

Use of topical haemoglobin on sloughy wounds in the community setting

Abstract

Aim: This evaluation aimed to determine whether the use of a haemoglobin spray solution expedited sloughy wound healing. **Method:** A descriptive evaluation was undertaken within a community setting exploring 25 patients presenting with sloughy healing and non-healing wounds, and the effects of 8 topically administered haemoglobin treatments over a 4-week period. Standard wound cleansing and dressing management were continued, with no changes to pre-evaluation regimens, and care being provided by the patients themselves or by a carer. Data were collected weekly with regard to primary outcomes of slough reduction, wound surface area reduction,

patient ease of use (self-care), and overall product experience. **Results:** At 4 weeks, all wounds demonstrated positive measured endpoints of slough elimination and continued wound-size reduction. Patients and carers found the product easy to use (self-caring) with an overall positive wound care experience. **Conclusion:** The administration of a haemoglobin spray solution on patients presenting with sloughy wounds resulted in positive healing outcomes of slough elimination and wound reduction alongside positive self-care and product satisfaction. Continued evaluation is recommended to build upon the evidence of this form of treatment.

■ slough ■ haemoglobin ■ wound healing ■ cleansing ■ debridement

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Wound management and its adjuncts, such as dressings and devices, are a continually evolving specialty, with an ongoing development of innovative concepts and products coming onto the market to aid practitioners in the challenging world of wounds (Gray et al, 2005). Alongside treatment development is the evolving nature of our patients, their wound groups, and holistic needs, all of which increase demand upon reducing services, resources, and clinician accessibility (While, 2015).

Clinicians, allied health practitioners, and industry are faced with an increasing number of younger patients developing traditionally 'mid-to-late-life' conditions such as vascular disease, diabetes, ischaemic heart disease, heart failure, and musculoskeletal disorders, along with an acceleration in the occurrence of

obesity, smoking, and mental health conditions (Hex et al, 2012; British Heart Foundation, 2014; Lifestyles Statistics Team and Health & Social Care Information Centre, 2015). In addition, the increasing ageing population requires specialist supportive services, who in turn need access to all remits of health care to maintain a quality standard of living (Ostbye et al, 2015; While, 2015). All these health issues have been well-documented across wound care literature; it highlights the negative effects on skin integrity and the wound-healing processes, which require ongoing care packages, increased length of stay in acute settings and frequent visits to accident and emergency (A&E), GPs, walk-in centers (WIC), and minor injury units (MIU) (Monitor, 2014).

Within the community setting, the concept of 'self-care' is becoming highly prominent on both NHS and private-sector agendas, as a productive way forward in supporting patients with their own lifestyle choices and health-care needs, inclusive of managing wounds and skin conditions. The update on new and innovative ways of providing care and managing wounds in this setting is absolutely essential for clinicians. It is invaluable to explore new avenues of wound healing to ensure that the right care is provided for the right patient at the right time, making best use of limited resources and ensuring patients are involved from the onset in packages of care (While, 2015). Consistency, continuity, and patient ownership is paramount if resources and outcomes are to be satisfactorily achieved (NHS England, 2014). The development of technologies that are simple to use,

supporting self-care management of patients, and reducing the reliance upon health care and its staff is the way forward, according to Dowsett (2015).

This paper explores the use of an innovative technology called Granulox (Infirst Healthcare), a haemoglobin spray therapy, for patients and carers who attend a GP/ WIC with sloughy wounds and who are able to self-manage within their own home setting. The primary outcomes aimed to examine: slough reduction, wound surface area reduction, patient ease of use (self-care), and overall product experience. All patients were supported by a wound care clinician on a weekly basis.

Slough

Slough is a combination of dead white cells, dead bacteria, rehydrated necrotic tissue, and fibrous tissue. It often presents as a creamy, yellow-coloured tissue containing wound healing debris and devitalised cells and can be wet or dry (Young, 2015). Sloughy tissue is often soft in texture, fibrous in consistency, and can quickly adhere to the wound bed, which cannot be removed with simple irrigation alone (Tong, 1999; Vuolo, 2009).

