## Foundations of Best Practice for Skin and Wound Management

BEST PRACTICE RECOMMENDATIONS FOR THE **Prevention and Management of Venous Leg Ulcers** 

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This 2019 update builds on the work of previous author teams and incorporates the latest research and expert opinion.

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# Introduction

### Introduction

A venous ulcer is an opening in the skin of the leg or foot in an area affected by venous hypertension and chronic venous insufficiency.<sup>1</sup> Chronic venous insufficiency (CVI) leads to approximately 80% of lower leg ulcers. Pathophysiology of lower leg ulcers is associated with sustained venous hypertension due to CVI, including failure of the calf-muscle pump, incompetent valves and reflux in the venous system.<sup>2</sup> Leg changes associated with venous disease are present in 10 to 35% of adults in the United States. This can lead to venous leg ulcers, which affect about 1% of the population. This prevalence increases with age to 4% in people older than 65.<sup>3-4</sup>

Venous leg ulcers are common and often recurrent, and result in significant economic and social burden to the patient, caregivers and health-care system.<sup>5</sup> Patient health-related quality of life is negatively affected, and pain management is essential.<sup>6</sup>

Unfortunately, venous leg ulcers have a long healing trajectory, with approximately 30% unhealed at 24 weeks.<sup>7-8</sup> Leading causes include age over 55, history of blood flow changes in the legs, history of blood clots, bone or joint disease (arthritis) in legs or ankles, obesity, sitting or standing for long periods of time, or multiple pregnancies.<sup>9</sup> Vascular risk factors should always be evaluated, and arterial flow should be quantitated, as mixed arterial venous disease is common, occurring in up to 25% of leg ulcers.<sup>10</sup> Because venous insufficiency is a chronic disease, management of venous leg ulcers requires a partnership with the patient to address their specific concerns and to develop a plan for treatment.

Chronic venous insufficiency (e.g., post-thrombotic syndrome) in the lower limb is also a risk factor for lymphedema and may lead to secondary lymphedema.<sup>11</sup> For more information specific to lymphedema, consult the Canadian Lymphedema Framework at www.canadalymph.ca.<sup>12</sup>

#### The following primary guidelines have been used in preparing this paper:

- Australian and New Zealand Wound Management Association. Australian and New Zealand Clinical Practice Guideline for Prevention and Management of Venous Leg Ulcers. 2011. Retrieved from: www. nzwcs.org.nz/images/luag/2011\_awma\_vlug.pdf.
- Burrows C, Miller R, Townsend D, Bellefontaine R, MacKean G, Orsted HL, et al. Best practice recommendations for the prevention and management of venous leg ulcers. A supplement of Wound Care Canada; 2006;4(1):45–55. Retrieved from: www.woundscanada.ca/docman/public/health-careprofessional/152-best-practice-recommendations-for-the-prevention-and-treatment-of-venous-legulcers-update-2006/file.
- Lymphoedema Framework. Best Practice for the Management of Lymphoedema. International consensus. London: MEP Ltd.; 2006. Retrieved from: www.lympho.org/wp-content/uploads/2016/03/ Best\_practice.pdf.
- Marston W, Tang J, Kirsner RS, Ennis W. Wound Healing Society 2015 update on guidelines for venous ulcers. Wound Repair Regen. 2016;24(1):136–44. Retrieved from: www.ncbi.nlm.nih.gov/ pubmed/26663616.
- Scottish Intercollegiate Guidelines Network. Management of Chronic Leg Ulcers: A National Clinical Guideline. 2010. Retrieved from: www.sign.ac.uk/assets/sign120.pdf.

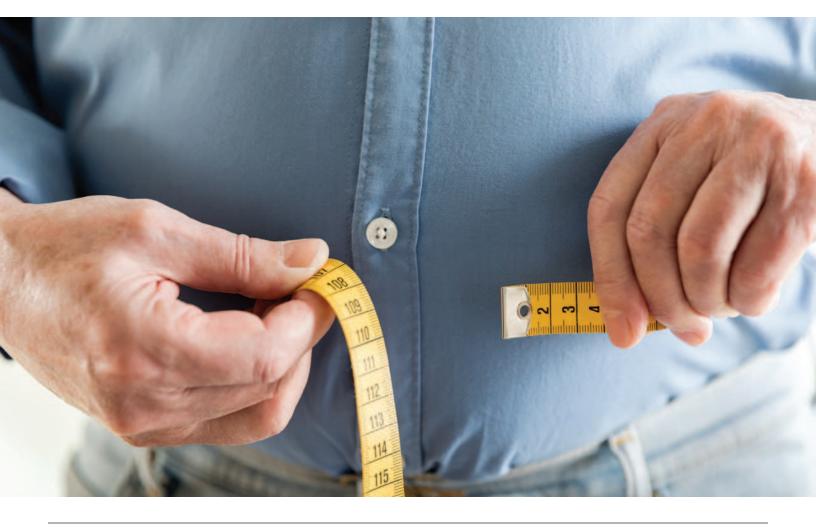
This best practice recommendation is built on evidence-based recommendations (searched PubMed, Medline, CINAHL, Open Access and Internet) and is meant to direct the integrated team's management of venous leg ulcers using the Wound Prevention and Management Cycle (see Figure 1). This ensures that the diagnosis is correct and factors that may affect healing—patient, environmental, system—are addressed.<sup>13</sup>

#### The Wound Prevention and Management Cycle

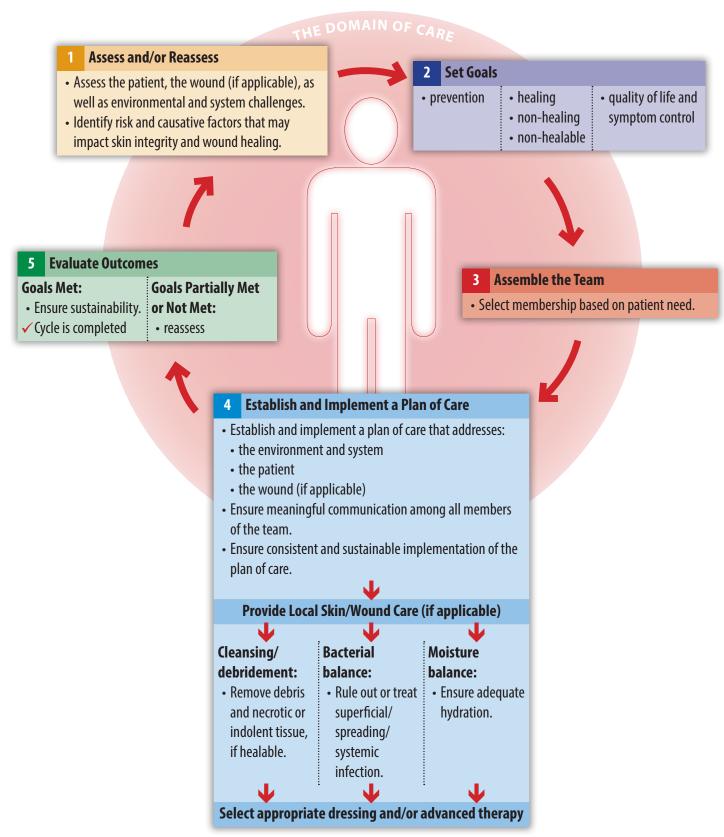
This paper offers a practical, easy-to-follow guide incorporating the best available evidence that outlines a process, or series of consecutive steps, supporting patient-driven care. The Wound Prevention and Management Cycle (see Figure 1) guides the clinician through a logical and systematic method for developing a customized plan for the prevention and management of wounds from the initial assessment to a sustainable plan targeting patient self-management.

The recommendations in this document are based on the best available evidence using electronic databases to identify relevant articles. They are intended to support the clinician, patient, family and health-care team in planning and delivering the best clinical practice. Two foundational papers supplement this document with additional evidence-informed information and recommendations that are general to all wound types:

- Skin: Anatomy, Physiology and Wound Healing,<sup>14</sup> and
- Best Practice Recommendations for the Prevention and Management of Wounds.<sup>13</sup>



#### Figure 1: The Wound Prevention and Management Cycle



Three guiding principles within the best practice recommendation papers (BPRs) support effective prevention and management of skin breakdown:

- 1. Use of the Wound Prevention and Management Cycle regardless of the specifics to prevent and manage skin breakdown
- 2. Constant, accurate and multidirectional flow of information within the team and across care settings
- 3. Patient as the core of all decision-making

#### **Quick Reference Guide**

The quick reference guide (QRG) (see Table 1) provides the recommendations associated with the five steps in the Wound Prevention and Management Cycle (see Figure 1, above). These recommendations are discussed with the supporting evidence.

**Table 1:** Wound Prevention and Management Quick Reference Guide

Step		Recommendation	
1	Assess and/or Reassess	<ul> <li>1.1 Select and use validated patient assessment tools.</li> <li>1.2 Identify risk and causative factors that may impact skin integrity and wound healing.</li> <li>1.2.1 Patient: Physical, emotional and lifestyle</li> <li>1.2.2 Environmental: Socio-economic, care setting, potential for self-management</li> <li>1.2.3 Systems: Health-care support and communication</li> <li>1.3 Complete a wound assessment, if applicable.</li> </ul>	la la–IV IV
2	Set Goals	<ul> <li>2.1 Set goals for prevention, healing, non-healing and non-healable wounds.</li> <li>2.1.1 Identify goals based on prevention or healability of wounds.</li> <li>2.1.2 Identify quality-of-life and symptom-control goals.</li> </ul>	IV
3	Assemble the Team	<ul><li>3.1 Identify appropriate health-care professionals and service providers.</li><li>3.2 Enlist the patient and their family and caregivers as part of the team.</li><li>3.3 Ensure organizational and system support.</li></ul>	IV IV IV
4	Establish and Implement a Plan of Care	<ul> <li>4.1 Identify and implement an evidence-informed plan to correct the causes or co-factors that affect skin integrity, including patient needs (physical, emotional and social), the wound (if applicable) and environmental/system challenges.</li> <li>4.2 Optimize the local wound environment aided through <ul> <li>4.2.1 Cleansing</li> <li>4.2.2 Debriding</li> <li>4.2.3 Managing bacterial balance</li> <li>4.2.4 Managing moisture balance</li> </ul> </li> <li>4.3 Select the appropriate dressings and/or advanced therapy.</li> <li>4.4 Engage the team to ensure consistent implementation of the plan of care.</li> </ul>	IV Ia-III III-IV IV
5	Evaluate Outcomes	<ul> <li>5.1 Determine if the outcomes have met the goals of care.</li> <li>5.2 Reassess patient, wound, environment and system if goals are partially met or unmet.</li> <li>5.3 Ensure sustainability to support prevention and reduce risk of recurrence.</li> </ul>	IV Ib–IV IV

Each recommendation above is supported by the level of evidence employed by the Registered Nurses' Association of Ontario (RNAO) guideline development panels (see Table 2). For more detailed information refer to the designated references.

#### Table 2: RNAO Levels of Evidence<sup>11</sup>

la	<ul> <li>evidence obtained from meta-analysis or systematic review of randomized con- trolled trials</li> </ul>
lb	<ul> <li>evidence obtained from at least one randomized controlled trial</li> </ul>
lla	<ul> <li>evidence obtained from at least one well-designed controlled study without rand- omization</li> </ul>
llb	<ul> <li>evidence obtained from at least one other type of well-designed quasi-experimental study</li> </ul>
Ш	<ul> <li>evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies</li> </ul>
IV	<ul> <li>evidence obtained from expert committee reports or opinions and/or clinical expe- riences of respected authorities</li> </ul>

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# Step 1: Assess and/or Reassess

### Step 1: Assess and/or Reassess

#### Recommendations

#### 1.1 Select and use validated patient assessment tools.

#### **Risk Assessment Tools**

Risk assessment tools can assist in predicting ulcer healing and guide appropriate management, as risk factors for VLU development are also often factors that delay

healing. Risk assessment tools that have been developed for venous leg ulcers are difficult to implement, as the variables to evaluate are not always present in the clinical setting.<sup>16</sup> Two validated tools have recently been developed by Parker et al. (2017) that incorporate medical, physiological and psychosocial factors for venous leg ulcers.<sup>16</sup> These tools can be accessed at www.vlur-risk-tools.org. au/.<sup>17</sup> From this work, four independent predictors of non-healing leg ulcers after 24 weeks have been identified:

- Living alone
- Compression level < 30 mm Hg</li>
- Pressure Ulcer Scale for Healing (PUSH) score ≥ 10
- Ulcer area reduction of < 25% in two weeks

As well, Meulendijks et al. (2018) have identified calf-muscle dysfunction as a strong predictor of VLU severity and healing.<sup>18</sup>

## Assessment of Chronic Venous Disorders

The Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification system is an international consensus method used to categorize chronic venous disorders (see Table 3).<sup>19</sup> This classification system has not been correlated with outcomes, but does provide the clinician with a structured framework, with the clinical findings (C) being the most useful in practice. However, calf-muscle pump dysfunction is not considered under the etiological section. More research is needed to update this tool.



