCANADA.ca
30 years supporting skin health and wound care

In conjunction with:

CPMA Canadian Podiatric Medical Association / L'association médicale podiatrique canadienne
D-FOOT international
American Limb Preservation Society
CariWN

Limb Preservation Journal
2025 · Volume 6, Issue 1

ISSN 2817-3309

Editorial inquiries should be directed to info@woundscanada.ca

Wounds Canada (www.woundscanada.ca) is a non-profit organization dedicated to the advancement of wound prevention and care. Wounds Canada was formed in 1995 as the Canadian Association of Wound Care.

IT'S TIME

to invest in your future

Register Now for the Latest Innovation in Skin Health Education:

The Skin Health Program for Personal Care Providers

This educational program is designed to enhance the knowledge of PSW's in monitoring health or skin changes in the individuals they care for, reporting observations to supervisors or health-care professionals, accurately documenting those observations and collaborating in follow-up care.

Apply today!
www.woundscanada.ca/programs/skin-health

Wounds CANADA Institute

RNAO

This program has just been awarded micro-credential recognition by Nipissing University!

NIPISSING UNIVERSITY

Structure of the Program

- 11 highly interactive online modules
- 1 live webinar featuring expert faculty
- 3 discussion boards on skin health and wound prevention
- 1 final exam to test knowledge

Program Topics

- Skin structure and functions
- Risk factors for skin breakdown
- Common types of skin breakdown, including skin tears, pressure injuries, moisture-associated skin damage, diabetic foot ulcers, leg ulcers and swelling, and thermal skin injuries
- Strategies to maintain healthy skin and prevent skin breakdown

We gratefully acknowledge the support and funding for the development of the Skin Health Program by the Government of Ontario

FROM THE EDITOR IN-CHIEF

Dear Colleagues,

As we move through 2025, there is a growing sense that the field of limb preservation is entering a new chapter - one that is defined by greater collaboration, sharper focus, and a deeper sense of purpose. This issue of the *Limb Preservation Journal* reflects that shift. It's not just a collection of studies, but a portrait of a field evolving toward something bigger: systems that prevent limb loss before it happens, care models rooted in equity and a global community that refuses to accept amputation as a foregone conclusion.

What stands out most in these pages is how far we have come in connecting the dots - between disciplines, between countries and between policy and practice. Across this issue, we see clinicians, educators, researchers, and advocates working together to build coordinated frameworks for diabetic foot care, especially in underserved communities. The emphasis isn't only on healing wounds but on reimagining how care is delivered.

Education takes centre stage too, and not just in the traditional sense, but through global initiatives and training programs that empower frontline providers in both low-resource and high-resource settings. When clinicians are equipped with knowledge and tools, outcomes change. Lives change. The impact is tangible.

Technology also has a powerful presence here, with AI stepping in, for example, to support more accurate and equitable wound assessments across diverse skin tones. It's a glimpse of how innovation, when guided by clinical insight and ethical design, can help reduce disparities and improve decision-making.

But perhaps what resonates most deeply are the stories - of patients who fought to keep their limbs, of clinicians navigating complex decisions, of missed moments and second chances. These are more than case reports. They're reminders of what's at stake. Limb preservation is never just about tissue - it's about time, trust and the quiet heroism of everyday care.

As always, we are grateful to the contributors who share their work, and to you - our readers - for continuing to engage, question, apply, and push the field forward. Thank you for being part of this journey.

We hope this issue informs and inspires.

Sincerely yours,

Ahmed Kayssi, MD MSc MPH CWSP FRCSC FACS

NEWS FROM OUR PARTNERS

Best Practice Recommendations for Skin Health and Wound Management 2025 Now Available

Wounds Canada's updated edition of its free digital book *Best Practice Recommendations for Skin Health and Wound Management 2025* is now available.

The previous versions have been an evidence-based cornerstone of skin health, wound prevention and management in Canada, providing health-care providers and health decision-makers with the latest evidence in a reader-friendly format that helps move wound-related knowledge into practice. Since their online introduction in 2018 they have been downloaded more than one million times.

The current edition improves on previous iterations by including new information, with an increased focus on prevention, as well as several other crucial features such as:

- An overview of the structures and physiology of skin and the process of skin healing
- A new Appendix focused on nutrition and wound healing in Chapter 4 Prevention and Management: An Overview
- A newly developed chapter focused on lymphedema and lower limb skin health and corresponding wounds
- The use of the Wound Prevention and Management Cycle to organize the information and provide clinical pathways for clinicians and health decision-makers by providing step-by-step processes they can incorporate into practice for improved outcomes
- Chapters that can be downloaded individually as PDFs for ease-of-use.

For more information, visit: https://www.woundscanada.ca/news/752-bpr-new

Pressure Injury Protocols Webinar Scheduled For June

This summer, Wounds Canada is hosting the *Shifting the Pressure: A Time for System Change in Pressure Injury Protocols* webinar. Details are as follows:

- Date: Tuesday, June 17, 2025 at 7:00 PM EST
- Co-chairs: Stephanie Chadwick NP-PHC MClSc-WH NSWOC WOCC(C) and David Wallace MD MSc FRCSC

In this online session, participants will be able to:

1. Understand the interdisciplinary preparation for pressure injury surgery and the surgical plan to ensure clear communications with the team
2. Examine evidence-based wound care techniques and infection prevention measures to minimize infection pre- and post-surgery to support skin health
3. Discuss pain management strategies and ensure proper use of pain relief medications to facilitate mobility and positioning
4. Describe best practices for teaching and supporting persons pre- and post-surgery to optimize pressure injury healing and minimize complications.

We look forward to your participation!

Those interested can register at: https://zoom.us/webinar/register/WN_lBqXrdcyQKSTsCG-cpRYLQ

Regional Conference Comes To Halifax, Canada In June

Wounds Canada and the Nova Scotia Health Innovation Hub have joined forces to bring you the best and latest in wound care innovations in a day-long event on Friday, June 6, 2025, focused on the health-care delivery challenges and facilitators faced by those working in the Atlantic region of Canada.

The event takes place at the Nova Scotia Health Innovation Hub. If you're a frontline health-care provider, administrator or policy maker, you won't want to miss it!

For more info visit: https://www.woundscanada.ca/health-care-professional/education-health-care-professional/regional-conference2025

Wounds Canada National Hybrid Conference 2025 To Be Held in June

Wounds Canada is hosting its biggest educational event of the year from October 2-4, 2025, at the Westin Harbour Castle, Toronto, Ontario. The Wounds Canada National Hybrid Conference showcases Canadian excellence in clinical practice, research, education and industry innovation.

This is the largest wound-related continuing education event in Canada, bringing together wound care professionals from across the country and from multiple disciplines to share information, connect with each other and support ongoing personal professional development over three days.

The academic and sponsored sessions, industry exhibits, networking opportunities, poster presentations and conversation cafés are designed to support both frontline health-care professionals and those who make policy, practice and/or funding decisions.

Exhibitors interested in booking a space should email Maureen Rego, Director of Events: maureen.rego@woundscanada.ca

For more info visit: https://www.woundscanada2025.ca/

CPMA's Strategy Aimed At Advancing Limb Preservation Initiatives

Limb preservation is critical in modern health care, requiring collaboration, education and advocacy. The Canadian Podiatric Medical Association (CPMA) remains committed to advancing best foot and lower limb care practices through strategic partnerships, policy advocacy and professional education. Our recent efforts demonstrate a proactive approach to strengthening podiatric care in Canada and beyond.

Strengthening advocacy and collaboration: CPMA actively shapes policy and advocates for improved foot and lower limb health care. We are assisting in developing new podiatry regulations in the province of Prince Edward Island and working with the Canadian Physiotherapy Association to expand diabetes-related orthotic coverage under the Diabetes Device Fund. Strengthening relationships with the American Podiatric Medical Association and supporting initiatives like the International Hyperhidrosis Society and the Limb Preservation Alliance reflect our commitment to global collaboration.

Engagement in conferences and industry events: We continue to ensure that podiatry has a strong presence at key industry events. CPMA exhibited at Wounds Canada 2024, participated in CLHIA 2024, and is already planning for CLHIA 2025. Our engagement with the Canadian Association of Foot Care Nurses has opened opportunities for CPMA speakers at future conferences, further reinforcing our role in interdisciplinary collaboration.

Empowering members through education: Education remains a cornerstone of our mission. Our monthly CPMA webinars feature expert-led discussions on podiatric advancements, while our mentorship program connects students with experienced practitioners. Additionally, we continue to enhance member benefits through strategic partnerships with industry leaders like RBC, Gallagher and PRESENT.

Enhancing communication and outreach: Effective communication is key to knowledge-sharing and advocacy. CPMA's digital newsletters, social media presence and media outreach efforts inform members and stakeholders about the latest podiatric medicine and limb preservation developments.

Investing in the future of podiatry: To support the next generation of podiatrists, CPMA actively engages with university programs, offers a student mentorship program, a scholarship fund and sponsors key student events such as the UQTR Ball. These initiatives ensure the continued growth and excellence of podiatric medicine in Canada.

Through these efforts, the CPMA remains dedicated to advancing podiatric medicine and limb preservation. By fostering collaboration, enhancing education and advocating for policy change, we aim to improve patient outcomes and support the broader health-care community.

For more information on CPMA's initiatives, visit podiatrycanada.org.

CariWN Raises Awareness Of Wound Care Across The Caribbean, Joins Limb Preservation Alliance

The Caribbean Wounds Network (CariWN), launched in 2024, marked a significant milestone in addressing the region's wound care crisis with our inaugural hybrid conference held in Barbados at the University of the West Indies (UWI) in June of 2024. The event, *T.I.M.E. to Heal*, brought together health-care professionals, researchers and industry leaders from across the Caribbean and beyond to tackle the escalating costs and challenges of wound care in the region. CariWN is built on four key pillars: Education, Advocacy, Research and Implementation, all of which are vital to our mission.

The conference and future initiatives are designed to support the overarching objective of raising awareness of wound care to health professionals, educators, medical institutions and the Caribbean diaspora. By focusing on our four pillars, CariWN aims to create a comprehensive and sustainable approach to wound management and limb preservation throughout the Caribbean.

The hybrid symposium, sponsored by Crucible International Inc., a local BPO organization operating in the insurance and health-care fields, and hosted in partnership with the University of the West Indies (UWI) Cave Hill Campus, attracted participation from 27 countries, with attendees from Aruba, Barbados, Cuba, Guyana, Trinidad and Tobago, Curacao, Sint Maarten, The Bahamas, St Kitts and Nevis, Antigua and Barbuda, Jamaica, and diaspora communities in Canada and the US.

We would like to thank the University of the West Indies (UWI), Crucible International Inc. and Wounds Canada for their participation.

Sessions included:

- Building a Collaborative Wounds Organization, Including Teams and Standards of Care
- Managing the Diabetic Foot Charcot Reconstruction and Limb Savage
- The First Year of Establishing a Public Limb Salvage Program in Barbados: A SWOT Analysis
- Oxidative Stress Created by Glycemic Variability and How This Can Impair Small Vessel Function Either Favourably or Otherwise.

This collaboration aims to share resources, expertise and advocacy initiatives to address the regional wound care crisis and enhances advocacy efforts by combining resources and expertise to influence policy and improve patient care. The partnerships allows CariWN to access evidence-based resources, education programs and research initiatives, enhancing its ability to improve wound care across the Caribbean.

With wound care costs in the Caribbean estimated at $7 billion USD annually, the conference served as a crucial platform for addressing this pressing health-care issue. The event underscored the need for education, policies and competencies in wound care at both governmental and health-care levels. CariWN's focus on research will help develop a strong understanding of wound care in the Caribbean context, leading to more effective treatments and prevention strategies.

In 2025, CariWN will support our colleagues in Aruba toward a successful collaboration with their Symposium scheduled to be held September 25 and 26 at the Embassy Suites by Hilton in Aruba.

CariWN is currently planning for our 2026 conference scheduled to be held in Jamaica.

In 2024 CariWN joined the Limb Preservation Alliance. As we continue to grow, our collaboration with organizations such as Wounds Canada and alignment with global initiatives promise to drive significant improvements in wound care and limb preservation across the region.

DFCon 2025 To Be Held In October In Anaheim

DFCon 2025, the Annual Conference of the American Limb Preservation Society, will be held on October 23-25, 2025, in Anaheim California, USA.

Highlights include:

- Leadership in Discovery: Be at the forefront of groundbreaking therapies and technologies.
- Collaborative Networking: Connect and collaborate with global experts, enhancing professional growth and innovative practices.
- Expert Insights: Learn from leading speakers and stay updated on the latest research

DFCon also represents the 25th Edition of the Interdisciplinary Global Diabetic Foot ConferenceDFCon2025.

For more information, visit:
https://limbpreservationsociety.org/dfcon/about/

D-Foot International Wound Care Conference 2025 Scheduled For May In Malaysia

The third D-Foot International Wound Conference will take place on May 9-10, 2025, at the Imperial Hotel, Kuching, Sarawak, Malaysia.

This highly anticipated event will bring together global experts, health-care professionals and stakeholders to discuss innovative solutions and strategies in wound care and diabetic foot management. The conference is organized in collaboration with Sarawak General Hospital, the Wound Care Unit and other key partners, with the mission to advance patient outcomes worldwide.

D-Foot International invites all relevant stakeholders to join us for this impactful gathering.

For more information, visit: https://d-foot.org/

American Limb Preservation Society

DFCon

Welcome to the American Limb Preservation Society, ALPS

We want to eliminate preventable amputations over the next generation!

By joining ALPS, you gain a network that's committed to advancing the specialties in limb preservation, strenghtening members' collective voice and providing solutions to enhance patient care.

Meet our Board of Directors

Dr. David Armstrong
PhD, DPM, MD
President

Dr. Stephanie Wu
DPM, MSc, FACFAS
Vice President

Dr. Michael Conte
MD
Scientific Chair

Dr. Joseph Mills
MD, FACS
Clinical Chair

Dr. Ryan Crews
PhD
Secretary

Dr. Brian Lepow
DPM, DABPM
Treasurer

Dr. Cy Dove
DPM
Board Member

Dr. Kate McGinigle
MD, MPH
Board Member

As a member, you will help advance this important specialty, and also have exclusive access to these benefits:

- Access to ALPS' **networking platform** to connect with international thought leaders on the diabetic foot.
- Access to ALPS' **international job board**.
- The opportunity to apply for our ALPS' **Traveling Fellowship**.
- Discount on your registration fee for **the official annual conference of ALPS, DFCon**.
- Eligibility to serve on ALPS' board and committees.
- Receive ALPS' society **newsletter**.
- Discount on your registration fee for **DFCon on Demand**, the enduring content platform for our annual conference.

Learn more!

www.limbpreservationsociety.org

CASE REPORT

Towards Limb Preservation: Treating A Blistered And Callused Diabetic Foot In A Clinic Setting In Barbados

Simone McConnie BSc Pod Med MRCPod MBA HCPCreg FFPM RCPS(glasg)

Abstract: This case study reports on a 73-year-old female labourer who presented at a clinic in Barbados with multi-factorial problems related to a diabetic foot. It discusses treatment approaches and outcomes based on the applications of international guidelines.

Key words: *diabetic foot, foot pain, blisters, callouses, amputation prevention, guidelines*

How to cite: McConnie S. Towards limb preservation: treating a blistered and callused diabetic foot in a clinic setting in Barbados. Limb Preservation Journal. 2025;6(1): 12-14. DOI: 10.56885/205731pltcia

Introduction

'Limb preservation' is a term coined for the first world but continues to be misunderstood in developing nations, with differing opinions on the relevance of international guidance (e.g., the International Working Group on the Diabetic Foot [IWGDF][1] in the treatment of the diabetic foot).

Over the coming months, the Caribbean Wounds Network hopes to establish the value and application of these guidance processes in order to create a more effective working framework for limb preservation in Barbados and other Caribbean nations.

The diabetic foot remains a mystery amongst general practitioners and surgeons alike, in part due to the initial aggressive and somewhat unappealing way the diabetic foot may present to emergency services or clinics.

The appropriate application of diabetic foot guidance on treatment of the diabetic foot turns these somewhat "maimed" feet into unamputated functional appendages, as they should be.

Patient Characteristics/Social And Medical History

Mrs B is a 73-year-old lady. She works as a labourer in the fields and gardens. She was not previously known to the clinic and was referred via a "friend of a friend". She had never seen a podiatrist before. She was known to be diabetic for over 15 years.

Mrs B was brought to the clinic by her daughter as an 'emergency' because she had developed a large blister on the dorsum of her left foot over the first ray area. She was experiencing pain when walking and had developed a fever and general unwellness due to her foot getting worse. She has previously been to see her GP who issued her with painkillers (paracetamols) and oral antibiotics (augmentin for seven days). These were started three days prior to her attendance in the clinic.

She was wearing poor footwear and exhibited a poor understanding of her diabetes (plus apparent poor compliance to medical advice). She had never considered the importance of good control, despite being counselled by her doctors, according to her family. As a result, she mostly wore slippers or flip flops and walked barefoot from time to time.

Care Plan

- Callous management and continued education on the importance of her diabetes control, as the fear of losing her foot made her willing to act on self-care. Her family also provided support in the form of food choices, frequency of follow-ups and a schedule for her medications.
- Footwear recommendations and wearing/care instructions.
- She is being monitored in the clinic to ensure compliance: initially four weeks later, then eight weeks and then three months, depending on her financial abilities and/or available charitable options.

Examination

On examination in the clinic she was weak, had a fever of 38º Celsius, complained of cold sweats and "bad feels". She was advised that she should be seen in emergency, but she refused and said she did not want to go. This left us no choice but to 'do our best'. Blood sugars were 11 mmolL (it was difficult to prick her skin because she is a labourer and her hands were very calloused with thickened skin on the pulps of most of her fingers).

On the left foot there was a blister on the dorsum of the foot, over the 5th ray area, mild redness, warmth and oedema of the dorsum of the foot. On the plantar 4th and 5th over the metatarsal heads there were very large callouses and corns. Reduced fibrofatty padding was noted from PMP 1 to 5, with forefoot supinatus ascertained. There was a distinct over loading of the 5th met area, explaining the heavy callouses area and corn. The corn under the 5th metatarsal head was dark in appearance and very tender to touch.

Treatment Approach

As per international guidelines for the diabetic foot ulcer,[1] vascular status was ascertained using a Doppler assessment. The results were normal (triphasic).

Infection was noted to be bullous in nature. We ruled out an ischaemic cause of the bullous presentation and noted the plantar corn. Removal of the corn revealed a fissure in the corn and calloused area, resulting in an infected corn with tracking onto the dorsum of the foot.

The corn was enucleated, drained and the blister was also drained; skin was left insitu in order not to create a large area for healing. A tissue sample was taken, sent for culture and the patient was advised to continue to take the antibiotics she was issued. X rays were requested to rule out osteomyelitis.

The tissue sample results were ascertained one week after and confirmed as GRAM'S STAIN / Gram negative bacilli:

- AEROBIC CULTURE: ISOLATE 1: *Proteus mirabilis,* sensitive to: ciprofloxacin, augmentin, cefazolin, cotrimoxazole. Resistant to: tetracycline ISOLATE 2: *Pseudomonas aeruginosa* Sensitive to: ciprofloxacin, tobramycin, ceftazidime piperacillin/ tazobactam.
- ANAEROBIC CULTURE: No anaerobes isolated.

The patient was asked to address her blood sugars and diabetic foot advice was issued. The patient received counselling and a care plan was discussed.

The patient was issued an offloading shoe and advised to not remove it or get it wet. She was reviewed in two days. The area was redressed.

Figure 1: Plantar aspect of the foot, January 6

Figure 2: Dorsal aspect of the foot- redness and blistering, January 6

Figure 3: Post debridement and drainage, January 6

Figure 4: X ray result - No osteomyletis

The wound had started to improve, redness was resolving and oedema had reduced.

Culture was received one week later and instead of continued oral therapy, antibiotic beads (Stimulan®) were used.

The patient returned four weeks later. Sequestra of the bone was removed although X rays revealed no osteomyelitis.

The patient was advised to continue to manage her corns and callouses appropriately and that she would be monitored post op.

Figure 5: Post antibiotic beads and wound management, January 3

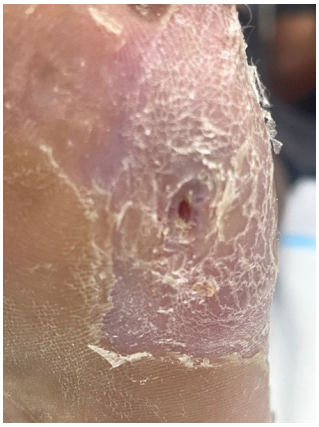


Figure 6: Plantar aspect after use of antibiotic beads, January 31

Conclusion

Stimulan®[2] has been a big asset to the clinic, reducing the need for oral medications and improving the outcomes of diabetic foot ulcers. The use of Stimulan® in this circumstance allowed the patient to not experience side effects from the oral medications, encouraged bony healing and resulted in a better outcome. This lady is now being managed for plantar callous and post op care until the skin returns to its normal texture.

Simone McConnie BSc Pod Med MRCPod MBA HCPCreg FFPM RCPS(glasg) is an advocate and diabetic footcare specialist podiatrist. She is Managing Chief Podiatrist at Comfeet Foot Care Clinic, Bridgetown Barbados; Cofounder and Chair of the Board for Caribbean Wounds Network; Regional co-Chair D-Foot International and Trustee, Save our Soles Charitable trust. She is a member of the APMA and ALPS.

References

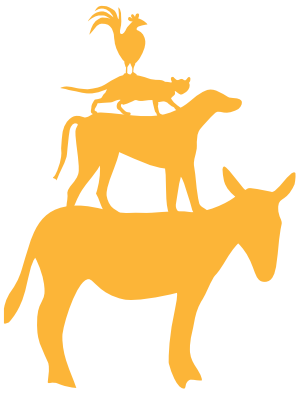
1. Schaper NC, van Netten JJ, Apelqvist J, Bus SA, Fitridge R, Game F, et al.; IWGDF Editorial Board. Practical guidelines on the prevention and management of diabetes-related foot disease (IWGDF 2023 update). Diabetes Metab Res Rev. 2024 Mar;40(3):e3657. DOI: 10.1002/dmrr.3657
2. Stimulan digital brochure. Keele UK: Biocomposites Ltd. (accessed 2025).Available from: https://www.nuvasive.com/wp-content/uploads/2022/02/EU-STIMULAN-digital-brochureMA0074R71-min.pdf

The 36th Conference of the
European Wound Management Association

EWMA 2026

DEUTSCHER
WUNDKONGRESS

WundD·A·CH



BREMEN, GERMANY
6 - 8 MAY 2026

The European Wound Management Association
EWMA

CONGRESS BREMEN

Initiative Chronische Wunden e.V.

DEUTSCHER WUNDRAT e.V.

ÖSTERREICHISCHE GESELLSCHAFT FÜR WUNDBEHANDLUNG

SAfW Sektion D-CH
Schweiz. Gesellschaft für Wundbehandlung

Global Preventive Foot Care And A Decrease In Amputations: A Positive Step For Diabetes-related Foot Complications

Zulfiqarali G Abbas FRCP

Abstract: Diabetes-related foot complications (DRFC) have the highest morbidity and mortality among all other complications. Every year, an estimated two million people with DRFC require amputation. It has long been established that education of people with diabetes and, importantly, health-care care professionals (HCPs) can lead to significant reductions in amputation rates. This article reports on the *Step-by-Step (SbS)* diabetic foot program and *Train the Foot Healthcare Professional (TtFHCP*) diabetic foot program, two successful international foot care education initiatives developed for HCPs.

Key words: *education program, step-by-step, health-care professional training, diabetes mellitus, diabetic foot, amputation prevention*

How to cite: Abbas ZG. Global preventive foot care and a decrease in amputations: a positive step for diabetes-related foot complications. Limb Preservation Journal. 2025;6(1): 16-24. DOI: 10.56885/137820gsstkn

The most recent 10th edition of the *International Diabetes Federation (IDF) Atlas* indicates that diabetes mellitus (DM) is one of the diseases with the most rapid global expansion of the twenty-first century. According to estimates, 537 million people were living with diabetes in 2021; by 2030, that number will rise to 643 million, and by 2045, it will reach 783 million. Every part of the world is at a different stage of the epidemiological shift due to the rise in DM.[1-5] Diabetes mellitus is becoming more common due to several reasons, including urbanisation, changes in lifestyle, the ageing of the population, and an increase in risk factors like obesity and physical inactivity. Sub-Saharan Africa, the Middle East and North Africa, South and Central America, the Western Pacific, and Southeast Asia are all experiencing rapid growth and rising prosperity.[1-6]

The IDF projects that over the next 20 years, low-middle-income countries (LMICs) will carry a heavy burden and have the largest potential rises in diabetes prevalence rates.[1-6] The majority of individuals (80%) with diabetes live in LMICs. In newly emerging nations, it is expected to become the most prevalent health concern.[1-6] Diabetes continues to be a prominent cause of morbidity and mortality in low, middle and high-income countries.[2-5]

Diabetes-related foot complications (DRFC) have the highest morbidity and mortality among all other complications.[2-5] Over 20 million people worldwide are believed to have DRFC, which is a prominent source of sickness and death. [2-4] Every year, an estimated two million people with DRFC require amputation, with less than half requiring hospitalisation due to infections or complications of peripheral artery disease.[3-5]

It is estimated that 40–60% of all lower limb non-traumatic amputations performed globally are due to diabetes.[2-5,7,8] Globally, the annual incidence of DRFC is between 2.5% and 5%, whereas the lifetime risk is estimated to be between 15% and 34%.[9,10]

The consequences of DRFC include substantial impairment, a lower quality of life, a shorter life expectancy, and high health-care costs.[1-8,11-13]

Every 20 seconds, a leg is amputated owing to diabetes, despite the fact that the majority of these, around 85%, could have been averted with relatively modest measures, backed by basic education on DRFC.[2-5, 7,14-22]

Five Pillars of Prevention of Diabetes Related Foot Complications

- Regular inspection and examination of feet
- Identification of the high risk foot
- Education of patients, family and health-care workers
- Appropriate footwear
- Treatment of non-ulcerative pathology

Education As A Preventative Strategy To Decrease Amputation Rates

It has long been established that preventive foot care, a multidisciplinary approach for foot ulcers, close monitoring of patients, and education of people with diabetes and health-care care professionals (HCPs) can lead to significant reductions in amputation rates, by up to 85%.[23,24] In particular, since the majority of diabetic foot ulcers in less developed settings seem to have neuropathy as an underlying risk factor, such ulcers are largely preventable or potentially curable.

Various studies have shown that simple education, care, motivation and action by patients with diabetes themselves are important in protecting the feet from complications.[17-28] The role of special diabetic foot clinics in reducing the incidence of foot problems has been shown by various clinical studies. It has been demonstrated in several studies globally that education given to patients with diabetes results in an unequivocal reduction of foot ulcers and amputations.[17-28]

This shows that the most important intervention for diabetic foot ulcers is preventive methods by educating individuals.[17-28] However, the primary obstacle still stands: which methods are most successful in lowering the prevalence of diabetic foot ulcers? Research in the prevention of diabetic foot disease is still sparse compared with the body of evidence for treatment. The most powerful preventive tool is education, and it should be a simple, repetitive and integral part of prevention programs.[20-22]

Foot education programs for people with diabetes usually include basic elements such as daily feet inspection for any changes (colour, temperature, swelling, discharge), avoidance of trauma (e.g., barefoot walking) and reporting immediately any new symptoms to their HCPs. It is important to educate patients regarding foot care, but educating the HCPs is as important. It is very important that HCPs should at least be able to perform a basic screening examination of feet that includes neurological examination, arterial, dermatological and musculoskeletal systems of the patient.[20-22,26]

Education, which is cost-effective, should be targeted at both patients and HCPs. A comprehensive foot care program should include education regarding DRFC, regular examination of feet, identification of high-risk feet, and educational programs for patients with diabetes and their HCPs. Several educational programs aimed at preventing DRFC have been carried out and executed successfully in both developed and less economically developed countries.[20-22,28]

One of these successful foot programs mentioned in this article and discussed as an illustrated example of foot care education among HCPs is the *Step-by-Step (SbS) Diabetic Foot Program,* which was piloted and carried out in Tanzania and India.[17-22] This program showed that infection, ulceration and limb amputation are potentially preventable through organised foot care programs and approaches that encompass comprehensive, preventive strategies, including patient and staff education, joint medical and surgical management of foot ulcers, appropriate use of microbiology resources, and regular follow-up. Importantly, the project was found to be associated with a more than 50% reduction in amputation rates.[17-20] Amputation rates of lower limbs in patients with diabetes can be reduced by 50% if the following recommendations are implemented: inspection of the feet and footwear regularly; high-risk feet (peripheral neuropathy and peripheral arterial disease) have to be diagnosed early; patients with

high-risk feet should be given preventive footwear and management of diabetic foot ulcers by implementation of a multidisciplinary approach; and patients with a high-risk foot, foot ulcer or past history of amputation must be followed up.

Key Message: Preventing Diabetic Foot Amputation

- Stratify people according to level of the risk, as not everybody with diabetes carries the same risk of ulceration / amputation in both feet
- Those at high risk need intensive education that involves practical demonstrations
- Patients at high risk require significant behavioural changes
- People need to learn to identify any problems that occur early
- Footwear is the most common cause of ulceration
- Problems should be identified early and treated promptly
- Health professionals need to be specially trained in caring for people with diabetic foot disease

Risk Stratification Education Aimed At Decreasing Amputation

To design interventions for the prevention of diabetic foot ulceration and amputation, and to ascertain patients' risks of developing foot ulcers, various epidemiologic studies have evaluated cohorts of patients with diabetes to identify and characterise risk factors associated with foot ulceration and lower limb amputation.

Educational programs may appear ineffective when applied in a standardised way to large, unselected populations. As yet, there is no hard scientific evidence that 'general education' of diabetes actually reduces the incidence of foot ulceration and lower limb amputation globally. By contrast, there is a growing body of evidence that structured, continuous education for individuals identified to be at risk of foot ulcerations reduces the incidence of foot ulcerations and lower limb amputation. Thus, it is more beneficial to patients when education is delivered according to the individual's risk classification for ulceration.

Generalised foot care education for all individuals with diabetes has questionable value: a person at relatively low risk may receive education that is irrelevant, while a person at high risk may receive education not intensive enough for preventing the condition. Identification of risk factors for foot ulceration is challenging and requires the conduct of epidemiologic studies that include all putative risk factors, including behaviour patterns associated with the pathogenesis of foot ulcers. Different people with diabetes require different levels of foot education.[17-20, 25] This is because there is a wide range of levels of foot risk (See Table 1). This needs to be taken into consideration when providing foot education programs.

No country in the world has the resources to provide comprehensive foot care to all people with diabetes. Therefore, a system has been developed for stratifying services based on levels of risk. This system is used widely around the world. We should stratify people with diabetes according to their level of risk – from low risk to very high risk.[17-20,25]

Category 0: *The people at low risk are those who have normal sensation in both feet and normal blood flow. These people need simple advice. They do not need to change their lifestyle, but it should be emphasised that they need an annual assessment of feet.*

Category 1: *Patients with a loss of sensation but good blood supply and no deformity in either foot or patients with no loss of sensation but peripheral arterial diseases and no deformity can be examined every six months and need intensive education to promote practical self-care skills and routine care.*

Category 2: *Those with diminished sensation, decreased blood flow and foot deformity should be examined at follow-up every three months, and they need intensive practical education that emphasises behaviour and lifestyle modification.*

Category 3: *Patients with previous history of ulcer or amputation should be examined at follow up every one to three months, and they need intensive education that emphasizes strategies to modify behaviour and lifestyle.*

Table 1: Diabetic foot risk categorization system for patients with diabetes

	No Ulcer ↓		General Information is enough ↓
Category	**Risk Profile**	**Follow up Frequency**	**Education Targeted**
0	No LPS / PAD (Loss of Protective Sensation / Peripheral Arterial Diseases)	Once a year	Basic care / no lifestyle changes
1	LPS OR PAD	Every six months	Intensive education to promote practical self-care skills, routine care
2	LPS + PAD + Deformity	Every three months	Intensive practical education that emphasizes strategies to modify behaviour and lifestyle
3	Previous Ulcer OR Amputation	Every one to three months	Intensive practical education that emphasizes strategies to modify behaviour and lifestyle
	Ulcer ↑		High risk foot needs Intensive foot education ↑

Risk stratification and screening of patients with diabetes should be carried out before a person with diabetes receives education on foot care. Individuals with diabetes should receive an education that corresponds to their individual level of risk.[18-28] Those with active foot problems, such as ulceration, ideally should be managed by a multidisciplinary team. Loss of protective sensation, care of the foot including nail and skin care, checking of the foot on a daily basis and selection of footwear are very important for the patients with high-risk feet. Importantly, patients' understanding of these issues and their ability to conduct proper self-evaluations and care should be assessed regularly. Patients with difficulties, physical or cognitive, that impair their ability to assess their own condition in order to take the necessary steps towards seeking or initiating the appropriate care will need special attention and assistance from their care providers.[18-28]

These practical approaches to stratify high-risk patients with diabetes can be applied globally in both developing and developed countries. This method can be practised by professionals dealing with this problem all over the world. Education is a powerful tool and can be used by everyone around the world. It all depends on what and how it is used and applied to reduce rates of amputations.

Who Should Be Targeted To Reduce Amputation And Prevent Foot Ulcers?

Ideally, all the HCPs who are dealing with people with diabetes become part of the prevention team and should be able to conduct simple screening of the neurological, arterial, dermatological and musculoskeletal systems to identify those at high risk. The *SbS Diabetic Foot Program* in Tanzania targeted district and regional centres in the country with limited resources, but who were already running diabetes clinics. HCPs at these centres were not well trained in foot management.[22-25] In addition to this, there were problems due to a lack of diabetic foot management, as well as podiatrists or trained persons in this field in Tanzania. This is common in many other countries globally, as there are no proper established training programs for training HCPs on how to identify high-risk

feet and manage diabetic foot ulcers effectively. However, in many parts of the world, HCPs are not trained to deliver simple but effective care for DRFC. To bridge this gap, the *Step by Step (SbS)* diabetic foot program was launched in 2003, aiming to educate HCPs in diabetic foot care.[20] This initiative later expanded to *Train the Foot Trainer (TtFT),* and recently *Train the Foot Healthcare Professional (TtFHCP).*[2]

The *Step-by-Step (SbS)* Diabetic Foot Program For Reducing Amputation rates

The aim of SbS program was to improve diabetes-related foot complications by training HCPs. The following objectives were set: creating more awareness of DRFC; providing sustainable training to HCPs in diabetic foot management; facilitating the transfer of information and expertise among HCPs and exporting ideas to other developing countries; reducing the risk of lower limb complications in people with diabetes; and empowering people with diabetes to care for their feet better, detect problems earlier and seek timely help when problems arise.[18-22]

The *SbS* diabetic foot program in Tanzania led to better management of patients with foot ulceration, resulting in an improved outcome among people with diabetic foot ulcers at local levels and fewer referrals to the secondary and tertiary referral care centre for amputation.[20] In Tanzania, the *SbS* diabetic foot program has enabled functioning foot clinics alone, or in combination with, diabetes clinics across the country. The program has also created awareness of diabetic foot complications among patients, relatives of patients, and nursing and medical personnel involved in diabetic foot care. It has also highlighted the importance of the development and training of staff and employing additional and more skilled personnel.[20]

To determine whether the *SbS* diabetic foot program was effective in diabetic foot ulcer patients' outcomes, we monitored temporal trends in rates of major amputation among people with foot ulcers in one of the centres that already had an established surveillance system for diabetic foot ulcers.[20] For this, we chose the diabetes clinic at Muhimbili National Hospital (MNH) in Dar es Salaam, Tanzania. It showed that a significant reduction in the number of amputations was noted at MNH after implementation of the *SbS* diabetic foot program, and this may be due to early observation and management of foot complications in trained centres.[20]

Several *Step by Step* Programs Conducted From 2003 to 2012

The success of the SbS training programs led to an increasing demand for the program to be rolled out in other countries, including other African countries, such as Congo, Guinea, Botswana, Malawi, Zimbabwe, Ethiopia, Mali, Nigeria, Egypt and South Africa; as well as outside Africa, in India, Pakistan, Dubai, Barbados, St. Lucia, Sint Marteen, St Lucia, St Kitts & Nevis, British Virgin Islands, Antigua, Grenada, Dominica, Trinidad and Tobago and other Caribbean islands.[17-20]

Implementation Of the *Train the Foot Healthcare Professional (TtFHCP)* Diabetic Foot Program

In 2023 the *TtFHCP* program was started by executive committee of D-Foot International. A core team from the D-Foot International 2023–2025 term created this initiative. The idea behind *TtFHCP* was that DRFC should be the responsibility of everybody who is involved in the care of patients with diabetes. Every HCPs who works in diabetes clinics should be able to manage and disseminate the knowledge of DRFC. Secondly, the demand for the *SbS* program to be implemented in other nations has grown as a result of the training program's success. It was unable to visit each and every country to conduct the *SbS* program. The idea came to call all the experts dealing in DRFC to bring them under one roof in each region and 'train' them so when they go back home, they can conduct *SbS* programs in their countries. The program's content was based on the *SbS* curriculum, with a particular emphasis on data collecting, fundraising, strategic planning, teaching, and installing the *SbS* programs. Over

the course of two to three days, the *TtHCPs* curriculum consists of a number of formal lectures, interactive workshops, live case presentations, group discussions, and demonstrations.

Aims/Objectives Of The *TtFHCP* Program

Aims

- To train local HCPs in DRFC within a global region to deliver effective, well-structured, sustainable training programs with demonstrable outcomes.

Objectives

- To organise and implement an S*b*S training program for their own country after attending a *TtFHCP* program.
- To identify barriers to implementation and find solutions for their needs.
- To train HCPs from their own communities to deliver S*b*S training programs.
- To evaluate the delivered program by collecting and disseminating outcomes of the program on a national, regional and international scale.
- To try to ensure that health ministers, health policy makers, patients and professional groups are involved and supportive.
- To determine ways in which teams developed by the S*b*S can be sustained, supported and, where possible, incorporated into health-care systems.

In order to attend the *TtFHCP* program as a delegate, a selection process exists with certain eligibility criteria This is to try to ensure post-program implementation is successful. This is vital as generally only two delegates can attend from each representing country, however, in some cases more delegates can attend if a country is large geographically. The selection criteria include evidence of active diabetes clinic(s), organisational skills and collaboration and support from patient organisations and the relevant ministry of health. The team should comprise a physician, a nurse and a surgeon with a willingness to work collaboratively as a team.[20] On a regular basis, the team should send reports of screening of patients and education sessions among HCPs and patients.

The *TtFHCP* core team recognised from the outset there was a fundamental need for a standardised and useful dataset and collection method for all participating delegates and countries. The original intention of this was to help individuals, centres and countries collect activity and outcome data, thus helping them develop their practice and lobby for continuing support.

Equally, the team needed to be able to identify the impact of the program and use this for further fundraising, program refinement and future developments. It was also hoped that there would be the potential to compare activity and outcome data from different regions. The program is intended to develop local, regional and national networks and study/working groups with sustainability of service and education development, as well as referral pathways. It is hoped that the delegates will be instrumental in driving and implementing policy decision making in their respective regions.

Finally, another key outcome is intended to be the provision of a support mechanism for local HCPs, encouraging the development of further training programs with a national faculty to meet local needs.

Regional *TtFHCP* Programs To Date

***Train the Foot Trainer* program from 2012 to 2020**

1st Train the Foot Trainer - South and Central America. 14 countries: Brazil, Argentina, Bolivia, Chile, Cuba, Colombia, Mexico, Panama, Paraguay, Peru, Uruguay, Ecuador, Venezuela, Guatamala.

