

# TIME to assess wounds – a clinical evaluation of Flaminal

## KEY WORDS

- ▶ Chronic wounds
- ▶ Enzyme Alginogel
- ▶ Flaminal
- ▶ Survey results
- ▶ TIME
- ▶ Wound assessment

This article discusses the assessment of wounds, in particular, wound specific factors, acknowledging the essential elements (aetiologic, systemic and wound specific), which need to be considered to ensure that a patient receives optimal wound management. It also reports on the findings of a large scale evaluation over 18 months of 356 patients whose wounds were treated with Flaminal® (an Enzyme Alginogel® by Flen Health). The results highlight the clinical effectiveness and safety of Flaminal Hydro and Flaminal Forte and the patient experience of pain with Flaminal as a primary dressing.

With a predicted year on year increase in the prevalence of wounds of approximately 11% (Guest et al, 2017a), the burden of wounds on the NHS in terms of cost and associated comorbidities is estimated to rise to around £8–£9 billion by 2018. In 2007, Drew et al reported that over 70% of wound care was carried out in the community; by 2014 this had risen to 86.7% (Dowsett et al, 2014). It is clear that the majority of wounds are managed in the community; this is set against a background of a continued reduction in the number of District Nurses. Demand has augmented, increasing strain on the service with a parallel increase in the ageing population, coupled with increasingly complex comorbidities and wounds (Royal College of Nursing, 2012). It is incumbent on clinicians to be mindful of the cost to the NHS, with dressings and nursing time being two of the greatest costs associated with wound care (Drew et al, 2007). This is before considering the enormous burden of living with a wound for patients and their families.

Wound assessment involves observation, data collection and an ongoing evaluation process. A systematic and evidence-based assessment provides objective data to confirm wound healing whilst also alerting practitioners about any deterioration in the wound. It enables patients and their family/carers to become involved whilst also giving them confidence in the care they are receiving. It must be seen by practitioners (and managers) as an important first step in wound management with education, time and resources being allocated for this process.

Without an accurate assessment that includes determining the underlying aetiology of a wound, it stands to reason that appropriate, effective and timely management is potentially absent. This subsequently impacts on healing of a wound increasing the burden of chronic wounds not only on the NHS but importantly for the patient and carers. We know from the Burden of Chronic Wounds' Study (Guest et al, 2015), that 41% of wounds were not accurately diagnosed with the inference that suboptimal care will have ensued.

This article discusses the assessment of wounds, in particular, wound specific factors, acknowledging the essential elements (aetiologic, systemic and wound specific), which need to be considered to ensure that a patient receives optimal wound management; thus enabling an effective strategy for wound healing to be devised (Scott-Thomas et al, 2017). It also reports on the findings of a large evaluation of Flaminal (Enzyme Alginogel by Flen Health), regarding the clinical effectiveness and safety of Flaminal Hydro and Flaminal Forte (the two forms of Flaminal available on the market) and the patient experience of pain with Flaminal as a primary dressing. Flaminal® and Enzyme Alginogel® are registered trademarks of Flen Health.

## THE ASSESSMENT OF WOUNDS

A comprehensive wound and skin assessment must be completed. This should be part of a structured assessment which needs to include a holistic assessment that considers any comorbid conditions,

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**Table 1: Generic wound assessment minimum data set (Coleman et al, 2017)**

