CLINICAL EVALUATION OF AN ABSORBENT HYDROGEL DRESSING
Solo and Combination Wound Management Approaches

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ABSTRACT

Twenty patients with one or more Stage II or Stage III pressure sores that were non, lightly, or moderately exudating were selected from two long-term care facilities for this open label, randomized study to evaluate an absorbent hydrogel dressing. Patients were assigned to a solo or combination treatment group based on wound assessment. Patients in the solo treatment group were treated with Elasto-Gel™ Hydrogel Sheet Dressing only; patients in the combination treatment group were treated with either Elasto-Gel™ Hydrogel Dressing plus silver sulfadiazine (SSD) or Elasto-Gel™ plus a liquid amorphous hydrogel dressing. Dressings in both groups were changed once daily. Patients in the solo treatment group experienced a mean healing time of 28.6 days, which was equal to the pre-treatment duration of their wounds, probably due to the initial resolution of the macerated tissue at the peri-wound margin. The absorptive capacity of the hydrogel managed the excess exudate while providing a moist healing environment. Patients in the combination therapy group experienced a mean healing time of 26.7 days, which was less time than the pre-treatment wound duration. Using a double strength approach to hyper-hydrate the wound bed appears to be beneficial for enhancing the healing environment. Once healing had occurred, the amorphous hydrogel or SSD was discontinued and the Elasto-Gel™ was used alone to provide cushioning and decrease friction to high impact sites.

INTRODUCTION

Pressure sores are a troublesome occurrence in the hospital and nursing home population. Non-ambulatory patients are at particular risk of developing pressure ulcers, since they lack the ability to move about freely and relieve continuous pressure on prominent areas. Also, patients with conditions which decrease sensation may not shift positions to relieve pressure on areas at risk. Pressure ulcers can develop in one to six hours depending on the amount of pressure, skin condition, vascular compromise and overall health status of the patient. Damage occurs in a conical fashion; destruction of deeper tissue is always more extensive than appears on the surface. While most pressure ulcers are Stage I and II, immobility can cause established ulcers to progress to full-thickness ulcers.

According to the Agency for Healthcare Policy Research and the National Pressure Ulcer Advisory Panel, the estimated prevalence of pressure ulcers in the U.S. is between 3 and 6 million. The prevalence in hospitals ranges between 3% and 20%; in nursing homes, the prevalence ranges between 15% and 25% but may be as high as 35% in extended care facilities. As many as 60% of pressure ulcer patients are over the age of 65. The cost to heal a single pressure ulcer averages between $15,000 and $27,000, placing an estimated burden of 3.5 to 7 billion dollars on the U.S. healthcare system annually. To address this serious problem, a major education effort is underway by the Agency for Healthcare Policy Research and the National Pressure Ulcer Advisory Panel to reduce the incidence of pressure ulcers.

The most common treatment modalities for pressure ulcers include regular repositioning and the use of wound dressings to prevent breakdown and promote healing of areas already ulcerated. Numerous wound dressings have been introduced in recent years, and new categories of products are constantly evolving. Elasto-Gel™, the first in a new category of dressings known as the absorbent hydrogels, was introduced in 1988 by Southwest Technologies, Inc. Composed of a mixture of glycerine and water entrapped in a cross-linked polymer matrix, the product absorbs up to three times its own water weight. Unlike water-based hydrogels, Elasto-Gel™ has a high glycerine content that does not macerate an open wound or the surrounding tissue. It does not dry out, maintaining a constant level of moisture and providing an environment most conducive to wound healing.

Using an absorbent hydrogel has become an accepted practice for management of exudating and non-exudating wounds. This study, conducted in two long-term care facilities, was designed to develop guidelines for the use of an absorbent hydrogel sheet dressing. In addition, the study assessed the benefits of using a combination approach (i.e., absorbent hydrogel plus a wound amorphous hydrogel or silver sulfadiazine).

A solo approach involved the use of Elasto-Gel™ alone as the primary dressing. It was hypothesized that wounds with evidence of light to moderate amounts of exudate would best benefit from the absorbing capabilities of the Elasto-Gel™ material. These wounds would not require additional moisture to rehydrate the wound bed. It was also hypothesized that a combination approach would work best on wounds with scant amounts of exudate or no exudate, and on wounds with slough or the presence of local infection. An amorphous hydrogel would be used for rehydration of slough tissue and for remoisturizing dry wound beds. Silver sulfadiazine would be used for wounds with symptoms of local infection, pale/dusky granulation tissue, or prophylactically for patients deemed to be at increased risk of infection.

