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Current Canadian Consensus Statement On The Management Of Venous Leg Ulcers

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The Canadian Consensus Statement on the Management of Venous Leg Ulcers

The Objective

The objective of this project was to incorporate new clinical research findings on the management of venous leg ulcers (VLUs) into a Consensus Statement. This document is intended as an up-to-date practical guide for health-care providers (HCPs) managing patients with VLUs. It is a short, easy to understand, document that can be used in a clinical setting.

The Development Process

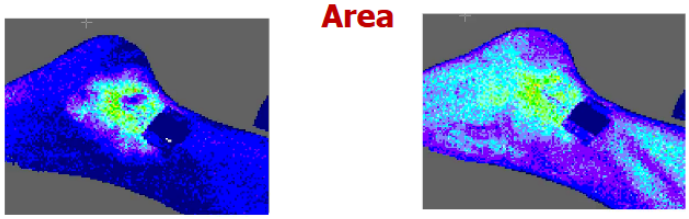
Nineteen HCPs of varying clinical backgrounds (e.g., physicians, nurses, NSWOCs, therapists) and different regions in Canada were involved in the development of this document. These HCPs have experience managing VLUs, with muscle pump activator device (MPA) and advanced wound treatments.

There are 23 sections in the Consensus Statement. The goal of the development process was to achieve at least 80% agreement by panelists on each section. The panel was able to achieve consensus on 20 of 23 sections and greater than 85% consensus on the remaining 3. The development of this document was independent of input from any wound care companies.

New Research Findings

The Conensus Statement incorporates new clinical research data on the management of VLUs. One major area of focus was the use of muscle pump activators (MPAs). MPAs address the underlying cause of VLUs by stimulating the common peroneal nerve and enhancing calf muscle pump function. The geko™ device, a muscle pump activator (MPA), has been shown to increase venous volumetric flow up to 100%;[1] increase arterial volumetric by up to 75%;[1] and increase microcirculatory flux by up to 400%.[2] MPA devices may also increase blood volume and velocity up to 60% of walking – without having to move or exert energy.[3]

Laser Speckle Contrast Imaging (LSCI) of Micro-circulatory Blood Flow in Wound and Peri-wound Area



Baseline MPA device

- LSCI has been used to determine if flow is augmented by using the MPA device
- The MPA device increases perfusion to both the wound bed & peri-wound area
- Wound bed – 225% increase in flux (p<0.001)
- Peri-wound – 67% increase in flux (p<0.001)

NB. Patient had active infection, this area therefore had more flux than usual so this increase over baseline is lower than expected

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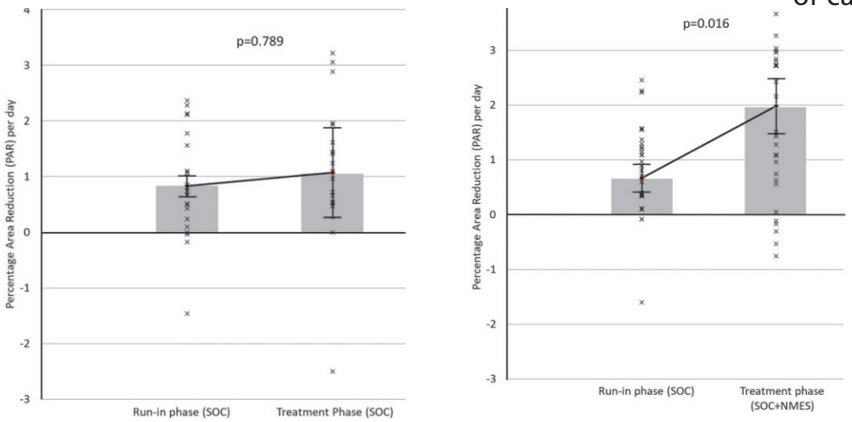
A study by Das et al. in 2020 demonstrated that the use of geko™ increased peak venous velocity in the popliteal vein pre-bifurcation with the patient in recumbent position (baseline) and when seated.[4] Another study by Das et al. in 2021 showed that geko™ increased microcirculatory pulsatility not just in the wound bed but also in the periwound.[5]

