A multi-centred retrospective analysis of 336 clinical evaluations of the Medi Derma Total Barrier Protection (TBP™) Product Range

Over the last decade, modern skin barrier products have steadily replaced the use of traditional barrier products to maintain the skin integrity of vulnerable patients. These cream, film and ointment preparations are designed to protect skin from the effects of mechanical or chemical injury. They are predominantly used in the prevention and management of moisture-associated skin damage (MASD), an umbrella term used to define the various causes of damage associated with prolonged, or continuous exposure of the skin to moisture (Young, 2017). They offer protection from moisture due to incontinence, perspiration or wound/stoma drainage, forming a transparent, waterproof protective coating on the skin, and can be applied to intact or broken skin. They may be formulated from a variety of substances including acrylates, polymers, and silicone (NHS Clinical Evaluation Team, 2017).

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A considerable amount of money is spent on skin barrier products in the UK, and there are a wide range of products available. Based on Prescription Cost Analysis (PCA) data, the combined use of skin barrier products via the FP10 prescription route has cost almost £40 million annually, for the past 2 years (PCA, 2020).

Within today's NHS, the challenge of balancing increasingly limited resources with patient needs is well recognised (Hughes, 2016) and clinicians should understand the multiple indications, contraindications and guidelines for the barrier products they use.

This article summarises the findings of multi-centred patient evaluations of three skin barrier product formulations: Medi Derma-S Total Barrier Cream, Medi Derma-S Total Barrier Film, Medi Derma-*PRO* Incontinence Foam & Spray Cleanser and Medi Derma-*PRO* Skin Protectant Ointment (Medicareplus International), and aims to demonstrate the clinical and cost benefits of using these products for the prevention and management of moisture-associated skin damage (MASD).

MEDI DERMA TOTAL BARRIER PROTECTION (TBP™) PRODUCT RANGE

Medi Derma Total Barrier Protection (TBP™) products are hypoallergenic, silicone-based, pH-balanced and suitable for use on adults and paediatrics. They are alcohol and preservative-free, ensuring a 'no-sting' application.

Medi Derma-S Total Barrier Cream is indicated for mild MASD *(Figure 1)*, defined as intact, erythematous skin, at-risk of further deterioration (Jones and Winterbottom, 2019). Once applied, and allowed to dry, it will not impede the adhesion of dressings, ostomy pouches or other adhesive devices, and forms a protective, transparent and durable barrier, that lasts for up to three washes (Dykes and Bradbury, 2017). Medi Derma-S Total Barrier Cream has also been demonstrated to not affect the absorbency of incontinence pads (Dykes and Bradbury, 2016) and does not need to be removed between applications, thus reducing the risk of additional friction damage and further skin breakdown due to overzealous washing and drying. It is available in 2g sachets, and 28g and 90g tubes.

Medi Derma-S Total Barrier Film is a quick-drying liquid that polymerises to form a thin, transparent, flexible barrier when in contact with the skin. It is indicated for mild to moderate skin damage, with moderate damage *(Figure 2)* being defined as moderate areas of erythema, with less than 50% of

Figure 1. Mild skin damage (Image courtesy of Sheffield Teaching Hospitals NHS Trust)

Figure 2. Moderate skin damage (Image courtesy of Sheffield Teaching Hospitals NHS Trust)

Figure 3. Severe skin damage (Image courtesy of the National Association of Tissue Viability Nurses Scotland [NATVNS])

the affected area impaired (Jones and Winterbottom, 2019). Barrier films should be considered for all types of mild to moderate MASD where skin protection is required (Parnham and Copson, 2020). Studies have also shown that silicone barrier films decrease the risk of medical adhesive-related skin injury (MARSI) by preventing erythema and skin stripping, following the removal of adhesives in vulnerable patients who may have thin, fragile skin, such as in the elderly or infants/neonates (Irving, 2001; Shannon and Chakravarthy, 2009; Jones et al, 2018). Medi Derma-S Total Barrier Film should be applied every 24–72 hours when treating incontinence-associated dermatitis (IAD) or intertrigo, or at each adhesive dressing/device change. It is available in wipes, an aerosol spray, pump spray and 1ml and 3ml sterile film applicators.

