

# Clinical Evaluation of a Polymeric Membrane Dressing in the Treatment of Dermal Ulcers

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# Clinical Evaluation Of A Polymeric Membrane Dressing In The Treatment Of Dermal Ulcers

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*A test of the performance characteristics of POLYMEM on open wounds.*

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**I**t is well documented that creating a moist environment can improve partial and full thickness wound healing.<sup>1</sup> Winter's classic works in the 1960s on epidermal resurfacing in dry and occluded wounds revealed that wounds kept moist under occlusion healed twice as fast as wounds exposed to air.<sup>2</sup>

Since Winter's findings, scientific research has proven that creating a moist environment can improve partial and full thickness wound healing.<sup>3,4,5</sup> Winter suggested that the ideal dressing "should keep the wound damp to obtain the benefits of accelerated healing. There should be no free-standing fluid between the

dressing and the wound. It would be helpful if the exudate can be partially concentrated by restricted evaporation of the water content. It would also be advantageous if an exchange of gases, oxygen, and carbon dioxide can take place between the atmosphere and the wound surface."<sup>6</sup> Winter described a desirable dressing as one that would "consist of a pad to absorb and disperse the exudate and provide some mechanical protection to the wound, covered by a microporous film imitating some of the functions of the epidermis. The film should be waterproof and prevent the ingress of foreign bodies and bacteria but sufficient-

ly porous to allow the passage of water vapor and oxygen molecules."<sup>6</sup>

Today, a wide selection of dressing choices are available that provide many of the functions of an ideal dressing. In the early 1970s, the first semipermeable transparent film dressing (OpSite®) was introduced in the United States. Clinicians evaluated the dressing and found that wound healing appeared to be more rapid under the film dressing. The thin film contained the wound's fluid at the wound site, creating a moist environment. This environment allowed the natural antibacterial activity of the wound's fluid to promote autolysis and the development of granulation tissue. The disadvantage of using the thin film was the accumulation of fluid under the dressing. The excess fluid would often macerate the surrounding skin or leak out from under the film. A common practice to increase the wear time was to aspirate the excess fluid through the dressing with a needle and syringe.

An opaque, occlusive hydrocolloid dressing (DuoDERM®) was introduced in the United States in 1982. The dressing did not allow for the passage of oxygen to the wound or evaporation of moisture.<sup>7</sup> Many clinicians were aware of the benefits of occlusive dressings, as a similar product (Stomahesive®) consisting of pectin, polyisobutylene, and carboxymethylcellulose had been used successfully for years to heal denuded peristomal skin.<sup>8</sup> Hydrocolloids became widely used as a treatment choice for partial thickness wounds. The dressing interacted with the wound's fluid to form a gel or the

fluid was absorbed into the wafer. The hydrocolloid dressings provided an absorptive property that allowed some fluid management, but it was not enough for moderate to heavily exuding wounds.<sup>9</sup> A variety of powders and pastes were developed to fill the wound bed and to be used in conjunction with the hydrocolloids for absorption of the wound fluid. Controversy exists in

research regarding the fear of infection with the use of occlusive dressings. This moist, dark, warm environment, which accelerates wound repair, also encourages the growth of bacteria.<sup>10,11</sup> Recent studies suggest that the benefits of hydrocolloids can be significantly enhanced by improving the biocompatibility and moisture transport rate of these dressings.<sup>12</sup>

**Table 1.**

**Description and Performance Characteristics of POLYMEM**

Ferris POLYMEM Dressing is an island dressing of absorbent membrane centered on a semipermeable film coated with a medical-grade pressure-sensitive adhesive. The absorbent membrane is soft, flexible, and non-adherent. It is composed of a hydrophilic prepolymer, along with water-soluble and water-absorbent components. The hydrophilic nature and lateral wicking of the absorbent and active membrane were designed to promote retention of fluid while creating a moist wound environment. The membrane is a patented product with a non-toxic cleansing agent, bacteriostatic agent, and other non-toxic components incorporated in the design.

