Evaluating the performance of a new carboxymethyl cellulose dressing in the community setting

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ABSTRACT
This article describes a single-centre, non-comparative evaluation set out to assess the clinical performance and patient acceptability of a new carboxymethyl cellulose (CMC) wound dressing. Twenty patients in a community setting, aged between 34–97 years, were recruited. The progression of various types of wounds with different levels of exudate was documented over 4 weeks. No adherence to the wound bed or painful removal was reported in 18 patients, and the peri-wound skin was the same or had improved in all patients. When compared with the previous CMC dressing used by the authors, the new CMC dressing reported a longer wear time. These findings show a positive clinical performance and suggest a potential financial advantage when using the new dressing.

Key words: Exudate management ■ Carboxymethyl cellulose ■ Wound dressings ■ Cost effectiveness

Wound care represents costs to the NHS of £4.5–5.1 billion per year, with 86% coming from indirect costs such as managing infections, maceration, delayed healing, pain and the additional nursing and hospital resources these complications consume (Guest et al, 2015). The challenge of wound management remains to deliver appropriate care and achieve positive clinical outcomes. In 2014, 86.7% of wound care in the UK was delivered by registered nurses in the community (Dowsett et al, 2014), where the management of wound exudate is considered a key contributing factor to the overall spend in community wound care practice. This is no minor detail, as another key objective to achieve best wound outcomes is to generate savings in dressing cost.

Patients with highly exuding wounds often require more frequent clinical visits and higher volumes of dressing materials and consumables. Morgan (2015) described the management of commonly treated wounds in the community which vary in exudate volume, such as pressure ulcers, as an expensive process. The cost to the patient, though largely immeasurable, is a priority consideration and can be based on the impact of quality of life (QoL), disruption to lifestyle, pain associated with dressing wear and removal, delayed wound healing and dressing failure or leakage, often resulting in social isolation (Stephen-Haynes, 2015). Patient involvement in dressing selection and evaluations is highly significant to achieve best patient outcomes. Beldon (2016) suggested that patients should be involved in the decision-making process concerning their treatment.

Exudate management
The concept of moist wound healing has been embedded in wound care practice for over 50 years based on the work of Winter (1963), who demonstrated increased cellular activity and improved healing rates in an experimental acute wound model. This concept was later applied to the chronic wound scenario and continues to be discussed. Through the decades, a more scientific focus has been established to further understand wound exudate and the importance of moisture balance. The TIME concept, which stands for tissue, infection, moisture and edge of wound, was developed by Schultz et al (2003). It identified key barriers to wound healing and introduced a new way of thinking about exudate, its components and volume to control wound-moisture balance.

Wound exudate is the fluid that leaks out of the blood vessels of a wound and occurs as a part of a normal healing process (Chadwick and McCardle, 2015). It is mainly water, but also contains electrolytes, nutrients, proteins, inflammatory mediators, protein ingesting enzymes, growth factors and waste products, as well as various types of cells (Romanelli et al, 2010). There are also key composition differences between exudate produced by an acute healthy wound and that of an unhealthy chronic wound. Exudate produced by chronic wounds is widely reported to contain destructive enzymes that compromise wound healing by degrading the extracellular matrix (ECM).

Wound exudate also varies in volume, consistency and composition, which can be detrimental to either the underlying tissue or surrounding skin (World Union of Wound Healing Societies (WUWHS), 2007) (Box 1). Although a moist wound environment is necessary for...
There is discomfort or pain. Peri-wound changes, such as maceration and skin stripping, occur. The dressing leaks or requires a high frequency of dressing changes. Assisting with the separation of dead or damaged tissue (known as autolysis). Enabling diffusion of immune and growth factors. Providing the essential nutrients for cell metabolism. Allowing for the migration of tissue-repairing cells. Preventing the wound bed from becoming dehydrated.

