BIOFILM HYDROGEL DRESSING:
A Clinical Evaluation in the Treatment of Pressure Sores

Sharon L. Darkovich, RN, BSN, BA; Marie Brown-Etris, RN, CETN; Marilyn Spencer, RN, BSPA, CETN.

Sharon Darkovich is a Nursing Quality Assurance Coordinator at Saint Luke's Hospital in Cleveland, Ohio. Marie Brown-Etris is President of ETRIS Associates, Inc., an ET consulting firm founded in 1984 in Philadelphia, PA. Marilyn Spencer is Head ET at the Cleveland Clinic Foundation and Faculty member at the Turnbull School of Enterostomal Therapy.

Abstract

A new dressing for chronic wounds, BioFilm™ hydrogel dressing, was compared to a hydrocolloid dressing (HCD) control in a clinical trial involving 90 patients and 129 Stage I and II wounds (defined by Enis and Sarmienti). The testing sites included both acute care and extended care facilities. A comparison of healing response and functional characteristics of both dressings was part of this assessment. Biofilm dressings demonstrated a healing advantage over the HCD. In addition, clinicians judged that the hydrogel dressings were easier to use and had superior fluid management capability and product integrity with minimal disruption to the healing wounds.

(cont'd)
The study showed that 43% of the wounds treated with the Biofilm dressings healed completely, versus 24% for the HCD group. An analysis of the change in mean wound size from start to finish of treatment showed a 68% improvement for the average hydrogel-treated wound, compared to 40% for the HCD. Mean treatment days for the hydrogel group was 12.0 days versus 11.3 for the HCD control.

For Stage II wounds, the Biofilm product was shown to be statistically superior to the HCD in both wound area healed and healing rate (p < 0.025). The differences for Stage I wounds were not statistically significant. Analysis of a more closely controlled grouping of Stage II ulcers of size ≥ 2 cm² to ≤ 20 cm² (65% of census) demonstrated an even greater statistical difference in favor of the hydrogel dressings; the difference was valid when comparing the wound area healed (72% vs. 38%) as well as healing rate in percent area/day (8.1% vs. 3.1%) (p < 0.01). The data proved even more favorable to the hydrogel group when the analysis was limited to the acute care centers: wound area healed (80% versus 15%) and healing rate-percent area/day (10.5% vs. 1.3%) (p < 0.001).

Introduction

Over the last 10 years, significant advances have been made in applying the principles of moist wound healing to specific wound care products. While products providing the advantages of moist wound healing have been available and in use for some time (e.g., petrolatum gauze), it is only recently that materials other than gauze have been utilized to provide new and more sophisticated products. Polyurethane films are an example of such a product. These films, with a thin, adhesive coating, create artificial blisters that provide protection for the wound while allowing for moisture vapor transfer. Their use represented the first significant application of technology in materials to create and maintain a moist wound microenvironment.

Table 1. Patient Selection Criteria

- Limited to Stage I and Stage II pressure sores (Enis and Sarmienti’s criteria). No venous stasis ulcers or diabetic ulcers.
  
  Stage I: Ulceration or skin breakdown limited to superficial epidermal and dermal layer.
  Stage II: Ulceration extending through the dermis but not through adipose tissue.

- Lesions ranging in size from at least 2 to 30 cm², with sites to include sacrum, trochanters, lower extremities, buttocks, scapula, and heels.

- The size range was expanded during the course of the study, as explained in the Results section.

- Not receiving radiation therapy.

- Blood sugar levels less than 180 mg/dl.

- Improved nutritional status (i.e., receiving oral supplement, enteral feedings, TPN, or PPN).

- No known infection, sinus tracts, or fistulae in the wound.
Hydrocolloid dressings (HCD) were at the heart of the next major product development advance. These products have been shown to facilitate healing, provide a protective barrier, aid in the management of wound exudate, and require less nursing time and fewer dressing changes than "traditional" dry dressings. However, current designs of these products also present some significant disadvantages. The dressings may flow or harden depending on the patient’s body temperature and/or room temperature conditions. Material that has degraded during the course of its interaction with wound fluid will flow from the edges of the dressing and stick to the patient and bedding, hampering cleanup and removal. Because these dressings are occlusive by necessity to maintain a moist environment, the potential for anaerobic bacterial growth is ever present. Their lack of oxygen transmission and ability to absorb significant amounts of wound fluid can also lead to the development of a malodorous purulent exudate seen at the time of dressing changes. Their biocompatibility has also been recently called into question. Attempts to modify the formula have generally resulted in hydrocolloids with significantly lower absorption rates and fluid capacity.

