

Evaluation of a chitosan dressing in the management of hard-to-heal wounds

The management of chronic or hard-to-heal wounds such as pressure ulcers, lower limb diabetic or venous ulcers, or wounds stalled in their healing trajectory such as open trauma or some surgical wounds, is an ever-increasing challenge. Although there is the financial burden to the NHS, hard-to-heal wounds taking a protracted period to heal often result in long-term morbidity for patients, negatively impacting on their quality of life (Guest et al, 2015; Guest, 2021; Sen, 2021). The cost of wound care to the NHS across the UK, originally suggested as comparable to the management of obesity in 2012/13 (£8.3 billion) (Guest et al, 2020), has now overtaken obesity costs and is approaching the combined cost of managing osteoarthritis and rheumatoid arthritis (£10.2 billion in 2017) (Guest, 2021). Dressings remain the mainstay and most accessible option for the management of hard-to-heal wounds. It is therefore important that clinicians have access to dressings that can be effective in wound progression while ensuring that patient comfort and quality of life remain acceptable.

This article reports on the findings of a case series involving patients with moderate-to-heavily exuding chronic wounds of various aetiologies, whose wounds were managed with a chitosan-based gelling fibre dressing for a 4-week period.

Hard-to-heal wounds

The number of people with hard-to-heal wounds is increasing year on year, parallel to the ageing population and coupled with the rise in incidence of long-term high-risk conditions, currently including COVID-19 (Dowsett et al, 2014; Sallustro et al, 2022). However, with the increase in diabetes and its sequelae and cardiovascular problems in the young, hard-to-heal wounds can no longer be viewed as the preserve of the elderly. It has been estimated that 80 000 people in the UK have one or more hard-to-heal wounds at any one time (Gray et al, 2018), with Järbrink et al (2016) suggesting that 1–2% of the population in developed countries experience a hard-to-heal wound during their lifetime. Wounds can impact on working lives, careers and relationships, with associated low self-esteem and a negative impact on quality of life (Murray, 2019), isolation and depression (Upton and Upton, 2015; Atkin, 2018). It is a vicious circle since underlying conditions (including stress, ubiquitous in today's society) (Guo et al, 2010), can predispose patients to non-healing wounds, often leading to disability with psychosocial stressors directly impacting healing outcomes. We also know from the literature that

ABSTRACT

It is vital that as tissue viability teams, we are constantly striving to improve service delivery, healing rates and positive patient outcomes. In 2021 the author's team were introduced to a unique bioactive microfibre gelling (BMG) dressing, MaxioCel®, which uses chitosan to maintain a cohesive structure to increase fluid handling, antimicrobial and wound-healing properties. Method: Following Isle of Wight NHS Foundation Trust guidelines and with patient consent, 11 patients with chronic wounds of various aetiologies and wound durations were enrolled in a multicentre, clinical 4-week evaluation. Results: Over a 4-week evaluation period, all patients showed a significant improvement in wound healing parameters including average tissue type, condition of periwound skin, patient comfort, exudate levels. The assessments demonstrated a significant decrease in necrotic and sloughy tissue (from >75% at the start of treatment), replaced with healthy granulation and epithelial tissue (>80% by week 4). Significant reduction in pain score was also reported in all patients, with average pain score at the start of the evaluation reducing from 5.8 ± 2.7 to a score of 2.5 ± 1.9 within 3 weeks. Conclusion: The complicated wounds seen in this study were previously non-healing and MaxioCel, with BMG technology, demonstrated both significant clinical improvement and a positive impact on patient quality of life within just 4 weeks, resulting in its addition to the team's woundcare formulary.

Key words: Hard-to-heal wounds ■ Biofilm ■ Dressing selection ■ Exudate ■ Product evaluation ■ Wound healing ■ Patient comfort

pain experienced from having a hard-to-heal wound is linked to stress (Woo, 2012), with poor wound outcomes increasing disability and stress.