| Domain                      | Core generic wound assessment minimum data set   |
|-----------------------------|--|
| General health information  | <ul style="list-style-type: none"> <li>• Risk factors for delayed healing (systemic and local blood supply to the wound, susceptibility to infection, medication affecting wound healing, skin integrity)</li> <li>• Allergies</li> <li>• Skin sensitivities</li> <li>• Impact of the wound on quality of life (physical, social and emotional)</li> <li>• Information provided to patient and carers</li> </ul> |
| Wound baseline information  | <ul style="list-style-type: none"> <li>• Number of wounds</li> <li>• Wound location</li> <li>• Wound type/classification</li> <li>• Wound duration</li> <li>• Treatment aim</li> <li>• Planned re-assessment date</li> </ul>   |
| Wound assessment parameters | <ul style="list-style-type: none"> <li>• Wound size (maximum length, width and depth)</li> <li>• Undermining/tunnelling</li> <li>• Category (pressure ulcers only)</li> <li>• Wound-bed tissue type</li> <li>• Wound-bed tissue amount</li> <li>• Description of wound margin/edges</li> <li>• Colour and condition of surrounding skin</li> <li>• Whether the wound has healed</li> </ul>                       |
| Wound symptoms              | <ul style="list-style-type: none"> <li>• Presence of wound pain</li> <li>• Wound pain frequency</li> <li>• Wound pain severity</li> <li>• Exudate amount</li> <li>• Exudate consistency/type/colour</li> <li>• Odour occurrence</li> <li>• Signs of systemic infection</li> <li>• Signs of local wound infection</li> <li>• Whether a wound swab has been taken</li> </ul>                                       |
| Surgical                    | <ul style="list-style-type: none"> <li>• Investigation for lower limb (ankle brachial pressure index)</li> <li>• Referrals (tissue viability service, hospital consultant)</li> </ul>  |

health, family history, medications and lifestyle plus identifying any potential underlying factors that could impact on healing together with the cause of the wound. In the Guest et al (2015) study it was noted that in a number of cases the cause of the wounds was not recorded. This is clearly contrary to all recommendations as it not only delays healing but puts the patient at potential risk, for example, compression therapy for a patient with underlying arterial disease. In an increasingly litigious society, the practitioner is also at risk from litigation.

Improving the assessment of wounds has been specified as a key goal of the Commissioning for Quality and Innovation (CQUIN) scheme for 2017-2019 (Department of Health, 2016). It has challenged community services to audit practice against the published minimum data set (MDS) for wound assessment (Coleman et al, 2017)

which comprises five main domains and 37 core generic MDS items (Table 1). The development of a MDS for generic wound assessment is part of NHS England's Leading Change Adding Value Framework — Improving Wound Care Project. A MDS is the minimum information needed to provide a baseline for monitoring improvement or deterioration thereby questioning wound management decisions. Using CQUIN guidance and ensuring that a thorough and comprehensive assessment is undertaken will ultimately save time whilst improving both practice and the experience for the patient. By focusing on wound assessment, the aim is to reduce the number of wounds which have failed to heal after 4 weeks (Wounds UK, 2017). In a retrospective analysis, Cardinal et al (2008) concluded that a 50% reduction in wound surface area at four weeks is a strong predictor of wound healing at 12 weeks. The patient at this stage may benefit from further investigation to determine any underlying problems such as vascular issues.

There are numerous wound assessment tools which Greatex-White and Moxey (2013) found to be lacking in some aspects of wound assessment, whilst not providing practitioners with a framework to enable goals to be set. Whilst it is not possible to expand on these tools, there is a useful framework for practitioners which has expanded on the T.I.M.E (tissue, infection/inflammation, moisture balance and wound edge) model of wound bed preparation (Schultz et al, 2004); namely the Triangle of Wound Assessment (Dowsett et al, 2015; WUWHS, 2016). In their model they considered wounds to have three distinct, yet interconnected zones of a triangle: wound bed, wound edge and periwound skin; the Triangle of Wound Assessment places a greater emphasis on beyond-the-wound margins. First introduced in 2002 and revised in 2012 (Leaper et al, 2012), the T.I.M.E framework has been an important tool for clinicians in wound management helping to identify the barriers to healing enabling a plan of care to be developed. This framework was utilised in the evaluation of Flaminal for wounds of varying aetiologies and is discussed in more detail below.

## TISSUE

The type and amount of tissue (in percentages) present in a wound is part of the MDS thus providing the clinician with vital information as to the progress or

deterioration within a wound and a guide towards dressing selection. Tissue types are usually described as necrotic, sloughy, granulating and epithelialising, with commonly more than one tissue type being present in a wound at any one time, hence the use of percentages.

