Comparing the effectiveness and wash-off resistance of skin barrier creams: a healthy volunteer study

Objective: Preventing moisture damage and breakdown of the skin can be a particular challenge for patients with incontinence. The level of protection offered by various skin protectant products can vary according to the chemical nature of the formulation and can decrease following wash procedures. The aim of this study was to compare five silicone-containing skin barrier creams indicated for use on incontinence-associated dermatitis (IAD) in terms of their resistance to a standardised wash cycle in healthy volunteer subjects.
Method: A skin surface hygrometer (Skicon 200EX) evaluated skin surface conduction non-invasively on 36 non-patient subjects using a high-frequency (3.5MHz) electric current. This provided an index of the degree of protection given by barrier products after a single application and also any reduction in barrier properties after a repeated wash procedure.
Results: Medi Derma-S barrier cream (MDS), Cavilon barrier cream (CBC) and LBF barrier cream (LBF) all demonstrated statistically significant differences ($p<0.001$) in the Skicon values following the first moisture challenge compared with Medihoney (MH), Remedy barrier cream (RBC) and the untreated control. All other comparisons were not significant ($p>0.05$). Statistical analysis following four moisture challenges reflected the results following the first, whereby Skicon values following treatment with MDS, CBC and LBF was significantly different compared with MH, RBC and the untreated control. Again, all other comparisons were not significant ($p>0.05$). When expressed as percentage barrier effectiveness, the results show a similar pattern to the absolute Skicon values.
Conclusion: The results of this study show that there were differences between the barrier creams in terms of the initial moisture challenge and the resistance to wash-off following a repeated standardised wash procedure. It was concluded that MDS, CBC and LBF barrier cream all showed significant and equally effective moisture barrier protection and wash-off resistance.
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barrier • cream • durability • moisture • protection

Preventing moisture damage and breakdown of the skin can be a particular challenge for patients with incontinence. When the skin is exposed to irritant substance such as urine and faeces, the activity of proteolytic enzymes alongside over-hydration of the stratum corneum leaves the skin at high risk of excoriation, maceration and denudation. This is otherwise referred to as incontinence-associated dermatitis (IAD), which is defined as skin breakdown related to faecal and/or urinary incontinence.[1] Gray et al.[2] further defined IAD as erythema and oedema of the skin surface, which may be accompanied by bullae with serous exudate, erosion or secondary cutaneous infection. This damage to the skin can cause pain, discomfort and distress for patients.[3] It is also recognised that over-hydrated skin with compromised barrier function heightens susceptibility of the skin to trauma from friction forces, and that the risk of developing pressure ulcers (PUs) is increased in the presence of IAD.[4]

The primary goals of care for management of IAD are adoption of a structured skin care regimen to proactively protect the skin from irritant bodily fluids, maceration and breakdown. Skin care pathways should incorporate risk assessment and reduction and regular skin inspection, alongside the use of appropriate skin-friendly products to cleanse, protect, repair and restore skin integrity.[5,6] The use of skin protectants provides a barrier on the stratum corneum against the damaging effects of prolonged exposure to urine and faeces and are widely used within both acute and community care environments. Many can be used to protect at-risk skin from exposure to prevent IAD, and also to manage IAD once it has occurred by providing a barrier against further moisture and irritation that will allow the skin barrier function to recover.

The level of protection offered from various skin protectant products can vary according to the chemical nature of the formulation and can decrease following wash procedures, even if the active ingredient providing the main barrier function is the same. In order for a barrier product to achieve optimum effectiveness, it needs to be able to maintain a waterproof barrier on the skin when exposed to varying degrees of moisture. As incontinence can also necessitate a need for more

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Table 1. Experimental schedule

Time (minutes)	Activity
0	Map six test sites
5	Take Skicon measurements
10	Apply study creams; drying time 30 minutes
40	Moisture challenge 1 (MC1) (10-minute immersion)
50	Take Skicon measurements
60	Wash 1
65	Drying time 30 minutes
95	Moisture challenge 2 (MC2) (10-minute immersion)
105	Take Skicon measurements
115	Wash 2
120	Drying time 30 minutes
150	Moisture challenge 3 (MC3) (10-minute immersion)
160	Take Skicon measurements
170	Wash 3
175	Drying time 30 minutes
205	Moisture challenge 4 (MC4) (10-minute immersion)
215	Take Skicon measurements
220	End of study

frequent skin cleansing, the ability of a skin barrier product to resist a degree of wash-off during cleansing procedures is also an appealing and practical feature, reducing the number of applications clinicians are required to apply, which in turn reduces the amount of product usage and associated costs.

