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ORIGINAL ARTICLE

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Clinical performance characteristics for bordered foam dressings in the treatment of complex wounds: An international wound dressing technology expert panel review

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Abstract

The aim of this article is to identify and describe clinical practice performance characteristics for bordered foam dressings in the treatment of complex wounds. Our recently published systematic review of outcomes and applied measurement instruments for the use of bordered foam dressings in complex wounds has led to us identifying a range of important clinical and patient-centred issues related to this dressing class. Specifically, here, we focus on an overview of performance criteria in the areas of application, adhesion, exudate management and debridement functions of bordered foam dressings. Our hope is that by highlighting the clinical performance criteria, future testing standards for wound

dressings will more closely match our clinical expectations and, thereby, assist clinicians to make better wound treatment choices based on meaningful and clinically relevant dressing product performance standards. complex wounds, complex wound care, treatment, bordered foam dressings, dressing performance.

KEYWORDS

bordered foam dressings, complex wounds, dressing performance, treatment

Key Messages

- bordered foam dressings are an important component of the treatment of complex and chronic wounds yet the standards for testing their clinical performance and rudimentary at best
- compared to the pharmaceutical industry, wound care dressing products do not have a rigorous, evidence based and clinically meaningful set of performance standards
- clinicians are not able to use the current performance standards for bordered foam dressing to differentiate between available products. This situation is potentially wasteful of resources and may result in sub-optimal patient outcomes
- wound research is limited by the current variation of effectiveness within the bordered foam dressing class because not all dressings perform in a comparable way
- we propose a number of essential performance criteria for this class of dressings that may form the basis of future performance standards

1 | BACKGROUND

Millions of people worldwide live with complex wounds and these wounds can have a major negative impact on individuals' quality of life through pain, suffering and economic burden. The prevalence of these wounds is relatively high and similar to that of heart failure, affecting 6.5 million people in the United States (i.e., approximately 2% of the US population) and leading to an expenditure of US $28 billion per year to the American Medicare system[1] and similar rates are seen in other developed countries across the world.[2] Bordered foam dressings (BFDs) are used for a wide variety of wound types, however here we focus on the management of complex wounds as we believe that this class of wound best highlights the performance requirements made of BFDs in the effective treatment of the wound. The use of BFDs is often a fundamental aspect of the treatment regimen for complex wounds and there are an ever-growing number of dressings on the market: The global foam dressing market size alone was valued at 1.67 billion US dollars in 2021 and is projected to expand at a compound annual growth rate of 4.7% from 2022 to 2030.[3]

Currently, there are minimal international performance standards for BFDs, and where standards exist, they are poorly conceptualised and of minimal relevance to the real-world clinical setting.[4] This situation is in stark contrast to that of the pharmaceutical industry where formulation and clinical efficacy standards are rigorously applied internationally. The consequence of this anomaly in the wound treatment sector is that clinicians may, therefore, be dependent on advertising, marketing, and individual experience when making clinical decisions about which product to use for this specific wound type. One would expect that clinicians would also refer to published, high-quality research findings as part of the clinical decision-making process when deciding on an appropriate dressing. However, once again, we find that there is a paucity of comparative research to distinguish the performance of individual dressing products within the same class. The use of BFDs in the treatment of complex wounds is commonly seen in practice where a clinician determines that the healing of a patient's wound would be enhanced by the properties and characteristics of this class of dressings. However, as mentioned previously, the treating clinician typically has minimal laboratory or clinical research data from which to draw on to make this important decision. The potential results of the choice of an inadequate dressing may include delayed wound healing,[5] poor patient-related outcomes (such as pain), increased complications (eg, risk of increased microbial burden and biofilm development, peri-wound

maceration, medical adhesive-related skin injury [MARSI] or allergic or irritant contact dermatitis), and cost ineffectiveness, or a combination of these.

This situation is perplexing, and we contend that this is no longer acceptable in modern clinical practice. Our current inability to justify the choice of the best BFD to treat the wound is therefore alarming.[6]

The goal of this study was to provide clinicians with a range of clinical performance characteristics for the assessment of various currently available BFDs. Our approach in describing these performance criteria is to build and expand on our recently published systematic review on outcome domains and measurements used in studies of BFDs.[7] The systematic review identified five outcome domains being (1) impact on life, (2) dressing performance, (3) pathophysiological manifestations, (4) resource use, and (5) adverse events. Within each outcome domain, there are multiple sub-outcomes that can be used to structure, define, and explain specific performance criteria for dressings, which can then be used to compare different dressings within the bordered foam class of products. Another benefit of this structured approach may be that future wound research will use similar study endpoints to facilitate comparison of study outcomes.