MATERIALS AND METHODS

This was an open label, randomized study of male and female patients with one or more pressure sores. Twenty patients with Stage II or Stage III, non, lightly, or moderately exudating pressure sores were selected from two long-term care facilities. Wounds were debrided of hard eschar, which prohibited the full assessment of the wound depth and involved tissue. Patients with any signs of systemic infection were treated with appropriate therapy until symptoms cleared. Patients with terminal illness or malignancy were excluded from the study. Consent forms were signed by all patients or the patient care representative for patients who were not mentally competent.

Prior to initiation of the study, appropriate pressure relief, nutritional supplements, management of incontinence and other physical or supportive procedures required by the patient were instituted. Baseline laboratory data including CBC, SMAC 6, albumin, total protein, and creatinine were obtained and recorded.

TABLE 1

Patient Selection Criteria

1. Stage II or III, as defined by the *WOCN Standards of Care Dermal Wounds: Pressure Sores*
2. Less than 80% eschar
3. Non, lightly, or moderately exudating
4. No known terminal illness or malignancy

METHODOLOGY

Patients were assigned to a solo combination treatment group based on assessment of their wounds. The solo therapy group was identified by tissue assessment demonstrating moderate amounts of exudate and tissue loss of more than 4 cm in depth. The combination therapy group was identified by tissue assessment which revealed wound characteristics including: (1) non-exudating to scant amount of exudate; (2) slough type tissue to 80% of the wound base, and; (3) pale/dusky granulation tissue. Wounds indicating the presence of local infection were also placed in the combination therapy group. The decision grid used for selecting the type of therapy to match the treatment to wound characteristics is shown below.

Decision Grid

Type of Wound	Solo	Combination
Exudating	x	
Non-Exudating		x
Infected		x
> 4 cm Depth Tissue Loss	x	x

Patients assigned to the solo treatment group were treated with Elasto-Gel™ Hydrogel Dressing only. Patients in the combination treatment group were treated with either Elasto-Gel™ Hydrogel Dressing plus silver sulfadiazine (SSD) (Thermazine®, Sherwood Medical) or Elasto-Gel™ plus a liquid amorphous hydrogel dressing (Royl-Derm™, Acme United or Curasol™, Health Point Medical).

In both groups, wounds were carefully rinsed with normal saline to remove any particulate matter. In the solo therapy group, Elasto-Gel™ Dressings were applied by placing the gel sheet directly on the wound and securing the dressing in place with hypoallergenic tape. For patients unable to tolerate tape, the dressing was secured with an elastic bandage, roll gauze, stretch netting, or comparable material. Dressings were changed once daily.

Silver sulfadiazine or wound amorphous hydrogel was used in combination with the Elasto-Gel™ Dressing in wounds treated using the combination therapy approach. Approximately one-half ounce of silver sulfadiazine or wound amorphous gel was applied to a thickness of 1/16 inch over the entire wound bed. The wound hydrogel was applied to increase the moisture content at the wound site. Silver sulfadiazine (SSD) was selected for the patients who were at the risk for wound infection or who demonstrated local symptoms/signs of infection. Dressings in this group were also changed once daily.

Wounds in both groups were measured once weekly throughout the course of the study. The length, width, and depth of the wounds were recorded in centimeters and millimeters. Linear wound measurements were taken, along with photographs. Wound assessments were scored using the Bates-Jensen Pressure Sore Status Tool (PSST). To ensure objective monitoring of wound care outcomes, all data were entered into the I-Star™ computerized wound documentation program. This software program is designed to compile comprehensive data of wound management utilizing Relational Database Management System (RDBMS) techniques. Pre-treatment and discharge photographs of each ulcer were taken with a ruler as a scale in each photograph. Photographs of the wounds were also taken once weekly at the time the wounds were measured.

No topical therapies other than those included in the treatment protocol or control were used during the study. All wounds were rinsed with normal saline at each dressing change. Patients were discontinued from the study when any wound exhibited changes not associated with the normal healing process such as erythema, edema, induration, purulent or foul-smelling exudate, or pain. The treatment duration was two months or until wound healing occurred.

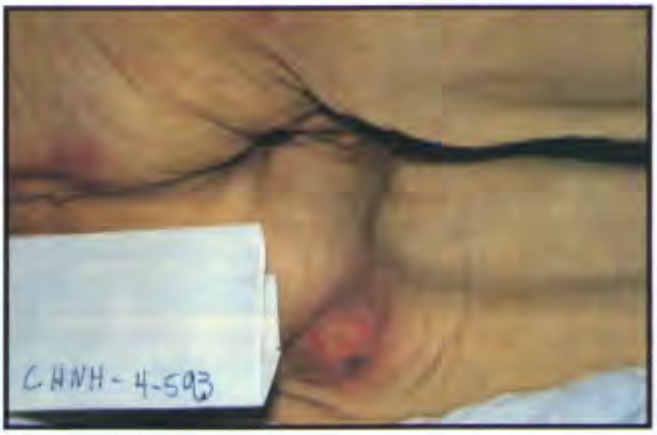
RESULTS

Solo Treatment Group

Tissue changes noted in the solo treatment group included: (1) wound exudate contained by the Elasto-Gel™ dressing; (2) peri-wound maceration resolved due to the absorption capabilities of the dressing; (3) wound healing as evidenced by the resolution of the wound areas within a six-week response time, and; (4) protective cushioning of the wound

sites. The solo treatment group experienced a mean healing time of 28.6 days after treatment was implemented.

