# An evaluation of the efficacy and cost-effectivness of octenilin® for chronic wounds

Non-healing chronic wounds can have a significant negative impact on a patient's quality of life as well as placing additional demands on NHS resources. Balancing health economics with optimal clinical outcomes for patients is a daily challenge for wound care specialists. Studies and case reports have demonstrated that wound care products that contain octenidine are both clinically and cost-effective when managing chronic wounds. This article looks at the role of wound irrigation solutions and gels that contain octenidine and considers their cost effectiveness and efficacy in two case reports of patients with non-healing surgical wounds.

KEY WORDS
- Chronic wounds
- Hydrogels
- octenilin®
- Wound irrigation

At any one time about 200,000 patients in the UK have a chronic wound, with the most common types of chronic wounds being leg ulcers, pressure ulcers and diabetic foot ulcers (Posnett and Franks, 2007). The cost to the NHS of caring for patients with chronic wounds is estimated to be about £4bn (Sheffield Hallam University, 2014). This cost is predicted to increase over the course of the next 20 years due to an ageing population (Posnett and Franks, 2007). Wound dressings account for about £120m of prescribing costs in primary care in England each year with more than £25m being spent on silver dressings alone (National Prescribing Centre, 2010).

The management of chronic wounds places a significant burden on NHS resources and can have a significant detrimental effect on a patient's life (Briggs and Fleming, 2007). Studies show that there appears to be a high incidence of non-healing wounds in the UK (O'Brien et al, 2002; Moore and Cowan, 2005; Drew et al, 2007). In a study in the East Riding of Yorkshire, involving 1644 patients with a total of 2300 wounds, 24% had their wound for six months or more, and almost 16% of patients had remained unhealed for a year or longer (Drew et al, 2007). In an Irish study involving 389 patients with leg ulcers, 27% were reported to have continuous ulceration for more than two years (O'Brien et al, 2002). Non-healing chronic wounds affect all aspects of patients' lives — emotionally, mentally, physically and socially. They can also prevent full recovery, increase hospital stays and increase the need for ongoing treatments (Spilsbury et al, 2007).

It is critical that wound care is both clinically effective and also cost-effective. Vowden (2011: p5) reported that: 'effective and timely diagnosis with treatment appropriate to the cause and condition of the wound, alongside active measures to avoid the incidence of wound complications and hospitalisation, can have a major impact on both costs and patient quality of life.'

This article examines the evidence for the clinical efficacy and cost-effectiveness of octenidine-based octenilin® wound gel and octenilin® wound irrigation solution (Schülke & Mayr) in the management of chronic wounds. Two case reports are included looking at atypical patients from an acute hospital setting in the UK. Both patients underwent extensive colorectal surgery and the duration of the acute surgical wounds healing by secondary intention in both cases was protracted with incomplete healing at 12 weeks.

## TOPICAL WOUND MANAGEMENT

Infections in a wound can delay healing and also lead to concomitant comorbidities (Dow et al, 1999). Regular wound cleansing combined with debridement is recognised as a critical first step in preventing wounds from becoming infected (Schultz et al, 2004). Effective cleansing is a basic principle in modern wound management as part of the process of wound

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bed preparation (Schultz et al, 2004). Cleansing and debridement of the wound surface help to remove bacteria and debris such as exudate and devitalised tissue, loose debris (including microorganisms) and any dressing material residues. This helps promote an optimal environment for healing, as well as facilitating wound assessment by optimising visualisation of the wound bed (Schultz et al, 2004).

## WOUND IRRIGATION SOLUTIONS

Wounds may be cleansed using a variety of methods and solutions. Although tap water has not been found to increase the risk of infection (Fernandez et al, 2010), consideration should be given to the use of sterile solutions and to specially-formulated wound irrigation solutions, which have the potential to improve outcomes through their additional actions. Most wound irrigation solutions, such as octenilin® and Prontosan® (Braun), contain surfactants that reduce the surface tension of the medium in which they are dissolved. This increases the ability of the solution to spread over the wound surface and penetrate wound coatings, thereby lifting bacteria and debris and suspending them in the solution. Such solutions may also help to disrupt and remove bacterial biofilms in the wound (Harbs and Siebert, 2007; Vasel-Biergans and Probst, 2011; Cutting and Westgate, 2012; Lessing and McNulty, 2012; Kramer et al, 2013).

