

# Treatments for Diabetic Foot Ulcers: A Summary of Evidence-Based Guidelines

It is estimated that more than three million Canadians are living with diabetes. With a continuously rising prevalence, it is projected that by 2025, the disease will have affected as many as five million people in Canada. Diabetes has a negative impact not only on patients' physical health, but also on their social and psychological well-being.

Diabetic foot ulcers are the most common complication of diabetes, affecting 4% to 10% of patients. A diabetic foot ulcer can lead to serious complications, such as wound infection, osteomyelitis (bone infection), cellulitis (skin infection), and amputation (surgical removal of infected foot or toe).

Many treatment options for diabetic foot ulcers are available. Treatments range substantially in benefits and costs and not all clinical practice is evidence-based. CADTH has reviewed the evidence on the following treatments for diabetic foot ulcers:

- Antimicrobial wound dressings<sup>2</sup>
- Compression therapy<sup>3</sup>
- Debridement<sup>4</sup>
- Negative pressure wound therapy<sup>5</sup>
- Off-loading devices.<sup>6</sup>

The recommendations from evidence-based guidelines and evidence statements regarding the use of these treatments are summarized in the "Summary of Evidence-Based Guidelines" section (Table 1 indicates which organizations provide recommendations for certain treatments). Three of the evidence-based guidelines are Canadian: one from the Canadian Diabetes Association, one from the Canadian Association for Enterostomal Therapy, and one from the Registered Nurses' Association of Ontario.



### **Overview of Evidence-Based Guidelines**

Table 1: Reviewed Evidence-Based Recommendations on the Treatment of Diabetic Foot Ulcers

	CDA	CAET	RNAO	WOCN	ConvaTec	IDSA	SVS <sup>a,b</sup>	NICE	NHMRC	SIGN	NPWT-EP
	2013	2013	2013	2012	2013	2012	2016	2011	2011	2010	Int.
Topical Antimicrobials and Antimicrobial Dressings	2013	2013	2013	2012	2013	2012	2016	2011	2011	2010	2011
Compression Therapy					•						
Debridement	•	•	•	•	•	•	•	•	•	•	
NPWT	•			•		•	•	•	•	•	•
Off-Loading	•		•	•	•	•	•	•	•	•	

#### • = Recommendation

CAET = Canadian Association for Enterostomal Therapy; CDA = Canadian Diabetes Association; IDSA = Infectious Diseases Society of America; Int. = international; NHMRC = National Health and Medical Research Council; NICE = National Institute for Health and Clinical Excellence; NPWT = negative pressure wound therapy; NPWT-EP = International Expert Panel on Negative Pressure Wound Therapy; RNAO = Registered Nurses' Association of Ontario; SIGN = Scottish Intercollegiate Guidelines Network; SVS = Society for Vascular Surgery; WOCN = Wound, Ostomy and Continence Nurses Society.

<sup>&</sup>lt;sup>a</sup> In collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine.

b Please note that this guideline was recently published and is not included in the formal review of the evidence included in the CADTH Rapid Response review.



## **Summary of Evidence-Based Guidelines**

## Topical Antimicrobials and Antimicrobial Dressings

#### **Canadian Diabetes Association:**

There is insufficient evidence to recommend any specific dressing type for diabetic foot ulcers (DFUs).

#### Registered Nurses' Association of Ontario:

"Topical antimicrobial medicine may be used [for non-limb-threatening infections] to reduce bacterial burden in superficial infections."

There is mixed evidence regarding silver-containing dressings and creams for promoting wound healing and preventing wound infections in DFUs.

"If topical antimicrobial agents are used and increased superficial bacterial burden or delayed healing are noted, treatment should be supplemented with debridement and moisture balance."

There is mixed evidence on the effectiveness of any particular dressing for DFUs.

#### Wound, Ostomy and Continence Nurses Society:

"Institute a short course of a topical antimicrobial agent along with careful daily monitoring of the neuropathic ulcer for signs of infection."

