

Collaborative working to evaluate clinician acceptability of a carboxymethyl cellulose dressing

KEY WORDS

- ▶ Carboxymethyl cellulose (CMC) fibre dressing
- ▶ Dressing selection
- ▶ Evaluation
- ▶ KerraCel

Exudate management and dressing selection remain some of the primary clinical challenges in wound management. This article explains how and why clinical product evaluations can help to inform best practice for dressing selection. Working in partnership with industry to conduct product evaluations can support healthcare professionals in a challenging NHS environment. Results from a review of a new carboxymethyl cellulose dressing (KerraCel, Crawford Healthcare) supports this guide on how to perform a product evaluation.

Evidence-based practice, which involves collecting and evaluating data to inform and enhance routine practice, is fundamental in improving patient care, safety and clinical outcomes; however, it can be challenging to deliver within clinical practice. In wound care, where large variations in practice occur and controversies remain regarding the treatment and care of acute and chronic wounds, evidence-based practice would achieve a more uniform policy for treatment in all settings, as well as improved effectiveness and quality of wound care (Ubbink et al, 2015).

The essential requirement for any wound dressing is to provide an environment conducive to wound healing (World Union of Wound Health Societies [WUWHS], 2007). Maintaining a moist environment plays a critical role in promoting healing, but achieving the right moisture balance in moderate to highly exuding wounds can be a clinical challenge. Complications arising from poor exudate management, including maceration and excoriation of surrounding skin, can often lead to delayed wound healing and subsequent skin trauma (White, 2009), which has a negative impact on patients' quality of life (WUWHS, 2007).

While there are several dressings available known to effectively manage exudate and optimise wound healing, there is often little guidance on which product most effectively meets the needs of the patient and wound (Jones et al, 2017). Wound care is managed across multiple settings by a range of healthcare professionals with varying levels of expertise, and dressing selection is not always based on best practice (Gray et al, 2018). Appropriate dressing selection should take into account the results of the holistic

patient and wound assessment, the desired outcomes of treatment and the impact to the patient's quality of life. Consideration must also be given to providing cost-effective care and streamlining product selection.

Conducting a product evaluation can help to establish evidence-based practice. A product evaluation assesses the performance of a product against various objective measures, examining how well a product performs in line with product claims, and in comparison with other products. It can also be used to demonstrate clinical equivalence or superiority, and therefore plays a key role in informing and assisting appropriate dressing selection, limiting the risk of adverse events associated with heavy exudate levels and hard-to-heal wounds.

Working in partnership with industry supports healthcare professionals to undertake effective, timely holistic dressing evaluations in the clinical environment when time and resources are at a premium. At Guy's and St Thomas' NHS Foundation Trust, a product evaluation was conducted comparing the currently used hydrofiber dressing with a new gelling fibre dressing (KerraCel, Crawford Healthcare). The evaluation aimed to determine patient and clinician acceptability of KerraCel dressings and to create a simple product evaluation blueprint, presented here.

For this evaluation, Crawford Healthcare worked alongside the TVN to help communicate the details of the evaluation through the distribution of posters and arranged meetings with other specialist areas to ensure the evaluation provided clinical results from different areas. They also provided product training where needed and ensured that the new dressing was available and in stock.

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COMPLETING A PRODUCT EVALUATION

There are three defined steps to conducting a clinical product evaluation as part of the devised blueprint: planning, doing and collecting data (*Figure 1*). It may also be useful to create a timeline for each stage of the product evaluation (*Figure 2*) that includes the responsibilities of each team member.

Step 1: Get organised □

This is the 'planning' phase, and it is crucial that you are systematic and organised during this phase. Key considerations include: understanding what you hope to achieve, selecting relevant outcomes to measure, and deciding and justifying what product you are going to evaluate. The geographical or clinical area to conduct the evaluation would be identified, as well as any resource limitations or advantages. The patient group to be included should be decided, including inclusion and exclusion criteria. Also consider if the product evaluation will focus on a specific wound aetiology, for example, for feet you are often interested in conformability, ability to withstand the walking pressures and shear and not contributing to more damage.

