Occlusive Dressings for Pressure Ulcers: A Controlled Clinical Trial of Elasto-Gel™ vs. DuoDerm®

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ABSTRACT

Twenty nursing home patients with a total of twenty-nine pressure ulcers that had not penetrated through the skin were randomly assigned to treatment with Elasto-Gel or DuoDerm, two brands of occlusive dressings. A comparable proportion of ulcers in both groups improved with initial therapy (6/14 vs. 6/15). Results from crossover treatment and reasons for withdrawal from the study are described. It is suggested that the low success rate from either treatment may be due to the fact that the development of pressure ulcers in chronically debilitated nursing home patients may be a predictor of imminent death.

Key Words: pressure ulcers, occlusive dressings, nursing homes

Various occlusive dressings have been reported to promote the healing of cutaneous pressure ulcers that do not involve underlying tissues. (1-3) There are no published controlled clinical trials comparing the clinical effectiveness of any of these various dressings. This is a report of a controlled, single blind, clinical trial comparing a new product, Elasto- Gel, to an established product, DuoDerm.

METHODS

Twenty nursing home patients with one or more partial thickness (Stage II) or full-thickness (Stage III) pressure ulcers without involvement of underlying tissues were randomly assigned to treatment with Elasto-Gel or DuoDerm after informed consent was obtained. The dressings were applied according to manufacturers instructions and changed every seven days or as often as needed. Ulcers were inspected on a daily basis by lifting the edge of the dressing. Treatment was crossed over to the alternate product if the ulcer was not doing well. If the ulcer was significantly worse, the study was terminated and non- protocol therapies were initiated. Photographs and surface area measurements were taken prior to treatment and at weekly intervals for three weeks. Results were categorized as "improved" if ulcer size or stage decreased as determined from blinded review of photographs and surface area measurements.

RESULTS

The clinical characteristics of patients in the Elasto-Gel and DuoDerm groups were comparable in average age (80.4 vs. 82.1 years), in proportion receiving tube feedings or total assistance with feeding (5/10 vs. 5/10), and in the proportion suffering dementia, either primary, multi-infarct or post-stroke etiology (7/10 vs 7/10). There were nine females in the Elasto-Gel group and seven in the other. Two patients in each group died during the study.

The proportion of ulcers that showed improvement in each group was comparable (Table I). Of the eight ulcers not showing improvement with Elasto-Gel as the primary treatment, one showed no change with treatment, one was crossed over to DuoDerm because perineal moisture caused the Elasto-Gel to be non-adherent, and six ulcers on five patients were withdrawn from the study. Two of those ulcers were on a patient who died during the first week of the study. The other four ulcers developed complications. Of the nine ulcers not showing improvement with DuoDerm as the primary treatment, six of these patients were crossed over to Elasto-Gel because of failure to improve, and three ulcers on three patients were withdrawn. The reasons for withdrawal include one death during the first week of the study, one death during the third week with an ulcer that was getting worse, and a third that showed rapid progression of the ulcer.

Complications that caused withdrawal of patients treated with Elasto-Gel were of three types. On one patient, the edges of the ulcer were compromised when the Elasto-Gel was applied. This led to the rapid development of a Stage IV ulcer penetrating into the underlying tissues. In another patient, a superficial heel ulcer progressed in spite of the dressing. Two patients experienced blistering of skin on the margin of the ulcers. One of these patients had an underlying vasculitis that may have contributed to this problem, but no apparent cause could be identified in the other patient.

DISCUSSION

The results failed to demonstrate that Elasto-Gel has any therapeutic advantage over DuoDerm in the treatment of Stage II and III pressure ulcers in nursing home patients. Clinical observations made during the study indicate that Elasto-Gel is somewhat more comfortable to the patients, adapts better to uneven body surfaces, but is less resistant to loosening in moist areas. DuoDerm is more likely to become crumbly and to be more difficult to remove.

An overall improvement rate of approximately 45% for pressure ulcers treated with either of these occlusive dressings is substantially lower than the 64-100% improvement reported in three uncontrolled clinical studies of patients with ulcers of comparable severity. (1-3) The results are comparable to those in the control group (47% improvement) of a controlled clinical trial for the treatment of somewhat more sever pressure ulcers.(4)

The underlying morbidity and imminent death of patients who develop pressure ulcers in a nursing home precludes success of any treatment. Four of the study patients died during the study; four died within a few weeks after completion of the study; and three patients initially selected for the study died before treatment was begun. The development of pressure ulcers in chronically debilitated nursing home patients may be a predictor of imminent death .

Table I
Treatment Results: Elasto-Gel vs. DuoDerm

	Elasto-Gel (n)	DuoDerm (n)
Primary Treatment		
Patients Improved	4/10	3/10
Ulcers Improved	6/14	6/15
Crossover Treatment*		
Patients Improved	3/3	1/1
Ulcers Improved	3/6	1/1
Totals		
Patients Improved	7/13	4/11
Ulcers Improved	9/20	7/16

Only Patients whose ulcers showed no improvement within one to two weeks were eligible for crossover treatment. See text for description of reasons for withdrawal from study.

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