2nd *Train the Foot Trainer* – Caribbean. 20 countries: Barbados, St. Lucia, Sint Marteen, St Kitts & Nevis, St. Thomas, British Virgin Islands, Bermuda, Haiti, Jamaica, Belize, Curacao, Antigua & Barbuda, Grenada, Dominica, Trinidad and Tobago, Guatemala, Cayman Islands.

3rd *Train the Foot Trainer* – Europe. 17 countries: Albania, Armenia, Bosnia-Herzegovina, Bulgaria, Croatia, Estonia, Greece, Kosovo, Latvia, Lithuania, Poland, Romania, Serbia, Slovenia, Sweden, Turkey, Ukraine.

4th *Train the Foot Trainer* - Western Pacific. 13 countries: Australia, China, Japan, South Korea, Singapore, Malaysia, Cambodia, Indonesia, Philippines, Taiwan, Thailand, Vietnam, Mongolia.

5th *Train the Foot Trainer* – French Speaking Countries. 13 countries.

6th *Train the Foot Trainer* – MENA Region (Middle East and North Africa). 14 countries.

***Train the Foot Healthcare Professional* Programs From 2023 to 2025**

TtFHCP was conducted in six World Health Organization (WHO) regions, namely Sub-Saharan Africa, Europe, Middle East and North Africa, the South and Central America), South East Asia and the Western Pacific. We will evaluate the cascading effect of education in prevention of ulcer leading to amputation and mortality.

7th *Train the Foot HCP*s - Southeast Asia. 4 Countries: India, Bangladesh, Nepal, Siri Lanka.

8th *TtFHCP* 2023-25 - Southern and Central America. 8 Countries; Argentina, Brazil, Chile, Columbia, Honduras, Ecuador, Panama, Peru.

9th *TtFHCP* 2023-25 - Western Pacific Region. 14 Countries: Malaysia, Myanmar, Taiwan, Thailand, Vietnam, Mongolia, Australia, Cambodia, Indonesia, Philippines, South Korea, Singapore.

10th *TtFHCP* 2023-25 – Europe. 10 Countries: North Macedonia, Slovenia, Croatia, Serbia, Romania, Kosovo, Czech Republic Montenegro, Poland.

11th *TtFHCP* 2023-25 – Africa. 11 Countries: Tanzania, Kenya, Uganda, Rwanda, Ethiopia, Nigeria, Ghana, Zambia, Zimbabwe, Libya, Tunisia.

12th *TtFHCP* 2023-25 – Middle East and North Africa. 5 Countries: Pakistan, Iran, Lebanon, Syria, Sudan.

All the feedback from these regions and countries are recorded and data is collected regarding screening and training of other HCPs in their countries.

The Future

The work has so far managed to cover six regions (Sub-Saharan Africa, South and Central America, Western Pacific, Southeast Asia, Middle East and North Africa and Europe) of the seven world regions and there is a desire to cover the seventh, as well as expand coverage in each region. In addition, further implementation programs and training modalities are being developed together with a supportive networking structure for all participants.

Conclusion:

Education still remains the most effective preventative strategy and should stand as a fundamental component of all diabetic foot care preventative program. It should be straightforward, repeated, and aimed at both patients and HCPs.

The *SbS* diabetic foot program is a unique educational program started in low-income countries in 2003 in Dar es Salaam, Tanzania, then spreading to middle-income countries, and later higher-income countries. It has already touched 128 countries providing education on preventing amputation globally. While it may not be possible to completely prevent foot ulcers; early intervention can effectively stop minor foot ulcers from progressing to serious complications including infection, sepsis, osteomyelitis, or gangrene.

Patients with diabetes need to be taught the value of taking good care of their feet and the necessity of seeing a doctor as soon as possible if they experience any foot-related symptoms. Ultimately, the ability of HCPs to instil the self-help and motivation necessary for people with diabetes well-being will determine success.

Acknowledgements

We acknowledge and thank the people involved in the first pilot project core team of the *SbS* training program in Tanzania, initiated in 2003 by Zulfiqarali G. Abbas (Tanzania), the late Sharad Pendsey (India), Vijay Vishwanathan (India), Karel Bakker (The Netherlands) and the late Alethea Foster (United Kingdom). We also acknowledge the *Train the Foot HCPs* core team and executive board members of D-Foot International (2023–25): Zulfiqarali G. Abbas, Harikrishna K.R. Nair, Vijay Viswanathan, Hermelinda Pedrosa, Mariam Botros, Roberto Anichini, and Beata Mrozikiewicsz-Rakowska. Finally, we are most grateful to all the staff of Abbas Medical Centre and the secretariat office of D-Foot International. Thanks to Shabneez Gangji and Kulsum Ramadhani in Dar es Salaam for their excellent secretarial assistance.

Ethical approval and consent to participate

This article did not require ethical approval. No patient identifiable information is included.

Zulfiqarali G Abbas FRCP is a consultant physician, endocrinologist and diabetologist with Muhimbili University of Health and Allied Sciences, Dar es Salaam, Tanzania; the Abbas Medical Centre, Dar es Salaam, Tanzania and Staffordshire University, Stoke-on-Trent, ST4 2DF, UK. He is currently President of D-Foot International.

Correspondence: Zulfiqarali Abbas, Abbas Medical Centre, P. O. Box 21361, Dar es Salaam, Tanzania. Email: zgabbas@hotmail.com

References

1. International Diabetes Federation, Diabetes Atlas, 10th edition, 2021. Available from: https://diabetesatlas.org/atlas/tenth-edition/
2. Abbas ZG, Boulton AJM. Diabetic foot ulcer disease in African continent: 'from clinical care to implementation' - review of diabetic foot in last 60 years - 1960 to 2020. Diabetes Res Clin Pract. 2022 Jan;183:109155.
3. Abbas ZG. Diabetic-foot complications in African and Antarctica continents, Chapter 2. In: Zubair M, Ahmad J, Malik A, Talluri MR, editors. Diabetic foot ulcer. Springer, Singapore, 2021: p. 29-40.
4. Abbas ZG. The diabetic foot worldwide: Sub-Saharan Africa. In: Boulton AJM, Rayman G, Wukich D, editors. The Foot in diabetes. 5th ed. John Wiley & Sons Ltd, Chichester, UK; 2020. p. 379–85.
5. Abbas ZG, Bal A, editors. Pocket Guideline of diabetic foot 2019. 2nd ed. Jaypee Brothers Medical Publishers (P) Ltd.; 2019. Available from : https://www.google.co.tz/books/edition/Pocket_Guideline_of_Diabetic_Foot/WlfuDwAAQBAJ?hl=en&gbpv=0
6. Atun R, Davies JI, Gale EAM, Bärnighausen T, Beran D, Kengne AP, et al. Diabetes in sub-Saharan Africa: from clinical care to health policy. Lancet Diabetes Endocrinol. 2017 Aug;5(8):622-667.
7. Schaper NC, van Netten JJ, Apelqvist J, Bus SA, Fitridge R, Game F, et al.; IWGDF Editorial Board. Practical guidelines on the prevention and management of diabetes-related foot disease (IWGDF 2023 update). Diabetes Metab Res Rev. 2024 Mar;40(3):e3657.

8. Senneville É, Albalawi Z, van Asten SA, Abbas ZG, Allison G, Aragón-Sánchez J, et al. IWGDF/IDSA guidelines on the diagnosis and treatment of diabetes-related foot infections (IWGDF/IDSA 2023). Diabetes Metab Res Rev. 2024 Mar;40(3):e3687.
9. Armstrong DG, Boulton AJM, Bus SA. Diabetic foot ulcers and their recurrence. N Engl J Med 2017 Jun 15;376 (24):2367–75.
10. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA 2005 Jan 12;293(2):217–28.
11. Abbas ZG. Low-cost management of diabetic foot. In: Zubair M, Ahmad J, Malik A, Talluri MR, editors. Diabetic foot ulcer. Singapore: Springer; 2021. p. 221-232.
12. Cavanagh P, Attinger C, Abbas Z, Bal A, Rojas N, Xu ZR. Cost of treating diabetic foot ulcers in five different countries. Diabetes Metab Res Rev. 2012 Feb;28 Suppl 1:107-11.
13. Dhatariya K, Abbas ZG; 7 Regions Foot Ulcer Costs Study Group. Estimated costs of treating two standardised diabetes-related foot ulcers of different severity - a comparison of 7 global regions. Diabetes Res Clin Pract. 2025 Mar;221:112036.
14. Abbas Z, Morbach S. Diabetes foot damage in developing countries: the urgent need for education. Diabetes Voice. 2005;50:15–7.
15. 25. Abbas ZG, Archibald LK. The diabetic foot in sub-saharan africa: a new management paradigm. The Diabetic Foot Journal. 2007;10:128-37.
16. Abbas ZG, Archibald LK. Challenges for management of the diabetic foot in Africa: doing more with less. Int Wound J. 2007 Dec;4(4):305–13.
17. Abbas ZG. Preventing foot care and reducing amputation: a step in right direction for diabetes care. Diabetes Manage. 2013;3:427–35.
18. Abbas ZG. The Diabetic Foot Chapter 39 Preventive foot care programs. Hinchliffe RJ, Schaper NC, Thompson MM, Tripathi RK, Timaran CH, editors. 1st ed. JP Medical Ltd.; 2014.
19. Abbas ZG. Reducing diabetic limb amputations in developing countries. Expert Rev Endocrinol Metab. 2015 Jul;10(4):425–34.
20. Abbas ZG, Lutale JK, Bakker K, Baker N, Archibald LK. The 'Step by Step' Diabetic Foot Project in Tanzania: a model for improving patient outcomes in less-developed countries. Int Wound J. 2011 Apr;8(2):169-75.
21. Bakker K, Abbas ZG, Pendsey S. Step by step, improving diabetic foot care in the developing world. A pilot study for India, Bangladesh, Sri Lanka and Tanzania. Pract. Diab Intern. 2006;23:365–9.
22. Pendsey S, Abbas ZG. The step-by-step program for reducing diabetic foot problems: a model for the developing world. Curr Diab Rep. 2007 Dec;7(6):425–8.
23. Larsson J, Apelqvist J, Agardh CD, Stenström A. Decreasing incidence of major amputation in diabetic patients: a consequence of a multidisciplinary foot care team approach? Diabet Med. 1995 Sep;12(9):770-6.
24. International Working Group on the Diabetic Foot (IWGDF). The development of global consensus guidelines on the management and prevention of the diabetic foot 2023. Available from: https://iwgdfguidelines.org/pad-guideline-2023/
25. Matwa P, Chabeli MM, Muller M, Levitt NS; Working Group of the National Diabetes Advisory Board; European IDDM Policy Group. Experiences and guidelines for footcare practices of patients with diabetes mellitus. Curationis. 2003 May;26(1):11-21.
26. Mayfield JA, Reiber GE, Sanders LJ, Janisse D, Pogach LM; American Diabetes Association. Preventive foot care in diabetes. Diabetes Care. 2004 Jan;27 Suppl 1:S63-4.
27. Mayfield JA, Reiber GE, Sanders LJ, Janisse D, Pogach LM. Preventive foot care in people with diabetes. Diabetes Care. 1998 Dec;21(12):2161-77.
28. Van Rensburg GJ. Preventative foot care in people with diabetes: quality patient education. JEMDSA 2009, 14, 1–2.

NOW OPEN!
APPLY FOR YOUR **2025 SCHOLARSHIP OR RESEARCH AWARD!**

Wounds CANADA Institute

Want to learn more about wound care?

Apply for the Skin Health Advocate and Resource Professional (SHARP) Scholarship!

MORE INFORMATION >

WoundsCANADA.ca

Tell us about your DFU or PI research and you could win!

Apply for the Wounds Canada Research Dissemination Award

MORE INFORMATION >

APPLY NOW!

Application deadline:
July 18, 2025

Toe Pressure As A Standalone Vascular Assessment Of The Foot

Maryse Beaumier RN PhD, **Théo Gignac, Stéphane Turcotte** MSc and **Jérôme Patry** DPM MD MScA

Abstract: This study aims to verify whether toe pressure (TP) or toe-brachial index (TBI) has better thresholds of sensitivity/specificity for PAD detection. A single-centre retrospective analysis was conducted of prospective data collected on 108 ambulatory patients recruited at the Complex Wound Care Clinic in Canada. Patients were included with any kind of lower limb wound without regard to any diagnosis of chronic kidney disease, diabetes, PAD or CLTI. TP with photoplethysmography (PPG) and laser Doppler flowmetry, dorsalis pedis and posterior tibialis arteries waveforms have been assessed. Of 108 patients, 43 (40%) presented with monophasic dorsalis pedis arteries (DPA) indicating insufficient vascularization on the left foot and 34 (31%) on the right foot and 55% of the patients had diabetes. According to the validation process of the toe laser pressures, the AUC results for the two measures (TBI and TP) show better threshold values for DPA waveforms than posterior tibialis arteries (PTA) waveforms. Sensitivity and specificity did not differ between TP and TBI for the established cutoffs of disease severity. For TBI measurements, there was a slight increase in sensitivity with DPA compared to TPA. Still, this difference was not significant according to the overlap of the confidence intervals (93% for DPA and 82% for TPA, similar for both feet). Both absolute systolic toe pressure measurement and toe brachial index had a stronger ROC curve AUC with the dorsalis pedis artery as the standard of comparison than the posterior tibialis artery waveform, as per the angiosome theory. In conclusion, toe pressure seems to be a standalone vascular test of the forefoot, while performing the calculation of TBI appears to be of no added values for detecting PAD, based on this study.

Key words: *peripheral artery disease, PAD detection, chronic limb-threatening ischemia, vascular assessment, toe pressure, toe-brachial index*

How to cite: Beaumier M, Gignac T, Turcotte S, Patry J. Toe pressure as a standalone vascular assessment of the foot. Limb Preservation Journal. 2025;6(1): 26-35. DOI: 10.56885/203259znyvty

Historically, the main recommendations for the management of peripheral arterial ulcers on lower limbs have focused on two primary objectives: determining if there is adequate blood flow to heal the wound and assessing for signs and symptoms of peripheral arterial disease (PAD).[1,2]

It is estimated that approximately 200 million people worldwide suffer from PAD of the lower extremities.[3] The epidemiology of PAD is likely to be similar across countries, such as the United States and the United Kingdom, and regions, such as the European Union.[4,6] Due to its numerous impacts on patients and health-care systems, as well as its socioeconomic burden, PAD demands a responsive approach to ensure both early detection with non-invasive tests and early treatment.[1,7-10] Chronic limb-threatening ischemia (CLTI) represents the end stage of PAD and is a problem of growing prevalence, increasing health-care costs around the globe, primarily associated with mortality, amputation and impaired quality of life.[8] Once at the stage of CLTI, patients may develop spontaneous ulcerations that fail to heal or that progress to gangrene and amputation processes.[8-10] According to the Global Vascular Guidelines on the Management of Chronic Limb-threatening Ischemia, all patients with suspected CLTI should be referred urgently to a vascular specialist.[8] Multiple health-care specialists are involved in the

management of PAD and CLTI, yet lack of public awareness and the frequent failure to make an early diagnosis continues to be a significant obstacle to effective treatment.[8]

Current clinical guidelines recommend performing a comprehensive vascular assessment of lower limbs with the ankle-brachial index (ABI) in patients with a lower limb wound.[7,8,11,12] However, the validity of this test is known to be suboptimal in the presence of medial wall calcification of the main arteries, especially in the population with diabetes.[1,13-15] This limitation may affect the ABI with falsely elevated or normal values in patients with diabetes, chronic kidney disease or advanced age.[8] Inconclusive, distorted results and/or overestimation of the actual vascular flow is often seen in individuals with diabetes,[8,16-18] a population peculiarly affected by PAD.[19-21] To overcome false negatives results, clinical guidelines for PAD and CLTI management recommend the use of the absolute systolic toe pressure (TP) measurement or the toe-brachial index (TBI) to be more sensitive in diagnosing PAD.[1,8,13,16,22-25] As previously shown, toe pressure measurement using photoplethysmography (PPG) was well correlated ($r=0.92$, $p < 0.001$) with Laser Doppler Flowmetry (LDF).[15] This makes toe pressure an accessible first-line screening tool with PPG. Arterial Doppler waveforms can also be helpful in detecting a significant blood flow obstruction, as a monophasic waveform is abnormal and significant PAD.[26,27] Angiosomes must be considered for all these tests; otherwise, the interpretation of the vascular evaluation could be distorted.[28,29]

In the 2019 CLTI guidelines, there is no recommendation as to which test is preferred or more appropriate between TP and TBI.[8] Few studies suggest that absolute pressure may be a better ulcer healing indicator and that symptoms of arterial insufficiency correlate better with absolute pressure than the index.[30,31] As acknowledged for the ABI methods, TBI is a ratio, and calculation errors could occur. The aim of this study is to verify whether TP or TBI has better thresholds of sensitivity and specificity when compared to the arterial blood flow waveform from the dorsalis pedis arteries (DPA) and posterior tibialis arteries (PTA) for peripheral arterial disease detection. We hypothesize that there are no differences between TP and TBI measurement in the detection of PAD, especially for patients with diabetes.

Methods

For this secondary analysis of a prospective population study from a doctoral research project,[32] 108 ambulatory patients aged ≥18 years and having at least one lower limb wound were recruited between May and August 2017 by convenience sampling technique at the Complex Wound Care Clinic, a Canadian university-affiliated regional hospital clinic. Institutional and University Ethics Board approvals (CER-17-235-10.02) were obtained for this study. According to the study protocol, written informed consent was obtained and documented from every patient retained. Patients were included if they presented with any kinds of lower limb wounds without regard to any diagnosis of chronic kidney disease, diabetes, PAD or CLTI. Exclusion criteria were having any condition, not providing proper consent and having received previous hyperbaric oxygen therapy.

Toe pressure measurement is recognized as the most predictive of macrovascularization in the foot in patients with diabetes; however, its use is controversial since correlations with angiographic examinations have not been established.[24,25,33] For this present study, we did not use contrast angiography as the 'gold standard' to compare TP and TBI because of its invasive nature. As shown by Criqui and al., the posterior tibialis pulse is the best predictor of PAD of the great vessels: sensitivity of 72.5%; specificity: 91.3%; negative predictive value: 96.5%; positive predictive value: 48.7%.[34] As shown by Beaumier et al.(2020), using the same sample as this present study, DPA arterial wave measurement obtained the best results of sensitivity (80.8%), specificity (89%), negative predictive value (88%) and positive predictive value (82.4%) when compared to monophasic arterial wave of posterior tibialis artery (PTA), which obtained respectively 76.9%, 86.2%, 85.1% and 48.7%.[32] Furthermore, the hallux for TP and TBI

measurement is considered within the dorsalis pedis artery (DPA) angiosome.[35,36] To our knowledge, there is currently no strong data comparing the different PAD non-invasive assessment methods to gold standard contrast angiography. However, a monophasic doppler waveform is deemed as always abnormal (a), whereas sensitivity of ABI may vary in individuals with advanced age, diabetes and non-compressible vessels (b).[1,37] Hence, the use of the monophasic arterial wave of the dorsalis pedis artery (DPA) has been chosen as the criterion measurement.

We assessed TP twice: manually, using photoplethysmography (PPG) and using Laser Doppler flowmetry (LDF). An appropriately sized mini cuff was placed around the base of the hallux and connected to the Huntleigh's DMX Digital Doppler® for the PPG, and on the PeriFlux System 5000® equipped with three PF 5010 LDPM channels and one PF 5050 Pressure from Perimed® for the laser. From laser and PPG toe pressures results, only laser results are presented since a previous study obtained similar results between the two techniques based on a high Pearson's r correlation coefficient of 0.920 ($p < 0.001$).[15] In addition, it should be noted that laser pressure values were obtained from the average of three consecutive readings for an accurate research measurement.

We then characterized whether the arterial waveform was triphasic, biphasic or monophasic, measured with the Huntleigh's DMX Digital Doppler®. A monophasic waveform indicates insufficient vascularization.[7,32,38] ROC curves were performed to assess TP and TBI sensitivity and specificity by comparing established[1] severity thresholds to monophasic DPA and PTA waveforms, as standard for insufficient vascularization. Thresholds for PAD severity was chosen, based on Wounds Canada Best Practice Recommendations for the Prevention and Management of Peripheral Arterial Ulcers,[1] as mild (TP=50-69mmHg), moderate (30-49 mmHg) and severe (<30mmHg) disease. Optimal thresholds of TP and TBI for the best sensitivity for around 70% specificity were also derived from the ROC curves. For statistical significance, p values ≤ 0.05 were considered as significative. For DPA and PTA comparisons, qualitative comparisons considering non-overlapping 95% confidence intervals were considered as clinically significative. A rough rule of thumb would be that the accuracy of tests with AUCs between 0.50 and 0.70 is low; between 0.70 and 0.90, the accuracy is moderate; for AUCs over 0.90 the accuracy is high.[39] An approximate 70% specificity threshold has been decided for the analysis to have the same comparison among the different models. Statistical analyses were performed with SAS software version 9.4. Diagnostic accuracy studies are at risk of bias due to shortcomings in design and conduct.[40] This study follows the Standards for Reporting of Diagnostic Accuracy Studies (STARD), which are internationally recognized for studies on a diagnostic accuracy test in biomedical sciences.[40,41]

Results

All patient's and group specific characteristics are summarized in Table 1. Median age was 71 for the sample, with 59% being men. Of 108 patients, 43 (40%) presented with monophasic DPA indicating insufficient vascularization on the left foot and 34 (31%) on the right foot. The percentage of insufficient vascularization measured with monophasic PTA was approximatively similar to monophasic DPA for both feet (See Table 1). In this sample, 55% of the patients had diabetes. Missing data, such as pulse waveform, TP and TBI are from patients having previous foot or toe amputation. According to the validation process of the toe laser pressures, the ROC curves AUC results for the two measures (TBI and TP) show better threshold values for DPA waveforms than PTA waveforms, without clinical differences as the confidence intervals significantly overlap (See Table 2). No statistical differences were noted either for TP or TBI ROC curves AUC, as the confidence intervals also significantly overlap.

For the left foot, at 70% specificity, TP thresholds were similar according to DPA or PTA waveforms (67 mmHg) with no clinical difference in sensitivity according to the overlap

of the confidence intervals. For the right foot, at 70% specificity, TP thresholds were relatively similar between the two monophasic waveforms (78 mmHg for DPA and 74 mmHg for PTA). Still, sensitivity was clinically higher for DPA than PTA (90% for DPA and 70% for PTA). The same pattern was observed for TBI measurements. These observations confirm the choice of monophasic dorsalis pedis artery as the best criteria value for this study regarding the angiosome's concept.

Overall, as shown in Table 2, sensitivity and specificity did not differ between TP and TBI for the established cutoffs of disease severity. Sensitivity did not differ between TP and TBI for the optimal cutoff around 70% specificity either. For confirmation, all p values were not significative.

We analyzed those results according to diabetes status in Table 3.

Most of the AUCs were more accurate in patients without diabetes, except for left DPA, where AUC values were superior for patients with diabetes. In addition, the cut-off points of the TP were also always higher in patients without diabetes, ranging from 78 to 86 mmHg, compared to individuals with diabetes, ranging from 62 to 71 mmHg. The same pattern was observed for TBI measurements (0.56 to 0.63 for patients without diabetes compared to 0.47 to 0.51 for patients with diabetes).

At approximately 70% specificity, the TP sensitivity in individuals with diabetes was higher when compared to monophasic DPA than monophasic PTA for both feet (left DPA foot: 81%, left PTA: 65%, right DPA foot: 80%, right PTA: 70%). A similar pattern was observed with TBI measurements (88% for DPA and 68% for PTA, similar for both feet). However, this pattern was less clear in individuals without diabetes. For TP measurements, sensitivities were not different according to DPA or PTA (left DPA foot: 78%, left PTA: 86%, right DPA foot: 78%, right PTA: 79%). For TBI measurements, there was a slight increase in sensitivity with DPA compared to PTA. Still, this difference was not clinically significant according to the overlap of the confidence intervals (93% for DPA and 82% for PTA, similar for both feet) as shown in Table 3.

Table 1: Baseline characteristics of included patients

Variables	All patients n [%]
Women, n [%]	44 [41]
Men, n [%]	64 [59]
Characteristics	
Age, median	70.5 [59-78]
Smokers or past smokers	67 [62]
Diabetes, n [%]	59 [55]
Chronic kidney disease, n [%]	19 [18]
Amputated, n [%]	15 [14]
PPG TP (mmHG), median	85 [56-110]
PPG TBI, median	0.64 [0.4-0.81]
Laser TP (mmHG), median	76 [50-101]
Laser TBI, median	0.57 [0.37-0.76]
Left foot	
Monophasic DPA [n]	43 [40]
Multiphasic DPA [n]	60 [56]
Monophasic PTA [n]	38 [35]
Multiphasic PTA [n]	59 [55]
Right foot	
Monophasic DPA [n]	34 [31]
Multiphasic DPA [n]	66 [61]
Monophasic PTA [n]	35 [32]
Multiphasic PTA [n]	64 [59]

Table 2: TP and TBI sensitivity and specifity for mild (A), moderate (B), severe (C) and optimum ROC curve (D) cutoffs of PAD according to DPA and PTA monophasic waveforms

		AUC		Sensitivity, %	Specificity, %	Cutoffs*
DPA Dorsalis pedis artery	Left TP	0.80 [0.72-0.89]	A	79 [67-92]	67 [55-79]	70
			B	44 [28-59]	90 [82-97]	50
			C	13 [2-23]	97 [92-100]	30
			D	69 [55-84]	74 [63-85]	67
	Left TBI	0.82 [0.74-0.90]	A	85 [73-96]	64 [51-76]	0.60
			B	54 [38-69]	86 [77--95]	0.40
			C	8 [0-16]	97 [92-100]	0.20
			D	79 [67-92]	71 [59-82]	0.53
	DPA Left TP vs DPA Left TBI: p = 0.3927					
	Right TP	0.85 [0.76-0.94]	A	83 [70-97]	79 [68-89]	70
			B	60 [42-78]	92 [85-99]	50
			C	10 [0-21]	97 [92-100]	30
			D	90 [79-100]	74 [63-85]	78
	Right TBI	0.87 [0.79-0.96]	A	90 [79-100]	69 [57-80]	0.60
			B	63 [46-81]	93 [87-100]	0.40
			C	17 [3-30]	98 [95-100]	0.20
			D	90 [79-100]	77 [66-88]	0.54
	DPA Right TP vs DPA Right TBI: p = 0.0804					
PTA Posterior tibialis artery	Left TP	0.77 [0.67-0.86]	A	76 [62-91]	65 [53-77]	70
			B	38 [22-55]	89 [82-97]	50
			C	12 [1-23]	96 [92-100]	30
			D	65 [49-81]	72 [60-84]	67
	Left TBI	0.76 [0.66-0.86]	A	76 [62-91]	60 [47-72]	0.60
			B	44 [27-61]	84 [75-94]	0.40
			C	6 [0-14]	98 [95-100]	0.20
			D	71 [59-88]	70 [58-82]	0.52
	PTA Left TP vs PTA Left TBI: p = 0.8290					
	Right TP	0.76 [0.64-0.87]	A	70 [54-85]	74 [63-85]	70
			B	55 [38-72]	90 [82-97]	50
			C	9 [0-19]	95 [89-100]	30
			D	70 [54-85]	72 [61-84]	74
	Right TBI	0.77 [0.66-0.88]	A	76 [61-90]	66 [53-78]	0.60
			B	52 [34-69]	90 [82-97]	0.40
			C	12 [1-23]	97 [92-100]	0.20
			D	76 [61-90]	71 [59-82]	0.56
	PTA Right TP vs PTA Right TBI: p = 0.4617					

Table 3: Model strengths and threshold comparisons of patients with and without diabetes (TP and TBI)

Measure			AUC	Sensitivity, %	Specificity, %	Cutoffs
DPA Dorsalis pedis artery	Left TP	Cohort	0.80 [0.72-0.89]	69 [55-84]	74 [63-85]	67
		Diabetes	0.82 [0.71-0.94]	81 [64-98]	70 [54-86]	64
		Without Diabetes	0.79 [0.66-0.92]	78 [59-97]	75 [59-91]	84
	Left TBI	Cohort	0.82 [0.74-0.90]	79 [67-92]	71 [59-82]	0.53
		Diabetes	0.84 [0.73-0.94]	80 [64-98]	70 [54-86]	0.50
		Without Diabetes	0.81 [0.68-0.94]	78 [59-97]	71 [59-91]	0.61
	Right TP	Cohort	0.85 [0.76-0.94]	90 [79-100]	74 [63-85]	78
		Diabetes	0.81 [0.66-0.97]	88 [71-100]	70 [54-86]	71
		Without Diabetes	0.89 [0.80-0.99]	93 [79-100]	71 [55-87]	84
	Right TBI	Cohort	0.87 [0.79-0.96]	90 [79-100]	77 [66-88]	0.54
		Diabetes	0.84 [0.69-0.98]	88 [71-100]	70 [54-86]	0.51
		Without Diabetes	0.93 [0.86-1.00]	93 [79-100]	71 [55-87]	0.61
PTA Posterior tibialis artery	Left TP	Cohort	0.77 [0.67-0.86]	65 [49-81]	72 [60-84]	67
		Diabetes	0.72 [0.57-0.87]	65 [44-86]	70 [54-86]	62
		Without Diabetes	0.84 [0.71-0.96]	86 [67-100]	70 [53-88]	86
	Left TBI	Cohort	0.76 [0.66-0.86]	71 [59-88]	70 [58-82]	0.52
		Diabetes	0.73 [0.59-0.88]	70 [50-90]	70 [54-86]	0.47
		Without Diabetes	0.82 [0.68-0.95]	79 [57-100]	70 [53-88]	0.63
	Right TP	Cohort	0.76 [0.64-0.87]	70 [54-85]	72 [61-84]	74
		Diabetes	0.70 [0.54-0.86]	68 [49-88]	73 [56-90]	63
		Without Diabetes	0.82 [0.64-1.00]	82 [59-100]	69 [53-84]	78
	Right TBI	Cohort	0.77 [0.66-0.88]	76 [61-90]	71 [59-82]	0.56
		Diabetes	0.70 [0.54-0.85]	68 [49-88]	69 [51-87]	0.50
		Without Diabetes	0.88 [0.76-1.00]	82 [59-100]	72 [56-87]	0.56

Discussion

Measurement of TP and TBI in all patients with suspected PAD, CLTI and tissue loss is a strong recommendation from the last Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia.[8] The aim of this study was to verify which had better threshold of sensitivity and specificity when compared with the arterial blood flow waveform DPA and PTA for PAD detection. We hypothesized that there were no differences between TP and TBI measurement in detection of PAD, especially for patients with diabetes.

Our results show that both TP and TBI had good screening capabilities in a clinical setting. However, the ROC curves AUC were slightly lower in individuals with than without diabetes, but still with good AUC, as well as sensitivity for a specificity of 70%. According to the Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia,[8] TBI and TP are simple, inexpensive, quick, helpful in the presence of small-vessel artery disease, useful in noncompressible tibial arteries, provide data to predict wound healing and limb survival and are valuable to monitor the efficacy of therapeutic intervention.[8] Based on the literature, the arteries of the halluces are considered less prone to calcification and, accordingly, measuring toe pressure gives more accurate results with fewer false positive values.[24,25,33,42] This high sensitivity, simultaneously considered with the angiosome for the artery choice, can influence the best practices for toe pressure measurements.

Our study shows that the accuracy for PAD detection between TP and TBI is not significatively different. Even if the sensitivity of TBI had a slight tendency of being higher than that of TP for the same specificity, this small gain in sensitivity is not clinically relevant. TBI is more exposed to errors during ratio calculation by clinicians performing time-consuming brachial pressure measurements. In this way, promoting the measurement's use with TP could be more accessible and easier for all health-care providers.

Høyer et al. (2013) showed a sensitivity of 90% to 100% and a specificity of 65% to 100% for detecting vessel stenosis using TBI.[33] In our study, for the most critical population with diabetes, we obtained a TBI sensitivities of 80% and 88% for the left and right foot compared to DPA for a specificity of 70%, decided as a threshold of clinical significance. We obtained sensitivities of 82% and 81% respectively for TP for the same specificity of 70%. If a specificity of 65% had been preferred, higher sensitivity could've been reached. Based on these results, we recommend the use of TP as a good screening test for individuals with diabetes in the community health-care system to enable earlier referral for more complex vascular assessments. Although previous guidelines have suggested a range of toe pressure (TP) thresholds for defining limb-threatening ischemia, such thresholds must be used cautiously and considered in the clinical context because of multiple confounding factors and the lack of a precise and reliable relationship to outcomes.[8]

Our area under the curve between 0.80 and 0.87 shows good TP and TBI measurement accuracy compared to the dorsalis pedis artery monophasic waveform within a population of 108 patients. The AUC was lower with the posterior tibialis artery monophasic waveform ranging from 0.76 to 0.77. These moderate-high results confirmed the use of the dorsalis pedis artery monophasic waveform as a criteria value in respect to pedal artery angiosomes. Although natural arterial anastomosis exist between angiosomes, the angiosome theory posits that superior results can be achieved by revascularizing the vessel that directly feeds an angiosome in the area where there is tissue loss, rather than relying on an indirect flow of arteries supplying adjacent angiosomes.[43] Neville et al. retrospectively examined 52 incurable wounds in bypass patients and found that indirectly revascularized wounds were amputated in 38% of cases, compared to 9% of cases where the angiosome containing the wound was directly revascularized.[43] An analysis of 203 limbs that underwent endovascular treatment for limb salvage found that limb salvage was 86% when wound angiosomes were directly revascularized, compared to 69% for indirect

revascularization.[44] A recent systematic review and meta-analysis suggest that direct revascularization of the artery of the angiosome of the wound (but also indirect revascularization via collateral flow) significantly improves wound healing rate when compared to indirect revascularization.[45] To date, the evidence supporting the angiosome concept is retrospective. Prospective trials will be needed to determine if it will be helpful in clinical practice.[46] Our data suggest the hypothesis that if the vascular area evaluated by the instruments is not the area of the angiosome where the wound is located, i.e., the less vascularized area, the measurements could contradict each other. In this sense, maintaining the clinical prediction with the monophasic wave of the dorsalis pedis artery was consistent with a measurement test with TP in its angiosomes.

This study has limitations. The secondary analysis design limits the control over the patient's characteristics and inclusion. As a result, the median age was high (71), and there were a lot of co-morbidities (e.g., 55% of patients had diabetes) which limits the generalization of our results to an older population. Since the patients were recruited in a specialized wound care clinic, patients were subject to a selection bias of having more severe diseases than the general population with PAD. Conversely, this sample has the most risk factors for screening pertinence. The use of monophasic waveform as the standard comparison criterion to assess for PAD is also a limitation of this study, as monophasic doppler waveform is a sign of more advanced disease. PAD can sometimes also be present in individuals with biphasic doppler waveform, but we did not include those individuals as having definitive PAD. This method increased the certainty of the PAD diagnosis but may have underestimated the TP and TBI thresholds and sensitivity for PAD detection. Also, since we evaluated lower limb measurements, patients with severe diseases may be underrepresented in the whole population if they underwent previous amputations. To overcome this limitation, we evaluated our results according to each foot. Aside from those limitations, our results are still interesting regarding improving the first line in wound care, as we suggest using TP instead of the ratio for easier and faster vascular assessment in respect of early detection as recommended.

Take-home Message
With similar metrologic properties between toe pressure and toe brachial index, using absolute systolic toe pressure is a standalone vascular test of the forefoot in a clinical setting for an early PAD detection, while performing the calculation of toe-brachial index appears to be of no added values for detecting PAD.

Conclusion

Absolute systolic toe pressure measurement and toe brachial index had a stronger, but not significantly clinically different, AUC with the dorsalis pedis artery than the posterior tibialis artery. This study suggests that a monophasic dorsalis pedis artery can predict better forefoot vascularization than a monophasic posterior tibialis artery. Toe pressure (TP) and Toe Brachial Index (TBI) had similar ROC curve AUC with both arteries (DPA and PTA) of the foot. Compared to the dorsal pedis artery waveform as a standard for vascularization, sensitivities and specificities for established disease severity thresholds of TP and TBI, as well as sensitivities for a 70% specificity, were also similar, between TP and TBI. Both absolute systolic toe pressure measurement and toe brachial index had slightly stronger ROC curve AUC, with the dorsalis pedis artery as the standard of comparison, than the posterior tibialis artery waveform, as per the angiosome theory. Therefore, health-care practitioners treating wounds should be aware of the angiosome concept, as well as the diagnostic properties and limits of TP and TBI when performing a lower limb vascular assessment.

In conclusion, both toe pressure and toe-brachial index seem to be standalone vascular tests of the forefoot. In patients with a lower limb wound, we suggest that performing the more tedious and time-consuming calculation of toe-brachial index appears to be of no added values for detecting PAD than assessing solely the systolic toe pressure measurement.

Maryse Beaumier* RN PhD is with the Health Sciences Department, Université du Québec à Rimouski, Lévis Campus, Lévis and Research Center of CISSS Chaudière-Appalaches, Lévis, Québec Canada.

Théo Gignac is a student at Lévis Campus, Lévis and Research Center of CISSS Chaudière-Appalaches, Lévis, Québec Canada.

Stéphane Turcotte MSc is with Lévis Campus, Lévis and Research Center of CISSS Chaudière-Appalaches, Lévis, Québec Canada.

Jérôme Patry DPM MD MSc is with Research Center of CISSS Chaudière-Appalaches, Lévis and Faculty of Medicine, Université Laval, Québec, Canada.

