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Use of DACCcoated dressings in diabetic foot ulcers: A case series

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A dialkylcarbamoylchloride-coated dressing was assessed for its ability to manage or prevent infection – and promote healing – in a case series of diabetic foot ulcers. Target ulcers were treated with good traditional wound care and dressed with the test dressing for a period of up to 4 weeks. Reductions in the number and severity of the symptoms and signs of infection were seen in the large majority of ulcers, and wound size decreased in all, during the study period. A larger clinical trial is required to confirm these findings.

t is estimated that caring for people in the UK with diabetes (2-3% of L population) consumes 5% of all NHS resources, 20% of that expenditure being attributable to the management of foot problems alone (Boulton, 2004). Infection of diabetic foot ulcers has been established as a delay to healing, a cause of wound deterioration and frequently precedes lowerlimb amputation (Dow et al, 1999). Thus, preventing and addressing infection are of central concern in the management of diabetic foot ulceration. Antimicrobial dressings play a role in reducing bioburden, decreasing the risk of infection, and creating an environment that supports the normal sequence of wound healing (Mulder et al, 2007).

This article describes a 19-person case series in which 29 diabetic foot wounds were dressed with products from a dialkylcarbamoylchloride (DACC)-coated dressing range.

Aims

The primary objective was to evaluate the ability of the test dressing range to reduce the symptoms and signs – and risk – of infection in diabetic foot ulcers. Secondary objectives were to assess a range of wound parameters, including maceration, malodour and healing, for change during the course of treatment, and also to obtain patient and clinician feedback on use of the dressings.

Method

The investigation was designed as a singlecentre, open, non-randomised case series. People attending a specialist podiatry clinic with active diabetic foot ulceration were enrolled when they met the inclusion criteria and consented. Data generated from this study are presented in a descriptive manner. No hypothesis testing was planned for this descriptive investigation.

Each participant was treated according to local clinical practice and evaluated over a

Article points

- 1. Infection of diabetic foot ulcers requires careful, urgent management.
- In the present case series clinical signs of local infection were amelorated by the end of the 4 weeks' treatment with dialkylcarbamoylchloridecoated test dressings.
- Dressing use resulted in reductions in the number and severity of the signs and symptoms of local wound infections, and overall wound size.

Keywords

- Antimicrobial dressing
- DACC-coated dressing
- Infection

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Page points

- 1. All participants received traditional wound care as part of their treatment (debridement and offloading appropriate for their foot and wound type) and systemic antibiotics were used concomitantly if judged necessary by the investigators.
- 2. DACC a fatty acid derivative – binds bacteria, without a chemically active agent, through a process of hydrophobic interaction between the surface of bacterial cells and the coating of the dressing fibres.
- 3. By irreversibly binding, rather than killing, the bacterial cells the test dressings do not promote endotoxin release from dead bacteria cells.

treatment period of 4 weeks or until the ulcer healed, whichever occurred first. Baseline participant demographic data and wound history were recorded at the first consultation and wound progress was monitored at weekly visits thereafter. Following a demonstration of the dressing's application, betweenclinic appointment dressing changes were undertaken, according to local clinical practice, by the participant or their carer.

All participants received traditional wound care as part of their treatment (debridement and offloading appropriate for their foot and wound type). Systemic antibiotics were used concomitantly if judged necessary by the investigators, or regimens completed from prescriptions commenced prior to enrolment.

Both patients and clinicians were asked to report on their experience of using the dressings, scoring their experience on a scale where 1 was "excellent" and 5 "unacceptable". A free-text comments box was also offered for feedback.

Inclusion and exclusion criteria

- People enrolled in this evaluation:
- Had either type 1 or 2 diabetes.
- Had peripheral neuropathy (demonstrated by sensory loss to a 10-g monofilament).
- Were aged between 18 and 80 years.
- Presented with a moist diabetic foot wound that conformed to the manufacturer's instructions for use.
- Had a vascular supply capable of supporting healing (demonstrated by the presence of at least one palpable foot pulse).

People were excluded from this evaluation if:

- They had participated in a previous study in the past 28 days.
- Had a positive history of poor compliance with prescribed treatment regimens.