Biofilm communities (clusters of cells encased in a protective matrix of polysaccharide polymers) develop on the surface of wounds and may contribute to chronicity. The protective matrix acts as a thick barrier, making it difficult for antimicrobial agents to penetrate the biofilm. Treatments should aim to disrupt the biofilm through regular and repeated debridement and vigorous wound cleansing (Phillips et al, 2010).

## OCTENILIN® WOUND IRRIGATION SOLUTION

octenilin® wound irrigation solution is a colourless, alcohol-free solution for cleansing and moisturising chronic wounds and burns. The solution can also be used to loosen encrusted dressings at dressing changes. It is a water-based solution containing the preservative octenidine dihydrochloride. octenilin® wound irrigation solution also contains ethylhexylglycerin, a surfactant-like molecule that reduces the surface tension of the solution, enhancing its wetting properties.

The surface tension of octenilin® wound irrigation solution is 30.6 mN/m, which is less than half that of Ringer's solution (71.7 mN/m) (Cutting and Westgate, 2012). Due to its low surface tension, it can penetrate even small fissures and wound pockets which saline and Ringer's solution cannot reach.

## CLINICAL EFFICACY OF OCTENILIN® WOUND IRRIGATION SOLUTION

There is evidence to suggest that octenilin® wound irrigation solution helps remove established biofilms; under laboratory testing conditions. An exposure time of five minutes was sufficient for almost complete removal of *Staphylococcus aureus* biofilms (Cutting and Westgate, 2012). A further investigation against *Pseudomonas aeruginosa* biofilms grown for seven days demonstrated biofilm removal of about 33.3% after a contact time of 60 minutes (Harbs and Siebert, 2007). Due to the higher tenacity of *Pseudomonas* and its biofilms, these results were to be expected and demonstrate the need for repeated treatments to manage a bacterial biofilm successfully (Phillips et al, 2010).

## THE ROLE OF HYDROGELS

Hydrogels have a high water content (usually between 30–95%) and help infuse the wound surface with moisture. This provides a moist wound environment that supports autolysis by loosening necrotic and sloughy tissue. Hydrogels are hypotonic and help diffuse patient-derived proteolytic enzymes and growth factors into the wound. An additional benefit of hydrogels lies in their moistening properties which reduce the likelihood of dressings adhering to the wound surface and helps minimise the risk of trauma when the dressing is changed (Dowsett and Newton, 2004). Hydrogels also have a cooling effect which is advantageous when managing burns (Burd, 2007).

## OCTENILIN® WOUND GEL

octenilin® wound gel is a hydroxyethyl cellulose-based hydrogel containing octenidine dihydrochloride as a preservative. This ingredient has demonstrated the ability to inhibit and kill bacteria absorbed by the gel matrix from the wound (Steinhauer, 2007). octenilin® wound gel

is a colourless gel that can be used alone or in combination with octenilin® irrigation solution to loosen difficult-to-remove wound coatings, moisten dry wounds and prevent further bacterial contamination of the wound.

In a placebo-controlled, double-blind, randomised controlled study, octenilin® wound gel's safety and efficacy to prevent wound contamination was demonstrated in 61 patients with superficial wounds requiring skin transplantation (Eisenbeiss et al, 2012). The site of split-skin excision was treated with either octenilin® wound gel or a placebo gel for three days. At the end of the treatment period the percentage of patients with a bacterial count >300 cfu on the wound surface was higher in the placebo group than in the octenilin® wound gel group. In addition, there was no delay in wound epithelialisation seen in the octenilin® wound gel treated wounds, demonstrating the good tissue tolerance of the product.

In a prospective open-label study conducted to compare the efficacy of octenilin® wound gel in the treatment of chronic venous leg ulcers, 49 wounds were treated with either modern phase-adapted dressings alone (including alginate or foam/silver for infected wounds), octenilin® wound gel plus modern phase-adapted dressings or octenilin® wound gel alone. The wound healing characteristics were analysed during the study period of 42 days, with dressing changes every 3–5 days. Wound size reduction was significantly better in both octenilin® wound gel treatment groups compared with modern dressings alone with total reductions of 14.6% (phase-adapted dressings alone), 64.1% (phase-adapted dressings with octenilin® wound gel) and 96.2% (octenilin® wound gel alone) (Hämmerle and Strohal, 2014). Patients receiving the hydrogel either alone or in combination had pain-free dressing changes and noted a cooling effect. The patients' perception of octenidine treatment with or without phase-adapted dressings was significantly better compared with modern wound dressings alone.