***Corresponding author:** Maryse Beaumier RNPhD. Université du Québec à Rimouski, Lévis Campus, 1595, boul. Alphonse-Desjardins, #4014, Lévis, (Québec), Canada, G6V 0A6. Phone (Office): (418) 833-8800, Ext.3188, maryse_beaumier@uqar.ca
https://orcid.org//0000-0003-1015-505X

References

1. Beaumier M, Murray BA, Despatis MA, Patry J, Murphy C, Jin S, et al. Best practice recommendations for the prevention and management of peripheral arterial ulcers. In: Foundations of Best Practice for Skin and Wound Management. A supplement of Wound Care Canada; 2020.
2. Sibbald RG, Elliott JA, Persaud-Jaimangal R, Goodman L, Armstrong DG, Harley C, et al. Wound Bed Preparation 2021. Adv Skin Wound Care. 2021 Apr 1;34(4):183-195.
3. Fowkes FG, Rudan D, Rudan I, Aboyans V, Denenberg JO, McDermott MM, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. Lancet. 2013 Oct 19;382(9901):1329-40.
4. Olinic DM, Spinu M, Olinic M, Homorodean C, Tataru DA, Liew A, et al. Epidemiology of peripheral artery disease in Europe: VAS Educational Paper. Int Angiol. 2018 Aug;37(4):327-334.5.
5. Howard DP, Banerjee A, Fairhead JF, Hands L, Silver LE, Rothwell PM; Oxford Vascular Study. Population-based study of incidence, risk factors, outcome, and prognosis of ischemic peripheral arterial events: implications for prevention. circulation. 2015 Nov 10;132(19):1805-15/
6. Marrett E, DiBonaventura Md, Zhang Q. Burden of peripheral arterial disease in Europe and the United States: a patient survey. Health Qual Life Outcomes. 2013 Oct 22;11:175.
7. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG; TASC II Working Group. Inter-society consensus for the management of peripheral arterial disease (TASC II). J Vasc Surg. 2007 Jan;45 Suppl S:S5-67.
8. Conte MS, Bradbury AW, Kolh P, White JV, Dick F, Fitridge R, et al.; GVG Writing Group for the Joint Guidelines of the Society for Vascular Surgery (SVS), European Society for Vascular Surgery (ESVS), and World Federation of Vascular Societies (WFVS). Global vascular guidelines on the management of chronic limb-threatening ischemia. Eur J Vasc Endovasc Surg. 2019 Jul;58(1S):S1-S109.e33.
9. Conte MS, Pomposelli FB, Clair DG, Geraghty PJ, McKinsey JF, Mills JL, et al.; Society for Vascular Surgery. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication. J Vasc Surg. 2015 Mar;61(3 Suppl):2S-41S.
10. Hopf HW, Ueno C, Aslam R, Burnand K, Fife C, Grant L, et al. Guidelines for the treatment of arterial insufficiency ulcers. Wound Repair Regen. 2006 Nov-Dec;14(6):693-710.
11. Bonham PA, Flemister BG, Droste LR, Johnson JJ, Kelechi T, Ratliff CR, et al. 2014 guideline for management of wounds in patients with lower-extremity arterial disease (LEAD): an executive summary. J Wound Ostomy Continence Nurs. 2016 Jan-Feb;43(1):23-31.
12. International Working Group on the Diabetic Foot, IWGDF guidelines on the prevention and management of diabetic foot disease. 2019.
13. Hembling BP, Hubler KC, Richard PM, O'Keefe WA, Husfloen C, Wicks R, et al. The limitations of ankle brachial index when used alone for the detection/screening of peripheral arterial disease in a population with an increased prevalence of diabetes. Journal for Vascular Ultrasound. 2007 Sep;31(3):149-51.
14. Hinchliffe RJ, Forsythe RO, Apelqvist J, Boyko EJ, Fitridge R, Hong JP, et al.; International Working Group on the Diabetic Foot (IWGDF). Guidelines on diagnosis, prognosis, and management of peripheral artery disease in patients with foot ulcers and diabetes (IWGDF 2019 update). Diabetes Metab Res Rev. 2020 Mar;36 Suppl 1:e3276.
15. Patry J, Laurencelle L, Bélisle J, Beaumier M. Vascular assessment in patients with a lower limb wound: a correlational study of photoplethysmography and Laser Doppler Flowmetry Toe pressure techniques. J Diabetes Sci Technol. 2022 Mar;16(2):470-477.
16. Aboyans V, Criqui MH, Abraham P, Allison MA, Creager MA, Diehm C, et al.; American Heart Association Council on Peripheral Vascular Disease; Council on Epidemiology and Prevention; Council on Clinical Cardiology; Council on Cardiovascular Nursing; Council on Cardiovascular Radiology and Intervention, and Council on Cardiovascular Surgery and Anesthesia. Measurement and interpretation of the ankle-brachial index: a scientific statement from the American Heart Association. Circulation. 2012 Dec 11;126(24):2890-909.
17. Aubert CE, Cluzel P, Kemel S, Michel PL, Lajat-Kiss F, Dadon M, et al. Influence of peripheral vascular calcification on efficiency of screening tests for peripheral arterial occlusive disease in diabetes--a cross-sectional study. Diabet Med. 2014 Feb;31(2):192-9.
18. Potier L, Abi Khalil C, Mohammedi K, Roussel R. Use and utility of ankle brachial index in patients with diabetes. Eur J Vasc Endovasc Surg. 2011 Jan;41(1):110-6.
19. Lee SJ, Lee IK, Jeon JH. Vascular calcification-new insights into its mechanism. Int J Mol Sci. 2020 Apr 13;21(8):2685

20. Wu M, Rementer C, Giachelli CM. Vascular calcification: an update on mechanisms and challenges in treatment. Calcif Tissue Int. 2013 Oct;93(4):365-73.
21. Yahagi K, Kolodgie FD, Lutter C, Mori H, Romero ME, Finn AV, et al. Pathology of human coronary and carotid artery atherosclerosis and vascular calcification in diabetes mellitus. Arterioscler Thromb Vasc Biol. 2017 Feb;37(2):191-204
22. Hopf HW, Ueno C, Aslam R, Dardik A, Fife C, Grant L, et al. Guidelines for the prevention of lower extremity arterial ulcers. Wound Repair Regen. 2008 Mar-Apr;16(2):175-88.
23. Álvaro-Afonso FJ, Lázaro-Martínez JL, Aragón-Sánchez J, García-Morales E, García-Álvarez Y, Molines-Barroso RJ. What is the clinical utility of the ankle-brachial index in patients with diabetic foot ulcers and radiographic arterial calcification? Int J Low Extrem Wounds. 2015 Dec;14(4):372-6.
24. Sansosti LE, Berger MD, Gerrity MA, Kelly P, Meyr AJ. Effect of patient positioning on toe pressure measurement using noninvasive vascular testing. Br J Community Nurs. 2015 Sep;Suppl Wound Care:S12, S14-6.
25. Williams DT, Harding KG, Price P. An evaluation of the efficacy of methods used in screening for lower-limb arterial disease in diabetes. Diabetes Care. 2005 Sep;28(9):2206-10.
26. Normahani P, Mustafa C, Shalhoub J, Davies AH, Norrie J, Sounderajah V, et al. A systematic review and meta-analysis of the diagnostic accuracy of point-of-care tests used to establish the presence of peripheral arterial disease in people with diabetes. J Vasc Surg. 2021 May;73(5):1811-1820.
27. Tehan PE, Sebastian M, Barwick AL, Chuter VH. How sensitive and specific is continuous-wave Doppler for detecting peripheral arterial disease in people with and without diabetes? A cross-sectional study. Diab Vasc Dis Res. 2018 Sep;15(5):396-401
28. Alexandrescu VA, Brochier S, Schoenen S, Antonelli E, Azdad K, Zekhnini I, et al. Grades of below-the-ankle arterial occlusive disease following the angiosome perfusion: a new morphological assessment and correlations with the inframalleolar GVG stratification in CLTI patients. Ann Vasc Surg. 2022 Apr;81:358-377.
29. Attinger CE, Evans KK, Bulan E, Blume P, Cooper P. Angiosomes of the foot and ankle and clinical implications for limb salvage: reconstruction, incisions, and revascularization. Plast Reconstr Surg. 2006 Jun;117(7 Suppl):261S-293S.
30. Attinger CE, Evans KK, Bulan E, Blume P, Cooper P. Angiosomes of the foot and ankle and clinical implications for limb salvage: reconstruction, incisions, and revascularization. Plast Reconstr Surg. 2006 Jun;117(7 Suppl):261S-293S.
31. 31. Weitz JI, Byrne J, Clagett GP, Farkouh ME, Porter JM, Sackett DL, et al. Diagnosis and treatment of chronic arterial insufficiency of the lower extremities: a critical review. Circulation. 1996 Dec 1;94(11):3026-49
32. Beaumier M. Élaboration et validation d'une grille prédictive de la vascularisation artérielle insuffisante à une plaie au membre inférieur. [Development and validation of a predictive grid of insufficient arterial blood supply to a lower limb wound.] sous la direction de Gilles Bronchti, PhD et Louis Laurencelle, PhD, in Faculté de médecine. Montreal (QC): Université de Montréal; 2019.
33. Høyer C, Sandermann J, Petersen LJ. The toe-brachial index in the diagnosis of peripheral arterial disease. J Vasc Surg. 2013 Jul;58(1):231-8.
34. Criqui MH, Fronek A, Klauber MR, Barrett-Connor E, Gabriel S. The sensitivity, specificity, and predictive value of traditional clinical evaluation of peripheral arterial disease: results from noninvasive testing in a defined population. Circulation. 1985 Mar;71(3):516-22.
35. Clemens MW, Attinger CE. Angiosomes and wound care in the diabetic foot. Foot Ankle Clin. 2010 Sep;15(3):439-64.
36. Rother U, Krenz K, Lang W, Horch RE, Schmid A, Heinz M, et al. Immediate changes of angiosome perfusion during tibial angioplasty. J Vasc Surg. 2017 Feb;65(2):422-430.
37. Sibley RC 3rd, Reis SP, MacFarlane JJ, Reddick MA, Kalva SP, Sutphin PD. Noninvasive physiologic vascular studies: a guide to diagnosing peripheral arterial disease. Radiographics. 2017 Jan-Feb;37(1):346-357.
38. Criqui MH, Vargas V, Denenberg JO, Ho E, Allison M, Langer RD, et al. Ethnicity and peripheral arterial disease: the San Diego Population Study. Circulation. 2005 Oct;25;112(17):2703-7.
39. 39. Fischer JE, Bachmann LM, Jaeschke R. A readers' guide to the interpretation of diagnostic test properties: clinical example of sepsis. Intensive Care Med. 2003 Jul;29(7):1043-51.
40. Cohen JF, Korevaar DA, Altman DG, Bruns DE, Gatsonis CA, Hooft L, et al. STARD 2015 guidelines for reporting diagnostic accuracy studies: explanation and elaboration. BMJ Open. 2016 Nov 14;6(11):e012799
41. Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig L, et al.; STARD Group. STARD 2015: An updated list of essential items for reporting diagnostic accuracy studies. Clin Chem. 2015 Dec;61(12):1446-52.
42. Romanos MT, Raspovic A, Perrin BM. The reliability of toe systolic pressure and the toe brachial index in patients with diabetes. J Foot Ankle Res. 2010 Dec 22;3:31.
43. Neville RF, Attinger CE, Bulan EJ, Ducic I, Thomassen M, Sidawy AN. Revascularization of a specific angiosome for limb salvage: does the target artery matter? Ann Vasc Surg. 2009 May-Jun;23(3):367-73.
44. Iida O, Nanto S, Uematsu M, Ikeoka K, Okamoto S, Dohi T, et al. Importance of the angiosome concept for endovascular therapy in patients with critical limb ischemia. Catheter Cardiovasc Interv. 2010 May 1;75(6):830-6.
45. Kim KG, Meshkin DH, Tirrell AR, Bekeny JC, Tefera EA, Fan KL, et al. A systematic review and meta-analysis of endovascular angiosomal revascularization in the setting of collateral vessels. J Vasc Surg. 2021 Oct;74(4):1406-1416.e3.
46. Cronenwett JL, Johnston KW. Rutherford's vascular surgery e-book. Elsevier Health Sciences; 2014 Mar 12.

The power of vashe® now available from the hospital to the home

vashe® wound solution + vashe® WOUND SOLUTION OTC

Vashe OTC is now available on Amazon Canada!

Get it here:

URGO Medical North America, LLC. Fort Worth, TX 76102. To order, call 1-855-888-8273 or visit www.urgomedical.us

204-AD001 Rev. 05/24

URGO MEDICAL Healing people®

An Equitable Vision For Wound Assessment: A Comparative Case Study Of AI And Human Wound Tissue Assessment Across Skin Tones

Heba Tallah Mohammed PhD MD, **Sheila Wang** PhD, **Samia Rahman** BSc, **Ryan SQ Geng** MSc, **Kaitlyn Ramsay** PhD, **Samantha Bestavros** BSc, **Katerina Bavaro** HBSc, **Robert DJ Fraser** MN RN WOCC© NSWOCC

Abstract: Accurate wound assessment is crucial for effective wound management, but visual assessment can be inconsistent due to various clinician (e.g., knowledge, skill) or patient (e.g., skin tone) factors. This study compares clinicians' subjective assessments of wound tissues with those made by an artificial intelligence (AI) model (SmartTissue™) across different skin tones. The study highlights the subjective nature of manual wound assessments and the potential value of AI-driven documentation in clinical practice. The integration of AI technology could offer clinicians real-time data aiding in standardizing measurements across diverse populations to reduce racial disparities in wound care. By providing consistent, standardized measurements across diverse patient populations, AI can support clinical judgment in evaluating wound healing, monitoring treatment efficacy and revising care planning.

Key words: *wound assessment, wound tissue, skin tones, artificial intelligence (AI), real time data*

How to cite: Mohammed HT, Wang S, Rahman S, Geng R, Ramsay K, Bestavros S et al. An equitable vision for wound assessment: a comparative case study of AI and human wound tissue assessment across skin tones. Limb Preservation Journal. 2025;6(1): 37-43. DOI: 10.56885/061916taiknw

Chronic wounds pose a significant challenge in health care, affecting millions of people worldwide and placing a substantial burden on health-care systems. An estimated 1-2% of the population in developed countries are affected by chronic wounds, with prevalence rates as high as 6% reported in some studies.[1,2] These treatment-resistant wounds, such as venous and arterial ulcers, impact patients' quality of life and impose a considerable financial burden on society.[3]

The accurate assessment of wound healing trajectory is crucial for effective wound management. This process relies heavily on the clinician's ability to identify and quantify different tissue types present in the wound bed, including slough, eschar, epithelialization, and granulation tissue.[4]

Despite the importance of accurately identifying and quantifying tissue types within wounds, several factors contribute to variability in clinician visual assessment, including knowledge gaps, visual perception limitations and skin colour.[5]

Clinicians may have varying expertise and training in identifying different tissue types, leading to inconsistent assessments.[5] Furthermore, wound care assessment training is often tailored to fair skin colour, while darker skin tones may influence the appearance of tissue colours within the wound bed.[6] Additionally, the human eye and brain are unsuited for accurately quantifying and segmenting tissue types, especially in complex, irregular shapes like wounds.[7] These limitations can hinder subjective assessments in accurately assessing tissue types.

These challenges can lead to inconsistent assessments, potentially impacting treatment decisions and patient outcomes. The variability in human assessment of wound tissues is a significant concern, as it can result in suboptimal care and delayed healing.[8] Therefore, there is a growing interest in developing more objective and consistent methods for wound assessment. Artificial intelligence (AI) and machine learning techniques have shown promise in improving the accuracy and consistency of wound evaluation.[9,10]

Swift Medical's (Toronto, Canada) AI tissue classification model (SmartTissue™) used 17,000 labelled images and 465,187 training images to predict tissue types to develop a classification algorithm.[11] Validation of the model found a high degree of intersection of the areas clinicians traced using software to estimate tissue types and rated 91% of reviewed SmartTissue™ predictions as 'very good to fair'.[11] These technologies have the potential to overcome the limitations of human visual assessment and provide more reliable data for clinical decision-making.[11] Research on creating a wound severity score using machine learning compared models and made better predictions when using AI model predictions for wound tissue types as inputs compared to clinician's assessment data.[12]

This exploratory case study aims to emphasize the variability in clinical assessment of wound tissues by assessing clinicians' subjective assessments and ratings of tissue types compared to those made by an AI model, demonstrating the potential benefits of integrating technology into wound care practice.

Methods

An exploratory case study was conducted by administering an online survey to 20 wound care clinicians with varying levels of expertise in wound care. We employed purposive non-random sampling to recruit clinicians at the Nurses Specialized in Wound, Ostomy and Continence Canada (NSWOCC) conference. The survey encompassed questions about clinicians' clinical experience, practice, education and wound care training. Subsequently, clinicians evaluated non-identified wound images from patients with diverse skin tones and wound complexities. Each clinician was tasked with identifying and estimating the different tissue types within each wound, such as granulation, slough, eschar and epithelialization, and their percentage composition.

Clinicians were asked to estimate the proportions of each tissue type within a wound, and these estimates were aggregated and averaged. The mean rating of each tissue type within a wound was then compared to ratings previously recorded for the same wound image using SmartTissue™ (referred to as the AI model or AI). Wounds were categorized as complex if they displayed a combination of diverse tissue types, and as non-complex if the wound presented with one or more tissue types. The Fitzpatrick scale was used to describe skin tone, with images classified as type I/II group for light/fair skin tone or type V/VI group for dark-darkest brown skin tone.

Results

Of the 20 clinicians surveyed, 70% (14/20) were nurses, while the remaining 30% (6/20) comprised physicians and medical residents. Location of practice included 50% (10/20) hospitals, 40% (8/20) ambulatory clinics and 10% (2/20) home care and long-term care facilities. Additionally, 75% (15/20) of the clinicians were wound care specialists and 65% (13/20) of the participants had received advanced wound and ostomy training, with an average of 13.75 years of wound care experience.

Study Overview

Exploratory case study comparing clinician assessments of wound tissues with AI-driven SmartTissue™ technology

20 wound care clinicians, with an average of 13.75 years of wound care experience, evaluated wound images from patients with a range of skin tones

Key Findings

- Clinicians frequently overestimated slough and granulation tissue
- Epithelialization was often underestimated, particularly in patients with darker skin tones
- Eschar was commonly reported by clinicians, even when not detected by AI

Implications for Practice with AI integration

- AI can enhance accuracy in wound assessments by correctly identifying tissue types across diverse skin tones, leading to more reliable evaluations
- Offers potential to reduce racial disparities in wound care by providing more precise and unbiased assessments, enabling more effective treatment planning

Future Directions

- Longitudinal studies are needed to evaluate the impact of AI technology on wound healing outcomes
- Emphasizes the need to develop educational tools that address diverse skin tones in wound care training and assessment

Take-Home Message

- AI-driven wound assessment tools hold promise for standardizing wound evaluations, reducing bias, and improving care for patients of all skin tones.

Table 1: Summary of AI and clinicians' outputs and differences in observations

	Patient 1: Complex wound (Light skin tone)	Patient 2: Complex wound (Dark skin tone)	Patient 3: Non-complex wound (Dark skin tone)
Clinicians Assessment			
Granulation	35.04% (10 – 50%)(±12.80)	23.30% (3 – 60%) (±14.26)	81.00% (0 – 100%) (±26.98)
Slough	61.78% (17 – 90%) (±18.33)	52.80% (20 – 90%)	7.70% (0 – 74%)
Eschar	5.20% (2 – 41%)	10.71% (0 – 30%)	0.00% (0 – 100%)
Epithelialization	36.94% (0 – 26%)	8.53% (0 – 36%)	7.15% (0 – 56%)
AI Prediction			
Granulation	30.64%	13.25%	44.00%
Slough	47.94%	41.22%	0.30%
Eschar	0.00%	0.00%	0.00 %
Epithelialization	21.42%	45.53%	55.50%
Difference			
Granulation	+4.40%	+10.05%	+37.00%
Slough	+13.84%	+11.58%	+7.40%
Eschar	+5.20%	+10.71%	0.00%
Epithelialization	+15.20%	-36.98%	-48.35%

Table 1 provides a comparative analysis of wound tissue assessments for the three patients with varying wound complexities and skin tones. The table displays the mean percentages of four tissue types (granulation, slough, eschar and epithelialization) as estimated by 20 clinicians and predicted by the AI model. Clinician assessment includes mean, minimum and maximum values (mean% [standard deviation]), reflecting variability across clinicians' evaluations. AI predictions are shown as a single percentage (%), derived from one measurement. The differences in the mean value of the clinician assessment compared to the AI prediction (clinician – AI) are also shown, highlighting discrepancies across wound types and skin tones

Patient 1: Complex Wound In A Light Skin-Tone Patient

Figure 1: Patient 1 is an example of a non-complex wound in a patient with light skin tone (Fitzpatrick type I/II)

In the first case, the AI model was used to assess a complex wound in a patient with a light skin tone. The AI analysis predicted that the wound consisted of 30.64% granulation tissue, 47.94% slough, 0% eschar and 21.42% epithelialization.

A comparison of the AI measurements with those taken by clinicians revealed significant variations. On average, clinicians estimated 4.40% more granulation tissue, 13.84% more slough and 15.52% more epithelialization tissue than the AI. Furthermore, clinicians reported the existence of eschar, while the AI detected none, estimating a 5.20% composition.

Overall, clinicians consistently reported more slough and less granulation and epithelialization. The deviation of clinicians' measurements to the AI ratings indicated a high degree of variability and inconsistency in their assessments of tissue types when in comparison, the AI model provided consistent, standardized measurements.

Patient 2: Complex Wound In A Dark Skin-Tone Patient

Figure 2: Patient 2 is an example of a complex wound in a patient with dark skin tone (Fitzpatrick type V/VI)

In this case, the AI model analyzed a complex wound in a dark-skin tone patient and estimated 13.25% granulation tissue, 41.22% slough, 0% eschar and 45.53% epithelialization.

The clinicians' assessments showed wide variations. The average of the clinicians' measurements for granulation tissue was 23.30%, a 10.05% increase from the AI's estimate. Clinicians' estimates of slough were 52.80%, which was 11.58% higher than the AI's estimate. Eschar was identified by clinicians at an average of 10.71%, while the AI model did not report eschar as present. Clinicians estimated epithelialization at 8.53%, which was 36.98% lower than the AI model's measurement.

Consistent with Patient 1's assessment, clinicians reported higher levels of eschar, slough and granulation tissue, and less epithelialization, highlighting discrepancies when compared to the AI model's assessments.

Patient 3: Non-Complex Wound In A Dark Skin-Tone Patient

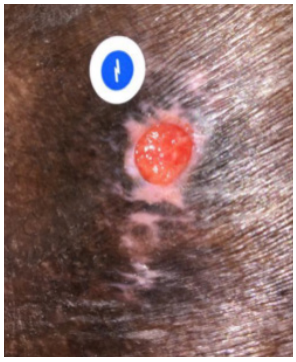


Figure 3: Patient 3 is an example of a non-complex wound in a patient with dark skin tone (Fitzpatrick type V/VI)

This patient presented with a non-complex wound and had a dark skin tone (Fitzpatrick type V). Upon analysis by the AI model, the wound was found to have 44% granulation tissue, 0.3% slough, 0% eschar and 55.5% epithelialization.

The clinicians' assessments differed notably from the AI's findings. Clinicians reported 37% more

granulation tissue than the AI's assessment. Their estimation of the slough was 7.4% higher than the AI's findings. Epithelialization was notably different, with clinicians reporting 48.35% less than the AI model.

Overall, clinicians tended to provide higher estimates of eschar and consistently lower estimates of the percentage composition of epithelial tissue. This case underscores the considerable variability in how clinicians assess wound tissue types, even in less complex wounds.

Discussion

This case series presented data on the differences in clinician manual wound assessments versus evaluations conducted by the AI wound assessment technology. Across all cases, clinicians frequently identified the presence of eschar when it was not predicted by the AI, overestimating its occurrence in wounds. Additionally, clinicians consistently noted elevated levels of slough and granulation tissue. This pattern of frequently reporting specific tissue types, especially eschar, along with the significantly wide standard deviation among clinicians, underscores the inconsistencies and variations among clinicians. Such discrepancies could result in unnecessary interventions or the adoption of more aggressive treatment strategies than necessary. Conversely, epithelialization, a crucial indicator of wound healing progress often characterized by subtle colour changes in the wound bed, was consistently underestimated by clinicians – particularly in darker skin tones. This highlights the need to acknowledge the potential inaccuracies in visual assessment across diverse skin tones and their potential effects on evaluating healing in patients with darker skin tones. This aligns with the existing literature indicating that clinicians might face more challenges in visually differentiating between different tissue types in people with darker skin tones.[13,14] This difficulty arises from the challenges in identifying discolouration and other subtle changes on dark skin, which makes it harder to distinguish between necrotic and healthy tissue.[13,14]

On the other hand, the AI model was trained with deep learning on hundreds of thousands of images to consider complex wound tissue characteristics, wound bed and background.[11] Using a consistent model, which can continue to be improved with new clinical data, can address subjective visual cues susceptible to the human bias of the clinician (e.g., knowledge, skill, experience, fatigue, previous cases) and patient factors (e.g., skin tone, environment) to offer more precise segmentation and quantification of tissue types. This underscores the potential for AI to be used to standardize wound assessments across diverse skin tones. AI models can also be improved by using additional training data and algorithm performance enhancing techniques. The provision of access to standardized assessment tools that can be improved over time, as can assessment skills that were previously constrained by educational programs.

The differences in how clinicians assess wounds compared to the AI model, especially when identifying eschar and epithelialization, raise concerns about the subjective nature of these evaluations. These disparities exist because many wound care protocols and educational tools primarily focus on lighter skin tones, resulting in gaps in clinical training for assessing wounds on darker skin.[6] These inconsistencies could potentially impede accurate tracking of wound progress, leading to delayed interventions or inappropriate treatments, especially for patients with darker skin tones.[6]

It is important to address racial disparities and strive for equity in wound care. Previous studies have highlighted that patients with darker skin face a higher risk of misdiagnosis and delayed wound healing due to perceptual challenges.[15] Recent studies have highlighted that AI technologies play a valuable role in improving diagnostic accuracy and minimizing variability in clinician assessments, particularly in the field of wound care.[16] The integration of AI technology into clinical practice can offer more consistent and unbiased wound assessments across diverse skin tones, potentially playing a crucial role in reducing racial disparities in wound care outcomes. By incorporating such features, health-care providers can ensure that all

patients receive accurate assessments irrespective of their skin tone, thus promoting equitable wound care.

The future of clinical practice increasingly relies on integrating AI models to enhance clinical expertise, providing a more nuanced and data-driven approach to patient care.[17] These tools will not replace clinicians and instead can empower clinicians to make better treatment decisions and provide more effective care.

Limitations

The case study's exploratory nature and limited sample size make it difficult to generalize findings to a broader population or various wound types. Furthermore, while the study recruited clinicians with wound care training and experience in wound care assessment, the study was unable to account for clinicians' familiarity with identifying tissue types in diverse skin tones.

Additionally, the study only utilized wound images, which may not fully capture the complexity of wounds in clinical practice where factors such as depth and exudate can also influence tissue type identification.

A limitation of this study, and of the field of wound assessment in general, is the lack of a universally accepted gold standard for wound tissue classification. While the AI model shows promise in providing consistent measurements, further research is needed to establish a reliable gold standard against which both human and AI assessments can be validated.

In the future, it would be beneficial to conduct longitudinal studies to assess different tissue types using AI technology and to track wound healing progress over time. These studies could offer valuable insights into how AI technology can enhance clinician assessment and its impact on clinical outcomes.

Conclusion

This case study underscores the inherent subjectivity in visual wound assessments and emphasizes the critical importance of accurate tissue typing. It reveals the pressing need for more objective clinical tools, especially when assessing diverse patient populations where skin colour variations can significantly impact visual evaluations.[5] The integration of AI-driven wound documentation into clinical practice offers a promising solution, providing clinicians with real-time, standardized data that can enhance the accuracy of tissue identification across all skin tones. This technological advancement has the potential to significantly improve wound care assessment and delivery for patients of all racial backgrounds. By augmenting clinical judgment, AI allows health-care professionals to focus their expertise on crucial aspects of patient care, including evaluating wound healing trajectories, monitoring treatment effectiveness and optimizing care planning and delivery. Ultimately, the adoption of AI in wound care represents a step towards more equitable, consistent and effective wound management practices.

Heba Tallah Mohammed PhD MD is with Swift Medical Inc., Toronto, Ontario, Canada.

Sheila Wang PhD is with Swift Medical Inc., Toronto, Women's College Hospital, Toronto and University of Toronto, Ontario, Canada.

Samia Rahman BSc is with the Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Alberta, Canada.

Ryan SQ Geng* MSc is with the Temerty Faculty of Medicine, University of Toronto, Ontario, Canada.

Kaitlyn Ramsay* PhD is with the Temerty Faculty of Medicine, University of Toronto, Ontario, Canada.

Samantha Bestavros* BSc is with the Temerty Faculty of Medicine, University of Toront, Ontario, Canada.

Katerina Bavaro* HBSc is with the Michener Institute of Education at University Health Network, Toronto, Ontario, Canada.

Robert DJ Fraser MN RN WOCC© NSWOCC is with Swift Medical Inc., Toronto, Ontario, Canada and Western University, London, Ontario, Canada.

*These authors contributed equally to this work

Corresponding author: Robert D.J. Fraser, MN RN, Swift Medical, 1 King St W Suite 4800 .Toronto, Ontario, M5H 1A1 Canada.
Email: Rob.fraser@swiftmedical.com

References

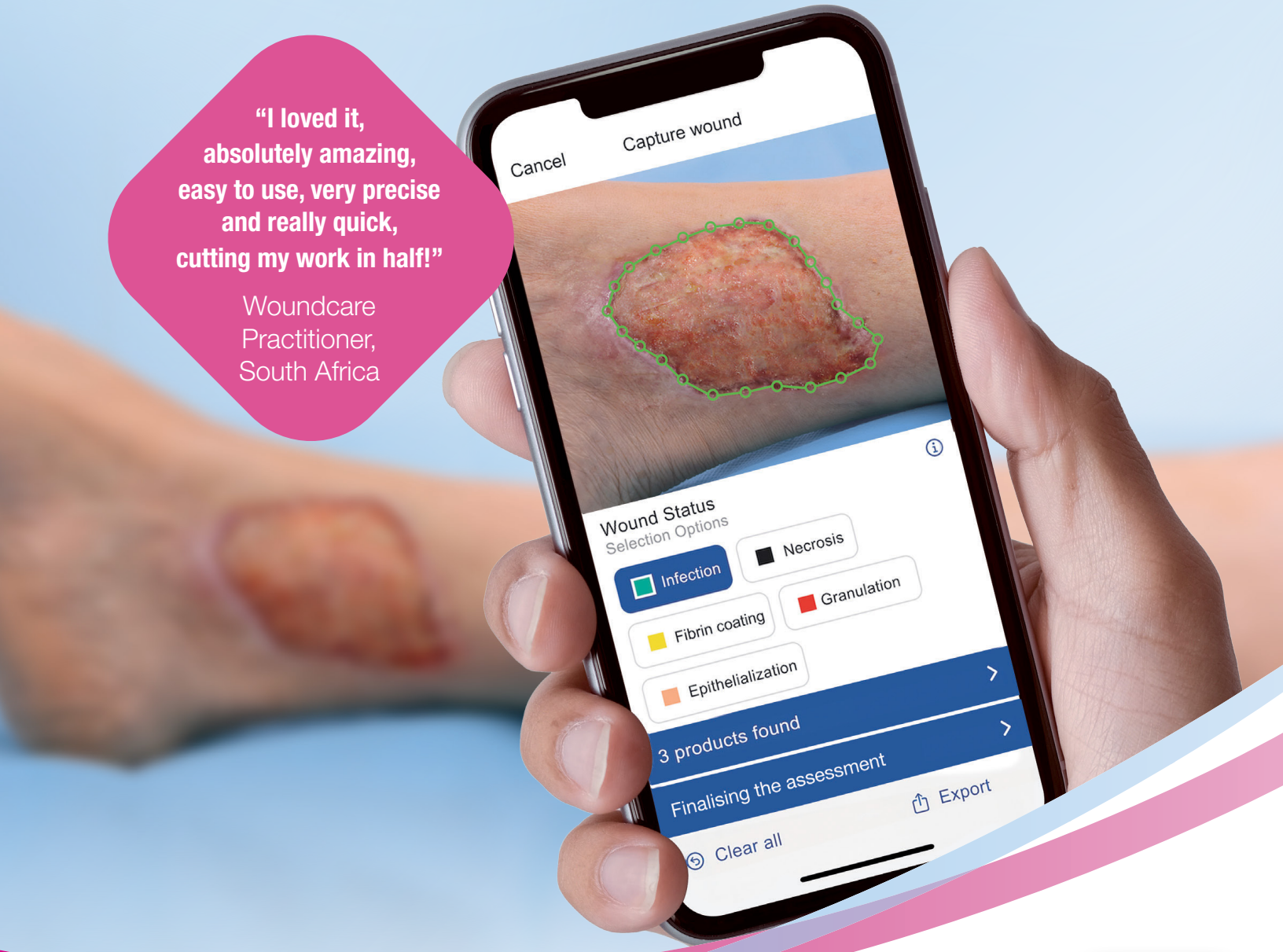
1. Järbrink K, Ni G, Sönnergren H, Schmidtchen A, Pang C, Bajpai R, et al. The humanistic and economic burden of chronic wounds: A protocol for a systematic review. Syst Rev. 2017;6(1):15.
2. Phillips CJ, Humphreys I, Fletcher J, Harding K, Chamberlain G, Macey S. Estimating the costs associated with the management of patients with chronic wounds using linked routine data. Int Wound J. 2016;13(6):1193-7.
3. Sen CK, Gordillo GM, Roy S, Kirsner R, Lambert L, Hunt TK, et al. Human skin wounds: A major and snowballing threat to public health and the economy. Wound Repair Regen. 2019;17(6):763-71.
4. Lazarus GS, Cooper DM, Knighton DR, Margolis DJ, Pecoraro RE, Rodeheaver G, et al. Definitions and guidelines for assessment of wounds and evaluation of healing. Wound Repair Regen. 1994;2(3):165-70.
5. Dhoonmoon L, Harikrishna KR, Abbas Z. Wound care and skin tone: Addressing skin tone bias in wound assessment. Wounds Int. 2023.
6. Edwards K, Hurd Y. Addressing racial disparities in pressure injury care. J Wound Care. 2019;28(9):604-10.
7. Vera MD. Wound assessment and documentation: practical guidance for health care professionals. Woundsource. Available from: https://www.woundsource.com/sites/default/files/whitepapers/wound_assessment_and_documentation.pdf.
8. Stotts NA, Rodeheaver GT, Thomas DR, Frantz RA, Bartolucci AA, Sussman C, et al. An instrument to measure healing in pressure ulcers: development and validation of the pressure ulcer scale for healing (PUSH). J Gerontol A Biol Sci Med Sci. 2001;56(12).
9. Wang C, Yan X, Smith M, Kochhar K, Rubin M, Warren SM, et al. A unified framework for automatic wound segmentation and analysis with deep convolutional neural networks. In: 2015 37th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC); 2015. p. 2415-8.
10. Kim RB, Moscoso-Kingsley W, Hirata R, Voronov L, Patel J. Utilization of smartphone and tablet camera photographs to predict healing of diabetes-related foot ulcers. Comput Biol Med. 2020;126:104042.
11. Ramachandram D, Ramirez-GarciaLuna JL, Fraser RDJ, Martínez-Jiménez MA, Arriaga-Caballero JE, Allport J. Fully automated wound tissue segmentation using deep learning on mobile devices: cohort study. JMIR Mhealth Uhealth. 2022;10(4).
12. Gupta R, Goldstone L, Eisen S, Ramachandram D, Cassata A, Fraser RDJ, et al. Towards an AI-based objective prognostic model for quantifying wound healing. 2022.
13. National Pressure Injury Advisory Panel (NPIAP), European Pressure Ulcer Advisory Panel (EPUAP), Pan Pacific Pressure Injury Alliance (PPPIA). Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. 2019.
14. Yap TL, Kennerly SM, Simmons MR. The economic impact of deep tissue injury in healthcare systems: litigation and beyond. J Wound Care. 2021;30(3):171-9.
15. Levine JM, Ayello EA, Zulkowski K. Preventing pressure ulcers in women: sex-specific interventions based on risk assessment. Adv Skin Wound Care. 2013;26(4):161-5.
16. Shamloul A, Daskalopoulou SS, Daskalopoulos G. The surge of digital wound care technologies: an emerging tool in clinical practice. Br J Dermatol. 2019;181(6):1155-7.
17. Subbiah V. The next generation of evidence-based medicine. Nat Med. 2023;29:49-58.

Cutimed® Wound Navigator

Your smart app for individual wound care

"I loved it, absolutely amazing, easy to use, very precise and really quick, cutting my work in half!"

Woundcare Practitioner, South Africa



Cutimed® WOUND NAVIGATOR

Scan here to download the free app to your smartphone or tablet.

- Determine the wound size with the interactive app
- Selection of suitable wound care products
- Direct access to all Cutimed® product information and exchange product selection with professional partners

Powered by imito

essity

Cutimed®, an Essity brand

Essity
1275 North Service Road West, Suite 800
Oakville, ON Canada L6M 3G4
Tel. 1-877-978-5526
Fax 1-877-978-9703

Cutimed® Your Power to Heal

A Mission With A Vision: The Canadian Diabetic Foot Ulcer Policy Roundtable

Kathleen Stevens RN PhD, **Ahtisham Younas** RN PhD and **Larry A Sawyer** BA

Abstract: Wounds Canada partnered with Memorial University and the Limb Preservation Alliance to host the Diabetic Foot Ulcer Policy Roundtable at the Wounds Canada National Conference on October 16, 2024, in London, Ontario. The roundtable brought key experts together to define strategies for each of the key policy areas in the prevention and management of diabetic foot ulcers towards the goal of improving quality of life for all Canadians and around the world. This article reports on some of the key discussion points and recommendations.

Key words: *diabetic foot ulcers, limb preservation, policy, Wounds Canada, Limb Preservation Alliance, revascularization, amputation prevention*

How to cite: Stevens K, Younas A, Sawyer LA. A mission with a vision: the Canadian diabetic foot ulcer policy roundtable. Limb Preservation Journal. 2025;6(1): 45-55. DOI: 10.56885/310523tegjqu

The burden of diabetic foot complications (e.g., diabetic foot ulceration [DFU] and amputations) is alarmingly high in Canada. For individuals with diabetes, these devastating foot complications can lead to illness, lower quality of life, amputation, disability and death.

For Canadian health-care systems, the financial costs are staggering. A recent report from the Canadian Institute of Health Information (CIHI) indicated that the annual hospital costs for diabetic foot ulcers (DFU) and amputations, excluding physician fees, rehabilitation, and other related expenses, amounted to $750 million CDN each year from 2020 to 2023 (CIHI, 2024).[1]

A factor contributing to this burden is limited health-care policies that address the prevention and treatment of these complications effectively. Wounds Canada took action to address this problem, by partnering with Memorial University in Newfoundland/Labrador and the Limb Preservation Alliance to bring the *Canadian DFU Policy Roundtable: Moving Recommendations to Action* to health-care professionals and the public at the 2024 Wounds Canada National Conference held on October 16, 2024, at RBC Place in London, Ontario Canada.

The goal of the Limb Preservation Alliance, which consists of Wounds Canada, CariWN, D-Foot International, American Limb Preservation Society and the Canadian Podiatric Medical Association, is to integrate into health policy in all jurisdictions over the next ten years the 2023 recommendations of the International Working Group on the Diabetic Foot (IWGDF).[2]

A study titled Systematic Priority Setting of the IWGDF Recommendations to Inform Health Policymakers: A Q-Methodological Study was conducted by researchers Dr. Kathleen Stevens and Dr. Ahtisham Younas and delivers valuable insights to inform advocacy efforts for health policies supporting the IWGDF recommendations.

Roundtable Participants

Building on this work, Wounds Canada hosted the Diabetic Foot Ulcer Policy Roundtable at their National Conference. The roundtable brought key experts together to define strategies for each of the key policy areas in the prevention and management of DFU towards the goal of improving quality of life for all Canadians.

The roundtable included a diverse group of participants from various health-care disciplines, including physicians, podiatrists, wound and ostomy care nurses, advanced foot care nurses, analysts and administrators.

These participants came from across Canada, representing Western, Central and Eastern regions. In addition, several organizations concerned with the prevention of ulceration and amputation were represented, such as Diabetes Canada, the Registered Nurses Association of Ontario, Ontario Health and Home, the Canadian Lymphedema Framework, the Canadian Podiatric Medical Association, the Canadian Federation of Podiatric Medicine and the Zivot Limb Preservation Centre.

"I am excited about sharing our study findings and engaging in collaborative problem-solving with key stakeholders, which will lead to an action plan to address the burden of diabetic foot complications in Canada."

Dr. Kathleen Stevens, Assistant Professor and researcher, Faculty of Nursing, Memorial University

Dr. Zulfiqarali Abbas, Joel Alleyne, Simone McConnie, Georgia Krehbiel, Dr. Kathleen Stevens and Dr. Ahtisham Younas, as well as Memorial University and Wounds Canada staff, should be acknowledged for their expert guidance and counsel in making this workshop possible.

What Is A Q-Methodological Study?