In this group of patients, the mean healing time was equal to the pre-treatment duration of their wounds. This we believe to be related to the initial resolution of the macerated tissue at the peri-wound margin. The average amount of time for the resolution to occur was 2 days. The absorptive capacity of the hydrogel managed the excess exudate while concurrently producing the moist healing environment.



Study Group A — Solo Therapy (N = 10)		
Sex	Male = 4	Female = 6
Age	Range 69-88 years	Mean = 79.0 years
Wound Size (cm^2)	Range 2 cm^2-22 cm^2	Mean = 8 cm^2
Wound Stage	II = 4	III = 6
Duration	Range 6-78 days	Mean = 26.5 days
Albumin	Range 1.3-3.4	Mean = 2.6
Exudate	Moderate to large amount	PSST Scores = 3-5
Treatment Time Until 100% Healed	Range 4-45 days	Mean = 28.6 days

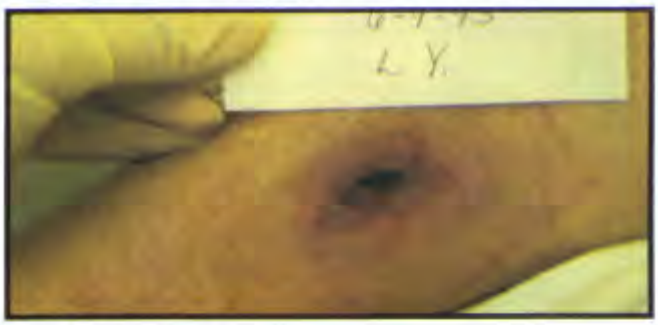
Combination Therapy Group

Tissue changes observed in patients in the combination therapy group included: (1) an increase in moisture at the wound site as demonstrated by a glossy, pink to red wound base; (2) absence of peri-wound maceration; (3) autolytic removal of slough tissue by day 16.2, and (4) 0% infection rate.

Combination therapy patients showed a mean healing time of 26.7 days. This group healed in less time than the pre-treatment wound duration. The healing time can be explained by the moisture enhancing properties of the sheet hydrogel combined with an amorphous hydrogel and SSD. Using a double strength approach to hyper-hydrate the wound bed was beneficial for enhancing the healing environment. Once healing had occurred, the primary gel or ointment was discontinued and the Elasto-Gel™ was continued to provide cushioning and decrease friction to the high impact site on three wounds on the coccyx area and five on the heels.

Study Group B — Combination Therapy (N = 10)		
Sex	Male = 5	Female = 5
Age	Range 41-89 years	Mean = 74.6 years
Wound Size (cm^2)	Range 4 cm^2-36 cm^2	Mean = 18.4 cm^2
Wound Stage	II = 3	III = 7
Duration	Range 3-92 days	Mean = 49.8 days
Albumin	Range 1.7-3.5	Mean = 2.8
Exudate	Non-Scant amount of exudate	PSST Scores = 1-.2
Treatment Time Until 100% Healed	Range 6-37 days	Mean = 26.7 days

Note: Wound care agents used in treating the combination therapy approach were amorphous wound hydrogel (5) and silver sulfadiazine (5).

