Best Practice Recommendations

for the Prevention, Diagnosis and Treatment of Diabetic Foot Ulcers: Update 2010

BY

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Abstract

These best practice recommendations update and incorporate evidence from several guidelines. They are intended for use by healthcare professionals of all levels who treat people with diabetic foot ulcers.

The best practices in this document focus on the clinical aspects of care related to the education of both the clinician and patient. Care components include assessment for and removal of factors that can affect healing, delivery of an adequate vascular supply, infection control, pressure offloading and provision of an optimal local wound environment. The adequate delivery of care requires an interprofessional team providing coordinated and integrated management.

These best practice recommendations offer a practical, easy-to-follow guide based on the available evidence. They will support the wound care clinician and team in planning and delivering the best clinical practice related to diabetic foot ulcers.

This guideline is not intended to be a comprehensive document; rather, it provides clinicians with a guide to the current best practice principles. The recommendations are summarized in the quick reference guide.

Quick Reference Guide

Best practice recommendation	RNAO level of evidence
Treat the cause	
1. Take a careful history to determine the risk of diabetic foot ulceration (i.e., prevention) and elicit the presence of any underlying factors that may interfere with healing (i.e., treatment)	1b–IV
2. Complete a physical assessment that includes vascular status, bony/structural deformities, footwear and sensation	1a–IV
3. Classify people with diabetes into a risk category to support coordination of care	IV
4. Modify factors that cause skin breakdown or influence healing and make referral(s) to ensure comprehensive care of the patient	IV
Address patient-centred concerns	
5. Provide individualized education as indicated by patient need and risk category	IV
Provide local wound care	
6. Provide pressure offloading if there is loss of protective sensation. Effective offloading is the ability to reduce pressure forces over the wound site	IIa
7. Describe and document the ulcer characteristics	IV
8. Provide an optimum wound environment: debridement, infection control, moisture balance	IIa–IV
Re-evaluate	
9. Reassess for additional correctable factors if healing does not occur at the expected rate	III–IV
10. Consider the use of biological agents and adjunctive therapies	Ia–IV
Provide organizational support	
11. Establish, train, sustain and empower a team to work with patients with diabetes	IV
12. Provide organizational support, including resource allocation. Improved outcomes, education and evidence bases must be tied to interprofessional teams with the cooperation of healthcare systems	IV

RNAO = Registered Nurses' Association of Ontario

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Introduction

Diabetes mellitus is a chronic, diffuse endocrine disease. The number of individuals with diabetes in the Canadian population is projected to rise to 2.4 million by the year 2016.[1] This number will continue to grow given Canada's aging population, increased immigration from high-risk populations (e.g., South Asia, India) and the increase in sedentary lifestyles.[2]

Diabetic foot ulcers are a frequent complication of diabetes. The lifetime risk for foot ulceration in people with diabetes is 15–25 per cent.[3] The most common permissive risk factor for foot ulceration is neuropathy. The structural changes that occur in neuropathic limbs—in conjunction with vascular insufficiency, infection and unrecognized pressure due to lack of peripheral sensation—predispose individuals with diabetes to foot ulceration.[4,5]

According to the International Diabetes Federation, people with diabetes are 15–40 times more likely to require lower limb amputation compared with the general population. Indeed, more than 50 per cent of lower extremity amputations are due to a non-healing foot ulcer,[4,6] despite the availability of many treatment modalities.

Foot ulcers can be complex and challenging to manage. They are one of the leading causes of hospitalization in people with diabetes and result in diminished quality of life, increased morbidity and increased mortality.[7]

Furthermore, diabetic foot ulcers place a tremendous financial burden on the healthcare system[1] and physical, emotional and financial burdens on patients and their families. Specialized teams are required to work closely and systematically with patients and their families to address the complex lifestyle, self-care and behavioural impacts of living without peripheral sensation.[8] A small window of opportunity exists for a specialized interprofessional team to deliver coordinated therapies, which may reduce the human and economic burdens associated with diabetic foot ulcers and amputations.

These best practice recommendations offer a practical, easy-to-follow guide based on the best available evidence. The guidelines included in this best practice recommendation are as follows:

- The Registered Nurses' Association of Ontario (RNAO) nursing best practice guideline "Reducing Foot Complications for People with Diabetes—Revised 2007."[9]
- The RNAO nursing best practice guideline "Assessment and Management of Foot Ulcers for People with Diabetes."[10]
- The International Working Group on the Diabetic Foot (IWGDF) "Recommendation on Footwear and Offloading."[11]
- The Canadian Diabetes Association "Clinical Practice Guidelines for the Management of Diabetes in Canada."[2]
- The National Institute for Health and Clinical Excellence clinical guideline "Type 2 diabetes: Prevention and Management of Foot Problems."[12]
- The Anti-Infective Review Panel "Anti-Infective Guidelines for Community-Acquired Infections."[13]

Table 1 shows the levels of evidence employed by the RNAO and used within this document.

The recommended pathway to the prevention and management of diabetic foot ulcers is shown in Figure 1.

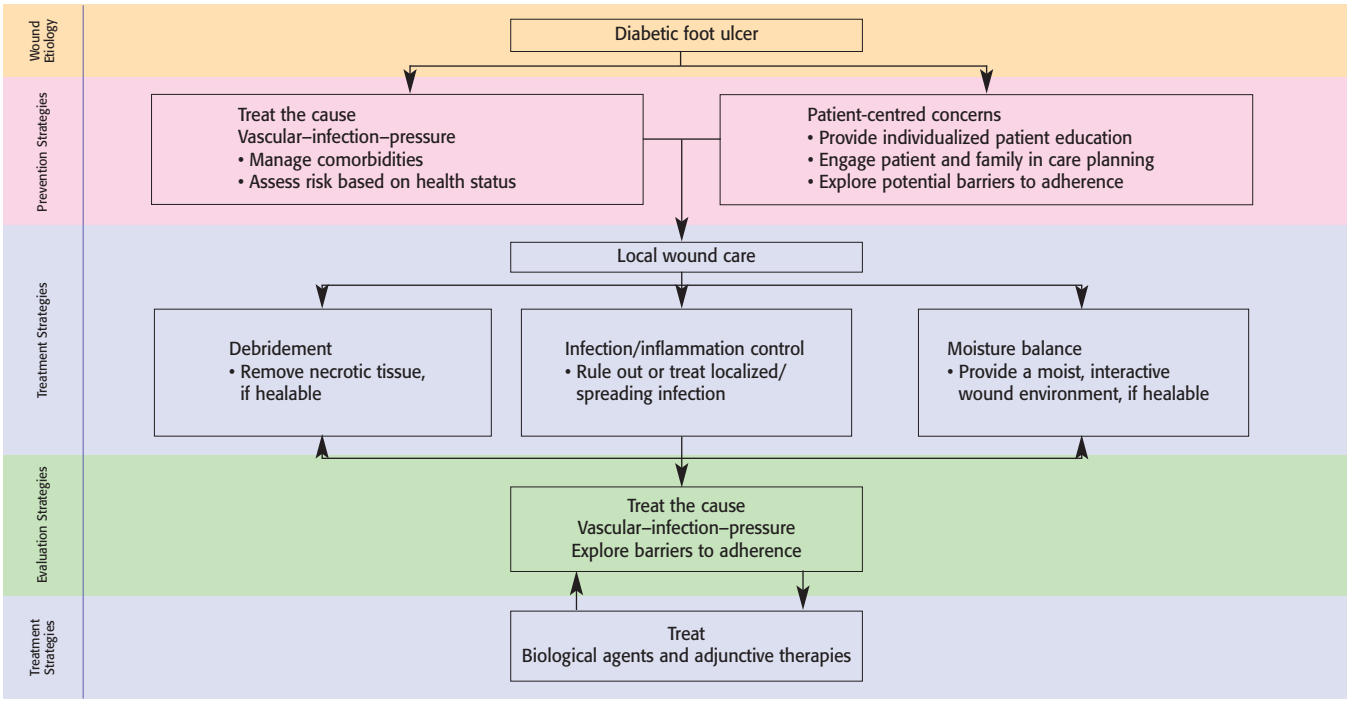
TABLE 1

Levels of Evidence Employed by the Registered Nurses' Association of Ontario

Level	Source of evidence
Ia	Evidence obtained from meta-analysis or systematic review of randomized controlled trials
Ib	Evidence obtained from at least one randomized controlled trial
IIa	Evidence obtained from at least one well-designed, controlled study without randomization
IIb	Evidence obtained from at least one other type of well-designed, quasi-experimental study, without randomization
III	Evidence obtained from well-designed, non-experimental descriptive studies, such as comparative studies, correlation studies and case studies

FIGURE 1

Pathway to the Prevention and Management of Diabetic Foot Ulcers



Recommendation 1 (Level of Evidence: 1b–IV)

Take a careful history to determine the risk of diabetic foot ulceration (i.e., prevention) and elicit the presence of any underlying factors that may interfere with healing (i.e., treatment).

Discussion

A complete patient history should elicit any active or past medical complications that may hinder wound healing, such as retinopathy, kidney disease, poor glycemic control, smoking, obesity or a previous history of foot ulcers. A patient history may also identify other areas of concern that may be barriers to the prevention and treatment of diabetic foot ulcers; for example, visual impairment would be a major barrier to patients examining their feet daily and would necessitate the implementation of an alternate plan for the prevention of foot ulcers.

Because diabetic foot ulcers are multifactorial, an interprofessional healthcare team should be involved in their assessment. This should include assessment of the presence or absence of sensory neuropathy (the single greatest risk factor for the development of diabetic foot ulcers),[5,14] offloading strategies, local wound management, nutritional status[15] and the presence of ischemia, edema or infection.[5,14]

A careful medication history may also aid in identifying an undisclosed medical history (e.g., a patient may indicate he or she has no pre-existing conditions, yet take levothyroxine for chronic hypothyroidism). In addition, this will help the clinician to identify potential barriers to wound healing (e.g., patients on long-term corticosteroid therapy may have epidermal or dermal atrophy, decreased fibroblast function in the skin and diminished skin immunity).

Adverse factors that can be modified will increase the chance of preventing diabetic foot ulcers or of healing existing foot ulcers and preventing limb loss through infection and amputation.

Components of the comprehensive diabetes evaluation are shown in Table 2.