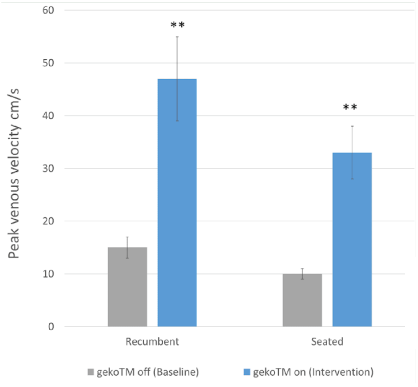
Percentage area reduction of wound with SOC alone (left graph) and with SOC plus MPA (right graph)[6]



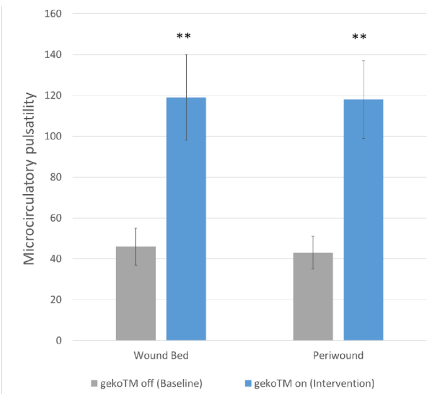
Bull et al. evaluated the difference between standard of care (SoC) alone and SoC with MPA. After four weeks of treatment, there was a significantly higher percentage area reduction (PAR) per day for patients receiving SoC with MPA compared to SoC alone.[6] The healing rate was also twice as fast when MPA was added to SoC.[6]

More recently (in 2024), Sibbald et al. evaluated 127 chronic wound patients (i.e., VLUs, diabetic foot ulcers, ischemic/mixed arterial venous ulcers, post-surgical/traumatic leg ulcers) in multi-centre clinics.[7] They found that MPA was effective in improving wound healing outcomes, including reduced pain, reduced edema, and enhanced patient quality of life.[7]

Changes in venous velocity with MPA[4]



Changes in micro-circulation with MPA[5]



The Key Components

The following section outlines the key components of the Consensus Statement and brief highlights for each:

Diagnosis of VLU: HCPs must first assess the cause of the wound and consider the patient's health literacy, environmental factors, and goals of care prior to initiating treatment. HCPs must conduct a thorough history of the ulcer, arterial and/or venous disease, underlying medical conditions and medications. A thorough examination of the patient (e.g., pedal pulses, ankle range of motion, gait, footwear, skin etc.) should also be performed.

Clinical features: HCPs should assess the location of the wound, the ulcer appearance, the surrounding tissue and for pain

Investigations: Non-invasive lower limb venous duplex ultrasound can be utilized for the diagnosis of venous disease. If there is limited access to such testing, management may start prior to investigation as long as **arterial status has been established**. HCPs should also investigate other co-existing medical conditions. Arterial status should be evaluated with ankle-brachial pressure index (ABPI) and/or toe-brachial index or toe pressures. In areas without access to these tests, a handheld Doppler can be utilized to assess the waveform of pedal