Flanagan (1997) emphasises that slough is a natural part of the healing process if hydrated, and that the presence of sloughy material on the wound bed should not be considered a default indicator that the wound is not healthy or progressing. Slough is an indicator that the body is removing devitalised tissue, waste products, and cells through the process of autolysis within the wound environment and allowing granulation to occur (Flanagan, 1992). The build-up of waste products within the wound bed encourages sloughy debris to attach itself to the granular base providing an optimum environment for bacterial growth and potential infection that may lead to stasis of wound healing, increase in maceration to the peri-wound skin, and reduced patient quality of life (Cutting, 2004). When wounds become slow in healing or non-healing, an increase in neutrophils can result in the release of excessive matrix metalloproteinases (MMPs), which degrade the developing matrix and stall healing (Hart, 2002).

The wound infection continuum devised by Kingsley (2001) and further clarified by White et al (2002), allows the identification of slough through colour-specification criteria, helping the clinician in the assessment and diagnosis of the wound infective stasis. This tool emphasises the likely presence of sloughy material within those wounds that have a higher level of bacterial activity (*Table 1*).

According to Kingsley (2003), any wound that is classified as yellow or sloughy should be assessed to rule out presence of 'pus' and the possibility of localised or spreading infection. Clinicians must be mindful that yellow tissue may not be slough at all and may indicate the presence of fat, tendon or bone. Robust assessment and diagnosis is key to ensuring appropriate management and optimal patient safety is maintained. Only once correct diagnosis has been ascertained, should the wound be acknowledged as containing sloughy tissue that necessitates timely removal via appropriate methods (Tong, 1999). Slough can develop on any wound bed surface, but given the

right environment, slough will be autolysed naturally as the inflammatory stage evolves (Young, 2015). However, Gardiner (2012) suggests that chronic wounds trapped in the inflammatory phase of healing have an increased incidence of slough being formed, often relating to increased levels of exudate.

The extent of slough formation will be determined by the stage of healing, wound type, and acuity or chronicity of the wound; it can be affected by the way in which the wound is managed. According to Tong (1999), slow healing or non-healing wounds such as venous leg ulcers, categories III and IV pressure ulcers, and diabetic foot ulcers, often present with high levels of slough owing to being stuck in the late inflammatory stage of wound healing. Slough reduction is managed through various methods, such as surgical debridement, antimicrobial irrigation, and gels alongside primary and secondary dressings, and its absence alongside epithelial and granular tissue often signifies a healing wound (Young, 2015).

Oxygenation and wound healing

It is universally accepted that wounds cannot progress to full healing without adequate oxygenation (Chadwick et al, 2015). Norris (2014) and Flanagan (2000) emphasise the importance of oxygen and its delivery within the overall wound-healing process of inflammation, granulation, and maturation. Within damaged tissues, demand on oxygen supply and its capacity is increased dramatically (Sen, 2009). Because the human body has no mechanics for oxygen retention, it requires a steady supply to the cells together with essential elements such as glucose, collagen, proteins, and metabolites to promote and maintain optimal tissue regeneration (Timmons, 2006; Chadwick et al, 2015). When the cells experience a reduction of oxygen at local and external levels, damaged or newly developing tissue cells can become inert and damaged, leading to wounds becoming static, necrotic, and sloughy (Flanagan, 2000; Dow, 2001). Oxygenation is therefore imperative systemically within the wound healing process.

Systemic oxygenation is facilitated using masks, nasal devices, or via tracheostomy, usually in a hospital or home setting. Topical delivery of oxygen direct to the wound bed through solution mediums or hyperbaric is a practice that provides positive benefits within the wound healing process (Ladizinsky et al, 2010; Norris, 2014; Winfeld, 2014; Tickle, 2015). According to Arenbergerova et al (2013) and Babadagi-Hardt et al (2014), the application of topical oxygen therapy allows haemoglobin-mediated oxygen diffusion within the wound bed through an aqueous solution that positively aids the wound-healing process through an increased uptake of oxygen. It is well-evidenced within the wound care literature that non-healing wounds are likely to have some degree of hypoxia present and that hypoxic wound tissue often fails to regenerate to complete healing (Hauser, 1987).

What is Granulox therapy?