Recommendation 2 (Level of Evidence: Ia–IV)

Complete a physical assessment that includes vascular status, bony/structural deformities, footwear and sensation.

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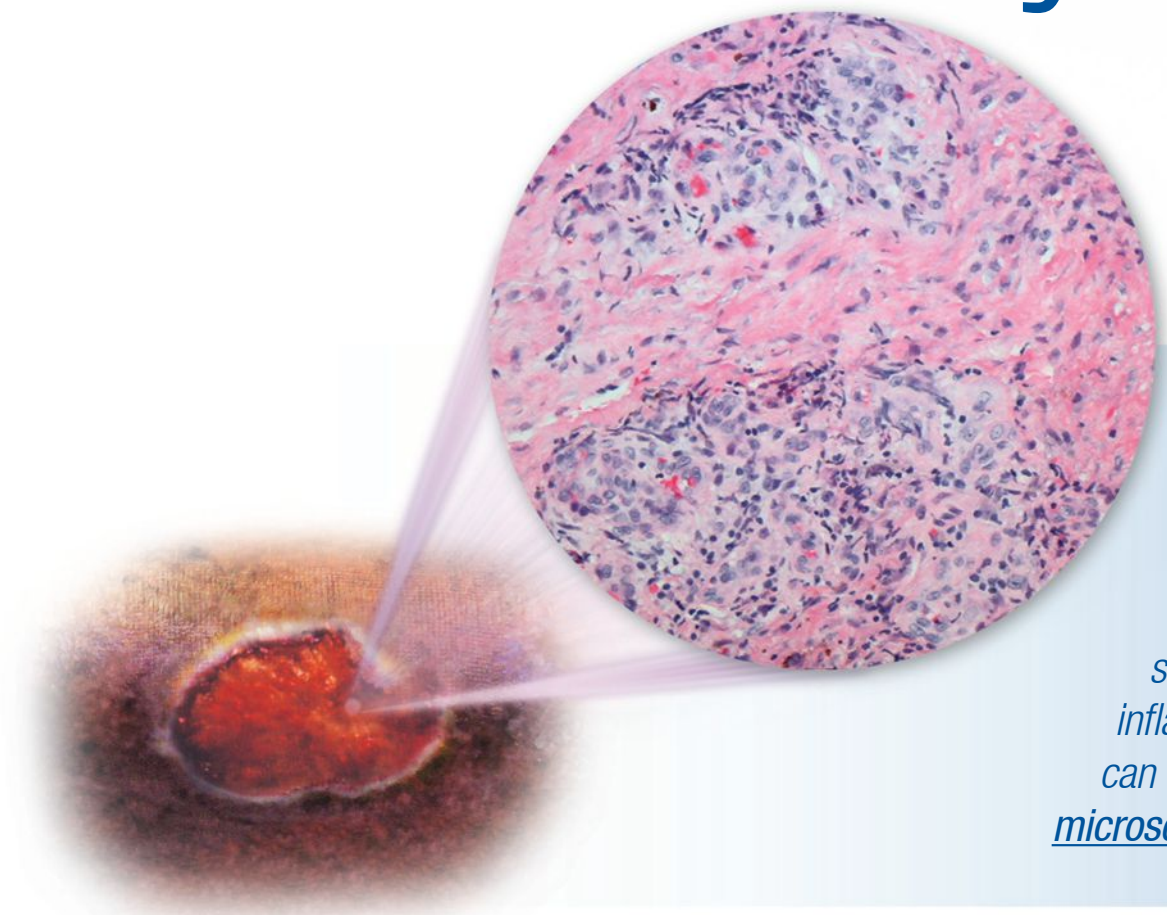

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CONTRAINDICATIONS: Application is contraindicated in patients who have shown local or systemic hypersensitivity to collagenase.

WARNINGS: Debilitated patients should be closely monitored for systemic bacterial infections because of the theoretical possibility that debriding enzymes may increase the risk of bacteremia.

PRECAUTIONS: The enzyme's optimal pH range is 6 to 8. Significantly lower pH conditions have a definitive adverse effect on the enzyme's activity, and appropriate precautions should be carefully taken. The enzymatic activity is also adversely effected by detergents, hexachlorophene and heavy metal ions such as mercury and silver that are used in some antiseptics and by cobalt, magnesium and manganese. When it is suspected such materials have been used, the site should be carefully cleansed by repeated washings with normal saline before Santyl® (collagenase) ointment is applied. Soaks containing metal ions or acidic solutions such as Burrow's solution should be avoided because of the metal ion and low pH. Cleansing materials such as hydrogen peroxide or Dakin's solution followed by sterile normal saline do not interfere with the activity of the enzyme. The ointment should be confined to the area of the lesion in order to avoid the possible risk of irritation or maceration of normal skin; however, the enzyme does not damage newly forming granular tissue. A slight erythema has been noted occasionally in the surrounding tissue particularly when the enzyme ointment was not confined to the lesion. This can be readily controlled by protecting the healthy skin with a material such as zinc oxide paste. Since the enzyme is a protein, sensitization may develop with prolonged use.

ADVERSE REACTIONS: Although no allergic sensitivity or toxic reactions have been noted in the recorded clinical investigations to date, one case of systemic manifestations of hypersensitivity has been reported in a patient treated for more than one year with a combination of collagenase and cortisone. Irritation, maceration or erythema has been noted where prolonged contact of normal skin with Santyl® (collagenase) ointment has been allowed, either by application of the ointment to areas of normal skin or excessive application of the ointment to the wound crater with subsequent spread to normal skin when dressings are applied. The reported incidence for this type of reaction was 1.8%.

SYMPTOMS AND TREATMENT OF OVERDOSE: Symptoms: To date, the irritation, maceration or erythema reported on prolonged contact of normal skin with Santyl® (collagenase) ointment consititute the only symptoms of overdosage reported. **Treatment:** Santyl® (collagenase) ointment can be rendered inert by the application of Burow's solution USP (pH 3.6 - 4.4) to the treatment site. If this should be necessary, reapplication should be made only with caution.

DOSAGE AND ADMINISTRATION: For external use only. Santyl® (collagenase) ointment should be applied once daily, or more frequently if the dressing becomes soiled (as from incontinence) in the following manner: **(1)** Prior to application the lesions should be gently cleansed with a gauze pad saturated with sterile normal saline, to remove any film and digested material. If a stronger cleansing solution is required, hydrogen peroxide or Dakin's solution may be used, followed by sterile normal saline. **(2)** Whenever infection is present, as evidenced by positive cultures, pus, inflammation or odor, it is desirable to use an appropriate antibacterial agent. Should the infection not respond, therapy with Santyl® (collagenase) ointment should be discontinued until remission of the infection. **(3)** Santyl® (collagenase) ointment should be applied (using a tongue depressor or spatula) directly to deep wounds, or when dealing with shallow wounds, to a non-adherent dressing or film dressing which is then applied to the wound. The wound is covered with an appropriate dressing such as a sterile gauze pad and properly secured. **(4)** Use of an occlusive or semi-occlusive dressing may promote softening of eschar, if present. Alternatively, crosshatching thick eschar with a #11 blade is helpful in speeding up debridement then cleanse with sterile saline. It is also desirable to remove as much loosened detritus as can be done readily with forceps and scissors. **(5)** All excess ointment should be removed each time the dressing is changed. **(6)** Use of Santyl® (collagenase) ointment should be terminated when debridement of necrotic tissue is complete and granulation is well under way.

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TABLE 2

Components of the Comprehensive Diabetes Evaluation[7]

Component	Points to assess
Medical history	Age and characteristics of onset of diabetes (e.g., DKA, asymptomatic laboratory finding) Eating patterns, physical activity habits, nutritional status and weight history; growth and development in children and adolescents Diabetes education history Review of previous treatment regimens and response to therapy (glycated hemoglobin records)
Current treatment of diabetes, including medications, meal plan, physical activity patterns and results of glucose monitoring and patient's use of data	DKA frequency, severity and cause Hypoglycemic episodes • Hypoglycemia awareness • Any severe hypoglycemia: frequency and cause History of diabetes-related complications • Microvascular: retinopathy, nephropathy, neuropathy (sensory, including history of foot lesions; autonomic, including sexual dysfunction and gastroparesis) • Macrovascular: coronary artery disease, cerebrovascular disease, peripheral arterial disease • Other: psychosocial problems, dental disease
Physical examination	Height, weight and body mass index Blood pressure determination, including orthostatic measurements when indicated Fundoscopic examination Thyroid palpation Skin examination (for acanthosis nigricans and insulin injection sites) Comprehensive foot examination: • Inspection • Palpation of dorsalis pedis and posterior tibial pulses • Presence/absence of patellar and Achilles reflexes • Determination of proprioception, vibration and monofilament sensation
Laboratory evaluation	Glycated hemoglobin level, if results not available within the past 2–3 months If not performed/available within the past year: • Fasting lipid profile, including total, LDL and HDL cholesterol and triglycerides • Liver function tests • Urine albumin excretion with spot urine albumin to creatinine ratio • Serum creatinine and calculated glomerular filtration rate • TSH in those with type 1 diabetes, dyslipidemia, or women aged >50 years
Referrals	Annual dilated eye examination Family planning for women of reproductive age Medical nutrition therapy Diabetes self-management education Dental examination Mental health professional, if needed

DKA = diabetic ketoacidosis; HDL = high-density lipoprotein; LDL = low-density lipoprotein; TSH = thyroid-stimulating hormone

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Discussion

Vascular Status (Level of Evidence: IIb–IV)

The recommendations remain unchanged from the last guideline.[16] The RNAO's "Assessment and Management of Foot Ulcers for People with Diabetes"[10] supports the present guideline recommendations.

Peripheral arterial disease (PAD) is four times more common in people with diabetes than in those without diabetes.[10] Vascular assessment and a vascular consult are therefore important to determining the ability of wounds to heal and to guide treatment decisions.[16,17] Vascular assessment begins with obtaining the patient's history.[16] Pain or cramping of the calves or thighs when walking can indicate intermittent claudication (insufficient blood supply to the muscles locally if the patient is mobile). This pain and cramping generally subsides after a period of rest, once the tissues have received the necessary oxygen. Advanced vascular insufficiency can result in pain while resting or at night.

