Local Management of Mace Diabetic Foot Ulcers



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Introduction

Diabetic foot ulcers (DFUs) are a major issue globally, with considerable economic and human cost. About 8.5% (422 million) of the world's adult population has diabetes (WHO, 2016) and of these up to 25% will develop a DFU (Singh et al, 2005; Armstrong et al, 2017). 'Compromised' patients, i.e. those who are overweight, smoke and drink alcohol, are at greater risk of developing a DFU (Armstrong et al, 2017). DFUs are associated with increased morbidity and mortality, with half of patients dying within 5 years (Jupiter et al, 2016; Brennan et al, 2017). DFUs are also expensive to treat. The costs associated with diabetes in the US and in Europe respectively are increasing by approximately US\$9–13bn and up to €10bn per year (Prompers et al, 2008; Rice et al, 2014). Ensuring the most appropriate treatments are used is essential in improving patient outcomes and preventing serious and expensive complications, such as infection and amputation (Alavi et al, 2014a; Hatch & Armstrong, 2016).

Authors: Chadwick P, Armstrong DG. Full author details can be found on page 5.

Multidisciplinary approach to care

Management of DFUs is complex and requires a multidisciplinary team (MDT) approach that may include doctors, podiatrists and nurses with specialist training in diabetes, vascular surgeons, orthopaedic surgeons, infection specialists, orthotists, social workers and psychologists (WUWHS, 2016). Ideally, one clinician (for example, in the UK this is commonly a podiatrist) should act as coordinator ('gatekeeper') of multidisciplinary care to ensure that appropriate referrals are made and that management is integrated.

A coordinated MDT approach to the management of DFUs has been shown to reduce amputation rates (Krishnan et al, 2008; Tseng et al, 2011; Rubio et al, 2014; Wang et al, 2016). Early referral to an MDT also has the potential to improve healing rates. In England and Wales, patients assessed by experts within 2 weeks of their first presentation to a health professional had higher rates of ulcer healing than those seen later (NHS Digital, 2017).

The potential for a MDT approach to improve outcomes is reflected in guidance from the UK's National Institute for Health and Care Excellence (NICE) that states all patients with an active diabetic foot problem should be referred within one working day to a multidisciplinary foot care service or foot protection service (NICE, 2015).

DFU assessment

Initial assessment of a patient with a DFU should include evaluation of:

- Diabetes management and blood glucose control
- Previous history of DFU and vascular or foot surgery
- Smoking status
- Symptoms and signs of peripheral arterial or venous disease, and of peripheral neuropathy
- Musculoskeletal factors, e.g. ankle movement, foot shape
- Systemic signs of infection
- Pain
- Socioeconomic circumstances, dexterity, visual acuity and disease insight (Woo et al, 2013; Miller et al, 2014).

Wound assessment

Local DFU assessment provides a baseline for evaluating progress, as well as indicating appropriate local management, need for referral, dressing type and whether treatment for infection is needed. Change in wound size is often used to monitor healing progress. A lack of change in size may indicate that healing is stalled or that infection is imminent. An increase in size may be due to infection. A reduction in wound area of 10-15% per week or $\geq 50\%$ after 4 weeks of treatment predicts wound healing (Hingorani et al, 2016).

Signs of infection

At the time of presentation about half of DFUs are clinically infected (Prompers et al, 2007). This is potentially serious as infection precedes about 85% of amputations related to DFUs (Pendsey, 2010). If infection is suspected, the DFU should be sampled after debridement for microbiological analysis, and the results used to guide antibiotic selection (Chadwick & McCardle, 2015; Richard et al, 2011).

Classification of DFUs

Several classification systems for DFUs exist. The most well

- Wagner scale assesses ulcer depth, gangrene and loss of perfusion over a 0–5 scale, but does not fully consider infection and ischaemia (Wagner, 1981; Wounds International, 2013)
- University of Texas scale includes assessment of ischaemia and infection to produce a two-part score that includes grade and stage (Lavery et al, 1996; Armstrong et al, 1998).