It is important that as clinicians we address the fundamental issues arising for patients from living with a hard-to-heal wound, such as pain, odour and exudate volume, which can cause untold misery. Longevity is worthless without quality of life, we need to constantly strive to improve quality of life, thereby adding life to years.

Wound healing and exudate

In hard-to-heal wounds the healing process is delayed as the 'normal wound healing cascade' (which in acute wounds is progressive and uneventful), becomes stalled in a persistent and exaggerated inflammatory phase (Barrett, 2016). There

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Box 1. Indicators of potential wound biofilm

- Failure of appropriate antibiotic treatment
- Resistance to appropriate antibiotic treatment
- Recurrence of delayed healing when antibiotic therapy has been completed
- Delayed healing despite optimal wound management
- Increase in exudate
- Low level chronic inflammation and erythema
- Poor granulation or hypergranulation
- Secondary signs of infection (eg, malodour, bridging of the wound, increase in size)

Source: International Wound Infection Institute, 2022

Box 2. Barriers to wound healing

- Diabetes
- Pain
- Obesity
- Corticosteroids
- Age (>60 years)
- Immunosuppressants
- Smoking
- Malignancy
- Impaired mobility
- Poor concordance
- Peripheral vascular disease
- Stress
- Malnutrition
- Depression

is an increase in inflammatory cells, a greater secretion of pro-inflammatory cytokines and proteolytic enzymes as well as an elevation of reactive oxygen species. This means that wounds are unable to regenerate new tissue and thus progress towards healing (Bjarnsholt et al, 2017) due to sustained matrix degradation and fibroblast senescence inhibiting tissue repair. There is a concomitant increase in wound exudate, which in hard-to-heal wounds is potentially corrosive due to its high levels of inflammatory mediators and activated matrix metalloproteinases with diminished levels of their inhibitors (McCarty and Percival, 2013). There is a subsequent negative impact on the wound and surrounding skin with degradation of growth factors and the breakdown of essential proteins necessary for healing (World Union of Wound Healing Societies, 2019).

Uncontrolled exudate can cause patients undue distress and pain as well as damaging the periwound skin. Patients can become anxious about dressings leaking and exudate can lead to malodour as well as potentially staining clothes, bedding, and furniture (Tickle, 2016). Dressings remain the mainstay of exudate management, together with the management of the aetiology, which means that both clinician and patient must have confidence in the capability of the dressing (Jones and Hampton, 2021). This is also important in terms of nursing time, which is the costliest aspect of wound care.

Biofilms

Biofilms are communities of multispecies bacteria that have encased themselves in an extracellular polymeric substance, which acts as a protective barrier and allows attachment to the wound bed (International Wound Infection Institute (IWII), 2022). They have been found to be ubiquitous in

hard-to-heal wounds, with Malone et al (2017), suggesting that almost 80% of hard-to-heal (chronic) wounds contain biofilm, which are a causative factor in infections in such wounds, contributing to delayed healing. Although biofilms cannot be seen in wounds, the consensus view is that they can be entrenched in slough and necrotic tissue (Bjarnsholt et al, 2017), contributing to the hyper-inflammatory environment.

In wounds that are failing to heal despite optimal care, clinicians should suspect that a biofilm is present, particularly if the wound exhibits signs and symptoms of chronic inflammation, and therefore clinicians need to appropriately disrupt or remove the biofilms to reduce bioburden in the wound and facilitate healing, plus treating or preventing infection (Metcalf and Bowler, 2013). The IWII (2022) has developed a list of criteria that should alert clinicians to the presence of biofilm in a wound that fails to heal despite optimal care (Box 1).

Dressing selection

Dressing selection needs to be integrated into any management plan such as offloading for diabetic foot ulceration or compression therapy for venous leg ulcers. A comprehensive, structured assessment is vital to determine the underlying aetiology of the wound and any comorbidities or patient-related barriers that might delay healing such as poor nutrition or smoking (Gray et al, 2018) (Box 2). A dressing needs to create the right microenvironment to enable healing to take place, with health professionals determining the ‘needs’ of the wound and patient. Often it is necessary to review dressing selection as the wound environment can change either positively or negatively and therefore a different dressing may be required.