Medi Derma-*PRO* Incontinence Foam & Spray Cleanser is a moisturising cleansing solution indicated for use on moderate to severely damaged skin. Severely damaged skin *(Figure 3)* can be defined as large areas of erythema, with more than 50% of the affected area disrupted (Jones and Winterbottom, 2019). It should be used in conjunction with Medi Derma-*PRO* Skin Protectant Ointment. The cleansing solution is available in a 250ml bottle and has a foam and spray mode (the foam mode enables the solution to stick better in hard to reach areas). It can be applied directly to the skin or onto a clean washcloth; the skin should be gently wiped clean and patted or air dried (there is no need to rinse it off). Medi Derma-*PRO* Skin Protectant Ointment is available in a 115g tube. A thin, uniform coating should be gently spread over the whole affected area, with reapplication after every episode of cleansing.

A TBP™ approach enables a 'step-up, step-down' approach to the prevention and management of MASD. If there is no significant skin improvement seen, using your clinical judgement, you can step up from barrier cream to barrier film, or from barrier film to the foam/spray cleanser and ointment. Alternatively, if there is significant improvement seen, you can step down through the product range, ensuring timely implementation of a structured skin care regimen using the most appropriate product at the right time.

METHOD

A retrospective review of clinical evaluation data of 336 patients from 47 UK acute and community sites was performed. All of the patients were treated with one of the three skin barrier product formulations for the prevention and/or management of varying severities of MASD.

Patient population

The evaluation inclusion criteria were:

- Patients 'at-risk' of, or already being treated for MASD, with an indication suitable for treatment.
- Participants must agree to treatment, have capacity to consent and be reviewed regularly by the clinical evaluator.

The participants were identified by a registered clinician and the Medi Derma formulation chosen was dependant on the assessment of their skin damage (i.e., mild, moderate or severe). On fulfilling the criteria, their existing skin barrier product or usual product was replaced with the most appropriate Medi Derma formulation.

Prior to the evaluations commencing, a Medicareplus International Clinical Nurse Advisor visited each site and provided an overview of the evaluation process and product training to all relevant staff. This included:

- Clinical indications for use
- Correct application/removal techniques
- Frequency of re-application
- How to complete the documentation.

Data collection

The data collected from a standardised product evaluation form was summarised in terms of the following:

- Type of Medi Derma product and number of patients that used it
- Demographics (Male/Female ratio and age range)
- Rationale for using the specific barrier product
- Previous or usual skin barrier products used
- Level of skin damage prior to commencing the evaluation
- Average duration of treatment
- Observations of the skin condition at the end of the evaluation
- Overall product performance compared to previous or usual barrier products used
- Clinician and patient additional feedback/comments.

RESULTS

Data from a total of 336 patient evaluations was reviewed from 47 UK acute and community sites: 125 patients used Medi Derma-S Total Barrier Cream, 101 patients used Medi Derma-S Total Barrier Film and 110 patients used Medi Derma-*PRO* Incontinence Foam & Spray Cleanser and Medi Derma-*PRO* Skin Protectant Ointment. *Table 1* shows the male to female ratio for each of the products evaluated.

The age ranges disclosed for these patients varied from 21 days to 98 years (*n*=200/336), although the majority of the cohort (77%) was over 70 years of age *(Figure 4)*.

The main rationale for using both the Medi Derma-S Total Barrier Cream & Film was for the treatment of patients suffering with IAD, which accounted for 66% (*n*=141) of 215/226 responses. This was followed by use for the prevention of MARSI, whereby 17% (*n*=37) of the total responses recorded this as a rationale *(Figure 5)*.