A thorough physical examination can help detect clinical signs of vascular compromise. Clinical signs of PAD include vascular dilation/flush (rubor) that blanches with elevation, hair loss and thickened nails, and a cold foot with absent pedal pulses. Blanching the skin of the foot can give an indication of the quality of the local microcirculation.[17] The blanching test is performed by pressing a finger on the dorsum of the dependent foot to produce a noticeable lightening of the skin colour. Normally, erythema should return within five seconds; if not, there is decreased local perfusion microcirculation time. This test is effective with all skin pigmentations as long as the lighter-toned dorsum of the foot is used.

Distal gangrene of the toes with a palpable pulse or adequate circulation may indicate microemboli from proximal atheromatous plaques. In the person with diabetes experiencing neuropathy, the classic trademarks of advanced PAD (e.g., pain at rest and at night) may not be present. Palpable pulses are also a poor indicator of vascular status. The ankle–brachial pressure indices may be falsely elevated related to vessel calcification. As a result, it is recommended that toe pressures or transcutaneous oxygen readings are taken to ascertain the quality of blood flow to the feet.[10]

It is important to realise that specialized equipment and training are required to assess the vasculature of a person with diabetes.[16] Appropriate referral for any patient diagnosed with or suspected of arterial insufficiency is essential for the prevention and treatment of diabetic neuropathic foot ulcers.

Bony/Structural Deformities (Level of Evidence: Ia–IV)

A body of evidence has shown that elevated plantar pressure is a major risk factor for ulcer development. There is a direct relationship between elevated pressures and deformity.

Foot deformities in the patient with diabetes can result from neuropathic changes, stiffening of the joints (cheiroarthropathy),[18] altered biomechanics or previous surgeries.

Motor neuropathy is characterized by intrinsic muscle atrophy and results in contracted digits and a displaced fat pad.[19] This makes the metatarsal heads prominent, leading to increased pressure and a potential ulceration site.[10] Abnormal pressure over bony deformities can lead to callus formation and ulceration in the absence of protective sensation.

The ability of the first toe joint to dorsiflex (lift upward) is essential to normal foot function. Limitation in the range of motion of the first metatarsophalangeal joint is called hallux limitus. When motion is completely gone, the condition is called hallux rigidus. When motion is limited or restricted, the gait is altered and pressure is increased on the plantar surface of the first toe (hallux), potentially leading to ulceration.[20,21]

Gait examination, assessment of the range of motion, X-rays of the deformity and pressure mapping (Figure 2) will help the clinician determine the extent of plantar pressures and any resulting forces on the foot.

Charcot osteoarthropathy (Charcot foot) is one of the major complications of diabetes mellitus. It is a progressive condition that is characterized by pathological fractures, joint dislocation and destruction of the pedal architecture.

Some of the well-recognized predisposing factors for this condition are peripheral neuropathy, increases in local blood flow, excessive osteoclastic activity, unrecognized injury and continued repetitive stress. This results in bony reabsorption and multiple spontaneous fractures.[18,22] Fractures may result from normal activities of daily living, rather than from an obvious trauma.[16] Table 3 describes the stages of Charcot foot.

Charcot foot is a clinical diagnosis that should include skin temperature assessment. Increased warmth is the

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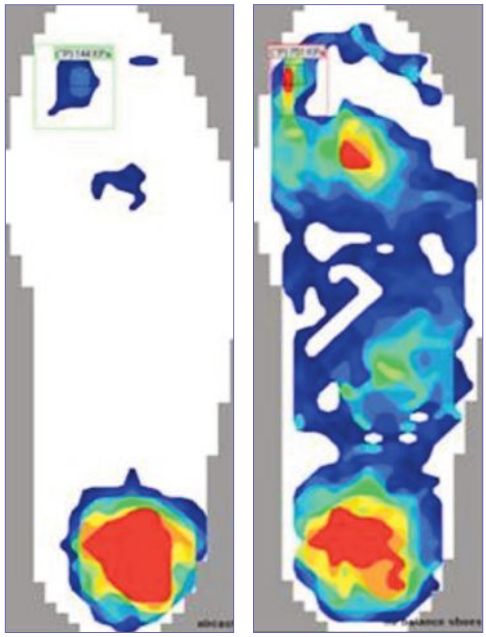
1. Lazaro-Martinez et all. Estudio aleatorizado y comparativo de un apósito de colágeno y celulosa oxidada regenerada en el tratamiento de úlceras neuropáticas de pie diabético. Cir Esp. 2007;82(1):27-31 **2.** Wysocki AB, Staniano-Coico L, Grinelli F. Wound Fluid from Chronic Leg Ulcers Contains Elevated Levels of Metalloproteinases MMP-2 and MMP-9. J Invest Dermatol. 1993; 101;64-68 **3.** Harris IR, Yee KC, Walters CE, Cunliffe WJ, Kearney JN, Wood EJ, Ingham E. Cytokine and protease levels in healing and non-healing chronic venous leg ulcers. Exper Dermatol 1995;4:342-349.

FIGURE 2

Image of Pressure Mapping Test Comparing a Patient's Own Footwear to a Removable Cast Walker



Pressure with removable cast walker

Pressure with footwear

first indicator of inflammation in an insensate foot and may be the first sign of acute Charcot foot.[23] The challenge is in distinguishing it from erythema, swelling and cellulites, which have similar clinical presentations.[24] In the early stages radiographs may not show any abnormalities and bone scans will show increased activity.[22] If available, magnetic resonance imaging will show micro-fractures. Failure to recognize Charcot foot in the early stages results in catastrophic bony changes. The resulting deformity is a risk for pressure ulceration.

Footwear

Ill-fitting footwear is a major cause of ulcers and amputations. This makes footwear and orthotic assessment essential at each patient visit. Indeed, this is required for all individuals with diabetes.[10] It is important to ensure that footwear and orthotics match the person's function and activity level, both indoor and outdoor, and are not a source of pressure.

Neuropathic patients may not feel pain. This underscores the value of a daily foot and shoe examination performed by patients or caregivers. The checklist shown in Figure 3 must be taught to all patients with diabetes and included in their daily routine. This daily examination can not only identify early signs of pressure-related trauma (e.g., redness, blisters, callusing), but can be limb saving in the absence of pain.

Sensation (Level of Evidence: II–IV)

Diabetic sensory neuropathy is the leading cause of foot ulcers. It generally presents as a distal symmetric sensorimotor neuropathy and is believed to contribute to ulcers because the patient cannot feel harmful stimuli.

Peripheral neuropathy affects sensory, motor and autonomic nerves. Loss of protective sensation is the most significant predictor of diabetic foot ulceration.[16]

People with diabetes are prone to serious injury from minor trauma because they cannot feel the injury to the foot as it occurs. In addition to single injurious incidents, such as stepping on a needle, repetitive stress simply from walking can lead to tissue breakdown in the absence of protective sensation.

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TABLE 3

Stages of Charcot foot[24]

Stage	Description
0	**Prodromal period:** Includes dermal flush/redness and increased skin temperature, with or without local edema and bounding pulses. There is evidence of instability of the foot. X-ray evidence may be seen
1	**Developmental stage:** An acute destructive period that is induced by minor trauma resulting in fragmentation of bone and joint dislocation and subluxation. This is the most important stage for clinicians to recognize and where they can make the greatest difference in prevention (Frykberg et al., 2006)
2	**Coalescence stage:** The patient presents with lessening of edema and healing of fractures
3	**Reconstruction:** Healing of bone and remodelling on X-ray, and evidence of deformity

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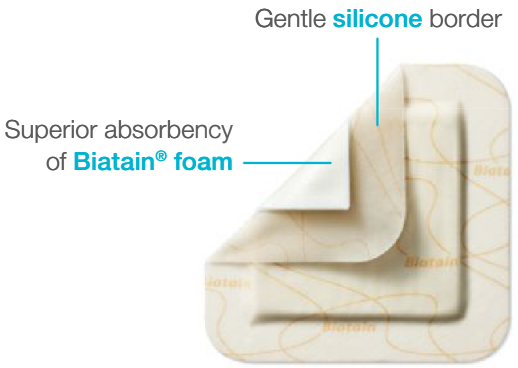

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Assessment of loss of protective sensation is easily accomplished by the clinician, patient or caregiver by using a Semmes Weinstein monofilament. The inability to perceive the 10-g bending force applied by the monofilament is associated with clinically significant large-fibre neuropathy. While the RNAO[10] advocates only four test sites on the foot, which will capture 90 per cent of patients with insensate feet, 10 test sites are preferable.[16]

Calibrated nylon monofilaments should be used to ensure optimal accuracy. Other purchased and handmade monofilaments can vary widely in accuracy due to differences in monofilament length and diameter. Due to the memory properties inherent in nylon, monofilaments require a two-hour rest period after 100 applications. Given that a patient will be tested at 20 sites (10 on each foot), after five such patients the monofilament will lose accuracy. In a busy clinic, several monofilaments will be needed to ensure accuracy. Further studies will help to determine when a nylon monofilament requires complete replacement.

It is important to avoid "leading" questions and cues when assessing with monofilaments.[10] The monofilament test is only one tool in the clinician's armamentarium and should not be used as the sole means of diagnosing peripheral neuropathy.[25]

The key pathway to the development of foot ulcers is as follows:

- Neuropathy, deformity, callus and elevated peak plantar pressure
- Ill-fitting shoes
- Penetrating trauma
- Peripheral arterial disease

Appropriate intervention strategies may reduce the risk for the cascade of events toward ulceration and subsequent amputation.

A uniform approach to a diabetic foot screening helps to ensure that all elements of the examination are completed. Recent work by the CAWC has led to the enhancement of Inlow's original work to "Inlow's 60-second Diabetic Foot Screen" screening tool. The tool captures the areas discussed in this best practice recommendation, aiding clinicians in identifying at-risk feet. The basic 12 elements of the tool require only a 10-g monofilament, as well as good clinical knowledge and assessment skills. The tool allows the clinician to assign a value to each of the 12 elements of the screening tool. Based on the value for each category, care recommendations may be provided specific to the patient's needs. The sum of the scores for each foot will dictate the recommended follow-up. Validation of this tool is currently underway.