Wound fluid can assist wound healing by:

- Preventing the wound bed from becoming dehydrated
- Allowing for the migration of tissue-repairing cells
- Providing the essential nutrients for cell metabolism
- Assisting with the separation of dead or damaged tissue (known as autolysis)

Box 1. Wound fluid (WUWHS, 2007)

Wound fluid can assist wound healing by:

- The dressing leaks or requires a high frequency of dressing changes
- Peri-wound changes, such as maceration and skin stripping, occur
- There is discomfort or pain
- There is fluid and electrolyte imbalance due to protein loss

Wound fluid can delay wound healing when:

- The dressing leaks or requires a high frequency of dressing changes
- Peri-wound changes, such as maceration and skin stripping, occur
- There is discomfort or pain
- There is fluid and electrolyte imbalance due to protein loss

Table 1. Types of exudate, appearance and significance (White and Cutting, 2006)

<table>
<thead>
<tr>
<th>Type</th>
<th>Colour</th>
<th>Consistency</th>
<th>Significance</th>
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<tbody>
<tr>
<td>Serous</td>
<td>Clear, straw-coloured</td>
<td>Thin, watery</td>
<td>Normal. Possibly a sign of infection. Some bacteria produce fibrinolysins, which degrade fibrin clots or coagulated plasma. Some strains of Staphylococcus aureus, β-haemolytic group A streptococci and Bacteroides fragilis produce fibrinolysins. Pseudomonas aeruginosa produces a non-specific enzyme that degrades fibrin.</td>
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<td>Fibrinous</td>
<td>Cloudy</td>
<td>Thin</td>
<td>Contains fibrin protein strands.</td>
</tr>
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<td>Normal.</td>
</tr>
<tr>
<td>Sanguine</td>
<td>Red</td>
<td>Thin, watery</td>
<td>Trauma to blood vessels.</td>
</tr>
<tr>
<td>Seropurulent</td>
<td>Murky, yellow, cream-coffee</td>
<td>Thick, creamy</td>
<td>Infection</td>
</tr>
<tr>
<td>Purulent</td>
<td>Yellow, grey, green</td>
<td>Thick</td>
<td>Infection. Contains pyogenic organisms and other inflammatory cells.</td>
</tr>
<tr>
<td>Haemopurulent</td>
<td>Dark, blood-stained</td>
<td>Viscous, sticky</td>
<td>Contains neutrophils, dead/dying bacteria and inflammatory cells. This means an established infection is present. Consequent damage to dermal capillaries leads to blood leakage.</td>
</tr>
<tr>
<td>Haemorrhagic</td>
<td>Red</td>
<td>Thick</td>
<td>Infection, Trauma. Capillaries are so friable they readily break down and spontaneous bleeding occurs. Not to be confused with bloody exudate produced by over-enthusiastic debridement.</td>
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Source: (White and Cutting 2006)

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Optimal wound healing, over- or under-production of exudate may adversely affect healing (Romanelli et al, 2010).

An excessive amount of exudate increases the risk of maceration and excoriation of the skin surrounding the wound (Wounds UK, 2013; Beldon, 2016). As well as posing difficulties for dressing procedures, high volumes of exudate can be distressing for patients. Highly exuding wounds are likely to leak through dressings and soil clothing, which is unpleasant to patients and may decrease their QoL as they may feel embarrassed (Wounds UK, 2013; Beldon, 2016). Dressings should be able to manage the levels of exudate in between dressing changes, and leakage should indicate when a more absorbent dressing is required (Benbow, 2015). Therefore, it is crucial to assess and manage the level of exudate as high volumes are both challenging to manage and likely to delay the healing process (Barrett, 2016).

White and Cutting (2006) provided more descriptive classifications of wound exudate, highlighting the clinical significance of correctly assessing and interpreting exudate type, colour and consistency (Table 1). In order to develop an effective management approach, a clinician must be able to accurately assess and understand the implications of the composition and quantity of exudate present in the wound (White and Cutting, 2006).

