Effective Venous Leg Ulcer Treatment with a New Dressing, Compression, and Skin Protection

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Kelsey Hei, 3M Health Care, St. Paul, MN, Shelley-Ann Walters, 3M Health Care, St. Paul, MN

Background

Foam dressings have become the predominant absorbent wound dressing. They can be designed to absorb varying amounts of exudate without sacrificing the benefits of a moist wound healing environment. Many foam dressing products are semi-occlusive systems composed of a polyurethane foam and an outer, semi-permeable film of polyurethane. Foam dressings have demonstrated many desirable characteristics to facilitate wound healing. They provide thermal insulation, do not shed fibers or particles, are easily cut or shaped, and help maintain a moist wound environment. They are intended to be water permeable, non-adherent, light-weight, and comfortable. The compressed foam cells in contact with the wound absorb exudate and facilitate capillary action, discouraging periwound maceration.

The use of polyurethane foam wound dressings with a high-compression bandage system is considered an accepted form of treatment of venous leg ulcers. The efficacy of a foam wound dressing used with a compression bandage is related to how well the dressing manages wound exudate and how well the bandage holds in place to provide continued effective compression and patient adherence to the recommended protocol.

Objective

The objective of this study was to evaluate a new non-adhesive foam wound dressing* performance on venous leg ulcers in a wound care clinic setting when used in conjunction with a 2-layer compression system** and an alcohol-free skin barrier film***.

Methods/Study Design

• Single-site, open-label, prospective non-randomized
• Ten patients were included in the study
• Patient’s wound and dressing history were collected
• Patient treatment was changed to incorporate the new non-adhesive foam dressing as the primary wound dressing
• Periwound skin was treated with an alcohol-free skin barrier film and the leg was bandaged with a 2-layer compression system
• Two sizes of the non-adhesive foam dressing were available to the investigator. The investigator selected the appropriate size/configuration for each wound
• Dressings could be cut as necessary to accommodate wound contours
• Dressings were changed at least every 7 days
• Patients were followed for a maximum of four weeks
• Data analyzed with descriptive statistics

Patient Demographics

- 70% (n=7) male and 30% (n=3) female
- Median (range) age: 63 (44-84) years
- All patients had at least 1 venous leg ulcer
  - 80% right leg
  - 20% left leg
- 70% of wounds were present for < 1 year; 30% were > 1 year

Results

Patients were in the study for a median of 30 days (23-32 day range) in which they wore the dressing under compression for a median of 7 days (1-18 days range). Eighty-three percent (34/41) of the dressings were changed for compression under 7 days. All wounds had moderate to severe levels of exudate and 60% had mild to moderate periwound maceration.

At the initial visits, the median wound area was 5.11 cm². The median percent wound area change observed in this study at the final visit relative to the initial visit was 37% reduction, with 80% of the patients showing a wound reduction, half of which showed at least 50% reduction (one subject healed). Six patients showed improvement in periwound maceration with 90% of patients with no macerated skin by the last study visit.

Among the 41 dressing change assessments completed, despite the high levels of drainage, the dressing maintained a moist environment and did not cause damage to wound bed, periwound skin or surrounding tissue.

Case Studies

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Table 1 - Comparison of Wound Area and Exudate Amount from Initial to Final Dressing Removal

<table>
<thead>
<tr>
<th>Category</th>
<th>Initial Wound Area (cm²)</th>
<th>Initial Exudate Amount</th>
<th>Final Wound Area (cm²)</th>
<th>Final Exudate Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subcategory</td>
<td>Initial 100%</td>
<td>Initial 50%</td>
<td>Final 100%</td>
<td>Final 50%</td>
</tr>
<tr>
<td>Percentage Change</td>
<td>100%</td>
<td>90%</td>
<td>100%</td>
<td>90%</td>
</tr>
<tr>
<td>Exudate Amount</td>
<td>60%</td>
<td>50%</td>
<td>30%</td>
<td>20%</td>
</tr>
<tr>
<td>Periwound Maceration</td>
<td>20%</td>
<td>10%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Patient #5: Female, age 45; VLU on right leg, present for 15 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2 - Additional Study Dressing Assessments

<table>
<thead>
<tr>
<th>Category</th>
<th>Initial Dressing Removal (n=10)</th>
<th>Final Dressing Removal (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain from the Wound Site</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Discomfort from the Wound</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Discomfort from the Compression Bandage</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Discomfort from the Dressing</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Redness of Wound Site</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Pain during Removal</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Ease of Dressing Application</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Ease of Dressing Removal</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 3 - Comparison of Patient Quality of Life from Initial to Final Dressing Removal

<table>
<thead>
<tr>
<th>Category</th>
<th>Initial Quality of Life (n=10)</th>
<th>Final Quality of Life (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain from the Wound Site</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Discomfort from the Wound</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Discomfort from the Dressing</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Nighttime Sleep</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

* 3M™ Cavilon™ No Sting Barrier Film
** 3M™ Coban™ 2 Layer Compression System
*** 3M™ Curaplex™ Super Film

Conclusion

- 80% of patients had a wound size reduction
- 60% of patient’s wounds showed improved pain in periwound maceration
- 100% patient satisfaction with dressing wear time, absorbency and overall performance.
- Dressing was rated as easy to remove and did not cause damage to wound bed, periwound skin or surrounding tissue.

Use of this new non-adhesive foam dressing, when combined with a 2-layer compression system and an alcohol-free skin barrier film is an effective total solution in the treatment of venous leg ulcers.

Case Studies

Patient #2: Male, age 62; VLU on right leg, present for > 1 year

Patient #5: Female, age 45; VLU on right leg, present for 15 weeks

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Patient #2: Male, age 62; VLU on right leg, present for > 1 year

Initial Study Visit: 10Sep2013
- Exudate Amount: Moderate
- Absent erythema
- Size: 4.0cm x 3.5cm x 0.2cm

Final Study Visit: 07Oct2013
- Exudate Amount: Severe
- Absent maceration
- Absent erythema
- Size: 2.4cm x 1.1cm x 0.1cm

Removal
- 50%

Patient #5: Female, age 45; VLU on right leg, present for 15 weeks

Initial Study Visit: 15Sep2013
- Exudate Amount: Moderate
- Moderate maceration
- Mild erythema
- Size: 2.4cm x 1.1cm x 0.1cm

Final Study Visit: 17Oct2013
- Exudate Amount: Moderate
- Absent maceration
- Absent erythema
- Size: 1.2cm x 0.7cm x 0.1cm

Removal
- 50%

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Patient #2: Male, age 62; VLU on right leg, present for > 1 year

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- Absent erythema
- Size: 4.0cm x 3.5cm x 0.2cm

Final Study Visit: 07Oct2013
- Exudate Amount: Severe
- Absent maceration
- Absent erythema
- Size: 2.4cm x 1.1cm x 0.2cm

Removal
- 50%