A pilot may be useful to conduct at this stage, which will highlight if any additional clinical training is required and if all relevant documentation is in place (i.e. consent and evaluation forms). Appropriate permissions, governance and compliance considerations as per local protocol should be adhered to, and the personnel who will be involved in the data capture should be identified, as well as the means to return documentation or results determined.

Step 2: Get busy □

This is the 'doing' phase. At the start of the evaluation, you will need to compile a list of all eligible participating patients. The consent process should be completed and the patient's wounds photographed to aid more accurate reporting and recording of outcomes. It's important that all staff are aware when a patient is participating in an evaluation; depending on the clinical setting, you can display a bedside inclusion poster or ensure this is marked clearly on the patient's notes.

This is the busiest phase and it's important to stay organised. You'll need to ensure the correct completion and appropriate storage of all evaluation forms, bearing in mind patient confidentiality and guidance around data protection (Department of Health, 2009).

Contact details for the evaluation lead should be clearly displayed in case any clinical staff have queries, and it's a good idea to establish adequate daily support for the clinical staff. Support may include daily stock checks, patient assessment review, feedback, and checking forms are completed. Lastly, maintain good communication throughout the process, including regular progress updates for the project, flagging any issues and escalating these where necessary as soon as they are identified.

Step 3: Get results □

This is the 'data collection' phase. All completed evaluation forms should be collected and collated. Once you've collated your results, be sure to feed back to all healthcare professionals who participated in the evaluation.

Working in collaboration with industry can facilitate successful clinical evaluations that can result in changes to clinical practice that will be evidenced-based, potentially cost effective and supported by real-time data. Without the support, such evaluations may not be possible or take longer to complete hampering potential positive clinical change in practice.

Practical tips when completing a product evaluation

Evaluate many wounds

» By conducting the product evaluation on a substantial number of wounds pertinent to your practice, you can ensure the dressing has been robustly tested.

Keep a close eye every day

» By taking a small amount of time each day to provide support to clinical staff, problems can be identified early and rectified. This ensures that set objectives are being met. With a degree of flexibility, comprehensive assessments can be gathered within a specified time frame.

Talk Talk Talk

» Open communication between all parties involved in the evaluation is key. By communicating honestly and openly, the findings and results can be used to implement change or to support current standard practice.

Many hands make light work

» When each member of the clinical team has their own defined role, working as a team can make the product evaluations run smoothly and efficiently.

A CLINICAL TRIAL RUN IN PARTNERSHIP WITH INDUSTRY - THE EFFECTIVENESS OF A CARBOXYMETHYL CELLULOSE DRESSING: A SUCCESSFUL OUTCOME

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GET ORGANISED

- Decide Product**
 - Product Characteristics - why trial this product and supporting evidence
 - Potential benefits to clinical area - cost/staff and patient acceptability
 - Realistic timeline for trial
 - Inclusion criteria
 - Minimum dressing changes
- Decide Area**
 - Where would benefit and use product being trialled
 - Patient demographics
 - Ward ability
 - Compliance by staff
 - Compliance by ward manager
- Education**
 - Product / benefits / inclusion criteria
 - Staff on ward > 90% - staff list and signatures
 - Teams who will treat patients on the ward and may use the dressing
- Organisation**
 - Posters detailing trial dates / product / contact details for people running the trial
 - Consent forms
 - Evaluation Form
- Stock**
 - Liaise with procurement / stockist of dressings to the ward
 - Inform them of trial
 - Ensure stock of dressings available on ward
 - If dressing is being used instead of another dressing ensure the dressing to be substituted is removed from ward stock and not replenished during course of the trial