Feature	Advantage	Benefit
POLYMEM Island Dressing	Non-adherent	No injury to wound bed  No pain on application/removal
	Cushions	Minimizes pain and injury to wound bed; soft, smooth gel in contact with wound minimizes pain
	Absorbent	Prevents pooling of wound fluid
	Moist wound bed	Facilitates autolysis  Prevents wound dessication
	Antimicrobial	Decreases bacterial proliferation
Moisture Vapor Permeable Outer Dressing (MVP)	Flexible/adhesive	Increases conformability and wear time
	Transparent	Allows observation of surrounding skin
	Waterproof	Minimizes external contamination
	Oxygen & water vapor permeable	Provides breathable barrier

In an attempt to find a dressing that is biocompatible and can accommodate moderate to heavily exudating wounds, foam dressings were developed. These dressings provide minimal adherence to the wound and surrounding skin, more absorption capacity, and permeability to water vapor. Most foam dressings require taping. Some have a tendency to macerate the periwound skin when saturated.

A new wound dressing that incorporates several features of the thin films, hydrocolloids, and foam dressings has been developed: Ferris POLYMEM™ Dressing (Ferris Manufacturing Corporation). POLYMEM is an island dressing of absorbent membrane centered on a semipermeable film that is coated with a medical-grade pressure-sensitive adhe-

sive. The absorbent membrane is soft, flexible, non-adherent, and biocompatible. It is composed of a hydrophilic prepolymer along with water-soluble and water-absorbent components. The hydrophilic nature and lateral wicking of the absorbent and active membrane were designed to promote retention of fluid while creating a moist wound environment (see Table 1). The membrane is a patented product with a non-toxic cleansing agent (non-ionic surfactant), a bacteriostatic agent, and other non-toxic components (such as starch graft copolymer) incorporated in the design. Laboratory studies were conducted to assess the cytotoxicity, acute systemic toxicity, dermal sensitization, primary skin irritation, and biocompatibility of the dressing.<sup>13</sup> The dressing met

acceptable levels in all areas. Subsequent studies determined the dressing to be non-hemolytic and non-pyrogenic.<sup>14</sup>

## Method

An open enrollment clinical evaluation was conducted to test the performance characteristics of the Ferris POLYMEM Dressing on open wounds. The objectives of the clinical evaluation included the following.

- Will the dressing loosen and clean the wound of debris?
- Will the dressing improve the color of the wound bed?
- Will the dressing improve the appearance and texture of the periwound skin?
- Will the dressing decrease the size and depth of the wound?

An initial assessment, wound profile, and monitoring forms were designed. Wounds were categorized as partial or full thickness. Pressure sores were classified using the staging system described by the International Association of Enterostomal Therapy (IAET) in 1987.

Patients were considered eligible to participate in the evaluation if they had a partial or full thickness open wound, leg ulcer, or pressure ulcer free of a hard eschar covering the wound. Patients were excluded from the study only if they were participating in another clinical trial at the time, if imminent death was apparent, or if consent could not be obtained.

The following changes in the wound profile were evaluated (by percentage):

- increase in the formation of granulation tissue.
- decrease in wound diameter.
- liquefaction and/or removal of necrotic debris.

**Table 2.**

### Procedure for Dressing Change

**Schedule:** Assess patient and wound every eight hours. Change immediately if leakage occurs, the dressing becomes dislodged, or wound drainage stain extends beyond the island dressing.

The dressing can be left in place for three to five days if intact and if the patient demonstrates no clinical signs of complications, i.e., fever or malodorous drainage. Record daily assessment on dressing record.

1. Using a pull-push technique, remove dressing by loosening all edges of the film adhesive system and peeling the dressing off the wound.
2. Cleanse the surrounding skin with water or saline. If wound bed is red and clean — DO NOT DISTURB. If wound base is yellow or black, remove loose necrotic debris with instruments or gauze (must be approved by the state nurses' association).
3. Pat surrounding skin dry.
4. Choose the appropriate size dressing so that the absorbent island dressing covers the entire wound.
5. Remove the liner of the dressing by grasping Tab 1, exposing the absorbent pad on the adhesive side of the film. Discard liner.
6. Grasp the clear end with the other hand and center the absorbent pad over the wound site. Secure the film dressing to the surrounding skin by smoothing toward edges.
7. Grasp Tab 2 and peel away covering to expose film dressing underneath.
8. While securing the film dressing edge with one hand, grasp Tab 3 and gently pull away from dressing site.
9. Press the dressing firmly against the wound surface to provide maximum absorption control.