Q methodology is a mixed methods approach combining qualitative and quantitative methods to explore subjective viewpoints and elicit shared perspectives of individuals about a complex issue (Watts & Stenner, 2005).[3] It is a useful when the intention is to understand differing views and examine the extent of consensus and disagreement among varied viewpoints (Younas et al., 2024;[4] Churruca et al., 2021).[5]

Q methodology was used because prioritized IWGDF recommendations would differ across

DFU Roundtable facilitators: (left to right) Georgia Krehbiel, American Limb Preservation Society; Kathleen Stevens, Memorial University of Newfoundland; Zulfiqarali Abbas, D-Foot International; Joel Alleyne, Canadian Podiatric Medical Association and Simone McConnie, Caribbean Wounds Network

countries/regions due to contextual differences such as health-care system, patient and population needs and public health structures and specific policies.

Study participants were recruited using the email distribution lists for Wounds Canada, The Canadian Podiatric Medical Association and The Canadian Association of Footcare Nurses. The research quesitons were:

1. What do diabetic foot experts determine are the priority IWGDF recommendations for policy implementation over the next ten years?
2. What do diabetic foot experts determine is the optimal timeline to implementation of the IWGDF recommendations?

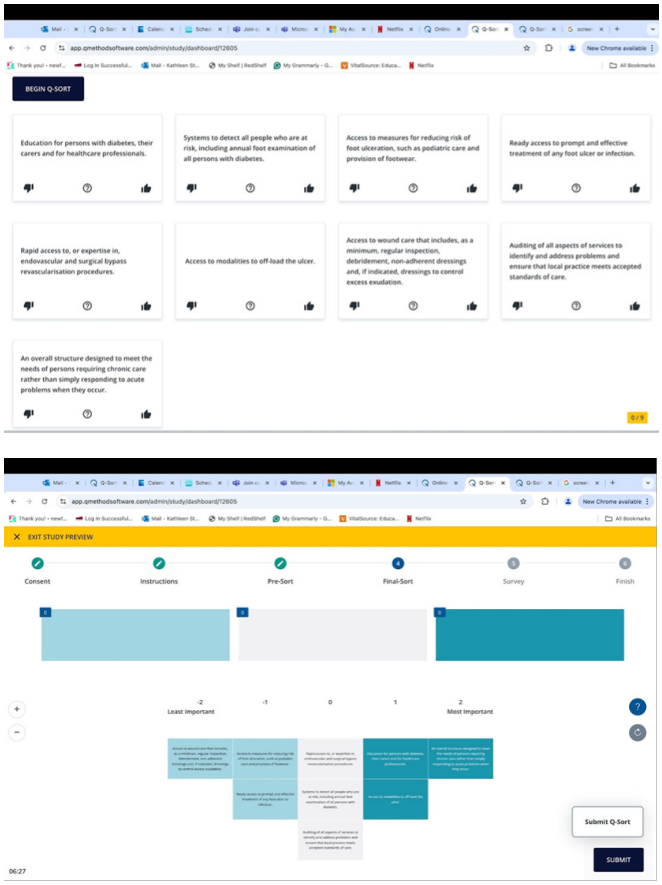


Figure 1 & 2: The Q-sort software interface captured crucial data that will be used to facilitate change *Source: Q Method Software (Lutfallah, S. & Buchanan, L. (2019). Quantifying subjective data using online Q-methodology software. The Mental Lexicon, 14(3), 415-423. doi: https://doi.org/10.1075/ml.20002.lut)*

Description Of Policy Roundtable

Attendees were seated at separate tables and received a handout (See Table 1). Each table had a facilitator and notetaker. Participants rotated through the three tables

Table 1: Attendee handout

Discussion Questions for Policy Roundtable

Each table will focus on an International Working Group on the Diabetic Foot (IWGDF) policy recommendation and address questions below as they apply. Groups will rotate from table to table.

Three Priority Recommendations for Canada for discussion:

- Access to wound care (e.g., regular inspection, debridement, non-adherent dressings and dressings to control excess exudation) (recommendation 5)
- An overall structure designed to meet the needs of persons requiring chronic care rather than simply responding to acute problems when they occur (recommendation 9)
- Rapid access to, or expertise in, endovascular and surgical bypass revascularisation procedures (recommendation 7)

Questions for each recommendation

1. Why is this a critical policy recommendation to address diabetic foot ulcers and amputation?
2. What contexts do we need to consider? (prompts: federal, provincial, rural, urban, acute care, community)
3. Who are the critical target populations? (prompts: individuals, staff, health-care providers, agencies) ***Consider the most critical target population to focus on; however, do not feel you need to restrict your discussion to this target only.
4. What are the barriers for implementing this policy recommendation? (prompts: how this recommendation might cause more burden on the system; aspects like what new infrastructure might be needed; how this will impact human resources)
5. What are the facilitators for implementing this policy recommendation? (prompts: what successes could we build on; are there policies we can piggyback on; are there any trends that we could build on)
6. What are possible strategies to implement this policy recommendation?
   a. directed at patients and care-partners,
   b. directed at health-care workers, and
   c. directed at organizations (e.g., coordination of care and management of care processes, information technology)
7. What does success look like, and how could success be measured and evaluated?
8. What are the key advocacy groups? What role would they play in shaping or implementing this policy?

What Were The Findings?

The results of the roundtable discussion were illuminating and will go far to help prioritize efforts to maximize implementation. Key recommendations include the following:

Policy Recommendation: An overall structure designed to meet the needs of persons requiring chronic care, rather than simply responding to acute problems when they occur.

1. *Why is this a critical policy recommendation to address diabetic foot ulcers and amputation?*
   Participants felt this was a critical policy recommendation as it is a proactive approach. Discussion ensued around how this policy aligns with the chronic care model, which aims to engage and empower patients to take an active role in their care. If the structure was designed to meet the needs of patients requiring chronic care, it would be "better equipped" to support patient behaviour change and would "force us not to ignore" chronicity.

2. *What contexts do we need to consider?*
   Several contexts were discussed considering the policy implementation: policy processes (e.g., how policies are developed and implemented), human resource availability and social factors that impact care delivery (e.g., culture, ethnicity, people with limited resources, such as lack of internet).

3. *Who are the critical target populations?*
   Participants discussed several critical target populations that should be considered when implementing structural system changes that would meet the needs of persons who require chronic care: funders, health-care providers in various settings, patients and families, and the public. Funders (e.g., politicians/policy makers) must support infrastructure and system change. Health-care providers were a critical target population, as these providers are often caring for high-risk populations. Participants highlighted providers in primary care, all levels of elderly care ("complex continuing care") and homecare interprofessional teams.

   Patients with type 1 and type 2 diabetes and their families were critical populations considering the genetic component of these diseases. The importance of chronic disease prevention and health promotion and how this should be targeted towards younger populations was also noted. Estheticians were considered another important population to engage with because of the role that they could play in promoting foot health.

4. *What are the barriers for implementing this policy recommendation?*
   Several barriers were discussion points for participants related to changing the overall structure to focus on meeting patients' needs with chronic disease. A clear hurdle was the political will to support this model. Participants discussed the importance of being clear about what is being asked for when advocating to politicians/policy makers for funding. For example, asking for specific services such as a professional wounds team and a yearly foot care assessment team. Another hurdle discussed was resistance to change by various "communities," which would be "exacerbated by a lack of education."

5. *What are the facilitators for implementing this policy recommendation?*
   Participants felt that having "buy-in" from key groups such as health-care organizations and professional associations (e.g., medical associations) would facilitate changing the structure. Demonstrating the impact on patients' quality of life was also considered a facilitator for these system changes. Engaging champions and care providers could also be drivers for change to a focus on chronic care.

6. *What are possible strategies to implement this policy recommendation?*
    a. directed at patients and care-partners: Participants identified and discussed many strategies that could be directed at patients and care partners by health-care providers and organizations that would support the implementation of this policy recommendation. Education of families and caregivers was a primary strategy, encouraging them to advocate for a system that meets the needs of patients with diabetes. A theme in all the strategies suggested was the importance of "early screening recognition," "catching it early" and "changing demographics" as key considerations when developing strategies directed at patients and caregivers. The education of caregivers should include recognizing early signs of complications to reduce the risk of adverse patient outcomes. The idea of an education campaign was brought forward that would "speak to people where they are" and target those "already in the field" and incorporate "hospital signage." Participants felt technology was a way for the system to support the needs of patients with diabetes, such as an app that patients and caregivers could use.
    b. directed at health-care workers: Overall, participants thought that strategies directed at health-care workers would support a paradigm shift towards a system that focuses more on chronic care and the prevention of complications. Participants discussed the importance of a system that empowered health-care workers to provide education, early intervention and continuing care to patients with diabetes.
    c. directed at organizations: Some practical suggestions were discussed regarding strategies that could be directed at organizations to support this policy, such as consistent terminology, messaging and hospital signage. Directing change from the "bottom-up" and employing "in-house efforts" were discussed as strategies. "In-house efforts" referred to initiatives and policies developed within an organization that are focused on meeting the needs of patients with chronic disease. Participants thought these efforts could be a powerful tool for driving change and supporting the implementation of the policy recommendation.

7. *What does success look like and how could success be measured and evaluated?* Participants discussed strategies for clearly providing evidence of success. These included decreasing amputation rates, completing screening tools and tracking screening rates.

8. *What are the key advocacy groups? What role would they play in shaping or implementing this policy?* Participants discussed categories of advocacy groups that should advocate for an overall structure designed to meet the needs of persons requiring chronic care. These categories were: long-term and community services, patient advocacy groups, chronic-disease associations, professional associations (e.g., physicians and nurses) and industry. Some of the specific groups discussed as being key were Diabetes Canada, Accreditation Canada, Alliance for Healthier Communities and New Balance.

Policy Recommendation: Access to wound care (e.g. regular inspection, debridement, non-adherent dressings and dressings to control excess exudation).

1. *Why is this a critical policy recommendation to address diabetic foot ulcers and amputation?* Participants agreed that access to wound care is essential because it is backed by best practice guidelines and evidence showing that proper care—like regular

inspection, debridement and appropriate dressings—prevents complications, including amputation. Without this care, diabetic foot ulcers can worsen rapidly. There was agreement that this recommendation needs to be implemented at the provincial level in primary care to improve outcomes and reduce the burden of amputations.

2. *What contexts do we need to consider?*
Participants emphasized several contexts that need to be considered. First, there are disparities between rural and urban areas, with rural regions facing challenges due to under-resourced health-care systems and a lack of private practice providers. People in these areas often must travel long distances to access care. The issue of federal vs. provincial funding was another important context, as there's often confusion over what is covered and how services are accessed.

   A key concern was the need for cross-training health-care teams so that all providers can effectively manage diabetic foot ulcers. In addition, participants noted that patients often feel that amputation is inevitable, especially if other family members have had an amputation, which can affect their mindset and willingness to engage in preventative care. Finally, community care systems should be considered as they often face challenges such as high turnover rates for home support workers and difficulties keeping these workers adequately trained.

3. *Who are the critical target populations?*
The critical target populations identified by participants were the general public (to raise awareness about the importance of foot health), migrant populations, policy makers, primary care workers and home support workers. Participants felt that these groups needed tailored messaging to effectively communicate the importance of diabetic foot health and prevention, using successful examples from other regions or countries where programs have worked.

"Policy makers need direction and manageable information."

Dr. Kathleen Stevens, Assistant Professor and researcher, Faculty of Nursing, Memorial University

4. *What are the barriers for implementing this policy recommendation?*
Participants identified several barriers for this policy recommendation. First is the issue of "siloed funding," where dressings are funded in community care but not in primary care. This funding structure creates confusion and unequal access. Additionally, a lack of research in Canada on wound care, inconsistent tracking of wounds in electronic medical records (EMRs) and the reactive nature of the health-care system (focusing on treatment rather than prevention) were also seen as significant barriers. Variations in the scope of practice for podiatrists across provinces, a lack of incentives for young health professionals to work in rural areas, and the absence of clear referral systems further complicate the situation.

5. *What are the facilitators for implementing this policy recommendation?*
Facilitators identified by participants included provide data to support funding requests, track wounds across the system through EMRs, so that all parts of the system are informed and raise public awareness about the severity of diabetic foot ulcers. There was also a strong push for a national training program focusing on competency-based education rather than professional designation. Educating all health-care team members—especially in podiatry and nursing—was highlighted as essential. Additionally, securing funding for ongoing wound care maintenance (not just healing) was vital for long-term success.

"Our patients with high-risk feet are walking step-by-step toward the road to amputation, and by implementing this project, we wish to take them step-by-step to the road of safety. Education is the only powerful tool we have in the world that is free for patients and effective, if properly implemented."

Dr. Zulfiqarali Abbas, International Working Group on the Diabetic Foot (IWGDF)

6. *What are possible strategies to implement this policy recommendation?*
   Participants suggested several strategies aimed at different groups. For patients and their care partners, raising awareness about the connection between diabetes and amputations is critical. For health-care workers, establishing clear care pathways and decreasing barriers for international health-care providers to practice in Canada would improve access to care. On the organizational and government level, participants recommended government-matched funding for private donations (a model that has worked in the province of Alberta), developing business plans for each province and territory that include a cost/benefit analysis, and incentivizing facilities to reduce amputation rates by tying funding to successful outcomes. Forming more multidisciplinary centres across regions and ensuring fair compensation for advanced foot care nurses and other providers were also key strategies discussed.

7. *What does success look like, and how could success be measured and evaluated?*
   Participants agreed that success would be a reduction in amputation rates and an improvement in the quality of life for patients. They further discussed that success could be measured by tracking wait times from wound diagnosis to assessment ("time is tissue"), the frequency of foot inspections and the number of education programs available to patients and health-care providers. Establishing clear funding structures at the provincial level and developing the infrastructure for comprehensive care were also discussed as important indicators of success. Evaluating these metrics would help ensure the policy is achieving its goals.

8. *What are the key advocacy groups?*
   Participants identified key advocacy groups, including Diabetes Canada, the Canadian Medical Association, D-Foot International, NSWOC, Wounds Canada, the Canadian Federation of Podiatric Medicine and the Canadian Association of Footcare Nurses. Participants viewed these organizations as essential partners in advocating for policy changes and securing the resources and frameworks necessary for successful implementation.

Policy Recommendation: Rapid access to, or expertise in, endovascular and surgical bypass revascularisation procedures.

1. *Why is this a critical policy recommendation to address diabetic foot ulcers and amputation?*
   Participants discussed how endovascular and surgical bypass revascularisation procedures align with best practices. These procedures are "limb and life-saving" and diabetic foot blockages are mainly below the knee and in the foot. Therefore, this is a critical policy recommendation to address DFU and amputation. Participants acknowledged that access to these procedures is vital, and more clinics are needed across Canada to support rapid access.

2. *What contexts do we need to consider?*
   Participants discussed several contexts that need to be considered in relation to the implementation of this policy. Discussion

centred around the health-care system and participants felt that federal, provincial and territorial jurisdiction, private and public systems, community, long-term, acute care and the rural perspective are critical contexts to consider. How each area tracks data is an important context to consider, as data are needed to implement change. Other contexts discussed were related to infrastructure and access to primary care (e.g., number of outpatient clinics), screening (e.g., screening for persons at risk) and workforce (lack of family physicians and nurse practitioners). It was suggested that policy makers consider the role of navigators for skin, wound and foot care. Participants discussed the context of education and awareness and the importance of this context for patients, health-care providers and the public. Gaps in knowledge for patients were not knowing about foot complications. Participants shared experiences with patients who felt angry because they did not know about potential complications that could occur. For health-care providers, there are gaps in knowledge related to assessment and when to refer. Participants discussed health-care provider education as necessary to prevent over-referring and patient deterioration.

3. *Who are the critical target populations?*
   Participants identified critical target populations for this policy as persons with diabetes, agencies, staff, health-care providers, health-care professional students (e.g., podiatry) and the public, with consideration for populations in rural and remote areas, unhoused clients and financially challenged clients.

4. *What are the barriers for implementing this policy recommendation?*
   Participants identified numerous barriers to implementing this policy. Funding was a significant barrier. There was discussion regarding "long standing disconnections" between community and acute care systems. The lack of clarity regarding referral systems or limited referral systems that do not consider the social determinants of health pose significant barriers. Other barriers identified were the lack of interprofessional teams screening and assessing clients; limited surgeons performing these procedures; and insufficient specialized wound centres.

   Participants also highlighted a lack of understanding and knowledge by patients and policy makers. The patient perception that it is normal and accepted that "if you have diabetes, you will ultimately lose your feet" was considered a barrier to implementing this policy. Policy makers not understanding the connection between peripheral artery disease and diabetes mellitus and how the increase in diabetes will result in the need for more vascular intervention were also thought to be barriers. Where a patient lives was also considered a barrier and affected whether a patient could access these interventions, with people in rural areas having less access. The need for these interventions will increase with obesity, smoking and inactivity increasing among Canadians. Although many do not qualify for endovascular surgery because of these risk factors. Participants felt these barriers must be urgently addressed before moving forward with this policy.

5. *What are the facilitators for implementing this policy recommendation?*
   Participants identified several facilitators that could support the implementation of this policy. Screening of patients where they live and using mobile vans with interprofessional teams (comprising foot care nurses, podiatrists, lab technicians, navigators and patients) was considered a facilitator. Education of family and caregivers. Communication using pathways for referral after screening and a universal record system so all providers can see what others are doing. Raising awareness of the public through the

use of data that shows there is a problem and using data to demonstrate the economic costs. Strong leaders who are and can lead change were thought to be drivers for implementing this policy. Current association-level policies could be facilitators, such as policies developed by the Canadian Podiatric Medical Association, Diabetes Canada, CLWK (BC), and Ontario Health at Home.

6. *What are possible strategies to implement this policy recommendation?*
   Advocating and obtaining funding to support this intervention was considered a key strategy. Participants felt that having data regarding the effectiveness and cost-benefit of these interventions could influence change and policy. Providing the federal government with a clear business reason would support implementation. Participants felt that we can learn lessons from the establishment of breast and colonoscopy screening.

7. *What does success look like, and how could success be measured and evaluated?*
   Participants thought success with this policy would be when there is an investment of government funds into interprofessional teams (integrated teams with foot care nurses, podiatry, lab, navigators and patients), clearer clinical care pathways, access to basic foot care, foot health teams that are involved when an issue is identified and funding of screening and prevention. Measuring success would include considering the impact of prevention activities, interprofessional teams, behavioural changes, amputation rates, hospitalizations (e.g., costs) and collaboration between provinces and territories for podiatry services.

8. *What are the key advocacy groups? What role would they play in shaping or implementing this policy?*
   There were many key advocacy groups that participants thought would be involved in shaping and implementing this policy: primary care groups (family physicians), professional associations (nurse practitioners and physician associations), chronic care groups, community service groups, Nurse Home Associations, Wounds Canada and Accreditation Canada. Wounds Canada could promote their *Diabetes, Healthy Feet, and You* program, which is ready to roll out across Canada if funding is obtained. Expanding *Diabetic Foot Day* in November to *Diabetic Foot Month* would support the shaping and implementation of this policy.

Reflections And Takeaways

At the end of the roundtable, the participants came together as a larger group to share reflections and takeaways on the roundtable discussions and to identify action steps. The reflections were positive, and participants felt it was a valuable experience to be involved in the exercise.

A review of the evaluations completed by participants showed that participants appreciated the collaborative discussion and interactions with other providers from different parts of Canada and gained an understanding of their perspectives and the barriers they face. One participant stated on the evaluation that they found the most valuable part of the day was the "diversity of responses and moments of consensus," and another noted the "open discussion regarding how specific recommendations may be implemented." Key takeaways captured the urgency and complexity of DFU prevention and management regarding policy and system changes. One participant stated, "diabetic foot needs a revamp in its care, specifically for screening." Another participant stated, "Implementation and policy change need to be done strategically and with careful planning and support."

Many participants planned to apply what they learned by continuing to advocate for change or increasing their advocacy efforts. One person stated, "I plan to educate each diabetic patient" and another stated, "I will apply in my everyday practice but also have to be part of the bigger aim/ strategy"

Action Steps

Action steps were discussed next, and participants were asked to suggest the specific tasks, initiatives and activities needed to move forward with combatting DFU amputation. Some general comments were that we should start with recommendations with fewer regional differences and start building a strategy to combat DFU and amputation, focusing on education, systemic changes and collaboration at the national level. There was consensus that a unified approach is critical.

It was also suggested that it was important to consider how we can use implementation science/research to support change and bring together different groups. Many action steps were identified that could be divided into three categories: collection of data to support change, working together and engaging with others, interventions and strategies that should be developed and implemented and strategies and tools that are available now (See Table 2).

The conclusion drawn following the action step discussion was that a national program needs to be implemented to increase knowledge of diabetic foot and its complications, targeting each stakeholder. However, we all must do what we can now and use the tools we have.

Table 2: Action Steps Identified by Policy Roundtable Participants

Collect Data to Support the Need for Policy	Working Together to Advocate for Policy Change	Development and Implementation (present and future)
• Establish a health equity committee to collect health economic data to provide a better case to government and insurers • Collect national data related to wounds (e.g., track the wound care diagnosis and what happens to patients as they move through the system to calculate costs/cost savings)	• Identify the key advocates involved in diabetes and wound care • Form a coalition of advocacy groups across Canada • Establish a task force focused on creating a vision and a strategy for what the future of diabetic foot looks like and, from this form a clear ask/vision for resources at the government level • Assemble a communications team to collate education/messaging so that it is targeted to each stakeholder (e.g., patients, caregivers, HCPs, the public and policy makers) • Establish regional multidisciplinary diabetic foot wound/care teams across Canada • Become part of the *Wounds Canada Diabetes, Healthy Feet and You* team	• Spend five minutes educating patients, caregivers, and health-care professionals • Implement mandatory standard foot screening across the health-care system • Utilize digital educational materials to educate patients • Explore AI-based solutions for home and health-care settings • Develop a clinical pathway for point-click care for diabetic feet • Review the current *Inlow's 60-second Diabetic Foot Screen*; update it to its most user-friendly version, and develop an e-version suitable for a database. • Conduct research related to diabetes and foot complications • Develop a competency framework for diabetic foot care for all health-care providers • Develop and implement a relay called "Defeat D-Foot" that would incorporate diabetic foot screening with the event • Implement mobile assessment units for isolated areas

Discussion And Conclusion

The policy roundtable approach offered several advantages, similar to those reported by Romich and Fentress (2019). This policy roundtable provided an opportunity for key stakeholders across Canada to discuss current research findings from the Q-Method study related to the priority recommendations for the organization of diabetic foot care in Canada, as well as provided the researchers an opportunity to share their research findings.

All participants indicated that they gained a further understanding of the incidence, prevalence and impact of DFUs and amputation. Another advantage was that the discussion, knowledge and perspectives shared by participants allowed for further refinement of the application of the research findings. The model also allowed for the establishment of connections between groups and individuals that hold promise in addressing the complexity of DFU and amputation and organizational and public policy development.

Finally, engaging with key groups and individuals with diverse expertise allowed for a fulsome discussion of a complex issue that would not readily happen in a "siloed" space (Romich & Fentress, 2019)[6] which resulted in action steps that we can now build on individually and together to combat DFU and amputations in Canada. As commented by two participants on their evaluations, "With collaboration, much can be achieved" and "Let's reconvene next year – I would like to continue these discussions."

Wounds Canada will provide an update on policy efforts at the next 2025 Wounds Canada National Conference to be held in Toronto, Ontario from October 2-4, where important efforts such as these will continue in order to better the quality of life for all Canadians. The latest updates can be found at https://www.woundscanada.ca/

About Wounds Canada: *Established in 1995, Wounds Canada is a charitable organization dedicated to the advancement of wound prevention and management. We accomplish this by advocating for a population health approach that promotes best practices to support persons at risk of or living with wounds, health decision makers and frontline clinicians. We develop and provide educational programs and resources as well as support research to further advance this holistic, risk-based approach. We foster relationships with interested individuals and organizations to expand and sustain a robust wound community in Canada that also has mutually beneficial global connections. Our goal is to reduce the prevalence and incidence of wounds of all types and the negative consequences they bring—including patient suffering and wasted health-care dollars.*

Kathleen Stevens RN PhD is Assistant Professor, Memorial University of Newfoundland, Canada.

Ahtisham Younas RN PhD is Assistant Professor, Memorial University of Newfoundland, Canada.

Larry A Sawyer* BA is with Wounds Canada.

**Editor's note: It is with great sadness that we note the sudden passing of co-author Larry A Sawyer shortly before publication of this article.*

References

1. Schaper NC, van Netten JJ, Apelqvist J, Bus SA, Fitridge R, et al; IWGDF Editorial Board. Practical guidelines on the prevention and management of diabetes-related foot disease (IWGDF 2023 update). Diabetes Metab Res Rev. 2024 Mar;40(3):e3657. doi: 10.1002/dmrr.3657.
2. Romich J, Fentress T. The policy roundtable model: encouraging scholar–practitioner collaborations to address poverty-related social problems. Journal of Social Service Research. 2019 Jan 1;45(1):76-86
3. Watts S, Stenner P. (2005). Doing Q methodology: theory, method and interpretation. Qualitative Research in Psychology. 2005; 2(1), 67–91.
4. Younas A, Maddigan J, Moore JE, Whitehead D. Designing and conducting Q methodology in implementation research: a methodological discussion. Global Implementation Research and Applications. 2024 Jun;4(2):125-38.
5. Canadian Institute of Health Information. Advancing equity in diabetes prevention and care. 2024. Available from: https://www.cihi.ca/en/equity-in-diabetes-care-a-focus-on-lower-limb-amputation/advancing-equity-in-diabetes-prevention-and-care
6. Churruca K, Ludlow K, Wu W, Gibbons K, Nguyen HM, Ellis LA, Braithwaite J. A scoping review of Q-methodology in healthcare research. BMC Med Res Methodol. 2021 Jun 21;21(1):125.

Nurses Specialized in Wound, Ostomy and Continence Canada (NSWOCC)

44th National Conference:

IDEAs: Inclusivity, Diversity, Equity, Accessibility shared

- May 21-25, 2025
- Montreal, Quebec

Canada's PREMIER Wound, Ostomy and Continence Conference

Attendees of our Conference can look forward to an event that embraces the theme "**IDEAs: Inclusivity, Diversity, Equity, Accessibility shared**," focusing on advancing specialized wound, ostomy, and continence care through a lens of inclusivity, diversity, equity & accessibility, ensuring that healthcare professionals are equipped to meet the diverse needs of all patients.

Bringing together a wide range of professionals—Nurses Specialized in Wound, Ostomy and Continence (NSWOCs), Skin Wellness Associate Nurses (SWANs), physicians, RNs, NPs, LPN/RPNs, and allied healthcare workers—the conference offers an inclusive platform for collaboration, knowledge-sharing, and networking, and fostering cross-discipline learning to elevate patient care.

Submit a Poster Abstract!
Deadline: March 31, 2025

Questions?
office@nswoc.ca
www.nswoc.ca

Learn more & register now:

www.nswoccconference.com

NURSES SPECIALIZED IN WOUND, OSTOMY AND CONTINENCE CANADA
INFIRMIÈRES SPÉCIALISÉES EN PLAIES, STOMIES ET CONTINENCE CANADA

Cyanoacrylate Closure For Treatment Of Venous Leg Ulcers

Ahmed Kayssi MD MSc MPH, **Leslie Summers-deLuca** PhD, **Julien Bernatchez** MD MSc, **Brandon Van Asseldonk** MD and **Andrew Dueck** MD MSc

Abstract: An open label, prospective single centre, single arm clinical trial enrolling patients with active venous ulcers with a planned enrollment of 20 patients was conducted to evaluate the effectiveness and safety of cyanoacrylate closure combined with standard of care compression therapy for the treatment of venous leg ulcers in the setting of an incompetent saphenous vein. Inclusion criteria were active venous ulceration, saphenous vein reflux confirmed by duplex ultrasound (US) and ankle brachial index ≥0.9. Primary outcomes included change in ulcer size, ulcer healing and adverse events at three months. At three months, 50.0% of ulcers were healed (14/28), and 56.2% of subjects were ulcer-free (10/19). At 12 months, 79.2.% of ulcers were healed (19/24), and 68.8% of subjects were ulcer-free (11/16) The average percent reduction in ulcer size at three months and 12 months was 88.1% and 95.6%, respectively. Cyanoacrylate closure of an incompetent saphenous vein was shown to be safe and effective for treating patients with chronic venous leg ulcers.

Key words: *venous leg ulcer, saphenous vein, cyanoacrylate, endovenous closure*

How to cite: Kayssi A, Summers-deLuca L, Bernatchez J, Van Asseldonk B, Dueck A. Cyanoacrylate closure for treatment of venous leg ulcers. Limb Preservation Journal. 2025;6(1): 57-64. DOI: 10.56885/752790udmlrl

Venous leg ulcers (VLUs) are a common wound with significant morbidity and cost, and suboptimal therapeutic options. VLUs result from chronic venous insufficiency, including venous reflux and post-thrombotic syndrome. About 1% of the adult population has a history of a healed or unhealed ulcer.[1,2] In France and Belgium in 1995, venous disease represented 2-2.6% of total national health-care spending. Similar figures were reported by other studies in Europe and in the US.[3] In the US, an estimated 600,000 people are affected per year,[4] and a study of patients at the Cleveland Clinic Foundation revealed a total medical cost per patient of $9685 USD, with 48% for home care, 25% for hospitalizations, and 21% for home dressing changes.[5]

Risk factors are advanced age, prior leg injury, obesity, deep venous thrombosis and phlebitis, legs in dependent position for long periods, and female gender. Individuals with VLUs in Canada often have multiple comorbidities (30% have three or more), and most have significant pain, and limitations to function and mobility.

VLU can take from months to years to heal, and 54-78% recur.[6-8] Current therapies include wound care (cleansing, debridement of damaged tissue, dressings and topical agents), compression therapy (bandages or stockings to limit blood pooling and fluid leak), and medications (agents to improve blood flow, e.g., pentoxifylline, aspirin, etc). These treatments can increase the rate of healing, and reduce recurrence, however these therapies can be burdensome, painful, and ineffective. Despite these therapies, ~50% of wounds become chronic.[9,10] Chronic VLUs can be painful, malodorous and infected, and they often significantly limit an individual's function and mobility.

An emerging therapy for symptomatic venous reflux is the closure of the culprit vein by endovenous closure with a cyanoacrylate adhesive implant. Recent studies show cyanoacrylate closure (CAC) to be a safe and effective treatment for varicosities resulting from symptomatic incompetent great saphenous veins.[11-13]

In these prospective, multi-centre studies, CAC was compared to conventional endothermal radiofrequency ablation (RFA) and post-interventional compression for treatment of varicose veins. A study of 70 patients at seven European sites demonstrated closure rates of 92.9% at 12 months, and an Average Venous Clinical Severity Score improvement from 4.3 +/- 0.3 at baseline to 1.1 +/- 1.3 at 12 months.[13] CAC was safe, with phlebitis occurring in five cases (8.6%), and no serious adverse events observed. In a subsequent study of 222 patients randomized to receive either RFA or CAC, three month closure rates were 99% for CAC and 96% for RFA.[11] CAC was found to be non-inferior to RFA, with less post-procedural ecchymosis in the CAC group, but otherwise similar safety profiles.

CAC is now increasingly used to treat VLUs. Despite promising anecdotal evidence, studies demonstrating safety and effectiveness of CAC for treating VLUs are lacking. This study evaluates the safety and effectiveness of CAC for VLUs.

Methods

This is an open-label uncontrolled clinical trial. Eligible patients had a venous leg ulcer, venous insufficiency, and an ABI of ≥0.9. Patients with coagulation disorders, occlusive deep venous thrombosis (DVT), diabetic foot ulcers, hypersensitivity to cyanoacrylates or the VenaSeal® adhesive, or an inability to tolerate compression were excluded. (See Table 1 for full list of inclusion and exclusion criteria). Institutional research ethics approval for this study was obtained from Sunnybrook Health Sciences Centre (REB #2974).

Informed consent was documented for all subjects. Subjects underwent a pre-procedure physical exam and clinical assessment of the ulcer, including a Revised Venous Clinical Severity Score (rVCSS), as well as a Doppler ultrasound of the superficial and deep venous systems of the legs to assess for venous reflux, obstruction, and the presence of deep-vein thrombosis if an adequate Doppler was not available in the last six months. A final determination of eligibility was made following review of information collected during the pre-procedure visit. Demographics, medical history, bloodwork (if not available in the previous 30 days) and baseline quality of life questionnaires (EQ-5D) were collected for all eligible subjects prior to CAC intervention.

Table 1: Eligibility Criteria

Inclusion Criteria	1. Age ≥18 years old at time of screening
	2. Venous leg ulcer
	3. Venous insufficiency (>0.5 seconds; confirmed by Doppler within last 6 months)
	4. ABI of ≥0.9
	5. Capable of understanding the study and providing informed consent
Exclusion Criteria	1. Previous hypersensitivity reactions to the VenaSeal® adhesive or cyanoacrylates
	2. Acute superficial thrombophlebitis
	3. Bilateral treatment
	4. Thrombophlebitis migrans
	5. Occlusive deep venous thrombosis (a recannalized DVT is not an exclusion)
	6. Deep venous incompetence or occlusion in external iliac or common iliac vein in the affected limb or the IVC (as assessed based on spontaneity, phasicity, augmentation, pulsatility, and compressibility on ultrasound)
	7. Post-thrombotic syndrome
	8. Acute sepsis
	9. Coagulation disorders
	10. Radiation or chemotherapy within three months of study
	11. Pregnant or lactating females
	12. Uncontrolled diabetes (HbA1c >10%)
	13. Diabetic foot ulcers
	14. Current use of systemic anticoagulation that cannot be held prior to the procedure, and resumed post-procedure
	15. Previous treatment of target vein
	16. Tortuous veins
	17. Current participation in another interventional study, or participation within 30 days prior to screening
	18. Inability to tolerate compression, or to receive endovenous treatment

Intervention: Compression therapy and wound care dressings were removed prior to the start of the procedure. Ultrasound was used to map the target vein and to guide the procedure. CAC was performed according to the directions provided in the VenaSeal® device *Instructions for Use*, and following surgical protocols of sterile technique. Briefly, the treated leg was cleaned with chlorhexidine solution, the leg was draped with sterile drapes, and the skin overlying the target vein below the knee was anesthetized with lidocaine solution. Under ultrasound guidance, a needle was used to access the target great saphenous vein in a retrograde fashion towards the groin and a guidewire was fed into the vein to position the catheter proximal to the saphenofemoral junction. After an initial injection of cyanoacrylate glue was dispensed, pressure was applied to the vein for three minutes. Adhesive injections were then serially administered in 3cm increments, with pressure held on each segment. Once the complete length of the target vein had been injected, the catheter was removed and pressure was applied to the entry site for five minutes. In some patients, the procedure was repeated in an antegrade fashion in the great saphenous vein up to the foot. The procedure was similarly repeated in the small saphenous vein when indicated. Refluxing perforators connected to the saphenous vein requiring treatment were also treated. After the procedure, the local area was cleaned, and a compression socks was placed on the leg. Complete vein blockage was confirmed post-procedure by ultrasound. The procedures were done on an outpatient basis and study subjects returned home following the procedure.

Post-procedure: Subjects were encouraged to walk around regularly following the procedure, and to take ibuprofen for any mild discomfort in the first 48 hours. Subjects were instructed to continue wearing the compression therapy, and to continue with wound care therapy as directed by the wound care physician (AK) until the wound healed completely, after which patient were transitioned to customized knee-high elastic compression stockings.

Subjects continued to receive wound care and compression therapy two to three times per week by a wound care nurse and assessment by a wound care physician (AK) every two to three weeks until the wound was deemed to be healed. Patients were be instructed to contact study staff with any concerns.

Subjects returned 3-10 days post-procedure for a clinical assessment and Doppler ultrasound to assess vein ablation. Subjects returned at one, two, three, six, and 12 months post-procedure for a clinical assessment, Doppler ultrasound and to complete quality of life questionnaires.

Data Analysis: The effectiveness of the procedure was determined by calculating the percent of ulcers healed at three and 12 months, and the percent change in ulcer size at three and 12 months. The closure rate of the target veins was calculated as the proportion of patients with absent flow in the treated saphenous vein segment on post-operative ultrasound.

Complete closure was defined as vein closure along the entire treated vein segment with no discrete segments of patency exceeding 5cm on Doppler ultrasound.

Quality of Life (QoL) and Functional Outcomes were determined by assessing the change in patient-reported function and QoL (EQ5D; rVCSS). Safety was measured as the adverse event rate at three months.

Adverse events related to the study procedure or device were collected up to 12 months post-procedure. Categorical variables were calculated as frequency and percentage changes. Continuous variables were calculated as mean +/- standard deviations (if normal distribution), or as median with interquartile ranges (if not normally distributed).

Results

Baseline Characteristics: Twenty one patients consented to participate. One subject was excluded following the pre-procedure visit. Twenty subjects were enrolled (11 male, 9 female). (See Table 2 for baseline characteristics). Subjects ranged in age from 33 to 89 years with a BMI range of 7.5 to 42.7. Most subjects (15, 75%) were ambulatory without assistance. Four subjects (20%) were ambulatory with assistance, and one subject (5%) required a wheelchair for mobility. More than half of the subjects engaged in regular exercise, either walking (9, 45%) or vigorous exercise (2, 10%). Twelve subjects had one ulcer (60%), six subjects had two ulcers (30%) and two subjects had three ulcers (10%), for a total of 30 study ulcers with an average size of 695.9 mm2 +/- 1382.6 (See Table 3.) Median ulcer duration was 641.5 days (158, 1571). Clinical outcome and QoL data for 19 and 16 subjects was collected at the three month and 12 month time-points, respectively. At the final time-point, two subjects were lost to follow-up and two were deceased.

Table 2: Baseline Characteristics

		n (%)
Sex	Male	9 (45.0)
	Female	11 (55.0)
Age	Average Age	66.3 +/- 16.77
Ethnicity	White or Caucasian	12 (60.0)
	Black	1 (5.0)
	Asian	4 (20.0)
	West Indian	2 (10.0)
	Middle Eastern	1 (5.0)
Smoking	Current	2 (10.0)
	Former <1 yr	2 (10.0)
	Former >1 yr	5 (25.0)
	Never	11 (55.0)
Comorbidities	Prior MI	1 (5.0)
	Diabetes	4 (20.0)
	Hyperlipidemia	2 (10.0)
	Asthma	2 (10.0)
	BMI	24.63 +/- 8.47
Ambulation	Ambulatory without assistance	15 (75.5)
	Ambulatory with assistance	4 (20.0)
	Uses wheelchair	1 (5.0)
ADL	Vigorous exercise	2 (10.0)
	Walking for exercise	9 (45.0)
	Walking around house only	5 (25.0)
	Limited walking from room to room	3 (15.0)
	Patient unable to walk	1 (5.0)

Table 3: Ulcer and Index Leg Characteristics

		n (%)
Index Leg	Right	9 (45.0)
	Left	11 (55.0)
Number Of Ulcers At Baseline	1 ulcer	12 (60.0)
	2 ulcers	6 (30.0)
	3 ulcers	2 (10.0)
Ulcer Location	Medial	11 (55.0)
	Lateral	4 (20.0)
	Middle	4 (20.0)
	Anterior	3 (15.0)
	Posterior	7 (35.0)
	Middle	9 (45.0)
	Below Knee - Upper	0 (0)
	Below Knee - Middle	3 (15.0)
	Below Knee - Lower	17 (85.0)
Ulcer Size	Average Size (mm2)	695.99 +/- 1382.6
Ulcer Duration	Median days (IQR)	641.5 (158, 1571)

Procedure Characteristics: All 20 subjects underwent the study CAC intervention between Nov 2019 and May 2021. Procedures duration on average was 73.6 +/- 20.9 minutes, with a range of 30-120 minutes. The great saphenous vein was the target vein for all subjects, and the small saphenous vein was additionally treated in three subjects (15%). Both retrograde and antegrade injections were performed on 16 subjects (80%), with four subjects undergoing retrograde-only treatment.