Recently, a new classification system for the assessment of 'limb threat' has been devised for use in diabetic and non-diabetic patients. The system stratifies risk according to three major factors: Wound, Ischaemia and foot Infection. This makes the very memorable acronym Wlfl (Mills et al, 2014) (Figure 1). The wound is graded 0 to 3 (none, mild, moderate and severe) based on clinical signs; ischaemia is graded 0 to 3 based on ankle-brachial pressure index (ABPI), ankle systolic pressure, toe pressure or transcutaneous oximetry/skin perfusion pressure; and infection is scored 0 or 1 on the basis of clinical

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BOX 1. SIGNS AND SYMPTOMS OF INFECTION IN A DFU (LIPSKY ET AL, 2012; RNAO, 2013; WUWHS, 2016)

	Signs and symptoms of infection in a DFU*	
	'Classic'	'Subtle'
	 Local swelling or induration Erythema Local tenderness or pain Local warmth Purulent discharge 	 Increased exudate Friable or discoloured granulation tissue Undermining of wound edges Foul odour
*A DELL is likely to be infected if two or more/classic/signs are present, or if one/classic/sign and two/subtle/signs are pre-		sent or if one 'classic' sign and two 'subtle' signs are present

signs and symptoms. The scores from these three factors are added, to produce a WIfl spectrum score that determines clinical stage and indicates risk of amputation (Mills et al, 2014; Zhan et al, 2015).

Principles of local management

Local management of a DFU (Figure 2) should take place in the context of holistic management of the patient and the wound, and should include optimisation of blood glucose control, treatment of vascular insufficiency, offloading/protection, management of comorbidities and patient/carer education (Frykberg & Banks, 2016). Local management includes:

- Regular, repeated debridement to remove slough, nonviable tissue and hyperkeratotic wound margins (callus); sharp debridement is used widely and requires specialist training but should be used with caution in a patient with an ischaemic foot; autolytic debridement may have a role (McIntosh, 2009; Wounds International, 2013)
- Cleansing usually with water or saline, unless the wound is infected (in which case an antiseptic solution may be considered); a gentle rubbing action may aid removal of slough (Wolcott & Fletcher, 2014; Alavi et al, 2014b)
- Exudate management usually aims to keep the wound bed moist while preventing maceration; for dry necrotic areas, the aim is often to keep the area dry to aid auto debridement and to prevent infection (Wounds International, 2013)
- Treatment of infection systemic antibiotics (oral or parenteral) are the mainstay of the treatment of an infected DFU; topical antimicrobial agents, as cleansers or in dressings, are sometimes also used in mild infections (Lipsky et al, 2012; Lipsky et al, 2016)
- Offloading/protection aims to redistribute pressure away from the area of the wound; devices may be removable or irremovable (Cavanagh & Bus, 2010; Lewis & Lipp, 2013).

Monitoring and reassessment

As signs of change in a DFU may be subtle, regular monitoring and reassessment are essential, particularly to detect signs of infection. A wound area reduction of <50% at 4 weeks after the start of treatment indicates that the DFU is unlikely to heal, and the patient and wound should be fully reassessed and management adjusted as appropriate (Frykberg & Banks, 2016) (Figure 2).

Wound

- 0. No ulcer and
- no gangrene Small ulcer and
- no gangrene Deep ulcer or gangrene limited to toes
- extensive gangrene

Ischaemia

- Toe pressure/TcPO2 0. >60mmHG 1. 40-59
- 30-39

Foot infection

- Not infected Mild (<2cm cellulitis)
- 2 Moderate (>2cm
- cellulitis/purulence) 3. Severe (systemic

Figure 1: Wound, Ischaemia and foot Infection (adapted from Armstrong & Mills, 2013)

Self-care

Self-care is of increasing importance in the context of increased demand on healthcare services and constraints on resources. Patients or carers employing self- or home-care need sufficient visual acuity, physical flexibility, dexterity and understanding of DFUs to be able to change dressings, check the wound and seek help if needed.

Patient-focused care

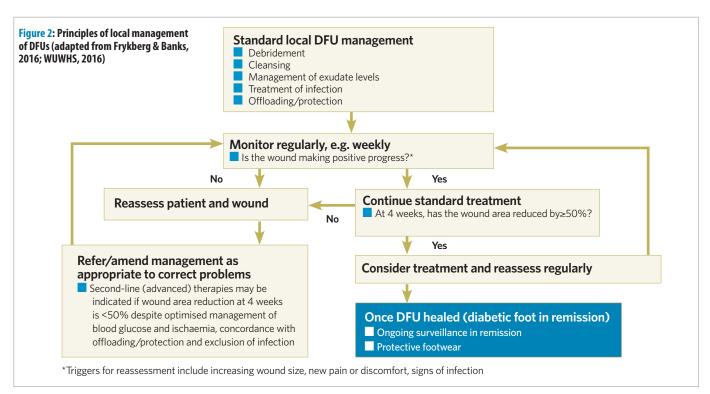
Understanding the patient's priorities is important, and provides an opportunity to ensure that the patient understands they have a role to play in treatment and outcomes. For example, a patient may prioritise a return to work over speed of healing. For other patients, total healing of a DFU may not be an appropriate goal. After consultation with the patient/carer, treatment aims may include prevention of infection or deterioration, management of exudate, odour and pain to maximise function, minimise impact on quality of life and simplify wound care (Dunning, 2016).