Granulox therapy is a mechanical topical spray containing an oxygen-haemoglobin treatment derived from sterile

porcine blood, which is indicated for those wounds that are deemed slow healing or non-healing. It acts by facilitating the diffusion of released oxygen from the atmosphere into the wound bed. A number of authors have emphasised the improvement of wound tissue oxygenation through the process of diffusion, with positive outcomes of supporting and benefiting wound healing through use of topical haemoglobin therapy (Green and Mohamud, 2014; Norris, 2014; Bateman, 2015; Tickle, 2015).

Bateman (2015) and Tickle (2015) state that the treatment requires very little education and training for its use; has had no negative side effects to date; and has been used by clinicians, allied health professionals, patients, and carers with no issues. The product is approved for multi-use as a non-wound contact spray, to be applied at least every 72 hours on all wounds deemed chronic (Arenbergerova et al, 2013). It is recognised by an expert working group that the optimum application rates and long-term benefits are not as yet evidenced (Chadwick et al, 2015).

According to manufactures guidelines, Granulox is not recommended for use with certain disinfectants, proteolysis, or mechanical debridement, as these may impair its effectiveness. They also suggest that wounds should be clean with no necrotic or non-viable tissue present before deployment of the product if optimum benefits are to be achieved. The product requires

a cold storage temperature (2–8°C) and, as with all wound management adjuncts, is not a replacement for referral to specialist wound care services particularly relating to the need for tissue viability advice, revascularisation, diabetes management, and plastics and general surgery (Chadwick et al, 2015).

Increasing evidence

Significant positive outcome studies have been undertaken by Arenberger et al (2011) and Arenbergerova et al (2013), who explored topical haemoglobin oxygenation of common chronic wounds and chronic leg ulcers, respectively. There have also been a published case study by Babadagi-Hardt et al (2014) on chronic wounds/compression and Budd-Chiari Syndrome, and recent clinical pilots using topical haemoglobin spray therapy on leg ulcers (Norris, 2014) and pressure ulcers (Tickle, 2015). The above authors promote the positive outcomes of increased healing potential, wound reduction, and no negative reactions. Recent evaluation work carried out by Bateman (2015) on diabetic foot ulcers (DFU) concurred with current evidence, with new outcomes of slough reduction in this patient group and the positive elements of patient education.

An expert working group (Chadwick et al, 2015) has been formed and the members have developed consensus recommendations for clinicians within the management of

Table 1. Slough characteristics highlighted across the wound-infection continuum

| | Spreading infection | Local infection | Critically colonised | Colonised |
|---|--|--|------------------------------------|---|
| Key local characteristics | >2 cm redness with pain (unless insensate) | <2 cm redness with pain | Static despite appropriate therapy | Expected progression toward healing |
| | | Sudden necrosis at wound bed | No cellulitis | No cellulitis |
| | | | | Minor inflammation maybe present within healing process |
| Other local characteristics | Heat and or swelling | Heat and or swelling | | |
| Additional local characteristics which may be present to addition of above | Extension to wound border | Extension to wound border | | |
| | Blistering | Extension to wound base | | |
| | New satellite wounds in erythemic area | Increased wetness | | |
| | Increased exudate | Purulent exudates | | |
| | Haemorrhagic spotting in surrounding skin | Maceration | | |
| | Purulent exudate | Extensive necrotic and or sloughy tissue | | |
| | Extensive necrotic and or sloughy tissue | Discolouration of granular tissue | | |
| | Malodour | Friable granulation | | |
| | Malodour | | | |
| Source: Adapted from wound infection continuum (White et al, 2004) | | | | |

chronic wounds with topical haemoglobin therapy, which highlights guidance regarding the benefits to patients and how it slots into our 'tool box' of adjuncts, notably, the use of topical haemoglobin in wounds that have failed to respond substantively within 2 to 4 weeks of standard care.

This paper aims to explore this product at the next level and assess potential benefits within 'healing' and 'non-healing' wounds that are deemed sloughy on presentation. This may suggest contraindication to the product use, as some levels of slough could be classed as 'infected' (Table 1). All 25 patients within the study had continuation of pre-evaluation cleansing and dressing product regimens and associated cares.

