Pilot Study into the Efficacy of Film Barrier Skin Care Products

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Abstract

Skin damage caused by excessive moisture either from perspiration, ostomy sites, wound exudate, urine and or faeces can cause significant suffering for patients.

Part of the treatment protocol for patients at risk of moisture-related skin damage includes the use of barrier films. However, there is little evidence on the durability and effectiveness of this product range.

This study examined the protective effect of a selection of film products in 11 subjects. The results show that the application of barrier films has a protective effect in delaying the removal of stained stratum corneum. Both **Derma-S Barrier Film (Medicareplus International)** and **3M™ Cavilon™ Barrier Film (3M)** demonstrated their ability to retain stained stratum corneum.

However, statistical analysis indicated that there is no difference in the protective effect of Derma-S Barrier Film and 3M Cavilon Barrier Film, and that both products were effective at providing suitable barrier protection.

'...both products were effective at providing suitable barrier protection.'

An independant study carried out on behalf of Medicareplus International Limited by:

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Skin damage attributed to excessive moisture is a significant threat to wellbeing, due to increased pain, discomfort and suffering for the patient. Common causes of skin breakdown include incontinence-associated dermatitis (IAD), due to the presence of urine and/or faeces on the surface of the skin (Bianchi, 2012), wound exudate and leakage of effluent from an ostomy site.

If allowed to remain in contact with the skin, enzymes and derivative chemicals can begin to break down the superficial layers of the skin resulting in ulcerated areas (Beldon, 2008). Prevention of moisture lesions relies on accurate assessment of the skin, addressing the underlying issues that may be causing incontinence, appropriate cleansing and the application of barrier films where appropriate.

Table 1

Products Included in the Study

Product Description:
Derma-S Barrier Film (Medicareplus International)
Cavilon Barrier Film (3M)

Aims of the Study

Despite a number of barrier products being available, there is little agreement on how best to examine the effectiveness of the products in use. Lutz and Pyrek (1995) first described the use of dye retention studies as a method of assessing durability of barrier preparations. Issberner and Schuren (2004) also used similar techniques in subsequent studies to highlight the durability of a new barrier film preparation. This study aimed to assess the protective function of the film products listed in *Table 1*.

Study Design

The products were tested in 11 healthy volunteers with no skin disorders *(Table 2)*. Each subject had all of the products applied to the designated test sites on the lower back *(Figure 1)*. The products were applied to sites that had been pre-stained with a water-soluble red dye. Test sites used were the mid to- lower back, avoiding the vertebral column and also avoiding any obvious blemishes or moles.

There was only one application of the test products, on day zero. An additional test site was stained with the dye, but did not have any test products applied and remained untreated (Control).

The test sites were measured for colour using a Chromameter CR400 (Konica Minolta) after the products had been applied on the first day. Measurements were also taken from the control site and adjacent normal skin.

A 1% red dye, often used in food and cosmetics, was applied to sites 1–7 using test chambers, which contained filter paper to prevent leakage. Test chambers were left in place for 30 minutes, after which they were removed and the sites allowed to dry for 10 minutes.

Application and Assessment Schedule

Film products were sprayed as per manufacturer's guidelines. All products were given 20 minutes to air dry.

Subjects were instructed to continue with their normal daily washing procedures, but to avoid excessive rubbing of the test area. They were also given advice on how to manage the test sites, such as avoiding heavy exercise, exposure to the sun and avoiding excessive rubbing when washing and drying.

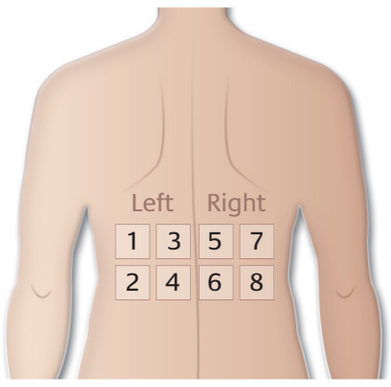

Figure 1:
The designated test sites on patients' backs.

The disappearance or otherwise of the red dye from the skin's surface was to be taken as an index of the protective effect of the barrier products. Under normal circumstances, the surface layers of the skin are removed daily by washing procedures, movement, friction with clothing, etc. The prevention of this removal by the barrier films indicates that this normal process is delayed, i.e. the sites are protected.

On day zero, subjects had dye applied, followed 40 minutes later by application of the chosen film preparations. Subjects returned daily for further measurements on days one, two, three, four, six and seven.

Chromameter readings were taken at 60 minutes and then daily until the end of the trial. Readings were not taken on Sunday.

Inclusion and Exclusion Criteria

All subjects were aged 18–65 years of age, with no significant illnesses or skin diseases present. Full subject consent was provided for all individuals.

Exclusion criteria included:

- Pregnancy
- People on systemic or topical steroids
- Previous testing on these sites with recent past
- Patients with allergies, significant skin disease
- Patients with a history of alcohol or drug abuse.

