Comparison of Allevyn Adhesive and Biatain Adhesive in the management of pressure ulcers

- **Objective:** The primary objective was to assess dressing delamination and the ensuing potential consequences during wear and/or removal, as well as the effect of residue remaining in the ulcer following foam breakdown.
- **Method:** In this prospective multicentre study, 32 patients with a grade I or III pressure ulcer were randomised to receive either Allevyn Adhesive or Biatain Adhesive. The performance of the dressings was assessed over seven dressing changes or a maximum of six weeks. The primary efficacy variable was the proportion of patients with one or more delaminated dressing (delamination being defined as the falling apart of a dressing during wear or removal, or the presence of residue from the dressing in the ulcer).
- **Results:** Allevyn Adhesive was significantly less likely to delaminate than Biatain Adhesive: 83% of patients given Biatain Adhesive had a dressing that delaminated compared with 14% for Allevyn Adhesive (p=0.014). Furthermore, a greater proportion of the Biatain Adhesive dressings delaminated compared with the Allevyn Adhesive dressings: 50% versus 4% (p<0.001). Allevyn Adhesive performed significantly better in the following parameters: handling exudate (p=0.044), comfort (p=0.007), ease of application (p=0.004), conformability during application (p=0.003) and removal (p<0.0001), and adherence to the skin during application (p=0.003) and prior to removal (p=0.011). Three patients given Allevyn Adhesive (21%) reported adverse events; six patients given Biatain Adhesive (33%) reported adverse events.
- **Conclusion:** Allevyn Adhesive is effective and well tolerated in the management of pressure ulcers and less likely to delaminate than Biatain Adhesive.
- **Declaration of interest:** This study was funded by Smith & Nephew Wound Management Division, Hull, UK.

allevyn adhesives; dressing delamination; exuding wound; pressure ulcer

Allevyn Adhesive (Smith & Nephew Medical, Hull, UK) and Biatain Adhesive (Coloplast, Peterborough, UK) are types of adhesive dressings for use on exuding wounds, such as ulcers. Their composition is outlined in Box 1.

The main difference between the two dressings is that Allevyn Adhesive has a wound-contact layer, which stops the foam coming into direct contact with the wound.

The benefits of a wound-contact layer should include non-adherence to the wound itself and a reduced potential for granulation tissue to grow into the dressing.

The absence of a contact layer can allow the dressing to adhere to the wound and granulation tissue to grow into the foam matrix.¹,²

No studies have directly compared the performance and handling of Allevyn Adhesive and Biatain Adhesive dressings.

The primary aim of this study was therefore to:

- Compare the potential for the two types of dressing to delaminate and, consequently, fall apart during wear and/or removal
- Assess the potential for residue from the dressings to remain in the wound

Secondary objectives were to evaluate:
- How well the dressings stayed in place on the wound and surrounding skin
- Ease of application and removal
- Exudate handling
- Patient comfort
- Durability of the dressings (mean duration of wear).

**Method**

**Study design**

The study was an open prospective randomised multicentre parallel-group comparison of two dressings. It was conducted in accordance with good clinical practice and the 1975 Declaration of Helsinki and subsequent revisions.

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research

Box 1. Composition of Allevyn Adhesive and Biatain Adhesive

**Allevyn Adhesive**
- Polyurethane outer layer
- Hydrophilic, absorbent middle layer
- Adhesive, polyurethane inner layer containing a low-allergy adhesive, which is placed directly onto the wound

**Biatain Adhesive**
- Foam layer (with three-dimensional polymer structure), with a hydrocolloid-based adhesive, which is placed directly on the wound
- Semipermeable polyurethane film backing