#### Infectious Diseases Society of America:

Topical antimicrobials for treating most clinically uninfected wounds are not recommended.

#### **Compression Therapy**

#### ConvaTec:

"Review surgical/medical management options to improve arterial circulation and [use] compression bandages if appropriate."

#### **Debridement**

#### **Canadian Diabetes Association:**

"General principles of wound management involve the provision of a moist wound environment, debridement of non-viable tissue (non-ischemic wounds), and off-loading of pressure areas."

#### Canadian Association for Enterostomal Therapy:

Conservative sharp wound debridement should be selected for wound bed preparation when appropriate.

DFUs should be treated with conservative sharp wound debridement "as part of a multimodal approach to optimal care."

#### Registered Nurses' Association of Ontario:

Wound care consisting of debridement (removal of necrotic tissue, if healable), infection control, and moisture balance should be provided where appropriate.

"If healing potential is not established, aggressive debridement and moist interactive healing is not recommended."

#### Wound, Ostomy and Continence Nurses Society:

"Selection of the methods for debridement should be determined by the condition of the wound, presence or absence of infection, biofilms, amount of necrotic tissue, vascularity of wound, and anticoagulation medications."

"Hydrogels, which may be an effective method of debridement as compared to gauze dressings, [should be considered]."

"Routine debridement of focal calluses decreases plantar pressure."

#### ConvaTec:

Debridement of DFUs with more than 25% necrotic tissue in the wound is recommended with autolytic, enzymatic, or surgical debridement.

#### Infectious Diseases Society of America:

"Clinicians should debride any wound that has necrotic tissue or surrounding callus; the required procedure may range from minor to extensive."

Appropriate wound care usually consists of debridement that removes debris, eschar, and surrounding callus.

"Sharp (or surgical) methods are generally best, but mechanical, autolytic, or larval debridement may be appropriate for some wounds."

#### Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine:

"Sharp debridement of all devitalized tissue and surrounding callus material from diabetic foot ulcerations at 1- to 4-week intervals [is recommended]."

"Considering lack of evidence for superiority of any given debridement technique, ...initial sharp debridement with subsequent choice of debridement method based on clinical context, availability of expertise and supplies, patient tolerance and preference, and cost-effectiveness [is recommended]."



#### National Institute for Health and Clinical Excellence:

No recommendation for specific techniques for debridement due to limited evidence of low quality.

Wound debridement should be offered as part of standard care for treating DFUs.

#### National Health and Medical Research Council:

"Local sharp debridement of non-ischaemic wounds should be performed as it improves ulcer healing."

"Topical hydrogel dressings may be considered for autolytic debridement to assist in the management of non-ischaemic, non-healing ulcers with dry, non-viable tissue."

"Debridement should be repeated as often as required to remove all non-viable tissue."

Larval therapy may be considered for foot ulcers in specialist centres, as part of a comprehensive wound management program.

#### Scottish Intercollegiate Guidelines Network:

"Evidence on local sharp debridement, surgical debridement, larvae therapy and hydrogel therapy proved insufficient to draw any conclusions."

"Clinical experience suggests that in an appropriate setting any of these methods of debridement are useful in the management of patients with diabetic foot disease. Local sharp debridement should be considered first followed by the others depending on the clinical presentation or response of a wound."

#### **Negative Pressure Wound Therapy**

#### **Canadian Diabetes Association:**

"There is ... insufficient evidence to make any recommendation about the role of negative pressure wound therapy (NPWT) in the routine management of neuropathic wounds. There is, however, some evidence to support NPWT as a post-operative intervention after extensive debridement."

#### Wound, Ostomy and Continence Nurses Society:

"[NPWT should be considered as it] may increase complete wound closure compared [with] standard wound dressings and is associated with lower risk of secondary infections."

