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ORIGINAL RESEARCH

Preliminary assessment of an adhesive gel barrier for the treatment of udder cleft dermatitis in dairy cows

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Abstract

Background: Udder cleft dermatitis (UCD) is increasingly recognised in dairy cows. Severe lesions present with foul odour and open wounds, resulting in pain and discomfort. There is no established treatment for UCD. This open-label pilot study aimed to investigate the potential for an adhesive gel barrier to treat UCD.

Methods: Two veterinary centres undertook the study on four farms. First, in five cows on one farm, proof-of-principle was sought in terms of benefit with weekly applications over 4 weeks, followed, second, by a small open-label study on a total of 25 cows on three other farms with weekly applications for up to 9 weeks.

Results: In the initial five cows, adverse events were not observed and there was marked improvement in the lesions. The subsequent 25 cows had UCD lesions ranging from grade 2 to 5 on day 0, and consistent improvements were seen over time, especially in terms of malodour, discharge, lesion depth and re-epithelisation.

Limitations: This is a small, uncontrolled, open-label study.

Conclusion: Adhesive gel barriers appear to offer a solution for the treatment and management of UCD and should now be tested in a larger controlled trial.

INTRODUCTION

Udder cleft dermatitis (UCD), also known as bovine ulcerative mammary dermatitis, udder foul, udder rot or udder intertrigo, is becoming an increasingly recognised skin problem impairing welfare and health in dairy cows. UCD affects either the fore-udder attachment with the ventral abdominal wall and/or the skin between the two udder halves, but particularly between the front two quarters.[1]

UCD lesions vary from mild erythema, small papules, pustules and crusts through to severe areas of skin affected with open wounds, necrotic and malodorous tissue, granulation tissue, pus and blood.[2] UCD may also increase the risk of clinical mastitis in the month following diagnosis,[2] although the common mastitis pathogens have not been found in abundance in UCD lesions.[3,4] Severe UCD lesions have been associated with non-responsive cases of embolic pneumonia,[5–7] featuring more frequently in the APHA Disease Surveillance reports in England and Wales.[8] Moreover, many practitioners will be familiar with the case presentation of haemorrhage from involvement and invasion of adjacent subcutaneous blood vessels,[8,9] although formal studies on this have not been reported.

There have been several published prevalence studies in randomly selected herds in Europe. Waller et al.[2] reported a prevalence of 18.4% in 1084 cows examined in 30 Swedish herds (of which 69% had mild lesions), Ekman et al.[10] found that 28% of 3479 cows in 98 of 99 Swedish herds studied had UCD (of which 68% had mild lesions), Riekerink et al.[11] noted that 5.2% of 948 animals within 16 out of 20 Dutch herds studied had UCD, and Groh et al.[12] reported that only 0.3% of 6208 cows examined in 152 German herds were affected (lesions were found in only 16 [10.5%] herds in total). The within-herd prevalence varied widely in these four studies: 0%–39% (mean 18.5%),[2] 0%–62% (varying from 0% to 43% for mild UCD and 0% to 33% for severe UCD lesions),[10] 0%–15%[11] and 0%–6.2% for all 152 herds and 0.9%–6.2% for the 16 herds with a positive UCD finding.[12]

There has been one reported prevalence study in the UK from a small region in the north-west of England, which found 10.6% (882/8302) of cows with UCD in 28 herds and a within-herd prevalence of 1.3%–26.2%.[13]

A number of different classification/scoring systems have been described based on the gross appearance and size of the lesion. One system, described by Riekerink et al.,[11] deems a cow to have UCD only if there is crusting, exudate or an open wound, whereas the

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other three systems[2,9,14] describe a cow as having UCD with any skin changes and divide the lesions into two categories (mild and severe). Mild lesions may exhibit erythema, hair loss, papules and/or small crusts but with no visible open wound (lower scores), while severe lesions are characterised by greater crusting, granulation tissue and open wounds (higher scores, increasing with greater size of the open wound). However, the system described by Ekman et al.[14] differs from those described by Persson Waller et al.[2] and Bouma et al.[9] by including the presence of large crusts without an open wound in the severe category.