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Allevyn Adhesive (n=14)</th>
<th>Biatain Adhesive (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) median (range)</td>
<td>81.8 (31.2–94.8)</td>
<td>79.1 (30.1–93.6)</td>
</tr>
<tr>
<td>Sex:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>6 (43%)</td>
<td>8 (44%)</td>
</tr>
<tr>
<td>Female</td>
<td>8 (57%)</td>
<td>10 (56%)</td>
</tr>
<tr>
<td>Ulcer grade:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade I</td>
<td>8 (57%)</td>
<td>10 (56%)</td>
</tr>
<tr>
<td>Grade III</td>
<td>6 (43%)</td>
<td>8 (44%)</td>
</tr>
<tr>
<td>Ulcer location:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sacrum</td>
<td>8 (57%)</td>
<td>7 (39%)</td>
</tr>
<tr>
<td>Trochanter</td>
<td>1 (7%)</td>
<td>3 (17%)</td>
</tr>
<tr>
<td>Ischium</td>
<td>1 (7%)</td>
<td>4 (22%)</td>
</tr>
<tr>
<td>Heel</td>
<td>3 (21%)</td>
<td>3 (17%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (7%)</td>
<td>1 (6%)</td>
</tr>
<tr>
<td>Incontinence:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>6 (42%)</td>
<td>5 (28%)</td>
</tr>
<tr>
<td>Faecal only</td>
<td>0</td>
<td>1 (6%)</td>
</tr>
<tr>
<td>Urinary only</td>
<td>1 (7%)</td>
<td>8 (44%)</td>
</tr>
<tr>
<td>Both</td>
<td>7 (50%)</td>
<td>4 (22%)</td>
</tr>
<tr>
<td>Any incontinence</td>
<td>8 (57%)</td>
<td>13 (72%)</td>
</tr>
<tr>
<td>Level of exudate:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slight</td>
<td>9 (64%)</td>
<td>12 (67%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>5 (36%)</td>
<td>6 (33%)</td>
</tr>
<tr>
<td>Median ulcer area (cm²)</td>
<td>16.3 (0.7–44.3)</td>
<td>9.3 (0.6–80.8)</td>
</tr>
</tbody>
</table>

Patients
Thirty-two patients from four wound-care centres were enrolled into the study. The investigators had intended to recruit 50 patients. The sample number was low due to the strict inclusion/exclusion criteria, and the fact that the participating centres had to have experience of using both Allevyn Adhesive and Biatain Adhesive. In addition, it is difficult to recruit patients with pressure ulcers into clinical trials and it is often not possible to follow them up for any significant length of time.

The first patient was recruited on 16 September 2002 and the last patient on 2 October 2003. Study participants comprised both inpatients and outpatients. All provided written informed consent.

**Inclusion criteria**
- Eighteen years of age and over
- Presence of a grade II or III pressure ulcer (EPUAP classification)
- Slight or moderate level of exudate.

If the patient had more than one ulcer, the largest eligible ulcer was used for the study. Grade II ulcers were defined as partial-thickness skin loss involving the epidermis or dermis. Such ulcers are superficial and present as an abrasion, blister or shallow crater. Grade III ulcers were defined as full-thickness skin loss involving damage to, or necrosis of, subcutaneous tissue. Such ulcers present as deep craters.

**Exclusion criteria**
- Grade 0 (healed), I or IV pressure ulcers
- Ulcers with more than 10% black necrotic tissue
- Ulcers caused by rheumatoid vasculitis, diabetes (foot ulcer only), cancer or venous leg ulceration
- Active cellulitis being treated with systemic antibiotics
- Ulcers more than 14 cm in length
- Ulcers with a cavity (as opposed to a crater)
- Surrounding skin on which the use of an adhesive dressing would be inappropriate — for example, macerated, inflamed or friable skin
- Ulcers with no exudate or heavy exudate
- Participation in another clinical trial
- Hypersensitivity to the dressings, identified from medical history.

**Treatment**
Patients were randomised to have their ulcer dressed with either Allevyn Adhesive or Biatain Adhesive. Block randomisation was used. Patients were stratified by baseline exudate level and treatment centre. There were two levels of exudate status: Ulcers with a slight level of exudate Ulcers with a moderate level of exudate.

After randomisation, patients underwent an initial ulcer assessment by the same person at each centre. This involved tracing and photographing the ulcer, and assessing its appearance.