Table 3: The CEAP Classification for Venous Disease<sup>19</sup>

Clinical findings	C0	No visible or palpable signs of venous disease	
	C1	Telangiectasias, or reticular veins	
	C2	Varicose veins	
	C3	Presence of edema	
	C4a	Eczema or pigmentation	
	C4b	Lipodermatosclerosis or atrophie blanche	
	C5	Evidence of a healed venous leg ulcer	
	C6	Active venous leg ulcer symptoms	
Etiological factors	Ec	Congenital	
	Ер	Primary	
	Es	Secondary (post-thrombosis)	
	En	No venous etiology	
Anatomical site	As	Superficial veins	
	Ар	Perforating veins	
	Ad	Deep veins	
	An	No venous location identified	
Pathophysiological	Pr	Reflux	
cause	Ро	Obstruction	
	Pr,o	Reflux and obstruction	
	Pn	No venous pathophysiology identified	

**Assessment of Nutritional Status:** It is important to assess the nutritional status of individuals with or at risk of VLUs using a validated tool.<sup>20</sup> Protein malnutrition and malabsorption from gastrointestinal distress can contribute to chronic leg edema associated with VLUs. As well, VLUs can be heavily exudating, making fluid and protein intake important to consider.<sup>21</sup> Visit the Wounds Canada resource page for more information about nutritional screening tools.<sup>22</sup>

**Assessment of Pain:** Assessment of pain related to venous leg ulcers using a validated tool is important, as patients regularly report mild to moderate or severe pain.<sup>21</sup> Clinicians have a range of tools that make it possible to evaluate the patient's pain pre-, during and post- procedure and at regular intervals. Pain affects patients' mental health and wellness, and therefore their behaviours and attitudes toward care planning.<sup>23</sup> Practitioners can access pain screening tools on the Wounds Canada resource page.<sup>22</sup>

**Assessment of Quality of Life (QoL):** A wide variety of quality-of-life and health-related quality-of-life assessment tools are available. To assess the patient's quality of life generally, the 36-Item Short Form Health Survey (SF-36) is effective in clinical practice. The Wound QoL tool can be used to measure quality of life in patients with non-healing wounds.<sup>24</sup> Of the tools recently reviewed, the Charing Cross Venous Leg Ulcer Questionnaire was found appropriate for measuring health-related quality of life, as it is disease specific.<sup>6</sup>

More specifically, evidence supports the use of validated venous disease-specific quality-of-life indicators, which can be found on the Wounds Canada website.<sup>22</sup>

#### **Wound Assessment Tools**

There are several validated tools available, but the Leg Ulcer Measurement Tool (LUMT) is one that consists of domains and parameters to systematically assess leg

ulcers and aid in assessing changes in wound healing.<sup>25</sup> To describe the wound, the clinician can use the MEASURE mnemonic (measure, exudate, appearance, suffering, undermining, re-evaluate, edge) to assess the basic parameters of a venous leg ulcer (see Section 1.3).

For more information about these assessment tools, please visit the resource section of the Wounds Canada website.<sup>22</sup>

#### **Spirituality and Venous Disease**

For patients living with VLUs and their families and caregivers, religiosity and spirituality may offer hope. A growing body of literature on spirituality and



wounds indicates patients may benefit from this discussion. Salome, de Almeida and Ferreira (2015) administered the Spirituality Self-Rating Scale (SSRS) and the Herth Hope Index (HHI). Patients whose venous leg ulcers had exudate and odour, those who were 20 to 39 years of age, retired, or had lived with the wound for one year or less reported the lowest HHI values.<sup>26</sup> Patients can benefit from knowing that clinicians holistically assess their needs and make appropriate referrals.

## **1.2 Identify risk and causative factors that may impact skin integrity and wound healing.**

A comprehensive patient history will identify the signs and symptoms of, and the risks for, venous disease as well as the co-morbidities that impact healing. The patient history should include assessing the following: present complaints; medical, surgical and smoking history; medications; and information regarding home, social and employment status.<sup>27</sup>

#### 1.2.1. Patient: Physical, emotional and lifestyle

Examination of the lower extremities should include a vascular assessment, identification of skin issues, evaluation of joint mobility, mobility aides and gait, and then a focused examination of the wound if one exists. Blood tests should be considered based on the specific medical issues related to the patient's co-morbidities and the possibility of infection.

#### The Lower Extremity Venous System

The lower extremity venous system comprises deep, superficial and communicating veins (Figure 2a). Supporting returning venous blood flow are unidirectional valves

in the "deep and superficial venous systems and in the perforator veins" (Figure 2b).<sup>27</sup> The contraction of the calf muscle helps propel venous blood from the superficial to the deep venous system via the communication veins (Figure 2c). Properly functioning valves prevent the retrograde flow of blood to the superficial venous system.

Figure 2a: The Lower Extremity Venous System

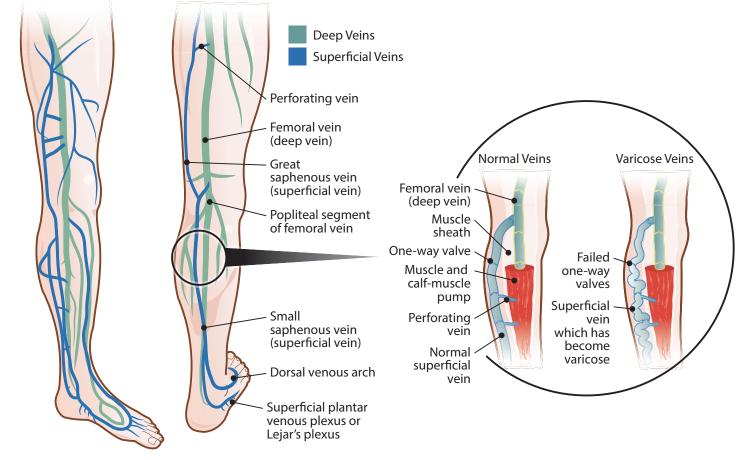
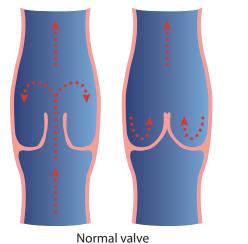


Figure 2b: Normal and Malfunctioning Valve



Malfunctioning valve

#### Figure 2c: Anatomy of the Lower Leg



Three hemodynamic abnormalities and associated risk factors result in venous disease:

- 1. Valvular reflux
  - Obesity
  - Multiple pregnancies
  - Prolonged sitting or standing (recreation or occupations)
  - History of varicose vein stripping
- 2. Obstruction
  - History of deep vein thrombosis (DVT)
  - May Thurner syndrome (anatomic variant at the left iliac vein)
- 3. Failure of the calf-muscle pump (comerota)
  - Joint issues in the lower extremity (ankle and leg)
    - Arthritis, surgery, trauma
  - Walking
    - Shuffling gait due to medical conditions such as Parkinson's disease

Abnormalities might also result from medications (e.g., hydroxyurea, methotrexate), family history, gender (female > male) and/or genetic conditions (e.g., Ehlers-Danlos syndrome, Klippel-Trénaunay syndrome).

At the macrocirculation level, there are definite changes that occur in the vein wall and valves. Veins are a high-capacitance system that can accommodate an increased volume of blood. This blood is transported proximally to the heart by the actions of respiration and cardiac function, but the largest volume is returned by the action of the calf-muscle pump, sometimes referred to as the *second heart*. Competent valves ensure one-way flow of blood, while incompetent valves allow blood to return into the tissues and further distend the veins; this is seen clinically as varicosities and edema (Figure 2b). Within microcirculation, other perturbations occur—such as shear stress due to venous hypertension—causing disruption of the endothelial cells, which play a key role in hemostasis, coagulation and vascular tone.<sup>1</sup>

#### **Venous Hypertension**

Ambulatory venous hypertension is a key risk factor for the development of venous insufficiency, which in turn predisposes patients to venous leg ulceration. For blood to circulate effectively throughout the lower extremity, several factors must work together:

- Central pump (the heart)
- Peripheral venous (calf-muscle) pump (the gastrocnemius and soleus muscles and to a lesser extent the other foot and thigh muscles, as well as the structure of the foot)
- Pressure gradient
- Competent veins and valves

Under normal conditions, when the calf-muscle pump is activated there is a decrease in pressure in the veins. Ambulatory hypertension is the failure to reduce these venous pressures.

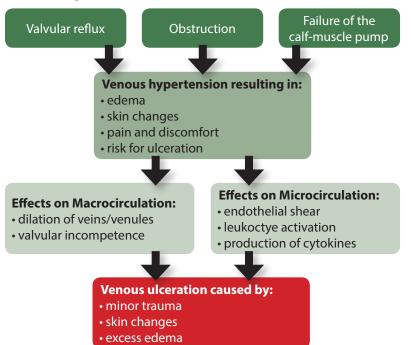
For the calf-muscle pump to function properly, the following are required:<sup>28</sup>

- Functional range of motion around the ankle joint into plantar and dorsiflexion
- Functional strength of the gastrocnemius and soleus muscles
- Proper heel-toe gait

A correctly functioning calf-muscle pump results in heartbeat-like contractions that help to push blood back toward the heart. Maintaining the foot in proper position by using appropriate footwear when ambulating is also important to ensure that the calf-muscle pump can work optimally during gait. The skeletal and muscular components must be coupled with properly functioning valves within the venous system to ensure that the blood does not flow in a retrograde fashion.<sup>28</sup>

The symptoms of venous disease are related to congestion in the venous system of the leg and skin changes. This could include patient complaints of heaviness, fatigue, throbbing, cramping, burning/aching, itchiness of the skin, and restlessness of the legs (see Figure 3).

## **Figure 3:** Pathophysiology for the Development of a Venous Leg Ulcer



#### **Physical Findings Associated with Venous Disease**

**Peripheral Edema:** Edema results in a palpable swelling in the extremity caused by fluid accumulation in the interstitium. The exchange of fluid in the tissues is tightly controlled and managed by hydrostatic pressure, oncotic pressure and the lymphatic system. Lower leg edema can be unilateral, bilateral, acute or chronic. A careful history is essential to understand the underlying process. Deep vein thrombosis should be considered with acute onset unilateral edema. The box (right) lists some causes of edema by primary mechanism.

The biochemical pathway of ulcer formation involves several key factors, including chemical mediators that are released with subsequent leukocytes recruitment. Leukocyte migration into the tissues then initiates an inflammatory cascade with the production of matrix metalloproteinases (MMP), transforming growth factor (TGF- $\beta$ 1), tumour necrosis factor (TNF- $\alpha$ ) and in-

#### Causes of Edema by Primary Mechanism

#### Increase in plasma volume:

- Heart failure
- Renal disease
- Hepatic cirrhosis
- Medications (e.g., non-steroidal anti-inflammatory drugs, glucocorticoids, aromatase inhibitors, vasodilators, calcium channel blockers)
- Venous insufficiency or obstruction

#### Low protein states:

- Nephrotic syndrome
- Protein-losing enteropathy
- Liver disease
- Malnutrition

#### Increase in capillary permeability:

- Burns
- Trauma
- Inflammation
- Allergic reactions

#### Lymphatic obstruction/damage:11

- Lymph node dissection
- Malignancy
- Trauma
- Venous disease
- Infection (e.g., lymphadenitis, filariasis)
- Inflammatory disease
- Immobility

terleukin-1. This series of events results in skin changes and ultimately ulcer formation; imbalance in the MMPs is associated with poor wound healing outcomes.<sup>29</sup>

Physical assessment includes identifying physical changes in both limbs for edema, stasis changes, hyperpigmentation of the skin or hemosiderin staining, corona phlebectatica, and varicosities. Acute lipodermatosclerosis (LDS) and chronic LDS (a woody texture to the skin) are evidence of progressive changes over months to years. As well, the shape of the limb should be assessed; for example, with chronic LDS, an inverted champagne bottle deformity may be present (see Table 4).