The rationale for using Medi Derma-*PRO* Incontinence Foam & Spray Cleanser and Medi Derma-*PRO* Skin Protectant Ointment was recorded for 100 of the total 110 patients. 77% (*n*=77) stated that it was used to treat patients with IAD, 19% (*n*=19) used it for the prevention of IAD and the remaining 4% (*n*=4) used it because the patient's skin was dry *(Figure 6)*.

The previous barrier products used for the Medi Derma-S Total Barrier Cream & Film cohort are illustrated in *Figure 7*. From 225 responses, 53% (*n*=120)

Table 1. Male to female ratio for each of the products evaluated

Product used	Male	Female	Unknown
Medi Derma-S Total Barrier Cream (*n*=125)	25% (*n*=32)	45% (*n*=56)	30% (*n*=37)
Medi Derma-S Total Barrier Film (*n*=101)	24% (*n*=24)	31% (*n*=31)	45% (*n*=46)
Medi Derma-*PRO* Incontinence Foam & Spray Cleanser and Medi Derma-*PRO* Skin Protectant Ointment (*n*=110)	37% (*n*=41)	38% (*n*=42)	25% (*n*=27)

Figure 4. The patient age range (200/336 responses)

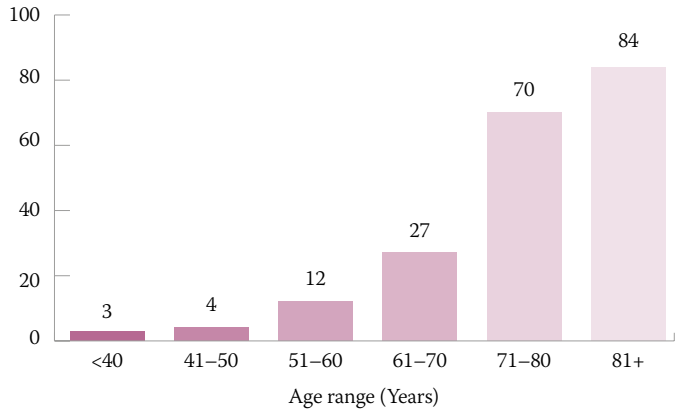


Figure 5. Rationale for using Medi Derma-S Total Barrier Cream & Film (215/226 responses)

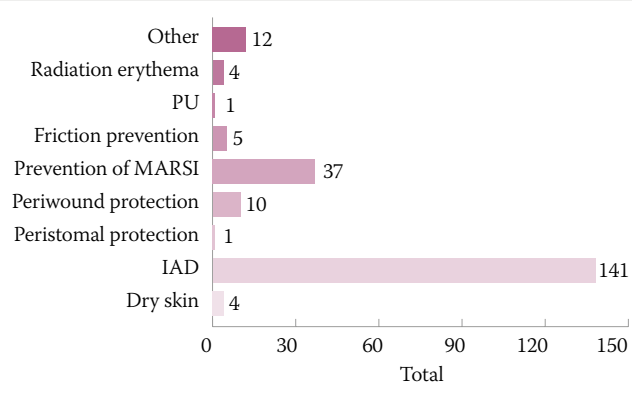


Figure 6. Rationale for using Medi Derma-*PRO* Incontinence Foam & Spray Cleanser and Medi Derma-*PRO* Skin Protectant Ointment (100/110 responses)

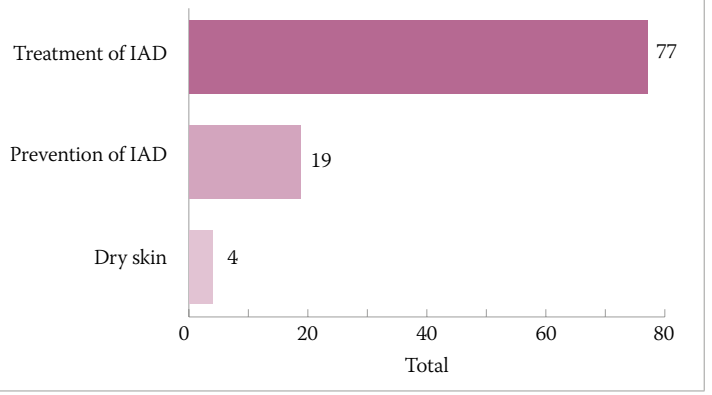


Figure 7. Previous barrier products used for the Medi Derma-S Total Barrier Cream & Film cohort (225/226 responses)