- decrease in periwound erythema/edema.

The following categories were used to classify the wounds.

- Resolved: resurfacing or closure.
- Significant Improvement: 75 to 99% improvement in the wound.
- Moderate Improvement: 50 to 74% improvement in the wound.
- Minimal Improvement: 25 to 49% improvement in the wound.
- No Improvement: 0 to 24% change in the wound.

Improvement in the wound and the performance of the wound covering were based on visual observations, serial photographs, and documentation of changes in the wound profile. This was assessed by two primary investigators. The initial patient assessment, wound profile, measurements, photographs, and dressing changes on Days 1, 3, and 7 and weekly for the duration of the study were performed by the investigators. The treatment nurse or primary caregiver was responsible for daily documentation of wound observations in addition to the care and monitoring of the dressing and/or wound. Clinical judgements of the progress of the wound were based on comparison from the initial to the final assessment of each wound.

### Setting and Patient Selection

Subjects were evaluated over a four-month period (120 days) in a chronic wound care outpatient clinic. Subjects were also seen for 90 days in two skilled nursing care facilities. Approval to con-

duct the study was obtained for each clinical setting and from the patient or consenting person.

The POLYMEM evaluation was introduced to the medical and nursing staffs, patients, or families through inservice presentations. The description and purpose of the project and the dressing were presented. A written procedure for wound cleansing and dressing application was

discussed and distributed (see Table 2). Local wound care and dressing change techniques were demonstrated. The periwound skin was gently cleansed with gauze pads soaked with water or saline. When necessary, loose debris was removed with sterile surgical instruments.

All of the patients and caregivers were given the opportunity to examine the dressing and

**Table 3.**

#### Location, Type, and Results

##### OUTPATIENT:

<u>Location</u>	<u>Partial Thickness</u>	<u>Full Thickness</u>	<u>Resolved</u>	<u>Significant Improvement</u>	<u>Minimal Improvement</u>
Foot		2	1F	1F	
Ankle	1	4	1P	4F	
Leg	1	4	3 (1P/2F)	2F	
<b>Totals</b>	<b>2</b>	<b>10</b>	<b>5</b>	<b>7</b>	

##### SKILLED NURSING FACILITY:

<u>Location</u>	<u>Partial Thickness</u>	<u>Full Thickness</u>	<u>Resolved</u>	<u>Significant Improvement</u>	<u>Minimal Improvement</u>
Foot		2	2F		
Ankle		1	1F		
Leg	2		2P		
Hip	2	2	2P	1F	1F
Ischium		2	2F		
Buttocks	4		3P	1P	
Sacrum		3	1F	1F	1F
Shoulder	1		1P		
<b>Totals</b>	<b>9</b>	<b>10</b>	<b>14</b>	<b>3</b>	<b>2</b>

##### LEGEND:

P = Partial Thickness/Stage II  
 F = Full Thickness/Stages III & IV  
 R = Resolved  
 S = Significant Improvement  
 M = Minimal Improvement

##### WOUNDS:

Resolved: 19  
 Significant Improvement: 10  
 Minimal Improvement: 2  
 Total Wounds: 31



ask questions regarding the evaluation. All of the caregivers were asked to give a return demonstration of the dressing application. Data collection forms for the monitoring and documentation of the dressing were distributed. Caregivers were asked to record

and comment on the following:

1. Was the island dressing stained?
2. Was the island membrane saturated?
3. Did the drainage leak out?
4. Was the dressing changed?
5. Did the dressing stick to the wound?

The importance of completing the forms on a daily basis was discussed. The importance of observing and reporting saturated, leaking, or dislodged dressings was stressed to the nursing assistants in the skilled nursing facilities.