## COST-EFFECTIVENESS OF OCTENILIN® WOUND GEL

The study conducted by Hämmerle and Strohal (2014) also examined the cost-effectiveness of using octenilin® wound gel to treat chronic venous leg ulcers. The three treatment groups described above were analysed in terms of the treatment costs of the different dressings. The findings demonstrated that the overall costs per patient were about 27% lower in the octenilin® wound gel group (Hämmerle and Strohal, 2014). Overall, the highest costs per patient were observed in patients in treatment group one (phase-adapted dressings alone) with locally infected wounds, due to the use of silver dressings. Both total treatment costs and average costs per patient were most expensive in treatment group one, whereas those in treatment group three (octenilin® alone) were the most cost-effective. The authors concluded that this substantial difference was due to the large number of early healings in treatment group three and the additional use of costly phase-adapted active dressings in treatment group one.

octenilin® wound gel was also used with phase-adapted dressings in treatment group two, but the slightly lower total treatment costs and total treatment costs per patient compared with group one resulted exclusively from the early healing of some wounds in treatment group two.

If a wound does not heal in an orderly or timely sequence, or if the healing process does not result in structural integrity after around six months, it is considered to be chronic (Gardner et al, 2001; Woo and Sibbald, 2009). Both of the following case reports describe surgical wounds which failed to heal in a timely manner. In both instances, heavy bacterial colonisation was implicated in the delay in healing and clinical presentation.

## CASE REPORT 1

A 60 year-old woman was diagnosed with extensive anal and vulval squamous cell carcinoma requiring total exenteration of the pelvis. Extensive radiotherapy treatment had significantly damaged the tissue in the surrounding area complicating the immediate reconstructive options. Porcine dermal collagen (Permacol®, Covidien) was used to reconstruct the defect as it provides strength and flexibility. Full tissue coverage was not possible and the defect was left to close by secondary intention. The three-dimensional collagen architecture of Permacol is similar to the human dermis and supports fibroblast infiltration and neovascularisation and may be of particular benefit in contaminated surgical cases (Catena et al, 2007).

Initially the wound was irrigated with povidone-iodine (Betadine®) solution and Betadine-soaked gauze was used to fill the cavity. The use of

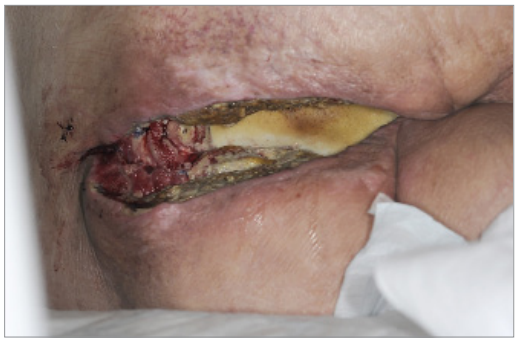

Figure 1. Week 3 post-op before commencement of treatment with octenilin®.

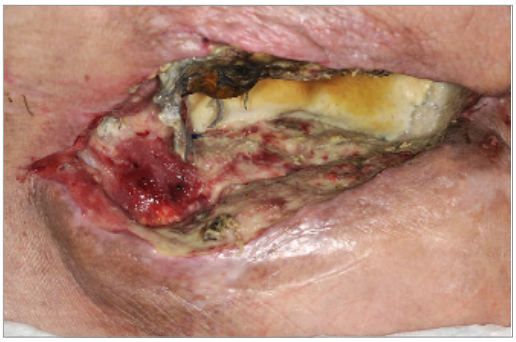

Figure 2. Week 5 post-op after 2 weeks of treatment with octenilin®.

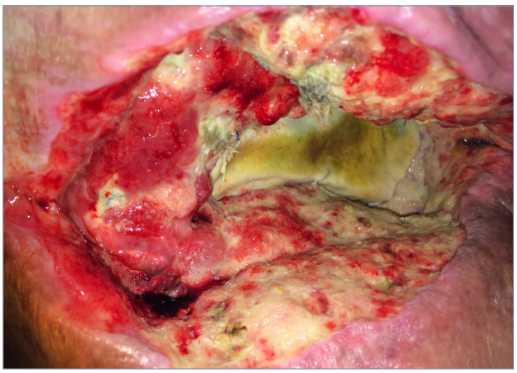

Figure 3. Week 6 post-op after treatment with larvae.