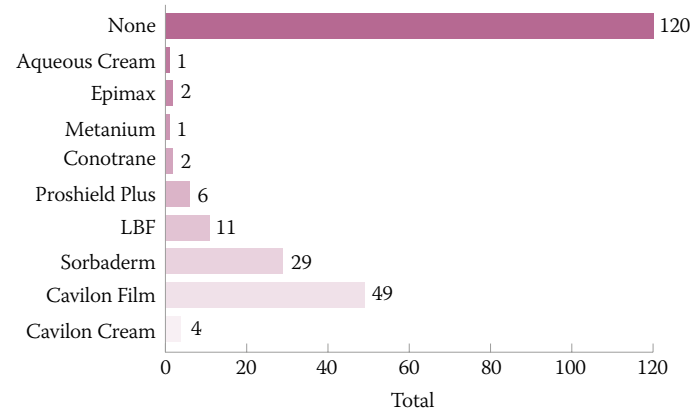


Figure 8. Previous skin cleanser used (79/110 responses)

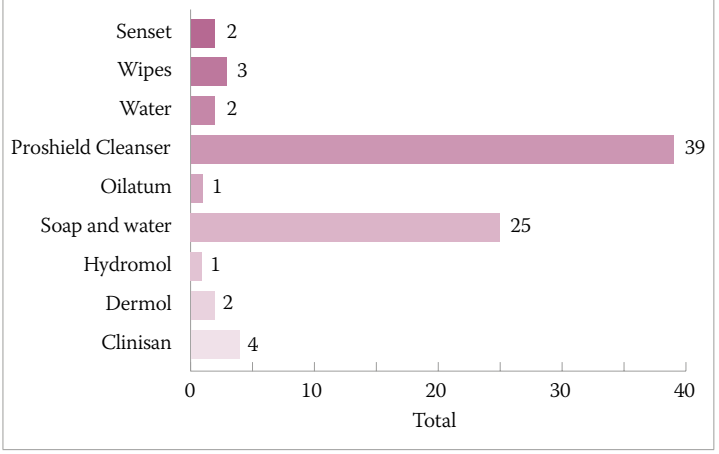


Figure 9. Previous barrier product used after skin cleansing (86/110 responses)

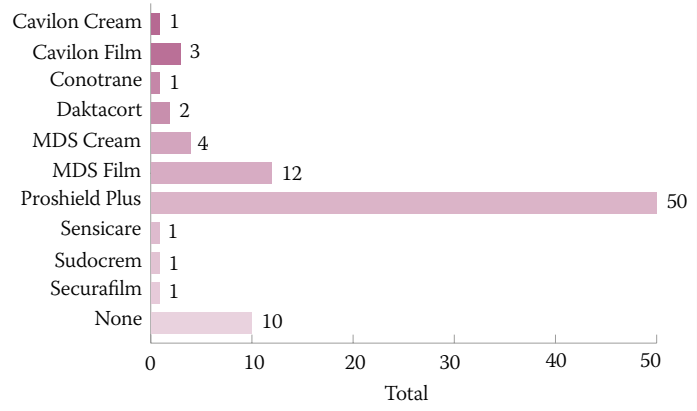


Figure 10. Level of skin damage for the Medi Derma-S Total Barrier Cream evaluations (87/125 responses)

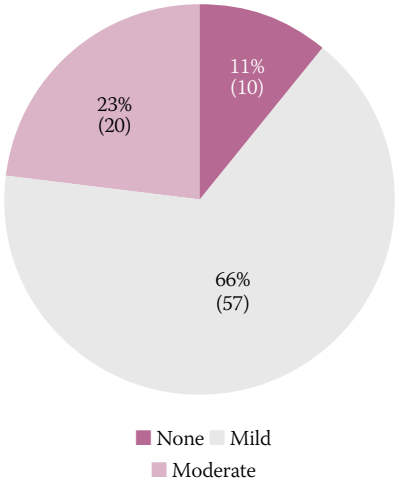


Figure 11. Level of skin damage for the Medi Derma-S Total Barrier Film evaluations (55/101 responses)