Clinical Outcomes: These were recorded in terms of Vein Closure and Ulcer Healing.

Vein Closure

Target vein closure was confirmed immediately post-procedure for 94.4% of subjects (17/18). (See Table 4.) Target vein closure rates were 88.9% and 84.6% at three and 12 months, respectively (16/18 subjects; 11/13 subjects). Two subjects had incomplete closure of the target veins. In the first subject, both antegrade and retrograde injections were performed from below knee access sites. Post-procedure, the retrograde segment was partially thrombosed but the antegrade segment was fully occluded. In the second subject, the device maldeployed, leading to incomplete delivery of glue and partial occlusion of the target vein.

Table 4: Target Vein Closure

	% fully ablated	#/total
Post-Procedure	94.4	17/18
1 Week	80.0	16/20
1 Month	93.3	14/15
2 Months	93.8	15/16
3 Months	88.9	16/18
6 Months	83.3	10/12
12 Months	84.6	11/13

Ulcer Healing

By three months post-CAC, 52.6% of subjects were ulcer-free (10/19), 50.0% of ulcers had healed (14/28) and the average reduction in ulcer size was 88.1% +/- 25.3. (See Figure 1.) At 12 months, 79.2% of ulcers had healed (19/24) and 68.8% of subjects were ulcer-free (11/16). Average rVCSS scores had significantly improved by three months (17.65 +/- 3.01 to 9.47 +/- 5.66, p<0.00005). (See Figure 2.) Ulcer recurrence was observed for two ulcers (6.7%), with one recurrence at two months

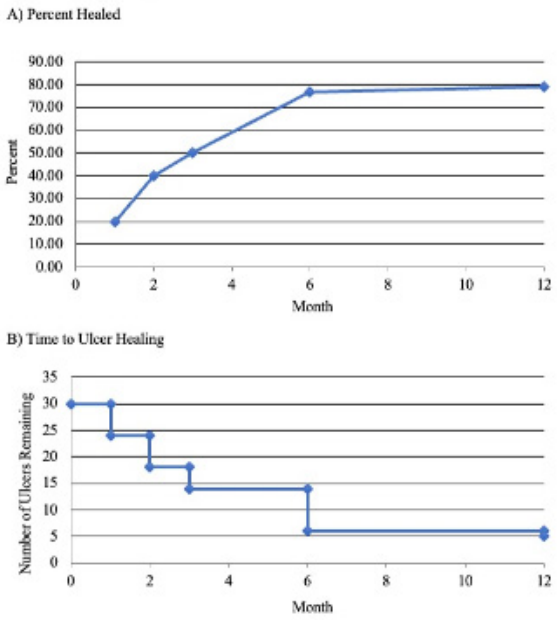


Figure 1A: Percent Healed: The percent of ulcers healed at each post-procedure follow-up (1 week, 2, 3, 6, and 12 months).
Figure 1B: Time to Ulcer Healing: The total number of open ulcers at each time point (baseline, 1 week, 2, 3, 6, and 12 months).

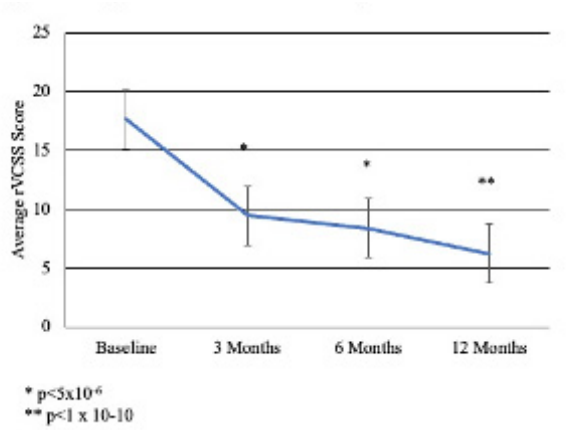


Figure 2: Average rVCSS scores at baseline, 3, 6, and 12 months.

and subsequent rehealing at six months, and the other ulcer recurring at 12 months.
Three subjects (15%) developed new ulcers post-procedure: one subject developed an ulcer at two months that subsequently healed by six months, and another subject developed two new ulcers at one month, both of which healed by two months.

Safety and QoL Outcomes: These were noted as Procedure and Device Events and Qualify of Life.

Procedure and Device Events
Adverse events related to the procedure within three months post-treatment included self-limiting thrombophlebitis (2, 10.0% [See Table 5]) and deep venous thrombosis (10.0%) at four days (n=1) and two months (n=1). Adverse events unrelated to the procedure within three months post-treatment included fever (5.0%), respiratory infection (5.0%), wound infection (5.0%) and new ulceration (2, 10.0%).

Attempted vein access was aborted during the procedure for three subjects due to a vein spasm during antegrade access (n=1, 5.0%), small veins size prohibiting antegrade access (n=1, 5.0%), or vein anatomy precluding retrograde access from GSV to SFJ from below the knee (n=1, 5.0%).
A maldeployment of the injection device during treatment of one subject's GSV resulted in aborted proximal treatment (n=1, 5.0%).

Table 5: Rates of Adverse Events

Adverse Event	n (%)
Related	
Thrombophlebitis	2 (10.0)
Deep vein thrombosis	2 (10.0)
Vein spasm	1 (5.0)
Vein size or anatomic limitation	2 (10.0)
Maldeployment of device	1 (5.0)
Unrelated	
Wound infection	1 (5.0)
New ulceration	3 (15.0)
Fever	1 (5.0)
Respiratory Infection	1 (5.0)

Quality of Life
No significant improvement in average EuroQoL EQ-5D scores was observed (data not shown).

Discussion

The purpose of this study was to examine the role of CAC in the management of chronic venous leg ulcers that are refractory to standard wound care. Our results demonstrate that CAC is a safe and successful treatment modality for this patient population and can help expedite healing.

The procedure was successful in completely occluding the target vein in all but two subjects. The first subject's great saphenous vein was large, measuring 1.41cm at the saphenofemoral junction, 1.03cm in the proximal thigh, and 1.02cm at the knee. He also received chronic anticoagulation therapy for a cardiac arrhythmia. Despite the large calibre of the vein and the anticoagulation therapy, however, the majority of his great saphenous vein was fully ablated and his wound healed entirely. The second subject experienced a device maldeployment and received an insufficient dose of the CAC therapy. We were not aware of this maldeployment during the procedure because the glue dispenser gun and delivery catheter appeared to function normally. We experienced similar issues with CAC packages from the same batch that were used with non-study patients and requested that the packages from that batch be replaced. We did not have any other application issues after this was done.

Most of the study subjects had no adverse complications or issues post-procedure. Two subjects experienced an episode of thrombophlebitis that resolved with a short course of over-the-counter oral anti-inflammatory therapy, with no recurrence or other complications. One subject developed a partial common femoral DVT that was noted on the first post-procedural ultrasound. This subject was morbidly obese and the procedure was technically challenging due to limited groin visualization. He was treated with oral anticoagulation therapy and remained asymptomatic and did not experience any further complications from his CAC treatment. A second

subject was noted to have a partial DVT in the left femoral vein at two months follow-up. The DVT was not visualized on any of his earlier post-procedural ultrasound studies and the patient was entirely asymptomatic. The subject was treated with oral anticoagulation and the DVT resolved with close follow-up. The subject's venous ulcer healed within two months post-procedure.

Our study is retrospective in nature and our sample size is small. Nonetheless, we observed a high success rate that confirms the importance of endovenous ablation for the management of venous leg ulcers. This study was mostly conducted during the COVID-19 pandemic and as such there were numerous subjects lost to follow-up due to an inability to adequately contact or see patients in person.

There are many advantages to using CAC for the management of venous leg ulcers. Most importantly, CAC offers a durable option for treating the infra-geniculate saphenous venous segments of the great saphenous vein and the small saphenous vein all the way to the malleoli, where most venous ulcers occur. This is a distinct advantage compared to thermal endovenous ablation modalities, which are more limited due to concern about injuring the saphenous and sural nerves that travel closely with the saphenous veins below the knee. Practitioners have addressed this limitation in the past by ablation the supra-geniculate and proximal small saphenous vein segments with thermal energy and injecting the more distal segments with foam, but this is not as durable as CAC therapy.

Conclusion

In conclusion, we have demonstrated that cyanoacrylate closure of an incompetent saphenous vein is safe and effective for treating patients with chronic venous leg ulcers. Further studies in a randomized controlled fashion are needed to compare this treatment with compression therapy alone.

Conflict of Interest Statement: Two authors (AK and AD) have received funding from Medtronic to facilitate educational workshops. There are no other relevant financial disclosures for the purposes of this study.

Financial Support Statement: This work was supported by an unrestricted research grant from Medtronic. The authors were responsible for all aspects of the study including study design, data gathering, analysis, and manuscript preparation and submission without input from Medtronic.

Ahmed Kayssi MD MSc MPH is with the Division of Vascular Surgery, University of Toronto, Ontario, Canada. (AK)

Leslie Summers-deLuca PhD is with the Division of Vascular Surgery, University of Toronto, Ontario, Canada. (LSD)

Julien Bernatchez MD MSc is with the Division of Vascular Surgery, University of Toronto, Ontario, Canada and the Division of Vascular Surgery, CHU de Québec-Université Laval, Québec, Canada. (JB)

Brandon Van Asseldonk MD, is with the Division of Vascular Surgery, University of Toronto, Ontario, Canada and the Division of Vascular Surgery, Scarborough Health Network, Scarborough, Ontario, Canada. (BVA)

Andrew Dueck MD MS is with the Division of Vascular Surgery, University of Toronto, Ontario, Canada. (AD)

Correspondence: Ahmed Kayssi MD MSc MPH, Division of Vascular Surgery, 2075 Bayview Ave., Toronto, Ontario M4N 3M5 Canada
Email: ahmed.kayssi@sunnybrook.ca

References

1. Callam MJ. Epidemiology of varicose veins. Br J Surg 1994 Feb;81(2):167-173.
2. Fowkes FG, Evans CJ, Lee AJ. Prevalence and risk factors of chronic venous insufficiency. Angiology. 2001 Aug;52 Suppl 1:S5-15.
3. Van den Oever R, Hepp B, Debbaut B, Simon I. Socio-economic impact of chronic venous insufficiency. An underestimated public health problem. Int Angiol. 1998 Sep;17(3):161-167.
4. Abbade LP, Lastoria S. Venous ulcer: epidemiology, physiopathology, diagnosis and treatment. Int J Dermatol. 2005 Jun;44(6):449-456.
5. Olin JW, Beusterien KM, Childs MB, Seavey C, McHugh L, Griffiths RI. Medical costs of treating venous stasis ulcers: evidence from a retrospective cohort study. Vasc Med. 1999;4(1):1-7.

6. Mayer W, Jochmann W, Partsch H. Varicose ulcer: healing in conservative therapy. A prospective study. Wien Med Wochenschr. 1994;144(10-11):250-252.
7. Bergqvist D, Lindholm C, Nelzen O. Chronic leg ulcers: the impact of venous disease. J Vasc Surg. 1999 Apr;29(4):752-755.
8. Evans CJ, Fowkes FG, Ruckley CV, Lee AJ. Prevalence of varicose veins and chronic venous insufficiency in men and women in the general population: Edinburgh Vein Study. J Epidemiol Community Health. 1999 Mar;53(3):149-153.
9. Lazarus GS, Cooper DM, Knighton DR, Percoraro RE, Rodeheaver G, Robson MC. Definitions and guidelines for assessment of wounds and evaluation of healing. Wound Repair Regen. 1994 Jul;2(3):165-170.
10. Kelechi TJ, Johnson JJ, Yates S. Chronic venous disease and venous leg ulcers: An evidence-based update. J Vasc Nurs. 2015 Jun;33(2):36-46.
11. Morrison N, Gibson K, McEnroe S, Goldman M, King T, Weiss R, et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). J Vasc Surg. 2015 Apr;61(4):985-994.
12. Almeida JI, Javier JJ, Mackay E, Bautista C, Proebstle TM. First human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. J Vasc Surg Venous Lymphat Disord. 2013 Apr;1(2):174-180.
13. Proebstle TM, Alm J, Dimitri S, Rasmussen L, Whiteley M, Lawson J, et al. Twelve-Month Follow-up of the European Multicenter Study on Cyanoacrylate Embolization of Incompetent Great Saphenous Veins. J Vasc Surg Venous Lymphat Disord. 2014 Jan;2(1):105-106.

Melissa Coates: A Champion's Fight Against Acute Limb Ischemia

John R Coates BSc MD CCFP FCFP and **Seka Zutic** RN HBScN

Abstract: Melissa Coates was a professional bodybuilder, model and wrestler, who underwent the amputation of her left leg at the age of 51, due to acute limb ischemia (ALI), eventually passing away within the year. This article offers a personal perspective on signs that were missed and steps that could have been taken along the way to dramatically impact outcomes, and presents a case for greater awareness and education on limb loss prevention.

Key words: *peripheral artery disease, acute limb ischemia, amputation, prevention, wound care, limb protection awareness, patient story*

How to cite: Coates JR, Zutic S. Melissa Coates: a champion's fight against acute limb ischemia. Limb Preservation Journal. 2025;6(1): 65-72. DOI: 10.56885/676449abbjck

Introduction

My late sister, Melissa Coates, lost her left leg due to blood clots in the arteries causing acute limb ischemia (ALI) – one of the most dangerous yet least well-known forms of peripheral arterial disease. Her condition was not recognized and treated soon enough. Patients with acute arterial occlusion usually present with some of the *six 'Ps'*: pain, pallor, pulselessness, perishingly cold, paraesthesia, and paralysis. It is vital that medical practitioners have a high level of suspicion and evaluate the neurovascular status of patients presenting with leg pain.

I am a family physician at the Windsor Family Health Team in Windsor, Ontario, Canada and the primary care consultant to the Windsor-Essex Lower Limb Wound Prevention and Treatment Clinic. This clinic serves as the Windsor-Essex Ontario Health Team's response to the urgent need for improved access to wound prevention, wound care and lower limb health education, with the ultimate goal of reducing amputations in Ontario. Province-wide, this endeavour is called the Lower Limb Preservation Strategy (LLPS). The Windsor Family Health Team has played a pivotal leadership role in advancing these critical initiatives.

Melissa Coates onstage at the Ms. Olympia competition, Chicago, 1996

At the International Sports Hall of Fame, Columbus, Ohio, March 2016

Born in Thunder Bay, Ontario, Melissa Coates was a trailblazer in the world of professional bodybuilding and pro wrestling. Throughout the 1990s, she competed in the International Federation of Bodybuilding, winning the *Canadian Women's Bodybuilding Championship,* along with her professional debut, the *Jan Tana Classic.* She also placed highly in the *Ms. Olympia* and *Ms. International* events, successes that led her to be ranked 9th in the world in women's bodybuilding.

Melissa also had a successful career as a fitness model, gracing many magazine covers. She was also an actress appearing on many television shows and movies.

After retiring from bodybuilding in the early 2000s, Melissa trained with Hall of Fame pro wrestler, Killer Kowalski. She would later compete in World Wresting Entertainment, Impact Wrestling and throughout independent wrestling leagues across North America. From 2014 on, Melissa performed as 'Super Genie', joining forces with legendary pro wrestler Sabu as his manager and partner. Together they performed for various pro wrestling companies across the globe.

Missed Diagnosis

In October 2020, my sister suffered from acute limb ischemia (ALI) of her left leg, which tragically resulted in an above knee amputation. At this time, she was 51-years-old and lived in Las Vegas. She had sought treatment for pain in this leg at an urgent care clinic six weeks prior to the amputation. The examining physician did not evaluate nor document her neurovascular status, according to Melissa, and this was confirmed on subsequent review of her medical records. These included no mention of pulses, capillary refill, warmth, colour, fine touch, strength, nor reflexes. In fact, she was diagnosed with a "strained muscle".

A venous doppler was ordered, which came back normal, and was only requested because my sister voiced her concern regarding our family history of deep vein thrombosis (DVT). No arterial doppler ultrasound was ordered. Notably she had seen multiple doctors on several occasions over the previous two years regarding pain in her left calf and was told she had a "pulled muscle" or similar.

On October 10, 2020, Melissa's leg pain was so excruciating she felt the need to go to an emergency department. She was assessed and a CT angiogram was performed, showing a left common iliac artery thrombus and complete occlusion of the profunda and popliteal arteries. Intravenous heparin was started and catheter-directed thrombolysis was attempted. This therapy had to be discontinued due to the complication of an upper gastrointestinal bleed from a gastric ulcer which was treated via gastroscopy. She required fluid resuscitation, transfusion of five units of packed red blood cells, and had to be closely monitored.

Over the next few days, interventions included placement of a left iliac artery stent, and a minimally effective endovascular thrombectomy. She also underwent fasciotomies and negative pressure wound therapy. Sadly, the acute limb ischemia was not recognized soon enough and despite these multiple attempts by interventional radiology and vascular surgery, she required an above knee amputation to save her life.

Hence, the family feels Melissa's initial physical examination at the urgent care clinic was inadequate and resulted in life-altering consequences.

Blood clots have plagued our family, but Melissa escaped these maladies until this acute limb ischemic event. Other than occasional cigarette smoking, and a remote left knee anterior cruciate ligament repair, she was the healthiest member of our family. Her athletic career required her to eat

Melissa as 'Super Genie' with Sabu, UK Tour, October 2017

healthy and to exercise on a regular basis.

We suspect the clots in her leg were caused by a combination of our family predisposition and a hypercoagulable state due to a COVID-19 infection. Although Melissa's nasal PCR swabs were negative during her prolonged hospitalization, her COVID-19 serology was tested shortly after discharge and came back positive. This confirmed that she had been infected with COVID-19 earlier that year.

Melissa spent over five weeks in hospital with no visitors allowed due to the pandemic restrictions. Then began the arduous process of getting fitted for a prosthetic leg and learning to walk. Changes in the residual limb's shape and volume, a natural part of the healing process, required repeat casting of the prosthetic which caused frustrating delays in her rehabilitation. She suffered from phantom limb pain, as well as depressed mood and anxiety and, required multiple medications.

My sister passed away unexpectedly in her sleep on June 23, 2021, just a few days after her 52nd birthday. Her autopsy showed a dilated cardiomyopathy, moderate coronary atherosclerosis, calcified ulcerated atherosclerotic plaques of the thoracic and abdominal aorta, and calcific atherosclerosis of the left popliteal artery. It was very frustrating for my brother David and I, who are both physicians, to be unable to assess our sister in-person due to the chaos from the pandemic, including the border closings, hospital visitation restrictions and the unavailability of vaccinations. My daughter, Kassandra, who had antibodies from the first wave of COVID-19, was able to visit and help Sabu take care of her Aunt Melissa during this difficult time.

Posts from my sister's social media poignantly illustrate the devastating effects, both physically and psychologically, that she endured as a result of her amputation (See Sidebar: *Melissa's Story*).

Medical Discussion

Acute limb ischemia (ALI) is defined as a sudden loss of arterial perfusion to a limb resulting in progressive ischemia, which can cause severe tissue damage and limb death. In ALI, the symptoms are present for less than two weeks.[1] Acute limb ischemia carries a very high risk of morbidity and mortality, with 20% of patients requiring amputation. The 30-day mortality rate is 10-15%, and the one-year mortality rate is 40%.[2] Annual incidence is approximately two per 10,000 population per year.[3]

Acute limb ischemia is a medical emergency requiring immediate diagnosis and treatment. Complete occlusion of blood flow without collateral perfusion may lead to irrevocable damage to the affected limb within four-six hours.[4] The longer the affected limb is not correctly recognized, the higher the risk of tissue damage, limb amputation and death. Therefore, it is imperative for clinicians to accurately assess symptoms relating to ALI in an effective and time-sensitive manner.

Patients with ALI usually present with sudden onset of some of the six 'Ps': pain, pallor, pulselessness (measured by palpation or hand held doppler), perishingly cold/poikilothermia (loss of temperature regulation), paraesthesia (numbness and/or loss of sensation) and paralysis (a change in the motor strength).[5]

The research published in cardiovascular literature points to inadequate clinical examinations in patients seeking treatment for ALI. A significant number of people do not always experience the anticipated or typical symptomology of this condition; they may have only some but not all of the six 'P's. Paresthesia and paralysis are often late signs of the ischemic damage. Pain may appear as an earlier symptom but may improve as nerve tissue dies.[6]

Risk factors of ALI include hypertension, smoking, hypercholesterolemia, diabetes mellitus,

Melissa's Story

Dec 11, 2020

I've been home from the hospital for two weeks now after going through an awful life-altering event that required my having to have my left leg amputated in order to save my life. The doctors still don't know the cause of the blood clots in my left leg arteries. So far, I've only been told it seems to be an autoimmune disorder. I'm 15 years younger than the age most people might have this happen. Never had a blood clot till now. Though I did go to the doctor about five times [over] the past two years about the pain in my left calf, including a trip six weeks before my surgery. I was always told it was a pulled calf muscle. So, I wasn't really, really concerned over the pain in my foot and calf that came back around Oct 10. It's very upsetting to think this all could have been avoided.

Jan 16, 2021

Here's my first day trying to learn to walk on a prosthetic leg since I lost my leg October 23. I was in the hospital five weeks dealing with this awful situation, no visitors allowed due to COVID. It was just the most shocking, sad, and painful experience. The doctors tried to save my leg but were unsuccessful. Too much damage had already been done to my lower leg. A trip to urgent care six weeks before the amputation had been my opportunity to save my leg, but the doctor didn't diagnose me properly or do the right tests. So this is where I'm at now. I'm trying to stay positive and fight the depression and trying to figure out a new course of life and ways of supporting myself, on top of handling medical bills and trying to get a good prosthetic leg that will allow me to function as closely as possible to before, but nothing will ever be the same. Just not sure how to handle this all. A friend set up a GoFundMe for me to help me pay off bills and to find a way to get a great prosthetic leg. I know COVID has wiped a lot of people out financially, but for anyone who can help, here's the link.

Jan 25, 2021

It's another new day to try to master this starter leg I've gotten to replace the real leg of mine. So very, very, very much harder to relearn to walk with my knee gone than if they had cut under my knee. I love all the positive comments and love sent my way... it helps make this bleak situation so much more bearable for me. I'm trying to raise enough money to afford the best leg that would return me to workouts and the wrestling ring. It was made for military amputees so that they could return to duty. So, you can tell it's an amazing leg and would give back to me, as close as possible, the quality of life I once had. I promise you if I get this prosthetic leg, that you will see me back in fitness shape doing photo shoots, and you will also see me back in the ring. I have to beat this challenge. I never would have thought how limiting and how much it affects me to not have two legs. I have to have someone around to help me at all times, and especially to make sure I don't fall down, which I did for the first time last week ... luckily it was on the side of my remaining left leg, and not on the bottom where the scar is. If an amputee falls on the end of their leg they have to have more tissue removed, and go through this whole three months of challenges everyday again, which would be just awful, especially for someone like me who has always been used to being active. So, I'm trying to be careful, trying to master this starter leg, and then I would be able to possibly get a much higher-end prosthetic leg that would allow me to do the things I used to do, help get me the quality of life I've been used to.

Feb 14, 2021

Working out so hard to be able to walk again after my terrifying situation last October that almost took my life, not just my leg. My final choice was either to die or let my left leg be amputated. What a terrible decision to make for someone like me, who's entire career, identity, and finances have been based off my body being fit and strong and athletic. This all has really broken my heart. But I try to feel good in that I'm still around to visit and be with my family and my closest friends. I love them all so much that the choice was obvious, as it should be to anyone over closing life or chasing life. It's just a tougher relationship that I'm having with myself now, as I've lost so much of my identity and my work. Please keep the prayers and good vibes coming. I can feel them healing me and I hope to be feeling like myself again very soon.

At the moment I have just gotten my starter leg, which I must learn how to walk with first before I can move onto a higher quality leg that can allow me to work out in the gym the way I used to, and to valet in the wrestling ring the way I used to also. I loved these parts of my life and it's been so hard having to give them up for now. All I can hope is that my ability to enjoy these things in my life again won't be too far off. I just want to be me again.

Keep in touch, and much love to all!

xo Melissa

peripheral arterial disease (PAD), atrial fibrillation, coronary artery disease and increased age. Symptoms of intermittent claudication, caused by PAD, include muscle pain often described as cramping of leg muscle distal to an arterial stenosis. Notably, this pain occurs when walking a specific distance and resolves within ten minutes of ceasing exercise. Screening for PAD, utilizing the Ankle-Brachial Index (ABI) test, could be performed within these populations as a preventative strategy against ALI. Clinicians should suspect ALI when patients with these risk factors present with any of the six 'Ps', especially sudden onset of limb pain.

Primary care providers should aggressively manage these cardiovascular risk factors to prevent ALI. Patients with symptomatic PAD should be prescribed the combination of rivaroxaban and aspirin, as per the COMPASS trial.[7]

Acute limb ischemia is a complex condition with numerous etiologies. These include thromboembolic events caused by atrial fibrillation or from aortic or popliteal aneurysms, as well as in-situ thrombosis caused by unstable arterial plaque rupture, congenital coagulopathies or hypercoagulability caused by malignancies and by infections such as COVID-19. Embolic ischemia causes the classic presentation of sudden onset of pain, whereas thrombotic ischemia tends to present more gradually.[1]

Melissa learning to walk on her prosthetic leg, February 2021

In patients with chronic PAD, collateral vessels may have formed. This can make onset of symptoms vague and patient presentation ambiguous.[1]

A retrospective study from Sweden showed that the initial clinical evaluation of patients with ALI is often inadequate. Current guidelines for the management of ALI recommend use of the six 'P's as well as the ankle brachial pressure index (ABI). Pain was best documented in 93.2 % of the patients, whereas ABIs and pulses were least documented at 55.3% and 47.2%, respectively. A sufficient examination was deemed to include documentation of at least five of the 6 P's and ABI, but was performed in only 55.3% of the patients. Complete documentation of pulses, ABI, and/or assessing ≥5 of these diagnostic criteria had the lowest major amputation/mortality rate at one-year follow-up. Lack of adequate initial clinical examination resulted in higher likelihood of the adverse outcomes of amputation or death.[5]

Common misdiagnoses include muscular sprain/strains, tendinopathies, compartment syndrome, gout, deep vein thrombosis, lumbar radiculopathy, cerebrovascular accidents and many other conditions. Acute limb ischemia also needs to be differentiated from chronic or critical limb ischemia (CLI), which presents with rest pain lasting more than two weeks, with or without foot wounds/gangrene.

Suspected cases of ALI should be referred immediately to vascular surgery as imaging prior to referral may delay limb-saving procedures.[8,9] Delayed treatment, as noted throughout the research, increases likelihood of limb loss and patient mortality.

Pesmatzoglou et al. (2025) performed a retrospective study which recorded all emergency department hospitalizations of patients with ALI between 2018 and 2024. Both groups of patients, including correctly identified ALI cases

and those initially misdiagnosed with a delayed diagnosis of 24 hours or more, were examined for negative health outcomes. Shockingly, of the patients who were misdiagnosed, the median time from initial symptom presentation to receiving a definite diagnosis was approximately 38.8 days. It was further noted that many of these patients with delayed diagnosis of ALI were primarily referred to non-vascular-related specialties, thereby perhaps, limiting treatment options vital to limb preservation and patient survival.[10]

Londero, Nørgaard, and Houlind (2014) suggested that delays in management and treatment of ALI occurred due to multiple reasons, including patient delay in seeking treatment, delay caused by a referring practitioner, emergency department wait times and wait times for diagnostic imaging. Although not all factors can be mitigated, enhancing public education and campaigning for ALI awareness could improve patient knowledge and encourage seeking of treatment.[11]

It is paramount that clinicians be vigilant with cases presenting with signs and symptoms of the six 'P's with the goal that they are assessed with a complete and accurate neurovascular evaluation. Furthermore, clinical evaluation of ALI utilizing the Rutherford classification system, arterial doppler ultrasound and/or CT angiogram, is recommended and helps to guide treatment modalities.[3]

Emergent restoration of tissue perfusion is needed via intravenous heparin administration, which prevents thrombus propagation, if not contraindicated by bleeding factors. Further intervention via endovascular methods including catheter-directed thrombolysis, embolectomy/thrombectomy and/or peripheral bypass is required if occlusion continues to persist.

If tissue revascularization cannot be established or is deemed irreversible, amputation may have to be performed as a life-saving measure. Although significant innovations in medical technologies and treatments have been made, the high rate of limb loss and patient mortality associated with ALI persists.

Given the high incidence of arterial thrombosis in patients during the COVID-19 pandemic,[12] we suspect that Melissa's case of ALI was due to post-thrombotic sequela of a recent COVID-19 infection. This devastating infection portends a 3.3-fold higher risk of death and a 2-fold higher risk of amputation from ALI than in cases of ALI without COVID-19.[13] Other contributing factors in Melissa's case may include rapid progression of atherosclerosis caused by COVID-19 infection,[14] family history of venous thromboembolism and cardiovascular disease, and occasional cigarette smoking. After her hospitalization, we recalled that our father had an angioplasty of a femoral artery stenosis at age 55. The fact that she complained of calf pain for two years suggests that Melissa may have had undiagnosed intermittent claudication, increasing her risk for ALI.

Awareness, Education And Future Steps

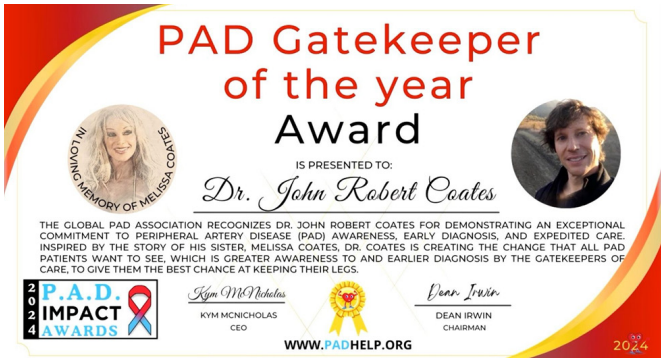
Acute limb ischemia is a condition with high morbidity/mortality that leaves patients with devastating and permanent health outcomes; however, it is not commonly recognized nor understood by the public. A 2007 American study indicated that only 26% of people surveyed were familiar with PAD. Within the "PAD-aware" group, only half were aware that smoking and diabetes increase the risk for PAD and only 14% knew that PAD could lead to amputation.[15] A Canadian survey showed that only 36% of adults 50 years of age and older were aware of PAD.[16]

Future steps and recommendations for effective ALI diagnosis and management include raising awareness and providing education initiatives for both the public and medical professionals. Research indicates that due to inadequate clinical diagnosis of ALI, combined with its high mortality rate, there is a strong impetus for enhanced clinical training for medical students and a necessity for change in curriculum to provide satisfactory education and examination of vascular status.[5] It is strongly encouraged that all health-care professionals be vigilant and act with a high index of suspicion and urgency when patients present with diagnostic characteristics of ALI.

Awareness campaigns by organizations such

as Wounds Canada and the American Limb Preservation Society are invaluable in this regard. In particular, patients with a diagnosis of PAD need to be educated about aggressive medical management of cardiovascular risk factors, smoking cessation, the benefits of regular exercise and a heart healthy diet. They should be encouraged to seek medical attention urgently if they experience sudden onset of limb pain and/or any of the other six 'P's. Referrals to regional lower limb preservation clinics or to other foot care providers should be considered. Furthermore, vaccination against COVID-19 and influenza should be encouraged to decrease the risk of ALI.[17-19]

One of my sister's goals before her passing was to raise awareness about limb loss to help prevent others from going through her ordeal and to help those in need of prosthetic limbs, which are incredibly expensive. My work with the Lower Limb Preservation Strategy in Windsor-Essex and with Wounds Canada will help to fulfill Melissa's wish to save limbs and lives. I speak for my sister to honour her life and legacy, and to warn others of the signs and symptoms of blood clots and peripheral arterial disease so that others do not have to suffer or die from these conditions.



In October 2024, I was honoured to be recognized by the Global PAD Association for my work on peripheral arterial disease including my efforts in helping develop the Windsor-Essex Lower Limb Preservation Strategy, and my participation in Wounds Canada's PAD Awareness Month campaign. I would like to dedicate this award to my late sister Melissa Coates who lost her left leg due to acute limb ischemia.

The Global PAD Association is a non-profit organization based in United States that helps patients with PAD access education and assistance to obtain timely and effective life and limb-saving care. padhelp.org

John R Coates BSc MD CCFP FCFP is Primary Care Consultant to the Windsor-Essex Lower Limb Preservation Strategy / Windsor-Essex Lower Limb Wound Prevention and Treatment Clinic, Adjunct Professor in the Department of Family Medicine, Schulich School of Medicine and Dentistry, Western University and Family Physician at Windsor Family Health Team, Ontario Canada.

Seka Zutic RN HBScN is an independent researcher based in Ontario, Canada.

***Correspondence:** jrcoates@windsorfht.ca / zuticseka@hotmail.com
https://www.windsorfht.ca/team-care-centre-programs/lower-limb-wound-prevention-and-treatment-clinic/

References

1. Olinic DM, Stanek A, Tătaru DA, Homorodean C, Olinic M. Acute limb ischemia: an update on diagnosis and management. J Clin Med. 2019 Aug 14;8(8):1215.
2. Rosenberg H, Rosenberg E, Kubelik D. Acute limb ischemia. CMAJ. 2023 Oct 16;195(40):E1383.
3. Hage AN, McDevitt JL, Chick JFB, Vadlamudi V. Acute limb ischemia therapies: when and how to treat endovascularly. Semin Intervent Radiol. 2018 Dec;35(5):453-460.
4. Nasto L, Kavrakov T. Delayed treatment and missed opportunities for limb salvage in patients with peripheral arterial embolism. Open Access Macedonian Journal of Medical Sciences. 2020 Sep 30;8(B):775-8.
5. Kulezic A, Macek M, Acosta S. Inadequacies of physical examination in patients with acute lower limb ischemia are associated with dreadful consequences. Ann Vasc Surg. 2022 May;82:190-196.
6. Obara H, Matsubara K, Kitagawa Y. Acute limb ischemia. Ann Vasc Dis. 2018 Dec 25;11(4):443-448. doi: 10.3400/avd.ra.18-00074.
7. Primary Panel:; Abramson BL, Al-Omran M, Anand SS, Albalawi Z, Coutinho T, de Mestral C, et al. Canadian Cardiovascular Society 2022 Guidelines for Peripheral Arterial Disease. Can J Cardiol. 2022 May;38(5):560-587.
8. Alberta Health Services: Alberta's Pathway Hub. Provincial lower limb ischemia primary care clinical pathway. 2024.
9. Ontario Health CorHealth Ontario. Acute Limb Ischemia (ALI) Assessment, consultation & referral guide. June 2023.
10. Pesmatzoglou M, Lioudaki S, Kontopodis N, Tzartzalou I, Litinas K, Tzouliadakis G, et al. Misdiagnosis of acute limb ischemia from non-vascular specialists results in a delayed presentation and negatively affects patients' outcomes. Medical Sciences. 2025 Feb 20;13(1):21.
11. Londero LS, Nørgaard B, Houlind K. Patient delay is the main cause of treatment delay in acute limb ischemia: an investigation of pre- and in-hospital time delay. World J Emerg Surg. 2014 Nov 5;9(1):56.
12. Borrelli MP, Buora A, Scrivere P, Sponza M, Frigatti P. Arterial thrombotic sequalae after covid-19: mind the gap. Ann Vasc Surg. 2021 Aug;75:128-135.

13. Pham A, Heib A, Goodman E, Lipsitz E, Indes J. Outcomes of acute limb ischemia in COVID-19. J Vasc Surg. 2022 Oct;76(4):1006-1013.e3.
14. Chidambaram V, Kumar A, Sadaf MI, Lu E, Al'Aref SJ, Tarun T, et al. COVID-19 in the initiation and progression of atherosclerosis: pathophysiology during and beyond the acute phase. JACC Adv. 2024 Jul 17;3(8):101107.
15. Hirsch AT, Murphy TP, Lovell MB, Twillman G, Treat-Jacobson D, Harwood EM, et al.; Peripheral Arterial Disease Coalition. Gaps in public knowledge of peripheral arterial disease: the first national PAD public awareness survey. Circulation. 2007 Oct 30;116(18):2086-94.
16. Lovell M, Harris K, Forbes T, Twillman G, Abramson B, Criqui MH, et al.; Peripheral Arterial Disease Coalition. Peripheral arterial disease: lack of awareness in Canada. Can J Cardiol. 2009 Jan;25(1):39-45.
17. Xie B, Semaan DB, Binko MA, Agrawal N, Kulkarni RN, Andraska EA, et al. COVID-associated acute limb ischemia during the Delta surge and the effect of vaccines. J Vasc Surg. 2023 Apr;77(4):1165-1173.e1.
18. Rubino R, Imburgia C, Bonura S, Trizzino M, Iaria C, Cascio A. Thromboembolic events in patients with influenza: a scoping review. Viruses. 2022 Dec 17;14(12):2817.
19. Cezard GI, Denholm RE, Knight R, Wei Y, Teece L, Toms R, et al.; Longitudinal Health and Wellbeing and Data and Connectivity UK COVID-19 National Core Studies, CONVALESCENCE study and the OpenSAFELY collaborative. Impact of vaccination on the association of COVID-19 with cardiovascular diseases: an OpenSAFELY cohort study. Nat Commun. 2024 Mar 11;15(1):2173

Bibliography

Basile G, Petrucci QA, Ghezzi M, Amadei F, Bianco Prevot L, Accetta R, et al. A case of critical ischemia of the lower limbs: critical elements and possible medico-legal implications. Acta Biomed. 2022 Aug 31;93(4):e2022286.

Darwood R. Acute limb ischaemia. Available from: https://www.rcemlearning.co.uk/reference/acute-limb-ischaemia/

Braun R, Lin M. Acute limb ischemia: a case report and literature review. J Emerg Med. 2015 Dec;49(6):1011-7.

Enea I, Martelli E. Focus on the prevention of acute limb ischemia: centrality of the general practitioner from the point of view of the internist. J Clin Med. 2023 May 24;12(11):3652.

Ehsan O, Khan MI, Raza MW. Management of COVID-19-related arterial thrombosis leading to acute limb-threatening ischemia. MedRxiv. 2021 Mar 24:2021-03.

Tinelli G, Sica S, Montanari F, Franceschi F, Covino M, Dionisio D, et al. Spontaneous acute aortic thrombosis in SARS-CoV-2 infection. Ann Vasc Surg. 2021 Aug;75:136-139.

Pasqui E, de Donato G, Brancaccio B, Casilli G, Ferrante G, Palasciano G. Misdiagnosed acute limb ischemia in three nonhospitalized patients recovering from a nonsevere COVID-19 infection. Ann Vasc Surg. 2021 Aug;75:140-143.

Godoy LC, Goligher EC, Lawler PR, Slutsky AS, Zarychanski R. Anticipating and managing coagulopathy and thrombotic manifestations of severe COVID-19. CMAJ. 2020 Oct 5;192(40):E1156-E1161.

Normahani P, Standfield NJ, Jaffer U. Sources of delay in the acute limb ischemia patient pathway. Ann Vasc Surg. 2017 Jan;38:279-285.

Verghese A, Charlton B, Kassirer JP, Ramsey M, Ioannidis JP. Inadequacies of physical examination as a cause of medical errors and adverse events: a collection of vignettes. Am J Med. 2015 Dec;128(12):1322-4.e3.

Rubino R, Imburgia C, Bonura S, Trizzino M, Iaria C, Cascio A. Thromboembolic events in patients with influenza: a scoping review. Viruses. 2022 Dec 17;14(12):2817.