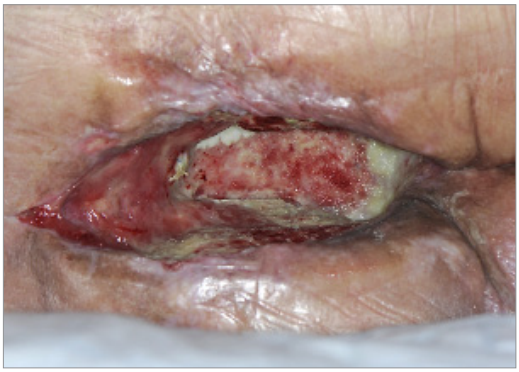

Figure 4. Week 8 post-op after two more weeks of treatment with octenilin®.

Betadine as an antimicrobial in the acute phase of wound healing is a common surgical practice (Pattana-arun and Wolff, 2008), when the reduction of microbial bioburden takes precedence over wound healing. Dressing changes were undertaken daily. During this time the patient had repeated wound infections and was systemically unwell.

Permacol was drying because of the heavy use of the povidone-iodine. Fat necrosis was present on the walls of the wound with slough covering up to 50% of the remaining tissue. All visible granulation tissue was inflamed and friable. There was a dried haematoma at the proximal right hand side of the wound. The wound was painful, malodorous and the exudate levels were high. The wound was 15 cm x 3 cm with a depth of 10 cm (*Figure 1*). The effect of the malodour was distressing for both the nurses and the patient, who became withdrawn and refused to engage in her physiotherapy or leave her room.

octenilin® irrigation solution was used instead of Betadine to wash out the wound cavity and then octenilin® wound irrigation solution soaked gauze was used as the cavity filler for use with negative pressure wound therapy (NPWT).

After 2 weeks of octenilin® therapy, pain levels had improved, the wound odour had reduced significantly; more granulation tissue was visible and looked less inflamed (*Figure 2*). The exudate levels had reduced significantly and were less purulent. There were no clinical signs of infection at this point but slough levels remained relatively high.

The patient received two cycles of larval debridement therapy. This was unsuccessful and during both cycles the larvae suffocated within 24 hours due to the anatomical region and the weight of the patient. Larval debridement removed the largest areas of sloughy tissue though about 30% of the wound remained obscured by superficial slough (*Figure 3*).

Wound management reverted to the same plan as before larval debridement (octenilin® wound irrigation solution to irrigate then octenilin®-soaked gauze and NPWT).

By week 8 the wound was covered by only 10% superficial slough and the remainder of the wound was now healthy granulation tissue (*Figure 4*). Exudate levels were low and there were no clinical

signs of infection. The wound at this point had reduced in depth and the patient was increasingly mobile. When the carrier for the NPWT was changed to foam for a short period of time to replace the octenilin®, the wound bed developed a haematoma in dead space where the foam was unable to conform. Although the NPWT was most likely to be the deciding factor in the rapid wound healing to this point, the debridement and control of the bioburden was as important for the wound progression.

## CASE REPORT 2

A 70-year-old man with a medical history of Crohn's disease and hemicolectomy four years previously who also had insulin-dependent diabetes secondary to pancreatitis, underwent a repair of an incisional hernia. Following surgical complications he had multiple laparotomies, fulminant organ failure and a protracted ITU admission. He had abdominal wall reconstruction with porcine dermal collagen with the wound left open to allow healing by secondary intention. He had multiple wound infections and Carbapenem-resistant *Enterobacteriaceae* (CRE) was isolated as one of the organisms, limiting the availability of effective systemic antibiotics (Gupta et al, 2011). The wound remained unhealed after 12 weeks.

The wound was managed for the first 12 weeks with daily changes of Betadine-soaked gauze. The patient developed moisture-associated skin damage due to leakage of Betadine from the wound dressing. The porcine collagen matrix became dehydrated and hard.

During the period when the patient's wound was dressed with Betadine-soaked gauze, the patient reported pain at dressing changes and required analgesia to tolerate the procedure. The wound produced moderate to high levels of exudate. The patient's blood tests demonstrated repeated peaks in C-reactive protein and white cell counts with ongoing signs of wound infection.