To support clinicians with decision-making based on clinical efficacy and cost-effectiveness regarding optimal product choice for skin barrier creams in their clinical environments, a study was performed to compare five silicone-containing skin barrier creams indicated for use on IAD in terms of their resistance to a standardised wash cycle in non-patient healthy volunteer subjects. All the products tested were similar in that their primary function is to act as a barrier cream and indication for use is to protect intact skin from the effects of moisture exposure. The aim was to demonstrate any differences in clinical performance and to provide supporting evidence on which guidance regarding required frequency of reapplication can be given.

Methods

The effectiveness of the barrier function was assessed by determining changes in the water content of the stratum corneum via skin surface conductance testing. The superficial stratum corneum rapidly takes up water when exposed to an aqueous environment, which causes changes in the conductance of the skin surface.[7] In the presence of an effective barrier this water uptake does not occur. A skin surface hygrometer (Skicon 200EX, I.B.S. Co. Ltd., Japan) evaluated skin surface conduction non-invasively using a high frequency (3.5MHz) electric current, providing an index of the degree of protection given by barrier products after a single application and also any reduction in barrier properties after a repeated wash procedure.

The study was an open, within-subject study of five test products: Medi Derma-S Barrier Cream (MDS), Medicareplus International, UK; Cavilon Barrier Cream (CBC), 3M, UK; LBF Barrier Cream (LBF), Clinimed, UK; Medihoney Barrier Cream (MH), Dermasciences, UK; Remedy Barrier Cream (RBC), Medline, UK. The subjects were healthy with no significant systemic or skin disease and within the age range 18 to 75 years. Subjects were excluded if they were taking any systemic or topical medication likely to interfere with the study, had taken part in a clinical trial involving their forearms within the previous four weeks, had a recent history (previous 12 months) of significant skin disease requiring medical intervention or if they had an allergy to any of the product ingredients.

We identified three test sites approximately 3x4cm each on the inner aspect of both forearms. Baseline electrical conductance measurements of the skin surface were taken five times from each randomly allocated sites, with the sixth test site acting as an unprotected, no treatment control. The products were applied to the skin surface at a dose of 4mg/cm^2 and spread evenly over the test area using a finger covered with a finger cot[8] and allowed to air dry for 30 minutes.

The test sites were then subjected to a moisture challenge (MC) consisting of an immersion of both of the hands and forearms in tepid tap water at 35–38°C for 10 minutes, with no recirculation or agitation of the water. Following the immersion procedure the arms were rested on a towel and soaked paper towels were used to cover the forearm and keep the test sites moist until skin surface conductance measurements were taken. A section of the moist paper towel was removed to expose a test site, which was then dried with a paper towel. Measurement of skin conductance was taken as soon as possible after drying. The next site was then exposed, dried and measured with the Skicon and so on until all six test sites had been measured.

The test sites were then subjected to three simulated wash cycles using a circular cotton pad soaked with 5mls of a standardised skin cleanser product (Medi Derma-Pro Foam & Spray Incontinence Cleanser, Medicareplus International). This cleanser was chosen as it is a non-rinse cleanser and represents similar products that are widely used in clinical situations for episodes of incontinence. The cleanser also contains a surfactant designed to remove irritants and debris, and thus should challenge the durability of the skin barrier creams as opposed to just using plain water. The pad was wiped seven times across the test sites with a gentle pressure

after which the test sites were exposed to ambient conditions for 30 minutes post-wash. Following the 30 minutes exposure, the ten-minute moisture challenge was repeated followed by further Skicon measurements. This whole process was then repeated a further two times, so three wash cycles in total were used (Table 1).

Data were analysed through calculation of the mean value of the five Skicon measurements for each time point and each test site, with this mean value used in all subsequent analysis. Other summary statistics of the Skicon values, standard deviation (SD), median, maximum, minimum were calculated over all subjects for each test site. The baseline-subtracted values post first moisture challenge (MC1) were analysed using the non-parametric Friedman test in order to determine if significant ($p<0.05$) differences existed between test sites, while avoiding any assumptions about the data distribution. Multiple comparisons procedures which made allowance for repeated significance testing were then performed to allow comparison of each treated site with all other treated sites. The analysis was repeated on the baseline-subtracted post fourth moisture challenge (MC4) values.