GET BUSY

- Patients**
 - All patients who meet the trial criteria and have consented should be commenced on the dressing trial
 - Comprehensive list of patients who are partaking in the trial should be recorded
 - Name/ ward/ wound/ dressing plan/ date commenced/ date completed/ if not completed why
 - When able to consent, wounds should be photo documented to monitor progression and aid feedback
 - When patients are on a dressing trial this should be included in the handover sheet and be handed over from shift to shift
 - Inclusion posters should be placed at the bedside
- Referrals**
 - Patients should still be referred to specialities as per trust policy
 - Complex wounds are to be reviewed by Tissue Viability and dressing plans implemented by ward staff
 - Other visiting specialities will have been made aware of the dressing trial in the pre-trial phase and can utilise the dressing throughout the trial period
- Evaluation**
 - All evaluation forms should be completed on initial wound assessment by the person initiating the treatment
 - All evaluation forms should be completed as agreed with dressing company and Tissue Viability
 - Evaluation forms to be kept in a safe area in a clearly marked box
- Support**
 - Daily support to gain feedback, check stock levels, assess patients if needed, ensure evaluation forms are being completed
 - Daily checklist completed with information above
 - Easily contactable - contact details visible on the ward
 - Weekly visits by BDM to answer any product related queries
- Communication**
 - Weekly updates on the progression of the trial
 - How many participants/how many ongoing/how many completed/ any issues/stock requirements
 - Communicate with company/team leaders/ward manager
 - Escalate any issues and communicate resolutions

GET RESULTS

- Evaluations**
 - All completed evaluation forms should be collected and the data collated
 - Evaluation results should be feedback to all healthcare professionals who participated in the trial
- Change in Practice**
 - If the dressing trial has a successful outcome all changes to clinical practice will be evidenced based and supported by real world trials

Extra Tips

- 1 Use lots of different wounds
- 2 Keep a close eye every day
- 3 Talk Talk Talk
- 4 Many hands make light work

Working in partnership with industry enables healthcare professionals to undertake effective, timely, holistic dressing trials in the clinical environment

Reference: Evaluating the performance of a carboxymethyl cellulose dressing: a UK summary of Kerracel user evaluations (Wounds UK 2017 Poster Presentation)

Figure 1. 'Completing a product evaluation' checklist (Acton and Moyna, 2017a)

Week	Attendees	Objectives
Step 1. Get organised		
Week 1	<ul style="list-style-type: none"> ▶▶ Industry representative ▶▶ Tissue viability representative ▶▶ Ward manager 	<ul style="list-style-type: none"> <input type="checkbox"/> Notify staff of product evaluation and education sessions <input type="checkbox"/> Receive staff list for education <input type="checkbox"/> Prepare consent and evaluation forms <input type="checkbox"/> Project stock required
Week 2–3	<ul style="list-style-type: none"> ▶▶ Industry representative ▶▶ Tissue viability representative ▶▶ Ward manager 	<ul style="list-style-type: none"> <input type="checkbox"/> Deliver education sessions to staff involved (staff must be trained to before evaluation begins)
Step 2. Get busy		
Week 4–6	<ul style="list-style-type: none"> ▶▶ Industry representative ▶▶ Tissue viability representative ▶▶ Ward manager 	<ul style="list-style-type: none"> <input type="checkbox"/> Start product evaluation, with daily ward visits <input type="checkbox"/> Identify patients during handover to commence product evaluation <input type="checkbox"/> Conduct bi-weekly follow-up and update, using checklist
Step 3. Get results		
Week 7	<ul style="list-style-type: none"> ▶▶ Industry representative ▶▶ Tissue viability representative ▶▶ Ward manager 	<ul style="list-style-type: none"> <input type="checkbox"/> Evaluation closing meeting <input type="checkbox"/> Submit evaluation forms <input type="checkbox"/> Discuss results to determine if a change in practice is required

Figure 2. Example timetable for completing a product evaluation

EVALUATING THE PERFORMANCE OF KERRACEL DRESSING: A UK SUMMARY OF PRODUCT EVALUATIONS

Using the principles discussed, a product evaluation of KerraCel dressing was conducted by Guy’s and St Thomas’ NHS Foundation Trust. The evaluation aimed to determine primarily clinician acceptability, and secondly clinical performance and efficacy of KerraCel dressings for a wide range of wound types (Acton and Moyna, 2017b) compared to a comparator carboxymethyl cellulose (CMC) fibre dressing that was currently in use.

KerraCel is a highly absorbent gelling fibre dressing used in the management of partial and full-thickness chronic and acute wounds of various aetiologies. This CMC dressing forms a soothing gel on contact with exudate that enables the dressing to conform to the contours of the wound bed. It locks in exudate to protect the periwound skin from maceration, whilst maintaining a moist wound environment to promote healing. In a 20-patient, non-comparative evaluation, KerraCel dressing has been shown to have a longer wear time when compared with the previous CMC dressing (Stephen-Haynes et al, 2017).

