Clinical Practice

Peri-wound Skin Protection: A Comparison of a New Skin Barrier vs. Traditional Therapies in Wound Management

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Abstract

The peri-wound skin has the potential to break down as a result of constant moisture exposure. Keeping the peri-wound skin intact has become a challenge for caregivers and patients alike. Traditionally, zinc oxide ointment or petrolatum preparations have been used as a protective barrier[1]. These products are often messy and difficult to remove.This study compared the protective function and clinical efficiency of a protective liquid acrylate skin barrier film to currently used barrier preparations.This was a prospective open labeled case series study with each patient being used as their own control in a split wound model. We have evaluated a new protective liquid film-forming acrylate skin barrier (Cavilon™ No Sting Barrier Film, 3M Canada) with the traditional, currently used zinc oxide ointment or petrolatum-based barrier preparations in 30 patients. In a bid to determine clinical versatility, we have evaluated these products across several wound etiologies: venous stasis ulcers, diabetic foot ulcers and pressure ulcers. Each wound acted as its own control, where half the peri-wound area was treated with the new skin barrier and the other with one of the traditional

products, with Steristrips™ (3M Healthcare) used to bisect the wound.The results indicate all preparations to be similar in clinical efficacy. The new liquid acrylate skin barrier product (Cavilon™ No Sting, 3M) had statistically superior efficiency/ performance benefits: it was more caregiver/patient friendly, allowed visualization of the wound edges and was quicker to apply in the clinical setting.

Introduction

A skin barrier will help with the challenge1 of protecting red, irritated incontinence-damaged skin, sealing healthy skin from body fluids, or preventing peri-wound maceration (Figures 1 and 2). Barriers can also help prevent stripping of fragile skin (Figure 3) by decreasing the separation force from aggressive adhesives/dressings. Skin protection is paramount to prevent breakdown as a result of exposure to caustic substances[2, 3].

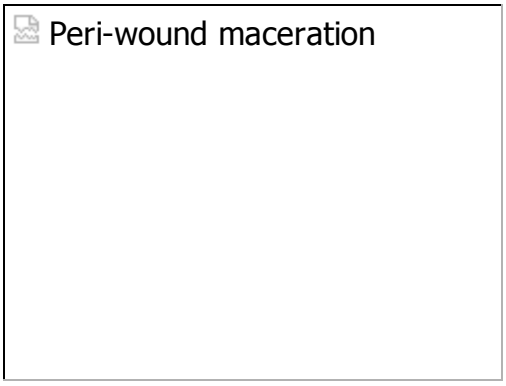

Figure 1 – Peri-wound maceration

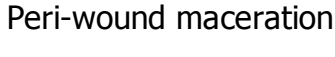

Figure 2 – Peri-wound maceration

Wounds are often excellent producers of moisture, which can be damaging to the peri-wound area [3]. Wound exudate contains not only water, which in itself can be detrimental, but often cellular debris and enzymes [4]. This cocktail can be very corrosive to the intact skin surrounding the wound.

In addition, although absorptive dressings are available, these often leak or are only changed after leakage has occurred. As a result, the surrounding skin is exposed to wound exudate on a frequent or prolonged basis [5,6].

Traditionally both zinc oxide and petrolatum ointments have been routinely used to protect the peri-wound area [1]. This approach is effective but can be problematic. These products can interfere with dressing function, including both absorption and adhesion. They are also messy to use and difficult to remove [1] (Figure 4).

With the advent of liquid film-forming technologies, new skin barrier products have been developed for this protective need[7]. These products convert a liquid spray to a continuous uniform barrier film on the skin surface. One of these

newer technologies (Cavilon™ No Sting, 3M) provides a flexible, durable, breathable moisture-repellent film on the skin. This film is delivered via an alcohol-free liquid acrylate using an applicator wand, foam wipe or spray bottle[8]. The acrylate film solidifies soon after skin contact. It has been shown that this product is cost effective in a number of treatment areas[9,10].