Comments
Edema is the perceptible increase in volume of fluid in skin and subcutaneous tissue, characteristically indented with pressure. Venous edema usually occurs in the ankle region but may extend to leg and foot. Edema worsens with dependency and improves with leg elevation. <sup>30</sup>
Eczematous changes make skin vulnerable, with redness and scaling often associated with pruritis. Management involves the use of emollients or topical corticosteroids. Contact dermatitis and allergies/sensitivities may occur from the use of some topical agents.
When vein valves fail and red blood cells are forced out of capillaries, they break down and release the pigment hemosiderin. This results in grey-brown pigmentation of the skin in the gaiter area. <sup>30</sup>
This fan-shaped pattern of numerous small interdermal veins on medial or lateral aspects of ankle or foot is commonly thought to be an early sign of advanced venous disease. Synonyms include malleolar flare, or ankle flare. "The corona phlebectatica (CP) is classically described as the presence of abnormally visible cutaneous blood vessels at the ankle with four components: 'venous cups,' blue and red telangiectases, and capillary 'stasis spots.'" <sup>31</sup>
Usually tortuous, but tubular, saphenous veins with demonstrated reflux may be classified as varicose veins. Synonyms include <i>varix</i> (plural <i>varices</i> ) and <i>varicosities</i> . Varicose veins are blue, swollen, twisted veins that may be superficial or deep. Common locations include the ankle, back of the calf or medial aspect of the leg. <sup>30</sup>

cont'd....

#### Acute lipodermatosclerosis (LDS)

Acute lipodermatosclerosis presents with an extremely painful red to purple indurated warm area on the lower leg. It is often misdiagnosed as cellulitis, phlebitis or panniculitis. These changes progress over months to years to the chronic form.<sup>32</sup>



Chronic lipodermatosclerosis (LDS)



Localized chronic inflammation and fibrosis of skin and subcutaneous tissues of lower leg, sometimes associated with scarring or contracture of Achilles tendon. LDS may be proceeded by a diffuse inflammatory edema of the skin, which may be painful, referred to as hypodermatitis LDS, or acute LDS. The chronic form is recognized as a sign of severe venous disease or C4 in the CEAP classification.<sup>30</sup>

Inverted champagne bottle deformity



This is a form of lipodermatosclerosis with subcutaneous fibrosis, which leads to proximal leg swelling with skin tightening and a narrowing band at the distal leg or ankle.

Atrophie blanche



Venous ulcer

This is characterized by localized, often circular, whitish and atrophic areas surrounded by dilated capillaries and sometimes hyperpigmentation, often described as porcelain white scars. Atrophie blanche is common, occurring in a third of patients with venous disease, but also may represent livedoid vasculopathy.<sup>33</sup> This livedoid vasculopathy is associated with coagulation abnormalities in 50% of cases. The most common location for this is the medial malleolus extending to the dorsal aspect of the foot. Atrophie blanche is painful due to vascular occlusion.<sup>30,33</sup>

This full-thickness defect of the skin, most frequently in ankle region, fails to heal spontaneously and is sustained by CVD.

Patients with venous disease and associated leg edema often have stasis dermatitis and are prone to contact dermatitis. Contact dermatitis must be differentiated from cellulitis (see Table 5). Breakdown of the epidermal barrier allows penetration of potential allergens and the development of sensitivities. Contact dermatitis is about 80% irritant and 20% allergic.<sup>34</sup> In the case of allergic dermatitis, activated Langerhans cells in the epidermis can migrate to regional lymph nodes, producing skin changes in sites distant from the original contact. Common allergens include balsam of Peru, neomycin, lanolin, latex and cetylsterol alcohol, preservatives (parabens, Quaternium 15) and components of adhesives such as rosin.<sup>34</sup>

Presentation	Dermatitis	Cellulitis
		Tao K /09
Symptoms	<ul> <li>Afebrile</li> <li>Itching</li> <li>Varicose veins/deep vein throm- bosis</li> </ul>	<ul><li> Possible fever</li><li> Painful</li><li> No relevant history</li></ul>
Signs	<ul> <li>Normal temperature</li> <li>Erythema, inflammation</li> <li>May be tender</li> <li>Vesicles and crusting</li> <li>Lesions on other body parts (e.g., other leg, arms)</li> <li>May be unilateral or bilateral</li> <li>The erythema may match the area where the product was used.</li> </ul>	<ul> <li>Elevated temperature</li> <li>Erythema, inflammation</li> <li>Tenderness</li> <li>One or few bullae</li> <li>No crusting</li> <li>No lesions elsewhere</li> <li>Unilateral</li> </ul>
Portals of entry	<ul> <li>Stasis dermatitis with loss of the epidermal barrier allows allergens to penetrate.</li> </ul>	<ul> <li>Usually unknown; break in skin, ulcers, trauma, tinea pedis, intertri- go implicated</li> </ul>
Laboratory tests	<ul> <li>Often nothing is seen.</li> </ul>	<ul> <li>May have elevated neutrophils</li> <li>Obtain skin swabs for <i>Staphylococcus aureus</i> or <i>Streptococcus</i> infections.</li> </ul>

Table 5: Differences between Dermatitis and Cellulitis<sup>30</sup>

#### Arterial Assessment

Evaluation of the lower limb must include an arterial assessment. Knowledge of the vascular status is important for the safe use of compression and sharp debridement, as well as the expected healing potential of an ulcer if one is present. The most common risk factors associated with peripheral arterial disease (PAD) are smoking, diabetes and advanced age. The prevalence of peripheral arterial disease is 14.5% in those older than 70 years.<sup>1</sup> Approximately 15 to 25% of patients with venous disease will

also have some arterial insufficiency.<sup>1</sup> Peripheral arterial disease (PAD) that occurs in the lower limbs is now more accurately referred to as lower-extremity arterial disease (LEAD).

Matic et al. (2016) looked at 162 patients with chronic venous insufficiency (CVI) who were categorized by severity using the CEAP guidelines. The results determined that peripheral arterial disease is more frequent in patients with the severe form of CVI than in patients without CVI.<sup>35</sup> Concomitant risk factors for CVI and PAD were high body-mass index (BMI) and hypertension.

Claudication and rest pain are two symptoms associated with arterial disease, and should be evaluated in the history. It is recommended that pulses be examined in the lower extremity; however, palpation of a pulse is not adequate to rule out arterial disease.<sup>1,36</sup> The dorsalis pedis pulse may be absent as a normal variant in about 8% of healthy adults.<sup>37</sup> Measurement of the ankle-brachial pressure index (ABPI) in all patients with a venous leg ulcer is recommended.<sup>1,36</sup> An ankle-brachial pressure index is a simple, reliable test to determine the presence of arterial disease.

Other clinical clues that may be assessed in the lower leg with arterial insufficiency are decreased capillary refill, dependent rubor (shown by Buerger's test), absence of

distal hair growth, coolness of the skin and thickening and discolouration of the nails. Ulcers due to arterial disease tend to be distally located and exhibit a "punched out" appearance with a pale base. Characteristics of venous and arterial ulcers are described in Section 1.3.

More extensive vascular testing or referral to a vascular surgeon may be necessary in high-risk patients when the ABPI is suggestive of arterial compromise or due to a falsely elevated ABPI. ABPI values over 1.4 indicate calcified, non-compressible vessels. This is a common finding in patients with diabetes. A vascular referral should be expedited in patients with symptoms suggestive of rest pain or an ABPI of less than 0.5.<sup>1,36–37</sup> Click here for more information on the science of an ABPI,<sup>38</sup> and here for more instruction on conducting an ABPI.<sup>39</sup>

#### **Investigations for Venous Disease**

While it is often possible to diagnose a venous leg ulcer based on the patient's clinical history and physical examination, it is still necessary to definitively establish venous insufficiency to determine whether the patient would benefit from interventions to assist in venous ulcer healing or to prevent ulcer recurrence.



Numerous hemodynamic modalities have been developed to investigate venous disease. One of the earliest was plethysmography, whereby a dorsal foot vein was cannulated, and a pressure probe was used to obtain direct measurements of venous pressures. Other less invasive approaches were subsequently developed and included impedance plethysmography, strain-gauge plethysmography, photoplethysmography (PPG) and air plethysmography. These investigations are not widely used today because the widespread availability and ease of use of duplex ultrasound has made them redundant. Duplex ultrasound is useful in assessing both the venous and arterial systems in the lower extremities. It can diagnose deep vein thrombosis and venous insufficiency as well as arterial flow-limiting lesions and occlusions. The test is safe, non-invasive, cost-effective and reliable.<sup>40–42</sup> B-mode imaging permits accurate placement of the pulsed Doppler sample volume, and the addition of colour helps to establish obstruction, turbulence and the direction of venous and arterial flow.<sup>43</sup>

Duplex scanning is excellent for the evaluation of infrainguinal venous obstruction and valvular incompetence. It also differentiates between acute venous thrombosis and chronic venous changes. Valvular incompetence can be identified by Doppler using reflex time. Today, PPG is mostly of academic value, as it takes a long time to conduct and does not add particularly useful information. Quantifying pump power can be useful in certain circumstances, but it is expensive and limited in its application. An evaluation of the veins of the lower extremity includes visualizing the superficial and deep venous systems. Flow is assessed throughout the course of the deep venous system to rule out deep vein thrombosis and venous reflux; this can also be useful in ruling out reflux and phlebitis in superficial veins. In the deep veins, a reflux duration of one second or greater is diagnostic of venous insufficiency, whereas a reflux of 0.5 seconds or greater in the superficial or perforator veins is diagnostic of venous insufficiency.<sup>1</sup>

**Investigation of the Calf-muscle Pump:** Screening of the calf-muscle pump is an important part of an assessment of a person at risk of venous insufficiency. Calf-muscle pump failure is a key contributor to chronic venous insufficiency. The function of the calf-muscle pump is assessed by determining the range of motion around the ankle joint, strength of the calf muscles and gait pattern. Normal function of the calf-muscle pump to support venous return requires a "mobile ankle and routine dorsiflexion beyond 90 degrees."<sup>30</sup> At least 10 degrees of dorsiflexion is needed to fully activate the calf-muscle pump (see Figure 4).<sup>44</sup>

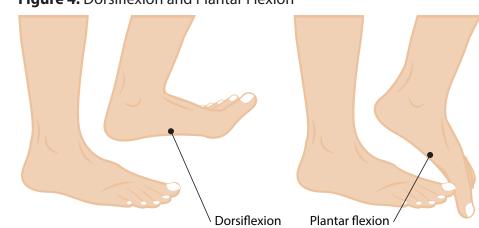
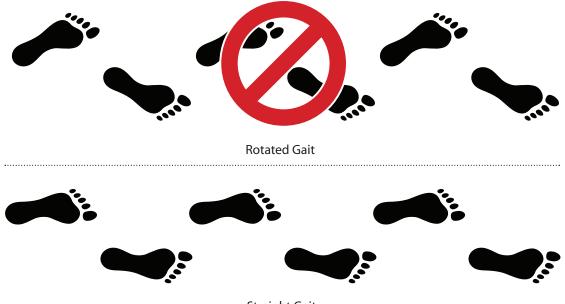


Figure 4: Dorsiflexion and Plantar Flexion

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The calf muscle should have adequate strength to optimize proper gait. While standing, the person should be able to go up and down on their toes. The calf-muscle pump is best activated during proper heel-toe gait.<sup>45</sup> Gait pattern (see Figure 5) should be carefully noted, as many people with venous disease develop a "shuffling gait." Those exhibiting this gait should be referred to physiotherapy.<sup>30</sup>

Figure 5: Gait with Feet Rotated (top), Compared to Those with Feet Straight (bottom)



Straight Gait

A clinician should not only screen for issues with the calf-muscle pump, but also note the patient's activity patterns, as the potential for activation of the system is key. If deficits are noted in range of motion, strength, gait pattern and activity level, clinicians should consider the involvement of a physical therapist or other health-care professionals with knowledge of anatomy, exercise prescription and hands-on techniques that can address these areas to improve calf-muscle pump function.