At week 12 the wound was not healing (*Figure 5*) and the wound management plan was amended. After ensuring that there was no open access to the abdominal cavity, the wound cavity and surface were irrigated with octenilin® wound irrigation solution and octenilin® wound gel was applied to necrotic and sloughy areas to the left lateral aspect of the wound. The wound was dressed with octenilin® wound irrigation solution-soaked gauze beneath a film dressing. Dressing changes were reduced from every day to every 72 hours.

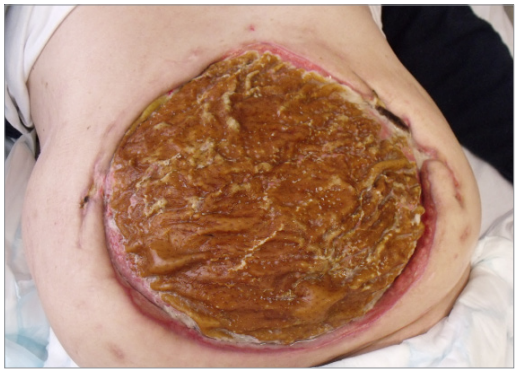

**Figure 5. Week 12 post-op before commencement of treatment with octenilin®.**

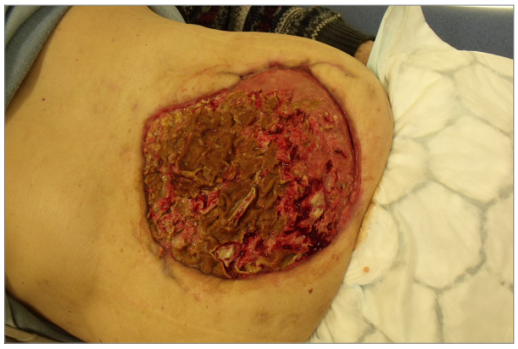

**Figure 6. Week 20 post-op after 8 weeks of treatment with octenilin®.**

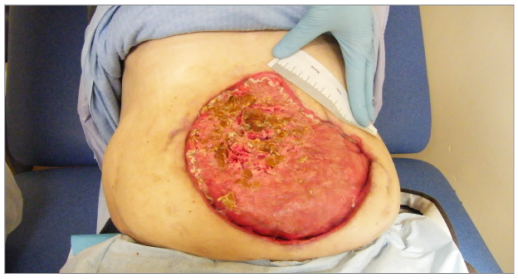

**Figure 7. Week 22 post-op after 10 weeks of treatment with octenilin®.**

Following 8 weeks of treatment with octenilin® the necrotic and sloughy tissue to the left lateral aspect of the wound had fully debrided and epithelialised (*Figure 6*). The porcine collagen was softer and granulation tissue was starting to infiltrate viable matrix while the unviable matrix was being autolytically debrided. The exudate levels at week 20 were sufficiently low that a low profile

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foam dressing could be used to manage the exudate levels and octenilin® wound irrigation solution was used to irrigate at dressing changes only. By week 22, the majority of the porcine collagen had lifted to reveal healthy granulation tissue and the wound margins had started to contract. There was no evidence of infection (*Figure 7*).

The clinical efficacy of the octenidine-based products in the reported cases and their use in the management of chronic wounds over the previous 12 months has led to octenilin® wound irrigation solution and octenilin® wound gel being added to the trust formulary as a primary means of reducing wound bioburden.

## CONCLUSION

Selecting the most appropriate wound care agents for chronic wounds requires careful clinical assessment of the patient's wound, their clinical condition, any co-morbidities and their personal preferences. In addition safety, efficacy and cost-effectiveness are important factors to consider when choosing dressings.

Studies have demonstrated the key role of octenidine wound care products in the effective management of chronic wounds (Cutting, 2012; Eisenbeiss, 2012; Lessing 2012; Hammerle, 2014). A recent paper concludes that: 'octenidine-based wound dressings are very cost-effective in the treatment of… wounds requiring frequent dressing. Compared to modern wound dressings, faster healing is achieved by a greater reduction of bioburden and a more rapid formation of granulation tissue… leading to an improved patient outcome and a reduction of healthcare costs and thus economic burden to society.' (Hammerle, 2014: p6)

Posnett and Franks (2008) suggested that with proper diagnosis and treatment much of the burden of chronic wound care should be avoidable and the delivery of optimal wound care could be achieved. The appropriate use of octenidine-based octenilin® wound gel and octenilin® wound irrigation solution may help clinicians to reach this goal. WUK

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