Role of dressings

Dressing choice is dependent on the aims of management and linked to the condition of the wound; an in-depth algorithm on the role of dressing in local management of DFUs (Figure 3) provides a guideline for use in practice. Acelity's advanced wound dressing range provides a varied portfolio to cover the needs of both the clinician and patient.

Dressings for exudate management

The aims of dressing use in a DFU containing slough and producing high exudate levels include achieving a moist wound environment while preventing periwound maceration and excoriation. The dressing chosen should be appropriate to exudate level, i.e. where levels are higher a more absorbent dressing may be required. Suitable dressings may include dressings containing low adherent viscose or silicone, foam, alginates or carboxymethylcellulose. BIOSORB™ Gelling Fibre Dressing is a soft conformable dressing, designed to aid intact removal, manage exudate and make dressing changes less painful. TIELLE LIQUALOCK™ Hydropolymer Foam Dressings with



Advanced Absorption Technology are designed to expand and conform to the wound bed, helping to avoid skin maceration and lock fluid away.

Where the DFU contains slough, but has low exudate levels, dressing use aims to aid autolytic debridement by retaining moisture, e.g. a foam dressing such as TIELLE™ Non Adhesive Hydropolymer Dressing with LIQUALOCK™ Technology, a low-profile dressing suitable with specialist footwear or offloading devices. Donating moisture therapies include hydrogels (e.g. NU-GEL™ Hydrogel with Alginate in combination with a thin hydrocolloid or film secondary dressing).

The aim for black, dry, necrotic toes due to ischaemia is to keep the area dry and to protect adjoining tissues. This may be achieved by a low adherent dressing placed between the toes or the use of tubular gauze sleeves. ADAPTIC TOUCH™ Non-Adhering Silicone Dressing has been designed to help prevent adherence to the wound bed. Alternatively, if there is a risk of infection, consider INADINE™ PVP-I Non Adherent Dressing.

Dressing deep wounds

The dressing material appropriate for exudate level in rope, ribbon or strip form should be used to fill deep wounds, eliminating dead space. The wound should not be over-packed and plugging of the wound should be avoided (e.g. $BIOSORB^{TM}$ Dressing [Size 2 x 45cm] and $TIELLE^{TM}$ Packing Hydropolymer Dressing with $LIQUALOCK^{TM}$ Technology that is designed for deeper cavity wounds).

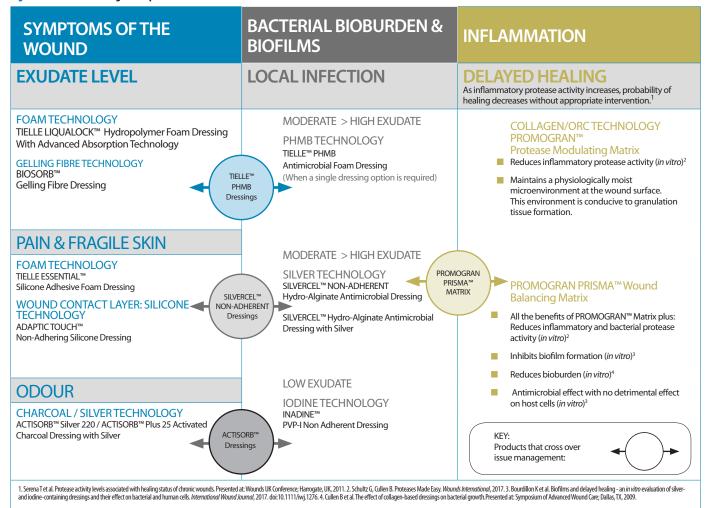
Negative pressure wound therapy (NPWT) may also be helpful in managing deep DFUs with high exudate levels by removing exudate, reducing oedema, encouraging granulation tissue formation and wound contraction (RNAO, 2013; Hasan et al, 2015).

Dressing infected wounds

Infected DFUs are usually treated with systemic antibiotics, and require close monitoring. Antimicrobial dressings are sometimes used in conjunction with antibiotics or when the wound is considered to be at risk (Lipsky et al, 2012; Lipsky et al, 2016). Indications that a DFU may be about to 'tip' into infection may be very subtle. Clinical experience, a high index of suspicion and close monitoring of the wound are important in identifying such DFUs and may indicate the need for antimicrobial dressings.