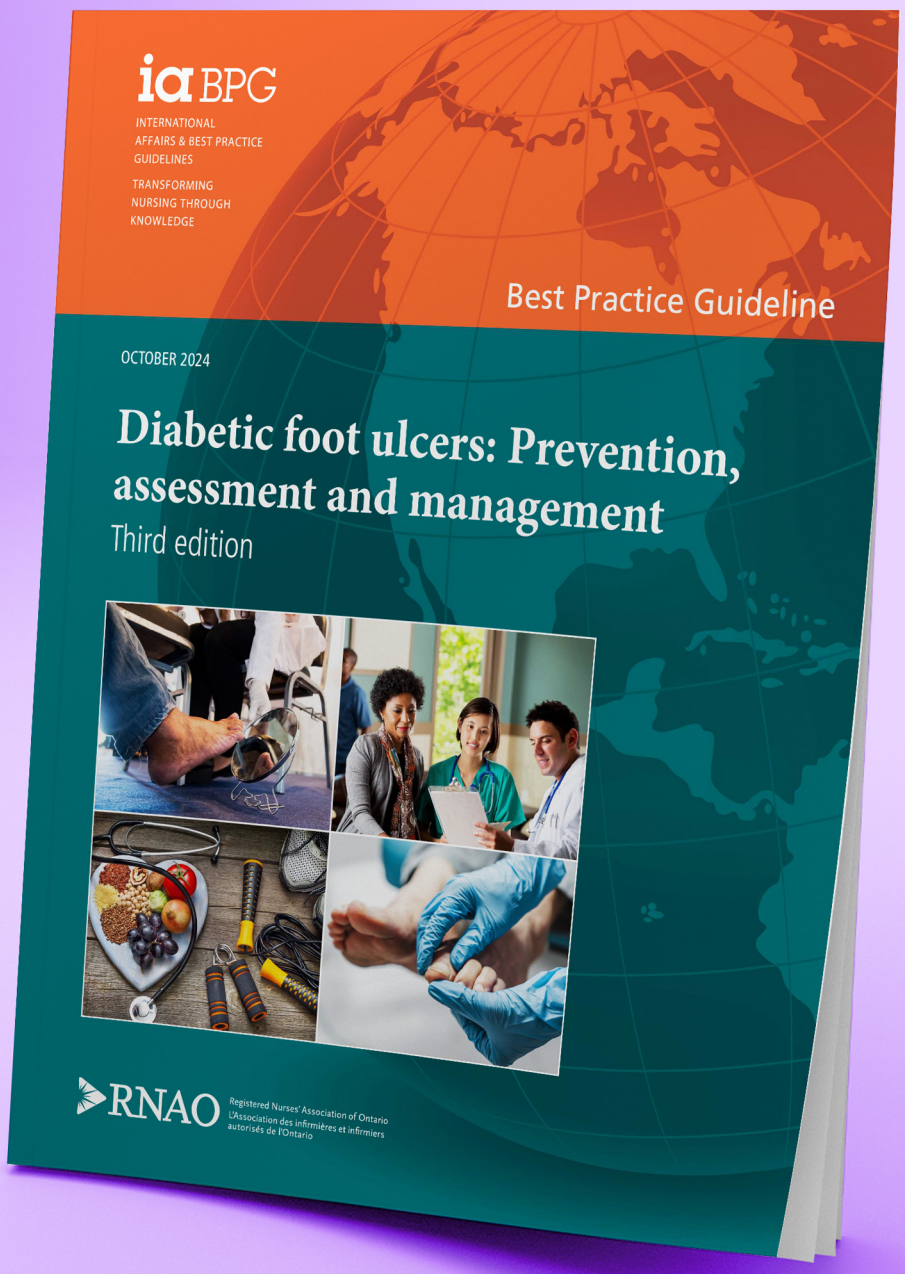
Hess CN, Huang Z, Patel MR, Baumgartner I, Berger JS, Blomster JI, et al. Acute limb ischemia in peripheral artery disease. Circulation. 2019 Aug 13;140(7):556-565.

Gornik HL, Aronow HD, Goodney PP, Arya S, Brewster LP, Byrd L, et al.; Peer Review Committee Members. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2024 Jun 11;149(24):e1313-e1410.

Björck M, Earnshaw JJ, Acosta S, Bastos Gonçalves F, Cochennec F, et al. Editor's Choice - European Society for Vascular Surgery (ESVS) 2020 Clinical Practice Guidelines on the Management of Acute Limb Ischaemia. Eur J Vasc Endovasc Surg. 2020 Feb;59(2):173-218.

RNAO

Available Now!



LEARN MORE

Diabetic foot ulcers: Prevention, assessment and management

RNAO's Best Practice Guidelines (BPG) Program is funded by Ontario's Ministry of Health. It was envisioned by CEO Dr. Doris Grinspun in 1998 and launched in 1999 to provide the best available evidence for patient care across all health sectors and settings, with more than 50 guidelines developed to date. The Best Practice Spotlight Organization® (BPSO®) program supports health service and academic institutions that have formally agreed to implement multiple RNAO BPGs over a three-year period, and evaluate their impact on patients, organizations and health system outcomes. Launched in 2003, the BPSO program now has more than 1,500 BPSOs in Ontario, Canada and internationally.

Foot Health During The COVID-19 Crisis: An Audit Of A Partnership Between Primary Care Physicians And A University Podiatric Medicine Clinic In Canada

Virginie Blanchette* PhD DPM, Yassin Andoulsi DPM (c), **Marie-Philippe Mercier** DPM MSc, **Olivier Hue** PhD and **Magali Brousseau-Foley** MD DPM Phd (c)

Abstract: This is an audit of a partnership formed between the university podiatry clinic located in Trois-Rivières, Québec, Canada and regional primary care physicians' groups affiliated with the Centre de santé et de services sociaux de la Mauricie-et-Centre-du-Québec (Québec, Canada), in the months following the beginning of the COVID-19 crisis. Podiatric medicine is not generally part of the public health system in Québec. However, the data from this audit enabled the creation of an initial overview of this partnership, including a referral form and the approach used to reach specific indicators.This provided insight into foot health needs in primary care to maximize students' training, foot health and limb preservation. Indeed, our data shows that we have partially achieved our objectives and that we need to improve our audit practices and data while charting a better course for the future.

Key words: *foot health, COVID-19, podiatric medicine, primary care, foot health, limb preservation, education*

How to cite: Blanchette V, Andoulsi Y, Mercier M-P, Hue O, Brousseau-Foley M. Foot health during the COVID-19 crisis: an audit of a partnership between primary care physicians and a university podiatric medicine clinic in Canada. Limb Preservation Journal. 2025;6(1): 74-84. DOI: 10.56885/773810fpfbpu

Podiatrist's field of practice in Canada consists of the evaluation of local conditions of the foot (from the malleoli to the toes) and their treatment by various means, including pharmacological, medical imaging and surgical treatments.[1] They are, therefore, well placed to manage foot health and preserve the lower limbs. However, within Canada with its various jurisdictions, podiatrists are exclusively in the private sector in the province of Québec. In Canada, a four-year program leading to a doctorate in podiatric medicine (DPM) has been offered at the University of Québec in Trois-Rivières (UQTR) since 2004.[2] This undergraduate DPM is the only one in Canada and in French-speaking countries. The final two years include rigorous clinical training through internships and externships in various clinical settings, mainly at the university teaching clinic, the University Podiatric Medicine Clinic (UPMC).[2]

Due to the COVID-19 pandemic and the total lockdown decreed by the Québec government from the end of March to June 2020, some internships and externships were cancelled in the academic year 2020-2021. It took more than two years for the students in our program to resume their normal activities. For example, it was necessary to reduce the number of patients present at the UPMC and increase the time between appointments. This lockdown limited public access to many health resources as well. More generally, all health-care professionals working in outpatient clinics, such

as those treating musculoskeletal conditions, for example podiatrists, physiotherapists, sports therapists and chiropractors, were also instructed to limit in person consultations to emergencies only.[3] This has compelled many stakeholders in the health sector to innovate, particularly by developing telemedicine services and revising priorities in primary care.[4,5] Therefore, the UPMC has also innovated by developing a new partnership, residing in a referencing trajectory with regional primary care services, to support foot health and limb preservation. It should be noted that podiatry is not a health profession included in the publicly funded health services basket anywhere in the province of Québec and that there is no formalized referral mechanism from primary care to podiatrists or vice versa. This therefore limits the referral of primary care physicians or nurse practitioners (Infirmière praticienne spécialisée de première ligne [IPS-PL]) to community podiatrists, including those at the UPMC, and to the very few practising in hospitals through partnerships with the UQTR training program.[6]

Foot Conditions As Primary Care Emergencies

Several foot conditions can be primary care emergencies, including acute musculoskeletal pain, diabetic foot disease, such as Charcot foot and foot ulcers, trauma, such as fractures, and local infections.[7,8]

The podiatry profession has proven its flexibility and adaptability during the COVID-19 pandemic, adjusting quickly to ensure patients had access to treatments to reduce the risk of infection, ulceration and amputation in the United Kingdom.[8] It has demonstrated the same capacity for musculoskeletal problems and supporting the public health-care system in the province of Québec.[3] Thus, in order to enable students studying podiatry at UQTR to achieve their training objectives in compliance with the program requirements,[2] for the duration of one semester (January to May 2021), patients referred by primary care physicians from the Centre de santé et de services sociaux de la Mauricie-et-Centre-du-Québec (CIUSSS-MCQ) territory were able to benefit from free consultations at the UPMC for certain targeted health conditions that may need minor surgery, wound care and imaging, such as ultrasound-guided injection.

Aim, Objective And Indicators

We aimed to evaluate the effects of this partnership with this clinical audit. The main objective was to determine whether the cases referred to the UPMC met the students' training needs (i.e., the main reasons for consultation that had been identified by the program at the outset).

The second objective was to describe the referred cases, which reveal the urgent foot conditions identified by primary care physicians in the region covered by the UPMC, and for which podiatrists can support primary care services.

The third objective was to conduct an initial audit of care at the UPMC to assess the future possibilities of introducing audits on the quality of care to support best practice recommendations and research.

Overall, this allowed us to assess how the allocated budget has been used to support training of future podiatrists.

The proposed indicators are based on arbitrary thresholds, public health data and exemplary recommendations, considering that we had no comparative internal data, accreditation or guidelines to follow. Indicators were measured after the four-month period. (See Table 1.)

Table 1: Indicators

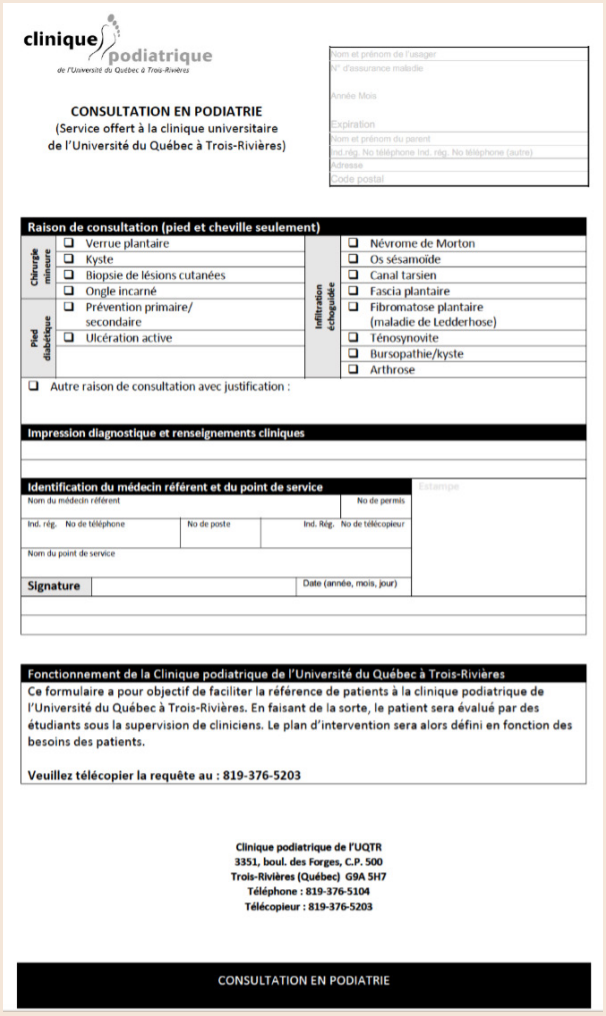
Indicator	Descriptive	Descriptive
Indicator 1	The project allows supporting a pre-COVID-19 level for new consultations so that students can be trained at initial history taking (past and current medical history).	Pre-COVID-19: This represented 154 new consultations per month for the UPMC. Thus, the trajectory makes it possible to reach 20% of new consultations, or about 31 consultations per month.
Indicator 2	The consultation profile fits the regional characteristics in terms of sex, age, and rurality to respect a certain equity of access.	The profile of the people who consulted is comparable to the regional averages.
Indicator 3	The consultations resulting from the trajectory are in accordance with the pre-established sheet for the UPMC management targeted needs, i.e., minor surgery (warts, cysts, biopsy of skin lesions, ingrown toenails), diabetic foot care (primary/secondary prevention and wound care) and ultrasound-guided infiltrations for neuromusculoskeletal problems (neuroma, sesamoid, tarsal tunnel, plantar fascia, fibromatosis, tenosynovitis, bursitis, osteoarthritis).	Consultation requests correspond to at least 80% of the UPMC management's targeted needs.
Indicator 4	The partnership stimulates and establishes good practices for the coordination and follow-up of care.	Arrange at least one follow-up with the patient after the initial consultation, for an average of two consultations per case. Follow up to the referring primary care physician.
Indicator 5	It respects the allocated budget ($10,000 CAD) with no consultation fee, but charges may apply to patients for specific treatments, which are generally not covered.	The distribution of costs between the UPMC and the patient is higher for the UPMC considering the coverage of consultations in this partnership.
Additional Subjective Indicator	The process of conducting an audit within the UPMC and collecting data for future research projects and audits.	Share the general experience, make comments and suggest a plan of action.

Methodology

We conducted a retrospective audit of all successive cases that were referred to the UPMC between January and May 2021 using a specific reference form developed by MPM and MBF (Figure 1). After securing the $10,000 CAD budget allocated by the university and determining how it would be used, the proposed referral mechanism was validated by the clinical leadership and stakeholders of the UPMC. Thereafter, an internal press release was sent to the staff, including lecturers and professors at the UPMC, and to the publicly-funded primary care clinics in the CIUSSS-MCQ territory. A reminder was sent approximately four months after the initial release. To avoid confusion regarding the service coverage through this partnership, the consultation request form had to be sent by fax to the UPMC.

The institutional ethics committee confirmed that this audit did not require ethical approval in accordance with the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS2, art. 2.1).[9] Our audit aimed to draw up a portrait of this partnership for educational and quality improvement purposes and, therefore, does not fall within the competence of research (EPTC2, art. 2.5).[9] In addition, all patients treated at the UPMC signed a consent form allowing the use of data for research and audit purposes during their first consultation. We used the adapted method in 14 steps to conduct a clinical practice audit suggested by Godwin in *Canadian Family Physician* to report our project.[10]

The audited cases were identified from the billing list by the clinic coordinator, considering that the costs of the initial and follow up consultation were covered. The list of potential cases was then validated in the clinic's appointment system CTRL (CTRL Informatique ltée, Québec, Canada) by the principal data reviewer (YA), as the consultation requests had been digitized and placed in the patient's medical file. A database was created from an extraction file validated by VB, YA, MBF. The extracted data concerned the case profile (e.g., sex, age, place of residence), reason for the first consultation, follow-up (e.g., total number of consultations at the UPMC and follow-up visits, feedback to the referring physician) and the costs incurred by the patient and by the university. The data were extracted (YA) anonymously and no patient identification data was recorded. We considered cases over a period of four months. The data was analyzed by YA and VB using simple descriptive statistics in Microsoft Excel.



clinique podiatrique
de l'Université du Québec à Trois-Rivières

CONSULTATION EN PODIATRIE
(Service offert à la clinique universitaire
de l'Université du Québec à Trois-Rivières)

Nom et prénom de l'usager
N° d'assurance maladie
Année Mois
Expiration
Nom et prénom du parent
Ind. rég. No téléphone Ind. rég. No téléphone (autre)
Adresse
Code postal

Raison de consultation (pied et cheville seulement)

Chirurgie mineure
- ❑ Verrue plantaire
- ❑ Kyste
- ❑ Biopsie de lésions cutanées
- ❑ Ongle incarné
- ❑ Prévention primaire/ secondaire
- ❑ Ulcération active

Pied diabétique

Infiltration échoguidée
- ❑ Névrome de Morton
- ❑ Os sésamoïde
- ❑ Canal tarsien
- ❑ Fascia plantaire
- ❑ Fibromatose plantaire (maladie de Ledderhose)
- ❑ Ténosynovite
- ❑ Bursopathie/kyste
- ❑ Arthrose

❑ Autre raison de consultation avec justification :

Impression diagnostique et renseignements cliniques

Identification du médecin référent et du point de service

Nom du médecin référent | No de permis | Estampe
Ind. rég. No de téléphone | No de poste | Ind. Rég. No de télécopieur
Nom du point de service
Signature | Date (année, mois, jour)

Fonctionnement de la Clinique podiatrique de l'Université du Québec à Trois-Rivières

Ce formulaire a pour objectif de faciliter la référence de patients à la clinique podiatrique de l'Université du Québec à Trois-Rivières. En faisant de la sorte, le patient sera évalué par des étudiants sous la supervision de cliniciens. Le plan d'intervention sera alors défini en fonction des besoins des patients.

Veuillez télécopier la requête au : 819-376-5203

Clinique podiatrique de l'UQTR
3351, boul. des Forges, C.P. 500
Trois-Rivières (Québec) G9A 5H7
Téléphone : 819-376-5104
Télécopieur : 819-376-5203

CONSULTATION EN PODIATRIE

Figure 1: Reference form developed by the UPMC

Results

Indicator 1: Number of new consultations with this partnership

The total number of cases audited during the studied period is 65. This represents approximately 16 new cases per month. We do not have comparable data for a similar period before COVID-19. However, this has contributed to an increase in the number of consultations at the clinic in 2021, when it was difficult to recruit new patients. Considering that the UPMC usually aims for around 154 new patients per month for training, the partnership has had a modest expected effect

Indicator 2: Profile of the cases

Figure 2 reports the distribution of the sex, age and place of residence of the cases, respectively.

Thus, the sex breakdown is fairly even and in line with regional data, as is the age distribution.[11] The age range of the cases was from five to 91 years-old, with an average age of 55. This is more than the average age of the population, which is 44 (not adjusted for sex) compared to the latest data available from the 2017 census profile of Statistic Canada.[12] This is consistent with the fact that foot problems preferentially affect adults and elderly people, particularly with aging and chronic diseases, and that this population sometimes encounters barriers to maintain adequate foot care, such as impaired dexterity, pain, difficulty in bending down, visual deficiency, etc.[13] The Mauricie-Centre-du-Québec region is particularly marked by demographic ageing.[14]

In addition, approximately 31% of the regional population lives in rural areas and our data shows a fairly similar proportion.[11] Moreover, the research data has shown that women consult more in primary care[15] and are more likely to suffer from foot pain,[16] which is similarly reflected in our audit data. Sex, age and place of residence are equity factors related to health care.[17] Rurality was identified as a barrier to access primary care foot health services.[18,19]

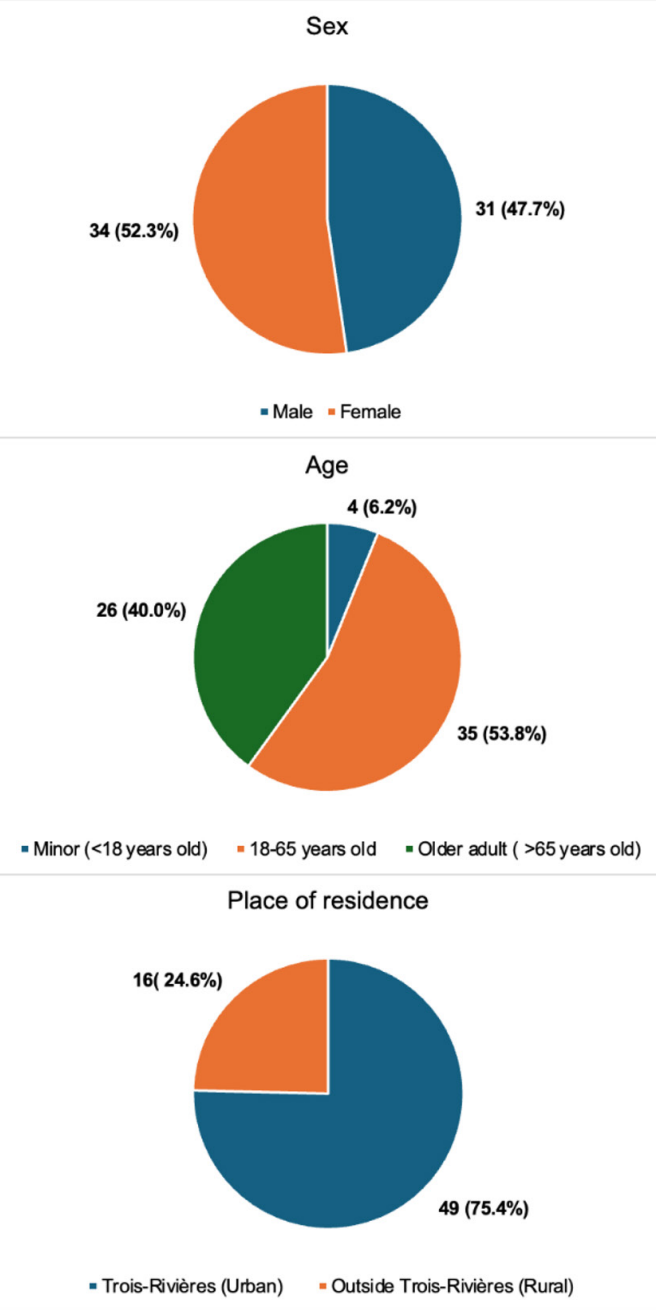


Figure 2: Sex, age and place of residence of the cases included in the audit

Indicator 3: Reason for consultation

The partnership led to a total of 168 consultations. The main reasons for consultation are presented in Figure 3. Approximately 17% of consultations were for primary or secondary prevention of diabetic feet or related wound care. This result is lower than expected considering that it was one of the three main categories of treatment targeted by the

UPMC and corresponded to a training need, which was diabetic foot disease. Foot and ankle problems affect 20 to 50% of individuals with diabetes and account for a high proportion of primary care consultations.[20]

Regarding the second category of treatment targeted by the UPMC, i.e., minor surgeries, the target was also not reached, since approximately 13% of consultations were related to ingrown toenails and only half of them led to minor surgery. There were no minor surgeries performed for warts or skin lesions.

Thirty-eight percent of the referred cases involved neuromusculoskeletal disorders, including diagnosis of neuropathy, tendinopathy, plantar fasciitis, capsulitis, foot deformities (flat feet, bunions, hammer toes), arthrosis, pain secondary to fibromyalgia, neuroma, tarsal tunnel syndrome, posterior tibial dysfunction and bursitis). The most common diagnosis was plantar fasciitis, which is consistent with the literature.[21] Women are more likely to consult for this type of problem in primary care.[22]

Finally, 32% of consultations were related to foot care, including nail cutting and removal of corns/calluses/keratoses for dermatology-related diagnosis, and patient education, which was not a category of care specifically targeted by the UPMC. Barriers to foot care, including diabetic foot care, in primary care have previously been identified as access, socioeconomic factors and a lack of service availability.[23] Our partnership has overcome all of these barriers to facilitate access and care for patients. Although our university is interested in promoting and supporting training and research in the area of diabetes-related foot complications, neuromusculoskeletal (symptomatic) needs remain one of the main reasons for consulting a podiatrist, especially related to aging and considering the increase of the prevalence of chronic deseases.[24]

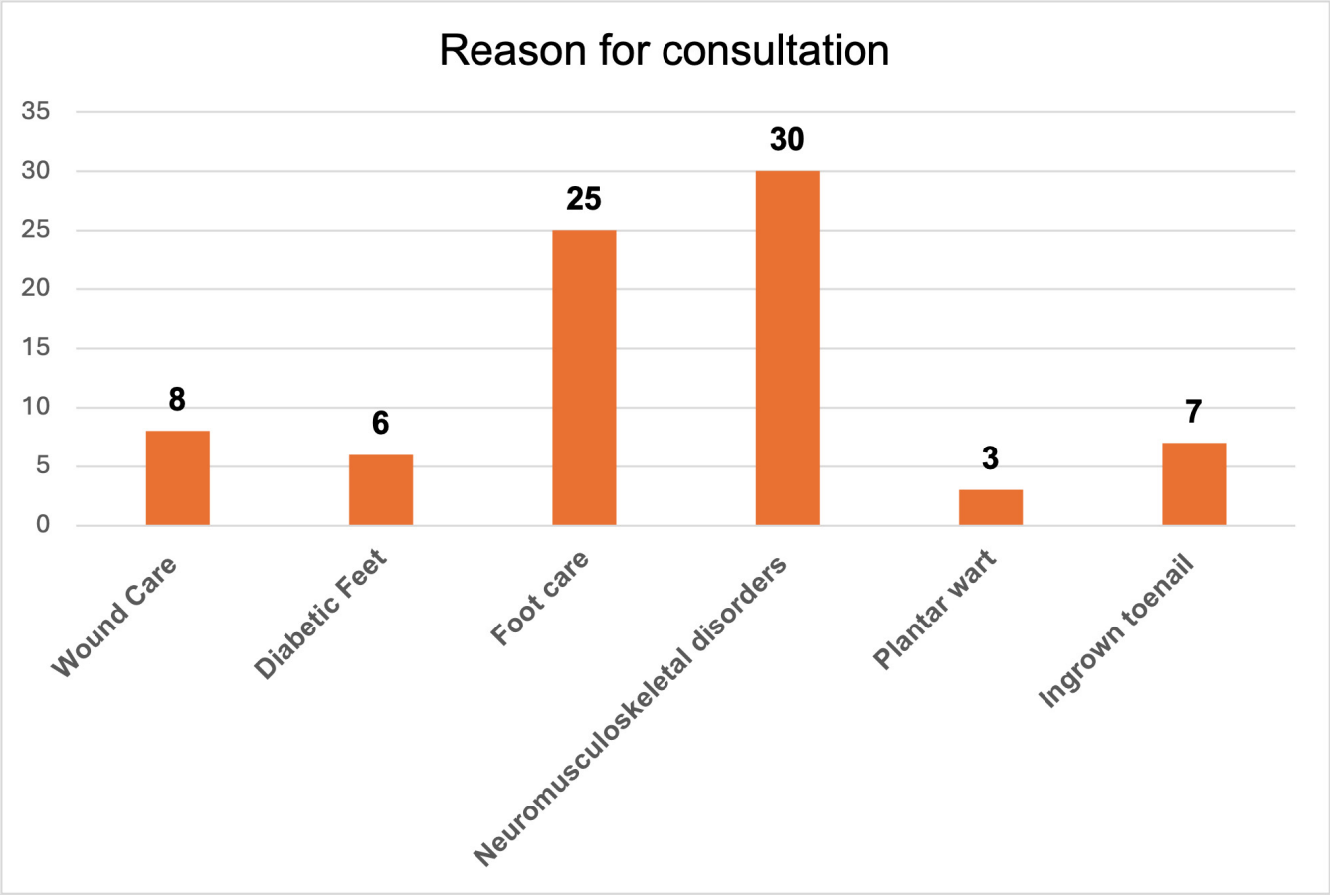


Figure 3: Reasons for consultation/diagnosis

Indicator 4: Follow-up

There was an average of 2.6 consultations per case. However, for 58% of cases, a single appointment was enough to resolve the issue within the four-month period retrospectively audited. One case alone accounted for 23 medical encounters for wound care, which slightly inflates the average. Feedback was provided to the referring physicians in 31% of cases. This does not comply with the instruction from the UPMC management (to students and supervisors) to make a follow-up report to the referring primary care physicians.

The number of follow-up consultations may be underestimated or incorrect, considering that we only monitored the first four months and that follow-ups may have taken place outside this period in some cases. As we analyzed successive cases, it is plausible that we missed follow-up visits, as some musculoskeletal diseases take a long time to heal (i.e., from six weeks to three months). It has been suggested in the literature that the number of consultations per patient ranged generally between one and 11 annually for foot and ankle problems in primary care.[22] This indicator has been achieved to a certain extent.

Indicator 5: Cost Incurred by the UPMC and the Patient

The total cost of the partnership with the UPMC was $10,027 CAD, which covered the initial and subsequent follow-up consultations. In the cases evaluated, patients had to pay a total of $4,155 CAD for expenses that would not have been covered by the public health system, e.g., foot orthotics, dressings, insoles, care products, specific medications, etc., In all cases, the average cost to the patient of their treatments was $64 CAD (minimum of $0 CAD for consultation only; maximum of $435 CAD for orthotic treatment) whereas for the UPMC, the average cost was $154 CAD (including initial consultation and subsequent follow-ups (minimum of $45 CAD for an initial consultation only; maximum of $1378 CAD for initial consultation and all follow-ups [wound care]). Some patients have been able to make claims to third-party payers, such as private insurance companies to cover their costs, but we do not have these details. This indicator has been achieved.

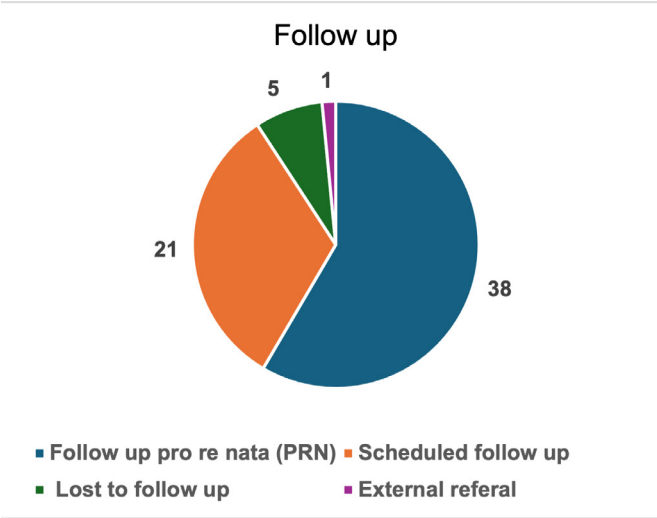


Figure 4: Follow-up

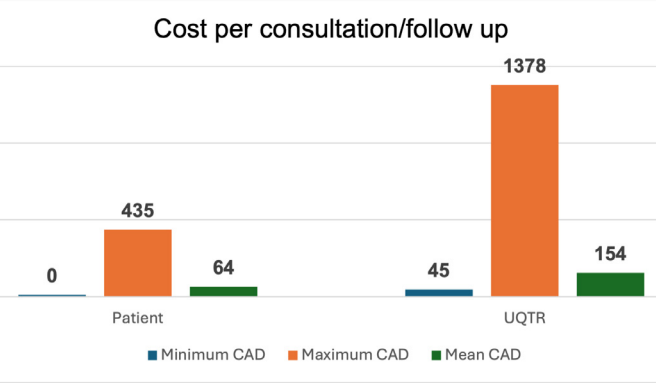


Figure 5: Cost in Canadian Dollars (CAD)

Subjective Indicator: Report on the Audit Process
Identifying cases from invoices was the easiest way to conduct this clinical audit. However, it would have been impossible to do so by going through the appointment system, as it is not possible to carry out data mining for specific data. The systems in place do not allow for easy retrieval of information, so it was necessary to search through patient files manually. This can lead to random and systematic errors in the accuracy of the data. The heterogeneity of information within the files, including the lack of standardized diagnosis, can lead to misinterpretation. Solutions to be explored undoubtedly include the use of information software to support rapid data searches within electronic medical files compatible with research and the use of coding to reduce the heterogeneity of treatments and diagnoses.[25] It was, unfortunately, not possible to find data on the experience of the stakeholders involved in this initiative (i.e. patients, clinicians, staff). In the future, it would be useful to implement an explicit feedback process for such initiatives. simultaneously. Indeed, improvements are needed to implement quality assessments for optimal care, teaching best practices and maximize the potential for clinical research within the UPMC.

Conclusion

The foot care trajectory between regional primary care providers and the UPCM should be better defined so that there is a common understanding of relevant cases for student training while meeting the needs of patients and primary care physicians. Against all expectations, the referred cases were more related to foot care and musculoskeletal disorders, which may reflect the regional characteristics of the ageing population and its needs. Although the initial idea was innovative, and the budget respected, the objectives were only partially achieved, even though the UPMC participation in the community's foot health services undoubtedly benefited from this primary care partnership. Before pursuing this type of initiative, it is necessary to better define the trajectory with our partners while improving our internal processes to enable us to evaluate the quality of care and impact of the investment.

Action Plan

Another audit is not planned for the moment. This audit demonstrates the urgency of developing and implementing a foot health care pathway between publicly-funded primary care clinics and the UPMC within the CIUSSS-MCQ's territory. We must not wait for another health crisis and other obstacles, or even budget renewal. Considering that the UPMC is part of the regional health system, action is needed to publicize available services, thus eliminating referral barriers, which are an obstacle to welcoming patients in need. Moreover, the budget allocated for this project was exceptional. However, it would still be appropriate for the University to investigate a sustainable long-term funding model, particularly to contribute to the community for the most vulnerable populations, and/or to meet training needs. There are already community partnership initiatives at UPCM (e.g., with COMPSEP [the Mauritian Organization Center for Services and Popular Education] which is a community organization bringing together individuals and families living in poverty), Municipal Housing Office of Trois-Rivières (OMH-TR); and for the members of Diabetes Mauricie, but we don't understand the impact of the UPCM (financial or otherwise). On the other hand, it would be a great opportunity to align these implications with the institutional strategic plan.

The audit revealed a gap in follow-up communication with referring physicians (only 31% compliance), despite clear request from the clinical director (MPM). Therefore, program and clinical leadership will need to look at concrete solutions with program committees, supervisors (professors and lecturers) and students, such as implementing mandatory procedure in the UPMC clinical practice guidelines for referral pathways and levers impacting student assessments. Considering that it has no accreditation within the podiatric medicine program, being the only one in Canada, it is important that indicators of the quality of care, indicators of the quality of teaching and the

minimum competencies required by students be developed, implemented and validated within the institution and across program-related clinical settings such as UPMC. Efforts have been made to establish a competency framework for podiatry training aligned with Québec College of podiatry and context,[26,27] but this project is slow to be implemented and prioritized.

Research projects could be set up to define and harmonize the expectations of both primary care clinics and the UPMC or other fee-for-service community podiatry clinics. This would allow podiatric medicine to take its rightful place within the primary health-care system, particularly within interprofessional teams. It might also be useful to obtain data to establish the podiatrist as a specialized professional in the professional services request form of the Regional Service Request Distribution Centre or, more easily, the podiatrist as professional services available in public establishments in the same way as occupational therapists, physiotherapists and stoma therapists. That makes it possible to limit requests to certain reasons for consultation, depending on locally available resources and the priorities determined by the CIUSSS. After all, considering that Trois-Rivières is the incubator of podiatric medicine education in Québec, the research and the methods can be useful and serve as an example for all of Québec. Due to its position, the UQTR has a political and organizational leadership role to play.

Finally, this audit also highlighted the difficulty of finding data in the clinical system and the heterogeneity of the information indexed. It is essential that the clinic develop a concrete audit and research plan with the stakeholders to facilitate data mining to ensure quality control and maximize the potential of an academic clinic for research projects.

Funding

This audit was financed by the discretionary research budgets of OH and VB, particularly to support YA's salary as a research assistant.

Acknowledgements

The authors wish to thank Nathalie Giroux, coordinator of the University Podiatric Medicine Clinic, for her support for this audit. Thanks also to the UQTR for the funds invested in patient care and support education, to the various partners, such as clinical staff, clinicians, including referring primary care physicians, students and patients.

