Unna's Boot vs Polyurethane Foam Dressings for the Treatment of Venous Ulceration

A Randomized Prospective Study

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• **Recent reports have suggested that polyurethane foam dressings provide a more rapid and comfortable healing of venous stasis cutaneous ulcerations than standard semirigid impregnated gauze dressings. This multi-institutional study consists of a randomized, prospective comparison of 36 consecutive patients who were treated with either polyurethane foam dressings (group 1, n = 17) or Unna's boot (group 2, n = 19) for venous ulceration of the lower extremities. Ulcer size ranged from 6.0 to 270 cm² (mean, 32.2 cm²) for group 1 and 0.2 to 600 cm² (mean, 76.0 cm²) for group 2. Nine (52.9%) of 17 group 1 patients withdrew from the study due to wound odor, while there was 100% compliance in group 2. Overall wound healing was superior in group 2 (18 [94.7%] of 19) as compared with group 1 (7 [41.2%] of 17) ($\chi^2 = 8.2$). The rate of healing was also better in group 2 (0.5 cm²/d) than in group 1 (0.07 cm²/d). Contrary to published European trials, impregnated gauze dressings exhibited superior treatment results when compared with polyurethane foam dressings in the current study.**

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Venous stasis ulceration is a chronic and incapacitating disease that is believed to affect more than 500 000 Americans.[1] It is believed to result principally from incompetence of venous valvular function secondary to previous venous thrombosis, congenital weakness, or long-standing varicose veins. This condition leads to an elevation of pressure in both the superficial and deep venous systems and leads to such typical signs of venous insufficiency as eczema, pigmentation, liposclerosis, superficial varicosities, edema, and skin ulceration.

Patients with venous stasis ulceration are frequently incapacitated and unable to work. The need for recurrent, temporary hospitalization, as well as the prolonged course of outpatient therapy, often results in a significant financial burden both to the individual and the community.

A variety of topical wound preparations have been used to treat stasis ulcerations, including hot oils and waxes, animal membranes, and vegetable and mineral ointments.[2] For the past century, Unna's boot, a gauze bandage impregnated with glycerin, zinc oxide, and calamine lotion has been set as the standard of treatment.[3] Although efficacious, therapy with Unna's boot has been limited by poor patient compliance due to local discomfort and limitation of movement, occasional contact sensitivity, and the need for weekly hospital or clinic visits for changes in dressings.

During the past decade, new wound products have been developed in an effort to achieve a reliable and acceptable means of ulcer care.[4,5] Polyurethane foam dressing (PFD; Synthaderm Armour Pharmaceutical Co Ltd, East Sussex, England) is a "synthetic skin" preparation consisting of a closed-cell polyoxyethylene glycol foam separating hydrophobic and hydrophilic surfaces.[6-8] European studies using this dressing, for the treatment of venous stasis ulcers, have indicated improved healing rates, healing of previously intractable ulcers, and greater cost-effectiveness as compared with standard impregnated gauze dressings.[9]

This multi-institutional, prospective, randomized, blinded study was performed to compare the results of PFD vs Unna's boot for the treatment of chronic venous stasis ulceration.

PATIENTS, MATERIALS, AND METHODS

During a 12-month period, 36 consecutive ambulatory patients with lower-extremity chronic venous stasis ulceration from the Cleveland (Ohio) Veterans Administration Medical Center, University Hospitals of Cleveland, and Cleveland Metropolitan General Hospital were randomized in a blinded and prospective manner in either Unna's boots or PFDs. Exclusion criteria consisted of a history of noncompliance, the presence of significant lower-extremity arterial insufficiency as determined by Doppler ankle-brachial pressure indexes of less than 0.8, and a history of significant associated medical risk factors such as collagen vascular disease, uncontrolled diabetes, other ongoing dermatologic disorders, and chronic corticosteroid therapy. At the time of enrollment, all patients underwent a complete history and physical examination, lower-extremity arterial segmental pressure and pulse volume recordings, photoplethysmography, venous doppler flow, wound cultures, wound tracings and measurements, and photographic documentation of the wound.

Each patient was randomized by the study coordinator to either a PFD or Unna boot dressing treatment protocol. The study coordinator did not see the randomization card and was therefore blinded as to the treatment cohort. All dressings were applied and removed by the individual hospital-based nursing personnel and all wounds were cleansed routinely with skin wound cleansing solution (Shur-Cleans, [20% Poloxamer 188] Merck & Co, St Louis, Mo). The nursing staff replaced the dressings in the prescribed manner, all patients having elastic bandages applied in an identical manner, from the toes to the knees. Dressing changes were scheduled on a weekly and/or biweekly schedule at which time the wounds were carefully mapped and wound areas calculated by the study coordinator after dressing removal and extremity cleansing. If elastic rewrapping was required between scheduled hospital visits, this was either performed at home or the patient was returned to the Medical Center for treatment.