The ulcer was then cleaned with sterile water or saline according to the normal hospital procedure, and the relevant dressing was applied. Before the study clinicians were trained on the manufacturers' guidelines to ensure that application/removal was conducted appropriately in all centres.
The most appropriate dressing size was selected for each ulcer (Allevyn Adhesive: 12.5cm x 12.5cm or 17.5cm x 17.5cm; Biatain Adhesive: 12cm x 12cm or 18cm x 18cm).

Dressings were changed when exudate came within 2cm of the edge. If there was little exudate, the dressing was changed only if the ulcer needed to be examined, but no dressing was left in place for longer than seven days.

At each dressing change the ulcer was cleaned and a fresh dressing applied.

Patients were followed up for a maximum of seven dressing changes. This was standardised to ensure consistency across sites and to allow for the fact that it is difficult to follow-up pressure ulcers for long periods (eight dressing applications or an ulcer duration of six weeks).

The dressings' performance was assessed at each dressing change. This involved recording:

- The presence of exudate
- Conformability
- Adherence
- Dressing residue in the wound
- Comfort
- Ease of removal
- Level of pain experienced at dressing removal
- Integrity of the dressing
- Whether the dressing removal caused any damage to the ulcer or surrounding skin.

All parameters, including pain, were assessed subjectively, but where possible they were undertaken by the same assessor. Photographs were taken before dressing removal, after dressing removal but before cleansing, and after cleansing. Ulcers were also traced after cleansing but before the next dressing was applied. Where possible, the same person performed the tracing at each visit.

Efficacy assessments

The primary efficacy variable was the proportion of patients with at least one delaminated dressing, delamination being defined as:

- Falling apart of a dressing during wear
- Falling apart of a dressing during removal
- The presence of a residue from the dressing in the wound after the dressing removal.

Secondary efficacy variables included the:

- Proportion of delaminated dressings
- Falling apart of dressings during wear or removal
- Presence of dressing residue in the wound at any dressing change.

Safety evaluations

Adverse events were monitored throughout the study. These were classified as severe or non-severe, and then as dressing or non-dressing related. Patients experiencing a severe dressing-related adverse event were withdrawn from the study.

**Statistical analysis**

All efficacy analyses and safety evaluations were performed on the full analysis set. This comprised data from patients who had grade II or III pressure ulcers and who also underwent the initial baseline assessment.

The primary efficacy analysis was also performed on the per protocol population. This consisted of all patients who met the inclusion/exclusion criteria and had at least one change of dressing assessed. It excluded dressing changes where the dressing had been worn for more than seven days.

A logistic regression model was used to compare differences in the odds between the two dressing types with respect to delamination at any point. A random effects logistic regression model was used to calculate both the odds of delamination at each dressing change, and the binary variables of the dressings that fell apart during wear. (Binary variables occur where only one of two values can be selected — for example, 'yes/no', 'male/female' and 'presence/absence'.)

The models included the following baseline covariates:

- Sex
- Age
- Presence or absence of incontinence
- Location, grade and area of the ulcer
- Pain experienced during the past week.

The baseline exudate level was included in each of these models. Differences between the two dressing types for the falling apart of dressings during removal and the proportion of patients in whom the ulcer healed were evaluated using the Fisher's exact test. For other efficacy variables, differences between the two dressing types were evaluated using the Mantel-Haenszel test. The level of significance was taken as p<0.05 for all analyses.

In addition to the above analyses, results for some of the efficacy variables were expressed in relation to baseline levels of exudate.

**Results**

Fourteen patients received Allevyn Adhesive and 18 patients received Biatain Adhesive. This difference in numbers was due to the randomisation codes used (there would have been a balance if the full 50 patients had been enrolled).

All 32 patients qualified for the full analysis set. Twenty-eight patients (88%) qualified for the per protocol population. Patient demographics are summarised in Table 1.

**Proportion of patients with a delaminated dressing**

In the full analysis set more patients who received Biatain Adhesive had at least one delaminated dressing during the study period (15/18, 83%) than
patients who received Allevyn Adhesive (2/14, 14%). The odds of a patient having at least one delaminated dressing were significantly increased in those who received Biatain Adhesive compared with Allevyn Adhesive (OR: 0.039; 95% CI: <0.001-0.266; p=0.014).