### Dressings used to manage exudate

The essential requirement for any wound dressing is the provision of an environment conducive to wound healing, which includes protecting and covering the wound, staying firmly in place, avoiding peri-wound or skin trauma during removal and maintaining an optimal moisture balance to maximise the rate of healing (Okan et al, 2007; WUWHS, 2007). Leaper et al (2012) suggested that dressings must also offer patient comfort, minimising the dressing’s bulk, avoiding the inconvenience of frequent and/or complicated dressing changes, and mitigating pain. Dressing efficacy in terms of exudate management capability, patient comfort during wear and removal, wound outcome, dressing wear time, ease of use, ease of removal and unit cost are all factors that will influence choice or future consideration to change clinical practice.

There are a plethora of dressing materials and secondary dressings available to address the challenges of managing excessive volumes of exudate, ranging from foam dressings to super absorbent pads designed to capture and lock away exudate. A dressing family frequently used as a highly absorbent contact dressing for its efficacy in exudate management and non-traumatic interaction with the wound bed is carboxymethyl cellulose (CMC), commonly known as hydrofibre or gelling fibre dressings. In the authors’ opinion, considering unit cost alone, CMC dressings are frequently deemed as more expensive, but clinical outcomes, patients’ QoL and extension of dressing life are more favourable cost-consideration measures.

A new CMC gelling fibre dressing, KerraCel (Crawford Healthcare), could offer savings of up to 40% per unit when compared with the gelling fibre dressing being used previously at the authors’ trust (NHS Business Services Authority (BSN) Drug Tariff, 2016).

### Method

A single-centre, non-comparative evaluation was undertaken at Worcestershire Health and Care NHS Trust to assess the clinical performance and patient acceptability of KerraCel.
PRODUCT FOCUS

and to evaluate if a saving on dressing cost could be achieved without compromising clinical outcomes.

All treatment pathways and secondary dressing regimes were unchanged during this evaluation. Clinicians followed the trust’s wound management formulary, which offers guidance on appropriate use of wound management items. The new CMC dressing replaced the one being used at the authors’ setting during the 4-week evaluation period. The new dressing, designed to be used on a variety of exuding wounds, forms a gel when wet and helps maintain a moist healing environment. Its manufacturer claims it can:

- Lock in exudate to protect peri-wound skin from maceration
- Be removed from the wound bed in one piece
- Contour to the wound bed, minimising dead space where bacteria can live
- Sequester harmful components found in exudate.

A bespoke data-collection tool was developed and submitted for clinical governance approval (the local evaluations approval service) to undertake this evaluation in a variety of wound aetiologies. Ethics committee approval was not required, as the product being evaluated was a commercially available, CE-marked medical device being used by qualified medical personnel as intended, not off-label.

The inclusion criteria is set out (Box 2). Those deemed suitable for or currently using CMC dressings with exuding wounds were eligible for inclusion in this evaluation. Twenty patients were recruited.

An initial patient assessment was carried out to capture relevant medical, wound and dressing history. Data capture included wound type, duration, recurrence, location, tissue type and size. Infection status included biofilm suspected, tissue biopsy, swab and blood culture results. Exudate volume and viscosity were descriptively measured using White and Cutting (2006) descriptors (Table 1). Peri-wound skin condition at baseline and any current barrier film protection use was recorded. Patient pain score was obtained as a baseline and recorded.

The patients being treated with the new CMC dressing were followed for a maximum period of 4 weeks. The dressing was discontinued earlier if the wound healed or its status changed in such way that it was no longer appropriate for use.

The dressings were changed as often as nurses deemed necessary. The evaluating clinicians carried out weekly assessments using a standard case report form, which documented ease of removal, adherence to wound bed, pain score, wear time, leakage, peri-wound skin status and wound measurements. Changes in exudate viscosity and volumes were also monitored.

The patients and clinicians involved in the evaluation gave feedback by providing a subjective assessment of performance, outcome, comfort and acceptability of the new dressing, considering its suitability for use in routine practice.

Results

Of the 20 patients recruited, 8 were male and 12 were female; their ages ranged from 34–97 years. Eight patients had received other hydrofibre or gelling fibre dressings for over 2 weeks before the evaluation.