2 | CLINICAL PRACTICE

BFDs provide clinicians with important advantages and choices for the treatment of several complex wound types such as diabetic foot ulcers (DFUs), pressure ulcers/injuries (PUs/PIs) and low to moderately exudating venous leg ulcers (VLUs), we acknowledge that there has been debate on the appropriateness of BFDs for the treatment of VLUs.[8,9] In addition, some specific dressings in this class have been shown to also be effective in the prevention of hospital-acquired PUs/PIs, however this feature is outside the scope of this paper.

Given that the current standards for this dressing class in terms of the formulation of the materials used, construction methods, moisture management performance and adherence characteristics are rudimentary, it is important that clinicians are provided with clear guidance on the essential characteristics of an effective BFD. We acknowledge that no single dressing will meet all the needs of the multitude of chronic/complex wound types encountered in clinical practice, still, we believe that there remains a need to clearly define important clinical performance criteria. To this end, the goal of this paper is to outline these criteria and to build on recently published work in this area.[7]

3 | DRESSING PERFORMANCE

3.1 | Dressing application

The application characteristics of BFD dressings relate firstly to the ease of application of the dressing to the relevant anatomical position of the wound. This may comprise a relatively flat and uncomplicated surface such as the sacrum or a more challenging surface such as the curvatures of the foot. A wound located at a joint, such as the elbow or knee, presents additional challenges because of the need for the dressing to flex especially during activities as well as adhere to the peri-wound skin and remain attached throughout the intended period of use. Wounds may also be located in concave anatomical locations, such as the axillae (where moisture is also relatively high), and require special consideration. In addition, BFDs should ideally allow showering with the dressing during the usage time but should not adhere too strongly to cause a medical adhesive related skin injury (MARSI) during removal (as discussed in more detailed later). The consequences of the above-mentioned requirements of BFD are that the dressings must therefore be available in a range of sizes and shapes to accommodate various wound dimensions and possess the requisite conformability to accommodate complex curved anatomical features such as the breast or the axilla.[10] Dressings are also required to feature flexibility in order to remain attached on or around joints during normal flexure of the joint. The required flexibility/conformity function is fundamentally influenced by the properties of the materials used for the dressing as well as by the construction methods of the dressing.[11] In addition to these requirements, dressings may need to function as intended whilst being subjected to additional mechanical loads, for example, in conjunction with orthotic offloading devices in the management of DFUs and under compression systems in VLU. These additional requirements will be dealt with in more detail under the heading of exudate management. Dressings applied incorrectly could lead to deleterious consequences. The steps for dressing application should be intuitive and easy to follow by patients and their families who have limited knowledge of wound care but are more involved in self-management. Complicated procedures can be frustrating and counterproductive leading to treatment non-compliance.

3.2 | Essential clinical features

- Availability of wide range of sizes appropriate to common wound shapes and dimensions

- Ease of application to a wide variety of anatomical sites
- Conformability to both convex and concave surfaces
- Flexibility to allow range of motion at joints
- Impervious to water ingress yet allows water vapour transpiration
- Retention of function under repeated external mechanical loading such as during walking

3.3 | Dressing adhesion

Central to the assessment of the application characteristics of BFDs is that of adhesion to the peri-wound skin. Adhesion of the dressing is obviously important for delivering moist wound environment and for the containment of the exudate that the dressing is being used to do. Therefore, dislodgement of the dressing entirely along the border presents a failure of its intended function in terms of wound healing and exposes the patient to the risk of infection of the wound, discomfort, and pain as well as social embarrassment, for example, because of leakage of exudate to clothing or increased wound odours. Often the early signs of the loss of adhesive function of a BFD are seen with the rolling of the bordered adhesive edge of the dressing. This is usually the result of friction between the dressing and an external surface such as bed sheets or other external surface such as overly tight clothing or the ingress of excess exudate not contained within the core of the dressing.[12] Clinicians are faced with balancing the required adhesive needs to ensure that the dressing remains in place for the intended duration with the need to protect the peri-wound skin from MARSI, associated discomfort and pain to the patient that may result from an overly aggressive adhesive and repeated dressing changes. Detachment of the epidermis at the delicate wound edges and skin around the wound from repeated dressing changes, which is a form of MARSI, is a potentially serious problem that can lead to local inflammation, loss of skin barrier function, and risk of dermatitis and/or infection.[13-15] The actual formulation of the adhesive used in dressings and the surface topography of the adhesive borders varies between manufactures as does the shape and surface area of the adhesive layer over the wound facing surface. In some dressings the adhesive surface is localised to the border area of the dressing whilst in others it covers the entire wound contact surface such as dressings with tacky soft silicone. Adhesives may be relatively aggressive, based on the force that is required to remove the dressing when a change is required. Dressings with acrylic adhesives are generally regarded as representing more aggressive adhesive qualities followed by polyurethane adhesives. Soft silicone adhesive dressings are classed as the least aggressive in adhesion to the peri-wound skin.[16,17] To ensure secure adhesion and prolonged wear, the wound edge with the adhesive component should cover the undamaged, intact skin, leaving a margin of 3–4 cm beyond the wound edge, if possible. It is important to note that the technique used by the clinician to remove the dressing also plays a role in whether the skin near the wound can be damaged. In recent advice for the prevention of MARSI, clinicians are urged to slowly remove the dressing at a low angle to the skin to reduce the potential for skin stripping during dressing removal which is associated with the viscoelastic response of skin – that stiffness more when it is pulled rapidly.[11,18-20]