Test dressings

A range of antimicrobial dressings are currently available for use in diabetic foot ulceration. Dressings impregnated with ionic silver, iodine, honey and polyhexamethylene biguanide address local wound microbial activities, however DACC-coated dressings offer an alternative approach to the management of wound bioburden (Kammerlander et al, 2008; Hampton, 2010), and may be used prophylactically in wounds at risk of infection or in unclean, colonised or infected exuding wounds (Derbyshire 2010).

DACC - a fatty acid derivative - binds bacteria, without a chemically active agent, through a process of hydrophobic interaction between the surface of bacterial cells and the coating of the dressing fibres. Most bacterial and fungal cells found in wounds express cell surface hydrophobicity - the more pathogenic the bacteria, the more hydrophobic they tend to be - making them highly susceptible to DACC (Ljungh et al, 2006). Once microbes are bound by the DACC-coating they are unable to move or multiply. In as little as 30 seconds after contact with the wound bed the DACC-coated dressing attracts and binds microorganisms - including Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans (Ljungh et al, 2006). Unlike many antimicrobial dressing types, the mode of action of DACC does not allow for the development of microbial resistance, is not cytotoxic to the body's own cells, and - by irreversibly binding, rather than killing, the bacterial cells - does not promote endotoxin release from dead bacteria cells.

DACC-coated dressings are available in six formats: round swabs (for deep wounds); amorphous hydrogel-coated swabs (for necrotic wounds); hydroactive gel sheets (for low to moderately exuding wounds); dressing pads (for moderately to heavily exuding wounds); swabs (for surface or deep wounds); and ribbon gauze (for deep or cavity wounds; all Cutimed Sorbact, BSN Medical, Hull). In the present case series, the format of the DACC-coated dressing was selected by the clinician based on its appropriateness for the wound in question.

Test dressings were held in place with either a tape (Hypafix; BSN Medical) or a conformable retention bandage (Easifix K; BSN Medical). Secondary dressings were absorbent foam dressings (Cutimed Siltec; BSN Medical), or Melolin (Smith & Nephew, Hull). In wounds with high exudate levels the test dressing was used in its absorbent pad formulation, which does not require a secondary dressing.

It was agreed by the local clinical governance committee that research ethics committee approval was not required for this study because it was an in-market evaluation of a CE-marked dressing in accordance with its instructions for use.

Results

Nineteen people (13 men; 6 women) with 29 wounds were enrolled. The average age of participants was 60 years (median age, 52 years; range, 27–79 years). The average duration of active ulceration at the time of enrolment was 11 months (range, 3 weeks–9 years). The average wound size was 4919 mm³ (range, 34500–12 mm³). One individual case is described in *Box 1*.

Infection

Of the 29 wounds, 24 had a positive history of infection prior to enrolment. Twentytwo wounds showed two or more signs of infection (i.e. erythema, heat, oedema, pain, high exudate levels; Lipsky et al, 2006) at baseline and 21 were receiving systemic antibiotic therapy for the treatment of wound-related infection at enrolment, with a further two receiving systemic antibiotic therapy for infections unrelated to their foot wound (gangrenous finger; chest infection; *Appendix I*). The seven wounds with fewer than two signs of infection at enrolment were considered to be at high risk of infection or reinfection.

By study end, all 29 wounds had one or no signs of local infection (*Table 1*). Of the eight wounds with maceration at their margins at enrolment, seven resolved during the 28-day wear time. Exudate levels reduced during the investigation period in all 24 wounds with high volume exudate at enrolment but one (23/24; 96%); the one wound with ongoing high exudate did, however, reduce in size and improvements in the quality of the wound margins were noted by the investigators.

All 19 wounds with associated erythema at enrolment experienced resolution of this sign by the end of the evaluation period.

Six wounds on three participants were associated with malodour at enrolment. In all of these cases the malodour resolved during the course of the treatment period.