Utilizing hydrogel technology, a newly developed wound dressing has recently become available, which appears to combine the best features of hydrocolloid and transparent film dressings. Biofilm dressings are multi-layered and consist of a polyurethane top film and foam that are bonded to a fabric containing the hydrogel, which, in turn, has a skin adhesive on the underside. The initially dry hydrogel layer of the product removes excess moisture from the wound site, providing a moist environment while still allowing for oxygen exchange. The hydrogel product was specifically designed to provide the advantages of hydrocolloid and transparent film dressings, while offering improved fluid management capability, product integrity in end-use and complete biocompatibility. The lack of dressing degradation eliminates any wound trauma associated with the cleanup of dressing meltdown. Improved healing characteristics were recently reported for this dressing compared to a hydrocolloid control using the swine model. BioFilm hydrogel dressings were specifically developed for managing pressure sores, the most prevalent type of chronic wound in this country. The purpose of this study was to test the potential efficacy of this new dressing technology in a clinical setting. A hydrocolloid dressing (HCD) was utilized as a control.

Materials and Methods

Materials

The Biofilm hydrogel dressings were manufactured by the BF Goodrich Company. The DuoDERM® hydrocolloid dressings were commercially available from the ConvaTec Division of Bristol-Myers Squibb. For both products, the four-by-four-inch size was the primary dressing. In the case of larger wounds, however, some eight-by-eight-inch HCD dressings or multiple hydrogel dressings were used to cover the treated areas.

Patient Selection/General Criteria

These clinical studies were undertaken to compare the performance of the Biofilm hydrogel dressing with that of the leading hydrocolloid dressing (HCD) used extensively in the treatment of pressure sores.

The study sites included two acute care facilities and several nursing homes. Approval was obtained as appropriate for each study setting. Only patients who met the entrance criteria were admitted to the study (see Table 1). Wounds were randomly assigned to either the hydrogel dressing group or the control group (HCD) as they were presented for admission to the study. The frequency of dressing
changes was based upon the clinician's judgement and patient condition, but, on average, dressings were changed every three to four days. Wounds were to be treated for a maximum of 60 days unless the wound healed, the patients were discharged, or in the judgement of the clinician, a change in treatment was necessary.

Clinical Procedure

The investigators were ET nurses/registered nurses who regularly and routinely treated pressure sores. Participants in the study were selected by the clinicians or the patient care staff. Upon entry to the study, baseline data were collected, which included measurement of the lesion, prior wound treatment history, nutritional sta-
Figure 1. Mean Area Healed — Stage I and II Wounds

Figure 2. Final Healed/Improved Status for All Wounds
tus, diagnoses, medication, age, and sex. In all cases, wound tracings were taken and, in some cases, photography was used to supplement the tracing procedure to determine the size of the wound. A Kundin gauge or metric ruler was used to measure wound depth. At each dressing change, or at least at weekly intervals, data were obtained for wound size (tracings), wound appearance, residue, odor, edema, maceration, and trauma to the skin. In addition, the most recent glucose and serum albumin levels were examined at the acute care centers. To ensure the relative absence of pathogens at the initiation of the trial, the wound was cleansed with a 50/50 solution of 3% hydrogen peroxide and normal saline, rinsed with normal saline, and patted dry. If the patient had excessively oily skin, defatting of the surrounding skin was done with either isopropyl alcohol or a standard skin preparation. The margin of healthy skin for adhesion was 1.25 inch surrounding the lesion. In the case of the 14% of wounds having area greater than 20 cm², however, this margin was generally not maintained utilizing four- by four-inch dressings. Following initial application, wounds were cleaned with normal saline, the surrounding skin was dried, and a new dressing was applied. Picture framing was permitted at the discretion of the clinician and these data were to be entered on the patient’s chart. Pressure-reducing air mattresses (Gaymar Sof•Care®) were utilized for all patients in the study.

Statistical Analysis

Two methods of analysis were utilized: Student’s t-test and multiple regression. The Student’s t-test takes like groups of hydrogel and HCD results, calculates the average and standard deviation(s) for each, and calculates the t-test, which compares the averages, and considers the variation within each group(s), and the number of results in each group. A t exceeding 2.0 approximates a significant difference at 95% confidence and as the magnitude of t increases, the level of significance increases. Exact levels of confidence were used in

![Figure 3. Final Healed/Improved Status for Stage II Wounds](image-url)
this study. With multiple regression, algebraic mathematical models are fitted to the results and the coefficients of the models are estimated by least squares. Multiple regression was utilized to study the complex interrelationships of the many variables present in this study.