#### Pain

In venous disease, pain is reported in about 64% of patients with venous ulcers.<sup>46</sup> Pain in venous leg ulcers is individualized and may be described as tender, dull aching or sharp. Pain may be exacerbated with dependency and improved with compression. It may be related to one or more of the following: edema, inflammation of woody fibrosis, bacterial infections, inflammation of the veins (superficial or deep phlebitis), atrophie blanche, arterial insufficiency or contact/allergic dermatitis.<sup>47</sup> Pain, for some, can be all-consuming. Stress for the patient due to pain is felt to negatively impact the healing process. Excess production of catecholamines and cortisol caused by stress can impact the immune system and cause tissue hypoxia.<sup>48</sup> Pain due to arthritis in lower extremity joints limits mobility, which is known to contribute to edema and delayed VLU healing.<sup>28</sup>

The treating clinician should assess pain using a validated approach and address these issues and identify and treat the causes. For example, new or increasing pain may be related to local infection<sup>49</sup> or changes in the wound status. It is also important to consider a deep vein thrombosis when there is new or increasing leg swelling. Pain that increases with application of compression should alert the clinician to ensure it is not related to arterial compromise. Pain should be understood in terms of type and im-

pact on the patient and underlying disease processes. Note that patients with diabetic neuropathy may have a reduced response to pain (for more information on pain, see Wounds Canada's Best Practice Recommendations for the Prevention and Management of Wounds<sup>13</sup>).

Pain is rated by the patient (assessed by the clinician) and treated and reassessed on an ongoing basis.<sup>50</sup> Pain for persons living with lower leg ulcers is a burden affecting activities of daily living (leisure and employment), sleep hygiene, mobility, footwear, and the mental, emotional, social and spiritual domains.<sup>51</sup> Wound pain affects the patient's participation in care planning, and in wearing preventative stockings and compression therapy.

For more information about pain assessment tools, visit www.woundscanada.ca/ health-care-professional/resources-health-care-pros/28-publications/wound-carecanada/200-library-2.<sup>22</sup>

#### Patient Assessment Summary

Venous leg disease includes important laboratory and historical elements that should be considered in the patient-focused assessment. Table 6 summarizes key elements of the assessment.



Table 6: Key Components of the History and Physical Examination

History	<ul> <li>Risk factors for venous or arterial disease</li> <li>Co-morbid conditions (diabetes mellitus, connective tissue diseases, and inflammatory conditions), arterial risk factors</li> <li>History of the ulcer(s)</li> </ul>
Bedside examination	<ul> <li>Blood pressure (BP)</li> <li>Examine lower leg and identify ulcer characteristics</li> <li>Feel for pulses at the femoral, popliteal, dorsal pedis and posterior tibial</li> <li>Ankle-brachial pressure index (ABPI)</li> <li>Gait assessment, including walking aids/footwear/physical activity and ankle-joint range of motion</li> </ul>
Laboratory	<ul> <li>Blood glucose level</li> <li>Creatinine, CBC, AST, plus others depending on co-morbid issues, diagnostic considerations (thrombophilia screen if DVT or history)</li> </ul>
Vascular laboratory	<ul><li>Venous duplex Doppler</li><li>ABPI and more extensive arterial studies if indicated</li></ul>
Allergies/ Sensitivities	<ul><li>Medications</li><li>Topical agents</li></ul>
Self-care abilities/ Psychosocial issues	<ul><li>Quality of life assessment</li><li>Continence status</li><li>Patient concerns</li></ul>
Nutrition	<ul><li>Weight</li><li>Use of validated tools to evaluate</li></ul>
Medications	<ul><li>Immunosuppressants</li><li>Possible drug interactions if adding antibiotics or other agents</li></ul>
Pain	<ul> <li>Procedural</li> <li>Related to disease</li> <li>Related to compression or dressings</li> <li>Use of validated tools to evaluate</li> </ul>

## 1.2.2. Environmental: Socio-economic, care setting, potential for self-management

The patient's ability to be motivated to participate and engage in establishing the treatment goal and care plan should also be assessed. The clinician should determine the patient's ability to conduct preventative self-care measures, including consistent management of leg edema. Ulcer formation and changes to mobility may contribute to employment changes, job loss or changes in one's level of social engagement.<sup>6</sup> As well, leg edema may have an impact on patients' ability to toilet safely and in a timely manner. Issues specific to venous disease to consider include the amount of exudate, possible odour and pain that can affect the patient's activities of daily living (e.g., bathing, walking) and instrumental activities of daily living (e.g., shopping, driving, computer use). Managing appropriately fitted footwear can be a challenge due to the bulk of some compression systems. As well, the frequency of dressing changes may vary, and large amounts of exudate can further challenge the patient and family supports. Financial concerns may prohibit patients from taking time off work for appointments

and impact their ability to purchase supplies, preventative leg garments, mobility aids and footwear. For some, transportation to and from appointments and parking costs may be prohibitive. The risk of altered skin integrity may change as will ability to participate in treatment plans. If patient needs are not met, the ability for wound healing and/or managing chronic venous insufficiency symptoms is diminished, potentially affecting the feasibility of a goal of healing.

#### 1.2.3. Systems: Health-care support and communication

People at risk of developing venous leg ulceration may live with multiple chronic diseases. Access to health care can significantly impact one's ability to manage these illnesses, including any impairments to skin integrity. Financial coverage of venous leg compression garments and therapies varies within each health region, and the fact that many health-care systems do not financially support treatment leads to a financial burden on patients. For patients living in rural and remote areas, access to diagnostics and specialized care may be challenging, and this can be the case in urban areas as well. Assessing the health-care system in which the patient is involved may require the health-care professional to guide and support the patient and family. Patients may need support to gain coverage for compression therapy and garments, and referrals for financial support may be necessary.

#### 1.3 Complete a wound assessment, if applicable.

Evaluation of ulcers on the lower leg requires careful consideration of the patient's history and a focused physical examination. The venous leg ulcer should be evaluated in terms of numerous parameters, including location (gaiter area, malleolar area), ulcer size (shallow), amount and type of exudate (mild to severe), appearance of the ulcer bed (irregular in shape), condition of the wound edge (attached, rolled), signs of clinical infection (see bacterial burden, section 4.2.3) and changes to the periwound skin (see Table 7).



**Table 7:** Example of the MEASURE Mnemonic Used with the Venous Leg Ulcer

 Patient<sup>52</sup>

Parameter	Comments	
Measure	Measure the longest length with the widest width at right angle. Also include the depth.	
<b>E</b> xudate	Record amount (none, scant, moderate or heavy), and characteristics (serous, sanguineous, purulent or combination of these). Comment on odour after cleansing.	
<b>A</b> ppearance	Consider type of tissue in the wound bed (necrotic, fibrin, slough, friable, granulating, hypergranulating).	
<b>S</b> uffering	Assess pain. It should be quantitated (pain quality, timing).	
<b>U</b> ndermining Determine location, often described using the hands of a clock, and measurement.		
<b>R</b> e-evaluate	Do so at intervals related to wound dressing.	
Edge	Determine whether the wound edge is normal, attached, hyperkeratotic, macerated or rolled.	

#### **Differential Diagnosis**

When the observed findings do not fit the classic characteristics, clinicians need to be aware of other categories of leg ulcers such as those identified in Tables 8 and 9.

Table 8: Differential Diagnosis of Leg Ulcers<sup>1</sup>

Categories	Examples	
Vascular	Venous disease, mixed arterial venous, Martorell hypertensive ulcer	
Inflammatory	<b>tory</b> Pyoderma gangrenosum, polyarteritis nodosa, necrobiosis lipoidica	
Hematologic	gic Sickle cell disease, polycythemia vera	
Autoimmune	Rheumatoid arthritis, leukocytoclastic vasculitis, Sjörgren's syndrome, cryoglobulinemia	
Malignancy	Basal cell, squamous cell, melanoma, cutaneous lymphoma	
Infectious	Bacterial, viral, fungal	
Metabolic	Diabetes, calciphylaxis	
Medication	Hydroxyurea, methotrexate	
Genetic defect	Klinefelter syndrome	
Exogenous	Trauma, radiation, pressure	

Table 9: Differences Between Venous and Arterial Ulcers<sup>53-54</sup>

Assessment	Venous Ulcer	Arterial Ulcer
Health history	Deep vein thrombosis, vein surgery, venous disease, leg trauma, failure of the calf-muscle pump	Cardiovascular disease, stroke, peripheral arterial disease (PAD), advanced age
Lifestyle	Sedentary, obesity, immobile or working in occupations requiring prolonged standing or sitting	Smoking, malnutrition or obesity
Anatomical location	Gaiter region (malleolar)	Below ankle, tip of toes
Measurement (size)	Shallow, irregular, larger in size	Deep, smaller size
Exudate	Moderate to large amount	None to minimal amount
Appearance	Granulation or fibrin	Black and dry tissue
Suffering	Discomfort at the end of the day, heaviness in legs	Pain with elevation of the legs or with activity
Edge	Attached edges	Unattached edges
Surrounding skin	Dry, scaly or macerated skin	Dry, shiny; loss of hair
Pedal pulses	Present	Weak or absent
Leg characteristics	Varicose veins, edema, hemosiderin staining; may also have lipodermatosclerosis, atrophie blanche and stasis dermatitis	Pallor, dependent rubor, poor capillary refill, changes to nails, possible gangrene of toes

#### Infection

Wound infection develops as a result of micro-organisms invading the tissues, causing damage and invoking a local or systemic response in patient with VLU. Certain factors make venous ulcers unique in terms of infection, including large size or multiple ulcers, significant exudate and edema, stasis changes of the skin, and arterial insufficiency, which coexists in about 25% of ulcers.<sup>10</sup> Edema and stasis changes predispose patients to small breaks in the skin, allowing microbes to enter. Edema fluid also neutralizes the fatty acids of sebum, reducing the inherent bactericidal properties of the skin.<sup>50</sup> Clinical evaluation of infection involves assessment of wound characteristics as well as the patient's symptoms and wound bed microbiological cultures. Swab cultures should only be obtained in the presence of clinical signs of infection. The International Wound Infection Institute (IWII) states wound infection exists on a continuum. The clinician should differentiate local versus spreading or systemic infection.<sup>49</sup>

The clinical signs and symptoms of infection in VLU have been described in the literature.<sup>55-58</sup> The classic or overt signs and symptoms of infection (erythema, purulence, pain and edema) can be altered in complex wounds despite a high bacterial bioburden.<sup>57,59</sup> Covert signs of infection are often apparent prior to the development of overt signs and symptoms, as identified by the IWII.<sup>49</sup> Host factors, micro-organism virulence and numbers impact the risk and progression of infection. Refer to Best Practice Recommendations for the Prevention and Management of Wounds, page 23, for signs and symptoms associated with stages of the wound infection continuum.<sup>13</sup>

#### Malignancies

Non-healing VLUs can be a risk factor for the development of malignancies. Characteristics associated with malignancy include friable surface tissue, raised borders, abnormal granulation tissue and failure to respond to treatment. A squamous cell carcinoma arising from a non-healing wound is known as a Marjolin's ulcer.<sup>60</sup> Basal cell carcinomas are the most common presenting malignant ulcer in the leg. Biopsy is recommended when there are atypical features or failure to improve after four to six weeks with appropriate management, including compression.<sup>1</sup> It may be necessary to do multiple biopsies to exclude malignancy if clinical suspicion is high. The history is important, as malignancies are more common in patients on immunosuppressants, and in areas of a scar or previous areas of radiation. Malignancy is also more common with advanced age and ulcers on the anterior shin.<sup>61</sup>



# Step 2: Set Goals

### Step 2: Set Goals

#### Recommendations

## 2.1 Set goals for prevention, healing, non-healing and non-healable wounds.

Goals are based on comprehensive patient, environmental and support system assessments and are developed in collaboration with the patient and caregivers.

#### 2.1.1 Identify goals based on prevention or healability of wounds.

Patient-driven SMART goals should be developed to support the management of leg edema and the prevention and/or healing of VLUs.