Methodology

A single community GP/WIC descriptive evaluation was undertaken. Ethical approval was not required for this evaluation, as it follows the Trust's policy with regard to clinical review of CE-marked products. Informed consent was documented in relevant notes. Inclusion criteria included:

- Patients who presented with a healing or non-healing wound with slough present
- Wounds that were not diagnosed as infected
- Patients and/or their carers who consented to Granulox therapy being used for 4 weeks
- Patients who were able to demonstrate self-use of the spray at home in between weekly reviews.

Exclusion criteria included:

- Patients diagnosed with an infected wound
- Patients who declined entry into the evaluation
- Patients who were unable to use the spray device.

Patients who met the inclusion criteria, and verbally consented to the therapy, had Granulox applied to the wound bed twice a week in conjunction with their normal cleansing and dressing regimen for a 4-week period. Those wounds that were present for <2 weeks were denoted as healing, and those >2 weeks were denoted as non-healing, in line with current consensus recommendations (Chadwick et al, 2015). Patients follow-up was a further 5 weeks irrespective of whether they continued with Granulox or other therapies.

During the evaluation period, all patients continued to have their dressing regimen changed twice a week, with the Granulox administered each time by the patient/carer at home or in the clinic. Pre-evaluation care included soft silicone foams (adhesive/non-adhesive) hydrofibre adhesive foams, and retention bandages.

The wound data was collated on designated evaluation forms using the recognised Applied Wound Management assessment documentation (Gray et al, 2005), which is the standard wound care documentation used within the Trust, with the clinician documenting the relevant weekly data sets. Data collected related to percentage of slough, wound size in cm (length, width, and depth), consistency of same standards/dressings of care, granulation, and epithelium present. The author observed the dressing changes weekly and cross checked the data for accuracy and to enable collection of the patient's experience.

At weeks 1 and 3, each patient and/or carer was asked verbally about their experience of the acceptability of use of the product (with 1=very difficult and 5=extremely easy), and their opinion about the product (with 1=poor and 4=excellent).

Results

A total of 25 patients who met the inclusion criteria were recruited with the products applied either by the patient 99.4% ($n=24$) or under parental assistance <1% ($n=1$). Table 2 denotes the wide spectrum of patients and their individual wound groups. The age range was 6–87 years, and the male to female ratio was 12:13. Wound groups included skin tears, abscess, leg ulcers, burns, trauma, post-surgery, and intravenous drug injection sites, typical of wounds that are slow or difficult to heal according to Flanagan (2000). At presentation, slough within the cohort's wound beds ranged from 10% covering to 100%. The length of time for wounds *in situ* before the application of Granulox was 1–56 weeks.

In the evaluation period, slough levels were reduced to 0% by week 1 for 20% ($n=5$) of the patients (2 Granulox applications per patient), with a reduction in slough of 68% ($n=17$) at week 2 (4 Granulox applications per patient), and a complete 100% slough-free cohort at week 3 (6 Granulox applications per patient) (Figure 1). These figures correlate with Bateman's (2015) work where, as an unexpected outcome, all 20 patients within the evaluation were deemed slough free by week 4.

Wound reduction to some degree was achieved in all the patients, with a total of 76% ($n=19$) reaching complete healing within the 4-week treatment and 5-week follow-up period, with a large peak (28%) of patients ($n=7$) at week 3 and 68% ($n=17$) at week 6, respectively (Figure 2).

Patient and clinician satisfaction

Of the 25 patients, 99% ($n=24$) were able to apply the Granulox therapy independently at both the clinic review appointment and within their own living environments, with 1% ($n=1$; aged 6 years) requiring assistance from the parent.

When asked the question 'How easy is the product to use?', 88% ($n=22$) found it extremely easy to use, with the remainder 12% ($n=3$) rating its use as very easy. Each patient received a short demonstration of use at the first dressing application and was supervised by the clinician thereafter at weekly appointments in case of support being required. This level of satisfaction replicates the previous experience outcomes of work on DFU with Granulox by Bateman (2015).