As per institutional review board protocol, all patients were carefully instructed regarding the nature of the study, as well as the need for leg elevation, the signs and symptoms of wound complications, and the need for strict follow-up compliance. All data regarding the change in ulcer size were analyzed in terms of rate of healing (square centimeters per day) and was interpreted using χ^2 analysis and Student's t test methods.

RESULTS

Seventeen individuals were randomized to PFD (group 1) and 19 were randomized to Unna's boot (group 2). At the time of initial presentation, ulcer size ranged from 6.0 to 270 cm² (mean, 32.2 cm²) for group 1 and 0.02 to 600 cm² (mean, 76.0 cm²) for group 2 limbs ($P = .03$, Student's t test).

Initial bacterial culture results were positive in 13 (76.4%)

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of 17 limbs from group 1 and 12 (63.1%) of 19 limbs from group 2, and are listed in the Table. This difference was not statistically significant.

During a total 12-month randomization and follow-up period, 9 (52.9%) of 17 patients of group 1 withdrew from the study due to wound odor, while there was 100% compliance in individuals of group 2. There were no wound complications in either group that necessitated hospital admission or cessation of therapy, although of the 9 patients of group 1 who withdrew from the study, 6 experienced enlargement of the ulceration during the treatment period. Complete wound healing was superior in 18 (94.7%) of 19 individuals of group 2, when compared with 7 (41.2%) of 17 of those of group 1 ($\chi^2 = 8.2$, $P < .005$). When those who withdrew from the study were excluded from analysis, the incidence of complete wound healing was similar (group 1, 7/8 [87.5%]; group 2, 18/19 [94.7%]). Overall wound healing rates while patients were enrolled in the study, were significantly better in group 2 (0.5 cm^2/d) than in group 1 (0.07 cm^2/d) ($P = .004$, Student's t test), this difference due mainly to the incidence of ulcer enlargement in 6 of 19 patients of group 1 prior to their withdrawal from the study.

Isolates Obtained From Pretreatment Wound Cultures

Isolate	Frequency	
	Group 1	Group 2
Staphylococcus aureus	10	8
Escherichia coli	5	5
Pseudomonas	5	2
Klebsiella	3	2
Proteus	3	2
Staphylococcus epidermidis	3	2
Streptococcus	1	2
Enterobacter	1	1

COMMENT

The overall management of lower-extremity skin ulceration due to venous insufficiency must be directed both toward healing of the lesion and treatment of its underlying cause. Healing of the ulcer may be enhanced by manipulation of local tissue factors to maximize tissue regeneration and epidermal coverage. Active alteration of the local environment can be achieved by means of the topical dressing.

The ideal dressing must have the ability to maintain tissue humidity and insulate against loss of heat so as to promote tissue growth. In addition, it must be sufficiently absorbent to remove exudate and nonviable components of the wound. It also must inhibit bacterial growth and provide protection against secondary infection, and prevent trauma to the wound itself. Finally, this dressing must be acceptable for patient use. This would require its easy handling, lack of allergic or hypersensitivity reactions, and adequate absorbance.

Polymer dressings, including PFD, have been noted for their ability to minimize fluid and heat loss, and bacterial penetration.[4,5,10,11] Their occlusive nature has also been shown to increase the rate of epithelialization through "moist wound healing."[11-13] Exudate is held within the foam component of the dressing. This leads to autolytic rather than mechanical wound débridement, which has been believed to be less traumatic to early granulation tissue. An additional advantage to this dressing has been an associated reduction in local discomfort.[7,14]

In the present study, the theoretical advantages of PFDs were not realized. Excessive malodorous drainage resulting from autolytic wound débridement required frequent dressing changes during the initial period of usage and led to the withdrawal of more than half of the study patients assigned to this dressing modality. This compared poorly with the uniform compliance seen in patients with Unna's boot dressings. In addition, the calculated rate of ulcer healing was significantly better in those patients treated with paste bandages rather than PFD.

While the difference in wound healing between the two groups is not clearly understood, it is believed that in this ambulatory population, adequate compression of the lower extremities, to reduce venous pressure, is an essential component in the treatment of stasis ulceration. Active manipulation of the local wound environment with hydroactive dressings, without rigid or semirigid casting as is achieved with Unna's boots, may be insufficient to accomplish this end. As suggested by Kikta et al,[15] the abnormality of hemodynamics associated with venous insufficiency must be addressed concurrently. Dressings that do not provide sustained compression would require a motivated, compliant patient population that can adjust the frequency of dressing changes, and continue to maintain decreased venous pressures with leg elevation, since the use of elastic wraps probably do not provide adequate compression. For those patients who are unable or unwilling to meet these demands, Unna's boot may still be the dressing of choice.

The authors use the term Unna's boot *in a generic sense. Unna's paste described by a dermatologist, Paul Gerson Unna (1850-1929), is a mixture of gelatin, zinc oxide, and glycerin. Unna's paste is no longer commercially available and has been replaced by other easily applied bandages containing glycerin, sorbitol, gelatin, magnesium aluminum silicate, zinc oxide, and calamine.* —ED.

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