#### **Examples of Preventative Goals**

- Edema reduced through continuous use of compression therapy (wraps or pumps) within two weeks
- Edema prevented through long-term use of garments once edema is reduced
- Edema reduced by elevating the affected limb above heart level for 30 minutes three times per day
- Calf muscle and calf-muscle pump activated using elastic bands 10 times three times per day
- Walking using heel-toe gait for 20 minutes two times per day
- Risk of injury reduced through the reduction of environmental hazards within two days
- Skin care regimen in place within one day
- Resumed ADLs within one month



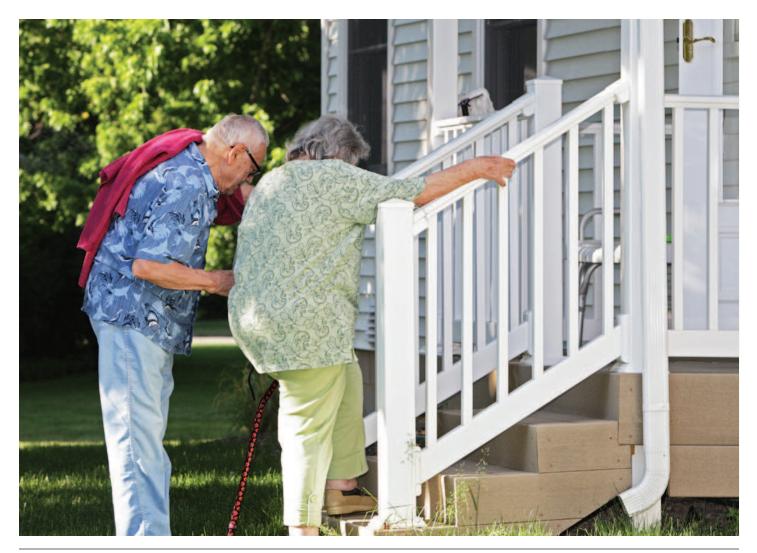
#### **Wound Healing Goals**

The designation of the wound as healing, non-healing or non-healable may change over time and affect goal setting. This is most obvious if arterial flow can be improved to the extremity through vascular surgery; in this case, the wound may transition from a non-healing to a healing wound. Responsible use of resources is necessary, and this is an important consideration in venous disease management. The type and re-usability of compression wraps will be a consideration if the wound is not considered healable.

#### **Examples of Goals for Patient with a Healing Ulcer**

These are goals where there is sufficient vascular supply, underlying causes have been corrected and health is optimized:

- Edema management goals, as in prevention
- Wound closure within three months
- Infection managed with antimicrobials within two days
- Exudate managed through dressing selections within two days
- Pain managed though analgesia within one day
- Awareness of signs and symptoms of infection learned within one day



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#### **Examples of Goals for Patient with a Non-healing Ulcer**

These are suitable goals where there is potential to heal, but where wide-ranging patient or health-care system factors are compromising wound healing, including the inability to accept or consistently wear compression therapy as prescribed and planned with the health-care professional. These issues may take weeks or months to address.

- Edema managed (identify specific method patient is able to accomplish)
- Independence established with dressing changes using clean technique
- Drainage and odour managed with recommended dressings
- Pain managed using analgesia
- Awareness confirmed of signs and symptoms of infection and/or deterioration, and to whom to report concerns
- Infection prevented and/or treated with antimicrobial dressings

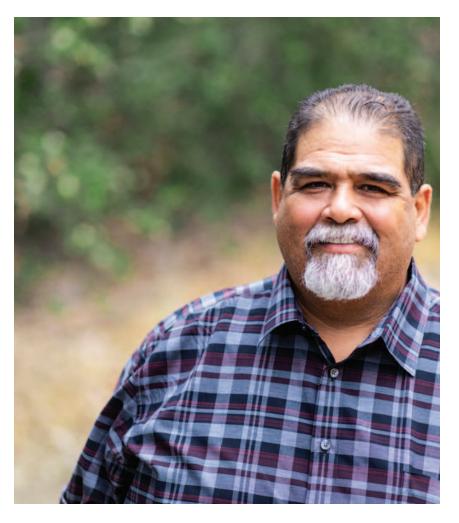
## Examples of Goals for Patient with a Non-healable Ulcer

These are suitable goals where there is no ability to heal due to untreatable co-morbidities such as severe PAD/LEAD, congestive heart failure (CHF) or an endof-life illness:

- Same as for non-healing ulcers
- Attendance at a chronic disease-management support group, as able
- Attendance at smoking cessation session(s), as able

## 2.1.2 Identify quality-of-life and symptom-control goals.

Quality-of-life and symptom-control goal setting requires coordination and communication to ensure patient involvement and effective management of venous disease. It is essential that the



integrated team set realistic goals around smoking cessation, appropriate garments and footwear, and medication management as well as ADLs such as exercise and physical activity. If patients experience an exacerbation of their disease, goals may need to be revisited and modified.

# Step3: Assemble the Team

### Step 3: Assemble the Team

By connecting health-care professionals with the patient, family members, caregivers and service providers, health care becomes the responsibility of an integrated team. Respectful team communication is essential, especially when not all team members are in the same clinical setting.

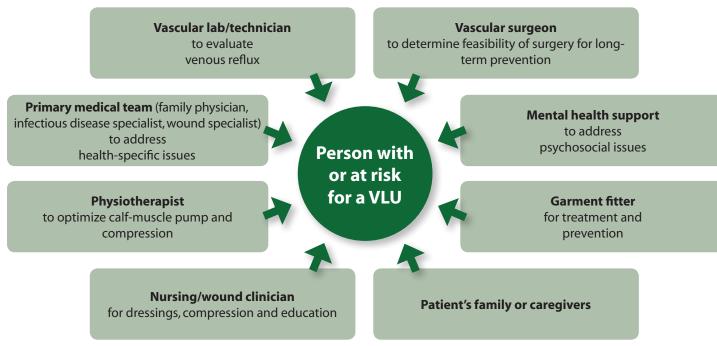
#### Recommendations

## 3.1 Identify appropriate health-care professionals and service providers.

Completing a comprehensive assessment of physical, psychological, spiritual and socio-economic needs will help determine which health-care members and service providers must be part of the care plan.

Patients with wounds such as venous leg ulcers may require the skill of numerous health-care disciplines, depending on the patient's needs, and availability in the community of nurses, physicians (general and specialist), pharmacists, social workers, psychologists, dietitians and spiritual advisers (see Figure 6). The team members will change over time depending on patient factors and the healing process. Specific to venous disease, physicians, vascular technicians and surgeons, physiotherapists and garment fitters would take an active role during the treatment.

Figure 6: Example of an Integrated VLU Team



## 3.2 Enlist the patient and their family and caregivers as part of the team.

Enlisting the patient and their caregivers within the health-care team is a critical component to the success of VLU treatment outcomes. As compression therapy is the mainstay in venous leg therapy—and a life-long commitment to the care plan is necessary—patients must receive instruction, not just on the mechanics of wearing compression therapy daily and in the long-term, but also why it is essential to do so.

This is most often the greatest challenge for clinicians, as many patients discontinue wearing compression garments once the ulcer is closed. Therefore, finding the most appropriate compression for the patient situation is critical in the long-term treatment and management of VLU. The patient and their caregivers must be involved in deciding which compression is the most suitable based on comfort, ease of application and cost of the compression therapy and prevention garments. Another mainstay includes ensuring the patient and caregiver(s) can commit to an activity program that allows for increased mobility and activity to maintain an active calf-muscle pump.

#### 3.3 Ensure organizational and system support.

Organizational and system support requires that decision-makers, and those who oversee financial budgets understand the importance of providing evidence-informed, cost-effective care for the prevention and management of venous leg ulcers. Often, due to limited budgets and resources, clinicians are challenged and can be strained to provide appropriate care. Hence, it is imperative that system allows for the use of the appropriate care provider to deliver care within the designated scope of



practice. As well, decision-makers on a macro level (administrators, managers, local and regional governments) must understand the value of best practices and continued education for team members as these translate to improved, cost-effective patient outcomes.

Organizational issues that need to be considered specifically for venous disease are:

- Adequate funding for compression garments or the newer self-adjustable hookand-loop fastener systems. This would be a consideration for the prevention and management of venous ulcers.
- The role of self-management for venous disease through education and access to compression garments and hook-and-loop fastener systems
- Funding for physiotherapy assessment and treatment programs to improve calf-muscle pump function
- Funding for footwear while the patient is wearing lower-limb devices and garments (compression). This may be short- or long-term funding, depending on the care plan.



# Step 4: Establish and Implement a Plan of Care

### Step 4: Establish and Implement a Plan of Care

#### Recommendations

4.1 Identify and implement an evidence-based plan to correct the causes or co-factors that affect skin integrity, including patient needs (physical, emotional and social), the wounds (if applicable) and environmental/system challenges.

#### **Compression Therapy**

Patients with venous insufficiency and/or lymphedema require the life-long use of therapeutic compression that may include compression bandaging systems, compression garments (stockings, or loop and fastener systems) or compression devices. Compression improves calf-muscle pump function and decreases reflux in the incompetent veins.

Compression garments may also be used in the early stages of chronic venous disease, including thrombotic disease (e.g., deep vein thrombosis [DVT]), to help prevent disease progression. High compression is the treatment of choice, but this needs to be reduced if there are concerns about arterial insufficiency.

Before applying modified compression, the practitioner should consider the patient's physical status (cardiac and renal function) and tolerance to pain. In 2017, Andreissen et al. evaluated the literature to clarify the contraindications, risk factors and adverse events as a result of the application of compression.<sup>62</sup> This

review of 20 papers on compression therapy for venous leg ulcers indicated consensus for absolute contraindications when there is arterial occlusive disease, heart failure and an ABPI of less than 0.5. There was conflicting information on relative contraindications and adverse events for patients. Other patient factors that were identified as issues that would need to be taken into consideration in using compression are the following: neuropathy, thrombosis, serious non-controlled hypertension, skin issues and intolerance to materials. Patient education and factoring in patient issues are important to the successful use of compression.

#### The Underlying Principle of Compression Therapy

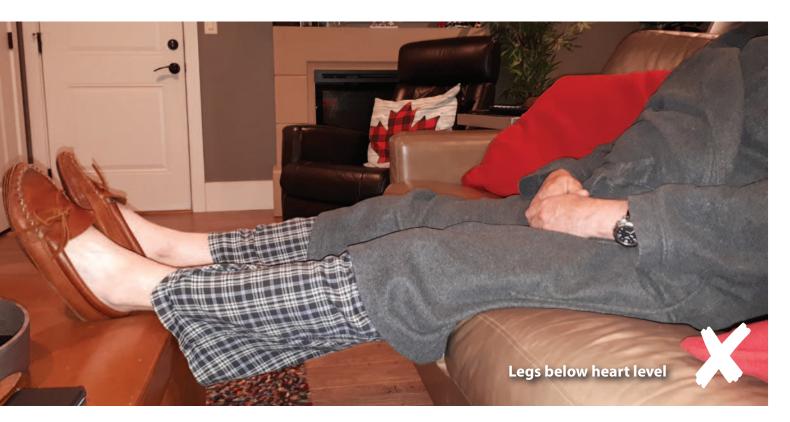
Compression therapy helps to reduce ambulatory venous pressure. The pressure measured at the ankle when standing is about 80 to 100 mmHg. When the calf-muscle pump is activated during walking, pressure drops to about 30 mmHg. This pressure does not drop appropriately when the legs are dependent or if there is valvular disease or obstruction.

Two physical laws are used to understand how compression works to improve venous return:

Pascal's Law states that "pressure applied to an enclosed system of an incompressible fluid is distributed evenly. This can be demonstrated using a capped tube of tooth-paste in which several equally sized-holes have been punched. When pressure is applied to the tube at one point, toothpaste will extrude from all of the holes at the same rate, no matter how far they are from the point of applied pressure."<sup>63</sup> Pascal's Law applies to rigid or short-stretch (inelastic) compression systems. With muscle movement

In general, **bandages** and **compression devices** are most commonly used for the treatment of active VLUs and the reduction of lower-leg edema. **Compression garments** are generally used once the edema is reduced, to prevent recurrence of VLUs. against the rigid system, pressure is generated and distributed equally along the lower leg.

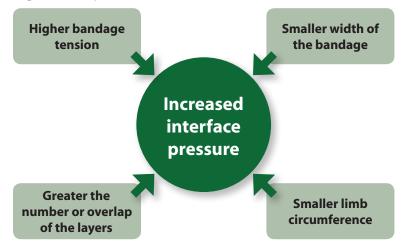
The variables defined by Laplace's Law are related to the size of the limb, the bandage width, the degree of overlap or numbers of layers, and the degree of tension applied (see Figure 7). In the lower leg with compression applied at the same tension, pressure is higher at the ankle and lower in the calf.





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#### Figure 7: Laplace's Law<sup>63</sup>



Compression therapy affects the blood vessels, lymphatic system and fluid content in the tissues.<sup>64</sup> By decongesting the venous and lymphatic system, arterial blood flow can be improved.<sup>65</sup> The compression pressure should not exceed the arterial perfusion pressure. An ABPI less than 0.5 is a contraindication to compression. Use of compression in patients with mixed arterial venous disease should only be considered following a comprehensive vascular assessment by appropriate personnel such as a vascular surgeon. Inelastic compression systems would be recommended in patients with mixed arterial venous disease. Caution: clinicians must remember that patients with calcified pedal vessels can have a normal ABPI.