Baseline levels of exudate had no effect on the odds of a patient having at least one delaminated dressing.

For the per protocol population, 13 out of 14 patients (93%) who received Biatain Adhesive had at least one delaminated dressing during the study period compared with two out of 14 patients (14%) receiving Allevyn Adhesive. Again, the odds of a patient having at least one delaminated dressing were significantly increased with Biatain Adhesive compared with Allevyn Adhesive (OR: 0.020; 95% CI: <0.001-0.455; p=0.029), and baseline levels of exudate had no effect on the odds of a patient having at least one delaminated dressing.

**Proportion of delaminated dressings**

In total 51 out of 102 Biatain Adhesive (50%) and three out of 85 Allevyn Adhesive dressings (4%) delaminated. Fig 1 shows the proportion of delaminated dressings at each assessment (full analysis set). The odds of delamination were significantly increased with Biatain Adhesive compared with Allevyn Adhesive (OR: 0.023; 95% CI: 0.004-0.144; p<0.001). Once again, baseline levels of exudate had no effect on the odds of dressing delamination.

Sample survey methodology showed that 3% of Allevyn Adhesive dressings delaminated (95% CI: 0-7.7%) compared with 42.5% of Biatain Adhesive dressings (95% CI: 24.9-60.1%). A sample survey methodology was used as it takes into account repeated measurements for an individual patient.

**Delamination during wear**

Overall, 46 out of 96 dressings (48%) fell apart compared with three out of 81 (4%) for Allevyn Adhesive. Fig 2 shows the proportion of dressings that fell apart during wear. The odds of a dressing falling apart were significantly increased with Biatain Adhesive compared with Allevyn Adhesive (OR: 0.027; 95% CI: 0.005-0.164; p<0.001).

**Dressings that fell apart on removal**

Based on the full analysis set, no patients randomised to Allevyn Adhesive experienced dressing delamination during removal, whereas 15 out of 18 patients (83%) using Biatain Adhesive did have this problem (p<0.001). Fig 3 shows the proportion of dressings that fell apart during removal.

**Residue in the wound**

No patients randomised to Allevyn Adhesive experienced dressing residue in the wound, whereas one patient in the Biatain Adhesive group did.

**Other secondary efficacy variables**

The results for other secondary efficacy variables are summarised in Table 2 (see page 370). Allevyn Adhesive proved significantly superior to Biatain Adhesive with respect to dressings changed for reasons other than routine (p=0.020), satisfactory exudate handling (p=0.044), comfort (p=0.007), ease of application (p=0.004), conformability during application (p=0.003) and conformability before removal (p<0.0001), and adherence to the skin on application (p=0.003) and before removal (p=0.011).
Safety results
Three patients (21%) in the Allevyn Adhesive group reported adverse events:
- Erosion of the surrounding skin
- Diarrhoea
- Necrosis.

None of these adverse events were severe. Only one (peri-ulcer erosion) was considered to be dressing related, but the patient had removed this dressing and the erosion resolved itself after three days. The patient with necrosis was withdrawn from the study.

At the end of the trial two of the adverse events (67%) had resolved and one was ongoing. The mean duration of an adverse event was 1.5 days.

By contrast, six patients (33%) who received Biatain Adhesive reported eight adverse events:
- Erythema of the surrounding skin twice (severe)
- Death due to stroke (severe)
- Erosions twice
- Diarrhoea twice
- Heavy exudate.

Three of the non-severe adverse events (erythema and erosions twice) and one of the severe adverse events (erythema) were considered to be dressing related. Patients with severe and device-related events were withdrawn. Those with non-severe and device-related events were only withdrawn at the discretion of the investigator.

At the end of the trial four of these eight adverse events had resolved, one was ongoing, one resulted in death and two resulted in unspecified outcomes. The mean recorded duration of an adverse event was 0.3 days.