The presence of devitalised tissue is not only distressing for patients (Wounds International, 2012), but it also impedes assessment since it can mask the true extent of a wound (Price and Young, 2013). Devitalised tissue is a barrier to healing and can act as a potential source of infection, especially in deteriorating wounds (Ayello et al, 2012). Percival and Suleman (2015) postulated that slough acts as a reservoir for microorganisms and biofilm formation which impedes healing (Metcalf et al, 2014) and that in order to stimulate healing devitalised tissue must be removed (Srohal et al, 2013). There are a range of debridement methods available including sharp, autolytic, biosurgical, mechanical, hydrosurgical discussed in detail elsewhere (Wounds UK, 2013a). However, this article will consider the most commonly utilised method of removing devitalised tissue, namely autolytic debridement, which is facilitated with the use of dressings. Devitalised tissue is able to liquefy in a moist environment and separate from healthy tissue via the process referred to as autolytic debridement. Therefore, the selection of a primary dressing which can enhance this process is important, with the aim of achieving a 'healthy and viable' granulating wound bed.

### INFECTION/INFLAMMATION

A comprehensive and holistic assessment should enable the clinician to differentiate between inflammation as a normal physiological response in wound healing, as part of an inflammatory condition, from inflammation caused by infection, or other impairments in the patient's resistance such as nutrition or comorbidities like diabetes. Only then is it possible to manage the inflammation effectively. This can be challenging since some of the classic symptoms of infection also mimic the markers of inflammation (swelling, pain and erythema).

It is imperative that clinicians have a sound knowledge of systemic and local risk factors together with the signs and symptoms of wound infection. Many wounds are being stalled in the inflammatory stage of healing because of imbalances in the inflammatory cells, growth factors and proteases,

such as matrix metalloproteinases (MMPs) (Harries et al, 2016).

### MOISTURE BALANCE

Exudate in acute wounds contains components vital to the healing process (Power et al, 2017) unlike the potentially harmful components of chronic wound exudate, namely MMPs, which can degrade healthy tissue (Humbert et al, 2017). When exudate is not controlled leakage and maceration can ensue, resulting in increased pain and distress for the patient (Gardner, 2012) coupled with the potential for skin breakdown. Clinicians have a responsibility to their patients to minimise the occurrence of harm by effective exudate management (Department of Health, 2009).

Whilst we know that a moist wound healing environment is necessary for the progression of healing (Junker et al, 2013; Ousey et al, 2016), uncontrolled exudate is often accompanied by malodour, pain, infection and unsightly soiled dressings. This can trigger feelings of self-loathing, disgust and low self-esteem ultimately impacting on quality of life (Jones et al, 2008). The exudate consistency, type, amount and colour should be documented as well as noting any accompanying odour (Wounds UK, 2013b).

### WOUND EDGE

Advancement of the wound edge is important for healing with the protection of the wound margins being paramount. Whilst prolonged exposure of skin to moisture can potentially result in maceration, Rippon et al (2016) suggested that it is rather the elevated destructive biological components present in wound exudate that is the culprit for maceration. It is essential that the clinician monitors the wound edge for signs of dehydration, undermining or rolling which all impact on the ability of the wound edges to advance to healing. Likewise, observation of the periwound skin for signs of damage can assist the clinician in making informed decisions as to management, e.g management of dry skin and eczema around venous leg ulcers. Ousey et al (2013) reported on the findings of a study in which 70% of patients had periwound skin that could be described as dry, macerated, excoriated or inflamed.

