Clinical Evaluation of a Semipermeable Polymeric Membrane Dressing for the Treatment of Chronic Diabetic Foot Ulcers

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OBJECTIVE — To evaluate the utility of a semipermeable polymeric membrane dressing for the treatment of chronic diabetic foot ulcers.

RESEARCH DESIGN AND METHODS — Nineteen subjects with either insulin-dependent diabetes mellitus (IDDM) or non-insulin-dependent diabetes mellitus (NIDDM) and foot ulcers were randomly assigned to the polymeric dressing or conventional wet-to-dry saline dressings. Subjects had foot ulcer site measurements performed every 3 weeks. The subjects using conventional therapy were allowed to cross over to polymeric dressing after 2 months.

RESULTS — At the end of 2 months, in the patients using the polymeric dressing, ulcer size was reduced to 35 ± 16% of baseline. The patients on conventional therapy had an ulcer size of 105 ± 28% of baseline ($P < 0.03$, polymeric vs. conventional). Patients initially treated with wet-to-dry saline were crossed over into the polymeric membrane treatment and demonstrated a decrease to 35 ± 11% of baseline size ($P < 0.02$) after an additional 2 months.

CONCLUSIONS — The semipermeable polymeric membrane dressing is a useful therapeutic option for treating uncomplicated chronic diabetic foot ulcers.

Diabetic foot ulcers are a serious cause of morbidity and mortality (1–4). Up to two-thirds of all non-traumatic amputations performed in the U.S. are performed on diabetic patients who initially present with an ulcer that progresses to gangrene (1–4). In addition, diabetic foot ulcers and infections have an estimated annual cost of hundreds of millions of dollars (1,4). Any therapy that would increase the rate, or improve the extent, of wound healing in these patients would be of considerable benefit for reducing morbidity and cost. A semipermeable polymeric membrane dressing has been found, in other studies, to be useful for treating chronic decubitus ulcers (5). In this report, we present the results of a prospective controlled study to evaluate the usefulness of this polymeric membrane dressing for the treatment of refractory diabetic foot ulcers.

RESEARCH DESIGN AND METHODS

— In a prospective study design, we evaluated the healing of chronic foot ulcers in 18 subjects with insulin-dependent diabetes mellitus (IDDM) or non-insulin-dependent diabetes mellitus (NIDDM) who were randomized into treatment with conventional therapy (wet-to-dry saline gauze dressings) or use of a polymeric membrane dressing (POLYMEM, Ferris, Burr Ridge, IL). The polymeric membrane is an absorbent dressing comprised of a combined urethane prepolymer along with water-soluble and hydrophylic components designed to promote retention of fluid. Glycerol is included as a bacteriostatic agent, and a nonionic surfactant is included as a wound-cleansing agent (5). Each subject's ulcer was evaluated and graded by the criteria developed by Wagner (6–8). All subjects had a partial- or full-thickness open wound or foot ulcer; free of hard eschar. All ulcers with an initial Wagner stage of III or higher were excluded from the study, as were subjects whose ulcers progressed to a Wagner stage III or higher, subjects needing vascular surgical therapy, subjects with ulcers from Charcot joints, or subjects with ulcers of nondiabetic origin.

Four wounds were surgically debrided before initiation of treatment with the polymeric membrane and three

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IDDM, insulin-dependent diabetes mellitus; NIDDM, non-insulin-dependent diabetes mellitus.

Table 1—*Clinical characteristics of study subjects*

	Conventional group	Polymeric group	*P* value
Age (years)	51 ± 4	59 ± 5	<0.21
Sex (M/F)	6/1	11/0	—
Duration of ulcer (weeks)	28 ± 6	25 ± 7	<0.78
Initial ulcer size (cm^2)	1.81 ± 0.75	2.67 ± 1.20	<0.51
GHb (%)	9.5 ± 1.1	8.4 ± 0.9	<0.47

Data are means ± SE.

wounds were debrided prior to the start of conventional therapy. All subjects were encouraged to obtain orthotic footwear and to minimize weight-bearing as much as possible. After qualifying for the study, subjects were randomly assigned to conventional or polymeric membrane treatment. Subjects were instructed in detail regarding the use of the polymeric dressing or the saline-soaked gauze dressing, and were instructed to change each dressing one time per day minimum or when the dressing was saturated. In keeping with the manufacturer's directions, subjects using the polymeric dressing were instructed not to use topical antibiotics or disinfectants or to have the ulcer debrided. One of the subjects randomized to the control group used topical antibiotics. None of the wounds were packed.

The 18 subjects were evaluated for diabetes complications and the degree of diabetes control. The surface area of each ulcer was measured by tracing the wound margins on a transparent membrane (Imaginative Medical Enterprises, San Pedro, CA). The surface area was calculated by placing the tracing over graph paper and counting the number of square centimeters within the tracing (9). This method was developed by Fergusson and Logan (9) and has been shown to have similar reliability to weighing and planimentary techniques in calculating ulcer surface area (10). Each subject's ulcer was measured at 3-week intervals. Five subjects who randomized to conventional therapy subsequently crossed over to the polymeric dressing after 2 months of treatment. Each subject was followed until the ulcer healed, or until 6 months had elapsed from the point they were treated with the polymeric membrane. The change in ulcer size was expressed as a percentage of the baseline ulcer size. All results are expressed as means ± SE. Mean values between the two groups were compared by unpaired Student's *t* test. Mean value differences for the crossover group were compared by paired Student's *t* test. Significance of differences was evaluated at the 5% level. All subjects gave informed consent. The study was approved by the Rush Presbyterian-St. Luke's Institutional Review Board.