The wound bed status, size, anatomical position, presence of biofilm and/or infection and treatment aim are all factors that need to be incorporated into any decisions made regarding dressing selection. To reduce wound bioburden any necrotic or sloughy tissue must be debrided. Dressings that provide a moist environment enable autolysis by enhancing the action of proteolytic enzymes to liquefy tissue, which can then separate from the wound bed (Brown, 2019). A dressing needs to remove excess exudate but also maintain humidity. It should provide thermal insulation, be comfortable and conform to the wound surface, thus avoiding dead space or gaps, which can become a focus for infection (Keast et al, 2020). Its use should not cause trauma for the patient or wound on application or removal (Rippon et al, 2012).

Chitosan and MaxioCel

Chitosan is a natural biopolymer derived from chitin, the second-largest naturally occurring polysaccharide (after cellulose), found mainly in the shells of crustaceans including crab, shrimp and lobster (Lopes et al, 2018) which are by-products of the seafood-processing industry. The seafood-processing industry creates a large quantity of waste every year: about 75% of the total body mass of

crustaceans ends up in landfill (head, tail, backbone, and shell) (Li et al, 2017). Converting marine industry by-products to value-added materials such as chitosan helps in sustainability. Chitosan is non-immunogenic, biodegradable and biocompatible without any toxicity (Baldrick, 2010); it also has haemostatic and bacteriostatic properties (Mo et al, 2015) and has long been used in the food industry for food preservation due to its antimicrobial properties (Leceta et al, 2013).

Chitosan has been shown to be effective against Gram-negative bacteria such as *Escherichia coli* and *Pseudomonas aeruginosa*, as well as Gram-positive bacteria such as *Staphylococcus aureus*. Its mechanism of action is thought to encompass positively-charged chitosan molecules binding to negatively-charged cell walls of microorganisms, resulting in their destruction through the leakage of proteinaceous and other intracellular constituents. Chitosan also promotes neutrophil and macrophage infiltration and migration thereby cleansing the wound (Simard et al, 2009) and accelerating healing potential (Singh et al, 2017). When chitosan was applied as a topical agent to open wounds, such as burns, skin abrasions, skin ulcers and skin-graft areas (Okamoto, 2002), a significant reduction in pain was also noted. Chitosan has also been found to exhibit analgesic properties due to the absorption of bradykinin and proton ions that are released within an inflammatory site (Mo et al, 2015).

MaxioCel® is a chitosan wound dressing with bioactive microfibre gelling (BMG) technology. The unique gelling mechanism of BMG fibres help it maintain a cohesive structure with increased fluid absorption capacity. The BMG dressings (with vertical wicking) are intended for the management of moderate to heavily exuding wounds with fluid-locking ability that prevents saturation, and consequently periwound skin maceration. The dressing conforms to the wound bed and is easy to apply and remove atraumatically. The objective of this case series was to evaluate the MaxioCel dressing in the management of exuding hard-to-heal wounds.

Due to the absorption of bradykinin and proton ions that are released within an inflammatory site MaxioCel (with chitosan) has also been found to have analgesic properties (Mo et al, 2015). However, the reduction in exudate due to its absorption capability also improves periwound skin, which helps reduce the pain experience for patients. It also helps reduce bioburden within the wound as pathogens are trapped and immobilised within the gelling structure.