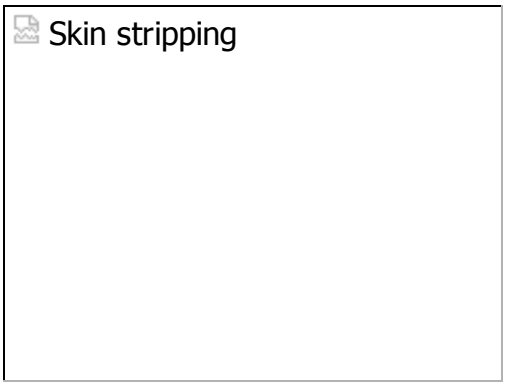

Figure 3 – Skin stripping

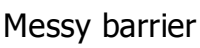

Figure 4 – Messy barrier in use

There was a need to compare the peri-wound protection performance of this new product against two routinely used barrier products, namely zinc oxide ointment and petrolatum.

Methods

The study was a prospective, open-labeled clinical case series and was designed to recruit 30 patients. The wounds had the following etiologies: venous stasis ulcers, diabetic foot ulcers (DFUs) and pressure ulcers. These patients were recruited from our routine wound-care outpatient clinic.
A formal protocol and case record forms were submitted to the local IRB and approval was obtained. The study was conducted in an outpatient specialized wound clinic, as well as through home-care patient visits and chronic-care facility nursing visits.

Patients were evaluated against exclusion/inclusion criteria and, if suitable for the study, asked for informed consent. The inclusion criteria were primarily the ability to provide informed consent and the presence of a chronic ulcer that was at risk of peri-wound maceration. The exclusion criteria included uncontrolled diabetes; poor compliance with medical treatments; prior participation in this study and any known sensitivity to any of the skin barrier components.

The interval between assessments was weekly, or sooner if a dressing change was necessary due to leakage.

Each wound was its own control, one half being protected via the new skin barrier and the other being protected with either zinc oxide ointment or a petrolatum product. The two areas were separated by local application of thin adhesive strips (Steristrips™, 3M).

The same study nurse at each visit (including the initial visit) measured, traced and photographed the wound. Both wound exudate and peri-wound skin condition were also assessed.

Exudate was assessed as mild (<25% dressing saturation); moderate (25-75% saturation) and heavy (>75% saturation).

The peri-wound skin was assessed for the presence of erythema, the intensity of the redness and any signs of skin erosion. A relative score was defined and evaluated between zero and three, depending on the severity of these parameters. A low score indicated little or no erythema, redness and skin erosion. A high score, on the other hand, indicated extensive erythema, redness and skin erosion. An increased score therefore represents peri-wound skin deterioration.

The above assessment parameters were used to determine product efficacy with respect to protection of the skin from damage (barrier function). Additional data were also collected at each visit to determine other performance attributes.

The nursing application time was recorded, using a stop-watch, as an indicator of user friendliness. The time to remove residual debris—the total cleansing time—was also recorded. Each individual patient was followed for a total of six visits and assessments.

Results

Our patient population comprised 20 males and 10 females. The average age was 61.3 ± 15.56 years, ranging from 24 to 86. Wound types included eight diabetic foot ulcers (DFUs); nine pressure ulcers and 13 venous ulcers. The average wound size was 2.1 x 1.9 cm, ranging from 0.2 x 0.6 cm to 9.0 x 6.0 cm. The majority (~ 80%) of the wounds exhibited mild to moderate exudation. The average initial peri-wound score for the No Sting/zinc and the No Sting/petrolatum groups were 1.94 ± 1.73 and 0.79 ± 1.31 respectively. These two groups were not too statistically different (Table 2). A subset analysis demonstrated there was no significant difference in initial peri-wound scores for the venous ulcers; diabetic and pressure ulcers were analyzed independently (Table 2).

All data were collected and recorded on case record forms, tabulated and analyzed statistically by computer. Patient demographics were recorded and evaluated to ensure similarity of the patient groups (Table 1).