FIGURE 3

The CAWC Steps for Healthy Feet Checklist

(available from: www.cawc.net/images/uploads/Checklist_form.pdf)

Steps for Healthy Feet Checklist

I will take care of my feet! I will make the changes needed to keep my feet healthy.

I will

- ❑ Control my blood glucose levels
- ❑ Have a healthcare professional trim my toenails and care for the skin on my feet if I cannot reach or feel my feet
- ❑ Have my shoes professionally fitted
- ❑ Quit smoking
- ❑ Begin exercising regularly as directed by my healthcare professional
- ❑ Wash my feet daily and dry them well
- ❑ Shake out my shoes before putting them on
- ❑ Wear shoes at all times, indoors and out
- ❑ Buy shoes with closed toes as they protect feet from injury
- ❑ Buy shoes late in the day as feet tend to swell
- ❑ Change my socks everyday
- ❑ Other _____

Keep this form where you can easily find it. Review it often to ensure you reach your goal of healthy feet.

For additional information, visit www.cawc.net/diabetesandhealthyfeet

This form is meant as a tool only and is not meant to be used for any diagnostic or therapeutic decisions. Specific medical concerns should be directly handled by a qualified healthcare professional.

Another successful screening tool is the modified "60-second foot screen," which has had a tremendous impact in foot clinics in Guyana (46 per cent amputation reduction).[27,28]

Regardless of the screening tool used in clinical practice, it is only as effective as the clinician using it. Risk factor recognition is vital in helping clinicians predict, and hopefully prevent, the occurrence of diabetic foot ulcers.[29]

The most effective method for amputation prevention may simply be to have all healthcare professionals remove the shoes and socks of persons with diabetes and examine their feet![8]

Recommendation 3 (Level of Evidence: IV)

Classify people with diabetes into a risk category to support coordination of care.

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TABLE 4

The International Working Group on the Diabetic Foot Risk Classification System: Original[31] and Modified[32] Criteria

Original		Modified	
Risk category	Criteria	Risk category	Criteria
0	Protective sensation intact	0	Normal—no neuropathy
1	Loss of protective sensation	1	Loss of protective sensation
2	Loss of protective sensation with deformity/peripheral arterial disease	2a	Loss of protective sensation and deformity
		2b	Peripheral arterial disease
3	Loss of protective sensation with deformity and history of ulcer	3a	Previous history of ulceration
		3b	Previous history of amputation

Discussion

Risk classification systems are effective predictors for ulceration and amputation. Assessment of risk category should drive initial and ongoing therapy. The risk category system can facilitate effective communication among team members and provide a framework for addressing client-centred needs.[30]

The IWGDF developed a straightforward risk classification system.[31] This quickly and accurately classifies patients with diabetic foot ulcers and guides the clinician in selecting the most appropriate therapeutic interventions, scheduling follow-up clinic visits and indicating activity levels for the prevention of future ulcerations. The risk categories are shown in Table 4.

The classification was later modified to include PAD and history of amputation (Table 4). The modified IWGDF classification has been found to be more effective at predicting diabetic foot complications than the original risk scheme.[32]

The Inlow CAWC 60-second screening tool contains recommendations for follow-up based on the IWGDF risk categories to help clinicians maintain a systematic approach.

Recent research has demonstrated that people with diabetes who are dependent on dialysis have an independent risk factor for foot ulceration.[33] Clinicians must be aware of the impact of dialysis and categorize risk appropriately. Risk assessment tools will need to account for this variable as the evidence grows.[5,33]

Recommendation 4 (Level of Evidence: IV)

Modify factors that cause skin breakdown or influence healing and make referral(s) to ensure comprehensive care of the patient.

Discussion

People with diabetes will present with modifiable and non-modifiable risk factors for the development of diabetic neuropathic foot ulcers. Every attempt should be made to educate the patient as to the risk factors that may be changed for the best possible long-term outcomes. An interprofessional team will be needed to achieve a complete and long-term result.[34]

Once an ulcer has developed, several mechanisms may underlie impaired wound healing in patients with diabetes. These include smoking, glycemic control, medications, nutritional factors and adherence or behavioural choices.

Smoking

The effects on smoking on health are well documented in the literature. Every effort should be made to encourage and support smoking cessation in people with diabetes. Consider appropriate referrals to smoking cessation programs to facilitate this crucial modifiable risk factor.

Glycemic control

Glycemic control is paramount to delaying complications of diabetes. A glycated hemoglobin (HbA1c) test shows blood glucose levels over the previous three months. Although glycemic targets must be individualized, most people with diabetes should aim

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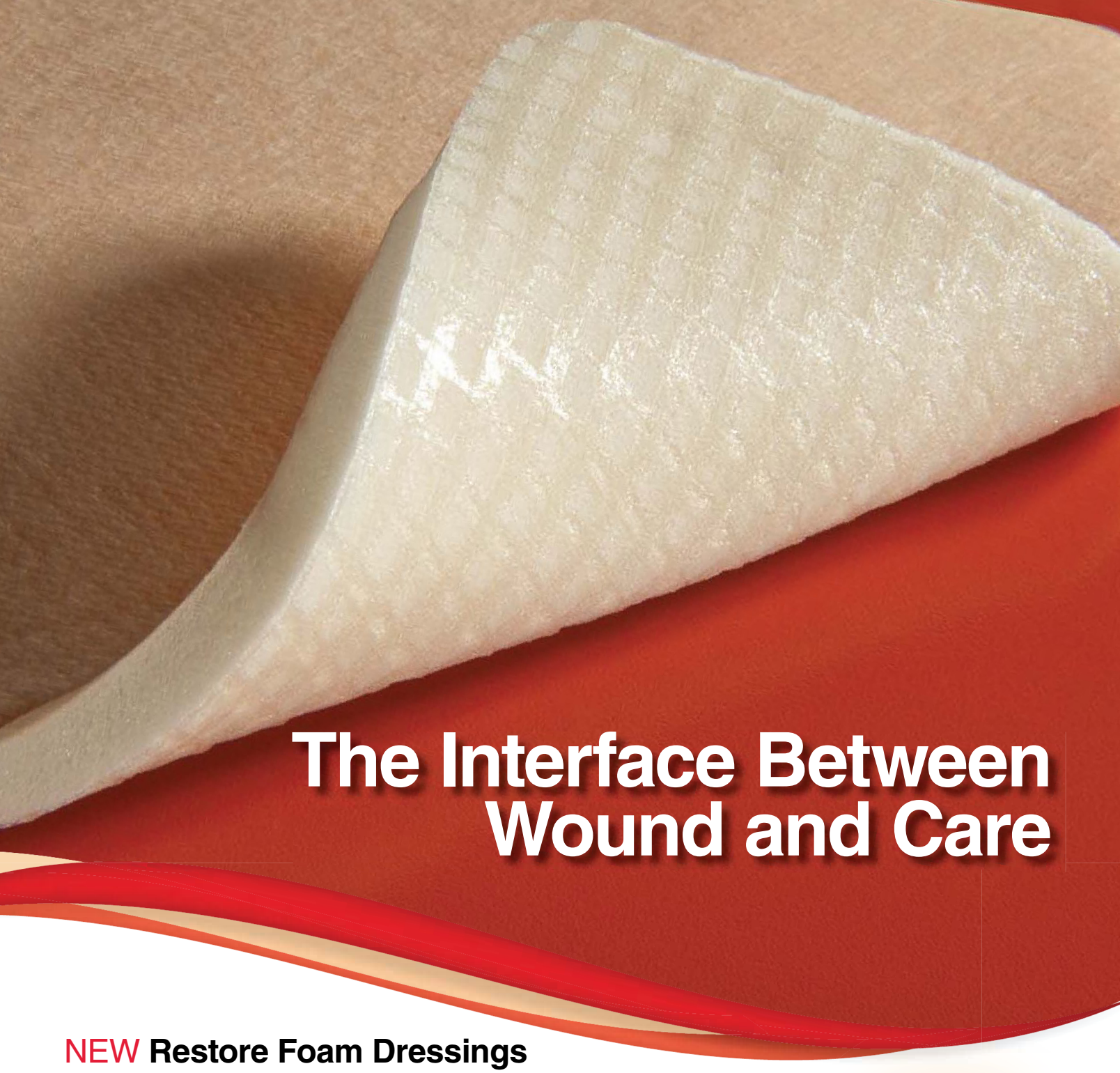

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for an HbA1c level of less than seven per cent to reduce the risk of micro- and macro-vascular complications.[2]

Although it is clear from the literature that tight glycemic control prevents or delays the complications of diabetes, the relationship between HbA1c and ulcer healing time is less well understood. Various studies have, however, demonstrated significantly decreased healing times in individuals with lower HbA1c. Decreased healing time results in a lower financial burden for both the patient and the healthcare system, and increased patient quality of life.[35,36]

If poor glycemic control is suspected, the wound care clinician should refer the patient to their primary care physician or specialist.

Medications

A medication list should be obtained to identify medications that may interfere with wound healing. A query to the prescribing physician may elicit another more suitable medication option.

Nutrition

Nutrition recommendations for people with diabetes and foot ulcers should be individualized, taking into consideration comorbidities, any previously documented abnormal laboratory test results, patient age and medications. People with infected wounds have increased nutritional requirements and often have decreased food intake, and the elderly often neglect nutrition for economic and other reasons.

If a wound is not healing as expected, nutrition should be assessed and the patient referred to a dietician, if appropriate. The most important micronutrients known to be associated with wound healing are iron, zinc and vitamins A and C.[37]

Adherence and Behavioural Choices

When wounds are not healing despite best wound practice principles, consider a lack of adherence to therapy. Careful exploration of the issue may reveal modifiable factors that can be addressed. Perhaps the patient is not wearing his or her offloading device because of balance issues with the device or perhaps dressings are being used conservatively because of cost. Unless these issues are discussed in a non-confrontational and sensitive manner, the patient may not progress to the desired outcome of a fully functional and healed state. If appropriate, referral to a social agency in the community may resolve many of these issues.

Any destructive behavioural choices, such as drug or alcohol abuse, should also be addressed. These issues are complex at best and although treatment is best left in the hands of trained professionals, the wound clinician or specialist may be the first point of contact for the healthcare system.