Discussion
The study demonstrated that:
- 83% of patients using Biatain Adhesive experienced delamination compared with 14% using Allevyn Adhesive (p=0.014) (Fig 1)
- Biatain Adhesive was also significantly more likely to fall apart during wear
- No Allevyn Adhesive dressings fell apart during removal. The delamination of the Biatain Adhesive dressings may be due to the absence of a wound-contact layer, resulting in greater adherence of the dressing to the wound surface
- Residue in the wound occurred in one patient using Biatain Adhesive
- Baseline levels of exudate had no effect on the performance of the two dressings.

Secondary efficacy analyses showed that Allevyn Adhesive was significantly less likely to need changing for reasons other than routine. This is an important factor in the clinic where dressing changes contribute significantly to the overall cost of care.

Allevyn Adhesive was significantly better at handling exudate, more comfortable, easier to apply, showed better conformability during application and removal, and adhered better to the skin on application and during wear.

The conformability and adherence to surrounding skin produced less buckling of the dressing. Conformability is a desirable property when body surfaces are irregular or are flexed frequently. Furthermore, buckling of the dressing may expose the wound to external contaminants. Better conformability and adhesion also lead to better handling of exudate and should maintain a constant moist environment at the wound bed, a factor widely accepted as conducive to good healing.

Allevyn Adhesive was marginally easier to remove (p=0.084). No significant differences were observed between the two types of dressing in terms of damage to the ulcer or surrounding skin during removal, ulcer pain on removal, the amount of time dressings were worn, the percentage decrease in the ulcer area, the proportion of patients in whom the ulcer healed and dressing residue in wound.

Both types of dressing were well tolerated. Twenty one per cent of patients who were given Allevyn Adhesive reported three adverse events and 33% of the patients who received Biatain Adhesive reported eight adverse events.

Conclusion
The results show that Allevyn Adhesive is effective and well tolerated in the management of pressure ulcers and significantly less likely to delaminate during wear or removal.

In addition, Allevyn Adhesive handles exudate better and is more comfortable, easier to apply, and better at adhering to the peri-ulcer skin surrounding the ulcer.
## Table 2. Secondary efficacy variables in the full analysis set (n=32)

