A Prospective, Randomized, Multi-site Clinical Evaluation of a Transparent Absorbent Acrylic Dressing and a Hydrocolloid Dressing in the Management of Stage II and Shallow Stage III Pressure Ulcers

by

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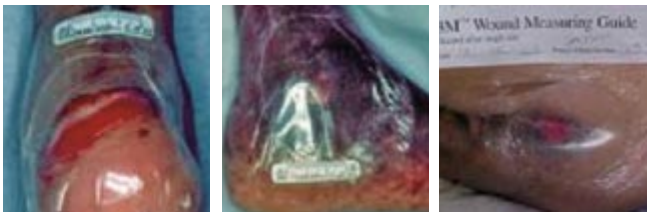
Background

Since their introduction in the 1980s, hydrocolloid dressings have become a common dressing of choice for use on Stage II and III, minimally to moderately draining pressure ulcers. While most hydrocolloid dressings have improved greatly in design and function since their initial introduction, they still have limitations which can vary by brand and formulation. Recently, a dressing manufactured with a new absorbent technology and a novel design has been introduced to address the shortcomings of hydrocolloid dressings. This study is the first to clinically evaluate this new dressing on pressure ulcers.

3M™ Tegaderm™ Absorbent Clear Acrylic Dressing



Transparent
- Allows for wound observations without removing the dressing

Unique absorbent acrylic polymer
- Manages up to moderate amounts of drainage
- Maintains structural integrity without melt down in the wound
- Eliminates odor derived from dressing decomposition

High wet & dry conformability
- Molds to difficult body contours and remains conformable after absorbing wound drainage

Objective

The objective of this study was to compare clinical performance of 3M™ Tegaderm™ Absorbent Clear Acrylic Dressing to DuoDERM® CGF® Dressing in the treatment of Stage II and III, minimally to moderately draining pressure ulcers.

Methods

This was a prospective, open-label, randomized, comparative, multi-site clinical evaluation of two adhesive absorbent wound dressings. Four study sites were located in the USA and one in Canada. Patients were randomized to receive one of the two study dressings to treat a Stage II or shallow Stage III pressure ulcer that did not require a wound filler.

Multiple sizes and configurations of each dressing were available to the investigators so that a variety of wound sizes could be enrolled into the study and the dressing could be optimally matched to the needs of the wound. Investigators involved in the study performed wound, peri-wound and dressing performance assessments at approximately weekly (7 ± 3 day) intervals throughout the follow up period. Dressings were changed only when they met specific change criteria. Ulcers were followed for 56 days, or until healing occurred.

Data Analysis

Differences in dressing performance were tested with the Wilcoxon Rank Sum Test. Multiple assessments were averaged for each patient across the treatment period. The percent of wounds that healed were compared with Chi-Squared Analysis. Significance was assessed at $p \leq 0.05$ and trends toward significance were assessed at $p \leq 0.1$.

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Results

Demographics

Except for ulcer location, there were no significant differences in patient or ulcer characteristics between the two treatment groups. There were significantly more difficult to treat sacral ulcers in the Tegaderm™ Absorbent dressing group than in the DuoDERM CGF dressing group.

Wear Time

Mean (SD) wear time was 5.7 (2.55) days for Tegaderm™ Absorbent dressing and 4.7 (2.29) days for DuoDERM CGF dressing, a difference of 1.0 days. This difference trended toward statistical significance (p=0.086) and was clinically noticeable, as the investigators involved in the study rated wear time of Tegaderm™ Absorbent dressing significantly better than DuoDERM CGF dressing (Table 2).

Wound Healing

In both groups 60% of the wounds reached wound closure within the 56 day study period.

Dressing Performance

The majority of assessments statistically favored Tegaderm™ Absorbent dressing both at application (Table 1) and removal (Table 2) of the dressings.

Table 1: Investigator Ratings of Dressing Performance During Application

Assessment	Dressing Rated Superior		P-value
	Tegaderm™ Absorbent Dressing	DuoDERM CGF	
Ease of Application			0.122
Ability to Center Dressing over Ulcer	•		0.005
Ability to Assess Ulcer before Absorption	•		<0.001
Conformability	•		0.026

Table 2: Investigator Ratings of Dressing Performance During Removal

Assessment	Dressing Rated Superior		P-value
	Tegaderm™ Absorbent Dressing	DuoDERM CGF	
Adhesion			0.923
Absorbency	•		0.074
Wear Time	•		0.035
Barrier Properties	•		0.039
Patient Comfort During Removal	•		<0.001
Overall Patient Comfort	•		0.048
Ease of Removal	•		<0.001
Conformability after Absorption	•		0.001
Non-Adherence to Wound Bed	•		<0.001
Overall Satisfaction	•		<0.001
Ability to Assess Ulcer after Absorption	•		<0.001
Overall Value of Transparency	•		<0.001
Residue in Wound	•		<0.001
Residue on Skin	•		0.002
Odor	•		<0.001

Conclusions

- Tegaderm™ Absorbent clear acrylic dressing retained all the positive features of hydrocolloid dressings while improving upon inherent limitations including lack of transparency, wear time, residue and odor.
- These features may facilitate fewer dressing changes resulting in improved nursing productivity and treatment cost.
- Results of this study suggest that use of Tegaderm™ Absorbent clear acrylic dressing as a standard approach for Stage II and shallow Stage III pressure ulcers may positively impact clinical outcomes, clinician satisfaction and wound care costs.

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