Six extreme results were removed from the analysis in order to make it more meaningful. Patients whose wounds enlarged more than 10% per day (3 HCD and 1 hydrogel) or decreased in size more than 25% per day prior to statistical evaluation (1 HCD and 1 hydrogel) were eliminated.

It was judged that the most meaningful comparative data analysis would be for wounds \( \geq 2 \text{ cm}^2 \) or \( \leq 20 \text{ cm}^2 \). Small wounds were not easily measured with enough precision to obtain good data on the rate of healing. For wounds greater than 20 \( \text{ cm}^2 \), a controlled wound management comparison was more difficult due to the single hydrogel dressing size available; in these cases, multiple hydrogel dressings generally had to be utilized.

**Results**

A total of 90 patients were entered into the clinical trial. Of the 129 wounds in this evaluation, 62 were treated with the Biofilm hydrogel dressing and 67 were treated with the HCD. The data were analyzed for comparison of the effectiveness of hydrogel dressings versus the HCD control, using wound size as the dependent variable. For patients with multiple wounds, only one dressing type was utilized to avoid cross-contamination of data (see Table 2).

Of the total 90 patients, 55 were female and 35 were male. Participants ranged in age from 30 to 98 years; the average age was 75 years. The patients were drawn from acute care and extended care settings. The average age of subjects in the acute care settings (69 years) was significantly lower than the average age of subjects enrolled in the extended care component (83 years). The serum albumin levels averaged 2.8 gm/dl for the hydrogel patient group and 2.7 gm/dl for the HCD patient group. The mean days of treatment for the hydrogel dressing and HCD group were 12.0 and 11.3, respectively. The difference between treatment days was not statistically significant.

As the study progressed and the clinicians had repeated success with the Biofilm hydrogel dressing, the protocol was expanded to include wounds of greater or lesser size than that specified in the original protocol. The minimum size treated with the hydrogel dressings was 0.2 \( \text{ cm}^2 \); the maximum was 100 \( \text{ cm}^2 \). Wounds outside the original parameters were also treated with HCD and ranged from a minimum of 0.4 \( \text{ cm}^2 \) to 63.75 \( \text{ cm}^2 \).

Wound size from treatment start to treatment termination was examined. Data from all trial sites were entered into analysis for comparison of wound healing between the hydrogel product and the control. The mean healing response was greater in the hydrogel dressing group. While the initial mean wound size was larger for the hydrogel than for the control group (11.0 \( \text{ cm}^2 \) vs. 9.2 \( \text{ cm}^2 \)), the final wound size was smaller for hydrogel–treated wounds than for the HCD control (3.5 \( \text{ cm}^2 \) vs. 5.5 \( \text{ cm}^2 \)). The result was a greater mean healing response on the part of the wounds treated with hydrogel dressings. In the hydrogel group, the mean healing response was 7.5 \( \text{ cm}^2 \) or a 68% improvement versus starting size. For the HCD group, the difference was 3.7 \( \text{ cm}^2 \), for a 40% difference or change in mean size (see Figure 1). Given that average treatment days were virtually equivalent for both groups, the difference in mean healing response indicates a favorable performance on the part of hydrogel dressings in the treatment of these wounds.

When the data are presented according to the categories of healed, improved, no change, or worse, there was a higher percentage of wounds that were considered healed.
or improved in the Biofilm hydrogel dressing group when compared to the control group in both the acute care hospitals and nursing homes (see Figure 2). For those wounds treated with the hydrogel dressing, 90% healed or improved compared to 78% of those in the control group. In this category of healed/improved, 43% of the hydrogel-treated ulcers completely healed, in contrast to 24% for the HCD group. There was no change in 7.5% (5) of the wounds treated with the hydrogel dressing versus 12% in the HCD group. Only one of the hydrogel-treated wounds (1.5%) was worse at the end of the study compared to the HCD control group, wherein seven wounds (10%) had deteriorated.

Data were also examined with regard to wound staging and healing response. Of 62 wounds in the Biofilm hydrogel dressing group, 27 were classified as Stage I and 35 as Stage II. In the HCD group, there were 31 Stage I wounds and 36 Stage II wounds. Figure 3 illustrates the classification of healing response for Stage II wounds.

Stage I hydrogel-treated wounds exhibited a 72% average mean wound closure, compared to 44% for the HCD. There was no statistically significant difference in Stage I wounds. Hydrogel-treated Stage II wounds yielded an average value of 64% compared to 34% for the control. Hydrogel-treated Stage II wounds were shown to be statistically superior to the HCD in both area healed (p < 0.01) and healing rate (p < 0.025).