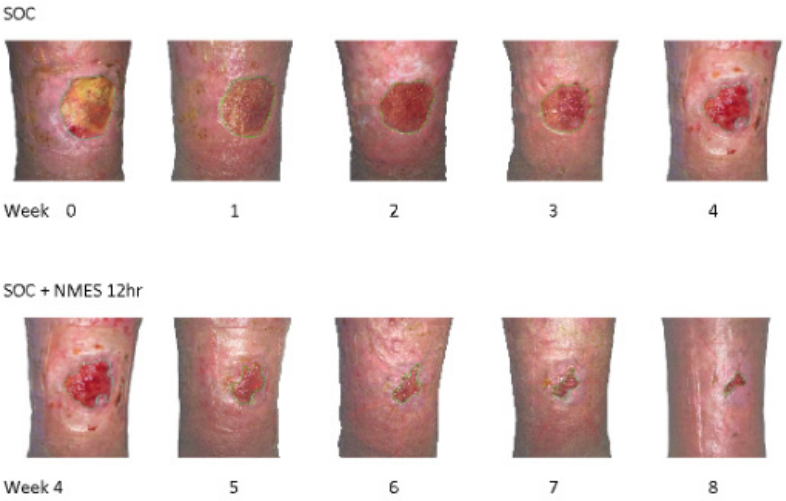
pulses; a multiphasic waveform is indicative of adequate arterial supply. HCPs should also investigate other co-existing health conditions (e.g., rheumatoid arthritis, lymphedema) and employ laboratory studies (e.g., blood panel, renal function, hemoglobin A1C). Not to be neglected, HCPs should assess the patient's gait and ankle mobility as these may impair the patient's calf muscle pump function.

Treatment of VLU – Treat the underlying cause of impaired calf muscle pump function

The key to treating VLU is to address the underlying cause – impaired calf muscle pump function. Compression therapy is the mainstay for the management of VLU. There are various compression system options, including but are not limited to inelastic bandages, elastic stockings, and adjustable wrap systems with hook and loop fasteners. Selection of modality may depend on patient mobility, pain, tolerance, ability to apply, environment, access and patient history and assessment findings seen below:

Patient history and assessment findings	Management considerations
Normal ABPI (0.9-1.4) or TBPI or toe pressures are normal if elevated ABPI or If hand-held Doppler waveform is multiphasic	Apply optimal multi-layer bandage system (30-40 mmHg at the ankle) Encourage calf muscle contract exercises, especially a daily walking regiment, to improve calf muscle pump function If limited ankle motion, strength, mobility or impaired gait, consider physiotherapy or rehabilitation medicine and daily leg elevation
If unable to tolerate optimal compression or ABPI is reduced but greater than 0.5 or If the patient has significant congestive heart failure that requires cardiologist evaluation	Apply a lower compression multilayer system that the patient will tolerate (with the aim to progress to optimal compression as symptoms and tolerance allow) Use caution at ABPI between 0.65 to 0.9 and extra caution between 0.5 and 0.65 Consider stockinette with tubular or longitudinal compression instead of compression wraps Add muscle pump activator (MPA) to enhance calf muscle pump function
If unable to tolerate any compression due to pain or other causes	Add muscle pump activator (MPA) to enhance calf muscle pump function Recommend daily leg elevation above the level of the heart and regular exercise regimen (especially daily walking) to improve calf muscle pump function Consider physiotherapy or rehabilitation medicine

Weekly ulcer appearance with SOC alone (weeks 0 to 4) and with SOC and MPA (weeks 4 to 8)[6]



Treatment of VLU – Treat the wound:

The treatment recommendations are founded on the concepts of the Wound Bed Preparation and the T.I.M.E. (tissue, infection, moisture, edge) principle.

The recommendations are as follows:

- Cleanse the wound and surround skin
- Debride devitalized tissue if vascular perfusion is normal
- Apply a dressing that ensures adequate moisture balance
- Treat infection in deep and surrounding tissue
- Manage pain if present
- Treat surrounding skin
- Treat wounds deemed to be non-healable
  - Cleanse with saline, clean potable water or antimicrobial solution; Use dressings to support wound maintenance goals
- Assess and measure the wound using a consistent method weekly or at each visit if seen less often.