## Box 1. Flaminal evaluation form

- Q1:** Removal of slough/necrotic tissue. How would you rate Flaminal in terms of debriding slough/necrotic tissue and cleaning the wound bed?  
Improved-----No change-----Worsened-----
- Q2:** Reduction in the signs of infection/critical colonisation. Please rate how well Flaminal dealt with infection/critical colonisation.  
Improved-----No change-----Worsened-----
- Q3:** Surrounding skin. During treatment with Flaminal, how did the condition of the wound edges and surrounding skin change?  
Improved-----No change-----Worsened-----  
Other (please state)-----
- Q4:** Granulation tissue. During treatment with Flaminal, how was granulation tissue affected?  
Improved-----No change-----Worsened-----
- Q5:** How well did Flaminal manage moisture balance in the wound?  
Managed well-----No difference-----Did not manage-----
- Q6:** Did the patient notice any change in wound pain during treatment with Flaminal?  
Improved-----No change-----Worsened-----
- Q7:** Overall, did Flaminal meet your expectations?  
Exceeded-----Met-----Did not meet-----
- Q8:** Would you be happy to continue using Flaminal and/or recommending to a colleague?  
Yes-----No-----
- Q9:** Which formulation of Flaminal were you using?  
Hydro-----Forte-----
- Q10:** Please indicate the level of exudate from the wound  
None-----Low-----  
Moderate-----High-----
- Q11:** How often was Flaminal being applied?  
Daily-----Every 2 days-----Every 3-4 days-----

## EVALUATION OF FLAMINAL

Flaminal (Flen Health) products (Hydro and Forte), are enzyme alginogels containing an antimicrobial enzyme system capable of, absorbing excess exudate (whilst remaining in a gelled state), promoting continuous autolytic debridement and controlling bioburden (Beele et al, 2012). Flaminal is a hydro-active, broad-spectrum Enzyme Alginate Alginate polymers in a polyethylene glycol (PEG) matrix embedded with

covering debridement, infection, moisture balance and wound edges. There was one question which required clinicians to ask the patient their views pertaining to pain.

Following collection of all survey forms, the data were analysed using a standard “binomial test” with 95% confidence intervals (CI) calculated using the Wilson method (Brown et al 2001). All *p* values reported were one-tailed, utilising GraphPad Prism software version 7.00 for Windows.

## RESULTS

A total of 356 evaluations were completed for wounds of varying aetiology with Flaminal over an 18 month period. The majority of exuding wounds treated during the evaluation period were representative of those frequently managed in the community including leg ulcers, pressure ulcers, diabetic foot ulcers; however, 26 evaluations did not state the aetiology of the wound (*Table 2*). This reflects the findings of Guest et al (2017b) who noted that approximately 30% of all wounds are being managed without a documented differential diagnosis being recorded; which could, in turn, infer that the assessment process was suboptimal. In 70% of cases, Flaminal Forte was utilised as the primary dressing, with Flaminal Hydro being selected in the remaining 30% of patients.

In order to stimulate healing devitalised non-viable tissue needs to be removed (Strohal et al, 2013; Ousey and McIntosh, 2010) since it is known to provide a focus for infection whilst exacerbating the inflammatory response (Wolcott et al, 2009). This includes foreign material (wound dressing residue, multiple organism-related biofilm or slough, exudate and debris) on the wound bed. Expedient removal of devitalised tissue from wounds is, therefore, an important factor for practitioners. Question 1 asked the respondents to rate the ability of Flaminal in the removal/debridement of slough/necrotic tissue from the wound bed. A statistically significant number of clinicians stated that the wound bed had improved by using Flaminal. Of the 331 that responded, 278 (84%) said that it improved (*Figure 1*) and 53(16%) reported ‘no change’ or ‘worsening.’

The difference was statistically significant, *p*<0.0001, 5% CI 79.65–87.55%, indicating that the number of clinicians reporting an improvement in the wound bed through the debridement of

a patented antimicrobial enzymatic complex of glucose oxidase and lactoperoxidase that are stabilised by guaiacol (White, 2006). These naturally occurring enzymes are found in milk and saliva and are important in the innate immune system. Only absorbed microbes are destroyed by the enzyme complex and not human cells within the wound bed.

Flaminal has a proven broad-spectrum antibacterial activity (De Smet et al, 2009), with the ability to inhibit biofilm formation (Cooper, 2013); whilst demonstrating the ability to reduce pain in a study of acute and chronic wounds (Durante, 2012). Although there is a paucity of evidence from randomised controlled trials (RCTs) on Flaminal, nonetheless there is a plethora of case study evidence on its overall efficacy (Jones and Williams, 2017).