These principles are important to consider in applying compression to patients with narrow limbs or over bony prominences. Irregularly shaped legs can be challenging and may require padding.

#### **Compression Bandaging Systems**

Several bandaging systems are available for VLU management. Compression systems are divided into short stretch and long stretch, and further by the number of component layers in the system (see Table 10). Multi-component bandage systems are more effective than single-component systems. Multi-component systems containing elastic bandage appear to be more effective than those composed mainly of inelastic constituents. Two-component bandage systems appear to perform as well as four-layer bandaging (4LB) systems. Patients receiving the 4LB system heal faster than those allocated to the short-stretch bandages (SSB). More patients heal while wearing high compression stocking systems than with SSB. Additional data are required before the difference between high-compression garments and the 4LB system can be established.<sup>66</sup>

The system chosen will depend on patient concerns. If pain is a problem, inelastic compression systems may be more comfortable. The increase in pressure exerted by the compression system in going from lying to standing is termed the *static stiffness index*.<sup>64</sup> This is an important characteristic of the inelastic system where the static stiffness is high, causing a massaging effect during walking. Elastic systems have a low static stiffness index and maintain a constant high pressure, and therefore would have a lower margin of safety. In addition, the bulk of some compression systems that assist in reducing ambulatory venous hypertension can actually decrease range of motion around the ankle joint, further adding to the problem of calf-muscle pump failure.<sup>67</sup>

**Table 10:** Types of Compression Bandages

Туре	Alternate Name	Static Stiffness	Compression	
			Resting	With Activity
Long Stretch	Elastic	Low	High	Lower
Short Stretch	Inelastic	High	Low (support)	Higher

#### **Compression Garments**

The standard of care for the long-term management of patients with edema and venous ulcers (classified as C3 to C6 using the CEAP system [see Table 3]) remains compression garments (see Table 11). Prescribing graduated compression garments requires that clinicians have a full understanding of the principles of this therapy. These require appropriate measurements of the area of the leg to be compressed as well as prescription if pressure over 20 mmHg is required.

**Table 11:** Compression Garments for Maintenance and Prevention of Leg Edema(American Classification)

Class	Pressure	Indication for Use
	15–20 mmHg	<ul> <li>Tired, achy feet and legs; slight edema; for airline travel</li> <li>Spider veins, early varicose veins</li> </ul>
I	20–30 mmHg	<ul><li>Varicose veins, mild edema</li><li>Deep vein thrombosis (DVT) prevention</li></ul>
II	30–40 mmHg	<ul> <li>Moderate varicose veins, mild edema</li> <li>Prevention of venous ulcer recurrence</li> <li>Lymphedema (but higher pressure is better)</li> </ul>
III	40–50 mmHg	<ul> <li>Severe varicose veins</li> <li>Prevention and treatment of venous leg ulcers</li> <li>Lymphedema</li> <li>Postphlebitic limb</li> <li>Chronic venous insufficiency</li> </ul>
IV	50–60 mmHg	Lymphedema

For more information see Wounds Canada's Product Picker for Control of Venous Leg Edema.<sup>68</sup>

Patients must be aware that ulcer recurrence rates can be higher when they do not adhere to wearing their garments. A Cochrane Review by Nelson and Bell-Syer (2012) examined four trials (979 participants) to determine the effect of compression (socks, garments, tights, bandages) in preventing recurrence of venous ulcers.<sup>69</sup> They concluded that there is evidence from one trial that compression hosiery reduces rates of

venous leg ulcer reoccurrence compared with no compression.<sup>70</sup> In a Cochrane Review, O'Meara et al. (2012) looked at 48 randomized control trials (RCTs) reporting 59 comparisons to evaluate the effects on venous ulcer healing using compression bandaging and garments.<sup>66</sup> They concluded that compression increases ulcer-healing rates when compared with no compression.

Compression garments are to be fitted only after edema has been reduced. Limb edema needs to be reduced through compression wraps or pumps, after which legs can be measured and fitted for compression garments.

#### Long-Stretch Systems

- While cohesive bandages have some stretch, they are best considered to be inelastic systems.
- Sub-bandage pressure in modified systems can vary based on the material of the bandage and, most importantly, the technique of the bandager.

#### Short-Stretch Systems Caution:

- High compression therapy should only be applied in the absence of arterial disease, ABPI = >0.9.
- High compression therapy should be handled by trained practitioners.

A 2016 Cochrane review conducted by Weller et al. looked at the literature to determine if specific interventions would improve adherence to compression, improve healing outcomes and reduce recurrence.<sup>71</sup> Their summation was, "It is unclear whether interventions designed to help people adhere to compression therapy improve venous ulcer healing and reduce recurrence. There is a lack of trials of interventions that promote adherence to compression therapy for venous ulcers."<sup>71</sup>

#### **Donners and Doffers**

Compression garment application may require the patient to obtain a donner to aid in the application of socks or stockings. There are various devices available commercially, and patients should be encouraged to obtain one and be instructed on how to prevent damage to the garment or skin during application and removal. Consistent education with patients and care providers is necessary.

#### **Compression Devices**

Intermittent pneumatic compression (IPC) has been used to reduce lower limb edema in the treatment and management of VLUs and lymphedema. In 2014, Nelson, Hillman and Thomas conducted a Cochrane Review of the effect of IPC and its impact on healing and health-related quality of life for patients with VLUs.<sup>70</sup> They reviewed nine randomized controlled trials (RCTs), involving a total of 489 people. The RCTs compared the effects of IPC with control (sham IPC or no IPC) in venous ulcer management. The authors concluded that IPC may increase healing compared with no compression, but it remains unclear whether it can be used instead of compression bandages.<sup>70</sup>

Young, Ng and Wilkies (2017) examined the use of IPC in the home of one female patient. They concluded that IPC in the home setting is anticipated to improve patient involvement, concordance, patient outcomes and reduce risk to staff applying conventional compression bandaging systems, particularly for obese patients with limited mobility.<sup>72</sup>

Williams et al. (2013) explored the comparison of venous hemodynamics and the effect of a neuromuscular stimulation (NMS) device to IPC in healthy subjects (n = 10).<sup>73</sup> Baseline





measurements were taken of superficial femoral venous velocity and volume flow. Subjects received bilateral therapy for 30 minutes with both devices. The measurements were repeated and then the devices swapped for another 30 minutes. The results showed a peak velocity of 19% with IPC versus 42% with NMS. Time averaged peak velocity was 12% with IPC compared with 27% with NMS. Volume flow was 7% with IPC versus 46% with NMS.

#### **Calf-muscle Pump Activation**

The impact of calf-muscle pump failure cannot be overestimated when addressing the treatment of venous ambulatory hypertension. Gross et al. (1993) reported that in a group of 43 patients with leg ulcers, 60% of patients who were considered to have valve deficiency also had an impaired calf-muscle pump.<sup>74</sup> In this study, 24% of the study participants had no obvious signs of valve insufficiency, but 95% of the subjects had a neuromuscular disorder that would impair calf-muscle pump function.<sup>74</sup>

A treatment program that addresses the range of motion around the ankle joint, muscle strength and gait training

is integral to the overall care plan for the patient at risk for or currently living with a venous leg ulcer.<sup>75</sup> Exercise programs tailored to address venous hypertension need to include stretches and strengthening for the gastrocnemius/soleus muscle complex in preferably weight-bearing positions, but may also be of benefit done in the non-weight-bearing position. It is of benefit for the exercises to be monitored by someone specifically trained in exercise prescription, but the intervention can be successful when incorporated in a self-management program. Exercises are particularly beneficial when done while wearing compression.<sup>76</sup>

Ideally, a clinician should prescribe supervised and safe exercise to patients with and at risk of venous ulceration to promote overall well-being and decrease the risks associated with a sedentary lifestyle, including cardiovascular events and metabolic syndromes. A study by Klonizakis et al. (2018) looked at 39 patients with venous leg ulcers. Patients were randomized to a 12-week supervised exercise program three times/ week with compression (n=18) and for compression alone (n=21). They found that the supervised exercise group showed a median healing time of 13 weeks compared with 34.7 weeks for the compression alone group.<sup>77</sup> Yang et al. (1999) studied the effects of a six-week intensive exercise program with 20 patients and the impact on calf muscle and calf-muscle pump. The results showed there was significant improvement in calf-muscle pump function, measured as increased ejection fraction and decreased

residual fraction (p < 0.05).<sup>78</sup> Orr et al. (2017) performed meta-analysis of eight articles and found a significant increase in calf-muscle pump function (as measured by ejection fraction) in favour of the exercise group as compared to the control (p < 0.001) in 83 participants. Ankle range of motion was higher in the exercise group (116 participants) but was not found to be significant when compared with the control group.<sup>79</sup> There is important emerging evidence of the importance of exercise directed at improving calf-muscle pump strength and range of motion for patients with or at risk for developing VLUs as it does improve hemodynamics and function.

#### Pharmacologic Treatment

The medications that have been studied in randomized controlled trials to support venous leg ulcer healing include flavonoids, horse chestnut seed extract, pentoxifylline and glycosaminoglycans.<sup>80</sup> Of these, pentoxifylline and micronized purified flavonoid fraction (MPFF) have been shown to improve venous leg ulcer healing in RCTs.<sup>81</sup>

MPFF is used worldwide but is not approved for use in the United States. MPFF has just been released in Canada as an over-the-counter medication. It is considered a vasotonic agent that can reduce venous distension and improve lymphatic drainage.<sup>82</sup> Pentoxifylline is a methylxanthine (caffeine derivative) that was initially used in the management of peripheral arterial disease. This drug is thought to improve blood flow to the tissues by reducing blood viscosity and improving red cell deformability, as well as inhibiting platelet aggregation.<sup>83</sup>

Robust evidence supports the use of pentoxifylline. Twelve studies compared pentoxifylline with placebo controls. Pentoxifylline plus compression improves ulcer healing. Adverse effects, primarily gastrointestinal disturbance, were common with pentoxifylline-treated patients.<sup>84</sup> The dosage studied was 400 mg orally three times daily. In patients where compression is not possible, there is evidence that pentoxifylline alone will improve healing. The Society for Vascular Surgery/American Venous Forum recommends the use of pentoxifylline or MPFF together with compression for longstanding venous leg ulcers.<sup>1</sup>

Based on the pathophysiology of venous ulcer development, there is interest in developing agents that inhibit platelet aggregation. Aspirin as a potent anti-inflammatory agent has been evaluated, with promising results. In conjunction with compression therapy, patients receiving aspirin achieved faster healing (46% reduction in healing time compared with the control group). The effects on wound healing and long-term effectiveness remain unclear, however.<sup>85</sup>

Diuretics are indicated for intravascular volume overload due to conditions such as congestive heart failure, hepatic failure and renal failure. They are not indicated for the treatment of peripheral edema that is due to pure venous disease. The underlying problem with venous insufficiency and edema is related to venous reflux and valvular incompetence, resulting in fluid in the interstitial spaces.

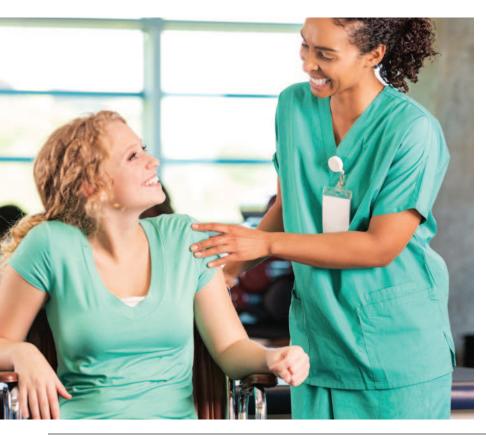
#### Pain

Specific management strategies should be targeted to the cause of pain specific to venous disease. Table 12 lists the causes and various options for management.