Topical antimicrobial agents frequently used include iodineor silver-impregnated dressings and antiseptic cleansers (WUWHS, 2008). The principle of the 'two-week challenge' should be used, i.e. if after 2 weeks there is no improvement, the antimicrobial agent should be discontinued and an alternative considered (Wounds International, 2012). For low exudating wounds INADINE™ (PVP-I) Non Adherent Dressing provides a broad spectrum of antimicrobial action while helping to minimise adherence (Sibbald et al, 2011). For moderate to high exuding wounds SILVERCEL™ NON-ADHERENT Hydro-Alginate Antimicrobial Dressing with Silver with EASYLIFT™ Precision Film Technology provides prolonged antimicrobial protection and exudate absorption while minimising adherence and fibre shedding (Clark & Bradbury, 2010). When an antimicrobial foam is preferred, TIELLE™ PHMB Antimicrobial Adhesive Foam Dressings help manage infected and at-risk wounds through fast-acting antimicrobial action and effective exudate management (Hart & Bell, 2009).

Figure 3: Guide to dressing use in practice



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Other factors

Other factors to consider when selecting dressings for DFUs:

- Protection of periwound skin contact by exudate with periwound skin should be avoided to prevent maceration and excoriation that may disrupt treatment or lead to wound enlargement. The use of low adherent or silicone dressings, or periwound skin protectant creams or barrier films, and the avoidance of tape fixatives may reduce the risk of skin damage (Bianchi, 2012)
- Odour regular debridement will aid removal of necrotic tissue that may be responsible for odour. The wound should also be assessed, and treated as appropriate, for infection. Charcoal dressings may absorb odour (RNAO, 2013)
- Pain about half of patients with a DFU experience wound-related pain (Bengtsson et al, 2008). Pain that suddenly increases in intensity or that is newly occurring may indicate infection. Careful attention to dressing change

technique and using easy-to-remove dressings that do not adhere can help to reduce dressing change-related pain (WUWHS, 2004; Baker, 2012).

Dressing change frequency

As a general principle in wound care, dressing change frequency is minimised to reduce the risk of contamination. However, DFUs may deteriorate very quickly and dressing change provides an opportunity to monitor the wound. For DFUs of concern, dressing change frequency should be increased. Where a DFU is infected, this may be to as often as every 1–2 days.

Second-line (advanced) topical treatments

Second-line (advanced) topical treatments may be indicated if a DFU has not reduced in size by ≥50% over 4 weeks despite optimised management of blood glucose and ischaemia, concordance with

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offloading/protection and exclusion of infection. The main second-line treatments in use are collagen dressings and NPWT. Other second-line treatments include skin grafts, topical growth factors, bioengineered skin equivalents, acellular matrices and stem cell therapy (Yazdanpanah et al, 2015).

Non-healing chronic wounds are characterised by elevated proteolytic enzymes and inflammatory markers. Collagen dressings, e.g. PROMOGRAN™ Protease Balancing Matrix, are designed to reduce levels of protease and inflammatory activity (Cullen & Ivins, 2010). Some collagen dressings also contain silver for antimicrobial activity, e.g. PROMOGRAN PRISMA™ Wound Balancing Matrix.

NPWT is used to manage heavily exuding, deep DFUs and following surgery. V.A.C.® Therapy uses a hydrophobic reticulated open cell foam under subatmospheric pressure to promote healing by secondary or tertiary intention by preparing the wound bed for closure, reducing oedema, promoting granulation tissue formation and perfusion and removing exudate and infectious material. V.A.C. VERAFLO™ Therapy consists of NPWT coupled with automated, controlled delivery to and removal of topical treatment solutions from the wound bed. The V.A.C. VERAFLO CLEANSE CHOICE™ Dressing, in conjunction with V.A.C. VERAFLO™ Therapy, can be used to initiate therapy and facilitate removal of infectious materials. V.A.C. VERAFLO CLEANSE CHOICE™ Dressing may be considered when surgical debridement is not appropriate.

As an alternative to conventional forms of NPWT, single-use disposable NPWT can also be used to treat smaller DFUs, with low to moderate exudate levels. Easy to use and portable, the SNAP $^{\text{TM}}$ Therapy System combines advanced wound dressings with the benefits of NPWT. The SNAP $^{\text{TM}}$ System is suitable for patients who are more active, and this has been found to improve patient quality of life (Piaggesi et al, 2012).

Management of healed wounds, prevention and recurrence

A patient with a healed DFU should be considered in remission rather than cured because of the high risk of recurrence. A patient who has a healed DFU has a 17–60% risk of another DFU occurring in the next 3 years (Dubsky et al, 2012; Armstrong et al, 2017).