**Table 4.**  
**Skilled Nursing Facility Information & Results**

Patient	Age	Location	Stage/Tissue Involvement	Size/Undermining	Days Studied	Results
SK	44	R. Ischium	III/F	3x1.5 cm	41	R
MW	17	L. Buttocks	II/P	3.3x2 cm	28	R
CM	34	R. Hip	II/P	2.5x1 cm	91	R
		R. Heel	III/F	3x2.5 cm (U=1.6 cm)	91	R
		L. Ischium	IV/F	4x2 cm (U=3.8 cm)	91	R
		L. Lat. Ankle	III/F	2.8x1.5 cm	91	R
		L. Lat. Shin	II/P	1.8x1 cm	91	R
		R.U. Thigh	II/P	1.7x0.9 cm	91	R
CS	43	L. Hip	IV/F	9.5x4 cm	91	M
ER	80	L. Buttocks	II/P	1x0.2 cm	2	R
		Sacrum	IV/F	2.8x1 cm (U=4.5 cm)	78	S
		R. Buttocks	II/P	5.3x3 cm	36	R
JD	46	L. Hip	IV/F	1x1.5 cm (U=4 cm)	91	S
CL	73	L. Hip	II/P	1.5x0.5 cm	8	R
FW	69	Sacrum	III/F	1.1x0.6 cm	22	R
HVB	89	R. Heel	III/F	2.1x0.9 cm	36	R
VD	85	R. Shoulder	II/P	2.8x2.2 cm	8	R
FB	92	Coccyx	III/F	7x1.3 cm	76	M
WC	72	R. Buttocks	II/P	1.6x1.2 cm	78	S

**LEGEND:**

P = Partial Thickness/Stage II  
 F = Full Thickness/Stages III & IV  
 U = Undermining  
 R = Resolved  
 S = Significant Improvement  
 M = Minimal Improvement

### Skilled Nursing Facilities

In the skilled nursing facilities, the Director of Nursing and the Treatment Nurse assessed patients with pressure ulcers to be selected for inclusion in the study. Patient rounds were performed with the clinical investigators to determine eligibility in the study. An informed consent form was completed by the appropriate personnel. The wounds were photographed and the profile was documented. Local wound care was completed, and the appropriate dressing size was chosen. The dressing was applied following the manufacturer's instructions. The monitoring records were placed in the treatment book and were completed daily. The nursing assistants on all three shifts were instructed to immediately report any dressings that were saturated, dislodged, or leaking to the charge nurse.

### Chronic Wound Care Outpatient Clinic

In the chronic wound care clinic, all patients were given the opportunity to evaluate the dressing. Product information and written instructions were provided to each patient. The dressing application technique was demonstrated and the data collection record was discussed. In the outpatient clinic, patients were seen

weekly. In the home setting, daily observation, care, monitoring, and documentation were completed by the patient or primary caregiver. At the weekly visit, the daily monitoring record was collected and the supply of products and data collection records was replenished.

## Results

During the clinical evaluation, 31 patients (19 in the skilled nursing facilities and 12 in the chronic wound care clinic) with 41 partial or full thickness open wounds were evaluated. Twenty-four (24) patients with 31 wounds completed the study. Ninety-four percent of the wounds significantly improved or resolved (see Table 3).

### *Patients in the Skilled Nursing Facilities*

In the skilled nursing facilities, 19 patients (9 males and 10 females ranging from 17 to 92 years of age) with a total of 29 pressure ulcers were admitted to the study and evaluated over a 90-day period. Seven patients did not complete the study: two expired and five were transferred to acute care facilities for other medical conditions.

Twelve patients with 19 wounds completed the study. All wounds improved: 14 were completely healed, three improved, and two showed minimal improvement (see Table 4).

All of the patients admitted to the study were chronically debilitated, diagnosed with a neurological condition, and suffered from a variety of medical conditions.

Nine patients were aphasic or unable to communicate, nine

were totally dependent, and eight were bedridden. Four patients were chairfast and spent at least 25% of their time out of bed. All patients received a high protein diet and/or dietary supplements. One patient had a feeding tube in place. Eleven patients were incontinent of urine and/or stool. Six had indwelling catheters in

place. All but one patient had some type of pressure-relieving device on the bed. The one patient without a pressure-relieving device had a heel ulcer and spent approximately 50% of the day in a wheelchair.