<table>
<thead>
<tr>
<th>Efficacy variable</th>
<th>Allevyn Adhesive (n=14)</th>
<th>Biatain Adhesive (n=18)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of assessments per patient where the patient was still wearing the dressing at assessment</td>
<td>93.8% (50.0–100%)</td>
<td>100% (37.5–100%)</td>
<td>NS</td>
</tr>
<tr>
<td>Percentage of assessments per patient where the dressing was changed for reasons other than routine</td>
<td>0% (0–100%)</td>
<td>29.2% (0–100%)</td>
<td>0.02</td>
</tr>
<tr>
<td>Percentage of assessments per patient where the ulcer was damaged on dressing removal</td>
<td>0% (0–33.3%)</td>
<td>0% (0–28.6%)</td>
<td>NS</td>
</tr>
<tr>
<td>Percentage of assessments per patient where dressing removal damaged the surrounding skin</td>
<td>0% (0–33.3%)</td>
<td>0% (0–28.6%)</td>
<td>NS</td>
</tr>
<tr>
<td>Exudate handling satisfactory</td>
<td>100% (100–100%)</td>
<td>77.8% (0–100%)</td>
<td>0.044</td>
</tr>
<tr>
<td>Mean patient pain from the ulcer since the last assessment</td>
<td>1.03 (1.00–1.33)</td>
<td>1.15 (1.00–2.25)</td>
<td>NS</td>
</tr>
<tr>
<td>No pain reported from the ulcer since the last assessment</td>
<td>98%</td>
<td>85%</td>
<td>—</td>
</tr>
<tr>
<td>Mean patient pain on removal of the dressing</td>
<td>1.01 (1.00–1.17)</td>
<td>1.10 (1.00–2.17)</td>
<td>NS</td>
</tr>
<tr>
<td>No pain on dressing removal</td>
<td>99%</td>
<td>89%</td>
<td>—</td>
</tr>
<tr>
<td>Mean patient comfort of dressing</td>
<td>1.84 (1.00–2.25)</td>
<td>2.11 (1.00–3.00)</td>
<td>0.006</td>
</tr>
<tr>
<td>Dressing comfortable or very comfortable</td>
<td>98%</td>
<td>88%</td>
<td>—</td>
</tr>
<tr>
<td>Mean patient ease of dressing application</td>
<td>1.00 (1.00–1.00)</td>
<td>1.13 (1.00–2.00)</td>
<td>0.004</td>
</tr>
<tr>
<td>Dressing easy to apply</td>
<td>100%</td>
<td>86%</td>
<td>—</td>
</tr>
<tr>
<td>Mean patient ease of dressing removal</td>
<td>1.17 (1.00–2.00)</td>
<td>1.41 (1.00–2.00)</td>
<td>0.084</td>
</tr>
<tr>
<td>Dressing easy to remove</td>
<td>82%</td>
<td>63%</td>
<td>—</td>
</tr>
<tr>
<td>Mean patient conformation of dressing on application</td>
<td>1.13 (1.00–1.87)</td>
<td>1.45 (1.00–2.00)</td>
<td>0.003</td>
</tr>
<tr>
<td>No rucking of dressing on application</td>
<td>83%</td>
<td>54%</td>
<td>—</td>
</tr>
<tr>
<td>Mean patient conformation of dressing before removal</td>
<td>1.52 (1.00–2.00)</td>
<td>2.21 (1.87–3.00)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>No rucking of dressing before removal</td>
<td>45%</td>
<td>4%</td>
<td>—</td>
</tr>
<tr>
<td>Mean patient dressing adherence on application</td>
<td>1.12 (1.00–1.87)</td>
<td>1.32 (1.00–2.00)</td>
<td>0.003</td>
</tr>
<tr>
<td>Dressing adhered to all areas of skin on application</td>
<td>84%</td>
<td>67%</td>
<td>—</td>
</tr>
<tr>
<td>Mean patient dressing adherence before removal</td>
<td>1.48 (1.00–2.14)</td>
<td>1.92 (1.00–3.00)</td>
<td>0.011</td>
</tr>
<tr>
<td>Dressing adhered to all areas of skin before removal</td>
<td>53%</td>
<td>20%</td>
<td>—</td>
</tr>
<tr>
<td>Median duration of dressing wear (days)</td>
<td>3.0 (1–7 days)</td>
<td>3.5 (1–10.5 days)</td>
<td>NS</td>
</tr>
<tr>
<td>Median percentage reduction in ulcer area</td>
<td>38.2% (23.9–99.4%)</td>
<td>45.8% (56.9–90.0%)</td>
<td>NS</td>
</tr>
<tr>
<td>Proportion of patients where ulcer healed</td>
<td>36%</td>
<td>28%</td>
<td>NS</td>
</tr>
<tr>
<td>Proportion of assessments where ulcer healed</td>
<td>6%</td>
<td>5%</td>
<td>—</td>
</tr>
<tr>
<td>Additional dressings used</td>
<td>30%</td>
<td>61%</td>
<td>—</td>
</tr>
</tbody>
</table>

Unless otherwise indicated, results are expressed as a percentage of the total number of assessments. Where applicable, ranges are shown in parentheses. NS=not significant.

1. Expressed as the median percentage of assessments
2. Expressed as the mean percentage of assessments as the median was 100% for both dressings. P value calculated from whole distribution
3. 1=mild, 2=moderate, 3=severe. Mean has been used as the median was 1.0 for both treatments
4. 1=very comfortable, 2=comfortable, 3=uncomfortable, 4=very uncomfortable. Mean has been used as the median was 2.0 for both treatments
5. 1=difficult, 2=acceptable. Mean has been used as the median was 1.0 for both treatments
6. 1=no rucking, 2=slight rucking, 3=moderate rucking, 4=major rucking
7. 1=adherence to all areas of ulcer, 2=adherence to most areas, 3=minimal adherence, 4=no adherence