A patient's work life may also need to be addressed. For example, a person on their feet all day may not be able to adequately prevent or offload an ulcer. Thus, job modification will need to be considered in order for the patient to progress to full recovery; indeed, the modification may be permanent.

Recommendation 5 (Level of Evidence: IV)

Provide individualized education as indicated by patient need and risk category.

Discussion

This recommendation remains essentially unchanged from the previous best practice recommendation. It s difficult to achieve a high internal validity score in a randomized controlled trial with respect to patient education; indeed, in many studies the methodology is poor.[38,39]

Despite this, the evidence continues to support educational intervention for improvements in foot-care knowledge and behaviour in the short-term for people with diabetes.[10,39] People with diabetes who are at higher risk for foot ulceration benefit from both diabetes and foot care education and regular reinforcement of that education.[9]

Furthermore, it has been demonstrated that people who receive formal diabetes education regarding treatment and prevention strategies have a lower risk of amputation than those who receive no formal education.[9]

In recommendation 7, it is noted that a hand-held infrared skin temperature device can be used to detect early signs of inflammation and tissue injury.[40] In addition, it has been reported that high temperature gradients between feet may predict the onset of neuropathic ulceration and that self-monitoring may

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reduce the risk of ulceration.[41] With further studies, an infrared skin temperature measuring device may become part of our routine patient education and self-monitoring advice.

When planning an education program, it should be remembered that many patients do not understand what neuropathy or foot ulcers are.[8] An educational program should use principles of adult education. The approach should be patient-centred with evidence-based, interactive and solution-focused teaching, based on the experiences of the learner. Clinicians should involve the patient's family and caregivers.

The clinician needs to develop a plan of care that takes into account the patient's socioeconomic, cultural and psychosocial and other needs and beliefs.[42]

A self-assessment tool is available to assist in patient education. A CAWC expert advisory group, in collaboration with a patient focus group, has developed a self-assessment brochure and an interactive website in many languages to help patients in recognizing risk factors and identifying foot issues that they may have been previously unaware of. The brochure and interactive website are available at www.cawc.net/diabetesandhealthyfeet.

Recommendation 6 (Level of Evidence: IIa)

Provide pressure offloading if there is loss of protective sensation. Effective offloading is the ability to reduce pressure forces over the wound site.

Discussion

There has been no new evidence retrieved to warrant changes to the recommendation from the previous update.[16] Pressure is a factor in 90 per cent of diabetic plantar ulcers[16] and the pressure must be modified or removed.

In addition to neuropathy and arterial disease, trauma is needed to cause tissue breakdown. Three main factors contribute to elevated foot pressure resulting in ulceration:

- Intrinsic: genetic or structural (results in pressure-induced ischemia, which occurs in tissues over bony areas of weight-bearing during ambulation and standing)
- Extrinsic: shoes, traumatic accident or surgery
- Behavioural: poor choice of footwear, lifestyle choices or poor walking pattern

Diabetic plantar ulcerations require aggressive and effective offloading in order to achieve wound healing.[10]

Non-surgical offloading

Risk Categories 0–3

Prevention or ulceration and re-ulceration of people in IWGDF risk categories 0–3[31] can be achieved through proper use, fitting and inspection of insoles and footwear. People with compromised sensation should be professionally fitted for insoles and footwear in order to redistribute plantar pressures to prevent ulceration.

Appropriate footwear is one of the key factors in reducing the risk of ulceration and amputations.[26] Unfortunately, there is very little in the scientific literature regarding testing or the effectiveness of over-the-counter therapeutic footwear. Studies that have measured footwear effectiveness have examined either ulcer prevention or peak pressure as an end-point. Results from a 2008 review on footwear effectiveness demonstrated that therapeutic shoes may be effective in preventing ulcerations compared with standard shoes (Figure 4), and that many studies have contrasting results due to differing study designs, practices and the equipment studied.[43] For example, a randomized controlled trial found that people with diabetes without severe deformity do not benefit from custom-made therapeutic footwear or orthotics.[44] However, this study did not evaluate peak pressure or address patient adherence.[43]

Any footwear selection and wearing regime must involve the patient and the patient must be educated regarding the following issues:

- Therapeutic footwear or orthotics must be worn at all times, both indoors and outdoors.
- Inappropriate footwear (e.g., high-heeled or narrow-toed shoes) can cause damage, even if worn for only a few hours.

In addition, the ability to put on and remove shoes and socks must be considered and assistive devices prescribed as appropriate (e.g., sock aid, long-handled shoe horn).

One way to facilitate improved pressure management, coupled with proper footwear and orthotics, is through participation in appropriate activities. Low-impact activities such as swimming, aqua-fit and bicycling are preferable to high-impact activities such as walking, jogging and aerobics.

TABLE 5

Management of Charcot Foot[45]

Stage	Management
0 (prodromal)	Non-weight-bearing cast Minimum immobilization: 8–12 weeks
1 (developmental, acute)	Non-weight-bearing cast Immobilization or graduate to a removable cast walker
2 (coalescence, subacute)	Patellar tendon-bearing brace (PTB) Charcot restraint orthotic walker (CROW walker)
3 (reconstruction, chronic)	Custom-made shoes with or without a brace

Charcot Foot

The management goals of the Charcot foot involve early intervention and immobilization. The key goal of treatment is to prevent deformity and subsequent ulceration. The management of Charcot foot is shown in Table 5.

Foot ulcers

Offloading the diabetic foot ulcer is one of the key areas to achieve healing. Multiple devices have been studied (Table 6), looking at peak pressure and healing time.[26,43] There is strong evidence to show that a total contact cast heals a diabetic neuropathic foot ulcer faster than other devices.[43] A non-removable cast walker (i.e., instant total contact cast) is more effective than a removable cast. This gained popularity because of its ease of application, usefulness in managing infected wounds and added benefit of forced adherence.[46,47]

Other offloading options, such as half shoes and surgical shoes, are not as effective in reducing peak pressure as the total contact cast or the instant cast. Some of their documented advantages, however, are that they are inexpensive, have some ability to reduce pressure and they are more acceptable to patients as they are less cumbersome. There is no available evidence to support the use of regular footwear for ulcer management.[16,43]

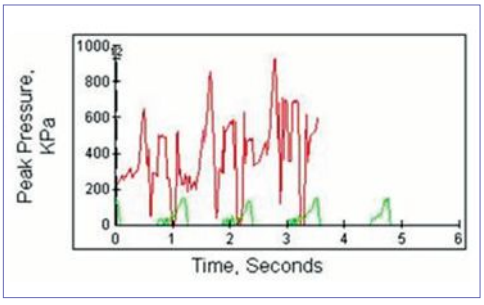
The choice of the offloading device should be determined by an interprofessional team after all factors—such as infection, vascular status, patient characteristics, environmental factors and resources—have been identified.

Failure to adequately offload the neuropathic foot may result from lack of knowledge regarding the concept of an insensate foot or pressure, lack of resources to acquire proper footwear or orthotics, improper fit or inconsistent use of the offloading device.[47]

Offloading is the key to managing patients with foot ulcers. Clinicians should always remember that considerations when offloading the foot are not limited to the device itself, but also include patient characteristics, environmental factors, appropriate use of the device, reduction of activity, reduction of walking speed and alteration of gait.[49]

FIGURE 4

Peak Pressure versus Time



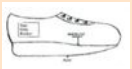
patient's shoes

removable cast walker

Using pressure mapping as part of the evaluation or revaluation process can help to determine if the offloading device is producing the desired pressure reduction at the ulcer site and serves as a visual aid for the patient to help aid in the adherence process.

TABLE 6

Plantar Pressure Redistribution[48]

Offloading device		Wound location				Advantages	Disadvantages
		Toes	Forefoot	Midfoot	Heel		
Total contact cast		✓✓	✓✓✓	✓✓✓	✓✓	Gold standard Reduces pressure under ulcer site between 84 and 92 per cent Forces patient adherence to device	Requires a trained professional to apply Can result in secondary ulceration with improper application Contraindicated for infected or ischemic wounds
Removable walker		✓✓✓	✓✓✓	✓✓	✗	Can be used for infected wounds Can be made irremovable to become an instant total contact cast	Removable Patient needs time to learn how to use it Contraindicated for heel ulcers and those with poor balance
Half shoe (forefoot)		✓✓	✓✓	✗	✗	Transfers pressure to mid and rearfoot by eliminating propulsion Low cost	Very unstable Contraindicated for patients with gait instability High risk of falls
Half shoe (rearfoot)		✗	✗	✗	✓	Low cost	Very unstable
Surgical shoe		O	✓✓	O	O	Low cost Accommodates edema Good for short-term management	Offloading property limited Use with orthotic or insert devices Not ideal for activity
Over-the-counter orthopaedic footwear		✓✓	✓✓	✓	✓	Affordable Easy to access Preventative care	Offloading property limited Use with orthotic or insert devices
Over-the-counter walking footwear		✓	✓✓	✓	✓	Affordable Easy to access Preventative care	Offloading property limited Use with orthotic or insert devices
Footwear modifications (rocker toe)		✓✓	✓✓	✓	✗	Moves pressure from forefoot to rearfoot	Requires trained professional to apply Expensive
Custom-made footwear		✓✓	✓✓	✓✓	✓✓	Distributes pressure under foot evenly Ideal for foot deformity	Requires trained professional to apply Very expensive
Custom-made orthotics		✓	✓✓	✓✓	✓	Distributes pressure underfoot evenly May be used with over-the-counter footwear	Requires trained professional to apply Expensive
Total contact inserts		✓	✓✓	✓✓	✓	Distributes pressure under foot evenly May be used with over-the-counter footwear	Requires trained professional to apply
Padding		✓	✓	✓	✓	Low cost	Offloading property limited Can cause "edge effect"
Crutches/cane[a]		✓	✓	✓	✓	Low cost	Offloading property limited Can cause shoulder dislocation

✓ = indicated; ✗ = contraindicated; **O** = can be used.

