

# A case series evaluating the use of a gelling fibre dressing for moderate to highly exuding wounds

## KEY WORDS

- ▶ Chronic wounds
- ▶ Exudate management
- ▶ Moist wound healing

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Maintaining a moist environment plays an important role in promoting wound healing, however, achieving the right moisture balance in moderate to highly exuding wounds can be a clinical challenge. Complications arising from poor exudate management can often lead to delayed wound healing and subsequent trauma to the surrounding skin (White, 2009). KerraCel™ is a new generation of gelling fibre dressing that maintains a moist wound environment on contact with moderate to high levels of exudate. The objective of this case series was to evaluate the clinical performance and patient acceptability of KerraCel dressings. Twenty patients from a specialised wound clinic in the South Wales area were recruited, all presenting with moderate to heavily exuding wounds of various aetiology. Objective measures, including wound tracings and photographs, were obtained at baseline and recorded once a week over the 4-week evaluation period. Patients were provided with best practice standard therapy. The wound-healing trajectory over the study period demonstrated a decrease in mean wound surface area (29.3 cm<sup>2</sup> versus 21.9 cm<sup>2</sup>) as well as an increase in mean percentage of granulation tissue at wound base of 68% at the end of the study. Exudate levels reduced in 14 out of the 19 (75%) patients who completed the study. Only 2 (1%) patients developed evidence of periwound maceration, which was unrelated to an increase in exudate or clinical features of infection. These findings suggest that KerraCel dressings are effective at maintaining a moist wound-healing environment, whilst reducing the risk of complications to the surrounding skin associated with poor exudate management.

The burden of living with chronic wounds is comprised of a number of psychological, emotional and physical factors, including anxiety, stress, fear, depression, wound malodour and high exudate levels, which can often exacerbate a patient's perception of pain (Mudge and Orsted, 2010). On a physiological level, there are many triggers of wound pain. Tissue trauma during routine changes can often induce nociceptive pain, when the dressing adheres to the surface of the wound bed as exudate levels decrease or when the periwound skin becomes macerated due to complications arising from high exudate (Price et al, 2008). This pain can further be exacerbated when wound exudate increases in response to colonisation or localised wound infection (Gardner et al, 2001). Therefore, the content of exudate

(Table 1) and volume of exudate produced can both be potential harbingers of healing (Adderley, 2010).

Addressing the underlying cause of increasing exudate levels and adopting an integrated approach to exudate management are imperative in protecting the periwound skin from maceration (Figure 1), whilst maintaining an optimal moist wound-healing environment (Chadwick and McCardle, 2015). This can be achieved by selecting a dressing that can effectively absorb and retain exudate even under pressure or therapeutic compression bandage systems.

Excluding superabsorbent polymer (SAP) technology, the main categories of dressings selected for their exudate management properties are alginates, gelling fibre dressings and foams. Alginates primarily absorb exudate into a

Table 1. Significance of exudate colour (World Union of Wound Healing Societies, 2007)

Colour	Cause
Clear or amber	Serous exudate, often considered 'normal' but may be associated with infection by fibrinolysin-producing bacteria, such as <i>Staphylococcus aureus</i> , may also be due to fluid from a urinary or lymphatic fistula.
Cloudy, milky or creamy	May indicate the presence of fibrin strands (fibrinous exudate, a response to inflammation) or infection (purulent exudate containing white blood cells and bacteria)
Pink or red	Due to the presence of red blood cells and indicating capillary damage (sanguineous or haemorrhagic exudate)
Green	May be indicative of bacterial infection, e.g. <i>Pseudomonas aeruginosa</i>
Yellow or brown	May be due to the presence of wound slough or material from an enteric or urinary fistula
Grey or blue	May be related to the use of silver-containing dressings

