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# A Comparison of the Effects of Semipermeable Foam and Film Secondary Dressings over Alginate Dressings on the Healing and Management of Venous Ulcers

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**ABSTRACT:** The choice of secondary dressing affects the performance of the primary dressing; this study assessed the effects of a foam and film secondary dressing, used with a calcium alginate dressing as the primary dressing and also with compression stockings, on the healing and management of venous ulcers. After the presence of venous ulcers was confirmed, 10 patients were treated with alginate + foam dressing, and 10 patients were treated with alginate + film dressing. Patients were assessed six times at weekly intervals, as follows: photographing and tracing of wound, with ulcer size determined by sonic digitizer measurement; observation of skin surrounding the ulcer; amount of pain and wound condition graded on four-point numeric scales; and recording of number of dressing changes. Both groups had similar results in terms of changes in ulcer size, counts for wound condition scores and reduction of pain scores. The group treated with the foam secondary dressing had significantly fewer dressing changes than the film dressing group (87 to 192, respectively,  $p = 0.0038$ ). The group receiving a foam dressing also had fewer problems with edgeroll and leakage, a lower incidence of sensitivity reaction, and higher patient acceptability. We conclude that, while both the foam and film dressings tested are efficacious as secondary dressings when used with an alginate dressing for management of venous ulcers, the foam dressings may be better suited for managing these patients.

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Desirable properties of a dressing for venous ulcers have been elucidated<sup>1</sup>: it should reduce ulcer pain and pruritus<sup>2,3</sup>; allow escape of excess fluid and exudate without permitting desiccation<sup>2-4</sup>; not cause an allergic reaction<sup>2-5</sup>; be easy to change with the least possible discomfort<sup>2-4</sup>; not leave dressing material in the wound when changed<sup>3,4</sup>; and be inexpensive, conserve the utilization of skilled professional care and encourage a supervised program of self-treatment.<sup>6-8</sup>

In addition, the "ideal" dressing has been described as one that would ensure that the wound remains moist with exudate but not macerated, free of clinical infection and excessive "slough," at the optimum temperature for cell division to take place and undisturbed by frequent or unnecessary dressing changes.<sup>9,10</sup>

Cavity wounds and high-exudate wounds such as ulcers are currently treated using primary dressings of very hydrophilic materials such as alginates or hydrocolloid, dextran or polysaccharide gel granules. When applied to an exuding wound, these materials absorb exudate, swelling as they hydrate. The level of free exudate and the degree of saturation of the primary dressing affect the level of wound and surrounding skin maceration.

Interest in alginate dressings has grown in recent years because they appear to fulfill many criteria suggested for the ideal dressing. In particular, Sorbsan™ (Dow Hickam, Inc., Sugar Land, TX) has been used to successfully treat a variety of lesions.<sup>10-12</sup> However, Sorbsan is usually covered by a secondary dressing, and the type of secondary dressing affects the performance of the primary dressing. If the secondary dressing is gauze (non-occlusive); there is continuous wicking of fluid from the primary dressing into the gauze, with continuous evaporation. In highly exuding wounds this results in rapid "strike through" of the gauze; in lower-exudate wounds this sometimes results in dehydration, causing the primary dressing to become hard and brittle. If the secondary dressing is totally occlusive, the primary dressing absorbs exudate until fully saturated; then free exudate collects and leakage occurs. Thus, the ability of a dressing combination to manage wound exudate depends in large part on the secondary dressing's moisture vapor transport rate.

The objective of this study was to compare the effects of two types of semipermeable secondary dressings with different moisture vapor transport rates, used in conjunction with a calcium alginate dressing (Sorbsan) as the primary dressing, on wound healing and wound management. Since the benefit of compression, either by means of compression stockings,<sup>13-17</sup> Unna's boot<sup>18,19</sup> or a combination of outer wrap and Unna wrap<sup>20,21</sup> in the treatment of venous ulcers is well established, compression stockings were utilized to cover the

dressings in both study groups.