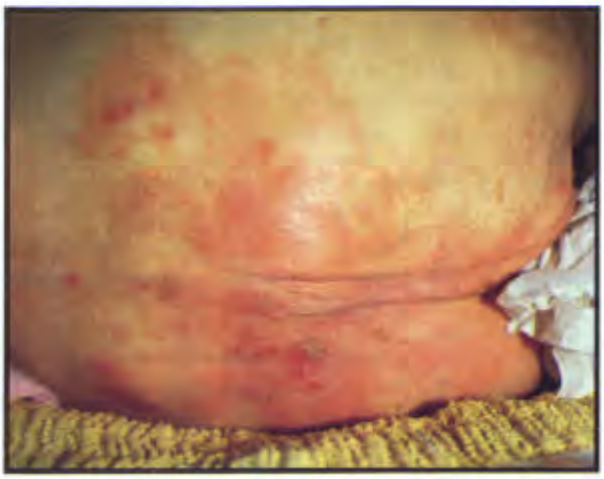


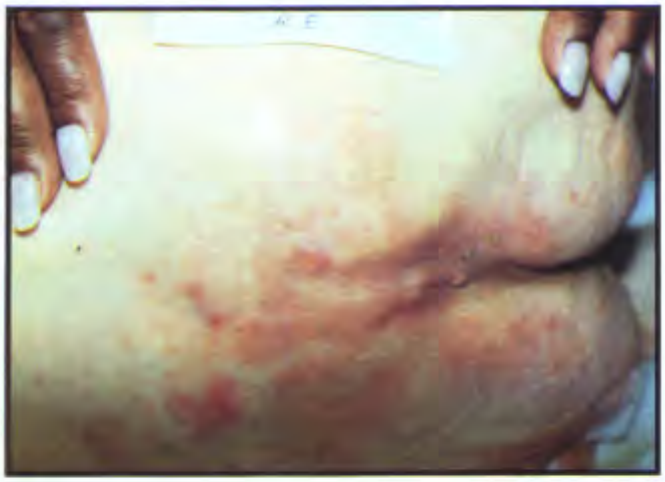
DISCUSSION

Most hydrogel wound dressing sheets are water-based products that tend to dry out rapidly when exposed to air and have the potential to macerate or soak the wound and surrounding tissue. Hydrogel sheets are usually not indicated for exudating wounds because they are not capable of absorbing wound fluid. Unlike most gel sheets that absorb very little exudate, the Elasto-Gel™ Dressing absorbed fluids and did not macerate tissue at the peri-wound margin. It also insulated the wound, provided an environment to promote moist wound healing, and protected the skin from both pressure and friction. Clinicians were able to lift the Elasto-Gel™ Sheet from the wound by its backing without the dressing disintegrating or leaving any residue. Another benefit of the product is that it exhibits bacteriostatic and fungistatic properties giving it the potential to reduce infection.

Wounds treated with Elasto-Gel™ Dressings in combination with silver sulfadizaine or an amorphous hydrogel resulted in reduced healing time as compared to wounds

treated with Elasto-Gel™ alone. For wounds that are non-exudating or exhibit a scant amount of exudate, the combination approach would appear to provide the optimum level of hydration to enhance healing. Wounds which demonstrated local infection and were treated with silver sulfadiazine (SSD) demonstrated no advancement of the infection (as demonstrated by cultures and systemic monitoring). In addition, the SSD group received the benefit of an enhanced moist environment.

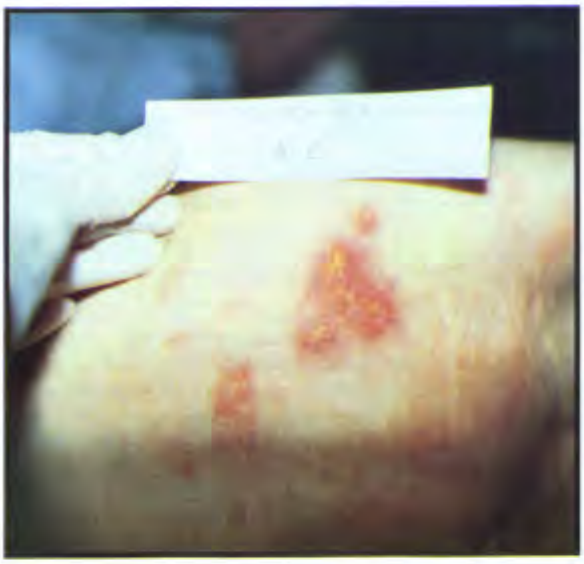




CONCLUSION

The use of an amorphous hydrogel and topical antimicrobial (SSD) is beneficial to enhancing the healing potential of many wounds when combined with an absorbent hydrogel dressing. One hydrogel sheet, Elasto-Gel™, provides a moist healing environment, absorbs exudate, and acts as a soft tissue cushion/simulator. Once healing occurs, the Elasto-Gel™ alone provides the necessary cushioning to decrease friction and shear to the high impact site and thereby help to prevent wound reoccurrence. The three patients with wounds on the ischial area received a secondary benefit from using the hydrogel. This benefit was the bony prominence cushioning and the unique property of Elasto-Gel™ of conforming to body contours which in each case actually simulated the lost soft tissue mass.

Study results help to differentiate the types of wounds that would benefit from a solo versus a combination approach. While a decision grid such as that developed for this study is useful in matching wound characteristics to the appropriate treatment, this study demonstrates the need for the development of an algorithm based on a comprehensive wound assessment coupled with the wound dressing features and benefits.



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