Determining the onset of the pressure ulcer was difficult. Nine of the patients were admitted to

**Table 5.**  
**Outpatient Information & Results**

Patient	Age	Etiology	Location	Duration	Stage/Tissue Involvement	Size/Undermining	Days Studied	Results
MO	55	Venous	R. Ankle	17 yrs.	Full	8.5x9 cm	120	S
LN	84	Venous	R. Lower Leg	2 yrs.	Full	6.5x5 cm 1.5x1 cm *1x1 cm	120	S
LE	71	Venous	R. Ankle	7 yrs.	Full	3.2x3.3 cm	57	S
JT	55	Venous	Ankle	4 yrs.	Full	10x7 cm	67	S
JIM	7	Injury	R. Achilles Tendon & Side	1 wk.	Full	5x4 cm	21	R
						3x2.5 cm	21	R
RH	62	Injury	L. Leg	2 wks.	Full	1.5x1 cm (U=3 cm)	97	R
BM	49	NIL	L. Lower Leg	3 mos.	Full	Multiple Openings	120	R
DP	56	NLD	L. Lower Leg	1 mo.	Full	1.5x1 cm	49	S
CB	48	RSG	Ankle	1 yr.	Partial	2x1.6 cm	Off Study	S
AH	16	RSG	L. Lower Leg	2 mos.	Partial	Multiple Openings	39	R
EW	82	Pressure	L. Heel	4 mos.	Full	1.5x1 cm	112	R
DC	52	Pressure	L. Heel	4 mos.	Full	1.5x1 cm	68	S

#### LEGEND:

NL = Necrobiosis Lipoidica  
 NLD = Necrobiosis Lipoidica Diabeticorum  
 RSG = Rejected Skin Graft  
 P = Partial Thickness/Stage II  
 F = Full Thickness/Stages III & IV

U = Undermining  
 R = Resolved  
 S = Significant Improvement  
 M = Minimal Improvement

\* Three connecting wounds forming an L shape.

the skilled nursing facility with an open wound. No documentation regarding the date of development was available from the transferring facility. The duration of the ulcer from the time of admission to the beginning of the POLYMEM evaluation ranged from two days to seven months. Most wounds were present for more than six weeks. A wide variety of dressing techniques had been used prior to beginning the POLYMEM evaluation: povidone-iodine, saline, or acetic acid wet/dry dressings, lubricating sprays and creams, and hydrocolloid dressings.

## *Patients in the Chronic Wound Care Clinic*

During the 120-day period, 12 patients with 12 open wounds were seen in the outpatient clinic and were included in the study. The wounds were located on the lower legs and were categorized as foot, ankle, or leg wounds. Ten of the 12 wounds were assessed as full thickness wounds, and the remaining two were assessed as partial thickness wounds. Of the 12 wounds, five healed completely and the remaining seven showed significant improvement (see Table 5).

## Case Presentation

Necrobiosis lipoidica is a degenerative disease of dermal connective tissue characterized clinically by an inflammatory pretibial sclerodermiforme plaque and is often associated with diabetes mellitus. The non-diabetic type of necrobiosis lipoidica is most common among persons 20 to 40 years of age. The lesion begins as an erythematous

papule or nodule in the pretibial area. As the lesion expands, it becomes a shiny, waxy, yellow-red sclerotic plaque with superficial telangiectatic vessels coursing over its surface and has a violet-red margin. The central part of the lesion becomes slightly scaly, atrophic, and depressed.

Ulceration is the most common and potentially most severe complication of necrobiosis lipoidica. The ulcers are usually bilateral, multiple, chronic, and recurrent over many years. Amputation of the lower extremity may be necessary because of severe unremitting ulceration and pain or a complicating squamous cell carcinoma. The ulcerations of the skin often require excision and graft but often recur.<sup>15</sup>

Ms. M, a 49-year-old non-diabetic white female, had a 10-year history of necrobiosis lipoidica of the right leg, which had been diagnosed by punch biopsy. An ulcer developed at the biopsy site, which did not heal for two years. During the following seven years, multiple ulcers developed in the pretibial area of her right leg. In 1986, the ulcers began to develop in the pretibial area of her left leg. Ms. M had undergone multiple debridements, grafts, antibiotic therapy, and hyperbaric oxygen treatment. She had developed a severe pseudomonas infection, which necessitated an above-the-knee amputation of the right leg.