The secondary dressings evaluated were OpSite™ (Smith & Nephew, Hull), a polyurethane film dressing with a moisture vapor transport rate of 850 g/m<sup>2</sup>/24 hours; and Flexzan™ (Dow B. Hickam, Inc. and PolyMedica Industries, Tarvin, Cheshire, England), a thin, pliable polyurethane foam adhesive dressing with a moisture vapor transport rate of >5,000 g/m<sup>2</sup>/24 hours. Compression (25-35 mm Hg at the ankle) was applied with a Grade 3 stocking (Venosan™ Stocking), which covered the surface of the secondary dressing. Coverage of the secondary dressings with the stocking material was determined to result in a 10% drop in the moisture vapor transport rate (inverted cup method at 30% relative humidity, 37°C and 0.4 m/sec air speed) versus that of the uncovered secondary dressing.

### Patients and Methods

Twenty patients, ranging in age from 16 to 75 years, participated in the study. Venous ulcers were confirmed by clinical examination, Duplex ultrasound scanning and photoplethysmography; all patients had ankle/brachial pressure indices > 0.9. Patients with arterial disease, rheumatoid disease, diabetes or ulcers of unknown etiology were excluded.

Ten patients were treated with alginate + film, and ten patients with alginate + foam. Patients were assessed six times at weekly intervals, with all assessments performed by the same observer. Assessment consisted of photographing the wound and tracing it onto an acetate sheet; ulcer size was determined by measuring tracings using a sonic digitizer. The condition of the skin surrounding the ulcer was noted, and the amount of the patient's pain and the condition of the wound bed were evaluated according to four-point numeric scales. For pain, 1 = painless, 2 = slightly painful, 3 = sufficiently painful to require analgesia, and 4 = painful enough so as to interfere with lifestyle and not to be relieved with high levels of analgesia. The condition of the wound bed was evaluated as follows: 1 = healed, 2 = clean and epithelializing, 3 = clean and sloughy or mildly sloughy, and 4 = infected/very sloughy and odorous.

The number of dressing changes was also

Figure 1. Changes in ulcer size for both treatment groups over the six visits during the study period.

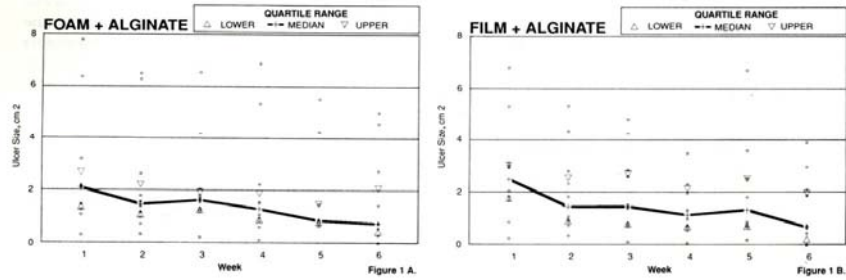


Figure 2. Comparison of total wound condition scores for Visits 1 and 6 for both treatment groups.

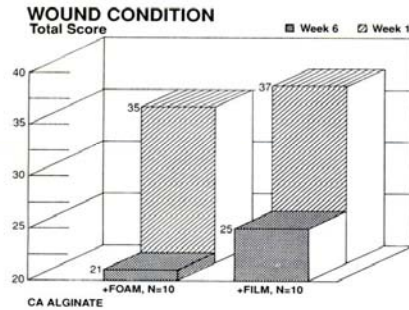


Figure 3. Comparison of total pain scores for Visits 1 and 6 for both treatment groups.

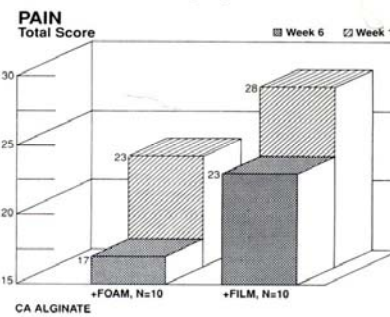
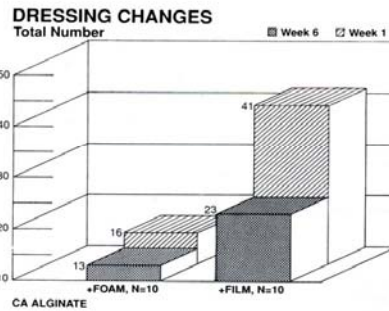


Figure 4. Comparison of total number of dressing changes for Visits 1 and 6 for both treatment groups.