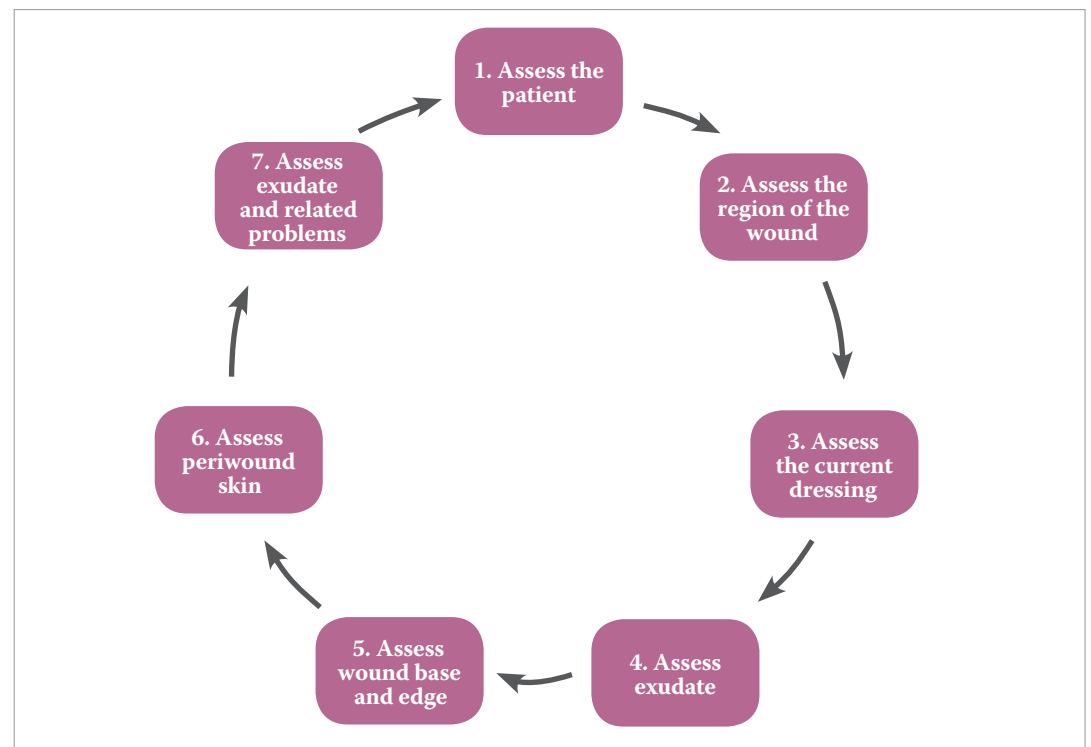


Figure 1. Integrated approach to exudate management (Chadwick and McCardle, 2015)

dressing matrix to produce a gel on contact with moderate levels of wound fluid, whereas gelling fibre dressings mode of action is capable of absorbing and retaining higher levels of exudate in comparison to both alginate and foam dressings (Vuolo, 2004).

Literature (Gardner, 2012; Rippon et al, 2012; Speak, 2014) suggests that the ideal primary dressing for highly exuding chronic wounds should:

- » Maintain a moist wound bed
- » Reduce the risk of periwound maceration
- » Act as a barrier to bacteria
- » Conform well to the wound bed to avoid pooling
- » Minimise dead space
- » Remain intact
- » Not cause tissue damage on removal
- » Optimise dressing change frequency
- » Be cost effective.

KerraCel is a highly absorbent gelling fibre dressing used in the management of partial and full-thickness chronic and acute wounds of various aetiology. This 100% carboxymethyl cellulose dressing forms a soothing gel on contact with moderate levels of exudate that enables the dressing to conform to the contours of the wound bed and minimise the dead space. It locks in exudate to protect the periwound skin from maceration, whilst maintaining a moist wound environment to promote healing. KerraCel is not indicated for wounds presenting with clinical features of infection that require topical antimicrobial therapy or in individuals with an established sensitivity to gelling fibre dressings. The aim of this case series was to evaluate the performance of KerraCel gelling fibre dressing on chronic wounds in the lower limb.

### METHODS

This case series evaluation recruited 20 patients from a local outpatient wound clinic in the South Wales area. The wound dressing (KerraCel) evaluated in this case series is a CE marked medical device and was used according to manufacturer's instructions by a team of qualified medical personnel. Patients for this study were recruited between April 2016 and January 2017. To be eligible, patients were required to have a hard-to-heal wound (duration  $\geq 3$  months) on the lower limb of either venous, mixed arteriovenous or diabetic foot aetiology, with moderate to high exudate levels in the absence of clinical features of infection.

Patients who were unable to provide informed consent were excluded from the evaluation. Peripheral arterial disease was excluded following a baseline assessment with a Doppler and ankle brachial pressure index (ABPI). Infected wounds and suspected osteomyelitis cases were also excluded.

Eligible patients meeting the inclusion and exclusion criteria signed consent in the presence of a dedicated research nurse responsible for collecting baseline data. Standard care was provided within the outpatient wound clinic where compression therapy and appropriate off-loading devices were prescribed in line with best

practice. Objective measures including wound tracings and photographs were undertaken at baseline and repeated once a week over the 4-week duration. These measures were recorded on the Wound Assessment Intervention and Evaluation form and the frequency of dressing changes were determined by the absorption and retention of exudate between visits.