## METHOD

District Nurses (DNs) were asked to complete one evaluation form per patient about their experiences of managing wounds with Flaminal, which was utilised as the primary dressing. The evaluation form consisted of 11 questions (*Box 1*)

**Table 2. Wound aetiology**

| Aetiology                      | No of Responses |
|--------------------------------|-----------------|
| Leg Ulcer                      | 84              |
| Pressure Ulcer                 | 75              |
| Diabetic Foot Ulcer            | 11              |
| Moisture Lesion                | 21              |
| Ulcer (not specified location) | 5               |
| Trauma/Skin Tear               | 28              |
| Burn                           | 5               |
| Other wound types              | 101             |
| Not specified                  | 26              |

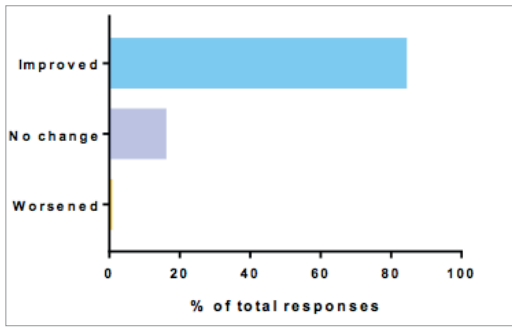


Figure 1. Removal of slough/necrotic tissue

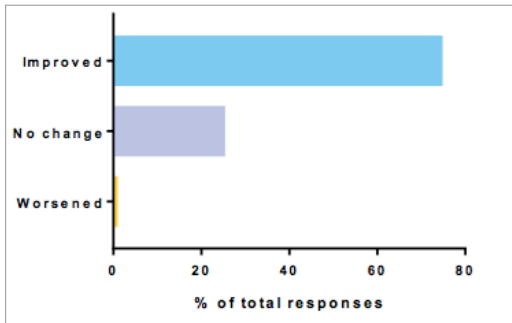


Figure 2. Signs of Infection

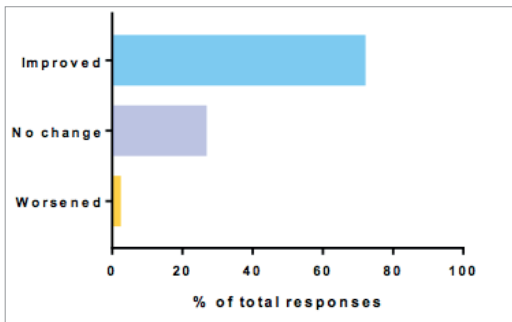


Figure 3. Wound edges and surrounding skin

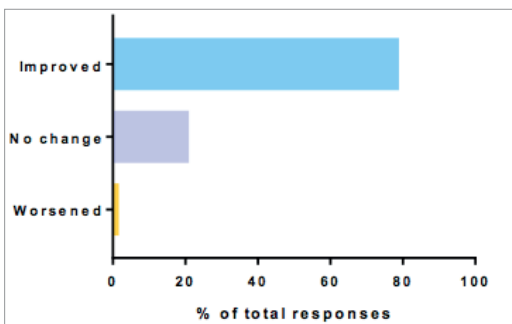


Figure 4. Granulation tissue

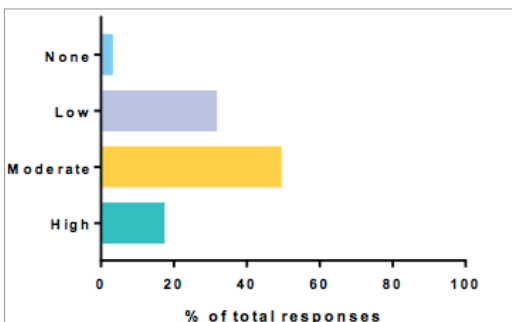


Figure 5. Level of Exudate

slough/necrotic tissue was larger than would be expected due to chance.

Question 2 asked clinicians to rate how well Flaminal was able to deal with an infection in the wound. Of the 340 clinicians that responded, 253 (74.41%) reported an improvement in the wound with 87 (25.59%) reporting no change or worsening (Figure 2).

