Incontinence pad absorption and skin barrier creams: a non-patient study

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ABSTRACT

Exposure of the skin to excessive moisture, such as in cases of incontinence, can damage its natural barrier function and lead to tissue damage and breakdown. Common methods for managing incontinence and preventing related skin damage include the use of incontinence pads and the application of skin barrier creams to reduce exposure to moisture and irritants. Previous reports have indicated that barrier creams can transfer onto incontinence pads from the skin and reduce their absorbency, and thus the efficacy of both products. This study, using non-patient volunteers, investigated the effect on incontinence pad absorbency of Medi Derma-S and Medi Derma-Pro; two products from the Medi Skin Protection range, in comparison with other market-leading products. Results indicated that, while there was a small degree of product transfer onto the incontinence pads, this did not have a major impact on the absorption of synthetic urine. Medi Derma-S and Medi Derma-Pro performed consistently with other similar market-leading products.

Key words: Incontinence ■ Absorbency ■ Moisture ■ Skin

The skin performs many important functions, including thermoregulation, protection of internal organs from trauma and acting as a barrier to the influx of micro-organisms (Timmons, 2006). Maintaining its integrity is therefore vitally important. When the skin is exposed to excessive moisture for prolonged periods of time, such as in cases of incontinence, wound exudate or perspiration, its natural barrier function can be disturbed, leading to overhydration and eventual skin breakdown (Dowsett and Allen, 2013). This is otherwise known as moisture-associated skin damage (MASD), an umbrella term encompassing conditions such as incontinence-associated dermatitis (IAD), moisture lesions and intertrigo. Preventing moisture damage and breakdown of the skin can be a particular challenge for patients with incontinence, as exposure of the skin to urine and faeces alters its normally acidic pH, a contributor to its natural barrier function, and leaves it susceptible to the activity of proteolytic faecal enzymes (Beeckman et al, 2015). These factors increase the risk of skin excoriation, maceration and denudation, particularly in the elderly where the ageing process has already altered barrier function, or the very young, where barrier function can be underdeveloped and the skin is particularly fragile. This damage to the skin can cause pain, discomfort and distress for patients, as well as increasing the risk of secondary skin infections (Newman et al, 2007).

The use of absorbent pads is a common management method for incontinence, wicking away moisture and separating urine from faeces, as the combination of the chemicals and enzymes contained within both can further exacerbate deterioration in skin barrier function (Beeckman et al, 2015). Skin barrier creams are frequently used in conjunction with incontinence pads to place a protective waterproof barrier on the skin that minimises exposure to urine and faeces and reduces the risk of skin damage. Previous studies, however, have indicated that some barrier creams may potentially reduce the capacity of the incontinence pad itself due to inadvertent transfer of the barrier cream from the skin to the pad surface (Hart, 2002; Zehrer et al, 2005; Fleming et al, 2014). The incontinence pad may therefore be compromised and its ability to absorb fluids reduced. This was particularly found to be the case for petrolatum- and zinc oxide-based barrier creams (Hart, 2002), whereby 63% of the applied amount of these creams transferred from skin to pad, compared with 37% of the silicone-based comparator product—a difference deemed statistically significant (p<0.001).

When the effect on pad absorbency was tested using application of synthetic urine, the silicone-based cream was found to be comparable to the control with 96% of synthetic urine absorbed, whereas the pads exposed to the zinc oxide- or petrolatum-based products only absorbed 66–67%—again a statistically significant difference.

A further study by Fleming et al (2014) also found that all four creams tested in the study (two silicone-based, one zinc-oxide, one silicone-based with copolymer bioadhesives) transferred to incontinence pads at the skin interface with some associated reduction in pad absorbency. The authors of the study also noted that the amount of cream transferred did not correlate with reduction in pad absorbency, with one product transferring the least amount of cream but resulting in the worst outcome in terms of urine absorbency. Overall, as the reduction in absorbency for the products tested was not huge, they concluded that the benefits of using an effective barrier cream outweighed the reduction in performance of incontinence pads.