Protective footwear should be ordered or availability ensured when a DFU is approaching complete epithelialisation. The patient should be encouraged to examine their feet regularly and should be referred to a foot surveillance service if available (Mayfield et al, 1998).

Frequently, a dressing or tubular bandage and offloading/protection are continued for 1–2 weeks after epithelialisation of a DFU is complete. Patients should be given details of who to contact if problems occur.

Primary prevention and recurrence

Primary prevention of DFUs centres on the holistic approach to the management of related comorbidities. This can include education, glycaemic control, lipid management, blood pressure control, smoking cessation, regular foot self-examination and appropriate surveillance by healthcare professionals (Boulton et al, 2008; Iraj et al, 2013; Miller et al, 2014; WUWHS, 2016). Smoking and obesity are common modifiable risk factors that are associated with the development of DFUs (Nehring et al, 2014; Al-Rubeaan et al, 2015). Another method that has been found to reduce the risk of DFU is foot thermometry (Armstrong et al, 2007; Bus et al, 2016).

The '3-minute diabetic foot exam' has been devised to provide a systematic way of conducting a foot examination that can also signal the need for further investigation or referral (Miller et al, 2014; Boulton et al, 2008) (Figure 4). The 'exam' is split into three areas: the patient's history, a physical examination and patient education.

WHAT TO ASK



Does the patient have a history of:

- Previous leg/foot ulcer or lower limb
- amputation/surgery?Prior angioplasty, stent or leg bypass surgery?
- Foot wound?
- Smoking or nicotine use?
- Diabetes? (if yes, what are the patient's current control measures?)

Does the patient have:

- Burning or tingling in legs/feet?
- Leg or foot pain with activity or rest?
- Changes in skin colour or skin lesions?
- Loss of sensation of lower extremity.

Has the patient established regular podiatric care?

Figure 4: The '3-minute diabetic foot exam' (Miller et al, 2014)

WHAT TO LOOK FOR



Dermatologic exam:

- Does the patient have discoloured, ingrown or elongated nails?
- Are there signs of fungal infection?
- Does the patient have discoloured and/or hypertrophic skin lesions, calluses or corns?
- Does the patient have open wounds or fissures?
- Does the patient have interdigital maceration?

Neurological exam:

Is the patient responsive to light touch (protective sensation) on the feet?

Musculoskeletal exam:

- Does the patient have full range of motion of the joints?
- Does the patient have obvious deformities? If so, for how long?
- Is the midfoot hot, red or inflamed?

Vascular exam:

- Is hair growth on the foot dorsum or lower limb decreased?
- Are the dorsalis pedis AND posterior tibial pulses palpable?
- Is there a temperature difference between the calves and feet or between the left and right foot?

WHAT TO TEACH



Recommendations for daily foot care:

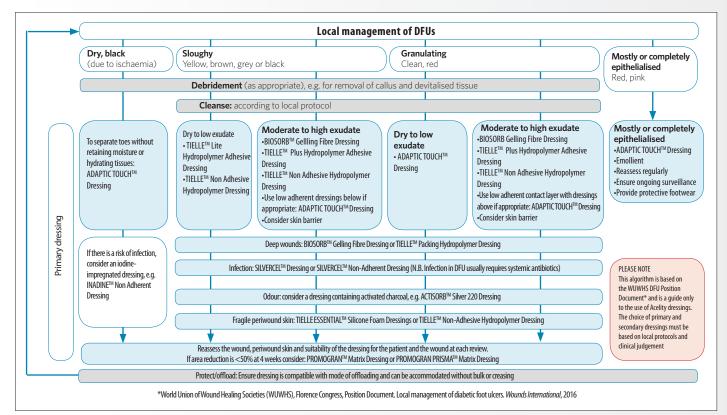
- Visually examine both feet, including the sole and between the toes. If the patient can't do this, have a family member do it
- Keep feet dry by regularly changing shoes and socks; dry feet after baths or exercise
- Report any new lesions, discolourations or swelling to an HCP

Education regarding shoes:

- Educate the patient on the risks of walking barefoot, even when indoors
- Recommend appropriate footwear and advise against shoes that are too small, tight or rub against a particular area of the foot
- Suggest yearly replacement of shoes more frequently if they exhibit high wear

Has the patient established regular podiatric care?

- Recommend smoking cessation (if applicable)
- Recommend appropriate glycaemic control



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Summary

Local management of DFUs requires consideration of a wide range of factors. Key to improving healing rates and prevention of amputation is early referral to a MDT. The choice of dressing type and change frequency should be tailored to the needs of the patient and the condition of the wound, and reviewed frequently. Monitoring change in the wound area can be used to indicate when second-line (advanced) topical treatments should be considered.