Wound pain in this group – with its high incidence of peripheral neuropathy – was expectedly low; only six wounds on three participants were associated with any level of pain. During the evaluation period all three participants with wound pain at enrolment reported reductions in this measure by study end: one reported severe pain reducing to mild pain; the second moderate pain reducing to mild; and the third mild pain that was resolved by study end.

Healing

All 29 wounds reduced in size from enrolment to the end of the evaluation period (*Table 2*). Eight (27.6%) wounds healed completely, and a further 20 (69.0%) showed a reduction of >50% in size – with 34.5% (10/29) reduced by >75% of their size at enrolment.

Patient and clinician assessment

The dressing was well-received by both participants (or carers) and clinicians. All 19 (100%) participants scored the dressings as "excellent" for (i) comfort, (ii) acceptability and (iii) ease of use. Participant comments

Table 1. Change in five wound parameters from baseline to study end.								
	Wounds		Participants					
	Present at baseline (n)	Improved at study end (n [%])	Present at baseline (n)	Improved at study end (n [%])				
Maceration	8	7 (88)	6	5 (1)				
Erythema	19	19 (100)	11	11 (0)				
High exudate	24	23 (96)	15	14 (1)				
Pain	6	6 (100)	3	3 (0)				
Malodour	6	6 (100)	3	3 (0)				

Page points

- 1. Nineteen people (13 men; 6 women) with 29 wounds were enrolled.
- 2. Of the 29 wounds, 24 had a positive history of infection prior to enrolment and 22 wounds showed two or more signs of infection.
- 3. By study end, all wounds had one or no signs of local infection.
- 4. All wounds reduced in size from enrolment to the end of the evaluation period. Eight wounds healed completely, and a further 20 showed a reduction of >50% in size.

included: "easy to use" and "good around the toes". Likewise, the clinicians involved scored the dressings as "excellent" for all wounds for dressing performance in application and dressing change.

Test dressings were typically held in place with either a tape (e.g. Hypafix; BSN Medical) or a conformable retention bandage (e.g. Easifix K; BSN Medical). Secondary dressings were absorbent foam

Box 1. A case from the present series.

Mr C, 51-year-old man with type 2 diabetes diagnosed in 2001, has profound sensory neuropathy but palpable dorsalis pedis and posterior tibial pulses. He had a history of poor diabetes control with a long-standing HbA_{1c} level of 9.8% (84 mmol/mol).

Mr C was admitted to hospital for systemic infection resulting from necrosis and osteomyelitis of the right 1st metatarsal phalangeal joint in July 2006. Following surgery and aggressive antibiotic therapy, Mr C's wound healed in January 2007 but he experienced recurrent breakdowns over the surgery site – despite the provision of various offloading modalities – in the years following. Mr C's job made it difficult for him to attend the podiatry clinic as regularly as required.

In April 2010 Mr C presented with reulceration of the surgical site resulting from the build-up of callus and incorrectly worn orthoses (Figure 1). On follow-up, the area had blistered, the foot was warm to the touch and erythema surrounded the wound site (Figure 2). Mr C was commenced on a DACC-coated swab dressing (Cutimed Sorbact [BSN Medical, Hull]; absorbent pad version for exudate management) and carried out his own dressing changes between weekly podiatry reviews. The patient reported the dressing easy to apply and comfortable. By 14 May 2010 the erythema had resolved and the ulcer had reduced in size (Figure 3). By 24 May 2010 the ulcer had healed. At the time of writing the wound remains healed.



Figure 1. Mr C's ulcer at enrolment.



Figure 2. Mr C's ulcer after a week of treatment.



Figure 3. Mr C's ulcer after a 10 days of treatment.

dressings (e.g. Cutimed Siltec; BSN Medical; used in 10 wounds), or Melolin (Smith & Nephew; eight wounds). In the remaining 11 wounds the test dressing was used in its pad formulation, which does not require a secondary dressing.

Discussion

The immunological impacts of diabetes render people with the condition highly susceptible to infection of open wounds. Increased bacterial burden in the wound increases the metabolic requirements of the tissues, stimulates a pro-inflammatory environment and encourages the migration of macrophages, leucocytes and monocytes, which - when poorly regulated by the impaired diabetic immune system - can negatively impact on healing. Bacteria also produce harmful cytokines which can lead to vasoconstriction and decreased blood flow to the wound (White et al, 2006). Thus ineffectively treated wound infection in people with diabetes often results in high morbidity and mortality.