The different wounds included pressure ulcers (9), leg ulcers (4), diabetic foot ulcer (1), fungating (2), burn (1), bursa (1) and traumatic, post-surgical and lymphatic compromised wounds (2). These were located in the torso (1), foot (1), heels (2), legs (6), arms (1), axilla (1), breast (1), residual limb (1) and sacral areas (6). The wound ages varied greatly—from 2 weeks to being present for several years—and two wounds were recurrent episodes.

Infection was suspected in 5 wounds, confirmed in 14 and not documented in 1 case. The tissue types were recorded as healthy granulation (5), unhealthy granulation (6), sloughy (6), fungating (2) and 1 was documented as full limb maceration.

The exudate levels (Figure 1) were copious (3), heavy (5) and moderate (12), and their consistency varied from thin, watery to thick, fibrous (Figure 2). Five patients presented thick, fibrous exudate during the 4-week evaluation period—this is important to consider, as many dressings do not absorb or cope with the thicker fibrous types of exudate.

Wound dimensions and photographs were taken, showing positive progression and healing outcomes at day 1 (Figures 3a and 4a) and week 4 (Figures 3b and 4b).

Dressing leakage was observed in two cases. In one case, the dressing wear time was reduced from 3 to 2 days, and in another case the dressing wear time fluctuated between 3 and 4 days; both cases resulted in no further dressing leakage. Interestingly, zero leakage was observed in the patients with the highest copious levels of exudate and a 3-day wear time. The average dressing wear time was 3 days and the exudate levels were mostly heavy. Overall, the dressing wear time increased in 5 cases, remained the same in 13, reduced in 1 and fluctuated in 1.

No adherence to the wound bed or painful removal was reported in 18 patients. One patient recorded adherence at three consecutive dressing changes; however, the exudate levels had dropped from moderate to low at the second change, deeming the new dressing inappropriate for this patient. Another patient reported adherence at the first change, but the dressing was continued with no adherence observed at changes 2, 3 and 4 despite no change in exudate volume being recorded.

The peri-wound skin was the same or had improved in all patients, with no deterioration reported. The use of a barrier

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Box 2. Inclusion and exclusion criteria

Eligible for inclusion and participation in this evaluation were patients:

- Over the age of 18 years
- Capable to understand the nature of the evaluation and provide consent
- Deemed as suitable for inclusion under the evaluators’ clinical judgement
- Who have received previous CMC dressing treatment, or were deemed suitable to receive CMC dressing treatment

Not eligible for participation or to be excluded from this evaluation were patients:

- Below the age of 18 years
- Without capacity to understand the nature of the evaluation or provide consent
- Deemed as unsuitable for inclusion for any other reason under the evaluators’ clinical judgement
- Whose wound type was unsuitable for CMC dressing treatment

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Table 1. Exudate volume and viscosity measurements using White and Cutting (2006) descriptors

- Thinnest (1): watery
- Thin (2): thin
- Moderate (3): moderately thick
- Heavy (4): thick
- Copious (5): very thick

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film, which would also prevent peri-wound maceration, was recorded in only 6 patients.

Pain scores remained unchanged in 12 patients, were reduced in 4 patients and increased in 2 patients (this was due to infection and bleeding). Two patients presented complex regional pain syndrome (CRPS) and their pain could not be scored—in patients with CRPS the brain memorises pain pathways, so the pain is immeasurable.

The ease of application of the new dressing was rated by the clinicians involved in the evaluation, where 10=very easy and 1=very difficult. Fourteen gave it a 10, one gave it a 9, four gave it an 8 and one gave it a 6. The ease of removal was rated with a 10 (11 cases), 9 (1 case), 8 (6 cases), 7 (1 case) and 6 (1 case).

When rating the exudate management and overall outcome, where 10=excellent and 0=poor, the dressing received a score between 8–10 (12 cases), 5–7 (7 cases) and 3 (1 case). All patients stated they would like to continue using the new dressing, except for one patient who did not complete this field in the data sheet.