**Table 1.** Percent changes in ulcer size shown by patient count per weekly visit.

Calcium Alginate + Film				
Wk	A Healed	B Improved <30%	C Unchanged ±30%	D Deteriorated >30%
2	0	4	5	1
3	0	5	5	0
4	0	9	1	0
5	0	6	4	0
6	2	8	0	0

Calcium Alginate + Foam				
Wk	A Healed	B Improved <30%	C Unchanged ±30%	D Deteriorated >30%
2	0	2	8	0
3	0	3	7	1
4	0	6	4	0
5	0	7	2	1
6	2	7	1	0

recorded weekly. The need for a dressing change was determined on the basis of the condition of the ulcer, the manufacturer's recommendations, and the amount of time the dressing stayed in place without leaking and without edgeroll or discomfort.

All patients were fitted with Grade 3 compression stockings (Venosan), which were worn throughout the trial.

Changes in ulcer size were compared and evaluated by means of the Wilcoxon paired test. Differences in the number of dressing changes were evaluated and compared by means of the Mann-Whitney test.

Approval for this study was obtained from the Ethics Committee at University College London Medical School, and all persons studied gave informed consent.

**Results**

In terms of changes in ulcer size, results were comparable for both groups. Analysis using the Wilcoxon paired test indicated that both treatments resulted in a decrease in size in nine ulcers (p<0.05), healing of two ulcers and an increase in size in one ulcer. Changes in ulcer size for both treatments over the study period are shown in

**Table 2.** Patient counts for wound condition scores by weekly visit.

Calcium Alginate + Film					
Wk	4	3	2	1	Total Score
1	7	3	0	0	37
2	3	6	1	0	32
3	2	7	1	0	31
4	2	5	3	0	29
5	4	3	3	0	31
6	1	4	2	2	25

Calcium Alginate + Foam					
Wk	4	3	2	1	Total Score
1	7	1	2	0	35
2	1	6	3	0	28
3	1	4	5	0	26
4	1	1	8	0	26
5	0	4	6	0	24
6	0	2	7	1	21

4 = infected/very sloughy and odorous,  
 3 = clean and sloughy or mildly sloughy,  
 2 = clean and epithelializing,  
 1 = healed.

Figure 1. Percentage changes in ulcer size, shown in Table 1, were also very similar.

Patient counts for wound condition scores by week are shown in Table 2. Overall, there was a 32% reduction in total wound condition scores for patients managed with alginate + film and a 40% reduction for patients managed with alginate + foam over the study period. Both groups began the study with a comparable number of sloughy/infected wounds, and both showed considerable improvement in wound condition by the end of the sixth visit. With alginate + foam there was a trend toward greater improvement; however, the numbers in this trial were insufficient to substantiate this finding. A comparison of total wound condition scores for Visits 1 and 6 is shown in Figure 2.

The number of patients falling into each of the four pain score categories per week for both treatment groups is shown in Table 3. Overall, pain scores were reduced by 18% and 26% for the alginate + film and alginate + foam groups, respectively. A significant reduction for both groups, but a statistically significant difference was not detected between groups. A comparison of the

Table 3.

D                      C                      B                      A  
Patient counts for pain scores by weekly visit.

Calcium Alginate + Film						Total Score
Wk	4	3	2	1	0	
1	1	6	3	0	0	28
2	1	6	1	2	2	26
3	2	3	4	1	1	26
4	2	1	6	1	1	24
5	3	2	3	2	2	26
6	2	1	5	2	2	23

Calcium Alginate + Foam						Total Score
Wk	4	3	2	1	0	
1	1	3	4	2	2	23
2	1	2	4	3	3	21
3	0	1	2	7	7	14
4	0	1	3	6	6	15
5	0	1	2	7	7	14
6	1	1	2	6	6	17

4 = painful enough so as to interfere with lifestyle and not to be relieved with high levels of analgesia, 3 = sufficiently painful to require analgesia, 2 = slightly painful, 1 = painless.

Table 4.

Patient counts for number of dressing changes by weekly visit.

Calcium Alginate + Film						Total Changes
Wk	7	4	3	2	1	
1	3	0	6	1	0	41
2	3	5	4	4	0	47
3	1	0	5	2	2	28
4	1	1	4	2	2	29
5	0	0	7	1	1	24
6	0	0	5	3	2	23

Calcium Alginate + Foam						Total Changes
Wk	7	4	3	2	1	
1	0	0	1	4	5	16
2	0	0	0	6	4	16
3	0	0	1	2	7	14
4	0	0	1	3	6	15
5	0	0	1	1	8	13
6	0	0	1	1	8	13

reduction in total pain scores for Visits 1 and 6 is illustrated in Figure 3.