The precise aetiology of UCD has not been elucidated but is likely to be multifactorial and polymicrobial as the lesions have been associated with mange mites,[15,16] treponemes[17] and bacterial colonisation.[4,18] A Dutch study found no evidence of infection with treponemes, fungi or mites but did detect the anaerobic bacteria *Trueperella pyogenes* and *Bacteroides pyogenes* more often in cattle with severe lesions.[4] This microbiota dysbiosis, with a higher proportion of the phylum Bacteroides and genus *Trueperella* in severe UCD cases, was also reported by Ekman et al.[3] Multiomics research studies suggest that the dysbiosis observed is manifest by a reduced diversity, increased proportion of certain bacteria and expression of virulence factors in severe UCD lesions, as well as different gene expression patterns leading to upregulation of inflammatory mediators when compared with healthy skin from the same body site, resulting in an impaired skin barrier, defective wound repair and a dysregulated inflammatory response.[19,20]

Cow-related factors such as udder conformation (e.g., deep udder relative to the hock, large front quarters, small angle between udder and abdominal wall) and parity, as well as herd-level environmental factors such as yield, type of cubicle base and length of cubicle, and use of a footbath, have been shown to determine the risk and severity of UCD.[9–11,21]

UCD lesions heal poorly and show similarities to human chronic wounds, such as pressure ulcers and venous leg ulcers[14,22]; both show delayed healing, which is a consequence of cellular and molecular imbalance in the wound.[19,20] The size of the wound has an effect on the likelihood of improvement; therefore, it is important to detect and treat lesions early. However, this does not often happen, and lesions tend to be detected at a late stage.[14]

Scientific research into the treatment and management of UCD in dairy cows is limited. Thus, treatment options are similarly limited. A randomised clinical trial by van Werven et al.[22] reported no effect of treating mild lesions with an alcohol-free film layer (Cavilon 3M). Daily treatment of more severe lesions with an enzyme (alginogel) for 12 weeks resulted in a 3.4 times greater likelihood of early-phase improvement compared to controls, but less than 10% of lesions healed during the 12-week treatment period. Alginogel is an enzymatic complex with propylene glycol and water that possesses debriding, antibacterial and absorbent properties while also maintaining a moist microenvironment, thus inhibiting and preventing biofilm formation.[23] A study in Swedish dairy herds by Ekman et al.[14] used a topical spray containing chelated copper and zinc daily for up to 28 days, depending on response, but found no difference in improvement in UCD status on day 56 after treatment started compared to untreated controls. However, Ekman et al.[14] did see a higher proportion of treated cows that moved from mild to severe lesions during the first 2 weeks of the study, compared with untreated controls, but a suggestion of the reverse of this for the last 4 weeks of the study (i.e., a higher proportion of treated cows that improved during days 28–56, albeit not significantly so).

In contrast, a non-peer-reviewed Dutch study using this same topical spray had shown some apparent efficacy, with 18 out of 22 mild UCD cases experiencing complete healing of the lesion, with a median time to this observation of 4 weeks (range 1–11 weeks), while 10 out of 12 with severe UCD showed improvement, of which one animal completely healed. The median time to first improvement was 5 weeks, with a range of 1–10 weeks.[24]

There have, to the authors' knowledge, been no previous studies on the treatment of UCD in dairy cattle in the UK. Topical antibiotic therapy is commonly used in practice due to the lack of alternative options with convincing efficacy data. Therefore, we aimed to investigate the potential of an adhesive gel barrier in the treatment of UCD in dairy cows, as this has shown promise in the treatment of bovine digital dermatitis[25]—a disease that may be associated with UCD.[17]

MATERIALS AND METHODS

The study was conducted in two stages on four herds where UCD had already been identified as being present by the veterinary centres either clinically or at postmortem examination but whose within-herd prevalence was not known.

- Stage 1: a 28-day observational study during October 2021 with five multiparous cows on one farm in the south-west of England (farm A) to establish that (i) there was apparent benefit of the adhesive gel barrier and (ii) there were no unexpected adverse events.
- Stage 2: this was a small open-label use study involving two separate veterinary practices (one private and one University-based) to assess the response to application of the adhesive gel barrier on three different farms (farms B, C, D) to cows with UCD.