A total of 80 dressing changes were recorded during this evaluation. When compared with the previous CMC dressing used by the authors, the new dressing reported an equal or longer wear time: the same number of days was reported in 13 cases, while an increase in number of wear days was seen in 6 cases. A decrease in number of wear days was observed in one case and fluctuations in wear time were reported in one case.

**Discussion**

These findings provide a good example on how the new CMC dressing can effectively manage a wide range of wound aetiologies with different exudate levels. The secondary dressing remained unchanged; therefore, the primary dressing (the new CMC dressing) was the only change that would impact directly on the increases or decreases of wear time. In the two cases where dressing leakage was observed, it is highly likely that this would have also occurred with the CMC dressing previously used by the authors, and was possibly the result of dressing failure involving primary and secondary dressings. It is also important to note that 12 of the 20 patients recruited were not receiving treatment with CMC before this evaluation; therefore, the reported improvements can be attributed to the introduction of CMC rather than to a change in the type of CMC dressing used.

Positive wound outcomes have been drawn from these data, and the evaluation feedback showed acceptance from both patients and clinicians. The new dressing stayed on for 3 days in most patients (62%). Other patients had it on for 1 day (5%), 2 days (26%), 4 days (4%) and 5 days (3%).

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**Figure 1. Exudate level**

- Copious – 15%
- Heavy – 25%
- Moderate – 60%

**Figure 2. Exudate consistency**

- Thin, watery – 40%
- Thin – 25%
- Sticky viscous – 10%
- Thick, fibrous – 25%

**Figure 3. Case study 1**

A 76-year-old woman was referred to the tissue viability team with an ungradable pressure ulcer on the sacrum. The wound was sloughy with moderate levels of thin, fibrous exudate; peri-wound maceration was present. Dressings were changed every 3 days. At dressing change number 4 (12 days) the wound bed had dramatically improved, showing 90% healthy granulation tissue and a small amount of slough. The peri-wound maceration had reversed (no barrier film products were used). The new CMC dressing did not leak during higher exudating periods, and did not adhere to the wound even when the exudate dropped to a low level at the end of the evaluation.
Conclusion

Exudate management remains a primary clinical challenge in wound management. This evaluation showed positive outcomes with the use of KerraCel in relation to exudate management, application, removal and wear time. The results have also demonstrated the ease of implementation into practice when using a CMC dressing 40% less expensive than the one previously used by the authors. The new dressings were changed less frequently than the CMC dressings previously used by the authors, which has significant implications for both patient convenience and cost of care. The findings in this evaluation showed that KerraCel is a promising dressing that could improve the clinical and financial outcomes in a community setting. BJN

Declaration of interest: Crawford Healthcare provided the dressing material under evaluation and funded independent consultant nurse support with designing the data tool, data analysis and assistance in the writing up of these results.


A 97-year-old woman was referred to the tissue viability team with a grade 3 pressure ulcer on her thigh. Moderate levels of watery, serous exudate with both peri-wound maceration and peri-wound excoriation to the wound edge and wound margins were observed. A barrier film skin protection was used before commencing treatment with the new CMC dressing. The wound bed presented 70% granulation tissue with a 30% island of fibrous slough. Dressing changes were performed every 3 days. At day 12, the wound showed significant improvement with no signs of peri-wound maceration. The new CMC dressing did not leak during higher exudating periods, and did not adhere to the wound even when the exudate dropped to a low level at the end of the evaluation

Figure 4. Case study 2

Use of a CMC dressing on a pressure ulcer on the thigh

KEY POINTS

- Wound care represents costs to the NHS of £4.5–5.1 billion per year
- Dressings should be able to manage the levels of exudate in between dressing changes
- Carboxymethyl cellulose (CMC) is a dressing family frequently used as a highly absorbent contact dressing
- The findings in this evaluation showed that the new dressing could improve the clinical and financial outcomes in the community setting