The number of dressing changes required by both groups consistently decreased throughout the study period, with both groups using fewer dressings per week at the end of the trial than at

the beginning (see Figure 4 for a comparison of totals used in Weeks 1 and 6 by both groups). However, the alginate + foam group required only 87 total dressing changes, compared to 192 in the alginate + film group, a significant difference ( $p=0.0038$ ) when analyzed by means of the

Mann-Whitney test. A breakdown showing number of dressing changes by group per visit is shown in Table 4.

In terms of factors influencing dressing changes, edgeroll occurred on 12 occasions in the alginate + film group and once in the alginate + foam group. Leakage was noted 18 times with the alginate + film treatment and only once with alginate + foam.

No major adverse effects were observed in either group. Eight patients treated with alginate + film complained of "itch" under the dressing on more than one occasion during the study period, with six patients developing a rash or irritation. Two patients in the alginate + foam group complained of "itch"; one developed irritated skin after scratching on one occasion, but no rash was observed.

General comments on ease of use of the two dressings tested suggested that alginate + film was associated with difficulty in handling and frequent complaints of irritation, and that alginate + foam was popular due to its neat appearance, capacity for wound concealment and lack of irritation on sensitive skin. However, the foam required some attention for proper adherence, as it is necessary to apply gentle pressure with the hand after application in order to "set" the pressure-sensitive adhesive.

### Discussion

The results of this study confirm the findings of previous studies involving the use of calcium alginate.<sup>10,12</sup> Sorbsan will absorb exudate equivalent to approximately 20 times its own dry weight, with a 5 x 5cm patch holding approximately 3.5 to 4.0 ml of exudate when fully saturated (an average of 1600 g/m<sup>2</sup>/day).

The hypothesis upon which this study was based was that, with a high-exudate wound dressed with calcium alginate and covered by a semipermeable secondary dressing, the dressing would buffer the exudate produced for about 6 to 12 hours before pooling and eventual leakage. If a secondary dressing with a higher moisture vapor transport rate were utilized, the buffering capacity of the secondary dressing would be extended until an equilibrium would be maintained and there would be no pooling or leakage.

For example, assuming a moisture vapor transport rate of 1000 g/m<sup>2</sup>/day for a film dressing, the exudate level of a wound would be buffered for only a further 3 to 4 hours; however, with the foam dressing tested, with a much higher moisture vapor transport rate, eg, 6000 g/m<sup>2</sup>/day, the exudate level of the wound would never theoretically exceed the capacity of the primary dressing and there would be no pooling or leakage.

In reality the amount of exudate produced by a wound varies according to conditions; and the moisture vapor transport rate of the dressing also varies, tending to decrease slightly as it fills with debris. Consequently, some pooling or leakage may be seen during the first 24 to 48 hours if exudate production is high, even with a dressing having a much higher moisture vapor transport rate. With either dressing tested, indications for change of dressing are usually clear, since discoloration caused by exudate level shows through the dressing and blister formation may also occur. However, in this study the hypothesis was confirmed, with far fewer incidents of leakage, and far fewer dressing changes achieved with the higher moisture vapor transport secondary dressing (Flexzan).

The alginate + foam combination was also associated with fewer sensitivity reactions, confirming our previous experience with Flexzan (JH Scurr, FRCS; LA Wilson, RSN, unpublished data, July 1989; LA Wilson, RSN, JH Scurr, FRCS, unpublished data, August 1990). In the former study, 12 patients underwent a patch test, evaluated at 24 hours and at 7 days. There were no sensitivity reactions at 24 hours. There were also no adverse reactions at 7 days among the 10 patients still wearing patches (one had removed the patch for social reasons; another had removed the patch during a shower). In the latter study, six patients failed to develop allergic reactions to the dressing, even though two had previously been shown to have allergic reactions with other forms of adhesive dressings.

Based on the data from this study, we conclude that Opsite and Flexzan are both efficacious as secondary dressings for the management of venous ulcers, when used with calcium alginate as a primary dressing and in conjunction with compression stockings. However, Flexzan may be particularly well suited for the management of patients with this disorder, since it required sig-

nificantly fewer dressing changes, had a much lower incidence of leakage, was less difficult to handle, and was associated with a lower incidence of adverse reactions.

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