Method

The study was designed as an open, non-comparative, multicentre case study series. Inpatients and outpatients were included. To evaluate the clinical efficacy of a BMG technology dressing (MaxioCel) in the management of hard-to-heal wounds, requiring wound-bed preparation, subjective assessment of the percentage of devitalised tissue present and its subsequent removal, and development of granulation/epithelial tissue was undertaken at each assessment time point. Secondary objectives included the evaluation of dressing-related pain, measured using a

Table 1. Patient inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Male or female, aged >18 years	Known allergy/hypersensitivity to any components of the dressing
Subjects requiring further treatment and management of chronic wounds including, but not limited to, pressure ulcers, diabetic foot ulcers, cavity wounds, venous leg ulcers, surgical site infections, donor sites, burns, post-traumatic wounds, with zero-moderate exudate, which require support for re-epithelialisation and enabling the healing process	Subjects with severe underlying disease(s) judged by the investigator likely to interfere with the study treatment
Signed consent form	Subjects who might have had problems following the protocol

Table 2. Wound assessment parameters and measurement descriptions

Assessment parameter	Measurement description
Wound size	Length and width
Appearance of wound bed	Percentage re-epithelialisation, granulation, necrosis, slough
Condition of periwound skin	Healthy/eczematous/excoriated/dry/inflamed/macerated
Evidence of wound infection	Yes/no
Level of wound exudate	High, moderate, low
Level of pain	Visual-analogue scale (VAS)

validated visual-analogue scale at both dressing changes and between dressing changes, changes in wound size and healing phase, exudate management, assessed according to the condition of periwound skin and clinician/patient opinions of the dressing. The parameters were evaluated in terms of changes from baseline assessments.

Patients

Inclusion and exclusion criteria are outlined in *Table 1*. Patients were drawn from nationally agreed centres including but not limited to clinics and outpatient departments and selected by the clinical investigator(s).

All participants were provided with patient information and were asked to sign an informed consent form before inclusion into the clinical evaluation. Patient participation was voluntary, patients had the right to refuse to enter the study. Those who took part completed consent forms

Table 3. Wound types of patients included

Wound type	Number of patients
Surgical	3
Pressure ulcer	3
Venous leg ulcer	1
Mixed aetiology leg ulcer	1
Diabetic foot ulcer	1
Traumatic wound	2

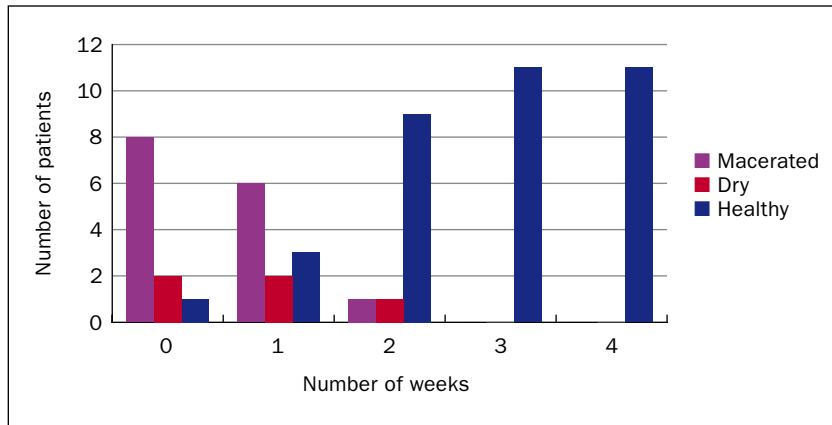


Figure 1. Periwound skin condition

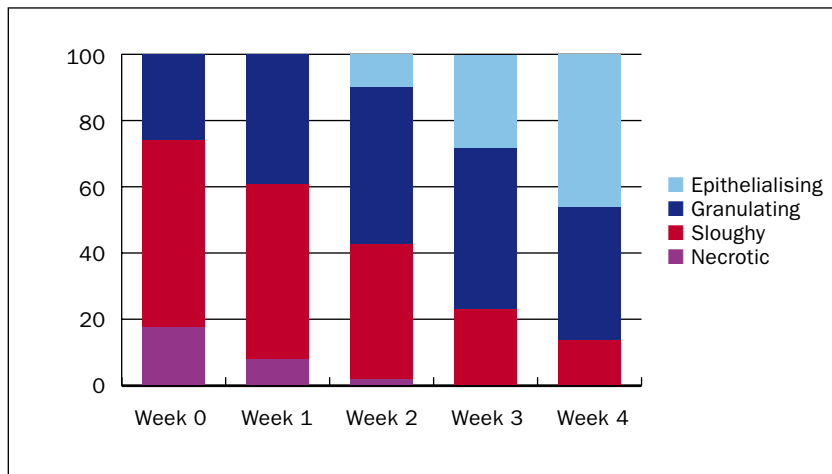


Figure 2. Tissue type in the wound over the 4-week period (average percentages)