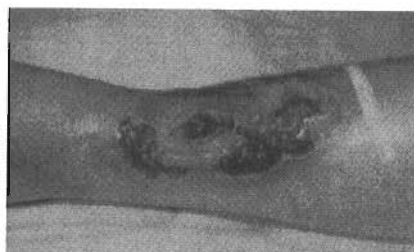
Ms. M progressed well for one year. In March 1989, she was seen in the plastics clinic for evaluation and presented with a well healed AKA stump. The left leg showed a well healed graft in the lower anterior leg. On April 6, she returned to the clinic with a recurring ulcer (1.5 x 1.5 cm) at



**Figure 1.** Begin use of POLYMEM Dressing (11/13/89).



**Figure 2.** Granulating wound (12/13/89).



**Figure 3.** Anterior wound epithelialized (1/24/90).



**Figure 4.** Wound 96% epithelialized (2/28/90).



**Figure 5.** Wound remains resurfaced (6/1/90).



the graft site of the left leg. The ulcer continued to enlarge despite aggressive local wound care with hydrocolloids, silver sulfadiazine cream, antibiotic therapy, and pigskin grafts. Because of the previous similar problem in the right leg, which ended in amputation, Ms. M was reluctant to undergo any further excision or grafting procedures.

On July 26, 1989, Ms. M was referred to the chronic care clinic for consultation on local wound care. The graft site on the left leg had two large open areas with necrotic tissue present. Smaller openings were developing. The open areas were treated with Elase® Ointment and covered with an absorption dressing and dry gauze every 12 hours. Ms. M was instructed in self care and was to remove loose necrotic tissue with scissors during the dressing change.

The treatment was continued until November 13, 1989, at which time most of the yellow slough had been removed. The dressing was changed to POLYMEM. Due to the tremendous amount of wound fluid, the dressing was changed twice daily for the following two months. As the wound continued to granulate and epithelialize, the dressing changes were less frequent.

When Ms. M was seen again on March 28, 1990, the wound was 96% epithelialized. She had been experiencing a rash with pruritus on her foot and upper thigh. Upon dermatology consult, Ms. M was diagnosed with eczema and treated with Corticosteroid cream four times per day. The POLYMEM dressing was discontinued.

At the time of the follow-up visit on June 1, 1990, Ms. M's

wound had remained epithelialized, with the exception of two small open areas.

## Conclusions

The patient population in this evaluation was widely varied in terms of age, wound location and profile, underlying medical conditions, activity and mobility, nutrition, and other physiological variables. Some patients were responsible for their own care, while others were totally dependent on their caregivers. Some patients had lower leg ulcers that had been present for years. Other patients had recurring ulcers. Most of the patients seen in the skilled nursing facility had pressure ulcers. Even with this wide variation, the performance of the dressing is encouraging. All 31 wounds treated with the POLYMEM dressing resolved (19) or improved (12). The wounds showed visual improvement, such as a decrease in necrotic tissue or a cleaner, red wound base. Nineteen of the wounds had yellow slough visible at the beginning of the evaluation. All of the wounds converted to red, clean wound beds shortly after using the dressing treatment. One wound had stringy necrotic debris, which liquified using the dressing and without sharp mechanical debridement.

The surrounding skin and edges of the wounds changed over time. Any edema and erythema noted resolved as the wounds improved in color, size, and depth. No maceration was noted on any wounds throughout the evaluation, even when the island dressing was saturated. Since this dressing does not dis-

solve into or on the wound, the need for cleansing upon removal of the dressing was minimal. When the membrane dressing becomes wet with wound fluid, it feels like a smooth gel in contact with the wound. This characteristic minimized pain or discomfort upon dressing application or removal. The dressings were left on the wounds until the island dressing was saturated or until leakage or dislodgement occurred. The wear time of the dressing was between 12 hours and three days. The scheduled dressing change was dictated by the condition and location of the wound and the amount of exudate.

Early experiences using Ferris POLYMEM dressing for open wounds have been successful. The handling and performance characteristics of this one-piece dressing are positive. Clinical studies with a larger sample and a comparison of other dressing techniques are recommended.

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