The researchers believed this to be are presentative sample for a study of this type, where the actual treatment of a skin lesion was not being tested, but rather the ability for the product to remain functional over a given time period.

Table 2
Trial Demographics

Screened	11
Enrolled	11
Age range/mean	24–65 years, mean 45 years
Data exclusions	None

Table 3
The Mean Values of the Light Readings as a Percentage of the Starting Value in Each Case for the Film Products

Product Code		Day 1	Day 2	Day 3	Day 4	Day 6	Day 7
B	Mean	77.35*	53.74	37.01	23.53	13.82	11.54
D	Mean	79.61	53.11	38.65	26.36	11.90	9.60
G (control)	Mean	67.35	35.36	20.05	9.97	7.41	6.15

**Figures are the mean percentage value of baseline reading at day zero.*

Ethical Considerations

Ethical approval for the study was sought and approved by the local Cardiff Independent Research Ethics Review Committee. Written, informed and witnessed consent was attained before commencement of the study.

Assessments

Colour Measurement

A Chromameter was used to take measurements of skin colour and readings were taken for all eight sites, 20 minutes after application and repeated on days one, two, three, four, six and seven.

Statistical Analysis

Summary statistics (mean, standard deviation) were calculated for both control corrected values and percentage of starting values.

Results

There were no subject withdrawals during the trial and there were no adverse events.

Statistical analysis of Derma-S Barrier Film, Cavilon Barrier Film and Control were contained within the synopsis report. The results indicated that significant differences ($p < 0.05$) exist between Derma-S Barrier Film and Control and Cavilon Barrier Film and Control, but that there was no difference between Derma-S Barrier Film and Cavilon Barrier Film.

Table 3 illustrates that both of the barrier films have higher values (more dye remaining) than the untreated site (G). *Figure 2* illustrates the reduction in values over time.

Discussion

The results of this study suggest that application of a barrier film can delay the removal of the stained stratum corneum.

These results are similar to those of Issbener and Schuren (2004), who compared Cavilon No Sting Barrier Film with four other available preparations. Using similar spectrophotometry techniques the authors measured dye attrition rates over a five-day period in healthy volunteers. The products tested were not similar to those tested in this study, and Issberner and Schuren (2004) demonstrated that Cavilon was superior to the other products tested at the time, however, there now exists a greater number of film-based products, which would account for the non-significant results achieved in this study. It may be worth noting that while the Issberner work found Cavilon dye retention to be greater than 30% at day seven, this study found Cavilon to have 9.6% retention at day seven.

Bliss et al (2005) compared four skin care regimens in the prevention of incontinence-associated dermatitis (IAD). Products included: acrylate polymer-based liquid film; 43% petroleum ointment; 12% zinc oxide in 1% dimethicone; and 98% petroleum ointment. There were no significant differences between the regimens and development of IAD. Therefore, it would appear that the use of high-quality products as part of an overall skin care regimen in at-risk patients, should prevent associated skin problems.

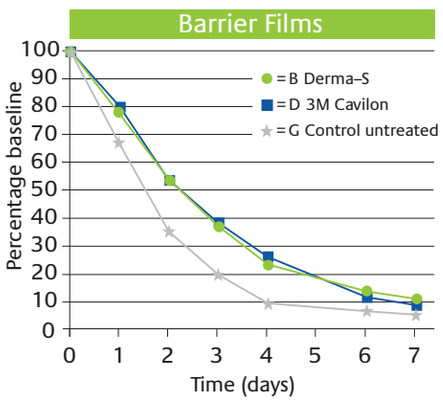

Figure 2:
Graph demonstrating values for all barrier films over time, compared with the control.

Conclusion

Skin care remains a critically important part of the nursing care of patients (Bianchi, 2012). Without accurate assessment of risk factors, many patients could develop skin problems caused by excessive moisture, incontinence, perspiration and wound exudate. In the past decade, a number of new skin protectant formulations have emerged, which offer greater long-term protection against moisture and the effects of adhesives on the skin.

The results of this study show that the application of barrier films has a protective effect in delaying the removal of the stained stratum corneum. Both Derma-S Barrier Film and Cavilon Barrier Film demonstrated higher Chromameter a* readings at all assessments, demonstrating their ability to retain stained stratum corneum.

However, statistical analysis indicated that there is no difference in the protective effect of Derma-S Barrier Film and 3M Cavilon Barrier Film, and that both products were equally effective at providing excellent barrier protection.

Wounds UK.

Declaration

This article was produced with the support of Medicareplus International.

For further information regarding **Derma-S** or to obtain samples, please contact Medicareplus International Limited using the details overleaf or email **info@medicare-plus.com**

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Derma-S Barrier Film
Product Information

Part of the Medi Skin & Wound Care Product Range

Description	Pack Size	Product Code	PIP Code
DERMA-S **Medical Barrier Film** Silicone Based, Healthcare Grade	**Aerosol** 75ml	60291	341-3176
	Wipes Pack 30	60307	341-3184
	Applicators 1ml Pack 5	61076	362-8716
	Applicators 3ml Pack 5	61090	362-8724

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