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Surgical Offloading

Prevention of Ulceration (Risk Categories 0–2)

Surgical (sharp) callus reduction significantly (approximately 30 per cent) reduces plantar pressure in patients with diabetes.[10]

The disadvantages of applying surgical techniques for the prevention of plantar ulcers in the diabetic foot are numerous. Therefore, the effectiveness and safety of preventive surgery to offload the diabetic foot should be carefully evaluated. Due to a lack of data, no definite conclusions can be drawn about surgical offloading of the diabetic foot when the goal is to prevent ulceration.[11]

If Wound Not Healing at Expected Rate or if Wound Recurrence (Risk Categories 3, 4A, 5)

Achilles tendon lengthening may be considered only for selected patients because the risk of heel ulceration is high.[11]

Other Surgical Offloading Techniques

No definite statement can be made about the effectiveness and safety of other surgical techniques (e.g., arthroplasty, osteotomy) when offloading of persistent and recurrent diabetic ulcers is attempted. More studies are needed.[11]

Charcot's Osteoarthropathy (Risk Category 4b)

Chronic Charcot's foot changes may require surgical treatment including bony reduction, fusion and reconstruction. This has been reported in several studies.[50–52] However, the studies did not monitor pressure distribution underneath the foot before and after the surgical approach. Therefore, meaningful conclusions about offloading characteristics of these techniques cannot be drawn.

Surgery in the acute stage of Charcot's osteoarthropathy is not advisable due to hyperemia, osteopenia and local edema.[24]

Recommendation 7 (Level of Evidence: IV)

Describe and document the ulcer characteristics.

Discussion

According to RNAO guidelines,[10] there is a lack of clearly established standards for assessing and documenting wound progress. Some of the recognized benefits of wound assessment are to determine the ability of the wound to heal, plan treatment, facilitate communication, monitor treatment and predict outcomes

Identify of the Ulcer Site on the Lower Extremity (Level of Evidence: IIa)

Multiple studies have shown that the majority of neuropathic foot ulcers occur at the fore foot. Determining the site of the diabetic foot ulcer is critical for further management and prevention of re-ulceration.

Measure Length and Width (Level of Evidence: Ia–IV)

Clinical studies have shown that a reduction in ulcer area (approximately 20–40 per cent after two to four weeks of treatment) is a good predictor of healing.[53] It is important when measuring an ulcer that the measurements are done using a consistent method such as tracings or standardized measurement tools. Documentation of pre- or post-debridement should be noted for consistency. This will greatly increase reliability in determining progress toward closure.

Assess Ulcer Bed, Exudates, Odour and Peri-Ulcer Skin (Level of Evidence: IV)

Assessing factors in the ulcer bed helps clinicians determine if the wound is healing, but can also be an indicator of increased burden. It is important to assess drainage, specifically with respect to colour, amount and consistency. Tissue in the wound bed should also be assessed with respect to quality, type and amount, epithelial tissue, granulation tissue and the presence of slough or necrotic tissue. Odour may be present or absent. Pain in the wound can be a clinical indicator of wound infection.[54]

Measure Depth (Level of Evidence: IV)

Neuropathic foot ulcers are often surrounded by overlying hyperkeratosis. This should be debrided adequately[7] to determine depth.

Ulcer depth is most commonly measured and quantified by gently inserting a sterile swab stick or probe into the ulcer (Figure 5). The presence of bone, undermining, a space between the surrounding skin and ulcer bed or tunnelling is suggestive of a deep foot infection. Increasingly, evidence has shown that if ulcer probes to bone, there is a high incidence of osteomyelitis (Table 7).[55,56]

Classification System (Level of Evidence: IIa)

Staging systems helps predict outcomes and direct treatment. They are commonly used in studies because they are reproducible.

Several different classification systems may be used with diabetic foot ulcers. These include the Wagner, Wagner Meggitt, University of Texas and SINBAD (Site, Ischemia, Neuropathy, Bacterial infection, Area and Depth) systems.

The University of Texas system (Table 8) is the most predictive and positively correlates to the risk of amputation and other adverse outcomes.[58]

Work performed on the SINBAD system also indicates favourable results relating to its accuracy in predicting ulcer outcome.[59]

Assess for Infection (Evidence Level: IIa)

Patients with diabetic foot ulcers should be assessed for signs and symptoms of infection. Appropriate diagnostic testing and treatment should be facilitated.

FIGURE 5

Identification of Ulcer Characteristics

Foot infections occur relatively frequently in persons with diabetes with chronic, deep or recurrent foot wounds.[60] This high incidence of infection can be attributed to immunopathy and a blunted cellular response in those with diabetes. However, 50 per cent of per-

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TABLE 7

Comparison of Probing to Bone in Two Studies[56,57]

	Grayson[56]	Lavery[57]
Sensitivity	66%	87%
Specificity	85%	91%
Positive predictive value	89%	57–62%
Reliability	No data	No data

sons with diabetes may not have systemic signs of fever or leukocytosis.[2]

While acute wound infections traditionally present with pain, redness, swelling, loss of function and heat, Gardner et al.[61] have validated the following signs and symptoms[62] indicative of a chronic wound infection:

- Increased pain (100 per cent specificity)
- Wound breakdown (100 per cent specificity)
- Foul odour (85 per cent specificity)
- Friable granulation tissue (76 per cent specificity)

In persons with diabetes, some of these symptoms—both acute and chronic—may not be present or may be difficult to assess due to objective assessments varying from clinician to clinician. Lavery et al. observed the use of a hand-held infrared skin temperature device by persons with diabetes at home to identify early warning signs of inflammation and tissue injury.[40] In the standard-therapy group there was a 20 per cent rate of foot complications, while in the group that used infrared temperature monitoring there was a two per cent complication rate. This indicates that the standard-therapy group was 10 times more likely to develop a foot complication than the group using the home infrared temperature monitoring.

Diagnosis of infection in foot ulcers is based upon clinical presentation of the wound. In addition, laboratory tests (including cultures) may suggest the presence of infection.[13,63] Ulcers should be evaluated for infection at every visit. Infection involving the deep tissue compartment will often cause erythema and warmth that extends two centimetres beyond the wound margin. Any wound that shows sinus tract formation or undermining must be probed.

All diabetic neuropathic foot ulcers that do not heal as expected should be evaluated for the possibility of infection or an underlying, chronic osteomyelitis to prevent limb loss. A diagnosis of osteomyelitis can be established with findings such as an erythrocyte sedimentation rate greater than 70 mm/hour or a positive plain radiograph finding.[55]

Recommendation 8 (Level of Evidence: IIa–IV)

Provide an optimum wound environment: debridement, infection control, moisture balance.

Discussion

Debridement (Level of Evidence: III)

Debridement is an important step in preventing or treating ulcers.[3] However, sharp or surgical debridement should only be performed by a trained healthcare professional and only if there is an adequate blood supply.[3,64]

Pressure points can cause the build up of calluses and increase the risk of ulcers. Debridement of the lesion will decrease the pressure. To be effective in the long-term, debridement should be performed with a complete biomechanical examination and pressure offloading techniques should be applied.[3,65] Removal of plantar calluses can reduce peak pressure by 26 per cent.[3]

Before performing debridement, the healthcare professional must clearly identify the tissue to be debrided. Debridement of nonviable tissue, as well as infected or contaminated tissue from the wound

TABLE 8

The University of Texas Staging System for Diabetic Foot Ulcers

Stage	Grade 0	Grade I	Grade II	Grade III
A	Pre- or post-ulcerative lesion completely epithelialized	Superficial ulcer, not involving tendon capsule or bone	Ulcer penetrating to tendon or capsule	Ulcer penetrating to bone or joint
B	Infection	Infection	Infection	Infection
C	Ischemia	Ischemia	Ischemia	Ischemia
D	Infection & Ischemia	Infection & Ischemia	Infection & Ischemia	Infection & Ischemia

bed, has been shown to improve the rate of healing of diabetic foot ulcers, and lower rates of wound healing have been correlated with less frequent debridement practices.[66] A variety of debridement methods are available (Table 9). Sharp debridement has been associated with better outcomes in patients with diabetic foot ulcers in a prospective trial.[67]

Other methods of debridement for diabetic foot ulcers include the following:

- Autolytic debridement using non-occlusive dressings
- Mechanical debridement (i.e., cleansing with normal saline solution or an appropriate wound cleanser)
- Biological debridement (i.e., maggot therapy)[69]

Infection Control (Level of Evidence: IIa)

Infection of an ulcer can be expressed as the balance between host resistance and the number and virulence of the microorganisms colonizing the wound.[64] If the host is capable of managing the colonizing microorganism, antimicrobial therapy aimed at reducing the bacterial bioburden of the wound is not beneficial. Therefore, chronic wounds that are colonized do not require any antimicrobial therapy.[10]

Since patients with diabetes have compromised immunity, their resistance to infection is significantly diminished. When the superficial tissue compartment is critically colonized, the wound starts to show signs of distress and healing will appear to be stalled on serial assessments. To increase host resistance with the aim of overcoming bacterial bioburden, simple devitalized tissue debridement in the wound bed and surrounding tissue should be applied. Because eschar is an optimal environment for microbial growth, its removal will rapidly reduce the number of microorganisms and provide an opportunity for the weakened host resistance to overcome the infection. Diabetic foot infections can be classified as shown in Table 10.

When debridement is inadequate to control infection and there are signs of superficial tissue infection, topical antimicrobials may have a role in controlling the wound environment and rebalancing host

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TABLE 9

Key Factors in Deciding on the Method of Debridement[68]

	Surgical	Enzymatic	Autolytic	Biologic	Mechanical
Speed	1	3	5	2	4
Tissue selectivity	3	1	4	2	5
Painful wound	5	2	1	3	4
Exudate	1	4	3	5	2
Infection	1	4	5	2	3
Cost	5	2	1	3	4

Where 1 is most desirable and 5 is least desirable.

defences. A topical antimicrobial should be used for no more than two weeks before reassessment.[10]

Failure to improve the wound environment within two weeks indicates the need for systemic therapy. In the first four weeks of a wound opening, the microbial flora in a chronic wound is mainly composed of Gram-positive aerobic cocci (beta-haemolytic streptococci and *Staphylococcus aureus*). After four weeks of a wound's appearance, Gram-negative aerobic bacteria (*Proteus, Escherichia coli, Klebsiella, Enterobacter, Pseudomonas*) and anaerobic bacteria (bacteroides, *Clostridium perfringens*, anaerobic streptococci and staphylococci) will be present.[24,71] Since microbial flora may be predicted in the chronic diabetic ulcer, initial antibiotic regimens are usually empirical.[63] The spectrum of antimicrobial activity should target the most likely causative organism. The 2010 "Anti-Infective Guidelines for Community-Acquired Infections"[13] provide an evidence-based approach to rational antimicrobial selection and recommendations for the treatment of mild to moderate or non-limb-threatening infections.