3.4 | Essential clinical features

- Adhesive ability – balance between adhesion and potential to damage peri-wound skin
- Resistance to shearing forces
- Avoidance of skin stripping at removal and reapplication
- Wear time – remains adhered for required time
- Does not leak exudate from detached boarded edges
- Minimises pain and discomfort at removal
- Does not leave dressing material in the wound or peri-wound surfaces following removal

3.5 | Exudate management

The principal function of a BFD is to foster wound healing through the effective management of wound exudate and to maintain a moist environment and physiological temperature level whether used as a primary or secondary dressing. In addition, these dressings provide mechanical protection from external loads on the wound. These performance functions are inextricably linked to the formulation of dressing material components, principally the foam, spreading layer (if present), and backing film of the dressing, and to the methods and processes used to combine these components into a final dressing product.

Chronic wounds of various aetiologies, whether infected or not, for which BFDs are indicated are usually associated with moderate to heavy wound exudate.[21] This fluid is characterised by the presence of many organic substances such as proteolytic enzymes that in high concentration and volumes, and if not effectively contained by the dressing materials, can impede wound healing, damage the peri-wound skin structure, and thereby, increase the risk for infection. Chronic wound exudates can contain dead or living bacteria, fibrin, matrix metalloproteases, and other substances that can impede wound healing. The treatment goal is to maintain a moist wound healing environment under FBD while transporting and

trapping excess amounts of wound exudate within the core of the dressing and away from the wound bed to prevent damage to the peri-wound skin. The ability of the dressing to maintain a moist wound healing environment is also dependant on the dressing's performance in terms of moisture vapour transmission.

Wound exudate presents in a variety of compositions and viscosities depending on the hydration status, wound aetiology and physiology and the presence or absence of bacteria in the form of biofilm and or active acute infection of the wound, including by fungi. The variability in the viscosity and volume of wound exudates presents a challenge to clinicians when choosing from several available BFDs. As mentioned previously, the ability of a dressing to achieve treatment goals, such as effective exudate management, is closely linked to its material composition and structure. Careful assessment of local wound infection may be helpful in deciding whether to use a BFD with antimicrobial barriers to treat bioburden in wounds. The clinician needs to ensure that the selected dressing has the capacity to both transport and contain the exudate from the wound bed to the internal foam core components. In addition, the dressing should not allow the excess exudate to contact the peri-wound skin nor should the dressing leak exudate through detachment of the adhesive border which would precipitate skin maceration, irritant dermatitis, pain and also pose an infection risk. Protection of the fragile healing wound bed from trauma associated with either static or dynamic mechanical loads, such as when the dressing is used under an orthotic off-loading device in DFU management, a further important consideration in dressing selection as is the issue of the level of adherence of the dressing to the wound bed and the potential for MARSI when the dressing is changed. There are significant differences between currently available BFDs in terms of composition of materials used, construction methods and adhesives. Consequently, the overall performance of this class of dressings in the area of exudate management also varies. Unfortunately, there are currently no clinically relevant standards for these performance criteria that would enable clinicians to compare different BFD products.

3.6 | Essential clinical features

- Ability to maintain an optimal moist wound healing environment through absorption and water vapour transmission.
- Capacity to transport and trap wound exudate regardless of viscosity and volume
- Ability to move exudate away from the wound bed.
- Maintains ability to manage exudate when used in conjunction with graduated venous compression systems or orthotic off-loading devices
- Ability to maintain a physiological temperature at the wound bed
- Resistance to leakage/strike through from detachment of adhesive layer from the peri-wound skin.
- Gentle adhesion to avoid wound bed and/or peri-wound trauma
- Capacity to protect wound bed from external mechanical loads