Farm A (south-west England) had 360 milking Holstein–Friesian cows, averaging 8488 L/305 days at 3.23% protein and 3.93% butterfat with a somatic cell count (SCC) of 143,000 cells/mL. Cows were fed a

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TABLE 1 Description of the udder cleft dermatitis (UCD) scoring system used for lesion assessment, adapted from adapted from Ekman et al.[14]

Lesion score	Clinical appearance
1—no UCD	No signs of UCD or very mild skin changes, such as redness of the skin or a single papule or pustule in the area of the fore udder attachment.
2—mild UCD	Small papules/pustules or crusts, redness of the skin, serum exudation and/or hyperkeratosis, total size of crusts <5 × 5 cm.
3—severe UCD	Large crusts, with or without signs of score 1–2, total size of crusts ≥5 × 5 cm. No open wound.
4—severe UCD	Open wound, with or without signs of score 1–3, total size of wound and crusts <5 × 5 cm.
5—severe UCD	Open wound, with or without signs of score 1–3, total size of wound and crusts ≥5 × 5 cm.

total mixed ratio (TMR) and housed all-year-round in cubicles with straw bedding and milked twice a day in a herringbone-style milking parlour.

Farm B (eastern England) had 230 milking Holstein–Friesian cows, averaging 9800 L/305 days at 3.20% protein and 4.38% butterfat with an SCC of 99,000 cells/mL. Cows were fed a TMR and housed all-year-round in cubicles with mattress bases lined with fine sawdust (replaced twice daily) and access to a voluntary milking system.

Farm C (south-west England) had 310 milking Holstein–Friesian cows, averaging 7785 L/305 days at 3.59% protein and 4.57% butterfat with an SCC of 166,000 cells/mL. Cows were fed a TMR and housed all-year-round in cubicles with recycled manure solids bedding and milked twice a day in a herringbone-style milking parlour.

Farm D (south-west England) had 390 milking Holstein–Friesian cows, averaging 9549 L/305 days at 3.44% protein and 4.49% butterfat with an SCC of 103,000 cells/mL. Cows were fed a TMR and housed October to May in cubicles with sand bedding and milked twice a day in a herringbone-style milking parlour.

Animal inclusion criteria

The scoring system employed in this study was that described by Ekman et al.[14] (Table 1). A convenience sample of animals with active UCD lesions of at least 4 weeks' duration and generally with malodour but with no comorbidities was selected by the herdsperson. The cows selected in stage 1 had received previous treatments, while those in stage 2 had received no prior treatments. The exact duration of each lesion at the start of the study was not known.

The herdsperson was requested not to use any other topical product on the UCD lesions during the course of the study.

Treatment and data collection

Stage 1

The enrolled cows on each farm were visited by the same veterinarian once a week for a minimum of four successive weeks, between morning and afternoon milkings. The same veterinarian examined all the animals on farms C and D, but a different veterinarian examined farms A and B.

At each visit for each enrolled animal, the cow was examined in a handling crush with one hindlimb raised to facilitate full access to the entire udder cleft. The UCD lesion was assessed for malodour, wound exudate, lesion depth and signs of healing (scab formation, granulation tissue bed and re-epithelisation), and then cleaned with a 0.75% (w/w) povidone–iodine solution (Vetasept Povidone Iodine solution), dried with a clean paper towel and photographed. During the cleaning procedure, only necrotic tissue, exudate and loose crusts were removed.

The adhesive gel barrier, originally developed at the Department of Veterinary Medicine, University of Cambridge, UK,[25] was provided by NoBACZ Healthcare. It contains a biopolymer (shellac) plus low levels of copper/zinc ions, dissolved in standard alcohol. This was applied over the entire lesion and its margins, to an average depth of 3 mm of product, with a clean gloved hand. The product dries to form a robust, flexible, long-acting barrier. There are no 'wound-active' components within the product, but rather, its hydrophobic nature means that it repels the ingress of bacteria, detritus and water, thereby effectively shielding the wound and its microbiome from the surrounding environment and allowing natural healing to progress; the barrier is also resistant to biofilm formation.[25]

Each enrolled animal was evaluated for any adverse reaction at each visit, and the assessment of any benefit was performed by comparing the UCD lesion on days 0 and 28.