The practices and procedures adopted during the conduct of this study were consistent with the principles of ICH, GCP and phase I clinic guidelines published by the Association of the British Pharmaceutical Industry (2012).[9] Ethics Committee and Regulatory approval for the study was not required due to the nature of the products being tested, all post-market, CE-marked (apart from RBC) and being used within the scope of their intended purpose and the study design, as outlined in guidance from the UK Health Department's 'Governance Arrangements for Research Ethics Committees' (GAfREC). All subjects had the nature of the study explained to them verbally and in writing, and written informed consent was obtained before study commencement.

Results

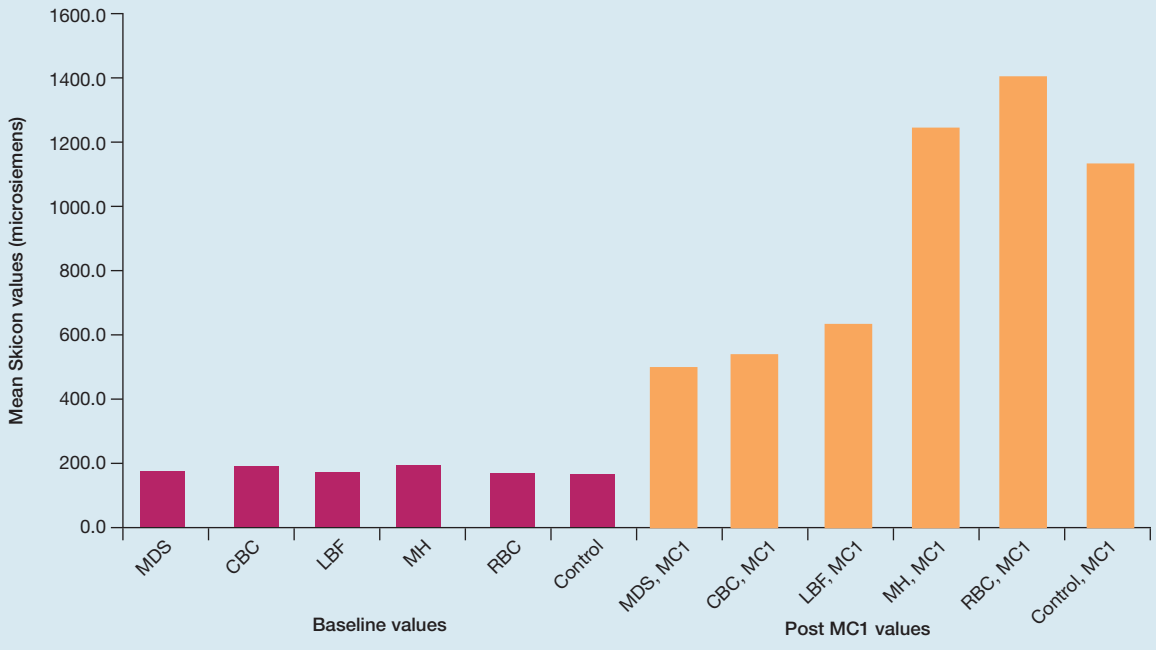
We recruited 36 healthy volunteers 31 females and 5 males, with a mean age of 51 years (range: 18–72 years). There were no subject withdrawals, protocol deviations or adverse events recorded.

Post moisture challenge 1

The summary statistics for the baseline and post-MC1 Skicon values are shown in Fig 1. The mean baseline values for each test site were low and in the range of 164.8–194.6 microsiemens (µs). After the first moisture challenge (MC1) the mean values increased substantially and ranged from 498.8–1413.4µs. The mean values for MH and RBC showed little difference from the untreated control, indicating no protection against the penetration of water into the stratum corneum. The remaining test products did show some protection against water penetration in that the mean values were lower than the untreated site.