3.7 | Debridement functions

An important element of chronic wound healing is that of the debridement of devitalised tissue from the wound bed to support fibroblast proliferation[22,23] extracellular matrix synthesis and enable the establishment and growth of granulation tissue. The body's natural process of debridement is termed autolytic debridement and involves the action of phagocytic cells such as macrophages and lymphocytes. Autolytic debridement is a relatively slow process and requires a moist environment to enable the action of phagocytic cells in the removal of devitalised, injured, or infected tissue.[24-26] It should be noted that autolytic debridement is indicated where the area for debridement is not too extensive. Autolytic debridement is contra-indicated in wounds with extensive areas of devitalised tissue particularly where the tissue is dry[27] because of the slowness of the process and increased risk of further delayed healing, in these cases, other debridement techniques may be more appropriate. In addition, it may not be appropriate for wounds with active wound infection (when rapid removal of dead tissue that harboured bacteria is desirable), exposed tendon and bone, and in severe cases of neutropenia and for immunocompromised patients.[24]

Clinicians may determine, following careful assessment of a wound, that it is appropriate to promote autolytic debridement and may choose to use BFD to assist in the debridement process. A well-designed BFD can be used as either a primary dressing or as a secondary dressing in conjunction with another dressing product in direct contact with the wound bed. A BFD can assist in maintaining a moist wound environment that promotes autolytic debridement; however, clinicians must monitor whether an appropriate level of moisture is maintained. There is a danger of maceration of surrounding peri-wound skin should exudate/moisture levels become excessive.[21] BFDs also can assist in the removal of slough and wound debris through the entrapment of the material in the absorbent pad of the dressing and its removal at dressing change.

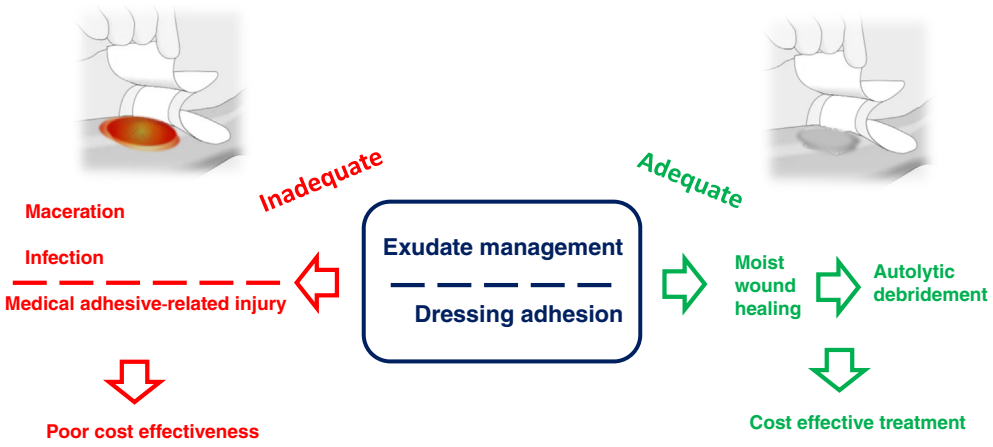

FIGURE 1 Adequate vs inadequate clinical performance of a bordered foam dressing

3.8 | Essential clinical features

- Effective management and maintenance of moist wound environment
- Ability to adhere to and remove devitalised tissue, slough, and wound debris at dressing removal
- Dressing does not adhere to wound bed causing trauma at removal (secondary effect)

4 | CONCLUSION

BFDs provide clinicians with an important treatment choice in the management of chronic/complex wounds. The effectiveness of this dressing class in treating chronic complex wounds is inextricably linked to the performance of the specific dressing and the performance of the dressing is dependent on the formulation of the dressing components and the methods used to combine the components into the final dressing product. These multiple components must function synergistically as a coherent whole and achieve a set of important clinical performance criteria to achieve effective wound healing. The current international standards that relate to the testing of BFDs are rudimentary and disconnected from the actual clinical environment where BFDs are used. The consequence of this unsatisfactory situation is that clinicians have no means with which to compare the performance of this important class of dressing product apart from using the product and seeing what the outcome may be, in a trial-and-error approach. The situation for the patient is similar in the sense that they will be the recipient of a dressing product whose performance is only minimally assessed to meet their specific needs. The current situation is unsatisfactory from a clinical perspective, patient experience and overall cost effectiveness management. We summarise the balance between dressing performance and outcome in Figure 1.

Our goal in this study is to raise awareness about the need to better standardize the performance of BFD through the development of clear, clinically meaningful, objective performance standards for this class of dressings. Through this work, we hope that future research and evaluation of the performance of these dressings will improve with the ultimate goal of better helping patients to heal their wounds.

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DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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