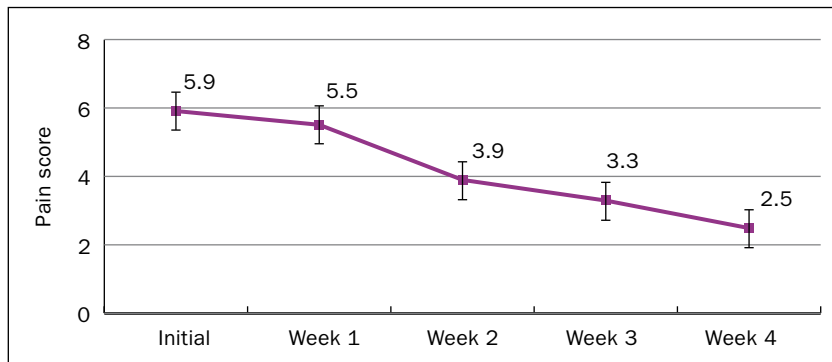


Figure 3. Average pain score over time

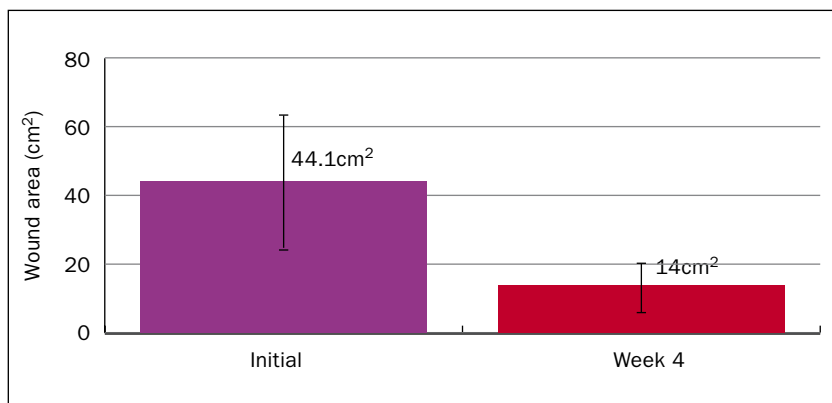


Figure 4. Average wound area reduction over the 4-week period

to allow further use of data in educational or commercial settings.

Test procedure and dressing evaluation

Each patient was treated according to the local clinical protocol and evaluated during a treatment period of 4 weeks. One patient only required treatment for 3 weeks and one patient received a final assessment at 6 weeks owing to the Christmas/New Year holidays occurring at the 4-week point.

All dressings were applied according to the manufacturer's instructions. Patients were assessed at baseline and again at subsequent dressing changes according to their clinical requirements. The assessment parameter are shown in Table 2. Previous wound treatment, medical history and surgical history and concomitant medications, including antibiotics, were also recorded.

At each dressing change a wound assessment was undertaken and recorded on evaluation forms developed for the study. Photographs were taken on dressing removal to monitor and record wound status and progression. At baseline and each assessment point, the investigators' opinions of the dressing were noted on the evaluation form.

At the end of each patient evaluation, a summary assessment form was completed identifying whether the clinical objectives had been reached and providing an overall evaluation of dressing performance from both patient and clinician perspectives.

Results

Eleven patients with chronic wounds of various aetiologies (Table 3), were included in the case series, five males (45%) and six females (55%) with an age range of 19–84 years (mean age of 67.5 years). A total of eight patients had endured their wounds for 6 weeks or longer (two patients had wounds present for 12 months); the remaining three had had their wounds for almost 4 weeks.