Virginie Blanchette* PhD DPM is a podiatrist and Associate Professor at the Université du Québec à Trois-Rivières (Trois-Rivières, Québec, Canada). She is a knowledge mobilization researcher for the prevention and management of diabetes-related foot complications. (VB)

Yassin Andoulsi DPM (c) is a podiatric medicine student at the Université du Québec à Trois-Rivières (Trois-Rivières, Québec, Canada). As part of a research internship, he collected these audit data to build his research capacity. (YA)

Marie-Philippe Mercier DPM MSc is a podiatrist and clinical professor at Université du Québec à Trois-Rivières (Trois-Rivières, Québec, Canada). She was the co-director of the University Podiatric Medicine Clinic at Trois-Rivières during the COVID-19 crisis and launched the partnership initiative. (MBM)

Olivier Hue PhD is Professor at the Université du Québec à Trois-Rivières (Trois-Rivières, Québec, Canada). He is the program director. He supported the instigation of the measures taken at the University Podiatric Medicine Clinic and ensured links with the university's decision-makers. (OH)

Magali Brousseau-Foley MD DPM Phd (c) is a family physician and Associate Professor at the Université du Québec à Trois-Rivières (Trois-Rivières, Québec, Canada). She is completing her doctoral studies on physical activity benefits and primary care management of people with diabetes and complex medical needs namely diabetic foot disease and cardiorespiratory complications. (MBF)

***Corresponding author:**
Virginie.Blanchette@uqtr.ca

References

1. Ordre des podiatres du Québec. Qu'est-ce qu'un podiatre? Avaialable from: http://ordredespodiatres.qc.ca/public/quest-ce-quun-podiatre/
2. UQTR. Doctorat de premier cycle en médecine podiatrique [dissertation]. Québec (QC): Université du Québec à Trois-Rivières; 2017.
3. Mochon R, Rose M, Blanchette V, Fait P, Corbin-Berrigan LA. Exploring workload, satisfaction and sense of safety of health care professionals dealing with musculoskeletal conditions in out-patient clinics during the COVID-19 pandemic. Musculoskeletal Care. 2023 Sep;21(3):926-931.
4. Etz RS, Solid CA, Gonzalez MM, Britton E, Stange KC, Reves SR. Telemedicine in Primary Care: Lessons Learned About Implementing Health Care Innovations During the COVID-19 Pandemic. Ann Fam Med. 2023 Jul-Aug;21(4):297-304.
5. Lin S, Sattler A, Smith M. Retooling primary care in the COVID-19 era. Elsevier; 2020:1831-1834.
6. Blanchette V, Hains S, Cloutier L. Establishing a multidisciplinary partnership integrating podiatric care into the Québec public health-care system to improve diabetic foot outcomes: A retrospective cohort. Foot (Edinb). 2019 Mar;38:54-60.
7. Paige NM, Nouvong A. The top 10 things foot and ankle specialists wish every primary care physician knew. Elsevier; 2006:818-822.
8. Chadwick P, Ambrose L, Barrow R, Fox M. A commentary on podiatry during the Covid-19 pandemic : Podiatry during the Covid-19 pandemic. J Foot Ankle Res. 2020 Oct 15;13(1):63.
9. Government of Canada. Panel on Resesarch Ethics. Tri-council policy statement: ethical conduct for research involving humans – TCPS 2 (2018). Available from: https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf
10. Godwin M. Conducting a clinical practice audit. Fourteen steps to better patient care. Can Fam Physician. 2001 Nov;47:2331-3.
11. Un regard averti sur l'état de santé de la population de la Maurie et du Centre-du-Québec. 2019.
12. Statistic Canada. Census profile: region de la Mauricie et Centre-du-Québec. Gouverrnement of Canada. Available from: https://www12.statcan.gc.ca/census-recensement/2016/dp-pd/prof/details/page.cfm?Lang=E&Geo1=HR&Code1=2404&Geo2=PR&Code2=24&SearchText=Region%20de%20la%20Mauricie%20et%20Centre-du-Québec&SearchType=Begins&SearchPR=01&B1=All&GeoLevel=PR&GeoCode=2404&TABID=1&type=0
13. Ordre des podiatres du Québec. Qu'est-ce qu'un podiatre? Avaialable from: http://ordredespodiatres.qc.ca/public/quest-ce-quun-podiatre/
14. UQTR. Doctorat de premier cycle en médecine podiatrique [dissertation]. Québec (QC): Université du Québec à Trois-Rivières; 2017.
15. Mochon R, Rose M, Blanchette V, Fait P, Corbin-Berrigan LA. Exploring workload, satisfaction and sense of safety of health care professionals dealing with musculoskeletal conditions in out-patient clinics during the COVID-19 pandemic. Musculoskeletal Care. 2023 Sep;21(3):926-931.
16. Etz RS, Solid CA, Gonzalez MM, Britton E, Stange KC, Reves SR. Telemedicine in Primary Care: Lessons Learned About Implementing Health Care Innovations During the COVID-19 Pandemic. Ann Fam Med. 2023 Jul-Aug;21(4):297-304.
17. Lin S, Sattler A, Smith M. Retooling primary care in the COVID-19 era. Elsevier; 2020:1831-1834.
18. Blanchette V, Hains S, Cloutier L. Establishing a multidisciplinary partnership integrating podiatric care into the Québec public health-care system to improve diabetic foot outcomes: A retrospective cohort. Foot (Edinb). 2019 Mar;38:54-60.
19. Paige NM, Nouvong A. The top 10 things foot and ankle specialists wish every primary care physician knew. Elsevier; 2006:818-822.
20. Chadwick P, Ambrose L, Barrow R, Fox M. A commentary on podiatry during the Covid-19 pandemic : Podiatry during the Covid-19 pandemic. J Foot Ankle Res. 2020 Oct 15;13(1):63.
21. Government of Canada. Panel on Resesarch Ethics. Tri-council policy statement: ethical conduct for research involving humans – TCPS 2 (2018). Available from: https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf
22. Godwin M. Conducting a clinical practice audit. Fourteen steps to better patient care. Can Fam Physician. 2001 Nov;47:2331-3.
23. Un regard averti sur l'état de santé de la population de la Maurie et du Centre-du-Québec. 2019.
24. Statistic Canada. Census profile: region de la Mauricie et Centre-du-Québec. Gouverrnement of Canada. Available from: https://www12.statcan.gc.ca/census-recensement/2016/dp-pd/prof/details/page.cfm?Lang=E&Geo1=HR&Code1=2404&Geo2=PR&Code2=24&SearchText=Region%20de%20la%20Mauricie%20et%20Centre-du-Québec&SearchType=Begins&SearchPR=01&B1=All&GeoLevel=PR&GeoCode=2404&TABID=1&type=0
25. James K, Orkaby AR, Schwartz AW. Foot Examination for Older Adults. Am J Med. 2021 Jan;134(1):30-35.
26. Thouez JP, Bussière Y. Vieillissement de la population et déséquilibres démographiques au Québec, 2001-2021. Canadian Journal of Regional Science/Revue canadienne des sciences régionales. 2008 Jul 1;31(2).
27. Hunt K, Ford G, Harkins L, Wyke S. Are women more ready to consult than men? Gender differences in family practitioner consultation for common chronic conditions. J Health Serv Res Policy. 1999 Apr;4(2):96-100.
28. Guidozzi F. Foot problems in older women. Climacteric. 2017 Dec;20(6):518-521.
29. O'Neill J, Tabish H, Welch V, Petticrew M, Pottie K, Clarke M, et al. Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. J Clin Epidemiol. 2014 Jan;67(1):56-64.
30. Corscadden L, Levesque JF, Lewis V, Strumpf E, Breton M, Russell G. Factors associated with multiple barriers to access to primary care: an international analysis. Int J Equity Health. 2018 Feb 20;17(1):28.
31. Tehan PE, Donnelly H, Martin E, Peterson B, Hawke F. Experiences and impact of a rural Australian high-risk foot service: A multiple-methods study. Aust J Rural Health. 2024 Apr;32(2):286-298.
32. Menz HB, Williams CM, Lazzarini PA, Gordon J, Harrison C. Foot, ankle, and leg problems in Australian primary care:

consultation patterns, management practices, and costs. Fam Pract. 2024 Aug 14;41(4):426-433.
33. Rhim HC, Kwon J, Park J, Borg-Stein J, Tenforde AS. A systematic review of systematic reviews on the epidemiology, evaluation, and treatment of plantar fasciitis. Life (Basel). 2021 Nov 24;11(12):1287.
34. 22. Menz HB, Jordan KP, Roddy E, Croft PR. Characteristics of primary care consultations for musculoskeletal foot and ankle problems in the UK. Rheumatology (Oxford). 2010 Jul;49(7):1391-8.
35. McPherson M, Carroll M, Stewart S. Patient-perceived and practitioner-perceived barriers to accessing foot care services for people with diabetes mellitus: a systematic literature review. J Foot Ankle Res. 2022 Dec 16;15(1):92.
36. Bennett PJ. Types of foot problems seen by Australian podiatrists. Foot (Edinb). 2012 Mar;22(1):40-5.
37. Blundell J. Health information and the importance of clinical coding. Anaesthesia & Intensive Care Medicine. 2023 Feb 1;24(2):96-8.
38. 26. Andoulsi Y, Hue O, Brousseau M, Hill J, Alleyne J, Blanchette V. Competency framework for podiatric medicine training: a validation report based on an adapted e-delphi across Canada. J Med Educ Curric Dev. 2024 Feb 26;11:23821205241234974.
39. 27. Blanchette V, Andoulsi Y, Brousseau M, Leblanc C, Guillemette F, Hue O. Competency framework for podiatric medicine training in canada: an adapted Delphi Study. Adv Med Educ Pract. 2022 Oct 1;13:1207-1241.

SANTYL◊ Collagenase Ointment is available to the Canadian Market

Smith+Nephew

Collagenase
SANTYL◊
Ointment 250 units/gram

What is SANTYL Ointment?

SANTYL Ointment is a sterile ointment indicated for the debridement of dermal ulcers or severely burned areas.

How is SANTYL Collagenase Ointment applied?

Follow the steps below to apply SANTYL Ointment

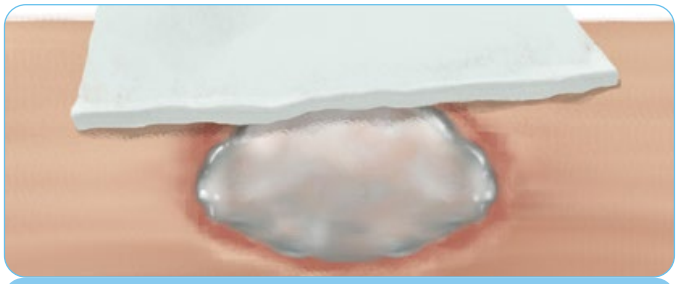
SANTYL Application steps:

1 Cleanse

Gently Cleanse the wound with a gauze pad saturated in normal saline.

2 Apply

Apply directly to deep wounds. In case of shallow wounds, apply to a sterile gauze pad which is then applied to the wound.
**Whenever infection is present, appropriate topical antibacterial agent is recommended.*



3 Cover

Cover with sterile gauze pad and secure.

4 Change

Change dressing daily.

For further guidance, please refer to the Canadian Product Monograph on the Drug Product Database.

Important Safety Information

Indications: SANTYL◊ Collagenase Ointment is indicated for debriding dermal ulcers and severely burned areas. **Contraindications:** SANTYL is contraindicated in patients who have shown local or systemic hypersensitivity to collagenase. **Warnings and Precautions:** The optimal pH range of collagenase is 6 to 8. Higher or lower pH conditions will decrease the enzyme's activity and appropriate precautions should be taken. The enzymatic activity is also adversely affected by certain detergents, and heavy metal ions such as mercury and silver which are used in some antiseptics. As such, the wound should be properly cleansed prior to application of SANTYL. Debilitated patients should be closely monitored for systemic bacterial infections because of the theoretical possibility that debriding enzymes may increase the risk of bacteremia. A slight transient erythema has been noted occasionally in the surrounding tissue, particularly when SANTYL was not confined to the wound. **Adverse Reactions:** No allergic sensitivity or toxic reactions have been noted in clinical use when used as directed. The risk information provided herein is not comprehensive. You are encouraged to report negative side effects of prescription drugs to Health Canada. Visit MedEffect Canada or call 1-866-234-2345.

Advanced Wound Management, Smith & Nephew, Medical Ltd, 2280 Argentia Road. Mississauga, Ontario. L5N 6H8. Canada.

Avoiding Long Antibiotic Regimen For Diabetic Foot Osteomyelitis Through Application Of Bioresorbable Calcium Sulfate Beads Impregnated With Tobramycin And Vancomycin: A Case Presentation

Catherine Boucher DPM, **Marie-Christine Torchon** DPM and **Sébastien Hains** DPM

Abstract: Diabetic foot osteomyelitis, given the multiple comorbidities of the patient, antibiotic resistance and potential for recurrence, poses a significant challenge for the treating clinicians and patients alike. Combinations of intravenous (IV) and oral (PO) antibiotic therapy, with or without surgical debridement, are standard treatment methods. The authors present a case of osteomyelitis cured through the application of bioresorbable calcium sulfate beads impregnated with tobramycin and vancomycin as an adjunct to surgical bone debridement. Simple offloading using isolation in felt was employed. This approach led to the complete healing of the infection and ulcer without recurrence, thereby avoiding hospitalization and amputation.

Key words: *osteomyelitis, diabetic foot, diabetic foot infection, antibiotics, antibiotic therapy, antibiotic beads, tobramycin, vancomycin*

How to cite: Boucher C, Torchon MC, Hains S. Avoiding long antibiotic regimen for diabetic foot osteomyelitis through application of bioresorbable calcium sulfate beads impregnated with tobramycin and vancomycin: a case presentation. 2025;6(1): 86-94. DOI: 10.56885/649254lcvszc

Infections of the diabetic foot, including osteomyelitis, present challenges at multiple levels for both clinicians and affected patients. Over a third of diabetic patients develop foot wounds during their lifetime, more than half of which complicate into infections involving soft tissues and bones.[1] Diabetic foot osteomyelitis (DFO) results from peripheral neuropathy causing insensitivity in the foot, allowing wounds to progress painlessly and unfavourably without strict offloading and regular monitoring. Intermittent loading of the wound directs surface bacteria towards deeper tissues, promoting their propagation. They are associated with high morbidity, prolonged hospital stays, amputations and significant health-care costs. In Canada, 70% of non-traumatic lower limb amputations in hospitals are diabetes-related, with 85% preceded by plantar ulcers.[2,3] Therefore, these comorbid patients require comprehensive management when ulceration with osteomyelitis occurs. However, there currently exists no precise consensus on treatment selection.

Historically, aggressive surgery with amputation was considered the treatment of choice, often leading to poor wound healing, further ulcers and the need for more proximal amputations. Today, systemic antibiotic therapy is prioritized, whether

parenteral, enteral or a combination, although detailed consensus on preferred antibiotics, route of administration or optimal treatment duration remains lacking. Oral therapy has shown similar efficacy to IV treatment, with lower costs and fewer side effects, but limitations persist, particularly in patients with concurrent arterial and kidney diseases, complicating antibiotic and dose selection.[4]

Many clinicians are now considering the use of local antibiotics for DFO. These methods have been studied and applied in non-diabetic orthopedic surgery and trauma, primarily using non-resorbable polymethylmethacrylate (PMMA) beads and more recently resorbable calcium sulfate beads.[5,6] These treatments aim to prevent infection from orthopedic implants and/or treat osteomyelitis.

Local delivery of antibiotics via resorbable calcium sulfate beads is relevant in DFO treatment due to their advantages: potential reduction in required antibiotic quantities, ability to achieve high local concentrations, limited systemic absorption, minimal side effects and safety in relation to antibiotic resistance.[7,8] During the beads' degradation, additional antibiotic is released, which prolongs their action, preventing biofilm formation on their surface.[9] Beads can also act as filling agents following resection of the affected bone.

This clinical case presents a patient with diabetic foot ulcer complicated by contiguous osteomyelitis and recurrent bone exposure, ultimately cured with the assistance of tobramycin and vancomycin-impregnated calcium sulfate beads as adjuncts to surgical debridement.

Case Presentation

A 57-year-old man with a medical history of type II diabetes since 2010, treated with insulin, presented with peripheral neuropathy, atherosclerotic vascular disease (ASVD) with a right femoropopliteal bypass in 2019. He is an active smoker (35 pack-years) with chronic obstructive pulmonary disease, congestive heart failure, hypertension, dyslipidemia, multiple osteomyelitis episodes in the right foot (2013, 2014, 2016, 2017, 2019) leading to amputations (right 4th metatarsal head in 2014, right 3rd toe and 3rd metatarsal head in 2012) and benign prostatic hyperplasia. He has been followed at the University Podiatric Wound Care Clinic at Lanaudière's Hospital in Québec since 2016. His lower limb vascular status shows right ankle-brachial index (ABI) of 0.94 and left ABI of 0.84. It should be noted that in diabetic patients with ASVD, the ABI measurement has low diagnostic sensitivity due to frequent peripheral arterial calcification.[10] Auditory Doppler would be a more representative measure of arterial status. In his case, the right posterior tibial and dorsal pedis arteries are biphasic (Saint-Bonnet stage A) and left arteries are monophasic with systolic crest blunting (Saint-Bonnet stage CD).[11]

On May 15, 2023, the patient presented a wound under the 2nd right metatarsal, chronicized since March 2022 due to non-compliance with offloading and suboptimal hygiene exacerbated by his physical maintenance work as a hunting and fishing outfitter. The wound now exposed the metatarsal head with a communicating sinus to the 2nd right toe medially. Heat, swelling and significant erythema are noted at the 2nd toe, radiating to the forefoot, but without systemic involvement. The patient cannot specify how long his right foot has been in this condition, but a month earlier during a podiatry appointment, no signs of infection were noted around the wound measuring 2.5x1.3x0.2 cm under the 2nd metatarsal.

The patient has a history of 2nd metatarsal head osteomyelitis, noted in July 2022 and treated with piperacillin/tazobactam for only five days, as the patient refused longer IV treatment. A switch to oral trimethoprim/sulfamethoxazole (TMP/SMX) for six weeks was implemented at that time. Healing of the osteomyelitis was confirmed by the normalization of the C-reactive protein and disappearance of bone contact on examination, but the ulcer persisted.

A radiograph on May 15, 2023, showed signs of osteomyelitis, metaphyseal-diaphyseal osteolysis with eccentric cortical rupture of the 2nd metatarsal head and periosteal reaction at the base of the proximal phalanx (See Figure 1).

Figure 1: Dorsoplantar (DP) X ray of the right foot, May 15, 2023

A conservative surgical debridement with sterile saline water of the wound was performed to remove calluses causing pressure on the wound and dead tissue. The application of an absorbable dressing under the 2nd metatarsal wound and a 1/4-inch wick for the 2nd toe to be changed every two days was performed. The recommendation to wear a short pneumatic offloading boot at all times was reiterated, since the wound is on a weight-bearing surface and a prescription of amoxicillin/clavulanate PO for four weeks was started because of the wound infection. A deep wound pus culture at that time revealed infection with *Staphylococcus epidermidis* and complex *Enterobacter cloacae*, both resistant to penicillin, prompting a change in antibiotics to TMP-SMX PO for two weeks on June 2nd. Blood test results showed an increase in the C-reactive protein to 10.6 mg/L, but no increase in leukocytes.

At the follow-up on May 19, no improvement of the wounds or the infection was noted in the patient's condition (See Figures 2 & 3). Therefore, 10 absorbable calcium sulfate beads in a mixture of 10 mL of the beads with 3 mg of tobramycin and 1 g of vancomycin were applied to both wounds as a local antibiotic treatment. Non-adherent dressings were now recommended for dressing changes.

Figure 2: Wound under the head of the 2nd right metatarsal bone exposing the bone, May 19, 2023

Figure 3: Transfixing wound on the 2nd right toe with redness and swelling of the toe, May 19, 2023

Four days later, on May 26, the patient mentioned feeling a burning sensation in his foot as the only side effect of the beads. This was only one day after the application of the beads. On physical examination, signs of infection persisted without improvement of the wounds, but without systemic infection symptoms. The wound edge was macerated, with serous discharge soiling the dressing by 40%, which was the norm for the patient even well before beads application. The treatment plan was maintained.

On June 2, the 2nd metatarsal head was now mobile at the centre of the wound. At this time, a diabafoam (made of plastazote and poron) sole with an isolation under the 2nd metatarsal head was applied in the offloading boot. Knowing he would not comply with complete offloading in the boot, pieces of 10 mm felt covering the forefoot with isolation at the 2nd metatarsal head were provided to the patient for his work boots. Plain radiographs (See Figure 4) showed that the beads applied on May 19 were no longer visible.

Figure 4: DP X-ray of the right foot, June 2, 2023

Despite the continued evolution of his condition, the patient refused to be seen in Infectious Diseases or Orthopaedics. He also rejected recommendations of complete bed rest and IV antibiotic therapy.

On June 9, no improvement was noted in the patient's condition, therefore a better control of the infection source was needed. Under sterile protocol, the right 2nd metatarsal head was resected via the wound with a double-action bone cutter and rongeur. Subsequently, 15 Stimulan Rapid Cure® beads of the same tobramycin mixture with vancomycin were inserted into and around the osseous resection site. A non-adherent greasy dressing, to be changed in two days, was applied. In addition, a new 10 mm felt piece with an isolation under the 2nd metatarsal head was adhered to the dressing

directly on the foot. The patient was advised on the importance of wearing the felt sole and the offloading boot at all times. A plain X ray was taken to ensure proper bead placement and complete transverse resection of the 2nd metatarsal head (See Figure 5).

Figure 5: DP X-ray of the right foot with antibiotics beads

Figure 6: DP X-ray of the right foot, August 28,2023

At the four-day post-op follow-up, the patient reported no pain or other side effects but had not changed his dressing as recommended. He claimed to have worn the offloading boot at all times but still seemed to be 'working with it' and the felt sole. Significant improvement in wound size and appearance was noted. Now linear and measuring 1x0.4 cm, the wound showed no signs of infection.

During follow-ups from July to September 2023, the wound continued to shrink, and probe-to-bone disappeared. Plain X rays taken on August 28 showed the disappearance of antibiotic beads and bone remodeling distally to the diaphysis of the 2nd metatarsal (See Figure 6).

As of September 6, 2023, the wound under the 2nd metatarsal was completely healed. Offloading with diabafoam and a felt sole in his shoes was continued until a custom accommodative foot orthosis was provided on March 26, 2024. More than 12 months post-op, there was no recurrence of the ulcer or osteomyelitis under the right 2nd metatarsal (See Figures 7 & 8).

Figure 7: Healed wound under right foot, September 6, 2023

Figure 8: No recurrence of the wound, May 13, 2024

Discussion

Treating diabetic foot osteomyelitis (DFO) poses a significant challenge due to the increasing prevalence of antibiotic-resistant bacteria and poor antibiotic penetration into bone. It is a costly complication of diabetic foot ulcers for patients and health-care systems. Despite adequate surgical and medical treatment, the recurrence rate of DFO exceeds 40%, thereby increasing the risk of major amputation.[12,13] Most of these patients also suffer from peripheral arterial disease, which further limits the effectiveness of systemic antibiotic therapy.[14] Minimum inhibitory concentration (MIC), the lowest concentration of antibiotic that inhibits bacterial growth, plays a crucial role in selecting appropriate antibiotics and their mode of administration. While current systemic antibiotics generally achieve sufficient concentrations to reach the target MIC, the biofilm present in these infections significantly increases antibiotic tolerance, sometimes up to 1000-fold, rendering MIC alone insufficient for predicting treatment efficacy.[15] In the vast majority of cases, microorganisms involved in DFO are organized within biofilms.[16,17] Therefore, it is essential to treat with antibiotics that penetrate bone well and maintain activity against bacteria in reduced metabolic states typical of biofilms. Several in vitro studies have demonstrated the effectiveness of absorbable calcium sulfate beads against bacterial biofilms, supporting their use in this context. [18-22]

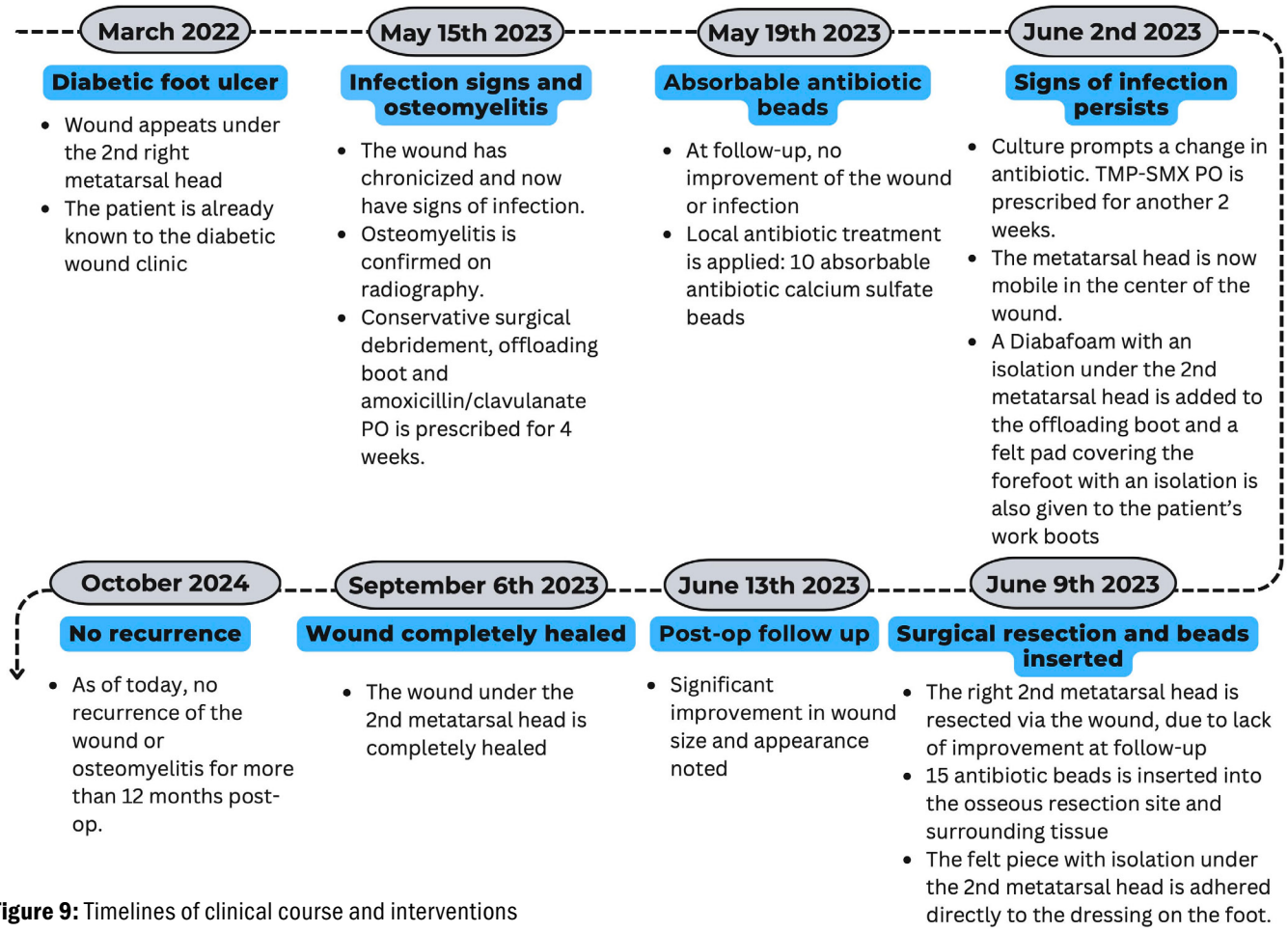


Figure 9: Timelines of clinical course and interventions

Furthermore, local administration of antibiotics via beads has been shown to achieve antibiotic concentrations more than 50 times higher than necessary to inhibit many bacteria found in intra-articular infections.[19,20]

Antibiotic-loaded bioresorbable calcium sulfate beads have been used for several years primarily for musculoskeletal infections (bone, soft tissue) with varying efficacy rates.[23,24] However, few published studies have evaluated their effectiveness for diabetic foot infections, most being case series with short-term follow-ups (less than three months).[25-29] A retrospective cohort study from 2024,[30] evaluating recurrence of DFO, found high rates of ulcer persistence and osteitis recurrence at 12 months among 45 patients who underwent surgical intervention with 10 mL calcium sulfate beads containing either vancomycin, tobramycin, gentamicin, linezolid or meropenem, along with a systemic antibiotic treatment. They noted increased wound drainage (in 28 patients) associated with ulcer persistence at three and six months as the main side effect. In contrast, our case study shows eradication of osteomyelitis without recurrence of osteomyelitis or ulcer at 12 months and no increase in exudate following beads application. We believe that resection of the infected 2nd metatarsal head with application of fewer mL of beads into the wound, along with pressure-relieving measures to prevent maceration, contributed to this outcome. A case series from 2021[31] demonstrated similar results. Out of 106 patients requiring surgical intervention for osteomyelitis, ranging from debridement to amputation, and receiving adjuvant bioresorbable beads with meropenem, colistin or vancomycin, 98 showed no recurrence of infection (follow-up up to 16 weeks). A recent review by Chatzipapas et al. (2021)[32] presents findings that differ from those of

our clinical case. The review analyzed 16 studies on local antibiotic delivery systems in DFO, including three randomized controlled trials (RCTs). The RCTs indicated that gentamicin-impregnated collagen sponges significantly improved clinical healing rates and slightly reduced hospitalization duration. However, retrospective studies on antibiotic-impregnated calcium sulfate beads showed non-significant improvements in healing parameters and no reduction in post-operative complications. Their results suggest that while certain local antibiotic delivery methods may offer benefits, the efficacy of antibiotic-loaded beads, particularly calcium sulfate-based ones, remains inconclusive. This contrasts with our findings of a successful healing using antibiotic loaded beads.

In 2011, Gauland used bioresorbable beads for lower limb osteomyelitis treatment without oral or IV antibiotics in 354 patients followed over five years.[13] Over 86% of patients showed wound healing without infection after surgical debridement and the application of antibiotic-impregnated bioresorbable beads. These results raise questions about the necessity of surgical debridement for local antibiotic application. This was evaluated in a retrospective cohort study of 50 patients, comparing the efficacy of calcium sulfate beads in healing osteomyelitis with and without surgical debridement.[31] Their results showed no significant difference in healing time between the two groups.

With increased use of bioresorbable calcium sulfate beads comes the discovery of associated complications. The main side effect in soft tissues appears to be increased wound drainage, promoting maceration in surrounding tissues and slowing healing time.[33] One explanation may be the more superficial placement in soft tissues for DFO compared to deeper placement in bones for knee orthopedic procedures. Using an adequate quantity of beads relative to wound size may help reduce drainage.[33] No systemic or local complications related to antibiotic beads use were noted in our patient's case.

To reduce recurrences and promote healing, it is crucial to manage underlying conditions predisposing patients to osteomyelitis episodes. This involves relieving pressure on the wound through offloading or surgically correcting foot deformities.[14] In this clinical case, isolation in 10mm felt ultimately allowed the patient to adhere to wound offloading, after attempts with a short pneumatic offloading boot that the patient could not properly wear. This technique, not tried earlier in the wound's evolution, was more suited to the patient's lifestyle and activities. We believe this contributed to osteomyelitis healing. Felt is an effective offloading modality, reducing pressure on the ulcer by 49%.[34] It requires regular changes, as its effectiveness diminishes to 32% after one week.[33]

Complications related to diabetic foot cost the Canadian health-care system over $150 million CAD annually.[5] The cost of Stimulan Rapid Cure® calcium sulfate bead treatment at time of publication is $870 CAD for 10 mL, and the cost of vancomycin and tobrsmycin is $48.23 CAD.[36] Less than a third of the mixture (beads and antibiotics) was applied to this patient for both combined applications. The total cost of this treatment would be $306.08 CAD, not including professional fees. By comparison, a six-week IV ertapenem antibiotic treatment in the province of Québec, excluding hospitalization costs and health-care professional fees, costs $2,337.75 CAD.[36]

IV treatment improves treatment adherence compared to oral treatment but entails significant costs and multiple complications. A study by Henry and Lundy[37] on systemic antibiotic treatment of hand osteomyelitis mentions an average cost of $482.85 USD for a patient taking oral antibiotics vs $21,646.90 USD for IV treatment in the United States. According to the OVIVA[4] study, switching from IV to oral antibiotics reduces hospitalization duration and associated costs. Although oral treatment seems an interesting option, it also has limitations such as longer antibiotic duration, increasing the risk of side effects, including *Clostridium difficile* diarrhea and antibiotic resistance. Thus, local antibiotic offers several advantages for DFO's treatment, both microbiologically and economically. The relevance

of this particular clinical case lies in the clinical healing of osteomyelitis and ulcers in 12 weeks without recurrence at 12 months. It is interesting to note that PO antibiotic treatment followed by administration of tobramycin and vancomycin-loaded calcium sulfate beads in the wound alone showed little improvement in the patient's clinical condition. Rather, complete healing was achieved with necrotic bone tissue resection combined with bead cavity filling and felt offloading. Additionally, the ease and speed of performing the procedure in an outpatient setting without hospitalization represent additional significant strengths of this clinical case. Indeed, like this patient, the diabetic population with DFO unfortunately does not always have the motivation or willingness for complete multi-day hospital-based care, given their history of multiple amputations and IV antibiotics. In this case, the 2022 DFU became chronic and infected primarily due to lack of adherence to offloading and regular wound care follow-ups. Given the patient's categorical refusal to consult with infectious disease or orthopaedic specialists, post-resection local antibiotic treatment with work-adapted offloading helped avoid hospitalization and amputation. However, this case presentation is limited by its single-patient design, which prevents generalization of the findings, and the lack of long-term comparative data to assess the broader efficacy of antibiotic beads in DFO.

Conclusion

Biodegradable calcium sulfate antibiotic beads impregnated with tobramycin and vancomycin have proven to be an effective adjunct local antibiotic therapy option in the treatment of diabetic foot osteomyelitis following surgical resection of infected bone. In the context of an integrated approach for patients without significant vascular compromise, they enable targeted treatment of infection combined with surgical offloading, resulting in durable healing without transfer lesions. These beads have demonstrated efficacy in resolving persistent infections, even alongside systemic antibiotic therapy and despite the patient's adamant refusal of infectious disease and orthopaedic consultations. This treatment modality is particularly beneficial in cases of polymicrobial osteomyelitis, offering flexibility to locally combine different antibiotics specific to isolated pathogens while achieving maximum concentrations with minimal or no systemic effects.

Moreover, this treatment is cost-effective and requires fewer resources compared to conventional intravenous antibiotic therapies. It is hoped that this article will increase awareness of this therapeutic approach, making it accessible to more patients and thereby reducing the human and financial burden associated with DFO, which often leads to hospitalizations and lower limb amputations. In conclusion, well-designed double-blind randomized controlled trials are needed to confirm whether the use of local antibiotics improves the healing of diabetic foot osteomyelitis and reduces recurrence rates.

Patient consent and Ethical Approval: Written informed consent was obtained from the patient for the publication of this case report, with the inclusion of clinical details and accompanying images. The authors have ensured that all identifying information has been removed to protect patient confidentiality. Authors were informed by Research Direction of Lanaudière's Hospital that ethical approval was not required for this case report, since it describes a single clinical case without experimental interventions.

Catherine Boucher DPM is in private practice and a third-year medical student at Université de Montréal, Québec, Canada

Marie-Christine Torchon DPM is Professor of Clinical Sciences Podiatric Medical Program, Université du Québec à Trois-Rivières, Québec, Canada

Sebastien Hains DPM is Professor of Clinical Sciences Podiatric Medical Program, Université du Québec à Trois-Rivières, Québec, Canada.

References

1. Ndosi M, Wright-Hughes A, Brown S, Backhouse M, Lipsky BA, Bhogal M, et al. Prognosis of the infected diabetic foot ulcer: a 12-month prospective observational study. Diabet Med. 2018 Jan;35(1):78-88.
2. Public Health Agency of Canada. Diabetes in Canada: facts and figures from a public health perspective. Ottawa; 2011. Available from: http://www.phac-aspc.gc.ca/cd-mc/diabetes-diabete/indexeng.php
3. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA. 2005 Jan 12;293(2):217-28.
4. Li HK, Rombach I, Zambellas R, Walker AS, McNally MA, Atkins BL, et al; OVIVA Trial Collaborators. Oral versus intravenous antibiotics for bone and joint infection. N Engl J Med. 2019 Jan 31;380(5):425-436.
5. Stabile DE, Jacobs AM. Local antibiotic treatment of soft tissue and bone infections of the foot. J Am Podiatr Med Assoc. 1990 Jul;80(7):345-53.
6. Jacobs AM, Seifert AM, Kirisits TJ, Protzel HR. Use of antibiotic-loaded bone cement in the management of common infections of the foot and ankle. Clin Podiatr Med Surg. 1990 Jul;7(3):523-44.
7. Markakis K, Faris AR, Sharaf H, Faris B, Rees S, Bowling FL. Local antibiotic delivery systems: current and future applications for diabetic foot infections. Int J Low Extrem Wounds. 2018 Mar;17(1):14-21.
8. Lipsky B, Hoey C. Topical antimicrobial therapy for treating chronic wounds. Clin Infect Dis. 2009;49(10):1541-1549.
9. Lipsky B, Kuss M, Edmonds M, Reyzelman A, Sigal F. Topical application of a gentamicin-collagen sponge combined with systemic antibiotic therapy for the treatment of diabetic foot infections of moderate severity: a randomized, controlled, multicenter clinical trial [published correction appears in J Am Podiatr Med Assoc. 2012 Jul-Aug;102(4):323]. J Am Podiatr Med Assoc. 2012;102(3):223-232.
10. Abouhamda A, Alturkstani M, Jan Y. Lower sensitivity of ankle-brachial index measurements among people suffering with diabetes-associated vascular disorders: a systematic review. SAGE Open Med. 2019 Mar 1;7:2050312119835038.
11. Mahé G, Boulon C, Désormais I, Lacroix P, Bressollette L, Guilmot J, et al. Recommandations du Collège des enseignants de médecine vasculaire (CEMV): analyse des flux artériels Doppler (classification de Saint-Bonnet simplifiée). J Med Vasc. 43(4):255-261.
12. Dutra LMA, Melo MC, Moura MC, Leme LAP, De Carvalho MR, Mascarenhas AN, et al. Prognosis of the outcome of severe diabetic foot ulcers with multidisciplinary care. J Multidiscip Healthc. 2019 May 2;12:349-359.
13. Gauland C. Managing lower-extremity osteomyelitis locally with surgical debridement and synthetic calcium sulfate antibiotic tablets. Adv Skin Wound Care. 2011;24(11):515-523.
14. Lipsky B, Aragón Sánchez J, Diggle M, Embil J, Kono S, Lavery L, et al. IWGDF guidance on the diagnosis and management of foot infections in persons with diabetes. Diabetes Metab Res Rev. 2016;32(1):45-74.
15. Howlin R, Brayford M, Webb J, Cooper J, Aiken S, Stoodley P. Antibiotic-loaded synthetic calcium sulfate beads for prevention of bacterial colonization and biofilm formation in periprosthetic infections. Antimicrob Agents Chemother. 2014;59(1):111-120.
16. Baudoux F, Neut C, Beltrand E, Lancelevee J, Lebrun C, Lemoiux O, et al. Pathogenicity factors in diabetic foot osteitis: study of bacterial care and capacity to form a biofilm. Diabetes Metab. 2012;38:A11.
17. Johani K, Fritz BG, Bjarnsholt T, Lipsky B, Jensen S, Yang M, et al. Understanding the microbiome of diabetic foot osteomyelitis: insights from molecular and microscopic approaches. Clin Microbiol Infect. 25(3):332-339.
18. Crowther G, Callaghan N, Bayliss M, Noel A, Morley R, Price B. Efficacy of topical vancomycin- and gentamicin-loaded calcium sulfate beads or systemic antibiotics in eradicating polymicrobial biofilms isolated from diabetic foot infections within an in vitro wound model. Antimicrob Agents Chemother. 2021;65(6).
19. Howlin R, Winnard C, Frapwell C, Webb J, Cooper J, Aiken S, et al. Biofilm prevention of gram-negative bacterial pathogens involved in periprosthetic infection by antibiotic-loaded calcium sulfate beads in vitro. Biomed Mater (Bristol, England). 2016;12(1):15002.
20. Batista Campos L, Kurihara M, Santos I, Dos Reis F, Salles M. In vitro elution characteristics of antibiotic-loaded polymethylmethacrylate cement and a calcium sulfate bone substitute using staphylococci isolated from orthopedic implant-associated infections. J Biomed Mater Res B Appl Biomater. 2023;111(6):1318-1327.
21. Kanellakopoulou K, Galanopoulos I, Soranoglou V, Tsaganos Y, Tziortzioti V, Maris I, et al. Treatment of experimental osteomyelitis caused by methicillin-resistant Staphylococcus aureus with a synthetic carrier of calcium sulfate (Stimulan) releasing moxifloxacin. Int J Antimicrob Agents. 2009;33(4):354-359.
22. Aiken S, Cooper J, Florance H, Robinson M, Michell S. Local release of antibiotics for surgical site infection management using high-purity calcium sulfate: an in vitro elution study. Surg Infect (Larchmt). 2015;16(1):54-61.
23. Gitelis S, Piasecki P, Turner T, Haggard W, Charters J, Urban R. Use of a calcium sulfate-based bone graft substitute for benign bone lesions. Orthopedics. 2001;24(2):162-166.
24. Papagelopoulos P, Mavrogenis A, Tsiodras S, Vlastou C, Giamarellou H, Soucacos P. Calcium sulfate delivery system with tobramycin for the treatment of chronic calcaneal osteomyelitis. J Int Med Res. 2006;34(6):704-712.
25. Patil P, Singh R, Agarwal A, Wadhwa R, Bal A, Vaidya S. Diabetic foot ulcers and osteomyelitis: use of biodegradable calcium sulfate beads impregnated with antibiotics for treatment of multidrug-resistant organisms. Wounds. 2021;33(3):70-76.
26. Armstrong D, Boulton A, Bus S. Diabetic foot ulcers and their recurrence. N Engl J Med. 2017;376(24):2367-2375.
27. Hutting K, Aan de Stegge W, van Netten J, Ten Cate W, Smeets L, Welten G et al. Surgical treatment of diabetic foot ulcers complicated by osteomyelitis with gentamicin-loaded calcium sulphate-hydroxyapatite biocomposite. J Clin Med. 2021;10(2):371.
28. Qin C, Zhou C, Song H, Cheng G, Zhang H, Fang J et al. Infected bone resection plus adjuvant antibiotic-impregnated calcium sulfate versus infected bone resection alone in the treatment of diabetic forefoot osteomyelitis. BMC Musculoskelet Disord. 2019;20(1):246.
29. Jogia R, Modha D, Nisal K, Berrington R, Kong M. Use of highly purified synthetic calcium sulfate impregnated with antibiotics for the management of diabetic foot

ulcers complicated by osteomyelitis. Diabetes Care. 2015;38(5):e79e80.
30. Alkayali T, Casciato D, Wynes J, Chua J, Doub J. Are biodegradable calcium sulfate antibiotic beads effective and safe adjuvants for diabetic foot osteomyelitis? Cureus. 2024;16(1):e52444.
31. Dekker A, Uzoho C, Scammell B. Do antibiotic-impregnated calcium sulfate beads improve the healing of neuropathic foot ulcers with osteomyelitis undergoing surgical debridement? Wounds. 2019;31(6):145-150.
32. Chatzipapas C, Karaglani M, Papanas N, Tilkeridis K, Drosos GI. Local antibiotic delivery systems in diabetic foot osteomyelitis: a brief review. Rev Diabet Stud. 2021 Nov 1;17(2):75-81.
33. McPherson E, Dipane M, Sherif S. Dissolvable antibiotic beads in treatment of periprosthetic joint infection and revision arthroplasty. The use of synthetic pure calcium sulfate (Stimulan®) impregnated with vancomycin & tobramycin. Reconstr Rev. 2013;3(1):32–43.
34. Raspovic A, Waller K, Wong W. The effectiveness of felt padding for offloading diabetes-related foot ulcers, at baseline and after one week of wear. Diabetes Res Clin Pract. 2016;121:166-172.
35. Health Care Innovation Working Group. From innovation to action: the first report of the Health Care Innovation Working Group. Ottawa, ON: Council of the Federation. 2012.
36. Sous-comité de surveillance de l'utilisation des Antibiotiques, CHU de Québec, Université Laval. Coûts des anti-infectieux (doses adultes) au CHU de Québec-Université Laval (bulletin numéro 26). Québec:CHU de Québec, 2017.
37. Henry M, Lundy FH. Oral antibiotic management of acute osteomyelitis of the hand: outcomes and cost comparison to standard intravenous regimen. Hand (N Y). 2021 Jul;16(4):535-541.

convatec
– forever caring –

DISRUPT, DESTROY, AND PREVENT REFORMATION OF BIOFILM![1-3]

Wounds not healing due to biofilm?