When an empirical regimen is chosen, culture of the wound should be also obtained (unless etiology of infection is highly predictable).[63] A bone biopsy is recommended in the presence of osteomyelitis.[72]

The wound should be reassessed within four days when culture and sensitivity results are available. If the infection is not improving, a review of culture and sensitivity results, local wound care and patient adherence to current therapy will be helpful in making an appropriate decision about further antibiotic regimens. If the infection is worsening then it should be treated as a severe or limb-threatening infection of the diabetic foot.[63] Again, the 2010 "Anti-infective Guidelines for Community-acquired Infections" provides an evidence-based approach to rational antimicrobial selection for the treatment of severe limb-threatening infections (Table 11 and Table 12).[13]

TABLE 10

Classification of Diabetic Foot Infection[70]

Grade	Clinical finding
1	No infection
2 (mild)	Infection of skin and subcutaneous tissue, ≤2 cm cellulitis around wound
3 (moderate)	Infection of deeper tissues or >2 cm cellulitis around wound
4 (severe)	Infection with systemic toxicity or metabolic instability

Moisture Balance (Level of Evidence: IV)

Moisture balance is an important factor in wound healing and as to be taken in consideration in the choice of the dressing. Re-epithelialization occurs best in a moist wound environment free of exudate.[64] Wound dressings can be categorized based on their ability to donate moisture to a dry wound or to remove moisture from an exudative wound. Proper dressing selection is key, as applying the wrong dressing can delay healing or even make an ulcer worse. An appropriately moisture-balanced dressing will help to activate leucocytes, suppress tissue necrosis and change the pH.[64]

When selecting a dressing for moisture balance, the clinician should consider the following factors:

- A dressing or combination of dressings should be chosen that will keep the wound bed continuously moist and the peri-wound skin dry.
- The dressing should control exudates.

TABLE 11

Cellulitis – Special Considerations: Diabetic Foot[a,b]

Anti-infective Review Panel. Anti-infective guidelines for community-acquired infections. Toronto: MUMS Guideline Clearinghouse; 2010. (www.mumshealth.com)

Modifying circumstances	Probable organism(s)		Antibiotic choices	Usual dosage	Cost per day
Mild[c] to moderate or non-limb threatening	*S. aureus* Group A Strep Group B Strep Enterococci *P. aeruginosa*[d] Mixed aerobic and anaerobic	FIRST LINE	[TMP/SMX[d]	1–2 DS tabs BID	$0.24–$0.48
			OR		
			Cephalexin]	500 mg QID	$1.80
			PLUS		
			Metronidazole[a]	500 mg BID	$0.24
		SECOND LINE	Amoxicillin/ Clavulanate[d,e]	500 mg TID or 875 mg BID	$2.00
			OR		
			[TMP/SMX[d]	1–2 DS tabs BID	$0.24–$0.48
			PLUS		
			Clindamycin[a]]	300–450 mg QID	$3.10–$4.65
		THIRD LINE[f]	Cefazolin IV	1–2 g q8h	$9.00–$18.00
			PLUS ONE of the following:		
			Metronidazole IV[a]	500 mg q12h	$3.78
			OR		
			Clindamycin IV[a]	600 mg q8h	$27.44

a) Deep cultures should be done in patients with diabetes if the cellulitis is recurrent or associated with a longstanding ulceration. Swabs of pus are useful, however, surface swabs are not. If anaerobes are an issue ("presence of necrotic tissue" or "foul smell"), clindamycin or metronidazole should be added. This will depend on the location, spectrum of pathogens and severity of infection. Most non-limb threatening or mild infections are monomicrobial, involving Gram-positive bacteria only; therefore, it may not be necessary to cover for anaerobes; severe infections are usually polymicrobial, involving anaerobes.

b) Empiric coverage for methicillin-resistant *S. aureus* (MRSA) should be considered in areas where MRSA is commonly isolated (>10–15% of *S. aureus*) or in patients with prior antibiotic use or hospital admissions over the last 6 to 12 months. TMP/SMX is active against community-acquired MRSA, whereas cloxacillin, all cephalosporins and amoxicillin/clavulanate are not.

c) No evidence of systemic toxicity, deep tissue involvement or spreading erythema. Non-limb threatening infections include superficial infections, <2 cm cellulitis, no evidence of serious ischemia or systemic illness. Usually monomicrobial: *S. aureus, Streptococci*. Topical agents (including silver-containing products) lack evidence for benefit and require further research before being recommended. Cloxacillin 500mg QID can be used if MSSA (methicillin sensitive *S. aureus*) is confirmed.

d) TMP/SMX or amoxicillin/clavulanate should not be used if *Pseudomonas* is present, use ciprofloxacin instead.

e) Amoxicillin/clavulanate covers anaerobes and can be used alone.

f) People with diabetes may have higher risk of decreased oral absorption due to gastric neuropathies therefore IV antibiotics may be warranted initially or subsequent to poor response (at two to four days after initiation) to oral agents.

- Wound dead space should be eliminated.
- The patient should be comfortable with using the dressing.

An often-forgotten area to consider when deciding on a dressing is offloading. If offloading is not appropriately addressed, a moist interactive dressing may lead to further maceration in the surrounding area.

Dressings for moisture balance come in several different categories. For further information on dressings, see the Product Picker available at www.cawc.net.

Recommendation 9 (Level of Evidence: III–IV)

Reassess for additional correctable factors if healing does not occur at the expected rate.

Discussion

If the wound is not healing at the expected rate, clinicians should revaluate the patient systemically, reviewing the parameters of vascular, infection and pressure. According to the RNAO guidelines these parameters can quickly change with a high risk of infection and

TABLE 12

Cellulitis – Special Considerations: Diabetic foot[a,b,c]

Anti-infective Review Panel. Anti-infective guidelines for community-acquired infections. Toronto: MUMS Guideline Clearinghouse; 2010. (www.mumshealth.com)

Modifying circumstances	Probable organism(s)		Antibiotic choices	Usual dosage	Cost per day
Severe[b] or limb-threatening	*S. aureus* Group A Strep Group B Strep Enterococci *P. aeruginosa*[d] Mixed aerobic and anaerobic	FIRST LINE	Ceftriaxone IM/IV	1–2 g q24h	$17.00–$33.50
			OR		
			Cefotaxime IV	1–2 g q8h	$27.60–$55.20
			PLUS ONE of the following:		
			Metronidazole[a]	500 mg BID	$0.24
			Clindamycin[a]	300–450 mg QID	$3.10–$4.65
		SECOND LINE	Ciprofloxacin PO/IV[d]	PO: 750 mg BID IV: 400 mg q12h	$4.73 $69.64
			PLUS		
			Clindamycin PO/IV[a]	PO: 300–450 mg QID IV: 600 mg q8h	$3.10–$4.65 $27.44
		THIRD LINE[e]	Imipenem/Cilastatin IV	500 mg q6h	$97.52
			Piperacillin/ Tazobactam IV	4.0 g/0.5 g q8h	$63.66

a) Cultures should be taken. Consider admission to hospital. If anaerobes are an issue ("presence of necrotic tissue" or "foul smell"), clindamycin or metronidazole should be added. This will depend on the location, spectrum of pathogens and severity of infection. Most non-limb-threatening or mild infections are monomicrobial, involving Gram-positive bacteria only; therefore, it may not be necessary to cover for anaerobes; severe infections are usually polymicrobial, involving anaerobes. Duration of therapy 14 to 28 days if severe soft tissue infection. If bone involvement, consult osteomyelitis guideline; between 4 and 12 weeks generally required.

b) Severe as evidenced by systemic toxicity, deep tissue involvement, or spreading erythema. Limb-threatening infections include full-thickness ulcer, >2 cm cellulitis, serious ischemia. Usually polymicrobial. Note that topical agents (including silver-containing products) lack evidence for benefit and require further research before being recommended.

c) Empiric coverage for methicillin resistant *S. aureus* (MRSA) should be considered in areas where MRSA is commonly isolated (>10–15% of *S. aureus*) or in patients with prior antibiotic use or hospital admissions over the last 6 to 12 months. TMP/SMX is active against community-acquired MRSA, whereas cloxacillin, all cephalosporins and amoxicillin/clavulanate are not.

d) If it is known that *Pseudomonas* is present, specific agent is determined by susceptibilities (e.g., ciprofloxacin).

e) Consideration can be given to using other agents including meropenem, ertapenem or levofloxacin plus metronidazole, in patients with multiple drug allergies or as part of a multi-drug regimen.

amputation, so frequent monitoring is required[10]—although the optimal reassessment frequency for diabetic foot ulcers has not yet been defined.[47]

Evaluation must be an ongoing step in the wound-healing process and the clinician needs to address three key issues:

1. How do you know if your treatment plan has been effective?
2. How do you currently evaluate wound healing?
3. Is wound closure the only successful wound-care outcome?

Examining the edge of the wound can help the clinician to determine if epidermal cell migration has begun.[10] Sheehan et al. demonstrated that a 50 per cent reduction in wound surface area at four weeks is a good predictor of wound healing at 12 weeks.[73] If the edge is not migrating then the wound requires a full reassessment and corrective therapies need to be implemented. If the wound is not optimized and the edge is still not migrating, the wound may need advanced therapies to kick-start the healing process. If signs of healing still do not occur, a biopsy should be performed to rule out disease.

The most common reason for delayed healing is inadequate offloading.[10] Increasing evidence suggests that the majority of patients with diabetes are non-

adherent to using offloading devices or footwear on a regular basis. In a study by Armstrong et al., patients with diabetic foot ulcers used the prescribed offloading device (a removable cast walker) only 30 per cent of the time during ambulation.[47] To prevent and facilitate healing of foot ulcers, pressure redistribution must be addressed with an appropriate offloading device and barriers to patient adherence must be explored.