At the start of treatment eight wounds had macerated periwound skin due to heavy exudate levels, by week 3 all wounds were reported as having healthy surrounding skin suggestive of a reduction in exudate levels (Figure 1). Two patients had wounds with necrotic tissue, nine patients had wounds with large amounts of sloughy tissue at the outset of treatment with MaxioCel BMG dressing. The wounds were dressed every 2–3 days (dependent on the level of exudate). As treatment progressed the wound bed improved with a significant decrease in necrotic and sloughy tissue (from >75% at the start of treatment), replaced with healthy granulation and epithelial tissue (>80% by week 4) (Figure 2). All patients showed a significant improvement in their wounds over the 4-week evaluation period with exudate levels particularly decreasing from very heavy and heavy levels to low or no exudate. There was a subsequent improvement in periwound skin due to the exudate-locking capability of the dressing.

The dressing also alleviated the pain experienced by patients; pain was measured using a visual analogue scale, with zero representing 'no pain' and 10 representing 'very painful' (pain level was a maximum of 6 for this group).

The average pain score at the start of the evaluation was 5.9 ± 2.7 . After 3 weeks there was a significant improvement for all 11 patients with the score being 2.5 ± 1.9 at 4 weeks (Figure 3).

Over the treatment period all wounds were progressing towards healing with almost complete healing observed in six patients, and significant improvement in the remaining five wounds. Two wounds healed completely within the 4 weeks with the average wound area reduced from 44.1 cm^2 to 14 cm^2 ; overall there was a trend towards healing (Figure 4).

Case study 1

Mrs F is a 64-year-old female with a history of a static traumatic wound to her left leg, following a gardening accident at home. When Mrs F was referred to the wound care service the wound had been present for 2 weeks. Mrs F was a smoker, but had no other comorbidities. Previous dressing regimen included a range of superabsorbent dressings together with reduced compression. The treatment aim was to manage her high levels of exudate and promote autolytic debridement.

On the initial wound assessment Mrs F's wound bed was 100% necrotic (Figure 5a). Periwound skin was dry and eczematous. Exudate levels were very high and pain level on the visual analogue scale was recorded as 8. MaxioCel evaluation was commenced on 17 November for a period of 4 weeks

On the final review on 15 December the wound bed had 70% granulation and 30% epithelialisation, with all necrotic tissue and slough removed (Figure 5b). Periwound skin was healthy and Mrs F's pain level had reduced to scoring 3 on the visual analogue scale.

Clinicians reported that they found MaxioCel easy to apply and to remove in one piece, and were impressed with its exudate-handling capabilities:

'MaxioCel assisted with reducing pain for this patient as MaxioCel could be removed easily, atraumatically and in one piece. The haemostatic properties of the dressing proved extremely beneficial for this very traumatic wound and subsequent haematoma.'

Case study 2

Mr J is a 63-year-old male, with a history of a pilonidal sinus that repeatedly became infected. Mr J had two admissions for surgical debridement, which resulted in a static sacral surgical wound of 12 weeks' duration. He also had diabetes and was on anticoagulant therapy, with no other comorbidities.

On initial assessment on 1 June, the wound measured 5 cm length x 3 cm width x 3 cm depth. The wound bed contained 10% slough, with 90% granulation, and no signs of infection (Figure 6a). Periwound skin was slightly macerated with moderate exudate levels. Mr J's pain score was 8 following assessment via the visual analogue scale.

MaxioCel evaluation commenced, with treatment aims



Figure 5. Mrs F's wound at baseline (a) and at 4 weeks (b)

to manage exudate, promote autolysis and granulation and protect any newly formed granulation tissue

At Mr J's final assessment on 22 June, the wound bed comprised 70% granulation and 30% epithelialisation (Figure 6b). Exudate levels had reduced to moderate and periwound skin was now healthy. A reduction in pain was also noted with Mr J's pain score reducing from 8 to 3. As the wound was now healthy he did not require a fourth week of treatment with the MaxioCel dressing.