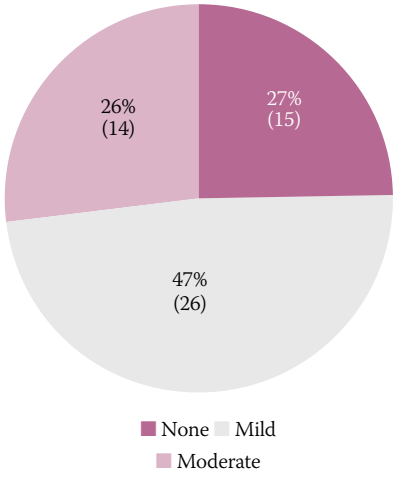
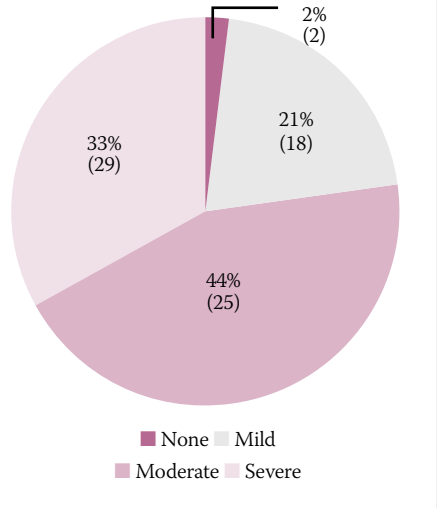


Figure 12. Level of skin damage for the Medi Derma-*PRO* evaluations (87/110 responses)



of patients had no barrier product used prior to evaluation. Of the remaining 105 patients, Cavilon Film was used on 22% (*n*=49), Sorbaderm on 13% (*n*=29), LBF on 5% (*n*=11), Proshield Plus on 3% (*n*=6) and Cavilon Cream on 2% (*n*=4). The remaining 6 patients were using either a different traditional barrier cream or an emollient/moisturiser cream.

Figure 8 shows the previous products used in the Medi Derma-*PRO* Incontinence Foam & Spray Cleanser and Medi Derma-*PRO* Skin Protectant Ointment cohort. The skin cleansing regimen for 79/110 patients was documented: 49% (*n*=39) were cleansed with Proshield Cleanser, and 32% (*n*=25) with soap and water. The remaining 15 patients had either cleansing foams (*n*=6), emollient soap substitutes (*n*=4), wipes (*n*=3) or water (*n*=2).

Following their cleansing regimen, these patients had a variety of topical barrier products applied *(Figure 9)*. A total of 86 responses were documented for this element of the evaluation: 46% (*n*=50) had Proshield Plus applied following skin cleansing, 20% (*n*=17) had a barrier film, 6% (*n*=5) were treated with a modern barrier cream, 12% (*n*=10) had no barrier applied. The remaining 4 patients had a traditional barrier cream, or antifungal cream.

Prior to commencing evaluations for each of the Medi Derma formulations, the clinicians visually assessed their patients' skin condition and recorded the extent of any MASD *(Figure 10, 11 and 12)*. There were 87/125 responses for the Medi Derma-S Total Barrier Cream evaluations, of which 23% (*n*=20) had moderate skin damage, 66% (*n*=57) had mild damage and the remaining 11% (*n*=10) had no damage but were considered 'at-risk'.

There were 55/101 responses for the Medi Derma-S Total Barrier Film evaluations: 26% (*n*=14) had moderate damage, 47% (*n*=26) were assessed as mild and 27% (*n*=15) had no damage. Of the 110 Medi Derma-*PRO* evaluations, 87 responses were documented: 33% (*n*=29) suffered with severe skin damage, 44% (*n*=25) with moderate damage, 21% (*n*=18) with mild and 2% (*n*=2) had no skin damage.