Table 12: Venous Disease-related Pain<sup>86</sup>

Pain Related To:	Pain Management
Edema	Sufficient compression, exercise to improve the calf-muscle pump
Deep vein thrombosis	Essential to evaluate with venous Doppler and treat with appropriate anticoagulant; this requires urgent evaluation
Superficial thrombophelbitis	Pain localized over a vein with associated inflammation and palpable tenderness; non-steroidal anti-inflammatory medications and compression
Acute lipodermatosclerosis	Compression bandages, analgesics
Chronic lipodermatosclerosis	Compression bandages/garments, oral medication (e.g., pentoxifylline)
Atrophie blanche	Analgesics
Cellulitis/infection	Topical antimicrobial or oral antibiotic depending on the extent of infection and patient's co-morbidities
Acute contact dermatitis	Removal of the offending agent; treatment with topical agents such as corticosteroid creams

Managing pain can be challenging. It is important to determine the timing of it. Pain can be chronic, related to ulcer factors, or related to dressing changes and cleansing or debridement procedures. Pain in leg ulcers is ranked as the most severe when compared with other wounds, and removal of dressings causes the greatest pain.<sup>47</sup> Having too dry a wound will cause discomfort in dressing removal. Conversely, the excessive



moisture common to venous leg ulcers can cause periwound maceration and further tissue breakdown, increasing pain and discomfort. If sharp debridement is considered and pain is a concern, lidocaine/prilocaine (eutectic mixture of local anesthetics, consisting of 2.5% lidocaine and 2.5% pilocarpaine) is an option.87 As well, certain topical agents or dressings can be used to reduce pain. In a recent systematic review, researchers state that for patients with painful venous ulcers, some evidence suggests ibuprofen dressings provide relief.<sup>87</sup> More research is needed. Table 13 lists the various treatment options for pain caused by a VLU. Pain related to venous disease can persist even after the ulcer has resolved.<sup>86</sup>

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Table 13: Venous Leg Ulcer-related Pain Management

Pain Related To:	Pain Management	
Dressings	Choose a product that absorbs enough fluid to protect the periwound area. If dressing changes are uncomfortable, choosing a dressing that can be left on longer may be helpful.	
Debridement	Use a topical analgesia such as lidocaine/prilocaine, or use topical 1–4% solutions prior to debridement. Consider using autolytic debridement if sharp is too painful.	
Bacterial balance	Some antimicrobial dressings may cause burning in certain patients, and changes may be necessary. More extensive infection would requires oral or intravenous antibiotics.	
Compression	Ideally, high compression systems are recommended if there is normal arterial blood flow. Inelastic systems do not exert pressure at rest and may be preferred when pain is an issue. If compression is not available, elevation is an option.	

A therapeutic relationship between the health-care provider and the patient is required to enhance outcomes and ensure an improved quality of life for the patient. Pain should be evaluated at each visit to determine the type the patient is experiencing, thus guiding the treatment strategy. For more information, see Best Practice Recommendations for the Prevention and Management of Wounds.<sup>13</sup>

#### 4.2 Optimize the local wound environment.

#### 4.2.1 Cleansing

#### Leg Hygiene and Cleansing

Patients living with venous leg edema or ulcers require routine skin care as well as wound cleansing as part of their care planning. When compression bandages and garments are removed from the patient's leg, it is essential that the full leg receive a careful cleansing. Many patients describe appreciation at having their "leg washed and report that the presence of exudate is distressing to them."<sup>88</sup>

Routine skin care regimens include washing the leg with a pH-appropriate skin cleanser.<sup>21</sup> To ensure that the skin pH is optimal, the clinician should avoid solutions that are too alkaline or contain allergens such as perfumes. To complete the leg hygiene process, a moisturizer should be applied to the skin for hydration and maintenance of healthy skin. Routine skin care aids in the removal of devitalized tissue and allows for careful examination of leg tissues. The use of compression wraps may result in retention hyperkeratosis; gentle washing and bathing of the limb must be done to manage this. A non-sensitizing moisturizing cream and emollients should be used—applied in a downward motion—to moisturize the skin. Clinicians can refer to manufacturers' product information sheets to ensure creams and emollients are compatible with leg compression wraps, stockings and garments.<sup>89</sup>

#### Wound Cleansing

Cleansing should be done at each dressing change and wound assessment, and prior to the application of a new dressing. Wound cleansing reduces the odour that is very common in highly exudative venous ulcers. Cleansing of the periwound skin and surrounding skin allows for visualization and management of tissue surrounding the ulcer. There are various methods of cleansing the wound, with the most common being the use of saline irrigation. Irrigation of the wound can be performed using a syringe (30 or 35 ml) and an 18- to 19-gauge needle. Saline also comes in prepared proprietary containers. It is also recommended to use water, as long as it is potable (drinkable).

Patients who are physically capable of showering may cleanse the wound at dressing change. Showering is beneficial to the patient's overall well-being, as it reduces odour and provides improved personal hygiene. Showering is done in consultation and communication with the care team, patient and caregivers.

For more information, refer to Wounds Canada's Product Picker: Skin and Wound Clean-up.<sup>90</sup>

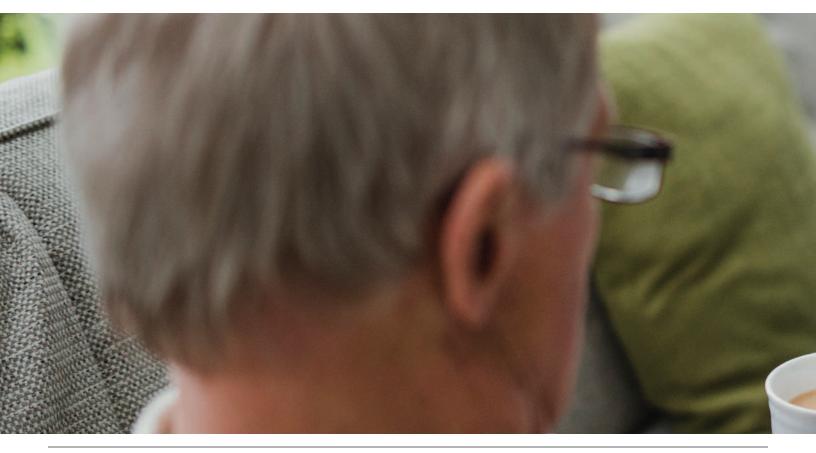
#### 4.2.2 Debriding

Evidence for the benefit of debridement of venous leg ulcers is limited. A study of 10 RCTs failed to show the benefit; however, this study did not include sharp surgical debridement, nor did it compare debridement with no debridement.<sup>91</sup> The choice of debridement method depends on the expertise of the clinician, availability of resources, and patient and wound factors. Pain is often an important consideration.<sup>92</sup>

Arterial flow should be evaluated before proceeding with debridement.

Debridement of the venous leg ulcer is important to accomplish the following:

- Prepare the wound bed to receive treatment
- Remove any necrotic and nonviable wound tissues to manage infection
- Disrupt the biofilm
- Identify the extent of the wound



Cardinal et al. (2009) evaluated serial debridement in 310 patients with venous disease and found a significantly higher closure rate following surgical debridement versus no debridement. Established wound care principles do recommend debridement.<sup>93</sup>

#### 4.2.3 Managing bacterial balance

It is recommended that infected ulcers be treated with topical agents if local infection is evident, and systemic agents with spreading or more systemic infection.<sup>1,49</sup> Beta-hemolytic streptococci is known to cause extensive tissue destruction and should be treated if identified at any level.<sup>50,94</sup> Debridement is also important for successful eradication of infection and disruption of surface biofilm. In evaluations of the evidence for use of topical antimicrobial agents, only cadexomer iodine has been shown to promote healing in venous leg ulcers with excessive bacterial burden.<sup>21,36</sup> Honey has shown no benefit over standard care in locally infected venous leg ulcers.<sup>36</sup>

Systemic therapy for infection should be limited to two weeks unless clinical signs and symptoms persist.<sup>1</sup> There is no evidence for the routine use of antibiotics to promote the healing of venous leg ulcers.<sup>95</sup> Antibiotic options can be found in Wounds Canada's Best Practice Recommendations for the Prevention and Management of Wounds.<sup>13</sup> The choice of antibiotics will depend on the patient's co-morbidities, allergies and drug interactions. Non-healing wounds are more likely to be polymicrobial and have gram-negative bacteria and anaerobes in addition to gram-positive bacteria.<sup>96-97</sup> The semi-quantitative swab is useful for ensuring the chosen antibiotic covers the bacteria grown and identifying resistant organisms. Oral antibiotics are usually sufficient unless deeper infection or patient co-morbidities warrant the use of intravenous antibiotics. If atypical infections are a consideration, a tissue biopsy should be obtained.



#### 4.2.4 Managing moisture balance

Managing moisture balance can be challenging in patients with venous leg ulcers.<sup>98</sup> Wounds may be large with excessive exudate that may be the result of inflammation/ infection or edema. Excessive drainage should be managed to prevent periwound maceration, wound extension or hypergranulation. The management of moisture can be achieved by using appropriate products and dressings, along with compression to control edema. Moffatt (2009) identifies key mechanisms that aid in obtaining proper moisture balance when compression is effectively used:<sup>98</sup>

- "by reducing venous hypertension and enhancing venous return,
- by enhancing local tissue perfusion,
- by reducing [edema] formation and promoting removal through the venous and lymphatic system,
- by reducing overall exudate production and [periwound] maceration, and
- by providing absorption of excess exudate away from the wound bed" (p. 82).

Some wounds may have a lack of moisture, which may be a result of inappropriate dressing selection or systemic problems such as dehydration, or be indicative of an ischemic ulcer. The objective of care is to ensure an adequate quantity of moisture to facilitate the wound healing process but not so much that it will impede healing and cause additional skin breakdown. Therefore, the moisture level should be assessed at each dressing change, as exudate/moisture may indicate a change in the wound status.<sup>99</sup>

#### **Surgical Management**

Numerous studies have examined the role of surgical intervention for the treatment of venous leg ulcers. The role of surgery is to remove the incompetent superficial vein and divert venous flow to the deep system, thereby mitigating the effect of venous hypertension on the ulcerated skin. Surgical interventions include ligation and stripping, endovenous laser or radiofrequency ablation, and injection with foam or cyanoacrylate glue to chemically ablate the superficial veins. In patients with deep venous occlusive disease, surgical interventions may include stenting of the deep veins or creation of a venous bypass.

The largest and most significant study to assess the role of superficial venous stripping was the ESCHAR study, which compared surgery and compression with compression alone for the treatment of venous leg ulcers.<sup>100</sup> In this multi-centre study, 500 patients with isolated superficial venous reflux and mixed superficial and deep reflux were randomized to either compression treatment alone or in combination with superficial venous surgery. The authors reported that, while the healing rates were similar between patients who underwent venous stripping and those who received only compression therapy, the recurrence rates of venous ulcers were lower in patients who underwent venous stripping procedures.

A randomized trial by Viarengo and colleagues found that endovenous laser ablation with laser therapy was associated with a shorter time to healing and a greater median reduction in ulcer size compared with compression therapy alone.<sup>101</sup> O'Hare and colleagues also compared injecting the saphenous vein with foam with compression therapy alone but found no statistically significant difference in would healing between the two groups.<sup>102</sup> This study, however, was not adequately powered to detect

small differences in healing rates. To date, there is a lack of well-powered, prospective randomized trials to definitively investigate the role of endovenous therapies for the treatment of venous leg ulcers.<sup>103</sup>

Currently, Canadian provincial health insurance plans will pay for saphenous vein ligation and stripping procedures for patients with venous ulcers. Endovenous technologies such as laser, radiofrequency ablation or chemical ablation are not covered by Canadian public insurance plans. Most vascular surgeons will consider offering the patient a venous intervention if the pathology is limited to the superficial system without involving the deep veins and after the ulcer has healed to prevent recurrence. Some patients have been able to privately obtain endovenous interventions for their venous leg ulcers, but this approach is not currently considered the standard of care in the absence of Level I evidence for its efficacy.

#### 4.3. Select the appropriate dressings and/or advanced therapy.

#### **Dressing Selection**

Dressings play an important supportive role in compression. Once the wound is cleansed, leg hygiene is conducted and the wound assessed, and the decision made as to what dressing to use. Dressings are chosen for a variety of reasons, including wound bed and periwound protection, exudate absorption and management, pain reduction and management, infection and odour control, and patient preference. There is no robust evidence that one dressing is superior to another.<sup>104</sup> For more information on dressing types and their attributes, refer to Wounds Canada's Product Picker for Dressing Selection.<sup>105</sup>



Dressings are worn without compression in some cases, or beneath compression bandages or garments. Dressings are most often held in place by the compression therapy; however, dressings worn without compression therapy must be attached with a device such as a roller gauze or tube netting. Dressings held in place with tube netting or gauze help to prevent further skin damage to the periwound skin from adhesives. Dressings applied when compression hosiery is used require patient and clinician skill and knowledge to ensure the dressing is not forced or moved out of position when the hosiery is applied.