Stage 2

The materials and methods were largely as described for stage 1 above (although povidone–iodine solution was not used on farm B, where the wound was only cleaned with a dry paper towel). However, malodour, wound exudate, lesion depth and signs of healing (scab formation, granulation tissue bed, re-epithelisation) were also assessed by the examining veterinarian weekly and scored as better, the same as or worse than at the previous visit.

The change in lesion progression was graphed cumulatively over time with values of +1 if recorded as

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TABLE 2 Summary of 28-day observational data for the five cows included in stage 1 of the study.

Cow	Day 0—pre-application	Day 28—after four weekly applications of adhesive gel
A1	Two-month-old deep grade 3 lesion. Malodour, purulent and highly exudative.	Lesion fully dry with no discharge or malodour. Skin predominantly closed with granulation tissue present on the edges.
A2	Seven-month-old deep grade 3 lesion. Malodour, purulent and exudative with some bleeding.	Lesion mostly dry with parts of the skin healing.
A3	Two-month-old grade 2 lesion. Mostly superficial. Malodour and purulent.	Dry with no malodour. Scab formation over the lesion with granulation tissue underneath.
A4	Two-month-old grade 2 lesion. Mostly superficial. Exudative.	Dry with scab formation over the lesion.
A5	Six-month-old grade 2 lesion. Exudative.	Dry with scab formation over the lesion.

better versus the week before, 0 if no change and –1 if worse.

RESULTS

Stage 1

The five cows with UCD (grade 2 or 3) had not been responsive to standard treatments, including topical spray containing oxytetracycline twice a day in parlour (Table 2). The adhesive gel barrier was applied weekly for 4 weeks, with outcomes observed on day 28. No adverse events were observed and, in all cases, there was marked improvement in the lesions (Table 2).

Stage 2

Applications of the adhesive gel barrier were made weekly for up to 9 weeks on farm B ($n = 12$), 5 weeks on farm C ($n = 5$) and 4 weeks on farm D ($n = 8$) (Table 3). All the animals had active UCD lesions ranging from grade 2 to 5 at week 0 but, consistently, marked improvements were seen by the end of the treatment course (Figure 1). Figure 2 shows the week-by-week change in lesion appearance, being better for 76% (97/128) of all new observations, no change for 21% (27/128) and becoming worse for only 3% (4/128). Similarly, malodour, discharge, lesion depth and re-epithelisation were all improved over time; for example, observations at week 4 showed that, versus baseline (week 0), there was a 72% reduction in the number of lesions with malodour (18/25), a 44% reduction in the numbers with exudate (11/25), a 76% reduction in numbers with deep involvement of the subcutis (19/25) and a 76% increase in the number of lesions showing re-epithelialisation (19/25) (Figure 3). Further improvement was seen with the extended treatments, up to week 9, that were carried out on farm B (Figure 4), with all 12 cows having either no UCD (grade 1) or having reached a mild grade 2 lesion from an initial grade ranging from 3 to 5 at week 0.

DISCUSSION

We report encouraging first data on the use of an adhesive gel barrier to treat UCD in dairy cattle. Once-weekly application of this copper/zinc-containing biopolymer elicited no adverse effects in either stage 1 or stage 2 of the study. This contrasts with the study of Ekman et al.,[14] who reported that several cows appeared irritated by the daily topical application of a chelated copper and zinc spray, as evidenced by kicking and stepping. They suggested that it might be due to a stinging or unpleasant sensation in the wounds of certain cows. The same study also suggested an initial adverse effect on UCD lesions in the first 2 weeks of application, with a higher proportion of treated cows changing from mild to severe when compared with untreated controls, but the opposite was observed in the present study, with lesions clearly improving.