The aim of this study was to demonstrate that a DACC-coated dressing range could effectively manage local wound infection in diabetic foot ulcers. All cases with local infection at enrolment had fewer or reduced symptoms by the end of the investigation period – however, the high rate of concomitant antibiotic therapy played an important role in these outcomes. Healing rates were good, with all wounds reduced

Table 2. Reduction in wound size from enrolment to study end.

Reduction in wound size† from enrolment					
to study end (%)	N(%)				
100‡	8 (27.6)				
75–99	10 (34.5)				
50–74	10 (34.5)				
25-49	1 (3.4)				
<25	0 (0)				
Total	29 (100)				
‡Healed.					

in size and eight wounds healed in this relatively short treatment period.

These results suggest that, in conjunction with good traditional wound care including appropriate systemic antibiotic therapy, the test dressings' have the ability to lift bacteria and debris from the site reduced the signs and symptoms of local infection. This supported healthy granulating tissue, free from critical colonisation, and ready for healing. The speed of positive change on the surrounding skin with regard to the improvement of exudate levels, maceration and erythema in the short treatment period indicates that the dressing works quickly to reduce the wound's bacterial load.

Conclusion

The DACC-coated range evaluated here met all of its objectives in terms of demonstrating its ability to provide a positive healing environment for people with diabetic foot wounds. Signs and symptoms of local infection, and its impact on a range of other wound parameters, were improved by study end. Wound healing was seen in less than 4 weeks in more than a quarter of cases, and wound exudate levels were reduced in 96% of cases. Both patients and clinicians reported a positive experience using the dressing as part of daily routine, at home or in the clinic.

In the high-risk diabetic foot, where infection frequently precedes life- and limb-threatening complications, the use of antimicrobial dressings can be an important part of a regimen for the safe and effective management of local infection, and can encourage wound closure. DACC-coated dressings are one such antimicrobial product in the clinician's toolkit for the management of the diabetic foot.

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Ulcer	History of target DFU infection prior to enrolment	≥2 signs of local infection at enrolment	Receiving DFU infection- related systemic antibiotic therapy at baseline	Commencement of DFU- related systemic antibiotic therapy during study perio	≥2 signs of local infection at study end	Healed at study end
1	YES	YES	YES	NO	NO	YES
2	YES	YES	YES	NO	NO	YES
3	YES	YES	YES	NO	NO	NO
4	NO	NO	NO	NO	NO	NO
5	YES	YES	YES	NO	NO	NO
6	YES	YES	YES	NO	NO	NO
7	YES	NO	YES	NO	NO	NO
8	NO	NO	NO	NO	NO	NO
9	NO	NO	NO*	NO NO	NO	NO
10	YES YES	NO YES	YES YES	NO	NO NO	NO NO
11 12	YES	YES	YES	NO	NO	NO
12	NO	NO	NO	NO	NO	NO
13	YES	YES	YES	NO	NO	NO
15	YES	YES	YES	NO	NO	YES
16	YES	YES	YES	NO	NO	YES
17	YES	YES	YES	NO	NO	YES
18	YES	YES	YES	NO	NO	YES
19	YES	YES	YES	NO	NO	NO
20	YES	YES	NO	YES	NO	NO
21	YES	YES	NO	NO	NO	YES
22	YES	YES	YES	NO	NO	NO
23	YES	YES	YES	NO	NO	NO
24	YES	YES	YES	NO	NO	NO
25	YES	YES	YES	NO	NO	NO
26	YES	YES	YES	NO	NO	NO
27	YES	YES	YES	NO	NO	NO
28	YES	YES	NO	NO	NO	YES
29	NO	NO	NO*	NO	NO	NO

"In the high-risk diabetic foot, where infection frequently precedes life- and limb-threatening complications, the use of antimicrobial dressings can be an important part of a regimen for the safe and effective management of local infection."