Topical antimicrobials may be used to aid in wound healing when evidence of clinical infection is evident, but not for bacterial colonization. Some evidence shows that cadexomer iodine is effective,<sup>106</sup> and more research is needed to support routine use of honey or silver-based products.<sup>95</sup>



Biofilm is a concern in slow- and non-healing VLUs. It has been shown that 60% of non-healing wounds and only 6% of wounds healing at a normal rate contain biofilm structures.<sup>107</sup> Disruption of a biofilm within a wound is an area of active research. The use of surfactant-containing antimicrobial cleansers has been shown to be useful for disrupting biofilm.<sup>108</sup> Various antimicrobial wound dressings have been evaluated in terms of effectiveness against biofilm. There is no clear recommendation, but there is evidence that time-release silver gel and cadexomer iodine are more effective than other dressings.<sup>109</sup>

Dressings that provide exudate management support wound healing by managing moisture amounts in and around the wound bed. Foam dressings may assist in venous ulcer healing but are not considered more effective than other wound dressing treatments.<sup>110</sup> In a recent meta-analysis of five RCTs, the evidence did not suggest that alginate dressings are more or less effective in the healing of venous leg ulcers than hydrocolloid or plain non-adherent dressings, and there is no evidence to indicate a difference between different proprietary alginate dressings.<sup>111</sup>

Treatments for venous leg ulcers may include protease-modulating matrix (PMM) therapy, especially for wounds that do not follow the normal trajectory toward closure. In a recent system-

atic review, Westby and colleagues (2016) determined that it was unclear whether PMM dressing treatments influenced venous leg ulcer healing relative to dressing regimens without PMM activity.<sup>112</sup> Testing and treating for elevated wound protease activity for healing in venous leg ulcers requires further research.<sup>113</sup>

Topical agents or dressings aimed at reducing wound pain are also available. In a recent systematic review, researchers state that, for patients living with painful venous ulcers, there is some evidence to suggest ibuprofen dressings provide relief, and topical lidocaine/prilocaine (5%) appears to aid in pain relief during debridement.<sup>87</sup> Again, more research is required.

#### **Advanced Wound Therapies**

For venous leg ulcers that are failing to progress toward healing despite optimal treatment and certainty of the diagnosis, advanced wound therapies should be considered. These advanced therapies include electrical stimulation, calf-muscle pump activator devices, negative pressure wound therapy, hyperbaric oxygen therapy, biologic skin equivalents and topical oxygen therapy. In the literature, there is evidence for electrical stimulation and biologic skin equivalents. Hyperbaric oxygen therapy and negative pressure wound therapy continue to be controversial, as there is not enough information to support their use in treating venous leg ulcers.<sup>1</sup> Hyperbaric oxygen, however, does have a role in treating arterial disease, and this can often be an issue in mixed arterial-venous-disease-type ulcers.<sup>114</sup> Therapeutic ultrasound is another modality that is sometimes used to promote wound healing in stalled wounds, including venous leg ulcerations. In a recent Cochrane review, Cullum and Liu (2017) concluded that "it is uncertain whether therapeutic ultrasound (either high or low frequency) improves the healing of venous leg ulcers" (p. 2).<sup>115</sup> There is no strong evidence to suggest that ultrasound speeds ulcer healing in this patient population. There was weak evidence, according to one study included in this review, to support the use of high-frequency ultrasound to speed wound healing.

#### **New Technologies**

#### Calf-muscle Pump Activator

A calf-muscle pump activator device improves calf- and foot-muscle pump activation. In 2016, an eight-week case series evaluation at the Welsh Wound Innovation Centre determined that this technology increases venous, arterial and microcirculatory blood flow in the lower limb in patients with chronic venous insufficiency and intermittent claudication.<sup>116</sup> It also reduces edema, activates the calf-muscle pump and maintains TCpO<sub>2</sub>—promoting conditions suitable for wound healing. Orsted et al. (2016) reviewed the literature on the use of calf-muscle pump activation and concluded that "Stimulation of the common peroneal nerve in the lower leg using low-frequency nerve stimulation (LFNS) may be a comfortable and practical method to support healing of venous leg ulcers."<sup>117</sup> Canadian evaluations conducted by Harris et al (2017) are demonstrating positive outcomes with improved healing.<sup>118-119</sup>

#### **Direct Wound Bed Electrical Stimulation**

Electrical stimulation applied to the wound and/or periulcer skin is believed to reduce bacterial load and improve wound healing by activating tissue repair processes and improving profusion to the area.<sup>120</sup> There is also some evidence that pain is diminished with electrical stimulation.<sup>121</sup> A comprehensive review by Houghton in 2017 identified and appraised 62 published articles that evaluated the effect of electrical stimulation on healing of various wound types.<sup>122</sup> After assessing methodological quality, 22 high-quality clinical trials and 10 systematic reviews were found to support that electrical stimulation applied at therapeutic doses to locations around the wound consistently produced faster wound size reduction and/or a greater number of closed wounds. This review included nine clinical trials involving a total of 361 subjects with leg ulcers primarily due to venous insufficiency. A wide range of electrical stimulation protocols and many different manufactured devices have been used to stimulate wound healing.<sup>123</sup> Improved healing outcomes are associated with applying pulsed current directly to the wound area at an intensity sufficient to produce sensory nerve stimulation (250–500uCi).<sup>120</sup> Novel electrical devices are emerging that automatically deliver electrical current at either ultra-low levels (microcurrent) to the wound bed, or

to peripheral nerves at levels sufficient to activate muscles (peroneal nerve stimulation device). Further research involving properly designed, controlled clinical trials are needed to determine if healing outcomes can be significantly improved when these innovative electrical devices are added to standard wound care programs.

#### **Biologic Skin Equivalents**

Biologic skin equivalents have been developed to address the suboptimal conditions occurring in the wound bed of chronic wounds. Skin substitutes have traditionally been used with burn patients, and more recently with other stalled wounds, including venous leg ulcers.<sup>124</sup> These new biological materials act as a template to which the host cells can migrate and proliferate. The host's own cells are still required to continue the healing process. It is important for the wound bed to be optimized and free of infection prior to the use of these agents. These skin substitutes are classified anatomically as either dermal, or dermal and epidermal layers (composite), and cellular or acellular.<sup>125</sup> Table 14 lists some of the products that have been evaluated.

Skin Substitute	Composition
Dermal/cellular	Woven or knitted mesh with neonatal foreskin fibroblast
Composite/cellular	Bovine-type collagen with human fibroblasts and keratinocytes
Dermal/cellular	Dehydrated human amniotic membrane with epithelial cells
Dermal/acellular	Porcine small intestine collagen
Dermal/acellular	Collagen and cellulose matrix

Table 14: Biologic Skin Equivalents

The evidence indicates further studies are necessary to fully evaluate the use of these products. There are studies showing some support for the use of all these products; however, the Cochrane Review of 2013 concluded that only the bilayer skin substitute increased the rate of healing in venous legs ulcers when used with compression.<sup>126</sup> This is also supported by the Society of Vascular Surgery.<sup>1</sup> This is an area of ongoing clinical evaluation.

#### Topical Oxygen Therapy

Topical oxygen therapy is an innovative technology that is showing promise in its early trials and evaluations to treat non-healing wounds, in particular refractory VLUs. Oxygen is required in cellular and molecular metabolism. It promotes angiogenesis, granulation and collagen deposition. Sultan et al. (2016) conducted a study with 67 limbs with 67 ulcers—who were managed using topical wound oxygen (TWO<sub>2</sub>) therapy—while 65 limbs with 65 ulcers were managed using conventional compression dressings (CCD). The study found that the proportion of ulcers that healed completely and the mean reduction in ulcer surface area were greater in patients managed with TWO<sub>2</sub>. This group also saw a shorter median healing time than the group managed with CCD.<sup>127</sup>

# 4.4 Engage the team to ensure consistent implementation of the plan of care.

Health-care professionals providing care for individuals living with venous leg disease and ulcers must understand their roles and responsibilities in communication and collaboration and in the provision of prevention, treatment and management of care. Prevention of lower leg ulcers requires all team members to encourage and support patients to participate in smoking cessation, physical activity, wearing of compression garments and use of appropriate, professionally fitted footwear. During all phases of care, team members must communicate patient status and collaborate around current treatment and compression options.

Patients, as the key team members, require assessment for depressive symptoms and suffering to ensure they can participate in care planning and decision-making.<sup>98</sup> Reporting patients as non-participatory does not contribute to care planning and patient concordance and engagement; more research is needed on this important topic.<sup>128</sup>

To engage the patient as the key team member, health-care professionals can employ effective communication strategies, including the following:

- Mentally prepare and provide education for the patient about the care plan process.
- Plan footwear and clothing changes ahead of initiating compression.
- Refer patient to physiotherapy to assess gait and equipment needs ahead of initiating compression.
- Provide effective education about the benefits of compression and leg hygiene.
- Where possible, have consistent, well-trained nurses wrapping and caring for this patient group. This builds trust on which health-care planning can be more effectively built.<sup>98</sup>



# Step 5: Evaluate Outcomes

### Step 5: Evaluate Outcomes

#### Recommendations

#### 5.1 Determine if the outcomes of the goals of care have been met.

Using validated and responsive tools and feedback from the team, clinicians should determine if all goals previously set have been met. If goals have been met, the team should continue with discharge planning and ensuring self-management strategies are effective and in place.

# 5.2 Reassess patient, wound, environment and system, if goals of care are partially met or unmet.

If the goals and response to the current management have been partially met or unmet, the team needs to return to Step 1 and reassess. The specific activities required will depend on patient and wound factors, but could involve further blood work, more in-depth evaluation of circulation, a wound biopsy or the involvement of other clinicians. Benchmark data show that, when compression is optimized, a VLU healing rate of 11 weeks is possible.<sup>129</sup>

## 5.3 Ensure sustainability to support prevention and reduce risk of recurrence.

Recurrence rates of venous ulcers have been reported as high as 70%. The ongoing use of compression is required to prevent venous leg ulcer recurrence. Compression can be underutilized due to the lack of clinician knowledge and unavailability of bandages/hosiery. The ideal compression system should be:<sup>130</sup>

- Affordable
- Comfortable
- Easy to apply
- Non-allergenic
- Able to fit into the patient's shoes

The treating clinician needs to be sensitive to and address these issues. Unfortunately, a recent Cochrane Review identified only two studies looking at educational intervention for prevention of recurrence, and neither study showed a difference in long-term healing, recurrence rates or adherence to compression between the control and the intervention group.<sup>71</sup> This area requires more research.

As this condition requires a life-long commitment to garments, the patient's arterial supply should be regularly assessed. Unfortunately, there is no evidence for the optimal frequency of this assessment.<sup>131</sup> As well, consistent efforts to manage activity and mobility (walking) are essential. Collaborative care is necessary to support the patient's efforts to improve and manage their health, as it has the potential to reverse underlying causes.

Ultimately, strengthened system support is required to ensure patient access to the resources necessary for preventing and managing venous ulcers.

### Conclusion

This document presents a systematic approach to the prevention and management of venous leg ulcers. It is incumbent on the clinician to make the correct diagnosis by evaluating the patient's risks and knowing the characteristics and pathophysiology of venous disease. Assessment of the lower leg can be complex, and it is essential to ensure arterial disease has been fully evaluated by physical exam and supported by quantitative vascular means, starting with an ankle-brachial pressure index (ABPI) test.

The most important consideration and the gold standard for treatment is the use of compression. This requires considerable knowledge on the part of the health-care provider in cooperation with the patient and needs to be done in a timely manner to prevent lengthy treatment times. This may require referral to a multidisciplinary wound clinic, if available in the care setting, or other subspecialties.

The important role of the calf-muscle pump in supporting edema management is well established, and exercises and activity to promote its function are necessary components of all treatment plans. Exercise and activity are ways that the patient can be actively engaged in their care.

Surgical management of venous disease is an important consideration that should be carefully evaluated. A wound biopsy is necessary for atypical-looking ulcers or when healing is not evident despite appropriate ulcer management. Venous legs ulcers are unique and challenging because of the large amount of exudate that must be managed. Skin issues need to be addressed along with assessment of infection and pain.

The quality of life for patients with VLUs is impacted significantly and needs to be a consideration throughout the treatment cycle. These issues are unique to each patient but must be evaluated by the treating health-care providers in a successful treatment plan.



Recognizing the early stages of venous changes is significant, and those who see these patients in a primary care setting have an opportunity to provide education about venous disease and the prevention of venous ulceration. Intervening early on with strategies to improve the function of the calf-muscle pump would be ideal.

Recurrence of venous ulcers is known to be common. Patients leaving care should know that compression therapy is a lifelong commitment.

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