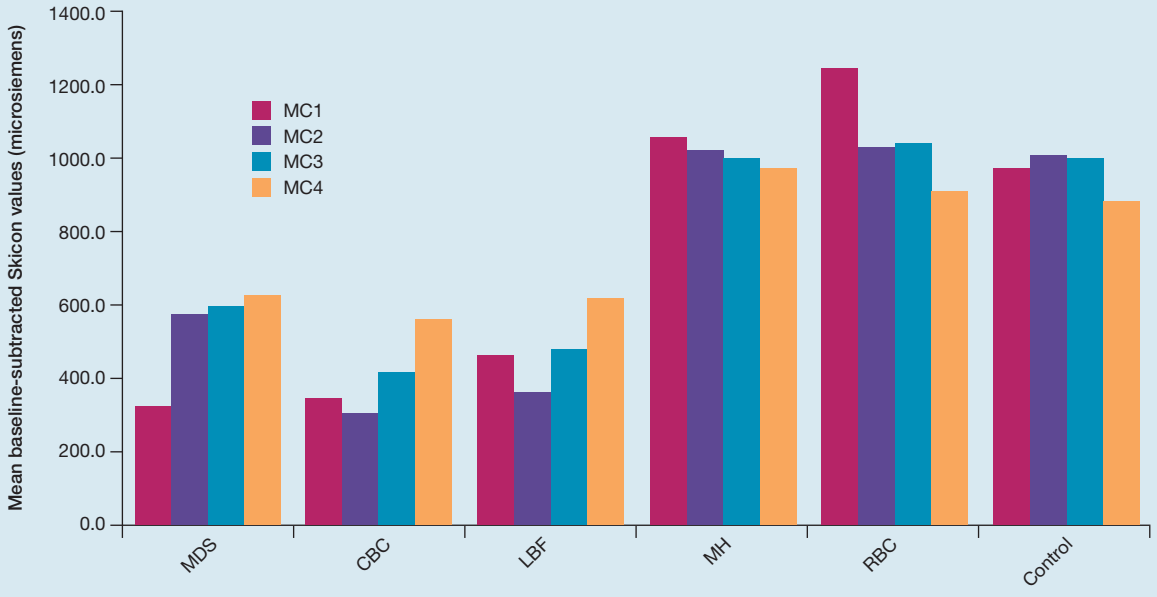
MDS, CBC and LBF all demonstrated statistically significant differences ($p<0.001$) in the Skicon values following the first moisture challenge compared with MH, RBC and the untreated control. All other comparisons were not significant ($p>0.05$).

Fig 1. Skicon values at baseline and after moisture challenge 1 (MC1)



MDS—Medi Derma-S; CBC—Cavilon barrier cream; LBF—LBF barrier cream; MH—Medihoney; RBC—Remedy barrier cream

Fig 2. Skicon values following four moisture challenges (MC)



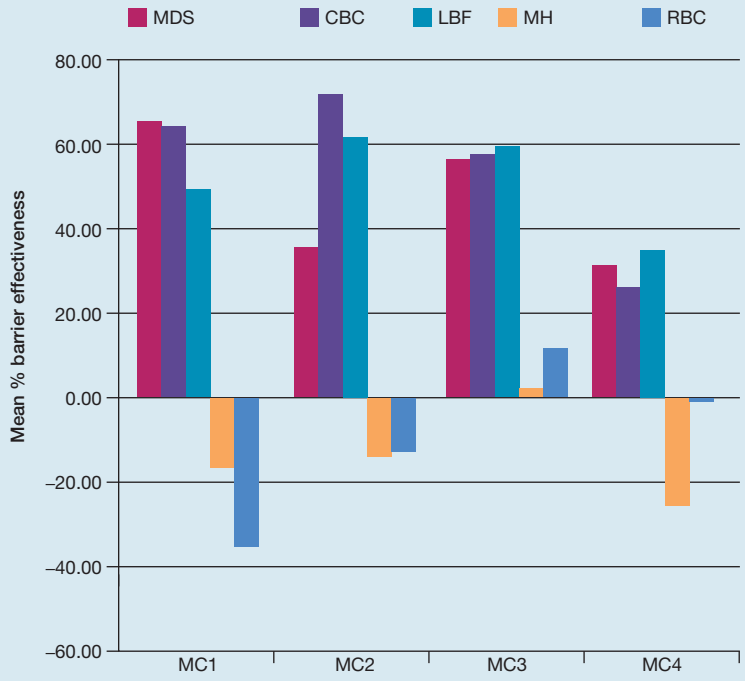
MDS—Medi Derma-S; CBC—Cavilon barrier cream; LBF—LBF barrier cream; M-H—Medihoney; RBC—Remedy barrier cream

Post moisture challenge 4 (MC4)

The mean baseline subtracted Skicon values following all four moisture challenges post wash 1, wash 2, wash 3 and wash 4 (MC1, MC2, MC3 and MC4) are summarised in Fig 2. The results following MC2, MC3 and MC4 were similar to the results following MC1, with MH and RBC showing little difference from the untreated control, with some degree of protection being seen with the remaining products.