This small study showed that the adhesive gel barrier appeared to allow healing of both mild (equivalent to score 2 in the Ekman et al.[14] classification of 2021) and more severe (scores 3, 4 and 5) UCD lesions in dairy cattle, with marked reductions in malodour, exudate and depth of the lesion as well as increased signs of re-epithelialisation. Again, this contrasts to the findings of Ekman et al.,[14] whose study in Sweden found no benefit of once-daily topical spraying with chelated copper and zinc for up to 28 days in terms of improvement in UCD lesion status, compared to untreated control cows. However, further comparison between the two studies is not merited because (i) the copper/zinc concentrations, the overall formulations and the products' modes of action are very different; (ii) treatment regimens differed greatly; (iii) the present study is a case series with no untreated controls; (iv) in about half of the cases presented here, a dilute 0.75% (w/w) povidone–iodine solution, which is known to have some antibacterial effect,[26] was used in the cleaning of the wound before application, while only water or no solution was used in the other studies,[14,22] and also the study of Ekman et al.[14] demonstrated that animals with severe UCD lesions that only underwent thorough cleaning of the wound had a higher rate of improvement compared to cows with severe UCD that received neither cleaning nor treatment of the lesion; and (v) a veterinarian performed every lesion's

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TABLE 3 Examination and product application schedule for the adhesive gel barrier for each cow on the three farms in stage 2 of the study.

	Individual cow code where B, C and D refer to the specific farm																			
Week	B1	B2	B3	B4	B5	B6	B7	B8	B9	B10	B11	B12	C1	C2	C3	C4	C5	D1	D2	D3	D4	D5	D6	D7	D8
0	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
1	X	X	X	X	E	X	X	E	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2	X	X	X	X		X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
3	X	X	X	X		X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
4	X	X	E	X		X	E		X	X	X	X	X	X		X	X	E	E	E	E	E	E	E	E
5	X	X		X		X			X	E	X	X	E	E	E	E	E								
6	X	X		X		X			X		X	X													
7	E	X		X		X			X		X	E													
8		E		E		X			X		X														
9						E			E		E														

Note: $n = 25$ cows in total. 'X' denotes examination and application made. 'E' denotes examination only.

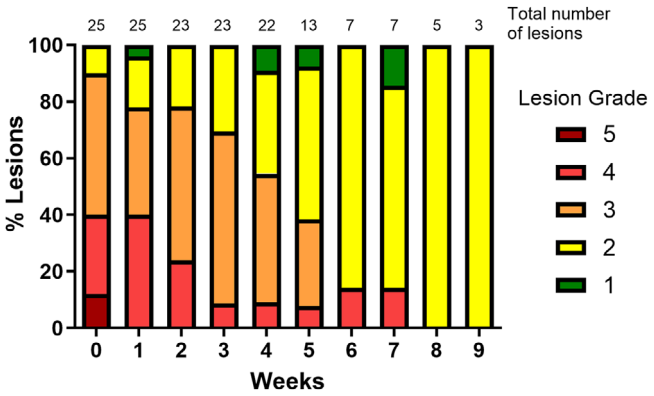

FIGURE 1 Lesion numbers and grade over the course of the 9-week study.

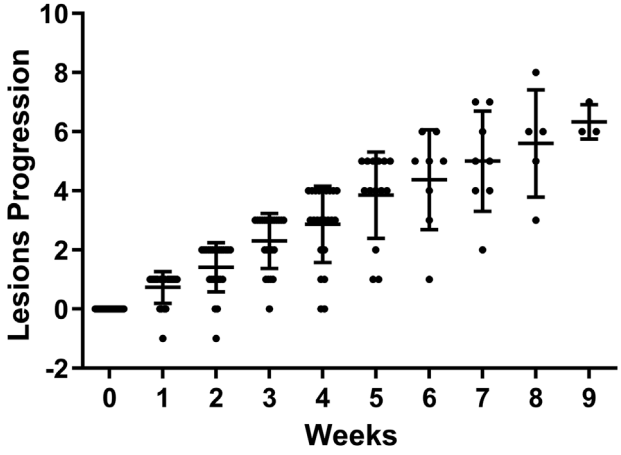

FIGURE 2 Cumulative lesion progression for all animals (filled circles) during the study, with median and interquartile ranges also shown (horizontal lines). Cumulative lesion progression was obtained by attributing a score of –1 if worse, 0 if the same or +1 if better compared to the previous week.

preparation and application of the barrier gel in this study whereas farm staff performed the majority of treatments in the other studies.