RESULTS— In the course of the study, two patients from each group progressed to Wagner stage III ulcers and were not included in the analysis. All patients continued to be followed by their referring physicians during the study. During the study, two patients in the control group and two patients in the polymeric membrane group underwent debridement in their referring physician's office. The decision to debride was made by the outside physician based on his independent assessment of the foot ulcer. No patient obtained new orthotic footwear. In addition, although patients in both groups were encouraged at the start of the study to restrict weight bearing, patients continued their usual activity during the study period. No significant differences were observed between the conventional and polymeric group with respect to mean results for age, sex, ulcer surface area and chronicity, and diabetes control as shown in Table 1.

After the 2-month interval, the patients treated with conventional wet-to-dry saline dressings had an ulcer size of 105 ± 26% of baseline, whereas the subjects treated with the polymeric membrane dressing had an average ulcer size of 35 ± 16% of baseline $P < 0.03$) (Table 2). In addition, after 2 months, 3 of 11 subjects treated with the polymeric membrane dressing had healed completely, whereas none of the seven subjects treated with the conventional therapy had ulcers that healed completely. Further, 10 of 11 subjects treated with the polymeric membrane demonstrated substantial improvement in ulcer size compared with 2 of 7 in the conventional therapy group.

Of the seven subjects that initially were treated with wet-to-dry saline, five were crossed over to the polymeric dressing (Table 3). In this group, the size of the ulcers 2 months after treatment with wet-to-dry saline dressings was 97 ± 18% of baseline. However, after 2 months of the polymeric membrane dressing, ulcer size was 35 ± 11% of the size at the time when the polymeric dressing was started ($P < 0.02$).

After 6 months of polymeric membrane treatment, 8 of 11 ulcers (73%) healed completely. Of the five subjects who had initially been treated with conventional therapy and switched to polymeric membrane therapy, three healed completely on the polymeric dressing (60%) and two were lost to follow-up.

CONCLUSIONS— Diabetic foot ulcers present a challenging clinical problem. Numerous nonoperative treatments have been used with variable success. These range from impermeable and semipermeable dressings (11–13), hyperbaric oxygen (14), dilantin (15), and total contact casts (16). We present data to show that a new polymeric semipermeable dressing is useful in healing chronic diabetic foot ulcers.

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Table 2—*Polymeric dressing versus conventional therapy*

Polymeric dressing group	Initial ulcer (cm^2)	After treatment (cm^2)	% of baseline
1	2.43	0	0
2	0.72	0	9
3	1.01	1.89	187
4	3.51	1.89	54
5	0.90	0.45	50
6	14.31	3.9	27
7	0.40	0	0
8	2.72	0.15	5
9	1.40	0.30	21
10	0.20	0.05	3
11	1.80	0.63	35
Mean ± SE	2.67 ± 1.20	0.84 ± 0.37	35 ± 16
Conventional wet-to-dry saline group			
1	0.36	0.45	125
2	1.71	2.25	132
3	0.75	0.20	027
4	2.22	2.12	095
5	6.05	13.7	226
6	0.30	0.30	100
7	1.30	0.40	031
Mean ± SE	1.81 ± 0.75	2.77 ± 1.85	105 ± 26

study had chronic ulcers of >20-weeks duration that had not healed with prior therapy. Furthermore, most patients when questioned at the end of the study did not change their weight-bearing status, a factor considered very important in healing foot ulcers (16).

Many investigators also believe that wound cleansing and disinfection are important for wound healing. However, several investigators have reported that disinfection will impede wound healing (17–19). In this study, we did not use antibiotics, disinfectants, or packing for the group using the polymeric dressings and ended with 73% of this group healing. Others also have reported successful wound healing without the use of disinfectants, including Mueller et al. (16), who used total contact casts, and Muthukumarasamy et al. (15), who used topical dilantin to heal diabetic foot ulcers. As an alternative approach to prevent infection, some investigators have recommended using occlusive dressings to prevent the penetration of bacteria into the wound (11,12), whereas others have found this not to be of value (20). We did not evaluate other semipermeable or impermeable dressings in this study, but Lithner (21) reported two diabetic patients treated with Duoderm (Convetec-Squibb, Princeton, NJ) who developed severe infections believed to be secondary to the occlusive dressing that was changed on a 3- to 7-day basis.

Pecoraro et al. (22) have found that periwound oxygen tension is an important determinant for wound healing. Although we did not measure cutaneous wound oxygen and carbon dioxide, it is possible that the polymeric dressing, by reducing wound drainage and local edema, allowed increased capillary blood flow and a resultant increase in oxygen tension. Further studies will be required to examine this hypothesis.

Table 3—*Crossover to polymeric membrane*

Conventional wet-to-dry saline group	Initial ulcer (cm^2)	Final ulcer (cm^2)	% of baseline
1	0.36	0.45	125
2	1.71	2.25	132
4	2.22	2.12	95
6	0.30	0.30	100
7	1.30	0.40	31
Mean ± SE	1.18 ± 0.38	1.10 ± 0.44	97 ± 18
Polymeric dressing group			
1	0.45	0.18	40
2	2.25	1.53	68
4	2.12	0.45	21
6	0.30	0	0
7	0.40	0.18	45
Mean ± SE	1.10 ± 0.44	0.47 ± 0.28	35 ± 11

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