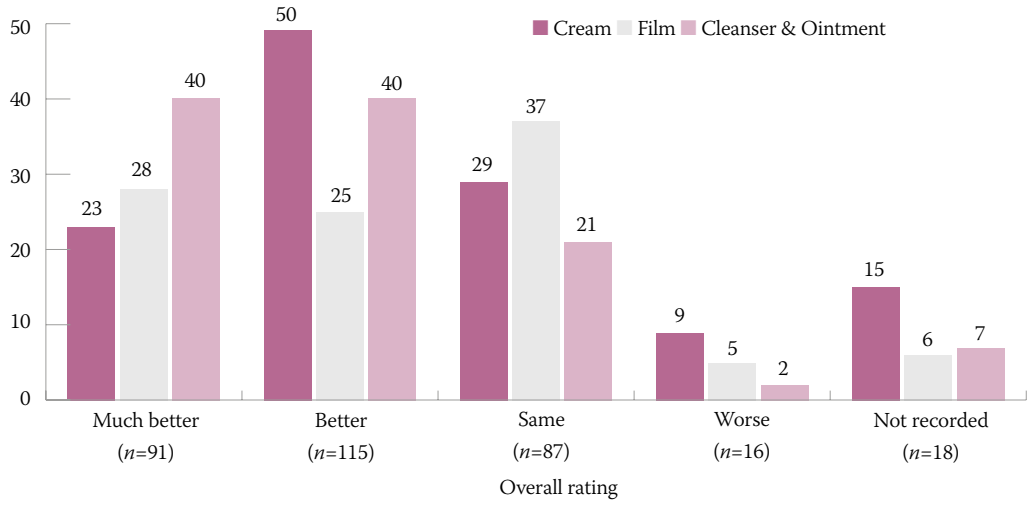
The average duration of use for the Medi Derma-S Total Barrier Cream & Film cohort was 5.5 days, based on 105/226 responses, and 10 days for the Medi Derma-*PRO* Incontinence Foam & Spray Cleanser and Medi Derma-*PRO* Skin Protectant Ointment cohort (based on 59/110 responses).

On completion of each evaluation, a visual assessment of the patients' skin condition was undertaken by the clinician. Observations were then recorded in terms of whether the skin had

Table 2. Patient skin condition after evaluation for each Medi Derma formulation

Product used	Deteriorated	Same	Improved
Medi Derma-S Total Barrier Cream (*n*=83)	0% (*n*=0)	28% (*n*=23)	72% (*n*=60)
Medi Derma-S Total Barrier Film (*n*=54)	4% (*n*=2)	33% (*n*=18)	63% (*n*=34)
Medi Derma-*PRO* Incontinence Foam & Spray Cleanser and Medi Derma-*PRO* Skin Protectant Ointment (*n*=85)	1% (*n*=1)	28% (*n*=24)	71% (*n*=60)

Figure 13. Overall Medi Derma product performance compared to previous or usual barrier product/s used



deteriorated, remained the same, or improved *(Table 2)*. Of the 125 Medi Derma-S Total Barrier Cream evaluations, 83 responses were recorded: 72% (*n*=60) noted an improvement in the skin condition and 28% (*n*=23) reported no change.

For the 101 Medi Derma-S Total Barrier Film evaluations, 54 responses were recorded: 63% (*n*=34) noted an improvement, 33% (*n*=18) reported no change and 4% (*n*=2) stated that the skin had deteriorated.

A total of 85 clinicians responded from the 110 Medi Derma-*PRO* Incontinence Foam & Spray Cleanser and Medi Derma-*PRO* Skin Protectant Ointment evaluations: 71% (*n*=60) noted an improvement, 28% (*n*=24) reported that it remained the same, and 1% (*n*=1) stated that the skin had deteriorated.