While the data from the current study with the adhesive gel barrier are most encouraging for a disease that has few treatment options once it is well established, it should be noted that spontaneous recovery can occur. Ekman et al.[14] followed 1106 cows for 1 year and demonstrated a 71% spontaneous recovery rate within 4 to 8 weeks for mild UCD lesions but only 6.5% for severe UCD lesions. Similarly, van Werven et al.[22] found only a 2.3% spontaneous recovery rate in control cows with severe UCD lesions (equivalent to scores of 4 and 5 in the Ekman et al.[14] classification). However, over the course of their 1-year observational study, Ekman et al.[14] also found that 47% of all affected cows had a recurrence; 24% of these had a second recurrence and 31% of these then had a third recurrence. Hence, the natural course of UCD lesions tends to be one of waxing and waning and then possibly recurring; although, if it advances from being a mild lesion, then the chances of spontaneous remission are low (<10%). As such, this study's finding of 76% (19/25) of animals having an improvement in their lesion

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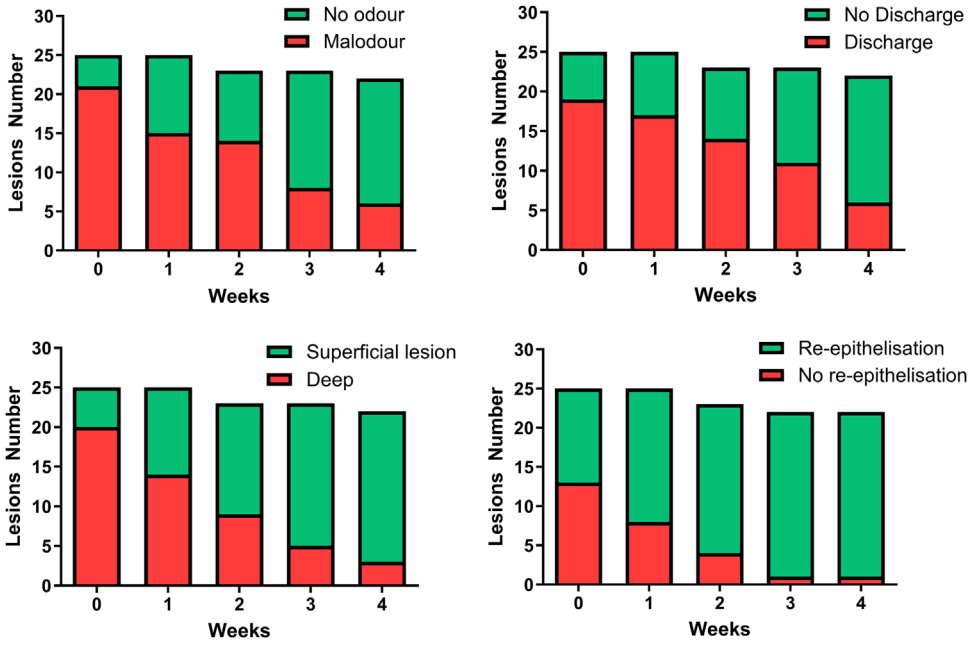

FIGURE 3 Outcomes after weekly applications of the adhesive gel barrier for 4 weeks in a total of 25 animals on three different farms. Not all animals could be followed on weeks 2 and 3 ($n = 23$) and week 4 ($n = 22$). On week 3, one animal had no assessment for re-epithelisation.