Aquacel® Ag+ Extra with Hydrofiber® and MORE THAN SILVER™ technology has **proven to heal or progress 78% of hard-to-heal wounds within 4 weeks.**[4]

= MORE THAN SILVER + Hydrofiber® TECHNOLOGY

References: 1. AWC-2023-036 More Than Silver™ antibiofilm technology differentiates Aquacel® Ag+ and Aquacel® Ag Advantage dressings from standard silver-containing dressings. Data on File. 2. 1708881v1 Instruction for Use, Convatec. 3. Bowler PG, Parsons, D. Combatting wound biofilm and recalcitrance with a novel anti-biofilm Hydrofiber® wound dressing. Wound Medicine 14 (2016) 6–11. 4. Metcalf DG, Parsons D, Bowler PG. Clinical safety and effectiveness evaluation of a new antimicrobial wound dressing designed to manage exudate, infection and biofilm. Int Wound J. 2017 Feb;14(1):203-213. doi: 10.1111/iwj.12590. Epub 2016 Mar 22. PMID: 27004423; PMCID: PMC7949869.

Scan for more information

For more information, please call our Customer Relations Center (Registered Nurses on staff) at **1-800-465-6302,** Monday through Friday, 8:00 AM to 6:00 PM (EST), or visit **convatec.ca**

Aquacel® Ag+ Extra

The Design Of A Psycho-Socioeconomic Biobehavioural Framework To Address Barriers To Adherence In Patients With Diabetes-Related Foot Ulceration

Jonathan Brocklehurst MSc MIRL MRCPod

Abstract: Diabetes mellitus is a chronic metabolic condition.[1] Related comorbidities such as peripheral neuropathy and lower extremity ischaemia can significantly increase the likelihood of the occurrence of a diabetes-related foot ulcer (DFU). The International Working Group on the Diabetic Foot (IWGDF) updated its latest guidelines in 2023 to address diabetes-related foot care across the world and champion lower limb preservation.[2,3] Further, with a podiatry workforce 'in crisis' in the United Kingdom and elsewhere, understanding the experiences of patients is important in establishing ways to provide and implement effective self-care regimes for patients in both private and public health practice.[4,5] Therefore, psycho-socioeconomic bio-behavioural barriers (PSB) are important in forming holistic considerations of patient adherence.[6] The Biopsychosocial Model (Engel 1977) and The Health Belief Model (Rosenstock 1988) provide an initial foundation for expansion on these themes.[8,9] The PSB framework is a novel concept which leverages these theories and suggests that motivational interviewing could serve as an initial psychological intervention to filter the key barriers to adherence in patients with a DFU.[10] This conceptual framework allows for the proposal of tailored multi-disciplinary interventions, such as accessible educational programs, to address specific barriers to adherence with the objective of contributing to lower limb preservation.[11-13]

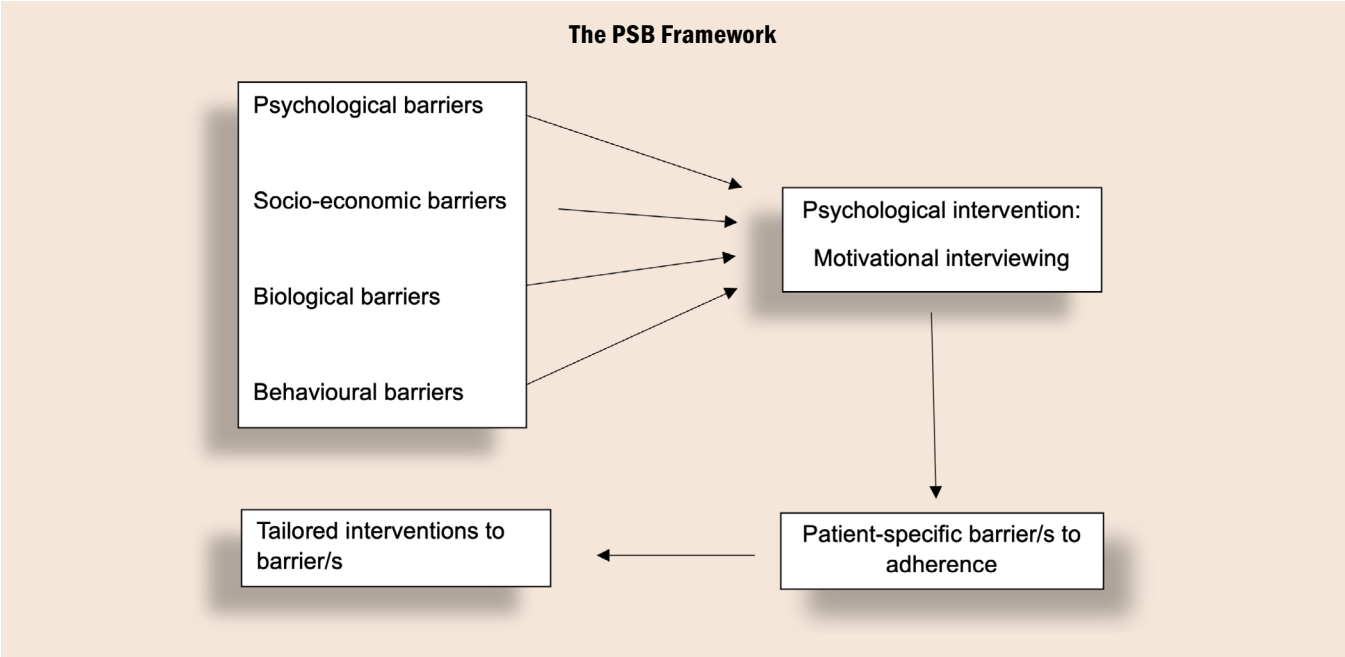
Key words: *diabetes mellitus, diabetic foot ulcer, podiatry, adherence, self-care, psycho-socioeconomic bio-behavioural barriers*

How to cite: Brocklehurst J. The design of a psycho-socioeconomic biobehavioural framework to address barriers to adherence in patients with diabetes-related foot ulceration. Limb Preservation Journal. 2025;6(1): 96-99. DOI: 10.56885/318249axecje

Holistic and compassionate care are synonymous with best practice in podiatry. However, achieving this with financial and resource constraints is a significant challenge to podiatrists both in the National Health Services in the United Kingdom (UK) and across Western Europe, as well as in private practices. For example, there are limited existing models which address barriers to adherence in health care, broadly spotlighting a need to focus on adherence in patients with diabetic foot ulcers (DFUs) to reduce the risk of complications that could lead to lower limb amputation.[14,15]

The International Working Group on the Diabetic Foot (IWGDF) have sought to advocate limb preservation by highlighting the importance of understanding an individual's barriers to adherence, particularly in offloading DFUs. Capturing the complexities of these barriers in a comprehendible format for clinicians is arguably vital in ensuring effective continuity of care and interprofessional communication.[16]

The objective for the innovation of the psycho-socioeconomic bio-behavioural barriers (PSB) framework is to establish barriers to adherence within a realistic and achievable timeframe with the goal of creating a tailored treatment and self-care plan for a patient with a DFU.[17]



Strengths

The PSB framework may be amendable and expandable, incorporating diversity within its demographic reach (i.e., Makaton/sign language) and harnessing cultural inclusivity to curb perceived barriers to adherence in a wide range of communities from remote rural villages to densely populated urban districts.[18] Therefore, socio-economic factors, such as modes of transportation, occupation and type of housing, can be ascertained from a patient within the introductory stages of a health-care appointment to assist a holistic management plan.[19]

Psychological and bio-behavioural factors can also be ascertained throughout an appointment with the use of motivational interviewing to establish the key barriers to adherence.[20] Using the PSB framework, the documentation of these barriers may provide individual clinicians and multi-disciplinary teams with a universally accessible reference point throughout a patient's treatment to support tailored care plans.[21] This increases the responsibility of establishing these barriers in the initial assessment period and may be an important timesaving guide for clinicians at each point across a patient's DFU care.[22]

By addressing barriers with the PSB framework, tailored interventions based on collective barrier identification could potentially provide national health services and systems with cost effective strategies to enhance neo-Weberian principles of citizen-orientated care while upholding the new public management structures across Western Europe and beyond.[6,23,24] By adopting both a neo-Weberian approach within a neo-liberal health-care system, the implementation of patient-orientated policies to the management of DFUs may pave the way for wider management reforms in addition to clinical judgments.[24]

Limitations

Potential drawbacks to using the PSB framework are the limited time and need for training to exercise motivational interviewing (MI) with desired effect. The skill and training required to achieve this leaves most clinicians subject to individual error and thus could limit the validity and reliability of the PSB framework.[25] Moreover, with MI reliant predominantly on face-to-face communication, a tailored approach is required for individuals with visual or audible impairments.[26] However, by prioritising some barriers over others, a progressive use of the PSB framework could be adopted to increase the specificity of the framework.[27] On the other hand, the responsibility of establishing these barriers in

the initial assessment period may not always be realistic within time constraints and is reliant on the rapport built between the clinician and patient, which may not always replicate in instances where there is a deficiency in continuity of care.[28]

Recently published data collated by Giarelli and Saks (2024) in *National Health Services of Western Europe* has suggested that neo-liberal societies, such as the United Kingdom and Sweden, have in recent years shown local variations and indications that, broadly speaking, health-care personnel experience a low degree of participation in strategic decision making.[23] This reveals a potential barrier to clinician-led innovation in response to non-adherence from patients.

Conclusion

In light of this analysis, a PSB-based template could be integrated into the 'Subjective' part of SOAP (Subjective, Objective, Assessment and Plan) notetaking in an initial assessment appointment. Qualitative studies are required to establish the efficacy of such a template in collecting important data pertaining to barriers to adherence.[29] The PSB framework has the potential to enhance tailorized care across all health-care sectors in addition to podiatry, particularly by creating a continuity of conveniently viewable information for the benefit of clinical handovers.[30] Establishing barriers to adherence could be more effective in counselling/psychotherapy appointments, which may account for more time to execute the PSB framework; crucially however, new patient assessment appointments could also incorporate the PSB framework to useful effect.[31] Therefore, future studies are required to establish barriers to adherence in patients with DFUs and establish the validity and reliability of the PSB framework with its potential application in clinical practice.[25] By changing the lens of a clinician, the focus becomes the patient with the objective of achieving lower limb preservation.

Jonathan Brocklehurst MSc MIRL MRCPod is a Member of the Royal College of Podiatry, Member of the Organizaton for Responsible Leadership and Member of the Society of Tissue Viability. He is based in the United Kingdom.

References

1. Bonnet JB, Sultan A. Social deprivation, healthcare access and diabetic foot ulcer: a narrative review. J Clin Med. 2022 Sep 15;11(18):5431.
2. International Working Group on the Diabetic Foot IWGDF guidelines. 2023 Update. Available from: https://iwgdfguidelines.org/wp-content/uploads/2023/07/IWGDF-2023-06-Offloading-Guideline.pdf
3. Bus SA, Armstrong DG, Crews RT, Gooday C, Jarl G, Kirketerp-Moller K, et al. Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2023 update). Diabetes Metab Res Rev. 2024 Mar;40(3):e3647.
4. Carroll M, Jepson H, Molyneux P, Brenton-Rule A. The New Zealand podiatry profession - a workforce in crisis? J Foot Ankle Res. 2020 Oct 12;13(1):62.
5. Beeler E, Brenton-Rule A, Carroll M. Recruitment and retention of the rural podiatry workforce in Aotearoa New Zealand: a qualitative descriptive study of podiatrist perceptions. J Foot Ankle Res. 2022 Aug 9;15(1):58.
6. Edwards MK, Loprinzi PD. Psycho-Socioeconomic bio-behavioral influences on health-related quality of life. Health Promot Perspect. 2017 Jun 14;7(3):124-127.
7. Loprinzi PD, Davis RE. Psycho-socioeconomic bio-behavioral associations on all-cause mortality: cohort study. Health Promot Perspect. 2016 Jun 11;6(2):66-70.
8. Engel GL. The need for a new medical model: a challenge for biomedicine. Psychodyn Psychiatry. 2012 Sep;40(3):377-96.
9. Rosenstock IM, Strecher VJ, Becker MH. Social learning theory and the Health Belief Model. Health Educ Q. 1988 Summer;15(2):175-83.
10. Binning J, Woodburn J, Bus SA, Barn R. Motivational interviewing to improve adherence behaviours for the prevention of diabetic foot ulceration. Diabetes Metab Res Rev. 2019 Feb;35(2):e3105.
11. Pyatak EA. The role of occupational therapy in diabetes self-management interventions. OTJR: Occupation, Participation and Health. 2011 Mar;31(2):89-96.
12. Zamani N, Chung J, Evans-Hudnall G, Martin LA, Gilani R, Poythress EL, et al. Engaging patients and caregivers to establish priorities for the management of diabetic foot ulcers. J Vasc Surg. 2021 Apr;73(4):1388-1395.e4.
13. Ferreira G, Carvalho A, Pereira MG. Educational interventions on diabetic foot self-care: a study protocol for a pragmatic randomized controlled trial. Health Commun. 2024 Jun;39(7):1383-1392.
14. Golden SD, Earp JA. Social ecological approaches to individuals and their contexts: twenty years of health education & behavior health promotion interventions. Health Educ Behav. 2012 Jun;39(3):364-72.
15. Willmott TJ, Pang B, Rundle-Thiele S. Capability, opportunity, and motivation: an across contexts empirical examination of the COM-B model. BMC Public Health. 2021 May 29;21(1):1014.

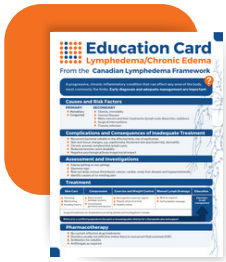
16. Gray TA, Wilson P, Dumville JC, Cullum NA. What factors influence community wound care in the UK? A focus group study using the Theoretical Domains Framework. BMJ Open. 2019 Jul 31;9(7):e024859.
17. Hamilton S, Jennings A, Forster AJ. Development and evaluation of a quality improvement framework for healthcare. Int J Qual Health Care. 2020 Sep 23;32(7):456-463.
18. Brocklehurst J. How good are we at addressing people's moral, cultural and religious views on animal-derived wound care products? Wounds UK. 2022 Mar 1;18(1).
19. Kolossváry E, Farkas K, Karahan O, Golledge J, Schernthaner GH, Karplus T, et al. The importance of socio-economic determinants of health in the care of patients with peripheral artery disease: a narrative review from VAS. Vasc Med. 2023 Jun;28(3):241-253.
20. Gabbay RA, Kaul S, Ulbrecht J, Scheffler NM, Armstrong DG. Motivational interviewing by podiatric physicians: a method for improving patient self-care of the diabetic foot. J Am Podiatr Med Assoc. 2011 Jan-Feb;101(1):78-84.
21. McPherson M, Carroll M, Stewart S. Patient-perceived and practitioner-perceived barriers to accessing foot care services for people with diabetes mellitus: a systematic literature review. J Foot Ankle Res. 2022 Dec 16;15(1):92.
22. Boulton AJM, Armstrong DG, Kirsner RS, Attinger CE, Lavery LA, Lipsky BA, et al. Diagnosis and management of diabetic foot complications. Arlington (VA): American Diabetes Association; 2018 Oct.
23. Giarelli G, Saks M, editors. National Health Services of Western Europe: challenges, reforms and future perspectives. Taylor & Francis; 2023 Aug 14.
24. Saks M, Zagrodney K. Health professionals, support workers and the precariat. In: Support Workers and the Health Professions in International Perspective. 2020 Jul 23 (pp. 15-32). Policy Press.
25. Brocklehurst JD. The Validity and Reliability of the SINBAD Classification System for Diabetic Foot Ulcers. Adv Skin Wound Care. 2023 Nov 1;36(11):1-5.
26. Callender LF, Johnson AL, Pignataro RM. Patient-centered education in wound management: improving outcomes and adherence. Adv Skin Wound Care. 2021 Aug 1;34(8):403-410.
27. Moffatt C, Murray S, Keeley V, Aubeeluck A. Non-adherence to treatment of chronic wounds: patient versus professional perspectives. Int Wound J. 2017 Dec;14(6):1305-1312.
28. Cho SK, Mattke S, Sheridan M, Ennis W. Association of wound healing with quality and continuity of care and sociodemographic characteristics. Am J Manag Care. 2022 Apr 1;28(4):e146-e152.
29. Lenert LA. Toward medical documentation that enhances situational awareness learning. AMIA Annu Symp Proc. 2017 Feb 10;2016:763-771.
30. Abraham J, Kannampallil TG, Patel VL. Bridging gaps in handoffs: a continuity of care based approach. J Biomed Inform. 2012 Apr;45(2):240-54.
31. van Netten JJ, Seng L, Lazzarini PA, Warnock J, Ploderer B. Reasons for (non-)adherence to self-care in people with a diabetic foot ulcer. Wound Repair Regen. 2019 Sep;27(5):530-539.

CLF
CANADIAN LYMPHEDEMA FRAMEWORK

Resources for Lymphedema

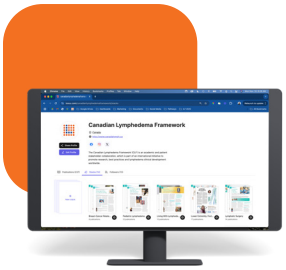
Lymphedema Education Pamphlet

tinyurl.com/2024LymphEd



What Every Physician Should Know

tinyurl.com/PhysiciansCard



Lymphedema Learning Library

tinyurl.com/2024LymphEd

Leg Swelling: Is it Lymphedema?

tinyurl.com/LegSwelling

Connect with us

Visit our website canadalymph.ca to learn about our mission, vision, and the work we do in partnership with our provincial lymphedema organizations and the International Lymphoedema Framework (ILF).

Subscribe to our email news and follow us on our social media channels for news, announcements and the latest on lymphedema research, education, partnerships, and events.

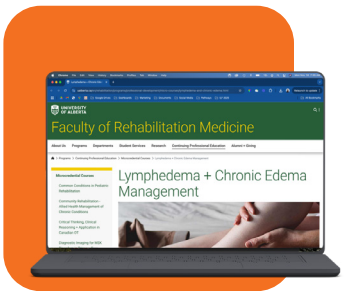
Scan to find and follow the CLF online

@canadalymph.ca

12th International Lymphedema Conference

Join us October 23-25, 2025 in Niagara Falls, Canada for this extraordinary event. Register now and use the code **LIMB25** to unlock exclusive early-bird pricing!

ILF2025.com



Lymphedema + Chronic Edema Management

- Microcourse for Health professionals
- Self-paced over 6 weeks
- Online Course, 4 Modules
- 35 education hours
- Learn from leading experts
- Course Fee: $350 CAD

tinyurl.com/uabmicrocourse

Subscribe to Pathways

- Quarterly publication by the CLF
- Up-to-date clinical perspectives
- Research news
- Patient hints & tips
- Written by leading experts
- For professionals and patients

canadalymph.ca/pathways

Leading The Global Charge In Diabetic Foot Education: The American Limb Preservation Society (ALPS)

Georgia Krehbiel MBA and **Annkathrin Mathe** MSc

Abstract: This paper outlines the position and educational initiatives currently being undertaken by the American Limb Preservation Society, a partner member, along with Wounds Canada, of the Limb Preservations Alliance. It highlights global outreach programs and collaborations in 2025.

Key words: *Limb preservation, diabetic foot, Toe and Flow, education, global partnerships*

How to cite: Krehbiel G, Mathe A. Leading the global charge in diabetic foot education: the American Limb Preservation Society (ALPS). Limb Preservation Journal. 2025;6(1): 101-102. DOI: 10.56885/704646sxxqtg

The American Limb Preservation Society (ALPS) has established itself as a global leader in diabetic foot education and multidisciplinary limb preservation initiatives. At the forefront of these efforts is *DFCon*, ALPS' flagship conference, which serves as the premier educational platform for advancing research, innovation and collaboration in diabetic foot care. Additionally, ALPS recently launched *DFU – Diabetic Foot Update*, a conference co-chaired by Dr. Lawrence Lavery and Dr. Lee Rogers, further reinforcing its commitment to evidence-based education and cutting-edge clinical advancements.

Building on the pioneering work of Dr. David Armstrong and Dr. Joe Mills and their "Toe and Flow" model, ALPS is reshaping care paradigms for diabetic foot complications. These efforts have led to reduced amputation rates and improved healing outcomes for patients with diabetic foot ulcers. As stated in the literature, "A single-center county hospital in the U.S. reduced major amputations by 72% after implementing a care process centered on podiatry and vascular services,"[1] highlighting the impact of multidisciplinary collaboration on patient outcomes.

The Toe and Flow Model

Diabetic foot complications remain one of the leading causes of non-traumatic amputations globally, placing a significant burden on health-care systems and patient well-being. The Toe and Flow model, pioneered by Dr. David Armstrong, Dr. Joe Mills and Dr. Lee Rogers, highlights the critical collaboration between podiatric (Toe) and vascular (Flow) specialists. This multidisciplinary approach has been instrumental in lowering amputation rates, accelerating wound healing and improving overall patient health outcomes.

The Toe and Flow philosophy is a cornerstone of ALPS mission, fostering collaboration among podiatrists, vascular surgeons, endocrinologists and wound care specialists. ALPS is driving advancements in patient-centred limb preservation strategies, directly leading to improved mobility, reduced health-care costs and better long-term survival rates.

Educational Partnerships

Recognizing the worldwide impact of diabetic foot disease, ALPS is expanding its reach through key international partnerships, while simultaneously integrating DFCon's educational platform into

these collaborations. These alliances amplify the reach of the Toe and Flow model and advance best practices in limb preservation, yielding tangible health benefits for diverse populations.

In March of 2025 ALPS will collaborate with the European Wound Management Association (EWMA) at their conference in Barcelona, Spain. EWMA is a global leader in evidence-based wound care. This collaboration will help to share insights and facilitate cross-disciplinary cooperation with European experts. Through the integration of DFCon, this partnership enhances global diabetic foot education, leading to better clinical practices and improved patient outcomes across Europe.

In May this year, ALPS will partner with PODOCON 2025, in Bangalore, India. With India facing a significant burden of diabetes-related complications, ALPS leverages PODOCON to engage with South Asian health-care professionals. By incorporating DFCon's educational sessions, practitioners gain access to advanced training and panel discussions, equipping them with critical tools to manage diabetic foot complications, reduce amputation rates and improve patient care.

ALPS will also partner with the Asian Society for Vascular Surgery (ASVS) in Singapore in August 2025. ALPS integrates DFCon's cutting-edge diabetic foot and limb preservation education into the conference, ensuring that vascular specialists across Asia have access to the latest research, techniques and best practices in limb salvage.

Through these strategic initiatives, ALPS ensures that DFCon remains the cornerstone of multidisciplinary global diabetic foot education, driving innovation, collaboration and transformative solutions that improve patient outcomes worldwide.

The Limb Preservation Alliance

In 2023, ALPS, Wounds Canada, the Canadian Podiatric Medical Association and D-Foot International formed the Limb Preservation Alliance, a strategic partnership aimed at strengthening multidisciplinary collaboration in limb preservation. This initiative unites expertise, research and clinical best practices to enhance patient outcomes and reduce preventable amputations. By leveraging the strengths of all organizations, the Alliance promotes a comprehensive approach to limb salvage through education, advocacy and innovation.

A key milestone of this partnership was ALPS' participation in the 2024 Wounds Canada National Conference, where ALPS leaders contributed to critical discussions on limb preservation strategies. Dr. Lee Rogers and Dr. David Alper led a Toe and Flow session, emphasizing the necessity of coordinated podiatric and vascular interventions for limb salvage. Additionally, ALPS CEO Georgia Krehbiel participated in a working group and panel discussion focused on prioritizing recommendations from international guidelines, reinforcing the Alliance's commitment to evidence-based solutions in limb preservation.

Since its inception, the Limb Preservation Alliance has facilitated greater knowledge-sharing and collaboration among health-care professionals across North America. By continuing to expand its initiatives in clinical excellence, education and policy development, the Alliance aims to set new standards in limb preservation and amputation prevention.

For Further Information:

- ALPS: https://limbpreservationsociety.org/
- DFCon: https://limbpreservationsociety.org/dfcon/

Georgia Krehbiel MBA is CEO, American Limb Preservation Society.

Annkathrin Mathe MSc is Program Director, American Limb Preservations Society.

References

1. Rogers LC, Andros G, Caporusso J, Harkless LB, Mills Sr JL, Armstrong DG. Toe and flow: essential components and structure of the amputation prevention team. J Vasc Surg. 2010 Sep;52(3 Suppl):23S-27S.

Mölnlycke®

Mepilex® Border Flex

Dressings for all stages of healing

Mepilex® Border Flex

Mepilex® Border Flex Oval

Stays on. Uniquely conforms.

Safetac® TECHNOLOGY

Learn More

CASE REPORT

Mission 'Possible': Saving A Limb

Emerson Jiang BA(Hons) DCh IIWCC

Abstract: A pressure injury is a localized damage to the skin and/or underlying soft tissue, usually over a bony prominence. A pressure injury has a significant impact on the patient's quality life, especially the associated complications, such as infection, compromised local circulation, etc. This case report details attempts to prevent amputation of the right limb in a mid-50s male patient who had previously undergone an above-knee amputation initiated by a pressure injury on his left plantar heel.

Key words: *amputation prevention, pressure injury, vascular status, offloading*

How to cite: Jiang H. Mission possible: saving a limb. Limb Preservation Journal. 2025;6(1): 104-107. DOI: 10.56885/129509fltiql

Patient Characteristics

A male patient in this mid-50s presented to the office for a pressure injury on right 1st apex. The patient did not have previous experience with foot care. Based on the assessment, other than the pressure injury, the patient presented skin (fungal infection), nail (ingrown, fungal infection) and biomechanical conditions which required chronic professional foot care treatment. Unfortunately, in 2023, the patient had an above-the-knee amputation on left side resulting from a diabetic foot ulcer.

Part of the reason for this current pressure injury was the use of inappropriate footwear. The toe-box of the footwear was too shallow and there was not enough space between the sidewall and the big toe (1.5 cm is suggested). Another reason was that because of the left above-knee-amputation, the patient is unable to maintain a good balance. As a result, excessive body weight goes to the plantar hallux.

The lesion started as a fluid-filled blister. The blister burst after three days. The patient had recently recovered from pressure injuries on right 5th plantar MPTJ, 2nd, 3rd and 4th apices. The patient was under tremendous stress, as he had already undergone an above-knee amputation initiated by a pressure injury on his left plantar heel in 2023.

Social History

The patient is in late 50s. Height is 170 cm, weight is 80 kg and BMI is 27.7.

The patient is single and currently unemployed. He lives in an urban setting; is a non-smoker and reports rare alcohol consumption. Due to the current situation, his life quality has gone down; however, the patient has very supportive family members who are taking care of his everyday needs and providing emotional support.

Medical History

The patient's history included multiple conditions/factors, including: type II diabetes (HbA1c: 9.6%), neuropathy (monofilament 5/10), peripheral vascular disease, hypertension, hypercholesterolemia, anticoagulation, anemia and above-knee amputation on the left side.

There are recovered pressure injuries on the right 5th plantar MPTJ, 2nd, 3rd and 4th apices. There was no significant change in nutritional status and no known allergies.

See Table 1 for Lab/test results and Table 2 for medication history.

Table 1: Lab and Test Results

Hb	133(LO)	135 - 175 g/L
RBS	15.9 (HI)	3.6 - 7.7 mmol/L
Hb A1C	93.6 (HI)	<6.0
Cr	60 (LO)	67 - 117 umol/L
Microalbumin/Creatinine Ratio	40.6 (HI)	3.0 mg/mmol
B12	206 (LO)	>220 pmol/L

Pedal Pulses: Monophasic waves on Audible Hand-held Doppler
ABPI: 7

Table 2: Medication History

- Acetaminophen 500 mg 1-2 tablets 3 times daily, PRN for 90 days
- Norvasc 10 mg 1 tablet 1 time daily
- Januvia 100 mg 1 tablet 1 time daily All meds to go in biweekly pill pack to help with compliance
- Crestor 40 mg 1 tablet 1 time daily
- Freestyle Libre as directed to help manage Blood sugar for 1 year
- Koffex DM Sucrose Free 5 ml 3 times daily, PRN
- Lyrica 50 mg 2 capsules 3 times daily for 90 days
- Apixaban 2.5 mg 2 times daily for 90 days
- Ferrous fumarate 90 tablets 1 time daily for 90 days
- Tresiba FlexTouch 100 unit/mL (3 mL) 16 units every morning for 3 months of 28 days
- Metformin 500 mg Various
- Trurapi SoloSTAR as directed 10 U ac meals
- Vitamin B-12 1 ml 1 time monthly for 30 days

Wound History

The current lesion started in early March 2024 as a blister lesion. The lesion was broken after three days, maceration presented in the wound bed. The size of the wound is approximately 2.6x2.4 cm. (See Figure 1.)

Figure 1:

Treatment Approaches And Timeline

A layer of eschar formed in late March. Due to the rigidity of the eschar, sharp debridement could not be performed. Intrasite (2x /week) application was initiated. (See Figure 2.)

Figure 2: This picture was taken on March 25, 2024.

After two weeks of intrasite application, the eschar was removed. Biofilm and mild maceration presented in the wound bed. The lesion was dressed with Inadine™ (3x/week).(See Figure 3.)

Figure 3: This picture was taken on April 11, 2024.

The lesion was fully recovered in late July. (See Figures 4, 5, 6 and 7.)

Figure 4: This picture was taken on April 15, 2024.

Figure 5: This picture was taken on May 14, 2024.

Figure 6: This picture was taken on June 17, 2024.

Figure 7: This picture was taken on August 1, 2024.

During the treatment course, patient was provided with post-op shoes to offload the pressure in the lesion area. Modification such as a Plantar Metatarsal Pad (PMP) with wing to the 1st (made by semi-compression felt) was provided to promote the range of motion on 1st metatarsophalangeal joint to reduce the pressure on the plantar 1st toe area. (See Figures 8 and 9.)

Figure 8:

Figure 9:

Management Team

The management team consisted of the following:

- Patient
- Family physician
- Vascular specialist
- Primary care nurse
- DM nurse
- Dietitian
- WoundPedia/ECHO Ontario Skin and Wound faculty team
- Chiropodist
- Supportive family members.

Conclusion

Saving a limb is a 'possible mission'. As clinicians, we should always treat the whole patient instead of 'the hole in the patient'. We should focus on the treatment of etiology and adopt a treatment approach based on patient-centred concerns.

The goal is to increase oxygen level to the lesion, decrease/eliminate infection and maintain the blood glucose level to create a favourable wound healing environment. As such the coordination of interprofessional care is crucial.[2,3]

Vascular status is crucial in wound care, as it involves the wound healing process directly. The comprised blood supply would impact the wound healing significantly. It is important for clinicians to have patients' vascular status before initiating the treatment. An audible handheld Doppler test can be performed on bedside if the history of vascular status is available.[2]

Pressure offloading is an essential component for pressure injury treatment. Even with the application of the best practice techniques, wound healing might stall without appropriate off-loading application.[3] Pressure off-loading not only prevents further tissue damage but also promotes the healing process. The Total Contact Cast is the 'golden' choice which provides the maximum pressure offloading.[4] The post-op shoes, custom orthotic devices and custom-made footwear are easy to wear which are more convenient to patients.

Emerson Jiang BA(Hons) DCh IIWCC is a chiropodist, foot and ankle specialist and wound care specialist at Flemingdon Health Centre, Toronto, Ontario, Canada.

References

1. Mondragon N, Zito PM. Pressure injury. StatPearls. 2024 Feb 28. Available from: https://www.ncbi.nlm.nih.gov/books/NBK557868/
2. Sibbald RG, Ayello EA. The audible handheld Doppler facilitates virtual and blended care models during COVID-19. Adv Skin Wound Care. 2021 Apr 1;34(4):175. DOI: 10.1097/01. ASW.0000735716.33518.87
3. Mrdjenovich DE. Off-loading practices for the wounded foot: concepts and choices. J Am Col Certif Wound Spec. 2011 Oct 3;2(4):73-8. DOI: 10.1016/j.jcws.2011.02.001
4. Lazzarini PA, Jarl G, Gooday C, Viswanathan V, Caravaggi CF, Armstrong DG, et al. Effectiveness of offloading interventions to heal foot ulcers in persons with diabetes: a systematic review. Diabetes Metab Res Rev. 2020 Mar;36 Suppl 1(Suppl 1):e3275. DOI: 10.1002/dmrr.3275

WoundsCANADA.ca
30 years supporting skin health and wound care

Membership Has Its Privileges!

Become a Wounds Canada Professional Member Today!

As the leading wound care organization in Canada we provide you, our member, with the information and tools to help advance your career, your practice and your team. Your professional membership provides you with:

- **Exclusive access** to members-only sections:
  Image bank: view and download images for personal or educational use
  Video gallery: view scientific presentations from the Wounds Canada's conferences and webinars
  Downloadable educational resources
- **Discounts** on our professional education conferences, programs and eBoutique
- **A member-only newsletter** with the latest in wound care information

How do I join?

Visit **www.woundscanada.ca/become-a-member** today to take your wound care knowledge to the next level!

- Individual Annual Membership: $100.00 CDN
- Student/Retiree Annual Membership: $50.00 CDN

Register today to take full advantage of these exclusive benefits!

Find us on social media

Find out more about us at **www.WoundsCanada.ca**

REGISTER NOW

Students can enroll at any time and complete this program at their own pace.

SHARP
Skin Health Advocate and Resource Professional

WOUNDS CANADA INSTITUTE SUPER PROGRAM #1

SKIN HEALTH ADVOCATE & RESOURCE PROFESSIONAL

23 MODULES

8 LIVE WEBINARS

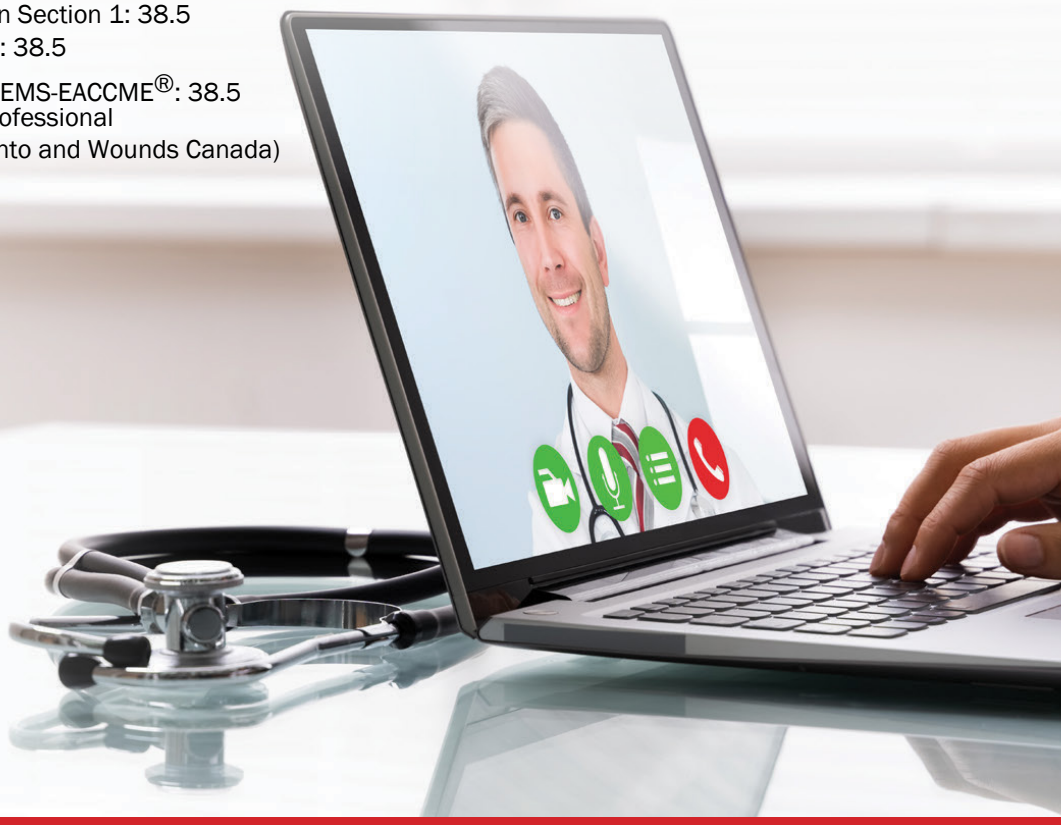
21 EXPERTS

38.5 CREDITS

- Develop the foundational knowledge, critical thinking skills and attitude to care for and support people with or at risk for common chronic and acute wounds
- Program consists of 23 interactive online modules, 8 live webinars, 2 robust outcome measures, and access to an asynchronous discussion forum with interdisciplinary program faculty
- Developed and reviewed by 21 of Canada's top wound care experts and educators – Chiropodists/Podiatrists, Dietitians, Nurses, Nurse Practitioners, Nurses Specialized in Wound, Ostomy and Continence, Occupational Therapists, Pedorthists, Pharmacists, Physicians, Physician Specialists and Physiotherapists
- Receive a digitial micro-credential from Nipissing University upon completion
- Continuing Professional Development, Temerty Faculty of Medicine, University of Toronto has awarded the Wounds Canada Institute Super Program #1 with the following credits:
  - College of Family Physicians of Canada Mainpro+ (1 credit/hour) Group Learning: 12.0
  - College of Family Physicians of Canada Mainpro+ (1 credit/hour) Self Learning: 26.5
  - Royal College Maintenance of Certification Section 1: 38.5
  - American Medical Association Category 1: 38.5
  - European Union for Medical Specialists UEMS-EACCME®: 38.5
  - Certificate of Completion in Continuing Professional Development (from the University of Toronto and Wounds Canada)

AMAZING VALUE!

$1,925+ tax



UNIVERSITY OF TORONTO
FACULTY OF MEDICINE
Continuing Professional Development

NIPISSING UNIVERSITY

Wounds CANADA Institute

WWW.WOUNDSCANADA.CA/SHARP