Following each evaluation, the clinicians were asked to rate the overall performance of the Medi Derma formulations against products used prior to evaluation, or usual product if no skin barrier had been previously used. From the total 336 evaluations, 308 responses were provided *(Figure 13)*.

The 110 responses received from the 125 Medi Derma-S Total Barrier Cream evaluations indicated that 66% (*n*=72) of the clinicians rated it much better or better than previously used products, 26% (*n*=29) rated it as the same, and 8% (*n*=9) rated it worse.

There were 95 responses from the 101 Medi Derma-S Total Barrier Film evaluations, in this cohort 56% (*n*=53) of clinicians rated it much better or better, 39% (*n*=37) the same and 5% (*n*=5) rated it worse.

A total of 103 responses from the 110 Medi Derma-*PRO* Incontinence Foam & Spray Cleanser and Medi Derma-*PRO* Skin Protectant Ointment evaluations were returned: 78% of clinicians (*n*=80) rated it as much better or better, 20% (*n*=21) rated it the same and 2% (*n*=2) worse than products previously or usually used.

The final element of the evaluations asked the clinician and/or patient to provide any additional feedback regarding the treatment provided or received. The majority of the feedback collected was positive and complimentary in relation to the cream and film. Statements included:

'The cream is not as thick as other products which I have used, I'm able to rub it into the skin more effectively' [Nurse]

'The cream had a cooling effect; it really soothed my sore area' [Patient]

'On the whole my patient's skin improved, she says the cream eases the pain' [Nurse and patient]

'The film spray is easy to use, it dries quickly…skin healed within a few days' [Nurse]

'The film is quick drying, with no sting or odour' [Nurse]

Feedback relating to the cleanser and ointment included:

'Much better than soap and water' [Patient]

'The staff really liked the cleanser, very effective at cleaning; the patient was very happy' [Nurse]

'Patient reported ointment gave her instant relief, very easy to apply' [Nurse and patient]

'This treatment does everything the old products did but costs less…will use this again!' [Nurse]

DISCUSSION

The evidence from these clinical evaluations reinforces that IAD is by far the most common cause of MASD, due to the prolonged or chronic exposure of urine and/or stool, particularly liquid stool on the skin (Ousey and O'Connor, 2017). This type of damage is also more prevalent in the elderly population, where continence problems are more common and skin integrity is susceptible to damage (Bradbury et al, 2017).

From the evaluation data reviewed, we can infer that the use of traditional barrier creams (such as, Sudocrem, Conotrane and Metanium) is decreasing. These products tend to contain zinc oxide or petrolatum as the primary ingredient and are no longer seen as the best option for skin care (Southgate and Bradbury, 2016). They also contain alcohol and preservatives, which can sting on application and cause allergies or skin sensitivities; it is evident that they are being superseded by modern silicone-containing barrier products.

In relation to skin cleansing, it appears that soap and water still remain a common cleansing method. However, this is generally believed to be sub-optimal practice (Beeckman et al, 2011). It is well known that traditional soaps are alkaline, can alter the protective acidic mantle of skin and remove the natural sebum, resulting in drier skin and reduced protection from skin commensals. This can further compromise the skin and increase the risk of MASD, especially in patients with vulnerable or fragile skin (Beldon, 2008; Beeckman et al, 2015).

The fundamental aspects of MASD prevention and management should be based on skin cleansing with a mild, pH-balanced soap substitute, or leave-

Table 3. Cost comparisons against the two main equivalents

Format	Medi Derma-S	3M Cavilon	S&N Sorbaderm	Cost savings w/MDS
2g Cream Sachet	£5.85	£6.47	£5.94	**-10%**
28g Cream Tube	£2.98	£3.32	£3.20	**-10%**
90g Cream Tube	£5.95	£6.55	£6.48	**-9%**
1ml Film Applicator	£3.70	£4.09	£4.00	**-10%**
3ml Film Applicator	£5.95	£6.62	£6.48	**-10%**
Film Wipes (30)	£19.40	£23.76	NA	**-15%**
30ml Film Pump Spray	£5.35	£5.85 (28ml)	£5.39 (28ml)	**-9%**