When asked the question 'What has been your overall experience with this product and your wound healing?', 80% ($n=20$) found the experience excellent and 20% ($n=5$) deemed it good. This result also concurs with previous patient overall experience within the work carried out by Bateman (2015). All 100% ($n=25$) of the patients/carers welcomed the product education and instruction leaflet and found it informative and helpful, particularly when independently using the product at home (Figure 3). All the patients and carers praised the product and wished to continue with it.

Table 2. Patient demographics and wound presentation at baseline (day 0)

| PT | Gender | Age | Wound status [†] | Wound group | Wound <i>in situ</i> | Wound length (cm) | Wound width (cm) | Wound depth (cm) | Slough (%) |
|----|--------|-----|---------------------------|-------------------|----------------------|-------------------|------------------|------------------|------------|
| 1 | Male | 34 | No heal | Abscess | 5 weeks | 4 | 4 | 3 | 100% |
| 2 | Male | 39 | No heal | Skin tear | 4 weeks | 3 | 3 | 1 | 80% |
| 3 | Male | 26 | No heal | IVD site* | 56 weeks | 6 | 4 | 1 | 10% |
| 4 | Female | 54 | No heal | Insect bite | 5 weeks | 2 | 2 | 0.3 | 40% |
| 5 | Female | 87 | No heal | Skin tear | 6 weeks | 4 | 3 | 0.5 | 60% |
| 6 | Female | 18 | No heal | IVD site* | 4 weeks | 3 | 3 | 1 | 50% |
| 7 | Female | 43 | No heal | Surgical | 8 weeks | 12 | 2 | 1 | 60% |
| 8 | Male | 48 | No heal | Surgical | 5 weeks | 2 | 2 | 1 | 30% |
| 9 | Female | 56 | No heal | VLU [†] | 12 weeks | 8 | 6 | 1 | 70% |
| 10 | Male | 20 | No heal | IVD site* | 7 weeks | 4 | 3 | 1 | 30% |
| 11 | Female | 48 | No heal | Surgical | 4 weeks | 1.5 | 1.5 | 0.5 | 30% |
| 12 | Male | 13 | No heal | Trauma | 3 weeks | 1 | 1 | 0.3 | 20% |
| 13 | Female | 87 | No heal | Burn | 3 weeks | 13 | 8 | 1 | 50% |
| 14 | Female | 87 | No heal | Burn | 3 weeks | 18 | 12 | 1.5 | 90% |
| 15 | Male | 62 | No heal | Trauma | 4 weeks | 2 | 2 | 1 | 50% |
| 16 | Male | 30 | No heal | Stab wound | 3 weeks | 3 | 2 | 2 | 70% |
| 17 | Male | 21 | No heal | Trauma | 4 weeks | 2 | 2 | 1 | 50% |
| 18 | Male | 48 | No heal | VLU [†] | 12 weeks | 5 | 4 | 1 | 80% |
| 19 | Female | 51 | No heal | VLU [†] | 12 weeks | 4 | 2 | 0.5 | 95% |
| 20 | Female | 39 | No heal | Burn | 16 weeks | 4 | 2 | 0.3 | 40% |
| 21 | Male | 78 | Healing | Skin tear | 1 week | 6 | 4 | 1.5 | 60% |
| 22 | Female | 20 | Healing | Abscess | 1 week | 7 | 7 | 1 | 50% |
| 23 | Female | 6 | Healing | DFU ^{**} | 1 week | 2 | 1 | 0.5 | 30% |
| 24 | Male | 57 | Healing | Trauma | 2 weeks | 4 | 3 | 1 | 20% |
| 25 | Female | 18 | No heal | Surgical | 3 weeks | 1 | 1 | 0.5 | 100% |

[†]Wound status at recruitment, based on Chadwick et al (2015) | *Intravenous drug injection; cavity formation from frequent sharp puncture | [†]Venous leg ulcer | **Diabetic foot ulcer