The difference between the observed value and the expected value of 50% was statistically significant,  $p < 0.0001$ , 95% score CI=69.52–78.76%, indicating that the number of respondents reporting an improvement in signs of infection/critical colonisation was larger than would be expected due to chance.

Whilst systemic antibiotics are recommended for overt and spreading infection, with concomitant signs and symptoms; in cases of milder localised infection antimicrobial wound therapy dressings are recommended to stimulate wound healing and manage wound bioburden (Cowan, 2010). This should be accompanied by therapeutic cleansing and debridement as necessary and/or appropriate.

Clinicians were asked in Question 3 to consider if Flaminal improved the condition of the wound edges and surrounding skin. In 255 (71.63%) out of the 356 clinicians who responded (Figure 3), they noted an improvement in the wound edges and surrounding skin; while 101 (28.37%) reported no change or worsening.

The difference between the observed value and the expected value of 50% was statistically

significant,  $p < 0.0001$ , 95% score CI=66.73–76.06%, indicating that the number of respondents reporting an improvement in the condition of the wound edges and surrounding skin was larger than would be expected due to chance.

The condition of the wound edge and periwound skin provides the clinician with important information, not only regarding the progress of the wound but also about the performance of the dressing regimen. If maceration of the surrounding skin is present it may be a sign that the dressing is unable to absorb the amount of drainage present. Equally excoriated or dehydrated dry skin can be a potential source of discomfort or pain as well as impede wound healing.

Question 4 asked clinicians to assess the effect of Flaminal on granulation tissue in the wounds they were managing during the evaluation. Clean and healthy granulation tissue is typically described as bright red, moist and granular or bubbly in appearance, unlike unhealthy granulation which is dark red in colour and bleeds easily. Only 76 (21.59%) of the 352 who responded reported no change or worsening (Figure 4), while 276 (78.41%) noted an improvement. The difference between the observed value and the expected value of 50% was statistically significant,  $p < 0.0001$ , 95% score CI=73.82–82.39%, indicating that the number of respondents reporting an improvement in the granulation tissue was larger than would be expected due to chance.

Clinicians were asked to indicate the level of exudate from the wound from none to high (Figure 5). Only 2% of wounds managed by clinicians were not exuding, with 67% of wounds described as having moderate to heavily exuding wounds.

This finding reflects the issues that clinicians and more importantly patients have with exudate and its management. In some chronic and/or large surface area wounds, under certain systemic or regional circumstances, the exudate can increase to unacceptable levels. This can be detrimental to healing, as it contains a corrosive cocktail of elements, which damage the wound bed as well as the periwound skin (Bishop et al, 2003).

It was, therefore, important to know if clinicians were positive regarding the ability of Flaminal to manage moisture balance in a wound. Of the 352 that responded, 294 (83.52%) said it improved, 58 (16.48%) reported no difference or that it did not manage

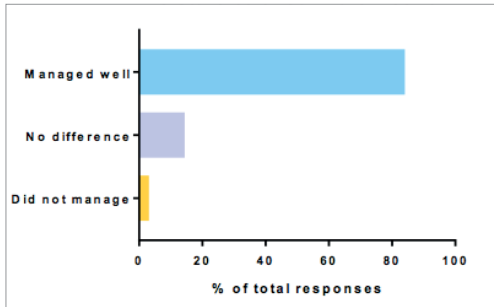


Figure 6. Moisture balance

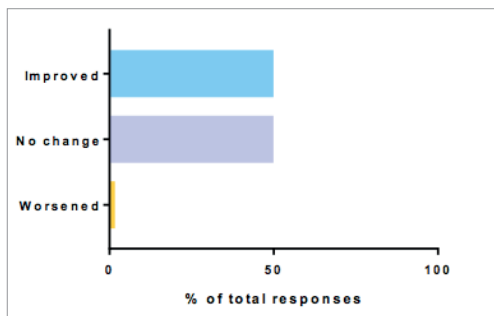


Figure 7. Pain

moisture balance (Figure 6).