Method

The KerraCel dressings were evaluated on a wide range of wound types. The primary outcome measure was clinician acceptability. Wound size, level of periwound maceration, and level and type of exudate were also monitored before and during KerraCel use. Wounds were assessed at the end of the evaluation period, which ranged from >1 week to <4 weeks. Clinicians rated the change in clinical markers following the treatment period, including pain and composition of the wound bed, and how easy it was to use and remove compared to previous dressing used.

Results

The evaluation was conducted among 29 patients, and there was varied aetiology of pressure ulcers, diabetic foot ulcers, leg ulcers and dehisced surgical wounds.

Clinicians were asked to identify whether KerraCel was easy to remove and use in comparison to their previous dressing choice: 37% of clinicians stated there was ‘some or much improvement’ while 59% stated ‘no change,’ compared with previously used dressings, indicating that KerraCel worked as well as or better than the previous dressing.

Box 1. A case study

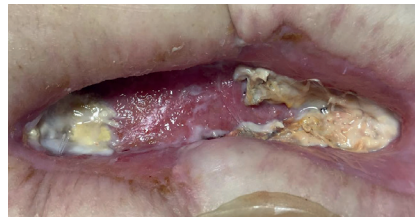
A 60-year-old patient presented with a dehisced abdominal wound following bowel surgery. They also had pneumonia, septic shock and multi-organ failure.

The wound had been present for 6 weeks and had been cleansed with a PHMB wound irrigation solution, medical-grade honey and a primary wound contact layer. A wound pad was used on top and secured with tegaderm film. For the product evaluation, the primary wound contact layer was changed to KerraCel and the wound dressing was changed daily.

After 2 weeks, the clinician reported that the wound was less sloughy and the exudate was better managed.



Start of the product evaluation



At 2 weeks

Conclusion

In this product evaluation, clinicians deemed KerraCel dressings to have met or exceeded their expectations (96%) compared with the previously used gelling fibre dressings for exudate management. Exudate management remains a primary clinical challenge in wound management, and this evaluation shows that KerraCel possesses positive attributes for exudate management, while also demonstrating good clinician and patient acceptability and a positive impact on wound outcomes on a wide range of wound aetiologies.

SUMMARY

Collecting, analysing and implementing real-world evidence has a vital role to play in informing best practice in wound care and treatment. Working partnerships with industry can enable the performance of these important and necessary evaluations, in a timely manner and with successful outcomes that bring about positive change in clinical practice in this challenging therapeutic area.

This summary of evaluations indicates the KerraCel dressing provides clinical equivalence and acceptability to previously used gelling fibre dressings for exudate management. Exudate management remains a primary clinical challenge in wound management, and the KerraCel dressing showed positive attributes in relation to maintaining a moist wound healing whilst reducing the risk of complications to the surrounding skin associated with poor exudate management (Jones et al, 2017).

By using the resources of both industry and healthcare professionals, we can conduct evaluations to contribute to evidence-based practice with the ultimate aim to benefit patient outcomes, while also examining cost effectiveness for the organisation.



Declaration

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Positive wound progression was recorded by clinicians along with good patient acceptability for the objectives set at the beginning of the treatment. In total, 96% of clinicians stated that it ‘met’ or ‘exceeded’ their expectation for fibre dressings. Endorsements for the product were high, with 100% of clinicians stating they were happy to continue using KerraCel dressings, with the most common reasons being that it locked away exudate, maintained a moist wound environment to aid wound healing and there was a high patient acceptability.

In total, 40% of wounds were identified as moist, 40% were identified with moderate exudate, and the remaining were identified as wet. The exudate management properties of the dressing during the evaluation period were recorded, with 90% of clinicians indicating KerraCel dressings were ‘good or very good’ and 10% stating they were still ‘adequate’ at maintaining a moist healing environment compared to the previous dressing choice. Clinician assessment at the end of the evaluation period described the wounds as having less exudate and more granulation tissue. Overall, there was a reduction in wound size, and the surrounding skin condition and periwound maceration were improved (*Box 1*).