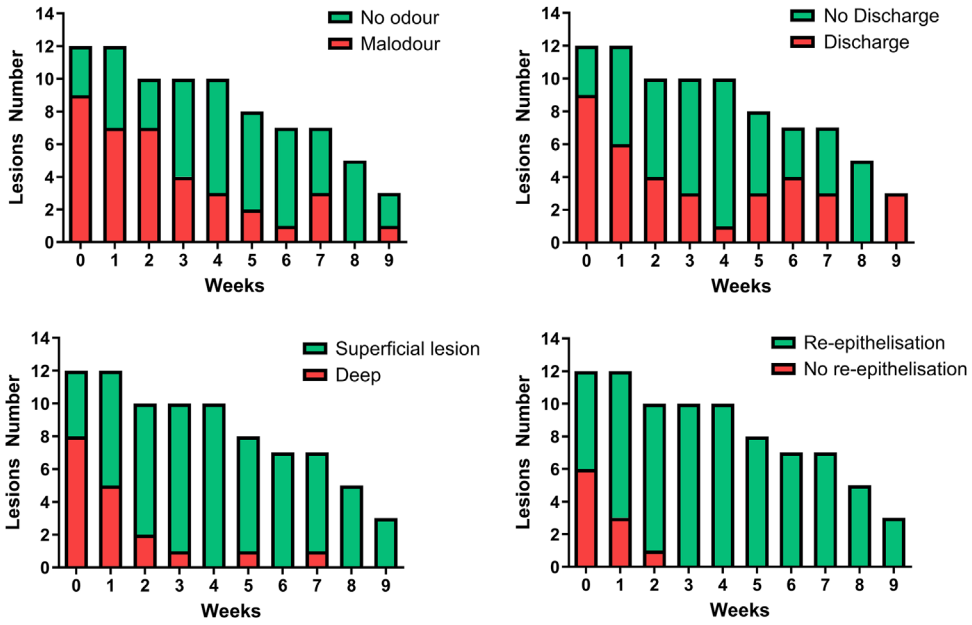

FIGURE 4 Outcomes after weekly applications of the adhesive gel barrier for up to 9 weeks on farm B ($n = 12$). Cows that had fully healed received no further treatment and were not assessed in subsequent weeks.

grade when compared to fairly severe baselines at week 0 (scores 3, 4 or 5) strongly suggesting a positive influence of the adhesive gel barrier. However, we note again that (i) there were no control cows; (ii) the duration of each lesion at enrolment was unknown; (iii) the recurrence rate for recovered cases is not known, as there were no follow-up examinations beyond the time frames of 10, 6 and 5 weeks for farms B, C and D respectively; (iv) the number of treated cows was small; and (v) there may have been some selection bias as the animals were chosen by each herdsperson with minimal criteria.

A further limitation of this study, in addition to the ones described above, was the fact that three different veterinarians were involved in the scoring and examination on farm, so there may have been some interobserver variation, as described by Bouma et al.[9] However, all three veterinarians were familiar with the UCD scoring system descriptors and photographic appearances, having each undergone training by a fourth independent veterinarian before the study commenced.

The clinical impression formed in stage 2 of this study by comparing the results obtained by four

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once-weekly and five once-weekly applications on farms C and D, respectively, with up to nine once-weekly applications on farm B was that a more prolonged course of application may be required to achieve full healing of severe UCD lesions. There may also be a place for more frequent application, as used by Hesseling and Lammers[24] and Ekman et al.[14] for other products, with potential to boost the healing progression; for example, daily applications for the first 2–5 days followed by once-a-week repeated treatments until full healing. Further studies using this adhesive gel barrier in protocols of both differing frequency and differing duration of application are therefore required.

CONCLUSIONS

Once-weekly application of a new adhesive gel barrier was associated with healing progression of severe UCD lesions in dairy cattle, with marked reductions in malodour, exudate and depth of the lesion as well as increased signs of re-epithelialisation, without eliciting any adverse clinical events.

AUTHOR CONTRIBUTIONS

Mike J. Kerby and Patricia B.A. Simões designed the methodology with input from the other authors. All the authors contributed to writing and/or editing the manuscript.

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CONFLICT OF INTEREST STATEMENT

Michael Kerby is an ad hoc veterinary advisor to, and a minor shareholder with, NoBACZ Healthcare but was not paid for this work.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

The use of the novel barrier solution for use in animals was granted approval by the University of Cambridge, Department of Veterinary Medicine's Ethics and Welfare Committee, reference number CR755. Informed consent was obtained from the keepers of animals that were involved in this study.

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