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Medi Skin Protection Range

The Medi Skin Protection Range (Medicareplus International) incorporates a range of products aimed at providing Total Barrier Protection™ for skin at risk of, or compromised by, MASD. It includes a silicone-based skin barrier cream and film (Medi Derma-S), a foam and spray incontinence cleanser and accompanying skin protectant ointment (Medi Derma-Pro) and a medical adhesive remover (Medi Lifteez). Medi Derma-Pro is a silicone-based ointment with bioadhesives, which is designed with a tacky consistency to adhere to even very moist skin, and is therefore aimed particularly at managing severe skin damage from incontinence. As the range contains two cream- or ointment-based products (Medi Derma-S Barrier Cream and Medi Derma-Pro Skin Protectant Ointment) indicated for use on incontinent patients, it was decided that the effect of both products on incontinence pad absorbency should be investigated and compared with other market-leading products with similar ingredients or formulations.

This study was therefore designed to compare the effect of five different barrier products on the absorbency of a commonly used incontinence pad in non-patient volunteer subjects to ensure that the products from the Medi Skin Protective Range do not compromise the absorbency of the pads to any significant degree that may impact on their effectiveness at preventing and treating incontinence-related MASD.

Method

The study was an open study of five test products (Medi Derma-S, Medi Derma-Pro, Cavilon, LBF, Proshield Plus) applied to the volar forearm of 20 non-patient volunteers (18 females, 2 males; mean age 45 years). The subjects were generally healthy with no significant systemic or skin disease, and had not taken part in a clinical trial involving their forearms within the previous 4 weeks. Subjects were excluded if they had taken any systemic or topical medication or had an allergy likely to interfere with the study, a recent history (previous 12 months) of significant skin disease requiring medical intervention or a recent history or evidence of alcohol, substance or drug abuse.

Each of the subjects received all five barrier products to approximately 3 x 4 cm test sites on the medial aspect of each forearm, with a sixth test site acting as an untreated control (no barrier protection applied). The products were applied to the skin surface at a dose of 11 mg/cm² and spread evenly over the test area using a finger covered with a finger cot. The sites were allowed to air dry for one minute before test-pad application.

Pre-weighed test pads were then applied to the test sites for 5 minutes to allow any potential transfer of barrier product to occur. Test pads were then removed and weighed in order to determine amounts of barrier product transferred. Following this, the section of incontinence pad was re-applied to the skin surface at the designated site and a measured amount (1 ml) of synthetic urine was then dispensed directly onto the skin surface with the previously applied section of pad held firmly against the subjects forearm adjacent to the site during dispensing. The pad was then pressed onto the skin surface for a further 5 minutes and re-weighed to determine amount of synthetic urine absorbed by the pad.

Pad weights at each measurement point were entered into a spreadsheet for analysis, with the difference between the initial pad weight and the weight after contact with the skin calculated, followed by the difference in weights following application of the synthetic urine.

Summary statistics of the product and urine absorption values (mean, standard deviation, median, maximum, minimum) were calculated over all subjects for each test site. A non-parametric Friedman test was used to determine if significant (p<0.05) difference existed between test sites as the multiple comparison procedure allowed comparison of each treated site with all other treated sites and made allowance for repeated significance testing.

Ethics Committee and Regulatory approval for the study was not required due to the nature of the products being tested.

Results

The study results indicate that Medi Derma-S and Medi Derma-Pro perform consistently with other similar market-leading barrier creams and ointments.

Product transfer

The summary statistics (mean, median) for the amounts of barrier product transferred to the incontinence pad during skin contact are summarised in Figure 1. This indicates that all the barrier products were transferred on to the pad to some degree, with both the measures of central tendency (mean and median) indicating differences in the amounts absorbed. There were some differences between the mean and median values, suggesting that the data was not normally distributed, but the method of statistical analysis chosen was distribution free. This analysis indicated that there was a statistical difference between the control versus all the barrier products (p<0.05). While there were statistically significant differences between the skin protectant ointments containing...
bioadhesives and some of the simpler silicone-based skin barrier creams, there were no significant differences between the products with comparative ingredients, i.e. Medi Derma-Pro v Proshield Plus and Medi Derma-S v Cavilon v LBF.

Urine absorption
The summary statistics (mean, median) for the amount of urine absorbed into the incontinence pad during skin contact are summarised in Figure 2.