Exploring barriers to the adherence process is an important aspect of care. Engaging patients in the decision-making process and ensuring they understand the implications of their choices (e.g., an increased risk of amputation) will ensure the delivery of patient-centred care.[74]

Clinicians must always remember that the endpoint is not just healing of the wound. Clinicians must also focus on patient factors, including prevention of wounds on the contralateral limb or other parts of the foot and limb preservation.[75]

The most desirable endpoint may not always be achievable in diabetic foot ulcers. Clinicians must therefore consider other wound care goals, such as wound stabilization, pain reduction, controlled bacteria load and a reduced frequency of dressing changes.[76]

Recommendation 10 (Level of Evidence: 1a–IV)

Consider the use of biological agents and adjunctive therapies.

Discussion

When wound infection, osteomyelitis, arterial ischemia, inflammatory skin conditions, vasculitis and malignancy have been ruled out as causes of a non-healing wound, adjunctive therapies may be considered. It must be reiterated, however, that the main reason for non-healing is often non-adherence to offloading strategies. Offloading must be addressed at every visit of a patient with diabetic foot ulceration to a wound specialist.

Adjuvant therapies include electrical stimulation,

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hyperbaric oxygen therapy (HBOT), use of granulocyte colony-stimulating factor, bioengineered skin substitutes and topical negative pressure wound therapy (NPWT). Although all of these modalities have some evidence to support their use in limited situations, availability, cost or the lack of good therapeutic evidence may limit their usefulness in the majority of patients.[77,78] Not all modalities are available in all centres and consultation with local experts familiar with these modalities should be sought before embarking on them as a therapeutic course of action.

Again it must be emphasized that these adjunctive therapies will never supplant the role of effective and complete adherence to offloading strategies and appropriate local wound care in the management of diabetic foot ulcers.

Electrical Stimulation (Level of Evidence: 1A)

The use of a low-voltage electrical current to stimulate wound healing in chronic wounds has been well documented.[79] It cannot, however, be used in the presence of infection, local wound infection or bone infection without the risk of compromising the wound. For this and other reasons, electrical stimulation should only be used by practitioners trained in its application. Despite these limitations it is a low-cost and readily available means of treating stalled chronic wounds once other underlying factors for non-progression have been ruled out.

Hyperbaric Oxygen Therapy (Level of Evidence: 1A)

HBOT is used in diabetic foot ulcers because of the therapeutic benefits of oxygen, which include angiogenesis, collagen synthesis, osteoclastic activity and the release of vascular endothelial growth factor.[80] The opinion from the 2009 Cochrane Review on HBOT for diabetic foot ulcers was that HBOT may reduce the number of major amputations. Therefore, the use of HBOT may be justified once the financial considerations of this therapy have been taken into consideration. This opinion is echoed in the RNAO guidelines on diabetic foot ulcers.

Biologically Active Dressings (Level of Evidence: 1B)

Biologically active dressings contain products such as living human fibroblasts, extracellular matrix, collagen, hyaluronic acid or platelet-derived growth factor. Although the use of biologically active dressings as an adjunctive to current best practice principles for diabetic foot ulcers may be effective in healing these wounds, it is important to note that there is no evidence to support using these modalities as a substitute for best practice principles of moist wound healing and effective offloading of the ulcer.[10]

Negative Pressure Wound Therapy (Level of Evidence: 1B)

NPWT supports a moist wound-bed environment and enhances circulation when interstitial fluid is removed, increasing oxygenation to compromised tissue.[81] Removal of edema in the surrounding tissues and removal of stagnant infected fluid in the wound result in increased development of granulation tissue[82,83] and the evidence suggests that there are direct effects on fibroblast growth from the negative pressure. Although NPWT can be costly in terms of consumables, it has a definite role to play in increasing the rate of granulation in deep wounds. Care must be taken to ensure that actively inflammatory wounds (e.g., active infection, pyoderma gangrenosum) are adequately treated before initiating NPWT therapy. In the correct circumstances, however, NPWT can significantly shorten the time to heal in some wounds.

Recommendation 11 (Level of Evidence: IV)

Establish, train, sustain and empower a team to work with patients with diabetes.

Discussion

Caring effectively and efficiently for a patient with a diabetic foot ulcer requires an interdisciplinary team approach. The team members should include the patient and his or her family or caregivers, the first point-of-care physician and a podiatrist/chiropodist, orthotist, pedorthist, nursing and rehabilitation professionals (e.g., occupational therapist, physiotherapist) and an enterostomal therapist. There should be contact with endocrinology, dermatology, vascular, orthopedic and infectious disease colleagues, as well as with social workers, dietitians, mental health workers and diabetes nurse educators. Ideally this team will be in one location, but this is rarely—if ever—possible.

A diabetic foot care program in collaboration with practice leaders, educators and administrators is clearly required. This would provide coordinated care between

healthcare agencies and the community, and promote a standardized approach to wound care to improve patient outcomes and efficiency. Such a program would involve collaboration between acute, long-term and primary care and community care access centres to align best practice in wound care across the board. Interdisciplinary team work and integration of services would alleviate confusion and duplication of services.

Healthcare professionals and other personnel involved in the assessment and treatment of diabetic feet should receive adequate training. Guidelines from the UK's National Institute for Health and Clinical Excellence refer to "trained personnel." We know that early detection and early intervention may be the key to more successful outcomes. Access to individuals with knowledge and training specific to diabetes and diabetic foot care will improve client outcomes. Healthcare professionals also need to recognize the impact of living without peripheral sensation and that neuropathy can lead to reduced motivation to heal and prevent injury.[8]

Individuals who are part of the interdisciplinary team will contribute to patient care in their specific area of expertise. There will always be a need for continuing education for all team members. With new information being discovered and continuing developments in treatments and medications, all team members have a professional responsibility to remain up to date and informed of best practices.[9,10]

Diabetes-specific education and additional training to help integrate new knowledge and transform old practices into new is essential. Investments must be made to ensure that specialized training in diabetes education and other chronic conditions is accessible to both patients and healthcare professionals.[84] In addition, people must also be taught how to implement changes.

Educational institutions are encouraged to incorporate best practice guidelines into their basic RN, RPN, MD and allied health professional curricula. These institutions also have an obligation to keep up to date with advances in wound management and develop standardized curricula to implement these changes in practice.

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Recommendation 12 (Level of Evidence: IV)

Provide organizational support, including resource allocation. Improved outcomes, education and evidence bases must be tied to interprofessional teams with the cooperation of healthcare systems.

Discussion

Best practice care for patients with diabetic foot ulcers demands a systematic team approach from knowledgeable and skilled healthcare professionals. These team members will vary depending on the needs of the individual patient. The development and implementation of a successful diabetic foot ulcer program not only involves collaboration with practice leaders, but also—as the RNAO guidelines demonstrate—collaboration with educators and administrators. Their support is required to ensure coordinated care between community and healthcare agencies and the specialized and knowledgeable interdisciplinary team of healthcare professionals striving for improved diabetic foot ulcer outcomes. All of the RNAO wound care clinical practice guidelines contain multiple recommendations related to the value of interprofessional teams and the need for organizational support.

Organizations are encouraged to do the following[9,10]:

- Establish and support an interdisciplinary, interagency team comprised of interested and knowledgeable persons to address and monitor quality improvements in the management of diabetic foot ulcers.
- Develop policies that acknowledge and designate human, material and financial resources to support the interdisciplinary team in diabetic foot ulcer management.
- Work with community and other partners to develop a process to facilitate patient referral and access to local diabetes resources and health professionals with specialized knowledge in diabetic foot ulcer management.
- Work with community and other partners to advocate for strategies and funding for all aspects of foot care, including footwear.
- Use globally recognized risk classifications to help allocate resources such as therapeutic shoes, patient education and clinical visits.
- Establish and sustain a communication network between the person with diabetes and the necessary healthcare and community systems.

With the projected rise in persons with diabetes mellitus,[1] organizations need to ensure an increase in the availability and accessibility of diabetic foot ulcer care for all.

Conclusion

Diabetic foot ulcers can have devastating complications, including infection, amputation and even death. The use of the traditional medical model to manage these ulcers has proved to be both ineffective and costly.

The current literature has demonstrated that an integrated team approach to diabetic foot ulcers can reduce the incidence of amputation.[9,11,12] It is crucial that interprofessional teams are developed and sustained to manage diabetic foot ulcers. These teams must recognize that the patient and their overall well-being are at the centre of care. They need to educate people with diabetes to care for their feet, detect problems early and seek help in a timely manner when problems arise.[9,11,12]

Moreover, interprofessional teams must recognize that their goal is not only management of the acute and chronic wound, but also correction of the factors that led to ulceration and triage of patients into the appropriate treatment pathway. In achieving these goals we may then be successful at breaking the cycle of diabetic foot ulcer recurrence and preserving limbs. Teams should have the full support of healthcare organizations that recognize and promote ulcer prevention. This will reduce hospital admissions and amputations—thus reducing the burden on the healthcare system—and improve health outcomes and quality of life.

Developing and sustaining successful interprofessional team models that have a strong impact requires standardized education, motivated healthcare workers, supportive organizations[9,10] and strong associations that engage provincial and federal support. The results will have not only a huge impact financially, but also socially, emotionally and psychologically for patients and their communities.

This best practice recommendation will serve as a guide to providing a systematic approach for the prevention and management of diabetic foot ulcers and assisting organizations in the successful development and implementation of such programs.

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TPOT

Topical Pressurized Oxygen Therapy

Tissue Oxygenation is Essential for Wound Healing

Etiology: Wagner Grade 3 DFU with Osteomyelitis present X 10 years.

Healed in 34 days with *TPOT*

Valerie Winberg, RN(EC), BScN, MN, NP-PHC, ENC(c), IIWCC

Progress in 30 days with *TPOT*

57 y/o w male with Bilateral BKA with IDDM. Left leg BKA 6 years prior due to sepsis to left foot DFU. A DFU developed on the right foot shortly thereafter which became septic and a right foot amputation then ensued. Due to PAD, a right BKA was performed which dehisced and became septic. A sinus then formed 6 cm along the periosteum. Osteomyelitis was ruled out via radiological exam. The patient was placed on topical antimicrobials and systemic antibiotics yet the wound had stalled. Topical Pressurized Oxygen was used as a last attempt to salvage the limb and avoid another surgery. The wound responded forming a nice bed of granulation tissue and complete closure of the sinus.

Dr. Kevin Y. Woo PhD RN ACNP GNC(C) FAPWCA

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