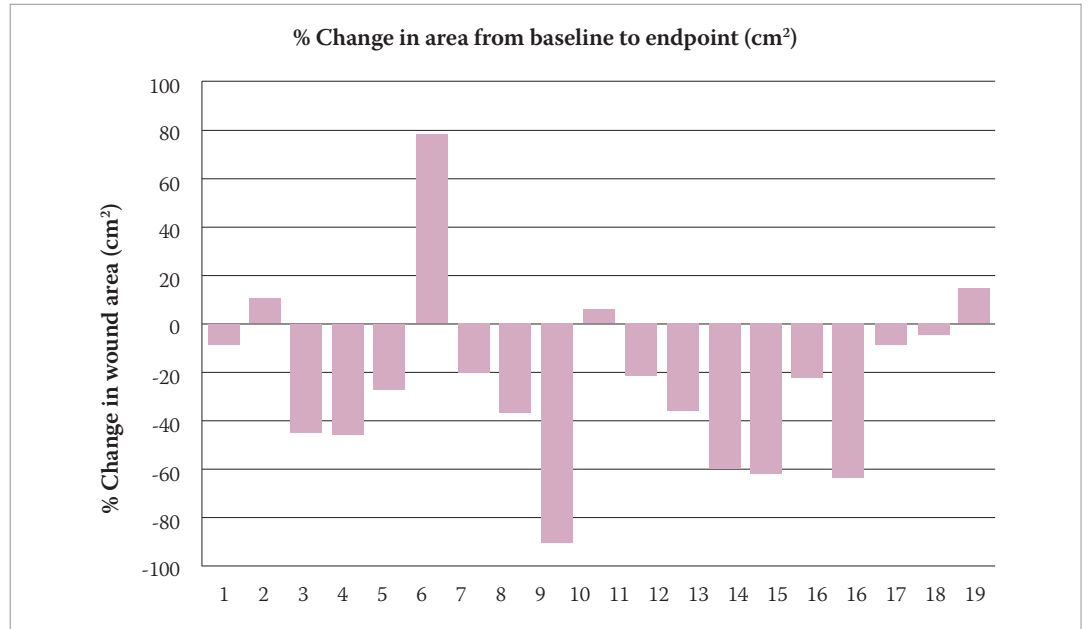
The main outcome of interest was the therapeutic effect of KerraCel on wound healing status and the condition of the surrounding skin. The wound healing status was assessed by measuring the wound surface area (cm<sup>2</sup>), which was calculated as length (cm) x width (cm) and subjective assessment of the condition of the wound bed (percentage of granulation tissue). Secondary outcomes of interest were conformability and moisture retention of the dressing, reduction of exudate levels, condition of the surrounding skin and any clinical features of infection. Exudate levels were graded on a Likert-type scale of 1 to 5 (1=none, 2=light, 3=moderate, 4=heavy, 5=copious). Information relating to these outcomes was documented by the research nurse at baseline and at each follow-up visit. At the end of the 4-week evaluation period, outcomes were recorded on an excel database (Microsoft, 2010) and analysed using descriptive statistics in the form of rates, means, ranges and percentages.

### RESULTS

Twenty patients were included in the case series evaluation. One patient was withdrawn at week 2 of the evaluation due to admission to hospital with systemic infection. This complication was deemed unrelated to the dressing.

#### Baseline patient characteristics

Nineteen patients,  $n=14$  (74%) male and  $n=5$  (26%) female were included in the final case series analysis. Patients age ranged from 38 to 97 years with a mean age of 71 years. Fourteen patients from the total cohort had a venous leg ulcer (VLU) and were treated with compression bandaging. Twelve of the patients with VLU had been in compression therapy prior to participation in the evaluation, another 3 patients had a mixed arteriovenous leg ulcer



**Figure 2. Change in wound surface area from baseline to final follow-up**

(MLU) and had modified compression therapy and the remaining 2 patients a diabetic foot ulcer (DFU). Mean wound duration was 43 months (range 3–240 months). The wound size at baseline for the total cohort ranged from 1.65 cm<sup>2</sup> to 255.0 cm<sup>2</sup> (mean 29.3 cm<sup>2</sup>).

**Patient outcomes**

A wound-healing trajectory was observed over the 4-week period. The mean wound surface area decreased (7.4 cm<sup>2</sup>) in 79% of the cohort (Figure 2) and a corresponding increase (68%) in the mean percentage of granulation tissue was documented at the wound bed.