The amounts of urine absorbed with the test products were slightly lower than the control of untreated skin, suggesting some impairment of urine absorption. However, the effects were small, regardless of whether the mean or median values were considered. As with the product transfer analysis, there was a statistically significant difference (p= 0.0126) between one of the skin barrier protectants containing bioadhesives (Proshield Plus) and a skin barrier cream (LBF), but all other comparisons were not statistically significant (p>0.05).

Discussion
The study results are consistent with previous research whereby silicone-based, film-forming products do not appear to affect the absorbency of incontinence pads to any significant degree, despite some product transfer occurring. There were some differences between the products in terms of amount of product transfer, with the most transfer occurring with the skin-protectant ointments containing bioadhesives (Medi Derma-Pro, Proshield Plus). This was somewhat anticipated, due to the deliberate tackiness of the products, which do not dry on the skin in the same way as simpler silicone-based creams. The difference between the two types of products was deemed statistically significant. However, as found in the study performed by Fleming et al (2014), this difference in product transfer, despite its statistical significance, did not consistently translate into a correlation in terms of reduction in pad absorbency. Despite a small amount of impairment in absorption being seen in absolute terms between all the products and the control where no barrier cream was applied, this difference was not statistically significant—thus indicating that the use of these skin barrier creams do not affect the absorption of incontinence pads to any significant degree and are therefore safe to use for preventing and managing skin damage incontinent patients.

Limitations
It could be argued that the performance of a non-patient volunteer study using forearms does not accurately reflect the realities of clinical practice and the anatomical areas where these skin barrier products are normally used with incontinence pads. While it is acknowledged that there are some limitations associated with this type of study and there is likely to be some impact on transfer and absorbency in reality due to patient movement, weight-bearing and the effect of shear and friction, measures were taken to counteract these issues where possible. Pressure was applied to the pads on the forearms following product application to mimic the constant pressure that may be found at the patient/pad interface during clinical use, a factor which is likely to have the most impact on product transfer, especially for immobile patients.

It should also be acknowledged that performance of a study to investigate the effect of barrier creams on pad absorbency using an actual patient population where these factors would be apparent would be very difficult, considering the lack of control with regards to the volume of urine to which the pads would be exposed between patients. It would also be difficult to accurately measure the degrees of pressure, shear and friction being exerted at the patient/pad interface to be able to take variations into account. Thus, while accepting its limitations, this study does at least provide a reference point for clinicians to make a decision in clinical practice as to whether the benefits of using skin barrier products with incontinence pads outweigh the potential risks.

Several studies of this nature have previously been performed and using similar methodologies, and while they have all been performed using healthy volunteers, differences in the behaviour of different types of skin barrier product have been apparent, thereby giving another indication that the risks with silicone-based products are likely less than with petrolatum- or zinc-based creams. This provides relevant information to help support clinicians when selecting products relevant to their patients’ needs.

Ultimately, successful management of both incontinence and skin integrity will commonly involve the use of incontinence pads and skin-barrier protection products in combination, giving real clinical relevance to the results of studies such as this. It is important that clinical staff involved in caring for these patients are aware of both factors in equal measure, choosing incontinence products of a suitable absorbency for the patient’s needs and applying appropriate barrier products to protect the skin from any excess moisture and irritants to promote skin integrity. Consideration should be given to involvement of tissue viability and continence specialists at an appropriate stage to effectively manage both incontinence and skin integrity before adverse effects are experienced by patients.
Conclusion

The results of this study show that, while there was a small degree of product transfer onto the incontinence pads, this did not have a major impact on the absorption of synthetic urine. Although there were some differences between barrier products in terms of the amounts transferred to an incontinence pad, there was no significant difference in the amounts of urine absorbed between these products.

It can be concluded, therefore, that the cream/ointment-based products from the Medi Skin Protection Range can be used in association with incontinence pads to prevent and protect skin from incontinence-related MASD without altering the pad’s function. It seems that these types of barrier products do not affect the absorbency of incontinence pads in the same way as the more traditional petrolatum- and zinc-based products, and therefore, as concluded in previous studies, the potential benefits of using silicone-based skin barrier cream and ointments to protect vulnerable skin outweigh the small risk associated with a degree of product transfer.

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