Actions if not on a healing trajectory: The treatment plan should be revisited if there is no wound size reduction in 2-4 weeks or if reduction is less than 30% four weeks after initiating treatment. HCPs should reassess the patient and the diagnosis of ulceration to exclude other etiologies of impaired healing (e.g., malignancy, autoimmune disorders, medications etc.). HCPs should also assess whether the treatment plan is properly implemented and adhered to or whether infection is present and being managed properly. Once all of these have been assessed, HCPs should review and optimize treatment of calf muscle pump function, including reassess the compression system; review the exercise and walking regimen; add MPA if not already in place; consider surgical referral.

Once the diagnosis is confirmed and calf muscle pump function is optimized, HCPs can consider the introduction of advanced wound treatments depending on local availability and in a sequential manner with assessment of healing responses at each step.

- Address biofilm and bioburden with:
  - An antimicrobial dressing that can disrupt or eradicate biofilm
- Address increased wound protease activity with:
  - A dressing with protease inhibition properties
- Improve the wound bed with:
  - Negative pressure wound therapy (NPWT) or matrix substitutes
- Add growth promoting factors by:
  - Delivering growth factors through dressings that release physiological growth factor levels
- Add new cells to the wound via:
  - Skin grafts, cultured cells, skin substitutes etc.
- Consider other adjunctive therapies (e.g., oral pentoxifylline, electrical stimulation of the wound bed, topical oxygen therapy, therapeutic ultrasound etc.).

Prevent Ulcer Recurrence

After wound closure is achieved, HCPs should reinforce patient education regarding venous disease and prevention of ulcer recurrence. Patient education should focus on:

1. Protecting the skin from trauma.
2. Lifelong compression:
   a. Compression bandages should be continued for at least two weeks or longer to ensure full ulcer healing. Fitted compression

stockings (below knee in most cases) ideally at 25-40 mmHg should be used in most instances. A lower pressure should be considered for patients with coexisting arterial disease and/or cannot tolerate high compression.

3. Calf muscle contraction exercises:
   a. Patients should be encouraged to continue with calf muscle contraction exercises, especially a daily walking regimen, to improve calf muscle pump. HCPs should consider recruiting physiotherapy or rehabilitation medicine for patients with limited mobility.

A limited subset of patients may also benefit from superficial venous ablation by surgery or other less invasive techniques if appropriate. Surgical referrals should be made accordingly in these cases.

Dr. Robyn Evans BSc Med CCFP FCFP is the Medical Director of the Wound Healing Clinic at Women's College Hospital, who is involved in research and teaching. She is also a full-time family physician in the community and part of the faculty of the International Interprofessional Wound Care Course (IIWCC) through the University of Toronto. She is senior faculty for Wounds Canada supporting the development of interprofessional education programs for clinicians.

Amanda Loney BScN WOCN IIWWCC, NSWOC earned a BScN from the University of Western Ontario, acquired her WOCN designation from Albany Medical Center in New York and has completed the IIWCC at the University of Toronto. She specializes in wounds, ostomy, and continence and is currently a Certified Nurse Specialized in Wound, Ostomy and Continence. She works with Bayshore Home Care Solutions, as well as in her private practice.

Dr. Gary Sibbald MD MEd DSC (Hon) FRCPC (Med (Derm) FAAD MAPWCA JM is a dermatologist and internist with a special interest in wound care and education. He is a professor of Medicine and Public Health at the University of Toronto, co-founder of the Canadian Association of Wound Care and former Director of the Wound Healing Clinic, Women's College Hospital. He is also a previous president of the World Union of Wound Healing Societies (2012 – 2016). Professor Sibbald received the Queen Elizabeth II Diamond Jubilee medal in 2013 and Honorary Doctor of Science from Excelsior College in 2014.

Dr. Michael Stacey MBBS, FRACS, Doctor of Surgery is a vascular surgeon who came to Canada as Surgeon in Chief at Hamilton Health Sciences and Professor in the Department of Surgery at McMaster University. He was the Chief Medical Executive and Executive Vice President Academic at Hamilton Health Sciences until mid-2023. He was the first Chair of the Australian Wound Management Association and the founder and first President of the World Union of Wound Healing Societies (2000-2004).

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