Exudate levels reduced in 14 out of the 19 (75%) patients who completed the study. Only 2 (1%) patients developed evidence of periwound maceration that was unrelated to an increase in exudate or clinical features of infection (Table 2). All 19 patients reported 100% satisfaction with the conformability, moisture retention and ease of removal of KerraCel between dressing changes. No dressing related adverse event was recorded during the evaluation period.

**DISCUSSION**

Maintaining a moist environment plays an

important role in promoting wound healing, but achieving the right moisture balance in moderate to highly exuding wounds can be a clinical challenge. Complications arising from poor exudate management can often lead to delayed wound healing and subsequent trauma to the surrounding skin (White, 2009).

There are several dressings available to optimise a moist wound healing environment but there is limited consensus on the rationale for selecting an appropriate dressing. This case series evaluation demonstrates how performing a comprehensive wound assessment, using the integrated approach model (Figure 1) can help inform clinicians with the selection of an appropriate dressing and limit the risk of adverse events associated with heavy exudate levels.

KerraCel was designed to overcome some of the subjective barriers associated with the use of gelling fibre dressings in the treatment of chronic wounds. It forms a soothing gel on contact with moderate levels of exudate that enables the dressing to be removed without signs of degradation and minimal fibre residue within the wound bed. The reported outcomes from this case series suggests that the dressing (KerraCel) attained a good level of conformability (100%) with the wound bed to

Table 2. Objective outcome measures for exudate management

Participant	Wound aetiology	Standard therapy	Exudate level decreased (Y/N)	Periwound maceration	Infection (Y/N)	Moisture retention	Conformability
1	VLU	Compression	Static	No	No	Excellent	Good
1	VLU	Compression	Static	No	No	Excellent	Good
2	VLU	Compression	Yes	No	No	Excellent	Good
4	VLU	Compression	Yes	No	No	Excellent	Good
5	VLU	Compression	Yes	No	No	Excellent	Good
6	MLU	Modified compression	Yes	No	No	Excellent	Good
7	DFU	Offloading	Yes	No	No	Excellent	Good
8	VLU	Compression	Yes	No	No	Excellent	Good
9	VLU	Compression	Yes	No	No	Excellent	Good
10	DFU	Offloading	Yes	No	No	Excellent	Good
11	VLU	Compression	Yes	No	No	Excellent	Good
12	VLU	Compression	Static	No	No	Excellent	Good
13	VLU	Compression	Yes	No	No	Excellent	Good
14	VLU	Compression	Yes	No	No	Excellent	Good
15	VLU	Compression*	Static	No	No	Excellent	Good
16	VLU	Compression*	Yes	No	No	Excellent	Good
17	VLU	Compression	Static	No	No	Excellent	Good
18	MLU	Modified compression	Yes	No	No	Excellent	Good
19	MLU	Modified compression	Yes	Yes	No	Excellent	Good
Total	n=19	n=19	75%	1%	0%	100%	100%

\*Compression therapy was initiated at the baseline visit and continued over the 4-week evaluation

minimise the dead space. None of the participants developed clinical features of infection over the 4-week evaluation period, which supports that minimising the dead space may inhibit the formation of biofilm in the wound bed and help reduce the risk of infection. However, further research is required to investigate the significance of this relationship.

Promotion of healthy granulation tissue was documented in 13 (68%) patients at endpoint and there was a serial reduction in mean wound surface

area (7.4cm<sup>2</sup>) over the 4-week duration. These findings demonstrate that the KerraCel gelling fibre dressing was effective at maintaining a moist wound healing environment, whilst reducing the risk of periwound maceration (1%). All patients (100%) reported that the dressing attained excellent moisture retention, which anecdotally resulted in fewer dressing changes. These subjective findings suggest that KerraCel may be a cost-effective alternative to other dressing types selected for their exudate management properties.





Figure 3. A patient with a lower limb wound treated with KerraCel over a 4-week period. The circumferential VLU before and after 4-weeks dressing with KerraCel



Figure 4. A patient with a lower limb wound treated with KerraCel over a 4-week period. The MLU before and after 4-weeks dressing with KerraCel

The evidence to support the use of KerraCel on hard-to-heal wounds of various aetiology in the lower limb is limited and further research needs to be conducted on the generalisability of these findings to the wider population. However, this case series evaluation highlights the benefits associated with the appropriate use of KerraCel in retaining exudate to promote a moist wound healing environment, whilst protecting the periwound skin from complications associated with soft tissue maceration. WUK

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