Source: National Health Service England and Wales - Electronic Drug Tariff - February 2021

Table 4. Cost comparison against the main equivalent

Format	Medi Derma-*PRO*	S&N Proshield	Cost savings w/MDP
Cleanser	£5.95 for 250ml	£6.61 for 235ml	**-10%**
Ointment	£8.50 for 115g	£9.94 for 115g	**-15%**

Source: National Health Service England and Wales - Electronic Drug Tariff - February 2021

on/no-rinse cleansers, to remove contaminants and microorganisms, followed by the application of a skin moisturiser and an impermeable barrier that provides total skin protection (Beldon, 2012; Beeckman et al, 2015; Lichterfeld-Kottner et al, 2020).

The overall improvement in the patients' skin condition at the end of the evaluation suggests the Medi Derma product formulations were effective at providing skin barrier protection, regardless of the level/extent of skin damage. Thus, these are suitable for use as part of a structured skin care regimen for prevention and management of MASD.

Considering the three patients whose skin condition appeared to have worsened after the evaluation, two were due to the product not being indicated for the level of skin damage those patients were experiencing. The other was due to the inappropriate use of the product — the patient did not receive the treatment as frequently as it should have been given; in this instance, after every episode of incontinence. Therefore, it could be considered to be an educational issue, as opposed to a reflection of the products' efficacy.

The overall performance ratings and additional feedback received for all the Medi Derma formulations, in comparison to equivalent products previously or usually used, is testimony to the products' efficacy. The majority found them to be better than, or at least the same as, similar products currently available at this time, further supporting the effectiveness of these products in clinical practice.

COST BENEFITS

The TBP™ range provides clinicians with a clinical and cost-effective solution for the prevention and management of MASD. The reality for healthcare is that choices have to be made about how money and resources are allocated for maximum overall benefit (International Consensus, 2013), and decisions are often made based on the unit cost of a product. Implementing a prevention or management strategy like TBP™ simplifies decision-making, prevents inappropriate product use and reduces costs, whilst still ensuring confidence in achieving good patient outcomes. *Table 3 and 4* show the potential FP10 prescription cost savings for the Medi Derma product range in comparison to the main equivalents.

LIMITATIONS

The interpretation of this data is not from a direct comparative evaluation study; it is a subjective comparison to previous or usual treatments provided by clinicians. Therefore, we should accept that there may be differences between the evaluator's interpretations. There were gaps in data collection, as not all parameters were completed as part of the clinical evaluation process. Moving forward, it is acknowledged that a more robust monitoring plan should be implemented to ensure that all the required data is captured, allowing for a more rigorous and representative analysis.

CONCLUSION

It is anticipated that the findings of this retrospective

analysis have demonstrated that the use of a TBP™ strategy can improve clinical outcomes for patients at-risk of, or suffering with, MASD. This type of approach offers a clinical and cost-effective rationale, ensuring that patients receive the most appropriate product at the right time and enables skin care regimens to be stepped up, or stepped down, according to patient need (Hughes, 2016).

While the use of skin barrier products contributes to the successful maintenance of skin integrity, it is essential that healthcare practitioners have a better understanding of the strategies and evidence to support clinical practice, and effectively manage healthcare resources. Additionally, it is of equal importance to continue to raise awareness that all forms of MASD can have a significant effect on patient wellbeing and quality of life (Fletcher et al, 2020). This can only be achieved through the provision of basic skin care education and training for all registered and non-registered healthcare practitioners, along with guidance for best practice, reducing the incidence of these and related skin conditions, such as cutaneous infection and pressure ulcers (Stephen-Haynes and Stephens, 2012; Beeckman et al, 2014; Fletcher et al, 2020). Adopting an integrated and holistic approach and focussing on the importance of skin integrity, and effective prevention and management strategies, may serve as a great benefit to improving practice (Beeckman et al, 2020). WUK

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