Clinicians commented:

'Patient's discomfort was reduced when using MaxioCel. The wound bed was successfully debrided by autolysis and granulation and epithelialisation increased within 12 days' treatment of a 12-week static chronic wound. Our patient's quality of life was significantly improved, and he could now leave the house more frequently due to the reduction in exudate volume and decrease in wound size. He felt more confident that the wound would not leak and cause him embarrassment.'

Case study 3

Mr C is an 81-year-old male who suffered a cerebrovascular accident (stroke). He developed a category three sacral pressure ulcer which, prior to the evaluation, had been present for 1 month.

On initial examination the wound bed comprised 90% devitalised tissue and 10% slough. The wound measured



Figure 6. Mr J's wound at baseline (a) and after 3 weeks (b)

KEY POINTS

- Improving patient quality of life is an important factor in the management of hard-to-heal wounds
- In this case series a chitosan-based dressing, MaxioCel, demonstrated efficiency in autolytic debridement of the wound bed
- The dressing facilitated the promotion of granulation and epithelialisation
- The dressing's bioactive microfibre gelling technology demonstrated good exudate absorption capabilities, having a positive impact on the condition of periwound skin, improving both patient and clinician experience
- It demonstrated significant pain reduction in several patients and could be removed atraumatically

6 cm length x 5 cm width x 4 cm depth. Periwound skin was macerated due to high levels of haemopurulent exudate (Figure 7a). Mr C presented with a significant level of wound pain, recording 8 on the visual analogue scale.

The treatment aim was to promote autolysis while managing both the type and amount of exudate present. Ensuring the reduction of the risk of biofilm reformation and corresponding risk of infection was also key.

Previous dressing regimens included alginate and sacral foam dressings, with dressing changes performed daily.

MaxioCel use commenced on 23 November. In line with the evaluation protocol the dressing was chosen in order to promote autolysis, reduce infection and biofilm reformation and manage exudate volume while repairing the macerated periwound skin. A sacral shaped foam dressing was applied as a secondary dressing. Dressing changes were performed daily to start with, before being reduced to three times per week.

After 7 days the periwound skin had improved from being macerated to a much more healthy condition. The type and level of exudate reduced and was absorbed and locked within the primary and secondary dressing effectively. Mr C's reported pain level reduced to 1 on the visual analogue scale and comfort levels increased.

Over the next few weeks Mr C's wound continued to improve and at the final review on 4 January (following the Christmas holidays) the wound measured 2 cm length x 0.3 cm width x 0 cm depth (Figure 7b). The clinical team noted that autolytic debridement occurred quickly, and during the 4-week period there were no further episodes of infection. This facilitated the promotion of both granulation and epithelialisation. Dressing removal was atraumatic, removed in one piece, with no fear of residual dressing being left within the wound.

Mr C commented that he was extremely pleased with the rapid improvement of his wound, which enabled him to return to independence as he no longer had to spend long periods of time in bed.

Conclusion

In this case series MaxioCel achieved positive outcomes and healing for various hard-to-heal wounds. Significant



Figure 7. Mr C's wound at baseline (a) and at final review (b)

healing, as measured by reduction in wound surface area, was observed in all wounds with an improvement to the periwound skin and a reduction in pain perception. Wounds can only progress to healing if they are clear of necrotic and sloughy tissue, and the bioburden is decreased. These objectives were clearly achieved with the BMG dressing. The dressing also demonstrated pain reduction in several patients as it could be removed easily, atraumatically and in one piece.

As discussed, a major challenge for clinicians and patients is the level of exudate, which can add to the burden for patients but also for clinicians since more dressing changes are necessary if the fluid-handling capacity of a dressing is suboptimal. The BMG dressing had good exudate absorption capability as well as being easy to use and potentially reducing dressing changes, it is therefore a useful addition to the woundcare formulary. **BJN**

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CPD reflective questions

- Why may exudate in hard-to-heal wounds be corrosive to the wound and periwound?
- How can chitosan assist/promote wound healing?
- In what type of wounds might you consider the use of chitosan?

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