#### Infectious Diseases Society of America:

While not proven to improve resolution of infection, clinicians might consider NPWT as an adjunctive therapy for selected diabetic foot wounds that are slow to heal.

#### Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine:

Use of NPWT is recommended for chronic diabetic foot wounds that do not demonstrate expected healing progression with standard or advanced wound dressings after 4 to 8 weeks of therapy.

#### National Institute for Health and Clinical Excellence:

NPWT should not be used routinely to treat diabetic foot problems but may be considered for clinical trials or when the only other option is amputation.

NPWT should be considered after surgical debridement for DFUs, on the advice of the multidisciplinary foot care service.

#### National Health and Medical Research Council:

Topical NPWT may be considered for foot ulcers in specialist centres as part of a comprehensive wound management program.

#### Scottish Intercollegiate Guidelines Network:

"Negative pressure wound therapy should be considered in patients with active diabetic foot ulcers or post-operative wounds."

#### **International Expert Panel on NPWT:**

"NPWT must be considered as an advanced wound care therapy [in patients with] post-operative Texas Grade 2 or 3 diabetic feet without ischaemia."

"NPWT must be considered to achieve healing by secondary intention."

"NPWT should be stopped when wound has [healed enough] to be closed by surgical means."

"NPWT should be considered in an attempt to prevent amputation or re-amputation."

#### Off-Loading

#### **Canadian Diabetes Association:**

"General principles of wound management involve the provision of a moist wound environment, debridement of non-viable tissue (non-ischemic wounds), and off-loading of pressure areas."

#### Registered Nurses' Association of Ontario:

Off-loading devices should be used to redistribute pressure applied to foot ulcer(s).



#### Wound, Ostomy and Continence Nurses Society:

- "Identify sites of high pressure, as evidenced by increased temperature, callus, and/or wound, and off-load the site/ sites with proper shoes or pedorthic devices to remove and redistribute pressure over entire foot surface.
- Refer patients with gait abnormality to a qualified pedorthic professional ... for shoe or device customization.
- Use dermal temperature monitoring to progress patients from off loading devices to customized shoes.
- Provide off loading through all phases of neuropathic foot and wound management, including and after remodelling, if foot deformity is present."

#### ConvaTec:

"Review surgical/medical management options and use appropriate off-loading techniques."

#### Infectious Diseases Society of America:

Appropriate wound care includes redistribution of pressure off the wound to the entire weight-bearing surface of the foot.

"While particularly important for plantar wounds, this is also necessary to relieve pressure caused by dressings, footwear, or ambulation to any surface of the wound."

# Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine:

"For DFUs that fail to demonstrate improvement (> 50% wound area reduction) after a minimum of 4 weeks of standard wound therapy ... re-evaluation of vascular status, infection control, and off-loading is recommended to ensure optimization before initiation of adjunctive wound therapy."

#### National Institute for Health and Clinical Excellence:

Non-removable casting to off-load plantar neuropathic, non-ischemic, uninfected forefoot and midfoot diabetic ulcers should be offered. (An alternative off-loading device until casting can be provided should be offered.)

When deciding about off-loading, the clinical assessment of the wound and the person's preference should be taken into account.

#### National Health and Medical Research Council:

"Off loading ... is required to optimise the healing of plantar foot ulcers."

"Off loading of the wound can be achieved with the use of a total contact cast or other device rendered irremovable."

"Other removable off loading devices may be considered in particular settings (e.g. wounds that require more regular debridement and dressing changes) or where patient factors (e.g. significant risk of falls) do not allow for the use of an irremovable device."

#### Scottish Intercollegiate Guidelines Network:

"Patients who have unilateral plantar ulcers should be assessed for treatment using total contact casting to optimise the healing rates of ulcers."

"Prefabricated walkers can be used as an alternative if they are rendered irremovable."

"The walkers should be specially designed for use with the diabetic foot and should always incorporate a total contact insole."



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