The difference between the observed value and the expected value of 50% was statistically significant,  $p < 0.0001$ , 95% score CI=79.29–87.03%, indicating that the number of respondents reporting that Flaminal managed moisture balance in the wound well was larger than would be expected due to chance.

If the fluid-handling capacity of a dressing regimen is less than optimum, this can cause problems for the patient in terms of striae, plus feelings of anxiety and unwillingness to socialise (Jones et al, 2008).

Pain is a very personal experience and, therefore, cannot be rated by the clinician, hence the need for the clinician to ask if the patient noticed

any improvement in wound pain when treated with Flaminal. Of the 344 that responded, 170 (49.42%) said it improved, 174 (50.58%) reported no change (Figure 7).

The difference between the observed value and the expected value of 50 % was not statistically significant,  $p = 0.4358$ , 95% score CI=44.17–54.68 %, indicating that the number of patients reporting an improvement in pain during treatment with Flaminal was not larger than would be expected due to chance.

Clinicians need to have confidence in a product to continue utilising it after an evaluation has concluded; a product must, therefore, meet their expectations. When asked if Flaminal met their expectations for a dressing, 94% said that it either met or exceeded expectations with 98% of clinicians involved in the evaluation would be happy to continue using Flaminal and/or recommending it to a colleague.

**DISCUSSION**

The results of this 356 patient evaluation mirror the findings of other studies in terms of the major types of wounds dealt with by DNs and consistent with the evolving demographics and comorbidities of the 21st-century patient which impact daily on the service.

A comprehensive wound and skin assessment where the aetiology of the wound is defined is vital

for an appropriate and efficacious treatment plan to be developed with the patient. This evaluation has highlighted that there are clearly gaps in this process as not all patients seemed to have a clear diagnosis of their wound. Wound assessment is finally ‘on the agenda’ which means it will receive the attention it deserves, and more importantly as a result, so will patients with chronic wounds. As discussed earlier in this article wound bed preparation provides clinicians with a framework to help identify the barriers to healing enabling the development of a plan of care. Any assessment should start and finish with the patient as any treatment administered is unlikely to be successful without patient concordance.

The importance of removing devitalised tissue is well documented in the literature (IWII, 2016; Wounds UK, 2013a); with its presence acting as a focus for microbial growth and infection thereby impeding healing (Wolcott et al, 2009). Wound debridement is one of the most effective methods of reducing bioburden as it helps to remove adherent microorganisms and cellular debris (Wolcott et al, 2009). It is, therefore, incumbent on the clinician to select a dressing which facilitates its removal without causing trauma to the wound, surrounding skin as well as to the patient. One way to minimise pain is to use dressings that do not cause trauma or damage to the wound or peri-wound skin, as well as being pain-free on removal.

Patient acceptability and symptom management are vitally important in any dressing regimen to ensure patient confidentiality and, ultimately concordance with a treatment plan (Solwiej et al, 2010). One of the most commonly cited issues for clinicians and patients in chronic wound management is the control of exudate and its concomitant problems. Therefore, timely and appropriate dressing selection can impact the progress of a wound, as well as the comfort and quality of life of the patient (Romanelli et al, 2010).

**CONCLUSION**

With the myriad of dressings available, it is important that clinicians ensure their selection of products is based on the most up-to-date evidence available, taking into consideration the results of a thorough and systematic assessment. Whilst cost is not (and should not be) the main driver in the selection process, at the same time there is a need in a cash-

Wound Care 18(2):54-56

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strapped NHS to be diligent. Selecting a product that has the ability to address several signs and/or symptoms is a useful addition to a DN formulary.

Flaminal's triple mode of action avoids the need for multiple products since it has the capability of absorbing excess exudate whilst remaining in a gelled state, promoting autolytic debridement and controlling bioburden which in turn potentially reduces the exudate, malodour and in many cases pain experienced by patients with chronic wounds. Flaminal is a product that can be utilised throughout the healing trajectory of chronic wounds and in turn is conformable and easy to use, particularly in small and hard-to-reach wounds.



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