Etiology	Product	Age	Sex	Baseline	Baseline	Average

	Assigned	**(years)**		**Wound Size** (cm)	**Exudate Assessment**	**Baseline Peri-wound Score**
Diabetic Foot (n = 8)	No Sting /Zinc 4 No Sting /Petro 4	Avg — 62.4 ± 8.37 Range (51 — 75)	5 Male 3 Female	Avg: 1.9 x 2.0 Smallest: 0.6 x 0.7 Largest: 5.1 x 5.3	0 Heavy 4 Moderate 3 Mild 1 Unknown	0.88 ± 1.13
Venous (n = 13)	No Sting /Zinc 6 No Sting /Petro 7	Avg — 61.6 ± 16.11 Range (24 — 83)	10 Male 3 Female	Avg: 2.6 x 2.1 Smallest: 0.6 x 0.5 Largest: 9.0 x 6.0	2 Heavy 3 Moderate 8 Mild	1.08 ± 1.71
Pressure (n = 9)	No Sting /Zinc 6 No Sting /Petro 3	Avg — 60.0 ± 20.59 Range (30 — 86)	5 Male 4 Female	Avg: 1.8 x 1.6 Smallest: 0.2 x 0.6 Largest: 3.2 x 2.3	1 Heavy 2 Moderate 6 Mild	2.22 ± 1.79

Table 1 – Demographics by Etiology at Initial Visit

Statistical Evaluation of Patient Groups	**P-value**
Age	

Diabetic (62.4 ± 8.37) **vs Venous** (61.6 ± 16.11)	**NS (0.64)**
Venous (61.6 ± 16.11) **vs Pressure** (60.0 ± 20.59)	**NS (0.88)**
Pressure (60.0 ± 20.59) **vs Diabetic** (62.4 ± 8.37)	**NS (0.82)**
Wound Size (area)	
Diabetic (5.59 ± 8.92) **vs Venous** (9.66 ± 15.16)	**NS (0.46)**
Venous (9.66 ± 15.16) **vs Pressure** (3.74 ± 3.67)	**NS (0.31)**
Pressure (3.74 ± 3.67) **vs Diabetic** (5.59 ± 8.92)	**NS (0.47)**
Initial Peri-Wound Score	
No Sting /Zinc (v1) (1.94 ± 1.73) **vs No Sting /Petrolatum (v1)** (0.79 ± 1.31)	**NS (0.06)**
Diabetic v1 (0.88 ± 1.13) **vs Venous v1** (1.08 ± 1.71)	**NS (0.60)**
Venous v1 (1.08 ± 1.71) **vs Pressure v1** (2.22 ± 1.79)	**NS (0.24)**

Pressure v1 (2.22 ± 1.79) **vs Diabetic v1** (0.88 ± 1.13)	**NS (0.13)**

Table 2 – Statistical Evaluation of Patient Groups

These patient groups were compared statistically using a student's t-test within the Microsoft Excel spreadsheet program.

Based on age, wound size and initial peri-wound score, all patient groups proved to be equivalent with no statistical difference observed between each group (Table 2).

Wound size, exudation level and peri-wound skin condition were utilized to show efficacy, and the changes observed are presented in Table 3.

Etiology	**Change In**		
	Size	**Exudate**	**Peri-Wound Skin**
Venous (n = 13)	66% decreased 25% no change 9% increased	66% no change 34% decreased	9% improved 66% no change 25% deteriorated
Diabetic (n =8)	50% no change 50% decreased	12.5% increased 75% no change 12.5% decreased	25% improved 75% no change
Pressure	34% no change	88% no	66% no change

		change	
(n = 9)	66% decreased	12% decreased	34% decreased

Table 3 – Overall Changes in Efficacy Parameters

Product efficiency was evaluated via application and cleansing time (Figures 5 and 6). These parameters were also analyzed by etiology (Figures 7 -10).

Statistical analysis was carried out to evaluate: product efficacy, based on change in size, exudation and peri-wound score; product efficiency, utilizing application time and cleansing time; and any etiological differences for both efficacy and performance.

These performance parameters were compared statistically using a student's t-test within the Excel spreadsheet program.

As a measurement of product efficacy—i.e. provision of barrier function—the changes in wound size, exudation level and peri-wound skin condition (Table 3) were evaluated statistically and shown not to be significantly different between product groups. Using a student's t-test, Visit 6 versus visit 1 peri-wound scores for No Sting, petrolatum and zinc oxide ointment were equivalent with no statistical difference (Table 4). This indicates that the wounds did not get worse over the duration of the study and that the barriers provided protection.