Figure 1. Existence of slough pre-, peri-, and post-Granulox therapy

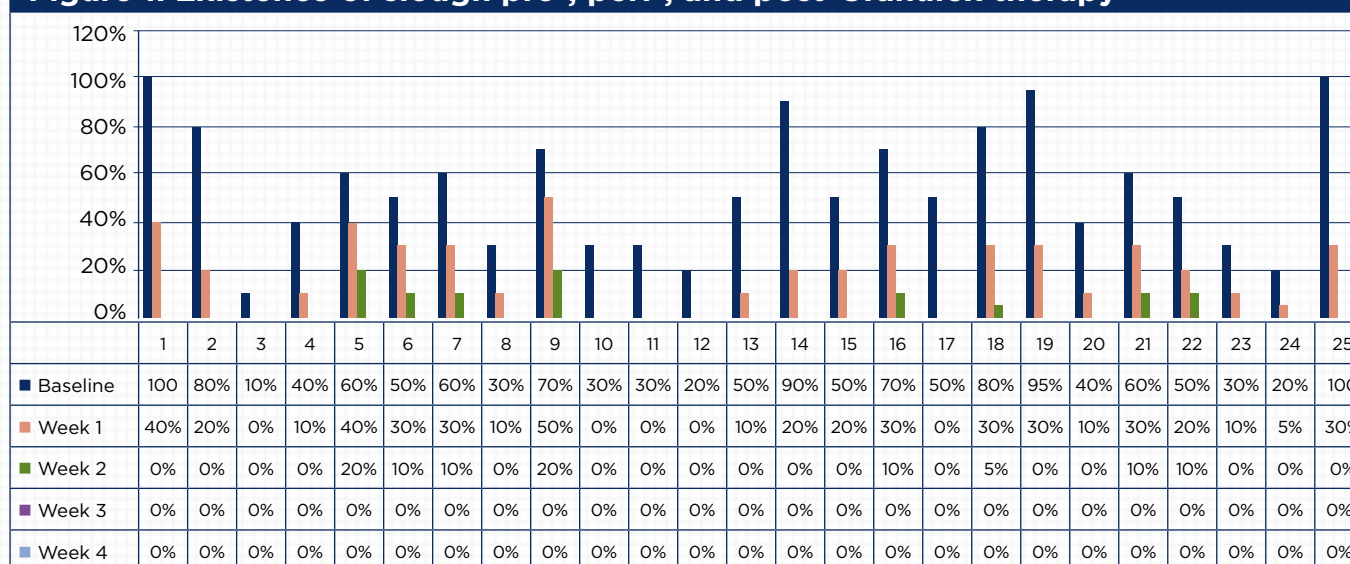
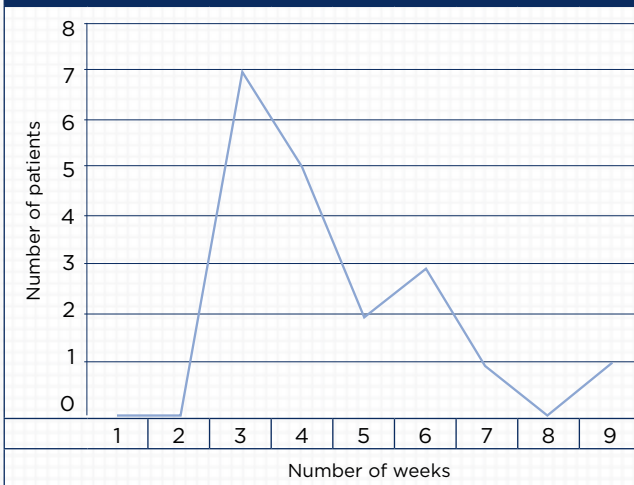


Figure 2. Wound reduction at close of follow-up period



throughout the 4-week evaluation period and beyond if their wound status required this.

Adverse events

Although the wounds within the 4-week evaluation had variant levels of slough on presentation, ranging from 10% to 100%, which was only cleansed with normal cleansing regimens and no debridement processes, there were no reports of adverse events. None of the patients reported any increase in irritation or skin reactions to the product.

Case study: patient no. 21

Patient no. 21 was male, aged 78 years, and an insulin-dependent stable diabetic. He attended a WIC with a large skin tear to his left hand after a fall onto a hard surface 7 days previously. He attended the A&E where a silicone-bordered adhesive dressing was applied. *Figures 3, 4, and 5* show the progression of the healing of his skin tear following 4 weeks of Granulox therapy.