Analysis of Stage II ulcers ≥ 2 cm² and ≤ 20 cm² for all sites (65% of census) demonstrated a greater statistical significance in favor of the hydrogel dressings in both wound area healed (72% versus 38%, p < 0.01) and healing rate in percent area/day (8.1% versus 3.1%, p < 0.01). The Stage II data from the two acute care centers exhibited an even larger statistical difference in favor of the hydrogel dressing (35% of census): 80% wound area healed versus 15% for the HCD control (p < 0.0001), and 10.6% area healed/day versus 1.3% for the control (p < 0.001; see Figures 4 and 5). Tabulation of Stage II wound data and its statistical significance are presented in Table 3.

Figures 6 through 8 show three pressure sores treated with hydrogel dressings at the extended care facilities. Illustrated are examples of an ulcerated heel (Figure 6), sacrum (Figure 7), and hip (Figure 8), at the beginning and end of treatment.

Discussion

The results of the study demonstrated the ability of Biofilm hydrogel dressings to be an effective treatment for Stage I and Stage II pressure sores. The Biofilm hydrogel group showed a more favorable overall healing response compared to the HCD control, exhibiting a significantly greater number of healed Stage I and II wounds and a significantly greater proportion of healed wound area.

More specifically, while 90% of the Stage I and II hydrogel-treated wounds healed or improved compared to 78% for the HCD control, nearly twice as many of the hydrogel-treated wounds healed (43% versus 24%). Wound healing, as measured by reduction in mean wound area, yielded 68% closure for the hydrogel-treated wounds compared to 40% for the hydrocolloid dressing. A breakout of Stage II wound data showed a statistically significant difference (p < 0.020) in favor of the hydrogel group in both wound area healed and healing rate. Stage I wound data were not statistically significant.

A better comparison of Stage II wound healing was obtained from analysis of wound sizes ≥ 2 cm² to ≤ 20 cm². Precision measurement of healing rates for wounds less than 2 cm² is difficult. Due to the single size of Biofilm hydrogel dressings available for this study (four by four inches), the majority of treated wounds greater than 20 cm² utilized multiple dressings, making wound management less than optimum compared to the HCD control, for which larger
dressing sizes were available. These data on Stage II wounds thus provided a normalized comparison of wounds treated and managed with identical dressing sizes for both the hydrogel and HCD cases.

Analysis of Stage II ulcers \( \geq 2 \text{ cm}^2 \) and \( \leq 20 \text{ cm}^2 \) for all sites (65% of census) demonstrated a greater statistical difference for the wounds treated with hydrogel in both wound area healed (72% versus 38%) and healing rate in percent area/day (8.1% versus 3.1%) \((p < 0.01)\). Stage II wound data for the acute care centers alone showed an even greater statistical advantage for the hydrogel group. In wound area healed, the hydrogel group exhibited an 80% closure versus 15% for the HCD group, and in percent area healed/day, the average for the hydrogel-treated wounds was 10.6%, compared to 1.3% for the HCD control \((p \leq 0.001)\).

In addition to these quantitative differences, Biofilm hydrogel dressings also demonstrated advantages in several qualitative aspects of performance. These observed aspects were evaluated through interviews with the clinicians, observations of dressing changes on patients, clinician comments on the patient record, and comments by physicians and floor staff.

The ability to absorb excess wound fluid without product degradation was a key functional advantage of the hydrogel product. Biofilm dressings offered this advantage while still providing a moist healing environment. The clinicians noted that the absence of a gel residue simplified dressing changes and made assessment and observation of the wound easier.

Several patients in the study indicated a preference for the hydrogel dressing for many of the same reasons cited by the clinicians, including lack of odor, cushioning, and the lightweight composition of the product.

The difficulties commonly reported with the use of the HCD control were noted by clinicians in this study. The major problem was the degradation of the gel layer, resulting in a gummy residue deposited in and around the wound. The residue necessitated mechanical cleansing of the wound. Such cleansing has the potential to disrupt fragile new tissue and consequently delay the healing process. Additionally, in highly exudative and/or large wounds, the gel layer degradation was accelerated and often resulted in leakage from the dressing. Gel degradation, cold flow, and leakage are features of the HCD control that, when present, complicate the process of dressing change and treatment.

Conclusion

In summary, Biofilm hydrogel dressings demonstrated clinical and functional advantages versus the HCD control in the treatment of Stage I and Stage II pressure sores. Overall, more wounds treated with Biofilm hydrogel dressings healed or improved; greater mean improvement in wound size was also experienced with the hydrogel group.

The authors wish to thank Crina Floruta, RN, CETN, Lois Brown, RN, ET, RoseAnn Myers, RN, CETN, Paty Pasceri, RN, C, and Cynthia Steele, RN, MSN for their support of this study.

References