Statistical Comparison	**P-value**
Peri-Wound Assessment	
No Sting/Zinc: visit 6 (2.78 ± 1.64) **vs visit 1**(1.94 ± 1.73)	**NS(0.06)**
No Sting/Petrolatum: visit 6 (0.62 ± 1.12) **vs visit 1**(0.79 ± 1.31)	**NS(0.66)**

Table 4 – Statistical Comparison of Peri-wound Score

As a measurement of product efficiency, cleansing time and application time were evaluated statistically. Using a student's t-test and analyzing the product application times, No Sting was shown to be significantly better, with shorter application times when compared with either petrolatum and zinc oxide ointments (Table 5). Analysis of the two No Sting groups showed no statistical significance between them, demonstrating equivalence. A subset analysis of the cleansing time demonstrated that venous ulcers had a longer cleansing time due to the initial visits, where prior therapies proved difficult to cleanse off. This analysis, however, showed there was no significant difference between diabetic and pressure ulcers when analyzed independently.

Statistical Comparison	P-value
Cleansing Time	
Zinc (11.27 ± 7.08) **vs Petrolatum** (11.73 ± 7.87)	**NS(0.65)**
Diabetic (12.86 ± 8.90) **vs Venous** (16.57 ± 17.24)	**NS(0.07)**
Venous (16.57 ± 17.24) **vs Pressure** (12.40 ± 8.74)	**S(0.05)**
Pressure (12.40± 8.74) **vs Diabetic** (12.86 ± 8.90)	**NS(0.56)**
Application Time	
No Sting (5.95 ± 3.56) **vs Zinc** (11.67 ± 8.04)	**S(0.00)**
Zinc (11.67 ± 8.04) **vs Petrolatum** (9.91 ± 5.74)	**NS(0.28)**
Petrolatum (9.91 ± 5.74) **vs No Sting** (5.56 ± 3.88)	**S(0.00)**

No Sting (zinc group) (5.95 ± 3.56) **vs No Sting (petro group)** (5.56 ± 3.88)	**NS(0.56)**

Table 5 – Statistical Comparison of Efficiency Parameters

Discussion

Our results show all skin barriers tested to be effective in the management and prevention of peri-wound skin maceration. This was shown across all etiologies with no statistical difference being observed between patients or products.

Our patient groups were similar enough across all patient demographics (Table 1). Our venous leg ulcer patients had slightly larger wounds in general, and the initial cleansing time was significantly longer due to prior dressing therapies and wound residue. This was not an issue with subsequent cleansing since previous cleansing had removed prior therapies. In these cases the initial cleansing times were excluded from our analysis.

As can be seen in Table 3, in general most wounds reduced in size or at least remained the same size. Similarly there was little difference observed in exudate severity and also the peri-wound assessment score (Table 4). This was indicative of effective management, with no compromise of intact peri-wound skin or further skin breakdown being observed. It can therefore be suggested that all products used are efficacious in the provision of skin-barrier protection.

Differences were observed in the area of user friendliness. Figures 5 and 6 demonstrate product efficiency using cleansing time. In venous ulcers the cleansing time was longer due to the long wear time of dressings used in the treatment and fixed residual debris on the ulcer surface.

Significant differences were observed with regard to application time (Table 5). As can be seen in Figure 7, the Cavilon™ No Sting skin barrier was twice as fast to apply (5.7 seconds average versus 10-12 seconds). In addition much lower amounts were required to provide effective skin protection. Its transparency allowed visualization of the underlying wound margin/skin surface. Zinc oxide ointment is opaque but has a longer wear time than the translucent petrolatum bases that tend to melt.

No adverse events were reported for any of the preparations used. They were all suitable for clinical use in the etiologies evaluated. One area of improvement for a future study would relate to the assessment of peri-wound skin. In this study the peri-wound skin was assessed globally. In future studies we would evaluate each half separately—i.e. No Sting versus zinc or petrolatum—to better

differentiate peri-wound skin barrier preparations.

The superior user-friendliness score of the liquid film-forming acrylate can be of significant importance for the patient and caregiver.

Conclusions

The barrier function of the zinc oxide ointment, petrolatum and liquid film-forming acrylate were equal in clinical efficacy.

The liquid acrylate products are quicker to apply and more user-friendly when compared with zinc oxide ointment or petrolatum.

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