Discussion

The 19 wounds that healed within the 4-week Granulox treatment time and 5-week follow-up period demonstrated no set themes; the patients' age, demographics, wound types, and secondary dressings all varied. However, as seen in *Figure 2*, there appeared to be a common peak of 3-week intervals for wound closure across the whole group, with the highest closure at three weeks reducing thereafter. This requires a much larger cohort remit to ascertain if Granulox has a highest peak of healing in sloughy wounds at 3-weeks of treatment. What is clear from the data is that none of the recruit's wounds relapsed and developed slough in the treatment period or follow-up, and no evidence in the patient's documentation highlighted any oral or intravenous antibiotic therapies being administered.

This small but unique evaluation explored the application of Granulox haemoglobin spray for those patients who presented with sloughy wounds to a community WIC setting. The wound healing results of this study support the work of Arenberger et al (2011) and Arenbergerova et al (2013) who found encouraging healing rates of 93% vs 7% at 6 months on standard care and 53% vs 21%, respectively, within leg ulcers. Work within the UK carried out by Norris (2014) on venous leg ulcers and Tickle (2015) on pressure ulcers, also demonstrated positively conforming results in wound-size reduction and exudate minimisation with the use of topical haemoglobin spray donation on chronic wounds.

Most recently, Bateman's (2015) work on non-healing diabetic foot ulceration suggesting that slough reduction was a significant factor as a non-set outcome in the evaluation, which warranted further investigation if product use is to be made accessible to a wider range of wound states. The results of the evaluation additionally support the concept of patient 'self-care'. The education card and minimal support the patients received was very positive in the data outcomes, with all patients happy

Figure 3. Day 0 on presentation following dressing removal; skin tears with 20% haematoma and 60% slough present



Figure 4. Week 1, day 4 following 1 application of Granulox and adhesive silicone foam dressing



Figure 5. Week 2, following 4 applications of Granulox and foam dressing. Full epithelialisation achieved.



to continue with their own self-care and being monitored weekly. This reduced nursing dressing time by 50% and empowered the patient within their care regimen.

Limitations of the evaluation

The cohort group represented a small sample of patients who presented to the community setting with healing and non-healing wounds that had varying degrees of slough present. Although clear benefits were seen, the products' effects over a longer period of time, increased applications has not been studied and thus the full benefits are not known. Although one could argue that the measurement of slough within the wounds by the clinician is subjective, being observational in its measurement, it was clearly noted that at week 3 all wounds were slough free. The author proposes that a larger cohort evaluation be carried out to support the outcomes achieved within this small group evaluation.

Conclusion and recommendations

Within the world of wound care, sloughy wounds continue to pose clinical and financial challenges to all clinicians and allied health workers, particularly in a resource-tight NHS, where budgets and staffing are being reduced and care is moving out further into the community setting (Dowsett, 2015). The promotion of patient self-awareness, self-care, and responsibility is high on the government's agenda, with all services having to change how they function and deliver care in order to meet today's holistic patient's needs (While, 2015).

The management of sloughy wounds requires timely assessment, management, evaluation, and review with referral to those specialists in wound care when standard conservative management is not aiding the wound-healing process. The use of innovative products, such as haemoglobin therapy, alongside robust patient and carer education and self-involvement in care are vital in ensuring that care is appropriate, consistent, beneficial, and cost-effective.

This evaluation, although a small cohort, has tested the use of Granulox in an area not explored to date, and has depicted positive and effective outcomes and positive experience for the patients involved with and directing their own self-care. Further comprehensive evidence-gathering is required within areas of slough management.

It is important that clinicians acknowledge and recognise innovative therapies such as Granulox and the role of oxygen in wound healing, that the manufacturer reviews its use and contraindications to ensure that more patients have access to and the choice in their wound care management, and to ensure that availability is open to all on FP10 and supply chain formularies. This evaluation data is a welcome addition to the increasing evidence within available literature on use of topical haemoglobin spray within the community setting. **CWC**

Declaration of interest: All products for the evaluation were provided by Infirst Healthcare, who did not have any control over or involvement in the data collection, analysis, or article write up.

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