Statistical analysis post MC4 reflected the results of post MC1, whereby Skicon values following treatment with MDS, CBC and LBF was significantly different compared with MH, RBC and the untreated control. Again, all other comparisons were not significant.

Fig 3. Mean % barrier effectiveness after each moisture challenge (MC)



MDS—Medi Derma-S; CBC—Cavilon barrier cream; LBF—LBF barrier cream; MH—Medihoney; RBC—Remedy barrier cream

Percentage barrier effectiveness

Percentage barrier effectiveness of the test products was also derived from the ratio of the test and untreated values (baseline subtracted) for each time point for each test product, and these values converted into percentages.

When expressed as percentage barrier effectiveness (Fig 3), the results show a similar pattern to the absolute Skicon values. Thus, MH and RBC showed no protection with the remaining products showing varying degrees of protection. MDS, CBC and LBF all showed protection even after four moisture challenges. Overall, these products did also show some reduction in effectiveness following the standardised wash procedures, indicating natural wear-off of the products. It should be noted that the negative values arise because the ratio of MC1 − baseline (product) to MC1 − baseline (no protection) is greater than 1. This is particularly notable with RBC at MC1 where the mean baseline-subtracted values are higher than for the control (unprotected).

Discussion

The results of this study suggest that there are statistically significant differences in the effectiveness of barrier creams in terms of waterproofing and resistance to wash-off. These differences may be important to clinicians when choosing the most suitable product for managing patients' IAD. Differences in the hydration of the skin test sites following application of the various barrier creams was evident even after the first 10 minute immersion, before cleansing of the skin and repeated moisture challenges. Skin hydration was much less at the areas where MDS, CBC and LBF were applied than seen at the control site, with this trend continuing through the successive moisture challenges. This suggests that these products are applying an effective barrier to moisture exposure on the skin, whereas the RBC and MH seemed to apply no significant additional barrier to the skin than when left untreated—an outcome with potential implications for providing effective skin protection to prevent and treat IAD.

The ability of MDS, CBC and LBF to resist wash-off even after multiple cleansing episodes is also an important consideration for clinical practice as there is the implication that these creams will need to be applied less frequently while maintaining clinician confidence that they are still proactively protecting the skin from irritant bodily fluids, maceration and breakdown. This will have a knock-on effect in terms of their potential ability to be cost-effective product choices, a consideration to be taken into account alongside unit cost.

Limitations

The product performance in the realities of clinical practice may vary due to multiple factors including; use on damaged as opposed to healthy skin,individual variations in application, use with different types of cleansing product.

Reflective questions

- What are the primary goals of care for managing incontinence-associated dermatitis (IAD)?
- How can the level of protection offered by different skin barrier creams vary?
- How do these study results support clinician's decision making when choosing skin barrier products?

Furthermore, while there is a big move away from the use of soap and water for cleansing, particularly on skin damaged or at risk of IAD, it is accepted that this can still be the cleansing method of choice in some areas, particularly within patient's homes. The decision was made to use a non-rinse cleanser for this study as this is the recommendation within best practice documents for cleansing associated with IAD.[5].

Conclusion

The results of this study show that there were differences between the barrier creams in terms of the initial moisture challenge and the resistance to wash off following a repeated standardised wash procedure.

Overall, MH and RBC showed little difference from the untreated control and offered no resistance to water penetration and subsequent hydration of the stratum corneum. This was evident at the first moisture challenge (MC1) before any wash procedures. Significant protection was seen with the remaining products tested, with no statistical difference observed between them.

As would be expected, with successive standard wash procedures the moisture challenge values (MC2, MC3 and MC4) showed a decrease in the effectiveness of the barrier properties. It may be concluded that MDS, CBC and LBF all showed significant and equally effective moisture barrier protection in this study, and thus meet the expected requirements for durability that promotes the potential for cost-effective usage in clinical settings. JWC

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